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(54) Title: METHOD AND SYSTEM FOR PACKAGING OF MEDICAL DEVICES INCLUDING SHAPE MEMORY MATERIALS

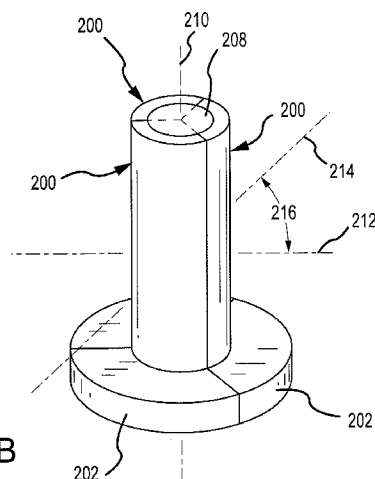


FIG. 2B

(57) Abstract: Packages are described for constraining expansion of medical devices along at least one axis. Removal devices for removing the medical devices from the packages are described. Medical devices stored in and removed from packages can include shape memory materials (e.g., polymers, alloys) which can cause the medical device to expand due to activation of the shape memory material. Medical devices can also expand due to other reasons, such as elastic recoil and/or thermal expansion. The methods and systems described herein may be used to limit the expansion of a medical device along at least one axis while inside a package. The methods and systems described herein may be used to relieve some of the stored strain in the medical device upon the opening of the package. Methods and systems are also described for opening a package which is subject to expansive forces from the medical device.



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**METHOD AND SYSTEM FOR PACKAGING OF MEDICAL DEVICES
INCLUDING SHAPE MEMORY MATERIALS**

Background

5 Medical devices may be packaged in order to protect the medical device from physical damage during shipment and/or storage. Medical devices may also be packaged in order to protect the sterility of the medical device. Packaging of medical devices is common because medical devices may be subjected to shock, temperature cycles, contaminated environments and other conditions detrimental to the medical device's
10 physical condition and/or sterility during storage and transport prior to use.

Summary

Methods and systems are described for packaging medical devices. Packages are described for constraining expansion of medical devices along at least one axis. Removal devices for removing the medical devices from the packages are described. Medical
15 devices stored in and removed from packages can include shape memory materials (e.g., polymers, alloys) which can cause the medical device to expand due to activation of the shape memory material. Medical devices can also expand due to other reasons, such as elastic recoil and/or thermal expansion. The methods and systems described herein may be used to limit the expansion of a medical device along at least one axis while inside a
20 package. The methods and systems described herein may be used to relieve some of the stored strain in the medical device upon the opening of the package. Methods and systems are also described for opening a package which is subject to expansive forces from the medical device.

In one aspect the disclosure describes a package for a medical device containing a
25 shape memory polymer. The package includes at least one intermediate member which has an interior surface capable of mating with a portion of the medical device, a constraining member disposed around the at least one intermediate member, and a compressing member disposed between the at least one intermediate member and the constraining member.

In another aspect, the disclosure describes a method of packaging a shape memory
30 medical device. The method includes packaging a shape memory medical device in a chamber created by interior surfaces of a plurality of sabots, and encompassing a circumference of the plurality of sabots with a constraining member. The method also includes initiating an expansion of the medical device, and limiting the expansion of the medical device via limiting movement of the sabots.

In another aspect, the disclosure describes a removal device for removing a medical device from a package. The removal device includes a housing for containing the package in an unopened state, wherein the housing comprises a handle body and a hinged lid body attached to the handle body. The removal device also includes a chamber defined by an interior surface of the handle body and the hinged lid body, the chamber adapted to contain the package in the unopened state. The removal device also includes a cylinder adapted to engage a constraining member of the package, wherein turning about the axis of the cylinder winds a removed portion of the constraining member of around the cylinder. The removal device also includes an opening shaped to allow the medical device to pass out of the chamber.

In another aspect, the disclosure describes a package for a medical device containing a shape memory polymer. The package includes at least one intermediate member which has an interior surface capable of mating with a portion of the medical device. The package also includes a means for constraining the at least one intermediate member, the means for constraining disposed around the at least one intermediate member. The package may also include a means for compressing the medical device disposed between the at least one intermediate member and the means for constraining the medical device.

A Brief Description of the Drawings

Fig. 1A shows an assembled package comprising three sabots and a constraining member.

Fig. 1B shows a sabot with a detail of an inner surface of the sabot.

Fig. 2 shows three sabots with key elements.

Fig. 3A shows another embodiment of an assembled package comprising sabots, a constraining member, and a compressing member.

Fig. 3B shows a side view of an assembled package with a compressing member partially removed from the assembled package.

Fig. 3C shows a side view of an assembled package and a removed compressing member.

Fig. 4A shows another embodiment of an assembled package comprising sabots and a constraining member, with the package in a heightened compression configuration.

Fig. 4B shows the assembled package in a lessened compression configuration.

Fig. 5 shows an assembled package comprising sabots, a constraining member, and a compressing member.

Fig. 6A shows a package with an elliptical compressing member in a greater compression position.

Fig. 6B shows a package with an elliptical compressing member in a lower compression position.

5 Fig. 7A shows a package with a handle attached to an elliptical compressing member in a compressed position.

Fig. 7B shows a package with a handle attached to an elliptical compressing member in an uncompressed position.

10 Fig. 8A shows a removal device for removing a medical device from a package with the housing of the removal device opened.

Fig. 8B shows a removal device for removing a medical device from a package with the housing of the removal device closed around a package.

15 Fig. 8C shows an embodiment of a removal device for removing a medical device from a package with a handle for opening the package actuated to a position indicating that the package is opened.

Fig. 8D shows the medical device outside of the removal device after the medical device has been removed from the package.

Fig. 9A shows a detail of a portion of a constraining member adapted to be torn/peeled from the rest of the constraining member.

20 Fig. 9B shows a detail of a portion of a constraining member being torn/peeled from the rest of the constraining member by a rotating opening device.

Fig. 10A shows a detail of a knife-type element for opening a package through engaging a constraining member.

25 Fig. 10B shows a detail of another embodiment of a knife-type element for opening a package through engaging a constraining member.

Detailed Description

30 The following description of various embodiments is merely exemplary in nature and is in no way intended to limit the disclosure. While various embodiments have been described for purposes of this specification, various changes and modifications may be made which will readily suggest themselves to those skilled in the art, and which are encompassed in the disclosure.

Medical devices may expand for a number of reasons, including activation of shape memory elements within the medical device. Because medical devices often require restrictive tolerances to be met in order to be used with a patient (e.g., inside a patient), the

expansion of medical devices may be controlled. Expansion of medical devices can include thermal expansion, expansion due to shape change of a shape memory element in a medical device, expansion due to absorption (e.g., absorption of water vapor from the air), or expansion for other reasons. The description herein includes packages and methods of packaging which constrain a medical device from expansion along at least one axis.

Fig. 1A shows an assembled package 100 comprising three intermediate members 102 and a constraining member 104. As discussed herein, the intermediate members 102 may be described as sabots as reference to the mated petal quality of some of the embodiments of the intermediate members. It should be recognized that other designs of intermediate members may be used as well in order to transmit expansive forces from a medical device to a constraining member. Potential forces of expansion exerted by the medical device are translated to the sabots at the interface of the medical device and the interior surface of the sabot, and the sabot, in turn, is constrained by a constraining member 104.

Exemplary embodiments of a sabot material include metals (e.g., stainless steel), polymer, and/or a composite material. The sabots 102 may be constructed in any manner which can withstand the expansive forces of a medical device. The sabots may be constructed as a solid element, as an element with porosity (e.g., honey comb, corrugated), or as other structures. Materials of sabots may be chosen for bio-compatibility as the medical devices which are contacted by the sabots may be used in surgery. The material may be formed into a sabot using any available method, including molding, extrusion, cutting, lathing, and/or etching.

Exemplary embodiments of a constraining member material include metals (e.g., stainless steel), polymer, and/or a composite material. The constraining member 104 can be formed into a band, web, tube or other structure capable of withstanding the expansive forces of the medical device.

In the embodiment shown, a system of sabots 102 contain the medical device 106 inside the package 100. The sabots 102 define an interior surface which mates with the medical device 106. The interior surfaces of the sabots provide constraint against expansion of the medical device by restraining any movement of the medical device. In addition, the medical device may conform to the interior surface(s) of the sabots.

The exterior surface of the medical device or the medical device itself may be shaped by expanding the medical device against the interior surface(s) of the sabots. Interior surfaces of the sabots can be used for in-package shaping and/or forming of the

exterior surface and/or shape of the medical device. For example, the shape of the medical device can be created by expanding the medical device against the interior surface(s) of the sabots. Alternatively or additionally, surface textures may be imparted on the medical device by expanding the medical device against the interior surface(s) of the sabots. Thus, forming of the medical device ("in-package" forming) may be accomplished through expanding the medical device against interior surface(s) of the sabot(s).

The expansive forces of the medical device can be related to recovery of a shape memory material in the medical device (e.g., shape memory polymer, shape memory alloy) and/or to elastic recoil of any material in the medical device due to deformation of that material while contained inside the package. In one embodiment, the medical device is reduced along one dimension in order to fit the medical device within the package. The medical device may then be allowed to partially expand, or may be activated to expand. Partial expansion may relieve a part of the stored strain in the medical device while it is in the package. The medical device may continue to have some stored strain which causes an expansive force to develop. The expansive force could be generated by recovery of a shape memory material which does not result in shape change (e.g., stored strain which can be recovered, but is not recovered due to the constraint). Any expansive force, no matter what its genesis, can be used for the in-package forming operations which are described further above.

Recovery of a shape memory material can be induced actively or passively. For example, active inducing of recovery may include intentional activation (e.g., heating, radiation) of the material. The recovery may be induced passively, through storage in an environment which induces recovery and/or subjecting the shape memory material to an environment which activates the material. For example, the storage and/or transportation of shape memory materials (e.g., included in medical devices) may passively induce recovery of the shape memory material through subjecting the shape memory material to temperatures which activate the shape memory material. As described herein, the activation of a shape memory material with an stored strain induces recovery of that material. Recovery of the material may include shape change, the development of force against a constraint, or both.

Fig. 1B shows a sabot 102 with a detail of an inner surface 108 of the sabot. In the embodiment shown, an interior surface 108 of the sabot defines part of an interface with the medical device with circular ridges, a blunt upper end, and a pointed lower end. The interior surface 108 shown creates with other interior surfaces of other sabots, an interior

cavity of the package. The cavity may serve to enclose the medical device and/or provide a restraint against expansion of the medical device. As described above, the cavity may be used for in-package forming operations on the medical device. For example, the cavity may define impressions (e.g., negatives of shapes, imprints of shapes) of the in-package forming desired for the medical device. The shape defined by the cavity may be an impression or negative of the shape of the final shape of the medical device after intended in-package forming, as described above.

With the sabots in an assembled configuration, the cavity may define the negative of the shape (e.g., impression) of the entire medical device, or only a part of the medical device. For example, as described further herein, portions of the medical device may not be expected to expand and/or intended to be constrained by the package.

As shown, there are internal flat surfaces 110 of the sabot which are meant to mate with other sabots of the package. In addition, in the embodiment shown, there are mating elements 112 designed to engage other mating elements on the other sabots of the package. In one embodiment, the interior surfaces 108 of the sabots of a package define an entire complete contiguous interior surface of a medical device. In another embodiment, the interior surfaces 108 of the sabots of a package define a partial surface of a medical device. For example, sabots of a package may define interior surfaces which engage surfaces of a medical device which are expected to expand and/or which are desired to be constrained.

In one embodiment, sabots may be linked, hinged, bonded or otherwise attached to each other to form a single intermediate member. For example, the single intermediate member may be able to be opened, unrolled or otherwise configured in a different configuration from the configuration which fits within the constraining member. In another embodiment, a plurality of intermediate members may each be a separate sabot. There are multiple embodiments using combinations of intermediate members, such as using separated sabots, attached sabots, partially attached sabots, and/or sabots with attachments which are destroyed when opening the sabots from an assembled configuration (e.g., with a constraining member) into another configuration.

For example, a medical device may be designed to expand along one axis in one direction or through the movement of a particular surface of a medical device. In such a medical device, the expansion of the medical device along that axis may be advantageously controlled through coupling of that surface of the medical device with an interior surface 108 of a sabot, and other sabots, coupling with other surfaces of the medical device, may not be necessary or required in order to limit expansion of the medical device.

The sabots of a package may define an exterior surface 114 which may be contiguous, such as the exterior surface of the constraining member as shown in Fig. 1A (e.g., a cylinder). In another embodiment, the exterior surface defined by the collective exterior surfaces 114 of sabots of the package may be a partial surface, or otherwise not a
5 contiguous, smooth, or standard shape, such as a circle, cylinder, or rectangle. For example, the sabots may define an exterior surface which is star shaped and/or ribbed.

An exterior surface 114 defined by the sabots may be tailored to control the exterior surface area of the sabots which contacts the constraining member. For example, an exterior surface with a star-shaped and/or ribbed cross-section will contact a constraining
10 member with a circular cross-section only at certain points of the circumference of the constraining member. By reducing the surface area of contact between the exterior surfaces 114 of the sabots and the constraining member, the frictional forces therebetween can be controlled. The frictional forces may be controlled depending on the expansive forces transmitted from the medical device through the intermediate members (e.g., sabots) to the
15 constraining member in order to facilitate removal of the constraining member from the sabots.

Fig. 2 shows three sabots 200 with key elements 202. Key elements 202 may be used to define a desired configuration of the sabots 200 when assembled. For example, the key elements may mate with each other in a desired configuration and may prevent or make
20 difficult assembly of the sabots in other configurations. Mating surfaces 204 of the sabots may be smooth or otherwise able to mate with several other mating surfaces of other sabots. The mating surfaces 204 of the sabots may, in some embodiments, allow assembly of the sabots in configurations other than the desired configuration. The key elements can provide mating surfaces 206 and/or interlocking elements thereon which allow the desired
25 configuration and prevent or hinder assembly in other configurations.

The key elements may be disposed outside of the constraining member and may not necessarily be subjected to the expansive forces of the medical device. Therefore, there may be fewer design constraints on the design of the key elements. For example, the key elements may be hinged together, and the hinge bodies need not be contained by the
30 constraining member. As another example, the key elements may be made larger, with respective larger mating surface areas, than the main body of the sabot. Furthermore, the size and shape of the medical device and the cavity created by the sabots do not affect the mating surfaces of the key elements, though they may affect the mating surface of the

sabots. As another example, the key elements may be made from a material different from the material of the sabot.

In some embodiments, as shown by Fig. 2, the cavity may have an opening. For example, the cavity may have an opening where expansion is not expected. Expansion
5 along an axis of a medical device, for example, may not be expected from a medical device which does not have any stored compressed strain along that axis. A medical device may have stored expansive strain along such an axis, and upon relief of the stored strain of the medical device may cause that axis to contract.

The opening may be at an angle to the axis of any expected expansion (e.g., relief of
10 stored compressive strain) so as to minimize the possibility that the opening will allow the medical device to expand and/or deform into the opening. For example, the angle may be about 45 degrees or greater.

Fig. 3A shows another embodiment of an assembled package 300 comprising sabots 302, a constraining member 304, and a compressing member 306. A compressing member
15 306 may be used to transmit part of an expansive force of the medical device to the constraining member 304. Removing the compressing member 306 may reduce expansive forces applied through the sabots to the constraining member 304. For example, removing the compressing member 306 may release some stored strain in the medical device and thereby alleviate some of expansive forces exerted by the medical device. Removing the
20 compressing member 306 may also reduce the frictional forces between the constraining member 304 and the sabots 302. For example, the compressing member 306 may contact the constraining member 304 across a significant portion of the interior area of the constraining member. By removing the compressing member 306, there may be less area of the constraining member that is contacted by material pressed against the constraining
25 member by expansive forces from the medical device.

In an embodiment where the compressing member 306 is removed as part of the opening process, such as the embodiment shown in Figs. 3A-3C, the compressing member may contact the constraining member 304 across a surface area which is only a portion of the interior surface area of the constraining member. The frictional forces between the
30 compressing member 306 and the constraining member 304 may be only a fraction of the frictional forces between the sabots 302 and the constraining member due to a reduced contact surface area.

For example, the contact surface area of the constraining member and the compressing member may be less than the contact surface area of constraining member and

the intermediate member(s). In other words, the constraining member and compressing member contact surface area may be up to about 100% of the constraining member and intermediate member(s) contact surface area in total. In other embodiments, the compressing member may contact up to about 40% of the surface area contacted in total by the intermediate member(s). In some embodiments, the compressing member may contact at a minimum about 10% of the surface area contacted in total by the intermediate member(s).

Other techniques, such as material selection, may be used to adjust the frictional force between the constraining member and the compressing member and/or to adjust the frictional force between the constraining member and the intermediate member(s).

Fig. 3B shows a side view of an assembled package 300 with a compressing member 306 in an inserted position inside the assembled package. The compressing member 306 contacts the constraining member 304 along a smaller portion of the interior area of the constraining member than do the plurality of sabots. Therefore, it is easier to remove the compressing member from the assembled package (of sabots and constraining member) than it is to remove the constraining member from the sabots. However, in the position shown, the compressing member 306 provides added compression between the sabot(s) and the constraining member.

Fig. 3C shows a side view of an assembled package 300 and a removed compressing member 306. After the compressing member 306 is removed from the package 300, the constraining member 304 may be more easily removed from the sabots. Stored strain may be relieved through the act of removing the compressing member and expansive forces from the medical device may be lessened through relief of the stored strain.

The removal of the compressing member 306 can reduce the surface area of contact between the sabots and the constraining member 304, allowing the frictional forces between the sabots and the compressing member to be varied. In some embodiments, removal of the compressing member 306 can allow the sabots to move relative to the constraining member 304 and relieve stored strain in the medical device and/or in the sabot(s). The space 308 left by the removal of the compressing member 306 may allow the sabot(s) to move relative to the constraining member 304.

The space 308 left by the removal of the compressing member 306 may allow the sabot(s) to move relative to other sabot(s). Such movement may allow for stored strain in the medical device and/or in one or more of the sabots to be relieved.

Relieving of stored strain (e.g., through recovery of a shape memory material in the medical device, through elastic recoil of part(s) of the medical device and/or sabot(s)) may reduce forces between one or more of the sabots and the constraining member. Reducing these forces may ease the removal of the constraining member 304 from around the sabots.

5 Fig. 4A shows another embodiment of an assembled package 400 comprising sabots 402 and a constraining member 404, with the package in a heightened compression configuration. The package shows an opening 410 which is situated, as described above, along an axis which does not require constraint of the medical device. For example, in this embodiment, expansive forces of the medical device are directed perpendicularly to the
10 opening 410 and against the sabot(s) 402, the compressing member 406, and the constraining member 404.

 The sabots are contacted by a rotational compressing member 406. Unlike the compressing member shown in Figs. 3A-3C, the rotational compressing member 406 does not need to be removed to release stored strain in the medical device and/or to relieve
15 expansive forces from the medical device. The rotational compressing member 406 may be connected with the constraining member 404, and/or one or more sabot(s) 402. The rotational compressing member 406 may also be separated from both the constraining member and the sabots.

 In the configuration shown, the sabots 402 are in a heightened compression
20 configuration due to the rotational position of the sabots relative to the grove in the rotational compressing member 406. The peak of the sabots, configured as shown, is not aligned with the grove 408 in the compressing member. Instead, the peak of the sabots is aligned with another part of the compressing member. The interface between the peak of the sabots and the rotational compressing member provides for a heightened compression
25 configuration of the package.

 Fig. 4B shows the assembled package 400 in a lessened compression configuration. The package shown has the sabots 402 in a different rotational configuration, comprising a lessened compression between the rotational compressing member 406 and the sabots. The peak of the sabots is rotated into a mating position with the grove 408 of the rotational
30 compressing member 406.

 In other embodiments, a compressing member does not need to have a grove which mates with a peak in the sabots to establish a lessened compression configuration. In one embodiment, for example, a rotational compressing member may have a ridge or peak and the sabots, as assembled, may have a grove into which the ridge or peak mates, thereby

establishing a lessened compression configuration. In another embodiment, a rotational compressing member may have a ridge or peak and the sabots, as assembled, may be shaped so as to provide a gradually increasing radius, thereby establishing a gradually increasing/decreasing compression in a plurality of configurations with different rotational relationships between the sabots and the compressing member.

The rotation of the rotational compressing member, the constraining member and/or the sabots, relative to one another, may be accomplished as described herein through the use of handles, knobs or other rotational devices. In addition, other elements may be used to apply rotational leverage to one or more of the rotational compressing member, the constraining member and/or the sabot(s).

Fig. 5 shows an assembled package 500 comprising sabots 502, a constraining member 504, and a compressing member 506. The compressing member 506 does not need to be removed from the package 500 in order to reduce the compression state of the package, sabot(s) and/or constraining member due to the expansive forces of the medical device. In a heightened compression state, a keystone element 512 is disposed in a grove 508 of the compressing member 506. The keystone element 512 displaces part of the grove 508, thereby compressing the sabot(s) 502 through a decrease in the internal radius of the compressing member 506. The compressing member 506 may decrease its internal radius due to material movement/repositioning of the compressing member due to the keystone's displacement of the grove. By removing the keystone element 512, the compressing member 506 is allowed to expand into the grove and release radial compression on the sabot(s) 502. This reduction in compression may reduce the expansive forces from the medical device, as described further herein.

Fig. 6A shows a package 600 with an elliptical compressing member 602 in a greater compression position. An elliptical compressing member 602 is an embodiment of a compressing member which has a dimension 608 which is greater (e.g., the longer axis of an ellipse) than another dimension 610 (e.g., the shorter axis of an ellipse). With the greater dimension 608 positioned perpendicularly to the constraining member, the configuration of the sabots 606 and the compressing member 602 creates a larger circumferential unit for the constraining member 604 to encompass. When expansive forces of the medical device are transmitted through the sabots 606 and the compressing member 602 to the constraining member 604, the constraining member limits resulting expansion, as described further above.

Fig. 6B shows a package with an elliptical compressing member in a lower compression position. With the elliptical compressing member rotated so that the shorter axis (e.g., smaller dimension) is perpendicular to the surface of the constraining member, the compression caused by the compressing member is lessened. When the compressing member 602 is rotated to a position where the lesser dimension 610 is positioned perpendicularly to the constraining member 604, the configuration of the sabots and the compressing member creates a smaller circumferential unit for the constraining member to encompass. In this configuration, the expansive forces between the constraining member 604 and the sabot(s) 606 and/or the compressing member 602 may be lessened and/or stored strain(s) may be relieved (e.g., from the medical device and/or sabot(s)), also as described further above. As described above, this can ease the removal of the constraining member 604 from configuration of the sabots 606 and the compressing member 602.

Alternatively, the compressing member 602 can be removed, as described further above. Removing the compressing member can further ease removal of the constraining member, also as described further above.

Rotating the elliptical compressing member 602 (e.g., such that a portion of the elliptical cross-section between the longer and shorter axes is perpendicular to the constraining member) can vary the compression/decompression of the sabots and compressing member within the constraining member. The description above of a greater compression state and a lower compression state is meant only to illustrate two states of the compressing member, and many more states are available at intermediate states thereof.

In addition, the compressing member may have a more complex cross-sectional shape than the ellipse shown. For example, the compressing member may have ridges, slopes, and/or discontinuities which can cause a gradual change in force when utilizing one region of the compressing member and a discontinuous change in force when utilizing another region of the compressing member. The compressing member may have a more complex shape along the axis of rotation ("rotational axis") of the compressing member. For example, the compressing member need not have the same cross-section along the entirety of the rotational axis of the compressing member. As described further above, the exterior surface of the sabot(s) may also be shaped to interface with the compressing member in order to cause varying degrees of compression as the sabot(s) and/or the compressing member are rotated relative to each other. Complex shapes of the compressing member and/or the exterior surface of the sabot(s) may be created and/or varied to meet

design considerations such as compression, expansion, in-package forming, and release of the medical device from the package.

Fig. 7A shows a package 700 with a handle 702 attached to an elliptical compressing member 704 in a higher compression position. A handle may be attached to a compressing member to facilitate manipulating the compressing member. Manipulating the compressing member 704 can comprise, as described further above, rotating, adjusting, removing, and/or inserting the compressing member. The forces between the medical device, the sabot(s), the compressing member and the constraining member may make manipulating the compressing member difficult. A handle 702 may provide leverage on the compressing member to allow easier manipulation of the compressing member.

Fig. 7B shows a package 700 with a handle 702 attached to an elliptical compressing member 704 in a lower compression position. Shown also in Fig. 7B are sabots 706 and a constraining member 708, as described in embodiments above.

The handle shown in Fig. 7A and in Fig. 7B is sized to match the size of the package 700 (e.g., the outer size of constraining member 708) as assembled when the compressing member 704 is rotated into a higher compression position. As shown in Fig. 7A, the handle is positioned such that the compressing member 704 is rotated around its rotational axis and the compressing member is in a lower compressions position. In the embodiment shown, the handle 702 is positioned out of line with the rest of the package 700. Such an embodiment may be used to indicate that the compressing member 704 is in a lower compression state. Such an embodiment may be used to ease removal of the compressing member by providing surfaces against which to push/pull the handle from the rest of the package.

As shown in Figs. 7A and 7B, the handle is generally smaller than the rest of the package. In other embodiments, the handle may be sized differently. For example, the handle may be shaped similarly to the rest of the package, but may be bigger than the rest of the package. As another example, the handle may be a different type of shape than the rest of the package.

Fig. 8A shows a removal device 800 for removing a medical device from a package with the housing 802 of the removal device opened. In the embodiment shown, the removal device has a housing 802, a chamber 804, and a handle 806. The housing is shown opened with a package 808 (holding a medical device) in relation thereto. The package 808 fits within the chamber 804, as indicated by the arrow. A handle 806 is provided for manually actuating the package 808 in order to open the package.

The removal device 800 has a base handle 812 which allows an operator (e.g., surgeon, nurse, technician) to hold the removal device while, for example, placing the package 808 containing the medical device into the removal device, and/or operating the handle 806 to open the packaging.

5 In the embodiment shown, the handle 806 is attached to a cylinder 814 with a slot for engaging a part of the constraining member of the package. As indicated by the dashed line 811, a portion of the package (specifically a portion of the constraining member of the package) fits into the cylinder 814 in order to engage the package 808 and the handle 806 and to allow the rotation of the cylinder to open the package. By rotating the cylinder 814,
10 a portion of the constraining member is torn and/or peeled away from the rest of the constraining member. By tearing and/or peeling a part of the constraining member from the rest of the constraining member, the constraining member is partially destroyed and may lose its ability to constrain expansive forces of the medical device transmitted through the intermediate members of the package (e.g., the sabots). This type of opening through
15 tearing/peeling a portion of the constraining member is described further below with respect to Figs. 9A and 9B.

 In another embodiment, the handle may be attached to a knife-type element (not shown) which can cut, score and/or destroy the constraining member while the package is in the chamber. For example, the handle may be attached to a blade which engages the
20 constraining member (e.g., externally contacting the constraining member, fitting between the constraining member and a sabot, pressing into the constraining member in multiple places) and the handle may be slid along a track to open the package. The blade may score the constraining member so that the expansive forces of the medical device rupture the constraining member. The blade may sever a portion of the constraining member allowing
25 the expansive forces to rupture the constraining member. The blade may sever all of the constraining portions of the constraining member, allowing the expansive forces to release unimpeded by the constraining member. The functions of a blade in opening a constraining member are described further below with respect to Figs. 10A and 10B.

 Fig. 8B shows a removal device 800 for removing a medical device from a package
30 with the housing 802 of the removal device closed around a package. The housing 802 of the removal device may hold the package in the chamber while the medical device is removed from the package. A plunger 810 is shown for discharging the medical device from the housing after the package has been opened.

In one embodiment, the handle 806 may be rotated (e.g., in the direction designated by the arrow 807) once the housing 802 is closed in order to destroy a constraining member of the package and allow the medical device to be removed from the package. As described above, the handle 806 may be rotated (in the direction shown by the arrow) in order to tear and/or peel part of the constraining member from the rest of the constraining member.

Also shown is a slot 816 in which the handle rotates and/or slides. In one embodiment, the handle travels along the slot 816 as the handle is rotated. The handle 806 may travel due to the rotation of the cylinder along the length of the package. The handle 806 may travel due to a gear attached to the handle (not shown) which engages with the slot 816. The gear may be provided to ensure a consistent translation of the handle while it is rotated along the length of the package.

In another embodiment, the package travels within the chamber while the handle is rotated. For example, the handle may be rotated and as the portion of the constraining member is torn/peeled from the rest of the constraining member, the package may translate. The package may be translated by the rotation of the cylinder, which may be engaged with a gearing mechanism to ensure that the package translates while the handle is rotated.

In another embodiment, the handle may be slid along the slot 816 in order to open the package. As described above, in some embodiments, the handle 806 may be slid in order to actuate a knife-type element with respect to the package. For example, as described above, the handle 806 may be attached to a blade or other knife-type element. The knife-type element may be actuated against the constraining member by sliding the handle 806 along the slot 816.

Fig. 8C shows an embodiment of a removal device 800 for removing a medical device from a package with a handle 806 for opening the package actuated to a position indicating that the package is opened. In this embodiment, the handle 806 translates down the slot 816 while the package is being opened. The handle 806 may be in the position shown after having been rotated to open the package by peeling/tearing the constraining member. The handle 806 may be in the position shown after being slid along the slot 816 to open the package by cutting, tearing, scoring or otherwise destroying the constraining member, as described above.

After the package has been opened inside the housing, the medical device may be removed from the housing without opening the housing. In the embodiment shown, a plunger 810 is shown in a position to push the medical device out of the housing 802 after

the package 808 has been opened. For example, the plunger 810 can be slid along the chamber 804 to clear the medical device out of the chamber and out of the housing 802.

The plunger 810 may be configured as a rod, as shown. In other embodiments, the plunger 810 may be configured in a different manner, such as with a scooped end for
5 cradling the medical device as it is pushed out. In some embodiments, the plunger may have elements which clear away parts of the package (e.g., sabots, portions of the constraining member) which may surround the medical device after the package is opened.

Fig. 8D shows the medical device 818 outside of the removal device 800 after the medical device has been removed from the package. When the plunger 810 is pushed into
10 the housing 802, the medical device 818 is pushed out of the housing 802. After the package is opened, the medical device may be freed from the package and/or may have parts of the package surrounding the medical device. The plunger 810 may clear the medical device from the parts of the package as the plunger moves the medical device out of the housing. There may be portions of the chamber in the housing 802 adapted to receive
15 these parts of the package as the package is opened and/or as the plunger is pushed into the housing. The plunger 810 may move these parts of the package into the portions of the chamber and hold the parts of the package there while the medical device 818 is pushed out of the housing 802. The medical device 818 may be pushed out of an opening 820 in the housing, as shown.

Fig. 9A shows a detail of a portion 902 of a constraining member 900 adapted to be
20 torn/peeled from the rest of the constraining member. The portion is defined by boundaries 904. The boundaries 904 may be, for example, score marks, ridges, areas of localized work-hardening, dislocations, and/or areas where material has been removed from the constraining member. The boundaries of the portion may be adapted to localize or focus
25 forces (e.g., shearing forces, pulling forces, flexing forces) causing the portion to separate from the rest of the constraining member.

A starting portion 906 may be separated from the constraining member 900. Alternatively, a starting portion 906 may be attached to the constraining member 900, specifically the portion 902 of the constraining member which is to be torn. A rotating
30 opening device 908 may engage the starting portion 906 in a similar fashion to a starting tab of a food can (e.g., a can of sardines) is held and twisted by a rotating opening device. The rotating opening device 908 may be used to tear/peel a portion 902 of constraining member 900 and roll the portion around the opening device.

Fig. 9B shows a detail of a portion 902 of a constraining member 900 being torn/peeled from the rest of the constraining member by a rotating opening device 908. The rotating opening device 908 may be actuated (e.g., rolled) both to impart forces on the portion 900 of the constraining member which tear the portion from the rest of the
5 constraining member and to wind the portion around the opening device. As shown, the portion 902 is partly wound around the opening device 908 and is partly torn /peeled from the constraining member 900.

Fig. 10A shows a detail of a knife-type element 1000 for opening a package through engaging a constraining member. As described above, a constraining member may be
10 opened, destroyed, removed and/or separated by a knife-type element 1000.

The knife-type element may impart forces on a boundary, such as described above, which concentrates forces applied on and near the boundary to facilitate separating of the constraining member along the boundary. The knife-type element may cut the constraining member. The knife-type element may score, weaken, and/or remove material from the
15 constraining member and allow expansive forces of the medical device and/or sabot(s) to separate the constraining member.

In the embodiment shown, the knife-type element 1000 has a concave blade 1002. Surrounding the concave blade 1002 are guide points 1004 which may span the constraining member when the concave blade is engaged with the constraining member. For example,
20 one of the guide points 1004 may be placed between a sabot and the constraining member while another of the guide points 1004 may be placed outside of the constraining member.

Fig. 10B shows a detail of another embodiment of a knife-type element 1006 for opening a package through engaging a constraining member. The knife-type element has a roller 1008 with a sharpened edge which engages the constraining member in a similar
25 fashion to a pipe cutter. The knife-type element 1006 may deform the constraining member, remove material from the constraining member and/or weaken the constraining member. A single pass of the knife-type element 1006 may be sufficient to weaken the constraining member so that the expansive forces of the medical device and/or sabot(s) may separate the constraining member from itself. The knife-type element may require multiple
30 passes to separate the constraining member from itself.

What is claimed is:

1. A package for a medical device containing a shape memory polymer, the package comprising:
 - at least one intermediate member which has an interior surface capable of mating with a portion of the medical device;
 - a constraining member disposed around the at least one intermediate member; and
 - a compressing member disposed between the at least one intermediate member and the constraining member.
2. The package of claim 1, wherein a first contact area between the constraining member and the compressing member comprises between about 10 percent and about 40 percent of a second contact area between the constraining member the at least one intermediate member.
3. The package of claim 1, wherein the compressing member comprises an annular element with a groove.
4. The package of claim 3, wherein at least one of the intermediate members comprises a ridge, and wherein the ridge is at least partially disposed within the groove of the annular element.
5. The package of claim 3, further comprising:
 - a keystone element disposed within the groove of the annular element.
6. The package of claim 5, wherein the groove of the annular element is displaced by the keystone element.
7. The package of claim 1, wherein the at least one intermediate member is a sabot.
8. The package of claim 1, wherein the at least one intermediate member is held in a desired configuration by the constraining member.
9. The package of claim 8, wherein the at least one intermediate member further comprises:
 - a plurality of intermediate members, with a plurality of interior surfaces which define a cavity forming an impression of the medical device when the intermediate members are in the desired configuration.
10. The package of claim 9, wherein the cavity completely encompasses the medical device.

11. The package of claim 9, wherein the cavity encloses a circumference of the medical device.
12. The package of claim 11, wherein the cavity has an opening.
13. The package of claim 12, wherein the opening has an axis which is at an angle to an expected axis of expansion of the medical device.
14. The package of claim 13, wherein the angle is about 45 degrees or greater.
15. The package of claim 9, wherein the each of the plurality of intermediate members comprises a key section which allows the intermediate members to align in the desired configuration and which inhibits the intermediate members from aligning in a configuration different from the desired configuration.
16. The package of claim 15, wherein the each of the key sections is enclosed by the constraining member.
17. The package of claim 16, wherein each of the plurality of intermediate members comprises a mating surface adapted to mate with a neighboring intermediate member of the plurality of intermediate members.
18. The package of claim 17, wherein a guide pin is disposed on at least one mating surface of at least one of the plurality of intermediate members, and wherein the guide pin is disposed to mate with a guide hole of a neighboring intermediate member of the plurality of intermediate members when the plurality of intermediate members is in the desired configuration.
19. A method of packaging a shape memory medical device, the method comprising:
 - packaging a shape memory medical device in a chamber created by interior surfaces of a plurality of sabots;
 - encompassing a circumference of the plurality of sabots with a constraining member;
 - initiating an expansion of the medical device; and
 - limiting the expansion of the medical device via limiting movement of the sabots.
20. The method of claim 19, wherein the expansion is due to an elastic recoil of the shape memory medical device.
21. The method of claim 19, wherein the expansion is due to a recovery of the shape memory medical device.

22. A removal device for removing a medical device from a package, the removal device comprising:

a housing for containing the package in an unopened state, wherein the housing comprises a handle body and a hinged lid body attached to the handle body;

a chamber defined by an interior surface of the handle body and the hinged lid body, the chamber adapted to contain the package in the unopened state;

a cylinder adapted to engage a constraining member of the package, wherein turning about the axis of the cylinder winds a removed portion of the constraining member of around the cylinder; and

an opening shaped to allow the medical device to pass out of the chamber.

23. The removal device of claim 22, further comprising:

a handle attached to the cylinder for rotating the cylinder about the axis of the cylinder.

24. The removal device of claim 22, wherein the housing is adapted to hold the constraining member in a fixed position relative to the housing while the cylinder is rotated.

25. The removal device of claim 24, wherein the cylinder is adapted to translate relative to the housing while the cylinder is rotated.

26. The removal device of claim 22, wherein the housing is adapted to hold the axis of the cylinder in a fixed position relative to the housing while the cylinder is rotated.

27. The removal device of claim 26, wherein the constraining member is adapted to translate relative to the housing while the cylinder is rotated.

28. The removal device of claim 22, further comprising:

an extraction element for removing the medical device from the chamber.

29. The removal device of claim 28, wherein the extraction element comprises:

a plunger for pushing the medical device out of the chamber.

30. A package for a medical device containing a shape memory polymer, the package comprising:

at least one intermediate member which has an interior surface capable of mating with a portion of the medical device; and

a means for constraining the at least one intermediate member, the means for constraining disposed around the at least one intermediate member.

31. The package of claim 30, further comprising:

a means for compressing the medical device disposed between the at least one intermediate member and the means for constraining the medical device.

32. The package of claim 31, wherein the means for compressing the medical device includes a means of varying a compression of the medical device continuously through a range of compressions.
33. The package of claim 31, wherein the means for compressing the medical device may be removed from the package to relieve at least a portion of the compression of the medical device.
34. The package of claim 31, wherein the means for constraining the medical device is a metallic tube, and wherein the means for compressing comprises a plurality of polymer sabots.

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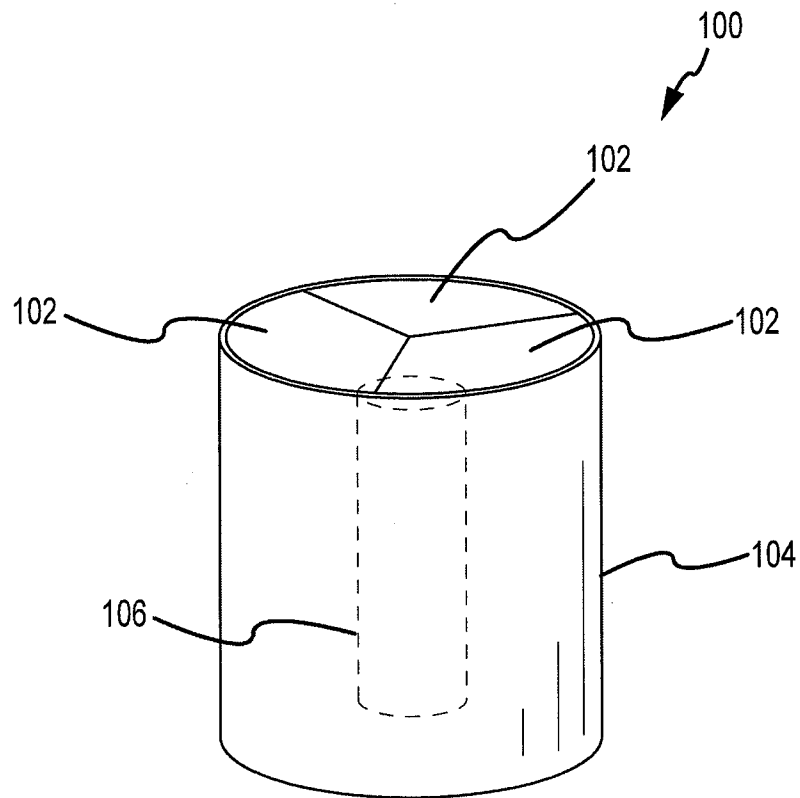


FIG. 1A

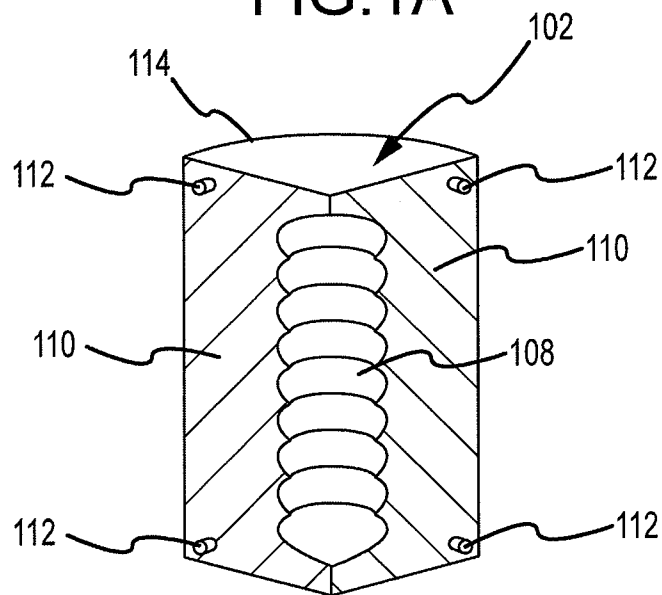


FIG. 1B

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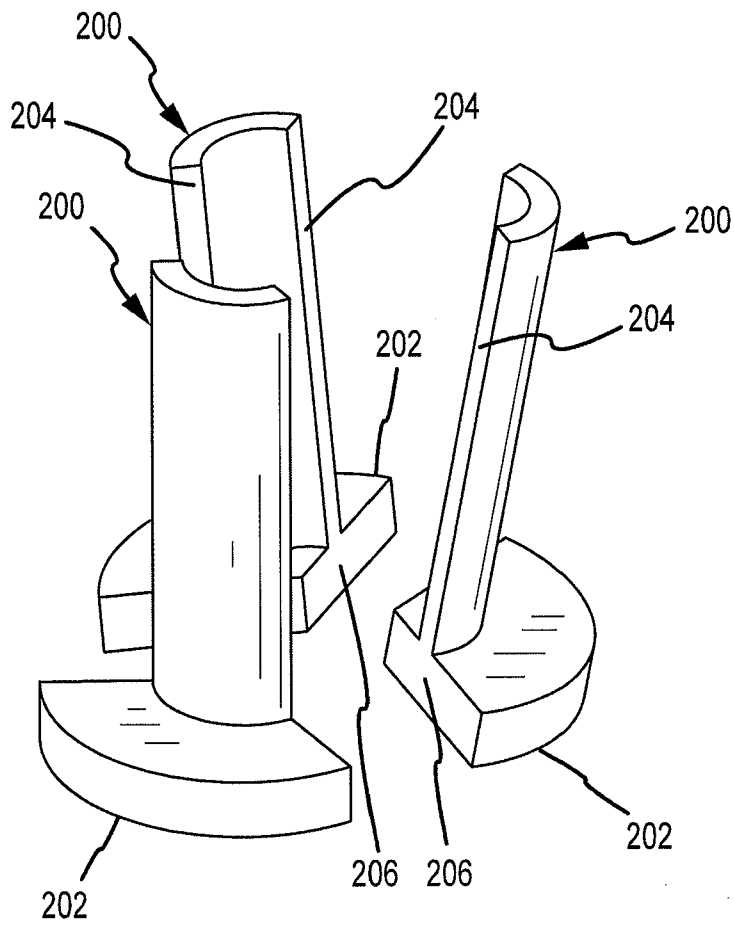


FIG. 2A

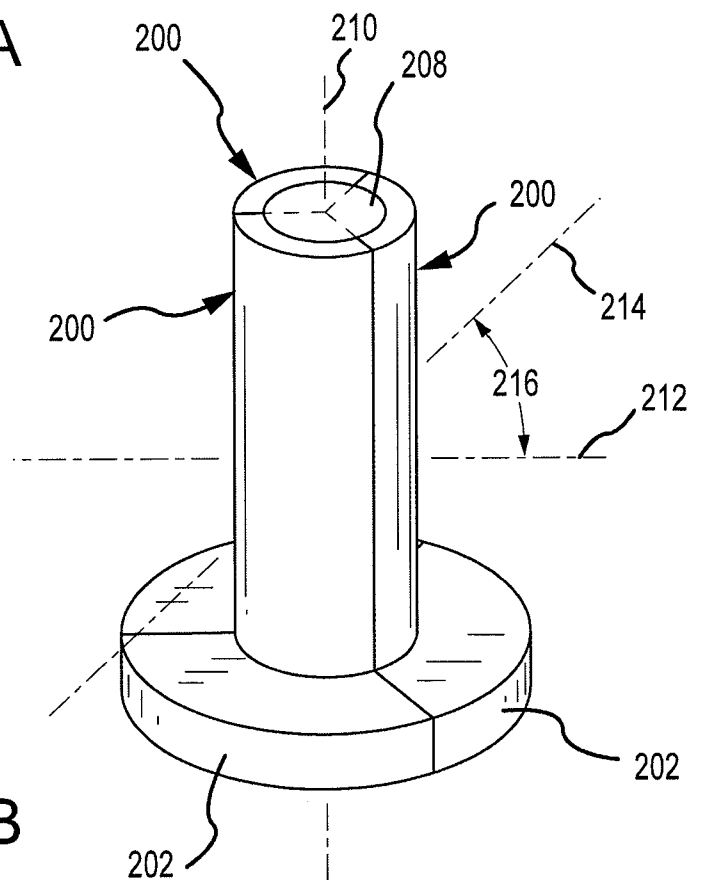


FIG. 2B

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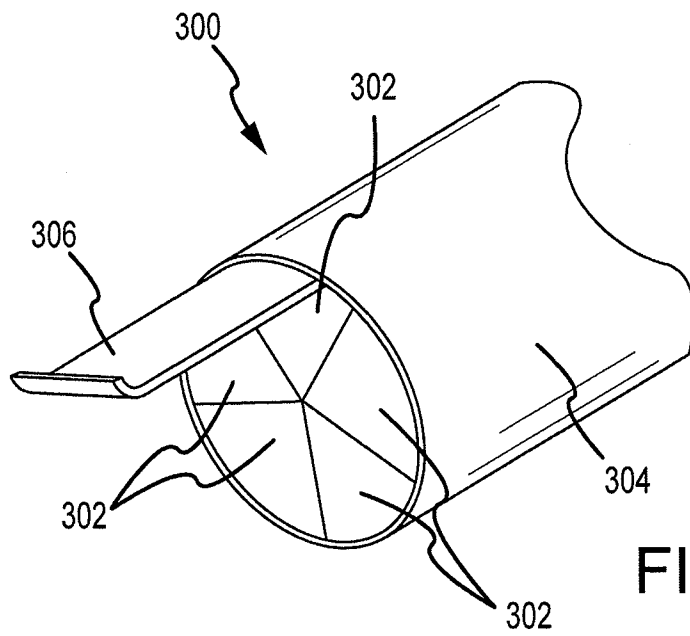


FIG. 3A

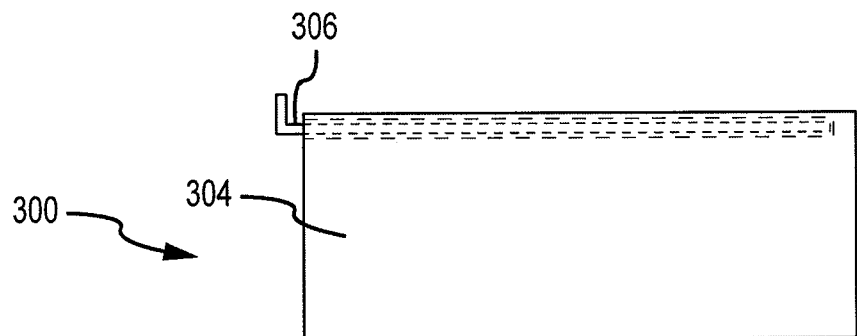


FIG. 3B

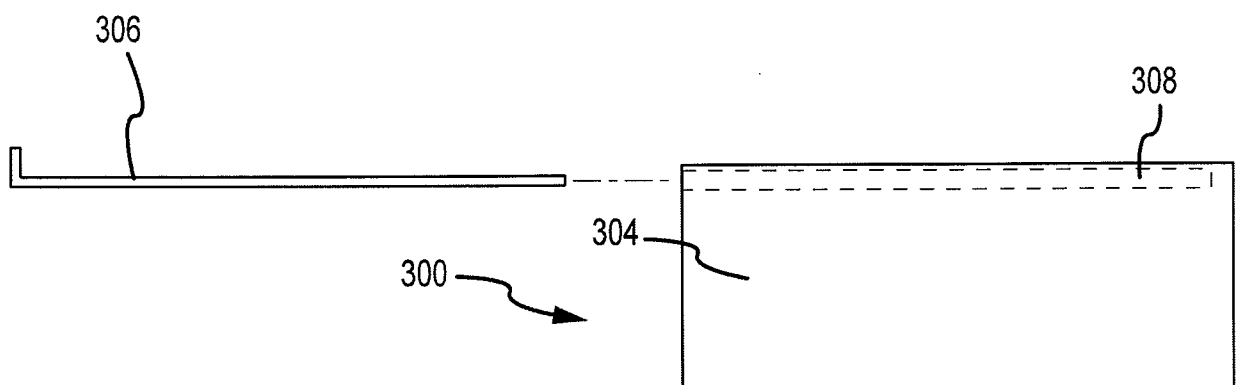


FIG. 3C

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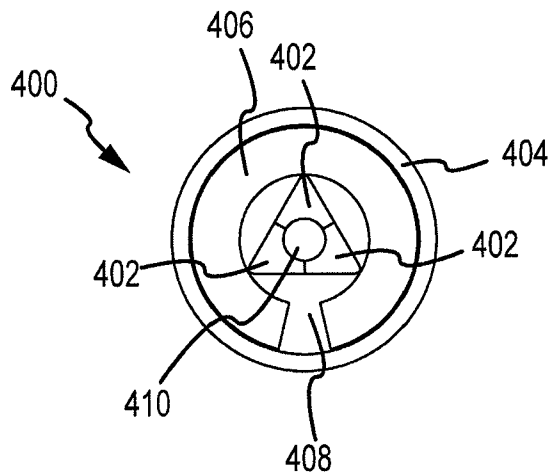


FIG. 4A

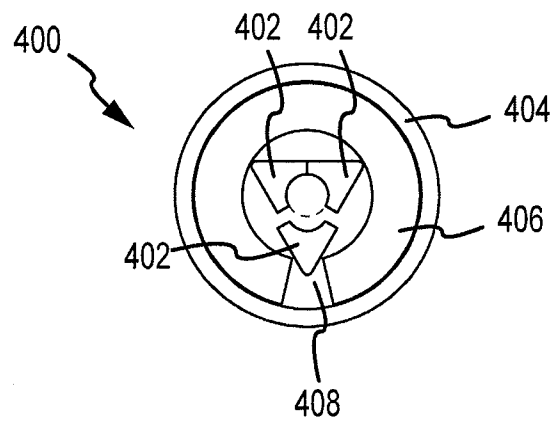


FIG. 4B

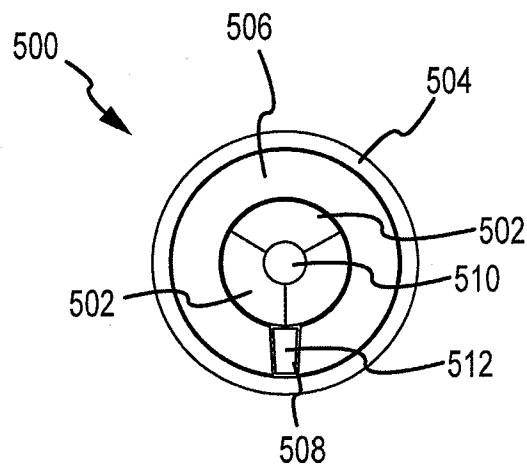


FIG. 5

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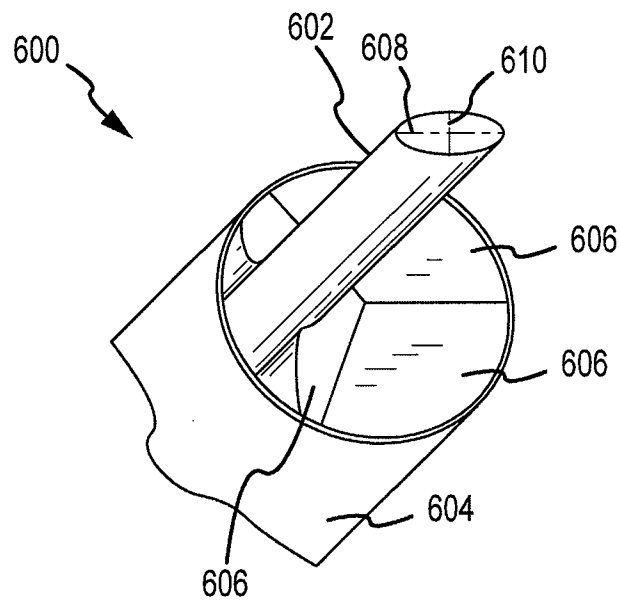


FIG. 6A

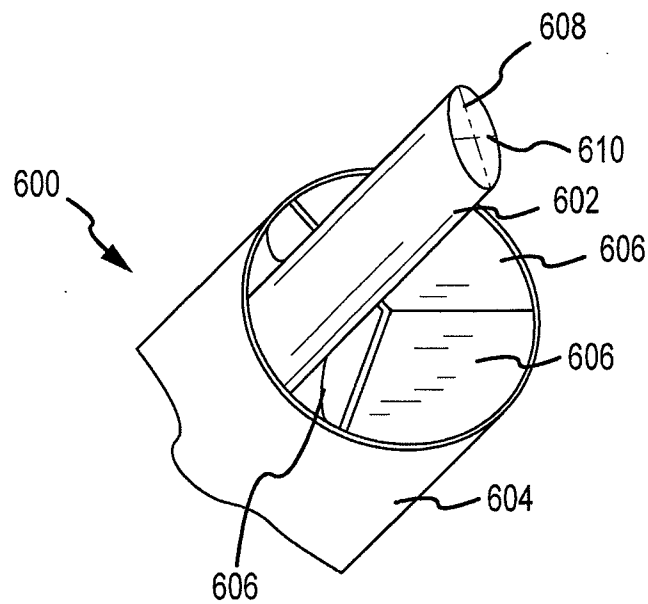


FIG. 6B

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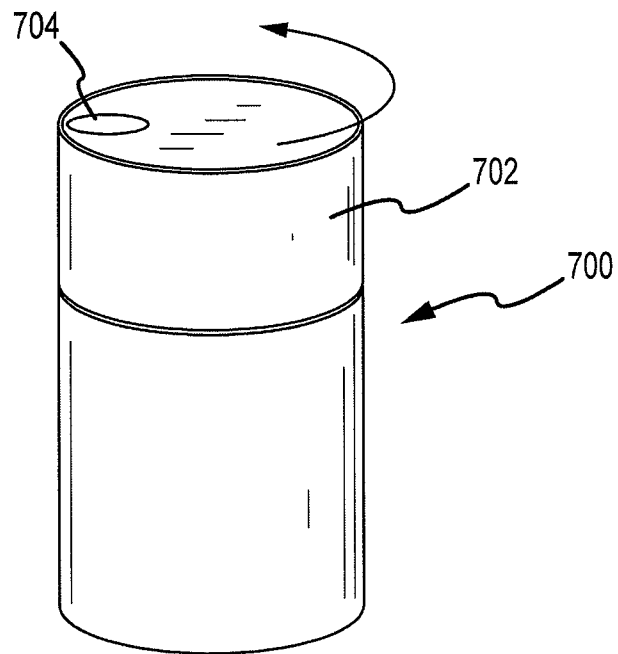


FIG. 7A

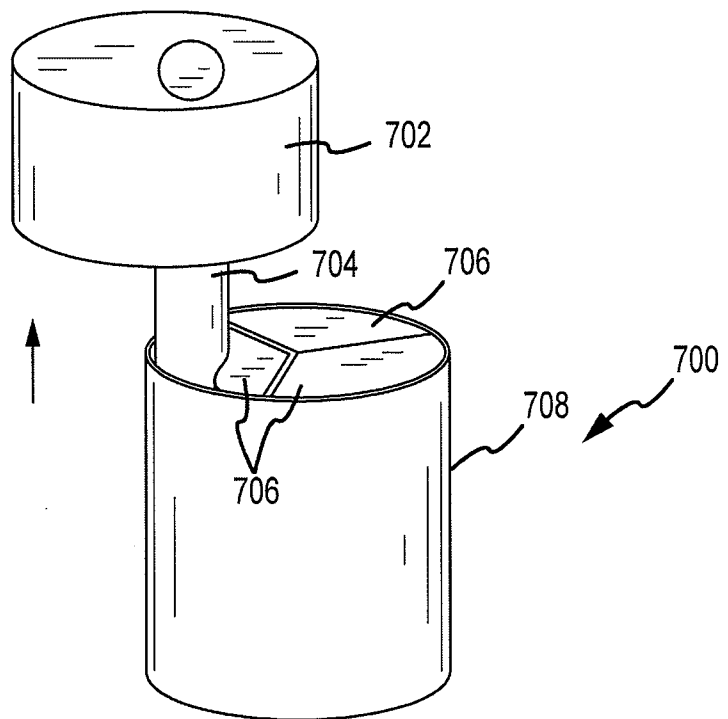


FIG. 7B

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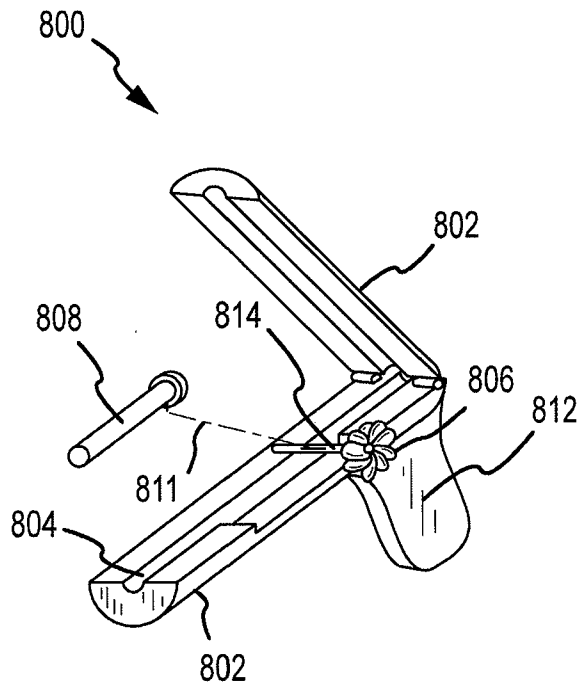


FIG. 8A

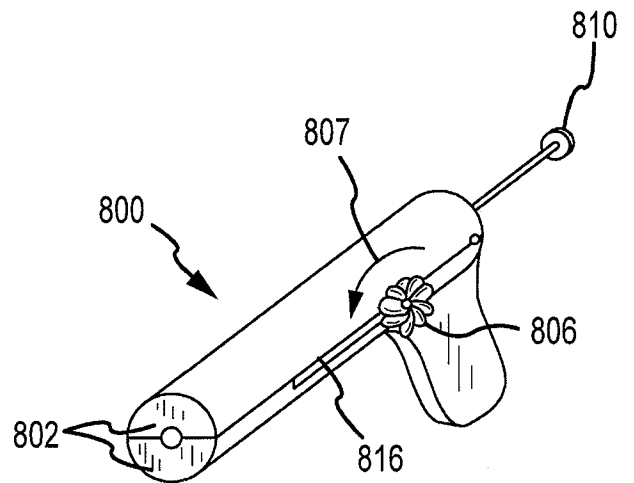


FIG. 8B

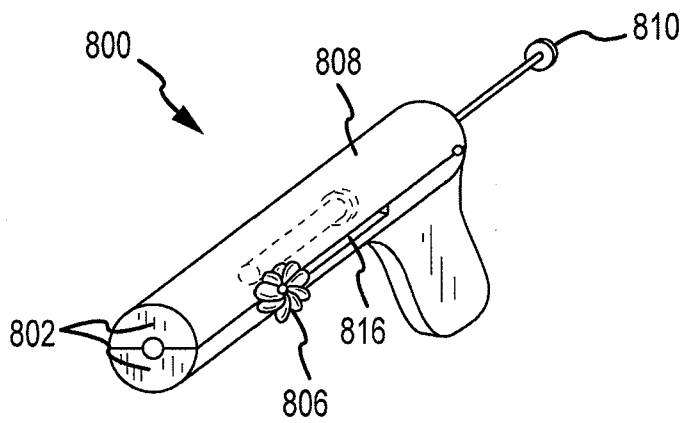


FIG. 8C

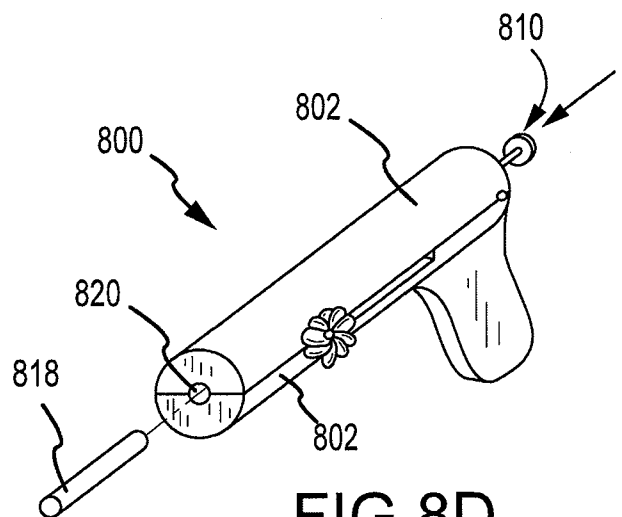


FIG. 8D

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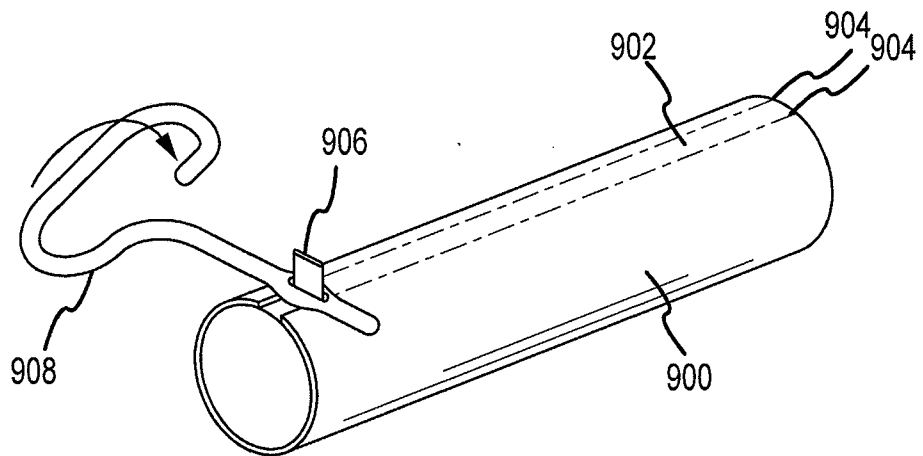


FIG. 9A

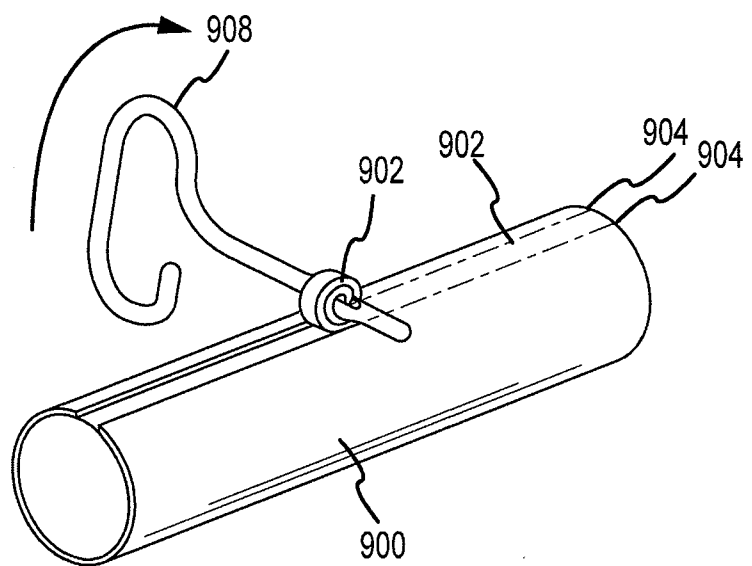


FIG. 9B

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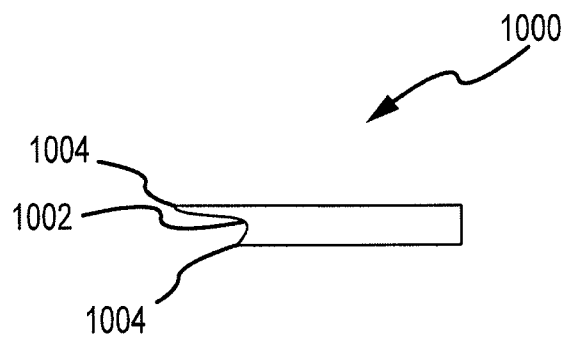


FIG. 10A

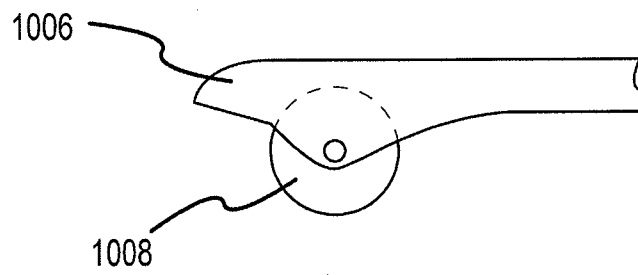


FIG. 10B