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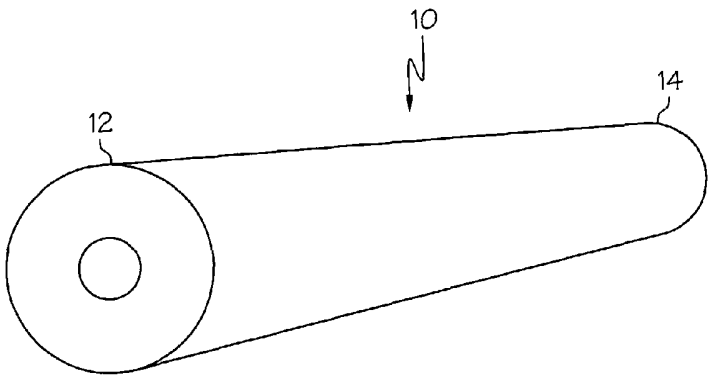

(57) **Abstract:** A method and apparatus for reducing the longitudinal aspect of the catheter to stent force comprises at least one grip member for use with a stent delivery system. The grip engages a stent in the unexpanded state prior to delivery of the stent by retracting a stent retaining sheath. The grip comprises a body region having an outer diameter, a first end and a second end. The outer diameter of the first end is greater than the outer diameter of the second end. The grip is at least partially constructed from a polymeric material.

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Stent Grip and System For Use Therewith.

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to a grip member for use with stent delivery systems and to systems employing one or more of such grips.

Description of Related Art

The use of stents, and other implantable medical devices such as grafts, stent-grafts, vena cava filters, etc, hereinafter referred to cumulatively as stents, to maintain the patency of bodily lumens is well known.

Stents are typically delivered via a catheter in an unexpanded configuration to a desired bodily location. Once at the desired bodily location, the stent is expanded and implanted in the bodily lumen.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding; some stents are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon; and some stents, known as hybrid stents, have one or more characteristics common to both self-expanding and mechanically expandable stents.

An example of a mechanically expandable stent and associated delivery system is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is

inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Self-expanding stents are constructed from a wide variety of materials including nitinol, spring steel, shape-memory polymers, etc.

In many stent delivery systems, particularly those used to deliver a self-expanding stent, the stent is typically retained on the catheter via a retention device such as a sheath. The stent may be deployed by retracting the sheath from over the stent. However it is known that in many cases when a sheath is withdrawn from a stent, particularly a self-expanding stent constructed of shape memory material, the individual struts or stent members of the stent will push outward as they expand back to their "remembered" shape. Often times, but undesirably, as the sheath is withdrawn from about the stent, the stent will tend to migrate longitudinally relative to the stent mounting region of the catheter. This migration is believed to be caused by a longitudinal component of the force that the stent delivery system exerts on the stent during withdrawal of the sheath. The tendency of the stent to migrate during sheath retraction may result in the imprecise delivery of the stent and/or distortion of the stent body.

It would thus be desirable to reduce the longitudinal component of the delivery system to stent force and/or provide a device for use in a stent delivery system that reduces or prevents stent migration during withdrawal of the stent retaining sheath.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract

is not intended to be used for interpreting the scope of the claims.

BRIEF SUMMARY OF THE INVENTION

This invention may be embodied in a variety of forms. For example, in at least one embodiment, the invention is directed to a stent delivery system that reduces or eliminates the longitudinal component of the system to stent force, which may influence or cause migration of the stent or one or more components thereof relative to the catheter during withdrawal of the retaining sheath. In some embodiments the reduction in the longitudinal component of the system to stent force is accomplished by reducing or minimizing the potential space between the inner catheter shaft or member, upon which the stent is mounted prior to delivery, and the retractable outer sheath which overlays the stent prior to delivery.

In some embodiments the potential space between the sheath and inner member/stent is reduced by providing a stent delivery system with one or more stent grips or grip members which underlie at least a portion of a stent prior to delivery. A stent grip comprises an annular ring mounted to the catheter shaft. In some embodiments the stent grip has an end portion and a body portion, in the reduced or pre-delivery state the stent is disposed about the body portion and an end of the stent abuts the end portion of the stent grip.

In at least one embodiment the stent grip comprises a body portion having a tapered or varying diameter. In at least one embodiment the diameter of the body tapers from a first diameter at a first end of the body to a second smaller diameter at a second end of the body. In some embodiment a stent delivery system includes a single tapered grip or a pair of tapered grips wherein each grip is respectively positioned on the catheter shaft to underlie an end of the stent.

In at least one embodiment a stent delivery system comprises a single stent grip, wherein the single grip has a body which has a length substantially the same as that of the stent. In some embodiments, multiple grips have body portions that have a combined length that is substantially less than or equal to that of the stent.

In some embodiments the invention is directed to a stent grip member for use in a stent delivery system wherein the stent grip is at least partially constructed of a polymer material. In some embodiments the material is preferably of a fairly soft durometer value to allow a stent to be effectively gripped or at least partially imbedded within the material of the grip.

In some embodiments a grip is insert molded, molded and then bonded to the catheter shaft, or otherwise formed separately or in conjunction with the catheter shaft or portion thereof.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages and objectives obtained by its use, reference should be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described a embodiments of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

FIG. 1 is a perspective view of an embodiment of the invention.

FIG. 2 is a cross-sectional side view of an embodiment of the invention.

FIG. 3 is a cross-sectional side view of an embodiment of the invention.

FIG. 4 is a cross-sectional side view of an embodiment of the invention.

FIG. 5 is a cross-sectional side view of an embodiment of the invention.

FIGs. 6 and 7 are close up cross-sectional side views of an embodiment of the invention shown during a stent delivery process.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

As mentioned above the present invention is embodied in a variety of forms. For example, in the embodiment shown in FIG. 1 the invention is embodied in a stent retaining member or grip, indicated generally at 10, which has an outer diameter that tapers from a first, larger diameter at a first end 12 of the grip 10 to a second, smaller diameter at a second end 14 of the grip.

In some embodiments, an example of which is shown in FIG. 2, the grip 10 includes a hub or dam 16 adjacent to the first end 12. At least a portion of the hub 16 has a diameter larger than the diameter of the grip body 18. In at least one embodiment such as is shown in FIG. 3 the a stent 20 or other implantable medical device may be positioned adjacent to or butted up against an inner surface 22 of the hub 16 when the stent is disposed about the grip body 18 prior to expansion of the stent.

As is illustrated in FIG. 4, in some embodiments, a stent delivery catheter, indicated generally at 100, comprises one or more grips 10. One or more grips 10 are engaged or incorporated onto the inner shaft or member 30 of the catheter 100. The position of the grips 10 on the inner member 30 substantially correspond to the area of the member which defines a stent mounting region 32. A stent 20 is disposed about the stent mounting region 32 and in the reduced or pre-delivery state is engaged to at least a portion of each grip 10.

Where a single grip 10 is utilized, such as is shown in FIG. 5 the body 18 of the grip underlies at least a portion of the stent. In at least one embodiment, the body 18 of the grip 10 has a length which is at least as long as that of the stent 20.

Where multiple grips are used such as in FIG. 4, the lengths of each grip body 18 are approximately half the length of the stent 20 or less. In at least one embodiment the diameter of the grips taper from a larger diameter at the ends 34 of the stent 20 to a smaller diameter under the body 36 of the stent 20.

In some embodiments of the invention stent 20 is a self-expandable device such as are known. Stent 20 may be at least partially constructed from nickel, titanium, stainless steel, other metals and alloys thereof, such as nitinol. Other materials suitable for use in constructing stent 20 may include shape memory polymers, etc.

In the various embodiments of the invention, the grip 10 effectively reduces the longitudinal aspect of the catheter to stent force by ensuring that the individual struts 40 of the stent 20 are at a shallower or smaller angle upon exiting the confines of a sheath, sleeve or other stent retaining device 42 when the sheath 42 is retracted to allow the stent 20 to expand such as is shown in FIGs. 6 and 7.

In some embodiments, a grip 10 is at least partially constructed of a polymer material. In some embodiments the material has a Shore-A durometer value of about 60 to about 90 and in some embodiments about 70 to about 90. In some embodiments the grip is at least partially constructed from one or more materials such as: polyether ester; HYTREL (polyether-ester copolymer) by Du Pont Co.; polyether block amides; ARNITEL (polyether-ester copolymer) by DSM Engineering Plastics; PELLETHANE (polyurethane with polyester, polyether, or polycaprolactone copolymers) by Dow Chemical; polyurethane; aromatic polyether based polyurethanes, such as TECOTHANE available from Thermedics Inc.; silicon, rubber, or foam, etc.

In at least one embodiment the grip 10 is at least partially constructed from a radiopaque polymer or other radiopaque material.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted,

the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

CLAIMS:

1. A grip for engaging a stent in a stent delivery catheter prior to delivery, the grip comprising a body region, the body region having an outer diameter, a first end and a second end, the outer diameter of the first end being greater than the outer diameter of the second end, the grip being at least partially constructed from a polymeric material.

2. The grip of claim 1 further comprising a hub region, the hub region being adjacent to the first end of the body region, the hub region having a diameter greater than the outer diameter of the first end of the body region.

3. The grip of claim 1 wherein the outer diameter of the body region is substantially tapered from the first end to the second end.

4. The grip of claim 1 wherein at least a portion of the grip has a hardness of about 60 to about 90 as measured on the Shore A hardness scale.

5. The grip of claim 1 wherein at least a portion of the grip has a hardness of 70 to about 90 as measured on the Shore A hardness scale.

6. The grip of claim 1 wherein at least a portion of the grip is constructed from at least one material of the group consisting of: polyether ester, polyether block amides, PELLETHANE, TECOTHANE, polyurethane, rubber foam, silicon and any combination there of.

7. The grip of claim 1 wherein a least a portion of the grip is radiopaque.

8. The grip of claim 1 wherein the grip is engaged to an inner shaft of a catheter assembly.

9. The grip of claim 8 wherein the grip defines at least a portion of a stent mounting region of the inner shaft.

10. The grip of claim 8 wherein the catheter assembly comprises a stent, the stent having an unexpanded state and an expanded state, in the unexpanded state at least a portion of the stent being disposed about and engaged to at least a portion of the body region of the grip.

11. A stent delivery system comprising:

a catheter, the catheter having an inner shaft and a retractable sheath, the inner shaft having at least one grip member engaged thereto, the at least one grip member comprising a body region, the body region having an outer diameter, a first end and a second end, the outer diameter of the first end being greater than the outer

diameter of the second end, the at least one grip member being at least partially constructed from a polymeric material; and

a stent, the stent being expandable from an unexpanded state to an expanded state, in the unexpanded state at least a portion of the stent being disposed about a portion of the inner shaft and engaged to at least a portion of the body region of the at least one grip, in the unexpanded state the retractable sheath being overlying the stent, when the retractable sheath is retracted off of the stent, the stent is expanded to the expanded state.

12. The stent delivery system of claim 11 wherein the stent comprises a plurality of struts.

13. The stent delivery system of claim 12 wherein the catheter exerts a longitudinal force upon individual struts of the stent when the sheath is retracted from about the stent, the at least one grip member reducing the longitudinal force the catheter exerts on the individual struts.

14. The stent delivery system of claim 11 wherein the at least one grip member further comprises a hub region, the hub region being adjacent to the first end of the body region, the hub region having a diameter greater than the outer diameter of the first end of the body region, in the unexpanded state an end of the stent being positioned adjacent to the hub region.

15. The stent delivery system of claim 11 wherein the outer diameter of the body region of the at least one grip member is substantially tapered from the first end to the second end.

16. The stent delivery system of claim 11 wherein the at least one grip member comprises a first grip member and a second grip member, the second end of the body region of the first grip member being substantially adjacent to the second end of the body region of the second grip member.

17. The stent delivery system of claim 16 wherein the stent comprises a first end portion, a second end portion and a body portion therebetween, in the unexpanded state the first end portion of the stent being engaged to at least a portion of the body region of the first grip member, and the second end portion of the stent being engaged to at least a portion of the body region of the second grip member.

18. The stent delivery system of claim 17 wherein in the unexpanded state the body portion of the stent overlies the second end of the body region of the first grip member and the second end of the body region of the second grip member.

19. The stent delivery system of claim 12 wherein the at least a portion of the at least one grip member has a hardness of about 60 to about 90 as measured on the Shore A hardness scale.

20. The stent delivery system of claim 12 wherein the at least a portion of the at least one grip member has a hardness of about 70 to about 90 as measured on the Shore A hardness scale.

21. The grip of claim 1 wherein at least a portion of the grip is constructed from at least one material of the group consisting of: polyether ester, polyether block amides, PELLETHANE, TECOTHANE, polyurethane, rubber foam, silicon and any combination there of.

22. The stent delivery system of claim 12 wherein the at least a portion of the at least one grip member is radiopaque.

23. A method of reducing the longitudinal aspect of a catheter to stent force in a stent delivery system comprising a catheter shaft, a retractable sheath and an expandable stent, the method comprising the step of:

minimizing the space between the catheter shaft and the retractable sheath.

24. The method of claim 23 wherein minimizing the space between the inner shaft and the retractable sheath is accomplished by providing a portion the catheter shaft with at least one grip member, the at least one grip member comprising a body region, the body region having an outer diameter, a first end and a second end, the outer diameter of the first end being greater than the outer diameter of the second end, the at least one grip member being at least partially constructed from a polymeric material; and

engaging at least a portion of the stent in an unexpanded state to at least a portion of the body region of the at least one grip, in the unexpanded state the retractable sheath being overlying the stent, when the retractable sheath is retracted off of the stent, the stent is expanded to an expanded state.

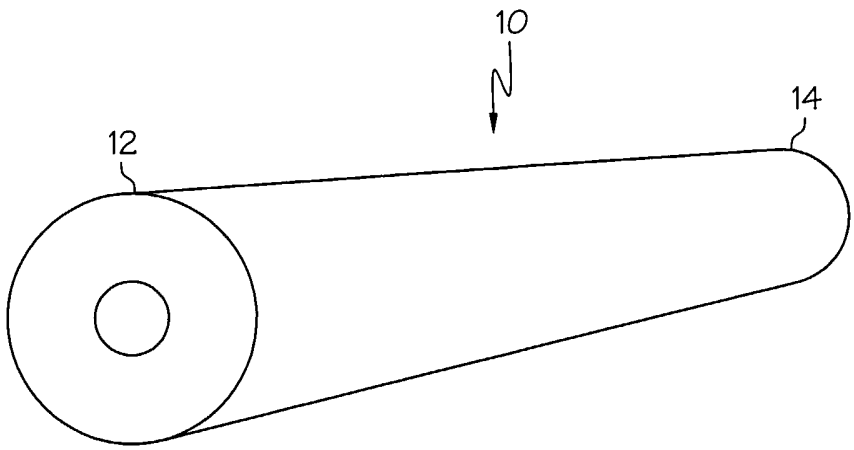

FIG. 1

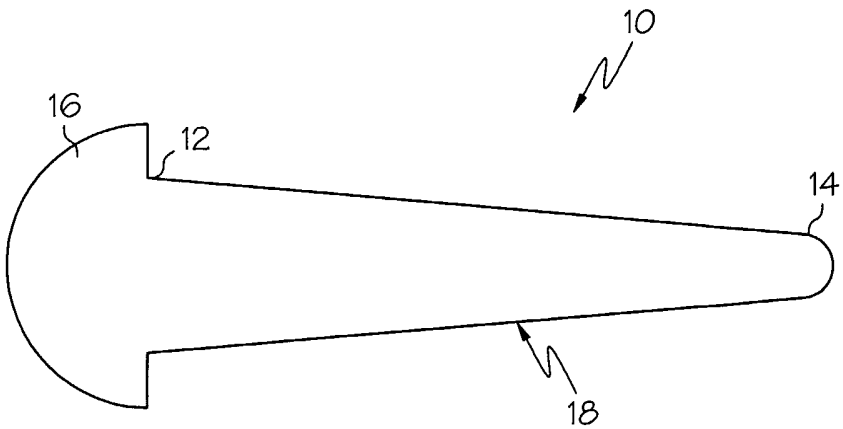

FIG. 2

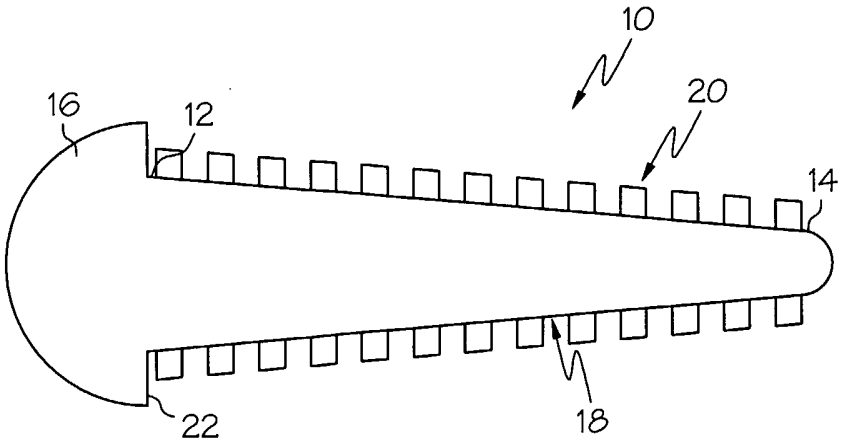

FIG. 3

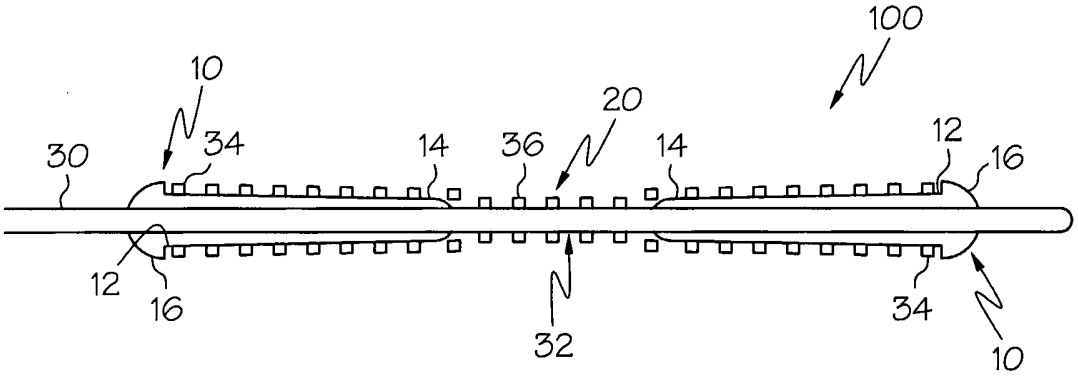

FIG. 4

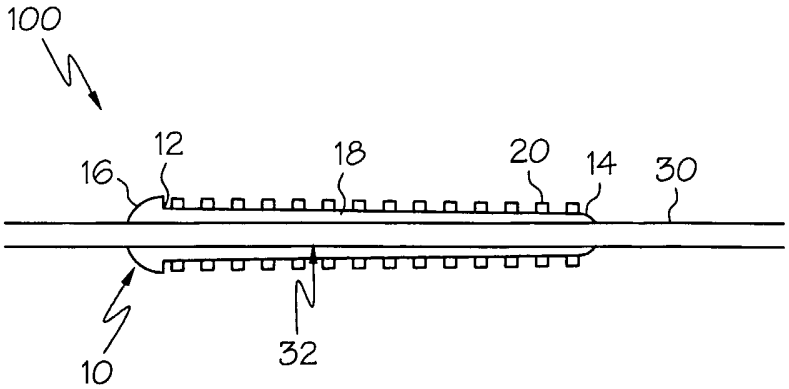

FIG. 5

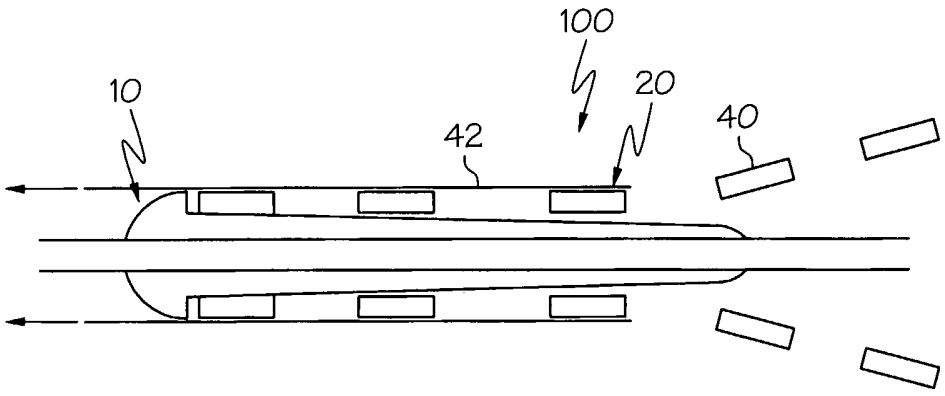

FIG. 6

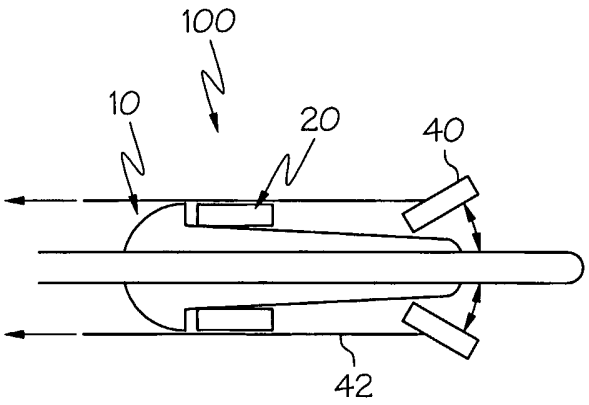

FIG. 7