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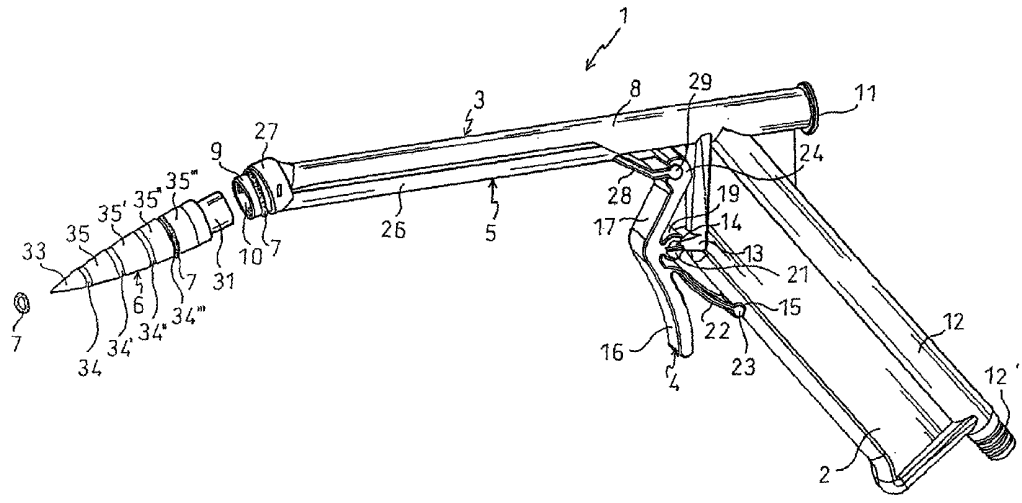
(54) Title: A HAEMORRHOIDAL LIGATURE APPLICATOR



(57) Abstract: The present invention relates to a medical device for applying resilient ligatures to haemorrhoids, commonly known as a haemorrhoidal ligature applicator. In particular, the present invention relates to a device for applying ligatures to haemorrhoids, comprising a barrel (3) provided with a grip (2) and having a distal end (9) which can receive resilient rings (7), a slidable actuator (5), operated by a trigger (4), being disposed on the outer surface of the barrel (3), the slidable actuator (5) being movable between a retracted position and an advanced position so as to cause the resilient ring (7) to be disengaged from the distal end (9) of the barrel (3) upon command.

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"A haemorrhoidal ligature applicator"

DESCRIPTION

The present invention relates to a medical device for the application of resilient ligatures to haemorrhoids, commonly known as a haemorrhoidal ligature applicator.

It is known that haemorrhoids are constituted by small venous swellings, so-called piles, which may even emerge from the anus and cause the patient pain, pruritis and even bleeding. The most recent surgical treatment for haemorrhoids is based on the application of a resilient means to the haemorrhoid so that the vein is closed at the base and then, since the haemorrhoid is no longer supplied with blood, it tends to become sclerosed and to fall off spontaneously. This operation is easier and quicker than the conventional operation and can also be carried out almost painlessly and as an outpatient operation, by giving the patient a local anaesthetic. This operation, which is known as "tying" the haemorrhoids, is carried out by means of a suitable ligature applicator constituted basically by a pistol the barrel of which is connected to suction means. A cylinder arranged coaxially and slidably outside the barrel is operated by a trigger. The slidable cylinder terminates slightly before the distal end of the barrel,

thus leaving a portion of the barrel free. Suitable resilient means for tying the haemorrhoids are fitted on this free portion. Clearly, for reasons of hygiene and convenience of use, these ligature applicators must be disposable. It is therefore extremely important for them to have considerable structural simplicity such as to minimize their production cost, and to be made of inexpensive materials.

A further problem which has been found in relation to the haemorrhoidal ligature applicators of the prior art is that the resilient ligature rings are fitted on the applicator with considerable difficulty, in spite of the use of a suitable loading cone. This difficulty is due to the fact that the resilient rings have to be force-fitted onto the ligature applicator so that, once they are fitted around the haemorrhoid, they can exert an adequate constricting force to achieve the desired result.

The problem upon which the present invention is based is therefore that of providing a haemorrhoidal ligature applicator which overcomes the disadvantages of the prior art and which, in particular, is of simple construction and low cost.

This problem is solved by a haemorrhoidal ligature applicator as outlined in the appended claims.

Further characteristics and advantages of the haemorrhoidal ligature applicator of the present invention will become clearer from the description of some preferred embodiments thereof, given below by way of non-limiting example, with reference to the following drawings:

Figure 1 is a perspective view of a first embodiment of the haemorrhoidal ligature applicator according to the present invention,

Figure 2 is a perspective view of a detail of the haemorrhoidal ligature applicator according to a second embodiment of the present invention,

Figure 3 is a side view showing the haemorrhoidal ligature applicator of Figure 1 in section,

Figure 4 is a perspective view showing the detail of the trigger of the haemorrhoidal ligature applicator according to the present invention,

Figure 5 is a perspective view showing the detail of the slidable actuator of the haemorrhoidal ligature applicator according to the present invention,

Figure 6 is a side view showing the detail of the loading cone and the distal end of the haemorrhoidal ligature applicator according to the present invention, in section,

Figure 7 is a perspective view of the haemorrhoidal

ligature applicator according to the present invention in the condition of use.

With reference to the drawings, the haemorrhoidal ligature applicator according to the present invention is generally indicated 1. The ligature applicator comprises, basically, a grip 2 fixed to a barrel 3. The applicator also comprises a trigger 4 which acts on a slidable actuator 5. Finally, the haemorrhoidal ligature applicator 1 is completed by a cone 6 for loading the resilient rings 7.

The barrel 3 is composed of a tubular body 8 the cylindrical distal end 9 of which is inclined downwardly relative to the longitudinal axis of the tubular body itself and terminates in an opening 10. The inclination of the distal end 9 is preferably 18°.

A second, vacuum-relief opening 11 is disposed at the opposite end of the tubular body 8.

The grip 2 extends along an axis inclined downwardly relative to the longitudinal axis of the tubular body 8 and comprises a vacuum duct 12 which opens into the inner portion of the tubular body 8 in the region of the point of attachment of the grip 2 to the barrel 3. The free end of the duct 12 has a ridged connector 12' for the fitting of a resilient vacuum tube.

The grip 2 and the barrel 3 are preferably formed integrally.

On the front of the grip 2, there is a pin 13 terminating in a cylindrical appendage 14 having a bulbous cross-section. Below the pin 13, the grip 2 also has a recess 15 the inner surface of which is semicylindrical.

With particular reference to Figure 4, the trigger 4 comprises a first arm 16 and a second arm 17 which are connected by a central portion 18 on which the trigger is mounted for pivoting. For this purpose, the central portion 18 has a projecting seat 19. This seat 19 is intended to house the pin 13 of the grip 2 by snap-engaging the appendage 14 of the pin. The seat 19 is thus constituted by two claws 19', 19'' with semicylindrical inner surfaces which extend from a stalk 20 connected to the central portion 18 of the trigger; the seat 19 therefore has a shape complementary to that of the appendage 14 of the pin 13 of the grip 2.

The seat 19 is partially closed laterally by a pair of side walls 21 (only one side wall is shown in the drawings) which extend from the edges of the lower claw 19'' as far as the connecting point of the two claws. Naturally, the side walls 21 could cover only the upper halves of the sides of the seat 19, or they could cover

the sides completely.

In the embodiment shown in the drawings, the arms 16, 17 of the trigger 4 do not lie on the same axis but on axes which converge in the region of the central portion 18 of the trigger, the seat 19 being included in the angle formed by the axes. It is, however, possible to form a trigger in which the two arms 16, 17 lie on the same axis.

The lower arm 16 comprises a tongue 22 on the same side on which the seat 19 is disposed. The tongue 22 extends downwards along an axis diverging from the arm 16 and has a substantially bent cross-section. The tongue 22 terminates in a cylindrical appendage 23 which has a bulbous cross-section and which is intended to engage the respective seat 15 of the grip 2. This appendage 23 therefore has a shape and a size complementary to those of the seat 15.

At the end of the upper arm 17, there is a seat 24 the function of which will become clear from the following description. In the same manner as the seat 19 described above, the seat 24 has a substantially C-shaped cross-section. In a central position on the inner surface of the seat 24 there is a tooth 25 with an arcuate edge.

With particular reference to Figure 5, the slidable

actuator 5 comprises a body 26 having a semicylindrical inner surface. The body 26 terminates at one end in a ring 27 having an inside diameter substantially corresponding to the outside diameter of the distal end 9 of the barrel 3. The ring 27 is inclined to the longitudinal axis of the body 26 at substantially the same angle as the inclination of the distal end 9 to the barrel 3. This angle is preferably 18°.

At the end remote from that carrying the ring 27, the body 26 of the slidable actuator 5 has a tongue 28 terminating in a cylindrical appendage 29 with a substantially bulbous cross-section. The appendage 29 has a notch 30 in its central portion. The appendage 29 can thus snap-engage the seat 24 of the upper arm 17 of the trigger 4, the tooth 25 of which fits in the notch 30.

With particular reference to Figures 1 and 6, the loading cone 6 comprises a tubular connecting portion 31 and a conical portion 32. In the drawings, the loading cone 6 is shown as a hollow body, but it could just as well be solid.

The outer surface of the conical portion 32 has a conical tip surface 33 adjoining a first step 34. A plurality of frustoconical surfaces 35, 35', 35'', 35''', spaced apart by respective steps 34', 34'',

34''', adjoin the step 34.

The steps 34, 34', 34'', 34''' are constituted by annular surfaces the diameters of which increase from step to step and which are arranged coaxially relative to the longitudinal axis of the loading cone 6.

The conical tip surface 33 and the successive frustoconical surfaces 35, 35', 35'', 35''' preferably have inclinations to the longitudinal axis of the loading cone 6 which decrease from one surface to the next. In a particularly preferred aspect of the present invention, the loading cone 6 comprises four frustoconical surfaces 35, 35', 35'', 35''' in addition to the conical tip surface 33. Even more preferably, these surfaces have inclinations to the longitudinal axis of the loading cone 6 of 15° (for the conical tip surface 33), 10°, 8°, 5° and 3°, respectively.

The tubular connecting portion 31 has an outside diameter substantially corresponding to the inside diameter of the distal end 9 of the barrel 3, so that the tubular portion can be fitted inside the distal end of the barrel. The joining region between the tubular connecting portion 31 and the conical portion 32 of the loading cone 6 has an annular seat 36 having a base 37 and an outer wall 38. The base 37 has a width substantially corresponding to the thickness of the

distal end 9 of the barrel 3 so that the end portion of the distal end 9 is inserted in the annular seat 36. The outer wall 38 of the annular seat 36 thus covers the outer surface of the end portion of the distal end 9 of the barrel 3.

The haemorrhoidal ligature applicator according to the present invention may be made of various materials. It is however, preferably made of plastics material, particularly for reasons of cost; the haemorrhoidal ligature applicator according to the present invention is in fact preferably disposable which would render applicators made of more expensive materials definitely disadvantageous.

It is, however, important that the material used, particularly with regard to the trigger 4 and the slidable actuator 5, should have adequate resilience properties, for the reasons which will become clear from the following description of the operation of the device. Particularly preferred materials are shock-resistant polystyrene or polycarbonate.

The haemorrhoidal ligature applicator 1 is assembled in the following manner. The trigger 4 is positioned on the grip 2 by snap-engaging the appendage 14 of the pin 13 in the respective seat 19 of the trigger and housing the appendage 23 of the tongue 22 of

the trigger in the respective seat 15 of the grip 2. The slidable actuator 5 is then mounted on the barrel 3 by fitting the ring 27 on the distal end 9 of the barrel and fitting the body 26 of the actuator closely against the lower surface of the tubular body 8 of the barrel. The appendage 29 of the tongue 28 of the slidable actuator 5 is then snap-engaged in the seat 24 disposed on the upper arm 17 of the trigger 4, so that the tooth 25 of the seat 24 is fitted in the notch 30 of the appendage 29. Finally, the loading cone 6 is positioned on the distal end 9 of the barrel 3.

The resilient rings 7 are then fitted on the distal end 9 of the barrel 3 in the following manner. The resilient ring is slid along the conical surface of the loading cone and is thus expanded to an ever greater extent. The steps 34, 34', 34'', 34''' represent a corresponding number of abutment points for the resilient ring; the rings can thus be loaded in steps and, should they slip out of the user's hand as a result of being stretched, they are prevented from returning to the initial position in which they are released from the cone. In fact, to give an example, if a user were to lose his grip on a resilient ring 7 which had reached the last frustoconical surface 35''', as the ring returned backwards, it would abut the immediately

preceding step 34''' rather than sliding as far as the position in which it is released from the cone 6.

The resilient ring 7 is thus positioned on the outer surface of the distal end 9 of the barrel 3. However, by virtue of the presence of the outer wall 38 of the annular seat 36 on the end portion of the barrel, the resilient ring 7 is disposed a certain distance from the edge of the distal end 9. This prevents the resilient ring from slipping off the distal end 9 of the barrel 3 easily once the loading cone has been removed.

By operating as described above, it is also possible to load more than one resilient ring 7 on the distal end of the barrel 3 so as to achieve a stronger ligature of the haemorrhoid.

The resilient rings 7 are made of a suitable elastomer which should ensure considerable deformability combined with good mechanical strength and chemical characteristics. A preferred material is natural rubber.

After the resilient ring 7 has been loaded on the distal end 9 of the barrel 3, the loading cone 6 is removed. The haemorrhoidal ligature applicator is then connected to a vacuum means, for example, to a pump, by fitting the respective tube onto the connector 12' on the grip 2.

As shown in Figure 7, the device is then inserted

in the patient's anus in the vicinity of a haemorrhoid 39. The instrument is gripped by the doctor with one hand, in the same manner as a pistol. The doctor's thumb can then be placed over the vacuum-relief opening 11 in the barrel 3, thus enabling the haemorrhoid 39 to be drawn into the barrel of the ligature applicator through the opening 10 in the distal end 9. At this point, by operation of the trigger, which pivots about the pin 13, the slidable actuator is advanced and acts on the resilient ring 7 until the ring is disengaged from the distal end 9 of the barrel 3; the resilient ring, which was force-fitted on the distal end of the barrel, will return to its initial shape, squeezing the base of the haemorrhoid 39 tightly. At this point, the thumb can be removed from the opening 11, thus interrupting the suction on the haemorrhoid. As stated above, the haemorrhoid, which is deprived of a blood supply, will tend to sclerose and fall off.

When the trigger is released, it returns to the starting position, also returning the slidable actuator 5 backwards. The trigger can be returned owing to the presence of the tongue 22 which acts as a spring against the wall of the grip 2. This is the reason why the material of which the trigger is made must have adequate resilience properties.

The operation is repeated on the various haemorrhoids 39 from which the patient is suffering.

In a second embodiment of the present invention, shown in Figure 2, the tubular body 8 has a slot-like opening 40 in its upper portion, in the vicinity of the distal end 9. Surgical forceps can be introduced through this opening and, by extending through the opening 10 in the distal end 9, can grip a haemorrhoid 39 and bring it into the distal end. The ligature is then applied to the haemorrhoid in exactly the same manner as described above for the first embodiment of the invention.

In the second embodiment just described, it is not therefore necessary to provide for a connection of the ligature applicator to vacuum means. The ligature applicator may therefore not comprise the duct 12 or the opening 11 in the barrel 3, although clearly their presence in no way hinders the use of forceps.

The haemorrhoidal ligature applicator according to the invention has many advantages.

First of all, as described above, the particular shape of the loading cone 6 enables the resilient rings 7 to be loaded particularly conveniently and securely. The presence of the outer wall 28 which abuts the resilient rings sufficiently far from the edge of the distal end 9 prevents the rings from inadvertently

coming off the distal end once the loading cone has been removed.

The inclination of the distal end 9 to the longitudinal axis of the barrel 3 is designed to facilitate the operation of locating the haemorrhoid, since the haemorrhoid is disposed along the anus wall, and to afford the operator an excellent view of the haemorrhoid.

The structural characteristics of the instrument have been designed to achieve maximum functionality at the lowest possible cost, which is also made possible by the preferred use of plastics material. In particular, the presence of the walls 21 on the seat 19 and of the coupling between the tooth 25 of the seat 24 and the notch 30 in the appendage 29 of the actuator keep the assembly constituted by the pin 13, the trigger 4 and the actuator 5 aligned.

The embodiment which comprises the slot-shaped opening 40 in the barrel 3 is particularly advantageous when a pump or other vacuum device is not available.

As stated, by virtue of its convenience in use, its simple construction and its low cost, the haemorrhoidal ligature applicator according to the present invention constitutes an ideal disposable instrument for applying ligatures to haemorrhoids.

Clearly, only some embodiments of the haemorrhoidal ligature applicator of the present invention have been described and an expert in the art will be able to apply thereto all of the modifications necessary for their adaptation to particular applications without, however, departing from the scope of protection of the present invention.

CLAIMS

1. A device for applying ligatures to haemorrhoids, comprising a barrel (3) provided with a grip (2) and having a distal end (9) which can receive resilient rings (7), a slidable actuator (5), operated by a trigger (4), being disposed on the outer surface of the barrel (3), the slidable actuator (5) being movable between a retracted position and an advanced position so as to cause the resilient ring (7) to be disengaged from the distal end (9) of the barrel (3) upon command.

2. A device according to Claim 1, further comprising a loading cone (6) for the resilient rings (7), the loading cone (6) being capable of being fitted removably in the opening (10) of the distal end (9) of the barrel (3).

3. A device according to Claim 1 or Claim 2, in which the barrel (3) is constituted basically by a tubular body (8) having a vacuum-relief opening (11) disposed at the end of the barrel (3) remote from the distal end (9), and in which the grip (2) comprises a vacuum duct (12), the tubular body (8) and the duct (12) being in fluid communication.

4. A device according to any one of Claims 1 to 3, in which the barrel (3) has a slot-like opening (40) in its upper portion in the vicinity of the distal end

(9), for the introduction of surgical forceps.

5. A device according to any one of Claims 2 to 4, in which the loading cone (6) for the resilient ring (7) comprises a conical portion (32) and a tubular connecting portion (31) which is intended to be fitted in the opening (10) in the distal end (9) of the barrel (3), the outer surface of the conical portion (32) comprising a conical tip surface (33) and a plurality of frustoconical surfaces (35, 35', 35'', 35'''), the conical tip surface and the frustoconical surfaces being spaced apart by respective steps (34, 34', 34'', 34''').

6. A device according to Claim 5, in which the conical tip surface (33) and the frustoconical surfaces (35, 35', 35'', 35''') have respective inclinations to the longitudinal axis of the loading cone (6) which decrease in order from one surface to the next.

7. A device according to Claim 6, in which the loading cone (6) comprises four frustoconical surfaces and in which the inclinations of the conical tip surface (33) and of the frustoconical surfaces (35, 35', 35'', 35''') to the longitudinal axis of the loading cone (6) are 15°, 10°, 8°, 5°, and 3°, respectively.

8. A device according to any one of Claims 5 to 7, in which the joining region between the conical portion (32) and the tubular connecting portion (31) of

the loading cone (6) comprises an annular seat (36) having a base (37) and an outer wall (38) so that, when the loading cone (6) is fitted in the opening (10) in the distal end (9) of the barrel (3), the outer wall (38) of the annular seat (36) covers the end portion of the distal end (9).

9. A device according to any one of Claims 1 to 8, in which the distal end (9) of the barrel (3) is inclined to the longitudinal axis of the barrel (3).

10. A device according to Claim 9, in which the distal end (9) is inclined downwardly by 18°.

11. A device according to any one of Claims 1 to 10, in which the trigger (4) is articulated to the grip (2) and to the slidable actuator (5) by snap means (14, 19; 24, 29).

12. A device according to Claim 11, in which the snap means comprise cylindrical appendages (14, 29) which have bulbous cross-sections and which can be snap-engaged in complementary seats (19, 24).

13. A device according to Claim 12, in which the seat (19) is partially or completely closed laterally by a pair of side walls (21).

14. A device according to Claim 12, in which a tooth (25) with an arcuate edge is disposed in a central position on the inner surface of the seat (24), and in

which the appendage (29) has a notch (30) in its central portion, the tooth (25) being intended to engage the notch (30).

15. A device according to any one of Claims 1 to 14, in which the trigger (4) comprises a tongue (22) which acts resiliently on the grip (2).

16. A device according to any one of Claims 1 to 15, in which the slidable actuator (5) comprises a body (26) having a semicylindrical inner surface and terminating at one end in a ring (27) which is intended to be engaged slidably on the distal end (9) of the barrel (3).

17. A device according to any one of Claims 1 to 16, in which the device is made of shock-resistant polystyrene or of polycarbonate.

18. A device according to any one of Claims 1 to 17 in which the device is disposable.

19. A loading cone (6) for a device for applying ligatures to haemorrhoids according to Claim 1, as described in any one of Claims 5 to 8.

20. A kit comprising a device for applying ligatures to haemorrhoids according to any one of Claims 1 to 18, one or more loading cones (6) according to Claim 19, and one or more resilient rings (7).

21. A kit according to Claim 20, in which the

resilient rings (7) are made of natural rubber.

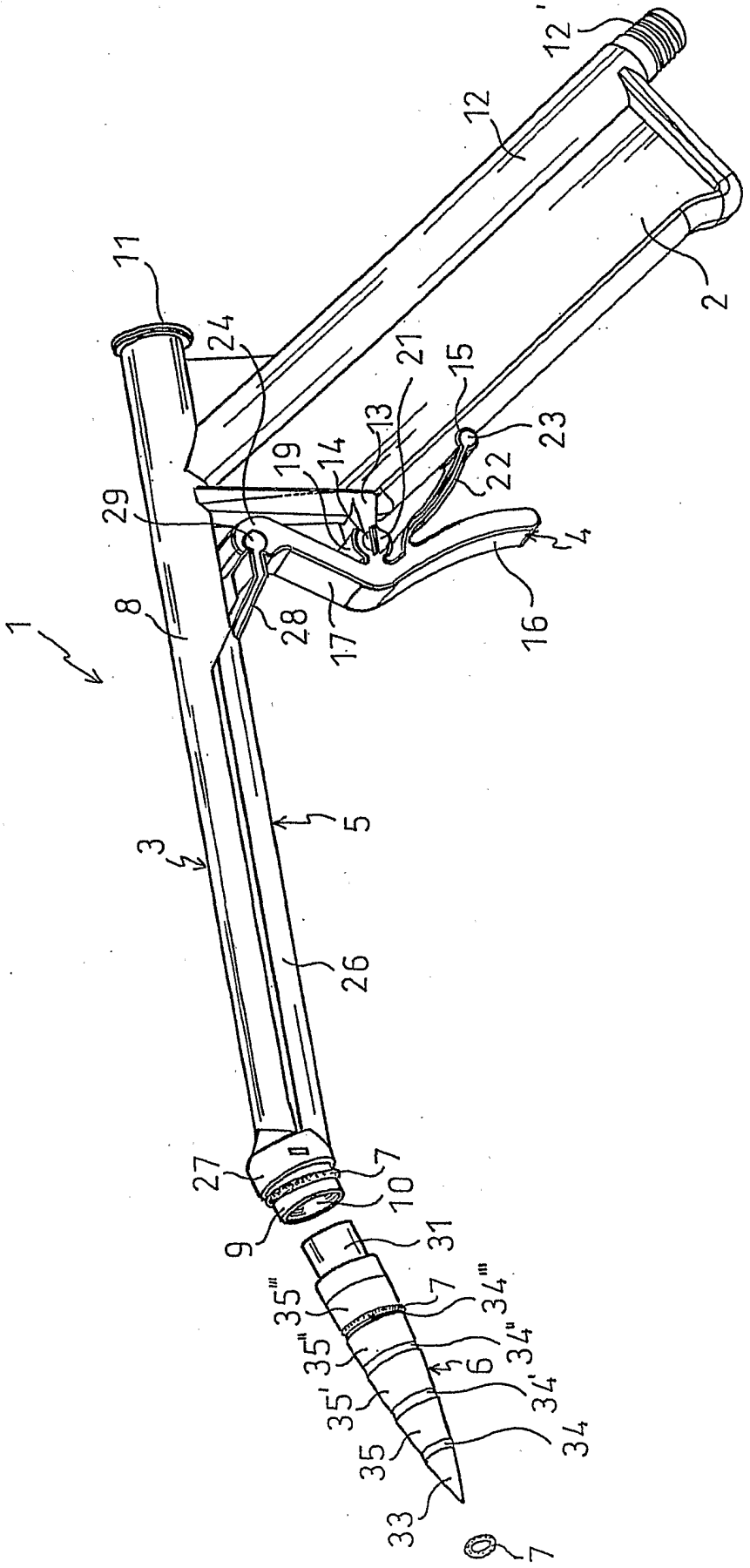
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FIG. 1

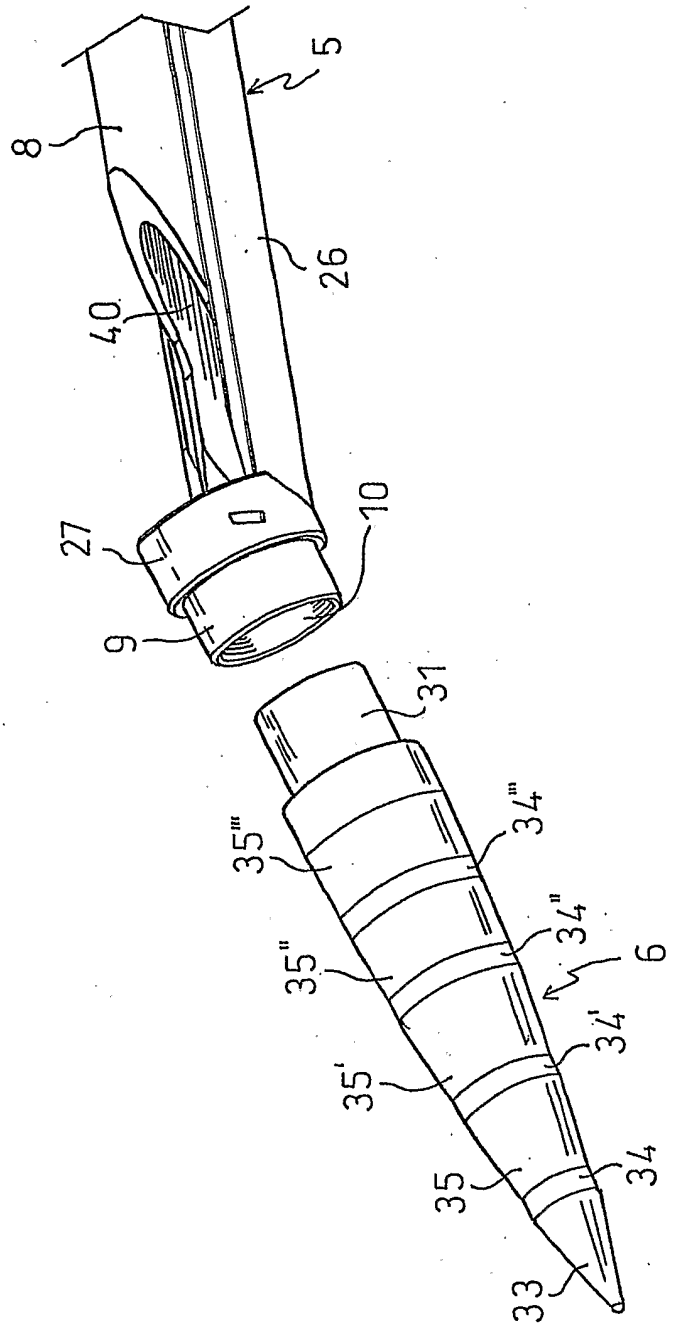

FIG. 2

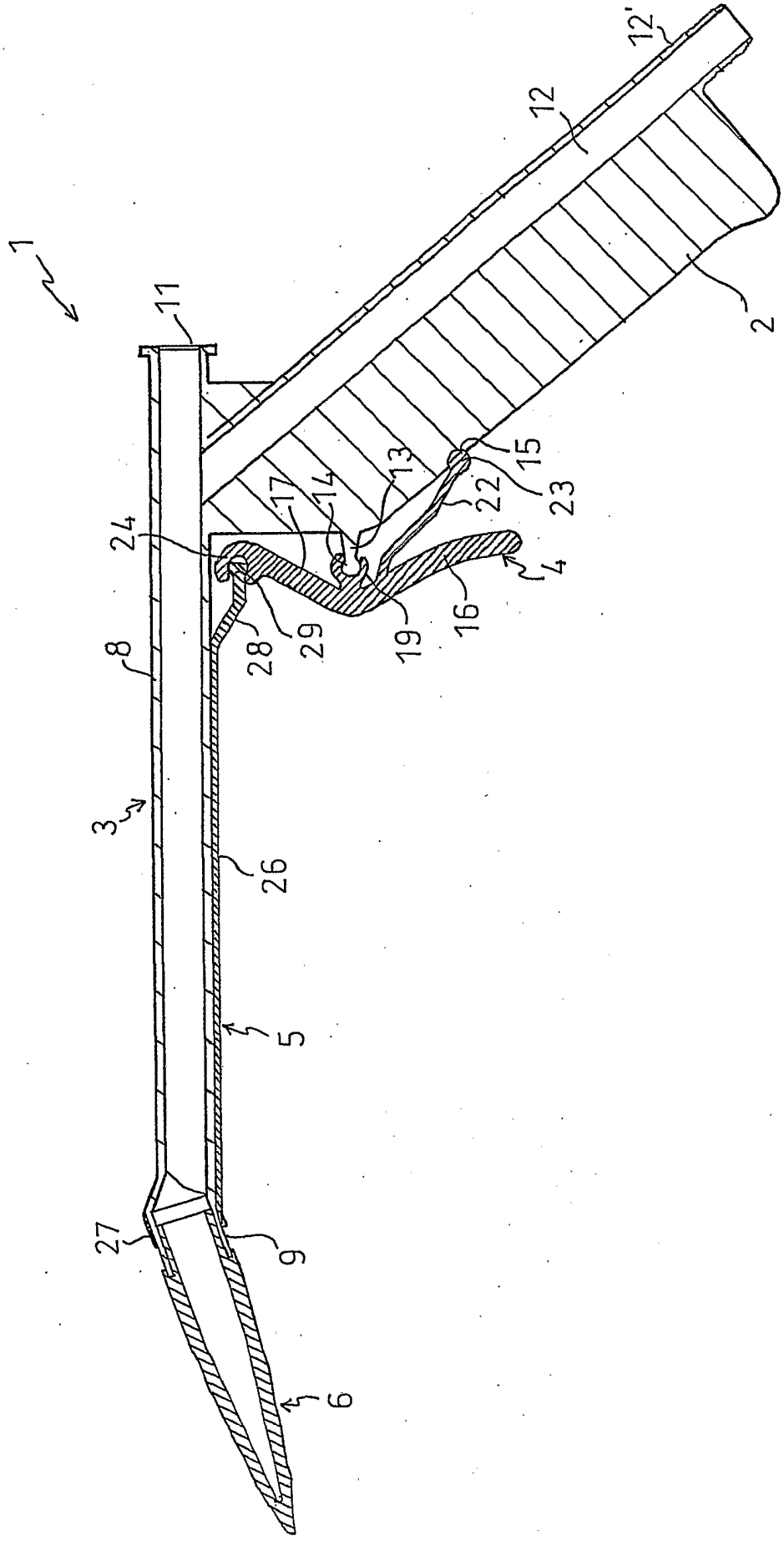

FIG.3

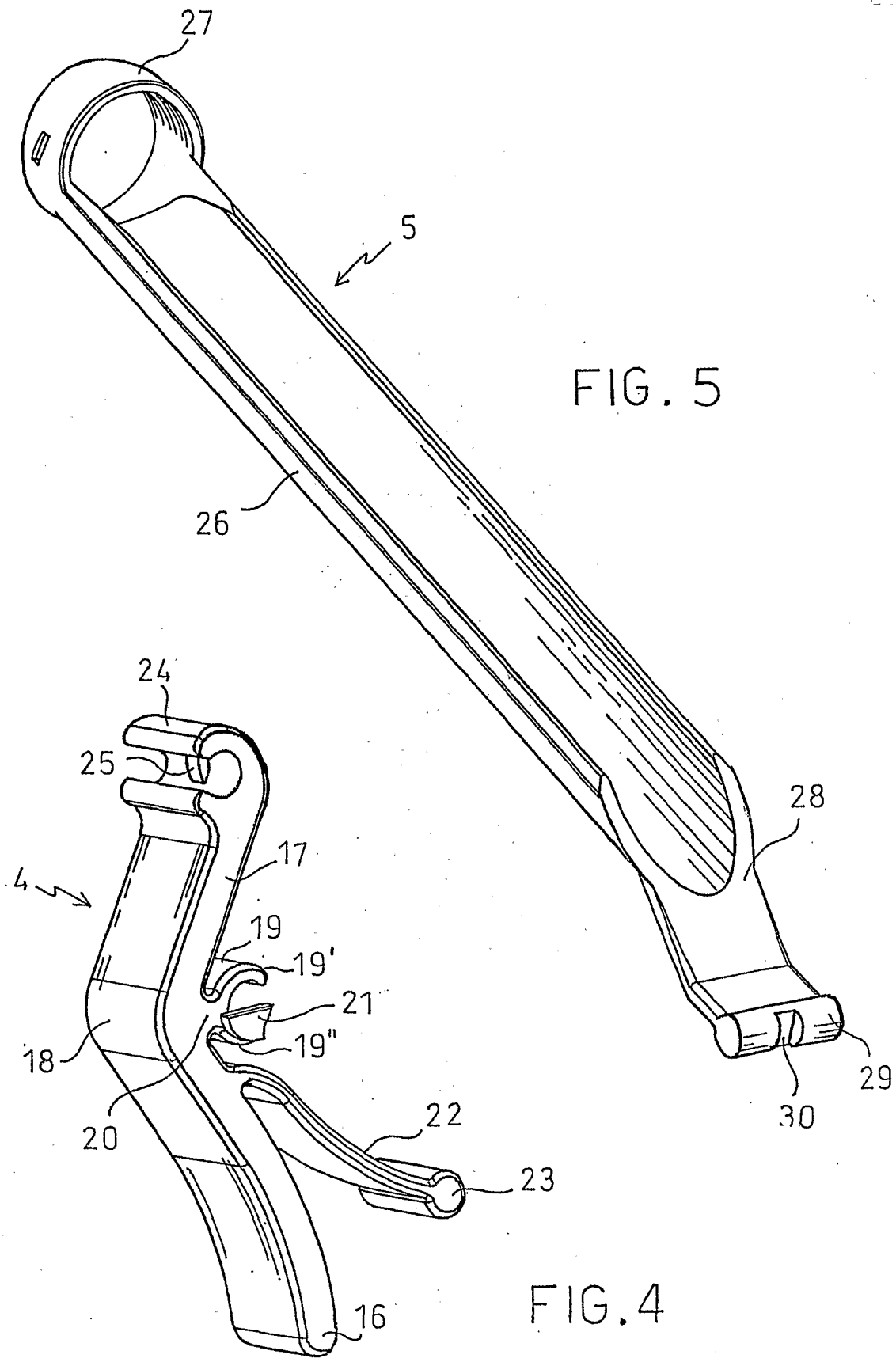

FIG. 5

FIG. 4

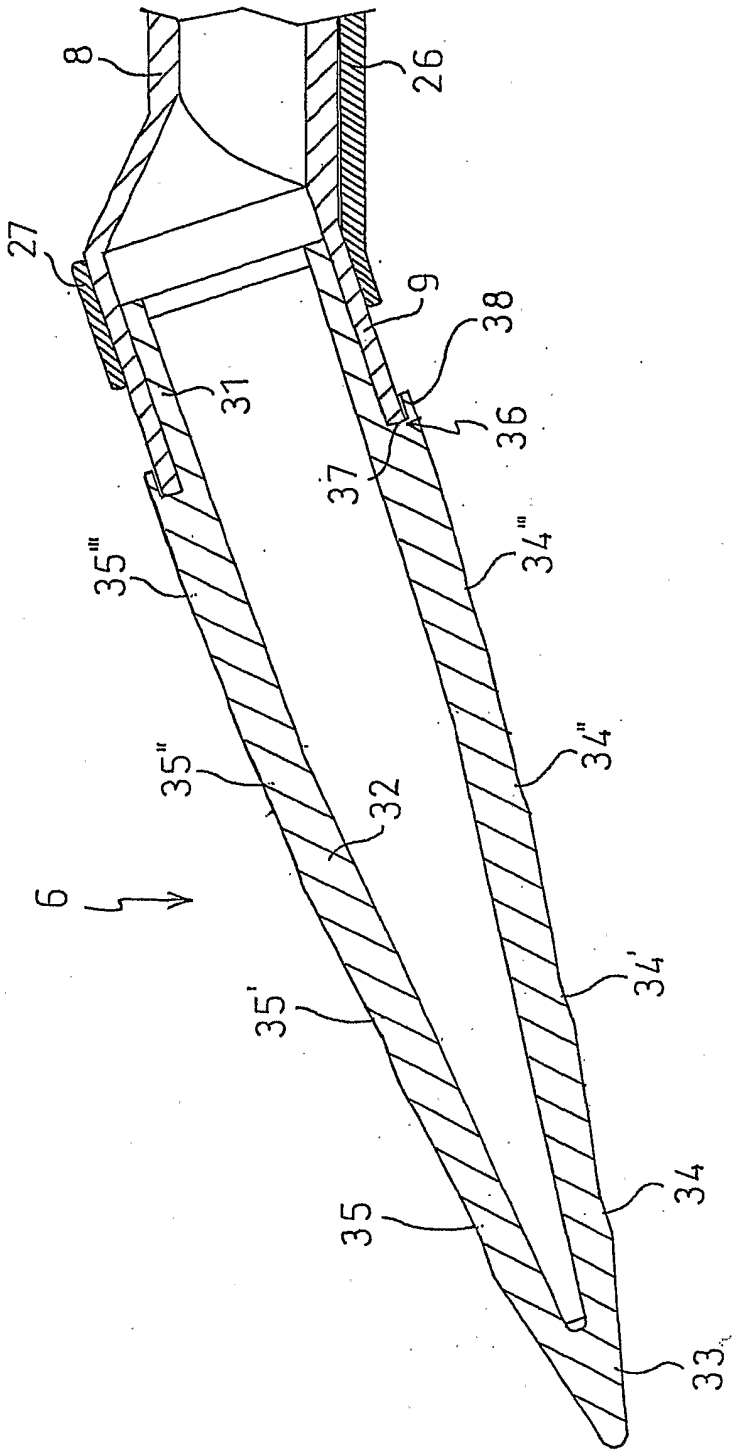

FIG. 6

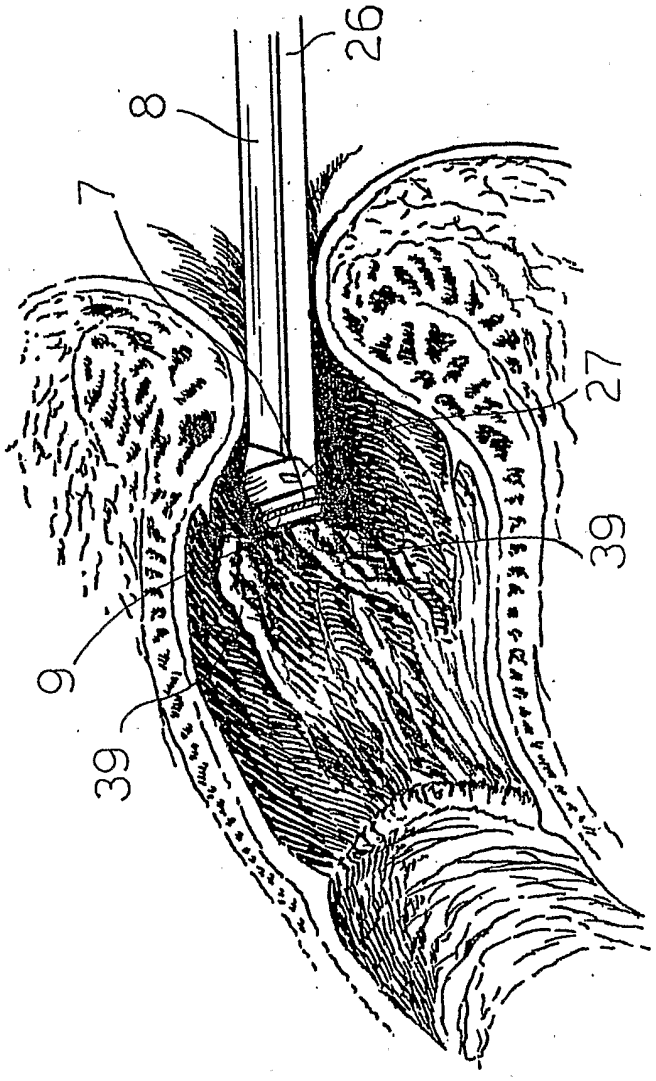

FIG. 7