Case 1:16-cv-01163-GMS Document 3 Filed 12/09/16 Page 1 of 2 PageID #: 315

AO 120 (Rev. 08/10)

TO:	Mail Stop 8
	Director of the U.S. Patent and Trademark Office
	P.O. Box 1450
	Alexandria, VA 22313-1450

#### REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

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

DOCKET NO.	DATE FILED 12/9/2016	U.S. DISTRICT COURT 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

DECISION/JUDGEMENT

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

DATE INCLUDED	INCLUDED BY	***************************************		
	Amen	dment 🗌 Answer	Cross Bill	Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDE	R OF PATENT OR T	FRADEMARK
1				
2				
3				
4				
5				

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

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.

Civil Action No.

Nevro Corp.,

Defendant.

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

Patent or Trademark No.	Date of Patent or	Holder of Patent or Trademark
	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 State	es Patent and Trademai	UNITED ST United Stat Address: COMM P.O. Bo	ria, Virginia 22313-1450
APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
13/013,599	8646172	3729	9200

## 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 page 1 of 1



## UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/013,599	02/11/2014	8646172	1362009-2093.2	9046

50638759001/22/2014Boston Scientific Neuromodulation Corp.c/o Frommer Lawrence & Haug LLP745 Fifth AveNEW 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 315 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;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit <u>SelectUSA.gov</u>.

IR103 (Rev. 10/09)

## Receipt date: 01/25/2011

## 13013599 - GAU: 3729

IDS Form PTO/S	3B/08: Substitute for for	m 1449A/PTO		Complete if Known		
				Application Number	Not Yet Assigned	
INF	ORMATION D	ISCLOSU	RE	Filing Date	January 25, 2011	
3	<b>TEMENT BY</b>			First Named Inventor	Janusz A. Kuzma et al.	
317	~ 1 L. 1911 19 1 1	MERLIOM	1878 E	Art Unit	Not Yet Assigned	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	Sheet 1 of 1		Attorney Docket Number	1362009-2093.2		

Exami	ne Cite	Document Number	Issue or	Name of Patentee or	Pages, Columns, Lines, Where
r Initial	No.1	Number-Kind Code <sup>2</sup> (it known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevan Figures Appear
		2005/0215945	09-29-2005	Harris, et al.	
		3,769,984	11-06-1973	Muench	
		5,555,618	09-17-1996	Winkler	
		6,055,456	04-25-2000	Gerber	
		6,205,361	03-20-2001	Baudino, et al. Kuzma et al.	
36(8/-0)	aphea	6,216,045 B1	04-10-2001	Black, et al.	
cument	,	6,249,708 B1	06-19-2001	Nelson, et al.	
1		6,551,302	04-22-2003	Rosinko, et al.	

11/6/2013

#### Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

				DOCUMENTS		
Examiner Initials	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>

	NONPATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>			
		U.S. Patent Application No. 11/329,907, Official Communication mailed November 17, 2008				
		U.S. Patent Application No. 11/329,907, Official Communication mailed April 2, 2009				
		U.S. Patent Application No. 11/329,907, Official Communication mailed July 1, 2009	·····			
		U.S. Patent Application No. 11/329,907, Official Communication mailed March 31, 2010				
		U.S. Patent Application No. 11/329,907, Notice of Allowance mailed November 15, 2010				

Examiner	/David Anguin/	Date	0.0.10.77 (7.0.1.5
Signature	/David Angwin/	Considered	02/25/2013
 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			***************************************

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.

## ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.A./

#### PART B -FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450

or <u>Fax</u> (571) 273-2885

INSTRUCTIONS: This appropriate. All further of as indicated unless corre for maintenance fee notifi	correspondence cted below or d fications.	including the irected otherw	Patent, advan ise in Block 1	ce orders a , by (a) sp	and notificat	ion of mainte	enance fees w	ill be mailed to the c	urrent corresp	ondence address
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) FROMMER LAWRENCE & HAUG LLP 745 5th Ave. New York, New York 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 accompanyir papers. Each additional paper, such as an assignment or formal drawing, mus 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 envelop 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)
						Via	EFS			(Signature) (Date)
ADDI ICATION NO	EIL DIC	DATE	EI	DOTNAN	ED INVEN		ATTOR	NEY DOCKET NO.	CONFIRI	MATION NO.
APPLICATION NO.	FILING		rl			IOK		62009-2093.2		9046
13/013,599	01/25/				A. Kuzma			02009-2093.2		9040
TITLE OF INVENTIO		ODE ARRAY					ISSUE FEE	TOTAL FEE(S) D	ne J r	DATE DUE
	TTY STATUS	ISSUE FEE D		ICATION	FEEDUE	TKEV, FAIL	1990FLF	\$960.00		01/04/2014
	DISCOUNTED	\$960.00			OT A BC		, 1	\$900.00	L. L.	11/04/2014
L	MINER		ART UN	11		-SUBCLASS	<b>)</b>			
D. P. A	Angwin		3729	. For print		29-825 itent front pag	a list			
Correspondenc "Fee Address" form PTO/SB/ Use of a Custo 3. ASSIGNEE NAME	rrespondence a e Address form indication (or "J 47; Rev 03-02 o <u>mer Number is</u> AND RESIDEJ aless an assigned t forth in 37 CF NEE leuromodulatior 45 / 0966 te assignee catego	PTO/SB/122) Fee Address" I r more recent) s required. NCE DATA T e is identified I R 3.11. Compl n Corporation	hange of c attached. ( indication attached. 1 O BE PRINT below, no assi letion of this f	or agents O (2) the name a registered up to 2 registered to 2 registered ED ON THE ignee data form is NO (E nted on the p	R, alternativ e of a single l attorney of istered paten ed, no name HE PATENT will appear T a substitu B) RESIDEN Valencia, patent) :	firm (having agent) and t t attorneys or will be printe: f (print or typ on the patent. te for filing an ACE: (CITY a California Individual	as a member he names of agents. If no d. e) If an assignment ind STATE C X Corpora	<u>Frommer Lat</u> <u>Bruce E. Bla</u> <u></u> e is identified below, DR COUNTRY) ttion or other private growiously paid issue fe	ck the document	t has been filed
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5. Change in Entity S	tatus (from stat	us indicated at	bove)							
Applicant certit	fying micro enti	ity status. See 3	37 CFR 1.29.	<u>NOTE:</u> A	Absent a vali	id certification	ount will not	tity Status (see form P be accepted at the risk	TO/SB/15A a	nd 15B), issue
Applicant asser	ts small entity s	status. See 37 (	CFR 1.27.	<u>NOTE:</u> taken to	If the applic be a notific:	ation was pre- ation of loss c	viously under	micro entity status, c to micro entity status	hecking this	box will be
	ging to regular			micro er	ntity status, a	as applicable.		notification of loss o		
NOTE: The Issue Fee and interest as shown by the re-	Publication Fee cords of the Uni	e (if required) w ted States Pater	vill not be acce nt and Tradema	epted from ark Office.	anyone other	than the appl	icant; a regist	ered attorney or agent;	or the assigne	e or other party in
Authorized Signatu	ıre	141	K				Ľ	Jate Jar	nuary 2, 2014	
Typed or printed na	ame	•	Bruce E.	Black			R	egistration No.	41,622	2

PTOL-85 (Rev. 02/11) Approved for use through 08/31/2013.

OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal						
Application Number:	13	013599				
Filing Date:	25	-Jan-2011				
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:	13	62009-2093.2				
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	960	960	
Extension-of-Time:						

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Total in USD (\$)			960

Electronic Acl	knowledgement Receipt
EFS ID:	17803771
Application Number:	13013599
International Application Number:	
Confirmation Number:	9046
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:	1362009-2093.2
Receipt Date:	02-JAN-2014
Filing Date:	25-JAN-2011
Time Stamp:	16:09:40
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted with Payment	yes				
Payment Type	Credit Card				
Payment was successfully received in RAM	\$ 960				
RAM confirmation Number	3308				
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. Se	ection 1.17 (Patent application and reexamination processing fees)				

Charge	any Additional Fees required under 37 C.F	.R. Section 1.21 (Miscellaneous fee	es and charges)		
File Listing	g:				
Document Number	<b>Document Description</b>	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		01379194.PDF	308912	2005	3
'		01379194.FDF	0c7d6822dceec95cc49feabe841120fcd64d 082d	yes	J
	Multij	oart Description/PDF files in	zip description		
	Document De	scription	Start	E	nd
	Miscellaneous Inco	oming Letter	1		1
	Transmittal Letter 2 2				
	Issue Fee Payment (PTO-85B) 3 3				3
Warnings:					
Information:		1			
2	Fee Worksheet (SB06)	fee-info.pdf	30415	no	2
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Warnings:					
Information:			1		
		Total Files Size (in bytes)	3:	39327	
characterized Post Card, as <u>New Applican</u> If a new appl 1.53(b)-(d) ar Acknowledge <u>National Stag</u> If a timely sul U.S.C. 371 an national stag <u>New Internat</u> If a new inter	ledgement Receipt evidences receip d by the applicant, and including pa described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> ication is being filed and the applica nd MPEP 506), a Filing Receipt (37 Cl ement Receipt will establish the filin <u>ge of an International Application un</u> bmission to enter the national stage of other applicable requirements a F ge submission under 35 U.S.C. 371 w <u>tional Application Filed with the USF</u> mational application is being filed a paal filing date (see PCT Article 11 an	ge counts, where applicable. Ation includes the necessary FR 1.54) will be issued in due ag date of the application. Ander 35 U.S.C. 371 Form PCT/DO/EO/903 indicat ill be issued in addition to th PTO as a Receiving Office nd the international applicat	It serves as evidence components for a filin course and the date s ion is compliant with ing acceptance of the e Filing Receipt, in du tion includes the nece	of receipt s ng date (see shown on th the condition application le course.	imilar to a 37 CFR is ons of 35 a as a onents for
and of the Int	ternational Filing Date (Form PCT/R urity, and the date shown on this Acl	O/105) will be issued in due o	ourse, subject to pres	scriptions co	oncerning

Applicat	on No. (if known): 13/013,599	Attorney Docket No.: 1362009-2093.2
	Cartificate of Electronic E	iling Under 37 C.F.R. § 1.8
14		
	I hereby certify that this correspondence is bein accordance with 37 C.F.R. § 1.6(a)(4):	g transmitted via the Office electronic filing system in
	MS Issue Fee Commissioner for Patents	
	P.O. Box 1450 Alexandria, VA 22313-1450	
	on January 2, 2014 . Date	
	But	
		Downey/
		ature
		Downey person signing Certificate
		(206) 336-5690
	Registration Number, if applicable	Telephone Number
	Note: Each paper must have its own certifica each submitted paper.	te of mailing, or this certificate must identify
	Part B - Fee(s) Transmittal (1 pg.) Transmittal (1 pg.)	

				and Tradema	PTO/SB/21 (07-09) red for use through 07/31/2012. OMB 0651-0031 rk Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork	Reduction Act of 1995, no pers	ons are required to res	Application		tion unless it displays a valid OMB control number 13/013,599
Т	RANSMITT	AL	Filing Date		January 25, 2011
-	FORM			I Inventor	Janusz A. Kuzma
			Art Unit		3729
(to be us	ed for all correspondence after	r initial filing)	Examiner N	ame	D. P. Angwin
	r of Pages in This Submiss		Attorney Do	cket Numbe	<sup>r</sup> 1362009-2093.2
	EN		Check all	that appl	 (۷
Amendmen After After Aftid Extension Express Al Information Certified C Document Reply to M Incomplete	Final avits/declaration(s) of Time Request bandonment Request n Disclosure Statement opy of Priority (s) issing Parts/ Application y to Missing Parts under	Drawing(s) Licensing-rel Petition Petition Petition to Cc Provisional A Power of Attor Change of Co Terminal Disc Request for CD, Number Landsc Remarks	onvert to a pplication ney, Revocati rrespondence claimer Refund	Address	After Allowance Communication to TC Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter X Other Enclosure(s) (please Identify below): Part B - Fee(s) Transmittal (1 pg.); Certificate of Electronic Filing (1 pg.)
	FR 1.52 or 1.53 SIGNATI	JRE OF APPLICA	NT, ATTOF	RNEY, OR	AGENT
Firm Name	FROMMER LAWRE	NCE & HAUG L	LP		
Signature	hsik	<u> </u>			
Printed name	Bruce E. Black				
Date	January 2, 2014			Reg. No.	41,622



UNITED STATES PATENT AND TRADEMARK OFFICE

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

## NOTICE OF ALLOWANCE AND FEE(S) DUE

50638759010/04/2013Boston Scientific Neuromodulation Corp.c/o Frommer Lawrence & Haug LLP745 Fifth AveNEW YORK, NY 10151

### EXAMINER ANGWIN, DAVID PATRICK ART UNIT PAPER NUMBER

3729

DATE MAILED: 10/04/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046		

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

APPL	N. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonpr	ovisional	UNDISCOUNTED	\$1780	\$300	\$0	\$2080	01/06/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. 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 <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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

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

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

Page 1 of 4

#### PART B - FEE(S) TRANSMITTAL

#### Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (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 fees will be mailed to the current correspondence address. maintenance fee notifications.

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

50638 7590 10/04/2013 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.
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1780	\$300	\$0	\$2080	01/06/2014
EXAN	IINER	ART UNIT	CLASS-SUBCLASS			
ANGWIN, DAVID PATRICK		3729	029-825000			
<ol> <li>Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</li> <li>Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</li> <li>"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.</li> </ol>			or agents OR, alternativ (2) the name of a single registered attorney or a	3 registered patent attorn	er a 2	

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 L Corporation or other private group entity	Government

4a. The following fee(s) are submitted:	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
Issue Fee	A check is enclosed.
Publication Fee (No small entity discount permitted)	Payment by credit card. Form PTO-2038 is attached.
Advance Order - # of Copies	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)

Applicant certifying micro entity status. See 37 CFR 1.29

Applicant asserting small entity status. See 37 CFR 1.27

Applicant changing to regular undiscounted fee status.

<u>NOTE:</u> Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. <u>NOTE:</u> If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

<u>NOTE:</u> Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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.

	TED STATES PATE	NT AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 223 www.uspto.gov	Trademark Office FOR PATENTS		
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046		
50638 75	90 10/04/2013		EXAN	IINER		
Boston Scientific c/o Frommer Lawr	Neuromodulation C ence & Haug LLP	orp.	ANGWIN, DAVID PATRICK			
745 Fifth Ave			ART UNIT	PAPER NUMBER		
NEW YORK, NY	10151		3729			
			DATE MAILED: 10/04/201	3		

## 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 298 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 298 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.

#### **Privacy Act Statement**

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

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

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

# Notices of Allowance and Fee(s) Due mailed between October 1, 2013 and December 31, 2013

(Addendum to PTOL-85)

If the "Notice of Allowance and Fee(s) Due" has a mailing date on or after October 1, 2013 and before January 1, 2014, the following information is applicable to this application.

If the issue fee is being timely paid on or after January 1, 2014, the amount due is the issue fee and publication fee in effect January 1, 2014. On January 1, 2014, the issue fees set forth in 37 CFR 1.18 decrease significantly and the publication fee set forth in 37 CFR 1.18(d)(1) decreases to \$0.

If an issue fee or publication fee has been previously paid in this application, applicant is not entitled to a refund of the difference between the amount paid and the amount in effect on January 1, 2014.

	Application No.	Applicant(s	
	13/013,599	KUZMA ET	
Notice of Allowability	Examiner DAVID ANGWIN	Art Unit 3729	AIA (First Inventor to File) Status
		5723	No
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this or other appropriate communicat IGHTS. This application is subject	application. If not ion will be mailed	included in due course. <b>THIS</b>
1. X This communication is responsive to applicant's response to	o Ex Parte Quayle dated 8/28/13.		
A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was	/were filed on <u> </u>		
2. An election was made by the applicant in response to a rest requirement and election have been incorporated into this a	-	ng the interview or	a; the restriction
3. X The allowed claim(s) is/are <u>29-33 and 35-40</u> . As a result of Prosecution Highway program at a participating intellectual please see <u>http://www.uspto.gov/patents/init_events/pph/inc</u>	al property office for the correspor	nding application.	For more information,
4. Acknowledgment is made of a claim for foreign priority under	er 35 U.S.C. § 119(a)-(d) or (f).		
Certified copies:			
a) All b) Some *c) None of the:	heen reactived		
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3. Copies of the certified copies of the priority documents have			application from the
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* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		oly complying with	the requirements
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	t be submitted.		
including changes required by the attached Examiner's Paper No./Mail Date			
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t			(not the back) of
6. DEPOSIT OF and/or INFORMATION about the deposit of E attached Examiner's comment regarding REQUIREMENT FC			the
Attachment(s)			
1.  Notice of References Cited (PTO-892)	5. 🔲 Examiner's Ame		
2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date	6. 🗌 Examiner's Stat	ement of Reasons	for Allowance
3. Examiner's Comment Regarding Requirement for Deposit of Biological Material	7. 🗌 Other		
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date			
/David P. Angwin/ Primary Examiner			
Art Unit: 3729			
U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13) Not	lice of Allowability	Part of Pape	r No./Mail Date 20130927

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Part of Paper No. :

Index of Claims			13 Ex	Application/Control No. 13013599 Examiner DAVID ANGWIN			Reexa KUZM	Applicant(s)/Patent Under Reexamination KUZMA ET AL. Art Unit 3729						
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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

CPC- SEARCHED						
Symbol	Date	Examiner				

CPC COMBINATION SETS - SEARCHED					
Symbol	Date	Examiner			

US CLASSIFICATION SEARCHED								
Class	Subclass	Date	Examiner					
29	825	2/25/13	DPA					
29	825	7/4/13	DPA					
607	115-122	7/4/13	DPA					

SEARCH NOTES							
Search Notes	Date	Examiner					
obtained search from Primary Examiner Carl Arbes (Class 29) for 11/329,907	11/12/08	DPA					
reviewed parent applications	7/4/13	DPA					
inventor name search	7/4/13	DPA					

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all listed above	all listed above	dates listed above	DPA									

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

## **BIB DATA SHEET**

#### **CONFIRMATION NO. 9046**

SERIAL NUME	BER	FILING or DATE			CLASS	GRC	UP ART	ORNEY DOCKET NO.					
13/013,599	9	01/25/2			029		3729		1362009-2093.2				
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APPLICANTS Janusz A. Kuzma, Parker, CO; Anne M. Pianca, Valencia, CA;													
** <b>CONTINUING DATA</b> ***********************************													
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Foreign Priority claimed 35 USC 119(a-d) condi			🗅 Met af	ter	STATE OR COUNTRY		EETS WINGS			INDEPENDENT CLAIMS			
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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

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CPC Combination Sets				
Symbol	Туре	Set	Ranking	Version

NONE	Total Claims Allowed:				
(Assistant Examiner)	(Date)	1	1		
/DAVID ANGWIN/ Primary Examiner.Art Unit 3729	9/27/13	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1(final)	6B		
J.S. Patent and Trademark Office			Part of Paper No		

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

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607	116															

NONE	Total Claims Allowed:				
(Assistant Examiner)	(Date)	1	1		
/DAVID ANGWIN/ Primary Examiner.Art Unit 3729	9/27/13	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1(final)	6B		
U.S. Patent and Trademark Office			Part of Paper No.		

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

	Claims renumbered in the same order as presented by applicant								СР	A C	] T.D.	C	] R.1.	47	
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NONE		Total Clain	ns Allowed:
(Assistant Examiner)	(Date)	1	1
/DAVID ANGWIN/ Primary Examiner.Art Unit 3729	9/27/13	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1(final)	6B
U.S. Patent and Trademark Office			Part of Paper No.

Docket No.: 1362009-2093.2 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 13/013,599

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Confirmation No.: 9046

Art Unit: 3729

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 Madam:

#### INTRODUCTORY COMMENTS

In response to the Ex Parte Quayle Office Action dated July 8, 2013, please consider the following amendments and remarks/arguments:

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 3.

Remarks/Arguments begin on page 6.

#### AMENDMENTS TO THE SPECIFICATION

Please amend the Abstract on page 19 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 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. A method of manufacturing a stimulation lead includes providing a lead body having an insulation section that defines a central lumen extending along the insulation section and conductor lumens extending along the insulation section and arranged around, and external to, the central lumen. The lead body also includes conductive contacts located along an axial end of the lead body and conductor wires with each conductor wire disposed within one of the conductor lumens and each of the conductor lumens having at least one of the conductor wires disposed therein. After providing the lead body, conductively coupling at least one of the conductor wires to each of the conductive contacts; and placing non-conductive material into a portion of at least one of the conductor lumens of the lead body. A portion of the conductor lumens and at least a portion of the non-conductive material are disposed radially beneath the conductive contacts.

#### AMENDMENT TO CLAIMS

1.-28. (Canceled)

29. (Previously Presented) A method of manufacturing a stimulation lead comprising: providing a lead body comprising an insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;

after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts; and

after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts.

30. (Previously Presented) The method of claim 29, further comprising heating the nonconductive material to cause the non-conductive material to thermally reflow or melt.

31. (Previously Presented) The method of claim 29, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed radially beneath the conductive contacts.

- 3 ---

32. (Previously Presented) The method of claim 29, further comprising placing spacers between pairs of adjacent conductive contacts.

33. (Previously Presented) The method of claim 32, further comprising heating the nonconductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

34. (Canceled)

35. (Previously Presented) A method of manufacturing a stimulation lead comprising:

providing a lead body comprising a insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;

after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts; and

after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

36. (Previously Presented) The method of claim 35, wherein the plurality of conductor lumens is exactly eight conductor lumens.

37. (Previously Presented) The method of claim 35, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed radially beneath the conductive contacts.

38. (Previously Presented) The method of claim 35, further comprising placing spacers between pairs of adjacent conductive contacts.

39. (Previously Presented) The method of claim 38, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

40. (Previously Presented) The method of claim 35, wherein the non-conductive material comprises polyurethane.

#### REMARKS

This amendment is in response to the Non-final Office Action of July 8, 2013. Claims 21-28 and 34 have been cancelled without prejudice. Claims 29-33 and 35-40 are currently pending. No new matter has been added. The Applicants thank the Examiner for indicating that claims 29-33 and 35-40 are allowed

#### ABSTRACT

The abstract of the disclosure is objected to because it is not directed to the disclosure of amended claims 29 and 35. The Abstract has been amended to correspond to the subject matter of claim 29. The Applicants respectfully request withdrawal of this objection to the Abstract.

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: August 28, 2013

Respectfully submitted,

Bruce'E. Black Registration No.: 41,622
FROMMER LAWRENCE & HAUG LLP 745 5th Ave.
New York, New York 10151
(206) 336-5668
(212) 588-0500 (Fax)
bblack@flhlaw.com (E-Mail)
Attorneys For Applicant

Electronic Acknowledgement Receipt			
EFS ID:	16712015		
Application Number:	13013599		
International Application Number:			
Confirmation Number:	9046		
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:	1362009-2093.2		
Receipt Date:	28-AUG-2013		
Filing Date:	25-JAN-2011		
Time Stamp:	16:22:34		
Application Type:	Utility under 35 USC 111(a)		

# Payment information:

Submitted wi	th Payment	no			
File Listin	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		01322685.PDF	2251324 1d3a9643a4d57adb06c8a7105e4e9e2622d 00793	yes	8

	Multipart Description/PDF files in .zip description			
	Document Description	Start	End	
	Miscellaneous Incoming Letter	1	1	
	Transmittal Letter	2	2	
	Amendment/Req. Reconsideration-After Non-Final Reject	3	3	
	Abstract	4	4	
	Claims	5	7	
	Applicant Arguments/Remarks Made in an Amendment	8	8	
Warnings:		1	1	
Information:				
	Total Files Size (in bytes):	22	251324	

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.

Application No. (	if known): 13/013,599	Attorney Docket No.: 1362009-2093.2
Cert	ificate of Electronic I	Filing Under 37 C.F.R. § 1.8
l heret accord	by certify that this correspondence is be lance with 37 C.F.R. § 1.6(a)(4):	ing transmitted via the Office electronic filing system in
	MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
on	August 28, 2013 Date	
		И. Downey/
		)nature
	Typed or printed name	A. Downey of person signing Certificate
Reg	istration Number, if applicable	(206) 336-5690 Telephone Number
Note:	Each paper must have its own certifi each submitted paper. Amendment Transmittal (1 page) Amendment (6 pages)	cate of mailing, or this certificate must identify

AME	NDMENT 7	<b>FRANSMI</b>	TTAL LE	TTER	Docket No. 1362009-2093.2
Application No. 13/013,599		Filing		Examine	
		January 2	5, 2011	D. P. Ang	win 3729
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P	ATENT APPL			E DETE Form P		N RECORD	Application or Docket Number 13/013,599			Filing Date 01/25/2011	To be Mailed	
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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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	èd States Patent a	ND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS		
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046		
	7590 07/08/2013 fic Neuromodulation Corp.		EXAMINER			
c/o Frommer L	awrence & Haug LLP		ANGWIN, DA'	VID PATRICK		
745 Fifth Ave NEW YORK, N	NY 10151		ART UNIT	PAPER NUMBER		
,			3729			
			MAIL DATE	DELIVERY MODE		
			07/08/2013	PAPER		

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

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

	Application No. 13/013,599	Applicant(s) KUZMA ET A							
Office Action Summary	Examiner DAVID ANGWIN	Art Unit 3729	AIA (First Inventor to File) Status No						
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet with the c	corresponden	ce address						
<ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>2</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.</li> <li>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.</li> <li>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.</li> <li>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).</li> </ul>									
Status									
1) Responsive to communication(s) filed on $31 M$									
A declaration(s)/affidavit(s) under <b>37 CFR 1.1</b>									
	action is non-final.	aat farth durir	a the interview on						
3) An election was made by the applicant in resp ; the restriction requirement and election			ig the interview on						
4) Since this application is in condition for allowar	-		o the merits is						
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.							
Disposition of Claims									
5) Claim(s) <u>21-40</u> is/are pending in the application									
5a) Of the above claim(s) $21-28$ and $34$ is/are w	withdrawn from consideration.								
6)⊠ Claim(s) <u>29-33 and 35-40</u> is/are allowed. 7)□ Claim(s) is/are rejected.									
8) Claim(s) is/are objected to.									
9) Claim(s) are subject to restriction and/o	r election requirement.								
* If any claims have been determined <u>allowable</u> , you may be el	igible to benefit from the Patent Pro	secution High	<b>way</b> program at a						
participating intellectual property office for the corresponding a									
http://www.uspto.gov/patents/init_events/pph/index.jsp or send	an inquiry to <u>PPHteedback@uspto.c</u>	<u>10V</u> .							
Application Papers           10) ☑ The specification is objected to by the Examine	Y								
11)⊠ The drawing(s) filed on <u>25 January 2011</u> is/are		to by the Ex	aminer						
Applicant may not request that any objection to the		-							
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is ob	jected to. See	37 CFR 1.121(d).						
Priority under 35 U.S.C. § 119									
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).							
Certified copies:									
a) All b) Some * c) None of the: 1. Certified copies of the priority documen	ts have been received								
2. Certified copies of the priority documen		tion No.							
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) X Notice of References Cited (PTO-892)	3) 🔲 Interview Summary								
2) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail D. 4)	ate							
U.S. Patent and Trademark Office PTOL-326 (Rev. 05-13) Office Action	Summary	Part of Paper No	./Mail Date 20130702						

#### DETAILED ACTION

#### Election/Restrictions

**Claims 29 and 31** are directed to an allowable process. Pursuant to the procedures set forth in MPEP § 821.04(B), **claims 30 and 32-33**, also directed to a process depending from allowable claim 29, along with **claims 35-40**, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because claims 30, 32-33, and 35-40, previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 1/17/13 is hereby partially withdrawn. In view of the partial 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.

Please cancel claims 21-28.

#### **Specification**

The abstract of the disclosure is objected to because it is not directed to the disclosure of amended claims 29 and 35. Correction is required. See MPEP § 608.01(b).

#### Allowable Subject Matter

Claims 29-33 and 35-40 are now allowed.

#### <u>Conclusion</u>

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

To correct the informalities above with the abstract and 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, 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.

Page 3

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.

> /David P. Angwin/ Primary Examiner Art Unit 3729

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		Notice of Poferson	e Cited		Application/0 13/013,599	Control No.	Applicant(s)/F Reexamination KUZMA ET A	on
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					DAVID ANG	WIN	3729	Page 1 of 2
				U.S. PA	TENT DOCUM	ENTS	•	
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*	А	US-3,769,984 A	11-1973	Muench,	, Lloyd D.			607/122
*	В	US-5,410,797 A	05-1995	Steinke e	et al.			29/435
*	С	US-5,555,618 A	09-1996	Winkler,	Josef			29/825
*	D	US-6,055,456 A	04-2000	Gerber,	Martin Theod	lore		607/117
*	Е	US-6,205,361 B1	03-2001	Kuzma e	et al.	607/116		
*	F	US-6,216,045 B1	04-2001	Black et	al.	607/122		
*	G	US-6,249,708 B1	06-2001	Nelson e	et al.	607/122		
*	н	US-6,551,302 B1	04-2003	Rosinko	et al.	604/505		
*	I	US-6,598,280 B1	07-2003	Giba et a	al.			29/447
*	J	US-2004/0024440 A1	02-2004	Cole, Ma	ary Lee			607/122
*	к	US-2004/0225175 A1	11-2004	Moody e	et al.			600/003
*	L	US-6,909,918 B2	06-2005	Stypulko	wski, Paul			607/117
*	М	US-2005/0215945 A1	09-2005	Harris et	al.			604/066
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#### NON-PATENT DOCUMENTS

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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

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Notice of References Cited

	Application/Control No. 13/013,599	Applicant(s)/P Reexamination KUZMA ET Al	n				
Notice of References Cited	Examiner	Art Unit					
	DAVID ANGWIN	3729	Page 2 of 2				
U.S. PATENT DOCUMENTS							

#### Document Number Country Code-Number-Kind Code Date MM-YYYY \* Name Classification \* US-2006/0036218 A1 02-2006 604/264 Goodson et al. А \* US-7,047,081 B2 05-2006 Kuzma, Janusz A 607/115 в \* 01-2007 US-2007/0021771 A1 Oepen et al. 606/194 С \* US-2007/0021821 A1 01-2007 Johnson et al. 623/001.11 D \* Е US-7,184,840 B2 02-2007 Stolz et al. 607/122 \* US-2007/0249997 A1 10-2007 Goodson et al. 604/093.01 F \* G US-2008/0097426 A1 04-2008 Root et al. 606/041 \* Doty, David US-2009/0018487 A1 01-2009 604/21 Н US-Т US-J US-Κ US-L US-Μ

#### FOREIGN PATENT DOCUMENTS

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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

#### Notice of References Cited

	Index	v of (					Application/Control No.						Applicant(s)/Patent Under Reexamination				
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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

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CPC COMBINATION SETS - SEARCHED					
Symbol Date Examiner					

US CLASSIFICATION SEARCHED							
Class	Subclass	Date	Examiner				
29	825	2/25/13	DPA				
29	825	7/4/13	DPA				
607	115-122	7/4/13	DPA				

SEARCH NOTES					
Search Notes	Date	Examiner			
obtained search from Primary Examiner Carl Arbes (Class 29) for 11/329,907	11/12/08	DPA			
reviewed parent applications	7/4/13	DPA			
inventor name search	7/4/13	DPA			

INTERFERENCE SEARCH						
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner			
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#### **EAST Search History**

#### EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3668	29/825.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 01:51
L2	904	607/115.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:07
L3	2562	607/116.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:13
L4	556	607/117.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:20
L5	407	607/118.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:23
L6	748	607/119.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:25
L7	229	607/120.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:27
L8	104	607/121.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:30
L9	1936	607/122.ccls.	US- PGPUB; USPAT	OR	OFF	2013/07/04 02:32
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	US-	AND	ON	2009/03/28

#### EAST Search History

		(conductive adj contacts)	PGPUB; USPAT; USOCR			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.cds.	US- PGPUB; USPAT; USOCR	AND	ON	2010/09/29 15:01
S13	644	607/115.cds.	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.cds.	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
S18	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
S19	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
S20	158	607/118.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:36

S21		(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
S22	352	607/119.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:43
S23	145	607/120.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:47
S24	65	607/121.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:53
S25	1282	607/122.ccls.	USPAT; USOCR	AND	ON	2010/11/03 05:57

7/4/2013 2:34:34 AM

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#### Doc Code: A.NE.AFCP Document Description: After Final Consideration Pilot Program Request

	***************************************			PTO/SB/434 (05-13)		
		AND REQUEST FC				
Practitic	mer Docket No.:	Application No.:		Filing Date:		
£	2009-2093.2	13/013,599		January 25, 2011		
{	ned Inventor:	Title:				
Janu	isz A. Kuzma	ELECTRODE AR	RAY ASSEMBLY	AND METHOD OF MAKING SAME		
APPLICA PROGRA	APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.					
I.	The above-identified application i 35 U.S.C. 111(a) [a continuing app eligible under (i)], or (ii) an interna	lication (e.g., a continuat	tion or divisional appli	risional application filed under ication) is filed under 35 U.S.C. 111(a) and is al stage in compliance with 35 U.S.C. 371(c).		
-2.	The above-identified application c	ontains an outstanding f	inal rejection.			
3,	Submitted herewith is a response amendment to at least one indeperance any aspect.	under 37 CFR 1.116 to th endent claim, and the arr	ie outstanding final re rendment does not br	jection. The response includes an roaden the scope of the independent claim in		
4.	This certification and request for c response to the outstanding final		2.0 is the only AFCP	2.0 certification and request filed in		
5.	Applicant is willing and available t	o participate in any inter	view requested by the	examiner concerning the present response.		
6.	This certification and request is be	ing filed electronically us	sing the Office's electr	onic filing system (EFS-Web).		
7.	Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, e.g., extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]					
8.	By filing this certification and requ	est, applicant acknowled	ges the following:			
8 9	<ul> <li>Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.</li> <li>The examiner will verify that the AFCP 2.0 submission is compliant, <i>i.e.</i>, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:         <ul> <li>The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, by mailing an advisory action.</li> <li>If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not necessitate addition for allowance (after completing the additional search and/or consideration, if required).</li> <li>The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.</li> <li>If the applicant declines the interview, or if the interview cannot be scheduled within tem (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed</li> </ul> </li> </ul>					
Signature			Date			
	-h $h$		May 31, 2013	3		
Name (Print/Typ	<sup>ped)</sup> Bruce E. Black	·	Practitioner Registration No. 41,6			
	is form must be signed in accordance w tore than one signature is required, see			equirements and certifications. Submit multiple		
[√] * то	tal of <u>1</u> forms are submitted.					

Docket No.: 1362009-2093.2 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 13/013,599

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Confirmation No.: 9046

Art Unit: 3729

Examiner: D. P. Angwin

#### AMENDMENT IN RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

### INTRODUCTORY COMMENTS

In response to the Final Office Action dated April 18, 2013, please amend the aboveidentified U.S. patent application as follows:

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

Remarks/Arguments begin on page 7 of this paper.

#### AMENDMENT TO CLAIMS

1.-20. (Canceled)

21. (Withdrawn) A method of manufacturing a stimulation lead comprising: providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead and providing a plurality of conductor wires disposed in a plurality of conductor lumens formed in the lead body, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

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

placing non-conductive material into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by a conductor wire, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts; and

heating the non-conductive material to cause the non-conductive material to thermally reflow or melt.

22. (Withdrawn) The method of claim 21, further comprising placing spacers between pairs of adjacent conductive contacts.

23. (Withdrawn) The method of claim 22, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

24. (Withdrawn) The method of claim 22, wherein a material of the spacers and the non-conductive material are a same material.

25. (Withdrawn) The method of claim 22, wherein a material of the spacers and the non-conductive material are different materials.

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26. (Withdrawn) The method of claim 21, wherein the non-conductive material comprises polyurethane.

27. (Withdrawn) The method of claim 21, further comprising placing a heat shrink tubing around the conductive contacts and the non-conductive material.

28. (Withdrawn) The method of claim 21, wherein heating the non-conductive material comprises heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

29. (Currently Amended) A method of manufacturing a stimulation lead comprising: providing a lead body comprising an insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located [[at]] along an axial end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor lumens is disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;

after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts; and

after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed <u>radially</u> beneath the conductive contacts.

30. (Withdrawn) The method of claim 29, further comprising heating the nonconductive material to cause the non-conductive material to thermally reflow or melt.

31. (Currently Amended) The method of claim 29, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed <u>radially</u> beneath the conductive contacts.

32. (Withdrawn) The method of claim 29, further comprising placing spacers between pairs of adjacent conductive contacts.

33. (Withdrawn) The method of claim 32, further comprising heating the nonconductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

34. (Withdrawn) The method of claim 21, wherein the non-conductive material comprises polyurethane.

35. (Withdrawn, Currently Amended) A method of manufacturing a stimulation lead comprising:

providing a lead body comprising a insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located [[at]] along an axial end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the

plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;

after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed <u>radially</u> beneath the conductive contacts; and

after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

36. (Previously Presented) The method of claim 35, wherein the plurality of conductor lumens is exactly eight conductor lumens.

37. (Currently Amended) The method of claim 35, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed <u>radially</u> beneath the conductive contacts.

38. (Withdrawn) The method of claim 35, further comprising placing spacers between pairs of adjacent conductive contacts.

39. (Withdrawn) The method of claim 38, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

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Application No. 13/013,599 Amendment dated May 31, 2013 Reply to Office Action dated April 18, 2013

40. (Withdrawn) The method of claim 35, wherein the non-conductive material comprises polyurethane.

#### REMARKS

This amendment is in response to the Final Office Action of April 18, 2013. Claims 29, 31, 35, and 37 have been amended. Claims 21-40 are currently pending. No new matter has been added.

#### § 112 Rejections

Claims 29, 31, 36, and 37 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Applicants traverse this rejection.

The Office Action asserts that the phrase "a plurality of conductor wires disposed in the plurality of conductor lumens" is indefinite. The Office Action asserts that "it is unclear as to whether all of the plurality of conductor [wires] are disposed in one lumens (sic), if some of the plurality of conductor [wires] are disposed in several lumens and no conductors (sic) in some lumens, or if one of the plurality of conductor wires is disposed in each conductor lumen." Office Action, p. 2. Claims 29 and 35 each explicitly recite "each of the conductor lumens of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor wires is disposed in the plurality of conductor wires disposed therein" which clearly addresses the assertions raised in the Office Action regarding whether a conductor wire is disposed in each conductor lumen. Accordingly, no amendment of the claims is necessary to render the claims definite.

The Office Action further asserts that the phrase "conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts" is indefinite. The Office Action asserts that "[i]t is unclear as to whether more than one plurality [sic] of conductor wires can be coupled to each of the contacts...." Office Action, p. 3. The Applicants respectfully submit that the phrase recited above is clear and definite. That the phrase may encompass more than one possibility does not render it indefinite. Accordingly, the Applicants respectfully submit that no amendment is necessary.

For the reasons provided above and the amendments to claims 29 and 35, the Applicants respectfully submit that claims 29, 31, 36, and 37 are definite. The Applicants request withdrawal of this rejection of the claims.

#### § 102 Rejections

Claims 29, 31, 36, and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,249,708 to Nelson et al. ("Nelson"). The Applicants traverse these rejections.

Claims 29 and 35 (from which claims 36 and 37 depend) recite "after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed <u>radially</u> beneath the conductive contacts." In rejecting the claims, the Office Action asserts that Nelson teaches these elements in Figure 13, item 90 of Nelson.

Nelson, however, teaches that item 90 is a support surface 90 for a mesh material 92 that is formed as an anchoring site 62. Nelson, Col. 9:34-53. Nelson explicitly states that "the various anchoring sites 62 [are] remote to the atrial electrodes 26." Nelson, Col. 9:34-36. Accordingly, the support surface 90 is not "disposed <u>radially beneath the conductive contacts</u>" as recited in claims 29 and 35.

For at least these reasons, claims 29, 31, 36, and 37 are patentable over Nelson. The Applicants respectfully request withdrawal of this rejection of these claims.

Docket No.: 1362009-2093.2

Application No. 13/013,599 Amendment dated May 31, 2013 Reply to Office Action dated April 18, 2013

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 31, 2013

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

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Electronic Acknowledgement Receipt					
EFS ID:	15919632				
Application Number:	13013599				
International Application Number:					
Confirmation Number:	9046				
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:	1362009-2093.2				
Receipt Date:	31-MAY-2013				
Filing Date:	25-JAN-2011				
Time Stamp:	15:13:10				
Application Type:	Utility under 35 USC 111(a)				

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File Listing:						
Document Number	Document Description	File Name File Size(Bytes)/ Multi Message Digest Part /.zip (i				
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Multipart Description/PDF files in .zip description						
Document Description	Start	End				
Transmittal Letter	1	1				
Miscellaneous Incoming Letter	2	2				
After Final Consideration Program Request	3	3				
Amendment After Final	4	4				
Claims	5	9				
Applicant Arguments/Remarks Made in an Amendment	10	12				
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	Document Description         Transmittal Letter         Miscellaneous Incoming Letter         After Final Consideration Program Request         Amendment After Final         Claims	Document DescriptionStartTransmittal Letter1Miscellaneous Incoming Letter2After Final Consideration Program Request3Amendment After Final4Claims5				

Total Files Size (in bytes):

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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.

Application 13/013,5		Cilina				1362009-2093.2
	(1)()	~	Date		Examiner	Art Unil
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Bruce E. Black	<u> </u>			Da	ited:	May 31, 2013
Attorney/Agent F	Reg. No.: 41,6	22				
ROMMER LAW						
745 5th Ave	NG					
New York, New ` (206) 336-5668	YOFK 10151					

Application No. (	if known): 13/013,599	Attorney Docket No.: 1362009-2093.2
Cert	ificate of Electronic F	iling Under 37 C.F.R. § 1.8
T hereb accord	y certify that this correspondence is bei ance with 37 C.F.R. § 1.6(a)(4):	ng transmitted via the Office electronic filing system in
	MS AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
on	May 31, 2013 Date	
	***************************************	. Downey/
*********	Terri M Typed or printed name o	. Downey f person signing Certificate
Regi	stration Number, if applicable	(206) 336-5690 Telephone Number
Note:	Each paper must have its own certific each submitted paper. Amendment Transmittal (1 pg.) After Final Consideration Pilot Pro Amendment (9 pgs.)	ate of mailing, or this certificate must identify gram Request (1 pg.)

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Filing Date 01/25/2011	To be Mailed			
ENTITY:							ARGE 🗌 SMA			
				APPLIC	ATION AS FIL	ED – PAR	RTI			
			(Column 1	)	(Column 2)					
	FOR		NUMBER FIL	.ED	NUMBER EXTRA		RATE (\$)		FEE (\$)	
	BASIC FEE (37 CFR 1.16(a), (b), (	or (c))	N/A		N/A		N/A			
	SEARCH FEE (37 CFR 1.16(k), (i), d	or (m))	N/A		N/A		М	I/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			
	TAL CLAIMS CFR 1.16(i))		mir	ius 20 = *			X \$ =			
	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$	=		
	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
	MULTIPLE DEPEN	IDENT CLAIM F	RESENT (3	7 CFR 1.16(j))						
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		(Column 1)		(Column 2)	ION AS AMEN (Column 3		ART II			
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In scallection 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 USP10 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 USP10. 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.
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046
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c/o Frommer L	awrence & Haug LLP	ap.	ANGWIN, DA	VID PATRICK
745 Fifth Ave NEW YORK, N	NY 10151		ART UNIT	PAPER NUMBER
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			04/18/2013	PAPER

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

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

Office Action Summary         Examiner         At Unit         And Unit         Add Teleform           - The MALLING DATE of this communication appears on the cover sheet with the correspondence address -         Period for Reply           A SHORTHEND STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE & MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.           - Interview of the representation.         - Interview address of the correspondence address -           - Interview of the representation.         - Interview address of the correspondence ad		Application No. 13/013,599	Applicant(s KUZMA ET				
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3) An election was made by the applicant in response to a restriction requirement set forth during the interview on	, , , ,						
<pre></pre>	2a)⊠ This action is <b>FINAL</b> . 2b)□ This	action is non-final.					
4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.         Disposition of Claims         5) Claim(s) <u>21-20</u> s/3re pending in the application.         5(a) Claim(s) <u>21-20</u> s/3re pending in the application.         6(a) Claim(s) <u>21-28</u> 30, 32-35, and 38-40 is/are withdrawn from consideration.         6(a) Claim(s) is/are allowed.         7(a) Claim(s) is/are allowed.         7(b) Claim(s) is/are objected to.         8(a) Claim(s) is/are objected to restriction and/or election requirement.         * If any claims have been determined allowable, you may be eligible to benefit from the Patent Prosecution Highway program at a participating intellectual property office for the corresponding application. For more information, please see         http://www.usoto.gov/patents/init_events/pph/index.isp or send an inquiry to PPH/feedback@uspto.gov.         Application Papers         10) The specification is objected to by the Examiner.         11) The drawing(s) filed onis/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 1.121(d).         Priority under 35 U.S.C. § 119         12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).         Certified copies of the priority documents have been received.         2(a) Certified co	3) An election was made by the applicant in respo	onse to a restriction requirement	set forth duri	ng the interview on			
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Office Action Summary

# DETAILED ACTION

# Claim Rejections - 35 USC §112

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

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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 29, 31, 36, and 37 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 29** recites the following limitations that are vague, indefinite, and

confusing:

• "a plurality of conductor wires disposed in the plurality of conductor lumens" (claim 29, line 5) - It is unclear as to whether multiple conductor wires of the plurality of conductor wires are disposed in one lumens, if some of the plurality of conductor wires are disposed in several lumens and no conductors in some lumens, or if one of the plurality of conductor wires is disposed in each conductor lumens. The shorthand phrasing utilized by the applicant is confusing in inhibits the reader from making a clear image, and the language is not literally correct. The examiner recommends indicating 'at least one conductor wire of the plurality of conductor wires is disposed within every conductor lumens of the plurality of conductor lumens,' or words to that effect, if that is what the applicant intends. Please be more precise with the claim language.

> • "conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts" (claim 29, lines 8-9) – It is unclear as to whether more than one plurality of conductor wires can be coupled to each of the contacts, or whether just one conductor wire is coupled to one conductive contact. Please be more precise with the claim language.

# Claim Rejections - 35 USC § 102

The following is a set of quotations of the appropriate paragraphs of 35 U.S.C.

§102 that form the basis for the rejections under this section made in this Office Action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 31, 36, and 37 are rejected under 35 U.S.C. § 102(b) as being

anticipated by Nelson et al (US Patent 6,249,708).

- a. *Nelson et al* discloses in his reference the following:
  - providing a lead body comprising an insulation section (Fig. 3, item 30), the insulation section defining a central lumen (item 36) extending along the insulation section and a plurality of conductor lumens (items 40 and 44) extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts (Fig. 6, item 22, 24, 26, 50, and 52) located at an end of the lead body (radial or axial end), and a plurality of conductor wires (Figs. 3-5, item 40) disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts (Fig. 11, item 26-1);

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

placing non-conductive material (Fig. 13, item 90; *the examiner notes that the applicant has not provided an order to this step*) into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts;

- ii. wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the nonconductive material in each of the conductor lumens is disposed beneath the conductive contacts (Fig. 13, item 90; *the examiner notes that the applicant has not provided an order to this step*);
- iii. wherein the plurality of conductor lumens is exactly eight conductor lumens (Fig. 3);
- iv. wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts (Fig. 13, item 90; *the examiner notes that the applicant has not provided an order to this step*).

## Response to Arguments

Regarding "a plurality of conductor wires disposed in the plurality of conductor lumens," the applicant argues that it is not indefinite because the claim later states "each of the conductor lumens has at least one of the conductor wires disposed therein" (Applicant's Arguments, 6:10-18). However, the examiner disagrees. It is confusing and leaves the reader wondering about the writer's interpretation. The applicant's other arguments with respect to the above captioned claims have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

#### Examiner's Recommendations

The examiner recommends (1) amending the phrase "a plurality of conductor wires disposed in the plurality of conductor lumens" to 'at least one conductor wire of the plurality of conductor wires is disposed within every conductor lumens of the plurality of conductor lumens,' or words to that effect, if that is what the applicant intends; (2) more clearly defining the phrase "at an end of the lead body" (radial or axial end); (3) amending "the non-conductive material is disposed beneath the conductive contacts" to 'radially beneath the conductive contacts' (the examiner notes that *Nelson et al* Fig. 6 shows the lead body curling around like a snake, which allows for the interpretation of 'beneath' in multiple ways); (4) providing an order to the steps (i.e. 'after providing, coupling..., after coupling, placing...).

#### <u>Conclusion</u>

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, 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.

> /David P. Angwin/ Primary Examiner Art Unit 3729

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*	Е	US-6,205,361 B1	03-2001	Kuzma	et al.			607/116
*	F	US-6,216,045 B1	04-2001	Black e	t al.			607/122
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*	К	US-2004/0225175 A1	11-2004	Moody	et al.			600/003
*	L	US-6,909,918 B2	06-2005	Stypulk	owski, Paul			607/117
*	М	US-2005/0215945 A1	09-2005	Harris e	et al.			604/066
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\*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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Notice of References Cited

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	DAVID ANGWIN	3729	Page 2 of 2			
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#### Document Number Date \* Name Classification Country Code-Number-Kind Code MM-YYYY \* US-2006/0036218 A1 02-2006 604/264 Goodson et al. А \* US-7,047,081 B2 05-2006 Kuzma, Janusz A 607/115 в \* US-2007/0021771 A1 01-2007 Oepen et al. 606/194 С \* US-2007/0021821 A1 01-2007 Johnson et al. 623/001.11 D \* Е US-7,184,840 B2 02-2007 Stolz et al. 607/122 \* US-2007/0249997 A1 10-2007 Goodson et al. 604/093.01 F \* G US-2008/0097426 A1 04-2008 Root et al. 606/041 \* US-2009/0018487 A1 Н 01-2009 Doty, David 604/21 US-T US-J US-Κ US-L US-Μ

#### FOREIGN PATENT DOCUMENTS

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#### NON-PATENT DOCUMENTS

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\*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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Index of Claims				Application/Control No.					Applicant(s)/Patent Under Reexamination KUZMA ET AL.					
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U.S. Patent and Trademark Office

Part of Paper No. : 20130416

Index of Claims			13 Ex	13013599 Examiner				Reexa KUZM	Applicant(s)/Patent Under Reexamination KUZMA ET AL. Art Unit 3729					
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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

CPC- SEARCHED		
Symbol	Date	Examiner

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SEARCH NOTES		
Search Notes	Date	Examiner

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

U.S. Patent and Trademark Office

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Part of Paper No. : 20130225

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Docket No.: 1362009-2093.2 (PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 13/013,599

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Confirmation No.: 9046

Art Unit: 3729

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 Non-Office Action dated February 27, 2013, please amend the aboveidentified U.S. patent application as follows:

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

Remarks/Arguments begin on page 6 of this paper.

### AMENDMENT TO CLAIMS

1.-20. (Canceled)

21. (Withdrawn) A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead and providing a plurality of conductor wires disposed in a plurality of conductor lumens formed in the lead body, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

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

placing non-conductive material into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by a conductor wire, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts; and

heating the non-conductive material to cause the non-conductive material to thermally reflow or melt.

22. (Withdrawn) The method of claim 21, further comprising placing spacers between pairs of adjacent conductive contacts.

23. (Withdrawn) The method of claim 22, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

24. (Withdrawn) The method of claim 22, wherein a material of the spacers and the non-conductive material are a same material.

25. (Withdrawn) The method of claim 22, wherein a material of the spacers and the non-conductive material are different materials.

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Docket No.: 1362009-2093.2

26. (Withdrawn) The method of claim 21, wherein the non-conductive material comprises polyurethane.

27. (Withdrawn) The method of claim 21, further comprising placing a heat shrink tubing around the conductive contacts and the non-conductive material.

28. (Withdrawn) The method of claim 21, wherein heating the non-conductive material comprises heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

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

providing a lead body comprising an insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductors conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located at an end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts; and

placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts.

30. (Withdrawn) The method of claim 29, further comprising heating the nonconductive material to cause the non-conductive material to thermally reflow or melt.

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31. (Previously Presented) The method of claim 29, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts.

32. (Withdrawn) The method of claim 29, further comprising placing spacers between pairs of adjacent conductive contacts.

33. (Withdrawn) The method of claim 32, further comprising heating the nonconductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

34. (Withdrawn) The method of claim 21, wherein the non-conductive material comprises polyurethane.

35. (Withdrawn, Currently Amended) A method of manufacturing a stimulation lead comprising:

providing a lead body comprising a insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductors conductor lumens extending along the insulation section and arranged around, and external to, the central lumen, the lead body further comprising a plurality of conductive contacts located at an end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts; and

heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

36. (Previously Presented) The method of claim 35, wherein the plurality of conductor lumens is exactly eight conductor lumens.

37. (Previously Presented) The method of claim 35, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts.

38. (Withdrawn) The method of claim 35, further comprising placing spacers between pairs of adjacent conductive contacts.

39. (Withdrawn) The method of claim 38, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

40. (Withdrawn) The method of claim 35, wherein the non-conductive material comprises polyurethane.

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### REMARKS

This amendment is in response to the Non-final Office Action of February 27, 2013. Claims 29 and 35 have been amended. Claims 21-40 are currently pending. No new matter has been added.

### § 112 Rejections

Claims 29, 31, 36, and 37 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 29 and 35 (from which claims 36 and 37 depend) have been amended to clarify that the central lumen and conductor lumens are defined by the insulation section and to correct the typographical error in the term "conductor lumen."

The Office Action also asserts that the phrase "a plurality of conductor wires disposed in the plurality of conductor lumens" is indefinite. The Office Action asserts that "it is unclear as to whether all of the plurality of conductor [wires] are disposed in one lumens (sic), if some of the plurality of conductor [wires] are disposed in several lumens and no conductors (sic) in some lumens, or if one of the plurality of conductor wires is disposed in each conductor lumen." Office Action, p. 3. Claims 29 and 35 each explicitly recite "each of the conductor lumens has at least one of the conductor wires disposed therein" which clearly addresses the assertions raised in the Office Action regarding whether a conductor wire is disposed in each conductor lumen. Accordingly, no amendment of the claims is necessary to render the claims definite.

The Office Action further asserts that the phrase "conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts" is indefinite. The Office Action asserts that "[i]t is unclear as to whether more than one plurality [sic] of conductor wires can be coupled to each of the contacts...." Office Action, p. 3. The Applicants respectfully submit that the phrase recited above is clear and definite. That the phrase may encompass more than one possibility does not render it indefinite. Accordingly, the Applicants respectfully submit that no amendment is necessary.

For the reasons provided above and the amendments to claims 29 and 35, the Applicants respectfully submit that claims 29, 31, 36, and 37 are definite. The Applicants request withdrawal of this rejection of the claims.

### § 102 Rejections

Claims 29, 31, 36, and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,216,045 to Black et al. ("Black"). The Applicants traverse these rejections.

Claims 29 and 35 (from which claims 36 and 37 depend) have been amended to clarify that the "conductor lumens extend[] along the insulation section and [are] arranged around, and external to, the central lumen." Examples are such arrangements are found in Figures 5A-5C of the present patent application with central lumen 114 and conductor lumens 116.

Black does not teach or suggest such an arrangement of a central lumen and a plurality of conductor lumens. The Office Action asserts that the recited central lumen corresponds to "the space inside items 22-23" and the conductor lumens correspond to "item 20b and surrounding space". Office Action, p. 4. As clearly illustrated in Figures 3 and 4 of Black, item 20b (the alleged conductor lumen) is within conductor 20 which is disposed within the "space inside items 22-23" (the alleged central lumen). As amended claims 29 and 35 clarify that the conductor lumens are "external to" the central lumen. The items of Black asserted as corresponding to the central lumen and conductor lumens do not have the recited relationship because the alleged conductor lumens of Black are within, not external to, the alleged central lumen of Black. Accordingly, Black does not teach or suggest that the "conductor lumens extend[] along the insulation section and [are] arranged around, and external to, the central lumen" as recited in the claims.

In addition, claims 29 and 35 recite "placing non-conductive material into a portion of at least one of the conductor lumens of the lead body." The Office Action asserts that this element of the claims is taught at Col. 3:45-54 of Black. Office Action, p. 4. This portion of Black states:

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#### Application No. 13/013,599 Amendment dated April 11, 2013 Reply to Office Action dated February 27, 2013

Spanning between electrodes 18 of the distal end 14 and terminals 16 of the proximal end 12, body 22 is formed from a medical grade, substantially inert material, for example, polyurethane, silicone, or the like. While the specific material used for body 22 is not critical to the present invention, body 22 must be non-reactive to the environment of the human body, provide a flexible and durable (i.e., fatigue resistant) exterior structure for the components of lead 10, and insulate adjacent terminals 16 and/or electrodes 18.

Thus, this selection from Black is directed to a description of the body 22. The Office Action, however, asserts that the conductor lumens correspond to "item 20b and surrounding space". Office Action, p. 4. As clearly shown in Figures 3 and 4 of Black item 20b (the alleged conductor lumen) is within conductor 20 and that conductor 20 resides within body 22. Thus, the reference in the Office Action to Col. 3:45-54 is irrelevant to the recited claim element "placing non-conductive material into a portion of at least one of the conductor lumens of the lead body" because the body 22 is not placed into a portion of the alleged conductor lumens (i.e., "item 20b and surrounding space" - Office Action, p. 4) as recited in the claims. In fact, body 22 has exactly the opposite relationship to the alleged conductor lumens as that recited in the claims because the alleged conductor lumens (i.e., "item 20b and surrounding space" - Office Action, p. 4) are placed inside of the body 22 as clearly illustrated in Figures 3 and 4 of Black. Accordingly, Black does not teach or suggest "placing non-conductive material into a portion of at least. Accordingly, Black does not teach or suggest "placing non-conductive material into a portion of at least one of the conductor lumens of the lead body" as recited in the claims.

For at least these reasons, claims 29, 31, 36, and 37 are patentable over Black. The Applicants respectfully request withdrawal of this rejection of these claims.

Docket No.: 1362009-2093.2

Application No. 13/013,599 Amendment dated April 11, 2013 Reply to Office Action dated February 27, 2013

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: April 11, 2013

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

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Electronic Ac	knowledgement Receipt
EFS ID:	15493476
Application Number:	13013599
International Application Number:	
Confirmation Number:	9046
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:	1362009-2093.2
Receipt Date:	11-APR-2013
Filing Date:	25-JAN-2011
Time Stamp:	14:53:46
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted wi	th Payment	no	no				
File Listing:							
Document Number	Document Description	File Name File Size(Bytes)/ Multi P Message Digest Part /.zip (if					
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	Multipart Description/PDF files in .zip description							
	Document Description	Start	End					
	Transmittal Letter	1	1					
	Miscellaneous Incoming Letter	2	2					
	Amendment/Req. Reconsideration-After Non-Final Reject	3	3					
	Claims	4	7					
	Applicant Arguments/Remarks Made in an Amendment	8	11					
Warnings:	1							
Information:								
	Total Files Size (in bytes):	31	89040					

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.

AMEN	IDMENT 1	RANSMI	TTAL LE	TTER	Docket No. 1362009-2093.2
Applicatio	n No.	Filing	Date	Examine	
13/013,599		January 2		D. P. Angv	vin 3729
olicant(s): Jan	usz A. Kuzma e	et al.			
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Total Claims	20	- 20 =	. 0	x 80.00	0.00
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1/2 4	l'and			Dated:	April 11, 2013
	Reg. No.: 41,6	522			
Bruce E. Black Attorney/Agent FROMMER LAN					
Attorney/Agent	WRENCE & HA				

Application No. (i	f known): 13/013,699	Attorney Docket No.: 1362009-2093.2
Certi	ficate of Electronic I	Filing Under 37 C.F.R. § 1.8
	y certify that this correspondence is be ance with 37 C.F.R. § 1.6(a)(4):	ing transmitted via the Office electronic filing system in
	MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
on	April 11, 2013 Date	
		A. Downey/
	Terri N Typed or printed name	f. Downey of person signing Certificate
Regi	stration Number, if applicable	(206) 336-5690 Telephone Number
Note:	Each paper must have its own certifice each submitted paper.	cate of mailing, or this certificate must identify
	Amendment Transmittal (1 page) Amendment (9 pages)	

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

P	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						n or Docket Numb 3/013,599		Filing Date 1/25/2011	To be Mailed
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			(Column	1)	(Column 2)					
	FOR		NUMBER FI	LED	NUMBER EXTRA		RATE (\$	RATE (\$) FEE (\$)		
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	SEARCH FEE (37 CFR 1.16(k), (i), or (m))				N/A		N/A			
	EXAMINATION FEE N/A				N/A		N/A			
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	INDEPENDENT CLAIMS (37 CFR 1.16(h)) minus 3 =			iinus 3 = *			X \$ =			
APPLICATION SIZE FEE (37 CFR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
	MULTIPLE DEPEN	IDENT CLAIN	M PRESENT (3	37 CFR 1.16(j))						
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							TOTAL ADD'L	FEE		
** lf ***	If the entry in column 1 is less than the entry in column 2, write "0" in column 3. LIE * If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". /ANITA JOHNSON/ ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". ** He "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.

	ed States Paten	T AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046
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c/o Frommer L	awrence & Haug LLP	ap.	ANGWIN, DA	VID PATRICK
745 Fifth Ave NEW YORK, N	NY 10151		ART UNIT	PAPER NUMBER
			3729	
			MAIL DATE	DELIVERY MODE
			02/27/2013	PAPER

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

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

	Application No.	Applicant(s)		
	13/013,599	KUZMA ET AL.		
Office Action Summary	Examiner	Art Unit		
	DAVID ANGWIN	3729		
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet with the	correspondence address		
<ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY</li> <li>WHICHEVER IS LONGER, FROM THE MAILING DJ</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period V</li> <li>Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS fro , cause the application to become ABANDOI	DN. timely filed on the mailing date of this communication. NED (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed on $31 J_{2}$	anuary 2013.			
· · · · · · · · · · · · · · · · · · ·	action is non-final.			
3) An election was made by the applicant in resp		nt set forth during the interview on		
; the restriction requirement and election	•	-		
4) Since this application is in condition for allowar	•			
closed in accordance with the practice under E				
Disposition of Claims				
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<ul> <li>5)  Claim(s) <u>21-40</u> is/are pending in the application 5a) Of the above claim(s) <u>21-28,30,32-35 and s</u></li> <li>6)  Claim(s) is/are allowed.</li> <li>7)  Claim(s) <u>29,31,36 and 37</u> is/are rejected.</li> <li>8)  Claim(s) is/are objected to.</li> <li>9)  Claim(s) or a subject to restriction and/o</li> </ul>	<u>38-40</u> is/are withdrawn from cor	nsideration.		
9) Claim(s) are subject to restriction and/o				
* If any claims have been determined <u>allowable</u> , you may program at a participating intellectual property office for t <u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> o	he corresponding application. F	or more information, please see		
Application Papers				
<ul> <li>10) The specification is objected to by the Examiner.</li> <li>11) The drawing(s) filed on <u>25 January 2011</u> is/are: a) accepted or b) objected to by the Examiner.</li> <li>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</li> <li>Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> </ul>				
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> </ol> </li> <li>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)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)				
1) X Notice of References Cited (PTO-892)	3) 🔲 Interview Summa			
<ol> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date <u>1/25/11</u>.</li> </ol>	Paper No(s)/Mail 4)	Date		
J.S. Patent and Trademark Office				

PTOL-326 (Rev. 09-12)

### DETAILED ACTION

### Election/Restrictions

Applicant's election without traverse of Group II-B (claims 29, 31, 36, and 37) in

the reply filed on 1/31/13 is acknowledged.

Claims 21-28, 30, 32-35, and 38-40 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. The examiner notes that upon the finding of an allowable generic claim, all non-elected claims depending from the allowable generic claim necessarily will be rejoined.

### Claim Rejections - 35 USC §112

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

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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 29, 31, 36, and 37 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 29** recites the following limitations that are vague, indefinite, and

confusing:

- "providing a lead body comprising an insulation section defining a central lumen... and a plurality of conductors lumens" (claim 29, lines 2-4) It is unclear as to which element the 'lead body' or 'an insulation section' defines the central lumen, because the applicant has listed two elements that could each modify the central lumen. The examiner recommends phrasing this portion, if this is what is intended, "providing a lead body comprising an insulation section, the insulation section defining a central lumen and a plurality of conductors lumens, the central lumen extending along the insulation section, the plurality of conductors lumens extending along the insulation section and arranged around the central lumen..." Please be more precise with the claim language.
- "a plurality of conductors lumens" (claim 29, line 3) It seems the appropriate term should be "conductor lumens" the word "conductor" in the singular. Please be more precise with the claim language.
- "a plurality of conductor wires disposed in the plurality of conductor lumens" (claim 29, line 5) - It is unclear as to whether all of the plurality of conductor lumens are disposed in one lumens, if some of the plurality of conductor lumens are disposed in several lumens and no conductors in some lumens, or if one of the plurality of conductor wires is disposed in each conductor lumens. The shorthand phrasing utilized by the applicant is confusing in inhibits the reader from making a clear image. Please be more precise with the claim language.
- "conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts" (claim 29, lines 8-9) – It is unclear as to whether more than one plurality of conductor wires can be coupled to each of the contacts, and whether this is disclosed in the Specification. (This is a 112(1) issue too.) Please be more precise with the claim language.

### Claim Rejections - 35 USC § 102

The following is a set of quotations of the appropriate paragraphs of 35 U.S.C.

§102 that form the basis for the rejections under this section made in this Office Action:

Claims 29, 31, 36, and 37 are rejected under 35 U.S.C. § 102(b) as being

anticipated by Black et al (US Patent 6,216,045).

- a. Black et al discloses in his reference the following:
  - providing a lead body comprising an insulation section (Figs. 1-5, items 22-23) defining a central lumen (*space inside items 22-23*) extending along the insulation section and a plurality of conductors lumens (*item 20b and surrounding space*) extending along the insulation section and arranged around the central lumen, a plurality of conductive contacts (Figs. 2 and 5, item 16) located at an end of the lead body, and a plurality of conductor wires (Figs. 3-5, item 20a) disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

placing non-conductive material (3:45-54) into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts;

ii. wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the nonconductive material in each of the conductor lumens is disposed beneath the conductive contacts (3:45-54; Figs. 1-5);

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- iii. wherein the plurality of conductor lumens is exactly eight conductor lumens (Figs. 1-5);
- iv. wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts (3:45-54; Figs. 1-5).

### <u>Conclusion</u>

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, 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.

/David P. Angwin/ Primary Examiner Art Unit 3729

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		Notice of Reference	c Citod	Application/ 13/013,599	Control No.	Applicant(s)/ Reexaminati KUZMA ET /	
			s cheu	Examiner		Art Unit	
				DAVID ANG	GWIN	3729	Page 1 of 2
				U.S. PATENT DOCUM	IENTS	•	
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY		Name		Classification
*	A	US-5,410,797 A	05-1995	Steinke et al.			29/435
*	в	US-6,551,302 B1	04-2003	Rosinko et al.			604/505
*	С	US-6,598,280 B1	07-2003	Giba et al.			29/447
*	D	US-2004/0024440 A1	02-2004	Cole, Mary Lee			607/122
*	Е	US-2004/0225175 A1	11-2004	Moody et al.	Moody et al.		
*	F	US-6,909,918 B2	06-2005	Stypulkowski, Paul	Stypulkowski, Paul		
*	G	US-2005/0215945 A1	09-2005	Harris et al.	Harris et al.		
*	н	US-2006/0036218 A1	02-2006	Goodson et al.	Goodson et al.		
*	I	US-7,047,081 B2	05-2006	Kuzma, Janusz A			607/115
*	J	US-2007/0021771 A1	01-2007	Oepen et al.			606/194
*	к	US-2007/0021821 A1	01-2007	Johnson et al.			623/001.11
*	L	US-7,184,840 B2	02-2007	Stolz et al.			607/122
*	м	US-2008/0097426 A1	04-2008	Root et al.		606/041	
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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

Notice of References Cited

Notice of References Cited	Application/Control No.Applicant(s)/Patent Under Reexamination KUZMA ET AL.		nt Under
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	DAVID ANGWIN	3729	Page 2 of 2

### U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	US-2009/0018487 A1	01-2009	Doty, David	604/21
	В	US-			
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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

### Notice of References Cited

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	13013599	KUZMA ET AL.
	Examiner	Art Unit
	DAVID ANGWIN	3729

CPC- SEARCHED		
Symbol	Date	Examiner

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### Receipt date: 01/25/2011

### 13013599 - GAU: 3729

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
				Application Number	Not Yet Assigned
INFO	ORMATION D	NSCLOSU	IRE	Filing Date	January 25, 2011
1				First Named Inventor	Janusz A. Kuzma et al.
017	STATEMENT BY APPLICANT			Art Unit	Not Yet Assigned
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	1362009-2093.2

Examine	Cite	Document Number	Issue or	Name of Patentee or	Pages, Columns, Lines, Where
r Initials	No,1	Number-Kind Code <sup>2</sup> (it known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		2005/0215945	09-29-2005	Harris, et al.	
		3,769,984	11-06-1973	Muench	
		5,555,618	09-17-1996	Winkler	
		6,055,456	04-25-2000	Gerber	······
		6,205,361	03-20-2001	Baudino, et al.	
		6,216,045 B1	04-10-2001	Black, et al.	
		6,249,708 B1	06-19-2001	Nelson, et al.	
		6,551,302	04-22-2003	Rosinko, et al.	

### Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

[	FOREIGN PATENT DOCUMENTS													
Examiner Initials	Cite No.1	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>it known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>								

NONPATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>			
		U.S. Patent Application No. 11/329,907, Official Communication mailed November 17, 2008				
		U.S. Patent Application No. 11/329,907, Official Communication mailed April 2, 2009				
		U.S. Patent Application No. 11/329,907, Official Communication mailed July 1, 2009				
		U.S. Patent Application No. 11/329,907, Official Communication mailed March 31, 2010				
		U.S. Patent Application No. 11/329,907, Notice of Allowance mailed November 15, 2010				

	Examiner Signature	/David Angwin/	Date Considered	02/25/2013
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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.

## ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.A./

Index of Claims					Application/Control No.				Applicant(s)/Patent Under Reexamination KUZMA ET AL.							
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Part of Paper No. : 20130225

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 13/013,599

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Confirmation No.: 9046

Art Unit: 3729

Examiner: D. P. Angwin

### **RESPONSE TO RESTRICTION REQUIREMENT**

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

Dear Madam:

In the Restriction Requirement mailed January 17, 2013, the Examiner requires election of one of the following species:

Species I: Claims 21-28, plurality of conductive lumens formed in the lead body embodiment;

Species II: Claims 29-40, plurality of conductors lumens extending along the insulation section and arranged around the central lumens embodiment.

If Species I (Claims 21-28) is elected, election of one of the following subspecies is required:

Group I-A: Claims 22-25, spacers feature; Group I-B: Claim 26, polyurethane feature; Group I-C: Claim 27, heat shrink;

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Application No.: 13/013,599

Docket No.: 1362009-2093.2

Group I-D: Claim 28, heat cycle feature.

If Group I-A is elected, election of one of the following sub-subspecies is required:

Group I-A-1: Claim 23, melting material feature; Group I-A-2: Claim 24, same material feature; Group I-A-3: Claim 25, dissimilar material feature.

If Species II (claims 29-40) is elected, restriction to one of the following subspecies is required:

Group II-A: Claims 30 and 35, heating feature; Group II-B: Claims 31, 36, and 37, non-conductor into conductor lumens feature; Group II-C: Claims 32-33 and 38-39, spacers feature; Group II-D: Claims 34 and 40, polyurethane feature.

Applicants hereby elect Species II, Group II-B for continued examination, without traverse. Claims 29, 31, 36, and 37 read on the elected Species and Group.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0320, under Order No. 1362009-2093.2 from which the undersigned is authorized to draw.

Dated: January 31, 2013

Respectfully submitted,

By

Bruce E. Black Registration No.: 41,622
FROMMER LAWRENCE & HAUG LLP 745 5th Ave.
New York, New York 10151
(206) 336-5668
(212) 588-0500 (Fax)
bblack@flhlaw.com (E-Mail)
Attorneys For Applicant

Electronic Ac	Electronic Acknowledgement Receipt							
EFS ID:	14845600							
Application Number:	13013599							
International Application Number:								
Confirmation Number:	9046							
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:	1362009-2093.2							
Receipt Date:	31-JAN-2013							
Filing Date:	25-JAN-2011							
Time Stamp:	16:34:46							
Application Type:	Utility under 35 USC 111(a)							

# Payment information:

Submitted wi	th Payment	no	no						
File Listin	g:								
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)				
1		01221447.PDF	658086 2c68a8aecbe5080/991bcf26b500277b77cd 5861	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:		1								
Information:										
	Total Files Size (in bytes	): 658	3086							

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.

Application No. (	if known): 13/013,599	Attorney Docket No.: 1362009-2093.2
Cert	ificate of Electronic Filing U	nder 37 C.F.R. § 1.8
l hereb accord	iv certify that this correspondence is being transmitte ance with 37 C.F.R. § 1.6(a)(4):	d via the Office electronic filing system in
	MS Amendment Commissioner for Patents P.O. Box 1450 Alexandría, VA 22313-1450	
on	January 31, 2013 Date	
	/Terri M. Downey/ Signature	
	Terri M. Downey	
<u></u>	Typed or printed name of person sign	ing Certificate
		(206) 336-5690
Keg	istration Number, if applicable	Telephone Number
Note:	Each paper must have its own certificate of mailing each submitted paper.	, or this certificate must identify
	Response to Restriction Requirement (2 pgs.)	)

	ed States Patent a	ND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22, www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2	9046
	7590 01/17/2013 Fic Neuromodulation Corp.		EXAM	IINER
c/o Frommer La	awrence & Haug LLP		ANGWIN, DA	VID PATRICK
745 Fifth Ave NEW YORK, N	NY 10151		ART UNIT	PAPER NUMBER
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			01/17/2013	PAPER

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

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

	Application No.	Applicant(s)									
	13/013,599	KUZMA ET AL.									
Office Action Summary	Examiner	Art Unit									
	DAVID ANGWIN	3729									
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply											
<ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.</li> <li>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.</li> <li>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.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 13). 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).</li> </ul>											
Status											
1) Responsive to communication(s) filed on 07 Sector	eptember 2012.										
	action is non-final.										
3) An election was made by the applicant in respo	onse to a restriction requirement	set forth during the interview on									
; the restriction requirement and election	have been incorporated into this	action.									
4) Since this application is in condition for allowar	nce except for formal matters, pro	esecution as to the merits is									
closed in accordance with the practice under E	<i>Ex parte Quayle</i> , 1935 C.D. 11, 45	53 O.G. 213.									
Disposition of Claims											
<ul> <li>5) Claim(s) <u>21-40</u> is/are pending in the application 5a) Of the above claim(s) is/are withdraw</li> <li>6) Claim(s) is/are allowed.</li> <li>7) Claim(s) is/are rejected.</li> <li>8) Claim(s) is/are objected to.</li> <li>9) Claim(s) <u>21-40</u> are subject to restriction and/or</li> </ul>	wn from consideration.										
* If any claims have been determined <u>allowable</u> , you may program at a participating intellectual property office for t <u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> of	he corresponding application. Fo	r more information, please see									
Application Papers											
<ul> <li>10) The specification is objected to by the Examine</li> <li>11) The drawing(s) filed on is/are: a) accelled a complexity of the complexity of the complexity of the complexity of the correct of the complexity of the correct of the context of the contex</li></ul>	epted or b)∏ objected to by the l drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).									
Priority under 35 U.S.C. § 119											
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> </ol> </li> <li>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)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>											
Attachment(s)	_										
1) Notice of References Cited (PTO-892)	3) 🔲 Interview Summary Paper No(s)/Mail Da	(PTO-413) ate.									
<ol> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	4) (Other:	·									
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PTOL-326 (Rev. 09-12)

### DETAILED ACTION

### Election/Restriction

This application contains claims directed to the following patentably distinct species:

- I. **Species I** plurality of conductive lumens formed in the lead body embodiment (**claims 21-28**); and
- Species II plurality of conductors lumens extending along the insulation section and arranged around the central lumens embodiment (claims 29-40).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. Specifically, **Species I** includes the limitation of a plurality of conductive lumens formed in the lead body, whereas **Species II** does not include this limitation. **Species II** includes the limitation of a plurality of conductors lumens extending along the insulation second and arranged around the central lumens, whereas **Species I** does not include this limitation. In addition, these species are not obvious variants of each other based on the current record. Finally, examining these species together is a serious burden to the examiner because they require separate searches. **No claims are generic. The examiner notes that upon the finding of an allowable generic claim, all non-elected species will be reconsidered for rejoinder.** 

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.

If the applicant elects **Species I** (claims 21-28), restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I-A. spacers feature (claims 22-25), classified in class 470, subclass 1.
- **Group I-B.** polyurethane feature (**claim 26**), classified in class 525, subclass 446.
- **Group I-C.** heat shrink feature (**claim 27**), classified in class 156, subclass 209.

Group I-D. heat cycle feature (claim 28), classified in class 219, subclass 491.

These groups are distinct processes. Related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different designs, modes of operation, function, or effect; (2) the inventions do not overlap in search, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP 806.05(j). In the instant case, the inventions as claimed have materially different designs (i.e. materially different manufacturing processes), require separate searches, and are not obvious variants. Specifically:

- **Group I-A.** spacers feature, whereas the other groups do not require this limitation.
- **Group I-B.** polyurethane feature, whereas the other groups do not require this limitation.
- **Group I-C.** heat shrink feature, whereas the other groups do not require this limitation.
- **Group I-D.** heat cycle feature, whereas the other groups do not require this limitation.

Claim 21 links Groups I-A to I-D. The examiner notes that upon the finding of an allowable linking claim (i.e. claim 21), all non-elected claims depending from the allowable linking claim necessarily will be rejoined.

If the applicant elects Group I-A (claims 22-25), restriction to one of the following

inventions is required under 35 U.S.C. 121:

- Group I-A-1. melting material feature (claim 23), classified in class 219, subclass 634.
- Group I-A-2. same material feature (claim 24), classified in class 219, subclass 543.
- Group I-A-3. dissimilar material feature (claim 25), classified in class 156, subclass 73.5.

These groups are distinct processes. Related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different designs, modes of operation, function, or effect; (2) the inventions do not overlap in search, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP 806.05(j). In the instant case, the inventions as claimed have materially different designs (i.e. materially different manufacturing processes), require separate searches, and are not obvious variants. Specifically:

- **Group I-A-1.** melting material feature, whereas the other groups do not require this limitation.
- Group I-A-2. same material feature, whereas the other groups do not require this limitation.
- **Group I-A-3.** dissimilar material feature, whereas the other groups do not require this limitation.

Claim 22 links Groups I-A-1 to I-A-3. The examiner notes that upon the

finding of an allowable linking claim (i.e. claim 22), all non-elected claims

depending from the allowable linking claim necessarily will be rejoined.

If the applicant elects Species II (claims 29-40), restriction to one of the following

inventions is required under 35 U.S.C. 121:

- Group II-A. heating feature (claims 30 and 35), classified in class 219, subclass 491.
- Group II-B. non-conductor into conductor lumens feature (claims 31, 36, and 37), classified in class 174, subclass 174.
- Group II-C. spacers feature (claims 32-33 and 38-39), classified in class 470, subclass 1.
- Group II-D. polyurethane feature (claims 34 and 40), classified in class 525, subclass 446.

These groups are distinct processes. Related inventions are distinct if: (1) the

inventions as claimed are either not capable of use together or can have a materially

different designs, modes of operation, function, or effect; (2) the inventions do not

overlap in search, i.e., are mutually exclusive; and (3) the inventions as claimed are not

obvious variants. See MPEP 806.05(j). In the instant case, the inventions as claimed

have materially different designs (i.e. materially different manufacturing processes),

require separate searches, and are not obvious variants. Specifically:

- **Group II-A.** heating feature, whereas the other groups do not require this limitation.
- **Group II-B.** non-conductor into conductor lumens feature, whereas the other groups do not require this limitation.

- **Group II-C.** spacers feature, whereas the other groups do not require this limitation.
- **Group II-D.** polyurethane feature, whereas the other groups do not require this limitation.

Claim 29 links Groups II-A to II-D. The examiner notes that upon the finding

of an allowable linking claim (i.e. claim 29), all non-elected claims depending from

### the allowable linking claim <u>necessarily</u> will be rejoined.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed group for

prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable.

As a result, the applicant may elect one of the following:

Group I-A-1 – claims 21, 22 and 23 will be examined. Group I-A-2 – claims 21, 22, and 24 will be examined. Group I-A-3 – claims 21, 22, and 25 will be examined. Group I-B – claims 21 and 26 will be examined. Group I-C – claims 21 and 27 will be examined. Group I-D – claims 21 and 28 will be examined. Group II-A – claims 29, 30, and 35 will be examined. Group II-B – claims 29, 31, 36, and 37 will be examined. Group II-C – claims 29, 32, 33, 38, and 39 will be examined. Group II-D – claims 29, 34, and 40 will be examined.

The examiner notes that upon a finding of an allowable generic claim, all the non-elected claims depending from the allowable generic claim <u>necessarily</u> will be rejoined. In addition, upon a finding of an allowable generic claim, all nonelected claims will be reconsidered for rejoinder. Further, the examiner has no objection to the applicant amending an independent claim with limitations from a non-elected claim to overcome a rejection. 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

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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.

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.

/David P. Angwin/ Primary Examiner, Art Unit 3729

DPA

Index of Claims				Application/Control No.				R	Applicant(s)/Patent Under Reexamination KUZMA ET AL.					
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U.S. Patent and Trademark Office

Part of Paper No. : 20130116

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Docket No.: 1362009-2093.2 (PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 13/013,599

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND

Confirmation No.: 9046

Art Unit: 3729

Examiner: D. P. Angwin

# METHOD OF MAKING SAME

### SECOND PRELIMINARY AMENDMENT

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

Dear Sir:

### INTRODUCTORY COMMENTS

Please amend the above-identified U.S. patent application as follows:

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

Remarks/Arguments begin on page 6 of this paper.

### AMENDMENT TO CLAIMS

1.-20. (Canceled)

21. (New) A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead and providing a plurality of conductor wires disposed in a plurality of conductor lumens formed in the lead body, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

connecting at least one of the plurality of conductor wires to each of the conductive contacts; placing non-conductive material into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by a conductor wire, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts; and

heating the non-conductive material to cause the non-conductive material to thermally reflow or melt.

22. (New) The method of claim 21, further comprising placing spacers between pairs of adjacent conductive contacts.

23. (New) The method of claim 22, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

24. (New) The method of claim 22, wherein a material of the spacers and the nonconductive material are a same material.

25. (New) The method of claim 22, wherein a material of the spacers and the nonconductive material are different materials.

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#### Application No. 13/013,599 Second Preliminary Amendment dated September 7, 2012

26. (New) The method of claim 21, wherein the non-conductive material comprises polyurethane.

27. (New) The method of claim 21, further comprising placing a heat shrink tubing around the conductive contacts and the non-conductive material.

28. (New) The method of claim 21, wherein heating the non-conductive material comprises heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

29. (New) A method of manufacturing a stimulation lead comprising:

providing a lead body comprising an insulation section defining a central lumen extending along the insulation section and a plurality of conductors lumens extending along the insulation section and arranged around the central lumen, a plurality of conductive contacts located at an end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts; and

placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts.

30. (New) The method of claim 29, further comprising heating the non-conductive material to cause the non-conductive material to thermally reflow or melt.

31. (New) The method of claim 29, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body,

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wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts.

32. (New) The method of claim 29, further comprising placing spacers between pairs of adjacent conductive contacts.

33. (New) The method of claim 32, further comprising heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

34. (New) The method of claim 21, wherein the non-conductive material comprises polyurethane.

35. (New) A method of manufacturing a stimulation lead comprising:

providing a lead body comprising a insulation section defining a central lumen extending along the insulation section and a plurality of conductors lumens extending along the insulation section and arranged around the central lumen, a plurality of conductive contacts located at an end of the lead body, and a plurality of conductor wires disposed in the plurality of conductor lumens, wherein each of the conductor lumens has at least one of the conductor wires disposed therein, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed beneath the conductive contacts; and

heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

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36. (New) The method of claim 35, wherein the plurality of conductor lumens is exactly eight conductor lumens.

37. (New) The method of claim 35, wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed beneath the conductive contacts.

38. (New) The method of claim 35, further comprising placing spacers between pairs of adjacent conductive contacts.

39. (New) The method of claim 38, wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together.

40. (New) The method of claim 35, wherein the non-conductive material comprises polyurethane.

### **REMARKS**

Claims 1-20 have been canceled without prejudice and new claims 21-40 have been added. Claims 21-40 are pending in this application. No new matter has been added.

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 7, 2012

Respectfully submitted,

Bv

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

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Electronic Ac	knowledgement Receipt
EFS ID:	13691104
Application Number:	13013599
International Application Number:	
Confirmation Number:	9046
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:	1362009-2093.2
Receipt Date:	07-SEP-2012
Filing Date:	25-JAN-2011
Time Stamp:	18:49:56
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted wi	th Payment	no	no					
File Listing:								
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)			
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	Document Description	Start	End								
	Transmittal Letter	1	1								
	Miscellaneous Incoming Letter	2	2								
	Preliminary Amendment	3	3								
	Claims	4	7								
	Applicant Arguments/Remarks Made in an Amendment	8	8								
Warnings:											
Information:											
	Total Files Size (in bytes):	35	65302								

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.

AME	<b>DMENT</b>	FRANSMI	TTAL LE	TTE	R		ocket No. 009-2093.2
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Attorney/Agent   FROMMER LAV							
745 5th Ave. New York, New (206) 336-5690							

Application No. (	if known): 13/013,599	Attorney Docket No.: 1362009-2093.2
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	MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
on	September 7, 2012 Date	
	/Terri M.	
	Sign	
	Terri M. Typed or printed name of	Downey person signing Certificate
Reg	istration Number, if applicable	(206) 336-5690 Telephone Number
Note:	Attached documents:	
	Second Preliminary Amendment (6 Amendment Transmittal (1 page)	pages)
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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. Application or Docket Number PATENT APPLICATION FEE DETERMINATION RECORD Filing Date To be Mailed 13/013.599 01/25/2011 Substitute for Form PTO-875 APPLICATION AS FILED - PART I OTHER THAN SMALL ENTITY (Column 1) (Column 2) SMALL ENTITY OB FOR NUMBER FILED NUMBER EXTRA RATE (\$) FEE (\$) RATE (\$) FEE (\$) BASIC FEE N/A N/A N/A N/A 37 CFR 1.16(a), (b), or (c)) SEARCH FEE N/A N/A N/A N/A (37 CFR 1.16(k), (i), or (m)) EXAMINATION FEE N/A N/A N/A N/A (37 CFR 1.16(o), (p), or (q)) TOTAL CLAIMS OR minus 20 = X \$ X \$ (37 CFR 1.16(i)) INDEPENDENT CLAIMS (37 CFR 1.16(h)) X \$ X \$ minus 3 = = = If the specification and drawings exceed 100 sheets of paper, the application size fee due APPLICATION SIZE FEE is \$250 (\$125 for small entity) for each (37 CFR 1.16(s)) 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 OTHER THAN SMALL ENTITY OR SMALL ENTITY (Column 1) (Column 3) (Column 2) CLAIMS HIGHEST REMAINING PRESENT ADDITIONAL ADDITIONAL NUMBER 09/07/2012 RATE (\$) RATE (\$) AFTER PREVIOUSLY EXTRA FEE (\$) FEE (\$) AMENDMENT AMENDMENT PAID FOR Total (37 CFR 1.16(i)) \* 20 Minus \*\* 20 = 0 Χ\$ OR X \$60= 0 Independ \* З \*\*\*3 = 0 X \$ OR X \$250= 0 Minus = Application Size Fee (37 CFR 1.16(s)) OR FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) TOTAL TOTAL 0 ADD'L OR ADD'L FFF FFF (Column 1) (Column 2) (Column 3) CLAIMS HIGHES REMAINING NUMBER ADDITIONAL PRESENT ADDITIONAL RATE (\$) RATE (\$) AFTER PREVIOUSLY EXTRA FEE (\$) FEE (\$) AMENDMENT PAID FOR Total (37 CFR 1.16(i)) AMENDMEN' Minus \*\* X \$ OR Χ\$ = 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 TOTAL ADD'L OR ADD'L FFF FFF \* If the entry in column 1 is less than the entry in column 2, write "0" in column 3, Legal Instrument Examiner: \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". /KĚVIN HORN/ \*\*\* 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

PTO/SB/06 (07-06)

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.

UNITED ST.	ates Patent and Trademai	UNITED STA' United States Address: COMMIS P.O. Box I	, Virginia 22313-1450
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2
			<b>CONFIRMATION NO. 9046</b>
50638		PUBLICAT	TION NOTICE
Boston Scientific Neuromo			

Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Publication No.US-2011-0118815-A1 Publication Date:05/19/2011

745 Fifth Ave

NEW YORK, NY 10151

### NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

page 1 of 1

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

	United State	<u>s Patent</u>	and Tradem	UNITED STA United State: Address: COMMI PO. Box	ia, Virginia 22313-1450
APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS IND CLAIMS
13/013,599	01/25/2011	3766	1090	1362009-2093.2	20 3
					<b>CONFIRMATION NO. 9046</b>
50638				FILING F	RECEIPT
Boston Scienti c/o Frommer L 745 Fifth Ave NEW YORK, N	awrence & Ha				*OC000000045896024*
					Date Mailed: 02/09/2011

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

Applicant(s)

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

#### **Assignment For Published Patent Application**

Boston Scientific Neuromodulation Corporation, Valencia, CA **Power of Attorney:** The patent practitioners associated with Customer Number <u>50638</u>

#### Domestic Priority data as claimed by applicant

This application is a CON of 11/329,907 01/11/2006 PAT 7,891,085 which claims benefit of 60/643,093 01/11/2005

**Foreign Applications** (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <u>http://www.uspto.gov</u> for more information.)

#### If Required, Foreign Filing License Granted: 02/08/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/013,599** 

Projected Publication Date: 05/19/2011

Non-Publication Request: No

Early Publication Request: No

page 1 of 3

#### Title

### ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

#### **Preliminary Class**

607

### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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### Title 37, Code of Federal Regulations, 5.11 & 5.15

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page 2 of 3

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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	PAT	ENT APPLI		N FEE DE ute for Form			ס		tion or Docket Nurr 3,599	ber
	APP	LICATION A	S FILED		umn 2)	SMALL	ENTITY	OR	OTHEF SMALL	
FOR NUMBER FILED NUMBER EXTRA		R EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
	IC FEE FR 1.16(a), (b), or (c))	N	/A	N	J/A	N/A		1	N/A	330
	RCH FEE FR 1.16(k), (i), or (m))	N	/A	N	J/A	N/A			N/A	540
	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	N	J/A	N/A			N/A	220
	AL CLAIMS FR 1.16(i))	20	minus 20	*				OR	× 52 =	0.00
	EPENDENT CLAIN FR 1.16(h))	<sup>MS</sup> 3	minus 3	= *					× 220 =	0.00
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A A		(Column 1) CLAIMS REMAINING AFTER		(Column 2) HIGHEST NUMBER PREVIOUSLY	(Column 3) PRESENT EXTRA	SMALL RATE(\$)	ADDITIONAL FEE(\$)	OR	OTHEF SMALL RATE(\$)	
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						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)			-		
NT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
NDMENT	Total (37 CFR 1.16(i))	•	Minus *	*	=	X =		OR	x =	
END	Independent (37 CFR 1.16(h))	*	Minus *	**	=	x =		OR	x =	
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UNITED ST	ates Patent and Tradem	UNITED STA United State Address: COMMI PO. Box	ia, Virginia 22313-1450
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/013,599	01/25/2011	Janusz A. Kuzma	1362009-2093.2
			<b>CONFIRMATION NO. 9046</b>
50638		POA ACC	EPTANCE LETTER
Boston Scientific Neuromo c/o Frommer Lawrence & 745 Fifth Ave	•		0C000000045896087*

Date Mailed: 02/09/2011

## NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/25/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/kung/

NEW YORK, NY 10151

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

page 1 of 1

Under the Pap	erwork Reduction Act of 1995, no persons are require	U.S. Patent and Tr	PTO/SB/05 (08-08) Approved for use through 09/30/2010. OMB 0651-0032 ademark Office. U.S. DEPARTMENT OF COMMERCE Imation unless it displays a valid OMB control number.			
(	UTILITY	Attorney Docket No.	1362009-2093.2			
PA	TENT APPLICATION	First Inventor	Janusz A. Kuzma			
	TRANSMITTAL	Title	ELECTRODE ARRAY ASSEMBLY AND ME			
(Only for new	nonprovisional applications under 37 CFR 1.53(b))	Express Mail Label N	o. Via EFS			
3	APPLICATION ELEMENTS oter 600 concerning utility patent application contents.	ADDRESS TO:	Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450			
1. 🔽 Fee Trans	smittal Form (e.g., PTO/SB/17)	ACCOMPA	NYING APPLICATION PARTS			
2. Applicant See 37 C	claims small entity status.	9. Assignmen	t Papers (cover sheet & document(s))			
3. Specifical Both the cl (For information		Name of A	.ssignee			
5. Oath or Declar a. Newly		] 10. 7 37 CFR 3.73	(b) Statement re is an assignee) Attorney			
(for co	ntinuation/divisional with Box 18 completed)	11. English Tra	nslation Document (if applicable)			
Sigr	ne in the prior application, see 37 CFR 3(d)(2) and 1.33(b).	12. 🕢 Information	Disclosure Statement (PTO/SB/08 or PTO-1449) ies of citations attached			
6. 🔽 Applicati	on Data Sheet. See 37 CFR 1.76	13. Z Preliminary	Amendment			
Compute	or CD-R in duplicate, large table or r Program ( <i>Appendix</i> ) Iscape Table on CD		14. Return Receipt Postcard (MPEP 503) (Should be specifically itemized)			
(if applicable, i	nd/or Amino Acid Sequence Submission items a. – c. are required)		15. Certified Copy of Priority Document(s) (if foreign priority is claimed)			
	nputer Readable Form (CRF) ecification Sequence Listing on:	16. Nonpublica	tion Request under 35 U.S.C. 122(b)(2)(B)(i), nust attach form PTO/SB/36 or equivalent.			
i, L ii,	CD-ROM or CD-R (2 copies); or Paper	17. 🗹 Other: <u>PTO</u>	Form SB/08			
	tements verifying identity of above copies					
specification follow	ING APPLICATION, check appropriate box, an ing the title, or in an Application Data Sheet un	der 37 CFR 1.76:	tion below and in the first sentence of the			
Continuat	ion Divisional Co	ntinuation-in-part (CIP) of	f prior application No.: 11/329,907.			
Prior application infor			Unit: <u>3729</u>			
	19. CORRESI	PONDENCE ADDRESS				
The address as	ssociated with Customer Number:	50638	OR Correspondence address below			
Name						
Address	,					
City	Stat		Zip Code			
Country	Telepho		Email			
Signature Name	Deven C. Disale		Date January 25, 2011 Registration No. 44, 000			
(Print/Type)	Bruce E. Black	****	(Attorney/Agent) 41,622			

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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				Filing Date	Ja	January 25, 2011		
	For FY 2009					nusz A. Kuz	ma	
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Signature	<u> </u>	<u> </u>	<u> </u>	Registration No. (Attorney/Agent)	1622	Telep	hone 206-336-5668	
Name (Print/Type)	Bruce E. Black					Date	January 25, 2011	
This collection of info	rmation is required by	37 CFR 1.136	The information is	required to obtain or	retain a bene	fit 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 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

PTO/SB/14 (11-08)

Approved for use through 09/30/2010, OME 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 contains a valid OMB control number.

Analiantian Da	to Chool 37 CED 4 70	Attorney Docket Number	1362009-2093.2
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME			NG SAME
bibliographic data arran This document may be	ged in a format specified by the Un	ited States Patent and Trademark C mitted to the Office in electronic fo	being submitted. The following form contains the office as outlined in 37 CFR 1.76. rmat using the Electronic Filing System (EFS) or the

# Secrecy Order 37 CFR 5.2

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

### **Applicant Information:**

Applic	Applicant 1											
Applic	ant	Authority 🖲	Inventor (	)l.ega	I Representativ	e und	ler 35 L	J.S.C. 11	7	OParty of In	terest under 35 U.S	.C. 118
Prefix	Gi	ven Name			Middle Na	me			Fam	ily Name		Suffix
	Ja	nusz			A.				Kuzm	a		
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Applic	ant	2						L			·	
		Authority ®	Inventor (	Clega	Representativ	e und	er 35 L	J.S.C. 11	7	OParty of In	terest under 35 U.S.	C. 118
		ven Name			Middle Name				Family Name			Suffix
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Postal	Co	de	91355			Cou	intry	US				
		Il Inventors Must Be Listed ~ Additional Inventor Information blocks may be Add button.						blocks i	may b	e	Add	

### **Correspondence Information:**

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

An Address is being provided for the correspondence information of this application.

#### PTO/SB/14 (11-08)

Approved for use through 09/30/2010. 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 contains a valid OMB control number.

Anniiantian Data Chant 27 CED 1 70			Attorney Docket Number	1362009	-2093.2		
Application Data Sheet 37 CFR 1.76		Application Number					
Title of Invention ELECTRODE ARRAY ASSE			MBLY AND METHOD OF MAKIN	NG SAME			
Customer Number 50638							
Email Address prosecutiondocketing		j@flhlaw.com		Add Email	Remove Email		

# **Application Information:**

Title of the Invention	ELECTRODE ARI	ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME					
Attorney Docket Number	1362009-2093.2		Small Entity Status Claimed				
Application Type	Nonprovisional						
Subject Matter	······································						
Suggested Class (if any)			Sub Class (if any)				
Suggested Technology C	enter (if any)	3729					
Total Number of Drawing	Sheets (if any)	6	Suggested Figure for Publication (if any)				
Publication Inform	ation:						

Request Early Publication (Fee required at time of Request 37 CFR 1.219)

Request Not to Publish. Thereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

# Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

	Please Select One:	Customer Number O US Patent Practitioner O Limited Recognition	· · · · · · · · · · · · · · · · · · ·	
-	Customer Number	50638		

# Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	11329907	2006-01-11
Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11329907	non provisional of	60643093	2005-01-11

EFS Web 2.2.2

#### PTO/SB/14 (11-08)

Approved for use through 09/30/2010. 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 contains a valid OMB control number.

	Annlingtion No	ta Sheet 37 CFR 1.76	Attorney Docket Number	1362009-2093.2
	Application Da	La officer of A 1.70	Application Number	
	Title of Invention ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME			
1	l			

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.

# **Foreign Priority Information:**

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	Country	Parent Filing Date (YYYY-MM-DD)	Priority Claimed			
			Yes O No			
Additional Foreign Priority Data may be generated within this form by selecting the Add button.						

# Assignee Information:

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

Assignee 1							
If the Assignee is an C	ne Assignee is an Organization check here.						
Organization Name Boston Scientific Neuromodulation Corporation							
Mailing Address Info	iling Address Information:						
Address 1	25155 Rye Canyon Loc	25155 Rye Canyon Loop					
Address 2							
City	Valencia	State/Province	CA				
Country US		Postal Code	91355				
Phone Number		Fax Number					
Email Address							
Additional Assignee Data may be generated within this form by selecting the <b>Add</b> button.							

# Signature:

	A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.				
Signature	ih s.hl		Date (YYYY-MM-DD)	2011-01-25	
First Name	Bruce E.	Last Name	Black	Registration Number	41622

# PTO/SB/14 (11-08) Approved for use through 09/30/2010. 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 contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	1362009-2093.2
		Application Number	
Title of Invention	ELECTRODE ARRAY ASSEM	MBLY AND METHOD OF MAKIN	NG SAME

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

#### 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 Peter K. Johnson, Reg. No.57,236 Laura Haburay Bishop, Reg. No. 47424 Victoria Poissant, Reg. No. 56,871 Philip H. Lee, Reg. No. 50645

Philip H. Lee

Citizenship: Australia

(661) 362-1964

Send Correspondence to: Bryant R. Gold Advanced Bionics Corporation 25129 Bye Canyon Road Valencia, CA 91355

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.

Full Name of Inventor: Janusz A: Kuzma
Residence: 7591 E. Ponderoja Circis, Parker, Colorado, 80138
Post Office Address: Steme
Inventor's Signature

11/200,6

**Direct Telephone Calls To:** 

#### DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)

Full Name of Inventor: Anne M. Pianca

Citizenship: United States of America

Residence: 24450 Valencia Blvd., #6106, Valencia, California, 91355

Post Office Address: Same Inventos's Signaturi

11 JAN '06

			TE APPLICATIONS BI	196; U.S. DEPARTMENT OF COMMERC Ness It displays a valk OMB control numb EFORE THE USPTO
I hereby re 37 CFR 3.	evoke all previous pov	wers of attorney given in	the application identified in	the attached statement under
I hereby ap				
OR		h the Customer Number:	50638	
Practi	itioner(s) named below (i	f more than ten patent practi	tioners are to be named, then a	customer number must be used):
	Name	Registration Number	Name	Registration Number
attached to this	s form in accordance with 2	only to the uncersigned accord 37 CFR 3.73(b).	d States Patent and Trademark Ol ing to the USPTO assignment reco	ords or assignment documents
	address associated wit		Identified in the attached states 50638	ment under 37 CFR 3.73(b) to:
X The	address associated wit		[	ment under 37 CFR 3.73(b) to:
OR Firm or	address associated wit		[	ment under 37 CFR 3.73(b) to:
OR Individu	address associated wit		[	ment under 37 CFR 3.73(b) to:
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Under the Paperwork Reduction Act of 19	Approved for use through 07/31/2012. OMB 0 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF CO 5. no persons are required to respond to a collection of information unless it displays a valid OMB contro
S	TATEMENT UNDER 37 CFR 3.73(b)
Applicant/Patent Owner: Janusz A. Kuzma e	al.
	Filed/Issue Date: January 11, 2006
Titled: ELECTRODE ARRAY ASSEMBL	AND METHOD OF MAKING SAME
Boston Scientific Neuromodulation Corpora	ion <sub>a</sub> corporation
(Name of Assignee)	(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.
states that it is:	
1. $\boxed{X}$ the assignee of the entire right, title,	and interest in;
2. an assignee of less than the entire r (The extent (by percentage) of its ov	ght, title, and interest in mership interest is%); or
3 the assignee of an undivided interes	in the entirely of (a complete assignment from one of the joint inventors was mad
the patent application/patent identified above, b	virtue of either:
<ul> <li>An assignment from the inventor(s) the United States Patent and Trader copy therefore is attached.</li> <li>OR</li> </ul>	of the patent application/patent identified above. The assignment was recorded in hark Office at Reel 021845 , Frame 0966 , or for which a
	f the patent application/patent identified above, to the current assignee as follows:
1. From:	То:
	ed in the United States Patent and Trademark Office at
Reel	, Frame, or for which a copy thereof is attached.
2. From:	То:
	ed in the United States Patent and Trademark Office at
Reel	, Frame, or for which a copy thereof is attached.
3. From:	To:
	ed 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	f title are listed on a supplemental sheet(s),
As required by 37 CFR 3.73(b)(1)(i), the or concurrently is being, submitted for red	documentary evidence of the chain of title from the original owner to the assigned ordation pursuant to 37 CFR 3.11.
INOTE: A separate copy (i.e., a true cop accordance with 37 CFR Part 3, to record	y of the original assignment document(s)) must be submitted to Assignment Divis I the assignment in the records of the USPTO. <u>See</u> MPEP 302.08]
The undersigned (whose title is supplied below)	
A7 5. 1401	January 25, 2011
	Date
Signature	
Signature Bruce E. Black	Attorney for Assignee

process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Docket No.: 1362009-2093.2 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: Not Yet Assigned

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME

Confirmation No.: Not Yet Assigned

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

### FIRST PRELIMINARY AMENDMENT

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

Dear Sir:

# INTRODUCTORY COMMENTS

Please amend the above-identified U.S. patent application as follows:

Amendment to the Specification begins on page 2 of this paper.

Remarks/Arguments begin on page 3 of this paper.

# REMARKS

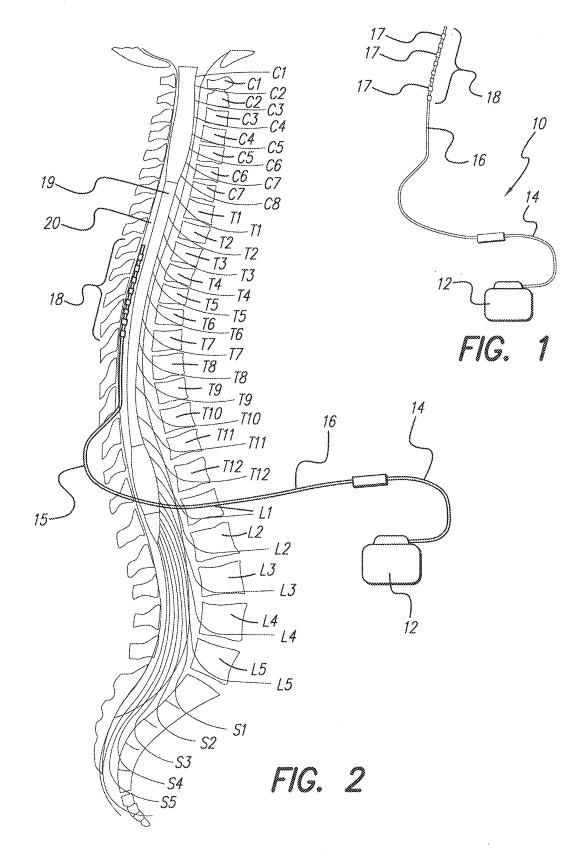
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicants encourage the Examiner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

Dated: January 25, 2011

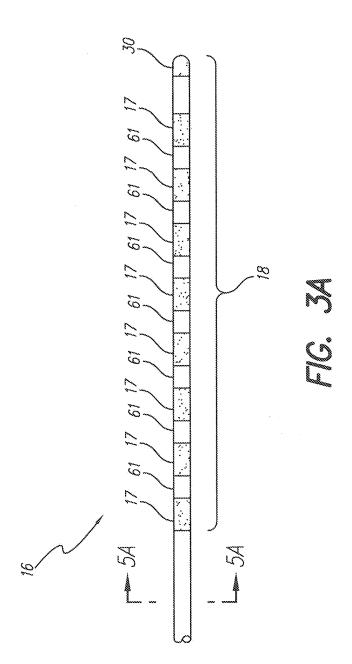
Respectfully submitted,

By

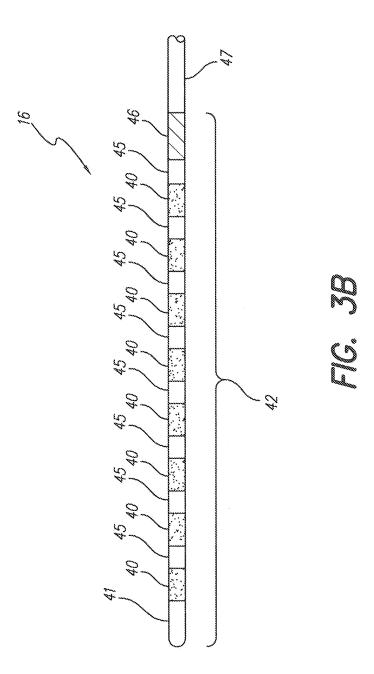
Bruce E. Black Registration No.: 41,622 FROMMER LAWRENCE & HAUG LLP 745 Fifth Avenue New York, New York 10151 (206) 336-5668 (212) 588-0500 (Fax) Attorneys/Agents For Applicant Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Tille: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor: Janusz A. Kuzma et al. Sheet 1 of 6



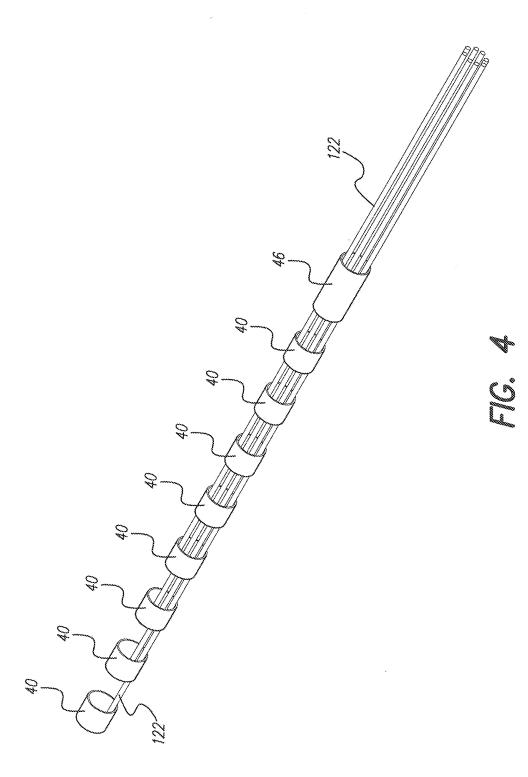
Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor: Janusz A. Kuzma et al. Sheet 2 of 6



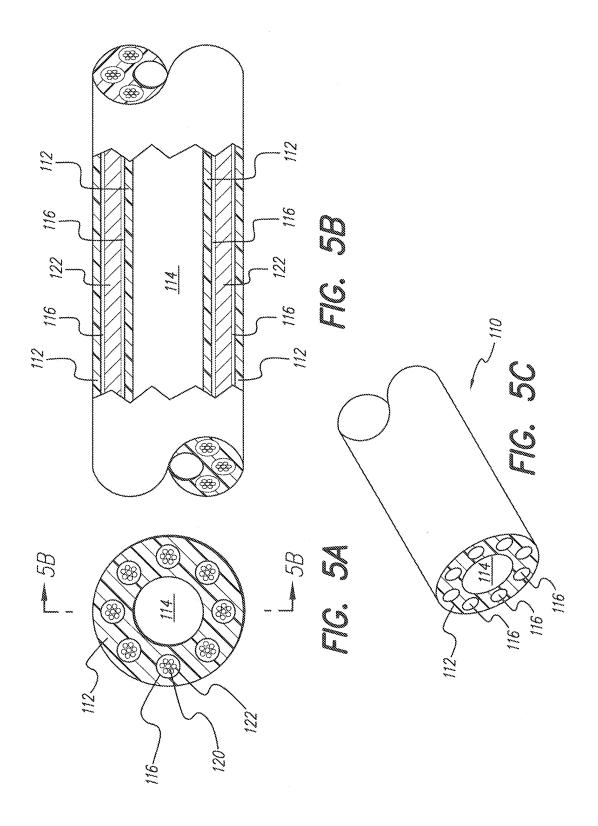
Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor: Janusz A. Kuzma et al. Sheet 3 of 6



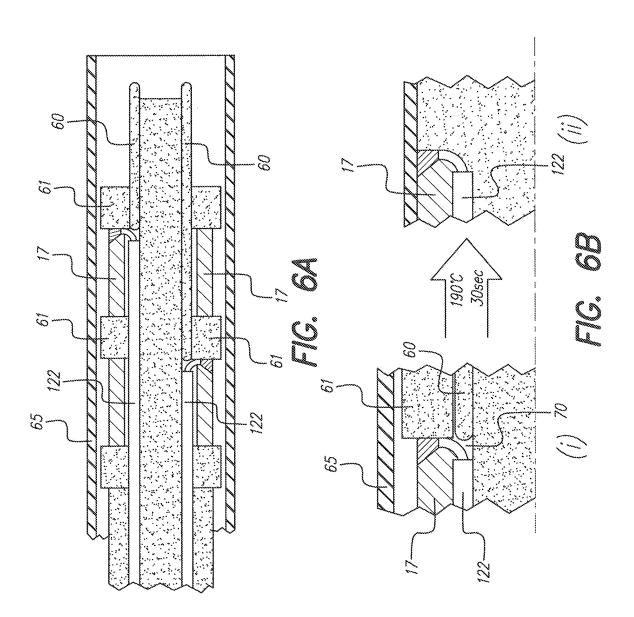
Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor: Janusz A. Kuzma et al. Sheet 4 of 6



Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor: Janusz A. Kuzma et al. Sheet 5 of 6



Appl. No.: Not Yet Assigned Docket No. 1362009-2093.2 Title: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Inventor; Janusz A. Kuzma et al. Sheet 6 of 6



Docket No.: 1362009-2093.2 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: Not Yet Assigned

Filed: January 25, 2011

For: ELECTRODE ARRAY ASSEMBLY AND METHOD OF MAKING SAME Confirmation No.: Not Yet Assigned

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

### **INFORMATION DISCLOSURE STATEMENT (IDS)**

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

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

Docket No.: 1362009-2093.2

Application No. Not Yet Assigned First Preliminary Amendment dated January 25, 2011

XA.	within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
<b>B</b> .	before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
C.	after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.
	(check one of the boxes "i" and "ii" below:)
	i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
	(a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
	(b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
	ii. Payment in the amount of the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
D.	after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(p) payment in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was
	(check one of the boxes "a" and "b" below:)

00873288.DOC

> (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

> (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated August 5, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. Patent(s) and/or U.S. Patent Application Publication(s) on PTO/SB/08 is/are not being submitted.
- B. Document(s) \_\_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

### <<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

3. Cite Nos. \_\_\_\_\_\_ are not in the English language. In accordance with 1.98(c), Applicant states:

3

An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
A concise explanation of the relevance of document(s)

\_ is set forth as follows: [Insert concise explanation of relevance]

A concise explanation of the relevance of document(s) can be found on page(s) of the specification.

A concise explanation of document(s) can be found on the attached sheet.

 $x \mid 4$ . No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

x 5. Other information being provided for the examiner's consideration follows:

U.S. Patent Application No. 11/329,907, Official Communication mailed November 17, 2008

U.S. Patent Application No. 11/329,907, Official Communication mailed April 2, 2009

U.S. Patent Application No. 11/329,907, Official Communication mailed July 1, 2009

U.S. Patent Application No. 11/329,907, Official Communication mailed March 31, 2010

U.S. Patent Application No. 11/329,907, Notice of Allowance mailed November 15, 2010

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

00873288.DOC

Docket No.: 1362009-2093.2

Early and favorable consideration is earnestly solicited.

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: January 25, 2011

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

	B/08: Substitute for for			Complete if Known		
				Application Number	Not Yet Assigned	
INF	ORMATION D	ISCLOSU	RE	Filing Date	January 25, 2011	
1				First Named Inventor	Janusz A. Kuzma et al.	
012	STATEMENT BY APPLICANT			Art Unit	Not Yet Assigned	
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned	
Sheet	Sheet 1 of 1			Attorney Docket Number	1362009-2093.2	

Examine	Cite		Cite	Document Number	Issue or	Name of Patentee or	Pages, Columns, Lines, Where
r Initials	No.1	Number-Kind Code <sup>2</sup> (it known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
		2005/0215945	09-29-2005	Harris, et al.			
		3,769,984	11-06-1973	Muench			
		5,555,618	09-17-1996	Winkler			
		6,055,456	04-25-2000	Gerber			
		6,205,361	03-20-2001	Baudino, et al.			
		6,216,045 B1	04-10-2001	Black, et al.			
		6,249,708 B1	06-19-2001	Nelson, et al.			
		6,551,302	04-22-2003	Rosinko, et al.			

# Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
 Examiner Initials	Cite No.1	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>8</sup> ( <i>it known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>

	NONPATENT LITERATURE DOCUMENTS				
Examiner Initials					
		U.S. Patent Application No. 11/329,907, Official Communication mailed November 17, 2008			
		U.S. Patent Application No. 11/329,907, Official Communication mailed April 2, 2009			
		U.S. Patent Application No. 11/329,907, Official Communication mailed July 1, 2009			
		U.S. Patent Application No. 11/329,907, Official Communication mailed March 31, 2010			
		U.S. Patent Application No. 11/329,907, Notice of Allowance mailed November 15, 2010			

Examiner	Date	
Signature	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.

Electronic Patent Application Fee Transmittal					
Application Number:					
Filing Date:					
Title of Invention:	ELECTRODE ARRA	Y ASSEMBLY AND N	IETHOD OF MAKIN	IG SAME	
First Named Inventor/Applicant Name:	Janusz A. Kuzma				
Filer:	Bruce Black/Terri Downey				
Attorney Docket Number:	1362009-2093.2				
Filed as Large Entity					
Utility under 35 USC 111(a) Filing Fees					
Description	Fee Code	e Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:	<b>I</b>				
Utility application filing	1011	1	330	330	
Utility Search Fee	1111	1	540	540	
Utility Examination Fee	1311	1	220	220	
Pages:		<b>.</b>			
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
	Tot	al in USD	(\$)	1090

Electronic Ac	knowledgement Receipt
EFS ID:	9304725
Application Number:	13013599
International Application Number:	
Confirmation Number:	9046
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:	1362009-2093.2
Receipt Date:	25-JAN-2011
Filing Date:	
Time Stamp:	18:03:45
Application Type:	Utility under 35 USC 111(a)

# Payment information:

Submitted with Payment	yes	
Payment Type	Credit Card	
Payment was successfully received in RAM	\$1090	
RAM confirmation Number	6057	
Deposit Account	500320	
Authorized User	FROMMER LAWRENCE & HAUG LLP	
The Director of the USPTO is hereby authorized to charg	e indicated fees and credit any overpayment as follows:	
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File Listing	J:							
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.			
1		2002 ADD TRANS add	8031229	Nor	13			
		2093_APP_TRANS.pdf -	71b95c7f4b5c76e7394eeca3e131a623211 73da5	yes				
	Multipart Description/PDF files in .zip description							
	Document Des	scription	Start	E	nd			
	Transmittal of New	Application	1		1			
	Miscellaneous Inco	ming Letter	2		2			
	Application Da	ta Sheet	3		6			
	Oath or Declara	7	8					
	Power of Attorney		9	9				
	Assignee showing of owners	hip per 37 CFR 3.73(b).	10	10				
-	Preliminary Amendment		11	13				
Warnings:								
Information:								
2		2093_SPEC.pdf	10409960	yes	19			
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-	Multip	art Description/PDF files ir	ı.zip description					
	Document De	scription	Start	End				
	Specificat	ion	1	1	4			
	Claims		15	1	8			
	Abstrac	t	19	19				
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3	Drawings-only black and white line drawings	2093_DRAWINGS.pdf	1971655	no	6			

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4		2093_IDS.pdf	3261984	yes	6
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	Document De	scription	Start	E	nd
	Transmittal	Letter	1		5
	Information Disclosure Stater	nent (IDS) Filed (SB/08)	6		6
Warnings:					
Information:					
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Information:					
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#### New Applications Under 35 U.S.C. 111

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

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

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

#### New International Application Filed with the USPTO as a Receiving Office

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

Electronic Ac	knowledgement Receipt
EFS ID:	9304725
Application Number:	13013599
International Application Number:	
Confirmation Number:	9046
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:	1362009-2093.2
Receipt Date:	25-JAN-2011
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Time Stamp:	18:03:45
Application Type:	Utility under 35 USC 111(a)

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File Listing	g:				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.
1		2002 ADD TRANS add	8031229	Was	13
		2093_APP_TRANS.pdf	71b95c7f4b5c76e7394eeca3e131a623211 73da5	yes	
	Multip	art Description/PDF files ir	.zip description		
	Document Des	scription	Start	E	nd
	Transmittal of New	Application	1		1
	Miscellaneous Inco	ming Letter	2		2
-	Application Da	3		6	
-	Oath or Declara	7	8		
-	Power of Att	9	9		
-	Assignee showing of ownership per 37 CFR 3.73(b).		10	10	
-	Preliminary Ame	endment	11	13	
Warnings:					
Information:			1		
2		2093_SPEC.pdf	10409960	yes	19
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_	Multip	art Description/PDF files ir	.zip description		
	Document Des	scription	Start	End	
-	Specification		1	14	
	Claims		15	18	
ľ	Abstract		19	19	
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Information:					
3	Drawings-only black and white line drawings	2093_DRAWINGS.pdf	1971655	no	6

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Information:		1			
4		2093_IDS.pdf	3261984	yes	6
-		2095_105.pdf	8f2de8505f0caced8169b0aae8431495e71e 7e26	yes	0
	Multip	oart Description/PDF files	s in .zip description		
	Document De	scription	Start	E	nd
	Transmittal	Letter	1		5
	Information Disclosure Stater	nent (IDS) Filed (SB/08)	6		6
Warnings:					
Information:					
5	NPL Documents	00873299.PDF	331525	20	9
5	NPL Documents	008/3299.PDF	6a7b247922da82a9f3d037c901a924c9da7 a3439	no	9
Warnings:			·		
Information:					
6		00873303.PDF	449174		10
6	NPL Documents		0b9b637c1cdb4a71cf8e8372f6de8f5cd677 1959	no	12
Warnings:		•	·		
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		00873298.PDF	445115		10
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Warnings:		•			
Information:					
8	NPL Documents	00873302.PDF	359849	20	9
8	NPL Documents	00873302.PDF	4f9a0b9f0f9f6a29da7eca4ec9d3e80f4a6cc 8b8	no	9
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9	NPL Documents	00873314.PDF	7dbed6371935ee03630a594c0c4331abd04 4363c	no	
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Docket No.: 1362009-2093.2

#### AMENDMENT TO SPECIFICATION

Please amend the following paragraph of the Specification:

# **CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] The present application This utility patent application is a continuation of allowed U.S. Patent Application No. 11/329,907 filed January 11, 2006, which claims the benefit of United States Provisional Patent Application Serial No. 60/643,093, filed January 11, 2005, <u>all of</u> which application is <u>are</u> herein incorporated by reference in its <u>their</u> entirety.

2

Attorney Docket No. 1362009-2093.2

#### **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 lead. A stylet may be placed

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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.

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#### **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.

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**[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

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[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;

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[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

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[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

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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

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abdomen or above the buttocks. Use of lead extension 14 facilitates locating the IPG 12 away from the lead exit point 15.

FIG. 3A shows, in accordance with the invention, a distal portion of [0032] 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

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extension lead should be configured to accept the proximal connector end of the stimulating lead 16.

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[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

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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.

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As previously indicated for FIG. 5C, the lead body 110 shown in FIG. 5B may be extruded as one piece.

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**[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

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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 adiacent 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.

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[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 illustrate 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, multifilament 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

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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

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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 and desired to be protected by Letters Patent of the United States is:

1. A stimulation lead assembly for making a lead, the assembly comprising:

a lead body defining a plurality of conductor lumens;

a plurality of electrically conductive contacts disposed along an end of the lead body, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

a plurality of conductor wires disposed in the conductor lumens, wherein at least one of the conductor wires is connected to each conductive contact; and

monofilament disposed, at least in part, beneath the conductive contacts and within portions of the conductor lumens not occupied by conductor wire; and

wherein the monofilament is thermally fused from heat applied to the lead assembly, which heat is at a temperature to cause the monofilament to thermally reflow or melt.

2. The lead assembly of claim 1, further comprising a plurality of spacers disposed between adjacent pairs of the conductive contacts.

3. The lead assembly of claim 2, wherein the spacers and the monofilament are thermally fused together from heat applied to the lead assembly.

4. The lead assembly of claim 3, wherein the monofilament is a different material than the spacers.

5. The lead assembly of claim 3, wherein the monofilament is a same material as the spacers.

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6. The lead assembly of claim 1, wherein the plurality of electrically conductive contacts are located on a proximal end of the stimulation lead.

7. The lead assembly of claim 1, wherein the plurality of electrically conductive contacts are located on a distal end of the stimulation lead.

8. The lead assembly of claim 1, wherein the monofilament comprises polyurethane.

9. A method of manufacturing a stimulation lead comprising:

providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead and providing a plurality of conductor wires disposed in a plurality of conductor lumens formed in the lead body, wherein a portion of the conductor lumens is disposed beneath the conductive contacts;

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

placing monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by a conductor wire, wherein at least a portion of the monofilament is disposed beneath the conductive contacts; and

heating the monofilament to cause the monofilament to thermally reflow or melt.

10. The method of claim 9, further comprising placing spacers between pairs of adjacent conductive contacts.

11. The method of claim 10, wherein heating the monofilament comprises heating the monofilament and spacers to cause the monofilament to thermally reflow or melt and to cause the monofilament and spacers to thermally fuse together.

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12. The method of claim 9, wherein a material of the spacers and the monofilament is the same.

13. The method of claim 9, wherein a material of the spacers and a material of the monofilament are different.

14. The method of claim 9, wherein the monofilament comprises polyurethane.

15. The method of claim 9, further comprising placing a heat shrink tubing around the conductive contacts and the monofilament.

16. A stimulation lead assembly for making a lead, the assembly comprising:

a lead body defining a plurality of conductor lumens;

a plurality of electrically conductive contacts disposed along an end of the lead body;

a plurality of spacers disposed between pairs of adjacent conductive contacts;

a plurality of conductor wires disposed in the conductor lumens, wherein at least one of the conductor wires is connected to each conductive contact; and

monofilament disposed, at least in part, beneath the conductive contacts and within portions of the conductor lumens not occupied by conductor wire; and

wherein the spacers and monofilament are thermally fused from heat applied to the lead assembly.

17. The lead assembly of claim 16, wherein the monofilament is a different material than the spacers.

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18. The lead assembly of claim 16, wherein the monofilament is a same material as the spacers.

19. The lead assembly of claim 16, wherein the plurality of electrically conductive contacts are located on a proximal end of the stimulation lead.

.20. The lead assembly of claim 16, wherein the plurality of electrically conductive contacts are located on a distal end of the stimulation lead.

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Attorney Docket No. 1362009-2093.2

## 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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