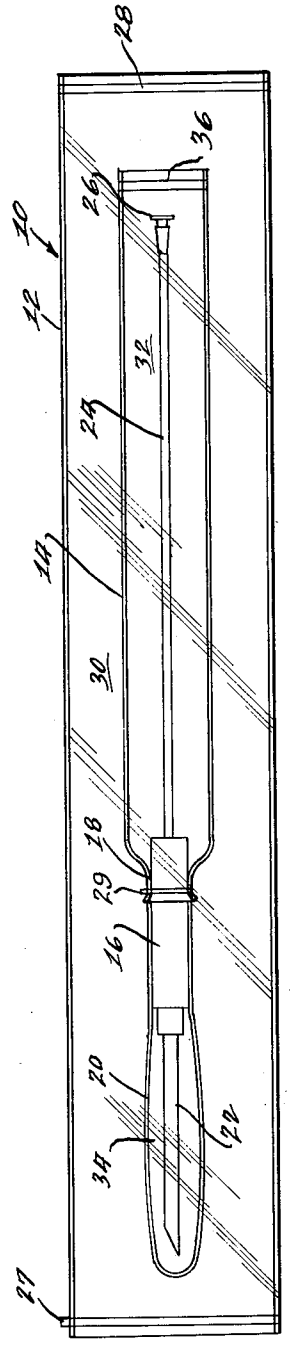
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MULTIPLE STERILE ZONE PACKAGE STRUCTURE

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MULTIPLE STERILE ZONE PACKAGE STRUCTURE

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1 Claim. (Cl. 206—63.2)

This invention relates to packaging for sterile surgical apparatus or the like, and more particularly to a multiple sterile zone packaging construction.

Heretofore, there has been considerable complexity of construction in surgical instrument packages such as packages for catheters and the like, with attendant difficulties in maintaining desirable standards of sterility. The present invention overcomes these difficulties and problems by means of a multiple zone sterile packaging construction wherein a first sterile zone is afforded by a plastic, preferably pliant envelope which may be used for a catheter and a needle, and a second sterile zone is formed by a fully protective envelope cooperatively surrounding the apparatus and the envelope forming the first sterile zone.

Further in accordance with the invention, the first sterile zone is releasably defined by a tear strip or string which may surround the needle hub in the embodiment referred to, while the second sterile zone is similarly secured by a tear strip or string at an end of the external envelope.

Accordingly, it is an object of the present invention to provide a multiple sterile zone packaging construction for sterile instruments and the like which permits the security of a basic packaging construction to be maintained intact despite hazards in shipping, storage and the like.

Another object of the invention is to provide a device as described which permits successive breaching of the security zones so that, for example, a needle may be utilized upon opening of the outer sterile zone and the encompassing package, with a second zone being opened when desired upon use of the needle.

Another object of the invention is to provide a device as described wherein the needle may be similarly retained in sterile condition by an envelope which can be penetrated thereby, although it is also within the scope of the invention to utilize a simple, relatively rigid cap for the needle since the basic apparatus is protected by the outer sterile zone.

Another object of the invention is to provide a device as described which permits access to the successive sterile zones by means of tear strip or string structures located for ready access as needed.

Yet another object of the invention is to provide a device which is simple in construction, easily manipulated without expensive training or skills for the purpose, and which is inexpensive to manufacture so that it may be utilized in automated production lines.

Other objects and advantages of the invention will become apparents as the description proceeds in accordance with the drawings in which a multiple zone sterile packaging construction is shown according to the present invention.

Referring to the drawing, a packaging construction **10** is provided which includes an outer envelope **12** of flexible plastic or the like, an inner envelope **14** of similar flexible plastic or the like, a needle hub **16** in snugly sealing relationship with a reduced end **18** of the envelope **14** and an envelope extension **20** also in preferably sealing relationship with the hub **16**, although being alternatively made as a separable rigid cover in accordance with the understanding of those skilled in the art.

In the embodiment shown, the instrument apparatus includes a needle **22** for veni-puncture or the like and of hollow construction for reception of a catheter **24** extending into the hub **16** and releasably closed by a cap **26** also as understood by those skilled in the art.

In order to permit multiple breach of successive sterile zones defined by the packaging construction described, the outer encompassing envelope **12** is provided with a tear string or tear strip **27** at at least one end thereof, or at a convenient location for opening the said outer envelope; and with a closure **28** at the other end, which may be a heat-seal seam in a preferred form of the invention.

Correspondingly, the inner envelope **14** at the reduced neck portion **18** thereof is provided with a tear string or strip **29** in juxtaposition with the hub **16** so that upon opening of the outer envelope by means of the strip or string **27**, the strip or string **29** may be operated to open the inner envelope **14** as hereinafter described.

It will thus be seen that the combined structures disclosed provide and define an outer sterile zone **30** between the outer envelope **12** and the inner envelope **14** and associated envelope structure, together with an inner sterile zone **32** specifically defined by the said inner envelope **14**. In this connection, it may be noted that a further sterile zone **34** may be formed by the forward envelope portion **20** when an envelope extension at the forward portion of the inner apparatus is utilized as shown.

Accordingly, sterility in depth is afforded by the multiple sterile zone construction defined, with the outer sterile zone being breachable by stripping off the tear strip or string **27** to place the inner apparatus in position for immediate use. Until such time, inadvertent destruction of the sterility of the apparatus is precluded.

Thereupon, the needle **22** may be maneuvered through the sac or envelope **20** and into a body cavity, as understood by those skilled in the art. Alternatively, an outer elongate rigid cap of polyethylene or the like may be removed, with the advantage that with the double sterile zone provided there is no penetration of the areas around the needle by a loose fit in such a cap, as in previously available devices.

The outer envelope **12** may be maintained in surrounding relationship to the inner apparatus, or alternatively, may be stripped off so that the manipulation of the catheter **24** may be accomplished through the inner sterile zone envelope **14**, with the result that even though the outer sterile zone is penetrated, a sterile relationship is maintained until the ultimate moment of use. Thus, the tear strip or string **29** may be taken off when full access to the catheter **24** is desired for medicinal infusions or the like. In this connection, it is noted that whereas the reduced end **18** of the envelope **14** is provided with the tear strip **29**, the outer end of this envelope may be a heat seal seam **36**.

The construction of the invention which affords sterility in depth through multiple sterile zones, thus has application in a wide variety of surgical and health situations.

Although I have described my invention with respect to certain specific principles in details thereof, it will be understood that the invention is not limited thereto, but is to be construed in accordance with the scope and spirit of the hereunto appended claims.

I claim as my invention:

In a sterile surgical package, a hollow needle, a hollow hub on said needle, a catheter extending into said hub for ultimate advancement through said needle, a flexible envelope enclosing said catheter and having one end closed and the other end sealed around said hub to maintain the catheter sterile, a second flexible envelope enclosing said needle and having one end in sealing engagement with said hub and the other end closed to maintain said needle sterile, a tear strip associated with said envelopes around said hub to effect complete removal of the envelopes one at a time when desired, a third envelope enclosing the other two envelopes and having

both ends closed to provide a sterile zone outside the other two envelopes, and a tear strip at one end of said third envelope, whereby upon removal of the third envelope the needle may be advanced through the second envelope into the body of a patient and the catheter advanced while in the first said envelope before complete removal of the first and second envelopes.

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