Title: PULL CAP FOR A PORT OF AN ADMINISTRATION ASSEMBLY

Abstract: A cap is provided for covering a port of a fluid administration assembly. The cap comprises a top wall, a side-cylindrical wall defining an opening into which said port can be inserted, and an inside surface of the top and side wall which defines a chamber. The cap further comprises a handle extending from said top wall and a plug extending from the inside surface of said top wall within said chamber.
PULL CAP FOR A PORT OF AN ADMINISTRATION ASSEMBLY

Field of Invention

The invention relates to a pull cap for a port on of an administration assembly which includes a container filled will fluid.

Background of the Invention

In the packaging arts, it is often necessary to provide the user with a port through which the contents of the package or container may be accessed. For example, in the medical field, ports allow a user to access the contents within the container such as a bag so that they can be infused into a patient, transferred to a second package or mixed with additional components. To access the contents, a sealed diaphragm, located within the port must be pierced by a needle or piercing pin. Thus, access ports have an open end for receiving the piercing pin which contacts and pierces the diaphragm. In many applications, such containers and ports are commonly made from a material known as polyvinylchloride or PVC. However, polypropylene material can be used as an alternative for those drugs that are incompatible with existing PVC delivery systems.

For intravenous solution containers made from polypropylene or any other material, it is particularly important that the open end of the access ports remain sterile to prevent the transfer of contaminants into the solution by the pin inserted into the port to pierce the diaphragm. To protect the sterility of the access port, current containers employ removable caps which cover the port opening during storage and transportation prior to use. There are several materials that can be used for the caps. Thermoplastic elastomers or polypropylene plastic are examples of such material. However, these types of caps are complicated and costly to assemble as well as more cumbersome to remove when used. Therefore, caps made from rubber have been used to eliminate these problems.

In a typical process of assembly of components, the polypropylene container (which includes a polypropylene tube for access to the container) is filled with
medicament. A rubber cap is installed on a polypropylene port and the port is heat sealed to the tube. The entire filled container assembly is then sterilized by way of autoclaving. During autoclaving, the structural components of the assembly are exposed to high temperatures. The high temperature may cause the polypropylene port to deform and set in undesired shapes. For example, the body of the port may retract inwardly due to radial compression from the rubber cap. Such deformation may create a problem with the integrity of the seal between the cap and port which may leave the assembly open to contamination. Further, inward deformation of the port will increase the force required for piercing pin insertion. Also, when the cap is installed on the port prior to sterilization, air may accumulate between the cap and port with no means of escape. As a result of the air accumulation, the cap may dislodge and fail to maintain the integrity seal between the cap and port which may cause contamination.

It would therefore be desirable to have a cap that overcomes the problems identified above. In particular, it would be desirable to have a cap that would help maintain the shape and functionality of the polypropylene port as well as maintain the integrity of the seal between the cap and port through the sterilization process.

**Summary of the Invention**

The present invention solves the problems above by providing a cap for covering a port of a fluid administration assembly. The cap comprises a top wall, a side cylindrical wall, and an opening by said side wall defined for receiving said port: said top and side wall define a chamber which communicates with the opening; a handle extending from said top wall; and a solid plug extending from the inside surface of said top wall within said chamber. The handle is offset from the center of said top wall. The handle extends along the edge of said top wall and has an arcuate shape. The side wall has an inner diameter less than the outer diameter of said port. The cap is made of a flexible material called silicone rubber.

The plug is generally cylindrically shaped. The plug is constructed to enable the plug to be easily inserted into the port, but provide physical support to the port.
through sterilization. The plug has an outer surface. The plug's outer surface and inside surface of side wall define an open annular channel therebetween for receiving a wall of said port.

The cap further comprises an annular pocket defined by said inside surface of said side wall, top wall and outer surface of said plug. The pocket communicates with said open annular channel. The pocket is rectangularly shaped in cross section. The plug extends beyond the end of said side wall.

In another aspect of the invention, there is provided an administration assembly including a container filled with fluid; a port assembly connected to said container for administering fluid from said container, said port assembly including a cylindrical port; and a flexible cap for covering said cylindrical port. The cap comprises a top wall, side cylindrical wall extending therefrom and an opening defined by said side wall for receiving said port; a handle extending from said cap; and a solid plug extending from the inside surface of said top wall. The top and side wall have an inside surface. The inside surface of the side wall and plug define an open annular channel therebetween. The cap further comprising a pocket defined by said the inside surface of said top wall, said side cylindrical wall and outer surface of said plug. The pocket communicates with said annular chamber.

Yet another aspect of the invention, a cap for covering the administration port on a container, said cap comprising a top wall, a side cylindrical wall, and an opening defined by said side wall into which said port can be inserted; a handle extending from said top wall; a plug extending from said top wall, said plug adapted to be inserted into said port; a pocket with said chamber defined by said plug, said side cylindrical wall and said top wall.

In another aspect of the invention, there is provided a cap for covering the port of an administration assembly. The cap comprises a top wall, a side cylindrical wall, and an opening defined by the cylindrical wall into which said port can be inserted; a handle extending from said top wall; a plug extending from said top wall within said chamber; and a pocket with said chamber defined by said side wall, said plug and said top wall.
Brief Description of the Drawings

Fig. 1 is a front perspective view of the cap in accordance with the invention installed on the port/container assembly;

Fig. 1A is a cross-sectional view of the cap of Fig. 1 prior to sterilization;

Fig. 2 is a side view of the cap of Fig. 1, installed on a port shown in dotted lines;

Fig. 3 is a view of the cap along lines 3-3 shown in Fig 2;

Fig. 4 is a top view of the cap along the line 4-4 in Fig. 2;

Fig. 5 is cross sectional view of the cap and container/port assembly along lines 5-5 in Fig. 1, after sterilization;

Fig. 6 is an enlarged view of the cap and port along lines 6-6 shown in Fig. 5;

Fig. 7 is a cross sectional view of the cap installed on the port shown in Fig 5, with a user pulling on the handle; and

Fig. 8 is a view of the cap shown in Fig. 5 completely removed from the port.

Description of the Preferred Embodiment

In Fig. 1, there is shown a fluid administration assembly 10 including a flexible solution container 12 for the maintenance and delivery of a sterile medical solution or fluid, a port assembly 14 and a cap 16. The port assembly 14 includes a cylindrical tube 18 and a port 20 attached to said tube 18. The container 12 is a pouch-type flexible bag made from webs of flexible film. The webs of film are sealed together along the peripheral edges. This type of container is a referred to as a fabricated package. The outer webs of film are made from a material known as polyolefin. The web of film along the inside of the container in contact with the solution is made of a polypropylene material. The port 20 is generally cylindrical shaped with the exception of the flange 17.

In brief, the process of assembly is as follows. The tube 18 is attached to the container 12 to enable filling of the container and later enable access to the contents of the container 12. One typical way to attach the tube 18 to the container is to use a thermal bonding process. Ultrasonic welding may also be used to seal the tube 18 to
the container 12. Once the tube 18 is properly attached to the container 12, the container is filled with medicament/liquid. The cap 16 is installed on the port 20 and the port 20 is heat sealed to the tube 18. The tube 18 and port 20 are both preferably made from polypropylene material. The cap 16 is made of a flexible material which is preferably silicone rubber. The inner and outer diameter of the wall 20a of the port 20 are preferably .208 inches and .258 inches, respectively. However, other dimensions (for the diameters) can be used.

As best seen in Fig. 1A, cap 16 is an integral component which includes a top wall 22 and a cylindrical wall 24 extending from the top wall 22. The edge of cylindrical side wall 24 defines an opening into which the port can be inserted. The top wall 22 and cylindrical wall 24 define a chamber therewithin that communicates with the opening to receive the port 20. The inner diameter of the side wall 24 is slightly less than the outer diameter of said port 20 so that the flexible cap 16 fits snugly over the port 20. Cap 16 also includes a solid cylindrical plug 26 extending from the inside surface of the top wall 22 within the chamber. The plug 26 includes a portion of constant diameter 26b and a portion 26a which tapers. The tapered portion 26a extends just beyond the length cylindrical side wall 24. The portion 26b of the plug 26 has a diameter of a sufficient size to fit easily into port 20, but provide stability or support to the cylindrical wall of the port 20 to maintain its shape during sterilization of the entire assembly.

The inner diameter of cylindrical wall 24 (from the inside surface) is larger than the diameter of the plug 26 to define an annular channel 28 therebetween to snugly receive the wall 20a of the port 20. The inside diameter of the cylindrical wall 24 is preferably .238 inches. However, other dimensions can be used. Deep within cap 16, there is an annular pocket 30 which communicates with the annular open channel 28. The pocket 30 is defined by the inside surface of the inner top wall 22, the inside surface 24a of the side cylindrical wall 24 and the outer surface of the plug 26. The pocket 30 is preferably rectangularly shaped in cross section, but could have other shapes.
The width of the rectangular pocket 30 is larger than the width of the annular channel (i.e., the distance between the inside surface 24a of the wall 24 and outer surface of the plug 26) in order to allow air to escape down the annular channel 28 along the exterior surface of the wall 20a of the port 20 which accumulates under pressure when the cap 16 is installed on the port 20. The width and length of the rectangular pocket 30 are preferably .027 inches and .07 inches, respectively. However, other dimensions may be used. The pocket 30 can be merely viewed as an extension of the annular channel 28 which expands at the end thereof.

The cap 16 also includes an integral handle 32 which is preferably positioned along the edge of the top wall 22 and extends away therefrom. That is, the handle 32 is offset from the center of the top wall 22 of the cap 16. The offset handle concentrates the force unequally on the port/cap thus allowing the removal of the cap at lower pull forces (see Fig. 7) as compared to a center pull handle. However, the handle could be positioned in other locations. The handle 32 has an arcuate shape, i.e., shaped in the form of a partial cylinder. The handle however could have different shapes.

Figs. 5-8 illustrate the administration assembly after sterilization. As presented earlier, the cylindrical wall 24 of the cap 16 applies a radial compressive force on the cylindrical wall 20a of the port 20, which can reduce the diameter of the cylindrical wall 20a during sterilization. Because the cylindrical wall 20a is not in contact with the inside surface 24a of the cylindrical wall 24 inside the pocket 30, the diameter of the cylindrical wall 20a inside pocket 30, edge 20b, is not reduced. This results in a deformed shape in the cylindrical wall 20a of port 20, best represented in Fig. 6. The deformation is beneficial because it increases the friction fit between the cap 16 and the port 20 during removal. In Fig. 7, the user is removing the cap 16 off of the port 20 by pulling the handle 32 of the cap 16 downwardly, causing the seal to break between the inside surface 24a of the cylindrical wall 24 and the exterior surface 20a of the wall 20 of the port 20. The deformation of the port also provides tamper evidence. The cap 16 is difficult to replace on port 20 because the diameter of edge
20b exceeds the diameter of the inside surface 24a of the cap 16. Further, cap 16 will not seat fully on the port 20 without extraordinary effort.

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modification can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.
We Claim:

1. A cap for covering a port of a fluid administration assembly, said cap comprising:
   a top wall, a side cylindrical wall, and an opening defined by said side wall for receiving said port; said top and side wall define a chamber which communicates with said opening;
   a handle extending from said top wall; and
   a solid plug extending from the said top wall within said chamber.

2. The cap of claim 1 wherein said handle is offset from the center of said top wall.

3. The cap of claim 2 wherein said handle extends along the edge of said top wall and has an arcuate shape.

4. The cap of claim 1 wherein said side wall has an inner diameter less than the outer diameter of said port.

5. The cap of claim 1 wherein said cap is made of a flexible material.

6. The cap of claim 5 wherein said material is silicone rubber.

7. The cap of claim 1 wherein said plug is generally cylindrically shaped.

8. The cap of claim 1 wherein said plug is constructed to fit easily within said port, but provide support during sterilization.

9. The cap of claim 1 wherein said plug has an outer surface, said plug outer surface and an inside surface of side wall define an open annular channel therebetween for receiving a wall of said port.
10. The cap of claim 7 further comprising an annular pocket defined by said inside surface of said side wall, top wall and outer surface of said plug, said pocket communicating with said open annular channel.

11. The cap of claim 8 wherein said pocket is rectangularly shaped in cross.

12. The cap of claim 1 wherein said plug extends beyond the end of said side wall.

13. An administration assembly including:
   a container filled with fluid;
   a port assembly connected to said container for administering fluid from said container, said port assembly including a cylindrical port; and
   a flexible cap for covering said cylindrical port, said cap comprising:
   a top wall, side cylindrical wall extending therefrom and an opening defined by side wall for receiving said port;
   a handle extending from said cap; and
   a solid plug extending from the inside surface of said top wall, said plug adapted for insertion into said opening of said port.

14. The assembly of claim 13 wherein said top and side wall have an inside surface, said inside surface of said side wall and plug define an open annular channel therebetween.

15. The assembly of claim 13 wherein said cap further comprising an annular pocket defined by said inside surface of said top wall, said side cylindrical wall and outer surface of said plug, said pocket communicating with said annular chamber.

16. A cap for covering the administration port on a container, said cap comprising:
a top wall, a side cylindrical wall, and an opening defined by said side wall into which said port can be inserted;
a handle extending from said top wall;
a plug extending from said top wall, said plug adapted to be inserted into said port;
a pocket with said chamber defined by said plug, said side cylindrical wall and said top wall.

17. The assembly of claim 13 wherein the port is made of polypropylene.

18. The cap of claim 1 wherein said port is made of a material that is deformable under heat.

19. The cap of claim 16 wherein said plug is solid.

20. The assembly of claim 13 wherein said port and cap can be sterilized and can maintain sterility therebetween until the cap is removed.

21. The assembly of claim 13 wherein said handle is positioned to provide a firm but comfortable removal force.

22. The assembly of claim 13 wherein said port is adapted to receive a piercing pin therein.

23. The assembly of claim 15 wherein the pocket is adapted to enable the port to deform during sterilization whereby the deformation provides tamper evidence.

24. The cap of claim 18 wherein the material is polypropylene.
25. The assembly of claim 13 wherein said port is made of a material that is deformable under heat.

26. The assembly of claim 25 wherein said material is polypropylene.