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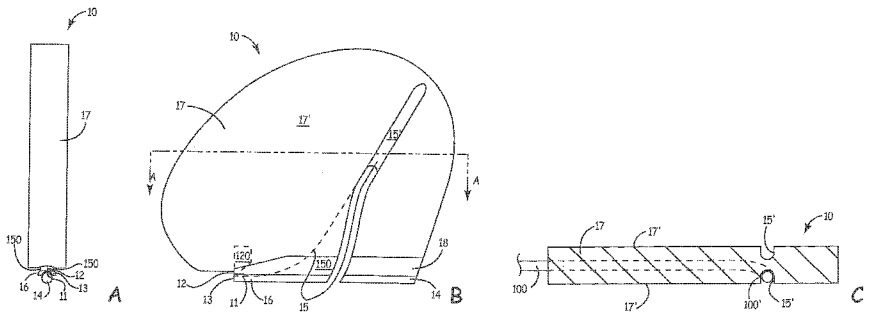
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(54) **Title:** DEVICE AND METHOD FOR MOVING FILL MATERIAL TO AN IMPLANT



(57) **Abstract:** Abstract Devices and methods for inserting an implant within a patient. The device may generally include an insertion body, a supply reservoir, and a delivery device. The insertion body can be used for moving and positioning the implant within the body. In one embodiment, implant is mounted to the end of the body prior to movement and positioning. Fill material is maintained within the supply reservoir. Delivery device functions to move the fill material from the supply reservoir, through the insertion body, and to the implant. The device thus provides for both movement and placement of the implant, and a mechanism for delivering fill material to the implant.

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SLITTING TOOL

FIELD OF THE INVENTION

The present invention pertains to slitting tools and more particularly to slitting tools facilitating removal of an elongate sheath or catheter from about an elongate member disposed therein.

BACKGROUND OF THE INVENTION

Sheaths, or catheters, are commonly used in minimally invasive medical procedures, for example, to provide a pathway for the introduction of elongate medical devices into the vascular system of a patient. Many medical devices, introduced in such a manner, through a lumen of the sheath, are intended to indwell within the patient for a prolonged period, for example, extending from a number of days to many years. After the indwelling medical device has been inserted within the lumen of the sheath, for positioning within the patient, it is desirable to remove the sheath from the patient without dislodging the indwelling device.

A number of slitting tools, known to those skilled in the art, are used to remove sheaths from about indwelling medical devices. However, these tools present one or more difficulties to the user, for example, with respect to handling.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

Figures 1A-B are an end view and a side plan view, respectively, of a slitting tool according to one embodiment of the present invention.

Figure 1C is a section view through section line A-A of Figure 1B.

Figure 2 is a schematic plan view, including a partial section, depicting a method for using a slitting tool according to some embodiments of the present invention.

Figure 3A is a top view of the slitting tool, shown in Figures 1A-C, cutting through a portion of a sheath wall.

Figure 3B is a section view through section line B-B of Figure 3A.

Figures 4A-B are a side plan view and an end view of a slitting tool according to another embodiment of the present invention.

Figure 5A is a schematic showing an alternate embodiment of a slitting tool in a position for slitting a sheath.

Figure 5B is an end view of Figure 5A.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments of the present invention.

Figures 1A-B are an end view and a side plan view, respectively, of a slitting tool 10, according to one embodiment of the present invention; and Figure 1C is a section view through line A-A of Figure 1B. Figures 1A-C illustrate tool 10 including a nose portion 16, a handle portion 17, a slitting edge 12 extending between nose portion 16 and handle portion 17, a longitudinally extending tail portion 14, and a passageway 15 disposed between nose portion 16 and tail portion 14, and extending upward into handle portion 17. Figures 1A-B further illustrate nose portion 16 including a lower surface 11 and a leading edge13. According to the illustrated embodiment, slitting edge 12 is part of a metallic blade member 120 mounted in handle 17; according to alternate embodiments, slitting edge is an integral part of material forming tool 10 as a whole. Tool 10 may be formed of a rigid plastic, a ceramic, a metallic material or a combination thereof.

According to the illustrated embodiment, lower surface 11 of nose portion 16 is adapted to engage an elongate member 100, and Figure 1C shows elongate member 100 extending from nose portion 16 into passageway 15 such that a proximal segment 100' of member 100 bends away from tail portion 14. With reference to Figures 1B-C,

passageway 15 extends from nose portion 16 up into handle 17, being flanked on either side by a sidewall 150; passageway 15 further extends into grooves 15', which are formed along opposing outer surfaces 17' of handle 17 and either of which can accommodate segment 100'. An operator, gripping handle 17 of tool 10, may hold proximal segment 100' of elongate member 100 in one of channel grooves 15', as illustrated in Figure 2.

Figure 2 is a schematic plan view, including a partial section, depicting a method for using slitting tool 10 according to some embodiments of the present invention. Figure 2 illustrates elongate member 100, for example, an implantable medical electrical lead, disposed within a lumen 25 of a sheath 200; sheath 200 is shown including a tubular sheath wall 20 terminated at a proximal end by a hub 22. Figure 2 further illustrates a first thumb 25 and forefinger 26 of an operator holding slitting tool 10 and proximal segment 100' of member 100, while a second thumb 205 and forefinger 206 hold a hub handle 220 to pull sheath 200, per arrow A, against slitting edge 12 of tool 10. Nose portion 16 of tool 10 is shown engaging elongate member 100 while proximal segment 100' bends through passageway 15 that extends along an operator grip zone 19, which, on opposing surfaces 17' of handle 17, is generally located in the zone indicated by cross-hatching. According to the illustrated embodiment, tail portion 14 of tool 10 is approximately aligned with sheath lumen 25 and is sized to fit within sheath lumen 25, when slit, so that tail portion 14 will ride within sheath lumen 25 after slitting edge 12 cuts through hub and sheath wall 20. According to some embodiments, tail portion 14 further includes a profile closely conforming with slit sheath lumen 25, for example as illustrated in Figure 3B.

Figure 3A is a top view of the slitting tool, shown in Figures 1A-C, cutting through a portion of sheath wall 20; and Figure 3B is a section view through section line B-B of Figure 3A. Figures 3A-B illustrate sheath 200 having been pulled, per arrow A, so that sheath wall 20 has been slit by tool slitting edge 12 (Figures 1A-B and 2) and tool tail portion 14 is disposed within lumen 25, downstream of slitting edge 12; slit edges 32 of sheath wall 20 emanate from slitting edge 12 beneath tool handle 17, shown by dashed lines, and extend downstream of tool 10; fingers 25, 26 and associated hand of the operator holding tool 10 (Figure 2) are not shown so that the view of tool 10 and slit edges 32 of sheath wall 20 is not obstructed. Figure 3B further illustrates a profile of tail portion 14, formed by a continuous exterior surface extending thereabout, which closely mates

with slit sheath lumen 25; a width P of tail portion 14 may be approximately equal to or slightly greater than a pre-slit diameter of sheath lumen 25, or may be up to two times greater than the pre-slit diameter of lumen 25. Figure 3B further illustrates tool 10 including a shank 18 joining handle 17 to tail portion 14; according to some embodiments, a thickness T of shank 18 is greater than approximately 0.01 inch and less than width P of tail portion 14.

According to embodiments of the present invention, tail portion 14 may serve to stabilize tool 10 as it cuts through sheath wall 20 and may further prevent slit edges 32 from collapsing toward one another in a way which may cause slit sheath lumen 25 to 'grab' elongate member 100, as sheath 200 is pulled, per arrow A, thereby dislodging a distal end of member 100. An effective length of tail portion 14, for stabilizing tool 10 as it cuts through sheath wall 20, may be approximately equal to or greater than 1/2 inch. Although, in Figure 2, tail portion 14 is illustrated extending proximally from operator grip zone 19 of handle portion 17, embodiments of the present invention are not so limited.

Figures 4A-B are a side plan view and an end view of a slitting tool 40 according to another embodiment of the present invention. Figures 4A-B illustrate tool 40 including a nose portion 46, a handle portion 47, a slitting edge 42 extending between nose portion 46 and handle portion 47, and a longitudinally extending tail portion 44. Figures 4A-B further illustrate nose portion 46 including a lower surface 41 extending from a leading edge 43 to a passageway 45 that extends from between nose portion 46 and tail portion 44, upward into handle portion 47. According to the illustrated embodiment, to facilitate loading of elongate member 100 into passageway 45, for example, as shown in Figure 4A, tail portion 44 is split into a first leg 404A and a second leg 404B. Figure 4B shows each leg 404A, B including a foot 44A and 44B, respectively; feet 44A, B together form a tail profile, to mate with a slit lumen of a sheath or catheter, when legs are forced, per arrows B, together, as shown with dashed lines; the resulting profile is similar to that of solid tail 14 illustrated in Figure 3B. Legs 404A, B would be forced together in such a way when a sheath is pulled past slitting edge 42 of tool 40 such that tail 44 is enclosed by the slit lumen of the sheath.

Figure 5A is a schematic showing an alternate embodiment of a slitting tool 50 in a position for slitting sheath 200; and Figure 5B is an end view of Figure 5A. Figure 5A illustrates tool 50 including a nose portion 56, a handle portion 57, a slitting edge 52, extending between nose portion 56 and handle portion 57, and a longitudinally extending tail portion 54, which is joined to handle portion 57 by a shank 58. Figure 5A further illustrates nose portion 56 engaging elongate member 100 and a passageway 55, disposed between nose portion 56 and tail portion 54, allowing proximal segment 100' of elongate member 100 to bend away from tail portion 54. According to the illustrated embodiment, fingers 25 and 26, associated with the hand of the operator, hold segment 100' against an operator grip zone 59 of handle 57, the extent of which generally corresponds to the cross-hatched area shown in Figure 5B.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

CLAIMS

1. A tool for slitting an elongate sheath from about an elongate member disposed within a longitudinally extending lumen of the sheath, the tool comprising:

a slitting edge;

a nose portion disposed beneath the slitting edge, the nose portion including a lower surface, for engaging a portion of the elongate member, and a leading edge;

a longitudinally extending tail portion projecting rearward of the slitting edge and the nose portion, the tail portion approximately aligned with the sheath lumen when the lower surface of the nose portion engages the elongate member and the leading edge of the nose portion is within the sheath lumen, the tail portion including a profile closely conforming with the sheath lumen after the sheath is slit by the slitting edge; and

a passageway disposed between the nose portion and the tail portion, the passageway allowing a segment of the elongate member to bend away from the tail portion when the lower surface of the nose portion engages the portion of the elongate member, the segment being proximal to the portion engaged by the lower surface.

2. The tool of claim 1, further comprising a handle portion projecting upward from the nose portion and rearward of the slitting edge, and wherein the passageway extends into the handle portion.

3. The tool of claim 1, further comprising a handle portion projecting upward from the lower surface of the nose portion and rearward of the slitting edge, and wherein the passageway extends to the handle portion.

4. The tool of claim 1, further comprising a shank extending upward from the tail portion, the shank including a thickness being greater than approximately 0.01 inch and less than approximately a maximum width of the profile of the tail portion.

5. The tool of claim 1, wherein the profile of the tail portion includes a maximum width being between approximately equal to a pre-slit diameter of the lumen and approximately two times greater than the pre-slit diameter of the sheath lumen.

6. The tool of claim 1, further comprising a handle portion projecting upward from the nose portion and rearward of the slitting edge, wherein the handle portion includes an operator grip zone and the tail portion further projects rearward of the grip zone.

7. The tool of claim 1, wherein the tail portion includes a longitudinal length greater than or equal to approximately one inch.

8. The tool of claim 1, wherein the tail portion is includes a continuous exterior surface extending around the profile mating with the slit sheath lumen.

9. The tool of claim 1, wherein the tail portion is split, including opposing interior surfaces.

10. A tool for slitting an elongate sheath from about an elongate member disposed within a longitudinally extending lumen of the sheath, the tool comprising:

a slitting edge;

a nose portion disposed beneath the slitting edge, the nose portion including a lower surface for engaging a portion of the elongate member and a leading edge;

a longitudinally extending tail portion projecting rearward of the slitting edge and the nose portion, the tail portion approximately aligned with the sheath lumen when the lower surface of the nose portion engages the elongate member and the leading edge of the nose portion is within the sheath lumen, the tail portion sized to fit within the sheath lumen after the sheath is slit by the slitting edge; and

a passageway disposed between the nose portion and the tail portion, the passageway allowing a segment of the elongate member to bend away from the tail portion when the lower surface of the nose portion engages the portion of the elongate member, the segment being proximal to the portion engaged by the lower surface, and the tail portion projecting a distance greater than about ½ inch rearward of the passageway.

11. The tool of claim 10, further comprising a handle portion projecting upward from the lower surface of the nose portion and rearward of the slitting edge, and wherein the passageway extends into the handle portion.

12. The tool of claim 10, further comprising a handle portion projecting upward from the lower surface of the nose portion and rearward of the slitting edge, and wherein the passageway extends to the handle portion.

13. The tool of claim 10, further comprising a shank extending upward from the tail portion, the shank including a thickness being greater than approximately 0.01 inch and less than approximately a maximum width of the profile of the tail portion.

14. The tool of claim 10, wherein the profile of the tail portion includes a maximum width being between approximately equal to a pre-slit diameter of the lumen and approximately two times greater than the pre-slit diameter of the sheath lumen.

15. The tool of claim 10, wherein the tail portion is includes a continuous exterior surface extending around the profile sized to fit within the slit sheath lumen.

16. The tool of claim 10, wherein the tail portion is split, including opposing interior surfaces.

17. A tool for slitting an elongate sheath from about an elongate member disposed within a longitudinally extending lumen of the sheath, the tool comprising:

a slitting edge;

a nose portion disposed beneath the slitting edge, the nose portion including a lower surface for engaging a portion of the elongate member and a leading edge;

a longitudinally extending tail portion projecting rearward of the slitting edge and the nose portion, the tail portion approximately aligned with the sheath lumen when the lower surface of the nose portion engages the elongate member and the leading edge of the lower surface is within the sheath lumen, the tail portion sized to fit within the

sheath lumen after the sheath is slit by the slitting edge and a continuous exterior surface extending around the profile; and

a passageway disposed between the nose portion and the tail portion, the passageway allowing a segment of the elongate member to bend away from the tail portion when the lower surface of the nose portion engages the portion of the elongate member, the segment being proximal to the portion engaged by the lower surface.

18. The tool of claim 17, further comprising a handle portion projecting upward from the lower surface of the nose portion and rearward of the slitting edge, and wherein the passageway extends into the handle portion.

19. The tool of claim 17, further comprising a handle portion projecting upward from the lower surface of the nose portion and rearward of the slitting edge, and wherein the passageway extends to the handle portion.

20. The tool of claim 17, further comprising a shank extending upward from the tail portion, the shank including a thickness being greater than approximately 0.01 inch and less than approximately a maximum width of the profile of the tail portion.

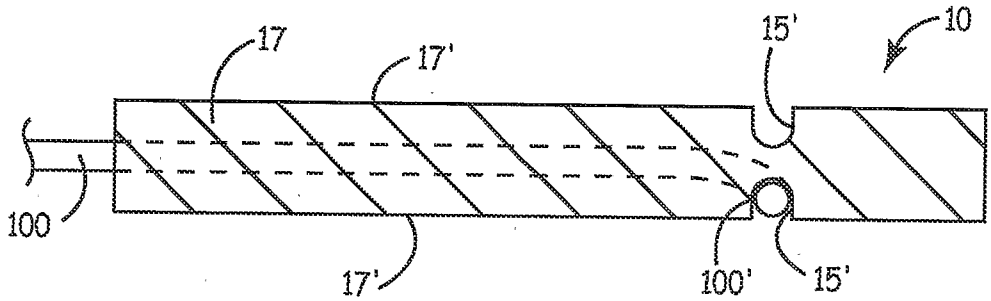


FIG. 1C

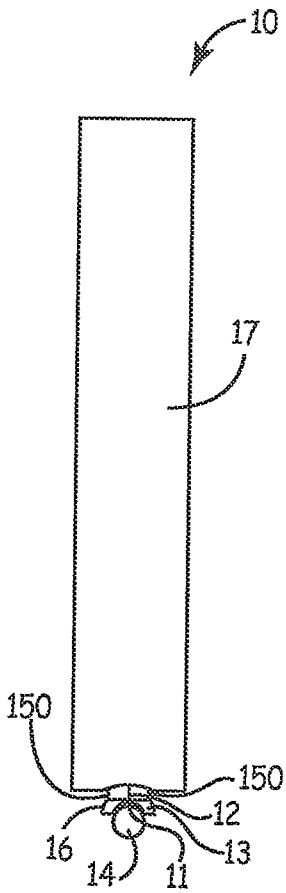


FIG. 1A

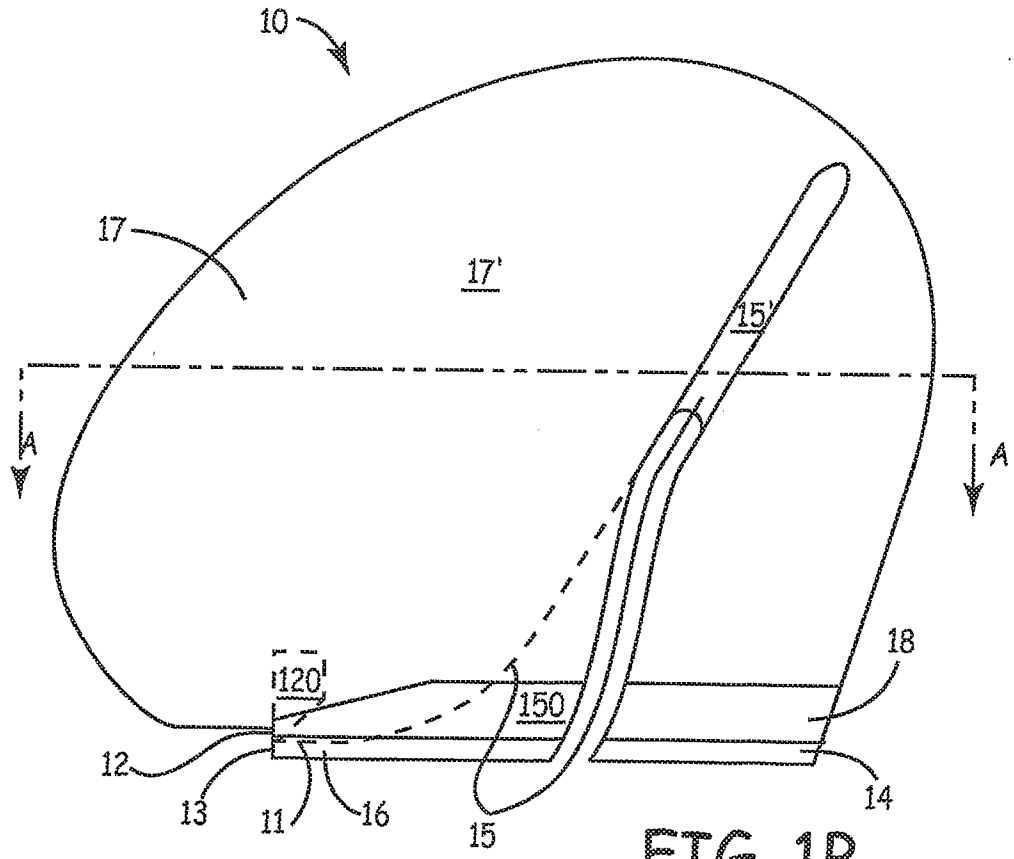


FIG. 1B

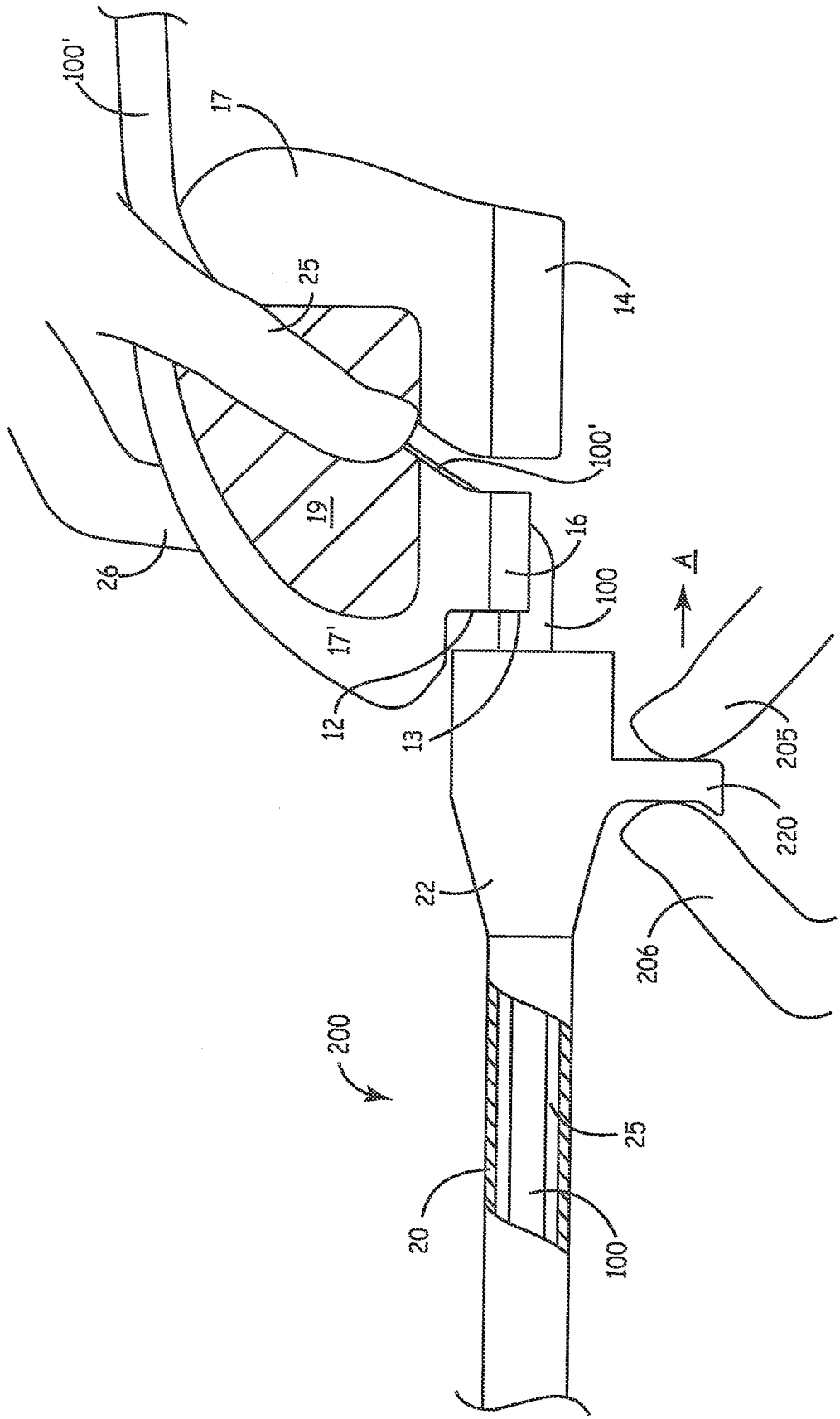


FIG. 2

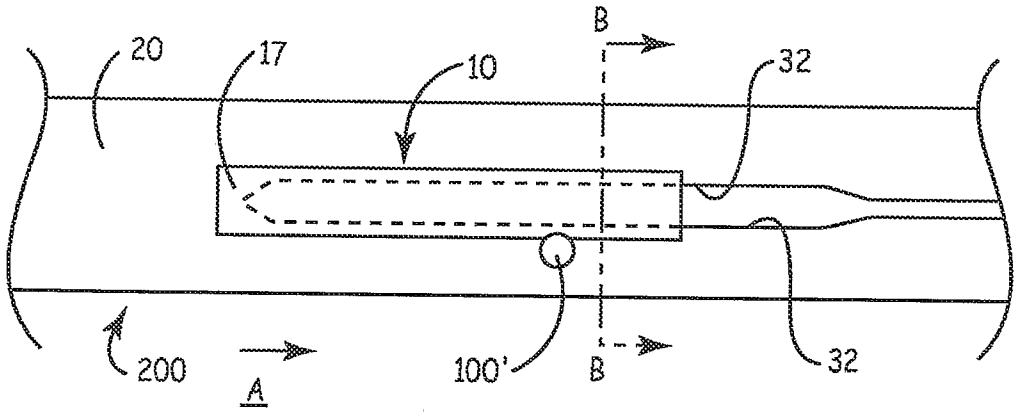


FIG. 3A

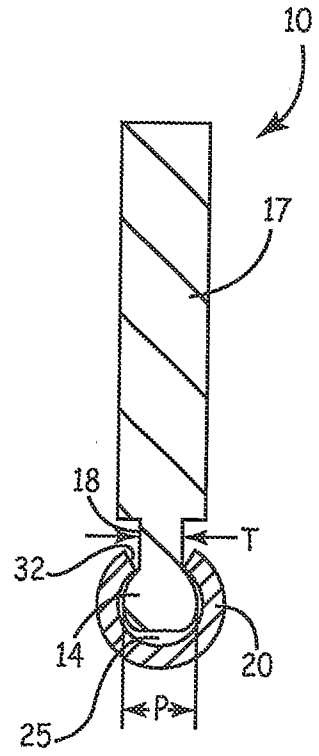


FIG. 3B

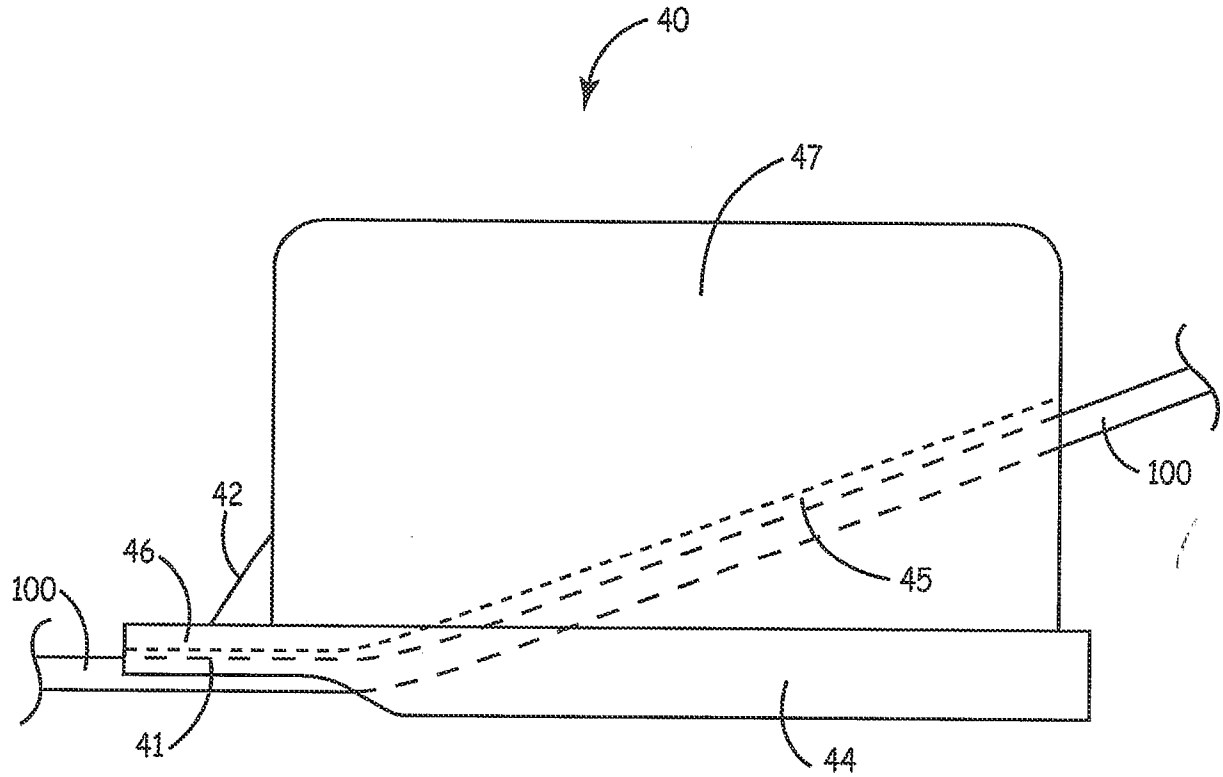


FIG. 4A

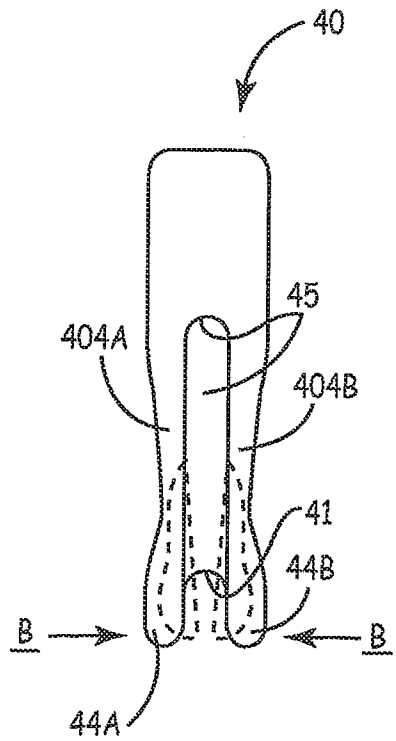


FIG. 4B

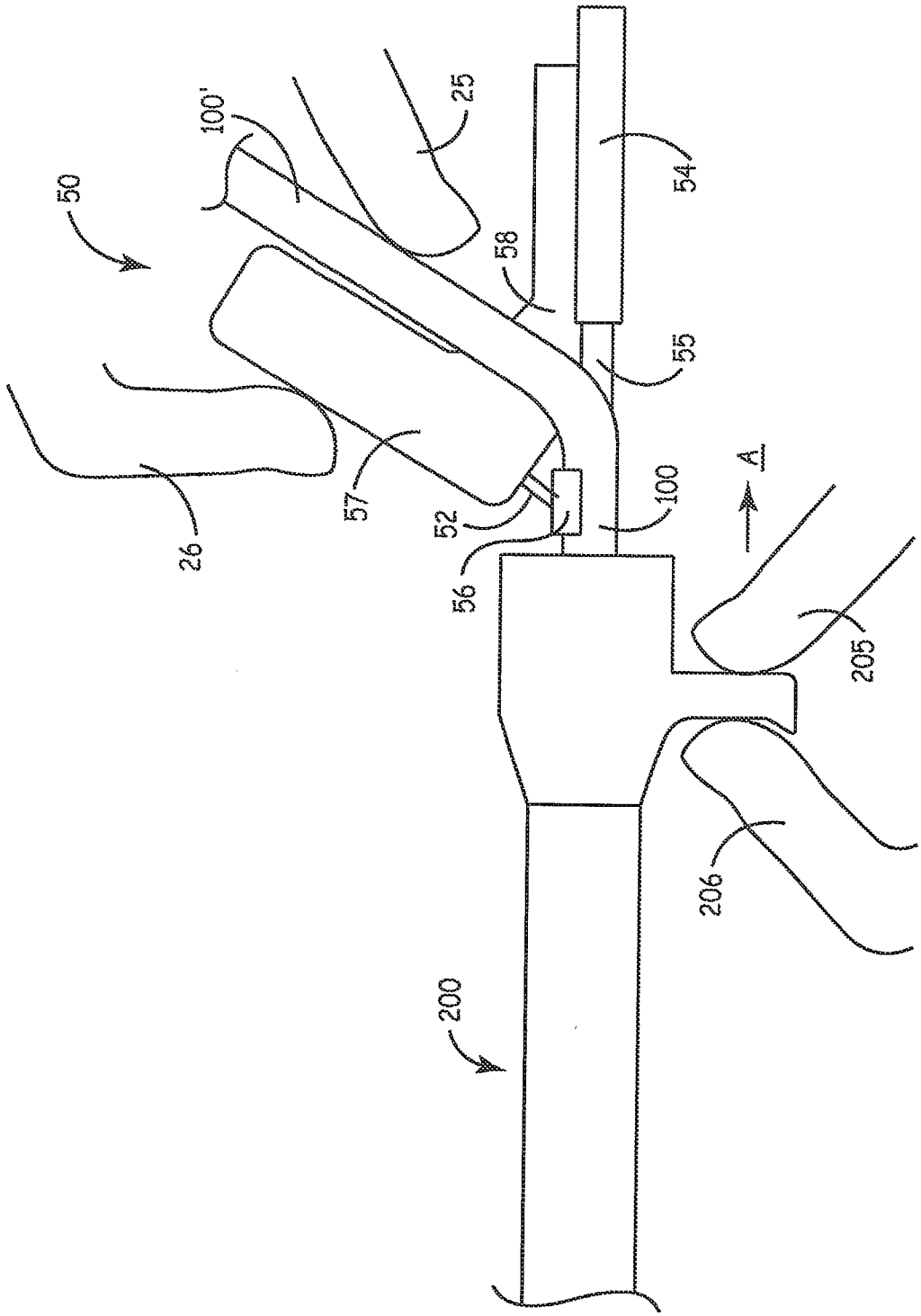


FIG. 5A

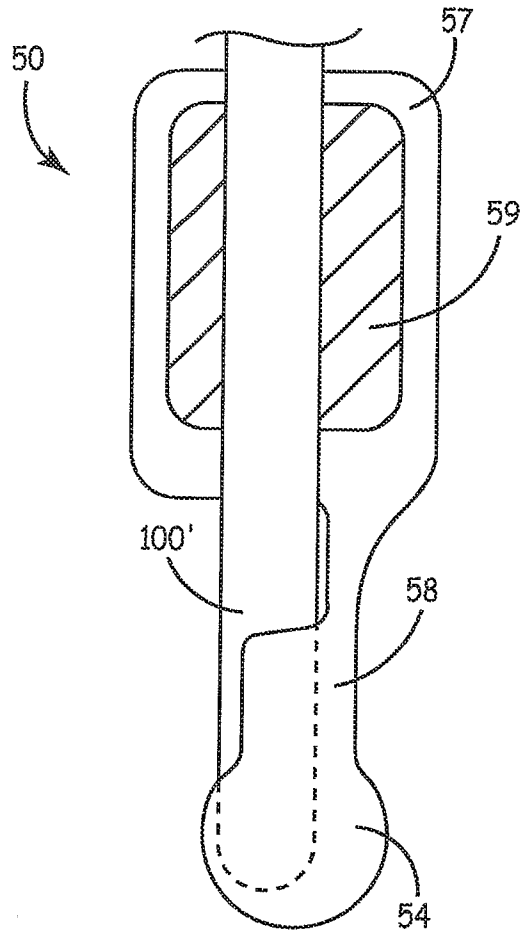


FIG. 5B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/060664

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/06

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)
A61M H02G

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/02047 A (MEDTRONIC INC [US]) 11 January 2001 (2001-01-11) page 4, line 7 - page 9, last line ; figures	1,5,8, 10,14, 15,17
X	US 5 330 460 A (MOSS GORDON L [US] ET AL) 19 July 1994 (1994-07-19) column 3, line 18 - column 8, line 24; figures	1,4-7, 10,13, 14,17,20
X A	US 6 497 681 B1 (BRENNER LAURENCE D [US]) 24 December 2002 (2002-12-24) column 3, line 66 - column 12, line 22; figures	1,4-7,9, 17,20 10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 April 2007	04/05/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Vänttinen, Henri

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/060664

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0102047 A	11-01-2001	DE 60023702 D1	08-12-2005
		DE 60023702 T2	20-07-2006
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