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CERTIFICATE OF EXPRESS MAIL

I hereby certify that on November 26, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Mail Stop: Patent Term Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10

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EV 308811881 US

Shauna Murray

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Mail Stop: Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

RE: Application for Patent Term Extension Pursuant to 35 U.S.C. § 156 (37 C.F.R. § 1.740) United States Patent Number 5,879,382

Dear Commissioner:

Enclosed is an application for patent term extension pursuant to 37 C.F.R. § 1.740. The owner of record, Medtronic Vascular is submitting this application. Medtronic Vascular (formally Medtronic AVE) acquired the entire assets of Applied Vascular Engineering (aka Arterial Vascular Engineering, aka AVE) through corporate acquisition on January 29, 1999. Thus all rights in United States Patent Number (USPN) 5,879,382 are held by and vested in Medtronic Vascular a Delaware Corporation and a wholly owned subsidiary of Medtronic, Inc., a Delaware company. Medtronic Vascular's corporate headquarters are located at 3576 Unocal Place, Santa Rosa, CA 95403. A brief chain of title summary follows.

Michael D. Boneau is the sole inventor of USPN 5,879,382 which is a continuation of United States Patent Application Serial Number (USPASN) 08/619,014, filed Mar. 20, 1996, now USPN 5,674,278, which is a continuation of USPASN 08/471,738, filed Jun. 6, 1995, now USPN 5,891,190, which is a division of USPASN. 08/172,420, filed Dec. 22, 1993, now abandoned, which is a division of USPASN 07/398,180, filed Aug. 24, 1989, now USPN 5,292,331. Boneau assigned

his entire right, title and interest in USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Accutrix, Inc. its successors, legal representatives and assigns on August 24, 1989. The assignment was recorded in the United States Patent and Trademark Office (USPTO) on August 24, 1989. A complete microfilm copy is available in the USPTO records on reel 5116, frame 0570.

Subsequently, Accutrix, Inc. assigned their entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Endovascular Support Systems, Inc. on August 9, 1991. A complete microfilm copy is available in the USPTO records on reel 5816, frame 0215.

Thereafter, Endovascular Support Systems, Inc. assigned their entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Applied Vascular Engineering, Inc. September 8, 1993. This assignment was recorded in the USPTO on September 8, 1993. A complete microfilm copy is available in the USPTO records on reel 6687, frame 0449.

On January 30th, 1996 Applied Vascular Engineering, Inc. changed its name to Arterial Vascular Engineering, Inc. Applied Vascular Engineering then assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Arterial Vascular Engineering. This assignment was executed January 30th, 1996 and was recorded March 20, 1996. A complete microfilm copy is available in the USPTO records on reel 8522, frame 0049.

Medtronic, Inc. acquired the assets of Arterial Vascular Engineering (AVE) through acquisition on January 29th, 1999 and formed a new Delaware Corporation named Medtronic AVE. Arterial Vascular Engineering assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Medtronic AVE. This assignment was executed January 28th, 1999 and was recorded January 31, 1999. A complete microfilm copy is available in the USPTO records on reel 011258, frame 0053.

Subsequently, Medtronic AVE changed its name to Medtronic Vascular, the present applicant, wherein all right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part now reside. Therefore, the application for patent term extension, Medtronic Vascular, is the owner of all rights title and interests in USPN 5,879,382, the subject patent of the present patent term extension application.

Documents supporting the above title chain for USPN 5,879,382 can be found in Appendix A of this application for patent term extension.

- 1) Complete Identification of the Approved Product by appropriate chemical and generic name, physical structure or characteristics:

The approved product is an over-the-wire coronary stent system for use in patients with symptomatic ischemic heart disease due to discrete single de novo and restenotic lesions. The FDA product code is MAF for Stents, Coronary. The Medtronic Vascular stent marketed as the "S8 Over-the-Wire System" or alternatively under the trademarked name "Driver Stent Delivery System." The System includes a cobalt-based modular stent mounted on a balloon catheter as depicted in Figure 1 below¹. Figure 2 shows the distal portion of the Medtronic Driver Stent Delivery System in detail. Figure 3 depicts a S8 modular stent member.

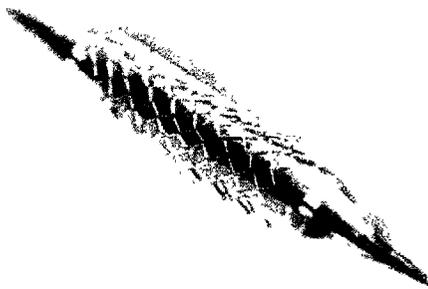


Figure 1

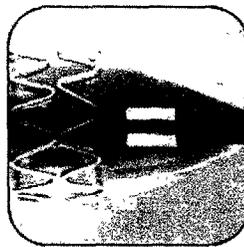


Figure 2



Figure 3

- 2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred:

The Federal Statute under which regulatory review took place for the Medtronic Vascular's S8 Over-the-Wire System is 37 C.F.R. §814.

- 3) The date on which the product received permission for commercial marketing or use under the provision of law which the applicable regulatory review period occurred.

The Medtronic Vascular S8 Over-the-Wire System was approved for marketing October 1, 2003.

- 4) Statement that the present application is being submitted within the sixty day period permitted for submission and an identification of the date of the last day on which the application could be submitted.

¹ See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

The present application for patent term extension is being submitted with the sixty day period permitted for submission pursuant to 37 C.F.R. §1.720(f). The last day for submission of the present application is November 30, 2003. However, because November 30, 2003 is a Sunday, this application may be filed December 1, 2003.

- 5) The complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the expiration date.

The present application for extension is for United States Patent Number 5,879,382 issued March 9, 1999 and expiring August 24, 2009. The inventor is Michael D. Boneau.

- 6) A copy of the entire patent for which extension is being sought, including the entire specification, claims and drawing.

A copy of U.S. patent number 5,879,382 is attached as Appendix B.

- 7) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

There are no disclaimers, certificates of correction or reexamination certificates issued on U.S. patent number 5,879,382. A copy of the maintenance fee payment record is provided as Appendix C.

- 8) Statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claims reads on the approved product.

United States patent number 5,879,382 claims the S8 Over-the-Wire Coronary Stent System approved October 1, 2003. The applicant also asserts that claims 1, 2 and 4 of the '382 patent read on the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

In particular, claim 1 reads on the approved device as follows:

Claim Chart Comparing Claim 1 of U.S. Patent 5,879,382 element-by-element with the S8 Over-the-Wire Coronary Stent

Claim 1 of U.S. Patent 5,879,382	Corresponding Features of the S8 Over-the-Wire Coronary Stent System
1 An endovascular support device for implantation in a vessel within the human body comprising:	The S8 is a coronary stent is an endovascular device and is approved for use in treating vascular occlusions including de novo and restenotic lesions of the coronary artery. Thus the S8 Over-the-Wire Coronary Stent System is intended for implantation in a vessel within the human body.
a plurality of stent members	The S8 coronary stent is composed of a plurality of stent members as depicted in Figures 1 and 2 of the present application. Individual stent members as used in reference to the '382 patent are depicted in Figure 3 of the present application and Figure 1 of the '382 patent.
each stent member formed of a plurality of substantially straight segments having ends,	See Figure 3 of this application below compared to Figure 1 of the 5,879,382 patent. It can be seen that the S8 stent member in Figure 3 of this application comprises a plurality of substantially straight segments, each having ends. The corresponding structures are seen in Figure 1 of the '382 patent at number 16 (the substantially straight segment) and at number 12 and 14 (the ends).
the ends of respective pairs of the plurality of substantially straight segments connected end to end at a plurality of axial turns; and	See Figure 3 of this application below compared to Figure 1 of the 5,879,382 patent. It can be seen that the S8 stent member segments in Figure 3 of this application are connected end to end at a plurality of axial turns. The corresponding structures are seen in Figure 1 of the '382 patent at numbers 12 and 14.
whereby each of the plurality of stent members are capable of retaining a compressed configuration while mounted onto an outer surface of a catheter for delivery to an affected area of a vessel until application of a radial force to form an expanded configuration.	The S8 stent is designed to be compressed onto a catheter for delivery to an affected area of the vessel. Figure 4 of this application depicts a compressed S8 stent on a balloon catheter (Below). Figure 1 of this application depicts the S8 in the expanded state.
and then forcibly expanded to maintain the affected area of a vessel at a diameter larger than if the support device were not implanted	See Figure 1 of this application below. The expansion of the S8 results in a vessel diameter being greater than the vessel diameter. The pre-expanded vessel generally has an occlusion, or narrowing at the implantation site. Therefore, once the stent is expanded, the vessel's diameter increases and is by necessity greater than the vessel prior to stent expansion and implantation.

The pictures and Figures that follow correlate to the claim elements discussed in the Claim Chart on the preceding page and clearly demonstrate that Claim 1 of U.S. patent 5,879,382 (the '382 patent) reads on the S8 Over-the-Wire Coronary Stent System.

Figure 1 of U.S. patent 5,879,382

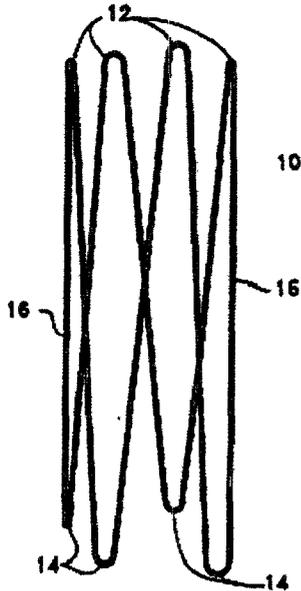
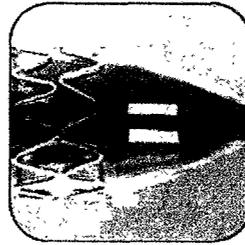
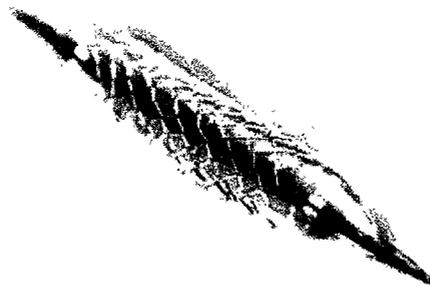


Figure 2 of this application: A plurality of S8 stent members attached end-to-end.²



In Figure 1 of US Patent 5,879,382 the upper axial turns (12) are connected to the lower axial turns (14) by substantially straight segments 16. The corresponding structures are clearly evident in Figures 2 and 3 of this application and juxtaposed to Figure 1 of the '382 patent.

Figure 1 of this application showing the S8 stent balloon mounted and forcibly expanded.

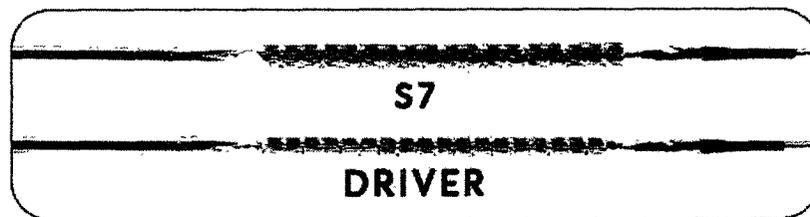


² See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

Figure 3 (below) of this application depicts a plurality of S8 stent segments connected end to end at a plurality of axial turns.³

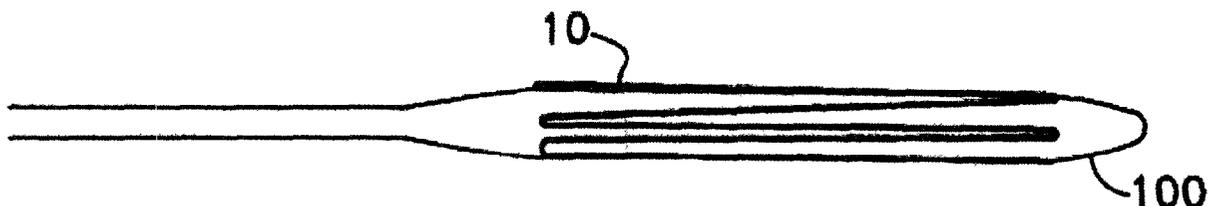


Figure 4 (below) of this application depicts the “Driver” (AKA S8Coronary stent) compressed onto catheter for delivery to an affected vessel.³



Therefore, based on the analysis above the Applicant respectfully asserts that Claim 1 of United States Patent number 5,879,382 reads on the approved device, the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

Figure 2 of the '382 patent (below) shows the stent as claimed compressed onto a catheter balloon. Compare this with the Driver Stent (S8) compressed on a balloon catheter immediately above.



³ See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

New Page:

- 9) The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable review period:
- A) The effective date of the investigational device exemption (IDE) and the IDE number:
- 1) Conditional approval of the Applicant's IDE was dated December 20, 2001 and signed by Dr. Bram Zuckerman, Acting Director, Division of Cardiovascular and Respiratory Diseases.
 - 2) The Applicant's IDE number is G010301, G010301/A1, A2 and A3.
- B) The date on which the application for product approval under Section 515 of the Federal Food Drug and Cosmetic Act was initially submitted and the number of the application.
- 1) A Pre-market Approval application (PMA) for the S8 Over-the-Wire Coronary Stent System was submitted April 9, 2003.
 - 2) The PMA number is P030009.
- C) The date on which the application was approved.
- The S8 Over-the-Wire Coronary Stent System PMA was approved on October 1, 2003.

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- 10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

No.	FDA Reviewer	Date	Description
G010301	Carolyn Vaughan	21-Nov-01	Original Driver Over-the-Wire Delivery System IDE Submission
G010301 / A001	Carolyn Vaughan	29-Nov-01	Submission provided on CD-ROM
G010301 / A002	Carolyn Vaughan	12-Dec-01	Histopathology/photomicrographs sent for GLP - 237
G010301 / A003	Carolyn Vaughan	14-Dec-01	List of Investigational Sites
NA	Bram Zuckerman	20-Dec-01	Conditional Approval Letter received from FDA
NA	NA	21-Dec-01	Fax sent to accounts informing them of conditional approval from FDA
G010301 / S001	Bram Zuckerman	01-Feb-02	Response to FDA Conditional Approval Letter Dated December 20, 2001
G010301 / S002	IDE Doc. Mail Ctr	05-Feb-02	Request for addition of patient guide to supply to patients
NA	NA	08-Feb-02	First patient implant for IDE Trial
G010301 / S003	IDE Doc. Mail Ctr	09-Apr-02	Report of status with ongoing animal studies
G010301 / S004	IDE Doc. Mail Ctr	11-Apr-02	Request extension to deadlines put forth in conditional approval letter
G010301 / S005	IDE Doc. Mail Ctr	22-Apr-02	Request approval for addition of 10 clinical trial sites
NA	NA	19-Apr-02	Teleconference regarding statistical questions received from the Driver conditional approval letter.
G010301 / S006	Donna-Bea Tillman	17-May-02	Response to FDA Conditional Approval Letter submitted
G010301 / S006	Donna-Bea Tillman	10-Jun-02	Approval of Driver IDE received from FDA
G010301 / S007	IDE Doc. Mail Ctr	17-Jun-02	6-Month Clinical Site Update submitted

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued).

No.	FDA Reviewer	Date	Description
NA	Ashley Boam	19-Aug-02	FDA determines based on new material of stent, the Driver PMA submission must be an original PMA, not a PMA supplement
G010301 / S008	IDE Doc. Mail Ctr	26-Aug-02	Report of status with ongoing animal studies
NA	NA	25-Sep-02	Last patient implant for IDE Trial
G010301 / S009	Bram Zuckerman	17-Oct-02	Report of status with ongoing animal studies
G010301 / S010	IDE Doc. Mail Ctr	23-Dec-02	Submission to FDA: Response to letter dated 11/14/2002 Final Animal Study Report (FS81)
G010301 / S011	IDE Doc. Mail Ctr	15-Jan-03	Submission response to request for additional information
G010301 / S012	IDE Doc. Mail Ctr	16-Jan-03	Annual Report Submitted
NA	Sue Bowley/ Ashley Boam	28-Feb-03	Teleconference regarding inclusion of 270-day clinical data as PMA Amendment.
P030009	PMA Doc Mail Ctr	9-Apr-03	Original FDA PMA Submission of Driver Coronary Stent Systems
P030009	Bram Zuckerman	23-May-03	FDA agreed to file PMA
P030009 / A001	PMA Doc Mail Ctr	3-Jul-03	Response submitted to FDA regarding questions from email dtd 27-May-03
P030009 / A002	PMA Doc Mail Ctr	11-Aug-03	270 day clinical data, changes to the packaging of the Over-The-Wire and Rapid Exchange delivery systems and proposed manufacturing changes to the Multi-Exchange delivery system
P030009 / A003	PMA Doc Mail Ctr	13-Aug-03	Response submitted to FDA regarding questions from email dated 12-Jul-03
P030009 / A004	PMA Doc Mail Ctr	15-Aug-03	Authorization letter for the FDA to discuss Driver PMA / STED with MHLW in Japan
P030009	Sue Bowley	19-Aug-03	Request from FDA for an additional hard copy of PMA Amendment which included 270d clinical data.
P030009 / A005	PMA Doc Mail Ctr	21-Aug-03	To notify FDA of findings from an internal audit performed by the Atlanta Cardiovascular Research Institute (ACRI) related to animal study FS70

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued)

No.	FDA Reviewer	Date	Description
NA	Sue Bowley/ Steve Hilbert	21-Aug-03	Samples of the OTW delivery system provided to reviewers at the request of FDA.
NA	NA	21-Aug-03	STED Desk Copies submitted to FDA
P030009	Ashley Boam	22-Aug-03	FDA confirmed with MHLW permission for cooperative review of STED
P030009 / A006	PMA Doc Mail Ctr	5-Sep-03	Request the withdrawal of Nutek Corp, located in Hayward, CA, from our list of sterilization facilities for the Driver coronary stent systems
NA	Sue Bowley/ Ashley Boam	14-Sep-03	Conclusion reached regarding format of compliance chart
P030009	Ashley Boam	22-Sep-03	Agreement with FDA to include claim for direct stenting in IFU
P030009 / A007	PMA Doc Mail Ctr	22-Sep-03	Response submitted to FDA regarding questions from email dated 17-Sep-03
P030009	Sue Bowley	25-Sep-03	90-day Status e-mail received
P030009 / A008	PMA Doc Mail Ctr	29-Sep-03	Response to FDA questions on final labeling, biomaterials compendium and conditions of approval letter
P030003	Bram Zuckerman	1-Oct-03	Driver PMA Approval received from FDA
P030009 / A009	PMA Doc Mail Ctr	8-Oct-03	Final Labeling

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- 11) Statement that in the opinion of the applicant that the patent is eligible for extension and a statement as to the length of extension claimed, including how the extension was calculated.

The applicant respectfully asserts that United States Patent Number 5,879,382 is eligible for extension. The applicant has demonstrated that at least one claim of U.S. Patent 5,879,382 reads on the approved device (S8 Over-the-Wire Coronary Stent) and that this application for extension is being timely filed.

The applicant respectfully asserts that U.S. Patent 5,879,382 is eligible for a 413 day extension as calculated pursuant to 37 CFR §1.777.

Calculations Under 37 CFR §1.777

1. Calculations under 37 CFR §1.777 (c)(1)

Determine the number of days in the period beginning on the date a clinical investigation on humans involving the device began and ending the date the PMA was initially submitted.

- i) Clinical investigations on humans are deemed to have begun on the date that the FDA determines that an IDE required under section 520(g) of the FDCA (21 U.S.C. 360j (g)) is substantially complete. In this case the records indicated that on December 20, 2001 the Medtronic Vascular IDE number G010301, G010301/A1, A2 and A3 received a Conditional Approval. Thus, this date will be used for the initial calculations .
- ii) The PMA was initially filed April 9, 2003.
- iii) The experimental period is thus calculated as the time between December 20, 2001 and April 9, 2003, or **476 days**.

2. Calculations under 37 CFR §1.777 (c)(2)

Determine the number of days in the period beginning on the date the PMA was initially filed and ending on the date the PMA was approved.

The PMA was initially submitted April 9, 2003 and was approved October 1, 2003. Thus the approval period was **175 days**.

The Sum of 37 CFR §1.777 c(1) and 37 CFR §1.777 (c)(2) equals 651 days.

3. Calculations under 37 CFR §1.777 (d)(1)

- i) Subtract the number of days in the periods (c)(1) and (c)2 of this section which were on and before the date the patent issued.

Zero for U.S. Patent 5,879,382.

- ii) Subtract the number of days in the periods (c)(1) and (c)2 of this section during which the applicant did not act with due diligence.

Zero for U.S. Patent 5,879,382.

- iii) Subtract one-half the number of days remaining in the period defined by (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii).

238 days for U.S. Patent 5,879,382.

Therefore, the maximum extension available for U.S. patent number 5,879,382 For U.S. is **476 (from step 1 (iii)) + 175 (from step 2) – 238 (from step 3 (iii)) = 413 days.**

4. Calculations Under 37 CFR §1.777 (d)(2)

Determine the number of days shortened by a terminal disclaimer.

Zero for U.S. Patent 5,879,382

5. Calculations Under 37 CFR §1.777 (d)(3)

Section (d)3 requires that 14 years be added to the date the PMA was approved, this equals the longest possible extension available (14 years from the approval date) in this case the 37 CFR §1.777 (d)(3) date is October 1, 2017).

6. Calculations Under 37 CFR §1.777 (d)(4)

The new expiration date is October 11, 2010 which is before October 1, 2017. Thus United States Patent 5,879,382 is eligible for the entire 413 day extension as calculated above.

7. Calculations Under 37 CFR §1.777 (d)(5)

United States Patent number 5,879,382 was filed after September 24, 1984.

- 12) Statement that the applicant acknowledges a duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

The applicant acknowledges his duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought. The applicant has no disclosures to that are material to the determination of entitlement to the extension sought.

- 13) The prescribed fee for receiving and acting upon the application for extension.

The Commissioner is hereby authorized to charge payment of the patent term extension application fee pursuant to 37 C.F.R. §1.20 (j)(1) in the amount of \$1,120.00 to Deposit Account number 01-2525.

- 14) The name address and telephone number of the person to whom inquires and correspondences relating to the application for patent term extension are to be directed.

Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

(707) 566-1746

Respectfully submitted on behalf of the applicant,



Louis C. Cullman, Esq.
USPTO Reg. No. 39,645
Stradling Yocca Carlson & Rauth

ASSIGNMENT

1
2 WHEREAS, I, MICHAEL D. BONEAU, a citizen of the United States of America,
3 residing at 342 W. Sunnyoaks, Campbell, California 95008, have invented a certain
4 new and useful ENDOVASCULAR SUPPORT DEVICE AND METHOD for which I am
5 about to make an application for Letters Patent of even date herewith; and

6 WHEREAS, ACCUTERIX, INC., a corporation existing under the laws of the
7 State of California and doing business at 342 W. Sunnyoaks, Campbell, California
8 95008, is desirous of obtaining the entire right, title and interest in, to and under the
9 said invention and application.

10 NOW, THEREFORE, for good and valuable consideration, the receipt of which
11 is hereby acknowledged, I, MICHAEL D. BONEAU, have sold, assigned, transferred
12 and set over, and by these presents do hereby sell, assign, transfer and set over
13 unto the said ACCUTERIX, INC, its successors, legal representatives and assigns,
14 my entire right, title and interest in, to and under the said invention and the said
15 application for Letters Patent, a copy of which as filed in the United States Patent
16 Office is contained in Docket No. H-1136-P in the offices of HARRISON & EAKIN, a
17 Partnership of Professional Corporations, 1700 South El Camino Real, Suite 405, San
18 Mateo, California 94402-3083 and all divisions, continuations and continuations-in-
19 part thereof, and all Letters Patent of the United States which may be granted
20 thereon and all applications for Letters Patent which may be filed for said invention
21 in any country or countries foreign to the United States, and all Letters Patent which
22 may be granted for said invention in any country or countries foreign to the United
23 States, and to all extensions, renewals, and reissues thereof, and the right to claim
24 priority under the International Convention for the Protection of Industrial Property;
25 and I hereby authorize and request the Commissioner of Patents and Trademarks
26 of the United States, and any Official of any country or countries foreign to the
27 United States whose duty it is to issues patents on applications as aforesaid, to issue
28 all Letters Patent for said invention to the said ACCUTERIX, INC., its successors,
29 legal representatives and assigns, in accordance with this instrument.

30 AND I hereby covenant that I have the full right to convey my entire interest
31 herein assigned, and that I have not executed, and will not execute, any agreement
32 in conflict herewith.

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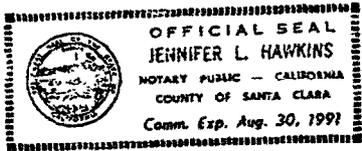
1 AND I hereby further covenant and agree that I will communicate to the said
2 ACCUTERIX, INC., its successors, legal representatives and assigns, any facts known
3 by me respecting said invention, and testify in any legal proceeding, sign all lawful
4 papers, execute all divisional, continuing or reissus applications, make all rightful
5 oaths, and generally do everything possible to aid the said ACCUTERIX, INC., its
6 successors, legal representatives and assigns to obtain and enforce proper patent
7 protection for said invention in all countries.

8 IN TESTIMONY WHEREOF, I have hereunto set my hand this Twenty-Fourth
9 day of August, 1989, at Santa Clara, California.

10
11 
12 Michael D. Boneau

13 STATE OF CALIFORNIA
14 COUNTY OF Santa Clara } ss.
15

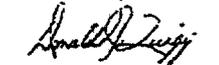
16 On this Twenty-Fourth day of August, 1989, before me personally appeared
17 Michael D. Boneau, personally known to me or proved to me on the basis of
18 satisfactory evidence to be the person whose name is subscribed to the within
19 instrument, and acknowledged that he executed it. Witness my hand and official
20 seal.



21 
22 Notary Public

23
24 RECORDED
PATENT & TRADEMARK OFFICE

25 AUG 24 89

26 
27 COMMISSIONER OF PATENTS
28 AND TRADEMARKS OFFICE
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 OF PATENTS AND TRADEMARKS
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 HARRISON & EAKIN
 A Partnership of Attorneys at Law

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 FILE _____

TO: JAMES E. EAKIN
 HARRISON & EAKIN
 1700 SOUTH EL CAMINO REAL, STE 405
 SAN MATEO, CA 94402-3083

UNITED STATES PATENT AND TRADEMARK OFFICE
 NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME NUMBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE AND APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

ASSIGNOR: 001 BONEAU, MICHAEL D.

DOC DATE: 08/24/89

RECORDATION DATE: 08/24/89 NUMBER OF PAGES 002 REEL/FRAME 5116/0570

DIGEST: ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE: 501 ACCUTERIX, INC., 342 W. SUNNYOAKS, CAMPBELL, CALIFORNIA 95008, A CORP. OF CA

SERIAL NUMBER 7-398180 FILING DATE 08/24/89
 PATENT NUMBER ISSUE DATE 00/00/00

TITLE OF INVENTION: ENDOVASCULAR SUPPORT DEVICE AND METHOD

INVENTOR: 001 BONEAU, MICHAEL D.

SEND STD LTR
 TO BONEAU, COPY
 TO STERZER BUT
 WE KEEP ORIG.
 ASE



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DATE: 09/18/91
TO:
JAMES E. EAKIN
HARRISON & EAKIN
1700 SOUTH EL CAMINO REAL, STE 405
SAN MATEO, CA 94402-3083

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ASSIGNOR: ACCUTERIX, INC., A CORPORATION OF CA DOC DATE: 08/09/91
RECORDATION DATE: 08/23/91 NUMBER OF PAGES 003 REEL/FRAME 5816/0215

DIGEST :ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE:
ENDOVASCULAR SUPPORT SYSTEMS, INC.
A CORPORATION OF CA
342 W. SUNNYOAKS
CAMPBELL, CALIFORNIA 95008

SERIAL NUMBER 7-398180 FILING DATE 08/24/89
PATENT PATENT ISSUE DATE 00/00/00

RECEIVED
Law Office Of
JAMES E. EAKIN, P.C.

OCT 15 1991

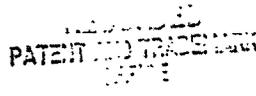
EE _____ JC _____
DOCKET _____

1 it is to issue patents on applications as aforesaid, to issue all Letters Patent for said
2 invention the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors, legal
3 representatives and assigns, in accordance with this instrument;

4 AND, ACCUTERIX, INC., hereby covenant that it have the full right to convey
5 my entire interest herein assigned, and that I have not executed, and will not execute,
6 any agreement in conflict therewith;

7 AND, ACCUTERIX, INC., hereby further covenant and agree that it will
8 communicate to the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors,
9 legal representatives and assigns, any facts known to it respecting said invention and
10 said application, and testify in any legal proceedings, execute all lawful papers, make
11 all rightful oaths and generally do everything possible to aid the said ENDOVASCULAR
12 SUPPORT SYSTEMS, INC., its successors, legal representatives and assigns to obtain
13 and enforce proper patent protection for said invention in all countries.

14 IN TESTIMONY WHEREOF, ACCUTERIX, INC., through an authorized officer,
15 has caused this Assignment to be executed this 9 day of AUG. 1991.

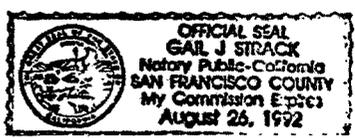


Ben Hidalgo
Ben Hidalgo,
Secretary & Treasurer
ACCUTERIX, INC.

20 State of California)
21 County of San Mateo)

22 On 9th day of August, 1991 before me, Gail J Strack personally
23 appeared Ben Hidalgo, ~~personally known to me~~ (or proved to me on the basis of
24 satisfactory evidence) to be the person whose name is subscribed to the within
25 instrument and acknowledged to me that he executed the same in his authorized
26 capacity, and that by his signature on the instrument the person, or the entity upon
27 behalf of which the person acted, executed the instrument.

26 WITNESS my hand and official seal.
27 Signature Gail J Strack Seal



REC-1916 (Rev. 11-77)

ASSIGNMENT

1
2
3
4 WHEREAS, ACCUTERIX, INC., a corporation existing under the law of the State
5 of California and doing business at 342 W. Sunnyoaks, Campbell, California 95008,
6 is the owner by assignment of U.S. Patent Application Serial Number 07/398,180,
7 filed August 24, 1989, entitled ENDOVASCULAR SUPPORT DEVICE AND METHOD
8 together with all right, title and interest in, to and under the invention described
9 therein including all foreign rights thereto; and

10 WHEREAS, ENDOVASCULAR SUPPORT SYSTEMS, INC., a corporation existing
11 under the laws of the State of California and doing business at 342 W. Sunnyoaks,
12 Campbell, California 95008, is desirous of obtaining the entire right, title and interest
13 in, to and under the said application, including all foreign rights;

14 NOW, THEREFORE, in consideration of a good and valuable consideration, the
15 receipt of which is hereby acknowledged, ACCUTERIX, INC., have sold, assigned,
16 transferred and set over, and by these presents do hereby sell, assign, transfer and
17 set over unto the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors,
18 legal representatives and assigns my entire right, title and interest in, to and under the
19 said invention and the said application of Letters Patent Serial No. 07/398,180 filed
20 August 24, 1989, and all divisions, continuations and continuations-in-part thereof,
21 and all Letters Patent of the United States which may be granted thereon and all
22 application for Letters Patent which may be granted for said invention in any country
23 or countries foreign to the United States of America, and to all extensions, renewal,
24 reissues, and reexamination certificates thereof, and the right to claim priority under
25 the International Convention of the Protection of Industrial Property, and all rights
26 under the Patent Cooperation Treaty; and ACCUTERIX, INC., hereby authorize and
27 request the Commissioner of Patents and Trademarks of the United States of America,
28 and any official of any country or countries foreign to the United States whose duty

916111916111

ASSIGNMENT

WHEREAS, ENDOVASCULAR SUPPORT SYSTEMS, INC., formerly named ENDOTHELIAL SUPPORT SYSTEMS, INC., a corporation existing under the laws of the State of California and doing business at 342 W. Sunnyoaks, Campbell, California 95008, is the owner by assignment of U.S. Patent Application Serial Number 07/398,180, filed August 24, 1989, entitled ENDOVASCULAR SUPPORT DEVICE AND METHOD, together with all right, title and interest in, to and under the invention described therein including all foreign rights thereto; and

WHEREAS, APPLIED VASCULAR ENGINEERING, INC., a corporation existing under the laws of the State of Delaware and doing business at 5345 Skylane Boulevard, Santa Rosa, CA 95403 is desirous of obtaining the entire right, title and interest in, to and under the said invention and application, including all foreign rights;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, ENDOVASCULAR SUPPORT SYSTEMS, INC., have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over unto the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, its entire right, title and interest in, to and under the said invention and the said application for Letters Patent serial number 07/398,180, filed August 24, 1989, and all divisions, continuations and continuations-in-part thereof, and all Letters Patent of the United States which may be granted thereon and all applications for Letters Patent which may be filed for said invention in any country or countries foreign to the United States, and all Letters Patent which may be granted for said invention in any country or countries foreign to the United States, and to all extensions, renewals, and reissues thereof, and the right to claim priority

12/11/89 10:00 AM

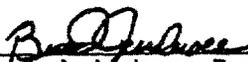
H-1136-P

under the International Convention for the Protection of Industrial Property; and ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby authorizes and requests the Commissioner of Patents and Trademarks 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 Letters Patent for said invention to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, in accordance with this instrument.

AND ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby covenants that it has the full right to convey its entire interest herein assigned, and that it has not executed, and will not execute, any agreement in conflict herewith.

AND ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby further covenants and agrees that it will communicate to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, any facts known by it respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing or reissue applications, make all rightful oaths, and generally do everything possible to aid the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns to obtain and enforce proper patent protection for said invention in all countries.

IN TESTIMONY WHEREOF, ENDOVASCULAR SUPPORT SYSTEMS, INC., through an authorized officer, has caused this Assignment to be executed this Eighth day of September, 1993, at Santa Rosa, California.



Brady A. Jendersee, President
ENDOVASCULAR SUPPORT SYSTEMS, INC.



57-081

11

RECORDATION FORM COVER SHEET PATENTS ONLY

To the Hon. Commissioner of Patents & Trademarks: Please record the attached original documents.

1. Name of conveying party(ies): ENDOVASCULAR SUPPORT SYSTEMS, INC. 2. Name and address of receiving party(ies):

Name: APPLIED VASCULAR ENGINEERING, INC.

Street Address: 5345 SKYLANE BLVD.

City: SANTA ROSA State: CA Zip: 95403

Additional name(s) of conveying party(ies)
Attached? Yes No

3. Nature of Conveyance:

Assignment Merger
 Security Agreement Change of Name
 Other

Execution Date: _____

Additional name(s) & addresses attached?
 Yes No

4. Application Number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)
07/398,180

B. Patent No.(s)

Additional numbers attached? Yes No

5. Name and address of party to whom correspondence concerning document should be mailed

Name: LAW OFFICES OF JAMES E. EAKIN

Street Address: 1301 SHOREWAY RD., STE. 324

City: BELMONT State: CA Zip: 94002-4106

6. Total number of applications and patents involved 1

7. Total fee (37CFR3.41) \$ 40.00
 Enclosed
 Authorized to be charged to deposit account.

8. Deposit Account Number 05-0150
(Attach duplicate copy of this page if paying by Deposit Account)

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. 91695613

JAMES E. EAKIN
Name of Person Signing

[Signature]
Signature

05 SEP 93
Date

Total number of pages comprising cover sheet: 1

Mail documents to be recorded with required cover sheet information to:
Hon. Commissioner of Patents and Trademarks
Box: Assignments
Washington, D.C. 20231

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UNITED STATES DEPARTMENT OF COMMERCE
 Patent and Trademark Office
 ASSISTANT SECRETARY AND COMMISSIONER
 OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

JULY 01, 1997

PTAS



100425106A

ARTERIAL VASCULAR ENGINEERING
 RICHARD L. KLEIN
 3576 UNOCAL PLACE
 SANTA ROSA, CA 95403

UNITED STATES PATENT AND TRADEMARK OFFICE
 NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS RECORDATION. IF YOU HAVE QUESTIONS CONCERNING THE NAME APPEARS ON THIS NOTICE OF RECORDATION, CONTACT THE ASSIGNMENT DIVISION, U.S. PATENT AND TRADEMARK OFFICE, BOX 1000, WASHINGTON, D.C. 20231.

Name Change from applied to Arterial

IS NOTICE. THE INFORMATION THE DATA PRESENT IN THE DOCUMENT SHOULD FIND ANY ERRORS OR CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE OF RECORDATION, PLEASE SEND REQUEST FOR CORRECTION TO THE ASSIGNMENT DIVISION, U.S. PATENT AND TRADEMARK OFFICE, BOX 1000, WASHINGTON, D.C. 20231.

RECORDATION DATE: 05/19/97

REEL/FRAME: 8522/0049
 NUMBER OF PAGES: 6

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

APPLIED VASCULAR ENGINEERING, INC. DOC DATE: 01/29/1996

ASSIGNEE:

ARTERIAL VASCULAR ENGINEERING, INC.
 3576 UNOCAL PLACE
 SANTA ROSA, CALIFORNIA 95403

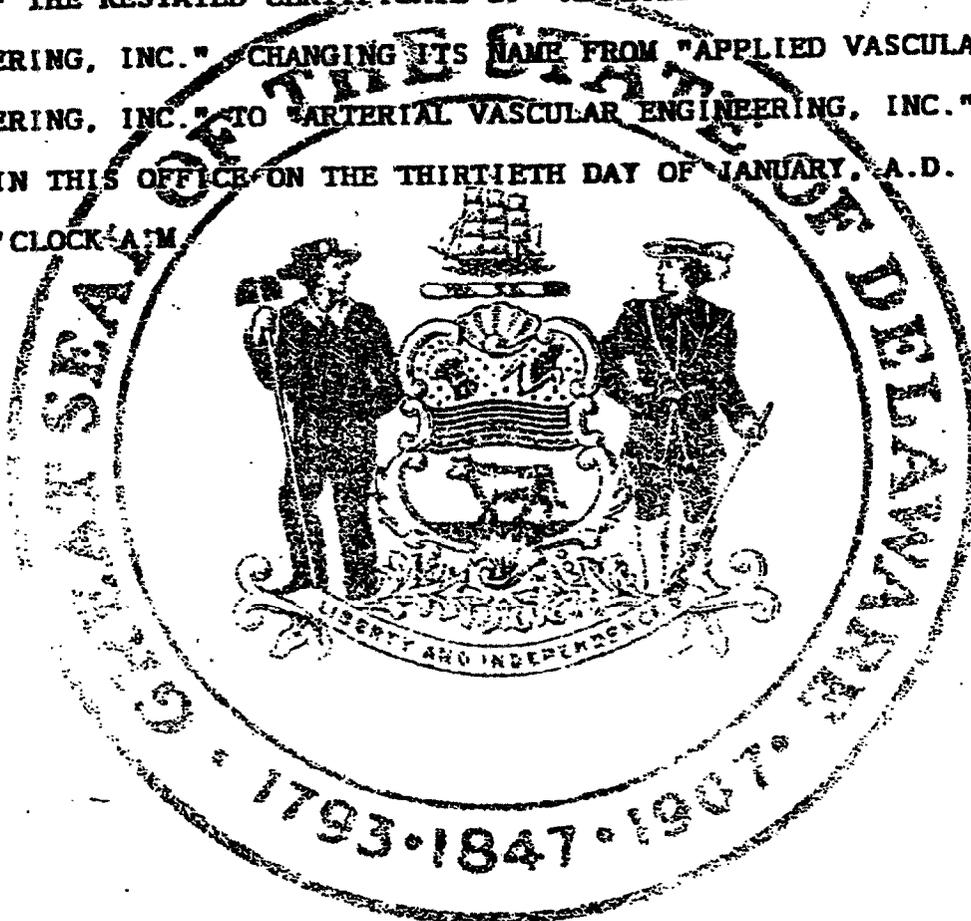
SERIAL NUMBER: 08619014
 PATENT NUMBER:

FILING DATE: 03/20/1996
 ISSUE DATE:

MAYA BENNETT, EXAMINER
 ASSIGNMENT DIVISION
 OFFICE OF PUBLIC RECORDS

Office of the Secretary of State

I, EDWARD J. FREEL, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "APPLIED VASCULAR ENGINEERING, INC." CHANGING ITS NAME FROM "APPLIED VASCULAR ENGINEERING, INC." TO "ARTERIAL VASCULAR ENGINEERING, INC.", FILED IN THIS OFFICE ON THE THIRTIETH DAY OF JANUARY, A.D. 1996, AT 9 O'CLOCK A.M.



Edward J. Freel

Edward J. Freel, Secretary of State

2269660 8100

960762289

AUTHENTICATION: 7851810

DATE: 03-04-96

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

I.

The name of this corporation is Arterial Vascular Engineering, Inc.

II.

The address of the registered office of the corporation in the State of Delaware is 1013 Centre Road, City of Wilmington, County of New Castle, and the name of the registered agent of the corporation in the State of Delaware at such address is The Prentice-Hall Corporation System, Inc.

III.

The purpose of this corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware.

IV.

A. This corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the corporation is authorized to issue is Fifty Million Five Hundred Thousand (50,500,000) shares. Fifty Million (50,000,000) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$.001). Five Hundred Thousand (500,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$.001). Each outstanding share of Common Stock, par value \$.01, shall, upon filing of this Amended and Restated Certificate of Incorporation be reconstituted as 5.5 shares of Common Stock, par value \$.001. No fractional shares will be issued and, in lieu thereof, any holder of less than one share of Common Stock shall be entitled to receive cash for such holder's fractional share based on the fair market value of such stock as determined by the Company's Board of Directors.

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by filing a certificate (a "Preferred Stock Designation") pursuant to the Delaware General Corporation Law, to fix or alter from time to time the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions of any wholly unissued series of Preferred Stock, and to establish from time to time the number of shares constituting any such series or any of them; and to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

V.

For the management of the business and for the conduct of the affairs of the corporation, and in further definition, limitation and regulation of the powers of the corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A.

(1) The management of the business and the conduct of the affairs of the corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted by the Board of Directors.

(2) Notwithstanding the foregoing provisions of this Article, each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, directors shall be elected at each annual meeting of stockholders. Each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

(3) Following the closing of the initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of the corporation's Common Stock to the public (the "Initial Public Offering"), and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

B.

(1) Subject to paragraph (h) of Section 43 of the Bylaws, the Bylaws may be altered or amended or new Bylaws adopted by the affirmative vote of at least eighty percent (80%) of the voting power of all of the then-outstanding shares of the Voting Stock. The Board of Directors shall also have the power to adopt, amend, or repeal Bylaws.

(2) The directors of the corporation need not be elected by written ballot unless the Bylaws so provide.

(3) Following the Initial Public Offering, no action shall be taken by the stockholders of the corporation except at an annual or special meeting of stockholders called in accordance with the Bylaws.

(4) Special meetings of the stockholders of the corporation may be called, for any purpose or purposes, by (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any such resolution is presented to the Board of Directors for adoption), and shall be held at such place, on such date, and at such time as the Board of Directors shall fix.

(5) Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the corporation shall be given in the manner provided in the Bylaws of the corporation.

VI.

A. A director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware General corporation Law, as so amended.

B. Any repeal or modification of this Article VI shall be prospective and shall not affect the rights under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

A. The corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF APPLIED VASCULAR ENGINEERING, INC.**

APPLIED VASCULAR ENGINEERING, INC., a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is APPLIED VASCULAR ENGINEERING, INC.

SECOND: The Certificate of Incorporation of the corporation was filed by the Secretary of State on July 30, 1991, under the name of Applied Vascular Engineering, Inc.

THIRD: The Amended and Restated Certificate of Incorporation of the corporation, in the form attached hereto as Exhibit A, has been duly adopted in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware by the Board of Directors of the corporation.

FOURTH: The Amended and Restated Certificate of Incorporation of the corporation, in the form attached hereto as Exhibit A, was approved by the written consent of a majority of the outstanding capital stock of the corporation in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware. Written consent has been provided, and written notice has been given, in accordance with Section 228 of the General Corporation Law of the State of Delaware. The corporation has one class of stock outstanding. The total number of outstanding shares of Common Stock of the corporation is four million eight hundred sixteen thousand nine hundred fifty-eight (4,816,958).

FIFTH: The Amended and Restated Certificate of Incorporation so adopted reads in full as set forth in Exhibit A attached hereto and hereby incorporated by reference.

IN WITNESS WHEREOF, APPLIED VASCULAR ENGINEERING, INC. has caused this Restated Certificate of Incorporation to be signed by its President and attested to by its Secretary this 29 day of January 1996.

APPLIED VASCULAR ENGINEERING, INC.

By: BAJ
Bradly A. Jendersee
Chief Executive Officer and President

ATTEST:

John D. Miller
John D. Miller
Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 01/30/1996
960028170 - 2269660



UNITED STATES DEPARTMENT OF COMMERCE
 Patent and Trademark Office
 ASSISTANT SECRETARY AND COMMISSIONER
 OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

JUNE 20, 1996

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JUL 01 1996



100166193A

FISH & NEAVE
 NICOLA A. PISANO
 1251 AVENUE OF THE AMERICAS
 NEW YORK, NEW YORK 10020

FISH & NEAVE = PATENT DEPT.
 REFERRED TO NABO
 FILED BY [Signature]

UNITED STATES PATENT AND TRADEMARK OFFICE
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RECORDATION DATE: 03/25/1996

REEL/FRAME: 7863/0672
 NUMBER OF PAGES: 6

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

APPLIED VASCULAR ENGINEERING, INC. DOC DATE: 01/29/1996

ASSIGNEE:

ARTERIAL VASCULAR ENGINEERING, INC.
 3624 WESTWIND BOULEVARD
 SANTA ROSA, CALIFORNIA 95403

SERIAL NUMBER: 08172420
 PATENT NUMBER:

FILING DATE: 12/22/1993
 ISSUE DATE:

SERIAL NUMBER: 08471738
 PATENT NUMBER: 5,891,190

FILING DATE: 06/06/1995
 ISSUE DATE: 4/6/99

SERIAL NUMBER: 08465842
 PATENT NUMBER: 5,800,509

FILING DATE: 06/06/1995
 ISSUE DATE: 9/1/98

SERIAL NUMBER: 08326023
 PATENT NUMBER:

FILING DATE: 10/19/1994
 ISSUE DATE:

ORIG/COPY
 SENT TO 7/1/96
 CALIFORNIA
 BY [Signature]

7863/0672 PAGE 2

SERIAL NUMBER: 08478192
PATENT NUMBER:

FILING DATE: 06/07/1995
ISSUE DATE:

SERIAL NUMBER: 08451270
PATENT NUMBER:

FILING DATE: 05/30/1995
ISSUE DATE:

SERIAL NUMBER: 08326031
PATENT NUMBER:

FILING DATE: 10/19/1994
ISSUE DATE:

SERIAL NUMBER: 08562138
PATENT NUMBER:

FILING DATE: 11/22/1995
ISSUE DATE:

SERIAL NUMBER: 08568543
PATENT NUMBER:

FILING DATE: 12/07/1995
ISSUE DATE:

SERIAL NUMBER: 08568834
PATENT NUMBER:

FILING DATE: 12/07/1995
ISSUE DATE:

SERIAL NUMBER: 07398180
PATENT NUMBER: 5292331

FILING DATE: 08/24/1989
ISSUE DATE: 03/08/1994

JERYL MCDOWELL, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

HEC ECOI
3-25-96

04-03-1996



581-440

Tab settings ▾ ▾ ▾ ▾ ▾

To the Honorable Commissioner of Patents 100166193

Send original documents or copy thereof.

1. Name of conveying party(ies):

Applied Vascular Engineering, Inc.

Additional name(s) of conveying party(ies) attached? Yes No

3. Nature of conveyance:

- Assignment Merger
- Security Agreement Change of Name
- Other _____

Execution Date: January 29, 1996

2. Name and address of receiving party(ies)

Name: Arterial Vascular Engineering, Inc.

Internal Address: _____

Street Address: 3621 Westwind Boulevard

City: Santa Rosa State: CA ZIP: 95403

Additional name(s) & address(es) attached? Yes No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)

08/172,420; 08/471,738; 08/465,842;
08/326,023; 08/478,192; 08/451,270;
08/326,031; 08/562,138; 08/568,543;
08/568,834

B. Patent No.(s)

5,292,331

Additional numbers attached? Yes No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nicola A. Pisano

Internal Address: c/o FISH & NEAVE

Street Address: 1251 Avenue of the

Americas

City: New York State: NY ZIP: 10020

6. Total number of applications and patents involved: 11

7. Total fee (37 CFR 3.41).....\$ 440.00

- Enclosed
- Authorized to be charged to deposit account

8. Deposit account number:

06-1075

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Nicola A. Pisano

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Applied Vascular Engineering, Inc.

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2. Name and address of receiving party(ies)

Name: Arterial Vascular Engineering
Inc

Internal Address: _____

Street Address: 3621 Westwind Boulevard

City: Santa Rosa State: CA ZIP: 9540

Additional name(s) & address(es) attached? Yes No

3. Nature of conveyance:

- Assignment Merger
- Security Agreement Change of Name
- Other _____

Execution Date: January 29, 1996

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)

08/172,420; 08/471,738; 08/465,842;
08/326,023; 08/478,192; 08/451,270;
08/326,031; 08/562,138; 08/568,543;
08/568,834

B. Patent No.(s)

5,292,331

Additional numbers attached? Yes No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nicola A. Pisano

Internal Address: c/o FISH & NEAVE

Street Address: 1251 Avenue of the
Americas

City: New York State: NY ZIP: 10020

6. Total number of applications and patents involved: 11

7. Total fee (37 CFR 3.41).....\$ 440.00

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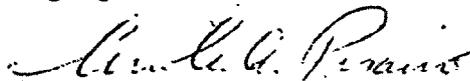
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Name of Person Signing


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Date

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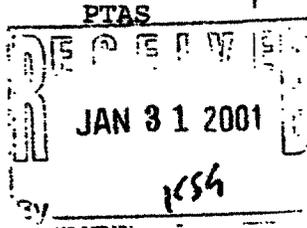
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JANUARY 24, 2001

MEDTRONIC AVE INC.
CATHERINE C. MARESH
IP LEGAL
3576 UNICAL PLACE
SANTA ROSA, CA 95403



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BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
ARTERIAL VASCULAR ENGINEERING,
INC.

DOC DATE: 01/28/1999

ASSIGNEE:
MEDTRONIC AVE, INC.
3576 UNICAL PLACE
SANTA ROSA, CALIFORNIA 94928

SERIAL NUMBER: 09287216
PATENT NUMBER:

FILING DATE: 04/05/1999
ISSUE DATE:

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2nd Review _____

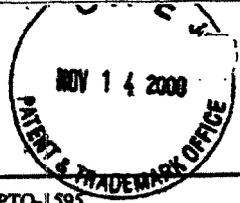
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(Rev. 6-93)

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3. Nature of conveyance:
 Assignment Merger
 Security Agreement Change of Name
 Other:
Execution Date: January 28, 1999

2. Name and address of receiving party (ies):

Name: MEDTRONIC AVE, INC.

Internal Address:

Street Address: 3576 Unocal Place

City: Santa Rosa State: CA ZIP: 94928

Additional names and addresses attached?
 Yes No

4. Application Number(s) or Patent Number(s):
U.S. Application Serial No: 09/287,216

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No(s): B. Patent No(s):

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5. Names and address of party to whom correspondence concerning document should be mailed:

Name: IP Legal
Medtronic AVE Inc.
3576 Unocal Place
Santa Rosa, CA. 95403
(707) 541-3155

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): \$40.00
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Catherine C. Maresh Catherine C. Maresh November 24 2000
Name of Person Signing Signature Date

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101444379

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Arterial Vascular Engineering, Inc.

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 Assignment Merger
 Security Agreement X Change of Name
 Other:
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2. Name and address of receiving party (ies):

Name: MEDTRONIC AVE, INC.

Internal Address:

Street Address: 3576 Unocal Place

City: Santa Rosa State: CA ZIP: 94928

Additional names and addresses attached?
 Yes No

NOV 21 2000 PM 12:10

4. Application Number(s) or Patent Number(s):
U.S. Application Serial No: 09/287,216

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No(s): B. Patent No(s):

Additional numbers attached? Yes No

5. Names and address of party to whom correspondence concerning document should be mailed:

Name: IP Legal
Medtronic AVE Inc.
3576 Unocal Place
Santa Rosa, CA. 95403
(707) 541-3155

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): \$40.00
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I, EDWARD J. FREEL, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"MAV MERGER CORP.", A DELAWARE CORPORATION,
WITH AND INTO "ARTERIAL VASCULAR ENGINEERING, INC." UNDER THE NAME OF "MEDTRONIC AVE, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE THE TWENTY-EIGHTH DAY OF JANUARY, A.D. 1999, AT 3 O'CLOCK P.M.



2269660 8100M

991196713

Edward J. Freel, Secretary of State

AUTHENTICATION: 9756414

DATE: 05-20-99



**CERTIFICATE OF MERGER
OF
MAV MERGER CORP.
INTO
ARTERIAL VASCULAR ENGINEERING, INC.**

The undersigned corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware,

DOES HEREBY CERTIFY:

FIRST, That the name and state of incorporation of each of the constituent corporations of the merger is as follows:

<u>Name</u>	<u>State of Incorporation</u>
Arterial Vascular Engineering, Inc.	Delaware
MAV Merger Corp.	Delaware

SECOND: That an Agreement and Plan of Merger between the parties to the merger has been approved, adopted, certified, executed and acknowledged by each of the constituent corporations in accordance with the requirements of subsection (c) of Section 251 of the General Corporation Law of the State of Delaware.

THIRD: That the name of the surviving corporation of the merger is Arterial Vascular Engineering, Inc., which upon the merger will change its name to "Medtronic AVE, Inc."

FOURTH: That the restated certificate of incorporation of the surviving corporation shall, as a result of the merger, be amended and restated in its entirety to read as set forth on Exhibit A hereto.

FIFTH: That the executed Agreement and Plan of Merger is on file at an office of the surviving corporation. The address of such office of the surviving corporation is 3576 Unocal Place; Santa Rosa, California 95403.

SIXTH: That a copy of the Agreement and Plan of Merger will be furnished by the surviving corporation, on request and without cost, to any stockholder of any constituent corporation.

ARTERIAL VASCULAR ENGINEERING, INC.

By: Lawrence J. Fassler
Lawrence J. Fassler
Vice President of Legal Affairs, General Counsel and
Secretary

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ARTERIAL VASCULAR ENGINEERING, INC.

ARTICLE 1 - NAME

The name of the corporation shall be Medtronic AVE, Inc.

ARTICLE 2 - REGISTERED OFFICE AND AGENT

The registered office of the corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE 3 - PURPOSES

The nature of the business or purposes to be conducted or promoted by the corporation is to engage in any lawful acts and activities for which corporations may be organized under the General Corporation Law of Delaware.

ARTICLE 4 - STOCK

The aggregate number of shares the corporation has authority to issue shall be 2,500 shares of Common Stock, \$.01 par value. Holders of Common Stock shall be entitled to one vote for each share of Common Stock held of record.

ARTICLE 5 - RIGHTS OF STOCKHOLDERS

5.1) No Preemptive Rights. No holder of shares of the corporation of any class now or hereafter authorized has any preferential or preemptive right to subscribe for, purchase or receive any shares of the corporation of any class now or hereafter authorized, or any options or warrants for such shares, which may at any time be issued, sold or offered for sale by the corporation.

5.2) No Cumulative Voting Rights. No holder of shares of the corporation of any class now or hereafter authorized shall be entitled to cumulative voting.

ARTICLE 6 - MEETINGS AND BOOKS

6.1) Meetings of Stockholders and Election of Directors. Meetings of stockholders may be held within or outside the State of Delaware, as the Bylaws may provide. Elections of directors need not be by written ballot unless and except to the extent that the Bylaws so provide.

6.2) Corporate Books. The books of the corporation may be kept within or (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the corporation.

ARTICLE 7 - LIMITATION OF DIRECTOR LIABILITY

7.1) Limitation of Liability. A director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

7.2) Amendment of this Article. Any repeal or modification of this Article 7 shall be prospective and shall not affect the rights under this Article 7 in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

ARTICLE 8 - BYLAWS

The Board of Directors is expressly authorized to make and alter Bylaws of this corporation, subject to the power of the stockholders to change or repeal such Bylaws and subject to any other limitations on such authority provided by the General Corporation Law of Delaware.

2200631-8



US005879382A

United States Patent [19]

[11] Patent Number: 5,879,382

Boneau

[45] Date of Patent: Mar. 9, 1999

[54] **ENDOVASCULAR SUPPORT DEVICE AND METHOD**

1-145076	6/1989	Japan .
1217402	5/1984	U.S.S.R. .
1457921	3/1987	U.S.S.R. .
8203810	2/1982	United Kingdom .

[76] Inventor: Michael D. Boneau, 342 W. Sunnyoaks, Campbell, Calif. 95008

OTHER PUBLICATIONS

[21] Appl. No.: 846,405

Wright et al., "Percutaneous Endovascular Stents: An Experimental Evaluation," Radiology, vol. 156, 1, 07-95, pp. 69-72.

[22] Filed: Apr. 30, 1997

Rosch et al., "Experimental Intrahepatic Portacaval Anastomosis: Use of Expandable Giantureo Stents," Radiology, vol. 162 #2, 02-87, pp. 481-485.

Related U.S. Application Data

[63] Continuation of Ser. No. 619,014, Mar. 20, 1996, Pat. No. 5,674,278, which is a continuation of Ser. No. 471,738, Jun. 6, 1995, which is a division of Ser. No. 172,420, Dec. 22, 1993, abandoned, which is a division of Ser. No. 398,180, Aug. 24, 1989, Pat. No. 5,292,331.

Lawrence, Jr. et al., "Percutaneous Endovascular Graft: Experimental Evaluation," Radiology, vol. 163, pp. 357-360.

[51] Int. Cl.⁶ A61F 2/06

Yoshioka et al., "Self Expanding Endovascular Graft: An Experimental Study in Dogs," AJR, vol. 151 10-88, pp. 673-676.

[52] U.S. Cl. 623/1; 623/12; 606/195

Mirich, M.D. et al., "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility," Study, Radiology, vol. 170 #3, 03-89. pp. 1033-1037.

[58] Field of Search 623/1, 11, 12; 606/194, 195, 198

References Cited

Primary Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Richard L. Klein

U.S. PATENT DOCUMENTS

[57] ABSTRACT

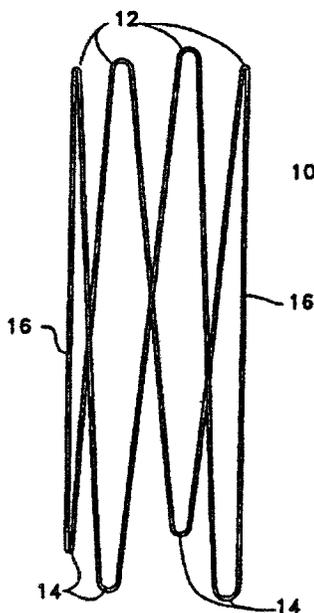
3,657,744	4/1972	Ersek	623/11
4,214,587	7/1980	Sakure, Jr. .	
4,830,003	5/1989	Wolff et al. .	
4,886,062	12/1989	Wiktor .	
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4,969,458	11/1990	Wiktor .	
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5,035,706	7/1991	Giantureo et al.	606/198
5,104,399	4/1992	Lazarus .	
5,562,728	10/1996	Lazarus et al.	623/1

An endovascular support device for treatment of chronic restenosis or other vascular narrowing is disclosed together with a method of manufacture and a method for delivering a plurality of such devices to an affected area of a vessel. In a preferred embodiment, the endovascular support device comprises a unitary wire-like structure configured to form a plurality of upper and lower peaks which may be compressed for delivery to an affected area of a coronary or peripheral vessel in a human, and then expanded to maintain a passageway through the vessel.

FOREIGN PATENT DOCUMENTS

0183372	6/1986	European Pat. Off.	623/1
88116594.8	10/1988	European Pat. Off. .	

4 Claims, 3 Drawing Sheets



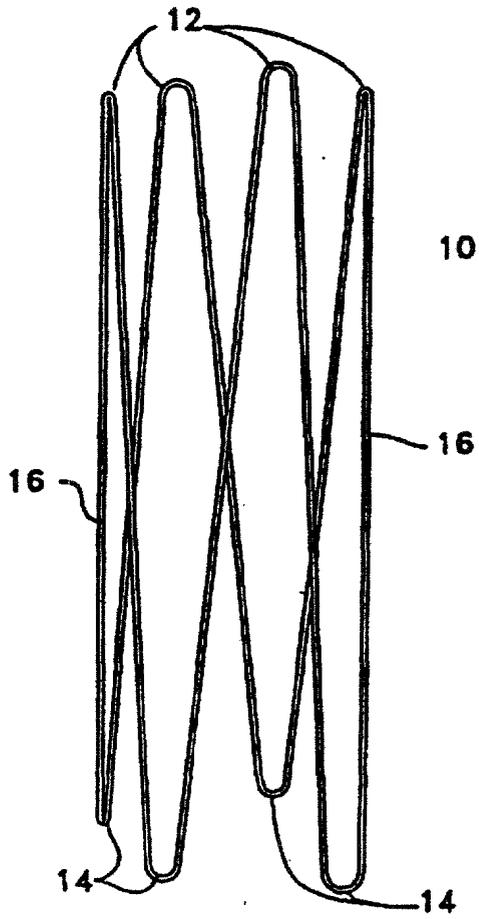


Figure 1

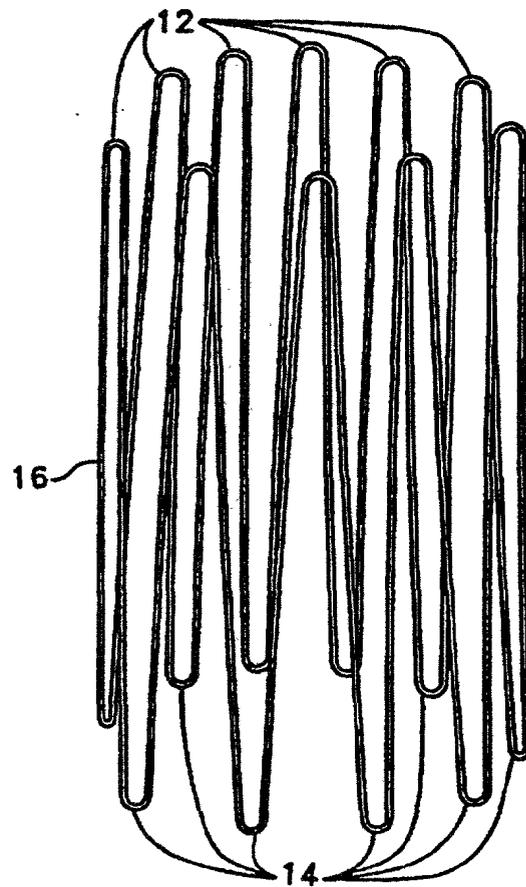


Figure 6b

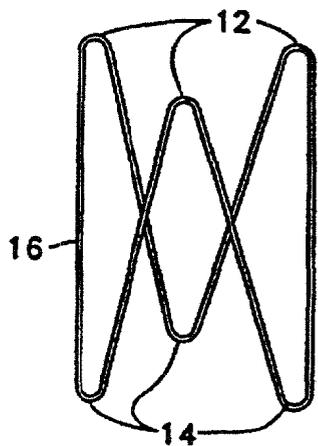


Figure 6a

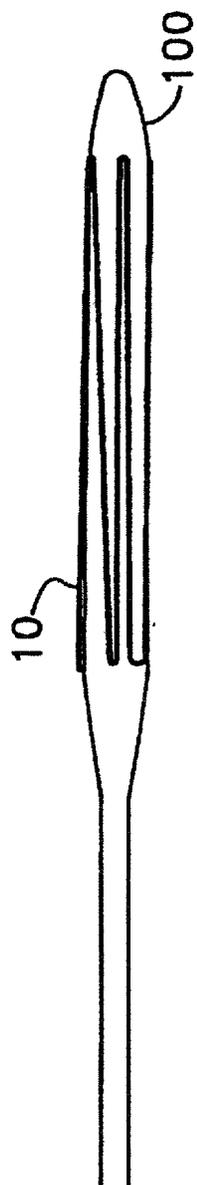


Figure 2

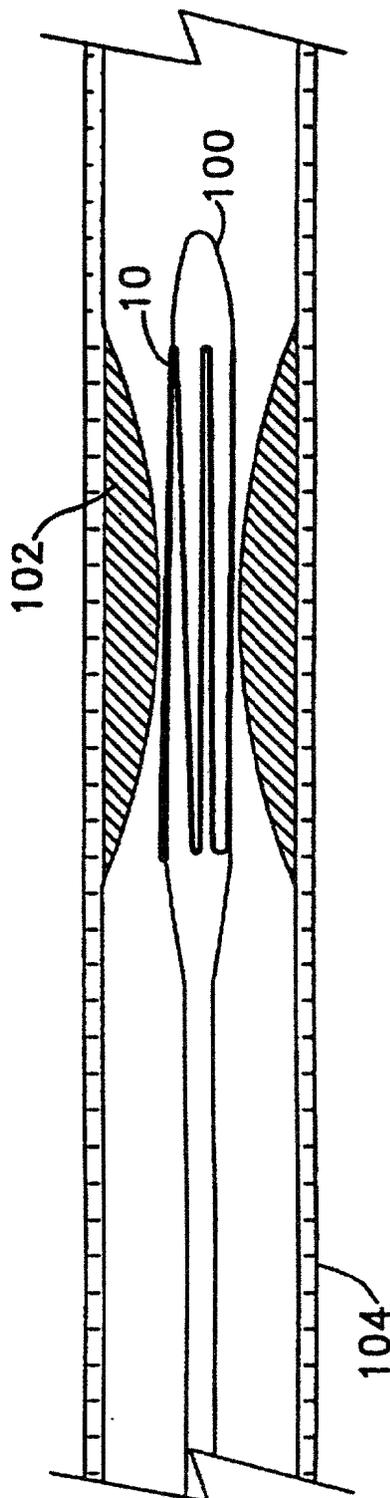


Figure 3

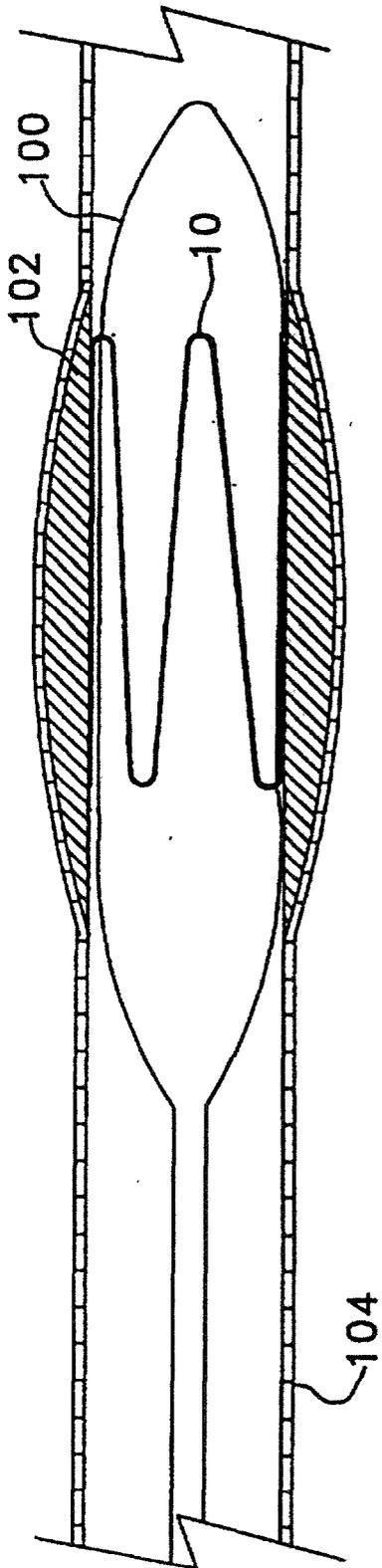


Figure 4

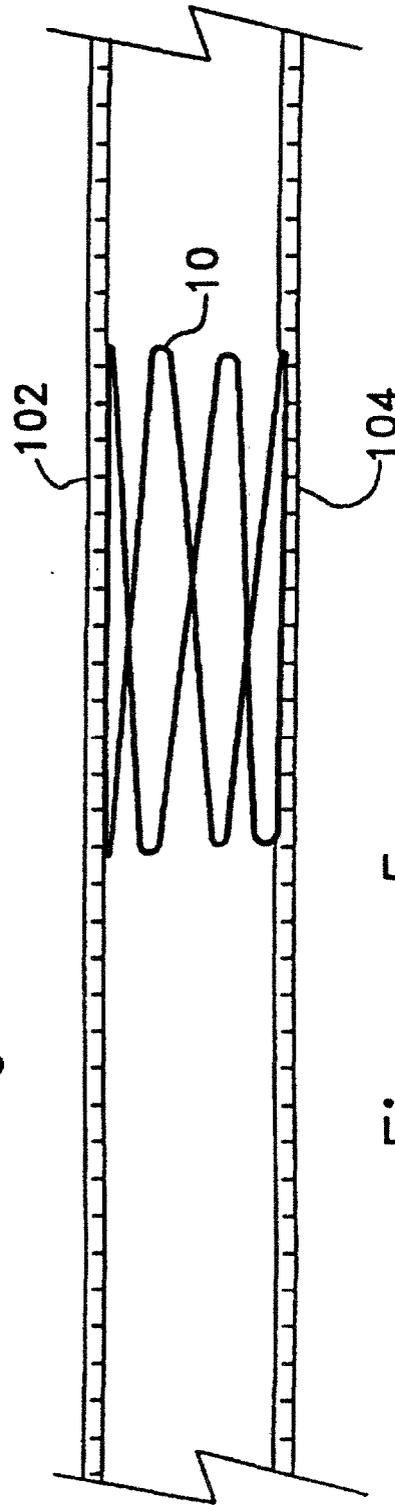


Figure 5

ENDOVASCULAR SUPPORT DEVICE AND METHOD

SPECIFICATION

This application is a continuation of application Ser. No. 08/619,014, filed Mar. 20, 1996, now U.S. Pat. No. 5,674,278, which is a continuation of application Ser. No. 08/471,738, filed Jun. 6, 1995, pending, which is a division of application Ser. No. 08/172,420, filed Dec. 22, 1993, now abandoned, which is a division of application Ser. No. 07/398,180, filed Aug. 24, 1989, now U.S. Pat. No. 5,292,331.

FIELD OF THE INVENTION

The present invention relates generally to medical devices, and particularly relates to implantable devices for treating narrowing of coronary or peripheral vessels in humans.

BACKGROUND OF THE INVENTION

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

The most impelling development in the past decade for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to simply as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon and hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

PTCA is performed as follows: A thin-walled, hollow guiding catheter is typically introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery is achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during PTCA. The flexible guiding catheter, which is typically polymer coated, and lined with Teflon, is inserted through the sheath into the femoral artery. The guiding catheter is advanced through the femoral artery into the iliac artery and into the ascending aorta. Further advancement of the flexible catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to be treated by PTCA, a flexible guidewire is inserted into the guiding catheter through a balloon and advanced to the area to be treated. The guidewire provides the necessary steerability for lesion passage. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a polyethylene, polyvinyl chloride, polyolefin, or other suitable substance balloon

catheter across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing during treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in extended form, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise. For example, one such stent is a self-expanding stainless steel wire braid. Other forms of stents include various types tubular metallic cylinders expanded by balloon dilatation. One such device is referred to as the Palmaz stent, discussed further below.

Another form of stent is a heat expandable device. This device, originally designed using NITINOL by Dotter has recently been modified to a new tin-coated, heat expandable coil by Regan. The stent is delivered to the affected area on a catheter capable of receiving heated fluids. Once properly positioned, heated saline is passed through the portion of the catheter on which the stent is located, causing the stent to expand. Numerous difficulties have been encountered with this device, including difficulty in obtaining reliable expansion, and difficulties in maintaining the stent in its expanded state.

Perhaps the most popular stent presently under investigation in the United States is referred to as the Palmaz stent. The Palmaz stent involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon.

Significant difficulties have been encountered with all prior art stents. Each has its percentage of thrombosis,

restenosis and tissue in-growth, as well as varying degrees of difficulty in deployment. Another difficulty with at least some of prior art stents is that they do not readily conform to the vessel shape. In addition, the relatively long length of such prior art stents has made it difficult to treat curved vessels, and has also effectively prevented successful implantation of multiple such stents. Anticoagulants have historically been required at least for the first three months after placement. These and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

Thus there has been a long felt need for a stent which is effective to maintain a vessel open, without resulting in significant thrombosis, which may be easily delivered to the affected area, easily expanded to the desired size, easily conformed to the affected vessel, and easily used in multiples to treat curved vessels and varying lengths of lesions.

SUMMARY OF THE INVENTION

The present invention substantially reduces the complications and overcomes the limitations of the prior art devices. The endovascular support device of the present invention comprises a device having very low mass which is capable of being delivered to the affected area by means of a slightly modified conventional balloon catheter similar to that used in a standard balloon angioplasty procedure.

The support device of the present invention may then be expanded by normal expansion of the balloon catheter used to deliver the stent to the affected area, and its size can be adjusted within a relatively broad range in accordance with the diagnosis of the treating physician.

Because of the range of diameters through which the support device of the present invention may be expanded, it may be custom expanded to the specific lesion diameter, and is readily conformable to the vessel shape. In addition, a plurality of support devices of the present invention may be readily implanted in a number commensurate with the length of the lesion under treatment. As a result, curved or "S" shaped vessels may be treated.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel, machined specially for intravascular applications. The support device may comprise, in effect, a metal circle or ellipsoid formed to create a plurality of axial bends, thereby permitting compression of the stent onto a delivery catheter, and subsequent expansion once in place at the affected area.

It is one object of the present invention to provide a stent which substantially overcomes the limitations of the prior art.

It is a further object of the present invention to provide a stent capable of being implanted simply and reliably.

Another object of the present invention is to provide a stent which does not result in significant thrombosis at the point of implant.

Yet another object of the present invention is to provide a stent which can be selectively sized in accordance with the anatomic configuration dictated by the lesion itself.

A still further object of the present invention is to provide a method for supplying an endovascular support device which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment.

These and other objects of the present invention can be better appreciated from the following detailed description of the invention, taken in conjunction with the attached drawings.

FIGURES

FIG. 1 shows a perspective view of an endovascular support device constructed according to the present invention, in its expanded form.

FIG. 2 shows a support device constructed according to the present invention and compressed onto a balloon catheter.

FIG. 3 shows a support device compressed onto a balloon catheter as shown in FIG. 2, and positioned within a sectioned portion of an affected area of an artery or other vessel.

FIG. 4 shows a support device according to the present invention in its expanded form within a sectioned portion of a vessel including a lesion.

FIG. 5 shows a support device of the present invention in its expanded form within a sectioned portion of a lesion after removal of the balloon catheter.

FIGS. 6a-b show alternative configurations of a support device according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to FIG. 1, an endovascular support device 10, referred to hereinafter more conveniently as a stent, constructed in accordance with the present invention can be seen in perspective view. The stent 10 of FIG. 1 is shown in its expanded form, prior to compression over a suitable delivery system as discussed in detail hereinafter.

In a preferred embodiment, the stent 10 comprises a single piece of material, bent to form a plurality of upper axial turns 12 and lower axial turns 14. In the embodiment shown in FIG. 1, four upper turns 12 are connected to the four lower turns 14 by substantially straight segments 16. The axial turns 12 and 14 can be seen to permit the stent 10 to be compressed or expanded over a wide range while still maintaining significant mechanical force, such as required to prevent a vessel from restenosing. While a preferred embodiment comprises a single piece of material, in some instances a suitably welded wire may be acceptable.

It will be appreciated that the number of turns 12 and 14 can vary over a reasonably wide range and may in fact vary between two and ten such turns or peaks. However, it is currently believed that the optimum number of turns or peaks will range between three and five for most applications, and particularly for cardiovascular applications.

The stent 10 is preferably constructed of implantable materials having good mechanical strength. An embodiment which has proven successful in preliminary testing is machined from 316LSS implantable quality stainless steel bar stock. The bar stock is machined to form substantially a toroid, which is then acid etched in phosphoric and sulfuric acid at approximately 180° to 185° to break the edges. The etched toroid is then plated with copper to avoid galling and to provide lubricity.

The copper plated toroid is then bent to the shape of the stent 10 shown in FIG. 1, after which the copper plating is stripped from the stent. The stent is then returned to the acid bath to reduce the wire size to the desired diameter, which is in the range of 0.002" to 0.025". It is presently believed that the optimum wire size for the final product is in the range of 0.008" to 0.009". It will be appreciated that the strength of the stent—that is, its ability to prevent restenosis—is inversely proportional to the number of peaks or turns in the stent, so that stents having a greater number of turns will typically be formed of larger wire diameters. Finally, although not required in all cases, the outside of the stent may be selectively plated with platinum to provide

improved visibility during fluoroscopy. The cross-sectional shape of the finished stent may be circular, ellipsoidal, rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of the stent, or the distance between the upper turns 12 and lower turns 14, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent 10 will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

Once the wire size of the stent 10 has been reduced to the desired size, the stent 10 may be crimped onto a balloon 100, as shown in FIG. 2, for delivery to the affected region 102 of a vessel 104 such as a coronary artery. For the sake of simplicity, the multiple layers of the vessel wall 104 are shown as a single layer, although it will be understood by those skilled in the art that the lesion typically is a plaque deposit within the intima of the vessel 104.

One suitable balloon for delivery of the stent 10 is manufactured by Advanced Cardiovascular Systems, Inc., of Santa Clara, Calif. ("ACS"), and is eight millimeters in length with Microglide on the shaft only. The stent-carrying balloon 100 is then advanced to the affected area and across the lesion 102 in a conventional manner, such as by use of a guide wire and a guide catheter (not shown). A suitable guide wire is the 0.014" Hi Torque Floppy manufactured by ACS, and a suitable guiding catheter is the ET.076 lumen guide catheter, also manufactured by ACS.

Once the balloon 100 is in place across the lesion 102, as shown in FIG. 3, the balloon 100 may be inflated, again substantially in a conventional manner. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the stent 10 will expand equally along each of the peaks. The inflation of the balloon 100, shown in FIG. 4, causes the expansion of the stent 10 from its crimped configuration back to a shape substantially like that shown in FIG. 1. The amount of inflation, and commensurate amount of expansion of the stent 10, may be varied as dictated by the lesion itself, making the stent of the present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion 102 in the vessel 104 is expanded, and causes the arterial wall of the vessel 104 to bulge radially, as simplistically depicted in FIG. 4. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent 10 is embedded in the plaque or other fibrotic material adhering to the intima of the vessel 104.

Following inflation of the balloon 100 and expansion of the stent 10 within the vessel 104, the balloon is deflated and removed. The exterior wall of the vessel 104 returns to its original shape through elastic recoil. The stent 10, however, remains in its expanded form within the vessel, and prevents further restenosis of the vessel. The stent maintains an open passageway through the vessel, as shown in FIG. 4, so long

as the tendency toward restenosis is not greater than the mechanical strength of the stent 10. Because of the low mass of the support device 10 of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent 10 will result in a smooth inside diameter of the vessel 104, although this ideal cannot be achieved in all cases.

One of the advantages of the stent 10 is that multiple stents may be used in the treatment of a single lesion. Thus, for example, in the event the affected area shown in FIGS. 3 and 4 was longer than the stent 10, additional stents 10 could be positioned elsewhere along the lesion to prevent restenosis. In preliminary testing, up to four stents have been used successfully along a single lesion. Due to the conformability of the stent 10, not only can varying lesion lengths be treated, but curved vessels and "S" shaped vessels may also be treated by the present invention. In instances where it is known in advance that multiple stents will be the preferred method of treatment, a plurality of such stents may be positioned along a single balloon catheter for simultaneous delivery to the affected area.

As discussed above, the number of peaks or turns 12 and 14 in the stent 10 may vary between two and ten. To this end, shown in FIGS. 6a and 6b are two alternative configurations of the stent 10. The alternative embodiment shown in 6a can be seen to have three upper and three lower peaks or turns, while the embodiment shown in FIG. 6b can be seen to have ten upper and ten lower peaks.

While the primary application for the stent 10 is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent 10 of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated, bearing in mind the sizing guidelines provided above.

Having fully described a preferred embodiment of the invention, those skilled in the art will immediately appreciate, given the teachings herein, that numerous alternatives and equivalents exist which do not depart from the present invention. It is therefore to be understood that the present invention is not to be limited by the foregoing description, but only by the appended claims.

I claim:

1. An endovascular support device for implantation in a vessel within the human body comprising:

a plurality of stent members;

each stent member formed of a plurality of substantially straight segments having ends;

the ends of respective pairs of the plurality of substantially straight segments connected end to end at a plurality of axial turns; and

whereby each of the plurality of stent members are capable of retaining a compressed configuration while mounted onto an outer surface of a catheter for delivery to an affected area of a vessel until application of a radial force to form an expanded configuration.

2. The endovascular support device according to claim 1 wherein the plurality of stent members are adjacent and non-overlapping.

3. The endovascular support device according to claim 1 wherein the plurality of stent members are not connected to one another.

4. The endovascular support device according to claim 1 wherein each stent member is continuous.

* * * * *



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Patent Number: 5879382 **Application Number:** 08846405

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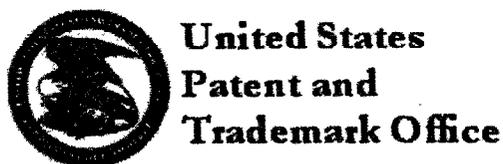
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