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(54) Title: PROTECTION DEVICE FOR A PROSTHESES AND/OR BALLOON CATHETER AND METHOD MAKING AND USING THE SAME

(57) Abstract: The invention provides for a protection device (1) including a mandrel (2) having a first end (11) and a second end (12) and a sleeve or sheath (3). A portion of the sleeve or sheath (3) surrounds a portion of the mandrel (2). A space (23) is disposed between the portion of the sleeve (3) and the portion of the mandrel (2) and is sized and configured to receive therein or accommodate at least one of; an insertion end of a medical lumen, an insertion end of a catheter, a medical balloon, a prostheses, and a stent.
PROTECTION DEVICE FOR A PROSTHESES AND/OR BALLOON CATHETER AND METHOD
MAKING AND USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The instant application is a PCT International Application based on U.S. provisional application No. 61/552,795, filed October 28, 2011, the disclosure of which is hereby expressly incorporated by reference hereto in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention relates to a protection device or protector which can be used with a catheter, thrombectomy device, and/or other medical device, which can be utilized to protect a distal end, a prostheses and/or a balloon, and/or which utilizes one or more features shown in the drawings and/or recited in the claims. A method of making and using the device is also disclosed.

2. Discussion of Background Information

[0003] Devices for installing a prostheses such as a stent are well known. Such devices typically include a hollow or tubular introduction lumen. The lumen is guided to a desired location (e.g., a specific area inside an artery or vein) inside a patient via a guide wire which can pass through the lumen. The insertion end of the lumen typically includes a balloon and a prostheses or stent arranged thereon. After the lumen is guided to the desired location, the balloon is inflated to cause radial expansion of the stent which is designed to remain in place in the expanded state. Thereafter, the balloon is deflated and the catheter is withdrawn.

[0004] However, the business or insertion end of such catheters, including the balloon and stent, can be damaged by, among other things, contact with objects or surfaces. This can occur during manufacturing, assembly, packaging, shipping and use, as well as during handling in a catheter lab environment.

[0005] Devices have been used and/or described which provide some protection for the catheter insertion or distal end. Such devices include those disclosed in US 7,691,136 to McMorrow, US 6,830,575 to Stenzel et al., US 6,592,569 to Bigus et al., US 6,383,171 to Gifford et al., US 5,647,857 to Anderson et al., US 2003/0187493 to Campbell et al., and US 2003/0105508 to Johnson et al. The disclosure of each of these documents is hereby incorporated by reference in its entirety as though set forth in full herein.

[0006] An improved device, however, would, among other things, offer better protection for the catheter end, be easier to use, be safer, be easier to assemble or install, and be less costly to make. Such a device would also have one or more additional advantages:

- a low co-efficient of friction, provide protection for coated medical devices such as stents by, e.g., having limiting or little contact therewith while also protecting the same;

- provide for greater retention or friction force between the mandrel and an inside of the medical lumen than that provided between the protector sheath and the device being protected thereby, among other things, reducing the rink of "hang-ups";

- provide a device which can automatically center the protective sheath (via the mandrel) to provide consistent and uniform shielding or to prevent contact - with the protector sheath providing protection;
to prevent and/or reduce damage to a stent or prostheses by abrasion with a protector;
to increase a retention force between a catheter tip and the protector so as to both protect the tip and/or insure that the protector remains on the catheter during insertion and removal of the catheter into a coiled packaging or storage lumen; and
to prevent and/or reduce damage to a medical lumen tip and/or a device arranged thereon (e.g., stent) which can occur during assembly, packaging, transport and use.

[0007] It is submitted that there is a continuing need for a protector of the type described herein which has one or more of the above-noted advantages and which are lacking in known devices.

SUMMARY OF THE INVENTION

[0008] According to one non-limiting aspect of the invention, there is provided a protection device comprising a mandrel having a first end and a second end and a sleeve. A portion of the sleeve surrounds a portion of the mandrel. A space is disposed between the portion of the sleeve and the portion of the mandrel. The space is sized and configured to receive therein or accommodate at least one of; an insertion end of a medical lumen, an insertion end of a catheter, a medical balloon, a prostheses, and a stent.

[0009] In embodiments, the mandrel is at least one of; an elongated wire, an elongate synthetic resin rod, an elongated metal rod, a solid stainless steel wire, and a wire insertable within a medical lumen.

[0010] In embodiments, the sleeve is arranged in an area of the first end and the second end of the mandrel is sized and configured to be insertable within at least one of; an insertion end of a medical lumen and an insertion end of a catheter.

[0011] In embodiments, the sleeve comprises a first end that is at least one of; encases a ring portion of the first end of the mandrel, encases an enlarged portion of the first end of the mandrel, encases the first end of the mandrel, non-movably secured to the first end of the mandrel, fixedly secured to the first end of the mandrel, non-removably secured to the first end of the mandrel, and non-axially movably secured to the first end of the mandrel.

[0012] In embodiments, the sleeve comprises a synthetic resin material and the mandrel comprises a metal and/or synthetic resin material. In embodiments, the sleeve may be a soft or flexible material and the mandrel comprises a harder material. In embodiments, the sleeve may be colored, e.g., red or green, and/or provide a visual indication to a user of the position of a device located therein.

[0013] In embodiments, the sleeve comprises PTFE and the mandrel comprises 304 stainless steel.

[0014] In embodiments, the sleeve comprises MDPE, HDPE, LLDPE, LDPE and/or PTFE and the mandrel comprises 304 or 318 stainless steel.

[0015] In embodiments, the sleeve comprises MDPE, 75% HDPE and 25% LLDPE and the mandrel comprises 304 stainless steel.

[0016] In embodiments, the sleeve comprises a connected portion and a non-connected portion that is axially longer than the connected portion, and wherein said space is arranged within the non-connected portion.

[0017] In embodiments, the sleeve comprises a connected portion and a non-connected portion that has a greater diameter than the connected portion, and wherein said space is arranged within the non-connected portion.

[0018] In embodiments, the sleeve further comprises at least one of; an open end communicating with said space, a flared open end, a generally tapered open end, and an open end sized and configured to receive therein an
injection end of a medical lumen.

[0019] In embodiments, the sleeve has an overall axial length that is less than an overall axial length of the mandrel.

[0020] In embodiments, the sleeve has an overall axial length that is at least one of; approximately greater than 10 mm, approximately greater than 20 mm, approximately greater than 50 mm, approximately 50 mm, approximately 60 mm, approximately 70 mm, approximately 80 mm, and approximately a fraction of an overall axial length of the mandrel.

[0021] In embodiments, the mandrel has an overall axial length that is at least one of; greater than 150 mm, greater than 300 mm, approximately 320 mm, approximately 330 mm, approximately 350 mm, approximately 380 mm, and approximately a multiple of an overall axial length of the sleeve. In embodiments, the mandrel need to be generally cylindrical and can be tapered.

[0022] In embodiments, the protection device has an overall axial length that is at least one of; greater than 300 mm, approximately 320 mm, approximately 330 mm, approximately 350 mm, approximately 380 mm, less than 500 mm, and approximately a multiple of an overall axial length of the sleeve.

[0023] In embodiments, an outside diameter of a main portion of the sleeve is at least one of; greater than or equal to 1.0 mm, greater than 1.5 mm, approximately 1.60 mm, approximately 1.70 mm, approximately 1.80 mm, approximately 1.90 mm, between approximately 2 mm and approximately 2.6 mm, and between approximately 1.5 mm and approximately 3 mm, and less than 13 mm.

[0024] In embodiments, the mandrel has an outside diameter that is at least one of; greater than 0.2 mm, greater than 0.3 mm, approximately 0.37 mm, approximately 0.38 mm, and between approximately 0.3 and 0.4 mm, and less than 1.5 mm.

[0025] In embodiments, the mandrel has a uniform generally cylindrical outer surface.

[0026] In embodiments, a main portion of the sleeve has a uniform generally cylindrical outer surface.

[0027] In embodiments, a main portion of the sleeve is a uniform generally cylindrical wall.

[0028] In embodiments, a main portion of the sleeve may have a portion that is a generally uniform wall thickness.

[0029] In embodiments, a main portion of the sleeve has a generally uniform wall thickness of at least one of; greater than approximately 0.10 mm, approximately 0.10 mm, approximately 0.2 mm, and approximately 0.3 mm, and less than approximately 1.0 mm.

[0030] In embodiments, a main portion of the sleeve has a generally uniform wall thickness that is thinner than a thickness of the space.

[0031] In embodiments, substantially an entire axial length of the sleeve has a uniform generally cylindrical outer surface.

[0032] In embodiments, an axial length and diameter of a first portion of the sleeve is less than an axial length and diameter of a second portion of the sleeve.

[0033] In embodiments, an axial length and diameter of a first portion of the sleeve is different than an axial length and diameter of a second portion of the sleeve.

[0034] In embodiments, an axial length and diameter of a first portion of the sleeve is different than an axial
length and diameter of a second portion of the sleeve, and wherein an axial length and diameter of a second portion of
the sleeve is different than an axial length and diameter of a third portion of the sleeve.

[0035] In embodiments, at least a main portion of the sleeve is substantially transparent or translucent. In
embodiments, at least a main portion of the sleeve is colored, e.g., red or green, or opaque.

[0036] According to one non-limiting aspect of the invention, there is provided a protection device
comprising an elongated member having a first end and a second end and a sleeve arranged in an area of the first end.
A main portion of the sleeve surrounds a portion of the member. A space is disposed between the main portion of the
sleeve and the portion of the member. The space is sized and configured to receive therein or accommodate at least one
of: an insertion end of a medical lumen, an insertion end of a catheter, a medical balloon, a prostheses and a stent. The
second end of the member is sized and configured to pass or extend into at least one of an insertion end of a medical
lumen and an insertion end of a catheter.

[0037] According to one non-limiting aspect of the invention, there is provided a stent or balloon protection
device comprising an elongate member having a first end and a second end. The second end of the member is sized
and configured to pass or extend into an insertion end of a medical lumen. A tubular protector is non axially movably
connected to the elongate member. A main portion of the tubular protector surrounds a portion of the elongate
member. An annular space is disposed inside the tubular protector. The space is sized and configured to receive
therein or accommodate at least one of; an insertion end of a medical lumen, an insertion end of a catheter, a medical
balloon, a prostheses, and a stent.

[0038] According to one non-limiting aspect of the invention, there is provided a method making the device
of anyone of the types described above, wherein the method comprises arranging a sleeve on a mandrel.

[0039] According to one non-limiting aspect of the invention, there is provided a method using the device of
anyone of the types described above, wherein the method comprises inserting the second end of the mandrel into a
medical lumen until the an insertion end of the medical lumen extends into the space.

[0040] Other exemplary embodiments and advantages of the present invention may be ascertained by
reviewing the present disclosure and the accompanying drawing.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0041] The present invention is further described in the detailed description which follows, in reference to
the noted plurality of drawings by way of non-limiting examples of exemplary embodiments of the present invention, in
which like reference numerals represent similar parts throughout the several views of the drawings, and wherein:

- Fig. 1 shows a side view of a first non-limiting embodiment of a medical protection device in accordance with
  the invention. The sheath is substantially transparent or substantially translucent;

- Fig. 2 shows a side cross-section view of Fig. 1 rotated 90 degrees so that the ring shown in Fig. 1 is seen in
top view;

- Fig. 3 shows an enlarged view of detail B shown in Fig. 2;

- Fig. 4 shows an enlarged view of one end of the mandrel shown in Fig. 2;

- Fig. 5 shows an enlarged view of a portion of Fig. 3 with an insertion end of a catheter (having a balloon and
  stent) inserted therein;
Fig. 6 shows a side view of a second non-limiting embodiment of a medical protection device with internal features shown in hidden-lines in accordance with the invention;

Fig. 7 shows a side view of Fig. 6. The sheath is substantially transparent or substantially translucent. In Fig. 7, the device is rotated 90 degrees relative to Fig. 6 so that the ring is seen in top view;

Fig. 8 shows a side cross-section view of Fig. 7;

Fig. 9 shows an enlarged view of detail C shown in Fig. 8;

Fig. 10 shows an enlarged view of detail D shown in Fig. 6;

Fig. 11 shows a side view of a third non-limiting embodiment of a medical protection device in accordance with the invention. The sheath is substantially transparent or substantially translucent;

Fig. 12 shows a side view of Fig. 11 rotated 90 degrees relative to Fig. 11 so that the ring is seen in top view;

Fig. 13 shows an enlarged view of detail F shown in Fig. 11;

Fig. 14 shows an enlarged view of detail G shown in Fig. 12;

Fig. 15 shows one non-limiting way in which a protection device in accordance with the invention can be slid onto/into an insertion end of a catheter having a balloon and stent installed thereon or vice versa;

Fig. 16 shows an enlarged portion of Fig. 15;

Fig. 17 shows a cross-section of another non-limiting embodiment of the protector in accordance with the invention;

Fig. 18 shows an enlarged portion of a first end of Fig. 17;

Fig. 19 shows an enlarged portion of a second end of Fig. 17;

Fig. 20 shows a cross-section of another non-limiting embodiment of the protector in accordance with the invention and shows a catheter installed therein; and

Fig. 21 shows an enlarged portion of Fig. 20.

**DETAILED DESCRIPTION OF THE INVENTION**

Figs. 1-4 show a first non-limiting embodiment of the medical protection device or assembly 1. The device 1 includes two main components. A first component is a mandrel 2. The mandrel 2 is a generally elongate member 10 sized and configured to pass into a lumen of another generally elongate medical device such as, e.g., a catheter, and can have a number of beneficial characteristics that will be discussed below. Another component is a protective sheath 3. The sheath 3 is a generally tubular member or sleeve sized and configured to receive therein a leading or free end of another generally elongate medical device such as, e.g., a catheter, is configured to protect the inserted free or leading end, and can have a number of beneficial characteristics that will be discussed below. When fully assembled, the device 1 has an overall length OL as well as a length PL defined by a free or leading end of the device 1 and the open or receiving end 26 of the sheath 3.

In the embodiment of Figs. 1-4, the mandrel 2 has the form of a solid material rod or wire member 10 having a generally uniform cross-sectional size and shape and can have a slightly tapered wall thickness. The member 10 includes a first end 11 and a second opposite end 12. It is also possible for the mandrel 2 to be tubular or have another configuration or cross-sectional shape other than generally circular. In embodiments, the first end 11 provides a location for fixing the mandrel 2 to the sheath 3 and also functions a leading end of an elongate medical device when installed thereon. As can be seen in Fig. 4, the second end 12 can also be blunted by having a rounded end.
Alternatively, in this or other embodiment disclosed herein, the end 12 can be angled, e.g., having a 45 degree angled cut, especially if the mandrel is made of synthetic resin material. This can both facilitate insertion into a lumen while also ensuring that no damage or little damage is created to an inner surface forming the lumen. As it is desirable to have a blunt or blunted end in the area of the first end 11 and also to provide a reliable connection, the first end 11 can have a connecting portion 13 which in this embodiment has the form or a ring. In embodiments, the ring 13 can be any shape that functions to anchor the rod to the sleeve can be formed by merely bending the end 11 into a ring shape. In this embodiment, the ring 13 is then covered by a material 21 further blunting the leading end. The material 21 can be formed generally into sphere. In a simple form, the material 21 is part of the material forming the sheath 3. In this or other herein disclosed embodiments, if both the mandrel 2 and sleeve 3 are made of synthetic resin, the connection between these elements can occur via a fusing or melting of the materials at the connection. In order to, among other things, make the leading end flexible and/or bendable, a transition area 22 is formed between the end 21 and a main section 20 of the sheath 3. The transition area 22 is formed with a smaller diameter or cross-section than either the end 21 or the main section 20. In a simple form, the section 22 has a length 1.1 and is part of the material forming the sheath 3 covering a portion of the mandrel 2 between end 13 and the portion covered by the main section 20.

With reference to Figs. 3 and 4, it can be seen how the material forming the sheath 3 covers the wire 10 in the section 22 and then transitions to form the tubular main section 20. This transition can have the form a tapered section 24 that extends from the section 22 to the section 20. As can be seen in Fig. 3, whereas the material forming the sheath 3 has the form of a covering layer contacting the member 10 in section 22, it transitions to being spaced from the member 10 in sections 24 and 20 thereby defining an elongate annular space 23. It is this space 23 which receives therein a free or leading end of an elongate medical device. Furthermore, it is the main section 20, and specifically the generally cylindrical wall thickness 25 of the tubular section 20 that covers and provides protection for that portion of the leading end of the elongate medical device inserted therein. In embodiments, the section 20 has a predetermined inner diameter 29 extending to an expanded open end 27 and an axial length 1.2.

With reference to Fig. 5, it can be seen how the device can be used to protect a leading end of an elongate medical device. In this example, the leading end of a catheter 50 having a balloon 30 mounted to an outer surface 52 and a stent 40 is inserted into the space 23 of the sheath 3 as follows. First, the end 12 (see Fig. 2) is aligned with the lumen 53 and is inserted or slid within the inner surface 51 of the catheter 50. When fully inserted, the free end of the catheter 50 should abut or almost abut section 24 (see Fig. 3). To facilitate insertion without or with minimal damage to the stent 40, the sheath 3 can include an open end 26 having a tapered or expanded section 27 (see Figs. 1 and 2) and having a diameter 28 (see Fig. 2). Moreover, in order to provide protection for the stent 40 mounted to the balloon 30 arranged on the free end of the catheter 50, the stent 40 should be completely covered by the sheath 3 while also providing a desirable clearance between the inside surface of the wall 25 and the outside surface of the stent 40. In the protection configuration shown in Fig. 5, the balloon 30 is in the non-inflated state. However, once the catheter 50 is removed from the protection device 1 (or vice versa), the balloon 30 can be inflated to expand the stent 40 in the usual manner via one or more inflation openings 10. The details of the inflation passage and how it connects to the opening 10 are not shown herein as they are well known in the art.

In the embodiment of Figs. 1-4, the mandrel 2 can be flexible so as to be bent into a circular configuration and then automatically assume or spring back to a generally straight configuration which released from
the circular configuration. Moreover, the sheath 3 can also be somewhat flexible so that when the device is bent into a circular configuration, the sheath 3 can also bend somewhat (while providing protection for a leading end of an elongate medical device inserted therein) and then automatically assume or spring back to a generally straight configuration which released from the circular configuration. In embodiments, the sheath 3 is made of a translucent or transparent material so that one can see (or visually determine) one or more portions of the leading end of the medical device inserted therein. This can also provide one with a visual indication of proper or full insertion. Also, in embodiments, the device 1 can function as a protection device for shipping or packaging of elongate medical devices such as, e.g., balloon catheters.

Furthermore, in the embodiment of Figs. 1-4, the device 1 can have the following characteristics:

An axial length PL that is at least one of: greater than 10 mm; greater than 20 mm; greater than 50 mm; approximately 50 mm; approximately 60 mm; approximately 70 mm; approximately 80 mm; and approximately a significant fraction of an overall axial length of the mandrel.

An overall axial length OL that is at least one of: greater than 150 mm; greater than 300 mm; approximately 320 mm; approximately 330 mm; approximately 350 mm; approximately 380 mm; less than 500 mm; and approximately a multiple of an overall axial length of the sleeve or sheath.

An outside diameter 29 is at least one of: greater or equal to 1.0 mm; greater than 1.5 mm; approximately 1.60 mm; approximately 1.70 mm; approximately 1.80 mm; approximately 1.90 mm; between approximately 2 mm and approximately 2.6 mm; and between approximately 1.5 mm and approximately 3 mm; as well as less than 13 mm.

An outside diameter of member 10 is at least one of: greater than 0.2 mm; greater than 0.3 mm; approximately 0.37 mm; approximately 0.38 mm; and between approximately 0.3 and 0.4 mm, as well as less than 1.5 and preferably less than 0.5.

Figs. 6-10 show another non-limiting embodiment of the medical protection device or assembly 1'. As with the previous embodiment, the device 1' includes two main components. A first component is a mandrel 2' that has the form of a generally elongate member 10' sized and configured to pass into a lumen of another generally elongate medical device such as, e.g., a catheter, and can have a number of beneficial characteristics that will be discussed below. Another component is a protective sheath 3' that has the form of a generally tubular member or sleeve sized and configured to receive therein a leading or free end of another generally elongate medical device such as, e.g., a catheter, is configured to protect the inserted free or leading end, and can have a number of beneficial characteristics that will be discussed below. When fully assembled, the device 1' has an overall length as well as a length PL defined by a free or leading end of the device 1' and the open or receiving end 26' of the sheath 3'.

In the embodiment of Figs. 6-10, the mandrel 2' also has the form of a solid material wire member 10' having a generally uniform cross-sectional size and shape and which includes a first end 11' and a second opposite end 12'. It is also possible for the mandrel 2' to be tubular or have another configuration or cross-sectional shape other than generally circular. In embodiments, the first end 11' provides a location for fixing the mandrel 2' to the sheath 3' and also functions a leading end of an elongate medical device when installed thereon. As can be seen in Fig. 4, the second end 12 can also be blunted by having a rounded end. This can both facilitate insertion into a lumen while also ensuring that no damage or little damage is created to an inner surface forming the lumen. As it is desirable to have a blunt or blunted end in the area of the first end 11' and also to provide a reliable connection, the first end 11'
can have a connecting portion 13' which also in this embodiment has the form or a ring. In embodiments, the ring 13' is formed by merely bending the end 11' into a ring shape. In this embodiment, the ring 13' is then encapsulated by a material 22' further blunting the leading end. The material 22' can be formed generally into cylindrical end. In a simple form, the material 22' is part of the material forming the sheath 3' which in this case can be, e.g., molded, fused together, and/or bonded with adhesive. In order to, among other things, make the leading end somewhat non-flexible and/or non-bendable, the end 22' extends into a transition area formed between the end 22' and a main section 20' of the sheath 3'. The transition area is formed with the same diameter or cross-section as the end 22' and the main section 20'. In a simple form, the section 22' has a length 22'a and is part of the material forming the sheath 3' covering a portion of the mandrel 2' between end 13' and the portion covered by the main section 20'.

With reference to Figs. 8 and 9, it can be seen how the material forming the sheath 3' covers the wire 10' in the section 22' and then transitions to form the tubular main section 20'. As can be seen in Fig. 9, whereas the material forming the sheath 3' has the form of a covering layer contacting the member 10' in section 22', it transitions to being spaced from the member 10' in section 20 thereby defining an elongate generally cylindrical annular space 23'. It is this space 23' which receives therein a free or leading end of an elongate medical device. This space 23' is defined by an outer diameter of member 10' and the inside surface of wall 25' having wall thickness W1 and diameter D1 (see Fig. 9). Furthermore, it is the main section 20', and specifically the generally cylindrical wall thickness 25' of the tubular section 20' that covers and provides protection for that portion of the leading end of the elongate medical device inserted therein. In embodiments, the section 20' has a predetermined outer diameter extending to an expanded open end 27' and an axial length defined by the difference between the length PL and the axial length 22'a (and excluding an axial length of enlarged section 27').

In a manner similar to that shown in Fig. 5, the device 1' can be used to protect a leading end of an elongate medical device. As with the previous example, the leading end of a catheter having a balloon mounted to an outer surface and a stent is inserted into the space 23' of the sheath 3' as follows. First, the end 12' (see Fig. 10) is aligned with the lumen of the catheter and is inserted or slid within the inner surface of the catheter. When fully inserted, the free end of the catheter should abut or almost abut the annular wall adjacent section 22' (see Fig. 9). To facilitate insertion without or with minimal damage to the stent, the sheath 3' can include an open end 26' having a tapered or expanded section 27' (see Figs. 6-8) and having a diameter 28' (see Fig. 7). Moreover, in order to provide protection for the stent mounted to the balloon arranged on the free end of the catheter, the stent should be completely covered by the sheath 3' while also providing a desirable clearance between the inside surface of the wall 25' and the outside surface of the stent.

In the embodiment of Figs. 6-10, the mandrel 2' can be flexible so as to be bent into a circular configuration and then automatically assume or spring back to a generally straight configuration which released from the circular configuration. Moreover, the sheath 3' can also be somewhat flexible so that when the device is bent into a circular configuration, the sheath 3' can also bend somewhat (while providing protection for a leading end of an elongate medical device inserted therein) and then automatically assume or spring back to a generally straight configuration which released from the circular configuration. In embodiments, the sheath 3' is made of a translucent, transparent, opaque, or even a colored material so that one can see (or visually determine) one or more portions of the leading end of the medical device inserted therein. This can also provide one with a visual indication of proper or full
insertion. Also, in embodiments, the device 1' can function as a protection device for shipping or packaging of elongate medical devices such as, e.g., balloon catheters or other elongate medical devices.

Furthermore, in the embodiment of Figs. 6-10, the device 1' can have the following characteristics:

An axial length PL that is at least one of: greater than 10 mm; greater than 20 mm; greater than 50 mm; approximately 50 mm; approximately 60 mm; approximately 70 mm; approximately 80 mm; and approximately a significant fraction of an overall axial length of the mandrel.

An overall axial length OL that is at least one of: greater than 150 mm; greater than 300 mm; approximately 320mm; approximately 330 mm; approximately 350 mm; approximately 380 mm; and approximately a multiple of an overall axial length of the sleeve or sheath.

An outside diameter of wall 25' is at least one of: greater or equal to 1.0 mm; greater than 1.5 mm; approximately 1.60 mm; approximately 1.70 mm; approximately 1.80 mm; approximately 1.90 mm; between approximately 2 mm and approximately 2.6 mm; and between approximately 1.5 mm and approximately 3 mm, as well as less than 15 mm.

An inside diameter D1 is at least one of: greater than 1.5 mm; approximately 1.60 mm; approximately 1.70 mm; approximately 1.80 mm; approximately 1.90 mm; between approximately 2 mm and approximately 2.6 mm; and between approximately 1.5 mm and approximately 3 mm.

An outside diameter of member 10' is at least one of: greater than 0.2; greater than approximately 0.3 mm; approximately 0.37 mm; approximately 0.38 mm; and between approximately 0.3 and 0.4 mm, as well as less than 1.5 mm.

Figs. 11-14 show another non-limiting embodiment of the medical protection device or assembly 1''. As with the previous embodiment, the device 1'' includes two main components. A first component is a mandrel 2'' that has the form of a generally elongate member 10'' sized and configured to pass into a lumen of another generally elongate medical device such as, e.g., a catheter, and can have a number of beneficial characteristics that will be discussed below. Another component is a protective sheath 3'' that has the form of a generally tubular member or sleeve sized and configured to receive therein a leading or free end of another generally elongate medical device such as, e.g., a catheter, is configured to protect the inserted free or leading end, and can have a number of beneficial characteristics that will be discussed below. When fully assembled, the device 1'' has an overall length (defined by an axial length between end 11'' and 12'') as well as a length of the protector defined by a free or leading end of the device 1'' and the open or receiving end 26'' of the sheath 3''. This length of the protector portion of the device 1'' can be defined by adding together axial lengths L1, L2 and L3.

In the embodiment of Figs. 11-14, the mandrel 2'' also has the form of a solid material wire or rod member 10'' having a generally uniform cross-sectional size and shape and which includes a first end 11'' and a second opposite end 12''. It is also possible for the mandrel 2'' to be tubular or have another configuration or cross-sectional shape other than generally circular. In embodiments, the first end 11'' provides a location for fixing the mandrel 2'' to the sheath 3'' and also functions a leading end of an elongate medical device when installed thereon. As can be seen in Fig. 12, the second end 12'' can also be blunted by having a rounded end (similar to that shown in Fig. 4). This can both facilitate insertion into a lumen while also ensuring that no damage or little damage is created to an inner surface forming the lumen. As it is desirable to have a blunt or blunted end in the area of the first end 11'' and also to provide
a reliable connection, the first end 11" can have a connecting portion 13" which also in this embodiment has the form or a ring. In embodiments, the ring 13" is formed by merely bending the end 11" into a ring shape. In this embodiment, the ring 13" is then covered or encapsulated by a material further blunting the leading end. The material can be formed generally into spherical end. In a simple form, the material is part of the material forming the sheath 3" which in this case can be, e.g., molded, fused together, and/or bonded with adhesive. In order to, among other things, make the leading end somewhat flexible and/or bendable, a first section 22"A forms a transition area between end 11" and an intermediate section 22"B of the sheath 3". The transition area 22"A is formed by the material covering and being essentially in direct contact with the member 10" while the section 22"B has a larger outside diameter, an axial length L3, and is spaced from the member 10" thereby defining a first elongate annular space 23"A with a diameter ID1 (see Fig. 14). A second larger diameter main section 20" (defined by wall 25") has an axial length L2 (if one includes the flared open end 26") and defines an internal annular space 23"B with a diameter ID2 (see Fig. 14). The wall 25" forming the section 20" is also part of the material forming the sheath 3". A significant advantage of section 22"B is that it can receive therein and grip the distal tip of a catheter (similar to that shown in Fig. 21) which then helps prevent or minimize any axial or radial loading of the installed stent.

With reference to Fig. 14, it can be seen how the material forming the sheath 3" covers the wire or member 10" in the section 22"A and then transitions to form the tubular smaller and larger sections 23"A and 23"B. As can be seen in Fig. 14, whereas the material forming the sheath 3" has the form of a covering layer contacting the member 10" in section 22"A, it transitions to being spaced from the member 10" in sections 22"B and 20" thereby defining a first elongate generally cylindrical annular space 23"A and a second elongate generally cylindrical annular space 23"B. It is this space 23"A which can receives therein a free or leading end of an elongate medical device while space 23"B receives a device mounted to the free end. If one looks to the example shown in Fig. 5 and utilizes the instant device 1" with the elongate medical device shown therein, the space 23"A would receive therein the free end of catheter 50 while the space 23"B would receive the stent 40 mounted thereto. This is described in more detail below. In embodiments, the section 20" has a predetermined outer diameter (of wall 25") extending to an expanded open end 27" (see Fig. 13) and this expanded section has an axial length L4 and an angle A. In embodiments, the angle A is also utilized in previous embodiments.

In a manner similar to that shown in Fig. 5, the device 1" can be used to protect a leading end of an elongate medical device. As with the previous example, the leading end of a catheter having a balloon mounted to an outer surface and a stent is inserted into the spaces 23"A and 23"B of the sheath 3" as follows. First, the end 12" (see Fig. 12) is aligned with the lumen of the catheter and is inserted or slid within the inner surface of the catheter. When fully inserted, the free end of the catheter should extend at least partially inside space 23"A (see Fig. 14) while the stent is located within space 23"B. To facilitate insertion without or with minimal damage to the stent, the sheath 3" can include an open end 26" having a tapered or expanded section 27" (see Figs. 12 and 13). Moreover, in order to provide protection for the stent mounted to the balloon arranged on the free end of the catheter, the stent should be completely covered by the sheath 3" while also providing a desirable clearance between the inside surface of the wall 25" and the outside surface of the stent.

In an advantageous variant, section 22"A does not receive therein any portion of the catheter and is a colored synthetic resin material that can be opaque. The color can be used to provide a user with a visual indicator of
the proper location to grip the device. Thus, section 22"A can be colored without a warning color, e.g., green. Section 22"B snugly receives therein the tip portion of a catheter while section 25" more loosely receives the balloon and stent portions of the catheter. These sections 22"B and 25" can also be a colored synthetic resin material that can be opaque. The color can be used to provide a user with a visual indicator of the improper location to grip the device. Thus, either or preferably both sections 22"B and 25" can be colored with a warning color, e.g., red. Providing the user with a color indicator of section 22"A (a color green informing him/her that it is okay to grip this section) can be a simply way to prevent the user from gripping other portions of the device and causing damage to any device being protected by the sheath. Warning the user not to grip at least section 25" (and advantageously also section 22"B) via a color indicator can be a simply way to prevent the user from causing accidental damage to the device being protected by the sheath. Of course, other ways can be used to provide such indications such as tactile, and the invention is not limited to this type of visual indicator.

[0059] In the embodiment of Figs. 11-14, the mandrel 2" can be flexible so as to be bent into a circular configuration and then automatically assume or spring back to a generally straight configuration which released from the circular configuration. Moreover, the sheath 3" can also be somewhat flexible so that when the device is bent into a circular configuration, the sheath 3" can also bend somewhat (while providing protection for a leading end of an elongate medical device inserted therein) and then automatically assume or spring back to a generally straight configuration which released from the circular configuration. In embodiments, the sheath 3" is made of a translucent or transparent material so that one can see (or visually determine) one or more portions of the leading end of the medical device inserted therein. This can also provide one with a visual indication of proper or full insertion. Also, in embodiments, the device 1" can function as a protection device for shipping or packaging of elongate medical devices such as, e.g., balloon catheters.

[0060] Furthermore, in the embodiment of Figs. 11-14, the device 1" can have the following characteristics:

An axial length L1 that is at least one of: 3 to 30 mm.
An axial length L2 that is at least one of: 10 to 170 mm.
An axial length L3 that is at least one of: 0.5 to 25 mm.
An axial length L4 that is at least one of: 0.5 to 5 mm; and about 1.32 mm.
An angle A that is at least one of: 0 to 60 degrees; and about 10 degrees.

An overall axial length that is at least one of: greater than 150 mm; greater than 300 mm; approximately 320
mm; approximately 330 mm; approximately 350 mm; approximately 380 mm; and approximately a multiple of an overall axial length of the sleeve or sheath.

An outside diameter of wall 25" is at least one of: greater than or equal to 1.0 mm; greater than 1.5 mm;
approximately 1.60 mm; approximately 1.70 mm; approximately 1.80 mm; approximately 1.90 mm; between
approximately 2 mm and approximately 2.6 mm; and between approximately 1.5 mm and approximately 3 mm, as well
as less than 13 mm.

An inside diameter ID1 is at least one of: 0.3 mm.
An inside diameter ID2 is at least one of: 0.4 mm.

An outside diameter of member 10" is at least one of: greater than 0.2 mm; greater than 0.3 mm;
approximately 0.37 mm; approximately 0.38 mm; and between approximately 0.3 and 0.4 mm, as well as less than 1.5
mm and preferably 0.5 mm.

Figs 15 and 16 show schematically how an embodiment similar to that shown in Fig. 1 can be used to protect a catheter 50 having mounted thereto a balloon 30 and a stent 40. As is more clearly shown in Fig. 15, to protect the leading end of a catheter 50 having a balloon 30 mounted to an outer surface and a stent 40, one may grip the device 1 at gripping end GE and then inserted the opposite or free end of the mandrel 2 into the catheter 50 by moving the device 1 along an insertion movement IM so that the mandrel 2 enters into the lumen 52 (see Fig. 16). The mandrel 2 is then fully inserted or slid within the lumen 52 of the catheter 50. When fully inserted, the free end of the catheter 50 should extend nearly fully inside space 23 and the stent 40 should be located completely within space 23. To facilitate guiding insertion without or with minimal damage to the stent 40, the sheath 3 can have a flared open end 26. Moreover, in order to provide protection for the stent 40 mounted to the balloon 30 arranged on the free end of the catheter 50, the stent 40 should remain completely covered by the sheath 3 while also providing a desirable clearance between the inside surface of the sheath 3 and the outside surface of the stent 40.

Figs 17-19 show another embodiment of the protector of the invention. In this embodiment, the mandrel 200 and sheath 300 can both be made of a synthetic resin material. As a result, the device first end shown in Fig. 18 can utilize a fused or integral connection FC between the mandrel 200 and sheath 300. The second end of the mandrel 200 can also utilize a cut or angled end and can utilize a 45 degree cut as shown in Fig. 19. The device shown in Figs. 17-19 can otherwise function similarly to that shown in Fig. 1.

Figs 20-21 show still another embodiment of the protector of the invention. In this embodiment, the device is similar to that of Figs. 11 and 12 and show how a catheter 50 leading end or tip enters or extends (e.g., snuggly or tightly) into section 22" 'B and is gripped or retained within section 22" 'B while the balloon and stent are protected within section 25" '. In this embodiment, the mandrel 10" ' can also be made of either metal or optionally synthetic resin. The device shown in Figs. 20 and 21 can otherwise function similarly to that shown in Figs. 11 and 12.

In any herein disclosed embodiments, the sleeve or sheath may be made of a synthetic resin material and the mandrel comprises a metal material. In embodiments, the sleeve or sheath may be a soft or flexible material and the mandrel comprises a harder material. In embodiments, the sleeve or sheath may be colored and/or provide a visual indication to a user of the position of a device located therein. In embodiments, the sleeve or sheath can be made of PTFE and the mandrel may be made of a synthetic resin material or 304 stainless steel. In other embodiments, the sleeve or sheath can be made of MDPE, HDPE, LLDPE, LDPE and/or PTFE and the mandrel can be made of 304 or 318 stainless steel. In still other embodiments, the sleeve or sheath may be made of MDPE, 75% HDPE and 25% LLDPE and the mandrel can be made of 304 stainless steel. The mandrel can also be slightly tapered with a decreasing diameter toward it free end.

It is noted that the foregoing examples have been provided merely for the purpose of explanation and are in no way to be construed as limiting of the present invention. While the present invention has been described with reference to one or more exemplary embodiments, it is understood that the words which have been used herein are words of description and illustration, rather than words of limitation. Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present invention in its aspects. Although the present invention has been described herein with reference to particular means,
materials and embodiments, the present invention is not intended to be limited to the particulars disclosed herein; rather, the present invention extends to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.
WHAT IS CLAIMED IS:

1. A protection device comprising:
   a mandrel having a first end and a second end;
   a sleeve;
   a portion of the sleeve surrounding a portion of the mandrel; and
   a space disposed between the portion of the sleeve and the portion of the mandrel being sized and configured to receive therein or accommodate at least one medical device.

2. The device of claim 1, wherein the at least one medical device comprises one of:
   an insertion end of a medical lumen;
   an insertion end of a catheter;
   a medical balloon;
   a protheses;
   a stent;
   a drug-eluting stent;
   a drug coated stent;
   a medicated stent;
   a retrieval thrombectomy device.

3. The device of claim 1, wherein the mandrel is at least one of:
   an elongate synthetic resin rod;
   an elongated wire;
   an elongated metal rod;
   a solid stainless steel wire; and
   a wire insertable within a medical lumen.

4. The device of claim 1, wherein the sleeve is arranged in an area of the first end and wherein the second end of the mandrel is sized and configured to be insertable within at least one of:
   an insertion end of a medical lumen; and
   an insertion end of a catheter.

5. The device of claim 1, wherein the sleeve comprises a first end that is at least one of:
   encases a ring portion of the first end of the mandrel;
   encases an enlarged portion of the first end of the mandrel;
   encases the first end of the mandrel;
   nonmovably secured to the first end of the mandrel;
   fixedly secured to the first end of the mandrel;
   nonremovably secured to the first end of the mandrel; and
   non axially movably secured to the first end of the mandrel.

6. The device of claim 1, wherein the sleeve comprises a synthetic resin material and the mandrel is made of one of a synthetic resin and a metal material.

7. The device of claim 1, wherein the sleeve comprises one of:
a connected portion and a non-connected portion that is axially longer than the connected portion, and wherein said space is arranged within the non-connected portion; and
a connected portion and a non-connected portion that has a greater diameter than the connected portion, and wherein said space is arranged within the non-connected portion.

8. The device of claim 1, wherein the sleeve further comprises at least one of:
   an open end communicating with said space;
   a flared open end;
   a generally tapered open end; and
   an open end sized and configured to receive therein an insertion end of a medical lumen.

9. The device of claim 1, wherein the sleeve has an overall axial length that is less than an overall axial length of the mandrel.

10. The device of claim 1, wherein the sleeve has an overall axial length that is at least one of:
    greater than 10 mm;
    greater than 20 mm;
    greater than 50 mm;
    approximately 50 mm;
    approximately 60 mm;
    approximately 70 mm;
    approximately 80 mm; and
    approximately a fraction of an overall axial length of the mandrel.

11. The device of claim 1, wherein the mandrel has an overall axial length that is at least one of:
    greater than 150 mm;
    greater than 300 mm;
    approximately 320 mm;
    approximately 330 mm;
    approximately 350 mm;
    approximately 380 mm;
    less than approximately 500 mm; and
    approximately a multiple of an overall axial length of the sleeve.

12. The device of claim 1, wherein the protection device has an overall axial length that is at least one of:
    greater than 150 mm;
    greater than 300 mm;
    approximately 320 mm;
    approximately 330 mm;
    approximately 350 mm;
    approximately 380 mm;
    less than approximately 500 mm; and
    approximately a multiple of an overall axial length of the sleeve.
13. The device of claim 1, wherein an outside diameter of a main portion of the sleeve is at least one of:
   greater than or equal to 1.0 mm;
   greater than 1.5 mm;
   approximately 1.60 mm;
   approximately 1.70 mm;
   approximately 1.80 mm;
   approximately 1.90 mm;
   between approximately 2 mm and approximately 2.6 mm;
   between approximately 1.5 mm and approximately 3 mm; and
   less than approximately 13 mm.

14. The device of claim 1, wherein the mandrel has an outside diameter that is at least one of:
   greater than 0.2 mm;
   greater than 0.3 mm;
   approximately 0.37 mm;
   approximately 0.38 mm;
   between approximately 0.3 and 0.4 mm;
   less than approximately 0.5 mm; and
   less than approximately 1.5 mm.

15. The device of claim 1, wherein at least a main portion of the sleeve is substantially transparent or translucent.

16. A protection device comprising:
   an elongated member having a first end and a second end;
   a sleeve or sheath arranged in an area of the first end;
   a main portion of the sleeve or sheath surrounding a portion of the member;
   a space disposed between the main portion and the portion of the member being sized and configured to receive therein or accommodate at least one of:
   an insertion end of a medical lumen;
   an insertion end of a catheter;
   a medical balloon;
   a prostheses;
   a stent;
   a stent arrangement; and
   the second end of the member being sized and configured to pass or extend into at least one of:
   an insertion end of a medical lumen; and
   an insertion end of a catheter.

17. A stent or balloon protection device comprising:
   an elongate member having a first end and a second end;
   the second end of the member being sized and configured to pass or extend into an insertion end of a medical lumen;
a tubular protector non axially movably connected to the elongate member;
a main portion of the tubular protector surrounding a portion of the elongate member;
an annular space disposed inside the tubular protector being sized and configured to receive therein or accommodate at least one of:

- an insertion end of a medical lumen;
- an insertion end of a catheter;
- a medical balloon;
- a prosthesis; and
- a stent; and

18. The device of claim 17, wherein the tubular protector comprises another portion having an annular space disposed inside the tubular protector being sized and configured to receive a tip of a catheter, whereby at least one of:

- a retention force is provided between the tip of the catheter and the other portion; and
- the other portion is substantially retained on the tip during sliding of the catheter into and out of a packaging lumen; and

- the other portion is substantially retained on the tip during sliding of the catheter into and out of a coiled tubing.

19. A method making the device of anyone of claims 1-18, the method comprising:

- arranging a sleeve on a mandrel.

20. A method using the device of anyone of claims 1-18, the method comprising:

- inserting the second end of the mandrel into a medical lumen until an insertion end of the medical lumen extends into the space.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/01 A61M25/06 A61F2/962
ADD.

According to International Patent Classification (IPC) and both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of database and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>1-17, 19, 20</td>
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[Box X] Further documents are listed in the continuation of Box C. [Box X] See patent family annex.

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Date of the actual completion of the international search: 30 January 2013

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European Patent Office, P.B. 5018 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer: Berndorfer, Urs

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