AMPOULE WITH PROTECTIVE SLEEVE FOR CONTAMINATION PREVENTION

Inventors: Chris Cindrich, Draper, UT (US); Robert D. Christensen, Layton, UT (US)

Appl. No.: 13/277,122

Filed: Oct. 19, 2011

Related U.S. Application Data

Provisional application No. 61/394,719, filed on Oct. 19, 2010.

Publication Classification

Int. Cl. B65D 49/00 (2006.01)

U.S. Cl. .................................................... 215/49

ABSTRACT

An apparatus includes and ampoule and a protective sleeve. The ampoule includes a body portion and an openable end portion. The body portion defines an internal cavity for containment of a substance. The openable end portion is configured to be opened by removal of a distal section, which upon removal creates an opening into the internal cavity of the body portion for liberation of the substance from the internal cavity. The protective sleeve is disposed over at least a portion of the openable end portion. The protective sleeve provides a contamination barrier to prevent contamination of an outer surface of the openable end portion covered by the protective sleeve.
AMPOULE WITH PROTECTIVE SLEEVE FOR CONTAMINATION PREVENTION

[0001] This application claims the benefit of U.S. Provisional Application No. 61/394,719, filed on Oct. 19, 2010, entitled “Ampoule with Protective Sleeve for Contamination Prevention,” which is incorporated by reference herein in its entirety.

[0002] The use of plastic ampoules for storing and dispensing fluid is widely known. Such ampoules serve as inexpensive and convenient methods for dispensing predetermined volumes of fluid. Generally, such ampoules are relatively thin-wall, blow-molded containers which are formed via a molding process, filled with fluid then sealed closed in order to completely contain the fluid therein. There are many variables which define the precise characteristics of the ampoule which may include the size of the ampoule, the type of plastic and its relative thickness and opacity. Further, there are post process features or characteristics which can be imparted onto the ampoule such as markings relating to the type of fluid inside, the volume of the contents, dates of manufacture or expiration, etc. One of the main reasons for the design and use of plastic ampoules is their eventual disposability. They are usually single use or single-patient use containers. In single use scenarios, the ampoule is opened, an amount of fluid is expelled, and the ampoule and any remaining fluid are discarded. In a single-patient use scenario, the ampoule may have more than a single dose of the fluid and can be capped off after partial use, with the constraint generally being that that ampoule be used only on the same patient. In either scenario, the ampoule is used and partially or completely discarded appropriately after use.

[0003] Generally speaking, ampoules have design characteristics that include a closed end, a hollow central cavity, and a selectively openable sealed end. Such ampoules can be generally cylindrical in nature or more cubic in nature and, as mentioned, offer at least one end designed to be opened. In some cases, this openable end will have an area of engineered weakness such as a discontinuous segment of wall thickness that is conducive to tearing at that location in order to open the ampoule at or near that location of discontinuity. In this manner, the opening of the ampoule is made feasible, particularly the opening of the ampoule by hand with a twisting motion or the like. The shape of the openable end is often identifiable owing to the shape of the discontinuity. In some cases, the shape is simply an elongate cross section of the main hollow central cavity. In other cases, the shape may be an elongate cross section of the main hollow central cavity which tapers over some distance in order to create a more conical shape. Additionally, the conical shape may be conducive to dispensing the contents of the ampoule into precise locations owing to the funnel-like attributes that such a conical taper would afford.

[0004] In some cases, rather small amounts of fluid are desired to be placed in an ampoule. In order to mitigate the expense of raw materials and the impact of disposal of used ampoules, the ampoule itself is sized in accordance with the relative volume of the fluid intended to be placed therein. In this case, there is a relationship between the eventual size of the ampoule and both the feasibility of manufacturing such an ampoule and the human factors relating to the ease of using such an ampoule. It can be appreciated that it is possible to create an ampoule that is generally too small to be handled, opened, or used easily and correctly. For this reason, ampoules are often designed with a vestige of material adjacent to the removable end of the ampoule that enlarges the handling surface of the removable end in order to afford users more grip onto the ampoule. A user grasps the body of the ampoule in one hand and grasps this enlarged handling surface of the removable end in the other hand in order to more easily impart the twisting motion required to open the ampoule. However, with such a design there is an implied invitation to the user, via the semantics of the device, to grasp anywhere on the body of the ampoule and anywhere on the removable end, generally, without regard to the precision of the placement of the grip, in order to open the ampoule. In some settings and with some fluids such a random and haphazard use scenario may be viewed as disadvantageous. One example of this is when the ampoule and its associated fluid are for use in medical applications where the fluid is clean and sterile and the opening of the ampoule and dispensing of the fluid must not contaminate the fluid. Specifically, there are ampoules which are filled with water or saline for rinsing or flushing associated with medical procedures where the water or saline is placed in the ampoule at the time of manufacture, and when sealed the ampoule and its contents are rendered sterile by any of several methods of terminal sterilization. In this case, the objective is for the fluid to be sterilized and to remain sterile up to and including the opening of the ampoule and the dispensing of the fluid. While a terminal sterilization process will yield an ampoule with a sterile exterior surface and sterile contents, the exterior of the ampoule will not remain sterile once removed from the sterilization process. Any further handling of the ampoule relating to the eventual packaging, storage and transportation of the ampoule can contaminate the previously sterilized portions of the ampoule. Despite the fact that the exterior of the ampoule may quickly become contaminated, the contents of the ampoule will remain sterile unless the integrity of the ampoule itself is somehow extraneously compromised, for example, resulting from a puncture or other similar intrusion. More precisely, the often haphazard nature of removing the openable end of an ampoule, by the user grasping and pinching on the ampoule, results in the general contamination of much of the surface adjacent to the openable end. In the case of sterile fluids, specifically those where the contents of the interior of the ampoule are sterile and the exterior of the ampoule is not sterile, there is an unpredictable and uncontrollable interface between the sterile interior and the non-sterile exterior of the ampoule upon opening which makes it difficult to ensure that the act of opening the ampoule doesn’t permit or promote the contamination of the exterior of the ampoule to migrate to and contaminate the interior of the ampoule, the contents within the ampoule, or the contents flowing out of the ampoule. Specifically, once the ampoule is opened, the sterile fluid is expelled from the interior of the ampoule to the environment with the fluid passing at or near the unpredictable and uncontrollable interface between the sterile interior and the non-sterile exterior. In this manner, it is easy to appreciate the
potential for contamination of the sterile fluid despite the best efforts of users not to touch, manipulate, or handle the surface immediately adjacent the openable end simply because the sterile fluid passes at or near this interface.

[0005] Typical manufacturing processes used to create plastic ampoules do not afford many opportunities to inexpensively provide for touch contamination prevention of the openable end of an ampoule. This is largely due to the “open and closed” molding process that does not readily allow for the presence of undercuts in the geometry of the molded part which may prevent ready ejection of the molded part from the mold tool on completion of the molding or plastic forming of the part. Thus, what are readily available in the market place are plastic ampoules which are highly suited for virtually all aspects of their use but are markedly lacking in their ability to promote their use in a manner which minimizes or prevents touch contamination and subsequent contamination of the contents of the ampoule on discharge.

[0006] Embodiments described herein illustrate various aspects of a design having the utility of a disposable plastic ampoule that incorporates touch contamination prevention measures. These, as well as other objects and advantages of this invention, will be more completely understood and appreciated by careful study of the following more detailed description taken in conjunction with the accompanying drawings.

[0007] FIG. 1 is a front view of one embodiment of a disposable plastic ampoule with a removable end.

[0008] FIG. 2 is a section view of one embodiment of a disposable plastic ampoule with a removable end.

[0009] FIG. 3 is a side view of one embodiment of a disposable plastic ampoule with a removable end in conjunction with a segment of an anti-touch contamination sleeve.

[0010] FIG. 4 is a front view of one embodiment of a disposable plastic ampoule with an anti-touch contamination sleeve in place at the removable end.

[0011] FIG. 5 is a section view of one embodiment of a disposable plastic ampoule with an anti-touch contamination sleeve in place at the removable end.

[0012] It will be readily understood that the components of the embodiments as generally described herein and illustrated in the appended figures could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of various embodiments, as represented in the figures, is not intended to limit the scope of the present disclosure, but is merely representative of various embodiments. While the various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.

[0013] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by this detailed description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

[0014] Reference throughout this specification to features, advantages, or similar language does not imply that all of the features and advantages that may be realized with the present invention should be or are in any single embodiment of the invention. Rather, language referring to the features and advantages is understood to mean that a specific feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the present invention. Thus, discussions of the features and advantages, and similar language, throughout this specification may, but do not necessarily, refer to the same embodiment.

[0015] Furthermore, the described features, advantages, and characteristics of the invention may be combined in any suitable manner in one or more embodiments. One skilled in the relevant art will recognize, in light of the description herein, that the invention can be practiced without one or more of the specific features or advantages of a particular embodiment. In other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments of the invention.

[0016] Reference throughout this specification to “one embodiment,” “an embodiment,” or similar language means that a particular feature, structure, or characteristic described in connection with the indicated embodiment is included in at least one embodiment of the present invention. Thus, the phrases “in one embodiment,” “in an embodiment,” and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

[0017] FIG. 1 illustrates one embodiment of a disposable plastic ampoule 10. The ampoule 10 has a closed end 20, an openable end 30, and a central body 40. Openable end 30 can be generally characterized as having an elongate section 31 with a proximal section 32 and a distal section 33 and a narrowed section 34 there between. Further, in some embodiments openable end 30 is tapered with the proximal section 32 being the start of the taper and with the taper getting generally smaller as it progresses toward distal section 33.

[0018] FIG. 2 is a cross section of ampoule 10 wherein narrowed section 34 of openable end 30 is seen to correspond to an interior section 50 having a single interior cavity that is segmented into the fluid cavity 51 and the tip cavity 52. In some embodiments, the distal section 33 is formed without an internal cavity.

[0019] FIG. 3 illustrates the application of one embodiment of an anti-touch contamination sleeve 60 that is made from a heat sensitive material such as heat shrink tubing used commonly to seal containers and the like. In other embodiments, the sleeve 60 may be made from elastic or other materials that are at least temporarily deformable either inherently or through the application of some environmental condition. Sleeve 60 is illustrated as an elongate cylindrical tube with a sidewall 61 and openings 62 and 63 on the ends. Alternatively, sleeve 60 may have another geometric configuration. For example, another embodiment of sleeve 60 is open on a single end. In another embodiment, sleeve 60 may be another shape other than cylindrical. Sleeve 60 is designed to fit cylindrically about openable end 30 of ampoule 10 such that portions of proximal section 32 and all of distal section 33 and narrowed section 34 of elongate section 31 can be covered by said sleeve. Alternatively, a portion of distal section 33 may be exposed and not covered by sleeve 60. In some embodiments, at least the narrowed section 34 and a portion of the proximal section 32 are covered so that upon removal of the sleeve the covered portions will be free from contamination.
This provides a substantially sterile surface at the open end of the ampoule 10 so that the fluid and/or patient are not contaminated by use of the ampoule 10.

[0020] FIG. 4 shows sleeve 60 in place on the elongate section 31 of openable end 30 of ampoule 10 wherein heat has been applied to sleeve 60 in order to cause it to constrict about openable end 30. The discontinuous nature of the elongate section 31 of openable end 30 allows the sleeve to constrict in a manner in which it substantially conforms to the profile of openable end 30. End 62 of sleeve 60 is generally adjacent the proximal section 32 of openable end 30. End 63 is generally adjacent the distal section (not visible in this view) of openable end 30. The length of sleeve 60 can be designed to be generally longer than elongate section 31 of openable end 30 such that portions of sleeve 60 are unsupported beyond the surfaces of distal section. In this configuration, unencumbered constriction of that portion of sleeve 60 will result in the final diameter of sleeve 60, after heating, being smaller than the general outside diameter or size of the distal section. This, in combination with the constriction of sleeve 60 into narrowed section 34 of elongate section 31 of openable end 30 causes sleeve 60 to be effectively locked onto and non-removable from distal section 33 of openable end 30. End 62 of sleeve 60 then effectively becomes a cover over and around at least a portion of proximal section 32 of the openable end 30 of ampoule 10. The size of sleeve 60 and the length of the ampoule 10 that is covered by the sleeve 60 determines the surface area of the ampoule 10 that remains free from contamination. In this manner when a user grips ampoule 10 in order to open it, one hand can be used to grasp the body 40 and the opposing hand can be used to grasp substantially the entirety of the elongate section 31 of openable end 30. End 62 of sleeve 60 blocks the grasp of the hand directly onto surfaces of openable end 30, thereby preventing touch contamination of said surface.

[0021] Although the operations of the method(s) herein are shown and described in a particular order, the order of the operations of each method may be altered so that certain operations may be performed in an inverse order or so that certain operations may be performed, at least in part, concurrently with other operations. In another embodiment, instructions or sub-operations of distinct operations may be implemented in an intermittent and/or alternating manner.

[0022] Although specific embodiments of the invention have been described and illustrated, the invention is not to be limited to the specific forms or arrangements of parts so described and illustrated. The scope of the invention is to be defined by the claims appended hereto and their equivalents.

What is claimed is:
1. An apparatus comprising:
an ampoule comprising:
a body portion which defines an internal cavity for containment of a substance; and
an openable end portion coupled to the body portion, wherein the openable end portion is configured to be opened by removal of a distal section, which upon removal creates an opening into the internal cavity of the body portion for liberation of the substance from the internal cavity; and
a protective sleeve disposed over at least a portion of the openable end portion, wherein the protective sleeve provides a contamination barrier to prevent contamination of an outer surface of the openable end portion covered by the protective sleeve.
2. The apparatus of claim 1, wherein the openable end portion of the ampoule is tapered so that the openable end portion is generally narrower near the distal section than at a proximal section adjacent to the body portion of the ampoule.
3. The apparatus of claim 2, wherein the protective sleeve is tapered to substantially fit the taper of the openable end portion of the ampoule.
4. The apparatus of claim 3, wherein removal of the distal section of the openable end portion of the ampoule additionally removes the protective sleeve from the proximal section of the openable end portion of the ampoule.
5. The apparatus of claim 1, wherein the protective sleeve comprises a closed end to fully encapsulate the openable end portion of the ampoule.
6. The apparatus of claim 1, wherein the protective sleeve comprises a deformable material configured to deform to substantially fit a surface feature of the openable end portion covered by the protective sleeve.
7. The apparatus of claim 6, wherein the protective sleeve comprises a heat shrink material.
8. A method of using an ampoule comprising:
grasping the ampoule at approximately a body portion of the ampoule;
grasping an openable end portion of the ampoule at approximately a distal section, the openable end portion at least partially covered by a protective sleeve to prevent contamination of an outer surface of the openable end portion of the ampoule;
breaking a weakness in the openable end portion of the ampoule to separate the distal section from the ampoule; and
removing the distal section of the ampoule, wherein removal of the distal section of the ampoule removes substantially all of the protective sleeve from the ampoule.
9. The method of claim 8, wherein the openable end portion of the ampoule has a surface feature to facilitate retention of the protective sleeve until removal of the distal section of the ampoule.
10. The device of claim 9, wherein the surface feature comprises a raised collar.
11. The device of claim 8, wherein the openable end portion of the ampoule is tapered so that the openable end portion is generally narrower near the distal section than at a proximal section adjacent to the body portion of the ampoule.
12. The device of claim 11, wherein the protective sleeve is tapered to substantially fit the taper of the openable end portion of the ampoule.
13. The device of claim 8, wherein breaking the weakness in the openable end of the ampoule comprises twisting the distal section of the ampoule.
14. The device of claim 8, wherein the protective sleeve comprises a closed end to fully encapsulate the openable end portion of the ampoule.
15. The device of claim 9, wherein the protective sleeve comprises a deformable material that is configured to deform to substantially fit the surface feature of the outer surface of the openable end portion covered by the protective sleeve.
16. The device of claim 15, wherein the protective sleeve comprises a heat shrink material.

17. A method comprising:
   forming an ampoule, the ampoule comprising:
   a body portion which defines an internal cavity for containment of a substance; and
   an openable end portion coupled to the body portion, wherein the openable end portion is configured to be opened to create an opening into the internal cavity of the body portion for liberation of the substance from the internal cavity; and
   disposing a protective sleeve over at least a portion of the openable end portion, wherein the protective sleeve provides a contamination barrier to prevent contamination of an outer surface of the openable end portion covered by the protective sleeve.

18. The method of claim 17, wherein disposing the protective sleeve over at least the portion of the openable end portion comprises sliding the protective sleeve over the openable end portion from a distal end relative to the body portion, the protective sleeve comprising a deformable material.

19. The method of claim 18, wherein disposing the protective sleeve over at least the portion of the openable end portion further comprises treating the protective sleeve to prevent contamination of the outer surface of the openable end portion of the ampoule.

20. The method of claim 19, wherein treating the protective sleeve comprises applying heat to the protective sleeve to shrink the protective sleeve.