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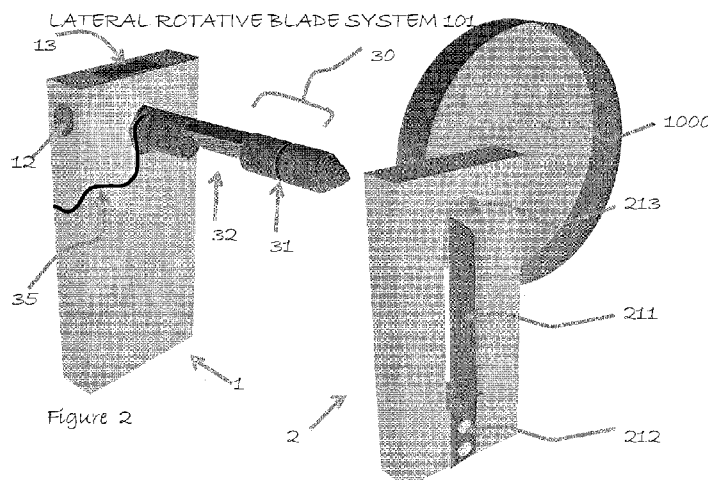
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(54) Title: AUTOMATIC NEEDLE PASSING DEVICE A NEW GENERATION OF NEEDLE HOLDERS



(57) Abstract: Needle passing' device' with at least 2 jaws using the needle shape activate the mechanism of needle passing from one jaw to another.

AUTOMATIC NEEDLE PASSING DEVICE

A NEW GENERATION OF NEEDLE HOLDERS

1. Technical Field

This invention relates to surgical suturing instruments, like needle holders, and more particularly to needle-passing suturing devices.

2. Background

Doing sutures with conventional needles and needle holders can be time consuming. This process requires two hands to change with the fingers the position of the needle between each tissue penetration and requires a good control of the force and orientation of the needle when penetrating into the tissue in order to penetrate the needle thru tissue. Good control in rotation and orientation is required mainly because of the lack of support, on the opposite side of the needle entry point, to force the needle into the tissue. The surgeon must poke the tissue and then rotate and push the needle thru the partially moving tissues. Care must be taken in the motion to limit the tissue movement in the same direction than the needle - this is especially true in denser tissues more difficult to penetrate.

In other words, it requires a substantial amount of time to repeatedly, for each stitch created, place the needle distally in the needle holder (near to the suture attachment point), penetrate tissue in a controlled fashion to puncture tissue sufficiently and create the correct motion to force the needle penetration. Then detach the needle from the needle holder after this first penetration in the tissue and grasping the emerging proximal portion of the needle (30) on the other side of the tissue (without losing it back in the tissue). Finally, once the needle is removed from the tissue with the suture the surgeon has to remove, with his fingers, the needle from the needle holder and put it back in the needle holder at a more distal portion (34) to make another stitch and repeat the previous steps.

Many devices have been designed to address this problem like the Endostitch® from Covidien. The Endostitch® is a device specialized in endoscopic surgery. The Endostitch® has hand actuators to control the transfer of needle from one jaw to the other and a relatively complex mechanism to achieve this. Other inventions have one direction needle transfer. None provide a bi-directional needle passing system without use of actuators, none describes a very simple mechanism to do so.

It could be beneficial to make a very simple mechanized device that can be operated easily in one hand without any actuators to do the steps of: needle passing and provide mechanical support on the opposite side of the tissue when penetrating to make the procedure more controllable and faster and to free the second hand of the surgeon to perform another task (visibility or retraction or other). It is known that a substantial portion of many surgical procedures is allocated for suturing so saving suturing time will result in substantial time saving in surgical procedure.

3.1 Preferred Embodiment

The low profile and very simple device presented is an actuator-less needle passing device. The device presented herein has at least two jaws and has the general shape of a conventional needle holder. The device allows holding the needle (3) with the first jaw (1) first and then use the second jaw (2) to grasp the needle (3) and pull it out of the punctured tissue (1000) from the opposite side.

To perform sutures using this device, the special needle (3) is placed in the first jaw (1) - the needle is held in place in the first jaw (1) by friction or another self retentive mechanism. The tissue (1000) is then placed between the two jaws with the erected needle. The jaws are closed together until the first portion of the needle penetrates thru the tissue (1000) and then enter and engages the mechanism (e.g (211-212) or (21-23-24-25)) of the second jaw (2). Once the proximal tip (30) of the needle is engaged in the second jaw (2), the needle holder is then opened (jaws separated) and the needle is pulled out of the tissue (1000) because the retentive force of the mechanism in the second jaw (2) is greater than the first jaw (1).

The first jaw (1) mechanism can include a flexible material (like Nitinol or other suited materials). A cylinder or rod is occupying a portion of the hole present in the first jaw (1), this allows friction grasping of the needle by friction forces created by the rod flexion when the needle is inserted in the first jaw mechanism. The distal portion of the needle deforms the flexible rod and creates a force on the needle. A cavity (13) inside the first jaw (1) around the cylinder (12) allows this cylinder to flex and move distributing therefore the deformation over a larger portion of the cylinder in order get a more ideal force with a more permissive tolerances in the design. This type of retention system has the benefit of being very durable and also allows the creation of an anti-rotational shape when a notch is present in the distal end of the needle. A notch in the

needle in the distal end matching the flexible rod position (36) enables the insertion of the needle in only one orientation in the first jaw (1).

When closing the jaws together to grasp the needle (3) by the second jaw (2) the surgeon must position the needle in the grasping area (30) of the needle against the retentive mechanism (Blade (211)& (21)). This area (30), typically proximal, includes the necessary physical features to engage in the second jaw (2) mechanism and creates unidirectional retention of the needle. This creates a very high retentive force that pulls the needle out of the tissue (1000) and out of the first jaw (1). If the needle penetrates the second jaw (2) but not positioned in the grasping area (30) inside the mechanism of the second jaw (2), the needle can easily travel bi-directionally across the second jaw (2). The areas of needle that penetrates in the second jaw and that are not a grasping area (30) do not create any retention in the preferred embodiment these other areas can be created by making, for example, a recess (32) that does not engage in the mechanism and features of the second jaw (2). In a more ideal embodiment the needle (3) would include a physical feature that would create a tactile or audible feedback to the user when in the grasping area (30) ; this can be for example a notch (31) that creates a "click" when engaged. It is not mandatory to have a notch in order to obtain retention even on a smooth needle surface, retention can be obtained using a harder material (than the needle) that can penetrate in the needle (creating a micro notch) to hold it in place.

Once the jaws are opened enough to remove the needle from the tissue (1000), the jaws are moved away from the tissue (1000) in order to begin transfer of the needle back to the first jaw (1). So when the needle holder is away from the tissue (1000), the jaws are simply closed together. This results in the distal portion of the needle (34) entering the hole (11) and being held by the first jaw (1). A blocking mechanism is required to prevent the needle from going completely thru the second jaw (2). This blocking mechanism prevent any further traveling of needle inside the second jaw and enables then force the penetration of the distal portion of the needle into the hole (11) of the first jaw (1). The block can be an increase of diameter of the needle in its middle-distal portion. This stopping mechanism can similarly be a groove inside the volume of the needle starting from the proximal end to terminate in a more distal portion of the needle resulting that the traveling of the needle is stopped when the matching feature, present in the second jaw, traveling inside this groove hits the end of this groove. In a more ideal embodiment a feedback would be provided to the user when the needle has

sufficiently penetrated in the first jaw (1). For example a depression or a notch (36) on the distal portion of the needle (34) matching the spring loaded retentive feature (12) of the first jaw (1).

The mechanism in the second jaw (2) can be spring loaded in order to maintain the needle securely in position once it is held only by the second jaw (2). The spring action allows the mechanism to return in a "ready" position once the needle is out of the second jaw (2) in order to allow the needle to re-engage the mechanism. The mechanism could be made of a high memory material like Nitinol in order to provide good spring effect in the blade or the mechanism. The blade or the area of the blade directly in contact with the blade could be made of Tungsten carbide in order to reduce the wear of this part.

Similarly the retention in the first jaw (1) can also be spring loaded in order to facilitate feedback and high retention of the needle. A device using only precision matching surface-surface retention can alternatively be used but is more difficult to control and is less robust in "harsh" environment with the presence of contaminants.

In order to load the needle in the mechanism the suture can be delivered in a delivery system that acts like the first jaw (1). In this fashion the needle packaging includes a retentive portion where the needle is placed. The user places the needle in the second jaw (2) and this pulls automatically the needle from the packaging. Similarly the user at the end of the suturing process can use the plastic packaging to recapture the needle from the second jaw (2) and dispose it.

Additionally, once the needle is held by the one of jaws only, the force exerted by the retentive mechanism on the needle must be sufficiently opposed by structures of the jaw to prevent excessive rotation, movement or escape of the needle. Proper high precision matching of dimensions between for both needle and jaws is necessary and it can be desirable to include features in the jaw to more robustly oppose the forces created and cope for all machining tolerances issues.

Additionally, even if it is not absolutely necessary, it can be envisioned to include an anti-rotation design in the needle and in the jaws in order to prevent rotation of the needle. Including keys or anti-rotation means could decrease the risk of having the needle not being aligned with jaws entry needle entry points and could cause the system not to function or could even lead to the loss of the needle.

Additionally, the device could be equipped with tissue retracting elements that would force the needle to penetrate but would prevent

having the tissue to be caught between the needle and the second jaw (2). For example if for a reason the tissue is not punctured early enough when entering the second jaw (2), tissue could be present between the needle surface and the second jaw (2) mechanism preventing therefore the proper closing of the jaws and the entry of the needle or the damage of the tissues. Spring loaded blades forcing an intimate contact with the needle would prevent any tissue capture. The main blade could also be the component that performs this task of tissue retraction if the blade is positioned on the opposite side of the second jaw (2). Alternatively a silicone sheet placed in front of the entry point of the second jaw (2) could also perform the task of tissue retraction.

Additionally, since the jaw of the present invention describes an arc the needle general shape is bended to conform to this arc curvature. This is not essential since the arc is close to a line in many long jaws needle holders. For smaller sized it is mandatory to have the rudimentary shape of the arc at the level of the entry points.

Additionally, the suture (35) in the preferred embodiment is attached close to the (34) portion of the needle not at the extremity. This point of attachment is not mandatory but preferable to simplify the design. In the case we want to have the exit point at the distal portion we would require to have a slot in the first jaw (1) to allow the insertion and the removal of the suture for each penetration.

Additionally, the needle could be made sharp at both extremities to enable penetration in both jaws directions: penetrate tissue when passing from Jaw 1 to 2 or when passing from jaw 2 to 1. The distal portion of the needle may have to be longer in this case.

Additionally, the needle can have different length for different tissues thickness.

Additional, since the mechanism of this needle passing device described here is so simple it can be adapted to a variety of needle holder types almost without limitation.

Additionally, one could envision to create an attachment feature on the needle to load sutures easily on needle. A whole could be a good mechanism to do so.

Additionally, one could design this needle holder in order to allow it to be used also like a conventional needle holder when no needle is in.

Additionally, knots can be made with this device without having to remove the needle from the needle holder by passing the needle from one jaw to the other around the suture.

Additionally, all the components and materials used can be chosen to allow the sterilization using heat or autoclaves or other means.

Additionally, in case one does not want to use tissue retraction means to prevent gripping of the tissue, one could use a more profile needle tip and/or a method where the user closes the jaws over the tissue without passing the grasping area (30) to push the tissue and then go out and then reopen the jaw and reclose it and stop at the grasping area. With this method the tissue has less chance of being trapped and pulled with the needle or damaged. Alternatively one could design the second jaw (2) to act as a cutting mechanism in order to pinch and cut any tissue that could have been trapped. This last technique has the disadvantage of being more invasive.

Additionally, the needle (3) could be curved (3b) to enable a rotation of the needle in tissues or for other surgical purposes, with this needle shape the jaws are placed in a offset position (Figure 26).

Additionally, for better access in some situations, the second jaw (2) maybe retractable in order to physical improve access to the tissue. With the second jaw retracted, one can more easily access tissues with the needle and maneuver the needle in different directions without the interference of the second jaw. Once the complete or partial penetration of the needle is performed the second jaw can be erected to grasp the needle with the closing motion and continue the cycle like in prior embodiments presented.

In the lateral Rotative blade model (101): the mechanism of the second jaw (2) creates retention of the needle by having the blade (211) rotating laterally and being blocked by the side wall of the jaw around the long groove (213) when the grasping area of the needle is at the level of the blade (211) it pushes laterally the blade. When the recessed area (32) is at the level of the blade (211) the blade can enter in the long groove (213) when the needle is pulled when the jaws are separated. See drawings below.

In the axial rotative blade model (100): the retention is created by unidirectional rotation of the blade (21) when the grasping area (30) is inserted. When the recessed area (32) is inserted at the level of the blade (21) this blade can freely rotate in both directions. See drawings below (100).

3.2 Another embodiment with actuators

In figures 27 to 34 we present a second embodiment with actuators. Figure 33 shows a top view of the device. Fig 32 is schematic view. In 3D. The general principle is the same than in the first preferred embodiment: needle passing device. In this embodiment however the operator has to depress the actuators to switch the needle from one jaw (202) to the other. In this embodiment the jaws have generally the same mechanism in opposition with the first embodiment.

It is fabricated with two needle holder (200) (Castroviejo type) attached with each other using a tweezers distal portion (205) in order to move as the two needle holder were the two arms of a tweezers.

A special relatively simple mechanism (figure 32 and others) is integrated in order to allow one needle holder to be in an opposite state compared to the other: when one closes the other opens. It is made for each needle holder (200) with: sliding elongated portion with two bends (206), a pushing angulated part (208) fixed to the upper arm of the needle holder upper arm (201up), a retentive portion (207) attached to the upper arm (201up), a transferring rotation arm (209), a pivot axe (210) in the middle of the pivot axe and fixed to the tweezers part (205).

In the initial stage, one jaw of a needle holder is open and the other needle holder jaw is closed. When the operator closes the open needle holder (figure 29a 29b) by closing together the arms (201) of the needle holder, the pushing angulated part (208) touches and forces the translation of the sliding bar (206) in the direction of the jaw (202). Figure 31a to 31h show the mechanism of one needle holder. The action of translation created on the sliding bar (206) results in the positioning of the sliding over the retentive arm (207). Once the needle holder is relaxed by the operator, the springs (209) create a force in the opening direction and since the sliding bar (206) is translated over the retentive arm (207) the jaw remains closed - see figures 31a to 31e. This action of translating the sliding bar toward the anterior portion (toward the jaw) results also in the rotation of the rotation arm (209) around its pivot point (210) see figure 34b.

This rotation of (209) then generates a pulling force on the opposite sliding bar (206) of the opposite needle arm in the opposite direction away from the jaw. This action results in the sliding bar (206) translating out of the retentive arm (207) and then the opening of this needle holder. In figure 31f to 31h we see the result of the pulling of the sliding arm (206) on the opposite needle holder. We

understand than in Figure 31f and 31g that the pulling action of (206) opens the needle holder because of the spring action of (204) always exerting a force in the opening direction.

This assembly enables the holding of the needle in one jaw and the grasping of the needle by the second arm like in the precedent embodiment. Figure 30a to 30g show the device in action suturing a blue tissue. In 30a the needle is held by one jaw. In 30b the needle penetrates in the tissue by bringing the two jaws together. In 30c the second jaws is closed on the needle by pressing on this needle holder - this results in the automatic opening of the first jaw and the release of the needle from this first jaw. In Fig 30d the needle is pulled out of the tissue by separating the two jaws. In Fig 30f the jaws are brought back together and a force is applied to close the first needle holder to grasp back the needle. In Fig 30g the jaws are separated again with the needle in the first jaw ready to penetrate the needle again in tissue.

In this embodiment, the action of closing on needle holder results in the closing of the jaw of this needle holder before opening the other needle holder jaw. This has to do with the angle and at the position of (208) in relation with (206) at different closing distances.

A groove in the interior portion of the jaw can be included to ease the positioning of the needle inside the jaw and therefore align the needle. The needle can be straight or slightly curved. The needle can be cutting on both ends and have the suture attachment placed between the two ends.

It is also possible to add a mechanism that would allow the automatic switching of jaws opening and closing with the action of closing the needle holder together and remove the need of pressing the needle holders. The action of closing and opening would alternatively close first jaw and open the second - the next closing would open the first and close the second.

Needle passing device with at least 2 jaws using the needle shape to activate the mechanism of needle passing from one jaw to another. No actuators are necessary - the mechanism of needle passing is all controlled by the closing and opening action of the jaws. This works along with a needle blocking mechanism that prevent the needle from penetrating too much in the second jaw.

Needle has one proximal portion with a physical feature compatible with the second jaw mechanism that blocks any backward movements (uni directional traveling like a tiwrap). One portion more distal that is not compatible with the unidirectional mechanism of the the second jaw. One portion to limit the penetration of the needle in the second jaw. One distal portion to fit with the retentive mechanism of the first jaw. The needle has the general shape required to fit the trajectory of the jaws travelling.

Notches to provide feedback audible or tactile can be present on the proximal portion and on the distal portion.

The needle can sharp on both sides for bilateral puncturing. The distal portion may be longer in this case.

Spring loaded mechanism of the second jaw and sufficient support to maintain needle in position when needle is only held by the second jaw.

First jaw mechanism could be a nitinol cylinder tangeant to the cavity that fits the distal portion

Antirotaion features can be included in the needle and the jaws to prevent movement of the needle.

Multiple jaws & multiple needles to make faster suturing with multiple stitches.

Use of tungsten carbide for blade material

Needle passing device using a mechanism in which the retentive force on one jaw is larger than the retentive force of the second jaw allowing the needle to successively pass from one jaw to the other.

This device has one jaw having a permanent friction mechanism and the second jaw having at least one moving part in which the

retentive action can be activated and deactivated by the needle action and shape.

Retraction tissues means to push tissue and force it in tissue to prevent jamming of tissue between the needle and the jaw.

Finger springs close together in front of the orifice of orifice of the second jaw. These jaws are pushed by the needle laterally in order to let the needle inside the orifice without letting any tissue inside the orifice.

Silicone sheet in front of the second jaw orifice that let only the needle penetrating in the orifice and keep tissue outside like claim 3.1.

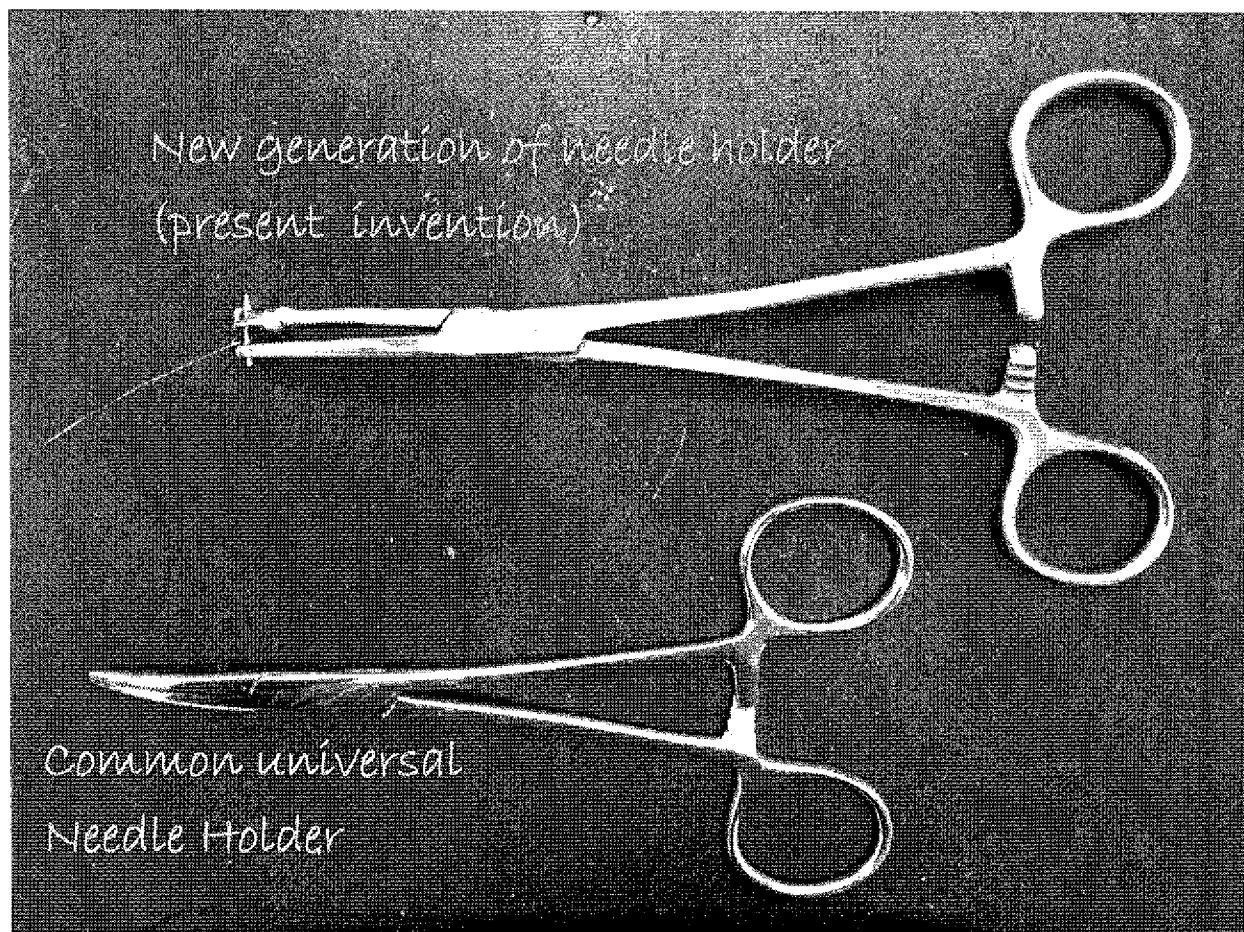
Dispenser that holds the distal portion of the needle to be inserted by hand in the second jaw. This is made in a material like plastic.

A needle passing device comprising two needle holder attached with a spring mechanism that generate sufficient force to open the jaws. A mechanism that links the two needle holders together in a fashion that one is closed the other automatically opens.

Claims:

1. A stitching device comprising: a jaw assembly having a first jaw and a second jaw; a needle that is passable between said first and second jaws; said needle having a shape that is used to activate the passing between said jaws; said needle having a physical feature that is not compatible with one of said first or said second jaws to limit the movement of said needle within said at least one of said first or said second jaws.

Figure 1



LATERAL ROTATIVE BLADE SYSTEM 101

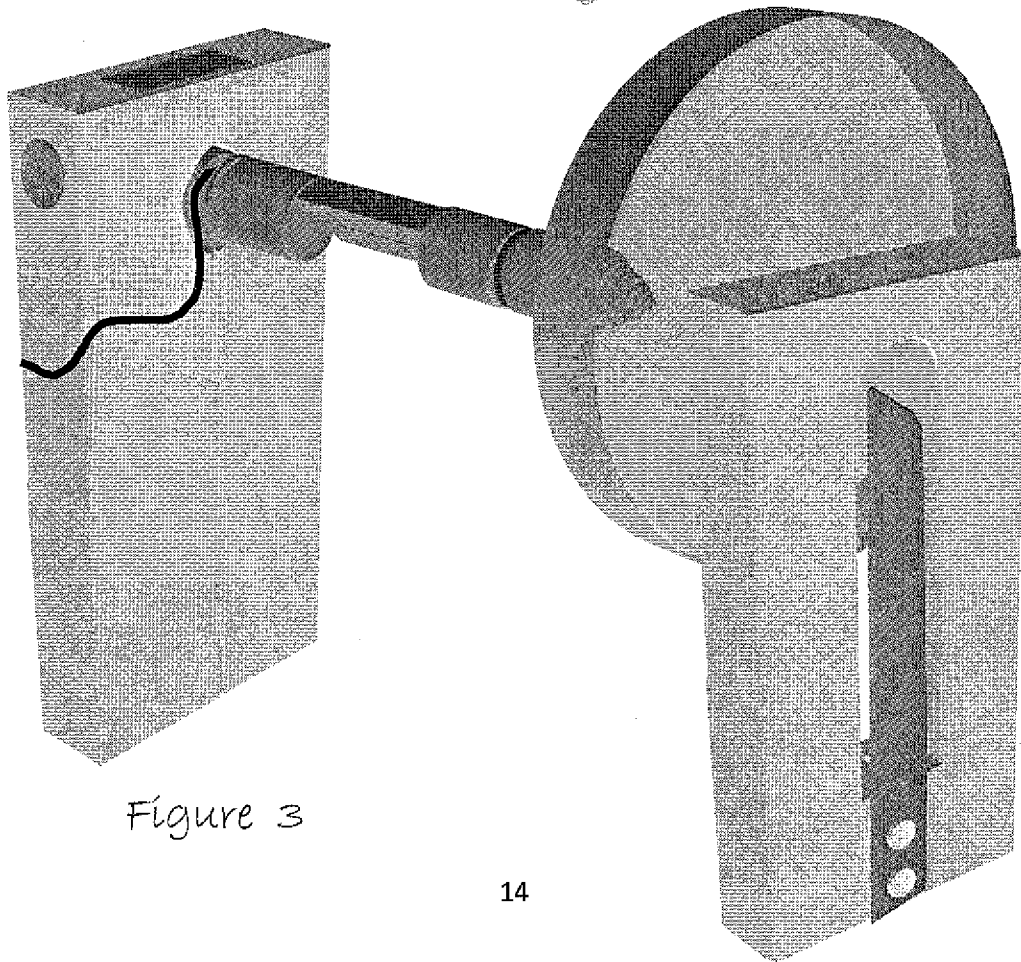
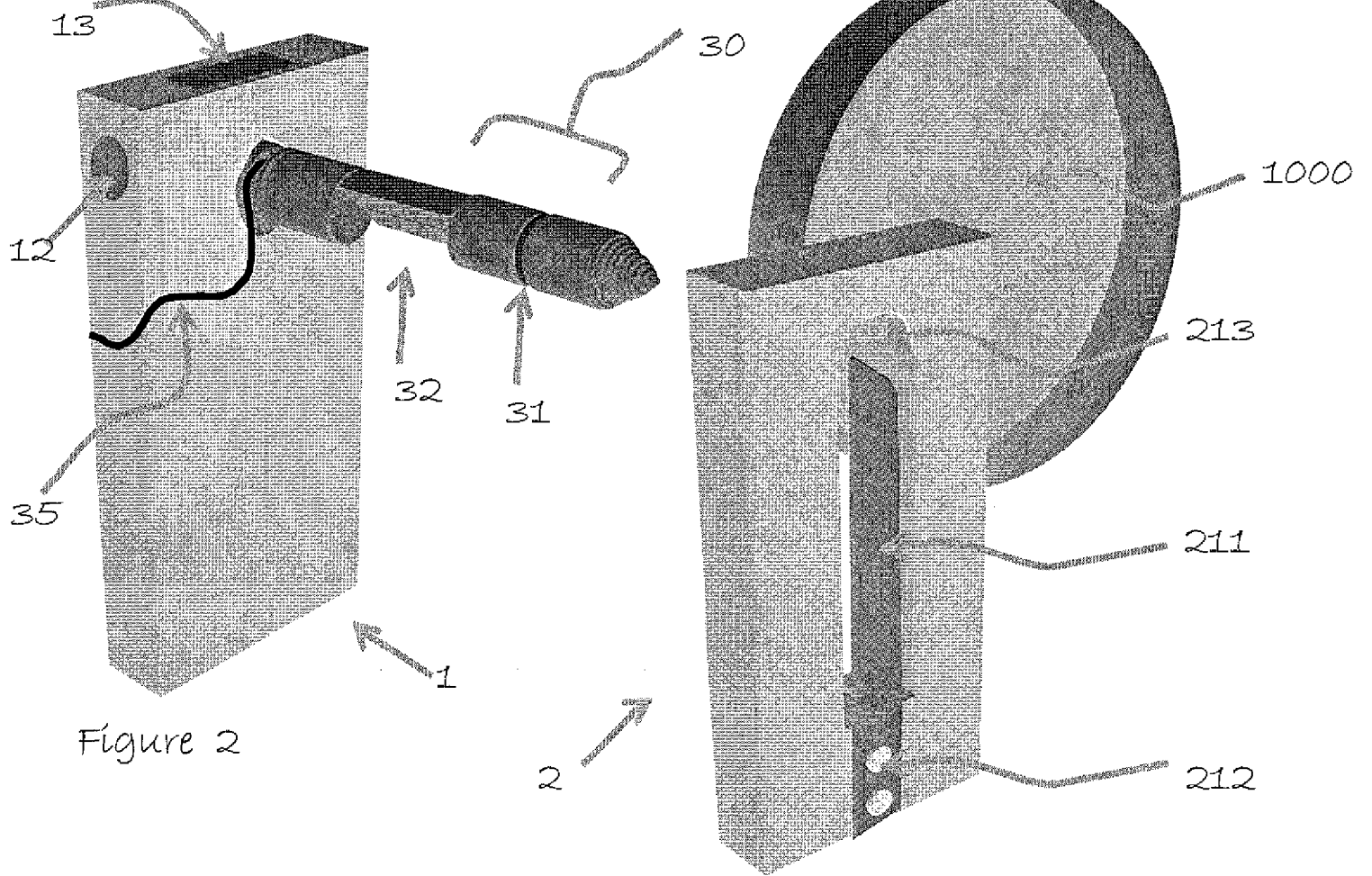


Figure 4

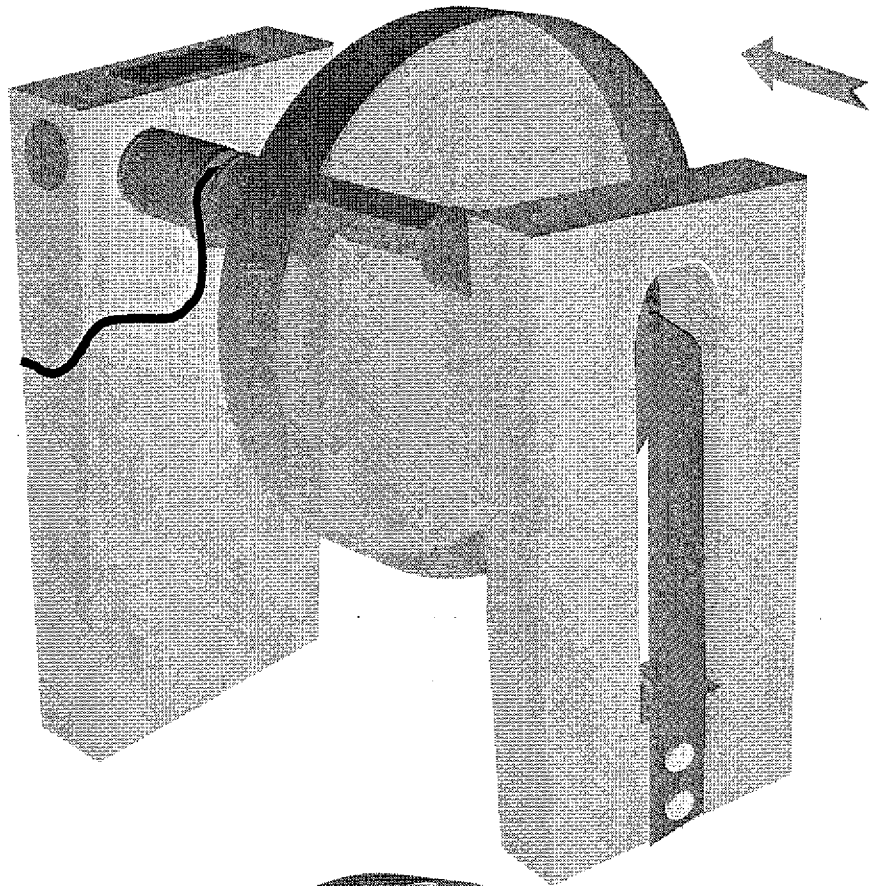


Figure 5

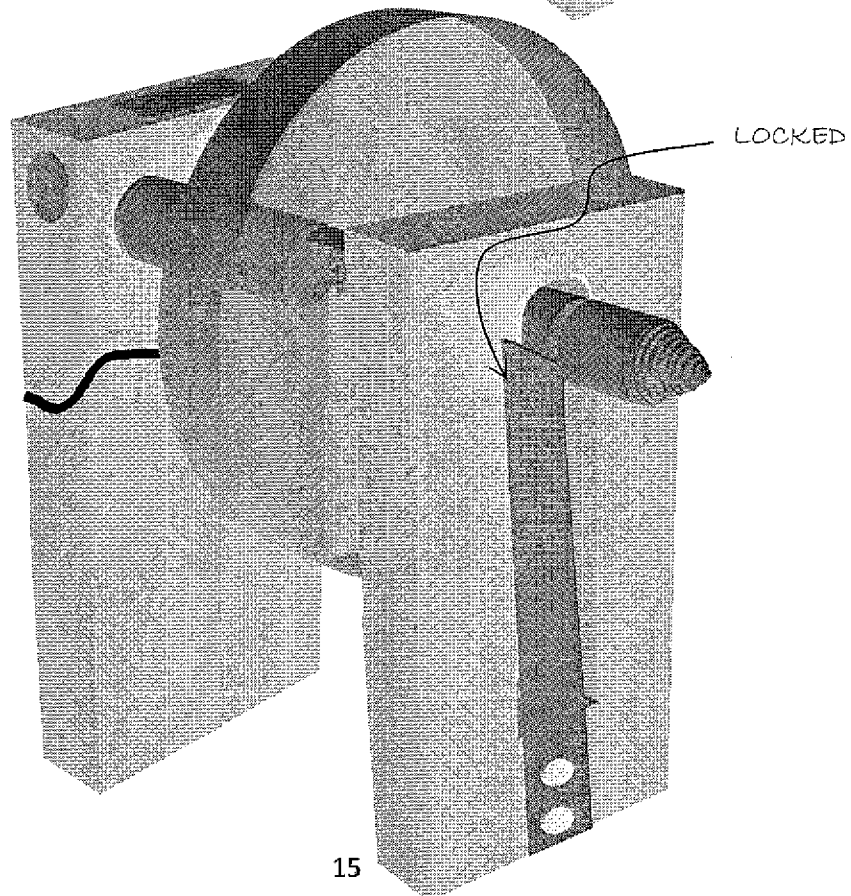


Figure 6

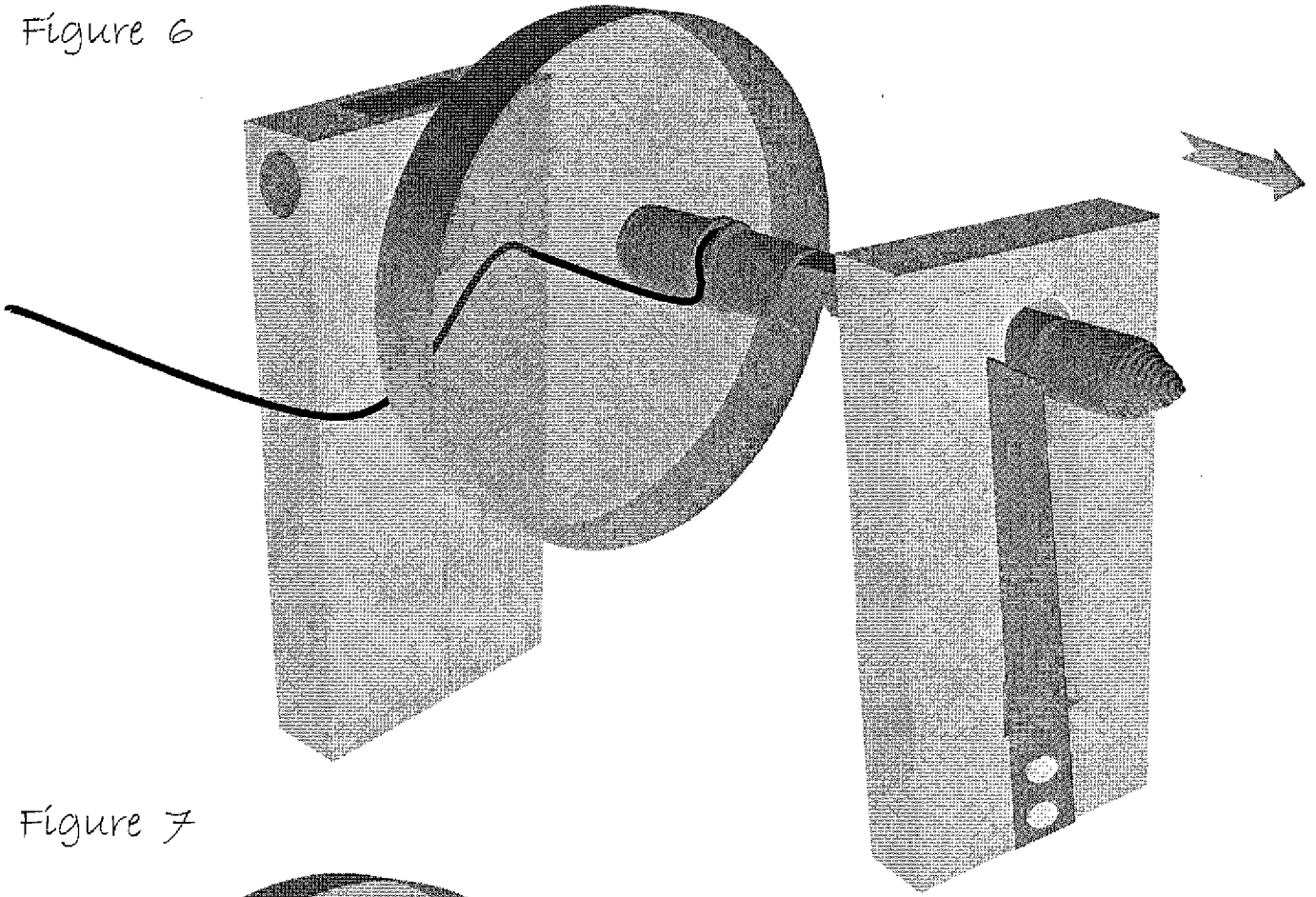


Figure 7

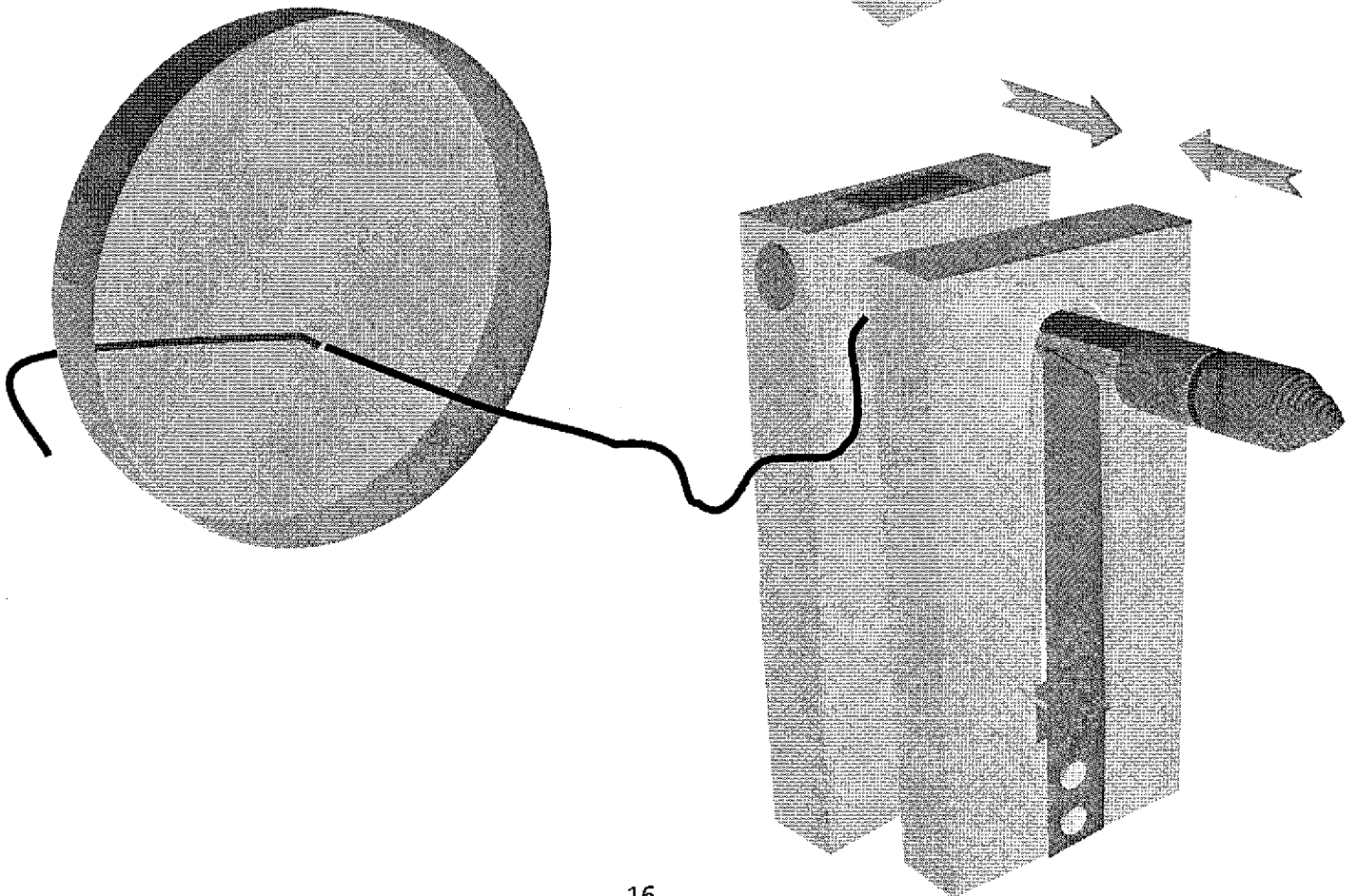


Figure 8

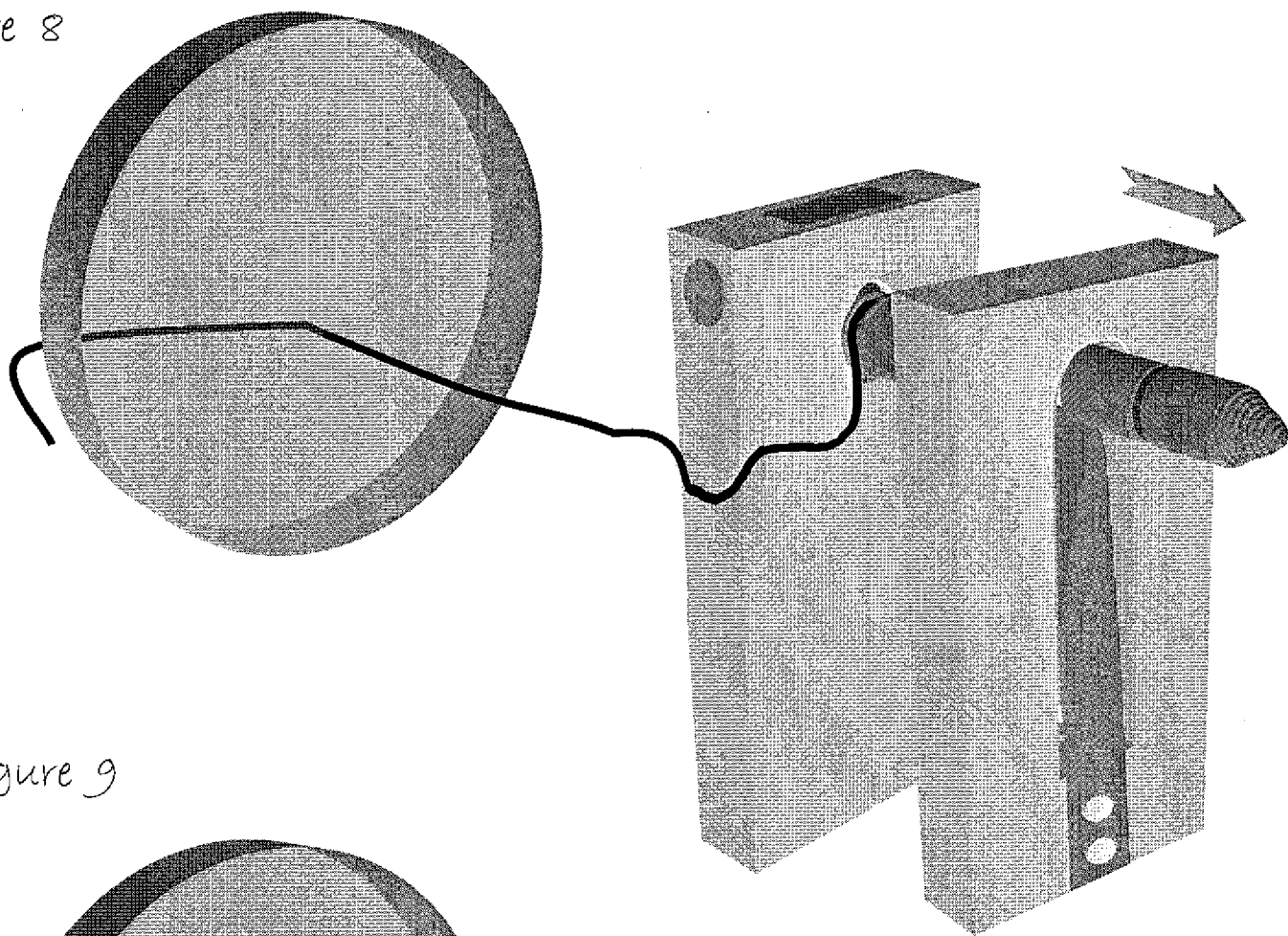


Figure 9

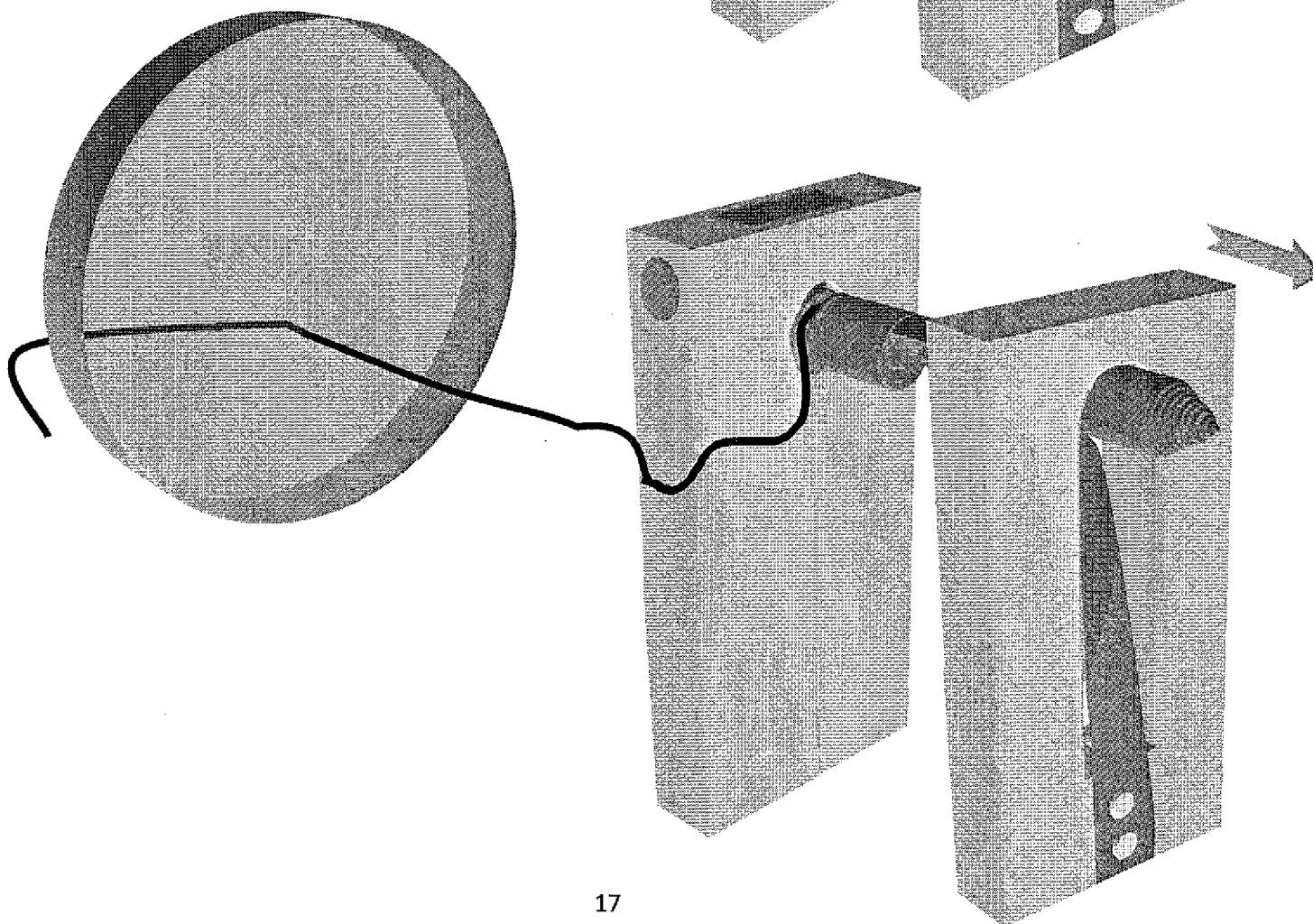


Figure 10

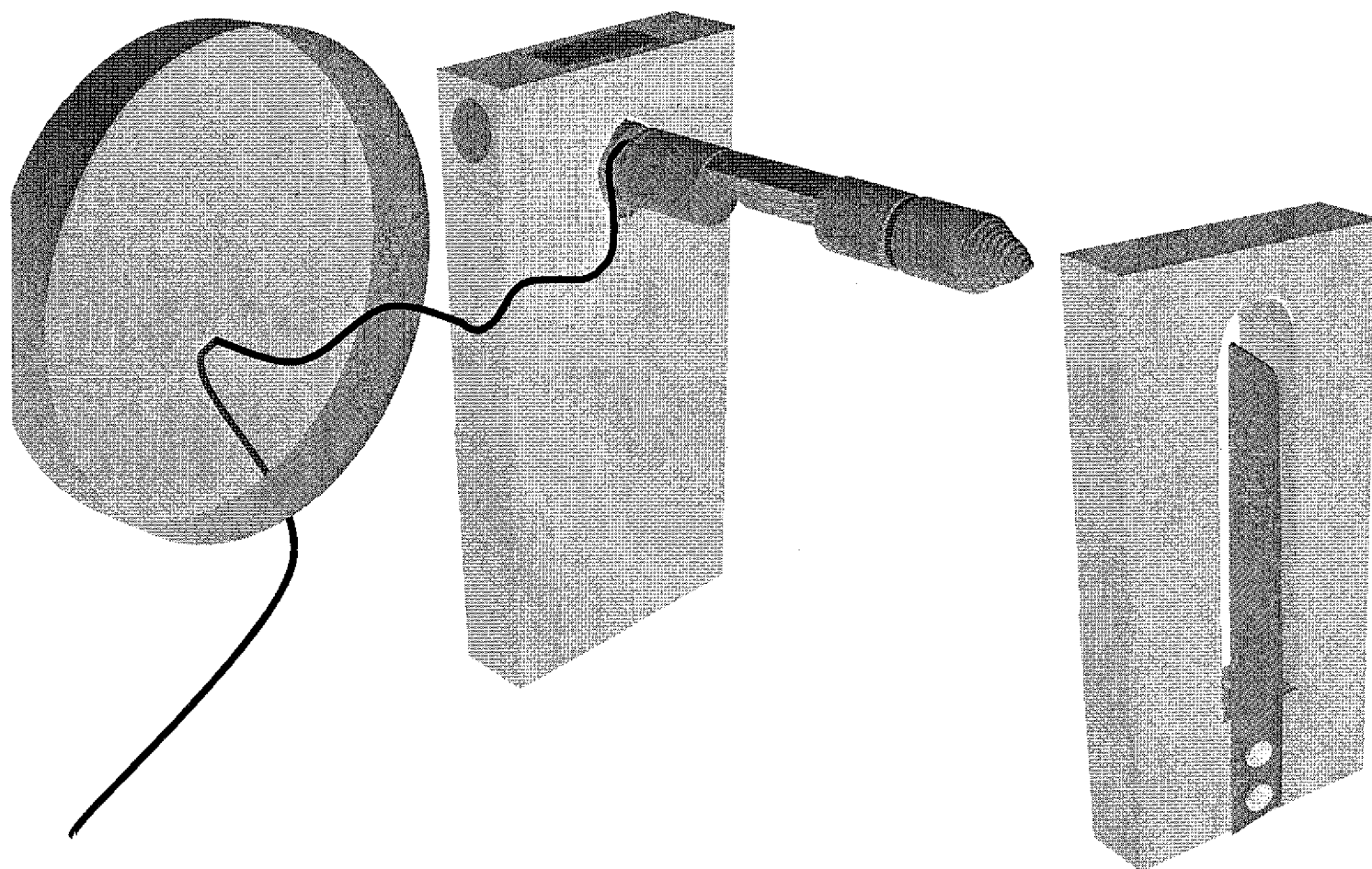


Figure 11

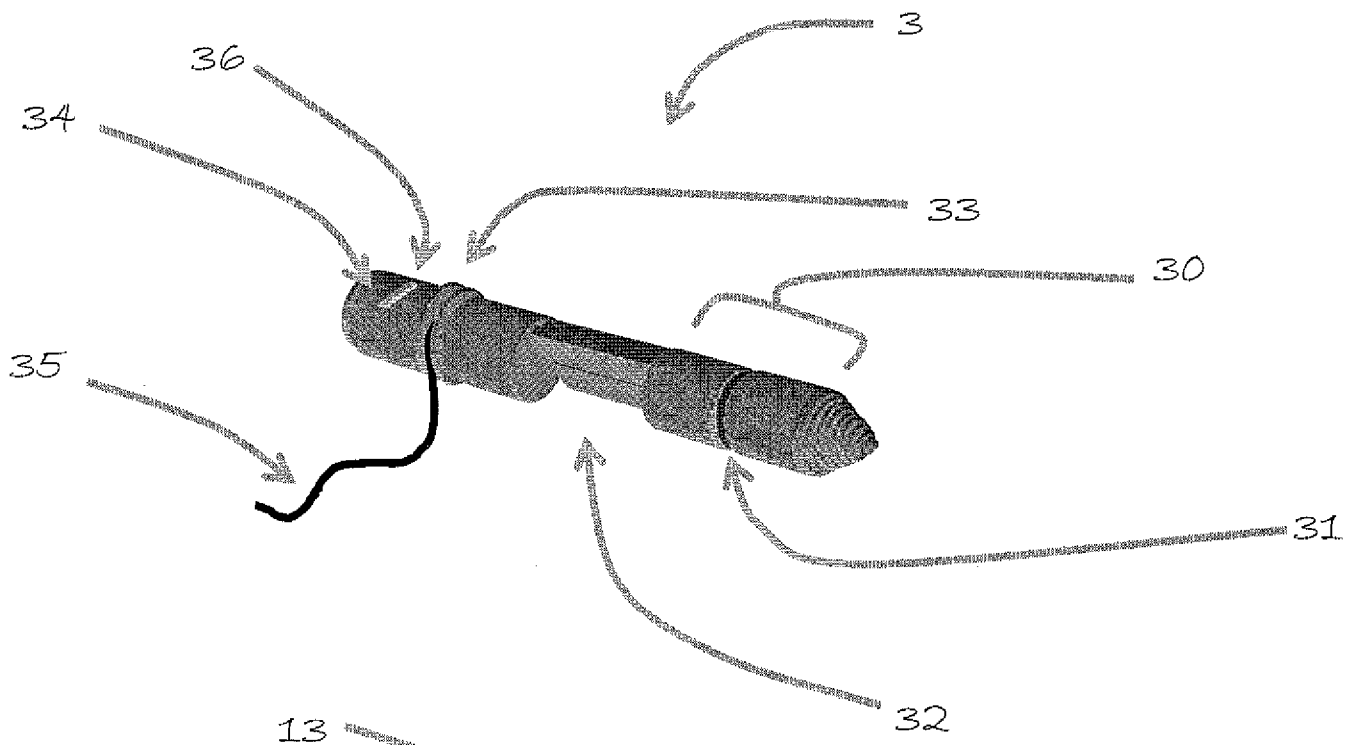
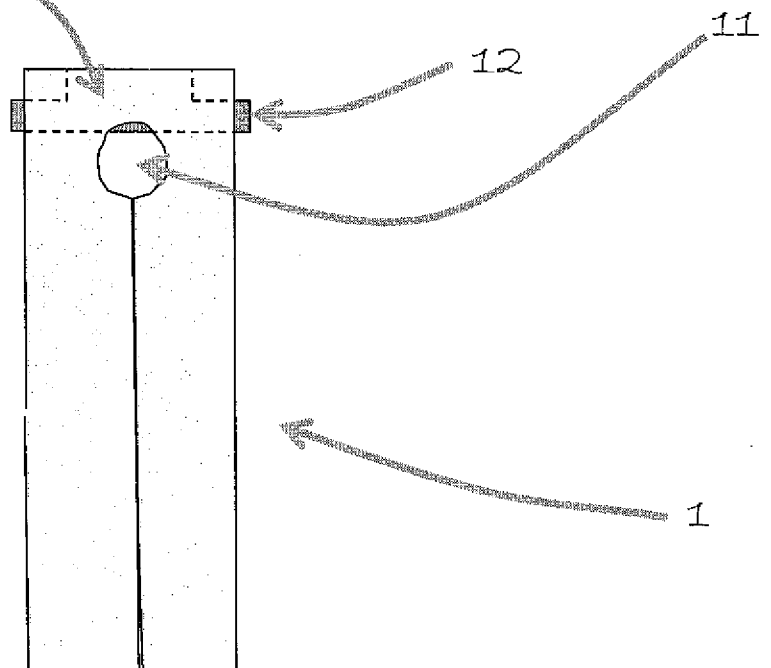


Figure 12



AXIAL ROTATIVE BLADE SYSTEM

Figure 13

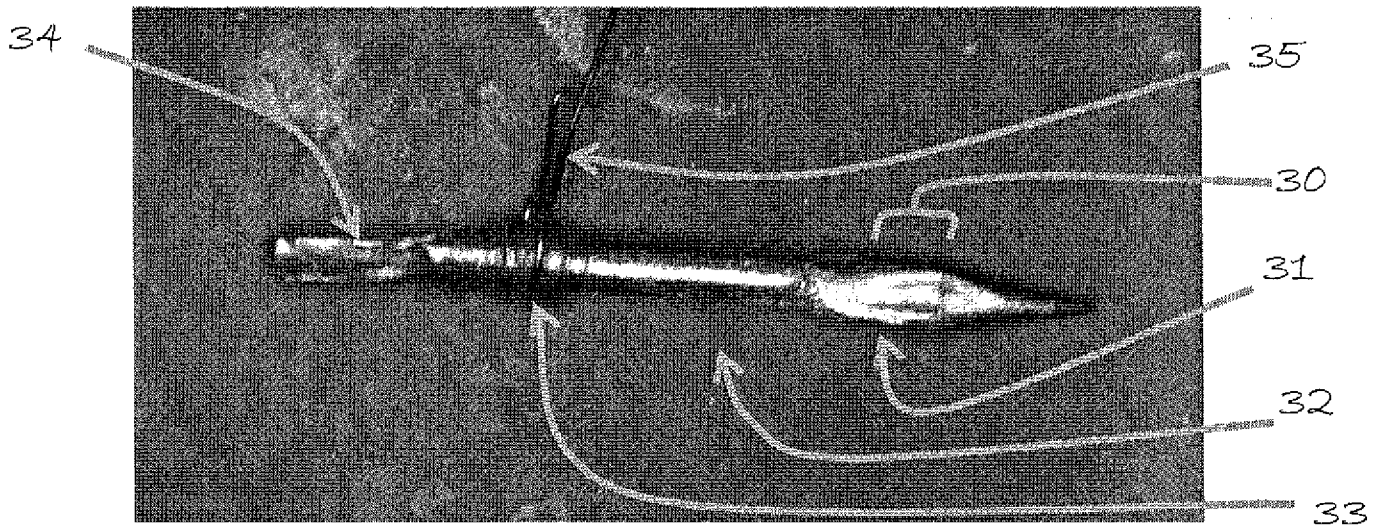


Figure 14

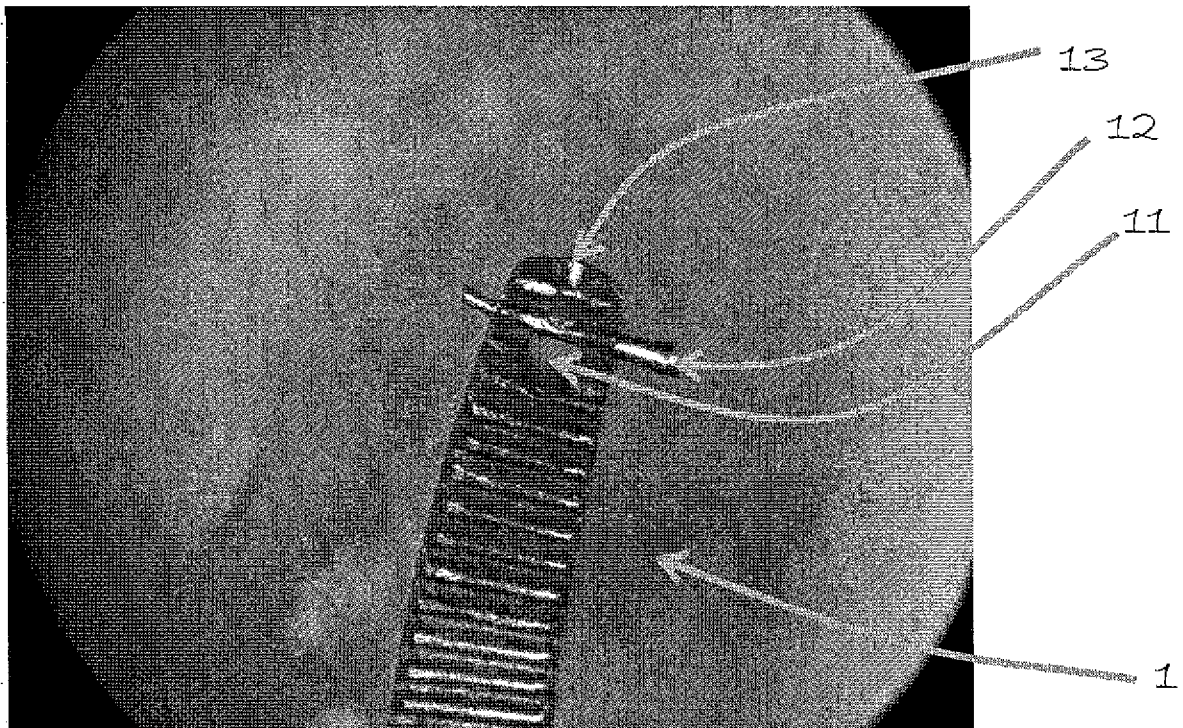


Figure 15

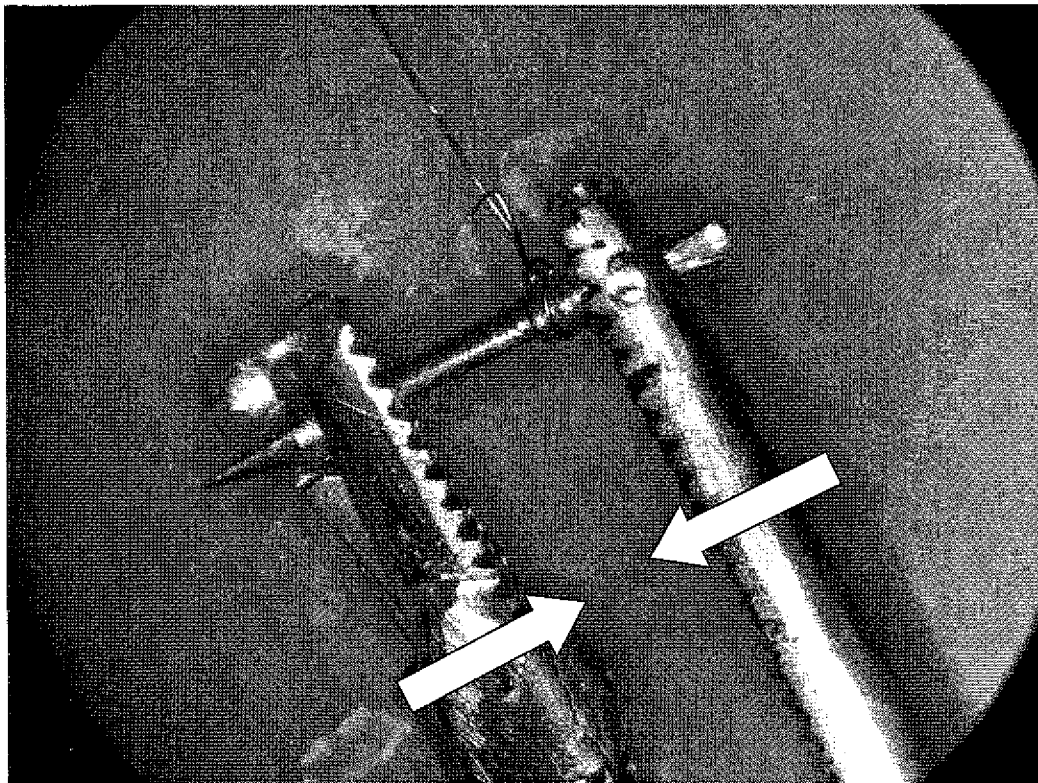
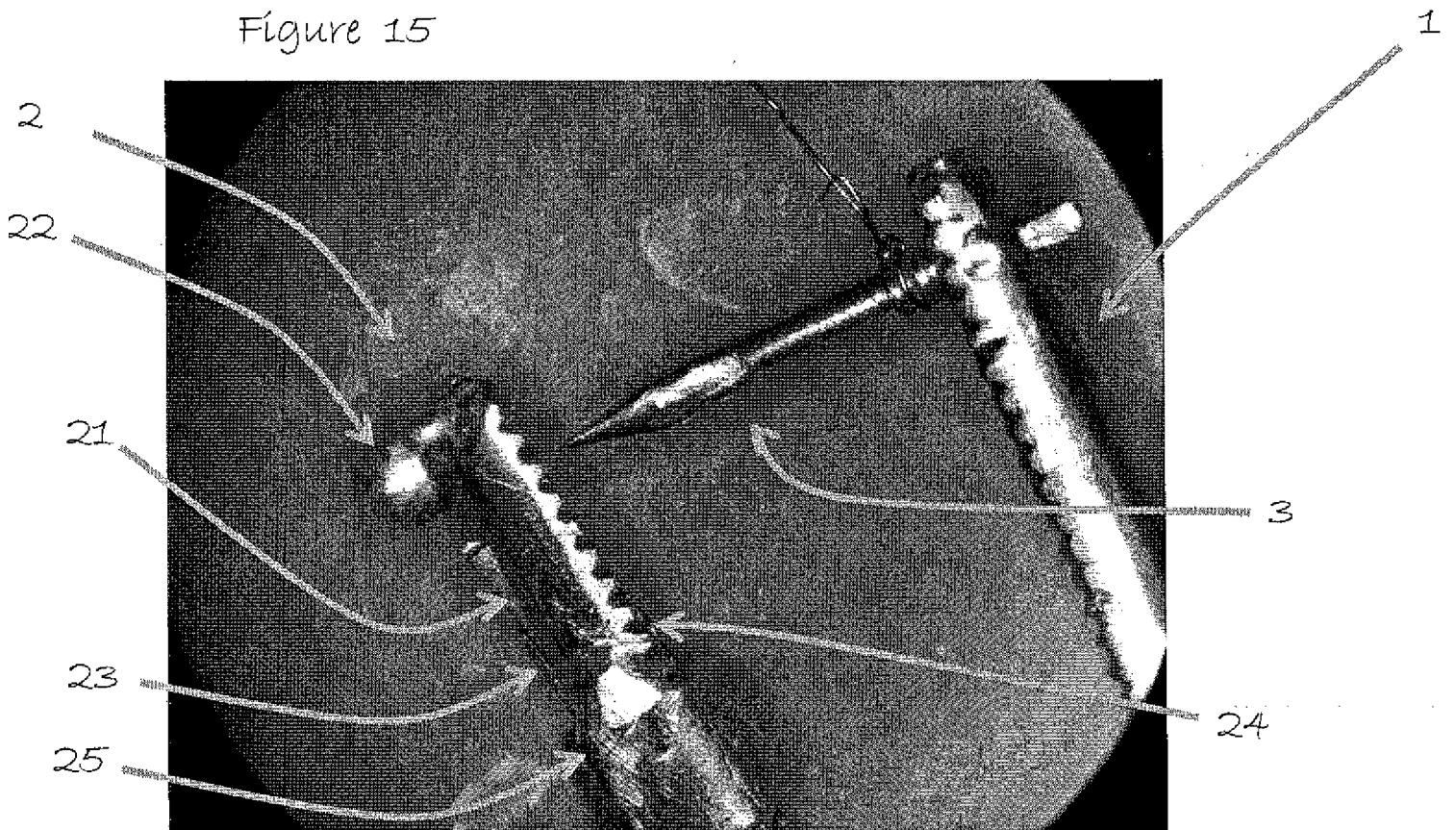


Figure 16

Figure 17

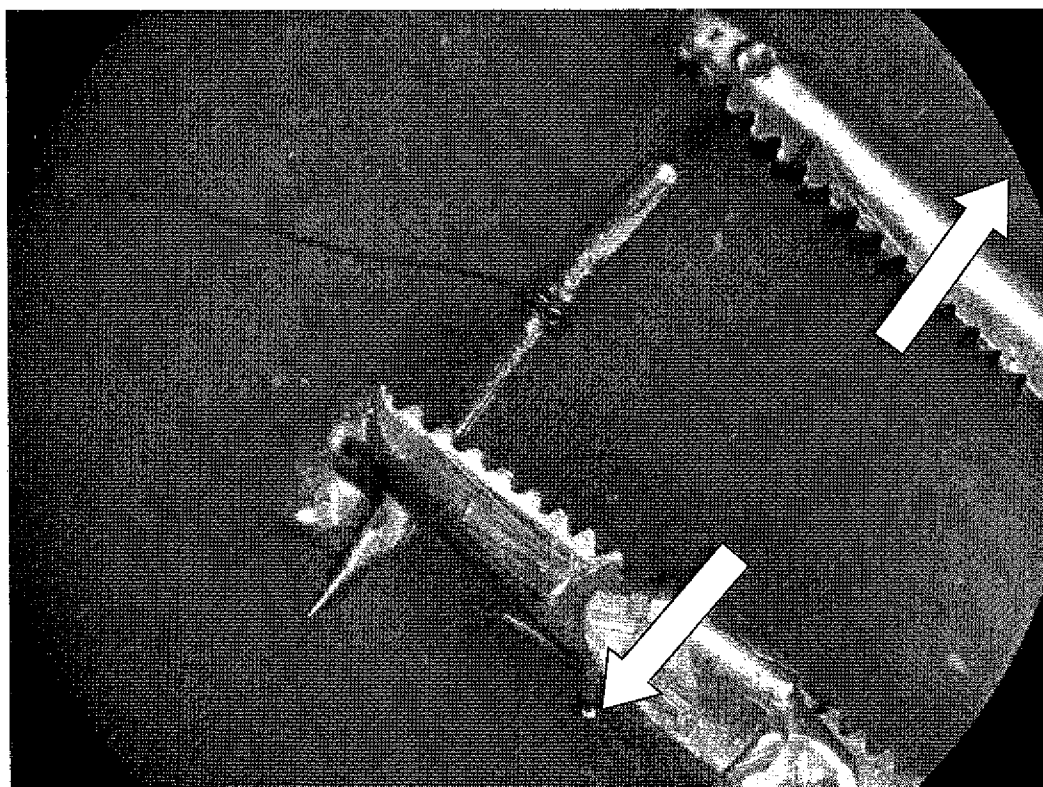
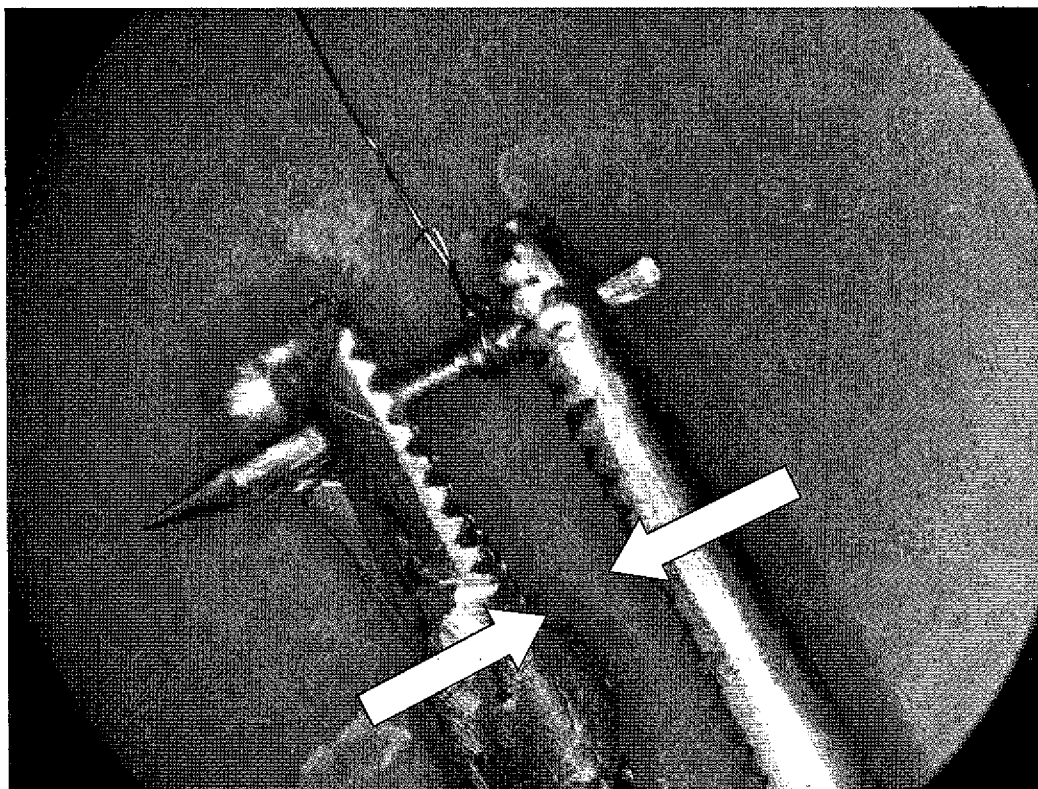


Figure 18

Figure 19

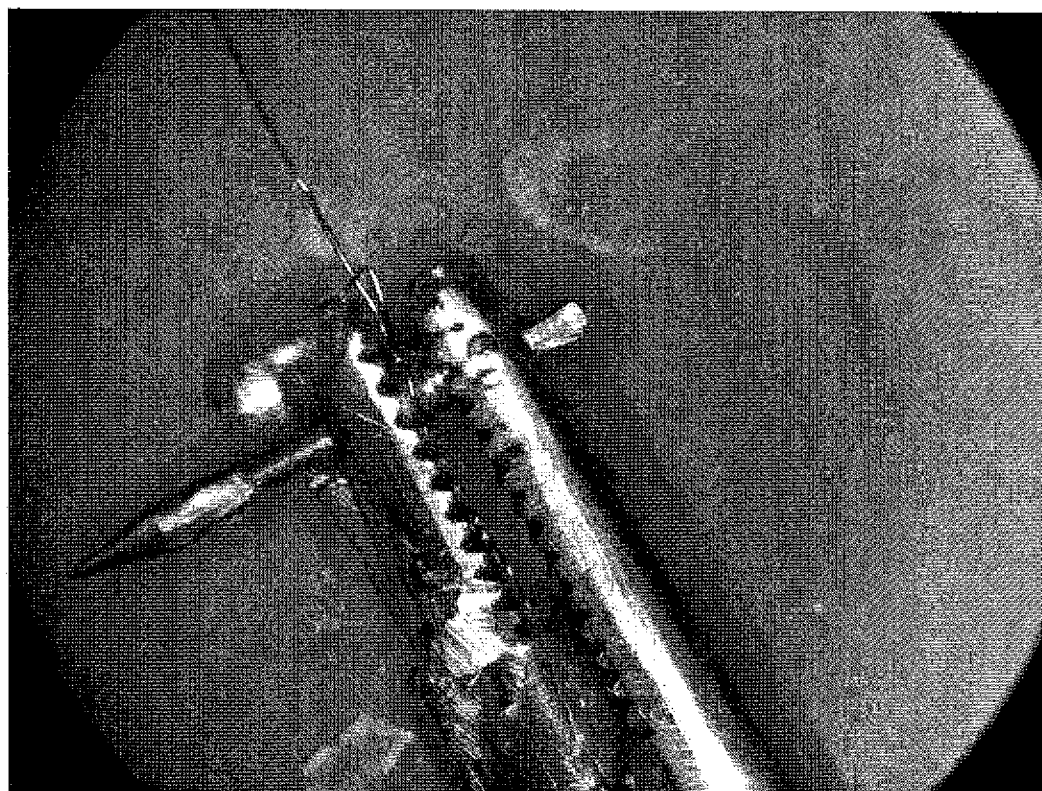
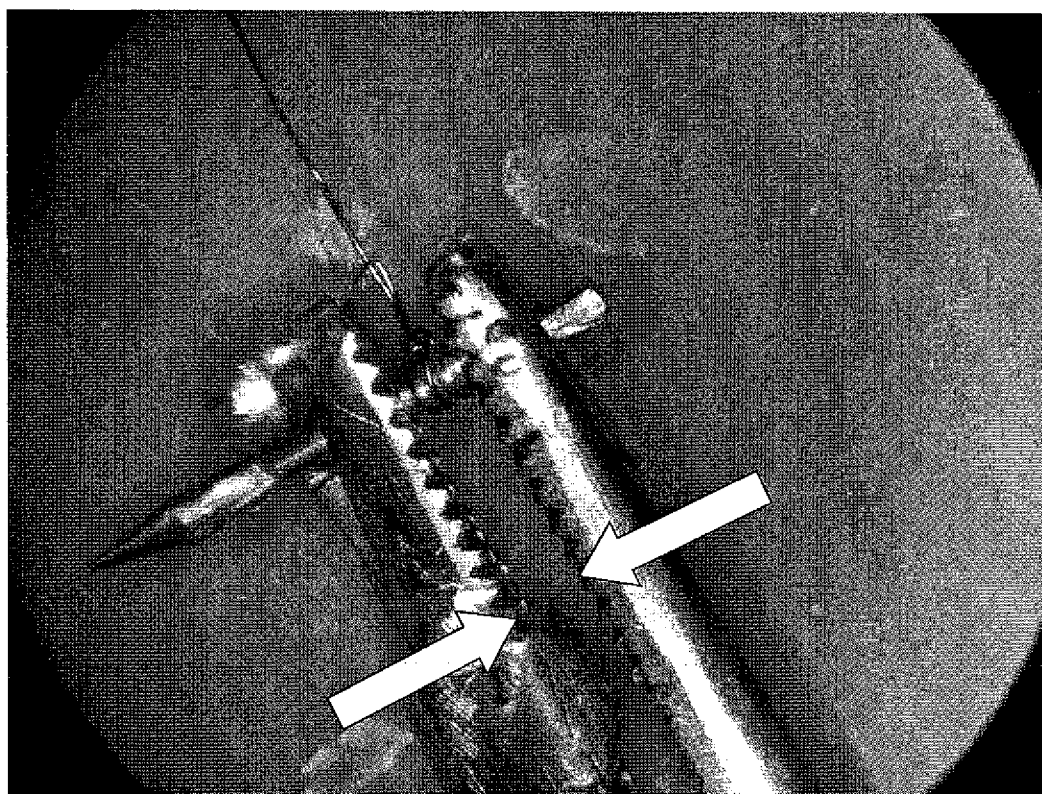


Figure 20

Figure 21

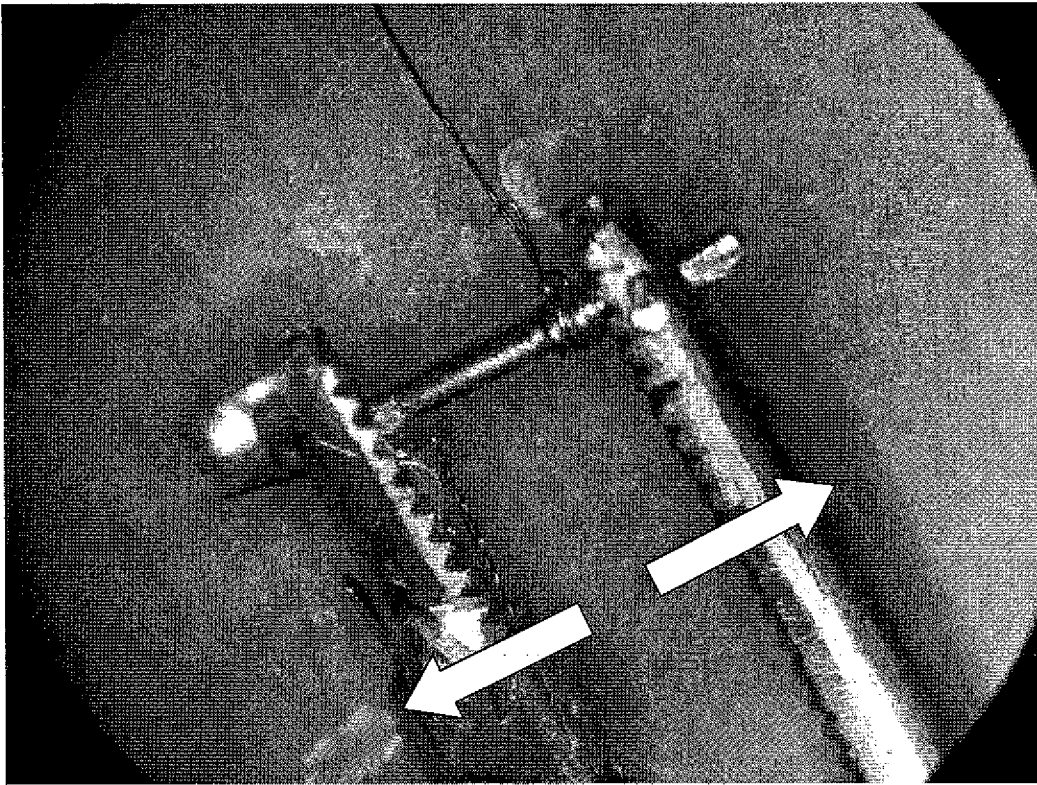


Figure 22

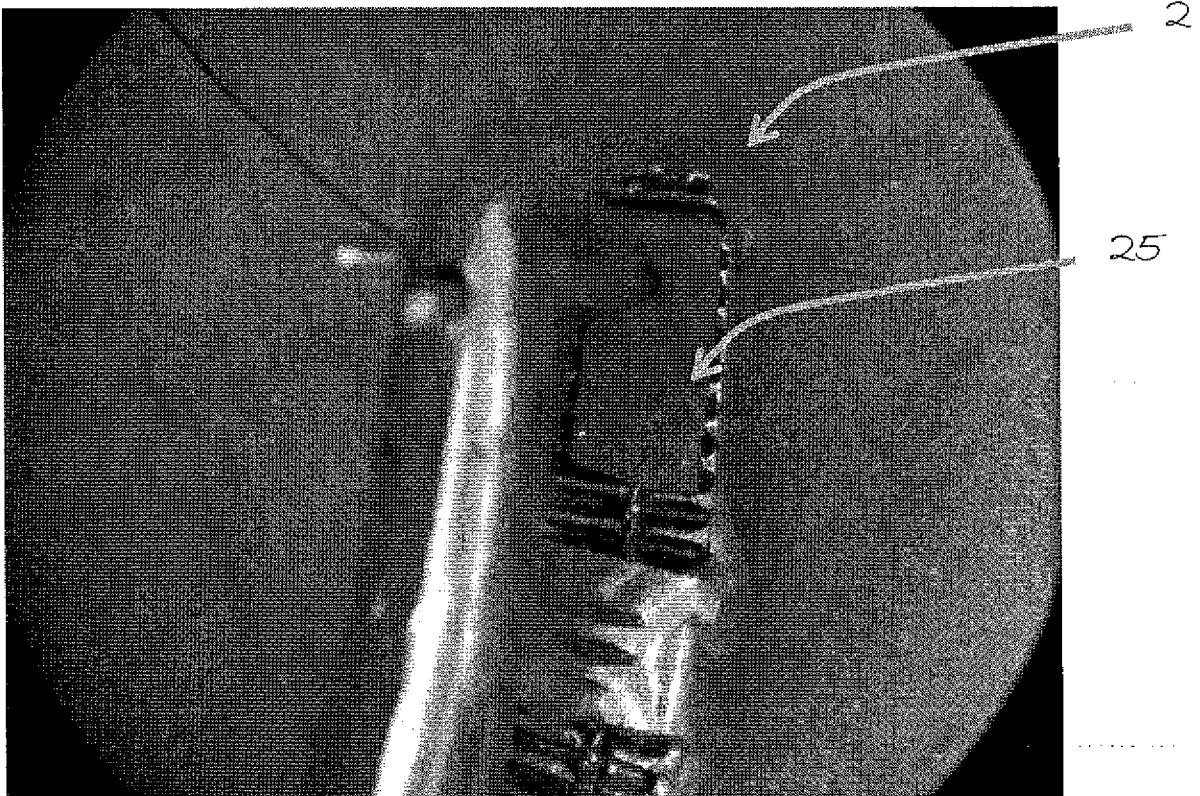


Figure 23

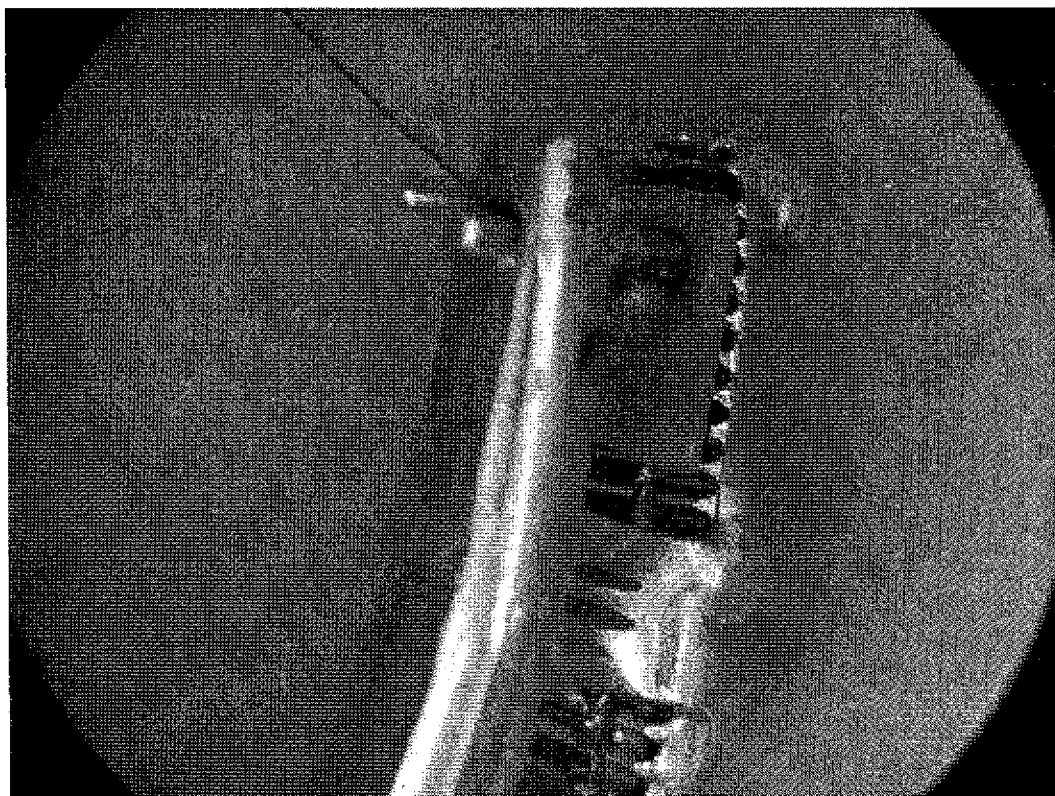


Figure 24

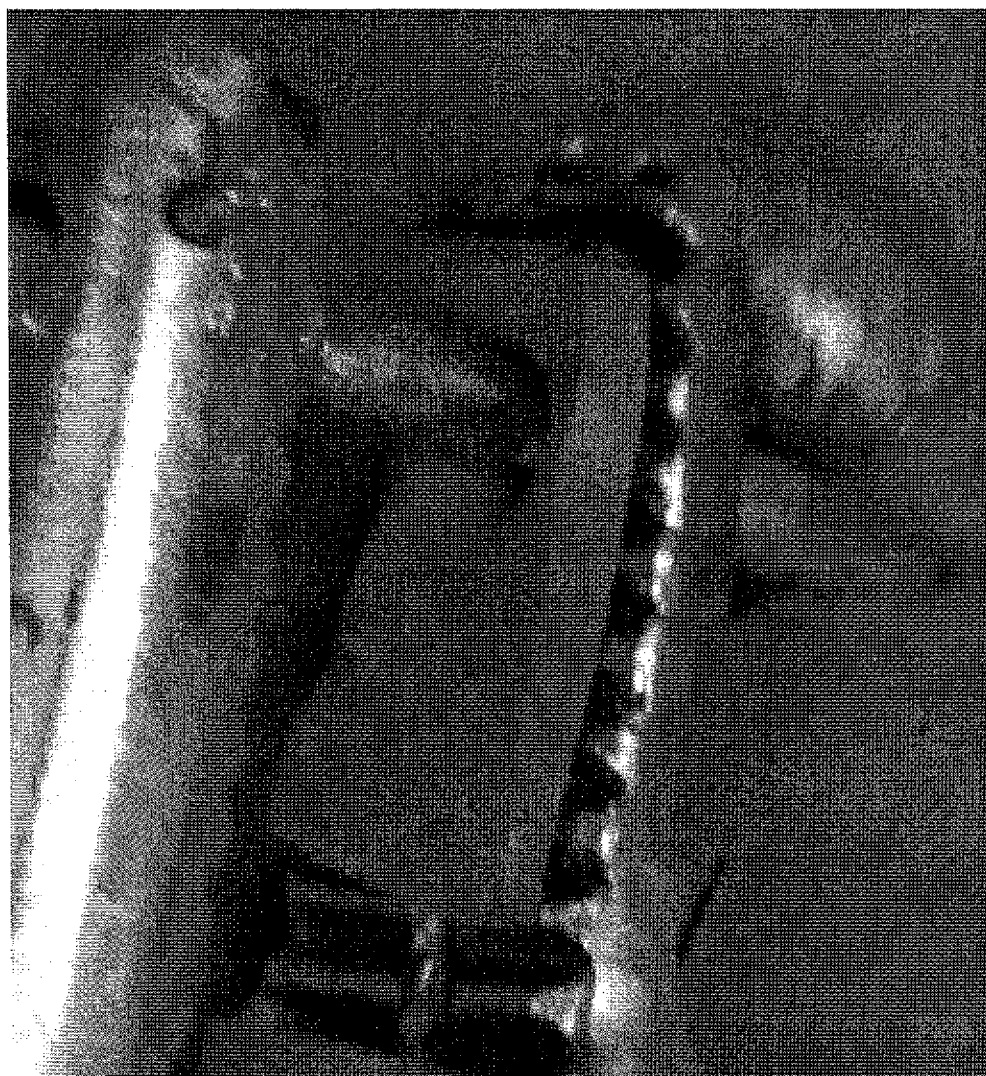
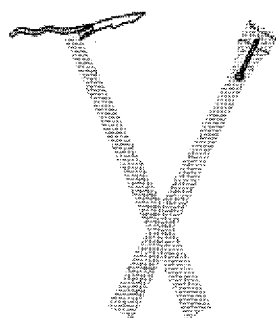


Figure 25



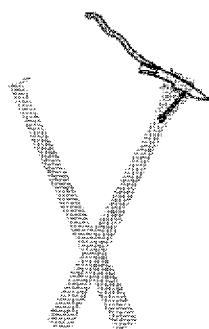
Device ready



Closing to latch needle



Needle latched



Needle held



Closing to release needle



Released

Figure 26

3b

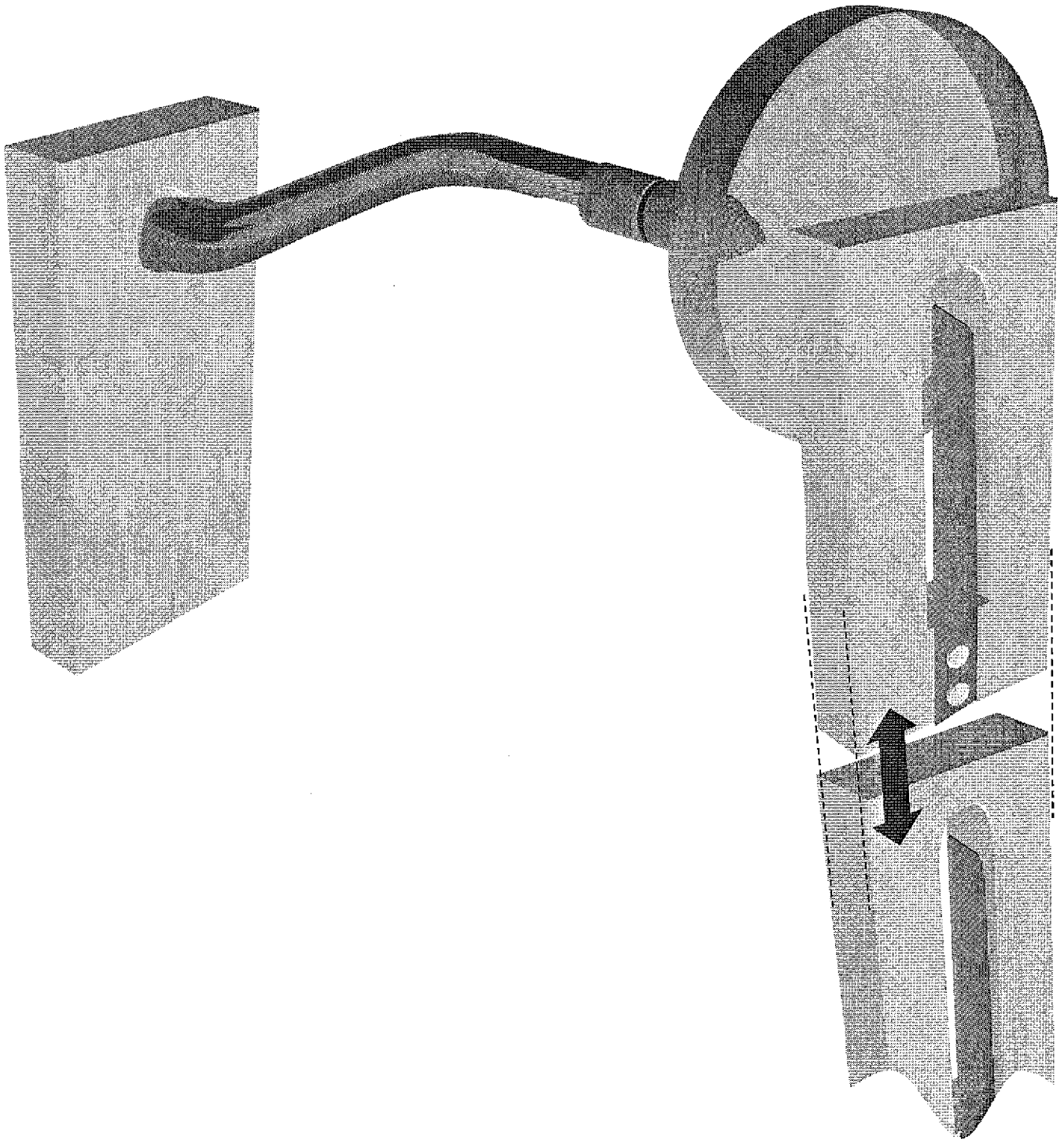


Figure 27

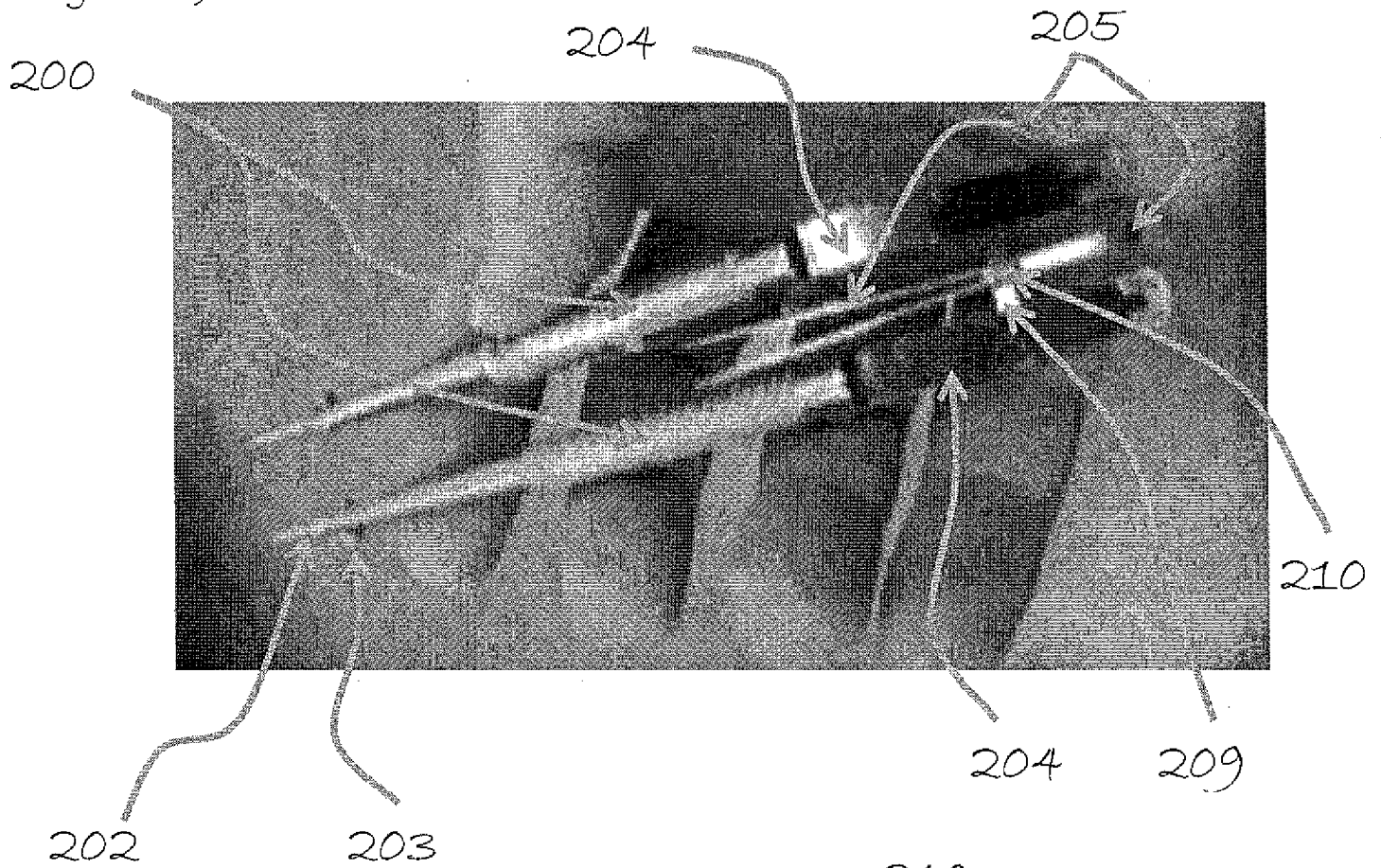
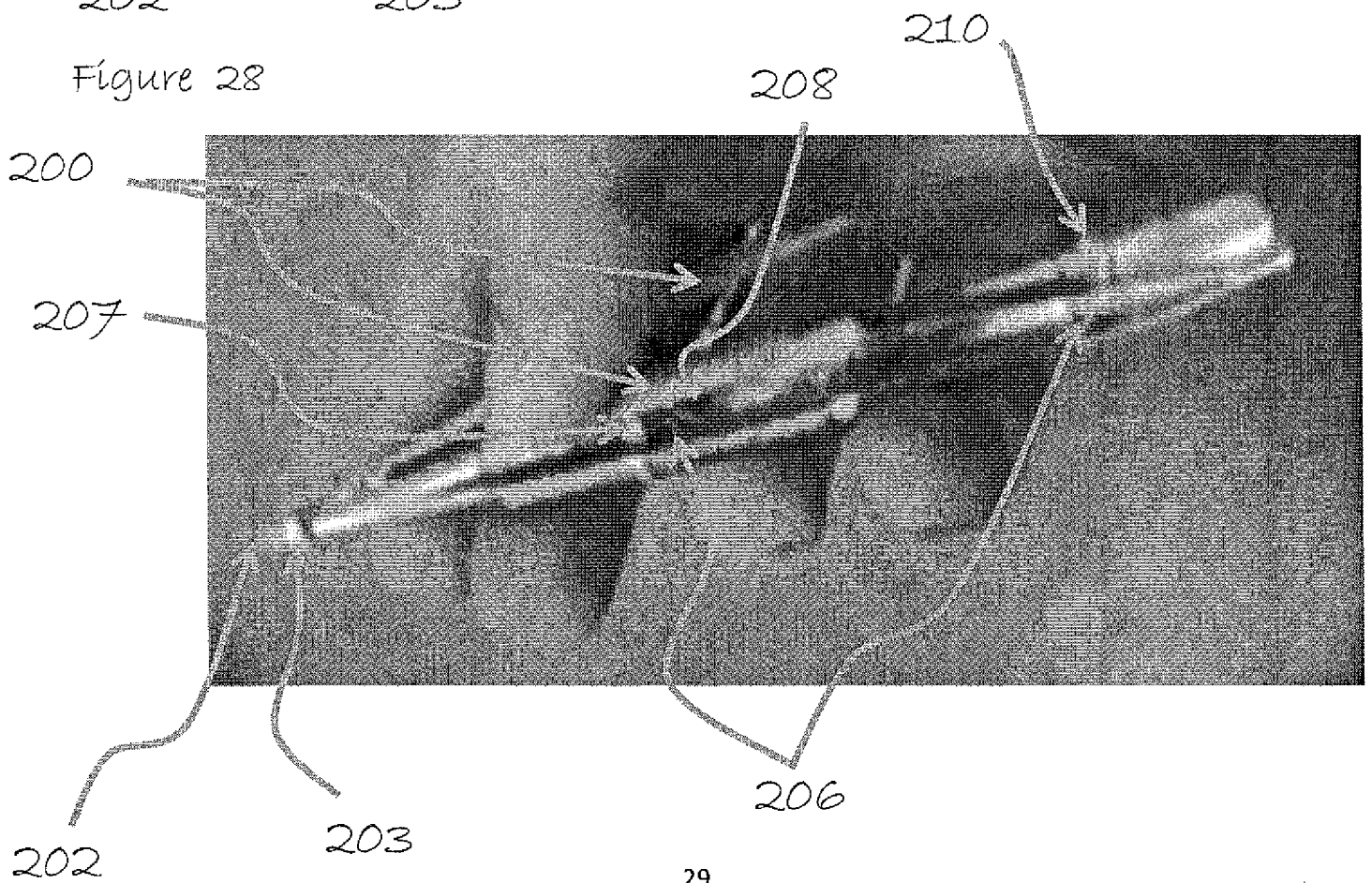


Figure 28



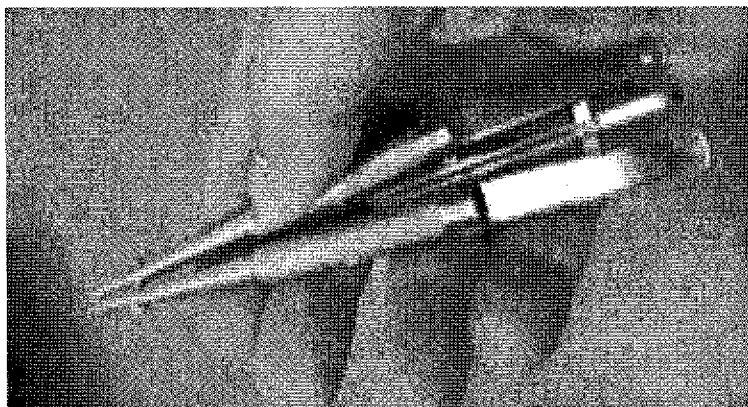


Figure 29a

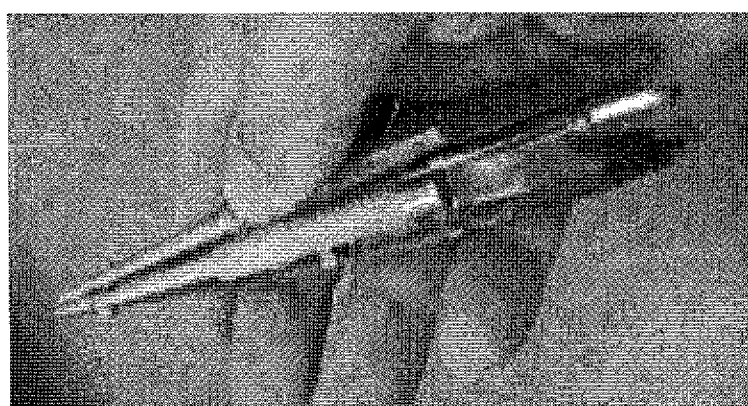


Figure 29b

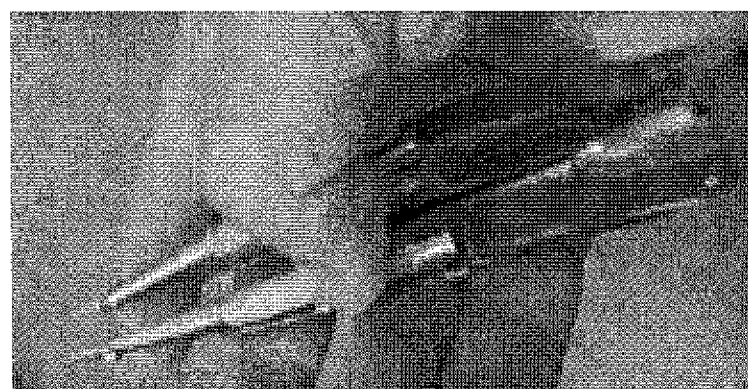


Figure 29c

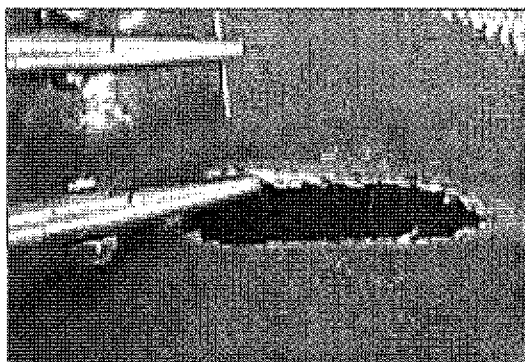


Figure 30a

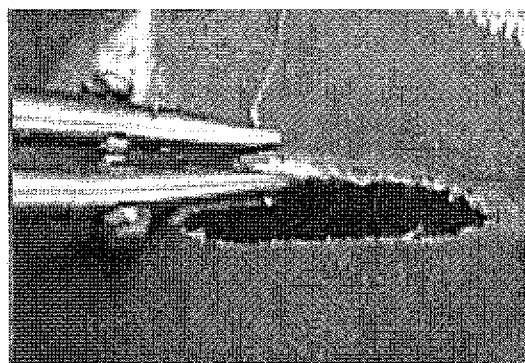


Figure 30b



Figure 30c

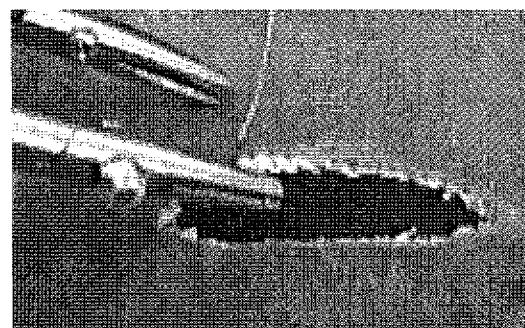


Figure 30d

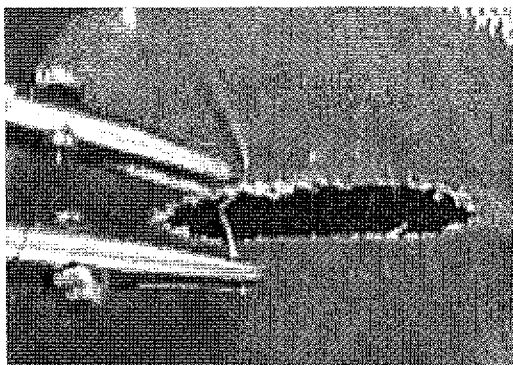


Figure 30e

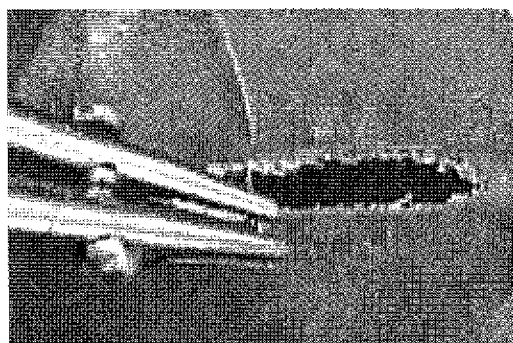


Figure 30f

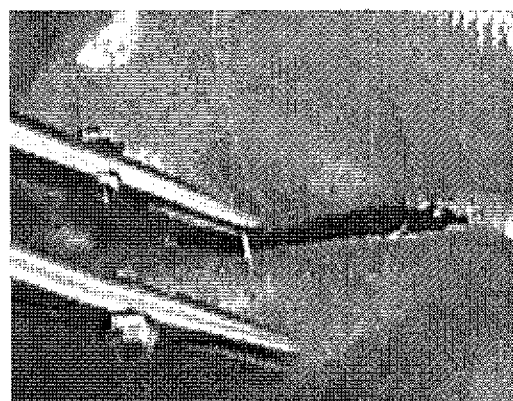


Figure 30g

Figure 31a

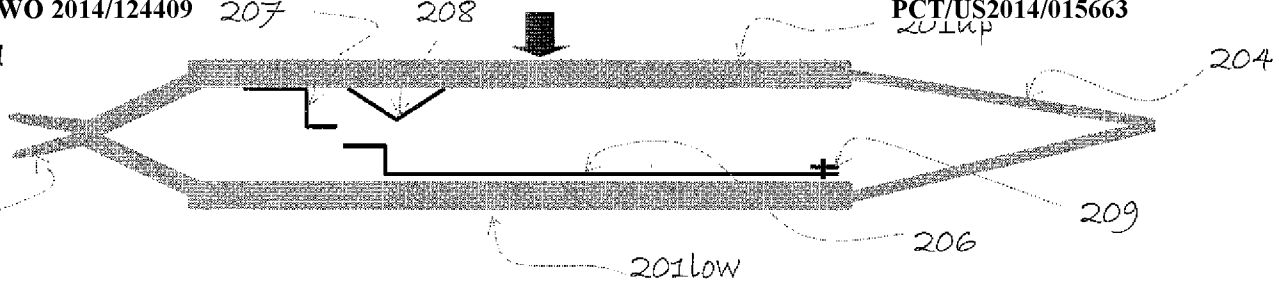


Figure 31b



Figure 31c

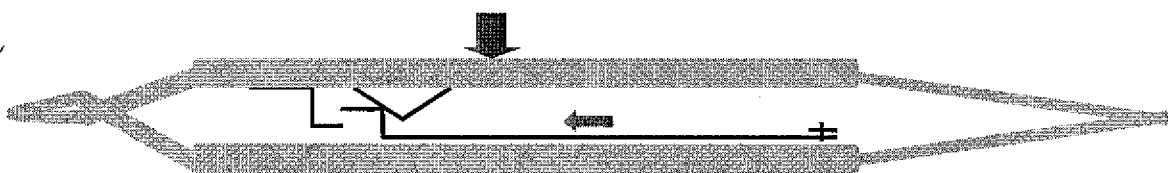


Figure 31d



Figure 31e

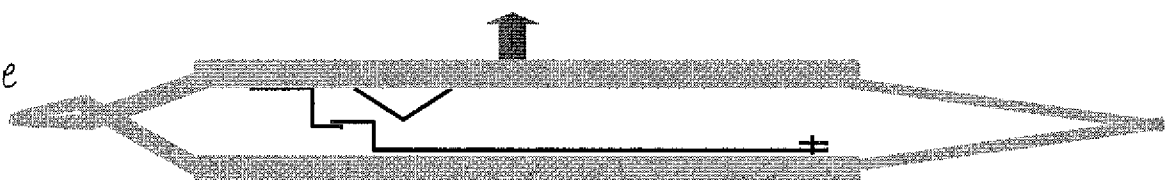


Figure 31f



Figure 31g

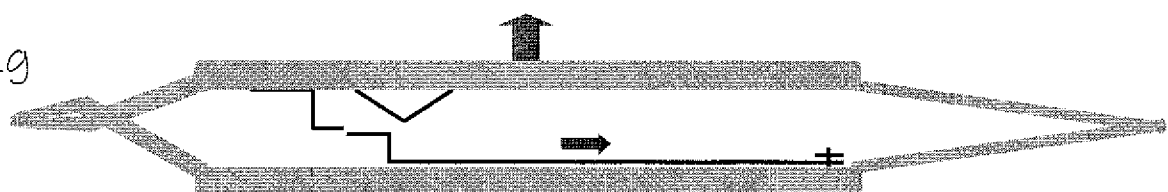


Figure 31h

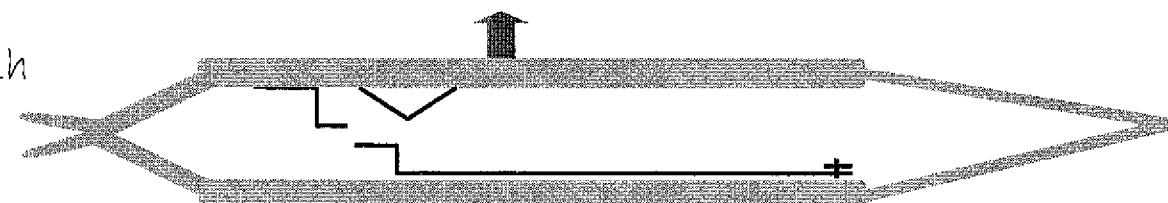


Figure 32

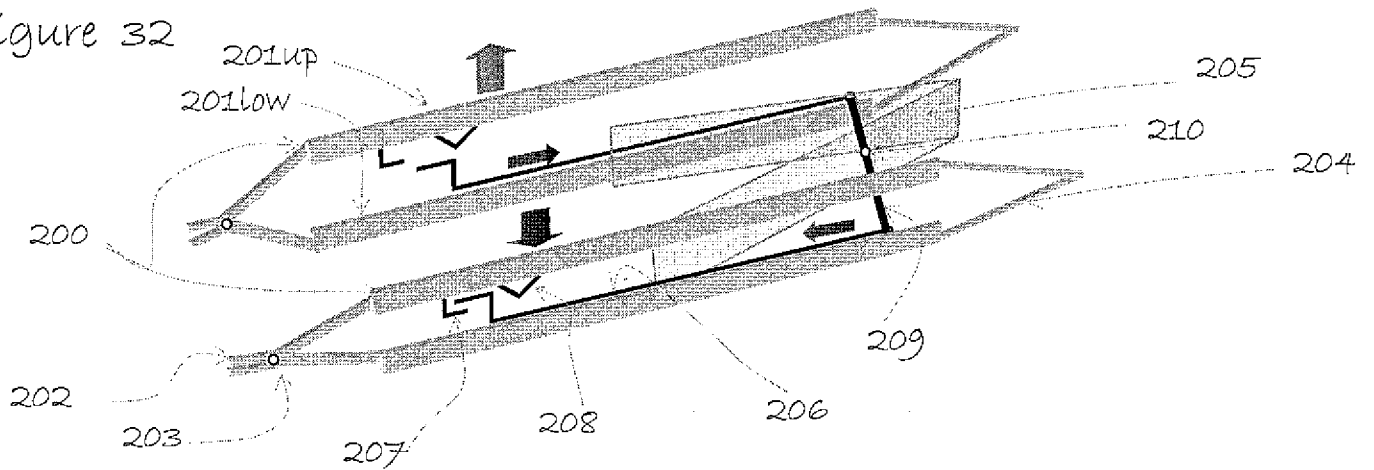


Figure 33a

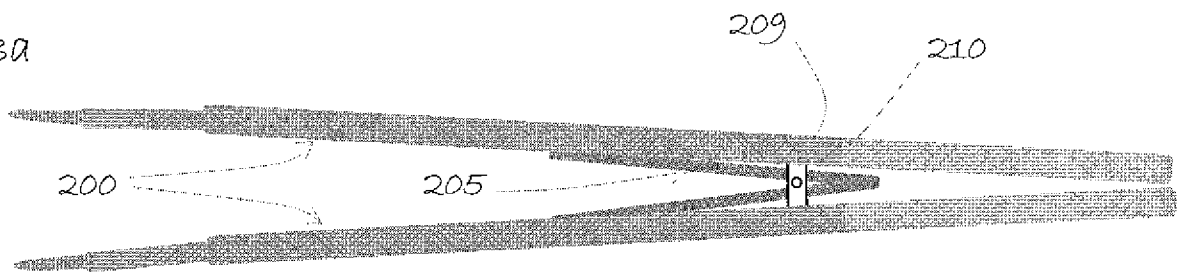


Figure 33b



Figure 34a

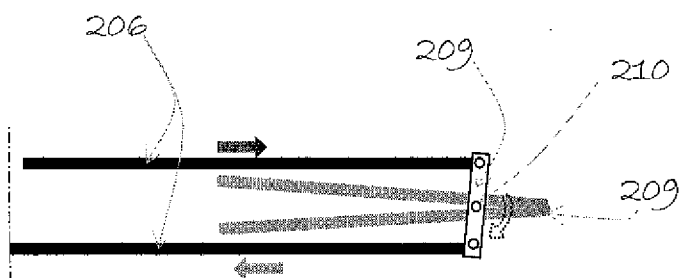
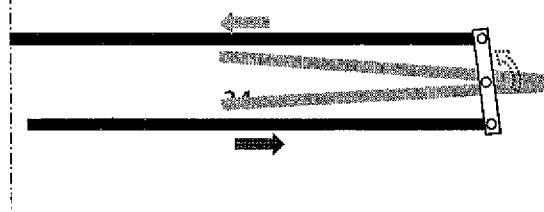


Figure 34b



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/015663

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61B17/062
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 2011/295277 A1 (LAU WILLIAM TRAVIS [US]) 1 December 2011 (2011-12-01) figures 1-8 paragraphs [0013], [0050] - [0054], [0098]	1
X	US 5 389 103 A (MELZER ANDREAS [DE] ET AL) 14 February 1995 (1995-02-14) figures 2,4-7 column 7, paragraph 1	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

13 May 2014

Date of mailing of the international search report

23/05/2014

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Authorized officer

Schießl, Werner

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/015663

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