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(54) **Title:** SYSTEM AND METHOD FOR THE INTRODUCTION OF INTRACORPOREAL DEVICE

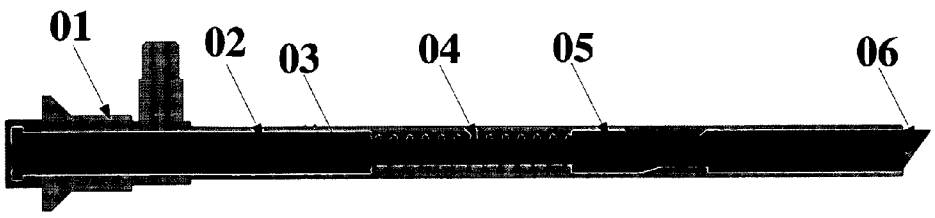

Fig. 01

(57) **Abstract:** The present invention refers to a new concept of a system and a method to aid the introduction of devices through corporeal tissues, such as in laparoscopy, consisting of a needle assembled on a power sensor coupled to a elastic element with memory form, allowing the perforation of only one structure at a time, resulting in a great decrease of the risk of perforating other structures.

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SYSTEM AND METHOD FOR THE INTRODUCTION OF INTRACORPOREAL DEVICE

The present invention refers to a system of controlled perforation of corporeal tissues, conjugating the function of perforating or cutting the tissues with a lower risk of damage of other tissues or adjacent corporeal structures, resulting a better control in the insertion of apparatus or devices through corporeal tissues as, for instance, upon laparoscopy.

Video-laparoscopy is a surgical technique minimally invasive, which comprises the visualization of, for instance, articular, pelvic and abdominal cavities, through an optical lens coupled to a camera, the images are seen in a video screen, with precise images amplified more than 20 times, showing anatomic structures and lesions hardly seen with the eyes. For such procedure to be possible, it is necessary to light inside the cavity by means of a source of light that, through a cable generally made of optical fiber or liquid crystal, directs a beam of light up to the optical, thus lighting the abdominal cavity.

In addition to the lighting, in order to enable the visibility inside the abdominal cavity, wherein all organs are all together, it is necessary to inflate the abdominal wall by insufflating gases, thus creating a space between them. The introduction of gas results a greater working space for this kind of surgery. For this purpose, it is necessary a device denominated insufflator.

Said insufflator carries the gas inside the abdomen and maintains the gas during a certain time necessary for the procedures to be carried out. According to several researches, the most appropriate gas to be used is CO_2 (carbon dioxide) since it does not represent any risk, such as explosion, and is very soluble with organic liquids, resulting

high decrease of pain during the postoperative phase. Currently, CO_2 is practically the only gas used for the procedures.

It is further necessary the creation of a passage at the abdominal wall for the complete introduction of this material inside the abdominal cavity. A small incision near the navel is made, whereby the optical is introduced. One or two other small incisions are made nearby, whereby the other instruments necessary to the procedure (either surgical or diagnostic) are introduced. In these cases, the cuts are a little bigger but still small, making video-laparoscopy a procedure that increases the value of the aesthetics without decreasing its efficiency. Through these small incisions, a cylindrical device is introduced, which is called laparoscope, comprising two parts: an outer part called jacket and an inner part comprising a blade to perforate, for example, the abdomen tissue, whereby the other instruments will be introduced.

The current technique comprises performing a *blind* introduction of a long needle inside the abdomen, whereby a gas is injected under certain pressure to inflate the abdomen. Subsequently, a tube (laparoscope) is *blindly* introduced under strong pressure through abdominal wall until perforating same. Through the tube, an instrument is introduced, which will enable to see the organs and other instruments necessary for the procedure.

The insertion of the laparoscope involves high risk in laparoscopy since it may cause immediate death by perforation of any important artery (for example, aorta) or intestine, stomach, cysts, uterus, etc. This is a very serious and important risk considering that introduction of the devices is on a *blindly* basis and under high pressure.

The risk is higher when the patient presents cardiac or respiratory diseases, obesity, diaphragmatic hernia, pregnancy, pelvic inflammatory disease or previous

diseases, extensive or multiple abdominal scars or scars adjacent to umbilical area and prior abdominal surgery.

A current question in the art refers to the knowledge of this technique to be advantageous regarding conventional surgical procedures. The answer is quite simple since almost all of the procedures in accordance with the conventional techniques may be performed as well through video-surgery, provided that the required learning curve is respected, as well as the development of instruments capable of execution of a higher number of procedures and decrease of risks inherent to this technique.

Currently, according to video-laparoscopy procedures, patients can be submitted to numberless surgeries on a minimally invasive and a safer basis. Most usual surgeries are those related to the tie of tubes, removal of ovarian cysts, liberation of adherences, ovarian biopsy, ovarian removal, endometriosis surgery, recanalization of tubes (reversion of the tie of tubes), surgery of urinary incontinence and hysterectomy (uterus removal), surgeries of uterus cancer, appendix and hernia surgeries, among others.

The device used for introducing the laparoscope is denominated Verres needle and dates from 1938. This device comprises two tubes, wherein one tube is external and has a bevel ending and the other tube is internal and longer and has a blunt ending, a lateral orifice and a springiness that allows its retreat in view of penetration through the skin, fascia, peritoneum, etc. Once reached the cavity, the blunt part is exposed, protecting the viscus.

Patents US 6,494,893, US 6,428,511, US 6,325,812, US 6,080,174, US 5,431,676, US 5,334,159, US 5,300,046, US 5,104,381, EP 1 393 768, US 6,193,692, US 5,827,221, US 5,669,883, US 5,383,859 and US 5,098,388 present differentiated forms and concepts for the Verres needle device. However, the blunt ending, which

would protect the viscus when the needle reaches the cavity, is not precise nor reliable as to protection when corporeal structures are nearby each other or gathered.

In order to decrease the risk of an undesired perforation of corporeal structures during introduction of the laparoscope or other devices used in these procedures, the present invention provides a new concept for introducing these devices, named *active introductory system.*

The active introductory system preferably comprises a substantially cylindrical body containing in its inner part an ending element denominated introductory element, which may be fixed or supported on a power sensor that is combined with a traction elastic element made of a material having form memory, which induces the power sensor, together with the introductory element, being built-in inside the cylindrical body, the power sensor and introductory element are prevented from returning to the inner part of the cylindrical body through another element, which is denominated lock.

The effect of the form memory of metallic alloys may be defined as the material capacity, after being deformed, to recover its original form. Concerning nickel-titanium alloys, the same happens through a transformation of their crystalline structure from martensite to austenite and vice-versa. This effect may be obtained via a mere heating of the previously deformed material, which returns to its original configuration after cooling.

The following description and the corresponding drawings refer to illustrative examples for a better understanding of the invention and may not be considered as limitative.

Fig. 1 refers to a model of the system that aids the introduction of a laparoscope (01), denominated active introductory system, which is assembled with a device having a camera (02), exemplified as the exposed ending of the introductory element (06).

Fig. 2 refers to an amplified view of the model mentioned above, wherein its components are better visualized, such as laparoscope (09), camera device (07), camera (16), introductory system base (10), introductory element (13), ending of the introductory element (14), lock (11), elastic element having form memory (08) and base of the power sensor (12). Figure 2 also refers to details of the lock fitting (15) and base of the power sensor (12), wherein a strain gauge or a displacement sensor (17) will be placed.

Fig. 3 refers to the system of the invention. The system further presents a part having a rounded ending (24), which is placed in front of the ending of the introductory element (25) by means of an elastic material (23), as a spring.

Fig. 4 refers to an amplified view of the model mentioned above, wherein it can be better visualized, such as laparoscope (28), central body (38), base of the introductory system (26), introductory element (29), elastic element having form memory (27), elastic element of the rounded part (31), lock (37), rounded part (32) and base of the power sensor (36).

Fig. 5 refers to another model of the system for aiding the introduction of a laparoscope, having a different constitution and containing basically the same functions mentioned above. Figure 5 presents said constitution assembled on said system.

Fig. 6 refers to an amplified view of the model mentioned above, wherein its components are better visualized, such as laparoscope (47), base of the introductory system (56), introductory element (51), elastic element having form memory (48), lock

(55), tip (50) and base of the power sensor (53). Figure 6 also refers to details related to the housing of the elastic element having form memory (57), base of the power sensor wherein strain gauge will be fixed (54), channel for the passage of auxiliary components (58), ending of the introductory element (52) and fitting of the tip with the base of the introductory system (49).

Figures 7 to 12 refer to an example of the movement of the active introductory system, presenting a consequent retraction of the ending of the introductory element (63) (69) (75) (81) (87) (93) to the interior of the laparoscope (59) (64) (70) (76) (82) (88), referring to the model described in Figures 1 and 2 and the system shown in Figures 3 and 4. This retraction is an effect of the traction power made by the elastic element having form memory (61) (66) (72) (78) (84) (90), after actuating the lock (62) (67) (73) (79) (85) (91).

Figures 13 to 18 refer to the movement of the active introductory system, presenting a consequent retraction of the ending of the introductory element (100) (107) (114) (121) (128) (135) to the interior of the laparoscope (94) (101) (108) (115) (122) (129), referring to the model described in Figures 5 and 6. This retraction is an effect of the traction power made by the elastic element having form memory (96) (103) (110) (117) (124) (131), after actuating the lock (97) (104) (111) (118) (125) (132).

As exemplified in the above-mentioned figures, the active introductory system of the invention presents a retraction system of the introductory element, when there is a sudden decrease in the power applied to the ending of this element, in order to be retreated back to the interior of the device at the moment that the introductory element breaks or perforates any structure, thus preventing the adjacent structure to be damaged.

The detection of the decrease in the power applied to the introductory element occurs upon a dimensional variance of the base of the power sensor, wherein a strain

gauge or another device capable to detect such deformation is assembled thereon. While there is power applied to the introductory element, the base of the power sensor stores some deformation, which is detected by the strain gauge. When said power is abruptly reduced, the introductory element brakes the structure that was being perforated. Therefore, deformation of the power sensor, at the base, is reduced and said reduction is detected by the strain gauge. At this moment, the lock is actuated, releasing the power sensor together with the introductory element. Since these two elements are being induced to enter into the device, due to the power made by the traction of the elastic element having form memory, when releasing the movement effected by the actuation of the lock, these two elements enter the device, thus preventing the adjacent structure from being perforated, even if the penetration movement of the active introductory system goes on.

With a view to perforate the next structure, the introductory element must be exposed, allowing a cutting element for the active introductory system. When the elastic element having form memory receives an electric charge that heats it and consequently changes its form, the traction elastic element transforms itself into a compression elastic element, pushing the base of the power sensor together with the introductory element, exposing the ending of the introductory element and allowing perforation of the next structure.

The base of the power sensor may have several forms, depending on the application. According to the present text, only one form is provided for clarification purposes, which means that said embodiment may not be considered as limitative to the scope of the invention.

The strain gauge that detects the deformation variance of the base of the power sensor may have several configurations, for instance, as listed in patent US 7,116,209.

Such configuration and the related peripheral equipment are not the object of the present invention.

The elastic element comprises a material having form memory, and only for clarification purposes, without limiting its scope, it comprises a nickel-titanium alloy. The material may also comprise other substance that presents the effects of form memory or the combination of another type of double actuation.

Concerning the lock, only for clarification purposes, without limiting its scope, it comprises a nickel-titanium alloy having thermal form memory. On the other hand, other forms of actuation may be used. The lock may have several forms, in order to adapt itself to the arrangement to which it will be assembled. The form of the lock will have the most appropriate configuration for the arrangement, depending on the power, diameter of the active introductory system and other variables.

Concerning the ending of the introductory element, only for clarification purposes, without limiting its scope, it comprises a bevel form. On the other hand, other forms may be used, as, for example, a conic form.

The size of the ending of the exposed introductory element may have variances. These variances may be obtained upon replacement of the introductory element, lock or other forms.

In this system, the retraction of the introductory element may happen at any time by external actuation. This is carried out in view of the use of a nickel-titanium lock having thermal form memory, combined with electric charge and lock, resulting its heating and consequent release of the introductory element and retraction thereof.

According to Figures 1 to 6, the concepts of the invention have been exemplified in two different embodiments. One embodiment refers to a hollow introductory element, wherein its orifice can be used to introduce laparoscopy instruments. The other embodiment refers to a closed arrangement, wherein the active introductory system is maintained, which may be removed from the laparoscope, for introduction of the instruments necessary to laparoscopic intervention similar to the procedure usually used in the art.

Upon the use of the form exemplified in Figures 1 to 4 and as already mentioned above, the orifice of the introductory element may be used for the insertion of the camera and other devices, including auxiliary devices for protecting structures that are adjacent to those perforated by the needle.

This device comprises a structure having a blunt tip, attached to a compression elastic element, which exposes a part having a rounded tip, in order to aid protection and prevent the adjacent structures from perforation.

The concepts of the present invention may have other applications as, for instance, in the mechanized suture and puncture, resulting the same advantages of not damaging the adjacent structures, thus reducing the possibilities of any undesired perforation.

CLAIMS

1. A system and a method for the introduction of an intracorporeal device, wherein a perforation system comprises a power sensor, an introductory element, a lock system of the introductory element and a system to actuate the introductory element.

2. The system and method for the introduction of an intracorporeal device according to claim 1, wherein the power sensor comprises a base and a system selected from the group consisting of a deformation detection element and a piezoelectric, magnetic and electrical-magnetic element.

3. The system and method for the introduction of an intracorporeal device according to claim 1, wherein a system that allows the retraction of the introductory element through a system comprising a material selected from the group consisting of an elastic, mechanic, hydraulic, pneumatic, electric, thermal and magnetic material.

4. The system and method for the introduction of an intracorporeal device according to claim 1, wherein a system wherein the retraction of the introductory element is a system comprising an elastic element comprising an element selected from the group consisting of an element having an elasticity originated from its form and material.

5. The system and method for the introduction of an intracorporeal device according to claim 1, wherein the lock system of the introductory element comprises an element selected from the group consisting of a mechanic, magnetic, hydraulic and pneumatic lock.

6. The system and method for the introduction of an intracorporeal device according to claim 5, comprising a system wherein the actuation of the introductory

element lock comprises an element selected from the group consisting of an electric, mechanic, magnetic, hydraulic and pneumatic element.

7. The system and method for the introduction of an intracorporeal device according to claim 1, wherein the lock system of the introductory element is an element comprising a material having a form memory with an electrical actuation.

8. The system and method for the introduction of an intracorporeal device according to claim 1, comprising an introductory element having an ending comprising an element selected from the group consisting of a cutting and perforating element.

9. The system and method for the introduction of an intracorporeal device according to claim 8, comprising a system wherein the introductory element comprises an element selected from group consisting of a pyramidal, bevel, double bevel and conic element.

10. The system and method for the introduction of an intracorporeal device according to claim 1, comprising a moving system of the introductory element comprising an element selected from the group consisting of an electric, mechanic, magnetic, hydraulic, pneumatic and mechanic element.

11. The system and method for the introduction of an intracorporeal device according to claim 1, comprising a moving system of the ending comprising an elastic element having a thermal form memory.

12. The system and method for the introduction of an intracorporeal device according to claim 1, wherein it presents a hollow ending, which allows the passage of tools, instruments and devices to the interior of a perforated cavity.

13. The system and method for the introduction of an intracorporeal device according to claim 12, wherein it presents an element having a substantially rounded ending assembled on an elastic element, at the orifice of the introductory element, resulting less aggression to the adjacent structures.

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14. The system and method for the introduction of an intracorporeal device according to claim 1, wherein it presents an ending substantially centralized at a device having a substantially rounded ending, resulting less aggression to the adjacent structures.

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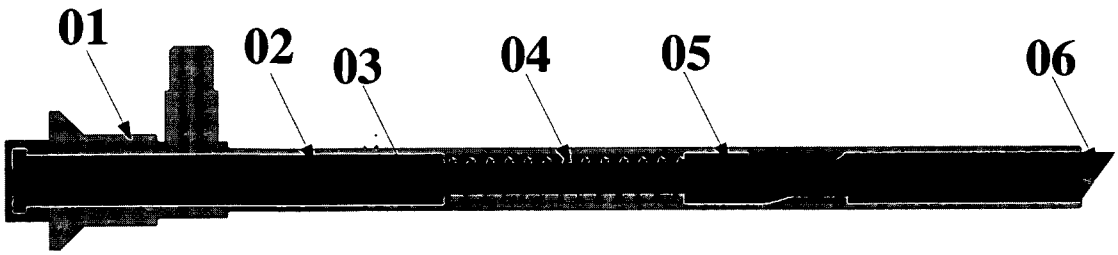

Fig. 01

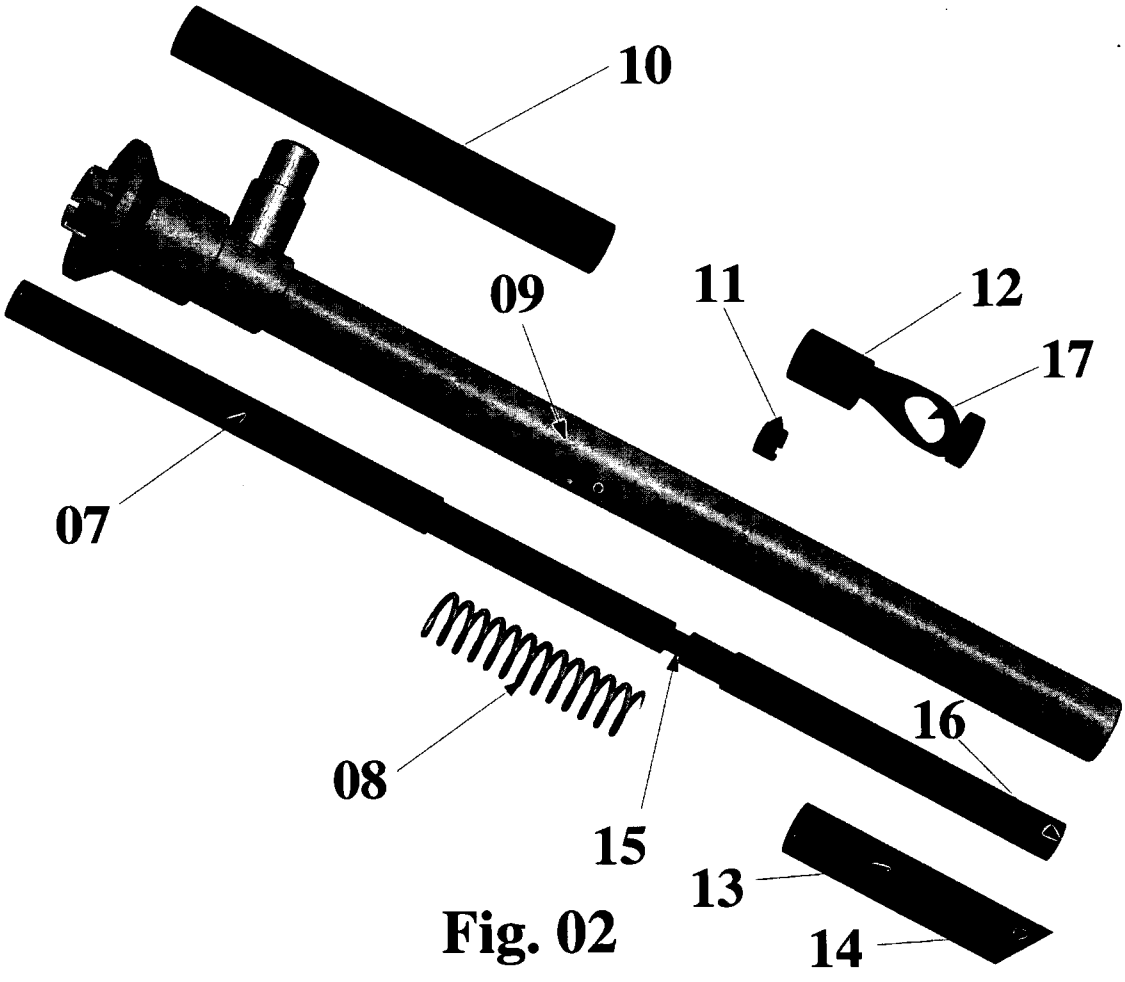

Fig. 02

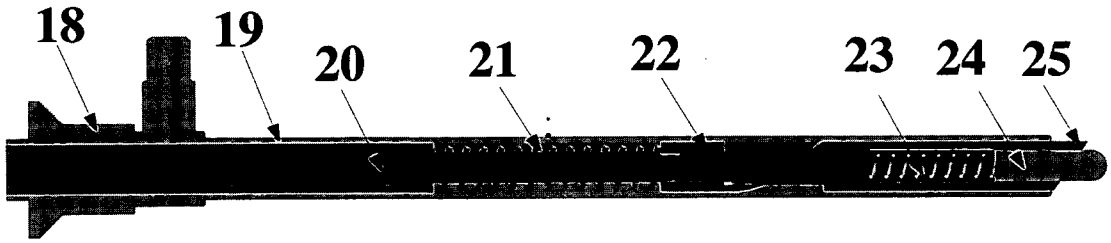

Fig. 03

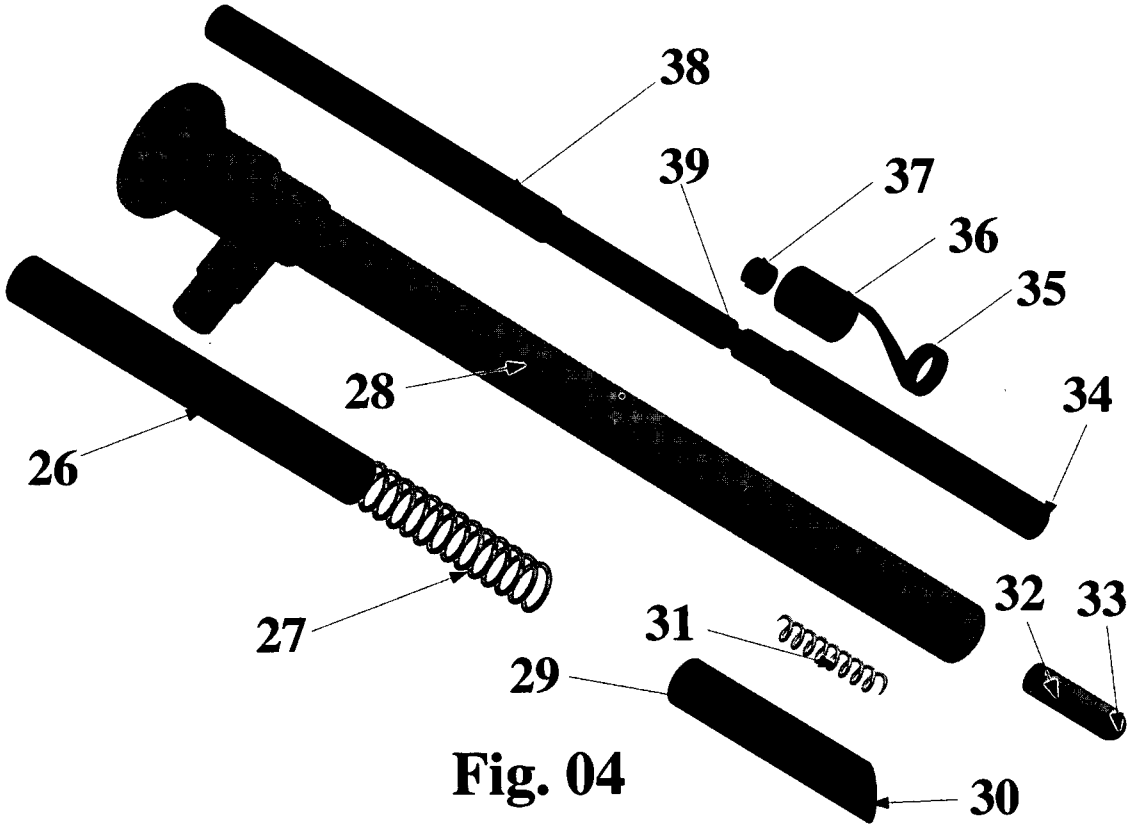

Fig. 04

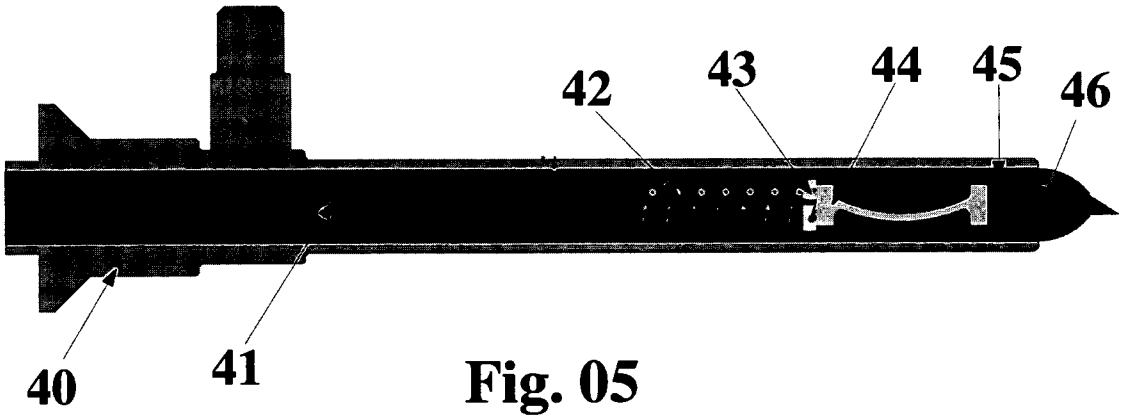

Fig. 05

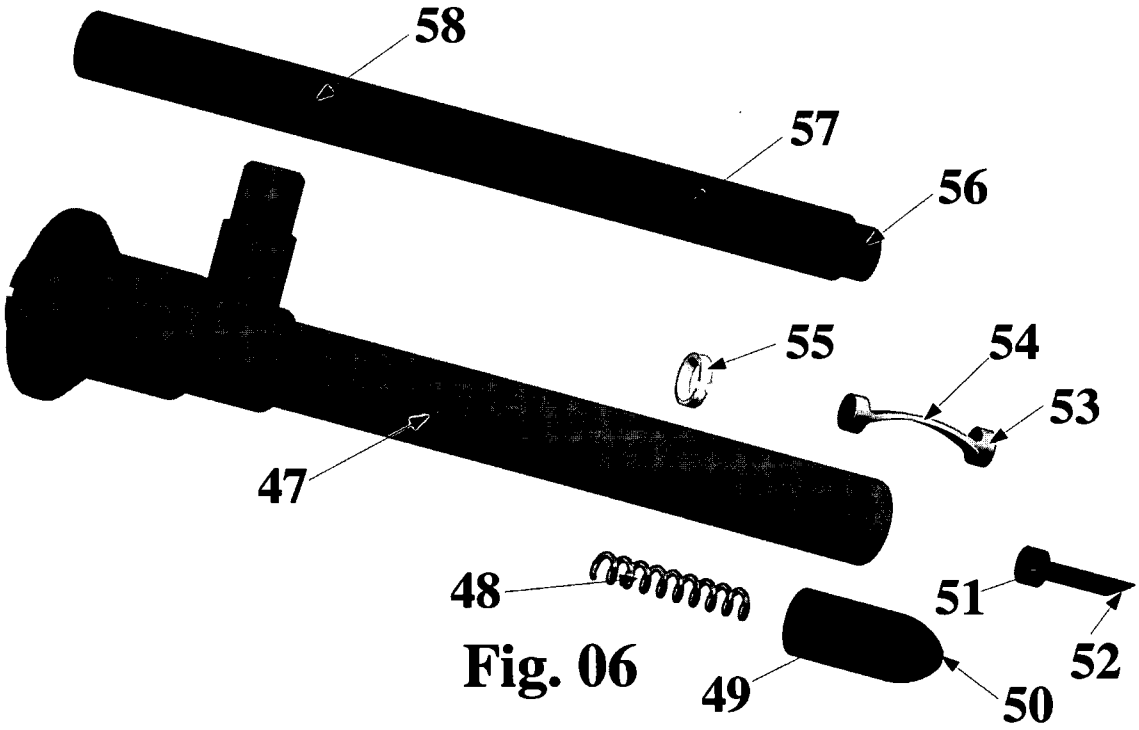

Fig. 06

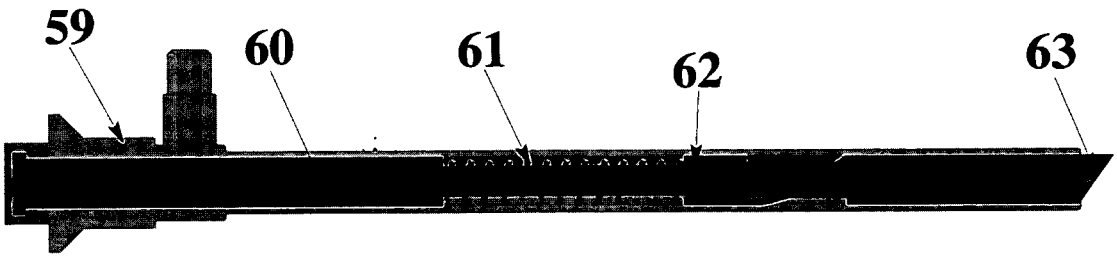

Fig. 07

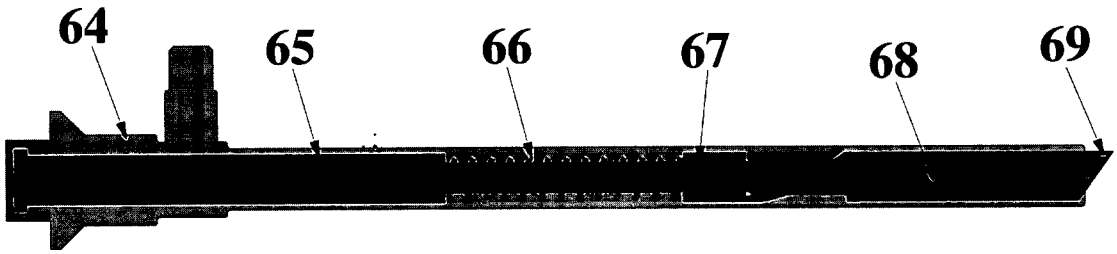

Fig. 08

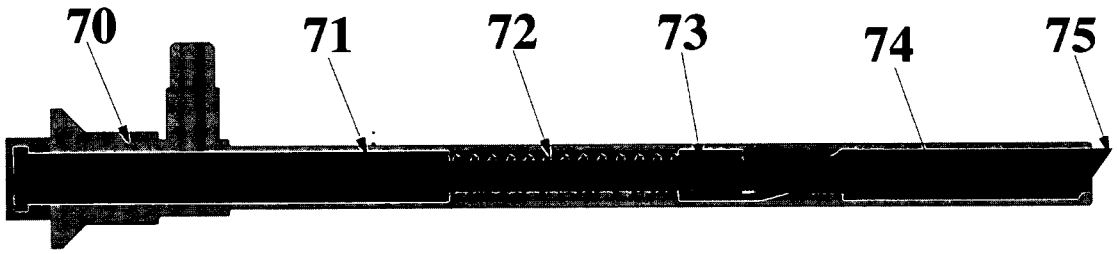

Fig. 09

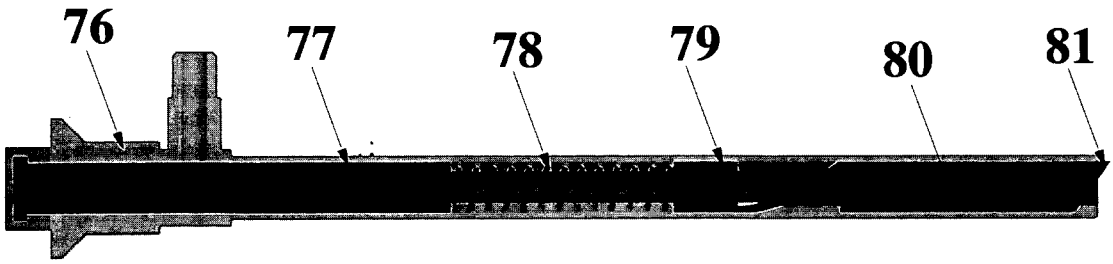

Fig. 10

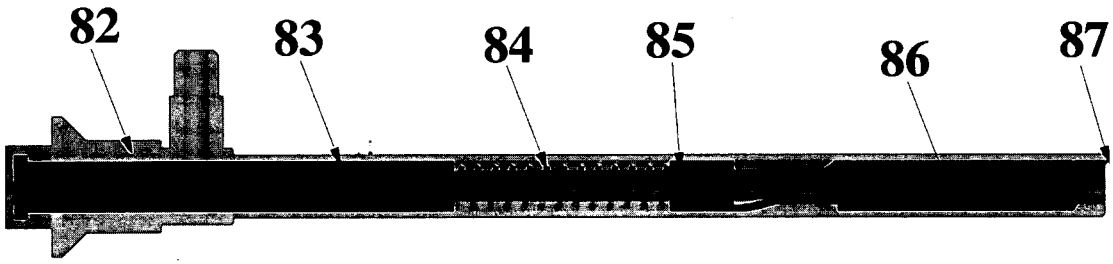

Fig. 11

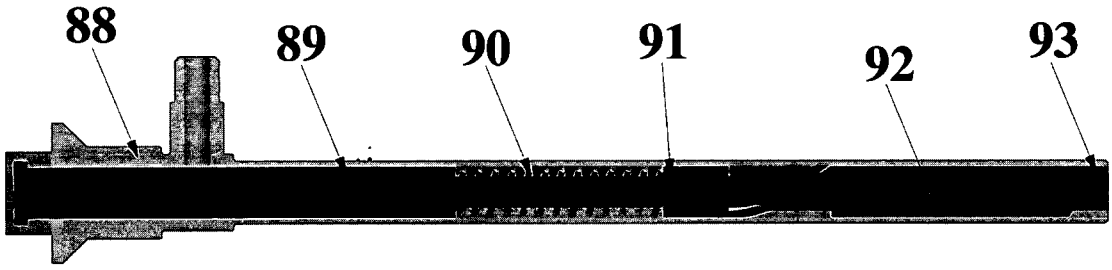

Fig. 12

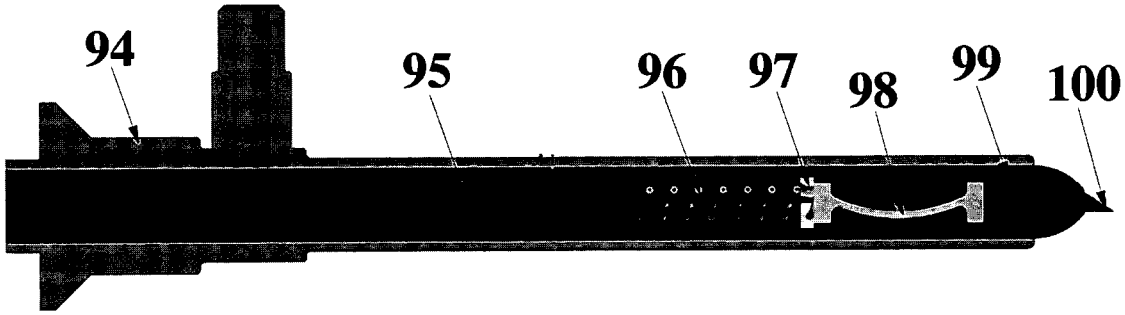

Fig. 13

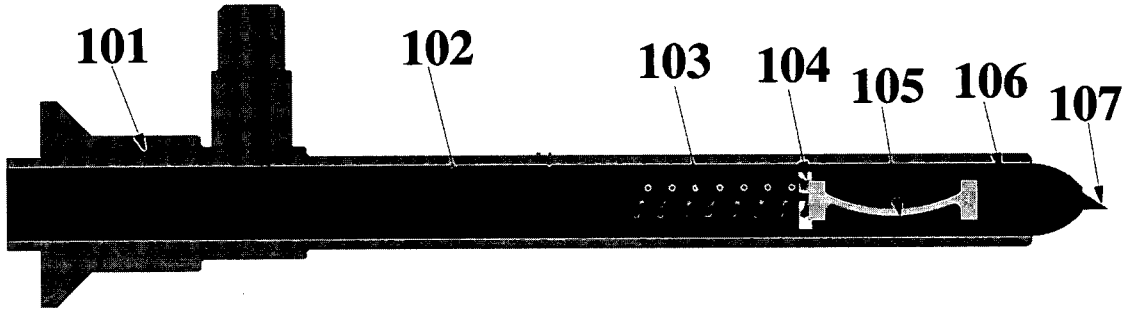

Fig. 14

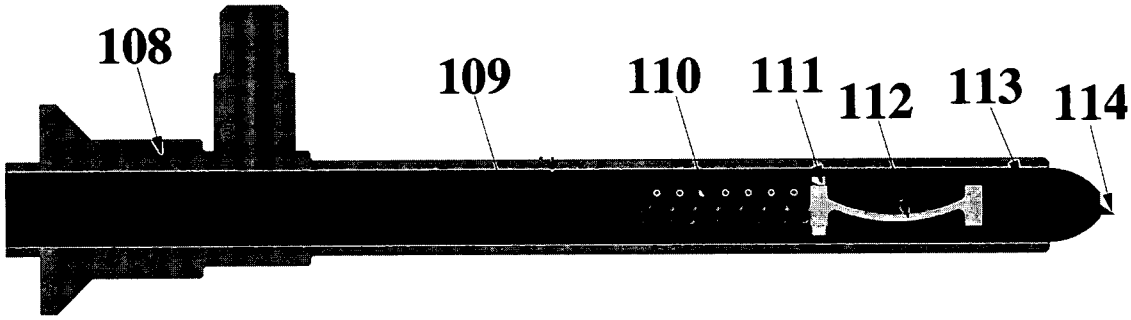

Fig. 15

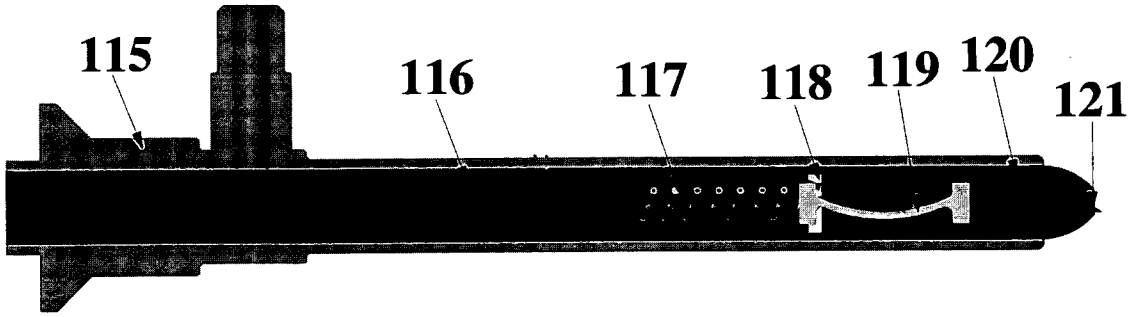

Fig. 16

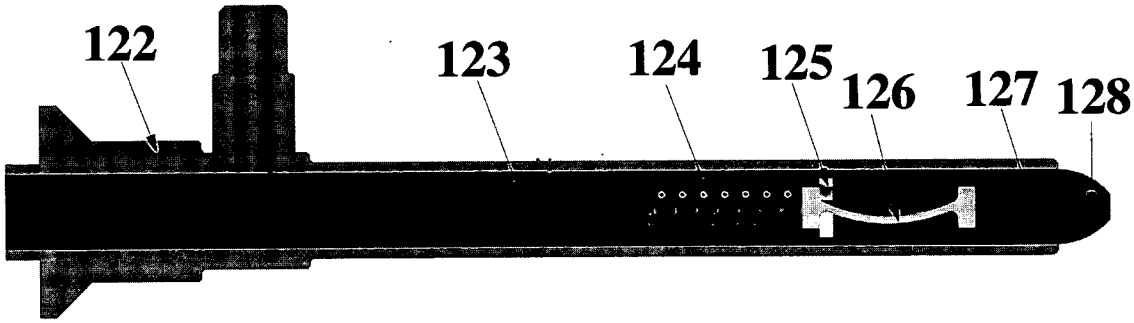

Fig. 17

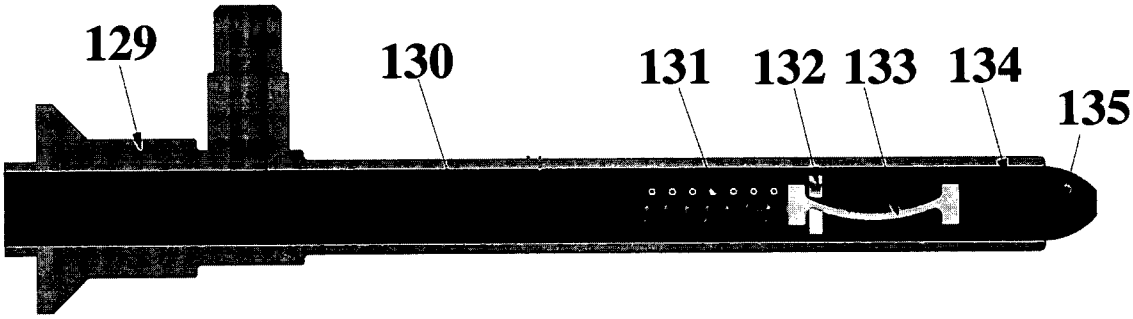

Fig. 18