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US 6508828

ABSTRACT

A device to seal an incision in a blood vessel includes an inner member (110) and an outer member (120). A suture (130) connects the inner member and the outer member. A first portion (134) of the suture is embedded within a second portion (133) of the
5 suture such that as tension in the suture increases the first and second portions are held together.

(Fig 1)

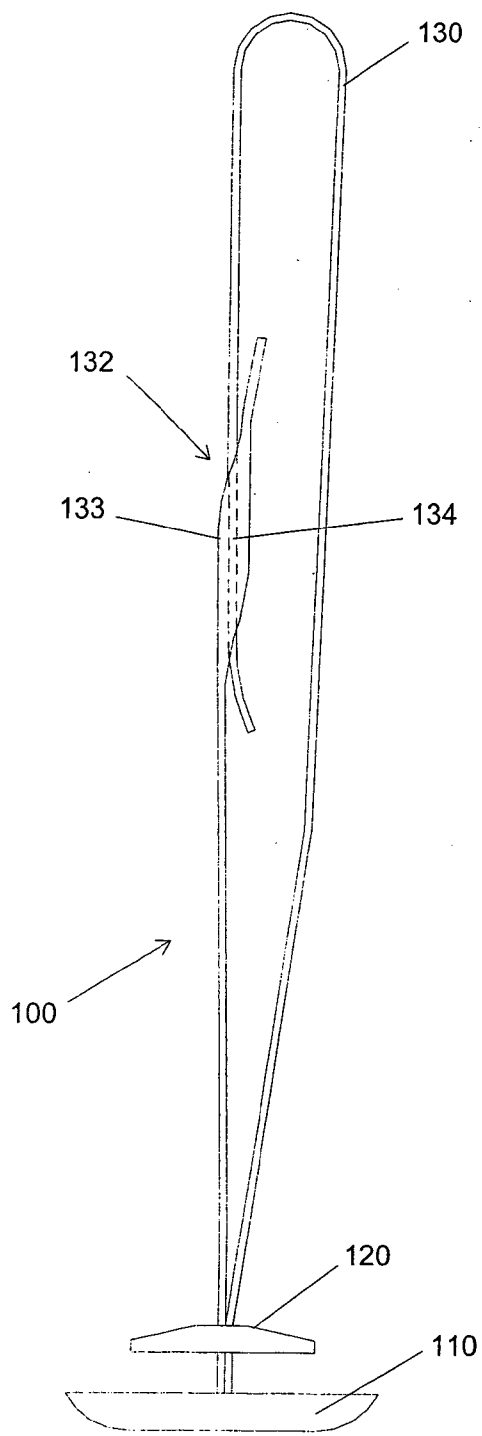


Fig. 1

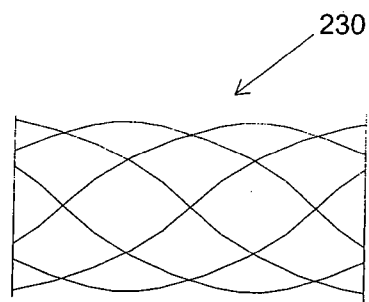


Fig. 2a

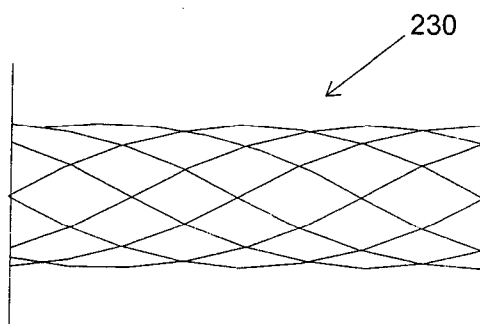


Fig. 2b

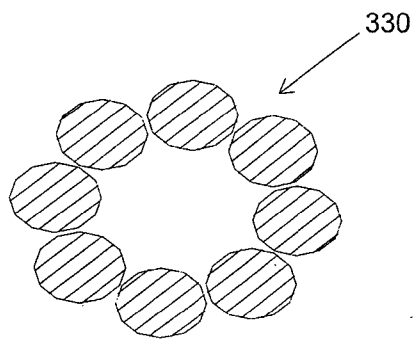


Fig. 2c

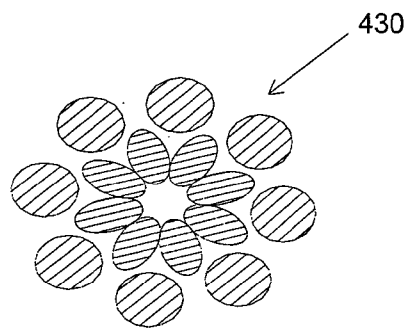


Fig. 2d

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FOR A STANDARD PATENT

ORIGINAL

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Invention Title: TECHNIQUE FOR SECURING A SUTURE

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

File: 44523AUP00

TITLE

TECHNIQUE FOR SECURING A SUTURE

BACKGROUND OF THE INVENTION

5 There are several medical procedures which require access to a patient's vascular system. Access to a patient's vascular system can be provided by making an incision (sometimes called a puncture, wound, or hole) in an artery (or other blood vessel) below the skin surface. At the conclusion of the medical procedure, the incision in the artery must be sealed.

10 Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

 One technique for sealing such an incision is to place an inner seal within the artery and an outer locking element outside the artery in such a fashion as to seal the
15 incision. The seal is made of bioabsorbable materials which are absorbed within the body over time. The inner seal, the outer locking element, and the suture are usually components of an introducer and sealing assembly. A suture loop is needed to guide and hold the seal, the locking element, and the suture during the sealing procedure. The suture (for example, a thread or a multifilament fiber) holds the inner seal in
20 place and guides the locking element to a position outside of the artery opposite the inner seal. Typically, in such a suture loop, the ends (or other portions) of the suture are glued or tied together to complete the loop.

 Similar suture loops can also be used when a closure comprises an inner anchor member and an outer seal, e.g., in the form of a collagen plug, which are held
25 together by a suture loop, or when an outer member and an inner member are clamped together to thereby seal a puncture in an intermediate blood vessel wall.

Additional background on the techniques described above is set forth in U.S. Patents 6,508,828 and 6,425,911, and U.S. Patent Applications 10/280,086, 10/341,599, and 10/341,598, whose entire contents are incorporated herein by reference.

SUMMARY OF THE INVENTION

According to a first aspect, the invention provides a device to seal an incision in a blood vessel, comprising:

an inner member being an inner seal;

an outer member being a sealing locking element; and

a suture connected to the inner member and the outer member, wherein a first portion of the suture is embedded within a second portion of the suture such that as tension in the suture increases, the first and second portions are held together, and the ends of the suture are secured together such that the ends do not stick out from the suture arrangement.

According to a second aspect, the invention provides a suture for medical use provided with a first portion and a second portion, wherein said first portion of the suture is adapted to be embedded within the second portion of the suture such that as tension in the suture increases, the first and second portions are held together.

Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

It has been discovered that the use of glue or knot(s) to form the loop has disadvantages. For example, the use of glue in the manufacturing process complicates manufacturing because the glue has to be applied properly, has to be immobilized while drying, etc. Knot(s) reduce the strength of a suture, and make the overall design more complicated because care must be taken to make sure that the knot(s) pass

through various components (e.g., components of an introducer device used to guide and push the sealing and/or locking members in place during a sealing procedure).

The present invention provides a technique to connect the ends (or other portions) of a suture used in sealing an incision in a blood vessel. In the present invention, portions of the suture are joined together (for example, to form a loop) by embedding one portion of the suture within another portion of the suture, such that as tension in the suture increases, the different portions of the suture are held together. This joining may be accomplished using a needle, by sticking a suture into itself, by a splice, by weaving, by embedding, or by any other technique wherein tension in the suture maintains or increases the holding power.

The tension in the suture contracts (i.e., reduces the cross-sectional area of) the suture such that the friction force between the walls of the suture portions (i.e., between a first portion and a second portion, which is enclosed by the first portion) increases and becomes larger than the force (tension) that tries to separate the portions (i.e., larger than the force pulling the two portions apart).

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are shown in the drawings wherein:

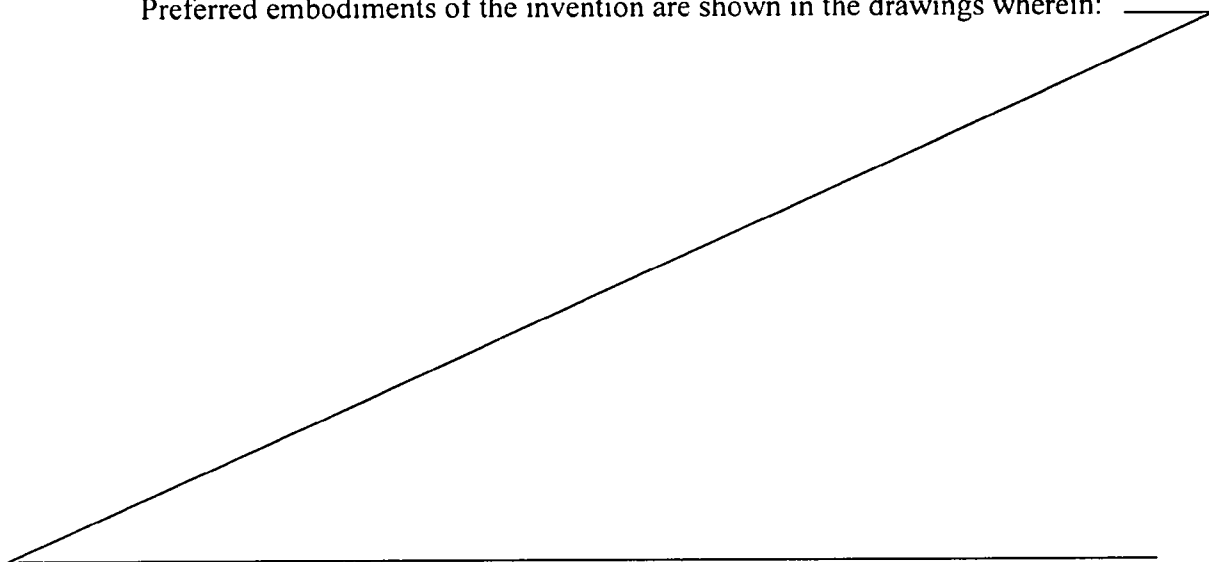


Figure 1 illustrates one embodiment of the invention wherein a suture is embedded in itself.

Figures 2a to 2d illustrate various sutures suitable for use in the invention.

Figures 3 and 4 illustrate second and third embodiments of the invention wherein the suture is embedded in itself at multiple places for additional strength.

Figures 5 and 6 illustrate fourth and fifth embodiments which are similar to Figures 3 and 4 except that glue is also used to join the sutures in Figures 5 and 6.

Figures 7(a) to 11 illustrate sixth to tenth embodiments of the invention.

10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 illustrates a first preferred embodiment 100. As shown in Figure 1, first preferred embodiment 100 includes an inner seal 110, an outer locking element 120, and a suture 130. The suture 130 has a portion 132 wherein a first portion 134 of the suture is embedded in a second portion 133 of the suture, as shown in Figure 1. In this manner, as tension in the suture increases, the portions 133 and 134 are held together due to portion 133 contracting (in cross section) and exerting friction on portion 134.

Figures 2a to 2d illustrate some examples of sutures which may be employed in the present invention. Figure 2a shows a suture 230 in a relaxed state and Figure 2b shows the same suture 230 in a state of tension. Figure 2c illustrates a suture 330 having a single layer of filaments and Figure 2d shows a suture 430 having two layers of filaments. Other suture designs may be used in the invention.

Figure 3 illustrates a second embodiment 500. The second embodiment includes an inner seal 510 and a locking element 520. A suture 530 is used to connect inner seal 510 and locking element 520. In the second embodiment, there are two portions 532 and 534 wherein one portion of the suture is embedded within another

portion of the suture such that as tension in the suture increases, the portions are held together. The second embodiment has the advantage over the first embodiment of additional strength.

Figure 4 illustrates a third embodiment 600 which includes an inner seal 610, a locking element 620, and a suture 630. The third embodiment 600 includes four portions 632, 634, 636, and 638 wherein one portion of the suture is embedded within another portion of the suture. In Figure 4, the end portions of the suture have been embedded into the suture such that there are no portions that stick out and thus no portions that can get stuck during a sealing procedure.

Figure 5 illustrates a fourth embodiment which includes an inner seal 710, a locking element 720, and a suture 730. In this fourth embodiment 700, two portions 732 and 734 are provided wherein a part of the suture is embedded within another part of the suture. The embodiment 700 also includes glue 733 which is used to fashion two portions of the suture together for added strength.

Figure 6 illustrates a fifth embodiment 800 which includes an inner seal 810, a locking element 820, and a suture 830. Three portions 832, 834, and 836 are provided wherein one portion of the suture is embedded within another portion of the suture. The embodiment 800 also utilizes glue 833, similar to the fourth embodiment. In Figure 6, one end portion of the suture is embedded into the suture and the other end portion is secured by glue at or near the end such that there are no portions that stick out and no portions that can get stuck.

Figures 7a and 7b illustrate a sixth embodiment 900 which includes an inner seal 910, a locking element 920, and a suture 930. As shown in Figure 7b (which illustrates a part of the arrangement of Figure 7a, with other parts removed for clarity), the sixth embodiment 900 includes a portion 932 wherein one portion of the suture is embedded in another portion of the suture. As illustrated in Figure 7a, this portion 932 is itself embedded within an additional portion 934.

Figures 8a and 8b illustrate a seventh embodiment 1000, which includes an inner seal 1010, a locking element 1020, and a suture 1030. As shown in Figure 8b

(which illustrates a part of the arrangement illustrated in Figure 8a, with other parts removed for clarity), the ends of the suture are looped around one another in an arrangement 1035. The arrangement 1035 is in turn embedded within a portion 1032 of the suture 1030.

5 Figure 9 illustrates an eighth embodiment 1100 which is used to connect an inner seal 1110 to a suture 1130. In the eighth embodiment 1100, the ends of the suture are looped around seal 1110 and then embedded into the suture at portions 1132 and 1134. Figure 10 illustrates a ninth embodiment 1200, which includes an inner seal 1210, an outer locking element 1220, and a suture 1230. In this
10 embodiment, the ends of suture 1230 are embedded into portions of the suture 1232 and 1234. In Figures 9 and 10, an enlarged cross-section created by the present way of joining portions of the suture is utilized to hold the inner seal and/or locking element in place by friction. In other words, the enlarged portions 1132, 1134, 1232, and 1234 can retain the locking element (e.g., locking element 1220) in place when
15 the locking element is slid over these portions. This is also generally applicable for all other embodiments, i.e. using the enlarged cross-section created by joining portions of the suture to hold the outer member (locking element) in place when the outer member is slid over the enlarged cross-section.

 Figure 11 illustrates a tenth embodiment 1300, which includes an inner seal
20 1310, a locking element 1320, and a suture 1330. In this embodiment, one end 1334 of suture 1330 is wrapped around the suture and then embedded in another portion of the suture, as shown in Figure 11.

 The foregoing description of preferred embodiments of the invention has been presented for purposes of illustration. It is not intended to be exhaustive or to limit
25 the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings. It is intended that the scope of the invention be defined with reference to the claims appended hereto, and their equivalents.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A device to seal an incision in a blood vessel, comprising:
an inner member being an inner seal;
an outer member being a sealing locking element; and
5 a suture connected to the inner member and the outer member, wherein a first portion of the suture is embedded within a second portion of the suture such that as tension in the suture increases, the first and second portions are held together, and the ends of the suture are secured together such that the ends do not stick out from the suture arrangement.
- 10 2. A device as set forth in claim 1, wherein a third portion of the suture is embedded within a fourth portion of the suture such that as tension in the suture increases the third and fourth portions are held together.
3. A device as set forth in claim 2, further comprising glue to secure different portions of the suture together.
- 15 4. A device as set forth in any one of the preceding claims, wherein the first portion comprises at least one suture loop.
5. A device as set forth in any one of the preceding claims, wherein the first portion comprises at least two suture loops.
6. A device as set forth in claim 2, wherein the second portion and the fourth
20 portion are configured to retain the outer member in place when the outer member is slid over the second portion and the fourth portion.
7. A device as set forth in any one of the preceding claims, wherein an enlarged cross-section created by the first portion embedded within the second portion of the suture is arranged to retain the outer member in place when the outer member is slid
25 over said enlarged cross-section.
8. A device as set forth in any one of the preceding claims, wherein the suture further comprises a third portion of the suture embedded within the second portion of

the suture such that as tension in the suture increases the first, second, and third portions are held together.

9. A device to seal an incision in a blood vessel substantially as herein described
5 with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

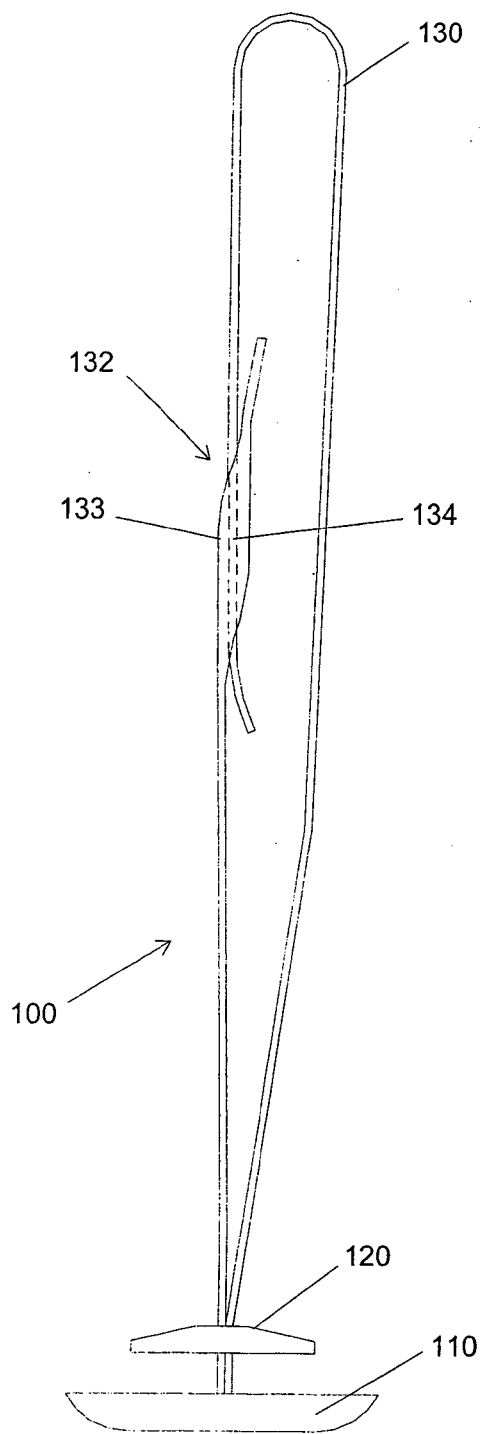


Fig. 1

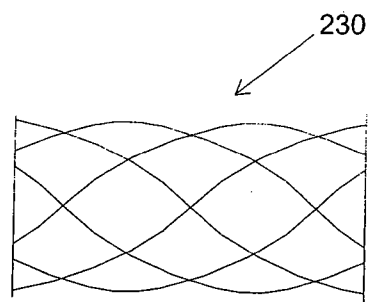


Fig. 2a

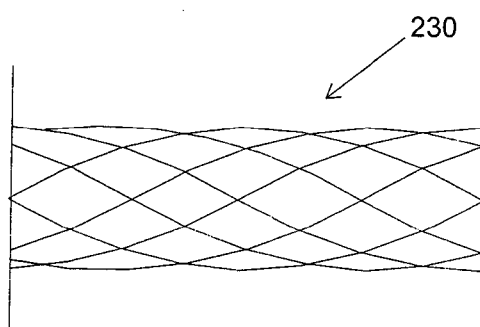


Fig. 2b

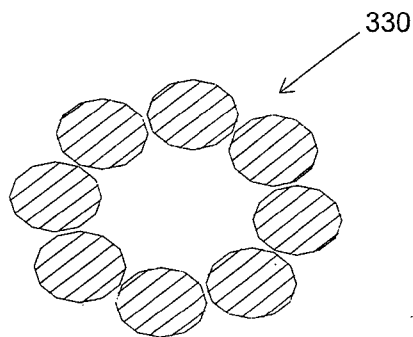


Fig. 2c

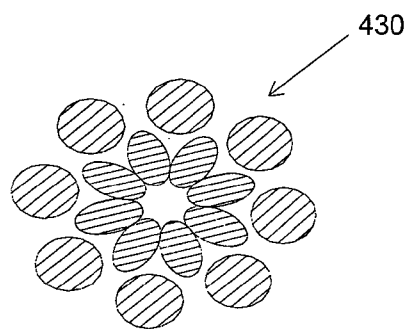


Fig. 2d

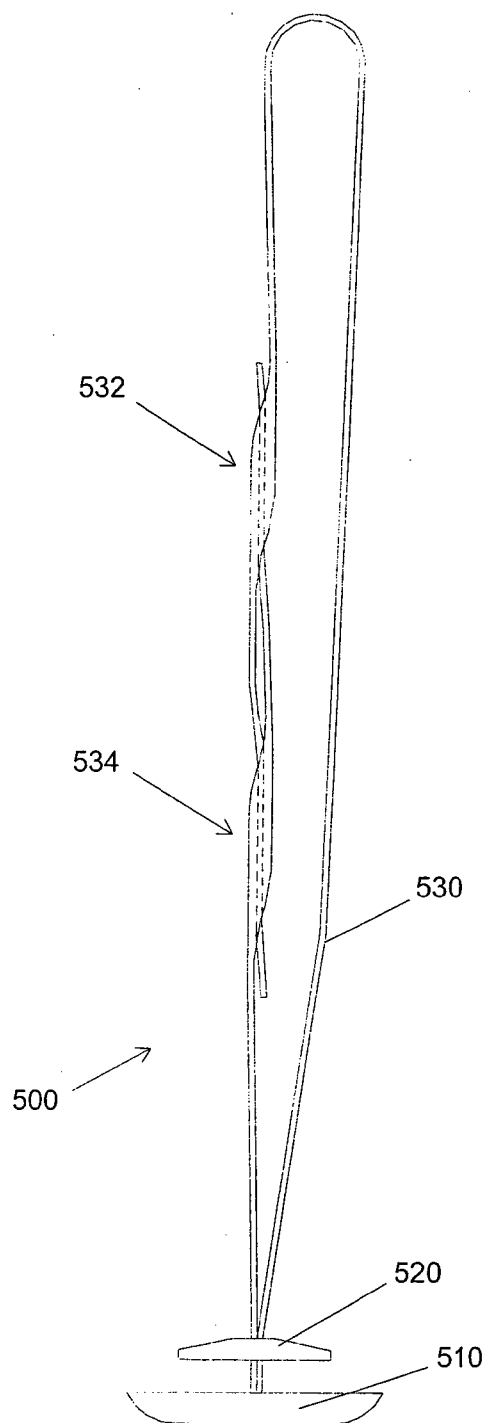


Fig. 3

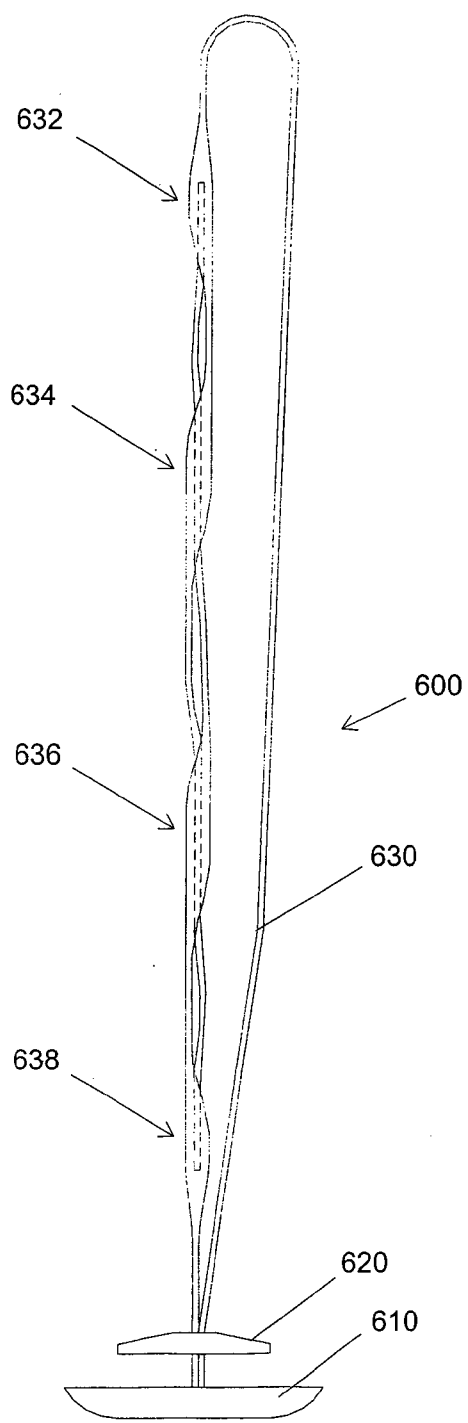


Fig. 4

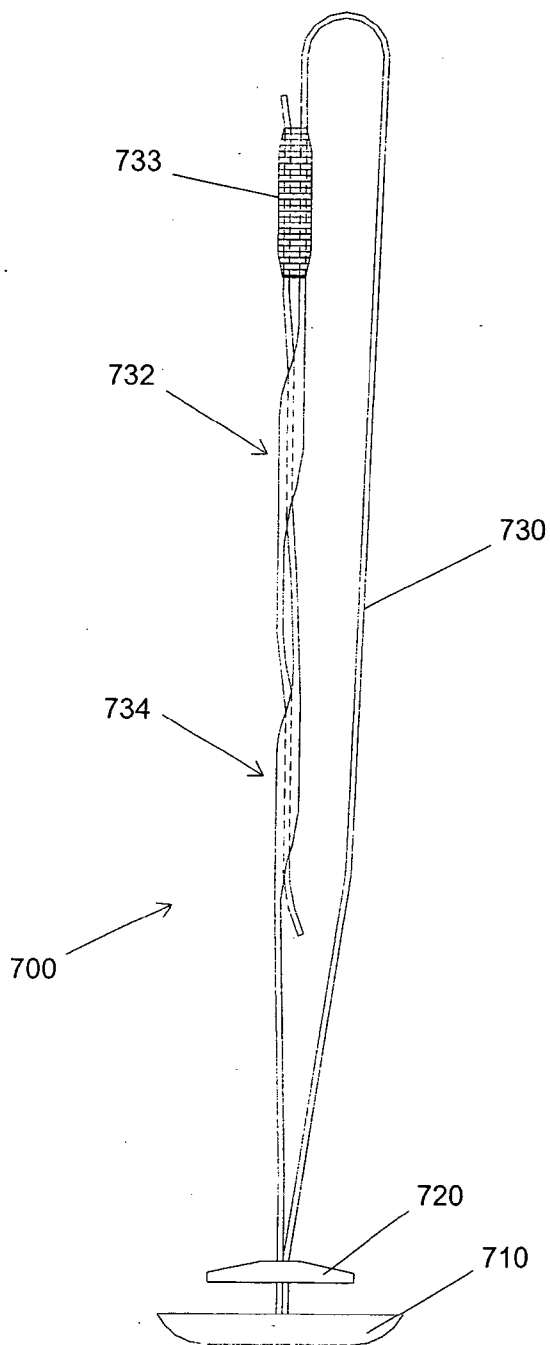


Fig. 5

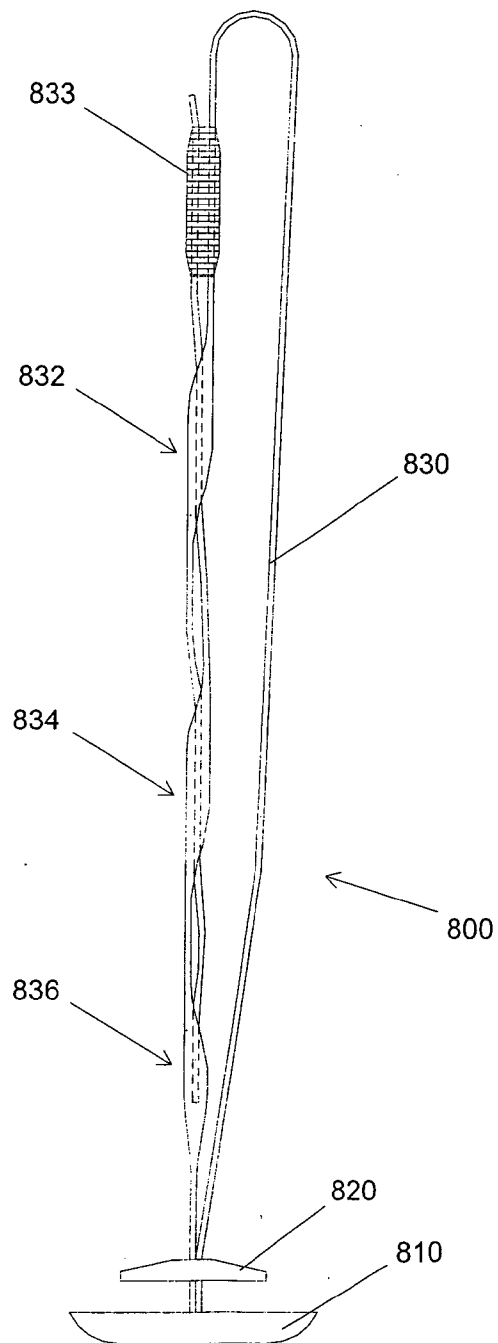


Fig. 6

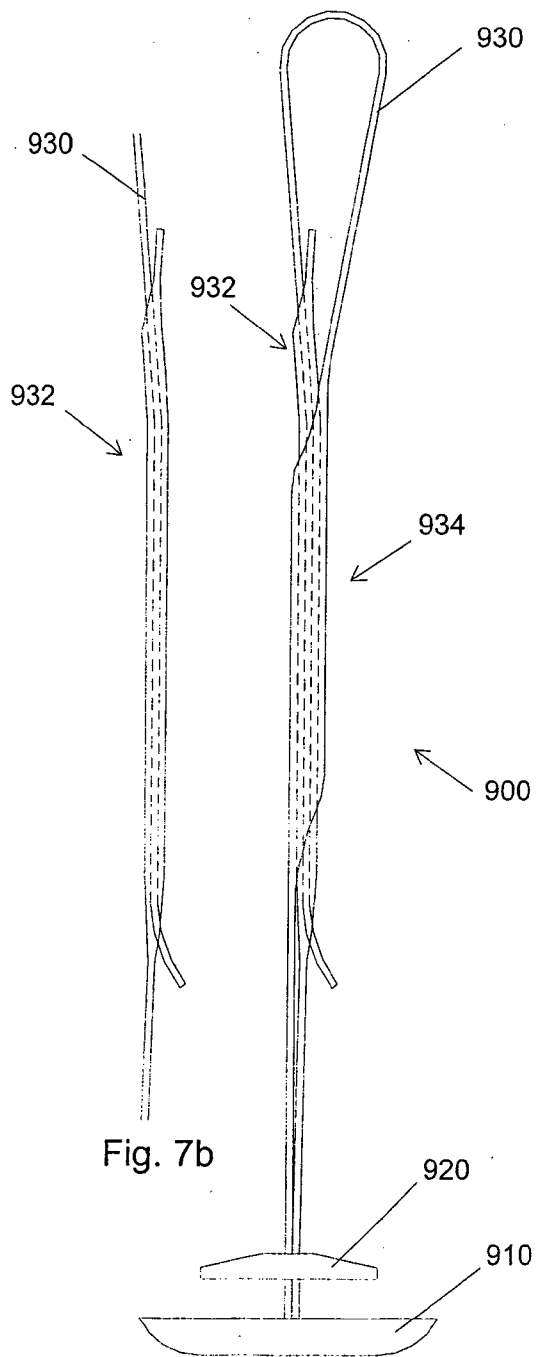


Fig. 7a

Fig. 7b

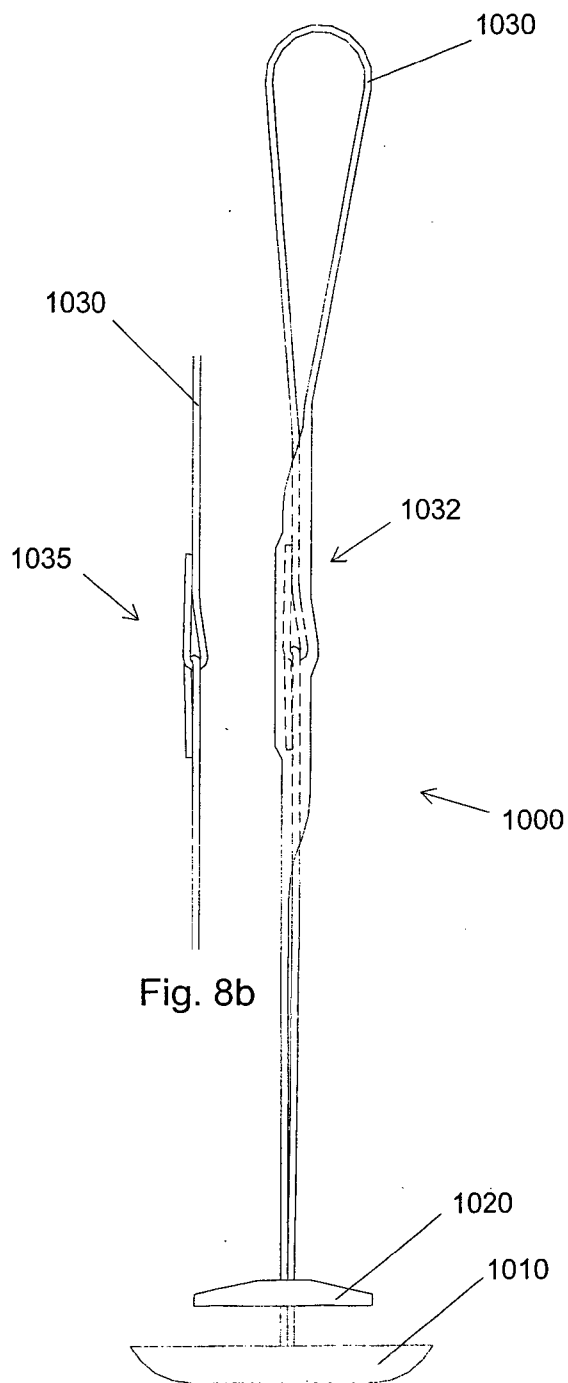
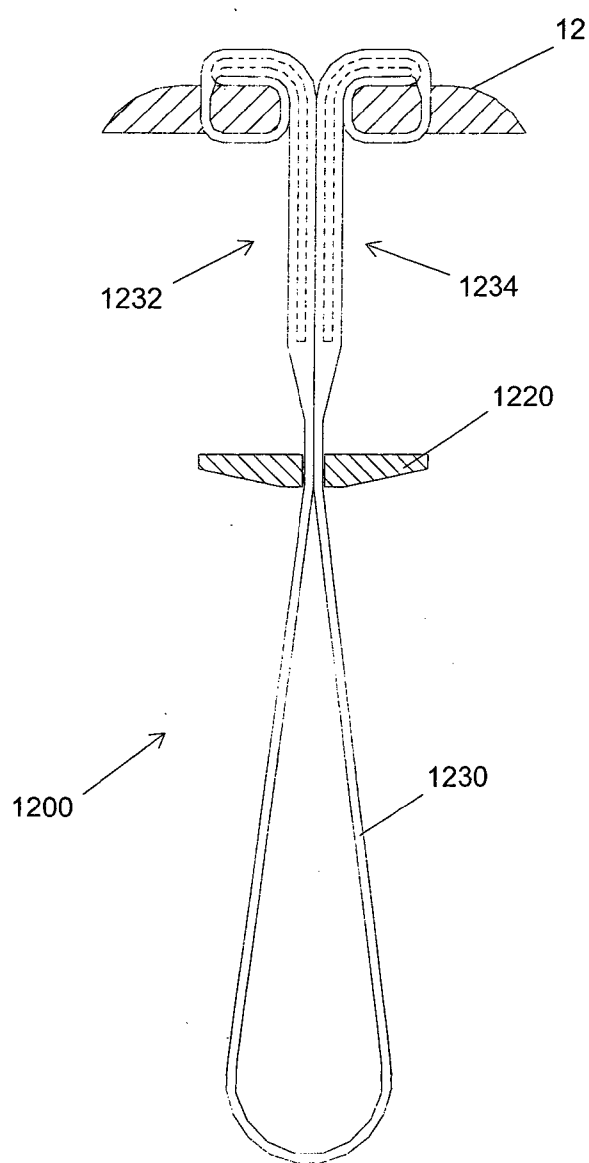
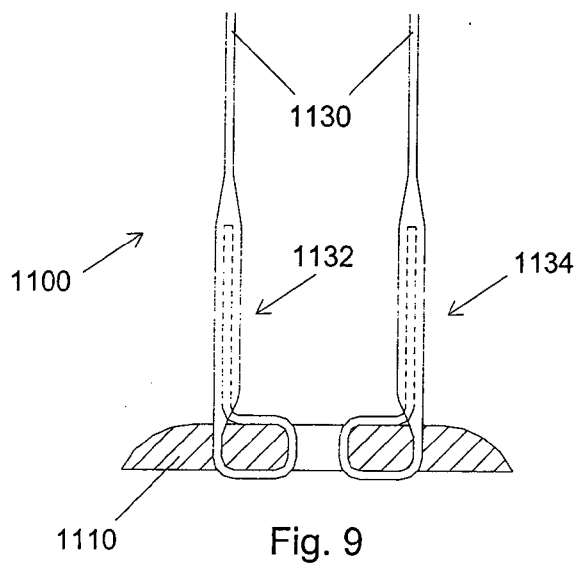


Fig. 8a

Fig. 8b



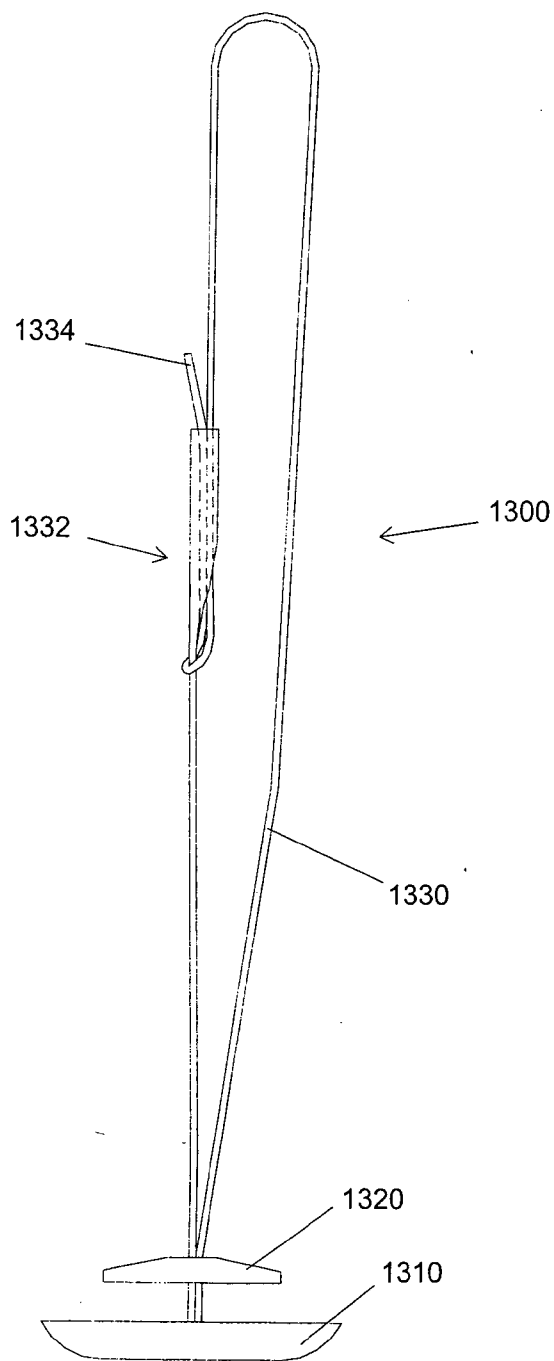


Fig. 11