

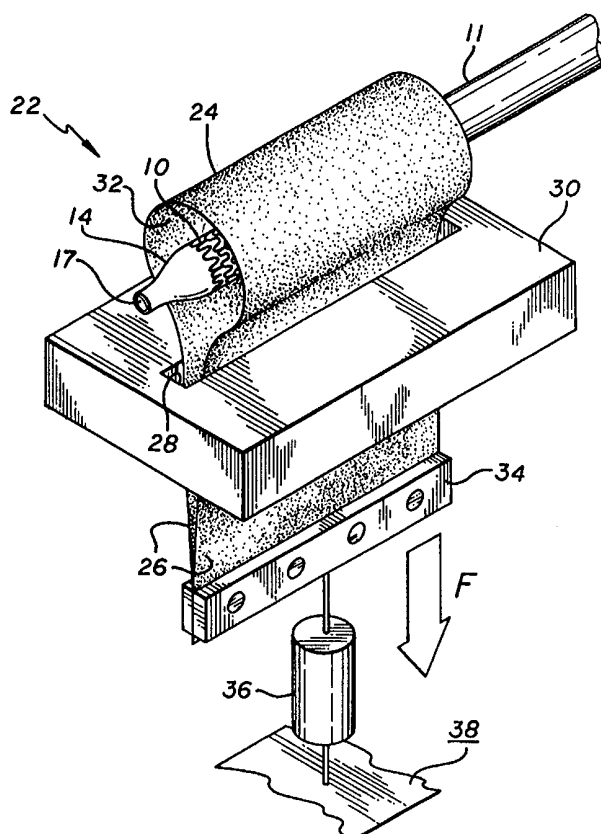


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06	A1	(11) International Publication Number: WO 99/55255 (43) International Publication Date: 4 November 1999 (04.11.99)
(21) International Application Number: PCT/US99/09050 (22) International Filing Date: 27 April 1999 (27.04.99) (30) Priority Data: 09/069,010 28 April 1998 (28.04.98) US (71) Applicant (for all designated States except US): ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 85054-8167 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): MORALES, Stephen, A. [-/US]; 811 E. Dana street, Mountain View, CA 94041 (US). (74) Agents: MAHER, Pamela, G. et al.; Fulwider Patton Lee & Utecht, LLP, 10th floor, 10877 Wilshire Boulevard, Los Angeles, CA 90024 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: STENT CRIMPING TOOL AND METHOD OF USE**(57) Abstract**

A stent (10) crimping tool for firmly and uniformly crimping a stent onto a balloon catheter (14). The stent crimping tool (22) is constructed by curving and overlapping the ends of a flexible Mylar sheet and inserting the end portions through a thin slot of a rigid panel. The uncrimped stent and catheter assembly are placed within a cylindrical space (32) formed by the curved and overlapping flexible sheet. A force is applied to the overlapping end portions to pull the flexible sheet through the slot (28) thereby collapsing the cylindrical space and crimping the stent, held therein, onto the balloon. In another embodiment, the crimping tool is constructed from a mount (46) having a grooved top with steeply sloped sides. The uncrimped catheter-stent assembly is placed on the mount and rests within the groove. A flexible sheet of Mylar is draped over the catheter-stent assembly and a downward force is applied to the end portions of the flexible sheet. This downward force places the flexible sheet in tension thereby compressing the catheter-stent assembly between it and the mount. Accordingly, the stent is crimped onto the balloon catheter.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

STENT CRIMPING TOOL AND METHOD OF USEBACKGROUND OF THE INVENTION

The present invention relates to an apparatus for loading a tubular graft, such as a stent, onto the distal end of a catheter assembly of the kind used, for example, in percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA) procedures.

5 In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral arteries and advanced through the vasculature until the distal end of the guiding catheter is in the ostium. A guide wire and a dilatation catheter having a balloon on the distal end are introduced through the guiding catheter with the guide wire sliding within the dilatation catheter. The guide wire
10 is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guide wire until the dilatation balloon is properly positioned across the arterial lesion. Once in position across the lesion, a flexible and expandable balloon is inflated to a predetermined size with a radiopaque liquid at relatively high pressures to radially compress the atherosclerotic plaque of the lesion against
15 the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in angioplasty.

20 In angioplasty procedures of the kind referenced above, restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the development of restenosis and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside
25 the artery at the lesion. The stent is crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site,

-2-

the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter. The stent also may be of the self-expanding type.

Since the catheter and stent travel through the patient's vasculature, and probably through the coronary arteries, the stent must have a small delivery diameter and must
5 be firmly attached to the catheter until the physician is ready to implant it. Thus, the stent must be loaded onto the catheter so that it does not interfere with delivery, and it must not come off the catheter until it is implanted.

In procedures where the stent is placed over the balloon portion of the catheter, it is necessary to crimp the stent onto the balloon portion to reduce its diameter and to prevent
10 it from sliding off the catheter when the catheter is advanced through the patient's vasculature. Non-uniform crimping can result in sharp edges being formed along the now uneven surface of the crimped stent. Furthermore, non-uniform stent crimping may not achieve the desired minimal profile for the stent and catheter assembly. Where the stent is not reliably crimped onto the catheter, the stent may slide off the catheter and into the patient's vasculature
15 prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Therefore, it is important to ensure the proper crimping of a stent onto a catheter in a uniform and reliable manner.

This crimping is often done by hand, which can be unsatisfactory due to the uneven application of force resulting in non-uniform crimps. In addition, it is difficult to
20 visually judge when a uniform and reliable crimp has been applied.

Some self-expanding stents are difficult to load by hand onto a delivery device such as a catheter. Furthermore, the more the stent is handled the higher the likelihood of human error, which would be antithetical to a properly crimped stent. Accordingly, there is a need in the art for a device for reliably crimping a stent onto a catheter.

25 There have been attempts at devising a tool for crimping a stent onto a balloon delivery catheter. An example of such a tool comprises a series of plates having substantially flat and parallel surfaces that move in a rectilinear fashion with respect to each other. A stent carrying catheter is disposed between these surfaces, which surfaces crimp the stent onto the outside of the catheter by their relative motion and applied pressure. The plates have multiple
30 degrees of freedom and may have force-indicating transducers to measure and indicate the force applied to the catheter during crimping of the stent.

Another stent loading tool design is comprised of a tubular member housing a bladder. The bladder is inside a guide catheter. The tubular member and bladder are constructed to hold a stent that is to be crimped onto a balloon catheter assembly. Upon placement of the stent over the balloon portion of the catheter, a valve in the loading tool is
5 activated to inflate the bladder. The bladder compresses the stent radially inward to a reduced diameter onto the balloon portion of the catheter to achieve a snug fit. In this way, the stent is crimped onto the distal end of a balloon catheter with a minimum of human handling. The foregoing stent crimping tools are disclosed in, for example, U.S. Patent Nos. 5,437,083 and 5,546,646 to Williams et al.

10 Yet another stent crimping tool is known in the art as the BARD XT, which is actually a stent loader. It is constructed of a tubular body with a ball at one end connected to a plurality of long, thin strips passing through the rigid tubular body. An uncrimped stent is placed over the plurality of long, thin strips, which hold the stent in an expanded state. The balloon portion of a catheter is inserted into the cylindrical space formed by the plurality of
15 strips. When the user pulls on the ball while holding the tubular body against the stent, the strips are slid from beneath the stent and the stent is transferred onto the balloon portion.

Still another conventional stent crimping tool is manufactured by Johnson & Johnson and appears similar to a hinged nutcracker. Specifically, the tool is comprised of two hand operated levers hinged at one end and gripped in the palm of the hand at the opposite end.
20 A cylindrical opening holding a crimping tube is provided through the mid-portion of the tool to receive therein a stent loaded onto a balloon catheter. The crimping operation is performed by the user squeezing the handle thereby pressing the crimping tube which in turn pinches the stent onto the balloon catheter.

SUMMARY OF THE INVENTION

25 Both PTCA and PTA procedures have become commonplace in treating stenoses or lesions in blood vessels and coronary arteries. In approximately 35% to 40% of the procedures, restenosis may develop requiring a further angioplasty, atherectomy or bypass procedure to return the patency of the vessel. Intravascular stents are now being deployed after PTCA and PTA procedures, and after atherectomies, in order to help prevent the development

-4-

of restenosis. Importantly, such stents, mounted on the balloon portion of a catheter, must be tightly crimped to provide a low profile delivery diameter, and to ensure that the stent stays on the balloon until the balloon is expanded and the stent is implanted in the vessel.

The present invention is directed to a crimping tool that can repeatedly provide
5 a uniform and tight crimp to ensure the low profile diameter of the stent on the balloon portion of the catheter, and to ensure that the stent remains firmly attached until it is implanted in the vessel by expanding the balloon. More precisely, the present invention is directed to a tool for crimping a stent onto a balloon catheter comprising a sheet of flexible material having a central portion and end portions, wherein the sheet is curved so that the end portions overlap. The
10 present invention tool further comprises a rigid panel having a top side and a bottom side, and having a thin slot therethrough, a cylindrical space defined by the curved sheet, wherein the uncrimped stent is placed over the catheter to form a catheter-stent assembly, and wherein the catheter-stent assembly is disposed within the cylindrical space, wherein the overlapping end portions pass through the slot of the rigid panel so that the cylindrical space is disposed at the
15 top side and the overlapping end portions are at the bottom side, and wherein the user pulls on the overlapping ends to collapse the sheet forming a significantly narrower cylindrical space thereby crimping the stent onto the catheter. In the preferred embodiment, the sheet of flexible material is made of Mylar. Further, to reduce friction between the Mylar sheet and the rigid panel, it is desirable to have a rounded edge around the thin slot.

20 To maximize the crimp on the stent to closely approximate the circle of the balloon catheter, the radius of curvature of the Mylar should not be less than the radius of curvature of the crimped stent. This demands that at the transition between the crimping portion of the Mylar and the part that is pulled through the thin slot, the Mylar must be plastically deformed. Indeed, the Mylar sheet undergoes a significant amount of stress at the
25 point where it slides into the thin slot because, by design, it is expected to undergo a 180 degree turn.

If the Mylar sheet were preformed or prestressed, it might be better suited to achieving a near perfect circle. The perfect circle would translate to a more circular shape crimp on the stent. Also, the slot size could be reduced, which would allow an even closer
30 approximation of the cylindrical shape over smaller sized balloons and stents.

-5-

Optionally, a rigid mandrel may be disposed within the guide wire lumen of the balloon catheter to help the structure maintain its shape during the crimping process. Thus, as the sheet squeezes down on the stent to crimp it to the balloon, the rigid mandrel resists the downward force and prevents the balloon from collapsing and losing its shape longitudinally.

5 In an alternative embodiment, the present invention stent crimping tool can be adapted to an actuator. The actuator may be spring loaded or pneumatically operated. For example, the user would initiate the actuator by moving a lever to release the spring which is biased to pull the overlapping end portions away from the panel thus tightly collapsing the cylindrical space thereby crimping the stent onto the balloon catheter. Alternatively, a piston
10 disposed inside a fluid operated cylinder is connected to the overlapping end portions of the sheet. When actuated, the cylinder fills with fluid thereby displacing the piston and pulling the overlapping end portions away from the rigid panel thereby again collapsing the cylindrical space around the catheter-stent assembly and performing the stent crimping operation. The foregoing are examples of time saving, high force generating devices to be preferably
15 incorporated into a high production procedure.

 In an alternative embodiment, the present invention is directed to a tool for crimping a stent onto a catheter wherein the tool is mounted to a fixture, comprising a sheet of flexible material having a central portion and opposite end portions, a mount having a raised end grooved support surface with sloping sides, mounted to the fixture, wherein the uncrimped
20 stent is mounted on the catheter and the catheter-stent assembly is placed on the grooved support surface which corresponds to the features of the stent, wherein the user curves the sheet to conform the central portion of the flexible sheet to the catheter-stent assembly, and so that the end portions overlie the sloping sides of the mount, and whereby the user pulls on the end portions to crimp the stent onto the catheter. In the preferred embodiment, the grooved
25 support surface has a preferably semicircular cross-sectional shape. Furthermore, the sloping sides of the mount have low friction surfaces. Moreover, the sheet of flexible material is preferably made from Mylar.

 During the stent crimping operation, the Mylar is pulled down over the mount, effectively squeezing the stent over the balloon portion of the catheter and the mount. By
30 forcing at least one row of cells in the stent length to collapse, the stent should theoretically fit

-6-

over the balloon perfectly, assuming correct sizing of the semicircular mount and assuming negligible friction between the stent and the Mylar sheet.

To insure secure and proper stent crimping, the Mylar should be released and the catheter-stent assembly rotated, and the foregoing process repeated. Again, an optional
5 mandrel can be inserted into the guide wire lumen of the balloon catheter. During the repeated stent crimping process, the limit of deformation and crimping is reached when the radial forces encounter the mandrel, which resist further deformation and resultant decreases in the stent diameter.

The present invention tool is thus capable of homogeneously and precisely
10 crimping a stent onto a balloon catheter. Such a crimping tool is highly useful to cardiologists, for example. Such physicians are constantly concerned with proper deployment of the stent within the patient that is desirable to have a consistently and reliably crimped stent. The present invention tool is further a time saver, because the stent crimping procedure can be performed efficiently and quickly. Indeed, these and other advantages of the present invention will become
15 apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view partially in section, depicting a stent that has been crimped onto a delivery catheter and disposed within a vessel.

20 FIG. 2 is a perspective view of a preferred embodiment stent crimping tool showing the curved flexible sheet passing through a slot formed in a rigid panel.

FIG. 3 is a side elevational view of the embodiment shown in FIG. 2.

FIGS. 4A, 4B, and 4C depict an alternative embodiment wherein the flexible sheet is creased or prestressed to create 90 degree angles that interact with the edges of the
25 slot.

-7-

FIGS 5A and 5B are front elevational and side elevational views, respectively, of an alternative embodiment stent crimping tool using a mount.

FIG. 6 is a front elevational view of the alternative embodiment shown in FIG. 5A, wherein the stent is undergoing the crimping procedure.

5 FIG. 7 is a front elevational view of the embodiment shown in FIG 5A, wherein the pressure on the flexible sheet has been released to rotate the catheter-stent assembly.

FIG. 8 is a front elevational view of the alternative embodiment shown in FIG. A wherein the flexible sheet is pulled downward to continue the crimping procedure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 FIG. 1 illustrates intravascular stent 10 which is mounted onto delivery catheter
11. Stent 10 generally comprises a plurality of radially expandable cylindrical elements 12
disposed generally coaxially and interconnected by members 13 disposed between adjacent
cylindrical elements 12. Delivery catheter 11 has an expandable portion or balloon 14 for
expanding stent 10 within coronary artery 15 or other vessel such as saphenous veins, carotid
15 arteries, arteries, and veins. Artery 15, as shown in FIG. 1, has dissected lining 16 which has
occluded a portion of the arterial passageway.

Delivery catheter 11 onto which stent 10 is mounted is essentially the same as
a conventional balloon dilatation catheter for angioplasty procedures. Balloon 14 may be
formed of suitable materials such as polyethylene, polyvinyl chloride, polyethylene terephthalate
20 and other like polymers. In order for stent 10 to remain in place on balloon 14 during delivery
to the site of the damage within artery 15, stent 10 is compressed onto balloon 14. This
compressing step is known as crimping.

An optional retractable protective delivery sleeve 20 may be provided to further
ensure that stent 10 stays in place on balloon 14 of delivery catheter 11 and to prevent abrasion
25 of the body lumen by the open surface of stent 10 during delivery to the desired arterial
location. Other means for securing stent 10 onto balloon 14 may also be used, such as

providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion of balloon 14.

In order to implant stent 10, it is first mounted onto inflation balloon 14 on the distal extremity of delivery catheter 11. Stent 10 is crimped down onto balloon 14 to ensure
5 a low profile. The present invention addresses this crimping procedure.

The catheter-stent assembly can be introduced into the patient's vasculature through processes known in the art. Briefly, guide wire 18 is disposed across the arterial section where an angioplasty or atherectomy has been performed requiring a follow-up stenting procedure. In some cases, the arterial wall lining may be detached so that guide wire 18 is
10 advanced past detached or dissected lining 16 and the catheter-stent assembly is advanced over guide wire 18 within artery 15 until stent 10 is directly under detached lining 16. Prior to inflation of balloon 14, delivery sleeve 20 is retracted to expose stent 10. Depending on the balloon and stent assembly, a delivery sleeve may be unnecessary. Balloon 14 of delivery catheter 11 is then inflated using an inflation fluid. Expansion of balloon 14 in turn expands
15 stent 10 against artery 15. Next, balloon 14 is deflated and catheter 11 is withdrawn leaving stent 10 to support the damaged arterial section. As mentioned above, in order to ensure proper seating of stent 10 on balloon 14, and to ensure proper deployment of stent 10 at the site of the damage within artery 15, the stent crimping procedure is important. FIG. 2 is a perspective view of a preferred embodiment of the present invention stent crimping tool 22.
20 Specifically, the present invention is directed to tool 22 for crimping intravascular stent 10 onto balloon 14 of delivery catheter 11. In a preferred embodiment, stent crimping tool 22 includes sheet 24 that is made from a flexible material, such as Mylar. Flexible sheet 24 is curved and folded over so that end portions 26 thereof overlap as shown in the perspective view of FIG. 2. As part of the invention, end portions 26 of flexible sheet 24 are designed to pass through
25 thin slot 28 formed in rigid panel 30. Preferably, rigid panel 30 is locked or mounted to a stationary work bench, fixture, or the like. The mounting hardware has been omitted from FIG. 2 for the sake of clarity.

As seen in FIG. 2, after uncrimped stent 10 is loaded onto balloon 14 of delivery catheter 11, the catheter-stent assembly is placed within cylindrical space 32 formed by curving
30 and overlapping flexible sheet 24. End portions 26 are held together by optional clamp 34, which is used to apply a downward force represented by arrow F. This downward force F pulls

flexible sheet 24 through thin slot 28 and simultaneously collapses cylindrical space 32. Continued downward force F on end portion 26 stretches flexible sheet 24 taut around the catheter-stent assembly. Because of its size relative to thin slot 28, the catheter-stent assembly cannot pass through thin slot 28 while flexible sheet 24 can slide therethrough. This is therefore
5 the preferred mechanism used to crimp stent 10 onto balloon 14.

Optionally, a rigid mandrel (not shown) may be disposed within guide wire lumen 17 of delivery catheter 11 to help the structure maintain its shape during the crimping process. Thus, as flexible sheet 24 squeezes down on stent 10 to crimp it onto balloon 14, the rigid mandrel resists the downward force and prevents balloon 14 from collapsing completely
10 and losing its shape.

In addition, the present invention crimp stenting tool can be adapted for use with an actuator. For example, actuator 36 is anchored to ground 38 and can be embodied in a spring or a pneumatically operated piston within a cylinder. Actuator 36 can be manually operated, lever operated, pneumatically operated, or triggered by a similar technology known
15 in the art in order to generate the downward force F. Primarily, actuator 36 would be used as a time saving measure for high cyclic rates in a production line for example. Moreover, a machine generated downward force would be uniform and controlled so that very precise crimping of stent 10 can be achieved.

FIG. 3 provides a front elevational view of the present invention stent crimping
20 tool 22. In the instant of time shown here, the catheter-stent assembly has been positioned within cylindrical space 32 of curved flexible sheet 24 similar to the depiction in FIG. 2. As best seen in FIG. 3, rigid panel 30 is represented in a cross-section to best illustrate thin slot 28 with rounded edges 40. Rounded edges 40 are preferable because as tension is applied to flexible sheet 24 to draw the material through thin slot 28, flexible sheet 24 assumes a tear drop
25 shape that does not conform stent 10 to balloon 14 very well. Rounded edges 40 therefore reduce frictional drag on the movement of flexible sheet 24 through thin slot 28, and further insures a tighter crimp as flexible sheet 24 pulls the catheter-stent assembly against rounded edges 40.

Ideally, to maximize the crimp of stent 10 onto balloon 14, the radius of
30 curvature of cylindrical space 32 formed by flexible sheet 24 should not be less than or greater than but exactly the radius of the crimped stent. This demands that at the transition between

-10-

the crimping portion of flexible sheet 24 and the portion thereof that is pulled through thin slot 28, flexible sheet 24 is plastically deformed. Indeed, flexible sheet 24 undergoes a significant amount of stress at the point where it slides into thin slot 28 because, by design, it is expected to undergo a 90 degree turn. This is illustrated in the front elevational view of FIG. 4A. If flexible sheet 24 were preformed (i.e., prestressed) as seen in the front elevational view of FIG. 4B, it is possible to achieve a near perfect circle surrounding the catheter-stent assembly resulting in a symmetrical crimp as shown in FIG. 4A. To be sure, FIG. 4C provides a front elevational view of a preformed or prestressed flexible sheet 24 which is shown being pulled through thin slot 28 of rigid panel 30. Because the process is not complete and flexible sheet 24 has not been pulled through thin slot 28 sufficiently to remove slack, 90 degree turn kinks 42 do not coincide with rounded edges 40.

FIGS. 5-8 depict an alternative embodiment of the present invention. FIGS. 5A and 5B provide a front elevational and a side elevational view of an alternative embodiment of the present invention stent crimping tool 44. In this preferred embodiment, stent crimping tool 44 includes mount 46 operating in conjunction with flexible sheet 48. In the front elevational view of FIG. 5A, the present invention is shown in connection with an uncrimped catheter-stent assembly placed upon mount 46. To insure stability, mount 46 preferably includes a grooved surface to help center the catheter-stent assembly thereon. In particular, groove 50 preferably has a radius that approximates the catheter-stent assembly.

FIG. 5B is a side elevational view wherein flexible sheet 48 has been omitted to expose placement of the catheter-stent assembly on mount 46. In this view, it can be seen that stent 10 has already been loaded onto balloon 14 of catheter 11. In the preferred embodiment, mount 46 generally has a lengthwise dimension approximating the length of stent 10. Mount 46 is situated on a work surface so that it is stable and immobile during the crimping process.

Mount 46 can be fashioned from a rigid material known in the art. Importantly, mount 46 has steeply sloped side walls 52 to minimize frictional drag and interference with movement of flexible sheet 48 during the crimping process.

FIGS. 6-8 illustrate use of the present invention stent crimping tool 44. FIG. 6 provides a front elevational view of stent crimping tool 44 when a downward force is exerted at end portions 54 of flexible sheet 48. The downward force is represented by arrows labeled

-11-

F. This force places flexible sheet 48 in tension and compresses the catheter-stent assembly between flexible sheet 48 and mount 46. As seen in the previous exemplary embodiment, the present invention may be used with an optional rigid mandrel that is inserted into a guide wire lumen of balloon 14 to provide internal support during the crimping process.

5 In FIG. 7, the downward force and tension in flexible sheet 48 have been removed; this state is depicted with flexible sheet 48 having slack. In this state, it is possible to rotate the catheter-stent assembly to reorient the parts before undergoing the next crimping step. To this end, FIG. 8 shows downward force F being reapplied to end portions 54 of flexible sheet 48 to again resume compressing the catheter-stent assembly between flexible
10 sheet 48 and mount 46. The steps shown in FIGS. 6-8 are repeated until stent 10 is firmly crimped onto balloon 14.

As seen with the previous embodiment of the present invention, it is possible to mechanize or automate this process by use of actuators discussed earlier. Once the process is complete, the downward force F is removed to remove the tension from flexible sheet 48. The
15 crimped catheter-stent assembly can then be removed from the crimping tool 44.

In the preferred embodiment, groove 50 has a cradle or semicircular cross-sectional shape to support the catheter-stent assembly during the crimping process. Other cross-sectional shapes are contemplated, and may be useful for various purposes or to accommodate varying stent profiles. Groove 50 may be optionally coated, covered, or include
20 other surface features. Such surface features include optional ribs, contours, bumps, indentations, and the like to accommodate the features of the catheter-stent assembly, to provide support and stability, or to achieve frictional contact with the catheter-stent assembly to minimize twisting.

Mount 46 is preferably held inside another enclosure (not shown) for correct
25 alignment of stent 10 and balloon 14. Again, as mentioned earlier, flexible sheet 48 is preferably made from Mylar or the like and should drape over side walls 52 of mount 46. Correct sizing between stent 10 and flexible sheet 48 insures a perfect fit of stent 10 over balloon 14. This is assuming negligible friction between stent 10 and flexible sheet 48. In either the present embodiment as with the earlier embodiment, the catheter-stent assembly can
30 be rotated during the crimping process to insure a symmetrical, homogenous and even crimping of the stent to the balloon catheter.

-12-

The present invention is sterilized and intended to be used in a cath lab by a trained technician or cardiologist. More precisely, as is appreciated by those skilled in the art, the present invention crimping tool 22 is designed both for single use applications in a cath lab by a physician, or for multiple use applications in a sterile environment in a high volume
5 manufacturing facility. In such a manufacturing facility where sterile conditions exist, stent crimping tool 22 can be used repeatedly to crimp stents onto balloons until the mechanism wears out. Thus, repeated uses of the present invention are contemplated for controlled, sterile, environments, as are single use applications when operated by cath lab personnel.

Furthermore, the present invention crimping tool can be used with any stent that
10 is released without a delivery system. The crimping tool may also be sold alone, because its design is robust enough to undergo many uses.

Other modifications can be made to the present invention without departing from the scope thereof. The specific dimensions, procedural steps, and materials of construction are provided as examples, and substitutes are readily contemplated which do not
15 depart from the invention.

WHAT IS CLAIMED IS:

1. A tool for crimping a stent on to a balloon catheter by a user, comprising:
 - a sheet of flexible material having a central portion and end portions, wherein the sheet is curved so that the end portions overlap;
 - 5 a rigid panel having a top side and a bottom side, and having a thin slot therethrough;
 - a cylindrical space defined by the curved sheet, wherein the uncrimped stent is placed over the catheter to form a catheter-stent assembly, and wherein the catheter-stent assembly is disposed within the cylindrical space;
 - 10 whereby the overlapping end portions pass through the slot of the rigid panel so that the cylindrical space is disposed at the top side and the overlapping end portions are at the bottom side; and
 - whereby the user pulls on the overlapping ends to collapse the sheet forming the cylindrical space thereby crimping the stent onto the catheter.
2. The crimping tool of claim 1, wherein the sheet of flexible material includes a polymer.
3. The crimping tool of claim 1, wherein the sheet of flexible material includes Mylar.
4. The crimping tool of claim 1, wherein the thin slot has a rounded edge.
5. The crimping tool of claim 1, wherein the rigid panel includes a low friction surface area proximate to the thin slot.

-14-

6. The crimping tool of claim 1, wherein a mandrel is disposed within a guide wire lumen of the catheter.

7. The crimping tool of claim 1, wherein the overlapping ends is connected to a spring biased to pull the overlapping ends away from the rigid panel.

8. The crimping tool of claim 1, wherein the overlapping ends is connected to a pressurized piston contained in a cylinder that pulls the overlapping ends away from the rigid panel when a fluid is injected into the cylinder.

9. A method for crimping a stent on to a catheter, comprising the steps of:
providing a sheet of flexible material having a central portion and opposed end portions;

5 providing a rigid panel having a first side and an opposed second side, and
having a thin slot therethrough;

folding the sheet to curve the central portion to define a cylindrical space and to overlap the opposed end portions;

placing the stent over the catheter to form a catheter-stent assembly;

inserting the catheter-stent assembly into the cylindrical space;

10 passing the overlapping end portions through the thin slot from the first side toward the second side so that the central portion is adjacent the first side and the overlapping end portions are adjacent the second side;

translating the rigid panel along the sheet toward the curved translating the overlapping end toward the curved central portion; and

15 collapsing the cylindrical space to crimp the stent onto the catheter.

-15-

10. The method of claim 9, wherein the sheet of flexible material includes Mylar.

11. The method of claim 9, wherein the edge of the thin slot is rounded.

12. The method of claim 9, wherein the step of folding the sheet provides a radius of curvature of the sheet that is greater than a radius of curvature of the crimped stent.

13. The method of claim 9, wherein the method further comprises the step of rotating the catheter-stent assembly.

14. A tool for crimping a stent onto a catheter by a user, wherein the tool is mounted to a fixture, comprising:

a sheet of flexible material having a central portion and opposite end portions;
a mount having a raised and grooved support surface with substantially smooth

5 sides, mounted to the fixture;

whereby the uncrimped stent is mounted on the catheter and the catheter-stent assembly is placed on the grooved support surface;

whereby the user curves the sheet to conform the central portion to the catheter-stent assembly, and so that the end portions overlie the sides of the mount; and

10 whereby the user pulls on the end portions to crimp the stent onto the catheter.

15. The crimping tool of claim 14, wherein the grooved support surface has a semicircular cross-sectional shape.

-16-

16. The crimping tool of claim 14, wherein the sides of the mount have low friction surfaces.

17. The crimping tool of claim 14, wherein the sheet includes a polymer.

18. The crimping tool of claim 14, wherein a diameter of the grooved support surface approximates a diameter of a crimped stent.

19. A method for crimping a stent on to a catheter, comprising the steps of:
providing a sheet of flexible material having a central portion and opposite end portions;

5 providing a mount having a first surface and a second surface intersected by sloping walls, wherein the first surface includes a raised and grooved support surface, and the mount is attached to the fixture;

mounting the uncrimped stent onto the catheter;

placing the catheter-stent assembly on the grooved support surface;

covering the catheter-stent assembly with the sheet;

10 curving the sheet to at least partially conform the central portion to the catheter-stent assembly and so that the end portions overlie the sloping walls of the mount; and

pulling on the end portions to displace the sheet along the sloping walls toward the second surface to crimp the stent onto the catheter.

20. The method of claim 19, wherein the sheet of flexible material includes a polymer.

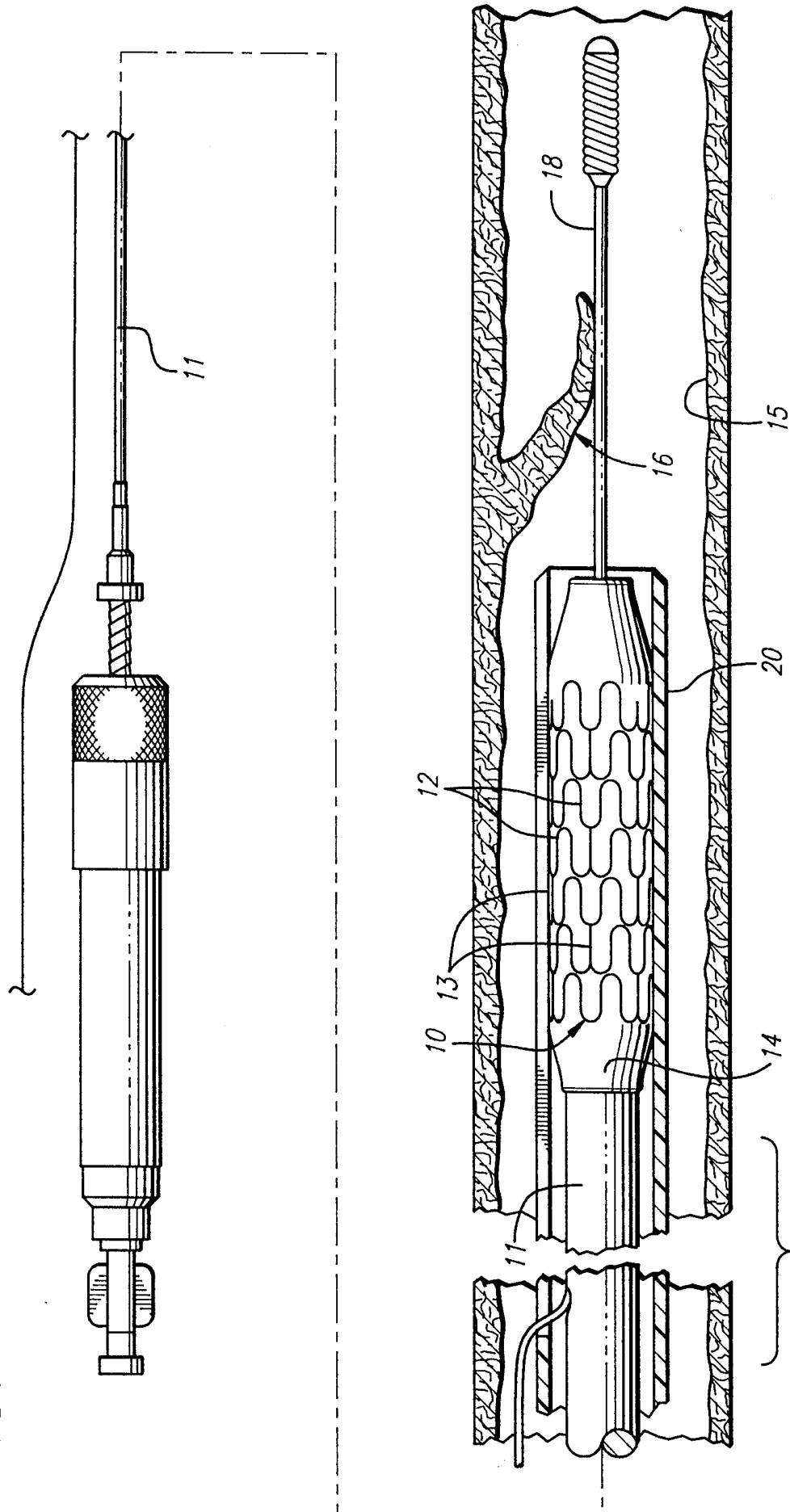
-17-

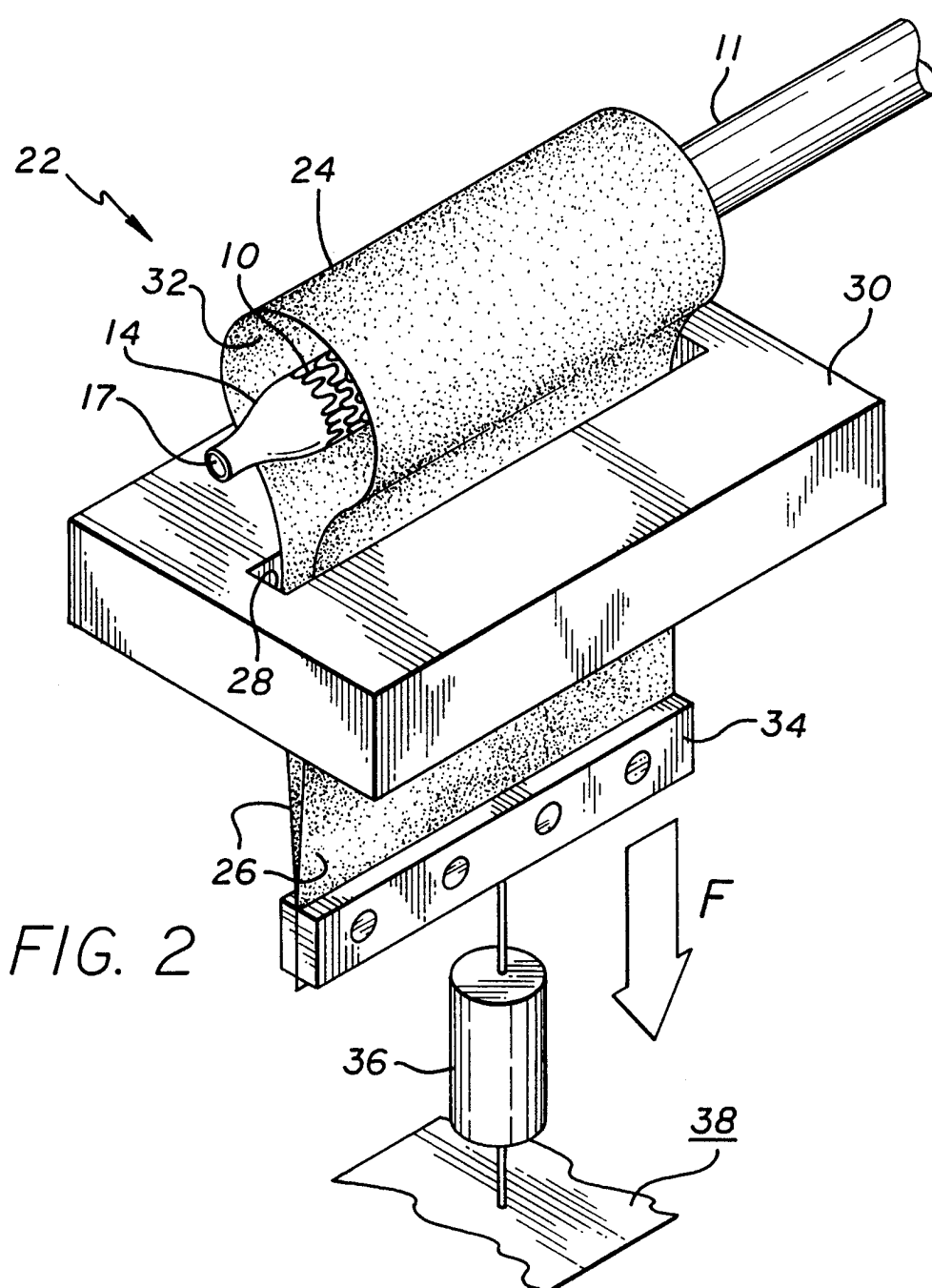
21. The method of claim 19, wherein the step of curving the sheet includes folding the sheet to approximate a diameter of the uncrimped stent.

22. The method of claim 19, wherein the method further comprises the step of rotating the catheter-stent assembly.

23. The method of claim 19, wherein the method further comprises the steps of providing a biasing member attached to the end portions, and actuating the biasing member to bias the end portions along the sloping walls toward the second surface.

FIG. 1





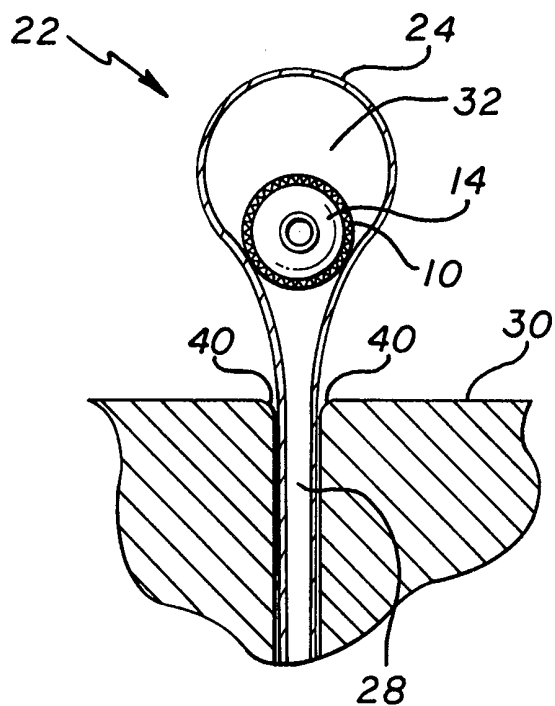


FIG. 3

FIG. 4A

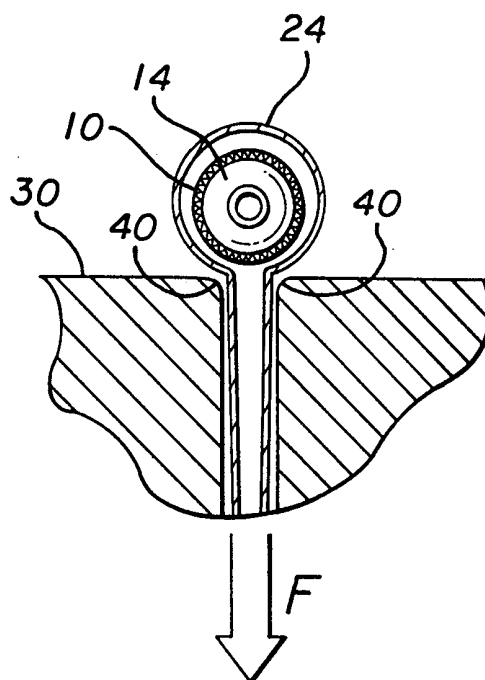
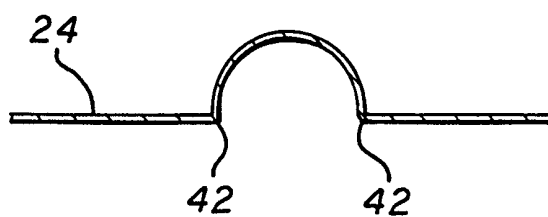


FIG. 4B



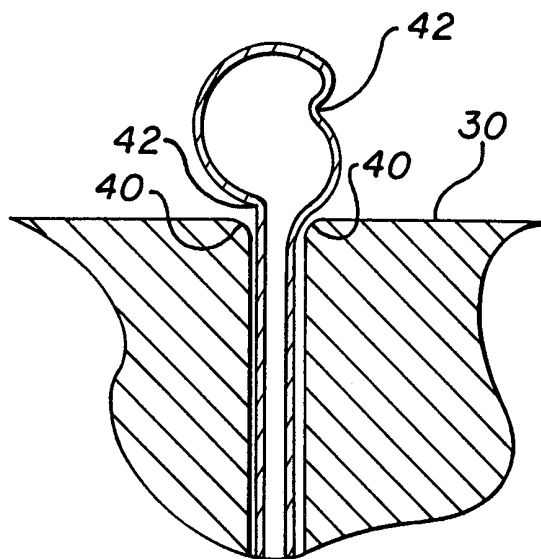


FIG. 4C

FIG. 5A

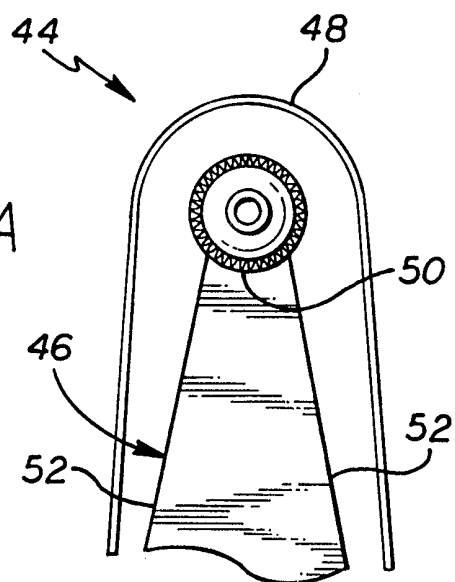
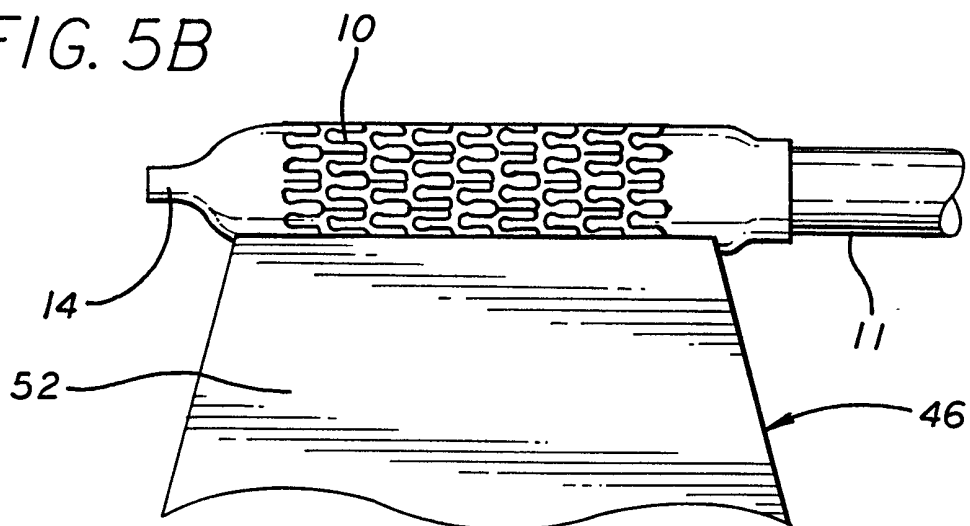


FIG. 5B



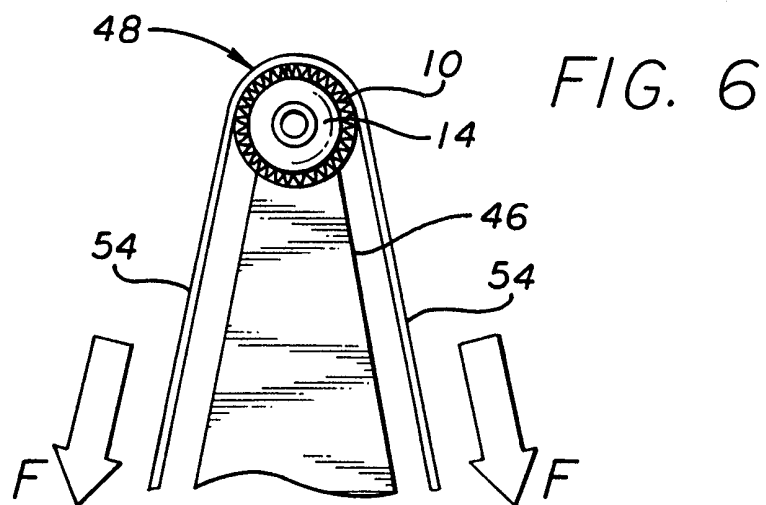


FIG. 7

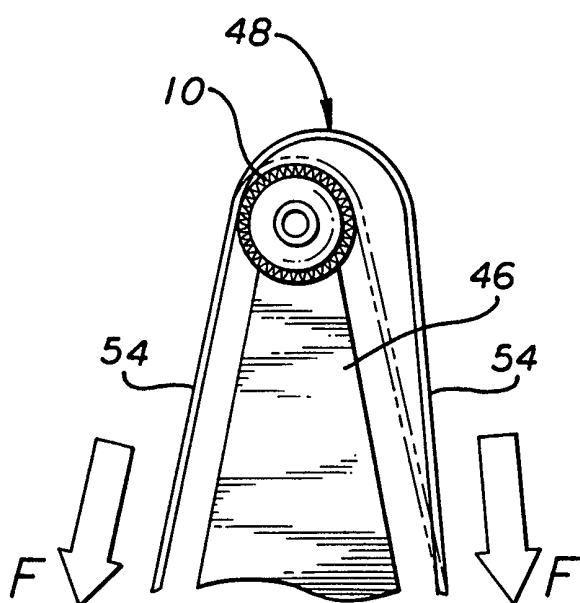
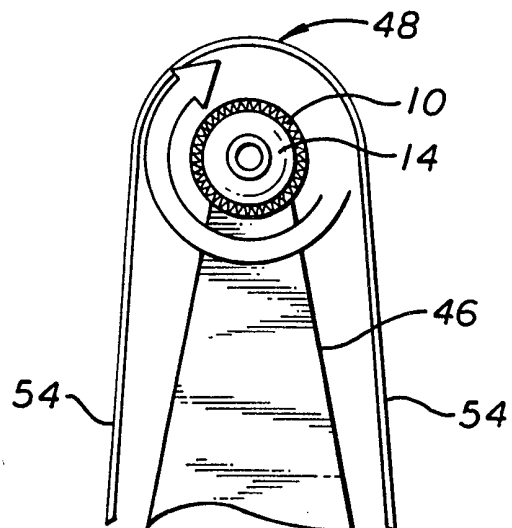


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09050

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 826 346 A (CORDIS CORP) 4 March 1998 (1998-03-04) the whole document	1, 9
A	---	2-8, 10-23
P, X	EP 0 873 731 A (ADVANCED CARDIOVASCULAR SYSTEM) 28 October 1998 (1998-10-28) the whole document -----	1, 9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

16 August 1999

Date of mailing of the international search report

24/08/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Korth, C-F

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/09050

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0826346 A	04-03-1998	US 5836952 A CA 2211694 A	17-11-1998 21-02-1998
EP 0873731 A	28-10-1998	CA 2235559 A JP 11057016 A	22-10-1998 02-03-1999