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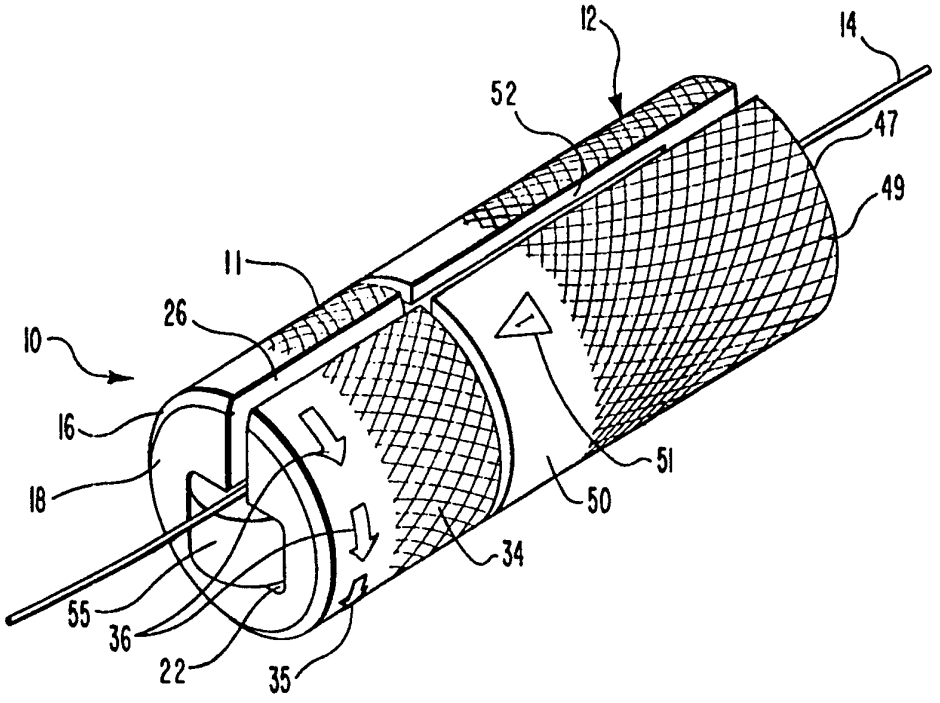

(57) **Abstract**

A gripping-knob rotation tool (10) for attachment to a medical guidewire (14) as used in angioplasty and other medical procedures. The tool (10) is installed laterally over the guidewire (14) at any desired position along the length of the wire (14), and is secured thereto by a simple rotational or twisting motion. The tool (10) provides a convenient gripping surface during rotation or translational movement of the guidewire (14), and is adjustable for repositioning along the length of the wire (14) after initial engagement.

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ROTATION TOOL FOR MEDICAL GUIDEWIRE

BACKGROUND

Field of the Invention

This invention relates to a knob-like tool for attachment to a medical guidewire as used, for example, to guide a catheter into an artery or arterial branch to a stenosis or partial blockage position where vessel enlargement is performed with an angioplasty balloon.

The Prior State of the Art

The use of guidewires in catheterization and angioplasty procedures is well known, and is further described in issued patents such as U.S. Patent 4,957,117.

The guidewire is long (typically six feet or more of stainless steel wire) and slender with a relatively limber and bendable distal tip which can be angled to assist the physician in negotiating arterial curves and junctions to the desired location by fluoroscopic monitoring.

The surface of the slender guidewire is smooth and slick, and some kind of auxiliary gripping surface is needed to enable the wire to be advanced into or retracted from the arterial vessels, and especially to enable twisting or torquing rotation of the wire as needed to reorient the angled distal tip. Existing partial solutions to this need include pin-vise grips.

A pin-vise is a device that is well known in the art and which comprises a structure like a small drill chuck with a cylindrical handle. The chuck is threaded over the proximal end of the long guidewire and advanced to a desired position. A chuck collet, a part of the pin-vise, can then be tightened onto the wire so that the pin-vise is firmly attached to the guidewire, and thereafter serves as a grip to facilitate manual rotation of the guidewire and/or longitudinal advancement of the same.

One of the problems which has been experienced in the art using pin-vise type grips is that they must be threaded onto the guidewire at the proximal end. This is time consuming and inconvenient because of the length of the guidewire. Thus, other types of gripping devices have been devised which attempt to overcome this problem.

One such gripping device is illustrated, for example, in U.S. Patent No. 4,829,999. This device is constructed with a cylindrical body which has a longitudinal slit and which is spring-actuated so that by pressing two handles together which are provided on the body of the device, the longitudinal slit can be opened and placed onto the guidewire. When the handles are released, the resilient or spring-action of the cylindrical body clamps the guidewire within the longitudinal slit, much like clamping a clothespin into a clothesline.

This device overcomes the problem of having to thread the device onto the proximal end of the guidewire, but suffers from other disadvantages. For example, the handles which are located on the side of the cylindrical body may get in the way of rotational manipulation of the device. Furthermore, it is typically necessary to reposition a gripping device on a guidewire as the guidewire is advanced further into the vessels. Thus, the side mount type gripping device as described for example in the above referenced patent requires that the device be taken off and repositioned on the guidewire. If the device is dropped while taking it off, it becomes unsterile and must be replaced.

Another device which has attempted to address the problems in the art is illustrated, for example, in U.S. Patent No. 4,858,810. This device utilizes a pin-vise constructed from two parts assembled together to provide a gripping handle for a guidewire. The device has an elongated cylindrical body which is slotted along the

length to receive the guidewire, and also has a sliding mechanism which fits within the slot and which, when pushed forward, tightens down upon the guidewire in order to secure the gripping device to the guidewire for purposes of manipulation. As in the case of the spring-actuated type gripping device described above, this device is also a side-mount type device, which eliminates the need for threading the device onto the proximal end of the guidewire. However, the placement of the device onto the guidewire is somewhat cumbersome and if the cylindrical body member is inadvertently dropped before the slide mechanism is placed into the longitudinal slot, once again the device may become unsterile. Another example of a device that utilizes a slide mechanism is that described in U.S. patent 5,159,861.

Still a further device which is known in the art is a side loading type of gripping device which, once again, employs a longitudinal slot along the length of the device, and which includes two cylindrical members that are threaded together. The distal end of one of the cylindrical members is formed with a plurality of fingers so that as the two members are threaded together the fingers clamp down and grip the guidewire. This device, like the others, partially solves some of the problems experienced in the art, but is otherwise more complicated in its construction and cumbersome to operate than is desirable.

SUMMARY OF THE INVENTION

The rotation tool of this invention overcomes the above and other problems in the art, and enables quick and simple lateral or sideways attachment at any desired position along a guidewire. The tool further provides two gripping modes, one in which the guidewire is captive within the tool, so that the tool cannot fall off the

guidewire, but the guidewire is otherwise not longitudinally or rotationally secured to the tool so that relative movement of the tool on the guidewire is permitted. The second gripping mode is one in which the guidewire is secured to the rotation tool, both longitudinally and rotationally so that the rotation tool can be used either to advance the guidewire or to rotationally orient the guidewire to effect steering of the distal end of the guidewire.

In one presently preferred embodiment of the invention, the rotation tool is comprised of a tubular housing that is formed from two cylindrical members that are adapted to fit together in a telescoping arrangement. The two members are provided with a passageway that runs through the length of each member. A slot also runs the length of each member and extends from an outer surface of each member to the passageway running therethrough. An elastomeric gripping and retention member has one end anchored in one of the cylindrical members and the other end anchored in the other cylindrical member at the ends of the passageways formed through the cylindrical members. An elongated body of the elastomeric member is situated in the passageway running between the two ends.

The guidewire is placed into the longitudinal slot and the two cylindrical members can then be rotated relative to each other to a first position which locks the guidewire within the device, but without securing the guidewire to the device. In this position, the rotation tool or device of the present invention is in the first gripping mode described above. The cylindrical members can then be rotated to a second position which causes the elastomeric member to twist around the guidewire, but without bending the guidewire. When locked in this second position, the rotation tool or device of the present invention is in the second gripping mode described above.

A groove and retention pin or locking ring serve to irreversibly secure the two cylindrical members together once they have been assembled with the elastomeric member. This prevents the cylindrical members from being pulled apart and rotated in the wrong direction with respect to each other, thus preventing the tool from becoming entangled with and stuck to the guidewire.

These and other features of the present invention will become more fully understood from reference to the accompanying drawings which are briefly summarized below and which are used to illustrate one presently preferred embodiment of the invention in its presently understood best mode for making and using the same.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1 and 2 are exploded pictorial views showing a pair of tubular members and an elastomeric retainer which comprise a preferred embodiment of this invention;

Figure 3 is a side elevation of a first tubular member;

Figure 4 is a top view of the first tubular member shown in Figure 3;

Figure 5 is an end view of one end of the first tubular member shown in Figure 3;

Figure 6 is an opposite end view of the first tubular member of Figure 3;

Figure 7 is a sectional side elevation on line 7-7 of Figure 6;

Figure 8 is a sectional side elevation on line 8-8 of Figure 6;

Figure 9 is an enlarged partial sectional view on line 9-9 of Figure 6 and showing a detent seat;

Figure 10 is a side elevation of a second tubular member;

Figure 11 is an end view of one end of the second tubular member of Figure 10;

Figure 12 is an opposite end view of the second tubular member;

Figure 13 is a sectional side elevation showing the first and second tubular members as assembled together;

Figure 14 is a pictorial view of the engaged tubular members, and showing the elastomeric member in a stretched position ready for installation;

Figure 15 shows the partially installed elastomeric member;

Figure 16 shows the completely assembled tool with a guidewire in an initial position;

Figure 17 shows the tubular members rotated to a first position which makes the guidewire captive, but longitudinally and rotationally free within the tool;

Figure 18 is a longitudinal cross-sectional view taken on line 18-18 of Figure 17, and more particularly shows the relationship between the elastomeric member and the guidewire when the tubular members are rotated to the first position;

Figure 19 is a cross-sectional view taken on line 19-19 of Figure 17 further showing the relationship between the elastomeric member and the guidewire when the tubular members are rotated into the first position;

Figure 20 shows the tubular members from a different angle, and rotated to a locked position in which the guidewire is longitudinally and rotationally secured relative to the tool;

Figure 21 is a sectional side elevation taken on line 21-21 of Figure 20, and more particularly showing the relationship of the elastomeric member and the guidewire when the first and second tubular members are rotated to the second position;

Figure 22 is a perspective view with portions broken away to further illustrate the relationship between the elastomeric member and guidewire when the first and second tubular members are rotated to the second position;

Figure 23 is a sectional view taken on line 23-23 of Figure 20 which further illustrates the relationship between the guidewire and the elastomeric member when the first and second tubular members are rotated to the second position; and

Figures 24 and 25 are exploded perspective views illustrating alternative ways of securing the first and second tubular members together after assembly to prevent them from being pulled apart and rotated the wrong way relative to one another.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The components of a rotation tool or gripping-knob assembly 10 are shown in exploded view in Figures 1 and 2. The components are a first tubular plug member generally designated at 11, a mating second tubular socket member generally designated at 12, and an elastomeric retainer generally designated at 13. The steps of assembling the tool are shown in Figure 14-15, and the assembled tool is shown as placed over and engaged with a medical guidewire 14 in Figures 16-23. The details of each component will first be described, and subsequently the assembly and use of the tool.

Referring to Figures 1-9, a first tubular member 11 has a cylindrical head 16, a coaxial cylindrical shank 17 extending from the head, a head end surface 18, and a shank end surface 19. The shank has a slightly reduced diameter as compared to the head, and the respective diameters are typically about 0.455 inch and 0.352 inch. An annular shoulder 20 is defined at the junction of the head 16 and shank 17.

A rectangular-in-cross-section recess 22 extends into head 16 from end surface 18 part way toward shoulder 20. As shown best in Figures 3-6, a cylindrical bore or passageway 23 extends from a base 24 of recess 22 to shank end surface 19. Passageway 23 has a typical diameter of 0.12 inch, and an axial centerline which is parallel to, but offset by slightly less than the radius of the passageway 23 from the axial centerline of the head 16 and shank 17.

A slot 26 (shown best in Figures 1-2 and 5-6) extends from recess 22 and passageway 23 radially outwardly to the outer surfaces of the head 16 and shank 17, and extends the full length of member 11 between end surfaces 18 and 19. A semiconical recess 27 (Figures 3 and 5) is concentric with the head 16 and shank 17, and converges from end surface 19 to terminate at passageway 23 adjacent shoulder 20. Recess 27 is formed in only one inner side of the shank 17, and the nearly semicircular outer perimeter of the recess 27 extends from a sidewall of slot 26 to terminate at a point of tangency 21 with the lower (as seen in Figure 5-6) perimeter of passageway 23.

An extension protrudes from shank end surface 19 to define a stop 29 with a shoulder 30 (see Figure 3) extending from passageway 23 to the outer surface of cylindrical shank 17. As hereinafter more fully described, stop 29 helps to assure that rotation of first tubular member 11 relative to second tubular member 12 will occur in the proper direction indicated by arrows 36. The stop 29 has a chamfered surface 31 adjacent slot 26 as best seen in Figures 2 and 4. A teardrop-shaped detent seat 33 is formed as a depression in end surface 19 below shoulder 30 (as shown in Figures 2, 6 and 9) and adjacent the perimeter of shank 17. A preferred cross-sectional shape of seat 33 is shown in Figure 9, and the blunt end of the seat 33 is

positioned about 54 degrees counterclockwise from the six o'clock position in Figure 6.

The outer surface of cylindrical head 16 has a knurled portion 34 (Figures 1-2) for secure gripping, and a smooth portion 35 surrounding recess 22. The smooth portion 35 is embossed with arrows 36 designating the proper rotation direction to turn plug member 11 to engage assembly 10 with guidewire 14 as explained below in greater detail.

Tubular socket member 12 is shown in detail in Figures 1-2 and 10-13, and is generally cylindrical in shape with first and second ends 39 and 47. A coaxial cylindrical bore 40 extends from first end 39 to a base surface 42 (see Figure 10) axially spaced from the second end 47. Bore 40 is dimensioned to receive shank 17 of the tubular plug member 11 in rotatable engagement, and has a typical inside diameter of 0.356 inch for a shank outside diameter of 0.352 inch. An off-axis cylindrical bore or passageway 43 (Figures 10-11) extends from surface 42 to a rectangular recess 44 which is identical to recess 22. The recess 44 has a base 45, and extends axially to second end 47.

A slot 52 is formed in socket member 12 between ends 39 and 47, and extends from the outer surface of the member radially inward to bore 40, passageway 43 and recess 44. A detent pin 48 extends from base surface 42, and is positioned adjacent the inner surface of bore 40, passageway 43 and recess 44. The detent pin 48 is positioned adjacent the inner surface of bore 40 about 110 degrees counterclockwise from the twelve o'clock position in Figure 11. The pin 48 is preferably integrally formed with member 12, and is slightly tapered for molding convenience, and for structural strength at the pin base.

Referring to Figures 1-2, the outer surface of member 12 has a knurled gripping portion 49, and a smooth portion 50 in which are embossed a pair of first and second position markers 51 and 57 (the latter is shown in

Figure 20). When members 11 and 12 are engaged, markers 51 and 52 are alternatively aligned with slot 26 of the plug member 11 in the several operational positions of the assembly as described below.

Elastomer retainer 13 is best seen in Figures 1-2 and 14-15, and is an integral member having enlarged circular heads 55 at its opposite ends. Heads 55 are dimensioned to seat securely in recesses 22 and 44 when assembled with plug and socket members 11 and 12. The heads 55 are connected by a body member 56 which is rectangular in cross section. The body member 56 is intended to fill a substantial portion of passageways 23 and 43 when assembled with the plug and socket members. For example, if the passageways 23 and 43 have matching diameters of about 0.12 inch, the cross-sectional dimensions of body member 56 are preferably about 0.10 and 0.15 inch.

Retainer 13 is preferably molded from neoprene or silicone rubber with a Shore A hardness of about 55. Plug and socket members 11 and 12 are preferably each integrally injection molded for economy and production convenience, and a suitable material is ABS plastic.

The assembly of the several components just described is shown in Figures 13-15. As shown best in Figure 13, the shank 17 of plug member 11 is inserted into bore 40 of the socket member 12 until the end 19 of shank 17 abuts against pin 48. Radial slots 26 and 52 are in alignment as shown in Figure 14.

Body member 56 is then tensioned to elongate retainer 13 as shown in Figure 14, and the body member 56 is fitted into aligned slots 26 and 52 to seat one of retainer heads 55 in rectangular recess 22 of the plug member 11 (Figure 15). The still-elongated body member 56 is then fully fitted through slots 26 and 52 into passages 23 and 43, and the second head 55 is seated in recess 44 of the socket member 12. In this fully assembled condition,

body member 56 remains under substantial tension, and the resulting restoring force urges the plug and socket members 11 and 12 together.

Initial engagement of the device 10 over guidewire 14 is illustrated in Figure 16. The device is simply moved laterally over the guidewire 14 which passes through aligned slots 26 and 52 to rest against retainer 13. Plug member 11 is then rotated about 25 degrees in the direction of arrows 36 to an intermediate position (Figures 17-19) in which detent pin 48 moves into seat 33. As noted above, stop 29 helps to assure that rotation will occur only in the direction of arrows 36, since stop 29 will prevent rotation in the other direction due to engagement of detent pin 48, when shank 17 is adequately seated in bore 40. Because of the tension exerted by retainer 13, the seating of the pin 48 into seat 33 occurs with a click so as to give an audible and a tactile signal that the intermediate position has been reached, and visual confirmation is also provided by the alignment of slot 26 with first position markers 51. As shown best in Figures 18-19, in the intermediate position, the guidewire 14 is captive within the shank 17 of socket member 11 by the misalignment of slots 26 and 52, but is not secured by the body member 56 of retainer 13, which is only slightly twisted in this position, thus device 10, permits longitudinal repositioning of the device along the guidewire 14 without having to remove it from guidewire 14.

To lock the device 10 to the guidewire 14 both longitudinally and rotationally, the plug and socket members 11 and 12 are lightly separated against the force of the tensioned retainer 13 to move detent pin 48 out of seat 33. The plug member is then rotated in the direction of arrows 36 by about 225 degrees to the final position as shown in Figures 20-23. Pin 48 rides along shank end surface 19 during this rotational movement, and provides a

tactile signal of reaching the final position, again due to the tension exerted by retainer 13, by dropping into the shank end of radigl slot 26. Visual confirmation of this position is provided by the alignment of slot 26 with second position marker 52, and further rotation is discouraged by stop 29.

Relative rotation of the plug and socket members 11 and 12 to this position twists the retainer 13 within the passageways 23, 27 and 43, and the guidewire 14 is thus gripped and secured by the body member 56 as it twists about guidewire 14. The semiconical recess 27 (see Figures 3 and 6) provides space for the body member 56 of retainer 13 to be twisted up and around guidewire 14, without bending the guidewire. Importantly, guidewire 14 is not bent so that rotation of device 10 results in a corresponding rotation at the distal end of guidewire 14 in the vessel. The conical passageway 27 in shank 17 permits the body member 56 of retainer 13 to twist up and around guidewire 14 to securely grip it. This is shown best in Figures 21-23. Guidewire 14 is thus now secured by device 10 to permit both longitudinal and/or rotational manipulation of guidewire 14 by manipulating the tool or device 10.

The central axis of passageways 23 and 43 are intentionally spaced from the common rotation axis of the plug and socket members to insure that after body member 56 is seated in passageways 23 and 43, the guidewire will come to rest on body member 56 (see Figures 18 and 19) in substantial alignment with the common rotation axis. This feature avoids the undesirable result of the guidewire extending from the assembly at an angle or off-centered axis which would result in inconvenient operation.

The design of the device permits quick and simple lateral or sideways installation at any position along the guidewire 14, and the rotational alignment of the plug and

socket members 11 and 12 is easily determined either visually or by tactile feel when the detent pin 48 moves into a partially or fully retained position. Should it be necessary to reposition the assembly during advancement of the guidewire 14 into an artery, the plug and socket members 11 and 12 are simply rotated from the final or locked position back to the intermediate position. When a new position along the guidewire is established, the members 11 and 12 are returned to the locked position in which the device provides secure gripping of the guidewire 14 for both longitudinal and rotational movement.

It has been found that in practice, not withstanding the tension exerted by the elastomeric retainer 13, it may be possible to pull the tubular members 11 and 12 far enough apart that the detent pin 48 may be pulled clear of the stop 29 thus permitting the tubular members 11 and 12 to be rotated in the wrong direction, in other words in the direction opposite to that shown by the arrows 36. When this happens, the guidewire 14 may become entangled in the elastomeric retainer 13 as the two tubular members 11 and 12 are rotated in the wrong direction so that the rotation tool 10 becomes completely entangled and stuck to the guidewire 14. This of course is an undesirable result. Accordingly, in another aspect of the invention, to assure that this cannot happen, the rotation tool 10 may be provided with a means for irreversibly securing the two tubular members 11 and 12 together after they are assembled so that they cannot be pulled far enough apart to permit the detent pin 48 to rotate past the stop 29 in the wrong direction.

By way of example, Figures 24 and 25 illustrate two ways in which this may be accomplished. In Figure 24, tubular member 11 is illustrated as having a circular groove 60 which is formed in the shank 17. The tubular socket member 12 on the other hand is provided with a small

bore 62 which extends through the tubular socket member 12. A retainer pin 64 is adapted to be inserted through the bore 62 after the rotation tool had been completely assembled as described above. When the retainer pin 64 is inserted through bore 62, the end of the retainer pin 64 engages the circular groove 60. This prevents the tubular socket member 12 from being able to be pulled far enough apart with respect to tubular member 11 that the detent pin 48 can be rotated in the wrong direction past the stop 29 on shank 17. However, the circular groove 60 is wide enough to allow a limited amount of separation between the two members 11 and 12, in order to permit the detent pin 48 to be easily disengaged from the teardrop shaped seat 33 when rotating the tool into the final position as previously described.

Figure 25 illustrates an alternative way of irreversibly securing the two tubular members 11 and 12 together after assembly. In the embodiment of Figure 25, the groove 60 is the same but instead of the retention pin 64, the tubular members 11 and 12 are irreversibly secured together by a snap ring 66 which is placed inside the bore 40 of the tubular socket member 12. The snap ring 66 is sized so that the tubular socket member 12 can be snapped on to the shank 17 and once the snap ring 66 drops into the groove 60, the tubular members 11 and 12 will only be permitted to be pulled apart to a limited degree. This preventing the tubular members 11 and 12 from being rotated relative to one another in the wrong direction or in other words in the direction counter to arrows 36. The width of snap ring 66 is somewhat smaller than the width of the groove 60 to permit the tubular members 11 and 12 to be pulled apart slightly in order to permit the detent pin 48 to be easily unseated from the tear dropped shaped seat 33 in the same manner as described in connection with the embodiment of Figure 24.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

Claims:

1. A device for selective attachment to or detachment from a catheter guidewire or the like, and for selectively gripping the guidewire when attached to permit either longitudinal or rotational manipulation of the guidewire for purposes of steering the guidewire through a vessel, comprising:

a tubular housing means for receiving and retaining the guidewire comprising a longitudinal passageway therethrough and a radial slot extending from an outer surface to the passageway along the full length of said housing means and further comprising first and second rotatably connected members which are rotatably operative such that when the members are rotated into a first position of alignment relative to each other the guidewire is adapted to be inserted into the passageway by slipping the guidewire through the slot, and such that when the members are rotated into a second position of alignment relative to each other the guidewire is secured both longitudinally and rotationally relative to the housing means; and

retention and gripping means situated within said passageway and having one enc anchored in the first member and another end anchored in the second member such that said retention and gripping means will urge and hold the first and second members together under compressive force, and said retention and gripping means securing the guidewire both longitudinally and rotationally relative to said housing means when the members are rotated into the second position.

2. A device as defined in claim 1 wherein said housing means comprises stop means for aligning said first and second members at said first position.

3. A device as defined in claim 2 wherein said housing means comprises first locking means for releasably securing the first and second members in the second position.

4. A device as defined in claim 3 wherein said members are operative so as to be rotated into a third position of alignment relative to each other such that the housing means is locked onto the guidewire but the housing means is not secured longitudinally and rotationally to the guidewire, and wherein said housing means comprises second locking means for releasably securing the first and second members in the third position.

5. A device as defined in claim 4 wherein said second locking means is disposed intermediate the stop means and the first locking means.

6. A device as defined in claim 1 wherein said first and second members comprise, respectively, first and second tubular members which are telescoped together, and wherein the longitudinal passageway is comprised of first and second passageways formed through each respective tubular members, and wherein the radial slot is comprise of first and second radial slots extending from an outer surface of the respective tubular member to the corresponding first and second passageways.

7. A device as defined in claim 6 wherein said retention and gripping means comprises an elastomeric member having first and second ends and an elongated body member, and wherein a first end of the elastomer member is anchored in an end of the first passageway in the first tubular member, the second end of the elastomeric member is anchored in an end of the second passageway in the second

tubular member, and the body member is situated in the first and second passageways therebetween.

8. A device as defined in claim 7 wherein said housing means comprises means for twisting the body member as the first and second ends of the elastomeric member are rotated relative to one another by rotating said first and second tubular members into the second position, such that the body ember is twisted about the guidewire so as to frictionally engage and secure the guidewire against longitudinal and rotational movement relative to the housing means without bending the guidewire.

9. A device as defined in claim 8 wherein said housing means comprises stop means for aligning said first and second members at said first position.

10. A device as defined in claim 9 wherein said housing means comprises first locking means for releasably securing the first and second members in the second position.

11. A device as defined in claim 10 wherein said members are operative so as to be rotated into a third position of alignment relative to each other such that the housing means is locked onto the guidewire but the housing means is not secured longitudinally and rotationally to the guidewire, and wherein said housing means comprises second locking means for releasably securing the first and second members in the third position.

12. A device as defined in claim 11 wherein said second locking means is disposed intermediate the stop means and the first locking means.

13. A device as defined in claim 1 further comprising an indicator means for providing visual verification of when said first and second members are rotated in the second portion of alignment.

14. A device as defined in claims 4 or 12 further comprising first and second indicator means for providing visual verification of when said first and second members are rotated to the second and third positions of alignment, respectively, relative to one another.

15. A device as defined in claims 1 or 13 further comprising rotational indicator means for providing visual directions to the direction of rotation of said first and second members relative to one another.

16. A device as defined in claim 1 further comprising means for irreversibly securing the first and second rotatable members together.

17. A device for selective attachment to or detachment from a catheter guidewire or the like, and for selectively gripping the guidewire when attached to permit either longitudinal or rotational manipulation of the guidewire for purposes of steering the guidewire through a vessel, comprising:

a tubular housing means for receiving and retaining the guidewire comprising a longitudinal passageway therethrough and a radial slot extending from an outer surface to the passageway along the full length of said housing means, and further comprising first and second rotatably connected members which are rotatably operative such that when the members are rotated into a first position of alignment relative to each other the guidewire is adapted to be inserted

into the passageway by slipping the guidewire through the slot, and such that when the members are rotated into a second position of alignment relative to each other the guidewire is locked within the passageway so that the housing means cannot fall off the guidewire but the guidewire is not secured longitudinally and rotationally relative to the housing means, and such that when the members are rotated into a third position of alignment the guidewire is secured both longitudinally and rotationally relative to the housing means;

said housing means further comprising stop means for aligning said first and second members at first position, first locking means for releasably securing the first and second members in the second position, and second locking means for releasably securing the first and second members in the third position; and

elastomeric retention and gripping means situated within said passageway and having one end anchored in the first member and another end anchored in the second member such that said elastomeric retention and gripping means will urge and hold the first and second members together under compressive force, and said elastomeric retention and gripping means securing the guidewire both longitudinally and rotationally relative to said housing means when the members are rotated into the third position.

18. A device as defined in claim 17 wherein said first and second members comprise, respectively, first and second tubular members which are telescoped together, and wherein the longitudinal passageway is comprised of first and second passageways formed through each respective tubular members, and wherein the radial slot is comprise of first and second radial slots extending from an outer

surface of the respective tubular member to the corresponding first and second passageways.

19. A device as defined in claim 18 wherein the elastomeric retention and gripping means comprises an elastomeric member having first and second ends and an elongated body member, and wherein a first end of the elastomeric member is anchored in an end of the first passageway in the first tubular member, the second end of the elastomeric member is anchored in an end of the second passageway in the second tubular member, and the body member is situated in the first and second passageways therebetween.

20. A device as defined in claim 19 wherein said housing means comprises means for twisting the body member as the first and second ends of the elastomeric member are rotated relative to one another by rotating said first and second tubular members into the third position, such that the body ember is twisted about the guidewire so as to frictionally engage and secure the guidewire against longitudinal and rotational movement relative to the housing means without bending the guidewire.

21. A device as defined in claims 17 or 20 further comprising first and second indicator means for providing visual verification of when said first and second members are rotated to the second and third positions of alignment, respectively, relative to one another.

22. A device as defined in claim 21 further comprising rotational indicator means for providing visual directions to the direction of rotation of said first and second members relative to one another.

23. A device as defined in claims 17 or 20 wherein said first and second members comprise, respectively, first and second tubular members which are telescoped together, and wherein the longitudinal passageway is comprised of first and second passageways formed through each respective tubular members, and wherein the radial slot is comprise of first and second radial slots extending from an outer surface of the respective tubular member to the corresponding first and second passageways.

24. A device for selective attachment to or detachment from a catheter guidewire or the like, and for selectively gripping the guidewire when attached to permit either longitudinal or rotational manipulation of the guidewire for purposes of steering the guidewire through a vessel, comprising:

a first tubular member having a head, a cylindrical shank with a first central axis and extending from the head, and a passage extending longitudinally through the member, the passage having a second central axis which is offset from the first axis, the passage further having an enlarged portion at its end within the head;

a second tubular member with first and second ends, and having a cylindrical bore extending from the first end to a base surface spaced from the second end, the bore being dimensioned to receive the cylindrical shank in coaxial telescoping fashion to place the first and second members in rotatable engagement; the second member having a passage extending longitudinally from the second end to the base surface, the passage further having an enlarged portion at its end adjacent the second surface;

the first and second members each having a slot extending longitudinally therethrough and extending

radially from each respective passage to a respective outer surface of the member; the slots of the members being aligned when the members are in a first rotational position, and misaligned when the members are relatively rotated to a second or a third position;

an elongated elastomeric member having a central shank with enlarged ends, the elastomer member being fitted in the passages of the first and second members with the enlarged ends seated in said enlarged portions to place the central shank in tension and thereby to urge the first and second members together;

the first and second members defining a stop means for limiting relative rotation therebetween to movement from the first to the second or third positions, and vice versa;

whereby the assembly can be moved laterally over the guidewire when the members are in the first position to place the guidewire in the passages against the elastomeric member, and rotation of the tubular members to the second position traps the guidewire within the assembly but without securing the guidewire against longitudinal and rotational movement relative to the assembly, and rotation of the tubular members to the third position traps the guidewire within the assembly and secures the guidewire against longitudinal and rotational movement relative to the assembly.

25. A device as defined in claim 24 further comprising means for twisting the central shank of the elastomeric member as the enlarged ends thereof are rotated relative to one another by rotating the tubular members to the third position, thereby frictionally engaging and securing the guidewire against longitudinal and rotational

movement relative to the assembly, without bending the guidewire.

26. A device as defined in claim 25 further comprising first locking means for releasably securing the first and second tubular members in the second position.

27. A device as defined in claim 26 for releasably securing the first and second tubular members in the third position.

28. A device as defined in claim 27 further comprising first and second indicator means for providing visual verification of when said first and second members are rotated to the second and third positions of alignment, respectively, relative to one another.

29. A device as defined in claim 27 further comprising rotational indicator means for providing visual directions to the direction of rotation of said first and second members relative to one another.

30. A device as defined in claim 29 further comprising means for irreversibly securing the first and second rotatable members together.

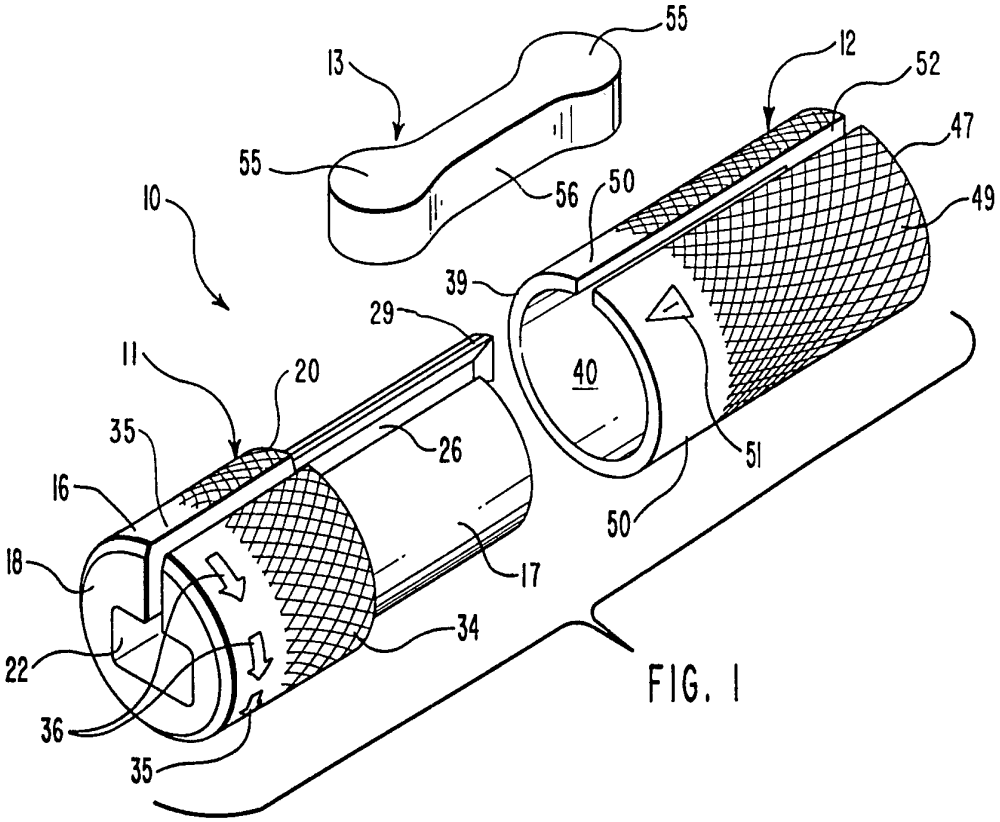
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FIG. 1

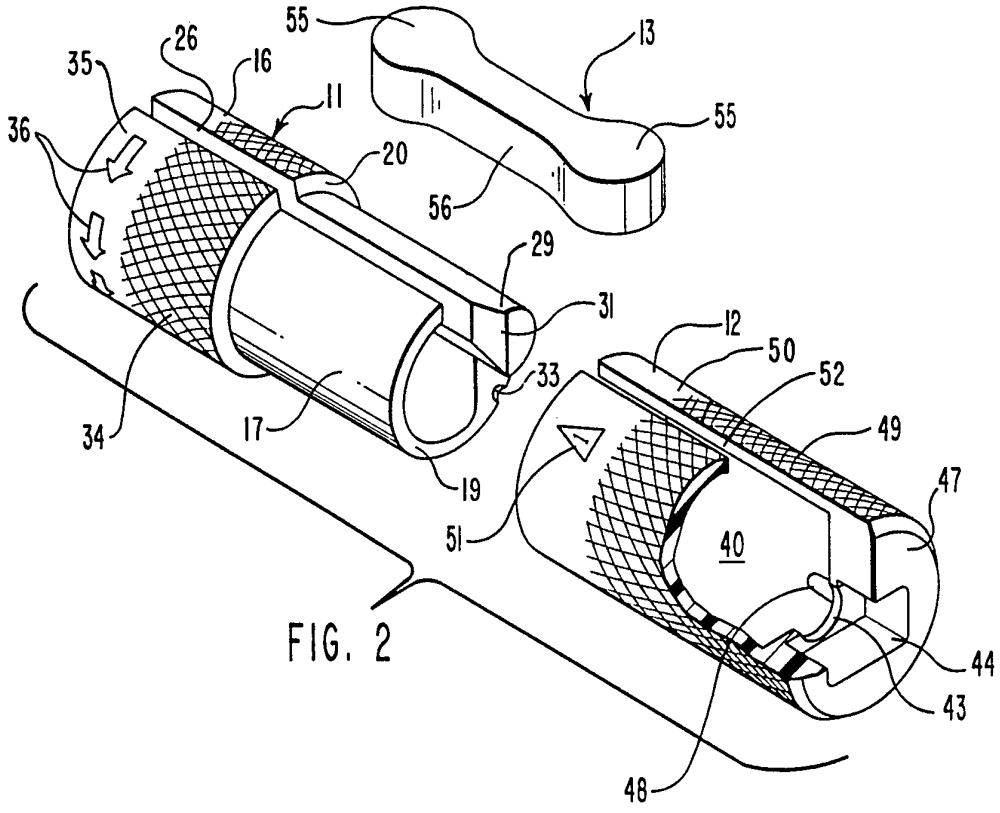
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FIG. 2

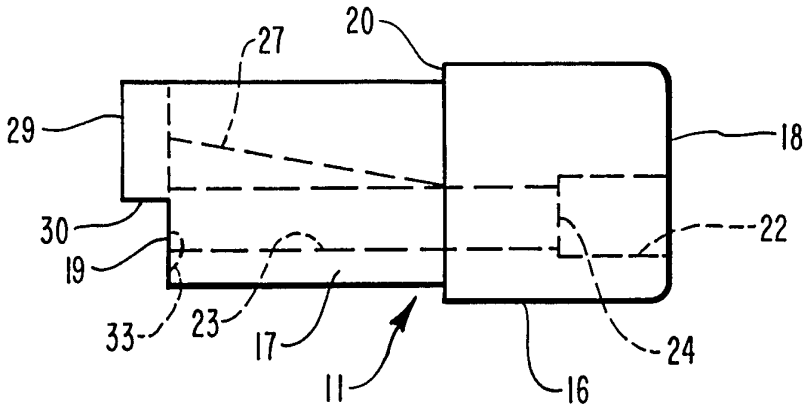
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FIG. 3

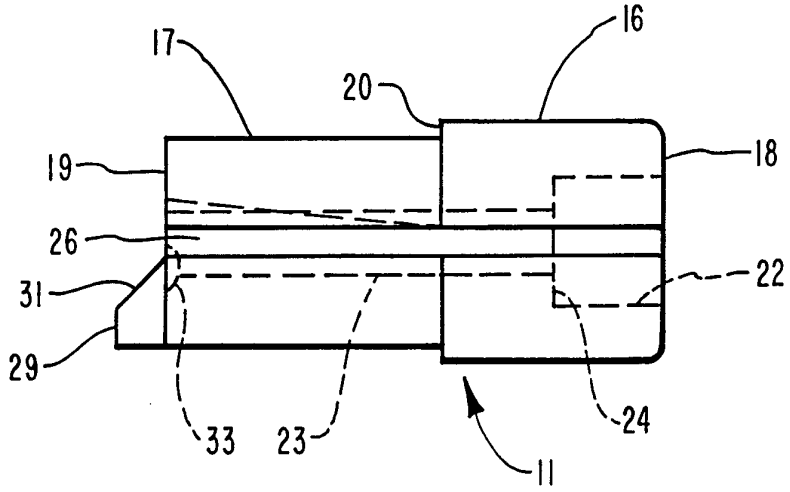
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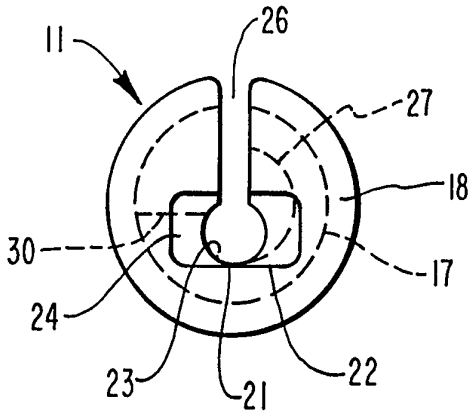
FIG. 4



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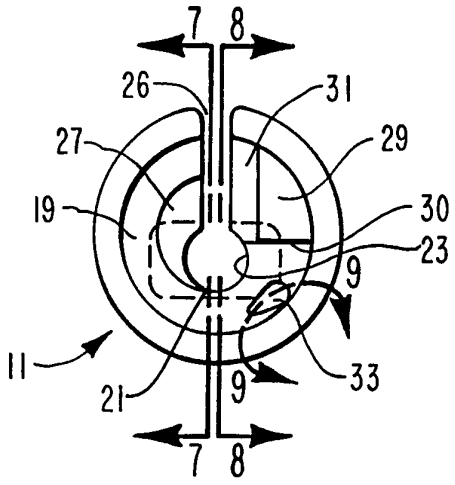

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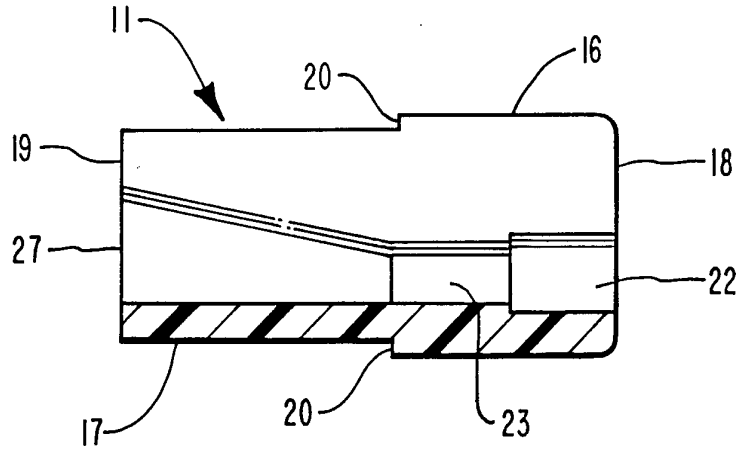

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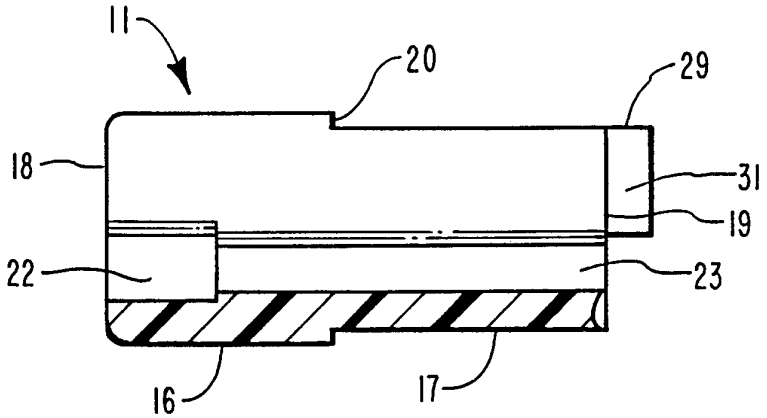
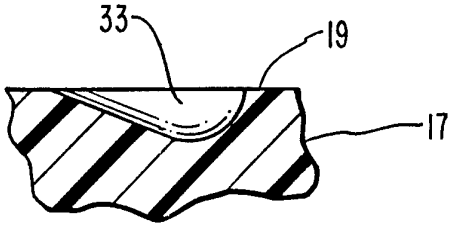


FIG. 8



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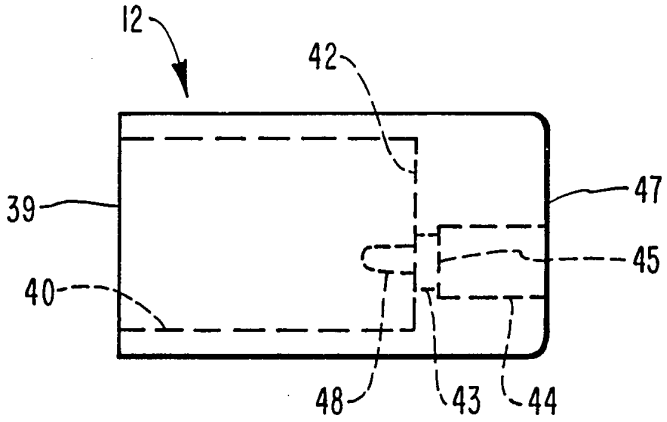
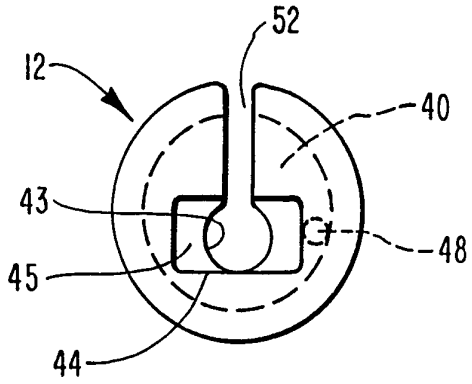


FIG. 10



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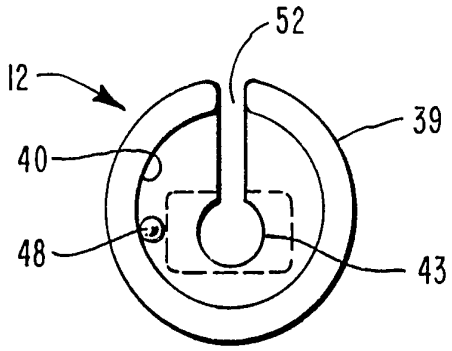

FIG. 12

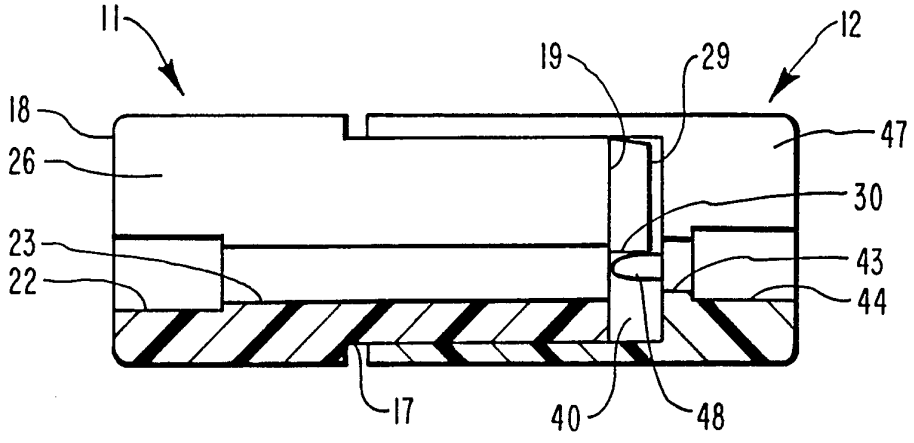

FIG. 13

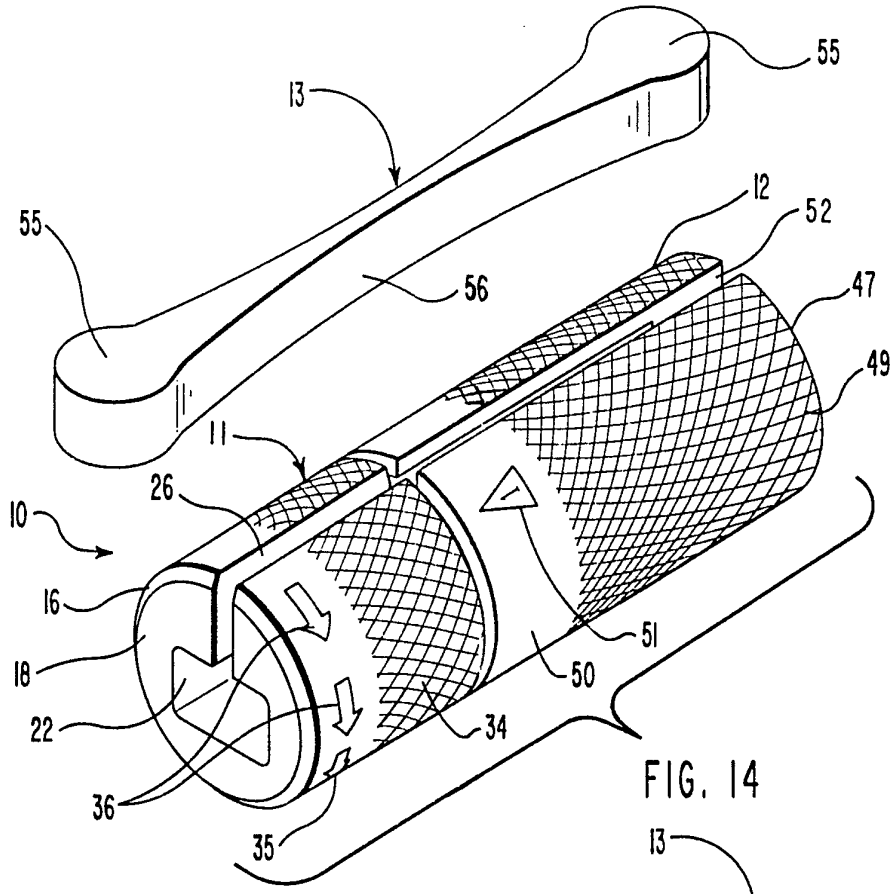
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FIG. 14

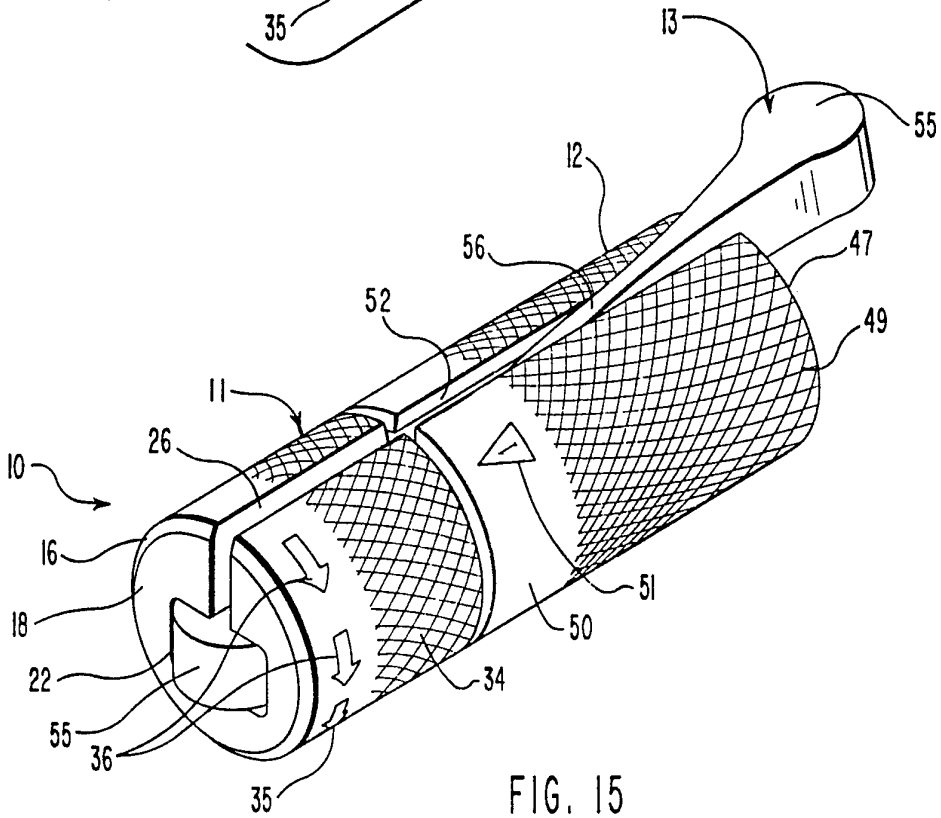
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FIG. 15

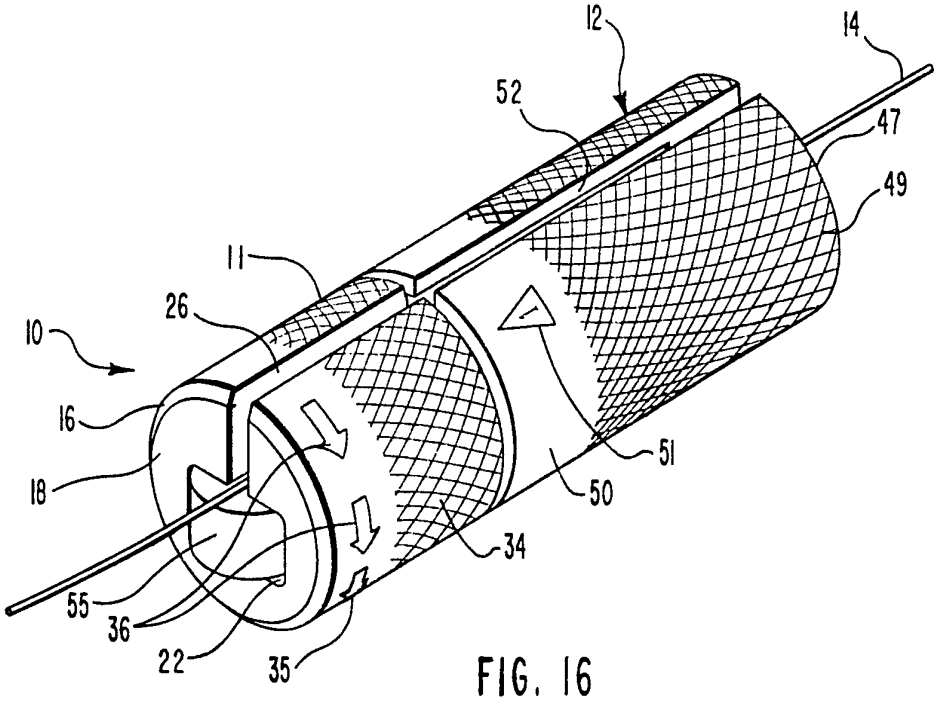
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FIG. 16

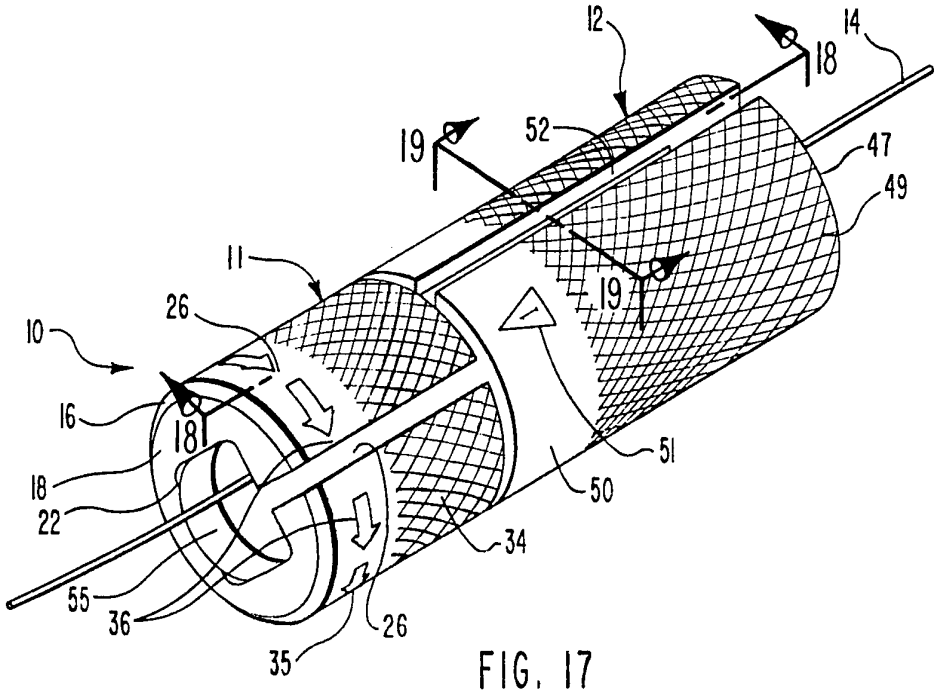
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FIG. 17

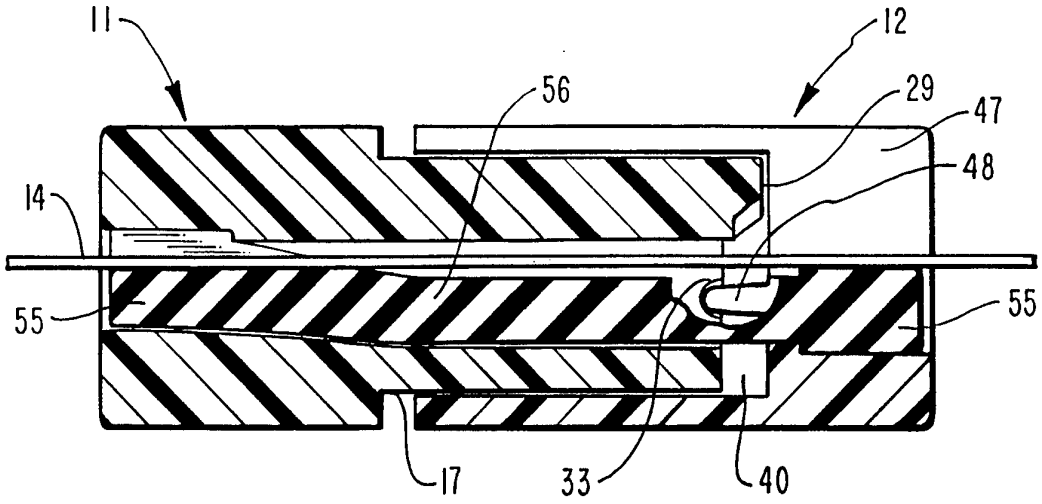

FIG. 18

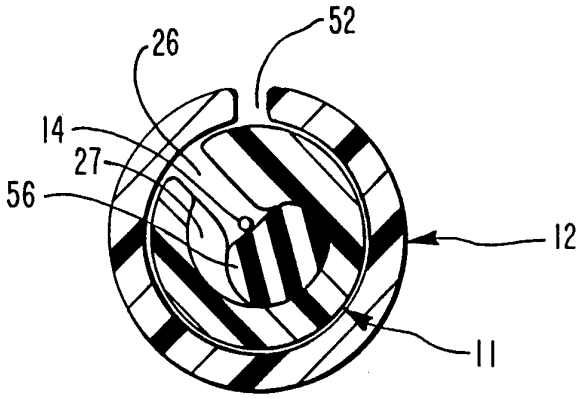

FIG. 19

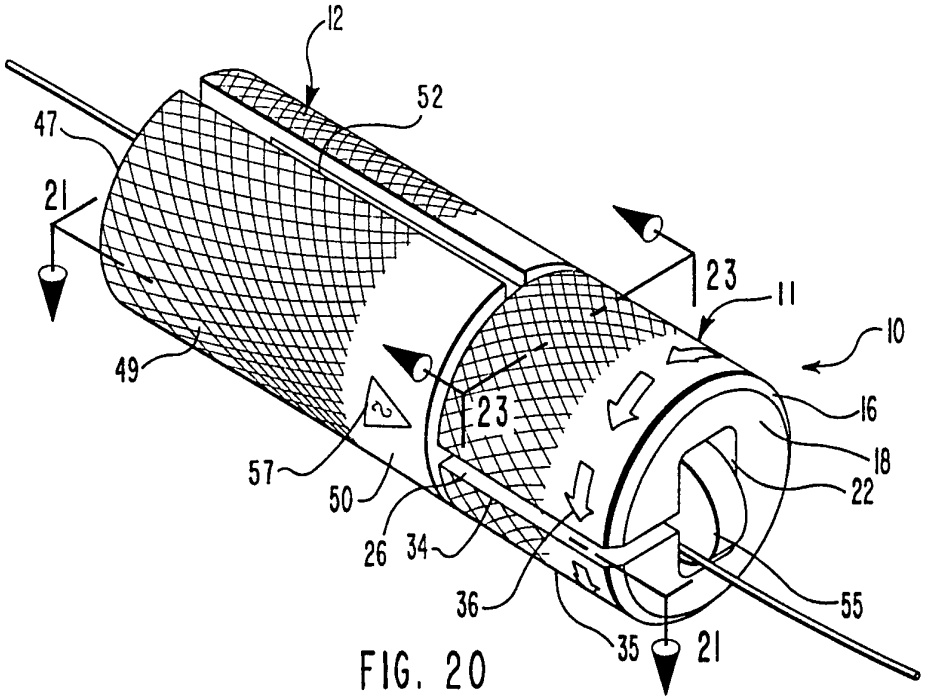
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FIG. 20

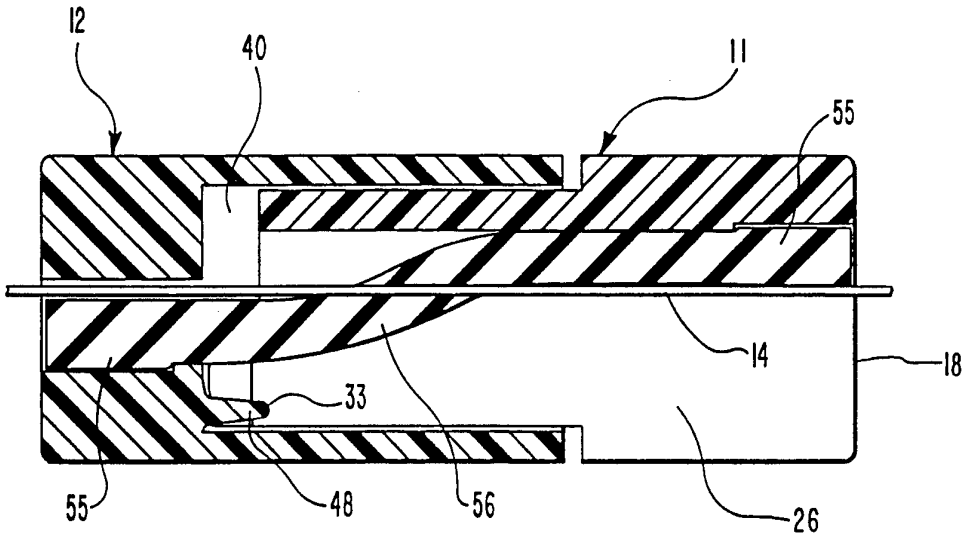
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FIG. 21

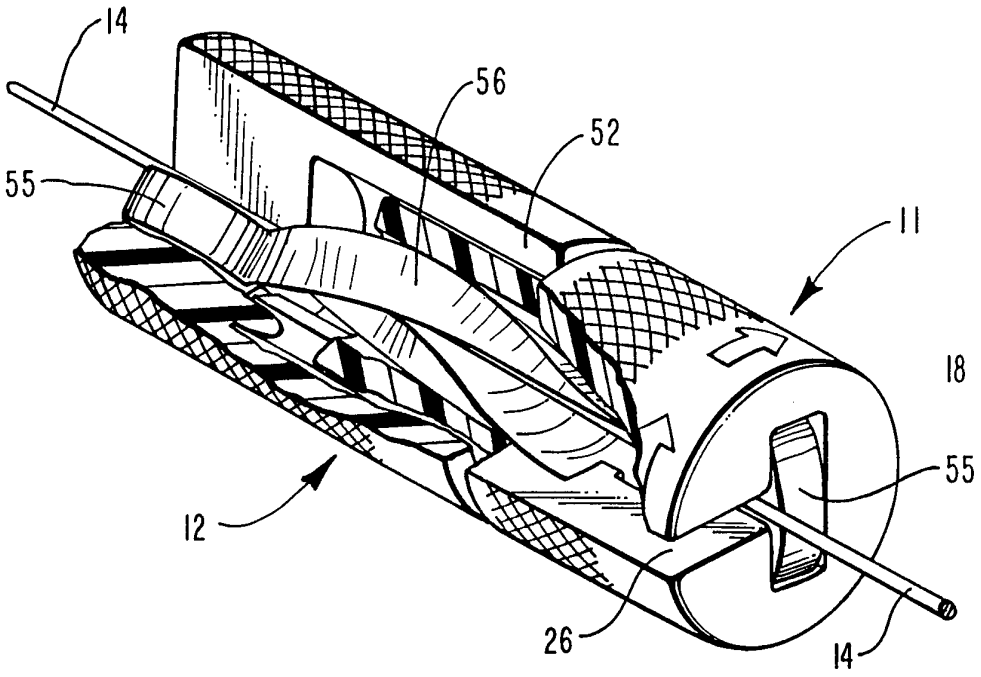
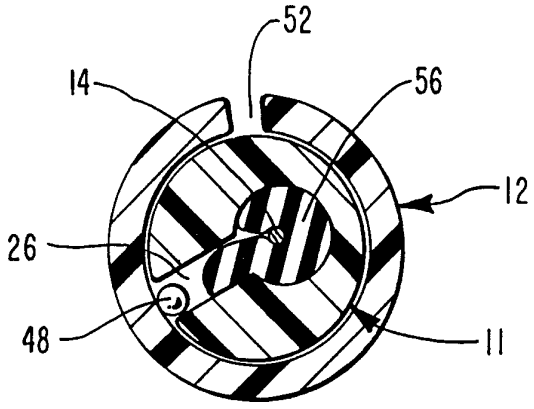


FIG. 22



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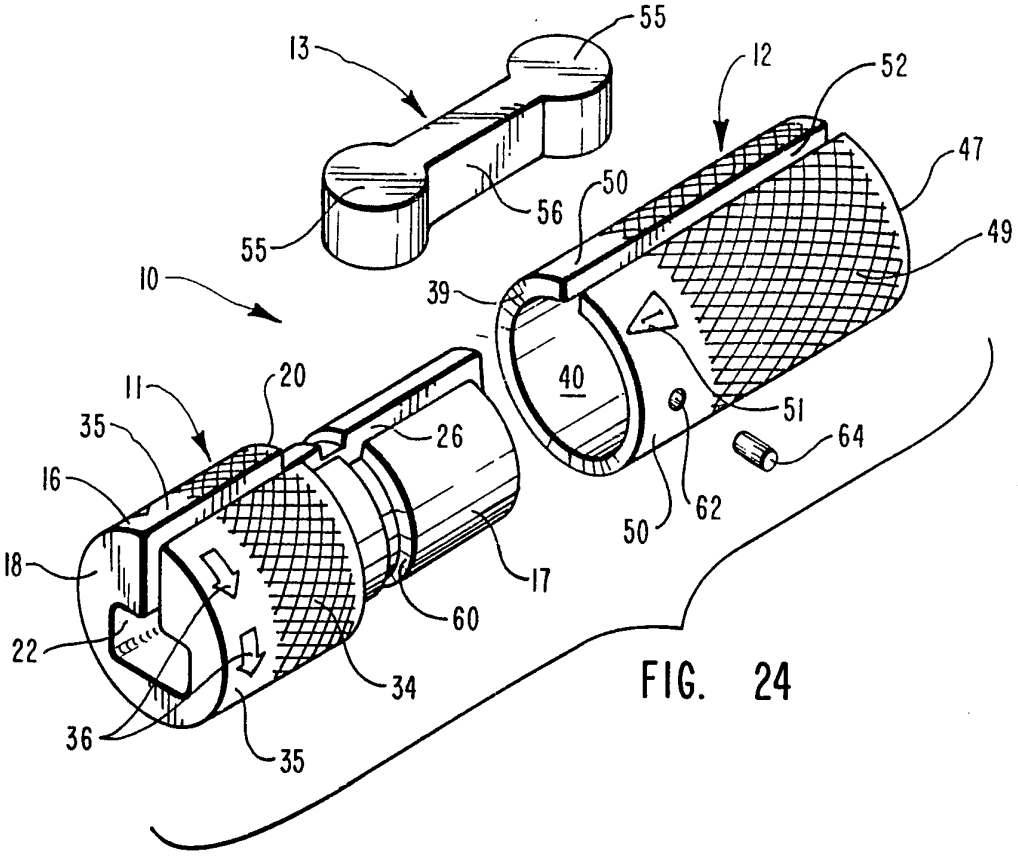
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FIG. 24

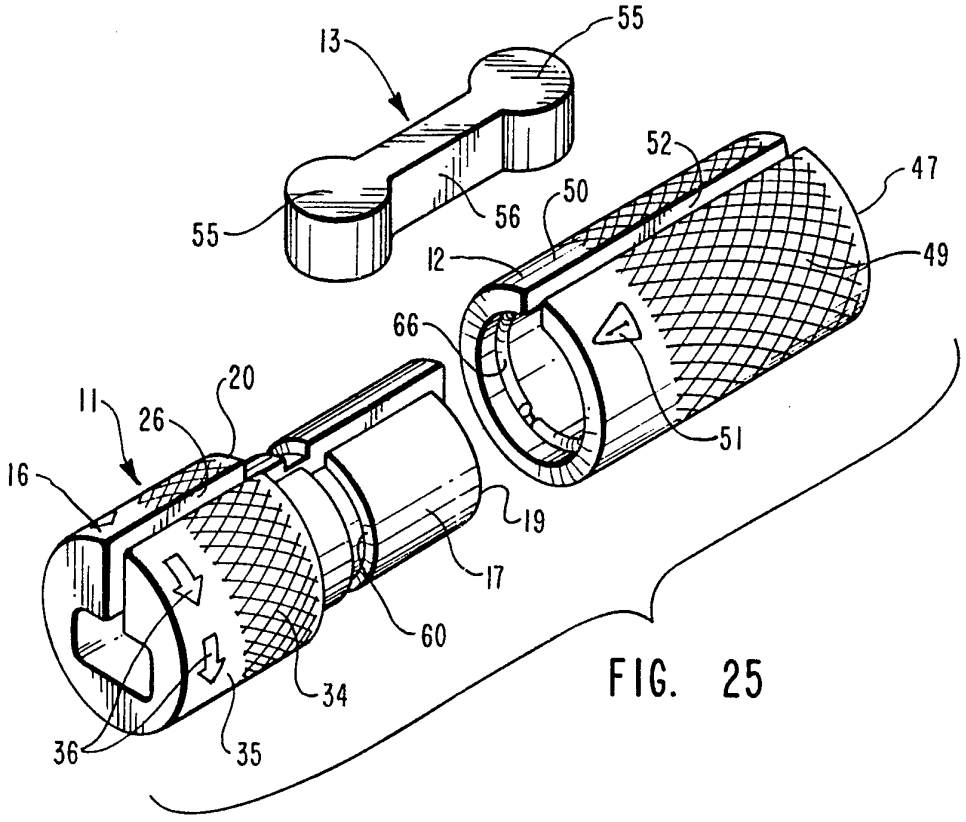
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FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
.T/US93/11047

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/00
US CL :604/95

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/656-658, 772; 604/159, 165, 170, 249, 250, 280, 283; 606/1, 127, 158, 162, 226

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,799,496, (HARGREAVES ET AL.), 24 January 1989. See entire document.	1-30
A	US, A, 4,957,117, (WYSHAM), 18 September 1990. See entire document.	1-30
A	US, A, 5,137, 517, (LONEY ET AL.), 11 August 1992. See entire document.	1-30
A	US, A, 5,161,534, (BERTHIAUME), 10 November 1992. See entire document.	1-30
A	US, A. 5,137,288, (STARKEY ET AL.), 11 August 1992. See entire document.	1-30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

11 JANUARY 1994

Date of mailing of the international search report

05 MAY 1994

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JOHN YASKO, JR.

Telephone No. (703) 308-2986

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