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PATENT
P-2331

MEDICAL DEVICE PACKAGE

1. Background of the Invention

This invention relates to a disposable medical device and its storage in a package which provides a sterility barrier and protection, both for the device and for medical personnel, from any sharp point which may be present on the device.

2. Description of Related Information

Generally speaking, packages for medical devices, particularly devices having a sharp point intended to be used to perform percutaneous punctures, have multiple requirements. The package must provide physical protection and function as a sterility barrier for the devices so that the device is presented to its intended user in an undamaged and sterile state. The package should also provide the user easy access to the device inside. Further, it should be easily possible to remove a sterile device from the protective package without contacting the non-sterile outside of the package.

In addition to the attributes related above for the package prior to and during the use of the device contained therein, there exists a need for the package to be able to safely contain the device after its use in a patient, even if the medical operator improperly performs the usage and disposal. There has always been a need to protect medical personnel from inadvertent sticks by used sharp medical devices ("sharps"), but the advent of Human Immunodeficiency Virus (HIV) and

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the continuing threat of other infectious diseases such as hepatitis have greatly increased awareness and demand for additional protection. Additionally, there exists a need to protect service personnel from medical devices improperly used and disposed of by medical personnel.

U.S. Patent 4,113,090 to Carstens discloses a package for a medical device, particularly a needle assembly. The package includes a hollow shield having an open end for insertion and removal of a medical instrument and means for supporting the instrument inside. This package comprises a shield, a cap and a closure. The cap is shiftable between a first position to cooperate with the shield in protecting the instrument and a second position exposing a portion of the instrument to facilitate grasping and removal. Further, the cap is removable from the shield, thus allowing separation of the cap from the shield. This facile separation renders the prior art device of little value in the now very important area of protection of medical personnel during improper reshielding, which is still widely practiced contrary to recommended practice and manufacturers' instructions. Further, if the tube is separated from the shield, service personnel unknowingly handling the improperly reshielded device during disposal subsequent to use will not enjoy the protection afforded by the presence of the secondary barrier.

Although the teachings of Carstens provide some of the attributes of the instant device, the problem of separation of the cap from the shield with the concomitant loss of protection for service personnel

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continues to provide an opportunity for improvement in this area.

Summary of the Invention

A packaging assembly for a medical device includes a container for a medical device having distal and proximal ends, an external side and a sidewall. The external side of the container has a rim extending outwardly at its proximal end. The packaging assembly additionally includes a generally cylindrical hollow tube having a proximal end and a distal end, an external and an internal side defining a sidewall. The ends are open forming an open bore. There is an outwardly extending flange at the proximal end which has a generally planar surface with an opening to the bore. The container is sized so that its distal end fits into the open bore of the tube. The bore has a proximal portion and an adjacent distal portion forming an interface. The distal portion allows passage of the container up to the rim. The proximal portion of the container is sized so that the container rim fits within it. An inner side of the proximal portion has an inward projection which allows the rim of the container to pass over it when the container is moved distally, but is shaped to resist passage of the rim with proximal movement of the container. The tube flange is provided with a barrier to passage of microorganisms.

The presence of the inward projection makes the needle shield difficult to remove unintentionally from the hollow tube. The presence of the hollow tube on the shield provides a secondary barrier to needle

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sticks for service personnel if a needle should penetrate through the shield when unknowingly handling an improperly reshielded product improperly disposed of.

Brief Description of the Drawings

Fig. 1 is a perspective view of the preferred embodiment of the packaging assembly for a needle assembly.

Fig. 2 is a perspective view of a syringe assembly shown in conjunction with the packaging of the present invention.

Fig. 3 is a partial cross-sectional view of the packaging assembly of Fig. 1 taken along line 3-3.

Fig. 4 is a partial cross-sectional view of the syringe assembly of Fig. 2 taken along line 4-4.

Fig. 5 is, similar to Fig. 3, a partial cross-sectional view of an alternative embodiment of the packaging assembly of Fig. 1.

Fig. 6 is a partial cross-sectional view of the packaging assembly of Fig. 5 with the microbial barrier opened.

Detailed Description

While this invention is satisfied by embodiments in

many different forms, there is shown in the drawings and will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. The scope of the invention will be measured by the appended claims and their equivalents.

For the purposes of the description of the present invention the term "distal end" is meant to refer to the end of the assembly furthest from the operator, whereas the term "proximal end" is meant to refer to the end of the assembly closest to the operator.

Referring to Figs. 1 and 3, a preferred packaging assembly 10 of the present invention comprises a container, such as a needle shield 11, a needle assembly 12 and a generally cylindrical hollow tube 13. This tube includes a proximal flange 14 optionally having a peelable microbial barrier 15 adhesively bonded to the flange. Needle assembly 12 includes a luer needle hub 16 with a needle 17 affixed thereto.

As shown in Fig. 3, proximal flange 14 has a generally planar surface 18 having an opening 19 to a tube bore 20. Tube 13 has a distal portion 21 with a radius A and a proximal portion 22 with a radius B adjacent at an interface 23. Radius B is larger than radius A. Needle shield 11 has an outwardly extending rim 24 that fits within proximal portion 22 of bore 20 and distal portion 21 is sized so that shield 11 fits slidably within it up to rim 24. Rim 24 passes through proximal portion 22 to rest on interface 23 between

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portions 21 and 22.

An inner wall 25 of proximal portion 22 has an inward projection 26 located proximally from interface 23. The inward projection is shaped to allow rim 24 to be passed thereover with a distal movement and to resist passage of rim 24 in a proximal direction, thereby serving to retain tube 13 on shield 11. In the embodiment shown in Fig. 3, projection 26 is located at a distance proximally from interface 23 to capture rim 24 to rest adjacent the interface. Additionally, proximal portion 22 may contain a plurality of sealing rings 27 located proximally from projection 26. Sealing rings 27 are sized to contact cooperatively with an interference fit to a device sized to be placed in proximal portion 22. The cooperative contact substantially serves as a barrier to the passage of microorganisms, allowing the tube to serve as a primary package including the device. In cases where there is no placement of a device in proximal portion 22, rings 27 may be deleted.

Barrier 15 is peeled from surface 18 of flange 14 preferrably by means of a tab 29. Barrier 15 is preferably tamper-indicating and peels without generation of particulates. In the case where the package assembly is not intended as a final package, barrier 15 may be deleted.

Distal portion 21 of tube 13 extends over at least a portion of shield 11. Tube 13 is shown with an internal side 25 of portion 21 preferably having a plurality of inwardly projecting sealing rings 28 which cooperatively contact an external surface 32 of a

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sidewall 33 of needle shield 11 with an interference. The cooperative contact substantially serves as a barrier to passage of microorganisms. If the intended application of the assembly is not a final sterile package, the rings may be deleted. The extension of distal portion 21 over shield 11 further serves as a secondary protective barrier for substantially reducing the incidence of accidental personnel sticks by a penetration of a sharp medical device such as a needle through sidewall 33 of the shield during improper reshielding or unknowning handling by service personnel during disposal after reshielding.

An embodiment of the present invention is shown in Figs. 2 and 4 wherein a packaged syringe assembly 34 includes a syringe 35 with a distal luer tip 36 having an external collar 37. The syringe 35 includes a finger flange 38, a syringe barrel 39, a plunger cap 40 and a plunger assembly 41. Self-contained syringe assembly package 34 further includes hollow tube 13 and needle assembly 12 detachably mounted with interference on distal luer tip 36 with luer hub 16. External collar 37 is fitted into hollow tube 13 having flange 14 and needle shield 11 fitted within it. Syringe assembly 34 includes all other elements of the previously described packaging assembly 10 with the exception of the optional barrier 15. Proximal portion 22 is sized to accept syringe external collar 37 with an interference fit and accept needle shield rim 24. Proximal portion 22 preferably has a plurality of sealing rings 27 located proximally to projection 26 sized to contact cooperatively external collar 37 with an interference fit. The cooperative contact substantially provides a barrier to the passage of

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microorganisms. The syringe assembly as shown in Figs. 2 and 4 and described above, when terminally sterilized, serves as a self-contained package providing microbial isolation of the fluid path of the syringe and the needle as well as the exterior of the needle, thus eliminating the need for additional packaging.

Referring to Figs. 5 and 6, an alternate embodiment of the instant invention is illustrated. In this alternate embodiment the structure of the hollow tube 13 is substantially similar to the embodiment presented in Figs. 1-4. Accordingly, substantially similar components that perform substantially similar functions will be numbered identically to that component of the embodiment of Figs. 1-4 except that a suffix "a" will be used. In this embodiment, an alternate placement is made of projection 26a on proximal portion inner wall 25a. Projection 26a is located proximally to interface 23a. Projection 26a is shaped to allow passage of rim 24a of shield 11a with movement in a distal direction and to resist movement of rim 24a with movement in a proximal direction. The proximal placement of projection 26a on proximal portion inner wall 25a permits proximal movement of shield 11a from interface 23a within portion 22a to allow exposure of needle hub 16a after removal of microbial barrier 15a for mounting a syringe. The microbial barrier 15a can be removed by use of tab 29a, or alternatively, barrier 15a can be provided without a tab. In this case barrier 15a would be removed by a proximal movement of needle shield 11a from shoulder 23a to projection 25a, pushing hub 16a against barrier 15a and detaching it from flange 18a. This ability for proximal movement avoids contact of

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the sterile hub 16a with the non-sterile package exterior. The design provides for retaining needle shield 11a within hollow tube 13a to provide added needle stick protection after improper disposal.

A benefit of the design of tube 13 is that placement of projection 26 or 26a may be simply accomplished when the tube is formed by injection molding by the use of alternate mold cores. Alternate cores can also be used to size the bore to suit particular size needle shields and for presence or absence and location of sealing rings. Tube 13 may be formed from a plastic, preferably polypropylene, polyamide, polyethylene, polyvinylchloride, polycarbonate and polystyrene, preferably polypropylene, and the like.

The barrier which is used to cover the tube flange can be a molded cap or preferably is a peelable membrane selected from the group consisting of paper, non-woven fabric and film. Medical device packages having all openings with barriers to the passage of microorganisms can be completely assembled and then subjected to terminal sterilization conditions by exposure to ionizing radiation, gas sterilization or any other method for which the materials employed in the manufacture of the device and package components have been qualified. Following this terminal sterilization, the device, or in the case of the self-contained syringe assembly, the fluid path, will remain sterile until the package is opened.

In addition to having the peelable membrane present in several embodiments of the invention as a

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tamper-evidence, one can employ heat shrink bands or heat stakes at caps or at the several interference junctions present on the device as indicia of package integrity.

In the case of improper disposal, the presence of the non-removable hollow tube over the needle shield substantially serves as a secondary barrier to accidental needle sticks by a needle protruding through the sidewall of the shield. Such a protrusion could occur as a result of improper techniques like reshielding of a needle which was bent during usage. Following this usage, subsequent safe handling by service personnel unknowingly handling the product for disposal is substantially facilitated because the hollow tube will still likely be present on the shield.

Thus it can be seen that the invention of a medical device package having a non-removable secondary barrier which serves as a packaging assembly and a barrier to guard against personnel contact with an improperly disposed of used needle represents an improvement to the state of medical device packaging.

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WHAT IS CLAIMED IS:

1. A packaging assembly for a medical device comprising:

a container for receiving a medical device having a distal and a proximal end, an external surface and a sidewall, said external surface of said container having a rim at said proximal end extending outwardly therefrom;

a formed generally cylindrical hollow tube having a proximal end and a distal end, an external side and an internal side forming a sidewall, said proximal end and said distal end of said tube being open so as to form an open bore extending therethrough, said proximal end of said tube having a flange extending outwardly from said external side thereof, said flange including a generally planar surface having an opening to said bore; and

said container being sized so that said distal end thereof fits slidably within said open bore of said tube, said tube having within said bore a distal portion and a proximal portion adjacent to said distal portion at an interface, said tube distal portion sized to allow passage of said container up to said outwardly extending rim, said proximal portion of said tube bore sized to accept said outwardly extending rim of said container, said tube proximal portion having an inwardly extending projection from the internal side thereof shaped to allow said rim of said container to be passed thereover with movement in a distal direction and to resist passage of said rim with movement in a proximal direction.

2. The packaging assembly of claim 1 wherein said inward projection portion is located at a distance proximally from said interface sufficient to capture said rim of said container adjacent to said interface.

3. The packaging assembly of claim 1 wherein said inward projection is located at a distance proximally from said interface to permit slidable movement of said rim between said interface and said proximal end of said tube.

4. The packaging assembly of claim 1 wherein said distal portion of said tube extends over at least a portion of said container and said bore has a plurality of raised sealing rings to contact cooperatively said external surface of said container



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with an interference, said cooperative contact substantially forming a barrier to passage of microorganisms and said extension of said tube over said container thereby acting as a secondary barrier to accidental personnel sticks by a penetration of said medical device through said sidewall of said container.

5. The packaging assembly of claim 1 wherein said flange further includes a barrier to passage of microorganisms, said barrier including a peelable membrane bonded to said flange and selected from the group consisting of paper, non-woven fabric and film

6. The packaging assembly of claim 1 wherein said tube is formed from a plastic selected from the group consisting of polypropylene, polyamide, polyethylene, polyvinylchloride, polycarbonate and polystyrene.

7. A packaging assembly for a medical device comprising:

a container for receiving a medical device having a distal and a proximal end, an external surface and a sidewall, said external surface of said container having a rim at said proximal end extending outwardly therefrom;

a formed generally cylindrical hollow tube having a proximal end and a distal end, an external side and an internal side forming a sidewall, said proximal end and said distal end of said tube being open so as to form an open bore extending therethrough, said proximal end of said tube having a flange extending outwardly from said external side thereof, said flange including a generally planar surface having an opening to said bore;

said container being sized so that said distal end thereof fits slidably within said open bore of said tube, said tube having within said bore a distal portion and a proximal portion adjacent to said distal portion at an interface, said distal portion sized to allow passage of said container up to said outwardly extending rim, said proximal portion of said tube bore sized to accept said outwardly extending rim of said container, said proximal portion having an inwardly extending projection from the internal side thereof shaped to allow said rim of said container to be passed thereover with movement in a distal direction and to resist passage of said rim with movement in a proximal direction;

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said distal portion of said tube extending over at least a portion of said container and said bore having a plurality of raised sealing rings to contact cooperatively said external surface of said container with an interference, said cooperative contact substantially forming a barrier to passage of microorganisms and said extension of said tube over said container thereby acting as a secondary barrier to accidental personnel sticks by a penetration of said medical device through said sidewall of said container; and

means for providing a barrier to passage of microorganisms past said flange.

8. A syringe assembly comprising:

a syringe having a distal luer tip for detachably mounting a needle and having an external collar on said distal tip;

a needle assembly comprising a proximal luer hub and a needle affixed thereto, said hub detachably mounted on said distal syringe tip;

a needle shield having a distal and a proximal end, a generally cylindrical sidewall having an external surface sized to removably fit at said proximal end with an interference over at least a portion of said proximal luer hub to enclose a needle of said needle assembly, said shield having a rim extending outwardly from said external surface at said proximal end thereof;

a formed generally cylindrical hollow tube having a proximal end and a distal end, an external side and an internal side forming a sidewall, said proximal end and said distal end being open so as to form an open bore extending therethrough, said proximal end of said tube having a flange extending outwardly from said external surface thereof, said flange including a generally planar surface having an opening to said bore, said bore having a distal portion and a proximal portion adjacent to said distal portion at an interface, said bore sized so that said distal end of said needle shield fits through said proximal portion and slidably through said distal portion of said bore so that said rim of said shield engages said interface, said proximal portion of said bore having an inwardly extending projection located proximally to said interface, said projection shaped to allow said rim of said shield to be passed thereover with movement in a distal direction and to resist passage of said rim with movement in a proximal direction; and

said proximal portion of said bore having a plurality of raised seal rings located proximally to said inward projection sized to fit cooperatively with said external collar



of said syringe luer tip with an interference, said cooperation of said rings and said collar functioning substantially as a barrier to passage of microorganisms.

9. The syringe assembly of claim 8 wherein said inward projection is located at a distance proximal to said interface in said tube sufficient to capture said rim of said needle shield adjacent to said interface.

10. The syringe assembly of claim 8 wherein said hollow tube distal portion has a length covering at least a portion of said needle shield, said distal portion having within said bore a plurality of sealing rings sized to fit cooperatively with an interference to said external surface of said needle shield, said cooperation of said rings and said surface functioning substantially as a barrier to passage of microorganisms and said coverage of said needle shield by said tube thereby substantially serving to prevent accidental personnel sticks by serving as a secondary barrier to penetration of the needle through said sidewall of said shield.

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