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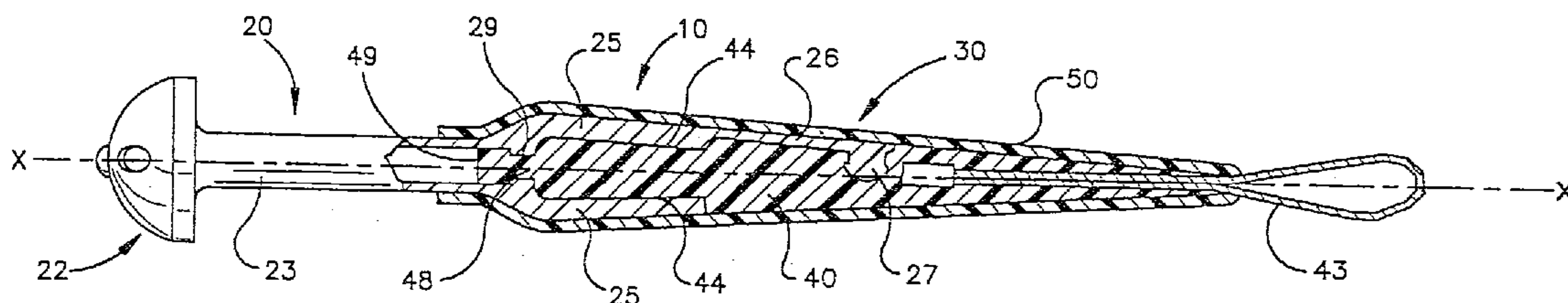
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(51) Int.Cl.<sup>5</sup> A61J 15/00

(30) 1990/12/13 (626,969) US

(54) **EMBALLAGE POUR INSTALLATION INITIALE D'APPAREIL  
DE GASTROSTOMIE A FAIBLE PROFIL ET METHODE DE  
PLACEMENT**

(54) **PACKAGE FOR INITIAL PLACEMENT OF LOW PROFILE  
GASTROSTOMY DEVICE AND METHOD OF PLACEMENT**



(57) A low profile or skin level gastrostomy device (20) for initial endoscopic placement in an incision provided through the stomach (64) and abdominal walls (62) of a patient having a collapsed resilient end portion (24) packaged and compressed within a shroud (30) that allows the end portion (24) of the device (20) positioned within the stomach (61) to easily pass from the inner to the outer end of the incision. The shroud (30) is pulled or pushed outwardly through the incision until the device (20) is properly positioned therein. Subsequent to device placement, the shroud (30) is removed and discarded, allowing the now external end portion (24) of the device (20) to expand to its normal position so as to engage the outer surface of the abdominal wall (62) to maintain the device (20) in position. Such a gastrostomy device package (10) and method of placement avoid the need for establishing a fistulas stoma tract before placement of a low profile gastrostomy device, as is the usual case.



2056085

PACKAGE FOR INITIAL PLACEMENT OF LOW PROFILE  
GASTROSTOMY DEVICE AND METHOD OF PLACEMENT

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ABSTRACT OF THE DISCLOSURE

2           A low profile or skin level gastrostomy device (20)  
3 for initial endoscopic placement in an incision provided  
4 through the stomach (64) and abdominal walls (62) of a  
5 patient having a collapsed resilient end portion (24) pack-  
6 aged and compressed within a shroud (30) that allows the end  
7 portion (24) of the device (20) positioned within the stomach  
8 (61) to easily pass from the inner to the outer end of the  
9 incision. The shroud (30) is pulled or pushed outwardly  
10 through the incision until the device (20) is properly posi-  
11 tioned therein. Subsequent to device placement, the shroud  
12 (30) is removed and discarded, allowing the now external end  
13 portion (24) of the device (20) to expand to its normal  
14 position so as to engage the outer surface of the abdominal  
15 wall (62) to maintain the device (20) in position. Such a  
16 gastrostomy device package (10) and method of placement avoid  
17 the need for establishing a fistulas stoma tract before  
18 placement of a low profile gastrostomy device, as is the  
19 usual case.

**PACKAGE FOR INITIAL PLACEMENT OF LOW PROFILE  
GASTROSTOMY DEVICE AND METHOD OF PLACEMENT**

**BACKGROUND OF THE INVENTION**

1           The present invention relates in general to gastrostomies providing long term  
2           enteral feeding and, more particularly, to a gastrostomy device packaging technique and  
3           installation method for initially placing a low profile gastrostomy device in a patient without  
4           first establishing a fistulas stoma tract as heretofore required by the prior art.

5           Low profile or skin level gastrostomy devices and the advantages attendant to  
6           their use are known in the art, as exemplified by U.S. patent 4,863,438. This patent,  
7           assigned to the assignee of the present invention, discloses a gastrostomy device having an  
8           intra-gastric end located within a body cavity such as the stomach of the patient, a tubular  
9           midportion extending from the intra-gastric end outwardly through the stomach and abdominal  
10          walls, and an external low profile end having a pair of winglike projections that engage the  
11          outer surface or skin of the patient's abdominal wall to maintain the gastrostomy device in  
12          proper position for intermittently receiving a conventional internal feeding tube projecting into  
13          the stomach.

14          Such a prior art device is often referred to as a "replacement" gastrostomy  
15          device, since it is substituted for the usual gastrostomy tube that is initially placed in a patient  
16          for six to eight weeks until a fistulas stoma tract is established. Once the stoma tract is  
17          established, the

1 gastrostomy tube is removed, and the "replacement" gastro-  
2 tomy device is inserted into the stoma tract.

3           It is a goal of the present invention to eliminate  
4 the need for first establishing a fistulas stoma tract prior  
5 to installation of a low profile gastrostomy device of the  
6 type disclosed in the earlier-noted patent. By eliminating  
7 the use of a gastrostomy tube to establish the stoma tract,  
8 medical costs associated therewith can be eliminated. Also,  
9 initial placement of a low profile gastrostomy device allows  
10 the patient to immediately benefit from the advantages  
11 inherent in the use of a low profile gastrostomy device as  
12 opposed to a gastrostomy tube.

13

14

#### SUMMARY OF THE INVENTION

15           In accordance with the present invention, a gas-  
16 trostomy device package is provided to permit initial place-  
17 ment of a low profile gastrostomy device in an incision  
18 extending from outside a living body into an internal body  
19 cavity such as a stomach. The gastrostomy device includes  
20 a tubular mid-portion having an inner end providing an  
21 intragastric portion and an outer end providing a collapsible  
22 external portion. A shroud means surrounds and encloses the  
23 external portion to maintain it in a collapsed condition  
24 within the shroud means. The shroud means facilitates  
25 movement of the external portion of the gastrostomy device  
26 through the incision and is removable to allow the external  
27 portion to expand to a normal uncollapsed condition subse-  
28 quent to the placement of the gastrostomy device in the  
29 incision.

30           Preferably, the shroud means is elongated and has  
31 a distal end that is at least partially tapered to function

1 as a dilator, facilitating movement of the shroud through the  
2 incision from the internal body cavity outwardly to the  
3 external surface of the body. In one embodiment, the tapered  
4 distal end of the shroud is provided with a wire loop so that  
5 it can be pulled outwardly through the incision. In another  
6 embodiment, the tapered distal end is provided with a longi-  
7 tudinally extending bore that can receive a guidewire so that  
8 the distal end can be pushed outwardly through the incision.

9 Preferably, at least the external portion of the  
10 gastrostomy device is formed of resilient elastomeric materi-  
11 al, such as biocompatible silicone rubber, so that it can be  
12 easily collapsed and compressed within the shroud means. The  
13 external portion includes at least two winglike projections  
14 extending radially away from the longitudinal axis of the  
15 gastrostomy device. When being retained within the shroud  
16 means, the winglike projections are folded towards each other  
17 so that they lie along generally parallel lines adjacent to  
18 and bracketing the longitudinal axis. A sleeve of plastic  
19 film material constituting a part of the shroud means extends  
20 over the winglike projections to retain them in their col-  
21 lapsed condition. After the gastrostomy device package is  
22 properly positioned within the incision, the plastic film is  
23 cut and peeled away so that the winglike projections can move  
24 to their normal laterally extending positions so as to engage  
25 the outer surface or skin of the body, thereby retaining the  
26 gastrostomy device in its proper position.

27 In further accordance with the invention, a method  
28 of placing a gastrostomy device of the above-noted type  
29 includes the steps of providing an incision extending from  
30 the external surface of a living body to an inner body cavity  
31 such as the stomach, positioning within said cavity a gas-  
32 trostomy device package as noted above, inserting the shroud  
33 means of the gastrostomy device into the incision and moving  
34 the shroud means from the inner end of the incision out

1 through the outer end thereof so as to position the tubular  
2 midportion of the device within the incision, and then  
3 removing the shroud means to allow the external portion to  
4 expand to a normal uncollapsed condition so that the now  
5 expanded external portion engages the outer surface of the  
6 body to maintain the gastrostomy device in position. In  
7 practicing the method of placing the gastrostomy device, the  
8 shroud can either be pulled through the incision or pushed  
9 through the incision, depending upon the type of gastrostomy  
10 device package utilized, as noted above.

11 BRIEF DESCRIPTION OF THE DRAWINGS

12

13 A fuller understanding of the invention may be had  
14 by referring to the following description and claims, taken  
15 in conjunction with the accompanying drawings, wherein:

16 FIG. 1 is a longitudinal, partial, cross-sectional  
17 view of a first embodiment of a gastrostomy device package  
18 in accordance with the present invention;

19 FIG. 2 is an exploded view of the gastrostomy  
20 device package of FIG. 1;

21 FIGS. 3A-3F sequentially illustrate the methodology  
22 for placing the gastrostomy device of FIGS. 1 and 2 in an  
23 incision in a living body, such as a human being;

24 FIG. 4 is a longitudinal, partial, cross-sectional  
25 view of a second embodiment of a gastrostomy device package  
26 in accordance with the present invention; and

1           FIGS. 5A-5F sequentially illustrate the methodology  
2 for placing the gastrostomy device of FIG. 4 in an incision  
3 in a living body, such as a human being.

4           DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

5           With reference to FIGS. 1 and 2, a first embodiment  
6 of a gastrostomy device package in accordance with the  
7 present invention is illustrated. The package 10 is general-  
8 ly elongated so as to extend along a longitudinal axis x-x,  
9 as illustrated. The package 10 is comprised of two major  
10 portions, namely, a low profile gastrostomy device 20, often  
11 referred to in the art as a "gastrostomy button," and a  
12 shroud means 30 comprised primarily of a dilator member 40,  
13 and a plastic film material 50 constituting a tubular sleeve  
14 extending generally completely over the dilator 40. The  
15 gastrostomy device 20 illustrated is of the type disclosed  
16 in earlier incorporated U.S. patent 4,863,438. The device  
17 20 includes an intragastric portion 22 located at one end of  
18 a tubular midportion 23 having at its other end a resilient  
19 external portion 24. The device 20 is preferably formed of  
20 biocompatible silicone rubber material so as to be flexible  
21 and elastomeric. The length of the tubular portion is sized  
22 to be dimensionally compatible with the combined thickness  
23 of, for example, a patient's stomach and abdominal walls.

24           The external portion 24 of the gastrostomy device  
25 20 includes a pair of diametrically opposed winglike projec-  
26 tions 25, one of which has extending from it a plug retainer  
27 26 which has a distal end providing a plug 27, wherein the  
28 plug retainer 26 can be folded over to permit insertion of  
29 the plug 27 into a feeding tube receptor port 28. As is  
30 known in the art, when positioned within, for example, a

1 human or animal patient undergoing medical treatment, an  
2 enteral feeding tube can be inserted into port 28 through  
3 the tubular midportion 23 and into the intragastric portion  
4 22 to effect the flow of fluid either into or out of a body  
5 cavity, such as the patient's stomach, within which the  
6 intragastric portion is located. It is to be noted that the  
7 intragastric portion 22 includes within it the usual normally  
8 closed reflux valve (not shown) which prevents egress of  
9 fluid outwardly through the tubular portion 23 when the  
10 enteral feeding tube is not maintaining the valve in an open  
11 position.

12           With particular reference to FIG. 1, the flexible  
13 winglike projections 25, including the associated plug  
14 retainer 26 and plug 27, are shown in a folded or collapsed  
15 condition so that they extend along parallel lines adjacent  
16 to the axis x-x, as illustrated. The dilator 40 provides a  
17 pair of opposed flats or recesses 44 against which the  
18 winglike projections 25 are held in their folded or collapsed  
19 position by the plastic film 50 in the preferred form of a  
20 tubular sleeve of heat-shrink or shrink-wrap type plastic  
21 film. In its collapsed condition, the external portion 24  
22 (FIG. 2) is contained within and compressed by the shroud  
23 means 30, and, more specifically, the plastic film 50. It  
24 is to be noted that, while the winglike projections 25 of  
25 FIG. 1 are shown folded and extending toward the right, they  
26 could also be folded toward the left against opposite sides  
27 of tubular midportion 23 and held in place by extending the  
28 plastic film 50 leftward to overlap them and maintain them  
29 in a collapsed condition. The dilator member 40 further  
30 includes a plug retainer recess or flat 46 having a plug  
31 recess 47 into which the plug 27 fits, as illustrated in FIG.  
32 1. It is contemplated that the plug retainer 26 and plug 27  
33 could be eliminated and, instead, a separate plug structure  
34 could be provided after placement of the device 20 in a

2056085

1 patient, as will become apparent. The dilator member 40 has  
2 a tapered distal end 42 which is provided with a pull wire  
3 loop 43 embedded within the dilator member, as illustrated.

4 With further reference to FIG. 1, the dilator 40  
5 is also provided with a reduced diameter portion 48 which  
6 forms an inboard part of a retainer tip 49 that extends and  
7 snaps into the external end 24, i.e., port 28, of the tubular  
8 portion 23, as illustrated. The gastrostomy device 20 is  
9 provided with an annular or circular lip 29 that fits into  
10 the reduced diameter portion 48, constituting a circular  
11 groove, so as to provide a releasable locking means holding  
12 the gastrostomy device 20 in position relative to the dilator  
13 40. It can also be seen that an open, or leftward end as  
14 viewed in FIG. 1, of the plastic film 50 constituting a  
15 tubular sleeve extends beyond and over both the circular lip  
16 29 and its associated annular groove constituted by reduced  
17 diameter portion 48, so as to hold and compress the circular  
18 lip 29 into the reduced diameter portion 48 of the dilator  
19 40.

20 With reference to FIG. 2, a guide groove 45 is  
21 provided, as illustrated, on a surface of the dilator member  
22 40 spaced from the external end portion 24 of the gastrostomy  
23 device 20 when in its position as illustrated in FIG. 1. The  
24 guide groove provides an indicator point for partially  
25 cutting the plastic film 50 and peeling it around and away  
26 from the dilator member 40, as illustrated in FIG. 2, so that  
27 the gastrostomy device 20 and the dilator member 40 can be  
28 separated from each other so as to allow the resilient  
29 winglike projections 25 to return to a normal expanded  
30 position as illustrated in FIG. 2.

31 Thus, FIG. 1 illustrates a gastrostomy device  
32 package for initial placement of the gastrostomy device 20  
33 in a patient, as discussed below, while FIG. 2 illustrates  
34 the package in a disassembled form after the device has been

1 placed within an incision in the patient, as will now be  
2 discussed.

3 With reference to FIGS. 3A-3F, a method of placing  
4 in a patient the gastrostomy device as illustrated and  
5 discussed with regard to FIGS. 1 and 2 will now be set forth.

6 Turning to FIG. 3A, there is schematically illus-  
7 trated a patient having an inner body cavity such as a  
8 stomach 61 within which is to be placed the gastrostomy  
9 device in accordance with the present invention. It is to  
10 be noted that the gastrostomy device package and method of  
11 placement disclosed and claimed herein can be used for  
12 inserting a gastrostomy device into other viscera of the body  
13 for other applications, such as, for example, urinary bladder  
14 drainage, ileostomy, jejunostomy, and cystostomy.

15 The outer surface 60 or skin of the patient extends  
16 over an abdominal wall 62, which in turn abuts the stomach  
17 wall 64. In a first step for placing the gastrostomy device  
18 package discussed earlier, the stomach 61 of the patient is  
19 insufflated via an endoscope tube 65 extending down through  
20 the esophagus 63 of the patient, as illustrated. As illus-  
21 trated in FIG. 3B, a conventional trocar needle 66 is in-  
22 serted through the abdominal and stomach wall of the patient  
23 to establish an incision that will receive a gastrostomy  
24 button.

25 As shown in FIG. 3C, a pull wire 67 is inserted  
26 down through the trocar needle 66 so that its end can be  
27 captured by a snare 68 extending through the endoscope tube  
28 65. With further reference to FIG. 3D, the pull wire 67 has  
29 been pulled outwardly through the patient's mouth 69 so that  
30 the pull wire 43 of the gastrostomy device package can be  
31 attached, as illustrated. Turning to FIG. 3E, the gastrosto-  
32 my device package 10, by use of the pull wire 67, has been  
33 pulled down the esophagus 63 of the patient, and then through  
34 the incision provided by the trocar needle 66. At this

1 point, the shroud means 30 (see FIGS. 1 and 2) is removed.

2 Turning to FIG. 3F, and as earlier discussed with  
3 regard to FIG. 2, the intragastric portion 22 of the gastro-  
4 tomy device 20 is now located within the stomach 61 of the  
5 patient, while the tubular midportion extends through the  
6 stomach wall 64 and abdominal wall 62, with the winglike  
7 projections 25 in their extended, uncollapsed, normal posi-  
8 tion engaging the outer surface 60 of the abdominal wall 62,  
9 wherein the gastrostomy device 20 is now retained in posi-  
10 tion.

11 By use of the gastrostomy device package illus-  
12 trated in FIGS. 1 and 2 and the methodology for placing it  
13 as illustrated in FIGS. 3A-3F, the use of the traditional  
14 gastrostomy tube to establish a fistulas stoma tract is  
15 avoided. Thus, the cost and patient trauma associated  
16 therewith are eliminated, and the benefits afforded by the  
17 low profile gastrostomy device 20 are available at an earlier  
18 point in time to the patient requiring a gastrostomy.

19 Turning to FIG. 4, another embodiment of the  
20 present invention is illustrated. An alternative gastrostomy  
21 device package 110 can also be used for initial placement of  
22 the gastrostomy device 20, which is identical to that illus-  
23 trated in FIGS. 1 and 2. As shown in FIG. 4, an alternative  
24 shroud means 130 includes additional components to permit  
25 installation of the gastrostomy device 20 by use of a guide-  
26 wire type method of the type disclosed in U.S. Patent No.  
27 4,758,219, incorporated herein by reference in its entirety.

28 As contrasted to the gastrostomy device package 10  
29 illustrated in FIGS. 1 and 2, a tapered dilator member 140  
30 has extending longitudinally through it a bore 141 that is  
31 of a diameter that will accept a guidewire (to be subsequent-  
32 ly illustrated). A secondary or lateral bore 142 extending  
33 between the central bore 141 and the exterior of the dilator  
34 140 as illustrated provides an alternative guidewire path so

2056085

1 as to avoid passing a guidewire through the gastrostomy  
2 device 20, as may be desirable in some cases. The distal  
3 end of the dilator member 140 is connected to one end of a  
4 flexible guide tube 174. The other end of the guide tube 174  
5 is provided with a tapered dilator tip 176 having a central  
6 bore 178. Thus, the shroud means 130 of the embodiment of  
7 the invention illustrated in FIG. 4 includes the dilator  
8 member 140, the guide tube 174, and the dilator tip 176.  
9 The shroud means 130 also includes a tubular sleeve of  
10 shrink-wrap type plastic film 150, serving the same function  
11 in terms of retention of the winglike projections 25 as dis-  
12 cussed earlier with regard to FIGS. 1 and 2. It can be seen  
13 that the dilator member 140 has a tapered outer surface  
14 portion extending toward the guide tube 174 to which it is  
15 connected. Also, the dilator tip 176 is tapered to a point.  
16 These sequential tapers facilitate movement of the shroud  
17 means 130 from the inward to the outward end of an incision  
18 in a patient, as will now be further illustrated with regard  
19 FIGS. 5A-5F.

20 With reference to FIG. 5A, an endoscope tube 65  
21 inserted into the esophagus 63 of the patient is used to  
22 insufflate the stomach 61 so that the stomach wall 64 is held  
23 tightly against the abdominal wall 62. Turning to FIG. 5B,  
24 a conventional trocar needle 66 is used to establish an  
25 incision from the outer surface 60 of the abdominal wall 62  
26 into the stomach 61. As shown in FIG. 5C, a guidewire 167  
27 is fed down through the trocar needle and then retrieved by  
28 a snare 68, wherein the endoscope tube 65 with guidewire 167  
29 is withdrawn from the esophagus 63.

30 As shown in FIG. 5D, the guidewire 167 extends  
31 through the trocar needle 66, through the patient's esophagus  
32 63, and out of the patient's mouth. The gastrostomy device  
33 package 110 is then, in effect, threaded over the guidewire  
34 167, using either central bore 141 or lateral bore 142, and

1 then pushed downwardly along the guidewire 167 through the  
2 esophagus 63 of the patient so that the dilator tip 176 and  
3 its associated flexible guide tube 174 are pushed outwardly  
4 through the incision in the abdominal wall of the patient.

5 With reference to FIG. 5E, the guide tube 174 has  
6 been pushed and then pulled completely through the incision,  
7 which now retains the gastrostomy device package 110, as  
8 illustrated. At this point, and as discussed earlier in  
9 connection with FIG. 4, the shroud means 130 is then removed  
10 by cutting and peeling away plastic material 150 so that, as  
11 shown in FIG. 5F, the winglike projections 25 will expand to  
12 their normal position so as to engage the outer surface 60  
13 or skin of the patient, whereby the tubular midportion 23  
14 extends through the abdominal wall of the patient, the  
15 intragastric portion 22 being maintained in its desired  
16 position within the patient's stomach 61.

17 From the foregoing, it may be seen that the two  
18 embodiments of the gastrostomy device package illustrated in  
19 FIGS. 1, 2 and 4 and their associated methodologies of  
20 placement illustrated in FIGS. 3A-3F and FIGS. 5A-5F provide  
21 for initial placement of a low profile gastrostomy device.

22 It should be evident that this disclosure is by way  
23 of example, and that various changes may be made by adding,  
24 modifying or eliminating details without departing from the  
25 fair scope of the teaching contained in this disclosure. The  
26 invention is therefore not limited to the particular details  
27 of the disclosure except to the extent that the following  
28 claims are necessarily so limited.

2056085

## WHAT IS CLAIMED IS:

- 1           1. A gastrostomy device package comprising:  
2                 a gastrostomy device with a tubular midportion  
3 having an inner end providing an intragastric portion locat-  
4 able in an internal cavity of a living body, and an outer end  
5 providing a collapsible external portion locatable at the  
6 outer surface of said living body; and  
7                 a shroud means surrounding and enclosing said  
8 external portion to maintain said external portion in a  
9 collapsed condition within said shroud means, said shroud  
10 means being removable to allow said external portion to  
11 expand to a normal uncollapsed condition subsequent to the  
12 placement of the gastrostomy device in said living body.
  
- 1           2. A package according to claim 1, wherein the  
2 shroud means is elongated and has a distal end that is at  
3 least partially tapered.
  
- 1           3. A package according to claim 2, wherein said  
2 distal end is provided with a wire loop.
  
- 1           4. A package according to claim 2, wherein said  
2 distal end is provided with a longitudinal bore extending  
3 therethrough for receiving a guidewire along which said  
4 distal end can be moved.
  
- 1           5. A package according to claim 1, wherein said  
2 collapsed external portion is compressed within said shroud  
3 means.

1           6. A package according to claim 1, wherein said  
2 external portion is formed of resilient elastomeric material.

1           7. A package according to claim 1, wherein said  
2 shroud means includes a heat shrinkable plastic film material  
3 constituting a shrink-wrap package containing said external  
4 portion.

1           8. A gastrostomy device package comprising:  
2           a gastrostomy device with an elongated tubular  
3 midportion coaxially extending along a longitudinal axis,  
4 said midportion having an inner end providing an intragastric  
5 portion locatable in an internal cavity of a living body, and  
6 an outer end providing a collapsible external portion locat-  
7 able at the outer surface of said living body, said external  
8 portion including at least two winglike projections extending  
9 radially away from said axis when said external portion is  
10 in a normal uncollapsed condition; and  
11           a shroud means including a tubular sleeve of  
12 plastic film material surrounding and enclosing said external  
13 portion to maintain said external portion in a collapsed  
14 condition within said sleeve wherein said projections extend  
15 along lines generally parallel to said longitudinal axis so  
16 that the lateral extension of said external portion is  
17 reduced, said sleeve being removable to allow said projec-  
18 tions to expand and extend radially away from said axis when  
19 said external portion is in a normal uncollapsed condition  
20 subsequent to the placement of the gastrostomy device in said  
21 living body.

1                   9.     A package according to claim 8, wherein said projections are in adjacent,  
2 generally parallel relationship with each other when said external portion is in a collapsed  
3 condition within said sleeve.

4                   10.    A package according to claim 8, wherein said projections are diametrically  
5 opposed to each other relative to said longitudinal axis.

6                   11.    A package according to claim 8, wherein said projections are formed of  
7 resilient elastomeric material.

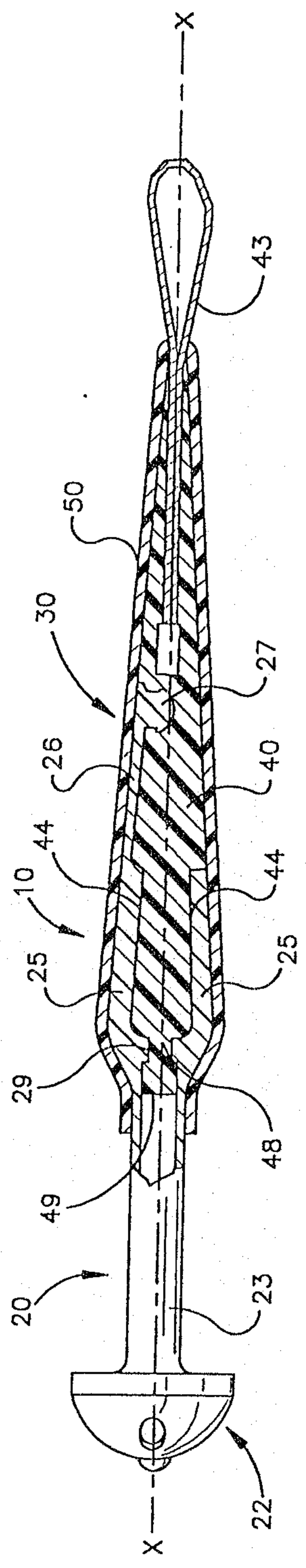


Fig. 1

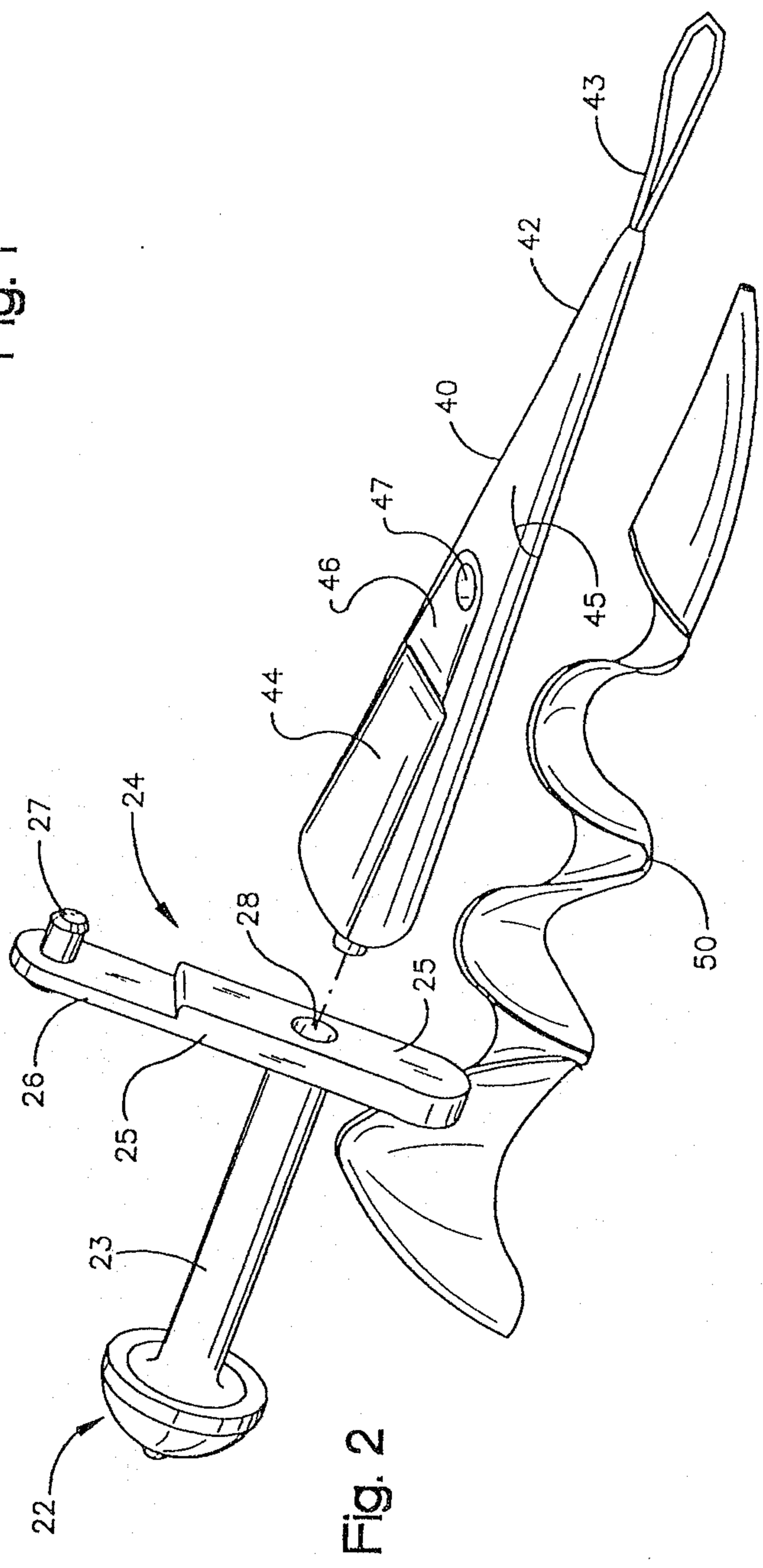


Fig. 2

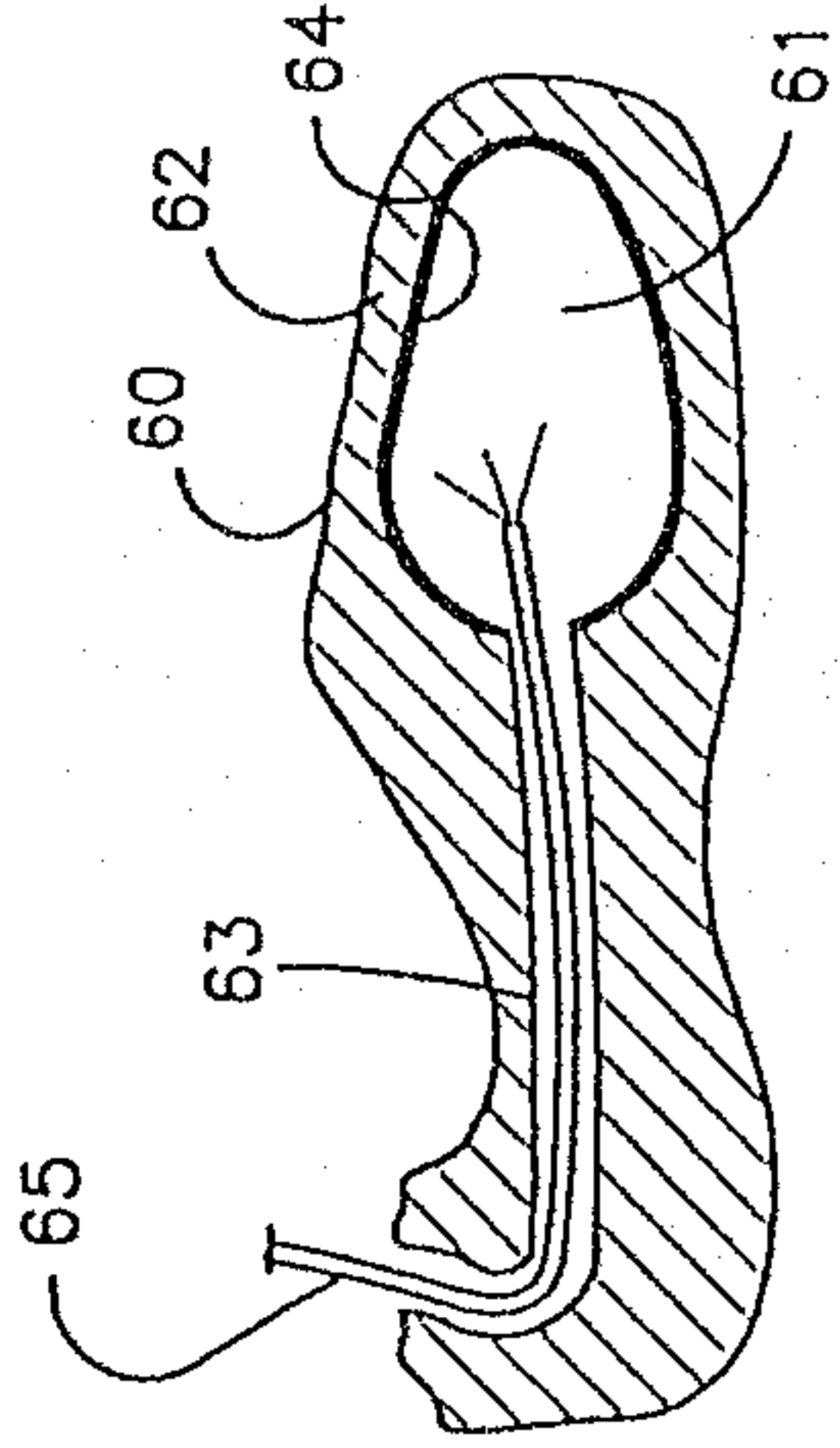


Fig. 3A

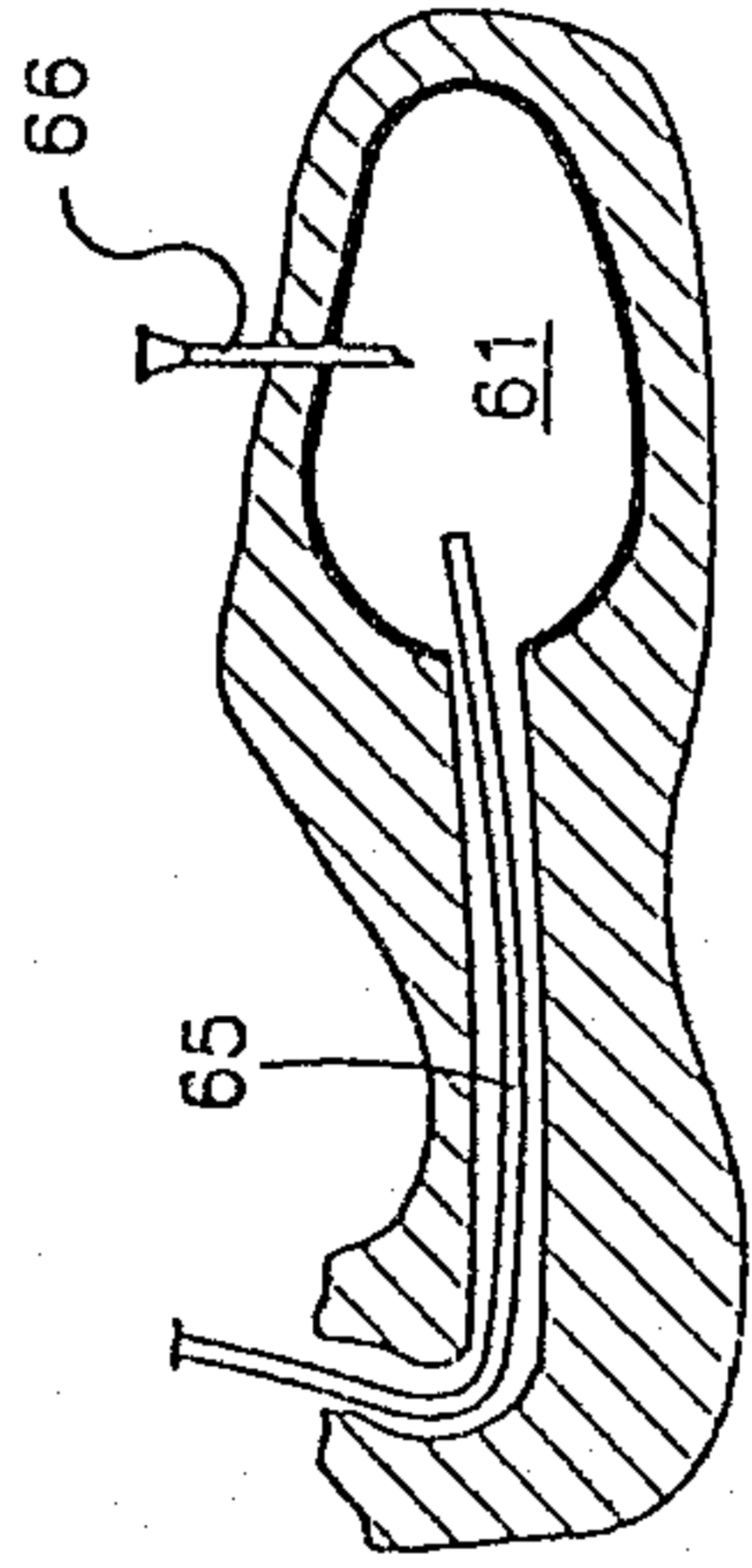


Fig. 3B

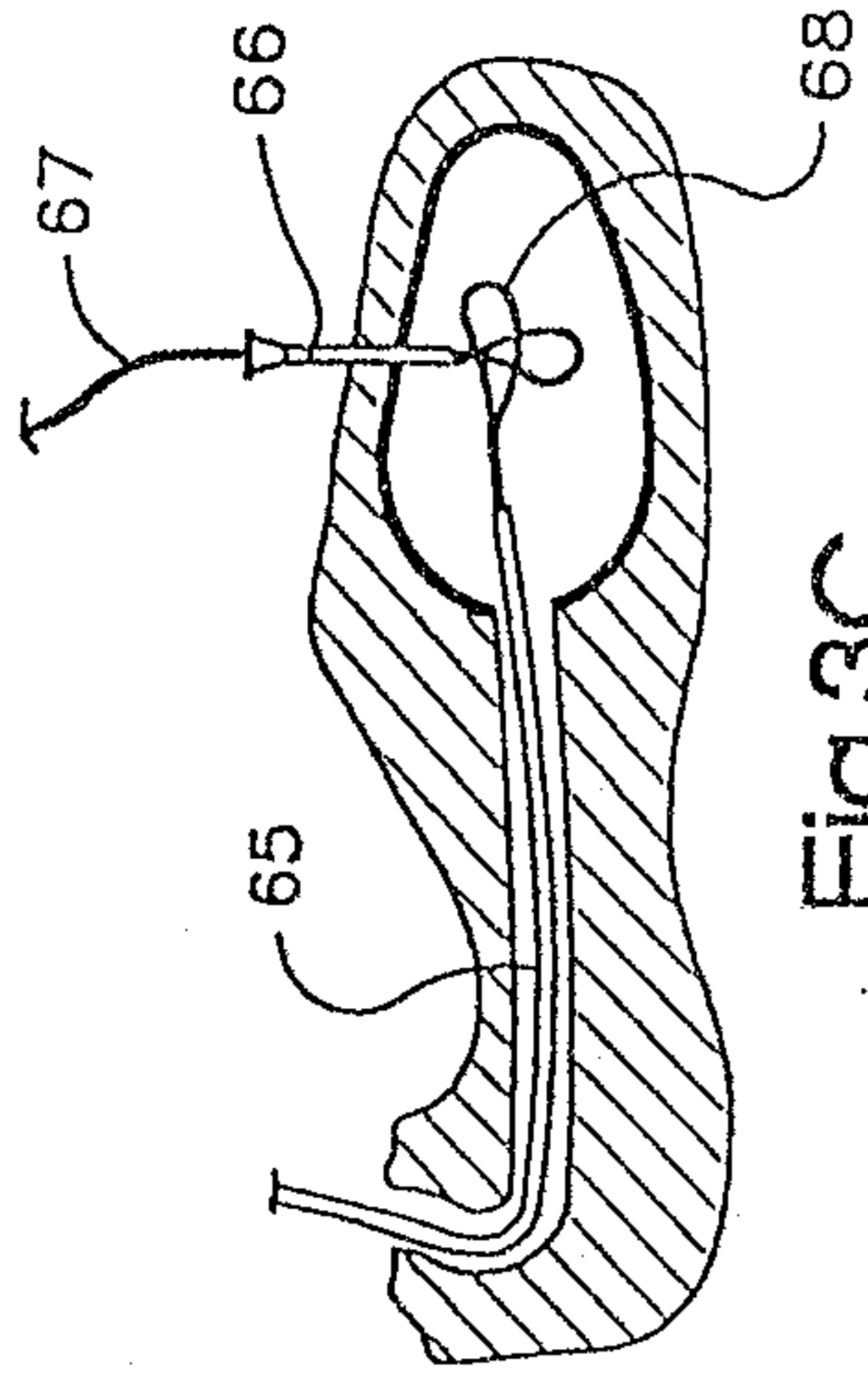


Fig. 3C

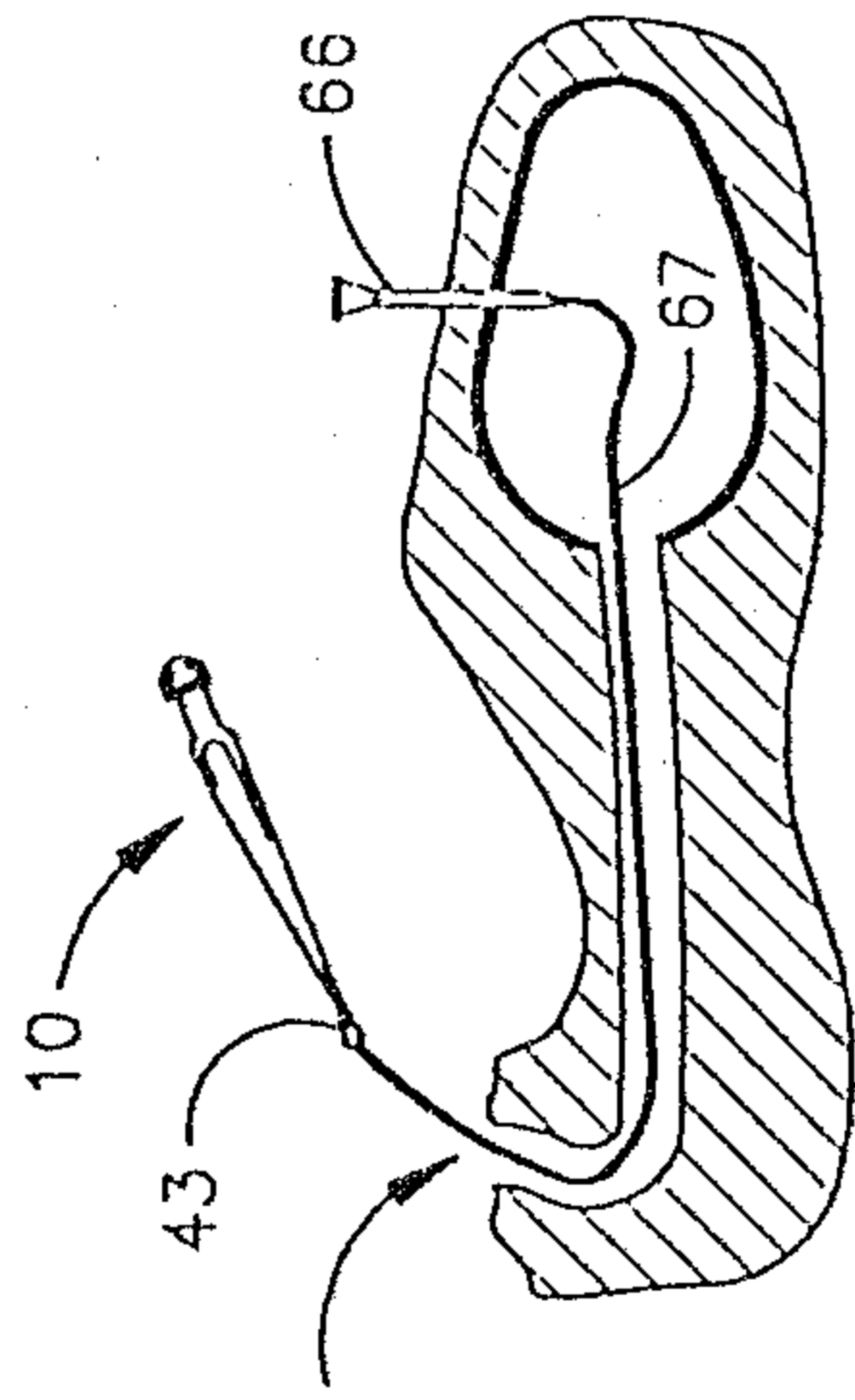


Fig. 3D

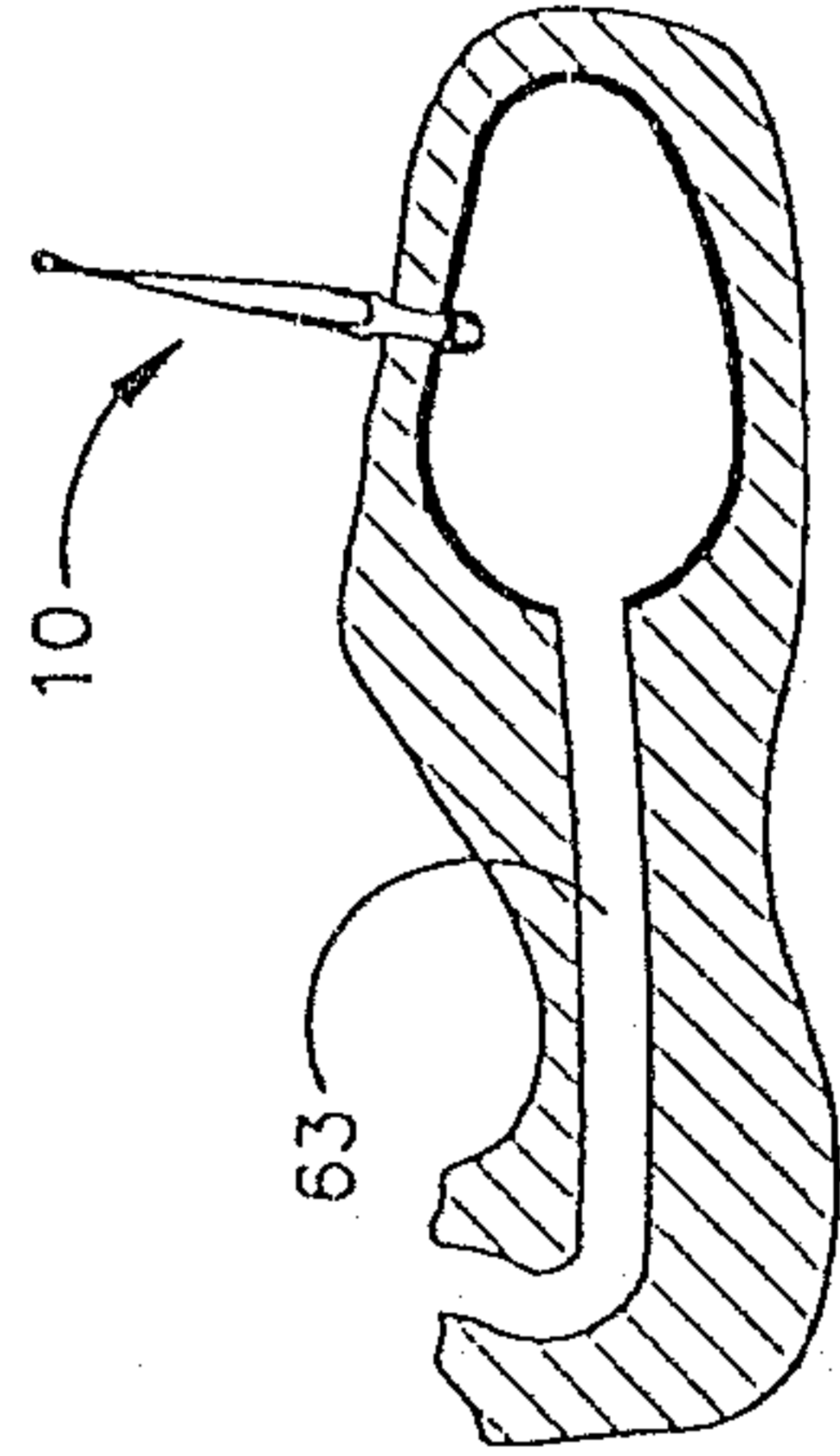


Fig. 3E

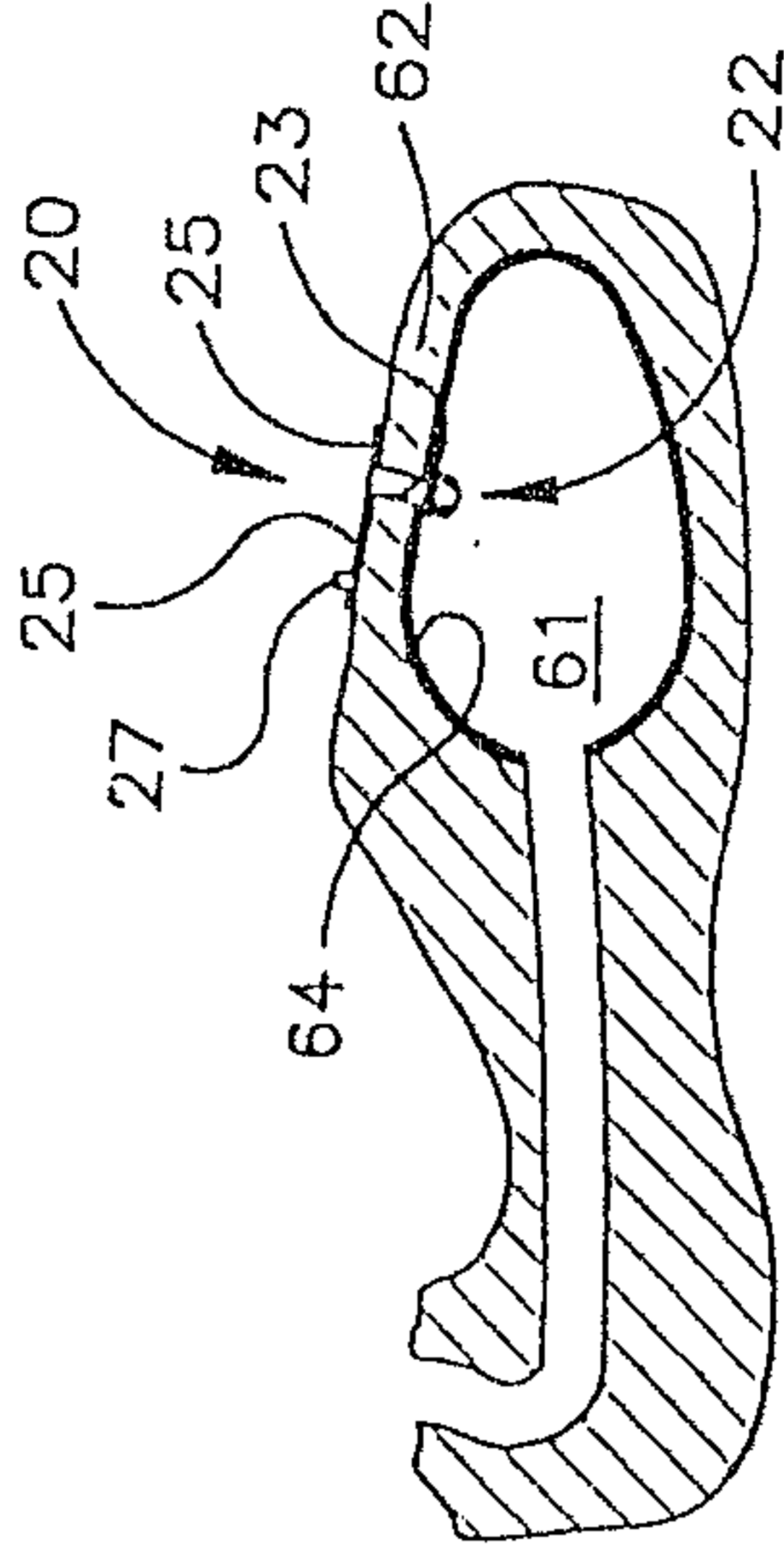


Fig. 3F

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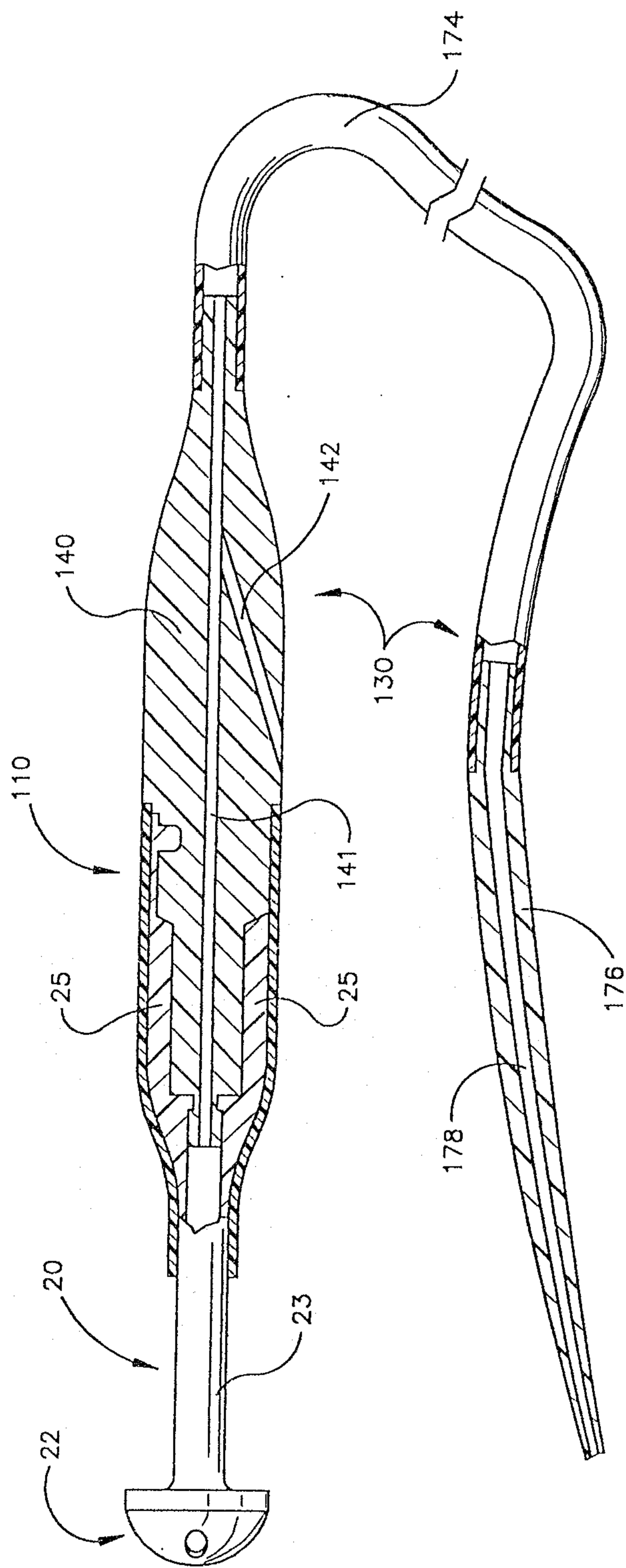


Fig.4

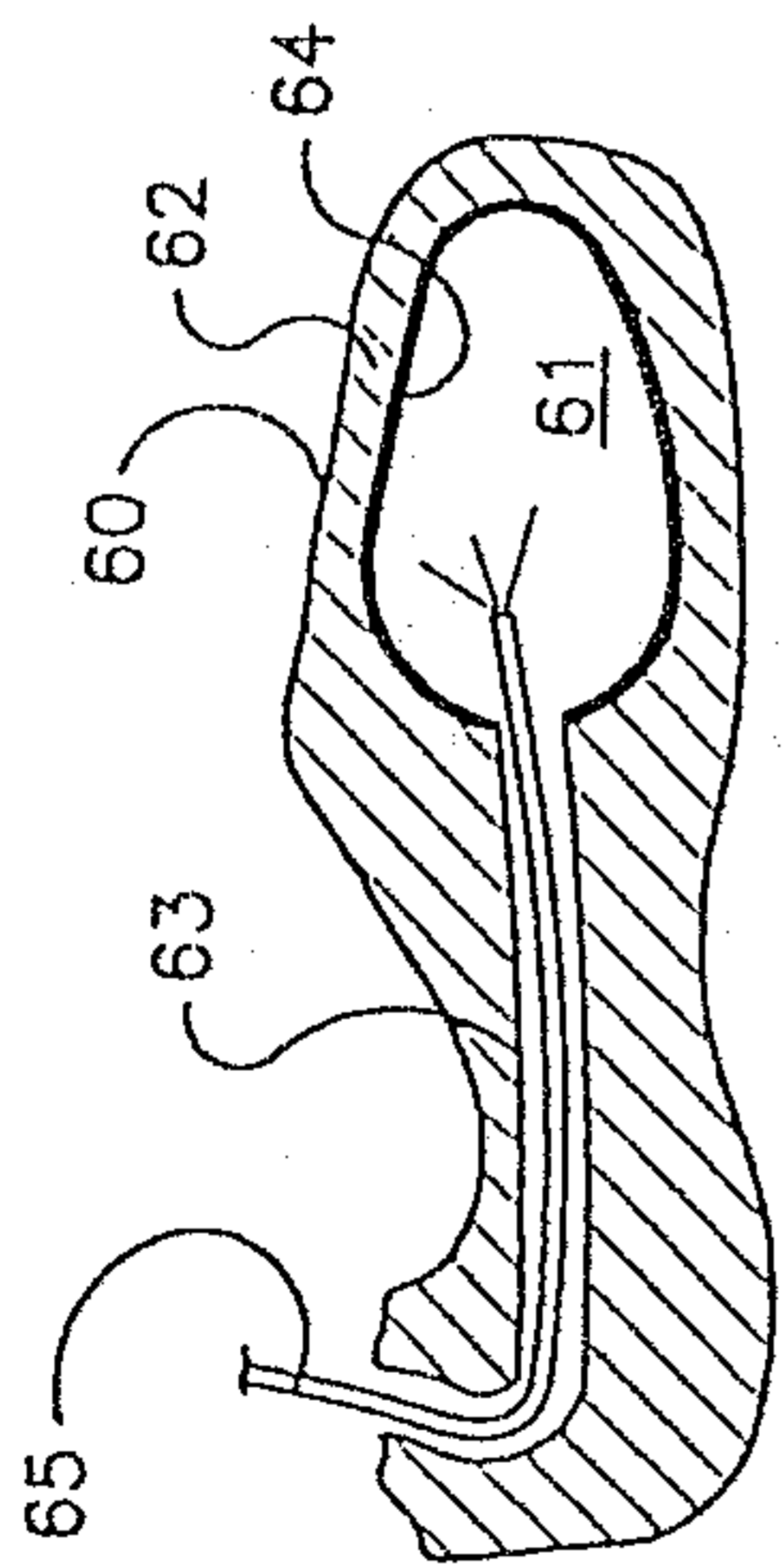


Fig. 5A

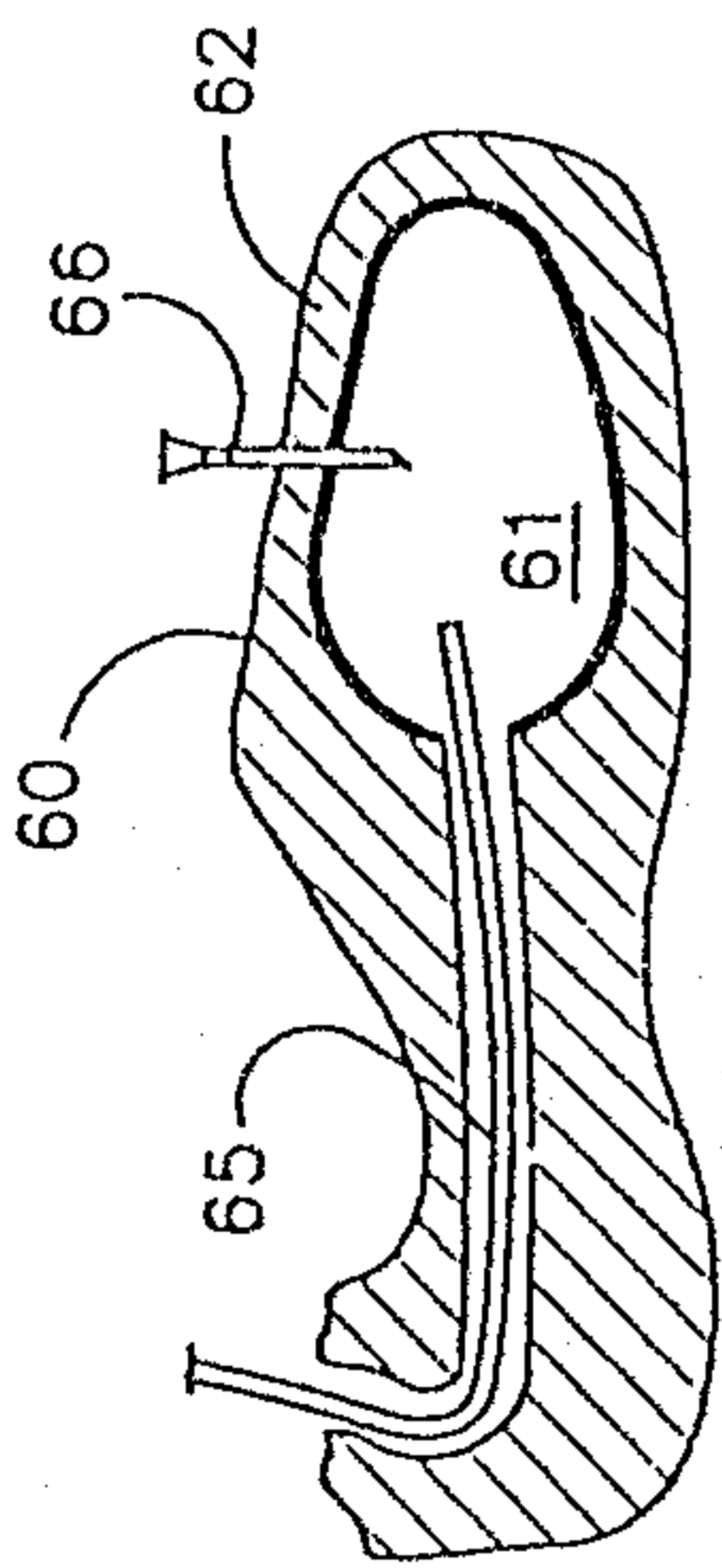


Fig. 5B

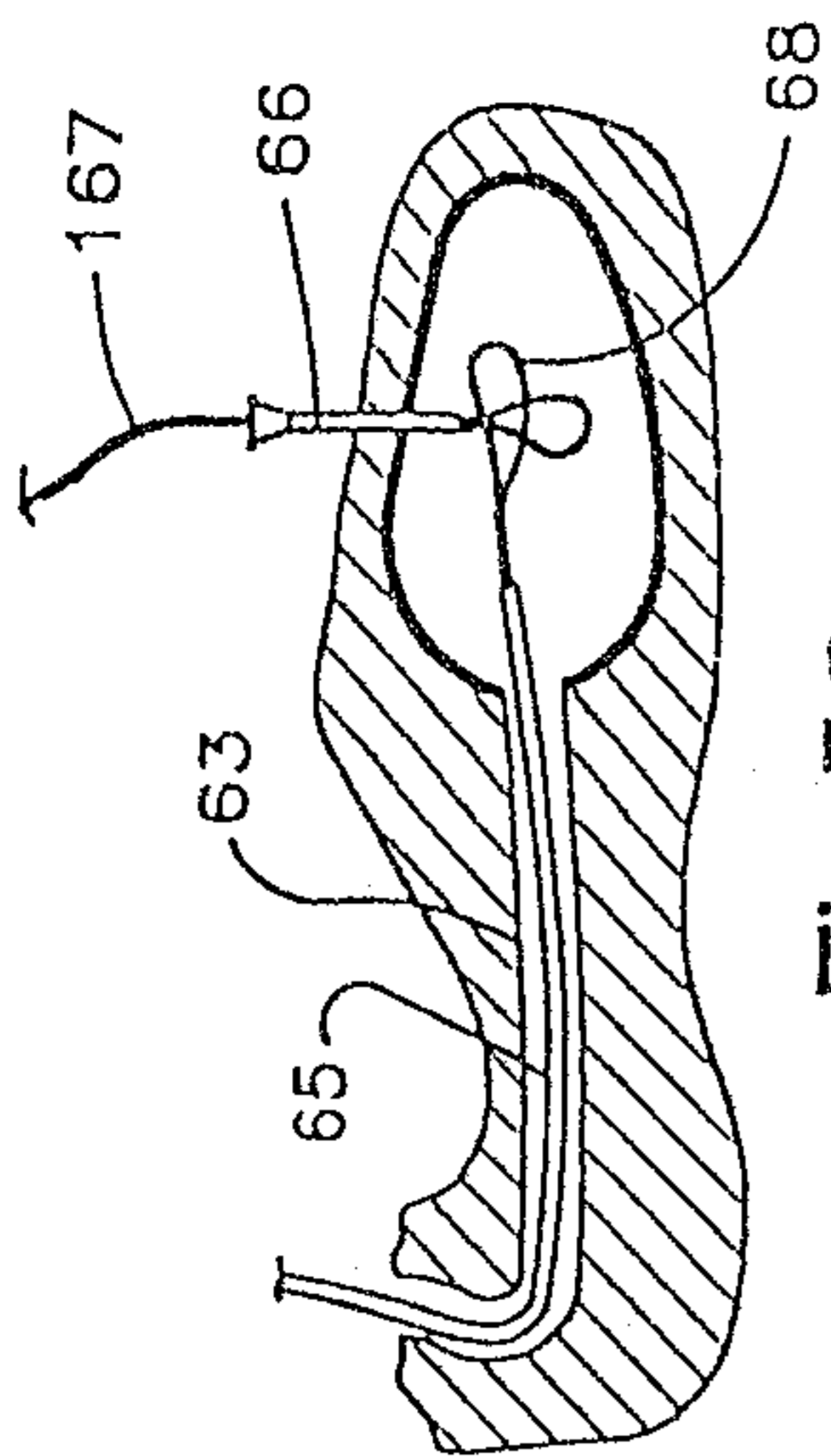


Fig. 5C

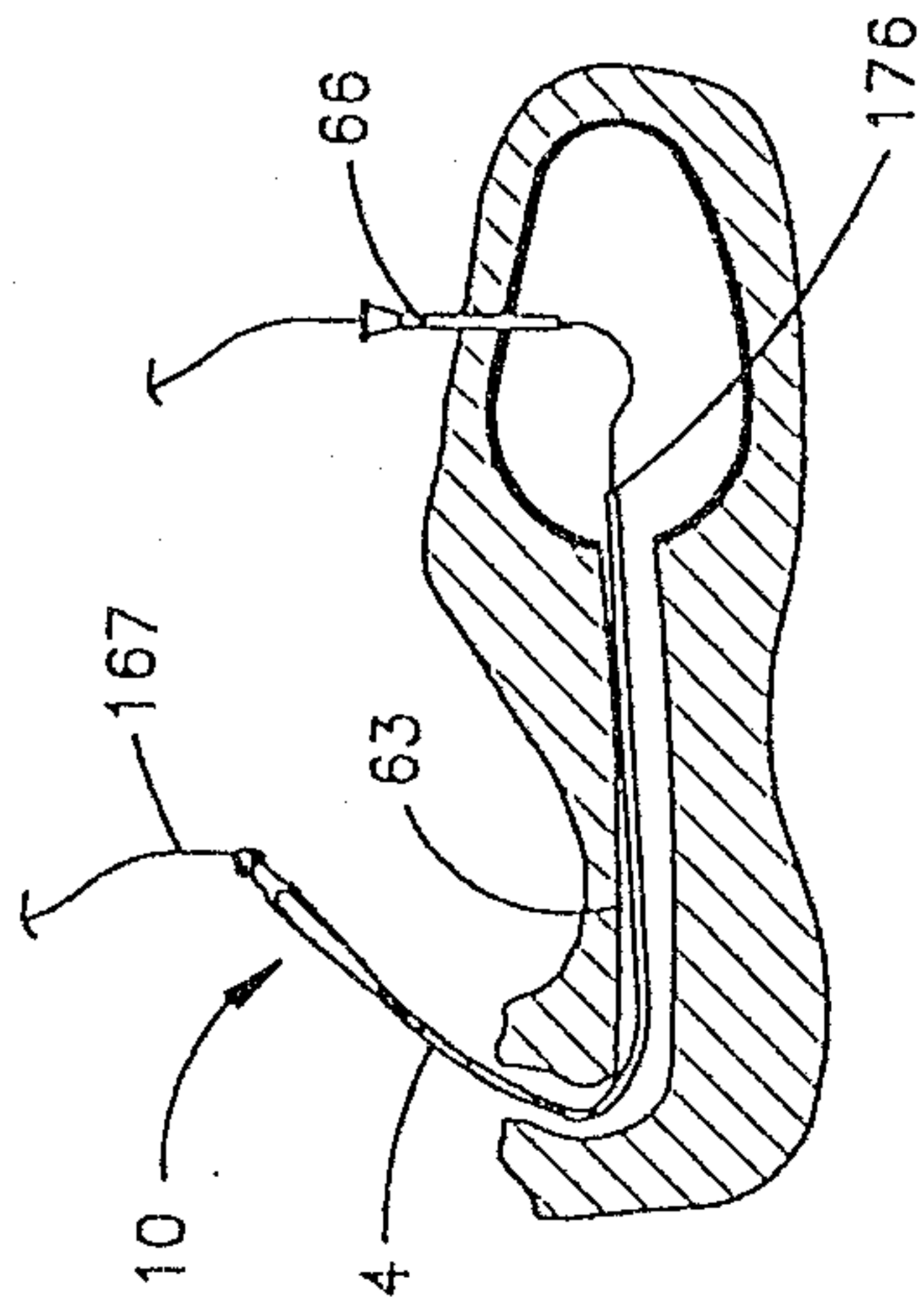


Fig. 5D

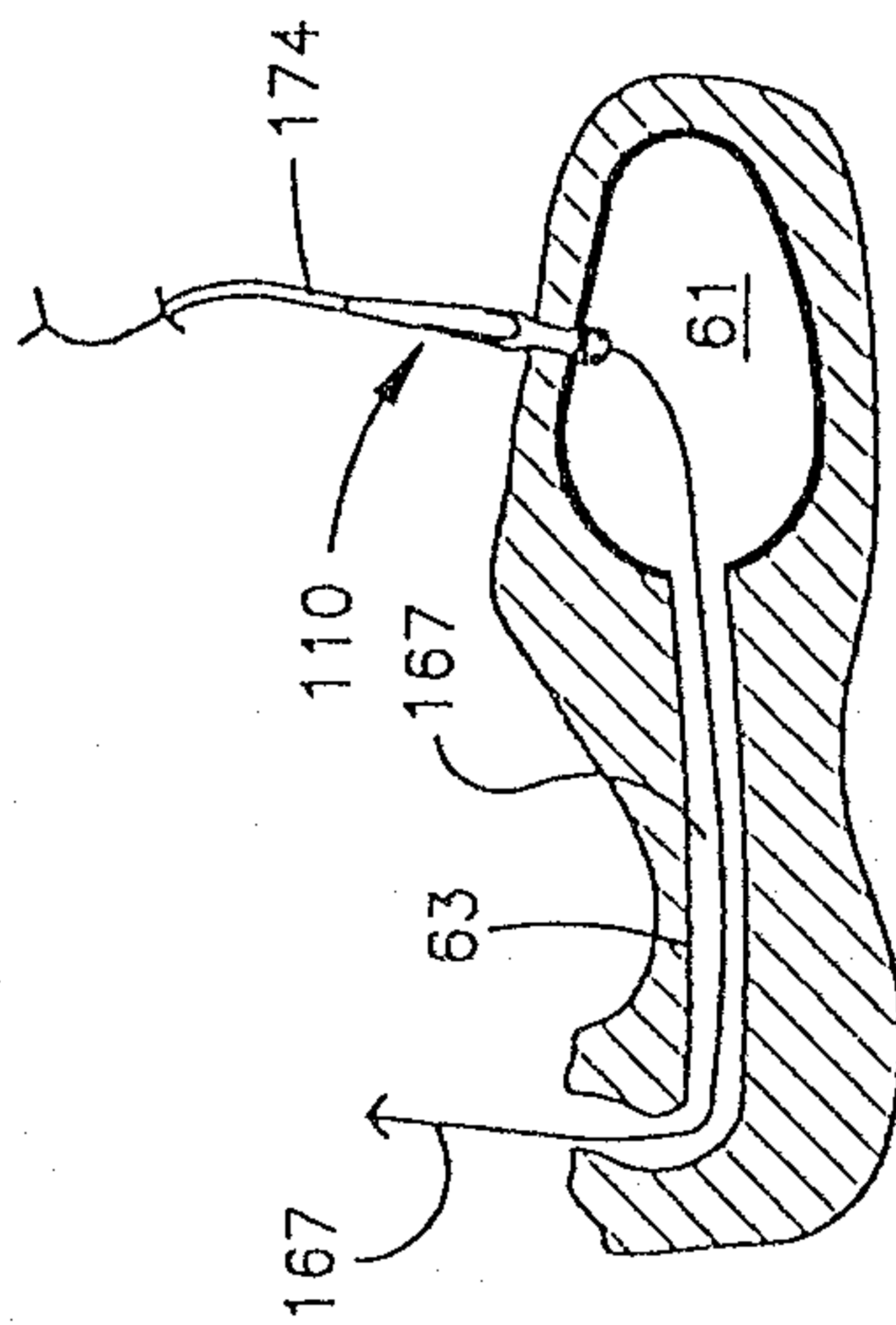


Fig. 5E

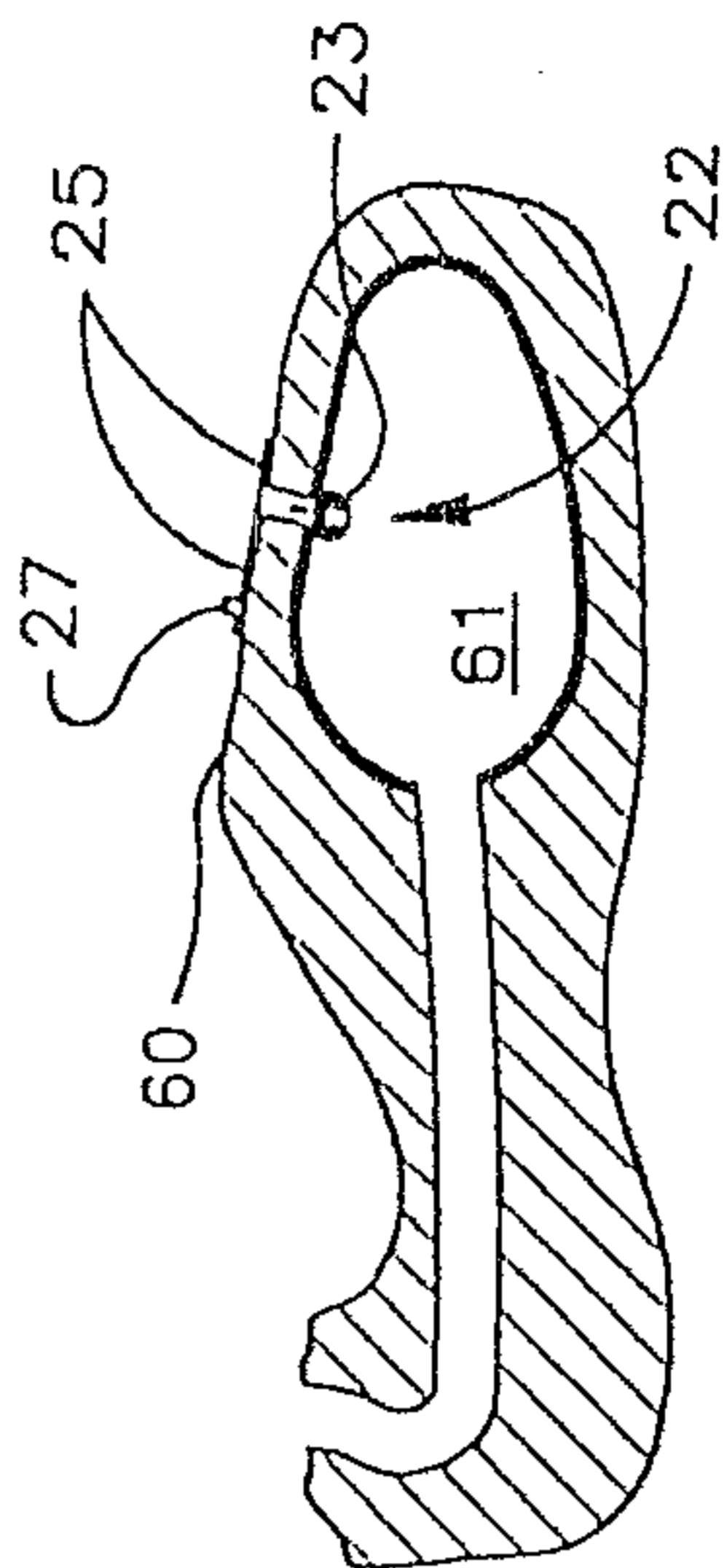


Fig. 5F

