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(54) **TRAY FOR A SOFT TISSUE CUTTING
DEVICE AND METHODS OF USE**

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(57) **ABSTRACT**

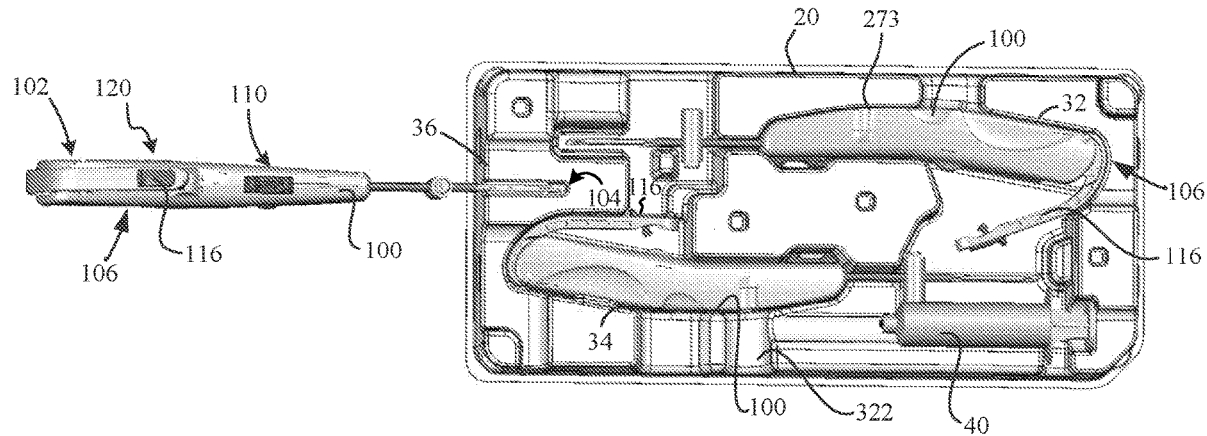
Methods of using a soft tissue cutting device are disclosed. The methods include providing the soft tissue cutting device, positioning the soft tissue cutting device in a priming slot of a tray configured for receiving and holding the soft tissue cutting device, attaching a priming syringe to the soft tissue cutting device, priming a balloon disposed on a distal end of the soft tissue cutting device by equalizing a first pressure inside the balloon to a second pressure inside the priming syringe, removing the soft tissue cutting device from the priming slot, and positioning the distal end of the soft tissue cutting device on a safety slot included in the tray to determine whether the tissue cutting device has been properly primed.

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Related U.S. Application Data

(63) Continuation of application No. 17/114,022, filed on Dec. 7, 2020, which is a continuation of application



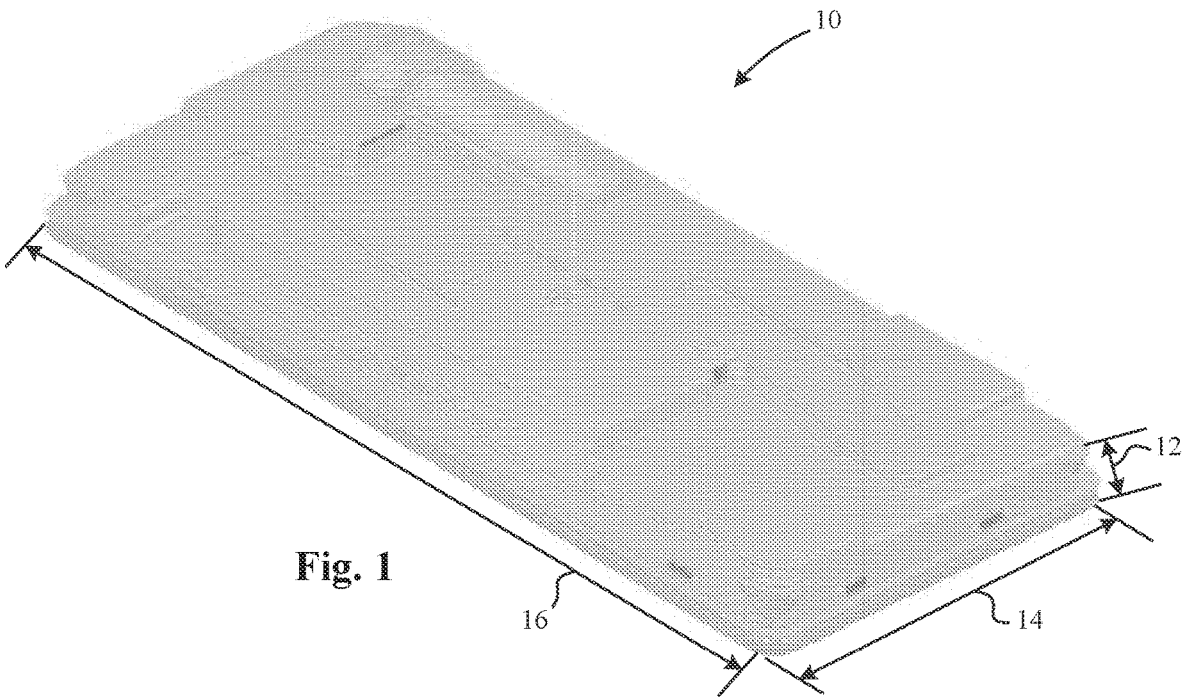


Fig. 1

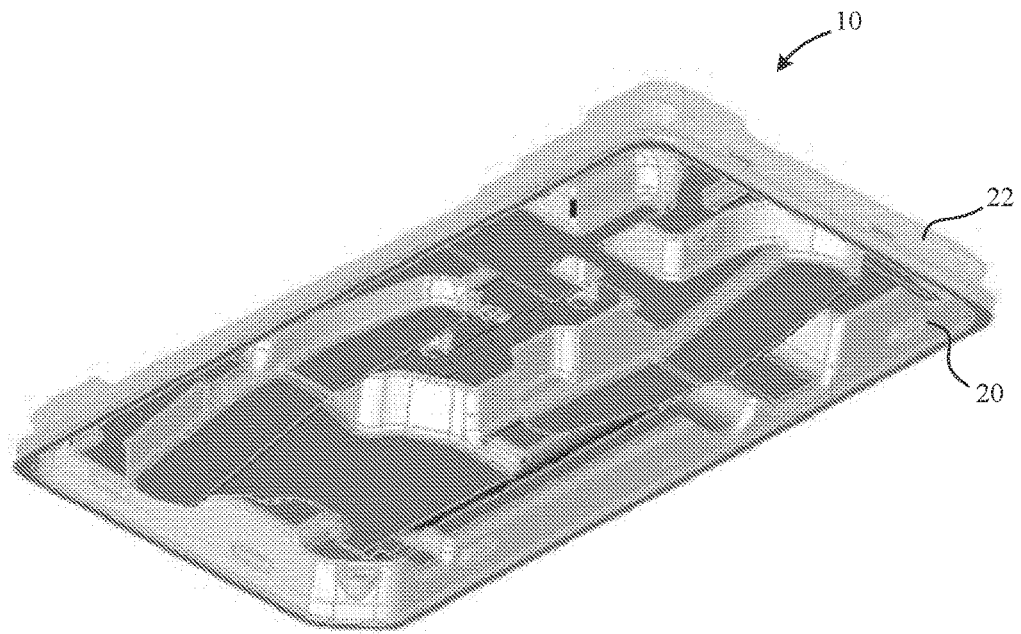


Fig. 2

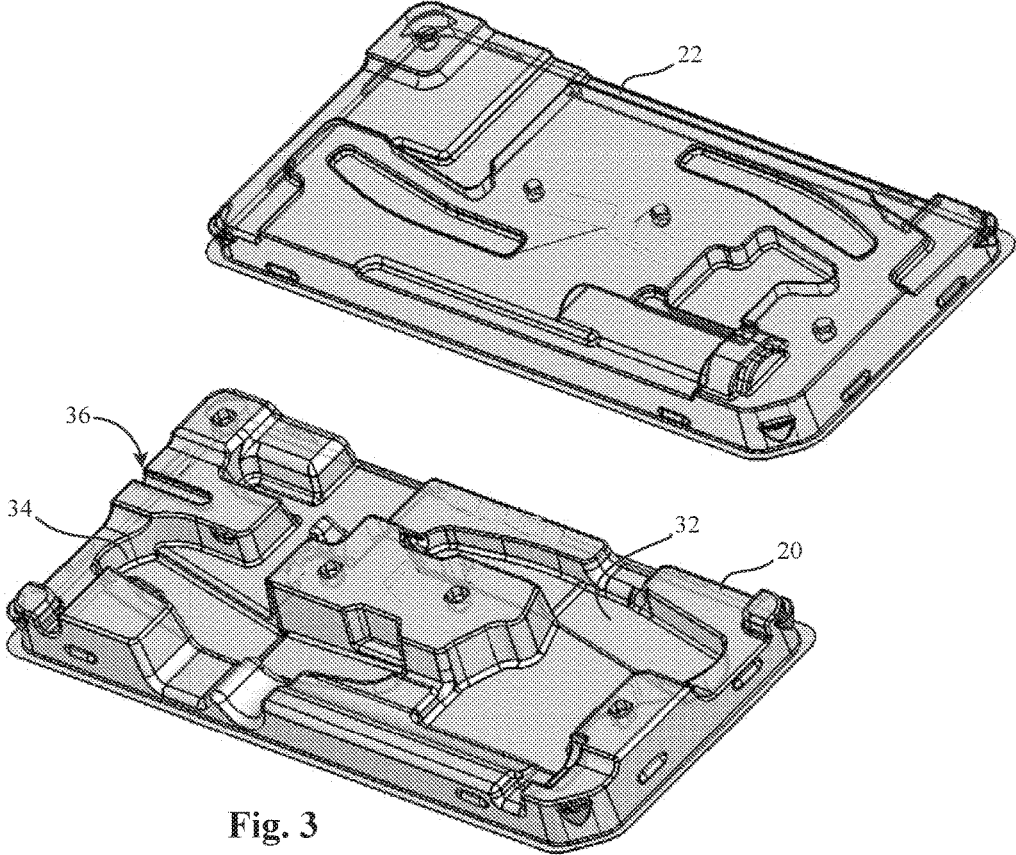


Fig. 3

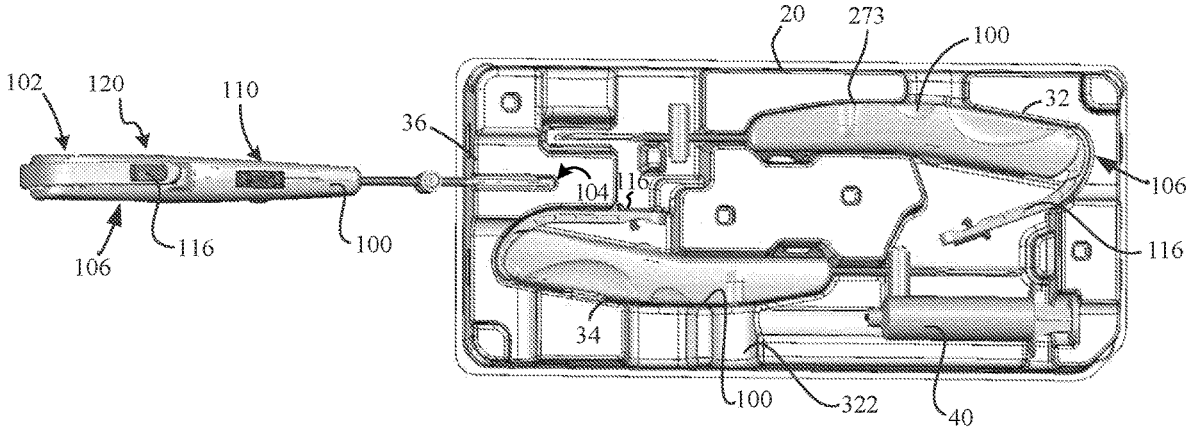


Fig. 4

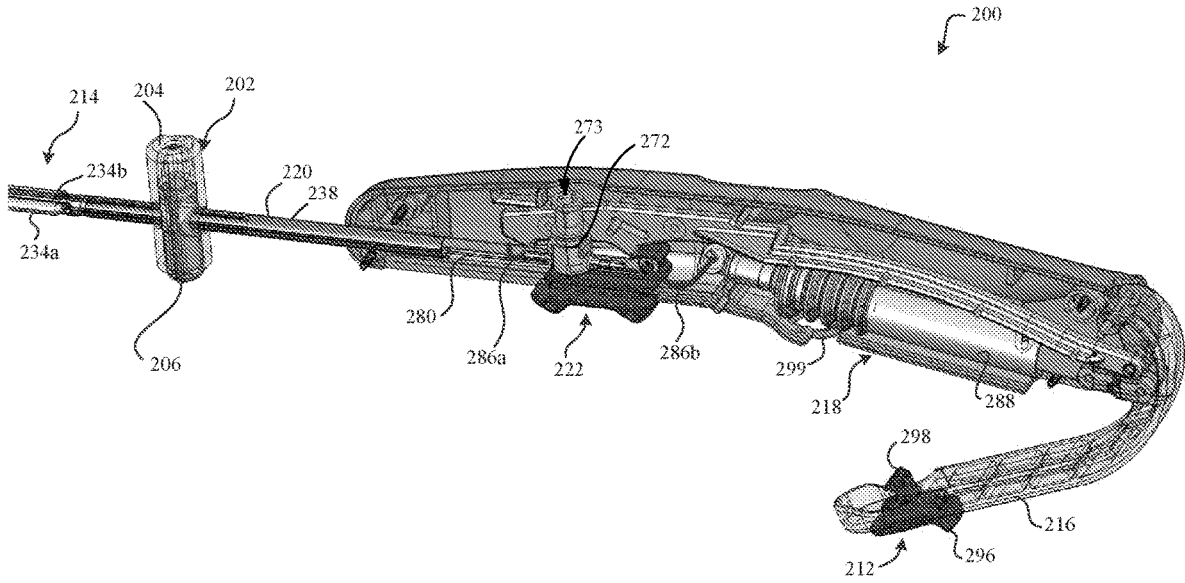


Fig. 5

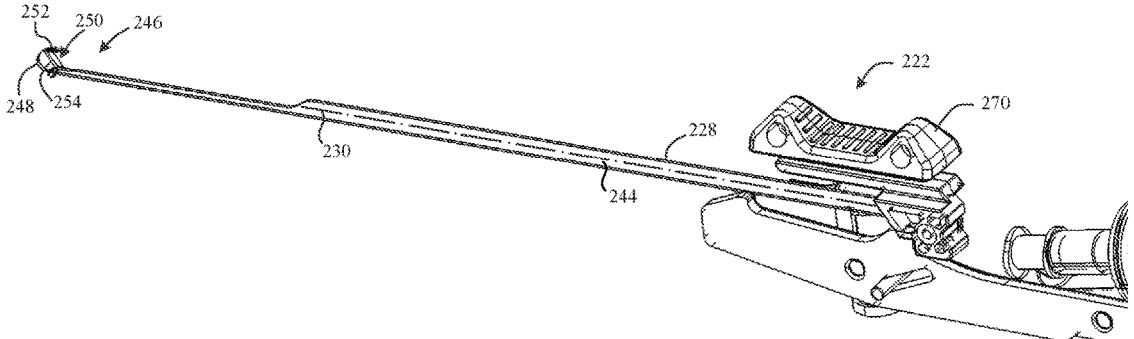


Fig. 6

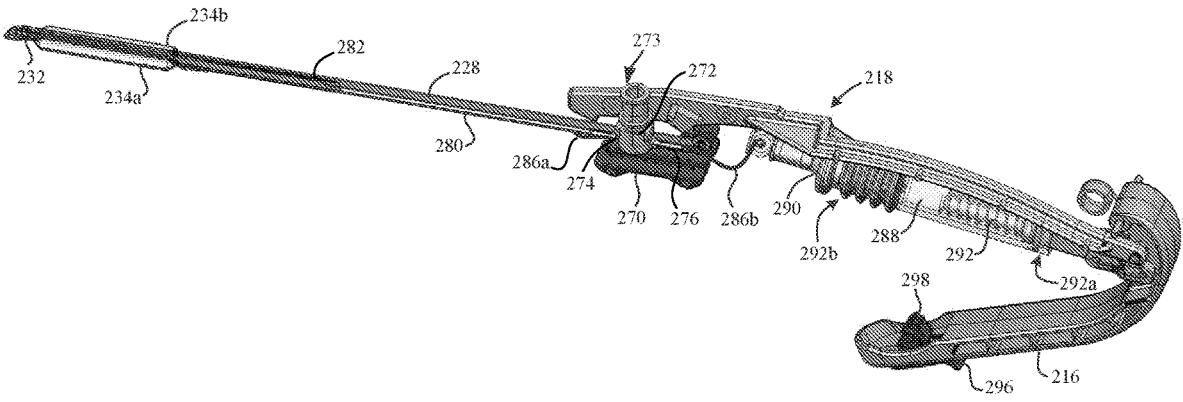


Fig. 7

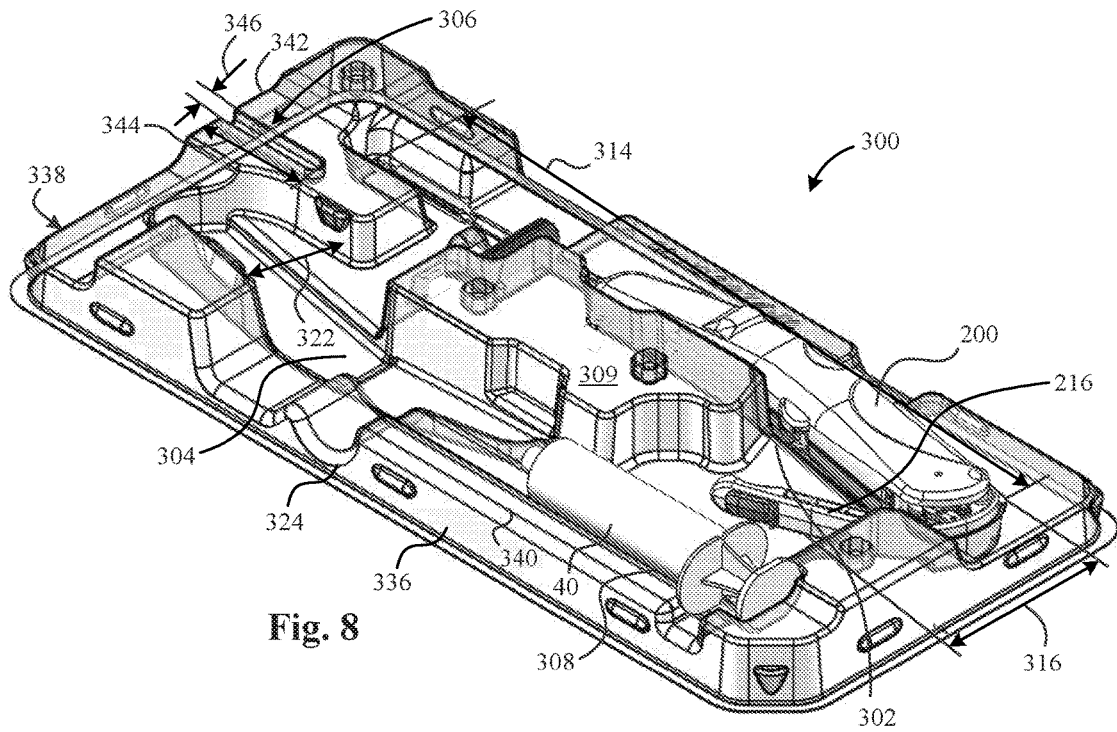


Fig. 8

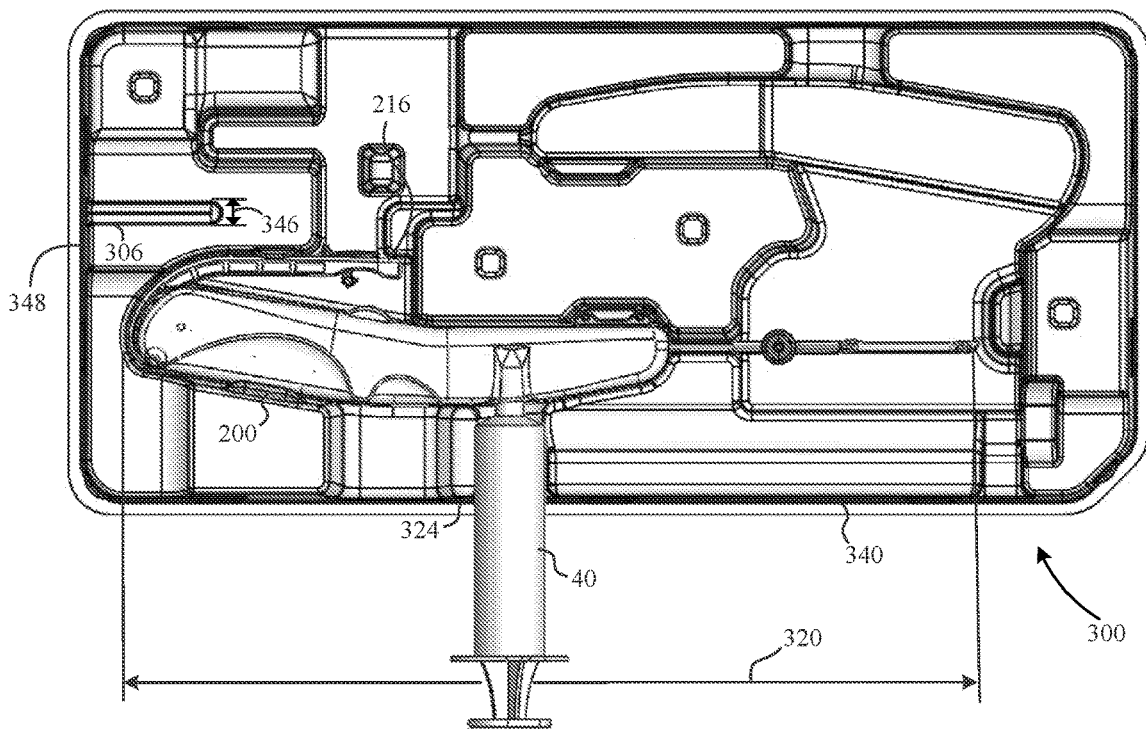


Fig. 9

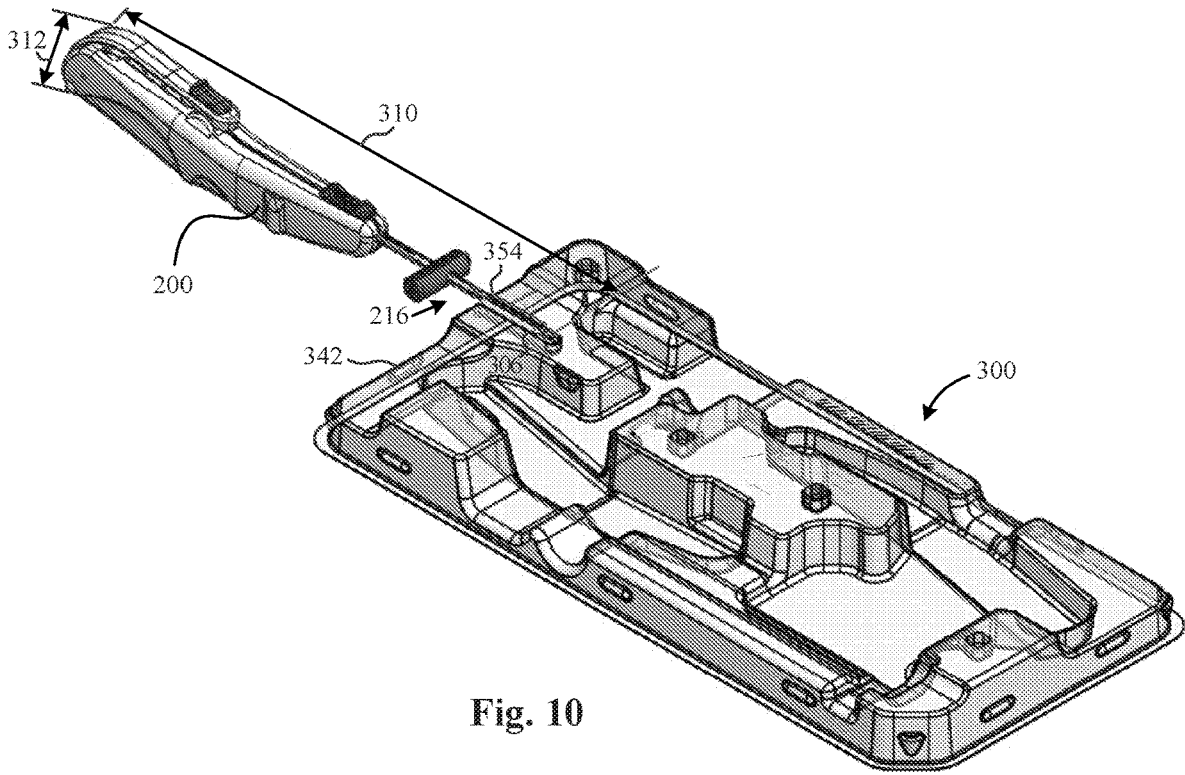


Fig. 10

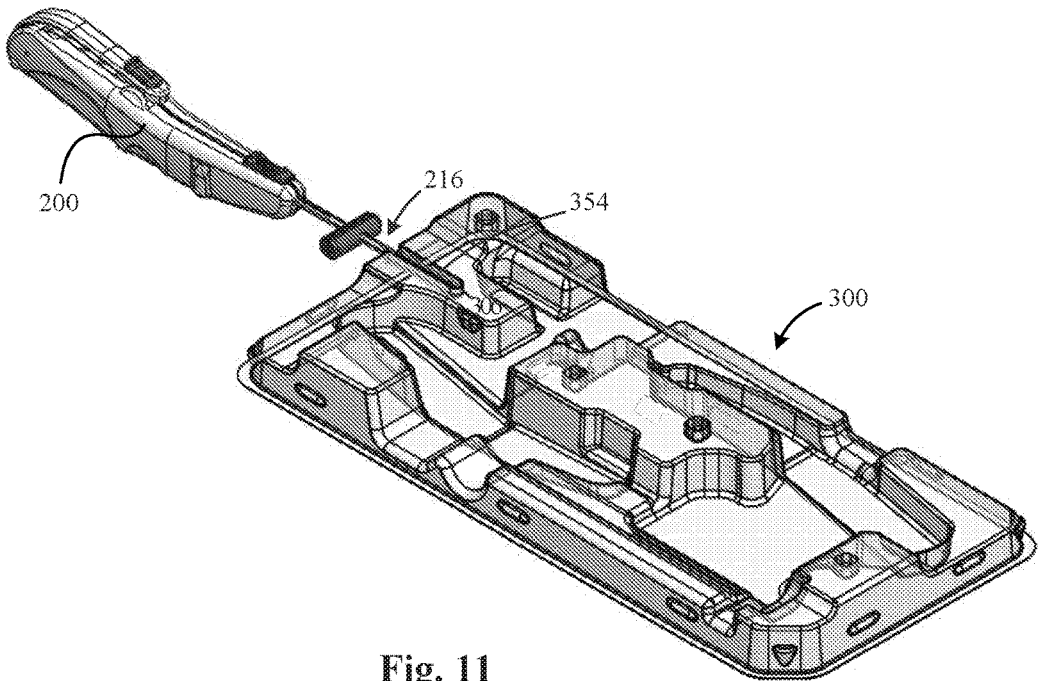


Fig. 11

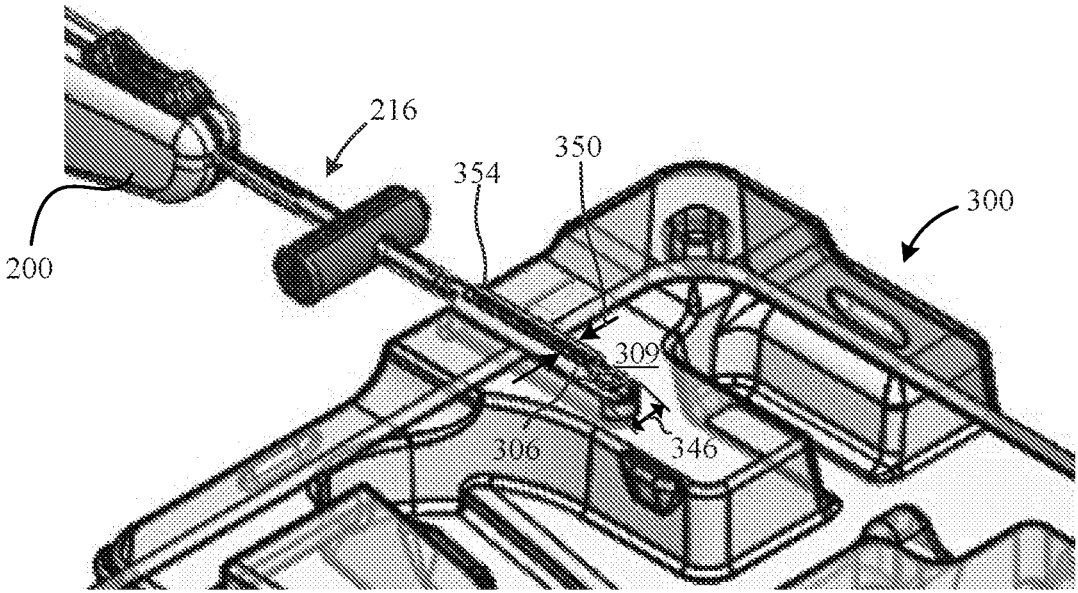


Fig. 12

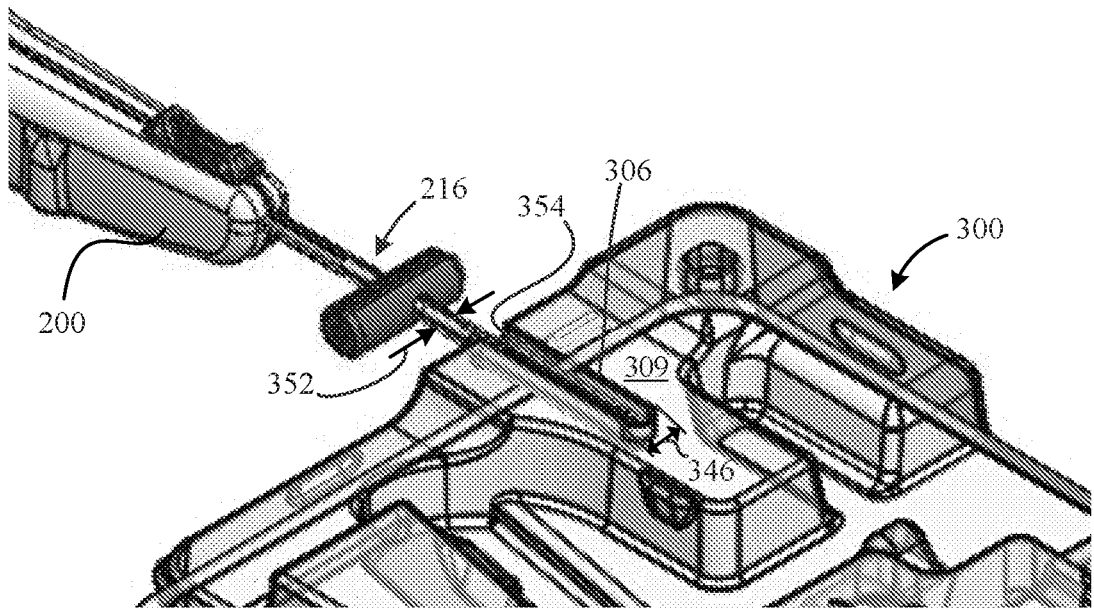


Fig. 13

TRAY FOR A SOFT TISSUE CUTTING DEVICE AND METHODS OF USE

RELATED APPLICATIONS AND CLAIM OF PRIORITY

[0001] The present application is a continuation application of U.S. application Ser. No. 17/114,022, filed Dec. 7, 2020, which is a continuation of U.S. application Ser. No. 15/783,224, filed Oct. 13, 2017, now U.S. Pat. No. 10,864,055. The disclosures of each are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to a tray for a soft tissue cutting device, and more particularly to a tray for storage, priming, and set up of a soft tissue cutting device used for treatment of carpal tunnel syndrome.

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] An example of a device used in a CTR procedure is described in the commonly-assigned U.S. application Ser. No. 14/854,775, titled “Soft Tissue Cutting Device and Methods of Use.” The device includes a blade having a top cutting edge that can be moved forward and backwards. The device also includes one or more balloons that can be inflatable. The balloons can expand radially so as to create and/or expand the “safe zone,” the narrow space between the median nerve and the ulnar artery in the carpal tunnel in which the transverse carpal tunnel ligament can be cut without risk to the median nerve or ulnar artery. As the radially expanding balloons inflate, they move the flexor tendons, median nerve, and ulnar neurovascular bundle away from the device to help create a region in which the transverse carpal ligament can be cut while preventing nearby at-risk structures from being cut.

SUMMARY

[0005] In general, this disclosure relates to a method of using a soft tissue cutting device. In various implementations, the methods may include providing the soft tissue cutting device, positioning the soft tissue cutting device in a priming slot of a tray configured for receiving and holding the soft tissue cutting device, attaching a priming syringe to the soft tissue cutting device, priming a balloon disposed on a distal end of the soft tissue cutting device by equalizing a first pressure inside the balloon to a second pressure inside the priming syringe, removing the soft tissue cutting device from the priming slot, and positioning the distal end of the soft tissue cutting device on a safety slot included in the tray to determine whether the tissue cutting device has been properly primed.

[0006] In some implementations, attaching the priming syringe may include attaching a priming syringe that include a plunger housed within and movable relative to a syringe

body. In such implementations, priming the balloon may include fluidly connecting the priming syringe to the soft tissue cutting device, depressing the plunger of the priming syringe a first time to deliver fluid into the balloon to fill the balloon with the fluid, and drawing back the plunger a first time to create a vacuum and deflate the balloon. Optionally, priming the balloon may also include depressing the plunger of the priming syringe a second time to refill the balloon with the fluid, drawing the plunger back a second time to create a vacuum and thereby deflate the balloon, depressing the plunger a third time, and allowing the pressure within the balloon to equalize with the pressure in the priming syringe.

[0007] In certain implementations, providing the soft tissue cutting device comprises providing a soft tissue cutting device that includes a balloon activation lever that is movable between a depressed position and an extended position and positioned on a proximal end opposite to the distal end. When the tissue cutting device is positioned in the priming slot for priming, the balloon activation lever is in an intermediate position between the depressed position and the extended position. In such implementations, the methods may also include moving the balloon activation lever from the intermediate position to the extended position when the tissue cutting device is removed from the priming slot after priming. Optionally, the methods may include:

[0008] Inserting the soft tissue cutting device into a soft tissue of a subject when the balloon activation lever is in the extended position, moving the balloon activation lever to the depressed position, and deploying a blade working end of a blade to cut the soft tissue. Moving the balloon activation lever to the depressed position may cause the balloon to expand outwardly from the blade. A slider button may be moved to cause the blade working end to protrude out of a housing shaft of the soft tissue cutting device such that the blade working end is deployed to cut the soft tissue. Optionally, the slider button can only be moved after expansion of the balloon. The methods may also include releasing the balloon activation lever from the depressed position to deflate the balloon, and pulling the soft tissue cutting device from the subject. Moving the balloon activation lever from the intermediate position to the extended position may cause the balloon to deflate. Additionally and/or alternatively, the methods may include depressing the balloon activation lever to the depressed position to inflate the balloon after removing the tissue cutting device from the priming slot prior to positioning the tissue cutting device on the safety slot to determine whether the tissue cutting device has been properly primed.

[0009] In some implementations, the safety slot may have a safety slot width configured to be narrower than a distal end width of a distal end of the soft tissue cutting device when the soft tissue cutting device is properly primed for use. As such, when the distal end of the soft tissue cutting device does not fall through the safety slot, the soft tissue device is determined to be properly primed.

[0010] The methods may also include providing the tray including the priming slot and the safety slot. Optionally, attaching the priming syringe to the soft tissue cutting device may include positioning the priming syringe in a priming syringe slot included in the tray.

[0011] The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0012] The following drawings are illustrative of particular embodiments of the present disclosure and therefore do not limit the scope of the invention. The drawings are not necessarily to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present disclosure will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

[0013] FIG. 1 is an upper perspective view of a tray with a device according to a non-limiting exemplary embodiment.

[0014] FIG. 2 is a lower perspective view of FIG. 1.

[0015] FIG. 3 is an exploded perspective view of the tray of FIG. 1 shown without a device.

[0016] FIG. 4 is a top view of the tray of FIG. 1 showing various positions of a device with the tray.

[0017] FIG. 5 is a perspective view of a soft tissue cutting device with its outer housing removed to illustrate interior detail.

[0018] FIG. 6 is partial perspective view of a blade and blade activation assembly of the soft tissue cutting device shown in FIG. 5.

[0019] FIG. 7 is a perspective view of the device shown in FIG. 5 with its outer housing removed to illustrate interior detail.

[0020] FIG. 8 is a side perspective view of the tray of FIG. 1 with the device housed in the housing slot.

[0021] FIG. 9 is a top view of the tray of FIG. 1 with the device housed in the priming slot.

[0022] FIG. 10 is an upper perspective view of the tray of FIG. 1 with the device near the safety slot when the priming has been correctly performed.

[0023] FIG. 11 is an upper perspective view of the tray of FIG. 1 with the device received in the safety slot when the priming has been incorrectly performed.

[0024] FIG. 12 is an enlarged perspective view of the safety slot of FIG. 10.

[0025] FIG. 13 is an enlarged perspective view of the safety slot of FIG. 12.

DETAILED DESCRIPTION

[0026] 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.

[0027] Certain embodiments of the present disclosure provide a tray for a device, such as a soft tissue cutting device. While the illustrated embodiments show an exemplary embodiment of a soft tissue cutting device, such as a transverse carpal ligament cutting device, it should be understood that many different types of devices can be shipped, primed and tested prior to use according to systems and methods disclosed herein.

[0028] FIGS. 1 and 2 are upper and lower perspective views of a tray 10 for enclosing a device 100 (not shown) according to an exemplary embodiment. Tray 10 has a tray thickness 12, a tray width 14, and a tray length 16. Tray 10 includes a body 20 and a cover 22.

[0029] The tray 10 can be made by molding polymers such as resins or copolyesters. In one embodiment, the tray 10 is made by molding polyethylene terephthalate-glycol (PET-G). Other materials are within the scope of the present disclosure. In addition, in certain embodiments, the tray 10 may be shipped in a sealed bag (not shown) so as to ensure that the tray 10 and the device (e.g., device 100) housed therein are sterile.

[0030] In some embodiments, the tray 10 has generally rounded corners and may not have sharp edges. Advantageously, this may promote ease of use during surgery. For instance, the rounded edges and corners of the tray 10 prevent catching on and/or tearing of surgical gloves worn by medical personnel when grasping and/or manipulating the tray 10. In the illustrated embodiment, the tray 10 is generally rectangular in shape, with a tray thickness 12 less than tray width 14 and tray length 16, though other shapes are contemplated within the scope of the present disclosure.

[0031] In certain exemplary embodiments, the tray length 16 is between about 10 inches and about 20 inches. Further, in some embodiments, the tray width 14 is between about 5 inches and about 10 inches, and the tray thickness 12 is between about 0.5 inch and 3 inches. In an exemplary embodiment, the tray length 16 is about 16 inches, the tray width 14 is about 7.5 inches and the tray thickness 12 is about 1.33 inches. It should be noted, however, that these dimensions are not limiting.

[0032] FIG. 3 is an exploded perspective view of the tray 10 according to an exemplary embodiment. The tray 10 includes a body 20, a cover 22, and a plurality of slots 32, 34, and 36. The cover 22 can be removably connectable to the body 20. When the cover 22 is connected to the body 20 of the tray 10, the cover 22 substantially encloses the body 20 and its contents. In certain advantageous embodiments, the cover 22 can be a sterile cover, and may not be removed except when the tray 10 is in use for a procedure, such as a CTR procedure.

[0033] FIG. 4 is a perspective view of the tray 10 with a device 100 shown in various positions within the tray 10. The tray includes a body 20 and a plurality of slots 32, 34, 36. Each of the slots 32, 34, and 36 of the tray 10 receive and/or are connected to the device 100 to illustrate various positions of the device 100 when housed in different slots 32, 34, 36 of the tray 10. It should be understood that in certain embodiments, the tray 10 is shipped with a single device 100 housed in the slot 32 and a priming syringe 40 as will be described further below.

[0034] In certain embodiments, the device 100 as illustrated in FIG. 4 can be a soft tissue cutting device 100, such as described in the commonly-assigned application Ser. No. 14/854,775 ("the '775 application"), the entire contents of which is hereby incorporated by reference. It should be noted however, that the present disclosure is not limited to the disclosed embodiment of device 100 in the '775 application and many variants thereof are contemplated within the scope of the present disclosure.

[0035] With continued reference to FIG. 4, the device 100, according to an embodiment, can be a soft tissue cutting device, such as a transverse carpal ligament cutting device.

The device **100** has a proximal end **102** and a distal end **104**. The proximal end **102** includes a handle **106** and a balloon activation lever **116**. The handle **106** includes a blade activation assembly **110**. The device **100** also includes an inflation assembly **120** coupled to the handle **106**. The inflation assembly **120** and blade activation assembly **110** each control various functions of the shaft at the distal end **104**.

[0036] FIGS. **5**, **6** and **7** are perspective views of a soft tissue cutting device **200** according to an embodiment of this disclosure. FIG. **5** is a perspective view of the soft tissue cutting device **200** with its outer housing removed to illustrate interior detail. FIG. **6** is partial perspective view of a blade activation assembly **222** and a blade **228** of the soft tissue cutting device **200** shown in FIG. **5**. FIG. **7** is a perspective view of the device **200** shown in FIG. **5** with its outer housing removed to illustrate interior detail.

[0037] The device **200** can be substantially similar to device **100**. The device **200** has a proximal end **212** and distal end **214**. The proximal end **212** includes a balloon activation lever **216** (similar to the balloon activation lever **116** of device **100**). The distal end **214** includes an axial depth indicator **202** with ends **204** and **206**. The axial depth indicator is located on a shaft **220** that has a top surface **238**. A blade **228** is housed at least partially within the shaft **220**. A pair of balloons **234a** and **234b** is located on shaft **220**. Device **200** also includes an inflation assembly **218** and a blade activation assembly **222**.

[0038] The shaft **220** of device **200** can have a tip that is smooth edged (e.g., rounded) to permit ease of insertion into the carpal tunnel region. The shaft **220** can optionally be echogenic and/or include diagnostic equipment to permit visualization of the carpal tunnel region during insertion or surgery. The axial depth indicator **202** can be a spring-loaded pin that is slidable along the shaft **220** by pressing ends **204** and **206** toward each other. The axial depth indicator **202** can thus be used to indicate the depth of insertion of the distal end **214** into the patient.

[0039] The balloons **234a** and **234b** expand radially outwardly from the shaft **220**. When inflated, the balloons **234a**, **234b** have a spherical, oval, bilobular or other configuration. When deflated, the balloons **234a**, **234b** are generally flush with the shaft **220**. The balloons **234a** and **234b** can be positioned anywhere along the shaft **220** such that they, for example, expand (or create) the safe zone in a patient's carpal tunnel region. While two lateral balloons **234a**, **234b** are illustrated, skilled artisans will understand that any number of radially expanding balloons can be used and be placed anywhere about the shaft **220** to secure the distal end **214** in position within the carpal tunnel region and to expand the safe zone. For instance, in an exemplary embodiment, as the radially expanding balloons **234a**, **234b** inflate, they move the flexor tendons, median nerve, and ulnar neurovascular bundle away from the device **200** to help create a region in which the transverse carpal ligament can be cut while preventing nearby at-risk structures from being cut, effectively increasing the "safe zone."

[0040] The balloons **234a**, **234b** can have any desired configuration that allows them to inflate and deflate. In some embodiments, the entire balloon is expandable and thus inflates and deflates. In other embodiments, only part of the balloon is expandable. For example, the balloon can have a fixed portion and an expandable portion. The balloons **234a**, **234b** also inflate to a desired size selected to accommodate

the size of a patient's wrist (and thus the patient's carpal tunnel region). For example, in some cases, the balloons **234a**, **234b** can be provided with a specific size such that when they are fully inflated, they have a specific inflated size. In one embodiment, each of the balloons **234a**, **234b** inflate to a similar or same diameter (e.g., a diameter of about 1.5 mm). In patients with larger wrists, larger balloons can be used. In patients with smaller wrists, smaller balloons can be used. In another embodiment one of the balloons **234a**, **234b** inflates to one size and another inflates to a different size. In other cases, the balloons **234a**, **234b** can have a standard size but can be partially inflated or fully inflated to have a variety of different inflated sizes. In some cases, the balloon inflation can be graded to allow the operator to choose a particular balloon diameter. In certain cases, the balloon inflation can be pressure dependent, such that the balloon manually or automatically inflates until a specific pressure is exerted on the balloon surface.

[0041] The blade activation assembly **222** actuates the blade **228** through a slot **232** located on distal end **214**. In the illustrated example, the slot **232** is positioned near (and between) the balloons **234a**, **234b**, though, of course, the slot **232** may be positioned at other locations in the distal end **214**. The blade activation assembly **222** is coupled to a blade shaft **244**. The blade **228** includes a blade working end **246**. The blade shaft **244** has a longitudinal axis **230** along which the blade **228** is actuated. In the illustrated embodiment, the blade working end **246** is configured as a hook and configured to cut a transverse carpal ligament. The blade working end **246** includes an inner surface **250** that adjoins an outer surface **248** at a point **252**. The blade working end **246** also includes a cutting edge **254**. In some embodiments, the cutting edge **254** can be non-parallel to the blade shaft **244**. Alternatively, the cutting edge **254** can be non-linear (e.g., curved). The blade shaft **244** engages with the blade activation assembly **222** to move the blade **228** forward (distally) and backward (toward the proximal end **212**) in a direction parallel to the longitudinal axis **230**.

[0042] In some embodiments, instead of including a cutting edge **254**, at least part of the entire outer surface **248** (or substantially the entire outer surface **248** or the entire outer surface **248**) can be a dull and/or blunt surface that would not cut body tissue. Likewise, the point **252** may be a dull and/or blunt surface. Additionally, a limiting stop can be positioned near the blade working end **246** to engage with and/or travel within a guided surface (e.g., a groove, guide, track or tunnel) that guides the forward and rearward movement of the blade **228**. Such embodiments are advantageous, as they assist in cutting the target tissue in a controlled fashion, while preventing inadvertent cutting of tissue other than the target tissue.

[0043] The blade activation assembly **222** includes a slider button **270** positioned on an external surface of the balloon activation lever **216**. The slider button **270** can move in both forward and backward directions (parallel to the longitudinal axis **230**) to move the blade **228** forward and backward. An operator can engage the slider button **270** with a finger (for example by engaging a thumb with the slider button **270**). When the slider button **270** is moved to extend the blade **228**, the blade working end **246** protrudes through the slot **232** in the distal end **214**.

[0044] The inflation assembly **218** includes a fluid coupling **272** and a fill port **273**. In the embodiment shown, the fluid coupling **272** is T-shaped and includes a first port **274**

and a second port 276 and is connected to the fill port 273. The inflation assembly 218 also includes a first tube 280, a second tube 282, a first conduit 286a, a second conduit 286b, and an inflation device 288.

[0045] The fluid coupling 272 is coupled to the fill port 273. The first port 274 is fluidly coupled to (e.g., by fluid fittings such as push-fit or barbed fitting) a first conduit 286a. The second port 276 is fluidly coupled to a second conduit 286b (e.g., by fluid fittings such as push-fit or barbed fitting). The first conduit 286a is fluidly coupled to the first tube 280 and the second tube 282. The first tube 280 is fluidly coupled to the first balloon 234a, and the second tube 282 is fluidly coupled to the second balloon 234b. Accordingly, when the fill port 273 engages with a priming device (e.g., priming syringe) that supplies pressurized fluid (e.g., by a plunger), the fluid travels through the fluid coupling 272, into the first conduit 286a (via the first port 274), through the first tube 280 and the second tube 282 and into the first balloon 234a and the second balloon 234b to inflate and pressurize the balloons.

[0046] The second conduit 286b is fluidly coupled to the inflation device 288. In the embodiment shown, the inflation device 288 is located inside of the balloon activation lever 216, though in other embodiments, the inflation device 288 can be located outside of the balloon activation lever 216. Skilled artisans will also understand that the inflation assembly 218 described in this embodiment can also be included in any of the other device embodiments (e.g., device 100) described herein. In the embodiment shown, the inflation device 288 is a bellows that includes a body 290 and a spring-biased plunger 292 with a distal end 292a and a proximal end 292b. The body 290 is shown as a transparent feature to illustrate interior detail. The spring-biased plunger 292 is pivotally coupled to the balloon activation lever 216. When the balloon activation lever 216 is depressed, the plunger 292 moves towards distal end 292a. When the balloon activation lever 216 is released, the spring-bias of the plunger 292 moves the plunger 292 toward proximal end 292b.

[0047] In other embodiments, the inflation device 288 can be in the form of a syringe with a piston or plunger or the like. Alternatively, the inflation device 288 can be any desired device known in the art that holds inflation material and both pushes inflation material out of the inflation device 288 and pulls inflation material back into the inflation device 288. The inflation device 288 is actuated by the balloon activation lever 216 to inflate or deflate the balloons 234a, 234b once primed.

[0048] When the balloons 234a, 234b are deflated, the fluid from the balloons 234a, 234b travel to and stay within the bellows 288. In order to re-inflate the balloons 234a, 234b, the balloon activation lever 216 is engaged, thereby applying pressure on the distal end 292a of the plunger 292 of the bellows 288 to pressurize fluid within the bellows 288. This causes fluid to move into the first conduit 286a, through the first tube 280 and the second tube 282, and into the balloons 234a, 234b. When the operator desires to deflate the balloons 234a, 234b, the balloon activation lever 216 is released. The plunger 292 of the bellows 288 then moves toward the proximal end 292b as a result of spring bias, thereby pulling fluid back towards the inflation device 288. As a result, the fluid moves out of the balloons 234a, 234b and back into first tube 280 and second tube 282, through the first conduit 286a, and into the bellows 288.

[0049] The balloon activation lever 216 includes a balloon locking mechanism. In the embodiment shown, the balloon locking mechanism includes a spring-biased button 296, which terminates in a pin 298. The device 200 includes a groove 299 for receiving the pin 298 of the button 296. If the operator desires to lock the balloons 234a, 234b in an inflated position, the balloon activation lever 216 is depressed to bring the spring-biased button 296 toward the groove 299 (e.g., by an operator's thumb or finger). The pin 298 of the spring-biased button 296 is then received within the groove 299. When the pin 298 rests within the groove 299, the plunger 292 of the inflation assembly 218 is held in tension against its spring-bias, thereby maintaining the position of the balloon activation lever 216 in the depressed position and the plunger 292 near the proximal end 292b of the bellows 288. As a result, the fluid would continue to be pressurized, thereby maintaining the balloons 234a, 234b in an inflated position.

[0050] Prior to use, the device 200 is in a first inactive position. In the first inactive position, the blade 228 is positioned such that the cutting edge 254 is fully housed and protected within the shaft 220 and the device 200 can be safely inserted into a carpal tunnel region. Additionally, the balloons 234a, 234b are in a deflated configuration. The operator inserts the distal end 214 of the device 200 into a carpal tunnel region such that the transverse carpal ligament is positioned adjacent the top surface 238 of the shaft 220. The operator then engages the balloon activation lever 216 to cause the balloons 234a, 234b to inflate and expand the safe zone within the carpal tunnel region. The balloons 234a, 234b can then be locked in the inflated state using the balloon locking mechanism to engage the spring-biased button 296 to maintain the pin 298 in the groove 299.

[0051] The operator next moves the slider button 270 to move the blade working end 246 to protrude out of the shaft 220, and fully expose the cutting edge 254 to cut the transverse carpal ligament. The operator continues to move the slider button 270 to move the blade working end 246 (and cutting edge 254) in a desired direction (e.g., backward). As the cutting edge 254 moves along the desired direction (e.g., backward), it cuts the transverse carpal ligament. Once the transverse carpal ligament is cut, the operator releases the spring-biased button 296 and the balloon activation lever 216. As a result of the spring-bias, the plunger 292 moves toward distal end 292a. As a result, the balloons 234a, 234b deflate. In this second position, the blade 228 is positioned such that the blade working end 246 does not protrude out of the shaft 220, the cutting edge 254 is fully housed and protected within the shaft 220, and the device 200 can thus be safely removed from the body.

[0052] FIG. 8 is a side perspective view of a tray 300 with the device 200 in a housing slot 302 and the priming syringe 40 in a priming syringe slot 308. FIG. 9 is a top view of the tray 300 with the device 200 housed in a priming slot 304. FIG. 10 is an upper perspective view of the tray 300 with the device 200 resting on safety slot 306 when priming of the device 200 has been correctly performed. FIG. 11 is an upper perspective view of the tray 300 with the device 200 received in the safety slot 306 when priming of the device 200 has not been correctly performed.

[0053] Referring to FIGS. 8-11, the tray 300 includes the housing slot 302, the priming slot 304, the safety slot 306, the priming syringe slot 308, and a top surface 309. The device 200 has a device length 310 and a device width 312.

The housing slot 302 has a housing slot length 314 and a housing slot width 316. The priming slot 304 has a priming slot length 320 and a priming slot width 322. A lateral groove 324 is adjacent to the priming slot 304. The tray 300 also includes a first side surface 336 and a second side surface 338, both of which are perpendicular to the top surface 309. A first edge 340 adjoins the top surface 309 and the first side surface 336. A second edge 342 adjoins the top surface 309 and the second side surface 338. The safety slot 306 has a safety slot length 344 and a safety slot width 346.

[0054] As shown in FIG. 8, the priming syringe 40 can be supplied along with the device 200 and housed in the tray 300 in the form of a surgical kit. During shipment and prior to use, the device 200 can be removably housed in the housing slot 302. Further, the priming syringe 40 can be removably housed in the priming syringe slot 308. The housing slot 302 is elongated in shape. As shown in FIG. 8, the elongated shape of the housing slot 302 generally matches the elongated shape of the device 200. The housing slot 302 is a cavity recessed from the top surface 309 of the tray 300. The priming syringe slot 308 is also a cavity recessed from the top surface 309 and is shaped to match the shape of the priming syringe 40.

[0055] The housing slot 302 can be shaped to match the shape of the device 200 prior to priming to receive the device 30 in a snug fashion. For instance, the housing slot width 316 can be equal to (or slightly greater than) the device width 312 and the housing slot length 314 can be equal to (or slightly greater than) the device length 310. The housing slot 302 is shaped such that the balloon activation lever 216 of the device 200 is in an extended (or released) position. The priming slot 304 is recessed from the top surface 309 and can be shaped to generally match the shape of the device 200 during a priming procedure. The priming slot length 320 can be about equal to the housing slot length 314. In some embodiments, the priming slot width 322 can be slightly less than the housing slot width 316, because, as discussed below, during priming, the balloon activation lever 216 is in a position different from its position when in the housing slot 302.

[0056] The safety slot 306 is located on the second edge 342 adjoining the top surface 309 and the second side surface 338. The safety slot 306 is recessed from the top surface 309 and is generally elongated in shape. The safety slot length 344 is generally shorter than the housing slot length 314 and/or the priming slot length 320. Further, in some embodiments, the safety slot width 346 can be narrower than both the housing slot width 316 and the priming slot width 322.

[0057] As shown in FIG. 9, once the device 200 is ready for priming, the device 200 can be removed from the housing slot 302, and the priming syringe 40 can be removed from the priming syringe slot 308 and placed laterally near the fill port 273. Once removed, the device 200 can be positioned and aligned with the lateral groove 324 so as to facilitate connection to the priming syringe 40. The lateral groove 324 is defined on the first side surface 336 near the first edge 340. As shown in FIG. 9, during priming, a portion of the priming syringe 40 is positioned and held within the lateral groove 324, such that the distal tip of the priming syringe 40 can engage with the fill port 273 of the device 200 positioned in the priming slot 304. When the device 200 is positioned in the priming slot 304, the balloon activation lever 216 is in an intermediate position between the

depressed position and the extended position. The balloon activation lever 216 is movable to the depressed position to inflate the balloons after priming, and to the extended position to deflate the balloons after priming.

[0058] In order to prime the device 200 prior to use, in certain exemplary embodiments, the priming syringe 40 is used. In one example, priming involves filling the balloons with a fluid and initially pressurizing the balloons prior to use. For example, the priming syringe 40 can have a plunger which is used to dispense a fluid through the distal tip into a fluid conduit and thereby into the balloons of the device 200. The plunger can be movable with respect to the body of the priming syringe 40. Other types of priming devices (e.g., injectors, pumps, and the like) are also contemplated within the scope of the present disclosure.

[0059] In some embodiments, the priming syringe 40 can be removably connectable with the fill port on the device 200. For instance, the removable connection between the fill port and the priming syringe 40 can be a Luer-Lok® connection. The fill port in turn can be fluidly connected to the balloons by way of conduits. Thus, the priming syringe 40 can be fluidly coupled to the balloons such that movement of the plunger of the priming syringe 40 can create a vacuum and/or deflate the balloons, or fill the balloons with a predetermined volume of fluid and/or inflate the balloons. In one embodiment, when the plunger of the priming syringe 40 is drawn, a vacuum is created within the balloons. When the plunger of the priming syringe 40 is depressed, the balloons may be filled with a predetermined volume of fluid. Further, the balloons can be deflated and re-inflated successively to equalize balloon pressure to the pressure within the syringe, as will be described further below.

[0060] In an exemplary embodiment, the priming syringe 40 contains about 20 milliliters of saline, and pressurizes the balloons by providing between about 1 milliliter and about 2 milliliter of saline. However, the volumes provided herein should not be construed as limiting. Further, fluids other than saline can also be used to prime the balloons.

[0061] After the device 200 has been primed, the safety slot 306 is used to determine whether the device 200 is primed such that it is ready for use. FIGS. 10-13 illustrate a test for determining whether the balloons have been properly primed for use. FIG. 12 is an enlarged perspective view of the device 200 in safety slot 306 as shown in FIG. 10. FIG. 13 is an enlarged perspective view of the device 200 in safety slot 306 as shown in FIG. 11.

[0062] FIGS. 10 and 12 show the device 200 in the safety slot 306 when the device 200 is properly primed. When the device 200 is properly primed, the balloons are inflated such that the distal end of the device 200 has a first distal end width 350. When the device 200 is properly primed, the first distal end width 350 is larger than the safety slot width 346 such that the distal end of the device 200 does not fall into the safety slot 306 and instead rests on top of the safety slot 306. Furthermore, a top portion 354 of the distal end extends above the top surface 309 of the tray 300. This indicates that the balloons are sufficiently inflated for use and thus that the device 200 has been properly primed.

[0063] FIGS. 11 and 13 show the device 200 in the safety slot 306 when the device 200 is not properly primed. When the device 200 has not been properly primed, the balloons are underinflated such that the distal end of the device has a second distal end width 352 that is narrower than the first distal end width 350. When the balloons have not been

properly primed, the second distal end width 352 is narrow enough such that the distal end of the device 200 falls into the safety slot 306 and is received within the safety slot 306. Furthermore, the top portion 354 of the distal end does not protrude past the top surface 309 of the tray 300. This indicates that the balloons are not sufficiently inflated for use and that the device 200 has not been properly primed.

[0064] Embodiments of the present disclosure include a method of priming the device 200. Referring to FIGS. 8-13, the method includes providing the device 200 according to any of the disclosed embodiments (or equivalents thereof) enclosed in the tray 300. The device 200 is enclosed in the tray 300 such that the device 200 is positioned in the housing slot 302 such that the balloon activation lever 216 is in the extended position. The priming syringe 40 is positioned in the priming syringe slot 308.

[0065] The device 200 is then removed from the housing slot 302 and the balloon activation lever 216 is depressed into an intermediate position such that the device 200 can be positioned in the priming slot 304. The balloon activation lever 216 is only depressed sufficiently to place the device 200 into the priming slot 304 and is not fully depressed. The priming syringe 40 is then removed from the priming syringe slot 308 and filled with a volume of a fluid (e.g., sterile saline). In one embodiment, the volume of fluid is 20 milliliters (ml). The priming syringe 40 is then placed into lateral groove 324, and attached to the fill port of the device 200.

[0066] In order to prime the device 200, the plunger of the priming syringe 40 is depressed a first time to deliver a priming volume of the fluid through the fill port and into the balloons to fill the balloons with the fluid. In one embodiment, the priming volume of fluid is between about 1 ml and 2 ml. The plunger is then drawn back to create a vacuum and thereby deflate the balloons. In certain embodiments, after the plunger is drawn back, the vacuum can be held for a first time interval. In an exemplary embodiment, the first time interval is between about 1 second and about 10 seconds (e.g., 5 seconds).

[0067] After the plunger is drawn back to create a vacuum, the plunger is then depressed a second time to refill the balloon with a priming volume of the fluid. In one embodiment, the priming volume of fluid is between about 1 ml and 2 ml. The plunger is then again drawn back to create a vacuum and thereby deflate the balloons a second time. In certain embodiments, after the plunger is drawn back, the vacuum can be held for a second time interval. In an exemplary embodiment, the second time interval is between about 1 second and about 10 seconds (e.g., 5 seconds).

[0068] After the plunger is drawn back to create a vacuum for a second time, the plunger is then depressed a third time to refill the balloons with the second volume of the fluid. In one embodiment, the second volume of fluid is between about 1 ml and 2 ml. In certain embodiments, the plunger may or not be drawn back and/or depressed again after the plunger has been depressed a third time. Additionally, in some embodiments, after the plunger is depressed a third time, the plunger may be held in its position for a third time interval. In an exemplary embodiment, the third time interval can be between about 1 second and about 5 seconds (e.g., 2 seconds). The plunger is then released after being held during the third time interval and the pressure within the balloons subsequently equalizes with the pressure within the priming syringe 40.

[0069] After the plunger is depressed a third time and the pressure in the balloons is equalized, the plunger is not drawn back and the priming syringe 40 is disconnected from the fill port of the device 200. The device 200 is then be removed from the priming slot 304, thereby permitting the balloon activation lever 216 to automatically un-depress and move to the extended position as a result of its spring-biasing.

[0070] After removal of the device 200 from the priming slot 304, the balloon activation lever 216 can be depressed to activate (inflate) the balloons. When the balloons are in an activated state, the cutting blade of device 200 becomes active and can be tested by gently moving the slide button on the handle of the device to expose the cutting knife from its distal recessed position. The slide button is used to cycle the cutting blade a minimum of one time from its distal to proximal recessed positions to ensure functionality.

[0071] With the balloon activation lever 216 remaining depressed and the balloons activated, a safety test can now be performed to determine whether the tissue cutting device 200 has been properly primed. The distal end of the tissue cutting device 200 is positioned near the safety slot 306. The axial depth indicator 202 can be optionally rotated so as to be non-parallel (e.g., perpendicular) to the balloon activation lever 216. Advantageously, this step permits the axial depth indicator 202 from interfering with the safety test, for instance, by abutting any surface and thereby inadvertently causing small axial extensions of the distal end of the device 200. The distal end of the device can then be gently placed in the safety slot 306. In some embodiments, pressure should not be applied on the distal end of the device 200 so as to force the distal end into the safety slot; the distal end 104 should simply be positioned over the safety slot 306.

[0072] When the device 200 is properly primed, the balloons are inflated such that the distal end of the device 200 has a first distal end width 350. When the device 200 is properly primed, the first distal end width 350 is larger than the safety slot width 346 such that the distal end of the device 200 does not fall into in the safety slot 306 and instead rests on top of the safety slot 306. It may also be visually apparent to the operator that the balloons are properly inflated. Furthermore, a top portion 354 of the distal end should extend above the top surface 309 of the tray 300. This indicates that the balloons are sufficiently inflated for use and thus that the device has been properly primed. If the balloons are not properly primed and are underinflated such that the distal end of the device 200 falls into the safety slot 306 and is received within the safety slot 306, the device 200 should be primed again and the safety test should be performed again until the device 200 passes the test.

[0073] Once the device 200 has been primed and has passed the safety test, the device 200 can be used to perform a procedure, such as cutting a transverse carpal ligament to treat carpal tunnel syndrome. In order to prepare the device 200 for such a procedure, the balloon activation lever 216 is released into an extended position such that the balloons are deflated. The device 200 can then be placed within the carpal tunnel of the patient, and its placement with respect to different anatomical features (e.g., median nerve, ulnar vessels, superficial palmar arterial arch, palmar digital nerves, and the transverse carpal ligament, etc.) can be verified. The balloons 234a, 234b are then inflated by depressing the balloon activation lever 216, which simulta-

neously unlocks the cutting blade. The balloons are then locked in the inflated position used the spring-biased button 296.

[0074] The cutting blade is then be deployed by using the slider button 270. For instance, the blade can be slid in a direction from the distal end of the device 200 toward the proximal end. Accordingly, the cutting blade would engage and cut a distal transverse carpal ligament from the distal end to the proximal end of device 200. After cutting, the slider button 270 is slid distally so as to place the blade in its distal resting position. The spring-biased button 296 is then released and the balloons are deflated by releasing the balloon activation lever 116 to the extended position. The device 200 is then removed from the patient and post-surgical care (e.g., wound closure, applying bandages, etc.) is administered.

[0075] While different embodiments of a tray for 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 tray for a soft tissue cutting device and are within the scope of the invention.

1. (canceled)
2. A device for cutting a transverse carpal ligament in a hand of a patient, the device comprising:
 - a handle comprising a bellows;
 - a shaft comprising a proximal end, a distal end, and an opening, wherein the proximal end is coupled to the handle and the opening is adjacent the distal end;
 - a blade slidably disposed within the shaft; and
 - at least one balloon coupled with the shaft adjacent the distal end, wherein the at least one balloon is in fluid communication with the bellows.
3. The device of claim 2, further comprising a balloon activation lever coupled with the handle and the bellows, wherein the balloon activation lever is configured to move from an extended position to a depressed position to activate the bellows and inflate the at least one balloon.
4. The device of claim 3, wherein the balloon activation lever is spring biased to remain in the extended position.
5. The device of claim 3, wherein the balloon activation lever is configured to deflate the at least one balloon by moving from the depressed position to the extended position.
6. The device of claim 3, further comprising a balloon locking mechanism on the handle, configured to hold the balloon activation lever in the depressed position.
7. The device of claim 2, wherein the blade comprises a working end with a cutting edge.
8. The device of claim 7, wherein the cutting edge faces proximally toward the handle of the device.
9. The device of claim 7, wherein an outer surface of the blade working end includes a blunt surface.

10. The device of claim 7, wherein the blade working end is echogenic.

11. The device of claim 2, wherein the handle further comprises a slider configured to move the blade from an inactive position inside the shaft to an active position at least partially extending through the opening on the shaft.

12. The device of claim 11, further comprising a balloon activation lever coupled with the handle and the bellows, wherein the blade is locked in the inactive position until the balloon activation lever is depressed.

13. The device of claim 2, wherein the shaft further comprises a blade guideway comprising a track having variable elevation along a length of the shaft, and wherein the blade is configured to be elevated and lowered as the blade moves along the length of the shaft via the blade guideway.

14. The device of claim 2, wherein the at least one balloon expands radially outwardly from the shaft.

15. A method for cutting a transverse carpal ligament in a hand of a patient, the method comprising:

- advancing a distal end of a shaft of a device into the patient's hand below the transverse carpal ligament;
- verifying a position of the distal end with an ultrasound device positioned outside the hand;
- activating a bellows in a handle of the device to inflate at least one balloon coupled at or near the distal end of the shaft;
- moving a blade of the device proximally along the shaft to cut the transverse carpal ligament;
- positioning the blade at least partially within the shaft;
- deflating the at least one balloon; and
- removing the shaft from the hand.

16. The method of claim 15, wherein activating the bellows comprises depressing a balloon activation lever on the handle.

17. The method of claim 16, wherein deflating the at least one balloon comprises releasing the balloon activation lever to cause gas or fluid to move from the at least one balloon into the bellows.

18. The method of claim 16, further comprising, before advancing the distal end of the shaft, priming the device by:

- filling the at least one balloon with gas or fluid via a fill port on the handle of the device; and
- releasing the balloon activation lever to cause the gas or the fluid to move from the at least one balloon into the bellows.

19. The method of claim 15, wherein the at least one balloon comprises two balloons that expand radially outwardly from the shaft.

20. The method of claim 15, wherein moving the blade proximally along the shaft comprises sliding a slider of the device proximally toward the handle to cause a cutting edge of the blade to extend out of an opening along a longitudinal length of the shaft.

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