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UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	NEOME-019A3US-G
First Inventor	SORENSEN, John T.
Title	TUBULAR CUTTER DEVICE AND METHOD
Express Mail Label No.	N/A

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 13]
   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. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☑ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ **Application Data Sheet.** See 37 CFR 1.76
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 Neomedix Corporation
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
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:

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☑ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 10/560,267

Prior application information: *Examiner* TRUONG, Kevin Thao *Art Unit:* 3734

19. 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	June 13, 2011	
Name (Print/Type)	Robert D. Buyan			Registration No. (Attorney/Agent)	32,460

This collection of information is required by 37 CFR 1.53(b). 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 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, 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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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.
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NEOME-019A3-US-G
	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.)

Applicant Information:

Applicant 1 Remove

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

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

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

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Citizenship under 37 CFR 1.41(b) i: US

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Applicant 2 Remove

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Citizenship under 37 CFR 1.41(b) i: US

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Address 2	

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Applicant 3 Remove

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

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

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

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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	

Citizenship under 37 CFR 1.41(b) [i]	US		
Mailing Address of Applicant:			
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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	rbuyan@patlawyers.com	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	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	3	**Suggested Figure for Publication (if any)**	2

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.

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).
Enter either 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)

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

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(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	10560267	2006-05-11
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
10560267	a 371 of international	PCT/US2004/018488	2004-06-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2004/018488	non provisional of	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:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. 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(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			(•) Yes ( ) No

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Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. [X]

Organization Name	Neomedix Corporation

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

Mailing Address Information:			
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Address 2			
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Country [i]	US	Postal Code	92780-6528
Phone Number		Fax Number	
Email Address			
Additional Assignee Data may be generated within this form by selecting the **Add** button.		Add	

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Robert D. Buyan/			Date (YYYY-MM-DD)	2011-06-13
First Name	Robert	Last Name	Buyan	Registration Number	32460

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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.

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. 10/560,267 filed May 11, 2006, 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 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

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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

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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,

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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

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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

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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

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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.

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[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

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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.

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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.

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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.

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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.

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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.

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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.

PAGE 6/13 * RCVD AT 5/11/2006 8:12:54 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/3 * DNIS:2738300 * CSID:+949 450 1764 * DURATION (mm-ss):03-50

Attorney Docket No. NEOME-019A3US

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

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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.

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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

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State of CALIFORNIA

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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)

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Commission # 1437202
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Orange County
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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

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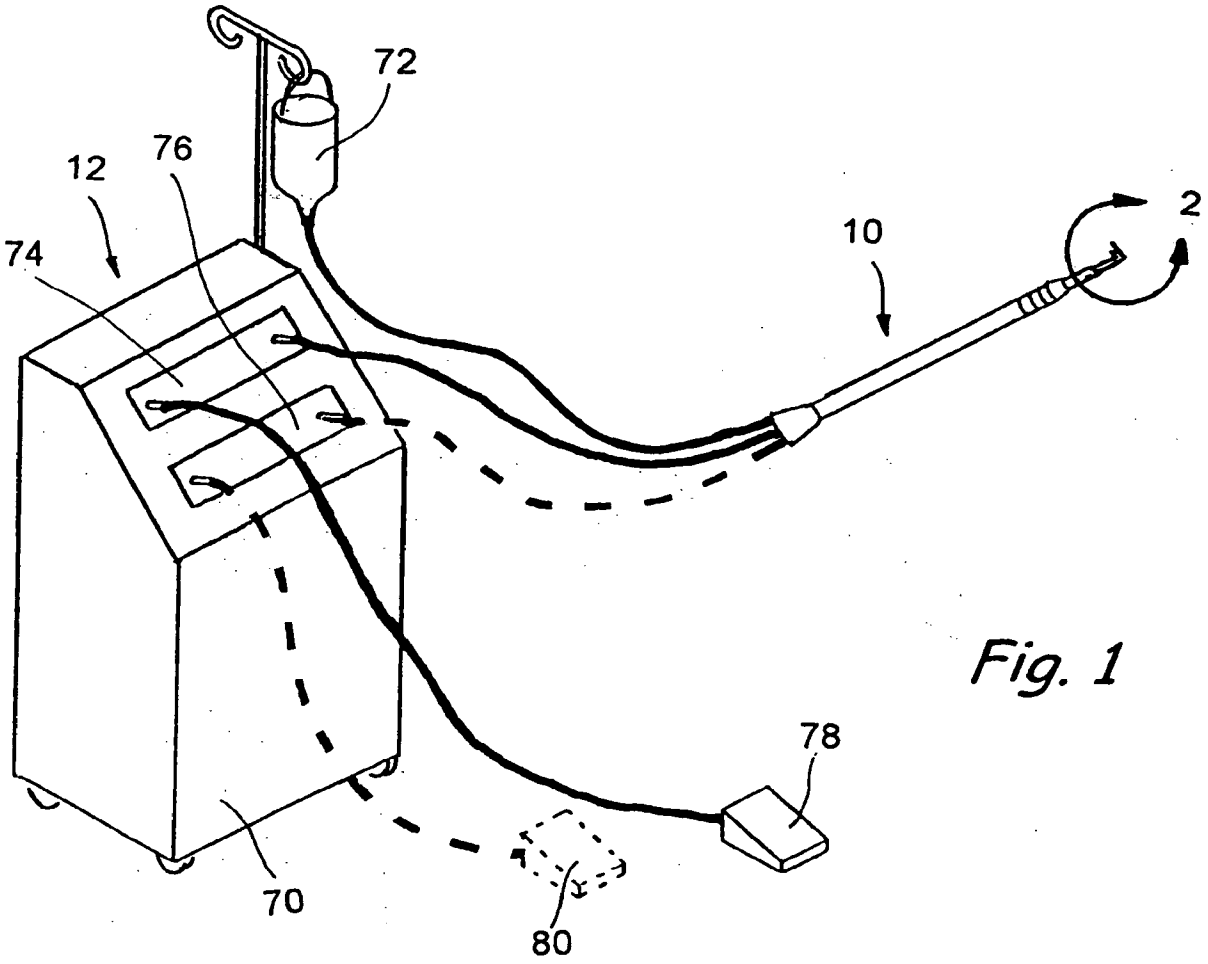

Fig. 1

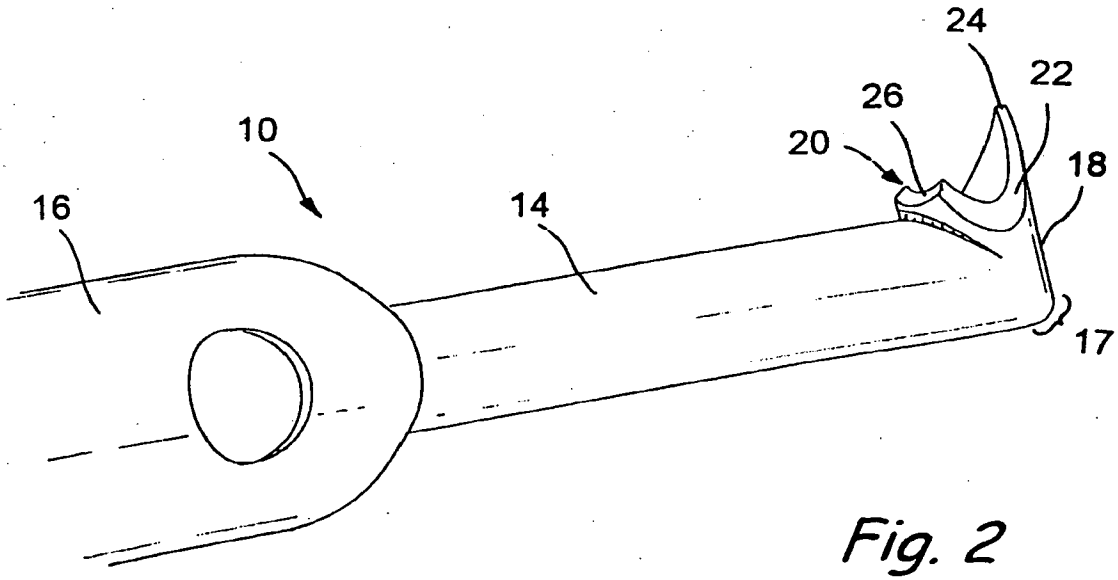

Fig. 2

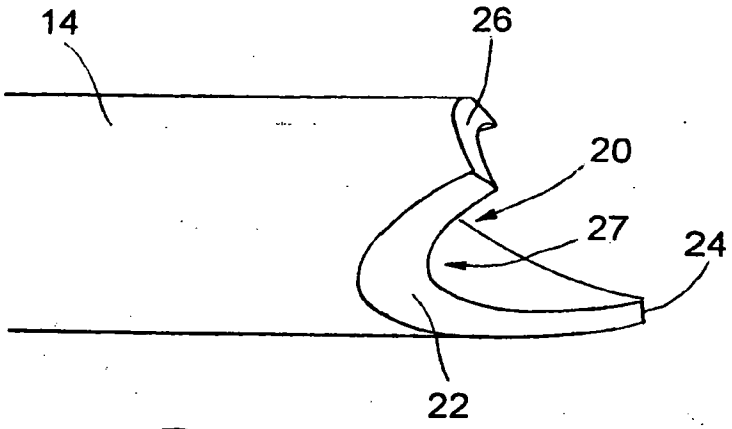

Fig. 3A

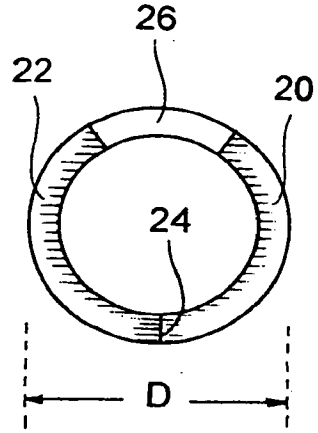

Fig. 3B

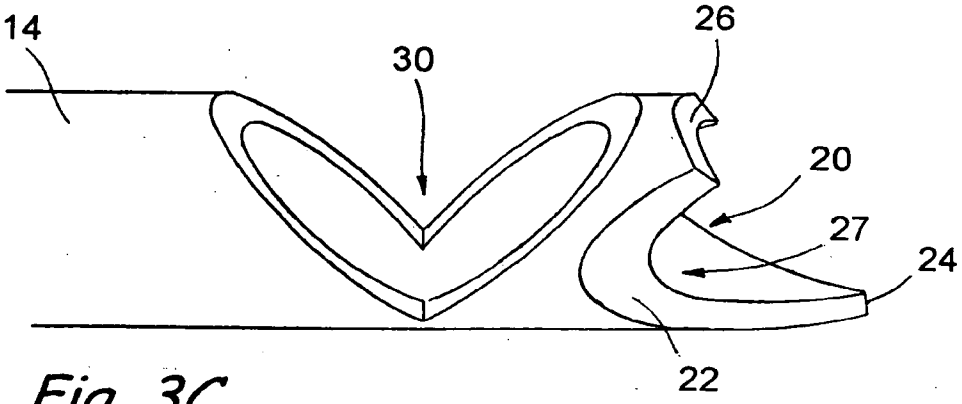

Fig. 3C

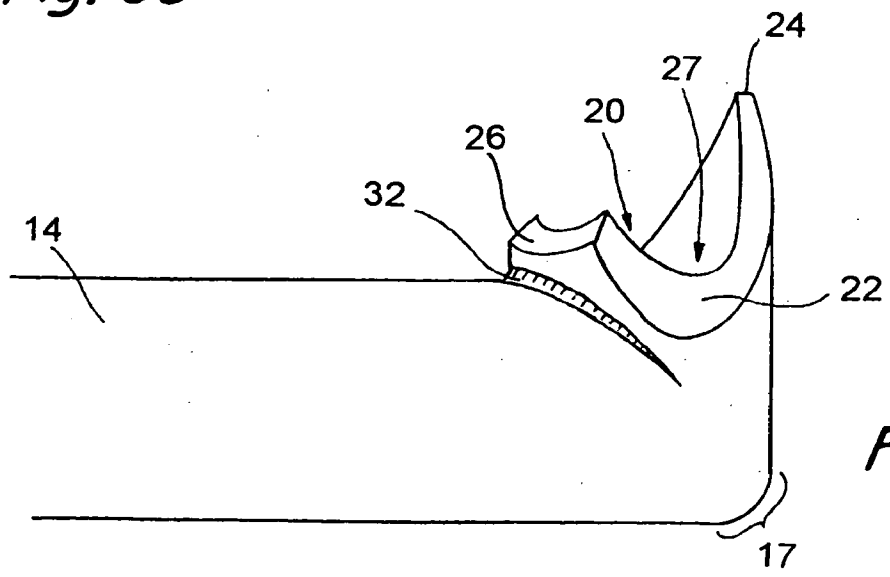

Fig. 3D

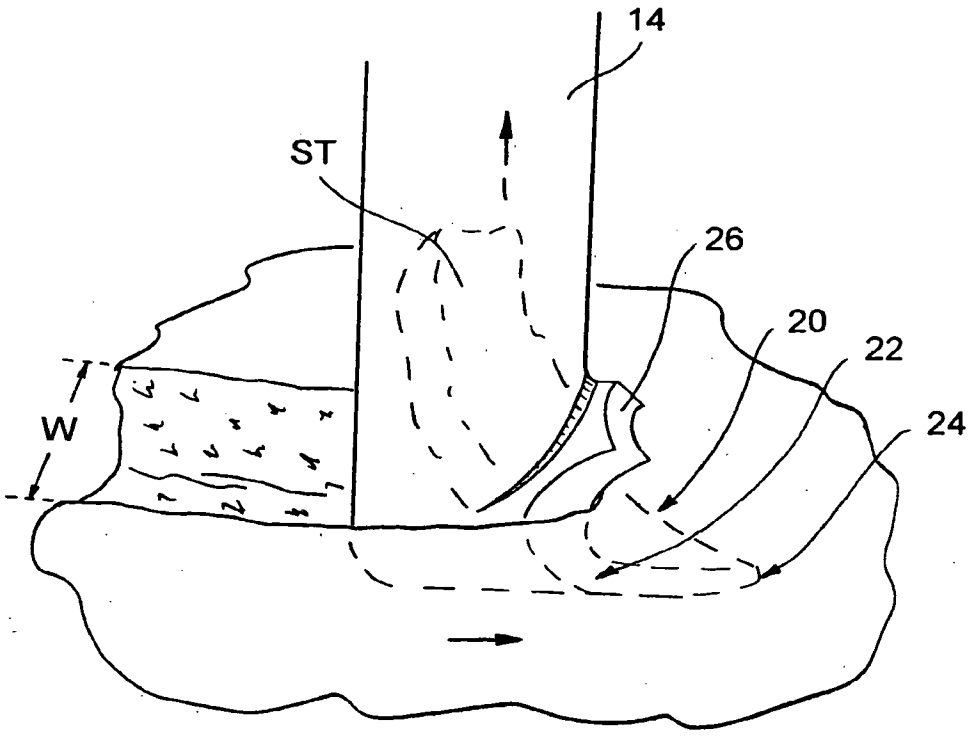

Fig. 4

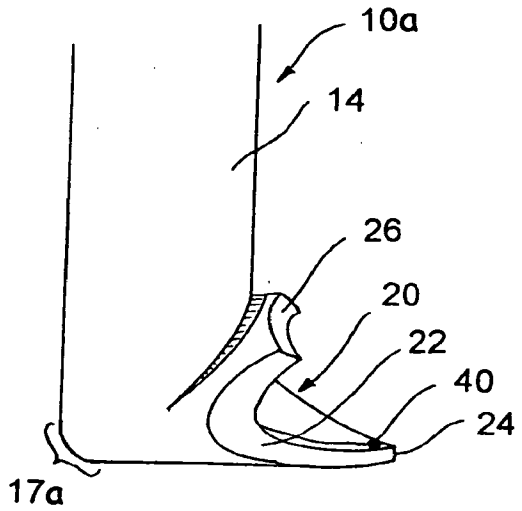

Fig. 5

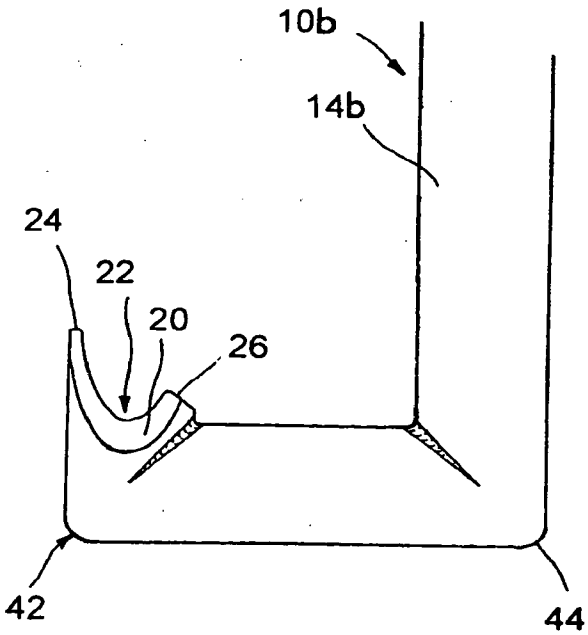

Fig. 6

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-019A3US-G

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	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Claims in excess of 20	2202	2	26	52
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**514**

Electronic Acknowledgement Receipt

EFS ID:	10294419
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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-019A3US-G
Receipt Date:	13-JUN-2011
Filing Date:	
Time Stamp:	21:00:50
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 of New Application	NEOME-019A3US-G-sb0005_fill.pdf	275263 13a1dc813568879a029a66054988653bd566037f	no	2

Warnings:	
Information:	

2	Application Data Sheet	NEOME-019A3US-G-sb0014_fill.pdf	1031712 4d831279cff5aad33ec113e454b0fecf88ea547c	no	5
Warnings:					
Information:					
3		NEOME-019A3-US-G-PatApp-Filed.pdf	1437021 2280bd9c85b0ac929b6efe8d2e51405e40be4897	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	9
	Claims	10	12
	Abstract	13	13

Warnings:					
Information:					
4	Oath or Declaration filed	NEOME-019A3US-G-Declaration.pdf	336585 4bde3681734b21438e0f290b680f2324014 2574f	no	8
Warnings:					
Information:					
5	Drawings-only black and white line drawings	NEOME-019A3-US-G-drawings.pdf	50328 ec1a5f32664f96d00ed36110c28a53a3a8c5 3ace	no	3
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	36783 43078318257c21cb257807762c00cb89783 7d87f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3167692		

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.

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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
13/159,356	06/13/2011	3731	0.00	NEOME-019A3-US-G	22	1

CONFIRMATION NO. 1298

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

FILING RECEIPT

OC000000048411971

Date Mailed: 06/27/2011

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**

Applicant(s)

John T. Sorensen, Ladera Ranch, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

Assignment For Published Patent Application

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 10/560,267 05/11/2006 PAT 7,959,641 *
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 (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 06/23/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/159,356**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

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

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 (1-866-999-4158).

Petitioner - New World Medical
Ex. 1019, p. 38 of 285

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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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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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
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3-US-G

CONFIRMATION NO. 1298

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

FORMALITIES LETTER

OC000000048411972

Date Mailed: 06/27/2011

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  *Applicant must submit $**82** to complete the basic filing fee for a small entity.*

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of $**52** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- A surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $**65** for a small entity in compliance with 37 CFR 1.27, must be submitted.

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is $**579** for a small entity

- $**82** Statutory basic filing fee.
- $**65** Surcharge.
- The application search fee has not been paid. Applicant must submit $**270** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit $**110** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.
- Total additional claim fee(s) for this application is $**52**
  - $**52** for **2** total claims over 20.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

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If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/jmilani/

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/159,356

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	82		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	270		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2	x 26 =	52	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 110 =	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 $270 ($135 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	514		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	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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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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
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3-US-G

CONFIRMATION NO. 1298

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

POA ACCEPTANCE LETTER

OC00000048419871

Date Mailed: 06/27/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/13/2011.

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.

/ttu/

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

NEOME-019A3US-G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	13/159,356	CONFIRMATION NO.: 1298
APPLICANT	:	JOHN T. SORENSEN, ET AL.	
FILED	:	JUNE 13, 2011	
TC/A.U.	:	TO BE DETERMINED	
EXAMINER	:	TO BE DETERMINED	
DOCKET NO.	:	NEOME-019A3US-G	
CUSTOMER NO.	:	33197	
TITLE	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT	

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

RESPONSE TO NOTICE TO FILE MISSING PARTS (FILING DATE GRANTED)

Dear Sir:

Applicant hereby responds to the Notice to File Missing Parts mailed June 27, 2011.

Small entity filing and extension fees due are being paid electronically concurrently with filing of this paper. The Commissioner is hereby authorized to charge any underpayment, or to credit any overpayment, to Deposit Account No.50-0878.

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

Date: November 28, 2011

/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

Petitioner - New World Medical
Ex. 1019, p. 44 of 285

Electronic Patent Application Fee Transmittal

Application Number:	13159356
Filing Date:	13-Jun-2011
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-019A3-US-G

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	95	95
Utility Search Fee	2111	1	310	310
Utility Examination Fee	2311	1	125	125
Pages:				
Claims:				
Claims in excess of 20	2202	2	30	60
Miscellaneous-Filing:				
Late filing fee for oath or declaration	2051	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	2253	1	635	635
Miscellaneous:				
		Total in USD ($)		**1290**

Electronic Acknowledgement Receipt

EFS ID:	11493489
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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-G
Receipt Date:	28-NOV-2011
Filing Date:	13-JUN-2011
Time Stamp:	20:00:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1290
RAM confirmation Number	6472
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 Letter	NEOME-019A3US-G-ResponseMP.pdf	81889 83cfb887974d2c63c128d38957e7eb0a164e3604	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40376 adfde0297efe266d9e3d1f2b731a6c34821a1a66	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	122265	

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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/159,356

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	95		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	310		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2	x 30 =	60	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 125 =	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	590		TOTAL	

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		(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	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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.
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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
13/159,356	06/13/2011	3731	655	NEOME-019A3US-G	22	1

CONFIRMATION NO. 1298

33197
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IRVINE, CA 92618

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OC00000051287243

Date Mailed: 12/09/2011

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**

Applicant(s)

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Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

Assignment For Published Patent Application

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 10/560,267 05/11/2006 PAT 7,959,641 *
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.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/159,356**

Projected Publication Date: 03/22/2012

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

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(Not for submission under 37 CFR 1.99)

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Filing Date	2011-06-13
First Named Inventor	Sorenson et al.
Art Unit	3731
Examiner Name	Unknown
Attorney Docket Number	NEOME-019A3-US-G

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	2	4900300	A	1990-02-13	Lee	
	3	5112299	A	1992-05-12	Pascaloff	
	4	5123904	A	1992-06-23	Shimomura et al.	
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	Examiner Name	Unknown
	Attorney Docket Number	NEOME-019A3-US-G

	9	6217598	B1	2001-04-17	Berman et al.	
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	Examiner Name	Unknown
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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.	
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	24	7959641	B2	2011-06-14	Sorensen et al.	

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	Art Unit	3731
	Examiner Name	Unknown
	Attorney Docket Number	NEOME-019A3-US-G

	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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	1	US Patent Office Action dated 09/29/2009 in related U.S. Application Serial No. 10/560,267 filed 05/11/2006.	☐
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	Art Unit	3731
	Examiner Name	Unknown
	Attorney Docket Number	NEOME-019A3-US-G

CERTIFICATION STATEMENT

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☒ None

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(51) International Patent Classification 6 : A61B 17/32

A1

(11) International Publication Number: **WO 98/27876**

(43) International Publication Date: 2 July 1998 (02.07.98)

(21) International Application Number: PCT/US97/23390

(22) International Filing Date: 17 December 1997 (17.12.97)

(30) Priority Data:
08/772,340 23 December 1996 (23.12.96) US

(71) Applicant: SMITH & NEPHEW, INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).

(72) Inventor: DION, Ernest, A.; 23 Garfield Avenue, Danvers, MA 01923 (US).

(74) Agents: STACEY, George, K. et al.; Smith & Nephew, Inc., 1450 Brooks Road, Memphis, TN 38116 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

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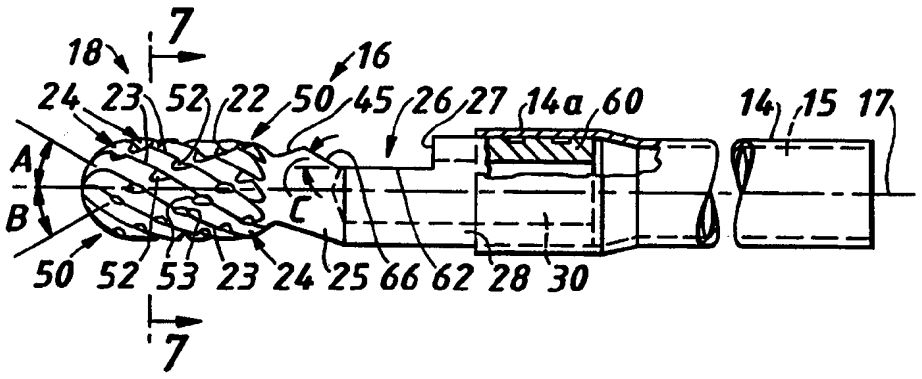

(57) Abstract

A surgical instrument comprises an inner tube which rotates within an outer tube and carries a surgical tool that includes a burr for cutting tissue exposed to the burr through an opening in the outer tube. The instrument includes several features which enhance the efficiency at which tissue fragments severed by the burr are aspirated through the inner tube, and which enable the burr to effectively cut relatively soft tissue as well as harder tissue such as bone. For example, the burr includes a proximal shank having a wall that has an aperture therein with a substantially width relative to an outer diameter of the wall for conveying tissue fragments cut by the burr into an interior chamber of the shank, and thence into a passage in the inner tube. The opening in the outer tube is axially elongated sufficiently to expose a major portion of the aperture. The large aperture and its exposure by the outer tube opening reduce the risk of clogging by admitting larger tissue fragments into the inner tube for aspiration. Additionally, the burr includes a plurality of grooves that are axially elongated and inclined transversely to the flutes, and the grooves define a plurality of axially spaced notches in each of the cutting edges. The notches divide the cutting edges into relatively small segments that produce correspondingly small tissue fragments (even when the burr is used to cut soft tissue) to further reduce the risk of clogging. In addition, the cutting edges are preferably provided with a positive rake that makes the cutting edges sharper and suitable for effectively cutting, rather than tearing or shredding, relatively soft tissue.

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DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
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SURGICAL INSTRUMENT

This invention relates to endoscopic surgical instruments, and in particular to powered endoscopic surgical instruments for, e.g., arthroscopy.

Powered endoscopic surgical instruments typically include a stationary outer tube within which an inner tube that carries a surgical tool on its distal end is rotated by a motor. Body tissue exposed to the surgical tool through an opening in the outer tube is cut by the rotating tool. Tissue fragments cut by the tool and irrigating fluid from the surgical site are drawn through an interior suction passage in the inner tube in response to suction applied at the proximal end of the instrument. Several such surgical instruments are described in U.S. Patent Nos. 4,203,444, 4,274,414, 4,834,729, 4,842,578, 4,983,179, and 5,322,505, all of which are assigned to the assignee of the present invention and incorporated herein by reference.

The configuration of the surgical tool is typically a function of the type of body tissue to be cut. For example, in instruments for cutting relatively soft tissue (such as cartilage and synovial tissue), the tool is a blade formed by sharpened edges of a window in the inner tube which cooperates with sharpened edges of the outer tube opening as the inner tube rotates. In an "abrader" for sculpting bone tissue, the surgical tool is a solid, fluted burr the proximal shank of which is mounted on the inner tube. The burr includes a series of axially elongated, inclined cutting edges spaced circumferentially around the burr by the flutes. A slot in the burr shank conveys bone fragments cut by the burr and irrigation fluid into the interior passage of the inner tube for removal by the applied suction.

This invention features a surgical instrument of the kind in which an inner tube rotates within an outer tube and carries a surgical tool that includes a burr for cutting tissue exposed to the burr through an opening in the outer tube. The invention provides several features which enhance the efficiency at which tissue fragments severed by the burr are aspirated through the inner tube, and which enable the burr to effectively cut relatively soft tissue as well as harder tissue such as bone.

In one general aspect of the invention, the burr includes a proximal shank having a wall that has an aperture therein with a substantial width relative to an outer diameter of the wall for conveying tissue fragments cut by the burr into an interior chamber of the shank, and thence into a passage in the inner tube.

Preferred embodiments may include one or more of the following features.

The width of the aperture is approximately one-half of the diameter of a wall of the shank. More preferably, the aperture width is greater than one-half of the wall diameter. A portion of the wall disposed adjacent to a distal end of the aperture includes an inclined surface that slopes proximally toward the aperture. The inclined surface is oriented at an acute angle to a pair of planar axial surfaces of the wall that define the sides of the aperture. The shank wall is tubular so that its interior chamber is substantially cylindrical.

The large aperture in the shank admits even large tissue fragments, thereby reducing the risk of clogging and enhancing the fluid flow rate supported by the instrument. The inclined surface

serves as a ramp which helps guide tissue fragments into the aperture for more efficient aspiration.

The burr includes a plurality of cutting edges circumferentially spaced by a plurality of flutes disposed in an exterior surface of the surgical tool, and at least one of the cutting edges includes at least one notch therein. Preferably, a plurality of axially spaced notches are provided in the cutting edge. More preferably, the axially spaced notches are provided in each one of the cutting edges. The cutting edges and the flutes are axially elongated and are inclined relative to a longitudinal axis of the burr.

In another general aspect of the invention, the opening in the outer tube is axially elongated sufficiently to expose a major portion of the aperture.

Preferred embodiments may include one or more of the following features.

The elongation of the outer tube opening is such that the proximal end of the opening is disposed adjacent to, and more preferably, proximally of, a proximal end of the aperture. The axially elongated opening exposes the burr to tissue along one side of the burr, and defines a hood in the outer tube for the opposite side of the burr. Because most, if not all, of the aperture is directly exposed to the tissue by the outer tube opening, tissue fragments more easily enter the aperture (and hence the suction passage) than if the fragments were required to travel proximally between the inner and outer tubes before reaching the aperture. This further reduces the risk of clogging and enhances aspiration efficiency.

In another general aspect of the invention, the burr includes a plurality of grooves that are axially elongated and inclined transversely to the flutes, and the grooves define a plurality of axially spaced notches in each of the cutting edges.

Preferred embodiments may include one or more of the following features.

The flutes and the grooves are oriented at opposite acute with angles respect to the longitudinal axis. Each flute defines a leading surface of a first one of the cutting edges and a trailing surface of a second, adjacent one of the cutting edges. The leading surface is oriented with respect to a radius of the cutting edge to define a positive rake for the cutting edge.

The notches provided in the cutting edges divide the cutting edges into relatively short, axially spaced segments. As a result, the cutting edges produce tissue fragments that are smaller than fragments that would be produced if the notches were not present. This is particularly useful when the burr is used to cut soft tissue, as the shorter cutting edge segments tend to chop up the soft tissue, rather than cutting long tissue strands that might become wound around the burr. The positive rake increases the sharpness of the cutting edges, thereby enabling the cutting edges to cut, rather than tear or shred, relatively soft tissue.

Other features and advantages will be apparent from the following detailed description and drawings, and from the claims.

Fig. 1 is a perspective view of a surgical instrument.

Fig. 2 is a side view, partially cut away, of the surgical instrument, showing an inner tube carrying a burr at its distal end disposed within an outer tube.

Fig. 3 is an enlarged, perspective view of the distal end of the surgical instrument, which shows the burr positioned within an axially elongated opening in the outer tube.

Fig. 4 is a side view, partially cut away, of the burr and the distal end of the inner tube.

Fig. 5 is an end view of the burr of Fig. 4.

Fig. 6 is a side view of the outer tube of the surgical instrument.

Fig. 7 is a cross-sectional view of the burr, taken along line 7-7 of Fig. 4.

Fig. 8 is an enlarged view of one of the cutting edges of the burr located within circle 8-8 of Fig. 7.

Fig. 9 shows the surgical instrument in use.

Referring to Figs. 1-3, surgical instrument 10 includes a stationary outer tube 12 within which an inner tube 14 is rotatably disposed. A surgical tool 16 including a fluted burr 18 and a proximal shank 19 is mounted to a distal end of inner tube 14. Burr 18 is exposed to tissue through an opening 20 in the distal end of outer tube 12. As discussed in more detail below, the configuration of burr 18 renders it suitable for cutting both bone tissue and softer tissue (such as cartilage and synovial tissue).

Briefly, burr 18 includes a plurality of axially elongated, inclined sharpened cutting edges 22 circumferentially spaced from each other by correspondingly axially elongated, inclined flutes 24 disposed in an exterior surface of burr 18. Burr 18 is a solid distal extension of shank 19, which is tubular, and is connected to shank

19 by a tapered neck 25. A large aperture 26 in an exterior wall 28 of shank 19 intersects a cylindrical interior chamber 30 in shank 19 for admitting tissue fragments and irrigating fluid into chamber 30.

Inner tube 14 includes a suction passage 15 that communicates with chamber 30. During use, as inner tube 14 rotates, tissue exposed to burr 18 is cut by rotating cutting edges 22, and the resulting tissue fragments and irrigating fluid are conveyed through aperture 26 into chamber 30. Suction applied to passage 15 at the proximal end 32 of instrument 10 transports the tissue fragments and irrigating fluid proximally through inner tube 14 for removal from the body, while surgical instrument 10 remains *in situ* for further cutting.

Outer tube 12 is rigidly mounted to a hub 34 at proximal end 33. Hub 34 rotatably receives a base 36 to which the proximal end of inner tube 14 is attached. Base 36 is retained in hub 30 by a pliable fitting 38. Passage 15 terminates proximally in a suction port 40 in base 34. This construction is described, for example, in the above-discussed U.S. Patent No. 5,322,505.

During use, proximal end 32 of instrument 10 is inserted into a handpiece 90 (shown in Fig. 9), which includes a motor 92 for engaging the proximal end 37 of base 36, which serves as a drive shaft for inner tube 14. Operation of the motor rotates inner tube 14 (and thus burr 18) within outer tube 12. (One example of such a handpiece is described in U.S. Pat. No. 4,705,038, assigned to the assignee of the present invention, and incorporated by reference herein.) Fitting 38 provides a fluid-tight seal with handpiece 90. As discussed below, handpiece 90 applies suction from an external

vacuum source 96 to suction port 40 to withdraw the tissue fragments and irrigating fluid from inner tube 14.

Surgical instrument 10 is preferably disposable, that is, the device is made to be discarded after a single (or relatively few) uses. Outer tube 12 is made from stainless steel, while inner tube 14 is fabricated from softer, phosphor bronze (e.g., Alloy A UNS 51000) for purposes to be described. Hub 34 and base 36 are plastic. Other materials may be used instead if, e.g., surgical instrument 10 is to be autoclavable and reusable.

Surgical tool 16 is shown in detail in Figs. 3-5. Cutting edges 22 of burr 18 are primarily constructed and arranged to cut relatively hard tissue such as bone, but as discussed below, the configuration of burr 18 enables cutting edges 22 to effectively cut softer tissue as well. Burr 18 and shank 19 comprise an integral unit made from a single member of stainless steel (e.g., Type S45500) and is hardened to a Rockwell hardness of at least 45. Cutting edges 22 are defined by a set of axially elongated flutes 24 formed (such as by machining) in the exterior surface of burr 18. Flutes 24 are inclined at an acute angle **A** (e.g., 30 degrees) with respect to a longitudinal axis 17 of surgical tool 16 and inner tube 14. As a result, cutting edges 22 are also axially elongated and inclined at acute angle **A** with respect to longitudinal axis 17. A total of twelve cutting edges 22 are distributed around the periphery of burr 18 and are equally circumferentially spaced from each other by flutes 24.

Cutting edges 22 extend axially from a generally hemispherical distal tip 44 of burr 18 to the junction 45 between burr 18 and neck 25. At distal tip 44, cutting edges 22 are oriented transversely to longitudinal axis 17 and extend radially from the center 47 of distal

tip 44 to the periphery of burr 18. Slightly proximally of tip 44, cutting edges 22 curve helically and extend axially along the periphery of burr 18 at inclination angle **A**, discussed above.

A plurality of axially elongated grooves 50 are formed in burr 18 transversely to cutting edges 22 and flutes 24. Grooves 50 are inclined at an acute angle **B** with respect to longitudinal axis 17. Preferably, groove angle **B** is equal to, but oppositely directed from, flute angle **A**, and thus in this embodiment grooves 50 are oriented at -30 degrees with respect to longitudinal axis 17. Grooves 50 define a series of axially spaced, sharpened V-shaped notches 52 in cutting edges 22. Notches 52 are cut relatively deeply into cutting edges 22; for example, notches 52 are 80% of the depth of flutes 24. Notches 52 interrupt each cutting edge 22, dividing it into a series of shorter, axially spaced segments 23 each of which includes a sharpened, transverse cutting surface 53 defined by an edge of a notch 52. The shorter segments 23 produce correspondingly smaller tissue fragments for easier aspiration from the surgical site without clogging aperture 26, chamber 30, or passage 15.

For example, when bone tissue is being cut by burr 18, the bone fragments produced by cutting edge segments 23 are smaller then they would be if notches 52 were not present, thereby allowing the fragments to more easily pass into suction passage 15 via aperture 26 and chamber 30. In addition, when burr 18 is used on softer tissue, the sharpened edges 53 of notches 52 cause cutting edge segments 23 to chop up the tissue into small pieces (rather than longer strips, as could be produced in cutting edges 22 were not interrupted by notches 52). As a result, the tendency of the severed tissue to wrap around and become caught on burr 18 is reduced, and the smaller pieces of tissue are easily conveyed

through shank aperture 26 and chamber 30 and into suction passage 15.

The risk of clogging is further reduced by the relatively large size of aperture 26 and the cylindrical configuration of chamber 30. That is, unlike conventional burrs which include a long, narrow slot (e.g., 0.075 inches in width) in the shank for conveying bone fragments into the inner tube suction passage, aperture 26 has a substantial width and opens into an even larger cylindrical chamber 30. Preferably, the width **W** of aperture 26 is at least one-half of, and more preferably greater than one-half of, the diameter of wall 28. For example, aperture 26 has a width **W** of approximately 0.135 inches, while the outer diameter of wall 28 is about 0.22 inches. Aperture 26 is approximately 0.210 inches long, and is thus much less oblong than the slots found in conventional burr shanks. Chamber 30 has a diameter of between 0.140 inches and 0.150 inches, and extends proximally from aperture 26 to the proximal end 60 of shank 19. Chamber 30 thus readily accommodates even large tissue fragments conveyed through aperture 26.

As shown in Figs. 3 and 4, the sides of aperture 26 are defined by a pair of flat axial surfaces 62, 64 that lie in a common plane recessed from the exterior surface of wall 28 and parallel to longitudinal axis 17. A flat, inclined surface 66 is formed in wall 28 at the distal end of aperture 28. Surface 66 slopes proximally toward aperture 26 from neck 25, and meets the plane defined by surfaces 62, 64 at the distal end of aperture 26. The angle **C** between surface 66 and the plane of surfaces 62, 64 is preferably shallow, such as approximately 30 degrees. As a result, surface 66 serves as a ramp which guides tissue fragments cut by burr 18 past neck 25 and into aperture 26.

Referring to Figs. 3 and 6, outer tube opening 20 is sufficiently axially elongated to expose substantially all of aperture 26. Thus, unlike typical abrading instruments, in which the majority of the tissue-admitting opening in the burr shank (i.e., the slot) is covered by the outer tube, substantially the entire length of aperture 26 is exposed by opening 20. This, combined with the increased size of aperture 26, significantly improves the flow path for the irrigation fluid and tissue fragments aspirated into inner tube passage 15, thereby dramatically increasing the efficiency at which the severed tissue fragments are aspirated through inner tube 14.

More specifically, the increased axial elongation of outer tube opening 20 is provided by decreasing the angle defined between the edges 70 of opening 20 and longitudinal axis 17. Edges 70 are flat and define an entrance plane for opening 20 which is oriented at a relatively shallow angle D, for example, approximately 15 degrees, to longitudinal axis 17. As a result, opening 20 is substantially longer than outer tube openings of typical abrading instruments (the edges of such openings are generally oriented at a relatively large angle, such as 25 degrees, to the longitudinal axis). As a result, outer tube opening 20 is "laid back" so that its proximal end 72 is positioned adjacent to -- and preferably proximally of -- the proximal end 27 of aperture 26 (Fig. 3). Put another way, proximal end 72 of opening 20 is located well behind (such as by 0.8 inches) the distal tip of outer tube 12.

At the distal tip of outer tube 12, the edges 70 of opening 20 are rounded to meet a distal transverse edge 74. Edge 74 is blunt and preferably is positioned slightly proximally of distal tip 44 of burr 18. This allows burr distal tip 44 to be used for end-on cutting, if

desired. The axial elongation of opening 20 defines a distal portion of outer tube 12 which serves as a hood 13 for one side of burr 18. Put another way, hood 13 partially surrounds one side of burr 18, to protect adjacent tissue from the cutting action of burr 18, while also exposing the opposite side (and distal tip 44) of burr 18 to the tissue that the surgeon desires to cut.

Referring to Figs. 7 and 8, cutting edges 22 are configured to enable burr 18 to effectively cut soft tissue as well as harder tissue such as bone. One aspect of this construction -- notches 52, which break up the cutting action of edges 22 -- is discussed above. Another feature is that the so-called "rake" of cutting edges 22 is made to be neutral to slightly positive, rather than highly negative as in conventional burrs.

The rake of a cutting edge is defined by the angle between the leading surface of the cutting edge (that is, the surface that first impacts the tissue during rotation of the burr) and the radius of the burr. Each cutting edge 22 is defined by a leading surface 80 from one flute 24 and a trailing surface 82 from an adjacent flute 24. Leading surface 80 defines an angle **E** with the radius 84 of the cutting edge 22. (Radius 84 is formed by a line which extends from the center of burr 18 on longitudinal axis 17 through cutting edge 22 at the periphery of burr 18.) As shown in Fig. 8, angle **E** is slightly negative (i.e., below radius 84), for example, between 5 degrees and 10 degrees. As a result, the cutting edge 22 shown in Fig. 8 has a slightly negative rake.

Preferably, however, flutes 24 are undercut further during fabrication to define leading surfaces 80' that lie on or below radius 84. In this case, the angle **E'** defined by surface 80' is zero to

slightly positive (by, e.g., a few degrees), and as a result cutting edges 22 have a neutral to slightly positive rake. When cutting edges 22 are made having this configuration, edges 22 are sharper than they would be if they had a negative rake. Accordingly, fabricating cutting edges 22 in this fashion renders edges 22 suitable for efficiently cutting (rather than tearing or shredding) relatively soft tissue.

Surgical tool 16 is manufactured from a cylindrical, stainless steel blank with a hemispherical tip as follows. First, shank 19 and neck 25 (Fig. 3) are machined at the proximal end of the blank, and chamber 30 is drilled out. Then, the blank is heat treated to harden it to the required Rockwell hardness. Twelve flutes 24 are then machined by grinding to define cutting edges 22 at the desired neutral to slightly positive rake discussed above. Next, the blank is repositioned in the grinding machine, and six grooves 50 are ground to define notches 52 in cutting edges 22.

Aperture 26 is cut into shank walls 28 by electric discharge machining (EDM). The EDM cutting wire first cuts inclined surface 66 at the selected acute angle, then proceeds distally parallel to axis 17, and finally makes a perpendicular cut to define proximal end 27 of aperture 26.

Referring again to Fig. 4, during assembly of instrument 10, proximal end 60 of burr shank 19 is inserted into a distal end 14a of inner tube 14, which is enlarged to accept shank 19. Proximal end 60 of shank 19 is secured within the distal end 14a of inner tube 14 swaging; a pair of circumferential grooves 61 are provided in shank 19 for this purpose. Other, alternative techniques for attaching

shank 19 to inner tube 14 include spot, laser or electron beam welding, brazing, or gluing.

The assembled inner tube 14 is inserted through hub 34 into outer tube 12 until base 36 becomes seated within hub 34 (Fig. 1). The outer diameter of inner tube 14 is significantly less than the inner diameter of outer tube 12 to provide clearance between tubes 12, 14. The outer diameter of inner tube distal end 14a is, however, only slightly smaller than the inner diameter of outer tube 12 so that distal end 14a serves as a bearing for burr 18 against side loads. A heat-shrunk plastic sleeve (not shown) having approximately the same outer diameter as distal end 14a is provided around inner tube 14 near its proximal end to provide a proximal bearing surface against outer tube 12.

Referring to Fig. 9, in use, surgical instrument 10 is inserted into the distal end of handpiece 90. As discussed above, handpiece 90 includes a motor 92 for engaging proximal end 37 of base 36 to rotate inner tube 14. Handpiece 90 also includes a vacuum fitting 94 through which suction from a vacuum source 96 is applied to suction port 40 (Fig. 2) of instrument 10.

The distal end of surgical instrument 10 is introduced through a puncture wound 100 into a patient's knee joint 102, below the patella. An endoscope 104 inserted into joint 102 through a second puncture 106 both provides illumination (from light source 108) to the surgical site and conveys an image of the surgical site to a television camera 110. The image is delivered by camera 110 to a television screen 112 for viewing by the surgeon. Alternatively, the surgeon may view the image using an eyepiece on endoscope 104, or the image may be recorded.

Joint 102 is inflated with fluid introduced through a third puncture wound 116 from a fluid source 118. The fluid irrigates the surgical site and provides a medium by which tissue fragments cut by burr 18 are drawn through aperture 26, into chamber 30, and thence into tube passage 15 by the suction applied by vacuum source 96.

The surgeon maneuvers the distal end of instrument 10 to urge burr 18 (exposed by outer tube opening 20) against the tissue 120 (e.g., a section of bone or softer tissue such as synovial tissue or cartilage) to be cut. The surgeon then activates motor 92 to rotate inner tube 14 and surgical tool 16. Motor 92 receives operating potential and current from power supply 114. The surgeon controls the rotational speed and direction (either unidirectional or oscillatory, although an abrader such as surgical tool 16 is typically operated in one direction only) using foot switches 114a, 114b, which control the magnitude and polarity of operating potential and current supplied by power supply 114 to motor 92. Motor 92 is capable of rotating inner tube 14 over a wide range of speeds, e.g., between 100 rpm and 5000 rpm, and can deliver a torque of up to 25 oz inches.

When abrading bone tissue 120, cutting edges 22 of burr 18 abrade the bone as tool rotates. When cutting softer tissue 120, on the other hand, the enhanced sharpness provided by the neutral to slightly positive rake allows cutting edges 22 to efficiently cut (rather than tear or sever) the tissue during rotation of burr 18. The aggressiveness of the abrading/cutting action is a function of the speed of rotation and the pressure applied to tissue 120 by the surgeon. The surgeon progressively cuts tissue 120 by moving

instrument 10 from side to side and axially, while viewing the surgical site on television screen 112.

Tissue fragments cut by burr 18 are broken or chopped up by the relatively short segments 23 of cutting edges 22, and are urged proximally by the rotation of fluted burr 18 and the irrigation fluid being drawn into aperture 26. The tissue fragments pass over neck 25 and inclined surface 66 and enter aperture 26 and chamber 30 along with the irrigation fluid. Inclined surface 66 acts as a ramp which guides the fragments into aperture 26, further reducing the risk of clogging. The fragments and irrigation fluid are then drawn into inner tube passage 15, are transported proximally through inner tube 14, and exit surgical instrument 10 at suction port 40.

Due to the large size of aperture 26 and its substantially complete exposure to the surgical site by outer tube opening 20, the tissue fragment and irrigation fluid flow rate supported by instrument 10 is increased by as much as 30% over conventional burr-equipped instruments. This substantially reduces the risk that instrument 10 will become clogged by the tissue fragments. The notched configuration of cutting edges 22 helps ensure that the tissue fragments are relatively small, further reducing chances of clogging. In addition, the rake of cutting edges 22 enables burr 18 to efficiently cut even soft tissue into small fragments that are easily carried into chamber 30 via aperture 26.

Enlarged distal end 14a of inner tube 14 serves as a bearing to maintain the rotating inner tube 14 and burr 18 spaced from the inner surface of outer tube 12. Because distal end 14a is located immediately proximally of cutting surfaces 22, distal end 14a provides proximal support for burr 18 against even relatively large

side loads imposed when the surgeon urges burr against hard tissue 120 such as bone. This helps prevent burr 18 from contacting the inner surface of outer tube 12, thereby reducing wear of surgical tool 16 and avoiding "shedding" of steel fragments. The excellent bearing characteristics of the phosphor-bronze material of inner tube 14 also contributes to reduced shedding and helps reduce the risk of seizing (even at the high rotational speeds, e.g., 5000 rpm, at which burrs are typically operated) without need to coat the interior surface of outer tube 12 with a soft, precious metal (such as silver).

After use, surgical instrument 10 is cleaned if it is to be reused. The large size of apertures 26 and its exposure by outer tube opening 20 renders aperture 25 (and thus chamber 30) readily accessible for cleaning, without having to remove inner tube 14 from outer tube 12.

Other embodiments are within the following claims.

For example, additional apertures may be provided in shank 19 to increase fluid flow rate even further. The shape of aperture 26 and the size of outer tube opening 20 can be adjusted.

Burr may be provided with more or fewer cutting edges 22, flutes 24, and grooves 50, as desired. In general, the number of cutting edges 22 is a function of the diameter of burr 18 and the desired aggressiveness of the cutting action. More or fewer grooves 50 than are shown in Figs. 3 and 4 may also be provided, as desired, according to burr 18 diameter. Notches 52 need not be disposed in every cutting edge 22.

Surgical tool 16 can have other "burr" shapes, if desired. Examples include tapered, oval, and round burrs.

Other cutting edge configurations are possible, depending upon the surgical application. In particular, cutting edges 22 can be helical to a greater or lesser extent than shown in Figs. 3-5. Cutting edges 22 may also define other inclination angles with respect to longitudinal axis 40 (as may grooves 50). The rake of cutting edges 22 may be changed depending on the type of tissue to be cut.

Distal tip 44 of burr 18 may be configured in other ways. For example, tip 44 may be blunt so that no end-on cutting action takes place. Alternatively, tip 44 may be configured for even more aggressive end-on cutting. Also, tip 44 need not be hemispherical. Possible alternative shapes include square, conical, convex, and concave.

Although the use of instrument 10 has been explained with reference to knee surgery, it will be understood that instrument 10 can be employed in other endoscopic and arthroscopic procedures.

Still other embodiments are within the scope of the claims.

CLAIMS

1. A surgical instrument comprising

an outer tube having an opening at a distal end thereof,

an inner tube disposed for rotation within said outer tube, said inner tube having an interior passage between a distal end and a proximal end thereof, and

a surgical tool including a proximal shank mounted to said distal end of said inner tube and a fluted tissue cutting burr disposed distally of said shank and positioned within said outer tube opening,

said shank including a wall that defines an interior chamber in communication with said passage, said wall including an aperture therein that intersects said chamber for conveying tissue fragments cut by said burr into said chamber and thence into said passage, said aperture having a substantial width relative to an outer diameter of said wall.

2. The surgical instrument of claim 1 wherein the width of said aperture is approximately one-half of said outer diameter of said wall.

3. The surgical instrument of claim 1 wherein the width of said aperture is greater than one-half of said outer diameter of said wall.

4. The surgical instrument of any preceding claim wherein a portion of said wall disposed adjacent to a distal end of said aperture includes an inclined surface that slopes proximally toward said aperture.

5. The surgical instrument of claim 4 wherein said wall defines a pair of axial surfaces that define sides of said opening and that are

disposed in a plane, said inclined surface being oriented at an acute angle with respect to said plane.

6. The surgical instrument of any preceding claim wherein said wall of said shank is tubular so that said interior chamber is substantially cylindrical.

7. The surgical instrument of any preceding claim wherein said outer tube opening is axially elongated between a distal end at said distal end of said outer tube and a proximal end disposed proximally of said burr, thereby to expose said burr along one side of said outer tube and define a portion of said outer tube that provides a hood for an opposite side of said burr.

8. The surgical instrument of any preceding claim wherein said outer tube opening is axially elongated sufficiently to expose a major portion of said aperture.

9. The surgical instrument of claim 7 wherein said outer tube opening is axially elongated so that said proximal end of said opening is disposed adjacent to a proximal end of said aperture.

10. The surgical instrument of claim 9 wherein said outer tube opening is axially elongated so that said proximal end of said opening is disposed proximally of said proximal end of said aperture.

11. The surgical instrument of any preceding claim wherein said burr includes a plurality of cutting edges circumferentially spaced by a plurality of flutes disposed in an exterior surface of said surgical tool for cutting tissue exposed to said burr by said opening in said outer tube during rotation of said inner tube.

12. The surgical instrument of claim 11 wherein at least one of said cutting edges includes at least one notch therein.

13. The surgical instrument of claim 11 wherein said cutting edge includes a plurality of axially spaced notches therein.

14. The surgical instrument of claim 11 wherein each one of said cutting edges includes a plurality of axially spaced notches therein.

15. The surgical instrument of claim 11 wherein said cutting edges and said flutes are axially elongated and inclined relative to a longitudinal axis of said burr.

16. The surgical instrument of claim 15 wherein said burr further comprises a plurality of grooves that are axially elongated and inclined transversely to said flutes, said grooves defining a plurality of axially spaced notches in each of said cutting edges.

17. The surgical instrument of claim 16 wherein said flutes and said grooves are oriented at opposite acute angles with respect to said longitudinal axis.

18. The surgical instrument of claim 11 wherein each one of said flutes defines a leading surface of a first one of said cutting edges and a trailing surface of a second, adjacent one of said cutting edges.

19. The surgical instrument of claim 18 wherein said leading surface is oriented with respect to a radius of said cutting edge to define a positive rake for said cutting edge.

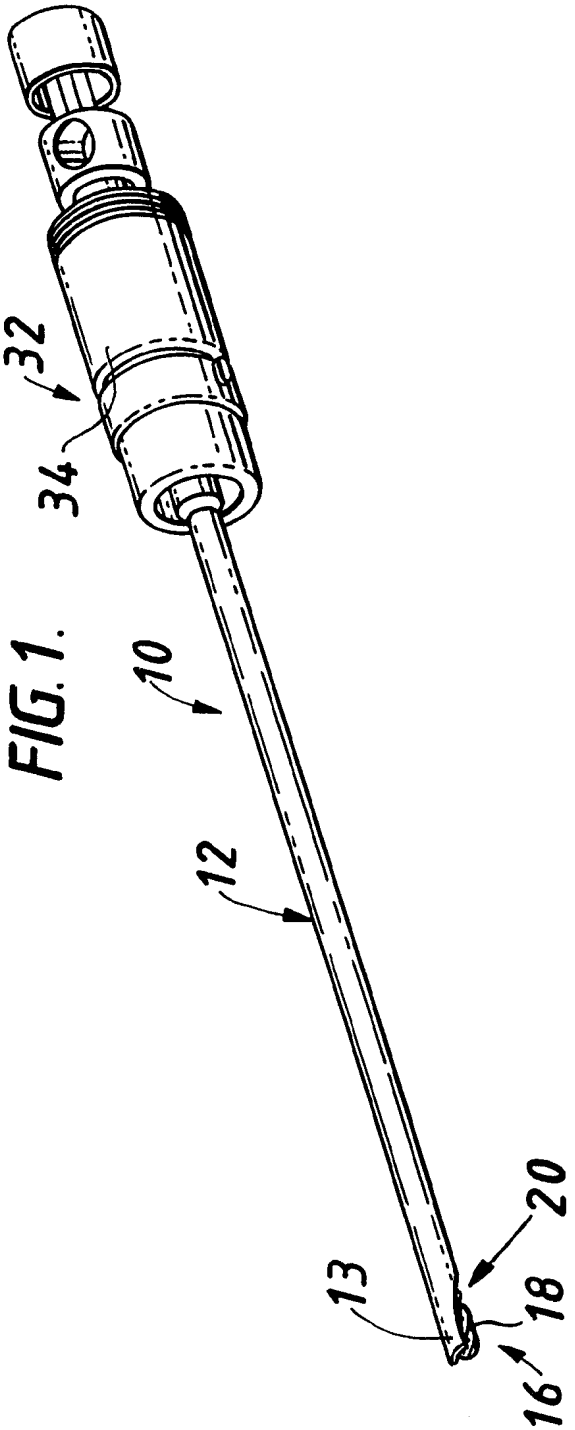

FIG. 1.

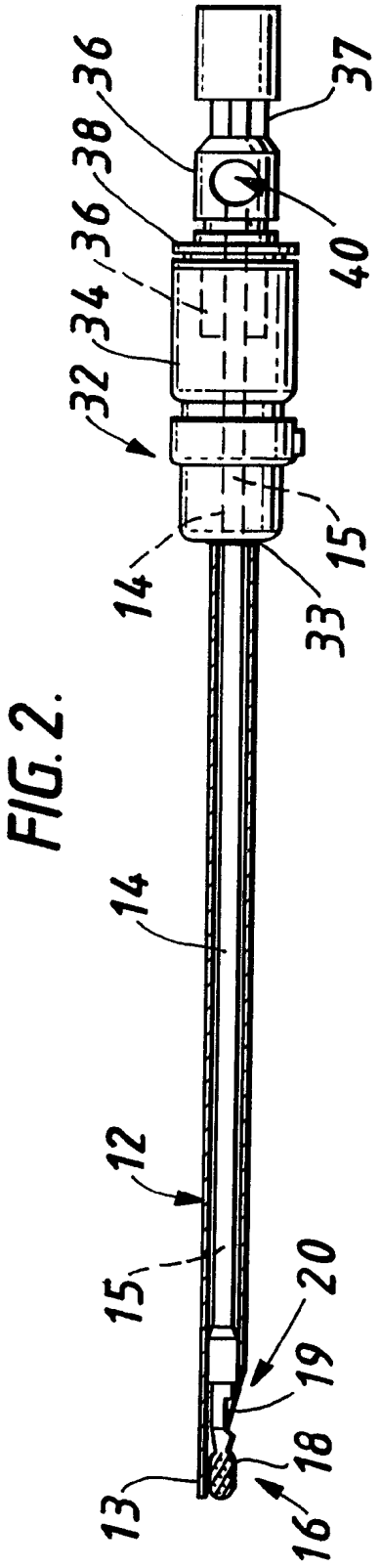

FIG. 2.

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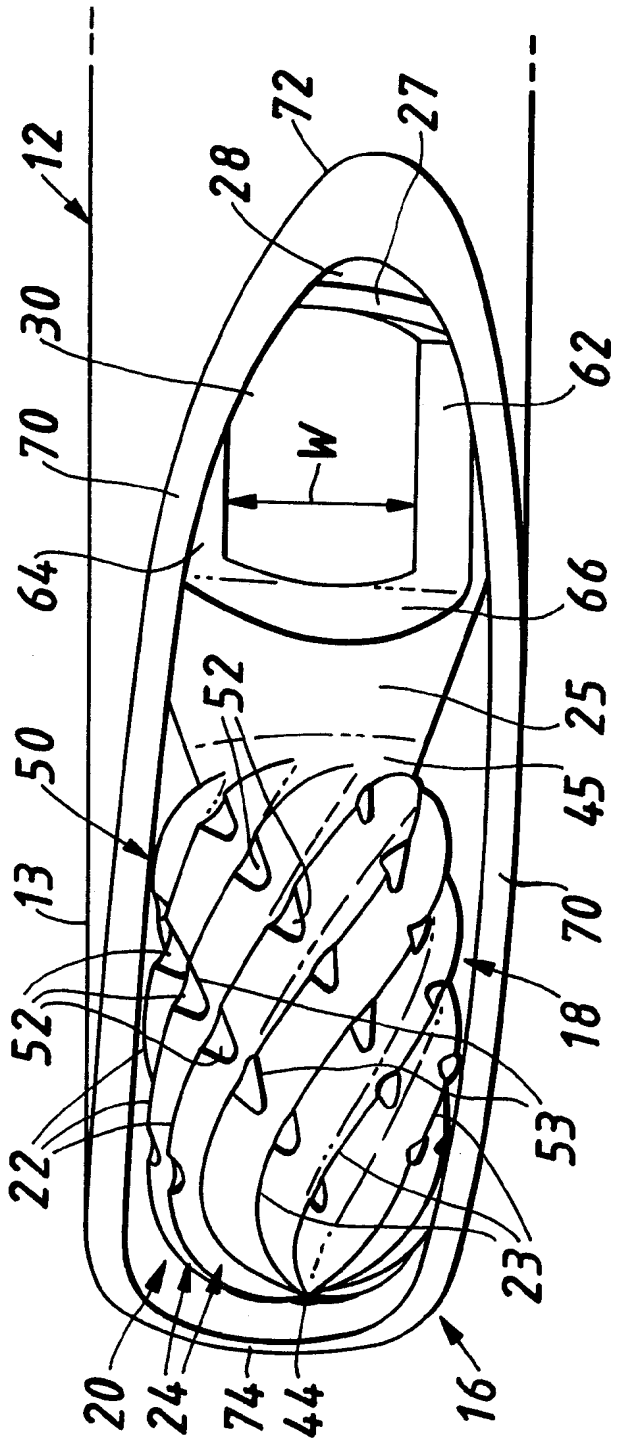
FIG. 3.



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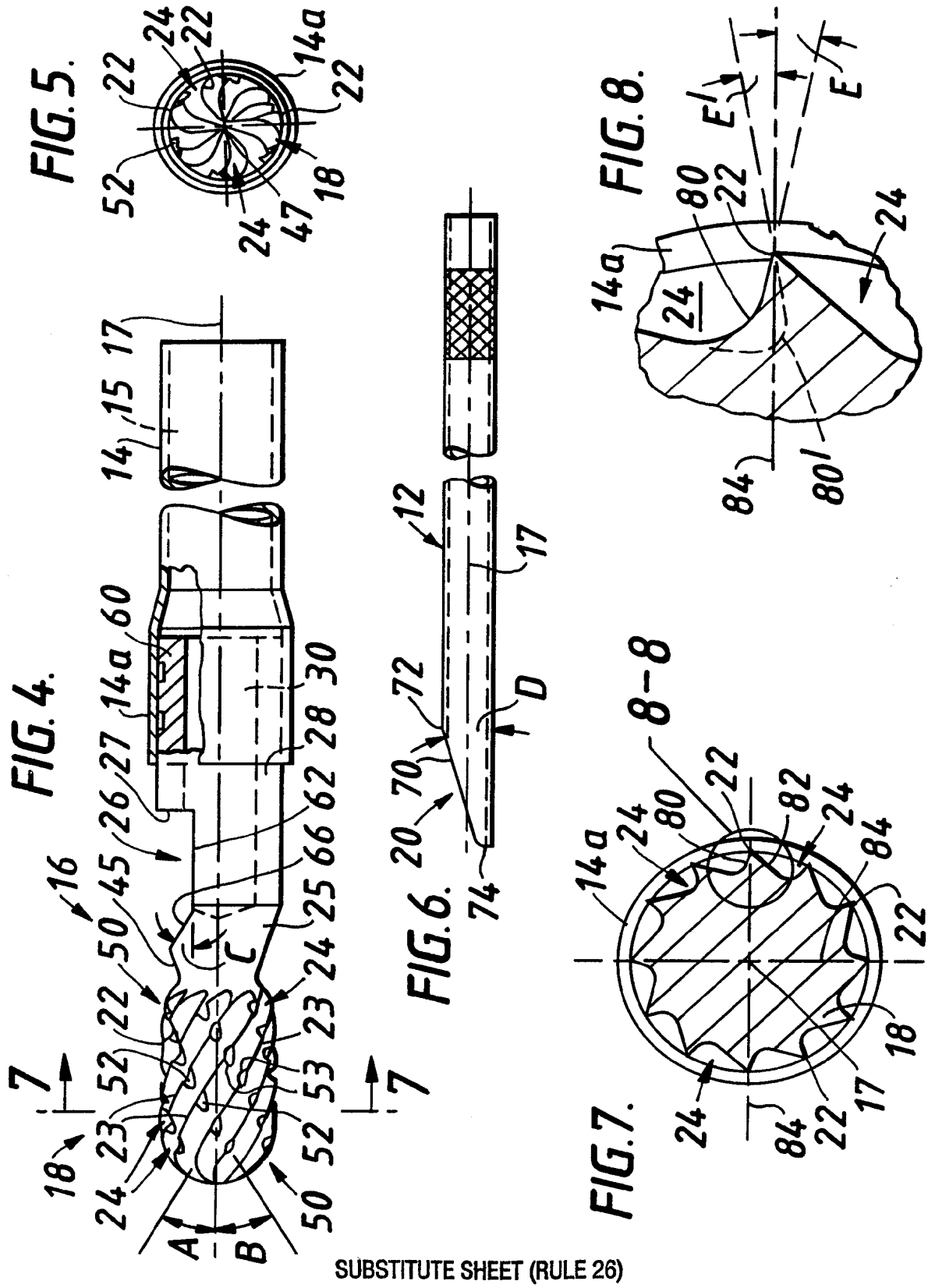

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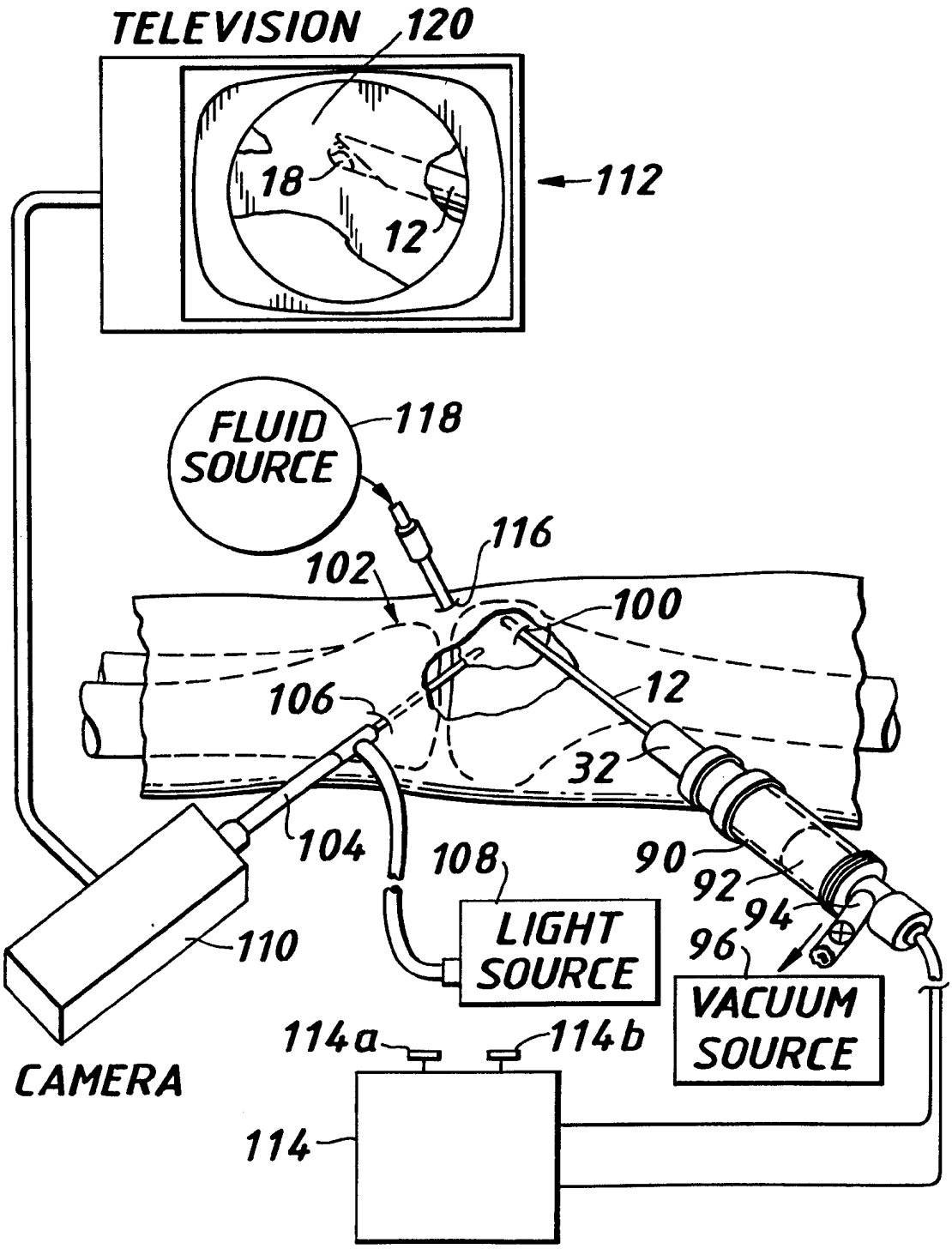
FIG. 9.



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INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/US 97/23390

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/32

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 6 A61B

Documentation searched other than minimumdocumentation 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	DE 296 16 633 U (AESCULAP) 14 November 1996 see page 6, paragraph 1; figures 1,2	1,4-7, 11-14,18 2,3
Y	DE 39 06 301 A (OLYMPUS) 14 December 1989 see column 12, line 52 - line 59; figure 43	2,3
A	US 5 366 468 A (LINVATEC) 22 November 1994 see column 8, line 66 - column 9, line 6; figure 6	1-4
A	US 5 437 630 A (DANIEL ET AL.) 1 August 1995 see column 9, line 10 - line 22; figure 3	1-3

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

[X] Patent family members are listed in annex.

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1

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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	Moers, R

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 489 291 A (WILEY) 6 February 1996 see column 5, line 5 - line 64; figures 4-6	1-3,8-10
A	WO 96 12453 A (SMITH & NEPHEW DYONICS) 2 May 1996 see abstract; figure 4	11-19

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INTERNATIONAL SEARCH REPORT

Information on patent family members

In. ational Application No
PCT/US 97/23390

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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DE 3906301 A	14-12-89	US 5123904 A	23-06-92
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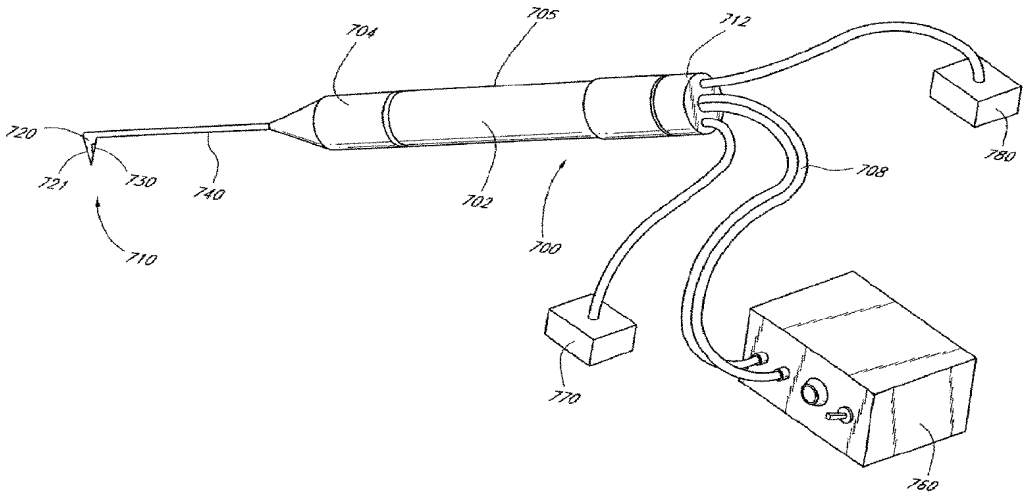
(54) Title: MINIMALLY INVASIVE GLAUCOMA SURGICAL INSTRUMENT AND METHOD



(57) Abstract: Apparatuses and methods for the treatment of glaucoma are provided. The instrument 700 uses either cauterization, a laser to ablate, sonic or ultrasonic energy to emulsify, or mechanical cutting of a portion of the trabecular meshwork. The instrument 700 may also be provided with irrigation, aspiration, and a footplate 721. The footplate 721 is used to enter Schlemm's canal, serves as a guide, and also protects Schlemm's canal.

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MINIMALLY INVASIVE GLAUCOMA SURGICAL INSTRUMENT AND METHOD

Background of the Invention

Field of the Invention

[0001] The present invention relates to a new glaucoma surgical instrument and method, and, in particular, removal of the trabecular meshwork by mechanical cautery, vaporization or other tissue destruction means optionally coupled to an instrument with infusion, aspiration, and a footplate.

Description of the Related Art

[0002] Aqueous is a clear, colorless fluid that fills the anterior and posterior chambers of the eye. The aqueous is formed by the ciliary body in the eye and supplies nutrients to the lens and cornea. In addition, the aqueous provides a continuous stream into which surrounding tissues can discharge the waste products of metabolism.

[0003] The aqueous produced in the ciliary process circulates from the posterior chamber to the anterior chamber of the eye through the pupil and is absorbed through the trabecular meshwork, a plurality of crisscrossing collagen cords covered by endothelium. Once through the trabecular meshwork, the aqueous passes through Schlemm's canal into collector channels that pass through the scleral and empty into the episcleral venous circulation. The rate of production in a normal eye is typically 2.1 μL/min. Intraocular pressure in the eye is maintained by the formation and drainage of the aqueous. All the tissues within the corneoscleral coat covering the eyeball are subject to this pressure, which is higher than pressure exerted on tissues at other locations in the body.

[0004] Glaucoma is a group of diseases characterized by progressive atrophy of the optic nerve head leading to visual field loss, and ultimately, blindness. Glaucoma is generally associated with elevated intraocular pressure, which is an important risk factor for visual field loss because it causes further damage to optic nerve fibers. Other causes of glaucoma may be that the nerve is particularly vulnerable to the pressure due to poor local circulation, tissue weakness or abnormality of structure. In a "normal" eye, intraocular pressure ranges from 10 to 21 mm mercury. In an eye with glaucoma, this pressure can rise to as much as 75 mm mercury.

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[0005] There are several types of glaucoma, including open and closed angle glaucoma, which involve the abnormal increase in intraocular pressure, primarily by obstruction of the outflow of aqueous humor from the eye, or, less frequently, by over production of aqueous humor within the eye. The most prevalent type is primary open angle glaucoma in which the aqueous humor has free access to the irridocorneal angle, but aqueous humor drainage is impaired through obstruction of the trabecular meshwork. In contrast, in closed angle glaucoma, the irridocorneal angle is closed by the peripheral iris. The angle block can usually be corrected by surgery. Less prevalent types of glaucoma include secondary glaucomas related to inflammation, trauma, and hemorrhage.

[0006] Aqueous humor is similar in electrolyte composition to plasma, but has a lower protein content. The aqueous humor keeps the eyeball inflated, supplies the nutritional needs of the vascular lens and cornea and washes away metabolites and toxic substances within the eye. The bulk of aqueous humor formation is the product of active cellular secretion by nonpigmented epithelial cells of the ciliary process from the active transport of solute, probably sodium, followed by the osmotic flow of water from the plasma. The nonpigmented epithelial cells of the ciliary process are connected at their apical cell membranes by tight junctions. These cells participate in forming the blood/aqueous barrier through which blood-borne large molecules, including proteins, do not pass.

[0007] Intraocular pressure (IOP) is a function of the difference between the rate at which aqueous humor enters and leaves the eye. Aqueous humor enters the posterior chamber by three means: 1) active secretion by nonpigmented epithelial cells of the ciliary process; 2) ultrafiltration of blood plasma; and 3) diffusion. Newly formed aqueous humor flows from the posterior chamber around the lens and through the pupil into the anterior chamber; aqueous humor leaves the eye by 1) passive bulk flow at the irridocorneal angle by means of the uveloscleral outflow, or by 2) active transportation through the trabecular meshwork, specifically the juxta canalicar portion. Any change in 1), 2), or 3) will disturb aqueous humor dynamics and likely alter intraocular pressure.

[0008] Primary open angle glaucoma is caused by a blockage in the trabecular meshwork. This leads to an increase in intraocular pressure. The major obstruction is at the juxta-canalicular portion which is situated adjacent to Schlemm's canal. In infants a goniotomy or a trabeculotomy can be performed. In goniotomy or trabeculotomy a small

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needle or probe is introduced into Schlemm's canal and the trabecular meshwork is mechanically disrupted into the anterior chamber. Approximately 90°-120° of trabecular meshwork can be disrupted. The anatomical difference between congenital glaucoma and adult glaucoma is that in congenital glaucoma the ciliary body muscle fibers insert into the trabecular meshwork and once disrupted the trabecular meshwork is pulled posteriorly allowing fluid to enter Schlemm's canal and to be removed through the normal collector channels that are present in the wall of Schlemm's canal. In adults the trabecular meshwork tears but remains intact and reattaches to the posterior scleral wall of Schlemm's canal blocking the collector channels.

[0009] Most treatments for glaucoma focus on reducing intraocular pressure. Treatment has involved administration of beta-blockers such as timolol to decrease aqueous humor production, adranergic agonists to lower intraocular pressure or diuretics such as acetazolamide to reduce aqueous production, administration of miotic eyedrops such as pilocarpine to facilitate the outflow of aqueous humor, or prostaglandin analogs to increase uveoscleral outflow. Acute forms of glaucoma may require peripheral iridectomy surgery to relieve pressure where drug therapy is ineffective and the patient's vision is at immediate risk. Other forms of treatment have included physical or thermal destruction ("cyclo-destruction") of the ciliary body of the eye, commonly by surgery or application of a laser beam, cryogenic fluid or high frequency ultrasound.

[0010] In guarded filtration surgery (trabeculectomy), a fistula created through the limbal sclera is protected by an overlying partial thickness sutured scleral flap. The scleral flap provides additional resistance to excessive loss of aqueous humor from the eyeball, thereby reducing the risk of early postoperative hypotony.

[0011] In accordance with one recently introduced procedure, a full thickness filtering fistula may be created by a holmium laser probe, with minimal surgically induced trauma. After retrobulbar anesthesia, a conjunctival incision (approximately 1 mm) is made about 12-15 mm posterior to the intended sclerostomy site, and a laser probe is advanced through the sub-conjunctival space to the limbus. Then, multiple laser pulses are applied until a full thickness fistula is created. This technique has sometimes resulted in early hypotony on account of a difficulty in controlling the sclerostomy size. In addition, early and late iris prolapse into the sclerostomy has resulted in abrupt closure of the fistula and eventual surgical failure. Further, despite its relative simplicity, the disadvantage of this

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procedure, as well as other types of glaucoma filtration surgery, is the propensity of the fistula to be sealed by scarring.

[0012] Various attempts have been made to overcome the problems of filtration surgery, for example, by using ophthalmic implant instruments such as the Baerveldt Glaucoma Implant. Typical ophthalmic implants utilize drainage tubes so as to maintain the integrity of the openings formed in the eyeball for the relief of the IOP.

[0013] Typical ophthalmic implants suffer from several disadvantages. For example, the implants may utilize a valve mechanism for regulating the flow of aqueous humor from the eyeball; defects in and/or failure of such valve mechanisms could lead to excessive loss of aqueous humor from the eyeball and possible hypotony. The implants also tend to clog over time, either from the inside by tissue, such as the iris, being sucked into the inlet, or from the outside by the proliferation of cells, for example by scarring. Additionally, the typical implant insertion operation is complicated, costly and takes a long time and is reserved for complicated glaucoma problems.

[0014] There are many problems, however, in effectively treating glaucoma with long term medicinal or surgical therapies. One problem is the difficulty in devising means to generate pharmacologically effective intraocular concentrations and to prevent extraocular side effects elicited by a systemic administration. Many drugs are administered topically or locally. The amount of a drug that gets into the eye is, however, only a small percentage of the topically applied dose because the tissues of the eye are protected from such substances by numerous mechanisms, including tear turnover, blinking, conjunctival absorption into systemic circulation, and a highly selective corneal barrier.

[0015] Pharmacological treatment is prohibitively expensive to a large majority of glaucoma patients. In addition, many people afflicted with the disease live in remote or undeveloped areas where the drugs are not readily accessible. The drugs used in the treatment often have undesirable side effects and many of the long-term effects resulting from prolonged use are not yet known. Twenty-five percent of patients do not use their medications correctly.

[0016] Glaucoma is a progressively worsening disease, so that a filtration operation for control of intraocular pressure may become necessary. Present surgical techniques to lower intraocular pressure, when medication fails to decrease fluid flow into the eye or to increase fluid outflow, include procedures that permit fluid to drain from

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within the eye to extraocular sites by creating a fluid passageway between the anterior chamber of the eye and the potential supra-scleral/sub-Tenon's space, or, alternatively, into or through the Canal of Schlemm (see, e.g., U.S. Patent No. 4,846,172). The most common operations for glaucoma are glaucoma filtering operations, particularly trabeculectomy. These operations involve creation of a fistula between the subconjunctival space and the anterior chamber. This fistula can be made by creating a hole at the limbus by either cutting out a portion of the limbal tissues with either a scalpel blade or by burning with a cautery through the subconjunctival space into the anterior chamber. Fluid then filters through the fistula and is absorbed by episcleral and conjunctival. In order for the surgery to be effective, the fistula must remain substantially unobstructed. These drainage or filtering procedures, however, often fail by virtue of closure of the passageway resulting from the healing of the very wound created for gaining access to the surgical site. Failures most frequently result from scarring at the site of the incisions in the conjunctiva and the Tenon's capsule. The surgery fails immediately in at least 15% of patients, and long term in a much higher percentage. Presently, this consequence of trabeculectomy, closure of the passageway, is treated with 5-fluorouracil and Mitomycin_C, which apparently prevent closure by inhibiting cellular proliferation. These drugs, however, are highly toxic and have undesirable side effects, including scleral melting, hypotony, leaks, and late infections.

[0017] Other surgical procedures have been developed in an effort to treat victims of glaucoma. An iridectomy, removal of a portion of the iris, is often used in angle-closure glaucoma wherein there is an occlusion of the trabecular meshwork by iris contact. Removal of a piece of the iris then gives the aqueous free passage from the posterior to the anterior chambers in the eye. The tissue of the eye can grow back to the pre-operative condition, thereby necessitating the need for further treatment.

[0018] In view of the limited effectiveness of treatment options, there is, therefore, a need to develop more effective treatments for glaucoma.

Summary of the Invention

[0019] The present invention is a surgical instrument and minimally invasive surgical method to remove at least a portion of the trabecular meshwork of the eye, providing for aqueous drainage in the treatment of glaucoma.

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[0020] A preferred embodiment of the present invention involves inserting a surgical instrument through a small corneal incision transcamerally under direct visualization to ablate the trabecular meshwork. The instrument may include a foot plate, such that the instrument can penetrate the trabecular meshwork into Schlemm's canal. The footplate may also act as a protective device for the endothelial cells and collector channels lining the scleral wall of Schlemm's canal. The instrument may also comprise an infusion system and aspiration system. Infusion maintains and deepens the anterior chamber so that easy access of the angle of the eye is obtained to the trabecular meshwork and Schlemm's canal. Infusion also allows fluid to flow out to the collector channels whilst the surgery is being performed, thus keeping the surgical site blood free. Aspiration is designed to remove ablated tissue, gas and bubble formation, and all intraocular debris generated. The aspiration may be directly linked to either a cutting mechanism, such as a guillotine cutting machine, laser probe, a piezo-electric crystal producing sonic or ultrasonic energy, or cautery element. These modalities are capable of substantially complete tissue removal by mechanical means, cautery, vaporization, or other tissue destruction techniques.

[0021] The surgical instrument is used to perform a goniectomy procedure, by removing a portion of the trabecular meshwork consisting of the pigmented trabecular meshwork, allowing free access of aqueous from the anterior chamber through to the scleral portion of Schlemm's canal that contains the endothelial cells and most importantly the collector channels that lead back to the episcleral venous system.

[0022] In another embodiment, a Schlemmectomy surgical procedure, similar to a trabeculotomy, a schlemmectomy probe is inserted into Schlemm's canal under direct visualization through a scleral incision, such that the surface of the instrument faces the trabecular meshwork and the tissue comprising the pigmented and a portion of the non-pigmented trabecular meshwork facing into Schlemm's canal is removed by a cautery element, radio-frequency electrode, or an ultrasound transducer formed from a piezo-electric crystal.

[0023] This instrument is advantageous because it combines existing procedures with new technology, providing a simple solution for glaucoma treatment.

Brief Description of the Drawings

[0024] Figure 1 is a cross sectional schematic diagram of a human eye.

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[0025] Figure 2 is a cross sectional schematic diagram which shows aqueous flow into and through the anterior chamber in a human eye.

[0026] Figures 3a-d shows diagrammatically the progression of the deformation of the lamina cribrosa in glaucoma.

[0027] Figures 4a-c show diagrammatically the steps of performing a goniectomy.

[0028] Figures 5a-d show diagrammatically the steps of performing a trabeculodialysis.

[0029] Figures 6a-e show diagrammatically the steps of a trabeculotomy procedure using a probe of a preferred embodiment.

[0030] Figure 7 is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

[0031] Figure 8 is a cross-sectional schematic diagram which shows the goniectomy cautery probe of Figure 7.

[0032] Figure 9 is a cross sectional schematic diagram which shows another embodiment of the goniectomy cautery probe of Figure 7.

[0033] Figure 10a is a detailed view which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0034] Figure 10b is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0035] Figure 11a is a detailed view which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0036] Figure 11b is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0037] Figure 12a is a detailed view which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0038] Figure 12b is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of Figure 7.

[0039] Figure 13 is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

[0040] Figure 14 is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

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[0041] Figure 15a is a detailed view which shows the probe tip of the goniectomy cautery probe of Figure 13.

[0042] Figure 15b is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of Figure 13.

[0043] Figure 16a is a detailed view which shows the probe tip of the cautery probe of Figure 14.

[0044] Figure 16b is a cross-sectional schematic diagram which shows the probe tip of the cautery probe of Figure 14.

[0045] Figure 17 shows a schematic of a circuit diagram of a preferred embodiment of a goniectomy probe.

[0046] Figure 18 is a perspective view which shows a goniectomy probe.

[0047] Figure 19 is a cross-sectional schematic diagram which shows an embodiment of the probe of Figure 18.

[0048] Figure 20 is a cross-sectional schematic diagram which shows an embodiment of the probe of Figure 18.

[0049] Figure 21 is a cross-sectional schematic diagram which shows an embodiment of the probe of Figure 18.

[0050] Figure 22 is a cross-sectional schematic diagram which shows an embodiment of the probe of Figure 18.

[0051] Figure 23 is a cross-sectional schematic diagram which shows an embodiment of the probe of Figure 18.

[0052] Figure 24a is a perspective view which shows a preferred embodiment of a laser goniectomy probe.

[0053] Figure 24b is a perspective view which shows a preferred embodiment of a laser goniectomy probe.

[0054] Figure 25 is a cross sectional schematic diagram of the laser goniectomy probe of Figure 24a.

[0055] Figure 26 is a cross sectional schematic diagram of the laser goniectomy probe of Figure 24b.

[0056] Figure 27 is a cross sectional schematic diagram of the laser goniectomy probe of Figure 24b.

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[0057] Figure 28 is a perspective view which shows a Schlemmectomy probe of a preferred embodiment.

[0058] Figures 29a-c are detailed views which show the probe tip of the probe of Figure 28.

[0059] Figure 30 is a perspective view of an alternative preferred embodiment of the probe of Figure 28.

[0060] Figures 31a,b,c are detailed views of the probe tip of Figure 30.

[0061] Figures 32a,b are detailed views which show the probe tip of the probe of Figure 30.

[0062] Figure 33a is a detailed view which shows the probe tip of the probe of Figure 30.

[0063] Figure 33b is a cross-sectional schematic diagram which shows the probe tip of the probe of Figure 30.

[0064] Figure 34a is a detailed view which shows the probe tip of the probe of Figure 30.

[0065] Figure 34b is a cross-sectional schematic diagram which shows the probe tip of the probe of Figure 30.

[0066] Figure 35a is a detailed view which shows the probe tip of the probe of Figure 30.

[0067] Figure 35b is a cross-sectional schematic diagram which shows the probe tip of the probe of Figure 30.

Detailed Description of the Preferred Embodiment

[0068] Referring to Figure 1, relevant structures of the eye will be briefly described, so as to provide background for the anatomical terms used herein. Certain anatomical details, well known to those skilled in the art, have been omitted for clarity and convenience.

[0069] As shown in Figure 1, the cornea 103 is a thin, transparent membrane which is part of the outer eye and lies in front of the iris 104. The cornea 103 merges into the sclera 102 at a juncture referred to as the limbus 108. A layer of tissue called bulbar conjunctiva 106 covers the exterior of the sclera 102. The bulbar conjunctiva 106 is thinnest anteriorly at the limbus 108 where it becomes a thin epithelial layer which

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continues over the cornea 103 to the corneal epithelium. As the bulbar conjunctiva 106 extends posteriorly, it becomes more substantial with greater amounts of fibrous tissue. The bulbar conjunctiva 106 descends over Tenon's capsule approximately 3 mm from the limbus 108. Tenon's capsule is thicker and more substantial encapsulatory tissue which covers the remaining portion of the eyeball. The subconjunctival and sub-Tenon's capsule space become one when these two tissues meet, approximately 3mm from the limbus. The ciliary body or ciliary process 110 is part of the uveal tract. It begins at the limbus 108 and extends along the interior of the sclera 102. The choroid 112 is the vascular membrane which extends along the retina back towards the optic nerve. The anterior chamber 114 of the eye is the space between the cornea 103 and a crystalline lens 116 of the eye. The crystalline lens of the eye is situated between the iris 104 and the vitreous body 120 and is enclosed in a transparent membrane called a lens capsule 122. The anterior chamber 114 is filled with aqueous humor 118. The trabecular meshwork 121 removes excess aqueous humor 118 from the anterior chamber 114 through Schlemm's canal 124 into collector channels which merge with blood-carrying veins to take the aqueous humor 118 away from the eye.

[0070] As shown in Figure 2, the flow of aqueous 118 is from the posterior chamber, through the pupil, into the anterior chamber 114.

[0071] Figures 3a-d show longitudinal sections through the optic nerve head, illustrating the progressive deepening of the cup 302 in the nerve head from normal to advanced glaucoma. Figure 3a shows a normal nerve and Figure 3d shows an effected nerve in advanced glaucoma. As the cup 302 deepens and the lamina cribrosa 306 becomes more curved, axons 304 passing through the lamina 306 are subject to kinking and pressure as they make their way through the lamina 306.

[0072] Goniotomy

[0073] Figures 4a-c show the steps for performing a goniotomy procedure. As shown in Figure 4a, locking forceps 406 are typically used to grasp the inferior and superior rectus muscles. A goniotomy lens 408 is positioned on the eye. A goniotomy knife 400 is inserted from the temporal aspect beneath the goniotomy lens and viewed through a microscope. The cornea is irrigated with balanced salt solution. The surgeon positions the

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goniotomy lens 408 on the cornea, holding the lens 408 with an angled, toothed forceps 406 placed into the two dimples at the top of the lens 408.

[0074] The surgeon places the goniotomy knife 400 into and through the cornea 1.0mm anterior to the limbus, maintaining the knife 400 parallel to the plane of the iris (Figure 4b). Slight rotation of the knife 400 facilitates smooth penetration into the anterior chamber without a sudden break through the cornea. The surgeon continues to gently apply pressure and rotate the goniotomy knife 400, directing it across the chamber, parallel to the plane of the iris, until reaching the trabecular meshwork in the opposite angle.

[0075] The surgeon visualizes the trabecular meshwork under direct microscopy and engages the superficial layers of the meshwork at the midpoint of the trabecular band. The incision is typically made 100° to 120° circumferentially, first incising clockwise 50° to 60°, then counterclockwise for 50° to 60°.

[0076] As the tissue is incised, a white line can be seen and the iris usually drops posteriorly. An assistant facilitates incision by rotating the eye in the opposite direction of the action of the blade (Figure 4c).

[0077] The surgeon completes the goniotomy incision and promptly withdraws the blade. If aqueous escapes from the wound and the chamber is shallow, the surgeon can slide the goniotomy lens over the incision as the blade is withdrawn. The anterior chamber can be reformed with an injection of balanced salt solution through the external edge of the corneal incision. The leak can be stopped using a suture and burying the knot.

[0078] Trabeculodialysis

[0079] Trabeculodialysis is similar to goniotomy but is performed primarily in young patients with glaucoma secondary to inflammation. Trabeculodialysis differs from goniotomy only in the position of the incision. Figures 5a-d show the steps of a trabeculodialysis procedure. The knife 500 passes across the anterior chamber and engages the trabecular meshwork at Schwalbe's line rather than at the midline of the meshwork, as shown in Figure 5a.

[0080] The incision is typically made 100° to 120° circumferentially, first incising clockwise 50° to 60°, then counterclockwise for 50° to 60° (Figure 5b).

[0081] With the flat side of the blade, the surgeon pushes the trabecular meshwork inferiorly toward the surface of the iris, as shown in Figure 5c. Figure 6d shows

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the meshwork, disinserted from the scleral sulcus, exposing the outer wall of Schlemm's canal.

[0082] Trabeculotomy

[0083] Trabeculotomy displaces trabecular meshwork as a barrier to aqueous outflow. Initially, the surgeon creates a triangular scleral flap 604 that is dissected anteriorly of the limbus, as shown in Figure 6a. A radial incision is made over the anticipated site of Schlemm's canal (Figure 6b). The incision is deepened until the roof of Schlemm's canal is opened (Figure 6c).

[0084] The surgeon locates Schlemm's canal through the external surface of the limbus, threads a trabeculotome 600 into the canal and rotates the instrument into the anterior chamber, as shown in Figure 6d. The upper arm 610 of the instrument should be kept parallel to the plane of the iris. The instrument 600 is then rotated within the anterior chamber and maintained parallel to the iris. After rotating the instrument 600 through the meshwork in one direction, the surgeon withdraws the instrument and inserts a second instrument with the opposite curve. The identical procedure is then performed in the opposite direction.

[0085] Collapse of the anterior chamber often occurs during the procedure. The chamber can be reformed by injecting irrigation fluid. Aspiration may be used to remove the tissue. The scleral flap 604 may then be sutured closed, as shown in Figure 6e.

[0086] Goniectomy Cauterization Probe

[0087] A preferred embodiment of a goniectomy probe, used to cauterize and ablate the trabecular meshwork is shown in Figures 7 and 8. The probe 700 comprises a handle 705 and a probe tip 710. Preferably, the handle is approximately 20 gauge and the probe tip is approximately 27 gauge. The proximal end of the handle is adapted for mating with a connector 712 to the output terminals of an energy source 760.

[0088] The probe also includes electrical leads 834 (Figure 8), a power cable 708, preferably a coaxial cable, and actuation means. These components extend from the handle 705, through an electrical lead lumen 832 (Figure 8) in the probe shaft 705, to the corresponding components of the probe 700 disposed on the distal end. The proximal ends

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of the cables and lumens connect to the corresponding connectors that extend from the distal end of the probe handle 705.

[0089] Aspiration and irrigation may be provided by an aspiration pump 770 and irrigation pump 780. The aspiration pump 770 is connected to a standard vacuum supply line to promote the withdrawal of the aspiration fluid. Aspiration vacuum control may be provided by an aspiration valve. In a preferred embodiment, as shown in Figure 8, both irrigation and aspiration may be provided by the same lumen 822, alternating the pump as needed. However, the irrigation lumen 922 and aspiration lumen 924 are separate in the embodiment of Figure 9, providing for simultaneous irrigation and aspiration. Irrigation under pressure flushes blood from the eye and expands the anterior chamber, providing more room for the procedure.

[0090] The handle 705 may be made of an electrically insulating polymeric material, configured in a pencil-shape form having a cylindrical body region 702 and a tapered forward region 704. A contoured handle helps to reduce the holding force required and increase proprioceptive sensitivity. Although a pencil-shape configuration is preferred, it is noted that any configuration of the handle 705 which is easily, comfortably and conveniently grasped by the operator will also be suitable and is considered to be within the scope of the present invention.

[0091] The probe tip 710 is connected to the main body of the handle 705. The probe tip further comprises a footplate 721, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm's canal. The cautery element 730, located at the distal end of the probe tip 710 may have a variety of configurations.

[0092] The tip 710 may be any material, such as titanium, brass, nickel, aluminum, stainless steel, other types of steels, or alloys. Alternatively, non-metallic substances may also be used, such as certain plastics. The malleable probe tips can be configured as straight, angled or curved, for example, which provides for optimal access to specific anatomy and pathology. Unique tip designs improve tactile feedback for optimal control and access, and provide for improved tissue visualization with greatly reduced bubbling or charring.

[0093] The probe tip 710 comprises an electrode 730, suitable for cautery, as known to those of skill in the art. Various electrode configurations and shapes may be

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suitable. The cautery element 730 may be any electrode that may provide ablation or cauterization of tissue, such as an ultrasound transducer, a RF electrode, or any other suitable electrode.

[0094] The cautery element may also include other cautery energy sources or sinks, and particularly may include a thermal conductor. Examples of suitable thermal conductor arrangements include a metallic element which may, for example, be constructed as previously described. However, in the thermal conductor embodiment such a metallic element would be generally resistively heated in a closed loop circuit internal to the probe, or conductively heated by a heat source coupled to the thermal conductor.

[0095] The probe tip may have a coating such as a non-stick plastic or a coating comprising diamond to prevent undesirable sticking or charring of tissue. The electrode may be provided on the inner surface of the tip. Alternatively, the electrode is embedded in a sheath of a tube. Insulation is provided around the cautery element so that other areas of the eye are not affected by the cauterization. A sleeve shield or a non-conductive layer may be provided on the probe tip to expose only a selected portion of the electrode. The sleeve preferably has sufficient thickness to prevent both current flow and capacitance coupling with the tissue.

[0096] The electrode or other device used to deliver energy can be made of a number of different materials including, but not limited to stainless steel, platinum, other noble metals, and the like. The electrode can also be made of a memory metal, such as nickel titanium. The electrode can also be made of composite construction, whereby different sections are constructed from different materials.

[0097] In a preferred embodiment, the probe assembly is bipolar. In a bipolar system, two electrodes of reversed polarity are located on the probe tip, thus eliminating the contact plate for completion of the circuit. Additionally, any number of pairs of electrodes may be provided on the probe tip.

[0098] In an alternative embodiment, the probe assembly is monopolar. In a monopolar system, the system comprises a single electrode and a contact plate is attached to the surface of the human body. The contact plate is further connected to the minus terminal of the power source via a lead wire. Voltages of reversed polarity are applied to the electrode and the contact plate.

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[0099] In a preferred embodiment as shown in Figures 10a and 10b, an electrode assembly of a bipolar probe includes one electrode 1020 made from a stainless steel 20 gauge hollow needle and a second electrode 1030 formed as a layer of electrically conductive material (such as silver or nickel) deposited over and adhered on an exterior surface of the needle electrode 1020. A thin electrical insulator 1028 separates the electrodes 1020, 1030, along their lengths to avoid short circuiting.

[0100] The electrode 1020 extends along a longitudinal axis 1072 of the footplate 721 (Fig. 7) from a proximal region at which bipolar electrical power is applied to a distal region of the electrode assembly.

[0101] In a preferred embodiment, the second electrode 1030 extends over a limited portion of the circumference of the first electrode 1020, rather than entirely around the first electrode. Current flows over a relatively small portion of the circumference and length of the first electrode 1020. This limits the area in the body that receives current, and provides the operator with a high degree of control as to where the current is applied. The second electrode 1030 extends over an arc of approximately one quarter of the circumference of the first electrode 1020. The second electrode 1030 is disposed symmetrically about an axis 1072.

[0102] In a preferred embodiment, the first electrode, and thus the footplate 721, has a central passage 1022 that is open at the distal region, providing for irrigation and aspiration. The irrigation and aspiration lumens extend from the distal end of the probe tip 1010, through the probe handle, to the connector, providing for irrigation and aspiration capability.

[0103] In an embodiment as shown in Figures 11a and 11b, the electrode assembly includes a central or axial electrode 1120 formed by a solid cylindrical metal member, and an elongate hollow outer electrode 1130 formed by a cylindrical metal tube member, which is coaxially positioned around the central electrode 1120. The cylindrical outer surface of electrode 1130 forms the circumferential surface of the probe. The outer electrode 1130 is preferably made of stainless steel or other corrosive resistant, conductive material for strength as well as conductivity. The inner electrode 1120 may be made of copper, but less conductive materials may also be employed. The coaxial relationship and spacing between the electrodes 1120, 1130, as well as their electrical isolation from one

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another, is provided by a tubular sleeve 1128 of an electrically insulating material between the electrode.

[0104] A layer of insulation 1132 may also surround the second electrode 1130. One or more regions of insulating area 1132 may be removed at any suitable location along the axis to expose a region of electrode 1130. Cauterization would occur at the exposed region. The circumferential extent of the second electrode 1130 can be further limited, depending on the degree of control desired over the size of the area to which current is applied.

[0105] In an alternative embodiment, as shown in Figure 12, the active region at a remote end of a bipolar electrode is formed by a hollow metal tube 1200 having a substantially cylindrical layer of insulation 1228 on the outer surface of the metal tube. The metallic tube 1200 is not an electrode and is provided only for the strength of the probe assembly. The tip supports two metal electrodes 1230, 1240. Each of the electrodes 1230, 1240 have electric leads, which extend through the hollow interior of the tube 1200 to a supporting insulative handle where it is coupled by appropriate means with a power source in the manner previously described. Energy flows between the electrodes 1230, 1240, heating only the tissue adjacent the gap therebetween. Aspiration and irrigation may be provided through a lumen 1222.

[0106] Figures 13 and 14 show alternative embodiments of a goniectomy cauterization probe 1300, 1400. The probe comprises a handle 1305, 1405 and a probe tip 1310, 1410. The probe tip includes a cautery element 1330, 1430.

[0107] The probes 1300, 1400 are provided with an energy source; however, probe 1400 also includes an irrigation supply 1480 and an aspiration pump 1470. These components connect to the probe 1300, 1400 at connector 1308, 1408.

[0108] Figures 15 a,b show detailed views of probe tip 1310. The probe tip 1510 is straight and includes an electrode 1530 attached to electrode 1520, which are separated by a layer of insulation 1528.

[0109] Figures 16 a,b show detailed views of probe tip 1410. The probe tip 1610 is straight and includes an electrode 1630 attached to a hollow electrode 1620, which are separated by a layer of insulation 1628. The hollow electrode 1620 forms a hollow passage 1622 for irrigation and aspiration.

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[0110] In an alternative embodiment, the needle tip of Figure 14 may comprise a hollow needle, with or without a cauterizing element, acoustically coupled to an ultrasonic handle and surrounded by a hollow sleeve. The handle includes an ultrasonic transducer, such as that used for phacoemulsification, which may be either piezoelectric or magnetostrictive. When the handle is activated, the needle is vibrated longitudinally at an ultrasonic rate. Simultaneously, a hydrodynamic flow of irrigation fluid may be introduced into the eye. The vibrating needle emulsifies the tissue, and the particles are preferably simultaneously aspirated, along with the fluid, out of the eye through the hollow needle tip. Aspiration is effected by a vacuum pump, which is connected to the handle. The ultrasonically vibrated needle emulsifies the tissue by combining i) the mechanical impact of the needle tip which varies depending on its mass, sharpness, and acceleration, ii) the ultrasonic acoustical waves generated by the metal surfaces of the vibrating needle, iii) the fluid wave created at the needle's leading edge, and iv) implosion of cavitation bubbles created at the tip of the vibrating needle.

[0111] In an alternative embodiment, sonic technology may be used to ablate the tissue. Sonic technology offers an innovative means of removing material without the generation of heat or cavitational energy by using sonic rather than ultrasonic technology. The tip expands and contracts, generating heat, due to intermolecular frictional forces at the tip, that can be conducted to the surrounding tissues. The tip does not need a hollow sleeve if sonic energy is used to remove the trabecular meshwork.

[0112] The use of acoustic energy, and particularly ultrasonic energy, offers the advantage of simultaneously applying a dose of energy sufficient to ablate the area without exposing the eye to current. The ultrasonic driver can also modulate the driving frequencies and/or vary power in order to smooth or unify the produced collimated ultrasonic beam.

[0113] The amount of heat generated is directly proportional to the operating frequency. The sonic tip does not generate cavitational effects and thus true fragmentation, rather than emulsification or vaporization, of the tissue takes place. This adds more precision and predictability in cutting and less likelihood of damage to other areas of the eye. The tip can be utilized for both sonic and ultrasonic modes. The surgeon can alternate between the two modes using a toggle switch on a foot pedal when more or less energy is required.

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[0114] Figure 17 shows the control system for a goniectomy cauterization probe. The cautery element 1730 is coupled to a cautery actuator. The cautery actuator generally includes a radio-frequency ("RF") current source 1760 that is coupled to both the RF electrode and also a ground patch 1750 which is in skin contact with the patient to complete an RF circuit, in the case of a monopolar system. The cautery actuator may include a monitoring circuit 1744 and a control circuit 1746 which together use either the electrical parameters of the RF circuit or tissue parameters such as temperature in a feedback control loop to drive current through the electrode element during cauterization. Also, where a plurality of cautery elements or electrodes are used, switching capability may be provided to multiplex the RF current source between the various elements or electrodes.

[0115] The probe is connected to a low voltage power source via a power cord that mates with the handle. The source may be a high frequency, bipolar power supply, preferably, a solid state unit having a bipolar output continuously adjustable between minimum and maximum power settings. The source is activated by an on/off switch, which may comprise a foot pedal, or a button on the probe or interface. The source provides a relatively low bipolar output voltage. A low voltage source is preferred to avoid arcing between the electrode tips, which could damage the eye tissue. The generator is coupled to first and second electrodes to apply a biologically safe voltage to the surgical site.

[0116] Delivery of energy to the tissue is commenced once the cautery element is positioned at the desired location. The energy source preferably provides RF energy, but is not limited to RF and can include microwave, ultrasonic, coherent and incoherent light thermal transfer and resistance heating or other forms of energy as known to those of skill in the art. Energy is typically delivered to the cautery element via electrical conductor leads. The cautery control system may include a current source for supplying current to the cautery element.

[0117] The current source is coupled to the cautery element via a lead set (and to a ground patch in some modes). The monitor circuit 1744 desirably communicates with one or more sensors (e.g., temperature) 1730 which monitor the operation of the cautery element. The control circuit 1746 may be connected to the monitoring circuit 1744 and to the current source 1760 in order to adjust the output level of the current driving the cautery element based upon the sensed condition (e.g. upon the relationship between the monitored temperature and a predetermined temperature set point).

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[0118] The procedure for performing goniectomy with the goniectomy cauterization probe of an embodiment of the present invention is similar to a traditional goniotomy surgery, as previously described. The surgeon preferably sits on the temporal side of the operating room table utilizing an operating microscope. The patient's head is rotated 45° away from the surgeon after a retrobulbar injection has anesthetized the eye. A knife, preferably 20 gauge, is used to make a clear corneal temporal incision. The goniectomy instrument is inserted into the anterior chamber up to the infusion sleeve to maintain the intraocular pressure and deepen the anterior chamber. The surgeon positions the gonio lens, preferably a Schwann-Jacobs lens or a modified Barkan goniotomy lens, on the cornea. The goniectomy probe is advanced to the trabecular meshwork. The sharp end point of the footplate incises the middle one third of the trabecular meshwork, which is known as the pigmented portion of the trabecular meshwork. The footplate 721 (Fig. 7) is further inserted into Schlemm's canal. The cautery element is activated, preferably by a footplate, which may also be used to activate irrigation and aspiration. The current provided to the cautery element heats the tissue. The instrument is slowly advanced through the trabecular meshwork maintaining the footplate 721 in Schlemm's canal, feeding the pigmented trabecular meshwork into the opening of the instrument where the tissue removal occurs. The instrument is advanced until no further tissue can be removed inferiorly. The tissue may also be aspirated through the probe, thus substantially removing a portion of the trabecular meshwork. The instrument may be rotated in the eye and reintroduced into Schlemm's canal where the initial incision began. The superior portion of the trabecular meshwork is then removed using cautery and aspiration. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. The corneal incision is preferably sealed by injecting a balanced salt solution into the corneal stroma or by placing a suture. The anterior chamber is reformed. A visceolastic substance may be utilized to maintain the anterior chamber with the initial incision and at the end of the surgery.

[0119] Trabeculodialysis

[0120] Trabeculodialysis is similar to goniectomy; therefore, a goniectomy cauterization probe may also be used to perform trabeculodialysis. The procedure for performing a trabeculodialysis procedure with a cauterization probe is similar to the

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trabeculodialysis procedure previously described. However, rather than cutting the tissue with a knife, the tissue is ablated with the probe. Similarly, in a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed.

[0121] Goniectomy Cutting Probe

[0122] Another preferred embodiment of a goniectomy cutting probe, used to cut and remove trabecular meshwork, is shown in Figure 18. The probe comprises a handle 1805 and a probe tip 1810. Preferably, the handle is 25 gauge and the probe tip is approximately 25 gauge. The handle 2405 is sized and configured to fit completely and comfortably within a hand. The handle 2405 may be formed of a variety of materials, including plastics, and may be designed in a variety of shapes. Generally, it will be preferred that a convenient shape for gripping, such as a cylindrical shape, be provided. The probe tip 1810 further comprises a footplate 1820, protecting endothelial cells and collector channels lining the scleral wall of Schlemm's canal. The footplate 1820 also serves as a guide in Schlemm's canal. The sharpened end of the footplate is used to penetrate the trabecular meshwork.

[0123] Figures 19-20 show sectional views of different embodiments of the internal components and construction of the probe 1800. The probe is configured to define therewithin a hollow inner chamber. A drive member, coupled to a rotatable drive cable within a drive cable assembly, extend into the hollow inner chamber, as shown. A rotatable drive shaft 1944, 2044 is rotatably connected or engaged to the drive member, such that the shaft may be rotatably driven at speeds required for the trabecular meshwork removal. The rotatable drive shaft is inserted into a bore formed in the distal face of the drive member.

[0124] The elongate rotatable drive shaft 1944, 2044 passes longitudinally through the probe and terminates, at its distal end, in a cutting head 1945, 2045. A protective tubular sheath may be disposed about the rotatable shaft. The rotatable shaft and/or sheath are axially movable so as to allow the cutting head to be alternately deployed in a) a first non-operative position wherein the cutting head is fully located within the inner bore of the tubular sheath so as to be shielded during insertion and retraction of the instrument or b) a second operative position wherein the cutting head is advanced out of the distal end of the sheath so as to contact and remove the trabecular meshwork. The cutting head 1945, 2045 may be configured such that rotation of the head will create and sustain a

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forced circulation of fluid within the meshwork. Such forced circulation causes the trabecular meshwork to be pulled or drawn into contact with the rotating cutting head, without the need for significant axial movement or manipulation of the probe while the cutting head is rotating.

[0125] A control pedal may be connected to the motor-drive system to induce actuation/deactuation, and speed control of the rotatable drive cable within the drive cable assembly by the operator. Additional switches or control pedals may be provided for triggering and actuating irrigation and/or aspiration of fluid and/or debris through the probe.

[0126] The probe of Figure 19, shows the probe 1900 having two separate lumens, 1922, 1924, for irrigation and aspiration. The hollow passageway 2022 extending longitudinally through the probe of Figure 20, containing the rotatable drive shaft, is in fluid communication with an irrigation pump (not shown). By such arrangement, a flow of irrigation fluid may be infused through the tube. A separate lumen 2024 is also provided for aspiration.

[0127] The independent processes of irrigation and aspiration may be performed simultaneously with the rotation of the head or while the head is in a non-rotating, stationary mode. It will also be appreciated that the infusion and aspiration pathways may be reversed or interchanged by alternately connecting the aspiration pump to the irrigation tubing and irrigation pump to the aspiration tubing.

[0128] In an alternative embodiment, as shown in Figures 21-23, the probe cuts tissue in a guillotine fashion. As shown in Figure 21, the probe 2100 may include an inner sleeve 2144 that moves relative to an outer sleeve 2146. The sleeves are coupled to the handle. The inner sleeve 2144 may be coupled to a vacuum system which pulls tissue into the port 2125 when the inner sleeve 2144 moves away from the port. The inner sleeve 2144 then moves in a reverse direction past the outer port to sever tissue in a guillotine fashion. The vacuum system draws the severed tissue away from the port, so the process may be repeated. The inner sleeve may be connected to a diaphragm and a spring, rigidly attached to the handle. The diaphragm is adjacent to a pneumatic drive chamber that is in fluid communication with a source of pressurized air (not shown). The drive chamber is pressurized, expanding the diaphragm. Expansion of the diaphragm moves the inner sleeve so that the tissue within the port is severed by the sleeve. Alternatively, the inner sleeve 2144 is driven by a motor located within the handle. The inner sleeve 2144 is coupled to

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the motor by a rotating lever mechanism or wobble plate, inducing an oscillating translational movement of the sleeve in response to a rotation of the output shaft. The motor is preferably an electrical device coupled to an external power source by wires that are attached to a control system at the handle.

[0129] Figure 22 shows an embodiment wherein the irrigation lumen 2222 contains the cutting sleeve 2244. Cutting sleeve 2244 has a cutting blade 2245 integrally formed at its distal end. Figure 23 shows an alternative embodiment, wherein the irrigation lumen 2322 does not contain the cutting sleeve. An aspiration lumen 2224, 2324 is also provided. The aspiration line may be directly coupled to an aspiration pump; the irrigation lumen may be directly coupled to an irrigation pump.

[0130] The procedure for goniectomy with the goniectomy cutting probe is similar to the goniectomy procedure discussed for the goniectomy cauterization probe. However, rather than cauterizing the trabecular meshwork, the tissue is cut using a rotatable blade or cut in a guillotine fashion, and subsequently aspirated. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed.

[0131] Goniectomy Laser Probe

[0132] A laser probe 2400, as shown in Figures 24a and 24b, is provided to ablate the trabecular meshwork. The probe 2400 comprises a handle 2405 and a probe tip 2410. The handle 2405 is sized and configured to fit completely and comfortably within a hand. It will be understood that the handle 2405 may be formed from a variety of materials, including plastics, and may be designed in a variety of shapes. Generally, it will be preferred that a convenient shape for gripping, such as a cylindrical shape, be provided. The main body of the handle 2405 comprises a plastic housing within which a laser system is contained. The plastic housing is provided to enable easy manipulation of the handle 2405 by the user. The laser is preferably an excimer laser.

[0133] Figure 24a shows an embodiment wherein the laser source is contained within the probe, but rather within the control system. A fiber is provided to direct the light energy from the source to the proximal end of the probe tip. The laser radiation is generated in close proximity to the eye, so that relatively little laser light is lost during transmission.

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[0134] Figure 24b shows an embodiment wherein the laser source is not contained within the probe. The source may include a longitudinal flashlamp. A fiber is provided to direct the light energy from the source to the proximal end of the probe tip.

[0135] The probe tip 2410 is connected to the main body 2405. The probe tip comprises a footplate to protect the outer wall of Schlemm's canal, such that only the tissue of the trabecular meshwork is cauterized. The footplate also is used to penetrate the trabecular meshwork and serves as a guide in Schlemm's canal. In general, the probe tip 2410 is straight or curved.

[0136] Figure 25 shows a detailed view of Figure 24a. The handle includes a reflective tube 2508 which has a mirrored inside surface. An Er: YAG rod 2513 is located along the axis of the tube 2508. The pump for the laser light source is preferably a high pressure flashtube 2512 or a similar suitable light source which is located adjacent the rod 2513 within the reflective tube 2508. The flashtube 2512 produces very brief, intense flashes of light, there being approximately 10 to 100 pulses per second.

[0137] Er:YAG rods generate an output wavelength of approximately 2.94 microns. Use of an erbium doped laser, such as an Er: YAG laser, is advantageous because it requires less power to ablate the eye tissue than do the Nd: YAG and Holmium:YAG lasers of the prior art. Preferably the Er: YAG laser has a pulse repetition rate of 5 to 100Hz, a pulse duration of 250 μs to 300 μs, and a pulse energy of 10 to 14mJ per pulse. Using an Er: YAG laser at the above parameters limits the thermal damage of surrounding tissue to a depth of 5 to 50 microns. By reducing the thermal damage of surrounding tissue, the amount of scar tissue buildup caused by the laser is minimal. Thus, the likelihood that the passageway will become blocked with scar tissue is reduced, and the likelihood that the procedure will need to be repeated is reduced.

[0138] The reflective inner surface 2546 of the tube 2508 serves to reflect light from the flashlamp 2512 to the rod 2513. Reflection of the light by the cylindrical mirror focuses as much light as possible toward the rod 2513. This results in efficient coupling between the light source 2512 and the laser rod 2513. Thus, essentially all light generated in the flashtube 2512 is absorbed by the laser rod 2513.

[0139] The rod 2513 has a totally reflective mirror 2514 and output mirror 2517 at its two ends. The mirror 2514 at the proximal end of the rod 2513 provides 100% reflection of light back to the rod 2513. At the remote end of the rod 2513, the output

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mirror 2517 provides less than 100% reflection. Thus, while most of the light energy directed toward the output mirror 2517 of the rod 2513 is reflected back into the rod 2513, intensifying the beam, some of the waves of energy pass through the output mirror 2517 and into the transmission system 2511 for conducting it toward the probe tip 2515. A reflective coating on the end of the laser rod 2513 may be used to supplement or replace the mirrors 2517, 2514.

[0140] The mirrors 2517, 2514 on either end of the rod form a resonator. Radiation that is directed straight along the axis of the rod 2513 bounces back and forth between the mirrors 2517, 2514 and builds a strong oscillation. Radiation is coupled out through the partially transparent mirror 2517.

[0141] The transmission system 251 is preferably an optical fiber. Preferably, a sapphire or fused silica fiber will be used with the laser, contained within the handle. A germanium oxide Type IV fiber is also suitable for carrying erbium laser light with reduced attenuation. It is also possible to deliver laser light through hollow waveguides. Such waveguides often include multi-layer dielectric coatings to enhance transmission.

[0142] Figure 26 shows a detailed view of one embodiment of a probe tip 2600, in which the fiber 2610 is centrally located within the probe tip 2600.

[0143] Alternatively, the probe tip may be hollow, forming an aspiration/irrigation lumen (not shown). The lumen extends the entire length of the probe. Alternatively, as shown in Figure 27, the lumen 2722 may extend adjacent the probe tip 2710. The aspiration lumen 2722 communicates with a vacuum source for withdrawal of emulsified material through an aperture or aspiration port. During use, the vacuum source can be employed to aspirate material which has been fragmented or ablated by the pulsed laser light. The vacuum source can also be used to draw the tissue into close proximity with the delivery end of the probe thereby facilitating its destruction. Fluid introduced through the lumen, chamber, and aperture can provide for flushing of the site and replacement of lost volume due to removal of the emulsified material.

[0144] The probe is inserted under direct vision to ablate the trabecular meshwork for use in treating glaucoma, thus obtaining a free flow of aqueous from the anterior chamber into Schlemm's canal and through the collector channels. The end of the probe is inserted through a relatively small incision in the eye, and can be maneuvered very close to the tissue to be emulsified.

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[0145] The procedure is similar to the goniectomy procedure previously discussed with reference to the goniectomy cauterization probe. The surgeon visualizes the trabecular meshwork under direct microscopy and engages the superficial layers of the meshwork at the midpoint of the trabecular band, by placing the tissue between the end 2521 of the fiber 2511 and the probe tip (footplate) 2519. Once inserted, the fiber 2511 is positioned to focus laser energy directly on the trabecular meshwork. The probe tip 2519 absorbs any laser energy which is not absorbed by the trabecular meshwork, thus protecting Schlemm's canal from damage. Light is transmitted to and through the probe, and the tissue is ablated. The area may be irrigated and aspirated, removing the tissue from the eye. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. After treatment, the probe is readily withdrawn from the eye. Leakage may be stopped using a suture and burying the knot.

[0146] Laser treatment with an Er:YAG laser is advantageous because as wavelength increases, contiguous thermal effects decrease. In the visible portion of the spectrum, water has minimal absorption. Above 2.1 μm however, this absorption increases to a level comparable to excimer lasers operating around 200nm. This increase is quite rapid. A marked difference therefore exists between radiation at 2.79 μm and 2.94 μm. This confines the energy delivered to a smaller volume, allowing more ablation to occur at lower total energy levels and limiting contiguous thermal damage. Er: YAG lasers produce ablations with minimal amounts of contiguous thermal damage. Light in the infrared region has an additional advantage over ultraviolet radiation in that it is not known to have mutagenic or carcinogenic potential.

[0147] Due to the large absorption band of the water at the wavelength of the erbium laser, no formation of sticky material on the probe tip takes place, which can be a serious problem at other wavelengths.

[0148] Schlemmectomy Cauterization Probe

[0149] Schlemmectomy is a new surgical procedure, similar to trabeculotomy. However, in a schlemmectomy procedure, disrupted tissue is removed using a schlemmectomy cauterization probe. Figure 28 illustrates a probe 2800 in accordance with this invention for removal of the trabecular meshwork, using a cautery element 2830 on a probe similar to a traditional trabeculotome, such as Harm's trabeculotome. The probe uses

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both cautery and mechanical disruption to ablate the fibers of the trabecular meshwork, leaving a patent open Schlemm's canal.

[0150] The probe 2800 comprises a handle 2805 and a probe tip 2810. The proximal end of the handle is adapted for mating with a connector 2812 to the output terminals of an energy source 2860.

[0151] The probe also includes electrical leads 2934 (Figure 29), a power cable 2808, preferably a coaxial cable, and an actuator. These components extend from the handle 2805, through an electrical lead lumen 2932 (Figure 29) in the probe shaft 2805, to the corresponding components of the probe 2800 disposed on the distal end. The proximal ends of the cables and lumens connect to the corresponding connectors that extend from the distal end of the probe handle 2805.

[0152] Figures 29a-c illustrate one probe tip configuration. The probe tip 2910 comprises two parallel arms 2920, 2950. The probe tip 2910 comprises an electrode 2930, which will be described in further detail below, disposed on the lower arm 2920. The probe tip 2910 comprises an electrical lead lumen 2932 which extends the length of the probe tip 2910 from the electrode 2930 through the cylindrical body 2802 to the connector of the probe handle 2812. (Figure 28)

[0153] Figure 30 shows a preferred embodiment of a probe 3000. The probe of Figure 30 is similar to the probe of Figure 28, except that probe 3000 further comprises irrigation means. Irrigation may be provided by an irrigation pump 3080 or hydrostatic pressure from a balanced salt solution bottle and tubing.

[0154] In a preferred embodiment, as shown in Figure 31a, the irrigation lumen 3122 is situated at the end of the probe. Irrigation under pressure flushes blood from the eye and expands Schlemm's canal and the anterior chamber, providing more room for the procedure. Alternatively, lumen 3122 provides for aspiration by connecting the lumen to an aspiration pump. Aspiration ports may be provided equidistantly along the length of the cauterizing element of the trabeculotome, as shown in Figure 31b. In an embodiment, as shown in Figure 31c, two lumens are provided, an irrigation lumen 3122 and an aspiration lumen 3124. Two separate lumens provide for simultaneous irrigation and aspiration.

[0155] With reference to the schlemmectomy probes of Figures 28 and 30, the handle 2805, 3005 may be made of an electrically insulating polymeric material, configured in a pencil-shape form having a cylindrical body region 2802, 3002 and a tapered forward

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region 2804, 3004. Although a pencil-shape configuration is preferred, it is noted that any configuration of the handle 2805, 3005 which is easily, comfortably and conveniently grasped by the operator will also be suitable and is considered to be within the scope of the present invention.

[0156] The probe tip 2810, 3010 is connected to the main body of the handle 2805, 3005. The cautery element 2830, 3030 at the distal end of the probe tip 2810, 3010 can have a variety of configurations.

[0157] The tip 2810, 3010 may be any material, such as titanium, brass, nickel, aluminum, stainless steel, other types of steels, or alloys. Alternatively, non-metallic substances may also be used, such as certain plastics. The tip may be conductive or non-conductive, depending on the specific embodiment, as will be discussed.

[0158] Figures 32a and 32b show alternative distal probe tip configurations, wherein the second electrode 3230 extends along the entire length of the first electrode 3220. The probe tip 3210 may be curved to better maneuver within the anatomy of the eye. The malleable probe tips can be configured as straight, angled or curved, for example, which provides for optimal access to specific anatomy and pathology. Unique tip designs improve tactile feedback for optimal control and access, and provide for improved tissue visualization with greatly reduced bubbling or charring.

[0159] Referring again to the probes of Figures 28 and 30, the probe tip 2810, 3010 comprises an electrode or cautery element 2830, 3030, suitable for cautery, as known to those of skill in the art. Various electrode configurations and shapes may be suitable. The cautery element 2830, 3030 is any electrode that may provide ablation or cauterization of tissue, such as a RF electrode, an ultrasound transducer, or any other suitable electrode. Alternatively, or in addition to the RF electrode variations, the cautery element may also include other cautery energy sources or sinks, and particularly may include a thermal conductor. Examples of suitable thermal conductor arrangements include a metallic element which may, for example, be constructed as previously described. In the thermal conductor embodiment such a metallic element would be generally resistively heated in a closed loop circuit internal to the probe, or conductively heated by a heat source coupled to the thermal conductor.

[0160] The electrode 2830, 3030 may be provided on the inner surface of the tip. Alternatively, the electrode 2830, 3030 may be embedded in a sheath of a tube.

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Insulation may be provided around the cautery element so that other areas of the eye are not affected by the cauterization. A sleeve shield or a non-conductive layer may also be provided on the probe tip to expose only a selected portion of the electrode. The sleeve preferably has sufficient thickness to prevent both current flow and capacitance coupling with the tissue.

[0161] The cautery element can be made of a number of different materials including, but not limited to stainless steel, platinum, other noble metals, and the like. The electrode can also be made of a memory metal, such as nickel titanium. The electrode can also be made of composite construction, whereby different sections are constructed from different materials.

[0162] In a preferred embodiment of an RF electrode, the electrode system is bipolar. In a bipolar system, two electrodes of reversed polarity are located on the probe tip and RF energy bridges the electrodes. Additionally, any number of pairs of electrodes may be provided on the probe tip.

[0163] In an alternative RF electrode embodiment, the electrode system is monopolar. In a monopolar system, the system comprises a single electrode and a contact plate. The contact plate is attached to the surface of the human body. The contact plate is further connected to the return terminal of the power source via a lead wire. Voltages of reverse polarity are applied to the electrode and the contact plate.

[0164] In a preferred embodiment, as shown in Figures 33a and 33b, an electrode assembly of a bipolar probe includes one electrode 3320 made from a stainless steel 20 gauge hollow needle and a second electrode 3330 formed as a layer of electrically conductive material (such as silver or nickel) deposited over and adhered to an exterior surface of the needle electrode. A thin electrical insulator 3324 separates the electrodes 3320, 3330, along their lengths to avoid short circuiting.

[0165] The electrodes 3320, 3330 extend along a longitudinal axis 3372 of the instrument from a proximal region at which bipolar electrical power is applied to a distal region of the electrode assembly.

[0166] In a preferred embodiment, the second electrode 3330 extends over a limited portion of the circumference of the first electrode 3320, rather than entirely around the first electrode 3320. Current flows from the relatively small portion of the circumference of the second electrode 3330 where heat is generated in the adjacent tissue,

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and into the layer surface of the first electrode 3320, where little heat is generated. This limits the area in the body that receives dense current, and provides the operator with a high degree of control as to where the current is applied. The second electrode 3330 extends over an arc of approximately one quarter of the circumference of the first electrode. The second electrode 3330 is disposed symmetrically about an axis 3372.

[0167] In a preferred embodiment, the first electrode 3320 has a central passage 3322 that is open at the distal region, providing for irrigation. The irrigation lumen 3322 extends from the distal end of the probe tip, through the probe handle, to the connector, providing for irrigation capability.

[0168] Figure 34 shows an alternative embodiment, wherein the electrode assembly includes a central or axial electrode 3420 formed by a solid cylindrical metal member, and an elongate hollow outer electrode 3430 formed by a cylindrical metal tube member, which is coaxially positioned around the central electrode. The cylindrical outer surface of electrode 3430 forms the circumferential surface of the probe. The outer electrode 3430 is preferably made of stainless steel or other corrosive resistant, conductive material for strength as well as conductivity. The inner electrode 3420 may be made of copper, but less conductive materials may also be employed. The coaxial relationship and spacing between the electrodes, as well as their electrical isolation from one another, is provided by a tubular sleeve 3424 of an electrically insulating material between the electrode, completing the probe assembly. An additional layer of insulation 3434 may be provided on outer electrode 3430 to expose only a limited portion of the electrode to concentrate RF energy at the limited exposed region.

[0169] Alternatively, one or more regions of insulating area 3434 may be removed at any suitable location along the axis to expose a region of electrode 3430. Cauterization would then occur at the exposed region. The circumferential extent of the second electrode 3430 can be further limited, depending on the degree of control desired over the size of the area to which current is applied.

[0170] In an alternative embodiment as shown in Figures 35a and 35b, the active region of a bipolar electrode probe assembly is formed by a hollow metal tube 3515 having a substantially semi-cylindrical sleeve 3524 on tube 3515. The metallic tube 3515 is not an electrode and is provided only for the strength of the probe assembly. The tip supports two cautery elements 3520, 3530. Each of the elements 3520, 3530 is connected

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to electrical leads, which extend through the hollow interior of the tip 3510 to a supporting insulative handle where it is coupled by appropriate means with a power source in the manner previously described.

[0171] The probe is connected to a low voltage RF power source via a power cord that mates with the handle. The source may be a high frequency, bipolar power supply, preferably, a solid state unit having a bipolar output continuously adjustable between minimum and maximum power settings. The source is activated by an on/off switch, which may comprise a foot pedal, or a button on the probe or interface. The source provides a relatively low bipolar output voltage. A low voltage source is preferred to avoid arcing between the electrode tips, which could damage the eye tissue. The RF generator is coupled to first and second electrodes to apply a biologically safe voltage to the surgical site. This probe has the advantage of cauterizing at both of the bipolar elements, each of which has a limited, RF current concentration area.

[0172] Delivery of energy to the tissue is commenced once the cautery element is positioned at the desired location. Energy is typically delivered to the cautery element via electrical conductor leads. The energy source preferably provides RF energy, but is not limited to RF and can include microwave, electrical, ultrasonic, coherent and incoherent light thermal transfer and resistance heating or other forms of energy, as known to those of skill in the art.

[0173] The cautery actuator may include a monitoring circuit 1744 and a control circuit 1746 (Figure 17) which together use either the electrical parameters of the RF circuit or tissue parameters such as temperature in a feedback control loop to drive current through the electrode element during cauterization. Feedback control systems can be used to obtain the desired degree of heating by maintaining the selected sight at a desired temperature for a desired time. A sensor, such as a thermocouple may be used to monitor temperature in a feedback loop. Where a plurality of cautery elements or electrodes are used, switching capability may be provided to multiplex the RF current source between the various elements or electrodes.

[0174] Figure 17 shows the monitor circuit 1744, which desirably communicates with one or more sensors (e.g., temperature) 1740 which monitor the operation of the cautery element 1730. The control circuit 1746 may be connected to the monitoring circuit 1744 and to the current source in order to adjust the output level of the

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current driving the cautery element 1730 based upon the sensed condition (e.g. upon the relationship between the monitored temperature and a predetermined temperature set point).

[0175] Circuitry, software and feedback to a controller, which result in full process control, may be used to change (i) power – including RF, incoherent light, microwave, ultrasound, and the like, (ii) the duty cycle, (iii) monopolar or bipolar energy delivery, (iv) fluid (electrolyte solution delivery, flow rate and pressure) and (v) determine when ablation is completed through time, temperature and/or impedance.

[0176] In a preferred embodiment, a bipolar electrode is part of a circuit that includes the RF signal generator, connecting cables, probe tip for insertion into the eye, a grounding electrode attached to the probe and a return cable that connects the grounding electrode to the RF generator completing the circuit. Because such a RF electrode is a relatively good conductor, the electrode itself does not heat up. The tissues that the electrode comes in contact with heat up in response to current passing from the electrode through the tissues. The tissue heats up because it is a relatively poor conductor as compared to the rest of the circuit. It is when the tissues heat up as a result of molecular friction, that heat is then conducted back to the electrode itself. At that point, a thermocouple senses the increase in temperature and supplies that information to the RF generator so that the feedback mechanism can attenuate the energy delivered in order to attain temperature control.

[0177] It may also be advantageous to regulate RF delivery through both temperature and impedance monitoring. It may also be advantageous to monitor irrigation fluid flow to maintain clarity at the site. There is also an opportunity for synergy between RF and irrigation fluid delivery to the surgical site to provide, for example, a greater level of control of temperatures at the site.

[0178] The controller may include an RF generator, temperature profile, temperature regulator, temperature monitor, surgical instrument, impedance monitor, impedance regulator, pump, flow regulator and flow monitor.

[0179] The RF generator may be capable of delivering monopolar or bipolar power to the probe. The probe is positioned at the surgical site. The impedance monitor obtains impedance measurements by, for example, measuring current and voltage and performing a RMS calculation. The measurements of the impedance monitor are delivered to the impedance regulator. The impedance regulator performs several functions.

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Generally the impedance regulator keeps the impedance levels within acceptable limits by controlling the power supplied by the RF generator. In one embodiment of the current invention the impedance regulator can control the flow regulator to deliver more or less irrigation fluid to the surgical site.

[0180] To maintain the appropriate temperature for cauterizing tissue, the distal tip of the probe may also be equipped with a thermocouple 1740. Temperature feedback, in combination with a timing device, permits a precise degree of cautery to be delivered, obtaining the desired effect without causing any intraocular heating. The heating effect on tissue may be mitigated with a viscoelastic agent to deepen the anterior chamber.

[0181] Referring to Figure 17, the temperature monitor 1744 may include one or more types of temperature sensors, e.g. thermocouples, thermistors, resistive temperature device (RTD), infrared detectors, etc.

[0182] Suitable shapes for the thermocouple include, but are not limited to, a loop, an oval loop, a "T" configuration, an "S" configuration, a hook configuration or a spherical ball configuration. These shapes provide more surface area for the thermocouple without lengthening the thermocouple. These thermocouples, with more exposed area than a straight thermocouple, are believed to have better accuracy and response time. The thermocouple is attached by a fastener. The fastener may be a bead of adhesive, such as, but not limited to, epoxies, cyanoacetate adhesives, silicone adhesives, flexible adhesives, etc. It may also be desirable to provide multiple thermocouples at different locations and compare their operating parameters (e.g. response times, etc.), which may provide useful information to allow certain such variables to be filtered and thereby calculate an accurate temperature at the thermocouple location.

[0183] The output of the temperature monitor 1744 is delivered to the temperature regulator 1746. The temperature regulator 1746 may control both the RF generator 1760 and the flow regulator. When, for example, temperatures have increased beyond an acceptable limit, power supplied by the RF generator to the surgical instrument may be reduced. Alternately, the temperature regulator may cause the flow regulator to increase irrigation fluid, thereby decreasing the temperature at the surgical site. Conversely, the temperature regulator can interface with either the RF generator or the flow regulator when measured temperatures do not match the required temperatures. The flow

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regulator interfaces with the pump to control the volume of irrigation fluid delivered to the surgical site.

[0184] The procedure for performing a Schlemmectomy with the probe of the present invention is similar to a traditional trabeculotomy procedure, as previously described. The surgeon preferably sits on the temporal side of the operating room table utilizing the operating microscope. An infrotemporal fornix based conjunctival flap is made and the conjunctive and Tenons capsule are mobilized posteriorly. A triangular flap is made and the superficial flab is mobilized into the cornea. A radial incision is made over the canal of Schlemm, thus creating an entrance into the canal. Vanna scissors are preferably introduced into the Schlemm's canal, opening the canal for approximately 1mm on either side. A clear corneal parenthesis is performed and the anterior chamber is deepened, preferably with Haelon GV. The probe is introduced into Schlemm's canal inferiorly. The instrument is now aligned such that the cauterization element faces into the deepened anterior chamber. Alternatively, the cauterization surface faces the trabecular meshwork and is activated by the foot switch at the time of the rotation of the probe into the anterior chamber. The foot switch may then be used to activate cauterization. Aspiration and irrigation may also be activated using the foot switch. The trabeculotome is slowly rotated into the anterior chamber and when the blade of the trabeculotome is seen in the anterior chamber, the cautery (and aspiration and/or irrigation) are deactivated. The superior aspect of Schlemm's canal may be entered with a trabeculotome having the opposite curvature. Following the same steps, more of the trabecular meshwork is removed. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. After removing the trabeculotome, the superficial trabeculotomy flap is sutured closed using sutures.

[0185] Radiowave surgery uses high frequency radio waves instead of heat to cut and coagulate tissue without the burning effect that is common with traditional electrosurgical devices and cautery equipment. The resistance of tissue to the spread of radio wave energy produces heat within the cell, causing the water within the cell to volatilize and destroy the cell without damaging other cellular layers.

[0186] While particular forms of the invention have been described, it will be apparent that various modifications can be made without departing from the spirit and

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scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

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WHAT IS CLAIMED IS:

1. A probe for the treatment of glaucoma, comprising:

a probe tip configured to access the trabecular meshwork;

an aspiration port on said probe tip; and

a laser providing light energy to said probe tip sufficient to ablate said trabecular meshwork.

2. The probe of Claim 1, additionally comprising a handle supporting said probe tip, and wherein said laser is contained within said handle.

3. The probe of Claim 1, further comprising an irrigation port on said probe tip.

4. The probe of Claim 3, further comprising a lumen extending through said probe tip and terminating at said irrigation port.

5. The probe of Claim 1, further comprising a lumen extending through said probe tip and terminating at said aspiration port.

6. The probe of Claim 1, further comprising a combined irrigation and aspiration port on said probe tip.

7. The probe of Claim 6, further comprising a lumen extending through said probe tip and terminating at said combined irrigation and aspiration port.

8. The probe of Claim 1, further comprising an optical fiber for conducting said light energy from said laser to said probe tip.

9. The probe of Claim 8, wherein said optical fiber is a sapphire fiber.

10. The probe of Claim 8, wherein said optical fiber is a fused silica fiber.

11. The probe of Claim 1, additionally comprising a shield configured to protect Schlemm's canal from damage by said laser light energy.

12. The probe of Claim 11, wherein said shield and said laser are separated by an opening sufficient to accommodate said trabecular meshwork.

13. The probe of Claim 11, wherein said shield is sharp enough to penetrate said trabecular meshwork.

14. The probe of Claim 11 wherein said shield is sized to guide said probe tip along Schlemm's canal.

15. The probe of Claim 11, wherein said shield extends at a right angle from said probe tip.

16. The probe of Claim 15, wherein said shield lies on the axis of said laser.

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17. The probe of Claim 1, wherein said laser comprises an Er:YAG laser.

18. The probe of Claim 1 wherein said probe tip is configured for goniectomy.

19. A probe for the treatment of glaucoma, comprising:

a probe tip configured to access the trabecular meshwork;

an aspiration port on said probe tip; and

a tissue ablator disposed on said probe tip and configured to ablate said trabecular meshwork.

20. The probe of Claim 19 wherein said probe tip is configured for schlemmectomy.

21. The probe of Claim 19 wherein said probe tip is configured for goniectomy.

22. The probe of Claim 19, further comprising an irrigation port on said probe tip.

23. The probe of Claim 22, further comprising a lumen extending through said probe tip and terminating at said irrigation port.

24. The probe of Claim 19, further comprising a lumen extending through said probe tip and terminating at said aspiration port.

25. The probe of Claim 19, further comprising a combined irrigation and aspiration port on said probe tip.

26. The probe of Claim 25, further comprising a lumen extending through said probe tip and terminating at said combined irrigation and aspiration port.

27. The probe of Claim 19, further comprising an electrical lead lumen extending through said probe, which runs between a distal port and a proximal port.

28. The probe of Claim 27, wherein electrical leads extend between said tissue ablator and said proximal port through said electrical lead lumen.

29. The probe of Claim 19, wherein said tissue ablator comprises a cautery element.

30. The probe of Claim 29, wherein said cautery element comprises a radio frequency (RF) electrode.

31. The probe of Claim 19, wherein said tissue ablator comprises an ultrasound transducer.

32. The probe of Claim 31 wherein said tissue ablator comprises an array of ultrasound transmissive panels.

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33. The probe of Claim 19, wherein said tissue ablator comprises a piezoceramic ultrasound transducer.

34. The probe of Claim 19, wherein said tissue ablator comprises a piezoelectric transducer having at least a first electrode on an exposed outer surface of said transducer.

35. The probe of Claim 19, wherein said tissue ablator comprises a cryogenic element.

36. The probe of Claim 19, wherein said tissue ablator comprises a monopolar electrode system.

37. The probe of Claim 19, wherein said tissue ablator comprises a bipolar electrode system.

38. The probe of Claim 19, further comprising a power source.

39. The probe of Claim 38, wherein said power source is a current power source.

40. The probe of Claim 39, wherein said current power source provides radio frequency power.

41. The probe of Claim 38, wherein said power source provides ultrasonic energy.

42. The probe of Claim 38, wherein said power source provides sonic energy.

43. The probe of Claim 38, wherein said power source provides electrical power.

44. The probe of Claim 19, wherein a portion of the length of said probe tip is sized to fit within schlemm's canal.

45. The probe of Claim 19, wherein said probe tip is hook-shaped.

46. The probe of Claim 45, wherein said tissue ablator is at the bite of said hook-shaped probe tip.

47. The probe of Claim 19, wherein said probe tip is configured for goniectomy

48. The probe of Claim 19, wherein said probe tip is configured for schlemmectomy.

49. A method for treating glaucoma, comprising:

inserting a probe into an eye;

ablating a region of the trabecular meshwork of said eye with said probe;

aspirating said region of the trabecular meshwork of said eye with said probe; and

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removing said probe.

50. The method of Claim 49, further comprising irrigating said eye.

51. A method for treating glaucoma, comprising:

inserting a probe into an eye;

aspirating a region of the trabecular meshwork of said eye with said probe; and

removing said probe.

52. The method of Claim 51, further comprising aspirating said region of the trabecular meshwork of said eye from said eye.

53. The method of Claim 52, further comprising irrigating said eye.

54. A probe for the treatment of glaucoma, comprising:

a probe tip configured to access the trabecular meshwork;

a tissue ablator disposed on said probe tip and configured to ablate said trabecular meshwork;

an aspiration port on said probe tip; and

a lumen extending through said probe tip and terminating at said aspiration port,

wherein said probe tip is configured for goniectomy.

55. The probe of Claim 54, wherein said tissue ablator is a cautery element.

56. The probe of Claim 54, wherein said tissue ablator is selected from the group consisting of a radio frequency (RF) electrode, ultrasound transducer, array of ultrasound transmissive panels, piezoceramic ultrasound transducer, and piezoelectric transducer.

57. The probe of Claim 54, further comprising an irrigation port on said probe tip.

58. The probe of Claim 57, further comprising an irrigation lumen extending through said probe tip and terminating at said irrigation port.

59. The probe of Claim 54, further comprising an electrical lead lumen extending through said probe, which runs between a distal port and a proximal port.

60. The probe of Claim 59, wherein electrical leads extend between said tissue ablator and said proximal port through said electrical lead lumen.

61. The probe of Claim 54, further comprising a power source.

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62. The probe of Claim 61, wherein said power source is selected from the group consisting of radio frequency, ultrasonic, sonic, and electrical energy.

63. A probe for the treatment of glaucoma, comprising:

a probe tip configured to access the trabecular meshwork;

a tissue ablator disposed on said probe tip and configured to ablate said trabecular meshwork;

an aspiration port on said probe tip;

an aspiration lumen extending through said probe tip and terminating at said aspiration port,

wherein said probe tip is configured for schlemmectomy, said probe tip comprising two parallel arms, wherein a first arm is located directly above a second arm.

64. The probe of Claim 63, wherein said tissue ablator is disposed on the lower arm of said probe tip.

65. The probe tip of Claim 63, wherein said tissue ablator is a cautery element.

66. The probe tip of Claim 63, wherein said tissue ablator is selected from the group consisting of a radio frequency (RF) electrode, ultrasound transducer, array of ultrasound transmissive panels, piezoceramic ultrasound transducer, and piezoelectric transducer.

67. The probe of Claim 54, further comprising an irrigation port on said probe tip.

68. The probe of Claim 67, further comprising an irrigation lumen extending through said probe tip and terminating at said irrigation port.

69. The probe of Claim 54, further comprising an electrical lead lumen extending through said probe, which runs between a distal port and a proximal port.

70. The probe of Claim 69, wherein electrical leads extend between said tissue ablator and said proximal port through said electrical lead lumen.

71. The probe of Claim 54, further comprising a power source.

72. The probe of Claim 71, wherein said power source is selected from the group consisting of radio frequency, ultrasonic, sonic, and electrical energy.

73. A probe for the treatment of glaucoma, comprising:

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a probe tip having a hollow chamber configured to access the trabecular meshwork;

a rotatable shaft disposed within said hollow chamber; and

a cutting head on the distal end of said rotatable shaft.

74. The probe of Claim 73, wherein said hollow chamber is in fluid communication with an irrigation supply.

75. The probe of Claim 73, further comprising an aspiration lumen extending through said probe tip.

76. A probe for the treatment of glaucoma, comprising:

a probe tip having a hollow chamber configured to access the trabecular meshwork;

a cutting sleeve disposed within said hollow chamber; and

a footplate formed at the distal end of said probe tip.

77. The probe of Claim 76, further comprising a cutting blade integrally formed at the distal end of said cutting sleeve.

78. The probe of Claim 76, wherein said cutting sleeve is hollow.

79. The probe of Claim 76, further comprising a combined irrigation and aspiration port.

80. The probe of Claim 79, wherein said hollow cutting sleeve forms an aspiration lumen, extending through said probe tip and terminating near said irrigation and aspiration port.

81. The probe of Claim 76, further comprising an irrigation lumen.

82. A method for treating glaucoma, comprising:

inserting a probe into an eye;

mechanically cutting a region of the trabecular meshwork of said eye with said probe;

aspirating said region of the trabecular meshwork with said probe; and

removing said probe.

83. The method of Claim 82, further comprising removing said region of the trabecular meshwork of said eye from said eye.

84. The method of Claim 82, further comprising irrigating said eye.

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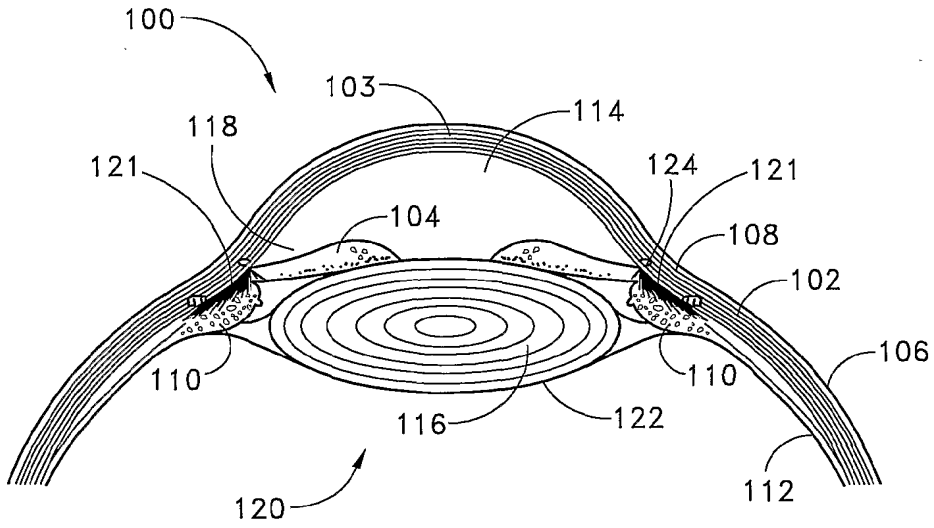

FIG. 1

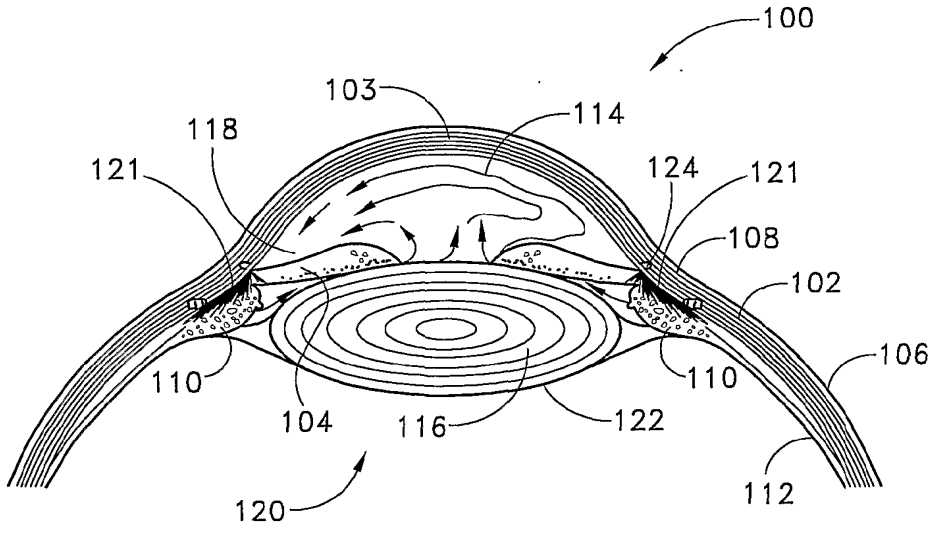

FIG. 2

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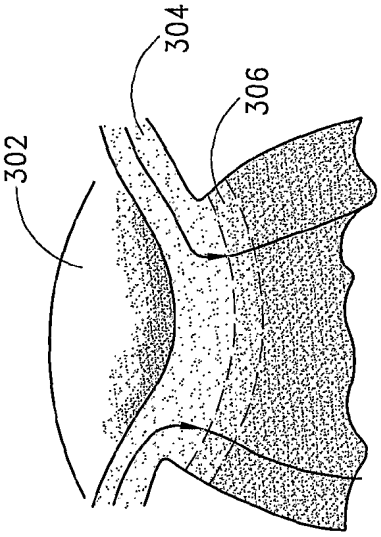

FIG. 3B

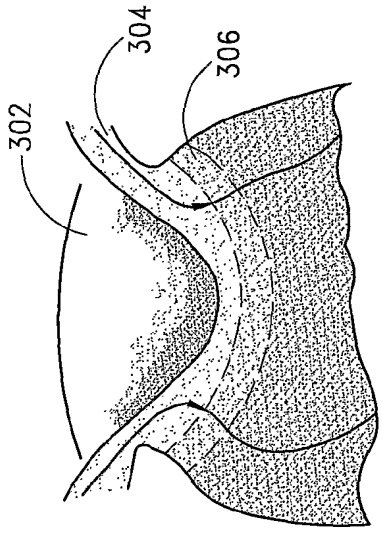

FIG. 3D

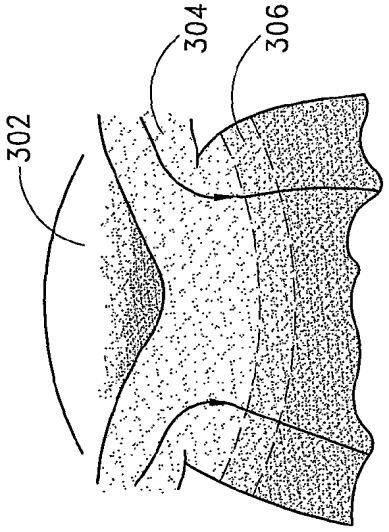

FIG. 3A

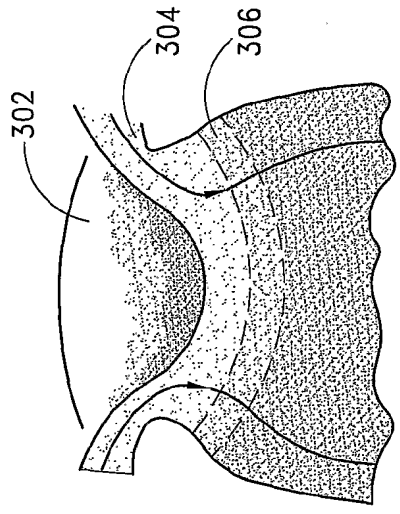

FIG. 3B

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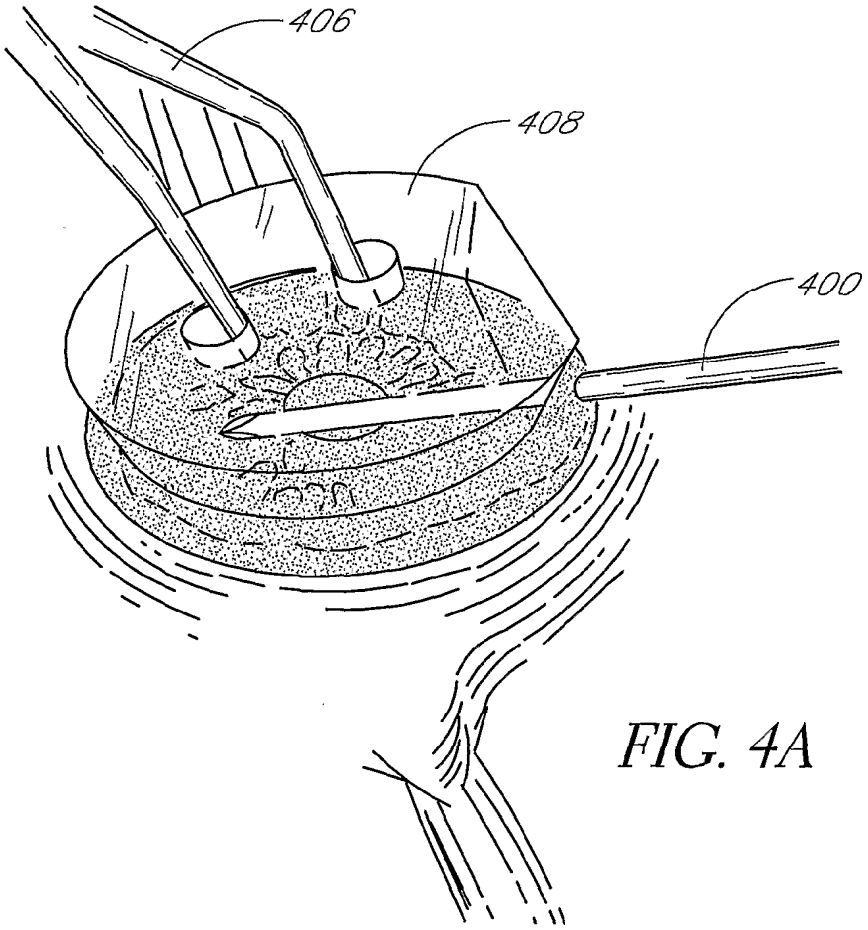
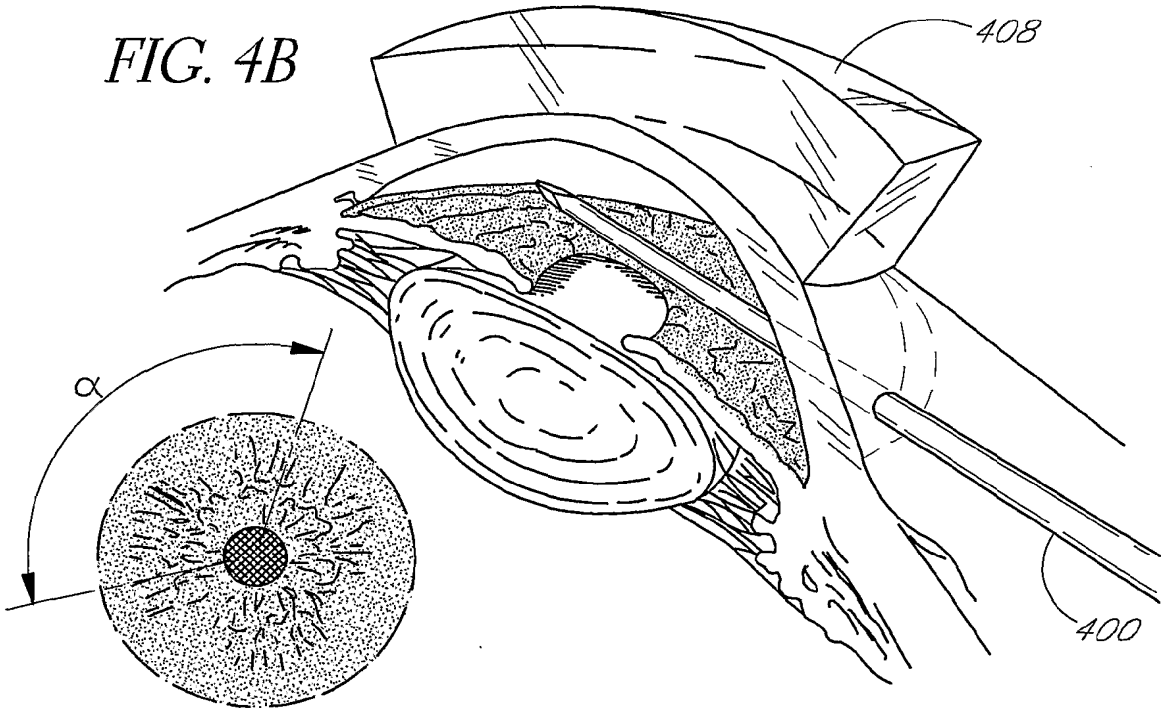


FIG. 4A

FIG. 4B



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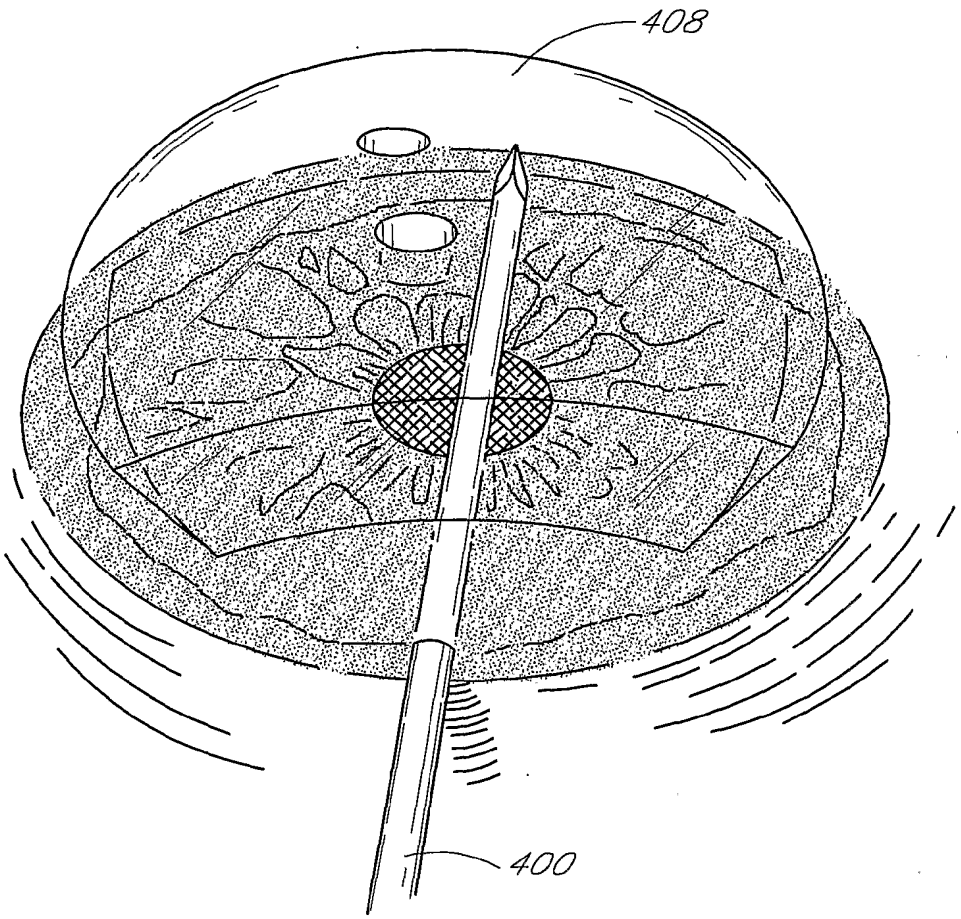

FIG. 4C

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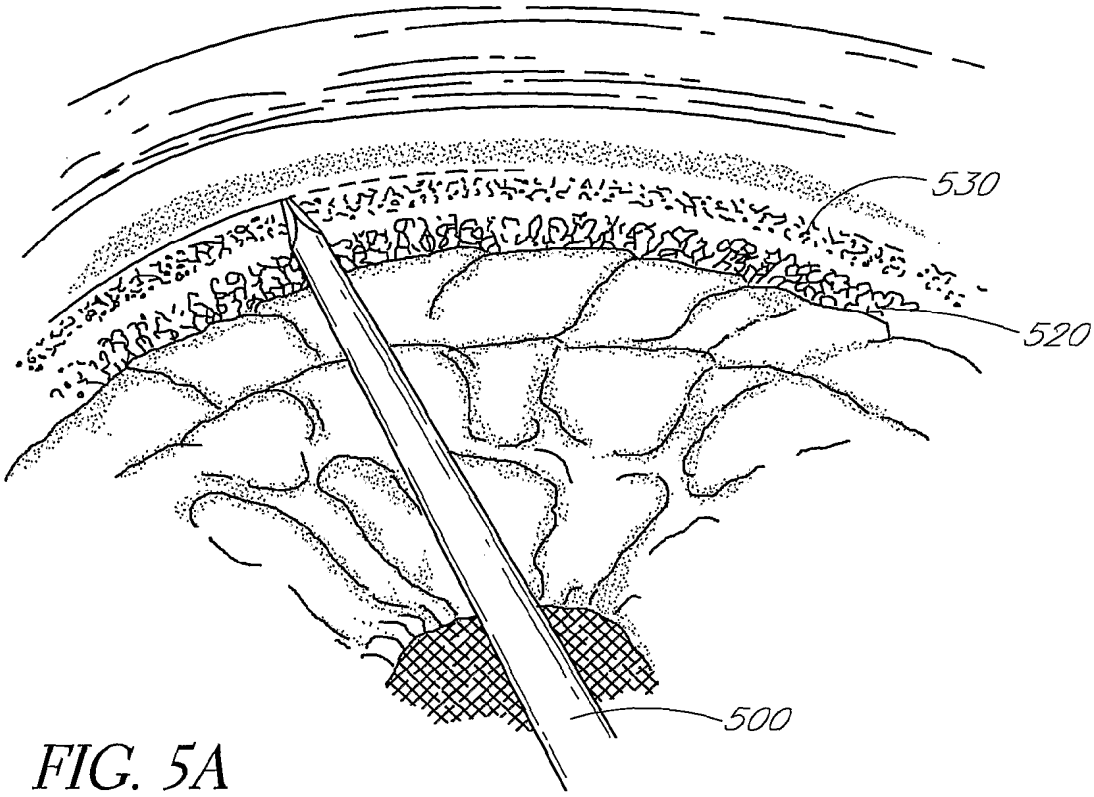

FIG. 5A

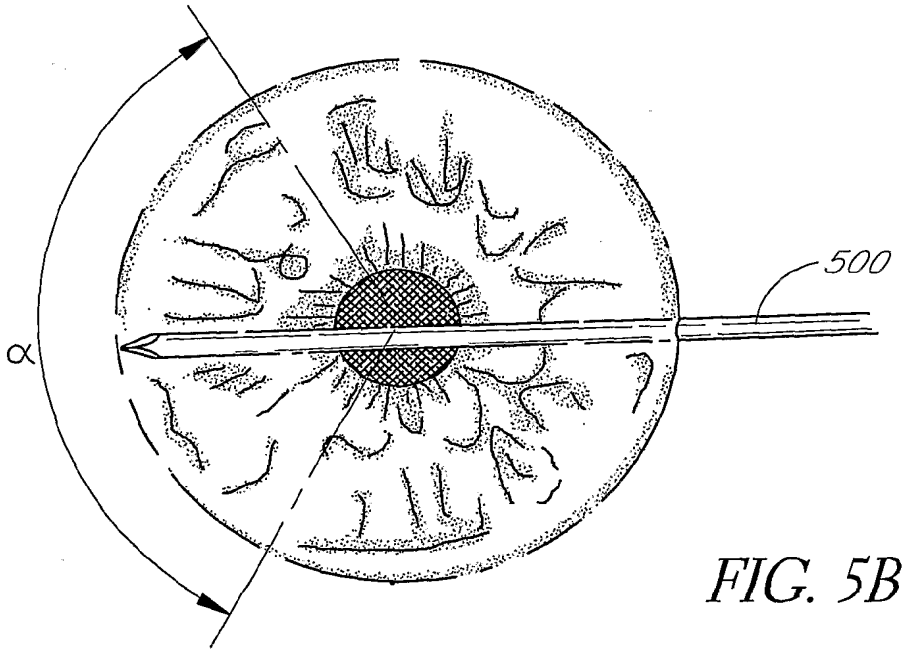

FIG. 5B

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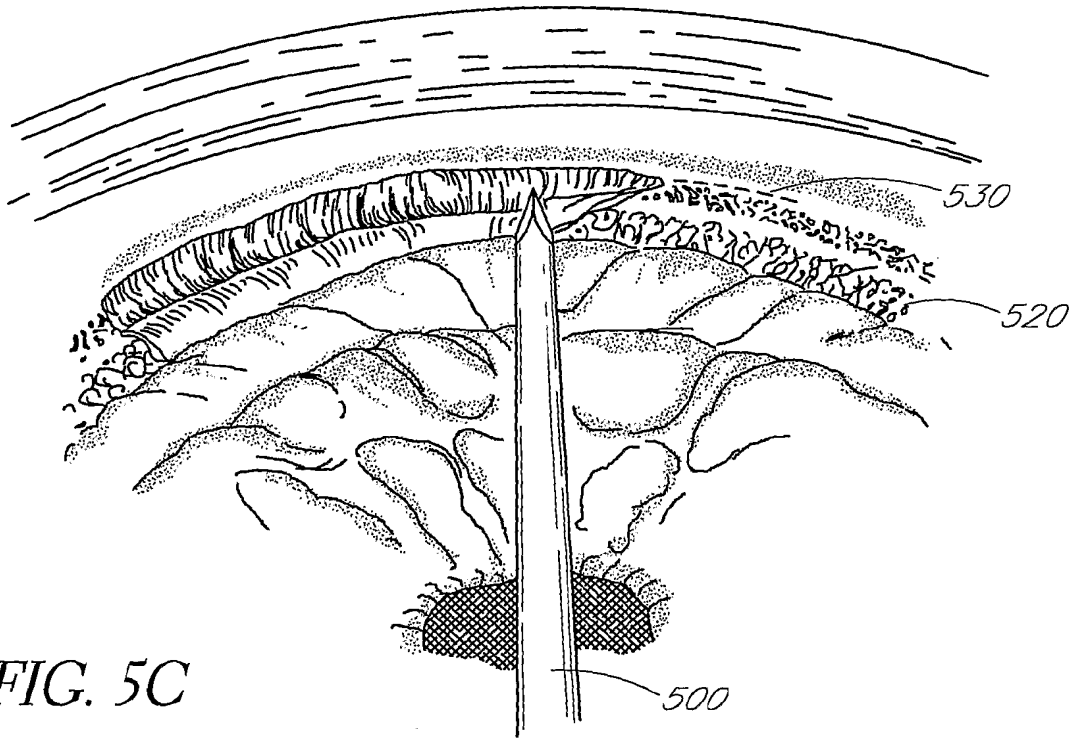

FIG. 5C

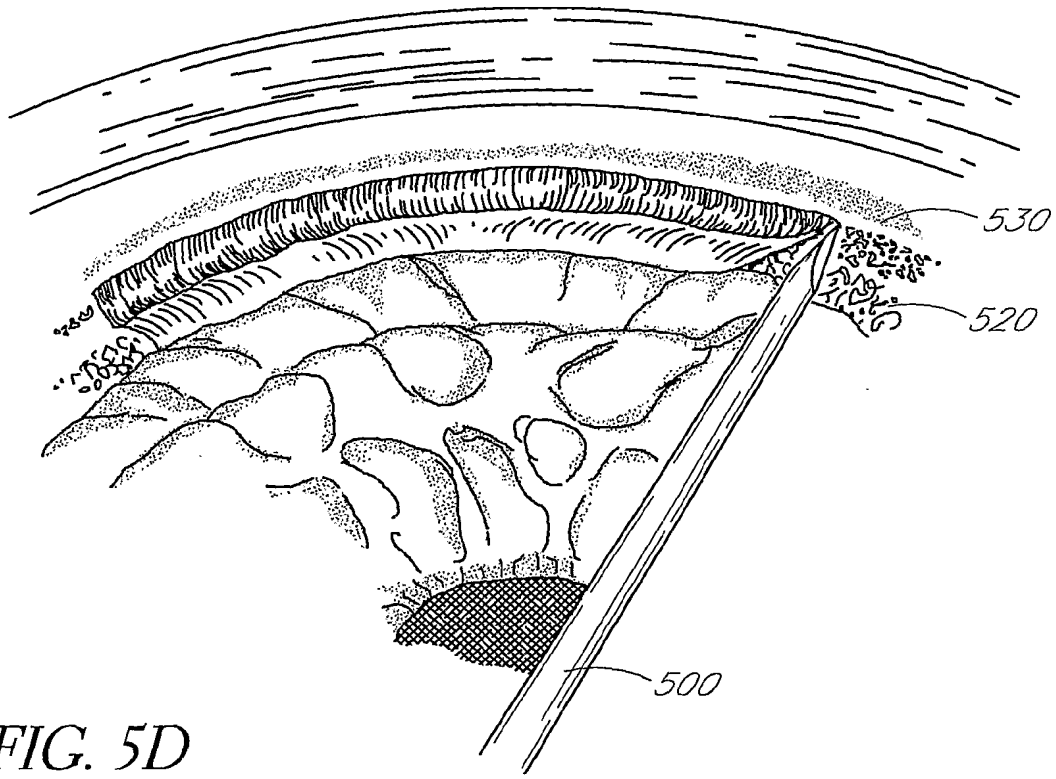

FIG. 5D

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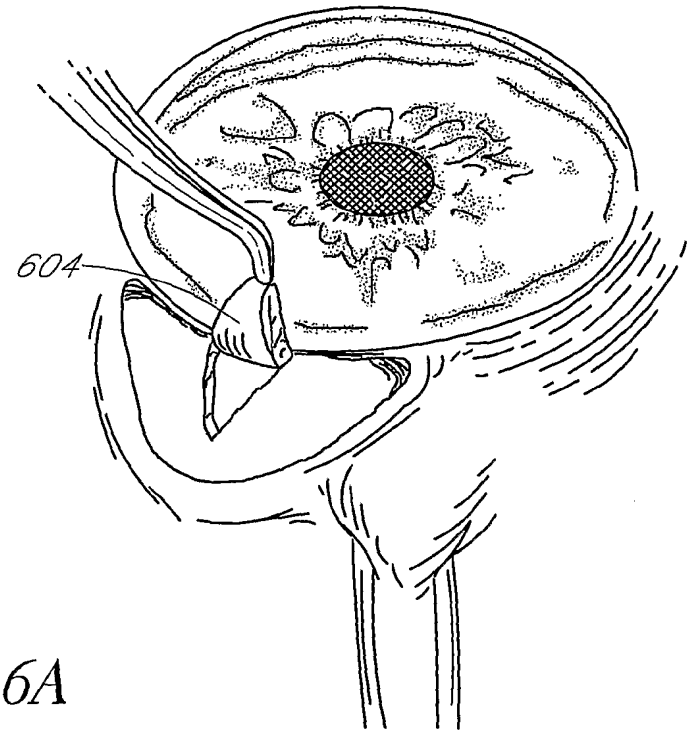

FIG. 6A

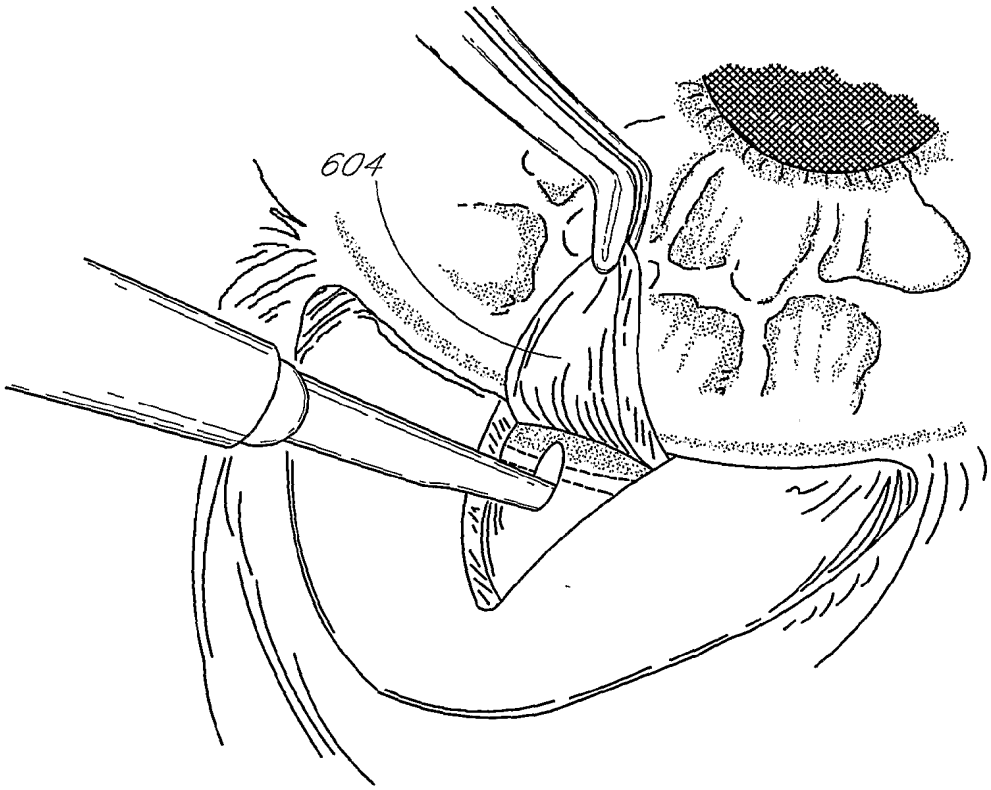

FIG. 6B

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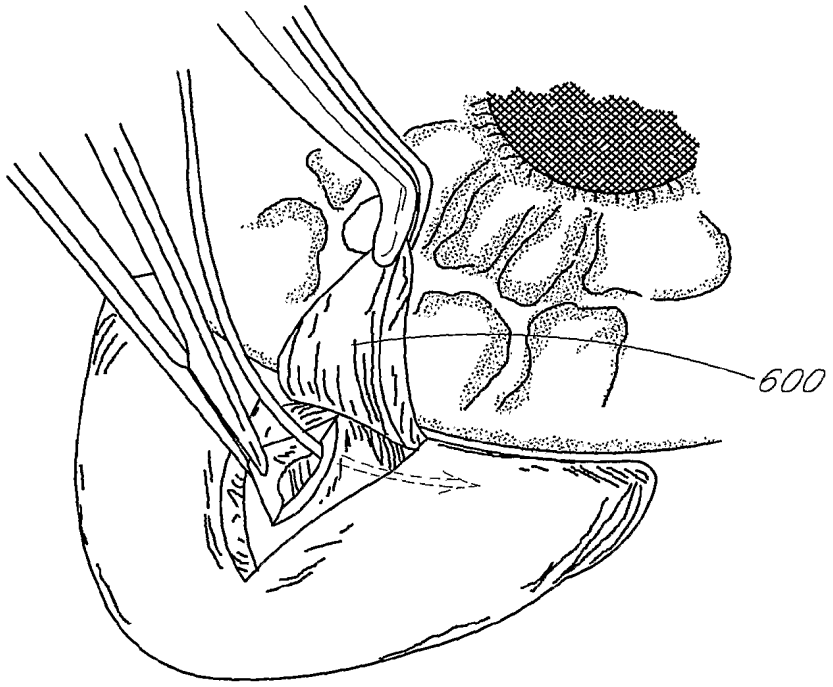

FIG. 6C

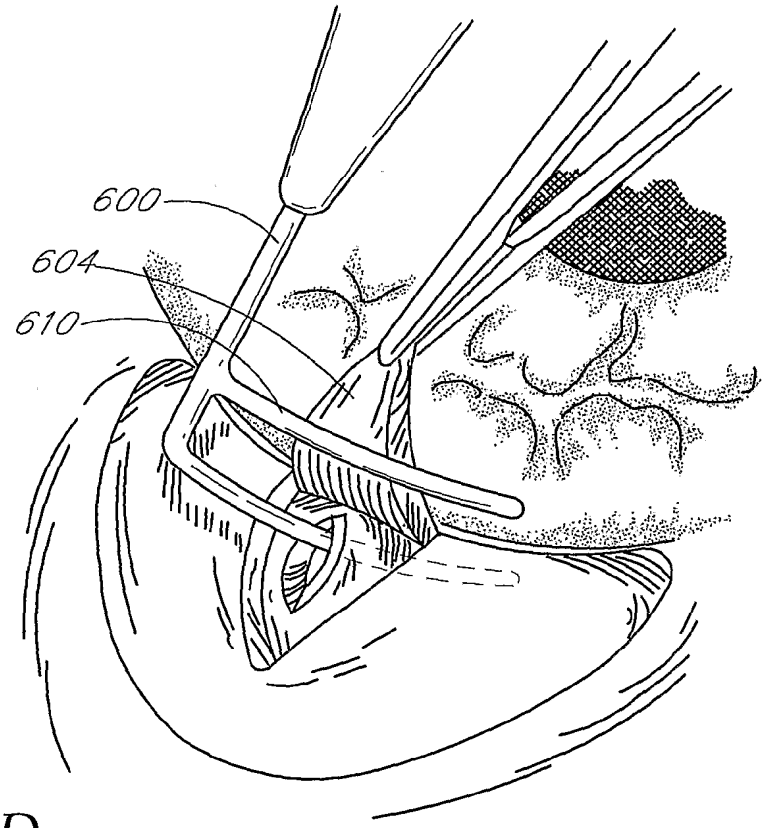

FIG. 6D

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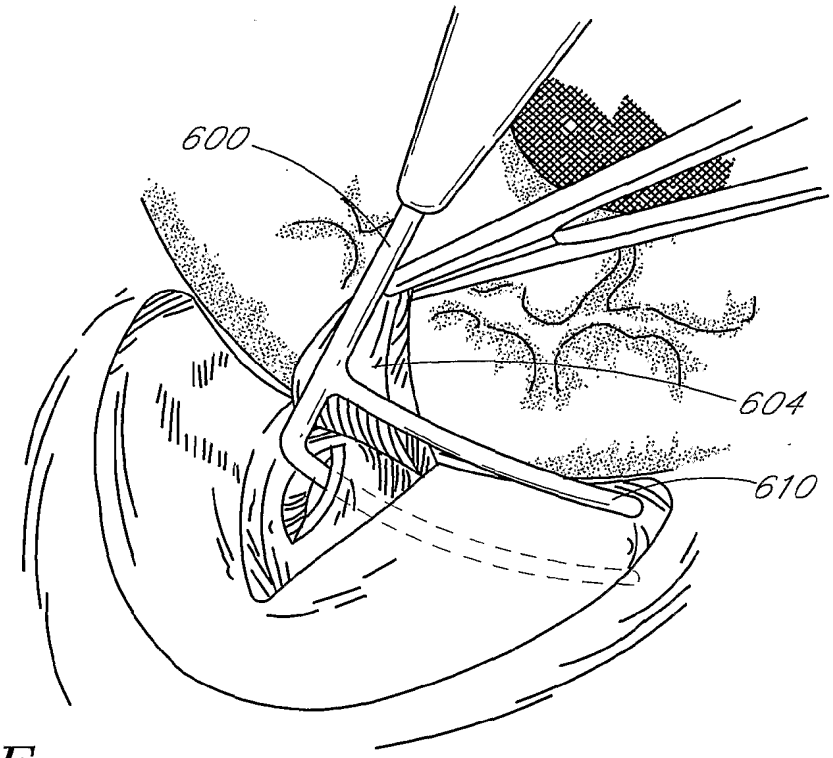

FIG. 6E

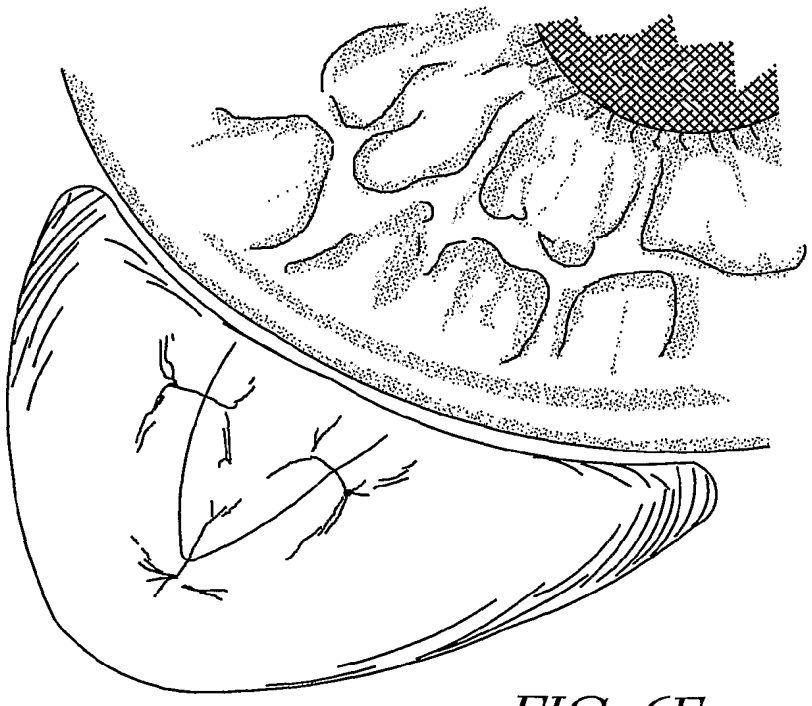

FIG. 6F

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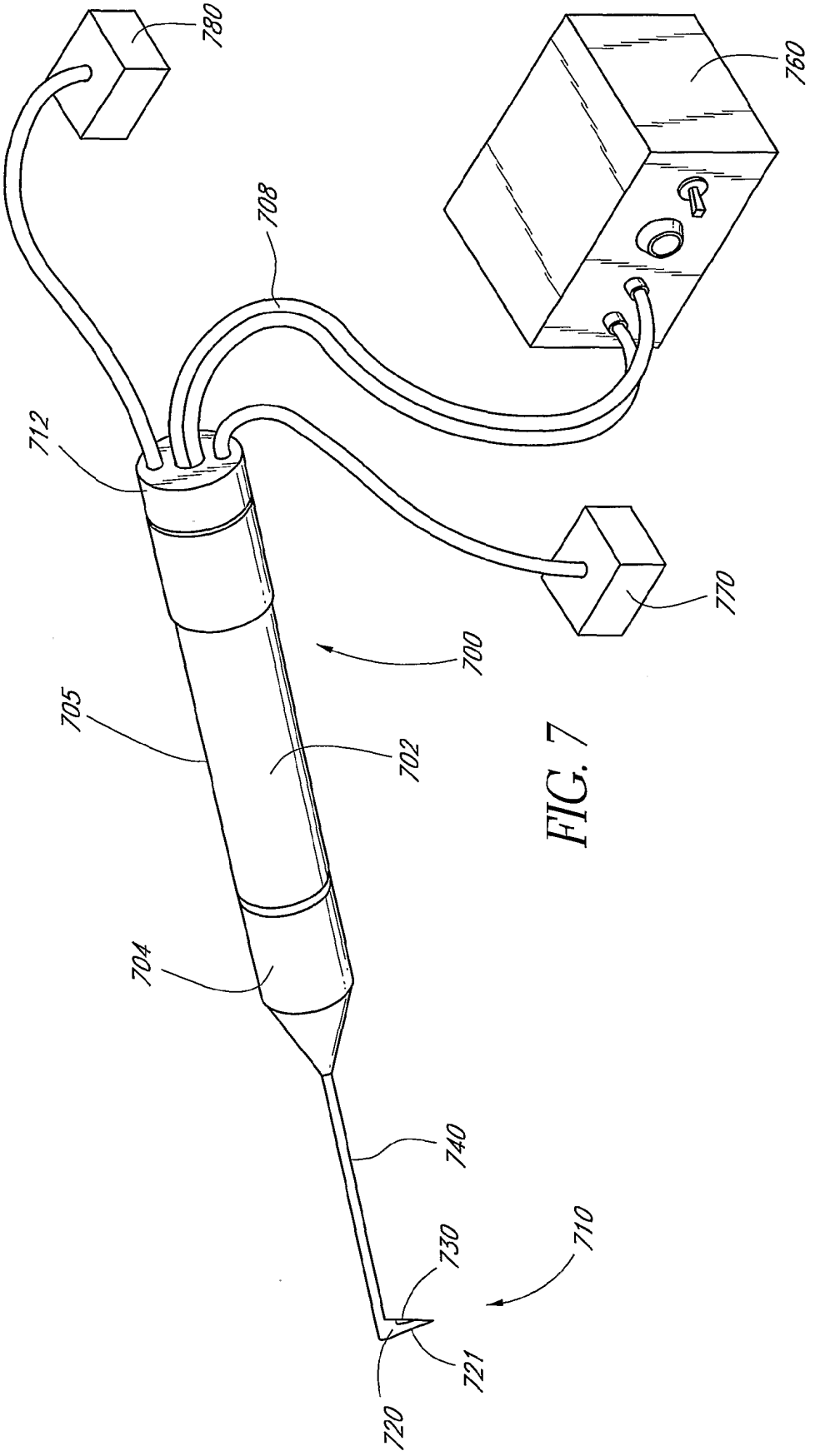

FIG. 7

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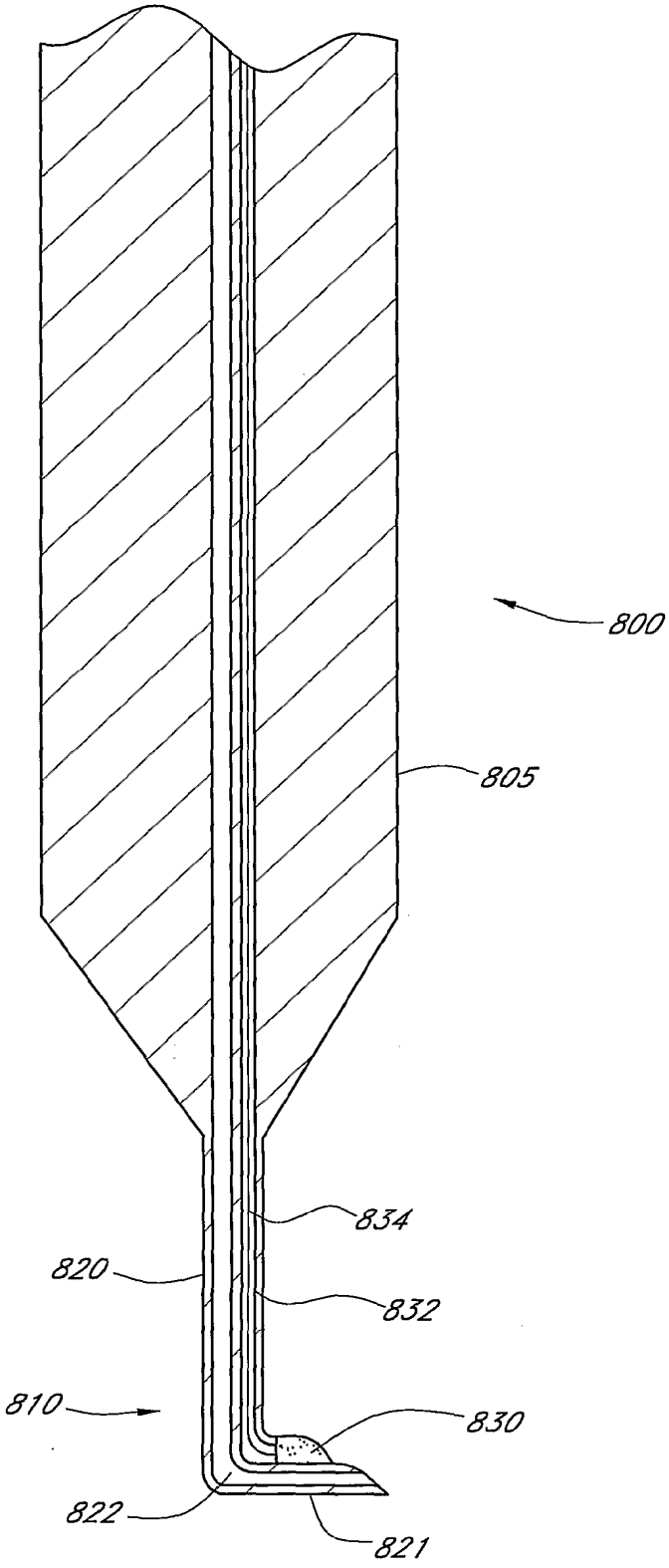

FIG. 8

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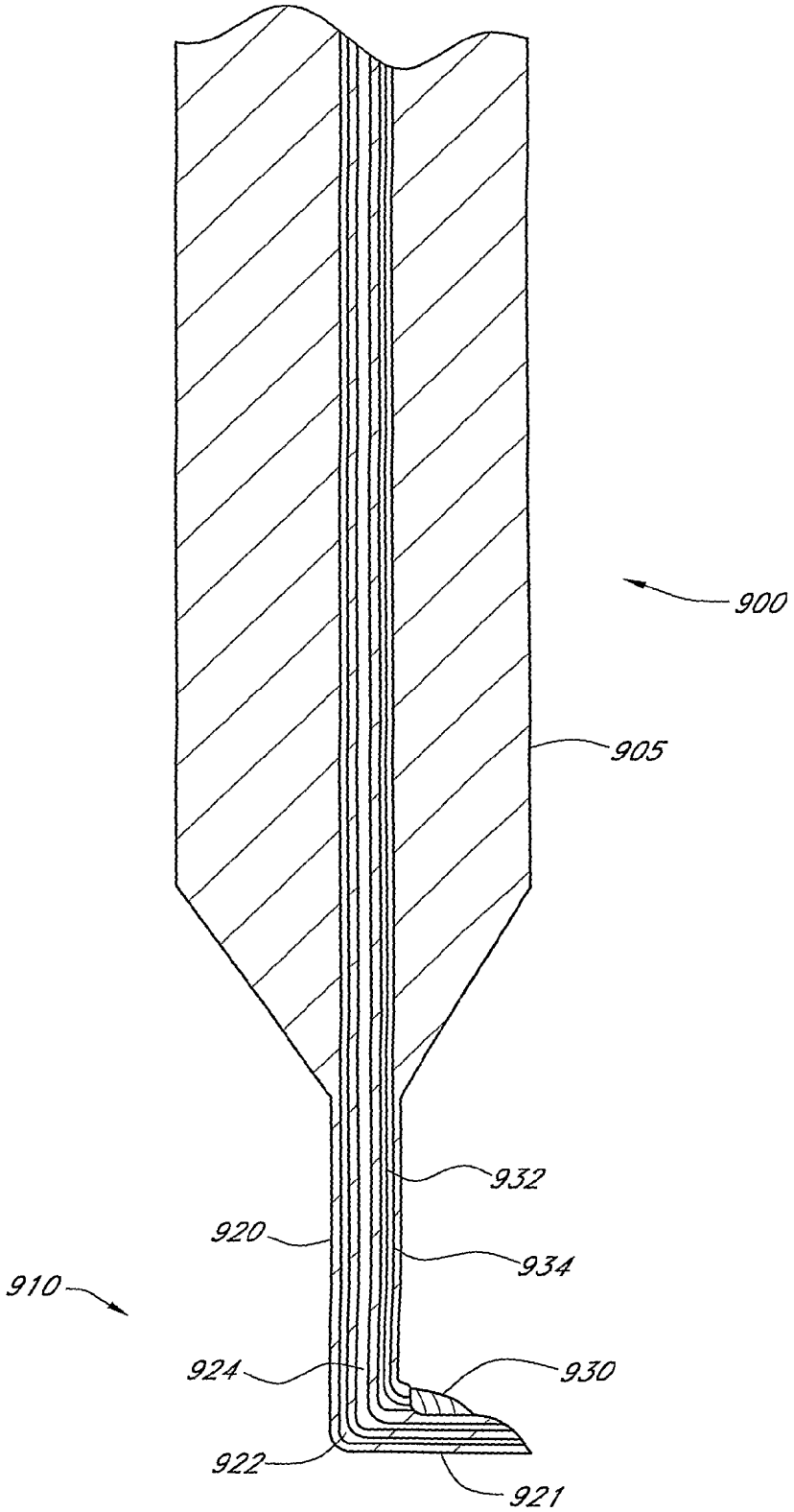

FIG. 9

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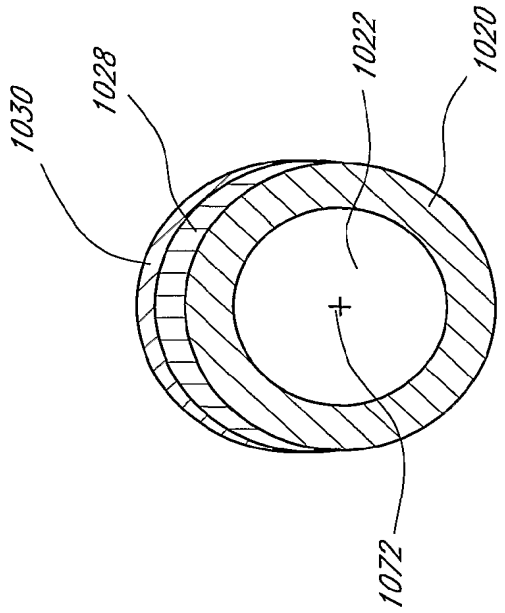

FIG. 10B

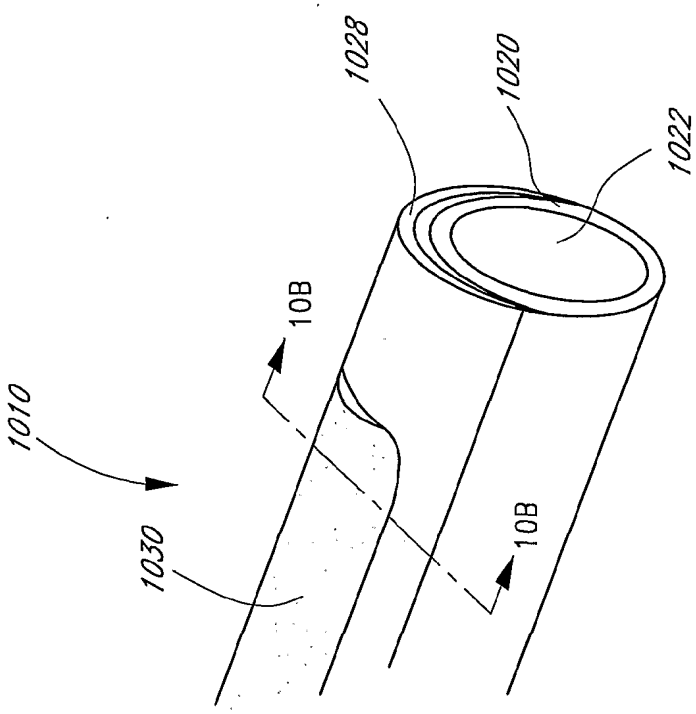

FIG. 10A

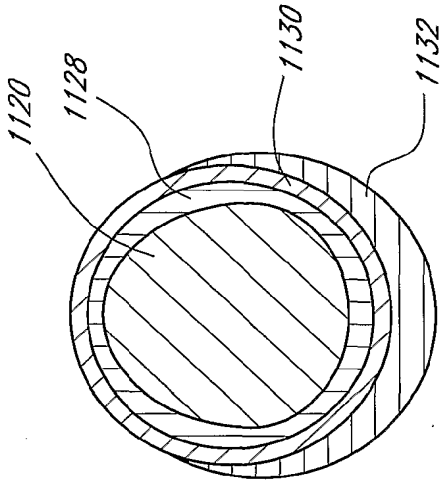

FIG. 11B

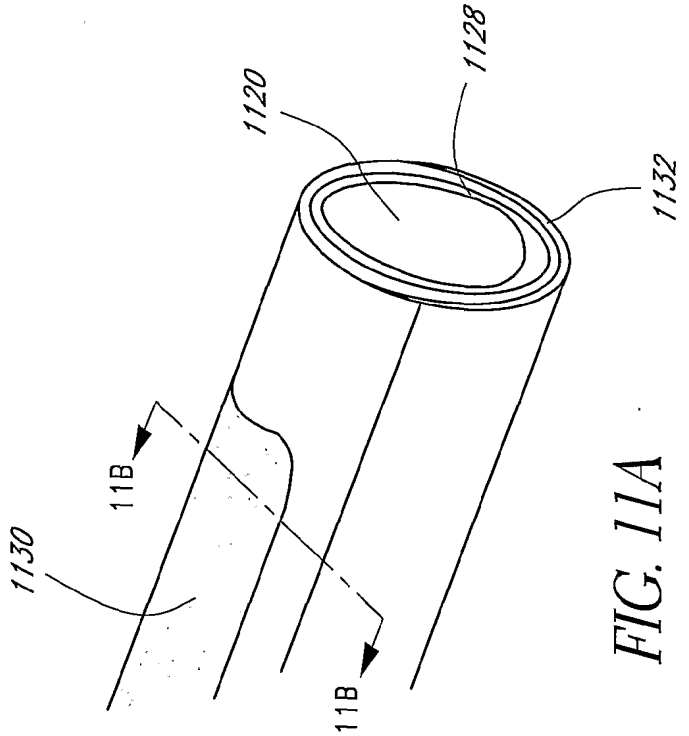

FIG. 11A

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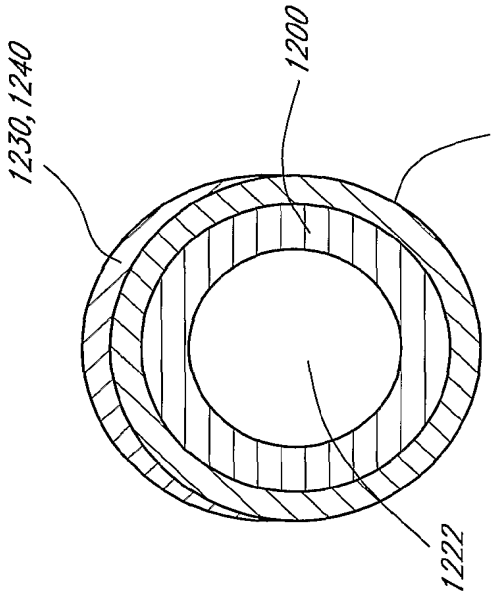

FIG. 12B

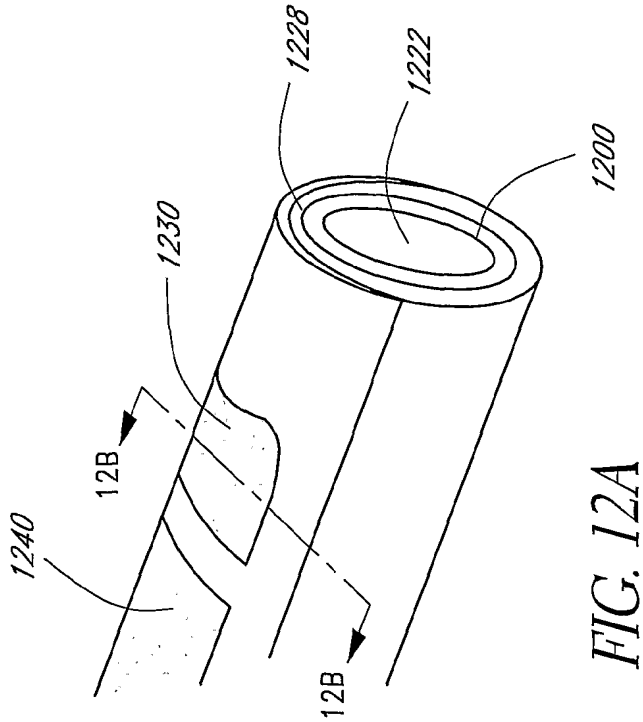

FIG. 12A

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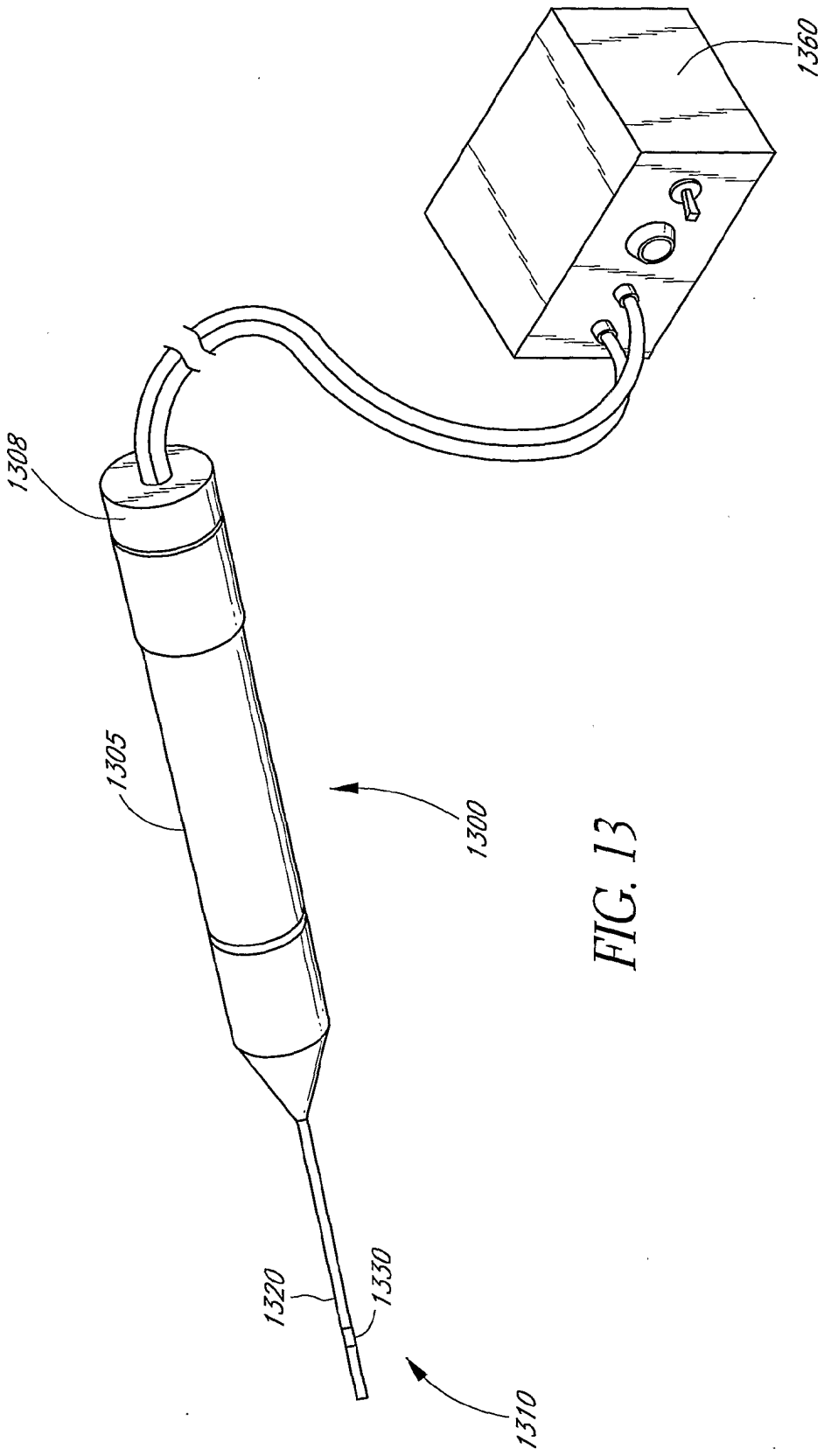

FIG. 13

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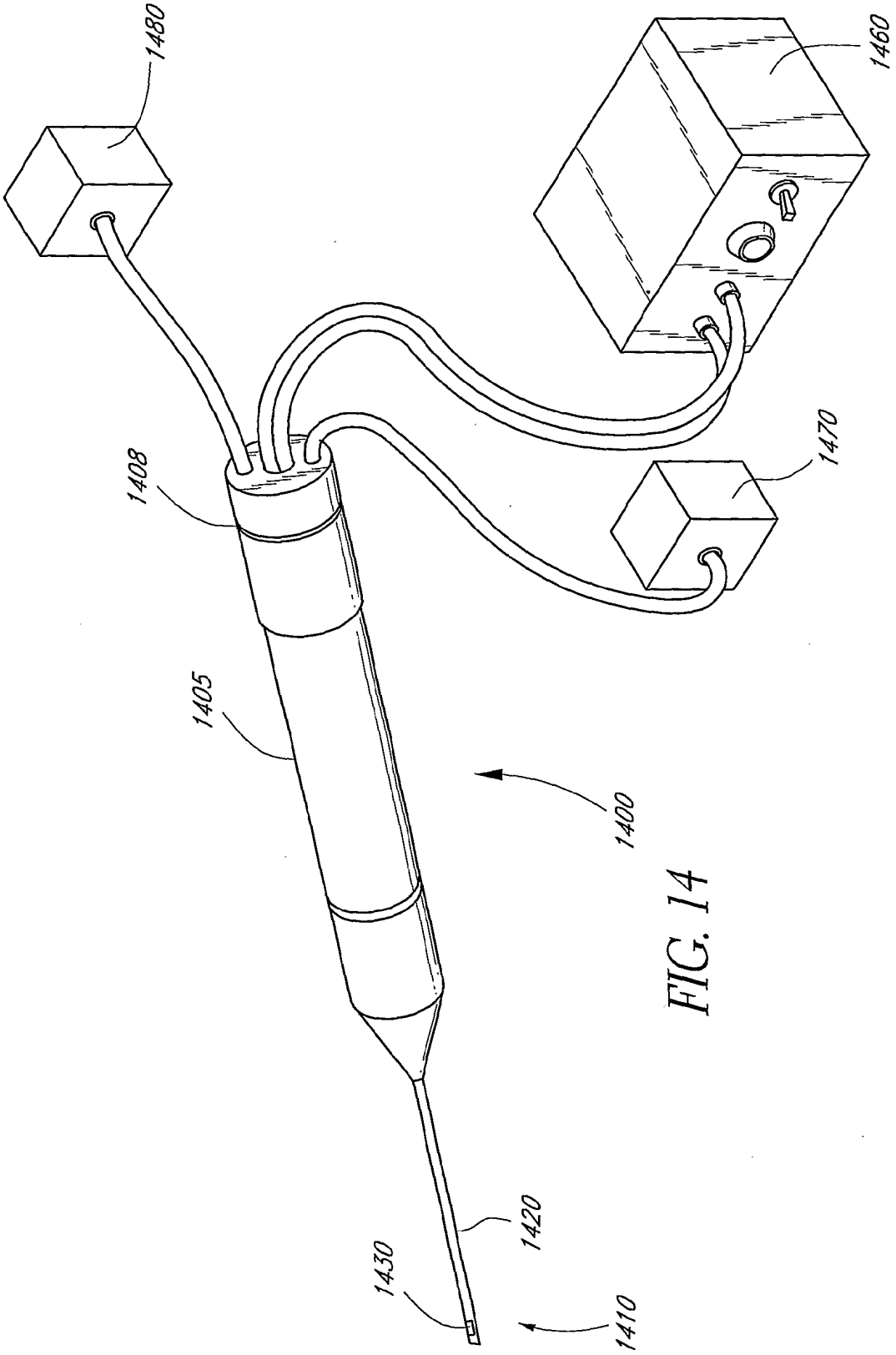

FIG. 14

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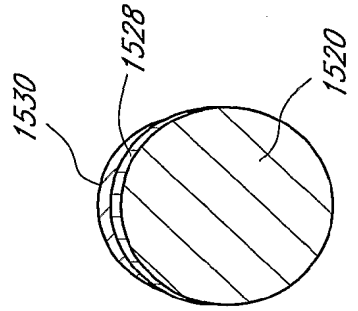

FIG. 15B

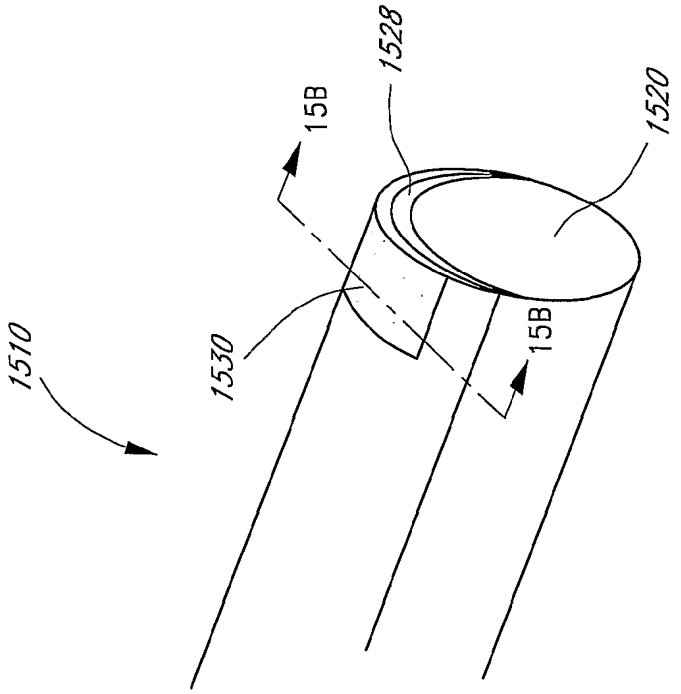

FIG. 15A

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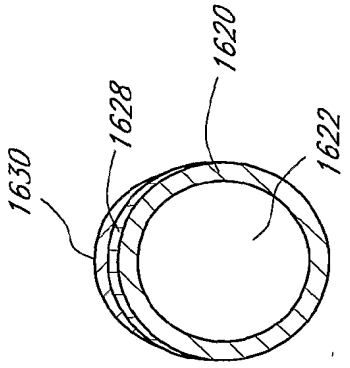

FIG. 16B

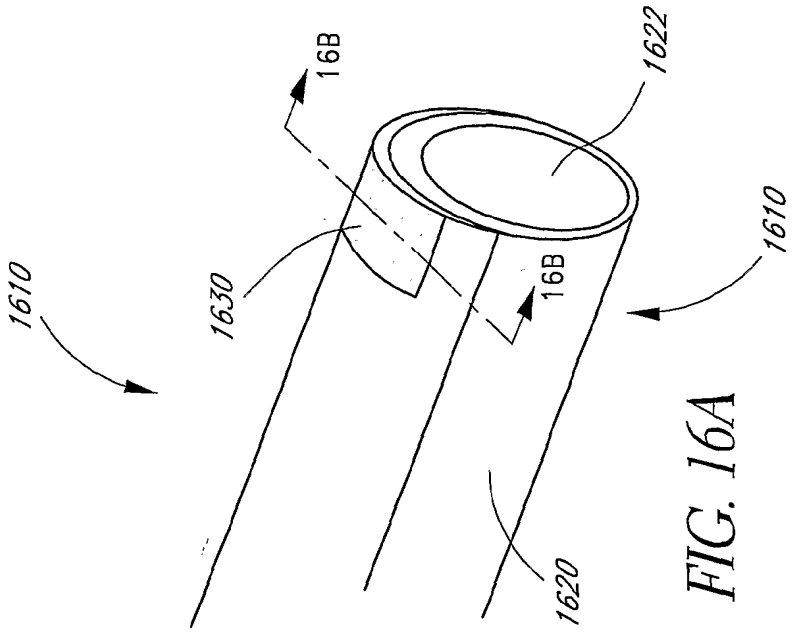

FIG. 16A

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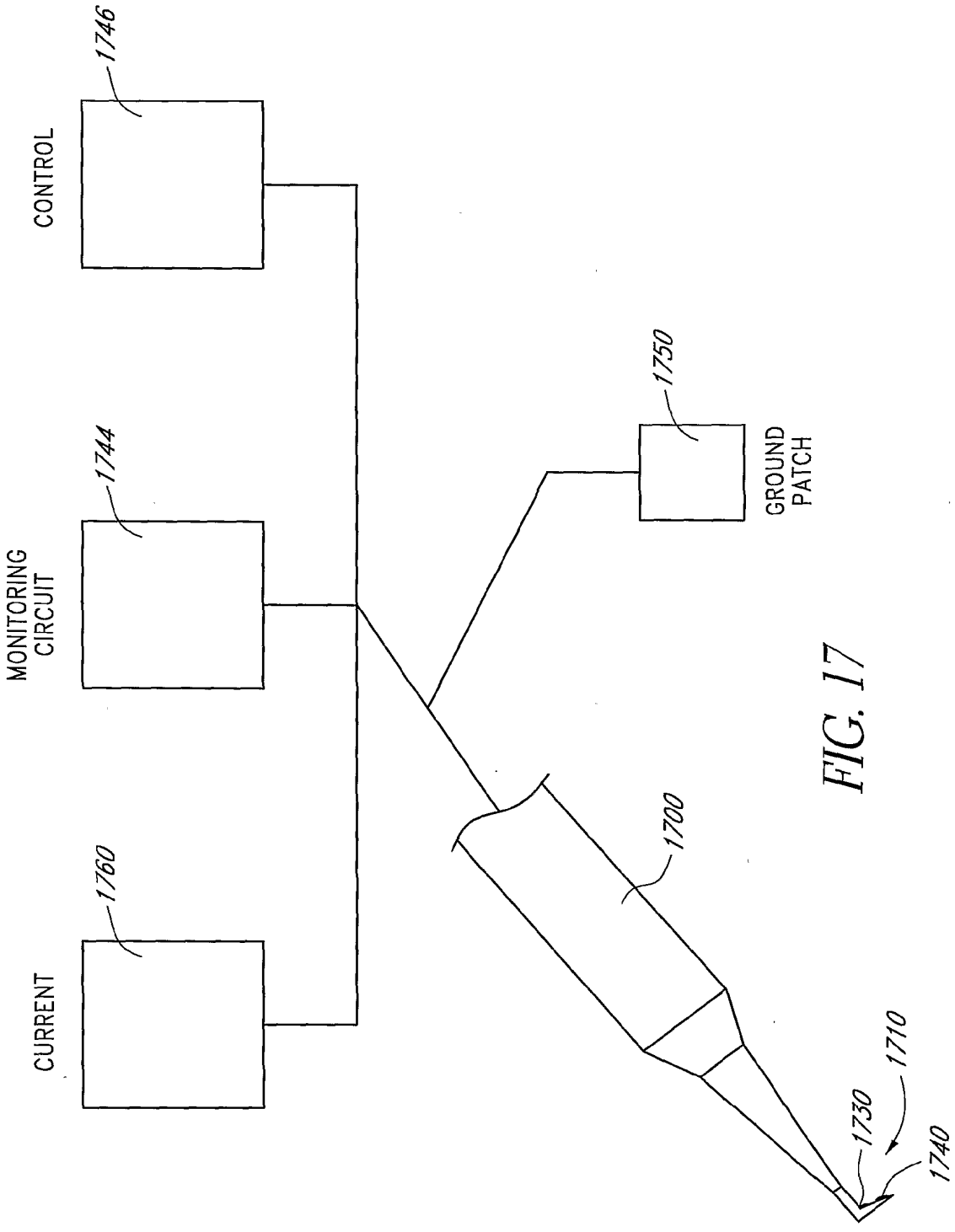

FIG. 17

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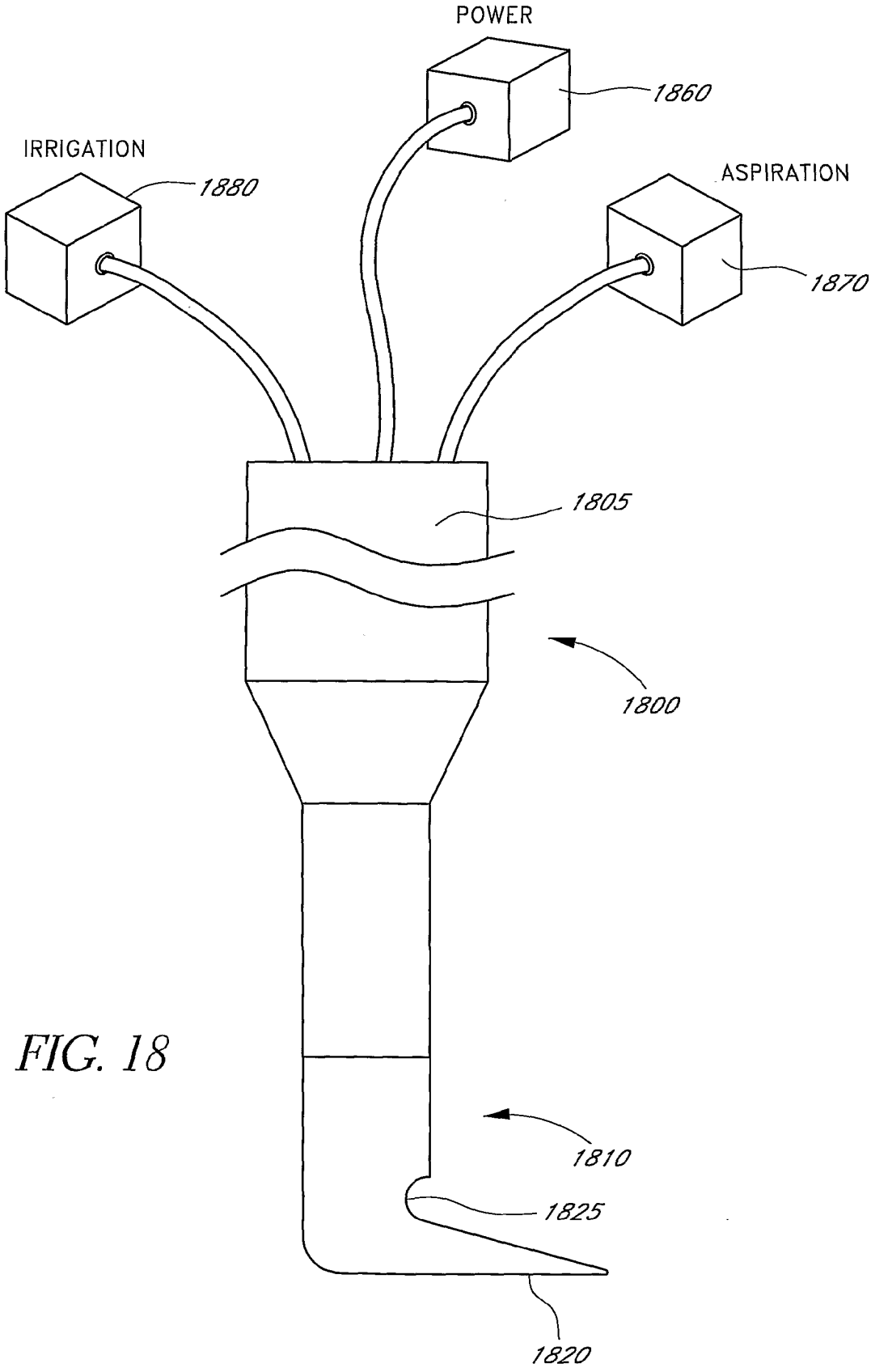

FIG. 18

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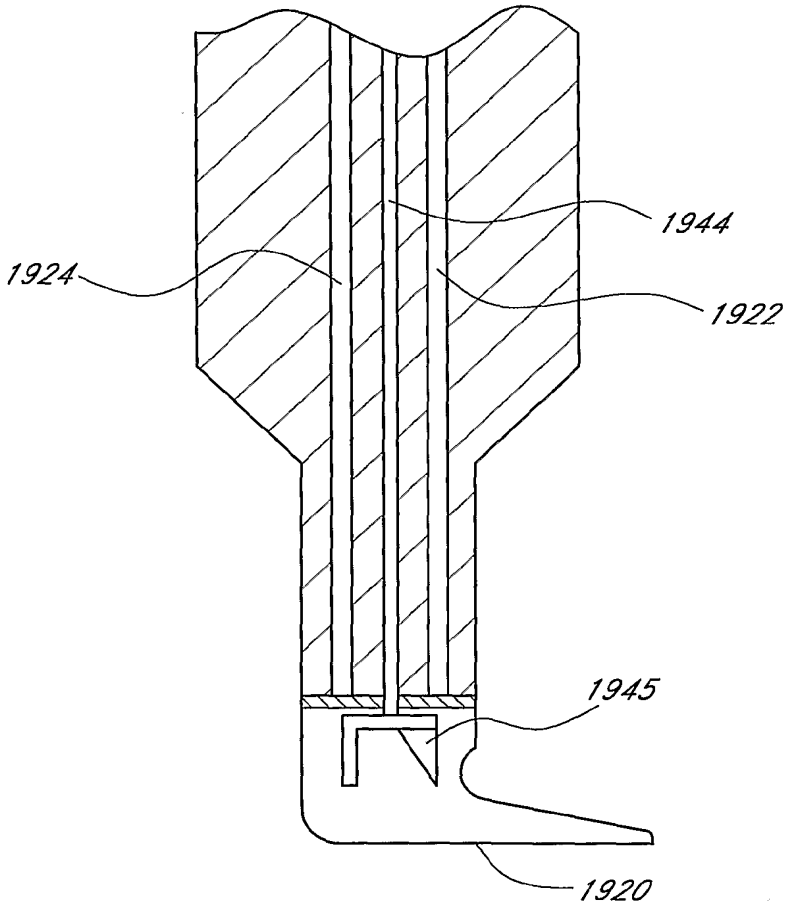

FIG. 19

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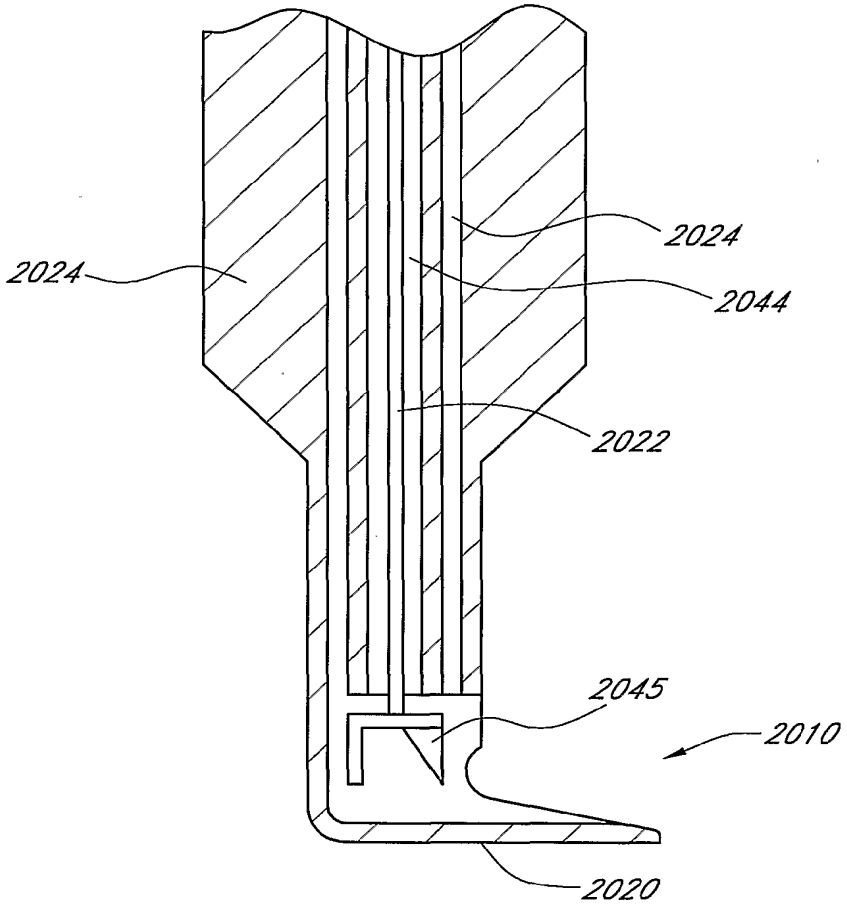

FIG. 20

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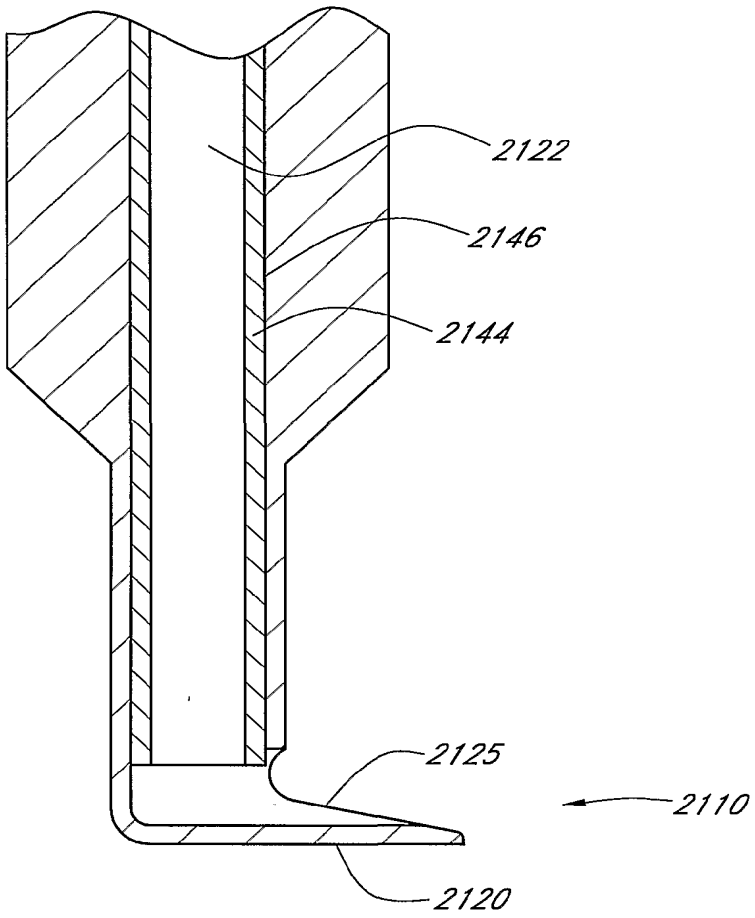

FIG. 21

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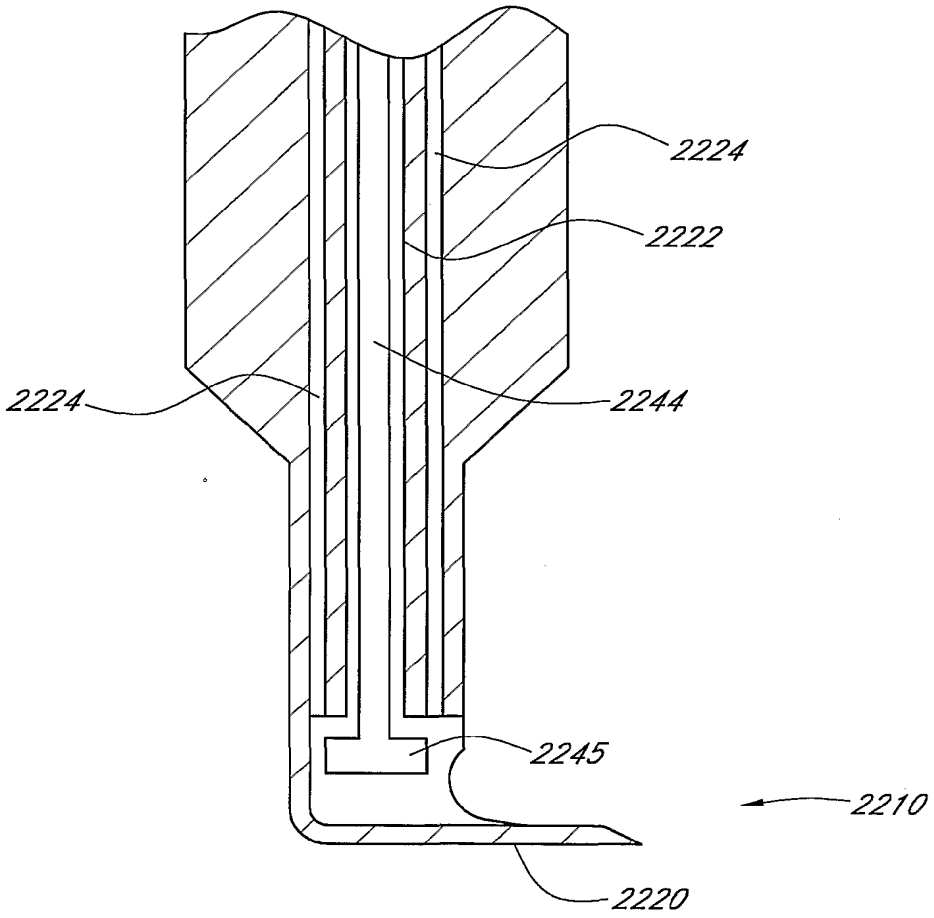

FIG. 22

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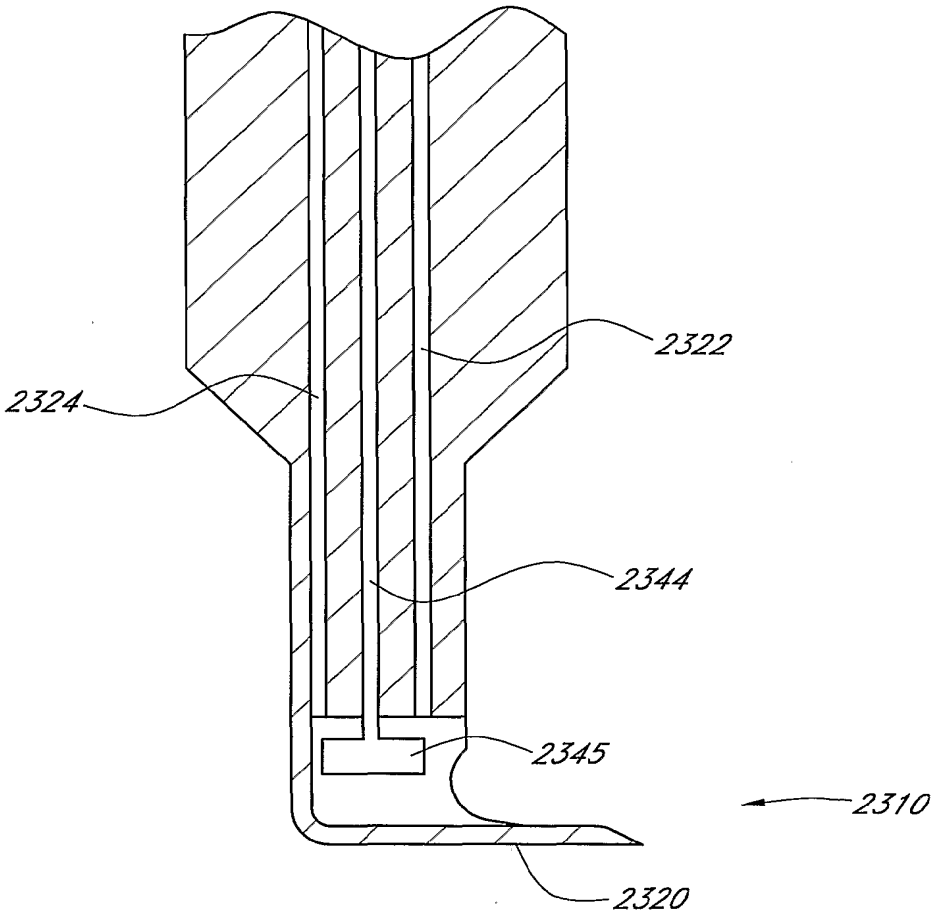

FIG. 23

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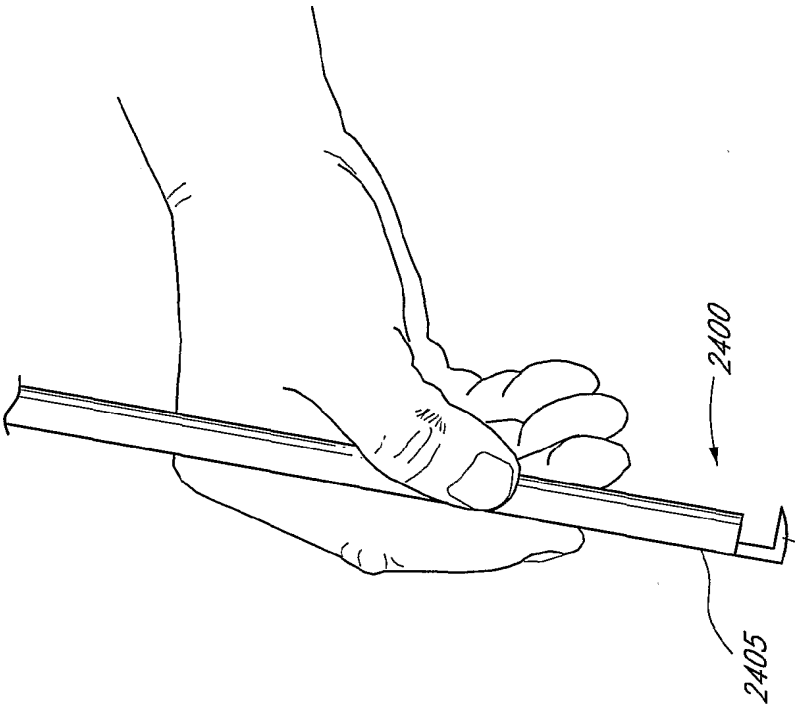

FIG. 24B

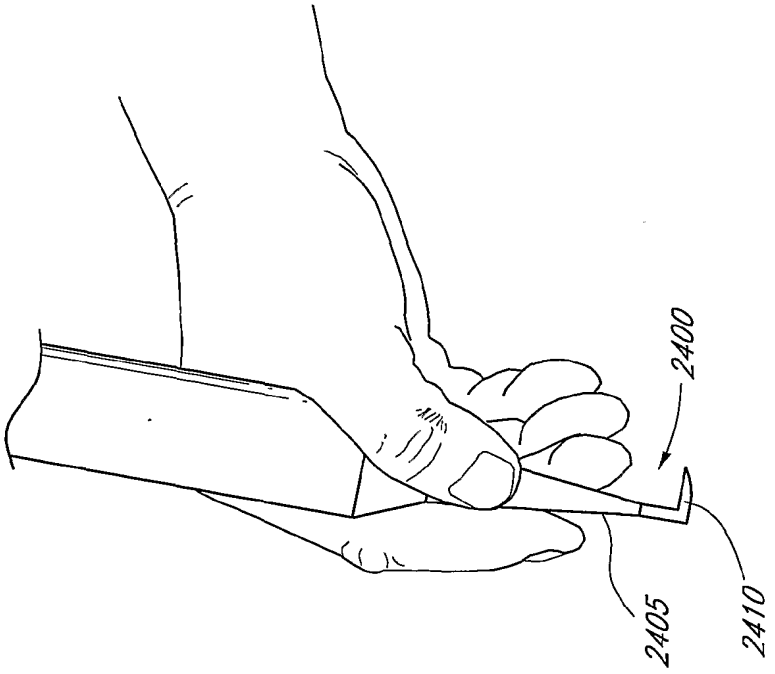

FIG. 24A

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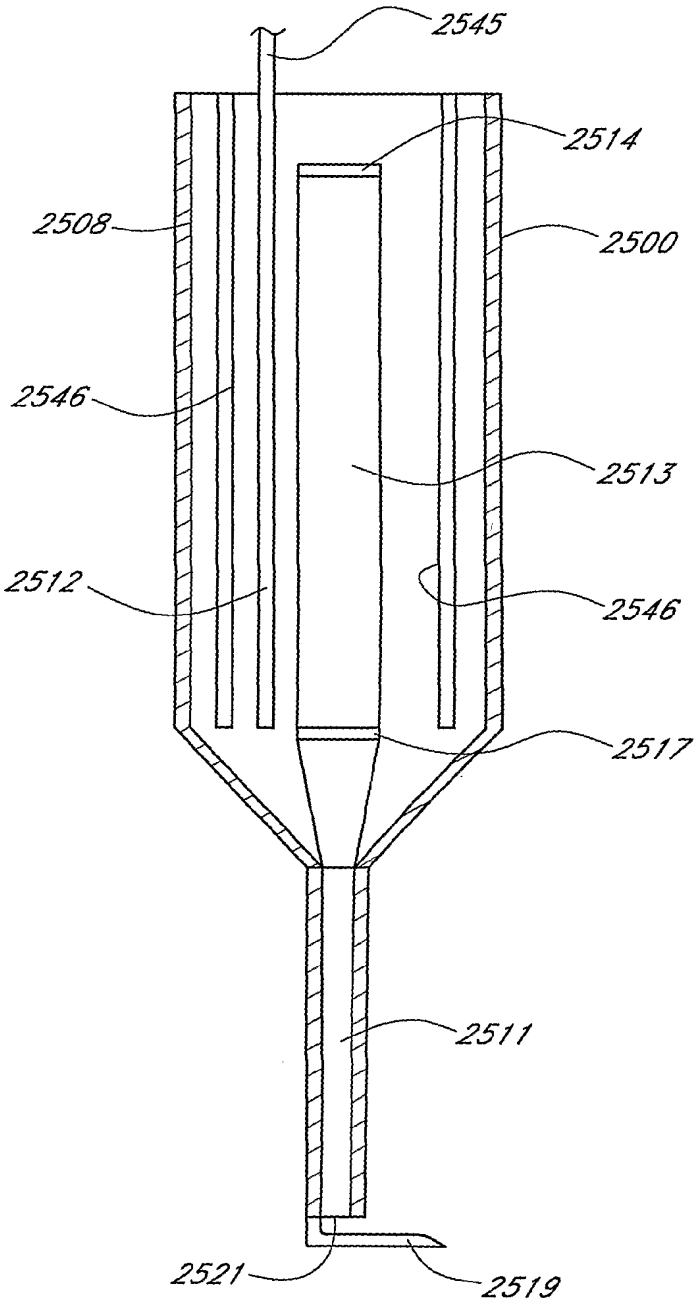

FIG. 25

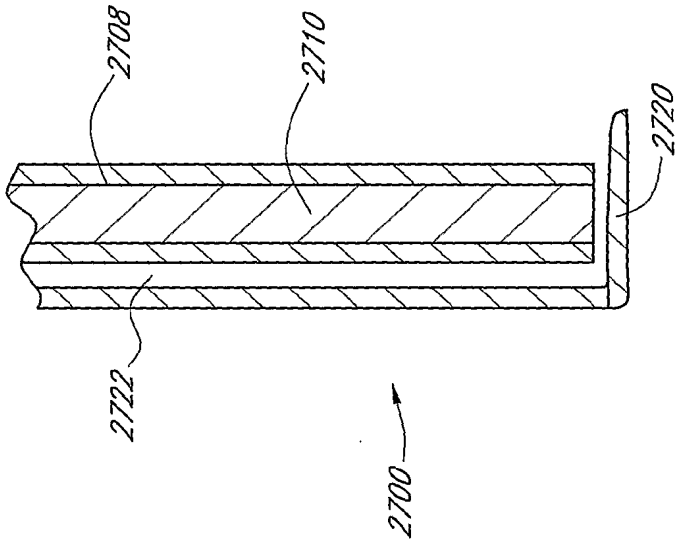

FIG. 27

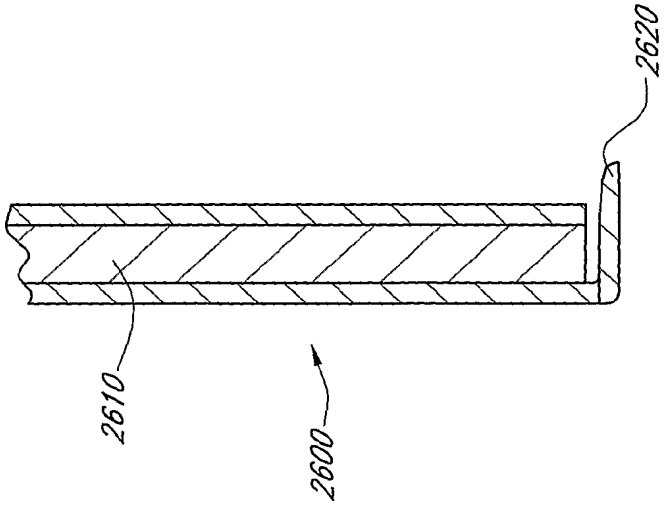

FIG. 26

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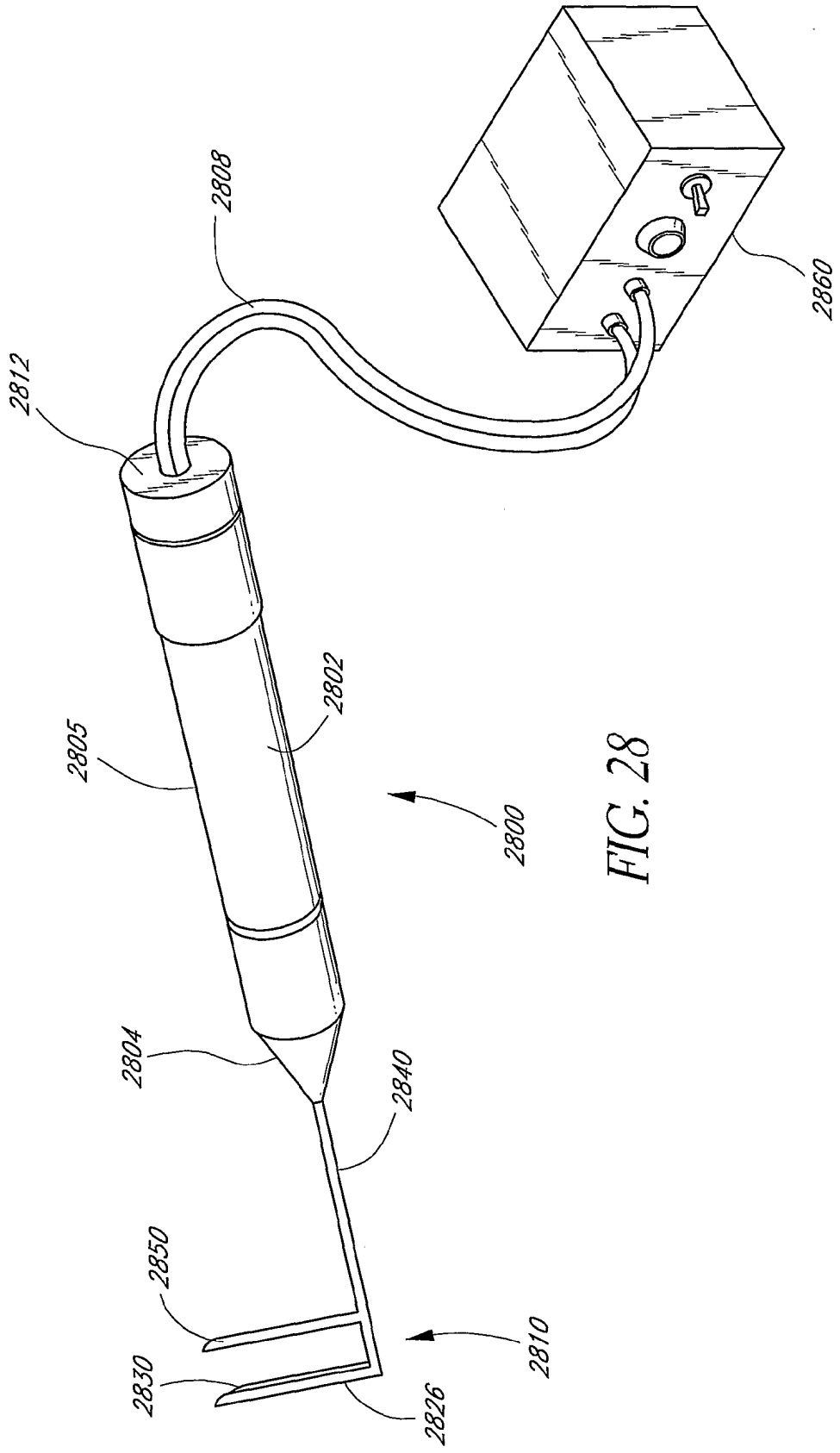

FIG. 28

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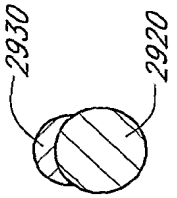

FIG. 29B

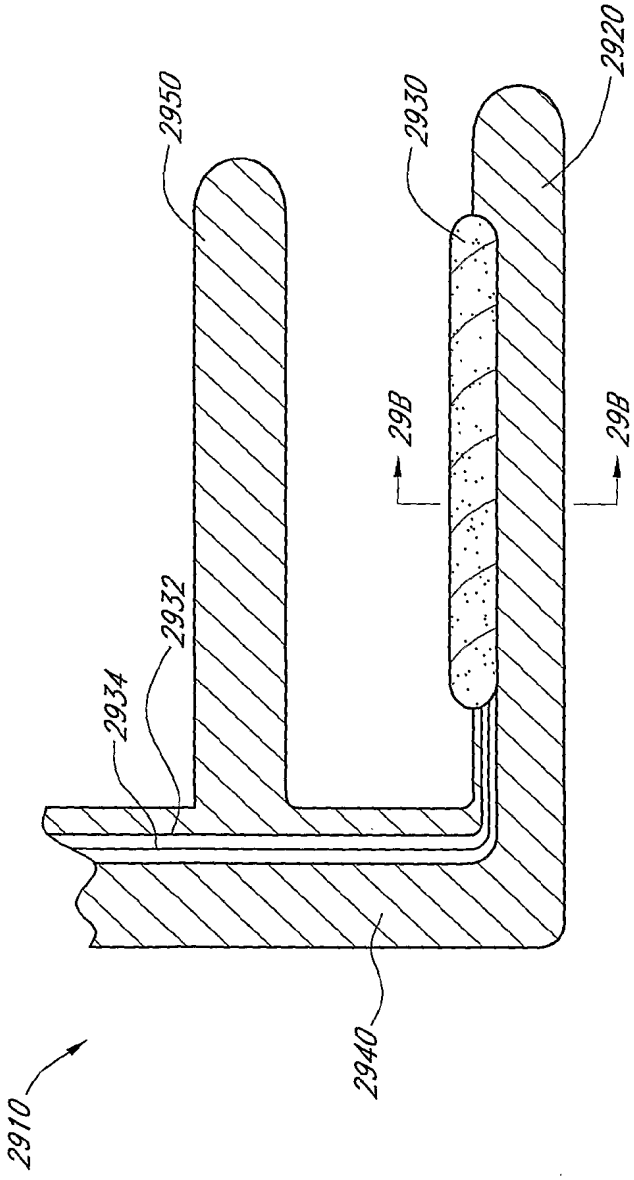

FIG. 29A

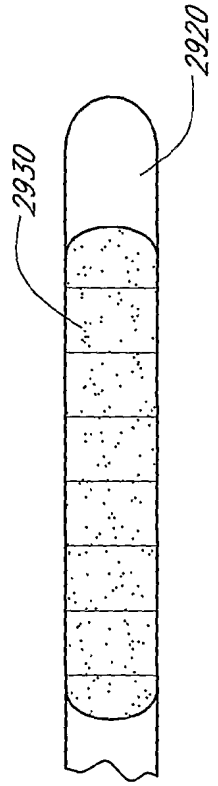

FIG. 29C

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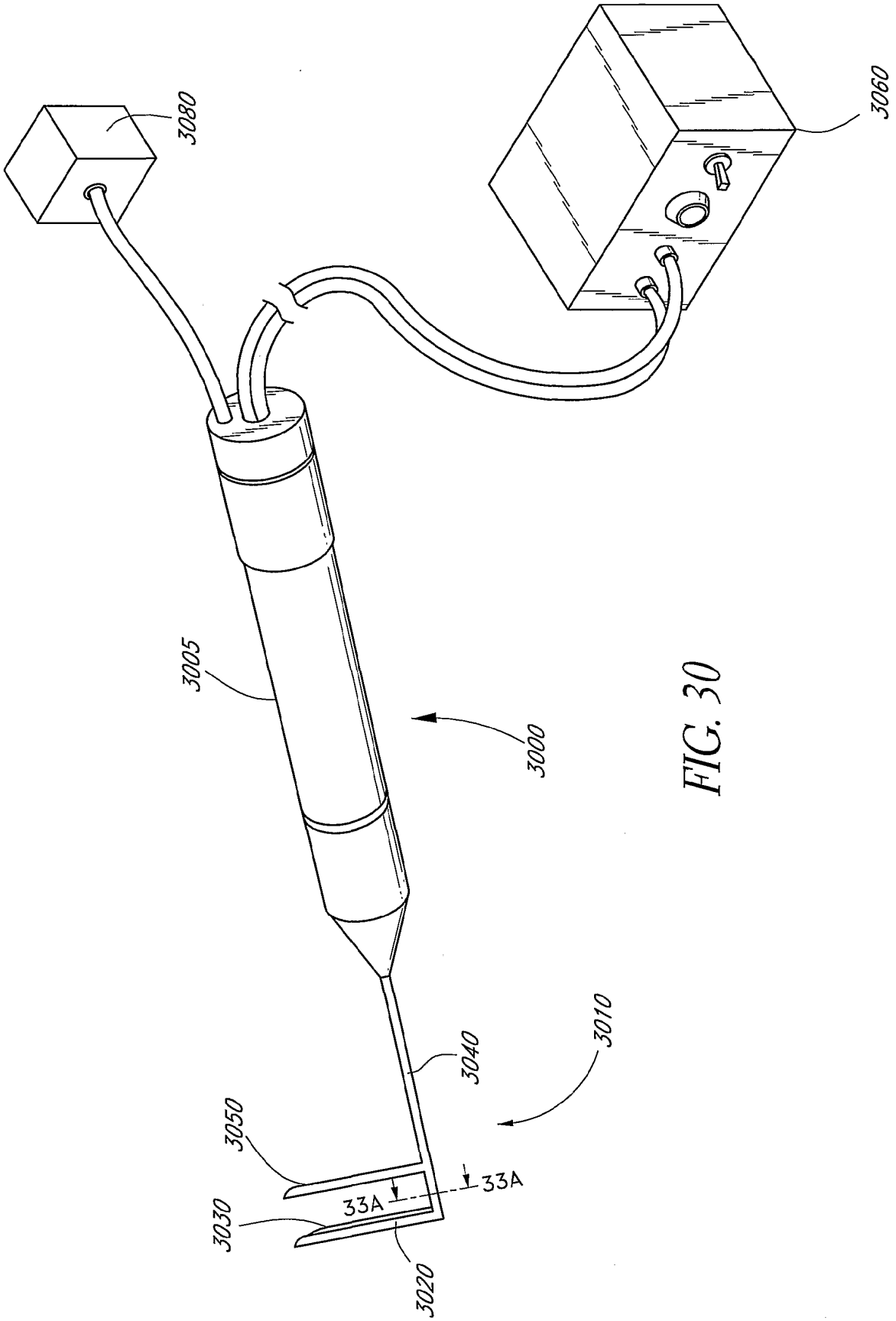

FIG. 30

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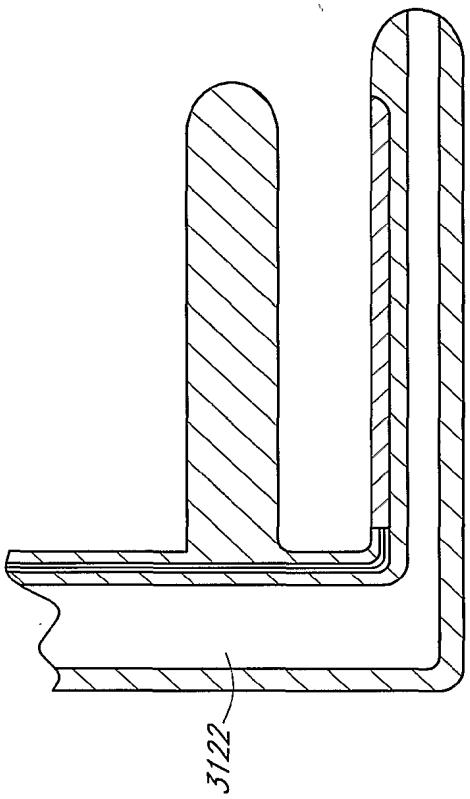

FIG. 31A

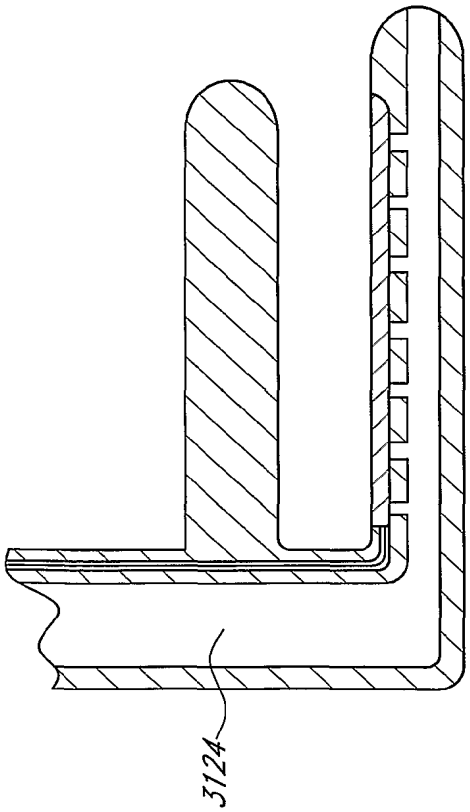

FIG. 31B

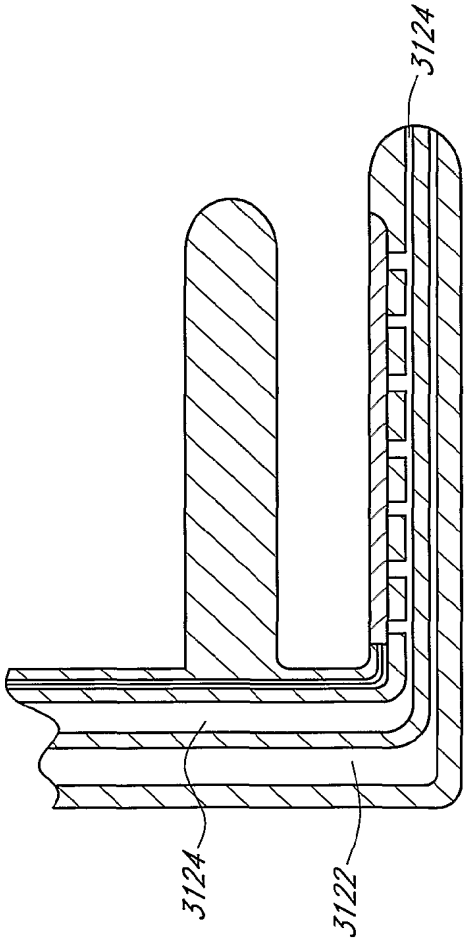

FIG. 31C

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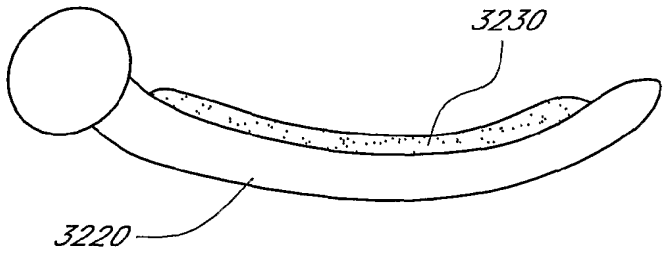

FIG. 32A

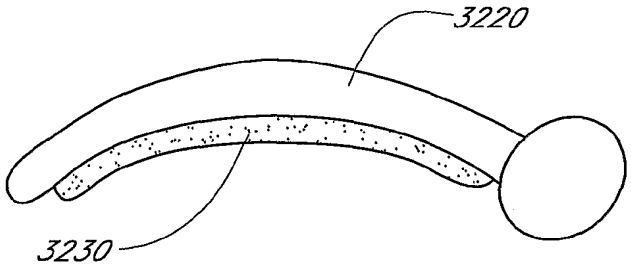

FIG. 32B

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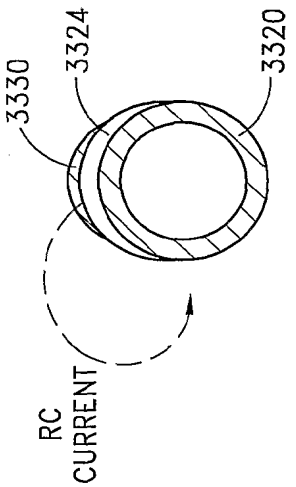

FIG. 33B

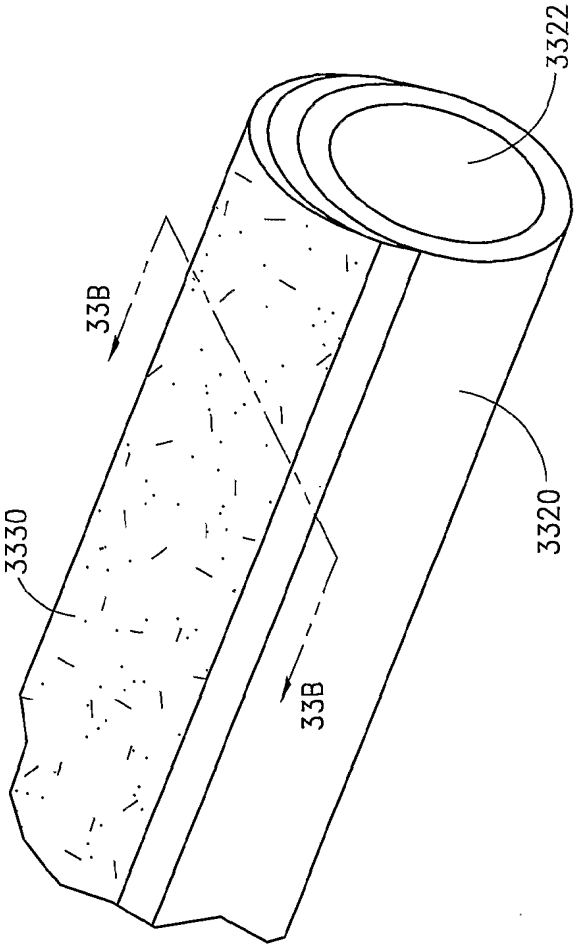

FIG. 33A

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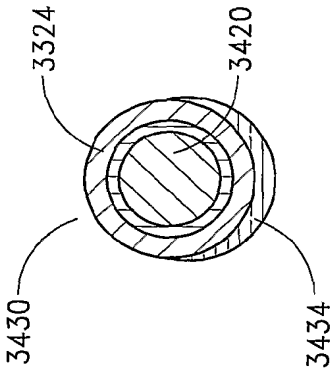

FIG. 34B

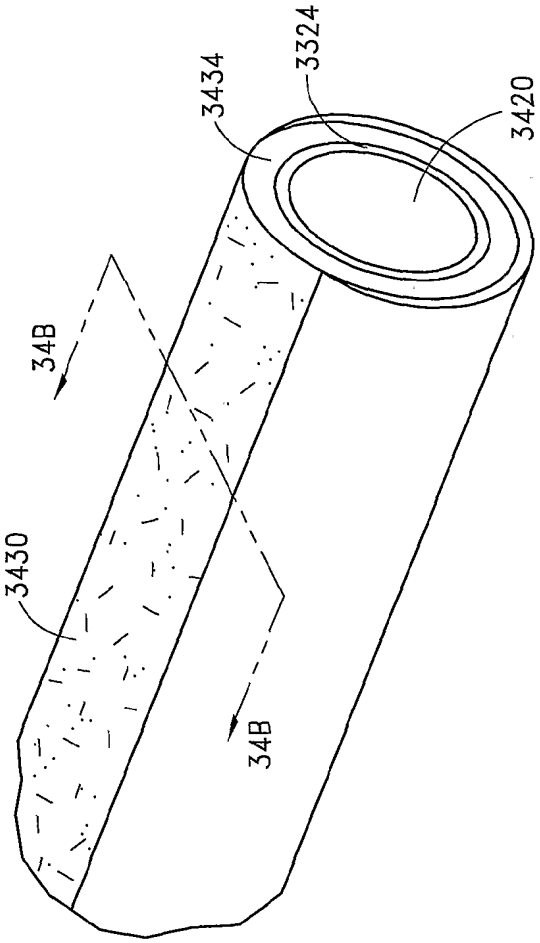

FIG. 34A

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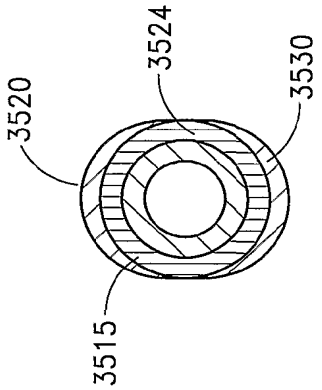

FIG. 35B

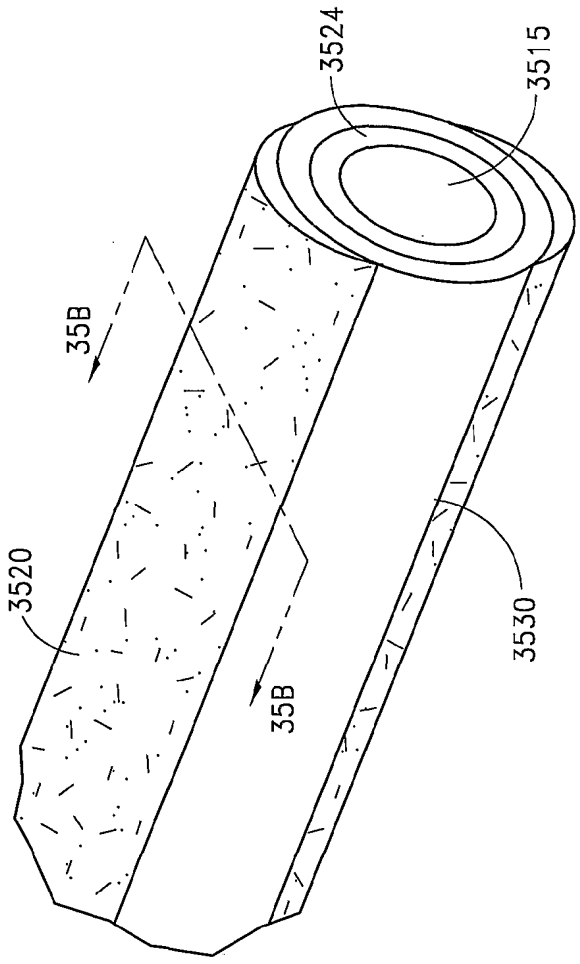

FIG. 35A

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English abstract of cited reference 1 (Japanese Examined Utility Model Publication No. 46-025677)

Cited reference 1 relates to a cell collecting device for use in an endoscope. The cell collecting device includes a cell collecting tube 1 made of metal or rigid synthetic resin. The cell collecting tube 1 includes one or more parts cut into a U-shape or a V-shape at the distal end and an abrasion part 3 formed by curving the remaining part inwardly toward the distal end. Cutting edges 4a, 4b are formed on opposite edges of the abrasion part 3.

A flexible tube or flexible shaft 6 connects the base part of the cell collecting tube 1 and a grip 7 which is rotatably operated near the operating part of the endoscope.

When the abrasion part 3 is delivered to a lesion site 5 of a patient by operating the grip 7, the cell collecting tube 1 is rotated with applying a suitable pressure to the lesion site. Then, a mucosal membrane of the lesion site is abraded by the cutting edges 4a, 4b and attached to an inner wall surface of the cell collecting tube 1.

Fig. 1

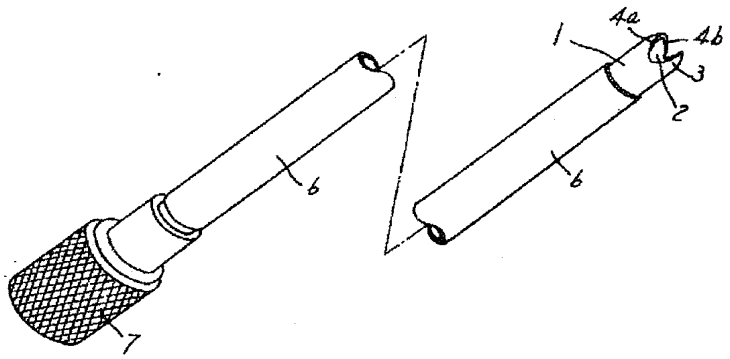
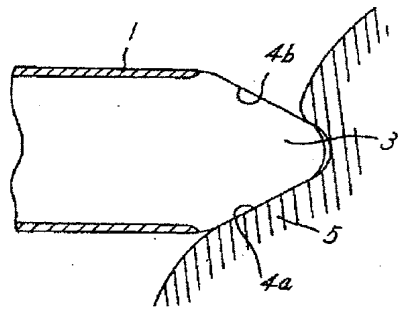


Fig. 2



⑤1Int.Cl.
A 61 b

⑤2日本分類
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日本国特許庁

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⑩実用新案公報

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1

⑤4細胞採取器

⑵1実　　願　昭42－18565
⑵2出　　願　昭42（1967）3月7日
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図面の簡単な説明

第1図は本考案に係わる細胞採取器の斜視図、第2図は細胞採取器の先端が病巣に到達した状態にて示せる中央断面図である。

考案の詳細な説明

本考案は内視鏡用細胞採取器に関し、更に詳しくは生体腔内特に気管支壁に発生せる癌細胞をファイバースコープ等直視下で採取可能ならしめた擦過採取器に関するものである。

近時増加の一途をたどる癌の診断に際して癌細胞を積極的に病巣より採取することが、癌早期診断上甚だ重要なのであり、特に近時ファイバースコープの開発に伴なつて気管支末梢部の探索が容易となるにつれこれに適合せる細胞採取器が必要となつている。即ち従来この種のものには直達鉗子の他、先端に軸着せる鋭匙を屈伸せしめて気管支壁を擦過し鋭匙に附着せる細胞を取り出す形式のものがあつたが、構造が複雑の上外径寸法を小さくすることが困難で、且つ硬直部分を短かくすることが出来ず、従つて鋭く屈曲する気管支用ファイバースコープのチヤンネルを通して直視下に細胞を採取する器具として利用することが不可能であつた。本考案は上記欠陥を除去したものであり以下実施例図につき詳述する。

符号1は金属又は硬質の合気樹脂等よりなる採取管で、先端部の一個所乃至複数個所をU型又はV型に切除2せしめ、且つ上記切除せられた残余

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の部分を先端に向つて内方に彎曲せる擦過部3として構成し、上記擦過部の両翼部周縁には削取刃4a，4bが形成されている。6は上記採取管基底部とファイバースコープ等内視鏡の手元操作部近傍にて回転操作自在になさしめるツマミ7とを連合せる可撓管又は可撓軸であり、上記採取管と一体構造とすることも可能である。

上記構成よりなる採取器を公知のファイバースコープ等内視鏡のチヤンネルに挿入し、気管支壁を観察しながらツマミ7を操作して擦過部3を病巣部5に到達せしめ、適宜の押圧力を上記病巣部に与えながら採取管1を回転せしめると、反発弾性により切除部2に隆出せる病巣部粘膜が削取刃4a，4bにより擦過せられて上記採取管内壁面に附着し、上記採取器を抜去してこれを取り出し細胞標本に塗付けることが出来る。

上記実施例に於ては採取管1の先端部を内方に彎曲せる擦過部となして粘膜内への侵入を出来るだけ阻止しているが、これを鉛直となして深部の細胞を採取出来る様にしても差支えない。

上記説明より明らかな如く本考案に係をる細胞採取器は構造が極めて簡単であるため採取管外径を1mm以下にすることが容易であり、且つ先端の擦過部を除いて可撓体とすることが出来るため気管支用ファイバースコープの多く細径且つ可撓性の強い内視鏡に挿入して直視下の細胞採取を行なう事を可能ならしめ、且つ細胞採取操作は極めて簡単で臨床的価値が高く肺癌の早期診断に有効である。

実用新案登録請求の範囲

採取管の先端にU型若しくはV型の切除部と、切除部以外の先端部を内方に彎曲せしめた擦過部と擦過部の両翼部を削取刃として形成したことを特徴とする内視鏡用細胞採取器。

引用文献
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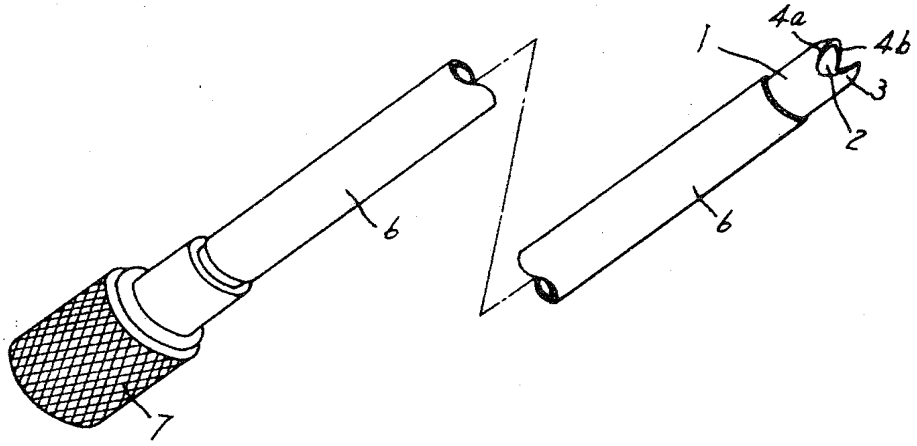
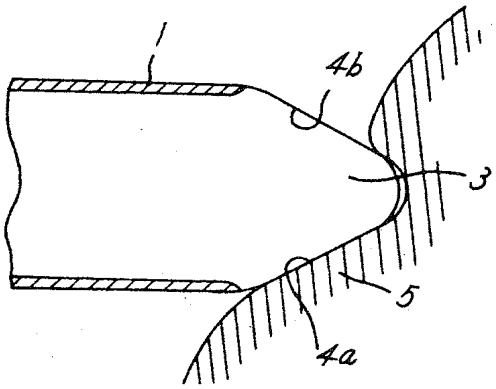
第１図



第２図



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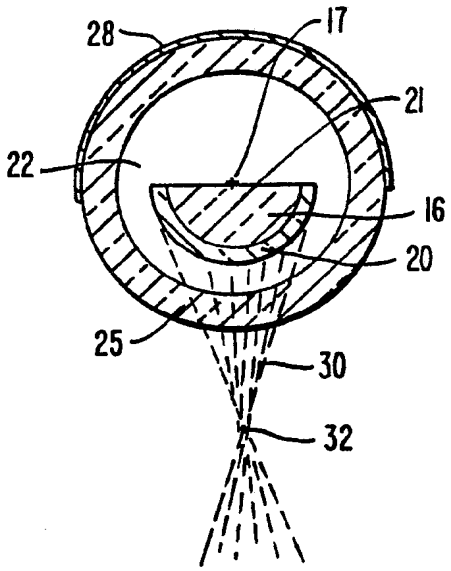

(57) Abstract

A fiber optic probe and its use in performing a sclerostomy (forming a small hole in the sclera of an eye) as a treatment for glaucoma. The minimally dimensioned probe is designed to direct laser light (30) out of its side (25), and, as a result, allows a sclerostomy procedure to be performed with minimal trauma to the conjunctiva and other surrounding ocular tissues of the patient. A series of pulses of infrared laser radiation delivered through the side of the probe forms the hole in the sclera.

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OPTICAL FIBER PROBE AND LASER SCLEROSTOMY PROCEDURE

Background of the Invention

The present invention relates generally to laser delivery probes and uses thereof, and more particularly, to a laser probe especially adapted for ophthalmologic applications and its use in treating glaucoma with a filtering procedure.

Glaucoma is a long-term condition where the fluid pressure inside the eye, the intraocular pressure, remains above normal for extended periods of time. This abnormal condition, if not treated properly, can lead to blindness. The high internal fluid pressure tends to cut off needed oxygen from the retina, which, if continued for a time, can cause retina cells to die. A healthy eye allows fluid to pass out through the trabecular meshwork adjacent the iris, and then through the schlemm canal and into the sinuses. Intraocular pressure builds up to unacceptable levels when this passage becomes blocked. Indeed, glaucoma is one of the chief causes of blindness, worldwide.

The current goal in the management of the patient with advanced glaucoma is the reduction and control of this intraocular pressure. Unfortunately, it is often difficult to achieve a desired pressure level in a particular patient by medical therapy because of the complexity of the disease. All too frequently, intraocular pressure continues to increase, or at least remains high, when the patient is being treated for the condition with a maximum level of medication. As a

result, other, more invasive alternatives generally must be used.

These invasive alternatives include various surgical techniques of forming an opening into the eye in order to provide a fluid passage that relieves the high intraocular pressure in glaucoma patients. One method involves treatment of the trabecular meshwork with a light beam from an argon laser, without surgery, in an attempt to restore an outflow of fluid through this meshwork. The laser beam is directed through the cornea and against the trabecular meshwork. Current studies, however, have shown that a significant percentage of these procedures fail after some period of time. Other lasers, such as Q-switched ruby and neodymium:YAG have also been used to perform trabeculo-punctures.

Another invasive method involves forming a new pathway through the sclera adjacent the cornea in order to allow aqueous fluid to pass from the anterior chamber of the eye, through the pathway and into a region under the conjunctiva. A flap is first opened in the covering conjunctiva by making straight line incisions along three sides of a rectangle, in a position alongside the cornea. The sclera is exposed by folding back this flap. A small opening is then formed in the sclera by either an incision (external filtration surgery) or a laser light beam. Carbon dioxide, neodymium:YAG in the free running mode, and excimer lasers have been used to perform sclerostomies. After the opening is formed, the conjunctival flap is sewn shut. Neither of these methods, however, have provided a complete solution. Surgical intervention of the conjunctiva can cause complications because of surgical trauma, and the necessary sewing shut of the conjunctival flap.

External filtering surgery results in successful lowering of the intraocular pressure in 65% to 85% of the cases, depending on the condition of the eye.

Accordingly, it is a primary object of the present invention to provide an improved sclerostomy procedure and fiber optic probe for use in the procedure that is simpler, more effective and long lasting, and which is less damaging than current procedures.

It is another object of the present invention to provide a procedure and fiber optic probe for use in the procedure that can be performed on an outpatient basis, in an office, clinic or hospital.

Summary of the Invention

These and additional objects are accomplished by the present invention, wherein, briefly and generally, according to one aspect, a round fiber optic probe is provided that directs focused light out of its side by use of a combination of a reflecting surface at the fiber end and lens action of a fiber side surface. Anti-reflection coatings for preventing escape of light from a backside of the probe are avoided. An appropriate light blocking element is used instead. In a preferred form, the probe includes a partial canula on an outside surface for added strength in addition to blocking light.

According to another aspect of the present invention, an improved sclerostomy procedure is performed with a probe, such as described above, that delivers laser light from its side. A small hole is first made in the conjunctiva layer of the eye so that the probe can be inserted through it. The probe is then gently advanced subconjunctivally and placed tangential to the limbus. This probe insertion produces minimal disturbance to the conjunctiva. The probe is then positioned with its light exiting side against the

sclera in a position at the limbus adjacent the cornea, and laser light delivered by the probe forms the desired hole in the sclera. Since only a small hole, rather than a larger flap, need be formed in the conjunctiva, there is minimal scarring in the healing process and no sutures are required, or at most, one suture is placed at the conjunctiva hole. This result of performing the procedure with a side delivery fiber optic probe greatly simplifies the procedure and improves the success rate of the procedure. In addition, because of minimal scarring, it is easy to repeat the procedure.

Additional objects, advantages and features of the various aspects of the present invention will become apparent from the following description of its preferred embodiments, which description should be taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 shows in general a laser delivery system in which the improved probe embodiments of the present invention may be utilized;

Figure 2 is a cross-sectional view of a probe provided as part of the system of Figure 1, according to a first embodiment;

Figure 3 is a sectional view of the probe of Figure 2, taken at section C-C thereof;

Figure 4 is a sectional view of the probe of Figure 2, taken at section D-D thereof;

Figure 5 shows a fiber optic probe provided as part of the system of Figure 1, according to a second embodiment;

Figure 6 is a sectional view of the probe of Figure 5, taken at section E-E;

Figure 7 is a cross-sectional view of a human eye; and

Figure 8 is an enlargement of a portion of the eye cross-section of Figure 7, additionally illustrating a sclerostomy procedure according to the present invention.

Description of the Preferred Embodiments

Referring initially to Figure 1, a probe assembly 11 includes a length of flexible optical fiber 13. In addition to an outer protective sheath that exists on the usual, commercially available optical fibers, an additional outer protective layer is usually desirable. At one end of this length of optical fiber is a connector 12 for attachment of the fiber to a laser. A laser 9 is schematically illustrated with an optical system 10 that focuses the laser output into the connector end of the optical fiber. At the other end of the assembly 11 is an enlarged diameter handle portion 14 and a probe 15. Optical radiation from the laser 9 travels along the optical fiber 13 and exits the probe 15 in a manner that has significant advantages for performing an ophthalmologic application described hereinafter.

Referring to Figure 2, a cross-sectional view of the probe 15 of Figure 1 is illustrated, in a first embodiment. This probe must be of minimal diameter in order to minimize the trauma, reach the target site more easily, and make a small hole in the sclera. The optical fiber preferably includes a round core 16 of 200 microns in diameter and a surrounding cladding 20 made of quartz material of different refractive indices. The core 17 and cladding 20 have centers of curvature at a longitudinal axis 17 of the optical fiber. A protective sheath 24 of the optical fiber is removed for a distance adjacent its end. A cylindrically shaped quartz tube 25 is opened at one end for receiving the optical fiber and forms an air tight attachment with its sheath 24. An

opposite end of the sleeve 25 is enclosed, thereby forming a trapped volume 22 of air within the sleeve 25. Thus, an air interface is provided adjacent an end surface 21 of the optical fiber core 16 and cladding 20. In addition, air surrounds the exposed core/cladding end segment of the fiber, the walls of the sleeve 25 being spaced apart from the fiber cladding 20 by the sheath 24. The sleeve 25 is positioned with a longitudinal center axis that is substantially coincident with the optical fiber axis 17.

The purpose of the fiber end surface 21 is to reflect out of the probe 15 as a beam 30 as much of the optical radiation as possible that reaches the fiber end. This reflection results from the core 16 having a much different refractive index than that of the surrounding air. The surface 21 is most conveniently made to be planar, but could be given a more complex shape in order to better control the characteristics of the emerging beam 30. The surface 21 is formed at an angle θ with the fiber axis 17. This surface 21 is at an incidence angle that exceeds the critical angle for substantially all of the optical rays travelling down the fiber. The surface 21 directs the beam 30 outward with an axis 31 that is as close to being orthogonal with the fiber axis 17 as possible. It is this side delivery of the laser radiation beam 30 that allows the probe 15 to be advantageously utilized in the ophthalmologic procedure described hereinafter.

The optimum angle θ depends upon the refractive index of the core material 16, the wavelength of the optical radiation to be reflected, and the numerical aperture of the optical fiber. Generally, it will be within a range of substantially 35 to 45 degrees. For radiation within the infrared range, an index refraction of 1.47 for a typical quartz fiber core 16, and a fiber numerical aperture of 0.21, the angle θ

which reflects substantially all of the radiation in the fiber is about 39°. That results in the exiting beam 30 having a center line 31 making an angle of about 79° with the optical fiber axis 21, or the angle ϕ of Figure 2 being about 11°, if it is assumed that the probe is submerged in water. Since the probe is designed for carrying out a surgical procedure on human patients, this assumption is generally correct since tissue to be contacted by the outside surface of the sleeve 25 is mostly water.

With reference to Figure 4, the operation of the probe 11 to deliver a focused beam 30 is described. Because of its air interface, the core 16 and cladding 20 of the fiber within the sleeve 25 act as a cylindrical lens to direct the radiation beam 30 to a substantial line focus 32 that extends generally in the same direction as the optical fiber axis 17. Assuming again that a radiation exiting area of the sleeve 25 is in contact with water, the sleeve/water interface has a lesser effect in shaping the beam 30. The shape is controlled primarily by the air interface of the cladding 20 in an area thereof through which the optical radiation exits after reflection from the surface 21. This one-dimensional focusing ability of the probe is an advantage in efficiently using the available laser optical radiation intensity. It also controls the size of the beam 30 in order to form a very small hole in the sclera of an eye by carrying out the ophthalmologic procedure described hereinafter. The position of the line focus 32 depends upon the refractive indices and the size of the fiber core 16 and cladding 20. For the size of the core used, 200 microns, the focus is about 0.5 mm from the outside of the sleeve 25 when commercially available quartz fibers are utilized. A focal distance of less than 1 mm is desirable for use in the ophthalmologic procedure described below.

It will be recognized that reflection of a small percentage of the exiting light beam 30 will be present at each interface of different materials through which it travels in exiting the probe. Some control of this reflected light is desirable, primarily to avoid burning tissue of the patient on the backside of the probe and for safety reasons. In the embodiment illustrated in Figures 2-5, a layer 28 of opaque, reflective material is coated on an outside surface area of the sleeve 25 to block the path of such reflected light. A pure gold coating is preferred. The coating 28 preferably extends over the top half of the sleeve 25, half-way around its outer circumference as shown in the cross-sectional view of Figure 3. Its dimension along the length of the sleeve 25 is sufficient to cover all regions where reflected or scattered light is likely to emerge.

Such a coating is difficult to make on surfaces having a small radius of curvature, and often do not come out uniform. For this reason, and in order to provide additional strength to the brittle quartz materials of the probe of Figures 2-4, a modification is shown in Figures 5 and 6 where a canula 37 replaces the reflective coating 28. Elements of the embodiment of Figures 5 and 6 which correspond to those of the embodiment of Figures 2-4 are identified by the same reference number, but with a prime (') added.

The canula 37 is a separate, single piece stainless steel element added to surround the sleeve 25'. The sleeve 25' is completely surrounded by a full canula at its open end while about one-half of the circumference of the sleeve is covered by a half canula along a length where optical radiation exits from the probe. Strips of adhesive 40 hold the canula 37 tightly against an outside surface of the quartz tube 25', thereby to add a considerable amount of strength to the probe assembly.

For use in the ophthalmologic procedure to be described, the diameter of the overall probe 15 (embodiment of Figures 2-4) or 35 (embodiment of Figures 5 and 6) needs to be very small. A maximum diameter of less than 1 mm is easily accomplished with these designs. Indeed, a preferred outside diameter of the sleeves 25 and 25' is less than 0.5 mm and, as a specific example, can be 0.46 mm. The diameter of the optical fiber core 16 is selected to be within a range of 0.1 to 0.3 mm, and in a specific example being 0.2 mm.

It is this small size and side delivery of optical radiation that makes possible an improved procedure for forming a small hole in the sclera adjacent the cornea of a patient's eye. As shown in Figure 8, the probe 15 or 35 is positioned under a patient's conjunctiva 51 in one eye. A side of the probe is positioned against the eye's sclera 53 in order to direct its radiation beam 30 through the sclera in a region immediately adjacent a cornea 55 tangential to the limbus. The goal of this procedure is to open a small passage in the sclera of 0.2 to 0.3 mm in cross-sectional size. This then provides a fluid path from the anterior chamber 57 within the eye to a region under the conjunctiva. This fluid path relieves internal eye pressure, thus providing a cure for glaucoma.

Because the probe is so small, and because the radiation beam 30 exits from its side, its positioning against the sclera 53 requires only that a hole of about 1 mm or less be made in the conjunctiva. The fiber probe is then positioned through that hole, and after the procedure is completed, the hole is usually allowed to heal itself, after the probe is removed, without the necessity of any sutures. However, one very fine suture is occasionally placed at the conjunctiva hole.

The type of laser 9 that is desired for this procedure is one generating an output beam that is within the infrared range of the optical radiation spectrum, preferably substantially within a wavelength range of from 1.8 microns to 3.2 microns. This wavelength range is highly absorbed by water, the primary component of the sclera through which a hole is being formed. High absorption of the radiation by the sclera results in efficient use of the energy and nearly complete absorption by the sclera itself without other portions of the eye under the sclera being undesirably heated. A holmium laser, having an output around 2.1 microns, is preferred. Alternatively, lithium, with an output of about 1.94 microns, or erbium, with an output of about 2.94 microns, may be utilized.

The optical radiation from the laser is preferably applied to the sclera by a series of pulses. Energy in each pulse within a range of from 50 mJoules to 350 mJoules is preferably generated in an output beam of the laser 9. An convenient pulse repetition rate can be utilized, a rate of 5 pulses per second typically being used. If the amount of energy per pulse is about 100 mJoules, a total exposure time of from 3-6 seconds duration is sufficient for the sclerostomy.

Although the various aspects of the present invention have been described with respect to their preferred embodiments, it will be understood that the invention is entitled to protection within the full scope of the appended claims.

IT IS CLAIMED:

1. A laser radiation delivery system adapted for use in ophthalmologic applications, comprising:

a length of optical fiber having first and second ends and characterized by having at least a core and surrounding cladding that are substantially round in cross-section with centers of curvature coincident with a longitudinal axis of the fiber,

said first end of said fiber being formed into a radiation delivery probe and said second end of said fiber being provided with a connector adapted for attachment of the fiber second end to a laser radiation source in a manner that laser light travels along the length of fiber toward said first end,

said probe including a sleeve attached to said fiber in a position surrounding and enclosing said first fiber end in a manner to provide an air interface with a surface formed by the fiber core and cladding at a critical finite angle with respect to said longitudinal axis in order that substantially all of any laser light traveling therealong is reflected out of a defined area of a side surface of said fiber and through a facing defined region of a side of said sleeve, at least the defined region of said sleeve being substantially transparent and positioned a distance from said fiber side defined area in a manner to provide an air gap therebetween, said probe further being characterized by an absence of any anti-reflection coating on said first fiber end and sleeve in the path of laser light passing out of the fiber and sleeve, thereby resulting in some laser light being reflected by fiber and sleeve surfaces back toward a region of the sleeve that is opposite its said defined region, and

means carried by said probe for blocking said reflected laser light from being directed away from the probe.

2. The system according to claim 1 wherein said reflected light blocking means includes a metal canula attached to at least a portion of an outside surface of said sleeve opposite to said sleeve defined region and extending substantially the length of said sleeve, whereby said canula also provides strength to the probe structure.

3. The system according to claim 2 wherein said sleeve is round in cross-section and said canula includes an arc in cross-section that substantially matches the sleeve curvature, said canula arc additionally extending around only a portion of the circumference of the sleeve in at least a length including said defined region, said canula additionally shaped to substantially surround the sleeve at an end thereof opposite its end that surrounds and encloses said first fiber end.

4. The system according to claim 1 wherein said sleeve is further characterized by being round in cross-section, with inner and outer surfaces having centers of curvature substantially coincident with said fiber longitudinal axis, for at least a portion of its length including said defined and opposite regions.

5. The system according to claim 4 wherein said reflected light blocking means includes a layer of material deposited onto an outside surface of said sleeve in an area including at least said opposite region.

6. The system according to claim 5 wherein said layer of material consists of gold.

7. The system according to claim 4 wherein an outside diameter of said sleeve round cross-section is less than one millimeter.

8. The system according to claim 1 wherein said fiber core has a diameter substantially within a range of from 0.1 to 0.3 millimeter.

9. The system according to claim 1 wherein said surface formed at said fiber core and cladding is substantially planar and said finite angle is within a range of substantially 35 to 45 degrees.

10. The system according to claim 1 wherein said surface formed at said fiber core and cladding is substantially planar and said finite angle is substantially 39 degrees.

11. The system according to claim 1 wherein the shape of said first fiber end surface, its said finite angle, diameters of said fiber core and cladding, and the shape of said sleeve at its said defined region all cooperate to provide a focus in at least one direction that is less than 1.0 millimeter outside of said sleeve when said sleeve is immersed in water.

12. The system according to claim 11 wherein said focus in at least one direction is substantially a line oriented in substantially the same way as said fiber longitudinal axis.

13. The system according to claim 1 which additionally includes a light source having an optical connector adapted to mate with said fiber connector, thereby to supply laser light to said probe, said light source including a laser emitting light substantially within a wavelength range of from 1.8 microns to 3.2 microns.

14. The system according to claim 13 wherein said light source includes a laser medium including a material selected from a group consisting of holmium, lithium and erbium.

15. An optical radiation delivery probe formed at an end of an optical fiber, comprising:

a substantially cylindrical sleeve of substantially optically transparent material that is enclosed at one end and opened at another end,

an end of a length of an optical fiber core and cladding inserted into said sleeve through its said opened end and held fixed thereto in a manner that a volume of air is trapped between an outside surface of said cladding and an inside surface of said sleeve, said fiber end terminating in a surface oriented at a critical finite angle with respect to a longitudinal axis of said fiber, thereby to reflect out of a side of the fiber through an exiting region of a side of said sleeve substantially all optical radiation traveling down said length of fiber toward said end, and

a canula positioned against an outside surface of said sleeve and extending substantially its entire length while extending around only a portion of its outside circumference for at least a portion of its length in order that said sleeve radiation exiting region remains uncovered by said canula, said canula being substantially opaque to optical radiation.

16. The probe of claim 15 wherein said canula is made substantially entirely of stainless steel.

17. The probe of claim 15 wherein said canula additionally is shaped to extend around substantially the entire circumference of said sleeve for a portion of its length adjacent its said open end.

18. The probe of claim 15 wherein said sleeve is made of quartz.

19. The probe of claim 15 wherein said fiber includes an outer sheath that is removed from a length of the fiber immediately adjacent said end but which remains along a portion of the fiber adjacent the open end of said sleeve, said sleeve being attached to said sheath, whereby said sheath provides a spacer to maintain a distance between said fiber cladding and said sleeve.

20. The probe of claim 15 wherein said canula is shaped to conform to an outside surface of said sleeve, and further wherein the probe structure is less than substantially one millimeter in outside diameter.

21. The probe of claim 1 wherein the shape of said first fiber end surface, its said finite angle, diameters of said fiber core and cladding, and the shape of said sleeve at its said radiation exiting region all cooperate to provide a focus in at least one direction that is less than 1.0 millimeter outside of said sleeve when said sleeve is immersed in water.

22. The system according to claim 21 wherein said focus in at least one direction is substantially a line oriented in substantially the same way as said fiber longitudinal axis.

23. An ophthalmologic procedure utilizing the delivery system of claim 1, comprising the steps of:

forming a hole through a conjunctiva layer of a patient's eye,

inserting the probe according to claim 1 through said hole,

gently advancing the probe subconjunctivally and placing it tangentially to the limbus, orienting the probe so that the exiting laser beam will enter the sclera adjacent to the cornea, thereby to direct laser light from the probe against the sclera, and

exposing the sclera to at least one pulse of laser light from the probe sufficient to make an opening through said sclera.

24. An ophthalmologic procedure utilizing the probe of claim 15, comprising the steps of:

forming a hole through a conjunctiva layer of a patient's eye,

inserting the probe according to claim 15 through said hole,

advancing the probe subconjunctivally and placing it tangential to the limbus with said exiting sleeve region directed against the sclera adjacent to the cornea, thereby to form a path of optical radiation from the probe to the sclera, and

exposing the sclera to at least one pulse of optical radiation from the probe that is sufficient to make an opening through said sclera.

25. An ophthalmologic procedure, comprising the steps of:

forming a hole through a conjunctiva layer of a patient's eye,

inserting through said hole a probe at the end of a length of an optical fiber, said probe being characterized by providing substantially its entire light output through a side area thereof near an extreme end,

positioning said probe with said side area thereof against an outer surface of a sclera of the patient's eye tangentially to the limbus and adjacent a cornea, thereby to form a light path from the probe against the sclera, and

exposing the sclera to at least one pulse of laser light through the probe side area sufficient to make an opening through said sclera.

26. The procedure according to claim 25 wherein the exposing step includes directing laser light along the length of the optical fiber within a wavelength range extending substantially from 1.8 microns to 3.2 microns.

27. The procedure according to claim 26 wherein the exposing step includes the use of a laser which utilizes a laser medium including a material selected from a group consisting of holmium, lithium and erbium.

28. The procedure according to claim 25 wherein said probe is further characterized by having an external diameter that is less than one millimeter.

29. The procedure according to claim 25 wherein no sutures are utilized to close the conjunctiva layer hole.

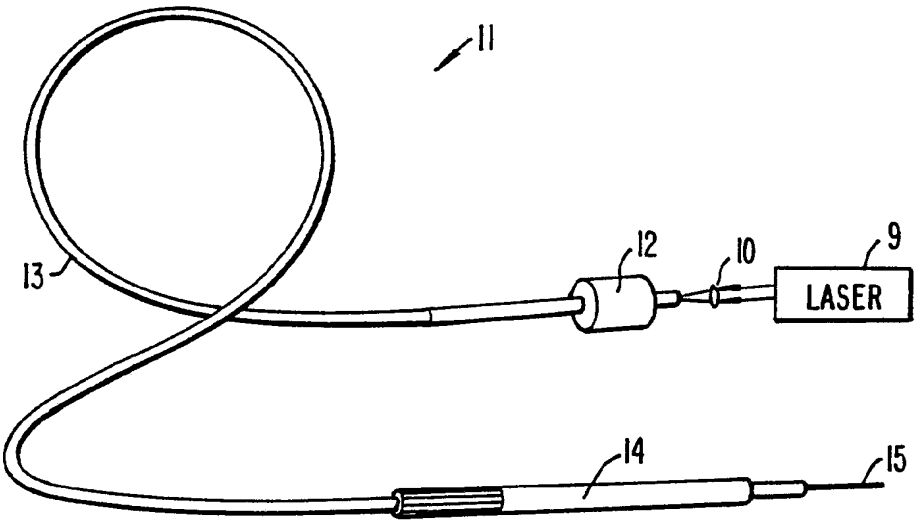

FIG._1.

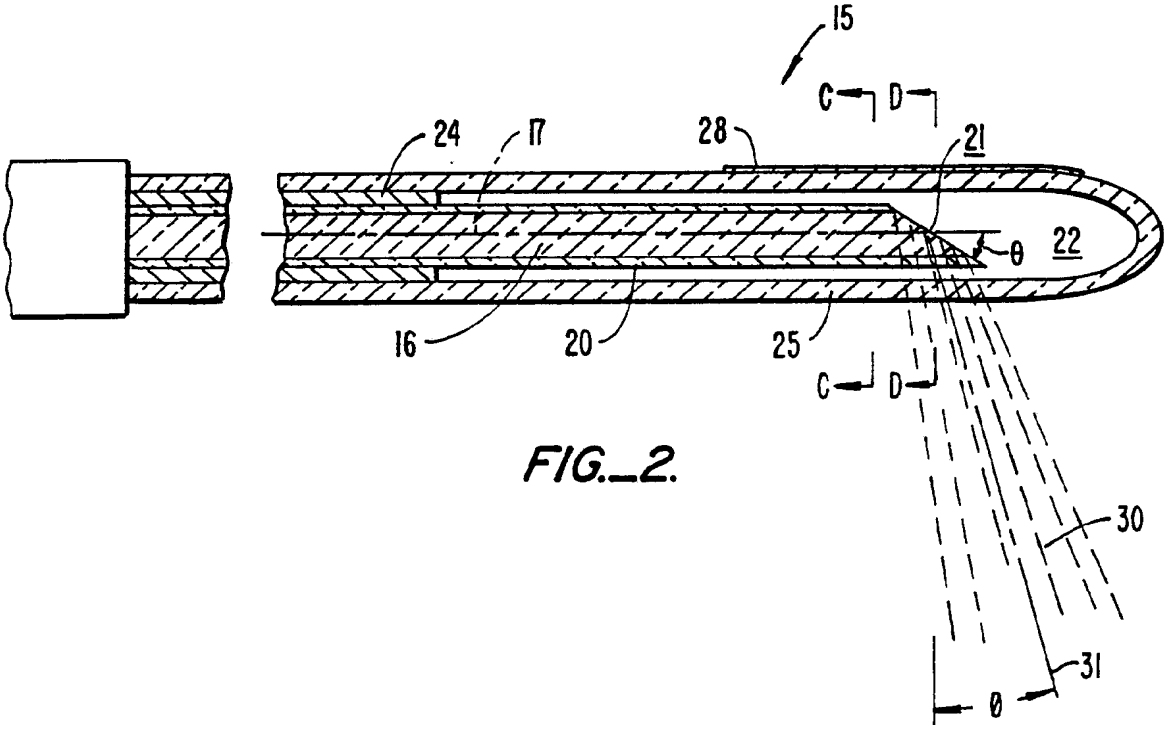

FIG._2.

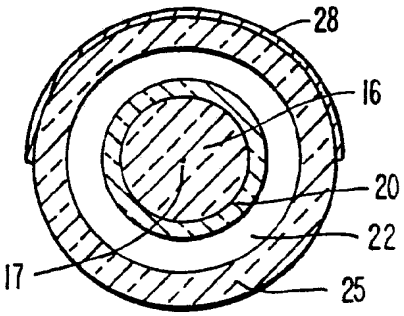

FIG._3.

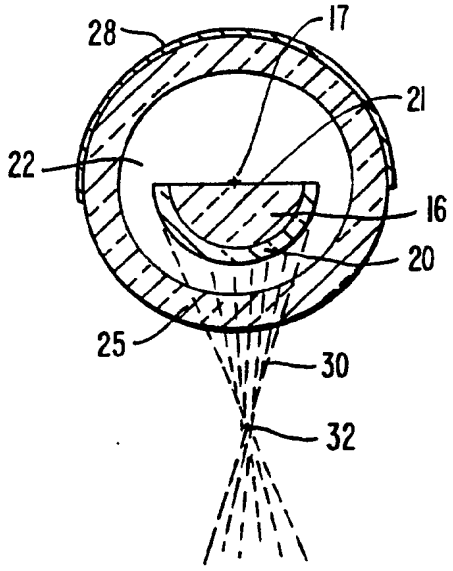

FIG._4.

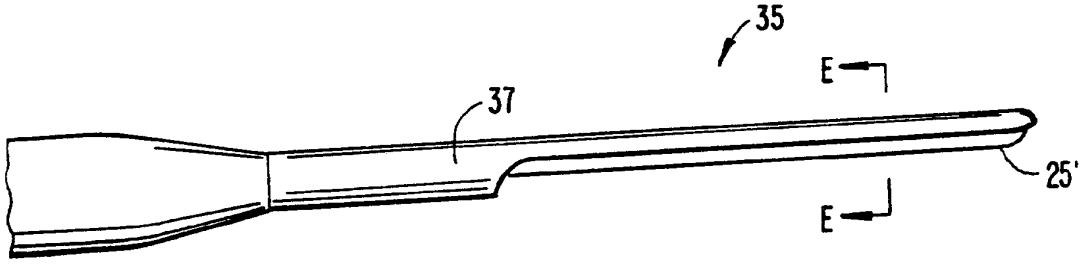

FIG._5.

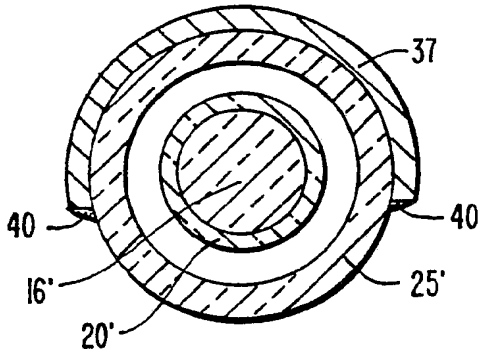

FIG._6.

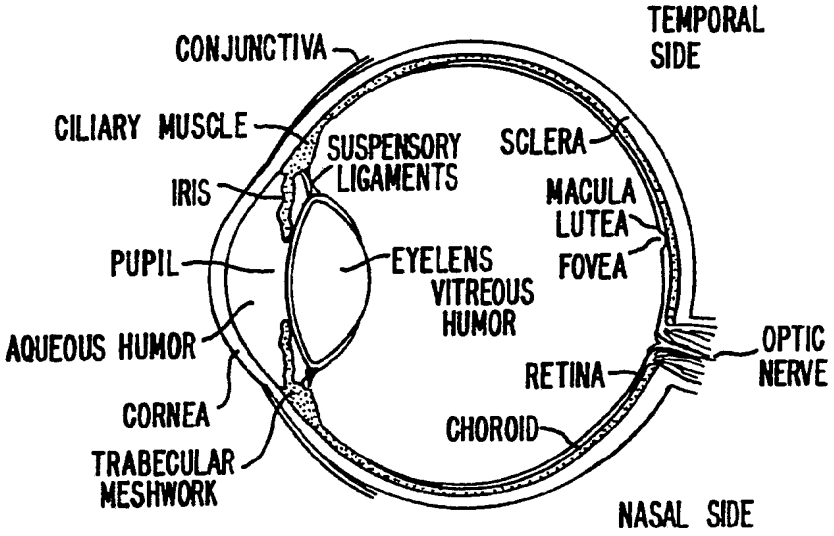
CONJUNCTIVA
TEMPORAL SIDE
CILIARY MUSCLE
SUSPENSORY LIGAMENTS
SCLERA
IRIS
MACULA LUTEA
PUPIL
EYELENS
FOVEA
VITREOUS HUMOR
AQUEOUS HUMOR
OPTIC NERVE
RETINA
CORNEA
CHOROID
TRABECULAR MESHWORK
NASAL SIDE

FIG._7.

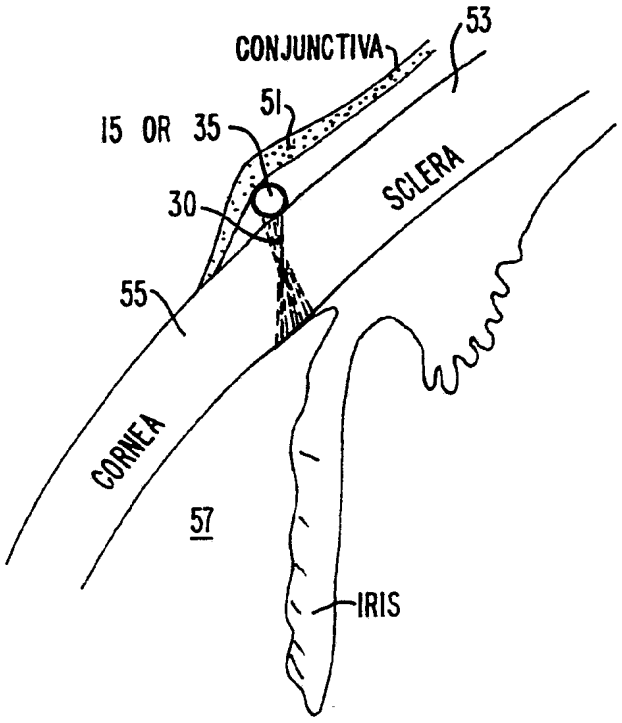
CONJUNCTIVA
53
51
15 OR 35
30
SCLERA
55
CORNEA
57
IRIS

FIG._8.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/03393

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61N 5/06
US CL.: 606/006

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	606/2,6,13-18 128/395,397,398

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A, 4,740,047 (ABE) 26 April 1988 See entire document.	1-22
Y	US, A, 3,834,391 (BLOCK) 10 September 1974 See entire document.	1-22
Y	EP, A, 214,712 (SINOFSKY) 18 March 1987 See abstract, and pages 3-4.	10-14,21,22
Y	US, A, 4,799,479 (SPEARS) 24 January 1989	6

* Special categories of cited documents: [10]

"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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search

03 SEPTEMBER 1991

Date of Mailing of this International Search Report

02 OCT 1991

International Searching Authority

ISA/US

Signature of Authorized Officer

Veronica Scalera for
DAVID SHAY

Form PCT/ISA/210 (second sheet) (Rev.11-87)

Electronic Acknowledgement Receipt

EFS ID:	12043862
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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/Alicia Curran
Filer Authorized By:	Robert D. Buyan
Attorney Docket Number:	NEOME-019A3US-G
Receipt Date:	09-FEB-2012
Filing Date:	13-JUN-2011
Time Stamp:	18:23:19
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	Transmittal Letter	NEOME-019A3US-G-IDS-Transmittal.pdf	135741 8a3c924a1a22982f5c7ed779fdf7b6315502d695	no	2

Warnings:

Information:

2	Information Disclosure Statement (IDS) Form (SB08)	NEOME-019A3-US-G-IDS-SB08aForm.pdf	615570 7c5ad6e4ec00c97a9023a2d4dfa14499a270f85e	no	6
Warnings:					
Information:					
3	Foreign Reference	WO9827876A1.pdf	1083562 b8819e30133b65a7c950cc2252538cd3dd42261f	no	29
Warnings:					
Information:					
4	Foreign Reference	WO02056805A2.pdf	3258895 4fafff6672a9ffcb6ae47cd42cfae9a174f58447	no	78
Warnings:					
Information:					
5	Foreign Reference	JP46-025677.pdf	352918 72046eea5d94483470ce34fcaa808aee5e1b8ea6	no	3
Warnings:					
Information:					
6	Foreign Reference	WO9117793A1.pdf	911424 ef985e78ebe0562b4af36239818f8b1b2c0d791f	no	23
Warnings:					
Information:					
7	Non Patent Literature	NEOME-019A3-OA.pdf	302114 0f41f768eb79eee250b2cfdc8f14359141682885	no	9
Warnings:					
Information:					
8	Non Patent Literature	NEOME-019A3-OA2.pdf	194589 2e659e647d9720ab277423afa1db62b8d939221e	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	6854813	

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 13/159,356
Applicant	: Sorenson et al.
Filed	: June 13, 2011
TC/A.U.	: 3731
Examiner	: To be determined
Confirmation No.	: 1298
Docket No.	: NEOME-019A3US-G
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

Sir:

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.

No representation is made that the reference(s) disclosed herein legally constitute prior art or that more relevant references are not available. The disclosure document(s) listed on the attached Forms PTO/SB/08A are printed in the English language and/or accompanied by an Abstract published in the English language.

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

Petitioner - New World Medical
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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 & MULLINS, LLP

Date: February 9, 2012

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

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Petitioner - New World Medical
Ex. 1019, p. 196 of 285

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3US-G

CONFIRMATION NO. 1298

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

PUBLICATION NOTICE

OC000000053282718

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

Publication No.US-2012-0071908-A1
Publication Date:03/22/2012

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3US-G	1298

33197 7590 03/26/2013

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4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER	
SHIPLEY, AMY R	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
03/26/2013	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.	Applicant(s)	
	13/159,356	SORENSEN ET AL.	
	Examiner	Art Unit	
	AMY SHIPLEY	3734	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *13 June 2011*.

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) *1-22* 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) *1-22* 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 *13 June 2011* 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).

a)☐ All b)☐ Some * c)☐ None of:

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/08) Paper No(s)/Mail Date *2/9/12*.

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

4) ☐ Other: _____.

Petitioner - New World Medical
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DETAILED ACTION

Drawings

1. The drawings filed 6/13/2011 are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 17, 18 and 32. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: see drawing objection above.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. 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.

4. Claims 21 and 22 recite the limitation "the outer tube". There is insufficient antecedent basis for this limitation in the claim.

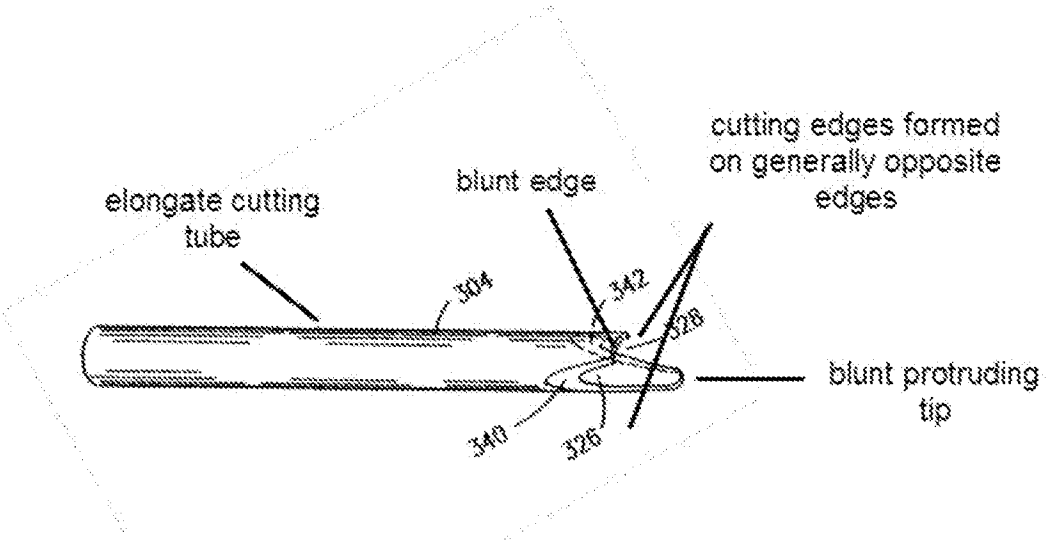
Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 3, 6, and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Heisler et al USP 6,419,684.



Regarding claim 1, Heisler discloses 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 (see figure above);

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, see figure above, distance D between cutting edges;

said cutting tube being capable of being advanced 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, see figure above and column 2 lines 22-40.

Regarding claim 3, Heisler discloses a device further comprising at least one protruding tip formed on the distal end of the cutting tube.

Regarding claim 6, Heisler discloses a device wherein the first and second cutting edges are located on opposite lateral sides of the distal end of the cutting tube, see figure above.

Regarding claim 15, Heisler discloses a device 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 (column 1 lines 14-51).

Regarding claim 16, Heisler discloses a device wherein the device further comprises a second lumen (302) see figure 9, wherein first lumen is (304).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 4, 5, 7, 8, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heisler et al USP 6,419,684 as applied to claim 1 above, and further in view of Baxter et al USP 6,428,539.

Regarding claim 2, Heisler fails to disclose a device wherein the cutting tube comprises a stainless steel hypodermic tubing. Baxter teaches a cutting tool made of stainless steel (column 10 lines 58-65). It would have been obvious at the time of the invention to utilize stainless steel as taught by Baxter to form the hypodermic tubing of Heisler, as to provide a rigid cutting device.

Regarding claim 4, the combination of Heisler and Baxter teach a device wherein the protruding tip is tapered, see figure above.

Regarding claim 5, the combination of Heisler and Baxter teach a device wherein the protruding tip is sufficiently blunt to be substantially a traumatic, see figure above.

Regarding claim 7, the combination of Heisler and Baxter teach a device 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, see figure above.

Regarding claim 8, the combination of Heisler and Baxter teach a device further

comprising a blunt edge located at the top of the distal end of the cutting tube, see figure above.

Regarding claim 18, Heisler fails to disclose a device wherein at least one of the cutting edges is heated such that it will cauterize as it cuts. Baxter teaches a cutting device which electrically cauterizes as it cuts (column 4 line 64-column 5 line 8). It would have been obvious at the time of the invention to cauterize while cutting as taught by Baxter as to stop bleeding after performing the cutting procedure.

Regarding claims 19 and 20, Heisler fails to teach the use of electrodes in combination with the cutting tool. Baxter teaches the use of electrodes as to provide both a cutting and cauterization simultaneously. The electrodes are on the inner and outer blades thus in combination, they severe the tissue. The device is controlled via a handle mechanism thus dictating the desired size of tissue (column 9 line 60-column 10 line 3). Baxter teaches a cutting device which electrically cauterizes as it cuts (column 4 line 64-column 5 line 8). It would have been obvious at the time of the invention to cauterize while cutting as taught by Baxter as to stop bleeding after performing the cutting procedure.

Regarding claim 21, Heisler fails to teach device wherein the device further comprises: an outer 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. Baxter teaches a cutting tube which extends distally of an outer tube (see figures 17 and 18) wherein outer tube (1110) surrounds cutting tube (1130). It would have been obvious at the time of the invention to provide an additional outer tube member to the cutting device of Heisler as taught by Baxter as to provide support to withstand the torque applied to the tube or shaft (column 10 lines 48-65).

Regarding claim 22, the combination of Heisler and Baxter teach a device wherein: the outer diameter of the cutting tube is smaller than the inner diameter of the second tube (such being required for a telescoping arrangement as taught by Baxter see figures 17 and 18 of Baxter) such that fluid is capable of flowing through the lumen of the second tube; and at least one aperture (at the distal end of 1110 in figure 18 of Baxter) is formed in the second tube to provide the capability of fluid to passing into or out of the lumen of the second tube.

9. Claims 9, 10, 12, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heisler et al USP 6,419,684 as applied to claims 1 and 16 above, and further in view of Anctil US RE38,018.

Regarding claim 9, Heisler fails to teach a device wherein there is a single bend or curve formed in the cutting tube. Anctil et al teaches a tissue cutting device with a single bend in the cutting tube (see figure 1). It would have been obvious

at the time of the invention to provide a bend in the cutting tube as taught by Anctil as to aid in reaching various portions of the body.

Regarding claim 10, the combination of Heisler and Anctil teach a device wherein there is a single bend of approximately 20 degrees to approximately 90 degrees formed in the cutting tube (see figure 1 and claim 11 of Anctil).

Regarding claim 12, Heisler fails to disclose a device wherein there are a plurality of bends or curves formed in the cutting tube. Anctil et al teaches a tissue cutting device with a plurality of bends in the cutting tube (see figure 26). It would have been obvious at the time of the invention to provide bends in the cutting tube as taught by Anctil as to aid in reaching various portions of the body.

Regarding claim 13, the combination of Heisler and Anctil teach a device wherein there are a plurality of bends of approximately 20 degrees to approximately 90 degrees each formed in the cutting tube (claim 19 of Anctil).

Regarding claim 17, Heisler discloses a device wherein said lumens (inner lumen) is connected to a source of negative pressure such that fluid or matter may be aspirated therethrough (column 1 lines 14-51). Heisler fails to teach the other lumen being connected to a fluid source. Anctil teaches connecting a fluid source (column 8 lines 9-24). It would have been obvious at the time of the

invention to provide a fluid source as taught by Anctil as to irrigate the site or clear blockages.

10. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heisler et al USP 6,419,684 and Anctil US RE38,018 as applied to claims 10 and 12 above, and further in view of Garfinkel USP 6,382,974.

Regarding claims 11 and 14, the combination of Heisler and Anctil fail to teach using a bend angle of approximately 90 degrees. However, it would have been obvious to one skilled in the art at the time of the invention to modify the angle of Anctil from about 45 degrees to about 90 degrees as "facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading" as in particular, Anctil teaches the need of having at least one angle between the cutting portion and the shaft. Furthermore, a closely related tissue cutting device as taught by Garfinkel, teaches specifically the use of 90 degree angles (column 2 line 54-column 3 line 5). It would have been obvious to alter the angle of the combination of Anctil and Heisler to be 90 degrees as taught by Garfinkel, as Garfinkel teaches a 90 degree angle between distal and proximal portions enhances accessibility, ease of manipulation, directional cutting, and efficiency (column 2 line 54-column 3 line 5).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Shipley 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 Gary Jackson, *at* (571) 272-4697**. 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 Shipley
Patent Examiner
/ARS/
AU 3734
3/22/13

/Katherine M Dowe/

Primary Examiner, Art Unit 3734

Notice of References Cited	Application/Control No. 13/159,356	Applicant(s)/Patent Under Reexamination SORENSEN ET AL.	
	Examiner AMY SHIPLEY	Art Unit 3734	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,428,539	08-2002	Baxter et al.	606/49
*	B	US-RE38,018	03-2003	Anctil et al.	606/170
*	C	US-6,419,684	07-2002	Heisler et al.	606/170
*	D	US-6,382,974	05-2002	Garfinkel, Leonard M.	433/144
	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					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13159356	SORENSEN ET AL.
	Examiner	Art Unit
	AMY SHIPLEY	3734

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	167	3/22/13	/ARS/

SEARCH NOTES		
Search Notes	Date	Examiner
inventor search; family history div of USP 7,959,641	3/22/13	/ARS/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

Petitioner - New World Medical
Ex. 1019, p. 212 of 285

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
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13159356
Filing Date	2011-06-13
First Named Inventor	Sorenson et al.
Art Unit	3731
Examiner Name	Unknown
Attorney Docket Number	NEOME-019A3-US-G

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	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Receipt date: 02/09/2012

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

Application Number	13159356
Filing Date	2011-06-13
First Named Inventor	Sorenson et al.
Art Unit	3731
Examiner Name	Unknown
Attorney Docket Number	NEOME-019A3-US-G

	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.	
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	17	5681282	A	1997-10-28	Eggers et al.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Receipt date: 02/09/2012	Application Number	13159356
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2011-06-13
(Not for submission under 37 CFR 1.99)	First Named Inventor	Sorenson et al.
	Art Unit	3731
	Examiner Name	Unknown
	Attorney Docket Number	NEOME-019A3-US-G

	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.	

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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.	

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Receipt date: 02/09/2012

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13159356
Filing Date	2011-06-13
First Named Inventor	Sorenson et al.
Art Unit	3731
Examiner Name	Unknown
Attorney Docket Number	NEOME-019A3-US-G

	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.	☐

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EXAMINER SIGNATURE

Examiner Signature	/Amy Shipley/	Date Considered	03/21/2013

*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.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	143	stent with graft adj cover	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 13:16
L4	2	("7959641").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 13:57
L5	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
L6	0	("l5andstainless").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 13:58
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L10	259	cutting with tissue with bend	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 14:11
L11	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
L12	3	enamel adj hatchet	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/22 15:36
L13	12	("0237062" | "1039235" | "5007831" | "5478235").PN. OR ("6042378").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/22 15:37
L14	2	("6,419,684").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 16:35
L15	5	(("4646738") or ("5411514")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/03/22 16:38
L16	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
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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

EAST Search History (Interference)

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3/22/2013 5:38:31 PM
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BIB DATA SHEET

CONFIRMATION NO. 1298

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/159,356	06/13/2011	606	3734	NEOME-019A3US-G

APPLICANTS

John T. Sorensen, Ladera Ranch, CA;
Michael Mittelstein, Laguna Niguel, CA;
Soheila Mirhashemi, Laguna Niguel, CA;

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

This application 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 **
06/23/2011

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /AMY R SHIPLEY/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	3	22	1

ADDRESS

STOUT, UXA, BUYAN & MULLINS 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		
655	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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13159356	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY SHIPLEY	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	03/22/2013								
	1	✓								
	2	✓								
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	4	✓								
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	21	✓								
	22	✓								

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	13/159,356 CONFIRMATION NO.: 1298
APPLICANT	:	JOHN T. SORENSEN, ET AL.
FILED	:	JUNE 13, 2011
TC/A.U.	:	3734
EXAMINER	:	AMY R. SHIPLEY
DOCKET NO.	:	NEOME-019A3US-G
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 NONFINAL OFFICE ACTION

Madam:

In response to the Office Action mailed March 26, 2013, please amend the above-identified application as set forth below.

Amendments to the Specification begin on page 2 of this paper.

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

Remarks/Arguments begin on page 8 of this paper.

Petitioner - New World Medical
Ex. 1019, p. 222 of 285

Amendments to the Specification:

- On page 1, please amend the title as follows:

~~TUBULAR CUTTER~~ DUAL BLADE DEVICE AND METHODS FOR LOWERING INTRAOCULAR PRESSURE ~~CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT~~

- Please replace Paragraph 0018 with the following amended paragraph:

[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 probe or cutting tube 14 that has a distal end 18 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.

- Please replace Paragraph 0022 with the following amended paragraph:

[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 19 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

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angular cut out 30 into apposition and weld 32, 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 17 in a more compact form than is possible by bending tubing 10 of a given diameter to said curve or angle 17 without kinking or damaging tube 10.

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Amendment to the Claims:

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

Listing of Claims:

1. A dual blade device useable for performing an *ab interno* surgical procedure wherein a ~~cutting a~~ strip of tissue of approximate width W is cut from the trabecular meshwork of the eye of a human subject to improve drainage of fluid from the eye's anterior chamber through Schlemm' Canal ~~a mass of tissue~~, said device comprising:

an elongate proximal handpeice sized to be grasped by the hand of a human operator;

an elongate probe extending from the handpeice, said elongate probe comprising 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) ~~cutting tube having a distal end and a lumen that opens through an opening in the distal end;~~ 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;

said elongate probe being constructed such that it is insertable through a small opening in the anterior chamber and advanceable across the anterior chamber, while the anterior chamber remains filled with fluid, to an operative position wherein the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork;

the device being maneuverable, when in said operative position, to cause the distal protruding tip to advance through a sector of Schlemm's Canal with the ~~cutting tube being advanceable through tissue such that the~~ first and second cutting edges concurrently cutting, from the trabecular meshwork, ~~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. (Cancelled)

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3. (Cancelled)

4. (Cancelled)

5. (Original) A device according to Claim 2 wherein the protruding tip is sufficiently blunt to be substantially a traumatic.

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Currently Amended) A device according to Claim 1 ~~10~~ wherein the distal protruding tip extends from the shaft at an angle of ~~bend is~~ approximately 90 degrees.

12. (Currently Amended) A device according to Claim 1 wherein there are a plurality of bends or curves formed in the elongate probe ~~cutting tube~~.

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13. (Currently Amended) 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 elongate probe ~~cutting tube~~.

14. (Currently Amended) A device according to Claim 1 ~~12~~ wherein the elongate probe has a lumen ~~there is a first bend of approximately 90 degrees and a second bend of approximately 90 degrees, formed in the tube~~.

15. (Currently Amended) A device according to Claim 14 [[1]] further comprising a source of negative pressure connected to the lumen of the elongate probe ~~cutting tube~~ so as to aspirate fluid or matter through the lumen of the elongate probe ~~tube~~.

16. (Currently Amended) A device according to Claim 14 [[1]] wherein the device further comprises a second lumen.

17. (Original) 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. (Original) 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. (Original) 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.

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20. (Cancelled)

21. (Cancelled)

22. (Cancelled)

23. (New) A device according to claim 1 further comprising a fluid infusion lumen connected to a source of fluid whereby fluid is delivered through the lumen under controlled pressure to keep the anterior chamber filled with fluid while the device is inserted in the anterior chamber.

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

forming 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.

25. (New) A method according to claim 24 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performace of the method.

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REMARKS/ARGUMENTS

By the foregoing amendment, amendments have been made to the specification for the purpose of clarification and to add call-outs for reference numerals 17, 18 and 32. Also, claims 1 and 11-16 have been amended, claims 2-4, 6-10, 20-22 21 have been cancelled and new dependent claims 23-25 have been added. No new matter has been added.

The amendments to the specification are believed to have overcome the objections to the drawings and specification stated in the office action.

Also, the cancellation of claims 20 and 21 has overcome the stated rejection under 35 U.S.C. 112.

Additionally, the amendments to the claims are believed to have clearly overcome the stated rejections under 35 U.S.C. 102 and 103 over Heisler et al. (United States Patent No. (6,419,684) alone or in combination with the cited secondary references Baxter et al. (United States Patent No. 6,428,539) and/or Anctil (United States Reissue Patent No. RE38,018).

As amended, independent claim 1 recites a dual blade device useable for performing an ab interno surgical procedure wherein a strip of tissue of approximate width W is cut from the trabecular meshwork of the eye of a human subject to improve drainage of fluid from the eye's anterior chamber through Schlemm' Canal. Claim 1 specifically requires the device to include 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. Moreover, claim 1 requires the elongate probe to comprise 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 separated by a distance D. Furthermore, claim 1 requires the elongate probe to be constructed so as to be insertable through a small opening in the anterior chamber and advanceable across the anterior chamber, while the anterior chamber remains filled with fluid, to an operative position wherein the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork. Moreover, claim 1 requires the device to be maneuverable, when in said operative

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position, to cause 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.

Applicant respectfully submits that neither Heisler et al. nor Baxter et al. nor Anctil, taken alone or in combination, describes or renders obvious the invention recited in the presently amended claims.

Conclusion

For the foregoing reasons, 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: September 26, 2013

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Electronic Patent Application Fee Transmittal

Application Number:	13159356
Filing Date:	13-Jun-2011
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-019A3US-G

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

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:				
Extension - 3 months with $0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**700**

Electronic Acknowledgement Receipt

EFS ID:	16972197
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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-019A3US-G
Receipt Date:	26-SEP-2013
Filing Date:	13-JUN-2011
Time Stamp:	21:15:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$700
RAM confirmation Number	7857
Deposit Account	
Authorized User	

File Listing:

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

1		NEOME-019A3US-G-Response1.pdf	396918 9e6844caad4285831cc37c029af10d9bb84eaa51	yes	9

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	3
Claims	4	7
Amendment/Req. Reconsideration-After Non-Final Reject	8	9

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30402 260944a764d78f772556b8c238060a9e83ca0bac	no	2

Warnings:

Information:

Total Files Size (in bytes):	427320

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.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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 13/159,356	Filing Date 06/13/2011	☐ 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 **09/26/2013**

	(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))	* 14	Minus	** 22	= 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
/NINA RATANAVONG/

This collection of information is required by 37 CFR 1.16. 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, 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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3US-G	1298

33197 7590 10/09/2013

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

EXAMINER	
SHIPLEY, AMY R	
ART UNIT	**PAPER NUMBER**
3734	
MAIL DATE	**DELIVERY MODE**
10/09/2013	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. 13/159,356	Applicant(s) SORENSEN ET AL.	
	Examiner AMY SHIPLEY	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 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *9/26/13*.

☐ 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) *1,5,11-19 and 23-25* is/are pending in the application.

5a) Of the above claim(s) *24 and 25* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,5,11-19 and 23* 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 *6/13/11* 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/08) 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.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5, 11-19 and 23, drawn to a cutter, classified in 606/167.

II. Claims 24-25, drawn to a method of using a cutting device to form an opening in the trabecular meshwork of a patient's eye, classified in 128/898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device can be used for a materially different method, in particular arthroscopic surgery, wherein a cutter is used to remove a strip of tissue.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

The device and method require separate searches thus presents a burdensome search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04.

Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Newly submitted claims 24 and 25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: see above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

6. Claim 1 is objected to because of the following informalities: “handpeice” is spelled incorrectly. Appropriate correction is required.

7. Claim 5 depends off a cancelled claim, should read –claim 1--.

Response to Amendment

This action is in response to the amendment filed 9/26/13. Claims 1, 11-16 are amended, claims 2-4, 6-10, 20-22 are cancelled, claims 23-25 are new, and claims 1, 5, 11-19, 23-25 are pending. Claims 24 and 25 are withdrawn, see above.

In light of the cancellation of claims 20-21, the 112 rejections are withdrawn. Likewise, drawings and specification objections are withdrawn.

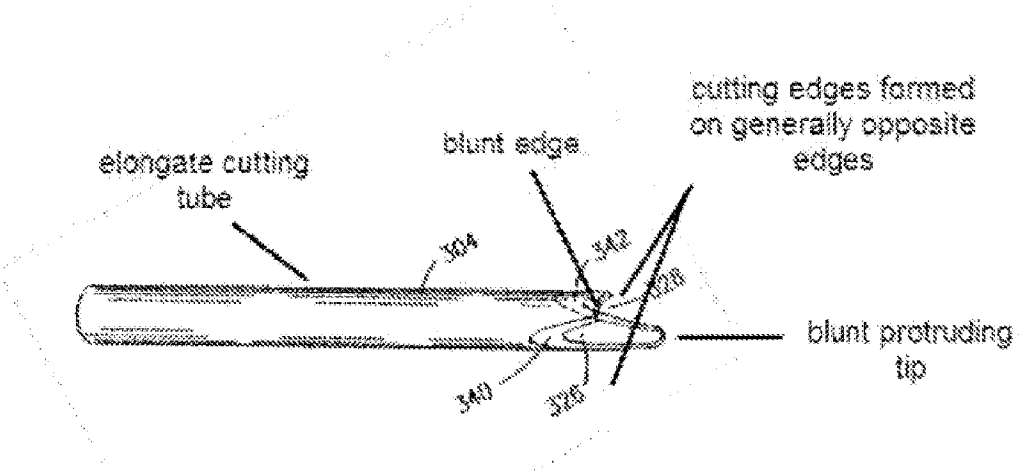
Claim Rejections - 35 USC § 103

8. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 5, 12-17, and 23 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Heisler USP 6,419,684 and in view of Anctil RE38,018.

Regarding claim 1, Heisler teaches a dual blade device **capable** of being used for performing an *ab interne* surgical procedure wherein a cutting a strip of tissue of approximate width W is cut from the trabecular meshwork of the eye of a human subject to improve drainage of fluid from the eye's anterior chamber through Schlemm's Canal, said device comprising:



an elongate proximal handpiece sized to be grasped by the hand of a human operator, see figure 8 where proximal end comprises a handpiece;

an elongate probe extending from the handpiece, said elongate probe comprising i) a shaft (304), ii) a distal protruding tip (distal end above) that extends from a distal end of the shaft and is **capable** of being 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 separated by a distance D, see figure above;

said elongate probe being constructed such that it is **capable** of being inserted through a small opening in the anterior chamber and advanceable across the anterior chamber, while the anterior chamber remains filled with fluid, to an operative position wherein the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork;

the device **capable** of being maneuvered, when in said operative position, to cause 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.

Regarding claim 1, Heisler fails to teach the probe extends at an angle of from 20 degrees to 90 degrees from the shaft. Anctil et al teaches a tissue cutting device with a bend in the cutting tube (see figure 1). It would have been obvious at the time of the invention to provide a bend in the cutting tube as taught by Anctil as to aid in reaching various portions of the body. Anctil teaches the bend is about 40 degrees relative to the longitudinal axis (column 5 lines 10-13).

Regarding claim 5, Heisler teaches a device according to claim 2 wherein the protruding tip is sufficiently blunt to be substantially a traumatic, see figure above.

Regarding claim 12, Heisler fails to disclose a device according to claim 1 above, wherein there are a plurality of bends or curves formed in the cutting tube. Anctil et al teaches a tissue cutting device with a plurality of bends in the cutting tube (see figure 26). It would have been obvious at the time of the invention to provide bends in the cutting tube as taught by Anctil as to aid in reaching various portions of the body.

Regarding claim 13, the combination of Heisler and Anctil teach a device according to claim 12 above, wherein there are a plurality of bends of approximately 20 degrees to approximately 90 degrees each formed in the cutting tube (claim 19 of Anctil).

Regarding claim 14, Heisler teaches a device according to claim 1 wherein the elongate probe has a lumen, see figure above.

Regarding claim 15, Heisler teaches a device according to Claim 14 further comprising a source of negative pressure connected to the lumen of the elongate probe so as to aspirate fluid or matter through the lumen of the elongate probe (column 1 lines 14-51).

Regarding claim 16, Heisler teaches a device according to Claim 14 wherein the device further comprises a second lumen (302) see figure 9 where first lumen is (304).

Regarding claim 17, Heisler discloses a device according to claim 16, wherein said lumens (inner lumen) is connected to a source of negative pressure such that fluid or matter may be aspirated therethrough (column 1 lines 14-51). Heisler fails to teach the other lumen being connected to a fluid source. Anctil teaches connecting a fluid source (column 8 lines 9-24). It would have been obvious at the time of the invention to provide a fluid source as taught by Anctil as to irrigate the site or clear blockages.

Regarding claim 23, Heisler discloses a device according to claim 1, wherein said lumens (inner lumen) is connected to a source of negative pressure such that fluid or matter may be aspirated therethrough (column 1 lines 14-51). Heisler fails to teach the other lumen being connected to a fluid source. Anctil teaches connecting a fluid source

(column 8 lines 9-24). It would have been obvious at the time of the invention to provide a fluid source as taught by Anctil as to irrigate the site or clear blockages. Wherein the combination of Heisler and Anctil teach fluid is delivered through the lumen, see column 8 lines 9-24 of Anctil, under controlled pressure to keep the anterior chamber (of the eye see claim 1) filled with fluid while the device is inserted in the anterior chamber (of the eye).

10. Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Heisler USP 6,419,684 and in view of Anctil RE38,018 as applied to claim 1 above and in further view of Garfinkel USP 6,382,974.

Regarding claims 11 and 14, the combination of Heisler and Anctil fail to teach using a bend angle of approximately 90 degrees. However, it would have been obvious to one skilled in the art at the time of the invention to modify the angle of Anctil from about 45 degrees to about 90 degrees as "facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading" as in particular, Anctil teaches the need of having at least one angle between the cutting portion and the shaft. Furthermore, a closely related tissue cutting device as taught by Garfinkel, teaches specifically the use of 90 degree angles (column 2 line 54-column 3 line 5). It would have been obvious to alter the angle of the combination of Anctil and Heisler to be 90 degrees as taught by Garfinkel, as Garfinkel teaches a 90 degree angle between distal and proximal portions enhances accessibility, ease of manipulation,

directional cutting, and efficiency (column 2 line 54-column 3 line 5).

11. Claims 18-19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Heisler USP 6,419,684 and in view of Anctil RE38,018 as applied to claim 1 above and in further view of Baxter USP 6,428,539.

Regarding claim 18, Heisler fails to disclose a device wherein at least one of the cutting edges is heated such that it will cauterize as it cuts. Baxter teaches a cutting device which electrically cauterizes as it cuts (column 4 line 64-column 5 line 8). It would have been obvious at the time of the invention to cauterize while cutting as taught by Baxter as to stop bleeding after performing the cutting procedure.

Regarding claim 19, Heisler fails to teach the use of electrodes in combination with the cutting tool. Baxter teaches the use of electrodes as to provide both a cutting and cauterization simultaneously. The electrodes are on the inner and outer blades thus in combination, they severe the tissue. The device is controlled via a handle mechanism thus dictating the desired size of tissue (column 9 line 60-column 10 line 3). Baxter teaches a cutting device which electrically cauterizes as it cuts (column 4 line 64-column 5 line 8). It would have been obvious at the time of the invention to cauterize while cutting as taught by Baxter as to stop bleeding after performing the cutting procedure.

Response to Arguments

12. Applicant's arguments filed 9/26/13 have been fully considered but they are not persuasive.

13. Applicant should submit an argument under the heading “Remarks” pointing out disagreements with the examiner’s contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

14. In response to applicant's amendments, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Shipley 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 Gary Jackson, at* (571) 272-4697**. 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 Shipley
Patent Examiner
/ARS/
AU 3734
10/2/13

/Katherine M Dowe/
Primary Examiner, Art Unit 3734

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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;	OR	ON	2013/03/21 17:52

			DERWENT; IBM_TDB			
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; 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
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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; 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;	OR	OFF	2013/10/01

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			18:39

EAST Search History (Interference)

<This search history is empty>

10/2/2013 11:36:54 AM
C:\Users\ashipley\Documents\EAST\Workspaces\13159356.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13159356	SORENSEN ET AL.
	Examiner	Art Unit
	AMY SHIPLEY	3734

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	167	3/22/13	/ARS/

SEARCH NOTES		
Search Notes	Date	Examiner
inventor search; family history div of USP 7,959,641	3/22/13	/ARS/
Julian Woo: 606/107, 166, 170, 184, 185; 600/566, 567. text limit keywords: blade, tooth, eye, cornea.	10/2/13	/ARS/
Darwin Erezo	10/2/13	/ARS/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13159356	SORENSEN ET AL.
	Examiner	**Art Unit**
	AMY SHIPLEY	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	03/22/2013	10/02/2013							
	1	✓	✓							
	2	✓	-							
	3	✓	-							
	4	✓	-							
	5	✓	✓							
	6	✓	-							
	7	✓	-							
	8	✓	-							
	9	✓	-							
	10	✓	-							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	✓	✓							
	19	✓	✓							
	20	✓	-							
	21	✓	-							
	22	✓	-							
	23		✓							
	24		N							
	25		N							

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	13/159,356 CONFIRMATION NO.: 1298
APPLICANT	:	JOHN T. SORENSEN, ET AL.
FILED	:	JUNE 13, 2011
TC/A.U.	:	3734
EXAMINER	:	AMY R. SHIPLEY
DOCKET NO.	:	NEOME-019A3US-G
CUSTOMER NO.	:	33197
TITLE	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

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

AMENDMENT ACCOMPANYING NOTICE OF APPEAL

Madam:

In response to the final Office Action mailed October 9, 2013, please amend the above-identified application as set forth below.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

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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) A dual blade device useable for performing an *ab interno* surgical procedure wherein a strip of tissue of approximate width W is cut from the trabecular meshwork of the eye of a human subject to improve drainage of fluid from the eye's anterior chamber through Schlemm's Canal, said device comprising:

an elongate proximal hand piece ~~handpeice~~ sized to be grasped by the hand of a human operator;

an elongate probe extending from the hand piece ~~handpeice~~, said elongate probe comprising 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 separated by a distance D;

said elongate probe being constructed such that it is insertable through a small opening in the anterior chamber and advanceable across the anterior chamber, while the anterior chamber remains filled with fluid, to an operative position wherein the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork;

the device being maneuverable, when in said operative position, to cause 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. (Cancelled)

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3. (Cancelled)

4. (Cancelled)

5. (Currently Amended) A device according to Claim 1 **[[2]]** wherein the protruding tip is sufficiently blunt to be substantially a traumatic.

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Previously Presented) A device according to Claim 1 wherein the distal protruding tip extends from the shaft at an angle of approximately 90 degrees.

12. (Previously Presented) A device according to Claim 1 wherein there are a plurality of bends or curves formed in the elongate probe.

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13. (Previously Presented) 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 elongate probe.

14. (Previously Presented) A device according to Claim 1 wherein the elongate probe has a lumen.

15. (Previously Presented) A device according to Claim 14 further comprising a source of negative pressure connected to the lumen of the elongate probe so as to aspirate fluid or matter through the lumen of the elongate probe.

16. (Previously Presented) A device according to Claim 14 wherein the device further comprises a second lumen.

17. (Original) 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. (Original) 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. (Original) 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.

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20. (Cancelled)

21. (Cancelled)

22. (Cancelled)

23. (Previously Presented) A device according to claim 1 further comprising a fluid infusion lumen connected to a source of fluid whereby fluid is delivered through the lumen under controlled pressure to keep the anterior chamber filled with fluid while the device is inserted in the anterior chamber.

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

forming 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.

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25. (Withdrawn) A method according to claim 24 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performace of the method.

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REMARKS/ARGUMENTS

By the foregoing amendments, minor typographical errors have been corrected in claims 1 and 5. No new matter has been added. These corrections overcome the claim objections raised in the final office action. Entry of this amendment is appropriate in that it eliminates minor issues and places the claims in better condition for appeal. A notice of appeal is filed herewith.

Applicant respectfully traverses the stated rejections under 35 U.S.C. §103. Contrary to what is stated in Paragraph 9 of the Office Action, there exists *no* basis to conclude that the straight tubular device described by Heisler, et al. would be capable of cutting a strip of tissue of a width W from the trabecular meshwork of the eye of a human subject by an *ab interno* approach. Furthermore, except for impermissible hindsight reconstruction of Applicant's invention, there would be no reason for anyone to modify the Heisler, et al. device to include an angle of 20 to 90 degrees as stated in the office action. These facts are particularly apparent when one considers how a

In the human eye, fluid known as aqueous humor accumulates in a cavity known as the anterior chamber. A circular canal, known as Schlemm's canal, extends around the periphery of the anterior chamber. The outer or peripheral wall of Schlemm's canal is formed by the junction of scleral and corneal tissue (i.e., the scleral-corneal junction) covered by delicate endothelial tissue. The inner "wall" of Schlemm's canal is a normally-porous structure formed of trabecular meshwork tissue. Typically, excess aqueous humor seeps from the anterior chamber, through the porous trabecular meshwork tissue, and into Schlemm's canal. After entering Schlemm's canal, that excess fluid then drains outwardly through small collector channels which open through the scleral wall of Schlemm's canal and is ultimately carried away through veins that drain the eyeball.

In at least some cases of open angle glaucoma, the porosity of the trabecular meshwork tissue is inadequate or clogged thereby impeding the normal seepage of fluid from the anterior chamber into Schlemm's canal. This impeded fluid drainage results in elevated intraocular pressure (IOP) which, if uncorrected, can lead to optic nerve damage and vision loss.

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The prior art has included stents or shunts that remain implanted in the eye to create an open conduit through the trabecular meshwork and into Schlemm's canal. Also, the prior art has included various devices for ablating or removing segments of trabecular meshwork tissue to improve drainage of fluid from the anterior chamber into Schlemm's canal without the need for placement of an implant.

The devices useable for ablating or removing segments of trabecular meshwork tissue have included some that are useable by an *ab interno* (from the inside) approach and others that are useable by an *ab externo* (from the outside) approach. The *ab externo* approach involves making an incision from the exterior of the eye to access the interior of Schlemm's canal. A segment of trabecular meshwork bordering the exposed portion of Schlemm's canal may then be removed through that external incision. The *ab interno* approach involves inserting operative instrument(s) into the anterior chamber of the eye and then using those instrument(s) to ablate or remove trabecular meshwork tissue from the anterior chamber, without requiring any external incision into Schlemm's canal.

Figure 10 of Heisler et al. is reproduced below:

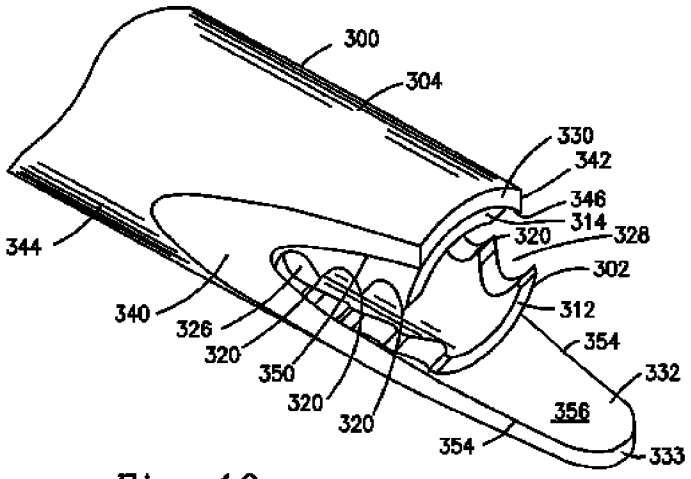

Fig. 10

Petitioner - New World Medical
Ex. 1019, p. 264 of 285

The Heisler et al. device is a straight tube with a bevel-cut distal end and a rotating cutting element positioned within the tube. Because it is a straight tube, the Heisler et al. device can only be used to remove a "strip" of tissue if it were advanced longitudinally (i.e., head on) into that tissue. The Office Action provides no suggestion or explanation as to how the Heisler et al. device could possible be advanced longitudinally along the trabecular meshwork tissue to remove a "strip" as required by Applicant's claims by an *ab interno* approach. While it may (arguably at least) be possible to use the Heisler et al. device to cut a strip of trabecular meshwork tissue via an *ab externo* approach, it does not appear feasible to do so by an *ab interno* approach for a number of reasons, including the fact that the Heisler et al. device lacks the claimed 20 to 90 degree angle.

Applicant requests a telephonic interview in advance of the deadline for filing the Appeal Brief to discuss possible insertion of claim term definitions into the prosecution history as a means for facilitating allowance of the present claims. It should not be necessary to expend PTAB resources in this case given that the claimed subject matter is clearly distinguishable over the cited prior art references when the claim language is properly construed.

Fees due will be paid through EFS at the time of filing. The Commissioner is hereby authorized to charge any underpayment, or to credit any overpayment, to Deposit Account No. 50-0878.

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

Date: April 9, 2014

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

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Telephone: (949) 450-1750
Facsimile: (949) 450-1764
e mail: rbuyan@patlawyers.com

Petitioner - New World Medical
Ex. 1019, p. 265 of 285

Electronic Patent Application Fee Transmittal

Application Number:	13159356
Filing Date:	13-Jun-2011
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-019A3US-G

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of Appeal	2401	1	400	400
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	700	700
Miscellaneous:				
			Total in USD ($)	**1100**

Electronic Acknowledgement Receipt

EFS ID:	18717571
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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-019A3US-G
Receipt Date:	09-APR-2014
Filing Date:	13-JUN-2011
Time Stamp:	15:39:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1100
RAM confirmation Number	2037
Deposit Account	
Authorized User	

File Listing:

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

1	Notice of Appeal Filed	NEOME-019A3US-G-sb0031.pdf	210404 12db0e0b3213487587a392162cbce148e7812751	no	2
Warnings:					
Information:					
2		NEOME-019A3USG-Response2-Filed.pdf	71189 47cbf1c4ced958ae22ea32339c62099db89f323f	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	9

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32224 6ea9a665ad2733180b2eab472634d68a02bdb9f6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	313817		

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/31 (02-14)
Approved for use through 07/31/2016. OMB 0651-0031
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.

NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): NEOME-019A3-G

I hereby certify that this correspondence is being facsimile transmitted to the USPTO EFS-Web transmitted to the USPTO, or or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

In re Application of: John T. Sorensen

Application Number	Filed
13/159,356	June 13, 2011

For: DUAL BLADE DEVICE AND METHODS FOR LOWERING INTRAOCULAR PRESSURE (As Amended)

Art Unit	Examiner
3734	Amy R. Shipley

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 800.00

☑ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 400.00

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ .

☑ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record. Registration number 32460.

☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

/Robert D. Buyan/
Signature

Robert D. Buyan
Typed or printed name

949-450-1750
Telephone number

April 9, 2014
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 41.31. 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, 1.14 and 41.6. 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, 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.

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/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 13/159,356	Filing Date 06/13/2011	☐ 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 **04/09/2014**

	(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))	* 14	Minus	** 22	= 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
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. 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, 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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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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3US-G	1298

33197 7590 04/16/2014

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

EXAMINER	
SHIPLEY, AMY R	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
04/16/2014	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.

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

Applicant argues Heisler would not be "capable of cutting a strip of tissue of a width W from the trabecular meshwork of the eye of a human subject by an *ab interno* approach"

In the previous office action, Heisler is modified by Anctil wherein Anctil teaches a cutting blade with an angled bend in the tube of about 40 degrees. Thus the combination teaches an angle between 20 and 90 degrees. In response to applicant's arguments against the references individually, or in this case only the primary reference of Heisler, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has failed to argue against the references in combination which anticipate the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Shipley 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 Shipley
Patent Examiner
/ARS/
AU 3734
4/11/14

/DARWIN EREZO/
Supervisory Patent Examiner, Art Unit 3734

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 13/159,356	**Applicant(s)** SORENSEN ET AL.	
	Examiner AMY SHIPLEY	**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 --

THE REPLY FILED 09 April 2014 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *09 April 2014*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☐ will not be entered, or (b) ☒ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1,5,11-19 and 23.
    Claim(s) withdrawn from consideration: 24-25.

/DARWIN EREZO/ Supervisory Patent Examiner, Art Unit 3734	/A. S./ Examiner, Art Unit 3734

OK TO ENTER: /A.S./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.	:	13/159,356 CONFIRMATION NO.: 1298
APPLICANT	:	JOHN T. SORENSEN, ET AL.
FILED	:	JUNE 13, 2011
TC/A.U.	:	3734
EXAMINER	:	AMY R. SHIPLEY
DOCKET NO.	:	NEOME-019A3US-G
CUSTOMER NO.	:	33197
TITLE	:	TUBULAR CUTTER DEVICE AND METHODS FOR CUTTING AND REMOVING STRIPS OF TISSUE FROM THE BODY OF A PATIENT

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

AMENDMENT ACCOMPANYING NOTICE OF APPEAL

Madam:

In response to the final Office Action mailed October 9, 2013, please amend the above-identified application as set forth below.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Petitioner - New World Medical
Ex. 1019, p. 277 of 285

PTO/SB/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
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.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): NEOME-019A3USG

Application Number: 13/159,356

Filed: June 13, 2011

For: DUAL BLADE DEVICE AND METHODS FOR LOWERING INTRAOCCULAR PRESSURE

Art Unit: 3734

Examiner: Amy B. Shipley

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700.00
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 500878.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration number 32460.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Robert D. Buyan/ — Signature

September 9, 2014 — Date

Robert D. Buyan — Typed or printed name

(949)450-1750 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 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.

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:	13159356
Filing Date:	13-Jun-2011
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-019A3US-G

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

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:				
Extension - 3 months with $0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**700**

Electronic Acknowledgement Receipt

EFS ID:	20092341
Application Number:	13159356
International Application Number:	
Confirmation Number:	1298
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-019A3US-G
Receipt Date:	09-SEP-2014
Filing Date:	13-JUN-2011
Time Stamp:	19:03:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$700
RAM confirmation Number	3139
Deposit Account	
Authorized User	

File Listing:

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

1	Extension of Time	NEOME-019USG-sb0022-FILED.pdf	187225 84a6c936a6423d2203fc54f8634d4f8955edf3ee	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30403 a86ac0a36d9e0aa564c16fda43a2205a19a9dd2c	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	217628	

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/159,356	06/13/2011	John T. Sorensen	NEOME-019A3US-G	1298

33197 7590 12/16/2014

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

EXAMINER	
SHIPLEY, AMY R	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
12/16/2014	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.

Notice of Abandonment	Application No.	Applicant(s)
	13/159,356	SORENSEN ET AL.
	Examiner	Art Unit
	AMY SHIPLEY	3734

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

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *09 October 2013*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record or other party authorized under 37 CFR 1.33(b). See 37 CFR 1.138(b).

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☒ The reason(s) below:

A notice of Appeal was filed on 4/9/13; no appeal brief was filed confirmed by Nancy Sundene on 12/3/14.

/A. S./ Examiner, Art Unit 3734	/A. S./ Examiner, Art Unit 3734

Petitions to revive under 37 CFR 1.137, or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.