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Yan

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[54] **APPARATUS AND METHOD FOR MOUNTING A STENT ONTO A CATHETER**

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[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

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[51] **Int. Cl.**[6] **B23P 11/00**; B23P 19/04

[52] **U.S. Cl.** **29/516**; 623/1; 606/194; 606/108; 606/1; 29/282; 425/392

[58] **Field of Search** 29/516, 407.08, 29/282, 280, 715; 606/108; 425/318, 391, 392

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Assistant Examiner—John Preta
Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht, LLP

[57] **ABSTRACT**

A system for loading a stent onto a catheter is disclosed. The system includes a housing having an internal chamber with a flexible tube extending therethrough. A stent is positioned at about a mid portion of the flexible tube, and the balloon portion of the catheter is inserted into the flexible tube and positioned within the stent. Pressurized fluid is injected into the internal chamber thereby circumferentially compressing the flexible tube and in turn compressing the stent and crimping it onto the balloon portion of the catheter. A balloon folding attachment can be mounted onto an end of the housing. The inner lumen of the attachment has progressively varying cross-sectional shapes that fold the flattened balloon portion of the catheter as it is advanced into the attachment. The folded balloon portion is continually advanced into the attachment into the flexible tube until it is aligned within the stent.

17 Claims, 2 Drawing Sheets

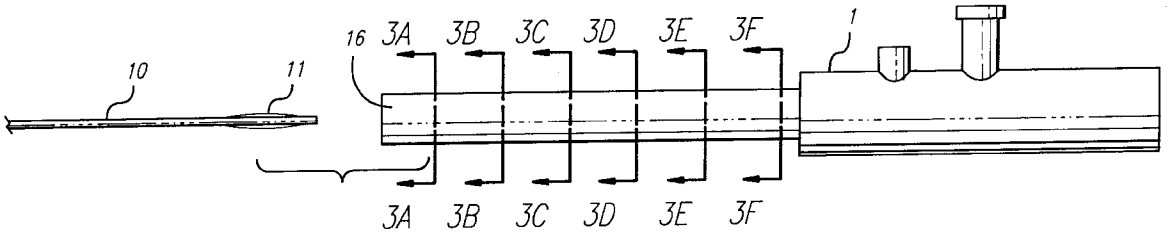


FIG. 1

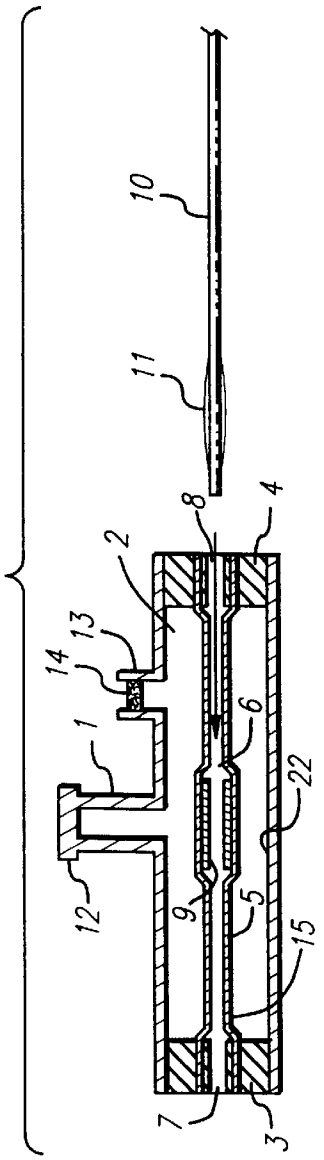


FIG. 4

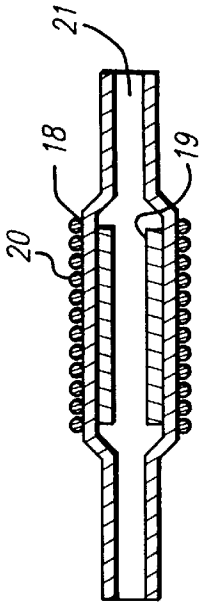
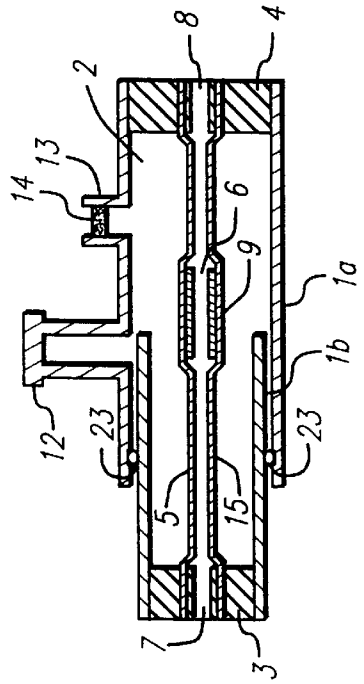


FIG. 5



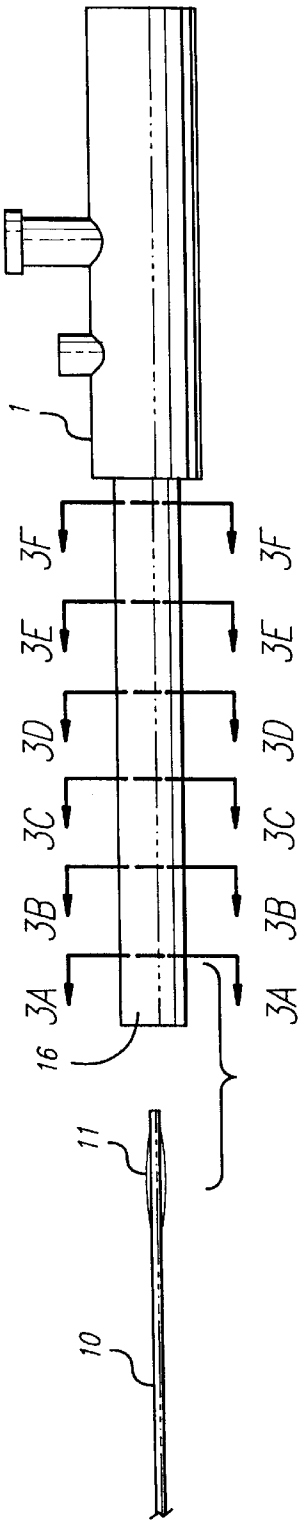


FIG. 2

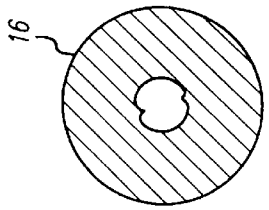


FIG. 3F

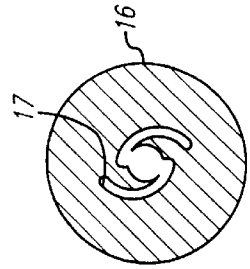


FIG. 3E

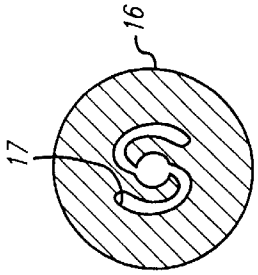


FIG. 3D

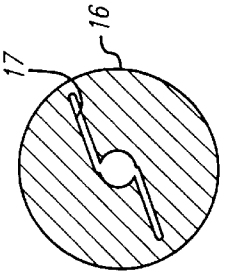


FIG. 3C

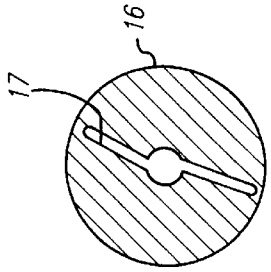


FIG. 3B

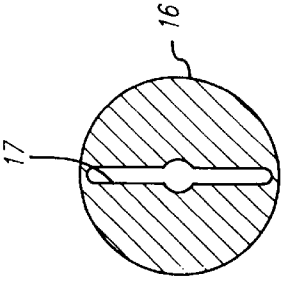


FIG. 3A

APPARATUS AND METHOD FOR MOUNTING A STENT ONTO A CATHETER

BACKGROUND OF THE INVENTION

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

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 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 the inside of the artery wall, thereby dilating 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.

In angioplasty procedures of the kind referenced above, restenosis may occur in the artery, 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 restenosis and to strengthen the area, an intravascular stent is implanted for maintaining vascular patency. The stent is typically transported through the patient's vasculature where it has a small delivery diameter, and then is expanded to a larger diameter, often by the balloon portion of the catheter. The stent also may be of the self-expanding type.

Since the catheter and stent will be traveling through the patient's vasculature, and probably through the coronary arteries, the stent must have a small, delivery diameter and must 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 of the catheter until it is implanted in the artery.

In conventional 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 it from sliding off the catheter when the catheter is advanced through a 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 prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Thus, 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, again resulting in non-uniform crimps. In addition, it is difficult to 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 crimping the stent properly. Hence, there is a need in the art for a device for reliably crimping a stent onto a catheter.

There have been mechanisms devised for loading a stent on to a catheter. For example, U.S. Pat. No. 5,437,083 to Williams et al. discloses a stent-loading mechanism for loading a stent onto a balloon delivery catheter of the kind typically used in PTCA procedures. The device comprises an arrangement of plates having substantially flat and parallel surfaces that move in rectilinear fashion with respect to each other. A stent carrying catheter can be crimped between the flat surfaces to affix the stent onto the outside of the catheter by relative motion between the plates. The plates have multiple degrees of freedom and may have force-indicating transducers to measure and indicate the force applied to the catheter during affixation of the stent.

Williams et al. also discloses a stent-loading device comprising an elongated tubular member having an open end and a sealed off end. The tubular member houses an elastic bladder which extends longitudinally along the inside of the tubular member. The tubular member and bladder are designed to hold a stent that is to be loaded onto a balloon catheter assembly. Upon placement of the stent over the balloon portion of the catheter, a valve in the loading device is activated to inflate the bladder. The bladder compresses the stent radially inward onto the balloon portion of the catheter to a reduced diameter to thus achieve a snug fit.

Although the above-described methods by which stents are crimped are simple, there is a potential for not crimping the stent sufficiently tight to prevent it from loosening in the tortuous anatomy of the coronary arteries. Because the amount of compression needed to be applied by the fingers will vary with the (a) strength of the operator, (b) day-to-day operation, (c) catheter and balloon material and configuration, (d) experience of the operator in crimping, and (e) other factors, the tightness in which the stent is crimped onto a balloon catheter may vary considerably.

Indeed, because of these factors, the tightness follows a normal or Chi square distribution. At the lower tail end of the distribution, the stents will be loose and susceptible to movement on the balloon during insertion. At the higher tail end, the stent will be too tight and will affect the expansion characteristics (i.e., a dog bone effect) of the balloon.

In view of the foregoing, there is a need for a stent crimping device that reliably and uniformly crimps stents onto the balloon portion of a catheter.

SUMMARY OF THE INVENTION

The present invention is directed to a stent loading system and method for crimping a stent onto a catheter, and preferably onto a balloon catheter. The system comprises a housing having opposite ends forming an internal chamber, a port disposed on the housing in fluid communication with the internal chamber, and a flexible tube extending through the internal chamber and passing through the opposite ends of the housing, wherein the flexible tube includes a hollow interior and open ends, and wherein the stent is disposed within the hollow interior.

A pressurized fluid is injected through the port into the chamber. As this fluid fills the internal chamber, the flexible

tube undergoes radial compression. When the balloon portion of the catheter is inserted into the open end of the flexible tube and into the stent, the pressurized fluid compresses the flexible tube reducing its diameter and thereby compressing the stent onto the balloon portion of the catheter.

In one embodiment of the present invention, a balloon folding attachment is connected to the housing end. In particular, the balloon folding attachment has a body with an interior passage therethrough that has progressively changing cross-sectional shapes and which is in communication with one opening of the flexible tube, and wherein the balloon portion of the catheter is inserted through the interior passage and is progressively folded into a desired shape.

Furthermore, the housing may include an optional second port having a hydrophobic filter, which filter allows air or gases to pass, but not liquids. While the internal chamber is filled with a fluid, the ambient gas within the internal chamber bleeds out through the filter.

Accordingly, the present invention provides a mechanism for uniformly crimping a stent onto a balloon portion of a catheter wherein the applied radial force on the stent is consistent and precise. The tightness of which the stent is crimped onto the balloon catheter can therefore be carefully controlled.

Another advantage of the present invention is that the housing and other parts can be readily made from a disposable material. In this embodiment, the stent can be preloaded inside the flexible tube and packaged and sterilized. The package is then ready for use by the cath lab physician when a stent needs to be mounted on a catheter of the physician's choice.

Alternatively, the stent can be loaded onto the balloon portion of the catheter and slightly crimped. Thereafter, the combination of the stent and balloon catheter are inserted into the flexible tube where the final crimping step takes place. Furthermore, the ports in the housing can be a Luer type, to be adaptable to the equipment already available to the physician.

In another embodiment, the housing is made from a shape memory alloy material. The housing wraps around the flexible tube that houses the stent. When a catalyst such as heat is applied to the shape memory alloy housing, the housing shrinks in size and compresses the flexible tube thereunder. In turn, the compressed flexible tube crimps the stent onto a balloon catheter inserted therein. Removing the heat from the shape memory alloy material of the housing causes the housing to restore to its initial size and shape, thus permitting withdrawal of the crimped stent and catheter combination.

These and other advantages of the invention will become apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevational view of a preferred embodiment of the present invention shown in a cross-section depicting the housing, flexible tube, stent, and catheter with a balloon portion, just prior to insertion.

FIG. **2** is a side elevational view showing the present invention with a balloon folding attachment connected thereto.

FIG. **3** is a series of cross-sectional views in which FIG. **3**A through FIG. **3**F are cross-sectional views taken along lines A—A through F—F of FIG. **2**.

FIG. **4** is a cross-sectional view depicting an alternative embodiment of the invention wherein the housing is formed of a shaped memory alloy capable of contracting and crimping the stent onto a catheter.

FIG. **5** is a cross-sectional view depicting an alternative embodiment wherein the length of the housing is adjustable.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a stent loading system for mounting a stent onto a balloon portion of a catheter. Beneficially, the present invention system facilitates controlled, repeatable, crimping pressure to be applied to a stent when the latter is loaded onto a balloon portion of a catheter. While the invention is described in detail as applied to the coronary arteries, those skilled in the art will appreciate that it can be applied to devices for use in other body lumens as well, such as peripheral arteries and veins. Also, although the invention is described with respect to mounting a stent on the balloon portion of a catheter, the invention is not so limited and includes mounting stents or grafts on any type of catheter used to deliver and implant such stents. Where different embodiments have like elements, like reference numbers have been used.

FIG. **1** provides a side elevational view of a preferred embodiment of the present invention stent loading system wherein the device is shown in a cross-section to depict the interior construction. As seen in this figure, housing **1** has a preferably long, cylindrical shape and includes internal chamber **2**. The opposite ends of housing **1** are sealed to completely enclose internal chamber **2**. To seal the opposite ends, in the preferred embodiment, housing **1** is enclosed by press fit seals **3**,**4**.

A flexible tube **5** is stretched across internal chamber **2**, and inner lumen **6** of flexible tube **5** is in communication with openings **7**, **8** formed in press fit seals **3**, **4**. An uncrimped stent **9** is positioned at about the midsection of flexible tube **5** within inner lumen **6**. The inner surface of inner lumen **6** is close to and perhaps in loose fitting contact with the outer surface of uncrimped stent **9**.

In a preferred embodiment, uncrimped stent **9** is inserted into inner lumen **6** of flexible tube **5** and is expanded slightly to enlarge its inside diameter. In this manner, the slightly enlarged inside diameter of stent **9** allows easy clearance of catheter **10** to be inserted therein. Furthermore, the pre-expansion step stretches flexible tube **5**, thereby securing stent **9** within tube **5**. This condition is shown in FIG. **1**.

As mentioned above, the present invention system is adapted for use with a PTCA balloon catheter **10** having balloon portion **11** at the distal end. Of course, the present invention can be used with a balloon catheter of any conventional design known in the art as well as any catheter without a balloon.

In the preferred embodiment, an adapter with a male-threaded Luer fitting (not shown) is used as an inflation port. A syringe, an inflation/deflation device commonly referred to as an "indeflator," a compressed fluid source, or any pressurized source known in the art, is attached to inflation port **12**. This serves as the inlet for the pressurized fluid that fills internal chamber **2**.

In an alternative embodiment, inflation port **12** can include a three-way stopcock (not shown) that is connected to the Luer fitting. Thus, a saline filled syringe or indeflator is connected to the inlet of the stopcock. Fluid is injected by the syringe into internal chamber **2** and air within the internal chamber **2** is purged through an extra side port on the three-way stockcock.

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