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Published:

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(54) **Title**: SURGICAL SEALING TOOL

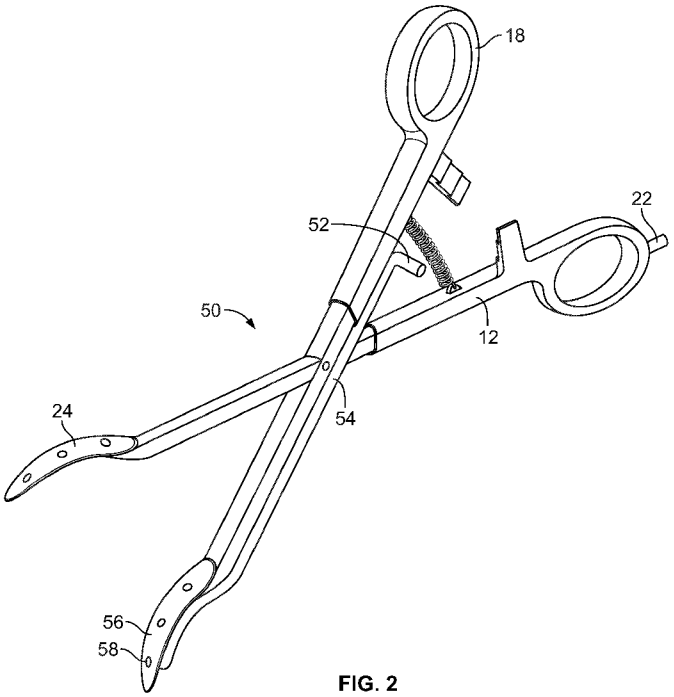

FIG. 2

(57) **Abstract**: A coaptive surgical sealing tool may be similar to an ordinary hemostat with long (50, 60, 70 or 80 mm) thin jaws for sliding into the liver parenchyma, without tearing the larger blood vessels. The jaws are spring loaded and are designed for uniform compression, and to avoid closing too quickly. The jaws are capable of sealing a 50, 60, 70 or 80 mm sealing length, in a single bite, although it can also seal shorter lengths as well. The tool can be used with existing radio frequency bi-polar cautery generators. The tool may be provided with irrigation and/or suction.

WO 2014/209440 A1

SURGICAL SEALING TOOL

BACKGROUND OF THE INVENTION

[0001] Removal of part of the liver (hepatic resection) is often performed to remove a tumor. Blood loss is a serious complication associated with this procedure. Multiple surgical techniques and devices have been developed to minimize blood loss and improve outcomes in hepatic resection. Several studies of techniques for liver parenchymal transection have examined the efficacy of different methods of liver resection. Based on this review, the clamp-crush technique was favored due to low cost and with newer techniques such as cavitron ultrasound surgical aspirator (CUSA), hydrojet, and radio frequency dissecting sealer (RFDS) showing no improvement in morbidity or blood transfusion in comparison to the clamp-crush technique.

[0002] The clamp-crush technique generally involves crushing the liver parenchyma using a hemostatic clamp tool to expose small vessels and biliary radicals, which are then divided and sealed via radio frequency (RF) energy provided to the jaws of the tool. Various tools have been proposed for this purpose. However, challenges remain in providing a coaptive surgical sealing tool offering superior performance and efficiency in a simple and low-cost design. It is an object of the invention to provide an improved coaptive surgical sealing tool

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] In the drawings, the same element number indicates the same element number in each of the views.

[0004] Fig. 1 is a perspective view of a coaptive surgical sealing tool.

[0005] Fig. 2 is a perspective view of another coaptive surgical sealing tool further including irrigation.

[0006] Fig. 3 is an enlarged partial section view design detail of an electrode pair that may be used on the jaws of the tool shown in Figs. 1 or 2.

[0007] Fig. 4 is an enlarged partial section view design detail of an insulated tool arm providing an irrigation or suction line.

[0008] Fig. 5 is an enlarged partial section view alternative design detail of an insulated tool arm providing an irrigation or suction line.

[0009] Fig. 6 is a perspective view of an alternative modification of the tool shown in Fig. 2 further including irrigation and suction.

DETAILED DESCRIPTION OF THE DRAWINGS

[0010] A coaptive surgical sealing tool may be similar to an ordinary hemostat with long (50, 60, 70 or 80 mm) thin jaws for sliding into the liver parenchyma, without tearing the larger blood vessels. The jaws are spring loaded and are designed for uniform compression, and to avoid closing too quickly. The jaws are capable of sealing a 50, 60, 70 or 80 mm sealing length, in a single bite, although it can also seal shorter lengths as well. The tool can be used with existing radio frequency/ bi-polar cautery generators. The tool is suitable for open surgery uses, and may also be adapted for laparoscopic surgery. The tool may be provided in different sizes for different caliber of vessels. In view of its simple design, the tool may be supplied at low cost, as either a reusable or single use unit. The jaws and arms may be rigid metal and so that they do not visibly bend with the nominal hand squeezing forces used in surgery.

[0011] In use, the jaws may be closed with a gradual compression process, with a compression spring acting against the closing movement, to prevent tearing of larger blood vessels. The jaws may a slot and/or ridge, to leave a pre-grooved line for transection after the seal has been completed. The tool may reduce parenchymal transection times in excess of 50%. With 55 mm or more of sealing length it can seal more tissue in one bite than any existing device yet it is also versatile enough to seal small lengths of tissue.

[0012] As shown in Fig. 1, an example of the tool 10 has first and second arms 12 and 14 pivotally connected via a hinge 16. A finger ring 18 is provided on the back or proximal end of each arm 12, 14. Each arm 12, 14 has a jaw 24 in front or distal of the hinge 16. A spring 26 may be provided to urge the jaws into an open position. A lock tab 20 may be provided adjacent to each finger ring 18, to allow the jaws 24 to remain clamped or closed, against the force of the spring. The tool 10 according is similar to a hemostat clamp, and consequently benefits from ergonomic design elements of a hemostat clamp. Hence the tool 10 provides ease of use when used in open surgery. Connectors 22 may connect electrodes 30 on the jaws 24 to an radio frequency or other type of electro surgery generator.

[0013] The jaws 24 are very thin and easy to slide through the liver parenchyma without disrupting it. For example, the jaws may a length AA of 50, 60, 70 or 80 mm, and a width BB of 4, 5, 6 or 7 mm. The spring 26 can help to prevent accidentally closing down on the parenchyma too quickly which prevents parenchymal disruption. The jaws 24 may be straight or curved with a radius R of about 3-10 cm. Typically, the

curvature of the jaws, if any, is in the downward direction, i.e., about an axis parallel to the axis of the hinge 16.

[0014] The electrodes 30 may extend over the full length of each jaw 24, or only partially over each jaw 24, as shown in Fig. 1. The electrodes 30 may optionally be removable and separately replaceable. The electrodes 30 may be integral with the jaws 24 or provided as separate components attached to the jaws. The electrodes are typically a conductive biocompatible material, for example, metals. The electrodes may be provided as a slide-on or press-on sleeve having an open back end and a closed off and tapered front end, as shown in Fig. 1.

[0015] A low cost embodiment of the tool may be provided by modifying a conventional hemostat clamp having long slender jaws, to include the spring 26, the electrodes 30 and connectors 22.

[0016] As used for hepatic resection, the surgeon slides the jaws 24 through the liver parenchyma. With the jaws appropriately positioned around a vessel or biliary radical, the jaws 24 are slowly closed via the surgeon squeezing the finger rings 18 towards each other. The electrodes 30 on the inside of the jaws are clamped or pressed onto opposite sides of the vessel. The spring 26 acts against this closing movement, helping to provide a slow and controlled movement. With the tool 10 held momentarily in a fixed position, radio frequency energy is then provided to the electrodes 30, sealing the vessel.

[0017] The tool may of course also be used for other surgical procedures on other organs apart from the liver. Although a bi-polar tool having two electrodes is shown, a

monopolar tool using a single electrode on the tool in combination with a remote return electrode may also be used.

[0018] In a study conducted from 2010 to 2012, a total of 51 patients underwent >30% liver resection for malignant disease. All patients underwent open laparotomy for hepatic resection. The patient sample was diverse. The majority of patients underwent resection for metastatic disease to the liver; four gallbladder cancer with radical liver resection; one hepatocellular carcinoma; and three patients had documented cirrhosis. Procedures included: seven patients were combined colorectal primary and liver resection; two patients underwent second resection for recurrence; seven patients had additional nanoknife procedures at the time of resection. Post-op adverse events within 30 days of surgery included no bile leaks; one blood transfusion; one return to operating room for colon anastomatic leak; and no intra-abdominal abscess. Use of the present tool as described appears to be a safe and effective technique for major hepatic resection with minimal post-operative adverse events.

[0019] During use of a bipolar surgical cautery tool, heat generated by the tool tends to result in char forming on the jaws. Char causes the jaws to stick to the tissue being cauterized, making the surgery more difficult. Char also increases the electrical resistance between the jaws, reducing the cautery effect of the tool. Char can be reduced by supplying an irrigation fluid to the cautery site, reducing the need for frequently stopping the procedure to clean char from the jaws.

[0020] As shown in Fig. 2, a bipolar surgical cautery tool 50 may be similar to the tool 10 shown in Fig. 1 and further include irrigation to reduce char. Irrigation may be provided via an irrigation port or fitting 52 adapted for connection to a source of

irrigation fluid, such as saline. The irrigation port 52 is connected to an irrigation line 54 on or in the tool leading to one or both of the electrodes 56. The irrigation line 54 may simply have a single outlet at the electrode 56, or it may have multiple outlets 58 spaced apart along the electrode. The irrigation line 54 may be provided as a flexible tube attached to the tool 50. Alternatively the irrigation line 54 may be provided as an internal duct leading from the arm 12 to the electrode 56.

[0021] As shown in Fig. 4, in another design, one or both arms 12 may optionally be covered or coated with an insulating material 66, such as plastic or rubber, with the irrigation line 54 formed in insulating material 66. The insulating material may also optionally cover one or both finger rings 18. As shown in Fig. 5, if the insulating material 66 is used, the irrigation line 54 may alternatively be provided as an open flow space between the arm 12 and the insulating material 66.

[0022] In use, the source of irrigation fluid connected to the irrigation port 52 may be linked to the radio frequency generator switch so that irrigation fluid flows onto or out of the electrode 56 whenever the switch is on. By applying a constant drip or flow of irrigation liquid during cautery, char build up is reduced.

[0023] Fig. 3 shows a modification of the jaw 24 where a projection 62 is provided on the electrode 30 on the upper jaw and a complementary groove 60 is provided on the electrode 30 on the lower jaw. The projection may extend parallel to the longitudinal axis of the arm 24 and typically has a height of 1-3 mm. Consequently, as the upper and lower jaws are brought together, while the electrodes are cauterizing tissue, they also form a pre-grooved line in the tissue for transection, after the seal has been completed.

[0024] Turning to Fig. 6, a tool 70 may be provided with the same design as the tool 50 shown in Fig. 2, further including suction for helping to remove excess blood and/or irrigation fluid. The tool 70 includes a port or fitting 72 for attachment to a suction source. One or more suction inlets 74 may be provided on one or both electrodes 30 or 58, with the suction inlets 74 connected to a suction line 76 connecting to the suction port 72. The suction line 76 may be designed in the same ways as the irrigation line 54 described above.

[0025] The finger rings 18 may be continuous rings or they may be C or U-shaped. The compression spring 26 may be replaced by other types of springs, such as a torsion spring at or in the hinge 16, and the lock tabs 20 may be omitted, so that the space between the back end of each of the arms 12 and 14 is open and not obstructed by any part of the tool

CLAIMS:

1. A surgical tool comprising:

first and second arms, each having a front section and a back section, and with the arms pivotally attached to each other at a pivot connection between the front and back section of each arm;

a finger ring on the back section of each arm;

a spring between the back sections of the arms, with the spring urging the back sections of the arms away from each other;

first and second jaws on the front section of the first and second arms, respectively, with the first and second jaws having a length of 5 to 9 cm;

first and second electrodes on the first and second jaws, respectively; and

an irrigation port on the first arm connected to an irrigation line leading to one or more irrigation fluid outlets in or adjacent to the first or second electrode.

2. The surgical tool of claim 1 with the first and second jaws each having a width of 3-7 mm.

3. The surgical tool of claims 1 or 2 with the first and second jaws each having a width of 4-6 mm.

4. The surgical tool of claims 1 or 3 further comprising first and second connectors electrically connected to the first and second electrodes connect to an radio frequency generator.

5. The surgical tool of claims 1 or 3 further including a suction port on the first arm connected to a suction line leading to one or more suction openings in or adjacent to the first or second electrode.

6. The surgical tool of claims 1 or 3 further including a longitudinal projection on the first electrode and a complementary groove on the second electrode.

7. A coaptive surgical sealing tool comprising:

first and second arms, each having a front section and a back section, and with the arms pivotally attached to each other at a pivot connection between the front and back section of each arm;

a finger ring on the back section of each arm;

a spring between the back sections of the arms, with the spring urging the back sections of the arms away from each other;

first and second jaws on the front section of the first and second arms, respectively, with the first and second jaws having a length of 5 to 9 cm and a width of 3-7 mm.;

first and second electrodes on the first and second jaws, respectively;

first and second connectors electrically connected to the first and second electrodes and adapted to connect to an radio frequency generator.;

an irrigation port on the first arm connected to an irrigation line leading to one or more irrigation fluid outlets in or adjacent to the first or second electrode; and

a suction port on the first arm or the second arm and connected to a suction line leading to one or more suction openings in or adjacent to the first or second electrode.

8. A surgical method, comprising:

sliding the jaws of a surgical hemostat clamp-type of tool through the liver parenchyma;

positioning the jaws around a vessel;

closing the jaws to press first and second electrodes on the inside of the jaws onto opposite sides of the vessel;

applying radio frequency energy to the electrodes to seal the vessel; and

applying an irrigation fluid onto the vessel in the jaws.

9. The method of claim 8 with the irrigation liquid applied through one or more openings in the first electrode.

10. The method of claim 8 further comprising closing a switch to apply the radio frequency energy, with the switch also controlling application of the irrigation fluid.

11. The method of claim 8 further including applying suction adjacent to the jaws.

12. A surgical tool comprising:

first and second arms, each having a front section and a back section, and with the arms pivotally attached to each other at a pivot connection between the front and back section of each arm;

first and second jaws on the front section of the first and second arms, respectively;

first and second electrodes on the first and second jaws, respectively;

an radio frequency electro cautery generator electrically connected to the electrodes; and

an irrigation port on the first arm connected to an irrigation line leading to one or more irrigation fluid outlets in or adjacent to one or both of the first and second electrodes.

13. The tool of claim 12 further including a finger ring on the back section of each arm, and a spring between the back sections of the arms, with the spring urging the back sections of the arms away from each other.

14. The tool of claim 12 with the first and second jaws having a length of 5 to 9 cm.

15. The tool of claim 12 with the first and second jaws each having a width of 3-7 mm.

16. The tool of claims 12 or 15 with the first and second jaws each having a width of 4-6 mm.

17. The tool of claim 12 further comprising first and second connectors electrically connected to the first and second electrodes and to the radio frequency generator.

18. The tool of claims 12 or 16 further including a suction port on the first arm connected to a suction line leading to one or more suction openings in or adjacent to the first or second electrode.

19. The tool of claims 12 or 16 further including a longitudinal projection on the first electrode and a complementary groove on the second electrode.

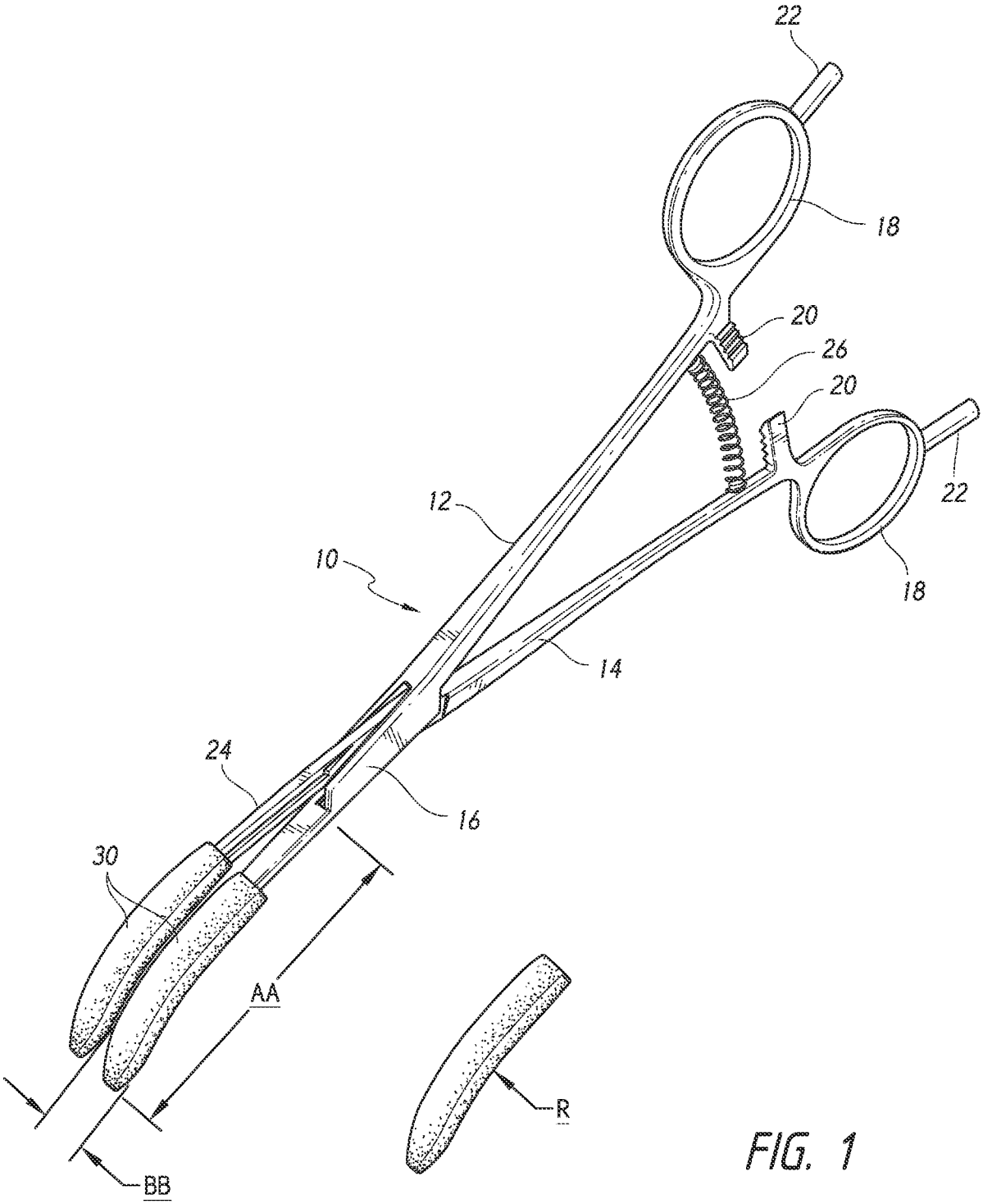

FIG. 1

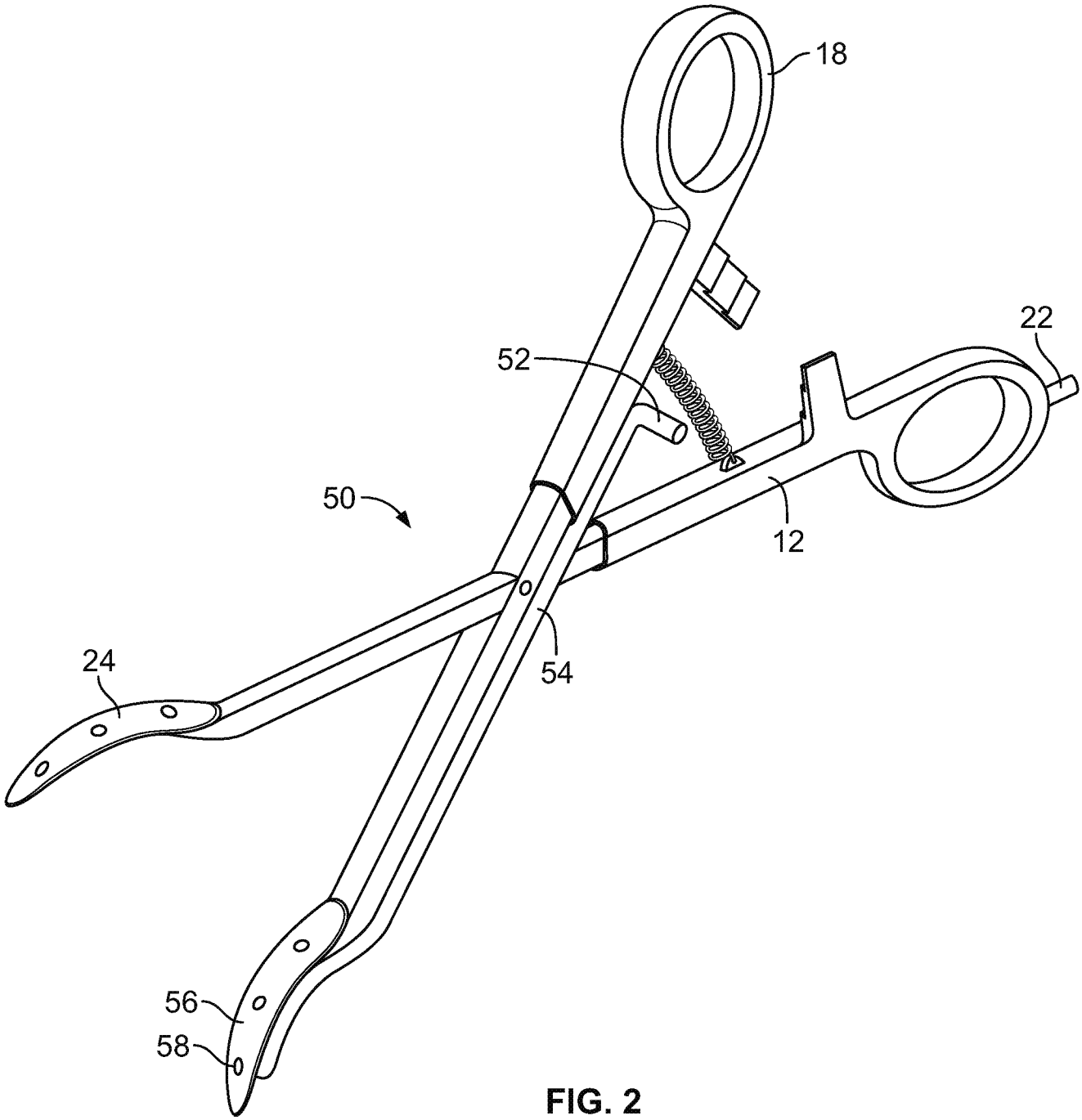

FIG. 2

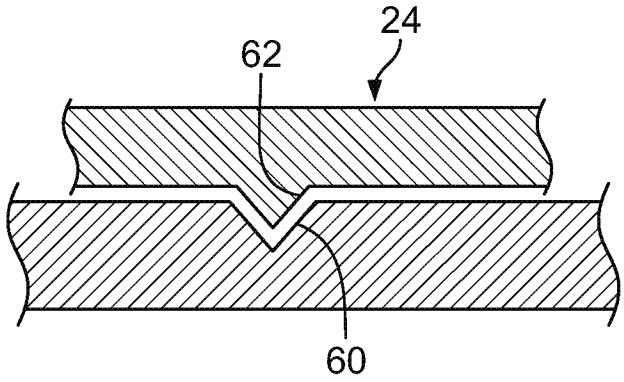

FIG. 3

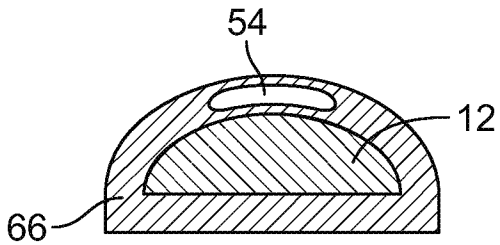

FIG. 4

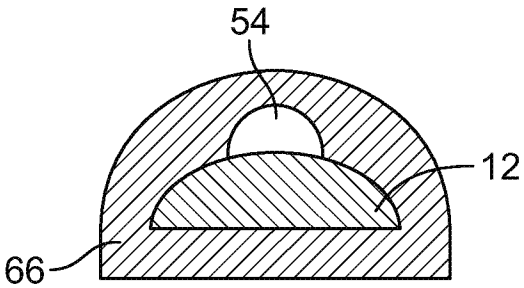

FIG. 5

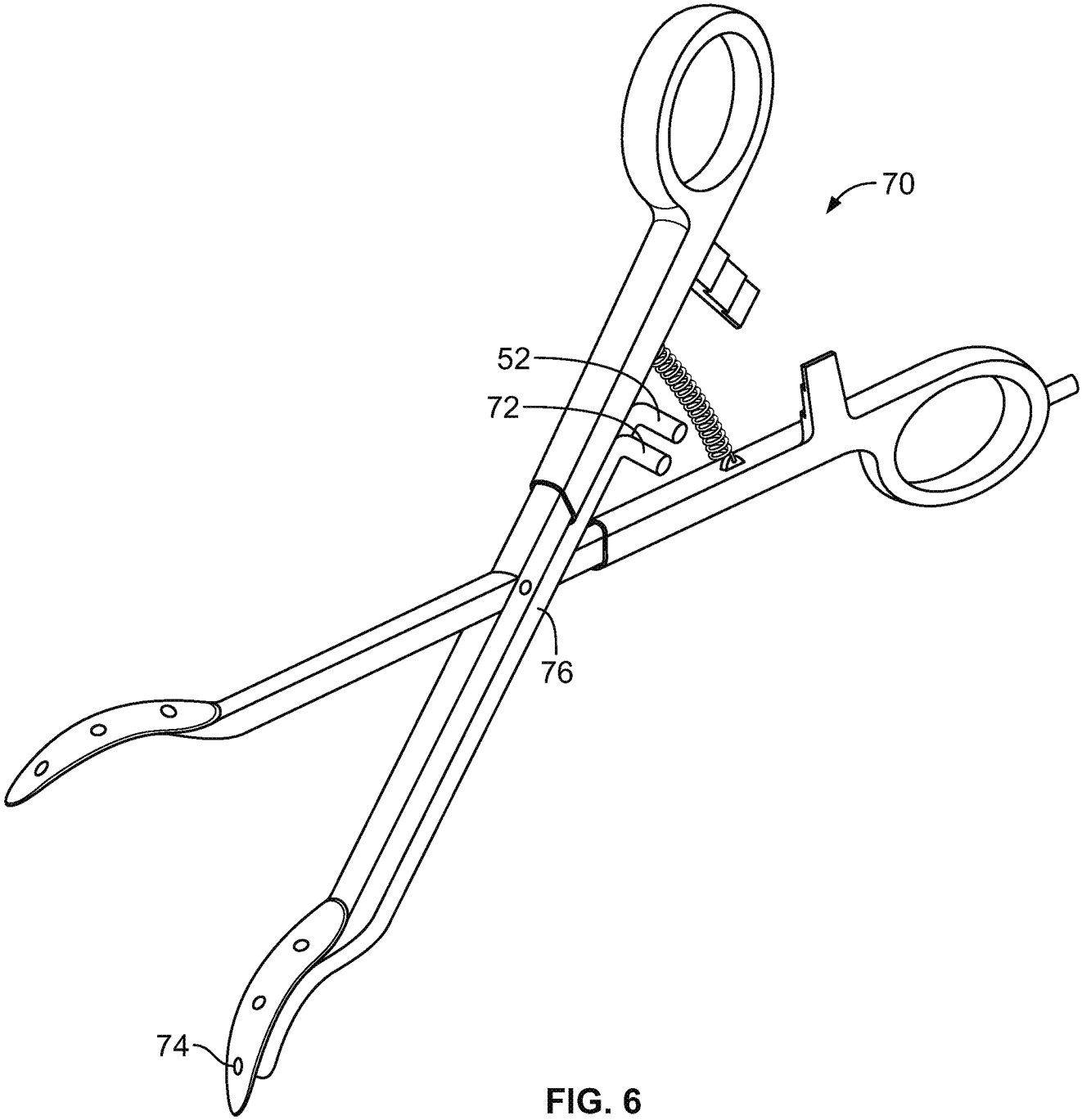

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/022824

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/18 (2014.01)
USPC - 606/51
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)
IPC(8) - A61B 17/28, 17/285, 17/32, 17/3201, 18/00, 18/12, 18/14, 18/18 (2014.01)
USPC -606/33, 39, 41, 45, 48, 51, 52

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 18/082, 18/085, 18/1442, 18/18 (2014.02)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2006/0235379 A1 (MCCLURKEN et al) 19 October 2006 (19.10.2006) entire document	8 --- 9-11
Y	US 2013/0018411 A1 (COLLINGS et al) 17 January 2013 (17.01.2013) entire document	1-3, 7, 12-17
Y	US 5,300,087 A (KNOEPFLER) 05 April 1994 (05.04.1994) entire document	1-3, 7, 9, 11-17
Y	US 5,395,312 A (DESAI) 07 March 1995 (07.03.1995) entire document	10

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 2014	01 JUL 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/022824

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-6, 18, 19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.