AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	12/9/2016	for the District of Delaware

PLAINTIFF	DEFENDANT
BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC NEUROMODULATION CORP.	NEVRO CORP.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 6,895,280 B2	5/17/2005	Boston Scientific Neuromodulation Corp.
2	US 7,428,438 B2	9/23/2008	Boston Scientific Neuromodulation Corp.
3	US 7,437,193 B2	10/14/2008	Boston Scientific Neuromodulation Corp.
4	US 7,587,241 B2	9/8/2009	Boston Scientific Neuromodulation Corp.
5	US 7,891,085 B1	2/22/2011	Boston Scientific Neuromodulation Corp.

Continued on attached sheet

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

Nevro Corp.
Ex. 1002
U.S. Patent No. 7,891,085

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Boston Scientific Corp. and
Boston Scientific Neuromodulation Corp.,

Plaintiffs,

v.

Nevro Corp.,

Defendant.

Civil Action No. _____

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK (continued)

Patent or Trademark No.	Date of Patent or Trademark	Holder of Patent or Trademark
6. US 8,019,439 B2	9/13/2011	Boston Scientific Neuromodulation Corp.
7. US 8,644,933 B2	2/4/2014	Boston Scientific Neuromodulation Corp.
8. US 8,646,172 B2	2/11/2014	Boston Scientific Neuromodulation Corp.
9. US 8,650,747 B2	2/18/2014	Boston Scientific Neuromodulation Corp.
10. US 9,370,664 B2	6/21/2016	Boston Scientific Neuromodulation Corp.

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	12/9/2016	for the District of Delaware

PLAINTIFF	DEFENDANT
BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC NEUROMODULATION CORP.	NEVRO CORP.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 6,895,280 B2	5/17/2005	Boston Scientific Neuromodulation Corp.
2	US 7,428,438 B2	9/23/2008	Boston Scientific Neuromodulation Corp.
3	US 7,437,193 B2	10/14/2008	Boston Scientific Neuromodulation Corp.
4	US 7,587,241 B2	9/8/2009	Boston Scientific Neuromodulation Corp.
5	US 7,891,085 B1	2/22/2011	Boston Scientific Neuromodulation Corp.

Continued on attached sheet

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Boston Scientific Corp. and
Boston Scientific Neuromodulation Corp.,

Plaintiffs,

v.

Nevro Corp.,

Defendant.

Civil Action No. _____

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK (continued)

Patent or Trademark No.	Date of Patent or Trademark	Holder of Patent or Trademark
6. US 8,019,439 B2	9/13/2011	Boston Scientific Neuromodulation Corp.
7. US 8,644,933 B2	2/4/2014	Boston Scientific Neuromodulation Corp.
8. US 8,646,172 B2	2/11/2014	Boston Scientific Neuromodulation Corp.
9. US 8,650,747 B2	2/18/2014	Boston Scientific Neuromodulation Corp.
10. US 9,370,664 B2	6/21/2016	Boston Scientific Neuromodulation Corp.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
11/329,907	7891085	3729	9200

OC000000073238445

Correspondence Address/Fee Address Change

The following fields have been set to Customer Number 81995 on 02/04/2015

- **Maintenance Fee Address**

The address of record for Customer Number 81995 is:

81995
Boston Scientific Corporation
4100 Hamline Avenue North
MS: 3-394
St. Paul, MN 55112-5798

PART 1 - ATTORNEY/APPLICANT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	02/22/2011	7891085	1362009-2093	6971

50638 7590 02/02/2011

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 639 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Janusz A. Kuzma, Parker, CO;
Anne M. Pianca, Valencia, CA;

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Boston Scientific Neuromodulation Corporation
c/o Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being faxsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
Via EFS (Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

TITLE OF INVENTION:

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$0	$1510	02/15/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Frommer Lawrence & Haug LLP
2 Bruce E. Black
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE	(B) RESIDENCE: (CITY and STATE OR COUNTRY)
Boston Scientific Neuromodulation Corporation	Valencia, California

Reel/Frame: 021845 / 0966

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:

☑ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☑ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 500320 .

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27 ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /B. E. Black/ Date January 19, 2011

Typed or printed name Bruce E. Black Registration No. 41,622

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11329907
Filing Date:	11-Jan-2006
Title of Invention:	ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Filer:	Bruce Black/Terri Downey
Attorney Docket Number:	1362009-2093

Filed as Large 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:				
Utility Appl issue fee	1501	1	1510	1510
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**1510**

Electronic Acknowledgement Receipt	
EFS ID:	9264258
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Terri Downey
Filer Authorized By:	Bruce Black
Attorney Docket Number:	1362009-2093
Receipt Date:	19-JAN-2011
Filing Date:	11-JAN-2006
Time Stamp:	17:34:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1510
RAM confirmation Number	4320
Deposit Account	500320
Authorized User	FROMMER LAWRENCE & HAUG LLP
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2093_issue_fee.pdf	1108517 19cd1d879fc466be4554e9bf30a808c782783ac5	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30273 9ed0494247d815b0dd94b5f4d0e0e91aa56f3e50	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1138790		

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.

Docket No.: 1362009-2093
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 Confirmation No.: 6971

Filed: January 11, 2006 Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Examiner: D. P. Angwin

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

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

Dear Sir:

In response to the Notice to File Corrected Application Papers -- Notice of Allowance Mailed, dated November 24, 2010, Applicants respectfully submit replacement drawings (5 figures, 2 sheets).

The Commissioner is authorized to charge any deficiency of up to $300.00 or credit any excess in this fee to Deposit Account No. 50-0320.

Dated: September 1, 2010

Respectfully submitted,

By _____

Bruce E. Black
Registration No.: 41,622
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(206) 336-5668
(212) 588-0500 (Fax)
Attorneys/Agents For Applicant

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 11329907
Applicant : Kuzma
Filing Date : 01/11/2006
Date Mailed : 11/24/2010

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 2 month(s) from the mail date of this Notice within which to respond.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED. **This period for reply is NOT extendable under 37 CFR 1.136(a).**

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee,Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Anthony McPhail/
Publishing Division
Office of Data Management
(571) 272-4200

Application No. 11329907 Drawings filed 01/11/2006

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [X] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s) 5a, 5b, 5c, 6a, 6b
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] The drawing is continued onto a second page (or more) without proper labeling under 37 CFR 1.84(u)(1). FIG(s)
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iv).
- [ ] OTHER:
- [ ] COMMENTS:

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.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

50638 7590 11/24/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	**PAPER NUMBER**
3729	

MAIL DATE	DELIVERY MODE
11/24/2010	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.

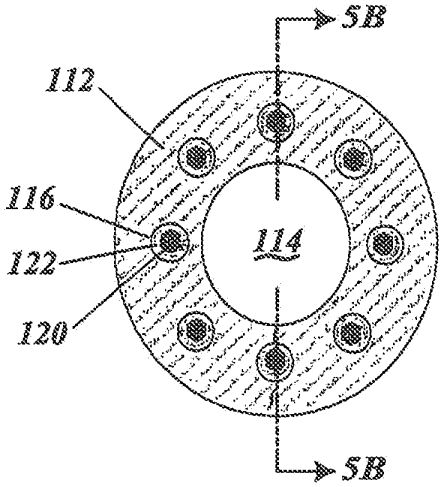

FIG.5A

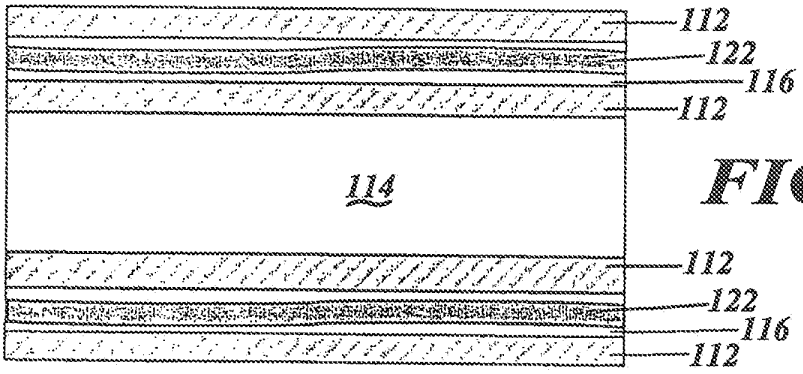

FIG.5B

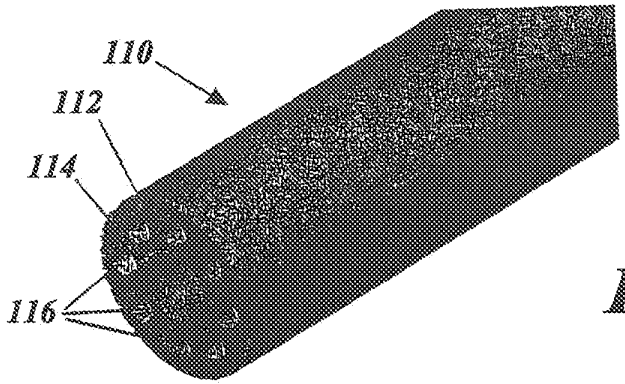

FIG.5C

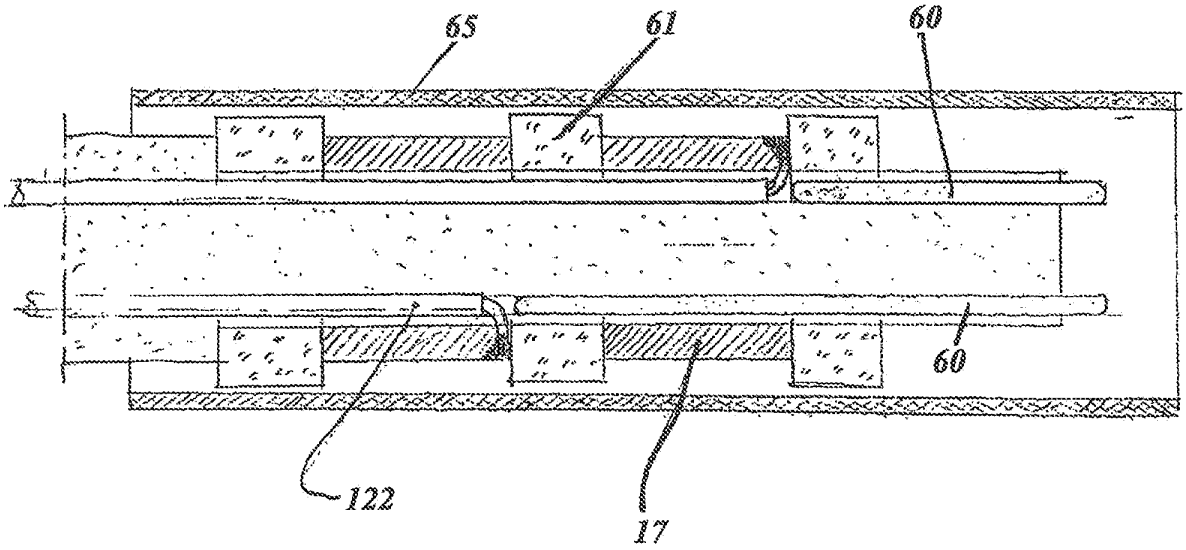

FIG.6A

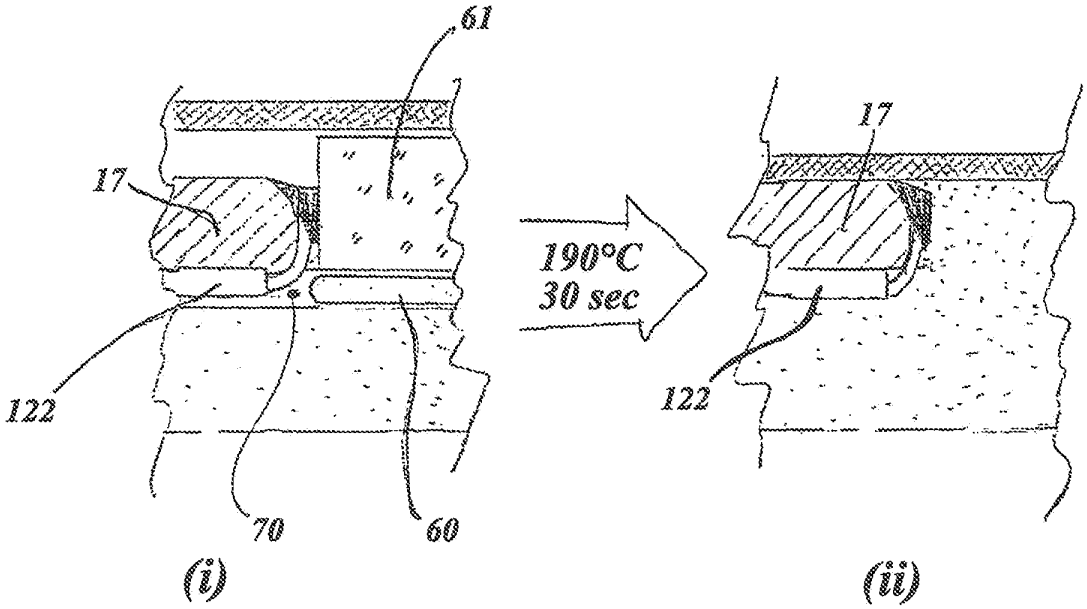

FIG.6B

Electronic Acknowledgement Receipt

EFS ID:	9191903
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Terri Downey
Filer Authorized By:	Bruce Black
Attorney Docket Number:	1362009-2093
Receipt Date:	07-JAN-2011
Filing Date:	11-JAN-2006
Time Stamp:	18:21:33
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		2093_response.pdf	2680888 2ead5720eaf4f2b85906448cc0191f7aaa86ee97	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	4
	Drawings-only black and white line drawings	5	6
Warnings:			
Information:			
	Total Files Size (in bytes):	2680888	

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.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

50638 7590 11/24/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	**PAPER NUMBER**
3729	

MAIL DATE	DELIVERY MODE
11/24/2010	PAPER

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 11329907
Applicant : Kuzma
Filing Date : 01/11/2006
Date Mailed : 11/24/2010

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 2 month(s) from the mail date of this Notice within which to respond.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED. **This period for reply is NOT extendable under 37 CFR 1.136(a).**

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee,Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Anthony McPhail/
Publishing Division
Office of Data Management
(571) 272-4200

Application No. 11329907 **Drawings filed 01/11/2006**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [X] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s) 5a, 5b, 5c, 6a, 6b
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [ ] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s)
- [ ] The drawing is continued onto a second page (or more) without proper labeling under 37 CFR 1.84(u)(1). FIG(s)
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iv).
- [ ] OTHER:
- [ ] COMMENTS:

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

50638 7590 11/15/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

DATE MAILED: 11/15/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

TITLE OF INVENTION: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$0	$0	$1510	02/15/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

50638 7590 11/15/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

TITLE OF INVENTION: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$0	$0	$1510	02/15/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
ANGWIN, DAVID PATRICK	3729	029-825000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	1362009-2093	6971

50638 7590 11/15/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

DATE MAILED: 11/15/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 557 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 557 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9/1/10*.

2. ☒ The allowed claim(s) is/are *11-21 and 24-31*.

3. ☐ 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 the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

David P. Angwin
Examiner
Art Unit: 3729

DETAILED ACTION

Election/Restrictions

Claims 11-15, 24-26, and 30 are directed to an allowable process. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 16-21, 27-29, and 31, withdrawn from consideration as a result of a restriction requirement dated 12/10/09, **are hereby rejoined and fully examined for patentability under 37 CFR 1.104**.

Because the claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 12/10/09 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 11-21 and 24-31 are now allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant, can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA

November 5, 2010

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008	03/28/2009	06/09/2009	11/17/2009	03/26/2010	07/18/2010	11/03/2010	
	1	÷	N	-	-	-	-	-	-	
	2	÷	N	-	-	-	-	-	-	
	3	÷	N	-	-	-	-	-	-	
	4	÷	N	-	-	-	-	-	-	
	5	÷	N	-	-	-	-	-	-	
	6	÷	N	-	-	-	-	-	-	
	7	÷	N	-	-	-	-	-	-	
	8	÷	N	-	-	-	-	-	-	
	9	÷	N	-	-	-	-	-	-	
	10	÷	N	-	-	-	-	-	-	
1	11	÷	✓	✓	✓	÷	✓	=	=	
2	12	÷	✓	✓	✓	÷	✓	=	=	
3	13	÷	✓	✓	✓	÷	✓	=	=	
4	14	÷	✓	✓	✓	÷	✓	=	=	
5	15	÷	✓	✓	✓	÷	✓	=	=	
19	16	÷	✓	✓	✓	÷	N	N	=	
6	17	÷	✓	✓	✓	÷	N	N	=	
7	18	÷	✓	✓	✓	÷	N	N	=	
8	19	÷	✓	✓	✓	÷	N	N	=	
9	20	÷	✓	✓	✓	÷	N	N	=	
10	21	÷	✓	✓	✓	÷	N	N	=	
	22	÷	N	N	N	N	N	N	-	
	23	÷	N	N	N	N	N	N	-	
11	24			✓	✓	÷	✓	=	=	
12	25			✓	✓	÷	✓	=	=	
13	26			✓	✓	÷	✓	=	=	
14	27			✓	✓	÷	N	N	=	
15	28			✓	✓	÷	N	N	=	
16	29				✓	÷	N	N	=	
17	30				✓	÷	✓	=	=	
18	31					÷	N	N	=	

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11329907	KUZMA ET AL.
Examiner	**Art Unit**
DAVID P ANGWIN	3729

ORIGINAL		INTERNATIONAL CLASSIFICATION															
CLASS	SUBCLASS	CLAIMED										NON-CLAIMED					
29	825	H	0	1	R	43 / 00 (2006.01.01)											
CROSS REFERENCE(S)		A	6	1	N	1 / 00 (2006.01.01)											
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																
607	116																

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	6	17												
	2	7	18												
	3	8	19												
	4	9	20												
	5	10	21												
	6		22												
	7		23												
	8	11	24												
	9	12	25												
	10	13	26												
1	11	14	27												
2	12	15	28												
3	13	16	29												
4	14	17	30												
5	15	18	31												
19	16														

/DAVID P ANGWIN/ Examiner.Art Unit 3729 (Assistant Examiner)	(Date)	**Total Claims Allowed:** 19
/A. Dexter Tugbang/ Primary Examiner.Art Unit 3729 (Primary Examiner)	11/05/2010 (Date)	O.G. Print Claim(s) 1(final)
		O.G. Print Figure 6B

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	Art Unit
	DAVID P ANGWIN	3729

SEARCHED			
Class	Subclass	Date	Examiner
29	825	11/12/08	DPA
607	115-122	9/29/10	DPA

SEARCH NOTES		
Search Notes	Date	Examiner
obtained search from Primary Examiner Carl Arbes (Class 29)	7/20/10	DPA
updated search	11/3/10	DPA

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
all listed above	all listed above	dates listed above	DPA

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

BIB DATA SHEET

CONFIRMATION NO. 6971

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/329,907	01/11/2006	257	3729	1362009-2093

APPLICANTS

Janusz A. Kuzma, Parker, CO;
Anne M. Pianca, Valencia, CA;

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

This appln claims benefit of 60/643,093 01/11/2005

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

02/16/2006

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No		CO	5	23	4
Verified and Acknowledged	/DAVID PATRICK ANGWIN/ Examiner's Signature	Initials				

ADDRESS

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151
UNITED STATES

TITLE

Electrode array assembly and method of making same

FILING FEE RECEIVED		
1350	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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	180	(607/115.ccls. or 607/116.ccls. or 607/117.ccls. or 607/118.ccls. or 607/119.ccls. or 607/120.ccls. or 607/121.ccls. or 607/122.ccls.) and (lumens with inside)	USPAT; USOCR	AND	ON	2010/11/03 05:10
L3	1	(607/115.ccls. or 607/116.ccls. or 607/117.ccls. or 607/118.ccls. or 607/119.ccls. or 607/120.ccls. or 607/121.ccls. or 607/122.ccls.) and (lumens with reflow $3)	USPAT; USOCR	AND	ON	2010/11/03 05:23
L4	158	607/118.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:36
L5	17	(607/115.ccls. or 607/116.ccls. or 607/117.ccls. or 607/118.ccls. or 607/119.ccls. or 607/120.ccls. or 607/121.ccls. or 607/122.ccls.) and reflow$3	USPAT; USOCR	AND	ON	2010/11/03 05:39
L6	352	607/119.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:43
L7	145	607/120.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:47
L8	65	607/121.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:53
L9	1282	607/122.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:57

S1	6	("3769984" OR "5555618" OR "6055456" OR "6205361" OR "6216045" OR "6249708").pn.	US-PGPUB; USPAT; USOCR	AND	ON	2008/11/11 17:57
S2	1806	29/825.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2008/11/12 19:12
S3	151	catheter.ti. (shrink adj wrap)	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 17:10
S4	3049	catheter.ti. percutaneous	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 20:15
S5	1165	catheter.ti. percutaneous same distal	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 20:15
S6	0	catheter.ti. percutaneous same distal same (conductive adj contacts)	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 20:16
S7	64	catheter.ti. percutaneous same distal same contacts	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 20:16
S8	1	"6205361".pn.	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/28 21:51
S9	82	catheter.ti. ((shrink adj tubing) or (shrink adj wrap)) with cover$3	US-PGPUB; USPAT; USOCR	AND	ON	2009/03/29 20:29
S10	86	"29"/$6.ccls. (catheter).ti. (heat $3 or melt$3)	US-PGPUB; USPAT; USOCR	AND	ON	2010/03/26 10:54
S11	40	("6216045").URPN.	USPAT	AND	ON	2010/07/19 22:57
S12	644	607/115.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2010/09/29 15:01
S13	644	607/115.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2010/09/29 15:01

S14	1574	607/116.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2010/09/29 15:25
S15	331	607/117.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2010/11/02 22:51
S16	29	607/117.ccls. and spacer	US-PGPUB; USPAT; USOCR	AND	ON	2010/11/02 22:55
S17	296	(607/115.ccls. or 607/116.ccls. or 607/117.ccls. or 607/118.ccls. or 607/119.ccls. or 607/120.ccls. or 607/121.ccls. or 607/122.ccls.) and (lumens with inside)	US-PGPUB; USPAT; USOCR	AND	ON	2010/11/03 03:49

11/3/2010 5:59:30 AM
C:\Documents and Settings\dangwin\My Documents\Critical Data\EAST\Workspaces\11329907.wsp

Docket No.: 1362009-2093
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D. P. Angwin

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

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

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated July 21, 2010, please amend the above-identified U.S. patent application as follows:

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

Amendments to the Abstract begin on page 5 of this paper.

Remarks/Arguments begin on page 6 of this paper.

REMARKS

This amendment is in response to the Office Action mailed March 31, 2010. Claims 22 and 23 have been canceled without prejudice as requested in the Office Action. Claims 11-21 and 24-31 are presently pending.

The Applicants thank the Examiner for indicating that claims 11-15, 24-26 and 30 are allowable and that claims 16-21, 27-29, and 31 are expected to be rejoined and allowed.

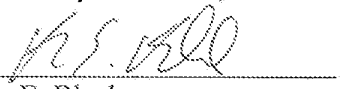
Abstract

The Office Action objected to the Abstract because it was allegedly not directed to claim 11. To facilitate prosecution, the Applicants have amended the Abstract to more closely track claim 11. No new matter has been added. The Applicants respectfully request withdrawal of this objection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner to contact the Applicants' representative, Bruce Black, by telephone to discuss the matter.

Dated: September 1, 2010

Respectfully submitted,

By 

Bruce E. Black
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745 Fifth Avenue
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(212) 588-0500 (Fax)
Attorneys/Agents For Applicant

Electronic Acknowledgement Receipt

EFS ID:	8335697
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Terri Downey
Filer Authorized By:	Bruce Black
Attorney Docket Number:	20334/0209380-US0
Receipt Date:	01-SEP-2010
Filing Date:	11-JAN-2006
Time Stamp:	13:56:59
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		2093AMD.pdf	2720227 74998e9668f7876a946eee1f3e2cabfd537524a4	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	4
	Abstract	5	5
	Applicant Arguments/Remarks Made in an Amendment	6	6
Warnings:			
Information:			
	Total Files Size (in bytes):	2720227	

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 (07-06)
Approved for use through 1/31/2007. 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	Filing Date	☐ To be Mailed
11/329,907	01/11/2006	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	09/01/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 19	Minus	** 23	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ 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	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/TINA J. BARDEN/

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.

AMENDMENTS TO THE CLAIMS

1-10. (Cancelled)

11. (Previously Presented) A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:

providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;

disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;

connecting [[a]] at least one of the plurality of conductor wires to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts, wherein portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers;

inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires; and

reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

12. (Original) The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. (Original) The method of claim 12, wherein the monofilament is a thermoplastic material.

14. (Original) The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. (Original) The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. (Withdrawn) The method of claim 31, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. (Withdrawn) The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. (Withdrawn) The method of claim 11, wherein conductive contacts are in the form of rings.

19. (Withdrawn) The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. (Withdrawn) The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. (Withdrawn) The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22-23. (Canceled)

24. (Previously Presented) The method of claim 11, wherein the monofilament is a different material than the spacers.

25. (Previously Presented) The method of claim 11, wherein the monofilament is the same material as the spacers.

26. (Previously Presented) The method of claim 15, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

27. (Withdrawn) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the proximal end of the stimulation lead.

28. (Withdrawn) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the distal end of the stimulation lead.

29. (Withdrawn) The method of claim 11, wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the conductor lumens are defined within the substantially cylindrical body.

30. (Previously Presented) The method of claim 11, wherein the monofilament is disposed in an orientation parallel to the conductor wires.

31. (Withdrawn) The method of claim 11, further comprising placing a heat shrink tubing around the spacers, conductive contacts, and monofilament and removing the heat shrink tubing after reflowing at least one of the spacers or monofilament.

AMENDMENTS TO THE ABSTRACT

Please amend the Abstract as follows:

[0053] A lead assembly and a method of making a lead are provided. The method of making a multi-contact lead assembly comprises providing conductive contacts located at an end of a lead body, disposing conductive wires in conductor lumens formed in the lead body, and connecting the conductive wires to the conductive contacts. The method further includes placing spacers between pairs of conductive contacts and inserting ~~placing~~ monofilament ~~placed~~ in ~~the void spaces~~ at least a portion of at least one of the conductor lumens not occupied by the ~~plurality of~~ conductor wires ~~and, in one embodiment, thermally fusing the monofilament to the like material spacer by applying heat just below the melting temperature of the monofilament and spacer material.~~ ~~Alternatively,~~ The method also includes reflowing at least one of the spacers or ~~the~~ monofilament into at least one portion of at least one of the conductor lumens by heating the spacers and monofilament to a temperature ~~and spacer may be of different materials and heat is applied~~ to cause thermal flow or melting of at least one of the spacers or monofilament ~~at least one material to thermally reflow or melt. The conductive contacts may be located at either the distal end and/or proximal end of the lead. Oversized spacers may be used in order to provide extra material to fill voids during the thermal fusion/reflow process.~~

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	20334/0209380-US0	6971

50638 7590 07/21/2010

Boston Scientific Neuromodulation Corp.
c/o Frommer Lawrence & Haug LLP
745 Fifth Ave
NEW YORK, NY 10151

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	**PAPER NUMBER**
3729	

MAIL DATE	DELIVERY MODE
07/21/2010	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 2 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 *26 May 2010*.

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

3)☐ 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

4)☒ Claim(s) *11-31* is/are pending in the application.

4a) Of the above claim(s) *16-23,27-29 and 31* is/are withdrawn from consideration.

5)☒ Claim(s) *11-15,24-26 and 30* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

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

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

Application Papers

9)☒ The specification is objected to by the Examiner.

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/16/10 has been entered.

Election/Restrictions

The examiner requests that the applicant cancel claims 22-23, as claims 16-21, 27-29, and 31 are expected to be rejoined upon proper amendment to overcome the listed objections.

Applicant is given TWO MONTHS to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue.

Specification

The abstract of the disclosure is objected to because the applicant has not directed the disclosure towards claim 11. As currently written, the abstract does not include the specific method of claim 11 as amended. Correction is required. See MPEP § 608.01(b).

Allowable Subject Matter

Claims 11-15, 24-26, and 30 are now allowable.

Conclusion

This application is in condition for allowance except for the following formal matters:

To correct the informalities above with the abstract and the claims.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks, can be reached on 571-272-4419. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA
July 19, 2010

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008	03/28/2009	06/09/2009	11/17/2009	03/26/2010	07/18/2010		
	1	÷	N	-	-	-	-	-		
	2	÷	N	-	-	-	-	-		
	3	÷	N	-	-	-	-	-		
	4	÷	N	-	-	-	-	-		
	5	÷	N	-	-	-	-	-		
	6	÷	N	-	-	-	-	-		
	7	÷	N	-	-	-	-	-		
	8	÷	N	-	-	-	-	-		
	9	÷	N	-	-	-	-	-		
	10	÷	N	-	-	-	-	-		
	11	÷	✓	✓	✓	÷	✓	=		
	12	÷	✓	✓	✓	÷	✓	=		
	13	÷	✓	✓	✓	÷	✓	=		
	14	÷	✓	✓	✓	÷	✓	=		
	15	÷	✓	✓	✓	÷	✓	=		
	16	÷	✓	✓	✓	÷	N	N		
	17	÷	✓	✓	✓	÷	N	N		
	18	÷	✓	✓	✓	÷	N	N		
	19	÷	✓	✓	✓	÷	N	N		
	20	÷	✓	✓	✓	÷	N	N		
	21	÷	✓	✓	✓	÷	N	N		
	22	÷	N	N	N	N	N	N		
	23	÷	N	N	N	N	N	N		
	24			✓	✓	÷	✓	=		
	25			✓	✓	÷	✓	=		
	26			✓	✓	÷	✓	=		
	27			✓	✓	÷	N	N		
	28			✓	✓	÷	N	N		
	29				✓	÷	N	N		
	30				✓	÷	✓	=		
	31					÷	N	N		

Docket No.: 1362009-2093(0209380-US0)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D. P. Angwin

AMENDMENT ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION

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

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated March 31, 2010 and in view of the accompanying Request for Continued Examination, please amend the above-identified U.S. patent application as follows:

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

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

1-10. (Cancelled)

11. (Currently Amended) A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:

providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;

disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;

connecting [[a]] at least one of the plurality of conductor wires to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts, wherein ~~the spacers and conductive contacts define a plurality of internal void spaces, wherein the plurality of internal void spaces~~ portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers;

~~placing~~ inserting monofilament ~~within~~ into at least one portion of at least one of the ~~internal void spaces~~ conductor lumens of the lead body that is not occupied by the conductor wires; and

reflowing at least one of the spacers or monofilament into at least one portion of at least one of the ~~internal void spaces~~ conductor lumens not occupied by the ~~conductive contacts and~~ conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

12. (Original) The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. (Original) The method of claim 12, wherein the monofilament is a thermoplastic material.

14. (Original) The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. (Original) The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. (Withdrawn) The method of claim 31, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. (Withdrawn) The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. (Withdrawn) The method of claim 11, wherein conductive contacts are in the form of rings.

19. (Withdrawn) The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. (Withdrawn) The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. (Withdrawn) The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and

wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

23. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and

wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

24. (Previously Presented) The method of claim 11, wherein the monofilament is a different material than the spacers.

25. (Previously Presented) The method of claim 11, wherein the monofilament is the same material as the spacers.

26. (Previously Presented) The method of claim 15, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

27. (Withdrawn) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the proximal end of the stimulation lead.

28. (Withdrawn) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the distal end of the stimulation lead.

29. (Withdrawn, Currently Amended) The method of claim 11, wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the ~~internal void spaces~~ conductor lumens are defined within the substantially cylindrical body.

30. (Currently Amended) The method of claim 11, wherein the monofilament is ~~placed within at least one of the internal void spaces not occupied by the conductor wires and~~ disposed in an orientation parallel to the conductor wires.

31. (Withdrawn) The method of claim 11, further comprising placing a heat shrink tubing around the spacers, conductive contacts, and monofilament and removing the heat shrink tubing after reflowing at least one of the spacers or monofilament.

REMARKS

This amendment is in response to the Office Action mailed March 31, 2010. Claims 11, 29, and 30 have been amended. Claims 11-31 are presently pending. No new matter has been added.

§103 Rejection

Claims 11-15, 24-26, and 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,216,045 to Black et al. ("Black") in view of U.S. Patent Application Publication No. 2005/0215945 Harris et al. ("Harris") and U.S. Patent No. 5,555,618 to Winkler ("Winkler"). The Applicants traverse this rejection.

Claim 11 recites a method of manufacturing a stimulation lead comprising disposing a plurality of conductor wires in a plurality of conductor lumens formed in a lead body; connecting at least one of the plurality of conductor wires to each of the conductive contacts; placing spacers between pairs of adjacent conductive contacts, wherein portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers; inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires; and reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

.Black discloses an implantable lead and method of manufacture. Black does not teach or suggest the step of placing monofilament within at least a portion of at least one of a plurality of conductor lumens formed in a lead body. The Office Action asserts that body 22 of Black corresponds to the recited monofilament of claim 11 (Office Action, p. 3). First, Black does not teach or suggest that body 22 is a monofilament.

Second, claim 11 recites that the monofilament is inserted into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires. The

body 22 of Black may correspond to the recited lead body, but it does not correspond to the recited monofilament because it is not inserted into at least one portion of at least one conductor lumen of the lead body.

The Office Action also points to outer layer 20 as allegedly corresponding to the recited monofilament of claim 11. (Office Action, p.4.) First, Winkler does not teach or suggest that outer layer 20 is a monofilament.

Second, outer layer 20 is not "inserted into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires" as recited in claim 11. Winkler teaches that the "outer layer 20 is preferably over-extruded" onto the wires 45 and core-covering layer 44. (Winkler, Col. 6:59-65.) Winkler does not teach or suggest inserting a monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires, as recited in claim 11.

For at least these reasons, claim 11, as well as claims 12-21 and 24-31, which depend therefrom, are patentable over the cited references. Applicants respectfully request withdrawal of the rejections of these claims.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner to contact the Applicants' representative, Bruce Black, by telephone to discuss the matter.

Dated: May 26, 2010

Respectfully submitted,

By _____

Bruce E. Black
Registration No.: 41,622
FROMMER LAWRENCE & HAUG LLP
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(206) 336-5668
(212) 588-0500 (Fax)
Attorneys/Agents For Applicant

Electronic Patent Application Fee Transmittal

Application Number:	11329907
Filing Date:	11-Jan-2006
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Filer:	Bruce Black/Aretha Pierre
Attorney Docket Number:	20334/0209380-US0

Filed as Large 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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	810	810
		Total in USD ($)		**810**

Electronic Acknowledgement Receipt

EFS ID:	7695068
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Aretha Pierre
Filer Authorized By:	Bruce Black
Attorney Docket Number:	20334/0209380-US0
Receipt Date:	26-MAY-2010
Filing Date:	11-JAN-2006
Time Stamp:	17:56:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$810
RAM confirmation Number	4208
Deposit Account	
Authorized User	

File Listing:

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

1		00769718.PDF	473973 7f0ce62ffa05a00035cc7f0f8851f92d8da88034	yes	9

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Request for Continued Examination (RCE)	1	1
Request for Continued Examination (RCE)	2	2
Claims	3	6
Applicant Arguments/Remarks Made in an Amendment	7	9

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30065 de982c9b549cf1fe949ca14e380267c279265206	no	2

Warnings:

Information:

Total Files Size (in bytes):	504038

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/30 (07-09)
Approved for use through 07/31/2012. 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 contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	11/329,907, Conf. # 6971
Filing Date	January 11, 2006
First Named Inventor	Janusz A. Kuzma et al.
Art Unit	3729
Examiner Name	D. P. Angwin
Attorney Docket Number	1362009-2093 (0209380-US0)

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. ☐ Other _____

b. ☑ Enclosed

I. ☑ Amendment/Reply

ii. ☐ Affidavit(s)/ Declaration(s)

iii. ☐ Information Disclosure Statement (IDS)

iv. ☐ Other _____

2. Miscellaneous

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-0320.

i. ☑ RCE fee required under 37 CFR 1.17(e)

ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

iii. ☐ Other _____

b. ☐ Check in the amount of $ _____ enclosed

c. ☑ Payment by credit card (Form PTO-2038 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.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/B E Black/	Date	May 26, 2010
Name (Print/Type)	Bruce E. Black	Registration No.	41,622

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	Via EFS		
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. 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 SE ND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/329,907	01/11/2006	

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			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	05/26/2010	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 21	Minus	** 23	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ 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	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/NINA RATANAVONG/

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.
11/329,907	01/11/2006	Janusz A. Kuzma	20334/0209380-US0	6971

50638 7590 03/31/2010

Boston Scientific Neuromodulation Corp.
c/o DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
NEW YORK, NY 10008-0770

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	**PAPER NUMBER**
3729	

MAIL DATE	DELIVERY MODE
03/31/2010	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *10 December 2009*.

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

3)☐ 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

4)☒ Claim(s) *11-31* is/are pending in the application.

4a) Of the above claim(s) *16-23,27-29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15, 24-26, and 30* is/are rejected.

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

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

Application Papers

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

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species I (claims 11-15, 24-26, and 30) in the reply filed on 12/10/09 is acknowledged.

Claims 16-23, 27-29, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that 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 taught 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-15, 24-26, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Harris et al* (US Patent Publication 2005/0215945) and *Winkler* (US Patent 5,555,618).

a. *Black et al* discloses in his reference the following:

i. providing a plurality of conductive contacts (Figs. 2 and 5, item 16) located at an end (item 12) of the stimulation lead;

ii. connecting a conductor wire (Fig. 3-5, item 20) to each of the conductive contacts (2:20-25);

iii. placing spacers (Fig. 5, item 30) between pairs of adjacent conductive contacts, wherein the spacers and conductive contact define a plurality of internal void spaces (Fig. 5, *spaces located between spacers and above conductive contact; the examiner notes that "a plurality of internal void spaces" is comprised of spacers, contacts, and monofilament because the applicant used the transition phrase "comprising;" the applicant can overcome this by writing "a plurality of internal void spaces consisting of" or "a plurality of internal void spaces made only of "*), wherein the plurality of internal void spaces are located beneath the plurality of conductive contacts and the spacers (Fig. 5, *internal void spaces shown to be located at a lower height than the conductive contacts*);

iv. placing monofilament (Fig. 3, items 22 and 23; 3:45-54) within at least one of the internal void spaces not occupied by the conductive wires (*the examiner notes that the monofilament occupies void spaces that are internal to the diameter of the stimulation lead*);

v. either the spacers or monofilament is polyurethane (3:45-54); and

vi. the monofilament is placed within at least one of the internal void spaces not occupied by the conductor wires and disposed in an orientation parallel to the conductor wires (Figs. 2-3).

b. Regarding claim 11, in addition to the above limitations, *Black et al* as modified may not expressly disclose in his reference reflowing at least one of the spacers or monofilament material into the internal void spaces not occupied by the conductive contacts and conductive traces by heating the spacers and monofilament to a temperature to cause thermal flow of melting of at least one of the spacers or monofilament.

   i. However, *Winkler* teaches in his reference reflowing a monofilament material (Figs. 2-3, item 20) into internal void spaces not occupied by the conductive contacts and conductive traces (Figs. 2-3; 6:17-30; 6:49-58; *the examiner notes that if the wires are not yet embedded, there inherently exists an internal void*). The advantage of reflowing a monofilament material into internal void spaces not occupied by the conductive contacts and conductive traces is to allow the internal wires to embed in the plastic (6:17-30; 6:54-58). Therefore, it would have been obvious to reflow a monofilament material into internal void spaces not occupied by the conductive contacts and conductive traces to allow the internal wires to embed in the plastic.

c. Regarding claim 13, in addition to the limitations in claim 12, *Black et al* as modified may not expressly disclose in his reference that the monofilament is a thermoplastic material.

   i. However, *Winkler* teaches in his reference that the core covering layer is a thermoplastic (6:17-30). The advantage of making the core-covering layer a thermoplastic is to effectively embed the wires into the core-covering layer (6:17-30). Therefore, it would have been obvious to make the core-covering layer a thermoplastic to effectively embed the wires into the core-covering layer.

d. Regarding claims 14-15 and 26, in addition to the limitations in claim 13, *Black et al* as modified may not expressly disclose in his reference that the

heat applied is between about 140 C to 250 C, for about 15 to 120

seconds, or for about 160 C for about 40 seconds.

i. However, *Winkler* teaches in his reference that the heat applied is between about 140 C to 250 C (6:17-30). The advantage of applying heat between about 140 C to 250 C is to melt the thermoplastic and embed the wires. Therefore, it would have been obvious to apply heat between about 140 C to 250 C to melt the thermoplastic and embed the wires.

ii. In addition, the examiner notes that temperature, time, and material are result effective variables that determine when a thermoplastic becomes melted and vary depending upon the conditions that are used. If one were to vary any one of these variables, one of ordinary skill in the art would know that the remaining result effective variables (temperature, time, and material) would also need to be varied. Therefore, it would have been obvious to one of ordinary skill in the art to vary the result effective variables (temperature, time, and material) accordingly. As a result, it would have been obvious to vary the temperature, time, and material, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. MPEP 2144.05.

iii. Further, the applicant has not disclosed that heat applied between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds solves any stated problem or provides any unexpected results. As such, the examiner considers this limitation to be a design choice. Therefore, it would have been obvious as a matter of design choice to apply heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, since the applicant has not disclosed that applying heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, solves any stated problem or provides any unexpected results, and it appears that the method of making the catheter would perform equally well if another heat cycle like taught in *Winkler et al* had been utilized.

e. Regarding claim 24, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is a different material than the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament can be different material than the spacers but with the same mechanical properties (7:18-24). The advantage of making the monofilament from a different material than the spacers is to utilize a cheaper but less effective material for either the monofilament or the spacers. Therefore, it would have been obvious to make the monofilament from a different material than the spacers to utilize a cheaper but less effective material for either the monofilament or the spacers.

f. Regarding claim 25, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is the same material as the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament is made of a mechanically equivalent material to that of the spacers (7:18-24). The advantage of making the monofilament from the same material as the spacers is to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials. Therefore, it would have been obvious to make the monofilament from the same material than the spacers to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials.

Response to Arguments

Applicant's arguments filed 9/28//09 have been fully considered but they are not persuasive.

The applicant argues that the references do not disclose "placing monofilament within internal void spaces located beneath the plurality of conductive contacts and the spacers" (applicant's arguments, 6:18-20). However, the examiner disagrees. *Black et al* discloses locating the plurality of internal void spaces beneath the plurality of conductive contacts and the spacers (Fig. 5, *internal void spaces shown to be located at a lower height than the conductive contacts*). In addition, *Winkler et al* teaches in his reference reflowing a monofilament material (Figs. 2-3, item 20) into internal void spaces not occupied by the conductive contacts and conductive traces (Figs. 2-3; 6:17-30; 6:49-58; *the examiner notes that if the wires are not yet embedded, there inherently exists an internal void*). As a result, the monofilament fills internal spaces (Figs. 1-6). Therefore, the examiner maintains the rejection.

Conclusion

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.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin, whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks, can be reached on 571-272-4419. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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DPA

/Derris H Banks/
Supervisory Patent Examiner, Art Unit 3729

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008	03/28/2009	06/09/2009	11/17/2009	03/26/2010			
3	1	÷	N	-	-	-	-			
	2	÷	N	-	-	-	-			
	3	÷	N	-	-	-	-			
	4	÷	N	-	-	-	-			
	5	÷	N	-	-	-	-			
	6	÷	N	-	-	-	-			
	7	÷	N	-	-	-	-			
	8	÷	N	-	-	-	-			
	9	÷	N	-	-	-	-			
	10	÷	N	-	-	-	-			
	11	÷	✓	✓	✓	÷	✓			
	12	÷	✓	✓	✓	÷	✓			
	13	÷	✓	✓	✓	÷	✓			
	14	÷	✓	✓	✓	÷	✓			
	15	÷	✓	✓	✓	÷	✓			
	16	÷	✓	✓	✓	÷	N			
	17	÷	✓	✓	✓	÷	N			
	18	÷	✓	✓	✓	÷	N			
	19	÷	✓	✓	✓	÷	N			
	20	÷	✓	✓	✓	÷	N			
	21	÷	✓	✓	✓	÷	N			
	22	÷	N	N	N	N	N			
	23	÷	N	N	N	N	N			
	24			✓	✓	÷	✓			
	25			✓	✓	÷	✓			
	26			✓	✓	÷	✓			
	27			✓	✓	÷	N			
	28			✓	✓	÷	N			
	29				✓	÷	N			
	30				✓	÷	✓			
	31					÷	N			

Docket No.: 20334/0209380-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D. P. Angwin

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

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

Dear Sir:

In the species election set forth in the Office Action mailed November 20, 2009, the Examiner has required election from the following species:

Species I, claims 12-15, 24-26, and 30, drawn to a method of manufacturing a stimulation lead including monofilament details embodiment;

Species II, claim 17, drawn to a method of manufacturing a stimulation lead including oversized spacers embodiment;

Species III, claims 18-20, drawn to a method of manufacturing a stimulation lead including conductive contacts details embodiment;

Species IV, claim 21, drawn to a method of manufacturing a stimulation lead including welding embodiment;

Species V, claims 27-29, drawn to a method of manufacturing a stimulation lead including conductive contacts details embodiment; and

Species VI, claims 31 and 16, drawn to a method of manufacturing a stimulation lead including heat shrink tubing embodiment.

The Applicant hereby elects Species I for continued examination, without traverse. Claims 12-15, 24-26, and 30 are readable upon the elected species. Claim 11 is generic to more than one species.

Applicant's election is made without prejudice. As noted by the Examiner, upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to not more than a reasonable number of species in addition to the elected species, provided that all claims to each additional species are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.146.

Each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicant encourages the Examiner to contact the Applicant's representative, Bruce Black, by telephone to discuss the matter.

Dated: December 10, 2009

Respectfully submitted,

By_____

Bruce E. Black
Registration No.: 41,622
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(206) 262-8908
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant

Electronic Acknowledgement Receipt

EFS ID:	6615236
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Lisa Small
Filer Authorized By:	Bruce Black
Attorney Docket Number:	20334/0209380-US0
Receipt Date:	10-DEC-2009
Filing Date:	11-JAN-2006
Time Stamp:	19:11:32
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		EFS_Response.PDF	250598 d0a9cd6dfc02e8f3cee6a5bad19de7a6f42477b0	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Response to Election / Restriction Filed	2	3
Warnings:			
Information:			
	Total Files Size (in bytes):	250598	

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.

AMENDMENT TRANSMITTAL LETTER

Docket No. 20334/0209380-US0

Application No.	Filing Date	Examiner	Art Unit
11/329,907-Conf. #6971	January 11, 2006	D. P. Angwin	3729

Applicant(s): Janusz A. Kuzma et al.

Invention: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is a Response in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED						
	Claims Remaining After Amendment	Highest Number Previously Paid		Number Extra Claims Present	Rate	
Total Claims	21	- 21	=	0	x 52.00	0.00
Independent Claims	3	- 3	=	0	x 220.00	0.00
Multiple Dependent Claims (check if applicable)	☐					
Other fee (please specify):						
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:						0.00

☒ Large Entity ☐ Small Entity

☒ No additional fee is required for this amendment.

☐ Please charge Deposit Account No. _____ in the amount of $ _____.

☐ A check in the amount of $ _____ to cover the filing fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director is hereby authorized to charge and credit Deposit Account No. 04-0100 as described below.

☒ Credit any overpayment.

☒ Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.

Dated: December 10, 2009

Bruce E. Black
Attorney/Agent Reg. No.: 41,622

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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.
11/329,907	01/11/2006	Janusz A. Kuzma	20334/0209380-US0	6971

50638 7590 11/20/2009

Boston Scientific Neuromodulation Corp.
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Church Street Station
NEW YORK, NY 10008-0770

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

MAIL DATE	DELIVERY MODE
11/20/2009	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *1* 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 *28 September 2009*.

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

3)☐ 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

4)☒ Claim(s) *11-31* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

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

8)☒ Claim(s) *11-21 and 24-31* are subject to restriction and/or election requirement.

Application Papers

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

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

In light of the newly added claim in the applicant's response dated 9/28/09, the examiner now imposes a new restriction requirement. This application contains claims directed to the following patentably distinct species:

I. **Species I** – a method of manufacturing a stimulation lead including monofilament details embodiment (**claims 12-15, 24-26, and 30**);

II. **Species II** – a method of manufacturing a stimulation lead including oversized spacers embodiment (**claim 17**);

III. **Species III** – a method of manufacturing a stimulation lead including conductive contacts details embodiment (**claim 18-20**);

IV. **Species IV** – a method of manufacturing a stimulation lead including welding embodiment (**claim 21**);

V. **Species V** – a method of manufacturing a stimulation lead including conductive contacts details embodiment (**claim 27-29**); and

VI. **Species VI** – a method of manufacturing a stimulation lead including heat shrink tubing embodiment (**claim 31 and 16**).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. Specifically, **Species I** includes monofilament details, whereas **Species II to VI** do not include these limitations. **Species II** includes oversized spacers, whereas **Species I and III to VI** do not include this limitation. **Species III** includes conductive contacts details, whereas **Species I to II and IV to VI** do not include these limitations. **Species IV** includes the limitation of welding, whereas **Species I to III and V to VI** do not include this limitation.

Species V includes conductive contact details, whereas **Species I to IV and VI** do not include these limitations. **Species VI** includes heat shrink tubing, whereas **Species I to V** do not include this limitation. In addition, these species are not obvious variants of each other based on the current record. **Claim 11 is generic**.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve 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 election of species 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 on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species 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 species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin whose telephone number is 571-270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks, can be reached on 571-272-4419. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA
November 18, 2009

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/14/2008	11/12/2008	03/28/2009	06/09/2009	11/17/2009				
	1	÷	N	-	-	-				
	2	÷	N	-	-	-				
	3	÷	N	-	-	-				
	4	÷	N	-	-	-				
	5	÷	N	-	-	-				
	6	÷	N	-	-	-				
	7	÷	N	-	-	-				
	8	÷	N	-	-	-				
	9	÷	N	-	-	-				
	10	÷	N	-	-	-				
	11	÷	✓	✓	✓	÷				
	12	÷	✓	✓	✓	÷				
	13	÷	✓	✓	✓	÷				
	14	÷	✓	✓	✓	÷				
	15	÷	✓	✓	✓	÷				
	16	÷	✓	✓	✓	÷				
	17	÷	✓	✓	✓	÷				
	18	÷	✓	✓	✓	÷				
	19	÷	✓	✓	✓	÷				
	20	÷	✓	✓	✓	÷				
	21	÷	✓	✓	✓	÷				
	22	÷	N	N	N	N				
	23	÷	N	N	N	N				
	24			✓	✓	÷				
	25			✓	✓	÷				
	26			✓	✓	÷				
	27			✓	✓	÷				
	28			✓	✓	÷				
	29				✓	÷				
	30				✓	÷				
	31					÷				

Docket No.: 20334/0209380-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D. P. Angwin

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

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

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated July 1, 2009, please amend the above-identified U.S. patent application as follows:

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

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

1-10. (Cancelled)

11. (Currently Amended) A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:

providing a plurality of conductive contacts located at an end of the stimulation lead;

connecting a conductor wire to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts, wherein the spacers and conductive contacts define a plurality of internal void spaces, wherein the plurality of internal void spaces are located beneath the plurality of conductive contacts and the spacers;

placing monofilament within at least one of the internal void spaces not occupied by the conductor wires;

~~placing a heat shrink tubing around the spacers, conductive contacts, and monofilament;~~ and

~~heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create~~ reflowing ~~of said~~ at least one of the spacers or monofilament into the internal void spaces not occupied by the conductive contacts and conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

12. (Original) The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. (Original) The method of claim 12, wherein the monofilament is a thermoplastic material.

14. (Original) The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. (Original) The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. (Currently Amended) The method of claim ~~11~~ 31, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. (Original) The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. (Original) The method of claim 11, wherein conductive contacts are in the form of rings.

19. (Original) The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. (Original) The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. (Original) The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and

wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

23. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and

wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

24. (Previously Presented) The method of claim 11, wherein the monofilament is a different material than the spacers.

25. (Previously Presented) The method of claim 11, wherein the monofilament is the same material as the spacers.

26. (Previously Presented) The method of claim 15, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

27. (Previously presented) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the proximal end of the stimulation lead.

28. (Previously presented) The method of claim 11, wherein the plurality of electrically conductive contacts are located on the distal end of the stimulation lead.

29. (Previously presented) The method of claim 11, wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the internal void spaces are defined within the substantially cylindrical body.

30. (Previously presented) The method of claim 11, wherein the monofilament is placed within at least one of the internal void spaces not occupied by the conductor wires and disposed in an orientation parallel to the conductor wires.

31. (New) The method of claim 11, further comprising placing a heat shrink tubing around the spacers, conductive contacts, and monofilament and removing the heat shrink tubing after reflowing at least one of the spacers or monofilament.

REMARKS

This amendment is in response to the Office Action mailed July 1, 2009. Claims 11 and 16 have been amended. Claim 31 has been added. Claims 11-31 are presently pending. No new matter has been added.

§103 Rejection

Claims 11-21 and 24-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Black et al. (U.S. Patent No. 6,216,045) in view of Harris et al. (U.S. Patent Publication 2005/0215945) and Winkler (U.S. Patent No. 5,555,618). In the alternative, Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Black et al. (U.S. Patent No. 6,216,045) in view of Harris et al. (U.S. Patent Publication 2005/0215945) and Winkler (U.S. Patent No. 5,555,618) and further in view of Rosinko et al. (U.S. Patent No. 6,551,302). The Applicants traverse these rejection.

Claim 11 recites a method of manufacturing a stimulation lead comprising the steps of placing spacers between pairs of adjacent conductive contacts, wherein the spacers and conductive contacts define a plurality of internal void spaces, wherein the plurality of internal void spaces are located beneath the plurality of conductive contacts and the spacers and placing monofilament within at least one of the internal void spaces not occupied by the conductor wires.

Black discloses an implantable lead and method of manufacture. Black does not teach or suggest the step of placing monofilament within internal void spaces located beneath the plurality of conductive contacts and the spacers. The Office Action relies on body 22 of Black as the monofilament of claim 11 (Office Action, p. 3). However, the body 22 is merely an exterior structure for the components of lead 10 and only "serves as a sheath...[and] substantially provides the exterior structure that contains the internalized elements of lead 10" (*see* Black, col. 3, lines 53-57 and Figure 3). The body 22 of Black is not placed within internal void spaces located beneath the plurality of conductive contacts and spacers, but is disposed above those elements. The Office Action further asserts that "a plurality of internal void spaces is comprised of spacers, contact and monofilament because the applicant used the transition phrase 'comprising:'" (Office Action, p. 3).

Applicants submit that claim 11 contains no such element. The only use of the word "comprising" in claims 11 appears in the preamble with respect to the series of steps of the claimed method. Thus, the Office Action's interpretation that the "internal void spaces comprise spacers, contacts and monofilament" is inconsistent with the claim language. Moreover, the body 22 is not located within internal void spaces as recited in claim 11. None of Harris, Winkler and Rosinko address this deficiency of Black.

Claim 11 further recites the step of reflowing at least one of the spacers or monofilament into the internal void spaces not occupied by the conductive contacts and conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament. The Examiner acknowledges that Black does not teach or suggest this step (Office Action, p. 5). Winkler discloses a method of making an electrode-carrying catheter. Winkler does not teach or suggest heating the spacers and monofilament. Instead, Winkler only discloses that a core-covering outer layer 44 is heated (Winkler col. 6, lines 17-23). However, the core-covering outer layer 44 of Winkler is neither a spacer placed between contacts nor a monofilament disposed within the inner void spaces. Instead, the core-covering layer 44 is an external cover formed "by overextruding a plastic over a core 42" (Winkler col. 5, lines 41-42).

Moreover, the heating that occurs in Winkler temporarily softens a core-covering outer layer 44 at the point where the wire contacts the layer 44 so that the wire may be set when placed under tension (*see* Winkler col. 6, lines 19-23, lines 54-58). There is no indication that the outer layer 44 of Winkler reflows. It is merely softened. Thus, the core-covering layer is neither the spacers nor the monofilament recited in claim 11, and the heating of the layer does not create a reflow of a spacer or a monofilament.

The Office Action asserts that even if Winkler does not teach the reflow process of claim 11, "the structure need only be capable of performing this function" (Office Action, p. 5). Claim 11 is not an apparatus claim, but a method claim, which recites steps that are carried out. Method steps describe functions that are performed. To reject a method claim, the prior art must teach or suggest

the recited method steps. Claim 11 recites the step of "reflowing at least one of the spacers or monofilament into the internal void spaces." Winkler does not teach or suggest this step.

Finally, Winkler does not teach or suggest the step of creating reflow of said at least one of the spacers or monofilament into internal void spaces. Because core-covering layer 44 encapsulates the core 42 and is surrounded by tubing 12, reflow into internal void spaces is not possible. Harris and Rosinko also fail to address this deficiency of Winkler.

For at least these reasons, claim 11, as well as claims 12-21 and 24-31, which depend therefrom, are patentable over the cited references. Applicants respectfully request withdrawal of the rejections of these claims.

The dependent claim contain additional patentable matter. For example, claim 29 recites the method of claim 11, wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the internal void spaces are defined within the substantially cylindrical body. The Office Action again relies on Black and points to the use of the term "comprising" as support. However, as outlined above, the term "comprising" only appears in the preamble with respect to the series of steps of the claimed method. Black does not teach internal void spaces defined within a substantially cylindrical body. For at least these reasons, claim 29 is patentable over the prior art. Applicants respectfully request withdrawal of the rejection of this claim.

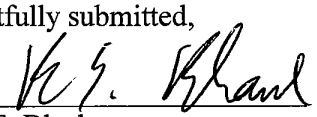
Claim 31 recites the method of claim 11 further comprising the step of placing a heat shrink tubing around the spacers, conductive contacts, and monofilament and removing the heat shrink tubing after reflowing at least one of the spacers or monofilament. The Office Action acknowledges that Black does not teach or suggest this step (Office Action, p. 4). Contrary to the assertion in the Office Action, Harris also does not teach or suggest placing a heat shrink tubing around the spacers, conductive contacts and monofilament. Harris merely teaches that a protective outer covering, such as a shrink-wrap may be disposed around the first lead wire 220 and around the second lead wire 230 to protect the wires (Harris, paragraph 0049). The first and second lead wires 220 and 230 do not include spacers, conductive contacts and/or a monofilament. The lead wires

220 and 230 may be connected to an end plates 112 and 122 of electrodes 110 and 120, and serve to connect the electrodes to monitoring equipment (Harris, paragraph 0049). Thus, Harris does not teach heat shrink tubing being disposed around spacers or monofilament, because Harris does not suggest the use of either element. Furthermore, Harris does not teach or suggest removing the heat shrink tubing after reflowing at least one of the spacers or monofilament. Instead, the heat shrink tubing of Harris is disposed around the first and second leads 220 and 230 and used as a protective covering that is not removed (Harris, paragraph 0049). Winkler and Rosinko fail to address this deficiency of Harris. For at least these reasons, claim 31 is patentable over the prior art. Applicants respectfully request withdrawal of the rejection of this claim.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner to contact the Applicants' representative, Bruce Black, by telephone to discuss the matter.

Dated: September 28, 2009

Respectfully submitted,

By 

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Electronic Acknowledgement Receipt

EFS ID:	6159936
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Lisa Small
Filer Authorized By:	Bruce Black
Attorney Docket Number:	20334/0209380-US0
Receipt Date:	28-SEP-2009
Filing Date:	11-JAN-2006
Time Stamp:	17:36:39
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		EFS_Amendment.PDF	460503 e095f9e614721b53603d438f2a7f3086c9b644fb	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Amendment/Req. Reconsideration-After Non-Final Reject	2	2
	Claims	3	6
	Applicant Arguments/Remarks Made in an Amendment	7	10
Warnings:			
Information:			
	Total Files Size (in bytes):	460503	

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.

AMENDMENT TRANSMITTAL LETTER

Docket No. 20334/0209380-US0

Application No.	Filing Date	Examiner	Art Unit
11/329,907-Conf. #6971	January 11, 2006	D. P. Angwin	3729

Applicant(s): Janusz A. Kuzma et al.

Invention: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED					
	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	21	- 23 =	0	x 52.00	0.00
Independent Claims	3	- 4 =	0	x 220.00	0.00
Multiple Dependent Claims (check if applicable) ☐					
Other fee (please specify):					
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:					

[x] Large Entity [ ] Small Entity

[x] No additional fee is required for this amendment.

[ ] Please charge Deposit Account No. _____ in the amount of $ _____.

[ ] A check in the amount of $ _____ to cover the filing fee is enclosed.

[ ] Payment by credit card. Form PTO-2038 is attached.

[x] The Director is hereby authorized to charge and credit Deposit Account No. 04-0100 as described below.

[x] Credit any overpayment.

[x] Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.

Dated: September 28, 2009

Bruce E. Black
Attorney/Agent Reg. No.: 41,622

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PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/329,907	01/11/2006	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
FOR	NUMBER FILED	NUMBER EXTRA					
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 09/28/2009	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 21	Minus	** 23	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 3	Minus	***4	= 0	X $ =		OR	X $220=	0
☐ 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	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/VENESSA JONES/

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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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	20334/0209380-US0	6971

50638 7590 07/01/2009

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EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

MAIL DATE	DELIVERY MODE
07/01/2009	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *21 May 2009*.

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

3)☐ 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

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21 and 24-30* is/are rejected.

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

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

Application Papers

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

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/09 has been entered.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that 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 taught 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-21 and 24-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Harris et al* (US Patent Publication 2005/0215945) and *Winkler* (US Patent 5,555,618).

a. *Black et al* discloses in his reference the following:

i. providing a plurality of conductive contacts (Figs. 2 and 5, item 16) located at an end (item 12) of the stimulation lead;

ii. connecting a conductor wire (Fig. 3-5, item 20) to each of the conductive contacts (2:20-25);

iii. placing spacers (Fig. 5, item 30) between pairs of adjacent conductive contacts, wherein the spacers and conductive contact define a plurality of internal void spaces (Fig. 5, *spaces located between spacers and above conductive contact; the examiner notes that "a plurality of internal void spaces" is comprised of spacers, contacts, and monofilament because the applicant used the transition phrase "comprising;" the applicant can overcome this by writing "a plurality of internal void spaces consisting of" or "a plurality of internal void spaces made only of "*);

iv. placing monofilament (Fig. 3, items 22 and 23; 3:45-54) within at least one of the internal void spaces not occupied by the conductive wires (*the examiner notes that the monofilament occupies void spaces that are internal to the diameter of the stimulation lead*);

v. either the spacers or monofilament is polyurethane (3:45-54);

vi. the spacers are oversized in diameter, relative to a predetermined final diameter of the lead (Figs. 2-4, 5, and 8, item 30);

vii. the conductive contacts are in the form of rings (Figs. 1-5);

viii. the conductive contacts are electrode contacts on the lead (Figs. 1-5, item 16);

ix. the conductive contacts are connector contacts on the proximal end of the lead (Figs. 1-5, item 16);

x. the step of connecting a connecting wire to each of the electrode contacts ins accomplished by welding each conductor wire to each respective contact (6:58-62);

xi. the plurality of electrically conductive contacts are located on a proximal end of the stimulation lead (Figs. 2 and 5; *proximal to stylet (item 100)*);

xii. the plurality of electrically conductive contacts are located on a distal end of the stimulation lead (Figs. 2 and 5; *distal to electrodes (item 18)*; *in the alternative*, Figs. 2 and 5, item 18);

xiii. the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body (Figs. 2-3; *the examiner notes that the "substantially cylindrical body" is comprised of conductive contacts, spacers, and monofilament because applicant utilized the transition phrase "comprising" in claim 11, line 2*) and wherein the internal void spaces are defined within the substantially cylindrical body; and

xiv. the monofilament is placed within at least one of the internal void spaces not occupied by the conductor wires and disposed in an orientation parallel to the conductor wires (Figs. 2-3).

b. Regarding claim 1, in addition to the above limitations, *Black et al* as modified may not expressly disclose in his reference placing a heat shrink tubing around the spacers, conductive contacts, and monofilament.

i. However, *Harris et al* teaches in his reference placing a heat shrink tubing around the internal portion of a catheter (49:31-31). The advantage of placing a heat shrink tubing around the internal portion of a catheter is to protect the inner portion from the

environment. Therefore, it would have been obvious to place a heat shrink tubing around the spacers, conductive contacts, and monofilament, to protect the inner portion from the environment.

c. Regarding claim 1, in addition to the above limitations, *Black et al* as modified may not expressly disclose in his reference heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of said at least one of the spacers or monofilament material into the internal void spaces not occupied by the conductive contacts and conductive traces.

i. However, *Winkler* teaches in his reference heating an electrode carrying catheter (Figs. 2-3; 6:17-30). The advantage of heating the electrode carrying catheter is to create reflow of a monofilament material into the internal void spaces not occupied by the conductive contacts and conductive traces to allow the internal wires to embed in the plastic (6:17-30; 6:54-58). Therefore, it would have been obvious to heat the spacers and monofilament to a temperature to create reflow of at least one of the spacers or monofilament material into the internal void spaces not occupied by the conductive contacts and conductive traces to allow the internal wires to embed in the plastic.

ii. The examiner notes that the language “to create reflow of said at least one of the spacers or monofilament material into the internal void spaces not occupied by the conductive contacts and conductive wires” (claim 11, lines 12-13) is functional language. As a result, the structure need only be capable of performing this function.

d. Regarding claim 13, in addition to the limitations in claim 12, *Black et al* as modified may not expressly disclose in his reference that the monofilament is a thermoplastic material.

i. However, *Winkler* teaches in his reference that the core covering layer is a thermoplastic (6:17-30). The advantage of making the core-covering layer a thermoplastic is to effectively embed the wires into the core-covering layer (6:17-30). Therefore, it would have been obvious to make the core-covering layer a thermoplastic to effectively embed the wires into the core-covering layer.

e. Regarding claims 14-15 and 26, in addition to the limitations in claim 13, *Black et al* as modified may not expressly disclose in his reference that the heat applied is between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds.

i. However, *Winkler* teaches in his reference that the heat applied is between about 140 C to 250 C (6:17-30). The advantage of applying heat between about 140 C to 250 C is to melt the thermoplastic and embed the wires. Therefore, it would have been obvious to apply heat between about 140 C to 250 C to melt the thermoplastic and embed the wires.

ii. In addition, the examiner notes that temperature, time, and material are result effective variables that determine when a thermoplastic becomes melted and vary depending upon the conditions that are used. If one were to vary any one of these variables, one of ordinary skill in the art would know that the remaining result effective variables (temperature, time, and material) would also need to be varied. Therefore, it would have been obvious to one of ordinary skill in the art to vary the result effective variables (temperature, time, and material) accordingly. As a result, it would have been obvious to vary the temperature, time, and material, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. MPEP 2144.05.

iii. Further, the applicant has not disclosed that heat applied between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds solves any stated problem or provides any unexpected results. As such, the examiner considers this limitation to be a design choice. Therefore, it would have been

obvious as a matter of design choice to apply heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, since the applicant has not disclosed that applying heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, solves any stated problem or provides any unexpected results, and it appears that the method of making the catheter would perform equally well if another heat cycle like taught in *Winkler et al* had been utilized.

f. Regarding claim 16, in addition to the limitations in claim 11, *Black et al* as modified may not expressly disclose in his reference making the heat shrink tubing from either PTFE or polyester.

i. However, *Nelson et al* teaches in his reference making the heat shrink material from PTFE (9:28-33). The advantage of making the heat shrink material from PTFE is to utilize a well known heat shrink material. Therefore, it would have been obvious to make the heat shrink material from PTFE to utilize a well known heat shrink material.

g. Regarding claim 24, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is a different material than the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament can be different material than the spacers but with the same mechanical properties (7:18-24). The advantage of making the monofilament from a different material than the spacers is to utilize a cheaper but less effective material for either the monofilament or the spacers. Therefore, it would have been obvious to make the monofilament from a different material than the spacers to utilize a cheaper but less effective material for either the monofilament or the spacers.

h. Regarding claim 24, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is the same material as the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament is made of a mechanically equivalent material to that of the spacers (7:18-24). The advantage of making the monofilament from the same material as the spacers is to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials. Therefore, it would have been obvious to make the monofilament from the same material than the spacers to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials.

In the alternative, **claim 28**, as best understood, is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Harris et al* (US Patent Publication 2005/0215945) and *Winkler* (US Patent 5,555,618) and further in view of *Rosinko et al* (US Patent 6,551,302).

a. Regarding claim 28, in addition to the limitations in claim 11, *Black et al* may not expressly disclose the plurality of conductive contacts are located on a distal end of the stimulation lead.

i. However, *Rosinko et al* teaches in his reference a handle for a catheter located at a distal end of a stimulation lead (Figs. 1 and 7A). The advantage of utilizing a handle located at a distal end of a stimulation lead is to make a steerable catheter. Therefore, it would have been obvious to design a plurality of conductive contacts located on a distal end of the stimulation lead to make a steerable catheter.

Response to Arguments

Applicant's arguments filed 5/21/09 have been fully considered but they are not persuasive.

First, the applicant argues that *Black et al* does not disclose "placing spacers between pairs of adjacent conductive contacts, wherein the spacers and conductive contacts define a plurality of internal void spaces, and placing monofilament within at least one of the internal void spaces not occupied by the conductor wires" (applicant's arguments, 6:16-19). However, the examiner disagrees. The examiner notes that "a plurality of internal void spaces" is comprised of spacers, contacts, and monofilament because the applicant used the transition phrase "comprising." As a result, the monofilament in fills internal spaces (Figs. 1-6). Therefore, the examiner maintains the rejection.

Second, the applicant argues that *Harris et al* does not teach "placing a heat shrink tubing around the spacers, conductive contacts, and monofilament" (applicant's arguments, 7:1-2). However, *Harris et al* teaches placing a heat shrink tubing around a catheter to protect the internal leads. Therefore, the examiner maintains the rejection.

Third, the applicant argues that the references do not disclose "heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of said at least one of the spacers or monofilament into the internal void spaces not occupied by the conductive contacts and conductive wires" (applicant's arguments, 6:13-16). However, the examiner disagrees. *Winkler et al* teaches reflowing of a monofilament into the internal void

spaces not occupied by the conductive contacts and conductive wires (Figs. 2-3; 6:17-30; 6:54-58). In addition, the applicant argues that the monofilament in *Winkler et al* does not reflow. However, the examiner disagrees. Figs. 3 and 5 show the outer tubular layer formed around the wire. Therefore, the examiner maintains the rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin, whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks, can be reached on 571-272-4419. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA
June 30, 2009

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008	03/28/2009	06/09/2009					
	1	÷	N	-	-					
	2	÷	N	-	-					
	3	÷	N	-	-					
	4	÷	N	-	-					
	5	÷	N	-	-					
	6	÷	N	-	-					
	7	÷	N	-	-					
	8	÷	N	-	-					
	9	÷	N	-	-					
	10	÷	N	-	-					
	11	÷	✓	✓	✓					
	12	÷	✓	✓	✓					
	13	÷	✓	✓	✓					
	14	÷	✓	✓	✓					
	15	÷	✓	✓	✓					
	16	÷	✓	✓	✓					
	17	÷	✓	✓	✓					
	18	÷	✓	✓	✓					
	19	÷	✓	✓	✓					
	20	÷	✓	✓	✓					
	21	÷	✓	✓	✓					
	22	÷	N	N	N					
	23	÷	N	N	N					
	24			✓	✓					
	25			✓	✓					
	26			✓	✓					
	27			✓	✓					
	28			✓	✓					
	29				✓					
	30				✓					

PTO/SB/30 (04-09)
Approved for use through 05/31/2009. OMB 0651-0031
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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	11/329,907-Conf. #6971
Filing Date	January 11, 2006
First Named Inventor	Janusz A. Kuzma
Art Unit	3729
Examiner Name	D. P. Angwin
Attorney Docket Number	20334/0209380-US0

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. [ ] Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
      i. [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
      ii. [ ] Other _____

   b. [X] Enclosed
      i. [X] Amendment/Reply
      ii. [ ] Affidavit(s)/Declaration(s)
      iii. [ ] Information Disclosure Statement (IDS)
      iv. [ ] Other _____

2. Miscellaneous

   a. [ ] Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. [X] Other Fee Transmittal

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

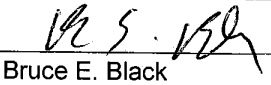
   a. [X] The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any Overpayments, to Deposit Account No. 04-0100 .
      i. [X] RCE fee required under 37 CFR 1.17(e)
      ii. [ ] Extension of time fee (37 CFR 1.136 and 1.17)
      iii. [ ] Other _____

   b. [ ] Check in the amount of $ _____ enclosed

   c. [ ] Payment by credit card (Form PTO-2038 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.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date	May 21, 2009
Name (Print/Type)	Bruce E. Black	Registration No.	41,622

4294328.1 0209380-US0

PTO/SB/17 (10-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2009

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 810.00

Complete if Known	
Application Number	11/329,907-Conf. #6971
Filing Date	January 11, 2006
First Named Inventor	Janusz A. Kuzma
Examiner Name	D. P. Angwin
Art Unit	3729
Attorney Docket No.	20334/0209380-US0

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 04-0100 Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	330	165	540	270	220	110	
Design	220	110	100	50	140	70	
Plant	220	110	330	165	170	85	
Reissue	330	165	540	270	650	325	
Provisional	220	110	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	52	26
Each independent claim over 3 (including Reissues)	220	110
Multiple dependent claims	390	195

Total Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
20 - 23 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
3 - 4 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims

Fee ($)	**Fee Paid ($)**
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), 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).

Total Sheets	**Extra Sheets**	**Number of each additional 50 or fraction thereof**	**Fee ($)**	**Fee Paid ($)**
_____ - 100 =	_____	/50 = _____ (round **up** to a whole number) x	_____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): 1801 Request for continued examination (RCE) (see 37 ...	810.00

SUBMITTED BY

Signature	R. E. Black	Registration No. (Attorney/Agent)	41,622	Telephone	(206) 262-8908
Name (Print/Type)	Bruce E. Black			Date	May 21, 2009

4294324.1 0209380-US0

Docket No.: 20334/0209380-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D. P. Angwin

AMENDMENT ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION

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

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated April 2, 2009 and in view of the accompanying Request for Continued Examination, please amend the above-identified U.S. patent application as follows:

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

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

1-10. (Cancelled)

11. (Currently Amended) A method of manufacturing a stimulation lead having a proximal end and a distal end comprising:

providing a plurality of conductive contacts located at an end of the stimulation lead;

connecting a conductor wire to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts, wherein the spacers and conductive contacts define a plurality of internal void spaces;

placing monofilament within at least one of the internal void spaces not occupied by the conductor wires;

placing a heat shrink tubing around the spacers, conductive contacts, and monofilament; and

heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of ~~material~~ said at least one of the spacers or monofilament into the internal void spaces not occupied by the conductive contacts and conductive wires.

12. (Original) The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. (Original) The method of claim 12, wherein the monofilament is a thermoplastic material.

14. (Original) The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. (Original) The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. (Original) The method of claim 11, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. (Original) The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. (Original) The method of claim 11, wherein conductive contacts are in the form of rings.

19. (Original) The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. (Original) The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. (Original) The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and

wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

23. (Withdrawn) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and

wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

24. (Previously Presented) The method of claim 11, wherein the monofilament is a different material than the spacers.

25. (Previously Presented) The method of claim 11, wherein the monofilament is the same material as the spacers.

26. (Previously Presented) The method of claim 15, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

27. (Currently Amended) The method of claim 11, wherein the plurality of electrically conductive contacts are located on ~~a~~ the proximal end of the stimulation lead.

28. (Currently Amended) The method of claim 11, wherein the plurality of electrically conductive contacts are located on ~~a~~ the distal end of the stimulation lead.

29. (New) The method of claim 11, wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the internal void spaces are defined within the substantially cylindrical body.

30. (New) The method of claim 11, wherein the monofilament is placed within at least one of the internal void spaces not occupied by the conductor wires and disposed in an orientation parallel to the conductor wires.

REMARKS

This amendment is in response to the Office Action mailed April 2, 2009. Claims 11, 27, and 28 have been amended. New claims 29 and 30 have been added. Claims 11-21 and 22-30 are presently pending. No new matter has been added.

§112 Rejection

Claims 11-21 and 24-28 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11, 27 and 28 have been amended to overcome the rejections. Applicants respectfully request withdrawal of the rejection of claims 11-21 and 24-28.

§103 Rejection

Claims 11-21 and 24-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,216,045 to Black et al. ("Black") in view of U.S. Patent Publication 2005/0215945 to Harris et al. ("Harris"), and U.S. Patent No. 5,555,618 to Winkler ("Winkler"). Claim 28 was rejected as being unpatentable over the cited references and further in view of U.S. Patent No. 6,551,302 to Rosinko et al. ("Rosinko"). The Applicants traverse this rejection.

Claim 11 recites a method of manufacturing a stimulation lead comprising the steps of placing spacers between pairs of adjacent conductive contacts, wherein the spacers and conductive contacts define a plurality of internal void spaces, and placing monofilament within at least one of the internal void spaces not occupied by the conductor wires. Black discloses an implantable lead and method of manufacture. Black does not teach or suggest the step of placing monofilament within the internal void spaces not occupied by the conductor wires. The body 22 is merely an exterior structure for the components of lead 10 and only "serves as a sheath...[and] substantially provides the exterior structure that contains the internalized elements of lead 10" (*see* Black, col. 3, lines 53-57 and Figure 3). Conversely, claim 11 recites that the spacers and conductive contacts define a plurality of internal void spaces and that the monofilament is placed within at least one of the internal void spaces. Accordingly, body 22 is not placed within internal void spaces as recited in claim 11. None of Harris, Winkler and Rosinko address this deficiency of Black.

Claim 11 also recites the step of placing a heat shrink tubing around the spacers, conductive contacts, and monofilament. The Examiner acknowledges that Black does not teach or suggest this step (Office Action, p. 5). Contrary to the assertion in the Office Action, Harris also does not teach or suggest placing a heat shrink tubing around the spacers, conductive contacts and monofilament. Harris merely teaches that a protective outer covering, such as a shrink-wrap may be disposed around the first lead wire 220 and around the second lead wire 230 to protect the wires (Harris, paragraph 0049). Harris does not teach heat shrink tubing being disposed around spacers or monofilament, because Harris does not suggest the use of either element. Winkler and Rosinko fail to address this deficiency of Harris.

Claim 11 further recites the step of heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of said at least one of the spacers or monofilament into the internal void spaces not occupied by the conductive contacts and conductive wires. The Examiner acknowledges that Black does not teach or suggest this step (Office Action, p. 5). Winkler discloses a method of making an electrode-carrying catheter. Winkler does not teach or suggest heating the spacers and monofilament to create reflow of said at least one of the spacers or monofilament into the spaces not occupied by the conductive contacts and conductive wires. Instead, Winkler only discloses that a core-covering outer layer 44 is heated (Winkler col. 6, lines 17-23). However, the core-covering outer layer 44 of Winkler is neither a spacer placed between contacts nor a monofilament disposed within the inner void spaces. Instead, the core-covering layer 44 is an external cover formed "by overextruding a plastic over a core 42" (Winkler col. 5, lines 41-42).

Moreover, the heating that occurs in Winkler temporarily softens a core-covering outer layer 44 at the point where the wire contacts the layer 44 so that the wire may be set when placed under tension (*see* Winkler col. 6, lines 19-23, lines 54-58). There is no indication that the outer layer 44 of Winkler reflows. It is merely softened. Thus, the core-covering layer is neither the spacers nor the monofilament recited in claim 11, and the heating of the layer does not create a reflow of a spacer or a monofilament.

The Office Action asserts that even if Harris does not teach the reflow process of claim 11, "the structure need only be capable of performing this function" (Office Action, p. 6). However, claim 11 is not an apparatus claim, but a method claim, which recites steps that are carried out. Method steps describe functions that are performed. To reject a method claim, the prior art must teach or suggest the recited method steps. Harris does not teach or suggest reflow.

Finally, Winkler does not teach or suggest the step of creating reflow of said at least one of the spacers or monofilament into internal void spaces. Because core-covering layer 44 encapsulates the core 42 and is surrounded by tubing 12, reflow into internal void spaces is not possible. Harris and Rosinko also fail to address this deficiency of Winkler.

For at least these reasons, claim 11, as well as claims 12-21 and 24-30, which depend therefrom, are patentable over the cited references. Applicants respectfully request withdrawal of the rejections of these claims.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner to contact the Applicants' representative, Bruce Black, by telephone to discuss the matter.

Dated: May 21, 2009

Respectfully submitted,

By _____

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Electronic Patent Application Fee Transmittal	
Application Number:	11329907
Filing Date:	11-Jan-2006
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Filer:	Bruce Black/Lisa Small
Attorney Docket Number:	20334/0209380-US0
Filed as Large 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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	810	810
		Total in USD ($)		**810**

Electronic Acknowledgement Receipt	
EFS ID:	5377185
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Lisa Small
Filer Authorized By:	Bruce Black
Attorney Docket Number:	20334/0209380-US0
Receipt Date:	21-MAY-2009
Filing Date:	11-JAN-2006
Time Stamp:	15:02:15
Application Type:	Utility under 35 USC 111(a)

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Payment Type	Deposit Account
Payment was successfully received in RAM	$810
RAM confirmation Number	1125
Deposit Account	040100
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		RCEFeeTransAmendment.PDF	521389 711a56bd590351dc647fd143c146d95e5caf5893	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Request for Continued Examination (RCE)	1	1
Miscellaneous Incoming Letter	2	2
Amendment Submitted/Entered with Filing of CPA/RCE	3	3
Claims	4	7
Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29982 f95cc8d94bcf92218e99df9bef447a9aa106789b	no	2

Warnings:

Information:

Total Files Size (in bytes):	551371

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

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

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/329,907	Filing Date 01/11/2006	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	05/21/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 23	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ 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	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Dorretta Brooks/

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	20334/0209380-US0	6971

50638 7590 04/02/2009

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EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

MAIL DATE	DELIVERY MODE
04/02/2009	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *29 January 2009*.

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

3)☐ 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

4)☒ Claim(s) *11-28* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21 and 24-28* is/are rejected.

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

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

Application Papers

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

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> 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.

Claims 11-21 and 24-28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

a. **Claim 11** recites the following limitations that are vague, indefinite, and confusing:

- "within internal void spaces" (claim 11, line 7) – It is unclear as to what "internal void spaces" the applicant is referring to. This term lacks antecedent basis. In addition, the applicant does not specify what the monofilament is filling - something internal – but the claims are not clear as to what the monofilament is filling. Please be more precise with the claim language.
- "reflow of material" (claim 11, line 12) – It is unclear as to what "material" the applicant is referring to. This term lacks antecedent basis. Please be more precise with the claim language.
- "the internal void spaces" (claim 11, line 13) – It is unclear as to what "internal void spaces" the applicant is referring to. This term lacks antecedent basis. Please be more precise with the claim language.

b. **Claim 27** recites the following limitations that are vague, indefinite, and confusing:

- "a proximal end" (claim 27, line 2) – It is unclear as to what the "proximal end" is proximal to. The term "proximal" is a relative term. For example, the examiner is unclear as to whether the "proximal end" is proximal to the attachment location in the body, a handle, a base, or another object. Please be more precise with the claim language.

c. **Claim 28** recites the following limitations that are vague, indefinite, and confusing:

- "a distal end" (claim 28, line 2) – It is unclear as to what the "distal end" is distal to. The term "distal" is a relative term. For example, the examiner is unclear as to whether the "distal end" is distal to the attachment location in the body, a handle, a base, or another object. Please be more precise with the claim language.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that 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 taught 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-21 and 24-28, as best understood, are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Harris et al* (US Patent Publication 2005/0215945) and *Winkler* (US Patent 5,555,618).

a. *Black et al* discloses in his reference the following:

i. providing a plurality of conductive contacts (Figs. 2 and 5, item 16) located at an end (item 12) of the stimulation lead;

ii. connecting a conductor wire (Fig. 3-5, item 20) to each of the conductive contacts (2:20-25);

iii. placing spacers (Fig. 5, item 30) between pairs of adjacent conductive contacts;

iv. placing monofilament (3:45-54) within internal void spaces not occupied by the conductive wires (*the examiner notes that the monofilament occupies void spaces that are internal to the diameter of the stimulation lead*);

v. either the spacers or monofilament is polyurethane (3:45-54);

vi. the spacers are oversized in diameter, relative to a predetermined final diameter of the lead (Figs. 2-4, 5, and 8, item 30);

vii. the conductive contacts are in the form of rings (Figs. 1-5);

viii. the conductive contacts are electrode contacts on the lead (Figs. 1-5, item 16);

ix. the conductive contacts are connector contacts on the proximal end of the lead (Figs. 1-5, item 16);

x. the step of connecting a connecting wire to each of the electrode contacts ins accomplished by welding each conductor wire to each respective contact (6:58-62);

xi. the plurality of electrically conductive contacts are located on a proximal end of the stimulation lead (Figs. 2 and 5; *proximal to stylet (item 100)*); and

xii. the plurality of electrically conductive contacts are located on a distal end of the stimulation lead (Figs. 2 and 5; *distal to electrodes (item 18)*; *in the alternative*, Figs. 2 and 5, item 18).

b. Regarding claim 1, in addition to the above limitations, *Black et al* as modified may not expressly disclose in his reference placing a heat shrink tubing around the spacers, conductive contacts, and monofilament.

i. However, *Harris et al* teaches in his reference placing a heat shrink tubing around the internal portion of a catheter (49:31-31). The advantage of placing a heat shrink tubing around the internal portion of a catheter is to protect the inner portion from the environment. Therefore, it would have been obvious to place a heat shrink tubing around the spacers, conductive contacts, and monofilament, to protect the inner portion from the environment.

c. Regarding claim 1, in addition to the above limitations, *Black et al* as modified may not expressly disclose in his reference heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive traces.

i. However, *Winkler* teaches in his reference heating an electrode carrying catheter (Figs. 2-3; 6:17-30). The advantage of heating

the electrode carrying catheter is to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive traces to allow the internal wires to embed in the plastic (6:17-30; 6:54-58). Therefore, it would have been obvious to heat the spacers and monofilament to a temperature to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive traces to allow the internal wires to embed in the plastic.

ii. The examiner notes that the language "to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive wires" (claim 11, lines 12-13) is functional language. As a result, the structure need only be capable of performing this function.

d. Regarding claim 13, in addition to the limitations in claim 12, *Black et al* as modified may not expressly disclose in his reference that the monofilament is a thermoplastic material.

i. However, *Winkler* teaches in his reference that the core covering layer is a thermoplastic (6:17-30). The advantage of making the core-covering layer a thermoplastic is to effectively embed the wires into the core-covering layer (6:17-30). Therefore, it would have been obvious to make the core-covering layer a thermoplastic to effectively embed the wires into the core-covering layer.

e. Regarding claims 14-15 and 26, in addition to the limitations in claim 13, *Black et al* as modified may not expressly disclose in his reference that the heat applied is between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds.

i. However, *Winkler* teaches in his reference that the heat applied is between about 140 C to 250 C (6:17-30). The advantage of applying heat between about 140 C to 250 C is to melt the thermoplastic and embed the wires. Therefore, it would have been

obvious to apply heat between about 140 C to 250 C to melt the thermoplastic and embed the wires.

ii. In addition, the examiner notes that temperature, time, and material are result effective variables that determine when a thermoplastic becomes melted and vary depending upon the conditions that are used. If one were to vary any one of these variables, one of ordinary skill in the art would know that the remaining result effective variables (temperature, time, and material) would also need to be varied. Therefore, it would have been obvious to one of ordinary skill in the art to vary the result effective variables (temperature, time, and material) accordingly. As a result, it would have been obvious to vary the temperature, time, and material, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. MPEP 2144.05.

iii. Further, the applicant has not disclosed that heat applied between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds solves any stated problem or provides any unexpected results. As such, the examiner considers this limitation to be a design choice. Therefore, it would have been obvious as a matter of design choice to apply heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, since the applicant has not disclosed that applying heat between about 140 C to 250 C, for about 15 to 120 seconds, or for about 160 C for about 40 seconds, solves any stated problem or provides any unexpected results, and it appears that the method of making the catheter would perform equally well if another heat cycle like taught in *Winkler et al* had been utilized.

f. Regarding claim 16, in addition to the limitations in claim 11, *Black et al* as modified may not expressly disclose in his reference making the heat shrink tubing from either PTFE or polyester.

i. However, *Nelson et al* teaches in his reference making the heat shrink material from PTFE (9:28-33). The advantage of making the heat shrink material from PTFE is to utilize a well known heat shrink material. Therefore, it would have been obvious to make the heat

shrink material from PTFE to utilize a well known heat shrink material.

g. Regarding claim 24, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is a different material than the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament can be different material than the spacers but with the same mechanical properties (7:18-24). The advantage of making the monofilament from a different material than the spacers is to utilize a cheaper but less effective material for either the monofilament or the spacers. Therefore, it would have been obvious to make the monofilament from a different material than the spacers to utilize a cheaper but less effective material for either the monofilament or the spacers.

h. Regarding claim 24, in addition to the limitations in claim 11, *Black et al* may not expressly disclose in his reference that the monofilament is the same material as the spacers.

i. However, *Black et al* further discloses in his reference that the monofilament is made of a mechanically equivalent material to that of the spacers (7:18-24). The advantage of making the monofilament from the same material as the spacers is to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials. Therefore, it would have been obvious to make the monofilament from the same material than the spacers to take advantage of cost savings associated with buying larger quantities of one material and to simplify the manufacturing process with fewer materials.

In the alternative, **claim 28**, as best understood, is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Harris et*

al (US Patent Publication 2005/0215945) and *Winkler* (US Patent 5,555,618) and further in view of *Rosinko et al* (US Patent 6,551,302).

a. Regarding claim 28, in addition to the limitations in claim 11, *Black et al* may not expressly disclose the plurality of conductive contacts are located on a distal end of the stimulation lead.

i. However, *Rosinko et al* teaches in his reference a handle for a catheter located at a distal end of a stimulation lead (Figs. 1 and 7A). The advantage of utilizing a handle located at a distal end of a stimulation lead is to make a steerable catheter. Therefore, it would have been obvious to design a plurality of conductive contacts located on a distal end of the stimulation lead to make a steerable catheter.

Response to Arguments

Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive.

The applicant argues that the references do not teach the step of placing monofilament within internal void spaces not occupied by the conductor wires (applicant's arguments, 5:22-23). However, the examiner disagrees. The monofilament in *Black et al* fills internal spaces of the stimulation lead (Figs. 1-6). Therefore, the examiner maintains the rejection.

Second, the applicant argues that the references do not disclose heating the spacers and monofilament to a temperature… to create reflow of material (6:13-16). However, the examiner disagrees. *Winkler et al* teaches reflowing of material into the internal void spaces not occupied by the conductive contacts and conductive wires (Figs. 2-3; 6:17-30; 6:54-58). Therefore, the examiner maintains the rejection.

Other arguments made by the applicant are addressed above by new references.

Conclusion

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.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin, whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant, can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA
March 29, 2009

Notice of References Cited	Application/Control No. 11/329,907	Applicant(s)/Patent Under Reexamination KUZMA ET AL.	
	Examiner DAVID P. ANGWIN	Art Unit 3729	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,216,045	04-2001	Black et al.	607/122
*	B	US-2005/0215945	09-2005	Harris et al.	604/066
*	C	US-5,555,618	09-1996	Winkler, Josef	29/825
*	D	US-6,551,302	04-2003	Rosinko et al.	604/505
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	Art Unit
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008	03/28/2009						
	1	÷	N	-						
	2	÷	N	-						
	3	÷	N	-						
	4	÷	N	-						
	5	÷	N	-						
	6	÷	N	-						
	7	÷	N	-						
	8	÷	N	-						
	9	÷	N	-						
	10	÷	N	-						
	11	÷	✓	✓						
	12	÷	✓	✓						
	13	÷	✓	✓						
	14	÷	✓	✓						
	15	÷	✓	✓						
	16	÷	✓	✓						
	17	÷	✓	✓						
	18	÷	✓	✓						
	19	÷	✓	✓						
	20	÷	✓	✓						
	21	÷	✓	✓						
	22	÷	N	N						
	23	÷	N	N						
	24			✓						
	25			✓						
	26			✓						
	27			✓						
	28			✓						

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/329,907	01/11/2006	Janusz A. Kuzma	AB-561U

CONFIRMATION NO. 6971

POA ACCEPTANCE LETTER

50638
Boston Scientific Neuromodulation Corp.
c/o DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
NEW YORK, NY 10008-0770

OC000000034255975

Date Mailed: 01/29/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/23/2009.

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.

/tle/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/329,907	01/11/2006	Janusz A. Kuzma	AB-561U

CONFIRMATION NO. 6971

POWER OF ATTORNEY NOTICE

23845
ADVANCED BIONICS, LLC
IP Dept. - Bryant Gold
25129 RYE CANYON LOOP
VALENCIA, CA 91355

OC000000034255956

Date Mailed: 01/29/2009

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/23/2009.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/tle/

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

Docket No.: 20334/0209380-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 — Confirmation No.: 6971

Filed: January 11, 2006 — Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME — Examiner: D. P. Angwin

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

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

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated November 17, 2008, please amend the above-identified U.S. patent application as follows:

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

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

1-10. (Cancelled)

11. (Currently Amended) A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at ~~the proximal~~ an end of the stimulation lead;

connecting a conductor wire to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts;

placing monofilament within internal void spaces not occupied by [[a]] the conductor wires~~, wherein the monofilament is a different material than the spacers~~;

placing a heat shrink tubing around the spacers, conductive contacts, and monofilament; and

heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive wires.

12. (Original) The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. (Original) The method of claim 12, wherein the monofilament is a thermoplastic material.

14. (Original) The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. (Original) The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. (Original) The method of claim 11, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. (Original) The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. (Original) The method of claim 11, wherein conductive contacts are in the form of rings.

19. (Original) The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. (Original) The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. (Original) The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22. (Withdrawn-Currently Amended) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts <u>on an end of the stimulation lead</u>;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and

wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

23. (Withdrawn-Currently Amended) A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts on an end of the stimulation lead;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and

wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

24. (New) The method of claim 11, wherein the monofilament is a different material than the spacers.

25. (New) The method of claim 11, wherein the monofilament is the same material as the spacers.

26. (New) The method of claim 15, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

27. (New) The method of claim 11, wherein the plurality of electrically conductive contacts are located on a proximal end of the stimulation lead.

28. (New) The method of claim 11, wherein the plurality of electrically conductive contacts are located on a distal end of the stimulation lead.

REMARKS

This amendment is in response to the Office Action mailed November 17, 2008. Claims 11, 22, and 23 have been amended. Claims 24-28 have been added. Claims 1-10 have been cancelled without prejudice. Claims 11-28 are presently pending. No new matter has been added.

Restriction Requirement

Applicants have introduced new dependent claims 24 and 25. These new claims link claims 22 and 23 to the pending claim set . In light of the new dependent claims, claims 22 and 23 are directed to the stimulation lead assembly recited in the method claims. Accordingly, Applicants request rejoinder of claims 22 and 23.

§112 Rejection

Claims 11-21 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 has been amended to overcome this rejection. Applicants respectfully request withdrawal of the rejection of claims 11-21.

§103 Rejection

Claims 11-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,216,045 to Black et al. ("Black") in view of U.S. Patent No. 6,249,708 to Nelson et al. ("Nelson") and U.S. Patent No. 5,555,618 to Winkler ("Winkler"). The Applicants traverse this rejection.

Claim 11 recites a method of manufacturing a stimulation lead comprising the step of placing monofilament within internal void spaces not occupied by the conductor wires. Black discloses an implantable lead and method of manufacture. Black does not teach or suggest the step of placing monofilament within internal void spaces not occupied by the conductor wires. The Examiner appears to assert that body 22 of Black corresponds to the monofilament of claim 11. Black never teaches or suggests that body 22 is a monofilament. Moreover, the body 22 is merely an exterior structure for the components of lead 10. Body 22 only "serves as a sheath...[and]

substantially provides the exterior structure that contains the internalized elements of lead 10" (*see* Black, col. 3, lines 53-57 and Figure 3). Because body 22 is an external structure, it is not placed within internal void spaces not occupied by the conductor wires. Accordingly, body 22 is not the monofilament recited in claim 11. Neither Nelson nor Winkler address this deficiency of Black.

Claims 11 also recites the step of placing a heat shrink tubing around the spacers, conductive contacts, and monofilament. The Examiner acknowledges that Black does not teach or suggest this step (Office Action, p. 5). Contrary to the assertion in the Office Action, Nelson also does not teach or suggest placing a heat shrink tubing around the spacers, conductive contacts and monofilament. Rather, the shrink tubing of Nelson is only placed over an RV shocking electrode to seal against rubber ingress into the shocking electrode coil during molding (Nelson, col. 9, lines 28-32). No shrink tubing is used around spacers or monofilaments because Nelson does teach or suggest the use of either element. Winkler fails to address this deficiency of Nelson.

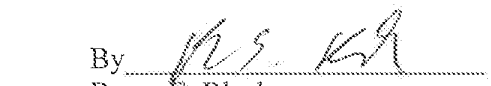
Claims 11 further recites the step of heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to create reflow of material into the internal void spaces not occupied by the conductive contacts and conductive wires. The Examiner acknowledges that Black does not teach or suggest this step (Office Action, p. 5-6). Winkler discloses a method of making an electrode-carrying catheter. Winkler does not teach or suggest heating the spacers and monofilament to create reflow of material between the spaces not occupied by the conductive contacts and conductive wires. Instead, the heating that occurs in Winkler temporarily softens a core-covering outer layer 44 (*see* Winkler col. 6, lines 54-58). Furthermore, the purpose of the heating is to allow embedding of a wire that is wrapped around the core-covering layer and not to create reflow of material between the spaces not occupied by the conductive contacts and conductive wires (*see* Winkler col. 5, lines 53-67). Winkler does not teach or suggest that the core-covering outer layer 44 reflows at all. The core-covering outer layer is only softened, not melted or reflowed. Nelson fails to address this deficiency of Winkler.

For at least these reasons, claim 11, as well as claims 12-21 and 24-28, which depend therefrom, are patentable over the cited references. Applicants respectfully request withdrawal of the rejections of these claims.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner to contact the Applicants' representative, Bruce Black, by telephone to discuss the matter.

Dated: January 29, 2009

Respectfully submitted,

By 

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Attorneys/Agents For Applicant

PTO/SB/96 (12-08)
Approved for use through 01/31/2009. OMB 0651-0031
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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Boston Scientific Neuromodulation Corporation

Application No./Patent No.: 11/329,907 Filed/Issue Date: January 11, 2006

Entitled: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Boston Scientific Neuromodulation Corporation (Name of Assignee) , a Corporation (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. [X] the assignee of the entire right, title, and interest; or

2. [ ] an assignee of less than the entire right, title and interest.
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 021845, Frame 0966, or for which a copy thereof is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

[X] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature	January 29, 2009 Date
Bruce E. Black Printed or Typed Name	(206) 262-8908 Telephone Number
Attorney for Assignee Title	

3762855.1 0209380-US0

PTO/SB/80 (01-06)
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

[X] Practitioners associated with the Customer Number: 50638

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

[X] The address associated with Customer Number: 50638

OR

[ ] Firm or Individual Name

Address					
City		State		Zip	
Country		Telephone		Email	

Assignee Name and Address:

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, California 91355

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Philip H Lee	Date	August 5, 2008
Name	Philip H. Lee	Telephone	(661) 949-4134
Title	Patent Counsel		

{S:\20334\9420334-000\80183165.DOC *203349420334-000* }

Electronic Acknowledgement Receipt

EFS ID:	4698065
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	50638
Filer:	Bruce Black/Lisa Small
Filer Authorized By:	Bruce Black
Attorney Docket Number:	AB-561U
Receipt Date:	29-JAN-2009
Filing Date:	11-JAN-2006
Time Stamp:	14:32:08
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		TransAmendment373bPOA.PDF	645484 7c08a646cc25227cb874dcd1fedbfc9528611c7b	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Amendment/Req. Reconsideration-After Non-Final Reject	2	2
	Claims	3	5
	Applicant Arguments/Remarks Made in an Amendment	6	8
	Assignee showing of ownership per 37 CFR 3.73(b).	9	9
	Power of Attorney	10	10
Warnings:			
Information:			
	Total Files Size (in bytes):	645484	

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.

AMENDMENT TRANSMITTAL LETTER

Docket No. 20334/0209380-US0

Application No.	Filing Date	Examiner	Art Unit
11/329,907-Conf. #6971	January 11, 2006	D. P. Angwin	3729

Applicant(s): Janusz A. Kuzma

Invention: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an Amendment, Power of Attorney, and Statement under 37 CFR 3.73(b) in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	18	- 23 =	0	x 52.00	0.00
Independent Claims	3	- 4 =	0	x 220.00	0.00
Multiple Dependent Claims (check if applicable)	☐				
Other fee (please specify):					
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:					0.00

☒ Large Entity ☐ Small Entity

☒ No additional fee is required for this amendment.

☐ Please charge Deposit Account No. _____ in the amount of $ _____
A duplicate copy of this sheet is enclosed.

☐ A check in the amount of $ _____ to cover the filing fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director is hereby authorized to charge and credit Deposit Account No. 04-0100 as described below.

☒ Credit any overpayment.

☒ Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.

Dated: January 29, 2009

Bruce E. Black
Attorney/Agent Reg. No.: 41,622

DARBY & DARBY P.C.
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New York, New York 10008-0770
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PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/329,907	01/11/2006	

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			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			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 $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	01/29/2009	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 23	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***4	= 0	X $ =		OR	X $220=	0
	☐ 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	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/EVELYN G. NIMMONS/

PTO/SB/80 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

[X] Practitioners associated with the Customer Number: 50638

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

[X] The address associated with Customer Number: 50638

OR

[ ] Firm or Individual Name

Address					
City		State		Zip	
Country		Telephone		Email	

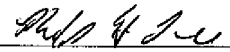
Assignee Name and Address:

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, California 91355

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	August 5, 2008
Name	Philip H. Lee	Telephone	(661) 949-4134
Title	Patent Counsel		

{S:\20334\9420334-000\80183165.DOC *203349420334-000* }

PTO/SB/96 (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Janusz A. Kuzma, et al.

Application No./Patent No.: 11/329,907 Filed/Issue Date: January 11, 2006

Entitled: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Boston Scientific Neuromodulation Corporation (Name of Assignee) , a Corporation (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. [x] the assignee of the entire right, title, and interest; or

2. [ ] an assignee of less than the entire right, title and interest.
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A. [x] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 021845 , Frame 0966 , or for which a copy thereof is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

[x] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.,* a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Flynn Barrison 53,970/	January 22, 2009
Signature	Date
Flynn Barrison	(212) 527-7700
Printed or Typed Name	Telephone Number
Authorized Agent for Assignee	
Title	

3750525.1 9420334-000

Electronic Acknowledgement Receipt

EFS ID:	4662283
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	23845
Filer:	Flynn Barrison/Brandi Jacobs-Glykis
Filer Authorized By:	Flynn Barrison
Attorney Docket Number:	AB-561U
Receipt Date:	23-JAN-2009
Filing Date:	11-JAN-2006
Time Stamp:	09:22:50
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		POA_STATEMENT1.pdf	53620 4be2352d3fc42e070618eec5ad71235139e2665c	yes	2

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Power of Attorney	1	1
	Assignee showing of ownership per 37 CFR 3.73(b).	2	2
Warnings:			
Information:			
	Total Files Size (in bytes):	53620	

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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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/329,907	01/11/2006	Janusz A. Kuzma	AB-561U	6971

23845 7590 11/17/2008

ADVANCED BIONICS, LLC
25129 RYE CANYON LOOP
VALENCIA, CA 91355

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

MAIL DATE	DELIVERY MODE
11/17/2008	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *15 October 2008*.

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

3)☐ 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

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-10,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *11 January 2006* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species II (claims 11-21) in the reply filed on 10/15/08 is acknowledged. The traversal is on the grounds that the species are not mutually exclusive is also acknowledged. However, this is not found persuasive because each species is mutually exclusive. Specifically, Species I requires conductive contacts at the distal ends of the stimulation lead which is not required by Species II, III, or IV, and also requires a heat shrink tubing which is not required by Species III and IV. Species II requires conductive contacts at the proximal ends of the stimulation lead which is not required by Species I, III, or IV, and also requires a heat shrink tubing which is not required by Species III or IV. Species III requires a monofilament made of the same insulative material as the spacer which is not required by Species I, II, or IV. Finally, Species IV requires a monofilament made of a different insulative material as the spacer which is not required by Species I, II, or III.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/15/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> 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.

Claims 11-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

a. **Claim 11** recites the following limitations that are vague, indefinite, and confusing:

- "the proximal end" (claim 11, line 2) – It is unclear as to what "proximal end" the applicant is referring to because this term lacks antecedent basis. Please be more precise with the claim language.
- "a conductor wire" (claim 11, lines 6-7) – It is unclear as to whether the "conductor wire" is referring to the "conductor wire" already introduced in line 4, or is presenting a new "conductor wire." Please be more precise with the claim language.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) that 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 taught 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-21, as best understood, are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Black et al* (US Patent 6,216,045) in view of *Nelson et al* (US Patent 6,249,708) and *Winkler* (US Patent 5,555,618).

a. *Black et al* discloses in his reference the following:

i. providing a plurality of conductive contacts (Figs. 2 and 5, item 16) located at the proximal end (item 12) of the stimulation lead;

ii. connecting a conductor wire (Fig. 3-5, item 20) to each of the conductive contacts (2:20-25);

iii. placing spacers (Fig. 5, item 30) between pairs of adjacent conductive contacts;

iv. placing monofilament (3:45-54) within void spaces not occupied by a conductive wire;

v. either the spacers or monofilament is polyurethane (3:45-54);

vi. the spacers are oversized in diameter, relative to a predetermined final diameter of the lead (Figs. 2-4, 5, and 8, item 30);

vii. the conductive contacts are in the form of rings (Figs. 1-5);

viii. the conductive contacts are electrode contacts on the lead (Figs. 1-5, item 16);

ix. the conductive contacts are connector contacts on the proximal end of the lead (Figs. 1-5, item 16); and

x. the step of connecting a connecting wire to each of the electrode contacts ins accomplished by welding each conductor wire to each respective contact (6:58-62).

b. In addition to the above limitations, *Black et al* does not expressly disclose in his reference that the monofilament is a different material than the spacers.

i. However, *Black et al* teaches in his reference that the monofilament can be different material than the spacers but with the same mechanical properties (7:18-24). The advantage of making the monofilament from a different material than the spacers is to utilize a cheaper but less effective material for either the monofilament or the spacers. Therefore, it would have been obvious to make the monofilament from a different material than the spacers to utilize a cheaper but less effective material for either the monofilament or the spacers.

c. In addition to the above limitations, *Black et al* as modified does not expressly disclose in his reference placing a heat shrink tubing around the spacers, conductive contacts, and monofilament.

i. However, *Nelson et al* teaches in his reference placing a heat shrink tubing around the spacers, conductive contacts, and monofilament (9:28-33). The advantage of placing a heat shrink tubing around the spacers, conductive contacts, and monofilament is to seal against rubber ingress into the shocking electrode during the molding process. Therefore, it would have been obvious to place a heat shrink tubing around the spacers, conductive contacts, and monofilament to seal against rubber ingress into the shocking electrode during the molding process.

d. In addition to the above limitations, *Black et al* as modified does not expressly disclose in his reference heating the spacers and monofilament

to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

i. However, *Winkler* teaches in his reference heating an electrode carrying catheter (Figs. 2-3; 6:17-30). The advantage of heating the electrode carrying catheter is to soften the plastic to allow the internal wires to embed in the plastic (6:54-58). Therefore, it would have been obvious to heat the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament to soften the plastic to allow the internal wires to embed in the plastic.

e. Regarding claim 13, in addition to the limitations in claim 12, *Black et al* as modified does not expressly disclose in his reference that the monofilament is a thermoplastic material.

i. However, *Winkler* teaches in his reference that the core covering layer is a thermoplastic (6:17-30). The advantage of making the core-covering layer a thermoplastic is to effectively embed the wires into the core-covering layer (6:17-30). Therefore, it would have been obvious to make the core-covering layer a thermoplastic to effectively embed the wires into the core-covering layer.

f. Regarding claim 14, in addition to the limitations in claim 13, *Black et al* as modified does not expressly disclose in his reference that the heat applied is between about 140 C to 250 C.

i. However, *Winkler* teaches in his reference that the heat applied is between about 140 C to 250 C (6:17-30). The advantage of applying heat between about 140 C to 250 C is to melt the thermoplastic and embed the wires. Therefore, it would have been obvious to apply heat between about 140 C to 250 C to melt the thermoplastic and embed the wires.

g. Regarding claim 15, in addition to the limitations in claim 14, *Black et al* as modified does not expressly disclose in his reference that the heat is applied for between about 15 to 120 seconds.

i. However, the examiner takes Official Notice that temperature, pressure, and time are result effective variables that determine when a thermoplastic becomes melted. Therefore, temperature, pressure, and time are result effective variables that vary depending upon the conditions that is used. If one were to vary any one of these variables, one of ordinary skill in the art would know that the remaining result effective variables (temperature, pressure, and time) would also need to be varied. Therefore, it would have been obvious to one of ordinary skill in the art to vary the result effective variables (temperature, pressure, and time) accordingly. As a result, it would have been obvious to vary the heating time, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. MPEP 2144.05.

h. Regarding claim 16, in addition to the limitations in claim 11, *Black et al* as modified does not expressly disclose in his reference making the heat shrink tubing from either PTFE or polyester.

i. However, *Nelson et al* teaches in his reference making the heat shrink material from PTFE (9:28-33). The advantage of making the heat shrink material from PTFE is to utilize a well known heat shrink material. Therefore, it would have been obvious to make the heat shrink material from PTFE to utilize a well known heat shrink material.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin, whose telephone number is (571) 270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant, can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/A. Dexter Tugbang/
Primary Examiner
Art Unit 3729

DPA

Notice of References Cited	Application/Control No. 11/329,907	Applicant(s)/Patent Under Reexamination KUZMA ET AL.	
	Examiner DAVID P. ANGWIN	Art Unit 3729	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,216,045	04-2001	Black et al.	607/122
*	B	US-6,249,708	06-2001	Nelson et al.	607/122
*	C	US-5,555,618	09-1996	Winkler, Josef	29/825
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

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BIB DATA SHEET

CONFIRMATION NO. 6971

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/329,907	01/11/2006	257	3729	AB-561U

APPLICANTS

Janusz A. Kuzma, Parker, CO;
Anne M. Pianca, Valencia, CA;

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

This appln claims benefit of 60/643,093 01/11/2005

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

02/16/2006

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /DAVID PATRICK ANGWIN/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CO	5	23	4

ADDRESS

ADVANCED BIONICS, LLC
25129 RYE CANYON LOOP
VALENCIA, CA 91355
UNITED STATES

TITLE

Electrode array assembly and method of making same

FILING FEE RECEIVED		
1350	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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	Art Unit
	DAVID P ANGWIN	3729

SEARCHED			
Class	Subclass	Date	Examiner
29	825	11/12/08	DPA

SEARCH NOTES		
Search Notes	Date	Examiner

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008	11/12/2008							
	1	÷	N							
	2	÷	N							
	3	÷	N							
	4	÷	N							
	5	÷	N							
	6	÷	N							
	7	÷	N							
	8	÷	N							
	9	÷	N							
	10	÷	N							
	11	÷	✓							
	12	÷	✓							
	13	÷	✓							
	14	÷	✓							
	15	÷	✓							
	16	÷	✓							
	17	÷	✓							
	18	÷	✓							
	19	÷	✓							
	20	÷	✓							
	21	÷	✓							
	22	÷	N							
	23	÷	N							

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1806	29/825.ccls.	US-PGPUB; USPAT; USOCR	AND	ON	2008/11/12 19:12
S1	6	("3769984" OR "5555618" OR "6055456" OR "6205361" OR "6216045" OR "6249708").pn.	US-PGPUB; USPAT; USOCR	AND	ON	2008/11/11 17:57

11/12/2008 7:24:07 PM
C:\Documents and Settings\dangwin\My Documents\Critical Data\EAST\Workspaces\11329907.wsp

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	11/329/907
Filing Date	January 11, 2006
First Named Inventor	Janusz A. Kuzma, et al.
Art Unit	2811
Examiner Name	not assigned
Attorney Docket	05-01302-02

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A 1	US-3,769,984	11-06-1973	Muench	
	A 2	US-5,555,618	09-17-1996	Winkler	
	A 3	US-6,055,456	04-25-2000	Gerber	
	A 4	US-6,205,361	03-20-2001	Baudino, et al.	
	A 5	US-6,216,045 B1	04-10-2001	Black, et al.	
	A 6	US-6,249,708 B1	06-19-2001	Nelson, et al.	

Examiner Signature	/David Angwin/	Date Considered	11/12/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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

Electronic Acknowledgement Receipt

EFS ID:	4121525
Application Number:	11329907
International Application Number:	
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor/Applicant Name:	Janusz A. Kuzma
Customer Number:	23845
Filer:	Marie Louise Collazo/Judy Yeddo
Filer Authorized By:	Marie Louise Collazo
Attorney Docket Number:	AB-561U
Receipt Date:	15-OCT-2008
Filing Date:	11-JAN-2006
Time Stamp:	18:07:07
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		Response_and_Transmittal_as_efiled.PDF	1835163 a77dd82c9dfc288bb71d87cd4e7527d954196486	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Response to Election / Restriction Filed	2	3
Warnings:			
Information:			
	Total Files Size (in bytes):	1835163	

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.

Docket No.: 20334/0209380-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Janusz A. Kuzma et al.

Application No.: 11/329,907 | Confirmation No.: 6971

Filed: January 11, 2006 | Art Unit: 3729

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME | Examiner: D.P. Angwin

RESPONSE TO RESTRICTION REQUIREMENT

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

Dear Sir:

In the restriction requirement set forth in the Office Action mailed September 18, 2008, the Examiner has required election of a species selected from:

Species I – method of manufacturing a stimulation lead with contacts at distal end;

Species II – method of manufacturing a stimulation lead with contacts at proximal end;

Species III – stimulation lead assembly with monofilament made of same insulative material; and

Species IV – stimulation lead assembly with monofilament made of different insulative material.

The Applicant elects Species II with traverse. Claims 11-21 read on Species II. The Applicant traverses because, contrary to the assertion in the Office Action, the species do not have

mutually exclusive characteristics. (See, M.P.E.P. §806.04(f).) For example Species II is directed to manufacturing a stimulation lead with contacts at the proximal end and Species I is directed to manufacturing a stimulation lead with contacts at the distal end. These two Species do not have mutually exclusive characteristics because both methods can be practiced on the same stimulation lead with contacts on both the proximal and distal ends; for example, a lead with contacts for connecting to an implantable pulse generator on the proximal end and contacts acting as electrodes on the distal end.

Moreover, both Species I and II can utilize monofilament (recited in both claims 1 and 11) made of the same insulative material as the spacers (Species III) or made of different insulative material than the spacers (Species IV). Accordingly, Species III and IV do not have mutually exclusive characteristics with respect to Species I and II. (Only Species III and IV have mutually exclusive characteristics with respect to each other because the monofilament can not be both the same insulative material and a different insulative material than the spacers.)

Moreover, the Office Action fails to establish an examination burden as described in M.P.E.P. §808.02 because the Office Action fails to establish separate classification; separate status in the art; or a different field of search. Accordingly, the Office Action fails to set forth a valid *prima facie* case for requiring an election of species. Therefore, the Applicant respectfully requests rejoinder, and examination, of Species I, III, and IV with elected Species II.

Dated: October 15, 2008

Respectfully submitted,

By _____

Bruce E. Black, Ph.D.
Registration No.: 41,622
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(206) 262-8908
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant

AMENDMENT TRANSMITTAL LETTER

Docket No. 20334/0209380-US0

Application No.	Filing Date	Examiner	Art Unit
11/329,907-Conf. #6971	January 11, 2006	D. P. Angwin	3729

Applicant(s): Janusz A. Kuzma et al.

Invention: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is a Response in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED						
	Claims Remaining After Amendment	Highest Number Previously Paid		Number Extra Claims Present	Rate	
Total Claims	23	- 23	=	0	x 52.00	0.00
Independent Claims	4	- 4	=	0	x 220.00	0.00
Multiple Dependent Claims (check if applicable) ☐						
Other fee (please specify):						
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:						0.00

[x] Large Entity ☐ Small Entity

[x] No additional fee is required for this amendment.

☐ Please charge Deposit Account No. _____ in the amount of $ _____.
A duplicate copy of this sheet is enclosed.

☐ A check in the amount of $ _____ to cover the filing fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

[x] The Director is hereby authorized to charge and credit Deposit Account No. 04-0100 as described below.

[x] Credit any overpayment.

[x] Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.

Dated: October 15, 2008

Bruce E. Black, Ph.D.
Attorney/Agent Reg. No.: 41,622

DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(206) 262-8908

{S:\20334\0209380-us0\80193215.DOC }

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.
11/329,907	01/11/2006	Janusz A. Kuzma	AB-561U	6971

23845 7590 09/18/2008
ADVANCED BIONICS, LLC
25129 RYE CANYON LOOP
VALENCIA, CA 91355

EXAMINER	
ANGWIN, DAVID PATRICK	
ART UNIT	PAPER NUMBER
3729	

MAIL DATE	DELIVERY MODE
09/18/2008	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)	
	11/329,907	KUZMA ET AL.	
	Examiner	Art Unit	
	DAVID P. ANGWIN	3729	

-- 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 *1* 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 *11 January 2006*.

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

3)☐ 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

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

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

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

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

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

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

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

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

This application contains claims directed to the following patentably distinct species:

I. **Species I** – method of manufacturing a stimulation lead with contacts at distal end (specification paragraphs [0008] and [0009]; believed to correspond to **claims 1-10**);

II. **Species II** – method of manufacturing a stimulation lead with contacts at proximal end (specification paragraph [0010]; believed to correspond to **claims 11-21**);

III. **Species III** – stimulation lead assembly with monofilament made of same insulative material (paragraph [0012]; believed to correspond to **claim 22**; and

IV. **Species IV** – stimulation lead assembly with monofilament made of different insulative material (paragraph [0013], believed to correspond to **claim 23**).

In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. No claims are believed to be generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve 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 election of species 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 on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species 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 species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Angwin whose telephone number is 571-270-3735. The examiner can normally be reached on 7:30 AM - 5 PM (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 571-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/Peter Vo/
Peter Vo
Supervisory Patent Examiner
Art Unit 3729

DPA
/Peter Vo/
Supervisory Patent Examiner, Art Unit 3729

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11329907	KUZMA ET AL.
	Examiner	**Art Unit**
	DAVID P ANGWIN	3729

✓	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	09/14/2008								
	1	÷								
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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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APR 07 2008

OFFICE OF PETITIONS

ADVANCED BIONICS, LLC
25129 RYE CANYON LOOP
VALENCIA, CA 91355

In re Application of :
Janusz A. KUZMA, et al :
Application No. 11/329,907 : DECISION ON PETITION
Filed: January 11, 2006 : TO WITHDRAW
Attorney Docket No. AB-56IU : FROM RECORD

This is a decision on the Request to Withdraw as attorney or agent of record under 37 C.F.R. § 1.36(b), filed February 15, 2008.

The request is **NOT APPROVED**.

The Office cannot approve the request at this time since the reason provided does not meet any of the conditions under the mandatory or permissive categories enumerated in 37 CFR 10.40. Section 10.40 of Title 37 of the Code of Federal Regulation states, "a practitioner shall not withdraw from employment in a proceeding before the Office without permission from the Office." More specifically, 37 CFR 10.40 states, "if paragraph (b) of this section is not applicable, a practitioner may not request permission to withdraw in matter pending before the Office unless such request or such withdrawal is" for one the permissive reasons listed in 37 CFR 10.40(c). The reason set forth in the request, ownership transfer, does not meet any of the conditions set forth in 37 CFR 10.40.

All future communications from the Office will continue to be directed to the above-listed address until otherwise notified by applicant.

Telephone inquiries concerning this decision should be directed to the undersigned at 571-272-6735.

Diane Goodwyn
Petitions Examiner
Office of Petitions

Attorney's Docket No.: 10527-783002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :
Serial No. : 11/329,907
Filed : 1/11/2006
Patent No. :
Issue Date :
Title : Electrode Array Assembly and Method of Making Same

Art Unit : Unknown
Examiner : Unknown

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

REQUEST FOR WITHDRAWAL AS ATTORNEY OR AGENT

Applicant hereby submits the attached Request for Withdrawal as Attorney or Agent for the above referenced patent application, listed in the attached Schedule, titled "Withdrawal Schedule for Bryant R. Gold and Laura Haburay Bishop – January 2008".

Please apply any charges or credits to Deposit Account No. 06-1050.

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

21847726.doc

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

2/13/2008
Date of Deposit

Signature

Rita M. Liston
Typed or Printed Name of Person Signing Certificate

Attorney's Docket No.: 10527-783002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

REQUEST FOR WITHDRAWAL AS ATTORNEY OR AGENT

Please withdraw the undersigned as attorney(s) or agent(s) for the patent(s) and/or patent application(s) listed in the attached Schedule, titled "Withdrawal Schedule for Bryant R. Gold and Laura Haburay Bishop – January 2008".

The reasons for this request are ownership transfer of the listed patents and patent applications.

The correspondence address is NOT affected by this withdrawal.

Respectfully submitted,

Date: 23 JAN 2008

Bryant R. Gold
Reg No. 29,715

Date: 2008 JAN 23

Laura Haburay Bishop
Reg No. 47,424

25129 Rye Canyon Loop
Valencia, CA 91355
Telephone: (661) 362-1771 or (760) 788-8138
Facsimile: (661) 362-1507 or (760) 788-9629

05-01272	2	11/230,052	9/19/2005			Devices and Methods Using an Implantable Pulse Generator for Brain Stimulation
05-01273	1	60/633,830	12/6/2004			Systems and Methods for Treating an Obese Patient
05-01273	2	11/295,783	12/6/2005			Stimulation of the Stomach in Response to Sensed Parameters to Treat Obesity
05-01274		60/631,061	11/23/2004			Systems and Methods for Providing Stimulation to a Target Site within a Patient
05-01274	2	11/285,983	11/23/2005			Affixation Member for Implantable Stimulators
05-01276	1	11/177,503	7/8/2005			Current Output Architecture for an Implantable Stimulator Device
05-01276	2	11/550,763	10/18/2006			Current Generation Architecture for an Implantable Stimulator Device Having Coarse and Fine Current Control
05-01281						Implantable Drug Eluting Electrodes
05-01282		60/569,872	5/10/2004			Implantable Electrode, Insertion Tool for use Therewith and Insertion Method
05-01282	1	11/124,843	5/9/2005			Implantable Electrode, Insertion Tool for use Therewith and Insertion Method
05-01289	1	11/125,780	5/10/2005			Implantable Medical Device with Polymer-Polymer Interfaces and Methods of Manufacture and Use
05-01300	1	11/138,598	5/25/2005			Implantable Microstimulator with Dissecting Tip and/or Retrieving Anchor and Methods of Manufacture and Use
05-01301	1	60/618,077	10/12/2004			Hermetically Bonding Ceramic and Titanium with a Palladium Braze
05-01301	2	11/238,602	9/29/2005			Hermetically Bonding Ceramic and Titanium with a Palladium Braze
05-01302	1	60/643,093	1/11/2005			Electrode Array Assembly and Method of Making Same
05-01302	2	11/329,907	1/11/2006			Electrode Array Assembly and Method of Making Same
05-01302	3	11/689,918	3/22/2007			Lead Assembly and Method of Making Same
05-01303	1	11/142,154	6/1/2005			Implantable Microstimulator with External Electrodes Disposed on a Film Substrate and Methods of Manufacture and Use
05-01304	1	11/232,540	9/21/2005			Methods and Systems for Placing an Implanted Stimulator for Stimulating Tissue
05-01305	1	11/280,620	11/16/2005			Implantable Stimulator
05-01306	1	60/678,692	5/6/2005			Methods and Systems for Treating a Matrix-Metalloproteinase-related Disorder
05-01306	2	11/430,541	5/8/2006			Methods and Systems for Treating a Matrix-Metalloproteinase-related Disorder
05-01307	1	11/176,763	7/7/2005			Methods and Systems for Treating Irritable Bowel Syndrome
05-01309		60/661,700	3/14/2005			HeadacheTreatment
05-01310	1					Multi-Electrode Nerve Cuff Prepulsing to Stimulate the Cavernous Nerve in the Treatment of Erectile Dysfunction
05-01311	1	11/256,356	10/21/2005			Occipital Nerve Stimulation to Treat Headaches and Other Conditions
05-01387	1	11/238,240	9/29/2005			Implantable Stimulator with Integrated Housing/Metal Contacts and Manufacture and Use
05-01388	1	11/294,283	12/5/2005			Cuff Electrode Arrangement for Nerve Stimulation and Methods of Treating Disorders
05-01389						Anatomical Paddle Electrode

BBB 1-21-08

AK 1/23/08

DOCKET NO. 05-01302-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Janusz A. Kuzma, et al.
Serial No.:	11/329/907
Filed:	January 11, 2006
For:	Electrode Array Assembly and Method of Making Same
Group Art Unit:	2811
Examiner:	not assigned

INFORMATION DISCLOSURE STATEMENT

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

Dear Examiner:

Submitted herewith is PTO/SB/08 containing a list of items that are being disclosed to the U.S. Patent & Trademark Office (PTO) pursuant to 37 C.F.R. §1.56, §1.97 and §1.98.

This application claims the benefit of U.S. Provisional Patent Application No. 60/643,093, filed January 11, 2005.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. See 37 C.F.R. §1.97(g).

Further, the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b). See 37 C.F.R. §1.97(h).

All of the items listed on PTO/SB/08 are in the English language.

Respectfully submitted,

/PhilipHLee/
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Dated: August 29, 2006

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PTO/SB/08A (10-01)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	11/329/907
Filing Date	January 11, 2006
First Named Inventor	Janusz A. Kuzma, et al.
Art Unit	2811
Examiner Name	not assigned
Attorney Docket	05-01302-02

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A 1	US-3,769,984	11-06-1973	Muench	
	A 2	US-5,555,618	09-17-1996	Winkler	
	A 3	US-6,055,456	04-25-2000	Gerber	
	A 4	US-6,205,361	03-20-2001	Baudino, et al.	
	A 5	US-6,216,045 B1	04-10-2001	Black, et al.	
	A 6	US-6,249,708 B1	06-19-2001	Nelson, et al.	

Examiner Signature		Date Considered	

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

EFS ID:	1176163
Application Number:	11329907
Confirmation Number:	6971
Title of Invention:	Electrode array assembly and method of making same
First Named Inventor:	Janusz A. Kuzma
Customer Number:	23845
Filer:	Philip H. Lee/Sandra Jackson
Filer Authorized By:	Philip H. Lee
Attorney Docket Number:	AB-561U
Receipt Date:	29-AUG-2006
Filing Date:	11-JAN-2006
Time Stamp:	13:50:30
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Information Disclosure Statement (IDS) Filed	05-01302-02-IDS-Statement.pdf	41248	no	2

Warnings:					
Information:					
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2	Information Disclosure Statement (IDS) Filed	05-01302-02-IDS.pdf	46924	no	1
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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.

UTILITY PATENT APPLICATION TRANSMITTAL (New Nonprovisional Applications Under 37 CFR § 1.53(b))	Attorney Docket No. **AB-561U**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is the patent application of ( ) application identifier or (X) first named inventor, Janusz A. Kuzma, entitled Electrode Array Assembly and Method of Making Same, for a(n):

(X) Original Patent Application.

( ) Continuing Application (prior application not abandoned):

( ) Continuation ( ) Divisional ( ) Continuation-in-part (CIP)
of prior Application No. __, filed on __.

Enclosed are:

(X) Application Data Sheet 2 Total Sheet(s).

(X) Non-Publication Request 1 Total Sheet(s).

(X) Specification; 19 Total Pages + cover sheet.

(X) Drawing(s); 5 Total Sheets of informal drawings.

(X) Oath or Declaration:

(X) A Newly Executed Combined Declaration and Power of Attorney:

(X) Signed. ( ) Unsigned. ( ) Partially Signed.

( ) A Copy from a Prior Application for Continuation/Divisional (37 CFR § 1.63(d)).

( ) Incorporation by Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered as being part of the disclosure of the accompanying application and is hereby incorporated herein by reference.

( ) Signed Statement Deleting Inventor(s) Named in the Prior Application. (37 CFR § 163(d)(2)).

(X) Return Receipt Postcard.

CLAIMS AS FILED				
FOR	NO. FILED	NO. EXTRA	RATE	FEE
Total Claims	23	3	$50.00	$150.00
Independent Claims	4	1	$200.00	$200.00
Multiple Dependent Claim Fee (if applicable)				$0.00
Assignment Recording Fee (if applicable)				$0.00
Basic Filing Fee				$300.00
Utility Search Fee				$500.00
Utility Examination Fee				$200.00
			Total Filing Fee	$1,350.00

Please charge $1,350.00 to Deposit Account No. 50-0648 pursuant to 37 CFR § 1.25. At any time during the pendency of this application, the Commissioner is hereby authorized to charge any fees required under any provision of 37 CFR § 1.16 or 37 CFR § 1.17, or credit any overpayment, to the indicated Deposit Account. A duplicate copy of this sheet is enclosed for fee processing against this Deposit Account.

Respectfully submitted,

By: _____
Philip H. Lee, Reg. No. 50,645

Date: January 11, 2006

Correspondence Address: Advanced Bionics Corporation
25129 Rye Canyon Road
Valencia, CA 91355

(X) Customer Number : 23845

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UTILITY PATENT APPLICATION TRANSMITTAL (New Nonprovisional Applications Under 37 CFR § 1.53(b))	Attorney Docket No. AB-561U

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is the patent application of ( ) application identifier or (X) first named inventor, Janusz A. Kuzma, entitled Electrode Array Assembly and Method of Making Same, for a(n):

(X) Original Patent Application.

( ) Continuing Application (prior application not abandoned):

( ) Continuation ( ) Divisional ( ) Continuation-in-part (CIP)
of prior Application No. __, filed on __.

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CLAIMS AS FILED				
FOR	NO. FILED	NO. EXTRA	RATE	FEE
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Multiple Dependent Claim Fee (if applicable)				$0.00
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Basic Filing Fee				$300.00
Utility Search Fee				$500.00
Utility Examination Fee				$200.00
			Total Filing Fee	$1,350.00

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By: _____
Typed Name: Philip H. Lee

Express Mail Label No.: EV500322548US

Date of Deposit: January 11, 2006

Docket No.: AB-561U

United States Patent Application

of

Janusz A. Kuzma,
a resident of Parker, Colorado
and a citizen of Australia

and

Anne M. Pianca
a resident of Valencia, California
and a citizen of the United States

Electrode Array Assembly and Method of Making Same

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25129 Rye Canyon Road
Valencia, California 91355

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Philip H. Lee
(Typed name of person mailing)


(Signature of person mailing)

Electrode Array Assembly and Method of Making Same

[0001] The present application claims the benefit of United States Provisional Patent Application Serial No. 60/643,093, filed January 11, 2005, which application is herein incorporated by reference in its entirety.

Field of the Invention

[0002] The present invention relates to implantable leads for providing electrical stimulation and, more particularly, relates to leads having multiple electrode contacts and methods of making such leads.

Background

[0003] Many types of implantable leads are currently used to treat a variety of maladies. Two common treatment applications use leads having multiple electrode contacts. Cochlear stimulator systems use a multiple electrode contact lead inserted into one of the cochlear chambers to stimulate the cochlear nerve. Another application where a multiple electrode contact lead is used is the treatment of chronic pain through stimulation of the spinal cord.

[0004] Spinal cord stimulation systems generally have two implantable components: an implantable pulse generator (IPG) and at least one lead connected to one output of the IPG. Generally, however, the IPG is a multi-channel device capable of delivering electrical current through the electrode contacts of the lead. The term "lead" used herein will refer to an elongate device having any conductor or conductors, covered with an insulated sheath and having at least one electrode contact attached to the elongate device, usually at the distal portion of the elongate device. The lead can have an inner stylet lumen running through most of the length of the lead and which lumen has an opening at the proximal end of the lead. A stylet may be placed

into this stylet lumen during steering and implantation of the lead. The inserted stylet in the lumen can help stiffen the lead so that the stylet/lead combination may be more easily inserted through tissue.

[0005] There are two types of leads that may be used with the IPG. The first type is a paddle lead, which has a multiplicity of electrode contacts spread out over a flat, paddle-like surface that is attached to one end of the lead. A paddle lead advantageously permits the electrode contacts to be spaced apart to provide wide coverage over a stimulation area. A disadvantage presented with a paddle lead is that it usually requires a laminectomy or laminotomy, which are highly invasive surgical procedures necessary to implant the large, non-isodiametric paddle.

[0006] A second type of lead that is commonly used is a percutaneous lead, which has multiple electrode contacts positioned along the distal portion of an elongate lead. U.S. Pat. No. 6,205,361 issued to Baudino et al. describes the making of a multi-contact electrode array for a lead. The distal end of the lead may be about the same thickness or diameter as the remainder of the lead. The percutaneous lead is dimensionally configured for tunneling to a target stimulation site. No invasive surgical procedure such as a laminotomy is required; the percutaneous lead may be placed through an epidural type needle reducing surgical trauma.

[0007] The method of making a multi-contact percutaneous lead can be involved. In general, it is desirable to make the lead efficiently, with the fewest number of process steps, maximize the manufacturing yield, and hence reduce the cost of goods of building the leads. There is thus a continual need to improve the design of a percutaneous lead in order to improve its performance and to improve the method of manufacturing the lead.

Brief Summary

[0008] A method of making a lead is provided. In one embodiment of the invention the method comprises: providing a plurality of conductive contacts located at the distal end of the stimulation lead; connecting a conductor wire to each of the conductive contacts; placing spacers between pairs of adjacent conductive contacts; placing monofilament within void spaces not occupied by a conductor wire, wherein the monofilament is the same material as the spacers; placing a heat shrink tubing around the spacers, conductive contacts and monofilament; and heating the spacers and monofilament just below the melting temperature to cause thermal fusion between the monofilament and spacer.

[0009] The conductive contacts may be connector contacts located at the proximal portion of the lead, which contacts are used to connect to the IPG, or the conductive contacts may be electrode contacts located somewhere on the lead (e.g., usually at the distal end of the lead).

[0010] In another embodiment of the method of making the lead, the method comprises: providing a plurality of conductive contacts located at the proximal end of the stimulation lead; connecting a conductor wire to each of the conductive contacts; placing spacers between pairs of adjacent conductive contacts; placing monofilament within void spaces not occupied by a conductor wire, wherein the monofilament is a different material than the spacers; placing a heat shrink tubing around the spacers, conductive contacts, and monofilament; and heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

[0011] Hence, while the monofilament and spacers may be the same material with the same melting temperatures, that is an optional part of the invention. The monofilament and spacers may actually be different materials, e.g., a type of thermoplastic polyurethane monofilament and another type thermoplastic polyurethane spacer, with different hardness and melting points in order to yield a particular stiffness.

[0012] In an embodiment of the invention, a lead assembly is provided comprising: a plurality of electrically conductive contacts; spacers placed between each adjacent contacts; a conductor wire connected to each conductive contact; and monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

[0013] In yet another embodiment, a lead assembly is provided comprising: a plurality of electrically conductive contacts; spacers placed between each adjacent contacts; a conductor wire connected to each conductive contact; and monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

[0014] The monofilament and spacer may be the same thermoplastic material to have the same melting point and to thereby allow thermal fusion upon heating at a temperature just below the melting temperature of the material or the monofilament and spacer may have different melting points.

Brief Description of the Drawings

[0015] The above and other aspects of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings wherein:

[0016] FIG. 1 shows a generalized spinal cord stimulation system with a percutaneous lead connected to an implantable pulse generator ("IPG");

[0017] FIG. 2 shows an illustration of the percutaneous lead implanted into the epidural space of a human spinal cord;

[0018] FIG. 3A shows a side view of the distal end of a percutaneous lead.

[0019] FIG. 3B shows a side view of the proximal (connector) end of the percutaneous lead shown in FIG. 3A;

[0020] FIG. 4 shows a view of the proximal end of the lead assembly showing the connector contacts and conductor wires that connect to each connector contact;

[0021] FIG. 5A shows a cross-sectional view of the percutaneous lead shown in FIG. 3A at line 5A-5A;

[0022] FIG. 5B shows a cross-sectional view of the percutaneous lead shown in FIG. 5A along line 5B-5B;

[0023] FIG. 5C shows a perspective view of the lead body, having a central stylet lumen and surrounding smaller lumens for containing conductor wires;

[0024] FIG. 6A shows a close-up, partial, longitudinal view of the lead assembly at the distal portion of the lead; and

[0025] FIG. 6B depicts how polyurethane monofilament or a thermoplastic material is used to fill the voids and is incorporated into the lead by applying heat.

[0026] Corresponding reference characters indicate corresponding components throughout the several views of the drawings.

Detailed Description of the Invention

[0027] The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

[0028] FIG. 1 shows a generalized stimulation system that may be used in spinal cord stimulation (SCS), as well as other stimulation applications. Such a

system typically comprises an implantable pulse generator ("IPG") 12, an optional lead extension 14, a lead 16 and an electrode array 18. The electrode array 18 includes a plurality of electrode contacts 17. In a percutaneous lead, the electrode contacts 17 can be arranged in an in-line electrode array 18 at the distal end of the lead 16. Other electrode array configurations can also be used. The IPG 12 generates stimulation current pulses that are applied to selected electrode contacts 17 within the electrode array 18.

[0029] The proximal end of the lead extension 14 can be removably connected to the IPG 12 and a distal end of the lead extension 14 can be removably connected to a proximal end of the lead 16. The electrode array 18 is formed on a distal end of the lead 16. The in-series combination of the lead extension 14 and lead 16 conduct the stimulation current from the IPG 12 to electrode contacts 17 of the electrode array 18. It is noted that the lead extension 14 need not always be used with the neural stimulation system 10. Instead, the lead extension 14 may be used when the physical distance between the IPG 12 and the electrode array 18 requires its use, or for the purpose of a temporary trial procedure.

[0030] The IPG 12 contains electrical circuitry, powered by an internal primary (one-time-use-only) or a rechargeable battery, which through the use of electrical circuitry can output current pulses to each stimulation channel. Communication with the IPG can be accomplished using an external programmer (not shown), typically through a radio-frequency (RF) link.

[0031] FIG. 2 shows a transverse, mid-sagittal view of a spinal cord and a generalized, implantable, spinal cord stimulation system. The stimulation system shown is being used as a spinal cord stimulator (SCS) system. In such an application, the lead 16 and, more particularly, the electrode array 18 are implanted in the epidural space 20 of a patient in close proximity to the spinal cord 19. Because of the lack of space near the lead exit point 15 where the electrode lead 16 exits the spinal column, the IPG 12 may be implanted in the

abdomen or above the buttocks. Use of lead extension 14 facilitates locating the IPG 12 away from the lead exit point 15.

[0032] FIG. 3A shows, in accordance with the invention, a distal portion of a percutaneous stimulating lead 16. The stimulating lead 16 is used to stimulate neural tissue by delivering electrical stimulus pulses through at least one of the electrode contacts 17. The electrode contacts 17 can be separated by electrode contact spacers (or an insulative material) 61 that insulate the electrode contacts 17 from each other. A radiopaque marker 30 located at the distal tip of the lead 16 may be optionally included. Alternatively, the tip of the lead may be the same material as the remainder of the lead insulation. The IPG 12 may be configured to permit connection to the two stimulating leads, each having eight electrode contacts 17. A pair of stimulating leads 16 may be connected to an IPG 12 and an electrical circuit may be created between one electrode contact on the first lead and another electrode contact located on the second lead. The IPG 12, for example, may have sixteen independently programmable outputs that allow programming of pulse amplitude, pulse width and frequency of the pulse width. The electrode contacts 17 are to be made of a bio-compatible, electrically conductive electrode material such as platinum/iridium alloy, platinum, titanium or the like.

[0033] As an example, the stimulating lead 16 may have a diameter of between about 0.03 to 0.07 inches for spinal cord stimulation applications. An insertion cannula (not shown), e.g., a 14 gauge insertion needle may be used, while a 0.05 inch diameter stimulating lead is inserted within the cannula to help implant the stimulating lead 16. The stimulating lead 16 may come in a variety of lengths, e.g., 30, 50, 70 and 90 cm. A practitioner can extend the length of any of the available lead lengths by opting to use an extension lead 14 (shown in FIG. 1). The proximal male end of the extension lead 14 should be configured to be insertable into the lead connector of the IPG and the distal female end of the

extension lead should be configured to accept the proximal connector end of the stimulating lead 16.

[0034] FIG. 3B shows, in accordance with the invention, a depiction of the proximal end of the lead 16. This proximal lead end, including the eight, electrically conductive, connector contacts 40, and a contact tip element 41, collectively will be called herein as the proximal lead connector end 42 of the stimulating lead 16. Connector contact spacers 45 are placed between the connector contacts 40. The spacers 45 may be made from an implantable grade polyurethane such as Pellethane® 55D thermoplastic material. The contacts 40 may be made from a non-corrosive, electrically conductive material, e.g., platinum/iridium alloy or platinum. Contact tip 41, however, is not electrically connected to any conductor and contact tip 41 may merely serve as a hard surface for a mechanical contact securing device, such as a set screw, which may be used to secure the lead connector end 42 with the connector block of the IPG 12. Contact tip 41 is optional and does not need to be included as part of the lead. Instead, the contact tip of the lead may be of similar or the same insulation material as the remainder of the lead 16 or lead body 110 (FIG. 5C).

[0035] Preferably the lead 16 is substantially isodiametric, meaning that the diameter along the lead's entire length is equal or nearly equal. However, the lead 16 does not need to be isodiametric. For example, the connector contacts 40 at the proximal end may be larger (oversized) or smaller in diameter compared to the remainder of the lead 16 or lead body 110 (shown in FIG. 5C). Likewise, the electrode contacts 17 may be larger (oversized) or smaller in diameter compared to the remainder of the lead 16 or lead body 110 (shown in FIG. 5C).

[0036] FIG. 4 shows a proximal lead assembly with each of the connector contacts 40 welded to a respective one of conductors 122. Each of the eight connector contacts 40, as shown, are connected to a conductor 122 which, in turn, are connected to a respective electrode contact 17 at the distal end of the

stimulating lead 16. The insulating material between the connector contacts 40 and around the conductors 122 is not shown in FIG. 4 for purposes of better illustrating the connection between each conductor and its respective connector contact. The connection may be a weld. Cylindrical element 46 is optional and is not connected to any conductor. Cylindrical element 46 may be used as a contact element for a mechanical securing device such as a set screw in order to secure the lead 16 to the IPG 12. Alternatively, or in addition, the cylindrical element 46 may function as a radiopaque element, provided that the material used for element 46 is radiopaque.

[0037] FIG. 5A shows a cross-sectional view of the lead of FIG. 3A along line 5A-5A.

[0038] FIG. 5B shows a partial, cross-sectional view of the lead along the line 5B-5B.

[0039] FIG. 5C shows a perspective view of an exemplary lead body 110 of the lead 16, excluding conductor wires. The lead body is that portion of the lead insulation 112 that is between the distal electrode contact array 18 and the array of connectors contacts 40 (FIG. 4) at the proximal lead connector end 42. The lead body 110 may be extruded as a one-piece component. Note the central stylet lumen 114 and the surrounding eight conductor lumens 116.

[0040] FIGS. 5A and 5B show an exemplary embodiment of an insulation section 112 of the lead body 110 having eight lumens 116 containing the conductor (wires) 122, having individual strands 120. For example 15 or 16 individual conductor strands 120 may be braided or bundled into a single conductor 122. Also shown is a central lumen 114 that may be used to accept an insertion stylet (not shown) within the lumen to facilitate lead implantation. The opening of the lumen occurs at the proximal end of the lead 16. The lead body 110 may be a biocompatible, insulating lead material. Preferably the lead body 110 is made from a polyurethane. In particular the material may be Pellethane® thermoplastic material, e.g. 55D, 65D, or other durometer hardness.

As previously indicated for FIG. 5C, the lead body 110 shown in FIG. 5B may be extruded as one piece.

[0041] FIG. 6A shows a partial view of a longitudinal, cross-section at the distal end of the lead, in accordance with an embodiment of the invention. FIG. 6A shows a ring-like electrode contact 17 (which may be platinum, for example), multi-stranded conductor 122 and electrode contact spacer 61 (or an insulative material). The spacer 61, which is ring-like in configuration, may be made of polyurethane insulative material, e.g., Pellethane®. Monofilament 60, also may be made of thermoplastic Pellethane® material or other insulation material, e.g., polyester. During manufacture, the monofilament 60 may be inserted into the void spaces that are not filled by the conductor 50. A heat shrink tube 65 is also shown placed around the electrode contacts 17 and conductor 122 assembly. The heat shrink tube 65 may be PTFE (e.g., Teflon® material) or a polyester heat shrink material. The heat shrink tube can be used during manufacturing and is not part of the stimulation lead.

[0042] FIG. 6B shows a two-frame, time-elapsed illustration of a partial view of the distal end of the lead as in FIG. 6A showing the conductor 122 connected (e.g., welded) to the electrode contact 17. The first frame (i) of FIG. 6B shows the sequence in which the monofilament 60 fills a large part of the void space 70. The part of the lead assembly shown is then placed into a heat, for example, at 190 degrees Celsius for a period of 30 seconds. The heat that may be used, e.g., for polyurethane material (such as Pellethane®), may range from about 140 to 250 degrees Celsius for a period of about between 15 to 120 seconds. However, importantly, the heat applied to the spacer and monofilament material, should be just below the melting temperature of the material. At this just-below-melting temperature, the spacer and monofilament will reflow and thermally fuse together as shown in the second frame (ii). The spacer 61 and the monofilament 60 may be exactly the same material with the same melting temperature in order to facilitate thermal fusion. For example, the

material may be the same implantable grade polyurethane such as Pellethane 55D or 75D.

[0043] Alternatively, however, the monofilament may be of a different material than the spacer to alter the mechanical characteristic of the final lead assembly. The monofilament and spacer may have different melting points or very close melting points. The monofilament and spacers may be the same type of material but with different formulations, e.g., to provide different hardness. For example, the monofilament may be a 55D (durometer hardness) material and the spacer may be a 75D material. The predetermined temperature chosen to heat both the monofilament and spacers should cause at least one of the materials used to thermally reflow or, alternatively to melt. In some cases, the temperature may be chosen that one material melts while the other material thermally reflows.

[0044] While FIGS. 6A and 6B show the distal end of the lead, the same process of using a monofilament to fill up void spaces may be used at the proximal end of the lead assembly. At the proximal end of the lead assembly, the conductive contacts are not electrode contacts but, are instead, electrically conductive connector contacts 40 that must be in electrical connection with complementary contacts in the IPG connector. The connector contact spacers 45 at the proximal end of the lead (shown in FIG. 3B) are placed between adjacent connector contacts 40. In one embodiment of the invention, the connector contact spacers 45 may be oversized — that is, the spacers may have an initial diameter that is larger than the final lead diameter. The proximal connector end of the lead assembly 42 may then be heated to a temperature (just below melting point of the spacer and monofilament) for a duration of time previously described in order to produce thermal fusion of the connector contact spacer 45 and monofilament 60 to create a continuous reflow of material between the spaces not occupied by the connector contacts 40 and conductor wires 122.

[0045] Alternatively, the monofilament 60 and spacer 45 may be different materials with different melting points or about the same melting points.

[0046] Hence, the method of placing monofilament into void spaces not occupied by the conductor 122, may be used solely at the distal end of a lead, solely at the proximal end of a lead, or may be employed concurrently at both ends of a lead. If only one end of a lead employs monofilament, the other end of the lead may employ another method to finish the build, e.g., overmolding using a mold or injecting material such as epoxy, e.g., Hysol® into the void spaces between the contacts and conductor wires.

Example

[0047] The following steps illustrates one example embodiment of a method for making the lead, in accordance with the invention. Embodiments of the method can include one or more of the following steps (although not necessarily in the order presented). (1) A braided or bundled, insulated, multi-filament conductor, e.g., having 2-200 filaments, can be ablated of insulation at one end to expose the conductor. (2) The exposed end of the conductor can be welded to an electrode contact (located on the distal end lead assembly). (3) Oversized, distal lead spacers may be placed between the electrode contacts. (4) The multi-lumen tube (lead body) may be pre-cut with ablated section located at the distal and proximal ends. (5) Each end of the conductor cable can be inserted through the corresponding conductor lumens in the lead body. (6) The oversized spacers can be placed between each ring-like electrode contact at the distal end of the lead assembly; the spacers 61 may be "oversized", meaning that they may have a diameter greater than the lead body 110 and in addition, the diameter of the electrode contacts 17 may be oversized compared to the diameter of the lead body 110. (7) The distal end of each conductor cable can be welded to the ring-shaped electrode contact. (8) Polyurethane monofilament may be placed inside the void space as shown in FIG. 6A, and inside any empty

conductor lumens 116. (9) A heat shrink tube or wrap, preferably, made from PTFE (Teflon) or polyester, can be placed over the distal end of the lead assembly and over the electrode array; this distal end can be placed into a high temperature block, e.g., between about 140-250 degrees Celsius for a period of about 30 to 120 seconds. (10) The distal assembly can be removed from the heat and the shrink tube or wrap can be removed. (10) Optionally, the distal tip of the lead can be formed using an RF welder.

[0048] Post processing of the lead is not always required. For example, grinding of the distal or proximal ends of the leads is not necessary with this method of manufacturing, although optionally, a centerless grinding process may be used, if desired.

[0049] The method of making the distal and proximal part of the lead, in accordance with the present invention, eliminates most, if not all tooling, including eliminating the use of molds.

[0050] The method of making a lead and the resulting multi-contact lead, in accordance with the invention, provides advantages over conventional leads and methods of making a lead. A prior method of making the distal portion of the lead uses epoxy to fill the voids between the spacer 61 and the contacts 17. This has certain disadvantages. For instance, use of an epoxy requires a curing step, e.g., of up to eight hours, adding to the total time required to build a lead. With use of epoxy, there may also be some variation in stiffness of the final lead assembly post-cure because the epoxy is generally a different material than the insulative body or spacers and because curing may occur unevenly. The use of like materials, e.g., polyurethane lead body, polyurethane spacers and polyurethane monofilament can yield a better bond between these parts.

[0051] Although the lead and method of making the lead are described in the context of a spinal cord stimulation lead, it will be understood by those skilled in the art that the same lead, albeit with appropriate dimensions for a particular application, and the method of making the lead may be used to make a

multi-contact lead suitable for use in other applications, such as deep brain stimulation, cardiac stimulation and peripheral nerve stimulation.

[0052] While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.

CLAIMS

What is claimed is:

1. A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at the distal end of the stimulation lead;

connecting a conductor wire to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts,;

placing monofilament within void spaces not occupied by a conductor wire, wherein the monofilament is the same material as the spacers;

placing a heat shrink tubing around the spacers, conductive contacts and monofilament; and

heating the spacers and monofilament just below the melting temperature to cause thermal fusion between the monofilament and spacer.

2. The method of claim 1, wherein the spacers and monofilament are polyurethane.

3. The method of claim 2, wherein the monofilament is a thermoplastic material.

4. The method of claim 3, wherein the heat applied is between about 140 to 250 degrees Celsius.

5. The method of claim 4, wherein the heat is applied for between about 15 to 120 seconds.

6. The method of claim 5, wherein the heat applied is about 160 degrees Celsius for about 40 seconds.

7. The method of claim 1, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE heat shrink material and polyester.

8. The method of claim 1, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

9. The method of claim 1, wherein conductive contacts are in the form of rings.

10. The method of claim 1, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

11. A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at the proximal end of the stimulation lead;

connecting a conductor wire to each of the conductive contacts;

placing spacers between pairs of adjacent conductive contacts,;

placing monofilament within void spaces not occupied by a conductor wire, wherein the monofilament is a different material than the spacers;

placing a heat shrink tubing around the spacers, conductive contacts, and monofilament; and

heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

12. The method of claim 11, wherein either the spacers or monofilament is polyurethane.

13. The method of claim 12, wherein the monofilament is a thermoplastic material.

14. The method of claim 13, wherein the heat applied is between about 140 to 250 degrees Celsius.

15. The method of claim 14, wherein the heat is applied for between about 15 to 120 seconds.

16. The method of claim 11, wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.

17. The method of claim 11, wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead.

18. The method of claim 11, wherein conductive contacts are in the form of rings.

19. The method of claim 11, wherein the conductive contacts are electrode contacts on the lead.

20. The method of claim 11, wherein the conductive contacts are connector contacts on the proximal end of the lead.

21. The method of claim 11, wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact.

22. A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts;

spacers placed between each adjacent contacts;

a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from the same insulative material as the spacer; and

wherein the spacer and monofilament are thermally fused from heat applied to the lead assembly, which heat is just below the melting temperature of the spacer and the monofilament material.

23. A stimulation lead assembly for making a lead, the assembly comprising:

a plurality of electrically conductive contacts;

spacers placed between each adjacent contacts;

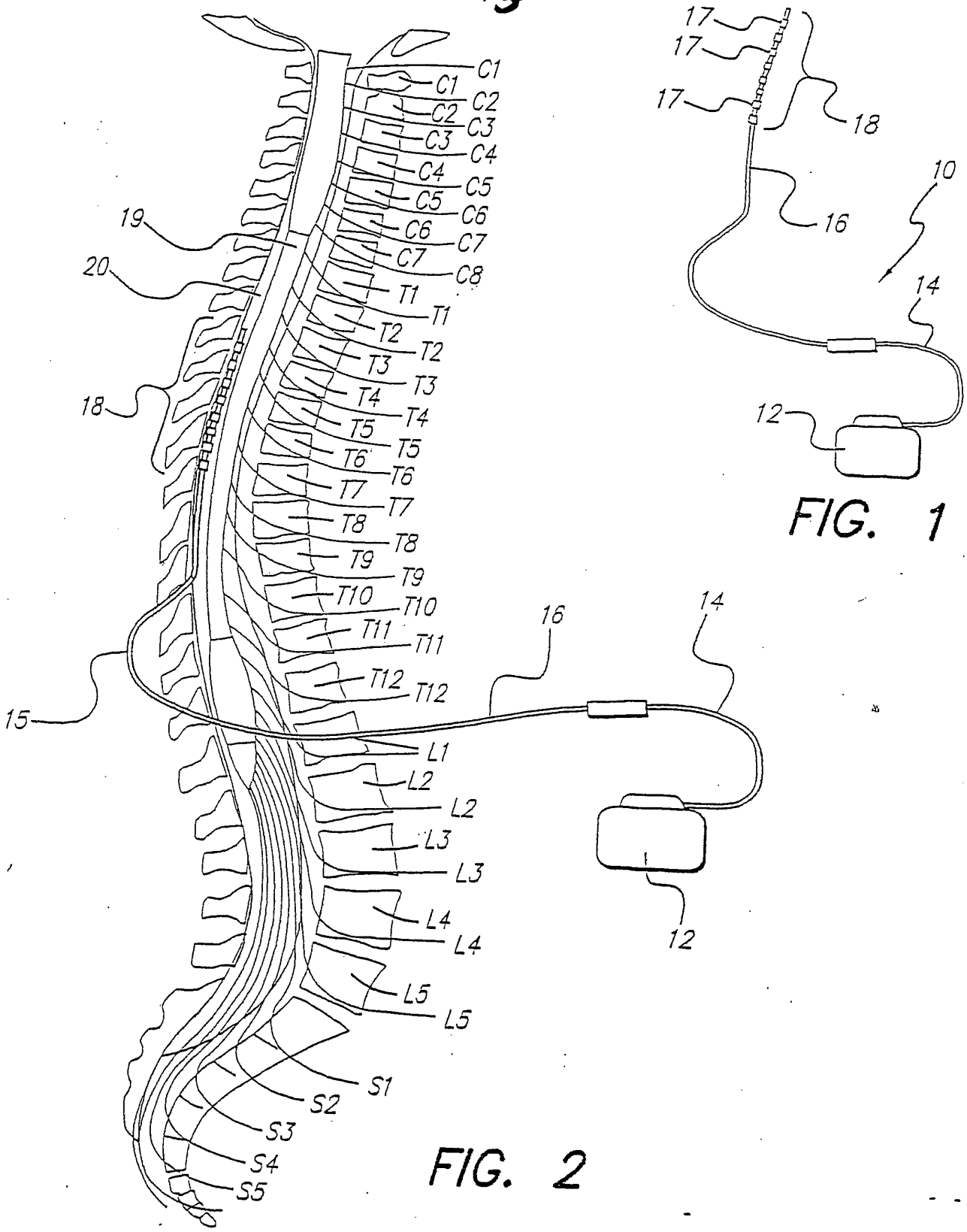
a conductor wire connected to each conductive contact; and

monofilament placed into void spaces not occupied by conductor wire, wherein the monofilament is made from a different insulative material as the spacer; and

wherein the spacer and monofilament are heated to a temperature to cause either the spacer or monofilament material to thermally reflow or melt.

ABSTRACT OF THE DISCLOSURE

[0053] A lead assembly and a method of making a lead are provided. The method of making a multi-contact lead assembly comprises placing monofilament placed in the void spaces not occupied by the plurality of conductor wires and, in one embodiment, thermally fusing the monofilament to the like material spacer by applying heat just below the melting temperature of the monofilament and spacer material. Alternatively, the monofilament and spacer may be of different materials and heat is applied to cause at least one material to thermally reflow or melt. The conductive contacts may be located at either the distal end and/or proximal end of the lead. Oversized spacers may be used in order to provide extra material to fill voids during the thermal fusion/reflow process.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C2
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C4
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T10
T11
T12
L1
L2
L3
L4
L5
S1
S2
S3
S4
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FIG. 2

17
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FIG. 1

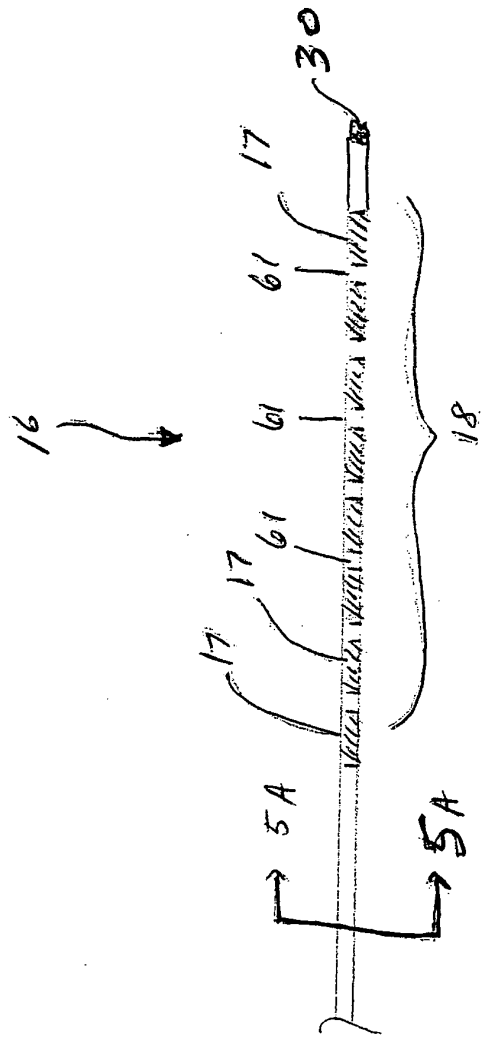

FIG. 3A

315

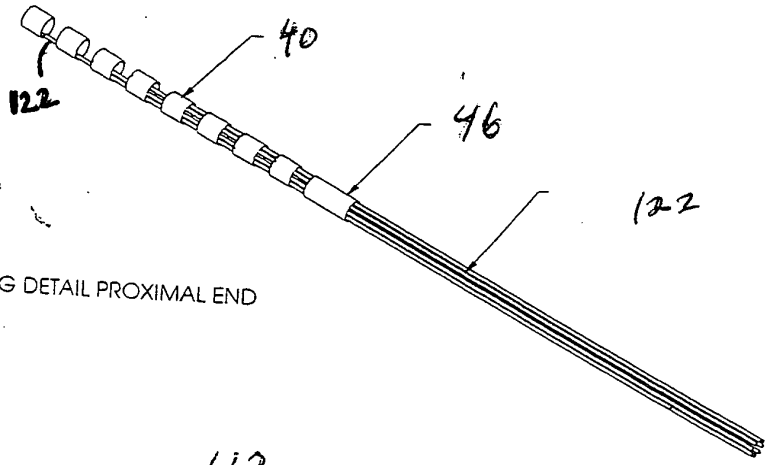

FIG. 4

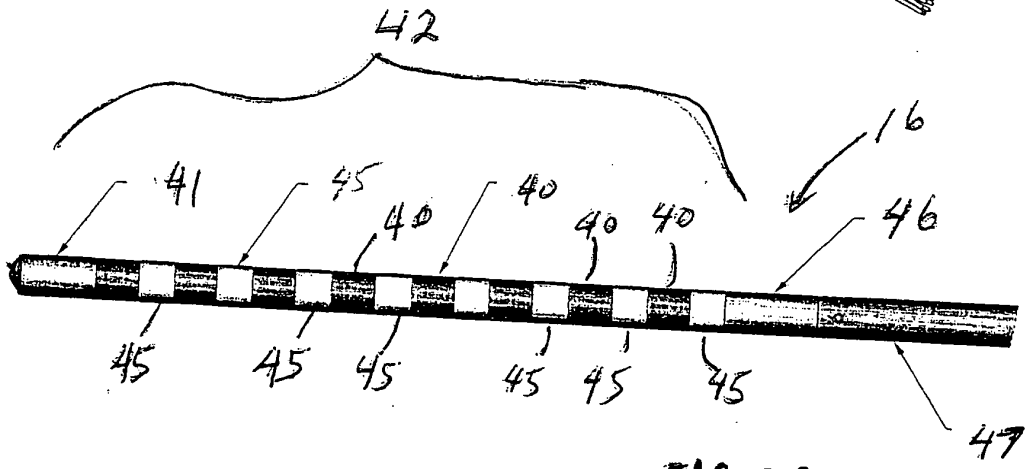

FIG. 3B

415

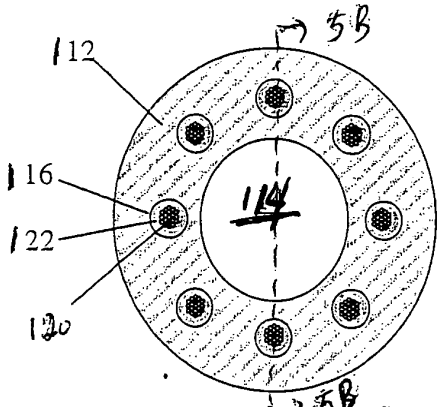

FIG. 5A

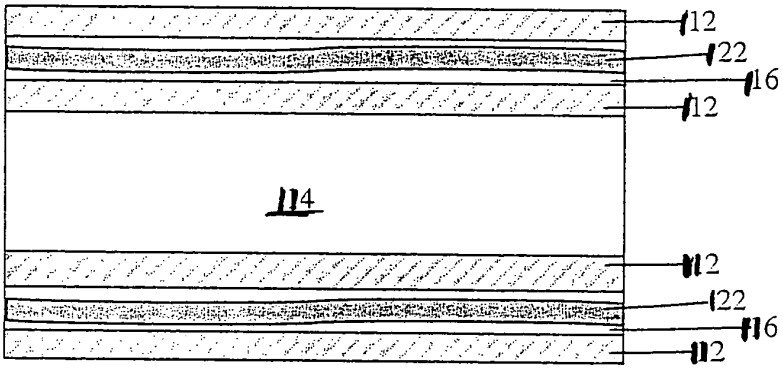

FIG. 5B

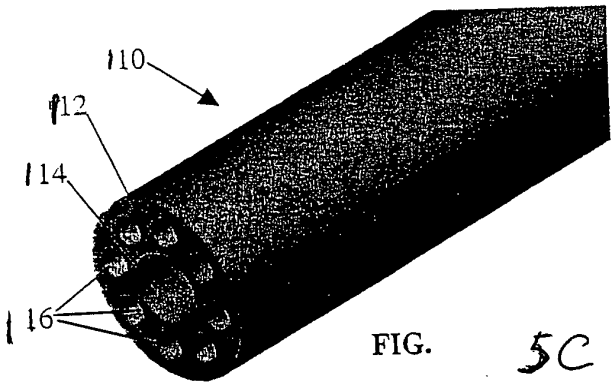

FIG. 5C

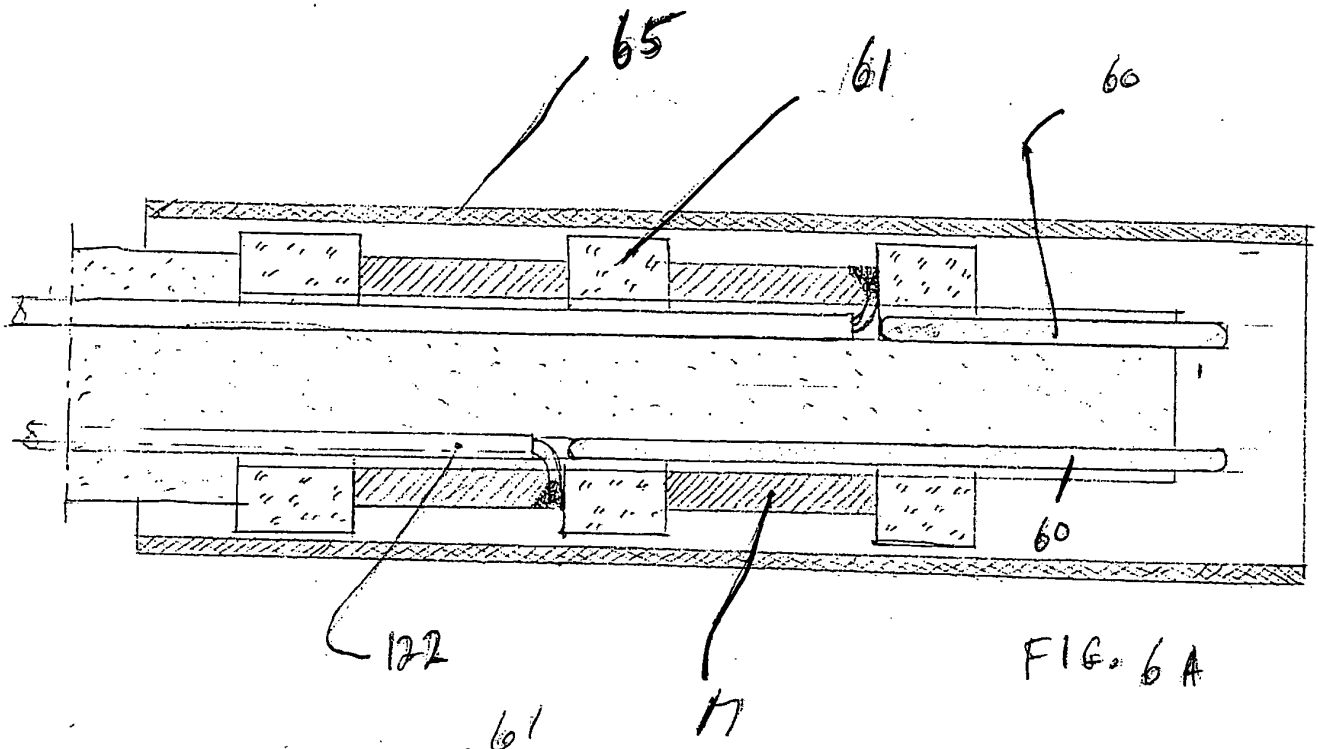

FIG. 6A

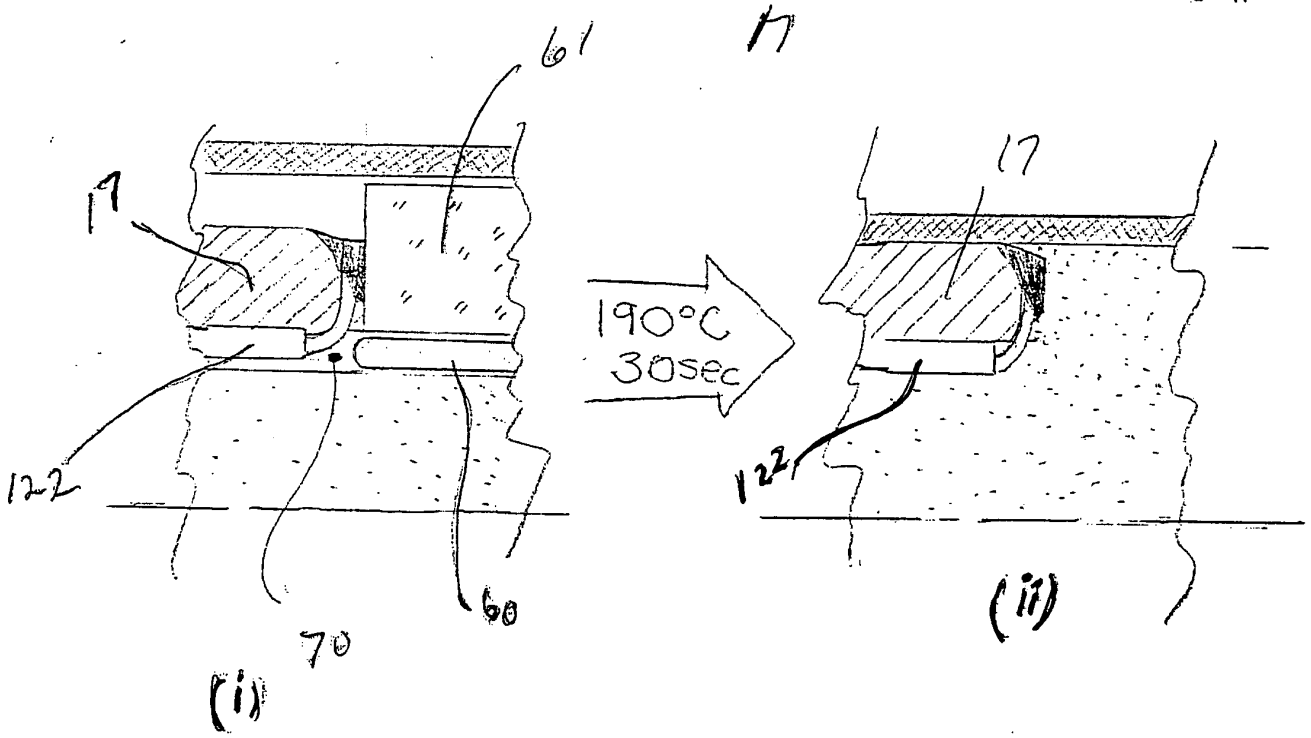

FIG. 6B

4/17/04

PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY **ATTORNEY DOCKET NO. AB-561U**

As a below named inventor, I hereby declare that:
My residence/post office address and citizenship are as stated below next to my name;
I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:
Electrode Array Assembly and Method of Making Same
the specification of which is attached hereto unless the following box is checked:
( ) was filed on _____ as US Application Serial No. or PCT International Application Number _____ and was amended on _____ (if applicable).
I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority
I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES: NO:
			YES: NO:

Provisional Application
I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/643,093	January 11, 2005

U.S. Priority Claim
I hereby claim the benefit under Title 35, United States Code, Section 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 Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)

POWER OF ATTORNEY:
As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Bryant R. Gold, Reg. No. 29715 **Laura Haburay Bishop, Reg. No. 47424** **Philip H. Lee, Reg. No. 50645**
Peter K. Johnson, Reg. No.57,236 **Victoria Poissant, Reg. No. 56,871**

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I hereby 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 these statements were made with the knowledge that willful false statements and the like so made 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 the application or any patent issued thereon.

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Inventor's Signature **Date** 01/11/2006

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. AB-561U

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Inventor's Signature

11 JAN '06
Date

PATENT APPLICATION SERIAL NO _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/13/2006 SDENBOB1 00000048 500648 11329907

01 FC:1011	300.00	DA
02 FC:1111	500.00	DA
03 FC:1311	200.00	DA
04 FC:1202	150.00	DA
05 FC:1201	200.00	DA

PTO-1556
(5/87)

U.S. Government Printing Office: 2002 — 466-247/69033

11, 22, 23

PTO/SB/06 (12-04)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11329907

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	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3	X$ 25 =		OR	X$50 =	150
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	X100 =			X200 =	200
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1350

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					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 number found in the appropriate box in column 1.

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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State or Province of Residence:: Californai
Country of Residence:: US
Citizenship Country:: US

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Electronic Mail One:: bryantg@advancedbionics.com
Fax Two:: 760-788-9629

APPLICATION INFORMATION

Title Line One:: Electrode Array Assembly and Method of M
Title Line Two:: aking Same
Total Drawing Sheets:: 5
Formal Drawings?:: No
Application Type:: Utility
Docket Number:: AB-561U
Secrecy Order in Parent Appl.?:: No

REPRESENTATIVE INFORMATION

Registration Number One:: 29715
Registration Number Two:: 47424
Registration Number Three:: 50645
Registration Number Four:: 57236
Registration Number Five:: 56871

CONTINUITY INFORMATION

This application is a:: NON PROV. OF PROVISIONAL
> Application One:: 60/643,093
Filing Date:: 01-11-2005

Source:: PrintEFS Version 1.0.1

PTO/SB/35 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)	First Named Inventor	Kuzma, et al.
	Title	Electrode Array Assembly and Method of Making Same
	Attorney Docket Number	AB-561U

I hereby 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 agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

January 11, 2006
Date

Signature

(661) 362-1964
Telephone number

Philip H. Lee, Reg. No. 50,645
Typed or printed name

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**