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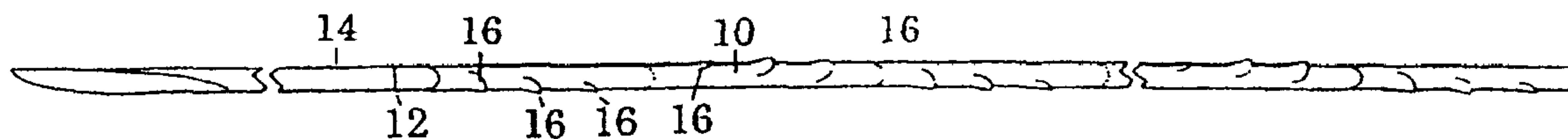
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(54) **Titre : PROCÉDES CHIRURGICAUX EMPLOYANT DES SUTURES UNIDIRECTIONNELLES**

(54) **Title: ONE-WAY SURGICAL SUTURES AND THE MANUFACTURE THEREOF**



(57) **Abrégé/Abstract:**

The invention concerns surgical sutures and the manufacture thereof, and in particular relates to a one-way suture which has barb elements enabling the suture to be pulled through tissue in one direction, but resisting movement in the opposite direction. The suture is useful in surgical methods which include closing wounds, tissue support and repair of internal tissues such as tendons and ligaments.

ABSTRACT

The invention concerns surgical sutures and the manufacture thereof, and in particular relates to a one-way suture which has barb elements enabling the suture to be pulled through tissue in one direction, but resisting movement in the opposite direction. The suture is useful in surgical methods which include closing wounds, tissue support and repair of internal tissues such as tendons and ligaments.

ONE-WAY SURGICAL SUTURES AND THE MANUFACTURE THEREOF

SPECIFICATION

Background of the Invention

The invention concerns surgical sutures and the manufacture thereof, and
5 in particular relates to a one-way suture which has barb elements enabling the suture to be pulled through tissue in one direction, but resisting movement in the opposite direction. The suture is useful in surgical methods which include closing wounds, tissue support and repair of internal tissues such as tendons and ligaments.

10 Sutures have been used in surgical procedures to close surgical and traumatic wounds, to close the skin in plastic surgery, to secure damaged or severed tendons, muscles or other internal tissues, and in microsurgery on nerves and blood vessels, all for holding tissues together to support healing and regrowth. Such sutures are attached to the shank end or trailing end of a needle.
15 The sutures can be a monofilament or a braided material and many are available as a one-piece unit pre-attached to a needle. Sutures can be of non-absorbable material such as silk, nylon, polyester, polypropylene or cotton, or of bioabsorbable material such as polymers and copolymers of glycolic and lactic acid. Loop stitching has been the primary procedure, particularly to close a
20 surface wound, whether an accidental or surgical wound. Such looped sutures, which are similar to the simplest method of seaming two pieces of fabric together, can leave ugly scars and a "Frankenstein" look to the fully healed wound. Although this can be alleviated in some cases and to some extent by using very fine suture material (e.g. 100 microns in diameter), the loop stitching still can
25 cause very visible scars, and for adequate closure of some wounds the suture material must be of a high tensile strength and thus a larger diameter, increasing scarring.

Surface adhesive tapes are often used on the skin to hold small wounds closed to permit healing, but these have relatively low tensile strength and are
30 not useful in many situations. Another approach, sometimes practical, has been the use of staples for holding closed a wound for healing. The staples have

relatively high strength and save time, but are not as accurate as sutures, are bulky and painful to remove.

Surgical sutures having barbs, for providing a non-slip attribute in one direction, are shown in U.S. Pat. No. 3,123,077. In addition, in about the 1960s a
5 metal tendon suture was produced and tried, the suture having a single, large barb for gripping of the tendon tissue. The metal suture was not successful and may no longer be available, and the technique is outdated.

U.S. Pat. Nos. 5,425,747 and 5,584,859 disclose a type of "suture" having external barbs for holding together the two sides of an open wound. Although the
10 theory of operation of the suture devices of these two patents is similar to that of the present invention, these prior suture devices were in essence a single relatively rigid frame. the disclosed devices had "lateral members" with barbs, the lateral members being shaped somewhat like small spears which were to be inserted into the tissue on opposite sides of a wound, to bind the wound together.
15 The arrays of barbed, parallel-extending spears on both sides of the wound were held together by a "central body member" which lay within the wound and parallel to the length of the wound and which was secured to the barbed spears on each of the two sides. All of these components were described as being of bioabsorbable material. In the '859 patent, stretchable elastic connectors secured
20 the spear-like lateral members to the central body member, so as to impose a tension force to pull the two sides of the wound together.

The spear-like barbed lateral members of the two described patents were required to be pushed into the patient's tissue, and therefore had to be of sufficient stiffness and large enough diameter such as to be capable of being
25 pushed into the tissue. The resulting tissue securement would appear to be bulky and painful. The larger foreign body would tend to cause excessive scarring and would tend to increase the possibility for wound infections.

It is an object of the present invention to provide improved surgical sutures and improved surgical suture and needle combinations which facilitate improved
30 suturing techniques for closing wounds and severed tissues, and for performing cosmetic surgery such as face lifts, while minimizing scarring and providing a strong retaining force between the two side of tissue.

Summary of the Invention

In accordance with one aspect of the present invention, there is provided a surgical needle and suture combination, the combination comprising a surgical needle having a trailing end; a one-way suture having a series of exterior barbs providing for gripping of tissue in one direction only, the barbs permitting movement of the suture through tissue in the direction the needle is inserted; and a detachable connection means securing the trailing end of the needle to a leading end of the suture, for releasing the needle from the suture when the needle pulls the suture with a prescribed amount of tension. Herein, such a needle is referred to as a pull-away needle.

In accordance with another aspect of the present invention, there is provided a suture comprising a one-way suture having a series of exterior barbs providing for gripping of tissue in one direction only, wherein the barbs have a pre-selected depth from about 30 microns to about 100 microns, and having a leading end, the barbs permitting movement of the suture through tissue in the direction of the leading end.

In accordance with yet another aspect of the present invention, there is provided suture comprising a one-way suture having a series of exterior barbs providing for gripping of tissue in one direction only, and having a leading end, the barbs permitting movement of the suture through tissue in the direction of the leading end, and a surgical needle having a trailing end secured to the one-way suture.

In accordance with a further aspect of the present invention, there is provided a suture comprising a suture having a length and having barbs oriented in one direction for a first portion of the length of the suture and in a direction opposite to the one direction for a second portion of the length of the suture, wherein the barbs have a pre-selected depth from about 30 microns to about 100 microns.

In accordance with a still further aspect of the present invention, there is provided a suture comprising a suture having a length and having barbs oriented in one direction for a first portion of the length of the suture and in a direction opposite to the one direction for a second portion of the length of the suture, and a first surgical needle having a trailing end secured to the suture.

Herein, a suture having barbs oriented in one direction for a first portion of the suture length and in an opposite direction for a second portion of the suture length is referred to as a type of "one-way" suture.

The present invention also provides methods for producing one-way, 5
barbed sutures from suture material. More particularly, in accordance with a first one of such methods, the method comprises providing a suture material of about 100 to 500 microns in diameter; using a precision-formed cutting blade, cutting into the side of the suture material at an oblique angle, to a pre-selected depth; then removing the cutting blade to leave a barb on the side of the suture material 10
with orientation in one direction of the suture; and, repeating the cutting step at a series of locations along the length of the suture material and at different positions around the periphery of the suture material to produce a length of one-way suture with barbs oriented in a common direction.

In accordance with a second one of such methods, the method comprises 15
providing a suture material of about 100 to 500 microns in diameter; using a laser beam, machining the suture material to remove sections of suture material so as to produce barbs with orientation in one direction, thus producing a length of one-way suture with barbs oriented in a common direction.

In accordance with a third one of such methods, the method comprises 20
providing a suture material, having a side, a length, and a periphery; providing a cutting blade; cutting into the side of the suture material with the cutting blade at an oblique angle, to a pre-selected depth; removing the cutting blade to leave a barb on the side of the suture material with orientation in one direction of the suture; and, repeating the cutting and removing steps at a series of locations 25
along the length of the suture material to produce a length of one-way suture with barbs oriented in a common direction.

In accordance with a fourth one of such methods, the method comprises providing a suture material; providing a laser beam; directing a laser beam at the suture material with the laser beam so as to produce barbs with orientation in one 30
direction, thus producing a length of one-way suture with barbs oriented in a common direction.

In accordance with a fifth one of such methods, the method comprises providing a suture material having a side, a length and a periphery; providing a

cutting blade; cutting into the side of the suture material with the cutting blade at an oblique angle, to a pre-selected depth; removing the cutting blade to leave a barb on the side of the suture material with orientation in one direction of the suture; repeating the cutting and removing steps at a series of locations along the length of the suture material to produce a first portion of the suture with barbs oriented in a first direction; and, repeating the cutting and removing steps at another series of locations along the length of the suture material to produce a second portion of the suture with barbs oriented in a second direction opposite to the first direction.

10 In accordance with a sixth one of such methods, the method comprises providing a suture material; providing a laser beam; directing a laser beam at the suture material so as to produce barbs with orientation in one direction, thus producing a first portion of the suture with barbs oriented in a first direction; and, repeating the directing a laser beam step to produce a second portion of the suture with barbs oriented in a second direction opposite to the first direction.

15 As is described hereinafter in more detail, one machine for producing a barbed suture which is in accordance with the present invention comprises a pair of movable and parallel bars, each of the two bars having a surface and set of cutting blades on each respective surface, the two sets of cutting blades being in facing relationship and being of a size and spacing to form the barbs in a desired size and spacing. Each of the two bars with the two respective sets of cutting blades are adapted to converge inwardly and downwardly in order to engage the two sets of cutting blades into exterior walls of the suture material to produce cuts and adapted to be then removed from the cuts, thereby producing a barbed suture.

25 As is also described hereinafter in more detail, another machine for producing a barbed suture which is in accordance with the present invention comprises a pair of rotatable cutting wheels, each of the two wheels having a surface and set of cutting blades on each respective surface, the two sets of cutting blades being in facing relationship and being of a size and spacing to form the barbs in a desired size and spacing. Each of the two wheels with the two respective sets of cutting blades is adapted to converge inwardly and downwardly in order to engage the two sets of cutting blades into exterior walls of the suture

material to produce cuts and adapted to be then removed from the cuts, thereby producing a barbed suture.

Using one-way sutures as described above having barbs on their exterior surfaces and a needle on one or both ends, tissue can be bound. The one-way
 5 sutures allow passage of a needle-drawn suture in one direction through tissue but not in the opposite direction, thus having the capability to put tension in the tissue when tension is placed on the trailing end of the suture.

In a procedure for closing a wound or surgical incision, the one-way sutures are passed through tissue at each of the opposed sides of the wound,
 10 forming suture pairs in which trailing ends of the sutures are positioned generally in alignment at opposite sides of the wound. On insertion of each suture, the needle is pushed to extend out of the flesh at a point laterally remote from the wound, then the needle is pulled out to draw the suture to the desired position, and the suture is severed from the needle. The number of suture pairs is chosen
 15 in accordance with the size of the wound and the strength required to hold the wound closed.

Once all sutures are in place, the wound is closed (as by holding or clamping), and ends of the sutures of each suture pair are secured together, and this may be by heat bonding or surgical knots.

20 By the described method of using one-way sutures to hold closed a wound, loop stitching is avoided and scarring is minimized.

In addition to closing wounds at the skin surface, the one-way sutures are useful in binding together partially or completely severed tendons or other internal tissue of a patient or animal, providing considerable tensile strength with a
 25 minimum of suturing. The procedure locates the tensile support precisely where it is needed.

In facelifts and other cosmetic operations, the surgeon uses the one-way sutures to provide lines of tissue support beneath the skin.

In procedures using the one-way sutures, the sutures are hidden and may
 30 be left in place. If desired, however, they may be formed of bioabsorbable material.

In a variation of the above procedure, double-armed sutures are used, with first and second surgical needles oriented in opposite directions and a single

suture extending between the shank ends of the two needles. The suture has exterior barbs oriented in one direction for about half the length of the suture and in the opposite direction for the other half of the suture, each portion having the barbs oriented so as to allow movement along with the adjacent needle secured to the suture. In the double-armed suture procedure, the surgeon may fully insert one side of the suture at one side of the wound or severed tissue, then manually close the wound as he draws the opposite needle through the tissue to draw into place the other side of the suture, thus closing the wound as the double-armed suture is fully secured in position. Both needles are severed from the sutures at the points of exit from the tissue.

In another variation of the procedure, the surgeon can use a pull-away needle which as indicated above is detachable from the one-way suture when the needle is pulled with sufficient tension. This enables the surgeon to leave the barbed suture well below the skin, avoiding "puckering" of the skin from the pull of the barbed suture just below the skin surface can be done with double-armed sutures as well.

In a facelift operation, the surgeon selects one or more paths through the patient's tissue where lines of tissue support are needed. The surgeon selects a surgical needle of sufficient length to be inserted through one of the selected paths in the tissue, the needle having a shank end secured to a one-way suture with exterior barbs providing for gripping of the tissue in one direction only, the direction opposite that in which the needle is pushed through the tissue. The surgeon inserts the needle into the tissue, below the skin and along the selected path for the desired line of tissue support, until the needle extends out through the skin at a distal end of the selected path. Then the surgeon grips the needle from the point end and pulls it out of the tissue, leaving the one-way suture lying within the tissue along the selected path. The suture is then severed from the surgical needle, at a point below the skin, leaving the leading end of the one-way suture hidden beneath the skin at that distal end.

The surgeon repeats the above procedure for additional lines of tissue support, as needed for the particular facelift operation. Once all one-way sutures are in place along the desired lines of tissue support, the surgeon applies tension to the trailing end of each suture, such tension being in a direction opposite the

direction in which the needle was drawn, to engage the barbs against the internal tissue along the desired lines of tissue support. The trailing end of each suture is secured in such a way that the desired line of support is placed in tension. The trailing end of each suture may be secured to the patient's adjacent tissue, or to another one-way suture
 5 which extends in essentially an opposite direction, or a double armed opposing barbed suture can be used.

Accordingly, it is among the objects of the described invention to provide surgical sutures and surgical suture and needle combinations which enable efficient procedures for closing wounds, incisions and severed tissue such as tendons, joint
 10 capsules and ligaments, as well as to establish a highly efficient and invisible tissue support procedure, especially for facelift operations. These and other objects, advantages and features of the invention will be apparent from the following description of preferred embodiments, considered along with the accompanying drawings.

In a further aspect, there is provided a suture comprising:

15 a one-way suture having a series of exterior barbs, wherein all of the barbs are oriented in only one direction for gripping of tissue in the one direction only, the barbs have a pre-selected depth from about 30 microns to about 100 microns, and having a leading end, the barbs permitting movement of the suture through tissue in the direction of the leading end; wherein the suture is for attachment only to a single needle at the
 20 leading end.

Description of the Drawings

Fig. 1 is a view showing a surgical needle with a one-way suture secured to the
 25 shank end of the needle, the suture including barbs on its exterior surface.

Fig. 1A is a cross sectional view showing the suture of Fig. 1.

Fig. 2 is a cross sectional view showing a portion of a patient's skin and subcutaneous tissue, with a surgical wound or incision from the skin surface down into the tissue, and showing the use of the needle and one-way suture of Fig. 1.

Fig. 3 is a cross sectional view of patient tissue similar to Fig. 2, but showing use of a needle and suture at both sides of the wound or incision and showing an alternate method for removing the needle from the suture below the skin.

5 Fig. 4 is another cross sectional view similar to Fig. 2, but with the surgical needles removed and sutures severed from the needles below the skin surface and with trailing ends of the sutures extending into the open wound.

Fig. 5 is a schematic perspective view indicating a series of one-way sutures inserted at one side of a wound, at different levels.

Fig. 5A is a plan view showing the patient's skin with the wound still open, and showing a series of opposed suture pairs which have been put in place by the procedure shown in Figs. 2-4.

Fig. 6 is a cross sectional view similar to Fig. 4, but with the wound closed and showing a knot being tied to join trailing ends of a sutured pair.

Fig. 7 is a cross sectional view similar to Fig. 6, with the wound closed but with the suture ends being joined by a heat bonding technique.

Fig. 8 is an enlarged detail view showing the use of a device for performing the heat bonding of Fig. 7.

Fig. 9 is a view showing a double-armed suture, with two needles and a barbed suture extending between the needles, the suture having two sections with oppositely-directed barbs.

Fig. 10 is a cross sectional view similar to Figs. 6 and 7 showing a surface wound joined together with a double-armed suture such as shown in Fig. 9, the needles having been removed.

Fig. 11 is a view schematically showing a severed tendon joined together by one-way sutures, which in this case are shown as double-armed barbed sutures.

Fig. 12 is a schematic view indicating a facelift procedure using the one-way sutures of the invention.

Fig. 13-18 are views showing schematically several different techniques for production of the one-way sutures.

Description of Preferred Embodiments

Figure 1 shows schematically a suture 10 secured to the trailing end 12 of a surgical needle 14 in accordance with the invention. As described above, the suture 10 is a one-way suture, allowing its travel through tissue in one direction only, toward the left as viewed in Figure 1, due to the presence of a multiplicity of barbs 16 on the exterior surface of the suture. The barbs 16 are configured to engage against a patient's tissue, much in the manner of a bee's stinger or a porcupine's quill. The surgical needle 14 is long enough to serve the type of tissue repair to be addressed, so that the needle can be completely removed, leaving the suture in the desired position within the tissue.

Figure 1A shows in cross section an example of one type of barb configuration which can be used on the sutures of the invention. The suture 10, which may be about 100 to 500 microns in diameter, has the barbs 16 formed in a helical pattern; however, the barbs can also be formed in other patterns and by various means, as explained below.

Figure 2 indicates schematically a cross section of a patient's tissue 20, showing an open wound or surgical incision 22 with sides 24 and 26. The figure shows surgical needles 14a and 14b which have drawn one-way sutures 10 through the tissue, to points 28, 30 of exit from the skin. The barbed, one-way sutures 10 remain in the tissue, at desired locations (at two different levels in the wound, in this example), with trailing ends 10b of the sutures left extending into the wound 22. Again, the needles 14a and 14b are selected to be sufficiently long to extend through the entire path where the sutures 10 are to be placed.

In all cases the leading ends 10a of the sutures will be cut off so as to lie below the surface of the skin, which is easily accomplished by depressing the skin immediately around the suture and severing the suture closely against the skin, with the trailing end of the suture tensioned, then allowing the skin to cover the end of the suture. However, in many cases it is important that the skin surface not "pucker" inwardly due to tension in the suture just below the skin. This potential problem can be addressed in several ways. One procedure is to provide, and to select, the proper needle and suture combination for the particular situation to be addressed, such that the leading end 10a of the suture will be free of barbs in an initial region, for a selected distance. In Figure 2 one of the sutures 10 is shown with a dotted line 10c indicating a location where the barbs 16 commence, continuing toward the trailing end 10b of the suture. Thus, the region between the leading end 10a and the dashed line 10c is free of barbs, so that no tension is exerted in the tissue to pull downwardly on the skin. Another method for avoiding this potential problem, and under many circumstances the best method, is to use a pull-away needle/suture combination, in which the needle is detachable from the leading end of the suture when sufficient force is applied. One such system is marketed as De-tach by Davis and Geck. The De-tach needle requires a pulling force equal to about one-third the tensile strength of the suture itself, to pull the needle free of the suture. Such a detachable arrangement

can easily be made with the barbed sutures of the invention, such as by swaging a metal end of the needle over the leading end of the suture with just sufficient force to allow the suture to be pulled through tissue but still allowing the needle to be pulled free when deliberate force is applied. To use such a detachable needle
 5 system, the surgeon simply holds the trailing end 10b of the suture after the suture has been emplaced and pulls the needle with the force required to detach it.

One aspect of the invention is that the detachable needle preferably has at its base end length markings, e.g., at one centimeter intervals from the trailing
 10 end of the needle, to show the surgeon how far the suture end lies beneath the skin. With reference to such markings the surgeon can gauge the depth of the suture, predetermining the depth of needle-suture separation.

Figure 3 gives a schematic indication of this procedure. A suture 10d which has been inserted at a lower level in the patient's tissue 20, from near the
 15 bottom of a wound 22, has been detached from a needle 14c by pulling the leading end of the needle 14c firmly while holding the trailing end 10b of the implanted suture. As a result of this procedure, the surgeon can select a shorter suture than otherwise needed, can place the suture 10d in a more horizontal or skin-parallel position, correctly aligned with the desired tension to close the
 20 wound 22, and the leading end of the suture need not be brought through or even close to the skin surface. In addition, there is no need for a selection of needles/suture combinations with different lengths of barb-free "blank" regions behind the needle, as discussed relative to Figure 2.

The sutures in Figure 3 other than the suture 10d are not shown as having
 25 been placed with detachable needles, since the figure is meant to illustrate different techniques. Normally, but not necessarily, the same procedure would be used for all procedures around a particular wound.

Figure 3A shows a detachable needle 14c, with distance markings 14e at the base end of the needle. The needle 14c is detachably secured to the leading
 30 end 10a of a one-way suture 10.

Figures 3 and 4 show two different stages in the procedure using the one-way sutures of the invention. Figure 3 shows that the sutures are emplaced in pairs, so that corresponding juxtaposed sutures can be attached when the wound

is to be closed, and Figure 4 shows the sutures, in place under the skin, after removal of the needles. Once all suture pairs have been put in place, the trailing ends of the sutures will be ready for attachment together with the wound 22 held closed. Figure 5 shows schematically, in plan view, series of suture pairs, each pair having sutures implanted in opposite sides of the wound 22.

Figure 5 shows suture pairs 32a, 32b; 34a, 34b; 36a, 36b; 38a, 38b; 40a, 40b, etc. As indicated, any number of suture pairs can be arranged for tying or otherwise securing them together upon closure of the wound, so that the wound is closed successively from one end to the other and held closed by the connected one-way suture pairs, providing for healing without loop suturing at the surface.

Figure 5A schematically shows in cross section one side of the wound or surgical incision 22, showing trailing ends 10b of sutures extending into the wound, from sutures which have been pulled into position using surgical needles.

Figure 6 is a schematic view showing in cross section the tying of a pair of trailing ends 10b of sutures 10 which have been placed in the patient's tissue 20. In this case the sutures 10d are shown extending in positions generally parallel to the surface of the skin, drawn into position by detachable needles such as shown and described with reference to Figure 3. As mentioned above, the advantages of using this type of detachable needle are (1) the suture can be kept more parallel to the skin surface, so that the tension is pulling in the most efficient direction to close the wound; (2) the suture need not come out through the skin, and can be left deep beneath the skin, preventing any "puckering" of the skin; and (3) the suture can be shorter.

In Figure 6 the suture ends 10b are tied in a knot, as the wound 22 is held closed, and the tying and drawing of the knot tightly can actually help draw the wound closed.

However, Figures 7 and 8 show an alternative procedure for tying the suture ends together, in which a heat sealing device 42 is used to secure the suture ends together. The device 42 may be shaped generally in the form of a pair of tweezers, with an electrical cord 44 supplying power to an isolated tungsten filament 46 on a first leg 47 of the tool. As can be seen in Figures 7 and 8, a metal tip 48 of an opposite leg 49 has a recess or notch 50 which engages

the two suture ends 10d. With the two suture ends securely engaged in this notch 50, the two legs of the tweezer-like tool are brought together and the filament 46 contacts the suture ends and simultaneously severs the excess ends of the sutures and bonds the sutures together by fusion. The filament is heated
 5 instantaneously by closure of a remote switch. The blade tips 47 and 49 of the instrument act as a heat sink to protect the surrounding tissue.

The surgeon will need to hold or temporarily clamp the wound 22 together while using the heat bonding tool 42. By using the tool 42 the surgeon can quickly bond a series of suture pairs, both shallow and deep pairs, eliminating the
 10 surgical knot 41 which is left in the wound by the procedure of Figure 6.

Figure 9 shows a double-armed suture 55, similar to the barbed suture 10 described above but having barbs 16 oriented in one direction to one side of a division line 56 and in the opposite direction on the other side. As reviewed earlier, this enables the use of such one-way sutures to close and bind a wound
 15 without the need to secure suture ends together in the wound. The double-armed suture 55 of Figure 9 has a left side 55a and a right side 55b.

Figure 10 shows a wound 22 held closed by double-armed sutures 55 according to procedures using the invention. The double-armed sutures 55 have barb reversal points, such as shown at 56 in Figure 9, located at or close to the
 20 closed wound 22, such that the two sides of the double-armed suture each exert tension on tissue at the respective side of the wound. The upper suture 55 in Figure 10 is shown with cut-off leading ends 55c, which are just below the surface of the skin in accordance with the first form of the invention described above, wherein the sutures are severed at the skin and the skin springs back
 25 over the severed ends 55c to cover them. However, the lower double-armed suture 55 shown in Figure 10 is shown with terminal leading ends 55c which are well down into the tissue, far below the skin surface 58. This is merely for the purpose of illustration and not to suggest that the suturing procedure should be different for the lower suture 55 than for the upper suture 55, although this can be
 30 done. The lower suture in Figure 10 is emplaced by the procedure shown on the lower left in Figure 3, by a pull-away needle, similar to the De-tach needle/suture combination described above, such that the suture can be drawn more horizontally through the tissue and can be left far below the skin. The patient's

tissue is flexible and pliable, and in most cases the surgeon can insert the needle horizontally, then make what is in effect a rather pronounced turn with the needle up toward the surface, by manipulating the skin to angle the needle toward the surface.

5 The procedure for use of the double-armed sutures 55 is described above, preferably involving first inserting one end of the suture through the tissue to the position desired, with the transition point or barb reversal point 56 located in the wound; then inserting the opposed needle of the double-armed suture into the tissue at the other side of the wound, and drawing this second arm of the suture
10 tight while closing the wound 22, to the closed position shown in Figure 10. The needles are removed after the suture ends are properly in place.

 Figure 11 shows double-armed sutures 60 used to repair a severed tendon 62. Figure 11 shows the use of double armed sutures, but the simpler barbed sutures shown in Figures 1 through 8 could also be used. In this case
15 there is no concern with "puckering" of the surface, so that the leading ends 60a of the sutures can be simply cut off at the surface of the tendon 62, as generally indicated in the figure. Again, if a double-armed suture 60 is used, the point of barb direction reversal will be located at or very close to the tendon wound 64.

 Figure 12 is a schematic illustration indicating procedures using the
20 invention in facelift surgery. A facelift patient 70 has a long surgical incision 72, in which skin has been elevated in order to tighten the facial skin, providing tissue support to remove some of the effects of aging. The drawing indicates a series of suture pairs 73a, 73b, . . . 73g, 73h and 73i, which may also be double-armed sutures as described above. As in the surface wound closure situations described
25 and illustrated above, the suture pairs (or double-armed sutures) have barbs for engaging the tissue and gripping the tissue in one direction, so as to pull the tissue toward the surgical wound 72. When each of the suture pairs or double-armed sutures 73a, 73b, etc. has been inserted and the wound has been closed at each suture, the sutures will hold and bind the wound tightly closed, without
30 loop stitching, staples or other means, resulting in reduced scarring. The one-way sutures may be on elongated paths, and the sutures themselves can provide tissue support in the facelift operation, rather than relying solely on the removal of skin at the wound 72 for tightening of the facial tissue. Figure 12 shows only one

example; the one-way sutures of the invention, whether in pairs or alone, can be used in a number of different ways for tissue support. The one-way sutures, inserted along lines beneath the skin, can support the subcutaneous layers better than current procedures.

5 Figure 13 shows schematically one method for producing one-way sutures for use in the invention. A pair of parallel and movable bars 80, 81 have cutting blades 83 on one surface, the two sets of cutting blades being in facing relationship and being of a size and spacing to form the suture barbs in the size and spacing desired. The cutting blades are precision-formed, since the raw
10 suture 84, which may be nylon or other suitable material, has a small diameter which may be in the range of about 100 to 500 microns. As an example, the barb spacings can be from about 100 microns to about 1 millimeter or even greater. The depth of the barbs formed in the suture material can be about 30 microns to 100 microns, depending, to a large extent, on the diameter of the suture material.

15 As indicated in Figure 13, the two bars 80 and 81, with the cutting blades 83, are in a machine which converges them inwardly and downwardly, with reference to the figure, to engage the cutting blades into the exterior walls of the suture filament material 84. The suture material is held stable during this operation, or the suture is advanced upwardly while the bars 80, 81 are moved
20 only inwardly. The distance of relative longitudinal movement between the bars and the suture will determine the depth of the barbs formed, limited by the length of the cutting blades 83 themselves.

 Figure 14 shows a resulting barbed suture 84a as produced by the device shown in Figure 13. Barbs 86 are closely spaced in the suture 84a, and can be
25 farther apart or in different configurations if desired. As the figure indicates, the barbs 86 are on opposite sides of the suture due to the method of their formation, and they extend outwardly somewhat on the suture due to the manufacturing process, wherein the cutting blades 83 may be removed from the cuts by simply spreading the two bars 80 and 81 (Figure 13) outwardly, without longitudinal
30 movement of the suture material 84.

 Figure 15 schematically indicates another method for forming a barbed suture 88a from suture filament material 88 such as nylon (or other suitable materials, including resorbable materials as discussed above). This method is

somewhat similar to that of Figure 13, but with rotating cutting wheels 90. These cutting wheels 90 may have cutting blades 92 somewhat similar to the cutting blades 83 shown in Figure 13. In this production method, the nylon suture material 88 is held with sufficient tension to cause the blades 92 of the wheels 90 to cut into the nylon, forming the barbs 94. The suture being formed nonetheless advances with the motion of the opposed cutting wheels 90, against the imposed resistance. Again, when the cutting blades 92 are pulled free from the formed barbs 94, this pulls outwardly on each barb and causes the barb to protrude slightly from the body of the suture, setting the barbs up for better engagement with the tissue during use.

Figure 16 indicates a barbed suture 96 having barbs 98 in staggered positions. Such a suture may be formed by a method generally similar to what is shown in Figures 13 and 15, but with cutting blades staggered as to height and in different positions around the periphery of the suture material. Figures 17 and 18 indicate another system for producing barbed sutures in accordance with the invention. Figure 17 shows a raw suture filament 100, which may be about 100 to 500 microns in diameter, being cut into a barbed suture 102 by laser machining.

As schematically indicated, a laser beam is directed at the cross hatched areas 104 in

Figure 17, removing these sections to produce barbs 106 as shown in Figure 18. The barbs can be on opposed sides of the suture, as shown, and staggered if desired. Further, they can be positioned in a spiral pattern if desired, as by rotating the suture filament 100 or moving the laser around the filament, during the material removal operation. Industrial lasers are capable of being focused very sharply, easily down to the range required for this laser machining operation.

Procedures described herein are useful in animal suturing as well as human.

I CLAIM:

1. A method for producing one-way, barbed sutures from suture material comprising:

providing a suture material of about 100 to 500 microns in diameter,

using a precision-formed cutting blade, cutting into the side of the suture material at an oblique angle, to a pre-selected depth,

then removing the cutting blade to leave a barb on the side of the suture material with orientation in one direction of the suture, and

repeating the cutting step at a series of locations along the length of the suture material and at different positions around the periphery of the suture material to produce a length of one-way suture with barbs oriented in a common direction.
2. The method of claim 1, wherein the step of removing the cutting blade includes removing the blade in such a way as to cause the barbs to extend outwardly somewhat on the suture.
3. The method of claim 1, wherein the pre-selected depth of the barbs formed on the suture material is about 30 microns to about 100 microns.
4. The method of claim 1, wherein the cutting step is performed by a machine having a pair of parallel and moveable bars each with a plurality of cutting blades facing toward the suture material, the cutting blades being set at an oblique angle on the movable bars relative to the suture material, and including converging the bars with cutting blades inwardly and longitudinally relative to the suture material to form a series of barbs simultaneously.
5. The method of claim 4, wherein, on removal of the cutting blades, the bars are spread apart without longitudinal movement relative to the suture material, thus causing the formed barbs to extend outwardly somewhat on the suture.

6. The method of claim 1, wherein the step of cutting in the suture material to form the barbs comprises using a pair of counter-rotating cutting wheels each having cutting blades on their outer surfaces, the cutting blades being set obliquely relative to the suture material which passes between the cutting blades, and including holding the suture material to impose a resistance against movement of the suture material with motion of the cutting blades, the imposed resistance being sufficient to cause the cutting blades to cut into the sides of the suture material while still allowing the suture material to advance with the motion of the opposed cutting wheel, the imposed resistance also causing the barbs to extend outwardly somewhat on the suture.
7. The method of claim 1, wherein the barbs are formed at staggered positions along the suture material.
8. A method for producing one-way, barbed sutures from suture material comprising:

providing a suture material of about 100 to 500 microns in diameter,

using a laser beam, machining the suture material to remove sections of suture material so as to produce barbs with orientation in one direction, thus producing a length of one-way suture with barbs oriented in a common direction.
9. The method of claim 8, wherein the barbs are formed at staggered positions along the suture material.
10. The method of claim 8, wherein the barbs are formed in a spiral pattern on the suture material.
11. The method of claim 1, wherein the barbs are formed at helical positions along the suture material.
12. The method of claim 1, wherein the barbs are formed at opposing positions on either side along the suture material.
13. The method of claim 1, wherein the cutting blade moves inwardly and downwardly into the side of the suture material relative to the length of the suture material.

14. The method of claim 13, wherein a plurality of cutting blades is used to cut into the side of the suture material.
15. The method of claim 1, wherein the step of cutting into the side of the suture material with the cutting blade includes the cutting blade moving inwardly while the suture material is advanced upwardly relative to the length of the suture material.
16. The method of claim 15, wherein a plurality of cutting blades is used to cut into the side of the suture material.
17. The method of claim 1, wherein the barbs extend outwardly somewhat on the suture.
18. The method of claim 1, further including a surgical needle having a trailing end secured to the one-way suture.
19. The method of claim 1, wherein the suture is formed of non-absorbable material.
20. The method of claim 1, wherein the suture is formed of bioabsorbable material.
21. The method of claim 8, further including a surgical needle having a trailing end secured to the one-way suture.
22. The method of claim 8, wherein the suture is formed of non-absorbable material.
23. The method of claim 8, wherein the suture is formed of bioabsorbable material.
24. The method of claim 8, wherein the barbs are formed at opposing positions on either side along the suture material.
25. The method of claim 8, wherein the suture material has a periphery, and the machining step is at a series of locations along the length of the suture material and at different positions around the periphery of the suture material.
26. A method for producing a one-way barbed suture from suture material comprising:

providing a suture material, having a side, a length, and a periphery,

providing a cutting blade,

cutting into the side of the suture material with the cutting blade at an oblique angle, to a pre-selected depth,

removing the cutting blade to leave a barb on the side of the suture material with orientation in one direction of the suture, and

repeating the cutting and removing steps at a series of locations along the length of the suture material to produce a length of one-way suture with barbs oriented in a common direction.

27. The method of claim 26, wherein the barbs extend outwardly somewhat on the suture.

28. The method of claim 26, wherein the step of removing the cutting blade includes removing the blade in such a way as to cause the barbs to extend outwardly from the periphery of the suture.

29. The method of claim 26, wherein the pre-selected depth of the barbs formed on the suture material is about 30 microns to about 100 microns.

30. The method of claim 26, wherein the cutting step is performed by a machine having a pair of parallel and moveable bars each with a plurality of cutting blades facing toward the suture material, the cutting blades being set at an oblique angle on the movable bars relative to the suture material, and including converging the bars with cutting blades inwardly and longitudinally relative to the suture material to form a series of barbs simultaneously.

31. The method of claim 30, wherein the step of removing the cutting blades comprises moving the bars apart without longitudinal movement relative to the suture material thus causing the formed barbs to extend outwardly from the periphery of the suture.

32. The method of claim 26, wherein the step of cutting into the suture material to form the barbs comprises using a pair of counter-rotating cutting wheels each having an outer surface and having cutting blades on the respective outer surfaces, the cutting blades being

set obliquely relative to the suture material which passes between the cutting blades, and including holding the suture material to impose a resistance against movement of the suture material with motion of the cutting blades, the imposed resistance being sufficient to cause the cutting blades to cut into the side of the suture material while still allowing the suture material to advance with the motion of the opposed cutting wheels, the imposed resistance also causing the barbs to extend outwardly from the periphery of the suture.

33. The method of claim 26, wherein the barbs are formed at staggered positions along the suture material.

34. The method of claim 26, wherein the barbs are formed at helical positions along the suture material.

35. The method of claim 26, wherein the barbs are formed at opposing positions on either side along the suture material.

36. The method of claim 26, wherein the cutting blade moves inwardly and downwardly into the side of the suture material relative to the length of the suture material.

37. The method of claim 36, wherein a plurality of cutting blades is used to cut into the side of the suture material.

38. The method of claim 26, wherein the step of cutting into the side of the suture material with the cutting blade includes the cutting blade moving inwardly while the suture material is advanced upwardly relative to the length of the suture material.

39. The method of claim 26, wherein a plurality of cutting blades is used to cut into the side of the suture material.

40. The method of claim 26, wherein repeating the cutting and removing steps is at a series of locations along the length of the suture material and at different positions around the periphery of the suture material.

41. The method of claim 26, further including a surgical needle having a trailing end secured to the one-way suture.

42. The method of claim 26, wherein the suture is formed of non-absorbable material.

43. The method of claim 26, wherein the suture is formed of bioabsorbable material.
44. A method for producing a one-way, barbed suture from suture material comprising:

providing a suture material, providing a laser beam,

directing a laser beam at the suture material with the laser beam so as to produce barbs with orientation in one direction, thus producing a length of one-way suture with barbs oriented in a common direction.
45. The method of claim 44, wherein the barbs are formed at staggered positions along the suture material.
46. The method of claim 44, wherein the barbs are formed in a spiral pattern on the suture material.
47. The method of claim 44, wherein the barbs have a pre-selected depth from about 30 microns to about 100 microns.
48. The method of claim 44, wherein the barbs extend outwardly somewhat on the suture.
49. The method of claim 44, wherein the barbs are at opposing positions on either side along the suture.
50. The method of claim 44, wherein the suture is about 100 to 500 microns in diameter.
51. The method of claim 44, further including a surgical needle having a trailing end secured to the one-way suture.
52. The method of claim 44, wherein the suture is formed of non-absorbable material.
53. The method of claim 44, wherein the suture is formed of bioabsorbable material.
54. The method of claim 44, wherein the cutting step is at a series of locations along the length of the suture material and at different positions around the periphery of the suture material.

55. A method for producing a barbed suture comprising:

providing a suture material having a side, a length and a periphery, providing a cutting blade,

cutting into the side of the suture material with the cutting blade at an oblique angle, to a pre-selected depth,

removing the cutting blade to leave a barb on the side of the suture material with orientation in one direction of the suture, and

repeating the cutting and removing steps at a series of locations along the length of the suture material to produce a first portion of the suture with barbs oriented in a first direction, and

repeating the cutting and removing steps at another series of locations along the length of the suture material to produce a second portion of the suture with barbs oriented in a second direction opposite to the first direction.

56. The method of claim 55, wherein the barbs extend outwardly somewhat on the suture.

57. The method of claim 56, wherein the step of removing the cutting blade includes removing the blade in such a way as to cause the barbs to extend outwardly from the periphery of the suture.

58. The method of claim 55, wherein the pre-selected depth of the barbs formed on the suture material is about 30 microns to about 100 microns.

59. The method of claim 55, wherein the cutting step is performed by a machine having a pair of parallel and moveable bars each with a plurality of cutting blades facing toward the suture material, the cutting blades being set at an oblique angle on the movable bars relative to the suture material, and including converging the bars with cutting blades inwardly and longitudinally relative to the suture material to form a series of barbs simultaneously.

60. The method of claim 59, wherein the step of removing the cutting blades comprises moving the bars apart without longitudinal movement relative to the suture material, thus causing the formed barbs to extend outwardly from the periphery of the suture.

61. The method of claim 55, wherein the step of cutting into the suture material to form the barbs comprises using a pair of counter-rotating cutting wheels each having an outer surface and having cutting blades on the respective outer surfaces, the cutting blades being set obliquely relative to the suture material which passes between the cutting blades, and including holding the suture material to impose a resistance against movement of the suture material with motion of the cutting blades, the imposed resistance being sufficient to cause the cutting blades to cut into the side of the suture material while still allowing the suture material to advance with the motion of the opposed cutting wheels, the imposed resistance also causing the barbs to extend outwardly from the periphery of the suture.

62. The method of claim 55, wherein the barbs are formed at staggered positions along the suture material.

63. The method of claim 55, wherein the barbs are formed at helical positions along the suture material.

64. The method of claim 55, wherein the barbs are formed at opposing positions on either side along the suture material.

65. The method of claim 55, wherein the cutting blade moves inwardly and downwardly into the side of the suture material relative to the length of the suture material.

66. The method of claim 65, wherein a plurality of cutting blades is used to cut into the side of the suture material.

67. The method of claim 55, wherein the step of cutting into the side of the suture material with the cutting blade includes the cutting blade moving inwardly while the suture material is advanced upwardly relative to the length of the suture material.

68. The method of claim 67, wherein a plurality of cutting blades is used to cut into the side of the suture material.

69. The method of claim 55, wherein the repeating steps are at a series of locations along the length of the suture material and at different positions around the periphery of the suture material.
70. The method of claim 55, wherein the suture is about 100 to 500 microns in diameter.
71. The method of claim 55, further including a surgical needle having a trailing end secured to the suture.
72. The method of claim 55, wherein the suture is formed of non-absorbable material.
73. The method of claim 55, wherein the suture is formed of bioabsorbable material.
74. A method for producing a barbed suture comprising:
- providing a suture material, providing a laser beam,
- directing a laser beam at the suture material so as to produce barbs with
- orientation in one direction, thus producing a first portion of the suture with barbs oriented in a first direction, and
- repeating the directing a laser beam step to produce a second portion of the suture with barbs oriented in a second direction opposite to the first direction.
75. The method of claim 74, wherein the barbs are formed at staggered positions along the suture material.
76. The method of claim 74, wherein the barbs are formed in a spiral pattern on the suture material.
77. The method of claim 74, wherein the barbs have a pre-selected depth from about 30 microns to about 100 microns.
78. The method of claim 74, wherein the barbs extend outwardly somewhat on the suture.

79. The method of claim 74, wherein the barbs are at opposing positions on either side along the suture.

80. The method of claim 74, wherein the suture is about 100 to 500 microns in diameter.

81. The method of claim 74, further including a surgical needle having a trailing end secured to the double-armed suture.

82. The method of claim 74, wherein the suture is formed of non-absorbable material.

83. The method of claim 74, wherein the suture is formed of bioabsorbable material.

84. The method of claim 74, wherein the directing a laser beam steps are at a series of locations along the length of the suture material and at different positions around the periphery of the suture material.

85. A machine for producing a barbed suture from suture material, the suture material having exterior walls, said machine comprising:

a pair of movable and parallel bars, each of the two bars having a surface and set of cutting blades on each respective surface, the two sets of cutting blades being in facing relationship and being of a size and spacing to form the barbs in a desired size and spacing,

each of the two bars with the two respective sets of cutting blades being adapted to converge inwardly and downwardly in order to engage the two sets of cutting blades into the exterior walls of the suture material to produce cuts and adapted to be then removed from the cuts, thereby producing a barbed suture.

86. The machine according to claim 85, wherein the bars are adapted for the blades to cut while the suture material is held stable and the bars are moved inwardly and downwardly.

87. The machine according to claim 85, wherein the bars are adapted for the blades to cut while the suture material is advanced upwardly and the bars are moved inwardly.

88. The machine according to claim 85, wherein the bars are adapted to be removed from the cuts by spreading the two bars outwardly, without longitudinal movement of the cut suture material.

89. A machine for producing a barbed suture from suture material, the suture material having exterior walls, said machine comprising:

a pair of rotatable cutting wheels, each of the two wheels having a surface and set of cutting blades on each respective surface, the two sets of cutting blades being in facing relationship and being of a size and spacing to form the barbs in a desired size and spacing,

each of the two wheels with the two respective sets of cutting blades being adapted to converge inwardly and downwardly in order to engage the two sets of cutting blades into the exterior walls of the suture material to produce cuts and adapted to be then removed from the cuts, thereby producing a barbed suture.

90. The machine according to claim 89, wherein the wheels are adapted for the blades to cut while the suture material is held stable and the wheels are moved inwardly and downwardly.

91. The machine according to claim 89, wherein the wheels are adapted for the blades to cut while the suture material is advanced upwardly and the wheels are moved inwardly.

92. The machine according to claim 89, wherein the wheels are adapted to be removed from the cuts by spreading the two wheels outwardly, without longitudinal movement of the cut suture material.

Fig. 1

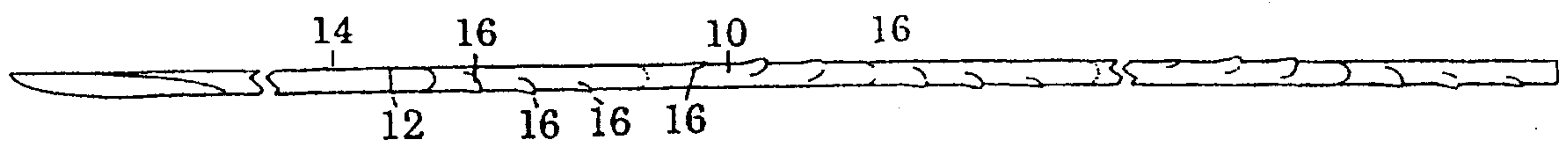


Fig. 1A

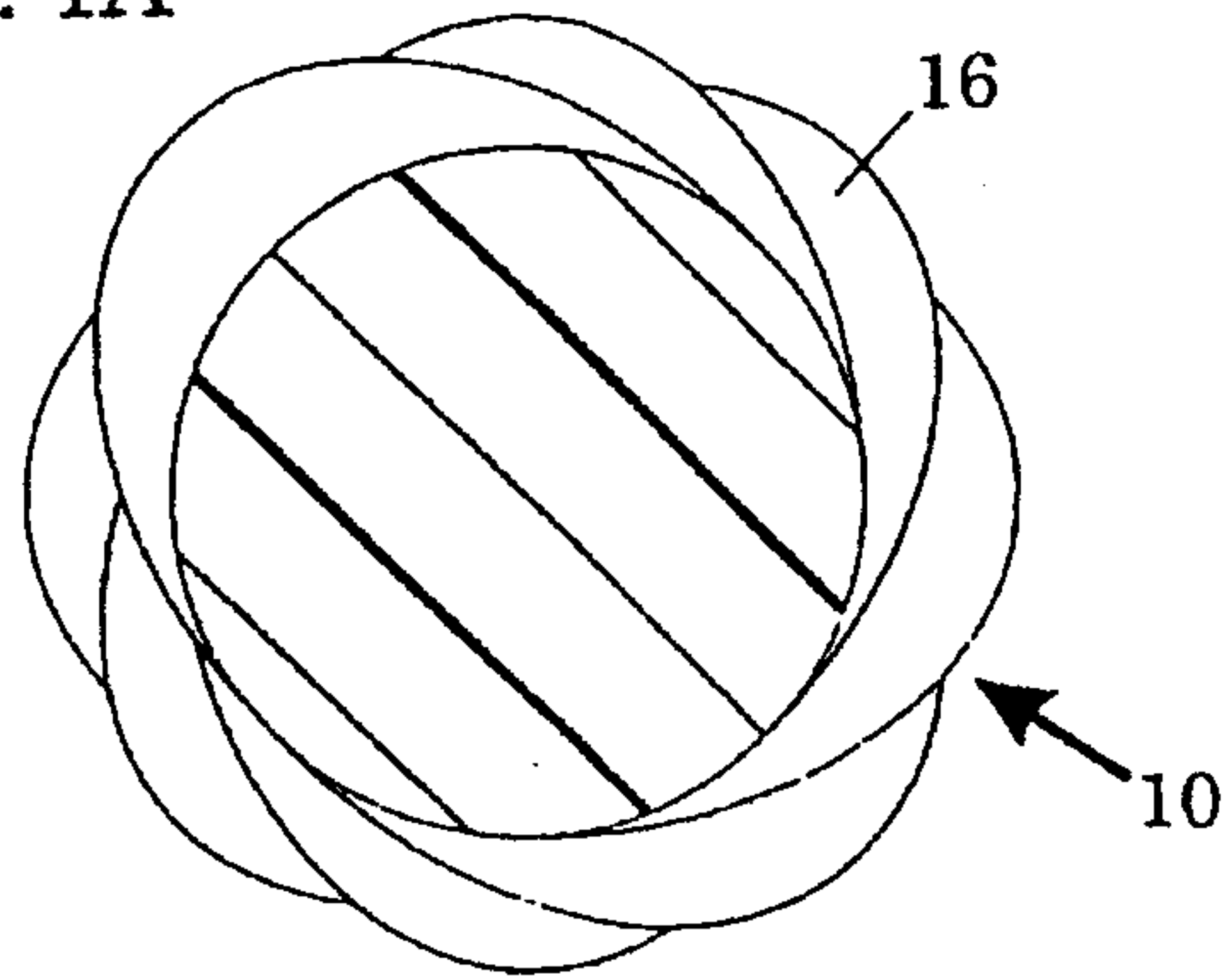


Fig. 2

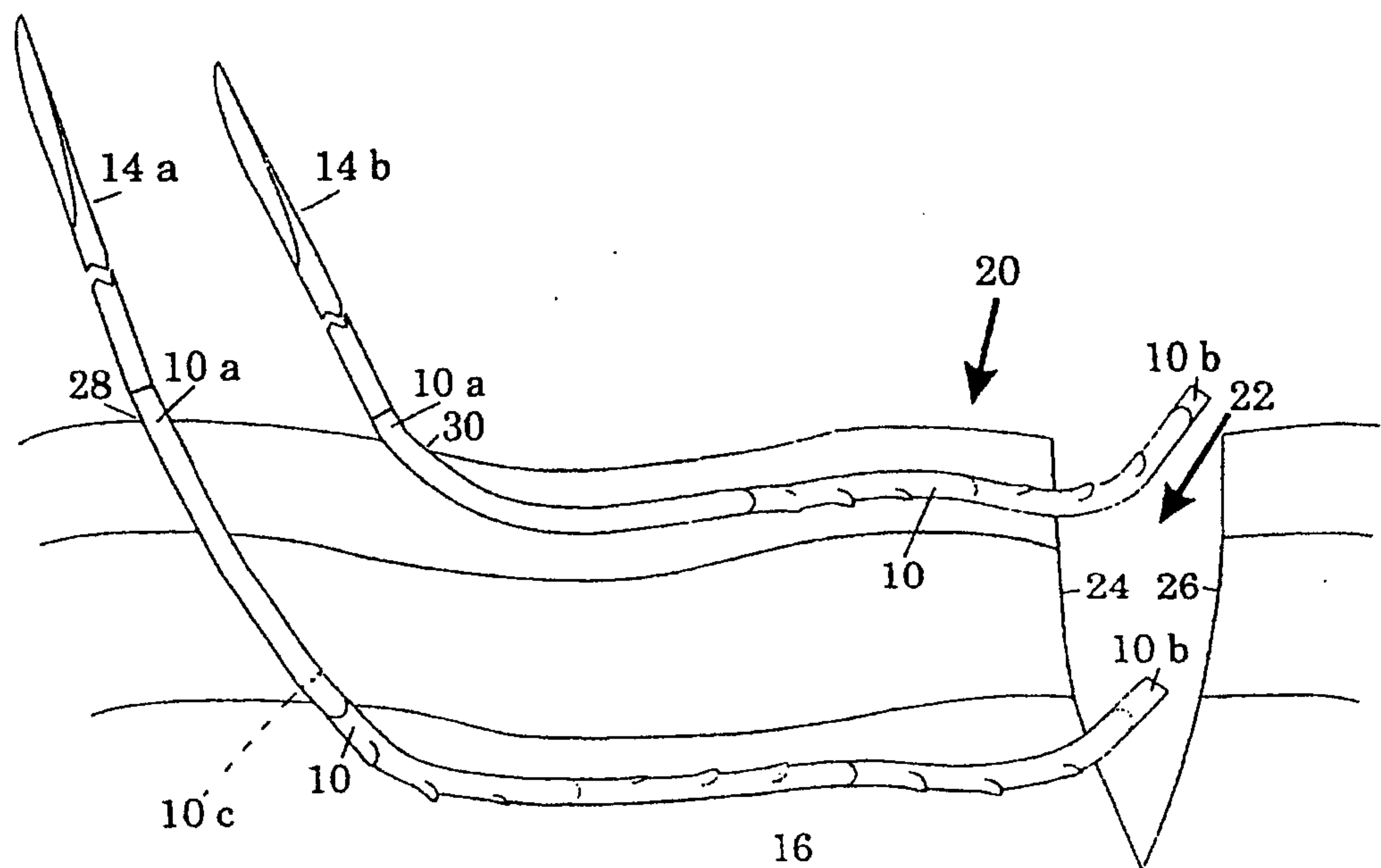


Fig. 3

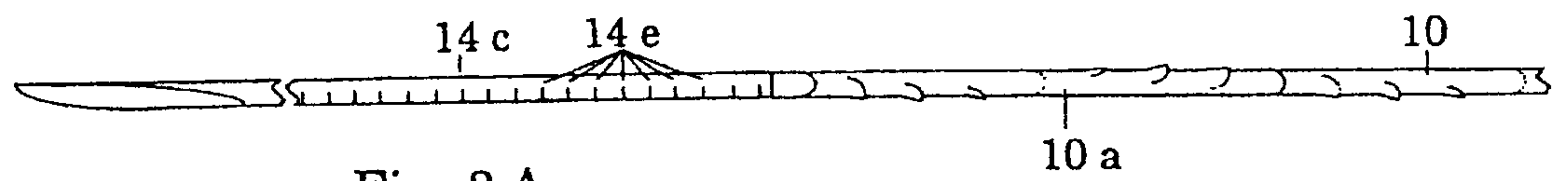
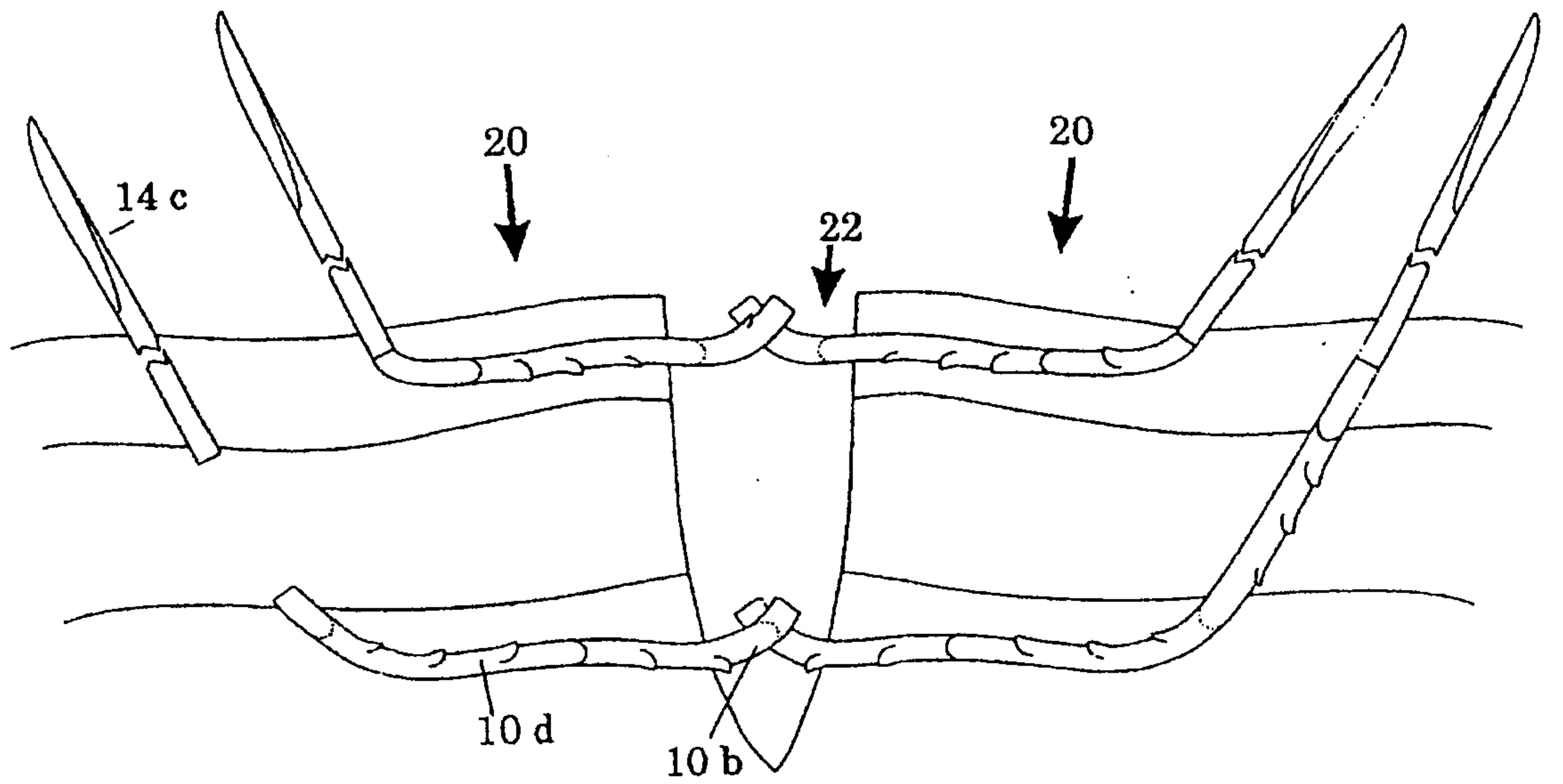
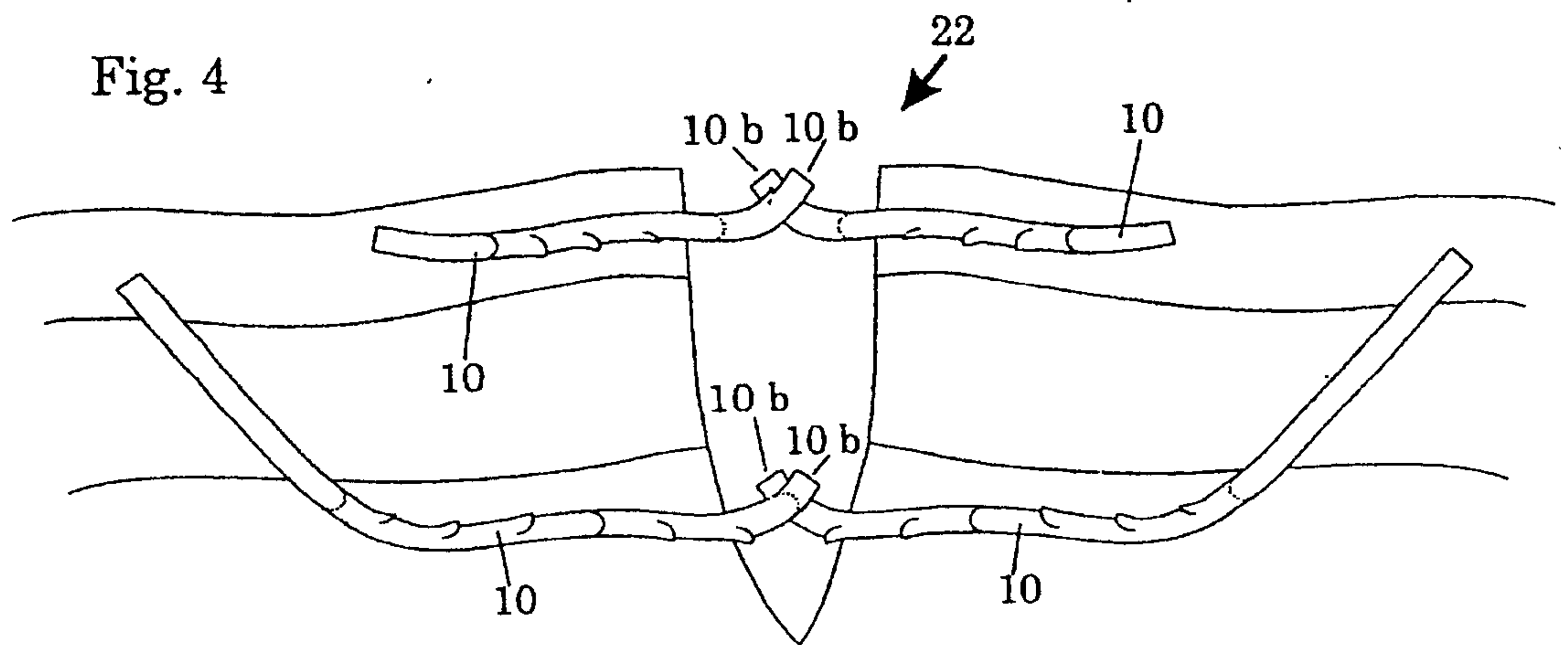


Fig. 3 A

Fig. 4



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Fig. 5a

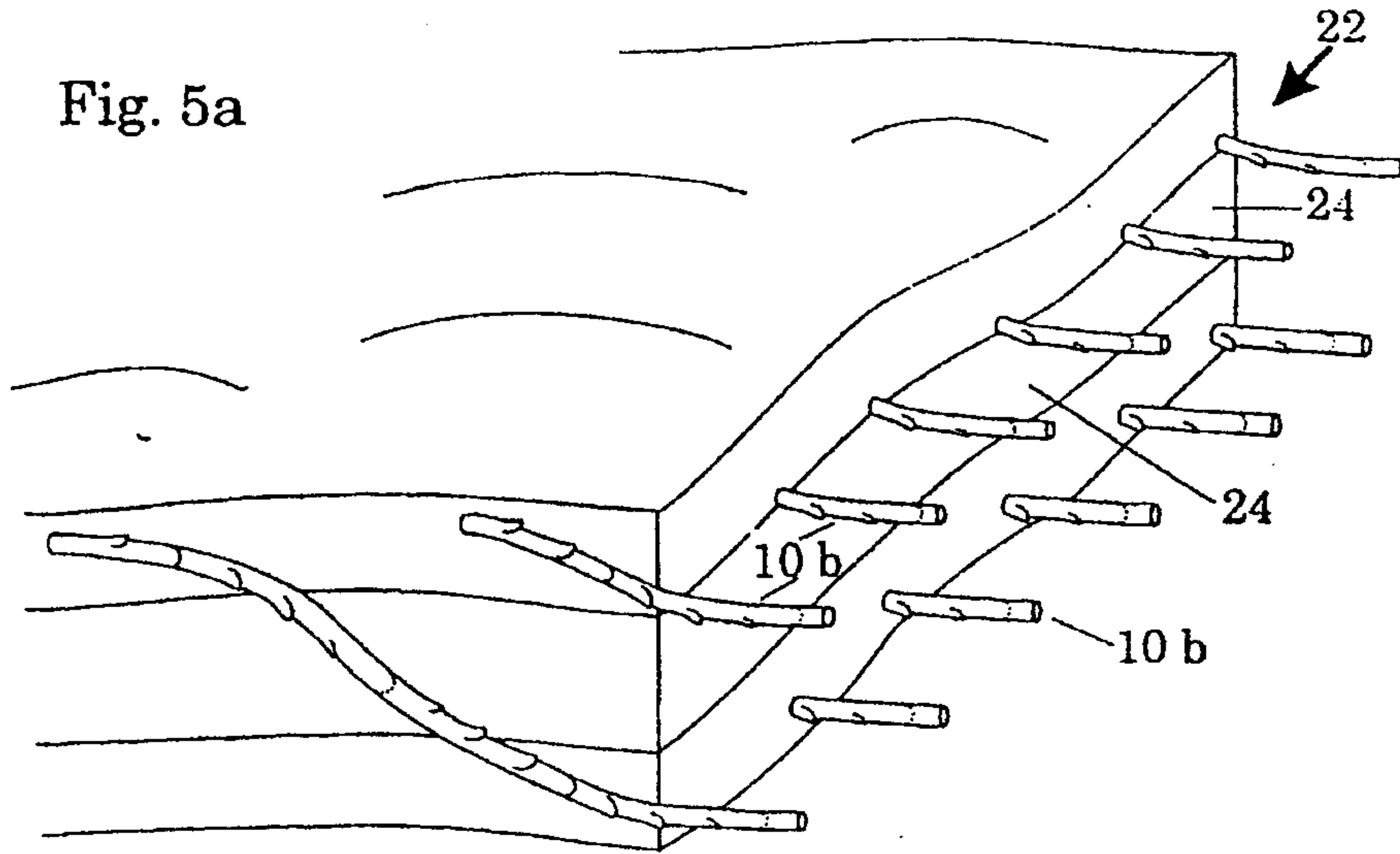


Fig. 5.

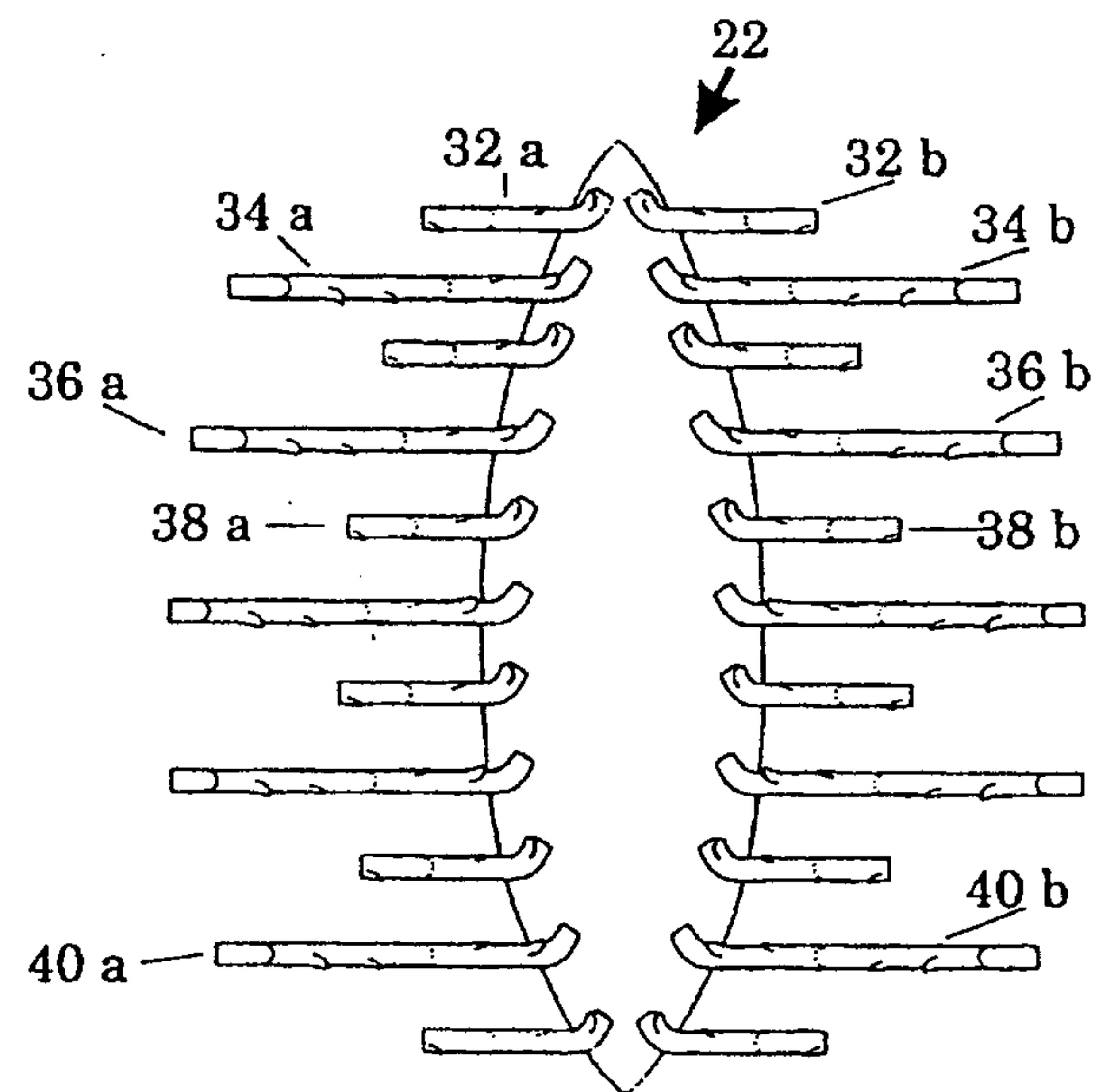
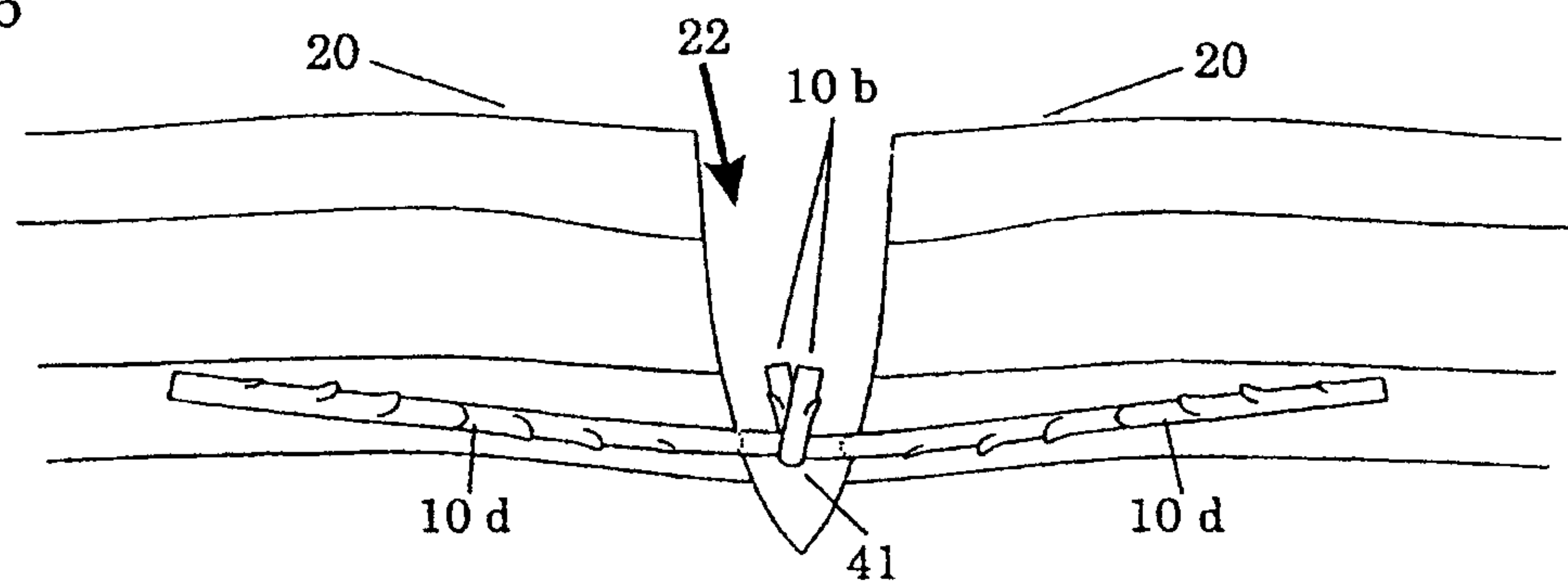
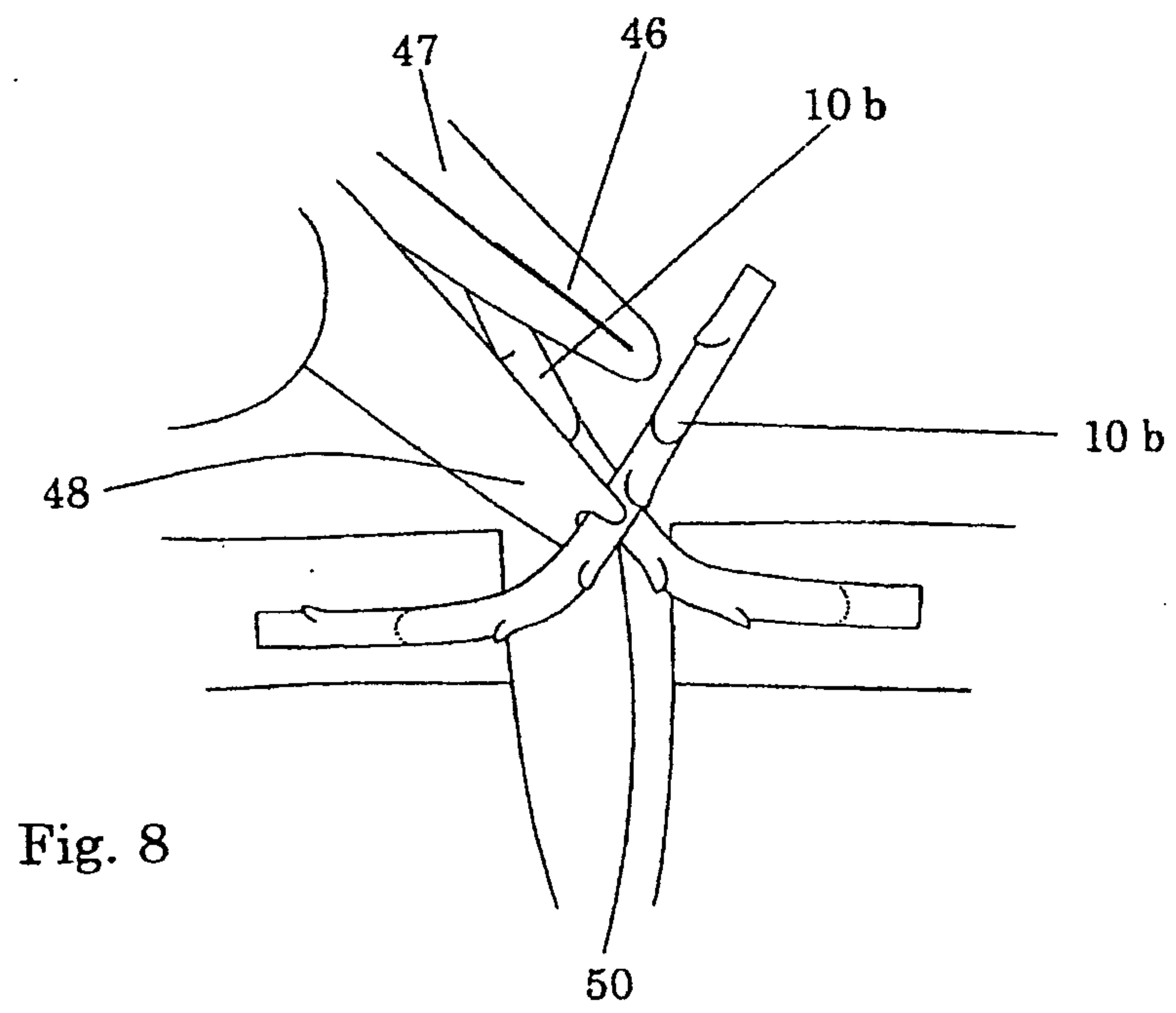
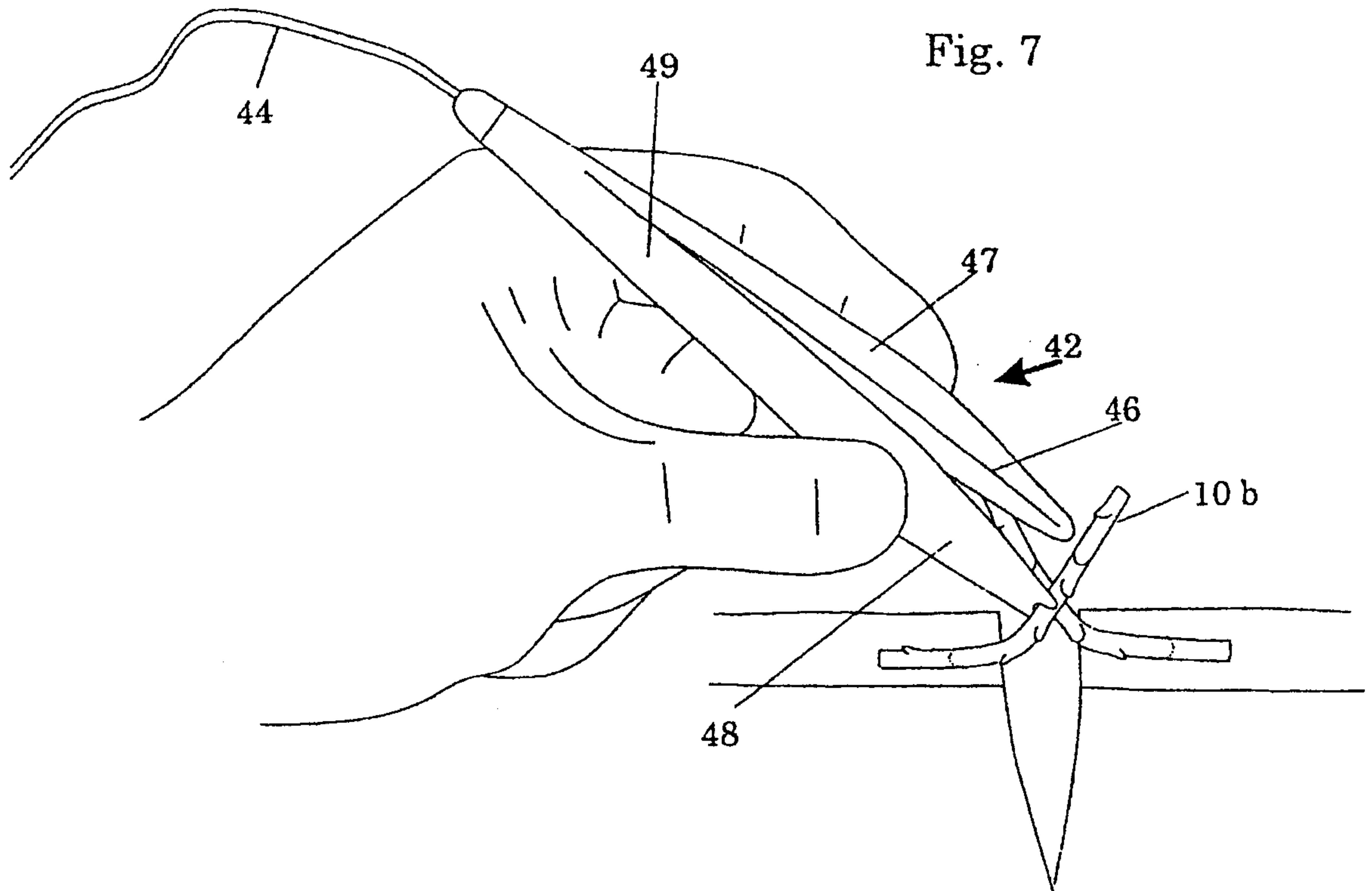


Fig. 6



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Fig. 7



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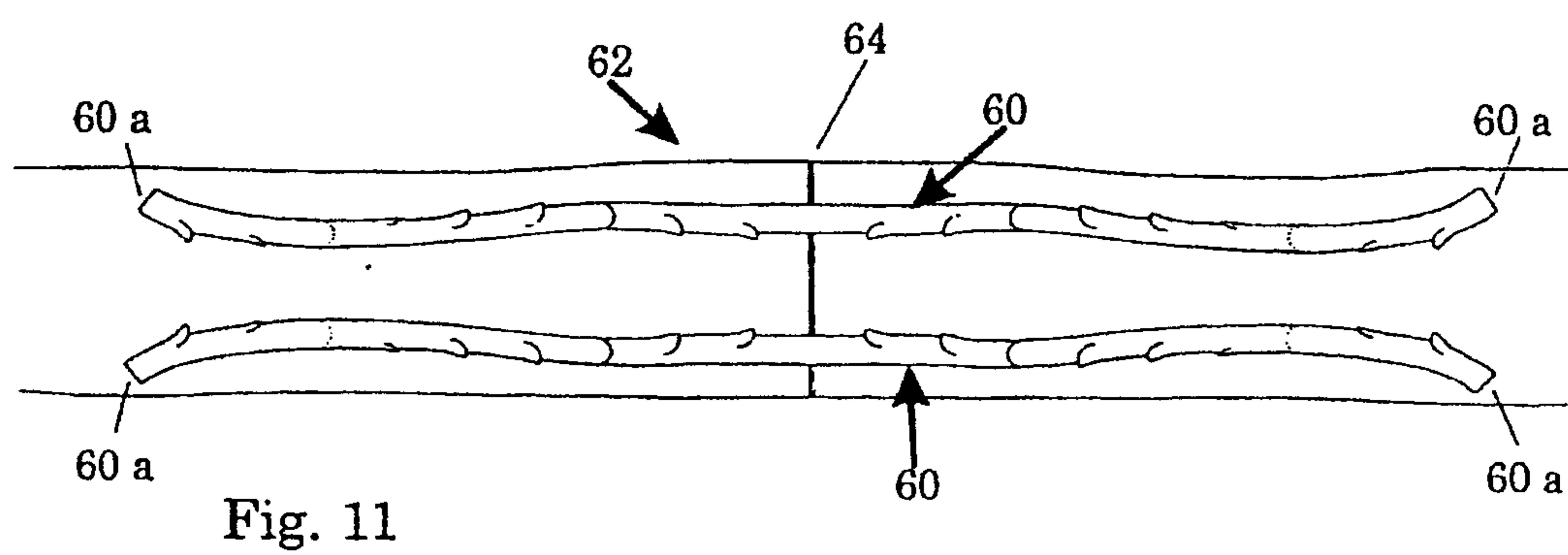
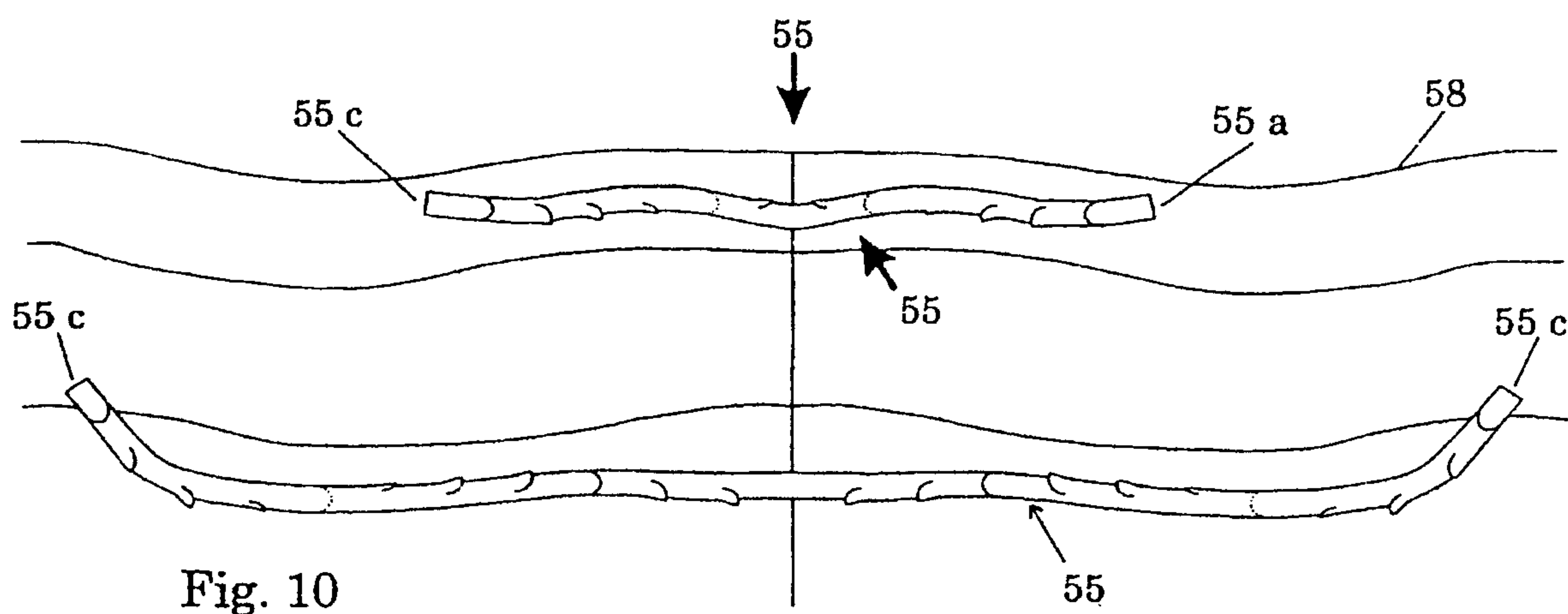
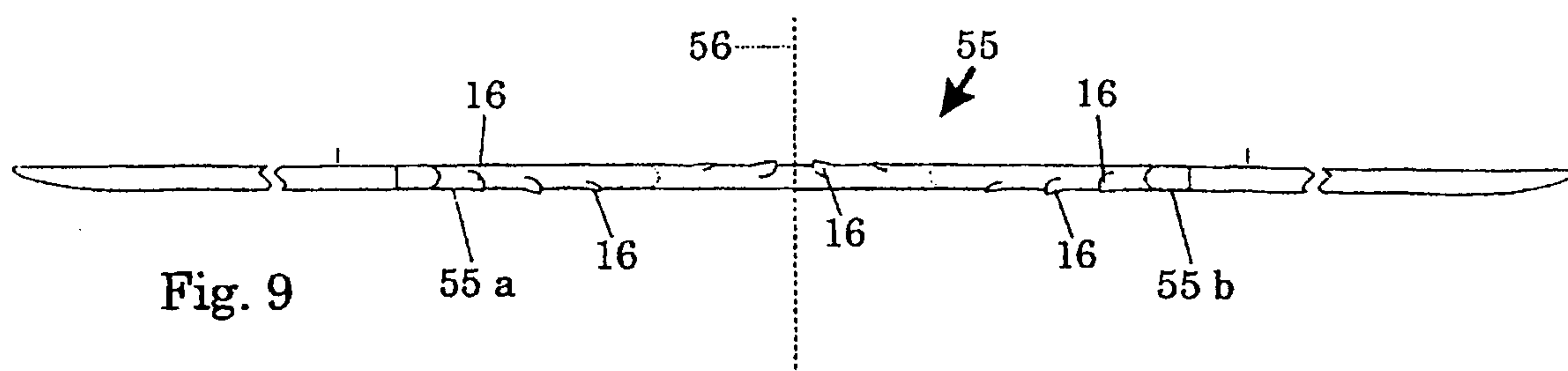


Fig. 12

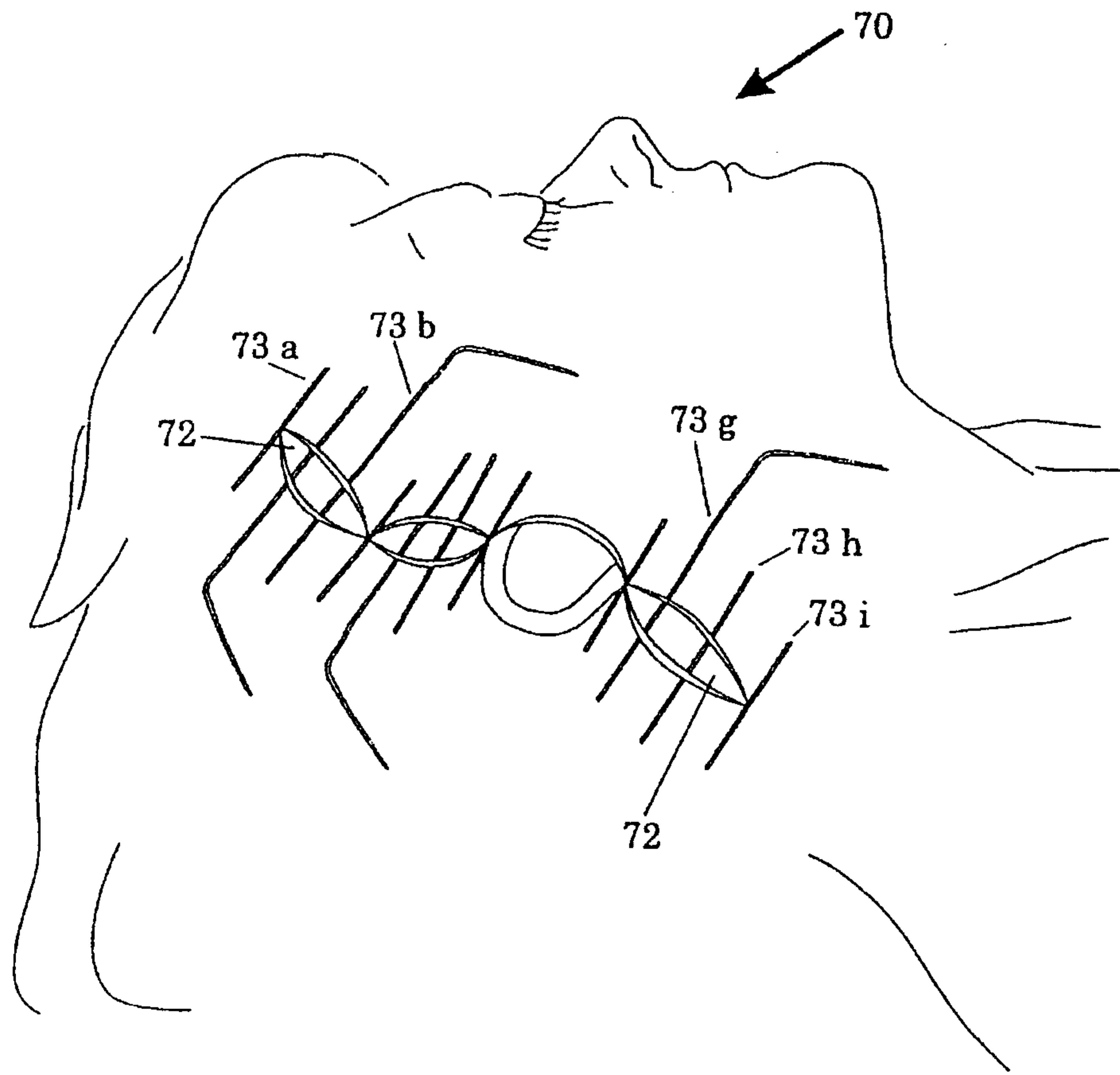
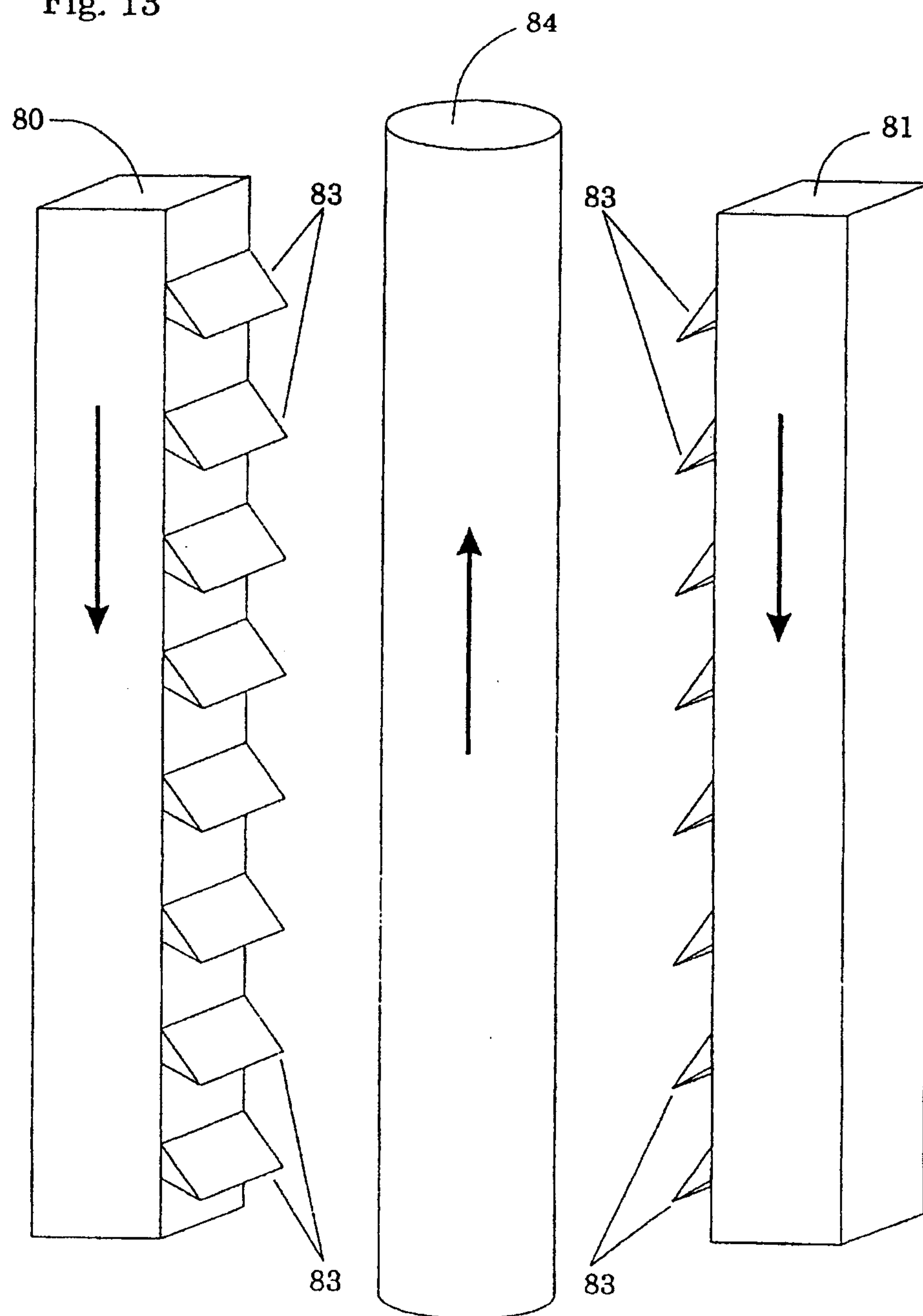


Fig. 13



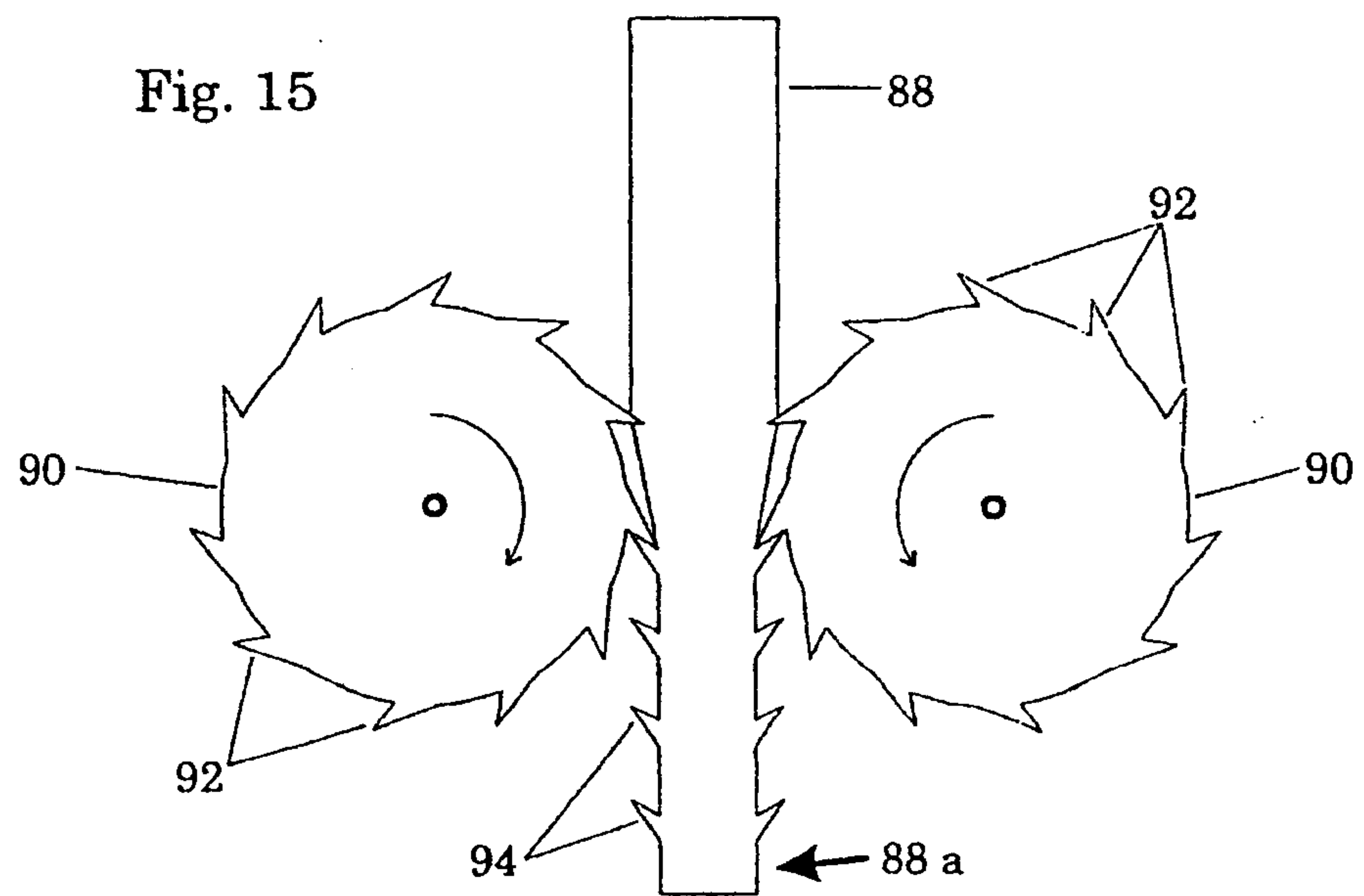
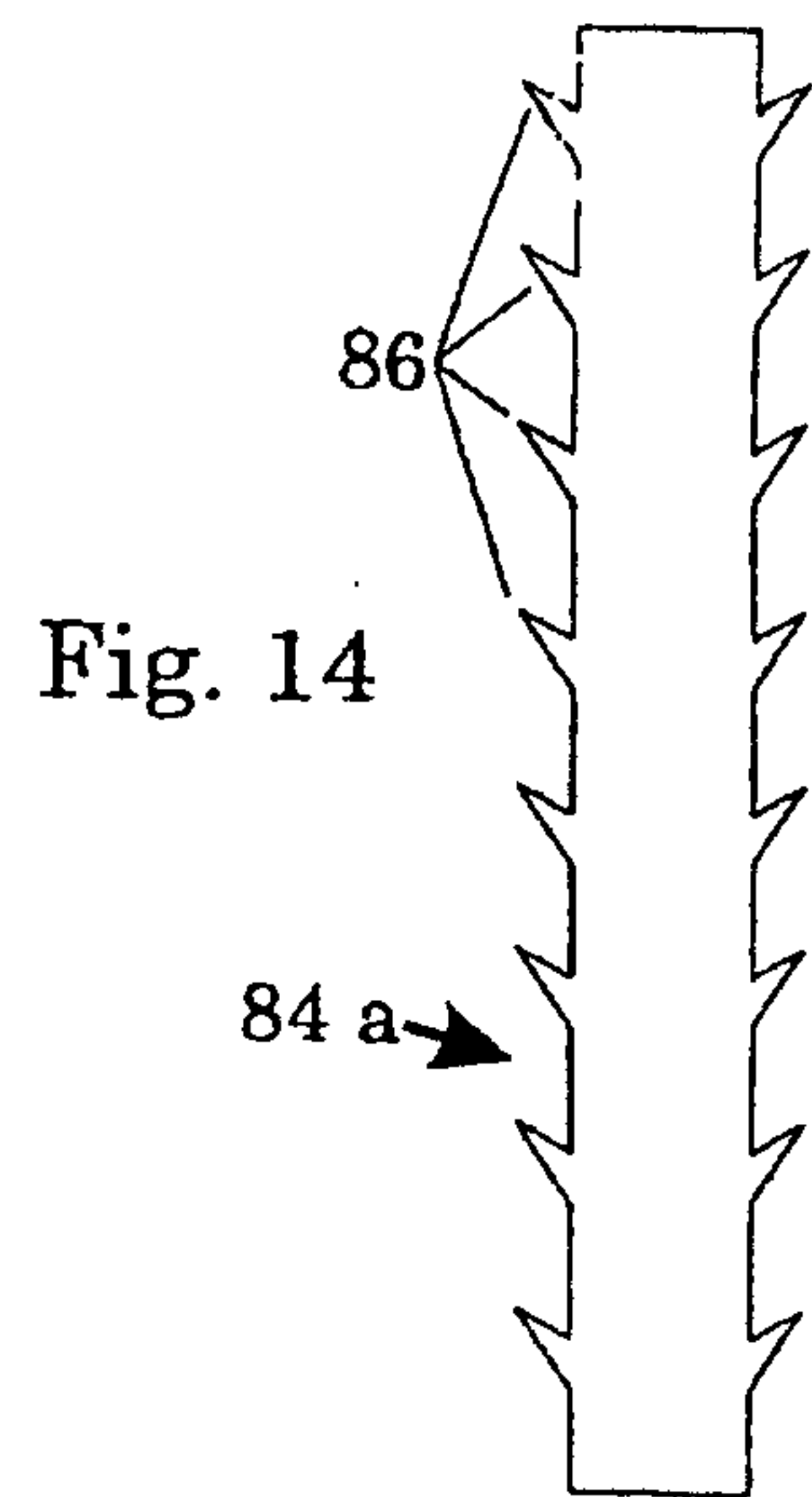
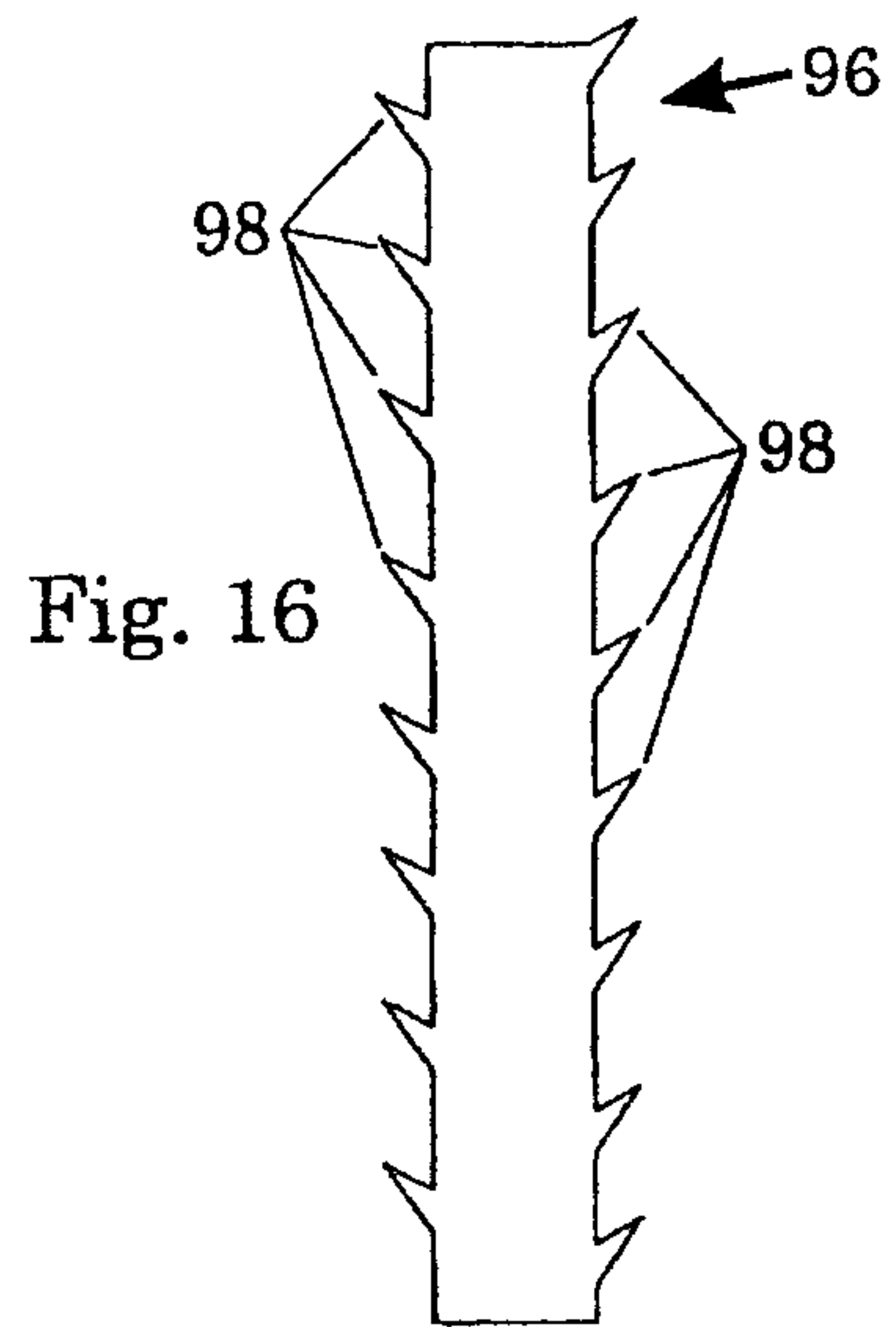


Fig. 17

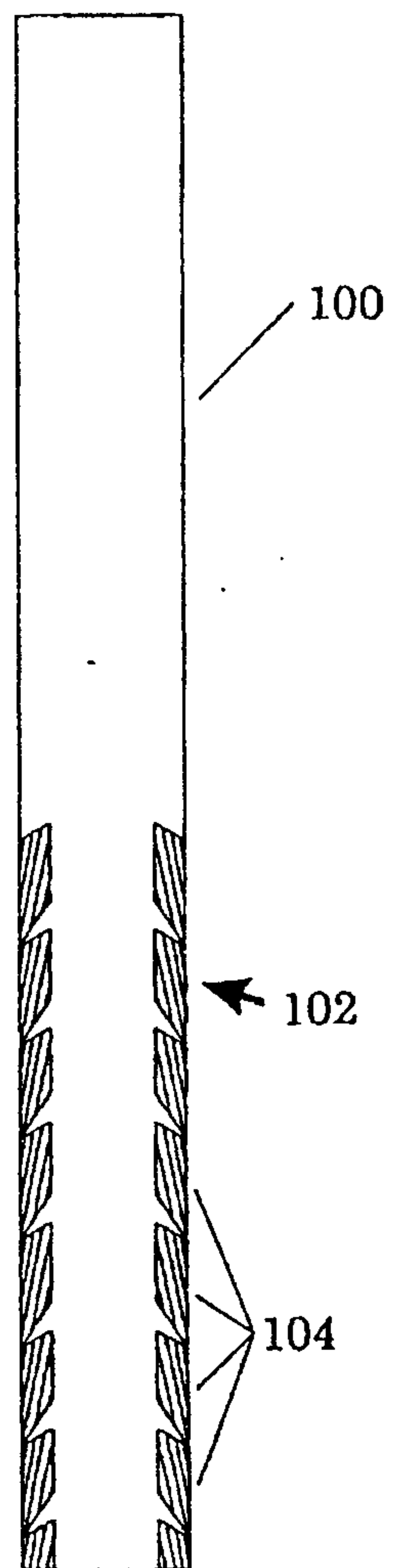


Fig. 18

