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(54) **Title**: DISPOSABLE AND REUSABLE MORCELLATOR

(57) **Abstract**: Provided is an improved morcellator for severing and removing tissue from a patient's body with functional and structural improvements in disposable cutter assembly and reusable drive assembly to prevent body fluid from entering the sterile region of the cutter assembly and infection from transmitting to reusable drive assembly.

Field of the Invention

The present invention in general relates to the field of surgical devices. More particularly the invention provides an improved morcellator for severing and removing tissue from a patient's body.

Background of the invention

Laparoscopic surgery also referred as minimally invasive surgery, bandaid surgery, keyhole surgery is commonly and widely accepted method of doing surgical procedures. Generally, these laparoscopic surgical procedures make use of one or more small incisions to access internal tissues, often through a cannula, trocar, or other surgical device. The popularity of laparoscopic procedure facilitated surgeons to perform complex surgeries with number of advantages to the patient such as less complication, less blood loss, smaller incisions, shorter recovering time and overall low cost.

Unfortunately, many surgical procedures involving removal of relatively large masses of tissue, for example, removal of uterus, fibroid, or the like are difficult to accomplish through laparoscopic cannulas or other surgical devices. Removing such large tissue masses laparoscopically through a small access lumen is fairly difficult and time consuming.

Specialized devices have lately developed to sever large tissue masses into segments, which are more easily removed using laparoscopic surgery. These devices generally include a rotating tube having a sharpened distal end which extends through a fixed outer tube. This sharpened end is inserted into the patient through a cannula, or directly through an incision. The surgeon inserts a forceps through the rotating tube. Grasping the large mass of tissue to be removed, the surgeon pulls the tissue up into the tube, so that the rotating edge severs the grasped portion from the large mass. The size of the severed tissue is generally limited by the outline of the rotating edge, so that the surgeon can continue to pull the severed tissue out of the patient through the rotating tube. By repeating the grasping and severing procedure, surgeons can remove relatively large masses of tissue quite quickly. As the large tissue mass is removed in small, individually grasped morcels, these devices are often referred to as "morcellators".

Morcellators are either single use disposable or reusable. However, the reusable morcellators carry of risk of cross infection from one patient to another if not sterilized properly. In addition, there are no specific tests or measures to ensure 100% sterility of these re-sterilized devices. Also, sterilizing these devices is fairly time consuming and so expensive.

Single use disposable morcellators are costly as whole morcellator is required to be disposed after surgery. Disposing off large amount of plastic and metal also leads to environmental pollution, wastage and significant cost put pressure on the healthcare system.

In the light of the above, it would be desirable to provide improved and cost-effective methods and devices for severing and removing tissue from a patient's body.

Summary of the Invention

In accordance with the present invention there is provided an improved morcellator, which prevents infection from transmitting to reusable parts of the morcellator. In addition, the improved morcellator of the present invention provides various functional and structural features in a reusable drive assembly and a disposable cutter assembly which prevents body fluid from entering the sterile region of the cutter assembly and infection from transmitting to a reusable drive assembly.

The improved morecellator includes a rotary tissue cutting tube, which passes through an outer sheath tube and is driven by a cutter gear mechanism of a cutter assembly, and a reusable drive assembly. A hydraulic seal is attached each at a distal and proximal end of the cutter assembly to maintain a sterile region between the distal and proximal end of the cutter assembly and preventing blood/ body fluid from entering into the sterile region.

The reusable drive assembly includes a drive gear mechanism below which a hydraulic seal is provided for preventing a body fluid or an infection seeping into the drive assembly. In addition, the reusable drive assembly may have protrusions designed over an integrated lever to facilitate proper and firm positioning of the drive assembly when attached to the cutter assembly.

In one embodiment of the present invention there is provided a rotary tissue cutting tube with improved cutter profile designed to facilitate low drag of forceps during tissue removal from the patient's body. The improved tissue cutting tube is variable in diameter and having a cutting edge with double shear angle.

In another embodiment of the present invention there is provided a cutter activation mechanism designed to prevent unintentional exposure of the rotary tissue cutting tube by controlling the movement of outer sheath tube. The cutter activation mechanism includes a pull collar and two locking slots. The cutter activation mechanism provides safe functioning of the morcellator.

In yet another embodiment of the present invention there is provided improved valve designed to facilitate low drag of forceps during tissue removal from the patient's body. The valve consists of two membranes, wherein first membrane is made of single material having uniform elasticity, and second membrane is partly made of a composite or a fused material having variable elasticity and partly made of a non-elastic material.

The present invention, including its embodiments and other features, will become more apparent from the following detailed description with reference to the accompanying drawings.

Brief Description of the Drawing

The present invention may best be understood by reference to the following description, taken in connection with the accompanying drawings in which the reference numerals designate like parts throughout the figures thereof and wherein:

Detailed Description of Preferred Embodiments

The improved morcellator of the present invention includes a rotary tissue cutting tube which passes through outer sheath tube as illustrated in FIG. 01 and FIG. 03, which is driven by a cutter gear mechanism of a cutter assembly as shown in FIG. 02 and FIG. 04. The outer sheath prevents surrounding tissue damage while the cutting tube rotates. There is a gap between outer sheath tube and rotary tissue cutting tube. Body fluids such as blood may seep through this space into the cutting assembly. If this fluid follows in and gets in contact with the drive gear mechanism mounted on the reusable drive assembly, it may pass infection from one patient to another, as it is reusable. To avoid infection from transmitting to drive assembly, a hydraulic seal is provided on the distal portion of shaft of the cutting assembly. The seal prevents the body fluids from getting into the sterile region of the cutter assembly.

The body fluid may also seep through the gap between the tissue cutting tube and pneumatic valve into the sterile region. To prevent body fluid seep into sterile region, a hydraulic seal is provided on the proximal portion of shaft of the cutting assembly. Due to the seal, the sterile region remains sterile during the use of the morcellator. The morcellator may terminate directly at the pneumatic seal.

Another hydraulic seal is mounted on the drive assembly below the drive gear mechanism. Though the drive gear mechanism is not supposed to get contaminated, in unlikely event, the infection is prevented from seeping into the body of driving assembly with the said hydraulic seal. The distal and proximal end of the cutter assembly is sealed onto the body of drive assembly thereby preventing infection transfer from drive assembly to the cutter assembly.

The cutter assembly is removed and disposed off after each use. The drive assembly may be used more than once thereby saving material, environment and healthcare cost.

The cutter assembly of traditional morcellators consists of three tubes viz. cutter tube, outer steady sheath, and inner stabilizing sheath tube. The morcelletor disclosed has unique twin tube design. The inner tube which is used in other traditional morcellators is eliminated

completely. Thus new design eliminates the seeping region, between, the cutting tube and inner stabilizing sheath tube.

Another advantage of twin tube over the conventional design using three tubes is that in the twin tube design, the inside space is increased as there is no tube inside the cutter tube unlike conventional morcellator design that consist of three tubes.. In addition to this advantage of more space that is available for removal of tissues, twin tube provides less space for fluid seepage, aiding in keeping the device sterile. Further reducing number of component reduces material, cost and weight of the morcellator, thus increasing overall effectiveness, efficiency of the device.

Partial Disposing off reduces wastage of plastic and metal that leads to environmental pollution, reduces wastage and significantly bring down the cost pressure on the healthcare system.

Use of traditional cutter tube without using the inner tube may cause drag as well as twisting of the forceps. The traditional design of the cutter tube of a morcellator is uniform cylindrical. Such cutter cuts the tissue which is of the same size of the size of the Inner diameter of the cutter tube. The same size of the tissue as that of cutter tube size causes drag. A novel profile of a tissue cutting tube FIG. 06 and FIG. 07 is disclosed which produce the minimum drag during tissue removal, as the size of tissue cut by cutting edge 33 FIG 06 and cutting edge 43 in the FIG 07 is less than the tubes inside diameter 31 in FIG. 06 and inside diameter 41 in the FIG. 07.

In traditional designs, cutting edge is formed by chamfering/ grounding at one end of a tube. As disclosed in the design illustrated in FIG. 08, double shear angle 47 is given to the rotary tissue cutting tube. The cutting tube 46 is ground at one end to form the cutting edge with double shear angle. This second shear angle is achieved by cutting the ground/ chamfer edge in variable plane. Due to this double shear angle 47, tissue get morcellated with less force than that required using traditional morcellator cutter.

A Cutter activation mechanism and safety lock to avoid unintentional cutter exposure is disclosed as illustrated in FIG 04 and FIG 05. The morcellator cutting tube is exposed by moving the outer sheath tube 01 towards proximal end. This movement of outer sheath tube 01 is done by using the buttons 103 provided on the cartridge 25 as shown in FIG 04 and FIG 05.

The design of a cutter activation mechanism, shown in FIG 05, prevents an unintentional exposure of a cutting tube 04. The outer sheath tube 01 can be moved only by activating this unique cutter tube activation mechanism as illustrated FIG 05. The outer sheath 01 can not

be moved by any other means such as a frictional force between skin and outer sheath. This is one of the safety features of the disclosed invention.

The cutter activation mechanism consists of a pull collar 101, first locking slot 251 and second locking slot 252. These locking slots are integrated in the main housing of a disposable cutter assembly 25. And pull collar 101 is attached on the outer sheath 01.

When pull collar 101 is locked in the locking slot 251, the cutting tube 04 is completely covered by outer sheath 01. When pull collar101 is locked in the locking slot 252, then the cutting edge of the cutter tube 04 is exposed. Pull collar 101 can be slide by using buttons 103 provided on the main housing of a disposable cutter assembly 25 (FIG 05). To expose the cutting edge of the cutter tube 04, buttons 103 required to be pressed and then pulled back towards the proximal end of the device. The pull collar 101 gets locked in the locking slot 252 and so the outer sheath 01 which is attached to the pull collar 101 remains at the new position exposing the cutting edge of a cutter tube 04. Levers of pull collar 101 remain in the locking slot 252 even after removing the external force by removing fingers from the buttons 101 due to the spring force. In one of the embodiment, this spring force is provided by the springiness of the material.

The buttons 101 needs to be pressed again to unlock the pull collar 101 from the locking slots 252. As pull collar 101 gets unlock, the outer sheath 01 moves towards distal end. Thus covers the cutting edge of a cutter tube 04. The outer sheath 01 moves forward after unlocking the pull collar 101 as the outer sheath 01 is mounted with spring load.

The buttons 103 are placed on the both sides of the main housing of the cutter assembly 25 (FIG. 04 and FIG. 05). Both these buttons 103 need to be operated simultaneously in order to activate the cutter that is to expose the cutting edge of cutter tube 04. This eliminates the unintentional opening or closing of a cutter tube 04 by movement of outer sheath 01.

A quick engage and quick release mechanism for morcellator is further disclosed as illustrated in FIG 03 and FIG 04. In one of the embodiment, a novel quick engage & quick release mechanism is a single piece mechanism. It is integrated with the main housing of a reusable drive assembly.

A disposable cutter assembly 25 can be detached from a reusable drive assembly 13 by pressing a lever 132 which is integrated in a reusable drive assembly 13. This integrated lever 132 is integrated at the bottom rear side of a reusable drive assembly 13. When a disposable cutter assembly 25 is attached to a reusable drive assembly, the integrated lever 132 of a reusable drive assembly 13 gets concealed. This eliminates accidental activation of integrated lever 132 of a reusable drive assembly 13 and thus eliminates unintentional release of a

disposable cutter assembly 25 from a reusable drive assembly 13. This integrated lever 132 can be activated by using index finger.

The reusable drive assembly 13 which drives the cutter tube 04 can be simply inserted into the disposable cutter assembly 25. The integrated lever 132 has protrusions 131 on it to enable correct positioning of the reusable drive assembly 13 into the reusable cutter assembly 25. The integrated lever 132 of the reusable drive assembly13 itself retracts during insertion. When the reusable drive assembly 13 comes to the predetermined position inside the disposable cutter assembly 25, the integrated lever 132 retracts back to its original position. The protrusions 131 on the integrated lever 132 gets lock in the disposable cutter assembly 25.

To release the disposable cutter assembly 25 from the reusable drive assembly 13, the integrated lever 132 has to be operated. The integrated lever 132 can be manually operated by pressing with the help of an index finger.

It further disclosed the designs of unique valves used in the morcellator. In a normal working condition, the tissue cut is pulled out with the help of forceps. The forceps inserted from the proximal end of the cutter assembly. During such insertion of forceps, inflation gas escapes from the open space around the forceps. It is necessary to design a valve which will provide positive sealing however is essential to keep the minimum drag on the forceps to remove the tissue with minimum resistant to the operator.

The disclosed design of a valve FIG. 09 is unique in construction and principal. The valve greatly reduces the unintentional leakage of CO_2. The unique design of this valve provides the greater sealing capacity.

The valve consists of two membranes 51 and 52. Upper Membrane 51 is made up of single material and has uniform elasticity. Lower membrane 52 is partly made up of composite/ fused material that has variable elasticity and partly made up of a non-elastic material.

When not in operation valve remains in the close position whereas when in operation valve opens by aligning the gates 54 and 55 on membrane 51 and 52 respectively, FIG 09.

Another embodiment of the valve design is disclosed in FIG 10. The novel design is unique in construction. It is designed to remain close in normal condition. It consists of two membranes 61 and 62. Upper membrane 61 has a gate 63 at the centre which is covered by lower membrane 62, thus provides sealing. When tools are inserted through the gate 63 of upper membrane 61, it further pushes the lower membrane 62 which opens the valve.

Yet another embodiment of valve design is disclosed as illustrated in FIG. 11. This novel design comprises of number of membranes placed with each other at two different levels i.e. upper level 71 and lower level 72. The membranes provide sealing while in operation by minimizing all possible gaps between an instrument and membranes. The unique construction of small individual membranes also exerts very low drag on the instrument while removing the tissue as compare to the drag exist while operating with traditional valves.

In the foregoing description, the method and device of the present invention have been described with reference to preferred embodiments. It is to be understood and expected that variations in the principles of the method and device herein disclosed may be made by one skilled in the art and it is intended that such modifications, changes, and substitutions are to be included within the scope of the present invention as set forth in the appended claims (if any are included). The specification and the drawings are accordingly to be regarded in an illustrative rather than in a restrictive sense.

Claims

1. A morcellator for morcellating tissue from a patient's body comprising:
   (a) a disposable cutter assembly comprising (i) a rotary tissue cutting tube, (ii) an outer sheath tube covering the rotary tissue cutting tube, (iii) a cutter driven mechanism, and (iv) a seal attached before and after to the cutter drive mechanism wherein the seal maintain a sterile region around the cutter driven mechanism of a disposable cutter assembly; and
   (b) a reusable drive assembly comprising (i) a drive mechanism and (ii) a seal attached below the drive mechanism, wherein the seal prevent transmission of an infection and/or a body fluid to the reusable drive assembly.

2. A morcellator for morcellating tissue from a patient's body comprising:
   (a) a disposable cutter assembly comprising (i) a rotary tissue cutting tube having variable diameter to remove morcellated tissue with lowest drag and double shear cutting edge to enable smooth, fast morcellation of tissue. (ii) an outer sheath tube covering the rotary tissue cutting tube, (iii) a cutter driven mechanism, and (iv) a seal attached before and after to the cutter assembly to maintain a sterile region around the cutter driven mechanism of a disposable cutter assembly; and
   (b) a reusable drive assembly comprising (i) a drive mechanism and (ii) a seal attached below the drive mechanism, wherein the hydraulic seal prevent transmission of an infection and/or a body fluid to the reusable drive assembly.

3. A morcellator for morcellating tissue from a patient's body comprising:
   (a) a disposable cutter assembly comprising (i) a rotary tissue cutting tube, (ii) an outer sheath tube covering the rotary tissue cutting tube, (iii) a cutter driven mechanism, (iv) a seal attached before and after to the cutter assembly to maintain a sterile region around the cutter driven mechanism of a disposable cutter assembly, and (v) a cutter activation mechanism, wherein the cutter activation mechanism prevent unintentional exposure of the rotary tissue cutting tube by controlling movement of the outer sheath tube; and
   (b) a reusable drive assembly comprising (i) a drive mechanism and (ii) a seal attached below the drive mechanism, wherein the seal prevents transmission of an infection and/or a body fluid to the reusable drive assembly.

4. A morcellator for morcellating tissue from a patient's body comprising:
   (a) a disposable cutter assembly comprising (i) a rotary tissue cutting tube, (ii) an outer sheath tube covering the rotary tissue cutting tube, (iii) a cutter driven mechanism, and (iv) a seal attached before and after to the cutter assembly, wherein the seal maintain a sterile region around a cutter driven mechanism of a disposable cutter assembly;

(b) a reusable drive assembly comprising (i) a drive mechanism and (ii) a seal attached below the drive mechanism, wherein the seal prevent transmission of an infection and/or a body fluid to the reusable drive assembly; and

(c) a valve having a first membrane and a second membrane, wherein the valve provide low drag on forceps during tissue removal from the patient's body.

5. The improved morcellator according to any of preceding claims, wherein the drive assembly further comprises an integrated lever.
6. The improved morcellator according to claim 5, wherein the integrated lever may have protrusions.
7. The improved morcellator according to any of preceding claims, wherein the rotary tissue cutting tube is having variable diameter and a cutting edge with double shear angle.
8. The improved morcellator according to claim 4, wherein the first membrane is single material with uniform elasticity.
9. The improved morcellator according to claim 4, wherein the second membrane is partly a composite or fused material with variable elasticity.
10. The improved morcellator according to claim 4, wherein the second membrane is partly a non-elastic material.

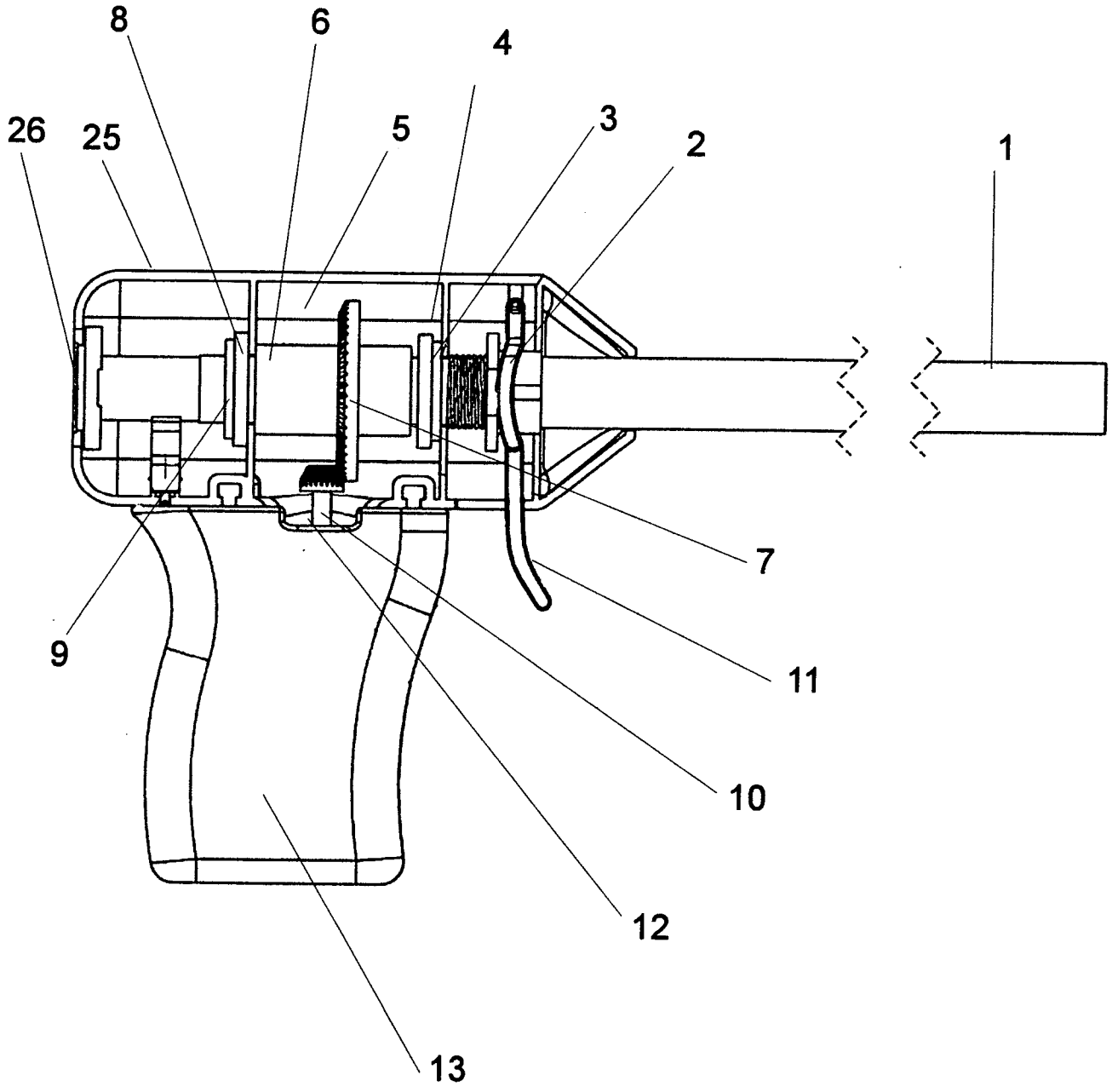

FIG-01

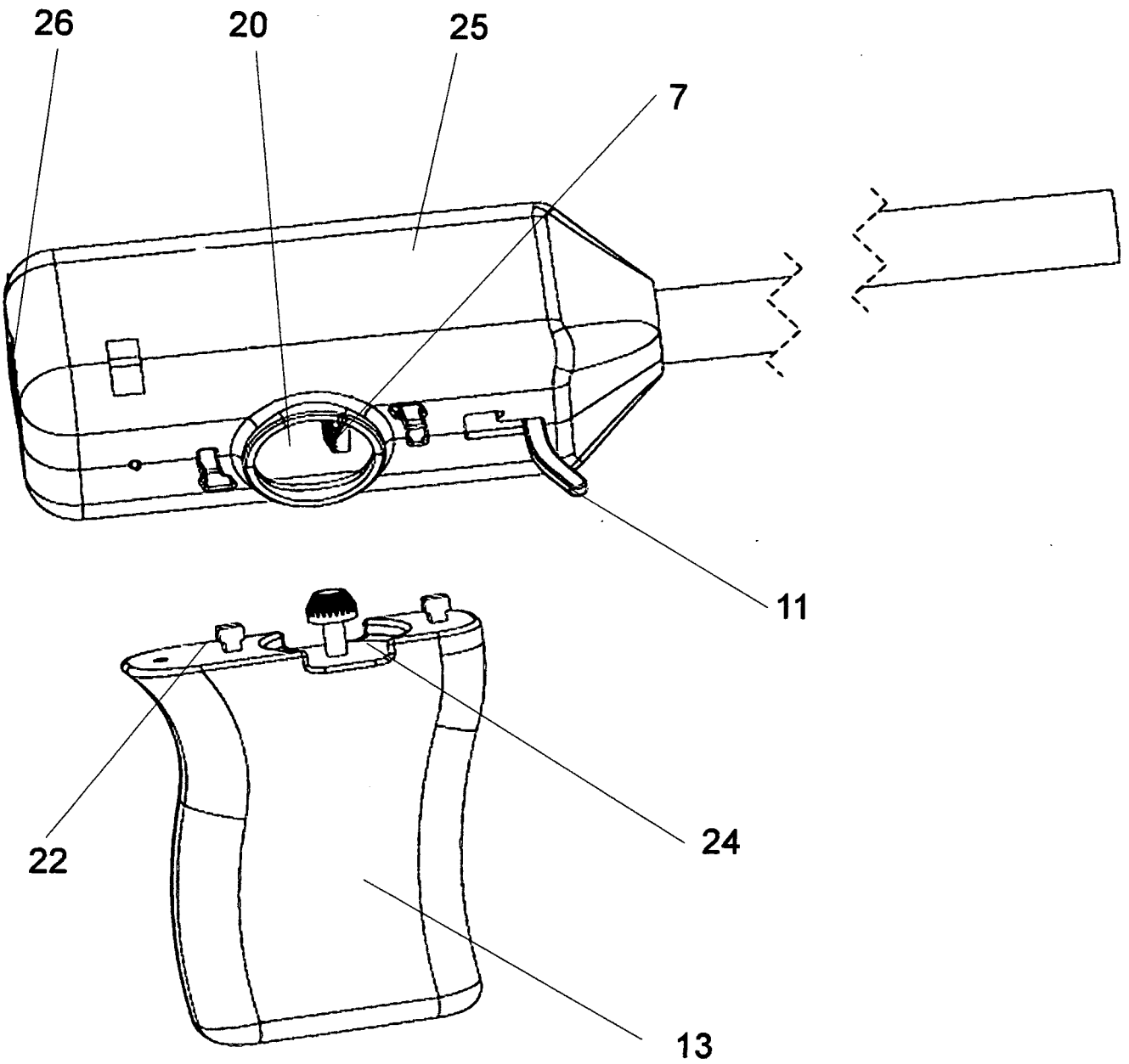

FIG-02

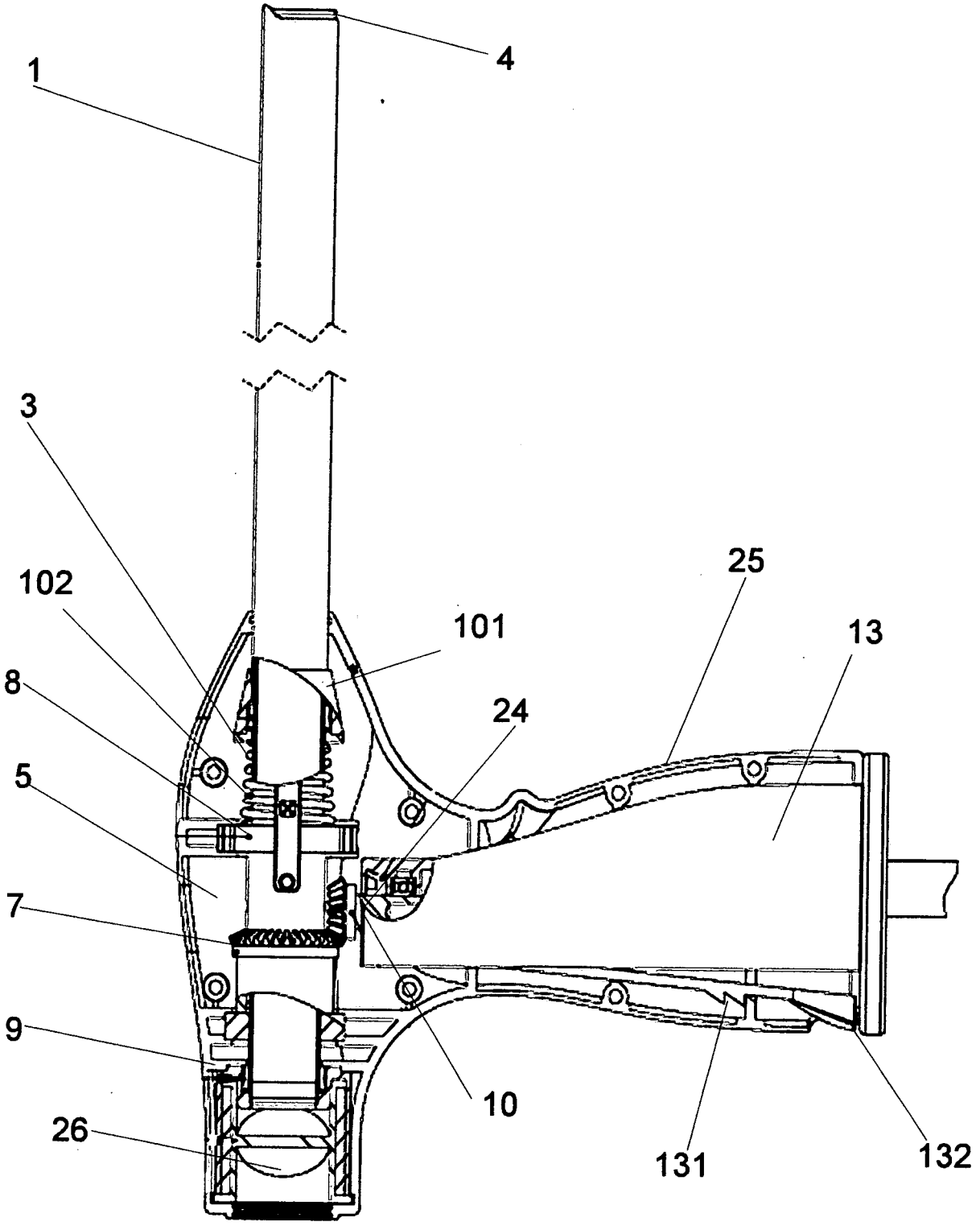

FIG-03

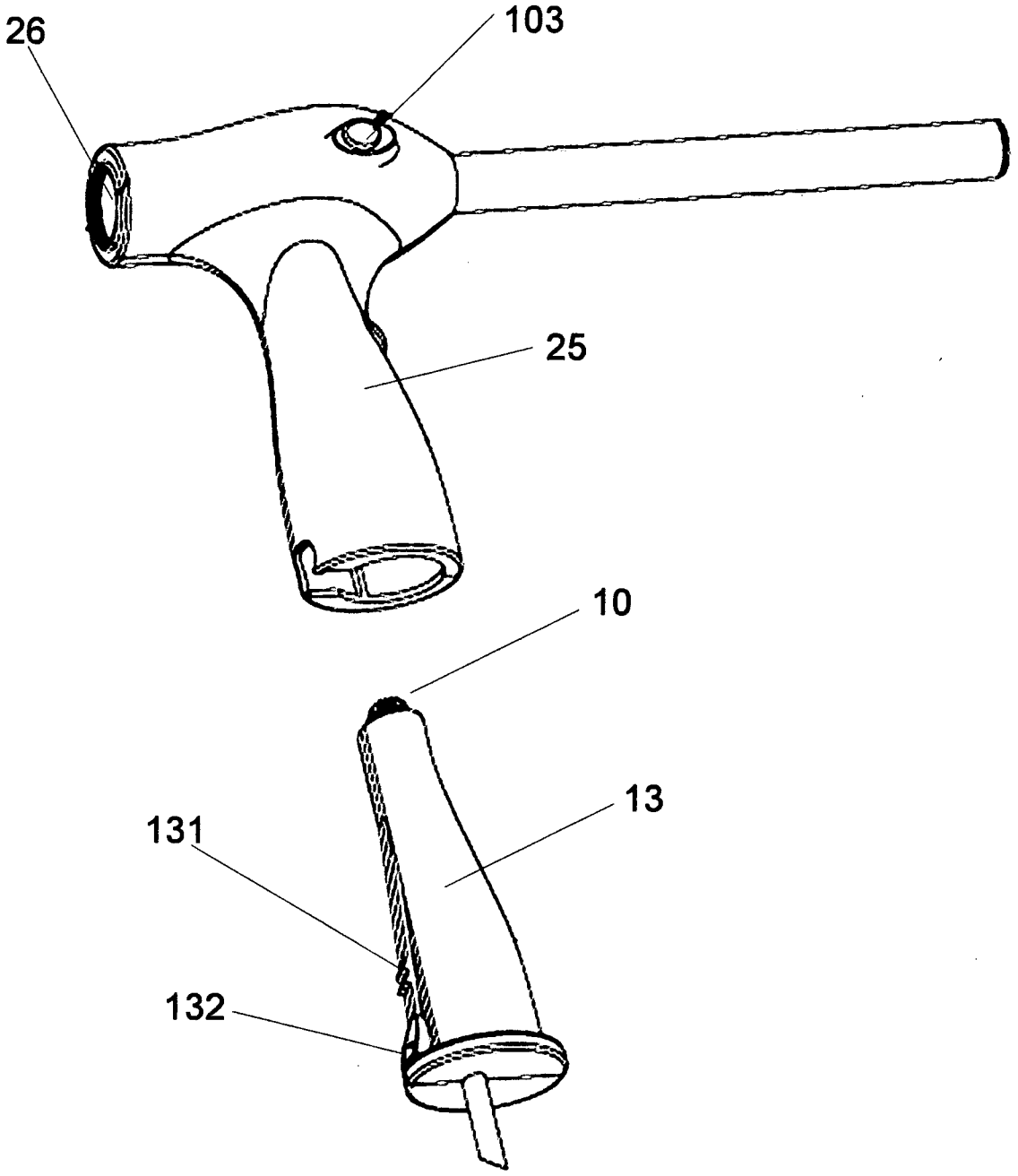

FIG-04

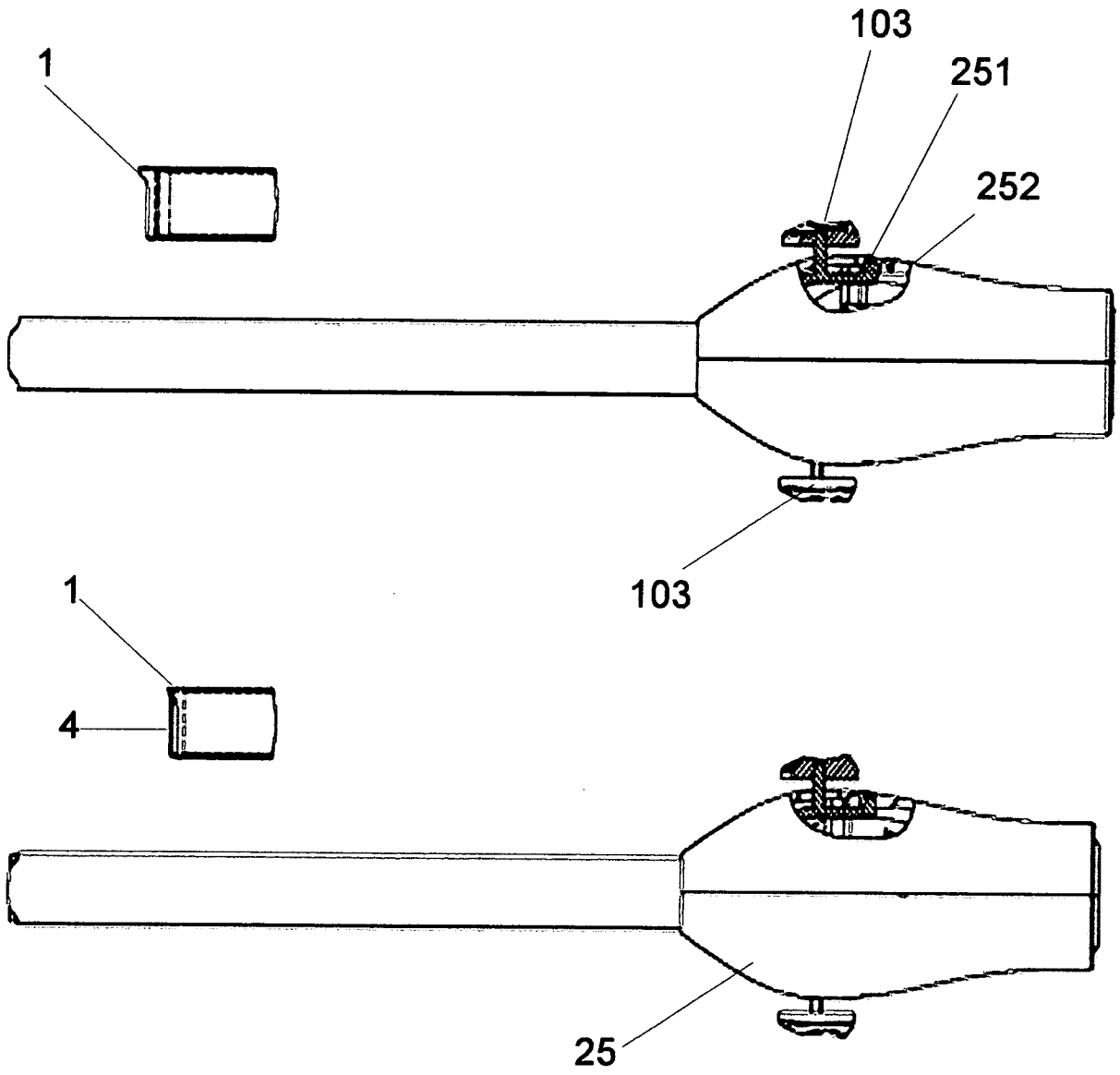

FIG-05

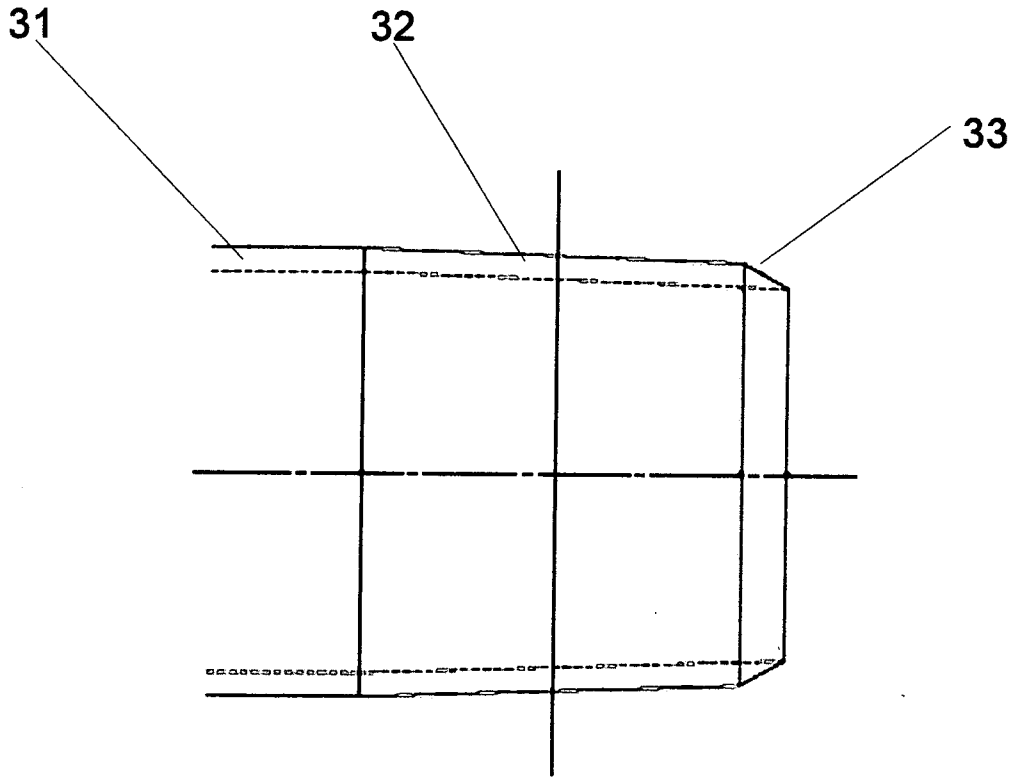

FIG-06

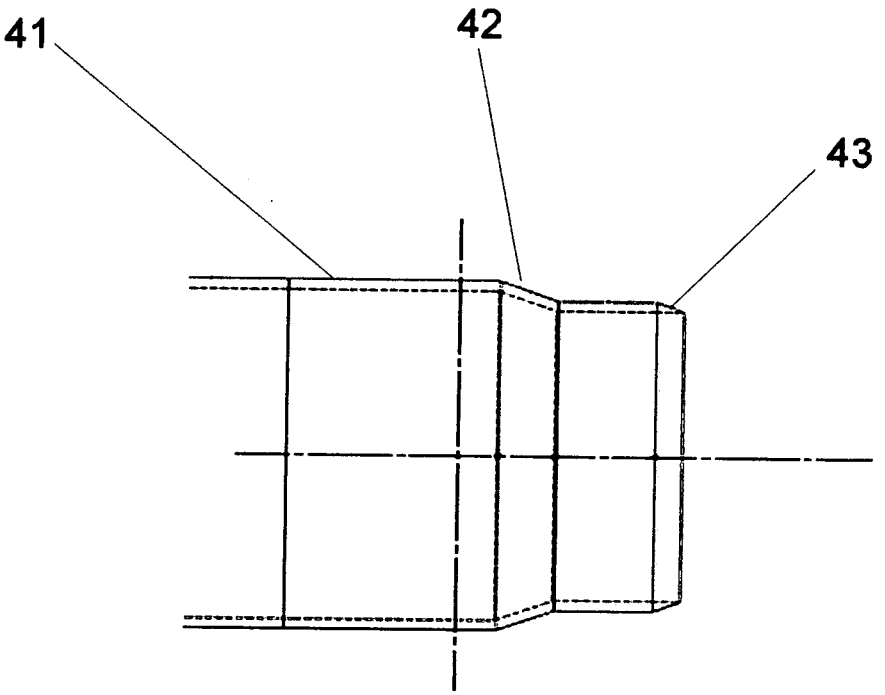

FIG-07

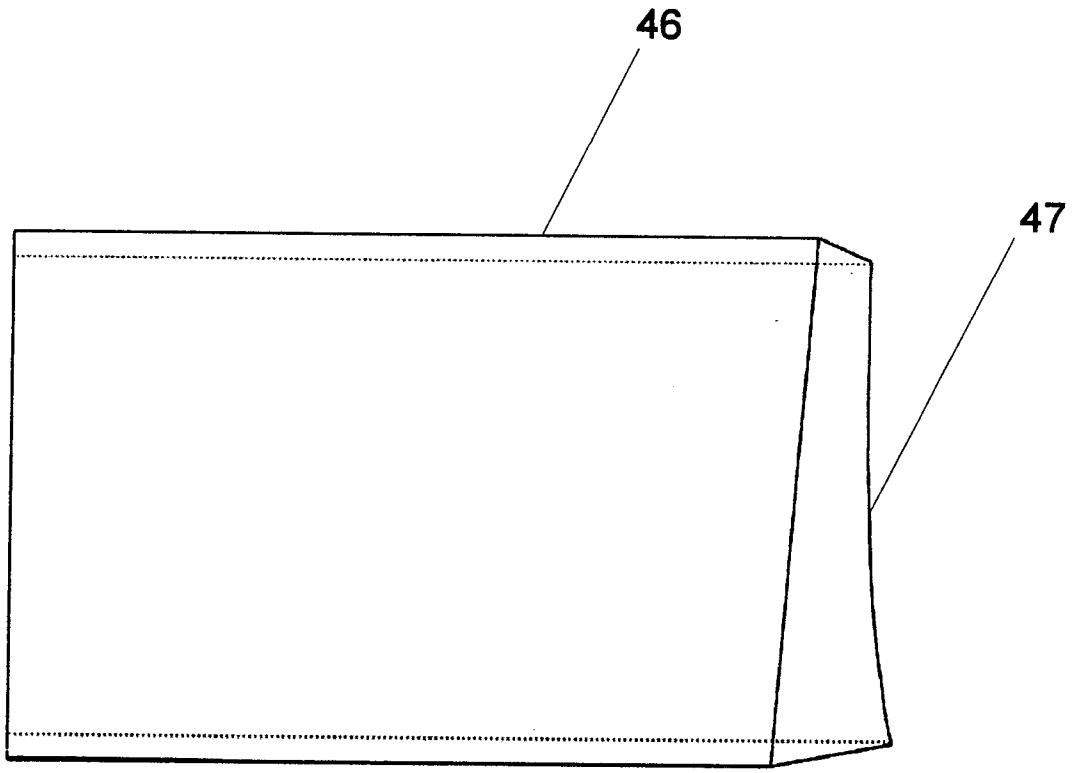

FIG-08

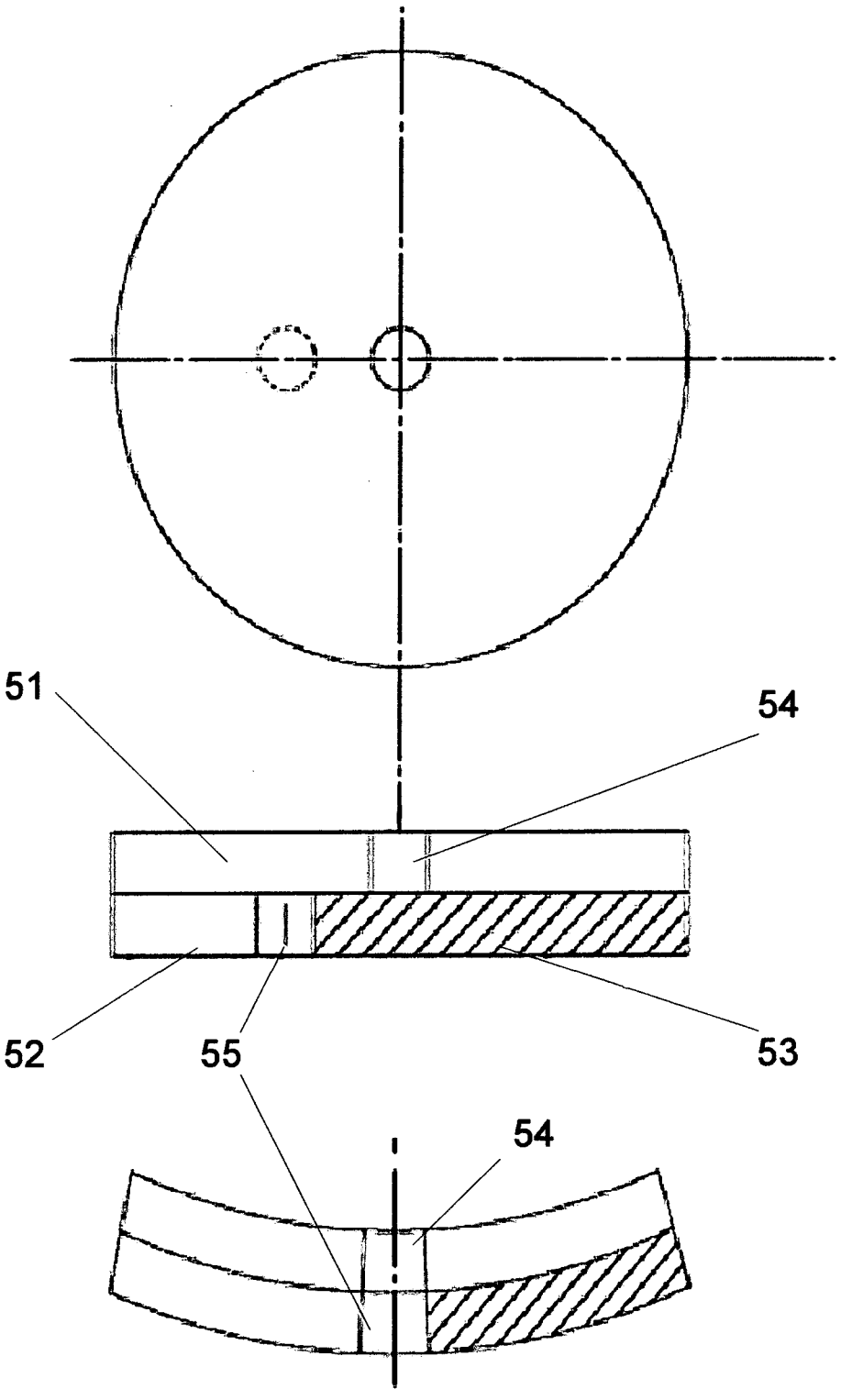

FIG-09

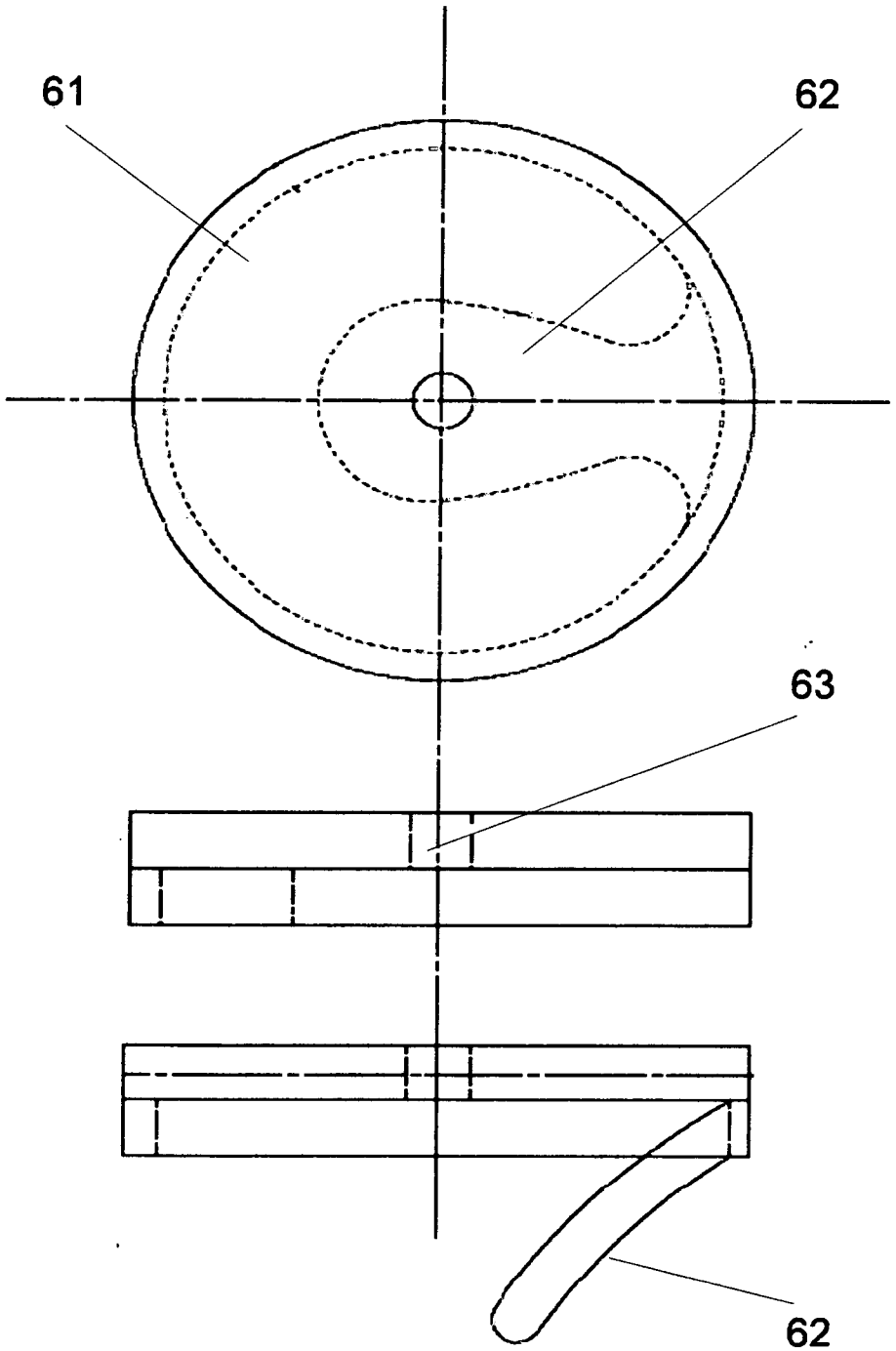

FIG-10

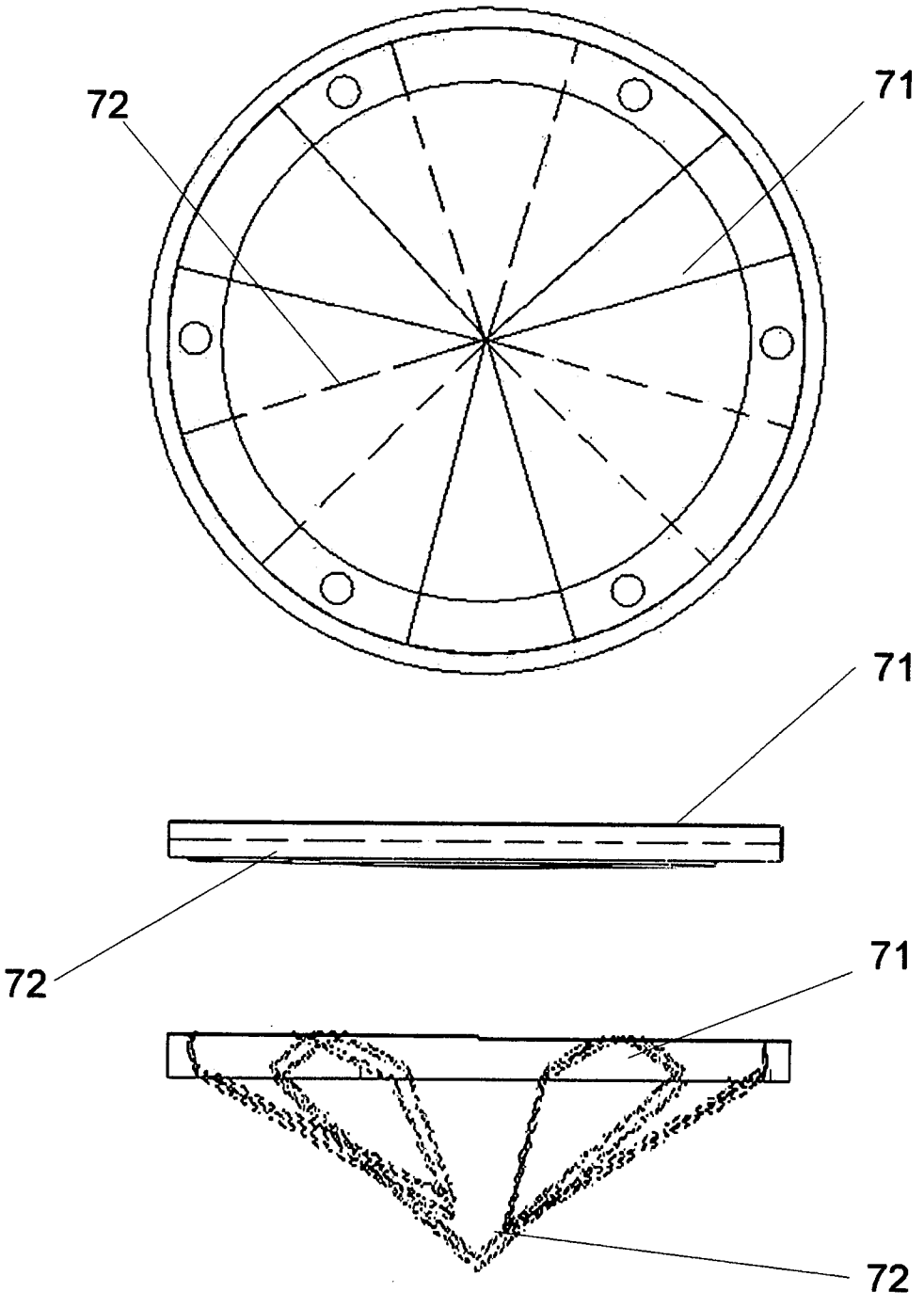

FIG-11