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(54) **Title:** ROTATING MAGNETIC LAPAROSCOPIC NEEDLE HOLDER

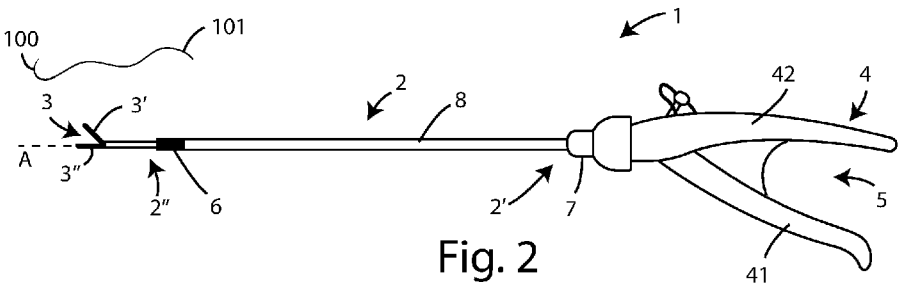

Fig. 2

(57) **Abstract:** The present invention relates to a laparoscopic device (1), intended to the formation of intracorporeal knots by an operator by means of a suture thread (101) connected to a needle (100), comprising: a first shaft (2) comprising a proximal portion (2') and a distal portion (2"); a grasping clamp (3) for grasping and releasing said needle (100) and/or of said suture thread (101), arranged in correspondence of said distal portion (2") of said first shaft (2); and an handle (4), arranged in correspondence of said proximal portion (2') of said first shaft (2), and operatively connected to said grasping clamp (3) for opening and closing it; said device (1) being characterized in that it comprises coupling means (6) to be coupled with said needle (100), wherein said coupling means (6) are arranged between said grasping clamp (3) and said proximal portion (2'), and wherein said coupling means (6) are rotatable around the symmetry axis (A) of said first shaft (2) in both rotation directions; and in that it comprises an actuation handle (7), operatively connected to said coupling means (6), and configured for rotating said coupling means (6) when activated by an operator.

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ROTATING MAGNETIC LAPAROSCOPIC NEEDLE HOLDER

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The present invention relates to a laparoscopic device, in particular an improved laparoscopic needle holder for the formation of intracorporeal knots.

Field of the invention

More specifically, the invention relates to a laparoscopic device of the mentioned type, studied and realized in particular to form intracorporeal knots for suturing human or animal tissues, but which can be used for the formation of any knot, where it is necessary to operate at a given distance and with limited maneuver room.

In the following the description will be addressed to the realization of intracorporeal knots, but it is clear that the same should not be considered limited to this specific use.

Introduction

As is well known, laparoscopy is a minimally invasive surgical technique, through which the surgeon can, for example, operate inside the abdominal or pelvic cavity of a patient, without resorting to large incisions required by the traditional “open air” surgery.

In fact, the laparoscopic surgical technique involves making small incisions, necessary for the introduction of the laparoscope.

The advantages of the laparoscopic surgical technique include:

- the reduction of post-operative hospitalization time;
- less post-operative pain; and
- less noticeable scars.

Generally, at the end of the laparoscopic surgical operation it is necessary to suture the intracorporeal tissues by using sutures respectively connected to suture needles, and introduced through laparoscopic guides (such as, for example, a trocar) with the aid of laparoscopic needle holders.

After suturing the tissue, the surgeon must make an intracorporeal knot, in order to ensure the tightness of the suture.

Prior art

As is well known, currently the technique of knotting in the

laparoscopy is divided into extracorporeal and intracorporeal knotting.

Extracorporeal knotting consists in the execution of knots outside the body.

Said extracorporeal knots are subsequently introduced, through the trocars, into the intracorporeal operative field to be firmly tightened.

Alternatively, the intracorporeal knots are performed directly inside the intracorporeal cavity through the combined use of a laparoscopic needle holder and a laparoscopic graspers, which have to be coordinated each other at the same time to rotate with respect to each other, so that they couple and decouple each other with the suture needle.

One of the most used intracorporeal suturing techniques consists in the formation of an intracorporeal knot comprising the following phases:

- create a first double semiknot;
- create a second single semiknot (with the function of tightening the first double semiknot) along a first direction;
- create a third single semiknot, preferably inverse, or along a second direction, opposite to said first direction of the second semiknot (to block the previous semiknots); and
- tighten these semiknots.

The length of the suture thread can affect the execution speed of said intracorporeal knot.

In fact, by way of example, during general, urological, gynecological, thoracic surgery, etc., achievable in laparoscopy, it is possible to use sutures with a length between 20 cm and 25 cm, as both a length less than 20 cm and a length greater than 25 cm could make the realization of the intracorporeal knot difficult.

However, one of the main drawbacks of these known solutions consists in that they require greater execution times compared to the extracorporeal technique, where a "open air" needle is used.

A further drawback of such known solutions is due to the fact that the learning curve for a laparoscopic surgeon is extremely steeper in the case of intracorporeal knots than the extracorporeal ones, and consequently the intracorporeal knots are easily formed only by more expert surgeons.

In fact, extracorporeal knots can be made only using one hand, while intracorporeal knots need two hands, each to operate with a respective laparoscopic instrument.

In particular, the maneuverability angle of the laparoscopic needle holder and the laparoscopic grasper is limited by the presence of the entry holes through the trocars, which act as a central fulcrum limiting the surgeon's movements.

Still another drawback of these solutions according to the prior art is due to the fact that it is necessary to operate with a reduced view, since visibility is defined only by the visibility area of the laparoscopic probe.

In addition, the suture thread type influences the ease of making the intracorporeal knot.

By way of example, monofilaments require a greater number of knots than woven threads and make the technique of making intracorporeal knots even more complex and difficult for the surgeon to perform.

In order to overcome these drawbacks, self-locking sutures threads are often used, which, however, only allow to make continuous sutures and not with detached stitches.

These sutures with detached stitches guarantee greater reliability and management to the surgeon, compared with the continuous sutures, allowing, for example, to repair a blood vessel or not to ischemise the operated tissues.

Summary of the invention

In light of the above, it is therefore an object of the present invention providing a laparoscopic device for the formation of intracorporeal knots.

Another object of the invention is to provide a laparoscopic device that is easy to use and that allows the surgeon to use only one hand for realizing the semiknots necessary for the formation of the intracorporeal knot, using, instead, both hands only in the final phase, to tighten the previously created semiknots.

A further object of the present invention is providing a laparoscopic device for making both continuous and with detached points intracorporeal knots.

Another object of the present invention is to provide a laparoscopic kit of laparoscopic devices for making intracorporeal knots in a simple, intuitive and fast way.

A further object of the present invention is to provide a laparoscopic device which is highly reliable and simple to manufacture, at competitive costs if compared to the prior art.

Object of the invention

It is specific object of the invention a laparoscopic device, intended to the formation of intracorporeal knots by an operator by means of a suture thread connected to a needle, comprising: a first shaft comprising a proximal portion and a distal portion; a grasping clamp for grasping and releasing said needle and/or said suture thread, arranged in correspondence of said distal portion of said first shaft; and an handle, arranged in correspondence of said proximal portion of said first shaft, and operatively connected to said grasping clamp for opening and closing it; said device being characterized in that it comprises coupling means to be coupled with said needle, wherein said coupling means are arranged between said grasping clamp and said proximal portion, and wherein said coupling means are rotatable around the symmetry axis of said first shaft in both rotation directions; and in that it comprises an actuation handle, operatively connected to said coupling means, and configured for rotating said coupling means when activated by an operator.

Always according to the invention, said device may comprise a second shaft that is hollow and concentric to said first shaft between said proximal portion and said grasping clamp, said second shaft being able to rotate around said symmetry axis in both rotation directions, and said coupling means may be arranged on said second shaft.

Advantageously according to the invention, said actuation handle may be operable by said operator and may be connected to said second shaft.

Still according to the invention, said first shaft may be adapted to rotate around said symmetry axis in both rotation directions, and said coupling means may be arranged on said first shaft.

Conveniently according to the invention, said coupling means may be magnetic elements magnetically couplable with a respective needle.

Always according to the invention, said grasping clamp may comprise a first jaw and a second jaw and may have a closed configuration for blocking said needle and/or said suture thread and an open configuration for releasing said needle and/or said suture thread.

Preferably according to the invention, said coupling means may be arranged proximately to said grasping clamp.

It is further object of the present invention a laparoscopic kit comprising a laparoscopic device as mentioned and at least one laparoscopic grasper having a shaft arranged along an axis, said shaft being rotatable around said axis in both rotation directions.

Always according to the invention, said laparoscopic grasper may comprise at least one magnetic element fixed on said shaft.

Preferred embodiments are defined in the dependent claims.

Brief description of the figures

The present invention will be now described, for illustrative but not limitative purposes, according to its preferred embodiments, with particular reference to the figures of the enclosed drawings, wherein:

figure 1 shows schematically an example of embodiment of an intracorporeal knot, according to the prior art;

figure 2 shows, in perspective view, a first embodiment of the laparoscopic needle holder, according to the present invention;

figure 3 shows, in perspective view and in detail, the laparoscopic needle holder according to figure 2;

figure 4 shows a partial longitudinal section of the laparoscopic needle holder, according to figure 3;

figure 5 shows, in perspective view, a second embodiment of the laparoscopic needle holder, according to the present invention; and

figure 6 shows, in perspective view, an embodiment of a laparoscopic grasper, according to the present invention.

In the various figures, similar parts will be indicated by the same reference numbers.

Detailed description

With reference to the aforementioned figures, the laparoscopic device according to the present invention will be complexively indicated with the reference number 1.

In the present embodiment, said device 1 is a laparoscopic needle holder; however, in further embodiments said device 1 can also comprise laparoscopic graspers or the like.

Said device 1 can couple with a needle 100 connected to one end of a suture thread 101, locking it.

Said device 1 substantially comprises a first shaft 2 and a handle 4, to which said first shaft 2 is coupled to a proximal portion 2'.

Said device 1 also comprises a grasping clamp 3 for holding said needle 100, arranged on the distal portion 2" with respect to said handle 4 of said first shaft 2.

Said device 1 also comprises a second shaft 8, which is hollow and concentric with said first shaft 2 and arranged between said proximal portion 2' and said grasping clamp 3.

In more detail, said first shaft 2 is preferably made with biocompatible metallic materials, such as for example titanium or steel.

In the following of the description, we will indicate with the reference letter A the axis of symmetry of said first shaft 2.

Said grasping clamp 3 of said needle 100 and/or of said suture thread 101 comprises two jaws 3' , 3".

Specifically, the first jaw 3' is movable, while the second jaw 3" is fixed.

The grasping clamp 3 is capable of passing from a closed configuration, in which said needle 100 and/or said suture thread 101 can be blocked and operated during the laparoscopic surgical operation, to an open configuration, in which said needle 100 and/or said suture thread 101 can be released.

More specifically, in said closed configuration said two jaws 3', 3" are substantially parallel to each other and aligned to said axis of symmetry A, while in said open configuration said first jaw 3' of said grasping clamp 3 is

movable forming a non-zero angle with said axis of symmetry A.

As can be seen from figures 2 and 3, said two jaws 3', 3", when in said open configuration, can form for example an angle equal to about 60°.

Said handle 4 is operatively connected to said grasping clamp 3. In particular, said handle 4 comprises a movable lever 41 and a fixed lever 42, between which elastic means 5 are arranged, in particular a return spring 5.

By acting on said handle 4, or by moving said movable lever 41 with respect to said fixed lever 42, at the hands of an operator, such as a surgeon, the grasping clamp 3 is closed or opened.

Said second shaft 8 (in jargon "shirt") is hollow and arranged concentrically with respect to said first shaft 2. In more detail, said second shaft 8 is preferably made of biocompatible materials, be they plastic or metallic.

In particular, said second shaft 8 can rotate around said axis of symmetry A in both directions of rotation to an operating knob 7 arranged in correspondence with said handle 4.

Advantageously, said actuation knob 7 is connected to said second shaft 8, so that by rotating said actuation knob 7, said second shaft 8 in its turn rotates with respect to said first shaft 2 and said handle 4.

In particular, said operator can rotate said actuation knob 7, for example by manually acting on it.

With particular reference to figures 2, 3 and 4, in the embodiment that is described, said second shaft 8 comprises a magnet 6, or coupling means 6, capable of magnetically coupling to said needle 100, allowing the winding of the thread suture 101 connected to said needle 100, when said second shaft 8 is rotating.

Said magnet 6 is arranged in correspondence with said distal portion 2", in particular in correspondence of the third distal of said first shaft 2.

In more detail, the expression "third distal" means a portion equal to one third of the total length of said first shaft 2, and comprising said distal portion 2".

With particular reference to figure 5, in a second embodiment of the present invention, said device 1 has only said first shaft 2 that is rotatable.

As can be seen from figure 5, said first shaft 2 in its turn comprises said magnet 6, or said coupling means 6, which are capable of magnetically coupling to said needle 100, allowing the winding of the connected suture thread 101 to said needle 100, when said first shaft 2 is rotating.

In this configuration, therefore, said first shaft 2 can rotate in both directions of rotation together with said magnet 6 and said grasping clamp 3.

The operation of the laparoscopic needle holder device 1 described above is as follows.

During the laparoscopic surgery, the surgeon, after suturing the tissue, must make an intracorporeal knot, in order to ensure the tightness of the suture.

Said first shaft 2 and said second shaft 8 of said device 1 are then inserted inside the surgical area by means of laparoscopic guides or trocars. In particular, said first shaft 2 and said second shaft 8 have a cross section with respect to said axis of symmetry A of smaller or equal dimensions of the section of the guide.

The device 1 according to the present invention allows the creation of intracorporeal knots through the following steps:

- coupling said magnet 6 to said needle 100 connected to said suture thread 101;
- rotation of said magnet 6 around said first shaft 2, which acts as a fulcrum, with the consequent formation of a double semicircle or a single semicircle in the direction chosen by said surgeon, so as to form the semiknots necessary for the realization of the intracorporeal knots;
- locking, by said jaws 3', 3", the tail of said suture thread 101, or the end of said suture thread 101 not coupled to said needle 100; and
- decoupling, by means of a second instrument, such as for example a laparoscopic graspers, said needle 100 from said magnet 6, and completing the intracorporeal knot by pulling the needle 100 and consequently the suture thread 101.

In this way, the aforementioned steps allow the creation of

intracorporeal knots in a simple, easily reproducible way and using just a laparoscopic surgical instrument in the semiknots formation step.

Figure 6 shows a laparoscopic grasper 10 according to the present invention.

Said laparoscopic grasper 10 is configured to be used, for example, in the formation of intracorporeal knots, in combination with said device 1.

Said laparoscopic grasper 10 comprises:

- a shaft 12 arranged along an axis A2;
- a handle 14 arranged on a proximal portion 12' of said shaft 12;
- a gripper 13 arranged on a distal portion 12" with respect to said handle 14 of said first shaft 12;
- an actuation knob 17 connected to said handle 14;
- magnetic elements 16, positioned between said gripper 13 and said proximal portion 12', capable of magnetically coupling to said needle 100.

Said gripper 13 is also equipped with two further movable jaws 13', 13".

In particular, said two further movable jaws 13', 13" can assume a closed configuration, in which they are substantially parallel to each other and aligned with the axis of symmetry A2, and an open configuration, in which both said two further movable jaws 13', 13" form a non-zero angle with said axis of symmetry A2.

Furthermore, said magnetic elements comprise at least one magnet 16, arranged in correspondence with said distal portion 12", in particular in correspondence with a third distal of said first shaft 12.

Finally, said actuation knob 17, operatively connected to said coupling means 16, is configured to rotate said shaft 12 around said axis A2.

As previously said, the laparoscopic grasper 10 can be used for the formation of intracorporeal knots using the same procedure described for the laparoscopic needle holder 1.

Alternatively, said laparoscopic gripper 10 can be used in combination with said laparoscopic needle holder 1 for the creation of

intracorporeal knots.

In this case, said laparoscopic gripper 10 allows to uncouple the suture needle 100 from the needle holder according to the present invention to complete an intracorporeal knot performed with said needle holder.

Subsequently it is possible to make a second knot with said laparoscopic gripper 10 and uncouple the suture needle 100 with said needle holder 1.

Advantageously, the combined use of the two laparoscopic devices allows to optimize the times for the formation of intracorporeal knots.

Advantages

An advantage of the laparoscopic device according to the present invention is that of guaranteeing greater manageability, an intuitive and simple use, which entail both a less steep learning curve for the surgeon, and a higher speed of execution of the intracorporeal knot.

A further advantage of the laparoscopic device according to the present invention consists in optimizing the formation of the intracorporeal knots, through the use of a single hand in the realization phases of the knot, excluding the conclusive step, in which said intracorporeal knot is pulled. In this way, complicated coordination maneuvers between laparoscopic instruments are advantageously avoided.

Finally, another advantage of the laparoscopic device according to the present invention is given by the fact that the ease of execution of the intracorporeal knot is independent of the length of the suture thread.

The present invention has been described for illustrative but not limitative purposes, according to its preferred embodiments, but it is to be understood that modifications and/or changes can be introduced by those skilled in the art without departing from the relevant scope as defined in the enclosed claims.

CLAIMS

1. Laparoscopic device (1), intended to the formation of intracorporeal knots by an operator by means of a suture thread (101) connected to a needle (100), comprising:

- a first shaft (2) comprising a proximal portion (2') and a distal portion (2");

- a grasping clamp (3) for grasping and releasing said needle (100) and/or said suture thread (101), arranged in correspondence of said distal portion (2") of said first shaft (2); and

- an handle (4), arranged in correspondence of said proximal portion (2') of said first shaft (2), and operatively connected to said grasping clamp (3) for opening and closing it;

said device (1) being characterised

in that it comprises coupling means (6) to be coupled with said needle (100), wherein said coupling means (6) are arranged between said grasping clamp (3) and said proximal portion (2'), and wherein said coupling means (6) are rotatable around the symmetry axis (A) of said first shaft (2) in both rotation directions; and

in that it comprises an actuation handle (7), operatively connected to said coupling means (6), and configured for rotating said coupling means (6) when activated by an operator.

2. Device (1) according to the preceding claim, characterised

in that it comprises a second shaft (8) that is hollow and concentric to said first shaft (2) between said proximal portion (2') and said grasping clamp (3), said second shaft (8) being able to rotate around said symmetry axis (A) in both rotation directions, and

in that said coupling means (6) are arranged on said second shaft (8).

3. Device (1) according to claim 2, characterised in that said actuation handle (7) is operable by said operator and is connected to said second shaft (8).

4. Device (1) according to claim 1, characterised in that said first shaft (2) is adapted to rotate around said symmetry axis (A) in both rotation

directions, and in that said coupling means (6) are arranged on said first shaft (2).

5. Device (1) according to any one of the preceding claims, characterised in that said coupling means (6) are magnetic elements magnetically couplable with a respective needle (100).

6. Device (1) according to any one of the preceding claims, characterised in that said grasping clamp (3) comprises a first jaw (3') and a second jaw (3") and has a closed configuration for blocking said needle (100) and/or said suture thread (101), and an open configuration for releasing said needle (100) and/or said suture thread (101).

7. Device (1) according to any one of the preceding claims, characterised in that said coupling means (6) are arranged proximately to said grasping clamp (3).

8. Laparoscopic kit comprising:

a laparoscopic device (1) according to any one of claims 1-7; and

at least one laparoscopic grasper (10) having a shaft (12) arranged along an axis (A2), said shaft (12) being rotatable around said axis (A2) in both rotation directions.

9. Laparoscopic kit according to claim 8, characterised in that said laparoscopic grasper (10) comprises at least one magnetic element (16) fixed on said shaft (12).

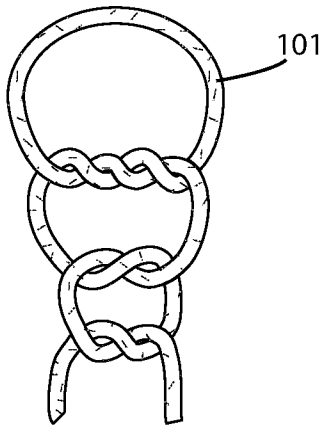

Fig. 1
(Prior Art)

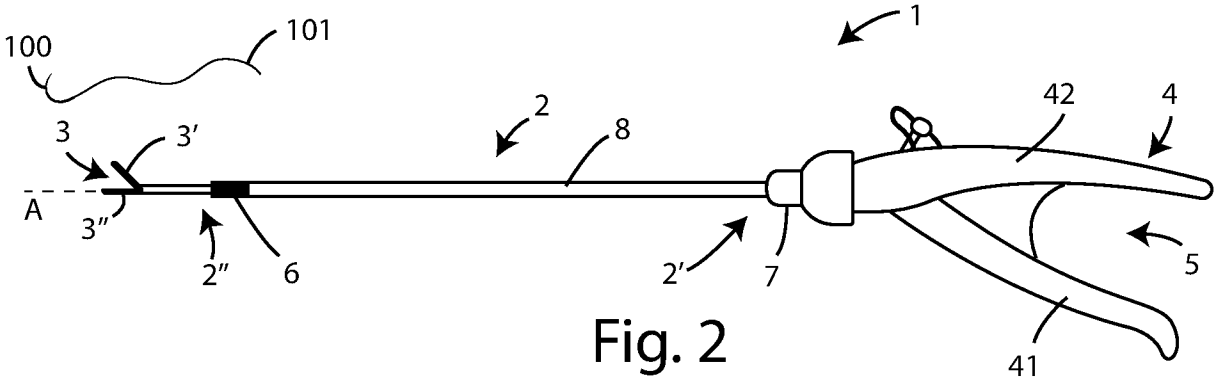

Fig. 2

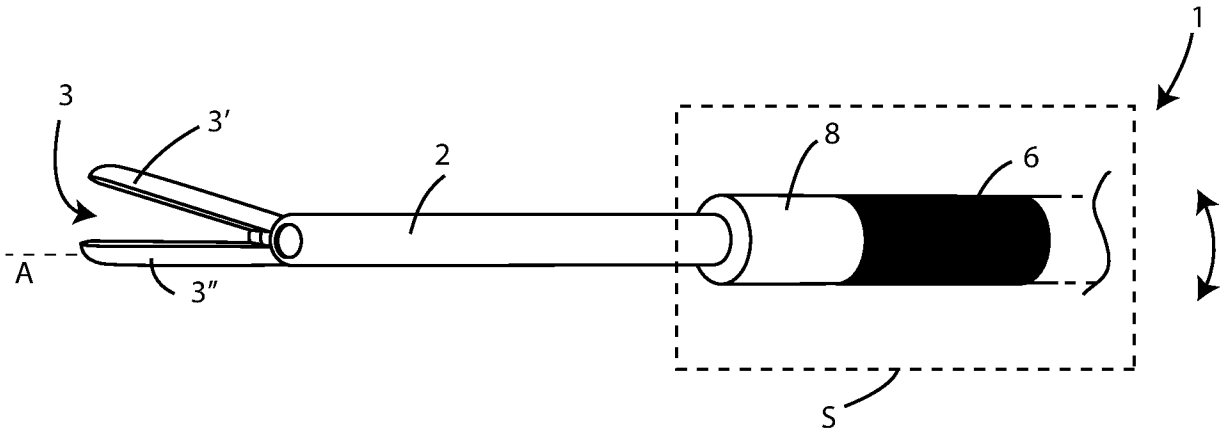

Fig. 3

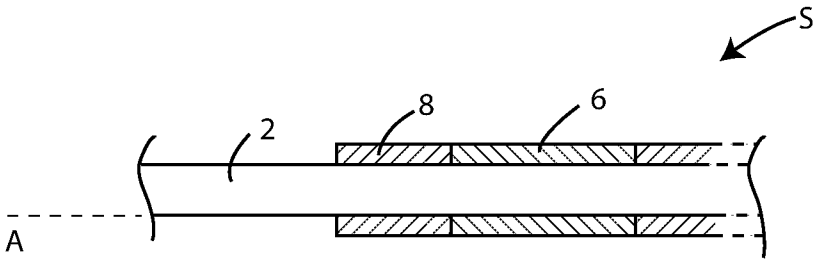

Fig. 4

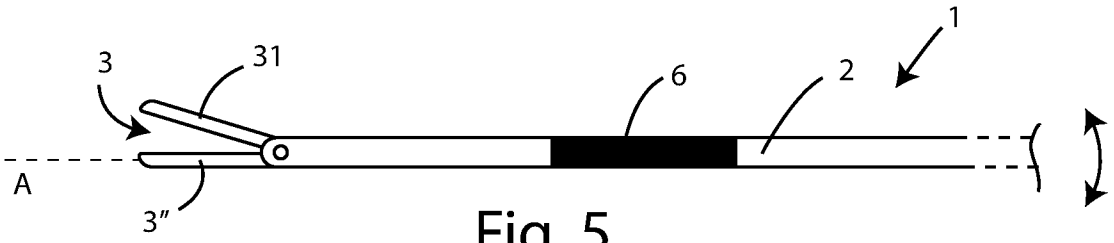

Fig. 5

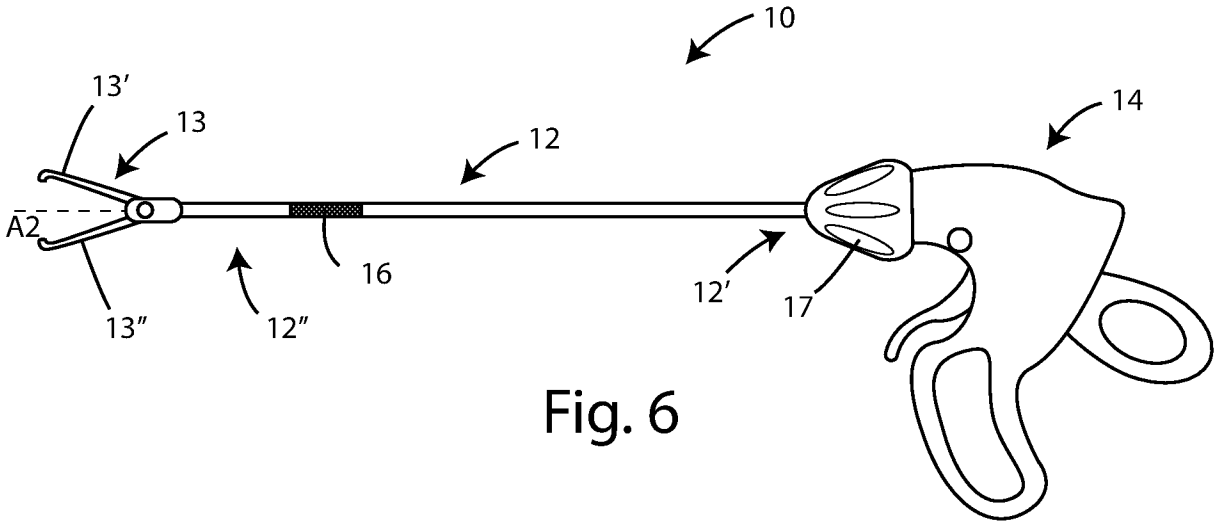

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2019/050263

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04
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 2014/277104 A1 (RODRIGUEZ-NAVARRO ALBERTO [US] ET AL) 18 September 2014 (2014-09-18) figures 1-2 paragraph [0021] paragraph [0030] - paragraph [0031] paragraph [0034] - paragraph [0035] paragraph [0066] paragraph [0078] - paragraph [0079] -----	1-9
X A	US 2007/135678 A1 (SUZUKI TAKAYUKI [JP]) 14 June 2007 (2007-06-14) figures 1-8 paragraph [0051] - paragraph [0058] -----	1-3,5-9 4

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 March 2020	16/03/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lüddemann, Tobias

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2019/050263

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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