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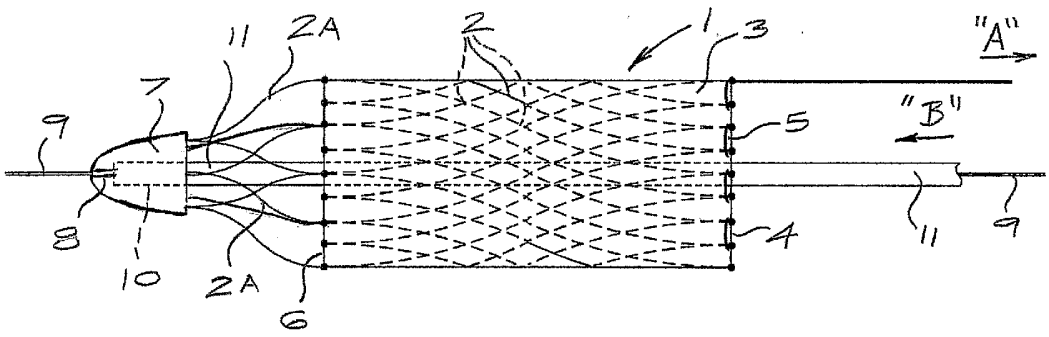
(54) Title: DILATORS AND DILATOR ASSEMBLIES



(57) Abstract: A dilator (1, 13, 22) is provided of the general type comprising a radially resilient tabular lattice (2) supporting a flexible tabular sheath (3) such that the tabular lattice and sheath can be constricted to reduce the diameter thereof with a consequent elongation of the tabular lattice. The dilator has means (5, 2a, 14, 15, 23, 25) associated with both its proximal end (4, 16, 24) and distal and (6, 12, 26) for decreasing the diameter of both ends against the resilience of the dilator. The means for decreasing the diameter of the proximal and of the dilator is a generally a drawstring (5, 15, 23). The means for decreasing the diameter of the distal and may be either a series of radially extending elements (2a) connected to the distal end of the lattice and connected to each other by a leading end cap (7) carried by a control tube or a second drawstring arrangement ('14, 25) wherein, for installation purposes, the drawstring or drawstrings pass through a small diameter control tube (17, 27).

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DILATORS AND DILATOR ASSEMBLIES

FIELD OF THE INVENTION

This invention relates to dilators and dilator assemblies used for the purpose of dilating strictures in tubular organs of the human or animal body, typically such organs as the oesophagus, trachea, anus, urethra, vagina, as well as other tubular organs. Dilators with which this invention is concerned are also widely known as self expanding stents and for purposes of simplicity of description the one term dilator will be used herein.

More particularly, the invention relates to tubular dilators of the general type comprising a resilient tubular supporting lattice having two sets of resiliently deformable, crossed, generally helically extending elongate elements that may either be separate and cross each other, or may be integral, in either case defining a lattice with generally diamond shaped apertures, and wherein the lattice supports a flexible, and generally resilient, tubular sheath. The diameter, and thus the circumference of such a dilator can be diminished resiliently, whilst simultaneously increasing its length consequentially, so that it can be inserted in a stricture to exert a continuous dilating effect by virtue of its resilience. Such dilators and their use is further described in an article published in the South African Journal of Surgery (SAJS) Vol 37 No 33 of August 1999 the content of which is incorporated herein by reference.

BACKGROUND TO THE INVENTION

Removal of a dilator of the type described above from its operative position, after it has served its purpose, typically for a period of five to ten days, is easily achieved by virtue of the presence of a drawstring (often referred to as a purse-string) that encircles the proximal end of the dilator such that by

pulling on an outer end of the drawstring, the proximal end of the dilator is diminished in diameter with a consequent extension of the length of the dilator. The combined effect on the dilator tends to release it from its operative position and enable its withdrawal relatively simply and easily.

The insertion of the dilator, on the other hand, has not been as easy to achieve as its removal. Various expedients and techniques have been tested and used. One of the more successful techniques is set out in the article referred to above and involves the use of a smooth Teflon introducer tube that has a duck's beak-like formation at one end that can be narrowed to facilitate its introduction into the constricted organ. The dilator itself is diametrically compressed and sort of extruded in a reduced diameter condition into the Teflon introducer tube. After insertion, the dilator is then left in its operative position by withdrawal of the introducer tube whilst the dilator is held in its desired axial position by an extruder rod that serves as a plunger to move the proximal end of the dilator along the length of the introducer tube (the dilator remaining stationary relative to the relevant organ) as the introducer tube is withdrawn.

This insertion procedure is relatively difficult to carry out, at least in particular circumstances.

OBJECT OF THE INVENTION

It is, accordingly, an object of this invention to provide dilators/stents of the general type described herein as well as dilator assemblies embodying same that are adapted for more expeditious insertion into an operative position.

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention there is provided a dilator of the general type comprising a radially resilient tubular lattice supporting a

flexible tubular sheath such that the tubular lattice and sheath can be constricted to reduce the diameter thereof with a consequent elongation of the tubular lattice and wherein the dilator has a proximal end and a distal end, the dilator being characterised in that each of the proximal end and the distal end have means associated therewith for decreasing the diameter of the end against the resilience of the dilator.

Further features of this aspect of the invention provide for the resilient tubular lattice to be defined by two sets of opposite handed helically extending resilient elements that are typically spring steel wires or the like; for said means for decreasing the diameter of the proximal end of the dilator to be a drawstring of substantially conventional configuration; and for said means for decreasing the diameter of the distal end to be selected from radially extending elements connected to the distal end of the lattice and connected to each other by a leading end cap cooperating, for installation purposes, with a small diameter control tube such that longitudinal movement of the tube relative to the dilator causes a radial pull on the radially extending elements to diminish the diameter of the distal end of the dilator, and a second drawstring arrangement wherein, for installation purposes, the drawstring or drawstrings pass through a small diameter control tube.

In a first variation of the invention the tubular lattice has two sets of opposite handed helically extending resilient elements at least some of which have extensions extending beyond the end of the dilator itself (and thus beyond the sheath), such extensions to the resilient elements being directed inwards towards an axially orientated leading end cap forming the distal end of the dilator. In this variation insertion is achieved with the aid of a small diameter control tube that operatively engages the end cap to impose an axial stretching force on the dilator that, by way of the extensions to the resilient elements, causes a radially inwards force to be exerted on the distal end of the dilator and thus a decrease in the diameter thereof. Simultaneous pulling on the cord associated with the drawstring configuration at the proximal end

of the dilator results in the diameter of the entire dilator diminishing to facilitate insertion. Insertion is typically carried out using a guide wire that is firstly inserted such as by gastroscopy into the stomach in which may be further helped and controlled by the use of X radiography.

In a second variation of the invention the distal end of the dilator is provided with a drawstring arrangement whereof the drawstring passes through a small diameter control tube. Pushing on the control tube and pulling on the cord associated with the drawstring configuration of the proximal end leads to the diameter of both ends of the dilator diminishing to facilitate insertion. In this variation of the invention the dilator can conveniently be inserted with the aid of a Teflon introducer tube having a duck's beak like end as described in the article referred to above.

In a third variation of the invention the distal end of the dilator is once more provided with a drawstring arrangement whereof the drawstring passes through a small diameter control tube, but in this case, the drawstrings (preferably two in number) pass through a lateral hole in the control tube towards its distal end that cooperates with a leading axially orientated end cap having a contoured skirt that is resiliently extensible to encircle the distal end of the dilator during installation but that can be removed from the dilator after installation and withdrawn by means of the control tube out through the dilator itself in the installed position. In this case the drawstring or drawstrings associated with the distal end of the dilator can be severed in order to withdraw the introducer tube and end cap assembly more easily. Alternatively, they can be left in situ, as long as they are not the same colour for easy identification as the drawstring attached to the proximal end, as this, and only this drawstring is generally used for extraction purposes.

In each case, the various novel components forming part of each of the dilator assemblies outlined above in a condition ready for insertion of a dilator

is intended to fall within the scope of this invention and be afforded protection as individual items of commerce.

In order that the above and other features of the invention may be more fully understood one embodiment of each of the three variations outlined above will now be described with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:-

Figure 1 is a schematic elevation of an embodiment of the first variation of the invention;

Figure 2 is a schematic elevation illustrating implementation of the second variation of the invention outlined above with the dilator being illustrated within a Teflon (registered trademark) introducer tube;

Figure 3 is a view similar to Figure 2 but illustrating the Teflon (registered trademark) introducer tube being retracted following insertion of the dilator;

Figure 4 is a schematic elevation of an embodiment of the third variation of the invention outlined above in a condition in which it is ready for insertion;

Figure 5 illustrates the variation of Figure 4 with the contoured skirt in the process of being installed in position;

Figure 6 illustrates the same embodiment with a cutting tube in the process of installation for severing the drawstrings associated with the distal end of the dilator;

Figure 7 illustrates the operation of the cutting tube at the distal end of the dilator; and,

Figure 8 illustrates the removal of the end cap and associated contoured skirt together with the small diameter control tube.

DETAILED DESCRIPTION WITH REFERENCE TO THE DRAWINGS

In the embodiment of the invention illustrated in Figure 1 a dilator, generally indicated by numeral (1), comprises two oppositely handed sets of helically extending elongate elements (2) embodied in, and supporting, a flexible, typically woven, elastomeric sheath (3) in substantially known manner. The elongate elements are typically stainless spring steel wires or other suitable material and they may be woven or braided with respect to each other.

The proximal end (4) of the dilator has a drawstring (5) associated with it such that pulling on the drawstring purstring in a generally axial direction away from the dilator, as indicated by arrow "A", will cause a radial constriction of the dilator against its resiliency and a consequent axial elongation.

As provided by the present invention, in this first variation thereof, selected elongate elements (2) have, at the distal end (6) of the dilator, extensions (2a) that converge towards, and have their free ends fixed to, an axially orientated leading end cap (7) that is smoothly contoured for ease of insertion. The end cap has an axial hole (8) through it for receiving a guide

wire (9) during insertion and also has a socket (10) for receiving the distal end of a small diameter control tube (11).

In use, an axial pushing force exerted on the control tube in the direction indicated by arrow "B", with the simultaneous pulling on the drawstring (5) in the direction indicated by arrow "A", will result in both ends of the dilator being positively contracted to diminish its diameter. In the case of the proximal end, this is achieved using the drawstring and in the case of the distal end the pulling action on the extensions (2a) to the selected elongate elements will have the effect of contracting the distal end of the dilator.

In this embodiment of the invention the extensions (2a) and end cap (7) are configured to remain in situ during the service life of the dilator which is, as indicated above, generally from five to ten days, or more. The spacing of the extensions enables the patient to receive soft and liquid diet that passes between the extensions in applicable instances.

Turning now to the embodiment of the invention illustrated in Figures 2 and 3, the distal end (12) of the dilator (13) is provided with a blue drawstring (14) encircling the end in a manner similar to a red drawstring (15) at the proximal end (16) and that is substantially as described above. The red coloured drawstring (14) associated with the distal end is used to pull the dilator into the introducer mentioned below and it passes through a small diameter control tube (17). In this embodiment of the invention the dilator is conveniently inserted utilizing a Teflon (registered trademark) introducer tube (18) of the general type described in the article referred to above and wherein the leading end (19) has a pair of deep Vee-shaped cut-outs (20) that are, for installation purposes, held together by sling cords (21) to form a tapering duck's beak configuration as shown clearly in Figure 2 for facilitating insertion of the introducer tube. This is inserted over a previously inserted guide wire with a savary Guilliard type bougie or tube over the guide wire to give the guide wire more body. During introduction of the introducer the sling cords

(21) are held taut enough so that the duck beaklike end grips the guide and after introduction, the cord is discarded.

Once the dilator is in its operative axial position within the relevant organ the small diameter control tube and red cord is (17) is used to hold it in its axial position whilst the Teflon introducer tube (18) is removed, as illustrated clearly in Figure 3.

Turning now to the third variation of the invention illustrated in Figures 4 to 8, the dilator (22) has a drawstring (23) at its proximal end (24) and a pair of drawstrings (25) and its distal end (26). The drawstrings (25) at its distal end are, in this case, passed through a small diameter control tube (27) by way of a hole (28) in the wall of the control tube towards its distal end (29). This distal end is received in a socket (30) in a leading end cap (31) to which it is fixed.

The leading end cap (31) has a resiliently extensible contoured skirt (32) that has a free edge (33) that can be stretched to encircle the distal end of the dilator as shown clearly in Figure 4. In this manner there is formed a convergent leading end to the dilator assembly for insertion in a tubular organ as described generally above. In this case, however, the distal end (26) can be held in a constricted configuration by pulling on the drawstrings (25) and anchoring them relative to the proximal end (34) of the small diameter control tube (27) by means of a pair of forceps (35).

Figure 5 illustrates the manner in which a pair of large forceps (36) is used to stretch the free edge (33) of the skirt (32) in order to install it on the distal end (26) of the dilator (22) by pulling on the drawstring (25). The recession is merely over a guide wire passed through the cutting tube (37) described further below and holding the drawstrings (25) taut.

Figure 6 illustrates a part of the insertion procedure in which the drawstrings (25) associated with the distal end of the dilator are drawn through a tubular cutting tube (37) having an inclined cutting edge (38). This is achieved by utilizing an elongate pull-through element (39) that is threaded through the cutting tube and consists of a wire having an eye (40) at one end through which the drawstrings (25) are threaded and by means of which they are drawn through the cutting tube.

With the drawstrings pulled through the cutting tube and the cutting tube positioned within the small diameter control tube (27), the cutting edge (38) can be employed to sever the drawstrings (25) after insertion by rotating the cutting tube as will be apparent from Figure 7.

As shown in Figure 8, with the drawstrings (25) now severed the small diameter control tube can be manipulated remotely so that the free end (33) of the skirt (32) becomes removed from the dilator whilst pulling, as may be required, on the drawstring (23) associated with the proximal end (24) of the dilator. With the skirt now collapsed, the small diameter control tube, together with the leading end cap (31), can be removed from the dilator thus leaving it in situ in the relevant organ.

It is to be noted that use of certain types of dilators made in accordance with this invention enables removal of previously inserted dilators that have become surrounded by fibrous growth or tumour where this was considered impossible to do previously. This is a result of the fact that the diameter of the dilator according to this invention can be reduced to a smaller diametrical size than was heretofore possible and this enables the dilator of this invention to be capable of being introduced into the previously inserted dilator particularly in the instance that an introduce tube is employed such as is described with reference to Figures 2 and 3. If left inside such previously inserted dilator for a period of time, typically several days and up to a week, the imprisoned dilator becomes clearly identified and may be grasped with

crocodile forceps. Clearly the expanded diameter of the newly installed dilator must be somewhat greater than the diameter of the imprisoned dilator.

It is also to be noted that use of dilators made according to the invention enable larger diameter dilators to be inserted into their operative positions than was practically possible previously.

It will be understood that numerous variations may be made to the embodiments of the invention described above without departing from the scope hereof.

CLAIMS:

1. A dilator (1, 13, 22) of the general type comprising a radially resilient tubular lattice (2) supporting a flexible tubular sheath (3) such that the tubular lattice and sheath can be constricted to reduce the diameter thereof with a consequent elongation of the tubular lattice and wherein the dilator has a proximal end (4, 16, 24) and a distal end (6, 12, 26), the dilator being characterised in that each of the proximal end and the distal end have means (5, 2a, 14, 15, 23, 25) associated therewith for decreasing the diameter of the end against the resilience of the dilator.

2. A dilator as claimed in claim 1 in which the resilient tubular lattice is defined by two sets of opposite handed helically extending resilient elements (2).

3. A dilator as claimed in either one of claims 1 or 2 in which said means for decreasing the diameter of the proximal end of the dilator is a drawstring (5, 15, 23).

4. A dilator as claimed in any one of the preceding claims in which said means for decreasing the diameter of the distal end is a series of radially extending elements (2a) connected to the distal end of the lattice and connected to each other by a leading end cap (7) cooperating, for installation purposes, with a small diameter control tube (11) such that longitudinal movement of the control tube relative to the dilator causes a radial pull on the radially extending elements to diminish the diameter of the distal end of the dilator.

5. A dilator as claimed in claim 4 in which the tubular lattice has two sets of opposite handed helically extending resilient elements at least some of which extend beyond the end of the dilator itself to form said radially

extending elements that are directed inwards towards the axially orientated leading end cap forming the distal end of the dilator.

6. A dilator as claimed in any one of claims 1 to 3 in which said means for decreasing the diameter of the distal end is a second drawstring arrangement (14, 25) wherein, for installation purposes, the drawstring or drawstrings pass through a small diameter control tube (17, 27).

7. A dilator as claimed in claim 6 in which the arrangement is such that that pushing on the control tube and pulling on a cord associated with the drawstring configuration (15) of the proximal end leads to the diameter of both ends of the dilator diminishing to facilitate insertion.

8. A dilator as claimed in claim 7 in combination with an introducer tube (18) having a duck's beak like end.

9. A dilator as claimed in claim 6 in which the distal end of the dilator is provided with a drawstring arrangement whereof the drawstring (25) passes through a small diameter control tube (27) with the drawstring passing through a lateral hole (28) in the control tube towards its distal end (29) that cooperates with a leading axially orientated end cap (31) having a contoured skirt (32) that is resiliently extensible to encircle the distal end of the dilator during installation and that is optionally removable from the dilator after installation by means of the control tube.

10. A dilator as claimed in claim 9 in which means (37) are provided for severing drawstrings in order to withdraw the end cap and contoured skirt.

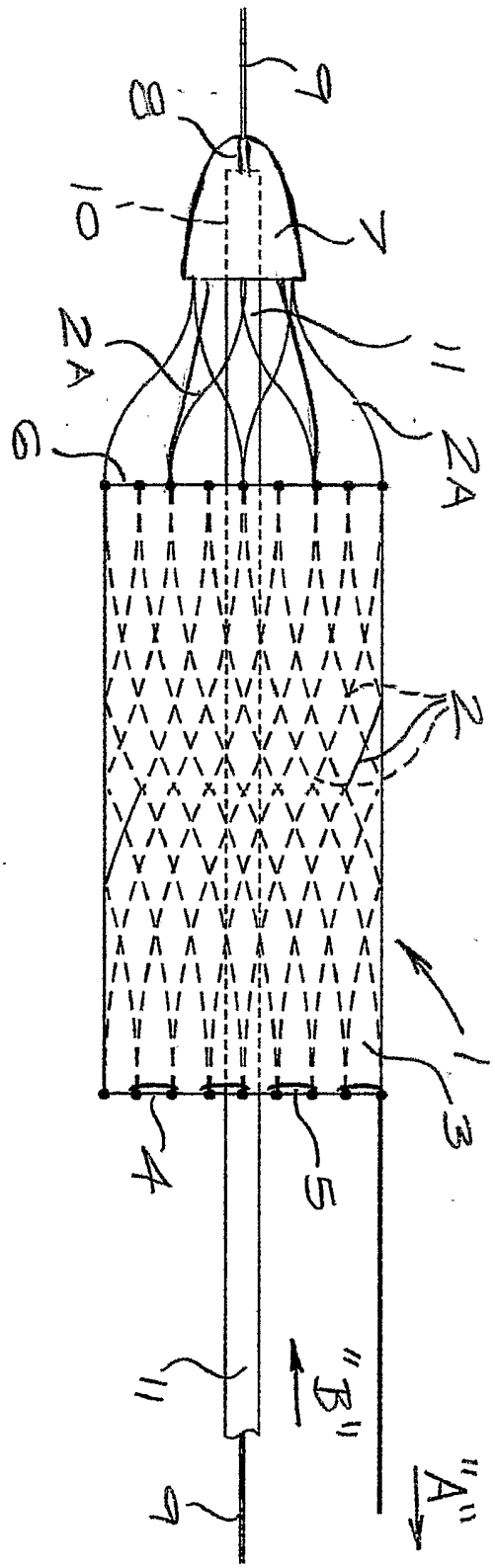

FIG 1

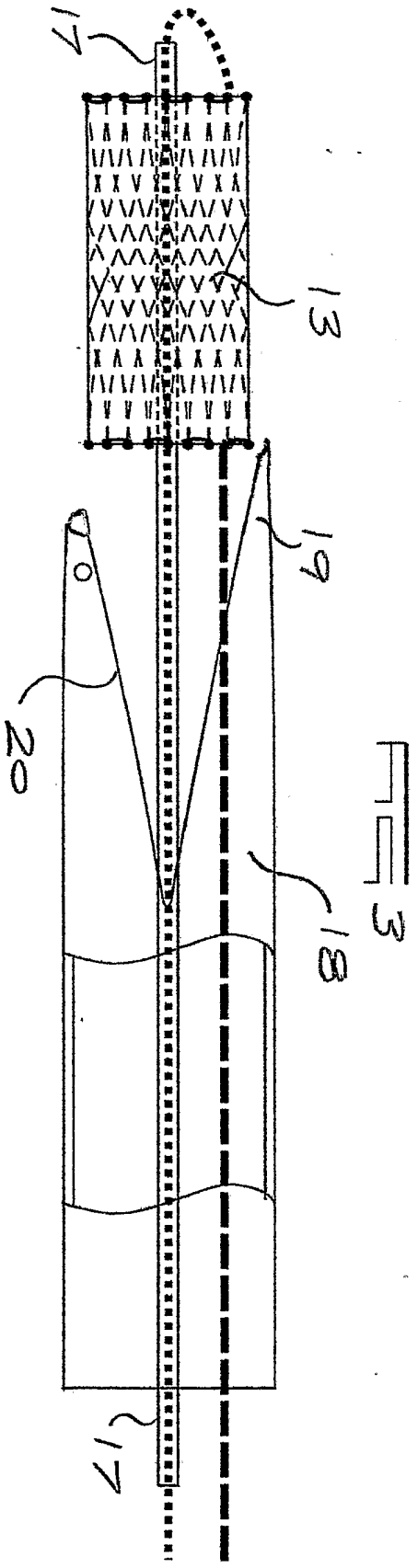

FIG 3

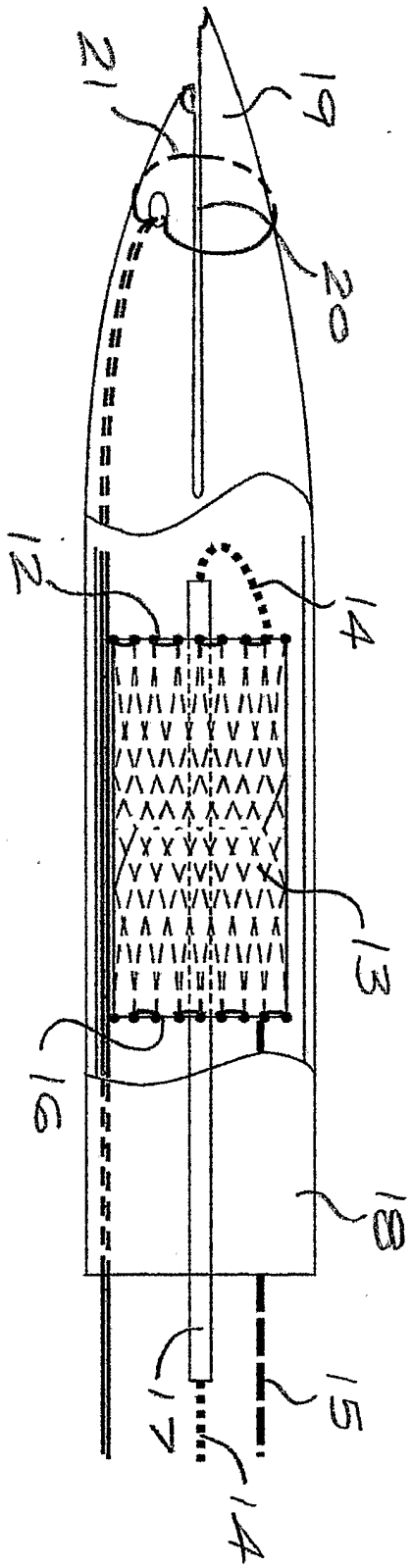

FIG 2

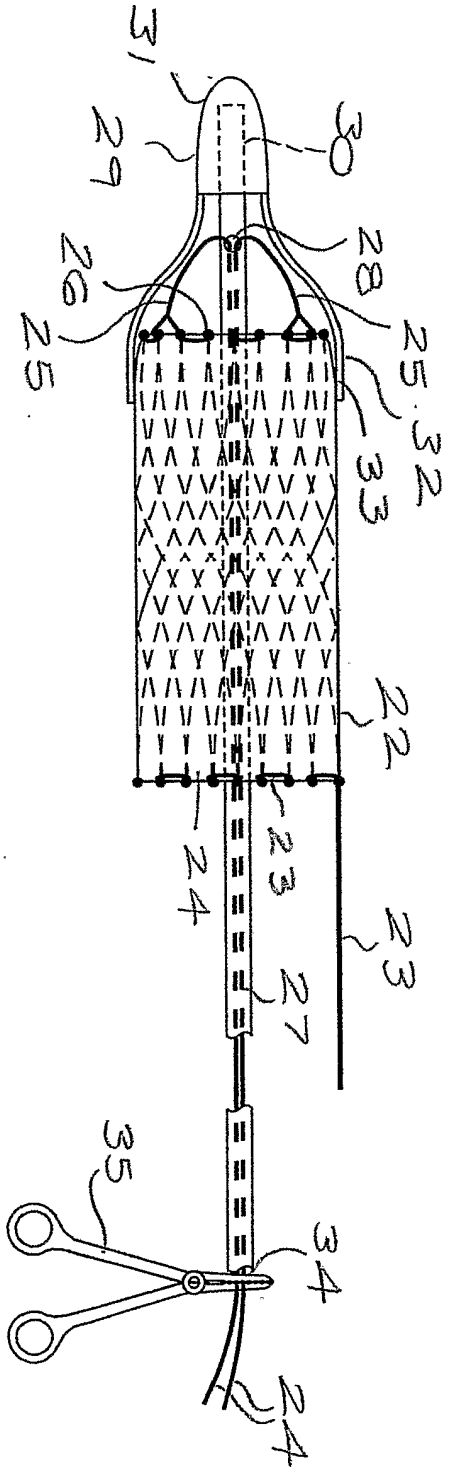

FIG 4

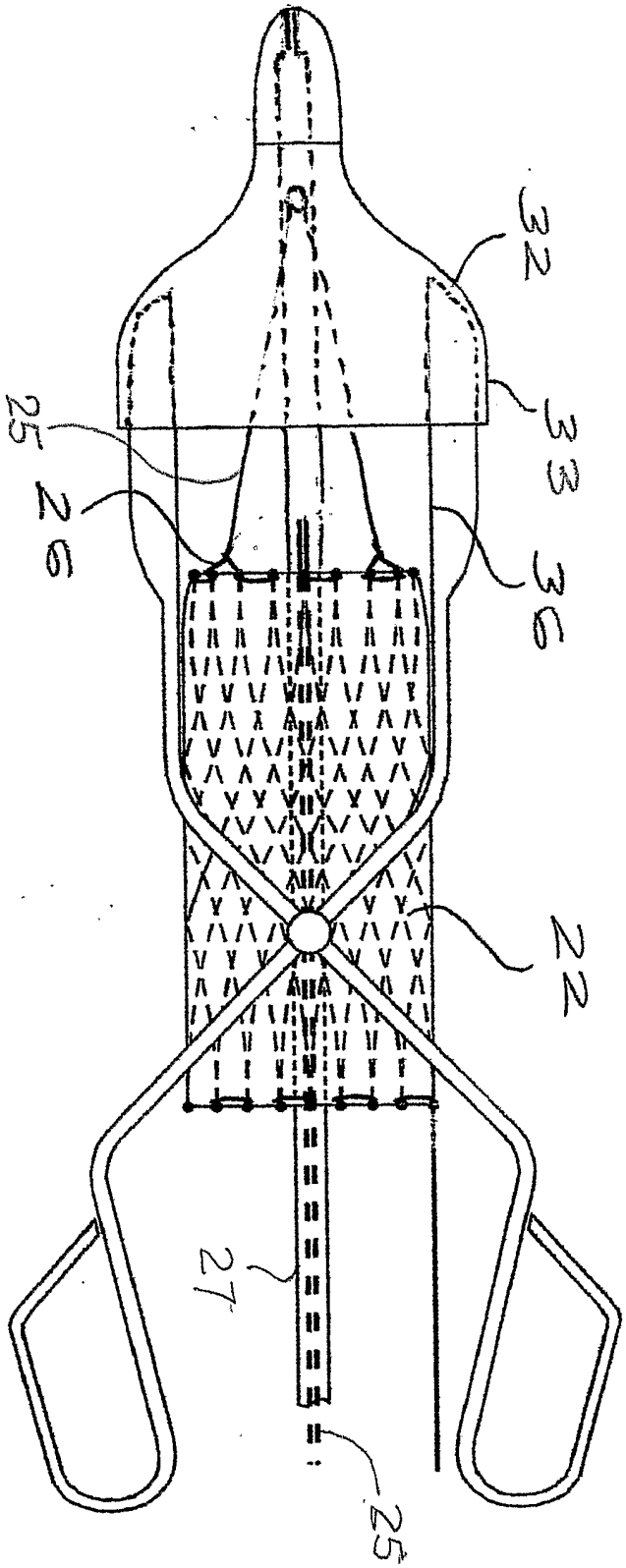

FIG 5

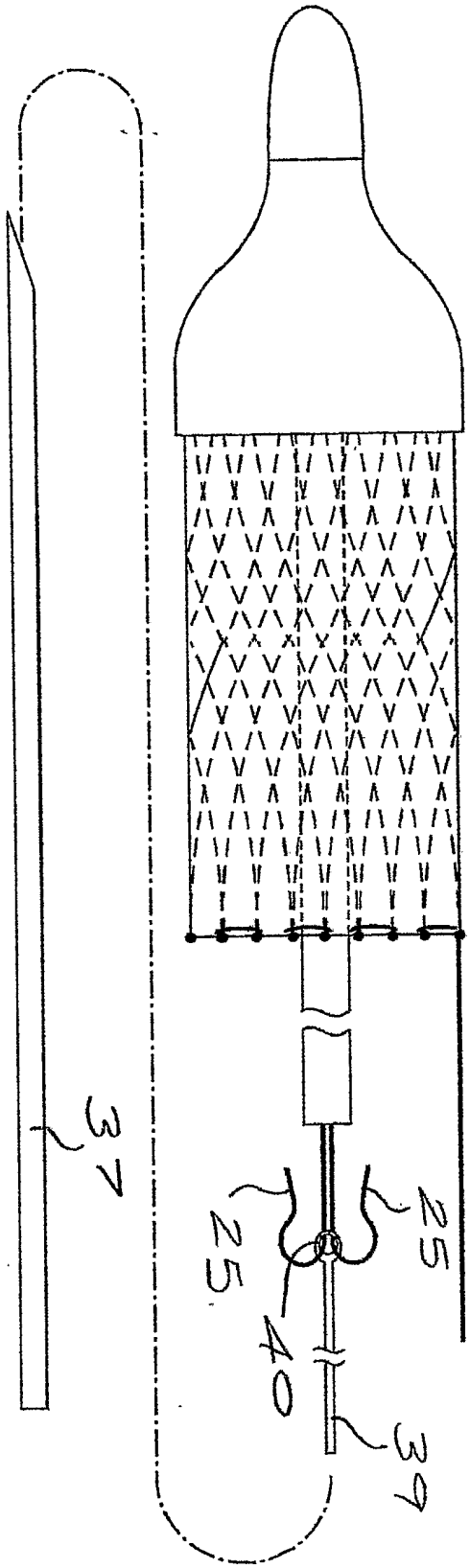

FIG 6

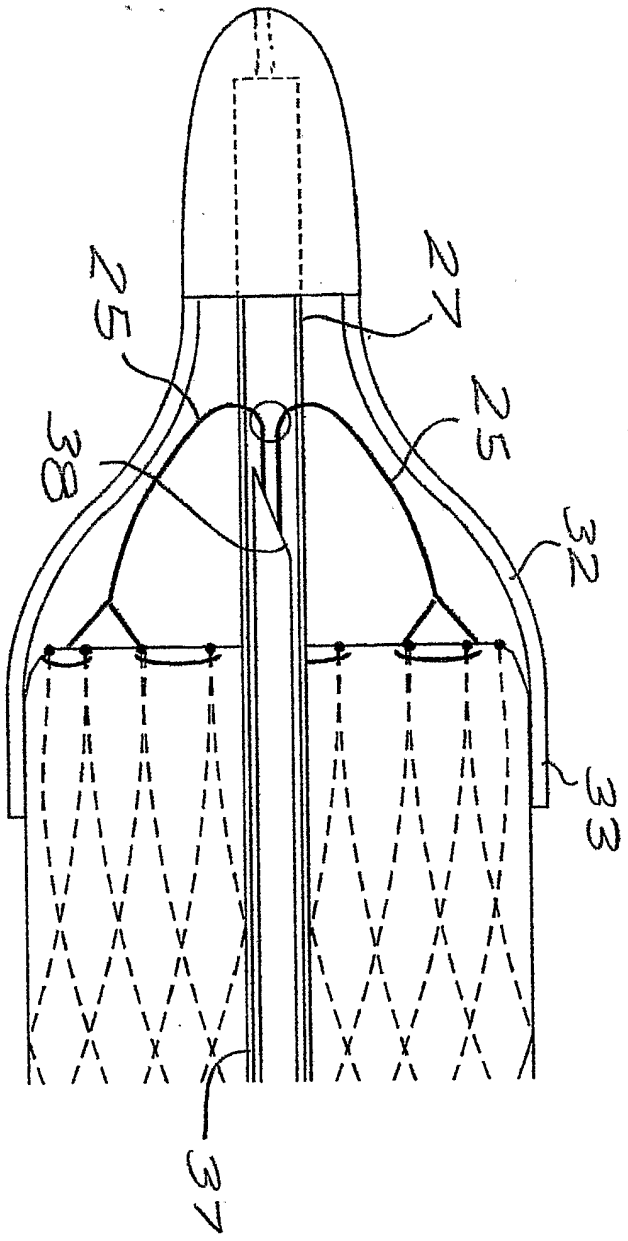

FIG 7

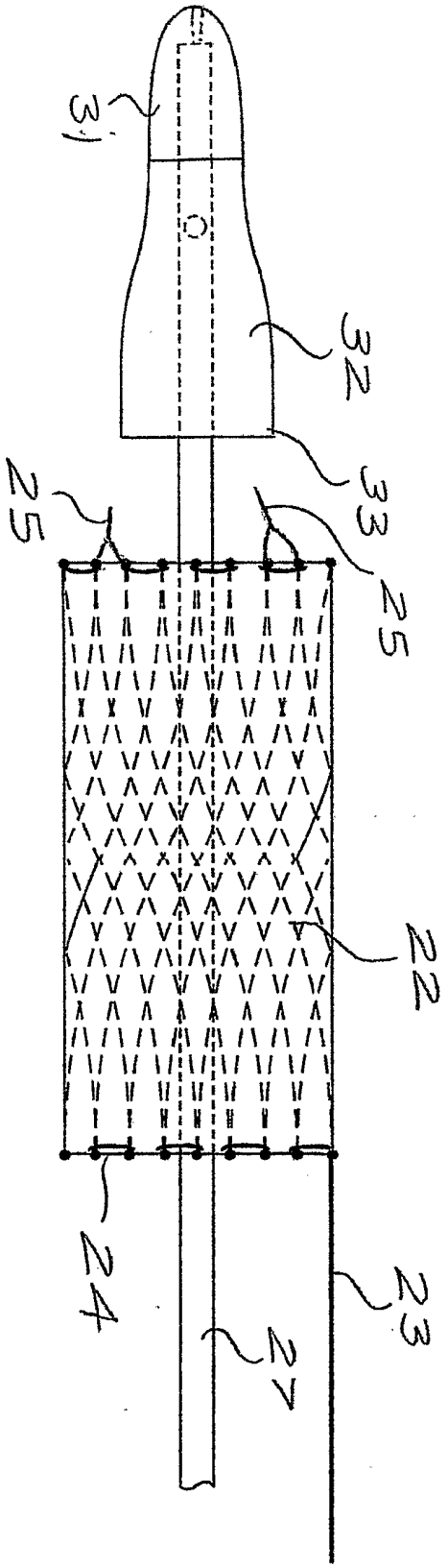

Fig 8