# United States Patent [19]

**MacGregor**

[11] **Patent Number: 4,994,071**

[45] **Date of Patent: Feb. 19, 1991**


[54] **BIFURCATING STENT APPARATUS AND METHOD**


[75] Inventor: **David C. MacGregor**, Miami, Fla.

[73] Assignee: **Cordis Corporation**, Miami, Fla.



[21] Appl. No.: **354,799**

[22] Filed: **May 22, 1989**

[51] **Int. Cl.**[5] ..... **A61M 29/00**; A61F 2/06

[52] **U.S. Cl.** ..... **606/194**; 606/192

[58] **Field of Search** ..... 606/191, 192, 198, 200, 606/194, 96, 151, 153; 623/1, 12



[56] **References Cited**

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| | | | |
|---|---|---|---|
| 3,993,078 | 11/1976 | Bergentz et al. | 606/156 |
| 4,501,264 | 2/1985 | Rockey | 606/192 X |
| 4,733,665 | 3/1988 | Palmaz | 606/191 X |
| 4,795,465 | 1/1989 | Marten | 623/12 X |
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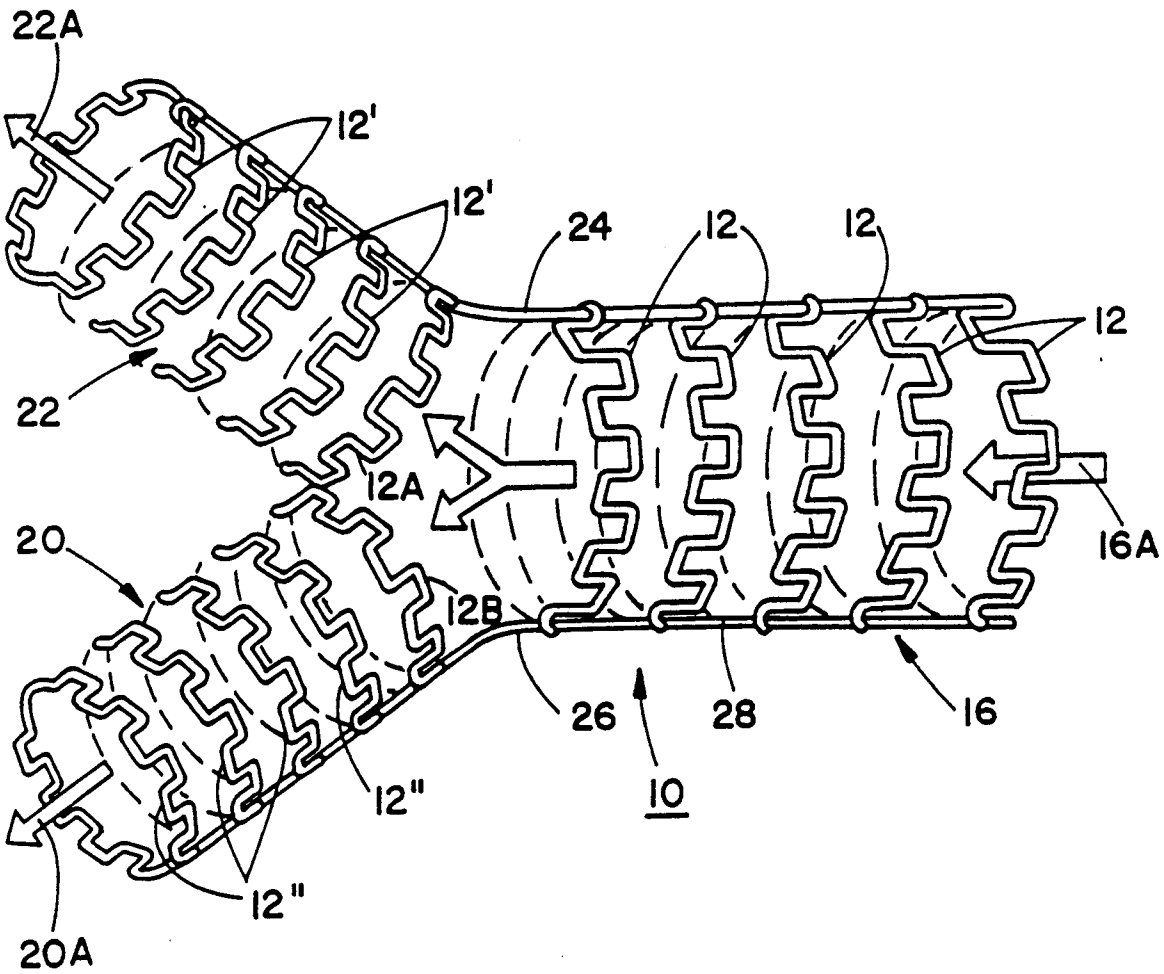
*Primary Examiner*—Robert A. Hafer
*Assistant Examiner*—Kevin G. Rooney
*Attorney, Agent, or Firm*—Watts, Hoffmann, Fisher & Heinke Co.



[57] **ABSTRACT**

A bifurcating stent for insertion into a bifurcating vessel such as a blood vessel. The stent can be expanded from an insertion configuration to an implanted configuration by the application of radially outward forces against a series of interconnected wire loops that make up the stent. The preferred and disclosed method of stent implantation is accomplished with the use of a balloon catheter that expands the stent into contact with inner walls of the vessel. The balloon is then deflated and withdrawn from the vessel, leaving the stent implanted within the vessel.


**16 Claims, 3 Drawing Sheets**



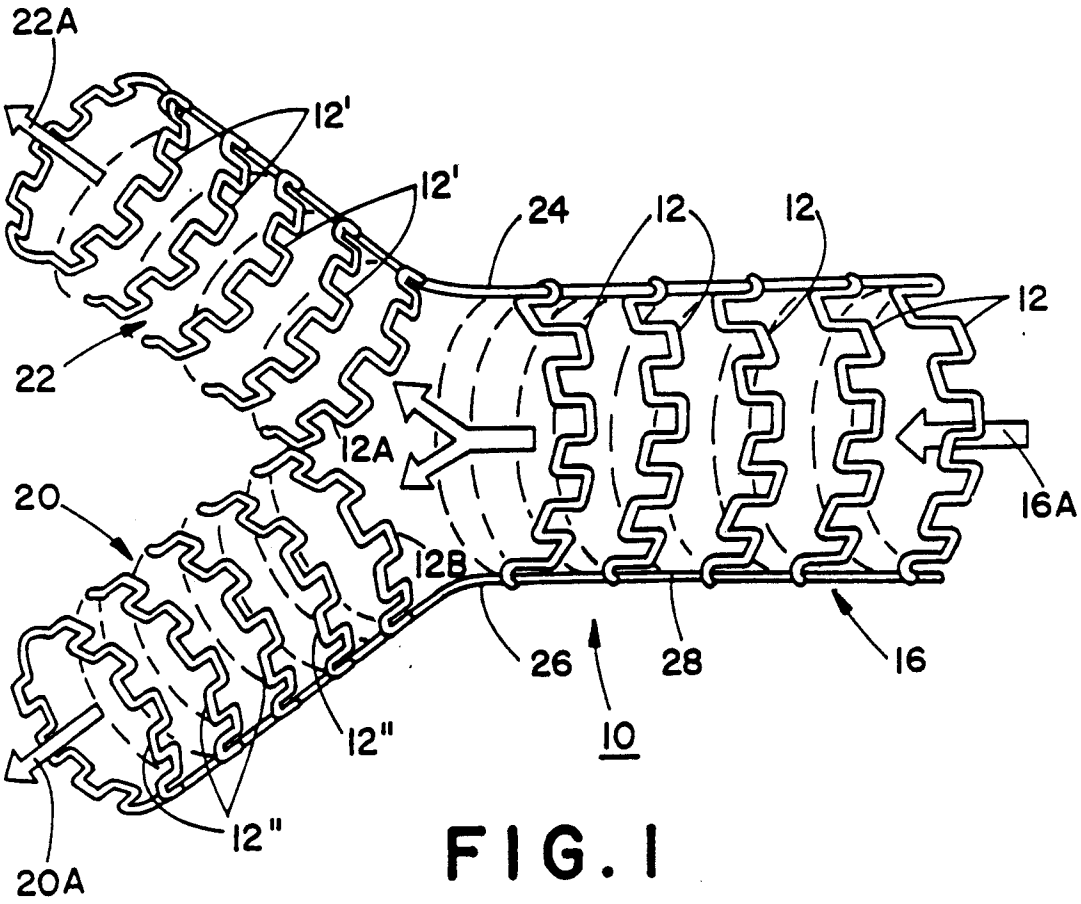



FIG. 1

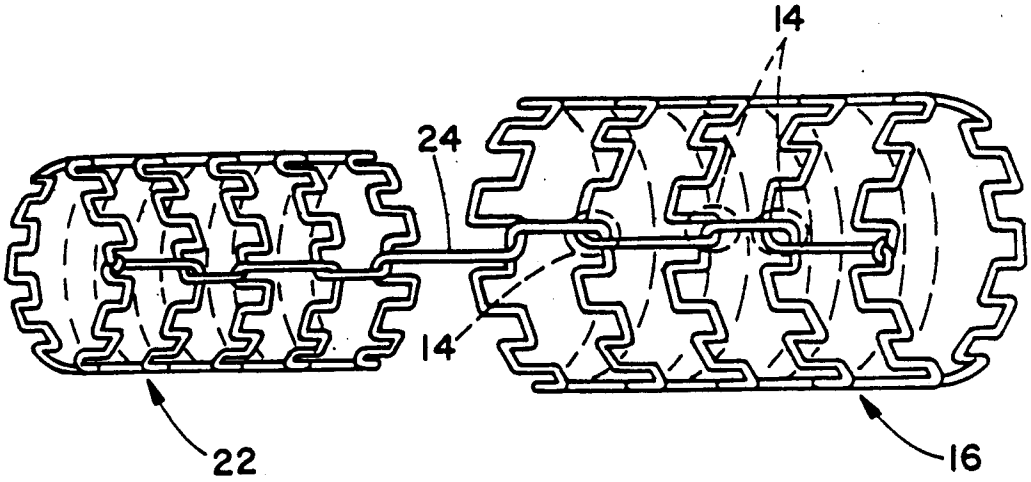



FIG. 1A

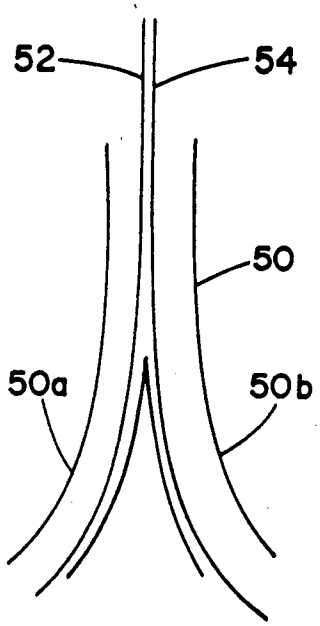



FIG. 2A

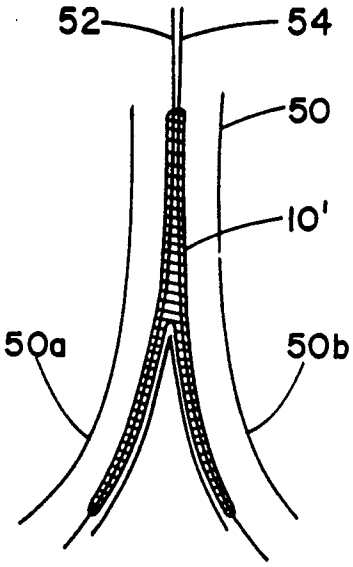



FIG. 2B

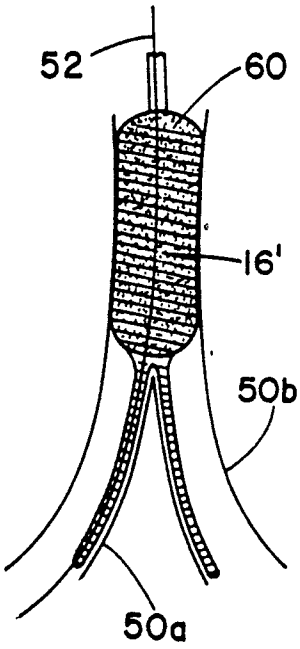



FIG. 2C

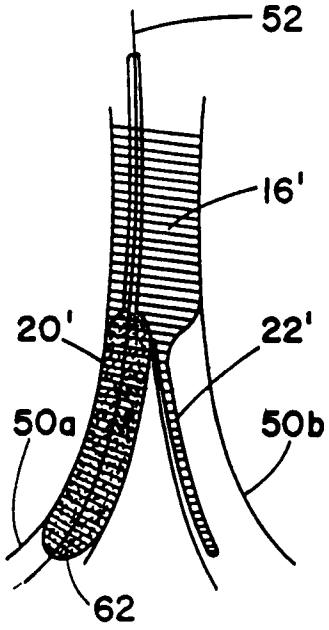



FIG. 2D

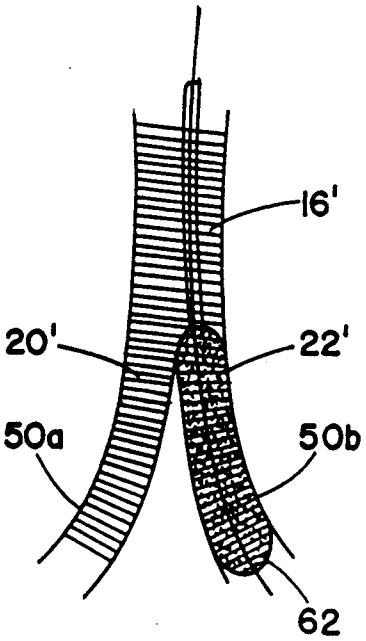



FIG. 2E

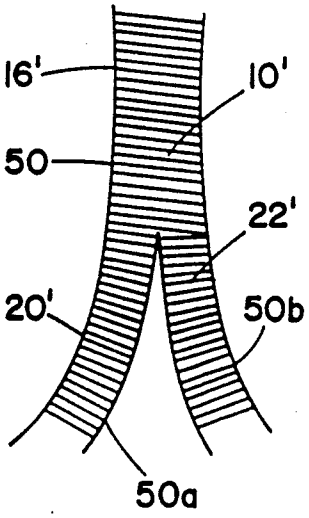



FIG. 2F

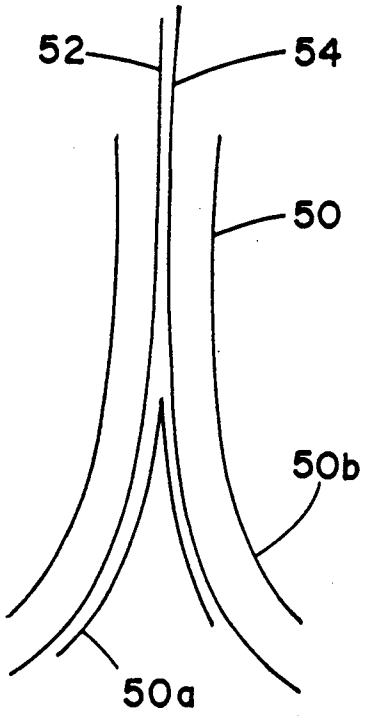



FIG. 3A

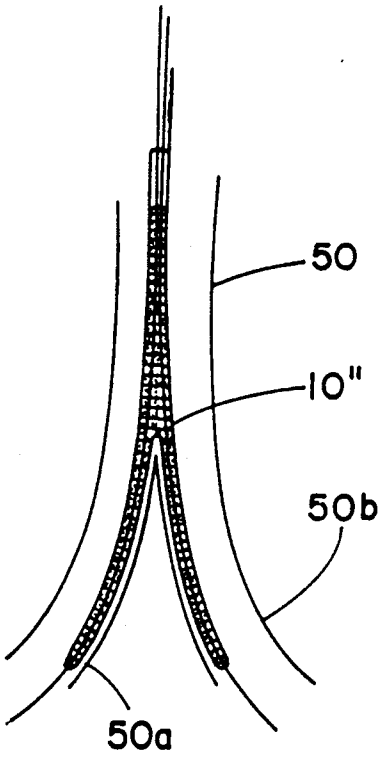



FIG. 3B

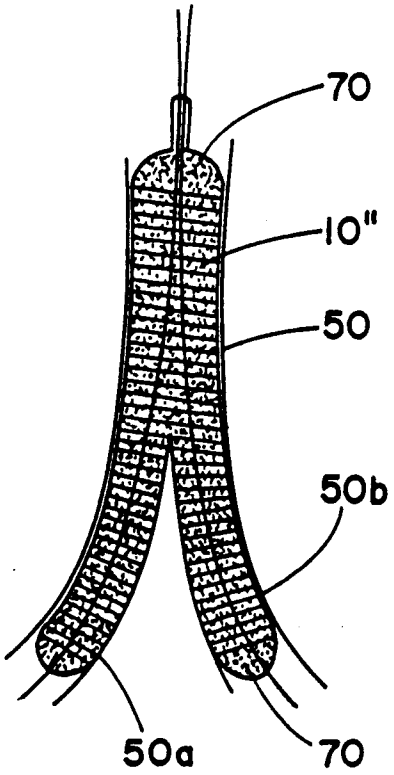



FIG. 3C

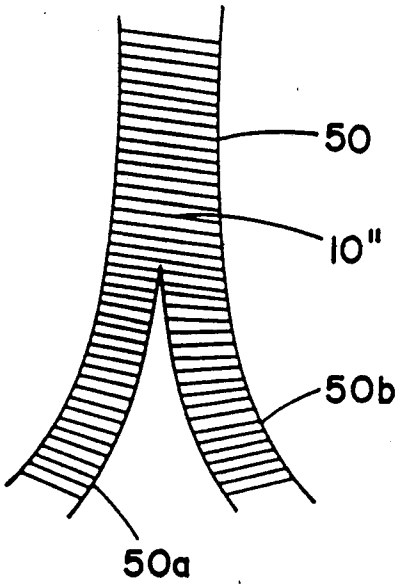



FIG. 3D

# BIFURCATING STENT APPARATUS AND METHOD

## TECHNICAL FIELD

The present invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel.

## BACKGROUND ART

A type of endoprosthesis device, commonly referred to as a stent, is placed or implanted within a blood vessel for treating occlusions, stenoses, or aneurysms in the blood vessel. These devices are implanted within the vascular system to reinforce collapsing, partially occluded, weakened, or abnormally dilated sections of the blood vessel. Stents also have been successfully implanted in the urinary tract or the bile duct to reinforce those body vessels.

One of the drawbacks of conventional stents is that they are produced in a straight tubular configuration. The use of such a stent to treat disease at or near a branch or bifurcation of a blood vessel runs the risk of compromising the degree of patency of the primary vessel and/or its branches or bifurcation. This may occur as a result of several problems such as displacing diseased tissue, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

One common procedure for implanting the endoprosthesis or stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the weakened portion of the vessel.

Prior art patents refer to the construction and design of both the stent as well as the apparatus for positioning the stent within the vessel. One representative patent is U.S. Pat. No. 4,140,126 to Chaudhury which issued Feb. 20, 1979. This patent discloses a technique for positioning an elongated cylindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall. The '126 patent discloses a cylinder that expands to its implanted configuration after insertion with the aid of a catheter

A second prior art patent to Dotter U.S. Pat. No. 4,503,569 which issued Mar. 12, 1985 discloses a spring stent which expands to an implanted configuration with a change in temperature. The spring stent is implanted in a coiled orientation and heated to cause the spring to expand.

U.S. Pat. No. 4,733,665 to Palmaz which issued Mar. 29, 1988 discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes a mechanism for mounting and retaining the vascular prosthesis or stent, preferably on an inflatable portion of the catheter The stent is implanted by positioning it within the blood vessel and monitoring its position on a viewing monitor. Once the stent is properly positioned, the catheter is expanded and the stent separated from the catheter body. The catheter can then be withdrawn from the subject, leaving the stent in place within the blood vessel.

U.S. Pat. No. 4,413,989 to Schjeldahl et al. which issued Nov. 8, 1983 discloses a variety of balloon catheter constructions. FIG. 5 of this patent discloses a bifurcating expander for insertion into diverging branches of a subject blood vessel.

U.S. Pat. No. 3,993,078 to Bergentz et al. discloses an insert for use in vascular surgery. The embodiment of this insert disclosed in FIG. 2 forms a "Y" tube. A distingishing feature of the inserts disclosed in this patent is the ability to take apart the insert by pulling a free end of a thread that forms the insert. This insert is surgically placed within a subject and no mention is made concerning the non-surgical placement of such an insert within a vessel.



U.S. patent application Ser. No. 240,000 entitled "Radially Expandable Endoprosthesis and the Like" discloses a generally cylindrical stent formed from a wire that is bent into a series of tight bends and then spirally wound about a cylindrical mandrel to form the stent. If a radially outward force is applied to the stent the sharp bends in the wire tend to straighten and the stent diameter enlarges. One technique for implanting this stent uses a deflated balloon catheter to position the stent within a vessel. Once the stent is properly positioned the balloon is inflated to press the stent against the inner wall linings of the vessel. The balloon is then deflated and withdrawn from the vessel, leaving the stent in place.

## DISCLOSURE OF THE INVENTION

The present invention concerns a stent and more particularly a bifurcating stent for insertion into a branching vessel of a subject. A stent constructed in accordance with the invention includes structure that defines a first flow path for fluid to flow through the stent. More particularly, a series of interconnected loops extend axially along and bound this first fluid flow path.

Additional structure, preferably constructed using a second series of interconnected loops, defines a second branching fluid flow path. A flexible interconnection joins the structure that defines the first and second flow paths. By proper bending of the flexible interconnection the first and second fluid flow paths can be made to conform to a shape of the vessel into which the bifurcating stent is inserted.

The bifurcating stent is constructed from a material that allows the stent to be expanded from an initial shape which can be inserted into a branching vessel to an expanded shape fixed within the branching vessel. A balloon catheter is preferably used to expand the stent by application of outward forces against the series of loops that make up the stent. To deposit the bifurcating stent within the subject, the balloon is expanded to bring the stent into contact with the inner walls of the vessel and then deflated, leaving the stent in place.

A preferred use for a bifurcating stent constructed in accordance with the present invention is for insertion into a branching blood vessel. A stent constructed in accordance with the present invention is typically intended for use in the coronary vasculature (the right, left common, left anterior descending, and circumflex coronary arteries and their branches) and the peripheral vasculature (branches of the carotid, aorta, femoral, popliteal, etc. arteries).

A stent constructed in accordance with the invention is suitable for implantation in other branching vessels of a subject. By way of example the invention has utility for implantation in the gastrointestinal system, the tracheobronchial tree, the biliary system and the genitourinary system.

From the above it is appreciated that one object of the invention is a bifurcating stent which can be expanded from an insertion to an in use configuration. This and other object advantages and features of the

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