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(71) Applicant and
(72) Inventor: **GLASER, Bert, M.** [US/US]; 2323 Boston Street, Unit 5, Baltimore, MD 21224 (US).

(74) Agents: **OZGU, Murat** et al.; Arent Fox, PLLC., 1050 Connecticut Avenue, Suite 400, Washington, DC 20036-5339 (US).

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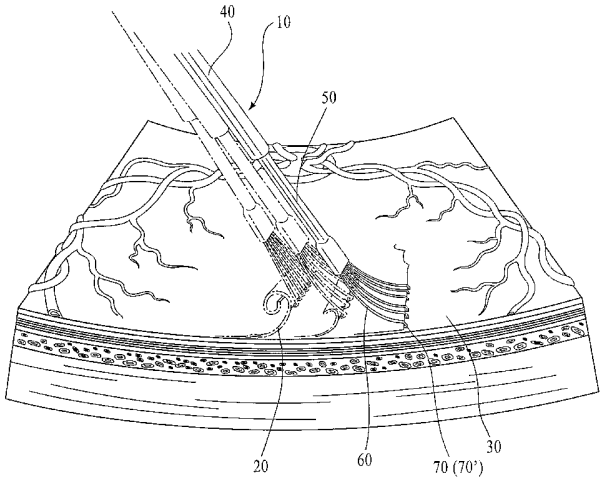
(54) **Title:** INTERNAL LIMITING MEMBRANE RAKE



(57) **Abstract:** A medical device for removing a thin membrane from the inner surface of an eye. The device comprises a rake that includes a handle having a hollow body from which a slide member telescopes. A plurality of tines are provided on a free end of the slide member, wherein each tine includes a tissue engaging feature provided on a free end of each tine. The tines are extended and retracted from an end of the handle, such that, when completely retracted, only the tissue engaging features protrude from the handle or all tissue engaging features can be retracted into the handle. In operation, the rake is manipulated along an upper surface of the membrane until the tissue engaging features engage the membrane. Once the tines engage the membrane, the rake is moved upward and tangentially away relative to an upper surface of the retina until the membrane is removed therefrom.

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INTERNAL LIMITING MEMBRANE RAKE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of Applicant's co-pending U.S. Design Application No. 29/215,250, entitled "Internal Limiting Membrane Rake", filed October 15, 2004; and U.S. Provisional Application No. 60/631,509, entitled "Internal Limiting Membrane Rake," filed November 30, 2004, which are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0002] The present invention relates to a medical device used for removing a membrane provided on an inner surface of a retina of an eye.

DISCUSSION OF RELATED ART

[0003] Certain diseases involve the presence of a thin membrane of scar tissue that must be removed via a medical procedure. Examples of these procedures are the peeling of epiretinal membranes and possibly internal limiting membranes that are the result of idiopathic epiretinal membranes. These membranes may also be associated with macular holes and in vitreo macular traction syndrome, the peeling of epiretinal membranes in diabetic retinopathy, peeling of epiretinal membranes in proliferative vitreo retinopathy, peeling of epiretinal membranes after trauma, and the peeling of epiretinal membranes after intraocular inflammation, including uveitis and ophthalmitis.

[0004] Currently, these procedures are typically performed using one of three types of medical devices. Referring to FIG. 1(a), the first type is a sharp pick 1 comprising a needle 2, typically of size 20 to 23 gage, that is bent at one end. The bent end of the needle 2 forms a sharp point 3, which is used to engage the membrane 20.

However, prior to using the sharp pick 1, a small incision often must be made in the membrane 20, as shown by the arrow in FIG. 1(a). Thereafter, the sharp pick 1 is inserted into the incision where the pick 1 is used to scrape along an edge of the incision between an inner surface of the retina 30 and a lower surface of the membrane 20 in an attempt to lift up the membrane 20 in a direction indicated by the arrows of FIG. 1(b).

[0005] However, the pick 1 has drawbacks. In particular, the pick 1 is able to engage a relatively small area of the membrane 20, making removal of all or large portions of the membrane 20 at the same time extremely problematic.

[0006] Referring to FIG. 2, the second medical device currently used to remove the membrane 20 is a pair of forceps 4, which are used to clamp a small portion of the membrane 20 along an outer edge or along an edge of an incision made therein. The forceps 4 grip the portion of the membrane 20 and lift the membrane 20 off of the retina 30. Because the forceps 4 engage such a small portion of the membrane 20, the forceps 4 have difficulty removing the membrane 20 in one piece and imparts the risk of leaving behind pieces of the membrane.

[0007] Referring to FIG. 3, the third medical device currently used to remove retinal membranes is a scraper 5, which commonly includes a piece of silicon tubing 6 with small pieces of diamonds 7 embedded onto an outer surface of the tubing 6. A region of the tubing 6 having the diamond pieces 7 embedded therein is applied to and scraped along an inner surface of the membrane 20, as indicated by the arrow in FIG. 3. The scraping action dislodges the membrane 20 from the surface of the retina 30. However, the scraping action requires downward pressure to be exerted on the retina 30, which creates a substantial risk of injury to the retina 30 and adjacent structures. Similarly, the scraper 6 is only able to engage a small area of

the membrane 20, making removal of the membrane 20 in one piece very difficult and increasing the possibility of leaving pieces of the membrane behind. Finally, the scraper 6 necessitates the insertion of an additional instrument (not shown) into the eye to complete removal of the membrane 20 from the retina 30.

[0008] An additional drawback associated with each of the above devices, that is, the pick 1, the forceps 4, and the scraper 6, is that relatively high magnification levels must be used during the corresponding procedures for removing the membrane 20. The high magnification levels inherently decrease the area of the retina 30 that can be viewed by medical personnel when attempting to remove the membrane 20, thereby extending the time necessary to perform the procedure as well as making it more difficult for the medical personnel to successfully remove the membrane 20 in a single piece.

SUMMARY OF THE INVENTION

[0009] The present invention addresses the above-discussed and other drawbacks in the known medical devices. The present invention provides a membrane rake which engages any region of the membrane along a large surface area of the membrane and is not limited to engaging an edge of the membrane or the edge of an incision made in the membrane. Moreover, the structural configuration of the membrane rake permits the user to engage a much larger surface area of the membrane than any of the known medical devices.

[0010] Furthermore, the present invention does not require the formation of an incision in the membrane or the introduction of an additional instrument into the eye to aid or complete the process of removing the membrane from the retina of the eye. Moreover, the present invention applies significantly less pressure onto the retina when initially engaging the membrane relative to the pressure applied onto the retina

by some of the known medical devices described above. Additionally, once the present invention has engaged the membrane on the retina, relatively minimal tangential and lifting forces are applied to the retina when using the present invention to remove the membrane from the retina.

[0011] Finally, the present invention is used at lower magnification levels relative to the relatively higher magnification levels which the known medical devices must be used, thereby providing a significantly larger field of view during the membrane removal procedure. The aforementioned benefits and features of the present invention greatly reduce the risk of injury to the eye while significantly simplifying the process of removing the membrane from the retina, as well as increasing the likelihood the membrane is removed entirely in a single piece.

[0012] To achieve the aforementioned and other benefits, the present invention provides a rake configured to remove a thin membrane formed on an inner surface of a retina of an eye. In one embodiment, the rake includes a handle and a plurality of tines which are retractable into and extendable from the handle either manually or mechanically. Ideally, the handle has a hollow body and at least one barb or other such tissue engaging mechanism is provided on a tip of each tine.

[0013] According to one embodiment of the invention, the tines are slidingly retracted into the hollow handle body as well as slidingly extended from the hollow handle body. Once extended from a working end of the handle body, the tines spread apart and outward from each other. As such, the rake is able to engage a relatively large area of the membrane surface.

[0014] In another embodiment of the present invention, the tines are flexible, wherein the flexibility of the tines depend on the amount the tines are extending from the working end of the handle body. The farther the tines extend from the working

end of the handle body, the greater the amount of flexibility. Similarly, the closer the tines are to the working end of the handle body, that is, the less the tines are extended from the working end of the handle body, the lesser the amount of flexibility the tines posses.

[0015] According to another aspect of the present invention, once the extended tines engage the upper surface of the membrane, the tines are retracted, drawing up and securing the membrane between the at least one barb or other tissue engaging feature and the working end of the handle.

[0016] Additional advantages and novel features of the present invention will be set forth in the following description, and will also become apparent to those skilled in the art upon examination of the following or upon learning by practice of the invention.

BRIEF DESCRIPTION OF DRAWINGS

[0017] Other aspects of the present invention will be better understood from the following description, along with the accompanying drawings, wherein:

[0018] FIGs. 1(a) and 1(b) illustrate a conventional sharp pick device used to remove a membrane from a retina;

[0019] FIG. 2 illustrates a conventional forceps device used to remove the membrane from the retina;

[0020] FIG. 3 illustrates a conventional scraper device used to remove the membrane from the retina;

[0021] FIG. 4 is a cross-sectional view of a rake according to an embodiment of the present invention;

[0022] FIG. 5 is a diagram illustrating the different states in which the tines of the rake shown in FIG. 4 can be extended from the handle of the rake

[0023] FIG. 6 illustrates an embodiment of the tissue engaging features provided at the free end of each tine;

[0024] FIG. 7 illustrates another embodiment of the tissue engaging features provided at the free end of each tine;

[0025] FIG. 8 illustrates the tangential and lifting forces created by the rake of the present invention that are used to remove a membrane from the retina of an eye;

[0026] FIG. 9 illustrates the different states of the rake engaging the membrane on the retina of an eye and removing the membrane therefrom; and

[0027] FIG. 10 illustrates the rake engaging the membrane in an intermediate portion of the membrane remote from the peripheral edges of the membrane.

DETAILED DESCRIPTION OF THE INVENTION

[0028] The present invention provides a membrane rake 10 which engages any region of the membrane 20 along the entire surface of the membrane 20. The structural configuration of the membrane rake 10 permits the user to engage a much larger surface area of the membrane 20 than any of the known medical devices. Furthermore, the present invention does not require the formation of an incision in the membrane 20 or the introduction of an additional instrument into the eye to aid or complete the process of removing the membrane 20 from the retina 30 of the eye. Moreover, the rake 10 applies significantly less pressure onto the retina and adjacent structures when initially engaging the membrane 20 relative to the pressure applied onto the retina by some of the known medical devices described above. Finally, the rake 10 is used at lower magnification levels relative to the relatively higher magnification levels which the known medical devices must be used, thereby providing a significantly larger field of view during the membrane removal procedure.

[0029] FIG. 4 illustrates an exemplary rake 10 of an embodiment of the present invention, for use in removing a membrane 20 (FIGs. 6 and 8-10) from an inner surface of the retina 30 (FIGs. 6 and 8-10) of the eye. The rake 10 of this embodiment comprises a handle 40 and a telescoping slide member 50. The handle 40 comprises a hollow tube, through which the slide member 50 telescopes freely within an interior surface of the handle 40 (e.g., a central opening extending the length of the handle). Although the body of the handle 40 is preferably tubular, it should be noted that it is within the scope of the invention to provide the body of the handle 40 with any suitable geometric shape that promotes gripability of the handle 40, such as, for example only, oval, rectangular, trapezoidal, hemi-spherical and the like in cross-section.

[0030] Fixedly provided at an end of the slide 50 are multiple tines 60 each having one end attached to the slide 50, with the opposite end freely extending therefrom. A free end of each tine 60 has a barb or other tissue engaging feature 70 (FIGs. 5-6) provided thereon.

[0031] As shown in FIG. 5, the rightmost rake 10, when the slide member 50 is fully retracted, such that the slide member 50 and most of the length of the tines 60 are contained within the body of the handle 40, the tissue engaging features 70 protrude from the end of the handle 40. As shown in the rake10 second from the right in FIG. 5, as the tines 60 extend from the handle 10, the outer ends of the tines 60 spread apart from each other and away from a longitudinal axis of the rake 10, allowing the tissue engaging features 70 to separate from one another in an unobstructed manner. Once fully extended, as shown in the rake 10 third from the right in FIG. 5, tines 60 increase the potential area of engagement, providing for better control when removing the membrane 20. Finally, the leftmost rake 10 shown

in FIG. 5 illustrates the feature of the fully extended tines 60, wherein the slide member 50 telescopes or slides out of the body of the handle 40.

[0032] In this embodiment, the amount the tines 60 are permitted to extend beyond the handle 40 is effectuated by pulling/pushing on an end of the slide member 50 that is opposite the end from which the tines 60 extend. It will be recognized by those familiar with the art that, for embodiments of the present invention incorporating extending and spreading tines, alternate features to provide such extension and spreading may be used. For example, the tines may be retracted or extended from the handle without the use of a slide member. Further, while the relative position of the slide member 50 and handle 40 of FIG. 5 are maintained by simple frictional engagement between the slide member 50 and the handle 40, other features may be provided to maintain the relative position, such as locking pins within openings, screw retainers, clips engaging slots, and the like, including mechanical, hydraulic, and electromechanical mechanisms.

[0033] Referring to FIG. 6, in one embodiment of the present invention, the tissue engaging features 70 comprise a plurality of serrated barbs 71 extending from the free end of each tine 60. As shown in FIG. 6, each tissue engaging feature 70 includes a flexible body portion 70a joined to an engaging portion 70c by a transverse portion 70b. In a fully retracted state, the transverse portion 70b extends orthogonally relative to the longitudinal axis of the rake 10. Further, while in the fully retracted state, the engaging portion 70c extends in a direction that is parallel relative to the longitudinal axis of the rake 10 and opposite to the direction in which the slide member 50 telescopes away from the body of the handle 40. Also, as shown in FIG. 6, at least one and preferably a plurality of barbs 71 are provided on a free end of each engaging portion 70c of the tine 60. Additionally, in the

embodiment of the FIG. 6, the tissue engaging features 70 may include a serrated end to increase friction or other gripping engagement with a surface of the membrane 20.

[0034] Although FIG. 6 illustrates the barbs 71 as having pointed or serrated bodies, it should be noted that it is within the scope of the invention for the barbs 71 to have any suitable geometric shape that will promote the gripping and lifting of the membrane 20 off of the retina 30. For example, in an envisioned alternate variation (not shown), the tissue engaging features 70 of the embodiment of FIG. 6 are not serrated but, rather, have a sharpened unserrated edge. In yet another example, FIG. 7 illustrates another embodiment of the present invention wherein the tissue engaging features 70' are curved.

[0035] As shown in FIG. 8, when engaged with the membrane 20, the tissue engaging features 70 and 70' create tangential and lifting forces to remove the membrane 20 and reduce downward pressure on the retina 30 as illustrated by the arrows. The extension and retraction of the tines 60 into and out of the handle 40, in combination with the tissue engaging features 70 and 70', offers yet another benefit. In particular, once the extended tines 60 engage the membrane 20, the tines 60 can thereafter be retracted, drawing up and clamping the membrane 20 between the tissue engaging features 70 and 70' and the end of the handle 40 from which the slide member 50 telescopes. Such clamping action further reduces the need to introduce a second instrument into the eye for removing the membrane 20. Further, the ability to retract the tines 60 into the handle 40 decreases the likelihood that the inner surface of the retina 30 and any other part of the eye may be damaged by the tines 60, by retracting the tines 60 when the rake 10 is inserted or withdrawn from the eye.

[0036] FIG. 9 illustrates an exemplary rake 10 removing a membrane 20 from the surface of the retina 30. The right-most representation of the rake 10 of FIG. 9 shows the tissue engaging features 70 and 70' engaging an edge of the membrane 20. The progression of figures of the rake 10, from right to left, as shown in FIG. 9, depicts how the rake 10 may be used to both pull and lift the membrane 10. FIG. 9 also shows the tines 60 flexing, in accordance with some embodiments of the present invention.

[0037] In the embodiment of FIG. 9, the further the tines 60 are extended from the handle 40, the more the tines 60 are able to flex when pressed against an object. The increased flexibility of the tines 60 decreases the pressure exerted upon the upper surface of retina 30 by the rake 10. For example, in one embodiment, when the tines 60 are fully extended and contacting the membrane 20, the handle 40 can be moved downward toward the retina 30 up to a millimeter without any significant or noticeable force on the retina 30. Such flexibility reduces the risk of injury to the eye during use of the rake 10. The flexibility of the tines 60 can be decreased, that is, the tines 60 can be made stiffer, by simply retracting the tines 60 into the handle 40 until a desired stiffness is reached.

[0038] FIG. 10 illustrates the ability of the rake 10 to engage the membrane 20 at a location along the inner surface of the membrane 20, with the location not being required to include an outer edge of the membrane 20 to be removed. The rake 10 is dragged along the upper surface of membrane 20 until the tissue engaging features 70 and 70' engage the surface of the membrane 20. Once the tissue engaging features 70 and 70' engage the membrane surface, the rake 10 is simply pulled upward and tangentially away from the upper surface of the retina 30 to remove the membrane 20 therefrom. Once the rake 10 engages the membrane 20,

no additional downward force is exerted upon the retina 30, which reduces the risk of eye injury.

[0039] Example embodiments of the present invention have now been described in accordance with the above advantages. It will be appreciated that these examples are merely illustrative of the invention. Many variations and modifications will be apparent to those skilled in the art without departing from the scope and spirit of the invention.

WHAT IS CLAIMED IS:

1. An internal limiting membrane rake for removing a membrane from an upper surface of a retina, the rake comprising:

a handle having a hollow body;

a telescoping slide member that extends from and retracts into the body of the handle; and

a plurality of tines extending from a free end of the slide member, wherein each tine includes at least one tissue engaging element provided at a free end of each tine.

2. The rake according to Claim 1, wherein the body of the handle has a shape in cross-section that is one of oval, rectangular, trapezoidal, and hemispherical.

3. The rake according to Claim 1, wherein the at least one tissue engaging element extends from the body of the handle when the slide member is in a substantially fully retracted state.

4. The rake according to Claim 1, wherein a degree of flexibility of each tine increases the further the slide member is extended away from the body of the handle.

5. The rake according to Claim 1, wherein each tine extends away from a neighboring tine in a direction substantially radial relative to a longitudinal axis of the rake when the slide member is in a fully extended state relative to the body of the handle.

6. The rake according to Claim 1, wherein the at least one tissue engaging element comprises:

a flexible body portion;

an engaging portion; and

a transverse portion which joins the body portion to the engaging portion.

7. The rake according to Claim 6, wherein the transverse portion extends orthogonally relative to a longitudinal axis of the rake when the slide member is in a fully retracted state.

8. The rake according to Claim 7, wherein the engaging portion extends in a direction parallel relative to the longitudinal axis and opposite to a direction in which the slide member extends away from the body of the handle.

9. The rake according to Claim 6, wherein at least one barb is provided

on a free end of the engaging portion of each tine.

10. The rake according to Claim 9, wherein the at least one barb has a serrated end.

11. The rake according to Claim 1, wherein the at least one tissue engaging element has a curved shape.

12. A membrane rake for use with an eye retina, the membrane rake comprising:

a handle; and

a tine extension mechanism having a plurality of tines attached thereto;

wherein the plurality of tines are extendable from the handle and wherein the plurality of tines are spreadable from one another, the extension and spreading of the plurality of tines being variably controllable via the tine extension mechanism.

13. The membrane rake of claim 12, wherein the handle includes an opening, and wherein the tine extension mechanism comprises a slide receivable in the handle opening.

14. The membrane rake of claim 12, wherein each of the plurality of tines has at least one barb extending therefrom.

15. The membrane rake of claim 14, wherein the plurality of tines are fully retractable into the handle.

16. The membrane rake of claim 14, wherein each tine has an axial direction, and wherein the at least one barb for each tine extends approximately perpendicularly to the axial direction of the tine.

17. The membrane rake of claim 12, wherein the tine extension mechanism is lockable at a fixed position relative to the handle.

18. The membrane rake of claim 16, wherein the tine extension mechanism is lockable via friction.

19. The membrane rake of claim 16, wherein extension of the plurality of tines is controlled by any one of a mechanical control, a hydraulic control, or an electromechanical control.

20. The membrane rake of claim 12, wherein the plurality of tines have a stiffness, the stiffness varying with the extension and spreading of the plurality of tines.

21. A membrane rake for use with an eye retina, the membrane rake comprising:

a handle; and

an extension means having a plurality of membrane engaging means connected thereto;

wherein the plurality of membrane engaging means are extendable from the handle and wherein the membrane engaging means are spreadable from one another, the extension and spreading of the plurality of membrane engaging means being variably controllable via the extension means.

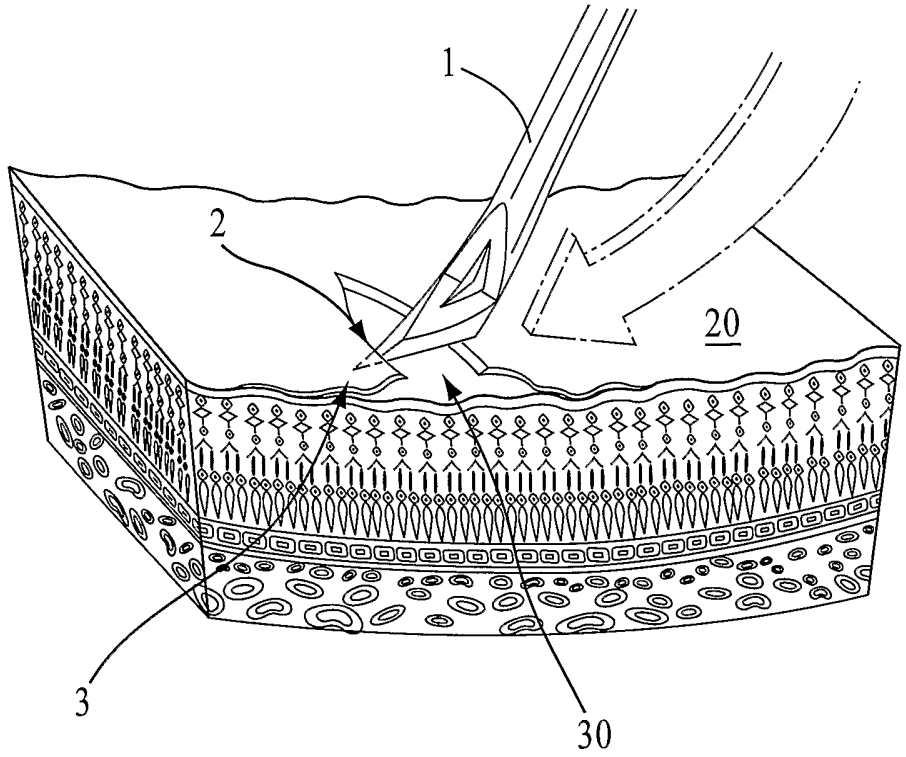


FIG. 1A

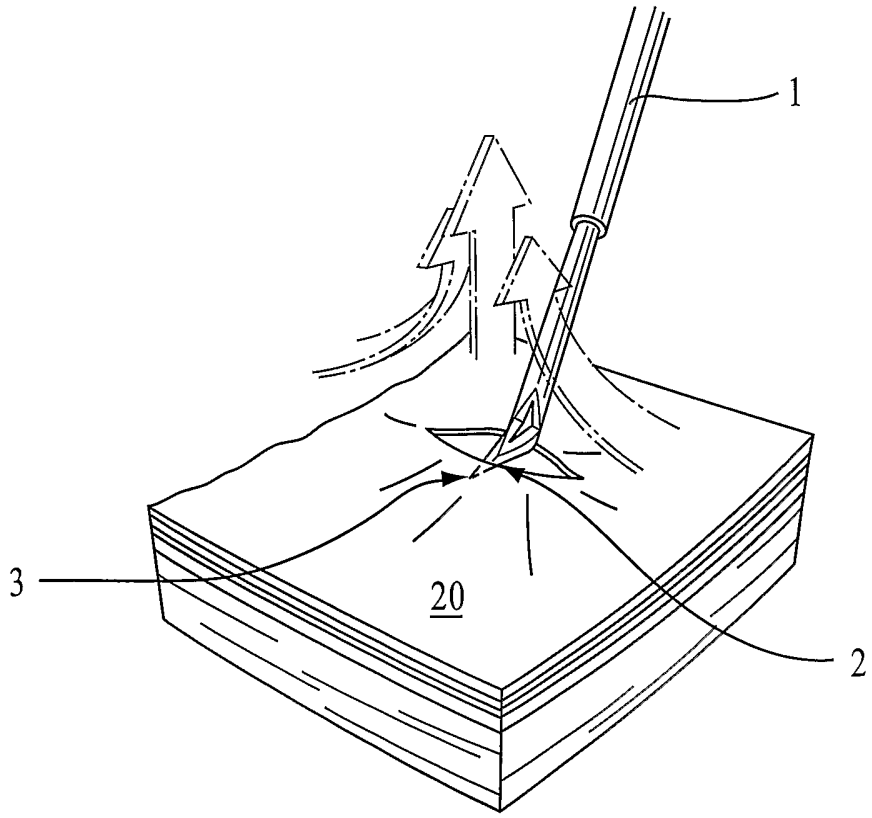


FIG. 1B

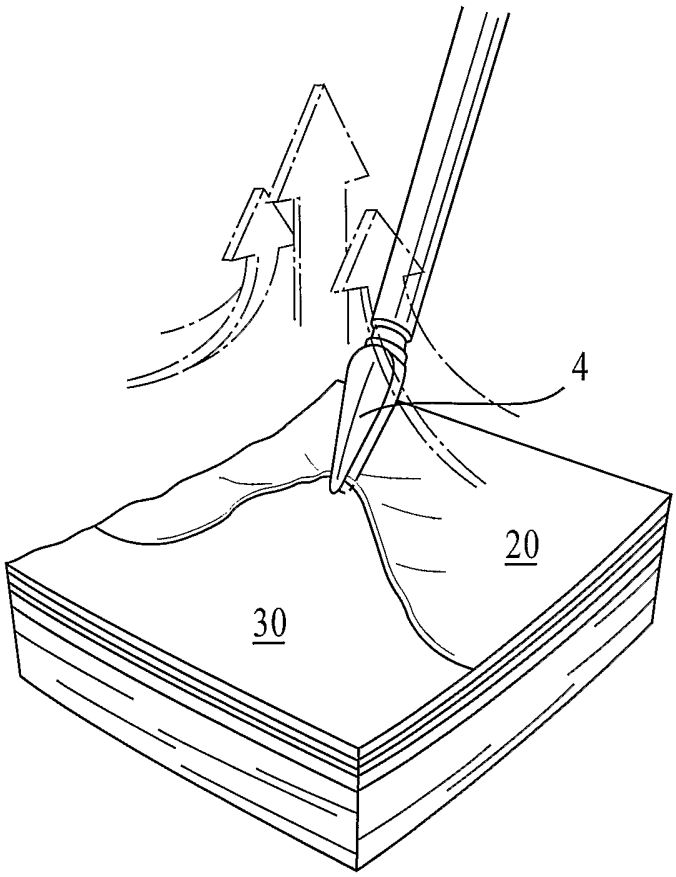


FIG. 2

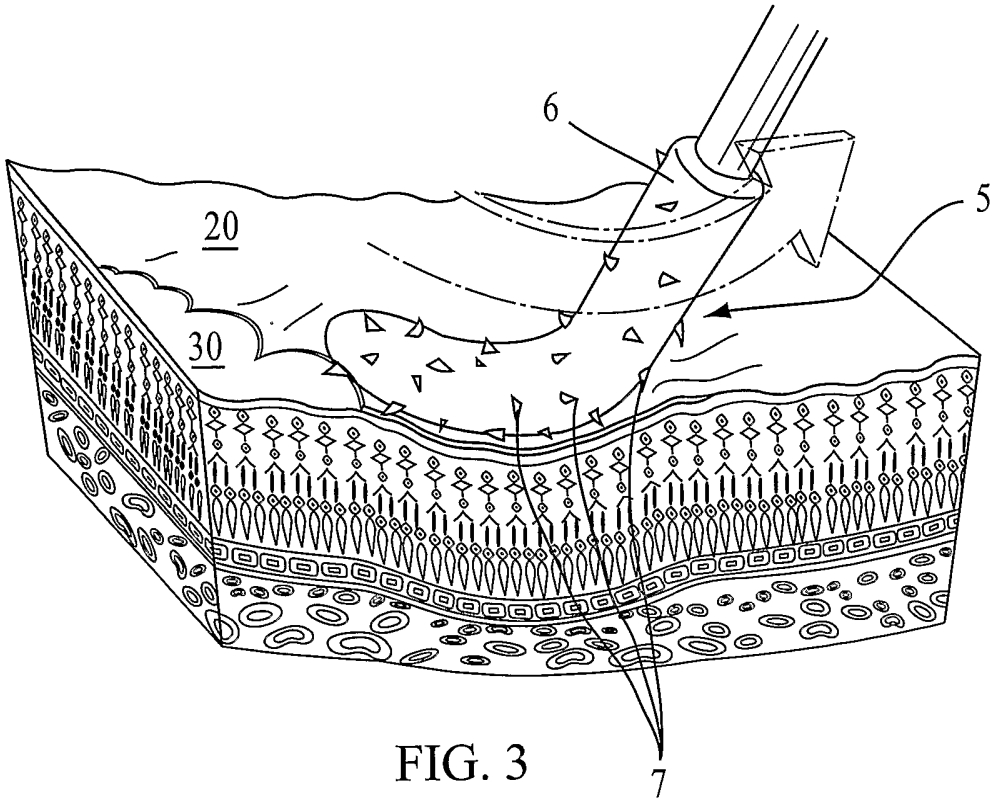


FIG. 3

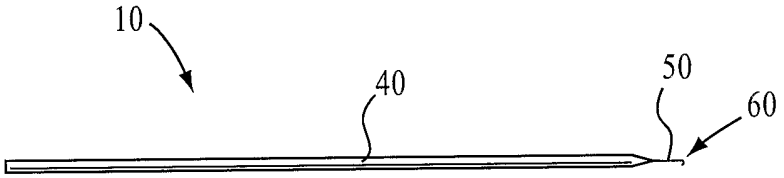


FIG. 4

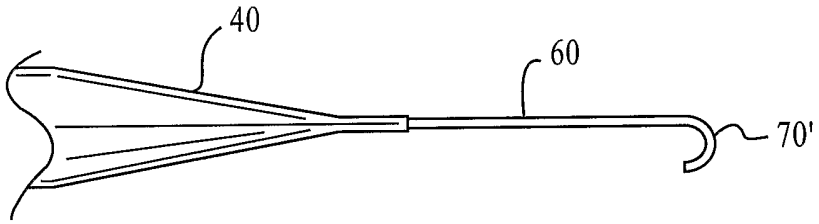


FIG. 7

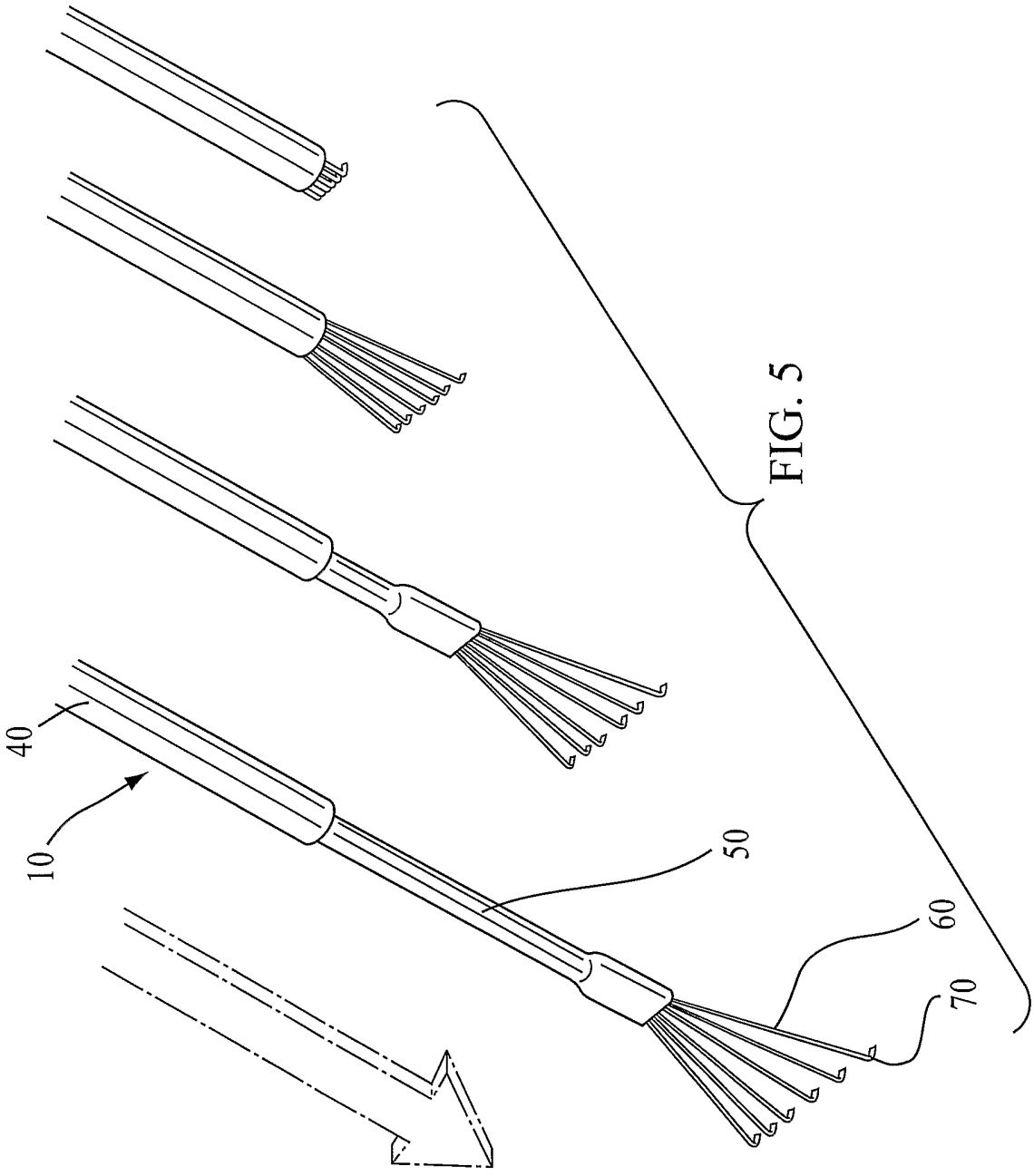


FIG. 5

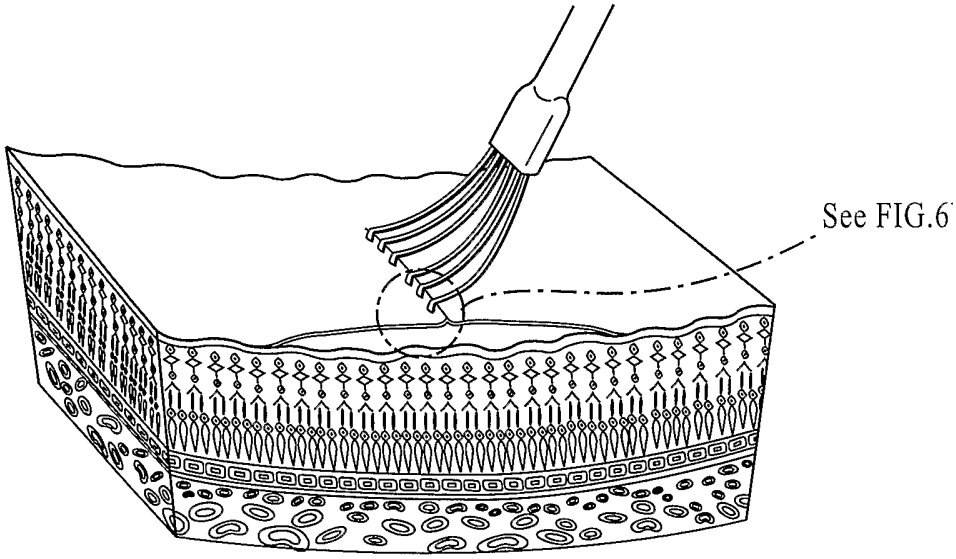
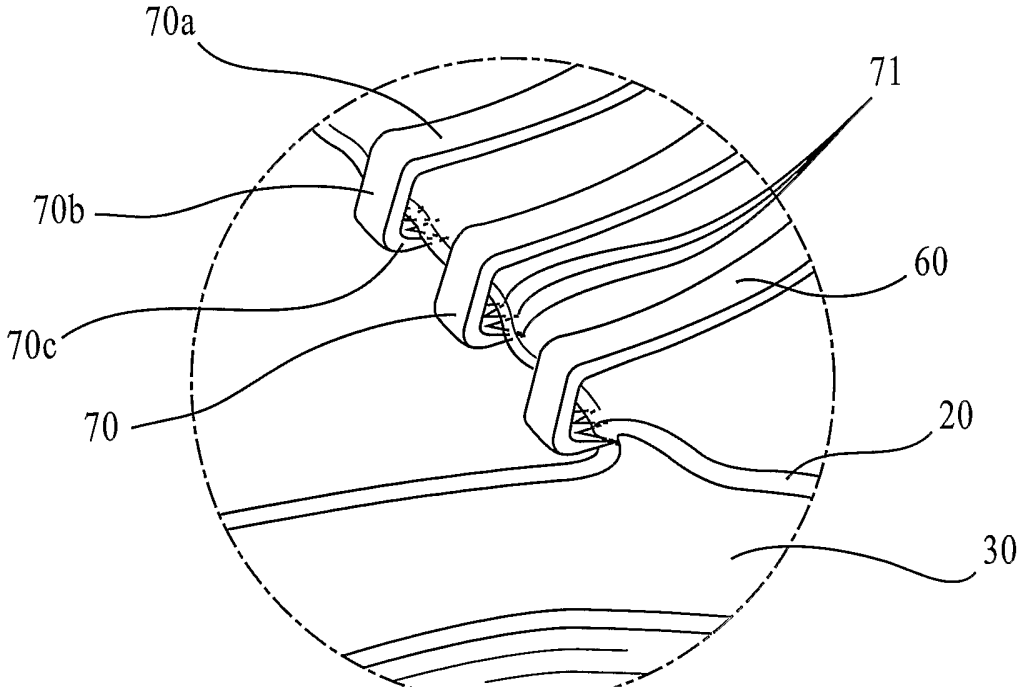


FIG. 6a



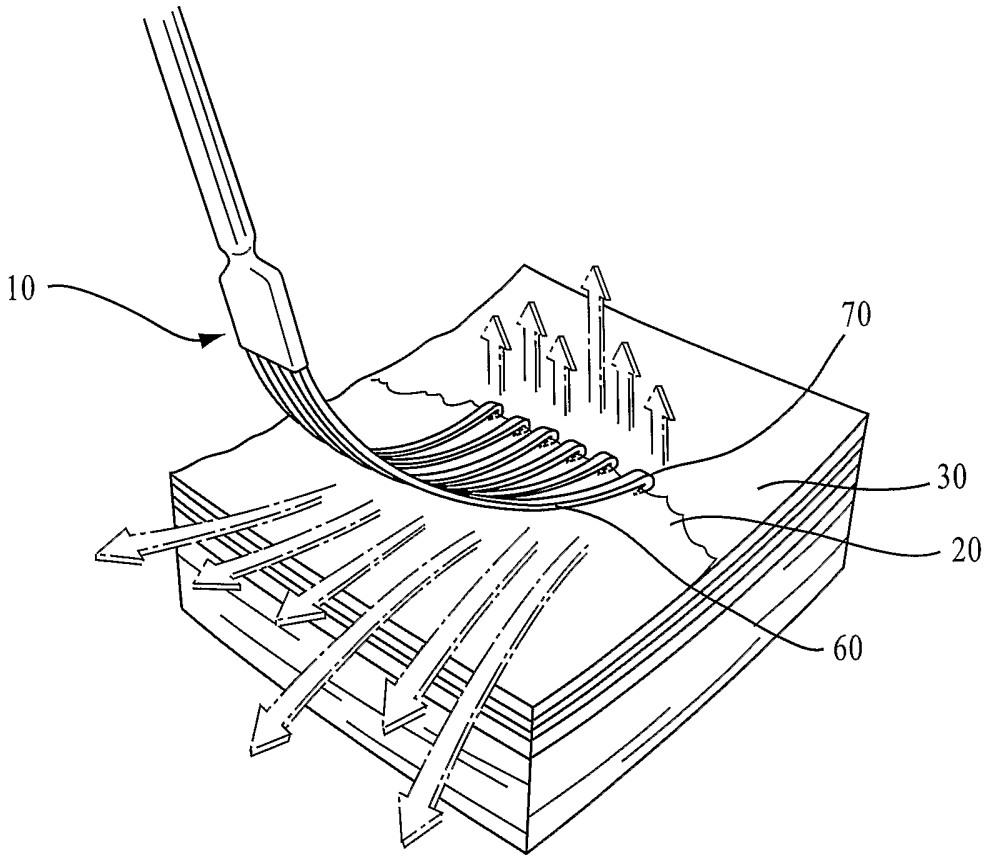


FIG. 8

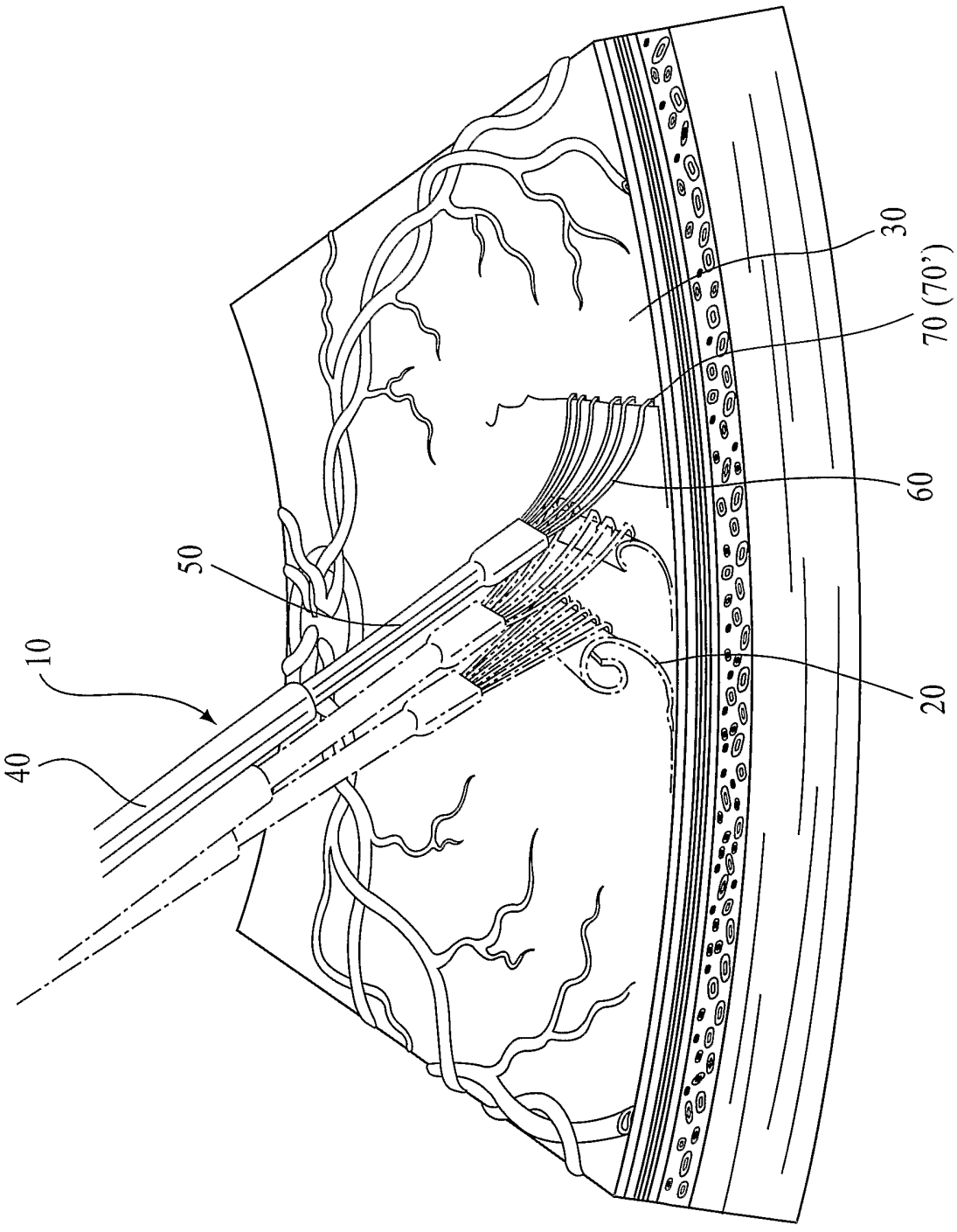


FIG. 9

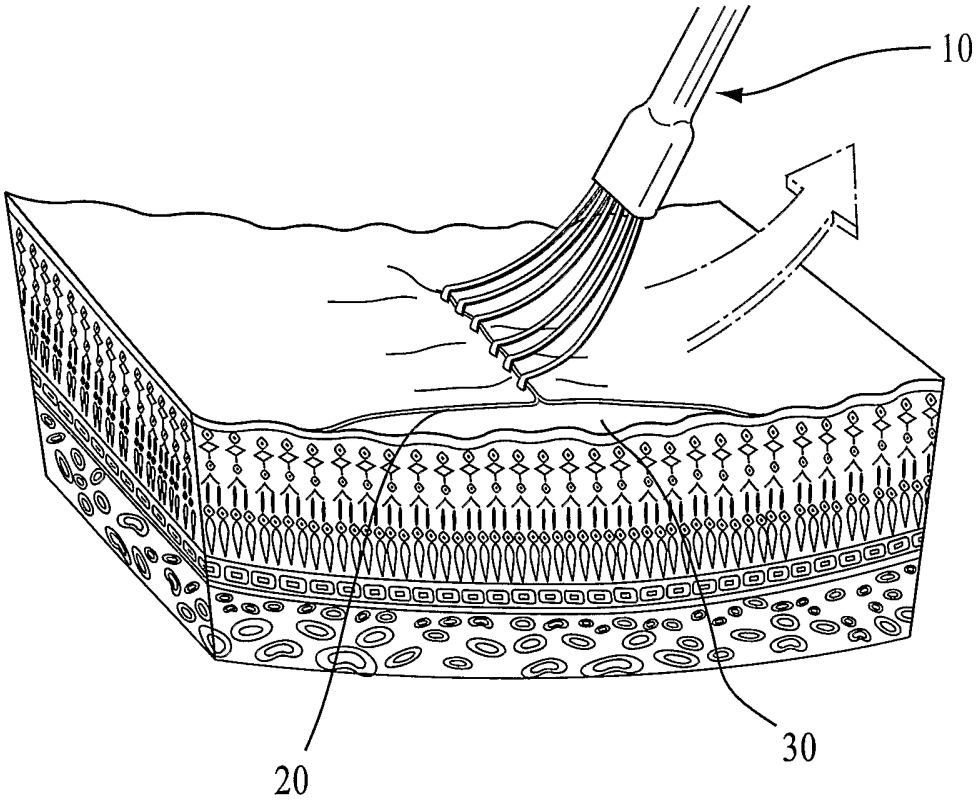


FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/012613

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 868 728 A (GIUNGO ET AL) 9 February 1999 (1999-02-09) column 1, line 54 - column 2, line 10; figure 6 column 9, line 49 - column 10, line 44	1,2,4-6, 8-11 3,7
X Y	US 2003/120305 A1 (JUD OLIVER ET AL) 26 June 2003 (2003-06-26) paragraph '0066! - paragraph '0073!; figure 9	1,2,4-6, 8-11 3,7
A	US 2003/040773 A1 (ARUMI JOSE GARCIA ET AL) 27 February 2003 (2003-02-27) the whole document	1-11
A	EP 0 864 310 A (INAMI & CO., LTD) 16 September 1998 (1998-09-16) the whole document	1-11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2005	18/08/2005

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

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/012613

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/097964 A1 (DHINDSA AVTAR S) 20 May 2004 (2004-05-20) figure 18	1-11

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/012613

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/012613

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