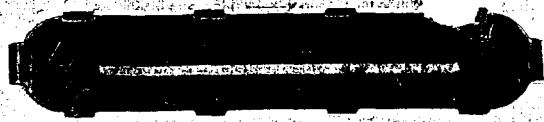


57 08/219179

Class	Subclass
600	600

ISSUE CLASSIFICATION



5411466

UTILITY SERIAL NUMBER	08/219179	PATENT DATE		PATENT NUMBER		5411466			
SERIAL NUMBER	08/219,179	FILING DATE	03/28/94 RULE 60	CLASS	600	GROUP ART UNIT	3305	EXAMINER	

APPLICANTS ROBERT L. HESS, PORTOLA VALLEY, CA.

CONTINUING DATA***
VERIFIED THIS APPLN IS A CON OF 07/755,480 09/05/91 PAT 5,302,166

FOREIGN/PCT APPLICATIONS***
VERIFIED

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Foreign priority claimed 35 USC 119 conditions met	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
Verified and Acknowledged	Examiner's Initials		→	CA	4	4	1	\$355.00	011683006

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TITLE METHOD AND APPARATUS FOR RESTENSIS TREATMENT

U.S. DEPT. of COMM.-Pat. & TM Office-PTO-436L (rev. 10-78)

PARTS OF APPLICATION FILED SEPARATELY		Applications Examiner 12/29	
NOTICE OF ALLOWANCE MAILED	Assistant Examiner		CLAIMS ALLOWED
28 DEC 1994			Total Claims: 5, Print Claim: 1
ISSUE FEE	LEE S. COHEN PRIMARY EXAMINER ART UNIT 335		DRAWING
Amount Due: 8505.00, Date Paid: 12/13/95	Primary Examiner		Sheets Drwg: 4, Figs. Drwg: 9, Print Fig: 4
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08/219179

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PATENT
011683-004

ROBERT L. HESS
(Typed or printed name of person submitting paper or fee)

(Signature of person mailing) METHOD AND APPARATUS FOR RESTENOSIS TREATMENT



Background of the Invention

5 This invention relates generally to angioplasty and more particularly to a method and apparatus for preventing restenosis after angioplasty or other stenosis treatment.

Background Description

10 In the past, catheters have been developed which may be effectively inserted into blood vessels and maneuvered through a vascular tree. A balloon may be used with such catheter to expand in the vessel and open blockages found therein. In a typical percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA)
15 procedure, a guiding catheter is percutaneously introduced into the vascular system of a patient through an artery and advanced therein until the distal tip of the guiding catheter is appropriately positioned. A dilation catheter having a balloon on the distal end thereof and a guide wire are slidably
20 disposed and introduced through the guiding catheter. The guide wire is first advanced through the distal tip of the guiding catheter until the distal end of the guide wire crosses the lesion to be dilated. The
25 dilation catheter is then advanced over the previously introduced guide wire until the dilation balloon on the distal extremity of the dilation catheter is properly positioned inside the lesion. The balloon portion of the dilation catheter is then inflated to a

2 A

predetermined size to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall to thereby reduce the annular stenosed area. After a period of time, the balloon is
5 deflated so that blood flow is resumed, allowing the dilation catheter to be removed.

A major problem encountered in a significant number of patients treated by this procedure is the subsequent narrowing of the artery after the expansion
10 treatment. Various methods and apparatus have been developed to address the restenosis problem including multiple inflations of the balloon during the original procedure, atherectomy, hot balloons, and lasers. Even the installation of permanent stents has been thought
15 to potentially have some value in reducing restenosis rates. See, for example, U.S. Patent No. 5,019,075 to Spears et al. wherein the region surrounding the balloon utilized in the angioplasty procedure is heated by means within the balloon, or within the skin of the
20 balloon, upon inflation of the balloon in order to ideally fuse together fragmented segments of tissue. U.S. Patent No. 4,733,655 to Palmaz discloses an expansible vascular graft which is expanded within a blood vessel by an angioplasty balloon to dilate and
25 expand the lumen of the blood vessel. The Palmaz method and apparatus leaves the expandable vascular graft in place to ideally prevent recurrence of stenosis in the body passageway.

However, recent data seems to indicate that
30 the prior art methods described above do not significantly reduce restenosis rates of occurrence. In restenosis, a proliferation of cells following angioplasty is believed to cause the lesion to reform. The rate of occurrence of restenosis is generally

considered to be about 33 percent. It would therefore be desirable to have a method and apparatus to treat a lesion in order to reduce the restenosis rate of occurrence. The present invention is believed to
5 provide a unique method and apparatus to reduce the restenosis rate of occurrence following an angioplasty or like-intended procedure.

Summary of the Invention

The purpose of the invention is to provide
10 method and apparatus to significantly reduce restenosis rates of occurrence following an angioplasty procedure. To accomplish this purpose, there is provided method and apparatus for exposing the dilated lesion to a radiation dose that will affect smooth muscle cell
15 growth. There is provided a catheter which has at its distal end a radioactive source, the source being maneuverable to the site of a lesion which has been dilated or removed, the apparatus allowing the site to be exposed to the radiation dose that will affect
20 smooth muscle cells such that the rapid growth of such cells can be prevented, thereby controlling restenosis.

In one aspect of the invention there is provided a method for treatment and post-treatment of the stenosed region of an artery comprising the steps
25 of:

reducing the annular stenosed area within an artery; and

applying a radioactive dose to the area of reduced stenosis.

30 In another aspect of the invention there is provided a method for treatment and post-treatment of the stenosed region of an artery after reduction of

said region by angioplasty or other means comprising the step of applying a radioactive dose to said reduced region of the artery.

In yet another aspect of the invention there
5 is provided apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means comprising:
radioactive dose means; and
positioning means operatively connected to
10 said dose means to position said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means.

Description of the Drawing

FIG. 1 is a partial cross-sectional view of
15 an embodiment of the invention wherein said dose applying means is a radioactive element contained within a wire wound housing for radioactive containment, the housing having a window cut-out. A larger wire wound sheath covers the window during
20 insertion and removal, the sheath being withdrawn to expose the radioactive element at the lesion site.

FIG. 2 is a partial perspective view of an alternate embodiment having a radioactive dose means positioned upon the balloon of an expandable balloon
25 catheter, said balloon catheter being provided with a means or perfusion to allow blood flow during the time the balloon is inflated.

FIG. 3 is an enlarged partial cross-sectional view of a portion of the apparatus shown in FIG. 2.

FIG. 4 is a partial perspective view of the apparatus shown in FIGS. 2 and 3 upon expansion of the balloon portion of the apparatus.

5 FIG. 5 is a partial perspective view of another embodiment of the invention wherein the radioactive dose means is an element that may be contained within a complementary containment means provided with a remotely actuated window.

10 FIG. 6 is a partial perspective cross-sectional view of a catheter tip containing radioactive dose means showing the remotely actuated window.

15 FIG. 7 is a partial perspective cross-sectional view of an alternate embodiment further including a stent wherein said radioactive dose means is in the form of a coating of radioactive material on the stent.

FIG. 8 is a partial cross-sectional view of the device shown in FIG. 7 after expansion of the stent shown in FIG. 7.

20 FIG. 9 is a partial perspective view of the stent illustrated in FIGS. 7 and 8 wherein the stent is implanted within the artery.

Description of the Preferred Embodiments

25 With continued reference to the drawing, FIG. 1 illustrates the apparatus and method for preventing restenosis of an artery that has been enlarged by angioplasty or other procedure. Specifically, apparatus, shown generally at 10, is positioned within artery segment 12 having lesion site 14 which has

previously been enlarged by angioplasty or other procedure such that atherosclerotic plaque 16 has been radially compressed by expansion of the balloon portion of an angioplasty device (not shown) or removed by
5 other means. Device 10 having distal end 18 with tip 20 and wire wound housing 22 is positioned such that housing 22 is positioned within the lesion site 14. Housing 22 contains radioactive dose means 30 and is provided with window cut-out 32. Device 10 includes a
10 wire wound retractable sheath 24 and catheter shaft 26 with guide wire and guide wire port 28. A radioactive dose means 30 is moveable by advancing or retracting catheter shaft 26 which may be referred to as a
15 **positioning means.** Sheath 24 is drawn back when the radioactive dose means is positioned directly proximate the lesion site 14 such that window cut-out 32 is opened to expose the lesion site 14, which has been previously dilated, to a radiation dose that will affect the smooth muscle cells/plaque.

20 In FIG. 2 there is illustrated a device shown generally at 34 which is an alternate embodiment of the invention further including an angioplasty balloon 36 with dose means in the form of radioactive elements 38 attached thereto. Device 34 includes catheter shaft 40
25 having perfusion capabilities provided by holes 41 positioned proximately and distally to the balloon portion.

FIG. 3 shows in expanded view details of balloon 36 of FIG. 2 positioned about catheter shaft 40
30 having two main lumens 42 and 44. Lumen 42 makes provision for guide wire capability and contains perfusion holes. Lumen 44 is the lumen which provides the passage to inflate the balloon from the inflation port 45 shown in FIG. 2 at the proximal end of the

device 34. The radioactive elements 38 are not shown in FIG. 3.

FIG. 4 illustrates the device 34 of FIGS. 2 and 3 wherein the balloon 36 is expanded in the vicinity of the lesion site 46, and the radioactive elements 38 are forced into contact with the lesion.

It is understood that the various embodiments of the subject invention are useful in the treatment of a lesion site within an artery. "Lesion site" includes those lesions which have been treated with balloon angioplasty, those lesions that have been treated by an atherectomy or laser angioplasty, those lesions that have been treated by rotational atherectomy or any other means of compressing or removing the material of the lesion which may cause trauma to the artery. It is this trauma which causes the proliferation of smooth muscle cells which method and apparatus of the subject invention is intended to inhibit.

With regard to all embodiments of the subject invention, "radioactive dose" means bombardment by particles emitted from radioactive materials including, but not limited to, materials such as Radon 222, Gold 198, Strontium 90, Radium 192, and Iodine 125. These materials may be incorporated into or delivered in a solid, liquid, or gaseous form, and the delivery of such forms is considered to be within the scope of the subject invention.

FIG. 5 illustrates an alternate embodiment of the subject invention in the form of apparatus shown generally at 48. Sheath 50 of said device is preferably made from a helically wire wound member to provide a measure of shielding for the radioactive dose

means. Device 48 includes positioning means 52 which is a motion wire providing slidable motion of the radioactive dose means 54 within the sheath. Radioactive dose means 54 is thus positionable
5 proximate to the lesion site 56 of artery segment 58 and retractable within sheath 50 for insertion and removal within the artery segment 58.

FIG. 6 illustrates yet another embodiment of the subject invention in the form of the device shown
10 generally at 60, similar to the device 10 shown in FIG. 1. In FIG. 6, device 60 is comprised of the shaft portion 62 and contains at its distal end a canister 64 containing the radioactive dose means. This canister 64 has a remotely actuated window 66 which can be
15 actuated through port 68 to expose the radioactive dose means to the lesion 70.

FIGS. 7, 8, and 9 illustrate yet another embodiment of the subject invention wherein a device shown generally at 72 is an inflatable stent delivery
20 balloon system for delivery and expansion of stent 74. Stent 74 may be removable or may be a permanent implant. In the case of a permanently implanted stent, the radioactive dose means has to be carefully chosen in terms of dose level and half-life in order to limit
25 the total radiation dose. In this embodiment, the radioactive dose means is associated with stent 74 and may be included as a cladding, a coating, an additive within the basic stent material itself, or an attachment by other means to the stent. In FIG. 7 the
30 device 72 includes an inflatable balloon dilation catheter to position stent 74 within lesion 76.

FIG. 8 shows the expanded balloon of the stent delivery system 78 having dilated stent 74 in close proximal contact with lesion 76.

5 FIG. 9 shows the stent 74 in place within lesion 76 with the stent delivery system having been removed from the artery.

The foregoing description of the drawing illustrates various methods of the invention. It should be understood that the methods of the invention include the treatment and post-treatment of an annularly stenosed region of an artery. Most methods of treatment currently available cause some trauma to the artery. The artery in response to this trauma proliferates the growth of smooth muscle cells in many cases, and this results in restenosis at the site of the original stenosis -- usually within a six-month period. The post-treatment consists of exposing the treated region of the stenosis to a radiation dose which is sufficient to retard or halt the proliferation of smooth muscle cells. It should also be pointed out that both the treatment and post-treatment could occur simultaneously if the device which removes or compresses the stenosis material also contains the radioactive dose means.

25 Having indicated above preferred embodiments of the present invention, it will occur to those skilled in the art that modification and alternatives can be practiced within the spirit of the invention. It is accordingly intended to define the scope of the invention only as indicated in the following claims.

30

What Is Claimed Is:

1 1. A method for treatment and post-
2 treatment of the stenosed region of an artery
3 comprising the steps of:
4 reducing the annular stenosed area within an
5 artery; and
6 **applying a radioactive dose to the area of**
7 **reduced stenosis.**

1 2. A method as defined in Claim 1 wherein
2 the step of applying the radioactive dose is sufficient
3 to affect smooth muscle cells within the area of
4 reduced stenosis to inhibit rapid growth of such cells,
5 thereby preventing restenosis of the artery.

1 3. A method as defined in Claim 1 further
2 including the step of continuing to reduce the annular
3 stenosed area while applying a radioactive dose to said
4 area.

1 4. A method as defined in Claim 1 including
2 the step of allowing blood flow through the area of
3 reduced stenosis while applying the radioactive dose.

1 5. A method as defined in Claim 1 including
2 the contacting of the tissue of the area of reduced
3 stenosis with a radioactive material.

1 6. A method as defined in Claim 1 further
2 including the step of containing a source of
3 radioactive dose before and after exposure to said area
4 of reduced stenosis.

1 7. A method for treatment and post-
2 treatment of the stenosed region of an artery after

3 reduction of said region by angioplasty or other means
4 comprising the step of applying a radioactive dose to
5 said reduced region of the artery.

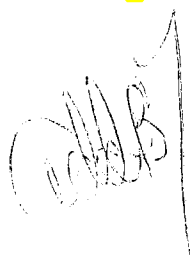
1 8. A method as defined in Claim 1 wherein
2 the step of applying the radioactive dose is sufficient
3 to affect smooth muscle cells within the area of
4 reduced stenosis, thereby inhibiting rapid growth of
5 such cells and preventing restenosis of the artery.

1 9. Apparatus for post-treatment of a
2 stenosed region of an artery that has been reduced by
3 angioplasty or other means comprising:
4 radioactive dose means; and
5 positioning means operatively connected to
6 said dose means to position said dose means within the
7 stenosed region of an artery that has been reduced by
8 angioplasty or other means.

1 10. Apparatus as in Claim 9 wherein the
2 positioning means includes a retractable sheath which
3 may be removably positioned over said radioactive dose
4 means.

1 11. Apparatus as in Claim 9 wherein the
2 positioning means further includes an angioplasty
3 balloon and said radioactive dose means is connected to
4 said balloon and is positioned in the stenosed region
5 by expansion of said balloon.

1 12. Apparatus as in Claim 9 wherein the
2 positioning means includes a stent and said radioactive
3 dose means is associated with said stent.



Abstract of the Disclosure

Method and apparatus for treatment and post-treatment of the stenosed region of an artery after reduction of the region by angioplasty or other means
5 by applying a radioactive dose to said reduced region of the artery by positioning a radioactive dose to the reduced region is disclosed.



Applicant or Patentee: Robert L. Hess Attorney's
 Serial or Patent No.: Unknown Docket No.: 011683-004
 Filed or Issued: September 5, 1991
 For: Method and Apparatus for Restenosis Treatment

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9 (f) and 1.27 (b)) — INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9 (c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled Method and Apparatus for Restenosis Treatment described in

- the specification filed herewith
- application serial no. _____, filed _____.
- patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9 (c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- no such person, concern, or organization
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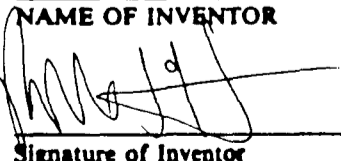

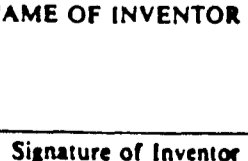
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Robert L. Hess /// ///
 NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR
  
 Signature of Inventor Signature of Inventor Signature of Inventor
September 5, 1991 _____
 Date Date Date

**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION**

Attorney Docket No.

011683-004

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (if only one name is listed below) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (if more than one name is listed below) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION

ENTITLED: Method and Apparatus for Restenosis Treatment

the specification of which

(check one)

is attached hereto;

was filed on _____ as

Application Serial No. _____

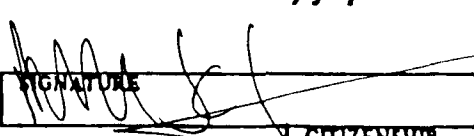
and was amended on _____ ;
(if applicable)

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE;

I ACKNOWLEDGE THE DUTY TO DISCLOSE INFORMATION WHICH IS MATERIAL TO THE EXAMINATION OF THIS APPLICATION IN ACCORDANCE WITH TITLE 37, CODE OF FEDERAL REGULATIONS, Sec. 1.56 (a) which states: "A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.";

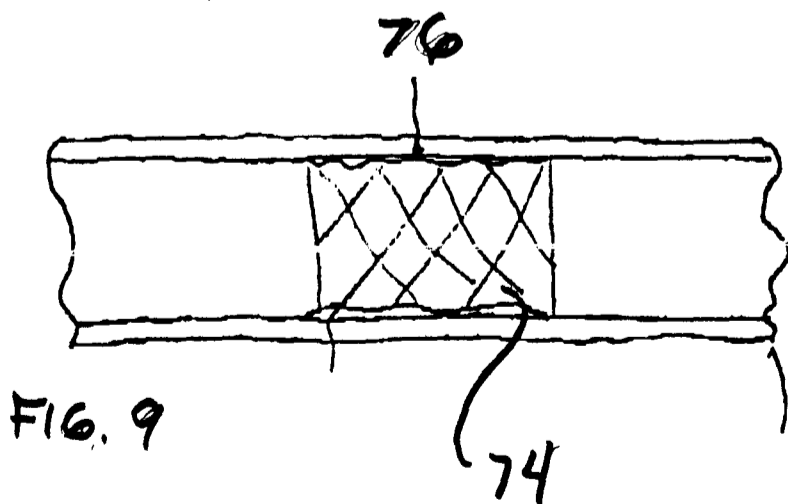
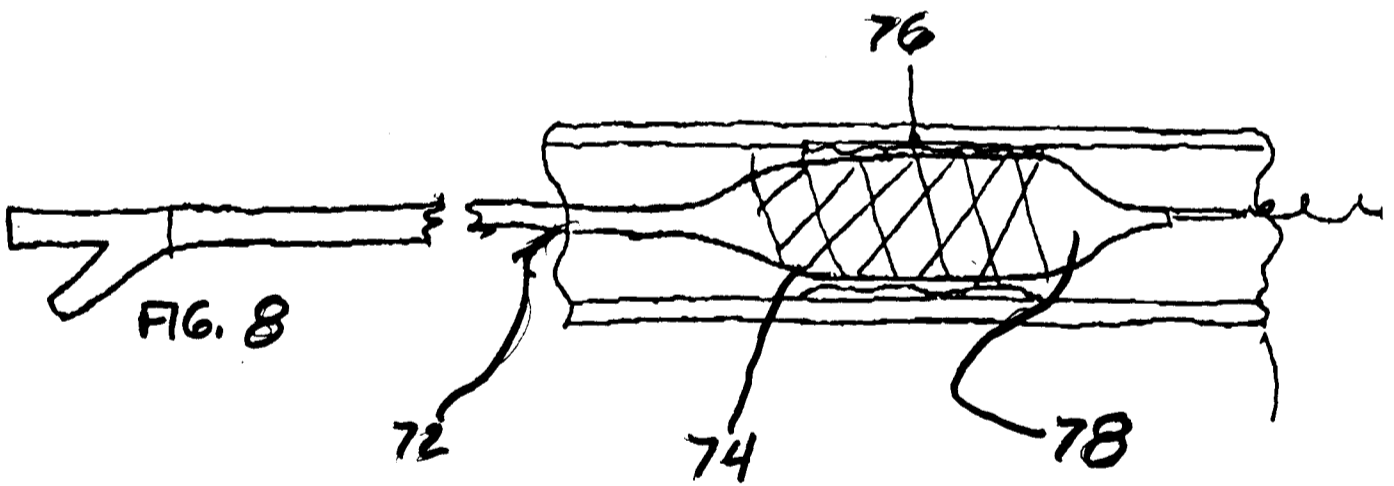
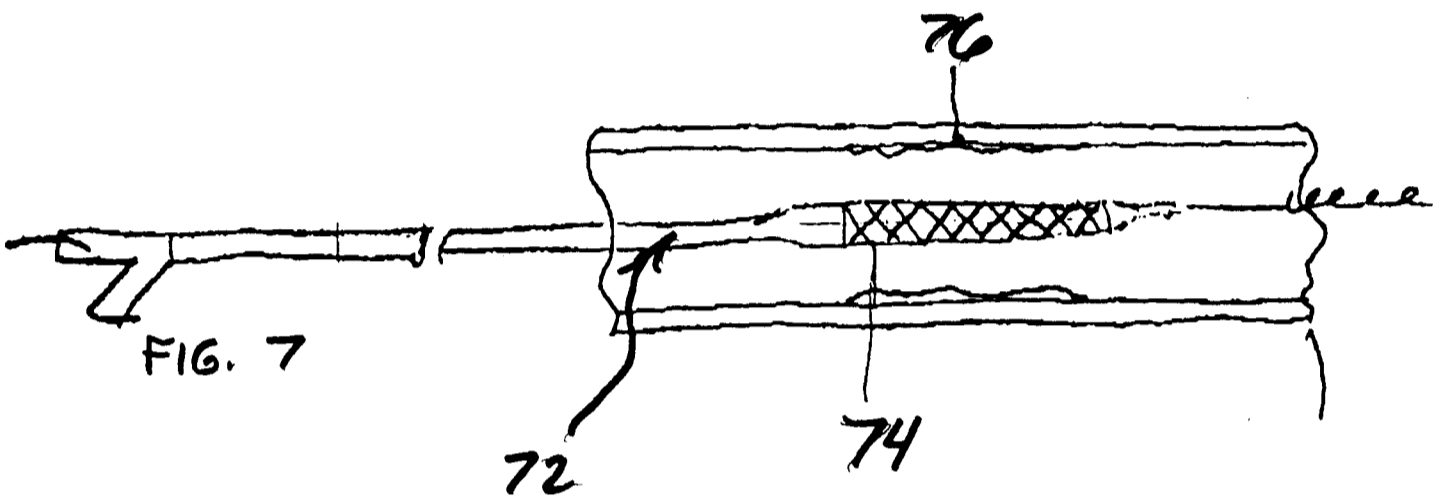
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I hereby claim foreign priority benefits under Title 35, United States Code Sec. 119 and/or Sec. 365 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application(s) on which priority is claimed:

COMBINED DECLARATION AND POWER OF ATTORNEY			Attorney Docket No. 011683-004																																																																			
COUNTRY/INTERNATIONAL	APPLICATION NUMBER	DATE OF FILING <small>(day, month, year)</small>	PRIORITY CLAIMED																																																																			
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<p>I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:</p> <table style="width:100%; border: none;"> <tr> <td style="width: 25%;">William L. Mathis</td> <td style="width: 10%;">17,337</td> <td style="width: 25%;">Regis E. Slutter</td> <td style="width: 10%;">26,999</td> <td style="width: 25%;">Teresa Stanek Rea</td> <td style="width: 10%;">30,427</td> </tr> <tr> <td>Peter H. Smolka</td> <td>15,913</td> <td>Samuel C. Miller, III</td> <td>27,360</td> <td>Robert E. Krebs</td> <td>25,885</td> </tr> <tr> <td>Robert S. Swecker</td> <td>19,885</td> <td>Ralph L. Freeland, Jr.</td> <td>16,110</td> <td>Lance W. Chandler</td> <td>29,467</td> </tr> <tr> <td>Platon N. Mandros</td> <td>22,124</td> <td>Robert G. Mukai</td> <td>28,531</td> <td>Robert M. Schulman</td> <td>31,196</td> </tr> <tr> <td>Benton S. Duffett, Jr.</td> <td>22,030</td> <td>George A. Hovanec, Jr.,</td> <td>28,223</td> <td>William C. Rowland</td> <td>30,888</td> </tr> <tr> <td>Joseph R. Magnone</td> <td>24,239</td> <td>James A. LaBarre</td> <td>28,632</td> <td>Richard H. Kjeldgaard</td> <td>30,186</td> </tr> <tr> <td>Joel M. Freed</td> <td>25,101</td> <td>E. Joseph Geas</td> <td>28,510</td> <td>T. Gene Dillahunt</td> <td>25,423</td> </tr> <tr> <td>Norman H. Stepno</td> <td>22,716</td> <td>David D. Reynolds</td> <td>29,273</td> <td>Patrick C. Keane</td> <td>32,858</td> </tr> <tr> <td>Ronald L. Grudziecki</td> <td>24,970</td> <td>R. Danny Huntington</td> <td>27,903</td> <td>Peter K. Skiff</td> <td>31,917</td> </tr> <tr> <td>Frederick G. Michaud, Jr.</td> <td>26,003</td> <td>Eric H. Weisblatt</td> <td>30,505</td> <td>Mathew L. Schneider</td> <td>32,814</td> </tr> <tr> <td>Alan E. Kopecki</td> <td>25,813</td> <td>James W. Peterson</td> <td>26,057</td> <td></td> <td></td> </tr> </table> <p>and: _____</p> <p>Address all correspondence to: James W. Peterson Burns, Doane, Swecker & Mathis George Mason Building Washington and Prince Streets P.O. Box 1404 Alexandria, Virginia 22313-1404</p> <p>Address all telephone calls to: James W. Peterson _____ at 415-854-7400</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>					William L. Mathis	17,337	Regis E. Slutter	26,999	Teresa Stanek Rea	30,427	Peter H. Smolka	15,913	Samuel C. Miller, III	27,360	Robert E. Krebs	25,885	Robert S. Swecker	19,885	Ralph L. Freeland, Jr.	16,110	Lance W. Chandler	29,467	Platon N. Mandros	22,124	Robert G. Mukai	28,531	Robert M. Schulman	31,196	Benton S. Duffett, Jr.	22,030	George A. Hovanec, Jr.,	28,223	William C. Rowland	30,888	Joseph R. Magnone	24,239	James A. LaBarre	28,632	Richard H. Kjeldgaard	30,186	Joel M. Freed	25,101	E. Joseph Geas	28,510	T. Gene Dillahunt	25,423	Norman H. Stepno	22,716	David D. Reynolds	29,273	Patrick C. Keane	32,858	Ronald L. Grudziecki	24,970	R. Danny Huntington	27,903	Peter K. Skiff	31,917	Frederick G. Michaud, Jr.	26,003	Eric H. Weisblatt	30,505	Mathew L. Schneider	32,814	Alan E. Kopecki	25,813	James W. Peterson	26,057		
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Joel M. Freed	25,101	E. Joseph Geas	28,510	T. Gene Dillahunt	25,423																																																																	
Norman H. Stepno	22,716	David D. Reynolds	29,273	Patrick C. Keane	32,858																																																																	
Ronald L. Grudziecki	24,970	R. Danny Huntington	27,903	Peter K. Skiff	31,917																																																																	
Frederick G. Michaud, Jr.	26,003	Eric H. Weisblatt	30,505	Mathew L. Schneider	32,814																																																																	
Alan E. Kopecki	25,813	James W. Peterson	26,057																																																																			
1-00 FULL NAME OF SOLE OR FIRST INVENTOR		SIGNATURE		DATE																																																																		
Robert L. Hess				9/5/91																																																																		
RESIDENCE		CITIZENSHIP																																																																				
222 Wyndham Drive, Portola Valley, CA 94025		U.S.																																																																				
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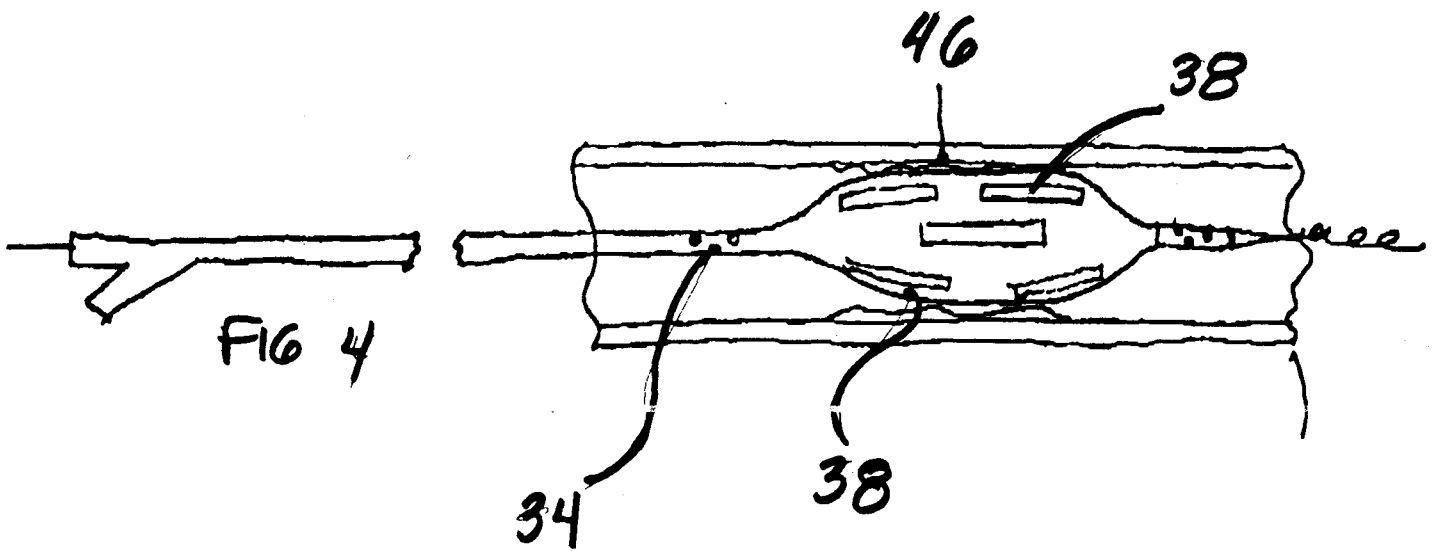
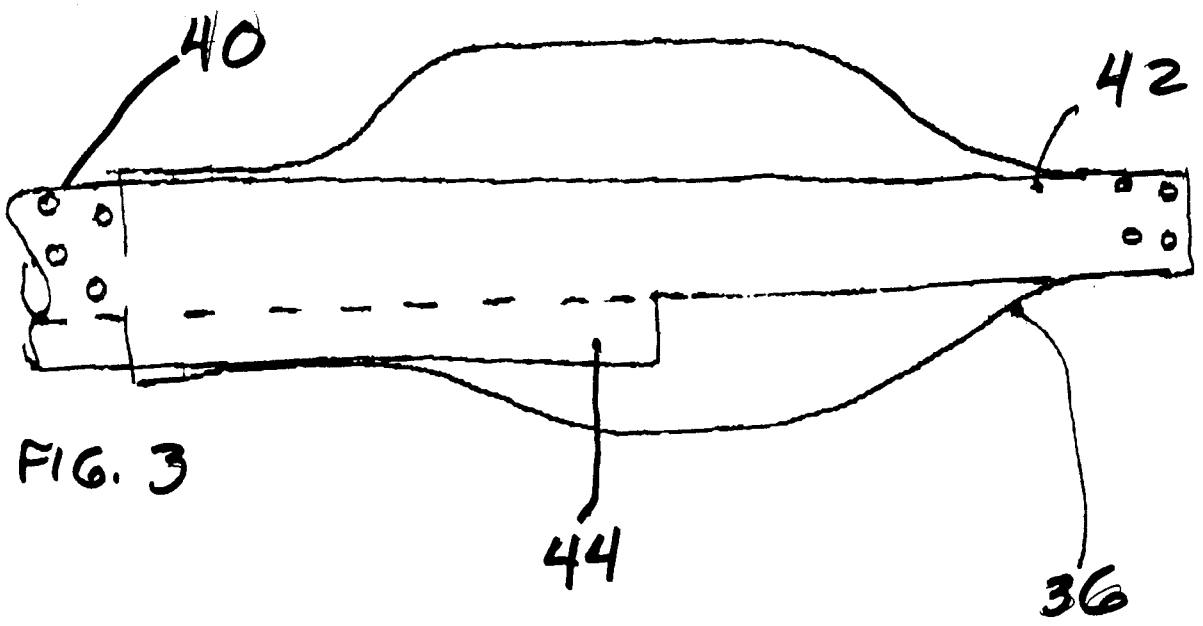
Please see attached continuation page for additional inventors.

011683-004
4/4

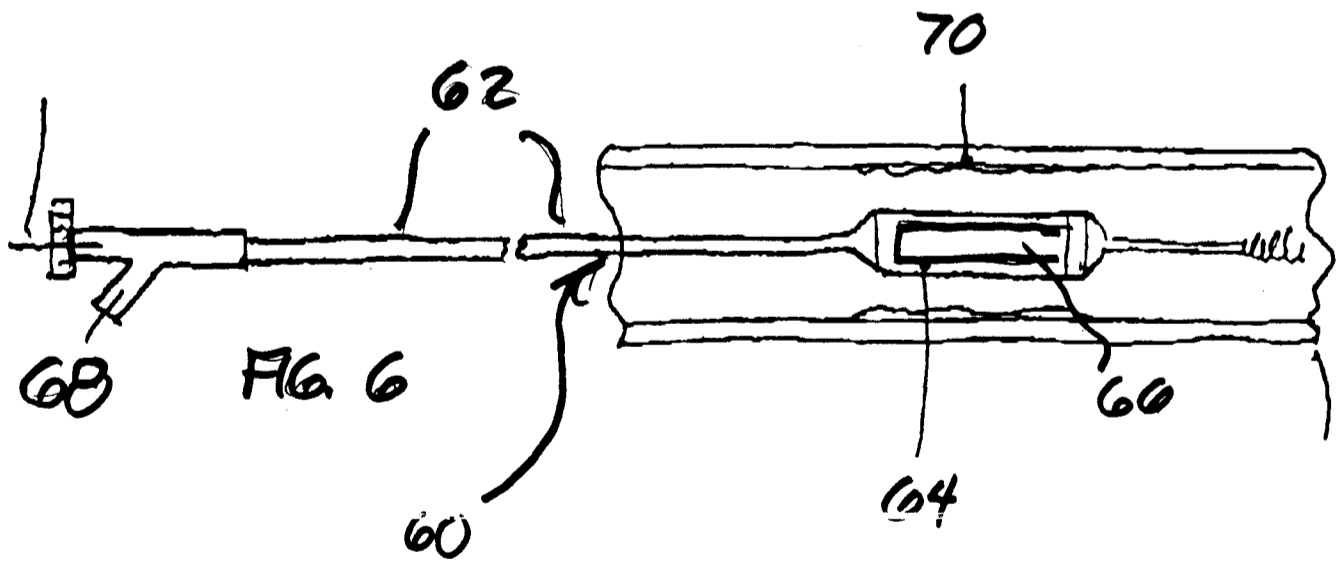
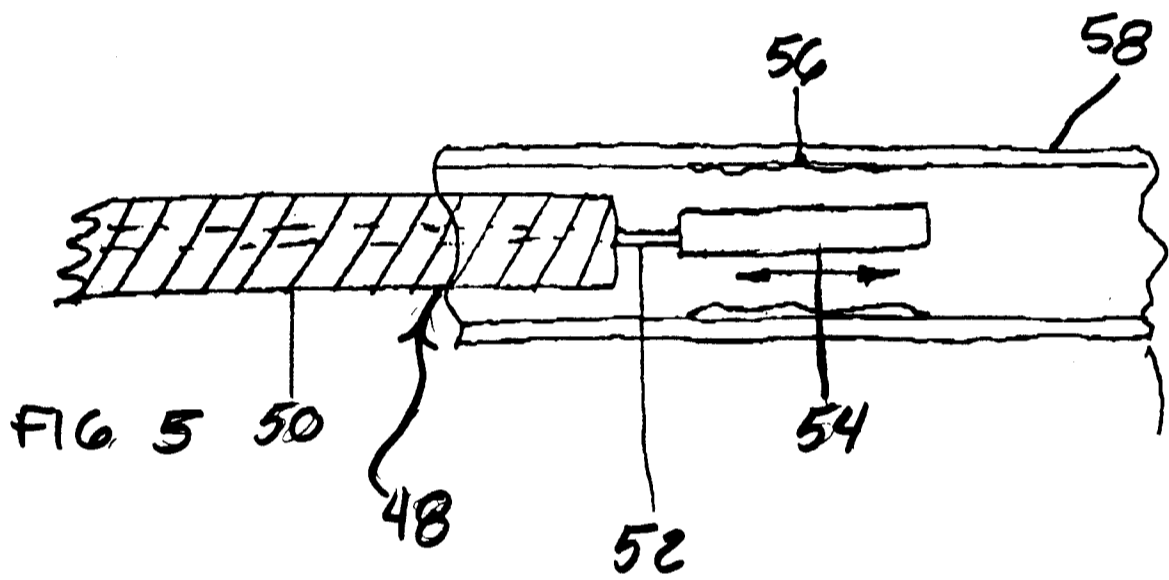


011683-004

2/4



011683-004
3/4

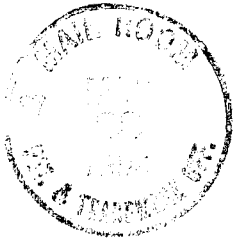


4

355D-201

08/219179

A



Patent
Attorney's Docket No. 011683-006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR FILING
CONTINUATION/DIVISIONAL APPLICATION UNDER 37 C.F.R. § 1.60

Amick
7/2/94
FR/PA

Box PATENT APPLICATION
Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is a request for filing a continuation divisional application under 37 C.F.R. § 1.60 of pending Application Serial No. 07/755,480 filed on September 5, 1991, for METHOD AND APPARATUS FOR RESTENOSIS TREATMENT, by the following named inventor(s):

(a) Full Name Robert L. HESS
Citizenship United States of America
Residence Portola Valley, California
Address 222 Wyndham Drive, Portola Valley, CA 94025

(b) Full Name _____
Citizenship _____
Residence _____
Address _____

(c) Full Name _____
Citizenship _____
Residence _____
Address _____

1. Enclosed is a copy of the latest inventor-signed prior application, including copies of the specification, claims, drawings and the executed oath or declaration as originally filed, and I hereby verify that the attached papers are a true copy of the latest inventor-signed prior Application Serial No. 07/755,480 as originally filed on September 5, 1991. Further, I declare that all statements made herein of my own knowledge are true; that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

A

NC 000267

2. One verified statement(s) claiming small entity status are enclosed
 were filed in prior Application Serial No. 07/755,480, filed on September 5, 1991.
3. The filing fee is calculated below:

CLAIMS					
	NO. OF CLAIMS		EXTRA CLAIMS	RATE	FEE
Basic Application Fee					\$ 710.00
Total Claims	12	MINUS 20 =	0	x \$22 =	
Independent Claims	3	MINUS 3 =	0	x \$74 =	
If multiple dependent claims are presented, add \$230.00					
Total Application Fee					710.00
If small entity status is claimed, subtract 50% of Total Application Fee					355.00
Add Assignment Recording Fee of \$40.00 if Assignment document is enclosed					
TOTAL APPLICATION FEE DUE					355.00

4. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.
5. A check in the amount of \$ 355.00 is enclosed.
6. Cancel in this application original claims 1-8 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
7. Amend the specification by inserting before the first line the sentence: --This application is a [x] continuation, [] divisional, of Application Serial No. 07/755,480 filed September 5 1991. /
8. Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate of this paper is enclosed for filing in the prior application file. (May only be used if signed by person authorized under 37 C.F.R. § 1.138 and before payment of issue fee.)
9. New drawings are enclosed.

NC 000268

10. Priority of Application Serial No. _____ filed on _____ in _____ (country) is claimed under 35 U.S.C. § 119.
- The certified copy of the priority application is enclosed was filed on _____ in prior Application Serial No. _____, filed on _____ has not yet been filed.
11. The prior application is assigned of record to __.
12. A preliminary amendment is enclosed.
13. Also enclosed Information Disclosure Statement _____.
14. The power of attorney in the prior application is to James W. Peterson and the partners of Burns, Doane, Swecker & Mathis.
- a. The power appears in the original papers in the prior application.
- b. Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- c. Recognize as Associate Attorney Peter K. Skiff, Reg. No. 31,917
- d. Address all future communications to: (May only be completed by applicant, or attorney or agent of record.)

James W. Peterson, Esq.
Burns, Doane, Swecker & Mathis
P.O. Box 1404
Alexandria, Virginia 22313-1404

March 28, 1994
Date

By: James W. Peterson by Peter K Skiff
James W. Peterson
Registration No. 26,057 Reg. No. 31917

Address of
signator:

Burns, Doane, Swecker & Mathis
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

- inventor(s)
 assignee of complete interest
 attorney or agent of record
 filed under 37 C.F.R. § 1.34(a)

08/219179



Smith
5-3-94
#3123

Patent

Attorney's Docket No. 011683-006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	
)	
Application No.: NOT YET ASSIGNED)	Group Art Unit: UNKNOWN
)	
Filed: March 28, 1994)	Examiner: UNKNOWN
)	
For: APPARATUS FOR)	
RESTENOSIS TREATMENT)	
)	

PRELIMINARY AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Prior to the examination of the above-referenced patent application, please amend the application as follows.

IN THE TITLE:

Delete "METHOD AND".

IN THE CLAIMS:

Please cancel Claims 9-12 without prejudice or disclaimer of the subject matter thereof and add new claims as follows.

--13. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means; and

positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that

lwb

B

has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means further including an angioplasty balloon, said radioactive dose means being connected to said balloon and positionable in the stenosed region by expansion of said balloon.

14. The apparatus of Claim 13, wherein the radioactive dose means comprises a plurality of radioactive sources distributed around the balloon.

15. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means; and

positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means including a retractable sheath which may be removably positioned over said radioactive dose means and the dose means being located in a housing having an opening therein, the dose means being exposed to the stenosed region by moving the sheath from a first position wherein the opening is covered by the sheath to a second position wherein the opening is not covered by the sheath.

16. The apparatus of Claim 15, wherein the housing is a wirewound housing and the opening comprises a cut-out in a sidewall of the wirewound housing.

17. Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means; and

positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means including a retractable remotely activated cover which may be removably positioned over said radioactive dose means and the dose means being

located in a housing having an opening therein, the dose means being exposed to the stenosed region by moving the remotely activated cover from a first position wherein the opening is covered by the remotely activated cover to a second position wherein the opening is not covered by the remotely activated cover.

REMARKS

The claims of the present application are directed to apparatus disclosed in the parent application.

In view of the foregoing, early and favorable consideration is requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: Peter K Skiff
Peter K. Skiff
Registration No. 31,917

P.O. Box 1404
Alexandria, VA 22313-1404
Phone: (703) 836-6620

Date: March 28, 1994



08 219179

Patent

Attorney's Docket No. 011683-006

Asmi
5-3-94
7/4/94
Disclosure
Statement

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	
)	
Application No.: NOT YET ASSIGNED)	Group Art Unit: UNKNOWN
)	
Filed: March 28, 1994)	Examiner: UNKNOWN
)	
For: APPARATUS FOR)	
RESTENOSIS TREATMENT)	
)	

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicant hereby submits the following information made of record in Serial No. 07/755,480. Pursuant to 37 C.F.R. § 1.98, copies of the documents cited are available in parent application Serial No. 07/755,480 upon which is based a claim for priority under 35 U.S.C. § 1.20. 37 C.F.R. § 1.98(d).

- U.S. Patent No. 3,168,092
- U.S. Patent No. 3,324,847
- U.S. Patent No. 4,202,323
- U.S. Patent No. 4,434,788
- U.S. Patent No. 4,588,395
- U.S. Patent No. 4,697,575
- U.S. Patent No. 4,733,665
- U.S. Patent No. 4,815,449
- U.S. Patent No. 4,878,492

U.S. Patent No. 5,019,075

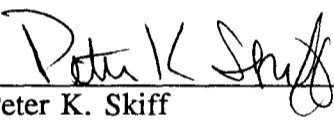
U.S. Patent No. 5,059,166

U.S. Patent No. 5,084,002

To assist the Examiner, the documents are listed on the attached form PTO-1449.
It is respectfully requested that an Examiner initialled copy of this form be returned to the undersigned.

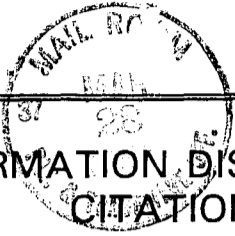
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
Peter K. Skiff
Registration No. 31,917

P.O. Box 1404
Alexandria, VA 22313-1404
Phone: (703) 836-6620

Date: March 28, 1994



INFORMATION DISCLOSURE CITATION PTO-1449			ATTY. DOCKET NO. 011683-006	SERIAL NO. NOT YET ASSIGNED			
			APPLICANT ROBERT L. HESS				
			FILING DATE March 28, 1994	GROUP NOT YET ASSIGNED			
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
<i>ph</i>	3,168,092	02/65	Silverman	—	—		
	3,324,847	06/67	Zoumboulis	—	—		
	4,202,323	05/80	Zweig et al.	—	—		
	4,434,788	03/84	Nakatsugawa	—	—		
	4,588,395	05/86	Lemelson	—	—		
	4,697,575	10/87	Horowitz	—	—		
	4,733,665	03/88	Palmaz	—	—		
	4,815,449	03/89	Horowitz	—	—		
	4,878,492	11/89	Sinofsky	—	—		
	5,019,075	05/91	Spears	—	—		
	5,059,166	10/91	Fischell et al.	—	—		
<i>ph</i>	5,084,002	01/92	Liprie	—	—		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
EXAMINER <i>Schaefer</i>			DATE CONSIDERED <i>5/12/94</i>				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

08/219,179 03/28/94 HESS

R 011683006

LACYK, J EXAMINER

33M1/0615

ART UNIT PAPER NUMBER

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

3305

5

DATE MAILED: 06/15/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 3/25/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- 1. Notice of References Cited by Examiner, PTO-892.
- 2. Notice of Draftsman's Patent Drawing Review, PTO-948.
- 3. Notice of Art Cited by Applicant, PTO-1449.
- 4. Notice of Informal Patent Application, PTO-152.
- 5. Information on How to Effect Drawing Changes, PTO-1474.
- 6. _____

Part II SUMMARY OF ACTION

- 1. Claims 13-17 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- 2. Claims 1-12 have been cancelled.
- 3. Claims _____ are allowed.
- 4. Claims 13-17 are rejected.
- 5. Claims _____ are objected to.
- 6. Claims _____ are subject to restriction or election requirement.
- 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- 8. Formal drawings are required in response to this Office action.
- 9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- 10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).
- 11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).
- 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.
- 13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- 14. Other

EXAMINER'S ACTION

NC 000276

Art Unit: 3305

1. Claims 13-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, line 9, the use of "positionable" is indefinite in that it is unclear if the device is positioned by the balloon or not. In claim 16 "the wirewound housing" lacks positive antecedent basis. Claims 13, 15, 17 recite a radioactive means but fails to further define any functional language associated with the means language. The claims should be amended to include proper means plus function language.

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

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

3. Claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by Lemelson.

Lemelson discloses a radioactive dose means that has a positioning means for advancing and withdrawing the dose means. The device also has a retractable sheath that is removed to expose the dose means to the treatment area.

4. Claims 13-14 and 17 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.


Serial Number: 08/219,179


-3-

Art Unit: 3305

5. Claim 16 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (703) 308-2995.


LEE S. COHEN
PRIMARY EXAMINER
ART UNIT 3305


J.P. Lacyk
June 15, 1994

NOTICE OF DRAFTER/PERSON'S PATENT DRAWING REVIEW

The attached is the review of your patent drawings regardless of whether they are designated as formal or informal. Additionally, you should comply with the current rules regarding the requirements with the regulations. Direct telephone inquiries concerning this review to the Patent Drawing Review Branch, (703) 305-9099

Drawings filed (insert date) 3/28/94 are considered to be filed by the Drafter and considered by the Drafter/Person under 37 CFR 1.84(a)(1) as to the date the Examiner will require modification of new, corrected drawings, if any. Corrected drawings must be filed according to the instructions on the back of this notice.

Material shown in different views must be shown in the same view, except for broken and hidden lines. Fig(s) _____
 Contour drawings are not acceptable and pictures are prohibited.

Photographs are not acceptable and pictures are prohibited.

Chemical formulas, 37 CFR 1.84(d)(1)
Chemical or mathematical formula not labeled as a separate figure. Fig(s) _____
Chemical or mathematical not presented as a single figure using common chemical notations which are recognizable in the art. Fig(s) _____

Abbreviations, 37 CFR 1.84(d)(2)
Abbreviations not identified with a separate symbol designation adjacent to the view or table. Fig(s) _____

Type of Figures, 37 CFR 1.84(e)
Types not durable, drawings must be durable and permanent. Fig(s) _____
Drawing, annotations, views, figures, markings, etc. must be clearly and durably attached. Fig(s) _____

Size of Figures, 37 CFR 1.84(f)(1) See entire page for details.
Drawing must be 35.3 cm (13 7/8 inches) by 25.4 cm (1 inch) or less.
Drawing must be 35.3 cm (13 7/8 inches) by 25.4 cm (1 inch) or less.
Drawing must be 35.3 cm (13 7/8 inches) by 25.4 cm (1 inch) or less.
Drawing must be 35.3 cm (13 7/8 inches) by 25.4 cm (1 inch) or less.
Drawing must be 35.3 cm (13 7/8 inches) by 25.4 cm (1 inch) or less.

Table 1: Paper Size

Paper Size	Length (cm)	Width (cm)	Length (inches)	Width (inches)
A	30.5	21.0	12 1/8	8 3/8
B	42.0	29.7	16 1/2	11 7/8
C	50.8	35.4	20 1/8	13 7/8
D	61.0	42.0	24 1/8	16 5/8
E	76.2	53.3	30 1/4	21 1/8

Drawings that do not conform to chart above. Fig(s) _____

Margins, 37 CFR 1.84(g)
Margins must be uniform and meet the following requirements. Fig(s) _____

Views, 37 CFR 1.84(h)
Views must be drawn in a single view, and the drawing must be clear. Fig(s) _____

Multiple Views, 37 CFR 1.84(h)(2)
Multiple views must be drawn in a single view, and the drawing must be clear. Fig(s) _____

Long View Relationship, 37 CFR 1.84(h)(3)
Long view relationship between different parts of an object must be unambiguous. Fig(s) _____

Section Views, 37 CFR 1.84(h)(4)
Hatching not indicated for sectional views. Fig(s) _____
Hatching not regularly spaced and parallel. Fig(s) _____
Hatching not at substantial angle to surrounding lines of principal lines. Fig(s) _____
Cross section not drawn same as view, with parts in cross section with regularly spaced parallel oblique strokes. Fig(s) _____
Hatching of two spaced different views is not allowed in a different way. Fig(s) _____

Other Position, 37 CFR 1.84(h)(5)
A separate view required for a different position. Fig(s) _____

Modified forms, 37 CFR 1.84(h)(5)
 Modified forms of construction must be shown in separate views. Fig(s) _____

8. ARRANGEMENT OF VIEWS, 37 CFR 1.84(i)
 View placed upon another view or within outline of another. Fig(s) _____
 Words do not appear in a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____

9. SCALE, 37 CFR 1.84(j)
 Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
 Indication such as "actual size" or "scale 1/2" not permitted. Fig(s) _____
 Elements of same view not in proportion to each other. Fig(s) _____

10. CHARACTER OF LINES, NUMBERS, & LETTERS, 37 CFR 1.84(k)
 Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s) 1-29

11. SHADING, 37 CFR 1.84(m)
 Shading used for other than shape of spherical, cylindrical, and conical elements of an object, or for flat parts. Fig(s) _____
 Solid black shading areas not permitted. Fig(s) _____

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS, 37 CFR 1.84(p)
 Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(1) Fig(s) 1-9
 Numbers and reference characters used in conjunction with brackets, inverted commas, or enclosed within outlines. 37 CFR 1.84(p)(1) Fig(s) _____
 Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(1) Fig(s) _____
 English alphabet not used. 37 CFR 1.84(p)(2) Fig(s) _____
 Numbers, letters, and reference characters do not measure at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____

13. LEAD LINES, 37 CFR 1.84(q)
 Lead lines cross each other. Fig(s) _____
 Lead lines missing. Fig(s) _____
 Lead lines not as shown as possible. Fig(s) _____

14. NUMBERING OF SHEETS OF DRAWINGS, 37 CFR 1.84(r)
 Number appears in top margin. Fig(s) _____
 Number not larger than reference characters. Fig(s) _____
 Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s) _____

15. NUMBER OF VIEWS, 37 CFR 1.84(s)
 Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
 View numbers not preceded by the abbreviation Fig. Fig(s) _____
 Single view contains a view number and the abbreviation Fig. Fig(s) _____
 Numbers not larger than reference characters. Fig(s) _____

16. CORRECTIONS, 37 CFR 1.84(w)
 Corrections not durable and permanent. Fig(s) _____

17. DESIGN DRAWING, 37 CFR 1.152
 Surface shading shown not appropriate. Fig(s) _____
 Solid black shading not used for color contrast. Fig(s) _____



185-214 335

Patent
Attorney's Docket No. 011686-006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	Group Art Unit: 3305
)	
Application No.: 08/219,179)	Examiner: J. Lacyk
)	
Filed: March 28, 1994)	
)	
For: APPARATUS FOR)	
RESTENOSIS TREATMENT)	

RECEIVED
SM DFC-5 PM 2:20
GROUP 300
#6
12/15

PETITION FOR EXTENSION OF TIME

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

The following extension of time is requested to extend the due date for responding to the Official Action of June 15, 1994 :

two months to November 15, 1994; the extension fee is \$ 185.00 \$ 370.00.

The shortened statutory period has been reset by an Advisory Action dated _____.

An extension fee in the amount of \$ 185.00 is enclosed.

Charge \$ _____ to Deposit Account No. 02-4800.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: Peter K. Skiff
 Peter K. Skiff
 Registration No. 31,917

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

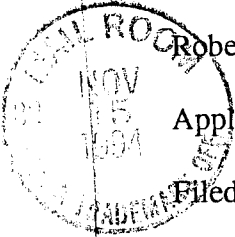
Date: November 15, 1994

070 AG 12/05/94 00219179

1 216 105.00 05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Robert L. HESS) Group Art Unit: 3305
)
Application No.: 08/219,179) Examiner: J. Lacyk
)
Filed: March 28, 1994)
)
For: APPARATUS FOR)
RESTENOSIS TREATMENT)



RECEIVED
94 DEC -5 PM 2:20
GROUP 3305
7/C
RD
2/15

AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the Official Action dated June 15, 1994, the period for response having been extended until November 15, 1994 by a Petition for a Two-month Extension of Time submitted herewith, please amend the above-identified application as follows.

IN THE CLAIMS:

Please amend the claims as follows.

13. (Amended) Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means for emitting radiation; and

positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means further including an angioplasty balloon, said radioactive

Q2

14

Serial No. 08/219,179

^{E¹} dose means being connected to said balloon and [positionable in] moveable into contact with the stenosed region by expansion of said balloon.

³
~~15.~~ (Amended) Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

radioactive dose means for emitting radiation; and

^{E²} positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means including a retractable sheath which may be removably positioned over said radioactive dose means and the dose means being located in a housing having a cut-out in a sidewall thereof [an opening therein], the dose means being exposed to the stenosed region by moving the sheath from a first position wherein the cut-out [opening] is covered by the sheath to a second position wherein the cut-out [opening] is not covered by the sheath.

⁴
~~16.~~ (Amended) The apparatus of Claim ³~~15~~, wherein the housing is a wirewound housing [and the opening comprises a cut-out in a sidewall of the wirewound housing].

⁵
~~17.~~ (Amended) Apparatus for post-treatment of stenosed region of an artery that has been reduced by angioplasty or other means comprising:

15

Serial No. 08/219,179

radioactive dose means for emitting radiation; and

positioning means operatively connected to said dose means for advancing said dose means and positioning said dose means within the stenosed region of an artery that has been reduced by angioplasty or other means, said positioning means also being operatively connected to said dose means for withdrawing said dose means from the artery, the positioning means including a retractable remotely activated cover which may be removably positioned over said radioactive dose means and the dose means being located in a housing having an opening therein, the dose means being exposed to the stenosed region by moving the remotely activated cover from a first position wherein the opening is covered by the remotely activated cover to a second position wherein the opening is not covered by the remotely activated cover.

REMARKS

Reconsideration of the June 15, 1994 Official Action is respectfully requested.

Initially, the indication that Claims 13, 14, 16 and 17 are directed to allowable subject matter is gratefully acknowledged. In order to place the application in condition for allowance, Claim 15 has been amended to incorporate a feature of Claim 16 and Claims 13, 15, 16 and 17 have been amended to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Claims 13-17 were rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth in paragraph 1, on page 2 of the Official Action. In particular, Claim 13 was objected to on the basis that "positionable" is allegedly indefinite. In order to

Serial No. 08/219,179

overcome this ground of rejection, Claim 13 has been amended to recite that the radioactive dose means is connected to the balloon and moveable into contact with the stenosed region by expansion of the balloon. Claim 16 was objected to on the basis that "the wirewound housing" allegedly lacks antecedent basis. However, Claim 16 specifically recites that the housing is a wirewound housing (see specification at page 6, lines 5-7). As such, it is submitted that there is no lack of antecedent basis in Claim 16 for the wirewound housing. Claims 13, 15 and 17 were objected to on the basis that the radioactive dose means allegedly does not include proper means-plus-function language. In order to overcome this ground of rejection, Claims 13, 15 and 17 have been amended to recite "radioactive dose means for emitting radiation."

The only remaining ground of rejection is the rejection of Claim 15 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,588,395 ("Lemelson"). The reasons for the rejection are set forth in paragraph 3, on page 2 of the Official Action. This rejection is respectfully traversed for the following reasons.

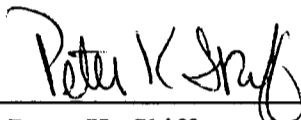
Claim 15 has been amended to include the "cut-out" feature of Claim 16. In the Official Action, Claim 16 was indicated as being directed to allowable subject matter. Along these lines, it is noted that Lemelson fails to disclose or suggest a cut-out in a sidewall of the retractable sheath. As such, the combination of features recited in Claim 15 is not disclosed or suggested by Lemelson.

Serial No. 08/219,179

In view of the foregoing, it is submitted that the present application is in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: 
Peter K. Skiff
Registration No. 31,917

Post Office Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: November 15, 1994



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APP. NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY Docket NO.
08/219,179	03/28/94	HESS	R 011683006

33M1/1228

LACYK, J. EXAMINER

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

ART UNIT	PAPER NUMBER
3305	8

12/28/94

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I.

- This communication is responsive to AMENDMENT FILED 12/15/94
- All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- The allowed claims are 13-17
- The drawings filed on 3/28/94 are acceptable.
- Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [] been received. [] not been received. [] been filed in parent application Serial No. _____, filed on _____
- Note the attached Examiner's Amendment.
- Note the attached Examiner Interview Summary Record, PTOL-413.
- Note the attached Examiner's Statement of Reasons for Allowance.
- Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
 - Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____ CORRECTION IS REQUIRED.
 - The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
 - Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
 - Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- Examiner's Amendment
- Examiner Interview Summary Record, PTOL-413
- Reasons for Allowance
- Notice of References Cited, PTO-892
- Information Disclosure Citation, PTO-1449
- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

LEE S. COHEN
PRIMARY EXAMINER
ART UNIT 335

NC 000286

PTOL-37 (REV. 4-89) *



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

83M1/1226

CHARLES W. DRYDENSON
MURPHY, LASHK, SWICKER & MATHEIS
P. O. BOX 1404
DUMFRIES, VA 22013-1404

**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**

- Note attached communication from the Examiner
- This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
83/219,100	03/08/94	005	LACYK, J	8305 12/26/94
First Named Applicant		ROBERT L.		

TITLE OF INVENTION
APPLICATOR FOR DENTURES TREATMENT
SALT ADDITION

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
83-005,100	01-005,100	113	UTILITY	YES	\$600.00	03/28/95

THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

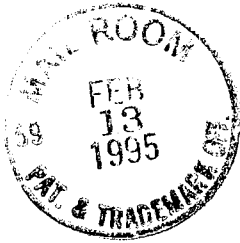
- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

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

NC 000287



Patent
Attorney's Docket No. 011683-006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Robert L. HESS)	Box Issue Fee
)	
Application No.: 08/219,179)	Batch No. H48
)	
Filed: March 28, 1994)	
)	
For: APPARATUS FOR RESTENOSIS)	
TREATMENT)	
)	

**PAYMENT OF ISSUE FEE AND AUTHORIZATION
TO CHARGE DEPOSIT ACCOUNT FOR ANY DEFICIENCY**

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

A check for the required Issue Fee in the above-identified application is enclosed. If the check has become separated from this paper, or if the amount of the check is incorrect, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.18, 1.19, and 1.21 that may be required by the attached Issue Fee Transmittal Form, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By: James W. Peterson
James W. Peterson
Registration No. 26,057

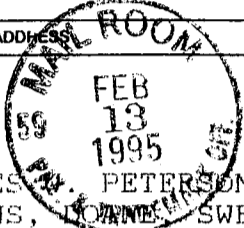
699 Prince Street
Alexandria, Virginia 22314-3187
(415) 854-7400

Date: February 10, 1995

605-242
39-561 B

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. See reverse for Certificate of Mailing.



1. CORRESPONDENCE ADDRESS

JAMES W. PETERSON
BURNS, DOANE, SWECKER & MATHIS
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

33M1/1228

2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)

INVENTOR'S NAME

Street Address

City, State and ZIP Code

CO-INVENTOR'S NAME

Street Address

City, State and ZIP Code

Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/219,179	03/28/94	005	LACYK, J 3305	12/28/94
First Named Applicant	HESS, ROBERT L.			

TITLE OF INVENTION: APPARATUS FOR RESTENOSIS TREATMENT (AS AMENDED)

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 011683006	600-003.000	H48	UTILITY	YES	\$605.00	03/28/95

3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1. Burns, Doane, Swecker & Mathis

2. _____

3. _____

DO NOT USE THIS SPACE

080 LH 02/23/95 08219179 1 242 605.00 CK
080 LH 02/23/95 08219179 1 561 39.00 CK

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (bold or type)

(1) NAME OF ASSIGNEE: Robert L. Hess

(2) ADDRESS: (CITY & STATE OR COUNTRY) Menlo Park, California

6a. The following fees are enclosed:
 Issue Fee Advance Order - # of Copies 13

6b. The following fees should be charged to:
 DEPOSIT ACCOUNT NUMBER 02-4800
 (ENCLOSE PART C)
 Issue Fee Advance Order - # of Copies _____
 Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) James W. Peterson (Date) 2-10-95

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

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

605-242
39-561

B

PART C—CHARGE TO DEPOSIT ACCO



1. CORRESPONDENCE ADDRESS

33M1/1228

JAMES W. PETERSON
BURNS, DOANE, SMITH & MATHIS
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/219,179	03/28/94	005	LACYK, J 3305	12/28/94
First Named Applicant	HESS, ROBERT L.			

TITLE OF INVENTION APPARATUS FOR RESTENOSIS TREATMENT (AS AMENDED)

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
011883006	600-003.000	H4B	UTILITY	YES	\$605.00	03/28/95

DO NOT USE THIS SPACE

2a. The following fees are enclosed:
 Issue Fee Advance Order - # of Copies 13

2b. The following fees should be charged to:
DEPOSIT ACCOUNT NUMBER 02-4800

Issue Fee Advance Order - # of Copies
 Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature)
James W. Peterson
James W. Peterson, 26,057

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

TRANSMIT THIS FORM WITH PART B WHEN AUTHORIZING USE OF A DEPOSIT ACCOUNT

5411466

4
600 003

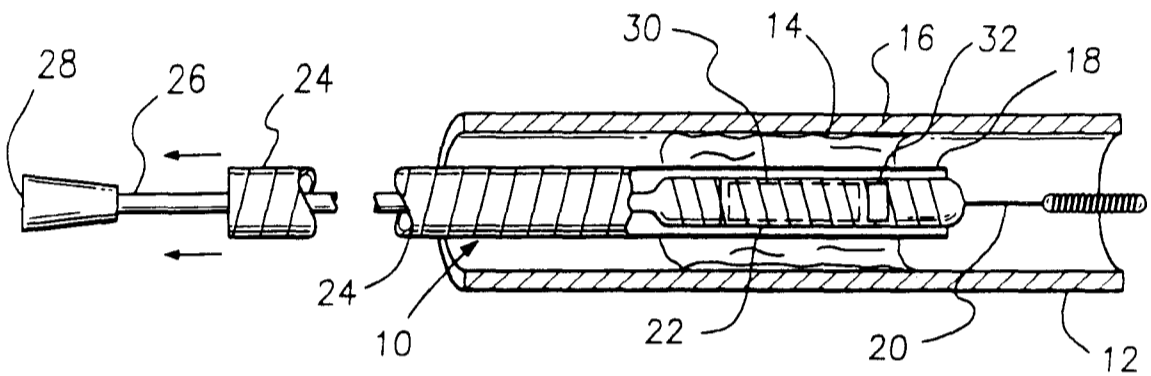


FIG. 1

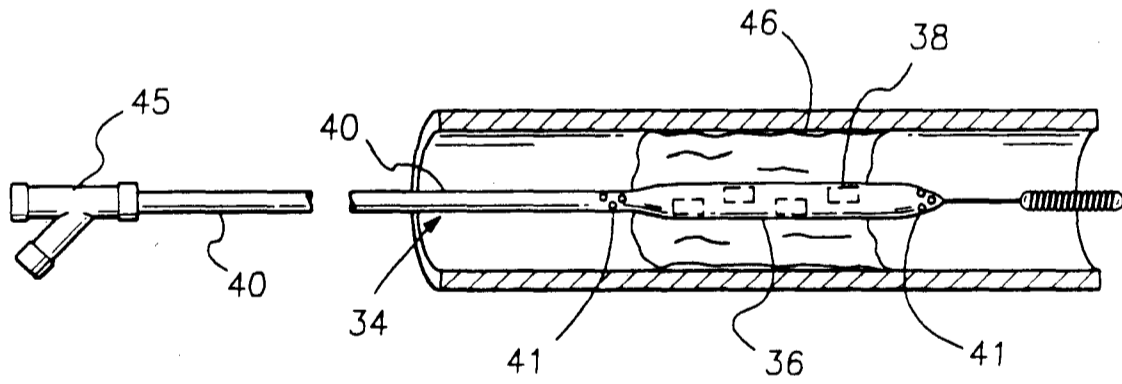


FIG. 2

4
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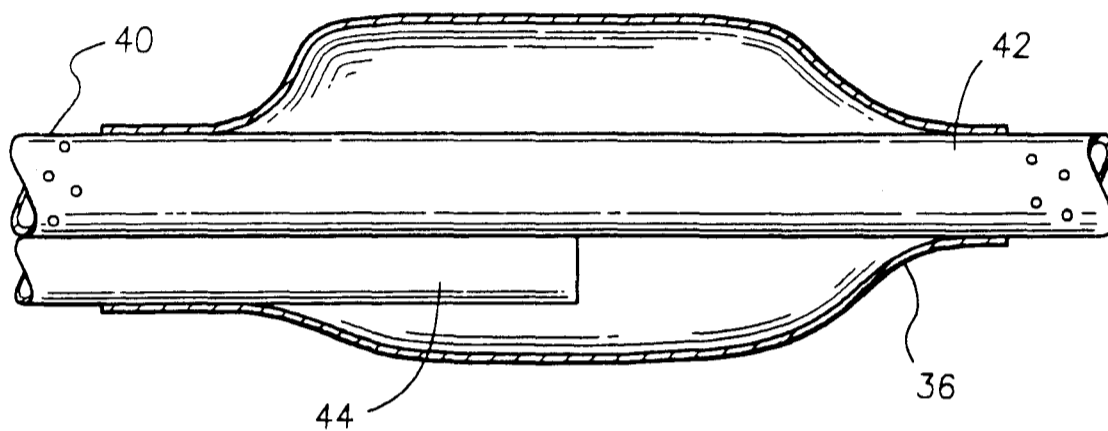


FIG. 3

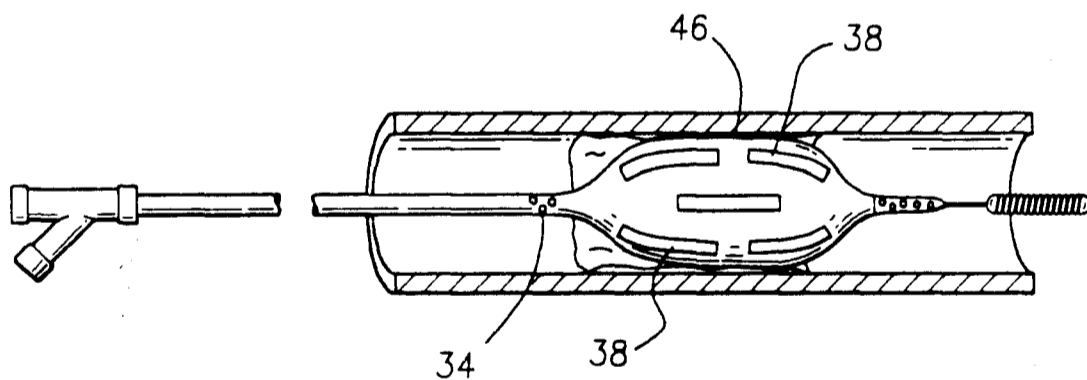


FIG. 4

4
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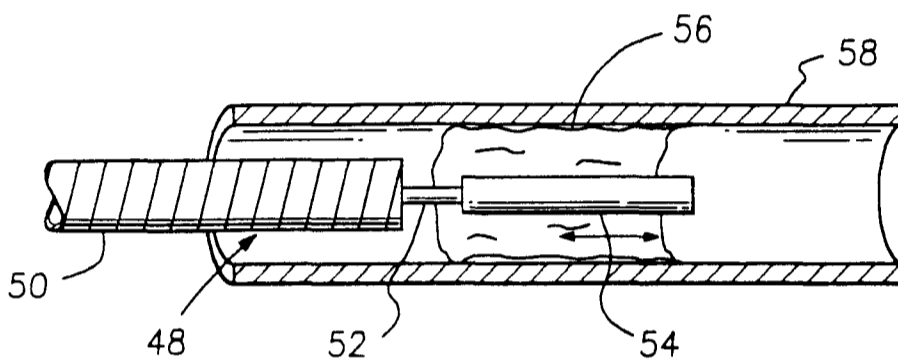


FIG. 5

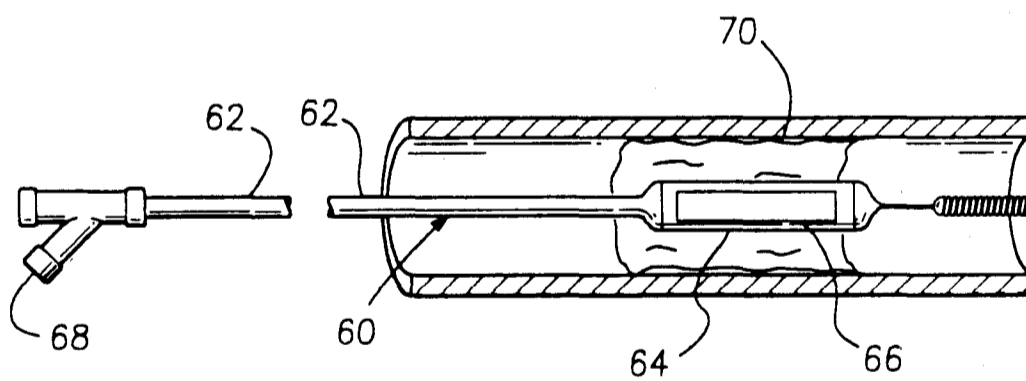


FIG. 6

4
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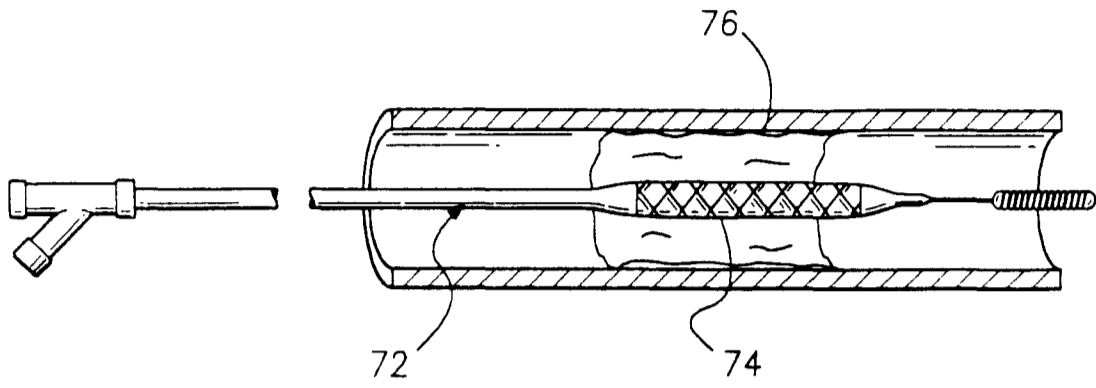


FIG. 7

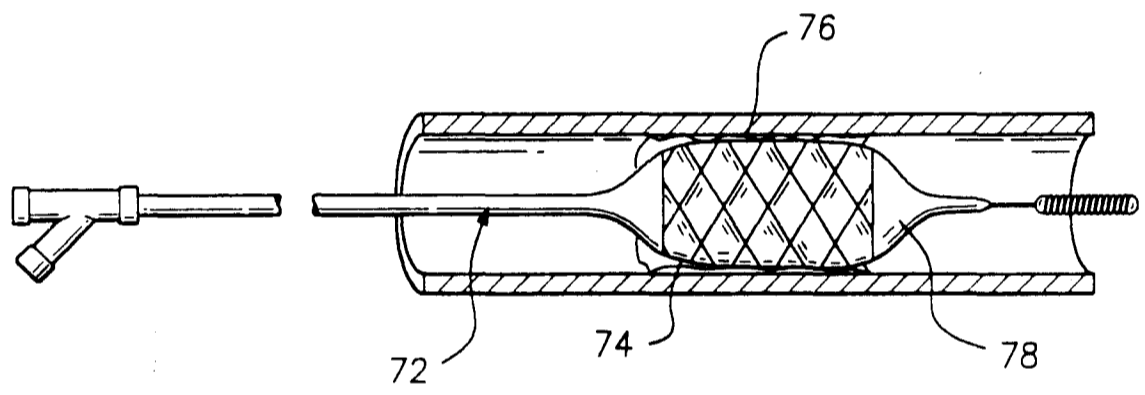


FIG. 8

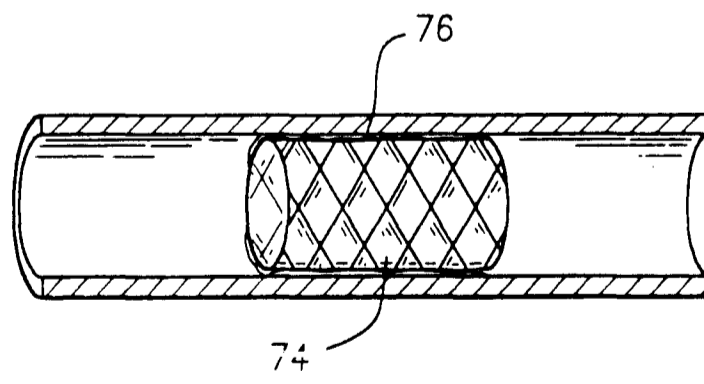
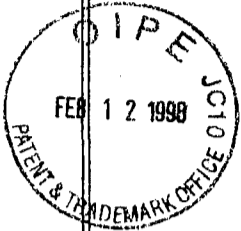


FIG. 9



DAC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert L. Hess

Patent No.: 5,411,466

8/219/79

Filed: May 2, 1995

Docket: 1944 CON (203-1944 CON)

Date: February 9, 1998

For: APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

RECEIVED
FEB 18 1998
OFFICE OF PETITIONS
A/C PATENTS

LETTER

Sir:

Enclosed herewith for filing with respect to the above-identified application are the following:

1. Notification of Loss of Entitlement to Small Entity Status under 37 C.F.R. §1.28(b)
2. Power of Attorney by Assignee of Entire Interest (Revocation of Prior Powers); and
3. Certificate under 37 C.F.R. §3.73(b) Establishing Right of Assignee to take action.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231 on February 9, 1998.

Dated: February 9, 1998

David M. Carter

David M. Carter



Practitioner's Docket No. 1944 CON (203-2201 CON)

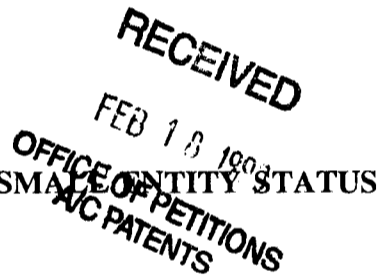
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTEE(S) : Robert L. Hess
 PATENT NO. : 5,411,466
 ISSUED : May 2, 1995
 FOR : APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

NOTIFICATION OF LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS
(37 C.F.R. 1.28(b))



Applicant hereby notifies the Patent and Trademark Office that it is no longer entitled to status as a small entity, and that the claim for small entity status, set forth in the verified statement filed on September 5, 1991 is hereby withdrawn.

Date 12-15-97

Thomas R. Bremer
(print or type name of person signing)

Thomas R. Bremer
Signature

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail, postpaid in an envelope, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

on February 9, 1998

Dated: 2/9/98

David M. Carter
David M. Carter

P.O. Address of signatory **UNITED STATES SURGICAL CORPORATION**
150 Glover Avenue
Norwalk, Connecticut 06856

Inventor(s)

Assignee of Complete interest

Person authorized to sign on behalf of assignee

Practitioner of record

Filed under Rule 34(a)

Registration No.

(if applicable)

Telephone No. ()

Reg. No.

Customer No.

(complete the following, if applicable)

UNITED STATES SURGICAL CORPORATION
(type name of assignee)

150 Glover Avenue
Address of assignee

Norwalk, Connecticut 06856

Sr. **Vice President and General Counsel**
Title of person authorized to sign on behalf of assignee

Assignment recorded in PTO _____

Reel _____ Frame _____

Note: A statement under 37 CFR 3.73(b) is not required to be submitted when the assignee signs a small entity declaration. Notice of April 30, 1993, 1150 O.G. 62-64.

NC 000297



PATENT

Applicant's Docket No. 1944 CON (203-2201 CON)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: **Robert L. Hess**

Patent No.: **5,411,466**

Issued: **May 2, 1995**

For: **APPARATUS FOR RESTENOSIS TREATMENT**

Patent No.": **Listed Above**

*NOTE: Insert name(s) of inventor(s) and title also for patent.

**Assistant Commissioner for Patents
Washington, D.C. 20231**

**POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST
(REVOCAION OF PRIOR POWERS)**

As assignee of record of the entire interest of the above identified

application,

patent,

REVOCAION OF PRIOR POWERS OF ATTORNEY

all powers of attorney previously given are hereby revoked and

NEW POWER OF ATTORNEY

the following attorney(s) and/or agent(s) are hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected therewith.

PETER G. DILWORTH, Reg. No. 26,450; **ROCCO S. BARRESE**, Reg. No. 25,253; **DAVID M. CARTER**, Reg. No. 30,949; **PAUL J. FARRELL**, Reg. No. 33,494; **PETER DELUCA**, Reg. No. 32,978; **FRANK CHAU**, Reg. No. 34,136; **ADRIAN T. CALDERONE**, Reg. No. 31,746; **GEORGE M. KAPLAN**, Reg. No. 28,375; **JEFFREY S. STEEN**, Reg. No. 32,063; **JOSEPH W. SCHMIDT**, Reg. No. 36,920; **RAYMOND E. FARRELL**, Reg. No. 34,816; **RUSSELL R. KASSNER**, Reg. No. 36,183; **CHRISTOPHER G. TRAINOR**, Reg. No. 39,517; **GEORGE LIKOUREZOS**, Reg. No. 40,067, **JAMES M. LOEFFLER**, Reg. No. 37,873; **WILLIAM E. LEWIS**, Reg. No. 39,274, **JAMES J. BITETTO**, Reg. No. 40,513, **JOHN G. TUTUNJIAN**, Reg. No. 39,405, and **MARK S. LEONARDO**, Reg. No. 41,433, each of them of **DILWORTH & BARRESE**, 333 Earle Ovington Boulevard, Uniondale, New York 11553 and; **JOHN C. ANDRES**, Reg. No. 30,931; **BASAM E. NABULSI**, Reg. No. 31,645; **NEIL D. GERSHON**, Reg. No. 32,225; **NEIL Y. GILBERT**, Reg. No. 35,156, and **CAROLYN BLANKENSHIP**, Reg. No. 35,449 each of them of **UNITED STATES SURGICAL CORPORATION**, 150 Glover Avenue, Norwalk, Connecticut 06856.

(check the following item, if applicable)

- Attached as part of this power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

John C. Andres, Esq.
UNITED STATES SURGICAL CORPORATION
150 Glover Avenue
Norwalk, Connecticut 06856

DIRECT TELEPHONE CALLS TO:

John C. Andres, Esq.
(203) 845-4018

UNITED STATES SURGICAL CORPORATION

(type or print identity of assignee of entire interest)

150 Glover Avenue

Address

Norwalk, CT 06856

Recorded in PTO on _____

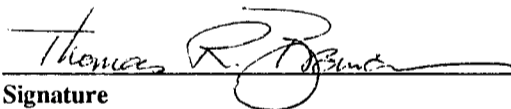
Reel _____

Frame _____

Recorded herewith

ASSIGNEE CERTIFICATION

Attached to this power is a "CERTIFICATE UNDER 37 C.F.R. 3.73(B)."



Signature

Date: 12-15-97

Thomas R. Bremer

(type or print name of person authorized to
sign on behalf of assignee)

Sr. Vice President and General Counsel
United States Surgical Corporation

Title

Note: The assignee of the entire interest may revoke previous powers and be represented by attorney of his or her selection. 37 C.F.R. 1.36.
(check the following item, if it forms a part of this power of attorney)

Added page - Authorization of attorney(s) to accept and follow instructions from representative.



Practitioner's Docket No. 1944 CON (203-2201 CON)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTEE(S) : Robert L. Hess
 PATENT NO. : 5,411,466
 ISSUED : May 2, 1995
 FOR : APPARATUS FOR RESTENOSIS TREATMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE UNDER 37 C.F.R. 3.73(b)
ESTABLISHING RIGHT OF ASSIGNEE TO TAKE ACTION

1. The assignee(s) of the entire right, title and interest hereby seek(s) to take action in the PTO in this matter.

IDENTIFICATION OF ASSIGNEE

2. UNITED STATES SURGICAL CORPORATION
 Name of assignee

Corporation
 Type of assignee, e.g., corporation, partnership, university, government agency, etc.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail, postpaid in an envelope, addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

on February 9, 1998
Dated: 2-9-98

David M. Carter
David M. Carter

PERSON AUTHORIZED TO SIGN

3. Thomas R. Bremer
(type name of person authorized to sign on behalf of assignee)

Senior Vice President and General Counsel
Title of person authorized to sign

I, the person signing below, aver that I am empowered to sign this statement on behalf of the assignee.

BASIS OF ASSIGNEE'S INTEREST

Ownership by the assignee is established as follows:

- A.
- An assignment from the inventor(s) of the matter identified above, which was recorded in the PTO at
Reel _____, Frame _____.
 - An assignment (document) separately being submitted for recordal herewith.

AND/OR

- B. A chain of title from the inventor(s) to the current assignee as shown below:
- From: _____
Name of inventor(s)
To: _____
Recorded in PTO: Reel _____, Fame _____
 - From: _____
Name of inventor(s) or assignee
To: _____
Recorded in PTO: Reel _____, Fame _____

3. From: _____
Name of inventor(s) or assignee

To: _____

Recorded in PTO: Reel _____, Page _____

COPIES OF DOCUMENTS IN CHAIN OF TITLE

Copies of the assignment(s) or other document(s) in the chain of title are attached as follows:

- A 1 2
- B 1 2 3

DECLARATIONS

I, the undersigned, have reviewed all the documents in the chain of title of the

patent application patent

reexamination or reissue

matter identified above and, to the best of my knowledge and belief, title is in the assignee identified above.

I, hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Thomas R. Bremer
(Signature of authorized person)

Thomas R. Bremer
(type or print name of authorized person)

Sr. **Vice President and General Counsel**
Title of authorized person

David M. Carter
SIGNATURE OF PRACTITIONER

Reg. No. 30.949

David M. Carter
(type or print name of practitioner)

Tel. No. (516) 228-8484

333 Earle Ovington Boulevard
P.O. Address

Customer No.:

Uniondale, New York 11553



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

LOCATION 9200 SERIAL NUMBER 08219179 PATENT NUMBER 5411466

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 21839

ON 12/14/99 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 21839 IS:

BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER: RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET, 'ADDRESS CHANGE TO CUSTOMER NUMBER'. LINE THROUGH THE OLD ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE 'CUSTOMER NUMBER' AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET. WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS OF RECORD, FILE LETTER IN THE FILE JACKET.

PTO UTILITY GRANT

Paper Number 9

The
United
States
of
America

The Commissioner of Patents
and Trademarks

*Has received an application for a patent
for a new and useful invention. The title
and description of the invention are en-
closed. The requirements of law have
been complied with, and it has been de-
termined that a patent on the invention
shall be granted under the law.*

Therefore, this

United States Patent

*Grants to the person or persons having
title to this patent the right to exclude
others from making, using or selling the
invention throughout the United States
of America for the term of seventeen
years from the date of this patent, sub-
ject to the payment of maintenance fees
as provided by law.*



Bruce Lehman

Commissioner of Patents and Trademarks

Kenneth Cooper

Attest

PTO-1584

NC 000306

PI-LOM

(RIGHT INSIDE)

POSITION	ID NO.	DATE
CLASSIFIER		4-14-94
EXAMINER	290	4-15-94
TYPIST	322	4/15/94
VERIFIER	252	4/15/94
CORPS CORR.		
SPEC. HAND		
FILE MAINT.		
DRAFTING		

INDEX OF CLAIMS

Claim		Date			
Final	Original				
	1				
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SYMBOLS

- ✓ Rejected
- = Allowed
- (Through numeral) Canceled
- + Restricted
- N Non-elected
- I Interference
- A Appeal
- O Objected



SEARCHED

Class	Sub.	Date	Exmr.
600	1-8		
600	7	7/13/74	zsh
	split	12/19/74	zsh

SEARCH NOTES

	Date	Exmr.

TITLE OF INVENTION

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
600	1-8		
600	7	12/19/74	zsh



APPROVED FOR LICENSE

INITIALS APR 14 94 85

Date Entered or Counted

CONTENTS

Date Received or Mailed

Date Entered or Counted	Item	Date Received or Mailed
	1. Application <u>Print</u> papers.	
	2. <u>Dr. [unclear]</u>	
	3. <u>[unclear]</u>	
	4. <u>[unclear]</u>	
5/16	5. <u>Reg 3 md</u>	6-15-94
	6. <u>Ext. 3 md.</u>	11-15-94 12/3
12/5	7. <u>Amult C</u>	11-15-94
	8. <u>National Availability</u>	28 DEC 1994
	9. <u>PROGRAM</u>	
	10.	
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