

**CAP SUITABLE FOR USE WITH ENTERAL FEEDING CONTAINER****CROSS REFERENCE TO RELATED APPLICATIONS**

[001] This application claims priority to and any benefit of U.S. Provisional Application No. 61/726,272, filed November 14, 2012, the entire contents of which are incorporated by reference in its entirety.

**Background**

[002] Enteral feeding developed from a need to maintain a sufficient caloric diet in a patient who might otherwise not digest enough calories by oral intake. The medical reasons for enteral feeding are numerous and relatively varied. Certain patients temporarily lose the ability to chew, such as for example, if the patient is comatose, in a prolonged unconscious state following surgery, or has suffered a jaw or throat injury. Other patients may lose the ability to swallow as a result of declining health from degenerative disorders of the muscle or nervous system, such as Parkinson's or Amyotrophic lateral sclerosis (ALS). In patients presenting with these or other conditions, a physician or care provider may elect to provide a diet by enteral feeding. The enteral feeding is often temporary until recovery, or until other feeding methods are initiated, such as for example, by percutaneous endoscopic gastrostomy (a PEG tube).

[003] Conventional enteral feeding involves the delivery of a liquid nutrition (e.g., a nutritional formula) through the oral tract into the digestive system. Using gravity or a pumping device, the liquid nutrition is delivered to the stomach from a container. Specifically, the liquid

nutrition travels through a tube which has been intubated into the oral tract, usually through the nose. A physician may choose liquid nutrition specific to the patient from many commercially available nutritional formulas.

[004] One type of liquid nutrition container used in the industry is a ready-to-hang plastic bottle. The bottle may include a mouth covered by a hermetic seal and a neck which is male threaded. In many enteral feeding systems, a removable cap is attached to the neck of the bottle. To initiate flow of the nutrition, the seal is removed by a caregiver, mechanically broken or otherwise compromised. The tube connecting the container to the patient has a proximal end, relative the caregiver, which may include a connector or otherwise have structure adapted for connection to the cap.

### Summary

[005] The present application describes parts and assemblies for use in enteral feeding, such as for example, a cap suitable for use with a ready-to-hang plastic bottle.

[005a] In one embodiment, there is provided a cap suitable for use in enteral feeding from a container, the cap comprising:

a base having a top surface, a bottom surface, and an outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to a container having a mouth, wherein the protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture; and

an insert cutter having a first end portion attached to the bottom surface of the base and about an edge of the spike connector outlet aperture and a second end portion extending over at least a portion of the spike connector outlet aperture;

wherein the insert cutter is capable of flexing at a hinge in an insertion direction of a spike connector inserted through the spike insertion chamber.

[005b] In one embodiment, there is provided a cap for use in enteral feeding from a container of liquid, the container having a mouth covered by a seal, the cap comprising:

a ring having a female threaded inner surface for attachment to the container;

a disk fixed to an upper edge of the ring, the disk having a top surface and a bottom surface, the

top surface having a protruding port suitable for insertion of a spike connector, wherein the protruding port defines a spike insertion aperture; and  
an insert cutter having a first end and a second end, the first end attached to the bottom surface of the disk;  
wherein the insert cutter is capable of flexing about a hinge in an insertion direction of a spike connector inserted through the spike insertion aperture.

[005c] In one embodiment, there is provided an assembly for use in enteral feeding, the assembly comprising:

a container having a mouth covered by a foil seal;  
a cap having a top surface, a bottom surface, and an outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to the mouth of the container, wherein the protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture;  
and  
an insert cutter having a first end portion attached to the bottom surface of the cap and about an edge of the spike connector outlet aperture and a second end portion extending over at least a portion of the spike connector outlet aperture;  
wherein the insert cutter is capable of flexing in an insertion direction of a spike connector inserted through the spike insertion chamber.

[006] In an exemplary embodiment, a cap includes a base and an insert cutter. The base has a top surface, a bottom surface, and an outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to a container having a mouth. The protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture. The insert cutter has a first end portion attached to the bottom surface of the base and about an edge of the spike connector outlet aperture and a second end portion extending over at least a portion of the spike connector outlet aperture. The insert cutter is capable of flexing at a hinge in an insertion direction of a spike connector inserted through the spike insertion chamber.

[007] In another embodiment, an assembly includes a container having a mouth covered by a foil seal, a cap, and an insert cutter. The cap has a top surface, a bottom surface, and an

outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to the mouth of the container. The protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture. The insert cutter has a first end portion attached to the bottom surface of the cap and about an edge of the spike connector outlet aperture and a second end portion

extending over at least a portion of the spike connector outlet aperture. The insert cutter is capable of flexing at a hinge in an insertion direction of a spike connector inserted through the spike insertion chamber.

### **Brief Description of the Drawings**

[008] Features and advantages of the general inventive concepts will become apparent from the following detailed description made with reference to the accompanying drawings.

[009] Figure 1 is an exploded view of an enteral feeding assembly, showing a connector, a cap, and a container;

[010] Figure 2a is a top perspective view of the cap of Figure 1;

[011] Figure 2b is an enlarged perspective view of the designated circular area of Figure 2a;

[012] Figure 3 is a bottom perspective view of the connector of Figure 1;

[013] Figure 4 is a bottom view of the connector of Figure 1;

[014] Figure 5a is a sectional view of a top portion of the assembly of Figure 1, shown with the cap secured to the container and with a dust cover over the cap;

[015] Figure 5b is an enlarged perspective view of the designated circular area of Figure 5a;

[016] Figure 5c is a sectional view of a top portion of the assembly of Figure 1, shown with the cap secured to the container and with the connector in an installable orientation;

[017] Figure 5d is a sectional view of a top portion of the assembly of Figure 1, shown with the cap secured to the container and with the connector in an installed position;

[018] Figure 6a is a bottom perspective view of a portion of the cap, showing an insert cutter and a filter;

[019] Figure 6b is a bottom perspective view of a portion of another cap, showing two doors of an insert cutter and a filter;

[020] Figure 7 is a bottom perspective view of a portion of the cap of Figure 1, shown with the connector in an installed position; and

[021] Figure 8 is a bottom perspective view of a portion of the assembly of Figure 1

shown with the connector in an installed position and with the insert cutter pierced through a seal over a mouth of the container.

### **Detailed Description**

[022] This Detailed Description merely describes exemplary embodiments in accordance with the general inventive concepts and is not intended to limit the scope of the invention in any way. Indeed, the invention as described by the claims is broader than and unlimited by the exemplary embodiments set forth herein, and the terms used herein have their full ordinary meaning.

[023] The general inventive concepts will now be described with occasional reference to the exemplary embodiments of the invention. This general inventive concept may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the general inventive concepts to those skilled in the art.

[024] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art encompassing the general inventive concepts. The terminology set forth in this detailed description is for describing particular embodiments only and is not intended to be limiting of the general inventive concepts. As used in this detailed description and the appended claims, the singular forms “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[025] Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth as used in the specification and claims are to be understood as being modified in all instances by the term “about.” Accordingly, unless otherwise indicated, the numerical properties set forth in the specification and claims are approximations that may vary depending on the suitable properties sought to be obtained in embodiments of the present invention. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the general inventive concepts are approximations, the numerical values set forth in the specific examples are reported as precisely

as possible. Any numerical values, however, inherently contain certain errors necessarily resulting from error found in their respective measurements.

**[026]** In the application of certain enteral feeding containers in the art, misconnections with other tubing have occurred. A tube connector was developed to prohibit this undesired situation. The SPIKERIGHT® PLUS connector is designed for connection to a soft-sided container, such as a plastic bag, having a protruding port compatible with the connector.

**[027]** The present application describes, in part, an adapter cap suitable for use with a ready-to-hang container used for enteral feeding. The cap is intended to be compatible with the SPIKERIGHT® PLUS connector and meets all known and current AAMI/ISO misconnection requirements. The underside of the cap includes a hinged insert cutter which is capable of flexing into the container seal upon insertion of the SPIKERIGHT® PLUS connector. The insert cutter compromises or pierces the seal to promote liquid flow from a container. The port also prohibits misconnection with other types of tubing. In certain embodiments, the cap includes a hole with a filter to help facilitate air flow into the container. In certain embodiments that contain a filter, a raised cover over the filter prohibits accidental connections of the tube connector with the filter.

**[028]** The cap functions as part of a closed system which allows connection of the SPIKERIGHT® PLUS connector, or a similar connector, without manual removal of the hermetic seal. In application, the SPIKERIGHT® PLUS connector, or a similar connector, acts as both the “key and the tool” to actuate flow of the liquid nutrition. After insertion of the connector into the protruding port on the cap, the spike end of the connector contacts the hinged insert cutter on the underside of the cap. The insert cutter will then flex at the hinge into the container seal to promote nutrition flow. Once the cap has been installed over the mouth of the container, insertion of the spike is the only practical way of allowing flow between the container and an inserted connector. In one exemplary embodiment, the insertion force necessary to break the seal and promote flow is less than the force required for insertion through the raised cover over the filter.

**[029]** Referring now to the drawings, one exemplary embodiment of an enteral feeding assembly 10 is shown in Figure 1. The exploded view illustrates a connector 12, a cap 14, and a container 16, all in an orientation in which a caregiver may use during initial assembly. The

connector 12 is illustrated to represent a SPIKERIGHT® PLUS connector. Any variations between the figures of this application and the actual shape, size, or structure of a SPIKERIGHT® PLUS connector are not intended. Further, any future modifications to the SPIKERIGHT® PLUS connector should not be interpreted to limit the scope of the present invention. However, it is specifically contemplated that the cap disclosed herein may be suitable for use with other connectors that may vary in one or more aspects from the SPIKERIGHT® PLUS connector.

**[030]** In a typical use, the cap 14 is threaded onto a neck 18 of the container 16, followed by insertion of the spike 20 into a protruding port 22 of the cap 14. Insertion of the spike 20 flexes a hinged insert cutter 24 (see Figures 6-8) into the seal 26 over a mouth of the container 16. The seal may be aluminum foil, a multi-laminate, or other suitable material sufficiently to hermetically seal the liquid within the container. After the distal end 28 of a tube 32 is intubated into the oral tract, the container 16 is hung upside down, such as on a hook or other fastening device, by an optional catch 30 to initiate flow by gravity or pump delivery. In the exemplary embodiment, the container 16 is a plastic bottle, but it will be understood by those skilled in the art that other containers may be suitable for use with the various embodiments of the cap disclosed herein.

**[031]** The exemplary cap 14 of Figure 1 is illustrated in Figures 2a and 2b. In certain embodiments, the cap is an integral plastic piece formed such as by injection molding. The cap includes a base 34 having a top 36 and bottom surface 38 (best seen in Figure 5b). An outer ring 40 has female threads on an inner surface 42 (see Figure 5a) and optional ridges 44 on an outer surface 46. Generally, the inner surface 42 is cooperatively threaded for attachment to male threads 48 on the neck 18 of the container 16. In certain embodiments, the cap may be constructed of two or more parts. For example, the cap may include a separate base, or disk, and a separate outer ring, which are joined to each other prior to assembly, or otherwise engage each other at or prior to the time of attachment to the container. Also, it will be understood by those skilled in the art that the cap may be constructed by alternative suitable manufacturing methods and alternative suitable materials in the practice of the present invention.

**[032]** The cap 14 is configured to prohibit compromise of the container seal 26 by any connector other than an enteral connector (e.g. a SPIKERIGHT® PLUS connector), such as for

example, connectors with different shape bores, or different size bores, such as a small bore IV tube connector. A top perspective view of the cap 14 is shown in Figure 2a. As shown, the top surface 36 of the cap 14 has a protruding port 22 suitable for insertion of a spike connector. The port 22 has a top surface which defines a spike connector insert aperture which is cooperatively shaped to accept a spike connector. As best seen in Figure 2b, the exemplary spike insertion aperture 50 is generally cross-shaped and includes a circular center 52 and four wing extensions 54a, 54b, 54c, 54d. Discussed herein, the exemplary wings are evenly spaced around the circumference of the circular center 52, and permit the connector 12 to be inserted in four unique positions. Other configurations for the spike insertion aperture may be utilized and should be considered to be within the scope of the present invention.

[033] In certain embodiments, the inside surface of the protruding port is generally shaped to cooperatively engage the spike connector. Further structural detail of an exemplary protruding port is illustrated in Figure 5a, in which a sectional view of the assembly 10 is shown. In Figure 5a, the cap 14 is illustrated in an assembled position on the neck 18 of the container 16. A sectional view of the protruding port 22 shows a spike insertion chamber 56 extending from a spike connector insert aperture 50 to a spike connector outlet aperture 58. The exemplary chamber 56 shown has a length  $L_1$  in which the chamber is cylindrical in shape. It will be understood by one skilled in the art that the shape of the chamber may vary, such as for example, the chamber may be cross shaped its entire length.

[034] In certain embodiments, the outside surface of the protruding port is also shaped to cooperatively engage the spike connector. Various configurations are possible for cooperative engagement. In exemplary protruding port 22 shown in Figures 2a and 2b, the outside surface has a threaded outer circumferential surface 60. The male threads of the port are capable of engaging female threads on a surface 62 of the spike connector 12 (see Figures 3 and 5d). As discussed herein, a threaded connection between the protruding port and the spike connector assists in inserting the connector 12 spike 20 from an initial engagement position to a lower assembled position.

[035] In certain embodiments, the cap is structured to permit air flow from outside the assembly to inside the container to aid the gravitational flow of fluid. As best seen in Figures 2a and 2b in the illustrated embodiment, the cap 14 includes an optional raised dome 68 which

generally covers an optional hole 70 in the base 34 of the cap 14. Although the hole is pictured in the base of the cap, other structures for permitting air flow from outside the container to inside the container may be utilized. As shown in the sectional views of the assembly 10 in Figures 5a-5d, the cap 22 further includes an optional filter 72. The filter 72 permits air flow through the hole 70 in the base 34. As positioned, the raised dome 68 prohibits insertion of an unintended or undesired object through the hole 70 in the insertion direction  $D_1$  of the spike connector 12.

**[036]** Referring again to Figure 2b, a possible structure for the exemplary raised dome is shown. In the illustrated embodiment, two buttress supports 78a, 78b are separated by a uniform wall 74 which extends from a side of the hole 70 to an opposing side. The supports 78a, 78b and wall 74 collectively support a dome ceiling 76. The underside of the wall 70 is shown in phantom in Figures 6a and 6b in a position above the filter 72. The exemplary ceiling 76 is a solid disk without holes. The solid disk prohibits a spike connector from being inserted through the hole 70. Relative to the embodiment illustrated, insertion forces were measured of prepared prototypes. The exemplary solid disk prevented a spike being inserted with at least 70 N of force. It should be understood that the insertion resistant strength of the raised dome may vary in the practice of the invention, such as for example, the force required to insert a spike through the hole may be more than or less than 70 N.

**[037]** The exemplary configuration of the raised dome 68 in Figure 2b allows air flow between the filter 72 and the dome, and into the container. Specifically, air flows from outside the assembly through entrance passages, each passage formed by one of the buttress supports 78a, 78b and the wall 74, and then through the filter 72 and into the container. It should be understood that the shape, size, and structure of the raised dome may vary in the practice of the invention, such as for example, the air passages, the buttress support, or the ceiling may be of a different size or shape. Further, it is specifically contemplated that the cap may be used in a configuration that does not have a hole and filter, in a configuration that has a hole and filter, but does not have a dome cover, or in a configuration that has more than one hole.

**[038]** Another inventive feature of the cap is an insert cutter for promoting nutrition flow from the container into the tube 32. Figure 6a illustrates one exemplary embodiment of an insert cutter 24. Specifically, Figures 6a and 7 are bottom perspective views of portion of the cap, shown in a disassembled position such that the container seal 26 is not visible. In contrast,

Figure 8 is a bottom perspective view of a portion of the cap in an assembled position on the container. The insert cutter 24 has a first end portion 82 attached to the bottom surface 38 of the base 34 and about an edge of the spike connector outlet aperture 58 (see Figures 5a-5d). A second end portion 84 extends over at least a portion of the spike connector outlet aperture, as viewed from within the container. The insert cutter 24 is capable of flexing at a hinge 86 in an insertion direction  $D_1$  of a spike connector 20 inserted through the spike insertion chamber 56. Discussed herein, flexing of the insert cutter 24 is shown in Figures 5d and 8. As shown, the insert cutter 24 remains rigid after contact by the spike 20 and rotation at the hinge. In the exemplary embodiment, the insert cutter remaining rigid should not be interpreted as the insert cutter does not flex about the hinge. Rather, rigid is used to mean the insert cutter, after being contacted by the end of a spike, does not deform or otherwise bend out of the way of the advancing spike, and flexes in a direction of the advancing spike to pierce the seal of the container.

**[039]** Referring again to Figure 6a, in the embodiment illustrated the inset cutter 24 is generally hourglass-shaped and is defined by two concave sides 80a, 80b. The second end portion 84 is triangle-shaped and ends in a point. At the farthestmost extending point, a bridge 88 joins the insert cutter 24 to an insert cutter housing 90. An inserted spike 20 through the spike insertion chamber 56 will break the bridge. In other words, the spike 20 will contact the insert cutter 24 prior to contact with the seal 26 (see Figure 5a). In another embodiment, the inserted spike contacts the seal 26 prior to contacting the insert cutter 24.

**[040]** In certain embodiments, exemplary housing 90 and insert cutter 24 is an integral substantially rigid piece of injection molded plastic. The housing 90 and insert cutter 24 are secured to the base such that only the insert cutter moves upon contact by the spike 20. For example, the insert cutter may be attached to the bottom surface 38 of the base 34 by ultrasonic welding, or for example, by a sealant, epoxy or adhesive.

**[041]** It should be understood that the housing and insert cutter may be constructed in separate pieces, and may be constructed by alternative suitable methods and alternative suitable materials. Also, the insert cutter may be of a different shape, or more than one insert cutter may be used. For example, an insert cutter with two generally triangle-shaped doors 92a, 92b are shown hinged to a housing 94 in Figure 6b. The farthest extending point of each door meets at a

joint 96. The pointed ends of each door 92a, 92b separate and rotate apart when contacted by a spike 20. As such, the door 92a, 92b open in a saloon-door style upon insertion of the spike.

**[042]** Referring to Figures 3 and 4, an exemplary connector 12 is illustrated in a bottom perspective view and a bottom view, respectively. The connector 12 includes a spike 20, a lower dial 100, and an upper dial 102, all axially arranged about a common longitudinal axis  $A_1$ . The outer surface of each dial 100, 102 are optionally ridged to allow for user gripping. In the embodiment illustrated, upper dial 102 is fixed relative to the spike 20, such that the user may facilitate insertion of the spike 20 into the protruding port 22 by grasping the upper dial. In the exemplary connector 12 illustrated in Figure 5d, the upper dial 102 and the spike are an integral piece. However, other embodiments the upper dial and spike may be constructed of two or more parts. The lower dial 100 rotates clockwise and counterclockwise relative to the spike 20 and upper dial 102.

**[043]** As discussed, in certain embodiments the spike 20 is generally cross-shaped. Specifically, the spike may be formed by a hollow cylinder 108. The cylinder extends to an opening 110. After the connector 12 fully engages the cap 14 and the container is inverted, liquid nutrition within the container enters the opening 110 under the force of gravity. Two shorter ribs 104a, 104b are each positioned along the length of the spike 20 on opposing sides. Between the rib 104a, 104b, two longer and thinner ribs 106a, 106b extend along the length of the cylinder to a leading or beveled edge 108a, 108b, respectively.

**[044]** The insertion end of the spike 20 is generally angled relative the top of the upper dial. In other words, the rib 106a is longer than the rib 106b, such that upon insertion of the spike 20 into the protruding port 22, the rib 106a contacts the insert cutter 24 prior to contact being made by the opposing rib 106b. For example, Figure 5d shows an assembly 10 in which the first portion of the spike 20 to make contact with the insert cutter was the rib 106a.

**[045]** Partial or complete examples of the assembly 10 are shown in Figures 5a-5d. Referring again to Figure 5a, in the illustrated embodiment a cap 14 is removably secured to the container 18 by a threaded connection. An optional dust cover 112, is attached over the cap 14 to protect the assembly when the container has not been initially used, or when it has been partially used and is in temporary storage.

**[046]** Referring now to Figure 5b, an enlarged perspective view of the designated

circular area of Figure 5a is illustrated. The exemplary dust cover 112 is removably fixed to the base 34. In the embodiment illustrated, the dust cover is manually press-fit on the base such that an inwardly protruding rim 114 advances downward and into a concave recess 116 in the circumference of the base 34. As shown, the dust cover 112 has an outer diameter equal to an outer diameter of the ring 40 at an essentially contiguous location, such that a user may conveniently grasp the assembled dust cover 112 and cap 34.

[047] Still referring to Figure 5b, detail of the seal 26 is also shown. The seal 26 hermetically protects liquid within the container 16 until ready for use. In certain embodiments, the edge portion of the seal may be crimped or otherwise fixed to the top portion of the neck. The seal may extend downward a constant length around the circumference of the neck. As shown in Figure 5b, a neck portion 18a is uncovered between the seal portion 118 and the ring 40.

[048] As discussed, the spike or spike connector is inserted into the protruding port to initiate liquid nutrition flow from the container. A sectional view of the cap 14 secured to the container 16 is shown in Figure 5c. The spike 20 is illustrated in an installable orientation to relative the protruding port 22. A caregiver may insert the spike in a downward direction  $D_1$  into the spike insertion aperture 50. As discussed, in certain embodiments the spike includes a leading rib 106a which a caregiver may insert into one of four wing extensions 54a, 54b, 54c, 54d in the spike insertion aperture 50 (see Figure 2b). In an exemplary embodiment, the leading rib 106a is inserted into one of the two wing extensions 54a, 54b closest to the center of the cap. For example, the leading rib 106a is inserted into wing extension 54b in Figure 7.

[049] In certain contemplated uses, securing the spike to the cap is a two step process for the caregiver. The caregiver initially inserts the spike 20 into the spike insertion aperture 50 of the protruding port 22. In certain embodiments, the protruding port will have an outer circumferential surface configured to limit an insertion depth of the spike connector to an initial engagement position. Specifically, in certain embodiments the ending thread edge 120 of the female thread within the lower dial 100 will contact a shoulder 122 (see Figure 5a) on the male threads on the protruding port 22, stopping movement of the spike 20 in the downward direction  $D_1$ . The caregiver may then rotate the lower dial 100 onto the threads of the protruding port to move the spike 22 to a lower assembled, or installed position, as seen in Figures 5b and 7. In

other contemplated uses, various other embodiments and steps may be utilized.

[050] As discussed, the insert cutter is configured to promote liquid flow from the container by sufficiently displacing the seal when a spike connector is in an installed position. Referring now to the embodiment illustrated in Figure 8, a bottom perspective view of a portion of the assembly 10 is shown, with the connector in an installed position and with the insert cutter pierced through a seal over a mouth of the container. The insert cutter 24 is configured to pierce the seal 26 over the mouth of the container 16. Upon insertion of a spike 20 and sufficient displacement of the insert cutter 24, the end portion of the insert cutter pierces a seal 26 of the container 16. As the spike connector is engaged with the threaded outer circumferential surface of the protruding port 22, a seal tab 130 is broken away from the seal itself, and driven away from the opening 110 of the hollow cylinder 108. By piercing the seal and driving the compromised tab 130 into an innocuous position, flow of fluid from the container is promoted. In another embodiment of the insert cutter, the leading edge of the spike 20 may pierce the seal at the same time or prior to the insert cutter contacting the seal. It will be understood by one skilled in the art that various structural features, such as for example, the shape and size of insert cutter, and the particular wing extension into which the leading rib is inserted, will contribute to what portion of the assembly 10 first pierces the seal.

[051] While various inventive aspects, concepts and features of the general inventive concepts are described and illustrated herein in the context of various 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 general inventive concepts. Still further, while various alternative embodiments as to the various aspects, concepts and features of the inventions (such as alternative materials, structures, configurations, methods, circuits, 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 general inventive concepts 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. 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.

**What is claimed is**

1. A cap suitable for use in enteral feeding from a container, the cap comprising:  
a base having a top surface, a bottom surface, and an outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to a container having a mouth, wherein the protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture;  
and  
an insert cutter having a first end portion attached to the bottom surface of the base and about an edge of the spike connector outlet aperture and a second end portion extending over at least a portion of the spike connector outlet aperture;  
wherein the insert cutter is capable of flexing at a hinge in an insertion direction of a spike connector inserted through the spike insertion chamber.
2. The cap of claim 1 wherein the spike connector insert aperture is cross-shaped.
3. The cap of claim 1 wherein the insert cutter is configured to extend over at least a portion of the spike connector outlet aperture such that an inserted spike connector will engage a seal over a mouth of a container.
4. The cap of claim 1 wherein the insert cutter is rigid and flexes in the insertion direction of a spike connector when the spike connector is in an installed position within the spike insertion chamber.
5. The cap of claim 1 wherein the insert cutter is configured to promote liquid flow from a container by sufficiently displacing a seal over a mouth of a container when a spike connector is in an installed position.
6. The cap of claim 1 wherein the insert cutter is hourglass-shaped and the second end portion substantially ends in a point.

7. The cap of claim 1 wherein at least a portion of the insert cutter is triangle-shaped and the second end portion ends in a point.

8. The cap of claim 1 wherein the insert cutter is attached to the bottom surface of the base by ultrasonic welding.

9. The cap of claim 1 comprising a second insert cutter, wherein each of the two insert cutters is capable of flexing at a hinge in the insertion direction of a spike connector inserted through the spike insertion chamber.

10. The cap of claim 9 wherein the two insert cutters are capable of opening in a saloon door style.

11. The cap of claim 1 wherein the protruding port has an outer circumferential surface configured to limit an insertion depth of a spike connector.

12. The cap of claim 1 wherein the protruding port has a threaded outer circumferential surface.

13. The cap of claim 12 wherein upon insertion of a spike connector, the leading edge of the spike connector pierces a seal of a container upon the spike connector engaging the threaded outer circumferential surface of the protruding port.

14. The cap of claim 1 further comprising at least one filter permitting air flow through at least one hole in the base.

15. The cap of claim 14 further comprising a raised dome covering the hole in the base, wherein the dome is configured to prohibit insertion of an object through the hole in the insertion direction of a spike connector.

16. The cap of claim 15 wherein the raised dome is configured to allow air flow between the filter and the dome.

17. The cap of claim 1 further comprising a dust cover removably fixed to the base of the cap, wherein the dust cover has an outer diameter equal to an outer diameter of the base at a contiguous location.

18. A cap for use in enteral feeding from a container of liquid, the container having a mouth covered by a seal, the cap comprising:

- a ring having a female threaded inner surface for attachment to the container;
- a disk fixed to an upper edge of the ring, the disk having a top surface and a bottom surface, the top surface having a protruding port suitable for insertion of a spike connector, wherein the protruding port defines a spike insertion aperture; and

- an insert cutter having a first end and a second end, the first end attached to the bottom surface of the disk;

- wherein the insert cutter is capable of flexing about a hinge in an insertion direction of a spike connector inserted through the spike insertion aperture.

19. The cap of claim 18 wherein the spike insertion aperture is cross-shaped.

20. The cap of claim 18 wherein the insert cutter is substantially rigid and extends in the insertion direction of a spike connector when the spike connector is in an installed position.

21. The cap of claim 18 wherein the insert cutter is configured to promote liquid flow from a container by sufficiently displacing a seal over a mouth of a container when a spike connector is in an installed position.

22. The cap of claim 18 wherein the insert cutter is hourglass-shaped.

23. The cap of claim 18 wherein the insert cutter is attached to the bottom surface of the disk by ultrasonic welding.

24. The cap of claim 18 further comprising:  
a filter permitting air flow through a hole in the disk; and  
a raised dome covering the hole in the disk, wherein the raised dome is configured to prohibit insertion of an object through the filter in an insertion direction of a spike connector, and further configured to allow air flow between the filter and the dome.

25. An assembly for use in enteral feeding, the assembly comprising:  
a container having a mouth covered by a foil seal;  
a cap having a top surface, a bottom surface, and an outer ring, the top surface having a protruding port suitable for insertion of a spike connector and the outer ring configured for attachment to the mouth of the container, wherein the protruding port defines a spike insertion chamber extending from a spike connector insert aperture to a spike connector outlet aperture; and

an insert cutter having a first end portion attached to the bottom surface of the cap and about an edge of the spike connector outlet aperture and a second end portion extending over at least a portion of the spike connector outlet aperture;

wherein the insert cutter is capable of flexing in an insertion direction of a spike connector inserted through the spike insertion chamber.

26. The assembly of claim 25 further comprising a catch on the container body suitable for engaging a hook.

27. The assembly of claim 25 wherein the container is filled with fluid.

28. The assembly of claim 27 wherein the insert cutter is configured to promote liquid flow from the container by sufficiently displacing the seal when a spike connector is in an

installed position.

29. The assembly of claim 25 wherein the insert cutter is rigid and extends in the insertion direction of a spike connector when the spike connector is in an installed position.

30. The assembly of claim 25 wherein hourglass-shaped and the second end portion ends in a point.

31. The assembly of claim 25 wherein the protruding port has an outer circumferential surface configured to limit an insertion depth of a spike connector.

32. The assembly of claim 25 further comprising:  
a filter permitting air flow through a hole in the cap; and  
a raised dome covering the hole in the cap, wherein the raised dome is configured to prohibit insertion of an object through the filter in an insertion direction of a spike connector, and further configured to allow air flow between the filter and the dome.