United States Patent

Reiss et al.

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[45] **Mar. 21, 1972**

[54] PACKAGE STRUCTURE

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[22] Filed: **Mar. 3, 1970**

[21] Appl. No.: **16,266**

Related U.S. Application Data

[63] Continuation of Ser. No. 707,165, Feb. 21, 1968, abandoned.

[52] **U.S. Cl.** **206/63.2**

[51] **Int. Cl.** **A61b 19/02**, B65d 77/30

[58] **Field of Search** ..... 206/63.2 R, 16 S, 46 SG

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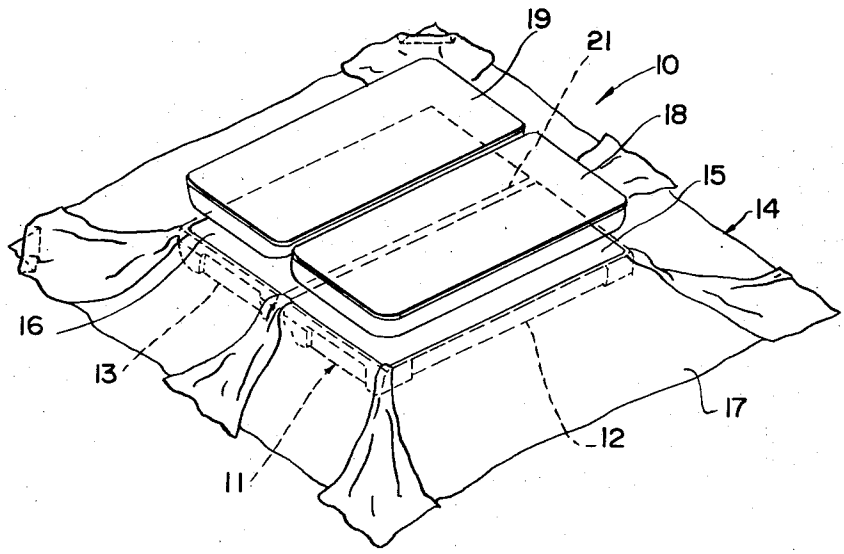
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[57] **ABSTRACT**

A packaged kit including an openable enclosure which is sealed in closed packaged arrangement with a set of articles compactly retained therein in sterile condition. The package structure further includes a flexible sheet enveloping the set within the closed package and arranged to define a passive sterile surface on which the articles are disposed when the package is opened. The articles may comprise a set of medical instruments, medicants, and the like suitable for performing a medical procedure such as a spinal anesthesia operation. The package structure is adapted to be delivered in a hospital pneumatic conveyor system. The package portions are retained in the sealed closed package arrangement by a removable tape. A label cooperates with the flexible sheet to define a hinge between the two portions for opening the enclosure in the manner of a book to make the articles therein accessible in the open arrangement. The label is placed on the outside of the package overlying the tape to further serve as a means for indicating the maintained closed condition of the package. The package is permeable for introduction of a sterilizing gas thereinto in the closed package arrangement.

16 Claims, 7 Drawing Figures



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2 Sheets-Sheet 1

FIG. 1

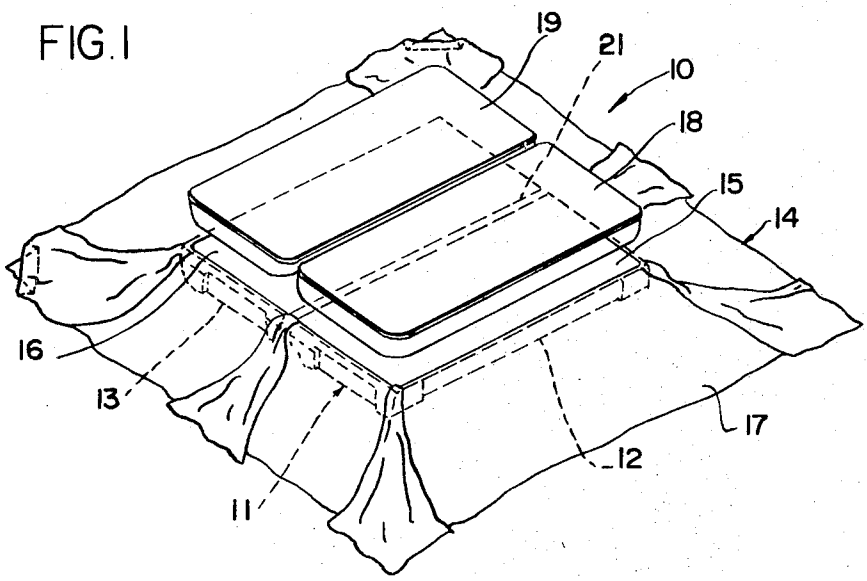


FIG. 2

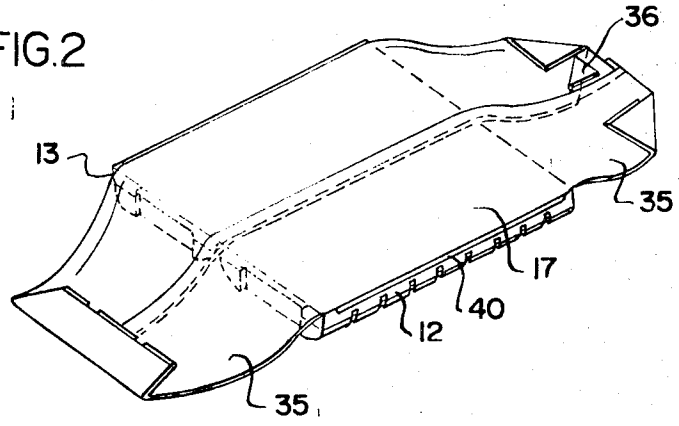


FIG. 3

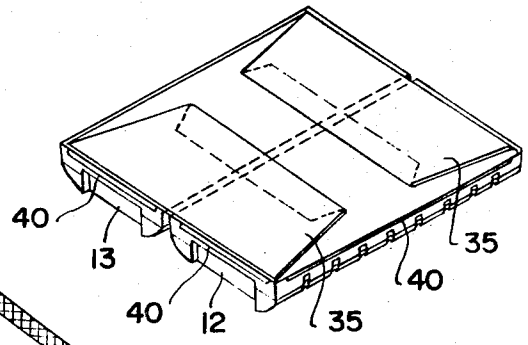
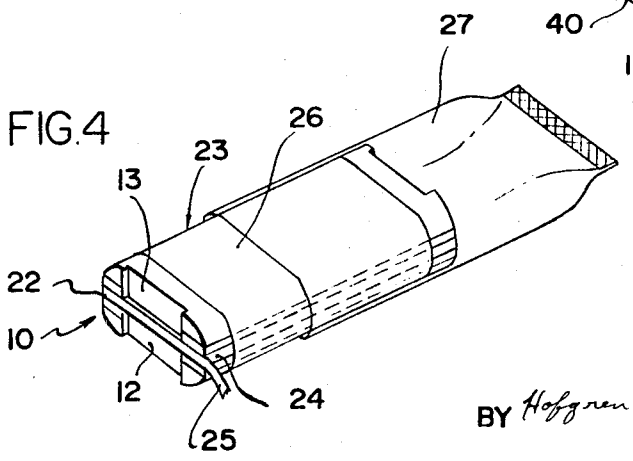


FIG. 4



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FIG.5

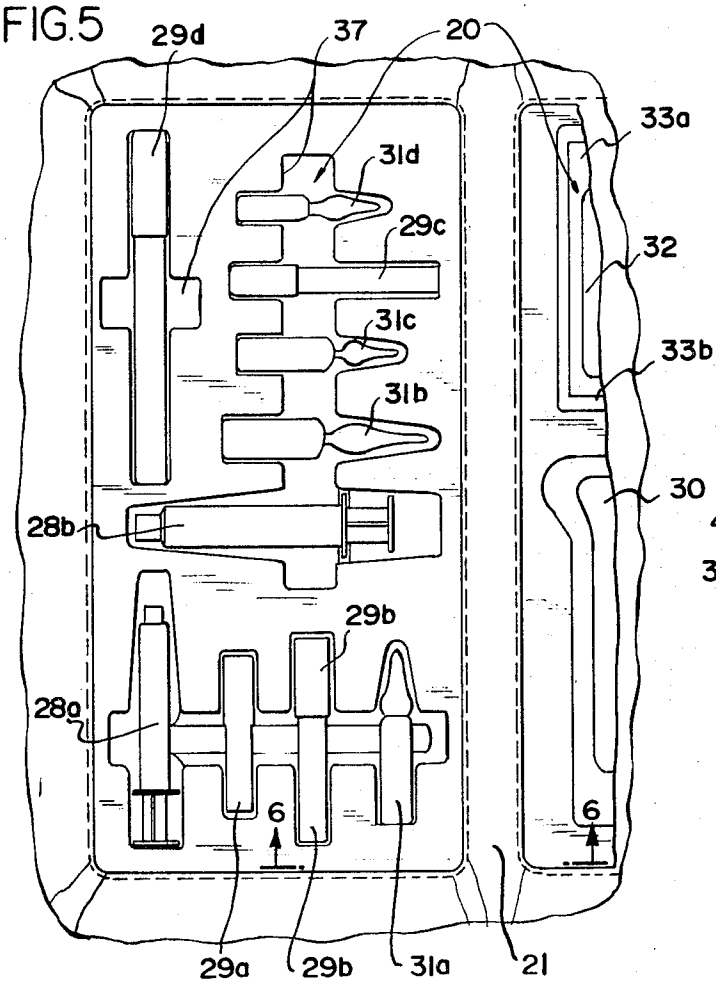


FIG.7

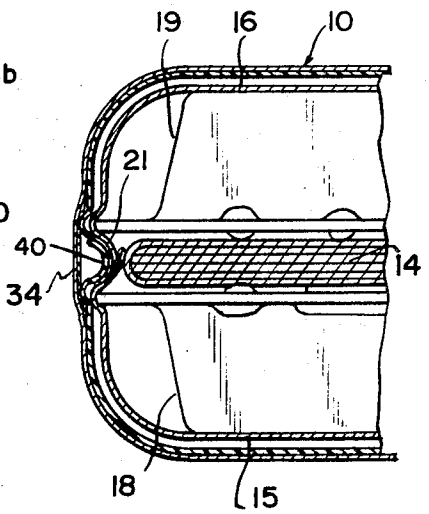
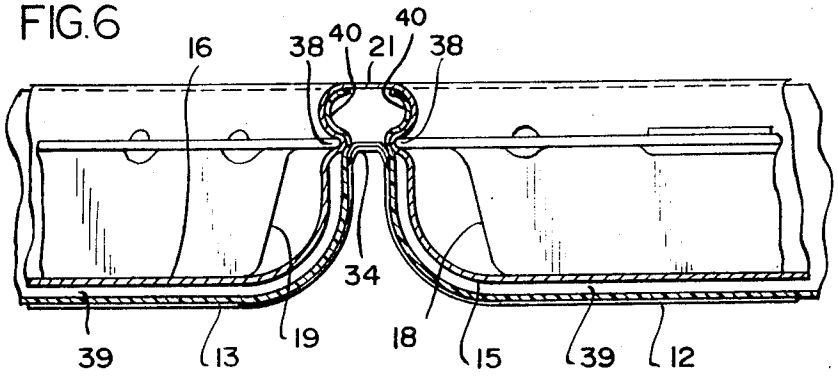


FIG.6



PACKAGE STRUCTURE

This application is a continuation of application, Ser. No. 707,165, filed on Feb. 21, 1968 now abandoned.

This invention relates to package structures and in particular to packaged kit structures.

In different medical operations including surgical operations, spinal anesthesia operations, and the like, a number of different articles such as medical instruments including syringes, swabs, and the like, medicants including anesthetics, bactericides, and the like, sterile sheets, etc., are conventionally collected by the nurse and brought to the medical operation site at the time of the operation. This requires that the nurse carefully check to see that every necessary article is obtained from the storage means and requires the maintaining of each of the articles in a separate sterile condition. The present invention comprehends an improved prepackaged kit of articles, such as such medical articles, obviating the need for such individual storage, collection and delivery. In the illustrated embodiment, a spinal anesthesia kit is disclosed.

Thus, a principal feature of the present invention is the provision of a new and improved package structure.

Another feature of the invention is the provision of such a package structure comprising a packaged sterile kit.

A further feature of the invention is the provision of such a package structure having new and improved means for maintaining the articles of the kit in sterile condition within the closed package structure and providing means defining a sterile area on which the articles are retained in the opened package arrangement.

Another feature of the invention is the provision of such a package structure wherein the articles comprise medical instruments and medicants for performing a preselected medical activity.

Another feature of the invention is the provision of such a package structure wherein the articles are retained on suitable trays within the package enclosure and the enclosure is arranged to be opened in the manner of a book whereby the articles are made accessible in the opened arrangement.

Still another feature of the invention is the provision of such a package structure including a flexible sheet within the enclosure and enveloping the articles in the closed package arrangement thereof and arranged to be extended outwardly from the enclosure in the opened arrangement thereof to define a sterile field on which the articles are disposed.

A further feature of the invention is the provision of such a package structure wherein the flexible sheet is arranged for facilitated laying out thereof in the opened arrangement of the enclosure by means obviating contact by the user with the inner sterile surface of the sheet whereby the sheet defines a sterile field.

Still another feature of the invention is the provision of such a package structure wherein the sheet defines a hinge means between the enclosure portions whereby the enclosure portions may be opened in the manner of a book.

A yet further feature of the invention is the provision of such a package structure including an outer label, and tape means for sealingly closing the juncture of the enclosure portions in the closed package arrangement, the label further defining hinge means for permitting the enclosure portions to be opened in the manner of a book.

A still further feature of the invention is the provision of such a package structure wherein the enclosure is provided with a vent means for introduction of a sterilizing gas thereinto in the closed package arrangement.

Another feature of the invention is the provision of such a package structure including label means on the outside of the package overlying the tape means whereby the label may serve as an indicator of the maintained closed package arrangement.

A still further feature of the invention is the provision of such a package structure wherein tray means are provided in the enclosure for retaining the articles therein and means are provided on the tray means and enclosure portions for releasably retaining the tray means in the enclosure portions.

A further feature of the invention is the provision of such a package structure adapted to be conveyed in a pneumatic tube conveyor in the sealed closed package arrangement.

Other features and advantages of the invention will be apparent from the following description taken in connection with the accompanying drawing wherein:

FIG. 1 is an exploded isometric view of a packaged kit structure embodying the invention with the package structure in the opened arrangement;

FIG. 2 is an isometric view illustrating a first step in the folding of the flexible sheet drape in assembling the packaged kit structure;

FIG. 3 is an isometric view illustrating a second step in the assembly;

FIG. 4 is an isometric view illustrating the arrangement of the packaged kit structure in a third step of the assembly;

FIG. 5 is a fragmentary top plan view of the packaged kit structure illustrating the arrangement of a set of articles in an accessible position on a tray thereof with the structure in the opened arrangement;

FIG. 6 is a fragmentary enlarged vertical section taken substantially along the line 6—6 of FIG. 5; and

FIG. 7 is a fragmentary vertical section similar to that of FIG. 6, but with the package kit structure in the closed arrangement.

In the exemplary embodiment of the invention as disclosed in the drawing, a packaged kit structure generally designated **10** is shown to comprise an enclosure generally designated **11** including a first portion **12** and a second portion **13**. A flexible sheet drape **14** includes a first inner portion **15** received in enclosure portion **12**, a second inner portion **16** received in enclosure portion **13**, and an outer portion **17**. The package structure **10** further includes a pair of trays **18** and **19**, tray **18** overlying drape portion **15** in enclosure portion **12** and tray **19** overlying drape portion **16** in enclosure portion **13**. The drape portion **17** is folded over the respective trays **18** and **19**, as illustrated in FIGS. **2** and **3**, so that in the closed arrangement of the package **10**, as shown in FIG. **4**, the drape envelopes the trays and a set of articles, such as articles **20** (FIG. **5**) carried on the trays. A midportion **21** of the drape **14** extends between the enclosures **12** and **13** to define a hinge means permitting the enclosure portions **12** and **13** to be swung from an open book type open arrangement of FIG. **3** to a closed book, closed arrangement of FIG. **4**.

In the closed package arrangement, the enclosure portions **12** and **13** are sealingly joined by a sealing tape **22** extending along the ends and one side of the package. The interior of the closed enclosure, generally designated **23**, may be maintained sterile by the introduction of a suitable sterilizing gas through a vent opening **24** therein. A label **26** may be provided about the enclosure **11** to overlie the tape **22**. When the tape is pulled from the enclosure in the opening of the package, the label will be torn along one side of the package thereby to indicate the opening of the package. The entire package may be placed in a suitable protective bag **27** which herein is formed of transparent plastic. The package may be sterilized by passing ethylene oxide thereinto as by permeating the package material.

As indicated briefly above, the articles **20** may comprise medical articles, such as medical instruments including syringes **28***a* and **28***b*, needles **29***a*, **29***b*, **29***c* and **29***d*, swabs **30** and the like, and medicants such as anesthetics **31***a*, **31***b*, **31***c* and **31***d*, bactericides **32** and the like, sterilized sheets **33***a* and **33***b*, etc. The articles **20** may comprise a complete set of articles necessary for a medical procedure, and herein illustratively comprise a set of medical articles for administering spinal anesthesia.

Conventionally, in administration of spinal anesthesia, the skin is cleaned by rubbing prepping solution over the area about 6 inches above and below the puncture site. The lumbar interspace for the spinal injection is selected, and a wheal is made by the subcutaneous injection of procaine hydrochloride (Novocain). Additional infiltration, if desired, is made by using a 20 or 21 gauge 1½-inch needle. A spinal

needle introducer may be inserted through the skin wheal. In normal adults, the distance from the patient's back to the dura in the lumbar region is about 1½ inch. The spinal needle must be within the subarachnoid space, but not far enough to penetrate the anterior wall of the space. Both the introducer needle and the spinal needle are usually inserted into the lumbar region while the patient's back is bent, with his head forward; but it may also be done in a lateral position. The spinal needle is passed into the introducer with the plane of its bevel being at a right angle to the spine to prevent cutting the dura. If the puncture is correct and complete, cerebrospinal fluid flows freely when the stylet of the spinal needle is withdrawn. Anesthetic solution (tetracaine/dextrose) is then injected into the subarachnoid space at the rate of approximately 0.5 cc. per second.

The illustrated kit comprises a kit providing all of the necessary components for effecting such a spinal anesthesia procedure. Thus, the kit includes the outer polyethylene tear bag **27** which acts as a dust cover, is nonconductive, and is usually removed outside the operating room. The sealing tape **22** is color-coded and printed to indicate the type of kit (spinal anesthesia) and the spinal needle gauge and length. As discussed above, the tape insures security in that it indicates whether the kit has ever been opened. When completely removed, it destroys the label — further insuring the sterility of the kit by offering a tamper-proof feature. The label **26** lists the contents of the kit with necessary precautions. Label **26** may further be provided with directions for use of the kit as required by the Food and Drug Administration.

The enclosure **11** may be approximately 10 5/8 × 5 3/16 × 2½. The kit is designed to fit onto the work table of the anesthesiologist, without overlapping the table, allowing further utilization of the work area for additional items. It will also fit into the conventional 4 × 7 pneumatic tube system used in hospitals for the transportation of materials from one division to another. The feel, weight, and sturdiness of the kit are designed to give the anesthesiologist the association that he feels when working with such kits prepared by the nurse or hospital employees.

The sheet **14** defines a sterile field 20 × 26 inches, and may be formed of white, nonabsorbent, corona discharged (nonconductive), poly-backed material, hospital folded for opening in a sterile, aseptic manner, enclosing the interior of the kit and is designed to lie flat after it is unfolded. Where a heavy-duty type paper is used as a sterile field, the anesthesiologist has to fight the paper to keep his tray unobstructed, because it has a memory and tends to refold itself.

The kit may include two specially designed prep swabs **30** of urethane foam, mounted on a sturdy polypropylene handle enabling the anesthesiologist to scrub the patient's back firmly, without the loss of solution due to spatter or leaking.

Tinted tincture of benzalkonium chloride (1:750 in 70 percent isopropanol) is packaged in a plastic bag **32** with a pour spout for use as a prepping solution.

A towel **33***a* 17 × 19 inches of white, poly-backed nonabsorbent material is provided to be placed under the patient to prevent contamination and discoloration of the operating field. A fenestrated sheet **33***b*, 22 × 26 inches, which is green to match the color of the operating field, is formed of gummed, nonabsorbent material, with a 4 × 4 inches oval fenestration. The sheet **33***b* is usually placed over the patient's back after the area has been scrubbed. The fenestration is centered over the interspace of the vertebra where the anesthesiologist plans on making his puncture.

A 2½ milliliter syringe **28***a* is normally used in combination with a 25 × 5/8 inch needle **29***a* to raise a skin wheal over the proposed puncture site. Prior to the introduction of the spinal needle, an attempt may be made to anesthetize the area by injecting a local anesthetic (Novocain or the equivalent) subcutaneously. A 21 × 1½ inch needle **29***b* is used after the skin wheat has been raised to further infiltrate the Novocain into the area of the proposed puncture. A 2 milliliter ampul **31***a* of procaine hydrochloride, 1 percent (10 mg./ml.), is used as a local anesthetic at the puncture site. A 6 milliliter syringe **28***b* is used by the anesthesiologist to mix the tetracaine hydrochloride and dextrose for injection into the spinal canal. The specific gravity of the cerebrospinal fluid averages about **1.005** to **1.009**. Depending upon the area where anesthesia is desired, the anesthesiologist can adjust the location of the anesthetic agent in the spinal canal by the addition of dextrose solution from a 3 milliliter ampul **31***b* of dextrose, 10 percent (100 mg./ml.). (For example, an isobaric solution has the same specific gravity as the cerebrospinal fluid causing the solution to remain and produce anesthesia at the level of injection; a hyperbaric solution has a specific gravity greater than the cerebrospinal fluid causing it to migrate downward and produce anesthesia below the level of injection; a hypobaric solution has a specific gravity less than that of the spinal fluid causing it to migrate upward and produce anesthesia above the level of injection.) The 2 milliliter ampul **31***c* of tetracaine hydrochloride, 1 percent (10 mg./ml.) is used as the primary anesthetic agent.

An **18** gauge by 1½ inch introducer/mixing needle **29***c* is provided with a specially designed hub to enable either a **20**, **22** or **25** gauge spinal needle to pass through the cannula without burring the spinal needle. When used as an introducer, the needle is inserted into the puncture area before the spinal needle is introduced. Its purpose is to minimize contamination of the spinal canal. For those doctors who prefer not to use an introducer, the needle may be used for drawing up and mixing of solutions from the drug ampuls.

One milliliter ampul **31***d* is of ephedrine sulfate (50 mg./ml.). Ephedrine is normally used prophylactically as a vasoconstrictor to maintain blood pressure. When desired, the ephedrine is injected subcutaneously or intramuscularly. The spinal needle **29**d may be 20, 22, or 25 gauge by 3½ inches.

Thus, the complete set of medical articles may be prepackaged in the package **10** by the manufacturer and maintained in a sterile condition for long periods of time. When it is desired to use the packaged kit structure **10**, the user need merely remove the protective bag **27**, pull the tape **22** free from the enclosure while leaving the hinge portion **34** of the label in place on the enclosure, as shown in FIGS. **6** and **7**. The enclosure portions **12** and **13** may then be swung open with the sheet portion **21** and the label portion **34** cooperatively defining hinge means to permit the opening of the enclosure in the manner of a book to the position of FIG. **3**. The folded ends **35** of the sheet are then unfolded to the extended position of FIG. **2**. The sheet may be folded to include a corner fold **36** which may be grasped by the user to facilitate the further unfolding of the sheet without contacting the inner sterile surface thereof to extend the outer portion **17** of the sheet laterally outwardly from the enclosure portions **12** and **13** as shown in FIG. **1**. Thus, the upper surface of the sheet portion **17** defines a sterile field on which the trays **18** and **19** rest with the articles **20** carried by the trays fully accessible to the user.

As shown in FIG. **5**, the trays may be formed with suitable recesses **37** for retaining the respective articles **20** for facilitated utilization thereof. The trays **18** and **19** are retained in the respective enclosure portions **12** and **13** by an interlocking rib means **38** thereon, as shown in FIG. **6**. The trays may be supported in the respective enclosure portions by ribs **39** upstanding on the enclosure portions. The enclosure portions **12** and **13** are similarly provided with interlocking portions **40** along the edges thereof which when the enclosure portions are swung to the closed package arrangement of FIG. **4** interengage to mechanically retain the enclosure portions in the closed package arrangement. Thus, each of the interlocking portions **38** and **40** and the ribs **39** function to strengthen the enclosure portions which may be formed of a relatively thin material such as plastic.

Thus, kit structure **10** provides an improved package which may be maintained in a sterile sealed condition while yet being readily openable to provide access to the articles retained on the trays therein. The sheet means provides an improved en-

larged sterile field laterally beyond the trays so that the kit may be used on relatively unsterile surfaces while maintaining the sterility of the articles. The kit structure **10** is extremely simple and economical of construction. As indicated above, the enclosure may be formed of a relatively thin plastic. Likewise, the trays may be formed of a relatively thin plastic as the recesses **37** effectively define reinforcing portions thereof. The sheet **14** may be formed of a suitable flexible material. The tape **22** may comprise a pressure adhesive tape. As the kit may be assembled by the manufacturer, omissions in the necessary articles is effectively eliminated. Relatively unskilled personnel may be used to provide the kits for use in the different medical procedures, thereby minimizing hospital and clerical expenses. The kit is adapted to be conveyed through pneumatic tube conveyor systems employed in the newer hospitals without damage to the articles contained therein by virtue of the padded resilient disposition of the trays within the enclosure.

While we have shown and described one embodiment of our invention, it is to be understood that it is capable of many modifications. Changes, therefore, in the construction and arrangement may be made without departing from the spirit and scope of the invention.

We claim:

1. A package structure comprising: an enclosure including first and second portions having juxtaposed side edges, a sheet lining the insides of the first and second portions and extending between said side edges when said first and second portions are opened to be in side-by-side relationship to define a fully opened package, a set of articles in sterile condition for performing a preselected activity enveloped by said sheet when the enclosure portions are in a closed arrangement and exposed for removal when said enclosure portions are in said fully opened package arrangement and said sheet is spread open over said enclosure portions, and means for maintaining said set sterile within said closed package arrangement, said sheet having outer edge portions arranged to extend outwardly from said first and second enclosure portions in said fully opened package arrangement.

2. The package structure of claim **1** wherein said set of articles comprises a set of medical articles for performing a preselected medical activity.

3. The package structure of claim **2** wherein said set of articles comprises a set of medical instruments and medicants.

4. The package structure of claim **1** including means secured to the outside of said package structure to define a hinged connection between said first and second enclosure portions parallel and juxtaposed to said sheet.

5. A package structure comprising: an enclosure including separable first and second portions having juxtaposed side edges, a sheet lining insides of the first and second portions and extending between said side edges to define a hinged connection therebetween when said first and second portions are opened to be in side-by-side relationship to define a fully opened package, a set of articles in sterile condition for performing a preselected activity enveloped by said sheet when the enclosure portions are in a closed arrangement and exposed for removal when said enclosure portions are in said fully opened package arrangement, means for maintaining said set sterile within said closed package arrangement, means for releasably retaining said first and second enclosure portions in a closed package arrangement, and a tray in said first enclosure portion, said set of articles being disposed in said tray, said sheet including a first portion disposed between said tray and said first enclosure portion and a second portion overlying said tray in said closed package arrangement for effectively enveloping said tray therein.

6. The package structure of claim **5** including means on said first enclosure portion and said tray for mechanically interlocking the tray in said first enclosure portion.

7. A package structure comprising: an enclosure including separable first and second portions having juxtaposed side edges, a sheet lining the insides of the first and second portions and extending between said side edges to define a hinged connection therebetween when said first and second portions are opened to be in side-by-side relationship to define a fully opened package, a set of articles in sterile condition for performing a preselected activity enveloped by said sheet when the enclosure portions are in a closed arrangement and exposed for removal when said enclosure portions are in said fully opened package arrangement, and means for maintaining said set sterile within said closed package arrangement; said sheet having a preselected size to extend beyond said first and second enclosure portions when they are opened thereby to define a controlled sterile field on which said articles are disposed in said open package arrangement.

8. A package structure comprising: an enclosure including separable first and second portions having juxtaposed side edge portions, a sheet lining the inside of said first and second portions and extending between said side edge portions to define a hinged connection therebetween when said first and second portions are opened to be in side-by-side relationship to define a fully opened package, means for releasably retaining said first and second enclosure portions in a closed package arrangement, a first tray in said first enclosure portion, said sheet including a first portion disposed between said first tray and said first enclosure portion and a second portion overlying said first tray in said closed package arrangement for effectively enveloping said first tray therein, and a second tray in said second enclosure portion, said sheet including a third portion disposed between said second tray and said second enclosure portion and a fourth portion overlying said second tray in said closed package arrangement for effectively enveloping said second tray therein.

9. The package structure of claim **8** wherein said sheet has a preselected size to extend beyond said first and second enclosure portions when they are opened thereby to define a controlled field on which said trays are disposed in said open package arrangement.

10. The package structure of claim **8** including means on said first enclosure portion and said first tray for mechanically interlocking the tray in said first enclosure portion, and means on said second enclosure portion and said second tray for mechanically interlocking the tray in said second enclosure portion.

11. The package structure of claim **8** wherein said first and second enclosure portions have interlocking edges for releasably retaining said first and second portions in a closed package arrangement with said sheet disposed fully therein.

12. The package structure of claim **8** wherein said first and second portions include edge portions in confronting relationship when said first and second portions are juxtaposed to form a closed package, and tape means is secured to said edge portions to extend therebetween for securing said first and second portions in the closed package arrangement.

13. The package structure of claim **12** including label means secured to the outside of said enclosure, said label means having a tearable portion overlying said tape means whereby said label portion will be torn when said tape means is removed to convert said package structure from a closed arrangement to an open arrangement.

14. The package structure of claim **8** including means secured to the outside of said package structure to define a second hinged connection between said first and second enclosure portions parallel and juxtaposed to said hinged connection defined by said sheet.

15. The package structure of claim **8** wherein said sheet is disposed in a folded arrangement in said closed package and has means thereon for unfolding said sheet without contacting the areas thereof overlying said first and second portions when said package is converted to said fully opened arrangement.

16. A package structure comprising: an enclosure including first and second portions having juxtaposed side edge portions, a sheet lining the inside of said first and second portions and extending between said side edge portions when said first and second portions are opened to be in side-by-side relation-

ship to define a fully opened package, means for releasably retaining said first and second enclosure portions in a closed package arrangement, a first tray in said first enclosure portion, said sheet including a first portion disposed between said first tray and said first enclosure portion and a second portion overlying said first tray in said closed package arrangement for effectively enveloping said first tray therein, and a second tray in said second enclosure portion, said sheet including a third portion disposed between said second tray and said second enclosure portion and a fourth portion overlying said second tray in said closed package arrangement for effectively enveloping said second tray therein.

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