Final Assignment

INSTRUCTIONS:

Please identify your Section Teacher and include EXAM NUMBERS ONLY on the assignment. The assignment is to be turned in to the Registrars Office by 4 p.m. on Thursday July 6. You are allowed to refer to any written materials that may help you (e.g., MPEP, course materials, and other reference materials on patent law and practice), except you may NOT conduct ANY patent searching and may NOT refer to any patents other than the patent provided with the assignment. You are NOT allowed to collaborate with or consult with ANYONE including, but not limited to, other students and teaching assistants! If you have any questions regarding the assignment, you may ask your section teacher or Professor Carroll. Any students that fail to comply with the above will be subject to honor code violations.

The following documents should be attached as part of this assignment:

1. *Patent Application (10 pages of specification and 3 pages of drawings)*
2. *Office Action (4 pages including cover sheet and PTO Form 1449)*
3. *Prior Art - Lind Patent (5 pages)*

In-house patent counsel at a medical device company has hired you to prepare a response to an Office action. In-house counsel has given you a copy of the patent application as filed, a copy of the Office action, and a copy of the only prior art patent of record.

You are instructed as follows:

- Prepare a response that will overcome the objections and rejections in the Office action and that will place the pending claims into condition for allowance.
- Include new claims that will cover the detachable forceps device and that will distinguish over the prior art patent of record and the conventional biopsy forceps device discussed in the Background.
- Do NOT incur any additional PTO fees.
- The response should comply with all applicable sections of the Patent Statute (Title 35 of the United States Code) and Patent Office rules (Title 37 of the Code of Federal Regulations).

Docket No.: MED-001XX

MODULAR MEDICAL INSTRUMENT AND FORCEPS DEVICE FOR USE THEREWITH

TECHNICAL FIELD

The present invention relates to modular medical instruments and in particular, relates to a modular medical instrument having a forceps device.

BACKGROUND INFORMATION

Endoscopy is a well known medical procedure that allows relatively noninvasive exploration and surgical procedures to be conducted within a patient while transmitting an image from within the patient to a monitor that is viewed by the surgeon or other medical personnel. A conventional endoscope includes an elongated scope body that is inserted into a body lumen or passageway and a handle that controls insertion of the scope body. A fiber optic sensor or video camera chip is disposed at the distal end of the elongated scope body, for transmitting an image of the body passageway to a monitor or video screen.

An instrument channel extends through the elongated scope body to receive different types of medical instruments or accessories used to perform the medical procedures within the patient's body. The medical instruments that are commonly used with endoscopes include, but are not limited to, foreign body graspers, wire snares, biopsy forceps, retrieval baskets, cautery tools, probes and other similar medical instruments or accessories. The endoscope allows the operator to observe the medical instrument in the body passageway during the medical procedure without having to perform invasive general surgery on the patient. Endoscopes are used for a number of different types of procedures including, but not limited to, gastrointestinal endoscopy, bronchoscopy, cystoscopy and laparoscopy.

The elongated medical instruments used with endoscopes present a number of problems to hospitals and other health care facilities. Initially the medical instruments were designed to be reusable. Although reusing the instruments appeared to be cost effective to the hospital or health care facility, the necessary repeated cleanings and reprocessing of the reusable instruments has been a problem. The elongated structure and the inability to disassemble the medical instruments make it particularly difficult to access the channels and other areas to be cleaned within the medical instrument. In order to clean the medical instruments effectively and to take advantage of the maximum number of uses from each instrument, the health care facility must train and control the

medical personnel responsible for carrying out the extensive cleaning process. The difficulty of properly training and controlling the medical personnel responsible for cleaning and reprocessing the medical instruments lowers the confidence level in the sanitation of the instruments.

In an attempt to eliminate the problems associated with cleaning these reusable medical instruments, disposable or "single-use" medical instruments were designed. The disposable medical instruments created a number of additional problems related to the proper disposal of medical waste. The health care facility must now control the proper disposal of these disposable or "single-use" devices, which involves additional costs as well as the ecological impact of medical waste disposal. As a result of the increased medical waste and costs associated with disposal, many medical facilities began reusing the disposable or "single-use" devices. However, these disposable medical instruments are not designed for reuse and are more easily worn and damaged if used more than once, possibly causing complications during use. Additionally, properly cleaning such devices is a serious problem and concern.

One type of medical instrument commonly used with an endoscope or the like is a biopsy forceps device. The conventional biopsy forceps device includes an elongated outer body portion made of a stainless steel coil, an inner stainless steel actuation cable extending within the outer body, and a head assembly disposed at a distal end of the outer body and inner cable. The head assembly includes jaws coupled to the inner cable with a clevis and 2 links to allow the jaws to be opened and closed by movement of the inner cable relative to the outer body portion. The typical biopsy forceps head assembly is soldered or brazed to the outer body and cannot be disassembled for cleaning and/or replacement. If one component of the biopsy forceps device is damaged, the medical facility must dispose of the entire device or return the device to the manufacturer for repair. The soldering or brazing of the head assembly components also causes annealing of the stainless steel material in the outer body coil, resulting in a susceptibility to kinks and therefore decreasing the usable life of the biopsy forceps device.

Another disadvantage of the conventional biopsy forceps devices is the connection of the jaws to the clevis and two links that are used to open and close the jaws. The clevis is typically attached by being soldered or brazed to the actuation cable extending within the outer body portion. The heat generated by the soldering or brazing causes annealing in the stainless steel actuation cable, resulting in cable breakage and a decreased usable life of the biopsy forceps device. The links of the biopsy forceps device also typically become lodged with debris, causing the physician to use a greater force to operate the device and eventually damaging the device. The clevis and links also inhibit the fluid passage through the outer jacket and prevent adequate cleaning of the

device. Attempts at eliminating the clevis and links have resulted in a biopsy forceps device that is more easily damaged and not able to be reused.

Another problem with existing medical instruments is the excessive wear caused by inserting and moving the medical instrument through the instrument channel of the endoscope, which is often an articulated endoscope having a bend. Damage to the endoscopes by these medical instruments or accessories results in additional costs for repair and/or replacement of the endoscopes. When using the conventional biopsy forceps device, for example, the outer diameter of the outer jacket and head assembly as well as the length of the head assembly cause friction as the biopsy forceps device is pushed through the instrument channel of an endoscope or the like.

Accordingly, there is a need for a medical instrument that can more easily be disassembled and cleaned by flushing with a fluid and reused without being worn and damaged. There is also a need for a biopsy forceps device that is detachable from a medical instrument and that eliminates the clevis and the links used in conventional forceps devices.

SUMMARY OF THE INVENTION

The present invention features a modular medical instrument assembly comprising an elongated guide member having a proximal end and a distal end and a channel extending from the proximal end to the distal end. The modular medical instrument further comprises an inner actuation cable adapted to be slidably disposed within the channel in the elongated guide member and an instrument head assembly disposed at the distal end of the inner actuation cable and extending from the distal end of the elongated guide member. An actuator handle is adapted to be detachably coupled to the proximal end of the elongated guide member and to the proximal end of the inner actuation cable such that the actuator handle moves the inner actuation cable within the channel in the elongated guide member to actuate the instrument head assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a side view of a modular medical instrument according to one embodiment of the present invention;

FIGS. 2 and 3 are side views of an instrument device that can be used with the modular medical instrument shown in FIG. 1;

FIG. 4 is a top view of a biopsy forceps device that can be used with the modular medical

instrument of the present invention, according to one embodiment of the present invention;

FIGS. 5-6 are side views of the biopsy forceps device shown in Fig. 4 in closed and opened positions respectively;

FIG. 7 is a top view of the body of the biopsy forceps device, according to one embodiment; and

FIG. 8 is a side view of the body shown in FIG. 7.

DETAILED DESCRIPTION OF THE INVENTION

A modular medical instrument 10, Fig. 1, according to the present invention, is used with an endoscope or other similar medical device. The modular medical instrument 10 is used to perform relatively noninvasive medical procedures within a body passageway of an individual including, but not limited to, gastrointestinal endoscopy, bronchoscopy, and laparoscopy. In these applications, the modular medical instrument is used to remove tissue or other objects from within the passageway. The present invention contemplates using the modular medical instrument and the concepts of the present invention with other types of medical devices and procedures such as vascular and other procedures.

The modular medical instrument 10 comprises an elongated instrument device 12, an optional port fitting 14 detachably coupled to the instrument device 12, and an actuator handle 16 detachably coupled to the port fitting 14. The instrument device 12 includes an elongated guide member 18, an inner actuation cable 20 slidably disposed within the guide member 18, and an instrument device head assembly 22 disposed at a distal end 24 of the guide member 18 and actuation cable 20. The instrument device 12 is inserted within the instrument channel of an endoscope or similar medical device. The actuator handle 16 moves the inner actuation cable 20 within the guide member 18 to actuate the head assembly 22, which is used to perform the procedure, e.g. grasping objects, within the patient. Each of the components or sub-assemblies - the guide member 18, actuation cable 20 and head assembly 22, the port fitting 14, and the handle 16 - are detachable for cleaning and/or replacement.

The handle actuator 16 includes a handle body 26 having a thumb ring 28 coupled at one end of the handle body 26. In one embodiment, a spool sliding member 30 is slidably disposed on the handle body 26. The spool sliding member 30 is coupled to a proximal end 32 of the actuator cable 20, for example, using a clamping mechanism 34. The clamping mechanism 34 preferably includes a cable clamp 36 disposed within the spool sliding member 30 and a thumb screw 38 threadably received in the cable clamp 36 such that the proximal end 32 of the actuation cable 20 is

clamped between the cable clamp 36 and the thumb screw 38. Thus, when the spool sliding member 30 slides along the handle body 26 generally in the direction of arrows 35, the actuator cable 20 slides relative to the guide member 18 and actuates, e.g. opens/closes, the instrument head assembly 22, as will be described in greater detail below. The present invention also contemplates other types of cable clamping mechanisms. The handle body 26, thumb ring 28, and slider members 30 preferably made of a material capable of repeated sterilization using methods, such as autoclave and ETO, or by repeated soak sterilization methods. In one example, the material is a polyetherimide material sold under the name ULTEM 1000 by GE Plastics.

The modular medical instrument 10 can be assembled with or without the flush port fitting 14 detachably coupled between the handle body 26 and the guide member 18. In the preferred embodiment, a first coupling member 40 is attached to the proximal end 39 of the guide member 18, and a second coupling member 42 is attached to one end of the flush port fitting 14. When the flush port fitting 14 is used, the flush port fitting 14 is coupled to the first coupling member 40 at the proximal end 39 of the guide member 18 and the second coupling member 42 of the flush port fitting 14 is coupled to a male luer fitting 44 extending from the nose 45 of the handle body 26. When the flush port fitting 14 is not used, the first coupling member 40 at the proximal end 39 of guide member 18 is coupled directly to the luer fitting 44 at the nose 45 of the handle body 26. In the exemplary embodiment, the coupling members 40, 42 include internal threads that engage corresponding external threads on the port fitting 14 and luer fitting 44 respectively.

The flush port fitting 14 includes a flush port 46 having a coupling portion 48 that attaches to a hose or the like for supplying a fluid to the guide member 18. The guide member 18 is formed by a TFE extruded outer jacket that allows for fluids to be flushed through. The flush port 46 can be used to flush the guide member 18 with cleaning fluid, thereby facilitating cleaning of the guide member 18. The flush port 46 can also be used during the medical procedure to flush with irrigation fluids or deliver medication to a target location in the patient. A cap can be coupled to the flush port 46 when not in use. The flush port fitting 14 is preferably made of nylon or other sterilizable material, e.g. using autoclave, soak sterilization, and ETO sterilization techniques. The present invention contemplates flush port fittings having any possible shape or design.

One type of instrument device that can be used with the modular medical instrument 10 of the present invention is the biopsy forceps device 49, Figs. 2 and 3. The biopsy forceps devices 49 include jaws 50, 52 pivotably coupled to a forceps body 54. One type of biopsy forceps device 49, Fig. 2, further includes a needle 56 secured to the forceps body 54 between the jaws 50, 52. An adapter 58 is attached to the stainless steel coil of the guide member 18, for example, using a class

VI epoxy, micro-precision crimping, laser welding and/or other suitable techniques that control the amount of heat to prevent annealing in the steel coil of the guide member. The forceps body 54 is detachably coupled to the adapter 58 by threading the body 54 into the adapter 58. The biopsy forceps devices 49 of the present invention can thus easily be detached from the adapter 58 and disassembled for cleaning and/or replacement of components.

As shown in greater detail in Figs. 4-7, the jaws are directly coupled to the actuation cable 20, which preferably includes a wound four strand stainless steel cable. Wires 60, 62 from the actuation cable 20 extend through an aperture 53 in the body 54 and pass through holes 63, 65 in the tangs 64, 66 of the jaws 50, 52. Movement of the sliding member 30 relative to the handle body 26 causes the actuation cable 20 to move generally in the direction of arrow 69, thereby opening the jaws 50, 52 (Fig. 6). Moving the sliding member 30 in the opposite direction closes the jaws 50, 52.

Using a stainless steel cable 20 attached directly to the jaws 50, 52 eliminates the need for the clevis, links and rivets used in the conventional biopsy forceps devices. Furthermore, eliminating the need for brazing or soldering prevents the annealing that causes failure in the guide member 18 or actuation cable 20, increasing the useful life of the biopsy forceps device of the present invention. The present invention contemplates using these novel concepts of attaching the biopsy forceps device to the guide member 18 and actuation cable 20 with other forceps-type assemblies or other types of jaw designs.

In the biopsy forceps embodiments, the guide member 18 is preferably a stainless steel spring coil having a FEP heat shrink outer jacket. The FEP outer jacket provides containment of the fluids being flushed through the inner lumen of the guide member 18 and is able to withstand repeated reprocessing and sterilization. The FEP outer jacket also provides a smooth and lubricious surface coating that reduces friction when inserted into an endoscope instrument channel. The FEP coating as well as a reduced outer diameter of the guide member 18 improves the tactile feel or "pushability" when pushing the instrument through the instrument channel of the endoscope.

In one example, the outer diameter of the guide member 18 is .086 inches (2.2 mm) and the thickness of the FEP outer jacket is about .005 inches. In this example, each of the wires 60, 62 have a diameter of about .008 inches and extend through an aperture 53 in the body 54 having a diameter of about .040 inches and holes 63, 65 in the tangs 64, 66 having a diameter of about .0205 inches. In addition to the 2.2 mm biopsy forceps device, the present invention includes other possible sizes, e.g. a 1.8 mm size (an outer diameter of .070 inches). Eliminating the clevis and links also reduces the overall length of the head assembly further improving pushability. The preferred embodiment of the biopsy forceps device, however, has elongated the jaws 50, 52 to

increase the tissue sample size. For example, the 2.2 mm biopsy forceps device according to the preferred embodiment can obtain a maximum tissue sample of 6.0 mm^3.

One example of the forceps body 54 is shown in greater detail in Figs. 7 and 8. The forceps body 54 includes a first end 94 to which the jaws 50, 52 are pivotably coupled and a second end 96 through which the actuation cable 20 extends (Fig. 4). One example of the jaws 50, 52 is shown in greater detail in Figs. 9 and 10. The jaws are preferably made by a drawn stamped process. One example of the needle 56 used in a forceps device 12' (Fig. 2) is shown in greater detail in Fig. 11. One example of the adapter 58 attached to the guide member 18 for detachably coupling the forceps device is shown in greater detail in Fig. 12. The adapter 58 includes a threaded region 98 that threadably engages the second end 96 of the forceps body 54.

The modular medical instrument 10 can be provided in either an assembled condition ready for use or in a disassembled condition to be assembled for use. One or more of the components of the modular medical instrument 10 can also be provided separately as replacement parts.

One method for assembling the modular medical device 10 begins by coupling the second coupling member 42 of the flush port fitting 14 to the extension 44 at the nose 45 of the handle body 26. The proximal end 32 of the actuation cable 20 extending out of the proximal end 39 of the guide member 18 is inserted through an aperture in the flush port fitting 14, which centers and guides the cable 20 into the aperture 41 in the nose 45 of the handle body 26 and through the gasket fitting 43 in the nose 45. The flush port fitting 14 is then coupled to the first coupling member at the proximal end 39 of the guide member 18. The proximal end 32 of the actuation cable 20 is then inserted through the cable clamp 36, thereby positioning the actuation cable 20 in a clamping region between the cable clamp 36 and thumb screw 38 within the sliding member 30, 70. The proximal end 32 of the cable 20 is positioned to a desired location that will allow the jaws 50, 52, and the thumb screw 38 is tightened to clamp the proximal end 32 of the actuation cable 20. This process can be reversed to disassemble the modular medical instrument 10, for cleaning and/or replacing any one of the component parts. Accordingly, the modular medical instrument of the present invention can be easily disassembled to facilitate cleaning and/or replacement of any one of the component parts.

Modifications and substitutions by one ordinary skill in the art are considered to be within the scope of the present invention.

What is claimed is:

CLAIMS

1. A modular medical instrument assembly comprising:

an elongated guide member having and a channel extending from said proximal end to said distal end of said guide member;

an actuation cable adapted to be slidably disposed within said channel in said elongated guide member and having a proximal end and a distal end;

an instrument head assembly attached at said distal end of said inner actuation cable and adapted to be connected to said distal end of said elongated guide member; and

an actuator handle adapted to be coupled to said proximal end of said elongated guide member and to said proximal end of said inner actuation cable such that said actuating handle moves said inner actuation cable within said channel in said elongated guide member to actuate said instrument head assembly.

2. The modular medical instrument assembly of claim 1 further comprising a port fitting adapted to be detachably coupled between said proximal end of said elongated guide member and said actuator handle, and wherein said port fitting includes at least one flush port in fluid communication with said channel in said elongated guide member.

3. The modular medical instrument assembly of claim 1 wherein said port fitting is made of a sterilizable material, for example, nylon.

4. The modular medical instrument assembly of claim 1 wherein said actuator handle includes:

a handle body having a first end adapted to be detachably coupled to said proximal end of said elongated guide member, and having a second end, for engagement by a hand of a user; and

a sliding member adapted to be slidably disposed on said handle body, wherein said sliding member is adapted to be detachably coupled to said proximal end of said inner actuation cable, and wherein said sliding member is adapted to be engaged by said hand of said user such that relative movement between said sliding member and said handle body causes relative movement of said inner actuation cable within said channel of said elongated guide member.

5. The modular medical instrument assembly of claim 4 wherein said handle body and sliding member are made of a sterilizable material selected from the group consisting of polyetherimide and nylon.

6. The modular medical instrument assembly of claim 4 wherein said actuator handle includes a thumb ring attached to one end of said handle body.

7. The modular medical instrument assembly of claim 1 wherein said instrument head assembly includes a forceps device.

8. The modular medical instrument assembly of claim 6 wherein said forceps device includes a needle.

9. The modular medical instrument assembly of claim 6 wherein said elongated guide member includes an adapter at said distal end of said elongated guide member, and wherein said forceps device is adapted to be detachably coupled to said adapter.

10. The modular medical instrument assembly of claim 8 wherein said elongated guide member includes a stainless steel spring coil and an FEP heat shrink outer jacket disposed over said stainless steel spring coil; and wherein said adapter is attached to said stainless steel spring coil.

11. A detachable biopsy forceps device substantially as disclosed in the drawings and the specification herein.

MODULAR MEDICAL INSTRUMENT AND METHOD OF USING SAME

ABSTRACT OF THE DISCLOSURE

A modular medical instrument is used with an endoscope or other similar medical instrument to perform medical procedures, such as endoscopy, bronchoscopy, and laparoscopy. The modular medical instrument comprises an elongated instrument device, an optional port fitting detachably coupled to the instrument device, and an actuator handle detachably coupled to the port fitting. The instrument device includes an elongated guide member, an inner actuation cable slidably disposed within the guide member, and an instrument device head assembly disposed at a distal end of the guide member and actuation cable. The guide member preferably has a smooth outer surface to facilitate insertion within the instrument channel of an endoscope or similar medical device. In one example, the instrument device head assembly includes a biopsy forceps device detachably coupled to an adapter at the distal end of the guide member. The actuation cable includes first and second portions or wires extending through the forceps body and coupled to the respective jaws such that relative movement of the actuation cable with respect to the forceps body causes the jaws to open and close. Each of the components or sub-assemblies of the modular medical instrument are detachable for cleaning and/or replacement.

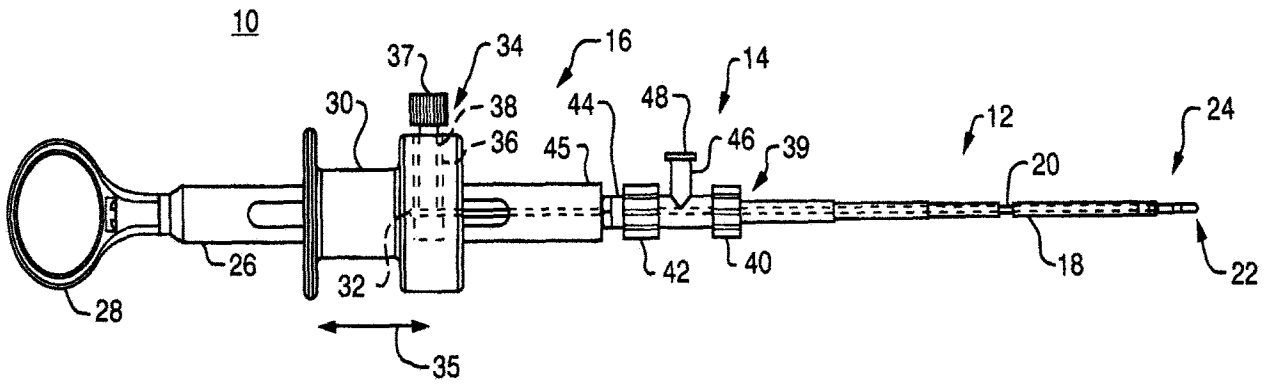


FIG. 1

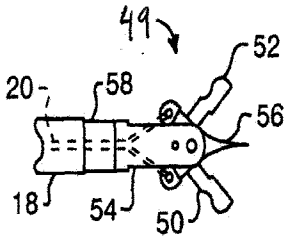


FIG. 2

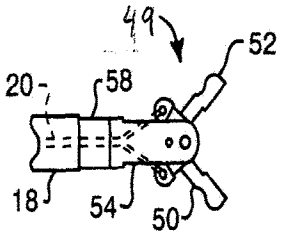


FIG.3

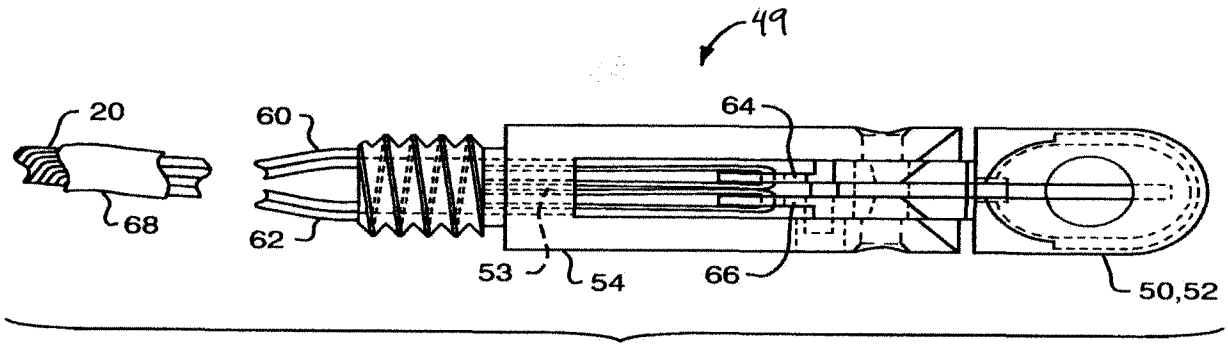


FIG. 4

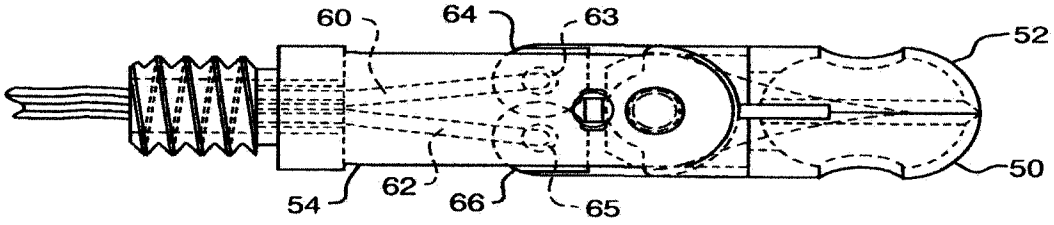


FIG. 5

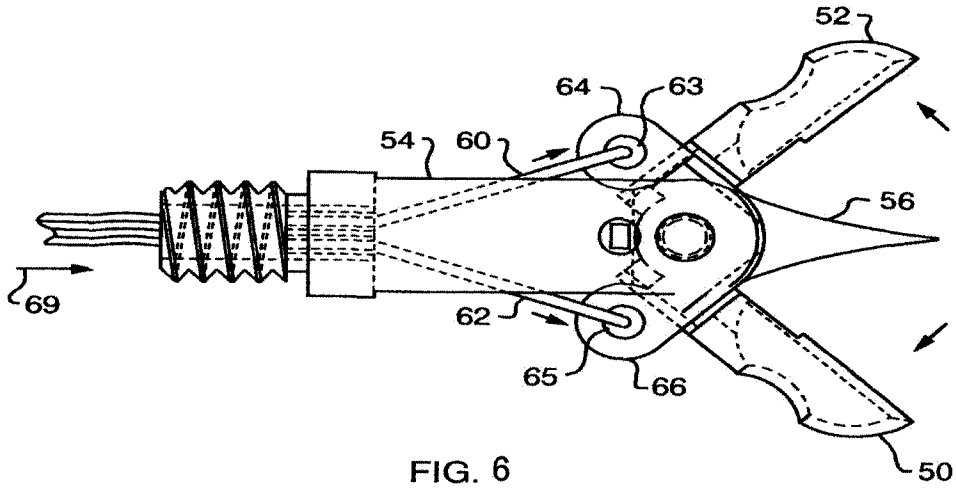


FIG. 6

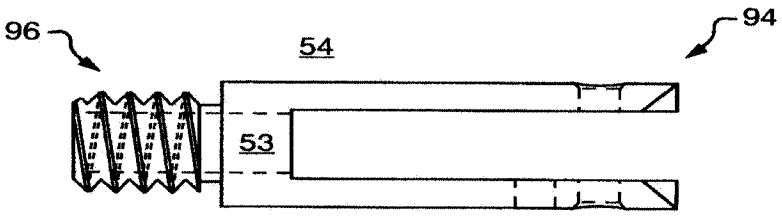


FIG. 7

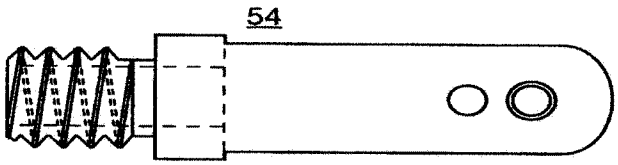


FIG. 8

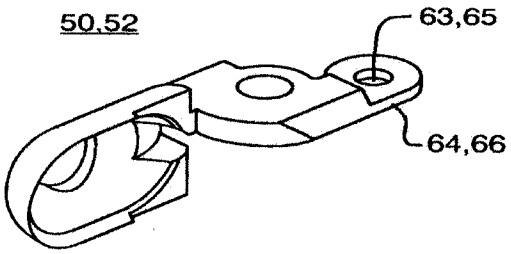


FIG. 9

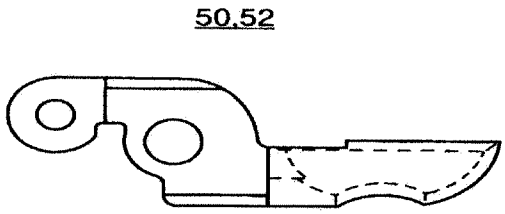


FIG.10

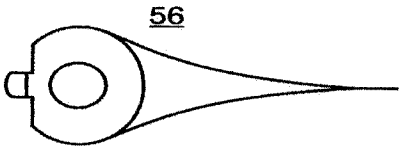


FIG.11

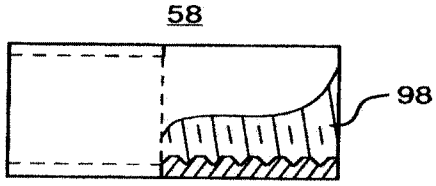


FIG. 12

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
01/111,111	08/07/99	Garciaparra, et al.	MED-001XX

EXAMINER	
Carroll	
ART UNIT	PAPER NUMBER
999	3

DATE MAILED: 04/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
01/111,111	Garciaparra et al.
Examiner	**Group Art Unit**
Carroll	999

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Objections

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1). The handle or sliding member made of nylon, as recited in claim 5, has no support in the specification.

2. The specification is objected to because there is no brief description of FIGS. 9-12. See 37 CFR 1.74.

Claim Rejections – 35 USC § 112, 2nd para.

3. Claims 1-11 are rejected under 35 USC § 112, 2nd paragraph as being indefinite and incomplete in not defining a complete article of manufacture. The elements in claim 1 are recited without present cooperation. The language such as "adapted to be connected" is futuristic and conditional. The language of the claim is directed to assembly to take place in the future, and no positive structural relationships are recited.

In claim 1, line 2, "elongated guide member having and a channel" is unclear. Also, on lines 2-3 of claim 1 "said proximal end" and "said distal end" lack antecedent basis and on line 9 of claim 1 "said inner actuation cable" and "said actuating handle" lack antecedent basis.

Regarding claim 3, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. Also, "said port fitting" in claim 3 lacks antecedent basis.

Claim 11 is an omnibus claim and fails to point out what is included or excluded by the claim language.

Allowable Subject Matter

4. Claims 1-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. Regarding claim 11, a detachable forceps device appears to distinguish over U.S. Pat. No. 5,820,630 to Lind in that the biopsy device of Lind does not have a threaded body that is detachable from the coil 30.

5. Any inquiry concerning this communication from the examiner should be directed to Examiner Carroll.

K. Carroll 4-6-00
Primary Examiner

KC

FORM PTO-1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. MED-001XX	Serial No. 01/111,111
	Applicants Garciaparra, et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))	Filing Date 08/07/99	Group 999

U.S. PATENT DOCUMENTS

EXAMINERS INITIALS		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
RJC		5,820,630	10-13-98	Lind	606	208	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION yes	TRANSLATION no

OTHER DOCUMENTS (Including Author, Title, Date**, Relevant Pages, Place of Publication***)

EXAMINER RJC	DATE CONSIDERED 4-6-00

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

US005820630A

United States Patent [19]

Lind

[11] Patent Number: 5,820,630

[45] Date of Patent: Oct. 13, 1998

[54] **MEDICAL FORCEPS JAW ASSEMBLY**

[75] Inventor: **Stuart J. Lind**, Edina, Minn.

[73] Assignee: **Annex Medical, Inc.**, Eden Prairie, Minn.

[21] Appl. No.: **735,239**

[22] Filed: **Oct. 22, 1996**

[51] **Int. Cl.**[6] **A61B 17/28**

[52] **U.S. Cl.** **606/208**; 606/205; 128/751

[58] **Field of Search** 128/751, 752; 606/205, 206, 208, 142, 119; 604/22; 600/221; 81/416

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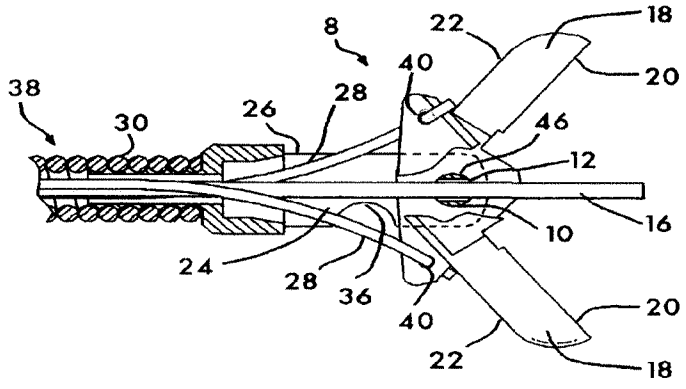
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Primary Examiner—Michael H. Thaler

[57] **ABSTRACT**

A medical forceps jaw assembly for obtaining biopsy specimens or grasping objects. The forceps has a jaw assembly which incorporates a clevis pivot. The clevis pivot has a cross hole which is parallel to the center line of the jaw assembly. This cross hole, along with the lumens of the clevis and the shaft comprise a passageway. A diagnostic or procedural member can be passed through this passageway. By incorporating the diagnostic or procedural member into the passageway of the medical forceps, the need for two separate devices is eliminated for procedures which require both. By locating the cross hole appropriately in the clevis pivot, the diagnostic or procedural member can be centered between the two jaws. When used with an endoscope, the device allows two functions to be simultaneously accomplished using an endoscope with only one working channel. The design of the device is simple and cost effective.

20 Claims, 1 Drawing Sheet



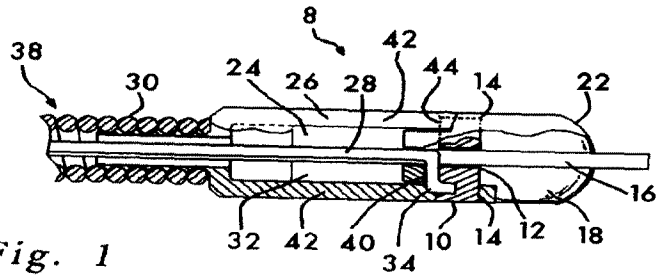


Fig. 1

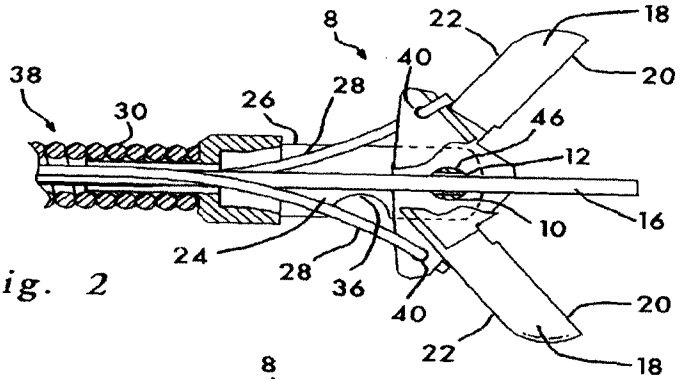


Fig. 2

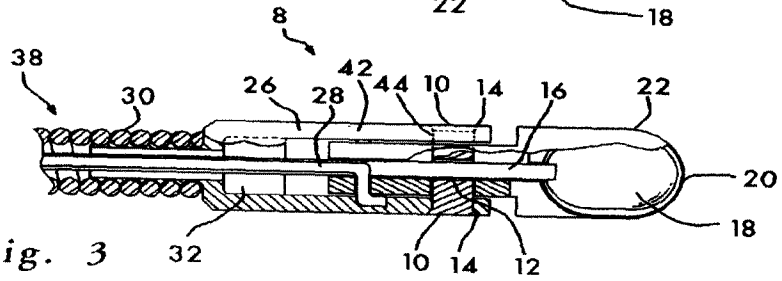


Fig. 3

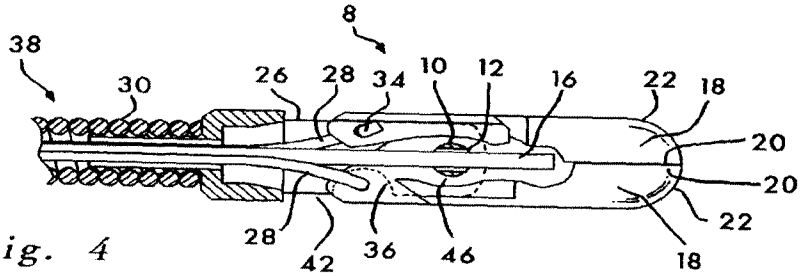


Fig. 4

MEDICAL FORCEPS JAW ASSEMBLY

BACKGROUND-FIELD OF INVENTION

This invention relates to biopsy forceps, specifically to such forceps which incorporate a passageway for diagnostic or procedural instrumentation.

BACKGROUND-DESCRIPTION OF PRIOR ART

When making an endoscopic examination of tissue in a particular site in a patient's body, it is common for the physician to take a tissue sample from that site for analysis. A number of different types of biopsy forceps for taking a small tissue sample are in use. Typically, such biopsy forceps consist of a small diameter flexible shaft which can be passed through the lumen of an endoscope. Attached to the distal end of this shaft is a pair of sharp jaws which can be opened and closed to cut and hold a small tissue sample for analysis. The opening and closing of the jaws is controlled manually by manipulating controls located at the proximal end of the shaft. One design of the jaw assembly incorporates a clevis pivot about which the two jaws rotate. Another design is for the two jaws to be hinged at their proximal end. The clevis pivot design allows the jaws to be closed with a greater closing force than designs which incorporate a hinge.

One example of a biopsy forceps which incorporates a hinge may be seen with reference to U.S. Pat. No. 5,172,700 to Bencini et al. Examples of biopsy forceps which incorporate a clevis pivot may be seen with reference to U.S. Pat. No. 4,721,116 to Schintgen et al., U.S. Pat. No. 4,887,612 to Esser et al., U.S. Pat. No. 5,133,727 to Bales et al., U.S. Pat. No. 5,228,451 to Bales et al., U.S. Pat. No. 5,238,002 to Devlin et al., and U.S. Pat. No. 5,325,866 to Krzyzanowski. None of the above referenced patents disclose a device for which a passageway exists which would allow passage of diagnostic or procedural instrumentation through the shaft and jaw assembly of the device.

Biopsy forceps which incorporate a hinge design have been made which will allow passage of diagnostic or procedural instrumentation through the shaft and jaw assembly of the device. Examples can be seen with reference to U.S. Pat. No. 5,373,854 to Kolozsi, and U.S. Pat. No. 5,471,992 to Banik et al. However, the hinged design of these devices results in less jaw closing force than devices which have a clevis pivot design.

For certain procedures, it may be necessary or desirable for the physician to use a second device in conjunction with the biopsy forceps for diagnostic or procedural purposes. With the prior art biopsy forceps which incorporate a clevis pivot, this requires an endoscope which has two working channels: one for the biopsy forceps and one for the second diagnostic or procedural device. An endoscope with two working channels has the disadvantage of having greater shaft diameter, which may inhibit its passage into narrow body channels. Additionally, the need to use an endoscope with two working channels for some procedures may require the physician to have available both one and two channel endoscopes.

It may also be desirable for the diagnostic or procedural device to actually pass through the biopsy forceps. Examples of this feature are a guidewire over which the biopsy forceps is placed to help guide the forceps to the proper location, or a device which could be used to verify the presence and size of the biopsy sample after it is secured in the jaws. With the prior art biopsy forceps which incorporate a clevis pivot, this would not be possible.

OBJECTS AND ADVANTAGES

Accordingly, several objects and advantages of the present invention are:

(a) to provide a novel biopsy forceps which incorporates a passageway for extending diagnostic or procedural instrumentation through the shaft and jaw assembly of the device, thus making the simultaneous use of two devices through an endoscope with only one working channel possible;

(b) to provide a novel biopsy forceps of the type described herein which uses a mechanism, such as a clevis pivot, which provides the jaws of the forceps with the greatest possible force for closing the jaws, thus providing effective sample retrieval.

(c) to provide a novel biopsy forceps of the type described herein, for which the diagnostic or procedural instrumentation can be centered between the jaws;

(d) to provide a novel biopsy forceps of the type described herein, for which diagnostic or procedural instrumentation can be incorporated into the device, thus eliminating the need for a second, separate device;

Further objects and advantages are to provide a biopsy forceps of the type described herein which is of simple design, is simple and inexpensive to manufacture, and is easy to use. Still further objects and advantages will become apparent from a consideration of the ensuing description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view, partly in section, of the jaw assembly with its jaws in the open position.

FIG. **2** is a side elevational view, partly in section, of the jaw assembly shown in FIG. **1** with its jaws in the open position.

FIG. **3** is a plan view, partly in section, of the jaw assembly with its jaws in the closed position.

FIG. **4** is a side elevational view, partly in section, of the jaw assembly shown in FIG. **3** with its jaws in the closed position.

REFERENCE NUMERALS IN DRAWINGS

8 jaw assembly	28 pull wires
10 clevis pivot	30 coil
12 cross hole	32 slot
14 flare	34 angled bends
16 elongated diagnostic or procedural member	36 notch
18 cup	38 shaft
20 sharp rim	40 engagement hole
22 jaw	42 clevis arm
24 passageway	44 clevis arm hole
26 clevis	46 jaw pivot hole

Description-FIGS. **1** to **4**

A typical embodiment of the biopsy forceps jaw assembly of the current invention is illustrated in FIGS. **1** and **3** (top view) and FIGS. **2** and **4** (side view). The biopsy forceps has a shaft **38**, constructed of a steel coil **30**, polymeric tubing, or other flexible material which has a lumen through its entire length. A suitable control mechanism (not shown) is located at the proximal end of shaft **38**, from which the control of the device is effected by the user. A jaw assembly **8** is located at the distal end of shaft **38**, and consists of a clevis **26**, two jaws **22**, and a clevis pivot **10**. The proximal end of clevis **26** is attached to the distal end of shaft **38**. Clevis **26** may be threaded, allowing it to be screwed into

coil **30**, which may comprise shaft **38**, or clevis **26** may be attached to shaft **38** by other similar means. Clevis **26** has two clevis arms **42** which are located at the distal of clevis **26**. Between clevis arms **42** is a slot **32**. Clevis **26** has a lumen extending from its proximal end to slot **32**. Located near the distal end of each clevis arm **42** is a clevis arm hole **44**. Jaws **22** each have a jaw pivot hole **46**. The proximal ends of both jaws **22** are located in slot **32**. Jaws **22** are attached to clevis **26** by means of clevis pivot **10**, which passes through each of the two jaw pivot holes **46** and each of the two clevis arm holes **44**. Clevis pivot **10** has a flare **14** at each end, securing it and jaws **22**, in place. Each jaw **22** has a cup **18** located at its distal end. The open portions of the two cups **18** face each other. Each cup **18** has a sharp rim **20**, which at minimum is located on the distal portion of each cup **18**, and may extend completely around the edge of each cup **18**. Referring to FIG. **4**, which shows jaws **22** in the closed position, sharp rims **20** of the two cups **18** are aligned so as to meet. The two cups **18** thus form a closed space between them.

The control mechanism (not shown) is connected to the proximal ends of a pair of pull wires **28**, which pass through shaft **38** and the proximal portion of clevis **26**. Pull wires **28** do not fill the lumen of shaft **38** nor the proximal end of clevis **26**. The distal end of one of the pull wires **28** passes through an engagement hole **40** located near the proximal end of one jaw **22**. Similarly, the distal end of the other pull wire **28** passes through an engagement hole **40** located near the proximal end of the other jaw **22**. At the distal end of each pull wire **28** are located two angled bends **34**. For each of the two pull wires **28**, one of the angled bends **34** is located on each side of respective engagement hole **40**, attaching each pull wire **28** to its respective jaw **22**. A notch **36** is located on each clevis arm **44**. Clevis pivot **10** has an opening, or cross hole **12**, through it, parallel to shaft **38**. Thus a passageway **24** exists which extends from the distal portion of clevis pivot **10** proximally through clevis **26** and shaft **38**. An elongated diagnostic or procedural member **16** can be passed through shaft **38**, clevis **26**, and cross hole **12**. In one embodiment of the biopsy forceps, elongated diagnostic or procedural member **16** is a separate device. In another embodiment, elongated diagnostic or procedural member **16** is a component of the biopsy forceps.

From the description above, a number of advantages of my biopsy forceps become evident:

(a) A diagnostic or procedural member can be passed through the shaft and jaw assembly of the biopsy forceps and into the jaw area. This eliminates the need to for a two channel endoscope when certain diagnostic or procedural instrumentation is used in conjunction with the biopsy forceps.

(b) The biopsy forceps uses a mechanism, such as a clevis pivot, which provides the jaws of the forceps with the greater force for closing the jaws than a hinged design, thus providing effective sample retrieval.

(c) By locating the cross hole appropriately in the clevis pivot, the diagnostic or procedural member can be centered between the two jaws.

(d) The diagnostic or procedural instrumentation can be incorporated into the biopsy forceps, eliminating the need for a second separate device.

(e) The design is simple and involves a minimum of components, which makes the device easy and inexpensive to manufacture.

Operation-FIGS. **2**, **4**

Referring to FIG. **4**, the biopsy forceps is shown with jaws **22** in the closed position and the distal end of elongated diagnostic or procedural member **16** retracted to the proximal end of two cups **18**. In this closed position, the distal portion of the biopsy forceps is advanced, usually through the working channel of an endoscope, to the tissue of which a sample is desired. This advancement is accomplished by manipulating the device from the proximal end of shaft **38**.

Referring to FIG. **2**, jaws **22** are then opened by manipulating the control mechanism (not shown) at the proximal end of shaft **38** in such a way that pull wires **28** are advanced distally through shaft **38** toward jaw assembly **8**. Jaws **22** are prevented from moving distally by clevis pivot **10** which attaches jaws **22** to clevis **26**. Thus, advancing pull wires **28** distally causes jaws **22** to rotate about clevis pivot **10**. As a result, cups **18** are propelled away from each other, more so at the distal end than the proximal end. If desired, elongated diagnostic or procedural member **16** can be extended distally past the distal end of open jaws **22**. In one embodiment of the invention, this may be done manually. In another embodiment, elongated diagnostic or procedural member **16** may be manipulated by the control mechanism (not shown), and possibly advanced automatically as jaws **22** are opened. The device is then advanced, by manipulation at the proximal end of shaft **38**, so that jaws **22**, and more particularly sharp rims **20**, are pushed against the tissue surface.

Referring to FIG. **4**, jaws **22** are then closed by manipulating the control mechanism (not shown) at the proximal end of shaft **38** in such a way that pull wires **28** are pulled proximally through shaft **38** away from jaw assembly **8**. This causes jaws **22** to rotate about clevis pivot **10**, resulting in cups **18** being propelled toward each other. The distal end of each pull wire **28**, beyond the angled bends **34**, fits into notch **36**. If desired, elongated diagnostic or procedural member **16** can be retracted proximally toward the proximal end of cups **18**. In one embodiment of the invention, this may be done manually. In another embodiment, elongated diagnostic or procedural member **16** may be manipulated by the control mechanism (not shown), and possibly retracted automatically as jaws **22** are closed. As the jaws close, sharp rims **20** of cups **18** cut into the tissue. As sharp rims **20** meet each other, the tissue sample becomes separated from the tissue and is held between the closed cups **18**. The device can then be removed from the patient, maintaining enough force on the control mechanism, and thus pull wires **28**, to keep jaws **22** closed in order to retain the tissue sample in cups **18**. The jaw assembly **8** has a diameter less than four millimeters in the closed position.

Summary, Ramifications, and Scope

Accordingly, the reader will see that the biopsy forceps of this invention provides a device which uses a clevis pivot and incorporates a passageway through the shaft and jaw assembly. This biopsy forceps allows a second device, such as a diagnostic or procedural member, to be passed through the passageway. This makes possible the simultaneous use of two devices through an endoscope having only one working channel. Furthermore, this biopsy forceps has the additional advantages in that

- the clevis pivot design allows the jaws to be closed with a significant amount of force, providing effective sample retrieval;
- the second device can be incorporated into the biopsy forceps, eliminating the need for two separate devices;
- the diagnostic or procedural member can be centered between the two jaws; and
- the simple design makes it easy and inexpensive to manufacture.

Although the description above contains many specificities, these should not be construed as limiting the scope of the invention, but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, the elongated member may be a guide wire over which the biopsy forceps could be passed, as in vascular applications; the elongated member may be a diagnostic device which could, for example, verify the presence and size of a biopsy sample the elongated member may be a catheter; the device may be a medical forceps used for purposes other than obtaining a biopsy sample, such as grasping a foreign object; one of the jaws could be fixed in place, with only one jaw rotating about the clevis pivot; a single pull wire could be used; the rims of the jaws may be serrated the clevis pivot pin may be a threaded screw, etc.

Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.

I claim:

1. A medical forceps jaw assembly comprising:

a clevis having a pivot; pin

a first jaw pivotally attached to said clevis by said clevis pivot pin, said first jaw having a limited rotation around said clevis pivot pin;

a second jaw which opposes said first jaw;

an opening through said clevis pivot pin said opening allows passage substantially along the center line of said jaw assembly;

a drive member which is used to actuate at least one of said jaws, said drive member is capable of movement between a first proximal position and a second distal position which effects opening or closing between said jaws;

an elongated member for diagnostic or procedural purposes with a center line substantially parallel to the center line of said jaw assembly, said elongated member passes through said opening in said clevis pivot pin whereby incorporation of said elongated member into said jaw assembly allows an additional diagnostic or procedural function to be performed by said medical forceps.

2. The medical forceps jaw assembly of claim **1** wherein each said jaw has a cup with a sharp rim for taking biopsy samples.

3. The medical forceps jaw assembly of claim **1** wherein each said jaw is a gripper.

4. The medical forceps jaw assembly of claim **1** wherein said drive member is a pair of pull wires, each of which has at least one angled bend at the distal end for engagement with said jaws.

5. The medical forceps jaw assembly of claim **1** wherein said clevis pivot pin is circular.

6. The medical forceps jaw assembly of claim **1** wherein said clevis pivot pin has a threaded portion.

7. The medical forceps jaw assembly of claim **1** wherein said elongated member is a guidewire.

8. The medical forceps jaw assembly of claim **1** wherein said elongated member is a catheter.

9. The medical forceps jaw assembly of claim **1** wherein said elongated member is a diagnostic probe.

10. The medical forceps jaw assembly of claim **1** wherein said jaw assembly has a diameter less than four millimeters in the closed position.

11. A medical forceps jaw assembly comprising:

opposed jaws, said jaws each having a distal and a proximal end;

an actuation means engaged at the proximal portion of at least one of said jaws to effect opening and closing movement at the distal portion of said jaws;

a clevis including a pivot pin having a cross hole approximately parallel to the center line of said jaw assembly, at least one of said jaws pivotally attached to said clevis by said pivot pin;

a passageway extending between the proximal portion of said jaws and through said clevis pivot pin, cross hole, whereby said passageway allows incorporation of an elongated member for diagnostic or procedural purposes.

12. The medical forceps jaw assembly of claim **11** wherein each said jaw has a cup with a sharp rim for taking biopsy samples.

13. The medical forceps jaw assembly of claim **11** wherein each said jaw is a gripper.

14. The medical forceps jaw assembly of claim **11** wherein said actuation means is a pair of pull wires, each of which has at least one angled bend at the distal end for engagement with said jaws.

15. The medical forceps jaw assembly of claim **11** wherein said clevis pivot pin is circular.

16. The medical forceps jaw assembly of claim **11** wherein said clevis pivot pin has a threaded portion.

17. The medical forceps jaw assembly of claim **11** further including a guidewire within said passageway.

18. The medical forceps jaw assembly of claim **11** further including a catheter within said passageway.

19. The medical forceps jaw assembly of claim **11** further including a diagnostic probe within said passageway.

20. The medical forceps jaw assembly of claim **11** wherein said jaw assembly has a diameter of less than four millimeters in the closed position.

* * * * *