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Tower

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[54] **METHOD OF SECURING A STENT ON A BALLOON CATHETER**

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[51] **Int. Cl.**[6] **A61B 17/00**

[52] **U.S. Cl.** **606/1**; 606/198

[58] **Field of Search** 606/1, 108, 191–200; 623/1, 11, 12

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,733,665	3/1988	Palmaz .	
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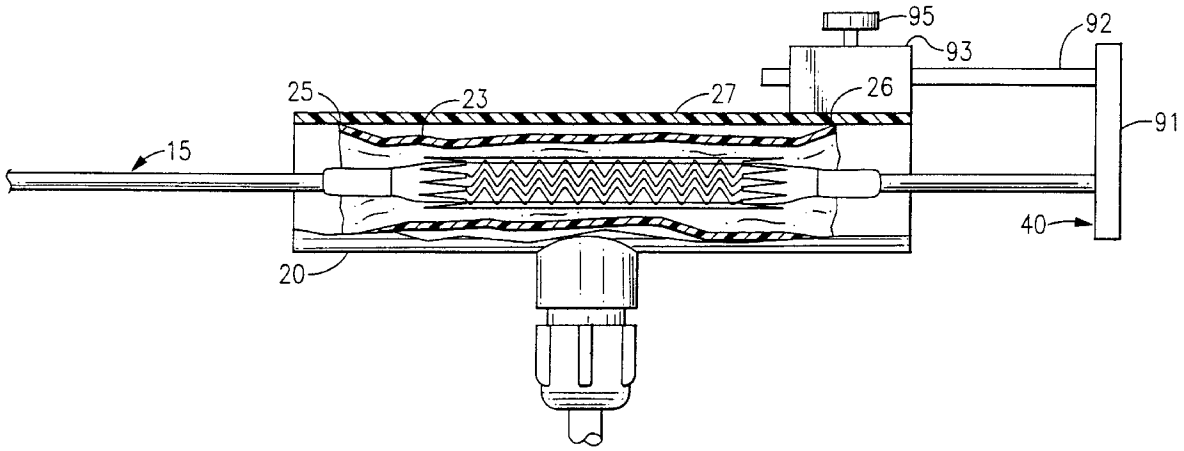
[57] **ABSTRACT**

Apparatus for securing a stent upon a balloon catheter. The apparatus has a tubular housing that is open at each end for containing a balloon catheter in a deflated state upon which is mounted a stent. An inflatable cylindrical membrane is mounted inside the housing and sealed at both ends to provide a fluid tight chamber between the membrane and the housing. A pressurized fluid is introduced into the chamber to inflate the membrane into pressure contact with the stent to urge the stent into gripping engagement with the balloon.

13 Claims, 3 Drawing Sheets



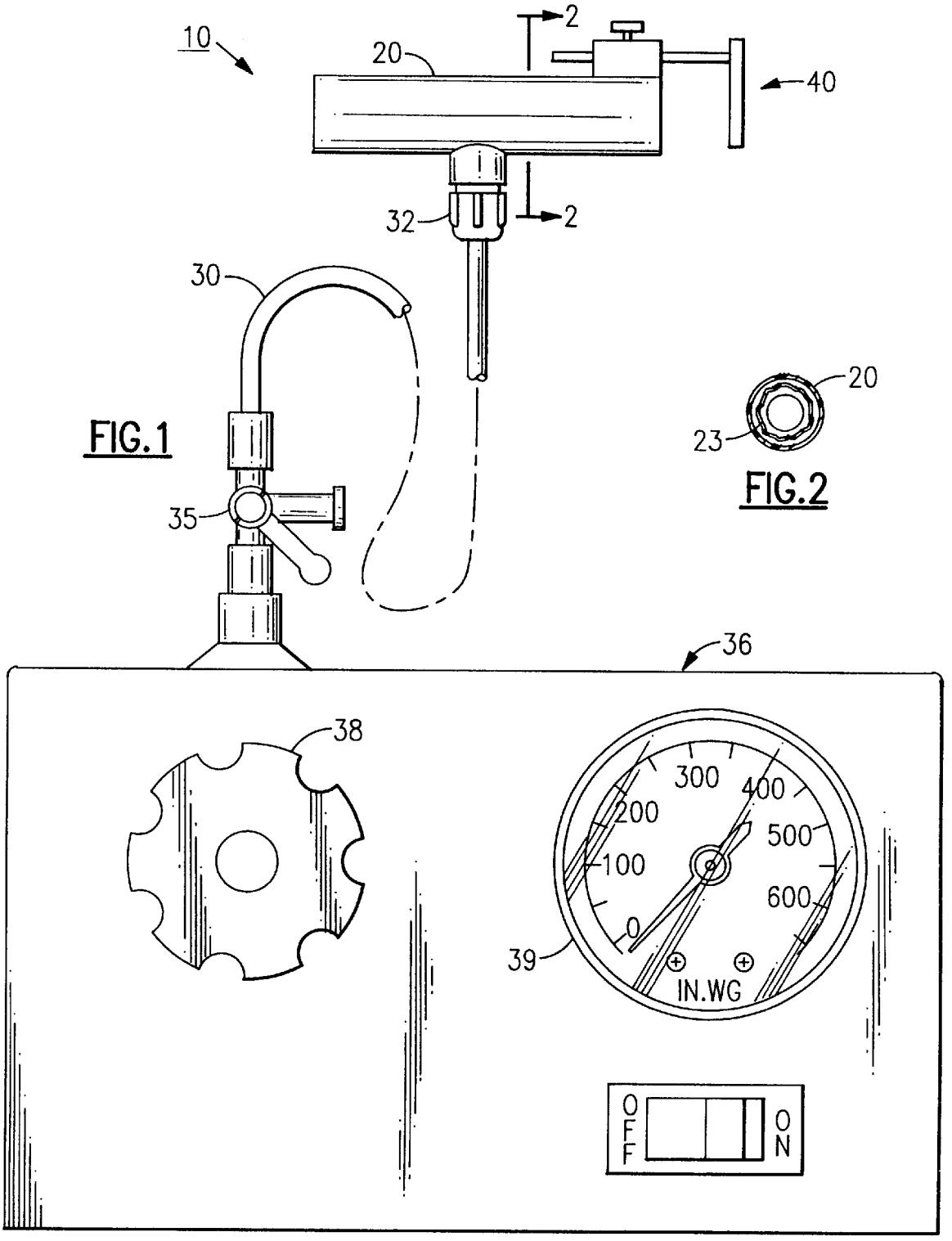


FIG.1

FIG.2

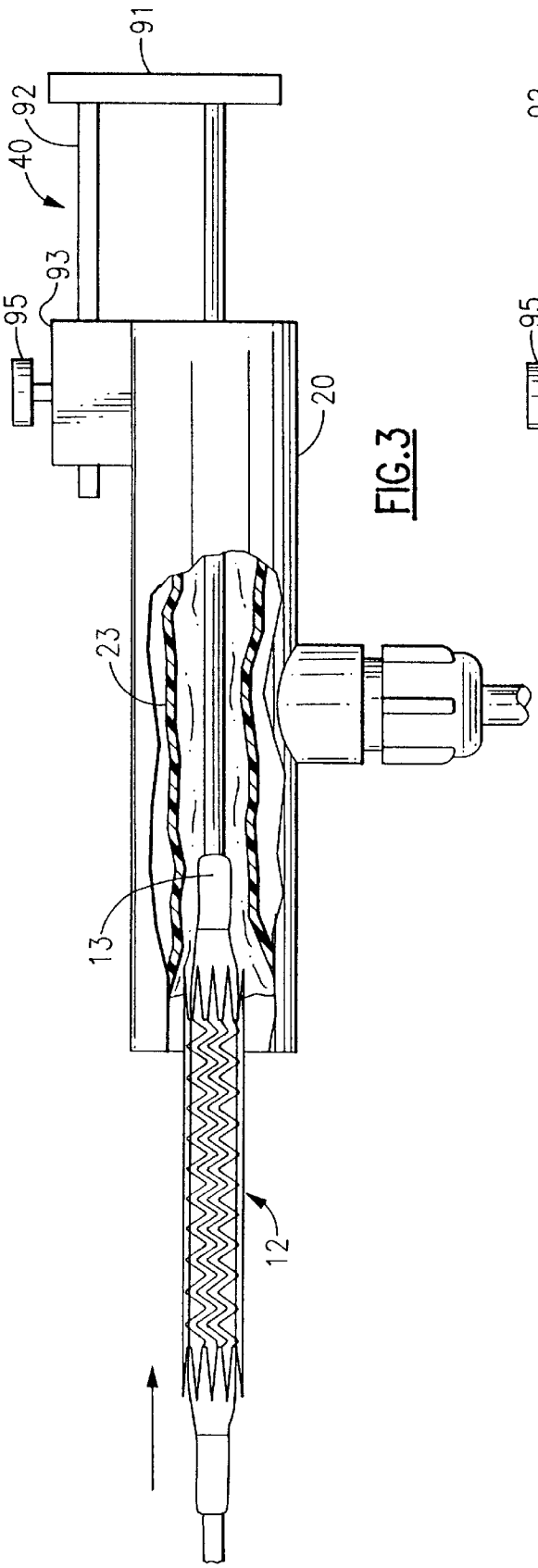


FIG.3

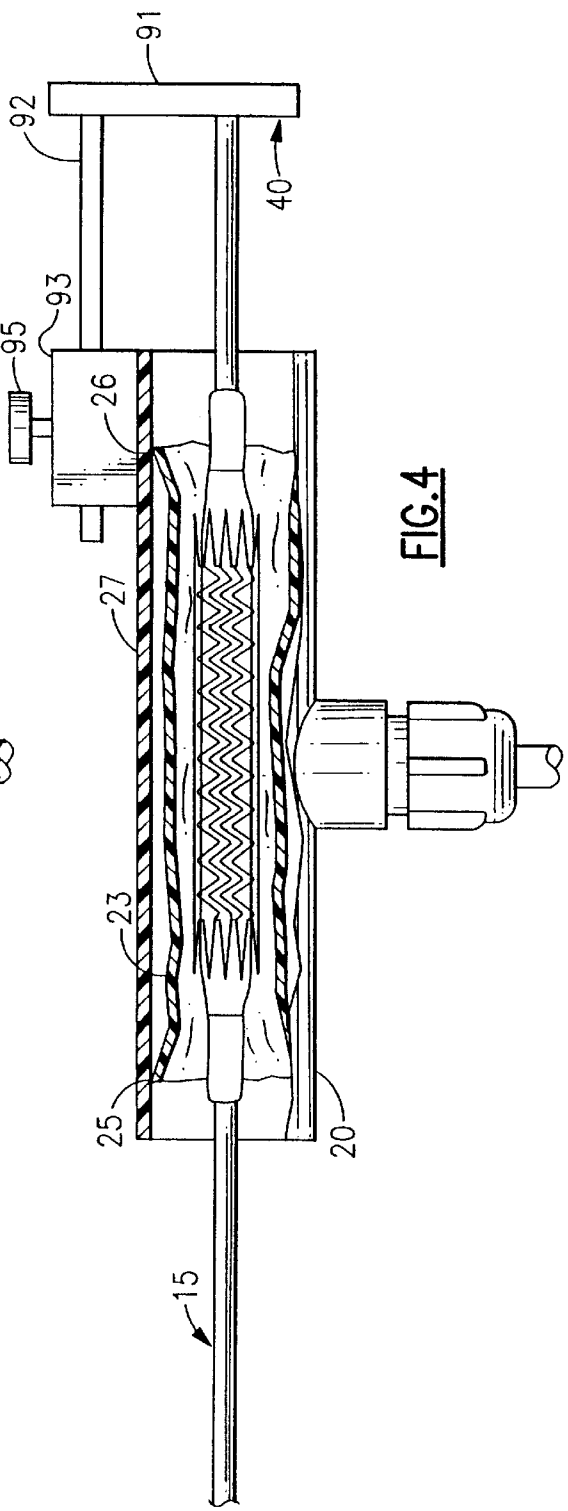


FIG.4

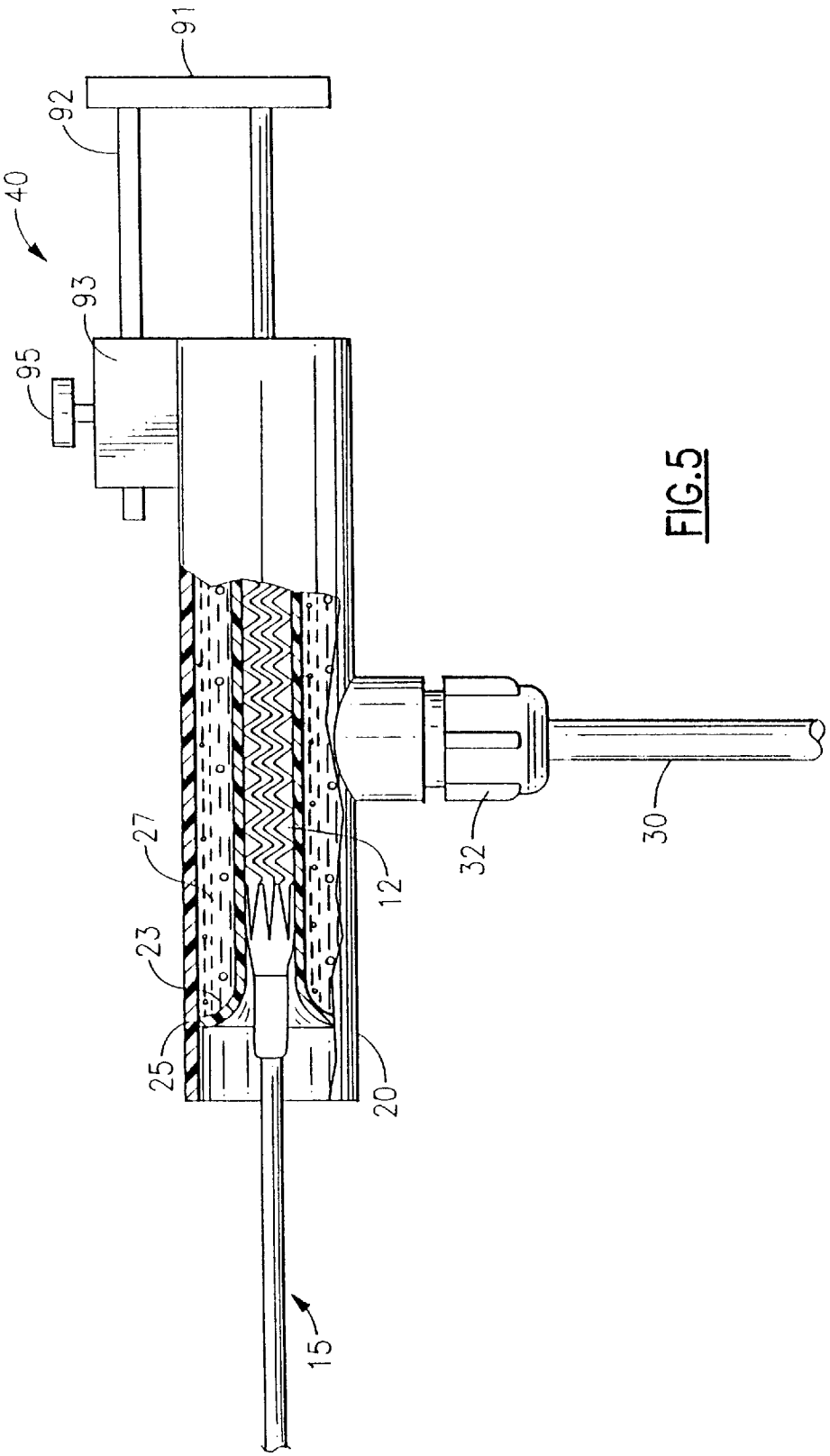


FIG.5

METHOD OF SECURING A STENT ON A BALLOON CATHETER

BACKGROUND OF THE INVENTION

This invention relates to stents, and in particular, to a method and apparatus for securely mounting a stent on a balloon catheter.

It is well known that a balloon catheter is well suited for use as a delivery and implantation system for an expandable stent. Typically, the stent is mounted over a balloon at the distal end of the catheter and is carried into a treatment zone through a blood vessel. Once properly positioned in the treatment zone, the balloon is inflated to expand the stent radially to open an occlude passage in the vessel caused by plaque or an aneurism. The catheter, during insertion, must oftentimes travel a rather tortuous path before reaching the treatment zone. If the stent is not securely mounted upon the balloon it can become dislodged or misaligned thus rendering the procedure ineffective. In severe cases, the stent may become entirely dislodged from the catheter while it is inside the patient, thus requiring its recovery through surgical procedures.

In an effort to more securely mount a stent upon a balloon catheter, it is common practice to compress the stent inwardly using special crimping tools similar to pliers. Because the crimping forces are applied repeatedly in different localized regions about the stent, the holding force around the stent tends to be non-uniform which can adversely effect the way the stent expands as the balloon inflates, thus leading to less than satisfactory implantation. More importantly, because the amount of force applied during the crimping operation is generally unregulated, the stent can penetrate the balloon rendering it uninflatable. The fact the balloon has been punctured by the stent generally is not discovered until such time as the stent has been positioned in the body. As a result, the catheter and stent must be retrieved from inside the patient and the procedure repeated.

Cylindrical crimping devices have also been devised wherein the balloon with a stent mounted thereupon are drawn into a cylinder having a predetermined inside diameter. The inside diameter of the cylinder is selected so that ideally the stent is collapsed just enough to apply a non-damaging, yet secure gripping force upon the balloon. This ideal relationship unfortunately is difficult to achieve in practice and puncturing of the balloon by the stent is not uncommon. Accurately guiding the stent bearing balloon into the cylinder can also be difficult and the stent may become misaligned or dislodged during this procedure.

SUMMARY OF THE INVENTION

It is therefore an object of this invention to securely mount an expandable stent upon a balloon catheter without harming the balloon.

A further object of the present invention is to improve the safety of stent delivery systems using balloon catheters.

A still further object of the present invention is to apply a uniform collapsing pressure to a stent as it is being mounted upon a deflated balloon at the distal end of a catheter.

Another object of the present invention is to protect the integrity of a balloon as an unexpanded stent is being secured thereto.

Yet another object of the present invention is to improve the reliability of balloon catheter delivery systems.

These and other objects of the present invention are attained by a tubular housing that is open at each end for

containing a balloon catheter in a deflated condition upon which is mounted a stent. An inflatable cylindrical membrane is mounted in the opening of the housing and is sealed against the housing to establish a leak-tight chamber therebetween. A pressurized fluid is introduced into the chamber to expand the membrane into contact with the stent to apply a uniform pressure thereagainst to urge the stent into secure gripping contact with the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of these and other objects of the present invention, reference will be made to the detailed description below which is to be read in association with the following drawings, wherein:

FIG. **1** is a side elevation of apparatus embodying the teachings of the present invention;

FIG. **2** is a sectional view taken along lines **2—2** in FIG. **1**;

FIG. **3** is an enlarged side elevation with portions broken away showing a balloon catheter carrying a stent being inserted into the housing of the present apparatus;

FIG. **4** is a side elevation similar to that illustrated in FIG. **3** showing the stent and the balloon of the catheter centered in the housing; and

FIG. **5** is also a side elevation showing the stent being compressed into gripping contact against the balloon.

DESCRIPTION OF THE INVENTION

Turning now to the drawings, there is shown stent mounting apparatus, generally referenced **10**, for securing an expandable stent **12** upon a balloon **13** located at the distal end of a catheter **15**. As is well known, the elongated body of the catheter contains at least one lumen that is adapted to carry air or fluid under pressure to the balloon whereby the balloon can be inflated to expand an occluded blood vessel or the like. The balloon catheter can also serve as a delivery vehicle for an expandable stent which is mounted upon the balloon and is guided into an occluded area caused by plaque, an aneurism or the like. Once the stent is properly inserted and its position verified by fluoroscopic means, the balloon is inflated to expand the stent into contact with the occluded vessel, thus opening the vessel. The stent remains in the expanded condition when the balloon is deflated, thus supporting the vessel in the expanded state.

As disclosed in U.S. Pat. No. 5,217,483, the present stent can be formed of a fully annealed platinum wire that is shaped into a cylinder that can be easily slipped over the deflated balloon of a catheter. As the stent is guided by the catheter through a blood vessel, it generally must move through a rather tortuous path of travel. Unless the stent is firmly attached to the balloon, it can become misaligned whereby it will not inflate properly or it may become dislodged entirely from the balloon which, in severe cases, may require a surgical recovery. As noted above, the stent is typically crimped against the balloon to force the stent into gripping contact with the balloon. The prior art method of attaching a stent to a balloon generally involved the application of uncontrolled, non-uniform compression forces to the stent which can result in the balloon becoming punctured when too much force is applied or the stent becoming misaligned during insertion when too little force is applied.

The apparatus of the present invention is specifically designed to apply a controlled, uniformly distributed crimping force to the stent which will provide the maximum desired gripping pressure to the balloon without causing damage to the balloon.

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