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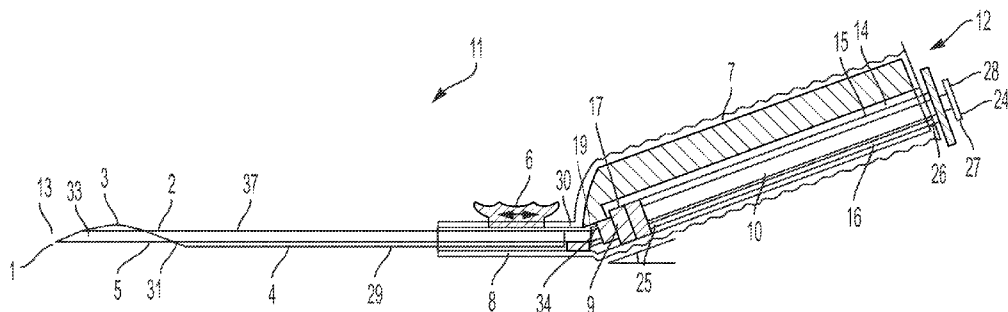


FIG. 1

(57) Abstract: The presently disclosed subject matter relates generally to a device for cutting soft tissue, such as transverse carpal ligaments and annular ligaments of the finger, and methods of using the soft tissue cutting device. A soft tissue cutting device includes an inner tubular member extending between a distal end and a proximal end of the inner tube, an outer tubular member disposed over at least a portion of the inner tubular member and movable between an initial position and an extended position, an outer tubular member movement controller that controls movement of the outer tubular member between the initial position and the extended position, and an attachment mechanism for removably coupling the proximal end of the inner tubular member to a dispensing member. A distal end of the outer tubular member includes a cutting member.



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## SURGICAL CUTTING DEVICE FOR ULTRASONIC GUIDED SOFT TISSUE SURGERY

### RELATED APPLICATION

**[0001]** The present application claims priority U.S. Provisional Patent Application No. 63/135,352, filed January 8, 2021, the entire contents of which are incorporated herein by reference.

### TECHNICAL FIELD

**[0002]** The present invention generally relates to a soft tissue cutting device and soft tissue cutting methods. The present invention also relates generally to a transverse carpal ligament cutting device, a pulley cutting device, and soft tissue cutting methods.

### BACKGROUND

**[0003]** Carpal tunnel syndrome affects approximately 3.7% of the general population and up to 7% of manual labor workers. Several varying surgical procedures are performed annually to treat patients with carpal tunnel syndrome. One of these surgical procedures is known as a carpal tunnel release procedure (“CTR procedure”). During the CTR procedure a transverse carpal ligament is cut in order to reduce median nerve compression and carpal tunnel pressures in the carpal tunnel region.

**[0004]** CTR procedures can be performed by accessing the carpal tunnel primarily from the outside, or accessing the carpal tunnel primarily from the inside. In the former, a palmar incision of various sizes is used to directly visualize and transect the transverse carpal ligament. In the latter, the transverse carpal ligament is visualized from within the carpal tunnel using either an endoscope advanced through a small palmar and/or proximal wrist incision, or ultrasound guidance. These visualization methods are important, as it is hard to visualize individual anatomical variations in the carpal tunnel region, as well as the transverse carpal ligament and at-risk structures nearby (e.g., a median nerve and an ulnar artery). Poor visualization can cause incomplete release of the transverse carpal ligament, or cause injuries to nearby structures.

**[0005]** While ultrasound guidance with CTR procedures enable better visualization of the carpal tunnel region during the procedure, there are still concerns associated with these procedures. One concern is that a sharp cutting instrument may be passed into the carpal tunnel without the ability to precisely control deployment of a sharp cutting instrument. Thus, the sharp cutting instrument presents a risk to both the patient and the operator. It would be desirable to provide an improved

device that includes a sharp cutting instrument that is not exposed until the cutting of the transverse carpal ligament is required (i.e., after proper positioning).

**[0006]** Also, because cutting instruments often require the use of two hands, several operators use ultrasound guidance to place a sharp cutting instrument in position to cut the transverse carpal ligament, but then abandon the ultrasound visualization during the actual cutting, as they are unable to simultaneously hold the ultrasound probe, and cut the ligament. It would be desirable to provide an improved device that allows an operator to continue using ultrasound guidance during cutting.

**[0007]** Further, it would be desirable to provide such a device that is capable of administering an anesthetic. Prior to the commencement of the CTR procedure, an anesthetic is injected subcutaneously at the palmar incision site. Additionally, an anesthetic is injected with ultrasound guidance, intracarpally, and may also be injected to areas surrounding the carpal ligament. The anesthetic-containing syringe must be withdrawn from the carpal ligament area to enable the cutting device to be inserted into the wrist, with ultrasound guidance, to perform the CTR procedure. There exists a risk of nerve or artery damage when inserting instruments into the wrist and hand. This risk is increased by the insertion of two independent instruments, namely, the anesthetic-containing syringe, followed by the CTR cutting device. Thus, it would be desirable to provide a device that can perform both functions of delivering the anesthetic, and performing the ligament cutting.

#### SUMMARY

**[0008]** The present disclosure provides a device for cutting soft tissue that is capable of administering an anesthetic to a cutting site.

**[0009]** A first aspect of the disclosure provides a soft tissue cutting device including an inner tubular member having an internal chamber extending between a distal end and a proximal end of the inner tube, an outer tubular member disposed over at least a portion of the inner tubular member and movable between an initial position and an extended position, a movement controller that controls movement of the outer tubular member between the initial position and the extended position, and an attachment mechanism for removably coupling the proximal end of the inner tubular member to a dispensing member. A distal end of the outer tubular member may include a cutting member

**[0010]** In some embodiments, the movement controller includes a thumb slide attached to a surface of the outer tubular member. In some embodiments, the outer tubular member movement mechanism further includes a housing disposed around a portion of the outer tubular member distal end; and the

thumb slide extends through a portion of a surface of the thumb slide housing. In some embodiments, the handle is molded to allow for single handed use of the soft tissue cutting device. In some embodiments, the thumb slide is lockable.

**[0011]** In some embodiments, the attachment mechanism is a locking mechanism. In some embodiments, the locking mechanism is a luer lock. In some embodiments, the cutting member is a blade having a cutting edge. In some embodiments, the dispensing member is a syringe. In some embodiments, the dispensing member includes a dispensing tube and a depressible member disposed within the dispensing tube, and the depressible member is movable from an initial position to an extended position within the dispensing tube to expel the fluid from the barrel into the inner tubular member. In some embodiments, the dispensing tube is removably attached to a distal end of the attachment mechanism.

**[0012]** In some embodiments, the inner tubular member further includes a ramp on the outer surface of the inner tubular member. In some embodiments, the outer tubular member is slidably movable over the ramp to elevate at least a portion of the outer tubular member above the inner tubular member. In some embodiments, the cutting member on the outer tubular member is elevated when the outer tubular member is in the extended position. In some embodiments, the soft tissue cutting device further includes one or more balloons coupled to the outer tubular member that expand radially inward from the outer tubular member.

**[0013]** A second aspect of the disclosure provides a soft tissue cutting device including: an inner tubular member including a ramp on an outer surface of the inner tubular member, and an internal chamber extending between an inner tube distal and an inner tube proximal end; an outer tubular member including a cutting member on a proximal end of the outer tubular member, wherein the outer tubular member is disposed around a portion of the inner tubular member, and is movable from an initial position to an extended position; a thumb slide attached to an outer surface of the outer tubular member; a locking mechanism removably attached on a proximal end to a distal end of the inner tubular member; and a syringe removably attached to a distal end of the locking mechanism. In some embodiments, the soft tissue cutting device further includes a thumb slide housing disposed around a portion of the inner tube distal end, wherein the thumb slide extends through a portion of a surface of the thumb slide housing.

**[0014]** A third aspect of the invention provides a method of using the soft tissue cutting device of the first or second aspect by: inserting a proximal end of the cutting device in a subject's body region;

applying pressure to the dispensing member to release a medicinal agent into the subject's body region; moving the outer tubular member toward the proximal end of the cutting device, thereby causing the cutting member to elevate; cutting a soft tissue in the subject's body region; and moving the outer tubular member toward the distal end of the cutting device. In some embodiments, the medicinal agent is a local anesthetic. In some embodiments, the subject's body region is a subject's hand. In some embodiments, the soft tissue is a transverse carpal ligament or an annular ligament of the finger. In some embodiments, the annular ligament of the finger is an A1 pulley.

[0015] These and other embodiments are described in greater detail in the detailed description which follows. An object of the presently disclosed subject matter having been stated hereinabove, and which is achieved in whole or in part by the presently disclosed subject matter, other objects will become evident as the description proceeds when taken in connection with the accompanying drawings as best described herein below.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 illustrates a side view of a soft tissue cutting device.

[0017] Figure 2A illustrates an enlarged side view of a cutting member of a soft tissue cutting device, where the cutting device is elevated on a ramp.

[0018] Figure 2B illustrates a side view of a proximal region of a soft tissue cutting device in an inactive position.

[0019] Figure 2C illustrates an inner tubular body having a ramp located distal to the proximal end of the inner tubular body.

[0020] Figure 3A illustrates a side view of the proximal end of an outer tubular body having a blade with a cutting edge.

[0021] Figure 3B illustrates a side view of a blade with a cutting edge located at the proximal end of an outer tubular body.

[0022] Figure 4 illustrates a side view of a soft tissue cutting device performing a trigger release procedure: Figure 4A illustrates the soft tissue cutting device in an inactive position inserted deep to an A1 pulley for injection of a suitable fluid between the A1 pulley and the surrounding tissue (e.g., flexor tendon); Figure 4B illustrates the soft tissue cutting device with the outer tubular body

elevated on a ramp; Figure 4C illustrates the soft tissue cutting device in an active position with the cutting member cutting the A1 pulley.

**[0023]** Figure 5A illustrates a top view of a soft tissue cutting device in active position, having a ramp at the proximal end of the inner tubular body, where the soft tissue cutting device is cutting through an A1 pulley.

**[0024]** Figure 5B illustrates a top view of a soft tissue cutting device in active position, having a ramp located distal to the proximal end of the inner tubular body, where the soft tissue cutting device is cutting through an A1 pulley.

**[0025]** Figure 6A illustrates a side view of a hollow tube and cutting member of an alternate embodiment of a soft tissue cutting device in an active position; and Figure 6B illustrates the cutting member of Figure 6A in an inactive position.

**[0026]** Figure 7 illustrates a side view of yet another embodiment of a soft tissue cutting device.

#### DETAILED DESCRIPTION

**[0027]** The presently disclosed subject matter, which will now be described more fully, can be embodied in different forms and should not be construed as limited to the embodiments set forth herein. The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the disclosure in any way. Rather, the following description provides some practical illustrations for implementing examples of the present disclosure. Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements, and all other elements employ that which is known to those of ordinary skill in the field of the disclosure. Those skilled in the art will recognize that many of the noted examples have a variety of suitable alternatives.

**[0028]** The cutting device disclosed herein is suitable for cutting soft tissue, and can be used to cut any desired soft tissue in the body. In certain embodiments, the soft tissue cutting device is a transverse carpal ligament cutting device that cuts a transverse carpal ligament in a carpal tunnel region. As described above, a CTR procedure involves cutting a transverse carpal ligament in order to reduce median nerve compression and carpal tunnel pressures in the carpal tunnel region. In some embodiments, the soft tissue cutting device is a pulley cutting device. In some examples, the pulley is an A1 pulley of a finger, and the soft tissue cutting device is a trigger release device that cuts the A1 pulley. While each finger has several pulleys, the A1 pulley is the pulley that is most often

involved in a condition called trigger finger. The A1 pulley is an annular ligament of the finger that sits near the head of the metacarpal bone, and lies in the flexor groove in the deep transverse metacarpal ligament. The A1 pulley, together with other annular pulleys, and cruciate pulleys, governs the flexor mechanism of the hand and wrist. The A1 pulley provides biomechanical support to the underlying metacarpophalangeal joint, and maintains joint stability and flexor tendon alignment. In a patient with trigger finger, the A1 pulley becomes inflamed or thickened, making it harder for the flexor tendon to glide through it as the finger bends. Over time, the flexor tendon may also become inflamed and develop a small nodule on its surface. When the finger flexes and the nodule passes through the pulley, there is a sensation of catching or locking. This condition, known as trigger finger or stenosing tenosynovitis, can be accompanied by pain or stiffness. The trigger release procedure involves cutting or releasing the A1 pulley to enable the flexor tendon to glide freely.

**[0029]** While the illustrated embodiments show an exemplary embodiment of a soft tissue cutting device, as noted above, it should be understood that the presently disclosed subject matter can be embodied in different forms and should not be construed as limited to the embodiments set forth herein below. Furthermore, the soft tissue cutting device of the current device may be used for other types of soft tissue cutting procedures.

**[0030]** Throughout the specification, in the embodiments generally shown herein, “distal” as used herein, shall generally refer to being closest to the target tissue when the soft tissue cutting device is inserted into the target tissue, and “proximal” as used herein, shall generally refer to being furthest from the target tissue when the soft tissue cutting device is inserted into the target tissue.

**[0031]** FIG. 1 is a side view of an embodiment of a soft tissue cutting device **11**. The soft tissue cutting device **11** may include a distal end **13** and a proximal end **12**. The proximal end **12** may be configured to enable an operator to control various functions on the distal end **13** of the soft tissue cutting device **11**. The distal end **13** may be configured to perform various functions, including cutting soft tissue in a body, and dispensing a medicinal agent, such as for example a numbing, pain relieving, or pain prevention agent, such as, for example, a local anesthetic. The proximal end **12** of the soft tissue cutting device may include a handpiece **7**.

**[0032]** In some embodiments, the handpiece is configured to allow an operator to operate the device using a single hand only. In some embodiments, the single-hand handpiece is a handle that includes one or more controls on the handle (e.g., top, bottom, sides, etc.) such that the operator can use a



finger to operate one or more controls. However, skilled artisans will understand that the single-hand handpiece is merely one embodiment of the present invention and is not required. Alternately, two hands or even two operators can operate the present device.

**[0033]** In some embodiments, the handpiece is molded. The handpiece can be molded in a configuration that provides a comfortable hold for the user when performing at least one of the cutting device injection or cutting functions. For example, finger grip indentations, raised ridges, etc. may be provided on the handpiece.

**[0034]** As shown in FIG. 1, within the handpiece 7 is a recess 14 that runs along the length of the handpiece 7, and that can receive the barrel 15 of a dispensing member 16. Thus, when a dispensing member 16 is inserted in the recess 14, the handpiece 7 is disposed at least partially around the dispensing member 16. In some embodiments, the dispensing member 16 is a syringe. At the distal end 17 of the recess 14, a removable attachment mechanism 9 may be disposed for removably coupling the dispensing member 16 (e.g., the barrel of the dispensing member 16) to the proximal end 19 of the inner tubular body 5. In some embodiments, the attachment mechanism 9 is a locking mechanism, such as for example, a luer lock. Optionally, other attachment mechanisms such as a threaded slot for receiving and end of the dispensing member, a fitted slot, or the like are within the scope of this disclosure. In some embodiments, the dispensing member is a syringe, and the attachment mechanism is a luer lock. Optionally, the dispensing member may be an external plunger in fluid communication with the recess 14.

**[0035]** As shown in FIG. 1, the barrel 15 of the dispensing member 16 forms a compartment for receiving a fluid (e.g., a medicinal agent, a therapeutic agent, a contrast fluid, or the like) and at least a portion of a depressible member 10. The depressible member 10 may be movable from an initial position to an extended position within the barrel 15. In the initial extended position, the depressible member 10 is positioned at least partially toward a proximal end 28 of the barrel 15. The initial position provides a space for the medicinal agent to reside in the barrel 15. In the extended position, the depressible member 10 is positioned toward a proximal end 28 of the dispensing tube 22. In the fully depressed position, the depressible member 10 is positioned at the distal end 25 of the barrel 15. As the depressible member 10 is moved from the initial to or toward the depressed position, at least a portion of any fluid within the dispensing member 16 is forced into the inner tubular body 5 of the soft tissue cutting device 11.

[0036] The dispensing member may, optionally, include or may be in communication with an actuator or controller that controls functions of the dispensing member. In some embodiments, the control may be positioned on the dispensing member. As shown in FIG. 1, in some cases, the controller 27 is located on the proximal end 28 of the depressible member 10. In some cases, the depressible member 10 is a plunger, and the controller 27 is a plunger flange located on the proximal end of the plunger. In some embodiments, the depressible member is a syringe, and the controller is a plunger flange located on the proximal end of the syringe plunger.

[0037] In some embodiments, the controller may be positioned outside of the handle. For example, the control can be a lever, slider button, push button and/or clamp. In some embodiments, the controller is a slider button positioned on an external surface of the handpiece. The slider button can be coupled to a plunger to control movement of the plunger. In some embodiments, the slider button is directly connected to the plunger. In some embodiments, the controller is a clamp. In such cases, the clamp can be coupled to a plunger to control movement of the plunger. Optionally, the controller may be a motor that controls the movement of the plunger.

[0038] As shown in FIG. 1, the handpiece 7 may be coupled to an outer tubular body 4 soft tissue cutting device 11. The outer tubular body 4 may form a hollow channel 29 running along the length of the outer tubular body 4, from the proximal end 30 to the distal end 31, such that an inner surface of the outer tubular body 4 defines the hollow channel 29.

[0039] The handpiece can be coupled to the outer tubular body using a variety of different configurations. In some cases, the handpiece and outer tubular body have a permanent junction. For example, the handpiece and outer tubular body can have a set angular junction or a set straight junction. In other cases, the handpiece and outer tubular body have an adjustable junction that can be adjusted to accommodate operator preference. In other cases, the handpiece and outer tubular body have a rotatable junction that can be rotated to accommodate operator preference. For example, the handpiece and outer tubular body can have a junction that is adjustable in length or angulation or rotation. In yet other cases, the handpiece and the outer tubular body can have a removable junction so that the handpiece and the outer tubular body are removable from one another.

[0040] As noted above, the handpiece can be arranged at any suitable angle from the outer tubular body. In some embodiments, the angle between the handpiece and the outer tubular body is adjustable. Examples of such angles can include, without limitation, between 175 degrees and 140

degrees, between 170 degrees and 150 degrees, or between 165 degrees and 155 degrees. In some embodiments, the angle between the handpiece and the outer tubular body is about 160 degrees.

**[0041]** The outer tubular body can also be provided as a single piece or as a plurality of different pieces. In some cases, the outer tubular body extends from the distal end to the proximal end as a single piece. In other cases, the outer tubular body extends from the distal end to the proximal end as a plurality of pieces. The outer tubular body is formed of any desired medically acceptable material.

**[0042]** As shown in FIG. 1, residing within at least a portion of the hollow channel **29** of the outer tubular body **4** may be an inner tubular body **5**. Thus, the inner tubular body **5** has a diameter that is smaller than the diameter of the outer tubular body **4**. Within the inner tubular body **5** lies a hollow internal chamber **33** extending through the length of the inner tubular body, from the proximal end **34** to the distal end **1**, such that an inner surface of the inner tubular body **5** defines the internal chamber **33**. The inner tubular body **5** may be configured to deliver a fluid (e.g., a medical agent, a contrast agent, etc.), withdrawn from the dispensing member **16**, to a subject's body. In some embodiments, the inner tubular body **5** may be a syringe needle. The inner tubular body may be formed of any desired medically acceptable material.

**[0043]** As noted above, and shown in FIGS. 1-3B, the outer tubular body **4** is disposed around at least a portion of the inner tubular body **5**. The distal end **31** of the outer tubular body **4** may include a cutting member **2** that is sufficiently sharp to cut through soft tissue. In some embodiments, the cutting member **2** is a blade having a cutting edge **36**. The cutting edge **36** may be created using any now or hereafter known methods such as, without limitation, etching, grinding, or the like.

**[0044]** In some embodiments, the cutting member **2** is located on an upper region **37** (or outside) of the distal end **31** of the outer tubular body **4**. The outer **4** and inner **5** tubular bodies are configured so that when the cutting member **2** is not in use, the inner surface of the outer tubular body **4** resides in close proximity to the outer surface of the inner tubular body **5**, such that the cutting member **2** resides in close proximity to the outer surface of the inner tubular body **5** and is not exposed. By "close proximity" is meant that the inner surface of the outer tubular body **4** is sufficiently close to the outer surface of the inner tubular body **5**, that when the soft tissue cutting device **11** is inserted into a body tissue, in the inactive position, the cutting member **2** will not cut the tissue, while at the same time, the inner surface of the outer tubular body **4** is sufficiently far from the outer surface of the inner tubular body **5**, that the outer tubular body **4** can move freely over the inner tubular body

5. Thus, the proximity of the inner 5 and outer 4 tubular members in the inactive position serves to protect against premature cutting of the tissue, without hindering the movement of the outer tubular body 4. In some embodiments of the invention, in the inactive position, the inner surface of the outer tubular body is about 0.5 mm - 3.5 mm, 0.5 mm – 1 mm, 1 mm – 1.5 mm, 1.5 mm to about 2 mm, about 1 mm to about 2.5 mm, 2.5 mm – 3.5 mm, etc., from the outer surface of the inner tubular body.

[0045] The outer tubular body and the inner tubular body can have any desired cross-section shape, as long as the shape does not interfere with the functioning of the device. In some embodiments, at least one of the outer or inner tubular bodies has a circle-shaped tubular cross-section shape. In some embodiments, at least one of the outer or inner tubular body has a non-circle-shaped tubular cross section shape. For example, in some cases, at least one of the outer or inner tubular body has a square-shaped tubular cross section shape, rectangle-shaped tubular cross section shape or square-shaped tubular cross section shape with round edges. In some embodiments, the outer and inner tubular bodies have the same cross-section shape. In some embodiments, the outer and inner tubular bodies have a different cross-section shape

[0046] The outer tubular body and the inner tubular body have any desired size that does not interfere with the functioning of the device, and that is suitable for the medical procedure being performed. As the outer tubular body extends from the distal end to the proximal end, it can maintain the same diameter, or it can assume a different diameter. In some cases, as the outer tubular body extends from the distal end to the proximal end, it increases in diameter. In other cases, as the outer tubular body extends from the distal end to the proximal end, it increases in diameter. Optionally, the outer tubular body may either be coaxial with the inner tubular body and/or the central axis of inner tubular body may be offset from the outer tubular body.

[0047] The outer tubular body is movable from an initial position to an extended position. In the initial position, the soft tissue cutting device is in the inactive position, and the outer tubular body is in close proximity with the inner tubular body, as described above, and the cutting member is not exposed to cut tissue that the soft tissue cutting device comes into contact. In the extended position, the outer tubular body moves from its initial position to a position closer to the distal end of the soft tissue cutting device, and elevated away from the outer surface of the inner tubular body. In this elevated position, when the soft tissue cutting device is exposed to soft tissue it is oriented so that it

will cut the tissue. The elevation of the cutting member can be achieved in any suitable manner, as described below.

**[0048]** As shown in FIGS. 1-2C, in some embodiments, the elevation of the cutting member **2** is achieved by a ramp **3** located on the outer surface of the inner tubular body **5**. The cutting member **2** may be slidably movable over the ramp **3** to elevate the cutting member. The ramp **3** is located on the inner tubular body **5** such that when the outer tubular body **4** is moved from the initial position toward the extended position, the cutting member **2** on the outer tubular body **4** makes contact with the ramp **3**, and the ramp **3** causes the cutting member **2** to elevate at least partially over the ramp **3**, thereby exposing the cutting member **2** and positioning it for cutting the soft tissue. Thus, the ramp **3** and the cutting member **2** are located on the same, upper plane of the inner **5** and outer **4** tubular bodies, respectively. It will be understood by those of ordinary skill in the art that the ramp and cutting member can be located on any suitable plane on the inner and outer tubular body, respectively, as long as the ramp is positioned so as to cause the cutting member to elevate. In some embodiments, the ramp and the cutting member are located on the upper portion of the inner and outer tubular body, respectively.

**[0049]** The ramp can be located at any suitable location along the length of the inner tubular body. In some embodiments, the ramp **3** is located toward the distal end **1** of the inner tubular body **5** (FIGS. 1 and 2B). In some embodiments, the ramp **3** is located between the distal end **1** and the midpoint (not shown) of the length of the inner tubular body **5** (FIG. 2C). In some embodiments, the ramp is located between the distal end and the proximal end of the length of the inner tubular body. In some embodiments, the ramp is located at the midpoint of the length of the inner tubular body.

**[0050]** In some embodiments, the soft tissue cutting device also has one or more balloons coupled to the outer tubular body that expand radially inward from the outer tubular body. In some cases, the outer tubular body is movable by inflating and deflating a blade balloon elevator. When inflated, the blade balloon elevator elevates the cutting member above the inner tubular body, and when deflated, it lowers the cutting member back to close proximity with the inner tubular body.

**[0051]** As noted above, the outer tubular body is movable from an initial position to an extended position. The outer tubular body may be caused to move by any suitable means. In some embodiments, the outer tubular body can be moved by an outer tubular body movement mechanism. As show in FIG. 1, in some embodiments, the movement mechanism may be a thumb slide **6** attached to the outer tubular body **4**. The thumb slide **6** can be pushed in the proximate or proximal direction,

and when so pushed, it causes the outer tubular body **4** to move in concert with it. In some embodiments, the movement mechanism may also include a thumb slide housing **8** that is disposed around a portion of the distal end **30** of the outer tubular body **4**. A portion of the thumb slide housing **8** may define a linear cutout (not shown) in the thumb slide housing **8**. The portion of the thumb slide **6** that is attached to the outer tubular body **4** extends through the linear cutout (not shown). The linear cutout (not shown) prevents the thumb slide **6** from causing the outer tubular body **4** to rotate. In some embodiments, the thumb slide is lockable. By “lockable” is meant that the thumb slide may be caused to remain in one position, preventing it from moving. Any suitable means can be used to cause the thumb slide to lock the outer tubular body in position, such as for example, using a spring latch.

**[0052]** This disclosure also provides a method of using the soft tissue cutting device. As noted above, the cutting device is capable of cutting any soft tissue. A medicinal agent, such as for example a local anesthetic is drawn into the dispensing tube, for example, by inserting the distal end of a sterilized cutting device into a container of the agent, and moving the depressible member from the depressed position to the initial extended position. In some embodiments, the amount of medicinal agent drawn into the dispensing tube may be determined based on the intended use. The distal end of the soft tissue cutting device is then placed into a region of the subject's body, and advanced to the vicinity of the cutting location. The medicinal agent is injected into, and optionally around the soft tissue to be cut, by relocating the distal end of the cutting device to different locations and depressing the depressible member, thereby releasing at least a portion of the medicinal agent from the inner tubular body. The distal end of the cutting device is then positioned at the desired cutting site. After placement in a suitable position for cutting the soft tissue, the outer tubular body is caused to move toward the distal end of the cutting device to expose the cutting member. In some embodiments this movement of the outer tubular body is performed by using a finger or thumb to push forward a thumb slide connected to the outer tubular body. The outer tubular body is advanced in the distal direction of the cutting device, until the cutting member is caused to elevate. In some embodiments, this elevation is caused by the distal end of the outer tubular body rising at least partially over a ramp on the inner tubular body. As the outer tubular body is elevated, the cutting member at the distal end of the outer tubular body is exposed, and cuts the target tissue. As the cutting device is advanced through the soft tissue, it continues to cut the tissue. When the desired portion of the soft tissue has been cut, the outer tubular body is caused to move back toward the

proximal end of the cutting device. In some embodiments this movement of the outer tubular body is performed by using a finger or thumb to pull back a thumb slide connected to the outer tubular body. The soft tissue cutting device is then safely removed from the subject's body.

**[0053]** The method can be performed with the aid of an ultrasound device that enables the user of the soft tissue cutting device to visualize the tissues below the epidermis and safely perform the procedure.

**[0054]** In some embodiments, the method is used to cut a transverse carpal ligament transverse carpal ligament. In some embodiments, the method is used to cut an annular ligament, such as for example, a pulley, such as for example, an A1 pulley in a subject's hand. As noted above, the A1 pulley overlies the metacarpophalangeal joint, and maintains joint stability and flexor tendon alignment. During a trigger release procedure, the A1 pulley is cut or released to enable the flexor tendon to glide freely. FIGs. 4A-4C shows a side view of an A1 pulley being cut using the soft tissue cutting device **11**, according to the method. FIG. 4A shows the soft tissue cutting device **11** in an inactive position, with its distal end **13** inserted deep to the A1 pulley, where it injects a medicinal agent. FIG. 4B shows the soft tissue cutting device **11** with the outer tubular body **4** in the process of being elevated on a ramp (not shown), preparing to cut the soft tissue. FIG. 4C shows the soft tissue cutting device **11** in an active position with the outer tubular body **4** fully extended, and the cutting member **2** cutting the A1 pulley.

**[0055]** FIGS. 5A and 5B show a top view of an A1 pulley being cut using the soft tissue cutting device **11**, according to the method. FIG 5A shows an A1 pulley being cut by a soft tissue cutting device **11** having a ramp **3** located toward the distal end **1** of the inner tubular body **5**. FIG 5B shows an A1 pulley being cut by a soft tissue cutting device **11** having a ramp **3** located distally on the inner tubular body **5**.

**[0056]** While the above disclosure describes an embodiment of a soft tissue cutting device including a outer tube with a cutting member disposed around an inner tube configured to dispense fluid in a subject tissue, the disclosure is not so limiting.

**[0057]** For example, FIGs. 6A and 6B illustrate an alternative embodiment of single tube including a cutting member that can be used to replace the outer and inner tube combination in the soft tissue cutting device described above. As shown in FIG. 6A, the arrangement may include a single hollow tube **207** that has a crimp (or another structure like an upside down ramp) **202** in the anterior aspect of the hollow tube **207**. A hook shaped (or any other suitable shape) cutting member **203** may be

biased such that in an inactive position (shown in FIG. 6B), the cutting member is at least partially stored between the crimp **202** and the inner wall of the hollow tube **207**, and a cutting edge **204** of the cutting member **203** is completely sheathed inside the hollow tube **207**. For example, a biasing member **205** (such as a spring) may be provided which when compressed allows the cutting member **203** to be stored between the crimp **202** and the inner wall of the hollow tube **207** in the inactive position. However, when the cutting member **203** is pushed out of from stored between the crimp **202** and the inner wall of the hollow tube **207**, the biasing member **205** may be decompressed allowing the cutting edge **204** to be exposed through a slot **208** (provided on the same side that includes the crimp) in the superior aspect of the hollow tube **207** (as shown in FIG. 6A). Optionally, the cutting member **203** is pushed out of from stored between the crimp **202** and the inner wall of the hollow tube **207** the cutting member **203** by pushing a handle **206** from the proximal end towards the distal end (for example, using a thumb slide mechanism as discussed above).

**[0058]** It should be noted that while FIGs. 6A and 6B only illustrate the hollow tube and the cutting member with the biasing arrangement, the hollow tube **207** may be coupled to the handle and/or the dispensing member of the soft tissue cutting device shown in FIGS. 1-3B such that the hollow tube **207** may receive a suitable fluid from a dispensing member and may inject it from the distal tip **201** before, after, and/or while the cutting member is in an active position (as described above).

**[0059]** FIG. 7 illustrates yet another configuration that includes a cutting member **303** within a single hollow tube **307** including a slot **304**. The hollow tube has a crimp (e.g., a ramp) **302** in the inferior aspect of the hollow tube **307**. The crimp **302** may be configured to include a ramp including an incline **321**, a flat plane **322**, and a decline **323**. A hook shaped (or any other suitable shape) cutting member **303** may be provided such that in an inactive position **A** or **A'**, the cutting member is completely sheathed inside the hollow tube **307**. However, when the cutting member **303** moves over the incline **321** to rest over the flat plan **322** (position **B**), and the cutting edge **310** to be exposed through a slot **308** in the superior aspect of the hollow tube **307**. Optionally, the cutting member **303** may be pushed over the crimp **302** the cutting member **303** by pushing or pulling a handle **306** from the proximal end towards the distal end (or vice versa) using, for example, a thumb slide mechanism as discussed above. The cutting member may include a cutting member guide **312** for stabilizing the cutting member **303** as it moves up and down the crimp **302**.

**[0060]** It should be noted that while FIG. 7 only illustrate the hollow tube and the cutting member that can move over the crimp, the hollow tube **307** may be coupled to the handle and/or the



dispensing member of the soft tissue cutting device shown in FIGS. 1-3B such that the hollow tube **307** may receive a suitable fluid from a dispensing member and may inject it from the distal tip **301** before, after, and/or while the cutting member is in an active position (as described above).

**[0061]** While different embodiments of a soft tissue cutting device are described, skilled artisans will understand that any of the features of one embodiment can be incorporated into the other embodiments. Any combination of the features described in any of the embodiments can be included in the soft tissue cutting device and are within the scope of the invention. It should be noted that while the current disclosure describes use of the soft tissue cutting device for carpal tunnel surgery, the disclosure is not so limiting and the soft tissue cutting device can be used during, for example, surgery of extensor compartment of the wrist, surgery of retinacula tissue of the ankle, surgery of cubital tunnel of the elbow, or the like.

**[0062]** In some embodiments, the soft tissue cutting device of this disclosure may also be used during hydrodissection procedures to, for example, inject fluid around the anatomical structure (e.g., a compressed nerve). Such fluid may be a contrast agent that creates a visible working space between planes of tissue for enhanced ultrasound visibility, may be fluid that frees a compressed nerve from scar tissue or lesions that trap it, or the like.

**[0063]** Similarly, the soft tissue cutting device of this disclosure may also be used during electrosurgery (e.g., devices that perform cutting using bipolar electrodes) for, for example, injecting electrically conductive fluids such as saline in and/or around the target tissue.

**[0064]** It will be understood that various details of the presently disclosed subject matter may be changed without departing from the scope of the presently disclosed subject matter. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation.

## CLAIMS

What is claimed is:

1. A soft tissue cutting device comprising:
  - an inner tubular member comprising an internal chamber extending between a distal end and a proximal end of the inner tube;
  - an outer tubular member disposed over at least a portion of the inner tubular member and movable between an initial position and an extended position, a distal end of the outer tubular member comprising a cutting member;
  - a movement controller that controls movement of the outer tubular member between the initial position and the extended position; and
  - an attachment mechanism for removably coupling the proximal end of the inner tubular member to a dispensing member.
2. The soft tissue cutting device according to claim 1, wherein the movement controller comprises a thumb slide attached to a surface of the outer tubular member.
3. The soft tissue cutting device according to claim 2, wherein the thumb slide is lockable to prevent movement of the outer tubular member.
4. The soft tissue cutting device according to claim 1, further comprising a handpiece disposed around at least a portion of the dispensing member.
5. The soft tissue cutting device according to claim 3, wherein the handpiece is molded to allow for single handed use of the soft tissue cutting device.
6. The soft tissue cutting device according to claim 1, wherein the attachment mechanism is a luer lock.

7. The soft tissue cutting device according to claim 1, wherein the cutting member is a blade having a cutting edge.

8. The soft tissue cutting device according to claim 1, wherein the dispensing member is a syringe.

9. The soft tissue cutting device according to claim 1, wherein:  
the dispensing member comprises a barrel for holding a fluid and a depressible member disposed within the barrel, and  
the depressible member is movable from an initial position to a depressed position within the barrel to expel the fluid from the barrel into the inner tubular member.

10. The soft tissue cutting device according to claim 1, wherein the inner tubular member further comprises a ramp on an outer surface of the inner tubular member.

11. The soft tissue cutting device according to claim 10, wherein the outer tubular member is slidably movable over the ramp to elevate at least a portion of the outer tubular member in the extended position.

12. The soft tissue cutting device according to claim 11, wherein the cutting member is elevated when the outer tubular member is in the extended position.

13. The soft tissue cutting device according to claim 11, wherein the ramp is located at the distal end of the inner tubular member.

14. The soft tissue cutting device according to claim 1, wherein the inner tubular member further comprises at least one inflatable balloon on an outer surface of the inner tubular member.

15. The soft tissue cutting device according to claim 14, wherein the outer tubular member is slidably movable over the inflatable balloon to elevate at least a portion of the outer tubular member in the extended position.

16. A soft tissue cutting device comprising:  
an inner tubular member comprising a ramp on an outer surface of the inner tubular member,  
and an internal chamber extending between an inner tube distal end and an inner tube proximal end;  
an outer tubular member comprising a cutting member on a distal end of the outer tubular member, wherein the outer tubular member is disposed around a portion of the inner tubular member, and is movable from an initial position to an extended position;  
a thumb slide attached to an outer surface of the outer tubular body; and  
a syringe removably attached to a proximal end the inner tubular member.
17. The soft tissue cutting device according to claim 16, further comprising a thumb slide housing disposed around a portion of the inner tube proximal end, wherein the thumb slide extends through a portion of a surface of the thumb slide housing.
18. The soft tissue cutting device according to claim 16, wherein the syringe is removably attached to the proximal end of the inner tubular member via a luer lock.
19. The soft tissue cutting device according to claim 16, wherein:  
the inner tubular member further comprises a ramp on an outer surface of the inner tubular member;  
the outer tubular member is slidably movable over the ramp to elevate at least a portion of the outer tubular member in the extended position; and  
the cutting member is elevated when the outer tubular member is in the extended position.
20. A method of using the soft tissue cutting device according to claim 1, comprising:  
inserting a distal end of the soft tissue cutting device in a body region of a subject;  
releasing, from the dispensing member, a medicinal agent into the body region;  
moving the outer tubular member to the extended position, thereby causing the cutting member to be exposed in an active position;  
cutting a soft tissue in the body region; and

moving the outer tubular body to the initial position before removal of the distal end of the soft tissue cutting device from the body region.

21. The method according to claim 20, wherein the medicinal agent is a local anesthetic.

22. The method according to claim 20, wherein the soft tissue is an A1 pulley in an annular ligament of a finger of the subject.

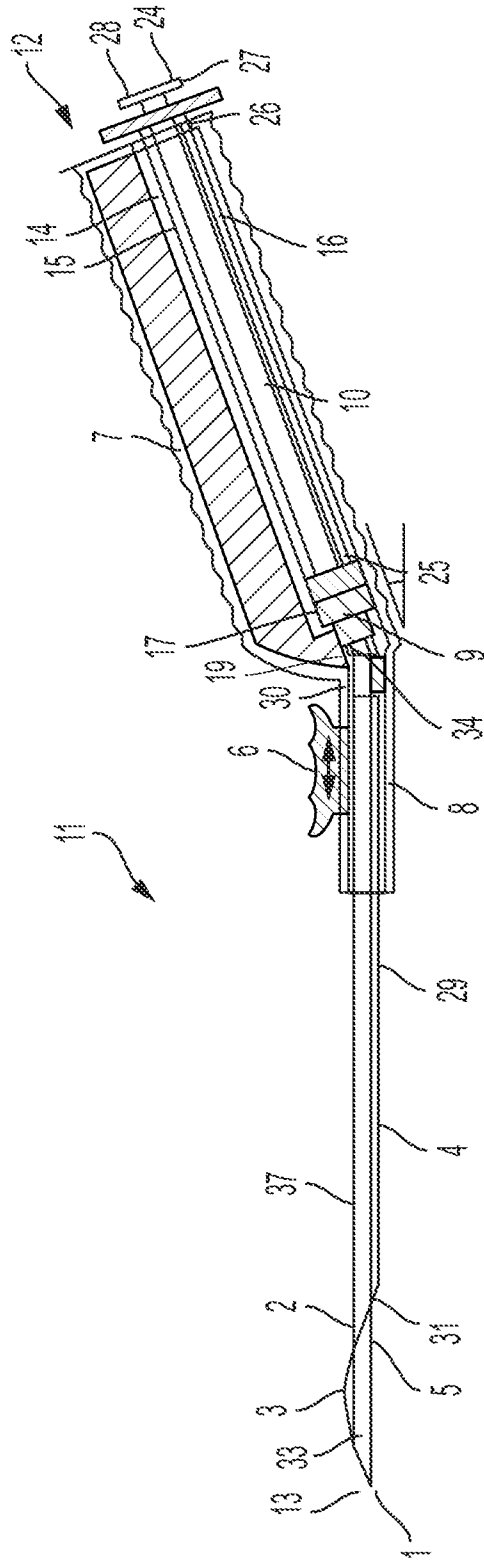


FIG. 1

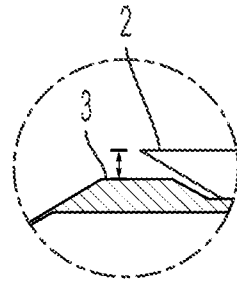


FIG. 2A

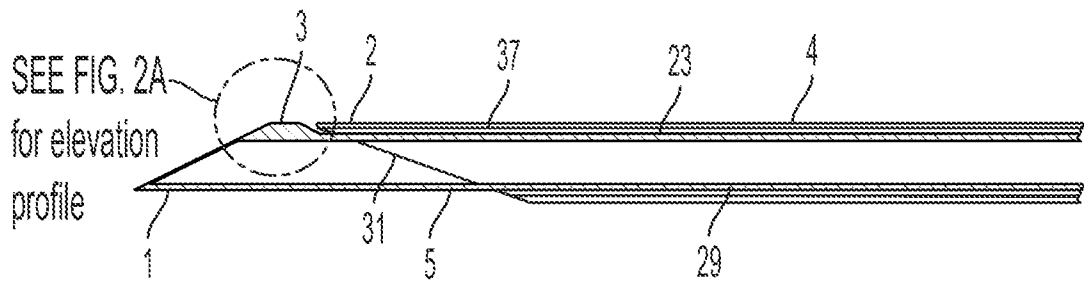


FIG. 2B

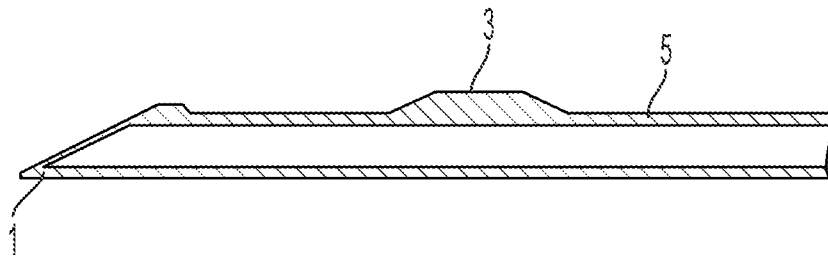


FIG. 2C

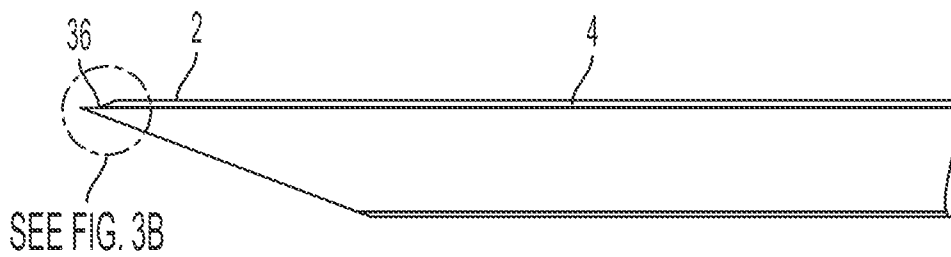


FIG. 3A



FIG. 3B

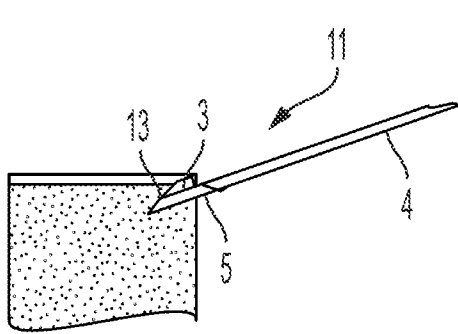


FIG. 4A

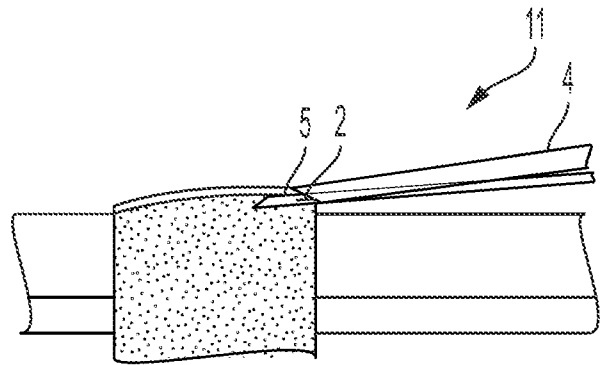


FIG. 4B

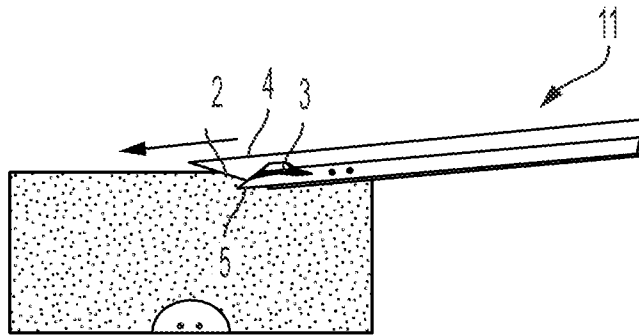


FIG. 4C

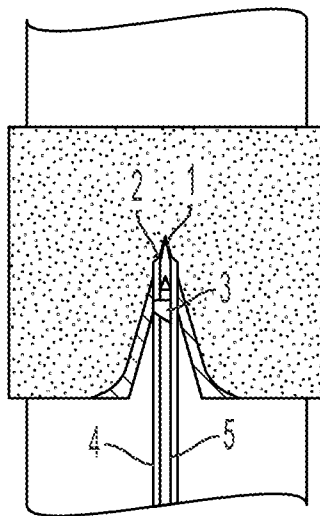


FIG. 5A

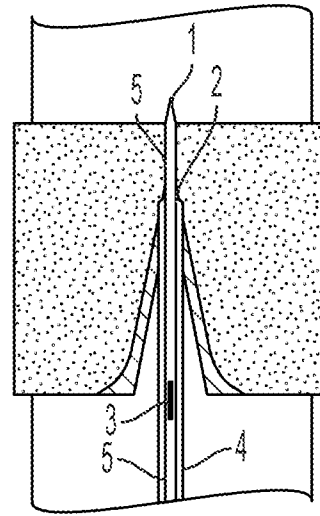


FIG. 5B



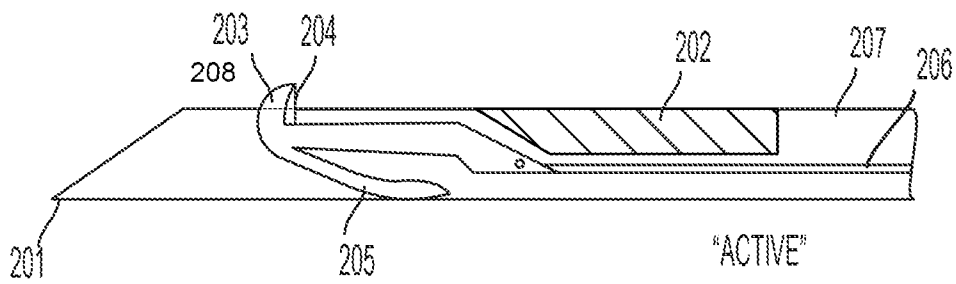


FIG. 6A

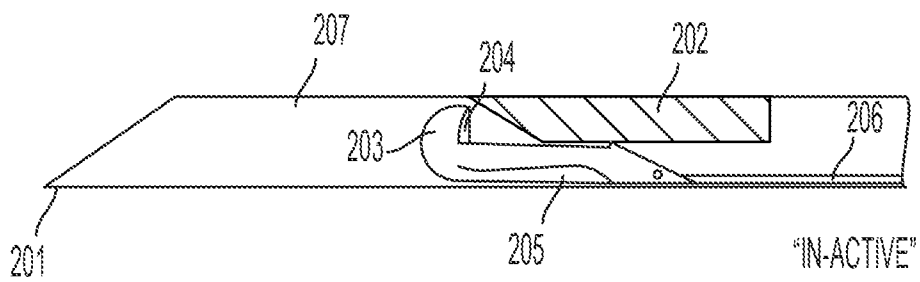


FIG. 6B

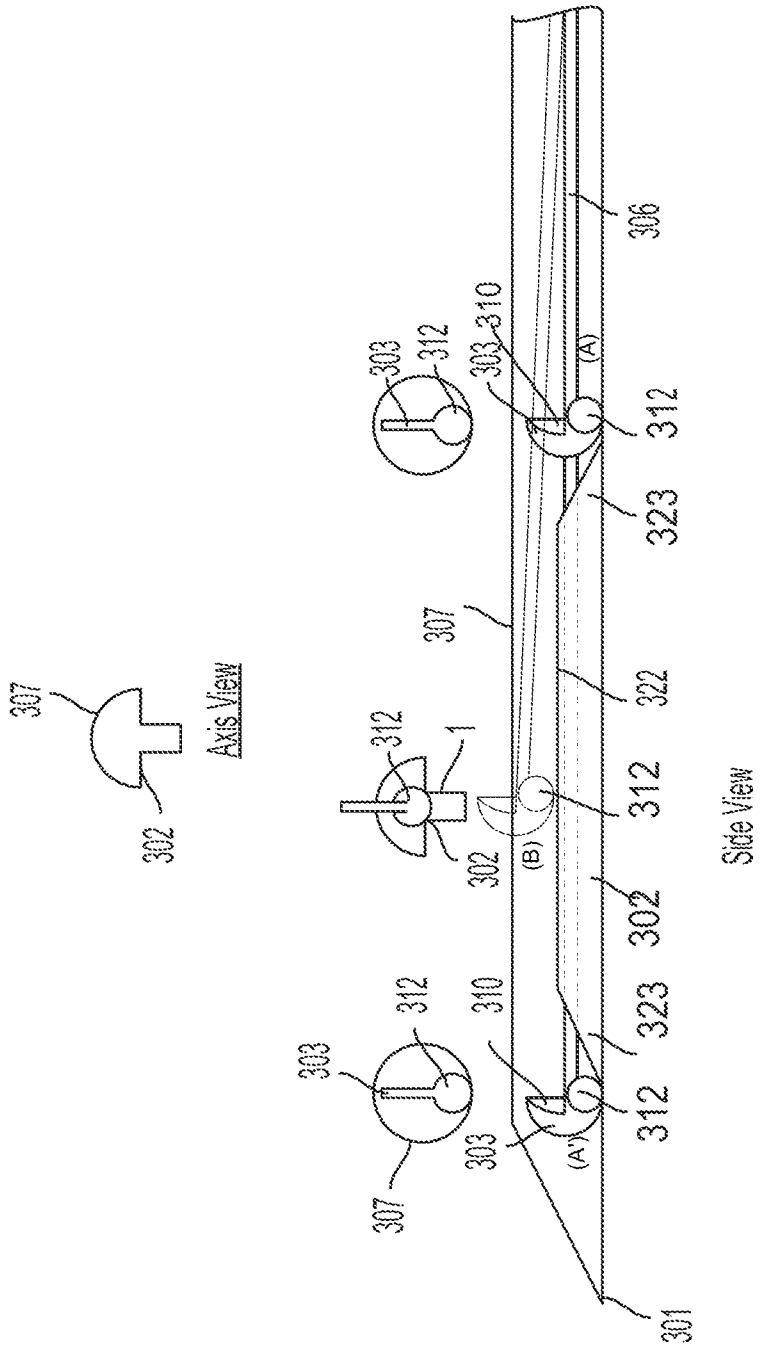


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 22/70088

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/32 (2022.01)

CPC - A61B 17/320036; A61B 17/320016

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- A	US 2009/0312807 A1 (Boudreault et al.) 17 December 2009 (17.12.2009), entire document, especially Fig 4A-4G; para [0102]-[0103]	1, 6, 14 ----- 15
Y ----- A	US US 2016/0235431 A1 (RELEASE MEDICAL, INC.) 18 August 2016 (18.08.2016), entire document, especially Fig 1-5; para [0051]-[0055]	1-5, 7-10, 16-18, 20-22 ----- 11-13, 19
Y ----- A	US 5,217,007 A (Ciaglia) 08 June 1993 (08.06.1993), entire document, especially Fig 1-5; col 3, ln 22 - col 5, ln 51	1-5, 7-10, 16-18, 20-22 ----- 11-13, 19
Y ----- A	WO 2020/247476 A1 (GREAT PLAINS IMAGING LLC) 10 December 2020 (10.12.2020), entire document, especially Fig 8-10; para [0034]-[0036]	21
A	US 2019/0262024 A1 (Mayo Foundation for Medical Education and Research) 29 August 2019 (29.08.2019), entire document	1-22
A	US 2017/0042565 A1 (Summit Medical Products, Inc.) 16 February 2017 (16.02.2017), entire document	1-22

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"D" document cited by the applicant in the international application	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

24 February 2022

Date of mailing of the international search report

MAR 25 2022

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