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UTILITY SERIAL NUMBER **08/562727** PATENT DATE **JAN** PATENT NUMBER



SERIAL NUMBER 08/562,727 FILING DATE 11/27/95 CLASS 606 SUBCLASS 191 GROUP ART UNIT 3309

APPLICANTS VALENTINE J. RHODES, BRICKTOWN, NJ.

\*\*CONTINUING DATA\*\*  
VERIFIED  
*et None*

\*\*FOREIGN/PCT APPLICATIONS\*\*  
VERIFIED  
*et None*

FOREIGN FILING LICENSE GRANTED 01/29/96 \*\*\*\*\* SMALL ENTITY \*\*\*\*\*

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Verified and Acknowledged  yes  no  
Examiner's initials *et* AS FILED STATE OR COUNTRY NJ SHEETS DRWGS. 3 TOTAL CLAIMS 15 INDEP. CLAIMS 1 FILING FEE RECEIVED \$375.00 ATTORNEY'S DOCKET NO. R1001/20002

ADDRESS CAESAR RIVISE BERNSTEIN COHEN AND POKOTILOV LTD SEVEN PENN CENTER 12TH FLOOR 1635 MARKET STREET PHILADELPHIA PA 19103-2212

TITLE INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

U.S. DEPT. of COMMERCE • Patent and Trademark Office-PCT-436L (rev. 7-94)

PARTS OF APPLICATION FILED SEPARATELY		Applications Examiner	
NOTICE OF ALLOWANCE MAILED		CLAIMS ALLOWED	
JUL 31 1996		Total Claims	Print Claim
KEVIN TRUONG Assistant Examiner		15	1
ISSUE FEE		DRAWING	
Amount Due	Date Paid	Sheets Drwg.	Figs. Drwg.
<i>625.00</i>	<i>10/9/96</i>	3	8
Label Area		Print Fig.	1
		ISSUE BATCH NUMBER <i>C60</i>	
PREPARED FOR ISSUE			
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Form PTO-436A (Rev. 8/92)

**ISSUE FEE IN FILE**

(FACE)

08/562727

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INITIALS \_\_\_\_\_

Date Entered or Counted

PATENT APPLICATION



08562727

Date Received or Mailed

JUL 1 1996

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|          | 1. Application _____ papers.           |                      |
| 4-1-96   | 2. <i>3 spec</i>                       | 4.9.96 <sup>AS</sup> |
|          | 3. <i>Ampt a</i>                       | 5-17-96              |
|          | 4. <i>IDS</i>                          | 5-17-96              |
|          | 5. <i>Entered in Summary</i>           | 7-29-96              |
| 1-30     | 6. <i>EXAMINER Ampt/S</i>              | JUL 31 1996          |
| 10/23/96 | 7. <i>Formal Examination 3rd set 1</i> | 10/9/96              |
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PATENT APPLICATION SERIAL NO. **08/562727**

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FEE RECORD SHEET

BA28102 01/04/96 08562727 03-0075 280 201 375.00CH R1001/20002

PTO-1556  
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BAR CODE LABEL		U.S. PATENT APPLICATION			
					
SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT		
08/562,727	11/27/95	606	3309		
APPLICANT	VALENTINE J. RHODES, BRICKTOWN, NJ.				
	**CONTINUING DATA***** VERIFIED   **FOREIGN/PCT APPLICATIONS***** VERIFIED   				
FOREIGN FILING LICENSE GRANTED 01/29/96					***** SMALL ENTITY *****
STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
NJ	3	15	1	\$375.00	R1001/20002
ADDRESS	CAESAR RIVISE BERNSTEIN COHEN AND POKOTILOW LTD SEVEN PENN CENTER 12TH FLOOR 1635 MARKET STREET PHILADELPHIA PA 19103-2212				
	TITLE INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS				
This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application which is identified above. By authority of the COMMISSIONER OF PATENTS AND TRADEMARKS					
Date		Certifying Officer			



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Applicant:  Valentine J. Rhodes, M.D.

For: INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

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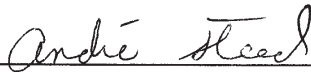
This is a patent application of the above identified invention, which includes the following:

1. Transmittal Letter in Duplicate
2. Specification - 20 pages
3. 15 Claims - 3 Pages
4. Abstract - 1 Page
5. Drawings - 3 Sheets
6. Declaration For Patent Application
7. Verified Statement Claiming Small Entity Status for Independent Inventor
8. Return Receipt Post Card

"Express Mail" Mailing Label No. EG443517597US  
Date of Deposit November 27, 1995

I hereby certify that the above-identified documents are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Hon. Commissioner of Patents and Trademarks, Washington, D.C. 20231

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Andre Steed

  
\_\_\_\_\_

R1001/20002

08/562727



(2-92)

PATENT APPLICATION TRANSMITTAL LETTER

Docket Number (Optional)

R1001/20002

To the Commissioner of Patents and Trademarks:

Transmitted herewith for filing under 35 U.S.C. 111 and 37 CFR 1.53 is the patent application of  
Valentine J. Rhodes, M.D.

entitled INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

Enclosed are:

- 24 pages of written description, claims and abstract.
- 3 sheets of drawings.
- an assignment of the invention to \_\_\_\_\_
- executed declaration of the inventors.
- a certified copy of a \_\_\_\_\_ application.
- associate power of attorney.
- a verified statement to establish small entity status under 37 CFR 1.9 and 1.27. -Independent Inventor
- information disclosure statement
- preliminary amendment
- other: \_\_\_\_\_

CLAIMS AS FILED

	NUMBER FILED	NUMBER EXTRA	RATE	FEE
BASIC FEE			\$750	\$750
TOTAL CLAIMS	15 - 20 =	*	X 22	
INDEPENDENT CLAIMS	1 - 3 =	*	X 78	
MULTIPLE DEPENDENT CLAIM PRESENT			\$250	

\* NUMBER EXTRA MUST BE ZERO OR LARGER

TOTAL \$ 750

If applicant has small entity status under 37 CFR 1.9 and 1.27, then divide total fee by 2, and enter amount here. SMALL ENTITY TOTAL \$ 375

- A check in the amount of \$ \_\_\_\_\_ to cover the filing fee is enclosed.
- The Commissioner is hereby authorized to charge and credit Deposit Account No. 03-0075 as described below. I have enclosed a duplicate copy of this sheet.
  - Charge the amount of \$ 375 as filing fee.
  - Credit any overpayment.
  - Charge any additional filing fees required under 37 CFR 1.16 and 1.17.
  - Charge the issue fee set in 37 CFR 1.18 at the mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).

November 27, 1995  
Date

Signature  
Barry A. Stein  
Typed or printed name

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

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
APPLICATION FOR LETTERS PATENT

APPLICANT : Valentine J. Rhodes, M.D.

POST OFFICE ADDRESS : 608 Winding River Road  
Brick Town, New Jersey 08723

INVENTION : INTRAVASCULAR STENT WITH SECURE  
MOUNTING MEANS

ATTORNEYS : Caesar, Rivise, Bernstein,  
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TO ALL WHOM IT MAY CONCERN:

Be it known that I, Valentine J. Rhodes, M.D., a citizen of the United States of America, residing in the City of Bricktown, County of Ocean, State of New Jersey, have made a certain new and useful invention in a Endovascular Stent With Secure Mounting Means, of which the following is a specification.

SPECIFICATION

BACKGROUND OF THE INVENTION

The invention relates generally to medical devices and methods of use in vessels, ducts or lumens of living beings, and more particularly to expandable grafts and methods of use for opening restrictions therein, e.g., revascularizing stenotic arteries.

Percutaneous balloon intraluminal dilation of vascular stenoses or blockages through the use of angioplasty balloon catheters have proven quite successful. However, such procedures are not without risk or some drawbacks. In particular, the

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angioplasty balloon is inflated within the narrowed vessel in order to shear and disrupt the wall components of the vessel to obtain a large lumen. The relative incompressible plaque remains unaltered by this procedure, while the more elastic medial and adventitial layers of the body passageways stretch around the plaque. This process produces subintimal dissection, splitting, tearing, and disruption of the intact intima and wall layers. If the section forms a transverse tear it produces a flap which may lift away from the artery and may produce an obstruction to the lumen, and therefore make the blockage and stenosis worse. In addition, if there is a heavy plaque on one side of the artery wall (as occurs in 80% of atherosclerotic stenotic lesions) the thinner layer may be disrupted by the inflation of the balloon and cause hemorrhage. Moreover, after the balloon is decompressed any loose material may dislodge completely and act as an embolic source to occlude the lumen of the vessel distally to such an acute extent as to result in significant emergency ischemic conditions. This situation has occurred frequently enough to pose a significant risk to the patient.

Laser assisted balloon angioplasty has been used frequently in recent years to revascularize a totally occluded vessel. In particular the occlusion is opened with the laser and then the opening is expanded further by balloon angioplasty. One of the problems with this revascularization procedure is that the laser causes intimal damage along with the balloon. Moreover, this procedure has only been useful for short segment occlusions. When long segment occlusions are attacked by this procedure the

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reocclusion rate has proven to be very high, and sometimes even made worse.

In both simple balloon angioplasty and in laser assisted balloon angioplasty there is a high incidence of recurrence of the stenosis or obstruction. This is, of course, in addition to the risk of embolization and acute occlusion and disruption of the artery with massive hemorrhage. In addition, there are certain vessels bearing areas of plaque which are not amenable to balloon angioplasty because of the fact that they are orificial plaques, i.e., plaques at the orifice of a branch artery. Thus, when the balloon is inserted across this type of lesion and inflated, it inflates differentially, that is the portion of the balloon in the larger part of the artery inflates more than the portion of the balloon crossing the narrowed or stenotic segment. In fact the portion of the balloon crossing the narrowed or stenotic segment frequently does not inflate at all. Therefore, unsuccessful attempts at inflation are the rule rather than the exception. This is particularly true in attempting the revascularization of renal arteries or the superior mesenteric artery.

Intraluminal endovascular grafting has been demonstrated by experimentation to present an alternative to conventional vascular bypass surgery. Such "grafting" involves either the percutaneous insertion into a blood vessel of a tubular prosthetic graft or stent or an open insertion thereof through a short segment exposed portion of the blood vessel. The graft is typically positioned in a predetermined location within the blood vessel and then expanded

by a catheter delivery system. However, the use of conventional bypass grafts exhibits the tendency of recurring stenosis. Such restenosis may progress to the point where the graft fails. In this connection the cause of stenosis in bypass grafts (including dialysis access fistulas) is usually fibro-intimal hyperplasia (also known as pseudo-intimal hyperplasia or neo-intimal hyperplasia), a very elastic fibrous tissue which recollapses almost immediately upon relaxation of the balloon. Such tissues are, however, ideal for being supported by a stent (i.e., a self supporting member).

Accordingly, it has been suggested, and there is some activity now occurring, to use stents in revascularization procedures to preclude restenosis. Another useful area of stent application is percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses, since those conditions may show poor response and reoccurrence which is very high due to the fibrotic nature of these lesions.

Examples of various types of expandable grafts/stents are disclosed in United States Patent Nos. 3,657,744 (Fursek); 4,047,252 (Liebig et al.); 4,503,569 (Dotter); 4,512,338 (Balko et al.); 4,580,568 (Gianturo); 4,655,771 (Wallsten); 4,733,665 (Palmaz); 4,740,207 (Kreamer); 4,766,337 (Palmaz); 4,795,458 (Regan); 4,830,003 (Wolff et al.); 4,856,516 (Hillstead); 4,994,071 (MacGregor); and 5,035,706 (Giantureo et al.), and in the following literature: "Balloon-Expandable Intracoronary Stents in the Adult Dog", *Circulation*, Aug. 1987, pages 450-456, Vol. 76, No.2; "Normal

and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting", Radiology, 1987, pages 705-708, Vol. 164, No. 3; "A Titanium-Nickel Alloy Intravascular Endoprosthesis", Transactions American Society of Artificial Internal Organs, 1988, pages 399-403, Vol. XXXIV; "Self-Expanding Endovascular Stent in Experimental Atherosclerosis", Radiology, Mar. 1989, pages 773-778, Vol. 170, No. 3; "Emergency Stenting for Acute Occlusion After Coronary Balloon Angioplasty", Circulation, Nov. 1988, pages 1121-1127, Vol. 78, No. 5; "Intravascular Stents for Angioplasty", CARDIO, Dec. 1987; "Intra-Arterial Stenting in the Atherosclerotic Rabbit", Circulation, Sept. 1988, pages 646-653, Vol. 78, No. 3; "Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty", The New England Journal of Medicine, Mar. 1987, pages 701-706, Vol. 316, No. 12; "A Polyester Intravascular Stent for Maintaining Luminal Patency", Texas Heart Institute Journal, Nov. 1, 1988, pages 12-16, Vol. 15. "Post Dilatation Stenting; Early Experience of the Use of an Endocoronary Prosthesis to Prevent Restenosis Reoccurrence After Angioplasty", J. Cardiovasc. Surg. 28, 1987, Session 8: CARDIAC -CORONARY (II); "Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty", Abstract from New England Journal of Medicine 1987, Volume 316, pages 701-706; "Vascular Stenting in Normal and Atherosclerotic Rabbits", Circulation, Feb. 1990, Vol. 81, No. 2, pages 667-683; Treatment of Major Venous Obstruction with an Expandable Endoluminal Spiral Prosthesis, J. Cardiovasc. Surg. 30, 1989, pages 112-117; and Venous Stenoses in Dialysis

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Shunts: Treatment with Self-Expanding Metallic Stents, Radiology, Feb. 1989, Vol. 170, No. 2, pages 401-405.

In my United States Letters Patent No. 5,122,154, whose disclosure is incorporated by reference herein, there is disclosed an intraluminal bypass graft which overcomes many of the disadvantages of the prior art devices. That bypass graft is arranged for placement in a blood vessel, duct, or lumen, to hold it open. The graft comprises a sleeve having plural stents thereon. The sleeve is an elongated tubular member formed of a conventional graft material which is flexible and impervious to the ingrowth of tissue therein. Each stent is a generally ring-like member formed a plurality of interconnected movable links and is mounted about the periphery of a surface, e.g., inner or outer, of the sleeve at selected points along the sleeve to form respective spaced first sleeve sections. Each of the first sections extends for only a portion of the length of the graft, thereby leaving a plurality of second sleeve sections interposed between the first sleeve sections. The stents and the sleeve are arranged to be expanded, e.g., by a balloon catheter, from a compact state to an expanded state to increase the inner cross sectional area diameter of the sleeve. In the expanded state the stents are resistant to contraction back to the compact state. The graft is able to bend with respect to its longitudinal axis to enable it to be readily accommodated within a curved blood vessel, duct, or lumen.

The graft of my aforementioned patent makes use of some anchoring means, e.g., small dome shaped projections, for aiding in



the securement of the graft in place within the vessel, duct, or lumen. While such anchoring means are believed effective for their intended purpose, they never the less appear to be amenable to improvement insofar as graft retention is concerned.

Various United States Letters Patent have disclosed devices for intraluminal location and securement, which devices include plural projections for effecting such securement, such as:

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5,167,614 (Tessman et al.); 5,207,695 (Trout III); 5,275,622 (Lazarus et al.); 5,306,286 (Stack et al.); 5,383,892 (Cardon et al.); 5,387,235 (Chuter); 5,397,345 (Lazarus); and 5,423,885 (Williams).

Notwithstanding the foregoing, a need exists for means for ensuring good retention from migration for intraluminal grafts.

OBJECTS OF THE INVENTION

It is a general object of this invention to provide intraluminal medical devices and methods of use of the same which overcome the disadvantages of the prior art.

It is a further object of this invention to provide anchoring means for intraluminal medical devices, e.g., endovascular grafts, stents, etc, arranged to be fixedly secured within a vessel, duct, or lumen of a living being.

It is a further object of this invention to provide anchoring means for intraluminal medical devices to be secured within in a vessel, duct, or lumen of a living being, and which anchoring means is simple in construction.

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It is a further object of this invention to provide anchoring means for intraluminal medical devices to be secured within in a vessel, duct, or lumen of a living being, and which anchoring means does not pose a significant risk of perforating the tissue of the vessel, duct, or lumen.

SUMMARY OF THE INVENTION

These and other objects of this invention are achieved by providing an intraluminal medical device for securement within a vessel, duct, or lumen of a living being. The vessel, duct, or lumen has an interior surface and is arranged to have a body fluid, e.g., blood, flow therethrough in a first direction.

The medical device basically comprising a tubular member and anchoring means. The tubular member has a passageway extending therethrough and outer periphery, and is arranged to have fluid flow through its passageway in a first direction when the device is located within the vessel, duct, or lumen, whereupon a force is applied to the tubular member. The anchoring means are located adjacent the outer periphery of the tubular member and comprise plural projections.

The projections are arranged for engagement with the interior of the wall of the vessel, duct, or lumen, and are preferentially oriented to include portions extending at an acute angle to the first direction. These portions tightly engage the interior of the wall of the vessel, duct, or lumen under the force applied to the tubular member by the fluid flowing through the passageway in the first direction. In particular, the force applied to the tubular

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member by the fluid flowing through the passageway produces on each of the preferentially oriented projections a force component extending in the first direction (the direction of fluid, e.g., blood, flow), and a force component extending perpendicularly (i.e., radially) to the first direction, to thereby cause the projections to tightly engage, e.g., burrow slightly into, the interior of the wall of the vessel, duct, or lumen to thereby fixedly secure the device in place.

In accordance with the preferred embodiment of the invention the device is endovascular graft, wherein the tubular member comprises a graft sleeve having plurality of ring-like stents disposed about the outer periphery thereof. The anchoring means are located on the outer surface of the stents. The stents and the graft sleeve are expandable from a compact state to an expanded state, whereupon the anchoring means engage the interior of the vessel, duct, or lumen. The flow of fluid, e.g., blood, through the device applies the force through the graft sleeve and the stents to the anchoring projections, to cause the anchoring projections to tightly engage, e.g., burrow slightly into, the interior of the vessel, duct, or lumen.

#### DESCRIPTION OF THE DRAWINGS

Other objects and many attendant advantages of this invention will become readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

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Fig. 1 is a longitudinal view, partially in section, of an artery revascularized by an endovascular bypass graft constructed in accordance with the subject invention, with the graft being shown in its expanded state;

Fig. 2 is an enlarged isometric view of a portion of the endovascular bypass graft shown in Fig. 1;

Fig. 3 is a more greatly enlarged isometric view of a stent portion of the graft shown within the area bounded by the broken lines bearing the designation 3 in Fig. 2;

Fig. 4 is a greatly enlarged sectional view taken along line 4 - 4 of Fig. 1;

Fig. 5 is a cross-sectional view through the artery of Fig. 1 and showing the graft in its compact state, prior to expansion;

Fig. 6 is an enlarged isometric view similar to Fig. 2 of another alternative embodiment of endovascular bypass graft constructed in accordance with this invention;

Fig. 7 is a plan view of a portion of yet another alternative embodiment of a graft constructed in accordance with this invention; and

Fig. 8 is an enlarged sectional view taken along line 8 - 8 of Fig. 7.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to various figures of the drawing where like reference numerals refer to like parts there is shown at 20 in Fig. 1 an expandable, intraluminal bypass graft device constructed in accordance with this invention. The graft device 20 is constructed

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in accordance with the teachings of my aforementioned patent, except for the means for fixedly holding it in place within the vessel, duct, or lumen. In this regard the subject invention makes use of anchoring means, to be described later, which offer an improvement in retention over the "protuberances" disclosed in my aforementioned patent.

Before describing the improved anchoring means of this invention a brief description of the graft device is in order. To that end, the graft device 20 is particularly suited for revascularizing lesions, e.g., atherosclerotic plaque lesions, in arteries. However, it should be appreciated that the graft device as disclosed herein can be used for other intraluminal applications, as well. Moreover, the anchoring means of this invention can be used in other intraluminal medical devices. In this regard, the anchoring means can be incorporated into any intraluminal device for securement in a vessel, duct, or lumen in the body of a living being, and through which a body fluid will flow.

In Fig. 1 the endovascular graft device 20 is shown in a typical long segment lesion 10 of an artery 12. The lesion is made up of atherosclerotic deposits forming a small or narrow, restricted passageway for flow of blood therethrough. The endovascular graft 20 is configured so that it is initially in a compact or compressed state shown in cross section in Fig. 5. In that state it is arranged to be readily inserted into the arterial passageway, via any conventional means, e.g., a balloon catheter 14 shown in phantom in Fig. 1 and positioned so that it extends

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through the restriction. Once in position the graft 20 is expanded to an expanded state, like that shown in Fig. 1 by inflating the balloon 14. In the maximum expanded state the graft 20 has a central passageway P (Fig. 2) which is of maximum internal cross-sectional area. When the graft 20 is in the expanded state a substantially greater cross-sectional area of the arterial section is open to the free flow of blood therethrough than prior to the use of the graft 20.

As discussed earlier, the expansion of the graft 20 from a compacted state shown in Fig. 5 to the expanded state shown in Fig. 1 is preferably accomplished by a conventional balloon catheter 14. However, any suitable other expansion means or instrument (not shown) may be used.

Referring now to Figs. 1, 2 and 5, it can be seen that the graft device 20 basically comprises an elongated tubular member or sleeve 24 having a plurality of expandable, ring-like, stent members or sections 26 located at equidistantly spaced positions along the longitudinal length of the sleeve member 24. The sleeve member is formed of a thin and highly flexible material, such as expanded polytetrafluoroethylene used for conventional vascular grafts. Examples of such prior art graft materials are those sold by W.C. Gore and Company under the trademark GORTEX or those sold by Impra, Inc. under the trademark IMPRAGRAFT.

The sleeve 24 is configured so that it is pleated, i.e., it includes a plurality of longitudinally extending pleats 28. Each of the pleats extends the entire length of the graft 20. The

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pleated tube or sleeve is normally in a compacted state as shown in Fig. 5, that is each of the pleats overlies and abuts a contiguous portion of an immediately adjacent pleat. The sleeve is arranged to be expanded to a maximum expanded state wherein its pleats open up and form a generally continuous curved, e.g., cylindrical, inner and outer surface. The inner surface forms the passageway P through the graft device through which blood will flow.

When the graft is in the compacted state of Fig. 5 its outside diameter is substantially less than when it is in the expanded state. Moreover, when the graft sleeve is in its expanded state, its internal cross-sectional area is substantially greater than in the compact state. It must be pointed out at this juncture that the graft may be partially expanded in an artery to be revascularized, whereupon its pleats do not fully open up (flatten out). In such a case the internal cross sectional area is less than in the fully expanded state, but more than in the compacted state, and thus still permits the freer flow of blood therethrough than would flow through natural passageway in the restriction.

The spaced stent members 26 serve as the means for holding or retaining the sleeve 24 in any desired expanded state (i.e., from a slightly partially expanded state, not shown, to the fully expanded state like shown in Fig. 1). Thus, as can be seen best in Fig. 3, each stent member 26 basically comprises a plurality of interconnected links 30. Each of the links is an elongated rigid member formed of stainless steel or some other suitable biocompatible material, e.g., tantalum, plastic. Each link has a

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pair of ends and is joined to an associated link via a pivotable joint 32. Each joint 32 is made up of one end of one link and the other end of the immediately adjacent link. The link ends are connected by any suitable means, e.g., a deformable member, a pin, etc., to enable the links to pivot outward with respect to each other so that the angle therebetween increases, yet which precludes the links from pivoting backward toward each other. When so arranged the links form a zig-zag pattern. In the embodiment shown herein each joint 32 comprises the material making up the links themselves, and such material is deformable, but not resilient, so that once deformed, i.e., the links pivoted outward, it doesn't return to its previous configuration.

As should be appreciated by those skilled in the art when the links are pivoted outward with respect to each other the stent 26 expands from its compact state to the expanded state, like that shown in Fig. 1.

In accordance with a preferred aspect of this invention the joints 42 at the interfaces of each of the links of the stents are arranged to maintain any angular orientation between the connected links from the compact state to the maximum expanded state such that once the stents 26 are expanded to any expanded state (whether partial or full) movement back to the compact state is precluded.

The links of the stents of this invention serve to hold the sleeve member 24 in its expanded state. To that end, in the embodiment shown herein each of the stents is mounted on the outside of the sleeve, whereupon the links of those stents are

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connected to one or more pleats 28 externally of the sleeve, i.e., on the outer surface of the sleeve. If desired, the stents 26 could be disposed or mounted within the sleeve. In the later case the links can be connected internally of the sleeve. Moreover, if desired, the stents may be completely encased in the graft material forming the sleeve.

In the preferred embodiment shown in Fig. 1, each of the stents 26 is made up of pairs of interconnected links to form two zig-zag patterns sharing common joints, thereby creating a diamond-like pattern stent. In Fig. 6 there is shown an alternative graft using plural spaced stents 34. Each stent 34 comprises a plurality of links 30 which are interconnected via joints 32 (like that of the embodiment shown in Fig. 1), except the links are not paired, so that a single zig-zag pattern is produced instead of the diamond-like pattern of Fig. 1. In all other regards the graft device utilizing stents 34 is the same as that described heretofore.

In order to help hold or secure the graft in position in the artery (or lumen or duct) once the graft has been expanded, the graft includes the heretofore mentioned anchoring means. Such anchoring means comprise plural protuberances or projections 40. In the preferred embodiments disclosed herein the protuberances are mounted on the stents 26 and 34. In particular, each stent includes a plurality of protuberances or projections projecting slightly outward therefrom and from the outer surface of the graft sleeve. As will be described in detail later, these projections 40

are preferentially oriented so that the force of the fluid, e.g., blood, flowing through the graft device 20 is applied to them to cause them to tightly engage the interior of the wall making up the vessel, duct, or lumen. In particular, as will be described in detail with respect to Figs. 3 and 4, the projections 40 include portions extending at an acute angle to the direction which the fluid flows through the device when the device is positioned intraluminally, whereupon the force applied to the projections by that fluid flow includes a force component extending in the direction of the fluid flow and a force component extending radially, i.e., perpendicularly to the direction of the fluid flow. This action causes the projections to tightly engage, e.g., burrow slightly into, the interior of the vessel, duct, or lumen to fixedly secure the device in place.

Before describing the construction of the projections 40, it should be pointed out, that they can be located on any exterior portion of the device 20 in order to engage the interior of the vessel, duct, or lumen to secure the device in place. In the preferred embodiment shown herein the projections 40 are located on the stents, and in particular, at the joints of the stents. This is merely exemplary. Thus, the projections can be located at any suitable portion on the stents, so long as when the stent is expanded the projections 40 are properly preferentially oriented (as will be described later). Moreover, the mechanism, e.g., pivot pin, deformable member, etc., forming each joint of the stent may itself form a projection.

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In the case of an interiorly located stent, i.e., a device wherein the stent is located on the interior of the sleeve or embedded within the material making up the sleeve (as discussed earlier), if the interior stent is to include the projections 40 as a part of it, those projections must extend through the sleeve so as to be located on the outer surface of the sleeve. Another suitable arrangement for an device using a interiorly located stent is to utilize projections which are not part of the stent itself. In such an alternative arrangement the projections may form a separate component of the device 20, e.g., be separate elements, mounted on the outer surface of the sleeve in order to engage the interior of the vessel, duct, or lumen.

Referring now to Figs. 3 and 4, the details of the projections 40 will now be described. As can be seen therein each projection is of a generally "arrow head" shape when viewed in plan. In particular, each projection includes a leading edge 42 defining the "tip" of the "arrow-head." The leading edge 42 extends upward at an acute angle to the exterior surface of the stent and terminates at the top surface 44 of the projection. The top surface 44 is generally planar and inclines upward in the direction of blood flow. That direction is designated by the arrow 46 in Figs. 3 and 4. The trailing edges of each projection 40 are designated by the reference numbers 48, 50, and 52 (Fig. 3), and each inclines upward in the direction of the blood flow to terminate at the top surface 44 in respective penetration points 54, 56, and 58, respectively. Thus, as can be appreciated each of the projections 40 includes

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portions which are preferentially oriented at an acute angle to the direction of blood flow. The acute angle is shown in Fig. 4 and designated by the reference numeral 60.

As will be appreciated by those skilled in the art, with blood (or some other fluid) flowing through the device 20 in the direction of arrow 46 a force will be applied by that flow to the interior surface of the sleeve 24, and from there through the stents to the projections 40. The force applied to the projections 40 will have a force component directed in the direction of the fluid flow, and a force component perpendicularly thereto, i.e., extending radially outward. Thus, the flow of fluid, e.g., blood, through the device 20 will tend to force the projections 40 into good engagement with the wall 12 of the vessel, duct, or lumen. In the embodiment shown herein the projections penetrate or burrow slightly into the artery wall, as shown clearly in Fig. 4. Such penetration may not be necessary for good resistance to migration of the device. If some penetration is deemed desirable the height of the projections is selected so that their penetrating points do not penetrate too deeply into the artery wall. In this regard, the height of the projections is selected so that they do not penetrate into the adventitial or medial layers of the artery wall, but can penetrate its intima. It is anticipated that for applications within the very largest arteries, such as the abdominal aorta, that the height of the projections will be in the range of approximately 1.0 mm to 1.5 mm. For intermediate arteries, the height of the projections will be in the range of approximately 0.75 mm to 1.0

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mm, and for small arteries, the height of the projections will be in the range of approximately 0.5 mm to 1.0 mm.

As should be appreciated by those skilled in the art the number of projections used in any device will also be a considerable factor in the amount of securement against migration provided thereby. Thus, as a general proposition, the more projections utilized the less "penetration" or "burrowing" will necessary for good securement against migration.

In Figs. 7 and 8, there is shown an alternative construction of locking projections constructed in accordance with the teaching of this invention. Those projections are of a general "wedge" shape and designated by the reference number 70. As should be appreciated by those skilled in the art the wedge shaped projections somewhat simpler construction to the "arrow-head" shaped projections 40, and hence will likely be easier to manufacture.

As can be seen in Fig. 8, each of the wedge shaped projections 70 includes a leading surface 72 defining the "front face" of the "wedge." The leading surface 72 extends upward at an acute angle to the exterior surface of the stent and terminates at the top surface 74 of the projection 70. The top surface 74 is generally planar and is either parallel to the plane of the stent portion from which it projects (as shown) or inclines upward in the direction of blood flow. Each projection also includes a trailing surface 76 which inclines upward in the direction of the blood flow to terminate at the top surface 74 in a penetration edge 78. Thus, as can be appreciated, each of the projections 70 also includes

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portions which are preferentially oriented at an acute angle to the direction of blood flow.

It should be pointed out that anchoring projections constructed in accordance with this invention can take numerous other shapes and sizes than those shown herein. In this regard, the projections need not include sharp edges and/or planar surfaces or points, and can be rounded, domed, or any other suitable shape, so long as they are preferentially oriented to project or extend at some acute angle to the direction of fluid flow, whereupon the force applied to them by the fluid flowing through the vessel, duct, or lumen, in which the device to be secured by them flows produces on each of them a force component extending in the direction of the fluid flow and a force component extending perpendicularly to that direction. As discussed above this action causes the projections to tightly engage (and not necessarily penetrate) the interior of the wall of the vessel, duct, or lumen to fixedly secure the device in place against migration.

Without further elaboration the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

CLAIMS

I Claim:

509  
A17

1. An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface, said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular member, said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural projections arranged for engagement with the interior of the wall of the vessel, duct, or lumen, said projections being preferentially oriented to include portions extending at an acute angle to the first direction, whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said preferentially oriented projections a force component extending in the first direction and a force component extending perpendicularly to said first direction, to thereby cause said projections to tightly engage the interior of the wall of the vessel, duct, or lumen to fixedly secure said device in place.

2. The device of Claim 1 wherein said projections include a surface portion which is inclined upward in the first direction flow.

3. The device of Claim 2 wherein said surface portion is a top surface.

4. The device of Claim 2 wherein said surface portion is a leading surface.

5. The device of Claim 4 wherein said surface portion is also a top surface.

6. The device of Claim 3 additionally comprising a trailing surface, said trailing surface meeting said top surface to form at least one penetrating edge.

7. The device of Claim 6 wherein said penetrating edge forms a portion of a point.

8. The device of Claim 7 wherein each of said projections include plural points.

9. The device of Claim 1 wherein said tubular member is a stent.

10. The device of Claim 9 wherein said stent is expandable from a contracted state to an expanded state, said anchoring means engaging the interior <sup>surface</sup> of the vessel, duct, or lumen when said stent is in said expanded state to secure said device in place.

11. The device of Claim 10 wherein said stent comprises a plurality of interconnected movable links.

12. The device of Claim 11 wherein said links are arranged in either diamond-like shaped configurations or in zig-zig shaped configurations.

13. The device of Claim 10 wherein said device is an endovascular graft, said endovascular graft additionally comprising



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a graft sleeve, said sleeve being coupled to said stent and having an outer surface and inner passageway through which the body fluid flows in the first direction to apply the force to said projections.

14. The device of Claim 13 wherein said stent is located on said outer surface of said sleeve.

15. The endovascular graft of Claim 13, wherein said graft sleeve comprises a plurality of longitudinally extending pleats.



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ABSTRACT OF THE DISCLOSURE

An endovascular graft for securement within a vessel, duct, or lumen of a living being. The graft comprises a tubular graft sleeve and a plurality of ring-like stents mounted on the outer surface of the sleeve. Anchoring projections are provided on the outer surface of the stents. The graft sleeve has a passageway extending therethrough, which when the graft is located within the vessel, duct, or lumen serves to carry body fluid, e.g., blood, through it in a single direction. This action produces a force on the tubular sleeve and the plural stents mounted thereon. The anchoring projections extend outward from the outer surface of the stents and are arranged for engagement with the interior of the wall of the vessel, duct, or lumen. The anchoring projections are preferentially oriented to include portions extending at an acute angle to the direction of the fluid flow to tightly engage the interior of the wall of the vessel, duct, or lumen under the force applied by the fluid flowing through the device.

**DECLARATION FOR PATENT APPLICATION**

Docket Number (optional)

R1001/20002

As a below named inventor, I hereby declare that:

BLDSTE

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 plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

the specification of which

is attached hereto unless the following box is checked:

Was filed on \_\_\_\_\_ as United States Application Number or PCT International Application Number \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable).

I hereby state that 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 patentability as defined in Title 37, Code of Federal Regulations, §1.56.

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

Prior Foreign Application(s)

Priority Claimed

<u>NONE</u> (number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____ (number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application (s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international date of this application.

<u>NONE</u> (Application Number)	_____ (Filing Date)	_____ (Status-patented, pending, abandoned)
_____ (Application Number)	_____ (Filing Date)	_____ (Status-patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

9 Alan H. Bernstein (Registration No. 19,315); Stanley H. Cohen (Registration No. 20,235); Manny D. Pokotilow (Registration No. 22,492); Barry A. Stein (Registration No. 25,257); Martin L. Faigus (Registration No. 24,364); Max Goldman (Registration No. 31,363); Eric S. Marzluf (Registration No. 27,454); Robert S. Silver (Registration No. 35,681) and Scott M. Slomowitz (Registration No. 39,032); Care of Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., 12th Floor, Seven Penn Center, 1635 Market Street, Philadelphia, Pennsylvania 19103-2212, my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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

Full name of sole or first inventor (given name, family name) Valentine J. Rhodes, M.D.

Inventor's signature Valentine J. Rhodes Date 4/22/95  
Residence Bricktown, New Jersey Citizenship United States

Post Office Address 608 Winding River Road, Bricktown, New Jersey 08723

Full name of second joint inventor, if any (given name, family name) \_\_\_\_\_

Second Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

Residence \_\_\_\_\_ Citizenship \_\_\_\_\_

Post Office Address \_\_\_\_\_

Additional inventors are being named on separately numbered sheets attached hereto.



**VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

Docket Number (Optional)  
R1001/20002

Applicant or Patentee: Valentine J. Rhodes, M.D.

Serial or Patent No.: \_\_\_\_\_

Filed or Issued: \_\_\_\_\_

Title: INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

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 to the Patent and Trademark Office described in:

- the specification filed herewith with title as listed above.
- the application identified above.
- the patent identified above.

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 would not qualify 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 exists.
- Each such person, concern or organization is listed below.

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

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))

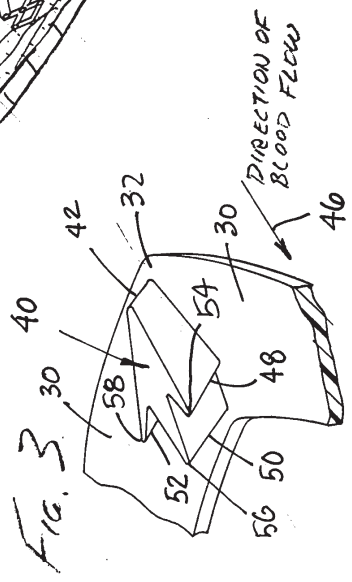
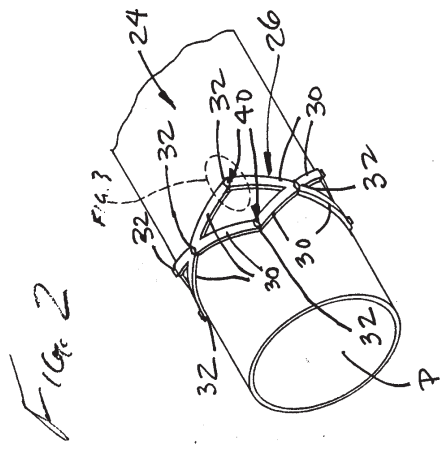
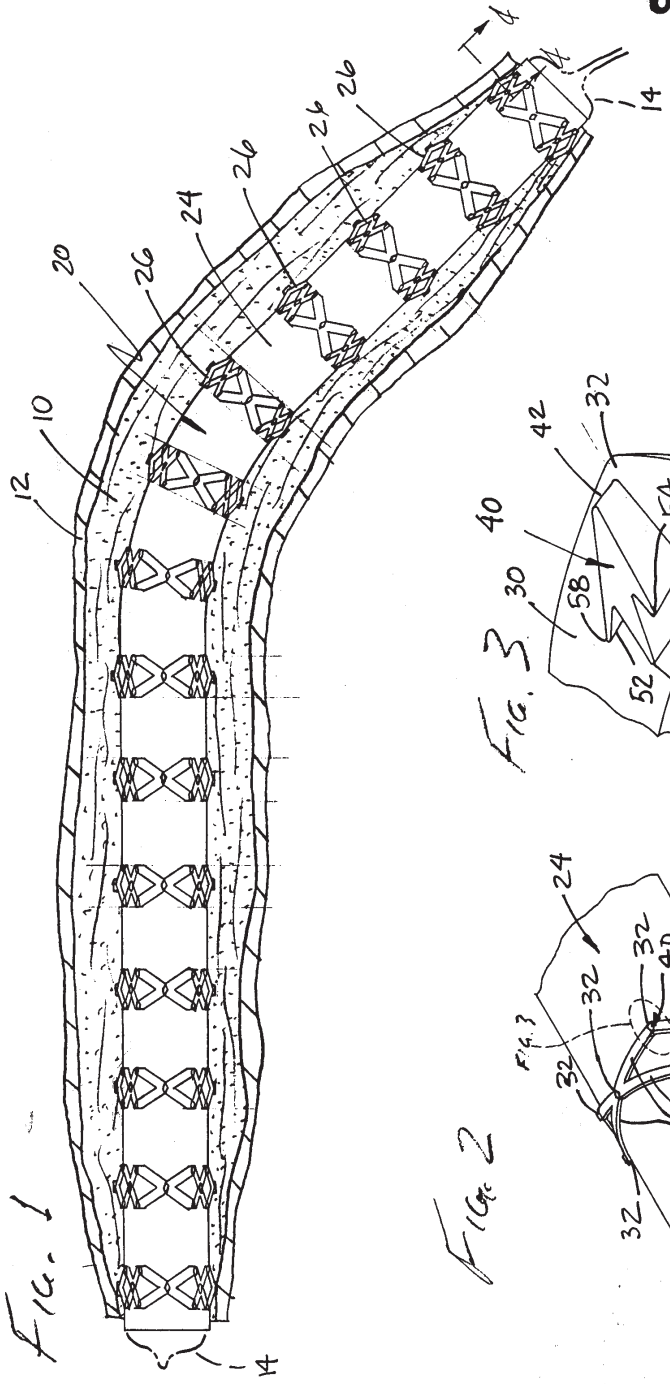
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, 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.

Valentine J. Rhodes, M.D.

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
<u>Valentine J. Rhodes, M.D.</u>	_____	_____
Signature of inventor	Signature of inventor	Signature of inventor
<u>11/22/95</u>	_____	_____
Date	Date	Date

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R1001/20002



08/562727

FIG. 4

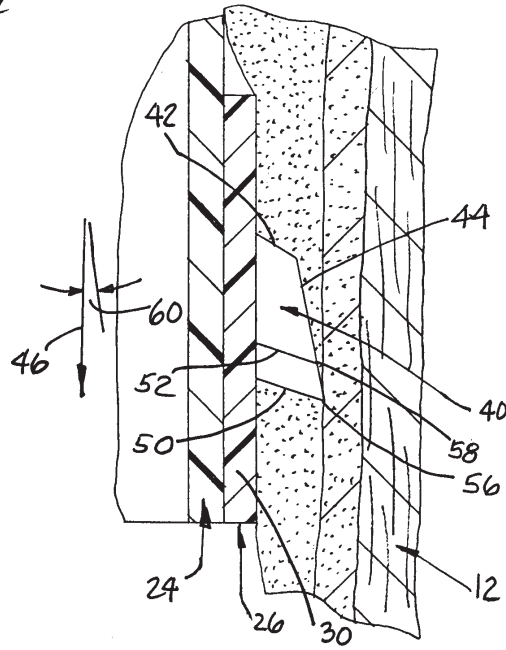
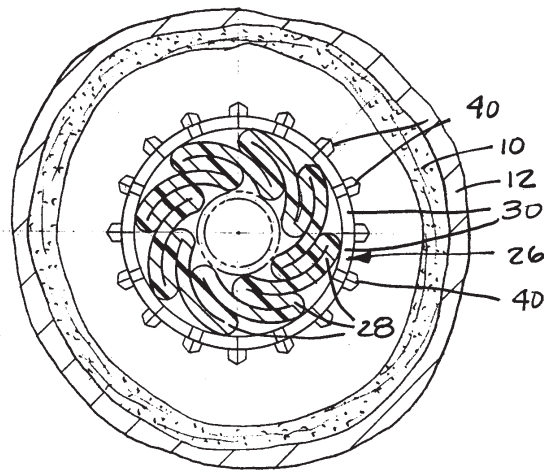


FIG. 5



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FIG. 6

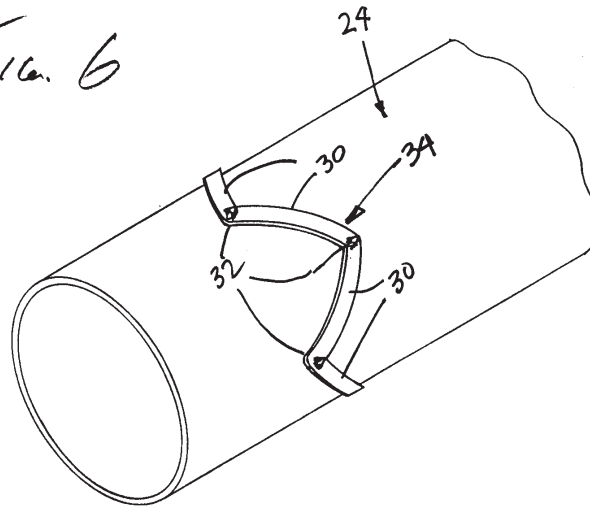


FIG. 7

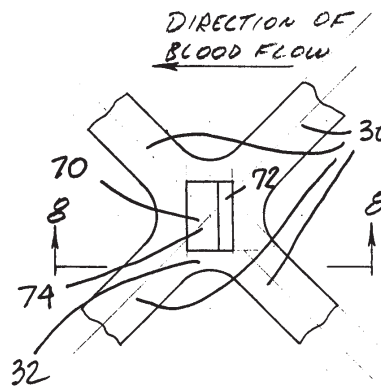
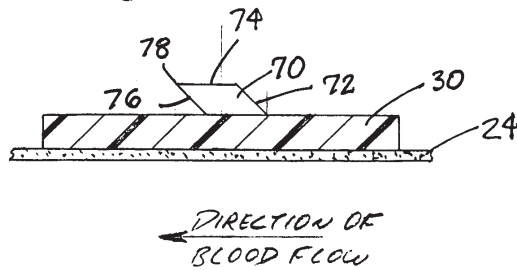


FIG. 8



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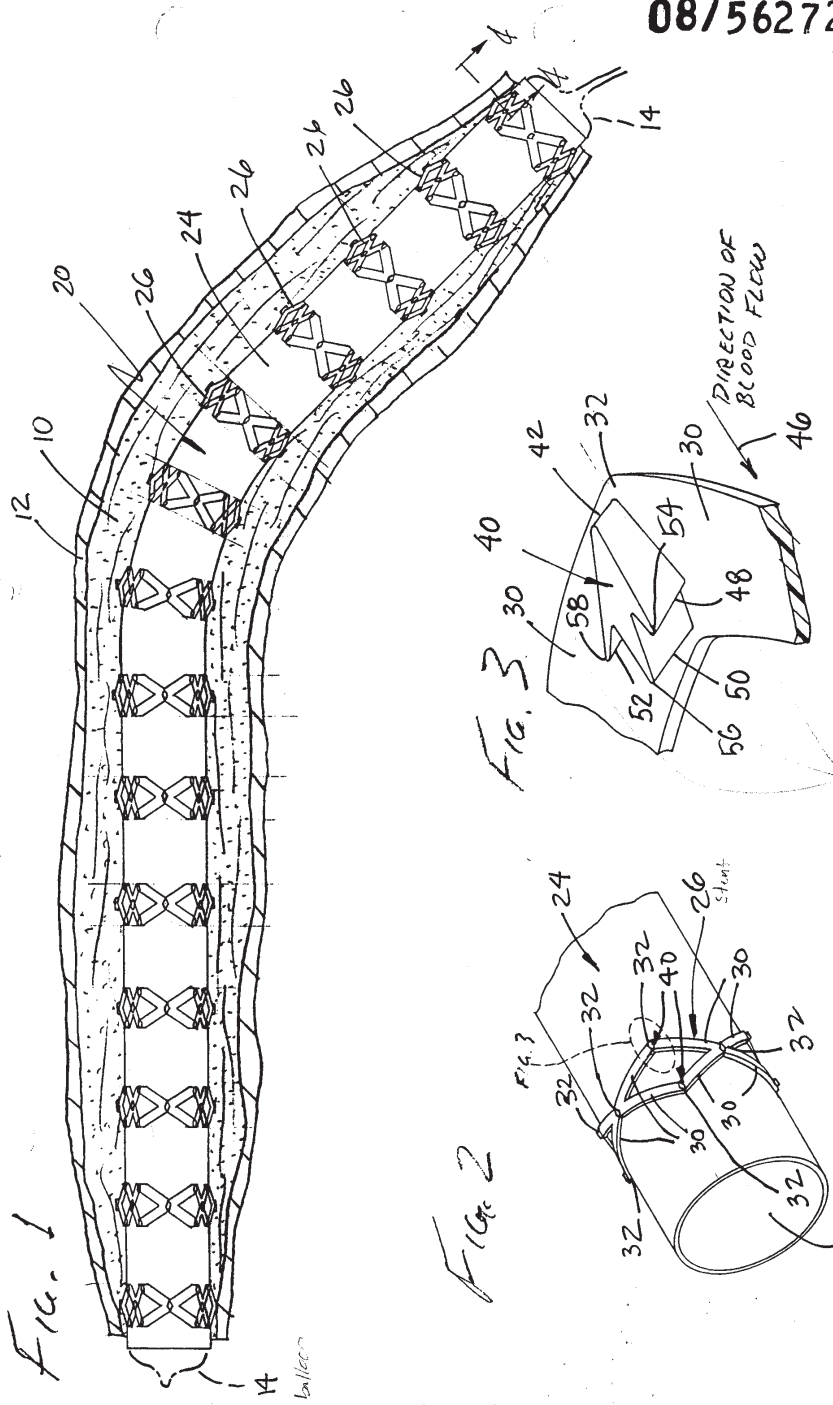




FIG. 4

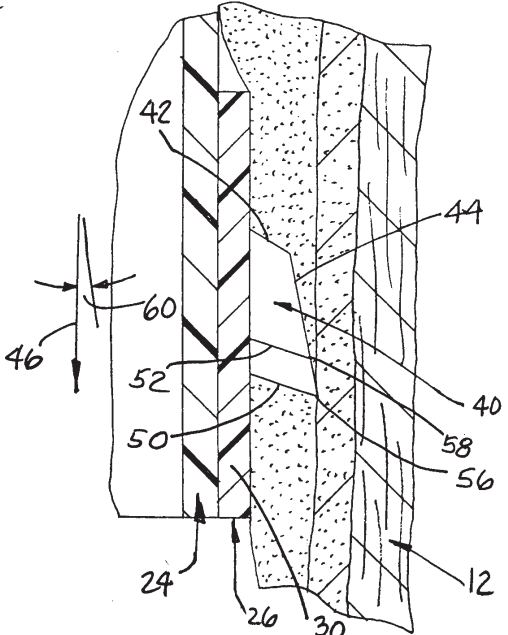
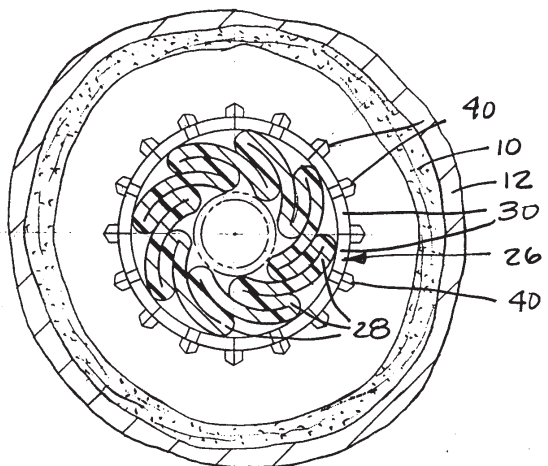


FIG. 5



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FIG. 6

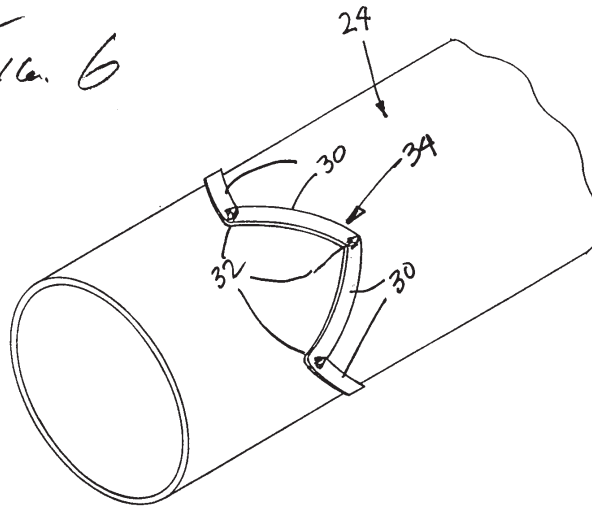


FIG. 7

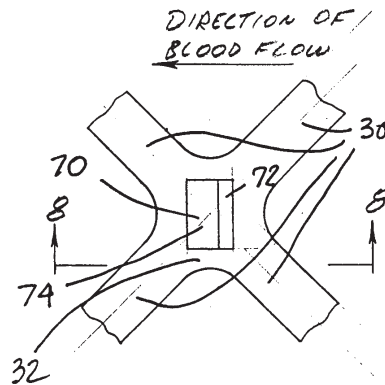
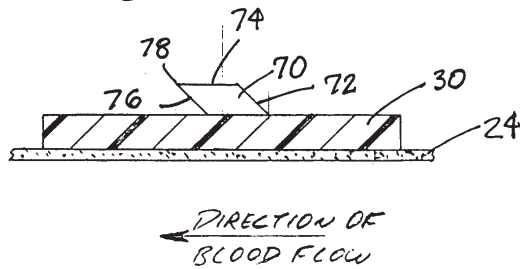


FIG. 8





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.
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08/562,727 11/27/95 RHODES

V R1001/20002

EXAMINER

TRUONG, K

ART UNIT PAPER NUMBER

3309

2

DATE MAILED:

04/09/96

3341/0409  
CAESAR RIVISE BERNSTEIN COHEN  
AND POKOTILOV LTD  
SEVEN PENN CENTER 12TH FLOOR  
1635 MARKET STREET  
PHILADELPHIA PA 19103-2212

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 \_\_\_\_\_  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 1-15 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 1, 9-15 are rejected.

5.  Claims 2-8 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

PTOL-326 (Rev. 2/93)

Serial Number: 08/562,727

-2-

Art Unit: 3309

**Part III DETAILED ACTION**

*Claim Rejections - 35 USC § 102*

1. 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.

2. Claims 1 and 9-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rhodes '154.

Rhodes discloses the claimed invention in figs. 1,6-9 and (Col.6-7).

*Allowable Subject Matter*

3. Claims 2-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Truong whose telephone number is (703) 308-3767.

DA  
kt  
March 29, 1996

*Michael Powell Bui*  
MICHAEL POWELL BUIZ  
Supervisor PRIMARY EXAMINER  
GROUP 3800  
4/1/96

**NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW**

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

The drawings filed (insert date) 11-27-95, are

A.  not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.

B.  objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.

- DRAWINGS.** 37 CFR 1.84(a): Acceptable categories of drawings:  
 Black ink. Color.  
 Not black solid lines. Fig(s) \_\_\_\_\_  
 Color drawings are not acceptable until petition is granted. Fig(s) \_\_\_\_\_
- PHOTOGRAPHS.** 37 CFR 1.84(b)  
 Photographs are not acceptable until petition is granted. Fig(s) \_\_\_\_\_  
 Photographs not properly mounted (must use brylston board or photographic double-weight paper). Fig(s) \_\_\_\_\_  
 Poor quality (half-tone). Fig(s) \_\_\_\_\_
- GRAPHIC FORMS.** 37 CFR 1.84 (d)  
 Chemical or mathematical formula not labeled as separate figure. Fig(s) \_\_\_\_\_  
 Group of waveforms not presented as a single figure, using common vertical axis with time extending along horizontal axis. Fig(s) \_\_\_\_\_  
 Individuals waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s) \_\_\_\_\_
- TYPE OF PAPER.** 37 CFR 1.84(c)  
 Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s) \_\_\_\_\_  
 Erasures, alterations, overwritings, interlineations, cracks, creases, and folds copy machine marks not accepted. Fig(s) SH. 1-3  
 Mylar, velum paper is not acceptable (too thin). Fig(s) \_\_\_\_\_
- SIZE OF PAPER.** 37 CFR 1.84(f): Acceptable sizes:  
 21.6 cm. by 35.6 cm. (8 1/2 by 14 inches)  
 21.6 cm. by 33.1 cm. (8 1/2 by 13 inches)  
 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)  
 21.0 cm. by 29.7 cm. (DIN size A4)  
 All drawing sheets not the same size. Sheet(s) \_\_\_\_\_  
 Drawing sheet not an acceptable size. Sheet(s) \_\_\_\_\_
- MARGINS.** 37 CFR 1.84(g): Acceptable margins:  

Paper size			
21.6 cm. X 35.6 cm. (8 1/2 X 14 inches)	21.6 cm. X 33.1 cm. (8 1/2 X 13 inches)	21.6 cm. X 27.9 cm. (8 1/2 X 11 inches)	21.0 cm. X 29.7 cm. (DIN Size A4)
T 5.1 cm. (2")	2.5 cm. (1")	2.5 cm. (1")	2.5 cm.
L .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	2.5 cm.
R .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.5 cm.
B .64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.0 cm.

Margins do not conform to chart above.  
 Sheet(s) 1-3  
 Top (T)  Left (L)  Right (R)  Bottom (B)
- VIEWS.** 37 CFR 1.84(h)  
 REMINDER: Specification may require revision to correspond to drawing changes.  
 All views not grouped together. Fig(s) \_\_\_\_\_  
 Views connected by projection lines or lead lines. Fig(s) \_\_\_\_\_  
 Partial views. 37 CFR 1.84(h) 2
- View and enlarged view not labeled separately or properly. Fig(s) \_\_\_\_\_  
 Sectional views. 37 CFR 1.84 (h) 3  
 Hatching not indicated for sectional portions of an object. Fig(s) \_\_\_\_\_  
 Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s) \_\_\_\_\_
- ARRANGEMENT OF VIEWS.** 37 CFR 1.84(i)  
 Words do not appear on 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) \_\_\_\_\_
- SCALE.** 37 CFR 1.84(k)  
 Scale not large enough to show mechanism with 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) \_\_\_\_\_
- CHARACTER OF LINES, NUMBERS, & LETTERS.** 37 CFR 1.84(l)  
 Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s) 1, 4, 5, 8
- SHADING.** 37 CFR 1.84(m)  
 Solid black shading areas not permitted. Fig(s) \_\_\_\_\_  
 Shade lines, pale, rough and blurred. Fig(s) \_\_\_\_\_
- NUMBERS, LETTERS, & REFERENCE CHARACTERS.** 37 CFR 1.84(p)  
 Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(l) Fig(s) 1-8  
 Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(l) 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(p)(3) Fig(s) \_\_\_\_\_
- LEAD LINES.** 37 CFR 1.84(q)  
 Lead lines cross each other. Fig(s) \_\_\_\_\_  
 Lead lines missing. Fig(s) \_\_\_\_\_
- NUMBERING OF SHEETS OF DRAWINGS.** 37 CFR 1.84(t)  
 Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s) \_\_\_\_\_
- NUMBER OF VIEWS.** 37 CFR 1.84(u)  
 Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) \_\_\_\_\_  
 View numbers not preceded by the abbreviation Fig. Fig(s) \_\_\_\_\_
- CORRECTIONS.** 37 CFR 1.84(w)  
 Corrections not made from prior PTO-948. Fig(s) \_\_\_\_\_
- DESIGN DRAWING.** 37 CFR 1.152  
 Surface shading shown not appropriate. Fig(s) \_\_\_\_\_  
 Solid black shading not used for color contrast. Fig(s) \_\_\_\_\_

**COMMENTS:**

ATTACHMENT TO PAPER NO. 2

REVIEWER SE

DATE 1-30-96

PTO Copy

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**REMINDER**

Drawing changes may also require changes in the specification, e.g., if Fig. 1 is changed to Fig. 1A, Fig. 1B, Fig. 1C, etc., the specification, at the Brief Description of the Drawings, must likewise be changed. Please make such changes by 37 CFR 1.312 Amendment at the time of submitting drawing changes.

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities--37 CFR 1.85**

File new drawings with the changes incorporated therein. The application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application, should be placed on the back of each sheet of drawings in accordance with 37 CFR 1.84(c). Applicant may delay filing of the new drawings until receipt of the Notice of Allowability (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Drawing Review Branch.

**2. Timing of Corrections**

Applicant is required to submit **acceptable** corrected drawings within the three-month shortened statutory period set in the Notice of Allowability (PTOL-37). If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction resubmitted within the original three-month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

**3. Corrections other than Informalities Noted by the Drawing Review Branch on the Form PTO 948**

All changes to the drawings, other than informalities noted by the Drawing Review Branch, **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

TO SEPARATE, FOLD TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		SERIAL NO. 08/562,727	GROUP/ART UNIT 3309	ATTACHMENT TO PAPER NUMBER 2		
NOTICE OF REFERENCES CITED				APPLICANT(S) Valentine Rhodes				
<b>I.S. PATENT DOCUMENTS</b>								
*	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE		
A	5122154	6/16/1992	Rhodes	623 <del>622</del>	1	8/15/90		
B								
C								
D								
E								
F								
G								
H								
I								
J								
K								
<b>FOREIGN PATENT DOCUMENTS</b>								
*	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
L								
M								
N								
O								
P								
Q								
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
R								
S								
T								
U								
EXAMINER K. TRUONG			DATE 3/22/96					
* A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)								



COMMISSIONER OF PATENTS AND TRADEMARKS  
WASHINGTON, D.C. 20231

RECEIVED

MAY 21 1996

GROUP 330

Applicant: Valentine J. Rhodes  
Serial No: 08/562,727  
Filing Date: 11/27/95  
Title: INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

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

- Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
- A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
- No additional fee is required.

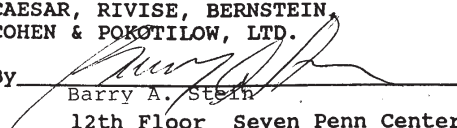
The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)	Small Entity	Other Than A Small Entity
	Claims Remaining After Amendment		Highest No Previously Paid For	Present Extra	Rate	Add'l Fee
Tot.	15	Minus	20	= 0	11=	\$ 0
Ind.	1	Minus	3	= 0	39	\$
First Presentation of Multi.Dep.Clm.					125	\$
Total Add'l. Fee					\$ 0	Total \$

- Please charge my Deposit Account No. 03-0075 in the amount of \$\_\_\_\_\_. A duplicate copy of this sheet is attached.
- The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account 03-0075. A duplicate copy of this sheet is attached.
  - Any filing fees under 37 CFR 1.16 for the presentation of extra claims.
  - Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOV, LTD.

By   
Barry A. Stein  
12th Floor Seven Penn Center  
1635 Market Street  
Philadelphia, PA 19103-2212  
Attorneys for Applicant

Dated: May 15, 1996  
File Ref: R1001/20002



GP3309



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION

RECEIVED

MAY 21 1996

GROUP 3300

DH  
S-22  
#3/a

Applicant : Valentine J. Rhodes

Serial No. : 08/562,727

Filed : November 27, 1995

For : INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

Group : 3309

Examiner : Kevin Truong

AMENDMENT

Hon. Commissioner of Patents  
and Trademarks  
Box Non-Fee Amendments (Pats)  
Washington, D.C. 20231

Sir:

Responsive to the Office Action dated April 9, 1996, please  
amend the above identified application as follows:

IN THE CLAIMS:

Rewrite Claim 1 as follows:

a/

1. (Amended) An intraluminal medical device for securement within a vessel, duct, or lumen of a living being, the vessel, duct, or lumen having an interior surface, said device comprising a tubular member and anchoring means, said tubular member having a passageway extending therethrough and an outer periphery, said tubular member being arranged to have a body fluid flow through said passageway in a first direction when said device is located within the vessel, duct, or lumen, whereupon a force is applied to said tubular member, said anchoring means being located adjacent said outer periphery of said tubular member and comprising plural

25

projections arranged for engagement with the interior <sup>Surface</sup> of the wall of the vessel, duct, or lumen, each of said projections having a leading portion located in the upstream direction of the fluid flow and a trailing portion located in the downstream direction thereof, said trailing portion including at least one surface [being] preferentially oriented to [include portions] extend[ing] at an acute angle to the first direction, whereupon the force applied to said tubular member by the fluid flowing through said passageway produces on each of said [preferentially oriented] projections a force component [extending in the first direction and a force component extending perpendicularly to said first direction,] to [thereby] cause said [projections] at least one surface to tightly engage the interior <sup>Surface</sup> of the wall of the vessel, duct, or lumen to fixedly secure said device in place.

Rewrite Claim 2 as follows:

2. (Amended) The device of Claim 1 wherein said [projections include a] at least one surface [portion which] is inclined upward in the first direction [flow].

Rewrite Claim 3 as follows:

3. (Amended) The device of Claim 2 wherein each of said projections includes a leading surface, a top surface, and a trailing surface, and wherein said at least one surface [portion] is [a] said top surface.

Rewrite Claim 4 as follows:

4. (Amended) The device of Claim 2 wherein each of said projections includes a leading surface, a top surface, and a

trailing surface, and wherein said at least one surface [portion] is [a leading] said trailing surface.

Rewrite Claim 5 as follows:

5. (Amended) The device of Claim [4] 2 wherein each of said projections includes a leading surface, a top surface, and a trailing surface, and wherein said at least one [surface] <sup>surface</sup> ~~portion~~ is [also a] said top surface and said trailing surface.

Rewrite Claim 6 as follows:

6. (Amended) The device of Claim [3] 1 wherein each of said projections includes a leading surface, a top surface, and [additionally comprising] a trailing surface, said trailing surface meeting said top surface to form at least one penetrating edge.

#### REMARKS

Claims 1 - 15 remain in this application, with Claims 1 - 6 having been amended to expedite the prosecution of this application.

As set forth in the specification of the instant application the subject invention relates to a medical device which is arranged to be located and secured within a vessel, duct or lumen and through which fluid, e.g., blood, will flow in one direction. The means for effecting the securement of the device in the vessel, duct or lumen, i.e., the anchoring means, basically comprise a plurality of projections arranged for engagement with the interior of the wall of the vessel, duct, or lumen. Each of the projections has a leading portion, e.g., a leading surface, located in the upstream direction of the fluid flow and a trailing portion, e.g.,

---

a top surface and a trailing surface, located in the downstream direction. The trailing portion includes at least one surface, e.g., the trailing surface, which is preferentially oriented to extend at an acute angle to the direction of the fluid flow.

The construction and arrangement of the projections is such that the force applied to the device by the fluid flowing through the device produces on each of the projections a force component to cause the at least one surface to tightly engage the interior of the wall of the vessel, duct, or lumen to fixedly secure the device in place.

Claim 1 has been amended to more fully set forth the above features of this invention and to clearly define over the prior art. With respect to the prior art, accompanying this Amendment is an Information Disclosure Statement identifying the prior art disclosed and discussed in the Specification of this application and accompanying petition fee so that such art will be made of record in this application.

The combined features as set forth in Claim 1 as amended herein define over all the prior art now of record. For example, while the primary reference relied upon to reject Claims 1, and 9 - 15, that is, the applicant's own patent 5,122,154 discloses a similar device with anchoring means to secure it to the wall of the vessel, duct, or lumen in which it is located, the teachings of this patent do not disclose nor suggest the anchoring means now being claimed. In this regard the anchoring means of applicant's earlier patent are protuberances which are disclosed in Column 7,

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lines 18 - 24 as projecting slightly out of the outer surface of the graft to act as small pressure points that help impact the graft into the artery wall to hold it in place. There isn't any disclosure the projections are of the shape being claimed herein, namely, that the projections include a trailing portion having at least one surface (e.g., a trailing surface) which is preferentially oriented to extend at an acute angle to the direction of the fluid flow. It is this preferentially oriented feature which enables portions of the projections to effectively tightly engage and/or burrow into to the wall of the vessel, duct, or lumen under the force applied to the device by the fluid flowing through the device to securely anchor the device in place against migration.

None of the other art cited in the specification of this application, and now made part of this record, disclose nor suggest the anchoring means being claimed herein.

Claims 2 - 15 are dependent, either directly or indirectly, upon Claim 1, and are hence patentable for reasons similar thereto. In addition Claims 2 - 6 have been amended in the interests of clarity and to be consistent with Claim 1, from which they depend.

The applicant is mindful of the objection to the drawings in this application but intends to defer the correction thereof until an indication of allowability of this application.

In view of the foregoing amendments and remarks it is respectfully submitted that Claims 1 - 15, all of the claims appearing in this application are allowable, and such favorable

action is respectfully requested.

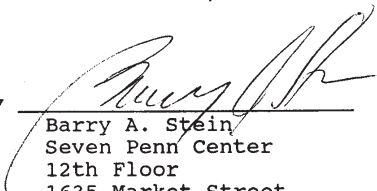
In the event that the subject amendment does not result in the allowance of the application, the undersigned respectfully requests that the Examiner telephone the undersigned to discuss any issues remaining.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

May 15, 1996

By

  
Barry A. Stein  
Seven Penn Center  
12th Floor  
1635 Market Street  
Philadelphia, PA 19103-2212  
(215) 567-2010  
Attorneys for Applicant

CERTIFICATE OF MAILING

I hereby certify that the foregoing AMENDMENT re Application Serial No. 08/562,727 is being deposited with the United States Postal services as first class mail, postage prepaid, in an envelope addressed to: Hon. Commissioner of Patents and Trademarks, Washington, D.C. on this 15th day of May, 1996.

  
Barry A. Stein



*114*

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION

Applicant : Valentine J. Rhodes, M.D.  
Serial No. : 08/562,727  
Filed : November 27, 1995  
For : INTRAVASCULAR STENT WITH SECURE  
MOUNTING MEANS  
Art Group Unit:  
Examiner :

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.97

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

Sir:

This Information Disclosure Statement is being filed pursuant to 37 CFR

1.97.

The following references are disclosed:

*42894  
WR*

U.S. Patent No. 3,657,744

U.S. Patent No. 4,047,252

U.S. Patent No. 4,503,569

U.S. Patent No. 4,512,338

U.S. Patent No. 4,580,568

U.S. Patent No. 4,655,771

7/27/96  
CX

- U.S. Patent No. 4,733,665
- U.S. Patent No. 4,740,207
- U.S. Patent No. 4,776,337
- U.S. Patent No. 4,795,458
- U.S. Patent No. 4,830,003
- U.S. Patent No. 4,856,516
- U.S. Patent No. 4,994,071
- U.S. Patent No. 5,035,706
- U.S. Patent No. 5,122,154
- U.S. Patent No. 5,167,614
- U.S. Patent No. 5,207,695
- U.S. Patent No. 5,275,622
- U.S. Patent No. 5,306,286
- U.S. Patent No. 5,383,892
- U.S. Patent No. 5,387,235
- U.S. Patent No. 5,397,345
- U.S. Patent No. 5,423,885



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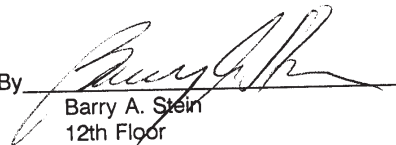
Attached is PTO Form 1449 listing the above documents and enclosing a  
copy of each.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

May 15, 1996

By



Barry A. Stein  
12th Floor  
Seven Penn Center  
1635 Market Street  
Philadelphia, PA 19103-2212  
(215) 567-2010  
Attorneys for Applicant

LP 3309

#4



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION

Applicant : Valentine J. Rhodes, M.D.  
 Serial No. : 08/562,727  
 Filed : November 27, 1995  
 For : INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS  
 Group Art Unit :  
 Examiner :

33X  
TEUONG

RECEIVED  
JUN 5 1996  
GROUP 3300

PETITION UNDER 37 CFR §1.97(d) (ii)

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

Sir:

Applicant hereby petitions under 37 CFR §1.907(d) (ii) to file the accompanying Information Disclosure Statement pursuant to 37 CFR 1.97 and 1.98.

Please charge the petition fee of Two Hundred-Twenty Dollars (\$220.00) as set forth in 37 CFR §1.17(p) and any other fee or deficiencies associated with the filing of this Petition and the Information Disclosure Statement to our deposit account No. 03-0075.

DF70050 05/30/96 08562727 03-0075 070 126 220.00CH

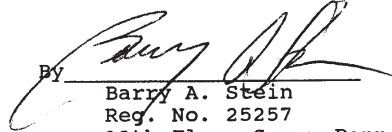
A duplicate copy of this Petition is enclosed.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOV, LTD.

May 15, 1996

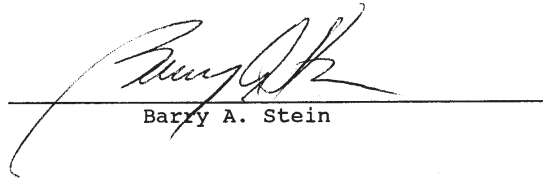
By



Barry A. Stein  
Reg. No. 25257  
12th Floor-Seven Penn Center  
1635 Market Street  
Philadelphia, PA 19103-2212  
(215) 567-2010

CERTIFICATE OF MAILING

I hereby certify that the foregoing PETITION UNDER 37 CFR §1.97(d) (ii), INFORMATION DISCLOSURE STATEMENT, PTO FORM 1449 and a copy of each of the cited references re Application Serial No. 08/562,727 are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Hon. Commissioner of Patents and Trademarks, Washington, DC 20231, Attn: Box DD on this 15th day of May, 1996.



Barry A. Stein



Form PTO-1449 (Rev. 7-50)  
U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Sheet 1 of 2

Applicant : Valentine J. Rhodes, M.D.  
Serial No. : 08/562,727  
Filing Date: November 27, 1995  
Group :

LIST OF REFERENCES CITED BY APPLICANT

U.S. PATENT DOCUMENTS

Examiner Initials	Document No.	Date	Name	Class	Sub-class
et	3,657,744	4/1972	Ersek		
	4,047,252	9/1977	Liebig et al.		
	4,503,569	3/1985	Dotter		
	4,512,338	4/1985	Balko et al.		
	4,580,568	4/1986	Gianturco		
	4,655,771	4/1987	Wallsten		
	4,733,665	3/1988	Palmaz		
	4,740,207	4/1988	Kreamer		
	4,776,337	10/1988	Palmaz		
	4,795,458	1/1989	Regan		
	4,830,003	5/1989	Wolff et al.		
	4,856,516	8/1989	Hillstead		
	4,994,071	2/1991	MacGregor		
5,122,154	6/1992	Rhodes			

Applicant : Valentine J. Rhodes, M.D.  
Serial No. : 08/562,727  
Filing Date: November 27, 1995  
Group :

LIST OF REFERENCES CITED BY APPLICANT

U.S. PATENT DOCUMENTS

Examiner Initials	Document No.	Date	Name	Class	Sub-Class
ET	5,035,706	7/1991	Giantureo et al.		
	5,167,614	12/1992	Tessmann et al.		
	5,207,695	5/1993	Trout, III		
	5,275,622	1/1994	Lazarus et al.		
	5,306,286	4/1994	Stack et al.		
	5,383,892	1/1995	Cardon et al.		
	5,387,235	2/1995	Chuter		
	5,397,345	3/1995	Lazarus		
	5,423,885	6/1995	Williams		

OTHER PRIOR ART (including Author, Title, Date, Pages)

Examiner K. TRUONG Date Considered 7/28/96



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 APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	5

DATE MAILED:

**EXAMINER INTERVIEW SUMMARY RECORD**

All participants (applicant, applicant's representative, PTO personnel):

- (1) Barry Stein (3) \_\_\_\_\_  
 (2) Kevin Truong (4) \_\_\_\_\_

Date of interview 7/29/96

Type:  Telephonic  Personal (copy is given to  applicant  applicant's representative).

Exhibit shown or demonstration conducted:  Yes  No. If yes, brief description: \_\_\_\_\_

Agreement  was reached with respect to some or all of the claims in question.  was not reached.

Claims discussed: 1, 5, and 10

Identification of prior art discussed: \_\_\_\_\_

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: Claim 1, lines 11 and 23, the recitation "of the wall" has changed to -- surface --. Claim 5, line 3, the recitation "portion" has changed to -- surface --. Claim 10, line 3, after "interior" inserted -- surface --.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

- It is not necessary for applicant to provide a separate record of the substance of the interview.
- Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

Kevin Truong  
 Examiner's Signature

PTOL-413 (REV. 1-84)

ORIGINAL FOR INSERTION IN RIGHT HAND FLAP OF FILE WRAPPER



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 APPLICANT	ATTORNEY DOCKET NO.
33/562,727	11/27/95	RHODEP	V R1001/20002

330317-021  
 CAESAR RIVISE BERNSTEIN COHEN  
 AND POKOTILOV LTD  
 SEVEN PENN CENTER 12TH FLOOR  
 1635 MARKET STREET  
 PHILADELPHIA PA 19103-0212

TRUONG, K EXAMINER

ART UNIT	PAPER NUMBER
3309	6

07/31/96

DATE MAILED:

**NOTICE OF ALLOWABILITY**

**PART I.**

- This communication is responsive to Amendment date 5/6/96 and Interview 7/29/96.
- 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 1-15.
- The drawings filed on \_\_\_\_\_ 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. 2. 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:**

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Examiner's Amendment                        | - Notice of Informal Application, PTO-152 |
| <input checked="" type="checkbox"/> Examiner Interview Summary Record, PTOL-413 | - Notice re Patent Drawings, PTO-948      |
| - Reasons for Allowance   | - Listing of Bonded Draftsmen             |
| - Notice of References Cited, PTO-892   | - Other                                   |
| <input checked="" type="checkbox"/> Information Disclosure Citation, PTO-1449   |   |

Serial Number: 08/

-2-

Art Unit: 3309

**Part III EXAMINER'S AMENDMENT**

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Barry Stein on July 29, 1996.

2. The application has been amended as follows:

In claim 1, lines 11 and 23, the recitation "of the wall" has been changed to ~~--surface--~~.

In claim 5, line 3, the recitation "portion" has been changed to ~~--surface--~~.

In claim 10, line 3, after "interior" inserted ~~--surface--~~.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Truong whose telephone number is (703) 308-3767. The examiner can normally be reached Monday through Friday from 7:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Buiz can be reached at (703) 308-0871. The fax number for the Group is (703) 308-0758.





Serial Number: 08/

-3-

Art Unit: 3309

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-0858.

  
Kevin T. Truong  
July 29, 1996

  
Michael Powell Buiz  
Supervisory Patent Examiner  
GAU 3309  
7/29/98



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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

33801/231  
CAESAR NIVISE BERNSTEIN COHEN  
AND POKOTILOV LTD  
SEVEN PENN CENTER 12TH FLOOR  
1635 MARKET STREET  
PHILADELPHIA PA 19103-2212

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
08/562,727	11/27/95	015	TRUONG, K	3309 07/31/96
First Named Applicant	RHODES, VALENTINE J.			

TITLE OF INVENTION INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 R1001/20002	606-191.000	060	UTILITY	YES	\$625.00	10/31/96

**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.**

PATENT AND TRADEMARK OFFICE COPY

PTOL-85B (REV. 4-94) (0651-0033)



*Copy*

PATENT

B  
#37

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION

APPLICANT : Valentine J. Rhodes  
 SERIAL NO. : 08/562,727  
 FILED : November 27, 1995  
 FOR : INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS  
 GROUP ART UNIT : 3309  
 EXAMINER : Kevin Truong

SUBMISSION OF FORMAL DRAWINGS

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

Attention: Official Draftsman

Sir:

Enclosed please find three (3) sheets of the formal drawings which should be placed in the file of this application.

Respectfully submitted,

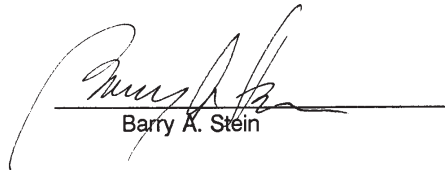
CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

October 7, 1996

By *Barry A. Stein*  
 Barry A. Stein  
 12th Floor, Seven Penn Center  
 1635 Market Street  
 Philadelphia, PA 19103-2212  
 (215) 567-2010

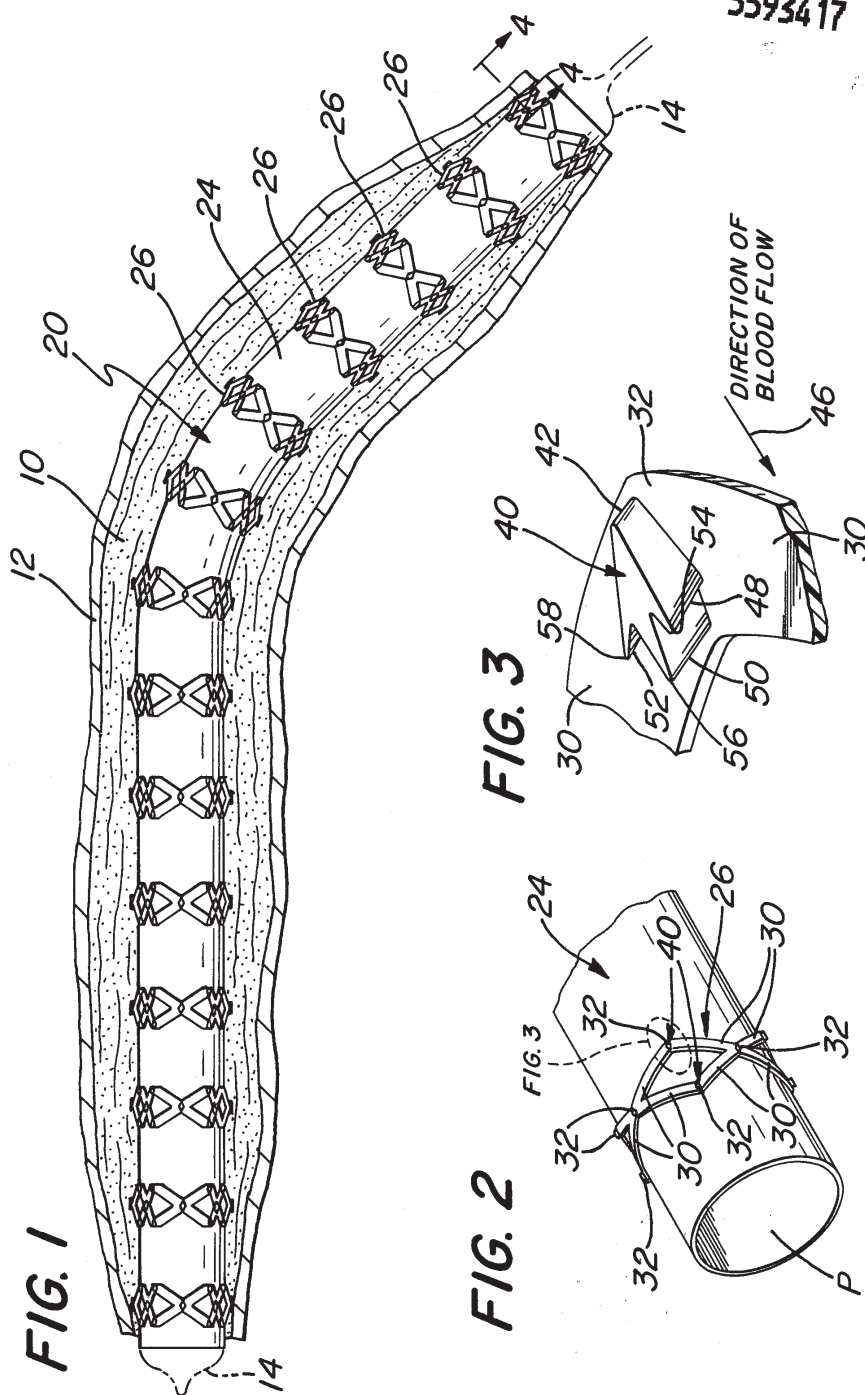
CERTIFICATE OF MAILING

I hereby certify that the foregoing SUBMISSION OF FORMAL DRAWINGS, and three (3) sheets of the formal drawings, re Application Serial No. 08/562,727 are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Honorable Commissioner of Patents and Trademarks, Washington, D.C. 20231, this 7<sup>th</sup> day of October, 1996.

  
Barry A. Stein

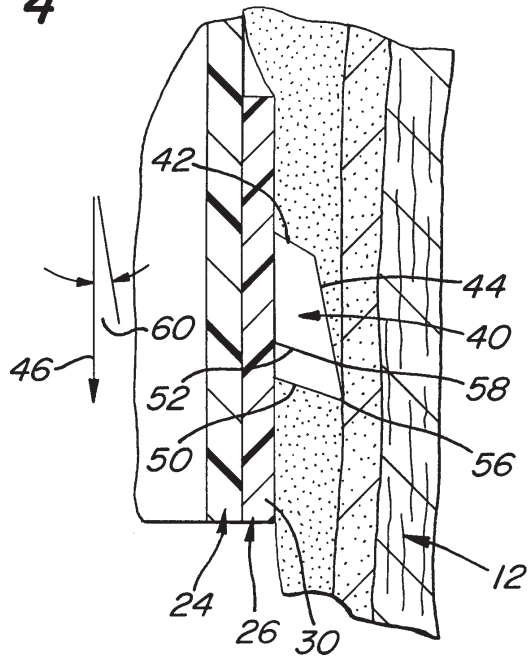
APPROVED FOR P. 1  
 BY CLASSIFICATION  
 606 191  
 DRAFTSMAN

5593417



Approved  
U.S. FIG.  
BY  
CLASS. INDEXING  
SECTION

**FIG. 4**



**FIG. 5**

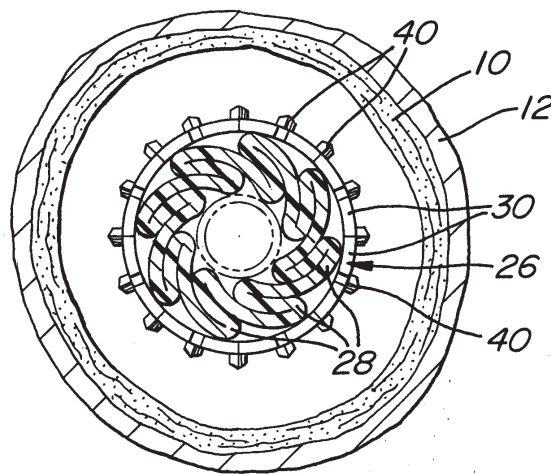
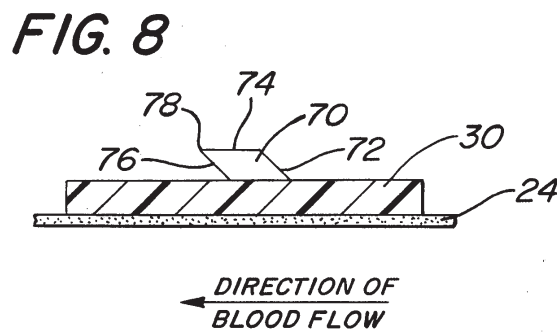
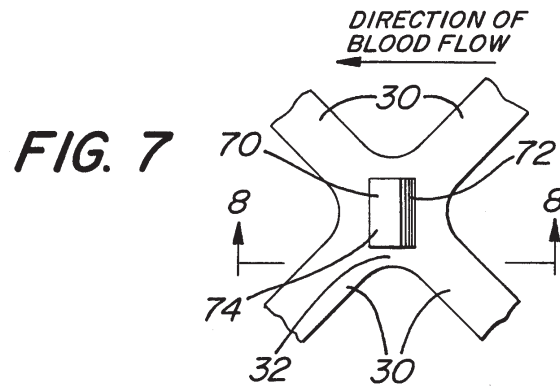
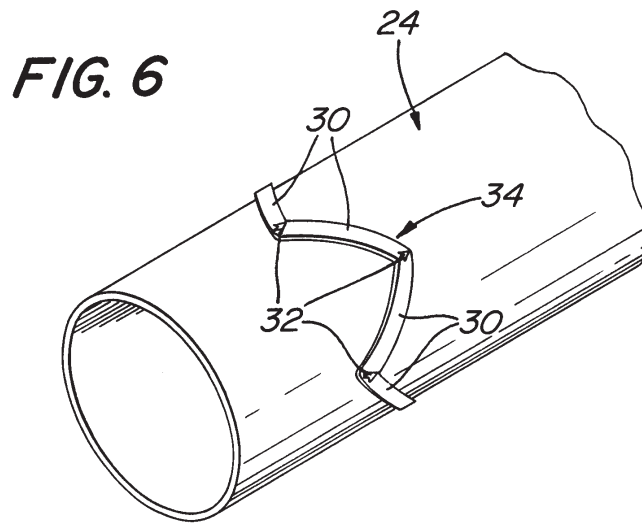


FIG. 6  
BY KLAS SUGALASS  
ATTORNEYS



**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		2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)	
33M1/0731 CAESAR RIVISE BERNSTEIN COHEN AND POKOTILOV LTD SEVEN PENN CENTER 12TH FLOOR 1635 MARKET STREET PHILADELPHIA PA 19103-2212		INVENTOR'S NAME <u>Caesar, Rivise, Bernstein, Cohen &amp; Pokotilov</u>	
		Street Address <u>Publication Division</u>	
		City, State and ZIP Code <u>OCT - 9 1996</u>	
		CO-INVENTOR'S NAME	
		Street Address <u>DT</u>	
		City, State and ZIP Code	
<input type="checkbox"/> Check if additional changes are on reverse side			

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/562,727	11/27/95	015	TRUONG, K	3309 07/31/96
First Named Applicant	RHODES, VALENTINE J.			

TITLE OF INVENTION  
INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 R1001/20002	606-191.000	C60	UTILITY	YES	<del>645.00</del> 645.00	10/31/96

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 <u>Caesar, Rivise,</u> 2 <u>Bernstein, Cohen &amp;</u> 3 <u>Pokotilov, Ltd.</u>

DO NOT USE THIS SPACE

820 TL 03-0075 10/25/96 08562727  
82147 242 645.00CH

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)	
(1) NAME OF ASSIGNEE:	6a. The following fees are enclosed: <input type="checkbox"/> Issue Fee <input type="checkbox"/> Advance Order - # of Copies _____
(2) ADDRESS: (CITY & STATE OR COUNTRY)	6b. The following fees should be charged to: DEPOSIT ACCOUNT NUMBER <u>03-0075</u> (ENCLOSE PART C) <input checked="" type="checkbox"/> Issue Fee <input type="checkbox"/> Advance Order - # of Copies _____ <input type="checkbox"/> Any Deficiencies in Enclosed Fees
A. <input checked="" type="checkbox"/> This application is NOT assigned. <input type="checkbox"/> Assignment previously submitted to the Patent and Trademark Office. <input type="checkbox"/> Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS. PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.	The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above. (Authorized Signature) _____ (Date) <u>10/7/96</u> 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

PTOL-85B (REV. 4-94) (0851-0033)



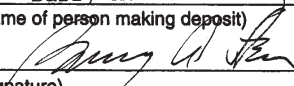
**Certificate of Mailing**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

on October 7, 1996  
(Date)

Barry A. Stein  
(Name of person making deposit)

  
(Signature)

October 7, 1996  
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Office of Information Systems, Patent and Trademark Office, Washington, D.C. 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, (Project 0651-0033), Washington, D.C. 20503. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents and Trademarks, Box Issue Fee, Washington, DC 20231.



The  
United  
States  
of  
America



PTO UTILITY GRANT  
Paper Number 8

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 enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.*

*Therefore, this*

United States Patent

*Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.*

*If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.*

*If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.*

*Bence Lehman*

Commissioner of Patents and Trademarks

*Melvinia Gary*  
Attest

Form PTO-1584 (Rev. 5/96)

(RIGHT INSIDE)

```

=> s stent
L1      722 STENT
=> s l1 or graft
      19629 GRAFT
L2      20157 L1 OR GRAFT
=> s l2 or projection or acute point

      165142 PROJECTION
      68895 ACUTE
      927015 POINT
      29 ACUTE POINT
          (ACUTE(W) POINT)

L3      184805 L2 OR PROJECTION OR ACUTE POINT
=> s l2 and projection
      165142 PROJECTION
L4      519 L2 AND PROJECTION
=> s l1 and projection
      165142 PROJECTION
L5      54 L1 AND PROJECTION
=> s l1 (p) projection
      165142 PROJECTION
L6      29 L1 (P) PROJECTION
=> s l1 (5) projection
MISSING OPERATOR 'L1 (5'
=> s l1 (5w) projection
      165142 PROJECTION
L7      3 L1 (5W) PROJECTION
=> d cit,kwic 1-3

```

1. 5,522,885, Jun. 4, 1996, Assembly tooling for an autologous tissue heart valve; Charles S. Love, et al., 623/2; 137/515.7; 251/365; 623/66, 901 [IMAGE AVAILABLE]

US PAT NO: 5,522,885 [IMAGE AVAILABLE] L7: 1 of 3

DETDESC:

DETD(22)

In . . . the inner stent 76 over the top of the assembly mandrel 72, aligning each of the posts 78 of the \*\*stent\*\* with the corresponding \*\*projection\*\* of the top portion of the mandrel. Next, the surgeon drapes the shedding cap 74 over the tissue covering the. . . .

2. 5,431,162, Jul. 11, 1995, Positioning method and apparatus for x-ray tomography; Phillip C. McArdle, 128/653.1; 378/162, 206 [IMAGE AVAILABLE]

US PAT NO: 5,431,162 [IMAGE AVAILABLE]

L7: 2 of 3

DRAWING DESC:

DRWD(5)

FIG. 3 is an isometric view which shows in detail the **stent** holder and the laser beam **projection** assembly which are components of the preferred embodiment of the positioning apparatus shown in FIGS. 1 and 2;

3. 5,167,614, Dec. 1, 1992, Prostatic stent; Terri L. Tessmann, et al., 604/8; 623/1 [IMAGE AVAILABLE]

US PAT NO: 5,167,614 [IMAGE AVAILABLE]

L7: 3 of 3

ABSTRACT:

A . . . one end, an outlet at the other end and a lumen extending from the inlet to the outlet. The preferred **stent** also includes at least one **projection** on the outer wall of the tubular member which enters the wall of the body passage when the stent is . . .

=> s l1 (10w) projection  
165142 PROJECTION

L8 9 L1 (10W) PROJECTION

=> d l8 1-8

1. 5,522,885, Jun. 4, 1996, Assembly tooling for an autologous tissue heart valve; Charles S. Love, et al., 623/2; 137/515.7; 251/365; 623/66, 901 [IMAGE AVAILABLE]

2. 5,431,162, Jul. 11, 1995, Positioning method and apparatus for x-ray tomography; Phillip C. McArdle, 128/653.1; 378/162, 206 [IMAGE AVAILABLE]

3. 5,167,614, Dec. 1, 1992, Prostatic stent; Terri L. Tessmann, et al., 604/8; 623/1 [IMAGE AVAILABLE]

4. 5,002,567, Mar. 26, 1991, Prosthetic heart valve; Gioachino Bona, et al., 623/2; 137/512.1, 527 [IMAGE AVAILABLE]

5. 4,759,759, Jul. 26, 1988, Bubble heart valve; David K. Walker, et al., 623/2, 900 [IMAGE AVAILABLE]

6. 4,705,516, Nov. 10, 1987, Setting for a cardiac valve; Hector D. Barone, et al., 623/2 [IMAGE AVAILABLE]

7. 4,699,611, Oct. 13, 1987, Biliary stent introducer; Russell W. Bowden, 604/51, 105, 165; 606/191 [IMAGE AVAILABLE]

8. 4,655,773, Apr. 7, 1987, Bicuspid valve prosthesis for an auriculo-ventricular cardiac aperture; Gino Grassi, 623/2 [IMAGE AVAILABLE]

=> d l8 cit, kwic 1

1. 5,522,885, Jun. 4, 1996, Assembly tooling for an autologous tissue heart valve; Charles S. Love, et al., 623/2; 137/515.7; 251/365; 623/66, 901 [IMAGE AVAILABLE]

US PAT NO: 5,522,885 [IMAGE AVAILABLE] L8: 1 of 9

DETDESC:

DETD(22)

In . . . the inner stent 76 over the top of the assembly mandrel 72, aligning each of the posts 78 of the \*\*stent\*\* with the corresponding \*\*projection\*\* of the top portion of the mandrel. Next, the surgeon drapes the shedding cap 74 over the tissue covering the. . .

=> d l8 cit, kwic 2-9

2. 5,431,162, Jul. 11, 1995, Positioning method and apparatus for x-ray tomography; Phillip C. McArdle, 128/653.1; 378/162, 206 [IMAGE AVAILABLE]

US PAT NO: 5,431,162 [IMAGE AVAILABLE] L8: 2 of 9

DRAWING DESC:

DRWD(5)

FIG. 3 is an isometric view which shows in detail the \*\*stent\*\* holder and the laser beam \*\*projection\*\* assembly which are components of the preferred embodiment of the positioning apparatus shown in FIGS. 1 and 2;

3. 5,167,614, Dec. 1, 1992, Prostatic stent; Terri L. Tessmann, et al., 604/8; 623/1 [IMAGE AVAILABLE]

US PAT NO: 5,167,614 [IMAGE AVAILABLE] L8: 3 of 9

ABSTRACT:

A . . . one end, an outlet at the other end and a lumen extending from the inlet to the outlet. The preferred \*\*stent\*\* also includes at least one \*\*projection\*\* on the outer wall of the tubular member which enters the wall of the body passage when the stent is. . .

4. 5,002,567, Mar. 26, 1991, Prosthetic heart valve; Gioachino Bona, et

al., 623/2; 137/512.1, 527 [IMAGE AVAILABLE]

US PAT NO: 5,002,567 [IMAGE AVAILABLE]

L8: 4 of 9

DETDESC:

DETD(14)

In . . . the projection 9 is constituted by an annular body of semicircular cross-section which projects from the inner wall of the **\*\*stent\*\*** 2 around its entire circumference. The **\*\*projection\*\*** 9 thus has two sides which face in opposite directions, towards the two axial ends of the stent 2 respectively.

5. 4,759,759, Jul. 26, 1988, Bubble heart valve; David K. Walker, et al., 623/2, 900 [IMAGE AVAILABLE]

US PAT NO: 4,759,759 [IMAGE AVAILABLE]

L8: 5 of 9

DETDESC:

DETD(7)

The **\*\*stent\*\*** boundary was defined as shown in FIG. 1. The **\*\*projection\*\*** of the stent boundary on the x-y plane was idealized as an ellipse with short side "a" and long side. . . .

6. 4,705,516, Nov. 10, 1987, Setting for a cardiac valve; Hector D. Barone, et al., 623/2 [IMAGE AVAILABLE]

US PAT NO: 4,705,516 [IMAGE AVAILABLE]

L8: 6 of 9

DETDESC:

DETD(9)

With . . . arrows in FIG. 2, and preferably teeth 3 of the valve member c and the circumferential groove 2 of the **\*\*stent\*\*** b are located completely outside the **\*\*projection\*\*** of the cardiac opening in that first direction.

CLAIMS:

CLMS(3)

3. . . . through the cardiac opening in a first direction, and the teeth of the valve member and the groove of the **\*\*stent\*\*** are adapted to

be located completely outside the **projection** of the cardiac opening in the first direction.

7. 4,699,611, Oct. 13, 1987, Biliary stent introducer; Russell W. Bowden, 604/51, 105, 165; 606/191 [IMAGE AVAILABLE]

US PAT NO: 4,699,611 [IMAGE AVAILABLE] L8: 7 of 9

DETDESC:

DETD(17)

From the foregoing it will be appreciated that the invention permits percutaneous placement of a tubular member, such as a biliary **stent** which, when placed, is intended to have an enlarged **projection** such as a Mallecot tip. The invention enables percutaneous placement of such a device but without the difficulty and discomfort. . . .

8. 4,655,773, Apr. 7, 1987, Bicuspid valve prosthesis for an auriculo-ventricular cardiac aperture; Gino Grassi, 623/2 [IMAGE AVAILABLE]

US PAT NO: 4,655,773 [IMAGE AVAILABLE] L8: 8 of 9

DETDESC:

DETD(24)

The basic outline of the **stent** (C-C1, D-D1) and the **projection** of the prongs (C-A-D, C1-A1-D1) are likewise illustrated in bold line.

9. 4,441,216, Apr. 10, 1984, Tissue heart valve and stent; Marian I. Ionescu, et al., 623/2, 900 [IMAGE AVAILABLE]

US PAT NO: 4,441,216 [IMAGE AVAILABLE] L8: 9 of 9

SUMMARY:

BSUM(21)

The . . . of the tabs. Generally this distance of inward projection is limited to forty thousandths of an inch in the naked **stent**, i.e., no more than forty thousandths inward **projection** of the bare plastic tab. The width of the tabs is also limited to aid in preventing the bottoms of. . . .

=



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
08/562,727	5593417	3309	9200 3 10022 1040 103

**Change of Address/Power of Attorney**

The following fields have been set to Customer Number 3000 on

- Correspondence Address
- Power of Attorney
- Maintenance Fee Address

The address of record for Customer Number 3000 is:

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOV, LTD.  
11TH FLOOR, SEVEN PENN CENTER  
1635 MARKET STREET  
PHILADELPHIA, PA 19103-2212

The Practitioners of record for Customer Number 3000 are:

**PTO INSTRUCTIONS:**

Please take the following action when the correspondence address has been changed to a customer number:

- 1) Add 'ADDRESS CHANGE TO CUSTOMER NUMBER' on the next available content line of the File Jacket.
- 2) Put a line through the old address on the File Jacket and enter the Customer Number as the new address.
- 3) File this Notice in the File Jacket.

Please take the following action when the correspondence address has NOT been changed:

- 1) File this Notice in the File Jacket



**PATENT APPLICATION FEE DETERMINATION RECORD**

Effective October 1, 1995

Application or Docket Number

562127

**CLAIMS AS FILED - PART I**

(Column 1) (Column 2)

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	15 minus 20 = *	*
INDEPENDENT CLAIMS	1 minus 3 = *	*
MULTIPLE DEPENDENT CLAIM PRESENT		

\* If the difference in column 1 is less than zero, enter "0" in column 2

**SMALL ENTITY**

OR

**OTHER THAN SMALL ENTITY**

RATE	FEE	RATE	FEE
	375.00		750.00
x\$11=		x\$22=	
x39=		x78=	
+125=		+250=	
TOTAL	375	TOTAL	

**CLAIMS AS AMENDED - PART II**

(Column 1) (Column 2) (Column 3)

AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus	**
Independent	* Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM			

**SMALL ENTITY**

OR

**OTHER THAN SMALL ENTITY**

RATE	ADDITIONAL FEE	RATE	ADDITIONAL FEE
x\$11=		x\$22=	
x39=		x78=	
+125=		+250=	
TOTAL ADDIT. FEE		TOTAL ADDIT. FEE	

(Column 1) (Column 2) (Column 3)

AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus	**
Independent	* Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM			

**SMALL ENTITY**

OR

**OTHER THAN SMALL ENTITY**

RATE	ADDITIONAL FEE	RATE	ADDITIONAL FEE
x\$11=		x\$22=	
x39=		x78=	
+125=		+250=	
TOTAL ADDIT. FEE		TOTAL ADDIT. FEE	

(Column 1) (Column 2) (Column 3)

AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus	**
Independent	* Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM			

**SMALL ENTITY**

OR

**OTHER THAN SMALL ENTITY**

RATE	ADDITIONAL FEE	RATE	ADDITIONAL FEE
x\$11=		x\$22=	
x39=		x78=	
+125=		+250=	
TOTAL ADDIT. FEE		TOTAL ADDIT. FEE	

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."  
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.



PACE DATA ENTRY CODING SHEET

U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office

1ST EXAMINER Forney DATE 10/29/94  
2ND EXAMINER

APPLICATION NUMBER  
**08/562727**

TYPE APPL  MONTH DAY YEAR  
11 07 95

SPECIAL HANDLING  GROUP ART UNIT  
3309

CLASS 6006 SHEETS OF DRAWING 53

TOTAL CLAIMS 15 INDEPENDENT CLAIMS 11

SMALL ENTITY?

FILING DATE MONTH DAY YEAR  
03 15 95

FOREIGN LICENSE

ATTORNEY DOCKET NUMBER  
81801766669

CONTINUITY DATA

CONT STATUS CODE	CONT CODE	PARENT APPLICATION SERIAL NUMBER	PCT APPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH DAY YEAR
			P C T / /		
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PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH DAY YEAR

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POSITION	ID NO.	DATE
CLASSIFIER		1/17-96
EXAMINER		1/29/96
TYPIST	21	1/29/96
VERIFIER	210	1-29-96
CORPS CORR.		
SPEC. HAND		
FILE MAINT.		
DRAFTING		

INDEX OF CLAIMS

Claim	Final	Original	Date
1	1	1	✓
2	2	2	0
3	3	3	0
4	4	4	0
5	5	5	0
6	6	6	0
7	7	7	0
8	8	8	0
9	9	9	✓
10	10	10	✓
11	11	11	✓
12	12	12	✓
13	13	13	✓
14	14	14	✓
15	15	15	✓
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Claim	Final	Original	Date
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SYMBOLS  
 ✓ ..... Rejected  
 = ..... Allowed  
 - (Through numerical) Canceled  
 + ..... Restricted  
 N ..... Non-elected  
 I ..... Interference  
 A ..... Appeal  
 O ..... Objected

(LEFT INSIDE)



SEARCHED			
Class	Sub.	Date	Exmr.
606	198	} 3/20/96	KT
	191		
623	1		
	12		
606	194	} 3/21/96	KT
	195		
	108		
604	96		
	104		
Update	Searched	7/29/96	KT

SEARCH NOTES		
<u>Consulted</u>	Date	Exmr.
William Lewis in class 606	3/22/96	KT
Michael Thaler in class 606	3/22/96	KT
APS Searched	7/29/96	KT

INTERFERENCE SEARCHED			
Class	Sub.	Date	Exmr.
As the above		7/29/96	KT

(RIGHT OUTSIDE)