(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 July 2013 (18.07.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/106726 A1

(51) International Patent Classification:
A61B 17/17 (2006.01)

(21) International Application Number:
PCT/US2013/021256

(22) International Filing Date:
11 January 2013 (11.01.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/585,724 12 January 2012 (12.01.2012) US

(72) Inventor; and
(71) Applicant : **GEIST, Wyatt Drake** [US/US]; 2621 West Abiaca Circle, Davie, FL 33328 (US).

(74) Agents: **CAMPBELL, Keith, A.** et al.; McHale & Slavin, P.A., 2855 PGA Boulevard, Palm Beach Gardens, FL 33410 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

WO 2013/106726 A1

(54) Title: ACCESS ASSEMBLY FOR ANTERIOR AND LATERAL SPINAL PROCEDURES

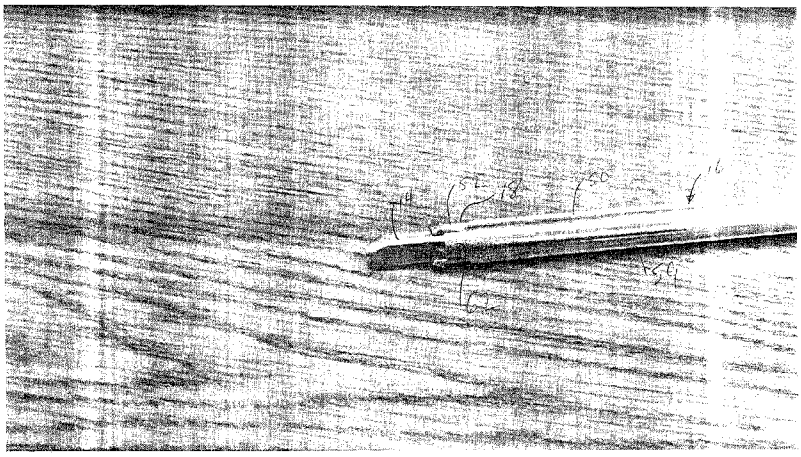

Fig. 2

(57) Abstract: Briefly, the present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side) and generally by a lateral, anterior or an anterolateral surgical approach, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

ACCESS ASSEMBLY FOR ANTERIOR AND LATERAL SPINAL PROCEDURES

FIELD OF INVENTION

The present invention relates generally to stabilization of adjacent bony structures of the spine and more particularly to an assembly and method for providing anterior and/or lateral access to the disc space of the vertebrae for providing stabilization to the bony structures thereof.

BACKGROUND INFORMATION

It is widely held that healing and/or structural correction is greatly facilitated when a bone is stabilized in the proper position. Various devices for stabilization of bone are well known and routinely practiced in the medical arts. For example, an abnormal spine can be stabilized using a substantially rigid or semi-rigid interconnecting means (rod or plate) and fastening means (screws, clamps, hooks, claws, anchors, or bolts). Multiple fasteners are placed into the spinal pedicle of each vertebra and linked by at least one interconnecting means. Once in place, these systems substantially immobilize the spine and promote bony fusion (arthrodesis).

With respect to the thoracic spine, it may be afflicted with a variety of ailments, some so severe as to require surgical intervention. A disc herniation may compress the spinal cord and/or nerve roots and cause pain, loss of function, and even complete paralysis of the legs with loss of bowel and bladder control. The correct treatment for such conditions is the removal of the offending discal tissue. However, this has proven both difficult and quite dangerous. When the discs of the

thoracic spine are approached posteriorly (from behind), the spinal cord is in the way. To approach the same herniation anteriorly (from the front) requires the very formidable procedure of thoracotomy (cutting open the chest) and moving the heart and lungs out of the way.

Quite recently surgeons have begun performing these procedures from a lateral approach to the spine (from the side) using fiber optic viewing instruments called thorascopes and numerous small surgical openings through the chest wall (portals) through which various surgical instruments, such as burrs, rongeurs and curettes, may be placed to remove these disc herniations while avoiding formal thoracotomy. Because the discs are very narrow in the thoracic spine and the surgeon is approaching the spine laterally, there is very little space in which to work as the disc is entered. Therefore, the amount of disc removal may be limited. Alternatively, the surgeon might remove the pedicle to gain access to the spinal canal risking further weakening of the already diseased area.

Sometimes, for a variety of reasons, including the removal of disc material, the thoracic spine may become unstable (too much motion) at any given level. Historically, this has been treated by fusion, the joining together permanently of the unstable vertebrae via a bridge of bone so as to eliminate all motion at that location. Fusions about the thoracic spine have been performed either anteriorly or posteriorly, either procedure being a serious surgical undertaking.

Stability of the spine is required for fusion to occur. For this reason, and for the purpose of correcting spinal deformity, it is often necessary to use hardware to rigidly internally fixate (stabilize) the spine. To date,

the only benefit the use of the thorascope has provided in this regard is to allow the previous thoracotomy incision to be somewhat smaller.

Thus, the prior art includes numerous drawbacks which have not been entirely addressed. Traditionally, the surgical techniques for stabilization of bone required large incisions (upwards of 6 cm in length) and a considerable amount of muscle be cut and stripped away (retracted) from the bone for an "open" visualization of the bone and access thereto for the placement of the fasteners and instrument implantation. Although this so-called "open" surgical technique has successfully treated non-unions, instability, injuries and disease of the spine, it is not without disadvantages. Given the invasive nature of this technique, a lengthy healing time and considerable post-operative pain for the patient is common.

With respect to the human lumbar spine, the treatment of discal disease with neural compression has generally been from a posterior (from behind) approach. Lumbar discs are generally quite large and it is only those protrusions occurring posteriorly which compress the neural elements, which are themselves posterior to the discs. These posterior approaches have included both true posterior approaches and posterolateral approaches to the discs. Further, such approaches have been made via open incisions or through percutaneous stab wounds. In the latter case, instruments are inserted through the stab wounds and monitored by the use of radiographic imaging or the use of an endoscopic viewing device. While it is possible to also decompress a posterior disc herniation in the lumbar spine from an anterior approach (from the front), doing so requires the removal of a very substantial portion or all

of the disc material in the front and mid portions of the disc, thus leaving that disc and that spinal segment generally unstable. Therefore, such an anterior approach to the lumbar spine has been reserved for those instances where a fusion is to be performed in conjunction with, and following such a disc removal.

Fusion is generally induced with the application of bone or bone like substances between bones to induce bony bridging; such procedures have been performed outside the vertebral bodies and/or between the vertebral bodies, the latter being known as an interbody fusion. Such interbody fusions have been performed from posterior, posterolateral and anterior. Interbody fusion from the posterior approach, while still in use, has been associated with significant complications generally related to the fact that the delicate dural sac and the spine nerves cover the back of the disc space and are thus clearly at risk for damage with such an approach. The posterolateral approach has generally been utilized as a compliment to percutaneous discectomy and has consisted of pushing tiny fragments of morsalized bone down through a tube and into the disc space.

In anterior interbody spinal fusion, the path of entry of the fusion material into the intervertebral space is performed from a straight anterior position. Such an anterior position is achieved in one of two ways. First, by a straight anterior approach which requires that the peritoneal cavity, which contains the intestines and other organs, be punctured twice, once through the front and once through the back on the way to the front of the spine; or secondly, by starting on the front of the abdomen off to one side and dissecting behind the peritoneal cavity on the

way to the front of the spine. Regardless of which approach to the front of the spine is used, and apart from the obvious dangers related to the dense anatomy and vital structures in that area, there are at least two major problems specific to the anterior interbody fusion angle of implant insertion itself. First, generally at the L.sub.4 and L.sub.5 discs, the great iliac vessels bifurcate from the inferior vena cava and lie in close apposition to and covering that disc space, making fusion from the front both difficult and dangerous. Secondly, anterior fusions have generally been done by filling the disc space with bone or by drilling across the disc space and then filling those holes with shaped implants. As presently practiced, the preferred method of filling the disc space consists of placing a ring of allograft (bone not from the patient) femur into that disc space. An attempt to get good fill of the disc space places the sympathetic nerves along the sides of the disc at great risk. Alternatively, when the dowel technique is used, because of the short path from the front of the vertebrae to the back and because of the height of the disc as compared to the width of the spine, only a portion of the cylindrical implant or implants actually engage the vertebrae; thus compromising the support provided to the vertebrae and the area of contact provided for the fusion to occur.

There is, therefore, in regard to the lumbar spine, a need for a new method and apparatus for achieving interbody fusion which avoids the problems associated with all prior methods, and which have included, but are not limited to, nerve damage when performed posteriorly, or the need to mobilize the great vessels when performed anteriorly. Further, the size of the implants are limited by the dural

sac posteriorly, and the width of the spine and the delicate vital structures therewith associated anteriorly. Such a method and apparatus for interbody fusion should provide for optimal fill of the interspace without endangering the associated structures, and allow for the optimal area of contact between the implant or implants and the vertebrae to be fused. The method and apparatus should also provide controlled distraction of the bony structures while also providing an interlocking connection to the bony structures to prevent movement or dislodgement of the apparatus.

SUMMARY OF THE INVENTION

Briefly, the present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side), and generally by a lateral, anterior or an anterolateral surgical approach, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

In the preferred embodiment, the access assembly of the present invention comprises a guide wire, a distractor, and a dynamic tube assembly that includes a manually operable locking member for securing the dynamic tube assembly to the bony structure. In at least one embodiment, the locking feature of the dynamic tube assembly may also be utilized for providing additional controlled distraction of the bony structures. The guide wire is provided for initial insertion into the disc space

through a small incision in the patient with the assistance of x-rays, thorascope, image intensifier, direct vision or the like. For example, for surgery in the thoracic spine, a small incision in the chest cavity of the patient is made from a lateral approach to the thoracic spine. For surgery in the lumbar spine, a small incision may be made in the abdominal wall of the patient. Once positioned, the guide wire extends between the disc space to outside of the patient to provide a guideway for the distractor member. The distractor is generally an elongated member having a small central aperture sized for cooperation with the guide wire. A first end of the distractor includes a tapered end and a pair of generally flat opposing side surfaces extending along a portion of the length thereof. The opposing side surfaces are spaced a predetermined distance apart to provide a desired distraction (spacing) and alignment of the vertebrae. The second end of the distractor is provided with a surface suitable for striking with a mallet or the like. The outer surface of the distractor is preferably round to act as a guide surface for the dynamic tube assembly.

The dynamic tube assembly includes an outer tube member and an inner lock member. The inner lock member includes an inner bore sized for cooperation with the outer surface of the distractor member. In this manner, the distractor acts as a guideway for the dynamic tube assembly. The dynamic tube assembly is constructed and arranged so that a portion of the lock member and outer tube member extend a short distance into the disc space adjacent the side surfaces of the distractor and between the two opposed surfaces. The lock member is then rotatable to engage the opposing bony surfaces of the disc

space. In this manner, the lock member secures the first end of the dynamic tube assembly into place and releases the distractor member for extraction from the patient through the bore of the dynamic tube assembly. In some embodiments the lock member may include a shaped cam surface that provides additional controlled distraction of the disc space during rotation thereof. The locking function prevents the first end of the dynamic tube assembly from being inadvertently moved from its intended position once placed, while maintaining the adjacent vertebrae in a distracted position and aligned position. Once the dynamic tube assembly is in place within the patient, the distractor and guide wire may be removed, providing an access tunnel to the disc space. The tunnel is provided with sufficient diameter for disc modification or removal as well as the placement of spacers, bone fragments, implants and the like to be passed therethrough to the disc space. Once the operation is completed, rotation of the lock member releases the dynamic tube assembly for removal from the patient.

Accordingly, it is an objective of the present invention to provide a device and method for performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine.

It is a further objective of the present invention to provide a device and method for performing a thoracic discectomy, an interbody fusion, and rigid internal fixation of the spine through the chest cavity from a lateral approach as a single integrated procedure.

It is yet a further objective of the present invention to provide a device and method for performing a lumbar fusion from the lateral aspect of the spine.

It is another objective of the present invention to provide a method and device for performing a lumbar fusion and spinal canal decompression from the lateral aspect of the spine.

It is yet another objective of the present invention to provide a device and method for performing a lumbar fusion, decompressive discectomy, and a rigid internal fixation of the spine as a single integrated surgical procedure.

It is still yet another objective of the present invention to provide a device and method to achieve discectomy, fusion and interbody stabilization of the lumbar without the need to mobilize the great vessels from the front of the vertebral bodies.

It is still yet another objective of the present invention to provide a device for performing surgery on the spine that includes a controlled locking mechanism for securing the surgical device to the bony structure.

It is still yet another objective of the present invention to provide a device for performing surgery on the spine that includes a cam surface for providing controlled distraction of a disc space.

Other objectives and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective view of one embodiment of the present invention;

Figure 2 is a partial perspective view of the embodiment shown in Fig. 1 illustrating the first end thereof;

Figure 3 is a perspective view of one embodiment of the guide wire of the present invention;

Figure 4 is a perspective view of one embodiment of the distractor member of the present invention;

Figure 5 is a partial perspective view of the first end of the distractor member illustrated in Figure 4;

Figure 6 is a partial perspective view of one embodiment of the dynamic tube assembly of the present invention;

Figure 7 is a partial perspective view of the dynamic tube assembly shown in Figure 6 illustrating the locking member positioned in the locking position;

Figure 8 is a partial perspective view of the dynamic tube assembly shown in Figure 6 illustrating the locking member positioned in the unlocked position;

Figure 9 is a partial perspective view of the dynamic tube assembly shown in Figure 6 illustrating the locking member positioned in the unlocked position;

Figure 10 is a perspective view of a segment of the thoractic spine and of the guide wire of the present invention being inserted from a lateral approach into the disc space between two adjacent vertebrae;

Figure 11 is a perspective view of the distractor member being inserted over the guide wire of Figure 10;

Figure 12 is a perspective view of the dynamic tube assembly being inserted over the distractor member of Figure 11;

Figure 13 is a front view of a portion of the segment of thoractic spine shown in Figure 1 illustrating the dynamic tube assembly fully seated into the disc space over the distractor member with the locking member in the unlocked position;

Figure 14 is a front view of the segment of the thoractic spine shown in Figure 13 illustrating the locking member in the locked position with the distractor member removed;

Figure 15 is an end view of one embodiment of the locking dynamic tube assembly;

Figure 16 is an end view of one embodiment of the dynamic tube assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While the present invention is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment with the understanding that the present disclosure is to be considered an exemplification of the invention and is not intended to limit the invention to the specific embodiments illustrated.

Referring generally to Figs. 1-16, an access assembly 10 constructed and arranged for anterior, lateral anterolateral spinal procedures is illustrated. The present invention provides for the entire surgical procedure to be performed through a relatively small incision, and may be performed in either the thoracic or lumbar spine. In the preferred embodiment, the access

assembly 10 comprises a guide wire 12, a distractor 14, and a dynamic tube assembly 16 that includes a manually operable locking member 18 for securing the dynamic tube assembly to a bony structure.

The guide wire 12 is provided for initial insertion into the disc space through a small incision in the patient with the assistance of x-rays, thorascope, image intensifier, direct vision or the like, see Fig. 10. For example, for surgery in the thoracic spine, a small incision in the chest cavity of the patient is made from a lateral approach to the thoracic spine. For surgery in the lumbar spine, a small incision may be made in the abdominal wall of the patient. The first end 22 of the guide wire 12 may be inserted with the assistance of a jam shidi needle or other suitable cannula. Alternatively, the guide wire may have sufficient rigidity for direct insertion. The first end 22 of the guide wire 12 may include a particular shape that aids in the insertion such as, but not limited to, a conical point, trocar, spherical or blunt. Once positioned, the central shaft 24 of the guide wire 12 extends between the disc space to outside of the patient to provide a guideway for the distractor member. The second end 26 of the guide wire 12 generally includes a blunt square cut. The guide wire 12 is preferably constructed from a biocompatible metal material such as spring temper stainless steel or nitinol. However, it should be noted that any material having sufficient rigidity to act as a guideway for the distractor member may be utilized without departing from the scope of the invention.

The distractor 14 is generally an elongated member having a first end 28, a central portion 30 and a second end 32. Extending through a central portion of the

distractor is a small central aperture 34 sized for cooperation with the outer surface of the center portion of the guide wire 12. The first end of the distractor preferably includes a tapered end 36 for ease of insertion into the disc space. In a most preferred embodiment, the tapered end includes a frustoconical shape. However, it should be noted that other shapes may be utilized for the tapered end so long as they provide a smooth transition from the outer diameter of the guide wire to the outer diameter of the distractor. Such shapes may include, but should not be limited to, spherical, bullet, pyramid or suitable combinations thereof. A pair of generally flat opposing side surfaces 38 extend along a portion of the length of the center portion 30. The opposing side surfaces are spaced a predetermined distance apart 40, which may include a taper, to provide a desired distraction (spacing) and alignment of the vertebrae. The second end 32 of the distractor 14 is provided with a surface 42 suitable for striking with a mallet or the like. The outer surface 44 of the distractor is preferably round to act as a guide surface for the dynamic tube assembly. It should be noted that while the inner and outer surfaces of the distractor member are illustrated as being round, other matched shapes may be utilized without departing from the scope of the invention.

The dynamic tube assembly 16 includes an outer tube member 50 and an inner lock member 52. The dynamic tube assembly 16 includes a first end 56, a center portion 58, a second end 60, an outer surface 59 and an inner surface 61. The first end 56 includes a pair of tab members 62 integrally formed thereto and sized so that they extend a short distance into the disc space adjacent the distractor

and between the two opposed surfaces. In this manner, the dynamic tube assembly may be easily traversed to its desired functional position. The second end 60 of the dynamic tube assembly 16 includes a gripping portion 64 for providing counter-rotation force to the dynamic tube assembly during actuation of the lock member 52. The inner surface of the outer tube member is sized to cooperate with the outer surface of the locking member so as to function as a bearing surface for rotation of the lock member.

The inner lock member 52 extends through the inner bore 54 of the outer tube member 50 and includes a first end 66, a center portion (not shown), a second end 70, an inner bore 54, and an outer surface 72. The first end of the lock member preferably includes at least two locks 74 extending beyond and having approximately the same width as the tabs 62, whereby the lock member may be rotated to align substantially therewith for insertion alongside the distractor. The distal ends of the locks each include at least one barb portion 76 which may include a ramp portion 78, a rear surface 80 and a pair of side surfaces 82. The ramp portion 78 provides easy entry through tissue and the like, while the side surfaces 82 may be constructed and arranged to bite and/or cut into the bone during rotation to create a secure engagement. The center portion 68 of the lock member is sized and shaped to cooperate with the inner surface 61 of the outer tube member 50 to allow free rotation therebetween. The second end 70 of the lock member 52 extends through the outer tube member terminating in a second gripping portion 84 which may include a hex 86 of shape constructed and arranged for providing rotational torque to the lock member for engagement or disengagement thereof. The inner bore 54 is sized for cooperation with

the outer surface 44 of the distractor member 14. In this manner, the distractor acts as a guideway for the dynamic tube assembly. The lock member is then rotatable to engage the opposing bony surfaces of the disc space. In this manner, the lock member secures the first end of the dynamic tube assembly into place and releases the distractor member for extraction from the patient while maintaining the adjacent vertebrae in a distracted and aligned position. In some embodiments the lock member may include a shaped cam surface 88 that provides additional controlled distraction of the disc space during rotation thereof. Once the dynamic tube assembly is in place within the patient, the distractor and guide wire may be removed providing an access tunnel to the disc space. The tunnel is provided with sufficient diameter for disc modification or removal as well as the placement of spacers, bone fragments, implants and the like to be passed therethrough to the disc space. Once the operation is completed, rotation of the lock member releases the dynamic tube assembly for removal from the patient.

CLAIMS

What is claimed is:

Claim 1. An access assembly kit for spinal procedures comprising:

a guide wire 12 for insertion into a disc space of a spine, said guide wire having sufficient length to extend from said disc space to a position outside of the body, said guide wire constructed of a material having sufficient rigidity to act as a guideway for a distractor member 14;

a distractor member 14, said distractor being a generally elongated member having a first end 28, a central portion 30 and a second end 32, said distractor member 14 having an aperture extending through a central portion thereof for cooperation with an outer surface of said guide wire 12, said first end 28 of said distractor member 14 being tapered for insertion into said disc space;

a dynamic tube assembly 16 that includes a manually operable locking member 18 for securing said dynamic tube assembly 16 to at least one of two opposed bony structures adjacent to said disc space.

Claim 2. The access assembly kit for spinal procedures of claim 1 wherein a portion of said dynamic tube assembly 16 is rotatable to cause said manually operable locking member 18 to engage said bony structure.

Claim 3. The access assembly kit for spinal procedures of claim 1 wherein said dynamic tube assembly 16 includes an outer tube member 50 and an inner lock member 52, said inner lock member 52 secured for rotation within said outer tube member 50.

Claim 4. The access assembly kit for spinal procedures of claim 3 wherein said dynamic tube assembly 16 includes a first end 56, a center portion 58, a second end 60, an outer surface 59 and an inner surface 61, said first end 56 including a pair of tab members 62 integrally formed thereto and sized to extend a short distance into said disc space adjacent said distractor and between said two opposed bony structures.

Claim 5. The access assembly kit for spinal procedures of claim 4 wherein said inner surface 61 of said outer tube member 50 is sized to cooperate with an outer surface of said inner lock member 52 so as to function as a bearing surface for rotation of said inner lock member 52.

Claim 6. The access assembly kit for spinal procedures of claim 5 wherein said inner lock member 52 extends through said inner surface 61 of said outer tube member 50 and includes a first end 66, a center portion, a second end 70, said inner surface 61, and an outer surface 72, said first end 66 of said lock member 52 includes at least two locks 74 extending beyond and having approximately the same width as said tab members 62, whereby said lock member may be rotated to align substantially therewith for insertion alongside said distractor member 14.

Claim 7. The access assembly kit for spinal procedures of claim 6 wherein said distal ends of said at least two locks 74 each include at least one barb portion 76, a rear surface 80, and a pair of side surfaces 82, said at least one barb portion being constructed and arranged to engage at least one of said at least two opposed bony structures.

Claim 8. The access assembly kit for spinal procedures of claim 7 wherein each of said at least one barb portions 76 include a ramp portion 78, each said ramp portion 78 providing easy entry through tissue and the like, said side surfaces 82 constructed and arranged to bite or cut into said bone during rotation to create a secure engagement therebetween.

Claim 9. The access assembly kit for spinal procedures of claim 6 wherein said second end 70 of said lock member 52 extends through said outer tube member 50 terminating in a second gripping portion 84 constructed and arranged for providing rotational torque to said lock member for engagement or disengagement thereof.

Claim 10. The access assembly kit for spinal procedures of claim 9 wherein said second end 70 of said lock member 52 includes a polygon shape 86 for providing rotational torque to said lock member for engagement or disengagement thereof.

Claim 11. The access assembly kit for spinal procedures of claim 7 wherein each of said locks include a shaped cam surface 88 that provides additional controlled distraction of said disc space during rotation thereof.

Claim 12. The access assembly kit for spinal procedures of claim 4 wherein said second end 60 of said dynamic tube assembly 16 includes a gripping portion 64 for providing counter-rotation force to the dynamic tube assembly during actuation of the lock member 52.

Claim 13. The access assembly kit for spinal procedures of claim 1 wherein said distractor member includes a pair of

generally flat opposing side surfaces 38 extending along a portion of the length of said central portion 30, said opposing side surfaces 38 being spaced a predetermined distance apart 40, to provide a desired distraction and alignment of said two opposed bony structures.

Claim 14. The access assembly kit for spinal procedures of claim 13 wherein said pair of generally flat opposing side surfaces 38 include a taper to provide a desired distraction and alignment of said two opposed bony structures.

Claim 15. The access assembly kit for spinal procedures of claim 1 wherein said second end 32 of said distractor 14 is provided with a surface 42 suitable for striking with a mallet.

Claim 16. A distractor assembly for providing access to a disc space comprising:

a distractor member 14, said distractor being a generally elongated member having a first end 28, a central portion 30 and a second end 32, said distractor member 14 having an aperture extending through a central portion thereof for cooperation with an outer surface of said guide wire 12, said first end 28 of said distractor member 14 being tapered for insertion into a disc space;

a dynamic tube assembly 16 that includes a manually operable locking member 18 for securing said dynamic tube assembly 16 to at least one of two opposed bony structures adjacent to said disc space, said dynamic tube assembly 16 including an outer tube member 50 and an inner lock member 52, said inner lock member 52 secured for rotation within said outer tube member 50, said dynamic tube assembly 16 including a first end 56, a center portion 58, a second end 60, an outer surface

59 and an inner surface 61, said first end 56 including a pair of tab members 62 integrally formed thereto and sized to extend a short distance into said disc space adjacent said distractor and between said two opposed bony structures, said inner lock member 52 extending through said inner bore 54 of said outer tube member 50 and including a first end 66, a center portion, a second end 70, an inner bore 54, and an outer surface 72, said first end 66 of said lock member 52 including at least two locks 74 extending beyond and having approximately the same width as said tabs 62, whereby said lock member may be rotated to align substantially therewith for insertion alongside said distractor member 14.

Claim 17. The distractor assembly of claim 16 wherein said distal ends of said at least two locks 74 each include at least one barb portion 76, a rear surface 80, and a pair of side surfaces 82, said at least one barb portion being constructed and arranged to engage at least one of said at least two opposed bony structures.

Claim 18. The access assembly kit for spinal procedures of claim 17 wherein each of said at least one barb portions include a ramp portion 78, each said ramp portion 78 providing easy entry through tissue and the like, said side surfaces 82 constructed and arranged to bite or cut into said bone during rotation to create a secure engagement therebetween.

Claim 19. A distractor assembly for providing access to a disc space comprising:

a distractor member 14, said distractor being a generally elongated member having a first end 28, a central portion 30 and

a second end 32, said first end 28 of said distractor member 14 being tapered for insertion into a disc space;

a dynamic tube assembly 16 that includes a manually operable locking member 18 journalled for rotation therein for securing said dynamic tube assembly 16 to at least one of two opposed bony structures adjacent to said disc space, said dynamic tube assembly 16 including a first end 56, a center portion 58, a second end 60, an outer surface 59 and an inner surface 61, said first end 56 including a pair of tab members 62 integrally formed thereto and sized to extend a short distance into said disc space adjacent said distractor and between said two opposed bony structures, said inner lock member 52 extending through said inner bore 54 of said outer tube member 50 and including a first end 66, a center portion, a second end 70, an inner bore 54, and an outer surface 72, said first end 66 of said lock member 52 including at least two locks 74 extending beyond and having approximately the same width as said tab members 62, whereby said lock member may be rotated to align substantially therewith for insertion alongside said distractor member 14, said locking member 18 rotatable to cause said at least two locks to engage at least one of said at least two opposed bony structures.

Claim 20. The distractor assembly of claim 17 wherein each of said at least two locks include a shaped cam surface 88 that provides additional controlled distraction of said disc space during rotation thereof.

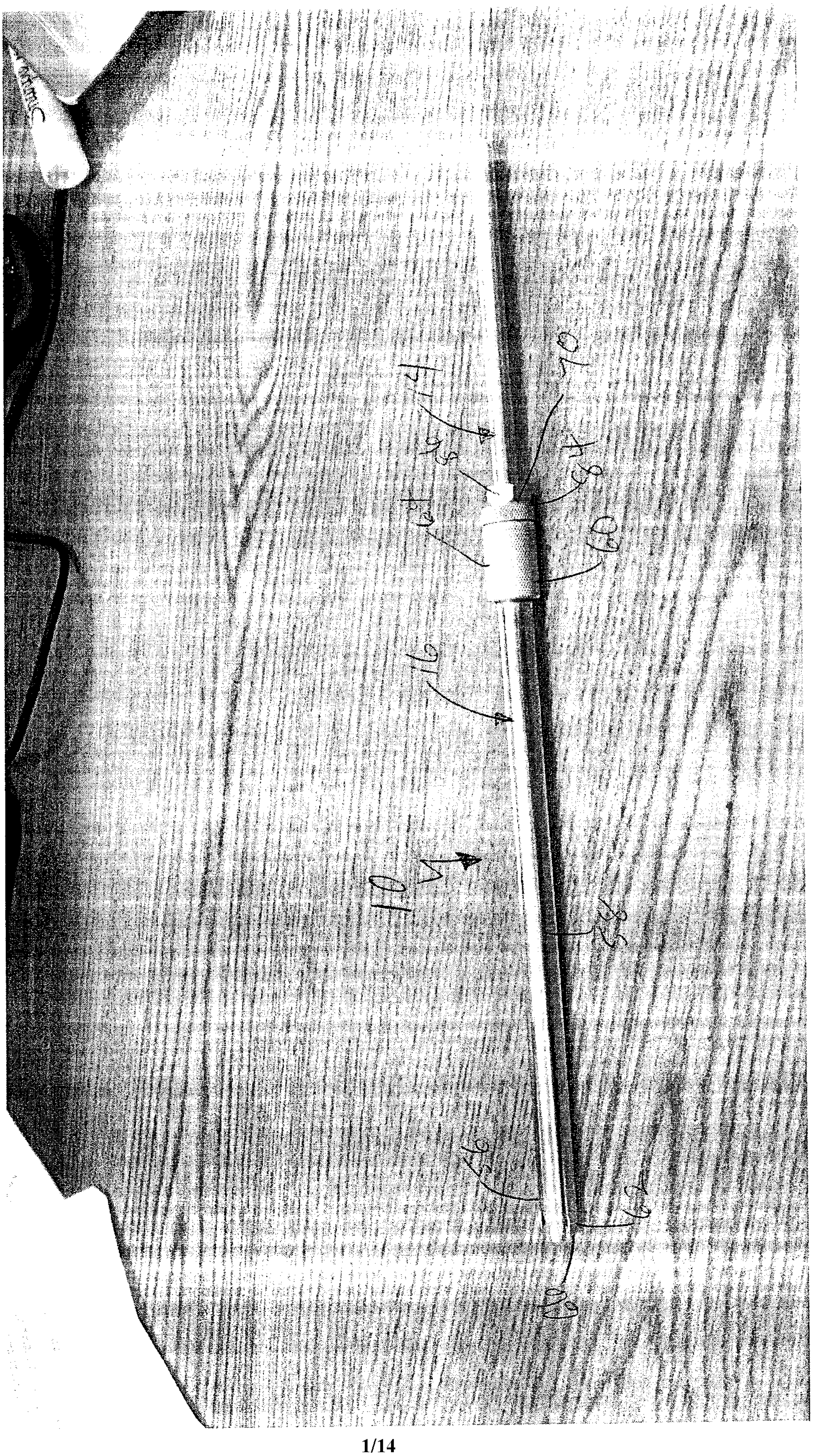

Fig. 1

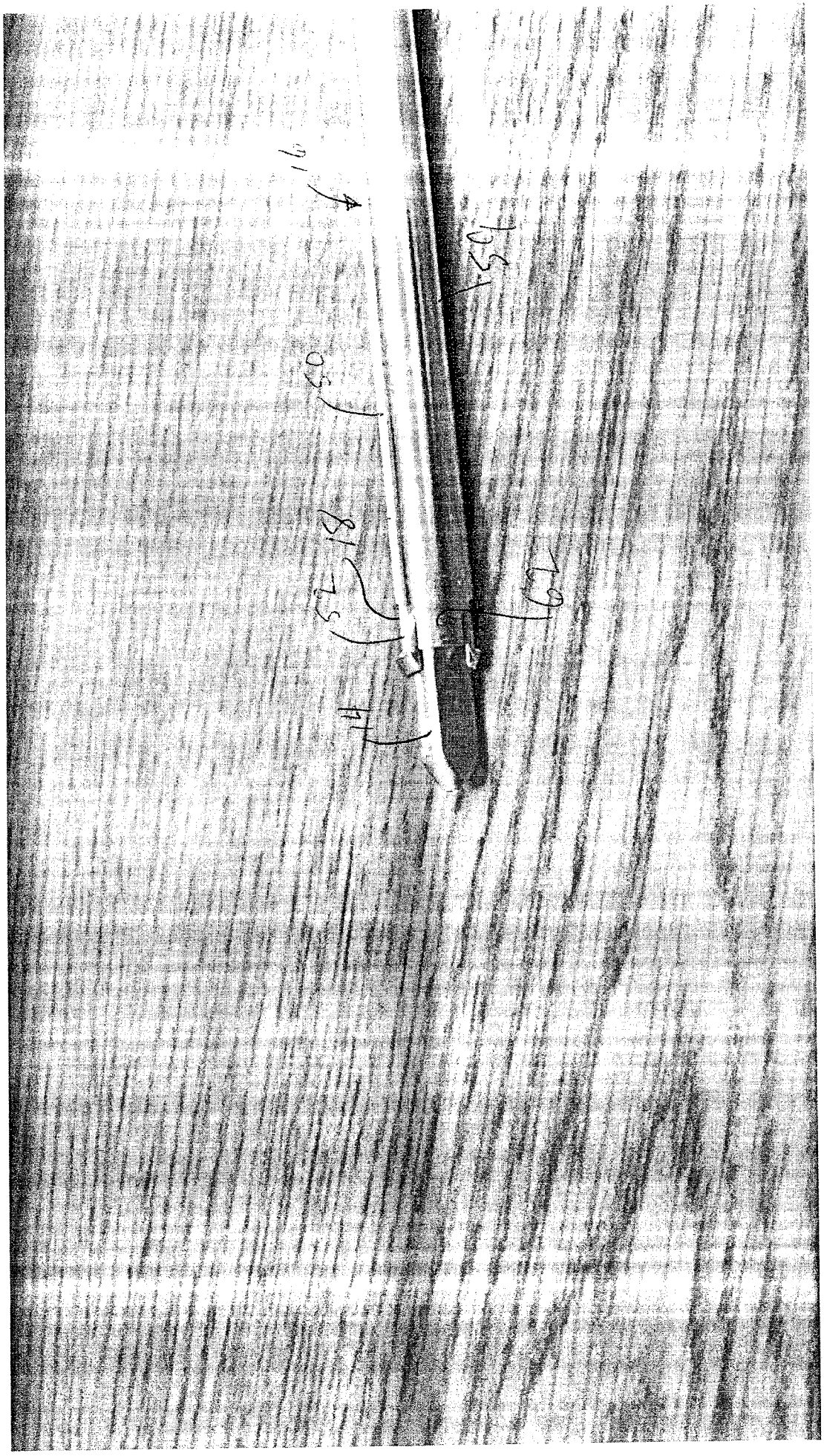

Fig. 2

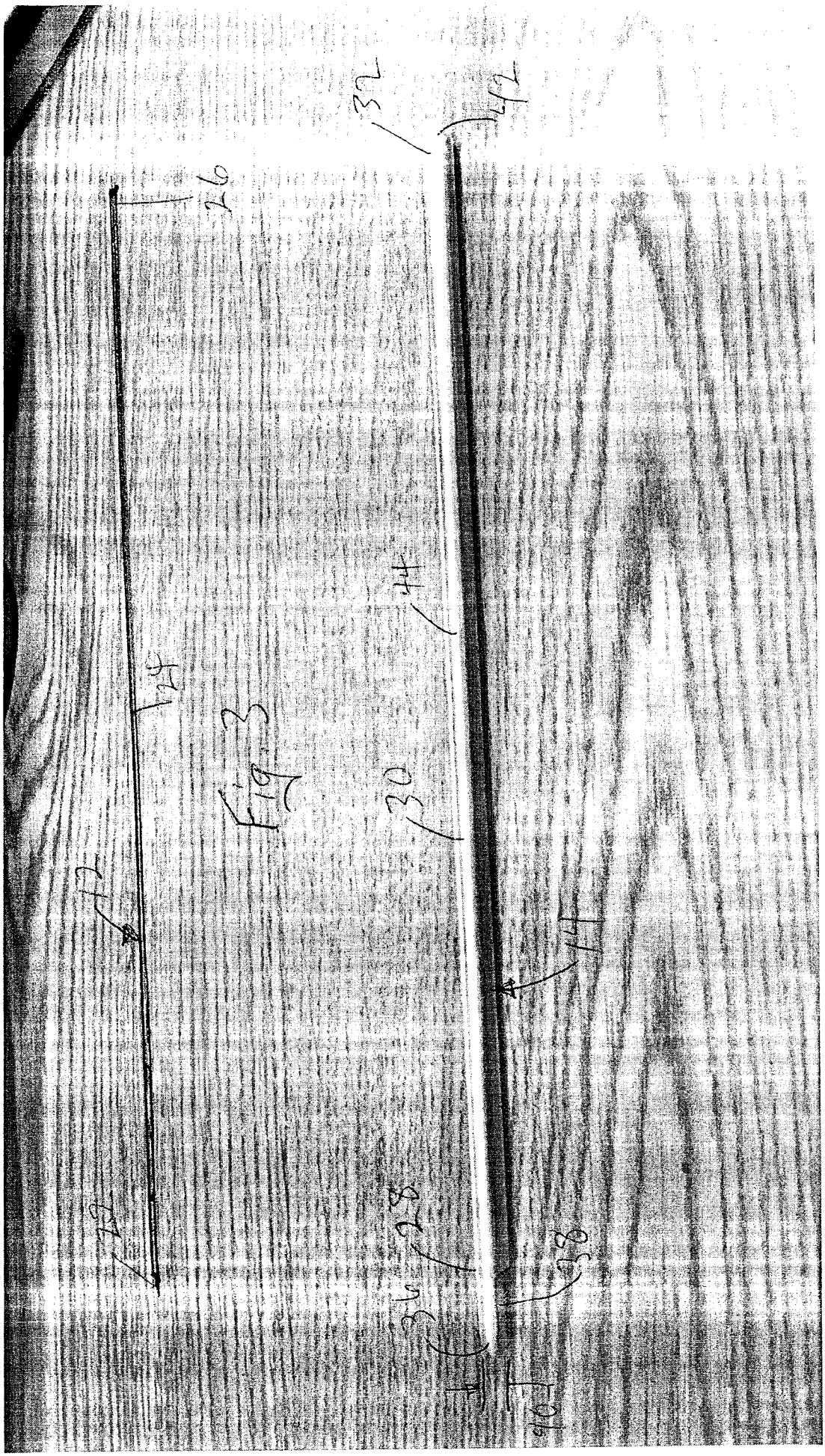

Fig. 4

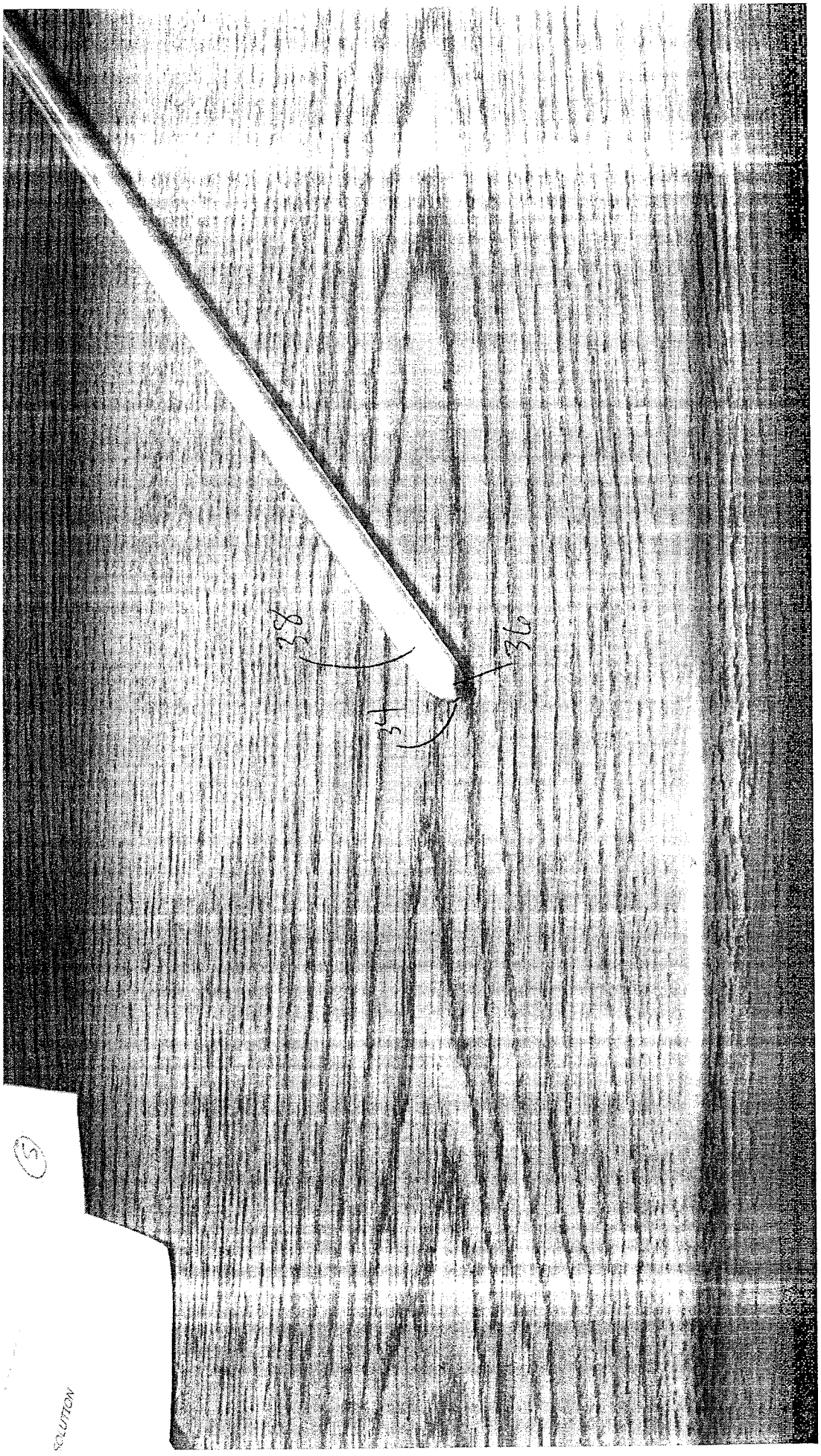

Fig. 5

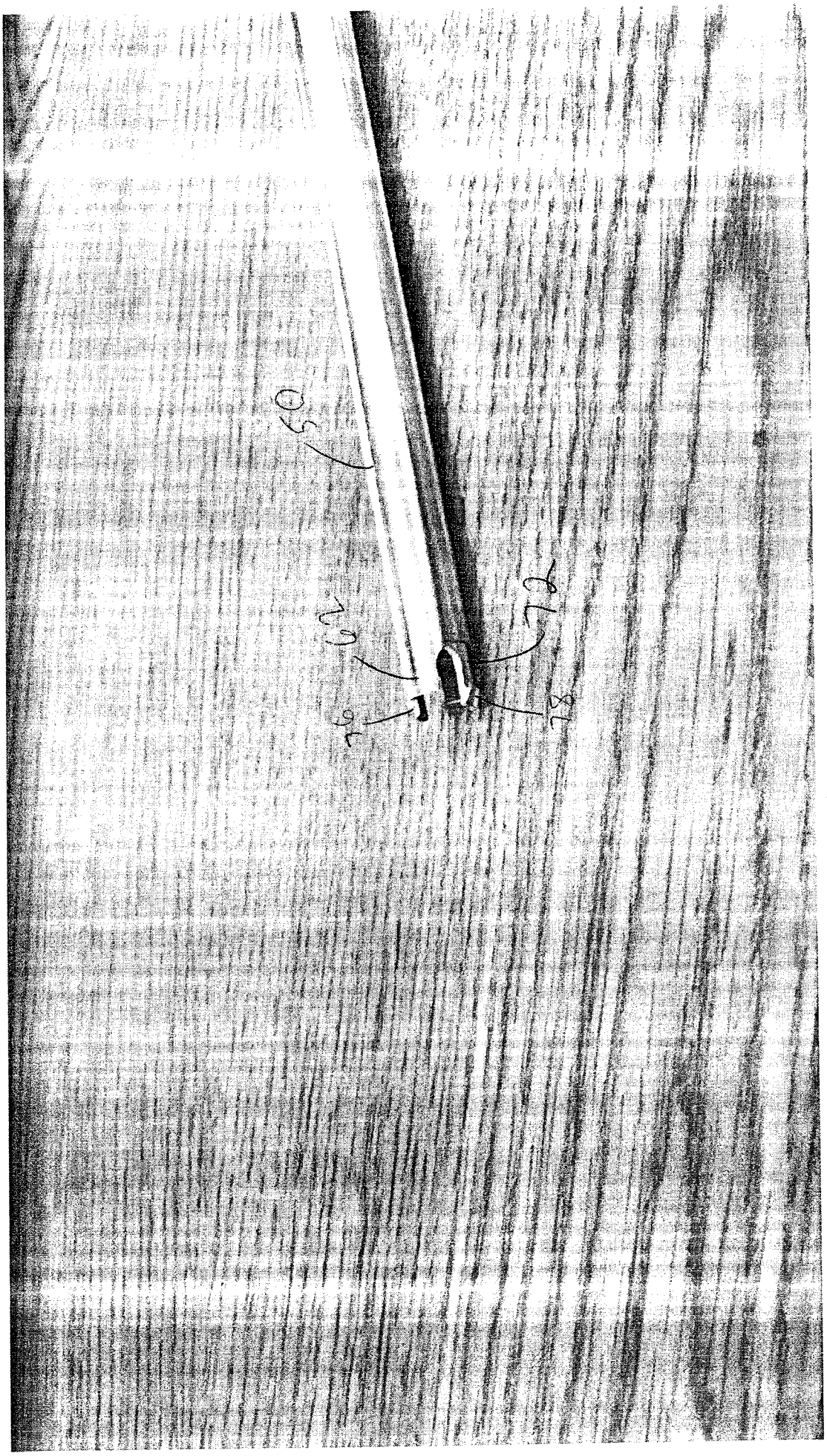

Fig. 6

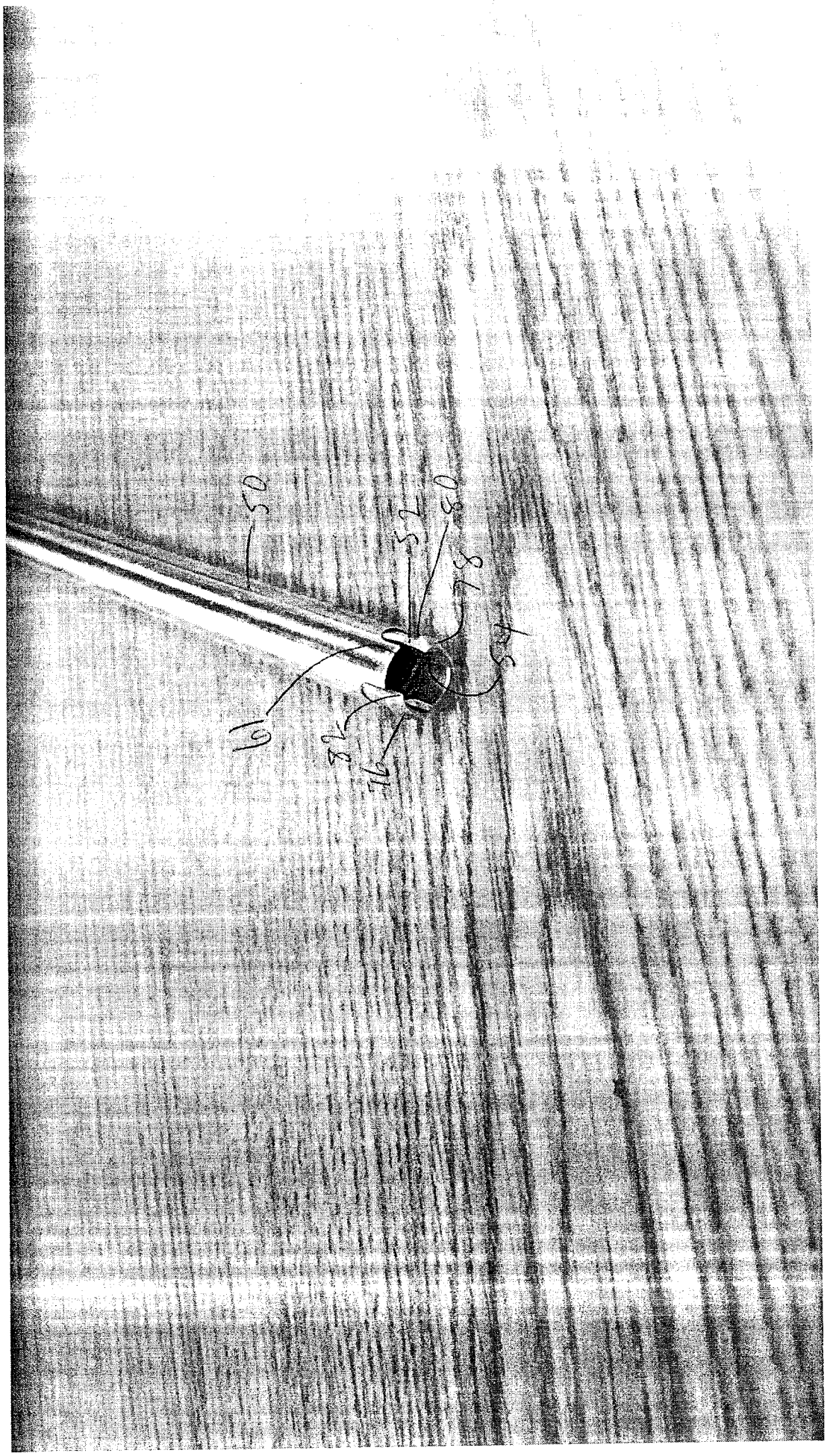

Fig. 7

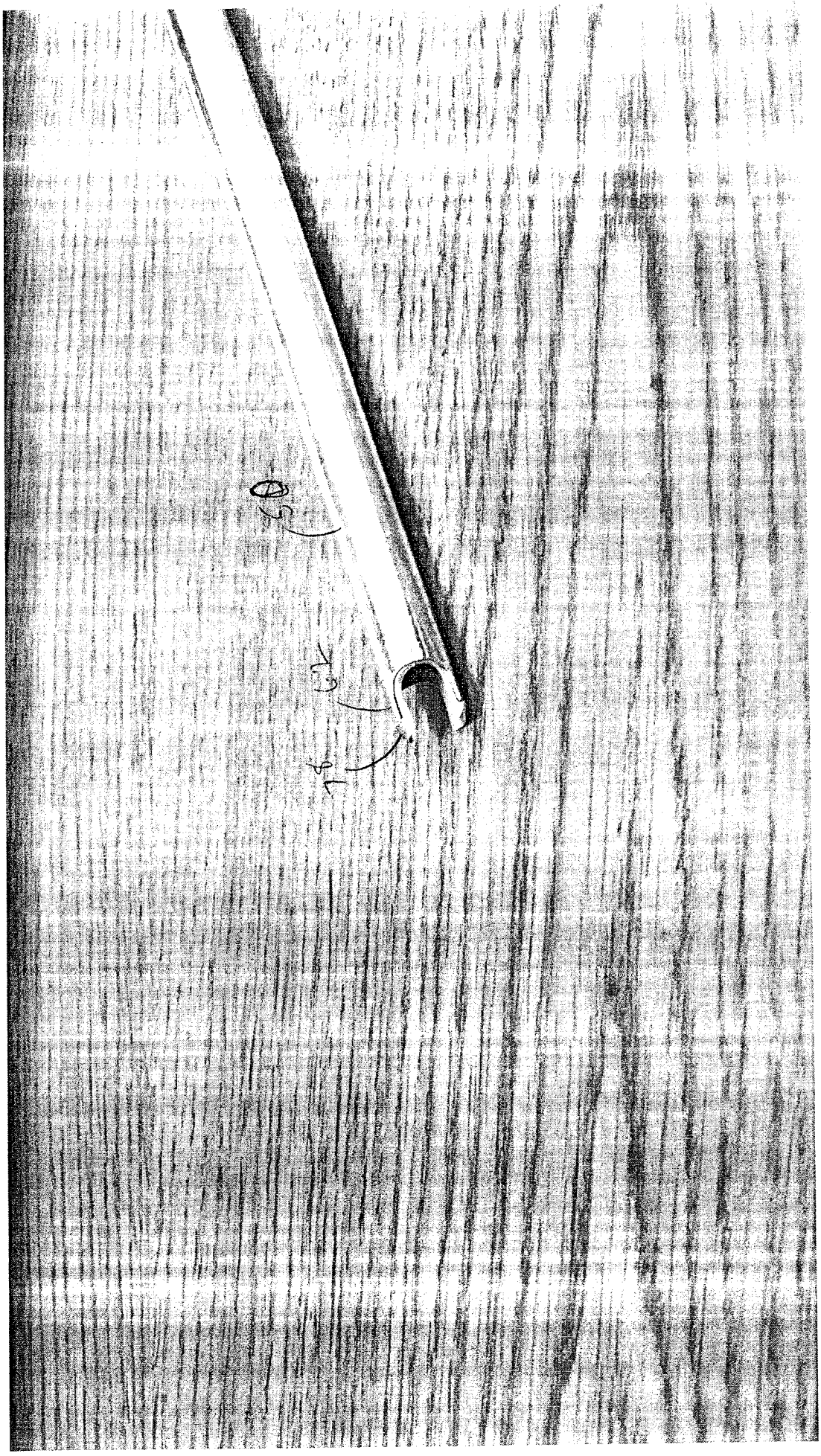

Fig. 8

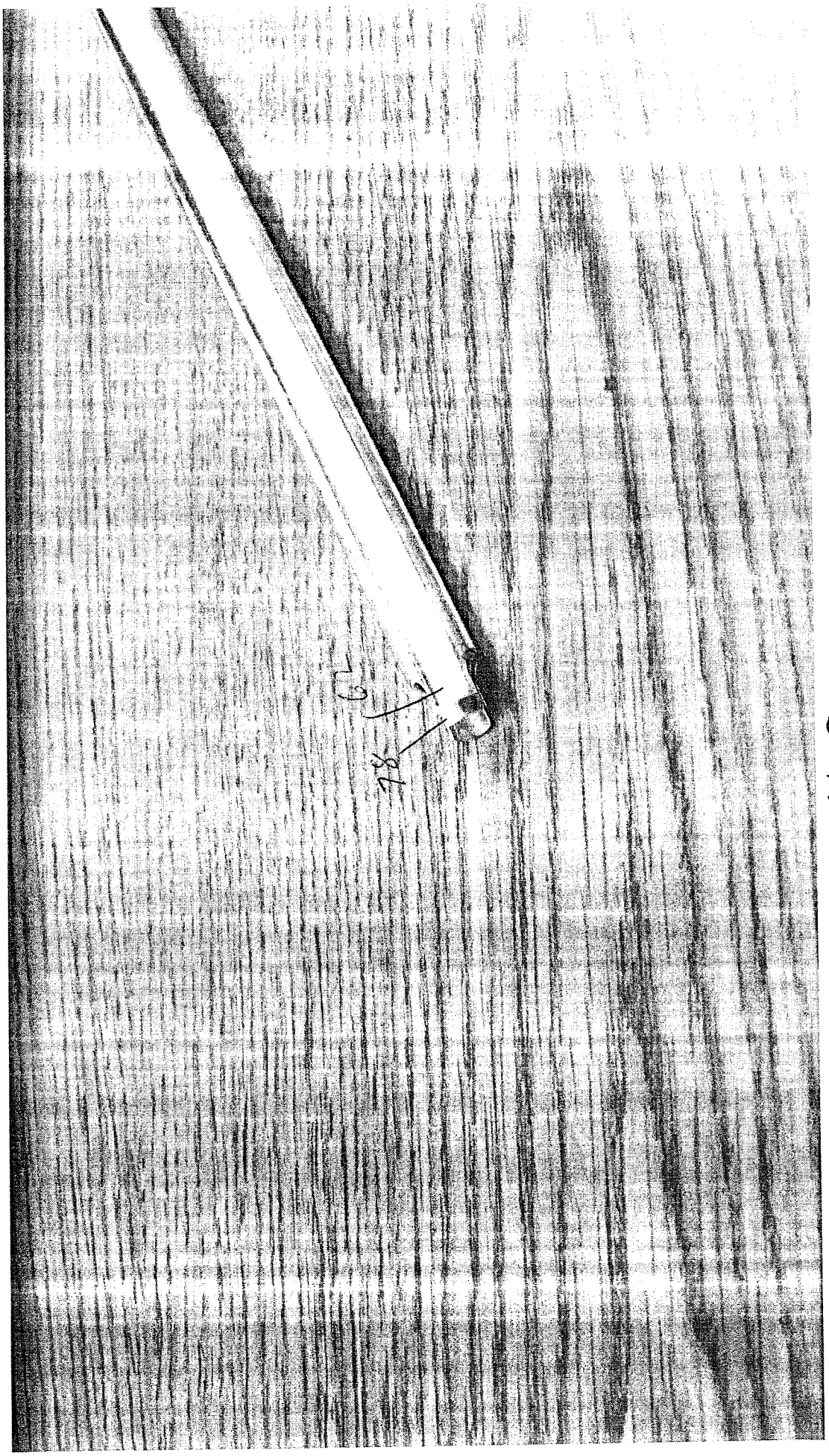

Fig. 9

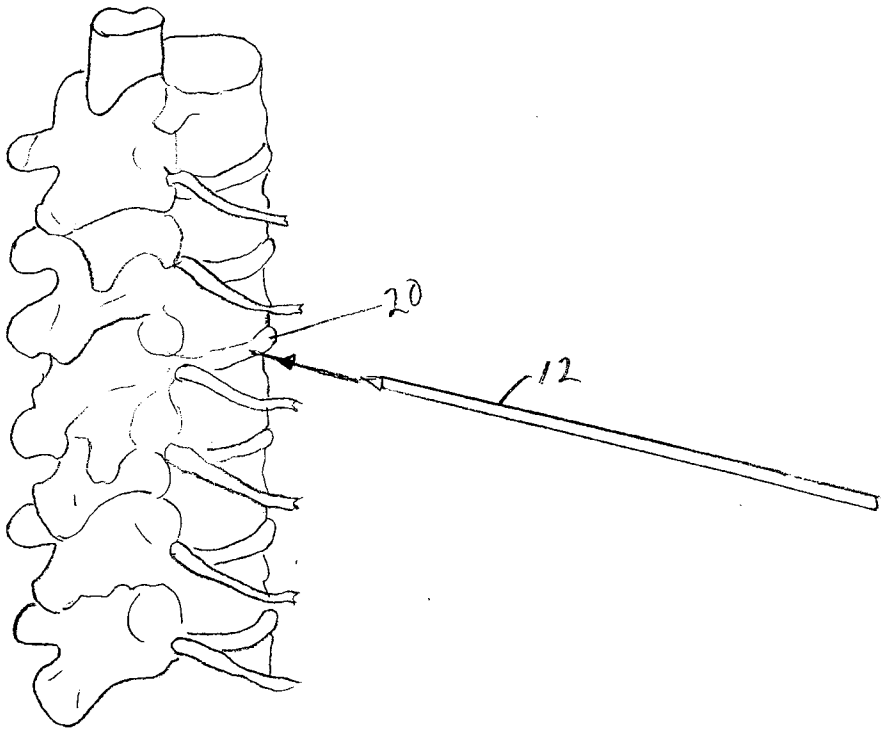

Fig. 10

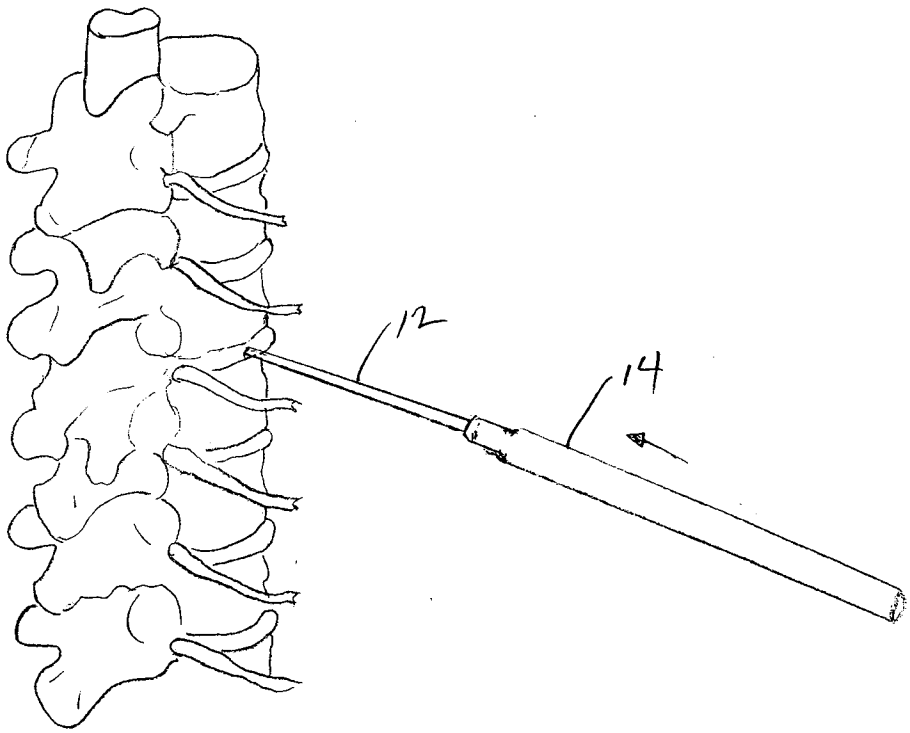

Fig. 11

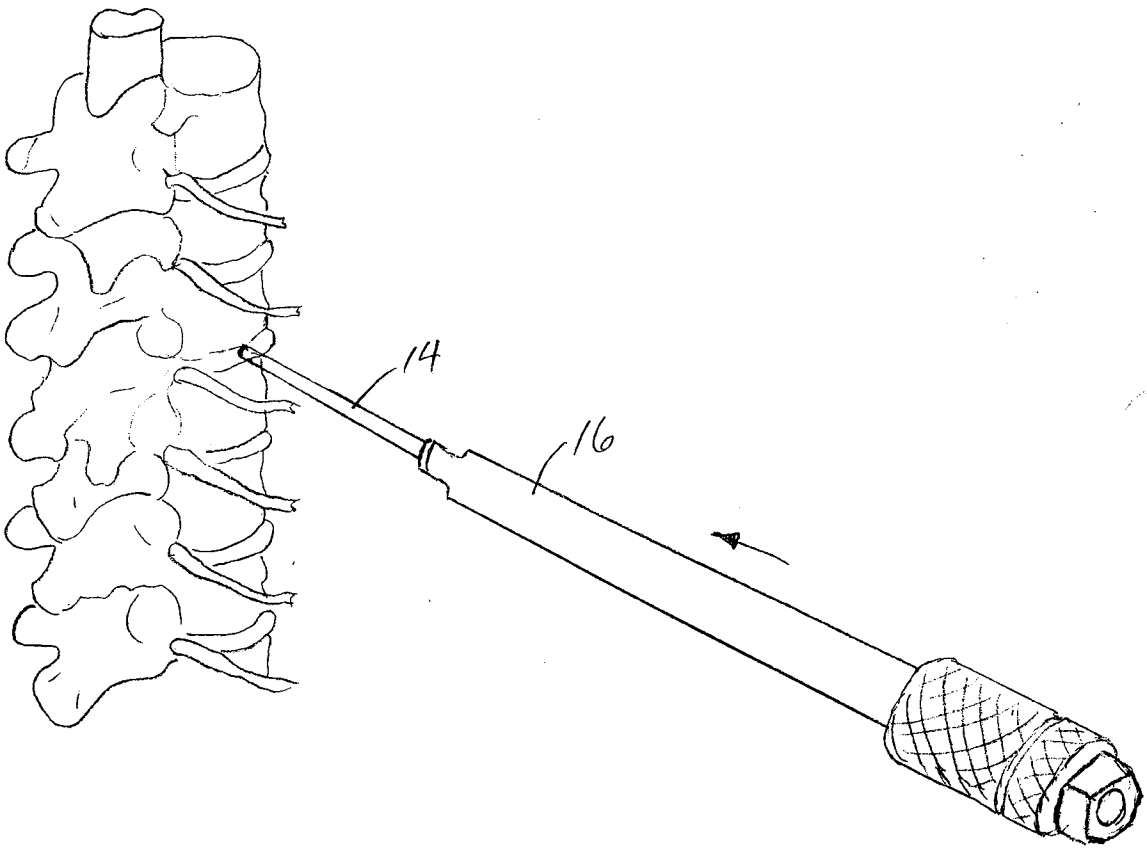

Fig. 12

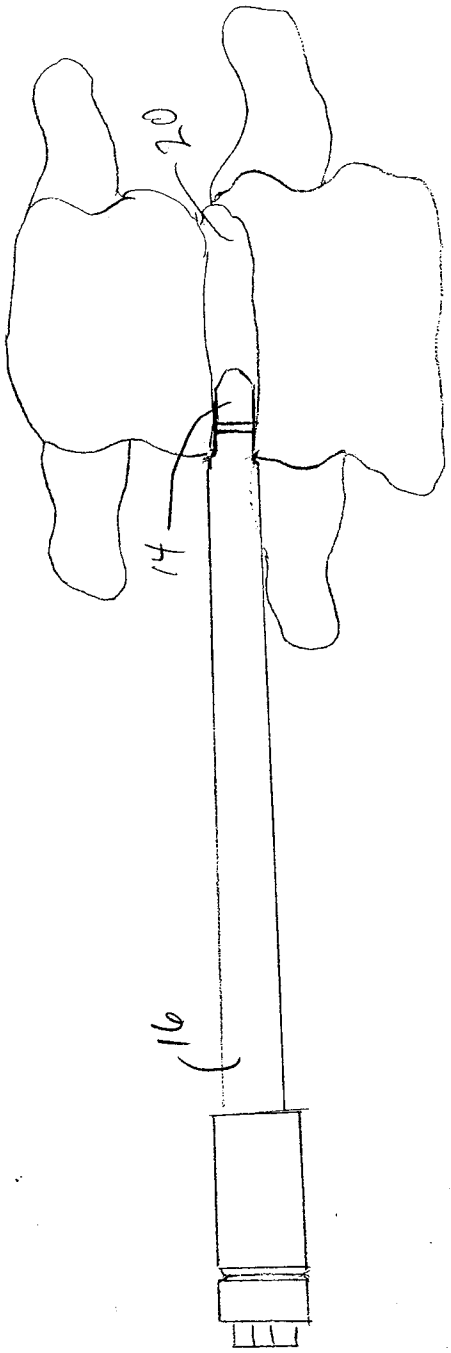

Fig. 13

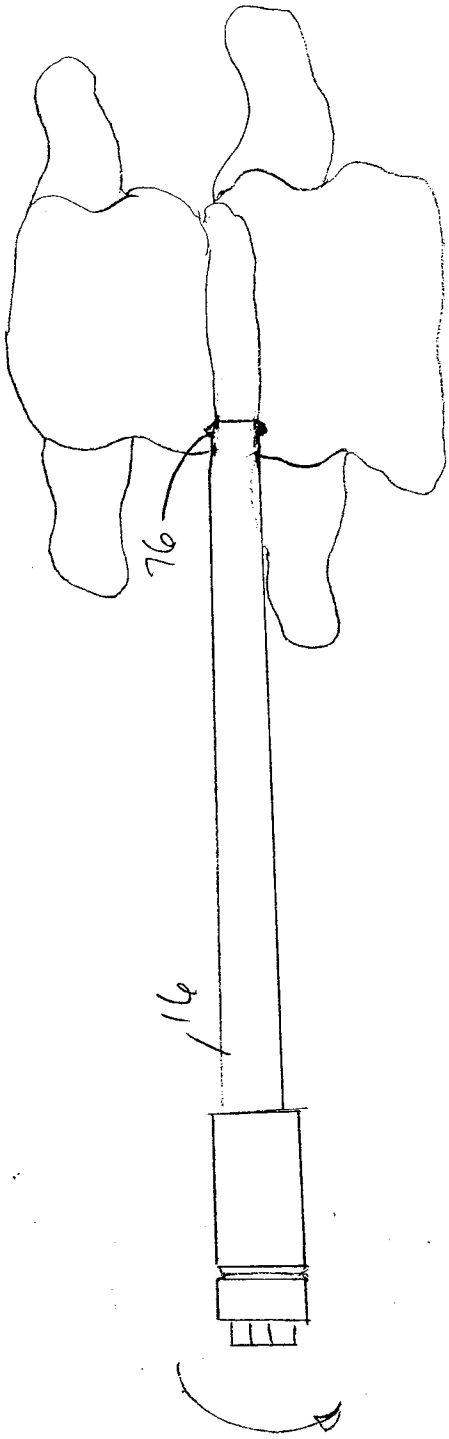

Fig. 14

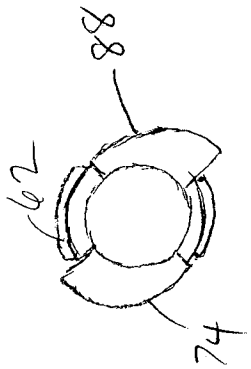

Fig. 16

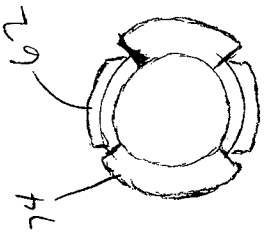

Fig. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/021256

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17
ADD.

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)
A61B

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/191241 A1 (MCCORMACK BRUCE M [US] ET AL) 29 July 2010 (2010-07-29) paragraphs [0238] - [0249]; figures 1-7,85-86	1-5, 12-15
X	US 2002/077641 A1 (MICHELSON GARY KARLIN [US]) 20 June 2002 (2002-06-20) paragraphs [0232] - [0234], [0241] - [0251]; figures 5-811A-C	1-5, 12-15
X	US 2009/216238 A1 (STARK JOHN G [US]) 27 August 2009 (2009-08-27) paragraphs [0070] - [0083]; figures 4-12	1-5, 12-15
X	US 2003/233094 A1 (SQUIRES CRAIG M [US] ET AL) 18 December 2003 (2003-12-18) the whole document	1-3, 12-15

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent 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
22 May 2013	31/05/2013

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, Fax: (+31-70) 340-3016	Cesari, Aude

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/021256

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 2010/331845 A1 (FOLEY KEVIN T [US] ET AL) 30 December 2010 (2010-12-30) paragraphs [0031] - [0042]; figures 1-7,11 -----	1-20

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/021256

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010191241 A1	29-07-2010	EP 2389127 A2	30-11-2011
		US 2009312763 A1	17-12-2009
		US 2010191241 A1	29-07-2010
		US 2013012994 A1	10-01-2013
		US 2013013070 A1	10-01-2013
		US 2013018474 A1	17-01-2013
		US 2013023995 A1	24-01-2013
		US 2013023996 A1	24-01-2013
		US 2013030440 A1	31-01-2013
		US 2013030532 A1	31-01-2013
		US 2013110168 A1	02-05-2013
		WO 2010074714 A2	01-07-2010
US 2002077641 A1	20-06-2002	US 2002077641 A1	20-06-2002
		US 2004236331 A1	25-11-2004
		US 2006200138 A1	07-09-2006
		US 2006200139 A1	07-09-2006
		US 2006200164 A1	07-09-2006
US 2009216238 A1	27-08-2009	EP 2262433 A2	22-12-2010
		JP 2011512943 A	28-04-2011
		US 2009216238 A1	27-08-2009
		US 2012316565 A1	13-12-2012
		WO 2009108318 A2	03-09-2009
US 2003233094 A1	18-12-2003	AU 2003276117 A1	31-12-2003
		US 2003233094 A1	18-12-2003
		WO 03105699 A1	24-12-2003
US 2010331845 A1	30-12-2010	AT 298534 T	15-07-2005
		AU 9697501 A	06-05-2002
		AU 2001296975 B2	23-09-2004
		CA 2426019 A1	02-05-2002
		DE 60111763 D1	04-08-2005
		DE 60111763 T2	15-12-2005
		DE 60117303 T2	02-11-2006
		EP 1328200 A1	23-07-2003
		EP 1466562 A1	13-10-2004
		EP 1468654 A1	20-10-2004
		ES 2243565 T3	01-12-2005
		ES 2258751 T3	01-09-2006
		JP 4018982 B2	05-12-2007
		JP 2004512084 A	22-04-2004
		US 6599291 B1	29-07-2003
		US 2004220581 A1	04-11-2004
		US 2007123901 A1	31-05-2007
		US 2010331845 A1	30-12-2010
		WO 0234144 A1	02-05-2002