A biopsy device includes a first jaw and a second jaw pivotally connected to the first jaw through a pivot. The second jaw has a lever arm extending rearward from the pivot when the second jaw is closed. A wire having an end is connected to the lever arm of the second jaw. A suction tube is disposed between the first and second jaw.
MULTIPLE BIOPSY DEVICE
CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 61/317,036 filed Mar. 24, 2010, the entirety of which is incorporated herein.

FIELD OF INVENTION

[0002] The present application relates to a biopsy device. More particularly, the present application relates to an endoscopic biopsy device configured to take multiple tissue samples.

BACKGROUND

[0003] Endoscopic biopsy procedures may be performed with an endoscope and an endoscopic biopsy forceps device. The endoscope is a long flexible tube with various optical features allowing for visualization and having a narrow lumen through which the biopsy forceps device is inserted. Known biopsy forceps devices for endoscope use include a long flexible cannula 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.

[0004] During a biopsy tissue sampling operation, an operator guides the endoscope to the biopsy site while viewing a video image of the site. When the device is inserted into the endoscope with the opposed jaws extended from the narrow lumen of the scope, the operator can position the jaws around a tissue to be sampled and manipulate the actuation means so that the jaws close around the tissue. The normal closing action of the jaws may sever a tissue sample and in some cases, the operator may need to apply an additional pulling or closing force to sever a tissue sample. In one known single biopsy embodiment, the operator must first deliver the jaws to the tissue site via the endoscope lumen, sever the tissue sample with the jaws, withdraw the biopsy forceps device from the endoscope, and open the jaws to collect the single biopsy tissue sample from within.

[0005] With the single biopsy embodiment, the device must be repeatedly inserted, actuated, and withdrawn to acquire multiple tissue samples in a one-at-a-time manner. In another known embodiment of a multiple biopsy device, suction is used to retrieve the tissue sample while the distal end of the biopsy forceps device remains in the patient. In yet another embodiment, a suction passage is added to the biopsy device so that each biopsy sample can be withdrawn out from the patient and retrieved from outside of the patient without withdrawing the instrument.

SUMMARY

[0006] A biopsy device includes a first jaw and a second jaw pivotally connected to the first jaw through a pivot. The second jaw has a lever arm extending rearward from the pivot when the second jaw is closed. A wire having an end is connected to the lever arm of the second jaw. A suction tube is disposed between the first and second jaw.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] In the accompanying drawings, structures are illustrated that, together with the detailed description provided below, describe exemplary embodiments of the claimed invention.

[0008] In the drawings and description that follows, like elements are identified with the same reference numerals. The drawings are not to scale, and the proportion of certain elements may be exaggerated for the purpose of illustration.

[0009] FIG. 1 is a perspective view of one embodiment of an endoscopic biopsy assembly.

[0010] FIG. 2A is a first perspective view of a distal end of one embodiment of a biopsy forceps device of the endoscopic biopsy assembly, showing jaws in an open position.

[0011] FIG. 2B is a second perspective view of the distal end of the biopsy forceps device, showing jaws in a closed position.

[0012] FIG. 2C is a top plan view of one embodiment of a movable jaw of the biopsy forceps device.

[0013] FIG. 2D is a top plan view of one embodiment of a stationary jaw of the biopsy forceps device.

[0014] FIG. 3 is a cross-section of the distal end of the biopsy forceps device.

[0015] FIG. 4 is a partial perspective view of one embodiment of a catheter and wire assembly of the endoscopic biopsy assembly.

[0016] FIG. 5 is a perspective view of an alternative embodiment of a catheter assembly of the endoscopic biopsy assembly.

[0017] FIG. 6 is a front view of another alternative embodiment of a catheter of the endoscopic biopsy assembly.

[0018] FIG. 7 is a side view of one embodiment of a connector and actuation handle of the endoscopic biopsy assembly.

[0019] FIG. 8 is a perspective view of assembled connecting components configured to be housed in the connector.

[0020] FIG. 9 is a cross-section of the connector of the endoscopic biopsy assembly.

[0021] FIG. 10 is a cross-section of an alternative embodiment of a connector of an endoscopic biopsy assembly.

[0022] FIG. 11 is a perspective view of one embodiment of a housing in the alternative embodiment of the connector.

[0023] FIG. 12 is a perspective view of an alternative embodiment of an endoscopic biopsy assembly.

[0024] FIGS. 13A-C are cross-sections of a biopsy forceps device in the alternative embodiment of the endoscopic biopsy assembly, at various stages of taking a biopsy sample.

[0025] FIG. 14 is a cross-section of another alternative embodiment of a biopsy forceps device, taking a biopsy sample.

[0026] FIG. 15 is a cross-section of another alternative embodiment of a biopsy forceps device, taking a biopsy sample.

DETAILED DESCRIPTION

[0027] FIG. 1 is a perspective view of one embodiment of an endoscopic biopsy assembly 100. The endoscopic biopsy assembly 100 is for use with an endoscope (not shown) and includes a biopsy forceps device 200 disposed therein. The endoscope may be any known endoscope. In one known embodiment, the endoscope is an Olympus 160-series endoscope.

[0028] A catheter 205 is operatively connected to the biopsy forceps device 200, and passes through the endoscope and a connector 300, to a sample collection chamber 105. In the illustrated embodiment, the collection chamber includes a tube 110, having an aperture for receiving a tray 115 with a handle. The tray 115 may be slidably removed from the aperture. In one embodiment, the tray 115 may be held in
place by a locking mechanism (not shown). Such a locking 
mechanism may include a pivoting or flexible member and a 
projection that is received in an aperture of the handle of the 
tray 115.

In the illustrated embodiment, the tray 115 has a 
single sample receiving surface. In an alternative embodi-
ment (not shown), the tray includes one or more dividers that 
define a plurality of sample receiving surfaces. The dividers 
may be walls that extend upwards from a bottom surface of 
the tray, or the dividers may be indentations formed in the 
bottom surface of the tray. Such a tray may be moved within 
the sample collection chamber 105, such as by sliding, piv-
oting, or rotating, to receive samples on the different sample 
receiving surfaces.

Alternatively, the sample collection chamber 105 
may be any existing collection chamber. In one known 
embodiment (not shown), the sample collection chamber 105 
is a polypectomy trap adapter commercially available under 
the name ETRAP polytrap and sold by U.S. Endoscopy. The 
sample collection chamber 105 may include multiple com-
ponents constructed of polymeric materials, such as thermo-
plastic elastomers or clear rigid plastic.

An actuation handle 400 is also operatively con-
tected to the biopsy forceps device 200 through connector 
300. As will be described in further detail below, the actuation 
handle 400 includes a sliding member and a shaft. The sliding 
member may be manually translated along the shaft, which 
causes the biopsy forceps device 200 to open and close. The 
actuation handle 400 may be constructed of metal or a poly-
meric material, such as acrylonitrile butadiene styrene 
(“ABS”) plastic.

In the illustrated embodiment, the sample collection 
chamber 105, connector 300, and actuation handle 400 are 
spaced from each other. In alternative embodiments (not 
shown) one or more of the sample collection chamber 105, 
connector 300, and actuation handle 400 may be directly 
attached to each other. Such attachments may be permanent 
attachments or releasable attachments. For example, in one 
embodiment (not shown), the sample collection chamber 105 
is fixedly or releasably attached to the actuation handle 400. 
In another embodiment (not shown), the sample collection 
chamber 105 is releasably attached to the connector 300. In 
yet another embodiment, the connector 300 is releasably 
attached to the actuation handle 400. Releasable attach-
ments may be formed by clips, VELCRO, snaps, threaded con-
nectors, or other known releasable connectors. Fixed attach-
ments may be formed by adhesive, bolts, rivets, welds, and 
other known fixed connectors. A fixed attachment may also 
be formed by molding two or more components as a single 
component.

In the illustrated embodiment, a suction device (not 
shown) is connected to a suction end S of a tube T, and the 
tube T is operatively connected to the sample collection 
chamber 105. A valve V is disposed along tube T. When the 
suction device is turned on and the valve V is open, suction is 
applied through the tube T, and through the sample collection 
chamber 105 and catheter 205 to the distal end of the biopsy 
forceps device 200. The tray 115 in the sample collection 
chamber 105 includes a plurality of apertures, so as not to 
interrupt suction along the tube T to the biopsy forceps device 
200. When the suction device is turned on and the valve V is 
closed, suction is only applied through a portion of the tube T.

In the illustrated embodiment, the valve V is biased 
in a closed position and is opened by a manually operated 
push button. In the illustrated embodiment, the valve is a 
trumpet valve. In an alternative embodiment (not shown), the 
valve is opened by a foot pump or a clamp. In another alter-
native embodiment (not shown) the valve is disposed on the 
sample collection chamber 105 or the catheter 205.

In operation, the operator guides the endoscope to 
the biopsy site while viewing the biopsy site through various 
optical features allowing for visualization. The operator posi-
tions the biopsy forceps device 200 at a desired location and 
actuates the actuation handle 400 to open the biopsy forceps 
device 200. The operator optionally applies suction through 
the biopsy forceps device 200 by opening the valve V. Apply-
ing suction at this time may cause “tenting” of the tissue, thus 
facilitating the taking of a sample. The operator then actuates 
the actuation handle 400 to close the biopsy forceps device 
200 around a tissue sample. The act of closing the biopsy 
forceps device 200 may sever the tissue sample in some 
instances. In other instances, the operator may need to apply 
force to withdraw the biopsy forceps device 200 from the 
biopsy site. This additional force may help to sever the tissue 
sample from the site. After the sample has been severed, if the 
valve V has not been previously opened, the operator opens 
the valve V to apply suction. The suction evacuates the sample 
from the biopsy forceps device 200 and draws it through the 
catheter 205 to the sample collection chamber 105. The valve 
V may be opened before or after the actuation handle 400 is 
actuated.

The endoscopic biopsy assembly 100 may be oper-
ated by one or more operators. For example, a first operator 
may guide the endoscope, a second operator may actuate the 
actuation handle 400, a third operator may open and close the 
valve V, and a fourth operator may retrieve the tissue sample 
from the sample collection chamber 105. Alternatively, a 
single operator may perform each of these tasks. As another 
alternative, two or three operators may operate the endo-
scopic biopsy assembly 100, with each operator performing 
one or more tasks.

FIGS. 2A and 2B illustrate first and second perspec-
tive views of the biopsy forceps device 200 connected to a 
catheter 205. The biopsy forceps device 200 includes a sta-
tionary jaw 210 having fenestration 215 and movable jaw 220 
also having fenestration 225. In alternative embodiments 
(not shown), the stationary jaw 210, movable jaw 220, or both 
are solid and do not include fenestrations. In another alterna-
tive embodiment (not shown), but jaws are movable.

FIGS. 2C and 2D illustrate top plan views of the 
movable jaw 220 and the stationary jaw 210. Referring now 
to FIGS. 2A-D, each of the stationary jaw 210 and movable jaw 
220 have sharpened edges configured to cut tissue. The sharp-
ened edges may be continuous edges or serrated edges. In 
the illustrated embodiment, each of the stationary jaw 210 and 
movable jaw 220 have a radial curve and are cup shaped. In 
alternative embodiments (not shown), the jaws may have 
non-radial curves, or straight edges that form a geometric 
shape.

Each of the stationary jaw 210 and movable jaw 220 
may be formed by a metal injection molding (“MIM”) or 
other processes including, but not limited to, stamping, laser 
welding, sintering, and molding. The jaws may be con-
structed of stainless steel, aluminum, titanium, ceramics, 
plastics, or other known materials.

The catheter 205 may be constructed of polymeric 
material, such as Teflon, polyethylene, polypropylene,
nylon, polyetherether ketone (PEEK), and other polymeric materials. The catheter 205 may be formed by an extrusion process.

[0041] The movable jaw 220 is connected to the stationary jaw 210 by a pivot 230. In the illustrated embodiment, the pivot 230 includes two posts that extend from the movable jaw 220 and are seated in corresponding apertures of the stationary jaw 210. In an alternative embodiment (not shown), the pivot 230 includes two posts that extend from the stationary jaw 210 and are seated in corresponding apertures of the movable jaw 220. In another alternative embodiment (not shown), both the stationary jaw 210 and the movable jaw 220 include a pair of corresponding apertures, and a pin is inserted therein to form a pivot. In each such embodiment, the pivot may be positioned so as not to interfere with a passageway for tissue samples. In such embodiments, the pivot may be described as an external pivot. Alternatively, the pivot may cross such a passageway.

[0042] The biopsy forceps device 200 further includes suction tubing 235 having a first end disposed within the chamber formed by stationary jaw 210 and movable jaw 220. In the illustrated embodiment, the end of the suction tubing 235 is positioned forward of the pivot 230, such that when the movable jaw 220 is opened, the first end of the suction tubing 235 may directly contact tissue. An operator may choose to apply suction prior to taking a tissue sample, such that when the valve V is open and suction is applied through the suction tubing 235, the tissue that is in direct contact with the suction tubing 235 is raised. This may be referred to as “tenting.” The tenting process pulls tissue between the jaws, so that when the movable jaw 220 is closed, the sharpened edges of the jaws may sever the tented tissue and capture a sample between the jaws. An additional backwards force may also be required to sever the tissue sample. The tissue sample is subsequently drawn down the catheter by the applied suction.

[0043] In one embodiment, the suction tubing 235 is an insert that extends partially into the catheter. In an alternative embodiment, the suction tubing 235 extends the length of the catheter.

[0044] The movable jaw 220 further includes a lever arm 240 having an aperture 245. A wire 250 engages the lever arm 240 through the aperture 245, such that manipulation of the wire 250 moves the lever arm 240 about the pivot 230, causing the movable jaw 220 to open and close. The wire 250 may be manipulated through the actuation handle 400.

[0045] FIG. 3 illustrates a cross-section of the biopsy forceps device 200. As can be seen in this view, the stationary jaw 210 further includes a ledge 255 disposed opposite the cutting surface of the stationary jaw 210. The ledge 255 may be created during the manufacturing process to form apertures in the stationary jaw 210 to accept the posts of the movable jaw 220. In one embodiment, a staking operation is performed to bend the ledge 255. In the illustrated embodiment, the ledge 255 forms a stop, thereby defining the arc through which the movable jaw 220 may pivot. Alternatively, the ledge 255 may be dimensioned so as not to interfere with the pivoting of the movable jaw 220.

[0046] With continued reference to FIG. 3, the aperture 245 in the lever arm 240 forms a socket that engages a ball 260 at the end of the wire 250. During the manufacturing process, the outer edges of the aperture 245 may be crimped or otherwise closed around the ball 260 after the wire is received, such that the ball will remain housed in the socket formed by aperture 245 during operation of the endoscopic biopsy assembly 100. In one embodiment, a staking operation is performed to secure the ball 260 in the socket. In an alternative embodiment (not shown), a stop is formed on the wire on the opposite side of the lever arm, such that the lever arm is sandwiched between the ball 260 and the stop.

[0047] In the illustrated embodiment, the distal end of the suction tubing 235 is slightly spaced from the distal end of the jaws 210, 220. In an alternative embodiment (not shown), the distal end of the suction tubing 235 may be positioned adjacent the distal end of the jaws 210, 220. In another alternative embodiment (not shown), the distal end of the suction tubing 235 may be further spaced from the distal end of the jaws 210, 220, such that the suction tubing 235 is below the ball 260 of the wire 250. In one known embodiment, the position of the suction tubing 235 may be varied before or during an operation.

[0048] FIG. 4 illustrates a partial perspective view of one embodiment of a catheter assembly 270. In this embodiment, the catheter assembly includes the catheter 205 and suction tubing 235. The suction tubing 235 may be a separate component or it may be integral with the catheter 205. The catheter 205 may be constructed of a polymeric material such as polytetrafluoroethylene (“PTFE”). The suction 235 tubing may also be constructed of a polymeric material such as PTFE.

[0049] The center of the suction tubing 235 is a hollow passageway 265 through which tissue samples may be drawn. The hollow passageway 265 is operatively connected to the suction device, such that when the suction device is turned on and the valve V is open, suction will be applied to the passageway 265 and draws a severed tissue sample to the capture container 105.

[0050] In the illustrated embodiment, the catheter 205 further includes a pair of lumens 275a, b configured to receive the wire 250. Although only one of the lumens (275a) is used, two lumens are formed for manufacturing purposes. Additionally, a pair of corresponding grooves 280a, b are formed on the suction tubing 235. The grooves 280a, b may extend the entire length of the suction tubing 235, or may only extend along a portion of the suction tubing 235. The corresponding grooves 280a, b are aligned with the lumens 275a, b and may restrict lateral movement of the wire 250. The inclusion of a lumen 275 for the wire 250 that is separate from the passageway 235 ensures that the tissue sample has a clear travel path to the collection chamber 105. However, it should be understood that the lumen 275 is optional and that the wire may be disposed along the passageway 235.

[0051] Additionally, the catheter 205 includes a pair of notches 285a, b or other apertures configured to receive tongs 290 of the stationary jaw 210 (as shown in FIG. 2D). The notches 285a, b may extend for a portion of the catheter 205, or they may extend the entire length of the catheter 205. During assembly of the biopsy forceps device 200, adhesive may be placed in the notches 285a, b such that the jaws are thereby affixed to the catheter 205. Where adhesive is to be used, the surface may be scored to aid in bonding. The notches 285a, b serve as an anchor point for the base of the stationary jaw 210 and prevents the jaws from rotating relative to the catheter.

[0052] In an alternative embodiment (not shown), the notches 285a, b are replaced with an annular groove configured to receive a flange of the jaws. In another alternative
embodiment (not shown), the catheter does not include notches or a groove, and the jaws are glued, welded, or otherwise affixed to the catheter.

[0053] FIG. 5 illustrates a perspective view of an alternative embodiment of a catheter assembly 500. In this embodiment, the catheter assembly includes the catheter 505 and suction tubing 510, wherein the suction tubing 510 is a separate insert that is received in a hollow passageway 515 of the catheter 505. The center of the suction tubing 510 is also a hollow passageway 520 for tissue samples.

[0054] In the illustrated embodiment, the catheter 505 further includes a lumen 525 configured to receive a wire. The inclusion of a lumen 525 for the wire ensures that the tissue sample has a clear travel path to the collection chamber 105. Therefore, in the illustrated embodiment, the side opening 325 is formed by a chamfer extending downwards to the cavity and outwards to an end of the aligning member 320. In an alternative embodiment (not shown), the side opening may extend the entire length of the aligning member 320. In another alternative embodiment (not shown), the side opening may be a hole or slot that does not extend to an end of the aligning member 320.

[0061] The connecting components may be assembled in the following manner. A first end of the first catheter 205a is inserted into a first end of the aligning member 320. The first catheter 205a may be affixed in its position with adhesive, or by a press fit. The first end of the first catheter 205a includes a notch 330 that provides an exit for the cable 315. The first catheter 205a is positioned such that the notch 330 and the cable 315 are accessible through the side opening 325 of the aligning member 320. In the illustrated embodiment, a flap of the catheter remains in place over the notch 330. This flap may shield the wire from adhesive that is applied during assembly.

[0062] A first end of the second catheter 205b is then inserted into a second end of the aligning member 320, such that it abuts the first end of the first catheter 205a. The second catheter 205b may be affixed in its position with adhesive or by a press fit.

[0063] FIG. 7 illustrates a side view of one embodiment of a connector 300 and actuation handle 400 of the endoscopic biopsy assembly 100. The connector 300 is a substantially “y-shaped” component, having a major chamber 305 and a minor chamber 310. The catheter 205 passes through the major chamber 305 to the sample collection chamber 105. A cable 315 leads from the minor chamber 310 to the actuation handle 400.

[0057] The actuation handle 400 includes a shaft 405 having a distal end 410 and a proximal end 415. In the illustrated embodiment, the proximal end 415 has a first ring 420 attached thereeto. The first ring 420 is configured to receive an operator’s thumb or finger. However, it should be understood that the ring may be omitted or replaced with a transversely oriented member.

[0058] A sliding member 425 is slidably mounted to the shaft 405. In the illustrated embodiment, the sliding member 425 includes a second ring 430 and a third ring 435, each configured to receive an operator’s finger or thumb. Alternatively, the sliding member 425 may be a spool, or include a transversely oriented member in lieu of rings.

[0059] A proximal end of the wire 250 is fixedly attached to the sliding member 425. When the sliding member is translated towards the proximal end 415 of the shaft 405, the wire 250 is refracted. This refraction causes the ball 260 at the opposite end of the wire 250 to pull the lever arm 240 of the movable jaw 220, which causes the movable jaw 220 to pivot towards the closed position. Likewise, when the sliding member is translated towards the distal end 410 of the shaft 405, the wire 250 is pushed forward. This movement causes the ball 260 at the opposite end of the wire 250 to push the lever arm 240 of the movable jaw 220, which causes the movable jaw 220 to pivot towards the open position.

[0060] FIG. 8 illustrates a perspective view of assembled connecting components disposed within the connector 300. In this embodiment, the catheter 205 connected to the biopsy forceps device 200 includes a first catheter 205a and a second catheter 205b. End portions of each of the first and second catheters 205a,b are disposed in an aligning member 320. The aligning member 320 is a hollow rod having an elongated cavity to receive the first and second catheters 205a,b. The aligning member 320 further includes a side opening 325. In the illustrated embodiment, the side opening 325 is formed by a chamfer extending downwards to the cavity and outwards to an end of the aligning member 320. In an alternative embodiment (not shown), the side opening may extend the entire length of the aligning member 320. In another alternative embodiment (not shown), the side opening may be a hole or slot that does not extend to an end of the aligning member 320.

[0061] The connecting components may be assembled in the following manner. A first end of the first catheter 205a is inserted into a first end of the aligning member 320. The first catheter 205a may be affixed in its position with adhesive, or by a press fit. The first end of the first catheter 205a includes a notch 330 that provides an exit for the cable 315. The first catheter 205a is positioned such that the notch 330 and the cable 315 are accessible through the side opening 325 of the aligning member 320. In the illustrated embodiment, a flap of the catheter remains in place over the notch 330. This flap may shield the wire from adhesive that is applied during assembly.

[0062] A first end of the second catheter 205b is then inserted into a second end of the aligning member 320, such that it abuts the first end of the first catheter 205a. The second catheter 205b may be affixed in its position with adhesive or by a press fit.

[0063] FIG. 7 illustrates a side view of one embodiment of a connector 300 and actuation handle 400 of the endoscopic biopsy assembly 100. The connector 300 is a substantially “y-shaped” component, having a major chamber 305 and a minor chamber 310. The catheter 205 passes through the major chamber 305 to the sample collection chamber 105. A cable 315 leads from the minor chamber 310 to the actuation handle 400.

[0057] The actuation handle 400 includes a shaft 405 having a distal end 410 and a proximal end 415. In the illustrated embodiment, the proximal end 415 has a first ring 420 attached thereeto. The first ring 420 is configured to receive an operator’s thumb or finger. However, it should be understood that the ring may be omitted or replaced with a transversely oriented member.

[0058] A sliding member 425 is slidably mounted to the shaft 405. In the illustrated embodiment, the sliding member 425 includes a second ring 430 and a third ring 435, each configured to receive an operator’s finger or thumb. Alternatively, the sliding member 425 may be a spool, or include a transversely oriented member in lieu of rings.

[0059] A proximal end of the wire 250 is fixedly attached to the sliding member 425. When the sliding member is translated towards the proximal end 415 of the shaft 405, the wire 250 is refracted. This refraction causes the ball 260 at the opposite end of the wire 250 to pull the lever arm 240 of the movable jaw 220, which causes the movable jaw 220 to pivot towards the closed position. Likewise, when the sliding member is translated towards the distal end 410 of the shaft 405, the wire 250 is pushed forward. This movement causes the ball 260 at the opposite end of the wire 250 to push the lever arm 240 of the movable jaw 220, which causes the movable jaw 220 to pivot towards the open position.

[0060] FIG. 8 illustrates a perspective view of assembled connecting components disposed within the connector 300. In this embodiment, the catheter 205 connected to the biopsy forceps device 200 includes a first catheter 205a and a second catheter 205b. End portions of each of the first and second catheters 205a,b are disposed in an aligning member 320. The aligning member 320 is a hollow rod having an elongated cavity to receive the first and second catheters 205a,b. The aligning member 320 further includes a side opening 325. In the illustrated embodiment, the side opening 325 is formed by a chamfer extending downwards to the cavity and outwards to an end of the aligning member 320. In an alternative embodiment (not shown), the side opening may extend the entire length of the aligning member 320. In another alternative embodiment (not shown), the side opening may be a hole or slot that does not extend to an end of the aligning member 320.

[0061] The connecting components may be assembled in the following manner. A first end of the first catheter 205a is inserted into a first end of the aligning member 320. The first catheter 205a may be affixed in its position with adhesive, or by a press fit. The first end of the first catheter 205a includes a notch 330 that provides an exit for the cable 315. The first catheter 205a is positioned such that the notch 330 and the cable 315 are accessible through the side opening 325 of the aligning member 320. In the illustrated embodiment, a flap of the catheter remains in place over the notch 330. This flap may shield the wire from adhesive that is applied during assembly.

[0062] A first end of the second catheter 205b is then inserted into a second end of the aligning member 320, such that it abuts the first end of the first catheter 205a. The second catheter 205b may be affixed in its position with adhesive or by a press fit.

[0063] FIG. 7 illustrates a side view of one embodiment of a connector 300 and actuation handle 400 of the endoscopic biopsy assembly 100. The connector 300 is a substantially “y-shaped” component, having a major chamber 305 and a minor chamber 310. The catheter 205 passes through the major chamber 305 to the sample collection chamber 105. A cable 315 leads from the minor chamber 310 to the actuation handle 400.
The connector 700 includes a major chamber 705 having an enlarged cavity portion 710 sized to accept a housing 715. The housing 715 surrounds portions of the aligining member 320, the first catheter 205a, and the second catheter 205b. FIG. 11 illustrates a perspective view of the housing 715. The housing 715 has a through hole 720 and tapered ends 725, 730, and may form a seal around the enclosed components. As best shown in FIG. 10, a distal end of the housing 715 surrounds a cylindrical distal end of aligining member 320 to create a seal therewith. If desired, small gaps or clearances can be filled with adhesive, greece, sealing compounds and the like to create an air-tight seal. A proximal end of aligining member 320 includes the side opening 325 (see FIG. 8). The side opening 325 creates a gap between housing 715 and second catheter 205b for the passage of an “S” portion of cable 315. While not shown, the gap may be filled around the cable 315 with a seal 316 such as an elastomeric seal or adhesive. The cable 315 may also be lubricated to prevent sticking with the seal 316. In an alternative embodiment (not shown), the ends of the housing are straight.

The housing 715 may be constructed of a polymeric material such as but not limited to ABS or any one of a number of metals. In one embodiment, the housing 715 is constructed at least partially of rubber to aid in sealing the enclosed components. In an alternative embodiment (not shown), o-rings or other seals may be disposed within the housing.

FIG. 12 illustrates a perspective view of an alternative embodiment of an endoscopic biopsy assembly 800. The endoscopic biopsy assembly 800 is substantially the same as the endoscopic biopsy assembly 100 shown in FIG. 1, except for the differences described herein. Like reference numbers indicate like components.

The endoscopic biopsy assembly 800 includes a radio frequency (RF) generator 805 connected to the actuation handle 400. In this embodiment, at least one of the jaws 210, 220 is formed from an electrically conductive material, such as stainless steel, and the RF generator 805 is in electrical communication with the electrically conductive jaw. In one particualr embodiment, both jaws 210, 220 are formed from an electrically conductive material. In FIG. 12, handle 400 includes an RF connector socket positioned distal to a dual ring portion of the handle. The RF connector socket is electrically connected to the jaws 210, 220 via at least wire 250 for the delivery of RF energy to the jaws.

In this embodiment, the RF generator 805 is in electrical communication with at least one of the jaws 210, 220 through the wire 250. The RF generator 805 is also in electrical communication with an actuator 810 that is used by the surgeon to deliver RF energy when required. When the actuator is activated, RF energy is provided to at least one of the jaws 210, 220 that can cautereze or cut the tissue. The RF generator 805 may include a wave form selection switch (not shown) that allows an operator to select between a cauterezing waveform and a cutting waveform. In the illustrated embodiment, the actuator 810 is a foot pedal. However, it should be understood that any actuator may be employed, such as buttons, dials, and switches.

In the illustrated embodiment, the RF generator 805 has a first pole 815 (i.e., a positive pole) and a second pole 820 (i.e., a negative pole or a ground pole). In the illustrated embodiment, only the first pole 815 is in electrical communication with at least one of the jaws 210, 220, making the biopsy forces device 200 a monopolar device. The second pole 820 is connected to a ground pad 825. The pad 825 is placed under the patient to form an electrical ground between the patient and the RF generator 805. In alternative embodiments (not shown), the second pole 820 may be in electrical communication with any conductive object that can come into contact with the patient.

In an alternative embodiment (not shown), both positive and negative poles are in electrical communication with the jaws 210, 220, making the biopsy forces device 200 a bipolar device. In such an embodiment, one of the first and second poles 815, 820 is in electrical communication with jaw 210 through a first wire, and the opposite pole is in electrical communication with jaw 220 through a second wire. Such an embodiment will electrically isolate each jaw 210, 220 and the first and second wires from electrical contact with the other to prevent shorting. To provide an electrical path to tissue, each electrically isolated jaw 210, 220 has an electrically conductive area exposed in the tissue clamping area, such as the horseshoe shaped sharpened edges that are shown contacted together when the jaws are fully closed.

With this embodiment, when the empty jaws are fully closed, the electrical contact areas will short together, and prevent the generator from activating. When tissue is between the clamped jaws, the tissue provides electrical resistance in the flow path between the exposed sharpened edges, and the generator will activate and coagulate the clamped tissue.

For the bipolar embodiment, each jaw 210, 220 may include additional insulation or electrically non-conductive materials or coatings. For example, portions of the jaws may be constructed of ceramic or a polymeric material. In one exemplary embodiment, not limited thereto, each jaw can be completely ceramic coated with an insulating layer, and portions of the insulating layer can be removed (by grinding, masking or the like) at the wire contact area and at the horsehoe shaped tension biting area. In this embodiment, electrical energy of one pole is conducted along the insulated wire, into the jaw 210 or jaw 220 at the wire contact area, and to tissue through the exposed horseshoe shaped tissue biting area. Such an embodiment may also deliver more focused energy that would not interfere with other electrical devices, such as a pacemaker in a patient.

FIGS. 13A-C illustrate cross-sections of the biopsy forces device 200 of the alternative embodiment of the endoscopic biopsy assembly 800, at various stages of taking a biopsy sample.

In FIG. 13A, the biopsy forces device 200 has been positioned at a desired location, the jaws 210, 220 have been opened, and a potential tissue sample, such as a polyp, is shown positioned partially inside the jaws 210, 220. Once the tissue is in the jaws, suction is applied through suction tubing 235, which causes “tenting” or drawing of the tissue at least partially into the suction tubing 235 as shown. If desired, a larger bite of tissue can be taken by pushing the jaws 210, 220 further into the tissue wall.

In FIG. 13B, the operator has actuated the actuation handle 400 to close the jaws 210, 220 of biopsy forces device 200 around a tissue sample as it is being tented and drawn into the suction tubing 235. The act of closing the biopsy forces device 200 pinches the “tented” tissue at the base of the polyp and in this view has fully severed the tissue sample just before it is drawn further into the suction tubing 235 by the applied suction. In other instances, the tissue sample may not be severed entirely between the jaws 210, 220 and the operator may apply force (i.e., by pulling or shaking) to fully sever the tissue sample from the site. In still other instances, the opera-
tor may activate the RF generator to apply RF energy at the jaws to cut the tissue sample from the site. The operator may select a cutting wave form prior to activating the RF generator.

In FIG. 13C, the closing of the jaws has failed to sever the tissue sample and, the operator is activating the RF generator to apply monopolar RF energy at the jaws to cauterize the tissue around the site. The operator may select a cauterizing wave form, such as a square wave, prior to activating the RF generator. Cauterizing the site in this manner may staunch bleeding caused by the severing, and may also kill cancer cells at the site. Because the un-severed sample is inside of the jaws, it is prevented from contacting the negatively charged patient and is not burned when the RF energy is applied. The tissue cannot be coagulated because it is exposed to only positive RF energy which travels along the external skin of the jaws and to the negatively charged patient. After applying RF energy, the operator elects to pull and shake the tissue sample free so that it can be sucked into the suction tubing 235.

FIG. 14 illustrates a cross-section of the biopsy forceps device 200 as it extends from a distal end of an endoscope 900, while taking a biopsy sample. The biopsy forceps device 200 is the same as biopsy forceps device 200 shown in FIGS. 1-3, except for the placement within the endoscope 900. Like reference numbers indicate like components.

The endoscope 900 has a tube 905 that includes a first lumen 915 that is configured to receive the biopsy forceps device 200. Catheter 205 is shown extending along the first lumen 915 of endoscope 900 with the jaws 210, 220 extending from the endoscope 910. Endoscope 900 further comprises a second lumen 910 in communication with a fluid source for providing irrigation to tissue and to the jaws 210, 220. In the illustrated embodiment, a plurality of tissue samples have accumulated within the suction tubing 235 and the operator may irrigate the surgical site by providing fluid through the second lumen 915 of the endoscope 900. The fluid may be used to clean the biopsy site or used to wash the accumulated tissue samples through the suction tubing 235. The fluid may enter the biopsy forceps device 200 through the fenestrations 215, 225 in the jaws 210, 220. The fluid entering the biopsy forceps device is drawn down the suction tubing 235 when suction is applied, and may aid in washing or drawing the tissue sample down the suction tubing 235. Exemplary fluids may include water, saline, drugs or any combination thereof.

FIG. 15 illustrates a cross-section of the biopsy forceps device 200 as it extends from the endoscope 900. In this view, suction is being applied to draw a stuck tissue sample down the suction tubing 235. If the suction has failed to dislodge the stuck biopsy sample, the operator can open and close the jaws 210, 210 to dislodge the tissue sample by activating the actuation handle 400. Repeating this opening and closing action causes the wire 250 to move longitudinally within the suction tubing 235 which may then rub wire 250 against the tissue sample and aid in drawing it through the suction tubing 235. This method may be effective in dislodging a tissue sample that has become stuck, and may be performed with or without irrigation.

It should be understood that in various embodiments, many elements of the endoscopic biopsy assembly 100 can be operably configured to be flexible such as, for example, but not limited to catheter 205, suction tubing 210, suction tubing 235, wire 250, cable 315, tubing 345, and catheter 505. Alternately, one or more of the flexible elements can be substantially rigid such as exemplary catheter 205 or any other element of assembly 100.

To the extent that the term "includes" or "including" is used in the specification or the claims, it is intended to be inclusive in a manner similar to the term "comprising" as that term is interpreted when employed as a transitional word in a claim. Furthermore, to the extent that the term "or" is employed (e.g., A or B) it is intended to mean "A or B or both." When the applicants intend to indicate "only A or B but not both" then the term "only A or B but not both" will be employed. Thus, use of the term "or" herein is the inclusive, and not the exclusive use. See, Bryan, Garner, A Dictionary of Modern Legal Usage 624 (2d. Ed. 1995). Also, to the extent that the terms "in" or "into" are used in the specification or the claims, it is intended to additionally mean "on" or "onto." Furthermore, to the extent the term "connect" is used in the specification or claims, it is intended to mean not only "directly connected to," but also "indirectly connected to" such as connected through another component or components.

While the present application has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not the intention of the applicants to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the application, in its broader aspects, is not limited to the specific details, the representative apparatus and method, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the applicant's general inventive concept.

What is claimed is:

1. A biopsy assembly comprising:
   a biopsy forceps device having at least one movable jaw, wherein the movable jaw is pivotally connected to a stationary jaw by a pivot;
   a connector;
   an actuation handle;
   a catheter extending from the biopsy forceps device and through the connector;
   a wire extending from the actuation handle, through the connector and into the catheter, to move the movable jaw; and
   a suction device operatively connected to the catheter.
2. The biopsy assembly of claim 1, further comprising a collection chamber operatively connected to the catheter.
3. The biopsy assembly of claim 2, wherein the collection chamber is configured to be connected to the actuation handle.
4. The biopsy assembly of claim 1, further comprising suction tubing disposed between the movable jaw and the stationary jaw, wherein an open end of the suction tubing is positioned forward of the pivot.
5. The biopsy assembly of claim 1, wherein the connector is a substantially y-shaped connector having a major chamber and a minor chamber.
6. The biopsy assembly of claim 5, wherein the catheter passes through the major chamber of the connector.
7. The biopsy assembly of claim 5, wherein a cannula is disposed between the minor chamber of the connector and the actuation handle.
8. The biopsy assembly of claim 7, wherein the wire is disposed within the cannula and passes through the minor chamber of the connector.

9. The biopsy assembly of claim 7, wherein the cannula comprises a spring.

10. The biopsy assembly of claim 1, wherein the catheter has at least one lumen, and the wire is at least partially disposed within the at least one lumen.

11. The biopsy assembly of claim 1, wherein the at least one of the jaws is operably configured to deliver radio frequency energy to tissue.

12. A biopsy device configured to be used with an endoscope, the biopsy device comprising:
   a biopsy forceps device having a first jaw and a second jaw;
   a pivot connecting the first jaw to the second jaw;
   a catheter extending from the biopsy forceps device; and
   a suction tube disposed between the first jaw and the second jaw, the suction tube having an end positioned forward and at least partially between the pivot.

13. The biopsy device of claim 12, wherein the first jaw includes a lever arm rearward of the pivot when the first jaw is closed.

14. The biopsy device of claim 13, further comprising a wire having a first end connected to the lever arm of the first jaw and a second end connected to an actuation mechanism.

15. The biopsy device of claim 14, wherein the wire of the biopsy device is operably configured to deliver RF energy to at least one jaw.

16. The biopsy device of claim 12, wherein at least one of the first jaw and second jaw is fenestrated.

17. A biopsy device comprising:
   a first jaw;
   a second jaw pivotally connected to the first jaw through a pivot, the second jaw having a lever arm extending rearward from the pivot when the second jaw is closed;
   a wire having an end connected to the lever arm of the second jaw; and
   a suction tube disposed between the first and second jaw.

18. The biopsy device of claim 17, further comprising a catheter extending from the first jaw with the suction tube and wire disposed within.

19. The biopsy device of claim 18, wherein the first jaw has at least one tang extending from a rear end, and a distal portion of the catheter includes at least one aperture configured to receive the at least one tang.

20. The biopsy device of claim 18, further comprising a tube having a plurality of lumens including at least a first lumen that receives the catheter and a second lumen in communication with a fluid source.

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