

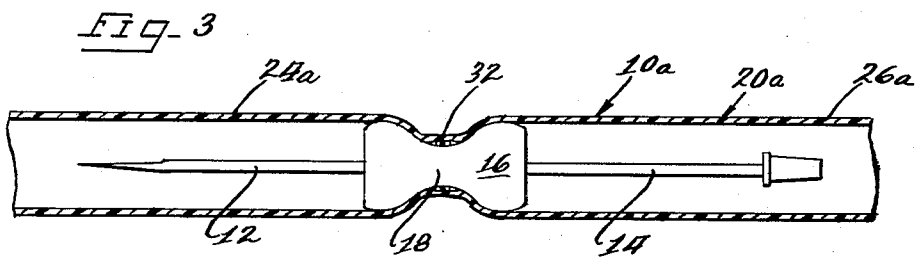
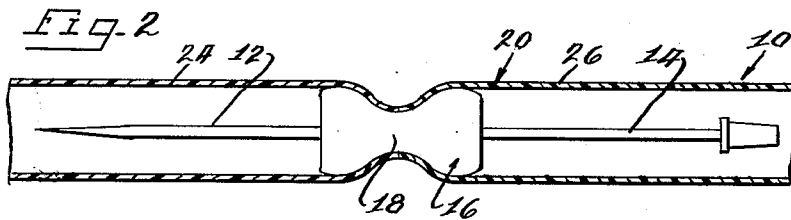
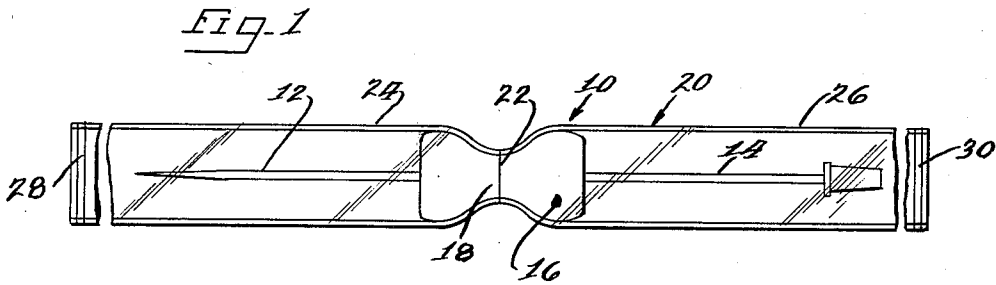
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SELF-SEALING STERILE PACKAGING AND METHOD

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SELF-SEALING STERILE PACKAGING AND METHOD

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This invention relates to a sterile packaging structure, and more particularly to a packaging structure effective to store equipment such as surgical elements or the like in sterile condition or otherwise protected relationship, and which permits pulling off one or another end of a flexible sac or envelope from a supporting member for the surgical elements as needed, to facilitate manipulation of the elements in use.

In accordance with the present invention, a central hub or supportive cylinder for a surgical needle and catheter, may be provided with a centrally inwardly arcuate configuration in the nature of a paraboloid or hour-glass in cross-section. In one embodiment of the invention, a pliant envelope structure covers and protects surgical elements or the like supported on opposite sides of the central hub, with sealed envelope sections having inner convergent ends which fit snugly on the parabolic or coved hub, the said inner ends preferably being disposed in abutting juxtaposition. The envelope structure may be formed initially as an integral unit and cut at the reduced central section thereof to provide the convergent ends described, and it will thus be seen that the ends may be pulled off successively in accordance with the sequence of procedure in a given operation, to expose, for example, a needle portion and subsequently a catheter portion to afford maximum sterility and ready maneuverability of any inside elements such as a catheter, etc., into a vein or body cavity.

Alternatively, a unitary envelope structure may be utilized having a tear strip, in substitution for the cut described, with corresponding advantages being retained in the resultant structure.

It is, therefore, an object of the present invention to provide an unusually simple sterile packaging structure wherein a single separation serves to afford removal of one end or another of a pliant envelope from protective relation to a two-part surgical instrument or the like.

Another object of the invention is to provide a packaging and surgical construction as described wherein the envelope affords maneuvering of one part of a surgical apparatus within another part as needed, with the envelope eliminating "scrubbing" or "gloving" and maintaining sterility in the operation.

Another object of the invention is to provide a packaging construction as described wherein separability of sealed envelope portions is afforded by a central cut, with a pull off action for the portions being afforded by a coved cylinder support coacting with correspondingly shaped convergent ends of the envelope portions which snugly and sealingly fit the coved cylinder or support.

Another object of the invention is to provide a device as described which is readily adaptable to packaging automation and which produces the advantageous result of permitting the opening of successive portions of a sterile zone formed by the envelope or sac.

Another object of the invention is to provide a device as described which, in one embodiment thereof, permits separability of a protective envelope by means of a single tear strip joining portions of the envelope to eliminate any complexity in construction and operation as compared with any previously available devices.

Other objects and advantages of the invention will become apparent as the description proceeds in accordance with the drawings, in which:

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FIGURE 1 is a side elevational view, partly broken away, of a sterile packaging unit according to the present invention;

FIGURE 2 is a fragmentary central vertical sectional view of the structure shown in FIGURE 1, with parts shown in elevation; and

FIGURE 3 is a vertical sectional view of another embodiment of the invention.

Referring now to the drawings, and to FIGURES 1 and 2 in particular, a self-sealing sterile packaging unit 10 is shown according to the present invention. Separate surgical elements or parts such as the needle and catheter 12 and 14 are secured in a central hub or coved cylinder support 15, which has a generally paraboloid or hourglass configuration providing a central circumferential concavity 18.

Also in accordance with the invention, an envelope structure 20 is provided which is cut centrally at 22 to define opposed envelope portions 24 and 26. The envelope may be of polyethylene, or other flexible, preferably heat-sealable material, and may have the ends 28 and 30 thereof heat-sealed or otherwise constructed to form a hermetically sealed seam.

To provide a self-sealing relationship for the envelope with respect to the hub or support structure 16, the inner ends of the envelope portions 24 and 26 are shaped convergently, to fit in snugly sealing relationship on the coved cylinder-shaped hub, with the inner ends formed by the cut 22 preferably being disposed in abutting relationship as shown. It will be seen, however, that the sealing surface afforded by the centrally coved hub 16 in fact assures a seal for the envelope portions 24 and 26 even in the event of axial outward displacement of the portions since the constricted neck areas thereof which otherwise fit around the circumferential concavity 18 will thereby be brought into increasingly tightly engaged relationship with the outer ends of the hub or support 16.

It will thus be seen that one portion of the envelope structure 20, such as the end or envelope portion 24, may be "pulled off" of the hub initially, as for example to afford entry of the needle 12 into a body cavity or vein; and the other portion 26 may then be axially pulled off in the opposite direction, as needed, to facilitate manipulation of any inside element such as the catheter 14 into a vein or body cavity. Maneuvering one part of the apparatus, such as the catheter, within the other element or part, as needed, and thereby using the sac or envelope cover 20 to eliminate "scrubbing or gloving" will maintain sterility and afford the advantages and more of constructions which may utilize a plurality of package elements. For example, removal of the sac from one part of the package construction while manipulating the other part thereof through the sac or package construction accomplishes a result which might otherwise require additional packaging elements.

Although a single initially cut envelope structure 20 has been disclosed, a single tear strip may be utilized in accordance with the invention, depending upon the mode of construction which may be easier and more feasible under packaging automation operations. In either case, the advantage is afforded of permitting the opening of successive portions of a sterile zone defined by the envelope, by pulling one portion such as the sac or envelope portion 24 and then the other portion such as the sac or envelope portion 26 from the hub or cylinder 16.

It may also be noted that the cylinder or hub 16 may be part of the surgical apparatus itself, or, if desired, may form a packaging member for receiving the sterile instrument or surgical apparatus. Thus, the hub or cylinder 16 may be used for packaging purposes only or

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may be part of the outside configuration of the sterile instrument which is housed in a plastic envelope or sheathing 20 as hereinabove indicated and set forth.

Referring now to FIGURE 3, the alternative mode construction, wherein a tear strip is utilized in substitution for the cut 22, is shown and designated generally by reference numeral 10a. In this construction, the hub or cylinder 16 is likewise coved to define a circumferential concavity 18 and the envelope 26a may be integrally formed with portions 24a and 26a converging at their inner ends over the correspondingly configured portions of the hub 16. Pursuant to the embodiment thus provided, a tear strip 32 surrounds the center of the concave portion 18 of the hub or cylinder 16, although this axial location may be varied if desired. Upon removal of the tear strip 32, the portions 24a and 26a will be in condition for removal from the hub or cylinder 16, in the manner hereinabove set forth, and it will be further appreciated that these portions 24a and 26a may, if desired, be kept in position with a self-sealing effect in the manner indicated with respect to the embodiment 10.

Also, the portions 24a and 26a may be successively removed so that first one end may be pulled off and the other end pulled off later as needed, to facilitate manipulation of any inside element such as the catheter 14 illustrated in conjunction with the needle 12. And the portion which is removed later will be maintained in the sealed position on the hub 16 so that one part may be maneuvered within the other part or element as needed, using the envelope portion remaining to eliminate "scrubbing or gloving" while maintaining sterility as above disclosed.

The invention thus combines an unusual simplicity of construction with great flexibility in application, and with utility in a wide variety of surgical instruments in addition to the indicated structure, which is exemplary of the possibilities of the device.

Although I have herein set forth and described my invention with respect to certain specific principles and details thereof, it will be understood by those skilled in the art that these may be varied without departing from the spirit and scope of the invention as set forth in the hereunto appended claims.

I claim as my invention:

1. A sterile package construction comprising a flexible envelope sealed at each end thereof and a hub having a circumferential concavity therein, said envelope having opposed portions extending over said hub and converging snugly into said concavity in sealing relationship to the hub, said portions being individually selectively removable and each maintainable in sealing relation to the hub after removal of the other portion.

2. A sterile package construction comprising a flexible envelope sealed at each end thereof and a hub having a circumferential concavity therein, said envelope having opposed portions extending over said hub and then snugly into said concavity in sealing relationship to the hub, said portions being individually selectively removable and each maintainable in sealing relation to the hub after removal of the other portion, said envelope being cut circumferentially to define said portions.

3. A surgical package construction comprising a surgical instrument, a hub receiving said surgical instrument and having a circumferential concavity therein, and an envelope structure having a pair of opposed portions with sealed outer ends and inner converging ends in sealing releasable relation with said hub and overlying the concavity of the hub, whereby to afford selective removal of said portions of the envelope successively while maintaining a sealed condition in the portion not removed.

4. A packaging device comprising an envelope structure having sealed ends and defining a circumferential cut intermediate said ends, and an interior hub-like element in sealing relationship with said envelope structure

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adjacent the cut therein, said envelope structure and said hub-like member being mutually configured to afford release of either of the similar envelope portions defined by said cut while maintaining a sealed condition relative to the other of the envelope portions defined by said cut.

5. A packaging device comprising an envelope structure having opposed closed ends, a circumferential tear strip intermediate said ends, and a hub-like member in sealing relationship with said envelope in register with said tear strip and sealing opposed portions of said envelope defined by said tear strip, said hub-like member and said envelope being mutually configured to permit release of either of the envelope portions defined by said tear strip while maintaining a sealed condition in the other envelope portion defined by said tear strip, upon removal of the tear strip.

6. A packaging construction comprising a surgical instrument apparatus, a hub on said surgical instrument apparatus, an envelope structure having inner ends releasably and sealingly joined by a tear strip construction in register with the hub, and sealing seams at ends of the envelope spaced on either side from the hub, said envelope having inner end portions immediately adjacent the tear strip formed convergently and the hub being complementarily inwardly convergent from its ends to form an inner annular concavity therearound in sealing relation with the convergently formed inner end portions of the envelope, whereby the envelope portions on either side of the tear strip may be selectively removed with the envelope portion on the other side of the tear strip maintained in sealing relation to the hub.

7. A packaging construction comprising a hub-like sealing element, a surgical instrument apparatus received in said hub-like sealing element, and an envelope structure having mutually axially separable portions in sealing relation with the hub-like sealing element, said envelope portions having inner converging ends and said hub-like sealing element having correspondingly convergent surfaces forming an inner circumferential concavity in sealing relation with said inner converging ends of said envelope portions.

8. A packaging construction comprising a plastic flexible envelope having a closed end and an end opposite the closed end convergently formed with respect to the overall diameter of the envelope, and a sealing element having a configuration complementary to said convergently formed end and disposed in sealing relation with said convergently formed end whereby said envelope may be pulled from said sealing element to unseal the envelope as desired.

9. A packaging construction comprising, a pliant plastic envelope having a hermetically sealed end and an open end opposite said hermetically sealed end, and a hub element for securing a surgical instrument in said envelope, said hub element converging inwardly from at least one end thereof, said open end of said envelope having marginal portions converging toward said open end with respect to the adjacent envelope portions, in complementary relation to the hub and said converging portions overlying said hub in complementary sealing relation thereto to automatically seal the envelope with respect to the hub, said envelope being removable from the hub but maintaining a sealed relation with the hub until fully removed.

10. A packaging construction comprising, a hub having relatively enlarged outer ends and a reduced inner portion with smoothly converging sides extending from said outer ends to the inner portion, and a plastic envelope portion on each end of the hub,

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each of said envelope portions having an outer hermetically closed end and an inner open end formed convergingly in complementary relation to substantially half of the hub and extended over the hub in snugly sealing relationship, said hub being configured to receive surgical instruments or the like with opposite portions of the instrument or the like in separate envelope portions,

the envelope portions being selectively separately removable and each maintaining a sealed relationship with the hub until fully removed.

11. A packaging construction comprising, a hub-like sealing element having an outer relatively enlarged end and an inner covered portion, and a pair of envelope portions each having an outer hermetically sealed end and an inner open end convergingly fitted in sealing relation over an end portion of the hub to afford selective removal thereof with sealing on the hub until removal, and a

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surgical assembly in said hub including a needle extending from the hub into one of the envelope portions and a catheter extending through the hub into the needle from the other envelope portion, whereby the separate parts of the instrument may be individually manipulated and individual envelope portions selectively removed as required.

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