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Fluid transfer device and packaging therefor

Abstract

A fluid transfer system includes a container having a body having a sidewall extending between an open top end and a bottom end along a central axis to define an interior cavity, and at least one protrusion extending from an interior portion of the sidewall into the interior cavity. The system further including a connector configured for receipt within the interior cavity. The connector having a body having a distal end, a proximal end, and a sidewall extending between the distal end and the proximal end and defining a fluid passageway therethrough, and a locking arrangement provided on at least a portion of an inner member of the connector and accessible through at least a portion of an outer member of the connector. The locking arrangement is configured for cooperating with the at least one protrusion to prevent rotation of the inner member relative to the outer member.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION (1) This application is a continuation of U.S. patent application Ser. No. 15/982,114, filed May 17, 2018, which is a continuation of U.S. patent application Ser. No. 14/691,845, filed Apr. 21, 2015 (now U.S. Pat. No. 9,999,570), which claims priority to U.S. Provisional Application Ser. No. 61/982,049, filed Apr. 21, 2014, each of which are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION
Field of the Invention
(1) The present invention relates to a fluid transfer device for a closed transfer of fluid from a medical device to a patient delivery device, such as an IV line or syringe. More specifically, the invention is directed to a fluid transfer device and packaging therefor configured for engaging/disengaging a connection element on the fluid transfer device using the packaging.
Description of Related Art
(2) Healthcare workers, such as pharmacists and nurses, can be subject to acute and long term health risks upon repeated exposure to drugs or solvents which might escape into the air during drug preparation, drug administration, and other similar handling. This problem is particularly serious when cytotoxins, antiviral drugs, antibiotics, and radiopharmaceuticals are concerned. The health risks faced by exposure to these drugs can include the development of cancer, reproductive problems, genetic conditions, and other serious concerns. Other hazardous areas may be sample taking, such as samples concerning virus infections or the like. When performing infusions, it is often necessary to inject a drug or other medical substance into the infusion fluid, inside an infusion bag or other infusion fluid container. This is often done by means of penetrating a septum or other fluid barrier of an injection port on the infusion bag or on the infusion fluid line with a needle of a syringe filled with the medical fluid in question. However, even before this, it may be necessary to transfer the medical fluid from a vial to a syringe and then from the syringe to a secondary container. In each of these steps, staff may be exposed to the medical fluid by means of contamination. Such contamination may be vaporized medical fluid or aerosol in the air. The contaminations may contaminate the staff through their lungs, or by vaporized medical fluid or aerosol in the air which condensates on the skin to thereafter penetrate the skin of the staff. Some medicaments are even known to penetrate protection gloves and thereby contaminate the staff.
(3) Exposure to contaminations like this may, on a long term basis, give rise to alarmingly high concentrations of medicaments in the blood or the human body of the staff as described above. It has been understood that, due to the many transferring steps between containers e.g., vials, syringes, infusion systems, etc., the risk for contamination during the actual insertion and retraction of a needle from the container, e.g., a vial, needs to be contained. Closed system transfer devices (CSTDs) have been developed to ensure that the medicament is contained in the transfer device

during transfer of the medicament.
(4) Generally, a CSTD includes an adapter for connection to a syringe and an adapter for connection to a vial, a second syringe, or a conduit providing fluid access to the patient's circulatory system. According to one arrangement, the healthcare practitioner may reconstitute a powdered or lyophilized compound with saline or some other reconstitution medium by attaching the syringe to the vial via connection of the respective adapters, reconstituting the drug, aspirating the compound into the syringe, disconnecting the adapters, and then attaching the syringe to the fluid conduit through the respective adapters to a patient delivery device, such as an IV line or syringe for administration to the patient.
(5) One type of an adapter that can be used in a CSTD has a first connector having a male or female luer-lock element that is arranged to be joined with a corresponding female or male luer-lock element of a second connector component. According to one aspect, the second connector component can be a patient delivery device, such as an IV line or a syringe. The luer-lock element can, thus, be screwed into and unscrewed from the corresponding luer-lock element. It is desirable to prevent an accidental or inadvertent unscrewing of the components, which could lead to the disconnection of the fluid passage. Such disconnection may entail a serious contamination risk for a patient and/or any other person in the vicinity of the disconnected medical connector. The issue of safety in administration of hazardous medical compounds is one that has been identified as being of critical importance by professional organizations and government agencies alike.
(6) It is, therefore, desirable to provide an adapter for enabling fluid transfer between the first connector and the second connector by facilitating a positive connection of the connectors and avoiding inadvertent or accidental disconnection of the connectors.

SUMMARY OF THE INVENTION

(7) According to one aspect, a fluid transfer system may include a container and a connector. The container may include a tubular body having a sidewall extending between an open top end and a bottom end along a central axis to define an interior cavity. At least one protrusion may be aligned with the central axis and extend from an interior portion of the sidewall into the interior cavity. The connector may be configured for being received within the interior cavity of the container. The connector may include a body having a distal end, a proximal end, and a generally cylindrical sidewall extending between the distal end and the proximal end and defining a fluid passageway therethrough. An inner member may be provided at one of the distal end and the proximal end of the body, such that the inner member is configured to cooperate with a patient delivery device to provide fluid communication between the body and the patient delivery device. Additionally, an outer member may surround at least a portion of the inner member, such that the inner member is configured to rotate freely relative to the outer member. A locking arrangement may be provided on at least a portion of the inner member and be accessible through at least a portion of the outer member. The locking arrangement may be configured for cooperating with the at least one protrusion to prevent rotation of the inner member relative to the outer member.
(8) The locking arrangement may be configured to engage the at least one protrusion to prevent rotation of the inner member relative to the outer member upon an application of a compressive force on the container.
(9) In accordance with another aspect, the at least one protrusion may include a pair of protrusions oriented opposite from each other around a circumference of the container. The container may further include a pair of tabs extending radially outward from an outer portion of the sidewall opposite the protrusions. The protrusions may be configured to deflect radially inward in response to the compressive force directed to the tabs. The sidewall of the container may be inclined relative to the central axis such that the sidewall narrows radially inward from the open top end to the closed bottom end. The at least one protrusion may be substantially parallel to the central axis of the container.
(10) In accordance with a further aspect, the connector may include at least one window recessed

within the body of the connector in a longitudinal direction of the connector. The at least one window may be configured to receive the at least one protrusion of the container when the connector is inserted into the interior cavity to prevent rotation of the connector relative to the container. Each window may extend through the sidewall of the connector such that, when deflected by the compressive force, the at least one protrusion engages the locking mechanism to prevent rotation of the inner member relative to the outer member of the connector. The locking arrangement may include at least one tooth extending from an engagement surface of the locking arrangement. The engagement surface of the locking arrangement may be engaged by the at least one protrusion upon the application of the compressive force. The inner member may include a luer-lock fitting.

(11) In accordance with yet another aspect, a container may be configured for engaging/disengaging a connector with a patient delivery device. The container may include a tubular body having a sidewall extending between an open top end and a bottom end along a central axis to define an interior cavity configured for receiving the connector therein. At least one protrusion may be aligned with the central axis and extend from an interior portion of the sidewall into the interior cavity. The at least one protrusion may be configured for aligning the connector and preventing rotation of the connector relative to the container. At least one tab may extend radially outward from an outer portion of the sidewall opposite the at least one protrusion. The at least one protrusion may be configured to deflect radially inward in response to a compressive force directed to the tab and engage a locking arrangement of the connector. The at least one protrusion may include a pair of protrusions oriented opposite from each other around a circumference of the container. The sidewall of the container may be inclined relative to the central axis such that the sidewall narrows radially inward from the open top end to the closed bottom end. The at least one protrusion may be substantially parallel to the central axis of the container.

(12) In another aspect, a connection device may be configured for engaging/disengaging a connector with a patient delivery device. The connection device may have a flexible body having an arcuate shape, at least one tab provided on one end of the body, and an engagement structure provided on the at least one tab. The engagement structure may be configured for engaging a locking arrangement on the connector to prevent rotation of an inner member of the connector relative to an outer member of the connector upon the application of a compressive force on the at least one tab. The at least one tab may further include a finger engagement surface. The at least one tab may be connected to a flexible joint.

(13) These and other features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and the claims, the singular form of “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) FIG. **1**A is a perspective view of a container and a connector in accordance with an aspect of the present invention.

(2) FIG. **1**B is a perspective view of a container shown with a cap removed from the container.

(3) FIG. **1**C is a side view of the container of FIG. **1**B.

(4) FIG. **1**D is a top view of the container of FIG. **1**B.
(5) FIG. **2**A is front view of the container of FIG. **1**B shown with the connector removed from the container.
(6) FIG. **2**B is a side view of the container of FIG. **2**A.
(7) FIG. **2**C is a top view of the container of FIG. **2**A.
(8) FIG. **3**A is perspective view of the connector of FIG. **1**A shown without the container.
(9) FIG. **3**B is a side view of the connector of FIG. **3**A.
(10) FIG. **3**C is a cross-sectional view of the connector of FIG. **3**A.
(11) FIG. **3**D is a perspective view of an inner member of the connector of FIG. **3**A.
(12) FIG. **4**A is a perspective view of the container of FIG. **2**A shown in an initial state prior to the application of a radially-directed force.
(13) FIG. **4**B is a perspective view of the container of FIG. **4**A in a state after the application of the radially-directed force.
(14) FIG. **4**C is a top view of the container of FIG. **4**A.
(15) FIG. **4**D is a top view of the container of FIG. **4**B.
(16) FIG. **5** is a cross-sectional view of an engagement region between a container and a connector in accordance with one aspect of the present invention.
(17) FIG. **6**A is a perspective view of a connector with a connection device in accordance with an aspect of the present invention.
(18) FIG. **6**B is a detailed perspective view of the connector with the connection device of FIG. **6**A.
(19) FIG. **6**C is a perspective view of the connection device of FIG. **6**A.

DESCRIPTION OF THE INVENTION

(20) The illustrations generally show preferred and non-limiting aspects of the systems and methods of the present disclosure. While the descriptions present various aspects of the devices, it should not be interpreted in any way as limiting the disclosure. Furthermore, modifications, concepts, and applications of the disclosure's aspects are to be interpreted by those skilled in the art as being encompassed by, but not limited to, the illustrations and descriptions herein.
(21) Further, for purposes of the description hereinafter, the terms “end”, “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives thereof shall relate to the disclosure as it is oriented in the drawing figures. The term “proximal” refers to the direction toward the center or central region of the device. The term “distal” refers to the outward direction extending away from the central region of the device. However, it is to be understood that the disclosure may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary aspects of the disclosure. Hence, specific dimensions and other physical characteristics related to the aspects disclosed herein are not to be considered as limiting. For the purpose of facilitating understanding of the disclosure, the accompanying drawings and description illustrate preferred aspects thereof, from which the disclosure, various aspects of its structures, construction and method of operation, and many advantages may be understood and appreciated.
(22) With reference to FIGS. **1**A-**1**D, a container, generally indicated as **10**, is shown in accordance with one aspect of the invention. The container **10** is generally configured as a vessel capable of receiving and housing a medical connector, generally indicated as **12**, which can be used as part of a CSTD. The connector **12** is desirably disposed entirely within an interior cavity **14** (shown in FIG. **1**B) of the container **10**. The container **10** and the connector **12** have correspondingly shaped features to facilitate the insertion and removal of the connector **12** into and from the container **10**, as will be described in greater detail hereinafter.
(23) A cap **16** (shown in FIG. **1**A) is provided to enclose the interior cavity **14** of the container **10**. The cap **16** may be in the form of a membrane that provides a seal with the container to prevent contaminants from entering the interior cavity **14**. Desirably, the cap **16** is removable from the

container **10** such that the interior cavity **14** may be accessed once the cap **16** is removed. The cap **16** and the container **10** may be separate components or formed together as a combined structure. A security feature (not shown) may be provided on the cap **16** or the container **10** to indicate an attempt to remove the cap **16** and access the interior cavity **14**. Optionally, the cap **16**, once removed, can be replaced on the container **10** to reclose the interior cavity **14**. In one aspect, the cap **16** may be connected to the container **10** by a connection element (not shown). The cap **16** has a tab **18** configured for being gripped by a user's fingers to facilitate removal of the cap **16**.

(24) With reference to FIGS. **2**A-**2**B, the container **10** is a generally tubular body having a sidewall **20** defining an open top end **22** and a closed bottom end **24**. The sidewall **20** extends continuously between the open top end **22** and the closed bottom end **24** along a central axis **26** to define the interior cavity **14**. The sidewall **20** may be inclined relative to the central axis **26** such that the container **10** has a substantially conical shape that narrows radially inward from the open top end **22** to the closed bottom end **24**. Alternatively, the sidewall is substantially parallel relative to the central axis **26** such that the container **10** has a substantially cylindrical shape.

(25) The container **10** is sealed at the top end **22** by the cap **16**. A lip **28** extends radially outward from the open top end **22** relative to the central axis **26**. The lip **28** provides an interface for the engagement of the cap **16** with the container **10**. The closed bottom end **24** may have a substantially flattened shape to enable the container **10** to be supported when the closed bottom end **24** is placed on a level surface. Alternatively, the closed bottom end **24** may have a rounded or arcuate shape, or a shape configured to correspond to a bottom end of the connector **12**. The container **10** may be constructed from any known material, such as a molded, injected, or thermo-formed plastic material. Desirably, the container **10** is constructed from a material that provides flexibility of the sidewall **20** in at least the radial direction with respect to the central axis **26**. In particular, the container **10** is desirably constructed from a material that allows the cross-sectional shape of the container **10** to change with an application of a radially-directed force, as will be described in greater detail hereinafter.

(26) With reference to FIGS. **2**A-**2**C, the container **10** has a pair of tabs **30** on an outer portion of the sidewall **20**. The tabs **30** extend radially outward from the sidewall **20** relative to the central axis **26**. In one aspect, each tab **30** may be in the form of a substantially cylindrical projection that extends radially outward in a direction substantially perpendicular to the central axis **26**. As shown in FIGS. **2**A and **2**C, the tabs **30** may be oriented 180 degrees apart around a circumference of the container **10**. As will be described hereinafter, the tabs **30** define a gripping surface by which the container **10** may be gripped. The container **10** is configured to deflect radially inward in response to a radially-directed force imparted on the tabs **30**. The tabs **30** may be hollow, such that the sidewall **20** has a uniform thickness throughout the longitudinal length of the container **10**. Alternatively, the tabs **30** may be solid, such that the sidewall **20** has an increased thickness in the region of the tabs **30**.

(27) With specific reference to FIG. **2**B, the container **10** further includes a recess **32** that is configured for receiving an activation tab of the connector **12**, as will be described hereinafter. The recess **32** extends radially outward relative to the central axis **26**. The recess **32** also extends along at least a portion of the longitudinal length of the container **10**. The recess **32** is shaped such that the sidewall **20** bulges radially outward in the area of the recess **32**. In addition to accommodating the activation tab of the connector **12**, the recess **32** also orients the connector **12** such that it can be received in the interior cavity **14** in one direction only. In this manner, the connector **12** is aligned with the tabs **30** and the recess **32**. Other features of the container **10** or the connector **12** may be used to align the connector **12** within the interior cavity **14** of the container **10**.

(28) With specific reference to FIG. **2**A, a pair of longitudinal protrusions **34** extend radially inward from the sidewall **20** inside the interior cavity **14**. The protrusions **34** extend in a direction substantially parallel to the central axis **26**. In certain aspects, the protrusions **34** may be angled relative to the central axis **26**. The protrusions **34** may have any desired shape, including, but not

limited to, square, rectangular, rounded, etc. In one aspect, the protrusions **34** extend from a region of the inner sidewall **20** proximate to the closed bottom end **24** to an area of the inner sidewall **20** opposite the tabs **30**. In an aspect where the sidewall **20** tapers outward from the closed bottom end **24** to the open top end **22**, such as shown in FIG. **2**A, the protrusions **34** may have a first surface that is parallel and coextensive with the tapering sidewall **20** and a second surface that is parallel to the central axis **26** and offset, at least in part, from the sidewall **20**. In an alternative aspect where the sidewall **20** is parallel with the central axis **26**, the protrusions **34** may have a first surface that is parallel and coextensive with the sidewall **20** and a second surface that is parallel and offset from the sidewall **20**. As shown in FIGS. **2**A and **2**C, the protrusions **34** may be oriented 180 degrees apart around a circumference of the container **10** such that each protrusion **34** is aligned with the corresponding tab **30**. For example, the longitudinal midpoint of each protrusion **34** may be aligned with an axis extending through the center of each tab **30**. As will be described hereinafter, the protrusions **34** define an alignment feature for aligning the connector **12** within the interior cavity **14** of the container **10**. In addition, the protrusions **34** interact with a corresponding slot on the connector **12** to prevent a rotation of the connector **12** within the container **10**. As will be described in greater detail hereinafter, the protrusions **34** are configured to deflect radially inward in response to a radially-directed force imparted on the tabs **30**. While FIGS. **2**A-**2**C illustrate a pair of protrusions **34** separated equally about the circumference of the container **10**, it is to be appreciated that more than two protrusions **34** may be provided with equal or unequal separation about the circumference of the container **10**. However, at least one protrusion **34** is provided on an inner sidewall **20** opposite a single tab **30**.

(29) With reference to FIGS. **3**A-**3**B, the connector **12** is an assembly of components adapted to create a tamper-proof connection interface between the connector **12** and a medical device or component, including, but not limited to, a vial, fluid bag, syringe, or patient fluid line. The connector **12** is configured to prevent accidental or inadvertent disconnection of the connector **12** and the medical device or component, which could compromise the integrity of the CSTD. The connector **12** is desirably disposed entirely within the interior cavity **14** (shown in FIG. **1**B) of the container **10**. The container **10** and the connector **12** have correspondingly shaped features to facilitate the insertion and removal of the connector **12** into and from the container **10**. The connector **12** has a body **36**, having a distal end **38**, a proximal end **40**, and a generally cylindrical sidewall **42** extending between the distal end **38** and the proximal end **40** and defining a fluid passageway **44** therethrough (shown in FIG. **3**A). An activation tab **72** is provided on the body **36** for connecting and/or disconnecting the connector **12** from a medical device or component. The activation tab **72** extends radially outward from the sidewall **42**. Desirably, the activation tab **72** is shaped to be received within a recess **32** provided on the container **10**, as shown in FIG. **1**C. Other features of the connector **12** may be used to align the connector **12** within the container **10** such that the container **10** is aligned relative to the protrusions **34**.

(30) With continuing reference to FIGS. **3**A-**3**B, the connector **12** includes an inner member **46** located at the proximal end **40** of the body **36**. The inner member **46** provides a connection interface with a patient delivery device **48**, such as a syringe or an IV line (shown in FIG. **3**B). It can be appreciated that depending upon the orientation of the connector **12** with respect to the patient delivery device **48**, the connection interface can be considered to be located at the distal end **38** of the body **36**. The inner member **46** is configured to cooperate with the patient delivery device **48** to provide fluid communication via the fluid passageway **44** between the connector **12** and the patient delivery device **48**. The inner member **46**, as shown in FIGS. **3**A-**3**D, has a luer-lock connector **50**, which is configured for cooperating with a corresponding luer connection **52** (shown in FIG. **3**B) on the patient delivery device **48**. While FIGS. **3**A-**3**D illustrate the luer-lock connector **50** as a male connector, the luer-lock connector **50** may be embodied as a female connector configured for connecting to a male connector on the corresponding luer connection **52** on the patient delivery device **48**. Alternatively, the luer-lock connector **50** can be embodied as any other

mating connection configured for coupling with the patient delivery device **48**.
(31) With reference to FIG. **3**C, an outer member **54** surrounds at least a portion of the inner member **46**. A radial extension **56** of the inner member **46** is received within an annular sleeve **58** on the outer member **54** such that the inner member **46** is configured to rotate freely with respect to the outer member **54** and with respect to the patient delivery device **48**. Once the patient delivery device **48** is connected to the inner member **46**, the freely rotating state prevents inadvertent and/or accidental disconnection of the patient delivery device **48** from the inner member **46**, as the application of rotational force to the patient delivery device **48** will cause the inner member **46** to rotate with the rotation of the patient delivery device **48** without applying the rotational force necessary to remove the patient delivery device **48** from the inner member **46**. It can be appreciated that the connector **12** of the present invention and/or the connection interface of the present invention is not limited for use with a patient delivery device **48** but can be used in association with other components in a CSTD or other medical devices.
(32) With reference to FIG. **3**D, and with continuing reference to FIG. **3**C, the inner member **46** has an annular skirt **60** extending distally from the radial extension **56**. The annular skirt **60** is recessed relative to the radial extension **56**. The annular skirt **60** has a locking arrangement **62** configured to prevent free rotation of the inner member **46** relative to the outer member **54** to enable connection of the inner member **46** to and/or disconnection of the inner member **46** from the patient delivery device **48**. The locking arrangement, generally indicated as **62**, is configured to be engaged by the protrusions **34** of the container **10** upon the application of a compressive force F, shown in FIGS. **4**A-**4**C. By engaging the locking arrangement **62**, the inner member **46** is locked relative to the outer member **54**, such that an axial or rotational force can be applied to the interface between the inner member **46** and the patient delivery device **48** to attach or detach the connector **12** from the patient delivery device **48**.
(33) According to one aspect, as shown in FIGS. **3**C and **3**D, the locking arrangement **62** can include a plurality of teeth **64** extending from an outer surface of the annular skirt **60**. The teeth **64** are spaced radially about the circumference of the annular skirt **60** at equal intervals. In another aspect, the teeth **64** may be spaced with unequal intervals about the circumference of the annular skirt **60**. The teeth **64** are configured to clear the inner surface of the outer member **54** during rotation of the inner member **46** relative to the outer member **54**. The teeth **64** are separated by a plurality of engagement surfaces **66** extending therebetween. The teeth **64** are generally concealed by the outer member **54** of the body **36**. It can be appreciated that other locking arrangements can be provided that enable locking of the inner and outer members **46**, **54** with respect to one another upon the engagement of the locking arrangement. For example, a single tooth **64** may be provided on the annular skirt **60**. Alternatively, the engagement surface **66** may provide a frictional interface with the inner member **46** to prevent the rotation of the inner member **46**. The surface finish, coating, and material of the engagement surface **66** and the inner member **46** may be optimized for achieving the desired frictional conditions for proper functioning of the locking arrangement **62**. The engagement surface **66** is configured to be engaged by the protrusions **34** of the container **10** upon the application of a compressive force F, shown in FIG. **5**. By engaging the engagement surface **66**, a protrusion **34** is disposed between two adjacent teeth **64** such that the inner member **46** is locked relative to the outer member **54**. In this manner, an axial or rotational force can be applied to the interface between the inner member **46** and the patient delivery device **48** to attach or detach the connector **12** to or from the patient delivery device **48**.
(34) With reference to FIG. **3**C, a pair of slots **68** is provided on the outer member **54** of the body **36**; however, a single slot **68** may be provided in alternative aspects. The slots **68** extend between the distal end **38** and the proximal end **40** over at least a portion of the longitudinal length of the body **36**. At least a portion of the slots **68** extends through the sidewall **42** of the connector **12** to define a window **70** for accessing an interior portion of the connector **12**. Specifically, the window **70** defined by the slots **68** is configured to provide access to the locking arrangement **62**. In other

aspects, the window **70** may be provided separately from the slots **68**. In addition, in an aspect where the activation tab **72** is used to align the connector **12** within the container **10**, the slots **68** need not be provided.

(35) With continued reference to FIG. **3**C, the slots **68** may be oriented 180 degrees apart around a circumference of the connector **12** such that each slot **68** is aligned with the corresponding tab **30** (FIG. **1**C). For example, the longitudinal midpoint of each slot **68** may be aligned with an axis extending through the center of each tab **30**. The slots **68** define an alignment feature for aligning the connector **12** with the protrusions **34** of the container **10**. In particular, the slots **68** are shaped to receive the protrusions **34** such that the connector **12** is guided by the protrusions **34** as the connector **12** is inserted in or removed from the container **10**. In an uncompressed state of the container **10**, the protrusions **34** are not biased against the locking arrangement **62**. While FIG. **3**C illustrates a pair of slots **68** separated equally about the circumference of the connector **12**, it is to be appreciated that more than two slots **68** may be provided with equal or unequal separation about the circumference of the connector **12**. However, at least one slot **68** is provided in alignment with at least one of the protrusions **34** and the tabs **30** when the connector **12** is inserted in the container **10**. In various aspects, the number of slots **68** need not correspond to the number of protrusions **34**.

(36) With reference to FIGS. **4**A-**4**D, the application of the compressive force F in a radial direction causes the container to be compressed radially in a direction of the force F. Specifically, by applying the force F on the tabs **30**, the container **10** is locally compressed such that the portions of the sidewall **20** proximate to the tabs **30** are compressed towards each other. In this manner, the protrusions **34** are also biased toward one another such that the distance between the opposing protrusions **34** is reduced when the compressive force F is applied to the tabs **30**. In an aspect where a single protrusion **34** is provided, the compressive force F causes the protrusion **34** to be biased toward an inner sidewall of the container **10** opposite the protrusion **34** such that the distance between the protrusion **34** and the opposing sidewall is reduced when the compressive force F is applied to the tabs **30**. The structure of the container **10** of the present invention is such that it requires the deliberate action of applying a radially-directed compressive force F on the tabs **30** to cause the protrusions **34** to be biased against the locking arrangement **62** in order to prevent rotational movement of the inner member **46** relative to the outer member **54**, and thereby permit tightening or loosening of the patient delivery device **48** by the application of a rotational force thereto.

(37) With reference to FIG. **5**, as the protrusions **34** are biased toward one another from an initial, uncompressed state (indicated by solid lines) to a compressed state (indicated by dashed lines) due to an application of a radially-directed compressive force F on the tabs **30**, the protrusions **34** engage the locking arrangement **62** by extending through the window **70** of the slots **68**. In this manner, the protrusions **34** engage the annular skirt **60** of the inner member **46**. In particular, the protrusions **34** engage the engagement surface **66** of the annular skirt **60** in a region between the teeth **64**. In another aspect, a frictional interface between the protrusions **34** and the engagement surface **66** may be created as a result of an application of a radially-directed compressive force F on the tabs **30**. By maintaining the force F, the protrusions **34** are biased against the engagement surface **66** to prevent the rotation of the inner member **46** relative to the outer member **54**. Engagement of the locking arrangement **62** by the protrusions **34** causes the inner member **46** to be locked relative to the outer member **54**, such that an axial or rotational force can be applied to the interface between the inner member **46** and the patient delivery device **48** to attach or detach the connector **12** to or from the patient delivery device **48**. By releasing the force F, the container **10** reverts to its original shape, where the relative distance between the protrusions **34** is increased such that the protrusions **34** are disengaged from the locking arrangement **62** and the inner member **46** can rotate freely relative to the outer member **54**, thereby preventing inadvertent or accidental removal of the patient delivery device **48** from the inner member **46**.

(38) Having described the structure of the container **10** and the connector **12** disposed therein, a

method of securing the connector **12** to the patient delivery device **48** using the container **10** will now be described. The method includes providing the container **10** and the connector **12**, as described hereinabove. Desirably, the connector **12** is disposed entirely within the container **10** and sealed by the cap **16**. After removing the cap **16**, a radially-directed compressive force F is applied to the tabs **30** of the container **10**, thereby causing compression of the container **10** and biasing of the protrusions **34** of the container **10** toward one another. The method further includes the engagement of the protrusions **34** with the locking arrangement **62** due to the radial deflection of the protrusions **34**. As the protrusions **34** are deflected radially, the protrusions **34** are advanced through the window **70** and biased into engagement with the engagement surface **66** of the locking arrangement **62**. Such engagement prevents free rotation of the inner member **46** relative to the outer member **54**, thereby allowing the connection between the patient delivery device **48** and the inner member **46** of the connector **12**. Although the protrusions **34** prevent rotation of the connector **12** within the container **10** while the patient delivery device **48** is secured to the inner member **46**, any other portion of the connector **12** may interface with the container **10** to prevent relative rotation between the container **10** and the connector **12**. In particular, the activation tab **72** of the connector **12** is received within the recess **32** of the container **10**, which acts to prevent relative rotation between the container **10** and the connector **12** when the connector **12** is positioned within the container **10**.

(39) Upon release of the compressive force F, the protrusions **34** of the container **10** are disengaged from the locking arrangement **62** to permit free rotation of the inner member **46** relative to the outer member **54**, thereby preventing inadvertent and/or accidental disconnection of the inner member **46** from the patient delivery device **48**. The method can also include the re-application of the compressive force F to cause the locking arrangement **62** to be re-engaged for removal of the patient delivery device **48** from the connector **12**.

(40) With reference to FIGS. **6**A-**6**C, a connection device **80** is shown in use with the connector **12** described hereinabove. The connection device **80** is configured for engaging the locking arrangement **62** on the connector **12** to prevent relative movement between the inner member **46** and the outer member **54**. With reference to FIG. **6**C, the connection device **80** has a substantially arcuate shape configured for enveloping a portion of the connector **12**. In one aspect, the connection device **80** envelops a portion of the circumference of the outer member **54**. The connection device **80** has a flexible body **82** with a pair of tabs **84** located at opposing ends of the body **82**. In another aspect, the connection device **80** may have a single tab **84** located at one end of the connection device **80**. An outer portion of the tabs **84** has a finger engagement surface **86** configured for engagement with the user's fingers. An inner portion of the tabs **84** has a projection **88** configured for engagement with the locking arrangement **62**. The projection **88** extends outward from the surface of the inner portion of the tabs **84**. The tabs **84** are connected together by a flexible joint **90** (shown in FIG. **6**C) configured to deflect with the movement of the tabs **84** toward or away from each other. The structure of the connection device **80** of the present invention is such that it requires the deliberate action of applying a radially-directed compressive force F on the tabs **84** to cause the projections **88** to be biased against the locking arrangement **62** in order to prevent rotational movement of the inner member **46** relative to the outer member **54**, and thereby permit tightening or loosening of the patient delivery device **48** (shown in FIG. **3**B) by the application of a rotational force thereto. In this manner, the patient delivery device **48** can be connected to or removed from the inner member **46** without the need for the container **10** described hereinabove with reference to FIGS. **1**A-**2**C.

(41) Referring to FIG. **6**B, the projection **88** of each tab **84** is configured for being received within the window **70** of the slot **68**. Once placed within the window **70**, the tabs **84** can be squeezed toward each other by applying a radially-directed compressive force F. Such force F causes the projections **88** to engage the engagement surface **66** of the locking arrangement **62**. In particular, the projections **88** engage the engagement surface **66** of the annular skirt **60** in a region between the

teeth **64**. In another aspect, a frictional interface between the projections **88** and the engagement surface **66** may be created as a result of an application of a radially-directed compressive force F on the tabs **84**. By maintaining the force F, the projections **88** are biased against the engagement surface **66** to prevent the rotation of the inner member **46** relative to the outer member **54**. Engagement of the locking arrangement **62** by the projections **88** causes the inner member **46** to be locked relative to the outer member **54**, such that an axial or rotational force can be applied to the interface between the inner member **46** and the patient delivery device **48** to attach or detach the connector **12** to or from the patient delivery device **48**. By releasing the force F, the connection device **80** reverts to its original shape, where the relative distance between the tabs **84** is increased such that the projections **88** are disengaged from the locking arrangement **62** and the inner member **46** can rotate freely relative to the outer member **54**, thereby preventing inadvertent or accidental removal of the patient delivery device **48** from the inner member **46**.

(42) In another aspect, the connection device **80** may be naturally biased to interface with the locking arrangement **62** without requiring the application of a radially-directed force F. In this aspect, the connection device **80** may be snap-fitted or clipped to the connector **12** such that the projections **88** are biased against the engagement surface **66** to prevent the rotation of the inner member **46** relative to the outer member **54**. The connection device **80** is disengaged by unsnapping or unclipping the projections **88** with an application of a force directed in a radially-outward direction. The connection device **80** may be completely removable from the connector **12**, or it may be formed integrally therewith such that the projections **88** can be disengaged from the engagement surface **66**.

(43) Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred aspects, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed aspects, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any aspect can be combined with one or more features of any other aspect.

Claims

1. A connection device configured for engaging/disengaging a connector with a patient delivery device, the connection device comprising: a flexible body having an arcuate shape; at least one tab provided at an end portion of the flexible body, the at least one tab comprising a finger engagement surface; and an engagement structure provided on the at least one tab, wherein the engagement structure is configured for engaging a locking arrangement on the connector to prevent rotation of an inner member of the connector relative to an outer member of the connector upon an application of a compressive force on the at least one tab, wherein the at least one tab comprises a pair of tabs located at opposing ends of the flexible body, wherein the pair of tabs are configured to be squeezed towards each other when the compressive force is applied to the finger engagement surface of each of the pair of tabs, and wherein the compressive force applied to the pair of tabs comprises a radially-directed compressive force.

2. The connection device of claim 1, wherein the at least one tab is connected to a flexible joint.

3. The connection device of claim 1, wherein the engagement structure comprises at least one projection configured for engagement with the locking arrangement on the connector.

4. The connection device of claim 3, wherein the at least one projection extends outward from a surface of an inner portion of the tab.

5. The connection device of claim 1, wherein the pair of tabs each comprise a radially inner portion comprising an engagement surface and a radially outer portion comprising the finger engagement surface configured for engagement with a user's fingers.

6. The connection device of claim 1, wherein the locking arrangement on the connector comprises at least one tooth extending from an engagement surface of the locking arrangement, and wherein the engagement structure of the connection device is configured to engage the at least one tooth.