

SPINNING FEMALE LUER WITH THREADABLY REMOVABLE FEATURE**CROSS-REFERENCE TO RELATED APPLICATION**

[0001] The present application claims priority to United States Provisional Application Serial No. 62/545,597, entitled “Spinning Female Luer with Threadably Removable Feature” filed August 15, 2017, the entire disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION**Field of the Invention**

[0002] The present invention relates to an adapter for a closed system transfer assembly that permits fluid delivery from a first fluid container to a second fluid container through the adapter. More specifically, the invention is directed to an adapter with a connection arrangement for engaging and disengaging the adapter from the fluid container.

Description of Related Art

[0003] 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/or other similar handling. This problem is particularly serious when cytotoxins, antiviral drugs, antibiotics, and radiopharmaceuticals are used by the healthcare workers. The health risks faced by exposure to these drugs can include the development of cancer, reproductive problems, genetic conditions, and other serious health concerns. Other hazardous areas may be sample taking, such as samples concerning virus infections or similar situations. 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 situation occurs, 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 contamination may contaminate the staff through their lungs or by vaporized medical fluid or

aerosol in the air that condensates on the skin to penetrate the skin of the staff. Some medicaments are even known to penetrate protection gloves and, thereby, contaminate the staff.

[0004] 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 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 (CSTD) have been developed to ensure that the medicament is contained in the transfer device during transfer of the medicament.

[0005] Generally, a CSTD includes an adapter (referred to hereinafter as a syringe adapter) for connection to a first fluid container, such as a syringe, and a second adapter (referred to hereinafter as a vial 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 through the syringe adapter and the vial adapter. The practitioner reconstitutes the drug, aspirates the compound into the syringe, disconnects the adapter, and then attaches the syringe adapter and syringe attached thereto to a patient delivery device, such as an IV line, for administration to the patient.

[0006] One type of syringe adapter that can be used in a CSTD has a proximal end with a male or female luer-lock element that is arranged to be joined with a corresponding female or male luer-lock element of the syringe. The luer-lock element can be screwed into and unscrewed from the corresponding luer-lock element. It is desirable to prevent accidental or inadvertent unscrewing of the components, which could lead to the disconnection of the fluid passageway extending through the adapter. Such disconnection may result in a serious contamination risk for a patient and/or any other person in the vicinity of the disconnected CSTD. 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.

[0007] It is, therefore, desirable to provide a syringe adapter for enabling fluid transfer from the syringe to the syringe adapter, vial adapter, and/or second fluid container, such as a line connector/adaptor, by facilitating a positive connection of the connectors and avoiding inadvertent or accidental disconnection of the syringe and the fluid connector. Specifically, it is

desirable that the syringe and the syringe adapter may be connected together via a simple intuitive connection activity.

SUMMARY OF THE INVENTION

[0008] According to one aspect of the invention, an adapter for connection with a fluid container includes an outer housing having a distal end, a proximal end, and a substantially cylindrical sidewall extending between the distal end and the proximal end, an inner member including a body rotatably inserted within the outer housing, a connector extending from the body configured to connect the adapter to a fluid container, and at least one grasping member extending from the inner member, the grasping member being configured for grasping by a user of the adapter, a first locking arrangement engageable with a distal end of the inner member and configured to restrict the inner member from rotating relative to the outer housing in a first direction, and a second locking arrangement engageable with a proximal surface of the inner member and configured to restrict the inner member from moving in a proximal direction relative to the outer housing. The adapter is transitionable between a disengaged state, in which the first locking arrangement and the second locking arrangement are not engaged with the inner member, a first fully engaged state in which the first locking arrangement engages the inner member, and a second fully engaged state in which the second locking arrangement engages the inner member.

[0009] According to another aspect of the invention, the inner member is rotatable in both the first direction and the second direction when the connector is in the disengaged state. The inner member is transitionable from an extended position to a recessed position by applying a compressive force to the inner member. The first locking arrangement includes at least one tooth extending inward from an inner surface of the sidewall of the outer housing and a corresponding tooth on the body of the inner member configured to engage the tooth on the sidewall. The at least one tooth extending inward from the inner surface of the sidewall of the outer housing and the corresponding tooth on the body of the inner member include an angled portion and a vertical locking surface. The first locking arrangement includes a plurality of teeth extending around a circumferential inner surface of the sidewall of the outer housing and a plurality of corresponding teeth extending from a distal end of the body of the inner member. The second locking arrangement includes at least one inwardly extending locking tab connected to a portion of an inner surface of the sidewall of the outer housing and configured to engage the proximal

surface of the inner member. The second locking arrangement includes at least two inwardly extending locking tabs positioned on opposing sides of the sidewall of the outer housing. The at least one locking tab includes a locking surface configured such that applying a compressive force to the inner member biases the tab outward to insert the inner member into the outer housing. The connector includes an outer surface with helical threads, configured to engage corresponding threads on an inner surface of a portion of the fluid container. The connector includes a luer connector configured to receive a corresponding luer connector of the fluid container. The at least one grasping member includes two curved flanges extending from a proximal surface of the inner member, each curved flange including a planar portion and an angled portion extending from each end of the planar portion. The curved flanges are configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction. The at least one grasping member includes two bumps extending from a proximal surface of the inner member, each bump having a substantially hemispherical shape. The bumps are configured for pressing by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction. The at least one grasping member includes two flanges positioned on the connector, each flange including a vertical portion that extends vertically along a side surface of the connector. The flanges are configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction. One of the flanges further includes a horizontal portion that extends horizontally from the connector and perpendicular to the vertical portion. The at least one grasping member includes a thumb stop extending horizontally from the connector and vertically from the body. The thumb stop is configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction. The at least one grasping member includes a groove defined in the body of the inner member. The groove is configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction.

[0010] In another aspect of the invention, a method of disconnecting a fluid container to an adapter includes the steps of providing an adapter; grasping the at least one grasping member; moving the fluid container in an axial direction towards the adapter; and rotating the fluid container to disconnect the fluid container from the inner member of the adapter. The adapter

including an outer housing having a distal end, a proximal end, and a substantially cylindrical sidewall extending between the distal end and the proximal end, an inner member including a body rotatably inserted within the outer housing, a connector extending from the body configured to connect the adapter to a fluid container, and at least one grasping member extending from the inner member, the grasping member being configured for grasping by a user of the adapter, a first locking arrangement engageable with a distal end of the inner member and configured to restrict the inner member from rotating relative to the outer housing in a first direction, and a second locking arrangement engageable with a proximal surface of the inner member and configured to restrict the inner member from moving in a proximal direction relative to the outer housing.

[0011] In another aspect of the invention, the at least one grasping member includes two curved flanges extending from a proximal surface of the inner member, each curved flange including a planar portion and an angled portion extending from each end of the planar portion. The curved flanges are configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction. The at least one grasping member includes two flanges positioned on the connector, each flange including a vertical portion that extends vertically along a side surface of the connector. The flanges are configured for grasping by the user to prevent rotation of the inner member in a second direction, in which the second direction is opposite the first direction.

[0012] In another aspect of the invention, an adapter for connection with a fluid container includes an outer housing having a distal end, a proximal end, and a sidewall extending between the distal end and the proximal end, a hub cover attached to the proximal end of the outer housing, an inner member including a rotatable body inserted within the outer housing and a connector extending from the body configured to connect the adapter to a fluid container, a first locking arrangement engageable with the outer housing and configured to restrict the inner member from rotating relative to the outer housing in a first direction, and a second locking arrangement engageable with the outer housing and configured to restrict the inner member from moving in a proximal direction relative to the outer housing. The adapter is transitionable between a disengaged state, in which both the first locking arrangement and the second locking arrangement are not engaged with the inner member, a first fully engaged state in which the first

locking arrangement engages the outer housing, and a second fully engaged state in which the second locking arrangement engages the outer housing.

[0013] The hub cover is integrally formed on the proximal end of the outer housing and is configured to surround the rotatable body of the inner member when the inner member is connected to the outer housing. The hub cover is substantially flexible so as to contact the inner member to prevent rotation of the inner member relative to the outer housing. The inner member is rotatable in both the first direction and the second direction when the connector is in the disengaged state, wherein the inner member is prevented from rotating in a first direction when the connector is in the first fully engaged state; and wherein the inner member is prevented from retracting proximally out of the housing while permitting the inner member to rotate freely in the second fully engaged state. The inner member is transitionable from an extended position to a recessed position by applying a compressive force to the inner member. The first locking arrangement includes at least one tooth extending inward from an inner surface of the inner member and at least one recess defined in the proximal end of the outer housing configured to engage the tooth on the inner member. The at least one tooth extending inward from the inner member and the corresponding recess defined in the outer housing include an angled portion and a vertical locking surface. The second locking arrangement includes at least one inwardly extending locking tab connected to a portion of an inner surface of the inner member and configured to engage a locking protrusion extending from the proximal end of the outer housing. The at least one locking tab includes a locking surface configured such that applying a compressive force to the inner member biases the locking tab outward to insert the inner member into the outer housing. The sidewall of the outer housing defines at least one indentation to assist a user in gripping the adapter.

[0014] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0015] **Fig. 1** is a perspective view of a closed system transfer device system according to an aspect of the invention;
- [0016] **Fig. 2** is a front perspective view of an adapter according to an aspect of the invention;
- [0017] **Fig. 3** is a top perspective view of the adapter of **Fig. 2**;
- [0018] **Fig. 4** is a side view of the adapter of **Fig. 2**;
- [0019] **Fig. 5** is a top view of the adapter of **Fig. 2**;
- [0020] **Fig. 6** is a cross-sectional view of the adapter of **Fig. 2**;
- [0021] **Fig. 7** is a top perspective view of an outer housing of the adapter of **Fig. 2** according to an aspect of the invention;
- [0022] **Fig. 8** is a cross-sectional view of the outer housing of **Fig. 7**;
- [0023] **Fig. 9** is a perspective view of an inner member of the adapter of **Fig. 2** according to an aspect of the invention;
- [0024] **Fig. 10** is a side view of the inner member of **Fig. 9**;
- [0025] **Fig. 11** is a cross-sectional view of the inner member of **Fig. 9**;
- [0026] **Fig. 12** is a perspective view of an inner member according to another aspect of the invention;
- [0027] **Fig. 13** is a side view of the inner member of **Fig. 12**;
- [0028] **Fig. 14** is a top view of the inner member of **Fig. 12**;
- [0029] **Fig. 15** is a perspective view of an inner member according to another aspect of the invention;
- [0030] **Fig. 16** is a side view of the inner member of **Fig. 15**;
- [0031] **Fig. 17** is a top view of the inner member of **Fig. 15**;
- [0032] **Fig. 18** is a perspective view of an inner member according to another aspect of the invention;
- [0033] **Fig. 19** is a side view of the inner member of **Fig. 18**;
- [0034] **Fig. 20** is a top view of the inner member of **Fig. 18**;
- [0035] **Fig. 21** is a side view of an alternative aspect of the inner member of **Fig. 18**;

- [0036] Fig. 22 is a perspective view of an inner member according to another aspect of the invention;
- [0037] Fig. 23 is a perspective view of an inner member according to another aspect of the invention;
- [0038] Fig. 24 is a cross-sectional view of the inner member of Fig. 23,
- [0039] Fig. 25 is a perspective view of an adapter according to another aspect of the disclosure;
- [0040] Fig. 26 is a perspective view of the adapter of Fig. 25 with an inner member removed;
- [0041] Fig. 27 is a cross-sectional view of the adapter of Fig. 25;
- [0042] Fig. 28 is an enlarged view of an outer housing of the adapter of Fig. 25;
- [0043] Fig. 29 is a bottom perspective view of the inner member of the adapter of Fig. 25;
- [0044] Fig. 30 is a side view of another aspect of the adapter according to the present disclosure;
- [0045] Fig. 31 is a perspective view of an inner member according to another aspect of the present disclosure; and
- [0046] Fig. 32 is a perspective view of a hub cover according to another aspect of the present disclosure.

DESCRIPTION OF THE INVENTION

[0047] 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.

[0048] 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. 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.

[0049] With reference to **Fig. 1**, a closed system transfer assembly **2** is illustrated. The closed system transfer assembly **2** includes a first fluid source or container, such as a syringe **4** or IV line, configured to be connected to a syringe adapter (referred to hereinafter as adapter **10**). The syringe **4** includes a male luer connector **6** that is configured to be secured to a corresponding female luer-lock connector **12** of the adapter **10**. However, it is understood that the arrangement of the male and female luer-lock fittings may be reversed for certain fluid delivery applications. Any other connection interface, as is known in the art, may also be added in place of the luer fittings as required. The distal end of the syringe **4** may also include a luer-lock **8** surrounding the male luer connector **6** with threads **9** configured to engage corresponding threads **14** surrounding the connector **12**. More specifically, the adapter **10** is an assembly of components adapted to create a tamper-proof connection interface with the syringe **4**. The adapter **10** is configured to prevent accidental or inadvertent disconnection of the adapter **10** and the syringe **4**, which could compromise the integrity of the closed system transfer assembly **2**. As will be described in detail hereinafter, the adapter **10** includes various locking arrangements for preventing a user from inadvertently disengaging the adapter **10** from the syringe **4**. As a result of the locking arrangements, to disengage the syringe **4** from the adapter **10**, the user must perform a compound motion activity. As referred to hereinafter, a compound motion activity refers to more than one distinct and independent motion performed in a predetermined order or sequence. For example, in one aspect of the adapter **10**, the compound motion activity includes at least three distinct motions, namely pressing the syringe **4** toward the adapter **10**, pressing a button, tab, or surface located on the adapter **10**, and rotating the syringe **4** relative to the adapter **10** to disengage the threads **14** of the connector **10** from the threads **9** on the luer-lock **8** of the syringe **4**. The sequence of predetermined steps may also be reversed or performed in a different order within the scope of the present invention.

[0050] With reference to **Figs. 2-8**, the adapter **10** includes an outer housing **16** having a distal end **18**, a proximal end **20**, and a generally cylindrical sidewall **22** extending between the distal end **18** and the proximal end **20**. The housing **16** defines a fluid passageway **24** (shown in **Fig.**

6) extending between the proximal end **20** and distal end **18** of the outer housing **16**. The housing **16** may be formed from any suitable structural material including medical grade plastic or metal. Optionally, the housing **16** may include various features that make holding or manipulating the housing **16** and adapter **10** easier. For example, the housing **16** may include a narrower grip portion **26** that is more comfortable for users to hold. The housing **16** may also include a plurality of ribs **27** or a textured portion or surface (not shown) so that the housing **16** does not slip or slide when held by the user. The housing **16** may also include various aesthetic features such as patterns, designs, logos, and the like for improving the appearance of the outer housing **16**.

[0051] With reference to **Fig. 6**, in certain aspects, the housing **16** includes a needle cannula **25** extending therethrough that forms the fluid passageway **24**. The cannula **25** may include a tip at a distal end thereof for establishing a fluid connection with a fluid container such as a medical vial. The housing **16** may also include a septum **17** or seal arrangement, capable of being pierced by the tip of the needle, extending across an inner portion of the housing **16**. The septum **17** is held within the housing **16** by a holding member **19** that rests on the distal end **18** of the housing **16**. A resilient member, such as a spring **21**, is also positioned in the housing **16** and rests against a proximal end of the holding member **19** and a flange **23** extending from an inner surface of the housing **16**. The spring **21** is biased against the holding member **19** to keep the septum **17** positioned in the housing **16**. During use, the needle tip and cannula **25** may be advanced through the septum **17** or seal arrangement to establish fluid communication through the housing **16**. The septum **17** or seal arrangement may be configured to prevent fluid from passing through the housing **16** and contaminating other elements of the adapter **10** and/or syringe **4**.

[0052] The adapter **10** further includes an inner member **28** inserted in the proximal end **20** of the housing **16**. For example, in one aspect, the inner member **28** may be inserted in an annular sleeve **30** extending around the proximal end **20** of the housing **16**. In one aspect, the inner member **28** rests on a proximal surface of the flange **23**. As will be described hereinafter, an inner surface **32** (shown in **Fig. 6**) of the sidewall **22** may include various structures for engaging the inner member **28** to restrict rotation thereof. The inner member **28** includes a substantially cylindrical body **34** having an outer diameter that generally corresponds with the inner diameter of the sidewall **22** of the housing **16**.

[0053] With reference to **Fig. 6**, the body **34** of the inner member **28** is a substantially cylindrical structure, although other suitable shapes may be utilized. The body **34** may include a cap **40** or top on a proximal end thereof. The cap **40** covers a portion of the proximal end of the body **34**. The connector **12** extends from the cap **40** of the body **34**. A proximal end of the cannula **25** may be inserted into a proximal end of the connector **12** for permitting fluid flow through the housing **16** of the adapter **10**. A plurality of teeth **35** extend distally from a distal end **42** of the inner member **28** and are spread around the circumferential surface of the distal end **42** of the inner member **28**. Each tooth **35** includes an angled portion **37a** and a locking surface **37b** that extend substantially perpendicular to and end of the angled portion **37a**. It is also contemplated that fewer or additional teeth **35** may be provided on the inner member **28**.

[0054] The connector **12** includes various structures for connecting the inner member **28** of the adapter **10** to the syringe **4** (shown in **Fig. 1**). As described above, in one aspect, the exterior sidewall of the connector **12** includes helical threads **14** extending therefrom. The threads **14** are configured to engage corresponding threads **9** on the syringe **4** (shown in **Fig. 1**). For example, the user may connect the syringe **4** to the connector **10** by twisting the syringe **4** in the first direction A.

[0055] The adapter **10** also includes a first locking arrangement **36** that is capable of engaging the housing **16** with the body **34** of the inner member **28** for restricting the inner member **28** from turning in a first direction, such as clockwise, and a second locking arrangement **38** that is capable of engaging the housing **16** with the body **34** of the inner member **28** for restricting the inner member **28** from being retracted in a proximal direction out of the housing **16**. In one aspect, the first locking arrangement **36** includes a plurality of teeth **39** extending around an inner circumferential surface of the housing **16**. Each tooth **39** includes an angled portion **41a** and a locking surface **41b** that extends substantially perpendicular to and end of the angled portion **41a**.

[0056] As shown in **Figs. 2, 3, and 9**, grasping surfaces, such as one or more flanges **92**, may extend from the proximal surface of the cap **40** of the inner member **28**. As shown in **Fig. 9**, in one aspect, two flanges **92** are provided on the cap **40** of the inner member **28**. The flanges **92** are positioned 180 degrees from one another on the cap **40**. In other aspects, fewer or additional flanges may be provided on the cap **40**. The flanges **92** may be positioned at any angular arrangement on the cap **40**. In one aspect, the flanges **92** are curved to extend around a portion of

the circumferential surface of the cap 40. As shown in Fig. 22, the flanges 92 may extend along a larger portion of the cap 40. When disconnecting the syringe 4 (as described below) from the inner member 28, the user can grasp at least one flange 92 with one hand with sufficient force to prevent the inner member 28 from rotating. The grasping surfaces, such as the flanges 92 illustrated in Fig. 3, may be easier for a user to hold for certain shapes of fluid sources or syringes. Each flange 92 includes a flat, planar portion 93a and two angled portions 93b, 93c. The angled portions 93b, 93c extend from the proximal surface of the cap 40 to the planar portion 93a. The user can grasp or press down on any portion of the flanges 92 to assist the user in preventing rotation of the inner member 28 relative to the housing 16 to disconnect the syringe 4 from the inner member 28.

[0057] As will be described in greater detail hereinafter, the adapter 10 is transitionable between three states or positions. First, the adapter 10 may be in a disengaged state, in which the first locking arrangement 36 and the second locking arrangement 38 are not engaged with the inner member 28. In the disengaged state, the inner member 28 can freely rotate relative to the stationary outer housing 16 in both the first direction A and the second direction B. Second, the adapter 10 may be in a first fully engaged state. In the first fully engaged state, the first locking arrangement 36 engages the inner member 28 so that rotation in the first direction A is substantially prevented. Finally, the adapter 10 may be transitioned to a second fully engaged state or position in which the second locking arrangement 38 engages the inner member 28, thereby preventing the inner member 28 from retracting proximally out of the housing 16 while permitting the inner member 28 to rotate freely. It is noted, however, that some rotation may still occur in the partially engaged and fully engaged states if the locking arrangements 36, 38 have not reached a hard stop or if the user is not gripping the locking arrangements 36, 38 strongly enough to fully prevent rotation of the inner member 28.

[0058] With reference to Figs. 6 and 10, the inner member 28 is configured to be transitionable from an extended position to a recessed position in which the inner member 28 is inserted farther into the outer housing 16. The user advances the inner member 28 in the distal direction D, relative to the housing 16, to transition the inner member 28 from the extended position to the recessed position by applying a compressive force thereto. As will be described hereinafter, the first locking arrangement 36 cannot engage the inner member 28 when it is in the extended position. When the inner member 28 is in the recessed position, the first locking

arrangement 36 is capable of engaging the inner member 28 to restrict rotation of the inner member 28 relative to the outer housing 16 in the first direction A. The inner member 28 is inserted into the housing 16 until the inner member 28 rests on the first locking arrangement 36. After the inner member 28 has been positioned against the flange 23, the inner member 28 is rotated or ratcheted until the teeth 35 extending from a distal end 42 of the inner member 28 engage the teeth 39 extending from the housing 16. Upon interconnection between the teeth 35, 39, the inner member 28 is permitted to rotate in the second direction B, but not the first direction A. The locking surfaces 37b of the teeth 35 abut the locking surfaces 41b of the first locking arrangement 36 to prevent rotation in the first direction A. During insertion and rotation of the inner member 28 within the housing 16, the teeth 35 of the inner member 28 are directed upwards along the angled portions 41a of the teeth 39 of the housing 16 so that the inner member 28 is permitted to freely rotate in the second direction B. However, when the inner member 28 is rotated in the first direction A, the locking surfaces 37b of the teeth 35 of the inner member 28 abut the locking surfaces 41b of the teeth 39 of the housing 16, such that rotation of the inner member 28 in the first direction A is prevented. Therefore, as a practitioner rotates the syringe 4 onto the inner member 28, the inner member 28 is prevented from rotating in the first or clockwise direction A to hold the inner member 28 stationary relative to the syringe 4 so the syringe 4 can be twisted onto the inner member 28. However, since the inner member 28 is not prevented from rotating in the second direction B, the inner member 28 cannot be held stationary relative to the syringe 4 to permit the practitioner to rotate the syringe 4 in a counterclockwise direction to disconnect the syringe 4 from the inner member 28. Using this arrangement, an unintentional or accidental disconnection of the syringe 4 from the inner member 28 is prevented.

[0059] Further, as the inner member 28 is inserted into the housing 16, the second locking arrangement 38 engages the cap 40 of the inner member 28 to prevent proximal movement of the inner member 28 in the housing 16. In one aspect, the second locking arrangement 38 includes a plurality of locking tabs 43 that extend around an inner circumferential surface of the housing 16. As the inner member 28 is advanced into the housing 16, the cap 40 is pushed past the locking tabs 43 to push the locking tabs 43 outwardly. Once the cap 40 advances past the locking tabs 43, the locking tabs 43 move inwardly to engage the upper surface of the cap 40, thereby preventing proximal movement of the inner member 28 out of the housing 16.

[0060] As described above, the adapter 10 of the present disclosure is configured to require a compound motion or activity to disconnect the syringe 4 (shown in Fig. 1) from the adapter 10. In a preferred and non-limiting aspect of the adapter 10, the first activation motion or maneuver is considered to be pressing the inner member 28 in the distal direction D with a compressive force that is sufficient to push the inner member 28 past the locking tabs 43.

[0061] With reference to Fig. 6, to connect the syringe 4 to the adapter 10, the user grasps the syringe 4 in a conventional manner. The user aligns the distal portion of the syringe 4 with the connector 12 of the adapter 10, such that helical threads 14 of the connector 12 contact corresponding threads 9 on the shield surrounding the male luer lock 6 of the syringe 4. It is noted, however, that since the adapter 10 is in the disengaged position, the inner member 28 spins freely in the second direction B. Therefore, if the user were to try to turn the syringe 4 in a counterclockwise direction relative to the connector 12, the inner member 28 would also rotate preventing connection therebetween. Instead, the user must press the syringe 4 against the connector 12 in distal direction D with sufficient compressive force to insert the inner member 28 into the housing 16. Once sufficient force is applied, the inner member 28 is transitioned to the recessed position.

[0062] In the recessed position, the teeth 35 (shown in Figs. 9 and 10) of the first locking arrangement 36 and the teeth 39 of the housing 16 are brought into contact with one another. More specifically, once the inner member 28 is in the recessed position, the user can slightly rotate the inner member 28 relative to the housing 16 to established contact and/or engagement between the teeth 35 of the inner member 28 and the teeth 39 extending from the housing 16. Once the engagement between the inner member 28 and the housing 16 is established, the inner member 28 is prevented from rotating any farther in the first direction A. Thus, the user can rotate the syringe 4 in direction A relative to the connector 12 to engage the threads 9 of the syringe 4 with the corresponding helical threads 14 of the connector 12. Since the inner member 28 is fixedly engaged with the first locking arrangement 36, twisting the syringe 4 in direction A does not cause the inner member 28 to rotate.

[0063] Once the syringe 4 is sufficiently tightly connected to the connector 12 of the inner member 28, the user can release the syringe 4. In this position, the inner member 28 and syringe 4 attached thereto can freely rotate in the first direction A and/or second direction B relative to the housing 16. Furthermore, since the inner member 28 and/or syringe 4 rotate freely in the

second direction B, it would be rather difficult or impossible for the user to remove the syringe 4 from the connector 12 of the inner member 28 when it is in the extended position. Thus, the chance that the user or patient could inadvertently remove the syringe 4 from the adapter 10 is effectively reduced.

[0064] To remove the syringe 4 from the adapter 10, the user first pushes the syringe 4 toward the adapter 10, in the same manner described above, to transition the inner member 28 from the extended position to the recessed position. This action is referred to as the first motion or maneuver. Specifically, to disconnect the syringe 4 from the connector 12, the user must rotate the syringe 4 in the second direction B. However, when the adapter 10 is in the first fully engaged position in which it cannot rotate in the first direction A, the inner member 28 is free to rotate in the second direction B, meaning that removing the syringe 4 from the connector 12 would be difficult or prevented. Therefore, the user must press the cap 40 of the inner member 28 downwardly to press the inner member 28 against the flange 23. Pressing the cap 40 is referred to as the second motion or maneuver. By pressing the inner member 28 against the first locking arrangement 36, the inner member 28 and, thereby, the syringe 4 are prevented from rotating in either direction due to friction established between the inner member 28 and the first locking arrangement 36. Since, in this position, the inner member 28 is prevented from rotating in the second direction B, the user can easily twist the syringe 4 in the second direction B to unscrew it from the connector 12. Unscrewing the syringe 4 from the connector 12 is referred to as the third motion of maneuver.

[0065] With reference to **Figs. 12-24**, additional arrangements for preventing rotation of the inner member 28 relative to the housing 16 to disconnect the syringe 4 from the inner member 28 are shown and described. As shown in **Figs. 12-14**, the inner member 28 includes the same features as the inner member 28 described above in **Figs. 1-11**. The flanges 92 of the inner member 28, however, are replaced with bumps 94 that extend from the proximal surface of the cap 40. The bumps 94 have a hemispherical shape that is raised from the proximal surface of the cap 40. The bumps 94 have substantially rounded edges to provide a smooth surface for a user to press down on when disconnecting the syringe 4 from the inner member 28. In one aspect, two bumps 94 are provided on the cap 40. The bumps 94 are spaced 180 degrees apart from one another on the cap 40. It is also contemplated, however, that fewer or additional bumps may be provided on the cap 40 at any different angular arrangement.

[0066] As shown in **Figs. 15-17**, the inner member **28** includes the same features as the inner member **28** described above in **Figs. 1-11**. The flanges **92** of the inner member **28**, however, are replaced with tabs **96** that extend from the proximal surface of the cap **40**. The tabs **96** include a planar portion that extends parallel to the proximal surface of the cap **40** and two curved portions that extend from the proximal surface of the cap **40** to connect to the planar portion. The curved portions have substantially rounded edges to provide a smooth surface for a user to press down on when disconnecting the syringe **4** from the inner member **28**. In one aspect, two tabs **96** are provided on the cap **40**. The tabs **96** are spaced 180 degrees apart from one another on the cap **40** and extend horizontally relative to the connector **12** of the inner member **28**. It is also contemplated, however, that fewer or additional tabs may be provided on the cap **40** at any different angular arrangement.

[0067] As shown in **Figs. 18-20**, the inner member **28** includes the same features as the inner member **28** described above in **Figs. 1-11**. The flanges **92** of the inner member **28**, however, are replaced with vertical flanges **98** that extend from the connector **12** of the inner member **28**. The vertical flanges **98** extend vertically along a portion of a side surface of the connector **12**. One of the vertical flanges **98** is substantially rectangular and includes a plurality of grasping surfaces that permit a user to stop rotation of the inner member **28** relative to the housing **16**. Another of the vertical flanges **98** includes a portion that extends vertically along a portion of the side surface of the connector **12** and a portion that extends horizontally along the proximal surface of the cap **40**. In this arrangement, the vertical flange **98** is positioned on the cap **40** and the connector **12**. In one aspect, two vertical flanges **98** are provided on the connector **12**. The vertical flanges **98** are spaced 180 degrees apart from one another on the connector **12** and extend vertically relative to the connector **12** of the inner member **28**. It is also contemplated, however, that fewer or additional vertical flanges may be provided on the connector **12** at any different angular arrangement. Further, as shown in **Fig. 21**, a thumb stop **100** may be provided on one of the vertical flanges **98**. The thumb stop **100** may extend vertically from the cap **40** and horizontally from the connector **12** to provide a larger surface for the user to grasp to prevent rotation of the inner member **28** relative to the housing **16**. The user can press or hold the thumb stop **100** to prevent the inner member **28** from rotating in the second direction **B** to allow disconnection of the syringe **4** from the inner member **28**.

[0068] As shown in **Figs. 23** and **24**, the inner member **28** includes the same features as the inner member **28** described above in **Figs. 1-11**. The flanges **92** of the inner member **28**, however, are replaced with a groove **102** defined in the proximal surface of the cap **40**. The groove **102** includes a flat bottom surface, two curved side surfaces, and two vertical side surfaces. The groove **102** is configured to permit a user to insert a finger or tool into the groove **102** to prevent rotation of the inner member **28** relative to the housing **16** to disconnect the syringe **4** from the inner member **28**. By defining a groove **102** in the cap **40**, no external grasping surface extends from the proximal surface of the cap **40**. In one aspect, one groove **102** is defined in the cap **40**. It is also contemplated, however, that additional grooves may be defined in the cap **40** at any different angular arrangement.

[0069] With reference to **Figs. 25-29**, another aspect of the adapter **200** according to the present disclosure is described. The adapter **200** is similar in construction and function as the adapter **10** described above, but with a few differences as described below. The adapter **200** includes an outer housing **202** having a distal end **204**, a proximal end **206**, and a generally cylindrical sidewall **208** extending between the distal end **204** and the proximal end **206**. A needle extending through the housing **202** defines a fluid passageway **210** (shown in **Fig. 26**) extending between the proximal end **206** and distal end **204** of the outer housing **202**. The housing **202** may be formed from any suitable structural material including medical grade plastic or metal. Optionally, the housing **202** may include various features that make holding or manipulating the housing **202** and adapter **200** easier. For example, the housing **202** may include a narrower grip portion **212** that is more comfortable for users to hold. The housing **202** may also include a plurality of indentations **214** that are sized and shaped to receive a user's fingers during use of the adapter **200** so that the housing **202** does not slip or slide when held by the user. The housing **202** may also include various aesthetic features such as patterns, designs, logos, and the like for improving the appearance of the outer housing **202**.

[0070] With reference to **Fig. 27**, in certain aspects, the housing **202** includes a needle cannula **216** extending therethrough that forms the fluid passageway **210**. The cannula **216** may include a tip at a distal end thereof for establishing a fluid connection with a fluid container such as a medical vial. The housing **202** may also include a septum **218** or seal arrangement, capable of being pierced by the tip of the needle, extending across an inner portion of the housing **202**. The septum **218** is held within the housing **202** by a holding member **220** that rests on the distal end

204 of the housing **202**. A resilient member, such as a spring **222**, is also positioned in the housing **202** and rests against a proximal end of the holding member **220** and a flange **224** extending from an inner surface of the housing **202**. The spring **222** is biased against the holding member **220** to keep the septum **218** positioned in the housing **202**. During use, the needle tip and cannula **216** may be advanced through the septum **218** or seal arrangement to establish fluid communication through the housing **202**. The septum **218** or seal arrangement may be configured to prevent fluid from passing through the housing **202** and contaminating other elements of the adapter **200**.

[0071] The adapter **200** further includes an inner member **226** inserted in the proximal end **206** of the housing **202**. For example, in one aspect, the inner member **226** may be inserted in a hub cover **228** extending around the proximal end **206** of the housing **202**. In one aspect, the inner member **226** rests on a proximal surface of the flange **224**. As will be described hereinafter, an inner surface **230** (shown in Fig. 28) of the sidewall **208** may include various structures for engaging the inner member **226** to restrict rotation thereof. The inner member **226** includes a substantially cylindrical body **232** having an outer diameter that generally corresponds with the inner diameter of the hub cover **228** of the housing **202**. The hub cover **228** is made of a substantially flexible material so that the hub cover **228** is configured to be pressed inwardly upon pressure applied by a user. After the pressure has been released by the user, the hub cover **228** will expand back to its original resting position. In one aspect, the hub cover **228** is made of a flexible, resilient plastic material.

[0072] With reference to Figs. 27 and 29, the body **232** of the inner member **226** is a substantially cylindrical structure, although other suitable shapes may be utilized. The body **232** may include a cap **234** or top on a proximal end thereof. The cap **234** covers a portion of the proximal end of the body **232**. A connector **236** extends from the cap **234** of the body **232** and is positioned such that the fluid passageway **210** extends therethrough. For example, a proximal end of the cannula **216** may be inserted into a proximal end of the connector **236** for permitting fluid flow through the needle of the adapter **200**. A plurality of locking tabs **238** (also referred to as a second locking arrangement) extend inwardly from an inner surface **240** of the inner member **236** and are spread around the circumferential surface of the inner surface **240** of the inner member **236**. As shown in Fig. 27, when the adapter **200** is assembled, the inner member **226** is inserted into the hub cover **228**. As the inner member **226** is inserted into the hub cover

228, the locking tabs 238 are pushed outwardly by sliding along a locking protrusion 242 that extends around an outer surface of the sidewall 208. After the locking tabs 238 are pushed past the locking protrusion 242, the locking tabs 238 snap back into place and are held a distal surface of the locking protrusion 242. When in the locked position, the inner member 236 is prevented from being displaced proximally within the hub cover 228, but is permitted to rotate within the hub cover 228. Further, the inner surface 230 also prevents the spring 222 from biasing the inner member 226 upwards.

[0073] With reference to Fig. 29, a first locking arrangement of the adapter 200 includes a plurality of teeth 244 extending from the proximal end of an inner surface of the inner member 226. In one aspect, a total of four teeth 244 are provided on the inner surface of the inner member 226. The teeth 244 are spread in a circular pattern around the inner surface of the inner member 226. Each tooth 244 includes an angled portion 246a and a locking surface 246b that extend substantially perpendicular to an end of the angled portion 246a. It is also contemplated that fewer or additional teeth 244 may be provided on the inner member 226.

[0074] With reference to Fig. 28, the proximal end 206 of the housing 202 includes a plurality of apertures 248 corresponding to the teeth 244 of the inner member 226. The apertures 248 are defined in the proximal surface of the housing 202 and are configured to receive the teeth 244 of the inner member 226 when the inner member 226 is inserted in the hub cover 228. The apertures 248 are spaced in a circular pattern in the proximal surface of the housing 202. In one aspect, the apertures 248 extend through the entire proximal surface of the housing 202. In another aspect, the apertures 248 only extend through a portion of the proximal surface of the housing 202. In one aspect, four apertures 248 are defined in the proximal surface of the housing 202. Each aperture 248 includes an angled portion 250a and a locking surface 250b. It is also contemplated that corresponding teeth may be used in place of the apertures 248.

[0075] After the inner member 226 has been locked in the hub cover 228, the teeth 244 of the inner member 226 and the apertures 248 defined in the housing 202 are configured to interact so as to permit rotation of the inner member 226 within the hub cover 228 in a counterclockwise direction and prevent rotation of the inner member 226 within the hub cover 228 in a clockwise direction. As the inner member 226 is rotated in the counterclockwise direction, the teeth 244 of the inner member 226 continue to slide along the angled portions 250a of the apertures 248 of the housing 202 so that rotation of the inner member 226 is not prevented. Since the inner

member **226** can continue to rotate in the counterclockwise direction, any accidental or inadvertent rotation of a fluid line connected to the connector **236** is also prevented. In one example, this accidental or inadvertent rotation of the fluid line may occur when a syringe or IV line is being attached. When the inner member **226** is rotated in the clockwise direction, the locking surface **246b** of the teeth **244** of the inner member **226** are held against the locking surfaces **250b** of the apertures **248** of the housing **202** so that rotation of the inner member **226** within the hub cover **228** is prevented. Since the inner member **226** is prevented from rotating in the clockwise direction, the inner member **226** remains stationary when a fluid line is being connected to the connector **236** of the inner member **226**.

[0076] When the user wishes to remove the fluid path line from the connector **236**, the user can grip and press the hub cover **228** inwardly against the inner member **226**. Since the hub cover **228** is pressed against the inner member **226**, the inner member **226** is prevented from rotating in either the clockwise or counterclockwise direction. Since the inner member **226** is held stationary in the counterclockwise direction in particular, the user can rotate the fluid line on the connector **236** in a counterclockwise direction to permit removal of the fluid line from the connector **236**. The removal of the fluid line from the connector **236** requires the user to actively grip and press the hub cover **228** against the inner member **226**. Using this configuration, the fluid line cannot inadvertently rotate on the connector **236** to allow for an inadvertent removal of the fluid line from the connector **236**.

[0077] As shown in **Fig. 30**, in another aspect of the disclosure the grip indentations **214** provided on the housing **202** of the adapter **200** can also be provided on the housing **16** of the adapter **10** described above. Furthermore, in this aspect, the thumb stop **100** of **Fig. 21** can also be used on the inner member **28** of the adapter **10**.

[0078] With reference to **Figs. 31** and **32**, another locking arrangement between the inner member **226** and the hub cover **228** of the adapter **200** is described. As shown in **Fig. 31**, instead of the teeth **244** being provided on a proximal inner surface of the inner member **226**, the teeth **244** are provided on a distal end of the inner member **226**. The teeth **244** are formed on the distal end of the inner member **226** and include the angled portion **246a** and the locking surface **246b**. As shown in **Fig. 32**, corresponding teeth **252** are provided on an inner surface of the hub cover **228** to interact with the teeth **244** of the inner member **226** when the inner member **226** is locked in the hub cover **228**. The teeth **244** of the inner member **226** and the teeth **252** of the hub cover

228 interact to provide the same locking features that are provided by the teeth **244** of the inner member **226** and the apertures **248** of the housing **202**. The teeth **252** of the hub cover **228** include an angled portion **254a** and a locking surface **254b**. The locking surfaces **246b**, **254b** of the inner member **226** and the hub cover **228**, respectively, are configured to interact to prevent clockwise rotation of the inner member **226** within the hub cover **228**.

[0079] 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.