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[Continued on next page]

(54) Title: METHODS AND DEVICES FOR EXCISION OF TISSUE

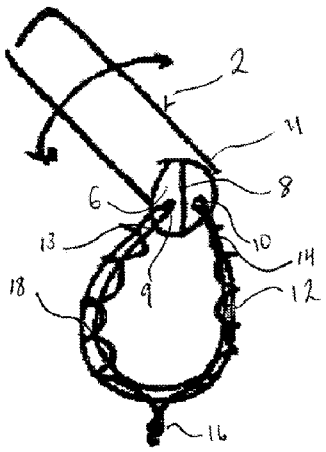


Figure 1A

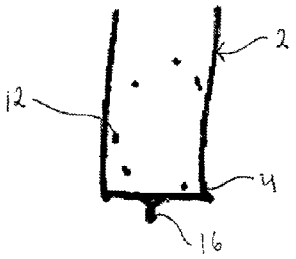


Figure 1B

(57) Abstract: Various apparatus and methods for excising tissue are described therein. In certain variations, a method of excising a target tissue mass from a subject, may include advancing an elongate instrument having an opening at its distal end into a subject. A cutting element, e.g., a snare or loop, may be advanced from the distal end of the elongate instrument, wherein the cutting element may be configured to cut tissue. The cutting element may be positioned near the target tissue mass. The cutting element may be actuated, e.g., expanded or deployed, and may perform energy based or mechanical cutting of a section of tissue encapsulating the target tissue mass. The cut section of tissue and the target tissue mass encapsulated therein may be removed from the subject.

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METHODS AND DEVICES FOR EXCISION OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Application Number 61/486,206 filed May 13, 2011 and U.S. Provisional Application Number 61/485,621 filed on May 13, 2011; and is a continuation-in-part of U.S. Application Number 13/107,720 filed May 13, 2011 and U.S. Application Number 13/107,759 filed May 13, 2011, the contents of each of which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

[0002] This application is directed to methods and devices for excising tissue. The procedures described herein may be performed in various regions of the body.

BACKGROUND

[0003] Current procedures for excising tissue involve invasive surgeries, e.g., cutting open a patient's chest to excise tissue in a lung. Other procedures involve the use of needles to remove portions of a tumor or diseased tissue. These procedures can cause complications and have their limitations. Because of the difficulties and risks associated with these current procedures, tumors are often left in place and monitored to determine whether or not they are cancerous. This exposes the patient to large amounts of radiation as well as the stress and worry of knowing a potentially lethal tumor or nodule remains in their body.

[0004] Therefore, there remains a need for more effective and efficient apparatus and methods for excising tissue in a minimally invasive fashion.

SUMMARY

[0005] Various apparatus and methods for excising tissue are described therein.

[0006] In certain variations, a method of excising a target tissue mass from a subject, may include one or more of the following steps. An elongate instrument having an opening at its distal end may be advanced into a subject. A cutting element e.g., a snare, may be advanced from the distal end of the elongate instrument, where the cutting element or snare

may be configured to cut tissue. The cutting element or snare may be positioned near the target tissue mass. The cutting element or snare may be actuated, e.g., expanded or deployed, and may perform energy based or mechanical cutting of a section of tissue encapsulating the target tissue mass. The cut section of tissue and the target tissue mass encapsulated therein may be removed from the subject. In certain variations, the cutting element or snare may be advanced while energized electrically to cut tissue, expanded and/or rotated around the tissue mass while energized electrically to cut tissue, and then used without electrical activation to encapsulate or fixate onto the tissue mass to enable withdrawal of the tissue mass from the body.

[0007] In certain variations, an apparatus for excising a target tissue mass from a subject may include an elongate instrument having an opening at its distal end. The opening may be divided by a septum or divider to create a first port and a second port. An actuatable cutting element or snare may have a first portion or leg extending from the first port and a second portion or leg extending from the second port. The cutting element or snare may be configured to cut tissue and the septum or divider may be configured to support the actuatable cutting element or snare during rotation.

[0008] In certain variations, various excision methods and apparatus described herein may be guided to or near a target tissue or may access a target tissue or tumor by being advanced into and through an airway, through an opening or extra-anatomic opening created in an airway wall and to or near the target tissue or tumor beyond, at, outside or near the created opening. In other variations, the methods and apparatus described herein may be utilized to perform excision procedures in various regions of the body utilizing various access techniques.

[0009] This application is also related to the following applications 61/485,621, filed on May 13, 2011; 13/107,720, filed on May 13, 2011; 13/107,759, filed on May 13, 2011; 61/563,369 filed November 23, 2011; 11/538,950 filed October 5, 2006; 12/939,968 filed November 4, 2010; 12/939,961 filed November 4, 2010; 12/939,956 filed November 4, 2010 and the patent application filed on the same day as the present application and titled "METHODS AND DEVICES FOR ABLATION OF TISSUE" and identified by attorney docket number BRON-N-E029.02-US; the contents of each of which are incorporated herein by reference in their entirety.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Figures 1A-1B illustrates various views of a variation of an apparatus for excising tissue.

[0011] Figure 2 illustrates a cross section of a variation of an elongate instrument of an apparatus for excising tissue.

[0012] Figure 3A illustrates a side view of another variation of an apparatus for excising tissue.

[0013] Figure 3B illustrates a front view of the apparatus for excising tissue of figure 3A.

[0014] Figures 4A-4B illustrates various shapes of cut tissue encapsulating a target tissue mass or tumor for removal.

[0015] Figure 5A illustrates a side view of another variation of an apparatus for excising tissue.

[0016] Figure 5B illustrates a front view of the apparatus for excising tissue of figure 5A.

[0017] Figures 6A-6B illustrate a side view of a variation of an apparatus for excising tissue having a side cutter.

DETAILED DESCRIPTION

[0018] Various apparatus and methods for excising tissue in a subject are described herein. Tissue may be excised from various parts of the body, including, e.g., the lung. Various types of tissue may be excised, including, e.g., diseased tissue, tumors or nodules. In certain variations, the procedures described herein may be performed through an opening, port or channel through an airway wall.

[0019] Figures 1A and 1B show one variation of an apparatus for excising tissue. The apparatus may include an elongate instrument 2, e.g., a rod, shaft or sheath. The elongate instrument 2 may have a proximal end and a distal end 4 or tip. The elongate instrument 2 may include one or more lumens extending from the proximal end to the distal end 4. The distal end 4 may include one or more openings 6. The distal end 4 of the elongate instrument may include a septum 8, wall or divider, which may divide the opening 6 into two or more ports, openings or holes, e.g., a first port 9 and a second port 10. The ports or holes may have a variety of shapes. For example, the septum 8 may divide the opening 6, providing two D shaped ports or circular ports.

[0020] A cutter or cutting element may be provided in or on the elongate instrument 2, e.g., at the distal end of the elongate instrument. The cutting element may be actuatable from the opening 6 at the distal end 4 of the elongate instrument 2, e.g., the cutting element may be extendable retractable, or rotatable. In certain variations, the cutting element may be in the form of a snare, loop, or other wire or cable having various configurations. The cutting element may include conductive material, such that the cutting element may be energized to deliver energy, e.g., electricity or heat, to perform the cutting of a tissue. For example, the cutting element may be an electrical cutting element having one or more electrodes through which electrical current flows, e.g., a snare or loop or partial loop electrode. The electrical cutting element may be monopolar or bipolar and utilize different wavelengths (e.g. radiofrequency) and waveforms (e.g. pulsed, continuous, or sinusoidal) of energy. In another variation, a mechanical cutting element having a sharpened edge, surface or blade may be utilized. A cutting element may have mechanical and/or energy based cutting functionality. Such cutting elements may be used separately or in combination.

[0021] Figures 1A and 1B show an example of a cutting element in the form of a snare 12. The snare 12 have a first portion 13, leg or member positioned in or extending from or into the first port 9 and a second portion 14, leg or member positioned in or extending from or into the second port 10. A snare is meant to include but is not limited to a loop, e.g., a partial loop, or complete loop, or other collapsible or expandable curved element or wire. The first and second portions or members 13, 14 of the snare may extend and join in an arc, loop or curved portion to form the snare 12. The snare may be constructed of a single piece of wire, cable or other material that is curved or doubled on itself or optionally, the snare may be formed from multiple pieces of wire, cable or other material. The snare 12 may include conductive material (e.g. stainless steel, nitinol, or nichrome), such that the snare may be energized to deliver energy, e.g., electricity or heat, to perform the cutting of a tissue. In certain variations the snare may be a loop or partial loop electrode. In certain variations, the snare may be a wire. The wire may have a variety of shapes, e.g., the wire may be circular or D-shaped. A D-shaped wire may provide enhanced rigidity to the wire or provide the wire with enhanced torsional strength or hoop strength. The snare may have sufficient hoop strength such that it may expand, e.g., passively or actively expand, within tissue as it cuts into tissue. In certain variations, the snare or wire may be a ribbon or have a ribbon-like shape, providing torsional rigidity to the snare or wire in the direction of rotation. The snare may or may not be operated under saline irrigation. The snare 12 may

be expandable, collapsible, and/or retractable. In certain variations, the snare 12 may have a sharpened edge or surface for mechanical cutting.

[0022] A protrusion 16, e.g., a piercing member, nipple or tip, may extend from the snare 12. As shown, in Figure 1A, the protrusion 16 may extend from a distal portion or point of the snare or from a distal turn in the snare or loop. The protrusion 16 may be used to pierce tissue, for example, to pierce through and create an opening through an airway wall. The protrusion 16 may provide concentrated or localized electron density such that the protrusion 16 may pierce, cut or form a hole through tissue. In certain variations, a wire may be twisted or bent to form the protrusion 16, creating a point or tip that can have a concentrated or increased energy density. In other variations the protrusion may have a pointed or sharpened end such that the protrusion may mechanically puncture, pierce cut or form a hole through tissue.

[0023] In certain variations, a conductive wire 18 may be wrapped around a snare 12. The wire 18 may provide points or focal points of increased or concentrated electron density along and/or on the snare 12 for cutting tissue. In certain variations, a snare having conductive properties may be utilized with or without a conductive wire or other conductive material wrapped around or positioned on the snare 12. In certain variations, a snare having a wire wrapped thereon to provide electron density focal points along the snare may require less power to perform cutting than a snare having no wire wrapped thereon. The conductive wire may be wrapped around the loop or partial loop portion of a snare and/or around the protrusion or nipple on the snare. The energized snare, protrusion, and/or wrapped wire may cut through tissue.

[0024] As shown in Figure 1A, the distal end 4 of the elongate instrument 2 may include a septum 8, wall or divider segment, which divides the opening 6 into at least a first port 9 and a second port 10. A port is meant to include but is not limited to any opening, hole, channel or slit. The septum 8 may vary in length along the longitudinal axis of the elongate instrument and may divide at least a portion of a lumen extending from the proximal end of the elongate instrument to the opening at the distal end of the elongate instrument, providing one or more channels or tunnels therein in communication with the first and/or second ports or openings.

[0025] The septum 8 may be rigid and/or may provide support, e.g., torsional or rotational rigidity or support, to the elongate instrument. The septum 8 may support a cutter, such as a snare. Where a septum is utilized to divide the opening into a first and second port, the size of the port openings and the size of the snare wire to be received or to

extend from the ports may be maximized, while the septum may be configured to still provide support, e.g., rotational or torsional support, to the snare.

[0026] In certain variations, the apparatus for excising tissue may include an elongate instrument having a flexible proximal portion that may provide the elongate instrument with flexibility and/or torquability for navigating or weaving the elongate instrument in one or more degrees of freedom, through the tortuous anatomy of a subject, e.g., through airways, and/or for rotating the elongate instrument and/or cutter or snare. For example, since the elongate instrument may be used to access airways deep within the lung, the elongate instrument may include a flexible material. The elongate instrument may be sufficiently flexible to pass through a fully articulated bronchoscope. The elongate instrument may also include a support or rigid or reinforced distal portion for supporting a snare or other cutter extending from the distal portion of the elongate instrument, e.g., to provide rotational, torsional or other support or rigidity to the cutter or snare during actuation, e.g., during rotation of the cutter or snare or in the direction of rotation.

[0027] In one variation, an apparatus for excising tissue may include a backend or a proximal portion having sufficient flexibility and torquability to navigate or weave through airways and a distal portion that includes an insulating tip and/or sufficient rigidity to provide support for a snare, loop or other cutter during rotation of the elongate instrument and/or the snare, loop or cutter. An apparatus for excising tissue may be configured to provide sufficient support such that a snare or loop may remain in an open or expanded position with sufficient energy density for cutting tissue (without shorting out) while the snare or loop is being torqued or rotated. The supportive distal portion and/or septum of the apparatus prevents the wires, first and second portions, members or legs of the snare or loop from coming together, contacting or crossing each other, or collapsing on each other, which may result in loss of electrical current density in the snare and decreased cutting functionality.

[0028] Figure 2 shows a cross section of another variation of an apparatus for excising tissue. The apparatus includes an elongate instrument 22 having two or more lumens 24, 25 within the elongate instrument 22, where each lumen is in communication with an opening 28, 29 at the distal end of the elongate instrument 22. For example, the lumens may extend from a proximal end 26 to a distal end 27 of the elongate instrument 22 or along any portion of the elongate instrument. A snare (not shown) may extend from the elongate instrument where a first portion or leg of the snare is positioned in or extends from

a first lumen 24 and a second portion or leg of the snare is positioned in or extends from the second lumen 25.

[0029] A variety of elongate instruments, e.g., shafts, rods or sheaths, having various opening, lumen, septum or divider configurations are contemplated herein. The variations may provide a rigid, stable and/or torsional or rotational supportive distal end or portion for an elongate instrument to effect cutting of tissue and/or to allow for rotation of a cutter or snare to effectively cut tissue while preventing the snare or other loop or wire from collapsing on itself and disrupting the flow of energy through the snare, loop or wire. At least a portion of the various elongate instruments, for example, a distal portion or end, may be made from one or more materials including glass, quartz, Pyrex, Peek, ceramic, or any other material having a high melting point, which may be insulated, may withstand high temperatures, and/or provide rotational or torsional support to the cutter. The elongate instruments may be insulating. In certain variations, only the distal end or tip or distal portion of an elongate instrument is made from glass or a similar insulating material, which may provide a rigid support on the elongate instrument. An elongate instrument may also have a flexible portion or end, e.g., proximal portion or end, providing the instrument with the flexibility and maneuverability to navigate through the anatomy of a subject.

[0030] In one variation, an apparatus for excising tissue may include an insulating rod. A snare or wire loop may extend from the insulating rod. Radiofrequency (RF) energy may be used to energize the snare or wire loop. A grounding plate may also be utilized. The insulating rod may have an opening at its distal end. The opening may be divided by a septum, such that the opening looks like a theta θ. The septum divides the opening into two ports or holes, through which the snare or wire loop extends.

[0031] In use, an apparatus for excising tissue, as described herein, may perform tissue excision in a variety of ways, e.g., by electrical or mechanical cutting. A target tissue mass may be located within a subject. The elongate instrument having a cutter may be inserted into the subject. The elongate instrument may be advanced percutaneously or intraluminally or in any minimally invasive manner.

[0032] In one variation, a method for excising a target tissue mass, e.g., a tumor, from a patient's lung may include one or more of the following steps. The elongate instrument may be navigated within a lumen of an airway in the lung. The elongate instrument may be advanced to, near or in the proximity of the target tissue mass, e.g., via an opening created in an airway wall. The cutting element, e.g., a snare, loop or partial loop configuration, may be in a retracted position within the elongate instrument, and the

protrusion on a distal portion of the snare may be positioned, extend or jut out through the opening at the distal end of the elongate instrument, providing a piercing member or tip for piercing through tissue (e.g., as shown in Figure 1B). The snare may be energized, and/or the protrusion or piercing member or tip may have a concentrated electron or energy density, allowing the piercing member to pierce through tissue. Optionally, the protrusion may be sharpened or pointed to facilitate mechanical piercing or cutting.

[0033] The protrusion may be advanced through an extra-anatomic opening created in the airway wall. Optionally, the protrusion may be advanced to the airway wall, and used to create an opening, channel or port through the airway wall. The protrusion may then be used to create an opening, channel or port through or into the parenchyma or lung tissue by advancing the protrusion through the parenchyma or lung tissue. This may be accomplished prior, during or after snare activation or expansion. The snare may be advanced out of the opening at the distal end of the elongate instrument, through the opening through the airway wall and into the parenchyma or lung tissue. The snare may be opened or expanded to create a slit in the lung tissue or to enlarge the hole or slit in the lung tissue, which was created by the protrusion. The tissue may be cut and a hole or slot or channel may be formed as the snare is advanced into the tissue and/or as the snare is pulled or retracted from the tissue. The snare may be advanced or retracted in a collapsed or expanded form.

[0034] The snare is advanced toward the target tissue mass and positioned next to, near or in the proximity of the target tissue mass. The snare is opened or expanded, if not already opened or expanded. The size of expansion can be varied to determine how much tissue is excised and expansion can take place before or during rotation. The elongate instrument and/or snare is rotated around the target tissue mass, such that the snare cuts an area or section of tissue encapsulating or enclosing the target tissue mass. Rotation of the snare causes the circular or loop shaped snare to cut a substantially spherical shaped section of tissue or ball of tissue with the target tissue mass or tumor located within the cut section of tissue, e.g., in the center of the cut section of tissue. Cutting performed by the protrusion and/or snare or loop may be performed by activating energy delivery to perform energy based cutting or by providing a sharpened or cutting surface or edge on the snare to perform mechanical cutting.

[0035] After turning off energy delivery, the snare may be closed down or cinched around the cut section of tissue or spherical shaped cut section of tissue, encapsulating the target tissue mass such that the snare holds and/or compresses the cut tissue and the target

tissue mass is encapsulated therein. The snare may be retracted or pulled out of the tissue, removing the excised or cut tissue mass from the parenchyma or lung tissue, through the opening through the airway wall and out of the patient. Removal of the target tissue or tumor, which is enclosed or encapsulated within healthy or normal tissue, may avoid or minimize tracking or seeding of any cancerous, tumor or diseased tissue from the target tissue mass or tumor in the patient. In certain variations, suction may be utilized to remove the cut section of tissue.

[0036] In one example, a snare may be positioned in tissue adjacent to or next to a target tissue or tumor, rather than through the target tissue, and as the snare is expanded or opened, the snare cuts through the adjacent tissue making a track or slit in the tissue. The snare may be expanded to a diameter having a size sufficient such that upon subsequent rotation of the expanded snare about a point outside or next to the target tissue, the snare will cut tissue around the target tissue. For example, the snare may be rotated about ninety degrees or any degree necessary to form a cut or track around the target tissue and then the snare may be closed or collapsed to complete the cut or track excision. This results in a cut out section of healthy tissue which fully encases or protects the target tissue or tumor within healthy or normal tissue. The snare may be re-expanded and positioned around the cut section of tissue to cinch or grab the cut section of tissue for removal. Optionally, suction may be utilized to remove the cut section of tissue.

[0037] Lung tissue is very compressible because there is a large amount of air in the lung. Cinching the snare down around the excised section of tissue may compress the tissue. Also, as the excised tissue is pulled through the opening through the airway wall, the opening tends to provide give or to expand. Thus, a large amount of inflated excised tissue may be removed through an opening in an airway wall that has a smaller diameter than the diameter of the inflated excised tissue by compressing the excised tissue and allowing the opening in the airway wall to expand. For example, a one centimeter tumor may be compressed and pulled out of an opening or hole in an airway wall, where the opening or hole is half a centimeter in size, i.e., half the size of the tumor or even smaller. The expandability of the tissue through which the excised tissue mass is being removed may be a factor in determining the size of the opening necessary to remove the tissue mass.

[0038] Optionally, vacuum may be applied to the excised tissue to compress and/or suck or draw down the excised tissue for removal. For example, suction may compress or pull the excised tissue down to about 10 to 1 from 8 to 1. In certain variations, suction or vacuum may be applied through an opening at the distal end of the elongate instrument.

[0039] As discussed supra, a rigid septum provided at the opening at the distal end of the elongate instrument may provide support to keep the first and second portion, members or legs of a snare or wire loop separated from one another and prevents the snare from collapsing and twisting on itself when the snare is rotated or otherwise actuated. If the snare were to collapse or twist into a spiral, energy or electrical current flow through the snare would stop, which would disrupt the ability of the snare to cut or excise tissue.

[0040] In certain variations, a bag or sleeve may be provided for catching the excised tissue as it is removed from the surrounding tissue, e.g., in the lung. For example, a bag or sleeve may be positioned at the distal end of the elongate instrument for receiving the excised tissue as it is pulled from the parenchyma or surrounding lung tissue by the snare. Similarly, a sheet of material may be unfurled from one side of the snare loop as it rotates around tissue, thereby fully encapsulating the tissue before it is withdrawn from the body.

[0041] In certain variations, a sealant may be delivered via the lumens, ports, or openings in the elongate instrument or the snare or from spines along the outside of the elongate instrument or snare. The sealant may be delivered in the slit or incision formed by the snare or protrusion to seal blood vessels or air leaks. For example, sealant may be delivered as the snare is being retracted from the lung tissue during removal of the excised section of tissue. Optionally, a blunt tipped extension or member may be used to compress airways to stop air leaks.

[0042] Where excision is performed on tissue in the lung, the lung is a low pressure system which facilitates sealing of blood vessels that may be cut during the excision process. The energy that is used to power the snare to cut tissue may also be used (by changing the wavelength, power, voltage, current, or wave form) to apply heat to seal the cut vessels.

[0043] In certain variations, various excision methods and apparatus described herein may be guided to or may access a target tissue or tumor by being advanced into and through an airway, through an opening or extra-anatomic opening created in an airway wall and to the target tissue or tumor beyond, at or near the created opening, where the target tissue is located in the lung, outside the lung or in another area of the body. The various excision apparatus described herein, may be guided or navigated to the target tissue or tumor and/or the target tissue or tumor may be located using one or more imaging technologies, such as, x-ray, CT, MRI, fluoroscopy, 3D fluoroscopy

[0044] In certain variations, methods or platforms for accessing target tissues (e.g., diseased

tissue, tumors, parenchyma or other tissues or structures) in a lung or other area of the body, through an opening, extra-anatomic opening or port through the airway wall may be utilized to access a target tissue with any of the excision apparatus or methods described herein. The target tissue may be located outside of the airway in which the opening is created or beyond the airway wall, e.g., in the parenchyma of the lung.

[0045] Access to the central airways may be achieved by using a standard bronchoscope or other scope or elongate instrument. A target site or point in a larger airway or central airway or smaller airway may be determined or selected, which may allow a straight or substantially straight tunnel, channel or path to be created leading directly to the target tissue. Once the target site on the airway wall is located an opening is created through the airway wall at the target site on the wall by advancing a piercing member or needle to the target site and through the airway wall at the target site. The created opening may be dilated with a balloon catheter or other expandable device.

[0046] Once the opening has been dilated, a sheath or other elongate instrument may be fed through the hole or opening and into the lung tissue. The sheath may contain a dissecting catheter and the tip of the dissecting catheter may be sharp to tunnel through tissue or it may be blunt or rounded to allow it to tunnel without perforating blood vessels or other structures. The tip may tunnel or advance through the lung tissue in a substantially straight path where turns are minimized or eliminated. Once the sheath and dissecting catheter are fed to or near the target tissue or tumor, the dissecting catheter may be removed, with the sheath remaining in position to be used to access the target tissue or tumor and to deliver any of the various excision apparatus described herein to or near the target tissue or tumor to perform excision. Various imaging techniques may be utilized to guide the bronchoscope and piercing member and to guide the sheath, dissecting catheter, and/or excision apparatus through the airway to the target site on the airway wall and/or to the target tissue for removal. Imaging techniques may include fluoroscopy, computed tomography, positron emission technology, magnetic resonance imaging, or ultrasound.

[0047] In certain variations, the multiple steps of the above procedure, i.e., creating an opening in the airway wall, going through the opening to dilate it and/or extending an instrument or apparatus through the opening to access a target tissue for excision, may be performed with a single device or with more than one device. For example, a multi purpose device, e.g., a variation of an excision apparatus as described herein, may create an

opening with an energized protrusion or piercing tip, and be advanced through the opening to dilate the opening and/or access a target tissue to perform excision. Alternatively, the above procedure may be performed with more than one device, e.g., utilizing separate devices to create an opening, to dilate the opening and/or access the target tissue via the created opening with an excision apparatus (as described herein) to excise or cut tissue.

[0048] The various excision methods or apparatus described herein may also be guided to or may access a target tissue or tumor using any of the various devices or methods for creating an extra-anatomic opening in an airway wall and/or accessing tissue through an extra- anatomic opening through an airway wall as described in the following: US. Pat. Applications: 61/485,621, filed on May 13, 2011; 13/107,720, filed on May 13, 2011; 13/107,759, filed on May 13, 2011; 61/563,369 filed November 23, 2011; 11/538,950 filed October 5, 2006; 12/939,968 filed November 4, 2010; 12/939,961 filed November 4, 2010; and 12/939,956 filed November 4, 2010; the contents of each of which are incorporated herein by reference in their entirety.

[0049] Also, in certain variations, any of the imaging technologies described above may be incorporated into an excision apparatus or may be performed through the elongate instrument of the apparatus such that navigation or tracking, tissue cutting, and tissue removal may be performed by a single device or multiple devices provided via the elongate instrument or other instrument.

[0050] As shown in Figures 3A-3B, another variation of an apparatus for excising tissue may include an elongate instrument 30 and a snare 32 or cutter loop extending from or positioned at an opening at the distal end of the elongate instrument 30. A rod 34, which may be positioned in or extend from the elongate instrument, may be connected or attached to the distal end of the snare 32. In use, the elongate instrument 30 may be advanced to, near or in proximity to the target tissue mass. The snare 32 may be advanced such that it cuts through tissue and positions the snare 32 next to the target tissue mass. In certain variations, where the apparatus is used to excise tissue from a lung, e.g., a lung tumor, the apparatus may be advanced within an airway of the lung. The snare 32 may cut or create an opening through the airway wall and may be advanced or pushed out, into the parenchyma or lung tissue, to or near the target tissue mass.

[0051] Once positioned near the target tissue mass, the rod 34 may be actuated or withdrawn, pulling the snare 32, from the snare distal end, such that the snare 32 folds back on itself, thereby cutting an area or section of tissue surrounding the target tissue mass. The cut section of tissue encapsulates or encloses the target tissue mass or tumor and cuts

of any blood vessels leading to the target tissue mass or tumor. The snare 32 may then be reopened or unfolded such that the snare may surround the cut section of tissue. The snare 32 may then be drawn down or cinched around the cut section of tissue to grab or hold the tissue. The snare 32 may then be retracted to remove the cut section of tissue from the lung and from the patient, e.g., via the opening through the airway wall. Optionally, the cut section of tissue may be left in place to shrivel and die in the body as the blood vessels and blood supply to the section of tissue have been cut off and no longer feed the tissue. Rotation of the snare may or may not be required to effect cutting of the tissue by the snare 32.

[0052] Figures 5A-5B show another variation of an apparatus for excising tissue including an elongate instrument 40 and a cutter in the form of a snare 42. The snare 42 includes a loop 43 and one or more portions, members or legs 44. The legs 44 connect to various points along the loop 43. The legs 44 expand or hold open the loop 43. In use, the snare 42 is advanced from the elongate instrument and pushed over and around a target tissue mass, with the loop advancing past the target tissue mass. As the snare 42 is advanced, it cuts a section of tissue around the target tissue mass. The cut section of tissue encapsulates or encloses the target tissue mass. Once the loop 43 is advanced over and passed the target tissue mass, the legs 44 are drawn toward each other or collapsed, flexing the legs 44 and closing the snare 42 around the cut section of tissue. This forms a cage or capsule around the cut section of tissue such that the snare may hold the cut section of tissue. The snare may be retracted or withdrawn to remove the cut section of tissue and the target tissue mass encapsulated therein.

[0053] In certain variations, the loop 43 may be round or configured in a variety of different shapes, such that the snare may be collapsed and positioned within a lumen of the elongate instrument. In certain variations, a lumen or working channel of the elongate instrument may have a diameter that measures about 1 to about 5 mm, e.g., 2.4 mm.

[0054] The legs, members or portions of a snare may be insulated in a nonconductive material for snares that are energized to perform electrical cutting. Optionally, a sealed sack or sheet may be positioned around the legs, such that when the legs are collapsed and the snare is closed down, the sealed sack or sheet would be wrapped around the snare and/or the cut tissue. Optionally, the snare may be configured for mechanical cutting, e.g., where the snare has a sharpened edge or blade.

[0055] As shown in figures 4A-4B, the various apparatus and methods described herein may cut a section of tissue 50 encapsulating a target tissue mass 52, where the cut section

of tissue 50 has a variety of shapes and configurations depending on the apparatus utilized and the shape or configuration of the cutter, e.g., a snare or loop or other cutting mechanism.

[0056] Figures 6A-6B show another variation of an apparatus 60 for excising tissue. The apparatus 60 includes a side cutter 60. In this embodiment, first and second members 61, 62 are positioned at the distal end of the apparatus. The first member 61 is more rigid than the second member 62 and is slidably actuatable along the axis of the apparatus 60. The second member 62 member is less rigid so when the first member 61 is pulled in a proximal direction, the second member 62 deploys outward to form a cutting snare (for example, the second member 62 may be a wire or cable). In this way, the cutting apparatus 60 can be electrically energized in the closed position, pushed forward, cutting through tissue to be located next to a target tissue mass, actuated to deploy (expand) the snare while energized, and rotated while energized to cut around the target tissue mass to cut or excise the tissue. Once the tissue mass encasing the target tissue mass has been excised, the snare can be rotated back to straddle the center of the tissue mass, electrical energy can be turned off, and the snare can then be drawn down to compress the mass for removal from the body. The amount of deployment or expansion can be varied as the snare is rotated to determine how much tissue is excised. For example, if the apparatus is placed next to the tissue mass to be excised, the user might start rotationally cutting with the snare collapsed, gradually deploying the snare as it is rotated to 180 degrees, and then gradually collapse the snare as it rotates through the final 180 degrees of rotation to achieve cutting only around the mass. Alternately, if the apparatus was placed in the center of the mass, the snare could be deployed to a specific size as it is rotated through 360 degrees to cut around the mass.

[0057] Electrical cutting or mechanical cutting may be utilized in any of the variations described herein. A cutter may be energized to cut tissue. Optionally, a cutter may include a sharp edge or may utilize ultrasound to cut tissue. In certain variations, ultracision or a rotary ultracision may be utilized to cut tissue. For example, an ultrasonically rotating cutter which may rotate in small degree intervals to create a cutting action may be utilized.

[0058] Any of the variations described herein may used for cutting or excising tissue in any region of the body, e.g., the lung, liver, or brain via various access points, utilizing minimally invasive or open surgery techniques.

[0059] All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. To the extent there is a conflict in a meaning of a term, or otherwise, the present application will control. Although variations

of the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims. It is also contemplated that combinations of the above described embodiments/variations or combinations of the specific aspects of the above described embodiments/variations are within the scope of this disclosure.

[0060] Each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other variations. Modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention.

[0061] Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as the recited order of events. Furthermore, where a range of values is provided, every intervening value between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. Also, any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein.

[0062] All existing subject matter mentioned herein (e.g., publications, patents, patent applications and hardware) is incorporated by reference herein in its entirety except insofar as the subject matter may conflict with that of the present invention (in which case what is present herein shall prevail). The referenced items are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such material by virtue of prior invention.

[0063] Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said" and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise,

all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0064] This disclosure is not intended to be limited to the scope of the particular forms set forth, but is intended to cover alternatives, modifications, and equivalents of the variations described herein. Further, the scope of the disclosure fully encompasses other variations that may become obvious to those skilled in the art in view of this disclosure. The scope of the present invention is limited only by the appended claims.

CLAIMS

We claim:

1. An apparatus for excising a target tissue mass from a subject comprising:

an elongate instrument having an opening at its distal end, wherein the opening is divided by a septum creating a first port and a second port;

an actuatable snare coupled to the elongate instrument, the snare having a first portion extending from the first port and a second portion extending from the second port, wherein the snare is configured to cut tissue; and

wherein the septum is configured to support the snare.

2. The apparatus of claim 1, wherein the elongate instrument includes a flexible proximal portion to facilitate navigation of the elongate instrument through the anatomy of a subject.

3. The apparatus of claim 1 or 2, wherein the snare is wrapped with a conductive wire which provides concentrated points of electron density on the snare to cut tissue.

4. The apparatus as claimed in any one of the preceding claims, further comprising a protrusion extending from a distal turn in the snare, wherein the protrusion is configured to pierce or cut through tissue.

5. The apparatus as claimed in any one of the preceding claims, wherein the distal end of the elongate instrument includes a rigid septum which provides rotational support to the snare such that the snare may be rotated without collapsing on itself.

6. The apparatus as claimed in any one of the preceding claims, wherein the snare is configured to expand once positioned next to a target tissue and to rotate in order to cut a section of tissue encasing the target tissue mass.

7. The apparatus as claimed in any one of the preceding claims, wherein the snare is configured to collapse around a cut section of tissue to hold the tissue for removal.

8. The apparatus as claimed in any one of the preceding claims, further comprising an imaging mechanism for guiding or tracking the apparatus.

9. The apparatus as claimed in any one of the preceding claims, wherein the elongate instrument includes a flexible proximal portion to facilitate navigation of the elongate instrument through the anatomy of a subject and a rigid distal portion to provide torsional rigidity or support to the snare.

10. The apparatus as claimed in any one of the preceding claims, wherein the snare is a ribbon such that it provides torsional rigidity in the direction of rotation.

11. The apparatus as claimed in any one of the preceding claims, wherein the snare comprises a loop or a partial loop.

12. A method of excising a target tissue mass from a subject, the method comprising:

advancing an elongate instrument having an opening at its distal end into a subject;

advancing a snare from the distal end of the elongate instrument, wherein the snare is configured to cut tissue;

positioning the snare near the target tissue mass;

actuating the snare to cut a section of tissue encapsulating the target tissue mass; and

removing the cut section of tissue and the target tissue mass encapsulated therein from the subject.

13. The method of claim 12, wherein actuating the snare comprises rotating the snare around the target tissue mass.

14. The method of claim 12, wherein actuating the snare comprises expanding the snare to cut tissue.

15. The method of claim 12, wherein the snare is positioned in healthy tissue adjacent the target tissue mass, wherein the snare is expanded and rotated to form a cut around the target tissue mass and collapsed to complete the cut, thereby creating a cut section of healthy tissue which fully encases the target tissue mass.

16. The method of claim 12, further comprising closing the snare around the cut section of tissue such that the snare holds the cut section of tissue and the target tissue mass encapsulated therein for removal.

17. The method of claim 12, wherein the cut section of tissue and the target tissue mass encapsulated therein are removed by retracting the snare into the elongate instrument.

18. The method of claim 12, where the cut section of tissue is captured by collapsing the snare around the cut section of tissue and extracting the cut section of tissue by removing the snare from subject.

19. The method of claim 12, wherein the snare cuts a slit through tissue as it is advanced from the elongate instrument and into position next to the target tissue mass.

20. The method of claim 12, further comprising delivering a sealant to seal cut airways or blood vessels.

21. The method of claim 12, further comprising applying suction through the elongate instrument to compress or draw down the cut section of tissue for removal.

22. The method of claim 12, wherein the snare is positioned in healthy tissue next to the target tissue and the cut section of tissue comprises healthy tissue encasing the target tissue mass.

23. The method of claim 12, wherein the target tissue mass is a lung tumor.

24. The method of claim 12, wherein the snare is advanced through an opening through an airway wall to access the target tissue mass or tumor in the lung.

25. The method of claim 12, wherein the snare is configured to collapse around the cut section of tissue to hold the tissue for removal.

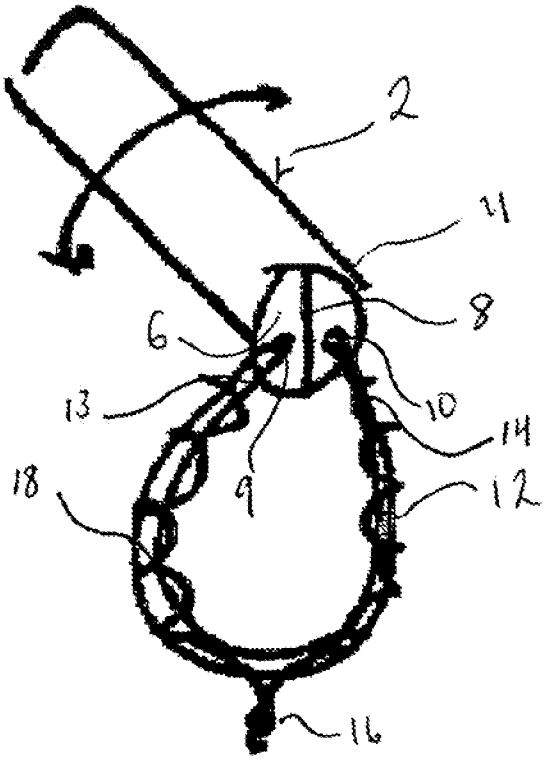


Figure 1A

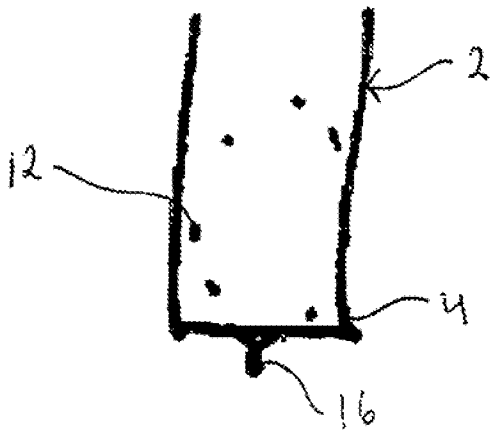


Figure 1B

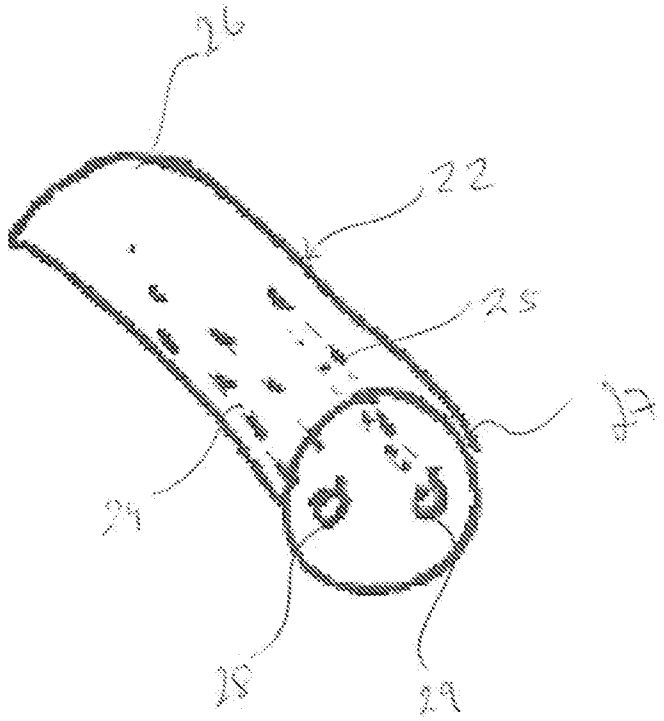


Figure 2

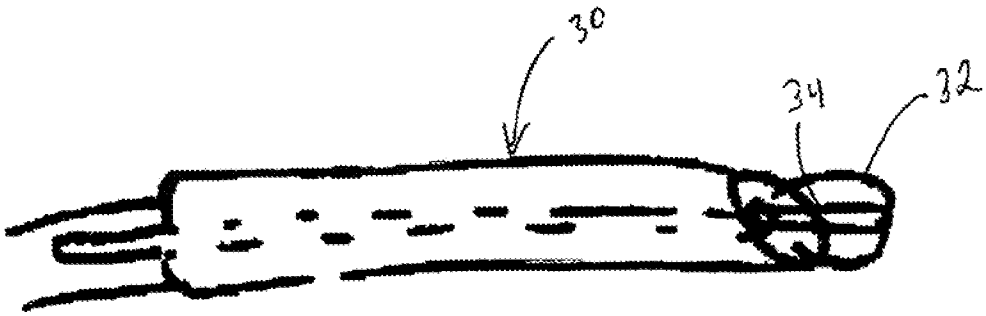


Figure 3A

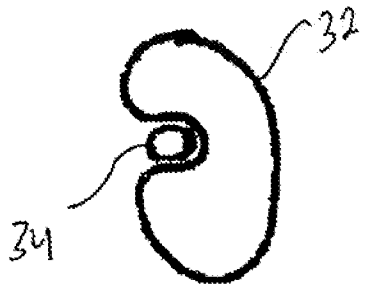


Figure 3B

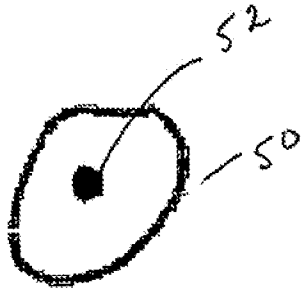


Figure 4A

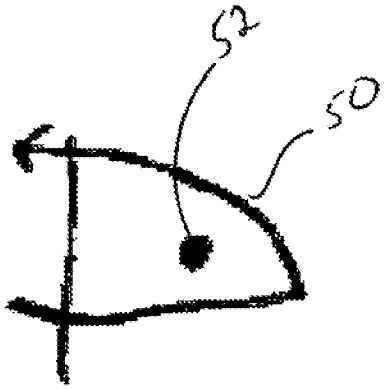


Figure 4B

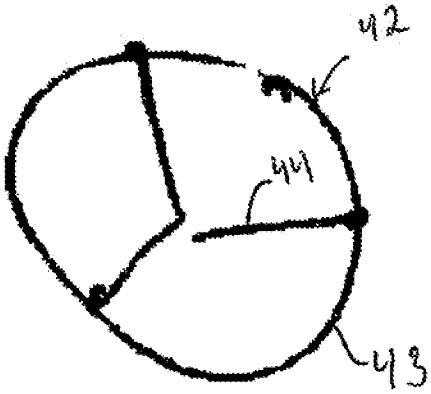


Figure 5A

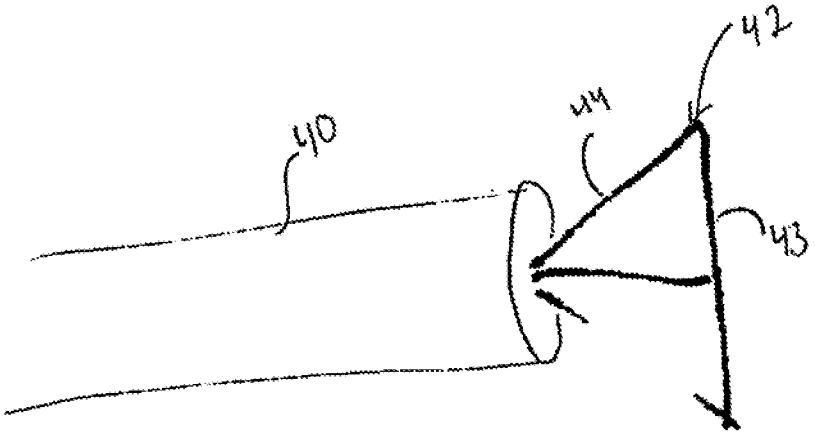
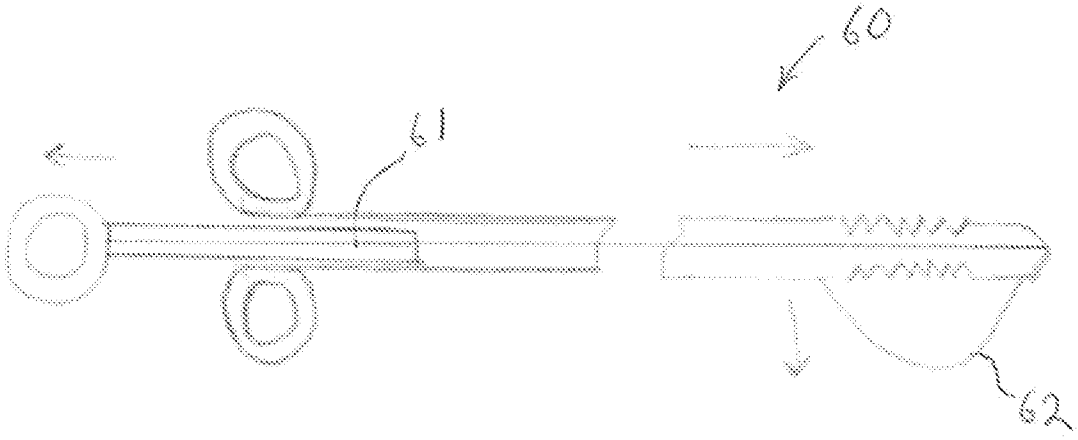


Figure 5B

Figure 6A



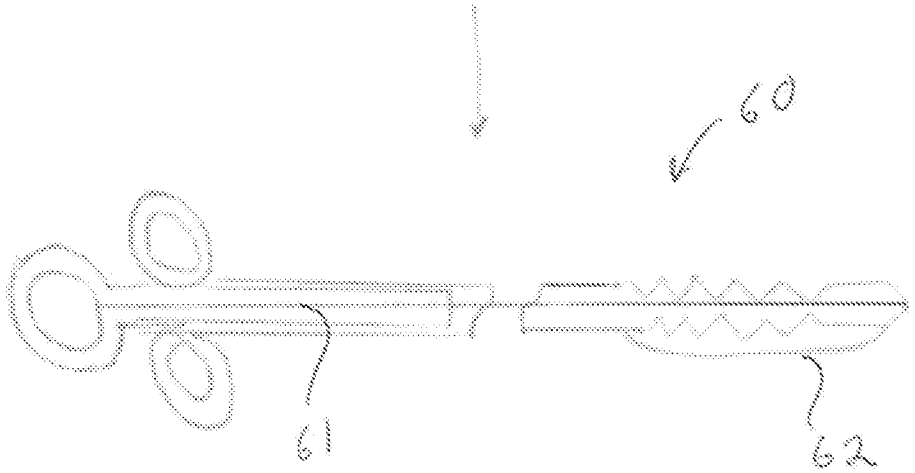


Figure 6B