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Inventor(s)	Momany; Tracy et al.

PACKAGE FOR MEDICAL DEVICES

Abstract

A package assembly for carrying medical devices is disclosed. The package assembly includes an outer cartridge and an inner cartridge. The inner cartridge receives the outer cartridge of the package assembly. The inner cartridge extends beyond the outer cartridge. A medical device is disposed in the inner cartridge to engage the inner cartridge.

Inventors: Momany; Tracy (Sylvania, OH), Groll; Robert (Oregon, OH), Morse; Shari (Temperance, MI)

Applicant: Guardian Medical USA, LLC (Swanton, OH)

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation-in-part patent application of U.S. patent application Ser. No. 17/758,672, filed on Jul. 12, 2022, which is a National Stage application of International Application No. PCT/US21/13497, filed on Jan. 14, 2021, which claims the benefit of U.S. Provisional Application No. 62/960,767, filed on Jan. 14, 2020. The entire disclosure of each of the above-identified patent applications is hereby incorporated herein by reference.

FIELD

[0002] The present invention relates generally to packages for medical devices, and more particularly to receptacles configured to secure various medical devices of a similar or common geometry within a single receptacle for antiseptic transportation.

BACKGROUND OF THE INVENTION

[0003] As is commonly known, medical devices, such as those used for implanting or using on a patient must be sterile, undamaged, or otherwise compromised before implanting or using on the patient. Particularly, the medical devices are transported from a manufacturer, distributor, medical-related facility, and/or area that may or may not be sterile to a facility or space that is required to be sterile. Therefore, packaging is used to transport the medical devices into a sterile atmosphere.

[0004] However, certain packaging for medical devices can be unstable or unsupportive of the device in transport, wherein the medical device moves around undesireably in the package to cause damage. This is often due to the fact medical devices are designed to be customizable to a patient and the needs of the patient. As such, one type of packaging may not be suitable or accommodating to each and every medical device to deliver the medical device undamaged and sterile. In many instances, one type of packaging is used to accommodate many devices even though they have differing sizes, shapes, and geometry which results in some of the medical devices be unsecure in the package because the devices may move around therein. Alternatively, in other instances, a package may be used for each and every varying type of medical device which can be very costly.

[0005] Additionally, an interest in ergonomic, sterile, and efficient ease of removal of the devices is becoming increasingly more desired. As such a hermetically sealed type package that also allows for the contents therein to be removed and safely passed to sterile zones is desired. Furthermore, a safe and organized storage of the medical devices within the packaging is also desired.

[0006] Therefore it is desirable to have a rigid sterile medical device package that is capable of securing related or similar medical devices having common geometry within the same holder that minimizes cost in producing custom packing.

SUMMARY OF THE INVENTION

[0007] In concordance and agreement with the present invention, a rigid sterile medical device package that is capable of securing related or similar medical devices having common geometry within the same holder that minimizes cost in producing custom packing has surprisingly been discovered.

[0008] In a first embodiment of the present disclosure, a package assembly for carrying medical devices is disclosed. The package assembly includes an outer cartridge and an inner cartridge. The inner cartridge receives the outer cartridge of the package assembly. The inner cartridge extends beyond the outer cartridge. A medical device is disposed in the inner cartridge to engage the inner cartridge.

[0009] In another embodiment of the disclosure, a package assembly for carrying medical devices is disclosed. The assembly includes an outer cartridge and an inner cartridge receiving the outer cartridge. The inner cartridge extends beyond the outer cartridge. A medical device is disposed in the inner cartridge, wherein the medical device expands beyond the inner cartridge.

[0010] In yet another embodiment of the disclosure, a package assembly for carrying medical devices is disclosed. The assembly includes an outer cartridge including a cap and a main body and an inner cartridge receiving the outer cartridge. The inner cartridge extends beyond the outer cartridge. The inner cartridge includes a cap and main body and a medical device is disposed in the inner cartridge, wherein the medical device expands beyond the inner cartridge.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The above-mentioned, and other features and objects of the invention, and the manner of attaining them will become more apparent and the invention itself will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

[0012] FIG. 1 is an exploded perspective view of a package assembly according to the invention;

[0013] FIG. 2 is a cross-sectional front elevation view of the package assembly according to FIG. 1, wherein a medical device is shown therein;

[0014] FIGS. 3-5 illustrate top perspective views of various embodiments of medical devices that can be inserted into the package assembly of FIGS. 1-2;

[0015] FIG. 6 is an exploded cross-sectional perspective view of a package assembly according to another embodiment of the disclosure;

[0016] FIG. 7 is an assembled cross-sectional front elevation view of the package assembly of FIG. 6;

[0017] FIG. 8 is an exploded perspective view of a package assembly according to another embodiment of the disclosure;

[0018] FIG. 9 is a cross-sectional front elevation view of the package assembly of FIG. 8;

[0019] FIG. 10 illustrates a pair of package assemblies according to another embodiment of the disclosure, wherein the pair of package assemblies are shown in a side-by-side position;

[0020] FIG. 11 illustrates the pair of package assemblies of FIG. 10, wherein the pair of package assemblies are shown in a stacked position;

[0021] FIG. 12 illustrates a top plan view of a sleeve for a package assembly according to another embodiment of the present disclosure;

[0022] FIG. 13 illustrates a perspective view of the sleeve receiving a medical device and being inserted into a package assembly according to an embodiment of the disclosure;

[0023] FIG. 14 illustrates a perspective view of a package assembly according to another embodiment of the disclosure;

[0024] FIG. 15 illustrates a cross-sectional front elevation view of the package assembly of FIG. 14;

[0025] FIG. 16 is a front elevation view of the package assembly of FIGS. 14-15; and

[0026] FIG. 17 is a bottom plan view of the package assembly of FIGS. 14-16.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0027] The following detailed description and appended drawings describe and illustrate various exemplary embodiments of the invention. The description and drawings serve to enable one skilled in the art to make, and use the invention, and are not intended to limit the scope of the invention in any manner. With respect to the methods disclosed, the steps presented are exemplary in nature, and thus, the order of the steps is not necessary or critical.

[0028] A "and" and "an" as used herein indicate "at least one" of the item is present; a plurality of such items may be present, when possible. Spatially relative terms, such as "front," "back," "inner," "outer," "bottom," "top," "horizontal," "vertical," "upper," "lower," "side," "above," "below," "beneath," and the like, may be used herein for ease of description to describe one element or

feature's relationship to another element(s) or feature(s) as illustrated in the figures. Spatially relative terms may be intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures.

[0029] As used herein, substantially is defined as “to a considerable degree” or “proximate” or as otherwise understood by one ordinarily skilled in the art. Except where otherwise expressly indicated, all numerical quantities in this description are to be understood as modified by the word “about” and all geometric and spatial descriptors are to be understood as modified by the word “substantially” in describing the broadest scope of the technology. “About” when applied to numerical values indicates that the calculation or the measurement allows some slight imprecision in the value (with some approach to exactness in the value; approximately or reasonably close to the value; nearly). If, for some reason, the imprecision provided by “about” and/or “substantially” is not otherwise understood in the art with this ordinary meaning, then “about” and/or “substantially” as used herein indicates at least variations that may arise from ordinary methods of measuring or using such parameters. Where any conflict or ambiguity may exist between a document incorporated by reference and this detailed description, the present detailed description controls. Although the terms first, second, third, etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms may be only used to distinguish one element, component, region, layer or section from another region, layer or section. Terms such as “first,” “second,” and other numerical terms when used herein do not imply a sequence or order unless clearly indicated by the context. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of the example embodiments.

[0030] The present invention relates to packages for transporting medical devices to a sterile work zone such as an area of an operating room. Examples of medical devices are given throughout the disclosures. For example, medical devices can refer to a screws, implants, and the like all of varying dimensions or geometries. However, it is understood the packages can be used to transport any other device for any other application. Additionally, the application uses the term “family” which is meant to refer to devices employed together on a patient or used simultaneously or within the same operating time or operating room. The term “family” can also refer to varying medical devices of different sizes and shapes that have at least one common geometry the package can accommodate for transporting without customizing a new package.

[0031] FIGS. 1-2 illustrate a package assembly **10** according to an embodiment of the instant disclosure. The package assembly **10** is configured for transporting a medical device **12**, described herein below. The package assembly **10** includes an outer cartridge **14**, an inner cartridge **16**, and the device **12**.

[0032] The outer cartridge **14** includes a cap **18** and a main housing **20** threading engaging each other. The cap **18** of the outer cartridge **14** includes threads **22** disposed on an internal surface thereof. The main housing **20** of the outer cartridge **14** includes threads **24** disposed on an outer surface thereof. The threads **24** of the main housing **20** engage and receive the threads **24** of the cap **18**. The cap **18** and the main housing **20** cooperate with each other to define an inner chamber **26** of the outer cartridge **14**. In the embodiment illustrated, the outer cartridge **14** is substantially cylindrical in shape. However, it is understood the outer cartridge **14** can have any shape as desired such as cubical, spherical, having a polygonal cross-sectional shape, having a ovular cross-sectional shape, pyramidal, or any shape or combination of shapes as desired. An outer cartridge seal **34** configured as an annular resilient seal such as an o-ring, for example, is disposed between a shoulder **36** and an end of the cap **18**. It is understood, the seal **34** can be configured as a metal seal or plastic seal or any other seal as desired.

[0033] The cap **18** of the outer cartridge **14** includes a plurality of grip features **38**. As shown, the grip features **38** are indentations formed in an outer surface of the cap **18**. However, the grip

features **38** can be ridges, a finger grip, or any other grip-type feature as desired.

[0034] The inner cartridge **16** includes a cap **58** with threads **68** formed on an inner surface thereof, [0035] and main body **62** and threads **66** formed on an outer surface thereof. The threads **68** of the cap **58** engage the threads **66** of the main body **62**.

[0036] The main body **62** includes a threaded portion **41** that contains the threads **66** of the internal cartridge **16** of the main body **62** and a receiving portion **42** for receiving the medical device **12**. The receiving portion **42** is a tube and has an inner diameter less than an inner diameter of the threaded portion **41**. The receiving portion **42** is substantially cylindrical. However, other shapes can be employed as desired. The difference in the diameters facilitates a stable disposal of the medical device **12**. An inner cartridge seal **78** configured as an annular resilient seal such as an o-ring, for example, is disposed between a shoulder **80** and an end of the cap **58**. It is understood, the seal **78** can be configured as a metal seal or plastic seal or any other seal as desired.

[0037] An inner surface **44** of the threaded portion **41** of the inner cartridge **16** includes a shoulder **46** for stopping a stabilizer **48** being received through an opening of the threaded portion **41** and extending through the receiving portion **42**. The stabilizer **48** is annular and has a first end **50** for receiving the medical device **12** and a second end **52** for conveying the medical device **12** therethrough into the receiving portion **42** of the inner cartridge **16**. The stabilizer **48** includes an inner aperture **54** extending therethrough with respect to a length thereof. An inner diameter of the stabilizer **48** at the first end **50** is greater than an inner diameter of the **48** stabilizer in an intermediate section **56** thereof. A cross-sectional shape of the stabilizer **48** at the first end has a frustoconical portion **72** configured to receive the medical device **12** such as a head **74** of a screw, wherein the remainder of the inner aperture **54** of the stabilizer **48** is for receiving a stem **76** of elongated part of the medical device **12**. A diameter of the frustoconical portion **72** increases constantly from adjacent the intermediate section **56** to the first end **52** of the stabilizer **48**. As a result, the head **74** of the medical device **12** is stabilized and supported.

[0038] As shown in FIG. 2, the main body **62** of the inner cartridge **16** extends beyond the main housing **20** of the outer cartridge **14**. As shown the threads **66** of the inner cartridge **16** extend beyond the threads **24** of the outer cartridge **14** with respect to a length direction of the outer cartridge **14** in a direction towards the cap **18** of the outer cartridge **14**. The threads **66** of the internal cartridge **16** extending beyond the threads **24** of the outer cartridge **14** is advantageous to grip and receive the inner cartridge **16** in a sterile setting. The stabilizer **48** extends beyond the threaded portion **41** of the inner cartridge **16** towards a cap **58** of the inner cartridge **16**.

[0039] The cap **58** of the inner cartridge **16** includes a plurality of grip features **60**. As shown, the grip features **60** are indentations formed in an outer surface of the cap **58**. However, the grip features **60** can be ridges, a finger grip, or any other grip-type feature as desired. The threaded portions **68** of the cap **58** engage the threads **66** of the main body **62**.

[0040] In application, the inner cartridge **16** is removed from the outer cartridge **14**. The inner cartridge **16** remains sterile. The cap **58** of the inner cartridge **16** is removed in a sterile environment. Because the stabilizer **48** extends outwardly from the inner cartridge **16**, the stabilizer can be easily removed with the medical device **12**.

[0041] FIGS. 3-5 illustrate various types of the medical devices **12**. In the embodiments, each of the medical devices **12** are configured as screws with the head **74** and the stem **76**. However, the medical devices **12** can be any medical devices configured with a head and stem as desired that can be packaged and transported in the package assembly **10**. Each of the medical devices **12** shown have a common geometry being the head **74** and the stem **76**. Therefore, even though a length among the medical devices **12** and a thread design are different, each of the medical devices shown can be interchangeably packaged in the package assembly **10** of FIGS. 1-2. Advantageously, a separate package geometry does not have to be manufactured for each different medical device.

[0042] FIGS. 6-7 illustrate a package assembly **110** according to another embodiment of the instant disclosure. The package assembly **110** of FIGS. 6-7 include features similar to the features of the

package assembly **10** of FIGS. **1-2**. Features of the package assembly **110** similar to the features of the package assembly **10** of FIGS. **1-2** are referenced with the same reference numerals but with a leading one “1” for convenience. The package assembly **110** is similar to the package assembly **10** of FIGS. **1-2**, except the stabilizer **148** is different. The package assembly **110** is configured for medical devices with a tulip, screw, and set screw.

[0043] The stabilizer **148** of FIGS. **6-7** is configured as a cap insert. The stabilizer **148** is cylindrical in shape and includes a closed end **190** and an open end **191**. An aperture **192** extends through the stabilizer **148** inwardly from the open end **191** of the stabilizer **148**. A diameter of the aperture **192** adjacent the open end **191** is larger than a diameter of an inner portion of the stabilizer. The aperture **192** adjacent the open end **191** is configured to receive the medical device **112** such as a set screw. The stabilizer **148** is configured to have an outer contour to substantially fill an inner contour of the cap **158** of the inner cartridge **116**. The open end **191** has a pair of notches **193** formed therein to facilitate removal of the medical device **112** disposed therein.

[0044] To assemble, a first portion of the medical device **112** is received in the inner cartridge **116**. As shown, the inner cartridge **116** has an inner contour for receiving the medical device **112**. The stabilizer **148** receives a second portion of the medical device **112** such as a set screw in the open end **191** thereof. The stabilizer **148** is then positioned to engage the first portion of the medical device **112**. The cap **158** of the inner cartridge **116** is then threaded onto the main body **162** to secure the stabilizer **148** and the medical device **112** therein. The inner cartridge **116** is then secured within the outer cartridge **114**. Once assembled, the package assembly **110** can then be transported to a desired location and disassembled in a sterile environment.

[0045] FIGS. **8-9** show a package assembly **210** according to another embodiment of the disclosure. The package assembly **210** of FIGS. **8-9** include features similar to the features of the package assembly **10**, **110** of FIGS. **1-2** and **6-7**. Features of the package assembly **210** similar to the features of the package assembly **10** of FIGS. **1-2** are referenced with the same reference numerals but with a leading two “2” for convenience. The package assembly **210** is similar to the package assembly **10** of FIGS. **1-2**, except the stabilizer **248** is different. The package assembly **210** is configured for medical devices with a tulip, screw, and set screw. Additionally, the inner cartridge is not employed, wherein a clam shell receptacle **295** is used.

[0046] The stabilizer **248** includes the clam shell receptacle **295** configured to receive the medical device **212** shown in FIGS. **10-11**. The clam shell receptacle **295** includes a first side **296** and a second side **297** with features configured to receive the medical device **212**. The first side **296** and the second side **297** can be substantially mirror images of each other and fold along a pivot portion **298a**. However, it is understood the first side **296** and the second side **297** can be different from each other. The first side **296** and the second side **297** each have indentations **299** to form an inner chamber **299a** for the medical device **212**. The receptacle **295** can receive like ones of the medical devices **212** even if the medical devices **212** have varying lengths and widths. A common geometry of like ones of the medical devices **212** can be received in the receptacle **295**. A tab end **298b** includes means such as a tab, for example, so the first side **296** and the second side **297** can be separated from each other about the pivot portion **198** to remove the medical device **212** therefrom.

[0047] FIGS. **10-11** show an outer package **300** that can be employed to house a medical device **312**. A blow molded housing **302** is used to house the medical device **312**. The housing **302** has an indentation **303** for receiving other ones of the outer package **300** for stacking that have protrusions **304** formed thereon.

[0048] FIGS. **12-13** show a card **400** for receiving the medical device **412**. The card **400** includes a plurality of poppable u-shaped holders **408** for receiving the medical device **412**. As shown, in FIG. **15**, the medical device **412** is coupled to the u-shaped holders **408** and the card **400** is curved around the medical device **412** to hold the card **400** and the medical device **412** securely in the package assembly **410**. The card **400** may also have extensions **407** to permit the card **400** to protrude from either the inner cartridge **416** and/or the outer cartridge **414**. Additionally, the

extensions **407** serve as a grip for grabbing the card **400** should the card **400** remain in a cap coupled to the inner cartridge **416** or outer cartridge **414**.

[0049] FIGS. **14-17** show an outer package **500** that can be employed to house a medical device **512**. A blow molded housing **502** is used to house the medical device **512**. The housing **502** has an indentation **503** for receiving other ones of the outer package **500** for stacking that have a protrusion **504** formed thereon. The outer package **500** of FIGS. **14-17** includes features similar to the features of the outer package **300** of FIGS. **10-11**. Features of the outer package **500** of FIGS. **14-17** similar to the features of the outer package **300** of FIGS. **10-11** are referenced with the same reference numerals but with a leading five "5" for convenience. The outer package **500** is similar to the outer package **300** of FIGS. **10-11**, except features of the housing **502** are different.

[0050] The housing **502** is elongate having a main compartment **505**, a first tapered end **506**, and a second tapered end **507**. The main compartment **505** is interposed between the first tapered end **506** and the second tapered end **507**. The main compartment **505** has a substantially rectangular cross-sectional shape. More particularly, the main compartment **505** has a substantially square cross-sectional shape. The rectangular cross-sectional dimensions, width w and height h , of the main compartment **505** are constant along a length l of the main compartment **505**. The height h and the width w can be substantially equal to each other or different from each other. While the specific cross-sectional shape of the housing **502** has advantages described herein-below, it is understood the main compartment **505** can include other cross-sectional shapes as desired. For example, the main compartment **505** can include a circular, ovular, triangular, polygonal and/or any other cross-sectional shape as desired.

[0051] The protrusion **504** is formed on an outer surface of the main compartment **505** on a first side wall **505a** and an indentation **508** is formed on a second side wall **505b**, opposing the first side wall **505a**, of the outer surface of the main compartment **505**. The protrusion **504** is configured to engage and be received in the indentation **508** of another one of the outer package **500** so multiple ones of the outer package **500** can be stacked upon one another.

[0052] The first tapered end **506** has a diameter less than the height h and the width w of the main compartment **505**. The first tapered end **506** has a transitional region **509** and a cylindrical region **511**. The cylindrical region **511** has a substantially constant diameter along a length thereof and the transitional region **509** converges the main compartment **505** to the cylindrical region **511**, wherein the transitional region **509** maintains a substantially rectangular cross-section shape until an outermost portion of the transitional region **509** with respect to the main compartment **505** becomes cylindrical. The dimensions of the transitional region (the height h and the width w) decrease at a constant rate until substantially equal to the diameter of the cylindrical region **511**.

[0053] The second tapered end **507** is similar to the first tapered end **506** except the second tapered end **507** has threads **513** formed in the outer surface of the cylindrical portion **511** thereof. The threads **513** are configured to receive threads **519** formed on an inner surface of a cap **518**. A shoulder **515** is formed intermediate the transitional region **509** and the cylindrical region of the second tapered end **507**. The shoulder **515** is configured as a stop for the cap **518** and for a seal **516** positioned intermediate the cap **518** and the cylindrical portion **511** of the second tapered end **507** to facilitate an impermeability or hermetical sealing of the outer package **500**.

[0054] The outer package **500** receives the medical device **512**. In the embodiment shown, the outer package **500** receives a receptacle **595**. The receptacle **595** includes a first side **596** and a second side **597** with features configured to receive the medical device **512**. The first side **596** is configured for storing a first part of the medical device **512** and the second side **597** is configured for storing a second part of the medical device **512**. The receptacle **595** includes bulges **599** formed near opposing ends that are positioned to engage the cylindrical portion **511** of the respective ones of the tapered ends **506**, **507** when the receptacle **595** is received within the outer package **500**. A tab end **598** extends lengthwise at opposing ends of the receptacle **595**, so the first side **596** and the second side **597** can be separated from each other to remove the medical device **512** therefrom.

[0055] The shape and features of the outer package **500** are advantageous to facilitate an efficient, quality, and cost-effective forming of the outer package **500** such as by a blow forming process. Although, other forming processes can be contemplated as desired. The outer package **500** stabilizes, supports, and protects the medical device **512** in transport or in storage while maintaining a sterile environment for the medical device **512**.

[0056] From the foregoing description, one ordinarily skilled in the art can easily ascertain the essential characteristics of this invention and, without departing from the spirit and scope thereof, can make various changes and modifications to the invention to adapt it to various usages and conditions.

Claims

1. An outer package for carrying a medical device comprising: a housing for receiving the medical device, the housing having a main compartment, a first tapered end, and a second tapered end, the main compartment is disposed between the first tapered end and the second tapered end; and an opening formed at the second tapered end configured for receiving the medical device.
2. The outer package of claim 1, wherein the housing is formed from a blow molding process.
3. The outer package of claim 1, further comprising a cap coupled to the second tapered end.
4. The outer package of claim 1, wherein the housing is formed from a plastic material.
5. The outer package of claim 1, wherein each of the first tapered end and the second tapered end include a transitional region and a cylindrical region.
6. The outer package of claim 1, wherein the first tapered end and the second tapered end have at least one of a diameter, a height, and a width less than a height and width of the main compartment.
7. The outer package of claim 1, wherein the first tapered end and the second tapered end work cooperatively to support the medical device within the main compartment.
8. The outer package of claim 1, wherein the housing creates a sterile barrier for the medical device.
9. The outer package of claim 1, wherein a protrusion is formed along a length of the main compartment on a first side wall of the main compartment.
10. The outer package of claim 9, wherein an indentation is formed along a length of the main compartment on a second side wall of the main compartment opposite the first side wall of the main compartment.
11. The outer package of claim 1, further comprising a receptacle received in the housing.
12. The outer package of claim 11, wherein the receptacle extends the length of the housing and is configured to receive the medical device therein.
13. The outer package of claim 11, wherein the first tapered end and the second tapered end work cooperatively to support the receptacle within the housing.
14. The outer package of claim 11, wherein the receptacle includes a first side and a second side engaging each other.
15. The outer package of claim 14, wherein the first side contains a first part of the medical device and the second side contains a second part of the medical device.
16. The outer package of claim 11, wherein the receptacle includes a pair of opposing tab ends.
17. The outer package of claim 11, wherein the receptacle includes bulges engaging an inner surface of at least one of the first tapered end and the second tapered end.
18. An outer package for carrying a medical device comprising: a blow formed housing having a tapered end; and a receptacle received in the housing, the receptacle extending from a first end of the housing to the second end of the housing, the receptacle supported in the housing by the tapered end.
19. The outer package of claim 18, wherein the housing is hermetically sealed.

20. The outer package of claim 19, wherein a cap is coupled to an open end of the housing to hermetically seal the medical device within the housing.
