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(54) Title: ENDOSCOPIC BIPOLAR MULTIPLE SAMPLE BIOPTOME <div data-bbox="295 1265 1316 1556" data-label="Image"> </div>		
(57) Abstract <p>An endoscopic bipolar bioptome includes a conductive flexible member (16) having a lumen with an axially displaceable conductive wire (18) extending therethrough and covered with an insulating sheath (19). The proximal ends of the flexible member (16) and the wire (18) are coupled to a manual actuation device (12) for displacing one of the wires (18) and the member (16) with respect to the other. The manual actuation device (12) is provided with bipolar electrical couplings for coupling one pole to the wire (18) and the other pole to the flexible member (16). The distal end of the flexible member (16) is connected to a partially conductive cylinder (40) and the distal end of the wire (18) is coupled to a jaw assembly (14).</p>		

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ENDOSCOPIC BIPOLAR MULTIPLE SAMPLE BIOPTOME

This application is related to co-owned applications Serial Number 08/189,937 filed Feb. 1, 1994, Serial Number 08/265,217 filed Jun. 24, 1994, Serial Numbers 08/440,326 and 08/440,327 both filed May 12, 1995, all of which are both hereby incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to endoscopic surgical instruments. More particularly, this invention relates to an instrument for taking multiple biopsy tissue samples and which is provided with bipolar cautery capability.

2. State of the Art

Endoscopic biopsy procedures are typically performed with an endoscope and an endoscopic biopsy forceps device (bioptome). The endoscope is a long flexible tube carrying fiber optics and having a narrow lumen through which the bioptome is inserted. The bioptome typically includes a long flexible coil having a pair of opposed jaws at the distal end and manual actuation means at the proximal end. Manipulation of the actuation means opens and closes the jaws. During a biopsy tissue sampling operation, the surgeon guides the endoscope to the biopsy site while viewing the biopsy site through the fiber optics of the endoscope. The bioptome is inserted through the narrow lumen of the endoscope until the opposed jaws arrive at the biopsy site. While viewing the biopsy site through the fiber optics of the endoscope, the surgeon positions the jaws around a tissue to be sampled and manipulates the actuation means so that the jaws close around the tissue. A sample of the tissue is then cut and/or torn away from the biopsy site while it is trapped between the jaws of the bioptome. Keeping the jaws closed, the surgeon withdraws the bioptome from the endoscope and then opens the jaws to collect the biopsy tissue sample.

A biopsy tissue sampling procedure often requires the taking of several tissue samples either from the same or from different biopsy sites. Unfortunately, most bioptomes are limited to taking a single tissue sample, after which the device must be withdrawn from the endoscope and the tissue collected before the device can be used again to take a second tissue sample. The single-sample limitation of most bioptomes is due to the limited space between the biopsy forceps jaws. Several attempts have been made to provide an instrument which will allow the taking of several tissue samples before the instrument must be withdrawn and the samples collected. Problems in providing such an instrument include the extremely small size required by the narrow lumen of the endoscope and the fact that the instrument must be flexible in order to be inserted through the lumen of the endoscope.

Co-owned application Serial No. 08/189,937 discloses an endoscopic multiple sample bioptome which includes a relatively long flexible member having a lumen with an axially displaceable wire extending therethrough. The proximal ends of the flexible member and wire are coupled to a manual actuation means for axially displacing one of the flexible member and wire relative to the other. The distal end of the flexible member is coupled to either a cylinder preferably having a knife sharp distal edge, or a jaw assembly. The distal end of the wire is coupled to the other of the cylinder and the jaw assembly. The jaw assembly includes a pair of opposed toothed jaw cups each of which is coupled by a narrow arm to a base member. The narrow arm of each jaw is preferably formed from Nitinol as described in Serial Numbers 08/440,326 and 08/440,327 and is arranged to urge the jaws away from each other. The base member of the jaw assembly is mounted inside the cylinder and axial movement of one of the jaw assembly and cylinder relative to the other draws the necks of the jaws into the cylinder or moves the cylinder over the necks of the jaws to bring the jaw cups together in a biting action.

Clearly, where traumatic procedures such as taking a biopsy are being conducted, the ability to conduct endoscopic cautery procedures is desirable in order to stem bleeding. While both monopolar and bipolar endoscopic cautery instruments are known (such as disclosed in U.S. Patent #4,418,692 to Guay), increasingly, bipolar cautery is preferred because it is less traumatic to the patient. In bipolar cautery instruments, the electric current path is from one electrode, through the tissue to be cauterized, and then through to the other electrode and out of the instrument. Thus, cauterization is limited to only that tissue between the two electrodes. On the other hand, in monopolar instruments, the patient effectively becomes the second electrode, and the cautery current is dissipated through the patient. In the monopolar situation, control of the cautery location is not exact, and tissue surrounding the tissue to be cauterized is also subject to different degrees of cautery.

In U.S. Patent #4,763,660 to Jaeger, a bipolar endoscopic microelectrocautery device is shown. The Jaeger patent also discloses a device for obtaining biopsies. However, the device disclosed in Jaeger requires a number of different single function "instrument heads" only one of which may be attached at any time to the instrument for performing a specific function such as grasping, cutting, or cauterizing. Thus, the biopsy forceps "head", is incapable of cauterizing, while the cauterizing "head" is incapable of obtaining a biopsy. This arrangement does not permit the surgeon to cauterize at the biopsy site at the time of taking a biopsy.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an endoscopic multiple sample bioptome which has bipolar cautery capability.

It is also an object of the invention to provide an endoscopic bipolar multiple sample bioptome which has all of the

advantages of traditional biopsy forceps with the added abilities to collect multiple samples and to apply bipolar cautery.

In accord with these objects which will be discussed in detail below, the endoscopic bipolar multiple sample biptome of the present invention includes a relatively long conductive flexible member having a lumen with an axially displaceable conductive wire extending therethrough which is covered with an electrically insulating sheath. The proximal ends of the flexible member and wire are coupled to a manual actuation means for axially displacing one of the flexible member and wire relative to the other and the manual actuation means is provided with bipolar electrical coupling means for electrically coupling one pole of a current source to the flexible member and the other pole of the current source to the wire. The distal end of the flexible member is mechanically and electrically coupled to one of a partially conductive cylinder having a distal edge and a conductive jaw assembly. The distal end of the wire is mechanically and electrically coupled to the other of the cylinder and the jaw assembly. The jaw assembly includes a pair of opposed jaw cups each of which is coupled by a narrow arm to a base member. The narrow arm of each jaw is a resilient member which urges each jaw away from the other. The base member of the jaw assembly is mounted inside the cylinder and axial movement of one of the jaw assembly and cylinder relative to the other draws the necks of the jaws into the cylinder or moves the cylinder over the necks of the jaws to bring the jaw cups together in a biting action. The partially conductive cylinder has a substantially non-conductive interior and portions of its exterior surface are conductive. When a source of cautery current is coupled to the bipolar couplings in the manual actuation means, cautery current flows between the jaw assembly and the conductive portion(s) of the cylinder. Since the interior of the cylinder is non-conductive, there is no short circuit caused by the interior of the cylinder embracing the necks of the jaw assembly.

Preferred aspects of the invention include: forming the flexible member as a coil; coupling the cylinder to the distal end of the coil; forming the jaw assembly from Nitinol; providing teeth on the jaw cups; coupling the jaw assembly to the axially displaceable wire; and providing both the wire and the coil with respective insulating sheaths along substantially their entire lengths. According to one embodiment of the invention, the cylinder is formed from a ceramic material and plated with electrically conductive traces which extend from its coupling with the coil to its distal edge. According to another embodiment, the cylinder is formed from anodized aluminum. A portion of the outer surface of the cylinder is masked before the cylinder is anodized to render the unmasked portions non-conductive.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a broken, transparent side elevation view in partial section of a first embodiment of a bipolar multiple sample bioptome according to the invention;

Figure 2 is an enlarged transparent side elevation view of the distal end of the bioptome of Figure 1 with the jaws open;

Figure 3 is an enlarged transparent side elevation view of the distal end of the bioptome of Figures 1 and 2 with the jaws closed;

Figure 4 is an enlarged side elevation view of the distal end of the bioptome of Figures 1-3 with the jaws closed;

Figure 5 is an enlarged top view of the distal end of the bioptome of Figures 1-4 with the jaws closed;

Figure 6 is an enlarged transparent side elevation view of the distal end of a second embodiment of a bipolar multiple sample bioptome according to the invention with the jaws in an open position;

Figure 7 is an enlarged transparent top view of the distal end of the bioptome of Figure 6; and

Figure 8 is an enlarged transparent side elevation view of the distal end the bioptome of Figures 6 and 7 with the jaws in a closed position .

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figures 1 through 5, the bipolar multiple sample bioptome 10 includes a proximal handle 12 and a distal end effector 14. A long flexible electrically conductive coil 16 having an axially displaceable control wire 18 extending therethrough couples the handle 12 and the end effector 14. The coil 16 is preferably covered with a non-conductive PTFE, FEP or polyethylene sheath 15 along substantially all of its length except for its proximal end 16a and its distal end 16b. A strain relief sleeve 17 preferably covers a portion of the coil 16 which extends from the handle 12. The control wire 18 is preferably covered with an electrically non-conductive sheath 19 substantially all of its length except for its proximal end 18a and its distal end 18b. The proximal handle 12 includes a central shaft 20 and a displaceable spool 22. The proximal end of the shaft 20 is provided with a thumb ring 24 and a longitudinal bore 26 is provided at the distal end of the shaft 20. A longitudinal slot 28 extends from the proximal end of bore 26 to a point distal of the thumb ring 24. The proximal end 16a of the coil 16 is mounted in the bore 26 and a radially engaging electrical connector 27 contacts the uninsulated end 16a of the coil 16. The displaceable spool 22 is provided with a cross member 30 which passes through the slot 28 in the central shaft 20. The cross member 30 is provided with a central through hole 32 and a radially engaging set screw 34 having an electrical

connector 35. The uninsulated proximal end 18a of the control wire 18 is engaged by the set screw 34. From the foregoing, those skilled in the art will appreciate that relative movement of the shaft 20 and spool 22 results in movement of the control wire 18 relative to the coil 16. Such action results in actuation of the end effector 14 as described in detail below.

Turning now to Figures 2 through 5, the end effector 14 includes a partially conductive cylindrical sleeve 40 having a (preferably sharp) distal edge 42, and a conductive jaw assembly 44. The jaw assembly 44 includes a pair of opposed jaw cups 46a, 46b each preferably having a plurality of sharp teeth 48a, 48b. A resilient, preferably narrow, arm 50a, 50b extends proximally from each jaw cup 46a, 46b. A cylindrical base member 52 joins the proximal ends of the arms 50a, 50b. The narrow resilient arms 50a, 50b are biased apart from each other, thereby urging the jaw cups 46a, 46b apart. According to a preferred embodiment of the invention, the cylindrical base member 52 of the jaw assembly 44 is mechanically and electrically coupled to the uninsulated distal end 18b of the control wire 18 by providing the base member 52 with a lateral hole 53 and providing the distal end 18b of the control wire with a substantially right angle bend. The distal end 18b of the control wire 18 is soldered or otherwise electrically and mechanically attached in the hole 53 in the base member 52. The cylindrical sleeve 40 is coupled to the uninsulated distal end 16b of the coil 16 by crimping and/or soldering. According to this embodiment of the invention, the partially conductive sleeve 40 has a first conductive area in the form of a ring 41 near the distal edge 42 and a second conductive area in the form of a longitudinal stripe 43 which extends from the ring 41 to the proximal end of the sleeve 40. The proximal end 43a of the stripe 43 is electrically coupled to the distal end 16b of the coil 16, preferably by soldering. Optionally, a third conductive area 45 is provided on the proximal edge and interior of the proximal end of the sleeve 40 and makes electrical contact with the distal end 16b of the coil 16. It will be appreciated that the conductive ring 41 is

therefore electrically coupled to the coil 16 via the stripe 43, and optionally the third conductive area 45.

From the foregoing description those skilled in the art will appreciate that when the spool 22 and the shaft 20 are axially displaced relative to each other, the cylindrical sleeve 40 and the jaw assembly 44 are similarly axially displaced relative to each other, from the positions shown in Figure 2 to the positions shown in Figure 3 and vice versa. It will also be appreciated that when the spool 22 and shaft 20 are in the approximate position shown in Figure 1, the cylindrical sleeve 40 and the jaw assembly 44 will be in the approximate position shown in Figure 2; i.e., with the jaws open. Thus, those skilled in the art will further appreciate that when the spool 22 is moved towards the thumb ring 24, or vice versa, the cylindrical sleeve 40 and the jaw assembly 44 will be brought into the approximate position shown in Figure 3 by movement of the jaws into the sleeve, thereby closing the jaws.

It will also be understood that one pole of a bipolar cautery source (not shown) which is coupled to the electrical connector 27 will be electrically coupled to the ring 41 on the sleeve 40 via the coil 16 and another pole of the bipolar cautery source which is coupled to the electrical connector 35 will be electrically coupled to the jaws 46a, 46b via the control wire 18. Since the jaw assembly 44 never comes in contact with the conductive portions 41, 43, 45 of the sleeve 40 (ring 41 being separated from the jaws by the non-conductive distal edge 42) and since the control wire 18 is insulated from the coil 16 by the sheath 19, short circuits are avoided during all phases of the biopsy procedure. When cautery current is supplied to the end effector assembly 14, if tissue is present at the edge 42, current passes between the conductive ring 41 and the arms 50a, 50b or the jaws 46a, 46b via the tissue (not shown) depending on the position of the jaw assembly 44 relative to the sleeve 40.

According to one embodiment of the invention, the sleeve 40 is made of a non-conductive ceramic material and the conductive

areas 41, 43, and optionally 45 are applied by tracing with a conductive material. For example, the conductive material may be applied by vapor deposition, thermal spray, or other means of metalization onto a ceramic sleeve where the sleeve is first masked to cover areas which will remain non-conductive.

According to another embodiment of the invention, sleeve 40 is made of aluminum which is then anodized. Prior to anodizing the sleeve, portions of the sleeve are masked so that they will remain conductive after the unmasked portions of the sleeve are anodized.

Turning now to Figures 6-8, according to a second embodiment of the invention, an end effector assembly 114 is coupled to the distal ends of the coil 16 and control wire 18. The end effector assembly 114 is similar to the end effector assembly 14 described above in that it includes a cylindrical sleeve 140 and a jaw assembly 144. The jaw assembly 144 is substantially the same as the jaw assembly 44 described above, with similar reference numerals indicating similar parts. In this embodiment, however, the cylindrical base 152 of the jaw assembly 144 is mechanically and electrically coupled to the distal end 16b of the coil 16 by crimping and/or soldering. The cylindrical sheath 140 is also similar to the cylindrical sheath 40 described above having a (preferably sharp) distal edge 142, a conductive ring 141 near the distal edge 142, and a conductive stripe or portion 143 which extends proximally from the conductive ring 141. In this embodiment, however, the sleeve 140 is electrically and mechanically coupled to the distal end 18b of the control wire 18. The coupling is effected by providing a lateral hole 147 in the sleeve 140 and a right angle bend in the distal end 18b of the control wire 18. The end of the control wire is inserted in the hole and is soldered or otherwise mechanically and electrically connected to the sleeve. As seen in Figures 6-8 the conductive portions 141 and 143 of the sleeve 140 make electrical contact with the distal end of the control wire 18 via the hole 147.

It should be appreciated that when the endoscopic instrument with the jaw assembly 114 is actuated, the sheath 140 will be moved by the control wire 18 over the arms 150a, 150b and jaw cups 146a, 146b. Because the arms are narrow, there is sufficient room for the right angled bend in the insulated wire 18 to extend between the arms and out to the sheath 140 without contact being made between the wire and the arms. In addition, if desired, the connection between the control wire and the sheath can be made more proximally along the sheath to avoid contact between the control wire and biopsy samples collected between the arms.

There have been described and illustrated herein several embodiments of an endoscopic bipolar multiple sample bioptome. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. Thus, while particular configurations of the handle have been disclosed, it will be appreciated that other types of handles could be utilized. Also, while specific couplings of the ends of the coil and control wire have been shown, it will be recognized that other types of couplings could be used with similar results obtained. Moreover, while particular configurations have been disclosed in reference to the jaw assembly, it will be appreciated that other configurations could be used as well. For example, while it is preferred to provide jaws with teeth, it will be appreciated that in lieu of teeth, the jaws can be provided with sharp edges which, in conjunction with a sharp cylindrical sleeve, will provide a cutting ability. Furthermore, while the jaw assembly has been disclosed as being formed from Nitinol, it will be understood that different formations of the jaw assembly can achieve the same or similar function as disclosed herein. Further yet, it will be appreciated that while the apparatus of the invention was described as advantageously permitting the obtaining of multiple biopsies without removal from the surgical site, the apparatus of the invention, if desired, could still be used for obtaining

single biopsies at a time. With regard to the partially conductive sleeve, it will be appreciated that the arrangement of the conductive portions may be varied considerably so long as the conductive portions of the sleeve do not contact the jaw assembly. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

We Claim:

1. An endoscopic bipolar bioptome, comprising:

a) a conductive hollow outer member having a proximal end and a distal end;

b) a conductive inner control member having a proximal end and a distal end, said control member being at least partially covered by an insulating sheath and extending through said hollow outer member;

c) a partially conductive cylinder having a distal edge, said cylinder being electrically and mechanically coupled to said distal end of one of said hollow outer member and said inner control member, said partially conductive cylinder having a substantially non-conductive interior surface and an exterior surface which is conductive in at least some areas;

d) a conductive jaw assembly including a base member and a pair of resilient arms extending distally from said base member, each of said resilient arms terminating in a jaw, said base member being coupled electrically and mechanically to said distal end of the other of said hollow outer member and said inner control member; and

e) actuation means coupled to said proximal end of said hollow outer member and to said proximal end of said inner control member for axially displacing one of said hollow outer member and said inner control member relative to the other of said hollow outer member and said inner control member such that said cylinder extends around said pair of resilient arms and closes said jaws, said actuation means including electrical coupling means for coupling one pole of a bipolar cautery source to said hollow outer member and another pole of the bipolar cautery source to said inner control member, wherein

cautery current applied to said electrical coupling means flows between said jaw assembly and said conductive areas of said cylinder via the tissue to be cauterized.

2. An endoscopic bipolar bioptome according to claim 1, wherein:

said hollow outer member is a flexible coil having a lumen and said inner control member is a flexible control wire.

3. An endoscopic bipolar bioptome according to claim 1, wherein:
said manual actuation means includes
 - i) a shaft having a distal bore, a proximal thumb ring, and a central slot, and
 - ii) a displaceable spool having a cross member extending through said central slot.
4. An endoscopic bipolar bioptome according to claim 3, wherein:
said proximal end of said hollow outer member is coupled to said shaft, and
said proximal end of said inner control member is coupled to said spool.
5. An endoscopic bipolar bioptome according to claim 1, wherein:
said cylinder is coupled to said distal end of said inner control member, and
said base member of said jaw assembly is coupled to said distal end of said outer hollow member.
6. An endoscopic bipolar bioptome according to claim 1, wherein:
said cylinder is coupled to said distal end of said hollow outer member, and
said base member of said jaw assembly is coupled to said distal end of said inner control member.
7. An endoscopic bipolar bioptome according to claim 5, wherein:
said cylinder has a radial hole, said distal end of said control member is bent and coupled to said radial hole, and said conductive areas of said cylinder include an area adjacent said radial hole.
8. An endoscopic bipolar bioptome according to claim 6, wherein:
said base member has a radial hole and said distal end of said control member is bent and coupled to said radial hole.
9. An endoscopic bipolar bioptome according to claim 6, wherein:
said conductive areas of said cylinder include an area adjacent said distal end of said hollow outer member.

10. An endoscopic bipolar bioptome according to claim 7, wherein:

said conductive areas of said cylinder include a ring adjacent said distal edge and a stripe from said ring to said radial hole.

11. An endoscopic bipolar bioptome according to claim 9, wherein:

said conductive areas of said cylinder include a first area adjacent said distal edge and a second area extending proximally from said first area.

12. An endoscopic bipolar bioptome according to claim 11, wherein:

said conductive areas of said cylinder include a third area at a proximal edge of said cylinder making contact with said hollow outer member.

13. An endoscopic bipolar bioptome according to claim 11, wherein:

said first area is a ring and said second area is a stripe.

14. An endoscopic bipolar bioptome according to claim 1, wherein:

said cylinder is a non-conductive ceramic and said conductive areas are conductive traces on said non-conductive ceramic.

15. An endoscopic bipolar bioptome according to claim 14, wherein:

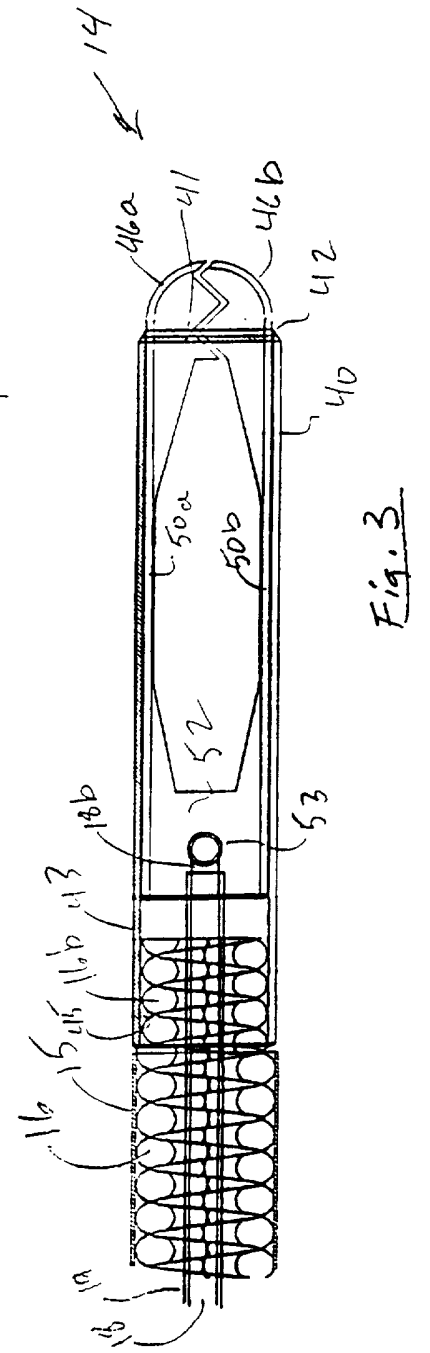
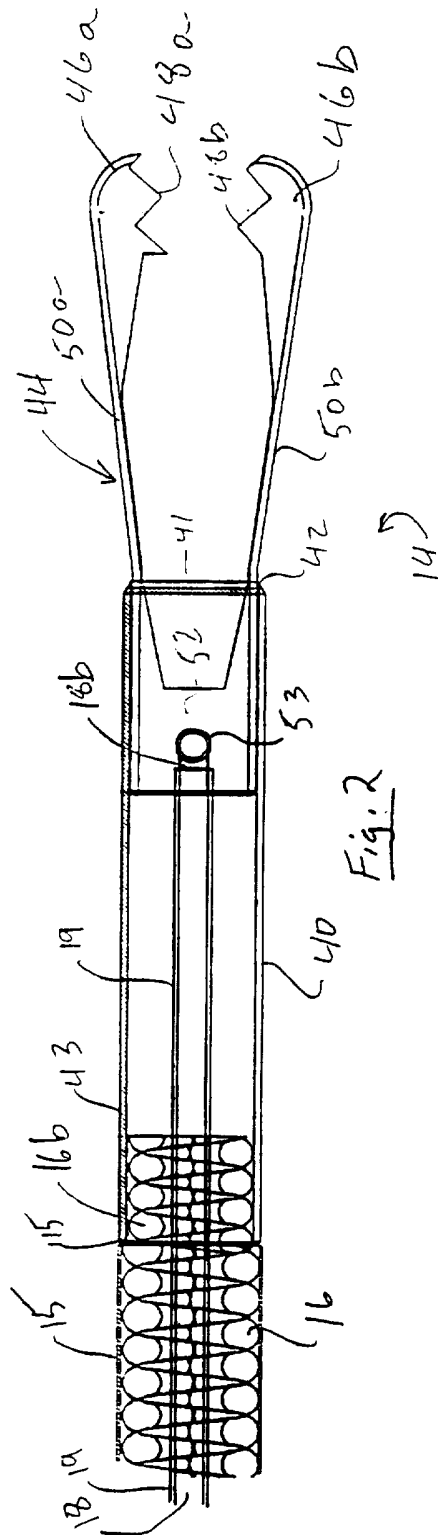
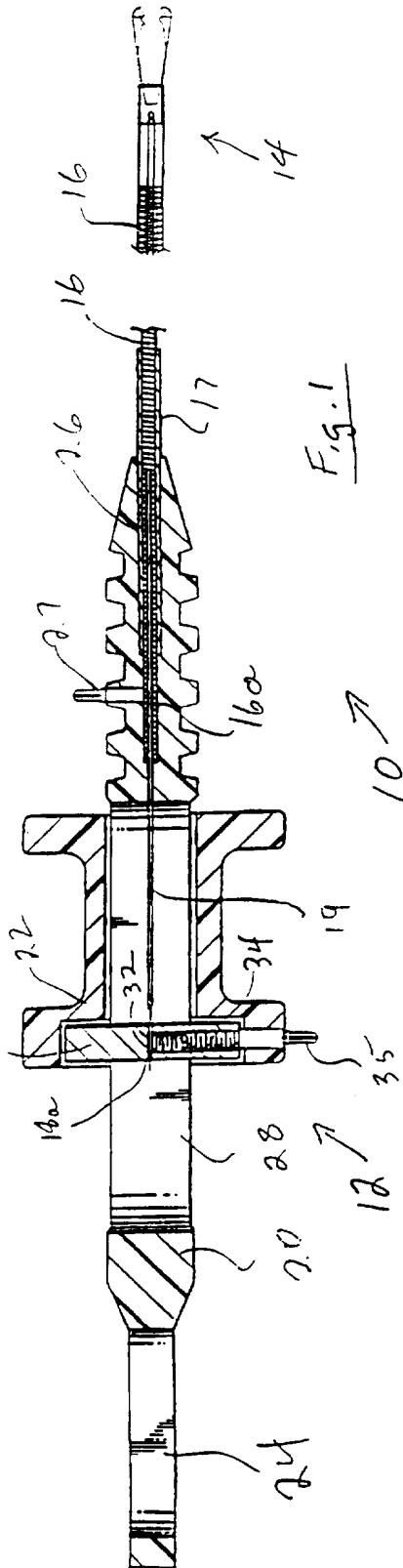
said conductive traces are formed by metallization.

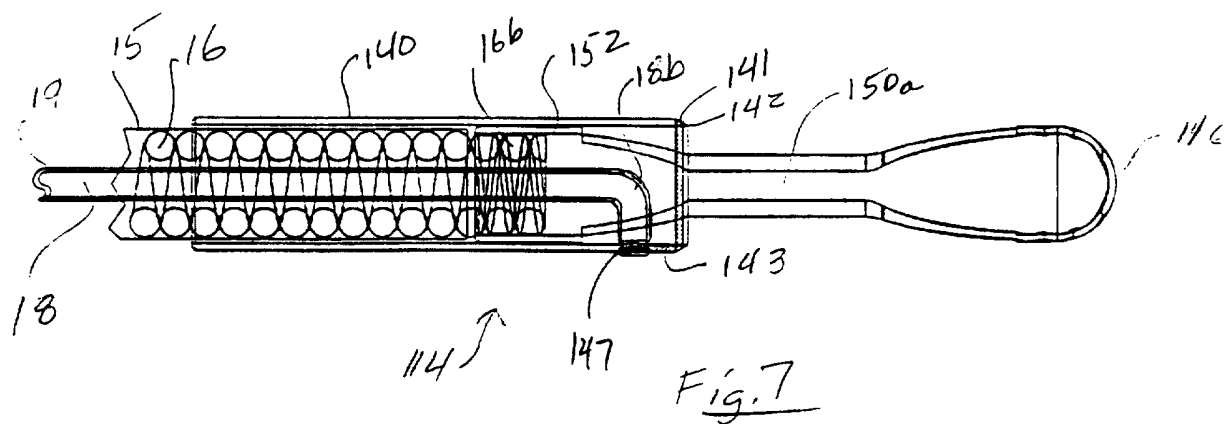
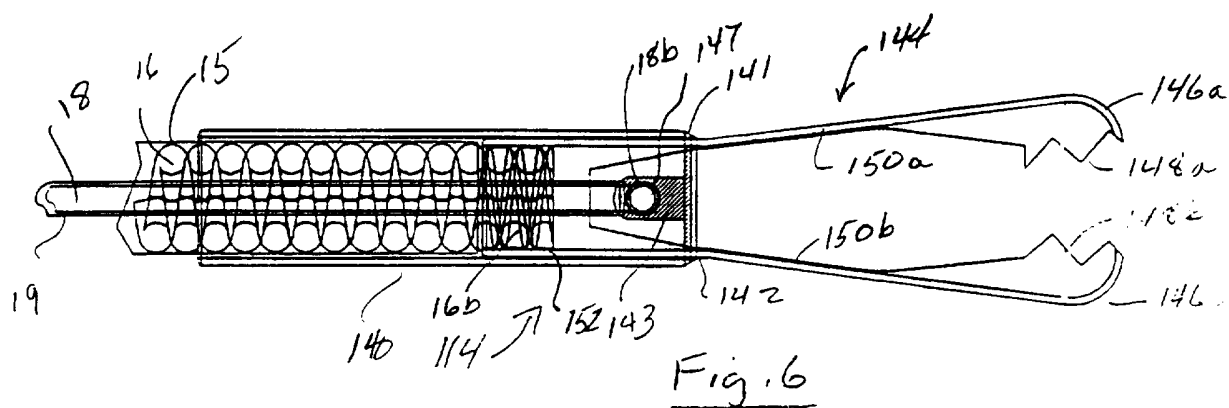
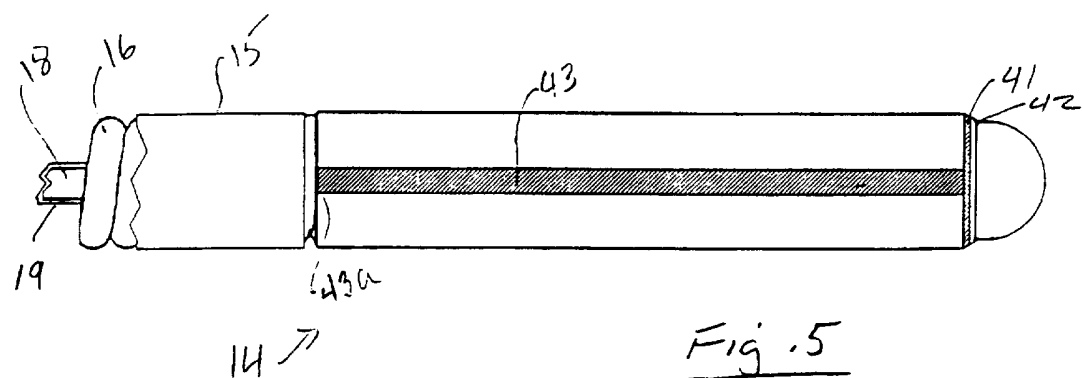
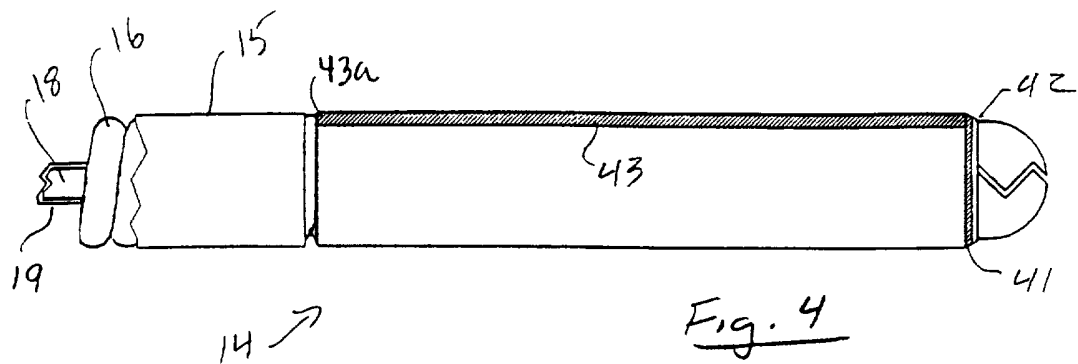
16. An endoscopic bipolar bioptome according to claim 1, wherein:

said cylinder is anodized aluminum with conductive areas on said exterior surface.

17. An endoscopic bipolar bioptome according to claim 16,
wherein:

- said conductive areas are non-anodized areas formed by
masking said cylinder prior to anodizing said cylinder.
-





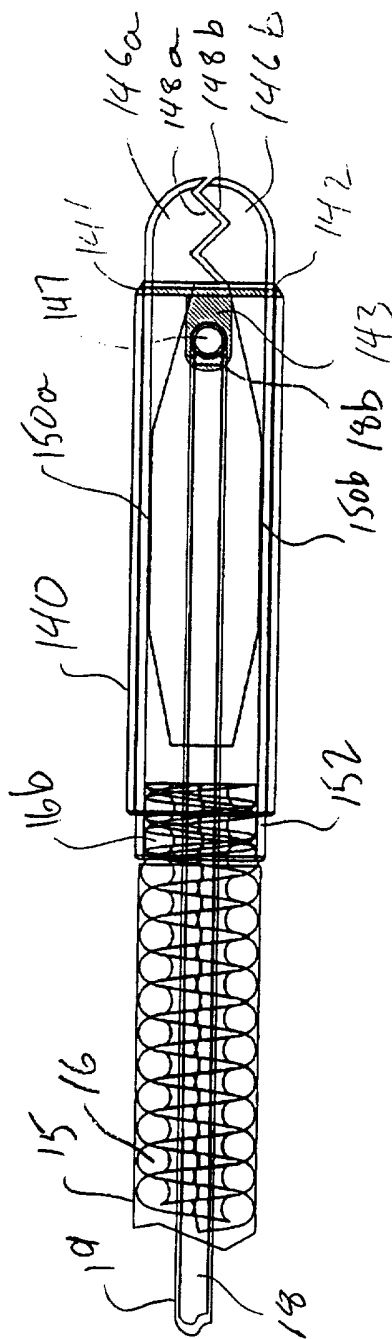


Fig. 8

114 →

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/00494

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39

US CL :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)

U.S. : 128/749, 750; 606/41, 45-52, 205-207

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 5,542,432 A (SLATER et al) 06 August 1996, whole document	1-17
A	US 3,920,021 A (HILTERBRANDT) 18 November 1975, whole document.	1-17
A	US 4,985,030 A (MELZER et al) 15 January 1991, whole document.	1-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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