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DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) **Title:** MALLEABLE INSTRUMENT FOR LAPAROSCOPIC PROCEDURES

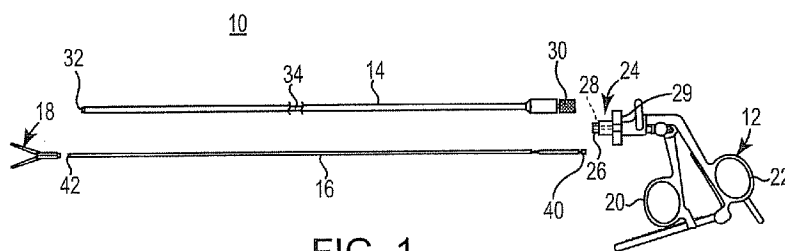


FIG. 1

(57) **Abstract:** A laparoscopic tool includes a handle assembly, a tool implement, an outer tube defining an inner lumen and a wire assembly positioned within the lumen of the outer tube and coupled to the handle assembly and the tool implement. The outer tube and the wire assembly are configured to be shaped to form at least one bend region.

WO 2012/142375 A1

MALLEABLE INSTRUMENT FOR LAPAROSCOPIC PROCEDURES

Background

[01] Laparoscopic surgery includes forming small incisions in a patient and performing a procedure through the incision using one or more laparoscopic surgical tools. Current laparoscopic surgical techniques utilize one or more trocars that establish a port for introduction of the surgical tools. One type of surgical technique is known as single incision laparoscopic surgery (“SILS”), where only a single incision and single trocar are used during the surgical procedure. In one example, SILS procedures utilize an umbilical trocar introduced through an incision in the umbilical region of a patient. As incisions in the umbilical region tend to be relatively invisible after surgery and allow for quicker recovery of the patient, SILS procedures can be a preferred method of surgery in many instances. Even with inherent benefits to utilizing the umbilical region for SILS procedures, procedures using entry through the umbilical region can be difficult due to lack of space and proximity with a targeted tissue site. As such, specialty curved or articulated tools have given physicians opportunity to have more clearance in reaching and operating upon a targeted tissue site. These curved tools can still be difficult to work with, since patients can be varied in size and varied target surgical sites can be difficult to access.

Summary

[02] A laparoscopic surgical tool is disclosed that includes a handle assembly, a tool implement, an outer tube and an inner wire assembly coupling the handle assembly to the tool implement. The outer tube and inner wire assembly can be manipulated to conform to a desired shape.

[03] In one embodiment, the wire assembly is positioned within an inner lumen of the outer tube. A surgical environment can be evaluated to identify a path from an incision to a targeted tissue site. Upon evaluation, the outer tube and wire assembly can be shaped to form one or more bend regions. As such, a surgeon is afforded easier access to the targeted tissue site. Subsequently, the laparoscopic tool can be withdrawn and the handle assembly and/or

tool implement can be replaced with an alternative handle assembly and/or tool implement while maintaining the one or more bend regions.

Brief Description of the Drawings

- [04] FIG. 1 is a side view of a laparoscopic tool in a disassembled state.
- [05] FIG. 2 is a side view of a laparoscopic tool after final assembly.
- [06] FIG. 3 is a side view of a laparoscopic tool in a first curved shape.
- [07] FIG. 4 is a side view of a laparoscopic tool in a second curved shape.
- [08] FIG. 5 is a schematic view of a surgical environment.

Detailed Description

- [09] FIG. 1 is an exploded side view of a laparoscopic tool 10 whereas FIG. 2 is a side view of tool 10 in an assembled state. The tool 10 includes a handle assembly 12, an outer tube or sleeve 14, an inner wire assembly 16 and a tool implement 18. Handle assembly 12 is operably coupled to tool implement 18 through wire assembly 16. Tube 14 is coaxially arranged around wire assembly 16 and coupled to handle assembly 12. A surgeon utilizing tool 10 is able to bend tube 14 and wire assembly 16 to a desired shape to form a configuration suitable to perform a procedure. As such, the surgeon conforms the outer tube 14/wire assembly 16 to a shape that leads from an incision to a target tissue site. Tube 14 and wire assembly 16 are configured to be coupled with alternative handle assemblies and tool implements as desired. As such, the shape of the tube 14 and wire assembly 16 can be maintained to perform various tasks within a surgical environment.
- [10] Handle assembly 12 includes a trigger handle 20 and a fixed handle 22 for operation of the tool implement 18. Additionally, handle assembly 12 includes a coupling portion 24 for attachment to the tube 14 and wire assembly 16. In particular, coupling portion 24 includes a threaded shaft 26 for coupling to tube 14 and an aperture 28 for receiving wire assembly 16, which is directly coupled to trigger handle 20. In addition, handle assembly 12 includes a control knob 29, which can be utilized to effect rotational movement of wire

assembly 16 and thus tool implement 18. Other handle assemblies can also be used having one or more features such as rotatable, fixed, axial, angled, with a monopolar connection, with a bipolar connection and/or combination thereof.

[11] Outer tube 14 includes a proximal end 30 and a distal end 32 opposite the proximal end 30. Proximal end 30, in one embodiment, defines a threaded bore configured to mate with threaded shaft 26 of handle assembly 12, so as to secure tube 14 to handle assembly 12. Outer tube 14 further defines a lumen 34 (referenced generally) configured to receive the wire assembly 16. In one embodiment, tube 14 is formed of annealed 300 series stainless steel, wherein an outer diameter of the tube 14 is approximately 4.0 millimeters and a diameter of lumen 34 is approximately 2.6 millimeters. In particular, the tube 14 is formed to be malleable to a degree such that outer tube 14 can be bent to a desired shape, yet maintain the desired shape during operation of the tool 10. Other diameters/dimensions of the tube 14 can be used in alternative embodiments. In one embodiment, tube 14 can be covered with an insulating material. As desired, tube 14 can be formed in various lengths, for example to accommodate normal patients, obese patients and/or pediatric patients.

[12] Wire assembly 16 includes a proximal end 40 and a distal end 42 positioned opposite the proximal end 40. In one embodiment, wire assembly 16 is formed of annealed 300 series stainless steel comprising a single wire having an outer diameter of approximately 1.4 to 1.8 millimeters. In an alternative embodiment, wire assembly 16 is a cable having a plurality of wires with an outer diameter of approximately 1.4 to 1.8 millimeters. In any event, wire assembly 16 is formed so as to conform to the shape of outer tube 14 and still move within lumen 34 relative to the outer tube 14 in a longitudinal direction upon actuation of handle assembly 12. To this end, wire assembly 16 can be coated with a non-sticking material, in one embodiment, so as to facilitate movement of the wire assembly 16 within lumen 34. In the embodiment illustrated, proximal end 40 defines a feature (e.g., a notch or ball) configured to be inserted into aperture 28 and coupled to trigger handle 20. Additionally, distal end 42 defines a feature (e.g., a notch or ball) configured to be coupled to tool implement 18. Wire assembly 16 is coupled to trigger handle 22 in such a way that by squeezing handle assembly 12 (i.e., by causing movement of trigger handle 20 relative to fixed handle 22), distal end 42 is actuated toward handle assembly 12. This actuation, in turn, causes operation of tool implement 18. As such, a surgeon can operate tool implement

18 remotely via actuation of the handle assembly 12. Moreover, as discussed above, control knob 29 can be rotated to cause rotation of wire assembly 16 and tool implement 18.

[13] As discussed above, outer tube 14 and inner wire assembly 16 are formed to be malleable such that a surgeon can deform and manipulate the shape of the outer tube 14 and inner wire assembly 16. As a result, prior to inserting tool 10 into a laparoscopic port, a surgeon can evaluate a surgical area and in particular a desired approach angle from a port opening (e.g., the umbilical region) to a target surgical site. The surgeon can then form the outer tube 14 and inner wire assembly 16 to a desired shape by creating one or more bend regions therein.

[14] Tool implement 18 is operably coupled to the handle assembly 12 through the wire assembly. As such, operation of the handle assembly 12 causes operation of the tool assembly 18. In various embodiments, tool implement 18 can take various forms in various shapes and sizes. Moreover, the tool implements can be configured to perform various functions such as grasping, cutting, clamping and/or coagulation.

[15] As illustrated in FIG. 3, the surgeon can form tool 10 such that outer tube 14 forms a first bend region 50 and a second bend region 52 along a length of the outer tube 14. In an alternative configuration, illustrated in FIG. 4, tool 10 forms a first bend region 60, a second bend region 62 and a third bend region 64 along a length of outer tube 14. Other bend regions can be formed within tool 10 as desired. Once a desired shape is selected, tool implement 18 can be delivered to a targeted tissue site to perform a desired procedure.

[16] FIG. 5 is a schematic illustration of a surgical environment 100. A patient body 102 includes an incision 104 formed therein for insertion of a port 106. A surgeon desires to operate on a target tissue site 108 located within patient body 102 and remote from the incision 104. After inspection and evaluating the location of target site 108, a surgeon forms a shape of tool 10 to include one or more bend regions. In the embodiment illustrated, tool 10 is formed to include a first bend region 110 and a second bend region 112. Once the desired bend regions are formed, tool 10 is inserted into port 106 until tool implement 18 engages tissue site 108. Handle assembly 12 can then be actuated so as to operate tool implement 18. After operating tool implement 18, tool 10 can be withdrawn from the patient body 102. After withdrawal of tool 10, handle assembly 12 and/or tool implement 18 can be

replaced with different handle assemblies or tool implements as desired while maintaining the shape of outer tube 14, in particular including bend region 110 and bend region 112.

[17] Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure.

What is claimed is:

1. A laparoscopic tool, comprising:
a handle assembly;
a tool implement;
an outer tube defining an inner lumen; and
a wire assembly positioned within the lumen of the outer tube and coupled to the handle assembly and the tool implement,
wherein the outer tube and the wire assembly are configured to be shaped to form at least one bend region.
2. The laparoscopic tool of claim 1, wherein the handle assembly includes a trigger handle and a fixed handle, wherein movement of the trigger handle relative to the fixed handle causes relative movement between the outer tube and the wire assembly.
3. The laparoscopic tool of claim 2, wherein movement of the wire assembly relative to the outer tube causes operation of the tool implement.
4. The laparoscopic tool of claim 1, wherein the handle assembly further includes a control knob, wherein rotation of the control knob causes rotation of the tool implement.
5. The laparoscopic tool of claim 1, wherein the outer tube and the wire assembly are configured to maintain the at least one bend region while the handle assembly is removed therefrom and a second handle assembly is coupled thereto.
6. The laparoscopic tool of claim 1, wherein the outer tube and the wire assembly are configured to maintain the at least one bend region while the tool implement is removed therefrom and a second tool implement is coupled thereto.
7. The laparoscopic tool of claim 1, wherein the outer tube and the wire assembly are configured to form at least two bend regions.

8. The laparoscopic tool of claim 1, wherein the outer tube and the wire assembly are configured to form at least three bend regions.
9. The laparoscopic tool of claim 1, wherein the outer tube and the wire assembly are formed of stainless steel.
10. A method of using a laparoscopic tool, comprising:
providing a tool having a handle assembly, a tool implement, an outer tube and a wire assembly coupled to the handle assembly and the tool implement; and
shaping the outer tube and wire assembly to form at least one bend region.
11. The method of claim 10, further comprising:
providing relative movement between a trigger handle and a fixed handle of the handle assembly so as to cause relative movement between the outer tube and the wire assembly.
12. The method of claim 11, wherein movement of the wire assembly relative to the outer tube causes operation of the tool implement.
13. The method of claim 10, further comprising:
providing a control knob on the handle assembly, wherein rotation of the control knob causes rotation of the tool implement.
14. The method of claim 10, further comprising:
removing the handle assembly from the wire assembly; and
attaching a second handle assembly to the wire assembly while maintaining the at least one bend region and the outer tube and the wire assembly.
15. The method of claim 10, further comprising:
removing the tool implement from the wire assembly; and
coupling a second tool implement to the wire assembly while maintaining the at least one bend region.

16. The method of claim 10, wherein shaping the outer tube and wire assembly includes forming at least two bend regions.
17. The method of claim 10, wherein shaping the outer tube and the wire assembly includes forming at least three bend regions.
18. The method of claim 10, wherein the outer tube and the wire assembly are formed of stainless steel.
19. The method of claim 10, further comprising:
 - inspecting a surgical environment to determine a path from an incision to targeted tissue; and
 - shaping the outer tube and the wire assembly to conform to the desired path.
20. The method of claim 10, wherein shaping the outer tube and wire assembly is performed by a hand of a user forming the at least one bend region.

1/2

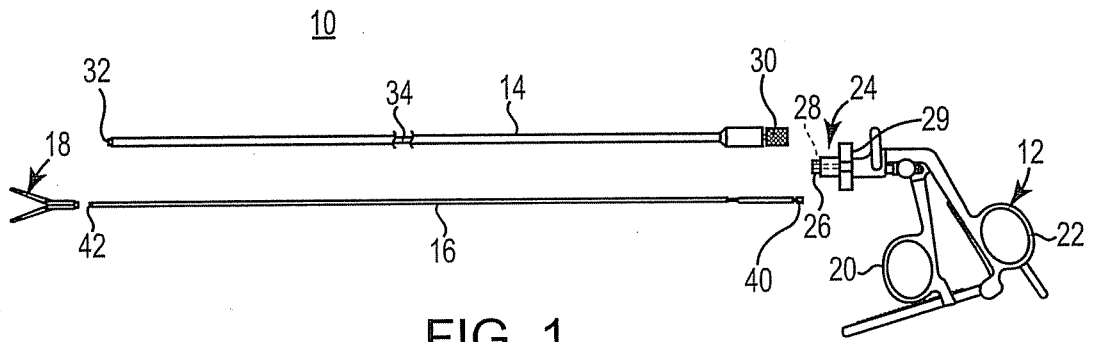


FIG. 1

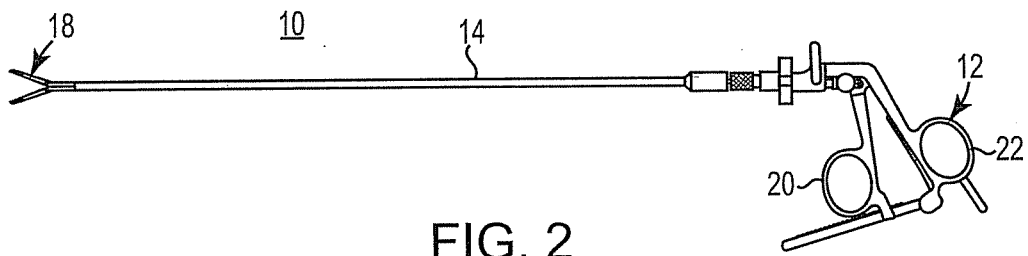


FIG. 2

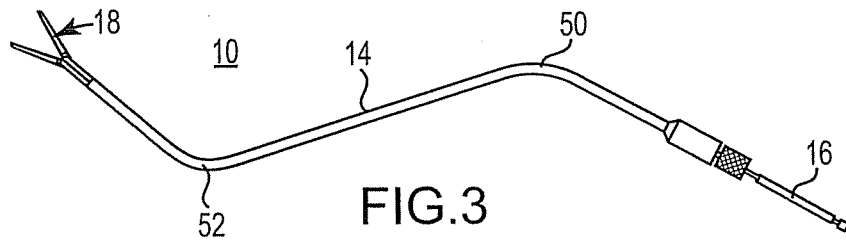


FIG. 3

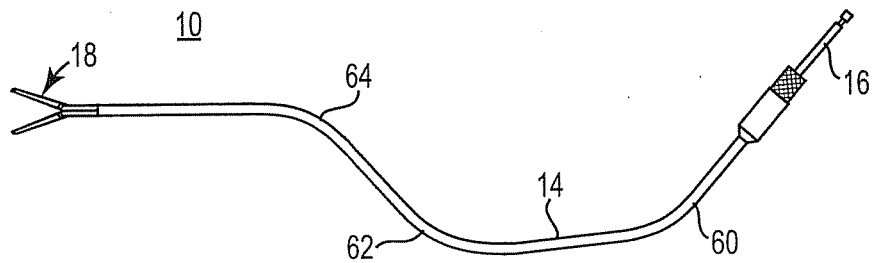


FIG. 4

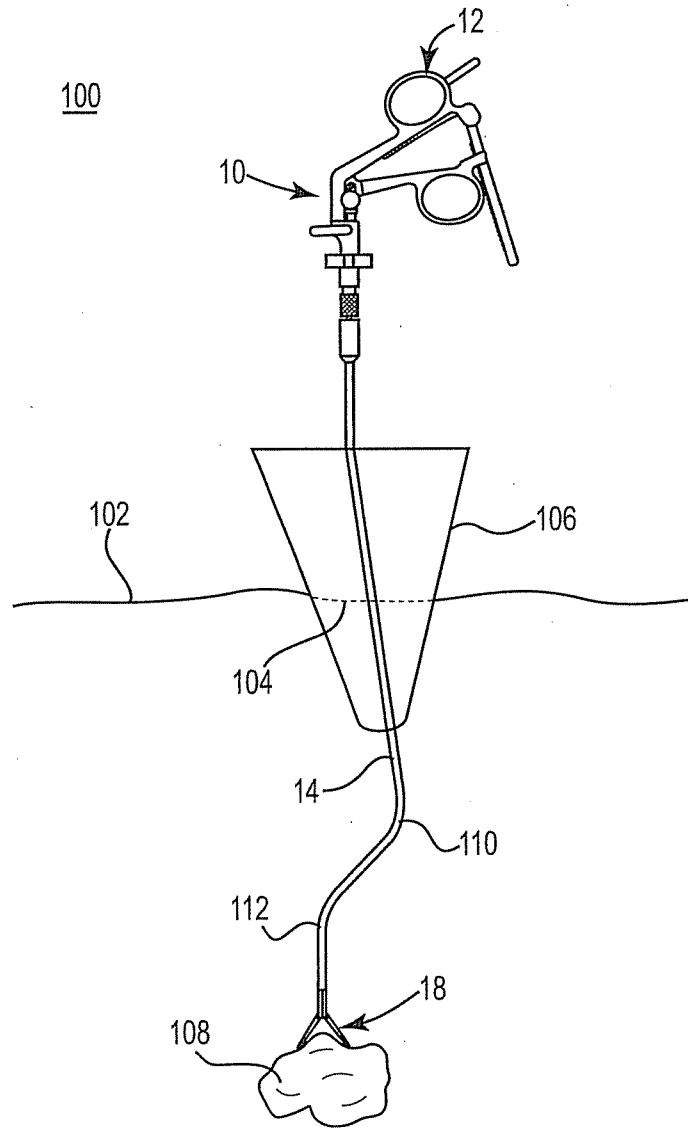


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/033464

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/29
ADD. A61B17/00

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 2003/236549 A1 (BONADIO FRANK [IE] ET AL) 25 December 2003 (2003-12-25) abstract; figures 1,29a-29d,32,38a-38b paragraphs [0017] - [0021], [0042], [0168] -----	1-9
X	US 2001/034536 A1 (LOOPER ANTHONY M [US] ET AL) 25 October 2001 (2001-10-25) abstractparagraphs 52,59,61; figures 1,3,9-10,20 -----	1-9
X	US 2010/234687 A1 (AZARBARZIN KURT [US] ET AL) 16 September 2010 (2010-09-16) abstractparagraph 73; figures 1-9c ----- -/--	1-9

Further documents are listed in the continuation of Box C.

See patent family annex.

* 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 18 September 2012	Date of mailing of the international search report 27/09/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/033464

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2011/140418 A1 (ETHICON ENDO SURGERY INC [US]; SHELTON FREDERICK E [US]; WIDENHOUSE CH) 10 November 2011 (2011-11-10) abstract; claim 1; figures 1a-3e,9d paragraphs [0011], [0015], [0046], [0051], [0060] -----	1-9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/033464

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.: 10-20
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Article 17(2)(a)(i) and Rule 39.1 (iv) PCT, the subject-matter of claims 10-20 has not been searched, since it is directed to a method for treatment of the human body by surgery (using a laparoscopic tool).
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.:
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 an 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2012/033464

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003236549	A1	25-12-2003	AU 2451902 A
			EP 1303221 A2
			US 2003236549 A1
			WO 0207611 A2

US 2001034536	A1	25-10-2001	NONE

US 2010234687	A1	16-09-2010	EP 2214575 A2
			US 2010234687 A1
			WO 2009073577 A2

WO 2011140418	A1	10-11-2011	US 2011276083 A1
			WO 2011140418 A1

专利名称(译)	用于腹腔镜手术的可锻仪器		
公开(公告)号	EP2696782A1	公开(公告)日	2014-02-19
申请号	EP2012717976	申请日	2012-04-13
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司XOMED , INC.		
当前申请(专利权)人(译)	美敦力公司XOMED , INC.		
[标]发明人	DEFLANDRE NICOLAS VIRMOUX FRANCOIS		
发明人	DEFLANDRE, NICOLAS VIRMOUX, FRANCOIS		
IPC分类号	A61B17/29 A61B17/00		
CPC分类号	A61B17/29 A61B17/00234 A61B2017/00946 A61B2017/2905		
优先权	13/087007 2011-04-14 US		
外部链接	Espacenet		

摘要(译)

一种腹腔镜工具，包括手柄组件，工具器具，限定内腔的外管和定位在外管的内腔中并连接到手柄组件和工具器具的线组件。外管和线组件构造成形成至少一个弯曲区域。