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TAMPER EVIDENT CAP WITH RFID FOR SYRINGES

Abstract

A syringe assembly includes a syringe with a tamper-evident cap over the Luer connection. The cap has a proximal end with an opening, a distal end, and a frangible connection between them. The frangible connection breaks under force, leaving the proximal end engaged with the syringe. An RFID tag on the syringe communicates with an RFID reader.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 17/235,909, filed Apr. 20, 2021, which is a continuation-in-part of U.S. patent application Ser. No. 16/850,396, filed Apr. 16, 2020, which is a continuation of U.S. patent application Ser. No. 16/409,203, filed May 10, 2019, which claims the benefit of U.S. Provisional Patent App. No. 62/772,461, filed Nov. 28, 2018, the disclosures of which are hereby incorporated by reference herein.

TECHNICAL FIELD

[0002] The present disclosure generally relates to tamper detection devices, and, more particularly, to a tamper evident cap with RFID capabilities for syringes filled with a material.

BACKGROUND

[0003] Syringe assemblies are used to hold, transport, and deliver materials. For example, syringes are often utilized in medical environments to administer one or more medicinal materials. Syringe assemblies may differ in size, and their specific dimensions are dictated by the desired application and the specific material to be administered. In some instances, syringes may be pre-filled with one or more materials that are then dispensed from the syringe and combined with other elements.

[0004] Many industrial applications require mechanisms that prevent tampering with a particular product. This is especially the case with syringes used in the medical profession, where it is important for medical staff and patients to be aware of any tampering with the syringe or the material contained therein. Existing technology for detecting and preventing tampering is often cumbersome, difficult to use, increases risks of injury to the user, and increase the likelihood of contaminating the patient or the medical environment. Further, the addition of a tampering device can often require changes to be made to the manufacturing process of a syringe or its constituent components, which increases associated production costs and complexity of manufacturing.

[0005] Therefore, there is a need for a tamper evident cap configured to be used with syringes having preexisting designs that are filled with a material.

[0006] Some industrial applications require identification or tracking of devices and materials. Within the medical field, it is important for staff to be aware of usage parameters of various medical devices or materials for proper storage, handling, and administration to patients. Existing technology for tracking medical devices and materials often relies on manual control and monitoring, which increase the likelihood of human error during the process. The existing technology is not automated, and tracking parameters cannot be easily controlled over the lifetime of the device or material. Furthermore, implementing such control processes after the device or material has been manufactured and prepared requires additional steps to be performed by the medical staff, as well as implementation of separate equipment and operating protocols.

[0007] Accordingly, there is a need for an identification and monitoring system configured to be used with medical devices, such as syringes filled with a medical material.

SUMMARY

[0008] An embodiment of the present disclosure is a syringe assembly comprising a syringe having a barrel body that extends from a proximal end to a distal end and defines a chamber extending along an axial direction therethrough, and a Luer connection extending from the distal end along

the axial direction and defining an outlet in fluid communication with the chamber, where the chamber contains a material. The syringe assembly includes a plunger received within the chamber of the syringe to create a fluid seal within the barrel body and a tip cap defining a central passage configured to receive a portion of the Luer connection such that the tip cap creates a fluid seal over the outlet. The syringe assembly also includes a tamper evident cap disposed over the Luer connection, the tamper evident cap having a main body that defines a proximal end defining an opening, a distal end opposite the proximal end along the axial direction, an outer surface, and an inner surface opposite the outer surface that defines a passage configured to receive the tip cap and the Luer connection, where he tamper evident cap is spaced from the tip cap. The main body further defines a frangible connection between the proximal and distal ends of the main body. The frangible connection is configured to break under a force applied to the distal end of the tamper evident cap such that the proximal end of the tamper evident cap is configured to remain engaged with the syringe when the frangible connection breaks. The syringe assembly further includes a radio-frequency identification (RFID) tag disposed on the syringe and configured to receive and store data related to the syringe assembly, The RFID tag includes an integrated circuit, configured to store electronic information thereon, and an antenna operatively connected to the integrated circuit and configured to receive a signal from an RFID reader to cause transmission of the electronic data to or from the integrated circuit.

[0009] Another embodiment of the present disclosure is a method of labeling a syringe assembly. The method comprises providing a label configured to be affixed to a syringe. The label includes a radio-frequency identification (RFID) tag, and the RFID tag has an integrated circuit and an antenna operatively connected to the integrated circuit. The method also includes transmitting a first set of data to the RFID tag and storing the first set of data in a memory of the integrated circuit of the RFID tag. The method further includes verifying the first set of data on the RFID tag. The method also includes transmitting a second set of data to the RFID tag and storing the second set of data in the integrated circuit, the second set of data being different from the first set of data.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The present application is further understood when read in conjunction with the appended drawings. For the purpose of illustrating the subject matter, there are shown in the drawings exemplary embodiments of the subject matter; however, the presently disclosed subject matter is not limited to the specific methods, devices, and systems disclosed. In the drawings:

[0011] FIG. **1** illustrates a perspective view of a syringe assembly in accordance with an embodiment of the present disclosure;

[0012] FIG. **2** illustrates a perspective view of a plunger rod and plunger of the syringe assembly shown in FIG. **1**;

[0013] FIG. **3** illustrates a perspective view of a syringe of the syringe assembly shown in FIG. **1**;

[0014] FIG. **4**A illustrates a side view of the syringe assembly shown in FIG. **1** with certain components removed for clarity, with the plunger and plunger rod in a first position;

[0015] FIG. **4**B illustrates a side view of the syringe assembly shown in FIG. **1** with certain components removed for clarity, with the plunger and plunger rod in a second position;

[0016] FIG. **5** illustrates an exploded view of a distal portion of the syringe assembly shown in FIG. **1**;

[0017] FIG. **6** illustrates a side view of a tamper evident cap of the syringe assembly shown in FIG. **1**;

[0018] FIG. **7** illustrates an expanded view of the encircled portion of the tamper evident cap shown in FIG. **6**;

[0019] FIG. **8** illustrates a cross-sectional view of a distal portion of the syringe assembly shown in FIG. **1**, taken along line **8**-**8** shown in FIG. **1**;
[0020] FIG. **9** illustrates a plurality of the syringe assemblies shown in FIG. **1**, each including films with different color-coded portions according to an embodiment of the present disclosure;
[0021] FIG. **10** illustrates a perspective view of a syringe assembly in accordance with another embodiment of the present disclosure;
[0022] FIG. **11** illustrates an exploded view of a distal portion of the syringe assembly shown in FIG. **10**;
[0023] FIG. **12** illustrates a side view of a tamper evident cap of the syringe assembly shown in FIG. **10**;
[0024] FIG. **13** illustrates an expanded view of the encircled portion of the tamper evident cap shown in FIG. **12**;
[0025] FIG. **14** illustrates a cross-sectional view of a distal portion of the syringe assembly shown in FIG. **10**, taken along line **10**-**10** shown in FIG. **10**;
[0026] FIG. **15**A illustrates a perspective view of a tamper evident cap according to another embodiment of the present disclosure;
[0027] FIG. **15**B illustrates a perspective view of a distal portion of a tamper evident cap according to another embodiment of the present disclosure;
[0028] FIG. **16** illustrates a process flow diagram of a method of filling a syringe with a material according to an embodiment of the present disclosure;
[0029] FIG. **17** illustrates a process flow diagram of a method of filling a syringe with material according to another embodiment of the present disclosure;
[0030] FIG. **18** illustrates a process flow diagram of a method of applying a tamper evident cap to a prefilled syringe according to an embodiment of the present disclosure;
[0031] FIG. **19** illustrates a perspective view of a syringe assembly with an RFID tag in accordance with an embodiment of the present disclosure;
[0032] FIG. **20**A illustrates an exploded perspective view of an RFID tag in accordance with an embodiment of the present disclosure;
[0033] FIG. **20**B illustrates a front perspective view of an RFID tag (shown in phantom) covered by a film in accordance with an embodiment of the present disclosure;
[0034] FIG. **21**A illustrates a front perspective view of an RFID tag in accordance with an embodiment of the present disclosure;
[0035] FIG. **21**B illustrates a schematic of an RFID tag in accordance with an embodiment of the present disclosure;
[0036] FIG. **22** illustrates a schematic of an RFID network in accordance with an embodiment of this disclosure; and
[0037] FIG. **23** illustrates a flow chart of a method of labeling a syringe assembly in accordance with an embodiment of this disclosure.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0038] Described herein is a syringe assembly **10**, **10**′ that includes a tamper evident cap **200**. Certain terminology is used to describe the syringe assembly **10**, **10**′ in the following description for convenience only and is not limiting. The words “right,” “left,” “lower,” “upper,” “proximal,” and “distal” designate directions in the drawings to which reference is made. The words “inner” and “outer” refer to directions toward and away from, respectively, the geometric center of the description to describe the syringe assembly **10**, **10**′ and related parts thereof. The words “axially” and “radially” refer to directions along the orthogonal axial and radial directions A, R, respectively. The terminology includes the above-listed words, derivatives thereof and words of similar import.
[0039] Referring to FIGS. **1**-**4**B, the syringe assembly **10** includes a syringe **100** having a barrel body **103**. The barrel body **103** can extend from a proximal end **100***a* to a distal end **100***b* along the axial direction A, and can be molded from a plastic. In one embodiment, the barrel body **103** can

comprise a substantially transparent material, such that a user of the syringe assembly **10** can monitor the material levels within the barrel body **103**, though barrel bodies **103** having various levels of opacity are contemplated. The barrel body **103** is depicted as comprising a substantially cylindrical shape, though the present disclosure is not intended to be limited to such. The barrel body **103** can be comprised of cyclic olefin copolymer (COC), cyclic olefin polymer (COP), glass, or various other materials. The barrel body **103** can have an outer surface **103***a* that extends from the proximal end **100***a* to the distal end **100***b* along the axial direction A, an inner surface **103***b* opposite the outer surface **103***a* that also extends from the proximal end **100***a* to the distal end **100***b* along the axial direction A, and a distal surface **103***c* that extends along the radial direction R at the distal end **100***b* of the barrel body **103**. The inner surface **103***b* of the barrel body **103** defines a chamber **109** that extends along the axial direction A from an opening **106** at the proximal end **100***a* to the Luer connection **120** at the distal end **100***b*, where the Luer connection **120** will be discussed further below. The chamber **109** is configured to receive and store a material, such as a liquid, for dispensing through the tip **126**. The syringe **100** also includes a flange **112** extending radially outwards from the proximal end **100***a* of the barrel body **103**, where the function of the flange **112** will be described further below. Though depicted as defining an oval shape with two flat, oppositely positioned sides, the flange **112** can define other shapes as desired.

[0040] The chamber **109** can be sized and configured to receive a plunger **50**, such that the plunger **50** is capable of sliding along the axial direction A through the chamber **109**. The plunger is configured to define the proximal-most extent to which the material can travel through the chamber **109**. The plunger **50** can have a substantially cylindrical body **53**, though the shape of the body **53** will generally conform to the shape of the chamber **109**. The body **53** can be comprised of a substantially flexible material such as rubber, though other embodiments are contemplated where the plunger defines other materials. The plunger **50** can further include a plurality of ridges **56** extending radially outwards from the body **53**. As shown, the plurality of ridges **56** extend substantially circumferentially around the body **53** and are aligned and spaced apart along the axial direction A. However, the ridges **56** can comprise different sizes, shapes, and arrangements in other embodiments. The ridges **56** can function to engage the inner surface **103***b* of the barrel body **103** of the syringe **100** so as to create a fluid seal between the plunger **50** and the syringe **100**. As the plunger **50** moves distally through the chamber **109** (such as from a first position shown in FIG. **4**A to a second position shown in FIG. **4**B), the plunger **50** can function to push material out of the chamber **109** through the tip **126**. Alternatively, as the plunger **50** moves proximally through the chamber **109**, the plunger **50** can function to draw material into the chamber **109** through the tip **126**.

[0041] The plunger **50** can define a bore **59** that extends into the body **53** from its proximal end. The bore **59** can be configured to engage a portion of a plunger rod **25**, which allows a user of the syringe assembly **10** to manually move the plunger **50** through the chamber **109** of the syringe **100** along the axial direction A. The plunger rod **25** extends from a proximal end **25***a* to a distal end **25***b* opposite the proximal end **25***a* along the axial direction A. The plunger rod **25** can comprise a rod body **28** at its center, where the rod body **28** comprises an elongated, axially-extending rod. Connected to the rod body **28**, the plunger rod **25** can include a plurality of walls **31** extending radially outwards from the rod body **28**. As depicted, each of the walls **31** defines a substantially rectangular body that extends radially outwards from the rod body **28** and axially along the length of the rod body **28**. The plunger rod **25** is shown as including four walls **31**, where the walls **31** are arranged about the rod body **28** circumferentially spaced apart 90 degrees, such that the arrangement of walls **31** forms a substantially plus-shaped orientation. However, the plunger rod **25** can include more or less walls **31** in other embodiments, and thus other arrangements of walls **31** can define other shapes. Additionally, it is contemplated that the walls **31** can define other shapes or extend to different extents along the axial length of the rod body **28** or radially outwards from the rod body **28**. The walls **31** define a height along the radial direction R that is less than the diameter

of the chamber **109**, so that the plunger rod **25** can freely move along the axial direction A within the chamber **109**, and the walls **31** may or may not contact the inner surface **103***b* of the syringe **100**. The walls **31** can function to provide stability and strength to the plunger rod **25**, while minimizing the cross-sectional footprint of the plunger rod **25** so as to reduce material requirements for the plunger rod **25**, thus reducing overall weight of the syringe assembly **10**.

[0042] The rod body **28**, as well as the walls **31**, can extend from a first flange **34** positioned at the distal end **25***b* of the plunger rod **25** to a second flange **37** positioned at the proximal end **25***a* of the plunger rod **25**. Each of the first and second flanges **34**, **37** can be substantially cylindrically shaped, though other shapes are contemplated. The plunger rod **25** can also include a connection extension **40** that extends from the distal end **25***b* along the axial direction A from the first flange **34** in a direction opposite the rod body **28**. The connection extension **40** is configured to be received within the bore **59** of the plunger **50** so as to couple the plunger **50** to the distal end **25***b* of the plunger rod **25**. To strengthen this connection, the connection extension **40** can define a plurality of barbs **43** extending outwards along the radial direction R. The barbs **43** increase in diameter as they extend proximally along the axial length of the connection extension **40**. These barbs **43** allow the connection extension **40** to be easily inserted into the bore **59** of the plunger **50** in a first axial direction, but upon attempted removal of the connection extension **40** from the bore **59**, the barbs **43** will engage the wall of the bore **59**, thus preventing disengagement of the plunger **50** from the plunger rod **25**. Though one method of engagement between the plunger **50** and plunger rod **25** is shown, other methods are contemplated, such as forming the plunger **50** onto the plunger rod **25**, a simple interference fit, threaded engagement, snap-fit, etc.

[0043] Once the plunger **50** and the distal end **25***b* of the plunger rod **25** are inserted into the chamber **109** of the syringe **100**, the proximal end **25***a* of the plunger rod **25** being located outside the chamber **109**, the plunger rod **25** can be used to control dispensing of the material from within the chamber **109**. In operation, movement of the plunger rod **25**, and thus the plunger **50**, distally through the chamber **109** along the axial direction A forces material to flow out of the chamber **109** through the tip **126**. To do this, a user can, using one hand, pull the flange **112** of the syringe **100** and the second flange **37** of the plunger rod **25** towards each other. Conversely, movement of the plunger rod **25**, and thus the plunger **50**, proximally through the chamber **109** along the axial direction A draws material into the chamber **109** through the tip **126**. To do this, a user can, using one or two hands, push the flange **112** of the syringe **100** and the second flange **37** of the plunger rod **25** away from each other.

[0044] Referring to FIGS. **3-5** and **8**, the Luer connection **120** of the syringe **100** will be described in greater detail. The Luer connection **120** can extend from the distal end **100***b* of the barrel body **103** along the axial direction A. In particular, the Luer connection **120** can extend from the distal surface **103***c* of the barrel body **103** along the axial direction A. At the center of the Luer connection **120**, the Luer connection **120** includes a tip **126** that extends from the distal end **100***b* of the barrel body **103** along the axial direction A. As depicted, the tip **126** takes the form of a tapered, hollow tube, though other embodiments of the tip **126** are contemplated, such as a cylindrical, hollow tube. The tip **126** has an outer surface **126***a* and an inner surface **126***b* opposite the outer surface **126***a*, where the inner surface **126***b* defines a passage **132** that extends through the tip **126**. The passage **132** can extend from the chamber **109** of the syringe **100** to an outlet **135** of the Luer connection **120**. As the passage **132** and the outlet **135** are in fluid communication with the chamber **109**, the passage **132** and the outlet **135** thus define the pathway for material being dispensed from the chamber **109** of the syringe **100**.

[0045] The Luer connection **120** further includes an outer wall **123** that extends from the distal end **100***b* of the barrel body **103** along the axial direction A. As depicted, the outer wall **123** takes the form of a substantially cylindrical, hollow tube, though other embodiments of the outer wall **123** are contemplated, such as a tapered, hollow tube. The outer wall **123** has an outer surface **123***a* and an inner surface **123***b* opposite the outer surface **123***a*. As depicted, the outer surface **123***a* is

smooth, though other embodiments of the outer surface **123***a* are contemplated, e.g., ridged or otherwise textured. Similarly, the inner surface **123***b* is depicted as smooth, though other embodiments of the inner surface **123***b* also are contemplated, e.g., threaded (female or male). The outer wall **123** extends circumferentially around the tip **126**, such that the inner surface **123***b* of the outer wall **123** faces the outer surface **126***a* of the tip **126**. As a result, a gap **129** can be defined between the outer wall **123** and the tip **126**, specifically between the inner surface **123***b* of the outer wall **123** and the outer surface **126***a* of the tip **126**. The gap **129** can be configured to receive a portion of the tip cap **150**, as will be described further below.

[0046] Now referring to FIGS. **5** and **8**, after the syringe **100** has been filled, the outlet **135** needs to be sealed so as to prevent material from leaking out of the chamber **109**. To do this, a tip cap **150** can be attached to the Luer connection **120** so as to seal the outlet **135**. The tip cap **150** can extend from a proximal end **150***a* to a distal end **150***b* opposite the proximal end **150***a* along the axial direction A. As depicted, the proximal end **150***a* defines an opening **158**, whereas the distal end **150***b* is closed. The tip cap **150** can define a central passage **154** extending along the axial direction A into the tip cap **150** from the opening **158**. The tip cap **150** can further define a ridge **162** extending radially outwards from the outer surface of the tip cap **150**, and substantially continuously around the entirety of the perimeter of the tip cap **150**. However, in other embodiments, the ridge **162** may only extend partially around the perimeter of the tip cap **150**, or may not be present at all. Further, a plurality of ribs **166** can extend radially outwards from the outer surface of the tip cap **150** distal to the ridge **162**. The ribs **166** can be arranged circumferentially around the tip cap **150** so as to provide a texture for grasping by a user of the syringe assembly **10**. Though one embodiment of ribs **166** are shown, the present disclosure is not intended to be limited to such.

[0047] In operation, as stated previously, the tip cap **150** is configured to be attached to the Luer connection **120** of the syringe **100** so as to create a fluid seal over the outlet **135**. To accomplish this, after the syringe **100** has been filled during assembly, the tip cap **150** can be pushed into the Luer connection **120** with a force along the axial direction A, such that the central passage **154** of the tip cap **150** receives the tip **126** of the Luer connection **120** and the portion of the tip cap **150** proximal to the ridge **162** is disposed in the gap **129** defined between the outer wall **123** and the tip **126**. Due to spacing of the wall **123** and tip **126** and the thickness of the tip cap **150**, as well as the diameter of the passage **132** of the tip cap **150** relative to the diameter of the tip **126**, the tip cap **150** can be secured to the Luer connection **120** through an interference fit. In other embodiments, the inner surface **123***b* comprises threads (female or male), the external portion of the tip cap **150** proximal to the ridge **162** comprises complementary threads, and the tip cap **150** is secured to the Luer connection **120** through a screw-in fit. The ridge **162** can contact the upper surface of the outer wall **123** so as to limit the extent to which the tip **126** can be disposed in the passage **132**. Once disposed into the Luer connection **120**, the outlet **135** can be located at a distal-most part of the passage **132** and the tip **126** can engage the inner surface of the passage **132**, thus creating a fluid seal over the outlet **135**.

[0048] Now referring to FIGS. **1** and **5-8**, the tamper evident cap **200** will be discussed in detail. The tamper evident cap **200** can include a main body **204** that extends from a proximal end **200***a* to a distal end **200***b* opposite the proximal end **200***a* along the axial direction A. The main body **204** can be configured as a substantially hollow cylinder, though other shapes are contemplated, as the shape of the tamper evident cap **200** can vary according to the shape of the syringe **100**, and specifically the Luer connection **120**. The tamper evident cap **200** can be formed through injection molding, and can comprise a plastic such as medical grade polypropylene, polycarbonate, or polyethylene terephthalate. However, other methods of forming the tamper evident cap **200** and other materials for forming the tamper evident cap **200** are contemplated. The main body **204** defines an outer surface **204***a* and an inner surface **204***b* opposite the outer surface **204***a*, where the inner surface **204***b* defines a passage **208** configured to receive the Luer connection **120** and the tip

cap **150**. The distal end **200***b* of the main body **204** can be closed, whereas the proximal end **200***a* can define an opening **212**, where the passage **208** extends from the opening **212** along the axial direction A and terminates within the main body **204** at a location proximal to the distal end **200***b*. However, in other embodiments the distal end **200***b* of the main body **204** can be open. In yet other embodiments, the distal end **200***b* of the main body **204** can be partially closed.

[0049] The proximal end **200***a* of the main body can define a collar **216** that substantially surrounds the Luer connection **120** when the tamper evident cap **200** is disposed over the Luer connection **120**, as will be discussed further below. As depicted, the collar **216** defines a substantially annular disc, though it is contemplated that the collar **216** can define other shapes as desired. The collar **216** can have a proximal surface **216***a*, a distal surface **216***b* opposite the proximal surface **216***a* along the axial direction A, an outer surface **216***c* that extends from the proximal surface **216***a* to the distal surface **216***b*, and an inner surface **216***d* opposite the outer surface **216***c*. In the depicted embodiment, the outer surface **216***c* of the collar **216** can comprise a portion of the outer surface **204***a* of the main body **204**, and the inner surface **216***d* can comprise a portion of the inner surface **204***d* of the main body **204**. The collar **216** can define a plurality of internal ribs **240** that extend radially inwards from the inner surface **216***d* and are positioned circumferentially around the inner surface **216***d*. Though one particular number and arrangement of internal ribs **240** is shown, other numbers and arrangements are contemplated. For example, though the internal ribs **240** are depicted as being substantially equidistantly spaced apart, non-equidistant spacing of the internal ribs **240** is contemplated. In other embodiments, the inner surface **216***d* is substantially smooth, i.e., lacking any internal ribs.

[0050] In operation, the tamper evident cap **200** can be attached to the syringe **100** by pressing the tamper evident cap **200** over the Luer connection **120** and the tip cap **150** via a force applied along the axial direction A. The internal ribs **240** can be configured such that, when this occurs, the internal ribs **240** of the tamper evident cap **200** form an interference fit with the Luer connection **120**, specifically the outer surface **123***a* of the outer wall **123** of the Luer connection **120**. This interference fit can cause the tamper evident cap **200**, and particularly the proximal end **200***a*, to resist disengagement from the Luer connection **120** as a result of a distally or rotationally applied force to the tamper evident cap **200**. In addition to the interference fit, in other embodiments it is contemplated that the collar **216** can be attached to the Luer connection **120** and/or another portion of the syringe **100** via a sonic weld, adhesive, gripping material, etc. In certain embodiments, the tamper evident cap **200** is further secured to the Luer connection **120** by a film **244** disposed over the collar **216** or a portion thereof, as discussed further below.

[0051] In some embodiments, the proximal surface **216***a* of the collar **216** can abut the distal surface **103***c* of the syringe **100** when the tamper evident cap **200** is fully disposed over the Luer connection **120**. This can function to limit the axial movement of the tamper evident cap **200** in relation to the syringe **100** and indicate to the user of the syringe assembly **10** that the tamper evident cap **200** is fully in place. Notably, the outer diameter of the collar **216** may not extend out past the outer diameter of the outer surface **103***a* of the barrel body **103**, and as well as not extend proximally past the distal surface **103***c*. As a result, the collar **216** can be spaced in an entirety from the outer surface **103***a* of the barrel body **103**. Because of this, a user of the syringe assembly **10** maintains a complete line of sight to the material within the chamber **109** of the syringe **100**, thus allowing the user to be constantly aware of the amount of material within the syringe **100**. The collar **216** does not prevent the user from viewing any portion of the material within the chamber **109**, as well as the distal end of the plunger **50** to determine whether material is still trapped within the chamber **109** between the plunger **50** and the syringe **100**. In other embodiments, the proximal surface **216***a* of the collar **216** can approach, but not abut, the distal surface **103***c* of the syringe **100** when the tamper evident cap **200** is fully disposed over the Luer connection **120**, thereby forming a gap between the proximal surface **216***a* of the collar **216** and the distal surface **103***c* of the syringe **100**. In yet other embodiments, the proximal surface **216***a* of the collar **216** can overlap the distal

surface **103***c* of the syringe **100** when the tamper evident cap **200** is fully disposed over the Luer connection **120**.

[0052] In certain embodiments, when the tamper evident cap **200** is attached to the Luer connection **120**, the tamper evident cap **200** can be spaced in an entirety from the tip cap **150**, such that a gap is formed between the tamper evident cap **200** and the tip cap **150** and no portion of the tamper evident cap **200** contacts the tip cap **150**. This lack of engagement between the tamper evident cap **200** and the tip cap **150** allows the tamper evident cap **200** to be used simply with existing syringe **100** and tip cap **150** assemblies without interfering with the seal the tip cap **150** creates with the Luer connection **120**. Other tamper evident cap designs can require complete redesign of the syringe and/or tip cap, which requires additional tooling for manufacture, thus increasing total manufacturing cost and complexity. The tamper evident cap **200** of the present applications presents none of these difficulties. Additionally, this spacing prevents the distal end **200***b* of the tamper evident cap **200** from being reattached to the syringe assembly **10** after the frangible connection **218** between the proximal and distal ends **200***a*, **200***b* has broken, as will be discussed below.

[0053] However, in other embodiments, a portion of the tamper evident cap **200** is in contact with the tip cap **150**. For example, in some embodiments, the inner surface **204***b* at the distal end **200***b* can contact the distal end **150***b* of the tip cap **150** when the tamper evident cap **200** is fully disposed over the Luer connection **120**. In other embodiments, at least a portion of the inner surface **204***b* along the axial direction A between the frangible connection **218** and the distal end **200***b* of the tamper evident cap **200** contacts an outer surface of the tip cap **150** when the tamper evident cap **200** is fully disposed over the Luer connection **120**. Preferably, any contact between the tamper evident cap **200** and the tip cap **150** is such that the fluid seal over the outlet **135** is not compromised by the attachment of the tamper evident cap **200** to the syringe **100** or the decoupling of the distal end **200***b* upon breakage of the frangible connection **218**.

[0054] Continuing with FIGS. **1** and **5-8**, the tamper evident cap **200** can include a frangible connection **218** positioned axially between the proximal and distal ends **200***a*, **200***b* of the main body **204**. The frangible connection **218** is configured to be the portion of the tamper evident cap **200** that enables the tamper evident cap **200** to indicate to a user whether the syringe assembly **10** has been tampered with. When the tamper evident cap **200** is attached to the Luer connection **120**, the frangible connection **218** is configured to break under a force applied to the distal end **200***b* of the main body **204**. This force can be a clockwise or counter-clockwise rotational force, or any other force as desired. As a result, the distal end **200***b* will be decoupled from the proximal end **200***a*, and the proximal end **200***a* of the main body **204** will remain attached to the Luer connection **120** of the syringe **100** as when the frangible connection **218** breaks. The frangible connection **218** is thus designed such that the force required to break the frangible connection **218** is less than the force required to decouple the proximal end **200***a* from the Luer connection **120**. If a user of the syringe assembly **10** sees that the frangible connection **218** of the tamper evident cap **200** is broken, the user knows that the material within the chamber **109** of the syringe **100** may have been tampered with. However, if the frangible connection **218** is intact, the user can be assured of a greatly reduced risk that the material has been tampered with.

[0055] The frangible connection **218** comprises a plurality of frangible bridges **224** positioned circumferentially around the main body **204**. The frangible bridges **224** can be positioned around an entirety of the circumference of the main body **204**, such that when the frangible connection **218** breaks, the distal end **200***b* of the main body **204** can be completely separated from the proximal end **200***a*. Each of the frangible bridges **224** can comprise a thin portion of the main body **204** that tapers inwards in width as it extends proximally. However, it is contemplated that the frangible bridges **224** can be alternatively configured. For example, the frangible bridges **224** can be configured as substantially elongate body portions having a constant width. Further, the frangible bridges **224** can be equidistantly spaced about the circumference of the main body **204**.

[0056] The frangible connection **218** can also define a plurality of gaps **220** that extend through the main body **204** from the outer surface **204***a* to the inner surface **204***b*, where a gap **220** can extend circumferentially between two frangible bridges **224**. Though each of the gaps **220** is shown as having a particular design, each of the gaps **220** can vary in design and spacing along with the design and spacing of each frangible bridge **224**. The inclusion of the frangible bridges **224** and gaps **220** allows the tamper evident cap **200** to be easily broken at the frangible connection **218**. The tamper evident cap **200** can also include at least one protrusion **236** that extends distally into the gap **220**, where the protrusion **236** can be useful during the injection molding of the tamper evident cap **200**. For example, the depicted tamper evident cap **200** includes two protrusions **236**, though more or less than two protrusions are contemplated. Also, embodiments of the tamper evident cap **200** without the protrusions **236** are contemplated.
[0057] The tamper evident cap **200** can also include a plurality of external ribs **228** that extend outwards from the outer surface **204***a* of the main body **204** at the proximal end **200***a* along the radial direction. Each of the external ribs **228** can substantially define a rectangular prism, and the external ribs **228** can be equidistantly spaced circumferentially around the proximal end **200***a* of the main body **204**. However, it is contemplated that the external ribs **228** can define alternate shapes, or can be non-equidistantly spaced around the proximal end **200***a* of the main body **204**. The external ribs **228** can be configured to secure a film **244** to the collar **216** of the tamper evident cap **200**, as will be discussed further below. The tamper evident cap **200** can also include a plurality of ribs **232** that extend outwards from the outer surface **204***a* of the main body **204** at the distal end **200***b* along the radial direction. As depicted, each of the ribs **232** can define a substantially hemispherical extension, and each of the ribs **232** can be equidistantly spaced circumferentially around the distal end **200***b* of the main body **204**. However, it is contemplated that the ribs **232** can define alternate shapes, or can be non-equidistantly spaced around the distal end **200***b* of the main body **204**. The ribs **232** can allow for the distal end **200***b* of the main body **204** to be easily grasped by a user so as to allow the user to twist the tamper evident cap **200** to break the frangible connection **218**.
[0058] Now referring to FIGS. **1**, **8**, and **9**, the syringe assembly **10** can include a film **244** disposed over portions of the syringe assembly **10**. The film **244** can define a substantially continuous, solid body and extend from a proximal end **244***a* to a distal end **244***b* opposite the proximal end **244***a* along the axial direction A. In the depicted embodiment, the proximal end **244***a* of the film **244** can be disposed around a portion of the barrel body **103** of the syringe **100**, while the distal end **244***b* of the film **244** can be disposed around a portion of the tamper evident cap **200**. Specifically, the distal end **244***b* of the film **244** can be disposed around the proximal end **200***a* of the tamper evident cap **200** to further secure the tamper evident cap **200** to the Luer connection **120**. In certain embodiments, the film **244** may extend on the syringe **100** for a length equal or more than 5 mm, e.g., 10 mm, 15 mm, 20 mm, 30 mm, or more, as measured from the distal end **100***b* of the syringe **100**. Alternatively, or additionally, the film **244** may extend onto the syringe **100** for a length equal to or more than 10%, e.g., 20%, 40%, 60%, or more of the length of the syringe barrel body **103**. In certain embodiments, the film **244** may extend on the tamper evident cap **200** for a length equal to or more than 2 mm, e.g., 3 mm, 4 mm, 5 mm, 6 mm, or more, as measured from the proximal end **200***a*. Alternatively, or additionally, the film **244** may extend onto the tamper evident cap **200** for a length equal to or more than 10%, e.g., 20%, 40%, 60%, or more of the length of the tamper evident cap **200**. In other embodiments, the film **244** is continuous through at least a distal portion of the syringe **100** and the entire proximal end **200***a* of the main body **204** of the tamper evident cap **200**. In certain embodiments, the film **244** does not extend over the frangible connection **218** or the distal end **200***b* of the main body **204** of the tamper evident cap **200**.
[0059] The film **244** can be blank, or the film **244** can be printed or written on so as to display information related to the type of the material contained within the chamber **109** of the syringe **100**. Examples of the type of information that can be printed on the film **244** includes the material's

chemical name, generic name, proprietary name, concentration, total volumetric content within the syringe **100**, manufacturer, lot number, date of manufacture, and expiration date. The film **244** can also be bar coded with any combination of this information. The film **244** can be fully transparent, partially transparent, or substantially opaque.

[0060] In some embodiments, the film **244** is a heat-shrinkable film made of a thermoplastic material selected from the group consisting of polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), polyethylene terephthalate (PET), oriented polystyrene (OPS), oriented polypropylene (OPP), polylactic acid (PLA) and mixtures thereof. In certain embodiments, the film **244** is made of PVC. In certain embodiments, the interior surface of the film **244** or a portion thereof further comprises an adhesive material, such as a glue or a heat-activated adhesive. In certain embodiments, the interior surface of the distal end **244***b* of the film **244** can be disposed around a portion of the tamper evident cap **200** comprising an adhesive material.

[0061] The film **244** can also include a color-coded portion **248** that is indicative of the type of material contained within the chamber **109** of the syringe **100**. This allows the user of the syringe assembly **10** to easily determine what material is within the syringe **100** and helps avoid incorrect medicaments from being mistakenly applied to a patient. In one embodiment, the color-coded portion **248** can comprise a substantially solid band positioned near the distal end **244***b* of the film **244** and extending circumferentially around the film **244**. However, alternative placements, shapes, and sizes of the color-coded portion **248** are contemplated. Examples of syringe assemblies **10** having films **244** with various colored color-coded portions **248**, **248′**, **248″**, **248‴**, **248⁗** are shown in FIG. **9**. The color-coded portion **248** can comprise a color selected from a plurality of colors that each correspond to a different material. The relationship between the color of the color-coded portion **248** and the material contained within the syringe **100** can conform to the labeling standards set by ASTM D4774, such that the color-coded portion **248** can be universally recognized and understood within any variety of medical environments. The standards set by ASTM D4774 are shown in the below table. The examples provided for each drug class are exemplary only and not meant to be exhaustive. Drugs that do not fit into the classes shown in Table I can be labeled with black printing on a white background under ASTM D4774 standards. Exceptions are noted by the “A” superscript.

TABLE-US-00001 TABLE 1 ASTM D4774 Standards Drug Class Examples Pantone Color Induction Agents Etomidate, Ketamine, Yellow Methohexital, Propofol, Thiamylal, Thiopental Benzodiazepines Diazepam, Midazolam Orange 151 Benodiazepine Flumazenil Orange 151 and Receptor White Diagonal Antagonist Stripes Muscle Relaxants Succinylcholine.sup.A Fluorescent (Depolarizer) Red 805 Muscle Atracurium, Fluorescent Relaxants (Non Cisatracurium, Mivacurium, Red 805 Depolarizer) Pancuronium, Rocuronium, Vecuronium Relaxant Endophonium, Fluorescent Red Antagonist Neostigmine, Pyridostigmine 805 and White (Non-Diagonal Stripes Depolarizer) Narcotics Alfentanil, Fentanyl, Blue 297 Hydromorphone, Meperidine, Morphine, Sufentanil, Remifentanil Narcotic Levallorphan, Naloxone Blue 297 and Antagonists White Diagonal Stripes Vasopressors Ephedrine, Violet 256 Norepinephrine, Phenylephrine, Epinephrine.sup.A Hypotensive Hydralazine, Violet 256 and Agents Nitroglycerine, Nitroprusside, White Diagonal Phentolamine, Trimethaphan Stripes Local Anesthetics Bupivacaine, Gray 401 Chloroprocaine, Lidocaine, Mepivacaine, Procaine, Ropivacaine, Tetracaine Anticholinergic Atropine, Glycopyrrolate, Green 367 Agents Scopolamine Beta Blockers Esmolol, Labetalol, White Background Metroprolol with Copper 876U Bar Across Drug Name Major Droperidol, Inapsine, Salmon 156 Tranquilizers and Haloperidol, Anti-Emetics Levomepromazine, Metoclopramide, Ondasetron .sup.APrinted against the background color as reversed plate letters with a black bar running from edge to edge of the film

[0062] Though the film **244** is described as including a color-coded portion **248**, it is also contemplated that in other embodiments all or a portion of the main body **204** of the tamper evident cap **200** defines a color-coded portion that is indicative of the type of material within the chamber

109 of the syringe **100** in combination with or in place of the color-coded portion **248**. Like the color-coded portion **248**, the color-coded portion of the tamper evident cap **200** can comprise a color selected from a plurality of colors that each correspond to a different material. This can be done through molding the color-coded portion of the tamper evident cap **200** out of a different material or a differently colored variety of the same material as the rest of the tamper evident cap **200**. In one embodiment, the collar **216** of the tamper evident cap **200** can define the color-coded portion, though other sections of the tamper evident cap **200** can define the color-coded portion as desired. Like the color-coded portion **248**, the color coded portion of the tamper evident cap **200** can conform to the labeling standards set by ASTM D4774.

[0063] As stated above, the proximal end **244***a* of the film **244** can be disposed around a portion of the barrel body **103** of the syringe **100**, while the distal end **244***b* of the film **244** can be disposed around a portion of the tamper evident cap **200**. The film **244** can be fitted over the tamper evident cap **200** and the syringe **100** such that the film **244** is configured to secure the proximal end **200***a* of the tamper evident cap **200** to the syringe **100** when the frangible connection **218** breaks. In particular, the external ribs **228** on the proximal end **200***a* can engage the film **244** so as to ensure that the film **244** retains the proximal end **200***a* attached to the syringe **100**. In one embodiment, this engagement is formed by shrink-wrapping the film **244** over the proximal end **200***a* of the tamper evident cap **200** and at least a portion of the syringe **100**. In other embodiments, the film **244** is adhesive-bonded to the proximal end **200***a* of the tamper evident cap **200** and at least a portion of the barrel body **103**. In yet other embodiments, the film **244** is secured to the proximal end **200***a* of the tamper evident cap **200** and at least a portion of the barrel body **103** by a combination of shrink-wrapping and adhesive-bonding. In addition to the above-described methods of attaching the film **244** to the tamper evident cap **200** and the syringe **100**, various other methods of attaching the film **244** may be utilized as desired.

[0064] In certain embodiments, the assembly further comprises a label (not shown) which is attached to at least a portion of the barrel body **103** of the syringe **100**. The label can be blank, or the label can be printed or written on so as to display information related to the type of the material contained within the chamber **109** of the syringe **100**. Examples of the type of information that can be printed on the label includes the material's chemical name, generic name, proprietary name, concentration, total volumetric content within the syringe **100**, manufacturer, lot number, date of manufacture, and expiration date. The label can also be bar coded with any combination of this information. The label can be colored or partially colored, and the label can be fully transparent, partially transparent, or substantially opaque. The label can be comprised of paper, a heat-shrinkable material, an adhesive, or any other suitable materials. In some embodiments, the label is imprisoned between at least a portion of the film **244** and the syringe **100**.

[0065] Now referring to FIGS. **10-14**, another embodiment of a syringe assembly **10′** will be discussed in detail, where the syringe assembly **10′** includes an alternative embodiment of a tamper evident cap **300**. The syringe assembly **10′** can include a plunger rod **25**, plunger **50**, and syringe **100** that are substantially similar to that of the syringe assembly **10**. As such, these components will not be described again here for brevity. The tamper evident cap **300** can include a main body **304** that extends from a proximal end **300***a* to a distal end **300***b* along the axial direction A. The main body **304** can be configured as a substantially hollow cylinder, though other shapes are contemplated, as the shape of the tamper evident cap **300** can vary according to the shape of the syringe **100**, and specifically the Luer connection **120**. Like the tamper evident cap **200**, the tamper evident cap **300** can be formed through injection molding, and can comprise a plastic such as medical grade polypropylene, polycarbonate, or polyethylene terephthalate. However, other methods of forming the tamper evident cap **300** and other materials for forming the tamper evident cap **300** are contemplated. The main body **304** defines an outer surface **304***a* and an inner surface **304***b* opposite the outer surface **304***a*, where the inner surface **304***b* defines a passage **308** configured to receive the Luer connection **120** and the tip cap **150**. The distal end **300***b* of the main

body **304** can be closed, opened, or partially closed, whereas the proximal end **300***a* can define an opening **312**, where the passage **308** extends from the opening **312** along the axial direction A and terminates within the main body **304** at a location proximal to the distal end **300***b*. The inner surface **304***b* of the main body **304**, and thus the passage **308**, can define a first diameter D.sub.1 that extends along the radial direction R, while the outer surface **123***a* of the outer wall **123** of the Luer connection **120** can define a second diameter D.sub.2 that extends along the radial direction R, where the second diameter D.sub.2 can be larger than the first diameter D.sub.1. The reasoning for this diameter discrepancy will be discussed further below.

[0066] In operation, the tamper evident cap **300** can be attached to the syringe **100** by pressing the tamper evident cap **300** over the Luer connection **120** and the tip cap **150** via a force applied along the axial direction A. When this occurs, the inner surface **304***b* of the main body **304** of the tamper evident cap **300** will form an interference fit with the Luer connection **120**, specifically the outer surface **123***a* of the outer wall **123** of the Luer connection **120**. This interference fit can cause the tamper evident cap **300**, and particularly the proximal end **300***a*, to resist being disengaged from the Luer connection **120** as a result of a distally or rotationally applied force. Due to the difference between the first and second diameters D.sub.1, D.sub.2, the main body **304** may be forced to bend outwards as it is disposed over the Luer connection **120**, which can strengthen the interference fit. Further, in one embodiment, to strengthen the interference fit a gripping material **314** may be attached to the inner surface **304***b* of the main body **304** at the proximal end **300***a*. The gripping material **314**, which can be an adhesive or rubber, can engage the Luer connection **120** and thus aid in preventing relative rotation or axial movement between the proximal end **300***a* of the main body **304** and the syringe **100**. However, it is contemplated that the tamper evident cap **300** can be devoid of any gripping material **314**. Additionally, in other embodiments the proximal end **300***a* of the main body **304** can be attached to the Luer connection **120** via a sonic weld. In certain embodiments, the tamper evident cap **300** is further secured to the Luer connection **120** by a film **244** as discussed hereinabove.

[0067] When the tamper evident cap **300** is attached to the Luer connection **120**, the tamper evident cap **300** can be spaced in an entirety from the tip cap **150**, such that a gap is formed between the tamper evident cap **300** and the tip cap **150** and no portion of the tamper evident cap **300** contacts the tip cap **150**. This lack of engagement between the tamper evident cap **300** and the tip cap **150** allows the tamper evident cap **300** to be used simply with existing syringe **100** and tip cap **150** assemblies without interfering with the seal the tip cap **150** creates with the Luer connection **120**. Other tamper evident cap designs can require complete redesign of the syringe and/or tip cap, which requires additional tooling for manufacture, thus increasing total manufacturing cost and complexity. The tamper evident cap **300** of the present application presents none of these difficulties. Additionally, this spacing prevents the distal end **300***b* of the tamper evident cap **300** from being reattached to the syringe assembly **10**′ after the frangible connection **318** between the proximal and distal ends **300***a*, **300***b* has broken, as will be discussed below.

[0068] The tamper evident cap **300** can also include a ridge **316** that extends radially outwards from the proximal end **300***a* of the main body **304**. The ridge **316** can have a proximal surface **316***a*, a distal surface **316***b* opposite the proximal surface **316***a* along the axial direction A, and a side surface **316***c* that extends from the proximal surface **316***a* to the distal surface **316***b*. Though depicted as a substantially annular disc, it is contemplated that the ridge **316** can define other shapes as desired. When the tamper evident cap **300** is engaged with the Luer connection **120**, the proximal surface **316***a* of the ridge **316** can abut the distal surface **103***c* of the barrel body **103** of the syringe **100** so as to limit the axial movement of the tamper evident cap **300** and indicate to the user of the syringe assembly **10**′ that the tamper evident cap **300** is fully in place. Notably, the diameter of the ridge **316** may not extend out past the diameter of the outer surface **103***a* of the barrel body **103**, and as well as not extend proximally past the distal surface **103***c*. As a result, the ridge **316** can be spaced in an entirety from the outer surface **103***a* of the barrel body **103**. Because

of this, a user of the syringe assembly **10′** maintains a complete line of sight with the material within the chamber **109** of the syringe **100**, thus allowing the user to be constantly aware of the amount of material within the syringe **100**. The ridge **316** does not prevent the user from viewing any portion of the material within the chamber **109**.

[0069] Continuing with FIGS. **10-14**, the tamper evident cap **300** can include a frangible connection **318** positioned axially between the proximal and distal ends **300***a*, **300***b* of the main body **304**. The frangible connection **318** is configured to be the portion of the tamper evident cap **300** that enables the tamper evident cap **300** to indicate to a user whether the syringe assembly **10′** has been tampered with. When the tamper evident cap **300** is attached to the Luer connection **120**, the frangible connection **318** is configured to break under a force applied to the distal end **300***b* of the main body **304**. The force can be a clockwise or counter-clockwise rotational force, though other forces are contemplated. As a result, the distal end **300***b* will be decoupled from the proximal end **300***a*, and the proximal end **300***a* of the main body **304** will remain attached to the Luer connection **120** of the syringe **100** when the frangible connection **318** breaks. The frangible connection **318** is thus designed such that the force required to break the frangible connection **318** is less than the force required to decouple the proximal end **300***a* from the Luer connection **120**. If a user of the syringe assembly **10′** sees that the frangible connection **318** of the tamper evident cap **300** is broken, the user knows that the material within the chamber **109** of the syringe **100** may have been tampered with. However, if the frangible connection **318** is intact, the user can be assured of a greatly reduced risk that the material has been tampered with.

[0070] The frangible connection **318** comprises a plurality of frangible bridges **324** positioned circumferentially around the main body **304**. The frangible bridges **324** can extend around an entirety of the circumference of the main body **304**, such that when the frangible connection **318** breaks, the distal end **300***b* of the main body **304** can be completely separated from the proximal end **300***a*. Each of the frangible bridges **324** can comprise a thin, elongate portion of the main body **304** having a height H measured along the axial direction A, a width W measured along the circumference of the main body **304**, and a thickness T measured along the radial direction R. The thickness T of the frangible bridges **324** can be consistent with the thickness of the rest of the main body **304**, though it is contemplated that the frangible bridges **324** may be thinner than the rest of the main body **304** so as to promote easier breaking. Also, the frangible bridges **324** can be equidistantly spaced about the circumference of the main body **304**. Though the frangible bridges **324** are shown as having a specific design and spacing, it is contemplated that the frangible bridges **324** can be differently sized or spaced as desired.

[0071] The frangible connection **318** can also define a plurality of gaps **320** that extend through the main body **304** from the outer surface **304***a* to the inner surface **304***b*, where a gap **320** can be extend circumferentially between two frangible bridges **324**. As depicted, each of the gaps **320** includes a central elongate section **320***b* between first and second semi-circular end portions **320***a*, **320***c*. As such, each of the gaps **320** can take the form of a substantially oval passage through the main body **304**, though other embodiments are contemplated. Though each of the gaps **320** is shown as being identical, each of the gaps **320** can vary in design and spacing along with the design and spacing of each frangible bridge **324**. The inclusion of the frangible bridges **324** and gaps **320** allows the tamper evident cap **300** to be easily broken at the frangible connection **318**.

[0072] Distal to the frangible connection **318**, the tamper evident cap **300** can include wings **328** that extend outwards from the outer surface **304***a* of the main body **304** along the radial direction R. The wings **328** can extend such that each defines the radially outward-most point on the tamper evident cap **300**, allowing the wings **328** to easily be grasped by a user so as to allow the user to twist the tamper evident cap **300** to break the frangible connection **318**. In the depicted embodiment, the tamper evident cap **300** includes two wings **328** extending from the outer surface **304***a* at opposed locations on the main body **304**. However, the tamper evident cap **300** can include more or less wings **328** as desired. For example, the tamper evident cap **300** can include one, three,

four, or more than four wings **328**.

[0073] Additionally, the tamper evident cap **300** can include ribs **332** that extend outwards from the outer surface **304***a* of the main body **304** along the radial direction R. Compared to the wings **328**, the ribs **332** can extend to a much smaller extent from the main body **304**, and can function as texturing for the user to easily grasp the main body **304** and break the frangible connection **318**. In the depicted embodiment, the tamper evident cap **300** includes a plurality of ribs **332** extending from the outer surface **304***a* and arranged circumferentially between the wings **328**. Though the tamper evident cap **300** is shown as including a certain number and design of ribs **332**, the ribs **332** can be differently configured as desired.

[0074] Now referring to FIG. **15**A, a tamper evident cap **400** according to another embodiment of the present disclosure is shown. The tamper evident cap **400** has a main body **404** that extends from a proximal end **400***a* to a distal end **400***b* opposite the proximal end **400***a* along the axial direction A. The tamper evident cap **400** can also define a ridge **416** extending radially outwards from the proximal end **400***a* of the main body **404**. The tamper evident cap **400** can also have a frangible connection **418** positioned between the proximal end **400***a* and the distal end **400***b*. When the tamper evident cap **400** is attached to the Luer connection **120**, the frangible connection **418** is configured to break under a force applied to the distal end **400***b* of the main body **404**. As a result, the distal end **400***b* will be decoupled from the proximal end **400***a*, and the proximal end **400***a* of the main body **404** will remain attached to the Luer connection **120**. Like the frangible connection **318**, the frangible connection **418** can be comprised of a plurality of gaps **420** and frangible bridges **424** arranged circumferentially around the main body **404**. Unlike the tamper evident cap **300**, the tamper evident cap **400** can include only wings **428** that extend outwards from the outer surface of the main body **404** along the radial direction R. The tamper evident cap **400** includes four wings **428** and no ridges, where the wings **428** are equidistantly spaced around the circumference of the main body **404** (each wing **428** is spaced from the adjacent wings **428** by 90 degrees). Like the wings **328**, the wings **428** allow for a user to more easily grasp the tamper evident cap **400** and apply a force to the distal end **400***b* of the tamper evident cap **400**.

[0075] Referring to FIG. **15**B, a tamper evident cap **500** according to another embodiment of the present disclosure is shown. The tamper evident cap **500** has a main body **504** that extends from a proximal end **500***a* to a distal end **500***b* opposite the proximal end **500***a* along the axial direction A. The tamper evident cap **500** can also define a ridge **516** extending radially outwards from the proximal end **500***a* of the main body **504**. The tamper evident cap **500** can also have a frangible connection **518** positioned between the proximal end **500***a* and the distal end **500***b*. When the tamper evident cap **500** is attached to the Luer connection **120**, the frangible connection **518** is configured to break under a force applied to the distal end **500***b* of the main body **504**. As a result, the distal end **500***b* will be decoupled from the proximal end **500***a*, and the proximal end **500***a* of the main body **504** will remain attached to the Luer connection **120**. Like the frangible connection **318**, the frangible connection **518** can be comprised of a plurality of gaps **520** and frangible bridges **524** arranged circumferentially around the main body **504**. Unlike the tamper evident cap **300**, the tamper evident cap **500** can include no wings and only ribs **532** that extend outwards from the outer surface of the main body **504** along the radial direction R. The tamper evident cap **500** can include a plurality of ribs **532** arranged around a substantial entirety of the circumference of the main body **504**. Like the ribs **332**, the ribs **532** allow a user to easily grasp the main body **504** and more easily apply a force to the distal end **500***b* of the tamper evident cap **500**.

[0076] As discussed herein, a tamper evident cap according to the present invention can have a plurality of ribs, wings or other protrusions that extend outwards from the outer surface of the main body. In some embodiments, the pattern and/or texture of the protrusions can be indicative of the type of material contained within the chamber of the syringe. This allows the user of the syringe assembly to easily determine what material is within the syringe and helps avoid incorrect medicaments from being mistakenly applied to a patient.

[0077] Another embodiment of the present disclosure is a pharmaceutical product comprising a syringe assembly **10**, **10′** and a secondary packaging system therefor. In some embodiments, the secondary packaging is a pouch, blister, flow wrapper, or bag. The secondary packaging can be comprised of an oxygen, light, and/or moisture barrier material, such as high density polyethylene (HDPE), ethylene/vinyl alcohol copolymer (EVOH), polypropylene (PP), polyethylene terephthalate (PET), polyethylene naphthalate (PEN), and polyamide (PA), metalized film, aluminum foil, oxide coated films, and combinations thereof. In certain embodiments, the secondary packaging system also comprises an oxygen absorber. The oxygen absorber can be a sachet, pouch, canister, capsule, sticker, or strip that is placed inside of the secondary packaging. Alternatively, or additionally, the oxygen absorber can be incorporated into the material of the secondary packaging. In some embodiments, the oxygen absorber is selected from the group consisting of reduced iron compounds, catechol, ascorbic acid and analogs thereof, metal ligands, unsaturated hydrocarbons and polyamides.
[0078] Yet another embodiment of the present disclosure is a pharmaceutical product comprising a plurality of syringe assemblies **10**, **10′** and a container therefor. In some embodiments, the container is a box, carton, case, package, tray, or tin. Optionally, one or more of the syringe assemblies **10**, **10′** can be enclosed within a secondary packaging system before being placed into the container. In certain embodiments, each syringe assembly **10**, **10′** enclosed within the container is filled with the same active ingredient. In other embodiments, each syringe assembly **10**, **10′** enclosed within the container is filled with a different active ingredient from the same drug class, a different active ingredient from a different drug class, or any combination thereof. For example, the pharmaceutical product can comprise a plurality of syringe assemblies **10**, **10′** enclosed with a container, wherein the two or more of the syringe assemblies **10**, **10′** are filled with a different active ingredient from a first drug class, and one or more syringe assemblies **10**, **10′** are filled with an active ingredient from a second drug class.
[0079] Now referring to FIG. **16**, a method **600** of filling the syringe **100** with material will be described. Method **600** begins with step **602**, which comprises receiving the syringe **100**, where the syringe **100** has the barrel body **103** extending from a distal end **100***b* to an open proximal end **100***a*. In step **602**, the syringe **100** can be received with the tip cap **150** placed over the outlet so as to create a fluid seal over the outlet **135**. Then, step **606** comprises filling the chamber **109** with the material through the outlet **135** of the Luer connection **120**, where the Luer connection **120** extends along the axial direction A from the barrel body **103**. Next, in step **610**, the plunger **50** is disposed at the proximal end **100***a* of the barrel body **103** within the chamber **109**. As stated above, the plunger rod **25** is connected to the plunger **50**, the plunger rod **25** having a rod body **28** that extends from the proximal end **28***a* disposed outside the chamber **109** to a distal end **28***b* disposed within the chamber **109** and connected to the plunger **50**. The chamber **109** is defined by the barrel body **103** and extends along the axial direction A, therethrough.
[0080] After step **610**, step **614** involves applying the tamper evident cap **200**, **300**, **400**, **500** over the Luer connection **120** and the tip cap **150**, such that the tamper evident cap **200**, **300**, **400**, **500** is spaced from the tip cap **150**. Step **614** can also involve pressing the tamper evident cap **200**, **300**, **400**, **500** over the Luer connection **120** and the tip cap **150** via a force applied along the axial direction A. Step **614** also can include forming an interference fit between the tamper evident cap **200**, **300**, **400**, **500** and the outer surface **123***a* of the outer wall **123** of the Luer connection. Alternatively, or additionally, step **614** can include engaging a gripping material **314** attached to an inner surface of the tamper evident cap **200**, **300**, **400**, **500** with the Luer connection **120**.
[0081] In certain embodiments, step **618** can also be performed, which involves shrink-wrapping a film **244** over the proximal end **200***a* of the tamper evident cap **200** and at least a portion of the syringe **100**. As such, through engagement between the film **244** and the syringe **100** and between the film **244** and the tamper evident cap **200**, in particular the external ribs **228** of the proximal end **200***a*, the film **244** can secure the proximal end **200***a* to the syringe **100**. This allows the film **244** to

secure the proximal end **200***a* in engagement with the syringe **100** even after the frangible bridge **224** is broken and the distal end **200***b* of the tamper evident cap **200** is detached. The film **244** can include a color-coded portion **248** that is indicative of the type of material within the chamber **109** of the syringe **100**. The color-coded portion can **248** can comprise a color selected from a plurality of colors that each correspond to a different material. The color of the color-coded portion **248** can correspond to the type of material within the chamber **109** in accordance with ASTM D4774. Step **618** can also include bonding the film **244** to the syringe **100** and/or the tamper evident cap **200**.
[0082] In another embodiment, as shown in FIG. **17**, a method **700** of filling the syringe **100** with material begins with step **702**, which comprises receiving the syringe **100**, where the barrel body **103** of the syringe **100** extends from a distal end **100***b* to an open proximal end **100***a*, and the tip cap **150** placed over the outlet **135** so as to create a fluid seal over the outlet **135**. Then, step **704** comprises applying the tamper evident cap **200**, **300**, **400**, **500** over the Luer connection **120** and the tip cap **150** ca before the chamber **109** is filled with material. Then, step **706** comprises filling the chamber **109** with the material through the opening **106** at the proximal end **100***a*. Next, in step **710**, the plunger is disposed at a proximal end of the chamber **109**.
[0083] In yet another embodiment of the invention, as shown in FIG. **18**, a method **800** of applying the tamper evident cap **200**, **300**, **400**, **500** to the syringe **100**, which is prefilled, is shown. Method **800** begins with step **802**, in which the syringe **100** is received prefilled with a material and including a tip cap **150** placed over the outlet **135**. Then, the tamper evident cap **200**, **300**, **400**, **500** is applied over the Luer connection **120** and the tip cap **150** in step **806** as described above in the context of method **600**.
[0084] The material contained within the chamber **109** of the syringe **100** in the syringe assemblies **10**, **10′** typically is a liquid, which can be aqueous, non-aqueous, or a combination of aqueous and non-aqueous liquids. In some embodiments, the liquid is a diluent intended for mixing with an active ingredient prior to administration to a subject. Exemplary diluents include, but are not limited to, water, 0.9% saline, 5% dextrose, Ringer's lactate solution, and other pharmaceutically acceptable diluents. In other embodiments, the liquid is a pharmaceutical formulation comprising an active ingredient and, optionally, one or more excipients. Thus, the invention provides a pharmaceutical product comprising a syringe assembly according to the present invention, wherein the liquid is a pharmaceutical formulation. Suitable excipients include, but are not limited to, a tonicity modifier, antioxidant, buffer, pH adjuster, preservative, solubilizer, stabilizer, or a combination of any of the forgoing. A diluent or pharmaceutical formulation can take on any suitable physical form including, but not limited to, solution, suspension, emulsion, or dispersion.
[0085] The active ingredient of the pharmaceutical formulation can be a therapeutic agent, a diagnostic agent, a nutrient, or a combination thereof. Examples of therapeutic agents include, but are not limited to antiinfectives, anesthetics, analgesics, anticoagulants, chemotherapeutics, hormones, antihypertensives, antiinflammatories, antiemetics, bronchodilators, adrenergics, immunoglobulins, antipsychotics, antidepressants, and combinations thereof. Examples of diagnostic agents include, but are not limited to x-ray, MRI and ultrasound contrast agents, cholecystokinetics, vasodilators, and combinations thereof. Examples of nutrients include, but are not limited to, salts, carbohydrates, minerals, vitamins, lipids, and combinations thereof.
[0086] In some embodiments, the active ingredient is a compound useful for pain management, muscle relaxation, sedation, and/or anesthesia. In certain embodiments, the active ingredient is an opioid, a benzodiazepine, beta blocker, or an α.sub.2-adrenergic receptor agonist. In particular embodiments, the active ingredient is morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, codeine, buprenorphine, naloxone, naltrexone, fentanyl, remifentanil, sufentanil, alfentanil, meperidine, rocuronium, vecuronium, midazolam, lorazepam, diazepam, neostigmine, atropine, glycopyrrolate, dexmedetomidine, cisastracurium, ropivacaine, lidocaine, propofol, ketamine, succinylcholine, or a combination of the foregoing.
[0087] In other embodiments, the active ingredient is moxifloxacin, linezolid, levofloxacin,

levetiracetam, vancomycin, cefepime, aztreonam, cefoxitin, ceftriaxone, cefazolin, cefotaxime, ceftazidime, gentamicin, oxacillin, nafcillin, penicillin, cefuroxime, ticarcillin, clavulanic acid, piperacillin, tazobactam, azithromycin, meropenem, ertapenem, tigecycline, micafungin, metronidazole, fluconazole, itraconazole, posaconazole, heparin, enoxaparin, dalteparin, theophylline, acetaminophen (paracetamol), ibuprofen, acetylcysteine, decitabine, azacitidine, docetaxel, pemetrexed, palonosetron, aprepitant, fosaprepitant, famotidine, amiodarone, nitroglycerin, nicardipine, clevidipine, dobutamine, esmolol, labetalol, metroprolol, somatropin, liraglutide, abaloparatide, semaglutide, teriparatide, degarelix, sumatriptan, epinephrine, ephedrine, vasopressin, methotrexate, testosterone, hydroxyprogesterone, or a combination of the foregoing.

[0088] In yet another embodiment, as shown in FIG. **19**, the syringe **100** can include one or more components for tracking, monitoring, and/or identifying the syringe assembly **10** and/or its contents. In some aspects, the film **244** disposed on the syringe **100** may include a radio frequency identification (RFID) label or tag **900**. Signal communication to or from an RFID label is a form of wireless communication that uses radio waves to identify and track objects.

[0089] The RFID tag **900** may be configured to be affixed to the film **244** or, alternatively, may be part of a unitary component of the film **244**. It will be appreciated that the RFID tag **900** can be utilized with any of the syringe assemblies disclosed throughout this application. The RFID tag **900** should be dimensioned and arranged relative to the syringe **100** such as to not interfere with the described structure or operation of the tamper evident caps **200**, **300**, **400**, or **500** of any of the embodiments disclosed herein. In some aspects, the RFID tag **900** may be affixed to the syringe **100** separate from the film **244**. In some aspects, an embodiment with the RFID tag **900** may be devoid of the film **244**. In some aspects, the RFID tag **900** may be affixed to the tamper evident cap **200**, **300**, **400**, or **500**. In some aspects, the RFID tag **900** may be affixed to both, the syringe **100** and the tamper evident cap **200**, **300**, **400**, or **500**.

[0090] Referring to FIG. **20**A, the RFID tag **900** may include a backing **904** configured to be received on the syringe **100**. The backing **904** may be secured to the syringe **100** via an adhesive or another suitable fixing mechanism. The backing **904** may include an adhesive thereon or, alternatively, may be configured to receive an adhesive between the syringe **100** and the backing **904**. In some aspects, the film **244**, as described throughout this application, may comprise the backing **904**. The backing **904** may be a separate component of the film **244** or, alternatively, at least a portion of the film **244** may be used as the entire backing **904** of the RFID tag **900**.

[0091] The RFID tag **900** further includes an integrated circuit **908** that is connected to an antenna **912**. The integrated circuit **908** is configured to store electronic data therein and to communicate with the antenna **912**. Referring to FIG. **21**B, the integrated circuit **908** may include a controller **909** and a memory **910**. The memory **910** may include non-volatile memory and is configured for read/write access to receive, store, and allow access to electronic data transmitted to or from the RFID tag **900**. The controller **909** is configured to read the electronic data from the memory **910** and to write electronic data to the memory **910**. The controller **909** is configured to cause the antenna **912** to transmit the electronic data from the memory **910** to a reader **930** and to receive electronic data from the antenna **912** into the memory **910**, as will be described in detail below. The antenna **912** is configured to communicate with the integrated circuit **908** and to transmit electronic data to and/or from the integrated circuit **908**. The antenna **912** may be configured to supply power to the integrated circuit **908** sufficient to actuate the read/write process on the integrated circuit **908** to initiate transmission of the electronic data.

[0092] The integrated circuit **908** and/or the antenna **912** may be disposed on the backing **904**, for example, opposite the syringe **100**. In some aspects, the integrated circuit **908** and/or the antenna **912** may be adhered to the backing **904**. In some aspects, the integrated circuit **908** and the antenna **912** may be secured relative to the syringe **100** by an external label **916**. The external label **916** may be configured to adhere to the backing **904** (or the film **244**) such that the integrated circuit **908** and the antenna **912** are held in friction fit between the external label **916** and the backing **904**

(or the film **244**). In some aspects, the external label **916** may be configured to contact the syringe **100** directly without contacting the backing **904** or the film **244**. The external label **916** may include printed text, barcodes, graphics, or other visual identifiers thereon. Exemplary visual identifiers that have been described throughout this application with respect to the film **244** may also apply to the external label **916** and/or to the backing **904**. In use, the RFID tag **900** may be hidden from view under the external label **916** or by the film **244** (see FIG. **20**B). In some aspects, such as shown in FIGS. **20**A and **21**A, the integrated circuit **908** and the antenna **912** may be held together on an inlay layer **906**. It will be understood that the inlay layer **906** serves to retain the integrated circuit **908** and the antenna **912** and may not be required for any other purpose in the RFID tag **900**. With reference to embodiments disclosed throughout this application, in some embodiments, at least a portion of the RFID tag **900** (e.g. the integrated circuit **908** and the antenna **912**) may be disposed between the film **244** and the syringe barrel body **103**.

[0093] In some aspects, an intermediate layer **920** may be disposed between the external label **916** and the integrated circuit **908** and antenna **912**. The intermediate layer **920** may provide structural and/or electromagnetic protection to the integrated circuit **908** and the antenna **912**. The intermediate layer **920** may be disposed adjacent the inlay layer **906**.

[0094] In some aspects, the backing **904** may be disposed such that the integrated circuit **908** and the antenna **912** are disposed between the backing **904** and the syringe **100**. In such embodiments, the RFID tag **900** may include the additional external label **916** contacting the backing **904** opposite the integrated circuit **908** and the antenna **912**, or, alternatively, such embodiments may be devoid of an external label **916** entirely.

[0095] The RFID tag **900** can be used to track and monitor the syringe assembly to which it is affixed, for example, syringe assemblies **10** and **10**′ as disclosed throughout this application. The RFID tag **900** can include active or passive RFID technology. In an active RFID system, the RFID tag includes a transmitter and a power source configured to activate the RFID tag and transmitter to broadcast an electronic signal with electronic data. The power source may include a battery or photovoltaic cell. In a passive RFID system, an RFID reader is configured to send a radio signal to the RFID tag. The antenna on the RFID tag can receive the signal and use that signal actuate transmittal of electronic data to/from the integrated circuit. The RFID tag **900** described herein can be designed and configured for either active or passive operation. It will be understood that if the RFID tag **900** is an active RFID tag, a transmitter and power source would need to be operationally connected thereto. In preferred embodiments, as shown in FIG. **22**, the RFID tag **900** may be configured to interact with various components of a network **940**. The RFID tag **900** can be a passive RFID tag that is configured to receive electronic power from an RFID reader **930**. The reader **930** is configured to receive data from the RFID tag **900**. Although referred to as a “reader,” it will be understood that such a device may be configured to transmit data to the RFID tag **900**. As such, the reader **930** may also be described as a writer **930**. In some aspects, the reading and writing functionalities can be performed by a single device **930**, which will be referred to as the reader **930**. The RFID reader **930** is configured to provide the connection between the RFID tag **900** and an external system configured to send and/or receive information to and/or from the RFID tag **900**. The external system may include a personal computing device, a network server, or a computing cloud. The RFID reader **930** is configured to communicate with the RFID tag **900** (or with a plurality of RFID tags **900**) that are within the read/write range of operation. The RFID reader **930** is configured to perform various tasks, such as simple continuous inventorying, searching for RFID tags **900** that meet predetermined criteria, writing (or encoding) to selected RFID tags **900**, or other electronic communications.

[0096] The RFID tag **900** can be designed to operate within known frequency ranges for RFID communication systems, including low frequency (LF), high frequency (HF), and ultra-high frequency (UHF). The LF band can cover frequencies from about 30 KHz to about 300 KHz. For RFID purposes, LF devices typically utilize either 125 KHz or 134.2 KHZ frequencies. The LF

band can be configured to operate within a range of up to approximately 10 cm for reading and/or writing from and/or to the RFID tag **900**. The HF band can include frequencies in the range of from about 3 MHz to about 30 MHz and may be configured to operate within a range of up to approximately 100 cm. For RFID purposes, HF devices typically operate at 13.56 MHz. The UHF frequency band can cover frequencies from about 300 MHz to about 3000 MHz and may be configured to operate within a range of up to approximately 1200 cm. For RFID purposes, UHF devices typically operate at a range of between about 860 MHz to about 960 MHz (for passive RFID) and at about 433 MHZ (for active RFID). In some embodiments, the RFID tag **900** can be configured to operate at a frequency within the UHF spectrum although it will be appreciated that this disclosure is not limited to any particular frequency range.

[0097] The RFID tag **900** can receive, store, transmit, and/or otherwise make available information that is electronically stored therein, for example in the integrated circuit **908**. With continued reference to FIG. **22**, the reader **930** can further communicate with a processor **944** that is configured to communicate with data in a database **942** to provide instructions to the reader **930** to receive data from the RFID tag **900** or send data to the RFID tag **900**, as well as to process the received data based on predetermined instructions. The RFID tag **900** can include various information, including at least a product identifier, product serial number, lot number, expiration date, or a combination of any of the above. The information can be sent to or received from the RFID tag **900** via the reader **930**. In some embodiments, the RFID tag **900** can include at least all four of the product identifier, serial number, lot number, and expiration date. The serial number may be unique and may pertain to the individual syringe assembly or component thereof or, alternatively, to a particular type of assembly or medicament therein. The product identifier can refer to a graphical or alpha-numeric string of characters that represents the particular products to which the RFID tag **900** is attributed, for example, a syringe assembly **10** or a medicament within the syringe assembly **10**. The product identifier may include a Global Trade Item Number (GTIN). The GTIN is an identifier for trade items that can be referenced within, or compared to, a database. In aspects where the RFID tag **900** is intended to correspond to a medicament, the GTIN may include a National Drug Code (NDC) that corresponds to a particular medicament or medicament component, such as a specific pharmaceutical compound. The particular NDC associated with a respective RFID tag **900** can be included in the NDC Directory maintained by the United States Food and Drug Administration (FDA). It will be appreciated that the GTIN may include a drug code that is different from the NDC, for example one that corresponds to a drug code directory outside of the United States. The RFID tag **900** may be designed to comply with one or more national or international standards for labeling, such as GSI and/or ISO. The RFID tag **900** may include the same information stored electronically within the integrated circuit **908** and appearing visually on the backing **904** or the external label **916**.

[0098] In some aspects, the RFID tag **900** may receive some or all of the information detailed above at substantially the same time or, alternatively, may receive data over a plurality of write cycles, in which the data is electronically transmitted from the reader **930** to the RFID tag **900**. In some aspects, the RFID tag **900** may be pre-encoded with the product identifier information and with the serial number prior to being applied to a syringe assembly, such as any of the assemblies described throughout this application. The RFID tag **900** may receive additional data, such as the lot number and expiration date, at a later time. In some aspects, some or all of the electronic data provided on the RFID tag **900** may be modified by the reader **930**.

[0099] An exemplary encoding process **950** is depicted in FIG. **23**. It will be appreciated that the RFID tag **900** may be encoded in a different process and that some of the steps described in the process **950** may be omitted, repeated, or changed in order relative to other steps. Referring to step **954**, the RFID tag **900** is placed in electronic communication with the reader **930**, and the reader **930** electronically transmits a first set of data to the RFID tag **900**. The first set of data may include the product identifier and/or the serial number. The first set of data may be associated with a

database **942** stored on the reader **930** or stored on an external computing device, server, network, or cloud and accessible by the reader **930**. The database **942** is configured to communicate with the reader **930** via a processor **944**. The processor **944** may be disposed on or in the reader **930** or on a separate computing device. The processor **944** and the database **942** may be disposed on the same device or on different devices. The processor **944** is configured to electronically communicate with the database **942** and with the reader **930**. The electronic communication may be wired or wireless. The reader **930** is configured to transmit the signal to the antenna **912** of the RFID tag **900**. The controller **909** in the integrated circuit **908** is configured to receive the signal from the antenna **912**, encode or decode the signal according to preprogrammed instructions to generate storable data associated with the signal, and move the data associated with the signal to the memory **910** in the integrated circuit **908**.

[0100] In step **958**, the RFID tag **900** is then be applied to the syringe assembly **10**, **10′**, or another embodiment disclosed herein. The RFID tag **900** can be applied to the syringe **100** as described above. In some aspects, this step may be performed prior to step **954**, such that the RFID tag **900** is affixed to the syringe **100** prior to the first set of data being transmitted to the RFID tag **900**. Alternatively, this step may be performed later in the process **950**, for example after the step **962** described below.

[0101] In step **962**, the reader **930** is configured to be placed in electronic connection with the RFID tag **900** such that data can be transmitted between the RFID tag **900** and the reader **930**. The reader **930** receives data that is stored on the RFID tag **900**, for example the first set of data that may include the product identifier and/or the serial number that was transmitted to the RFID tag **900** in step **954**. The controller **909** accesses the data stored on the memory **910**, performed any necessary encoding or decoding step according to preprogrammed instructions, and sends the data to the reader **930** through the antenna **912**. The reader **930** communicates the received information with a processor **944** configured to relate the received information with predetermined instructions, such as with a threshold, algorithm, or other computer programmed instruction. The processor **944** is configured to compare the received information per the predetermined instructions to determine if the information meets predetermined criteria. The comparison may be done with a predetermined set of data (for example a “control” set of data). In some aspects, the received set of data may include the first set of data that was transmitted to the RFID tag **900** in step **954**, and the control set of data may include the same information as the first set of data. The comparison step may include determining if the received set of data matches the control set of data. If the information meets the criteria (e.g. if the received set of data matches the control set of data), the RFID tag **900** (and the assembly to which the RFID tag **900** is affixed) is considered to be “verified,” and the process can continue to the next step. If the information received by the reader **930** in this step does not meet the predetermined criteria, the RFID tag **900** and the related assembly are not verified, and additional checking or verification steps may be performed. For example, if the RFID tag **900** is not verified, this could mean that the RFID tag **900** is damaged or improperly affixed to the syringe **100**, in which case the RFID tag **900** may be replaced. In some aspects, lack of verification could mean that the first set of data transmitted to the RFID tag **900** in step **954** was not successful, in which case, step **954** may be repeated. In some aspects, the RFID tag **900** may have been tampered with, in which case the RFID tag **900** and/or any other component of the syringe assembly may be fixed or replaced.

[0102] In step **966**, the reader **930** is configured to be placed in electronic connection with the RFID tag **900** (or remain in electronic connection with the RFID tag **900**. The reader **930** is configured to transmit a second set of data to the RFID tag **900**. The second set of data may include the lot number and/or the expiration date of the product or assembly. In some aspects, step **966** may be performed a plurality of times to transmit individual portions of data separately, for example, performed a first time to transmit the lot number to the RFID tag **900** and performed a second time to transmit the expiration date. It will be appreciated that additional information may be

electronically transmitted to, and stored in, the integrated circuit **908** of the RFID tag **900**.
[0103] In step **970**, the reader **930** and/or the connected processor **944** may update a database with information pertaining to the RFID tag **900** processed in steps **954** to **966**, for example to update inventory.
[0104] In some aspects, an additional step of printing visual indicators on the RFID tag **900** may be conducted. Although visual information does not affect the electronic reading or writing to the RFID tag **900**, visual information may provide a level of redundancy to ensure that the necessary information appears on the label.
[0105] By using radio waves to encode the RFID tags **900** and then read information from those RFID tags **900**, a user can track and monitor inventory without a visual line of sight. Because RFID readers **930** can receive electronic data from a plurality of RFID tags **900** simultaneously, less time can be spent on verifying individual tags (as would need to be done if utilizing a different tracking technique, such as visual inspection or barcode scanning). Information related to the RFID tags **900** can be stored in the database **942** and can be easily accessed. In some aspects, the database **942** may be configured to be updated automatically when information received by the reader **930** is different from the information stored in the database **942** with respect to the particular RFID tag **900** (i.e. with respect to the particular product identifier or serial number assigned to the RFID tag **900** or the syringe assembly). This allows for real-time updating of the database when a product with an RFID tag **900** is accessed, moved, or tampered with. In some aspects, a plurality of products may be disposed within a storage container, such as a cabinet. As the product is placed into the storage container, the reader **930** receives information related to the product, and the database **942** is updated to account for that product. If the product is removed from the storage container, the reader **930** no longer receives information related to that product and its affixed RFID tag **900**. The database **942** may be updated to account for removal of that product.
[0106] By relying on RFID technology, inventory can be monitored and tracked more easily to ensure sufficient amount of desired products. Similarly, by monitoring expiration date, the inventory can be adjusted to remove expired products and ensure unexpired products are maintained at the desired quantities. Digitally monitoring and storing inventory information can also reduce information loss that often accompanies manual record keeping. Furthermore, as the process can be automated for all products, individual user approach differences are eliminated to increase precision in inventory management. Additionally, time spent on inventorying, locating expired products, and locating recalled lots is decreased. Using RFID technology further allows for immediate updating of the inventory when a product is removed and reduces chances of human error, such as when a user forgets to update inventory upon adding or removing a product. Additionally, monitoring how each tagged product or assembly is used, how often, how much, and in which circumstances can help users determine future inventory needs and/or efficacy of treatments. Information written to the RFID tag **900** can be validated through cGMP to ensure high quality and accuracy.
[0107] While various inventive aspects, concepts and features of the inventions may be described and illustrated herein as embodied in combination in the exemplary embodiments, these various aspects, concepts and features may be used in many alternative embodiments, either individually or in various combinations and sub-combinations thereof. Unless expressly excluded herein all such combinations and sub-combinations are intended to be within the scope of the present inventions. Still further, while various alternative embodiments as to the various aspects, concepts, and features of the inventions-such as alternative materials, structures, configurations, methods, devices and components, alternatives as to form, fit and function, and so on—may be described herein, such descriptions are not intended to be a complete or exhaustive list of available alternative embodiments, whether presently known or later developed. Those skilled in the art may readily adopt one or more of the inventive aspects, concepts or features into additional embodiments and uses within the scope of the present inventions even if such embodiments are not expressly

disclosed herein. Additionally, even though some features, concepts or aspects of the inventions may be described herein as being a preferred arrangement or method, such description is not intended to suggest that such feature is required or necessary unless expressly so stated. Still further, exemplary or representative values and ranges may be included to assist in understanding the present disclosure; however, such values and ranges are not to be construed in a limiting sense and are intended to be critical values or ranges only if so expressly stated. Moreover, while various aspects, features, and concepts may be expressly identified herein as being inventive or forming part of an invention, such identification is not intended to be exclusive, but rather there may be inventive aspects, concepts, and features that are fully described herein without being expressly identified as such or as part of a specific invention, the scope of the inventions instead being set forth in the appended claims or the claims of related or continuing applications. Descriptions of exemplary methods or processes are not limited to inclusion of all steps as being required in all cases, nor is the order that the steps are presented to be construed as required or necessary unless expressly so stated.

[0108] While the invention is described herein using a limited number of embodiments, these specific embodiments are not intended to limit the scope of the invention as otherwise described and claimed herein. The precise arrangement of various elements and order of the steps of articles and methods described herein are not to be considered limiting. For instance, although the steps of the methods are described with reference to sequential series of reference signs and progression of the blocks in the figures, the method can be implemented in a particular order as desired.

Claims

1. A tamper evident cap, comprising: a main body having a proximal end defining an opening and a distal end opposite the proximal end along an axial direction, wherein the main body defines an outer surface and an inner surface opposite the outer surface, the inner surface defining a passage configured to receive a tip cap and a Luer connection of a syringe such that a portion of the inner surface is configured to engage with the Luer connection, the main body further defining a frangible connection between the proximal end and the distal end, wherein the frangible connection is configured to break under a force applied to the distal end such that, when the distal end is decoupled from the proximal end, the proximal end is configured to remain engaged with the Luer connection.

2. The tamper evident cap of claim 1, wherein the distal end comprises a distal wall that closes the distal end.

3. The tamper evident cap of claim 1, wherein the proximal end includes a plurality of internal ribs extending radially inwards from the inner surface and configured to form an interference fit with the Luer connection.

4. The tamper evident cap of claim 1, wherein the distal end includes a plurality of external ribs extending radially outward from the outer surface at the distal end.

5. The tamper evident cap of claim 1, wherein the distal end includes a plurality of wings that extend radially outward from the outer surface at the distal end such that each wing of the plurality of wings defines the radially outward-most point on the tamper evident cap.

6. The tamper evident cap of claim 1, wherein the proximal end is attached to the Luer connection via a sonic weld.

7. The tamper evident cap of claim 1, wherein the proximal end is attached to the Luer connection using an adhesive or a gripping material.

8. The tamper evident cap of claim 1, wherein a fluid seal created by the tip cap over an outlet of the Luer connection is not compromised when the tamper evident cap is disposed over the Luer connection or when the frangible connection is broken.

9. The tamper evident cap of claim 1, further comprising a film over the proximal end and at least a

portion of the syringe.
10. The tamper evident cap of claim 9, wherein the film is configured to secure the proximal end of the tamper evident cap to the syringe when the frangible connection breaks.
11. The tamper evident cap of claim 9, wherein the film includes a color-coded portion that comprises a color selected from a plurality of colors that each correspond to a different material.
12. The tamper evident cap of claim 11, wherein the color of the color-coded portion corresponds to the material in accordance with ASTM D4774.
13. The tamper evident cap of claim 9, wherein the film is shrink-wrapped to the tamper evident cap.
14. The tamper evident cap of claim 9, wherein the film is adhesive-bonded to the tamper evident cap.
15. The tamper evident cap of claim 14, wherein the film is adhesive-bonded to the syringe.
16. The tamper evident cap of claim 9, wherein the proximal end includes a plurality of external ribs extending radially outwards from the outer surface at the proximal end and configured to secure the film to the tamper evident cap.
17. The tamper evident cap of claim 1, wherein a portion of the main body defines a color-coded portion that comprises a color selected from a plurality of colors that each correspond to a different material.
18. The tamper evident cap of claim 1, wherein the frangible connection comprises a plurality of frangible bridges positioned circumferentially around the main body.
19. The tamper evident cap of claim 1, wherein the syringe contains a material that includes an active ingredient that is (a) a therapeutic agent selected from a group consisting of antiinfectives, anesthetics, analgesics, anticoagulants, chemotherapeutics, hormones, antihypertensives, anti-inflammatoirentiemetics, bronchodilators, adrenergics, immunoglobulins, antipsychotics, and antidepressants, or (b) a diagnostic agent selected from a group consisting of x-ray, MM and ultrasound contrast agents, cholecystokinetics, and vasodilators.
20. The tamper evident cap of claim 1, wherein the syringe contains a material that includes an active ingredient selected from a group consisting of an opioid, benzodiazepine, α2-adrenergic receptor agonist, beta blocker, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, codeine, buprenorphine, naloxone, naltrexone, fentanyl, remifentanil, sufentanil, alfentanil, meperidine, rocuronium, vecuronium, midazolam, lorazepam, diazepam, neostigmine, atropine, glycopyrrolate, dexmedetomidine, cisastracurium, ropivacaine, lidocaine, propofol, ketamine, succinylcholine, moxifloxacin, linezolid, levofloxacin, levetiracetam, vancomycin, cefepime, aztreonam, cefoxitin, ceftriaxone, cefazolin, cefotaxime, ceftazidime, gentamicin, oxacillin, nafcillin, penicillin, cefuroxime, ticarcillin, clavulanic acid, piperacillin, tazobactam, azithromycin, meropenem, ertapenem, tigecycline, micafungin, metronidazole, fluconazole, itraconazole, posaconazole, heparin, enoxaparin, dalteparin, theophylline, acetaminophen (paracetamol), ibuprofen, acetylcysteine, decitabine, azacitidine, docetaxel, pemetrexed, palonosetron, aprepitant, fosaprepitant, famotidine, amiodarone, nitroglycerin, nicardipine, clevidipine, dobutamine, esmolol, labetalol, metroprolol, somatropin, liraglutide, abaloparatide, semaglutide, teriparatide, degarelix, sumatriptan, epinephrine, ephedrine, vasopressin, methotrexate, testosterone, and hydroxyprogesterone.