



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
61/280,557	11/05/2009	Robert E. Wright	NBUS.000GEN

CONFIRMATION NO. 9990

POA ACCEPTANCE LETTER



20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Date Mailed: 05/13/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/29/2011.

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.

/ttran/

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



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
61/280,557	11/05/2009	Robert E. Wright	82945

23685
KRIEGSMAN & KRIEGSMAN
30 TURNPIKE ROAD, SUITE 9
SOUTHBOROUGH, MA 01772

CONFIRMATION NO. 9990
POWER OF ATTORNEY NOTICE



OC000000047588679

Date Mailed: 05/13/2011

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/29/2011.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71.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

/ttran/

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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Address: COMMISSIONER FOR PATENTS
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
61/280,557	11/05/2009		110	NBUS.000GEN		

CONFIRMATION NO. 9990

CORRECTED FILING RECEIPT



20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Date Mailed: 05/13/2011

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. 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)

Robert E. Wright, Denver, CO;
Scott A. Brandt, Denver, CO;

Power of Attorney: The patent practitioners associated with Customer Number 20995

If Required, Foreign Filing License Granted: 11/19/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/280,557**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Novel medical needle incorporating multiple filaments for improved energy delivery

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and

Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**REVOCATION & GENERAL POWER OF ATTORNEY
and
CHANGE IN CORRESPONDENCE ADDRESS**

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

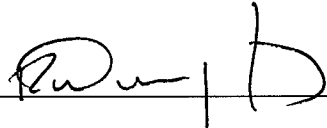
Dear Sir:

The undersigned is an empowered representative of the Assignee and hereby appoints the registrants of Knobbe, Martens, Olson & Bear, LLP, **Customer No. 20,995**, as attorneys and agents to represent the Assignee before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned to the Assignee according to the USPTO assignment records or assignment documents supplied with an accompanying Statement Under 37 C.F.R. § 3.73(b). This appointment is to be to the exclusion of the inventor(s) and his attorney(s) in accordance with the provisions of 37 C.F.R. § 3.71.

Submission of this paper in connection with any matter of the below named assignee, together with a statement under 37 C.F.R. § 3.73(b), shall serve to revoke any previous powers of attorney in that matter.

Attached is a Statement Under 37 C.F.R. § 3.73(b), signed by a registrant of Knobbe, Martens, Olson & Bear, LLP, setting forth a full chain of title for the subject application owned by the Assignee named below.

Please recognize or change the correspondence address for the application identified in the attached Statement to **Customer No. 20,995**.

By:  Date: 4/26/2011
Name: Robert E. Wright Title: Manager

Assignee: Nimbus Concepts, LLC

Address: 333 South Monroe Street #113
Denver, CO 80209

11080463
041811

Please Direct All Correspondence to Customer Number **20,995**

PETITION TO CORRECT INVENTORSHIP

Applicant	: Robert E. Wright et al.
App. No.	: 61/280,557
Filed	: November 5, 2009
For	: NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY
Conf. No.	: 9990

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

Dear Sir:

Applicants respectfully request that inventorship in the above-referenced provisional patent application be corrected to reflect the following:

Please delete Mark L. Adams of Sandy, Utah as an inventor

Please add Scott A. Brandt of Denver, Colorado as an inventor.

Accordingly, the correct inventorship for this application is as follows:

Robert E. Wright, Denver, Colorado

Scott A. Brandt, Denver, Colorado

Pursuant to 37 C.F.R. §§ 1.48(d) and 1.48(e), this Petition includes the following items:

1. A Request for Correction of Inventorship that sets forth the desired inventorship change including a statement, signed by all of the Applicants (as corrected, Robert E. Wright and Scott A. Brandt) and signed by the person whose name is being deleted (Mark L. Adams), that the inventorship error occurred without deceptive intention on the part of the omitted inventor and without deceptive intention on the part of the person whose name is being deleted.
2. Written Consent of the Assignee to Correction of Inventorship, including a copy of the Assignment from inventors Robert E. Wright and Scott A. Brandt to Assignee Nimbus Concepts, LLC.
3. Petition fee of \$50 as directed under 37 C.F.R. § 1.17(q).

Please Direct All Correspondence to Customer Number **20,995**

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR LLP

Dated: April 29, 2011

By: /Adam Gilbert/

Adam Gilbert

Registration No. 59,967

Attorney of Record

Customer No. 20,995

(949) 760-0404

11138611
042911

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wright et al.
Appl. No. : 61/280,557
Filed : November 5, 2009
For : NOVEL MEDICAL NEEDLE
INCORPORATING MULTIPLE
FILAMENTS FOR IMPROVED
ENERGY DELIVERY

REQUEST FOR CORRECTION OF INVENTORSHIP
UNDER 37 C.F.R. §§ 1.48(d) & 1.48(e)

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

Dear Sir:

Applicants hereby request that the name of the following person named in the Provisional Application for Patent Cover Sheet provided in the above-captioned application be deleted from the inventorship of the present application:

Mark L. Adams, Sandy, Utah

Additionally, please correct this application to add the following inventor:

Scott A. Brandt, Denver, Colorado

Accordingly, the correct inventorship for this application is as follows:

Robert E. Wright, Denver, Colorado

Scott A. Brandt, Denver, Colorado

Appl. No. : 61/280,557
Filed : November 5, 2009

The inventorship errors occurred without deceptive intention on the part of the omitted inventor and without deceptive intention on the part of the person whose name is being deleted.

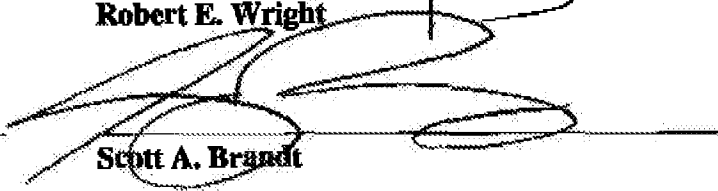
The \$50 processing fee set forth in 37 C.F.R. § 1.17(q) accompanies this request.

Applicants pursuant to 37 C.F.R. § 1.33(b)(4),

Dated: 4/29/2011

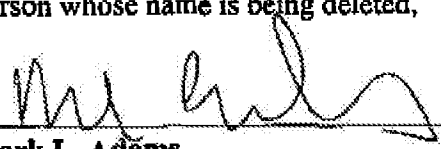

Robert E. Wright

Dated: 4/29/11


Scott A. Brandt

Person whose name is being deleted,

Dated: 1/7/2011


Mark L. Adams

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Wright et al.
Appl. No.	:	61/280,557
Filed	:	November 5, 2009
For	:	NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY

WRITTEN CONSENT OF THE ASSIGNEE TO CORRECTION OF INVENTORSHIP

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

Dear Sir:

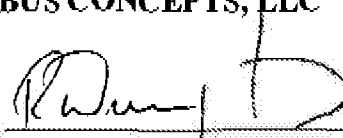
Nimbus Concepts, LLC, a limited liability company, is the Assignee of the entire right, title, and interest of the above-referenced provisional patent application by virtue of an Assignment from the inventors to the Assignee, a true copy of which is attached hereto. This Assignment represents the entire chain of title for the above-referenced provisional patent application from the inventors to the Assignee.

The undersigned is an empowered representative of the Assignee.

In accordance with 37 C.F.R. § 1.48(e)(4), **Nimbus Concepts, LLC**, understands and fully consents to the correction of inventorship in the above-identified provisional patent application deleting **Mark L. Adams** of Sandy, Utah as inventor.

NIMBUS CONCEPTS, LLC

Date: 4/28/2011

By: 

Name: Robert E. Wright
Title: Manager
Nimbus Concepts, LLC
333 South Monroe Street #113
Denver, Colorado 80209

11136973

ASSIGNMENT

WHEREAS, **Robert E. Wright**, a United States citizen residing at Denver, Colorado, and **Scott A. Brandt**, a United States citizen residing at Denver, Colorado (individuals collectively hereinafter the "ASSIGNOR") invented certain new and useful improvements, technology, inventions, developments, ideas, or discoveries related to NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY (collectively hereinafter referred to as the "Work") for which a provisional application was filed with the United States Patent and Trademark Office as Serial No. 61/280,557 on November 5, 2009 (hereinafter the "Application");

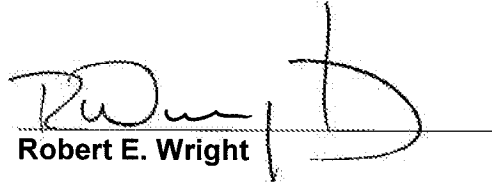
AND WHEREAS, **NIMBUS CONCEPTS, LLC**, a Delaware Limited Liability Company, with its principal place of business at 333 South Monroe Street #113, Denver, Colorado 80209 (hereinafter the "ASSIGNEE"), desires to acquire the entire right, title, and interest in and to the Application and the Work:

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, ASSIGNOR hereby acknowledges that ASSIGNOR has sold, assigned, transferred, and set over, and by these presents does hereby sell, assign, transfer, and set over, unto said ASSIGNEE, its successors, legal representatives, and assigns, the entire right, title, and interest throughout the world in the Application and the Work, including all provisional and nonprovisional applications relating and/or claiming priority thereto that have been or may hereafter be filed (including, but not limited to, U.S. Provisional Application No. 61/347,351, filed May 21, 2010, and U.S. Application No. 12/940,974, filed November 5, 2010), including all divisions, continuations, continuations-in-part, reissues, and reexaminations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and any related Letters Patent which may hereafter be granted or filed in any country or countries foreign to the United States (including, but not limited to, PCT App. No. PCT/US10/055744, filed November 5, 2010), all extensions, renewals, and reissues thereof; and ASSIGNOR hereby authorizes and requests the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all related Letters Patent to the ASSIGNEE, its successors, legal representatives, and assigns, in accordance with the terms of this instrument.

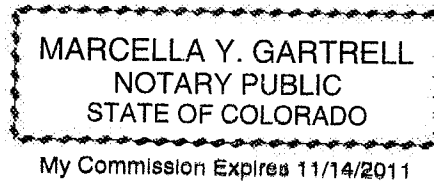
AND ASSIGNOR DOES HEREBY sell, assign, transfer, and convey to ASSIGNEE, its successors, legal representatives, and assigns all claims for damages and all remedies arising out of any violation of the rights assigned hereby that may have accrued prior to the date of assignment to ASSIGNEE, or may accrue hereafter, including, but not limited to, the right to sue for, collect, and retain damages for past infringements of said Letters Patent before or after issuance.

AND ASSIGNOR DOES HEREBY covenant and agree that ASSIGNOR will communicate to said ASSIGNEE, its successors, legal representatives, and assigns, any facts known to ASSIGNOR respecting the Work, and testify in any legal proceeding, assist in the preparation of any other provisional or non-provisional applications relating to the Application and the Work or any improvements made thereto, sign all lawful papers, execute and make all rightful oaths and/or declarations in connection with the Application and the Work including any improvements made thereto, any patent applications filed therefrom, and any continuing application filed from any of the aforementioned applications, and generally do everything possible to aid the ASSIGNEE, its successors, legal representatives, and assigns, in obtaining and enforcing proper patent protection for the Work in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 26 day of April, 2011.


Robert E. Wright

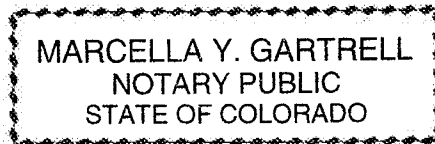
**Sign in presence of a Notary and have
Notary attach Acknowledgement**



IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 26 day of April, 2011.


Scott A. Brandt

**Sign in presence of a Notary and have
Notary attach Acknowledgement**



My Commission Expires 11/14/2011

10831555
042111

Electronic Patent Application Fee Transmittal

Application Number:	61280557			
Filing Date:	05-Nov-2009			
Title of Invention:	Novel medical needle incorporating multiple filaments for improved energy delivery			
First Named Inventor/Applicant Name:	Robert E. Wright			
Filer:	Adam J. Gilbert/Lee Ann Kemp			
Attorney Docket Number:	82945			
Filed as Small Entity				
Provisional Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Processing Fee for Provis. applications	1807	1	50	50
Total in USD (\$)				50

Electronic Acknowledgement Receipt

EFS ID:	9990930
Application Number:	61280557
International Application Number:	
Confirmation Number:	9990
Title of Invention:	Novel medical needle incorporating multiple filaments for improved energy delivery
First Named Inventor/Applicant Name:	Robert E. Wright
Customer Number:	23685
Filer:	Adam J. Gilbert/Shirley Martinez
Filer Authorized By:	Adam J. Gilbert
Attorney Docket Number:	82945
Receipt Date:	29-APR-2011
Filing Date:	05-NOV-2009
Time Stamp:	18:33:21
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$50
RAM confirmation Number	5341
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Petitioner's Exhibit 1054
Avanos v. Stratus

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		NBUS-001PR1_3-73_Statement.PDF	351701 67bd869be4f7c4685f3b62708e5bb26581d3c7eb	yes	5
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Assignee showing of ownership per 37 CFR 3.73(b).		1	4	
	Power of Attorney		5	5	
Warnings:					
Information:					
2	Request under Rule 48 correcting inventorship	NBUS-001PR1_Petition_to_Correct_Inventorship.PDF	561692 24041176b6160aca21516e2caaded9db8fd45a3	no	8
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	29779 813bae61786c2225ef1bf20ba30c895b949a9d59	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			943172		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

STATEMENT UNDER 37 C.F.R. § 3.73(b)
ESTABLISHMENT OF ASSIGNEE

Applicant	: Robert E. Wright et al.
App. No.	: 61/280,557
Filed	: November 5, 2009
For	: NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY
Conf. No.	: 9990

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

Dear Sir:

This document is being filed with a copy of a Power of Attorney signed by the Assignee. This Statement sets forth the chain of title of the above-identified application.

NIMBUS CONCEPTS, LLC, a Delaware Limited Liability Company, is the Assignee of the entire right, title, and interest of the above-referenced application by virtue of:

The attached copy of the Assignment being forwarded to the Recordation
Branch concurrently under separate cover.

The undersigned is an agent of Customer Number 20,995 and is authorized to act on behalf of the Assignee. Please recognize or change the correspondence address for the above-identified application to **Customer No. 20,995**.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 29, 2011

By: /Adam Gilbert/
Adam Gilbert
Registration No. 59,967
Attorney of Record
Customer No. 20,995
(949) 760-0404

11146223
042911

ASSIGNMENT

WHEREAS, **Robert E. Wright**, a United States citizen residing at Denver, Colorado, and **Scott A. Brandt**, a United States citizen residing at Denver, Colorado (individuals collectively hereinafter the "ASSIGNOR") invented certain new and useful improvements, technology, inventions, developments, ideas, or discoveries related to NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY (collectively hereinafter referred to as the "Work") for which a provisional application was filed with the United States Patent and Trademark Office as Serial No. 61/280,557 on November 5, 2009 (hereinafter the "Application");

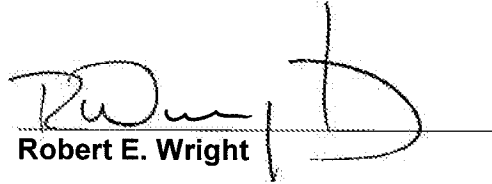
AND WHEREAS, **NIMBUS CONCEPTS, LLC**, a Delaware Limited Liability Company, with its principal place of business at 333 South Monroe Street #113, Denver, Colorado 80209 (hereinafter the "ASSIGNEE"), desires to acquire the entire right, title, and interest in and to the Application and the Work:

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, ASSIGNOR hereby acknowledges that ASSIGNOR has sold, assigned, transferred, and set over, and by these presents does hereby sell, assign, transfer, and set over, unto said ASSIGNEE, its successors, legal representatives, and assigns, the entire right, title, and interest throughout the world in the Application and the Work, including all provisional and nonprovisional applications relating and/or claiming priority thereto that have been or may hereafter be filed (including, but not limited to, U.S. Provisional Application No. 61/347,351, filed May 21, 2010, and U.S. Application No. 12/940,974, filed November 5, 2010), including all divisions, continuations, continuations-in-part, reissues, and reexaminations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and any related Letters Patent which may hereafter be granted or filed in any country or countries foreign to the United States (including, but not limited to, PCT App. No. PCT/US10/055744, filed November 5, 2010), all extensions, renewals, and reissues thereof; and ASSIGNOR hereby authorizes and requests the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all related Letters Patent to the ASSIGNEE, its successors, legal representatives, and assigns, in accordance with the terms of this instrument.

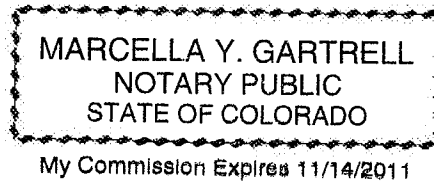
AND ASSIGNOR DOES HEREBY sell, assign, transfer, and convey to ASSIGNEE, its successors, legal representatives, and assigns all claims for damages and all remedies arising out of any violation of the rights assigned hereby that may have accrued prior to the date of assignment to ASSIGNEE, or may accrue hereafter, including, but not limited to, the right to sue for, collect, and retain damages for past infringements of said Letters Patent before or after issuance.

AND ASSIGNOR DOES HEREBY covenant and agree that ASSIGNOR will communicate to said ASSIGNEE, its successors, legal representatives, and assigns, any facts known to ASSIGNOR respecting the Work, and testify in any legal proceeding, assist in the preparation of any other provisional or non-provisional applications relating to the Application and the Work or any improvements made thereto, sign all lawful papers, execute and make all rightful oaths and/or declarations in connection with the Application and the Work including any improvements made thereto, any patent applications filed therefrom, and any continuing application filed from any of the aforementioned applications, and generally do everything possible to aid the ASSIGNEE, its successors, legal representatives, and assigns, in obtaining and enforcing proper patent protection for the Work in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 26 day of April, 2011.


Robert E. Wright

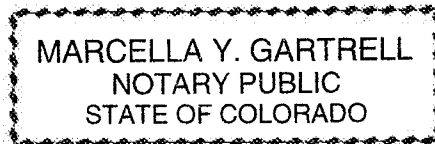
**Sign in presence of a Notary and have
Notary attach Acknowledgement**



IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 26 day of April, 2011.


Scott A. Brandt

**Sign in presence of a Notary and have
Notary attach Acknowledgement**



My Commission Expires 11/14/2011

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042111



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
61/280,557	11/05/2009		110	82945		

CONFIRMATION NO. 9990

23685
KRIEGSMAN & KRIEGSMAN
30 TURNPIKE ROAD, SUITE 9
SOUTHBOROUGH, MA 01772

FILING RECEIPT



OC00000038879767

Date Mailed: 11/24/2009

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. 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)

Robert E. Wright, Denver, CO;
Mark L. Adams, Sandy, UT;

Power of Attorney:

Edward Kriegsman--33529

If Required, Foreign Filing License Granted: 11/19/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/280,557**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Novel medical needle incorporating multiple filaments for improved energy delivery

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and

Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EM144721667US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
ROBERT E.	WRIGHT	DENVER, CO
MARK L.	ADAMS	SANDY, UT

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max):

NOVEL MEDICAL NEEDLE INCORPORATING MULTIPLE FILAMENTS FOR IMPROVED ENERGY DELIVERY

Direct all correspondence to:

CORRESPONDENCE ADDRESS☒ The address corresponding to Customer Number:

23685

OR

☐ Firm or
Individual Name

Address

City	State	Zip
Country	Telephone	Email

ENCLOSED APPLICATION PARTS (check all that apply)

- ☐ Application Data Sheet. See 37 CFR 1.76
- ☐ Drawing(s) Number of Sheets _____
- ☒ Specification (e.g. description of the invention) Number of Pages 13 w/figs.
- ☐ CD(s), Number of CDs _____
- ☒ Other (specify) Express Mail Cert. and postcard _____

Fees Due: Filing Fee of \$210 (\$105 for small entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is \$260 (\$130 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).

METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

- ☒ Applicant claims small entity status. See 37 CFR 1.27.
- ☒ A check or money order is enclosed to cover the filing fee and application size fee (if applicable).
- ☐ Payment by credit card. Form PTO-2038 is attached
- ☐ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit
- Account Number: _____ A duplicative copy of this form is enclosed for fee processing.

110

TOTAL FEE AMOUNT (\$)**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. 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 8 hours 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.

Petitioner's Exhibit 1054

Avanos v. Stratus

Page 26 of 42

PROVISIONAL APPLICATION COVER SHEET
Page 2 of 2

PTO/SB/16 (10-07)

Approved for use through 06/30/2010. 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 displays a valid OMB control number.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.



No.

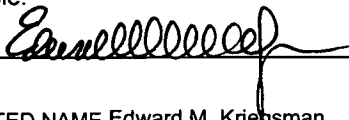


Yes, the name of the U.S. Government agency and the Government contract number are: _____

WARNING:

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

SIGNATURE _____



Date November 5, 2009

TYPED or PRINTED NAME Edward M. Kriegsman

REGISTRATION NO. 33,529
(if appropriate)

TELEPHONE 508-481-3500

Docket Number: 82945

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

Dear Sir:

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

In re: U.S. Provisional Patent Application entitled NOVEL
MEDICAL NEEDLE INCORPORATING
MULTIPLE FILAMENTS FOR IMPROVED
ENERGY DELIVERY

Included are: A Provisional Application for Patent Cover Sheet; a combined
specification and drawings of 13 pages; a check for \$110; and a
postcard

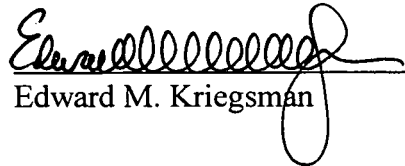
Applicant: Robert E. Wright and Mark L. Adams

Attorney Docket No.: 82945

Express Mail Mailing Label Number: EM144721667US

Date of Deposit: November 5, 2009

I hereby certify that these papers and/or fee is being deposited with the United States
Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date
indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA
22313-1450.


Edward M. Kriegsman

TITLE
Novel Medical Needle Incorporating Multiple Filaments for Improved Energy Delivery
KEYWORDS
Radio Frequency (RF), Electrocautary, ablation, tissue ablation, pain management, electrode, filament, multi-filament, lesion
ABSTRACT & FIGURES PLEASE SUMMARIZE YOUR IDEA/INVENTION
The invention described here is of a medical needle, consisting of more than one filament, used to deliver Radio Frequency (RF) energy from a source, to the human anatomy. The major advancement of the needle described below (over existing RF needle technology) is that it has the ability to deliver energy over a larger area of the anatomy. This is accomplished without an increase in needle diameter. For example, a standard RF needle of 18 Ga diameter can, on average, ablate a spherical area of tissue in the range of 5mm. A modified version of the 18 Ga needle, incorporating multiple filaments, can ablate a spherical area of tissue in the range of 10mm, or greater. This is accomplished by increasing the relative area from which the RF energy emanates. In a traditional, single element needle design, the energy emanates from a singular point. Similarly, and another downfall of the single element needle, is that as the surrounding tissue is ablated, it is theorized that it becomes more difficult for the RF energy to pass through that tissue. This theory can be described by considering how food is cooked. If for example one tried to cook a turkey by placing a hot metal rod in the center of the turkey, it would take an extremely long time for the outer flesh of the turkey to become cooked. Further, by the time the entire turkey was cooked, the center of the turkey (near the hot metal rod) would likely be burned. The multiple filament needle overcomes these obstacles by providing several points from which the RF energy can emanate. Further, because the elements are at some distance from one another (after being deployed from within the sheath), the energy will emanate in a pattern more conducive to ablating a larger area of tissue. This is analogous to taking the single, hot metal rod in the previous example and replacing it with a multitude of hot metal rods, equally spaced throughout the turkey. Obviously, this would produce more uniform cooking.

BACKGROUND

PLEASE DISCUSS PRESENT DISEASE CONDITIONS AND STATE OF THE ART RELATED TO YOUR IDEA/ INVENTION INCLUDING EXISTING DEVICES, THERAPIES, APPLICATIONS, MANUFACTURING PROCESSES, ETC.

Procedures

The primary use of the needle device described here is for the creation of spherical tissue lesions, for the purposes of pain management in the sacroiliac joint (SIJ or SI joint). It should be noted though that the delivery of RF energy to tissue in the anatomy is practiced for a multitude of reasons. This invention can be easily adapted (modified or scaled) for use in other medical procedures.

As an example, in other pain management procedures, it may be desirable to create a non-spherical, flattened lesion (unilateral lesion). Modifications of the invention which would facilitate this are described below.

In addition to applications related to pain management, the needle could be used to deliver RF as a means to cauterize "feeder vessels", as in bleeding ulcers.

The device could also be adapted to procedures such as cardiac ablation, in which cardiac tissue is destroyed in an effort to restore a normal electrical rhythm in the heart. This application could be further enhanced by this invention's ability to deliver fluids to the target site as well. Emerging procedures in cardiac therapy require the ability to deliver stem cells, vascular endothelial growth factor (VEGF), or other growth factors to cardiac tissue.

Generally, this invention can be tailored to any procedure requiring tissue ablation or the combination of tissue ablation and fluid delivery.

EXEMPLARY EMBODIMENTS

IN DETAIL, PLEASE DESCRIBE THE SPECIFIC FEATURES OF YOUR IDEA/INVENTION INCLUDING, DESIGN, APPLICATIONS, OPERATION, PROCESS, MATERIALS, COATINGS, AND METHOD OF USE AND MANUFACTURE. PLEASE ATTACH ANY RELEVANT FIGURES, SKETCHES, DIAGRAMS, CAD DRAWINGS, NOTEBOOK PAGES, AND ANY OTHER SUPPORTING MATERIAL THAT SUPPLEMENTS YOUR IDEA/INVENTION. PLEASE INCLUDE AN INDEX OF FIGURES IF NECESSARY.

The primary embodiment of this device consist of two main elements; an outer needle, or *sheath*, and an inner, *multiple filament needle*. Both elements have distal *hubs*, to facilitate manipulation of the elements by the user. The elements are designed to be used in conjunction with an *RF probe*.

Sheath – A hollow outer cannula that is used to facilitate delivery of the multiple filament needle to the target anatomy. The unique feature of this sheath (as compared to currently available needle sheaths) is that is specifically designed to house the multiple filament needle. As such, the sheath has a unique distal segment. This segment has a sharpened point and acts as one of the energy delivering elements. Further, the internal geometry of the sheath's tip is designed such that the needle filaments can be easily retracted and advanced. Important to note, the geometry of the sheath's tip is crucial to insuring that the needle filaments are adequately retracted while the sheath is inserted into the body, so that the filaments do not cause any unintended damage to the patient. Further, the geometry is also designed such that the features that house the filaments do not cause coring (shearing of the tissue into the needle as in biopsy procedures) of the tissue.

Multiple filament needle – The multiple filament needle consists of a central needle shaft, attached at its proximal end to a hub. The hub at the proximal end contains an internal luer taper, compatible with the geometry of the RF Probe. The central needle element transitions along its shaft, within the sheath, into three elements. This splitting of the shaft into multiple elements is the central feature, allowing the RF energy to be dispersed over a larger area (as compared to conventional RF needles). The distal elements reside within lumens that communicate with the features of the sheath's distal tip. As the elements are advanced along these passageways, they exit the sheath's tip, along the trajectory of the openings in the sheath's tip. In the primary embodiment, these passageways are shown at an angle of approximately 30 degrees in relation to the central axis of the device. The angle at which the elements are designed to exit the sheath, in combination with the distance to which they escape (which could also be modified), determines the size spherical area within the tissue to which the RF energy will be applied. As an example, if the elements exit at a distance of 2.0 mm from the central axis of the needle, a 4.0 mm spherical area will be approximated.

It should be noted that the 4.0 mm area proposed is not the size of the lesion that will be created. Based on the time that the energy is applied, and the amount of energy applied, the lesion will be some amount greater than the 4.0 mm.

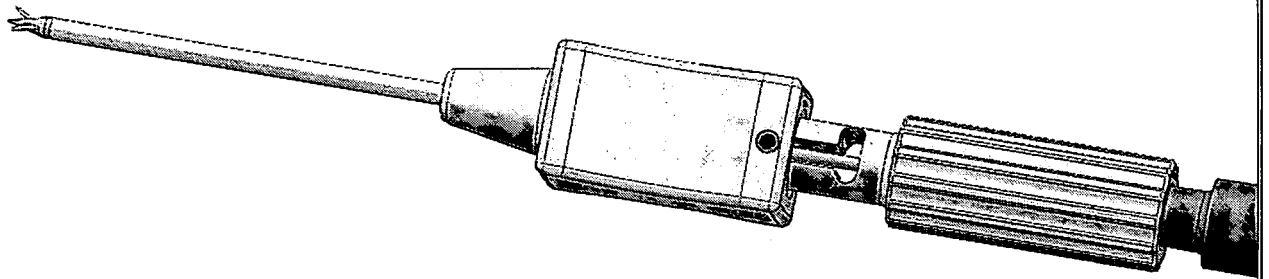


Figure 1- multiple Filament Needle Assmebly

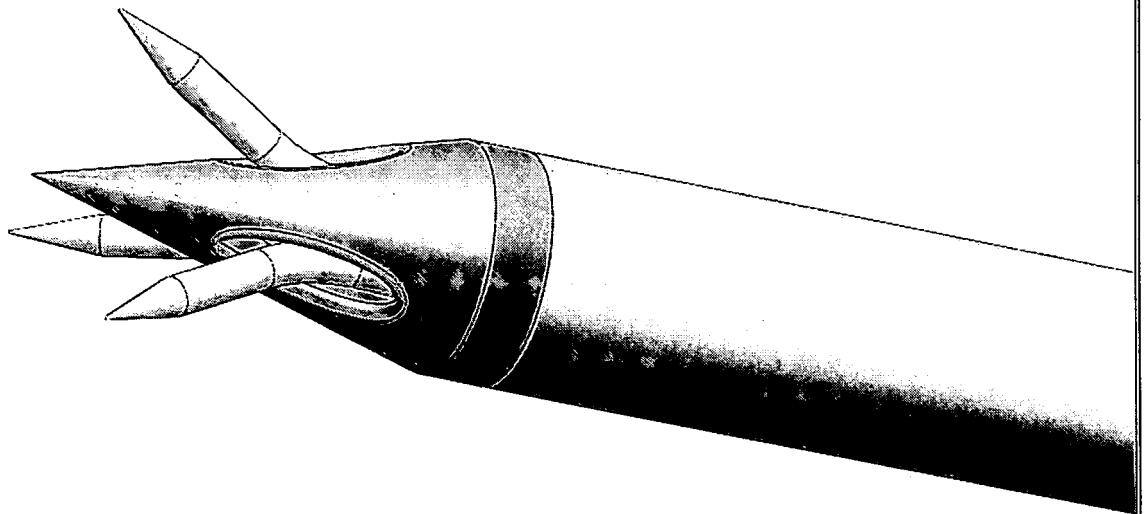


Figure 2 - Needle Tip in Deployed State

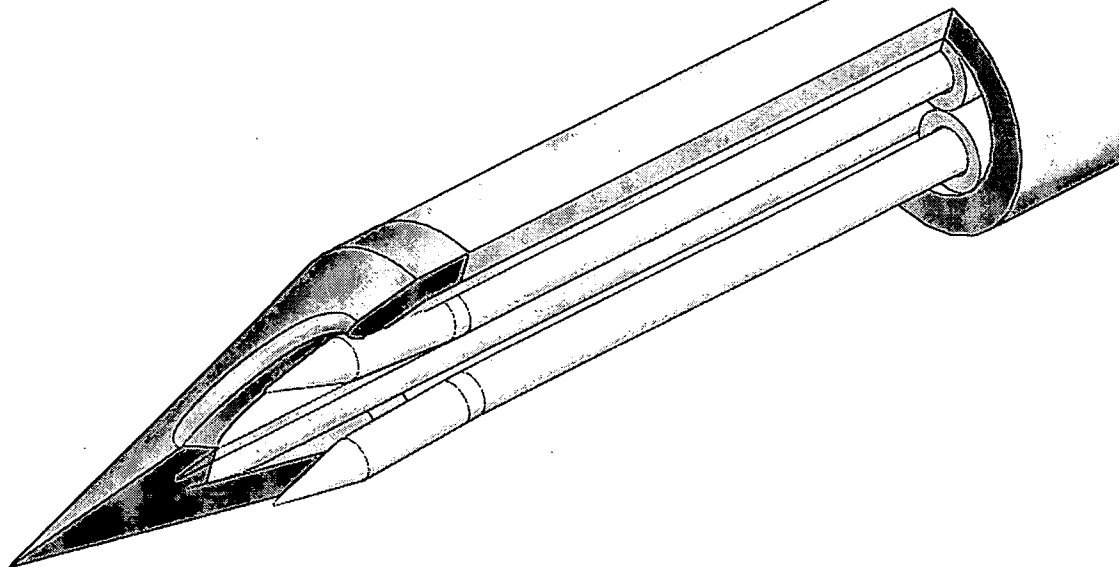


Figure 3 - Needle in Retracted State, Cross Section

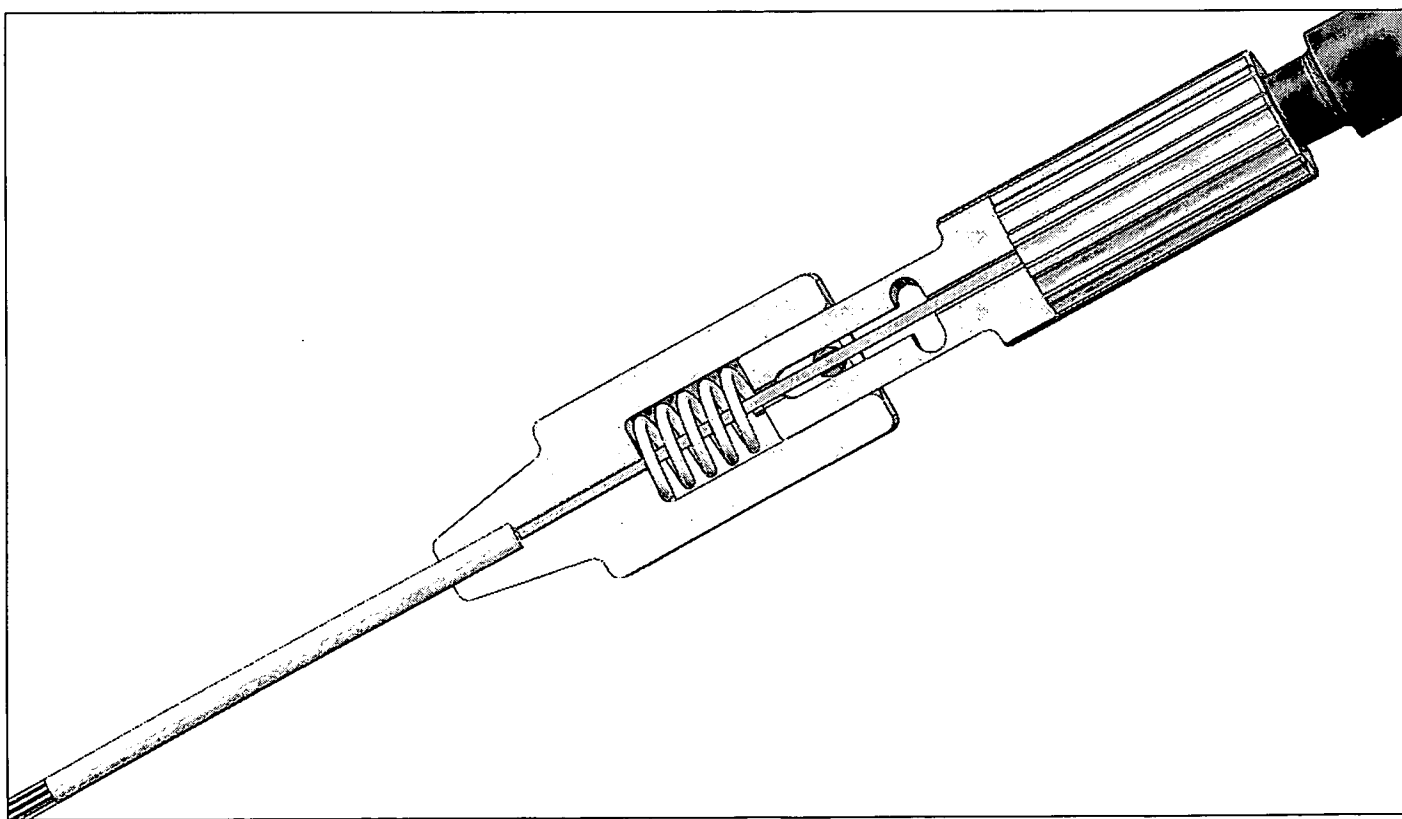


Figure 4 - Hub Cross section Showing Spring

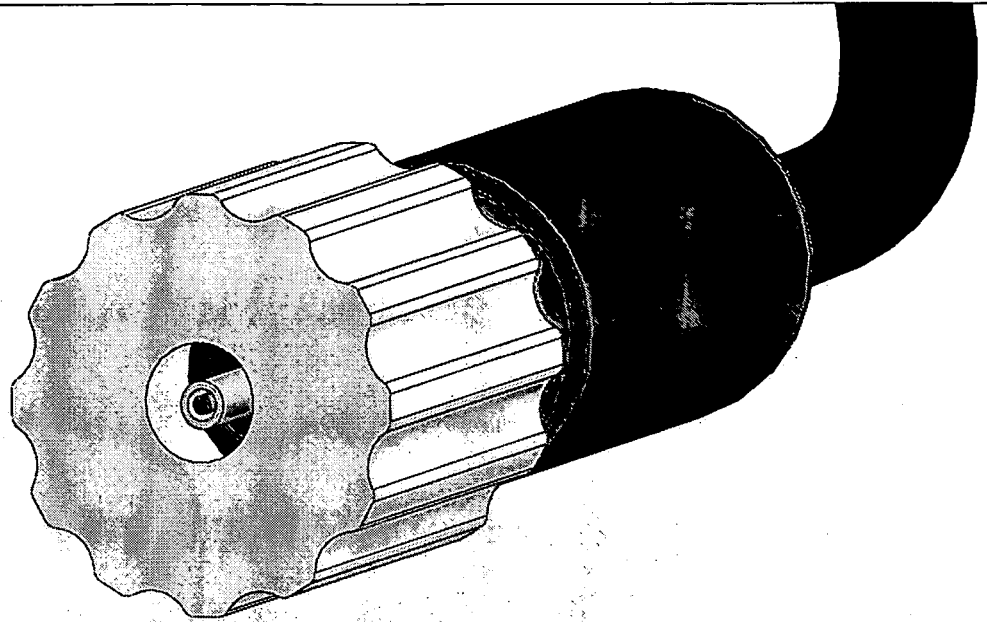


Figure 5 - Cross Section of Prox. Section of Needle

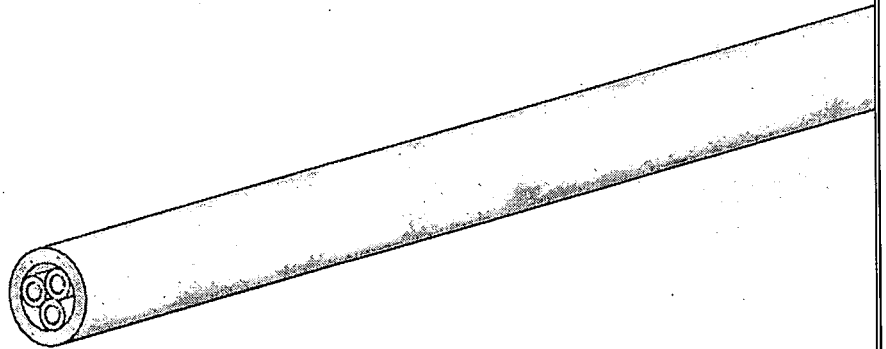


Figure 6 - Cross Section of Distal Needle Segment

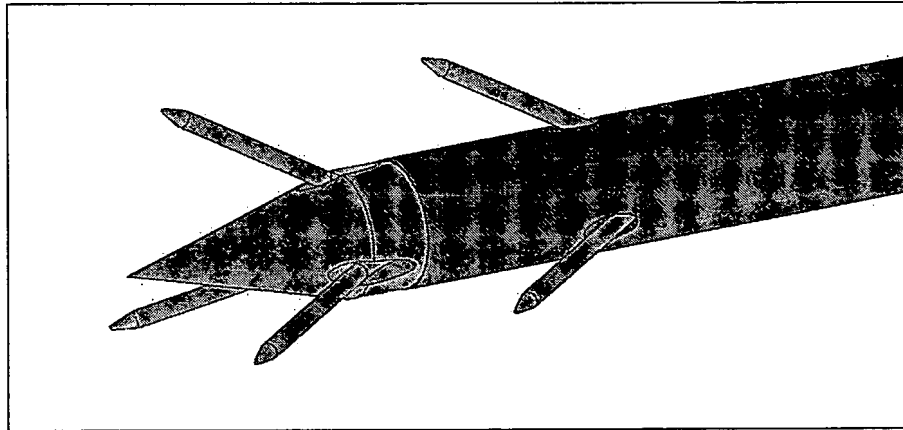
ALTERNATE EMBODIMENTS

A) PLEASE DISCLOSE ANY ALTERNATE EMBODIMENTS OF YOUR IDEA/INVENTION ADDRESSING THE FOLLOWING POINTS: DESIGNS, COMPONENTS, APPLICATIONS, MATERIALS, COATINGS, USES, ACCESSORIES, CONSTRUCTION PROCESSES, COSTS, ETC.

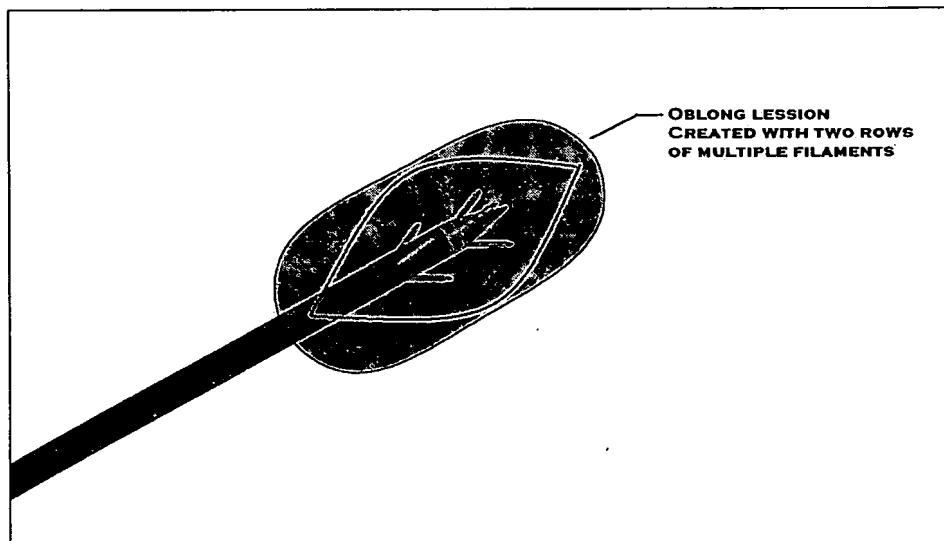
B) THINK LIKE A COMPETITOR AND TRY TO IDENTIFY ANY ALTERNATE WAYS YOU COULD WORK AROUND THE EXEMPLARY EMBODIMENT. ALSO, PLEASE ASSESS THE APPLICABILITY OF YOUR IDEA/INVENTION WITH OTHER PRODUCTS, PROCEDURES, AND PROCESSES.

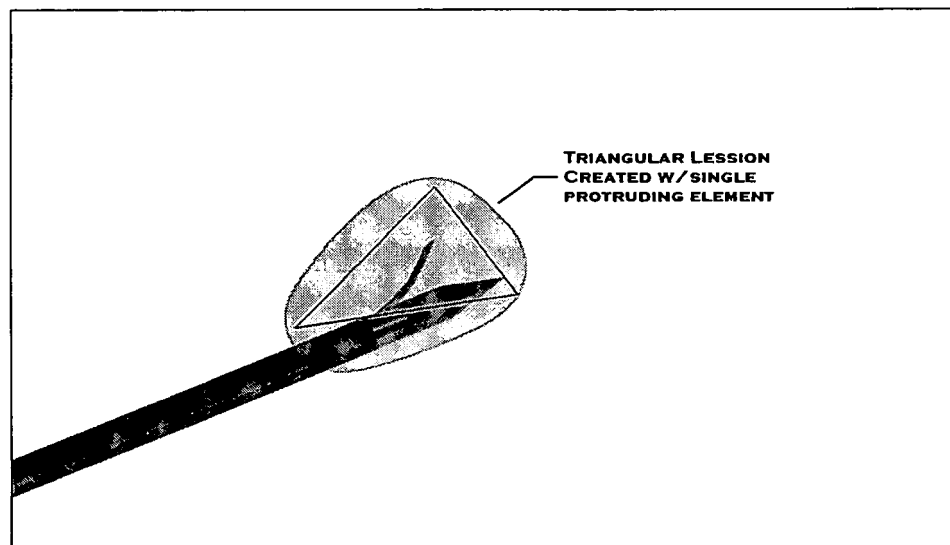
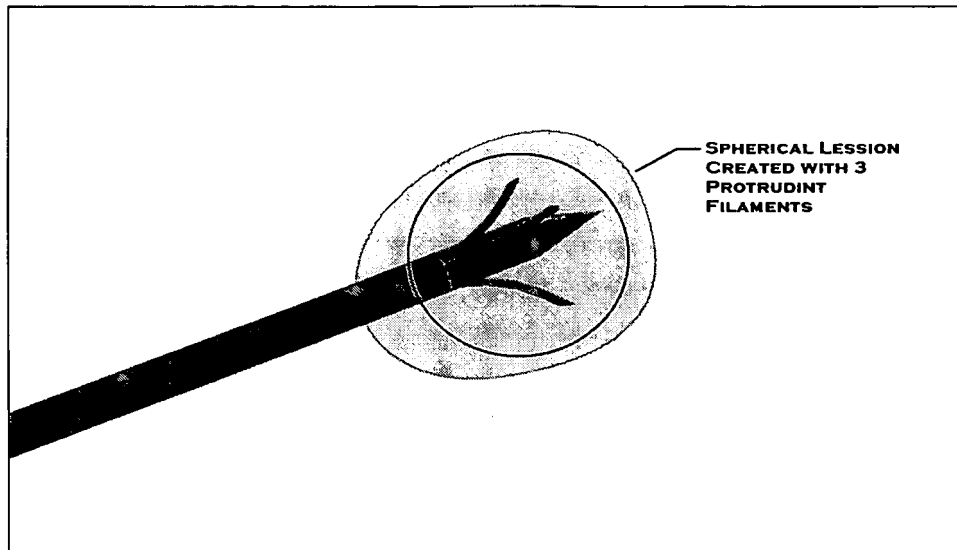
Number of filaments – The number of filament may be modified from the design described above. For certain applications, it may be desirable to have only one filament extending from the central needle. Conversely, in certain applications, it may be desirable to incorporate 2, 3, 4 or more elements into the design.

Pattern of filaments – for certain applications, it may be desirable for the filaments to exit the central member at various distances from the proximal end of the device. The sketch below shows two rows of filaments along the central axis of the needle. Depending on the size of the lesion that is desired, and/or specific geometric features of the target anatomy, more than two rows may be desirable. Further, the orientation of the filaments to one another may also be varied. As an example, the filaments in successive rows may be staggered in various ways so that the pattern of RF energy is uniform or non uniform.



Changes in the number of filaments and pattern of filaments is desirable so that lesions of specific size and shape can be created. As shown in the examples below, spherical, oblong and triangular lesions can all be created with variations to the number of filaments and pattern of filaments.

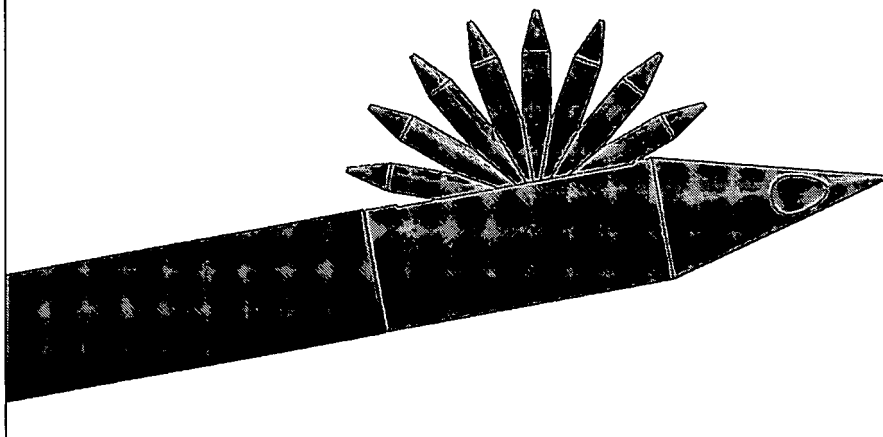




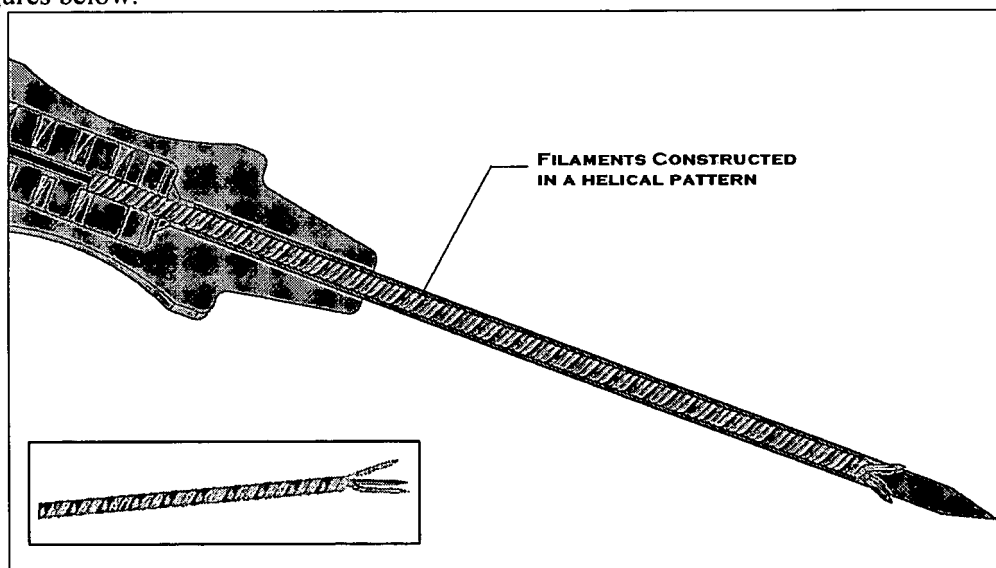
It should be noted that a single device could be designed in which the operator has the choice of using 0, 1, 2, 3 or more elements. In this iteration, each element would be individually controlled at the proximal section of the needle, such that the operator could selectively engage the desired number of elements.

Similarly, the filaments may exit the needle tip at different angles, in relation to the central axis of the needle. In the above sketch, the filaments exit at an angle of approximately 30 degrees to the central axis. Additionally, the filaments may each have varying degrees of separation or spacing, radially, from the central axis.

One example of these variations is a "Chinese fan" design (see figure below). This design may be applicable in specific medical applications where the creation of a unilateral lesion is desired.

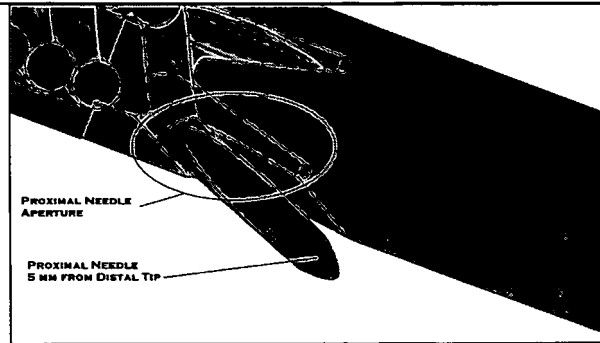


Variations in construction – As shown above, internal to the needle, the filaments each run parallel to the major axis of the needle, and terminate at a proximal hub. The filaments are advanced and retracted by manipulated the hub. The construction of the device may also be modified so that the filaments are constructed in a helical pattern, as shown in the figures below.



There are two main advantages to modifying the construction in this manner:

1. The nested filaments will have increased compressive strength, so that when compressive forces (resistance from tissue) act upon the filament's distal tip, the needles will have less tendency to buckle inside of the assembly.
2. The filaments will exit the needle tip in a "corkscrew" like fashion (see below). This may be beneficial to insure that the filaments remain anchored to the tissue during the delivery of RF energy.



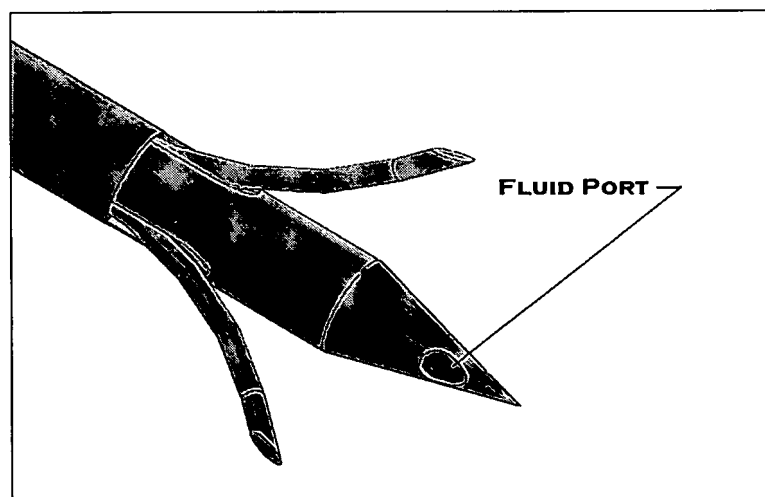
The filaments may also be constructed in a braided fashion, intertwining in an overlap (or similar) pattern, about a central axis. Like the corkscrew design, this design too would exhibit higher resistance to compressive loads.

Another alternative embodiment relates to the incorporation of the temperature probe directly into the needle assembly, thereby eliminating the number of elements and simplifying the design. This would also eliminate the need to reserve a central lumen throughout the device for the RF probe to reside within.

Other alternative embodiments relate to coatings and alternative materials which may be used in the construction of the device. Coating already existing in the prior art may be incorporated into the design to; improve radiopacity, improve electrical properties (either as an insulation, reducing conductivity in areas, or to promote conduction), improve lubricity or reduce tissue adhesion.

The primary embodiment of the design is of a needle constructed of stainless steel. However, other materials may be incorporated to enhance the design. As an example, Nitinol (NiTi), a nickel titanium alloy (characterized by its ability to be shaped without yielding) could be incorporated.

Other alternative embodiments may include the incorporation of additional lumens and/or ports to facilitate injection and/or irrigation in the area of the needle tip. The sketch below show the incorporation of a single injection lumen, that communicates from the distal needle tip to the needle hub. In this embodiment, upon removal of the RF probe, fluid can be injected by attaching a common medical syringe to the needle hub.



It should be noted that additional fluid ports may be added in various locations. Further, the internal construction may be modified such that the injected fluid flows from the filament pathways, around the filaments. Further, the design may also be modified to incorporate hollow filaments that would allow for fluid flow through each filament as well.

Additional embodiments may also include incorporation of features into the needle sheath to facilitate removal of the sheath from around the needle. This is analogous to medical introducer sheaths known in the prior art as peel away sheaths, split sheath introducers, access sheaths, or peelable introducers).

Additional embodiments may also include Incorporation of marks along the axis of the needle and/or sheath to indicate the depth to which the needle has entered into the anatomy. The marks may be radiopaque so that they can be viewed under fluoroscopy.

Further embodiments may include the incorporation of deformable needle tips or filaments to allow the user to “shape” the needle prior to insertion, thereby biasing the needle in a desired direction, toward target anatomy. This is analogous to medical guidewires currently used in vascular procedures, which can be shaped prior to insertion into the anatomy. In the design described above, the filaments are such small diameter that they could be easily deformed.

Additional embodiments of the device may include the incorporation of the RF probe directly into the needle device. Incorporation of the RF probe would allow the device to be a “stand alone” device, not relying upon a separate probe element to apply the RF energy, or provide temperature feedback..

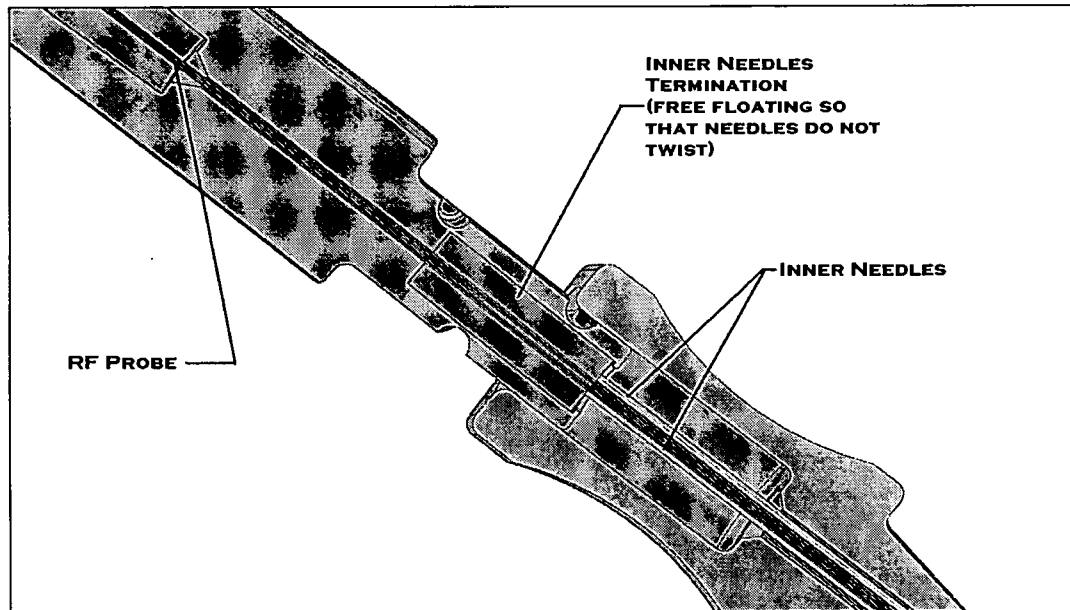
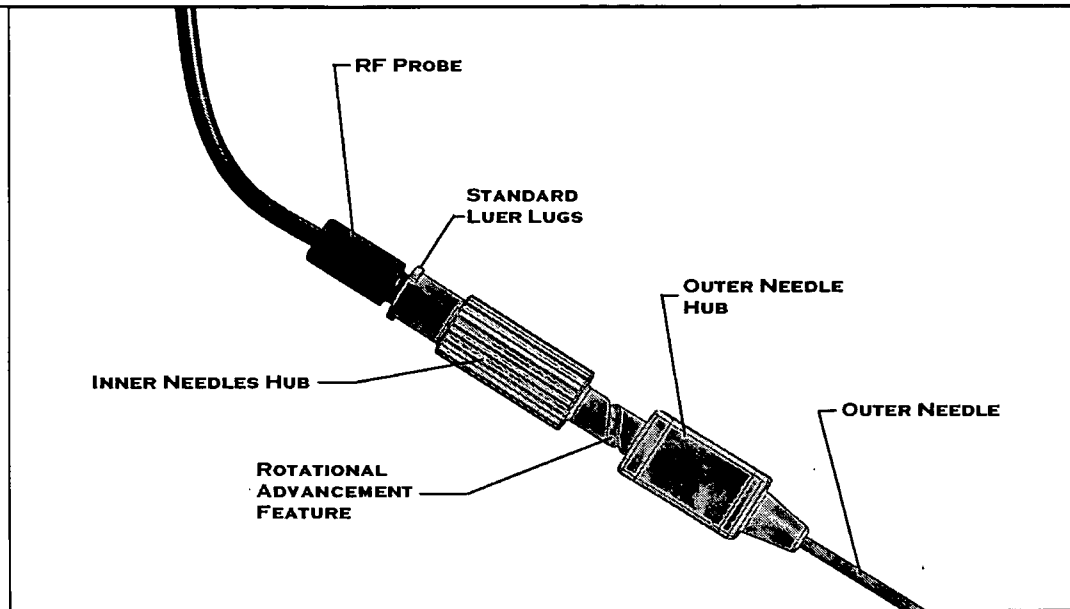
Other embodiments may include the use of “Steerable”, deflectable or articulating needle tips, incorporating controlling mechanisms allowing the needle to be deflected or steered after insertion into the anatomy. This may be accomplished via modifications to the needle sheath’s geometry, thusly allowing the needle to be steered as it is advanced and retracted through the sheath. This is analogous to how guide catheters and micro catheters are used in cardiac catheterization procedures.

The application of such steerable features may have great benefit to the multiple filament needle in the field of cardiovascular drug delivery. Techniques in that field are currently emerging in which stem cells, growth factors (VEG-F) and drugs are delivered to specific regions within the hart. As with the pain management procedure, the success of these procedures can be attributed (at least in part) to the ability to deliver the treatment with pinpoint accuracy, and/or to deliver the treatment to a large area of tissue.

Similarly, applications of this design to specific medical procedures may require the design of pre-shaped needle tip configurations, offering the user geometric choices to better target specific anatomies. Specific lengths, angles, curvatures, etc. may be applicable to specific medical procedures.

The primary embodiment of the design describes the needle hub and sheath hub incorporating a “push and click” design (analogous to a spring loaded ballpoint pen) to control the advancement and retraction of the needle. However, the advancement and retraction could be managed via the incorporation of a multitude of other mechanism to accomplish the same result.

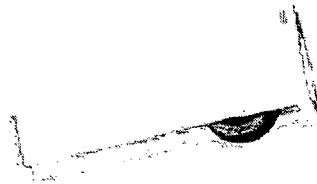
Screw lock mechanism – The needle hub and sheath hub interact via opposing threaded features (see figures belo). As the needle hub is threaded into or out of mating threads within the sheath hub, the needle is advanced or retracted respectively. A major advantage of this type of design is that it would provide an infinite number of distances that the needles could be advanced from the distal tip.



To facilitate an advancement mechanism that uses motion other than linear (parallel to the major axis), the filaments must be decoupled from the hub. If they are not, the filaments will be twisted as the hub is advanced or retracted. To accomplish this, the filaments are terminated in a component ("Inner Needles Termination") that is decoupled, or free-floating in the rotational direction, from the hub.

This type of mechanism could also incorporate a Tuohy Borst fitting, acting as a locking mechanism, to fix the distance that the needle is advanced from the sheath.

Roll clamp mechanism – A roller wheel could be incorporated into the outer sheath hub such that as the wheel is rotated with the users thumb, the needle would advance or retract. This mechanism is analogous to roll clamps commonly used in medical tubing clamps.



Force generating, spring loaded mechanism – The primary embodiment shows the use of a spring that acts upon the needle, causing the needle to be retracted when desired. This spring force could be reversed such that the spring force is applied to the needle in the direction which would advance the needle into the tissue. This would be a means of mechanically controlling the force used to pierce the desired tissue. This may have some advantages for the user, especially when the device is being used on more muscular or fibrotic tissue. This design would be analogous to spring loaded laparoscopic trocars.

The primary embodiment describes the assembly as having a needle that moves in relation to the sheath. In other words, the needle advances/retracts from the distal tip of the sheath. It should be noted that the design could be easily modified such that this action is reversed, causing the sheath to move relative to the needle. This may have benefit in procedures where the user does not want the needle to penetrate deeper into the tissue. Perhaps in some instances, the sheath may be brought up in close proximity to anatomy such as bone. In this case, the needle could not be easily advanced, so the best option would be to move the sheath proximally, thereby exposing the needle tips.

It should be noted that the invention described here is described as a device for the delivery of RF energy. As is the case in many medical procedures and associated devices, the invention could be adapted to perform as a means of monopolar or bipolar electro-cauterization, as well.

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