PTO/AIA/15 (07-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	NEOME-019A3-US-G2
First Inventor	John T. Sorensen
Title	Tubular Cutter Device and Methods for Cutting and Removing Strips of Tissue from The B
Express Mail Label No.	N/A

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form.** (PTO/SB/17 or equivalent)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification.** [*Total Pages* 12] Both the claims and abstract must start on a new page *(For information on the preferred arrangement, see MPEP § 608.01(a))*
4. ☑ **Drawing(s).** (*35 U.S.C. 113*) [*Total Sheets* 3]
5. **Inventor's Oath or Declaration.** [*Total Sheets* 8] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. ☐ Newly executed (original or copy)
   b. ☑ A copy from a prior application (37 CFR 1.63(d))
6. ☑ **Application Data Sheet.** **See Note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
7. ☐ **CD-ROM or CD-R.** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission.** *(if applicable, items a. – c. are required)*
   a. ☐ Computer Readable Form (CRF)
   b. ☐ Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers.** (cover sheet & document(s))
   Name of Assignee_____
10. ☐ **37 CFR 3.73(c) Statement.** ☐ **Power of Attorney.** *(when there is an assignee)*
11. ☐ **English Translation Document.** *(if applicable)*
12. ☐ **Information Disclosure Statement.** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment.**
14. ☐ **Return Receipt Postcard.** *(MPEP § 503) (Should be specifically itemized)*
15. ☐ **Certified Copy of Priority Document(s).** *(if foreign priority is claimed)*
16. ☐ **Nonpublication Request.** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ **Other:**_____

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

18. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 33197 ***OR*** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Robert D. Buyan/	Date	September 9, 2014
Name (Print/Type)	Robert D. Buyan	Registration No. (Attorney/Agent)	32,460

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

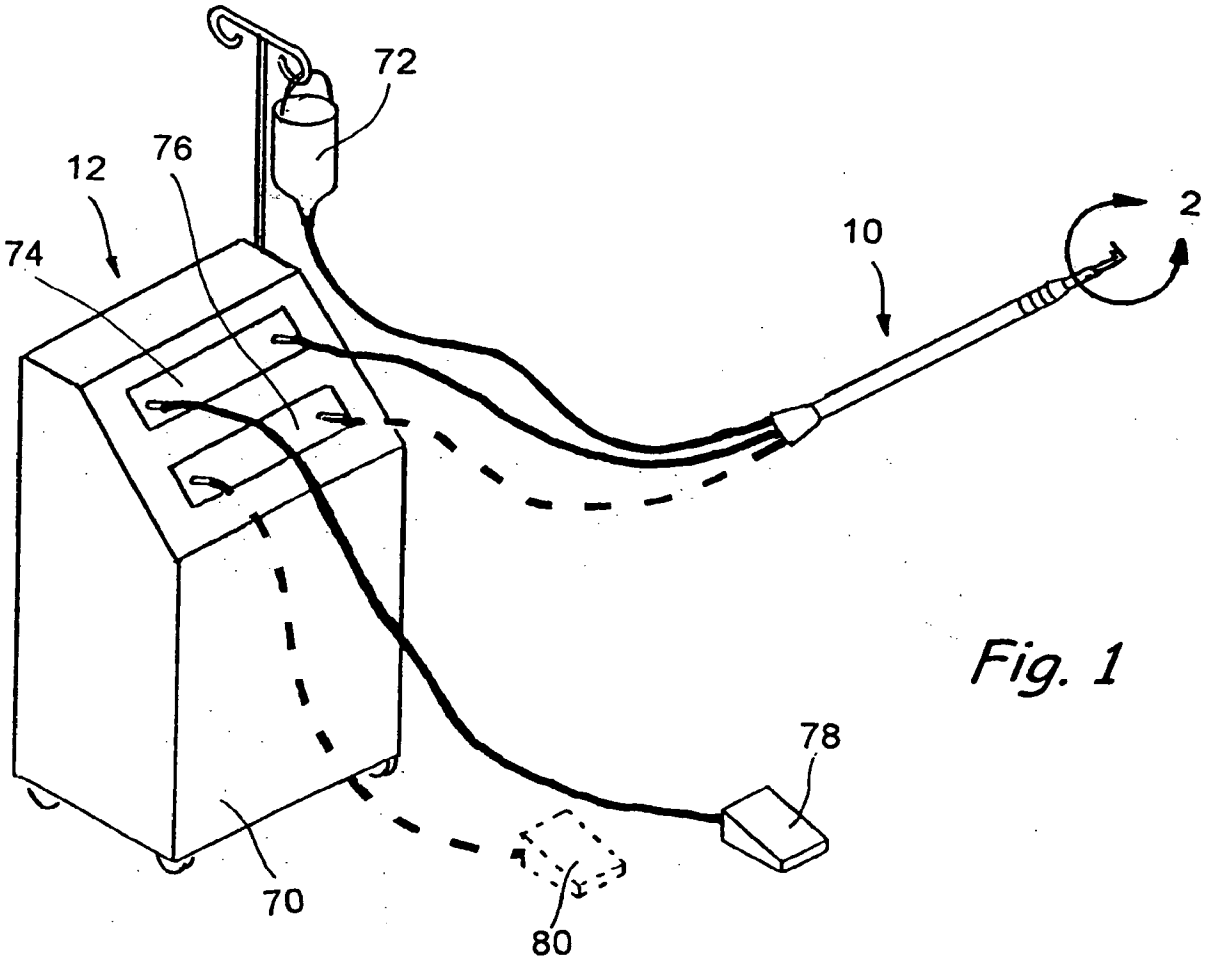

Fig. 1

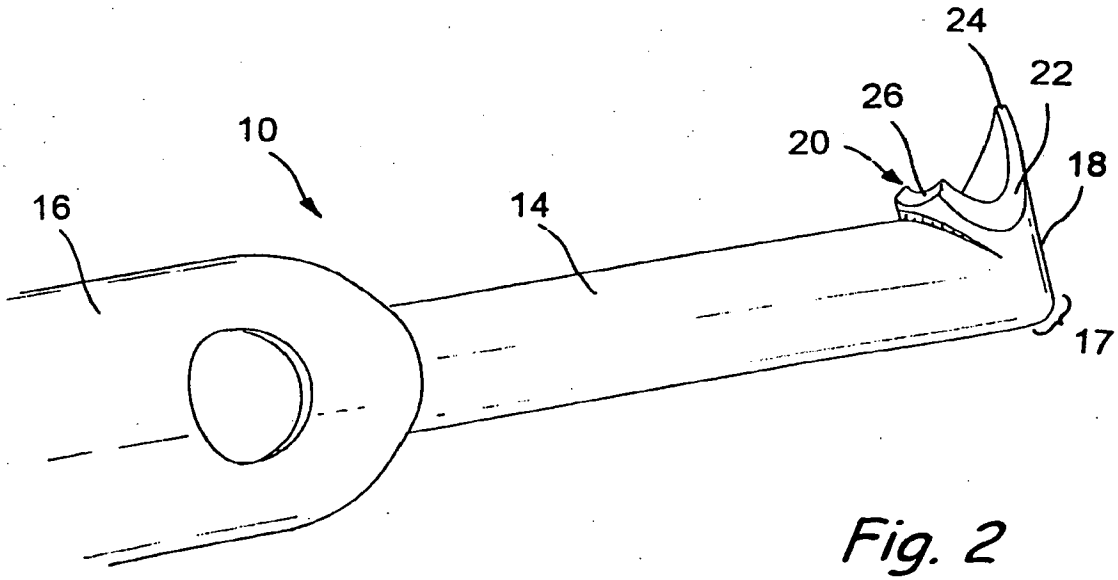

Fig. 2

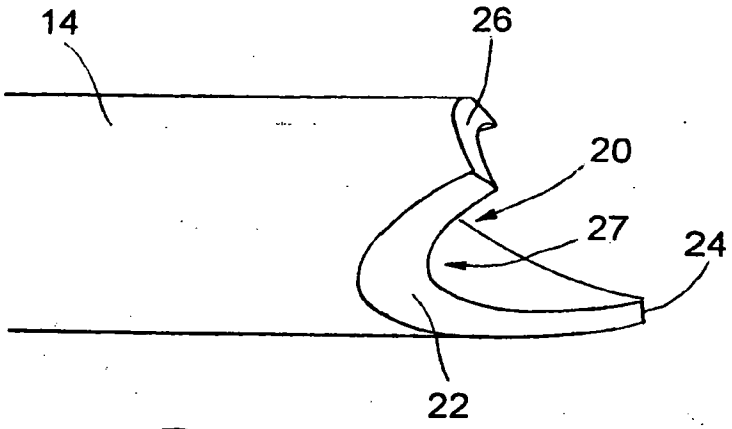

Fig. 3A

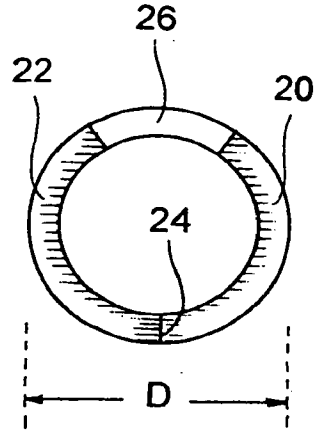

Fig. 3B

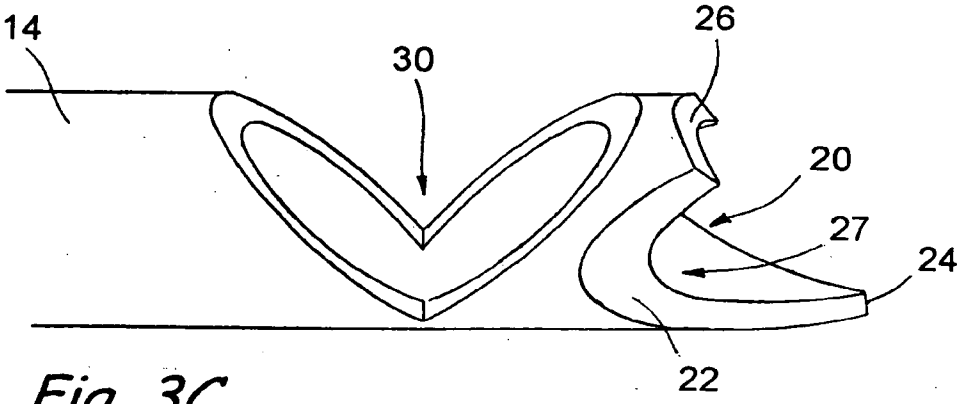

Fig. 3C

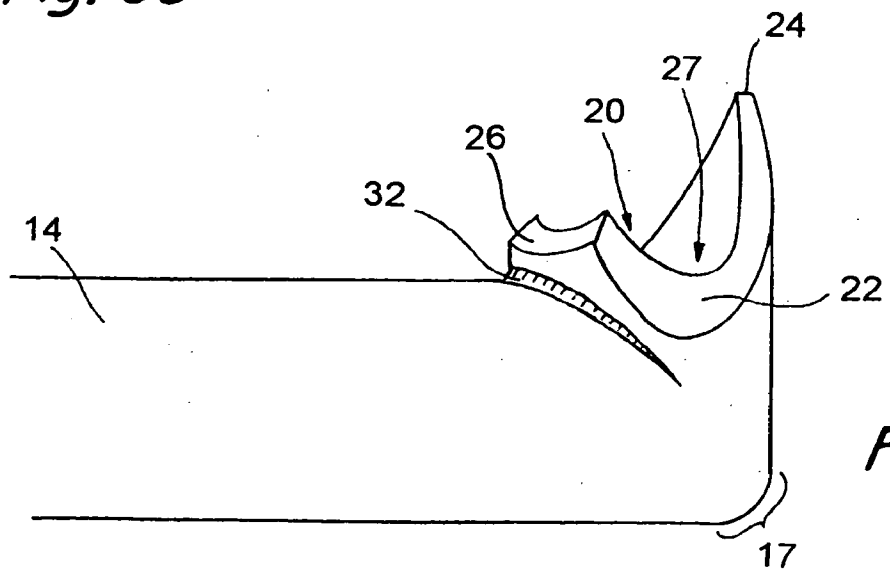

Fig. 3D

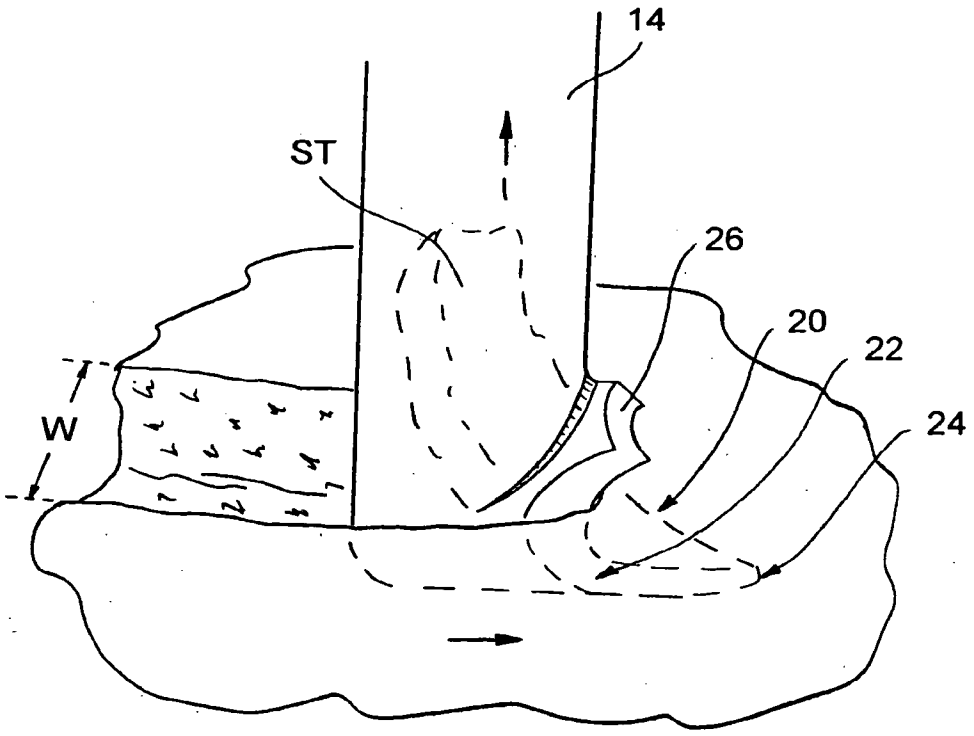

Fig. 4

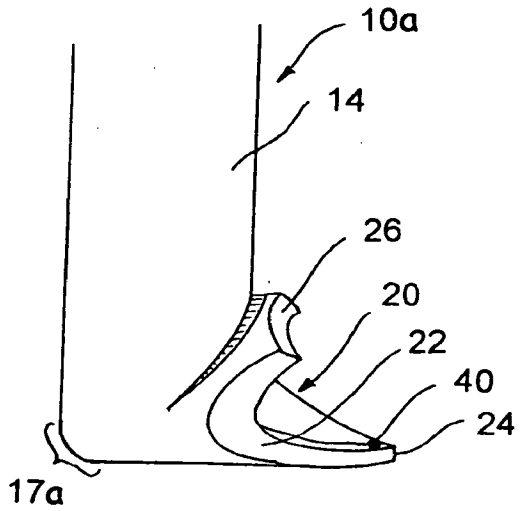

Fig. 5

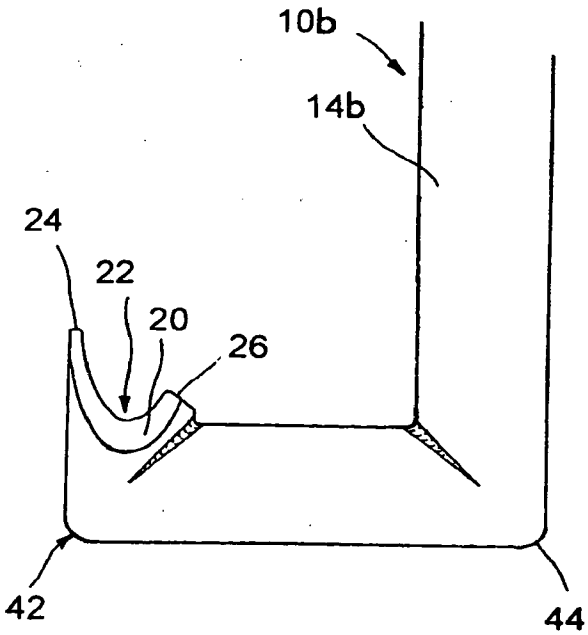

Fig. 6

Attorney Docket No. NEOME-019A3US

DECLARATION OF INVENTORSHIP and LIMITED POWER OF ATTORNEY

As a below named inventor, I believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled "Tubular Cutter Device and Methods for Cutting and Removing Strips of Tissue from the Body of a Patient" which is described and claimed in Application No. 10/560,267 (PCT/US04/18488) for which a patent is sought. My residence, post office address and citizenship are as stated below next to my name.

I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment referred to herein.

I acknowledge my duty under Title 37, Code of Federal Regulations § 1.56(a) to disclose information which is material to the patentability of the invention I am claiming.

☒ I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: U.S. Provisional Patent Application No. 60/477,258 filed on June 10, 2003.

As a named inventor and until I assign my rights to the invention, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith on my behalf: **Frank J. Uxa**, Reg. No. 25,612; **Donald E. Stout**, Reg. No. 34,493; **Robert D. Buyan**, Reg. No. 32,460; **Kenton R. Mullins**, Reg. No. 36,331; and **Linda Allyson Fox**, Reg. No.38,883, all of the firm STOUT, UXA, BUYAN & MULLINS, LLP. **Send correspondence and direct telephone calls to: Robert D. Buyan, Stout, Uxa, Buyan & Mullins, LLP, 4 Venture, Suite 300, Irvine, CA 92618; telephone (949) 450-1750, facsimile (949) 450-1764, email: rbuyan@patlawyers.com.**

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that there statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

John T. Sorensen, of, Lake Elsinore, California, a citizen of the U.S.A. Post office address: 35 Volta del Tintori St., Lake Elsinore, California 92532.

Signature: John T. Sorensen Date: MAY 8, 2006
John T. Sorensen

Michael Mittelstein, of, Laguna Niguel, California, a citizen of Germany. Post office address: 29412 Clipper Way, Laguna Niguel, California 92677.

Signature: Michael Mittelstein Date: 05/09/06
Michael Mittelstein

Soheila Mirhashemi, of, Laguna Niguel, California, a citizen of the U.S.A. Post office address: 29412 Clipper Way, Laguna Niguel, California 92677.

Signature: S. Mirhashemi Date: 5/10/06
Soheila Mirhashemi

Attorney Docket No. NEOME-019A3US

STATEMENT OF OWNERSHIP (37 CFR 3.73(b)) and POWER OF ATTORNEY BY ASSIGNEE

Inventor(s): John T. Sorensen, Michael Mittelstein, Soheila Mirhashemi

Application Serial No: 10/560,267

Filing Date: _____

Entitled: Tubular Cutter Device and Methods for Cutting and Removing Strips of Tissue from the Body of a Patient

NeoMedix Corporation, a California corporation,
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)
is the assignee of the entire right, title and interest in the patent identified above by virtue of:

☒ An assignment from the inventor(s)/owner(s) of the patent application as identified above.

☒ Copies of assignment(s) or other document(s) in the chain of title are attached.

The authority and rights of the inventor(s) with respect to this patent are hereby excluded in accordance with the provisions of 37 CFR 1.32.

All power(s) of attorney relating to this patent are hereby revoked, and the following attorneys are hereby appointed to receive all correspondence from the United States Patent and Trademark Office and to transact all business in the United States Patent and Trademark Office connected therewith: DONALD E. STOUT, Reg. No. 34,493; FRANK J. UXA, Reg. No. 25,612; ROBERT D. BUYAN, Reg. No. 32,460; KENTON R. MULLINS, Reg. No. 36,331; and LINDA ALLYSON FOX, Reg. No. 38,883, all of STOUT, UXA, BUYAN & MULLINS, LLP, 4 Venture, Suite 300, Irvine, CA 92618.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that there statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

The undersigned is empowered to sign this certificate on behalf of the assignee.

5/10/2006
Date

S. Mirhashemi
Signature

SOHEILA MIRHASHEMI
Typed or printed name

PRESIDENT
Title

Attorney Docket No. NEOME-019A3US

ASSIGNMENT

Name(s) of Inventor(s): John T. Sorensen, Michael Mittelstein, and Soheila Mirhashemi
Name of Assignee: NeoMedix Corporation
State of Incorporation of Assignee: California
Address of Assignee: 15042 Parkway Loop, Suite A, Tustin, California 92780
Title of Application: Tubular Cutter Device and Methods for Cutting and Removing Strips of Tissue from the Body of a Patient
Application No.: 10/560,267 (PCT/US04/18488) Filing Date: (To Be Inserted)

1. The receipt and sufficiency of which are hereby acknowledged, the undersigned agree(s) to sell, assign and transfer and does (do) hereby sell, assign and transfer to the above-named Assignee, its successors and assigns, the entire and exclusive right, title and interest in and to the inventions claimed and described in the above-identified patent application in the United States and throughout the world, and in and to any applications for patent and patents which may be granted and issued thereon in any and all countries, and in and to any continuations, divisions, reissues and extensions of said application(s) and patent(s) and all international priority rights associated therewith. The undersigned agree(s) to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

2. The undersigned agree(s) to execute all papers necessary in connection with any interference which may be declared concerning this application or continuation or division thereof and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such interference.

3. The undersigned agree(s) to execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

4. The undersigned agree(s) to perform all affirmative acts which may be necessary to obtain a grant of a valid United States patent to the Assignee.

5. The undersigned hereby represent(s) and warrant(s) that no other assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

6. The undersigned hereby authorize and request the Commissioner of Patents to issue any and all Letters Patents of the United States resulting from said application or any division or divisions or continuing applications thereof to the Assignee, as Assignee of the entire interest, and hereby covenant that they have full right to convey the entire interest herein assigned, and that they have not executed any agreement in conflict herewith.

7. The undersigned hereby grant Frank J. Uxa, Reg. No. 25,612; Donald E. Stout, Reg. No. 34,493; Robert D. Buyan, Reg. No. 32,460; Kenton R. Mullins, Reg. No. 36,331 and Linda Allyson Fox, Reg. No. 38,883, all of the firm of STOUT, UXA, BUYAN & MULLINS, LLP, the power to insert on this assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

Signature of Inventor: _____ Date: Mar 8, 2006
John T. Sorensen

Signature of Inventor: _____ Date: 05/10/06
Michael Mittelstein

Signature of Inventor: _____ Date: May 10, 2006
Soheila Mirhashemi

ALL-PURPOSE NOTARIAL ACKNOWLEDGMENT

State of CALIFORNIA

County of ORANGE

On MAY 8, 2006 (Date) before me, TERRY R. FINN, NOTARY PUBLIC (Name, Title of Officer)

personally appeared JOHN T. SORENSEN

☐ personally known to me
- OR -
☒ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that he/~~she/they~~ executed the same in his/~~her/their~~ authorized capacity(~~ies~~), and that by his/~~her/their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Signature Terry R. Finn (Seal)

TERRY R. FINN
Commission # 1437202
Notary Public - California
Orange County
My Comm. Expires Sep 29, 2007

Though the data below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent reattachment of this form.

CAPACITY CLAIMED BY SIGNER:

☒ INDIVIDUAL
☐ CORPORATE OFFICER

_____
(TITLE)

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☐ LIMITED ☐ GENERAL
☐ ATTORNEY-IN-FACT
☐ TRUSTEE
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☐ OTHER:

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TITLE OR TYPE OF DOCUMENT
Invention/Patent Assignment

NUMBER OF PAGES: 2

DATE OF DOCUMENT: MAY 8, 2006

SIGNER (OTHER THAN NAMED ABOVE):

SIGNER IS REPRESENTING: _____

ALL-PURPOSE NOTARIAL ACKNOWLEDGMENT

State of CALIFORNIA

County of ORANGE

On MAY 10, 2006 (Date) before me, TERRY R. FINN, NOTARY PUBLIC (Name, Title of Officer)

personally appeared MICHAEL MITTELSTEIN

☐ personally known to me
- OR -
☑ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he/she/they~~ executed the same in ~~his/her/their~~ authorized capacity(ies), and that by ~~his/her/their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) ~~acted~~, executed the instrument.

WITNESS my hand and official seal.

Signature Terry R. Finn (Seal)

TERRY R. FINN
Commission # 1437202
Notary Public - California
Orange County
My Comm. Expires Sep 29, 2007

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☐ CORPORATE OFFICER

_____
(TITLE)

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☐ LIMITED ☐ GENERAL
☐ ATTORNEY-IN-FACT
☐ TRUSTEE
☐ GUARDIAN/CONSERVATOR
☐ OTHER:

DESCRIPTION OF ATTACHED DOCUMENT
Assignment
TITLE OR TYPE OF DOCUMENT
Invention/Patent Assignment

NUMBER OF PAGES: 2

DATE OF DOCUMENT: MAY 10, 2006

SIGNER (OTHER THAN NAMED ABOVE):

SIGNER IS REPRESENTING: ———

ALL-PURPOSE NOTARIAL ACKNOWLEDGMENT

State of CALIFORNIA

County of ORANGE

On MAY 10 2006 (Date) before me, TERRY R. FINN NOTARY PUBLIC (Name, Title of Officer)

personally appeared SOHEILA MIRHASHEMI

☐ personally known to me
- OR -
☑ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Signature _____ (Seal)

TERRY R. FINN
Commission # 1437202
Notary Public - California
Orange County
My Comm. Expires Sep 29, 2007

Though the data below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent reattachment of this form.

CAPACITY CLAIMED BY SIGNER:

☒ INDIVIDUAL
☐ CORPORATE OFFICER

_____
(TITLE)

☐ PARTNERSHIP
☐ LIMITED ☐ GENERAL
☐ ATTORNEY-IN-FACT
☐ TRUSTEE
☐ GUARDIAN/CONSERVATOR
☐ OTHER:

DESCRIPTION OF ATTACHED DOCUMENT
Assignment
TITLE OR TYPE OF DOCUMENT
Invention/Patent Assignment

NUMBER OF PAGES: 2

DATE OF DOCUMENT: MAY 10, 2006

SIGNER (OTHER THAN NAMED ABOVE):

SIGNER IS REPRESENTING: ———

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	T.	Sorensen	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Lake Elsinore	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	21 Via del Macci Court		
Address 2			
City	Lake Elsinore	State/Province	CA
Postal Code	92532	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		Mittelstein	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Soheila		Mirhashemi	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	**State/Province**	CA
Postal Code	92677	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	33197		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT		
Attorney Docket Number	NEOME-019A3-US-G2	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference :

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For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

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Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	13159356	2010-06-13
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13159356	Division of	10560267	2006-05-11	7959641	2011-06-14

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10560267	Claims benefit of provisional	PCTUS2004018488	2004-06-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTUS2004018488	Claims benefit of provisional	60477258	2003-06-10

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
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Organization Name	Neomedix Corporation		
Mailing Address Information:			
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Address 2			
City	Tustin	**State/Province**	CA
Country [i]	US	Postal Code	92780-6528
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
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Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

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TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

RELATED APPLICATIONS

[0001] This application is a division of copending United States Patent Application No. 13/159,356 filed June 13, 2011 which is a division of United States Patent Application Serial No. 10/560,267 filed May 11, 2006 and issued as United States Patent No. 7,959,641 on June 14, 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed June 10, 2004, which claims priority to United States Provisional Patent Application No. 60/477,258 filed on June 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider than an incision made by a typical scalpel or cutting blade) in the skin, mucous membrane, tumor, organ or other tissue or a human or animal. Also, it may sometimes desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes, etc. Also, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.

[0003] One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes refered to as a goniectomy. In a goniectomy procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 μm in width is inserted into

the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosly organized, porous network of tissue that overlies a collecting canal known as Schlemm's canal. A fluid, known as aqueous humor, is continually produced in the anterior chamber of the eye. In normal individuals, aqueous humor flows through the trabecular meshwork, into Shlemm's Canal and out of the eye through a series of ducts. In patients who suffer from glaucoma, the drainage of aqueous humor from the eye may be impared by elevated flow resistance through the trabecular meshwork, thereby resulting in an increase in intraoccular pressure. The goniectomy procedure can restore normal drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork, thus allowing the aqueous humor to drain through the open area from which the strip of trabecular meshwork has been removed. The goniectomy procedure and certain prior art instruments useable to perform such procedure are described in United States Patent Application Serial No. 10/052,473 published as No. 2002/011608A1 (Baerveldt), the entirety of which is expressly incorporated herein by reference.

[0004] At present there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.

SUMMARY OF THE INVENTION

[0005] The present invention provides a device for cutting a strip of tissue of approximate width W from a mass of tissue. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The cutting tube is advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W, wherein the approximate width W is approximately equal to the distance D between the first and second cutting edges. In some embodiments, the strip of tissue may be aspirated or otherwise removed through the lumen of the cutter

tube. In some embodiments, the device may include apparatus useable to sever (e.g., transversely cut or transect) the strip of tissue when the strip of tissue has reached a desired length.

[0006] Further in accordance with the invention there is provided a method for cutting a strip of tissue of width W from a tissue mass. This method generally comprises the steps of a) providing a device that comprises i) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and ii) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and b) advancing the distal end of the cutting tube through the mass of tissue such that the first and second cutting edges cut a strip of tissue of approximate width W. Further aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Figure 1 is a perspective view of a system incorporating a needle cutting device of the present invention.

[0008] Figure 2 is an enlarged perspective view of section 2 of Figure 1.

[0009] Figures 3A-3D show various steps in a method for manufacturing a needle cutter of the present invention.

[0010] Figure 4 is a side view of a distal portion of a needle cutter device of the present invention being used to cut a strip of tissue of approximate width W.

[0011] Figure 5 is a perspective view of the distal portion of a needle cuter device of the present invention incorporating apparatus for severing a strip of tissue cut by the needle cutter device after the strip of tissue has reached a desired length.

[0012] Figure 6 is a side view of the distal portion of another embodiment of a needle cutter device of the present invention having a plurality of curves or bends formed in the cutting tube.

DETAILED DESCRIPTION

[0013] The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the invention. Thus, the following detailed description and the accompanying drawings shall not be construed to limit, in any way, the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

[0014] One example of a needle cutter device 10 of the present invention is shown in Figures 1-4. This needle cutter device 10 generally comprises an elongate cutting tube 14 that has a distal end and a lumen 27 that opens through an opening in the distal end. First and second cutting edges 20, 22 are formed on generally opposite edges of the distal end of the cutting tube 14. These first and second cutting edges 20, 22 are separated by a distance D, as shown in the distal end view of Figure 3B. In the particular example shown in the drawings, the first and second cutting edges 20, 22 are located on opposite lateral sides of the distal end of the cutting tube 14 and a blunt, protruding tip 24 is located on the bottom of the distal end of the cutting tube. Also, a blunt edge 26 is located at the top of the distal end of the cutting tube 14. Thus, only the lateral cutting edges 20, 22 are sharp and intended to cut tissue. The blunt, protruding tip 24 can, in some applications, be configured and used to facilitate insertion of the device 10 to its intended location and/or the blunt protruding tip 24 may be placed in an anatomical or man made grove or channel (e.g., Schlemm's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device 10.

[0015] One or more bends or curves may optionally be formed in the cutting tube 14 to facilitate its use for its intended purpose. For example, in the embodiment of the device 10 shown in Figure 2, a single bend 17 of approximately 90 degrees is formed near the distal end of the cutting tube 14. In the embodiment of the device 10b shown in Figure 6, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube 14, thereby giving the cutting tube 14 a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any

direction and of any severity may be formed in the cutting tube 14 to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube 14 each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

[0016] As shown in Figure 4, when the cutting tube 14 is advanced through tissue, distal end first, the first and second cutting edges 20, 22 will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges 20, 22. The severed strip ST of tissue will enter the lumen 27 of the cutting tube 14 as the device advances. Negative pressure may be applied to lumen 27 to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen 27.

[0017] The device 10 may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device 10 or for other purposes. In the embodiment shown in Figures 1 and 2, the device 10 comprises an outer tube 16 in addition to the cutting tube 14. The cutting tube 14 is of smaller diameter than the outer tube 16 and the cutting tube 14 may extend through the lumen 19 of the outer tube 16 such that a distal portion of the cutting tube 14 extends out of and beyond the distal end of the outer tube 16, as may be seen in Figure 2. The distal end of the outer tube 16 is tapered and in close approximation with the outer surface of the cutting tube 14. Fluid may be infused through the lumen 19 of the outer tube 16, through the space between the outer surface of the cutting tube 14 and the inner surface of the outer tube 16. Fluid that is infused through the lumen 19 of the outer tube 16 may flow out of one or more apertures 11 formed near the distal end of the outer tube.

[0018] In some embodiments, the device 10 may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue

mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. Figure 5 shows an example of an embodiment of the device 10a wherein monopolar or bipolar electrode(s) 40 are located on the distal end of the cutting tube 14. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

[0019] In some embodiments of the device 10, the cutting edges 20, 22 may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges 20, 22 may be accomplished by placement of electrode(s) near the cutting edges 20, 22 such that, when the electrode(s) is/are energized, the cutting edges 20, 22 will become heated to a temperature suitable for the desired cauterization function.

[0020] The needle cutter device 10 of the present invention may optionally be used as part of a system 12, as shown in Figure 1. The basic components of the system 12 comprise an aspiration pump module 74 and a source of irrigation fluid 72, mounted on a surgical roller cart 70. Control of the console functions during procedures may be accomplished by an aspiration foot pedal 78 which controls an aspiration pump 74 and variation in the height of the source of infusion fluid 72 to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device 10. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges 20, 22 and/or for severing the strip ST of tissue (Figure 5), the system 11 may additionally comprise an electrical current source, such as an electrosurgical generator 76 and electrosurgical foot pedal 80 which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device 10. As an option, all of the basic control functions of system 12 may be integrated into a single footpedal to facilitate use.

[0021] The device 10 may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Florida. After the device 10 has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module 76, aspiration pump module 74 and the source of irrigation fluid 72, as shown. Thus, the device 10 may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

[0022] Figures 3A-3D show an example of a method for manufacturing the cutting tube 14 from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges 20, 22, the protruding tip 24 and the blunt top edge 26. Thereafter, if it is desired to have one or more bends or curves in the cutting tube 14, angular cut out(s) 30 may be formed in the tube 14, as shown in Figure 3C. Thereafter, the tube 14 is bent to bring the edges of each angular cut out 30 into apposition and weld, adhesive or other joining techniques are used to weld or join the apposed edges of the cut outs together, thereby forming the desired bend(s) or curve(s) in the cutting tube 14. Likewise, if it is desired to have one or more bends or curves in the cutting tube 14, the tube 14 may be directly bent to form said curves or bends without the use of angular cut outs(s) 30. It may be appreciated that the use of angular cut-out(s) 30 allow a tube 10 of a given diameter to incorporate a curve or angle in a more compact form than is possible by bending tubing 10 of a given diameter to said curve or angle without kinking or damaging tube 10.

[0023] The device 10 and system 12 are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove, from a mass of tissue, a strip ST of tissue of a desired width.

[0024] One particular procedure that may be performed to treat glaucoma, using the device 10 and system 12 of the present invention, is a goniectomy. As explained herein a goniectomy procedure is an *ab interno* surgical procedure wherein a sector of the trabecular meshwork is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber of the

eye through Schlemm's Canal and the associated collector channels, thereby relieving elevated intraocular pressure.

[0025] To perform a goniectomy procedure using the device 10, first a small incision is made in the cornea at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision .

[0026] The device 10 is attached to the source of irrigation fluid 72 (e.g., basic balanced salt solution) such that irrigation fluid will flow through lumen 19 of the outer tube 16 and out of outflow aperture 11. The device 10 is then inserted through the incision and into the anterior chamber of the eye (with irrigation flowing). In some cases, during the insertion of the device 10, the source of irrigation fluid 72 may initially connected to the device such that the irrigation fluid will flow through the lumen 27 of the cutter tube 14. In this manner, irrigation fluid will begin to infuse into the anterior chamber of the eye as soon as the distal end of the cutter tube 14 has entered the anterior chamber, rather than being delayed until the larger outer tube 16 and aperture 11 have been advanced through the incision and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the distal end of the cutter tube 14 as the device 10 is being inserted, thereby spreading or opening the incision by hydraulic force while in addition increasing the fluid pressure in the anterior chamber. Such spreading or opening of the incision may facilitate advancement of the larger diameter outer tube 16 through the incision. Pressurizing the fluid in the anterior chamber causes the anterior chamber to deepen and may facilitate maneuvering of device 10 within the anterior chamber. In cases where this alternative approach is used, the source of infusion fluid 72 may be disconnected from lumen 27 of the cutter tube 14 after the device 10 has been inserted into the anterior chamber and, thereafter, the infusion fluid source 72 may be reconnected to lumen 19 of outer tube 16 such that infusion fluid will flow out of aperture 11. Negative pressure (e.g., via aspiration pump module 74) may then be applied to lumen 27 of the cutter tube 14 so as to aspirate fluid and debris through lumen 27 as shown in Figure 4. The vertical height of the infusion fluid source 72 may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior

chamber through lumen 27, thereby
maintaining the desired pressure of fluid within the anterior chamber during the procedure.

[0027] A lens device (e.g., Ocular Swan-Jacob Autoclavable Gonioprism, Model OSJAG, Ocular Instruments Inc., Bellevue, Washington) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle of the eye where the segment of trabecular meshwork is to be removed. Under direct visualization, the device 10 is advanced until the distal tip of the cutter tube 14 is positioned adjacent to the trabecular meshwork at the location where the strip ST is to be removed. Thereafter, the protruding tip 24 is advanced through the trabecular meshwork and into Schlemm's Canal.

[0028] The device 10 is then advanced along Schlemm's Canal, thereby causing the cutting edges 20, 22 to cut a strip of the trabecular meshwork, thereby creating an opening through which aqueous humor may drain from the anterior chamber of the eye.

[0029] After a strip of tissue of the desired length (e.g., about 2-10 mm) has been cut by the lateral cutting edges 20, 22, any optional tisue severing apparatus (e.g., electrode(s) 40 may be used (if present) to transect or sever the strp ST of tissue thereby disconnecting it from the patient's body and allowing it to be aspirated or drawn into or through lumen 27.

[0030] Thereafter, the aspiration is stopped, the device 10 is removed from the eye, and the infusion is stopped.

[0031] Following completion of the surgery, aqueous humor will drain from the anterior chamberthrough the opening that was created by removal of the strip of tissue from the trabecular meshwork TM.

[0032] Although the invention has been described above with respect to certain embodiments and examples, it is to be appreciated that such embodiments and examples are non-limiting and are not purported to define all embodiments and examples of the invention. Indeed, those of skill in the art will recognize that various modifications may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention and it is intended that all such modifications be included within the scope of the following claims.

CLAIMS

What is claimed is:

1. An *ab interno* method for using a device to form an opening in the trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal handpeice sized to be grasped by the hand of a human operator and b) an elongate probe extending from the handpeice, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends at an angle of from 20 degrees to 90 degrees from a distal end of the shaft and is sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at the junction of the shaft and the distal protruding tip, said first and second cutting edges being formed on generally opposite edges of the distal end of the cutting tube said first and second cutting edges being separated by a distance D;

an opening into the anterior chamber of the eye;

inserting the elongate probe through the opening;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to said operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

ABSTRACT

Methods and devices for cutting strips of tissue from masses of tissue inside or outside of the bodies of human or animal subjects. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The device is advanced through tissue to cut a strip of tissue of approximate width W. Width W is approximaely equal to distance D.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Filer:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3USG2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**800**

Electronic Acknowledgement Receipt

EFS ID:	20092486
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan
Filer Authorized By:	
Attorney Docket Number:	NEOME-019A3USG2
Receipt Date:	09-SEP-2014
Filing Date:	
Time Stamp:	19:19:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$800
RAM confirmation Number	3243
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Transmittal of New Application	NEOME-019A3-US-G2-Trans-FILED.pdf	138487 d20b730464edffdcb034d6fd1c3c249fe59d70ad	no	2
Warnings:					
Information:					
2	Drawings-only black and white line drawings	NEOME-019A3-US-G2-Drawings-FILED.pdf	50632 41ff9555fac32000239405e0459414fb5d61c993	no	3
Warnings:					
Information:					
3	Oath or Declaration filed	NEOME-019A3US-G2-Declaration-FILED.pdf	336606 bd6fa1c15e04f683b0e0290d14afac8c89c2131e	no	8
Warnings:					
Information:					
4	Application Data Sheet	NEOME-019A3US-G2-ADS-FILED.pdf	1561525 802baa962f6425ca753765e0df6937a9508e2aa1	no	8
Warnings:					
Information:					
5		NEOME-019A3US-G2-PatApp-FILED.pdf	60780 bfc7e10413287dd0cedfdc89ab93011e8773549f	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	9
Claims	10	10
Abstract	11	11

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	36784 c924ba9c3a4f318fca0decd87ad7446e5692bf80	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2184814	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2

CONFIRMATION NO. 9581

33197
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

NOTICE

OC000000070781886

Date Mailed: 09/17/2014

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

A new inventor's oath or declaration that identifies this application (e.g., by Application Number and filing date) is required. The inventor's oath or declaration does not comply with 37 CFR 1.63 in that it:

- does not state that the above-identified application was made or authorized to be made by the person executing the oath or declaration.

  John T. Sorensen
  Michael Mittelstein
  Soheila Mirhashemi

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/481,754

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	2 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/481,754	09/09/2014	3773	800	NEOME-019A3-US-G2	2	1

CONFIRMATION NO. 9581

33197
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

FILING RECEIPT

OC000000070781885

Date Mailed: 09/17/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

John T. Sorensen, Lake Elsinore, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

Applicant(s)

Neomedix Corporation, Tustin, CA

Power of Attorney:
Frank Uxa Jr--25612
Robert Buyan--32460
Donald Stout--34493
Kenton Mullins--36331
Linda Fox--38883

Domestic Priority data as claimed by applicant

This application is a DIV of 13/159,356 06/13/2011 *
which is a DIV of 10/560,267 05/11/2006 PAT 7959641
which is a 371 of PCT/US2004/018488 06/10/2004
which claims benefit of 60/477,258 06/10/2003
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 09/16/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/481,754**

Projected Publication Date: 12/25/2014

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 14/481,754 filed on September 9, 2014.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: John T. Sorensen Date (Optional): Dec. 12, 2014

Signature: /John T. Sorensen/

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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LEGAL NAME OF INVENTOR

Inventor: Michael Mittelstein Date (Optional): X Dec 12 2014

Signature: X

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

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☐ The attached application, or

☒ United States application or PCT international application number 14/481,754 filed on September 9, 2014.

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LEGAL NAME OF INVENTOR

Inventor: Soheila Mirhashemi Date (Optional) X 12/23/14

Signature: X S Mirhashemi

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

Electronic Acknowledgement Receipt

EFS ID:	21054534
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan/Dana Sundene
Filer Authorized By:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	23-DEC-2014
Filing Date:	09-SEP-2014
Time Stamp:	16:45:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	NEOME-019A3USG2_Declarations-Filed.pdf	553876 af0575bc7d892d1fa8e53fcd35faec92a764a7f7	no	3

Warnings:	
Information:	

Total Files Size (in bytes):	553876

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2

CONFIRMATION NO. 9581

33197
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

PUBLICATION NOTICE

OC000000072576628

Title:TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

Publication No.US-2014-0379015-A1
Publication Date:12/25/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14481754
Filing Date	2014-09-09
First Named Inventor	Sorensen et al.
Art Unit	3734
Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4501274	A	1985-02-26	Skjaerpe	
	2	4900300	A	1990-02-13	Lee	
	3	5112299	A	1992-05-12	Pascaloff	
	4	5123904	A	1992-06-23	Shimomura et al.	
	5	5269782	A	1993-12-14	Sutter	
	6	5755716	A	1998-05-06	Garito et al.	
	7	5807277	A	1998-09-15	Swaim	
	8	6068629	A	2000-05-30	Haissaguerre	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Sorensen et al.
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	9	6217598	B1	2001-04-17	Berman et al.	
	10	6283961	B1	2001-09-04	Underwood et al.	
	11	6290699	B1	2001-09-18	Hall et al.	
	12	6419684	B1	2002-07-16	Heisler et al.	
	13	6428539	B1	2002-08-06	Baxter et al.	
	14	3294085	A	1966-12-27	Wallace	
	15	5431646	A	1995-07-11	Vassiliadis et al.	
	16	5458596	A	1995-10-17	Lax et al.	
	17	5681282	A	1997-10-28	Eggers et al.	
	18	5885279	A	1999-03-23	Bretton	
	19	5957914	A	1999-09-28	Cook et al.	

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	First Named Inventor	Sorensen et al.
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	20	6432104	B1	2002-08-13	Durgin et al.	
	21	6979328	B2	2005-12-27	Baerveldt et al.	
	22	7244256	B2	2007-07-17	DeCesare et al.	
	23	7842034	B2	2010-11-30	Mittelstein et al.	
	24	7959641	B2	2011-06-14	Sorensen et al.	
	25	RE38018	E	2003-03-04	Anctil et al.	
	26	6382974	B1	2002-05-07	Garfinkel	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020002372	A1	2002-01-03	Jahns et al.	
	2	20020111608	A1	2002-08-15	Baerveldt et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14481754
Filing Date	2014-09-09
First Named Inventor	Sorensen et al.
Art Unit	3734
Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	WO 98/27876	WO	A	1998-07-02	Smith & Nephew Inc.		☐
	2	WO 02/056805	WO	A	2002-07-25	University of California		☐
	3	JP 46-25677	JP	Y1	1971-09-03	(Unknown)	See Attached English Abstract	☐
	4	WO 91/17793	WO	A1	1991-11-28	Sunrise Technologies, Inc.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	US Patent Office Action dated 09/29/2009 in related U.S. Application Serial No. 10/560,267 filed 05/11/2006.	☐
	2	US Patent Office Action dated 03/12/2010 in related U.S. Application Serial No. 10/560,267 filed 05/11/2006.	☐
	3	JACOBI, PHILIPP C., et al. "Technique of Goniocurettage: A Potential Treatment for Advanced Chronic Open Angle Glaucoma," British Journal of Ophthalmology, 1997; 81, pp. 302-307.	☐
	4	SOOHOO, JEFFREY R., et al. "Ab Interno Trabeculectomy in the Adult Patient," Middle East African Journal of Ophthalmology, Vol. 22, No. 1, January - March 2015, pp. 25 - 29.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	Sorensen et al.
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

If you wish to add additional non-patent literature document citation information please click the Add button Add			
EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	Sorensen et al.
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Robert D. Buyan/	Date (YYYY-MM-DD)	2015-03-09
Name/Print	Robert D. Buyan	Registration Number	32,460

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	21711620
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan/Dana Sundene
Filer Authorized By:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	09-MAR-2015
Filing Date:	09-SEP-2014
Time Stamp:	15:22:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	NEOME-019A3-US-G2-IDSTrans-filed.pdf	25526 ed54472b2be9e3b09bd434674b88b99ad60a4dc9	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	NEOME-019A3USG2-updated_IDS.pdf	613617 935be0af4bcebc9ae5a04cf3e57d0452962a0d88	no	7
Warnings:					
Information:					
3	Non Patent Literature	Jacobi-etal.pdf	1697901 d5c79ca7742e15ab49681b2c291ddfb04431e834	no	6
Warnings:					
Information:					
4	Non Patent Literature	SooHoo-etal.pdf	1136095 c882ec58f0e0c7aa113ef79d52d6d092c4c9d4f7	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	3473139		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	14/481,754
APPLICANT	:	SORENSEN, ET AL.
FILED	:	SEPTEMBER 9, 2014
TC/A.U.	:	3734
EXAMINER	:	AMY REGINA WEISBERG
CONFIRMATION NO.	:	9581
DOCKET NO.	:	NEOME-019A3-US-G2
CUSTOMER NO.	:	33197
TITLE:	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

An Information Disclosure Statement is submitted as listed on Form(s) PTO/SB/08A enclosed herewith. Copies of the non-patent literature references listed are believed to already be in the possession of the Examiner as they were previously cited in the parent application related to this application. Copies of non-patent literature references not available in the parent application are attached hereto.

The listed documents are brought to the Examiner's attention because they are known to the applicant and/or the applicant's attorney and may be considered by the Examiner to be material to his/her examination. These submissions shall not be construed as representation that a search has been made or that no better art exists. No inference should be made that any of these submissions are in fact material or that they constitute prior art. Moreover, Applicant makes no admission regarding the relative dates of the invention and these submissions. Furthermore, no aspect of these submissions constitutes a disclaimer of claim scope.

The Examiner is requested to carefully consider the complete text of these documents in connection with the examination of the above-identified application in accordance with 37 CFR 1.104(a). It is requested that the documents listed on the attached Form Form(s) PTO/SB/08A be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. 1302.12), and that the Examiner initial and return a copy of the form to evidence consideration of the documents.

As no office action on the merits has been issued prior to the filing of this Information Disclosure Statement, it is believed that no fee is due. However, in the event that any fee is properly deemed to be due in connection with this filing, the Commissioner is authorized to deduct such fee from Deposit Account No. 50-0878.

Respectfully submitted,

STOUT, UXA & BUYAN, LLP

Date: March 9, 2015

/Robert D. Buyan/
Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764
Email: rbuyan@patlawyers.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2	9581

33197 7590 04/09/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER
WEISBERG, AMY REGINA

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
04/09/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 14/481,754	Applicant(s) SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/9/14*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1 and 2* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-2* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 112

1. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-2 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. In particular in the third paragraph of claim 1, Applicant recites “an opening into the anterior chamber of the eye” it is unclear if the opening was already there or is being formed.

3. Claim 1 recites the limitations "the trabecular meshwork"; "the hand"; "the junction"; "the cutting tube"; "the anterior chamber"; and "said operative position". There is insufficient antecedent basis for these limitations in the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Weisberg whose telephone number is (571)270-5500. The examiner can normally be reached on 7:00-5:30pm M-Th.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, SPE Darwin Erezo, at* (571)272-4695**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy Weisberg
Patent Examiner
/Amy Weisberg/
AU 3734
3/9/15

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,689,040 A	08-1987	Thompson, Robert J.	604/22
*	B	US-4,706,669 A	11-1987	Schlegel, Hans-Joachim	606/107
*	C	US-4,753,234 A	06-1988	Martinez, Miguel	606/171
*	D	US-4,759,746 A	07-1988	Straus, Jeffrey G.	604/512
*	E	US-4,841,984 A	06-1989	Armeniades et al.	600/561
*	F	US-4,900,300 A	02-1990	Lee, David A.	604/22
*	G	US-4,955,887 A	09-1990	Zirm, Mathias	606/107
*	H	US-4,955,883 A	09-1990	Nevyas et al.	606/28
*	I	US-5,019,035 A	05-1991	Missirlian et al.	604/22
*	J	US-5,112,299 A	05-1992	Pascaloff, John	604/22
*	K	US-5,123,904 A	06-1992	Shimomura et al.	604/22
*	L	US-5,284,472 A	02-1994	Sussman et al.	604/22
*	M	US-5,540,706 A	07-1996	Aust et al.	606/170

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Minckler et al "clinical results with the trabesctome, a novel surgical device for treatment of open angle glaucoma" trans am opthalmol soc/ vol 104/ 2006
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 2 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,733,297 A	03-1998	Wang, Carl C. T.	606/167
*	B	US-5,807,277 A	09-1998	Swaim, William R.	600/567
*	C	US-5,843,106 A	12-1998	Heisler, Gary R.	606/167
*	D	US-5,885,279 A	03-1999	Bretton, Randolph H.	606/41
*	E	US-5,922,003 A	07-1999	Anctil et al.	606/170
*	F	US-5,957,914 A	09-1999	Cook et al.	606/6
*	G	US-5,957,881 A	09-1999	Peters et al.	604/22
*	H	US-5,964,777 A	10-1999	Drucker, Karen	606/180
*	I	US-6,004,199 A	12-1999	Habenicht et al.	452/166
*	J	US-6,217,598 B1	04-2001	Berman et al.	606/167
*	K	US-6,293,957 B1	09-2001	Peters et al.	606/167
*	L	US-2002/0038129 A1	03-2002	Peters et al.	606/167
*	M	US-6,382,974 B1	05-2002	Garfinkel, Leonard M.	433/144

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 3 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,419,684 B1	07-2002	Heisler et al.	606/170
*	B	US-2002/0111608 A1	08-2002	Baerveldt et al.	606/6
*	C	US-6,428,539 B1	08-2002	Baxter et al.	606/49
*	D	US-RE38,018 E	03-2003	Anctil et al.	606/170
*	E	US-2004/0204732 A1	10-2004	Muchnik, Semeyn	606/171
*	F	US-2004/0210245 A1	10-2004	Erickson et al.	606/167
*	G	US-2005/0159767 A1	07-2005	Adams et al.	606/180
*	H	US-2006/0212060 A1	09-2006	Hacker et al.	606/180
*	I	US-2006/0241580 A1	10-2006	Mittelstein et al.	606/041
*	J	US-2007/0010812 A1	01-2007	Mittelstein et al.	606/048
*	K	US-7,244,256 B2	07-2007	DeCesare et al.	606/41
*	L	US-2007/0276420 A1	11-2007	Sorensen et al.	606/167
*	M	US-2009/0287233 A1	11-2009	Huculak, John C.	606/167

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

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	U	
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 4 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-8,147,424 B2	04-2012	Kassab et al.	600/564
*	B	US-2012/0123533 A1	05-2012	Shiuey, Yichieh	623/5.11
*	C	US-2015/0045820 A1	02-2015	Kahook, Malik Y	606/170
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
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	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	W	
	X	

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	Art Unit
	AMY R WEISBERG	3734

CPC- SEARCHED		
Symbol	Date	Examiner
(A61F2009/00868 or A61F9/007,00736-00763,013-0133).cpc.	3/9/15	/ARW/
(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc.	3/9/15	/ARW/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	107, 161-162, 166-167, 170, 184-185,	3/9/15	/ARW/
600	566, 567	3/9/15	/ARW/

SEARCH NOTES		
Search Notes	Date	Examiner
STIC search, inventor search, cpc search	3/9/15	/ARW/
Julian Woo Search 606/107, 161, 162, 166, 167, 170. Try combining with keywords: eye, trabeculae, schlemm, glaucoma, gouge.	3/9/15	/ARW/
Jon Hollm CPC QN A61F2009/00868 and A61F9/007,00736-00763013-0133;	3/9/15	/ARW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	(cutting adj edges and schlemm$2).clm.	3/9/15	/ARW/
	(dual adj blade and schlemm$2).clm.	3/9/15	/ARW/

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BIB DATA SHEET

CONFIRMATION NO. 9581

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/481,754	09/09/2014	606	3734	NEOME-019A3-US-G2

APPLICANTS

Neomedix Corporation, Tustin, CA, Assignee (with 37 CFR 1.172 Interest);

INVENTORS

John T. Sorensen, Lake Elsinore, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

**** CONTINUING DATA ***************************

This application is a DIV of 13/159,356 06/13/2011 ABN *
which is a DIV of 10/560,267 05/11/2006 PAT 7959641
which is a 371 of PCT/US2004/018488 06/10/2004
which claims benefit of 60/477,258 06/10/2003
(*)Data provided by applicant is not consistent with PTO records.

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
09/16/2014

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/AMY REGINA WEISBERG/ Examiner's Signature	☐ Initials	CA	3	2	1

ADDRESS

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618
UNITED STATES

TITLE

TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

FILING FEE RECEIVED		
800	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

STIC Search Results 14481754	Fern Birtwistle Searcher, EIC-3700 March 6, 2015

Examiner Weisberg,

A search of the prior art has been conducted pertaining to claim 1 of the noted application:

> *An ab inferno method for using a device to form an opening in the trabecular meshwork of a patient's eye, said method comprising the steps of:*
>
> *obtaining a dual blade device which comprises a) an elongate proximal handpiece sized to be grasped by the hand of a human operator and b) an elongate probe extending from the handpiece, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends at an angle of from 20 degrees to 90 degrees from a distal end of the shaft and is sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at the junction of the shaft and the distal protruding tip, said first and second cutting edges being formed on generally opposite edges of the distal end of the cutting tube said first and second cutting edges being separated by a distance D;*
>
> *an opening into the anterior chamber of the eye;*
>
> *inserting the elongate probe through the opening;*
>
> *advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to said operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork; and, thereafter*
>
> *causing the distal protruding tip to advance through a sector of Schlemm's Canal with first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.*

This search was conducted utilizing the NPL search resources of ProQuest Dialog (PQD), Google Scholar, Espacenet, and Ip.Com. The applied search histories of two PQD searches are appended as pdf documents. The application priority date of 6-10-2004 was acknowledged.

Two references of particular note were found as a result of this investigation: USPN 4501274 A, issued to Skjaerpe, and USPN 20150045820 A1 to Kahook. Kahook, '820, describing dual cutting blades with a tracking foot plate within the Schlemm's canal, notes the following as pertaining to Skjaerpe, '274: *"…While the reference discloses a dual-knife with at least one sharp cutting edge for cutting the trabecular meshwork and the inner wall of Schlemm's canal it does not per se mention a curvature for navigating Schlemm's canal."* (paragraph 0084)

Another patent noted in Kahook, '820, USPN 6979328 B2, issued to Baeveldt et al., is also of interest as it describes a device which utilizes the Schlemm canal as a device tracking guide. The method claims were restricted out of that application, reappearing in USPN 7785321 B2 to Baerveldt et al., claiming a priority date of 1/18/2001. The latter claims a method for treating glaucoma wherein a cutting or ablation device is guided by a element of the tip being inserted into the Schlemm canal; however, dual cutting blades are not noted.

The goniotomy procedure apparently originated in the mid 1930's, as discussed in the appended article to Minckler et al.. The article also shows and discusses the trabectome instrument which cauterizes a passage through the trabecular meshwork. The many reviewed articles indicated that a persistent problem of various means of tunneling through this tissue without edge removal tends to lead to a filling in of the formed channel as the created pathway becomes clogged with regrowth or blebs.

Please do not hesitate to contact me if there are any questions or comments concerning any aspect of this search or the presented results. Also, even though this search was far extended beyond the time and typical information resources accorded to a STIC Fast & Focused Search, there is always more searching effort that could be invested.

We at STIC welcome your feedback and invite you to complete an interactive feedback form which can be found at: http://usptopat/SIRA/STICSP/Shared_Documents/OFFICIAL_STIC_FORMS/Updated/EIC-Spec_Sch_Feedback.

Thanks very much for using STIC search services!

Fern

Appended: Minkler, et al., CLINICAL RESULTS WITH THE TRABECTOME, A NOVEL SURGICAL DEVICE FOR TREATMENT OF OPEN-ANGLE GLAUCOMA, 2006, Trans Am Ophthalmol Soc, 104:40-50

14481754 STIC ProQuest Dialog Search Strategies and Results

Report Information from ProQuest Dialog
05 and 06 March 2015

Search One

Accessed ProQuest Dialog Files

ABI/INFORM® Professional Advanced
Abstracts in New Technology & Engineering
Adis Clinical Trials Insight
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ESPICOM Pharmaceutical & Medical Device News
FDAnews
FLUIDEX (Fluid Engineering Abstracts)
Foodline®: MARKET
Foodline®: PRODUCT
Foodline®: SCIENCE
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Gale Group Health Periodicals Database
Gale Group New Product Announcements / Plus®
Gale Group Newsletter Database™
Gale Group PharmaBiomed Business Journals
Gale Group PROMT®
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GEOBASE
GeoRef
HSELINE: Health and Safety
ICONDA - International Construction Database
IMS Company Profiles
IMS New Product Focus
IMS Pharma Trademarks
IMS R&D Focus
IMS R&D Focus Drug News
Incidence & Prevalence Database
Inspec®
International Pharmaceutical Abstracts
Jane's Defense & Aerospace News
King's Fund
KOSMET: Cosmetic Science
Lancet Titles
Material Safety Datasheets -OHS™
Mechanical & Transportation Engineering Abstracts
MEDLINE®
New England Journal of Medicine
NTIS: National Technical Information Service
PAIS International
Paperbase
PAPERCHEM
PASCAL
PIRABASE
Polymer Library
ProQuest Advanced Tech & Aerospace Professional
ProQuest Biological & Health Science Professional
ProQuest Dissertations and Theses Professional
ProQuest Environmental Science Professional
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ProQuest Newsstand Professional
Prous Science Daily Essentials
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SciSearch®: a Cited Reference Science Database
Social SciSearch®
ToxFile®
Transport Research International Documentation
TULSA™ (Petroleum Abstracts)
UBM Computer Full Text
Weldasearch®
Zoological Record Plus

Applied Search Strategy:

Set#	Searched for	Results
S1	((intraocular or ocular or eye) n/2 fluid) or "aqueous humor"	100079*
S2	trabecular or mesh or meshwork or ((spong* or reticulat* or net*) n/2 tissue or structure or filter)	57550067*
S3	(Schlemm* n/2 canal) or (((fluid or humor) n/3 (pathway or canal or drain* or flow* or outflow*)) and eye) or "scleral venous sinus" or "sinus venosus sclerae"	56700*
S4	core or cored or coring or cut or cutting or bore or bored or boring or ream or	53101449*

	reamed or reaming or canaloplast* or tunnel*	
S5	dual or double or pair or paired or twin or coupled	51340702*
S6	blade or bevel or edge	15424382*
S7	(((intraocular OR ocular OR eye) NEAR/2 fluid) OR "aqueous humor") NEAR/10 (trabecular OR mesh OR meshwork OR ((spong* OR reticulat* OR net*) NEAR/2 tissue OR structure OR filter))	5535*
S8	(trabecular OR mesh OR meshwork OR ((spong* OR reticulat* OR net*) NEAR/2 tissue OR structure OR filter)) NEAR/10 (core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel*)	1089594*
S9	(dual OR double OR pair OR paired OR twin OR coupled) NEAR/5 (blade OR bevel OR edge)	166062*
S10	((trabecular OR mesh OR meshwork OR ((spong* OR reticulat* OR net*) NEAR/2 tissue OR structure OR filter)) NEAR/10 (core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel*)) AND ((dual OR double OR pair OR paired OR twin OR coupled) NEAR/5 (blade OR bevel OR edge))	6354*
S11	((((intraocular OR ocular OR eye) NEAR/2 fluid) OR "aqueous humor") NEAR/10 (trabecular OR mesh OR meshwork OR ((spong* OR reticulat* OR net*) NEAR/2 tissue OR structure OR filter))) AND (((trabecular OR mesh OR meshwork OR ((spong* OR reticulat* OR net*) NEAR/2 tissue OR structure OR filter)) NEAR/10 (core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel*)) AND ((dual OR double OR pair OR paired OR twin OR coupled) NEAR/5 (blade OR bevel OR edge)))	2°
S12	goniotom* or goniocurettag* or glaucoma	506635*
S13	core or cored or coring or cut or cutting or bore or bored or boring or ream or reamed or reaming or canaloplast* or tunnel* or curettag*	53170468*
S14	blade or bevel or edge or razor	15800859*
S15	trabecular or mesh or meshwork	6516385*
S16	(core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel* OR curettag*) NEAR/10 (trabecular OR mesh OR	39629*

	meshwork)	
S17	(dual OR double OR pair OR paired OR twin OR coupled) NEAR/7 (blade OR bevel OR edge OR razor)	212969*
S18	((core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel* OR curettag*) NEAR/10 (trabecular OR mesh OR meshwork)) AND ((dual OR double OR pair OR paired OR twin OR coupled) NEAR/7 (blade OR bevel OR edge OR razor))	874°
S19	(((core OR cored OR coring OR cut OR cutting OR bore OR bored OR boring OR ream OR reamed OR reaming OR canaloplast* OR tunnel* OR curettag*) NEAR/10 (trabecular OR mesh OR meshwork)) AND ((dual OR double OR pair OR paired OR twin OR coupled) NEAR/7 (blade OR bevel OR edge OR razor))) AND ((Schlemm* NEAR/2 canal) OR (((fluid OR humor) NEAR/3 (pathway OR canal OR drain* OR flow* OR outflow*)) AND eye) OR "scleral venous sinus" OR "sinus venosus sclerae")	21°

* Duplicates are removed from the search, but included in the result count.
° Duplicates are removed from the search and from the result count.

Search Results:

Patents; "MODIFIED DUAL-BLADE CUTTING SYSTEM" in Patent Application Approval Process
Publication info: Politics & Government Week (Mar 5, 2015): 2455.
Full text:
2015 MAR 5 (VerticalNews) -- By a News Reporter-Staff News Editor at Politics &Government Week -- A patent application by the inventor Kahook, Malik Y (Denver, CO), filed on April 19, 2013, was made available online on February 19, 2015, according to news reporting originating from Washington, D.C., by VerticalNews correspondents.
This patent application has not been assigned to a company or institution.
The following quote was obtained by the news editors from the background information supplied by the inventors: "There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider than an incision made by a typical scalpel, cutting blade or needle) in the eye, skin, mucous membrane, tumor, organ or other tissue or a human or animal. In addition, it may sometimes be desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes, etc. In addition, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.
"One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes referred to as a goniotomy. In a gonioctomy procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length or more and about 50-200 .mu.m in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosely organized, porous network of tissue that overlies a collecting canal known as Schlemm's canal. A fluid, known as aqueous humor, is continually produced in the anterior chamber of the eye. In normal individuals, aqueous humor flows through the trabecular meshwork, into Schlemm's canal and out of the eye through a series of ducts called collector channels. In patients who suffer from glaucoma, the drainage of aqueous humor from the eye may be impaired by elevated flow resistance through the trabecular meshwork, thereby resulting in an Increase in intraocular pressure. The gonioctomy procedure can restore normal drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork, thus allowing the aqueous humor to drain through

the open area from which the strip of trabecular meshwork has been removed. The gonioctomy procedure and certain prior art instruments useable to perform such procedure are described In U.S. patent application Ser. No. 10/052,473 issued as U.S. Pat. No. 6,979,328 (Baerveldt) [2], the entirety of which is expressly incorporated herein by reference.

"At present there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the procedure of cutting the trabecular meshwork TM in the eye and effectively remove a complete full thickness strip of TM without leaving TM leaflets as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue."

In addition to the background information obtained for this patent application, VerticalNews journalists also obtained the inventor's summary information for this patent application: "This invention is in the field of surgical medicinal intervention. For example, the present invention relates to a microsurgical device and methods of its use for treatment of various medical conditions including but not limited to eye diseases, such as glaucoma, using minimally invasive surgical techniques. Specifically, the device may be a dual-blade device for cutting the trabecular meshwork TM in the eye. In particular, the device may have a device tip providing entry into the Schlemm's canal via its size (i.e., for example, between approximately 0.3-2 mm width) and a configuration where the entry blade tip curves up providing a ramp-like action for cutting the TM.

"In one embodiment, the invention relates to a device comprising: a handle 1, interface of tool shaft and handle 2, a tool shaft 3, interface of tool shaft and beveled platform 4, beveled platform 5, a first end/beveled platform tip/insertion blade tip 6, a second end/back of the beveled platform 7, a first side 8, a second side 9, a first blade 10, and a second blade 11.

"In one embodiment, the invention relates to a device 12 comprising: a handle 1 that necks down to a tool shaft 3 by a first interface 2 wherein said tool shaft widens into a beveled platform 5 by a second interface 4, wherein said beveled platform comprises a insertion blade tip 6 on a distal end of the beveled platform comprising a ramp from said insertion blade tip back towards the posterior end the beveled platform, and a first lateral blade 10 and second lateral blade 11 along the sides of said beveled platform. In one embodiment, said sides of said beveled platform comprise a first side 8 and a second side 9. In one embodiment, said first lateral blade 10 and second lateral blade 11 are in a perpendicular alignment to the bottom of the beveled platform. In one embodiment, the platform 5 is set at a specific angle and orientation relative to said handle 1. In one embodiment, the platform 5 freely rotates in at least two dimensions. In one embodiment, said handle 1 and beveled platform 5 are operably attached at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said handle 1 and beveled platform 5 are operably attached at an angle ranging between 90 and 180 degrees in the X-Z axis. In one embodiment, said platform 5 freely rotates in an X-Y dimension relative to said handle 1. In one embodiment, said platform 5 remains at a fixed angle in the X-Y, X-Z, and Y-Z dimensions relative to said handle 1. In one embodiment, said platform 5 freely rotates in a positive Z dimension relative to said handle 1. In one embodiment, said beveled platform 5 comprises a first end/beveled platform tip/insertion blade tip 6 and a second end/back of the beveled platform 7, wherein said second end/back of the beveled platform 7 is between 2 and 30 greater in thickness relative to the thickness of said first end/beveled platform tip/insertion blade tip 6. In one embodiment, the dimensions of the beveled platform 5 are calculated using the formula A.sup.2+B.sup.2=C.sup.2, wherein A is the length of said beveled platform 5 from said insertion blade tip 6 to the back of the beveled platform 7, B is the height of the beveled platform 5 and C is the length of the ramp formed by the beveled platform insertion blade tip up to the height of said beveled platform. In one embodiment, the height of said beveled platform 5 is not to exceed 0.5 millimeters. In one embodiment, the length of said beveled platform 5 from said insertion blade tip 6 to the back of the beveled platform 7 is not to exceed 1.0 millimeters. In one embodiment, the width of said beveled platform 5 is not to exceed 0.35 millimeters. In one embodiment, said beveled platform 5 increases in thickness from a fine blade tip towards the second end/back of the beveled platform 7 in the direction of the Y-axis. In one embodiment, said first end/beveled platform tip/insertion blade tip 6 comprises a pointed tip with fine edges of surgical sharpness. In one embodiment, said first end/beveled platform tip/insertion blade tip 6 comprises a lancet. In one embodiment, said beveled platform 5 further comprises a first blade 10 and a second blade 11. In one embodiment, said first blade 10 is attached to a first side 8 of said second end/back of the beveled platform 7. In one embodiment, said first blade 10 and beveled platform 5 are operably attached at an angle ranging between 90 and 180 degrees in the Y-Z axis. In one embodiment, said angle is preferably between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second blade 11 and beveled platform 5 are operably attached at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said first blade 10 and handle 1 are operably positioned at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second blade 11 and handle 1 are operably positioned at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second blade 11 is attached to a second side 9 of said second end/back of the beveled platform 7. In one embodiment, said beveled platform 5 increases in thickness from said second side 9 towards the first side 8 in the direction of the X-axis. In one embodiment, said beveled platform 5 increases in thickness from said first side 8 towards the second side 9 in the direction of the X-axis. In one embodiment, said beveled platform 5 increases in thickness from said second side 9 towards the first side 8 in the direction of the X-axis and said beveled platform 5 increases in thickness from a fine blade tip of the first end 6 towards the second end/back of the beveled platform 7 in the direction of the Y-axis. In one embodiment, said beveled platform 5 increases in thickness from said first side 8 towards the second side 9 in the direction of the X-axis and said beveled platform 5 increases in thickness from a fine blade tip of the first end 6 towards the second end/back of the beveled platform 7 in the direction of the Y-axis. In one embodiment, said first blade 10 and said second blade 11 are parallel. In one embodiment, said first blade 10

and said second blade 11 extend above the top surface of said second end/back of the beveled platform 7. In one embodiment, said first blade 10 and said second blade 11 are positioned at an angle between approximately 100 to 140 degrees relative to the top surface of said second end/back of the beveled platform 7. In one embodiment, said beveled platform 5 is approximately 0.3 millimeters wide. In one embodiment, said beveled platform 5 is approximately 0.2 millimeters wide. In a preferred embodiment, said beveled platform 5 is approximately 0.25 millimeters wide.

"In one embodiment, the invention relates to a device comprising a handle and a beveled platform, wherein said platform freely rotates in at least two dimensions. In one embodiment, said handle and beveled platform are operably attached at an angle ranging between 90 and 120 degrees. In one embodiment, said platform freely rotates in an X-Y dimension relative to said handle. In one embodiment, said platform freely rotates in a positive Z dimension relative to said handle. In one embodiment, said beveled platform comprises a first end and a second end, wherein said second end is at least 20 times greater in thickness relative to said first end. In one embodiment, said beveled platform further comprises a first blade and a second blade. In one embodiment, said first blade is attached to a first side of said second end. In one embodiment, said second blade is attached to a second side of said second end. In one embodiment, said first blade and said second blade are parallel. In one embodiment, said first blade and said second blade extend above the top surface of said second end. In one embodiment, said first lateral blade and said second lateral blade are positioned at an angle between approximately 100-140 degrees in the Y-Z axis relative to the bottom surface of said beveled platform. In one embodiment, said beveled platform is approximately 0.3 millimeters wide. In one embodiment, said beveled platform 5 is approximately 0.2 millimeters wide. In a preferred embodiment, said beveled platform 5 is approximately 0.25 millimeters wide.

"In one embodiment, said beveled platform is set at a specific angle and orientation relative to said handle. In one embodiment, said handle and beveled platform are operably attached at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said handle and beveled platform are operably attached at an angle ranging between 90 and 180 degrees in the X-Z axis. In one embodiment, said platform freely rotates in an X-Y dimension relative to said handle. In one embodiment, said platform remains at a fixed angle in the X-Y, X-Z, and Y-Z dimensions relative to said handle. In one embodiment, said platform freely rotates in a positive Z dimension relative to said handle. In one embodiment, the dimensions of the beveled platform are calculated by the formula A.sup.2+B.sup.2=C.sup.2, wherein A is the length of said beveled platform from said beveled platform insertion blade tip to the posterior end of the beveled platform, B is the height of the beveled platform and C is the length of the ramp formed by the beveled platform insertion blade tip up to the height of said beveled platform. In one embodiment, the height of said beveled platform is not to exceed 0.5 millimeters. In one embodiment, the length of said beveled platform from said beveled platform insertion blade tip to the posterior end of the beveled platform is not to exceed 1.0 millimeters. In one embodiment, the height of said beveled platform is greater than 0.5 millimeters. In one embodiment, the length of said beveled platform from said beveled platform insertion blade tip to the posterior end of the beveled platform is greater than 1.0 millimeters. In one embodiment, the width of said beveled platform 5 is not to exceed 0.35 millimeters. In one embodiment, said beveled platform 5 is approximately 0.2 millimeters wide. In a preferred embodiment, said beveled platform 5 is approximately 0.25 millimeters wide. In one embodiment, said beveled platform increases in thickness from a fine blade tip towards the posterior end of the beveled platform in the direction of the Y-axis. In one embodiment, said beveled platform insertion blade tip comprises a pointed tip with fine edges of surgical sharpness. In one embodiment, said beveled platform insertion blade tip comprises a lancet. In one embodiment, said beveled platform further comprises a first lateral blade and a second lateral blade. In one embodiment, said first lateral blade is attached to a first side of said posterior end of the beveled platform. In one embodiment, said first lateral blade and beveled platform are operably attached at an angle ranging between 90 and 180 degrees in the Y-Z axis. In one embodiment, said angle is preferably between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second blade and beveled platform are operably attached at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said first lateral blade and handle are operably positioned at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second lateral blade and handle are operably positioned at an angle ranging between 90 and 120 degrees in the Y-Z axis. In one embodiment, said second lateral blade is attached to a second side 9 of said posterior end of the beveled platform. In one embodiment, said beveled platform increases in thickness from said second side towards the first side in the direction of the X-axis. In one embodiment, said beveled platform increases in thickness from said first side towards the second side in the direction of the X-axis. In one embodiment, said beveled platform increases in thickness from said second side towards the first side in the direction of the X-axis and said beveled platform increases in thickness from a fine blade tip of the beveled platform insertion blade tip towards the posterior end of the beveled platform in the direction of the Y-axis. In one embodiment, said beveled platform increases in thickness from said first side towards the second side in the direction of the X-axis and said beveled platform increases in thickness from a fine blade tip of the beveled platform insertion blade tip towards the posterior end of the beveled platform in the direction of the Y-axis. In one embodiment, said first lateral blade and said second lateral blade are parallel. In one embodiment, said first lateral blade and said second lateral blade extend above the top surface of said posterior end of the beveled platform. In one embodiment, said first lateral blade and said second lateral blade are positioned at an angle between approximately 100 to 140 degrees in the Y-Z axis relative to the bottom surface of said posterior end of the beveled platform. In one embodiment, said beveled platform is approximately 0.3 millimeters wide. In one embodiment, said beveled platform 5 is approximately 0.2 millimeters wide. In a preferred embodiment, said beveled platform 5 is approximately

0.25 millimeters wide. In one embodiment, said device is integrated into an endoscope. In one embodiment, said device is placed on the end of the endoscope. In one embodiment, said device is made from at least one of the following materials: titanium, stainless steel, polyether ether ketone, shape memory alloy, and shape memory polymers. In one embodiment, said device is rigid at room temperature, but is more flexible at body temperature. In one embodiment, portions of the device of the current invention are rigid at room temperature, but are more flexible at body temperature. In one embodiment, portions of the device are made from different materials. In one embodiment, portions of the device are made from materials of various rigidity. In one embodiment, said tool shaft is flexible. In one embodiment, said tool shaft is made from a lower density material.

"In one embodiment, the invention relate to a method for cutting a strip of tissue of width W from a tissue mass, said method comprising the steps of: a) providing a device which comprises; i) a handle attached to a beveled platform, ii) an anterior insertion blade tip of the beveled platform expanding backwards to a posterior end of the beveled platform, iii) a first side of the beveled platform upon which is affixed a first lateral blade, iv) a second side of the beveled platform upon which is affixed a second lateral blade; v) at least first and second lateral cutting edges formed by blades in a generally perpendicular and posterior position to said opposite edges of said anterior insertion blade tip of the beveled platform, said first and second cutting edges being separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; b) advancing the anterior insertion blade tip of the beveled platform through tissue such that the first and second cutting edges are positioned adjacent to tissue to be cut; c) advancing the distal end such that the cutting edges cut a strip of tissue of approximate width W and the cut strip of tissue remains substantially intact. In one embodiment, the mass of tissue is in vivo. In one embodiment, the mass of tissue is in vitro. In one embodiment, said device is integrated into an endoscope. In one embodiment, said cutting is under direct visualization. In one embodiment, the mass of tissue is located within the body of a human or animal subject. In one embodiment, the strip of tissue is removed for a diagnostic or therapeutic purpose. In one embodiment, the subject suffers from glaucoma and wherein the method is carried out to remove a strip of trabecular meshwork from an eye of the subject to facilitate drainage of aqueous humor from the eye thereby lowering intraocular pressure. In one embodiment, said eye has a dilated pupil. In one embodiment, step b comprises inserting the device into the anterior chamber of the eye; positioning the anterior insertion blade tip of the beveled platform adjacent to or within the trabecular meshwork of the eye; and advancing the cutting tube such that the cutting edges cut a strip of approximate width W from the trabecular meshwork. In one embodiment, the device provided in step a of the method further comprises an anterior insertion blade tip of the beveled platform and wherein the anterior insertion blade tip of the beveled platform is advanced through the trabecular meshwork and into Schlemm's canal and, thereafter, the anterior insertion blade tip of the beveled platform is advanced through Schlemm's canal as the cutting tube is advanced to cut the strip of tissue. In one embodiment, the device provided in step a further comprises apparatus for severing the strip of tissue after the strip of tissue has reached a desired length and wherein the method further comprises the step of: severing the strip of tissue after the strip of tissue has reached a desired length. In one embodiment, the method is carried out to form an incision in skin, mucous membrane, an organ, a tumor or other anatomical structure. In one embodiment, the method further comprises the step of: c) removing the entire strip of tissue.

"In one embodiment, the invention relates to a method for cutting a strip of tissue of width W from a tissue mass, said method comprising the steps of: a) providing a device which comprises; i) a handle attached to a beveled platform, ii) an anterior insertion blade tip of the beveled platform expanding backwards to a posterior end of the beveled platform, iii) a first side of the beveled platform upon which is affixed a first lateral blade, iv) a second side of the beveled platform upon which is affixed a second lateral blade; v) at least first and second lateral cutting edges formed by blades in a generally perpendicular and posterior position to said opposite edges of said anterior insertion blade tip of the beveled platform, said first and second cutting edges being separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; b) advancing the anterior insertion blade tip of the beveled platform through tissue such that the first and second cutting edges are positioned adjacent to tissue to be cut; c) advancing the distal end such that the cutting edges cut a strip of tissue of approximate width W and the cut strip of tissue remains substantially intact. In one embodiment, the mass of tissue is in vivo. In one embodiment, the mass of tissue is in vitro. In one embodiment, the mass of tissue is located within the body of a human or animal subject. In one embodiment, the strip of tissue is removed for a diagnostic or therapeutic purpose. In one embodiment, the subject suffers from glaucoma and wherein the method is carried out to remove a strip of trabecular meshwork from an eye of the subject to facilitate drainage of aqueous humor from the eye thereby lowering intraocular pressure. In one embodiment, step b comprises inserting the device into the anterior chamber of the eye; positioning the anterior insertion blade tip of the beveled platform adjacent to or within the trabecular meshwork of the eye; and advancing the cutting tube such that the cutting edges cut a strip of approximate width W from the trabecular meshwork. In one embodiment, the device provided in step a of the method further comprises an anterior insertion blade tip of the beveled platform and wherein the anterior insertion blade tip of the beveled platform is advanced through the trabecular meshwork and into Schlemm's canal and, thereafter, the anterior insertion blade tip of the beveled platform is advanced through Schlemm's canal as the cutting tube is advanced to cut the strip of tissue. In one embodiment, the device provided in step a further comprises apparatus for severing the strip of tissue after the strip of tissue has reached a desired length and wherein the method further comprises the step of severing the strip of tissue after the strip of tissue has reached a desired length. In

one embodiment, the method is carried out to form an incision in skin, mucous membrane, an organ, a tumor or other anatomical structure. In one embodiment, the method is carried out to remove tissue from the vascular system. In one embodiment, the method is carried out to remove tissue from the lymphatic system. In one embodiment, the invention further comprises the step of: c) removing the strip of tissue.

"It is not intended that embodiments of the invention be limited to any particular method, medical target, or device confirmation; however, it is believed that the device may be optimally designed to remove trabecular meshwork of the eye, unroofing small vessels (such as veins, arteries, lymphatic vessels, or other vessel with a lumen), and for creating a hole or opening in the tympanic membrane of the ear. It is not intended that embodiments of the invention be limited to any particular mechanism; however, it is believed that creating an opening in the tympanic membrane of the ear may help aid in treating ear disease.

"It is not intended that embodiments of the invention be limited to any particular endoscope, it is believed that the device may be optimally designed for an ophthalmic endoscopy system endoscope. One such system is commercially called 'Endo Optiks.'"

URL and more information on this patent application, see: Kahook, Malik Y. Modified Dual-Blade Cutting System. Filed April 19, 2013 and posted February 19, 2015. Patent URL: http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1265&p=26&f=G&l=50&d=PG01&S1=20150212.PD.&OS=PD/20150212&RS=PD/20150212

Keywords for this news article include: Patents.

Document 2 of 2

U.S. Patent and Trademark Office Receives The Regents of the University of Colorado a Body Corporate's Patent Application for Modified Dual-Blade Cutting System

Publication info: Global IP News. Medical Patent News [New Delhi] 12 Feb 2015.

Publication Name: Medical Patent News

Patent Application Number: 14/375350

Patent Publication Number: 20150045820

International Patent Classification Codes: A61F 9/007 20060101 A61F009/007, A61F 9/013 20060101 A61F009/013

Patent Status: Application

Alexandria, Feb. 12 -- U.S. Patent and Trademark Office has received The Regents of the University of Colorado a body Corporate's patent application for modified dual-blade cutting system. Kahook Malik Y developed the invention.

The patent application number is 14/375350. International Patent Classification codes are A61F 9/007 20060101 A61F009/007 and A61F 9/013 20060101 A61F009/013. Cooperative Patent Classification codes are A61F 9/00736 20130101, A61F 9/00781 20130101 and A61F 9/0133 20130101.

U.S. Patent and Trademark Office has released the abstract. According to the abstract, "The present invention relates to a microsurgical device and methods of its use for treatment of various conditions including eye diseases, such as glaucoma, using minimally invasive surgical techniques. The invention relates to a dual-blade device for cutting the trabecular meshwork (TM) in the eye. The device tip provides entry into the Schlemm's canal via its size (i.e., for example, 0.3-0.2 mm width) and configuration where the blade tip curves up providing a ramp-like action for cutting the TM. The dimensions and configuration of the blade is such that an entire strip of TM is removed without leaving TM leaflets behind and without causing collateral damage to adjacent tissues."

14481754 STIC ProQuest Dialog Search Strategies and Results

Report Information from ProQuest Dialog
06 March 2015

Search Two

Accessed ProQuest Dialog Files

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Abstracts in New Technology & Engineering
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TULSA™ (Petroleum Abstracts)
UBM Computer Full Text
Weldasearch®
Zoological Record Plus

Applied Search Strategy:

Set#	Searchedf for	Results
S1	((intraocular or ocular or eye) n/2 fluid) or "aqueous humor"	100079*

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	3610	(A61F2009/00868 or A61F9/007,00736-00763,013-0133).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 10:47
L3	2215	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 10:47
L4	2631	l2 not L3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 10:47
L5	9	(("4501274") or ("20150045820") or ("6979328") or ("7785321")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 12:55
L6	220	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/03/09 13:05
L7	1	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in. and (dual adj blade).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/03/09 13:05
L8	5	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in. and (blade).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/03/09 13:06
L13	86	(606/107 or 606/161-162 or 606/166-167	US-PGPUB;	OR	ON	2015/03/09

		or 606/170).ccls. and (eye and schlemm)	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			13:18
S1	58	("3294085" | "5681282" | "5755716" | "5885279" | "6290699" | "5123904" | "7244256" | "3294085" | "5807277" | "6068629" | "6217598" | "4900300" | "5755716" | "7842034" | "20020002372" | "4900300" | "5431646" | "6979328" | "4501274" | "5269782" | "5807277" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "4501274" | "5123904" | "6283961" | "6432104" | "7842034" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "20020111608" | "20020002372" | "6419684" | "6432104" | "6979328" | "5112299" | "5269782" | "5957914" | "6419684" | "7959641" | "6217598" | "6428539" | "5458595" | "6428539" | "7244256").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:31
S2	79	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:47
S3	9	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in. and cutting.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:47
S4	2291	606/167.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:50
S5	1751	606/167.ccls. and cutting	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:51
S6	1010	606/167.ccls. and cutting with tissue	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:52
S7	143	stent with graft adj cover	US-PGPUB; USPAT; USOCR;	OR	ON	2013/03/22 13:16

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S8	2	("7959641").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 13:57
S9	12	(US-20090287233-$ or US-20050159767-$ or US-20040210245-$ or US-20020038129-$).did. or (US-6419684-$ or US-6217598-$ or US-6428539-$ or US-6293957-$ or US-5964777-$ or US-5957881-$ or US-5843106-$).did. or (US-6419684-$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2013/03/22 13:58
S10	0	("l5andstainless").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 13:58
S11	3	S9 and stainless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 13:58
S12	58	("3294085" | "5681282" | "5755716" | "5885279" | "6290699" | "5123904" | "7244256" | "3294085" | "5807277" | "6068629" | "6217598" | "4900300" | "5755716" | "7842034" | "20020002372" | "4900300" | "5431646" | "6979328" | "4501274" | "5269782" | "5807277" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "4501274" | "5123904" | "6283961" | "6432104" | "7842034" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "20020111608" | "20020002372" | "6419684" | "6432104" | "6979328" | "5112299" | "5269782" | "5957914" | "6419684" | "7959641" | "6217598" | "6428539" | "5458595" | "6428539" | "7244256").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 14:09
S13	6	S12 and bend	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 14:09
S14	259	cutting with tissue with bend	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2013/03/22 14:11

			DERWENT; IBM_TDB			
S15	29	scaler and dental and angle near3 "90"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 15:24
S16	3	enamel adj hatchet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 15:36
S17	12	("0237062" | "1039235" | "5007831" | "5478235").PN. OR ("6042378").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/22 15:37
S18	2	("6,419,684").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 16:35
S19	5	(("4646738") or ("5411514")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 16:38
S20	37	cutting with tissue with angle with "90"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 17:19
S21	7860	(606/107 or 606/166 or 606/170 or 606/184 or 606/185 or 600/566 or 600/567).ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/01 17:34
S22	606	(606/107 or 606/166 or 606/170 or 606/184 or 606/185 or 600/566 or 600/567).ccls. and (blade and eye and cornea)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/01 17:38
S23	4	(("6419684") or ("7959641")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/10/01 18:39

S24	2	("7959641").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/12/29 11:52
S25	1	"14481754"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:23
S26	20973	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:29
S27	4741	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:30
S28	2054	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye and (cut or slice or incise or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:46
S29	2213	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:48

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L9	1	(dual adj blade and schlemm$2).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:08
L10	9	("20020111608" | "6428539" | "6419684" | "5112299" | "4900300" | "4501274" | "6217598" | "5123904" | "5807277" | "20020111608").PN.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:12
L11	29	("3294085" | "5681282" | "5755716" | "5885279" | "6290699" | "5123904" | "7244256" | "3294085" | "5807277" | "6068629" | "6217598" | "6419684" | "4900300" | "5755716" | "7842034" | "20020002372" | "4900300" | "5431646" |	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:15

		"6979328" | "6428539" | "4501274" | "5269782" | "5807277" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "4501274" | "5123904" | "6283961" | "6432104" | "7842034" | "RE38018" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "20020111608" | "6382974" | "20020002372" | "6419684" | "6432104" | "6979328" | "5112299" | "5269782" | "5957914" | "6419684" | "7959641" | "6217598" | "6428539" | "5458595" | "6428539" | "7244256").PN.				
L12	73	(606/107 or 606/161-162 or 606/166-167 or 606/170).ccls. and (eye and schlemm)	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:18
L14	14	(cutting adj edges and schlemm$2).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:23

3/9/2015 2:03:02 PM
C:\Users\aweisberg\Documents\EAST\Workspaces\14481754.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY R WEISBERG	3734

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/09/2015								
	1	✓								
	2	✓								

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	14/481,754
APPLICANT	:	SORENSEN, ET AL.
FILED	:	SEPTEMBER 9, 2014
TC/A.U.	:	3734
EXAMINER	:	AMY REGINA WEISBERG
CONFIRMATION NO.	:	9581
DOCKET NO.	:	NEOME-019A3-US-G2
CUSTOMER NO.	:	33197
TITLE:	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

Madam:

In response to the Office Action mailed April 9, 2015, please amend the above-identified application as set forth below.

Amendments to the Specification are shown on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Amendments to the Specification:

On page 1, please amend the title of the application as follows:

~~TUBULAR CUTTER DEVICE AND~~ METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE ~~CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY~~ OF A PATIENT

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) An *ab interno* method for forming ~~using a device to form~~ an opening in ~~the~~ trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal portion ~~handpeice~~ sized to be grasped by a ~~the~~ hand of a human operator and b) an elongate probe extending from the proximal portion ~~handpeice~~, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends at an angle ~~of from 20 degrees to 90 degrees~~ from a distal end of the shaft and is sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a ~~the~~ junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on ~~generally opposite edges of~~ the distal end of the shaft, ~~cutting tube~~ said first and second cutting edges being separated by a distance D;

forming an opening into an ~~the~~ anterior chamber of the eye;

inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an ~~said~~ operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges ~~surfaces~~ are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. (Original) A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

3. (New) A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.

4. (New) A method according to claim 1 further comprising the step of:

removing the strip of tissue from the subject's eye.

5. (New) A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of:

disconnecting the strip of tissue such that it may be removed from the eye.

6. (New) A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

7. (New) A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

8. (New) A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

9. (New) A method according to claim 1 wherein the distal protruding tip extends from the shaft at an angle of be between approximately 30 and approximately 90 degrees.

10. (New) A method according to claim 9 wherein the distal protruding tip extends from the shaft at an angle of approximately 90 degrees.

REMARKS / ARGUMENTS

By the foregoing amendment the title has been amended to more clearly reflect the subject matter being claimed in this divisional/continuation application. Also, claim 1 has been amended to correct typographical errors, remove unnecessary limitations, clarify the claimed subject matter and ensure that clear antecedent basis exists for all claim terms. Additionally, new dependent claims 3 through 10 have been added.

The present amendments have added no new matter. Support for new dependent claims 3 through 10 is found in the specification, including but not necessarily limited to the paragraphs indicated below:

New Claim	Example(s) of Support in pecification
3	¶ 0029
4	¶ ¶ 0018, 0029
5	¶ 0029
6	¶ ¶ 0018, 0029
7	¶ 0025
8	¶ 0027
9	¶ 0015
10	¶ 0015

35 U.S.C. §112 Rejections

No rejections under 35 U.S.C. 102 or 103 were stated in the Office Action. The Office Action contains only rejections under 35 U.S.C. § 112. Specifically, claims 1 and 2 were rejected for indefiniteness on grounds that the third paragraph of claim recited "an opening into the anterior chamber of the eye" leaving it unclear as to whether the opening was already there or is being formed. Also, claim 1 was rejected on grounds that antecedent basis was lacking for the limitations "the trabecular meshwork"; "the hand"; "the junction"; "the cutting tube"; "the anterior chamber"; and "said operative position."

By the present amendment, the inadvertently omitted word "forming" has been inserted in claim 1 before the words "an opening into the anterior chamber of the eye" thereby making it clear that the opening into the anterior chamber is not a preexisting opening but rather is being formed at the time of the surgical procedure.

Also by the present amendment, minor changes have been made to claim 1 to eliminate or establish clear antecedent basis for each of the terms, eliminate unnecessary language and further clarify the claimed subject matter. New dependent claims 3 through 10 add further limitations to the subject matter of independent claim 1.

Conclusion

Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any underpayment, or to credit any overpayment, to Deposit Account No. 50-0878.

Respectfully submitted,

Date: May 3, 2015

STOUT, UXA & BUYAN, LLP

/Robert D. Buyan/

Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764
e mail: rbuyan@patlawyers.com

Electronic Acknowledgement Receipt

EFS ID:	22299163
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan
Filer Authorized By:	
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	08-MAY-2015
Filing Date:	09-SEP-2014
Time Stamp:	18:40:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		NEOME-019A3US-G2-Response1-FILED.pdf	50873 a47e3f5082efc05d383bdfef1d87237008042714	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	4
	Applicant Arguments/Remarks Made in an Amendment	5	6

Warnings:	
Information:	
Total Files Size (in bytes):	50873

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/481,754	Filing Date 09/09/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **05/08/2015**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/SHARAIN MORELAND/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14481754
Filing Date	2014-09-09
First Named Inventor	John T. Sorensen
Art Unit	3734
Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6388043	B1	2002-05-14	Langer et al.	
	2	6720402	B2	2004-04-13	Langer et al.	
	3	6759481	B2	2004-07-06	Tong	
	4	7604663	B1	2009-10-20	Reimink et al.	
	5	7632303	B1	2009-12-15	Stalker et al.	
	6	7648591	B2	2010-01-19	Furst et al.	
	7	7785321	B2	2010-08-31	Baerveldt et al.	
	8	7935131	B2	2011-05-03	Anthamatten et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	9	7955387	B2	2011-06-07	Richter	
	10	8038923	B2	2011-10-18	Berger et al.	
	11	3882872		1975-05-13	Douvas et al.	
	12	5569283	A	1996-10-29	Green et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060149194	A1	2006-07-06	Conston et al.	
	2	20070073275	A1	2007-03-29	Conston et al.	
	3	20060106370	A1	2006-05-18	Baerveldt et al.	
	4	20090248141	A1	2009-10-01	Shandas et al.	
	5	20110230877	A1	2011-09-22	Huculak et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	6	20110077626	A1	2011-03-31	Baerveldt et al.	
	7	20030208217	A1	2003-11-06	Dan	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	WO2001/078631	WO	A2	2001-10-25	Bergheim et al.		☐
	2	WO2003/045290	WO	A1	2003-06-05	Conston et al.		☐
	3	WO2004/093761	WO	A1	2004-11-04	Conston et al.		☐
	4	WO2004/110501	WO	A2	2004-12-23	Sorensen et al.		☐
	5	WO2009/140185	WO	A1	2009-11-19	Lind et al.		☐
	6	KR1020040058309	KR	A	2004-03-07	Conston et al.		☐
	7	EP0073803	EP	A1	1983-03-16	Skjaerpe		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	8	EP1615604	EP	A1	2006-01-18	Conston et al.		☐
	9	EP2303203	EP	A1	2011-04-06	Lind et al.		☐
	10	EP1455698	EP	A1	2004-09-15	Conston et al.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	TING, J. L. M. et al., (2012) "Ab interno trabeculectomy: Outcomes in exfoliation versus primary open-angle glaucoma," J Cataract. Refract. Surg. 38(2),315-323.	☐
	2	FRANCIS, B. A. et al., (2006) "Ab interno trabeculectomy: development of a novel device (Trabectome) and surgery for open-angle glaucoma," J Glaucoma 15(1), 68-73.	☐
	3	MINCKLER, D. S. et al., (2005) "Clinical Results with the Trabectome for Treatment of Open-Angle Glaucoma," Ophthalmology 112(6), 962-967.	☐
	4	TAN, YAR-LI, et al., "Postoperative Complications after Glaucoma Surgery for Primary Angle-Closure Glaucoma vs Primary Open-Angle Glaucoma," Arch Ophthalmol. 2011; 129(8), pp. 987-992.	☐
	5	JOHNSON, DOUGLAS H. et al., "Human Trabecular Meshwork Organ Culture. A New Method." Invest. Ophthalmol. Vis. Sci. 28(6),945-953.	☐
	6	QUIGLEY, H. A. and BROMAN, A. T., (2006) "The number of people with glaucoma worldwide in 2010 and 2020," Br. J Ophthalmol. 90(3),262-267.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	7	JACOBI, P. C. et al., (1999) "Goniocurettage for removing trabecular meshwork: clinical results of a new surgical technique in advanced chronic open-angle glaucoma," Am. J Ophthalmol. 127(5),505-510.	☐
	8	PANTCHEVA, M. B. and KAHOOK, M. Y., (2010) "Ab Interno Trabeculectomy," Middle East African Journal of Ophthalmology 17(4), 287-289.	☐
	9	SEIBOLD, L. K. et al., (2013) "Preclinical Investigation of Ab Interno Trabeculectomy Using a Novel Dual-Blade Device," Am. J Ophthalmol. 155(3), 524-529.e522.	☐
	10	ANDERSON, D.R., (1983) "Trabeculotomy compared to goniotomy for glaucoma in children," Ophthalmology 90 (7),805-806.	☐
	11	GRANT, W., (1963) "Experimental aqueous perfusion in enucleated human eyes," Arch.Ophthalmol. 69(6), 783-801.	☐
	12	GRANT, W. M., (1951) "Clinical measurements of aqueous outflow," AMA Archives of Ophthalmology 46(2), 113-131.	☐
	13	HERSCHLER, J. and DAVIS, E. B., (1980) "Modified goniotomy for inflammatory glaucoma. Histologic evidence for the mechanism of pressure reduction," Arch. Ophthalmol. 98(4), 684-687.	☐
	14	JEA, S. Y. et al., (2012) "Ab Interno Trabeculectomy Versus Trabeculectomy for Open Angle Glaucoma," Ophthalmology 119(1), 36-42.	☐
	15	LUNTZ, M. H. and LIVINGSTON, D. G., (1977) "Trabeculotomy ab externo and trabeculectomy in congenital and adult-onset glaucoma," Am. J Ophthalmol. 83(2), 174-179.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	John T. Sorensen
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Robert D. Buyan/	Date (YYYY-MM-DD)	2015-05-11
Name/Print	Robert D. Buyan	Registration Number	32460

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(25) Filing Language: English

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09/549,350 14 April 2000 (14.04.2000) US

(71) Applicant: GLAUKOS CORPORATION [US/US]; 26061 Merit Circle, #101, Laguna Hills, CA 92653 (US).

(72) Inventors: BERGHEIM, Olav, B.; 27722 Deputy Circle, Laguna Hills, CA 92653 (US). GHARIB, Morteza; 556 South Berkley Avenue, San Marino, CA 91108 (US).

(74) Agent: DELANEY, Karoline, A.; Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, 16th floor, Newport Beach, CA 92660 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

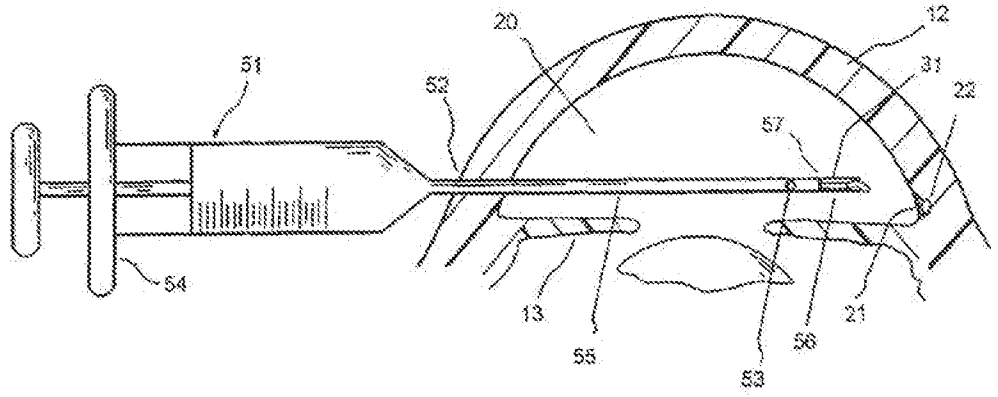
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
18 April 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR TREATING GLAUCOMA



(57) Abstract: Surgical methods and related medical devices for treating glaucoma are disclosed. The method comprises trabecular bypass surgery, which involve bypassing diseased trabecular meshwork with the use of a seton implant. The seton implant is used to prevent a healing process known as filling in, which has a tendency to close surgically created openings in the trabecular meshwork. The surgical method and novel implant are addressed to the trabecular meshwork, which is a major site of resistance to outflow in glaucoma. In addition to bypassing the diseased trabecular meshwork at the level of the trabecular meshwork, existing outflow pathways are also used or restored. The seton implant is positioned through the trabecular meshwork so that an inlet end of the seton implant is exposed to the anterior chamber of the eye and an outlet end is positioned into fluid collection channels at about an exterior surface of the trabecular meshwork or up to the level of aqueous veins.

WO 01/78631 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/07398

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 30181 A (ALLAN BRUCE DUNCAN SAMUEL ;JONES STEPHEN ALISTER (GB); MUIR ANDREW) 16 July 1998 (1998-07-16) page 31, line 32 -page 32, line 4; figure 14	1-6
E	EP 1 114 627 A (GRIESHABER & CO AG) 11 July 2001 (2001-07-11) paragraph '0017!; figures	1-6
X	US 6 004 302 A (BRIERLEY LAWRENCE A) 21 December 1999 (1999-12-21) column 3, line 65 -column 4, line 19; figures	7-9

-/--

[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
8 February 2002	20. 02. 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/07398

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 72788 A (OPTONOL LTD ;YARDEN ORIT (IL); YARON IRA (IL); WERNER MARY C (US)) 7 December 2000 (2000-12-07) page 8, line 4 - line 18; figures	7,8
X	US 5 626 559 A (SOLOMON ARIE) 6 May 1997 (1997-05-06) column 2, line 60 - line 65; figures	10
A	WO 89 00869 A (WHITE THOMAS C) 9 February 1989 (1989-02-09) claims; figures	10
X	US 6 007 511 A (PRYWES ARNOLD S) 28 December 1999 (1999-12-28) column 3, line 6 -column 4, line 6; claims 8-15; figures	14,15, 17,18
X	US 5 893 837 A (FEINGOLD VLADIMIR ET AL) 13 April 1999 (1999-04-13) column 1, line 11 - line 16; claims; figures	14
X	US 5 180 362 A (WORST J G F) 19 January 1993 (1993-01-19) abstract; figures	14
A		15,17
X	US 5 676 679 A (LEGEAIS JEAN-MARC ET AL) 14 October 1997 (1997-10-14) claims; figures	18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/07398

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11-13
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-6

A seton for treating glaucoma comprising an inlet and outlet portion wherein the inlet portion is disposed at an angle relative to the outlet portion

(Problem: Providing an anatomical insertion through the trabecular meshwork into Schlemm's canal)

2. Claims: 7-9

A seton for treating glaucoma comprising an inlet and outlet portion wherein the outlet portion has at least one protrusion

(Problem: Exertion of traction against the inner surface of Schlemm's canal)

3. Claim : 10

A seton for treating glaucoma comprising an inlet and outlet portion and an one-way valve in at least one of the inlet and outlet portion

(Problem: drainage of aqueous humor in only one direction)

4. Claims: 14-17

An apparatus for delivering a seton comprising an elongate tube having a lumen and a removable, elongate guide member within said lumen

(Problem: Positioning a seton in the trabecular meshwork in an eye)

5. Claims: 18,19

An apparatus for delivering a seton comprising an elongate tube having a distal end portion comprising a cutting member

(Problem: Forming an opening in the trabecular meshwork of an eye)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/07398

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9830181 A	16-07-1998	AU 5566698 A	03-08-1998
		AU 5567698 A	03-08-1998
		EP 0953001 A1	03-11-1999
		EP 0977531 A1	09-02-2000
		WO 9830615 A1	16-07-1998
		WO 9830181 A1	16-07-1998
		JP 2001508480 T	26-06-2001
		JP 2001507969 T	19-06-2001
		US 6186974 B1	13-02-2001
		ZA 9800174 A	11-01-1999
EP 1114627 A	11-07-2001	AU 7205900 A	12-07-2001
		EP 1114627 A1	11-07-2001
		JP 2001218785 A	14-08-2001
US 6004302 A	21-12-1999	NONE	
WO 0072788 A	07-12-2000	AU 5315100 A	18-12-2000
		WO 0072788 A1	07-12-2000
US 5626559 A	06-05-1997	IL 109499 A	04-01-1998
WO 8900869 A	09-02-1989	AU 2308988 A	01-03-1989
		CA 1295907 A1	18-02-1992
		WO 8900869 A1	09-02-1989
		US 4886488 A	12-12-1989
US 6007511 A	28-12-1999	WO 9219294 A1	12-11-1992
US 5893837 A	13-04-1999	AU 728354 B2	04-01-2001
		AU 6416498 A	18-09-1998
		CN 1249693 T	05-04-2000
		EP 0973465 A2	26-01-2000
		WO 9837831 A2	03-09-1998
		JP 2001515379 T	18-09-2001
US 5180362 A	19-01-1993	NONE	
US 5676679 A	14-10-1997	US 5573544 A	12-11-1996
		US 5342370 A	30-08-1994
		US 5651782 A	29-07-1997
		CA 2153418 A1	29-09-1994
		EP 0700334 A1	13-03-1996
		EP 0881055 A1	02-12-1998
		JP 2950619 B2	20-09-1999
		JP 8508181 T	03-09-1996
		WO 9421443 A1	29-09-1994

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International Bureau

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PCT

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(21) International Application Number: PCT/US02/37572

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60/331,970 21 November 2001 (21.11.2001) US

(71) Applicant *(for all designated States except US)*: **ISCIENCE CORPORATION** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CONSTON, Stanley, R.** [US/US]; 148 Rogers Avenue, San Carlos, CA 94070 (US). **YAMAMOTO, Ronald, K.** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

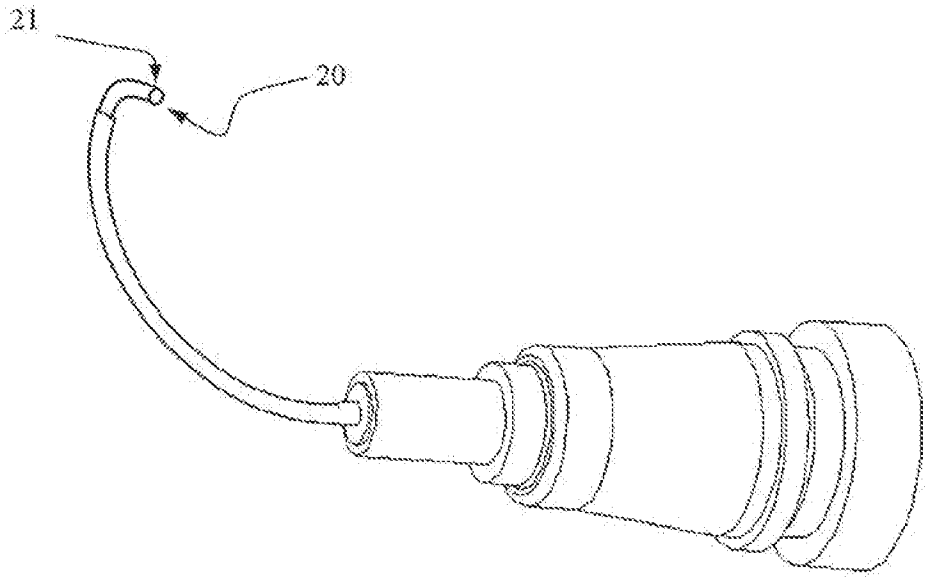
(74) Agents: **SMITH, Gregory, Scott** et al., Gregory Smith & Associates, 3900 Newpark Mall Road, Suite 317, Newark, CA 94560 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,

[Continued on next page]

(54) Title: OPHTHALMIC MICROSURGICAL SYSTEM



(57) Abstract: An ophthalmic microsurgical system is described for treatment of eye diseases, such as glaucoma, using minimally invasive surgical techniques. The microsurgical system includes a thin walled outer sheath microcannula 1 slidably disposed about an inner member 4, which extends slightly beyond the distal end of the microcannula 1. The inner member 4 may be straight or curved and may optionally include a surgical instrument and/or a sensor or signaling beacon. The microsurgical system is used in a surgical procedure for opening Schlemm's Canal to provide drainage of aqueous fluid in order to relieve excess intraocular that results from glaucoma an other diseases of the eye.

WO 03/045290 A1

TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

Ophthalmic Microsurgical System

Field of the Invention

The present invention relates to a microsurgical system for treatment of eye diseases, such as glaucoma, using minimally invasive surgical techniques.

Background of the Invention

Glaucoma is a disease condition of the eye in which increased intraocular pressure (IOP) is created by reduction or blockage of the drainage mechanism for the aqueous fluid produced in the anterior portion of the eye. Such conditions are usually treated by topical drugs in the form of eye drops, but may result in surgical treatment if drug treatment becomes ineffective or if patient compliance is an issue. Traditional glaucoma surgery, such as a trabeculotomy or trabeculectomy, involve dissection of the eye and the forming of new passages through or near the trabecular meshwork portion of the drainage pathway and directing the fluid to a subconjunctival pocket known as a bleb. Although effective for a short period, long-term follow-up of these treatments shows marked increases in intraocular pressure and therefore low success rates. Other serious complications include hypotony, in which too much drainage is accomplished and the IOP drops to sight threatening levels. These procedures also involve post surgical complications, such as infection and long-term issues related to bleb management.

A recently developed surgical treatment for glaucoma is known as viscocanalostomy. The procedure involves surgically opening a flap of the sclera and dissecting down to de-roof Schlemm's canal to increase aqueous humor drainage. A high viscosity viscoelastic material is injected into the canal to dilate it, and may act to open the trabecular meshwork from the canalicular space. The viscoelastic material may also act as a fibrosis inhibitor, reducing the influx of fibroblastic cells from the healing response, which would negate the effects of the procedure by blocking fluid flow. Stegmann, et al. in US 5,486,165 discloses a microcannula designed for delivery of substances to Schlemm's

canal during this procedure. In EP 089847, Grieshaber, et al. disclose an improvement to the Stegmann apparatus to deliver substances or stents for maintaining the passage of fluid in the canal.

Other surgical procedures, such as non-penetrating deep sclerectomy and trabeculectomy involve accessing and treating the aqueous drainage system in various manners. Minimally invasive access to the requisite tissues involved in aqueous fluid drainage, such as the trabecular meshwork, Schlemm's Canal, aqueous collector channels and aqueous veins can provide treatment with fewer complications.

The invention is directed at an ophthalmic microsurgical system comprised of a microcannula and associated microsurgical tools, which may be directly inserted into the sclera, Schlemm's Canal, aqueous collector channels, aqueous veins or other ocular tissues to allow minimally invasive access and progressive treatment with surgical materials and tools.

The following patent documents relate to methods and apparatus for treatment of glaucoma and other ocular diseases.

US Patent 5,360,399 METHOD AND APPARATUS FOR MAINTAINING THE NORMAL INTRAOCULAR PRESSURE, inventor Robert Stegmann

US Patent 5,486,165 METHOD AND APPLIANCE FOR MAINTAINING THE NATURAL INTRAOCULAR PRESSURE, inventor Robert Stegmann

US Patent 6,142,990 MEDICAL APPARATUS, ESPECIALLY FOR REDUCING INTRAOCULAR PRESSURE, inventor Reinhard O.W. Burk

WO 0064389 TRABECULOTOMY DEVICE AND METHOD FOR TREATING GLAUCOMA, inventors Brown Reay H, Lynch Mary G, King Spencer B III

WO 02/089699 MEDICAL DEVICE AND METHODS FOR USE FOR GLAUCOMA TREATMENT, inventors Tu Hosheng, Smedley Gregory, Niksch Barbara, Haffner David

WO 02/080811 GLAUCOMA STENT AND METHODS THEREOF FOR GLAUCOMA TREATMENT, inventors Tu Hosheng, Smedley Gregory, Niksch Barbara, Haffner David

WO 02/070045 GLAUCOMA TREATMENT DEVICE AND METHOD, inventors Brown David, Anderson Richard

US 6,471,666 INJECTABLE GLAUCOMA DEVICE, inventor Odrich Steven

US 6,464,724 STENT DEVICE AND METHOD FOR TREATING GLAUCOMA, inventors Lynch Mary, Brown Reay

WO 01/78656 DEVICE FOR GLAUCOMA TREATMENT AND METHODS THEREOF, inventor Hill Richard

Brief Description of the Drawings

FIG 1 shows an exploded view of the outer sheath microcannula and the inner member of the ophthalmic microsurgical system.

FIG 2 shows a curved inner member for use with the ophthalmic microsurgical system.

FIG 3 shows an assembled view of the outer sheath microcannula and the inner member of the ophthalmic microsurgical system.

FIG 4 is an enlarged detail drawing of the distal tip of the outer sheath microcannula and the inner member shown in FIG 3.

FIG 5 is an enlarged detail drawing of an inner member with a conical distal cutting tip.

FIG 6 is an enlarged detail drawing of an inner member with a spatula shaped distal cutting tip.

FIG 7 shows an inner member that includes a surgical tool for creating controlled punctures in the trabecular meshwork from within Schlemm's Canal.

FIG 8 shows the inner member and surgical tool of FIG 7 inserted through the outer microcannula of the ophthalmic microsurgical system.

FIG 9 shows the ophthalmic microsurgical system of FIG 8 with the surgical tool extended from the inner member.

FIG 10 shows a surgical cutting tool for use with the ophthalmic microsurgical system.

FIGS 11 and 12 show a dissecting tool for use with the ophthalmic microsurgical system.

FIG 13 illustrates an ophthalmic microsurgical system that includes a signaling beacon on the inner member.

Description of the Invention

FIG 1 shows an exploded view of the ophthalmic microsurgical system of the present invention. The ophthalmic microsurgical system comprises a thin walled outer sheath microcannula **1** with a connector **2** at the proximal end, a distal tip **3** and a communicating channel between. The microcannula outer sheath **1** is disposed about an inner member **4**, which fits and slides within the channel of the microcannula **1**, the inner member **4** comprising at least a proximal end **5** and a distal tip **6**. FIG 3 shows an assembled view of the ophthalmic microsurgical system with the inner member **4** inserted through the channel of the outer sheath microcannula **1**. The inner member **4** is designed to extend beyond the distal tip **3** of the microcannula **1** a specified distance depending upon the requirements of the specific inner member **4**. FIG 4 is an enlarged detail drawing showing the distal tip **6** of the inner member **4** extending a specified distance beyond the distal tip **3** of the microcannula **1**. The inner member **4** may comprise a trocar, needle or microsurgical tool and may also be used to transport fluids, energy, sensors, or gases. The tissues of the eye along the tissue tract may be treated in discrete regions by using the outer sheath to localize the site of action for the inner member. Different configurations of inner members **4** may be used in sequence with the outer sheath **1** to accomplish different surgical tasks.

The microcannula 1 may be introduced manually or as part of a system to provide surgical support or guidance. The microcannula 1 may be inserted into an existing tissue tract of the eye such as Schlemm's Canal, aqueous collector channels, and aqueous veins, or may be used to create a tract within tissues of the eye such as the sclera. The positioning of the microcannula 1 in tissues such as Schlemm's Canal can be verified by several means including such means as a change in pressure/vacuum resistance in the surrounding environment as the system enters the Canal, a change in tissue color of the tissues of the Canal, direct visual location during surgical cut-down or by external image guidance. Accurate positioning within the Canal or other eye tissues may be aided by features of the microcannula 1.

Various inner members 4 may be inserted into the microcannula for the progressive steps to introduce the microcannula 1 into a tissue tract such as Schlemm's Canal, advance the microcannula 1 along the tract, and perform surgical intervention of the tissues near the tip 3 of the microcannula 1. Once inserted into a tissue tract, the microcannula 1 may be progressively advanced to the appropriate areas for treatment. The microcannula sheath 1 and inner member 4 for such use are configured to form an assembly with sufficient stiffness to progress along the tissue tract with minimal tissue damage. Tissue damage may induce fibrosis, complicating procedures such as filtration surgery for glaucoma or viscocanalostomy. The microcannula 1, which may be more flexible than the inner member 4, may be advanced into the tissue tract without the inner member 4, to advance the microcannula 1 atraumatically. The distal tip 6 of the inner member is preferred to be limited in extension from the tip 3 of the microcannula 1 to prevent tissue damage. With the increased flexibility and mobility, large sections of Schlemm's Canal or long tissue tracts may be treated from a single access point with the microcannula 1.

The microcannula 1 may be comprised of a thin walled polymer or metallic tube of sufficient stiffness to allow it to be advanced into tissues or along the tissue tract such as Schlemm's Canal, and sufficient flexibility to follow the radial tract of Schlemm's Canal. The proximal connector 2 may be of a Luer type or similar system for the attachment or

introduction of secondary elements, fluids or surgical tools. The proximal connector **2** is preferably configured to allow fluid-tight introduction of materials and tools through the channel of the outer sheath microcannula **1**. This can be accomplished with a close sliding fit between the channel of the microcannula **1** and the inner member **4** and/or with a hemostasis seal built into the proximal connector **2**. Due to the small size of Schlemm's Canal and other tissue tracts of the eye, approximately 50 to 200 microns in diameter, the microsurgical system must be appropriately sized. Typically, the microcannula **1** is sized in the range of 50 - 250 microns inner diameter with a wall thickness from 10-100 microns. The length of the microsurgical system can be varied for different applications or for use with different delivery systems and surgical tools. Due to the curvature of a tissue tract such as Schlemm's Canal, the microcannula **1** may be flexible in the appropriate dimensions. In some embodiments, a predetermined curvature **7** may be applied to the inner member **4** and/or the outer sheath **1** during fabrication, as shown in FIG 2 and in the assembled view of the microsurgical system in FIG 3. The distal tip **3** of the microcannula **1** is formed so as to provide a smooth entry into the target tissues. Suitable materials for the microcannula **1** include metallic films, polyetheretherketone (PEEK), polyimide, polyamide, polysulfone, nylon, urethane, PTFE, FEP or similar materials. The microcannula **1** may also comprise surface treatments such as lubricious coatings to assist in tissue penetration or reflective coatings to aid in location and guidance during medical imaging.

The microcannula **1** may also have markings on the exterior for assessment of depth in the tissue tract or Schlemm's Canal. The external markings allow user assessment of the length of the tissue tract or Schlemm's Canal accessed by the microcannula **1**, and the approximate location of the microcannula tip **3**.

Depending on the application, the inner member **4** may be a guide wire, hollow needle, micro-trocar or similar element and comprises a proximal end **5** and a distal tip **6**, and may contain a communicating channel between them. The inner member **4** may also comprise sensing means such as a pressure transducer, light pipe or optical fiber to aid in

determining location, local fluid pressure, blood flow or other parameters. The inner member 4 is sized correspondingly to fit slidably within the microcannula 1 and therefore will be in the range of 50-240 microns in outer diameter. If hollow, the inner diameter of the inner member 4 will be in the range of 40-210 microns.

In one preferred embodiment for introducing and advancing the microcannula 1 along a tissue tract such as Schlemm's Canal, the inner member 4 may comprise a solid element or wire to provide rigidity with the distal end of the assembly. Highly elastic, high modulus materials such as metals including stainless steel, tungsten and nickel titanium alloys, and structural polymers such as nylon, polyethylene, polypropylene and PEEK are particularly preferred for construction of the inner member 4. The inner member 4 may be shaped to provide curvature to the microcannula 1 or to provide support for lower modulus microcannula materials.

In an alternate embodiment, the distal end 6 of the inner member 4 may be sharpened and adapted to the microcannula 1 to penetrate and guide the microcannula 1 through scleral and other ocular tissues to reach desired locations for surgical intervention such as Schlemm's Canal, or to create tissue tracts for the drainage of aqueous humor. The distal end 6 of the inner member 4 may comprise or alternately hold a sharpened member for such applications. The distal end may be conically tapered 8, as shown in FIG 5, or beveled or spatula shaped 9, as shown in FIG 6, to optimize the desired tissue penetration characteristics. The distal tip 6 of the inner member 4 may be designed to penetrate scleral tissues with minimal deflection of the microcannula 1 and surrounding tissues, or it may be shaped in a specific manner to provide a predetermined deflection angle or curvature. For example, a "spatula" or "spade" type faceted cutting tip will provide for straight cutting penetration with minimal tissue deflection, while a conventional suture type triangular cutting tip will provide for deflection in one direction. A hypodermic needle may act as the inner member 4, which provides a sharpened end for penetration while allowing for a working channel to deliver fluids or gases. Preferred materials include stainless steel, tungsten, and nickel titanium alloys.

Once the microcannula **1** is introduced and advanced appropriately into Schlemm's Canal, the inner member **4** may be exchanged for one designed for surgical intervention. The inner member **4** may be disposed such that its distal tip is extensible beyond the distal tip of the microcannula **1**. In one embodiment, the inner member **4** comprises a fine wire with a cutting tip to provide support and for the initial introduction of the microcannula **1** into the target tissues. In another embodiment, the inner member **4** comprises a blunt tip **19**, as shown in FIG 3, which is designed to bluntly dissect a tract in the tissue, and is disposed distally from the microcannula **1** for a set distance. Other embodiments involve microsurgical tools and sensors. Each inner member **4** is precisely mated to the inner diameter and proximal coupling of the microcannula outer sheath **1** to provide a high level of surgical control for delicate microsurgery.

In another embodiment shown in FIG 7, the microsurgical system comprises a surgical tool **20** for creating controlled punctures in the trabecular meshwork from within Schlemm's Canal. The surgical tool **20** may be constructed separate from or integral with the inner member **4**. The diameter of the surgical tool **20** is such that it may be inserted through the channel of the microcannula **1** or, alternatively, through a channel in a hollow tubular inner member **4**. The surgical tool **20** may be comprised of a superelastic material such as a nickel tinanium alloy, and configured such that the distal tip **21** is shaped and bent at an angle with respect to the axis of the inner member **4**. The surgical tool **20** is constructed such that the practitioner knows where the angulation of the tip **21** is directed. Features such as markings or guides may be used to provide tip direction. The microcannula **1** is placed into Schlemm's Canal through means as detailed above. When the surgical tool **20** is disposed within the microcannula **1** and/or within a tubular inner member **4**, as shown in FIG 8, the distal tip **21** is straightened. The microcannula **1** is advanced to the location where the surgical puncture is to be created and the surgical tool **20** is advanced within the microcannula **1** until the tip **21** extends from the microcannula **1**, bending at the predetermined angle and directed towards the trabecular meshwork, as

shown in FIG 9. The surgical tool **20** is advanced until it penetrates the meshwork and then is withdrawn. The microcannula **1** can then be advanced to the next treatment site. In this manner, size and location of drainage openings can be precisely controlled, providing optimum treatment regimen for the patient. The angle of the tip **21** may be in the range of 45 to 135° from the axis, and the tip **21** may comprise a cutting element as described above.

In another embodiment shown in FIG 10, the microsurgical system includes a surgical cutting tool **23** mountable to or interchangeable with the inner member **4**. The surgical cutting tool **23** may utilize a separate penetrating or cutting element such as a diamond or sapphire tip or blade **12**. In one such design, a basket **22** is created from wire of a shape memory alloy such as a nickel tinanium alloy. The basket **22** is expanded in order to place a sharpened segment of diamond or sapphire blade **12** or similar element within, and then released to grip the element tightly. The basket **22** may be mounted on the end of a solid element **13** to create a surgical tool compatible with the microcannula **1**.

In another embodiment, the inner member **4** may comprise a sensing means. Such means may comprise a stiff tube surrounding a fluid channel for communicating of ambient pressure at the distal tip, or similarly the channel may contain an optical fiber for the transmission and relay of optical signals. Pressures at the distal tip **6** may be used for *in situ* fluid pressure measurements, or for differential pressure measurements to assist in providing locating means for the microcannula **1**. In such a system, the pressure differential will change when the distal tip **6** with the sensing means transits from scleral tissues into the fluid-filled Schlemm's Canal, or into the anterior chamber. Optical sensing may also be used for locating means, or to provide blood flow, blood oxygen, or other sensing parameters. Sensing means may also comprise various tissue or disease sensing means utilizing "chip" type sensors. Suitable materials for an inner member **4** for structural support of a sensing means include but are not limited to stainless steel, nickel

tinanium alloy, titanium, and structural polymers such as nylon, polysulfone, polypropylene, polyethylene, and PEEK.

Similar to the use of sensing means, the inner member 4 may comprise a signaling beacon 18, as shown in FIG 13, to identify the location of the microcannula tip 3 relative to the target tissues. The beacon 18 may comprise an echogenic material for ultrasound guidance or a light source for visual guidance. In one embodiment, a beacon 18 comprising a fibcroptic light source emitting 90 degrees from the tip of the microcannula 1 is advanced and rotated along Schlemm's Canal until the light source targets the appropriate tissues such as the trabecular meshwork. The light source may be emitted 45 to 135 degrees from the axis of the microcannula beacon 18 as long as the tissue target area is coincident with the path of the inner member 4.

In another embodiment shown in FIGS 11 and 12, the microsurgical system comprises a surgical tool 16 designed to provide blunt microdissection of tissues for the creation of drainage tracts or the implantation of shunts or similar elements. The surgical tool 16 may be constructed integrally with or interchangeable with the inner member 4. The surgical tool 16 is comprised of a conductive shaft 14 and a distal tip configured with two or more splines 15 constructed of a shape memory alloy. The splines 15 are fabricated such that a bipolar memory shape set is applied to them. In the first configuration shown in FIG 11, the splines are gathered together on the axis of the shaft 14. In the second configuration shown in FIG 12, the splines 15 are angled outward from the axis of the shaft 14. The splines 15 are transitioned from one configuration to the other by a square wave electrical voltage applied to the conductive shaft 14 by an electronic controlling system. The pulsing of the voltage induces the phase transformation of the splines 15, causing them to open and close rapidly. As the surgical tool 16 is advanced through the tissue, the opening and closing splines 15 bluntly dissect a microtract.

In another embodiment, the microcannula 1 is used to access or create a tissue tract in the eye and subsequently used to deliver an implant to the tract. The implant may comprise stent-like devices to hold open tissue spaces or drug eluting materials to provide localized drug delivery. An implant such as a tubular stent, may be loaded into the lumen of the microcannula 1 in a compressed or folded state and the inner member used to deploy the implant at the desired location. In another embodiment, a stent-like implant may be previously attached to the microcannula body or comprise the distal portion of the microcannula, and deployed by mechanical action of the inner member. An inner member or surgical tool may be used to create or access a tissue tract with the microcannula implant mounted on it.

Examples:

Example 1:

A microcannula system was fabricated for experimentation on ex-vivo human eyes obtained from an eye bank. The microcannula consisted of a 30 gauge tubing adapter (Small Parts, Inc., Miami Lakes, FL) with a distal tip comprised of polyimide tubing bonded into the lumen of the tube adapter. The tube adapter is a standard hypodermic needle, cut to ½" (12.5mm) length with a perpendicular (straight) cut distal end and a female Luer at the proximal end. The tube adapter has an inner diameter of 150 microns and an outer diameter of 300 microns. A section of polyimide tubing (MicroLumen, Tampa, FL) with inner diameter of 110 microns and a wall thickness of 14 microns was bonded into the distal tip of the tube adapter with cyanoacrylate adhesive and allowed to cure overnight. Assemblies were fabricated with 1.0 and 1.5 cm of polyimide tubing extending from the tube adapter. A 2 cm section of stainless steel wire (Fort Wayne Metals, Fort Wayne, IN) 100 microns diameter was mounted onto a Luer cap for attachment to the Luer connector of the microcannula. The wire tips were hand ground to a spade type point and a tapered cone type point. In some assemblies, the stainless wires were bent by hand into a curve of approximately 14 mm radius, to allow easier advancement through the curvature of Schlemm's Canal.

Ex-vivo human eyes were used to perform experiments with the cannulae. The human eyes were placed under a stereomicroscope. Using ophthalmic scalpels, successive layers of the sclera were cut away until Schlemm's Canal was located. Various examples of the microcannula system were successfully guided into the Canal. When the tip of the microcannula was into the ostium of the Canal approximately 1-2 mm, the inner member was removed. The microcannulae were advanced to determine their ability to track the Canal. In all cases the microcannulae were able to be advanced at least 1 cm or more into the Canal. If the wire is left in place, the curved wires allowed for advancement into the Canal while the straight wires were only able to be advanced a short distance.

In a second experiment, the microcannulae were evaluated for the ability to pierce the scleral tissues. The system with a distal tip in a tapered cone had difficulty in penetrating the tissues, causing tissue deformation and requiring a fair amount of force to begin penetration. The tip ground in a spade type distal end was able to penetrate the tissues with much less deformation.

In a third set of experiments, ophthalmic suture needles with different tip configurations were used to pierce the sclera to assess the differences in terms of tissue and needle deflection. The suture needles (Surgical Specialties, Reading, PA) used were Center Point Spatula and Side Cutting Lancet. In each trial the spatula point allowed easiest penetration with minimal tissue deflection.

Example 2:

In another example, a surgical tool to provide for controlled punctures in the trabecular meshwork was created using Nitinol (nickel titanium alloy) wire, 0.004" (100 microns) diameter (Ft. Wayne Metals, Ft. Wayne, IN). The wire was formed with a 10 mm diameter curve for the distal 3 cm. The distal 2 mm of the tip was further formed with a small radius bend at approximately 90 degrees from the axis of the wire, directed toward the inside and remaining in the plane of the curve.

A microcannula was fabricated comprised of a 3 cm long polyimide tube (Microlumen, Tampa, FL), with an inner diameter of 140 microns and an outer diameter of 200 microns, adhesively bonded to a section of 26 gauge hypodermic tubing (Small Parts, Inc, Miami Lakes, FL). The hypodermic tubing was mounted in a short plastic sleeve for ease of manipulation. The polyimide tubing was heat set with a curvature of approximately 2.5 cm. A stainless steel guiding sheath was fabricated from sections of hypodermic tubing (Small Parts, Inc, Miami Lakes, FL) to create a stepped sheath with an inner diameter of approximately 300 microns. The guiding sheath was cut to 10 mm long and the mounted in a plastic shaft. The guiding sheath was mounted at the distal end of the shaft and at a right angle to the shaft axis. This configuration of the sheath allowed for the tip of the guiding sheath to be directed at Schlemm's Canal by one hand, while the cannulation was performed by the other hand, which provided better positioning control for the procedure.

An ex-vivo human eye was placed in a holding cup and positioned under a stereomicroscope. A rectangular flap was cut approximately 4 mm on a side at the limbus. The flap was excised to approximately ½ scleral thickness. The tissue bed was further dissected to reveal Schlemm's Canal, and the Canal was de-roofed to allow access. The microsurgical tool was loaded into the microcannula by advancing the tool proximal end into the cannula distal end and continuing until the proximal end could be grasped at the proximal end of the cannula. The tool was oriented so that the curvature of the bend was approximate to the curvature of Schlemm's Canal. The tool was then withdrawn into the cannula approximately 3 mm, and the tip of the microcannula was inserted into the proximal end of the guiding sheath. Under the microscope, the distal tip of the guiding sheath was placed at the ostium of Schlemm's Canal. The microcannula was advanced into the canal approximately 30 degrees. While holding the microcannula steady, the tool was advanced slowly until the distal tip extended beyond the cannula tip and pierced the trabecular meshwork. The distal tip of the tool could be observed through the cornea, entering the anterior chamber. The microcannula was withdrawn slightly,

further tearing the trabecular meshwork. The tool was then withdrawn into the cannula and the system withdrawn from the Canal.

Example 3.

In another example, a signaling means for determining the location of the microcannula distal tip was fabricated. A small battery powered laser diode light source illuminator was constructed, with the diode operating in the visible red light range. A single plastic optical fiber (POF) (South Coast Fiber Optics, Achua, FL) of approximately 100 microns in diameter and 20 cm in length was mounted to an adapter which provides adjustable alignment capabilities to bring the fiber tip into the focus of the laser illuminator. The POF distal tip was cut flat, and hence the illumination was directed toward all radial angles from the tip. A cylindrical handpiece mount was fabricated to hold a microcannula. The microcannula was constructed of nylon with dimensions of approximately 120 microns inner diameter and 180 microns outer diameter. The operative end of the microcannula was 15 mm in length and the proximal end was flared for mounting on the handpiece. The fiber is disposed through the handpiece and within the microcannula as detailed in Example 1, and the fiber adapter mounted to the laser illuminator. The adapter alignment was adjusted to provide the brightest spot at the end of the POF.

Ex-vivo human eyes were surgically dissected with a small rectangular flap at the limbus to reveal Schlemm's Canal. The microcannula and light fiber were advanced into the canal with the light source on. The illuminated tip of the fiber was seen through the scleral tissues and also from the anterior chamber of the eye through the trabecular meshwork. In multiple trials, the microcannula with beacon tip was able to be advanced up to 120° around from the access point within Schlemm's Canal.

Example 4.

In another example, a microcannula is used to access Schlemm's Canal as described in example 1. The tip of the microcannula is positioned at the desired location along

Schlemm's Canal for treatment. The inner member is removed while keeping the outer microcannula sheath in position. A stent type of implant is folded or compressed and inserted into the lumen of the microcannula. The stent is releasably secured to the distal end of an inner member, and pushed along the microcannula lumen by the mechanical action of the inner member. When deployed out from the end of the microcannula into the tissue tract, the stent is expanded and is released from the inner member. The microcannula is moved to another location along Schlemm's Canal for delivery of another implant as desired.

What is claimed is:

1. A microcannula based microsurgical system designed to operate within a tissue tract of the eye, comprising:

a flexible tubular outer sheath with an outer diameter of 250 microns or less, with proximal and distal ends, to fit within the tissue tract;

a proximal connector on the outer sheath for introduction of materials and tools; and an inner member with a proximal end and a distal tip, wherein the tip is restricted from advancement past a predetermined length from the outer sheath, with the outer sheath and inner member sized such that the inner member fits slidably within the outer sheath and may be removed separately from the outer sheath while in the tissue tract.

2. A microsurgical system of claim 1, wherein the tissue tract is Schlemm's Canal of the eye.

3. A microsurgical system of claim 1, wherein the tissue tract is created by the flexible outer sheath and inner member.

4. The microsurgical system of claim 1, wherein the microsurgical system provides blunt dissection of the tissue tract.

5. The microsurgical system of claim 1, wherein the flexible tubular outer sheath comprises polyimide or a fluoropolymer.

6. The surgical system of claim 1, wherein the flexible tubular outer sheath is curved in the range of 10 – 15 mm diameter.

7. The microsurgical system of claim 1, wherein the inner member comprises nickel titanium alloy.

8. The microsurgical system of claim 1, wherein the inner member comprises tungsten.

9. The microsurgical system of claim 1, wherein the inner member is curved in the range of 10 – 15 mm diameter.

10. The microsurgical system of claim 1, further comprising a tool to cut or ablate tissues that interchanges with the inner member to position the tool tip to a predetermined position from the tip of the flexible tubular outer sheath.

11. The microsurgical system of claim 1, wherein the inner member has a distal tip that is shaped for tissue dissection.

12. The microsurgical system of claim 11, wherein the distal tip comprises a multi-faceted shape or a tapered conical shape.

13. The microsurgical system of claim 11, wherein the distal tip is sharpened for tissue penetration.

14. The microsurgical system of claim 11, wherein the distal tip is shaped to provide for controlled surgical penetration of the trabecular meshwork.

15. The microsurgical system of claim 14, wherein the distal tip advances and penetrates the trabecular meshwork from a 45 to 135 degree direction from the axis of the outer sheath.

16. The microsurgical system of claim 1, wherein the outer sheath additionally comprises a plurality of markers set at regular intervals such that each marker is spaced from adjacent markers by a fixed distance along the outer sheath to provide depth measurement.

17. The microsurgical system of claim 1, wherein the inner member comprises a sensing means.

18. The microsurgical system of claim 1, wherein the inner member comprises a signaling means.

19. The microsurgical system of claim 18, wherein the signaling means is an optical fiber.

20. The microsurgical system of claim 19, wherein the optical fiber directs illumination at an angle of 45 to 135 degrees from the axis of the microcannula, from the proximal end of the microcannula.

21. The microsurgical system of claim 20, wherein the optical fiber directs illumination to coincide with the target of an inner member directed at an angle of 45 to 135 degrees from the axis of the microcannula.

22. The microsurgical system of claim 1, wherein the system is sized to deliver an implant to the tissue tract by action of the inner member.

23. The microsurgical system of claim 22, wherein the implant is a stent-like tube.

FIG 1

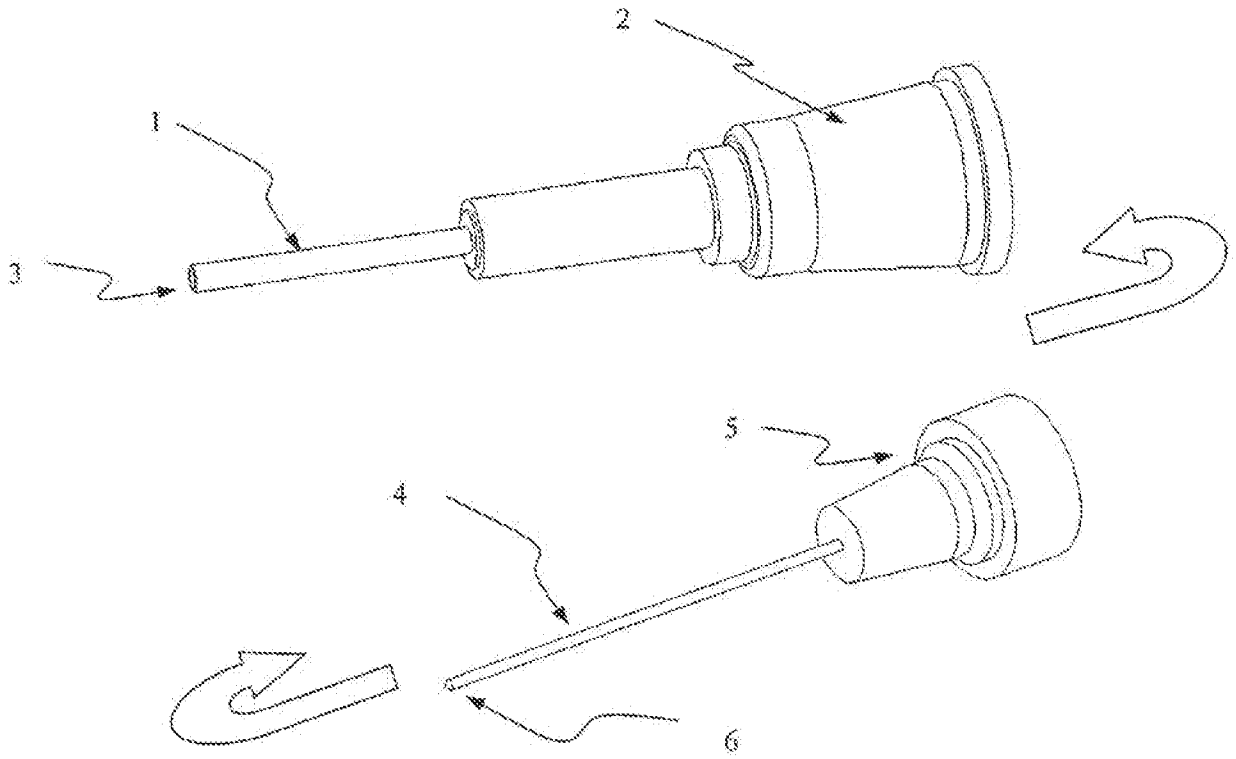
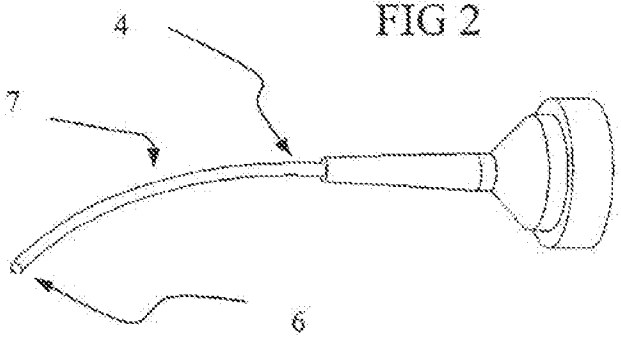


FIG 2



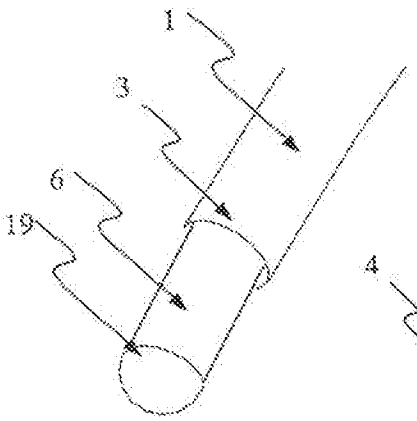


FIG 3

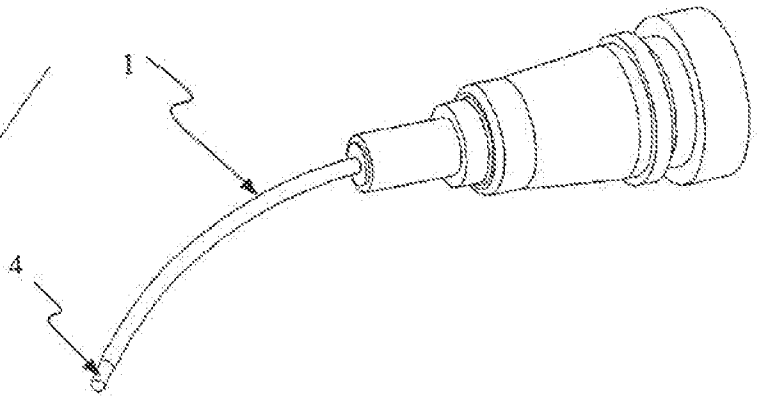


FIG 4

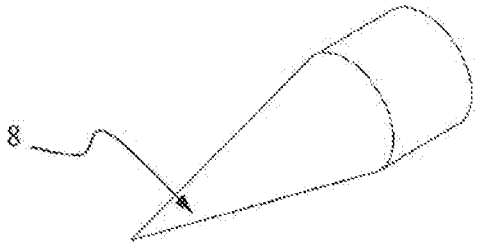


FIG 5

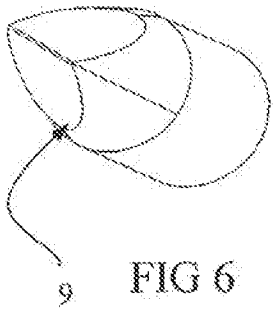


FIG 6

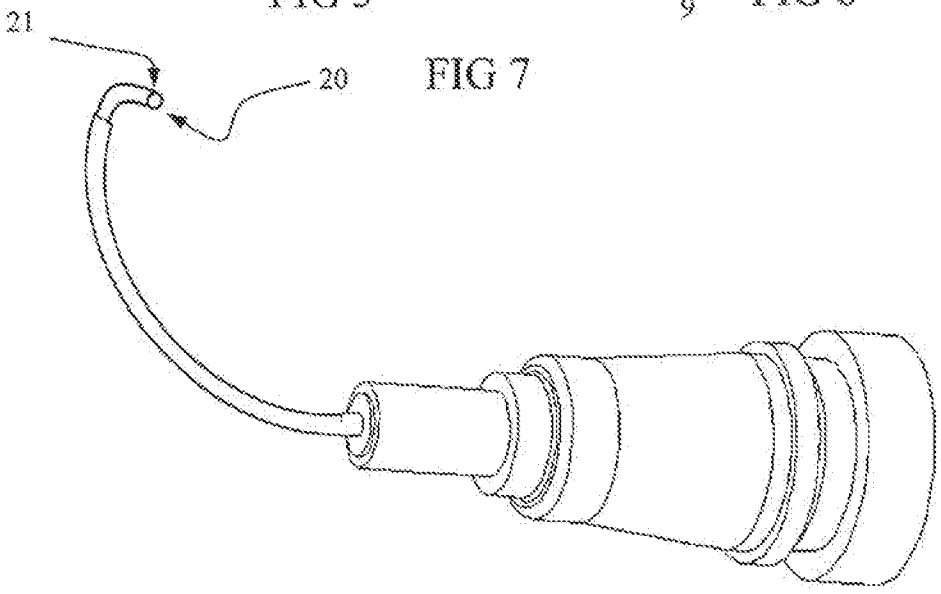


FIG 7

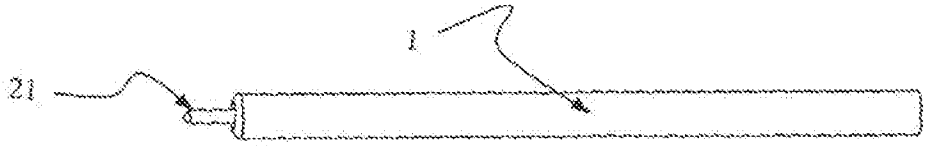


FIG 8

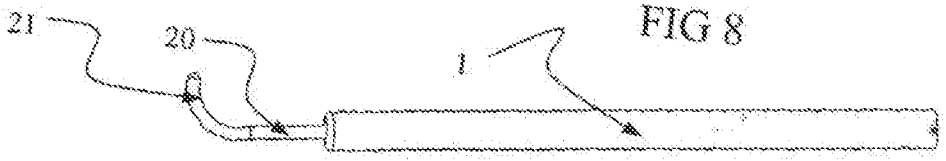


FIG 9

FIG 10

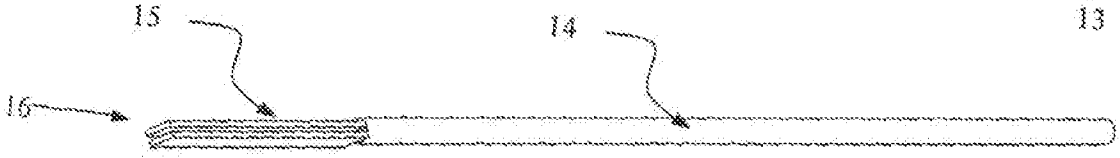


FIG 11

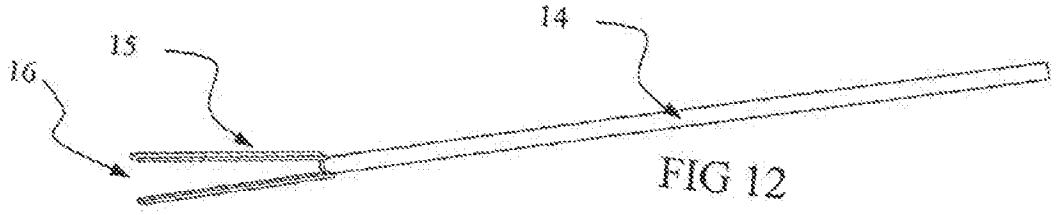


FIG 12

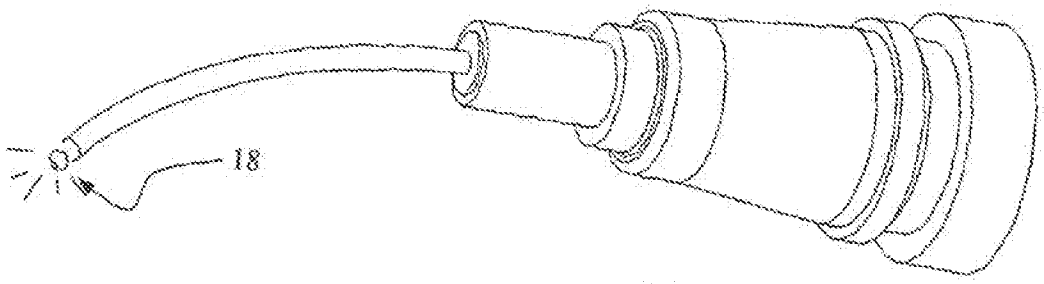


FIG 13

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/37572

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 37767 A (MAAG WERNER ;GRIESHABER & CO AG (CH); SCHAAF HANSGEORG (DE); STEGM) 31 May 2001 (2001-05-31) page 7, line 4 -page 28, line 2	1-23
A	US 6 142 990 A (BURK REINHARD O W) 7 November 2000 (2000-11-07) cited in the application column 4, line 19 -column 6, line 4	1-23
A	WO 00 64389 A (BROWN REAY H ;LYNCH MARY G (US); KING SPENCER B III (US)) 2 November 2000 (2000-11-02) cited in the application page 10, line 6 -page 16, line 29	1-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 March 2003	14/03/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/37572

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 0137767 A	31-05-2001	DE	19956515 A1	21-06-2001
		DE	19956517 A1	21-06-2001
		AU	1376901 A	04-06-2001
		WO	0137767 A1	31-05-2001
		US	2001053873 A1	20-12-2001
		EP	1152722 A1	14-11-2001
US 6142990 A	07-11-2000	DE	19705815 A1	20-08-1998
		EP	0858788 A1	19-08-1998
		JP	10248869 A	22-09-1998
WO 0064389 A	02-11-2000	AU	4371100 A	10-11-2000
		AU	4371300 A	10-11-2000
		AU	4666100 A	10-11-2000
		AU	4975900 A	10-11-2000
		BR	0010054 A	15-01-2002
		BR	0010055 A	09-04-2002
		CN	1354642 T	19-06-2002
		CZ	20013822 A3	13-03-2002
		CZ	20013823 A3	13-03-2002
		EP	1173123 A1	23-01-2002
		EP	1173124 A1	23-01-2002
		EP	1173125 A1	23-01-2002
		EP	1173126 A1	23-01-2002
		HU	0200860 A2	29-07-2002
		HU	0201111 A2	28-12-2002
		JP	2002541975 T	10-12-2002
		JP	2002541976 T	10-12-2002
		JP	2002541977 T	10-12-2002
		NO	20015208 A	20-12-2001
		NO	20015209 A	21-12-2001
		NO	20015210 A	21-12-2001
		NO	20015211 A	20-12-2001
		NZ	514932 A	20-12-2002
		SK	15392001 A3	04-06-2002
		SK	15402001 A3	06-08-2002
		TR	200103098 T2	22-04-2002
		WO	0064389 A1	02-11-2000
		WO	0064390 A1	02-11-2000
		WO	0064391 A1	02-11-2000
		WO	0064393 A1	02-11-2000
		US	2003009124 A1	09-01-2003
		US	6464724 B1	15-10-2002
		US	6480984 B1	17-09-2002

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60/463,549 16 April 2003 (16.04.2003) US

(71) Applicant (*for all designated States except US*): **ISCIENCE SURGICAL CORPORATION** [US/US]; 1321 Waller St., San Francisco, CA 94117 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **CONSTON, Stanley, R.,** [US/US]; 148 Rogers Avenue, San Carlos, CA 94070 (US). **KUPIECKI, David, J.,** [US/US]; 1410 Shrader Street, San Francisco, CA 94117 (US). **MCKENZIE, John** [US/US]; 1742 Eaton Avenue, San Carlos, CA 94070 (US). **YAMAMOTO, Ronald, K.,** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

(74) Agents: **SMITH, Gregory** et al., 3600 Newpark Mall Rd., Third Floor, Suite 317, Newark, CA 94560 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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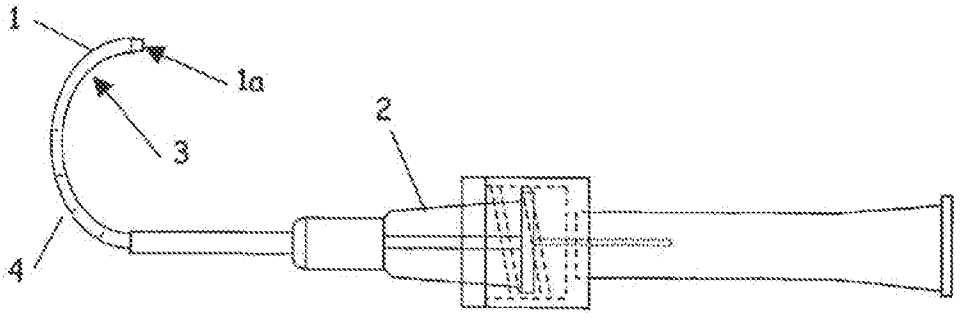
Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: OPHTHALMIC MICROSURGICAL INSTRUMENTS



(57) Abstract: Ophthalmic microsurgical instruments may be directly inserted into Schlemm's Canal to allow controlled treatment or removal of adjacent tissues such as the trabecular meshwork or the juxtacanalicular tissues to affect an increase in aqueous outflow and the reduction of intra-ocular pressure. The instrument allows the directed access to Schlemm's Canal by a flexible microcannula (1). The instrument is useful in allowing controlled guidance by the surgeon while viewing through a surgical microscope or by non-invasive medical imaging.

WO 2004/093761 A1

Ophthalmic Microsurgical Instruments

Incorporation by Reference:

Co-pending PCT application number PCT/US03/08866 is hereby incorporated by reference in its entirety.

Background of Invention:

Glaucoma is a disease condition of the eye in which increased intraocular pressure (IOP) is created by blockage of the drainage mechanism for the aqueous fluid produced in the anterior portion of the eye. Such conditions are usually treated by topical drugs in the form of eye drops, but may result in surgical treatment if drug treatment becomes ineffective or if patient compliance is an issue. Traditional glaucoma surgery such as trabeculectomy, involves a flap dissection of the eye and the removal of a portion of the trabecular meshwork (TM) or the corneo-scleral junction. The aqueous fluid is directed posteriorly under the surgical flap and to a sub-conjunctival lake known as a bleb. Post-surgical complications and bleb management are significant issues with trabeculectomy and similar procedures. Furthermore, the control of the aqueous outflow is achieved through the management of the integrity of the surgical flap rather than controlling the opening into the anterior chamber. Other procedures involving laser energy to create holes in the TM are partially successful, however long term results are limited as compared to trabeculectomy.

Recently developed surgical treatments for glaucoma involve surgically accessing Schlemm's Canal by manner of a surgical flap or flaps and subsequently dilating or expanding the canal to increase aqueous humor drainage into the natural drainage pathway. Current procedures and instruments can only access a short passage of Schlemm's Canal from either side of the surgical site. US 5,486,165 to Stegmann et al. in discloses a microcannula designed for delivery of substances to Schlemm's Canal during such a procedure. EP 0898947A2 to Grieshaber et al. discloses an improvement to the Stegmann apparatus to deliver substances or stents for maintaining the passage of fluid in the canal. Other inventions disclose the use of microcatheters to introduce water-jet type cutting apparatus or bladed mechanisms to

the canal for disruption of the TM. However these methods cut the TM network open in a non-controlled manner and do not remove tissue or debris from the operative field.

The treatment of glaucoma usually involves patient specific requirements for the amount of drainage increase desired by the physician. It is therefore of advantage to be able to treat or remove a controlled amount of the TM or associated juxtacanalicular tissues in order to be able to titrate drainage rates and control the disease process on a patient specific basis. Furthermore, it is desired to perform the controlled treatment or removal of tissues from within Schlemm's Canal in order to facilitate the restoration of natural aqueous drainage system without the requirement for blebs and the concomitant complications, and to enable less invasive surgical methods. It is also advantageous to physically stabilize the tissues in order to facilitate control of the amount of tissues being treated or removed.

This invention is directed at ophthalmic microsurgical instruments which may be directly inserted into Schlemm's Canal to allow controlled treatment or removal of adjacent tissues such as the TM or the juxtacanalicular tissues to effect the reduction of intra-ocular pressure. It is a further object of this invention to describe an instrument which allows the directed access to Schlemm's Canal by a flexible microcannula. The instrument is useful in allowing controlled guidance by the surgeon while viewing through a surgical microscope or by non-invasive medical imaging.

Known prior art:

United States Patent 4,501,274
Skjaerpe February 26, 1985
Microsurgical instrument

United States Patent 5,486,165
Stegmann January 23, 1996
Method and appliance for maintaining the natural intraocular pressure

United States Patent 6,142,990
Burk November 7, 2000
Medical apparatus, especially for reducing intraocular pressure

United States Patent 6,221,078
Bylsma April 24, 2001
Surgical implantation apparatus

United States Patent 6,283,940
Mulholland September 4, 2001
Catheter

United States Patent 6,375,642 B1
Grieshaber , et al. April 23, 2002
Method of and device for improving drainage of aqueous humor within the eye

United States Patent 6,494,857 B1
Neuhann December 17, 2002
Device for improving in a targeted manner and/or permanently ensuring the ability of the aqueous humor to pass through the trabecular meshwork

United States Patent Application 20020013546
Grieshaber, Hans R. ; et al. January 31, 2002
Method and device to improve aqueous humor drainage in an eye

United States Patent Application 20020111608
Baerveldt, George ; et al. August 15, 2002
Minimally invasive glaucoma surgical instrument and method

United States Patent Application 20020082591
Haefliger, Eduard June 27, 2002
Device for the treatment of glaucoma

United States Patent Application 2003014092
Inventor(s): Neuhann Thomas (De)
Apparatus for the treatment of glaucoma

Patent Number: EP0898947 A2
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: EP1114627 A1
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: WO0064389
Inventor(s): Brown Reay H (Us); Lynch Mary G (Us); King Spencer B Iii (Us)
Trabeculotomy device and method for treating glaucoma

Patent Number: WO02056805
Inventor(s): Roy Chuck; Baerveldt George
Minimally invasive glaucoma surgical instrument and method

Patent Number: WO02074052
Inventor(s): Smedley Gregory T; Gharib Morteza; Tu Hosheng
Applicator and methods for placing a trabecular shunt for glaucoma treatment

Patent Number WO03045290
Inventor(s): Conston Stanley R; Yamamoto Ronald K
Ophthalmic Microsurgical System

Brief Description of the Drawings

Figure 1 illustrates a sheath microcannula with an inner member.
Figure 2 illustrates a microcannula with expandable segments.
Figure 3 illustrates a microcannula with a signaling beacon tip.
Figure 4 illustrates a microcannula with a side connection fitting.

Figure 5 illustrates a microcannula with an open distal tip with a side channel for application of suction.

Figure 6 illustrates a microcannula with fenestrations and an inner member for controlled tissue removal.

Figure 7 illustrates a microcannula with a single fenestration for controlled tissue removal.

Figure 8 illustrates a microcannula with a rotating inner member for tissue cutting.

Figure 9 illustrates a microcannula with a side fenestration and tissue cutting flap.

Figure 10 illustrates a microcannula with a side fenestration and inner member for directed tissue abrasion.

Description of Invention:

Schlemm's Canal is a channel in the corneo-scleral junction of the eye and is the primary pathway for the drainage of aqueous humor. The inner wall of the Canal comprises the TM and juxtacanalicular tissues through which the aqueous humor drains from the anterior chamber. The outer wall of is comprised of scleral tissue with openings to collector channels for the passage of aqueous humor from the Canal to the venous system. Due to its relative positioning to the TM, the Canal forms a circular channel that encircles the anterior chamber. The Canal is approximately 10 to 15 mm in diameter and 200 microns by 50 microns in cross-section. The drainage of aqueous humor through the TM and juxtacanalicular tissues into Schlemm's Canal is believed to be the predominant route for aqueous drainage. In open surgery for glaucoma, surgical treatment of the inner wall of Schlemm's Canal and removal of associated tissue such as the TM and juxtacanalicular tissues has demonstrated an increase in aqueous outflow and reduction of intraocular pressure. It is an object of the present invention to enable treatment and removal of tissues in these specific regions by use of minimally invasive surgical instruments. It is also an object of the invention to treat a specific segment of the tissue tract and also to treat specific regions of the selected segment to minimize surgical trauma and post-surgical scarring.

The ophthalmic microsurgical instruments of the present invention comprise a thin walled outer sheath microcannula with a connector at the proximal end, a distal tip

and a communicating channel therebetween, as shown in Figure 1. The microcannula lumen provides a fluid and gas tight, sealed passage from the proximal end to the distal tip of the instruments. An inner member which fits and slides or rotates within the sheath may also be incorporated, the inner member comprising at least a proximal end and a distal tip. The distal end of the instruments may be curved in a manner to approximate the curvature of Schlemm's Canal. The instruments may also comprise a guidance means to effect proper advancement of the distal portion. Furthermore the instruments may comprise means to mechanically stabilize the target tissues. The tissues may be held in tension or compression for controlled treatment or removal of tissue. The instruments may also comprise cutting means to excise targeted tissues. The instruments may also be used to deliver drugs or implants to the tissue tract to treat adjacent tissues.

The microcannula may be introduced into Schlemm's Canal manually or as part of a system to provide surgical support or guidance. Once inserted into Schlemm's Canal, the microcannula may be progressively advanced to the appropriate areas for treatment. The distal end is preferably sized and curved or compliant enough to access at least one half the length of Schlemm's Canal, approximately 15 to 25 mm. Treatment of the entire Canal may be effected by inserting the instrument in the opposite direction from the first treatment at the surgical access point. The positioning of the instrument in the Canal can be verified by several means including a fiber-optic beacon tip inner member, a change in pressure or vacuum resistance in the surrounding environment as the system enters the Canal, a change in tissue color, direct visual location during surgical cut-down or by external image guidance such as ultrasound or optical coherence tomography. Features of the instrument can aid accurate positioning within the Canal.

The selective treatment or removal of tissues adjacent to Schlemm's Canal such as TM or juxtacanalicular tissues may be accomplished by various means. One means incorporates the use of side holes or fenestrations on the outer sheath directed at the target tissues adjacent to the inner radius. The outer sheath may be configured to allow for tissue treatment or removal separately or in conjunction with an inner member that works in alignment with the side holes or fenestrations. Another means

for selective treatment of the TM or juxtacanalicular tissues may be accomplished by the use of suction through the microcannula, which has been observed to act predominantly on the inner wall of the Canal. Both means may also be combined, such as the use of suction to pull a region of the target tissue into a side hole or fenestration of the outer sheath for subsequent treatment or excision.

Suction or vacuum may also be incorporated to clear the operative field and the microcannula lumen, either concurrent with tissue treatment or subsequent to tissue treatment since the sheath also functions to provide a disposal path for the excised tissues and surgical debris. Furthermore the ability of the cannula to remove particles and debris may be used by itself or in conjunction with other treatment methods such as laser trabeculoplasty in order to enhance the outcome by removal of waste particles.

The microcannula may comprise a thin walled polymer or metallic tube **1** of sufficient stiffness to allow it to be advanced into Schlemm's Canal, and of sufficient flexibility or compliance to follow the curvature of the Canal. It is preferable that the distal tip **1a** be beveled or radiused so as to provide for atraumatic advancement into the Canal. The proximal connector **2** may be of a Luer type or similar system for the attachment or introduction of secondary elements or may be designed for attachment only to specific components. Due to the small size of Schlemm's Canal, approximately 200 microns in diameter, the microcannula must be appropriately sized. Typically, the microcannula is sized in the range of 100 to 350 microns outer diameter with a wall thickness from 10 to 100 microns to allow cannulation of Schlemm's Canal. However, Schlemm's Canal may be expanded prior to insertion of the microcannula with for example, the injection of a surgical viscoelastic material. With prior expansion of the Canal, cannulation becomes much easier to perform without damaging tissues. Expansion of Schlemm's Canal also allows a microcannula of up to 500 microns outer diameter to be used to access the Canal.

Due to the curvature of Schlemm's Canal, the microcannula should be flexible in the appropriate dimensions. In some embodiments, a predetermined curvature **3** may be applied to the inner member and/or the outer sheath during fabrication. The

curvature is preferably slightly greater than the curvature of the Canal in order to prevent the instrument from perforating the inner wall while advancing the microcannula. It is also desirable for a portion of the instrument to be able to be swiveled at least 180° around to provide for handedness to the curved microcannula. This allows the surgeon to cannulate the entire circumference of Schlemm's Canal from a comfortable working position.

Suitable materials for the microcannula sheath include metals, polyetheretherketone (PEEK), polyimide, polyamide, polysulfone, or similar materials. The sheath may also comprise surface treatments such as lubricious coatings to assist in cannulation and ultrasound or light interactive coatings to aid in location and guidance. The microcannula may also have markings **4** on the exterior for assessment of depth in the tissue tract. The external markings allow user assessment of the length of the tissue tract accessed by the microcannula, and the approximate location of the microcannula tip.

The microcannula **5** may also comprise a segment or series of segments capable of being expanded in a radial direction in order to place tension on the target tissues for treatment, as shown in Figure 2. The segments may comprise means such as stent-like structures, balloons or elastomeric sections **6** which may be inflated or deformed in a radial manner **7**. Multiple expandable segments may be used to stabilize and isolate segments of Schlemm's Canal for surgical or drug treatment through the microcannula lumen. Furthermore, the expandable segments may be slidably disposed about the central axis such that the segments may be translated axially apart from each other to provide further tension on the tissues. The expandable segments may comprise polymers and elastomers such as latex, silicone rubber, urethane, vinyl, polyether block amide (Pebax) or may be a metallic structure comprised of shape-memory or superelastic alloy, stainless steel, tungsten or similar materials. Alternatively, another outer member may be disposed about the microcannula as a tissue stabilization means. The expandable structure would be activated or mechanically released to expand during the procedure and then retracted or compressed for removal.

Depending on the application, the inner member may be used to guide the positioning of the microcannula, surgical tools and instrumentation or act as a surgical tool. The inner member may comprise a guide wire, hollow needle or tube, micro-trocar, cutting tool or similar element and comprises a proximal end and a distal tip, and may contain a communicating channel between. The inner member may also comprise sensing means such as a pressure transducer or fiber optic to aid in determining location, local fluid pressure, blood flow or other parameters. The inner element is sized correspondingly to fit slidably within the microcannula and therefore will be in the range of 90 to 450 microns in outer diameter. If hollow, the inner diameter will be in the range of 40 to 400 microns. The inner member may be removed during the surgical procedure and replaced sequentially with other inner members acting as instruments or tools.

A first inner member used for initial placement may comprise a signaling beacon to identify the location of the microcannula tip relative to the target tissues, as shown in Figure 3. The beacon may comprise an echogenic material for ultrasound guidance, an optically active material for optical guidance or a light source for visual guidance. In one embodiment, a plastic optical fiber (POF) **8** is used to provide a bright visual light source at its distal tip **9**. The distal tip of the POF **10** may be positioned at or slightly beyond the end of the microcannula sheath **11** and the emitted signal may be detected through the scleral tissues visually or using sensing means such as infrared imaging. The POF may also comprise a tip which is beveled or mirrored or otherwise configured to provide for a directional beacon. If the emitted directional light is directed toward the inner radius at the TM, the surgeon may view the illuminated spot in the anterior angle using a goniometer lens, and verify placement of the operative instrument at the targeted tissues. The beacon may be illuminated by a high intensity light source, laser, laser diode or light-emitting diode **12**, which may be powered by batteries **13** or standard AC power. Upon arrival of the microcannula distal end at the target tissues, the beacon assembly and POF may be removed, leaving the microcannula sheath at the desired location for treatment. The connection point between the outer microcannula sheath and the inner member may be sealed with a cap or preferably with a self-sealing mechanism such as a one-way valve or an elastomer seal.

In one embodiment, the instrument set also comprises a fitting as the connection point for the illumination package. Additionally, as shown in Figure 4, the instrument may contain a central section **14** comprising a single or multiple side fittings **15** to allow the attachment of ancillary equipment such as syringes, vacuum or pressures sources, sensing means and the like. The attachment fittings may comprise standard designs such as Luer fittings or may be designed to only accept connection with specific components.

The operative function of the invention is an instrument to treat or remove specific tissues adjacent to Schlemm's Canal such as the TM in such a manner that the area of the treatment or removal is controlled and repeatable. In some applications, the instrument may be used to remove a controlled layer of adjacent target tissue, such as the juxtacanalicular tissues at the inner wall of Schlemm's Canal. Furthermore, the procedure can be performed at multiple sites within the eye to effect treatment per the patient's requirements by using the microcannula sheath for repositioning to other target locations from within the Canal.

In one embodiment the microcannula **16** alone is used to remove portions of the adjacent tissue using suction means **17**, as shown in Figure 5. The microcannula is advanced into Schlemm's Canal **18**. A vacuum syringe, vacuum or aspiration pump is used to provide suction and a portion of the inner wall is pulled into the lumen **19** and removed. Due the large difference in mechanical properties between the thick scleral outer wall of the Canal and the flexible tissues of the inner wall, suction applied by a microcannula has demonstrated preferential ability to manipulate the inner wall. Control of the suction characteristics may be used to control the amount of tissue treated or removed from the inner wall. In some cases, suction alone may be applied to the TM to remove tissue debris and improve aqueous outflow, without removing a portion of the TM.

In another embodiment, shown in Figure 6, the distal tip of the microcannula **20** is closed off **21**. A fenestration or series of fenestrations **22** are disposed along the inner radius wall **23** of the microcannula, directed toward the TM. Suction is applied

24 to pull a small amount of TM into the lumen and apply tension to the target tissue. An inner member 25, comprised of a thin hollow shaft, is then extended through the microcannula 20 and may be rotated or axially advanced, to cut off the intruding tissues. The inner member may comprise a beveled or sharpened leading edge to facilitate tissue cutting. The excised tissue may be removed by a suction mechanism through the lumen. The amount of tissue removal may be controlled through the sizing of the ingress holes and the amount of suction applied. The outermost layer of the TM, including the juxtacanalicular tissues, interfacing Schlemm's Canal may be removed by minimal application of suction, or alternatively openings through the TM of controlled geometry may be formed with greater amounts of suction.

In a similar embodiment, Fig 7, a single fenestration 26 is created along the inner radius wall of the microcannula 29. The distal tip 27 is closed and is fully radiused to produce a ball-end tip. A single cutting element 28 is disposed in the lumen at the distal end, with the cutting edge oriented proximally. The target tissues are pulled into the lumen, and the cannula is withdrawn which allows the cutting element to remove tissue to a determined depth. The cutting depth may be set and adjusted by the cutting element design, the dimensions of the fenestration and the amount of suction applied.

Furthermore, the microcannula may contain stabilization means in conjunction with cutting means thereby applying traction to the tissues to improve cutting efficiency and control. The microcannula may comprise a multilumen tube such that each lumen is connected separately to a hole or a series of holes along the inside radius facing the target tissues. For example, a two-lumen microcannula may be constructed comprised with three holes a set distance apart along the inner radius wall. The outermost two holes are connected to one lumen of the microcannula and the central hole to the second lumen. In this manner, a low suction pressure may be applied to the outermost holes, providing tissue stabilizing forces, while a higher suction pressure may be applied to the center hole, removing a controlled portion of tissue.

In another embodiment shown in Figure 8, the microcannula lumen is open **30** and a rotating hollow inner member **31** is employed. The distal tip of the inner member may be beveled or sharpened and is extended just slightly beyond the end of the cannula **32** or adjacent to a fenestration along the inner radius. Suction is applied to the cannula and the inner member is rotated **33** to provide a cutting action. As the instrument is advanced, the TM tissues are preferentially pulled **34** toward the microcannula axis allowing the inner member to cut away portions as required. The amount of tissue removal is controlled by extent of advancement and applied suction during the cutting process.

In another embodiment shown in Figure 9, the instrument distal end is comprised of two concentric thin-walled tubes. The outer tube **35** contains a window or fenestration **36** near the distal end and aligned along the inner radius wall of the tube **37** which interfaces the adjacent TM. The inner tube **38** contains an angled slit **39** partially through the tube which creates a sharp pointed flap **40** directed proximally and also aligned with the window in the outer tube and the TM. The flap **40** is pre-bent to allow it to project outward from the tubing **38**, in the direction of the TM and is used as a piercing and cutting member. The outer tube **35** is slidably disposed about the inner tube. During insertion into Schlemm's Canal, the outer tube is positioned such that the window is not adjacent to the flap and the flap is thereby constrained within the outer tube. At the operative target position, the outer tube is advanced so that the window is over the flap, allowing the flap to protrude from the assembly. The instrument is retracted slightly allowing the flap to pierce the TM and then retracted a specified amount such that the full length of the flap has pierced the tissues. The outer tube is then retracted, moving the window proximally, causing the flap to be pulled back and thereby cutting a portion of the TM approximating the geometry of the flap and constraining the excised tissue within the inner tube for disposal. Suction may be used to remove the tissue from the lumen and the procedure repeated as required.

In another embodiment shown in Figure 10, the inner wall of Schlemm's Canal may be removed by the application of controlled abrasion. The inner member **41** may comprise a brush or rasp like tool **42** on the distal end which abrades the tissue

surface. The abrading tool may be used by passing the distal portion of the inner member past the distal tip of the microcannula with concurrent suction, or by positioning it in a window or fenestration **43** in the side of the microcannula **44** near the distal tip **45**. The use of a side opening allows a controlled portion of the tissue tract, such as the TM adjacent to Schlemm's Canal to be treated selectively. Suction may also be applied concurrently through the microcannula lumen to stabilize the tissues during treatment and remove resultant tissue debris.

The microcannula may also be used to deliver a fiber optic for laser ablation of the tissues from within Schlemm's Canal. The microcannula may be used to provide suction to remove the ablative residue and any tissue debris from the site and deliver treatment adjuvants or medications to minimize fibrosis during wound healing.

Examples:

Example 1: A single element microcannula was fabricated with polyimide tubing (MicroLumen, Inc.), 0.0101" (256μ) inner diameter by 0.0141" (358μ) outer diameter. The distal end was sealed with epoxy to create a ball end. The distal portion was curved with a radius of approximately 15mm for a distance of 2 cm. A fenestration approximately 1.2 mm long was cut into the inner wall of the curvature and extending inward to 1/2 the diameter. A Luer fitting was bonded to the proximal end. The microcannula was attached to a collection bottle and then to a vacuum pump generating up to 27 inches of Hg.

An enucleated human eye was prepared for the experiment by inflating the posterior chamber to a pressure of 10mm Hg with phosphate buffered saline (PBS). A scleral flap was surgically excised and Schlemm's Canal unroofed. The microcannula was inserted into Schlemm's Canal and vacuum was applied. Suction was confirmed by observing fluid flow within the microcannula.

Subsequently, the globe was hemisected and the vitreous, ciliary body, lens and iris removed allowing visualization of the TM and Schlemm's Canal from inside. The microcannula was advanced into the Canal to a point approximately 100° from the

surgical site. Suction was applied and the results observed visually under the surgical microscope. Upon application of vacuum, the inner wall of Schlemm's Canal at the fenestration site was seen to be pulled into the lumen of the microcannula. The vacuum level was varied from 1 to 27 inches Hg. In each case the inner wall was observed being pulled into the lumen at approximately 4 inches Hg or greater, while the outer wall was not noticeably deformed. The microcannula was withdrawn under vacuum and upon examination, excised tissue was observed adhered to the distal edge of the fenestration. An open ended microcannula of approximately the same size, without side fenestration, was placed in Schlemm's Canal and the suction experiments repeated at various vacuum levels. The inner wall of the Canal was observed to be preferentially deflected toward the microcannula tip at approximately 4 inches of Hg or greater.

Example 2: A microcannula with an inner member and outer sheath was fabricated. The outer sheath was fabricated with a single fenestration as in Example 1 but with a polyimide tube of 0.0087" inner diameter and 0.0117" outer diameter. The inner member was comprised of polyimide tubing 0.0049" inner diameter by 0.0067" outer diameter and was slidably disposed within the outer member.

An enucleated human eye was prepared as in Example 1. The microcannula was placed with the fenestration toward the inner wall of Schlemm's Canal. The vacuum was applied and tissue was seen being pulled into the lumen. The inner member was then advanced until it stopped against the closed distal tip of the outer member. Upon removal of the microcannula, excised tissue was observed attached to the inner member.

Example 3: A microcannula with an inner member and outer sheath was fabricated. The outer sheath was similar to the outer sheath in Example 2. An inner member designed to abrade the tissues was fabricated comprised of a stainless steel wire 0.006" diameter to which the distal end was roughened using a grinding wheel. The inner member was slidably disposed within the outer sheath.

An enucleated human eye was prepared as in Example 1 with the addition of placing a 27 gauge needle into the cornea, and attaching the needle to a flow meter and reservoir of PBS. The reservoir was raised to provide constant pressure flow into the anterior chamber, and the flow meter used to observe changes in flow.

The microcannula was advanced into Schlemm's Canal. Suction was applied to pull the inner wall of the Canal into the lumen and then the inner member was slid back and forth across the tissues. The microcannula was removed and surgical flap sealed. An increase in aqueous outflow was observed after the procedure.

Example 4: A microcannula was fabricated similar to the outer sheath in Example 2. A cutting element inner member was fabricated from Nitinol wire, incorporating a flat blade situated at the axis of the wire. The cutting element was bonded into the distal lumen of the microcannula with the cutting blade facing proximally and extending into the fenestration area.

Enucleated human eyes were prepared as in Example 3. The microcannula was advanced into Schlemm's Canal. Suction was applied, drawing the inner wall of the Canal into the lumen, and the microcannula was retracted while still under vacuum. Upon removal from the eye, the cutting element was observed to have excised tissue attached. Subsequently aqueous outflow was seen to increase.

Example 5: A signaling means for determining the location of the microcannula was fabricated and incorporated into a microcannula instrument. A single strand plastic optical fiber (POF) (Biogeneral, Inc.) 100 microns in diameter was used with a flat distal tip. The fiber was disposed within an instrument assembly comprising a polyimide microcannula 110 microns ID and 160 microns OD (MicroLumen, Inc.), which was bonded to a needle assembly. The needle assembly consisted of a base section of 18 gauge hypodermic tubing, with a 14 gauge tubing guide tube fabricated so as to slide forward and backward along the 18 gauge tube for a fixed distance of 15 mm. The distal tip of the guide tube was comprised of a 28 gauge tube to direct the microcannula and POF during insertion. The POF was illuminated using a battery powered red laser diode (Digikey Corp.). A second POF was also fabricated

with a distal tip cut at approximately 60° and the jacket removed opposite the bevel. This provided a partially directed illumination spot toward the inner radius.

An ex-vivo human eye was placed in a soft holding cup stage under a stereomicroscope. A surgical flap was created at the limbus and the flap removed to access Schlemm's Canal. The tip of the guide tube was placed at the ostium of the Canal. The microcannula and POF were advanced into the canal with the light source on. The illuminated tip of the fiber was seen through the scleral tissues in the case of the flat tipped POF. Using the beveled POF, illumination could be viewed from within the anterior chamber of the eye depending on the rotation of the microcannula, allowing the appropriate surgical tissues such as the TM to be targeted.

Example 6: In another example, Schlemm's Canal of an eye is cannulated with the microcannula described in example 3. The signaling beacon inner member is used to verify the position of the tip of the microcannula in the desired location of the eye and with proper rotational alignment with respect to the TM. The signaling beacon inner member is removed and a surgical tool inner member to remove tissue from the TM is guided into the lumen of the microcannula and advanced to the distal tip. The inner member also incorporates suction to remove tissue debris. After removal of TM tissue, the surgical tool inner member is exchanged for the signal beacon inner member. The microcannula may be positioned to another area of Schlemm's Canal to repeat the process as needed to increase aqueous outflow to an appropriate level.

While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.

What is claimed is:

1. A microcannula based microsurgical device designed to operate within Schlemm's Canal of the eye and to treat a controlled amount of adjacent ocular tissue comprising:

a flexible tubular sheath having an outer diameter of no more than 500 microns, having proximal and distal ends, and configured to fit within Schlemm's Canal;

a distal assembly for sealed introduction and removal of materials and tools;

wherein suction is provided through the microcannula sheath during treatment of adjacent tissue.

2. A microcannula based microsurgical device as described in claim 1, wherein the tissues to be treated include at least one of the trabecular meshwork and juxtacanalicular tissues adjacent to the inner radius of Schlemm's Canal.

3. A microcannula based microsurgical device as in claim 1, wherein the microcannula has one or more openings directed toward an inner radius thereof.

4. A microcannula based microsurgical device as described in claim 1, wherein the suction level is at least 4 inches of Hg.

5. A microcannula based microsurgical device as described in claim 1, further comprising at least one inflatable or expandable member to provide stabilization of the microsurgical device and surrounding tissues.

6. A microcannula based microsurgical device as described in claim 1, further comprising at least one inflatable or expandable member to provide sealing of Schlemm's Canal during treatment.

7. A microcannula based microsurgical device as described in claim 1, wherein the microcannula has a length of at least 15 mm.

8. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath is curved in the range of 10–15 mm diameter.

9. A microcannula based microsurgical device as described in claim 1, further comprising a plurality of markers set at regular intervals along the tubular sheath such that each marker is spaced from adjacent markers by a fixed distance along the sheath to provide depth measurement.

10. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath additionally comprises materials to enhance observation of the device positioning under image guidance.

11. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath comprises a polyimide or a fluoropolymer.

12. A microcannula based microsurgical device as described in claim 1, wherein the microcannula additionally comprises an inner member with a proximal end and a distal tip;

and wherein the sheath and inner member are sized such that the inner member fits slidably within the sheath and the distal tip of the inner member acts to treat adjacent tissue through one or more openings in the distal end of the microcannula.

13. The microcannula based microsurgical device of claim 12, wherein the inner member acts to remove tissues from an inner wall of Schlemm's Canal.

14. A microcannula based microsurgical device designed to operate within Schlemm's Canal of the eye and to remove a controlled amount of adjacent ocular tissue comprising,

a flexible tubular sheath having an outer diameter of no more than 500 microns, having proximal and distal ends, and configured to fit within Schlemm's Canal;

a distal assembly for sealed introduction and removal of materials and tools;

an inner member with a proximal end and a distal tip sized such that the inner member fits slidably within the sheath,

wherein the sheath has one or more openings directed toward an inner radius at the distal end,

and the sheath and inner member act to remove adjacent tissue through the one or more openings in the distal end of the sheath.

15. A microcannula based microsurgical device as in claim 14, further comprising a lumen extending through the tubular sheath and wherein suction is provided through the lumen during removal of adjacent tissue.

16. A microcannula based microsurgical device as described in claim 14, wherein the distal tip of the inner member is shaped for tissue dissection, cutting, ablation or removal.

17. A microcannula based microsurgical device as described in claim 14, wherein suction is used to position the adjacent tissue to be removed into a lumen of the tubular sheath.

18. A microcannula based microsurgical device as described in claim 17, wherein the inner member performs removal of tissue within the lumen of the tubular sheath.

19. A microcannula based microsurgical device as described in claim 14, further comprising a plurality of markers set at regular intervals along the tubular sheath such that each marker is spaced from adjacent markers by a fixed distance along the sheath to provide depth measurement.

20. A microcannula based microsurgical device as described in claim 14, wherein, the tubular sheath additionally comprises materials to enhance observation of the device positioning under image guidance.

21. A microcannula based microsurgical device as described in claim 14, wherein the tubular sheath comprises a polyimide or a fluoropolymer.

22. A microcannula based microsurgical device as described in claim 14, wherein the microcannula has a length of at least 15 mm.

23. A microcannula based microsurgical device as described in claim 14, wherein the flexible tubular sheath is curved in the range of 10–15 mm diameter.

24. A microcannula based microsurgical device as described in claim 14, wherein the inner member is curved in the range of 10–15 mm diameter.

25. A microcannula based microsurgical device as described in claim 14, wherein the outer member is formed of a multi-lumen tube.

26. A microcannula based microsurgical device as described in claim 14, wherein the inner member comprises steel, nickel titanium alloy or tungsten.

27. A microcannula based microsurgical device as described in claim 14, wherein the inner member comprises an optical fiber.

28. A microcannula based microsurgical device as described in claim 27, wherein illumination from the optical fiber is directed from the distal end of the microcannula at an angle of 45 to 135 degrees from an axis of the microcannula to be coincident with an area of tissue removal.

29. A microcannula based microsurgical device as described in claim 14 wherein the tubular sheath comprises at least one inflatable or expandable member to provide stabilization of the device and surrounding tissues.

30. A method for treating Schlemm's Canal of an eye comprising inserting a flexible microcannula based microsurgical device with an outer diameter of no more than 500 microns into Schlemm's Canal and applying suction at a level of at least 4 inches of Hg.

31. A method for treating Schlemm's Canal of the eye as described in claim 30 wherein the microcannula comprises one or more openings directed toward an inner radius thereof to treat specific tissues adjacent to Schlemm's Canal.

32. A method for treating Schlemm's Canal of the eye as described in claim 30 wherein the microcannula additionally comprises an inner member that acts to remove tissue.

33. A method for treating Schlemm's Canal of an eye comprising the steps of:

(a) inserting a flexible microcannula with an outer diameter of no more than 350 microns into Schlemm's Canal;

(b) injecting a flowable material to expand at least a segment of Schlemm's Canal to facilitate microcannula access;

(c) removing the microcannula;

(d) inserting a microcannula based microsurgical device with an outer diameter of no more than 500 microns into Schlemm's Canal;

(e) and effecting a modification in the tissues adjacent to Schlemm's Canal to increase aqueous outflow.

34. The method of treating Schlemm's Canal of the eye of claim 33 wherein step (e) comprises removal of tissues from the inner wall of Schlemm's Canal.

35. The method of treating Schlemm's Canal of the eye of claim 33 wherein step (e) comprises placing of an implant at least partially residing in Schlemm's Canal.

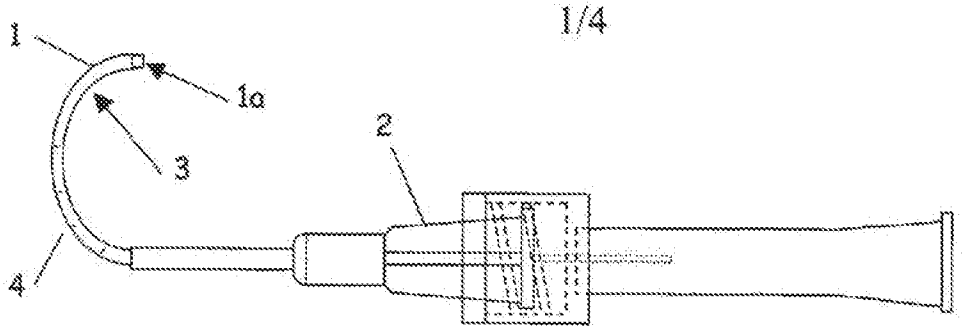


Fig. 1

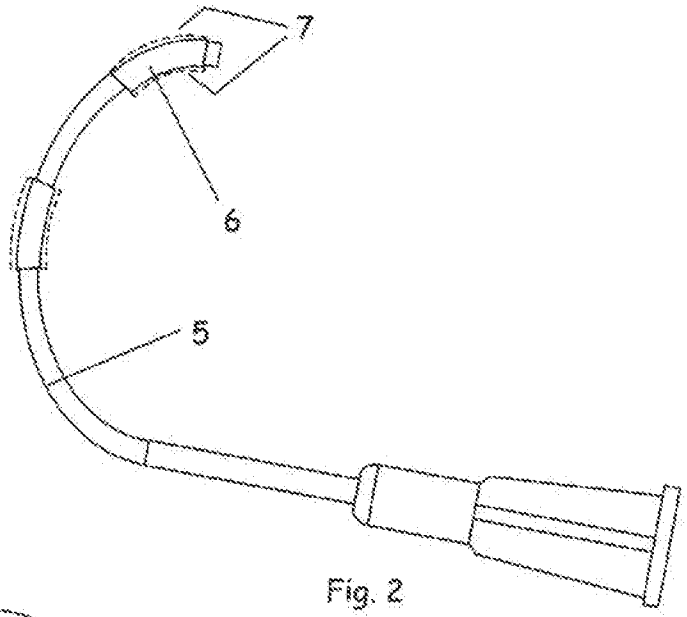


Fig. 2

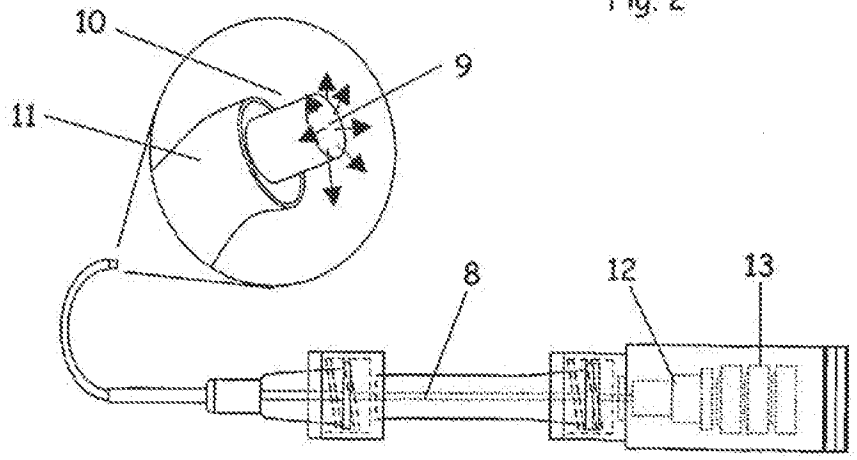


Fig. 3

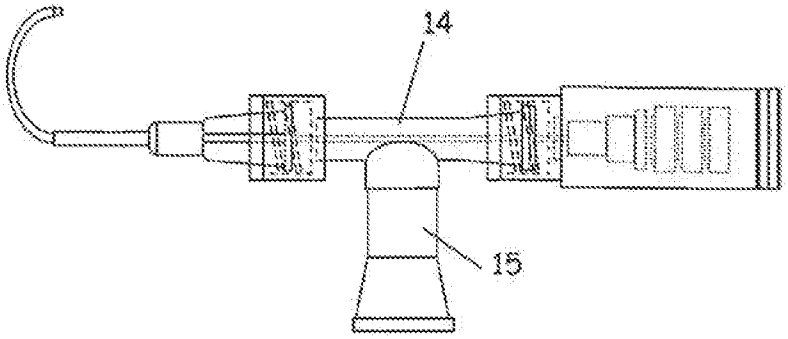


Fig. 4

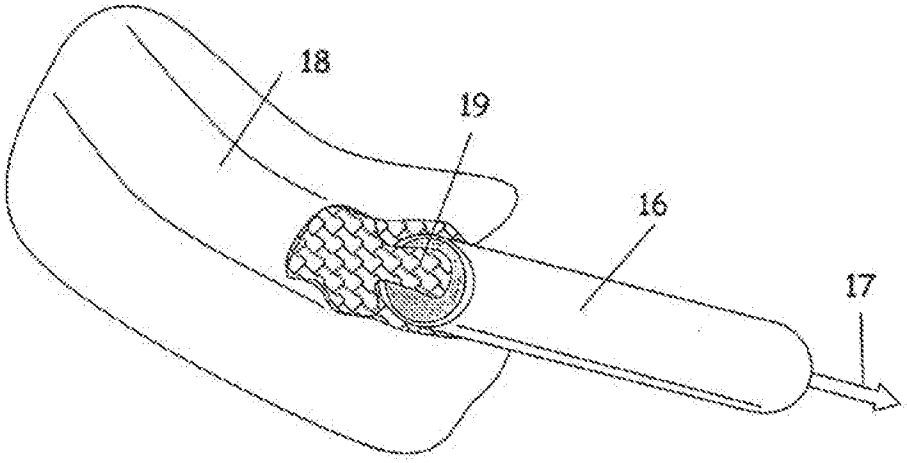


Fig. 5

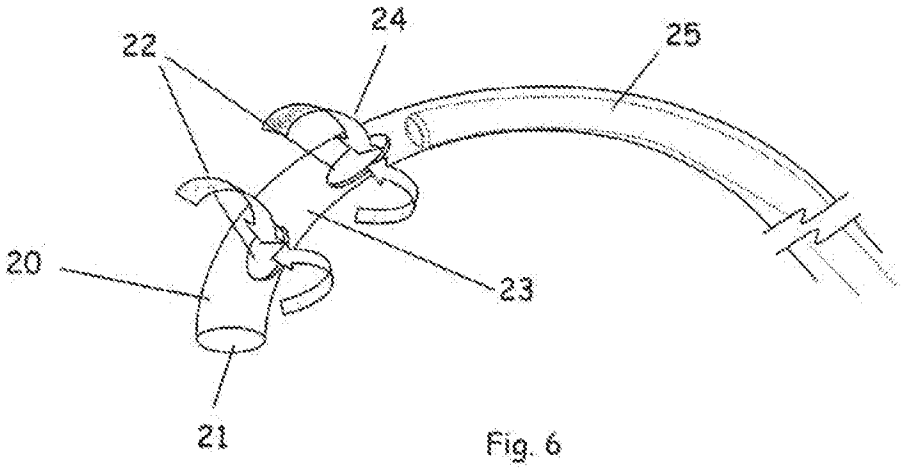


Fig. 6

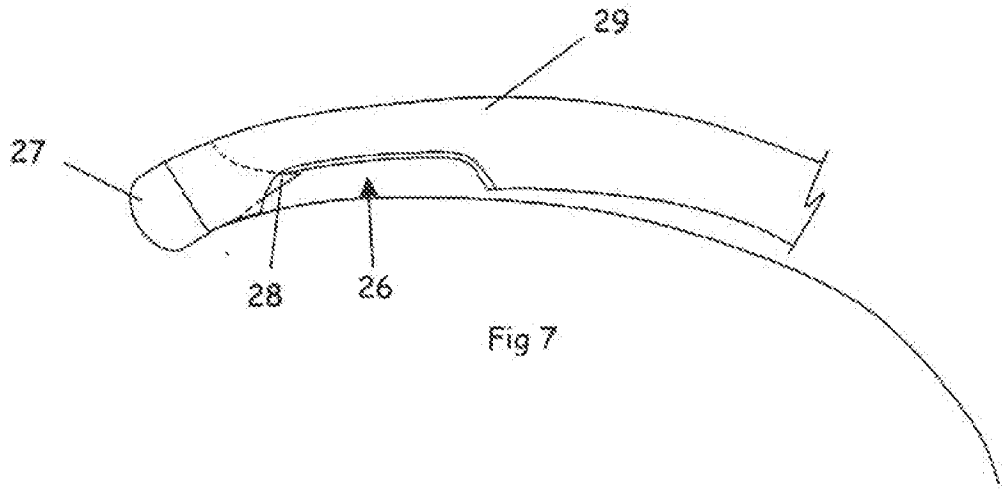


Fig 7

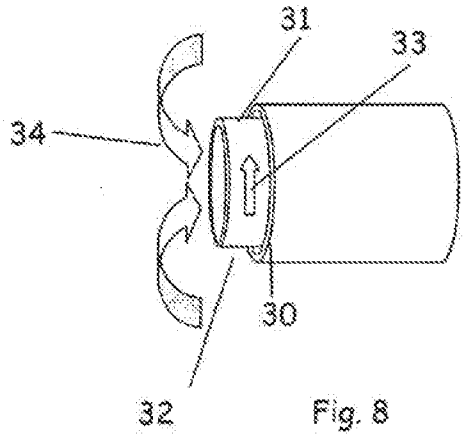


Fig. 8

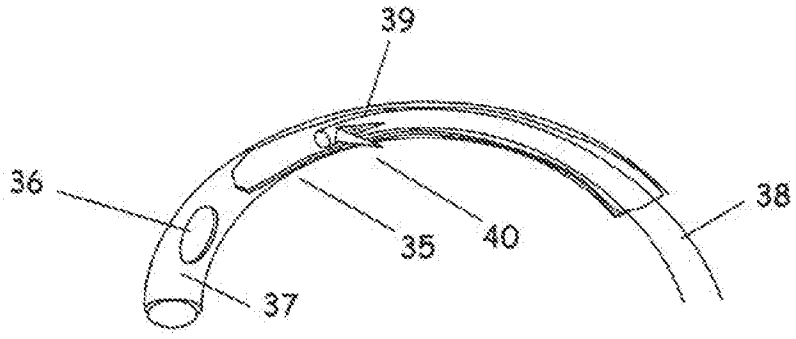


Fig. 9

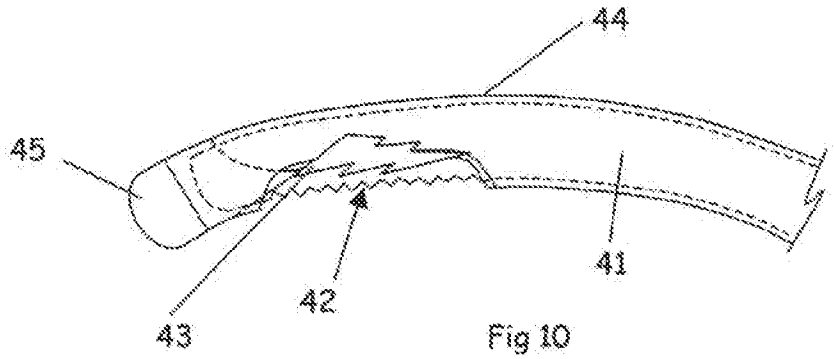


Fig 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/011783

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/053873 A1 (MAAG WERNER ET AL) 20 December 2001 (2001-12-20)	1,14,16
A	page 1, paragraph 8 page 3, paragraph 45 -page 3, line 46 page 4, paragraph 55 -page 4, paragraph 60 page 5, paragraph 71; claims 1,35; figures 1,2,3A3D,4A	3-6,12, 13,17, 18,25, 27,28
Y	US 6 142 990 A (BURK REINHARD O W) 7 November 2000 (2000-11-07) cited in the application	1,14
A	column 4, line 19 -column 4, line 44; claims 8,12; figure 4	3,7,8, 12,16

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 September 2004	17/09/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Merté, B

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/011783

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 501 274 A (SKJAERPE FINN) 26 February 1985 (1985-02-26) cited in the application	1,14,16
A	column 3, line 51 -column 3, line 56; claim 1; figure 3	10,14, 20,26
A	US 5 891 084 A (LEE VINCENT W) 6 April 1999 (1999-04-06) column 6, line 63 -column 7, line 11 column 9, line 15 -column 9, line 43	1,3,5,6, 12,15,29
P,X	WO 03/045290 A (CONSTON STANLEY R ;YAMAMOTO RONALD K (US); ISCIENCE CORP (US)) 5 June 2003 (2003-06-05)	1,7,8, 10-12
A	page 5, line 4 -page 5, line 10; claims 1,2,5-9,11,15,20; figures 3,7; example 3	13-16, 18,20-28

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/011783

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 30-35
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery. The methods comprise the invasive step of "inserting a cannula into a Schlemm's canal" which has to be carried out by an ophthalmic surgeon.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/011783

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001053873 A1	20-12-2001	DE 19956515 A1	21-06-2001
		DE 19956517 A1	21-06-2001
		AU 1376901 A	04-06-2001
		CA 2370369 A1	31-05-2001
		WO 0137767 A1	31-05-2001
		JP 2003514616 T	22-04-2003
		EP 1152722 A1	14-11-2001
		ZA 200105509 A	07-03-2002
US 6142990 A	07-11-2000	DE 19705815 A1	20-08-1998
		DE 59811404 D1	24-06-2004
		EP 0858788 A1	19-08-1998
		JP 10248869 A	22-09-1998
US 4501274 A	26-02-1985	NO 810849 A	13-09-1982
		DE 3264617 D1	14-08-1985
		EP 0073803 A1	16-03-1983
		JP 58500237 T	17-02-1983
		WO 8203168 A1	30-09-1982
US 5891084 A	06-04-1999	NONE	
WO 03045290 A	05-06-2003	CA 2466835 A1	05-06-2003
		WO 03045290 A1	05-06-2003

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(71) Applicant *(for all designated States except US)*: **NEOMEDIX CORPORATION** [US/US]; 27452 Calle Arroyo, San Juan Capistrano, CA 92675 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SORENSEN, John, T.** [US/US]; 19 Barnstable Way, Ladera Ranch, CA 92694 (US); **MITTELSTEIN, Michael** [DE/US]; 29412 Clipper Way, Laguna Niguel, CA 92677 (US); **MIRHASHEMI, Soheila** [US/US]; 29412 Clipper Way, Laguna Niguel, CA 92677 (US).

(74) Agent: **BUYAN, Robert, D.**; Stout, Uxa, Buyan & Mullins, LLP, 4 Venture, Suite 300, Irvine, CA 92618 (US).

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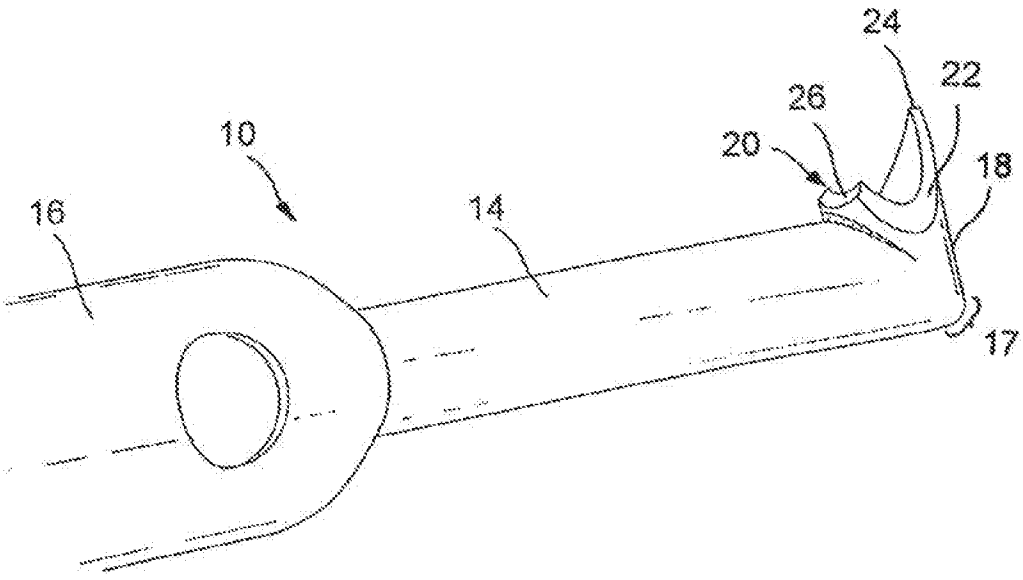
(54) Title: TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT



(57) Abstract: Methods and devices for cutting strips of tissue from masses of tissue inside or outside of the bodies of human or animal subjects. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The device is advanced through tissue to cut a strip of tissue of approximate width W. Width W is approximately equal to distance D.

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TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

RELATED APPLICATIONS

This application claims priority to United States Provisional Patent Application No. 60/477,258 filed on June 10, 2003, the entirety of which is expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider than an incision made by a typical scalpel or cutting blade) in the skin, mucous membrane, tumor, organ or other tissue or a human or animal. Also, it may sometimes desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes, etc. Also, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.

One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes refered to as a goniectomy. In a goniectomy procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 µm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosly organized, porous network of tissue that overlies a collecting canal known as Schlemm's canal. A fluid, known as aqueous humor, is continually produced in the anterior chamber of the eye. In normal individuals, aqueous humor flows through the trabecular meshwork, into Shlemm's Canal and out of the

eye through a series of ducts. In patients who suffer from glaucoma, the drainage of aqueous humor from the eye may be impared by elevated flow resistance through the trabecular meshwork, thereby resulting in an increase in intraoccular pressure. The goniectomy procedure can restore normal drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork, thus allowing the aqueous humor to drain through the open area from which the strip of trabecular meshwork has been removed. The goniectomy procedure and certain prior art instruments useable to perform such procedure are described in United States Patent Application Serial No. 10/052,473 published as No. 2002/011608A1 (Baerveldt), the entirety of which is expressly incorporated herein by reference.

At present there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.

SUMMARY OF THE INVENTION

The present invention provides a device for cutting a strip of tissue of approximate width W from a mass of tissue. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The cutting tube is advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W, wherein the approximate width W is approximately equal to the distance D between the first and second cutting edges. In some embodiments, the strip of tissue may be aspirated or otherwise removed through the lumen of the cutter tube. In some embodiments, the device may include apparatus useable to sever (e.g., transversely cut or transect) the strip of tissue when the strip of tissue has reached a desired length.

Further in accordance with the invention there is provided a method for cutting a strip of tissue of width W from a tissue mass. This method generally

comprises the steps of a) providing a device that comprises i) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and ii) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and b) advancing the distal end of the cutting tube through the mass of tissue such that the first and second cutting edges cut a strip of tissue of approximate width W. Further aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a system incorporating a needle cutting device of the present invention.

Figure 2 is an enlarged perspective view of section 2 of Figure 1.

Figures 3A-3D show various steps in a method for manufacturing a needle cutter of the present invention.

Figure 4 is a side view of a distal portion of a needle cutter device of the present invention being used to cut a strip of tissue of approximate width W.

Figure 5 is a perspective view of the distal portion of a needle cuter device of the present invention incorporating apparatus for severing a strip of tissue cut by the needle cutter device after the strip of tissue has reached a desired length.

Figure 6 is a side view of the distal portion of another embodiment of a needle cutter device of the present invention having a plurality of curves or bends formed in the cutting tube.

DETAILED DESCRIPTION

The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the

invention. Thus, the following detailed description and the accompanying drawings shall not be construed to limit, in any way, the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device 10 of the present invention is shown in Figures 1-4. This needle cutter device 10 generally comprises an elongate cutting tube 14 that has a distal end and a lumen 27 that opens through an opening in the distal end. First and second cutting edges 20, 22 are formed on generally opposite edges of the distal end of the cutting tube 14. These first and second cutting edges 20, 22 are separated by a distance D, as shown in the distal end view of Figure 3B. In the particular example shown in the drawings, the first and second cutting edges 20, 22 are located on opposite lateral sides of the distal end of the cutting tube 14 and a blunt, protruding tip 24 is located on the bottom of the distal end of the cutting tube. Also, a blunt edge 26 is located at the top of the distal end of the cutting tube 14. Thus, only the lateral cutting edges 20, 22 are sharp and intended to cut tissue. The blunt, protruding tip 24 can, in some applications, be configured and used to facilitate insertion of the device 10 to its intended location and/or the blunt protruding tip 24 may be placed in an anatomical or man made grove or channel (e.g., Schlemm's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device 10.

One or more bends or curves may optionally be formed in the cutting tube 14 to facilitate its use for its intended purpose. For example, in the embodiment of the device 10 shown in Figure 2, a single bend 17 of approximately 90 degrees is formed near the distal end of the cutting tube 14. In the embodiment of the device 10b shown in Figure 6, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube 14, thereby giving the cutting tube 14 a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any direction and of any severity may be formed in the cutting tube 14 to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be

between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube 14 each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

As shown in Figure 4, when the cutting tube 14 is advanced through tissue, distal end first, the first and second cutting edges 20, 22 will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges 20, 22. The severed strip ST of tissue will enter the lumen 27 of the cutting tube 14 as the device advances. Negative pressure may be applied to lumen 27 to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen 27.

The device 10 may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device 10 or for other purposes. In the embodiment shown in Figures 1 and 2, the device 10 comprises an outer tube 16 in addition to the cutting tube 14. The cutting tube 14 is of smaller diameter than the outer tube 16 and the cutting tube 14 may extend through the lumen 19 of the outer tube 16 such that a distal portion of the cutting tube 14 extends out of and beyond the distal end of the outer tube 16, as may be seen in Figure 2. The distal end of the outer tube 16 is tapered and in close approximation with the outer surface of the cutting tube 14. Fluid may be infused through the lumen 19 of the outer tube 16, through the space between the outer surface of the cutting tube 14 and the inner surface of the outer tube 16. Fluid that is infused through the lumen 19 of the outer tube 16 may flow out of one or more apertures 11 formed near the distal end of the outer tube.

In some embodiments, the device 10 may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. Figure 5 shows an example of an embodiment

of the device 10a wherein monopolar or bipolar electrode(s) 40 are located on the distal end of the cutting tube 14. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device 10, the cutting edges 20, 22 may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges 20, 22 may be accomplished by placement of electrode(s) near the cutting edges 20, 22 such that, when the electrode(s) is/are energized, the cutting edges 20, 22 will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device 10 of the present invention may optionally be used as part of a system 12, as shown in Figure 1. The basic components of the system 12 comprise an aspiration pump module 74 and a source of irrigation fluid 72, mounted on a surgical roller cart 70. Control of the console functions during procedures may be accomplished by an aspiration foot pedal 78 which controls an aspiration pump 74 and variation in the height of the source of infusion fluid 72 to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device 10. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges 20, 22 and/or for severing the strip ST of tissue (Figure 5), the system 11 may additionally comprise an electrical current source, such as an electrosurgical generator 76 and electrosurgical foot pedal 80 which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device 10. As an option, all of the basic control functions of system 12 may be integrated into a single footpedal to facilitate use.

The device 10 may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Florida. After the

device 10 has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module 76, aspiration pump module 74 and the source of irrigation fluid 72, as shown. Thus, the device 10 may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

Figures 3A-3D show an example of a method for manufacturing the cutting tube 14 from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges 20, 22, the protruding tip 24 and the blunt top edge 26. Thereafter, if it is desired to have one or more bends or curves in the cutting tube 14, angular cut out(s) 30 may be formed in the tube 14, as shown in Figure 3C. Thereafter, the tube 14 is bent to bring the edges of each angular cut out 30 into apposition and weld, adhesive or other joining techniques are used to weld or join the apposed edges of the cut outs together, thereby forming the desired bend(s) or curve(s) in the cutting tube 14. Likewise, if it is desired to have one or more bends or curves in the cutting tube 14, the tube 14 may be directly bent to form said curves or bends without the use of angular cut outs(s) 30. It may be appreciated that the use of angular cut-out(s) 30 allow a tube 10 of a given diameter to incorporate a curve or angle in a more compact form than is possible by bending tubing 10 of a given diameter to said curve or angle without kinking or damaging tube 10.

The device 10 and system 12 are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove, from a mass of tissue, a strip ST of tissue of a desired width.

One particular procedure that may be performed to treat glaucoma, using the device 10 and system 12 of the present invention, is a goniectomy. As explained herein a goniectomy procedure is an *ab interno* surgical procedure wherein a sector of the trabecular meshwork is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber of the eye through Schlemm's Canal and the associated collector channels, thereby relieving elevated intraocular pressure.

To perform a goniectomy procedure using the device 10, first a small incision is made in the cornea at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision .

The device 10 is attached to the source of irrigation fluid 72 (e.g., basic balanced salt solution) such that irrigation fluid will flow through lumen 19 of the outer tube 16 and out of outflow aperture 11. The device 10 is then inserted through the incision and into the anterior chamber of the eye (with irrigation flowing). In some cases, during the insertion of the device 10, the source of irrigation fluid 72 may initially connected to the device such that the irrigation fluid will flow through the lumen 27 of the cutter tube 14. In this manner, irrigation fluid will begin to infuse into the anterior chamber of the eye as soon as the distal end of the cutter tube 14 has entered the anterior chamber, rather than being delayed until the larger outer tube 16 and aperture 11 have been advanced through the incision and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the distal end of the cutter tube 14 as the device 10 is being inserted, thereby spreading or opening the incision by hydraulic force while in addition increasing the fluid pressure in the anterior chamber. Such spreading or opening of the incision may facilitate advancement of the larger diameter outer tube 16 through the incision. Pressurizing the fluid in the anterior chamber causes the anterior chamber to deepen and may facilitate maneuvering of device 10 within the anterior chamber. In cases where this alternative approach is used, the source of infusion fluid 72 may be disconnected from lumen 27 of the cutter tube 14 after the device 10 has been inserted into the anterior chamber and, thereafter, the infusion fluid source 72 may be reconnected to lumen 19 of outer tube 16 such that infusion fluid will flow out of aperture 11. Negative pressure (e.g., via aspiration pump module 74) may then be applied to lumen 27 of the cutter tube 14 so as to aspirate fluid and debris through lumen 27 as shown in Figure 4. The vertical height of the infusion fluid source 72 may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber through lumen 27, thereby maintaining the desired pressure of fluid within the anterior chamber during the procedure.

A lens device (e.g., Ocular Swan-Jacob Autoclavable Gonioprism, Model OSJAG, Ocular Instruments Inc., Bellevue, Washington) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle of the eye where the segment of trabecular meshwork is to be removed. Under direct visualization, the device 10 is advanced until the distal tip of the cutter tube 14 is positioned adjacent to the trabecular meshwork at the location where the strip ST is to be removed. Thereafter, the protruding tip 24 is advanced through the trabecular meshwork and into Schlemm's Canal.

The device 10 is then advanced along Schlemm's Canal, thereby causing the cutting edges 20, 22 to cut a strip of the trabecular meshwork, thereby creating an opening through which aqueous humor may drain from the anterior chamber of the eye.

After a strip of tissue of the desired length (e.g., about 2-10 mm) has been cut by the lateral cutting edges 20, 22, any optional tisue severing apparatus (e.g., electrode(s) 40 may be used (if present) to transect or sever the strp ST of tissue thereby disconnecting it from the patient's body and allowing it to be aspirated or drawn into or through lumen 27.

Thereafter, the aspiration is stopped, the device 10 is removed from the eye, and the infusion is stopped.

Following completion of the surgery, aqueous humor will drain from the anterior chamberthrough the opening that was created by removal of the strip of tissue from the trabecular meshwork TM.

Although the invention has been described above with respect to certain embodiments and examples, it is to be appreciated that such embodiments and examples are non-limiting and are not purported to define all embodiments and examples of the invention. Indeed, those of skill in the art will recognize that various modifications may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention and it is intended that all such modifications be included within the scope of the following claims.

CLAIMS

What is claimed is:

1. A device for cutting a strip of tissue of approximate width W from a mass of tissue, said device comprising:

an elongate cutting tube having a distal end and a lumen that opens through an opening in the distal end;

first and second cutting edges being formed on generally opposite edges of the distal end of the cutting tube said first and second cutting edges being separated by a distance D;

said cutting tube being advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. A device according to Claim 1 wherein the cutting tube comprises a stainless steel hypodermic tubing.

3. A device according to Claim 1 further comprising at least one protruding tip formed on the distal end of the cutting tube.

4. A device according to Claim 2 wherein the protruding tip is tapered.

5. A device according to Claim 2 wherein the protruding tip is sufficiently blunt to be substantially a traumatic.

6. A device according to Claim 1 wherein the first and second cutting edges are located on opposite lateral sides of the distal end of the cutting tube.

7. A device according to Claim 4 wherein the first and second cutting edges are located on opposite lateral sides of the distal end of the cutting tube and the protruding tip is located on the bottom of the distal end of the cutting tube.

8. A device according to Claim 7 further comprising a blunt edge located at the top of the distal end of the cutting tube.

9. A device according to Claim 1 wherein there is a single bend or curve formed in the cutting tube.

10. A device according to Claim 9 wherein there is a single bend of approximately 20 degrees to approximately 90 degrees formed in the cutting tube.

11. A device according to Claim 10 wherein the bend is approximately 90 degrees.

12. A device according to Claim 1 wherein there are a plurality of bends or curves formed in the cutting tube.

13. A device according to Claim 12 wherein there are a plurality of bends of approximately 20 degrees to approximately 90 degrees each formed in the cutting tube.

14. A device according to Claim 12 wherein there is a first bend of approximately 90 degrees and a second bend of approximately 90 degrees, formed in the tube.

15. A device according to Claim 1 further comprising a source of negative pressure connected to the lumen of the cutting tube so as to aspirate fluid or matter through the lumen of the tube.

16. A device according to Claim 1 wherein the device further comprises a second lumen.

17. A device according to Claim 16 wherein one of the lumens is connected to a source of fluid such that fluid may be infused therethrough and the other of said lumens is connected to a source of negative pressure such that fluid or matter may be aspirated therethrough.

18. A device according to Claim 1 wherein at least one of the cutting edges is heated such that it will cauterize as it cuts.

19. A device according to Claim 1 further comprising apparatus for severing the strip of tissue when the strip of tissue has reached a desired length.

20. A device according to Claim 19 wherein the apparatus for severing the strip of tissue comprises at least one electrode which, when energized, will sever the strip of tissue.

21. A device according to Claim 1 wherein the device further comprises:

a second tube that has a lumen and a distal end;

wherein the cutting tube extends through the lumen of the outer tube with a distal portion of the cutting tube extending out of and beyond the distal end of the outer tube.

22. A device according to Claim 21 wherein:

the outer diameter of the cutting tube is smaller than the inner diameter of the second tube such that fluid may flow through the lumen of the second tube; and

at least one aperture is formed in the second tube to permit fluid to pass into or out of the lumen of the second tube.

23. A method for cutting a strip of tissue of width W from a tissue mass, said method comprising the steps of:

A) providing a device which comprises;

i. an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end; and

ii. first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube, said first and second cutting edges being separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and

B) advancing the distal end of the cutting tube through the mass of tissue such that the first and second cutting edges cut a strip of tissue of approximate width W.

24. A method according to Claim 23 wherein the mass of tissue is *in vivo*.

25. A method according to Claim 23 wherein the mass of tissue is *in vitro*.

26. A method according to Claim 23 wherein the mass of tissue is located within the body of a human or animal subject.

27. A method according to Claim 26 wherein the strip of tissue is removed for a diagnostic or therapeutic purpose.

28. A method according to Claim 27 wherein the subject suffers from glaucoma and wherein the method is carried out to remove a strip of trabecular meshwork from an eye of the subject to facilitate drainage of aqueous humor from the eye thereby lowering intraocular pressure.

29. A method according to Claim 28 wherein Step B comprises:

inserting the device into the anterior chamber of the eye;

positioning the distal end of the cutting tube adjacent to or within the trabecular meshwork of the eye; and

advancing the cutting tube such that the cutting edges cut a strip of approximate width W from the trabecular meshwork.

30. A method according to Claim 29 wherein the device provided in Step A of the method further comprises a protruding tip and wherein the protruding tip is advanced through the trabecular meshwork and into Schlemm's Canal and, thereafter, the protruding tip is advanced through Schlemm's Canal as the cutting tube is advanced to cut the strip of tissue.

31. A method according to Claim 23 wherein the device provided in Step A further comprises apparatus for severing the strip of tissue after the strip of tissue has reached a desired length and wherein the method further comprises the step of:

C) severing the strip of tissue after the strip of tissue has reached a desired length.

32. A method according to Claim 23 wherein the method is carried out to form an incision in skin, mucous membrane, an organ, a tumor or other anatomical structure.

33. A method according to Claim 23 further comprising the step of:

C) removing the strip of tissue through the lumen of the cutting tube.

34. A method according to Claim 33 wherein the lumen of the cutting tube is attached to a source of negative pressure to aspirate the strip of tissue through the lumen of the cutting tube.

35. A method according to Claim 23 wherein the device provided in Step A further comprises a second lumen and wherein the method further comprises:

infusing a fluid through one of said lumens; and

aspirating fluid and/or matter through the other of said lumens.

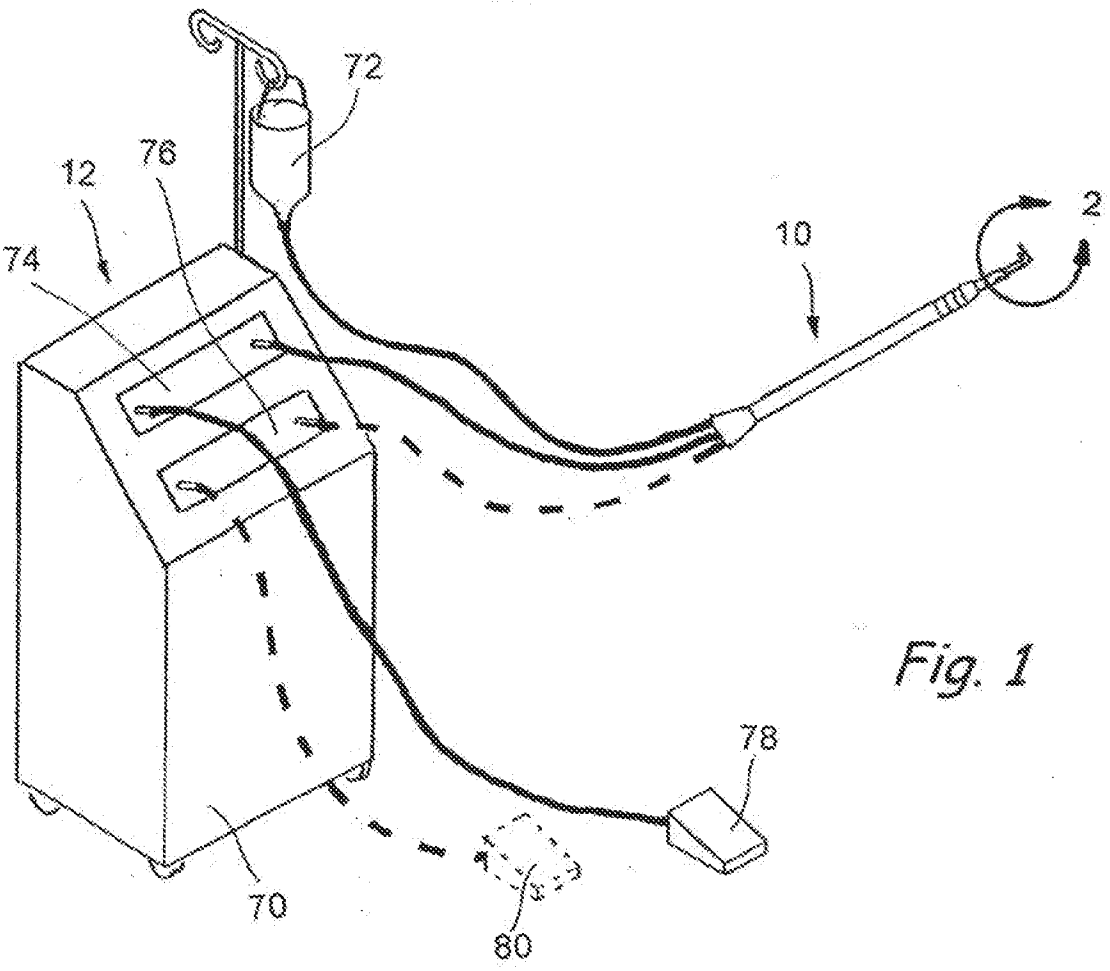

Fig. 1

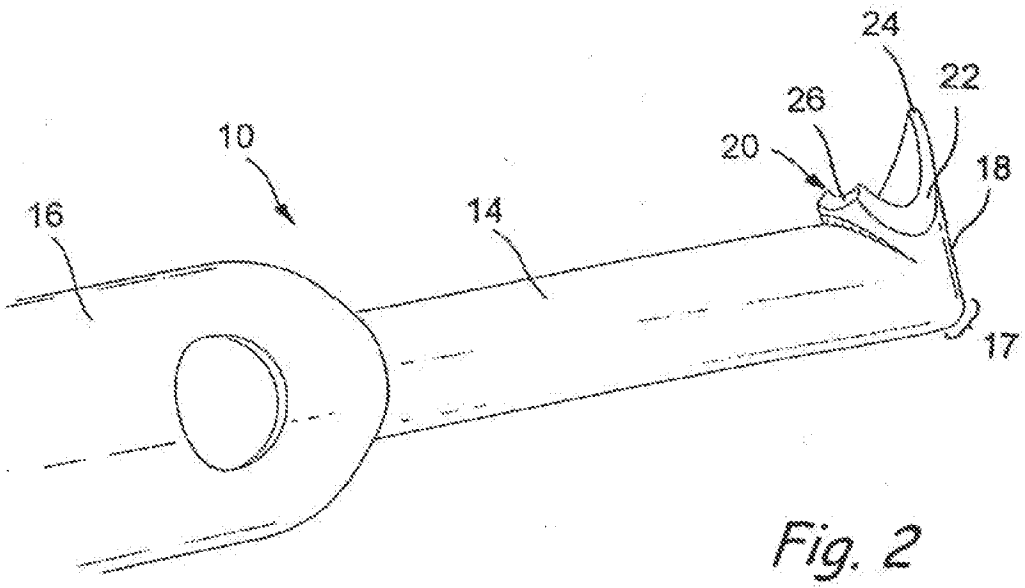

Fig. 2

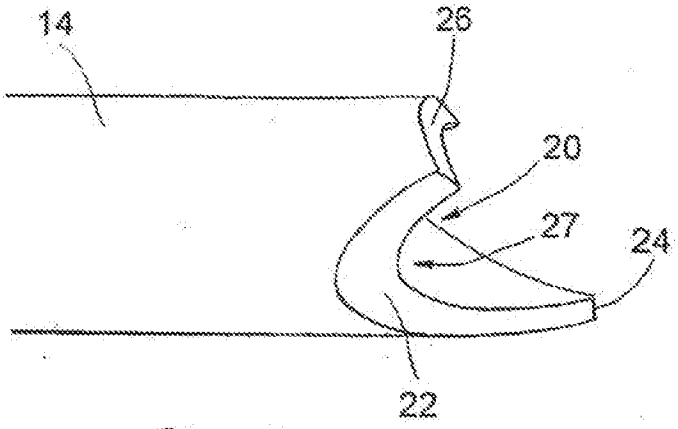

Fig. 3A

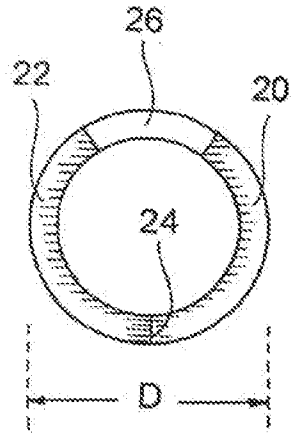

Fig. 3B

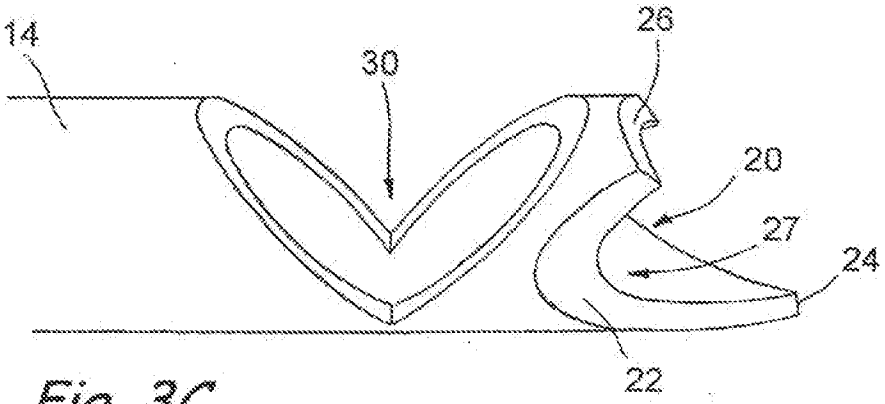

Fig. 3C

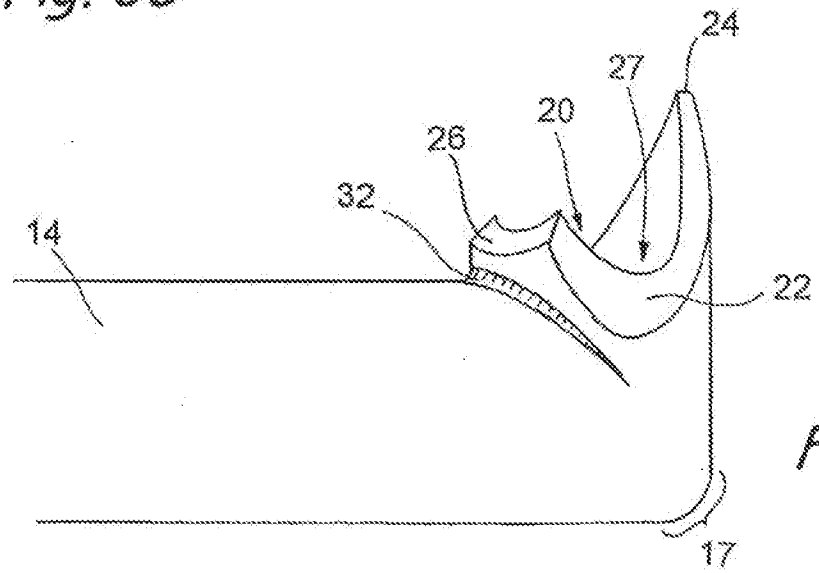

Fig. 3D

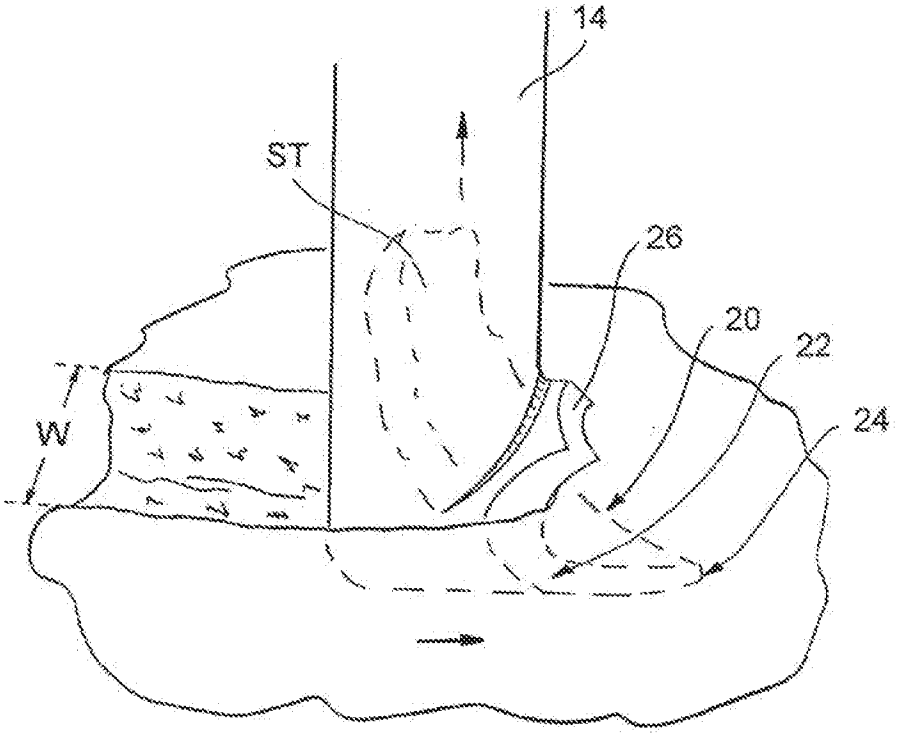

Fig. 4

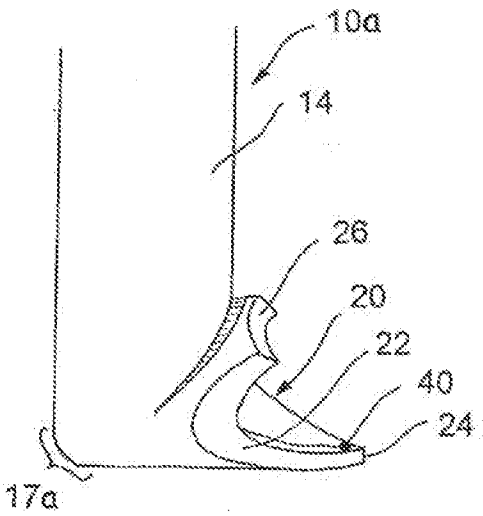

Fig. 5

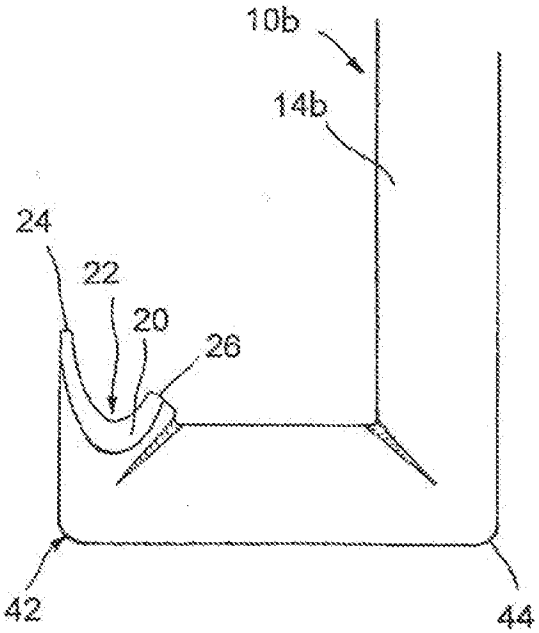

Fig. 6

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(71) Applicant *(for all designated States except US)*: **ALCON RESEARCH, LTD.** [US/US]; 6201 South Freeway, Fort Worth, TX 76134 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LIND, Casey** [US/US]; 7 Filmridge, Irvine, CA 92603 (US). **HUCULAK, John C.** [US/US]; 25551 Aria Drive, Mission Viejo, CA 92692 (US).

(74) Agents: **BASSINGER, Kenneth, D.** et al.; 6201 South Freeway, Tb4-8, Fort Worth, TX 76134 (US).

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[Continued on next page]

(54) Title: SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

(57) Abstract: A small gauge mechanical tissue cutter/aspirator probe useful for removing the trabecular meshwork of a human eye has a generally cylindrical outer cannula, an inner cannula that reciprocates in the outer cannula, a port located near or at the distal end of the outer cannula on a side or tip of the outer cannula, and a guide with a distal surface located on the distal end of the outer cannula. A distance between the distal surface of the guide and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork.

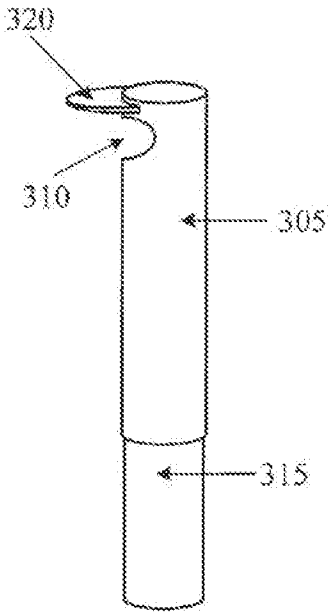

Fig. 3

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SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

This application is a continuation-in-part of US 12/120,867 filed May 15, 2008.

BACKGROUND OF THE INVENTION

The present invention relates to glaucoma surgery and more particularly to a method and device for performing glaucoma surgery using a small gauge mechanical tissue cutter/aspirator probe with a retractable pick.

Glaucoma, a group of eye diseases affecting the retina and optic nerve, is one of the leading causes of blindness worldwide. Glaucoma results when the intraocular pressure (IOP) increases to pressures above normal for prolonged periods of time. IOP can increase due to an imbalance of the production of aqueous humor and the drainage of the aqueous humor. Left untreated, an elevated IOP causes irreversible damage the optic nerve and retinal fibers resulting in a progressive, permanent loss of vision.

The eye's ciliary body epithelium constantly produces aqueous humor, the clear fluid that fills the anterior chamber of the eye (the space between the cornea and iris). The aqueous humor flows out of the anterior chamber through the uveoscleral pathways, a complex drainage system. The delicate balance between the production and drainage of aqueous humor determines the eye's IOP.

Open angle (also called chronic open angle or primary open angle) is the most common type of glaucoma. With this type, even though the anterior structures of the eye appear normal, aqueous fluid builds within the anterior chamber, causing the IOP to become elevated. Left untreated, this may result in permanent damage of the optic nerve and retina. Eye drops are generally prescribed to lower the eye pressure. In some cases, surgery is performed if the IOP cannot be adequately controlled with medical therapy.

Only about 10% of the population suffers from acute angle closure glaucoma. Acute angle closure occurs because of an abnormality of the structures in the front of the eye. In most of these cases, the space between the iris and cornea is more narrow than normal, leaving a smaller channel for the aqueous to pass through. If the flow of

aqueous becomes completely blocked, the IOP rises sharply, causing a sudden angle closure attack.

Secondary glaucoma occurs as a result of another disease or problem within the eye such as: inflammation, trauma, previous surgery, diabetes, tumor, and certain medications. For this type, both the glaucoma and the underlying problem must be treated.

Figure 1 is a diagram of the front portion of an eye that helps to explain the processes of glaucoma. In Figure 1, representations of the lens 110, cornea 120, iris 130, ciliary bodies 140, trabecular meshwork 150, and Schlemm's canal 160 are pictured. Anatomically, the anterior chamber of the eye includes the structures that cause glaucoma. Aqueous fluid is produced by the ciliary bodies 140 that lie beneath the iris 130 and adjacent to the lens 110 in the anterior chamber. This aqueous humor washes over the lens 110 and iris 130 and flows to the drainage system located in the angle of the anterior chamber. The angle of the anterior chamber, which extends circumferentially around the eye, contains structures that allow the aqueous humor to drain. The first structure, and the one most commonly implicated in glaucoma, is the trabecular meshwork 150. The trabecular meshwork 150 extends circumferentially around the anterior chamber in the angle. The trabecular meshwork 150 seems to act as a filter, limiting the outflow of aqueous humor and providing a back pressure producing the IOP. Schlemm's canal 160 is located beyond the trabecular meshwork 150. Schlemm's canal 160 has collector channels that allow aqueous humor to flow out of the anterior chamber. The two arrows in the anterior chamber of Figure 1 show the flow of aqueous humor from the ciliary bodies 140, over the lens 110, over the iris 130, through the trabecular meshwork 150, and into Schlemm's canal 160 and its collector channels.

If the trabecular meshwork becomes malformed or malfunctions, the flow of aqueous humor out of the anterior chamber can be restricted resulting in an increased IOP. The trabecular meshwork may become clogged or inflamed resulting in a restriction on aqueous humor flow. The trabecular meshwork, thus, sometimes blocks the normal flow of aqueous humor into Schlemm's canal and its collector channels.

Surgical intervention is sometimes indicated for such a blockage. Numerous surgical procedures have been developed to either remove or bypass the trabecular meshwork. The trabecular meshwork can be surgically removed by cutting, ablation, or by means of a laser. Several stents or conduits are available that can be implanted

through the trabecular meshwork in order to restore a pathway for aqueous humor flow. Each of these surgical procedures, however, has drawbacks.

One approach that does not have the drawbacks of existing procedures involves using a small gauge mechanical tissue cutter/aspirator probe to remove trabecular meshwork tissue. A small gauge cutting device can be guided into Schlemm's canal and moved in a forward motion following the curvature of the trabecular meshwork. The motion causes the trabecular meshwork to be fed into the cutting port of the cutter, cutting and removing the trabecular meshwork blocking the outflow of the aqueous humor.

SUMMARY OF THE INVENTION

In one embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a retractable pick. A distance between the distal end of the outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula with a smooth distal end, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a distance between the distal end of the first outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a method of cutting and removing trabecular meshwork from a human eye, the method comprising: providing a small gauge mechanical tissue cutter/aspirator probe with a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, such that

the location of the port on the first outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, such that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and aspirating the cut trabecular meshwork from the eye.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a diagram of the front portion of an eye.

Figures 2A and 2B are perspective views of a small gauge mechanical tissue cutter/aspirator probe (traditional vitrectomy probe).

Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figure 4 is a perspective view of a tapered small mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 5A and 5B are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 6A-6C are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts.

Figures 2A and 2B are perspective views of a traditional mechanical tissue cutter/aspirator probe (vitrectomy probe). In a typical mechanical tissue cutter/aspirator probe, an outer cannula 205 includes port 210. An inner cannula 215 reciprocates in cannula 205. One end of inner cannula 215 is configured so that it can cut tissue when as it enters port 210. As shown in Figures 2A and 2B, inner cannula 215 moves up and down in outer cannula 205 to produce a cutting action. Tissue enters port 210 when the mechanical tissue cutter/aspirator probe is in the position shown in Figure 2A. The tissue is cut as inner cannula 215 moves upward closing off port 210 as shown in Figure 2B. Cut tissue is aspirated through the inner cannula and away from the cutting location. Outer cannula 205 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer cannula 205, allows the top surface of outer cannula 205 to remain smooth.

Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. In the embodiment of Figure 3, an outer cannula 305 includes port 310. An inner cannula 315 reciprocates in outer cannula 305. One end of inner cannula 315 is configured so that it can cut tissue when as it enters port 310. Inner cannula 315 moves up and down in outer cannula 305 to produce a cutting action. Cut tissue can be aspirated through inner cannula 315 and removed from the cutting location. Outer cannula 305 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer

cannula 305, allows the top surface of outer cannula 305 to remain smooth. A retractable pick 320 is located on a distal end of outer cannula 305.

Retractable pick 320 is adapted to fit into Schlemm's canal so that mechanical tissue cutter/aspirator probe cutting action can be used to cut and remove the trabecular meshwork (through aspiration provided through port 310). Retractable pick 320 is a short protrusion that extends outward from the distal tip of outer cannula 305 in the direction of port 310. In one embodiment of the present invention, retractable pick 320 has a sharp end that can be used to pierce the trabecular meshwork so that retractable pick 320 can be placed in Schlemm's canal. In another embodiment of the present invention, retractable pick 320 is optional. While retractable pick 320 facilitates entry into Schlemm's canal, once port 310 is located on the trabecular meshwork, retractable pick 320 is largely unnecessary. As such, retractable pick 320 is retracted into outer cannula 305. Cutting action is provided at port 310 which is located along the trabecular meshwork (as best seen below). The distance between port 310 and the distal end of outer cannula 320 determines the location of port 310 in relation to the back wall of Schlemm's canal. This distance is such that port 310 is located at the trabecular meshwork (preferably the distance from the distal end of outer cannula 305 to the center of port 310 is equal to the distance between the trabecular meshwork and the back wall of Schlemm's canal). Locating port 310 at the trabecular meshwork ensures effective removal of it.

Figure 4 is a perspective view of a tapered small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. In this embodiment, the distal end of outer cannula 305 is tapered. While taper 325 is depicted, any type of taper can be employed. Due to the size of Schlemm's canal, it is preferable to have the distal end of outer cannula measure about 0.25 to 0.36 mm diameter (the approximate diameter of Schlemm's canal is about 0.3 mm). In one embodiment, a 27 gauge cannula is used for outer cannula 305. In other embodiments, a tapered 27 gauge or larger cannula is used. Such a cannula is tapered in some fashion so that its distal end measures about 0.25 to 0.36 mm.

Figures 5A and 5B are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figure 5A shows retractable pick 520 in an extended position. Figure 5B shows the retractable pick 520 in a retracted position. In the embodiment of Figure 5A, retractable pick 520 is located at the distal end of cannula 305. Retractable pick 520 may have a sharp tip 525 to pierce the trabecular

meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 520 (or the distal end of cannula 305, if retractable pick 520 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In this manner, as outer cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 520 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

When retracted, retractable pick 520 is located inside of cannula 305. When extended, retractable pick 520 protrudes through an opening on the outer surface of cannula 305. In one embodiment of the present invention, retractable pick 520 is located between inner cannula 315 and outer cannula 305. Retractable pick 520 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer cannula 305. In this case, retractable pick 520 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 520 travels in a passageway formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 520 may be made of any resilient, durable substance. In one embodiment of the present invention, retractable pick 520 is made of a nitinol wire with a sharpened (or beveled) distal tip. 525. In this case, the sharp tip 525, when extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 525 is then retracted before the outer cannula is placed in Schlemm's canal.

Figures 6A, 6B, and 6C are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 6A and 6B show retractable pick 620 in an extended position. Figure 6C shows the retractable pick 620 in a retracted position. In the embodiment of Figure 6A, retractable pick 620 is located at the distal end of cannula 305. Retractable pick 620 may have a sharp tip 625 to pierce the trabecular meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 620 (or the distal end of cannula 305, if retractable pick 620 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In this manner, as outer cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 620 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

In Figure 6B, retractable pick 620 has a curved profile when in an extended position. In this manner, retractable pick 620 can be oriented with respect to the distal end of cannula 305. In Figure 6A, retractable pick extends outward from the distal end of cannula 305. In Figure 6B, retractable pick extends at an angle from the distal end of cannula 305.

When retracted, retractable pick 620 is located inside of cannula 305. When extended, retractable pick 620 protrudes through an opening on the distal end of cannula 305. In one embodiment of the present invention, retractable pick 620 is located between inner cannula 315 and outer cannula 305. Retractable pick 620 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer cannula 305. In this case, retractable pick 620 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 620 travels in a passageway formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 620 may be made of any resilient, durable substance. In one embodiment of the present invention, retractable pick 620 is made of a nitinol wire with a sharpened (or beveled) distal tip. 625. In this case, the sharp tip 625, when extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 625 is then retracted before the outer cannula is placed in Schlemm's canal. As is commonly known, a nitinol wire retains its shape so as to facilitate the retractable pick arrangement pf Figure 6B.

Regardless of what type of pick is used (if any at all), the distance between the back wall of Schlemm's canal to the trabecular meshwork is about 0.3 mm. The approximate thickness of the trabecular meshwork is 0.1 mm. Accordingly, in one embodiment of the present invention, port 310 has an opening that is greater than 0.1 mm, and the distance from port 310 to the distal tip of cannula 305 is about 0.3 mm. In other words, port 310 is located such that it can effectively cut and remove the trabecular meshwork.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 7 and 8 depict two different embodiments of retractable picks, such as retractable picks 320 or 520. In Figure 7, retractable pick 720 is generally egg shaped with a leading edge 705 and a trailing edge 710. Leading edge 705 extends outward from an outer cannula and is used to pierce the trabecular

meshwork. Trailing edge 710 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 7, leading edge is generally curved and may be sharp or blunt. If leading edge 705 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork. In Figure 8, retractable pick 820 has a point at leading edge 805. Leading edge 805 extends outward from an outer cannula and is used to pierce the trabecular meshwork. Trailing edge 810 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 8, leading edge is pointed and may be sharp or blunt. If leading edge 805 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork.

Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery. In Figure 9, outer cannula 305 is inserted through a small incision in the cornea 120. The distal end of cannula 305 (the end that has port 310) is advanced through the angle to the trabecular meshwork 150. The retractable pick is extended so that an opening can be made in the trabecular meshwork. The retractable pick is then retracted so as to avoid damaging a wall of Schlemm's canal 160. The distal end of cannula 305 is then advanced through the opening in the trabecular meshwork 150 and into Schlemm's canal 160. In this position, port 310 is located at the trabecular meshwork 150 and is ready to be cut and removed from the eye.

Figure 10 is an exploded view of the location of the distal end of outer cannula 305 during the removal of the trabecular meshwork 150 (note that in this position, the retractable pick is in a retracted position). In this position, port 310 is located at the trabecular meshwork 150. Outer cannula 305 is then advanced in the direction of port 310 to cut and remove the trabecular meshwork 150. Outer cannula 305 is advanced through an arc in one direction, port 310 is then rotated 180 degrees, and outer cannula 305 is then advanced in an arc in the other direction. In this manner, the distal end of cannula 305 (and port 310) is moved in an arc around the circumference of the angle to remove a substantial portion of the trabecular meshwork through a single corneal incision. If desired, a second corneal incision opposite the first corneal incision can be made so that the outer cannula 305 can be swept through a second arc of the angle. In this manner, either through one or two corneal incisions, a significant portion of the trabecular meshwork can be cut and removed by the mechanical tissue cutter/aspirator probe.

From the above, it may be appreciated that the present invention provides a system and methods for performing glaucoma surgery with a small gauge mechanical tissue cutter/aspirator probe. The present invention provides a small gauge mechanical tissue cutter/aspirator probe with an optional guide that can be advanced into Schlemm's canal to cut and aspirate the trabecular meshwork. Methods of using the probe are also disclosed. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A mechanical tissue cutter/aspirator probe comprising:

a generally cylindrical outer cannula, the outer cannula having a distal end that defines a generally planar surface;

an inner cannula that reciprocates in the outer cannula;

a port located near a distal end of the outer cannula;

a retractable pick located on the distal end of the outer cannula;

wherein a distance between the generally planar surface of the distal end of the outer cannula and the port is approximately equal to the distance between a back wall of Schlemm's canal and a trabecular meshwork in a human eye.

2. The probe of claim 1 wherein the retractable pick further comprises a sharp edge for piercing the trabecular meshwork.

3. The probe of claim 1wherein the retractable pick is located between the inner cannula and the outer cannula.

4. The probe of claim 1wherein the retractable pick is located between the outer cannula and a sleeve.

5. The probe of claim 1 wherein the outer cannula is tapered.

6. The probe of claim 1 wherein the outer cannula has a diameter between about 0.25 and 0.36 millimeters.

7. The probe of claim 1 wherein the distance between the generally planar surface of the distal end of the outer cannula and the port is approximately 0.3 millimeters.

8. The probe of claim 1 wherein cut tissue is aspirated through the port.

9. The probe of claim 1 wherein the retractable pick is made of nitinol.

10. A mechanical tissue cutter/aspirator probe comprising:

a generally cylindrical outer cannula with a generally smooth distal end;

an inner cannula that reciprocates in the outer cannula;

a port located near a distal end of the outer cannula on a side or end of the outer cannula;

wherein a distance between the distal end of the outer cannula and the port is approximately equal to the distance between a back wall of Schlemm's canal and a trabecular meshwork in a human eye.

11. The probe of claim 10 wherein the distal end of the outer cannula is configured to rest against the outer wall of Schlemm's canal.

12. The probe of claim 10 wherein the outer cannula is tapered.

13. The probe of claim 10 wherein the distal end of the outer cannula has a diameter between about 0.25 and 0.36 millimeters.

14. The probe of claim 10 wherein the distance between the distal end of the outer cannula and the port is approximately 0.3 millimeters.

15. The probe of claim 10 wherein cut tissue is aspirated through the port.

16. A method of cutting and removing trabecular meshwork from a human eye, the method comprising:

providing a mechanical tissue cutter/aspirator probe with a generally cylindrical outer cannula, an inner cannula that reciprocates within the outer cannula, and a port located near a distal end of the outer cannula on a side of the outer cannula, such that the location of the port on the outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye;

actuating the inner cannula so that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and

aspirating the cut trabecular meshwork from the eye.

17. The method of claim 16 wherein aspirating the cut trabecular meshwork from the eye further comprises aspirating the cut trabecular meshwork through the port and through the inner cannula.

18. The method of claim 16 wherein the mechanical tissue cutter/aspirator probe is provided with a retractable pick located on the distal end of the outer cannula.

19. The method of claim 18 further comprising:

extending the retractable pick so that an opening can be formed in the trabecular meshwork;

retracting the retractable pick; and

inserting the distal end of the outer cannula in Schlemm's canal.

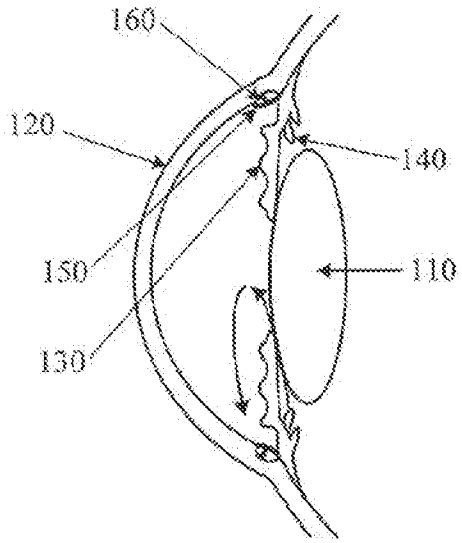


Fig. 1

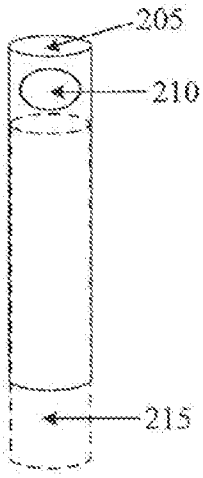


Fig. 2A
(Prior Art)

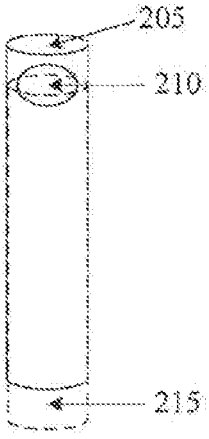


Fig. 2B
(Prior Art)

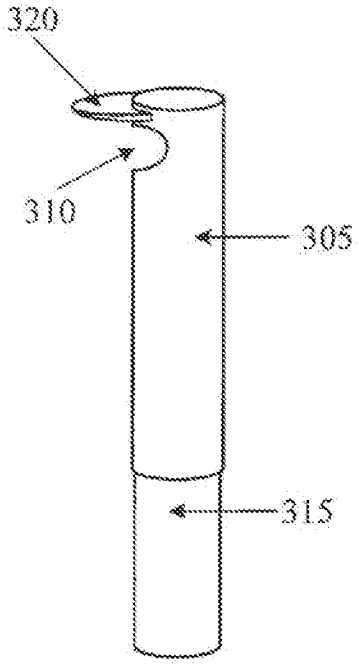


Fig. 3

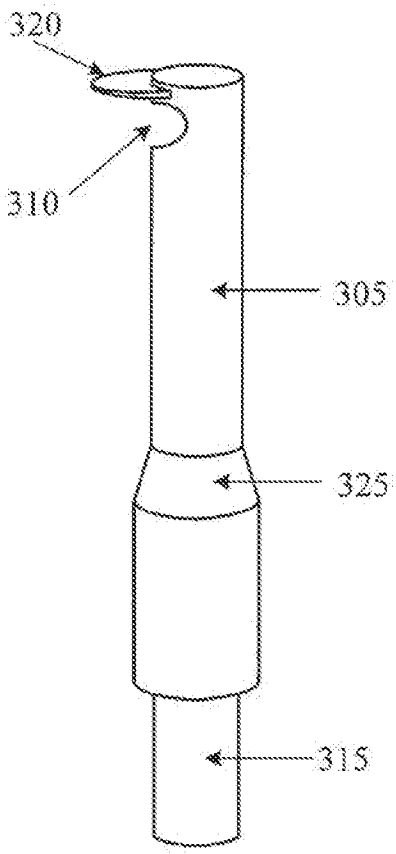


Fig. 4

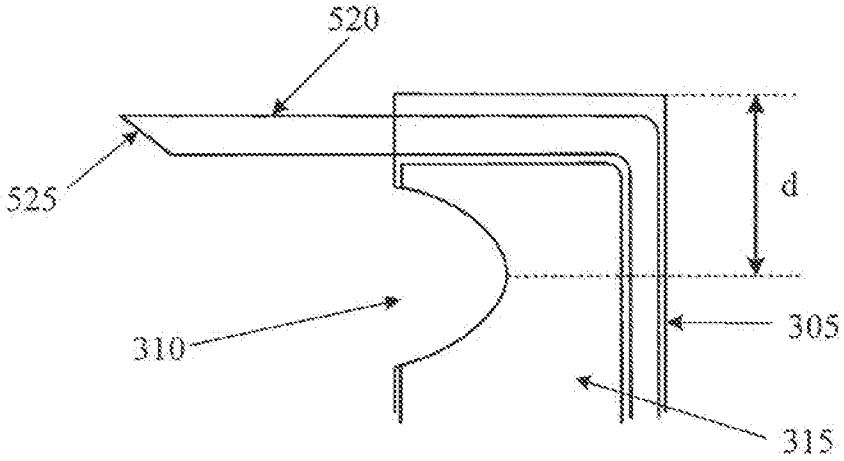


Fig. 5A

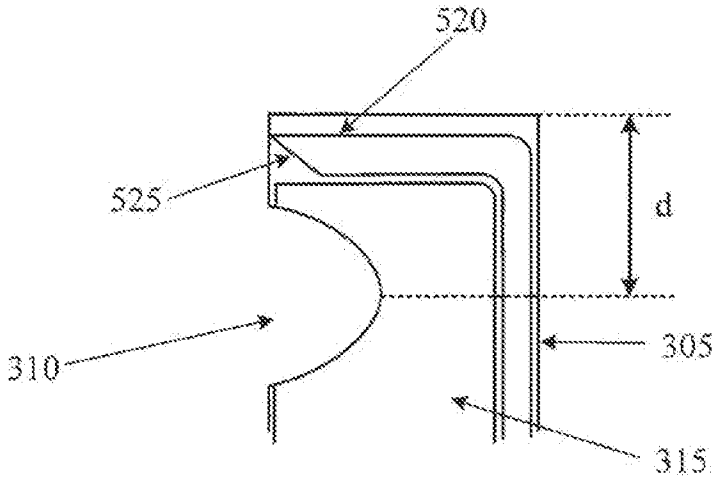


Fig. 5B

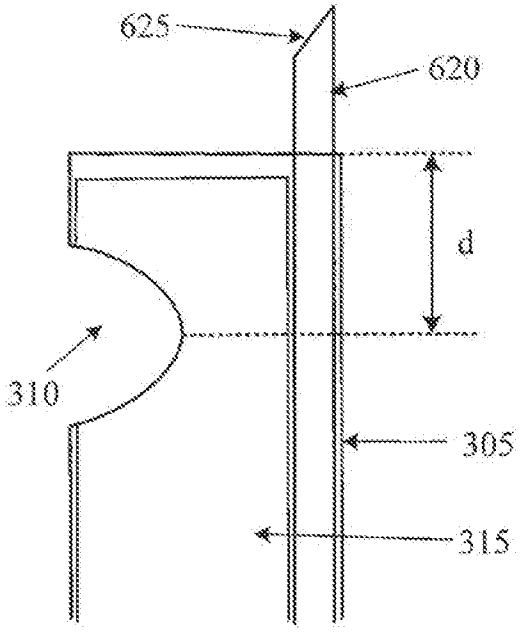


Fig. 6A

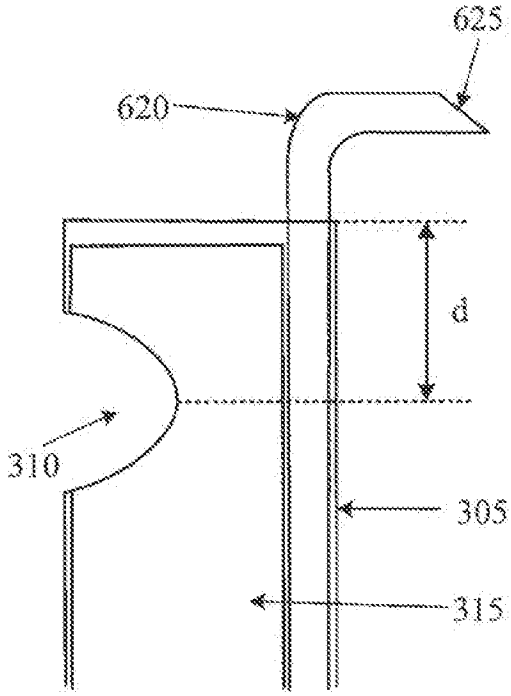


Fig. 6B

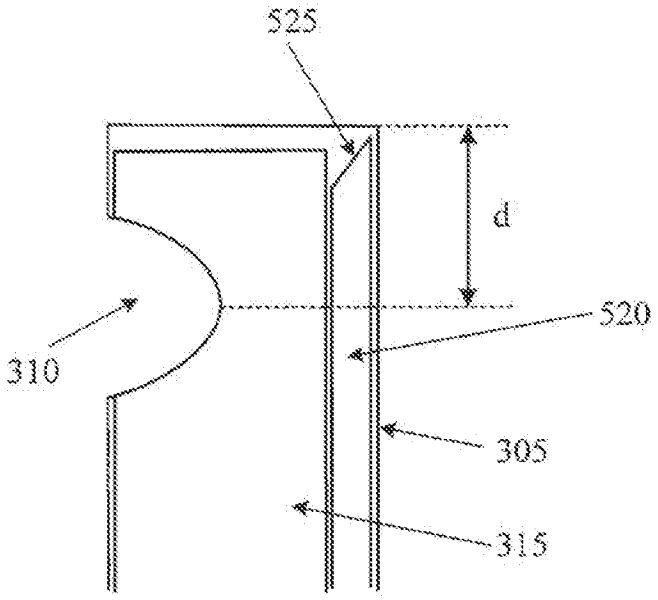


Fig. 6C

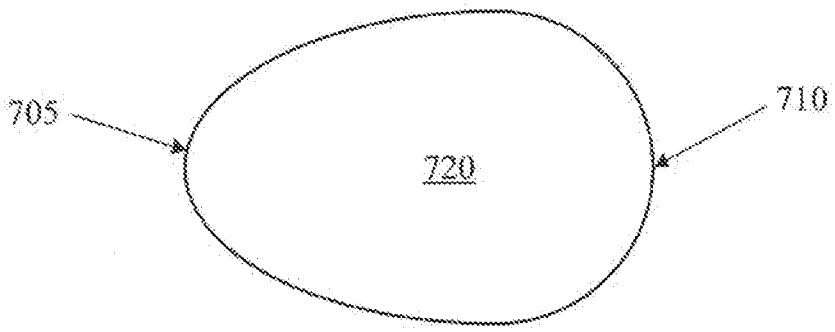


Fig. 7

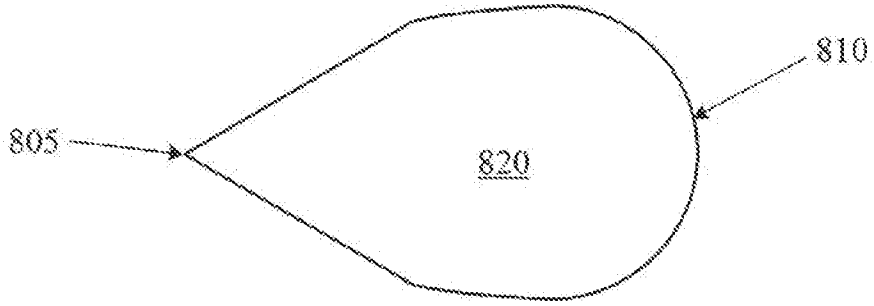


Fig. 8

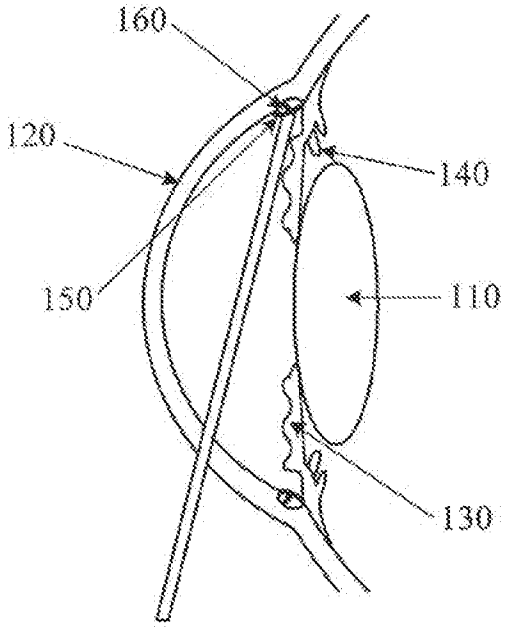


Fig. 9

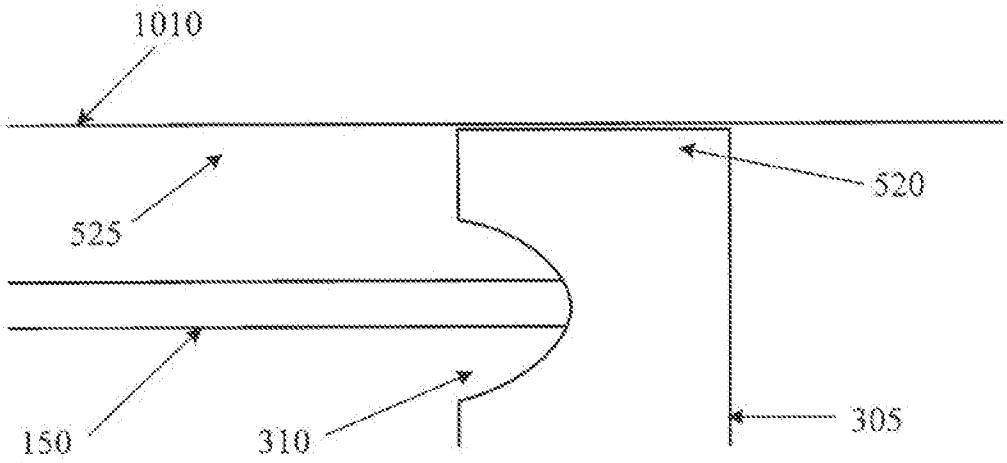


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/043420

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007 A61B17/32 A61B17/34
ADD. A61B17/30 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 527 332 A (CLEMENT THOMAS P [US]) 18 June 1996 (1996-06-18)	10,11,15
Y		12-14
A		1
	abstract; figures 2,3 column 7, line 17 - line 19 column 6, line 11 - line 16	
X	US 4 530 359 A (HELFGOTT MAXWELL A [US] ET AL) 23 July 1985 (1985-07-23) claim 18; figures 6,7	1-4,8
Y	column 3, line 63 - column 3, line 14 column 6, line 37 - line 42 column 11, line 48 - line 58 column 12, line 37 - line 43	5-7,9
	-/--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 2009	27/07/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kajzar, Anna

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/043420

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 733 297 A (WANG CARL C T [US]) 31 March 1998 (1998-03-31) column 2, line 21 - line 26; figure 3	7,14
Y	WO 03/045290 A (ISCIENCE CORP [US]; CONSTON STANLEY R [US]; YAMAMOTO RONALD K [US]) 5 June 2003 (2003-06-05) page 12, line 25 - line 28	9
Y	WO 2007/121485 A (CASCADE OPHTHALMICS [US]; PARDO GEOFFREY [US]; CONNORS KEVIN S [US]; C) 25 October 2007 (2007-10-25) paragraph [0142]	6,13
Y	EP 0 537 116 A (CAPONI MAURO [IT]) 14 April 1993 (1993-04-14) figure 1	5,12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/043420

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/043420

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5527332	A	18-06-1996	NONE		
US 4530359	A	23-07-1985	CA	1233718 A1	08-03-1988
US 5733297	A	31-03-1998	NONE		
WO 03045290	A	05-06-2003	AU	2002365403 A1	10-06-2003
			CA	2466835 A1	05-06-2003
			EP	1455698 A1	15-09-2004
			JP	2005521435 T	21-07-2005
			US	2006149194 A1	06-07-2006
WO 2007121485	A	25-10-2007	AU	2007237905 A1	25-10-2007
			CA	2649721 A1	25-10-2007
			EP	2012654 A2	14-01-2009
			US	2008027304 A1	31-01-2008
EP 0537116	A	14-04-1993	IT	1249714 B	09-03-1995

(19) KOREAN INTELLECTUAL PROPERTY OFFICE

KOREAN PATENT ABSTRACTS

(11) Publication number: 1020040058309 A
(43) Date of publication of application: 03.07.2004

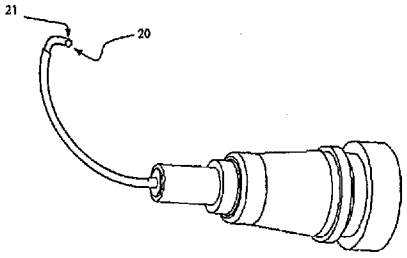
(21) Application number: 1020047007781
(22) Date of filing: 21.05.2004
(30) Priority: 2001 331970 US 21.11.2001
(51) Int. Cl: *A61F 9/007 (2006.01);*
A61F 9/00 (2006.01);

(71) Applicant: ISCIENCE CORPORATION
(72) Inventor: CONSTON STANLEY R.
YAMAMOTO RONALD K.

(54) **OPHTHALMIC MICROSURGICAL SYSTEM**

(57) Abstract:

An ophthalmic microsurgical system is described for treatment of eye diseases, such as glaucoma, using minimally invasive surgical techniques. The microsurgical system includes a thin walled outer sheath microcannula 1 slidably disposed about an inner member 4, which extends slightly beyond the distal end of the microcannula 1. The inner member 4 may be straight or curved and may optionally include a surgical instrument and/or a sensor or signaling beacon. The microsurgical system is used in a surgical procedure for opening Schlemm's Canal to provide drainage of aqueous fluid in order to relieve excess intraocular that results from glaucoma an other diseases of the eye.



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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 073 803**
B1

(12) # EUROPEAN PATENT SPECIFICATION

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(51) Int. Cl.⁴: **A 61 B 17/32**

(21) Application number: **82900833.3**

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(86) International application number:
PCT/NO82/00014

(87) International publication number:
WO 82/03168 30.09.82 Gazette 82/23

(54) **MICROSURGICAL INSTRUMENT.**

(30) Priority: **12.03.81 NO 810849**

(43) Date of publication of application:
16.03.83 Bulletin 83/11

(45) Publication of the grant of the patent:
10.07.85 Bulletin 85/28

(84) Designated Contracting States:
BE CH DE FR GB LI LU NL

(56) References cited:
US-A-2 521 161
US-A-2 944 552
US-A-3 815 604
US-A-3 882 872

(73) Proprietor: **SKJAERPE, Finn**
Nedreveien 1
N-4000 Stavanger (NO)

(72) Inventor: **SKJAERPE, Finn**
Nedreveien 1
N-4000 Stavanger (NO)

(74) Representative: **Needle, Jacqueline et al**
PAGE, WHITE & FARRER 5 Plough Place
New Fetter Lane
London EC4A 1HY (GB)

EP 0 073 803 B1

Courier Press, Leamington Spa, England.

Description

The present invention relates to a microsurgical instrument for use in the surgical treatment of glaucoma by means of a novel operational procedure which may be called "selective trabeculectomy".

Glaucoma is an ailment in which the internal pressure in the eyeball is increased. Within the eye aqueous humour is produced at a fairly constant rate. This liquid is drained out through filter-like tissue (trabecular meshwork) in the angle between the iris and the cornea into a collector canal which runs circularly along the transition between the cornea and the sclera (Canal of Schlemm), and from this canal through 20—30 drainage outlets in the eye wall into blood vessels (water veins).

The cause of glaucoma is believed to be a type of "clogging" of the trabecular meshwork, so that the outflow resistance increases. The internal pressure then increases to allow the same volume of liquid to be drained per unit time. All treatment aims at reducing the eye pressure. Such treatment is primarily medical, but when this is intolerable and/or insufficient, surgical treatment is used.

The surgical treatments may be subdivided according to three principles, namely:

1. Operations aimed at the reduced production of aqueous humour.

2. Fistulizing procedures, i.e. surgical provision of artificial slits in the eye walls, through which the liquid may drain out of the eye.

3. Operations on the trabecular meshwork. Existing procedures of this kind are of two types, i.e.:

a) Approach through the anterior chamber of the eye by means of goniotomy or cautery of the trabecular meshwork with laser beams.

b) Approach through the Canal of Schlemm. Such approach consists in opening this canal through a radial incision in the eye wall above the canal and insertion of a blunt probe or probe means with a cutting edge (trabeculotome). This instrument is then manipulated in such a way that it tears open or cuts through the trabecular meshwork into the anterior chamber of the eye. With such procedure a narrow slitlike opening is formed through the trabecular meshwork. Such slits exhibit, however, a considerable tendency to close.

In order to inhibit such closure it is an object of the invention to provide a microsurgical instrument, which through appropriate use may form a permanent opening from the anterior chamber of the eye to the Canal of Schlemm by selective removal of the inner wall of this canal along a certain sector. In this manner the aqueous humour gains direct access to the outer wall of the Canal of Schlemm, which has outlets or drainage canals, so that normal drainage of aqueous humour may be re-established.

Thus, the invention provides a microsurgical instrument for performing selective trabeculectomy in surgical treatment of glaucoma, the instrument including flexible probe means and a cutting member fixed to the same.

US—A—2944552 describes an instrument for treating arteriosclerotic occlusive disease which includes flexible probe means and a cutting member affixed to the same, the cutting member comprising two knife blades protruding in different directions from the probe means and each providing at least one sharp cutting edge.

The present invention is characterised in that each cutting edge is turned towards a free end of the probe means, and in that at least one catching device for cut-away tissue is mounted on the cutting member C behind the sharp cutting edges.

An instrument of the invention may be called a trabeculectome, as it is designed to be pulled through the Canal of Schlemm along a certain peripheral sector of the eye. By this the inner wall of the canal and the corresponding portion of the 0.1 mm thick trabecular meshwork are cut away.

In an embodiment, the probe means is knob-shaped at its extreme end and is made of a flexible material. However, the probe means is still sufficiently rigid to be inserted into and directed through the Canal of Schlemm. The cutting member has at least two cutting edges which are angularly separated to such an extent that the V-form defined fits into the scleral groove in the eye wall, in which the trabecular meshwork is embedded. Advantageously, the cutting member is asymmetrical, the two knife edges extending over different lengths. Thus, one knife blade may project perpendicularly into the anterior chamber towards the iris and this blade is short, whereas the other blade may project obliquely into the anterior chamber and forms a small angle with the back side of the cornea, and this other blade is longer. This feature stabilizes the correct position of the knife.

The probe means of the trabeculectome is directed through an incision in the eye wall into and along the Canal of Schlemm, and is pulled out through another incision at a certain distance from the first one. The cutting member of the trabeculectome is pulled after the probe means through the Canal of Schlemm with the two knife edges projecting into the anterior chamber of the eye and thereby cutting away a strip of the trabecular tissue and the inner wall of the Canal of Schlemm which are located between the cutting edges. This tissue strip is generally removed together with the trabeculectome when it is pulled out through the second incision in the eye wall. Such removal of the tissue strip is secured by the catching device mounted on the cutting member. The catching device may be formed by one or more hooks with the hook opening turned towards a free end of the probe means. In an alternative embodiment, the catching device is formed by a plate member connected to an edge-free rim of the knife blades and preferably formed as a trapping hook, to partly or completely cover the space between the knife blades.

A microsurgical instrument of the invention

enables a surgical procedure to be performed which secures a permanent broad opening between the anterior chamber of the eye and the outlets from the Canal of Schlemm by removing the trabecular meshwork and the inner wall of the canal. Tissue removal together with maintained cell casing on the outer wall of the Canal of Schlemm make a closure of this opening improbable, even in the long run.

Experiences with this method to date suggest a low rate of complications, so that the operational indications probably may be extended. This means that the patients may be operated at an earlier stage and thus expensive and troublesome medical treatment is avoided.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which

Figure 1 shows a first embodiment of an instrument of the invention and shows a cross-section of the cutting member taken at right angles to the longitudinal axis of the probe means,

Figure 2 shows a side elevation of the instrument of Figure 1,

Figure 3 shows a perspective view of the instrument of Figures 1 and 2,

Figure 4 shows a side elevation of a further embodiment of an instrument of the invention, and

Figure 5 shows a cross-section of the cutting member taken at right angles to the longitudinal axis of the probe means of the embodiment of Figure 4.

The instrument shown in Figures 1 to 3 comprises a probe A formed by a monofilament of nylon or by a synthetic fibre suture, which is fused at one end to form a rounded knob. The other end of the probe A is inserted into a hole in a metallic holding member B and rigidly clamped to this member. Preferably, the holding member B is made of steel. A cutting member C is formed from a 1/100—5/100 mm thick stainless steel foil, which is finely sharpened at its front edge and bent into an approximate V-form adapted to the local anatomical features of the eye at the Canal of Schlemm and the trabecular meshwork. The cutting member C is fixed to the holding member B and thereby to the probe A by means of a two-component epoxy glue. A point welding technique may also be used if the probe A is mounted on the member B after the welding step.

The cutting member C defines two knife blades C1, C2 which protrude in different directions from the probe A. The sharpened edge defines a cutting edge E1, E2 on each knife blade C1, C2, the cutting edges facing towards said one end of the probe A. An arrow above the probe in Figure 2 shows the pulling direction in use.

Between the knife blades C1, C2, a barbed hook D is fixed to the member B in order to catch the tissue strip which is cut free between the knives. This hook D is also fastened by means of epoxy resin. Finally, a layer of epoxy resin is applied to the joints and transitions between the holding member B and the probe A to provide a completely smooth surface. Teflon and similar polymers may also be used as covering layer and silicone is considered particularly advantageous for this purpose.

Another embodiment of an instrument of the invention is illustrated in Figures 4 and 5.

In this case the probe A is made of flexible metal and is welded to the cutting member C. The extreme rear end of the probe A is bent forward between the knife blades C1, C2 to form a small sharp hook D. All joints are provided with a cover of epoxy resin and the probe is furnished with a layer of resin at the end to form a finely rounded knob.

The knife blades C1, C2 need not necessarily have a free end. Thus, the extreme ends of the knife blades may well be interconnected to form a closed knife blade ring, e.g. of approximate triangular shape.

The cut-away tissue strip may be captured by closing the rear opening of the knife ring to thereby catch the strip in the "container" thus formed. For example, a plate member (not shown) can be connected to a rim of the blades on which no cutting edge is provided to partly or completely cover the space between the blades. This plate member may be formed as a trapping hook. The instrument must necessarily be quite small to allow the intended surgical treatment of the eye. Thus, in the illustrated embodiments the probe has a diameter of approximately 0.25 mm and a length of the order of magnitude 4—8 cm and rathe freely adaptable to the requirements of the eye surgeon. The shorter knife blade C1 of the cutting member may suitably have a length of about 0.7—1.0 mm, whilst the longer, preferably curved knife blade C2 may have a length of 1.5—1.8 mm. The width of the knife blades may be of the order of magnitude 0.3—0.5 mm.

In the embodiments shown in the drawings and described above the cutting member is fixed at one end of the probe means. However, the cutting member may be fixed to the probe at another location, e.g. on the central part of the same. The portion of the probe projecting from the rear side of the cutting member may then be used for improved steering of the instrument, when it is guided between the two incisions in the eye wall. If the cutting member is located approximately centrally on the probe, the protruding knife blades may further be provided with a cutting edge on both sides, so that the instrument may be effectively pulled in both directions through the Canal of Schlemm.

Although the cutting edges E1, E2 are shown in the drawings to extend substantially at right angles with respect to the longitudinal axis of the probe, these edges may be inclined at an angle between 45° and 90° in the pulling direction with respect to the probe axis. An inwardly directed radial force is then exercised against the tissue strip during the movement of the cutting member through the Canal of Schlemm.

Claims

1. Microsurgical instrument for performing selective trabeculectomy in surgical treatment of glaucoma, the instrument including flexible probe means (A) and a cutting member (C) fixed to the probe means and comprising two knife blades (C1, C2) protruding in different directions from the probe means (A) and each providing at least one sharp cutting edge (E1, E2), characterised in that each cutting edge (E1, E2) is turned towards a free end of the probe means (A), and in that at least one catching device (D) for cut-away tissue is mounted on the cutting member (C) behind the sharp cutting edges (E1, E2).

2. An instrument as claimed in Claim 1, characterised in that the two cutting edges (E1, E2) extend for different lengths from the probe means, the shorter edges (E1) being straight and the longer side (E2) having a curvature, preferably adapted to the boundary surface of the tissue to be cut away.

3. An instrument as claimed in Claim 1 or Claim 2, characterised in that the extreme ends of the two knife blades (C1, C2) are interconnected to form a closed knife blade ring.

4. An instrument as claimed in any preceding claim, characterised in that the catching device is formed by one or more hooks (D) with the hook opening turned towards a free end of the probe means.

5. An instrument as claimed in any of Claims 1 to 3, characterised in that the catching device (D) is formed by a plate member connected to an edgefree rim of the knife blades (C1, C2), and preferably formed as a trapping hook, to partly or completely cover the space between the knife blades.

6. An instrument as claimed in any preceding claim, characterised in that the cutting edges (E1, E2) of the knife blades form an angle between 45° and 90° with the longitudinal axis of the probe means (A).

7. An instrument as claimed in any preceding claim, characterised in that the probe means (A) is formed by a synthetic fibre suture with a metallic holder (B) clamped to the suture, e.g. at an extreme end of the same, the cutting member (C) being glued or welded to the holder.

8. An instrument as claimed in any of Claims 1 to 6, characterised in that the probe means (A) is made from flexible metallic material which is welded to the cutting member (C), e.g. at an extreme end, and may be covered with plastics material, preferably silicone.

9. An instrument as claimed in any of Claims 1 to 6, characterised in that the cutting member (C) is moulded in hard plastics material and is integral with or connected to the probe means (A).

Patentansprüche

1. Mikrochirurgisches Instrument zum Ausführen der selektiven Trabeculektomie beim chirurgischen Behandeln des Glaukom, mit einem flexiblen Eindringmittel (A) und einem Schneidglied (C), das am Eindringmittel befestigt ist und zwei Messerklingen (C1, C2) umfasst, die in verschiedenen Richtungen von dem Eindringmittel (A) vorstehen und jedes wenigstens eine scharfe Schneidekante (E1, E2) aufweist, dadurch gekennzeichnet, dass jede Schneidekante (E1, E2) gegen ein freies Ende des Eindringmittels (A) hin geformt ist und dass wenigstens eine Greifvorrichtung (D) für weggeschnittens Gewebe auf dem Schneidglied (C) hinter der scharfen Schneidekante (E1, E2) angeordnet ist.

2. Instrument nach Anspruch 1, dadurch gekennzeichnet, dass die zwei Schneidekanten (E1, E2) sich in verschiedenen Längen von dem Eindringmittel wegerstrecken, dass die kürzere Schneidekante gerade ist und dass die längere Schneidekante bogenformig, vorzugsweise an die Grenzfläche des wegzuschneidenden Gewebes angepasst ist.

3. Instrument nach einem der Ansprüche 1 oder 2, dadurch gekennzeichnet, dass die äusseren Enden der zwei Messerklingen (C1, C2) zum Bilden eines geschlossenen Messerklingenringes miteinander verbunden sind.

4. Instrument nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass die Greifvorrichtung durch einen oder mehrere Haken (D) gebildet ist und dass die Hakenöffnung gegen ein freies Endes des Eindringmittels gerichtet ist.

5. Instrument nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Greifvorrichtung (D) durch ein Plattenglied gebildet ist, dass mit dem schneidekantenfreien Rand der Messerklingen (C1, C2) verbunden ist, und vorzugsweise als Fanghaken ausgebildet ist und teilweise oder vollständig den Raum zwischen den Messerklingen einnimmt.

6. Instrument nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass die Schneidekanten (E1, E2) der Messerklingen mit der Längsachse des Eindringmittels (A) einen Winkel von 45° und 90° einschliessen.

7. Instrument nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass das Eindringmittel (A) aus einer Kunstfaserstruktur mit einem metallischen Halter (B) gebildet ist, der an einem Ende der Kunstfaserstruktur angeklemmt ist und dass das Schneidglied (C) an den Halter angeklebt oder angeschweisst ist.

8. Instrument nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass das Eindringmittel (A) aus einem flexiblen metallischen Material gebildet ist, dessen eines Ende mit dem Schneidglied (C) verschweisst ist und mit Kunststoff, vorzugsweise Silikon, überzogen sein kann.

9. Instrument nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass das Schneidglied (C) aus hartem Kunststoffmaterial geformt ist und einstückig mit dem Eindringmittel (A) oder mit dem Eindringmittel verbunden ist.

Revendications

1. Instrument microchirurgical pour réaliser une trabéculectomie sélective dans le traitement chirurgical du glaucome, cet instrument comprenant des moyens de sonde souples (A) et un organe de coupe (C) fixé aux moyens de sonde et comprenant deux lames de couteau (C1, C2) faisant saillie dans des directions différentes par rapport aux moyens de sonde (A) et comportant chacun au moins un tranchant effilé (E1, E2), caractérisé en ce que chaque tranchant (E1, E2) est orienté vers une extrémité libre des moyens de sonde (A) et en ce qu'au moins un dispositif de prise (D) pour le tissu découpé est fixé sur l'organe de coupe (C) derrière les tranchants effilés (E1, E2).

2. Instrument suivant la revendication 1, caractérisé en ce que les deux tranchants (E1, E2) s'étendent suivant des longueurs différentes à partir des moyens de sonde, le bord le plus court (E1) étant droit et le bord le plus long (E2) ayant une courbure, de préférence adaptée à la surface de délimitation du tissu à découper.

3. Instrument suivant l'une ou l'autre des revendications 1 et 2, caractérisé en ce que les extrémités des deux lames de couteau (C1, C2) sont reliées entre elles pour former un anneau à lames de couteau fermé.

4. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que le dispositif de prise est formé par un ou plusieurs crochets (D), l'ouverture du ou des crochets étant orientée vers une extrémité libre des moyens de sonde.

5. Instrument suivant l'une quelconque des revendications 1 à 3, caractérisé en ce que le dispositif de prise (D) est formé par un élément de plaque relié à un bord sans tranchant des lames de couteau (C1, C2), façonné de préférence sous la forme d'un crochet de fixation, de manière à recouvrir partiellement ou totalement l'espace entre les lames de couteau.

6. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que les bords de coupe (E1, E2) des lames de couteau forment un angle de 45° à 90° avec l'axe longitudinal des moyens de sonde (A).

7. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que les moyens de sonde (A) sont formés par une suture en fibres synthétiques, un support métallique (B) étant fixé à la suture, par exemple à une extrémité de celle-ci, l'organe de coupe (C) étant collé ou soudé au support.

8. Instrument suivant l'une quelconque des revendications 1 à 6, caractérisé en ce que les moyens de sonde (A) sont réalisés en une matière métallique souple qui est soudée à l'organe de coupe (C), par exemple à une extrémité, et en ce qu'ils peuvent être recouverts d'une matière plastique, de préférence de la silicone.

9. Instrument suivant l'une quelconque des revendications 1 à 6, caractérisé en ce que l'organe de coupe (C) est moulé dans une matière plastique dure et est solidaire des moyens de sonde (A) ou relié à ces derniers.

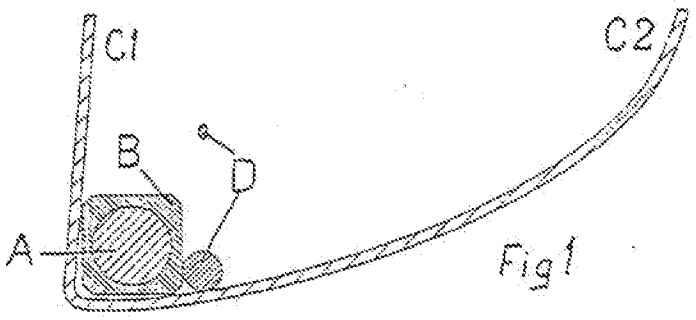

Fig 1

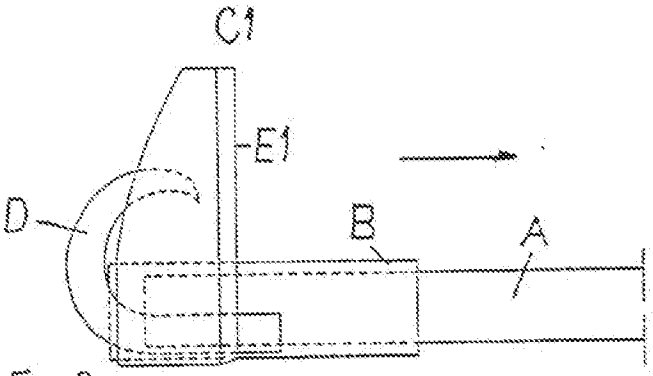

Fig 2

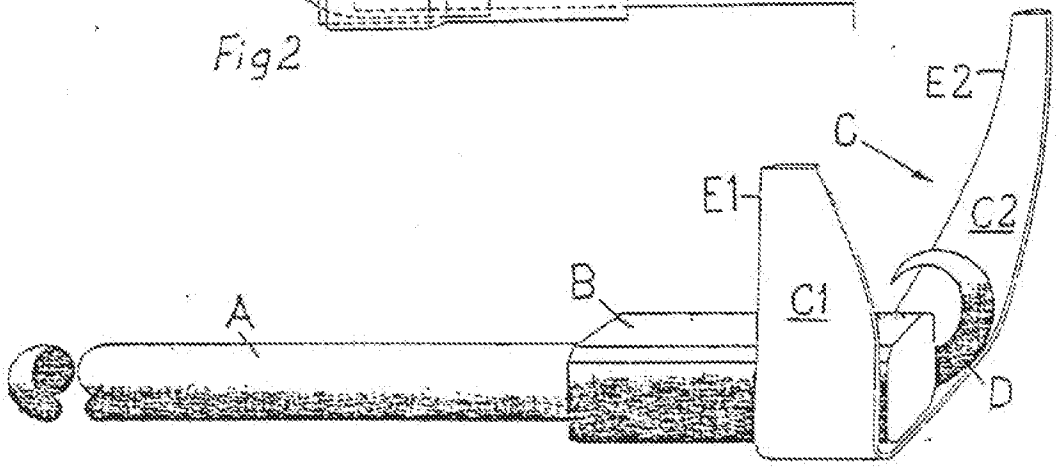

Fig 3

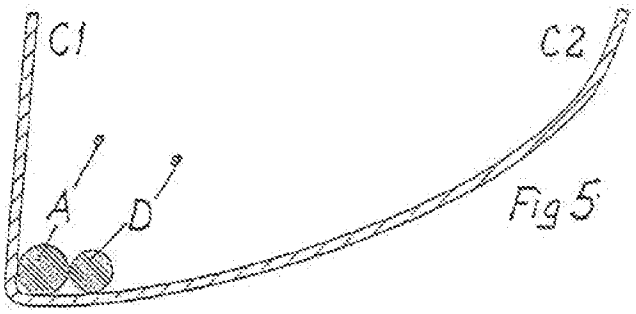

Fig 5

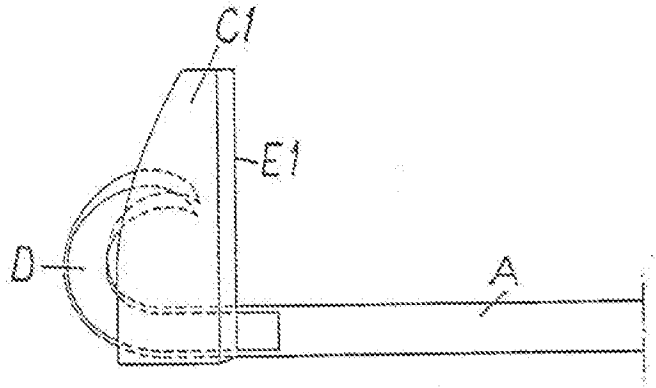

Fig 4

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(71) Applicant (*for all designated States except US*): **ISCIENCE SURGICAL CORPORATION** [US/US]; 1321 Waller St., San Francisco, CA 94117 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **CONSTON, Stanley, R.,** [US/US]; 148 Rogers Avenue, San Carlos, CA 94070 (US). **KUPIECKI, David, J.,** [US/US]; 1410 Shrader Street, San Francisco, CA 94117 (US). **MCKENZIE, John** [US/US]; 1742 Eaton Avenue, San Carlos, CA 94070 (US). **YAMAMOTO, Ronald, K.,** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

(74) Agents: **SMITH, Gregory** et al., 3600 Newpark Mall Rd., Third Floor, Suite 317, Newark, CA 94560 (US).

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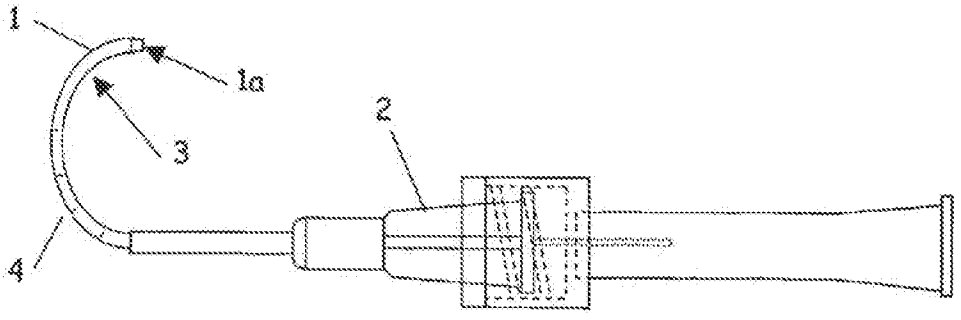
(54) Title: OPHTHALMIC MICROSURGICAL INSTRUMENTS



(57) Abstract: Ophthalmic microsurgical instruments may be directly inserted into Schlemm's Canal to allow controlled treatment or removal of adjacent tissues such as the trabecular meshwork or the juxtacanalicular tissues to affect an increase in aqueous outflow and the reduction of intra-ocular pressure. The instrument allows the directed access to Schlemm's Canal by a flexible microcannula (1). The instrument is useful in allowing controlled guidance by the surgeon while viewing through a surgical microscope or by non-invasive medical imaging.

WO 2004/093761 A1

Ophthalmic Microsurgical Instruments

Incorporation by Reference:

Co-pending PCT application number PCT/US03/08866 is hereby incorporated by reference in its entirety.

Background of Invention:

Glaucoma is a disease condition of the eye in which increased intraocular pressure (IOP) is created by blockage of the drainage mechanism for the aqueous fluid produced in the anterior portion of the eye. Such conditions are usually treated by topical drugs in the form of eye drops, but may result in surgical treatment if drug treatment becomes ineffective or if patient compliance is an issue. Traditional glaucoma surgery such as trabeculectomy, involves a flap dissection of the eye and the removal of a portion of the trabecular meshwork (TM) or the corneo-scleral junction. The aqueous fluid is directed posteriorly under the surgical flap and to a sub-conjunctival lake known as a bleb. Post-surgical complications and bleb management are significant issues with trabeculectomy and similar procedures. Furthermore, the control of the aqueous outflow is achieved through the management of the integrity of the surgical flap rather than controlling the opening into the anterior chamber. Other procedures involving laser energy to create holes in the TM are partially successful, however long term results are limited as compared to trabeculectomy.

Recently developed surgical treatments for glaucoma involve surgically accessing Schlemm's Canal by manner of a surgical flap or flaps and subsequently dilating or expanding the canal to increase aqueous humor drainage into the natural drainage pathway. Current procedures and instruments can only access a short passage of Schlemm's Canal from either side of the surgical site. US 5,486,165 to Stegmann et al. in discloses a microcannula designed for delivery of substances to Schlemm's Canal during such a procedure. EP 0898947A2 to Grieshaber et al. discloses an improvement to the Stegmann apparatus to deliver substances or stents for maintaining the passage of fluid in the canal. Other inventions disclose the use of microcatheters to introduce water-jet type cutting apparatus or bladed mechanisms to

the canal for disruption of the TM. However these methods cut the TM network open in a non-controlled manner and do not remove tissue or debris from the operative field.

The treatment of glaucoma usually involves patient specific requirements for the amount of drainage increase desired by the physician. It is therefore of advantage to be able to treat or remove a controlled amount of the TM or associated juxtacanalicular tissues in order to be able to titrate drainage rates and control the disease process on a patient specific basis. Furthermore, it is desired to perform the controlled treatment or removal of tissues from within Schlemm's Canal in order to facilitate the restoration of natural aqueous drainage system without the requirement for blebs and the concomitant complications, and to enable less invasive surgical methods. It is also advantageous to physically stabilize the tissues in order to facilitate control of the amount of tissues being treated or removed.

This invention is directed at ophthalmic microsurgical instruments which may be directly inserted into Schlemm's Canal to allow controlled treatment or removal of adjacent tissues such as the TM or the juxtacanalicular tissues to effect the reduction of intra-ocular pressure. It is a further object of this invention to describe an instrument which allows the directed access to Schlemm's Canal by a flexible microcannula. The instrument is useful in allowing controlled guidance by the surgeon while viewing through a surgical microscope or by non-invasive medical imaging.

Known prior art:

United States Patent 4,501,274
Skjaerpe February 26, 1985
Microsurgical instrument

United States Patent 5,486,165
Stegmann January 23, 1996
Method and appliance for maintaining the natural intraocular pressure

United States Patent 6,142,990
Burk November 7, 2000
Medical apparatus, especially for reducing intraocular pressure

United States Patent 6,221,078
Bylsma April 24, 2001
Surgical implantation apparatus

United States Patent 6,283,940
Mulholland September 4, 2001
Catheter

United States Patent 6,375,642 B1
Grieshaber , et al. April 23, 2002
Method of and device for improving drainage of aqueous humor within the eye

United States Patent 6,494,857 B1
Neuhann December 17, 2002
Device for improving in a targeted manner and/or permanently ensuring the ability of the aqueous humor to pass through the trabecular meshwork

United States Patent Application 20020013546
Grieshaber, Hans R. ; et al. January 31, 2002
Method and device to improve aqueous humor drainage in an eye

United States Patent Application 20020111608
Baerveldt, George ; et al. August 15, 2002
Minimally invasive glaucoma surgical instrument and method

United States Patent Application 20020082591
Haefliger, Eduard June 27, 2002
Device for the treatment of glaucoma

United States Patent Application 2003014092
Inventor(s): Neuhann Thomas (De)
Apparatus for the treatment of glaucoma

Patent Number: EP0898947 A2
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: EP1114627 A1
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: WO0064389
Inventor(s): Brown Reay H (Us); Lynch Mary G (Us); King Spencer B Iii (Us)
Trabeculotomy device and method for treating glaucoma

Patent Number: WO02056805
Inventor(s): Roy Chuck; Baerveldt George
Minimally invasive glaucoma surgical instrument and method

Patent Number: WO02074052
Inventor(s): Smedley Gregory T; Gharib Morteza; Tu Hosheng
Applicator and methods for placing a trabecular shunt for glaucoma treatment

Patent Number WO03045290
Inventor(s): Conston Stanley R; Yamamoto Ronald K
Ophthalmic Microsurgical System

Brief Description of the Drawings

Figure 1 illustrates a sheath microcannula with an inner member.
Figure 2 illustrates a microcannula with expandable segments.
Figure 3 illustrates a microcannula with a signaling beacon tip.
Figure 4 illustrates a microcannula with a side connection fitting.

Figure 5 illustrates a microcannula with an open distal tip with a side channel for application of suction.

Figure 6 illustrates a microcannula with fenestrations and an inner member for controlled tissue removal.

Figure 7 illustrates a microcannula with a single fenestration for controlled tissue removal.

Figure 8 illustrates a microcannula with a rotating inner member for tissue cutting.

Figure 9 illustrates a microcannula with a side fenestration and tissue cutting flap.

Figure 10 illustrates a microcannula with a side fenestration and inner member for directed tissue abrasion.

Description of Invention:

Schlemm's Canal is a channel in the corneo-scleral junction of the eye and is the primary pathway for the drainage of aqueous humor. The inner wall of the Canal comprises the TM and juxtacanalicular tissues through which the aqueous humor drains from the anterior chamber. The outer wall of is comprised of scleral tissue with openings to collector channels for the passage of aqueous humor from the Canal to the venous system. Due to its relative positioning to the TM, the Canal forms a circular channel that encircles the anterior chamber. The Canal is approximately 10 to 15 mm in diameter and 200 microns by 50 microns in cross-section. The drainage of aqueous humor through the TM and juxtacanalicular tissues into Schlemm's Canal is believed to be the predominant route for aqueous drainage. In open surgery for glaucoma, surgical treatment of the inner wall of Schlemm's Canal and removal of associated tissue such as the TM and juxtacanalicular tissues has demonstrated an increase in aqueous outflow and reduction of intraocular pressure. It is an object of the present invention to enable treatment and removal of tissues in these specific regions by use of minimally invasive surgical instruments. It is also an object of the invention to treat a specific segment of the tissue tract and also to treat specific regions of the selected segment to minimize surgical trauma and post-surgical scarring.

The ophthalmic microsurgical instruments of the present invention comprise a thin walled outer sheath microcannula with a connector at the proximal end, a distal tip

and a communicating channel therebetween, as shown in Figure 1. The microcannula lumen provides a fluid and gas tight, sealed passage from the proximal end to the distal tip of the instruments. An inner member which fits and slides or rotates within the sheath may also be incorporated, the inner member comprising at least a proximal end and a distal tip. The distal end of the instruments may be curved in a manner to approximate the curvature of Schlemm's Canal. The instruments may also comprise a guidance means to effect proper advancement of the distal portion. Furthermore the instruments may comprise means to mechanically stabilize the target tissues. The tissues may be held in tension or compression for controlled treatment or removal of tissue. The instruments may also comprise cutting means to excise targeted tissues. The instruments may also be used to deliver drugs or implants to the tissue tract to treat adjacent tissues.

The microcannula may be introduced into Schlemm's Canal manually or as part of a system to provide surgical support or guidance. Once inserted into Schlemm's Canal, the microcannula may be progressively advanced to the appropriate areas for treatment. The distal end is preferably sized and curved or compliant enough to access at least one half the length of Schlemm's Canal, approximately 15 to 25 mm. Treatment of the entire Canal may be effected by inserting the instrument in the opposite direction from the first treatment at the surgical access point. The positioning of the instrument in the Canal can be verified by several means including a fiber-optic beacon tip inner member, a change in pressure or vacuum resistance in the surrounding environment as the system enters the Canal, a change in tissue color, direct visual location during surgical cut-down or by external image guidance such as ultrasound or optical coherence tomography. Features of the instrument can aid accurate positioning within the Canal.

The selective treatment or removal of tissues adjacent to Schlemm's Canal such as TM or juxtacanalicular tissues may be accomplished by various means. One means incorporates the use of side holes or fenestrations on the outer sheath directed at the target tissues adjacent to the inner radius. The outer sheath may be configured to allow for tissue treatment or removal separately or in conjunction with an inner member that works in alignment with the side holes or fenestrations. Another means

for selective treatment of the TM or juxtacanalicular tissues may be accomplished by the use of suction through the microcannula, which has been observed to act predominantly on the inner wall of the Canal. Both means may also be combined, such as the use of suction to pull a region of the target tissue into a side hole or fenestration of the outer sheath for subsequent treatment or excision.

Suction or vacuum may also be incorporated to clear the operative field and the microcannula lumen, either concurrent with tissue treatment or subsequent to tissue treatment since the sheath also functions to provide a disposal path for the excised tissues and surgical debris. Furthermore the ability of the cannula to remove particles and debris may be used by itself or in conjunction with other treatment methods such as laser trabeculoplasty in order to enhance the outcome by removal of waste particles.

The microcannula may comprise a thin walled polymer or metallic tube **1** of sufficient stiffness to allow it to be advanced into Schlemm's Canal, and of sufficient flexibility or compliance to follow the curvature of the Canal. It is preferable that the distal tip **1a** be beveled or radiused so as to provide for atraumatic advancement into the Canal. The proximal connector **2** may be of a Luer type or similar system for the attachment or introduction of secondary elements or may be designed for attachment only to specific components. Due to the small size of Schlemm's Canal, approximately 200 microns in diameter, the microcannula must be appropriately sized. Typically, the microcannula is sized in the range of 100 to 350 microns outer diameter with a wall thickness from 10 to 100 microns to allow cannulation of Schlemm's Canal. However, Schlemm's Canal may be expanded prior to insertion of the microcannula with for example, the injection of a surgical viscoelastic material. With prior expansion of the Canal, cannulation becomes much easier to perform without damaging tissues. Expansion of Schlemm's Canal also allows a microcannula of up to 500 microns outer diameter to be used to access the Canal.

Due to the curvature of Schlemm's Canal, the microcannula should be flexible in the appropriate dimensions. In some embodiments, a predetermined curvature **3** may be applied to the inner member and/or the outer sheath during fabrication. The

curvature is preferably slightly greater than the curvature of the Canal in order to prevent the instrument from perforating the inner wall while advancing the microcannula. It is also desirable for a portion of the instrument to be able to be swiveled at least 180° around to provide for handedness to the curved microcannula. This allows the surgeon to cannulate the entire circumference of Schlemm's Canal from a comfortable working position.

Suitable materials for the microcannula sheath include metals, polyetheretherketone (PEEK), polyimide, polyamide, polysulfone, or similar materials. The sheath may also comprise surface treatments such as lubricious coatings to assist in cannulation and ultrasound or light interactive coatings to aid in location and guidance. The microcannula may also have markings **4** on the exterior for assessment of depth in the tissue tract. The external markings allow user assessment of the length of the tissue tract accessed by the microcannula, and the approximate location of the microcannula tip.

The microcannula **5** may also comprise a segment or series of segments capable of being expanded in a radial direction in order to place tension on the target tissues for treatment, as shown in Figure 2. The segments may comprise means such as stent-like structures, balloons or elastomeric sections **6** which may be inflated or deformed in a radial manner **7**. Multiple expandable segments may be used to stabilize and isolate segments of Schlemm's Canal for surgical or drug treatment through the microcannula lumen. Furthermore, the expandable segments may be slidably disposed about the central axis such that the segments may be translated axially apart from each other to provide further tension on the tissues. The expandable segments may comprise polymers and elastomers such as latex, silicone rubber, urethane, vinyl, polyether block amide (Pebax) or may be a metallic structure comprised of shape-memory or superelastic alloy, stainless steel, tungsten or similar materials. Alternatively, another outer member may be disposed about the microcannula as a tissue stabilization means. The expandable structure would be activated or mechanically released to expand during the procedure and then retracted or compressed for removal.

Depending on the application, the inner member may be used to guide the positioning of the microcannula, surgical tools and instrumentation or act as a surgical tool. The inner member may comprise a guide wire, hollow needle or tube, micro-trocar, cutting tool or similar element and comprises a proximal end and a distal tip, and may contain a communicating channel between. The inner member may also comprise sensing means such as a pressure transducer or fiber optic to aid in determining location, local fluid pressure, blood flow or other parameters. The inner element is sized correspondingly to fit slidably within the microcannula and therefore will be in the range of 90 to 450 microns in outer diameter. If hollow, the inner diameter will be in the range of 40 to 400 microns. The inner member may be removed during the surgical procedure and replaced sequentially with other inner members acting as instruments or tools.

A first inner member used for initial placement may comprise a signaling beacon to identify the location of the microcannula tip relative to the target tissues, as shown in Figure 3. The beacon may comprise an echogenic material for ultrasound guidance, an optically active material for optical guidance or a light source for visual guidance. In one embodiment, a plastic optical fiber (POF) **8** is used to provide a bright visual light source at its distal tip **9**. The distal tip of the POF **10** may be positioned at or slightly beyond the end of the microcannula sheath **11** and the emitted signal may be detected through the scleral tissues visually or using sensing means such as infrared imaging. The POF may also comprise a tip which is beveled or mirrored or otherwise configured to provide for a directional beacon. If the emitted directional light is directed toward the inner radius at the TM, the surgeon may view the illuminated spot in the anterior angle using a goniometer lens, and verify placement of the operative instrument at the targeted tissues. The beacon may be illuminated by a high intensity light source, laser, laser diode or light-emitting diode **12**, which may be powered by batteries **13** or standard AC power. Upon arrival of the microcannula distal end at the target tissues, the beacon assembly and POF may be removed, leaving the microcannula sheath at the desired location for treatment. The connection point between the outer microcannula sheath and the inner member may be sealed with a cap or preferably with a self-sealing mechanism such as a one-way valve or an elastomer seal.

In one embodiment, the instrument set also comprises a fitting as the connection point for the illumination package. Additionally, as shown in Figure 4, the instrument may contain a central section **14** comprising a single or multiple side fittings **15** to allow the attachment of ancillary equipment such as syringes, vacuum or pressures sources, sensing means and the like. The attachment fittings may comprise standard designs such as Luer fittings or may be designed to only accept connection with specific components.

The operative function of the invention is an instrument to treat or remove specific tissues adjacent to Schlemm's Canal such as the TM in such a manner that the area of the treatment or removal is controlled and repeatable. In some applications, the instrument may be used to remove a controlled layer of adjacent target tissue, such as the juxtacanalicular tissues at the inner wall of Schlemm's Canal. Furthermore, the procedure can be performed at multiple sites within the eye to effect treatment per the patient's requirements by using the microcannula sheath for repositioning to other target locations from within the Canal.

In one embodiment the microcannula **16** alone is used to remove portions of the adjacent tissue using suction means **17**, as shown in Figure 5. The microcannula is advanced into Schlemm's Canal **18**. A vacuum syringe, vacuum or aspiration pump is used to provide suction and a portion of the inner wall is pulled into the lumen **19** and removed. Due the large difference in mechanical properties between the thick scleral outer wall of the Canal and the flexible tissues of the inner wall, suction applied by a microcannula has demonstrated preferential ability to manipulate the inner wall. Control of the suction characteristics may be used to control the amount of tissue treated or removed from the inner wall. In some cases, suction alone may be applied to the TM to remove tissue debris and improve aqueous outflow, without removing a portion of the TM.

In another embodiment, shown in Figure 6, the distal tip of the microcannula **20** is closed off **21**. A fenestration or series of fenestrations **22** are disposed along the inner radius wall **23** of the microcannula, directed toward the TM. Suction is applied

24 to pull a small amount of TM into the lumen and apply tension to the target tissue. An inner member 25, comprised of a thin hollow shaft, is then extended through the microcannula 20 and may be rotated or axially advanced, to cut off the intruding tissues. The inner member may comprise a beveled or sharpened leading edge to facilitate tissue cutting. The excised tissue may be removed by a suction mechanism through the lumen. The amount of tissue removal may be controlled through the sizing of the ingress holes and the amount of suction applied. The outermost layer of the TM, including the juxtacanalicular tissues, interfacing Schlemm's Canal may be removed by minimal application of suction, or alternatively openings through the TM of controlled geometry may be formed with greater amounts of suction.

In a similar embodiment, Fig 7, a single fenestration 26 is created along the inner radius wall of the microcannula 29. The distal tip 27 is closed and is fully radiused to produce a ball-end tip. A single cutting element 28 is disposed in the lumen at the distal end, with the cutting edge oriented proximally. The target tissues are pulled into the lumen, and the cannula is withdrawn which allows the cutting element to remove tissue to a determined depth. The cutting depth may be set and adjusted by the cutting element design, the dimensions of the fenestration and the amount of suction applied.

Furthermore, the microcannula may contain stabilization means in conjunction with cutting means thereby applying traction to the tissues to improve cutting efficiency and control. The microcannula may comprise a multilumen tube such that each lumen is connected separately to a hole or a series of holes along the inside radius facing the target tissues. For example, a two-lumen microcannula may be constructed comprised with three holes a set distance apart along the inner radius wall. The outermost two holes are connected to one lumen of the microcannula and the central hole to the second lumen. In this manner, a low suction pressure may be applied to the outermost holes, providing tissue stabilizing forces, while a higher suction pressure may be applied to the center hole, removing a controlled portion of tissue.

In another embodiment shown in Figure 8, the microcannula lumen is open **30** and a rotating hollow inner member **31** is employed. The distal tip of the inner member may be beveled or sharpened and is extended just slightly beyond the end of the cannula **32** or adjacent to a fenestration along the inner radius. Suction is applied to the cannula and the inner member is rotated **33** to provide a cutting action. As the instrument is advanced, the TM tissues are preferentially pulled **34** toward the microcannula axis allowing the inner member to cut away portions as required. The amount of tissue removal is controlled by extent of advancement and applied suction during the cutting process.

In another embodiment shown in Figure 9, the instrument distal end is comprised of two concentric thin-walled tubes. The outer tube **35** contains a window or fenestration **36** near the distal end and aligned along the inner radius wall of the tube **37** which interfaces the adjacent TM. The inner tube **38** contains an angled slit **39** partially through the tube which creates a sharp pointed flap **40** directed proximally and also aligned with the window in the outer tube and the TM. The flap **40** is pre-bent to allow it to project outward from the tubing **38**, in the direction of the TM and is used as a piercing and cutting member. The outer tube **35** is slidably disposed about the inner tube. During insertion into Schlemm's Canal, the outer tube is positioned such that the window is not adjacent to the flap and the flap is thereby constrained within the outer tube. At the operative target position, the outer tube is advanced so that the window is over the flap, allowing the flap to protrude from the assembly. The instrument is retracted slightly allowing the flap to pierce the TM and then retracted a specified amount such that the full length of the flap has pierced the tissues. The outer tube is then retracted, moving the window proximally, causing the flap to be pulled back and thereby cutting a portion of the TM approximating the geometry of the flap and constraining the excised tissue within the inner tube for disposal. Suction may be used to remove the tissue from the lumen and the procedure repeated as required.

In another embodiment shown in Figure 10, the inner wall of Schlemm's Canal may be removed by the application of controlled abrasion. The inner member **41** may comprise a brush or rasp like tool **42** on the distal end which abrades the tissue

surface. The abrading tool may be used by passing the distal portion of the inner member past the distal tip of the microcannula with concurrent suction, or by positioning it in a window or fenestration **43** in the side of the microcannula **44** near the distal tip **45**. The use of a side opening allows a controlled portion of the tissue tract, such as the TM adjacent to Schlemm's Canal to be treated selectively. Suction may also be applied concurrently through the microcannula lumen to stabilize the tissues during treatment and remove resultant tissue debris.

The microcannula may also be used to deliver a fiber optic for laser ablation of the tissues from within Schlemm's Canal. The microcannula may be used to provide suction to remove the ablative residue and any tissue debris from the site and deliver treatment adjuvants or medications to minimize fibrosis during wound healing.

Examples:

Example 1: A single element microcannula was fabricated with polyimide tubing (MicroLumen, Inc.), 0.0101" (256μ) inner diameter by 0.0141" (358μ) outer diameter. The distal end was sealed with epoxy to create a ball end. The distal portion was curved with a radius of approximately 15mm for a distance of 2 cm. A fenestration approximately 1.2 mm long was cut into the inner wall of the curvature and extending inward to 1/2 the diameter. A Luer fitting was bonded to the proximal end. The microcannula was attached to a collection bottle and then to a vacuum pump generating up to 27 inches of Hg.

An enucleated human eye was prepared for the experiment by inflating the posterior chamber to a pressure of 10mm Hg with phosphate buffered saline (PBS). A scleral flap was surgically excised and Schlemm's Canal unroofed. The microcannula was inserted into Schlemm's Canal and vacuum was applied. Suction was confirmed by observing fluid flow within the microcannula.

Subsequently, the globe was hemisected and the vitreous, ciliary body, lens and iris removed allowing visualization of the TM and Schlemm's Canal from inside. The microcannula was advanced into the Canal to a point approximately 100° from the

surgical site. Suction was applied and the results observed visually under the surgical microscope. Upon application of vacuum, the inner wall of Schlemm's Canal at the fenestration site was seen to be pulled into the lumen of the microcannula. The vacuum level was varied from 1 to 27 inches Hg. In each case the inner wall was observed being pulled into the lumen at approximately 4 inches Hg or greater, while the outer wall was not noticeably deformed. The microcannula was withdrawn under vacuum and upon examination, excised tissue was observed adhered to the distal edge of the fenestration. An open ended microcannula of approximately the same size, without side fenestration, was placed in Schlemm's Canal and the suction experiments repeated at various vacuum levels. The inner wall of the Canal was observed to be preferentially deflected toward the microcannula tip at approximately 4 inches of Hg or greater.

Example 2: A microcannula with an inner member and outer sheath was fabricated. The outer sheath was fabricated with a single fenestration as in Example 1 but with a polyimide tube of 0.0087" inner diameter and 0.0117" outer diameter. The inner member was comprised of polyimide tubing 0.0049" inner diameter by 0.0067" outer diameter and was slidably disposed within the outer member.

An enucleated human eye was prepared as in Example 1. The microcannula was placed with the fenestration toward the inner wall of Schlemm's Canal. The vacuum was applied and tissue was seen being pulled into the lumen. The inner member was then advanced until it stopped against the closed distal tip of the outer member. Upon removal of the microcannula, excised tissue was observed attached to the inner member.

Example 3: A microcannula with an inner member and outer sheath was fabricated. The outer sheath was similar to the outer sheath in Example 2. An inner member designed to abrade the tissues was fabricated comprised of a stainless steel wire 0.006" diameter to which the distal end was roughened using a grinding wheel. The inner member was slidably disposed within the outer sheath.

An enucleated human eye was prepared as in Example 1 with the addition of placing a 27 gauge needle into the cornea, and attaching the needle to a flow meter and reservoir of PBS. The reservoir was raised to provide constant pressure flow into the anterior chamber, and the flow meter used to observe changes in flow.

The microcannula was advanced into Schlemm's Canal. Suction was applied to pull the inner wall of the Canal into the lumen and then the inner member was slid back and forth across the tissues. The microcannula was removed and surgical flap sealed. An increase in aqueous outflow was observed after the procedure.

Example 4: A microcannula was fabricated similar to the outer sheath in Example 2. A cutting element inner member was fabricated from Nitinol wire, incorporating a flat blade situated at the axis of the wire. The cutting element was bonded into the distal lumen of the microcannula with the cutting blade facing proximally and extending into the fenestration area.

Enucleated human eyes were prepared as in Example 3. The microcannula was advanced into Schlemm's Canal. Suction was applied, drawing the inner wall of the Canal into the lumen, and the microcannula was retracted while still under vacuum. Upon removal from the eye, the cutting element was observed to have excised tissue attached. Subsequently aqueous outflow was seen to increase.

Example 5: A signaling means for determining the location of the microcannula was fabricated and incorporated into a microcannula instrument. A single strand plastic optical fiber (POF) (Biogeneral, Inc.) 100 microns in diameter was used with a flat distal tip. The fiber was disposed within an instrument assembly comprising a polyimide microcannula 110 microns ID and 160 microns OD (MicroLumen, Inc.), which was bonded to a needle assembly. The needle assembly consisted of a base section of 18 gauge hypodermic tubing, with a 14 gauge tubing guide tube fabricated so as to slide forward and backward along the 18 gauge tube for a fixed distance of 15 mm. The distal tip of the guide tube was comprised of a 28 gauge tube to direct the microcannula and POF during insertion. The POF was illuminated using a battery powered red laser diode (Digikey Corp.). A second POF was also fabricated

with a distal tip cut at approximately 60° and the jacket removed opposite the bevel. This provided a partially directed illumination spot toward the inner radius.

An ex-vivo human eye was placed in a soft holding cup stage under a stereomicroscope. A surgical flap was created at the limbus and the flap removed to access Schlemm's Canal. The tip of the guide tube was placed at the ostium of the Canal. The microcannula and POF were advanced into the canal with the light source on. The illuminated tip of the fiber was seen through the scleral tissues in the case of the flat tipped POF. Using the beveled POF, illumination could be viewed from within the anterior chamber of the eye depending on the rotation of the microcannula, allowing the appropriate surgical tissues such as the TM to be targeted.

Example 6: In another example, Schlemm's Canal of an eye is cannulated with the microcannula described in example 3. The signaling beacon inner member is used to verify the position of the tip of the microcannula in the desired location of the eye and with proper rotational alignment with respect to the TM. The signaling beacon inner member is removed and a surgical tool inner member to remove tissue from the TM is guided into the lumen of the microcannula and advanced to the distal tip. The inner member also incorporates suction to remove tissue debris. After removal of TM tissue, the surgical tool inner member is exchanged for the signal beacon inner member. The microcannula may be positioned to another area of Schlemm's Canal to repeat the process as needed to increase aqueous outflow to an appropriate level.

While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.

What is claimed is:

1. A microcannula based microsurgical device designed to operate within Schlemm's Canal of the eye and to treat a controlled amount of adjacent ocular tissue comprising:

a flexible tubular sheath having an outer diameter of no more than 500 microns, having proximal and distal ends, and configured to fit within Schlemm's Canal;

a distal assembly for sealed introduction and removal of materials and tools;

wherein suction is provided through the microcannula sheath during treatment of adjacent tissue.

2. A microcannula based microsurgical device as described in claim 1, wherein the tissues to be treated include at least one of the trabecular meshwork and juxtacanalicular tissues adjacent to the inner radius of Schlemm's Canal.

3. A microcannula based microsurgical device as in claim 1, wherein the microcannula has one or more openings directed toward an inner radius thereof.

4. A microcannula based microsurgical device as described in claim 1, wherein the suction level is at least 4 inches of Hg.

5. A microcannula based microsurgical device as described in claim 1, further comprising at least one inflatable or expandable member to provide stabilization of the microsurgical device and surrounding tissues.

6. A microcannula based microsurgical device as described in claim 1, further comprising at least one inflatable or expandable member to provide sealing of Schlemm's Canal during treatment.

7. A microcannula based microsurgical device as described in claim 1, wherein the microcannula has a length of at least 15 mm.

8. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath is curved in the range of 10–15 mm diameter.

9. A microcannula based microsurgical device as described in claim 1, further comprising a plurality of markers set at regular intervals along the tubular sheath such that each marker is spaced from adjacent markers by a fixed distance along the sheath to provide depth measurement.

10. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath additionally comprises materials to enhance observation of the device positioning under image guidance.

11. A microcannula based microsurgical device as described in claim 1, wherein the tubular sheath comprises a polyimide or a fluoropolymer.

12. A microcannula based microsurgical device as described in claim 1, wherein the microcannula additionally comprises an inner member with a proximal end and a distal tip;

and wherein the sheath and inner member are sized such that the inner member fits slidably within the sheath and the distal tip of the inner member acts to treat adjacent tissue through one or more openings in the distal end of the microcannula.

13. The microcannula based microsurgical device of claim 12, wherein the inner member acts to remove tissues from an inner wall of Schlemm's Canal.

14. A microcannula based microsurgical device designed to operate within Schlemm's Canal of the eye and to remove a controlled amount of adjacent ocular tissue comprising,

a flexible tubular sheath having an outer diameter of no more than 500 microns, having proximal and distal ends, and configured to fit within Schlemm's Canal;

a distal assembly for sealed introduction and removal of materials and tools;

an inner member with a proximal end and a distal tip sized such that the inner member fits slidably within the sheath,

wherein the sheath has one or more openings directed toward an inner radius at the distal end,

and the sheath and inner member act to remove adjacent tissue through the one or more openings in the distal end of the sheath.

15. A microcannula based microsurgical device as in claim 14, further comprising a lumen extending through the tubular sheath and wherein suction is provided through the lumen during removal of adjacent tissue.

16. A microcannula based microsurgical device as described in claim 14, wherein the distal tip of the inner member is shaped for tissue dissection, cutting, ablation or removal.

17. A microcannula based microsurgical device as described in claim 14, wherein suction is used to position the adjacent tissue to be removed into a lumen of the tubular sheath.

18. A microcannula based microsurgical device as described in claim 17, wherein the inner member performs removal of tissue within the lumen of the tubular sheath.

19. A microcannula based microsurgical device as described in claim 14, further comprising a plurality of markers set at regular intervals along the tubular sheath such that each marker is spaced from adjacent markers by a fixed distance along the sheath to provide depth measurement.

20. A microcannula based microsurgical device as described in claim 14, wherein, the tubular sheath additionally comprises materials to enhance observation of the device positioning under image guidance.

21. A microcannula based microsurgical device as described in claim 14, wherein the tubular sheath comprises a polyimide or a fluoropolymer.

22. A microcannula based microsurgical device as described in claim 14, wherein the microcannula has a length of at least 15 mm.

23. A microcannula based microsurgical device as described in claim 14, wherein the flexible tubular sheath is curved in the range of 10–15 mm diameter.

24. A microcannula based microsurgical device as described in claim 14, wherein the inner member is curved in the range of 10–15 mm diameter.

25. A microcannula based microsurgical device as described in claim 14, wherein the outer member is formed of a multi-lumen tube.

26. A microcannula based microsurgical device as described in claim 14, wherein the inner member comprises steel, nickel titanium alloy or tungsten.

27. A microcannula based microsurgical device as described in claim 14, wherein the inner member comprises an optical fiber.

28. A microcannula based microsurgical device as described in claim 27, wherein illumination from the optical fiber is directed from the distal end of the microcannula at an angle of 45 to 135 degrees from an axis of the microcannula to be coincident with an area of tissue removal.

29. A microcannula based microsurgical device as described in claim 14 wherein the tubular sheath comprises at least one inflatable or expandable member to provide stabilization of the device and surrounding tissues.

30. A method for treating Schlemm's Canal of an eye comprising inserting a flexible microcannula based microsurgical device with an outer diameter of no more than 500 microns into Schlemm's Canal and applying suction at a level of at least 4 inches of Hg.

31. A method for treating Schlemm's Canal of the eye as described in claim 30 wherein the microcannula comprises one or more openings directed toward an inner radius thereof to treat specific tissues adjacent to Schlemm's Canal.

32. A method for treating Schlemm's Canal of the eye as described in claim 30 wherein the microcannula additionally comprises an inner member that acts to remove tissue.

33. A method for treating Schlemm's Canal of an eye comprising the steps of:

(a) inserting a flexible microcannula with an outer diameter of no more than 350 microns into Schlemm's Canal;

(b) injecting a flowable material to expand at least a segment of Schlemm's Canal to facilitate microcannula access;

(c) removing the microcannula;

(d) inserting a microcannula based microsurgical device with an outer diameter of no more than 500 microns into Schlemm's Canal;

(e) and effecting a modification in the tissues adjacent to Schlemm's Canal to increase aqueous outflow.

34. The method of treating Schlemm's Canal of the eye of claim 33 wherein step (e) comprises removal of tissues from the inner wall of Schlemm's Canal.

35. The method of treating Schlemm's Canal of the eye of claim 33 wherein step (e) comprises placing of an implant at least partially residing in Schlemm's Canal.

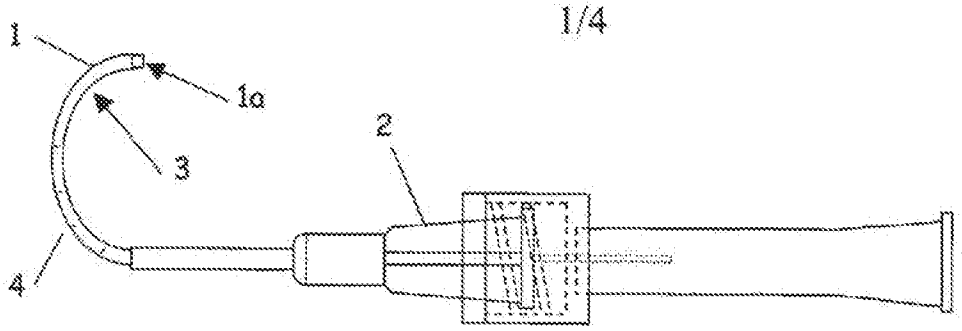


Fig. 1

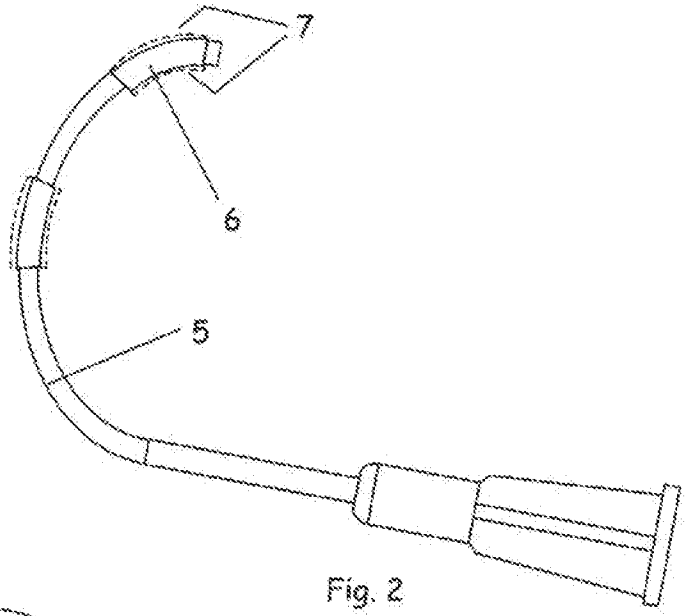


Fig. 2

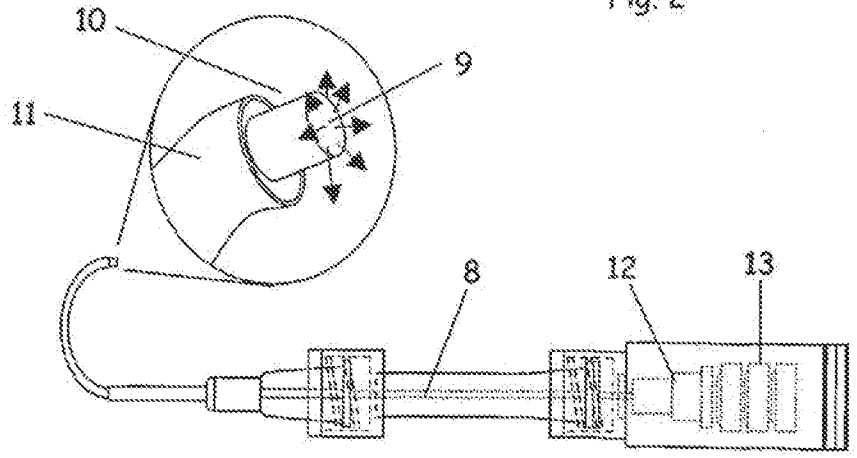


Fig. 3

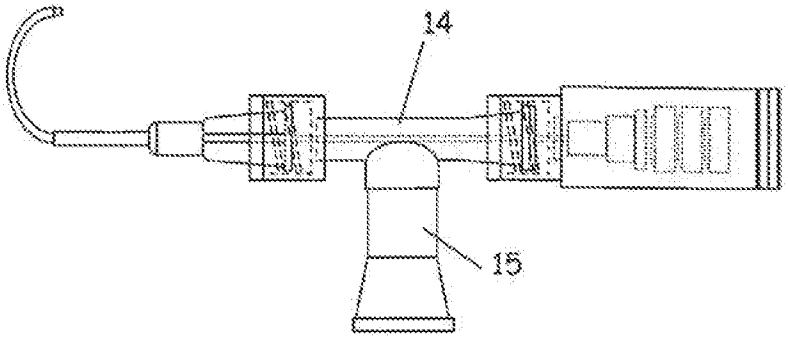


Fig. 4

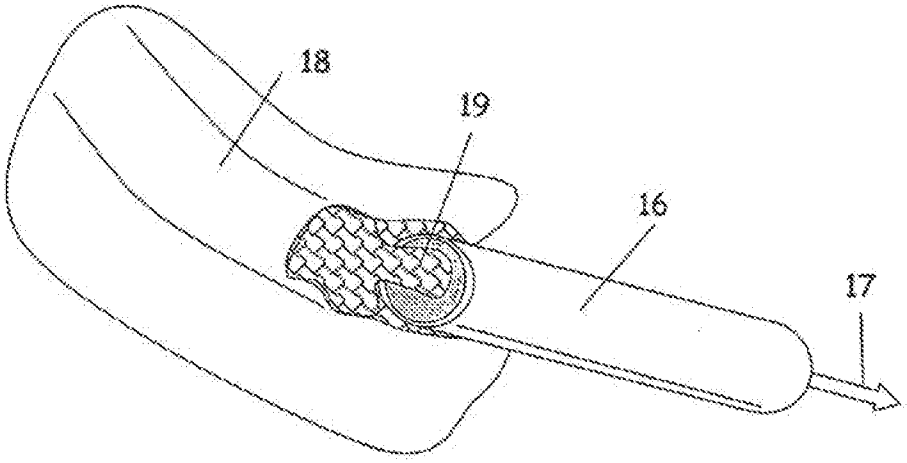


Fig. 5

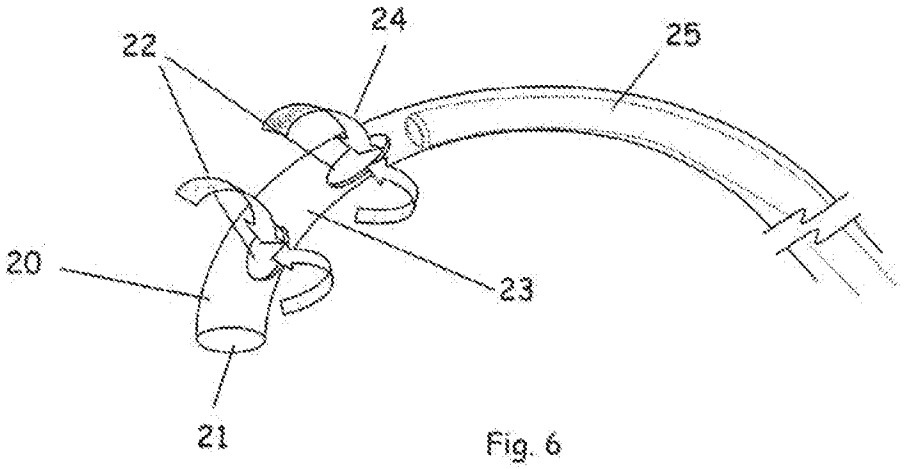


Fig. 6

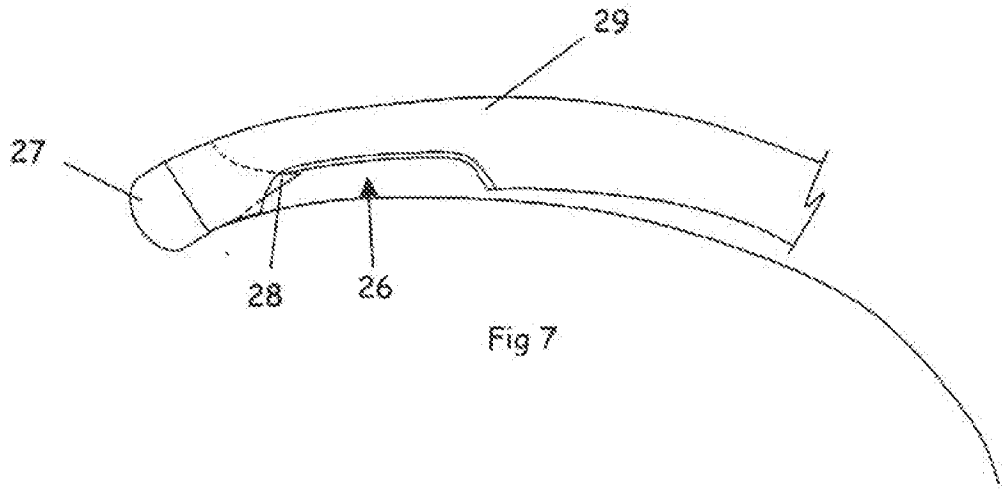


Fig 7

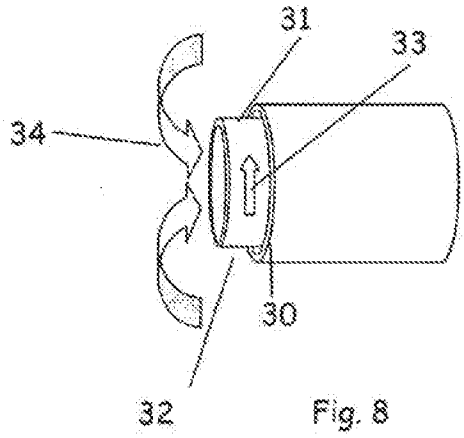


Fig. 8

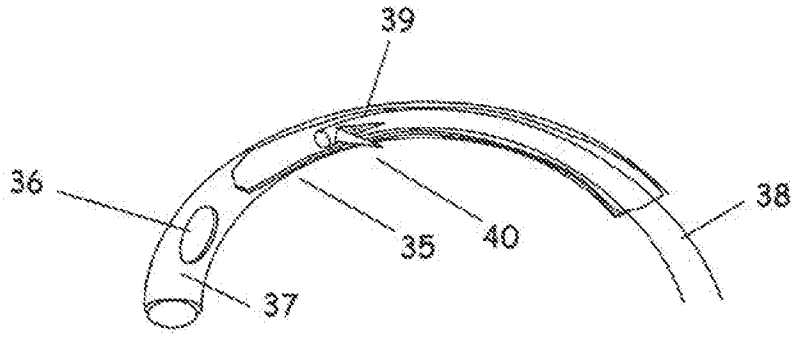


Fig. 9

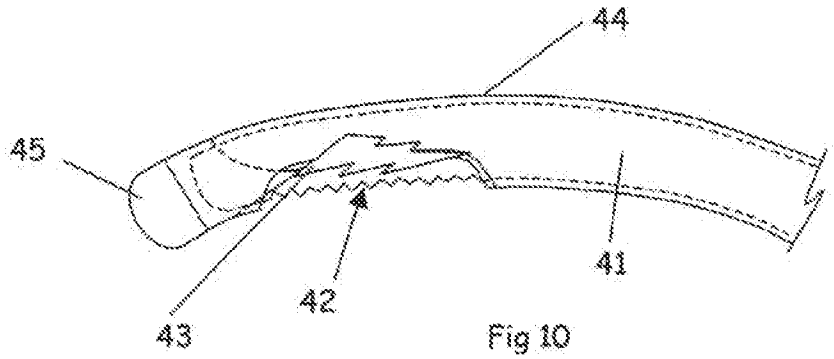


Fig 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/011783

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/053873 A1 (MAAG WERNER ET AL) 20 December 2001 (2001-12-20)	1,14,16
A	page 1, paragraph 8 page 3, paragraph 45 -page 3, line 46 page 4, paragraph 55 -page 4, paragraph 60 page 5, paragraph 71; claims 1,35; figures 1,2,3A3D,4A	3-6,12, 13,17, 18,25, 27,28
Y	US 6 142 990 A (BURK REINHARD O W) 7 November 2000 (2000-11-07) cited in the application	1,14
A	column 4, line 19 -column 4, line 44; claims 8,12; figure 4	3,7,8, 12,16

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 September 2004	17/09/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Merté, B

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/011783

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 501 274 A (SKJAERPE FINN) 26 February 1985 (1985-02-26) cited in the application	1,14,16
A	column 3, line 51 -column 3, line 56; claim 1; figure 3	10,14, 20,26
A	US 5 891 084 A (LEE VINCENT W) 6 April 1999 (1999-04-06) column 6, line 63 -column 7, line 11 column 9, line 15 -column 9, line 43	1,3,5,6, 12,15,29
P,X	WO 03/045290 A (CONSTON STANLEY R ;YAMAMOTO RONALD K (US); ISCIENCE CORP (US)) 5 June 2003 (2003-06-05)	1,7,8, 10-12
A	page 5, line 4 -page 5, line 10; claims 1,2,5-9,11,15,20; figures 3,7; example 3	13-16, 18,20-28

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/011783

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 30-35
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery. The methods comprise the invasive step of "inserting a cannula into a Schlemm's canal" which has to be carried out by an ophthalmic surgeon.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/011783

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001053873 A1	20-12-2001	DE 19956515 A1	21-06-2001
		DE 19956517 A1	21-06-2001
		AU 1376901 A	04-06-2001
		CA 2370369 A1	31-05-2001
		WO 0137767 A1	31-05-2001
		JP 2003514616 T	22-04-2003
		EP 1152722 A1	14-11-2001
		ZA 200105509 A	07-03-2002
US 6142990 A	07-11-2000	DE 19705815 A1	20-08-1998
		DE 59811404 D1	24-06-2004
		EP 0858788 A1	19-08-1998
		JP 10248869 A	22-09-1998
US 4501274 A	26-02-1985	NO 810849 A	13-09-1982
		DE 3264617 D1	14-08-1985
		EP 0073803 A1	16-03-1983
		JP 58500237 T	17-02-1983
		WO 8203168 A1	30-09-1982
US 5891084 A	06-04-1999	NONE	
WO 03045290 A	05-06-2003	CA 2466835 A1	05-06-2003
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(71) Applicant *(for all designated States except US)*: **ALCON RESEARCH, LTD.** [US/US]; 6201 South Freeway, Fort Worth, TX 76134 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LIND, Casey** [US/US]; 7 Filmridge, Irvine, CA 92603 (US). **HUCULAK, John C.** [US/US]; 25551 Aria Drive, Mission Viejo, CA 92692 (US).

(74) Agents: **BASSINGER, Kenneth, D.** et al.; 6201 South Freeway, Tb4-8, Fort Worth, TX 76134 (US).

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[Continued on next page]

(54) Title: SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

(57) Abstract: A small gauge mechanical tissue cutter/aspirator probe useful for removing the trabecular meshwork of a human eye has a generally cylindrical outer cannula, an inner cannula that reciprocates in the outer cannula, a port located near or at the distal end of the outer cannula on a side or tip of the outer cannula, and a guide with a distal surface located on the distal end of the outer cannula. A distance between the distal surface of the guide and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork.

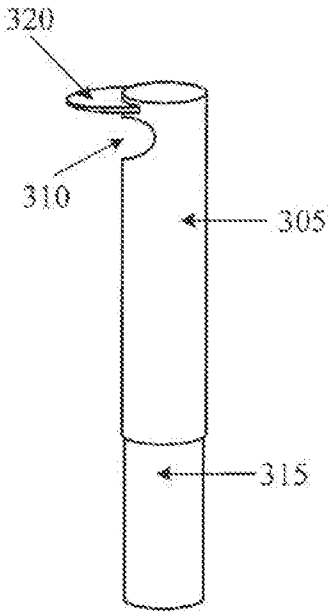

Fig. 3

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SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

This application is a continuation-in-part of US 12/120,867 filed May 15, 2008.

BACKGROUND OF THE INVENTION

The present invention relates to glaucoma surgery and more particularly to a method and device for performing glaucoma surgery using a small gauge mechanical tissue cutter/aspirator probe with a retractable pick.

Glaucoma, a group of eye diseases affecting the retina and optic nerve, is one of the leading causes of blindness worldwide. Glaucoma results when the intraocular pressure (IOP) increases to pressures above normal for prolonged periods of time. IOP can increase due to an imbalance of the production of aqueous humor and the drainage of the aqueous humor. Left untreated, an elevated IOP causes irreversible damage the optic nerve and retinal fibers resulting in a progressive, permanent loss of vision.

The eye's ciliary body epithelium constantly produces aqueous humor, the clear fluid that fills the anterior chamber of the eye (the space between the cornea and iris). The aqueous humor flows out of the anterior chamber through the uveoscleral pathways, a complex drainage system. The delicate balance between the production and drainage of aqueous humor determines the eye's IOP.

Open angle (also called chronic open angle or primary open angle) is the most common type of glaucoma. With this type, even though the anterior structures of the eye appear normal, aqueous fluid builds within the anterior chamber, causing the IOP to become elevated. Left untreated, this may result in permanent damage of the optic nerve and retina. Eye drops are generally prescribed to lower the eye pressure. In some cases, surgery is performed if the IOP cannot be adequately controlled with medical therapy.

Only about 10% of the population suffers from acute angle closure glaucoma. Acute angle closure occurs because of an abnormality of the structures in the front of the eye. In most of these cases, the space between the iris and cornea is more narrow than normal, leaving a smaller channel for the aqueous to pass through. If the flow of

aqueous becomes completely blocked, the IOP rises sharply, causing a sudden angle closure attack.

Secondary glaucoma occurs as a result of another disease or problem within the eye such as: inflammation, trauma, previous surgery, diabetes, tumor, and certain medications. For this type, both the glaucoma and the underlying problem must be treated.

Figure 1 is a diagram of the front portion of an eye that helps to explain the processes of glaucoma. In Figure 1, representations of the lens 110, cornea 120, iris 130, ciliary bodies 140, trabecular meshwork 150, and Schlemm's canal 160 are pictured. Anatomically, the anterior chamber of the eye includes the structures that cause glaucoma. Aqueous fluid is produced by the ciliary bodies 140 that lie beneath the iris 130 and adjacent to the lens 110 in the anterior chamber. This aqueous humor washes over the lens 110 and iris 130 and flows to the drainage system located in the angle of the anterior chamber. The angle of the anterior chamber, which extends circumferentially around the eye, contains structures that allow the aqueous humor to drain. The first structure, and the one most commonly implicated in glaucoma, is the trabecular meshwork 150. The trabecular meshwork 150 extends circumferentially around the anterior chamber in the angle. The trabecular meshwork 150 seems to act as a filter, limiting the outflow of aqueous humor and providing a back pressure producing the IOP. Schlemm's canal 160 is located beyond the trabecular meshwork 150. Schlemm's canal 160 has collector channels that allow aqueous humor to flow out of the anterior chamber. The two arrows in the anterior chamber of Figure 1 show the flow of aqueous humor from the ciliary bodies 140, over the lens 110, over the iris 130, through the trabecular meshwork 150, and into Schlemm's canal 160 and its collector channels.

If the trabecular meshwork becomes malformed or malfunctions, the flow of aqueous humor out of the anterior chamber can be restricted resulting in an increased IOP. The trabecular meshwork may become clogged or inflamed resulting in a restriction on aqueous humor flow. The trabecular meshwork, thus, sometimes blocks the normal flow of aqueous humor into Schlemm's canal and its collector channels.

Surgical intervention is sometimes indicated for such a blockage. Numerous surgical procedures have been developed to either remove or bypass the trabecular meshwork. The trabecular meshwork can be surgically removed by cutting, ablation, or by means of a laser. Several stents or conduits are available that can be implanted

through the trabecular meshwork in order to restore a pathway for aqueous humor flow. Each of these surgical procedures, however, has drawbacks.

One approach that does not have the drawbacks of existing procedures involves using a small gauge mechanical tissue cutter/aspirator probe to remove trabecular meshwork tissue. A small gauge cutting device can be guided into Schlemm's canal and moved in a forward motion following the curvature of the trabecular meshwork. The motion causes the trabecular meshwork to be fed into the cutting port of the cutter, cutting and removing the trabecular meshwork blocking the outflow of the aqueous humor.

SUMMARY OF THE INVENTION

In one embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a retractable pick. A distance between the distal end of the outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula with a smooth distal end, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a distance between the distal end of the first outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a method of cutting and removing trabecular meshwork from a human eye, the method comprising: providing a small gauge mechanical tissue cutter/aspirator probe with a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, such that

the location of the port on the first outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, such that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and aspirating the cut trabecular meshwork from the eye.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a diagram of the front portion of an eye.

Figures 2A and 2B are perspective views of a small gauge mechanical tissue cutter/aspirator probe (traditional vitrectomy probe).

Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figure 4 is a perspective view of a tapered small mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 5A and 5B are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 6A-6C are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts.

Figures 2A and 2B are perspective views of a traditional mechanical tissue cutter/aspirator probe (vitrectomy probe). In a typical mechanical tissue cutter/aspirator probe, an outer cannula 205 includes port 210. An inner cannula 215 reciprocates in cannula 205. One end of inner cannula 215 is configured so that it can cut tissue when as it enters port 210. As shown in Figures 2A and 2B, inner cannula 215 moves up and down in outer cannula 205 to produce a cutting action. Tissue enters port 210 when the mechanical tissue cutter/aspirator probe is in the position shown in Figure 2A. The tissue is cut as inner cannula 215 moves upward closing off port 210 as shown in Figure 2B. Cut tissue is aspirated through the inner cannula and away from the cutting location. Outer cannula 205 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer cannula 205, allows the top surface of outer cannula 205 to remain smooth.

Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. In the embodiment of Figure 3, an outer cannula 305 includes port 310. An inner cannula 315 reciprocates in outer cannula 305. One end of inner cannula 315 is configured so that it can cut tissue when as it enters port 310. Inner cannula 315 moves up and down in outer cannula 305 to produce a cutting action. Cut tissue can be aspirated through inner cannula 315 and removed from the cutting location. Outer cannula 305 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer

cannula 305, allows the top surface of outer cannula 305 to remain smooth. A retractable pick 320 is located on a distal end of outer cannula 305.

Retractable pick 320 is adapted to fit into Schlemm's canal so that mechanical tissue cutter/aspirator probe cutting action can be used to cut and remove the trabecular meshwork (through aspiration provided through port 310). Retractable pick 320 is a short protrusion that extends outward from the distal tip of outer cannula 305 in the direction of port 310. In one embodiment of the present invention, retractable pick 320 has a sharp end that can be used to pierce the trabecular meshwork so that retractable pick 320 can be placed in Schlemm's canal. In another embodiment of the present invention, retractable pick 320 is optional. While retractable pick 320 facilitates entry into Schlemm's canal, once port 310 is located on the trabecular meshwork, retractable pick 320 is largely unnecessary. As such, retractable pick 320 is retracted into outer cannula 305. Cutting action is provided at port 310 which is located along the trabecular meshwork (as best seen below). The distance between port 310 and the distal end of outer cannula 320 determines the location of port 310 in relation to the back wall of Schlemm's canal. This distance is such that port 310 is located at the trabecular meshwork (preferably the distance from the distal end of outer cannula 305 to the center of port 310 is equal to the distance between the trabecular meshwork and the back wall of Schlemm's canal). Locating port 310 at the trabecular meshwork ensures effective removal of it.

Figure 4 is a perspective view of a tapered small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. In this embodiment, the distal end of outer cannula 305 is tapered. While taper 325 is depicted, any type of taper can be employed. Due to the size of Schlemm's canal, it is preferable to have the distal end of outer cannula measure about 0.25 to 0.36 mm diameter (the approximate diameter of Schlemm's canal is about 0.3 mm). In one embodiment, a 27 gauge cannula is used for outer cannula 305. In other embodiments, a tapered 27 gauge or larger cannula is used. Such a cannula is tapered in some fashion so that its distal end measures about 0.25 to 0.36 mm.

Figures 5A and 5B are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figure 5A shows retractable pick 520 in an extended position. Figure 5B shows the retractable pick 520 in a retracted position. In the embodiment of Figure 5A, retractable pick 520 is located at the distal end of cannula 305. Retractable pick 520 may have a sharp tip 525 to pierce the trabecular

meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 520 (or the distal end of cannula 305, if retractable pick 520 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In this manner, as outer cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 520 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

When retracted, retractable pick 520 is located inside of cannula 305. When extended, retractable pick 520 protrudes through an opening on the outer surface of cannula 305. In one embodiment of the present invention, retractable pick 520 is located between inner cannula 315 and outer cannula 305. Retractable pick 520 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer cannula 305. In this case, retractable pick 520 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 520 travels in a passageway formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 520 may be made of any resilient, durable substance. In one embodiment of the present invention, retractable pick 520 is made of a nitinol wire with a sharpened (or beveled) distal tip. 525. In this case, the sharp tip 525, when extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 525 is then retracted before the outer cannula is placed in Schlemm's canal.

Figures 6A, 6B, and 6C are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 6A and 6B show retractable pick 620 in an extended position. Figure 6C shows the retractable pick 620 in a retracted position. In the embodiment of Figure 6A, retractable pick 620 is located at the distal end of cannula 305. Retractable pick 620 may have a sharp tip 625 to pierce the trabecular meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 620 (or the distal end of cannula 305, if retractable pick 620 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In this manner, as outer cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 620 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

In Figure 6B, retractable pick 620 has a curved profile when in an extended position. In this manner, retractable pick 620 can be oriented with respect to the distal end of cannula 305. In Figure 6A, retractable pick extends outward from the distal end of cannula 305. In Figure 6B, retractable pick extends at an angle from the distal end of cannula 305.

When retracted, retractable pick 620 is located inside of cannula 305. When extended, retractable pick 620 protrudes through an opening on the distal end of cannula 305. In one embodiment of the present invention, retractable pick 620 is located between inner cannula 315 and outer cannula 305. Retractable pick 620 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer cannula 305. In this case, retractable pick 620 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 620 travels in a passageway formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 620 may be made of any resilient, durable substance. In one embodiment of the present invention, retractable pick 620 is made of a nitinol wire with a sharpened (or beveled) distal tip. 625. In this case, the sharp tip 625, when extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 625 is then retracted before the outer cannula is placed in Schlemm's canal. As is commonly known, a nitinol wire retains its shape so as to facilitate the retractable pick arrangement pf Figure 6B.

Regardless of what type of pick is used (if any at all), the distance between the back wall of Schlemm's canal to the trabecular meshwork is about 0.3 mm. The approximate thickness of the trabecular meshwork is 0.1 mm. Accordingly, in one embodiment of the present invention, port 310 has an opening that is greater than 0.1 mm, and the distance from port 310 to the distal tip of cannula 305 is about 0.3 mm. In other words, port 310 is located such that it can effectively cut and remove the trabecular meshwork.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 7 and 8 depict two different embodiments of retractable picks, such as retractable picks 320 or 520. In Figure 7, retractable pick 720 is generally egg shaped with a leading edge 705 and a trailing edge 710. Leading edge 705 extends outward from an outer cannula and is used to pierce the trabecular

meshwork. Trailing edge 710 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 7, leading edge is generally curved and may be sharp or blunt. If leading edge 705 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork. In Figure 8, retractable pick 820 has a point at leading edge 805. Leading edge 805 extends outward from an outer cannula and is used to pierce the trabecular meshwork. Trailing edge 810 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 8, leading edge is pointed and may be sharp or blunt. If leading edge 805 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork.

Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery. In Figure 9, outer cannula 305 is inserted through a small incision in the cornea 120. The distal end of cannula 305 (the end that has port 310) is advanced through the angle to the trabecular meshwork 150. The retractable pick is extended so that an opening can be made in the trabecular meshwork. The retractable pick is then retracted so as to avoid damaging a wall of Schlemm's canal 160. The distal end of cannula 305 is then advanced through the opening in the trabecular meshwork 150 and into Schlemm's canal 160. In this position, port 310 is located at the trabecular meshwork 150 and is ready to be cut and removed from the eye.

Figure 10 is an exploded view of the location of the distal end of outer cannula 305 during the removal of the trabecular meshwork 150 (note that in this position, the retractable pick is in a retracted position). In this position, port 310 is located at the trabecular meshwork 150. Outer cannula 305 is then advanced in the direction of port 310 to cut and remove the trabecular meshwork 150. Outer cannula 305 is advanced through an arc in one direction, port 310 is then rotated 180 degrees, and outer cannula 305 is then advanced in an arc in the other direction. In this manner, the distal end of cannula 305 (and port 310) is moved in an arc around the circumference of the angle to remove a substantial portion of the trabecular meshwork through a single corneal incision. If desired, a second corneal incision opposite the first corneal incision can be made so that the outer cannula 305 can be swept through a second arc of the angle. In this manner, either through one or two corneal incisions, a significant portion of the trabecular meshwork can be cut and removed by the mechanical tissue cutter/aspirator probe.

From the above, it may be appreciated that the present invention provides a system and methods for performing glaucoma surgery with a small gauge mechanical tissue cutter/aspirator probe. The present invention provides a small gauge mechanical tissue cutter/aspirator probe with an optional guide that can be advanced into Schlemm's canal to cut and aspirate the trabecular meshwork. Methods of using the probe are also disclosed. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A mechanical tissue cutter/aspirator probe comprising:

a generally cylindrical outer cannula, the outer cannula having a distal end that defines a generally planar surface;

an inner cannula that reciprocates in the outer cannula;

a port located near a distal end of the outer cannula;

a retractable pick located on the distal end of the outer cannula;

wherein a distance between the generally planar surface of the distal end of the outer cannula and the port is approximately equal to the distance between a back wall of Schlemm's canal and a trabecular meshwork in a human eye.

2. The probe of claim 1 wherein the retractable pick further comprises a sharp edge for piercing the trabecular meshwork.

3. The probe of claim 1wherein the retractable pick is located between the inner cannula and the outer cannula.

4. The probe of claim 1wherein the retractable pick is located between the outer cannula and a sleeve.

5. The probe of claim 1 wherein the outer cannula is tapered.

6. The probe of claim 1 wherein the outer cannula has a diameter between about 0.25 and 0.36 millimeters.

7. The probe of claim 1 wherein the distance between the generally planar surface of the distal end of the outer cannula and the port is approximately 0.3 millimeters.

8. The probe of claim 1 wherein cut tissue is aspirated through the port.

9. The probe of claim 1 wherein the retractable pick is made of nitinol.

10. A mechanical tissue cutter/aspirator probe comprising:

a generally cylindrical outer cannula with a generally smooth distal end;

an inner cannula that reciprocates in the outer cannula;

a port located near a distal end of the outer cannula on a side or end of the outer cannula;

wherein a distance between the distal end of the outer cannula and the port is approximately equal to the distance between a back wall of Schlemm's canal and a trabecular meshwork in a human eye.

11. The probe of claim 10 wherein the distal end of the outer cannula is configured to rest against the outer wall of Schlemm's canal.

12. The probe of claim 10 wherein the outer cannula is tapered.

13. The probe of claim 10 wherein the distal end of the outer cannula has a diameter between about 0.25 and 0.36 millimeters.

14. The probe of claim 10 wherein the distance between the distal end of the outer cannula and the port is approximately 0.3 millimeters.

15. The probe of claim 10 wherein cut tissue is aspirated through the port.

16. A method of cutting and removing trabecular meshwork from a human eye, the method comprising:

providing a mechanical tissue cutter/aspirator probe with a generally cylindrical outer cannula, an inner cannula that reciprocates within the outer cannula, and a port located near a distal end of the outer cannula on a side of the outer cannula, such that the location of the port on the outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye;

actuating the inner cannula so that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and

aspirating the cut trabecular meshwork from the eye.

17. The method of claim 16 wherein aspirating the cut trabecular meshwork from the eye further comprises aspirating the cut trabecular meshwork through the port and through the inner cannula.

18. The method of claim 16 wherein the mechanical tissue cutter/aspirator probe is provided with a retractable pick located on the distal end of the outer cannula.

19. The method of claim 18 further comprising:

extending the retractable pick so that an opening can be formed in the trabecular meshwork;

retracting the retractable pick; and

inserting the distal end of the outer cannula in Schlemm's canal.

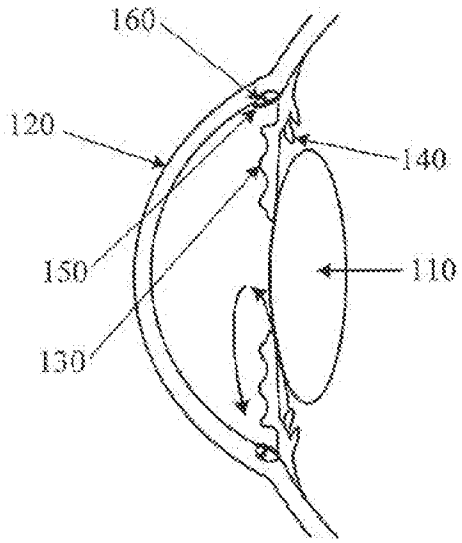

Fig. 1

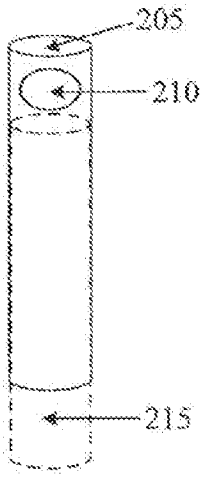

Fig. 2A
(Prior Art)

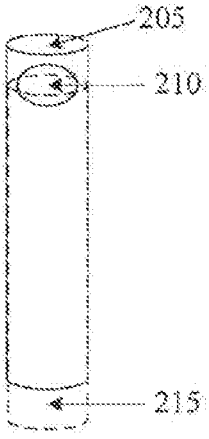

Fig. 2B
(Prior Art)

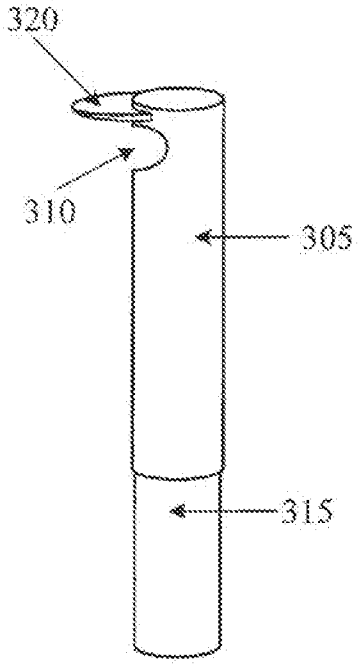

Fig. 3

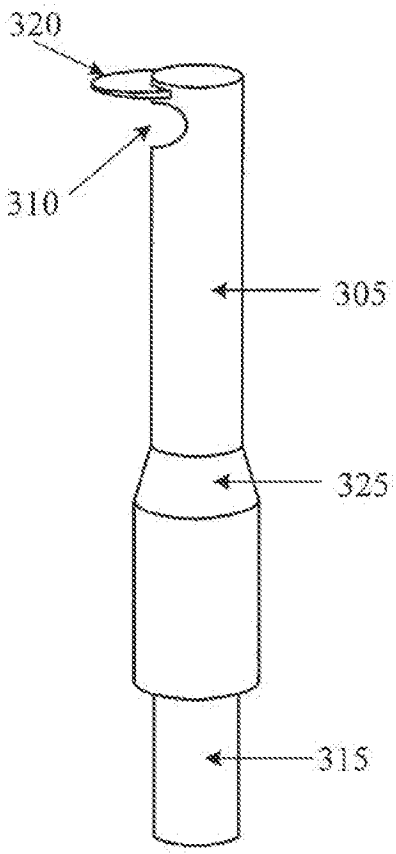

Fig. 4

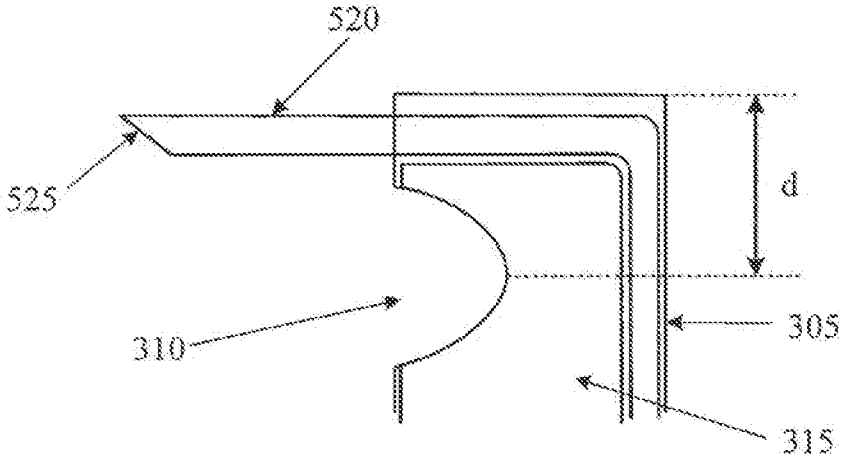

Fig. 5A

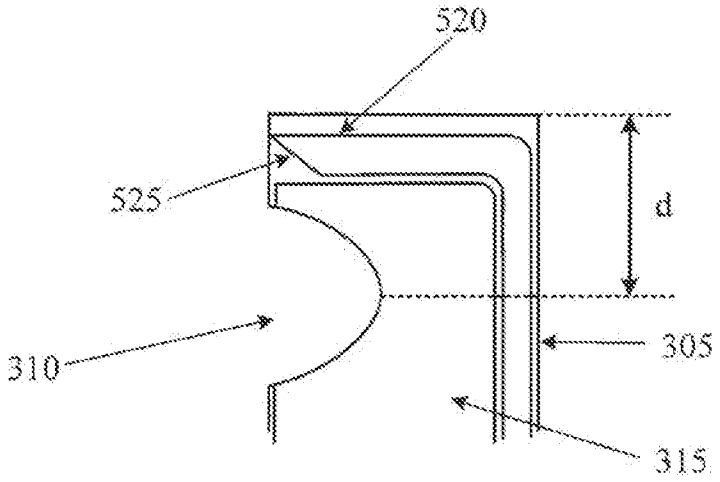

Fig. 5B

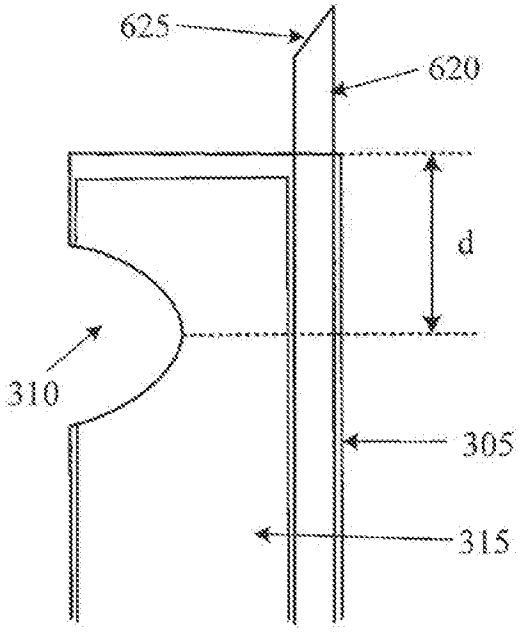

Fig. 6A

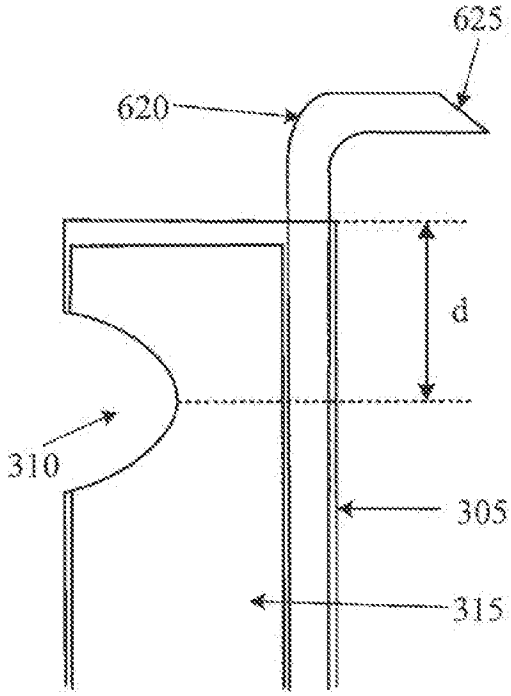

Fig. 6B

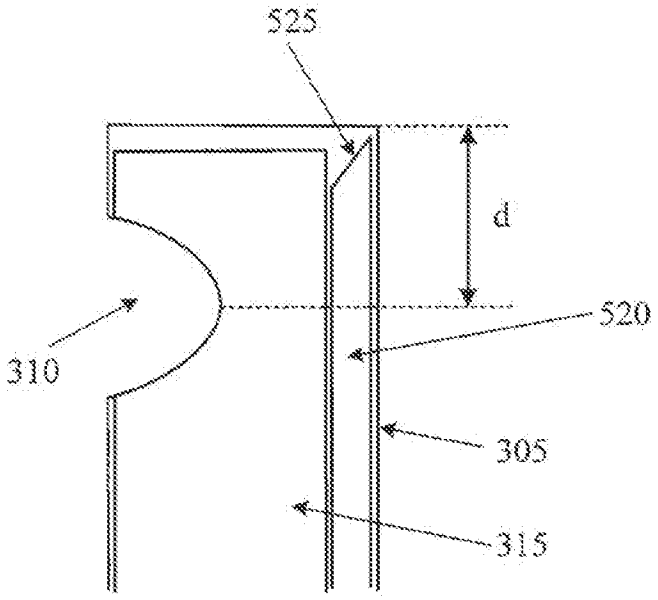

Fig. 6C

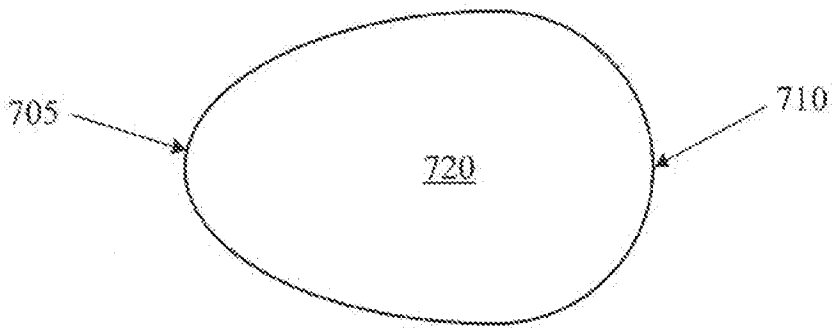

Fig. 7

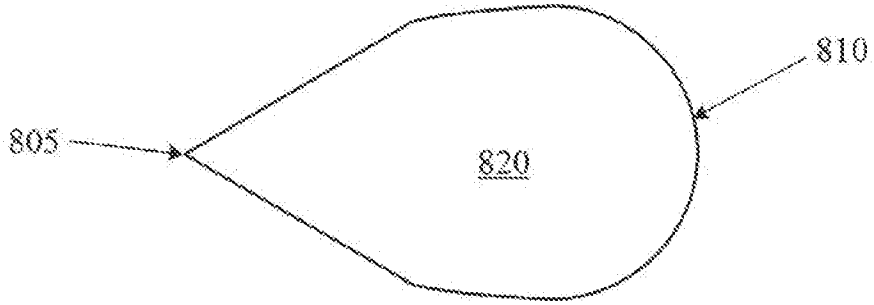

Fig. 8

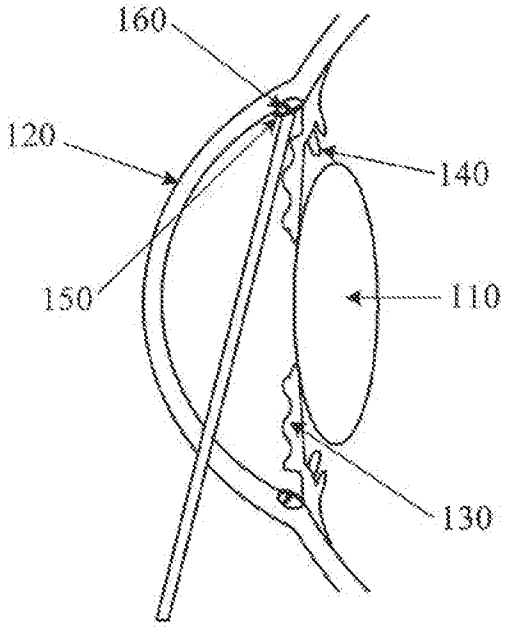

Fig. 9

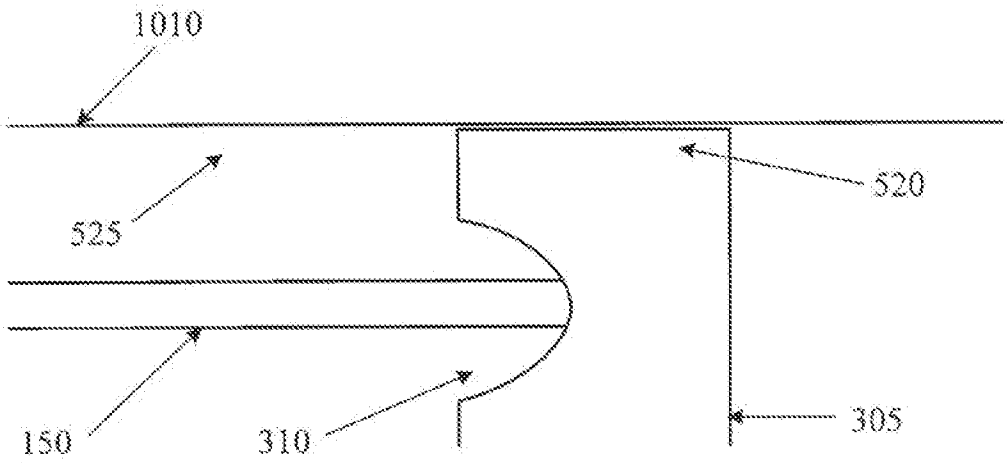

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/043420

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007 A61B17/32 A61B17/34
ADD. A61B17/30 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 527 332 A (CLEMENT THOMAS P [US]) 18 June 1996 (1996-06-18)	10,11,15
Y		12-14
A		1
	abstract; figures 2,3 column 7, line 17 - line 19 column 6, line 11 - line 16	
X	US 4 530 359 A (HELFGOTT MAXWELL A [US] ET AL) 23 July 1985 (1985-07-23) claim 18; figures 6,7	1-4,8
Y	column 3, line 63 - column 3, line 14 column 6, line 37 - line 42 column 11, line 48 - line 58 column 12, line 37 - line 43	5-7,9
	-/--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 2009	27/07/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kajzar, Anna

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 733 297 A (WANG CARL C T [US]) 31 March 1998 (1998-03-31) column 2, line 21 - line 26; figure 3	7,14
Y	WO 03/045290 A (ISCIENCE CORP [US]; CONSTON STANLEY R [US]; YAMAMOTO RONALD K [US]) 5 June 2003 (2003-06-05) page 12, line 25 - line 28	9
Y	WO 2007/121485 A (CASCADE OPHTHALMICS [US]; PARDO GEOFFREY [US]; CONNORS KEVIN S [US]; C) 25 October 2007 (2007-10-25) paragraph [0142]	6,13
Y	EP 0 537 116 A (CAPONI MAURO [IT]) 14 April 1993 (1993-04-14) figure 1	5,12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/043420

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/043420

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5527332	A	18-06-1996	NONE		
US 4530359	A	23-07-1985	CA	1233718 A1	08-03-1988
US 5733297	A	31-03-1998	NONE		
WO 03045290	A	05-06-2003	AU	2002365403 A1	10-06-2003
			CA	2466835 A1	05-06-2003
			EP	1455698 A1	15-09-2004
			JP	2005521435 T	21-07-2005
			US	2006149194 A1	06-07-2006
WO 2007121485	A	25-10-2007	AU	2007237905 A1	25-10-2007
			CA	2649721 A1	25-10-2007
			EP	2012654 A2	14-01-2009
			US	2008027304 A1	31-01-2008
EP 0537116	A	14-04-1993	IT	1249714 B	09-03-1995

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer:
(11) Publication number: **EP 1 455 698 A0**
(11) Numéro de publication:

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International application published by the World Intellectual Property Organisation under number:

WO 03/045290 (art. 158 of the EPC).

Demande internationale publiée par l'Organisation Mondiale de la Propriété sous le numéro:

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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5 June 2003 (05.06.2003)

PCT

(10) International Publication Number
WO 03/045290 A1

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21 November 2002 (21.11.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/331,970 21 November 2001 (21.11.2001) US

(71) Applicant *(for all designated States except US)*: **ISCIENCE CORPORATION** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CONSTON, Stanley, R.** [US/US]; 148 Rogers Avenue, San Carlos, CA 94070 (US). **YAMAMOTO, Ronald, K.** [US/US]; 1321 Waller Street, San Francisco, CA 94117 (US).

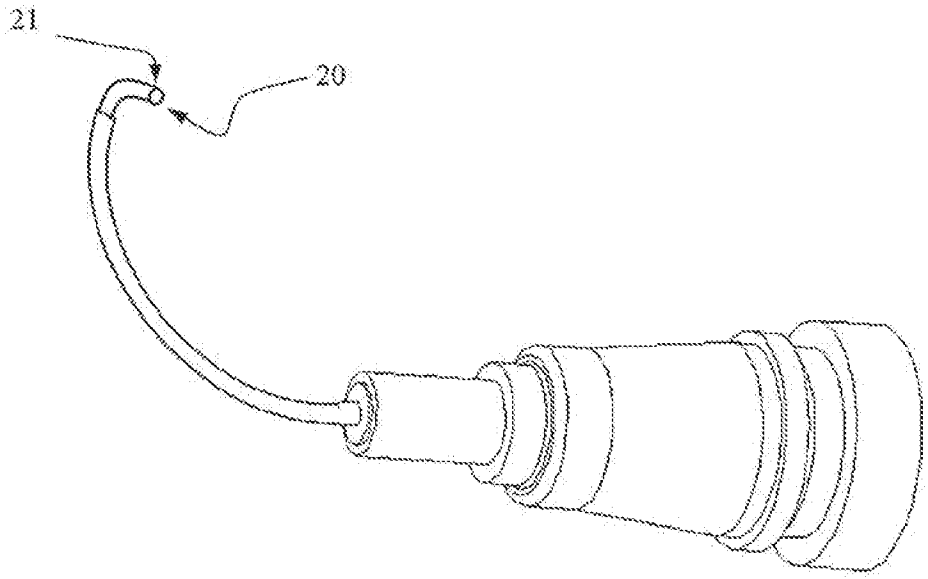
(74) Agents: **SMITH, Gregory, Scott** et al., Gregory Smith & Associates, 3900 Newpark Mall Road, Suite 317, Newark, CA 94560 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,

[Continued on next page]

(54) Title: OPHTHALMIC MICROSURGICAL SYSTEM



(57) Abstract: An ophthalmic microsurgical system is described for treatment of eye diseases, such as glaucoma, using minimally invasive surgical techniques. The microsurgical system includes a thin walled outer sheath microcannula 1 slidably disposed about an inner member 4, which extends slightly beyond the distal end of the microcannula 1. The inner member 4 may be straight or curved and may optionally include a surgical instrument and/or a sensor or signaling beacon. The microsurgical system is used in a surgical procedure for opening Schlemm's Canal to provide drainage of aqueous fluid in order to relieve excess intraocular that results from glaucoma an other diseases of the eye.

WO 03/045290 A1

TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

Ophthalmic Microsurgical System

Field of the Invention

The present invention relates to a microsurgical system for treatment of eye diseases, such as glaucoma, using minimally invasive surgical techniques.

Background of the Invention

Glaucoma is a disease condition of the eye in which increased intraocular pressure (IOP) is created by reduction or blockage of the drainage mechanism for the aqueous fluid produced in the anterior portion of the eye. Such conditions are usually treated by topical drugs in the form of eye drops, but may result in surgical treatment if drug treatment becomes ineffective or if patient compliance is an issue. Traditional glaucoma surgery, such as a trabeculotomy or trabeculectomy, involve dissection of the eye and the forming of new passages through or near the trabecular meshwork portion of the drainage pathway and directing the fluid to a subconjunctival pocket known as a bleb. Although effective for a short period, long-term follow-up of these treatments shows marked increases in intraocular pressure and therefore low success rates. Other serious complications include hypotony, in which too much drainage is accomplished and the IOP drops to sight threatening levels. These procedures also involve post surgical complications, such as infection and long-term issues related to bleb management.

A recently developed surgical treatment for glaucoma is known as viscocanalostomy. The procedure involves surgically opening a flap of the sclera and dissecting down to de-roof Schlemm's canal to increase aqueous humor drainage. A high viscosity viscoelastic material is injected into the canal to dilate it, and may act to open the trabecular meshwork from the canalicular space. The viscoelastic material may also act as a fibrosis inhibitor, reducing the influx of fibroblastic cells from the healing response, which would negate the effects of the procedure by blocking fluid flow. Stegmann, et al. in US 5,486,165 discloses a microcannula designed for delivery of substances to Schlemm's

canal during this procedure. In EP 089847, Grieshaber, et al. disclose an improvement to the Stegmann apparatus to deliver substances or stents for maintaining the passage of fluid in the canal.

Other surgical procedures, such as non-penetrating deep sclerectomy and trabeculectomy involve accessing and treating the aqueous drainage system in various manners. Minimally invasive access to the requisite tissues involved in aqueous fluid drainage, such as the trabecular meshwork, Schlemm's Canal, aqueous collector channels and aqueous veins can provide treatment with fewer complications.

The invention is directed at an ophthalmic microsurgical system comprised of a microcannula and associated microsurgical tools, which may be directly inserted into the sclera, Schlemm's Canal, aqueous collector channels, aqueous veins or other ocular tissues to allow minimally invasive access and progressive treatment with surgical materials and tools.

The following patent documents relate to methods and apparatus for treatment of glaucoma and other ocular diseases.

US Patent 5,360,399 METHOD AND APPARATUS FOR MAINTAINING THE NORMAL INTRAOCULAR PRESSURE, inventor Robert Stegmann

US Patent 5,486,165 METHOD AND APPLIANCE FOR MAINTAINING THE NATURAL INTRAOCULAR PRESSURE, inventor Robert Stegmann

US Patent 6,142,990 MEDICAL APPARATUS, ESPECIALLY FOR REDUCING INTRAOCULAR PRESSURE, inventor Reinhard O.W. Burk

WO 0064389 TRABECULOTOMY DEVICE AND METHOD FOR TREATING GLAUCOMA, inventors Brown Reay H, Lynch Mary G, King Spencer B III

WO 02/089699 MEDICAL DEVICE AND METHODS FOR USE FOR GLAUCOMA TREATMENT, inventors Tu Hosheng, Smedley Gregory, Niksch Barbara, Haffner David

WO 02/080811 GLAUCOMA STENT AND METHODS THEREOF FOR GLAUCOMA TREATMENT, inventors Tu Hosheng, Smedley Gregory, Niksch Barbara, Haffner David

WO 02/070045 GLAUCOMA TREATMENT DEVICE AND METHOD, inventors Brown David, Anderson Richard

US 6,471,666 INJECTABLE GLAUCOMA DEVICE, inventor Odrich Steven

US 6,464,724 STENT DEVICE AND METHOD FOR TREATING GLAUCOMA, inventors Lynch Mary, Brown Reay

WO 01/78656 DEVICE FOR GLAUCOMA TREATMENT AND METHODS THEREOF, inventor Hill Richard

Brief Description of the Drawings

FIG 1 shows an exploded view of the outer sheath microcannula and the inner member of the ophthalmic microsurgical system.

FIG 2 shows a curved inner member for use with the ophthalmic microsurgical system.

FIG 3 shows an assembled view of the outer sheath microcannula and the inner member of the ophthalmic microsurgical system.

FIG 4 is an enlarged detail drawing of the distal tip of the outer sheath microcannula and the inner member shown in FIG 3.

FIG 5 is an enlarged detail drawing of an inner member with a conical distal cutting tip.

FIG 6 is an enlarged detail drawing of an inner member with a spatula shaped distal cutting tip.

FIG 7 shows an inner member that includes a surgical tool for creating controlled punctures in the trabecular meshwork from within Schlemm's Canal.

FIG 8 shows the inner member and surgical tool of FIG 7 inserted through the outer microcannula of the ophthalmic microsurgical system.

FIG 9 shows the ophthalmic microsurgical system of FIG 8 with the surgical tool extended from the inner member.

FIG 10 shows a surgical cutting tool for use with the ophthalmic microsurgical system.

FIGS 11 and 12 show a dissecting tool for use with the ophthalmic microsurgical system.

FIG 13 illustrates an ophthalmic microsurgical system that includes a signaling beacon on the inner member.

Description of the Invention

FIG 1 shows an exploded view of the ophthalmic microsurgical system of the present invention. The ophthalmic microsurgical system comprises a thin walled outer sheath microcannula **1** with a connector **2** at the proximal end, a distal tip **3** and a communicating channel between. The microcannula outer sheath **1** is disposed about an inner member **4**, which fits and slides within the channel of the microcannula **1**, the inner member **4** comprising at least a proximal end **5** and a distal tip **6**. FIG 3 shows an assembled view of the ophthalmic microsurgical system with the inner member **4** inserted through the channel of the outer sheath microcannula **1**. The inner member **4** is designed to extend beyond the distal tip **3** of the microcannula **1** a specified distance depending upon the requirements of the specific inner member **4**. FIG 4 is an enlarged detail drawing showing the distal tip **6** of the inner member **4** extending a specified distance beyond the distal tip **3** of the microcannula **1**. The inner member **4** may comprise a trocar, needle or microsurgical tool and may also be used to transport fluids, energy, sensors, or gases. The tissues of the eye along the tissue tract may be treated in discrete regions by using the outer sheath to localize the site of action for the inner member. Different configurations of inner members **4** may be used in sequence with the outer sheath **1** to accomplish different surgical tasks.

The microcannula 1 may be introduced manually or as part of a system to provide surgical support or guidance. The microcannula 1 may be inserted into an existing tissue tract of the eye such as Schlemm's Canal, aqueous collector channels, and aqueous veins, or may be used to create a tract within tissues of the eye such as the sclera. The positioning of the microcannula 1 in tissues such as Schlemm's Canal can be verified by several means including such means as a change in pressure/vacuum resistance in the surrounding environment as the system enters the Canal, a change in tissue color of the tissues of the Canal, direct visual location during surgical cut-down or by external image guidance. Accurate positioning within the Canal or other eye tissues may be aided by features of the microcannula 1.

Various inner members 4 may be inserted into the microcannula for the progressive steps to introduce the microcannula 1 into a tissue tract such as Schlemm's Canal, advance the microcannula 1 along the tract, and perform surgical intervention of the tissues near the tip 3 of the microcannula 1. Once inserted into a tissue tract, the microcannula 1 may be progressively advanced to the appropriate areas for treatment. The microcannula sheath 1 and inner member 4 for such use are configured to form an assembly with sufficient stiffness to progress along the tissue tract with minimal tissue damage. Tissue damage may induce fibrosis, complicating procedures such as filtration surgery for glaucoma or viscocanalostomy. The microcannula 1, which may be more flexible than the inner member 4, may be advanced into the tissue tract without the inner member 4, to advance the microcannula 1 atraumatically. The distal tip 6 of the inner member is preferred to be limited in extension from the tip 3 of the microcannula 1 to prevent tissue damage. With the increased flexibility and mobility, large sections of Schlemm's Canal or long tissue tracts may be treated from a single access point with the microcannula 1.

The microcannula 1 may be comprised of a thin walled polymer or metallic tube of sufficient stiffness to allow it to be advanced into tissues or along the tissue tract such as Schlemm's Canal, and sufficient flexibility to follow the radial tract of Schlemm's Canal. The proximal connector 2 may be of a Luer type or similar system for the attachment or

introduction of secondary elements, fluids or surgical tools. The proximal connector **2** is preferably configured to allow fluid-tight introduction of materials and tools through the channel of the outer sheath microcannula **1**. This can be accomplished with a close sliding fit between the channel of the microcannula **1** and the inner member **4** and/or with a hemostasis seal built into the proximal connector **2**. Due to the small size of Schlemm's Canal and other tissue tracts of the eye, approximately 50 to 200 microns in diameter, the microsurgical system must be appropriately sized. Typically, the microcannula **1** is sized in the range of 50 - 250 microns inner diameter with a wall thickness from 10-100 microns. The length of the microsurgical system can be varied for different applications or for use with different delivery systems and surgical tools. Due to the curvature of a tissue tract such as Schlemm's Canal, the microcannula **1** may be flexible in the appropriate dimensions. In some embodiments, a predetermined curvature **7** may be applied to the inner member **4** and/or the outer sheath **1** during fabrication, as shown in FIG 2 and in the assembled view of the microsurgical system in FIG 3. The distal tip **3** of the microcannula **1** is formed so as to provide a smooth entry into the target tissues. Suitable materials for the microcannula **1** include metallic films, polyetheretherketone (PEEK), polyimide, polyamide, polysulfone, nylon, urethane, PTFE, FEP or similar materials. The microcannula **1** may also comprise surface treatments such as lubricious coatings to assist in tissue penetration or reflective coatings to aid in location and guidance during medical imaging.

The microcannula **1** may also have markings on the exterior for assessment of depth in the tissue tract or Schlemm's Canal. The external markings allow user assessment of the length of the tissue tract or Schlemm's Canal accessed by the microcannula **1**, and the approximate location of the microcannula tip **3**.

Depending on the application, the inner member **4** may be a guide wire, hollow needle, micro-trocar or similar element and comprises a proximal end **5** and a distal tip **6**, and may contain a communicating channel between them. The inner member **4** may also comprise sensing means such as a pressure transducer, light pipe or optical fiber to aid in

determining location, local fluid pressure, blood flow or other parameters. The inner member 4 is sized correspondingly to fit slidably within the microcannula 1 and therefore will be in the range of 50-240 microns in outer diameter. If hollow, the inner diameter of the inner member 4 will be in the range of 40-210 microns.

In one preferred embodiment for introducing and advancing the microcannula 1 along a tissue tract such as Schlemm's Canal, the inner member 4 may comprise a solid element or wire to provide rigidity with the distal end of the assembly. Highly elastic, high modulus materials such as metals including stainless steel, tungsten and nickel titanium alloys, and structural polymers such as nylon, polyethylene, polypropylene and PEEK are particularly preferred for construction of the inner member 4. The inner member 4 may be shaped to provide curvature to the microcannula 1 or to provide support for lower modulus microcannula materials.

In an alternate embodiment, the distal end 6 of the inner member 4 may be sharpened and adapted to the microcannula 1 to penetrate and guide the microcannula 1 through scleral and other ocular tissues to reach desired locations for surgical intervention such as Schlemm's Canal, or to create tissue tracts for the drainage of aqueous humor. The distal end 6 of the inner member 4 may comprise or alternately hold a sharpened member for such applications. The distal end may be conically tapered 8, as shown in FIG 5, or beveled or spatula shaped 9, as shown in FIG 6, to optimize the desired tissue penetration characteristics. The distal tip 6 of the inner member 4 may be designed to penetrate scleral tissues with minimal deflection of the microcannula 1 and surrounding tissues, or it may be shaped in a specific manner to provide a predetermined deflection angle or curvature. For example, a "spatula" or "spade" type faceted cutting tip will provide for straight cutting penetration with minimal tissue deflection, while a conventional suture type triangular cutting tip will provide for deflection in one direction. A hypodermic needle may act as the inner member 4, which provides a sharpened end for penetration while allowing for a working channel to deliver fluids or gases. Preferred materials include stainless steel, tungsten, and nickel titanium alloys.

Once the microcannula **1** is introduced and advanced appropriately into Schlemm's Canal, the inner member **4** may be exchanged for one designed for surgical intervention. The inner member **4** may be disposed such that its distal tip is extensible beyond the distal tip of the microcannula **1**. In one embodiment, the inner member **4** comprises a fine wire with a cutting tip to provide support and for the initial introduction of the microcannula **1** into the target tissues. In another embodiment, the inner member **4** comprises a blunt tip **19**, as shown in FIG 3, which is designed to bluntly dissect a tract in the tissue, and is disposed distally from the microcannula **1** for a set distance. Other embodiments involve microsurgical tools and sensors. Each inner member **4** is precisely mated to the inner diameter and proximal coupling of the microcannula outer sheath **1** to provide a high level of surgical control for delicate microsurgery.

In another embodiment shown in FIG 7, the microsurgical system comprises a surgical tool **20** for creating controlled punctures in the trabecular meshwork from within Schlemm's Canal. The surgical tool **20** may be constructed separate from or integral with the inner member **4**. The diameter of the surgical tool **20** is such that it may be inserted through the channel of the microcannula **1** or, alternatively, through a channel in a hollow tubular inner member **4**. The surgical tool **20** may be comprised of a superelastic material such as a nickel tinanium alloy, and configured such that the distal tip **21** is shaped and bent at an angle with respect to the axis of the inner member **4**. The surgical tool **20** is constructed such that the practitioner knows where the angulation of the tip **21** is directed. Features such as markings or guides may be used to provide tip direction. The microcannula **1** is placed into Schlemm's Canal through means as detailed above. When the surgical tool **20** is disposed within the microcannula **1** and/or within a tubular inner member **4**, as shown in FIG 8, the distal tip **21** is straightened. The microcannula **1** is advanced to the location where the surgical puncture is to be created and the surgical tool **20** is advanced within the microcannula **1** until the tip **21** extends from the microcannula **1**, bending at the predetermined angle and directed towards the trabecular meshwork, as

shown in FIG 9. The surgical tool **20** is advanced until it penetrates the meshwork and then is withdrawn. The microcannula **1** can then be advanced to the next treatment site. In this manner, size and location of drainage openings can be precisely controlled, providing optimum treatment regimen for the patient. The angle of the tip **21** may be in the range of 45 to 135° from the axis, and the tip **21** may comprise a cutting element as described above.

In another embodiment shown in FIG 10, the microsurgical system includes a surgical cutting tool **23** mountable to or interchangeable with the inner member **4**. The surgical cutting tool **23** may utilize a separate penetrating or cutting element such as a diamond or sapphire tip or blade **12**. In one such design, a basket **22** is created from wire of a shape memory alloy such as a nickel tinanium alloy. The basket **22** is expanded in order to place a sharpened segment of diamond or sapphire blade **12** or similar element within, and then released to grip the element tightly. The basket **22** may be mounted on the end of a solid element **13** to create a surgical tool compatible with the microcannula **1**.

In another embodiment, the inner member **4** may comprise a sensing means. Such means may comprise a stiff tube surrounding a fluid channel for communicating of ambient pressure at the distal tip, or similarly the channel may contain an optical fiber for the transmission and relay of optical signals. Pressures at the distal tip **6** may be used for *in situ* fluid pressure measurements, or for differential pressure measurements to assist in providing locating means for the microcannula **1**. In such a system, the pressure differential will change when the distal tip **6** with the sensing means transits from scleral tissues into the fluid-filled Schlemm's Canal, or into the anterior chamber. Optical sensing may also be used for locating means, or to provide blood flow, blood oxygen, or other sensing parameters. Sensing means may also comprise various tissue or disease sensing means utilizing "chip" type sensors. Suitable materials for an inner member **4** for structural support of a sensing means include but are not limited to stainless steel, nickel

tinanium alloy, titanium, and structural polymers such as nylon, polysulfone, polypropylene, polyethylene, and PEEK.

Similar to the use of sensing means, the inner member 4 may comprise a signaling beacon 18, as shown in FIG 13, to identify the location of the microcannula tip 3 relative to the target tissues. The beacon 18 may comprise an echogenic material for ultrasound guidance or a light source for visual guidance. In one embodiment, a beacon 18 comprising a fibcroptic light source emitting 90 degrees from the tip of the microcannula 1 is advanced and rotated along Schlemm's Canal until the light source targets the appropriate tissues such as the trabecular meshwork. The light source may be emitted 45 to 135 degrees from the axis of the microcannula beacon 18 as long as the tissue target area is coincident with the path of the inner member 4.

In another embodiment shown in FIGS 11 and 12, the microsurgical system comprises a surgical tool 16 designed to provide blunt microdissection of tissues for the creation of drainage tracts or the implantation of shunts or similar elements. The surgical tool 16 may be constructed integrally with or interchangeable with the inner member 4. The surgical tool 16 is comprised of a conductive shaft 14 and a distal tip configured with two or more splines 15 constructed of a shape memory alloy. The splines 15 are fabricated such that a bipolar memory shape set is applied to them. In the first configuration shown in FIG 11, the splines are gathered together on the axis of the shaft 14. In the second configuration shown in FIG 12, the splines 15 are angled outward from the axis of the shaft 14. The splines 15 are transitioned from one configuration to the other by a square wave electrical voltage applied to the conductive shaft 14 by an electronic controlling system. The pulsing of the voltage induces the phase transformation of the splines 15, causing them to open and close rapidly. As the surgical tool 16 is advanced through the tissue, the opening and closing splines 15 bluntly dissect a microtract.

In another embodiment, the microcannula 1 is used to access or create a tissue tract in the eye and subsequently used to deliver an implant to the tract. The implant may comprise stent-like devices to hold open tissue spaces or drug eluting materials to provide localized drug delivery. An implant such as a tubular stent, may be loaded into the lumen of the microcannula 1 in a compressed or folded state and the inner member used to deploy the implant at the desired location. In another embodiment, a stent-like implant may be previously attached to the microcannula body or comprise the distal portion of the microcannula, and deployed by mechanical action of the inner member. An inner member or surgical tool may be used to create or access a tissue tract with the microcannula implant mounted on it.

Examples:

Example 1:

A microcannula system was fabricated for experimentation on ex-vivo human eyes obtained from an eye bank. The microcannula consisted of a 30 gauge tubing adapter (Small Parts, Inc., Miami Lakes, FL) with a distal tip comprised of polyimide tubing bonded into the lumen of the tube adapter. The tube adapter is a standard hypodermic needle, cut to ½" (12.5mm) length with a perpendicular (straight) cut distal end and a female Luer at the proximal end. The tube adapter has an inner diameter of 150 microns and an outer diameter of 300 microns. A section of polyimide tubing (MicroLumen, Tampa, FL) with inner diameter of 110 microns and a wall thickness of 14 microns was bonded into the distal tip of the tube adapter with cyanoacrylate adhesive and allowed to cure overnight. Assemblies were fabricated with 1.0 and 1.5 cm of polyimide tubing extending from the tube adapter. A 2 cm section of stainless steel wire (Fort Wayne Metals, Fort Wayne, IN) 100 microns diameter was mounted onto a Luer cap for attachment to the Luer connector of the microcannula. The wire tips were hand ground to a spade type point and a tapered cone type point. In some assemblies, the stainless wires were bent by hand into a curve of approximately 14 mm radius, to allow easier advancement through the curvature of Schlemm's Canal.

Ex-vivo human eyes were used to perform experiments with the cannulae. The human eyes were placed under a stereomicroscope. Using ophthalmic scalpels, successive layers of the sclera were cut away until Schlemm's Canal was located. Various examples of the microcannula system were successfully guided into the Canal. When the tip of the microcannula was into the ostium of the Canal approximately 1-2 mm, the inner member was removed. The microcannulae were advanced to determine their ability to track the Canal. In all cases the microcannulae were able to be advanced at least 1 cm or more into the Canal. If the wire is left in place, the curved wires allowed for advancement into the Canal while the straight wires were only able to be advanced a short distance.

In a second experiment, the microcannulae were evaluated for the ability to pierce the scleral tissues. The system with a distal tip in a tapered cone had difficulty in penetrating the tissues, causing tissue deformation and requiring a fair amount of force to begin penetration. The tip ground in a spade type distal end was able to penetrate the tissues with much less deformation.

In a third set of experiments, ophthalmic suture needles with different tip configurations were used to pierce the sclera to assess the differences in terms of tissue and needle deflection. The suture needles (Surgical Specialties, Reading, PA) used were Center Point Spatula and Side Cutting Lancet. In each trial the spatula point allowed easiest penetration with minimal tissue deflection.

Example 2:

In another example, a surgical tool to provide for controlled punctures in the trabecular meshwork was created using Nitinol (nickel titanium alloy) wire, 0.004" (100 microns) diameter (Ft. Wayne Metals, Ft. Wayne, IN). The wire was formed with a 10 mm diameter curve for the distal 3 cm. The distal 2 mm of the tip was further formed with a small radius bend at approximately 90 degrees from the axis of the wire, directed toward the inside and remaining in the plane of the curve.

A microcannula was fabricated comprised of a 3 cm long polyimide tube (Microlumen, Tampa, FL), with an inner diameter of 140 microns and an outer diameter of 200 microns, adhesively bonded to a section of 26 gauge hypodermic tubing (Small Parts, Inc, Miami Lakes, FL). The hypodermic tubing was mounted in a short plastic sleeve for ease of manipulation. The polyimide tubing was heat set with a curvature of approximately 2.5 cm. A stainless steel guiding sheath was fabricated from sections of hypodermic tubing (Small Parts, Inc, Miami Lakes, FL) to create a stepped sheath with an inner diameter of approximately 300 microns. The guiding sheath was cut to 10 mm long and the mounted in a plastic shaft. The guiding sheath was mounted at the distal end of the shaft and at a right angle to the shaft axis. This configuration of the sheath allowed for the tip of the guiding sheath to be directed at Schlemm's Canal by one hand, while the cannulation was performed by the other hand, which provided better positioning control for the procedure.

An ex-vivo human eye was placed in a holding cup and positioned under a stereomicroscope. A rectangular flap was cut approximately 4 mm on a side at the limbus. The flap was excised to approximately ½ scleral thickness. The tissue bed was further dissected to reveal Schlemm's Canal, and the Canal was de-roofed to allow access. The microsurgical tool was loaded into the microcannula by advancing the tool proximal end into the cannula distal end and continuing until the proximal end could be grasped at the proximal end of the cannula. The tool was oriented so that the curvature of the bend was approximate to the curvature of Schlemm's Canal. The tool was then withdrawn into the cannula approximately 3 mm, and the tip of the microcannula was inserted into the proximal end of the guiding sheath. Under the microscope, the distal tip of the guiding sheath was placed at the ostium of Schlemm's Canal. The microcannula was advanced into the canal approximately 30 degrees. While holding the microcannula steady, the tool was advanced slowly until the distal tip extended beyond the cannula tip and pierced the trabecular meshwork. The distal tip of the tool could be observed through the cornea, entering the anterior chamber. The microcannula was withdrawn slightly,

further tearing the trabecular meshwork. The tool was then withdrawn into the cannula and the system withdrawn from the Canal.

Example 3.

In another example, a signaling means for determining the location of the microcannula distal tip was fabricated. A small battery powered laser diode light source illuminator was constructed, with the diode operating in the visible red light range. A single plastic optical fiber (POF) (South Coast Fiber Optics, Achua, FL) of approximately 100 microns in diameter and 20 cm in length was mounted to an adapter which provides adjustable alignment capabilities to bring the fiber tip into the focus of the laser illuminator. The POF distal tip was cut flat, and hence the illumination was directed toward all radial angles from the tip. A cylindrical handpiece mount was fabricated to hold a microcannula. The microcannula was constructed of nylon with dimensions of approximately 120 microns inner diameter and 180 microns outer diameter. The operative end of the microcannula was 15 mm in length and the proximal end was flared for mounting on the handpiece. The fiber is disposed through the handpiece and within the microcannula as detailed in Example 1, and the fiber adapter mounted to the laser illuminator. The adapter alignment was adjusted to provide the brightest spot at the end of the POF.

Ex-vivo human eyes were surgically dissected with a small rectangular flap at the limbus to reveal Schlemm's Canal. The microcannula and light fiber were advanced into the canal with the light source on. The illuminated tip of the fiber was seen through the scleral tissues and also from the anterior chamber of the eye through the trabecular meshwork. In multiple trials, the microcannula with beacon tip was able to be advanced up to 120° around from the access point within Schlemm's Canal.

Example 4.

In another example, a microcannula is used to access Schlemm's Canal as described in example 1. The tip of the microcannula is positioned at the desired location along

Schlemm's Canal for treatment. The inner member is removed while keeping the outer microcannula sheath in position. A stent type of implant is folded or compressed and inserted into the lumen of the microcannula. The stent is releasably secured to the distal end of an inner member, and pushed along the microcannula lumen by the mechanical action of the inner member. When deployed out from the end of the microcannula into the tissue tract, the stent is expanded and is released from the inner member. The microcannula is moved to another location along Schlemm's Canal for delivery of another implant as desired.

What is claimed is:

1. A microcannula based microsurgical system designed to operate within a tissue tract of the eye, comprising:

a flexible tubular outer sheath with an outer diameter of 250 microns or less, with proximal and distal ends, to fit within the tissue tract;

a proximal connector on the outer sheath for introduction of materials and tools; and an inner member with a proximal end and a distal tip, wherein the tip is restricted from advancement past a predetermined length from the outer sheath, with the outer sheath and inner member sized such that the inner member fits slidably within the outer sheath and may be removed separately from the outer sheath while in the tissue tract.

2. A microsurgical system of claim 1, wherein the tissue tract is Schlemm's Canal of the eye.

3. A microsurgical system of claim 1, wherein the tissue tract is created by the flexible outer sheath and inner member.

4. The microsurgical system of claim 1, wherein the microsurgical system provides blunt dissection of the tissue tract.

5. The microsurgical system of claim 1, wherein the flexible tubular outer sheath comprises polyimide or a fluoropolymer.

6. The surgical system of claim 1, wherein the flexible tubular outer sheath is curved in the range of 10 – 15 mm diameter.

7. The microsurgical system of claim 1, wherein the inner member comprises nickel titanium alloy.

8. The microsurgical system of claim 1, wherein the inner member comprises tungsten.

9. The microsurgical system of claim 1, wherein the inner member is curved in the range of 10 – 15 mm diameter.

10. The microsurgical system of claim 1, further comprising a tool to cut or ablate tissues that interchanges with the inner member to position the tool tip to a predetermined position from the tip of the flexible tubular outer sheath.

11. The microsurgical system of claim 1, wherein the inner member has a distal tip that is shaped for tissue dissection.

12. The microsurgical system of claim 11, wherein the distal tip comprises a multi-faceted shape or a tapered conical shape.

13. The microsurgical system of claim 11, wherein the distal tip is sharpened for tissue penetration.

14. The microsurgical system of claim 11, wherein the distal tip is shaped to provide for controlled surgical penetration of the trabecular meshwork.

15. The microsurgical system of claim 14, wherein the distal tip advances and penetrates the trabecular meshwork from a 45 to 135 degree direction from the axis of the outer sheath.

16. The microsurgical system of claim 1, wherein the outer sheath additionally comprises a plurality of markers set at regular intervals such that each marker is spaced from adjacent markers by a fixed distance along the outer sheath to provide depth measurement.

17. The microsurgical system of claim 1, wherein the inner member comprises a sensing means.

18. The microsurgical system of claim 1, wherein the inner member comprises a signaling means.

19. The microsurgical system of claim 18, wherein the signaling means is an optical fiber.

20. The microsurgical system of claim 19, wherein the optical fiber directs illumination at an angle of 45 to 135 degrees from the axis of the microcannula, from the proximal end of the microcannula.

21. The microsurgical system of claim 20, wherein the optical fiber directs illumination to coincide with the target of an inner member directed at an angle of 45 to 135 degrees from the axis of the microcannula.

22. The microsurgical system of claim 1, wherein the system is sized to deliver an implant to the tissue tract by action of the inner member.

23. The microsurgical system of claim 22, wherein the implant is a stent-like tube.

FIG 1

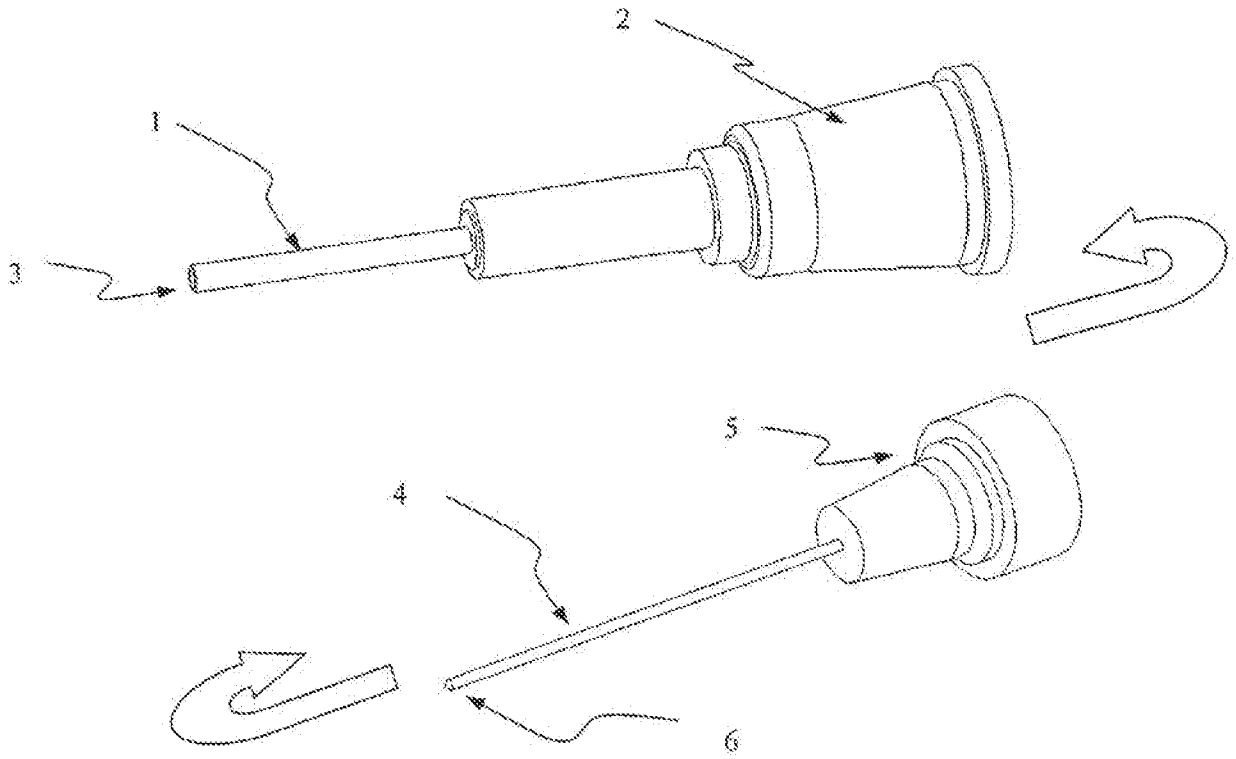
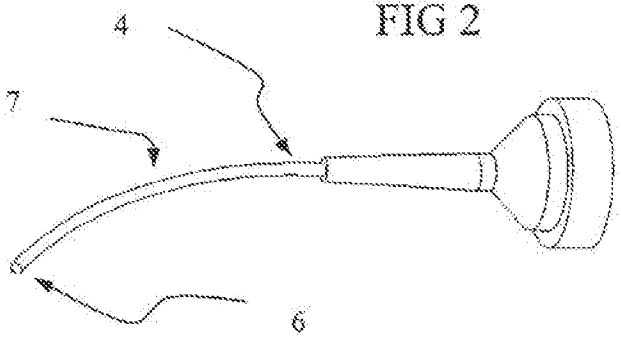


FIG 2



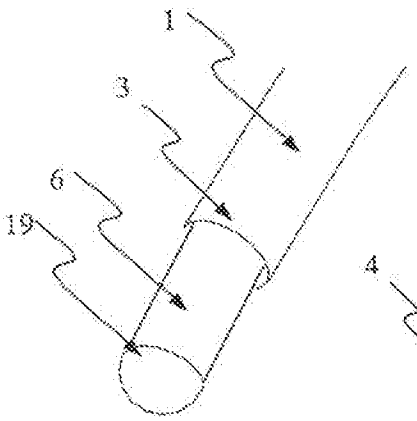


FIG 3

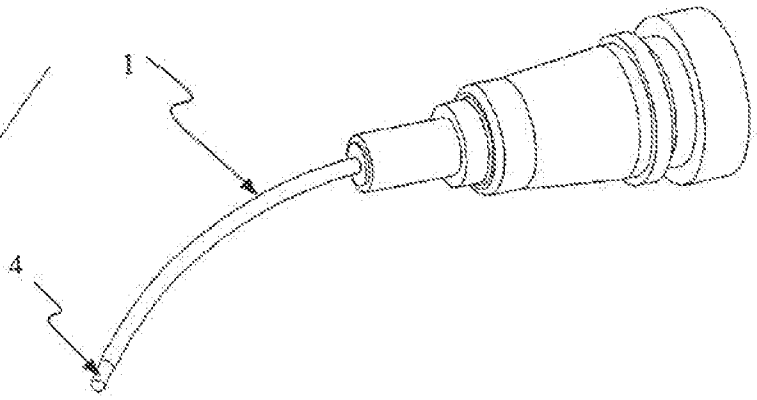


FIG 4

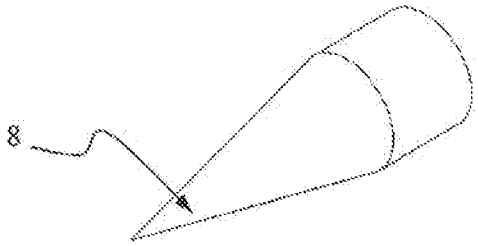


FIG 5

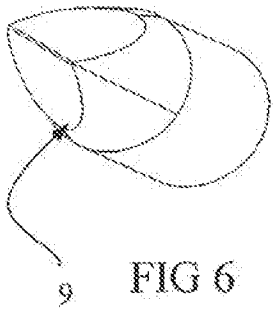


FIG 6

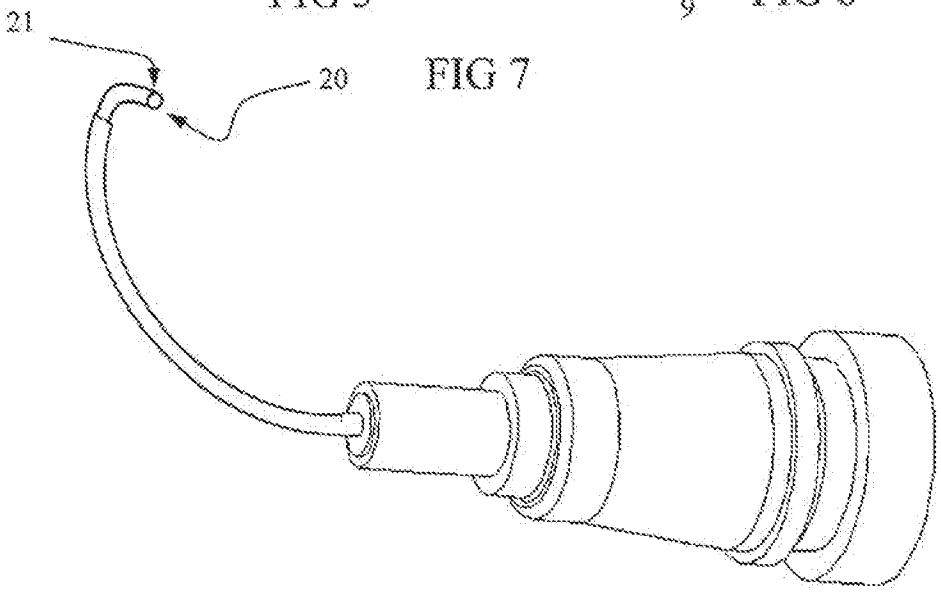


FIG 7

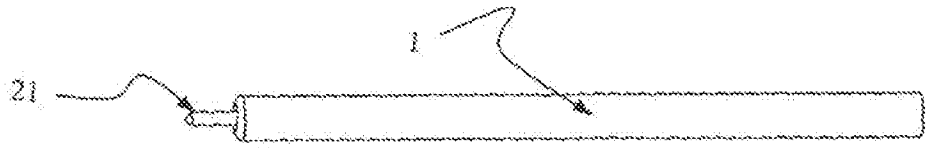


FIG 8

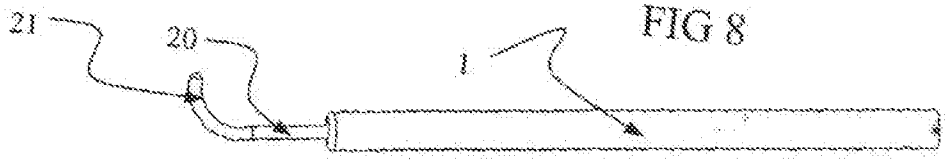


FIG 9

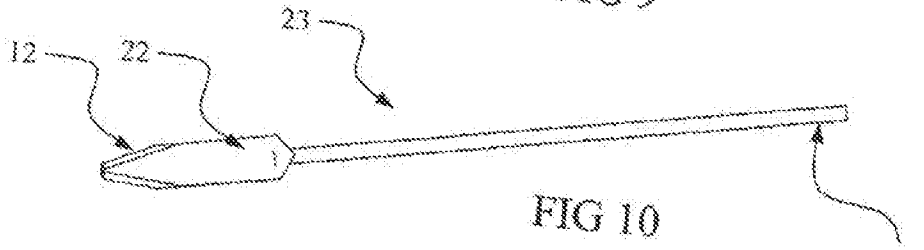


FIG 10

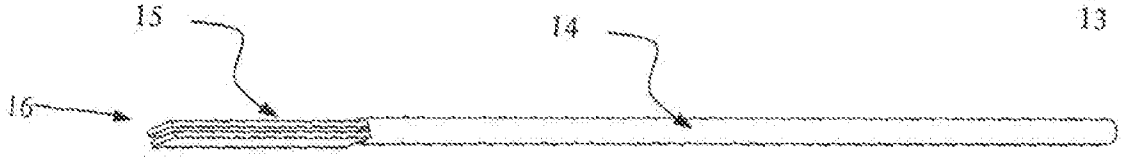


FIG 11

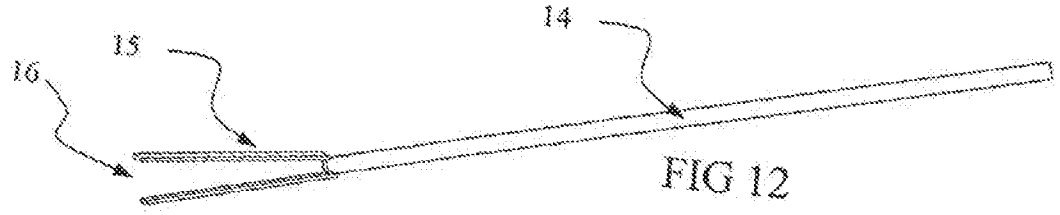


FIG 12

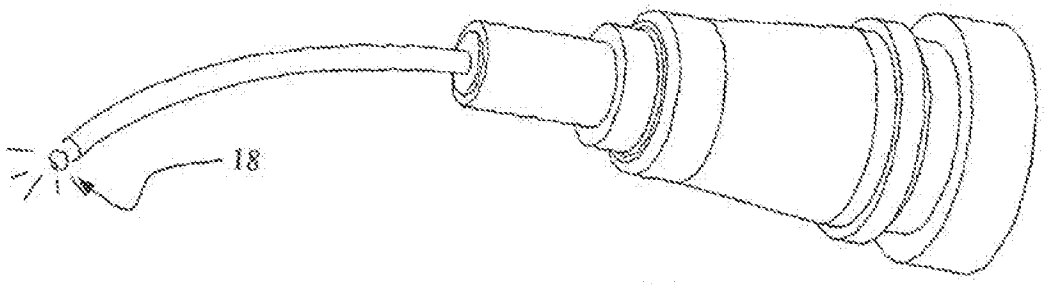


FIG 13

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/37572

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 37767 A (MAAG WERNER ;GRIESHABER & CO AG (CH); SCHAAF HANSGEORG (DE); STEGM) 31 May 2001 (2001-05-31) page 7, line 4 -page 28, line 2	1-23
A	US 6 142 990 A (BURK REINHARD O W) 7 November 2000 (2000-11-07) cited in the application column 4, line 19 -column 6, line 4	1-23
A	WO 00 64389 A (BROWN REAY H ;LYNCH MARY G (US); KING SPENCER B III (US)) 2 November 2000 (2000-11-02) cited in the application page 10, line 6 -page 16, line 29	1-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 March 2003	14/03/2003

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer
Mary, C

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/37572

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0137767 A	31-05-2001	DE 19956515 A1	21-06-2001
		DE 19956517 A1	21-06-2001
		AU 1376901 A	04-06-2001
		WO 0137767 A1	31-05-2001
		US 2001053873 A1	20-12-2001
		EP 1152722 A1	14-11-2001
US 6142990 A	07-11-2000	DE 19705815 A1	20-08-1998
		EP 0858788 A1	19-08-1998
		JP 10248869 A	22-09-1998
WO 0064389 A	02-11-2000	AU 4371100 A	10-11-2000
		AU 4371300 A	10-11-2000
		AU 4666100 A	10-11-2000
		AU 4975900 A	10-11-2000
		BR 0010054 A	15-01-2002
		BR 0010055 A	09-04-2002
		CN 1354642 T	19-06-2002
		CZ 20013822 A3	13-03-2002
		CZ 20013823 A3	13-03-2002
		EP 1173123 A1	23-01-2002
		EP 1173124 A1	23-01-2002
		EP 1173125 A1	23-01-2002
		EP 1173126 A1	23-01-2002
		HU 0200860 A2	29-07-2002
		HU 0201111 A2	28-12-2002
		JP 2002541975 T	10-12-2002
		JP 2002541976 T	10-12-2002
		JP 2002541977 T	10-12-2002
		NO 20015208 A	20-12-2001
		NO 20015209 A	21-12-2001
		NO 20015210 A	21-12-2001
		NO 20015211 A	20-12-2001
		NZ 514932 A	20-12-2002
		SK 15392001 A3	04-06-2002
		SK 15402001 A3	06-08-2002
		TR 200103098 T2	22-04-2002
		WO 0064389 A1	02-11-2000
		WO 0064390 A1	02-11-2000
		WO 0064391 A1	02-11-2000
		WO 0064393 A1	02-11-2000
		US 2003009124 A1	09-01-2003
		US 6464724 B1	15-10-2002
		US 6480984 B1	17-09-2002

Electronic Patent Application Fee Transmittal

Application Number:	14481754
Filing Date:	09-Sep-2014
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Filer:	Robert D. Buyan/Dana Sundene
Attorney Docket Number:	NEOME-019A3-US-G2

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	22310670
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan/Dana Sundene
Filer Authorized By:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	11-MAY-2015
Filing Date:	09-SEP-2014
Time Stamp:	16:25:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$90
RAM confirmation Number	3412
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	NEOME-019A3US-G2-SuppIDSTrans.pdf	87454 3d33b2d0742fff5af312e927cf61f84b1ab03a42	no	2
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	NEOME-019A3USG2-SupplementalIDS.pdf	614588 5b1c2bcd1d14b788f0ac341300ef2aaa32cba3be	no	8
Warnings:					
Information:					
3	Foreign Reference	WO2001078631.pdf	978797 4d4cb785d23b2447d7a80836b76d8d39ed6b8e35	no	6
Warnings:					
Information:					
4	Foreign Reference	WO2003045290.pdf	3702786 f646c80d778ef18b42a1d58acc91fcfdf56268da	no	25
Warnings:					
Information:					
5	Foreign Reference	WO2004093761.pdf	4901613 f28f2fe4b7b27d9932214002851bf5093a092cb3	no	30
Warnings:					
Information:					
6	Foreign Reference	WO2004110501.pdf	2916295 24346f5d79cc0ff2e790e3ab2b179c3fc04b1c34	no	19
Warnings:					
Information:					
7	Foreign Reference	WO2009140185.pdf	3265356 95d58cca074a93b4eec61d2a419c2ba760aa2332	no	24
Warnings:					
Information:					

8	Foreign Reference	KR1020040058309A-Abstract.pdf	38527 f75f3be3de5c0ce5b7b8113ebec684b7d66da496	no	1
Warnings:					
Information:					
9	Foreign Reference	EP0073803.pdf	1546430 4ebcd4a62fba17b7b44cde7ec188407164855f6c	no	7
Warnings:					
Information:					
10	Foreign Reference	EP1615604.pdf	4979219 92651fefa6f1312c49eeec5371cebd883707dea9	no	31
Warnings:					
Information:					
11	Foreign Reference	EP2303203.pdf	3341754 d6c09268ab89c0235005ff081eacdd306e2dda39	no	25
Warnings:					
Information:					
12	Foreign Reference	EP1455698.pdf	3779515 3165bd4efb3d6958171192f83b563e5d73c7422b	no	26
Warnings:					
Information:					
13	Non Patent Literature	Ting-etal.pdf	494464 a460476407a1eabc95a0b7ef23104eb0cad39077	no	9
Warnings:					
Information:					
14	Non Patent Literature	Francis-etal.pdf	216858 66626a8bfe25acd56bc5c5850d28095f2f43252c	no	6
Warnings:					
Information:					
15	Non Patent Literature	Minckler-etal.pdf	174099 c12dda063be40b008837b801ed0648f2caccef51	no	6
Warnings:					
Information:					
16	Non Patent Literature	TAN-etal.pdf	1058152 596937e0eb2e4f7723811c9e79ad4fb16238277b	no	12
Warnings:					
Information:					

17	Non Patent Literature	Johnson-etal.pdf	4203957 ddb71bdecda9fbb3864eb1863cfc312062843f21	no	9
Warnings:					
Information:					
18	Non Patent Literature	Quigley-etal.pdf	1929516 ed23c1c87573387a7dd34b9ed0104e893231bd9a	no	6
Warnings:					
Information:					
19	Non Patent Literature	Jacobi-etal-goniocurettage.pdf	170571 6c8a71f5ccea0e595c4241547b6c74c4fdc61885	no	6
Warnings:					
Information:					
20	Non Patent Literature	Pantcheva-Kahook.pdf	73099 641e3303ee018d5add6cb6a9aee2eeae845869c7	no	5
Warnings:					
Information:					
21	Fee Worksheet (SB06)	fee-info.pdf	30797 a390f34ca4651f2568b1518b10c9d1c74d7e7a39	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	38503847		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	14/481,754
APPLICANT	:	SORENSEN, ET AL.
FILED	:	SEPTEMBER 9, 2014
TC/A.U.	:	3734
EXAMINER	:	AMY REGINA WEISBERG
CONFIRMATION NO.	:	9581
DOCKET NO.	:	NEOME-019A3-US-G2
CUSTOMER NO.	:	33197
TITLE:	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

An Information Disclosure Statement is submitted as listed on Form(s) PTO/SB/08A enclosed herewith. Copies of all cited references other than United States patents and published United States applications are attached hereto for the Examiner's review.

The listed documents are brought to the Examiner's attention because they are known to the applicant and/or the applicant's attorney and may be considered by the Examiner to be material to his/her examination. These submissions shall not be construed as representation that a search has been made or that no better art exists. No inference should be made that any of these submissions are in fact material or that they constitute prior art. Moreover, Applicant makes no admission regarding the relative dates of the invention and these submissions. Furthermore, no aspect of these submissions constitutes a disclaimer of claim scope.

The Examiner is requested to carefully consider the complete text of these documents in connection with the examination of the above-identified application in accordance with 37 CFR 1.104(a). It is requested that the documents listed on the attached Form Form(s) PTO/SB/08A be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. 1302.12), and that the Examiner initial and return a copy of the form to evidence consideration of the documents.

This Information Disclosure Statement is being filed after receipt of an office action on the merits but before receipt of a final office action or notice of allowance. The fees due will be paid electronically at the time of filing. However, the Commissioner is hereby authorized to deduct any underpayment from, or credit any overpayment, to Deposit Account No. 50-0878.

Respectfully submitted,

STOUT, UXA & BUYAN, LLP

Date: May 11, 2015

/Robert D. Buyan/
Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764
Email: rbuyan@patlawyers.com

Electronic Acknowledgement Receipt

EFS ID:	22310960
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan/Dana Sundene
Filer Authorized By:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	11-MAY-2015
Filing Date:	09-SEP-2014
Time Stamp:	16:34:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Seibold-etal.pdf	342530 005b815b289bb69c14fcde988476a90bfacc05a3	no	9

Warnings:	
Information:	

2	Non Patent Literature	Anderson.pdf	228712 024bc208ec35e31caac910b05e344e1901d1660e	no	2
Warnings:					
Information:					
3	Non Patent Literature	Grant-ClinicalMeasurementsAqueousOutflow.pdf	8686488 231e23e1c970a46b8b68435e4a366580913f9842	no	19
Warnings:					
Information:					
4	Non Patent Literature	Grant-ExperimenalAqueousPerfusion.pdf	9376001 919ed29f126e8dba7a2321b8b2b5fc25bd00018b	no	19
Warnings:					
Information:					
5	Non Patent Literature	Herschler-Davis.pdf	2240369 6ea2abc0b94747e32807b5e60b646f08d4e428bd	no	4
Warnings:					
Information:					
6	Non Patent Literature	Jea-etal.pdf	812108 650f02a54f61d3b41716ce7f0f323b1f6d46255e	no	7
Warnings:					
Information:					
7	Non Patent Literature	Luntz-Livingston.pdf	741390 d3dbf9740b490e86ca3844ab57c108ce6266ebf6	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	22427598	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/481,754	Filing Date 09/09/2014	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **05/17/2015**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DAWN BREWER/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

33197 7590 05/19/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER
WEISBERG, AMY REGINA

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 05/19/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2	9581

TITLE OF INVENTION: METHOD FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	08/19/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

33197 7590 05/19/2015
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2	9581

TITLE OF INVENTION: METHOD FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	08/19/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
WEISBERG, AMY REGINA	3734	606-167000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2	9581

33197 7590 05/19/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER	
WEISBERG, AMY REGINA	

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 05/19/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	14/481,754	SORENSEN ET AL.	
	Examiner	Art Unit	
	AMY R. WEISBERG	3734	

All participants (applicant, applicant's representative, PTO personnel):

(1) *AMY R. WEISBERG*. (3)_____.

(2) *Robert Buyen*. (4)_____.

Date of Interview: *14 May 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *all*.

Identification of prior art discussed: *n/a*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner suggested claim amendments to expedite prosecution.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/AMY R WEISBERG/ Examiner, Art Unit 3734	

Notice of Allowability	Application No. 14/481,754	Applicant(s) SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 5/8/15*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-10*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☒ Other *interview supplemental amendment*.

/AMY R WEISBERG/
Examiner, Art Unit 3734

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Buyen on 5/14/15.

The application has been amended as follows:

In the specification (replace [0001] with the following:

[0001] This application is a division of copending United States Patent Application No. 131159,356 filed June 13, 2011 currently abandoned which is a division of United States Patent Application Serial No. 10/560,267 filed May 11,2006 and issued as United States Patent NO. 7,959,641 on June 14, 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed June 10, 2004, which claims priority to United States Provisional Patent Application No. 60/477,258 timed on June 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

In the claims (replace with the following):

1. (Currently Amended) An *ab interno* method for forming an opening in ~~the~~ trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends ~~at an angle~~ from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

forming an opening into an anterior chamber of the eye;

inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. (Original) A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

3. (Previously Presented) A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.

4. (Previously Presented) A method according to claim 1 further comprising the step of:

removing the strip of tissue from the ~~subject's~~ patient's eye.

5. (Previously Presented) A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of:

disconnecting the strip of tissue such that it may be removed from the eye.

6. (Previously Presented) A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

7. (Previously Presented) A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

8. (Previously Presented) A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

9. (Currently Amended) A method according to claim 1 wherein the angle is less than ~~distal protruding tip extends from the shaft at an angle is of be between approximately 30 and~~ approximately 90 degrees.

10. (Currently Amended) A method according to claim 9 wherein the ~~distal protruding tip extends from the shaft at an~~ angle is ~~of~~ approximately 90 degrees.

2. The following is an examiner's statement of reasons for allowance:

The present invention pertains to an *ab interno* method for forming an opening in the trabecular meshwork of a patient's eye, said method comprising the steps of obtaining a dual blade device comprising a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D; forming an opening into an anterior chamber of the eye; inserting the device through the opening and into the anterior chamber; and advancing the device into the Schlemm's Canal with the first and second cutting edges concurrently cutting a strip of tissue having an approximate width equal to the distance between the first and second cutting blades.

The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However Lee fails to teach a device comprising a shaft and a distal protruding tip that extends from a distal end of the

shaft to form a bend or curve having an angle of at least 30 degrees. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Weisberg whose telephone number is (571)270-5500. The examiner can normally be reached on 7:00-5:30pm M-Th.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, SPE Darwin Erezo, at* (571)272-4695**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy Weisberg
Patent Examiner
/Amy Weisberg/
AU 3734
5/14/15

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	14/481,754	SORENSEN ET AL.	
	Examiner	Art Unit	
	AMY R. WEISBERG	3734	

All participants (applicant, applicant's representative, PTO personnel):

(1) *AMY R. WEISBERG*. (3)_____.

(2) *Robert Buyen*. (4)_____.

Date of Interview: *14 May 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *all*.

Identification of prior art discussed: *n/a*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner suggested claim amendments to expedite prosecution.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/AMY R WEISBERG/ Examiner, Art Unit 3734	

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,689,040 A	08-1987	Thompson, Robert J.	604/22
*	B	US-4,706,669 A	11-1987	Schlegel, Hans-Joachim	606/107
*	C	US-4,900,300 A	02-1990	Lee, David A.	604/22
*	D	US-5,843,106 A	12-1998	Heisler, Gary R.	606/167
*	E	US-5,885,279 A	03-1999	Bretton, Randolph H.	606/41
*	F	US-5,922,003 A	07-1999	Anctil et al.	606/170
*	G	US-6,004,199 A	12-1999	Habenicht et al.	452/166
*	H	US-2001/0053873 A1	12-2001	Schaaf et al.	600/104
*	I	US-6,382,974 B1	05-2002	Garfinkel, Leonard M.	433/144
*	J	US-6,419,684 B1	07-2002	Heisler et al.	606/170
*	K	US-6,428,539 B1	08-2002	Baxter et al.	606/49
*	L	US-2004/0210245 A1	10-2004	Erickson et al.	606/167
*	M	US-2006/0241580 A1	10-2006	Mittelstein et al.	606/041

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 14/481,754	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2009/0287233 A1	11-2009	Huculak, John C.	606/167
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	Art Unit
	AMY R WEISBERG	3734

CPC- SEARCHED		
Symbol	Date	Examiner
(A61F2009/00868 or A61F9/007,00736-00763,013-0133).cpc.	3/9/15	/ARW/
(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc.	3/9/15	/ARW/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	107, 161-162, 166-167, 170, 184-185,	3/9/15	/ARW/
600	566, 567	3/9/15	/ARW/

SEARCH NOTES		
Search Notes	Date	Examiner
STIC search, inventor search, cpc search	3/9/15	/ARW/
Julian Woo Search 606/107, 161, 162, 166, 167, 170. Try combining with keywords: eye, trabeculae, schlemm, glaucoma, gouge.	3/9/15	/ARW/
Jon Hollm CPC QN A61F2009/00868 and A61F9/007,00736-00763013-0133;	3/9/15	/ARW/
updated search, reviewed IDS	5/14/15	/ARW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	(cutting adj edges and schlemm$2).clm.	3/9/15	/ARW/
	(dual adj blade and schlemm$2).clm.	3/9/15	/ARW/
	(dual adj blade and schlemm$2).clm.	5/14/15	/ARW/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
	(cutting adj edges and schlemm$2).clm.	5/14/15	/ARW/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	14/481,754
APPLICANT	:	SORENSEN, ET AL.
FILED	:	SEPTEMBER 9, 2014
TC/A.U.	:	3734
EXAMINER	:	AMY REGINA WEISBERG
CONFIRMATION NO.	:	9581
DOCKET NO.	:	NEOME-019A3-US-G2
CUSTOMER NO.	:	33197
TITLE:	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL MENDMENT

Madam:

Please amend the above-identified application as set forth below.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) An *ab interno* method for forming an opening in ~~the~~ trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends ~~at an angle~~ from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

forming an opening into an anterior chamber of the eye;

inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. (Original) A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

3. (Previously Presented) A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.

4. (Previously Presented) A method according to claim 1 further comprising the step of:

removing the strip of tissue from the subject's eye.

5. (Previously Presented) A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of:

disconnecting the strip of tissue such that it may be removed from the eye.

6. (Previously Presented) A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

7. (Previously Presented) A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

8. (Previously Presented) A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

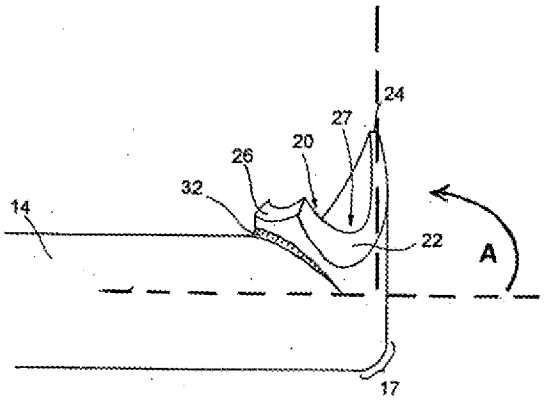
9. (Currently Amended) A method according to claim 1 wherein the angle is less than ~~distal protruding tip extends from the shaft at an angle~~ is ~~of be between approximately 30 and~~ approximately 90 degrees.

10. (Currently Amended) A method according to claim 9 wherein the ~~distal protruding tip extends from the shaft at an~~ angle is ~~of~~ approximately 90 degrees.

REMARKS/ARGUMENTS

By the foregoing amendment Applicant has further amended claim 1 to specify that the distal protruding tip extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees. Also, amendments have been made to dependent claims 9 and 10 to comport with the amended language of claim 1. These amendments are made solely for purposes of clarification.

Support for the amended language of claim 1 is found in the specification at, for example, Paragraph 0015. For avoidance of doubt, the angle being referred to in the claims is labeled "A" on the marked-up reproduction of Figure 3D below.



Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any underpayment, or to credit any overpayment, to Deposit Account No. 50-0878.

Respectfully submitted,
Date: May 14, 2015 STOUT, UXA & BUYAN, LLP

/Robert D. Buyan/

Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764
e mail: rbuyan@patlawyers.com

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BIB DATA SHEET

CONFIRMATION NO. 9581

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/481,754	09/09/2014	606	3734	NEOME-019A3-US-G2

APPLICANTS

Neomedix Corporation, Tustin, CA;

INVENTORS

John T. Sorensen, Lake Elsinore, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

/ARW/

**** CONTINUING DATA ***************************

This application is a DIV of 13/159,356 06/13/2011 ABN *
which is a DIV of 10/560,267 05/11/2006 PAT 7959641 /ARW/
which is a 371 of PCT/US2004/018488 06/10/2004
which claims benefit of 60/477,258 06/10/2003
(*)Data provided by applicant is not consistent with PTO records.

**** FOREIGN APPLICATIONS ***************************

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09/16/2014

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /AMY REGINA WEISBERG/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	3	~~2~~ 10 /ARW/	1

ADDRESS

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
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UNITED STATES

TITLE

TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY R WEISBERG	3734

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/09/2015	05/14/2015							
	1	✓	=							
	2	✓	=							
	3		=							
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14481754
Filing Date	2014-09-09
First Named Inventor	John T. Sorensen
Art Unit	3734
Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6388043	B1	2002-05-14	Langer et al.	
	2	6720402	B2	2004-04-13	Langer et al.	
	3	6759481	B2	2004-07-06	Tong	
	4	7604663	B1	2009-10-20	Reimink et al.	
	5	7632303	B1	2009-12-15	Stalker et al.	
	6	7648591	B2	2010-01-19	Furst et al.	
	7	7785321	B2	2010-08-31	Baerveldt et al.	
	8	7935131	B2	2011-05-03	Anthamatten et al.	

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Receipt date: 05/11/2015	Application Number	14481754
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	9	7955387	B2	2011-06-07	Richter	
	10	8038923	B2	2011-10-18	Berger et al.	
	11	3882872		1975-05-13	Douvas et al.	
	12	5569283	A	1996-10-29	Green et al.	

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	1	20060149194	A1	2006-07-06	Conston et al.	
	2	20070073275	A1	2007-03-29	Conston et al.	
	3	20060106370	A1	2006-05-18	Baerveldt et al.	
	4	20090248141	A1	2009-10-01	Shandas et al.	
	5	20110230877	A1	2011-09-22	Huculak et al.	

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	6	20110077626	A1	2011-03-31	Baerveldt et al.		
	7	20030208217	A1	2003-11-06	Dan		

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	1	WO2001/078631	WO	A2	2001-10-25	Bergheim et al.		☐
	2	WO2003/045290	WO	A1	2003-06-05	Conston et al.		☐
	3	WO2004/093761	WO	A1	2004-11-04	Conston et al.		☐
	4	WO2004/110501	WO	A2	2004-12-23	Sorensen et al.		☐
	5	WO2009/140185	WO	A1	2009-11-19	Lind et al.		☐
	6	KR1020040058309	KR	A	2004-03-07	Conston et al.		☐
	7	EP0073803	EP	A1	1983-03-16	Skjaerpe		☐

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	8	EP1615604	EP	A1	2006-01-18	Conston et al.		☐
	9	EP2303203	EP	A1	2011-04-06	Lind et al.		☐
	10	EP1455698	EP	A1	2004-09-15	Conston et al.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	TING, J. L. M. et al., (2012) "Ab interno trabeculectomy: Outcomes in exfoliation versus primary open-angle glaucoma," J Cataract. Refract. Surg. 38(2),315-323.	☐
	2	FRANCIS, B. A. et al., (2006) "Ab interno trabeculectomy: development of a novel device (Trabectome) and surgery for open-angle glaucoma," J Glaucoma 15(1), 68-73.	☐
	3	MINCKLER, D. S. et al., (2005) "Clinical Results with the Trabectome for Treatment of Open-Angle Glaucoma," Ophthalmology 112(6), 962-967.	☐
	4	TAN, YAR-LI, et al., "Postoperative Complications after Glaucoma Surgery for Primary Angle-Closure Glaucoma vs Primary Open-Angle Glaucoma," Arch Ophthalmol. 2011; 129(8), pp. 987-992.	☐
	5	JOHNSON, DOUGLAS H. et al., "Human Trabecular Meshwork Organ Culture. A New Method." Invest. Ophthalmol. Vis. Sci. 28(6),945-953. 1987	☐
	6	QUIGLEY, H. A. and BROMAN, A. T., (2006) "The number of people with glaucoma worldwide in 2010 and 2020," Br. J Ophthalmol. 90(3),262-267.	☐

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	7	JACOBI, P. C. et al., (1999) "Goniocurettage for removing trabecular meshwork: clinical results of a new surgical technique in advanced chronic open-angle glaucoma," Am. J Ophthalmol. 127(5),505-510.	☐
	8	PANTCHEVA, M. B. and KAHOOK, M. Y., (2010) "Ab Interno Trabeculectomy," Middle East African Journal of Ophthalmology 17(4), 287-289.	☐
	9	SEIBOLD, L. K. et al., (2013) "Preclinical Investigation of Ab Interno Trabeculectomy Using a Novel Dual-Blade Device," Am. J Ophthalmol. 155(3), 524-529.e522.	☐
	10	ANDERSON, D.R., (1983) "Trabeculotomy compared to goniotomy for glaucoma in children," Ophthalmology 90 (7),805-806.	☐
	11	GRANT, W., (1963) "Experimental aqueous perfusion in enucleated human eyes," Arch.Ophthalmol. 69(6), 783-801.	☐
	12	GRANT, W. M., (1951) "Clinical measurements of aqueous outflow," AMA Archives of Ophthalmology 46(2), 113-131.	☐
	13	HERSCHLER, J. and DAVIS, E. B., (1980) "Modified goniotomy for inflammatory glaucoma. Histologic evidence for the mechanism of pressure reduction," Arch. Ophthalmol. 98(4), 684-687.	☐
	14	JEA, S. Y. et al., (2012) "Ab Interno Trabeculectomy Versus Trabeculectomy for Open Angle Glaucoma," Ophthalmology 119(1), 36-42.	☐
	15	LUNTZ, M. H. and LIVINGSTON, D. G., (1977) "Trabeculotomy ab externo and trabeculectomy in congenital and adult-onset glaucoma," Am. J Ophthalmol. 83(2), 174-179.	☐

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Attorney Docket Number	NEOME-019A3-US-G2

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Robert D. Buyan/	Date (YYYY-MM-DD)	2015-05-11
Name/Print	Robert D. Buyan	Registration Number	32460

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4501274	A	1985-02-26	Skjaerpe	
	2	4900300	A	1990-02-13	Lee	
	3	5112299	A	1992-05-12	Pascaloff	
	4	5123904	A	1992-06-23	Shimomura et al.	
	5	5269782	A	1993-12-14	Sutter	
	6	5755716	A	1998-05-06	Garito et al.	
	7	5807277	A	1998-09-15	Swaim	
	8	6068629	A	2000-05-30	Haissaguerre	

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Receipt date: 03/09/2015	Application Number	14481754
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	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

	9	6217598	B1	2001-04-17	Berman et al.	
	10	6283961	B1	2001-09-04	Underwood et al.	
	11	6290699	B1	2001-09-18	Hall et al.	
	12	6419684	B1	2002-07-16	Heisler et al.	
	13	6428539	B1	2002-08-06	Baxter et al.	
	14	3294085	A	1966-12-27	Wallace	
	15	5431646	A	1995-07-11	Vassiliadis et al.	
	16	5458596	A	1995-10-17	Lax et al.	
	17	5681282	A	1997-10-28	Eggers et al.	
	18	5885279	A	1999-03-23	Bretton	
	19	5957914	A	1999-09-28	Cook et al.	

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	20	6432104	B1	2002-08-13	Durgin et al.	
	21	6979328	B2	2005-12-27	Baerveldt et al.	
	22	7244256	B2	2007-07-17	DeCesare et al.	
	23	7842034	B2	2010-11-30	Mittelstein et al.	
	24	7959641	B2	2011-06-14	Sorensen et al.	
	25	RE38018	E	2003-03-04	Anctil et al.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14481754
Filing Date	2014-09-09
First Named Inventor	Sorensen et al.
Art Unit	3734
Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	WO 98/27876	WO	A	1998-07-02	Smith & Nephew Inc.		☐
	2	WO 02/056805	WO	A	2002-07-25	University of California		☐
	3	JP 46-25677	JP	Y1	1971-09-03	(Unknown)	See Attached English Abstract	☐
	4	WO 91/17793	WO	A1	1991-11-28	Sunrise Technologies, Inc.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	US Patent Office Action dated 09/29/2009 in related U.S. Application Serial No. 10/560,267 filed 05/11/2006.	☐
	2	US Patent Office Action dated 03/12/2010 in related U.S. Application Serial No. 10/560,267 filed 05/11/2006.	☐
	3	JACOBI, PHILIPP C., et al. "Technique of Goniocurettage: A Potential Treatment for Advanced Chronic Open Angle Glaucoma," British Journal of Ophthalmology, 1997; 81, pp. 302-307.	☐
	4	SOOHOO, JEFFREY R., et al. "Ab Interno Trabeculectomy in the Adult Patient," Middle East African Journal of Ophthalmology, Vol. 22, No. 1, January - March 2015, pp. 25 - 29.	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.W./

Receipt date: 03/09/2015		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Application Number	14481754
	Filing Date	2014-09-09
	First Named Inventor	Sorensen et al.
	Art Unit	3734
	Examiner Name	Amy Regina Weisberg
	Attorney Docket Number	NEOME-019A3-US-G2

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EXAMINER SIGNATURE

Examiner Signature	/Amy Weisberg/	Date Considered	05/14/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.W./

Receipt date: 03/09/2015

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Examiner Name	Amy Regina Weisberg
Attorney Docket Number	NEOME-019A3-US-G2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Robert D. Buyan/	Date (YYYY-MM-DD)	2015-03-09
Name/Print	Robert D. Buyan	Registration Number	32,460

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	219	("20050159767" | "20150045820" | "4689040" | "4955887" | "6419684" | "3294085" | "6382974" | "6388043" | "20070010812" | "4753234" | "4759746" | "5123904" | "7244256" | "20040210245" | "4900300" | "5112299" | "5540706" | "5733297" | "6217598" | "7244256" | "8147424" | "RE38018" | "4900300" | "5755716" | "7842034" | "20060149194" | "7935131" | "20040204732" | "20060241580" | "5284472" | "5957881" | "5964777" | "6382974" | "6428539" | "4501274" | "5269782" | "5807277" | "20070073275" | "20110077626" | "20110230877" | "6720402" | "7632303" | "20020111608" | "4841984" | "4955883" | "5123904" | "5807277" | "5843106" | "5922003" | "5957914" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "20060106370" | "3882872" | "7785321" | "8038923" | "20060212060" | "20070276420" | "20120123533" | "6004199" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "RE38018" | "20090248141" | "5569283" | "20090287233" | "4706669" | "6293957" | "20020002372" | "6419684" | "6432104" | "6979328" | "20030208217" | "6759481" | "7604663" | "7648591" | "20020038129" | "5019035" | "5885279" | "6217598" | "6428539" | "7955387").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/14 20:24
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S2	79	(john near3 sorensen or michael near3	US-PGPUB;	OR	ON	2013/03/21

		mittelstein or sohella near3 mirhashemi).in.	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			17:47
S3	9	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in. and cutting.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:47
S4	2291	606/167.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:50
S5	1751	606/167.ccls. and cutting	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:51
S6	1010	606/167.ccls. and cutting with tissue	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/21 17:52
S7	143	stent with graft adj cover	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 13:16
S8	2	("7959641").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 13:57
S9	12	(US-20090287233-$ or US-20050159767-$ or US-20040210245-$ or US-20020038129-$).did. or (US-6419684-$ or US-6217598-$ or US-6428539-$ or US-6293957-$ or US-5964777-$ or US-5957881-$ or US-5843106-$).did. or (US-6419684-$).did.	US-PGPUB; USPAT; DERWENT	OR	ON	2013/03/22 13:58
S10	0	("l5andstainless").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2013/03/22 13:58

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S11	3	S9 and stainless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 13:58
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S13	6	S12 and bend	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 14:09
S14	259	cutting with tissue with bend	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 14:11
S15	29	scaler and dental and angle near3 "90"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 15:24
S16	3	enamel adj hatchet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 15:36
S17	12	("0237062" | "1039235" | "5007831" | "5478235").PN. OR ("6042378").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/22 15:37
S18	2	("6,419,684").PN.	US-PGPUB; USPAT; USOCR; FPRS;	OR	OFF	2013/03/22 16:35

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S20	37	cutting with tissue with angle with "90"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 17:19
S21	7860	(606/107 or 606/166 or 606/170 or 606/184 or 606/185 or 600/566 or 600/567).ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/01 17:34
S22	606	(606/107 or 606/166 or 606/170 or 606/184 or 606/185 or 600/566 or 600/567).ccls. and (blade and eye and cornea)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/10/01 17:38
S23	4	(("6419684") or ("7959641")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/10/01 18:39
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S26	20973	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:29
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S29	2213	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/05 12:48
S30	3610	(A61F2009/00868 or A61F9/007,00736-00763,013-0133).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 10:47
S31	2215	(a61f9/00781 or a61b17/320016 or A61F9/00781 or A61B17/320016 or A61B18/1482 or A61B2018/00083 or A61F9/0079 or A61B2018/1497 or A61F9/007).cpc. and eye and (cut$3 or slic$4 or incis$4 or incision)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 10:47
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S33	9	(("4501274") or ("20150045820") or ("6979328") or ("7785321")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/03/09 12:55
S34	220	(john near3 sorensen or michael near3 mittelstein or sohella near3 mirhashemi).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/03/09 13:05
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S51	332514	S50 or "l9"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:18
S52	83	(US-20090287233-$ or US-20050159767-$ or US-20040210245-$ or US-20020038129-$ or US-20120123533-$ or US-20060212060-$ or US-20060241580-$ or US-20070010812-$ or US-20070276420-$ or US-20040204732-$ or US-20150045820-$ or US-20020111608-$).did. or (US-6419684-$ or US-6217598-$ or US-6428539-$ or US-6293957-$ or US-5964777-$ or US-5957881-$ or US-5843106-$ or US-5885279-$ or US-5540706-$ or US-5922003-$ or US-6004199-$ or US-RE38018-$ or US-8147424-$ or US-6382974-$ or US-7959641-$ or US-4759746-$ or US-4900300-$ or US-4955883-$ or US-4955887-$ or US-4689040-$ or US-4706669-$ or US-4753234-$ or US-4841984-$ or US-5019035-$ or US-5284472-$ or US-5733297-$).did. or (US-5807277-$ or US-5112299-$ or US-5123904-$ or US-7842034-$ or US-7244256-$ or US-5957914-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:18
S53	219	S50 or S52	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:18
S54	0	S53 and schlemms	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:18

S55	21	S53 and schlemm$2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:19
S56	199	blade$1 and schlemm$2 adj canal	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/05/13 11:43

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	1	(dual adj blade and schlemm$2).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/05/14 20:28
L3	14	(cutting adj edges and schlemm$2).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/05/14 20:28
S39	1	(dual adj blade and schlemm$2).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:08
S40	9	("20020111608" | "6428539" | "6419684" | "5112299" | "4900300" | "4501274" | "6217598" | "5123904" | "5807277" | "20020111608").PN.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:12
S41	29	("3294085" | "5681282" | "5755716" | "5885279" | "6290699" | "5123904" | "7244256" | "3294085" | "5807277" | "6068629" | "6217598" | "6419684" | "4900300" | "5755716" | "7842034" | "20020002372" | "4900300" | "5431646" | "6979328" | "6428539" | "4501274" | "5269782" | "5807277" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "4501274" | "5123904" | "6283961" | "6432104" | "7842034" | "RE38018" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "20020111608" | "6382974" | "20020002372" | "6419684" | "6432104" | "6979328" | "5112299" | "5269782" | "5957914" | "6419684" | "7959641" | "6217598" | "6428539" | "5458595" | "6428539" | "7244256").PN.	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:15
S42	73	(606/107 or 606/161-162 or 606/166-167 or 606/170).ccls. and (eye and schlemm)	US-PGPUB; USPAT; UPAD	OR	ON	2015/03/09 13:18
S43	14	(cutting adj edges and schlemm$2).clm.	US-PGPUB; USPAT;	OR	ON	2015/03/09 13:23

			UPAD			
S44	76	("20050159767" | "20150045820" | "4689040" | "4955887" | "6419684" | "3294085" | "6382974" | "6388043" | "20070010812" | "4753234" | "4759746" | "5123904" | "7244256" | "20040210245" | "4900300" | "5112299" | "5540706" | "5733297" | "6217598" | "7244256" | "8147424" | "RE38018" | "4900300" | "5755716" | "7842034" | "20060149194" | "7935131" | "20040204732" | "20060241580" | "5284472" | "5957881" | "5964777" | "6382974" | "6428539" | "4501274" | "5269782" | "5807277" | "20070073275" | "20110077626" | "20110230877" | "6720402" | "7632303" | "20020111608" | "4841984" | "4955883" | "5123904" | "5807277" | "5843106" | "5922003" | "5957914" | "20020111608" | "5112299" | "5458596" | "5885279" | "5957914" | "20060106370" | "3882872" | "7785321" | "8038923" | "20060212060" | "20070276420" | "20120123533" | "6004199" | "5431646" | "5681282" | "6068629" | "6283961" | "6290699" | "7959641" | "RE38018" | "20090248141" | "5569283" | "20090287233" | "4706669" | "6293957" | "20020002372" | "6419684" | "6432104" | "6979328" | "20030208217" | "6759481" | "7604663" | "7648591" | "20020038129" | "5019035" | "5885279" | "6217598" | "6428539" | "7955387").PN.	US-PGPUB; USPAT; UPAD	OR	ON	2015/05/13 08:25
S57	44	"Term Removed" or "Term Removed" or "Term Removed"	US-PGPUB; USPAT	OR	OFF	2015/05/13 11:11
S58	44	"Term Removed" or "Term Removed" or "Term Removed"	US-PGPUB; USPAT	OR	OFF	2015/05/13 11:13
S59	44	"Term Removed" or "Term Removed" or "Term Removed"	US-PGPUB; USPAT	OR	OFF	2015/05/13 11:15

5/ 14/ 2015 9:43:28 PM
C:\ Users\ aweisberg\ Documents\ EAST\ Workspaces\ 14481754.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY R WEISBERG	3734

CPC						
Symbol					**Type**	**Version**
A61F		9	/	00781	F	2013-01-01
A61B		18	/	1482	I	2013-01-01
A61B		2018	/	00083	A	2013-01-01
A61B		2018	/	1497	A	2013-01-01
A61F		9	/	007	A	2013-01-01
A61F		9	/	0079	A	2013-01-01
A61B		17	/	320016	I	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	10	
/AMY R WEISBERG/ Examiner.Art Unit 3734	05/14/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY R WEISBERG	3734

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
606	167	A	6	1	B	17 / 32 (2006.01.01)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

(Assistant Examiner)	(Date)	Total Claims Allowed: 10	
/AMY R WEISBERG/ Examiner.Art Unit 3734	05/14/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14481754	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY R WEISBERG	3734

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	2														
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7	7														
8	8														
9	9														
10	10														

(Assistant Examiner)	(Date)	**Total Claims Allowed:** 10	
/AMY R WEISBERG/ Examiner.Art Unit 3734	05/14/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/481,754	09/09/2014	3734	800	NEOME-019A3-US-G2	2	1

CONFIRMATION NO. 9581

CORRECTED FILING RECEIPT

33197
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

Date Mailed: 06/10/2015

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

John T. Sorensen, Lake Elsinore, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

Applicant(s)

Neomedix Corporation, Tustin, CA;

Power of Attorney:
Frank Uxa Jr--25612
Robert Buyan--32460
Donald Stout--34493
Kenton Mullins--36331
Linda Nassif--38883

Domestic Priority data as claimed by applicant

This application is a DIV of 13/159,356 06/13/2011 ABN *
which is a DIV of 10/560,267 05/11/2006 PAT 7959641
which is a 371 of PCT/US2004/018488 06/10/2004
which claims benefit of 60/477,258 06/10/2003
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 09/16/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/481,754**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2	9581

33197 7590 06/10/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER
WEISBERG, AMY REGINA

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
06/10/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 14481754
Applicant : Sorensen
Filing Date : 09/09/2014
Date Mailed : 06/10/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

Even if the Office has recognized a benefit claim and has entered it into the Office's database and included it on applicant's filing receipt, the benefit claim is not a proper benefit claim unless the reference in compliance with 37 CFR 1.78 is included, depending upon the application's filing date and as indicated in the attachment, in an application data sheet or in the first sentence(s) of the specification and all other requirements are met.

See attachment.

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Vermel Wilson/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 14481754

APPLICATION FILED ON OR AFTER MARCH 16, 2013, NOT IN COMPLIANCE WITH 37 CFR 1.78

☐ The 37 CFR 1.78(c)(2) reference on the application data sheet does not indicate the relationship (continuation, division, continuation-in-part) to the prior U.S. nonprovisional application or international application designating the U.S. See document coded dated , listing application number(s) .

☐ The 37 CFR 1.78(c)(2) reference on the application data sheet does not provide the U.S. nonprovisional application number (series code and serial number) or, with respect to an international PCT application designating the U.S., it provides the international application number or international filing date but not both. See document coded dated , in which the following is missing: .

☐ The 37 CFR 1.78(c)(2) reference on the application data sheet shows an incorrect, incomplete, or illegible U.S. nonprovisional application number, international PCT application number, or international PCT filing date. See document coded dated , in which the following error was made: .

☐ The 37 CFR 1.78(c)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet, thus removing the validating link under 35 U.S.C. 119(a)-(d) to a prior foreign application or under 35 U.S.C. 119(e) to a prior U.S. provisional application.

☐ The 37 CFR 1.78(c)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet.

☐ The 37 CFR 1.78(a)(3) reference to the prior U.S. provisional application is not present on an application data sheet.

☐ The 37 CFR 1.78(a)(3) reference to the prior U.S. provisional application on an application data sheet does not provide the provisional application number (series code and serial number). See document coded dated , in which the following is missing: .

☐ The 37 CFR 1.78(a)(3) reference to the prior U.S. provisional application on an application data sheet shows an incorrect, incomplete, or illegible U.S. provisional application number. See document coded dated , in which the following error was made: .

☒ Other: The 37 CFR 1.78 (a)(2) reference does not indicate that application 10/560267 is the national stage of prior international application PCT/US2004/018488. See document coded ADS dated 9/9/14..

HOW TO RESPOND

A proper response to this notice would include: (1) a corrected Application Data Sheet (ADS) pursuant to 37 CFR 1.76(c) which provides the benefit information from the attached filing receipt which would make the benefit information comply with 37 CFR 1.78(c)(2) or 37 CFR 1.78(a)(3) or (2) a petition filed pursuant to the provisions of 37 CFR 1.78(b) or 37 CFR 1.78(d) if the benefit information from the attached filing receipt does not accurately reflect the benefits under 35 U.S.C. 119(e), 120, 121 or 365(c) as claimed by applicant (a grantable petition would include a corrected ADS as required by 37 CFR 1.78(b)(1) or 37 CFR 1.78(d)(1)).

WARNING: If Applicant fails to timely submit a proper response, the benefit information will be deleted and the patent will be printed without the benefit information present.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

STOUT, UXA & BUYAN, LLP
4 Venture, Suite 300
Irvine, CA 92618

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOME019A3-US-G2	9581

TITLE OF INVENTION:

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
Nonprovisional	Yes	$480	$0	$0	$480	08/19/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Robert D. Buyan
2 Stout, Uxa & Buyan, LLP
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: NeoMedix Corporation

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Tustin, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ■ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☑ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-0878 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Robert D. Buyan/ Date 06/24/2015

Typed or printed name Robert D. Buyan Registration No. 32,460

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	14481754
Filing Date:	09-Sep-2014
Title of Invention:	METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Filer:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3-US-G2

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt

EFS ID:	22731590
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Robert D. Buyan
Filer Authorized By:	
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	24-JUN-2015
Filing Date:	09-SEP-2014
Time Stamp:	17:35:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$480
RAM confirmation Number	15784
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	NEOME-019A3US-G2-ADS-REVISED-FILED.pdf	1561560 eb83604db486f6bd0d28c3906de8f9d53b3ce557	no	8
Warnings:					
Information:					
2	Application Data Sheet	NEOME-019A3US-G2-ADS-REVISED-MARKED.pdf	588219 61f7c20881aefbe8ffae36aea05aad3599b29ad3	no	8
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Transmittal Letter	NEOME-019A3US-G2-Response2-PostAllowance-FILED.pdf	30233 bbd2b187f56975732454dfa60a65e6d2d658864a	no	1
Warnings:					
Information:					
4	Issue Fee Payment (PTO-85B)	NEOME-019A3-US-G2-ptol85b.pdf	75114 f3db8e46a9ecd2252688e18af5cc71c1bdf697f9	no	2
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30687 5320a1bf5c3a556c671e2566e96f85cd06eeec76	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2285813		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	T.	Sorensen	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Lake Elsinore	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	21 Via del Macci Court		
Address 2			
City	Lake Elsinore	State/Province	CA
Postal Code	92532	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		Mittelstein	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Soheila		Mirhashemi	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	**State/Province**	CA
Postal Code	92677	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	33197		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT		
Attorney Docket Number	NEOME-019A3-US-G2	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(•) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	33197		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	13159356	2011-06-13

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13159356	Division of	10560267	2006-05-11	7959641	2011-06-14

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10560267	a 371 of international	PCTUS2004018488	2004-06-10

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTUS2004018488	Claims benefit of provisional	60477258	2003-06-10

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	Neomedix Corporation

Mailing Address Information:

Address 1	15042 Parkway Loop # A		
Address 2			
City	Tustin	**State/Province**	CA
Country [i]	US	Postal Code	92780-6528
Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Email Address	

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/Robert D. Buyan/			Date (YYYY-MM-DD)	2014-09-09
First Name	Robert	Last Name	Buyan	Registration Number	32460

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	T.	Sorensen	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Lake Elsinore	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	21 Via del Macci Court		
Address 2			
City	Lake Elsinore	State/Province	CA
Postal Code	92532	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		Mittelstein	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Laguna Niguel	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Soheila		Mirhashemi	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

City	Laguna Niguel	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	33197		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT		
Attorney Docket Number	NEOME-019A3-US-G2	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(●) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	33197		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	13159356	2011-06-13

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13159356	Division of	10560267	2006-05-11	7959641	2011-06-14

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10560267	a 371 of international	PCTUS2004018488	2004-06-10

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTUS2004018488	Claims benefit of provisional	60477258	2003-06-10

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name	Neomedix Corporation		
Mailing Address Information For Applicant:			
Address 1	15042 Parkway Loop # A		
Address 2			
City	Tustin	**State/Province**	CA
Country	US	Postal Code	92780-6528
Phone Number		Fax Number	

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Email Address	

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Signature	/Robert D. Buyan/			Date (YYYY-MM-DD)	2014-09-09
First Name	Robert	Last Name	Buyan	Registration Number	32460

Additional Signature may be generated within this form by selecting the Add button.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent C o o p eration Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	14/481,754	CONFIRMATION NO.: 9581
APPLICANT	:	JOHN T. SORENSEN ET AL.	
FILED	:	SEPTEMBER 9, 2014	
TC/A.U.	:	3734	
EXAMINER	:	AMY REGINA WEISBERG	
ATTY. DOCKET NO.	:	NEOME-019A3-US-G2	
CUSTOMER NO.		: 33197	
TITLE	:	METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT	

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT IN RESPONSE TO POST-ALLOWANCE FORMALITY NOTICE

Madam:

In response to the Notice to File Corrected Application Papers dated June 10, 2015, filed herewith is a corrected Application Data Sheet (ADS) Form PTO/AIA/14 along with a photocopy of such revised ADS on which the corrections are underlined.

No additional fee is seen to be due. However, the Commissioner is hereby authorized to charge any fee properly deemed to be due from Deposit Account No. 50-0878.

Respectfully submitted,

Date: June 24, 2015

STOUT, UXA, BUYAN & MULLINS, LLP

/Robert D. Buyan/

Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750 / Facsimile: (949) 450-1764

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	08/18/2015	9107729	NEOME-019A3-US-G2	9581

33197 7590 07/29/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

John T. Sorensen, Lake Elsinore, CA;
Neomedix Corporation, Tustin, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	14/481,754
Filing Date	09-09-2014
First Named Inventor	John T. Sorensen
Title	METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT
Art Unit	3734
Examiner Name	WEISBERG, AMY REGINA
Attorney Docket Number	88928.0006\US3

SIGNATURE of Applicant or Patent Practitioner

Signature	/Xiaomin Su/	Date (Optional)	
Name	Xiaomin Su	Registration Number	73,445
Title (if Applicant is a juristic entity)	Patent Practitioner		
Applicant Name (if Applicant is a juristic entity)	MICROSURGICAL TECHNOLOGY, INC.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/80 (07-17)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

[X] Practitioners associated with Customer Number: 29693

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

[ ] The address associated with Customer Number:

OR

[ ]

Firm or individual name		
Address		
City	State	Zip
Country		
Telephone	Email	

Assignee name and address: MICROSURGICAL TECHNOLOGY, INC.
8415 154th Avenue NE, Redmond, Washington 98052

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature	Date 02 December 2019
Name Ramin Mojdehbakhsh	Telephone 425-577-8373
Title President	

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: John T. Sorensen et al.

Application No./Patent No.: 14/481,754 Filed/Issue Date: 2014-09-09

Titled: METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

MICROSURGICAL TECHNOLOGY, INC., a Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: SORENSEN, JOHN T. et al. To: NEOMEDIX CORPORATION

   The document was recorded in the United States Patent and Trademark Office at

   Reel 017604, Frame 0694, or for which a copy thereof is attached.

2. From: NEOMEDIX To: MICROSURGICAL TECHNOLOGY, INC.

   The document was recorded in the United States Patent and Trademark Office at

   Reel 050798, Frame 0501, or for which a copy thereof is attached.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Xiaomin Su/	2020-03-06
Signature	Date
Xiaomin Su	73,445
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Corrected ADS

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NE[redacted]2 88928.0006\US3
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	T.	Sorensen	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Lake Elsinore	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	21 Via del Macci Court		
Address 2			
City	Lake Elsinore	State/Province	CA
Postal Code	92532	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Michael		Mittelstein	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Soheila		Mirhashemi	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

City	Laguna Niguel	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	29412 Clipper Way		
Address 2			
City	Laguna Niguel	State/Province	CA
Postal Code	92677	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	~~89157~~ 29693		
Email Address	ptodocket@wiley.law	Add Email	Remove Email

Application Information:

Title of the Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT		
Attorney Docket Number	~~NEOME-019A3-US-G~~2 88928.0006\US3	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	(•) Customer Number	( ) US Patent Practitioner	( ) Limited Recognition (37 CFR 11.9)
Customer Number	~~55197~~ 29693		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	13159356	2011-06-13
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13159356	Division of	10560267	2006-05-11	7959641	2011-06-14

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10560267	a 371 of international	PCTUS2004018488	2004-06-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTUS2004018488	Claims benefit of provisional	60477258	2003-06-10

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [j] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name ~~Neomedix Corporation~~ Microsurgical Technology, Inc.

Mailing Address Information:

Address 1	~~15042 Parkway Loop #~~ A 8415 154th Avenue NE		
Address 2			
City	~~Tustin~~ Redmond	**State/Province**	~~CA~~ WA
Country [i] US		Postal Code	~~92780-6529~~ 98052
Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

Email Address	

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	~~/Robert D. Buyan~~/ /Xiaomin Su/			Date (YYYY-MM-DD)	~~2014-09-09~~ 2020-03-06
First Name	~~Robert~~ Xiaomin	Last Name	~~Buyan~~ Su	Registration Number	~~52400~~ 73445

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (12-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G2
	Application Number	
Title of Invention	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	38791786
Application Number:	14481754
International Application Number:	
Confirmation Number:	9581
Title of Invention:	METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT
First Named Inventor/Applicant Name:	John T. Sorensen
Customer Number:	33197
Filer:	Xiaomin Su
Filer Authorized By:	
Attorney Docket Number:	NEOME-019A3-US-G2
Receipt Date:	06-MAR-2020
Filing Date:	09-SEP-2014
Time Stamp:	13:39:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	88928_0006_US3_POA_executed.pdf	1468124 a56ede4666c41c3a4b1a934d566183ef9ef4fbb4	no	3

Warnings:

Information:					
2	Assignee showing of ownership per 37 CFR 3.73	aia0096.pdf	120489 bfb297b2eb094dd4bed8351c3caa6b9cf709bbfb	no	3
Warnings:					
Information:					
3	Application Data Sheet	88928_0006_US3_corrected_ADS.pdf	672067 82b50b54691fcf6d4b509150a65f61ab8890af2a	no	8
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
			Total Files Size (in bytes):	2260680	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/481,754	09/09/2014	John T. Sorensen	88928.0006/US3

CONFIRMATION NO. 9581

POA ACCEPTANCE LETTER

29693
WILEY
1776 K STREET N.W.
WASHINGTON, DC 20006

OC000000115392198

Date Mailed: 03/13/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/06/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sibrahim/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/481,754	09/09/2014	John T. Sorensen	NEOME-019A3-US-G2

CONFIRMATION NO. 9581

POWER OF ATTORNEY NOTICE

33197
STOUT, UXA & BUYAN, LLP
23461 South Pointe Drive
Suite 120
Laguna Hills, CA 92653

OC000000115392158

Date Mailed: 03/13/2020

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/06/2020.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sibrahim/