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Fischell et al.

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[45] **Date of Patent: Sep. 6, 1988**

[54] **INTRAVASCULAR STENT AND PERCUTANEOUS INSERTION CATHETER SYSTEM FOR THE DILATION OF AN ARTERIAL STENOSIS AND THE PREVENTION OF ARTERIAL RESTENOSIS**

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[73] Assignee: **MedInnovations, Inc.**, Dayton, Md.

[21] Appl. No.: **93,110**

[22] Filed: **Aug. 31, 1987**

Related U.S. Application Data

[63] Continuation of Ser. No. 832,216, Feb. 14, 1986, abandoned.

[51] **Int. Cl.**[4] **A61B 17/00**

[52] **U.S. Cl.** ..... **128/303 R;** 128/341

[58] **Field of Search** ..... 128/303 R, 341, 343, 128/345, 334 R, 348.1; 623/1

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,503,569	3/1985	Dotter	128/303 R X
4,553,545	11/1985	Maass et al.	128/341

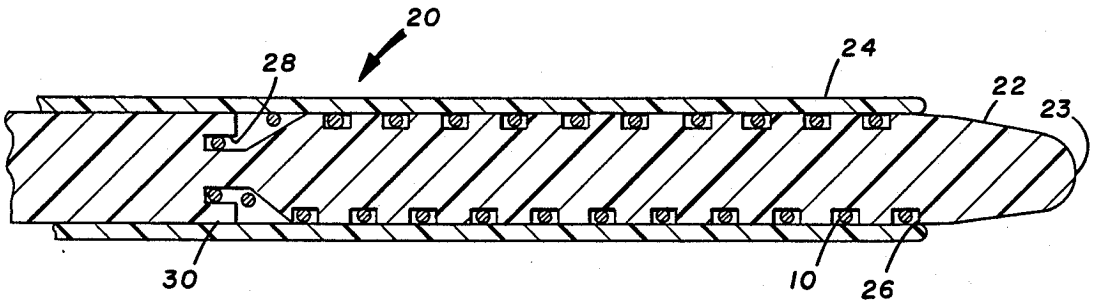
Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—Howard W. Califano

[57] **ABSTRACT**

This invention is in the field of percutaneous insertion catheters that are used for placing a coil spring stent into a vessel of a living body for the purposes of enhancing luminal dilation, preventing arterial restenosis and preventing vessel blockage resulting from intimal dissection following balloon and other methods of angioplasty. The stent can also be used for the maintaining patency of many different ducts or vessels within a living body.

6 Claims, 3 Drawing Sheets



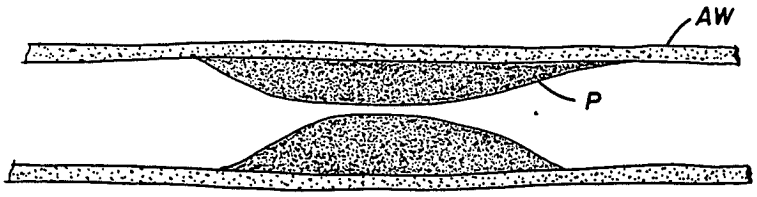


FIG. 1A

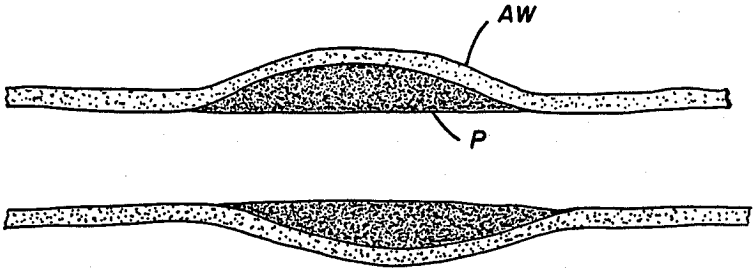


FIG. 1B

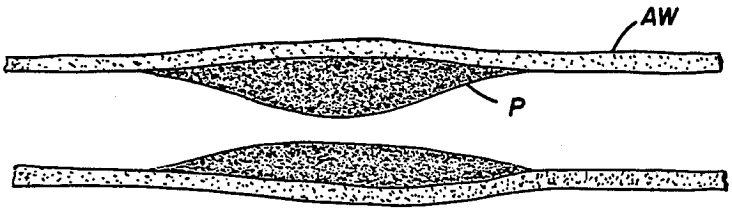


FIG. 1C

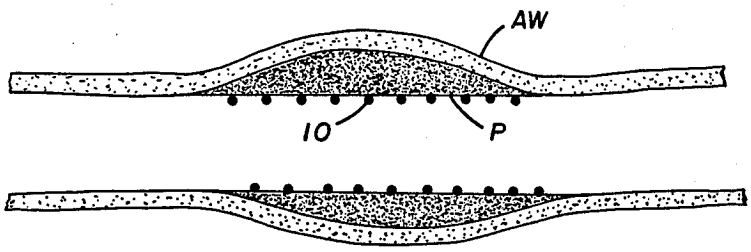


FIG. 2

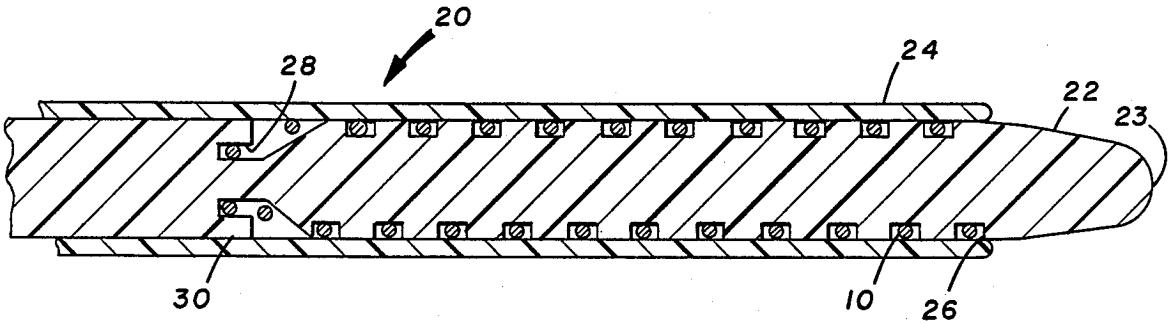


FIG. 3

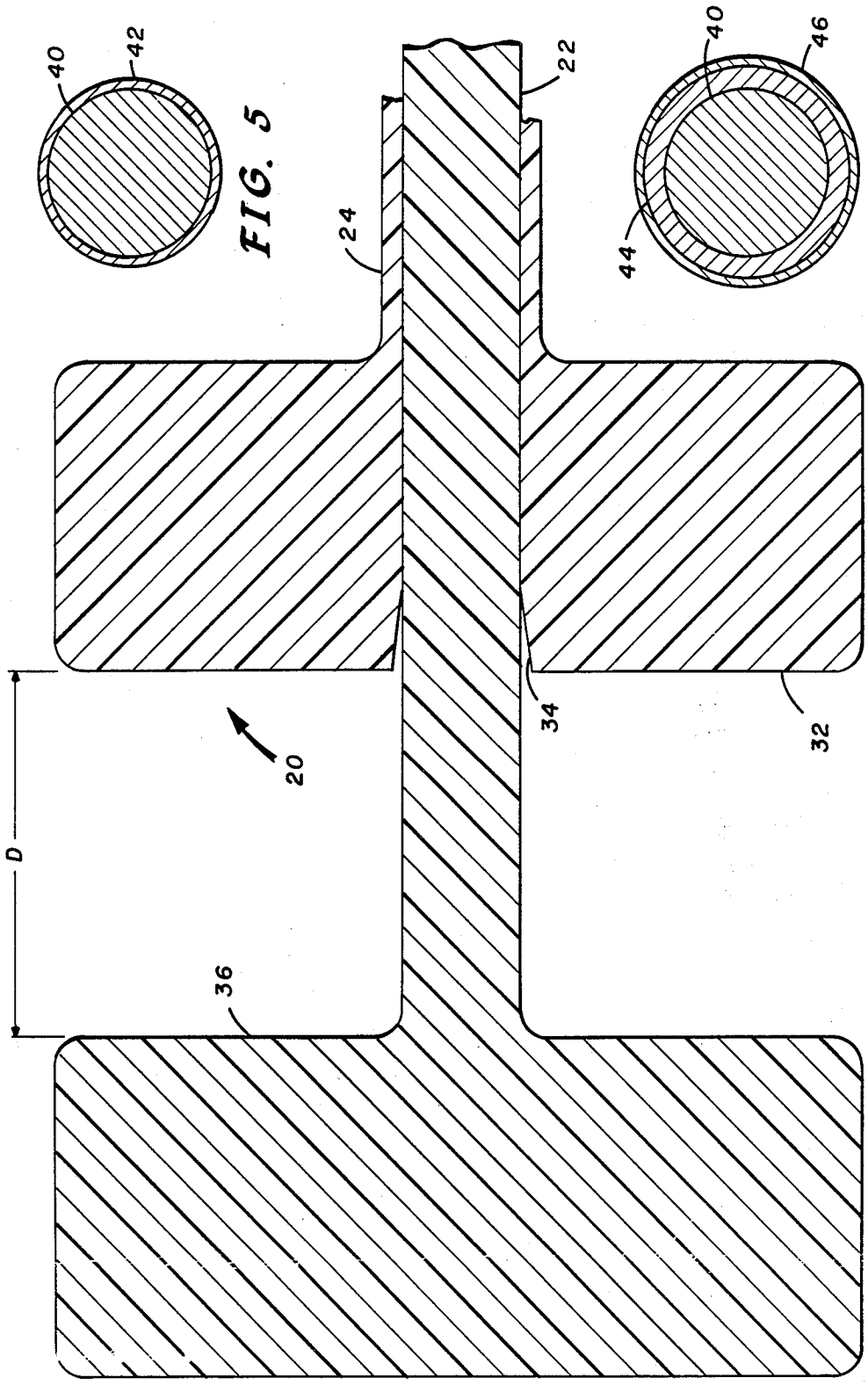


FIG. 5

FIG. 6

FIG. 4

INTRAVASCULAR STENT AND PERCUTANEOUS INSERTION CATHETER SYSTEM FOR THE DILATION OF AN ARTERIAL STENOSIS AND THE PREVENTION OF ARTERIAL RESTENOSIS

This is a continuation of co-pending application Ser. No. 832,216, filed on 2-14-86, now abandoned.

BACKGROUND OF THE INVENTION

In the last decade there has been increasing use of percutaneous transluminal balloon angioplasty for the opening of stenoses of the peripheral and coronary arteries. In this procedure the uninflated balloon at the tip of the catheter is advanced into the narrowed portion of the arterial lumen. The balloon is then inflated so as to push the stenotic plaque outward thereby enlarging the luminal diameter and improving distal perfusion. The balloon is then deflated and the catheter is withdrawn from the body. Initially the blood flow at that point is typically improved to a significant degree. However, within six months, restenosis, defined as a loss of more than 50% of the initial enlargment of arterial diameter, occurs in approximately 30% of cases. It would therefore be of great value if a means could be devised to retain patency (i.e. opening) of the artery so that adequate blood flow would be maintained.

The concept of placing a coil spring intravascular stent within an artery is not new. In the September-October 1969 edition of *Investigative Radiology,* C. T. Dotter reported the insertion of 6 coil spring intravascular stents in the arteries of dogs. Three of these springs which were covered with silicone rubber occluded within 24 hours. Two out of three, bare stainless steel wire springs remained patent at 2½ years. Dotter also described a "pusher-catheter" of equal diameter with the spring outer diameter which was used to place the springs within the artery.

In more recent work, D. Maas et al in the September 1984 edition of *Radiology* described improved stainless steel coil spring intravascular stents that were implanted in 65 dogs and 5 calves. A 100% success rate was reported using bare, heat treated steel alloy springs that were torqued to a reduced diameter and inserted with a special device designed for that purpose.

Neither Dotter nor Maas at all were able to perform a percutaneous procedure for the stent insertion. Dotter describes a "pusher-catheter" that was of equal diameter to the outside diameter of the coil spring. Maas et. al. used a 7 mm diameter special insertion device that applied torque to the coil spring to reduce its diameter to 7 mm; i.e., the deployed outside diameter was greater than 7 mm. Since the largest practical outside diameter for percutaneous delivery is less than 4 mm, the device and methods used by Maas et al are not practical for percutaneous insertion.

The results of Dotter i.e. 2 of 3 patent arteries at the end of 2½ years using comparatively small (3.5 mm) diameter coil are probably not good enough for clinical applications. The results of Maas et al were very good, but these were for inside diameters greater than 7 mm.

What is really needed and not described by either Dotter or Maas et al or anyone else is a safe and simple method for percutaneous transluminal insertion of a coil spring stent whose insertion device structure allows an insertion catheter of outer diameter less than 4 mm. Another requirement of the insertion device is that it maintains the reduced diameter of the coil spring stent during insertion and allows the coil to expand to a diameter greater than the diameter of the arterial lumen after removal of the insertion catheter.

To make the intravascular stent (IS) safe for human use even in small diameter coronary arteries, it is necessary for the spring material to be biocompatible and non-thrombogenic. The greatest success by Dotter and Maas et al was with bare metal coil springs. However, no investigation to date has described use of these stents in either human subjects or in animal coronary arteries. Furthermore, Dotter quotes an article which states that "It appears that success or failure of an arterial substitute in dogs bears no direct relationship to the results one will obtain when a similar substitute is used clinically for the peripheral arteries". Hence one must be concerned with the human biocompatability of the material used for the IS.

Many articles such as "ULTI Carbon Goretex: A New Vascular Graft" by R. Debski et al in the May-June 1983 edition of *Current Surgery* describe the superior non-thrombogenic characteristics of ultra low-temperature isotropic (ULTI) carbon as such a blood compatible material. The use of carbon as a blood compatible material for humans is well known among those skilled in the art of vascular grafts and prosthetic heart valves. However, no investigator of IS devices has ever described the use of carbon coated coil springs or carbon coated polytetrafluoroethylene (PTFE) covered coil springs to solve the problem of thrombosis of small diameter IS devices in humans.

It should be noted that nothing in the prior art describes the use of a coil spring stent for the prevention of arterial blockage due to intimal dissection (tearing away of the intima layer) following balloon angioplasty. There is appproximately a 30% incidence of radiologically detectable intimal dissection following routine percutaneous transluminal coronary angioplasty (PTCA). In many of these cases this is not a problem. Vessel wall healing and remodeling typically restores a smooth luminal contour with good vessel patency within several weeks following the angioplasty. In a small but significant subset of these patients, the intimal dissection may be severe, resulting in a high risk of vessel closure within 24 hours following PTCA. These patients will typically sustain some degree of myocardial infarction despite further aggressive attempts at revascularization, including coronary artery bypass surgery.

SUMMARY OF THE INVENTION

Thus it is an objective of the present invention to utilize a coil spring intravascular stent (IS) for the prevention of arterial restenosis.

A second objective of the invention is to utilize an IS to further enlarge the luminal diameter after successful percutaneous transluminal angioplasty.

Another objective is to provide a percutaneous transluminal catheter means for placing the IS at the appropriate place within the artery.

Still another objective is to describe a method for percutaneous insertion of intravascular stents.

Still another objective is to provide a means and method for preventing arterial blockage due to intimal dissection following balloon or other types of angioplasty.

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