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DISPOSABLE STERILE FIELD SURGICAL KIT

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3 Sheets-Sheet 1

FIG. 1

FIG. 2

FIG. 3

FIG. 4

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DISPOSABLE STERILE FIELD SURGICAL KIT

FIG. 10

FIG. 11

FIG. 12

FIG. 13

FIG. 14

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Disposa le Sterile Field Surgical Kit
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This invention relates to disposable sterile surgical kits adapted to provide their own full size sterile field or work area.

It is well known that ideal techniques of patient treatment require a sterile work area or field, as well as sterile equipment, to insure the greatest possible protection of the patient and equipment from contamination and incident cross infection. In view of this fact there has been an urgent need for self-contained disposable sterile field surgical equipment kits for use in catheterization and other surgical operations. Such a self-contained sterile field surgical kit must also be adapted for storing and subject to subsequent opening and one-time use without fear of contamination.

The main objects of this invention are to provide an improved form of disposable self-contained sterile field surgical kit; to provide an improved kit of this kind formed of sheet material, sections of which are folded over into successive superimposed relationships on an interior part adapted to retain the necessary instruments or other means and, thereupon, be sterilized for storage so as to be readily available for subsequent opening to spread out the sheet for one-time use as a sterile field and to allow the sterilized contents for immediate use; to provide an improved kit of this kind for enclosing composite-arranged surgical accessories available for use upon the opening of the kit to provide a disposable self-contained sterile field surgical kit of this kind which may be opened and the sheet spread out without the use of sterile instruments and absolutely free of normal incident of contamination; to provide a kit of this kind which, after effective sterilization, is suitable for storage without fear of contamination and subsequently available for instant use for general or emergency situations; and to provide an improved disposable sterile surgical kit of this kind of such simple construction as to make its manufacture and sterilization extremely economical, its use very facile, and its immunization from contamination beneficial to the patient or otherwise substantially certain.

Specific embodiments of this invention are shown in the accompanying drawings in which:

FIGURE 1 is a miniature perspective view of an enveloped, disposable, sterile field, surgical kit constructed in accordance with this invention;

FIG. 2 is a plan view showing one form of the invention as initially made preparatory to being folded for packaging, the sheet comprising the sterile field having scores and slits to facilitate folding of the several sections of the sheet into compact superimposed relationships on the interior part and encasing desired accessories, wherein it is insertable into an envelope for sterilization and storage ready for later use;

FIG. 3 is a perspective view of the same illustrating the manner in which the several portions and sections of the sterile field sheet are folded into final superimposed relationship to constitute a kit in accordance with this invention;

FIG. 4 is an enlarged, fragmentary, cross-sectional detail taken on the plane of the line 4-4 of FIG. 2 to show the details of an integral compartment for the reception of liquid drained from the patient as during a catheterization operation;

FIG. 5 is a perspective view of a sterile field sheet similar to that shown in FIG. 2 but with parts broken away and illustrating a different structuring of the central part and a different manner of folding the portions and sections of the sheet to form a kit;

FIGS. 6 and 7 are views illustrating the manner in which the several portions and sections of the sheet of FIG. 5 are folded into compact superimposed relationships to constitute a kit constructed in accordance with this invention;

FIGS. 8 and 9 are enlarged fragmentary details of a liquid container structured for use in the kit adaptation of FIGS. 5-6.

FIG. 10 is a view showing an arrangement of two sheets of material adapted to constitute a modified form of disposable sterile field surgical kit constructed in accordance with this invention;

FIG. 11 is a perspective view illustrating the manner in which the several sections of the inner sheet of the structure of FIG. 10 are folded into compact superimposed relationship to constitute the inner division of a sterile surgical kit constructed in accordance with this invention; and

FIGS. 12, 13 and 14 are perspective views illustrating the manner in which the several sections of the outer sheet of the FIG. 10 adaptation are folded successively into superimposed relationships to complete the kit with encased accessories ready for having the kit inserted into an envelope for sterilization and storage.

The essential concept of this invention involves the structuring of a sheet of material with an interior part for the collection of liquid and/or the storage of operational accessories with the bordering sections of the sheet successively folded over into superimposed relationship onto the interior part to constitute a kit insertable into an envelope for sterilization and storage, and subject to later uncontaminated opening and spreading out of the sheet within the operative area to serve as a sterile field for performing a surgical procedure upon a patient.

As shown in FIG. 2, a disposable sterile field surgical kit embodying the foregoing concept comprises a sheet of selected material, an interior part 16 of which is structured to constitute a compartment 17 for the subsequent collection of a liquid, the sheet 15 preferably having scores 18 and possibly slits 19 so arranged relative to the interior part 16 and to each other that portions of the main sections 21, 22, 23 and 24 of the sheet 15, bordering the interior part 16, when folded over into successive superimposed relationships onto the interior part 16 constitute a kit 20, encasing surgical and medical accessories and insertable into an envelope 25 and sterilized to permit storing of the kit ready for subsequent, instant and uncontaminated opening for access to sterile accessories and spreading out of the sheet 15 to serve as a sterile field for a surgical operation or procedure.

The sheet 15 may be any suitable sheet material permitting ready formation into the herein indicated kit adaptations and capable of being subject to and retaining thorough sterilization. Certain types of polyethylene and certain grades of paper have been found to be acceptable.

In one way or another the interior part 16 may be structured to form a chamber 17 suitable for the subsequent collection of a fluid or other matter. In the adaptation shown in FIG. 2, this compartment 17 is formed by a rectangular strip 26 one end of which is overlaid on and sealed around its perimeters to the interior part 16 of the sheet 15. The half 26' of the strip 26, overlies the intermediate portion of the section 22, of the adaptation shown in FIG. 2, when the sheet 15 is spread out. In the adaptation shown in FIG. 5 the compartment 17 is provided for by a trapezoidal shaped strip 27 overlaid on, and sealed along three of its perimeters to, the interior part 16 of the sheet 15 to constitute a pocket 28 for the insertion of a separately-structured container 29. In the adaptation shown in FIG. 5.
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The compartment 17 is formed by interposing a dish-like tray 31, made of cardboard, plastic, or other suitably stiff material, between and adhering to two sheets of material 15 and 15a. This tray 31 should be sufficiently stiff to hold its form independently of any extrinsic support.

In its spread-out form the sheet 15 has the four major sections 21, 22, 23 and 24 (21a, 22a, 23a, 24a) bordering the four edges of a rectangular interior part 16. These bordering sections 21, 22, 23 and 24 (21a, 22a, 23a, 24a) in the three adaptations vary somewhat in their dimensions and form to get into special results, particularly the provision of, at least, a compartment 32 (32a) for the retention of a pair of gloves and/or other accessories (see FIGS. 3 and 6).

The sheet 15, for the adaptations of FIGS. 2 and 5, has the pairs of scores 18 extending inwardly from the end edges of the sheet 15 in alignment with the lateral defining edges 33 of the interior part 16, and the pairs of slits 19 extend transversely inwardly from the side edges of the sheet 15 in alignment with the transverse defining edges 34 of the interior body part 16 (see FIGS. 2 and 5).

The sheets 15 and 15a, for the adaptation shown in FIG. 10, have no slits. However, the pairs of scores 18 and 18a, respectively, extend inwardly from the edges of the sheets and transversely thereof, as explained above, defining the central area 16.

The section 21 of the sheet 15, for the adaptations of FIGS. 2 and 5, has an opening 36 formed therein appropriately intermediate the lateral edges of the section 21, the end edge thereof and the interior part 16. Such an opening is to permit the insertion of a member of the patient's body or a conventional length of tubing when the kit is used, for example, for catheterization. Should this opening be required, a tackd marginal portion 36', defined by suitable slits or perforations, can be quickly torn out.

The liquid compartment 17, of the adaptation shown in FIG. 2 has a pair of short tubular stems 37 and 38, arranged as most clearly shown in FIG. 4, for access to the compartment 17 when the sheet 15 has been spread out as a sterile field incident to a catheterization operation. The stem 37 terminates in a conventional butter valve 39 (FIG. 4) and is adapted for connection to the end of a piece of tubing 40 (shown in dotted outline) through which the desired liquid is collected, and the port in the compartment 17. The stem 38 mounts a cap 41, the later removal of which permits access to the compartment 17 for disposal of the liquid or for the extraction of a specimen of the liquid for examination. The sheet 15, the strip 26, and these stems 37 and 38 being formed of flexible material, the stems 37 and 38 are folded down onto the strip 26 when the sections 21, 22, 23 and 24 are folded over onto the interior part 16 as shown in FIG. 3.

As shown in FIG. 2, that portion 26' of the strip 26, forming a part of the compartment 17, is calibrated by printed lines and figures to provide a ready means for determining the volume of liquid collected.

The container 29, of the adaptation shown in FIGS. 5-9, is a receptacle formed of two superimposed pieces of suitable plastic material heat-sealed around their perimeters. A conventional butterfly-valve-controlled stem 37-48 is fixed to the container 29 (not shown) through which the desired liquid is collected in the container 29. A strap 43, having one end integrally attached to the container 29 and the other end adapted to be secured as by a snap fastener 43', and a pair of ears 44, are secured to the rim of the container 29 for conventional use to attach the container 29 either to a bed rail or to a mattress covering in the well-known manner. The container 29, here shown, mounts a small tear-away auxiliary container 46 equipped with a butterfly-valve-controlled stem 47 and a drain tube 47', the drain tube being closed by a rubber plug 47'.

This auxiliary container 46 is provided to permit the collection of a desired amount of liquid for laboratory test purposes and for that use this auxiliary container 46 is preferably arranged to be ripped off along a perforated tear line junction to the main container for immediate and convenient delivery to a test station without the need for awaiting the collection of the main body of liquid for which the main container 29 is intended. The plug 47' is adapted for perforation by a syringe needle when a sterile specimen is desired. The auxiliary container itself may also serve as a test tube for certain test purposes.

The kit 29, which with its encased accessories is to be sterilized after being inserted into an envelope 25, results from a particular folding in of lateral portions of the sections 21 and 22 along the score lines 18 (18a) and the folding over of the sections 21, 22, 23 and 24 of FIGS. 2 and 5, and 21a, 22a, 23a, and 24a, and 21b, 22b, 23b and 24b (FIGS. 10-14) into successive super-imposed relationship onto the interior part 16. Such folding in and folding over differs in the three adaptations herein shown, as presently will be explained.

In the kit adaptations of FIGS. 2 and 5 the lateral portions 48 and 49 of the section 22 are narrower than the lateral portions 50 and 51 of the section 21. Hence, the combined width of the lateral portions 48 and 49 is less than the transverse width of the section 22 intermediate the score-lines 18. Thus, when these portions are folded inwardly and secured, as shown in FIG. 3, they provide the partially-open glove compartments 32 or 32a. On the other hand, when the sheet 15 is spread out for one-time use as a sterile field, it is advantageous to have as large a sterile field as practically is possible. Hence, the folded-in portions 50 and 51 of the section 21 in combination with can be as great, or possibly a little greater than the transverse width of the section 22 between the score-lines 18. This affords the greatest possible width for the sterile field work area nearby the patient.

To avoid all possibility of contamination of the kit, incident to opening it for use, a pull-tab 53 is integrated with the section 22 at its outer edge and lift-tab 54 are integrated with the portions 48 and 49 of the section 22.

The tab 53, located on the section 22 and the tabs 54 formed by the turned-out corners of the portions 48 and 49 of the section 22, are the only areas of the sterile kit 20 that need to be subjected to contact with unwashed fingers of the one preparing to make use of the kit. Moreover, being located as they are, these tabs 53 and 54 are a part of the finally-spread-out sheet 15 which has the least possible incident, if any, of imparting contamination to the sterile field work area.

The variable structuring of the interior part 16 of the adaptation of FIG. 2 and that of FIG. 5 makes advisable a slightly different manner of forming the glove compartments 32 or 32a on section 22. In the adaptation of FIG. 2 the portions 48 and 49 are folded in and secured onto the inner face of the intermediate portion of the section 22 (FIG. 3). This would be done before application of the section 26. In the FIG. 5 adaptation these portion 48 and 49 are folded in onto the outer face of the intermediate portion of the section 22 (FIG. 5 and 7). To better insure the retention of the gloves in these compartments 32 and 32a, the portions 48 and 49 are heat-sealed along their outer-end edges to the opposite edge of the intermediate portion of the section 22, as shown at 56 in FIGS. 3 and 6. If desired these portions 48 and 49 also may be sealed along the inner end-edges outwardly of the tabs 54, as shown at 57 in FIG. 5 and FIG. 6.

In the kit 20 of FIGS. 10-14 the tray 31 could be a conventional item such as is provided for household use incident to infant feeding. Or, it could be a specially-formed article for this particular use. As shown in the drawings, the tray is interposed between the two sheets.
and 15a with the interior portions of the sheets adhered to the opposite faces of the tray. In the form shown, the bottom sheet 15a is disposed in a 45 degree angular relation to the top sheet 15.

The primary purpose of this adaptation is for laying out a sterile field for accessories at the side of a patient requiring surgical attention. However, in certain emergencies, if there were need for doing so, liquid could be collected in the tray 31.

Being for such a different purpose from the other adaptations the sheet 15, of the adaptation of FIGS. 10–14, is not as large and is not provided with the opening 36 as shown in the other adaptations. Hence the sheet 15 of FIGS. 10–14 is practically the same as is scored only, substantially the same as the adaptations of FIGS. 2 and 5 are scored and slit. There are no slits in this FIG. 10–14 adaptation. Thus the fold-in portions 49a, 50a, and 51a in width, outwardly of the scores 18 are of substantially the same width as the intermediate sections 22a and 21a, respectively.

As shown, the sheet 15a of the kit adaptation of FIGS. 10–14 is disposed at an angle of 45 degrees to the sheet 15. Thus the scores 18b in the sheet 15a are diagonal to the scores 18a and 18b of the sheet 15. The four corners of the sheet 15a are scored diagonally (FIG. 11) to form lift tabs 58 as shown in FIG. 12. Also, as indicated at 59 in FIG. 11, the corner of section 24b is provided with three score lines to permit the formation of a tuck-tab 60 for securing the folded sections of the kit as indicated in FIG. 12.

The accessories encased in the respective adaptations of the kit 20 depend upon the intended use of the kit. For example, a bacterizer kit generally would contain at least the following:

- 1 plastic 14–16 Fr. catheter and tube
- 1 pkg. sterile lubricating jelly
- 1 pkg. antiseptic skin cleanser
- 1 4" x 4" gauze sponge
- 2 pair plastic gloves (cuffed)
- 1 specimen label
- 1 tube clamp (plastic)

A kit 20, such as shown in FIGS. 10–14, would contain various one-time-use instruments, made of plastic or other suitable material, and such accessories as may be needed for bed-side surgical procedures.

The gloves, already cuffed, would be placed in the respective glove compartments 32 and 32a of the respective adaptations shown in FIGS. 2–3 and 5–6. In the adaptation of FIGS. 10–14, the initial lifting of the portions 49a and 50a of the fold-in sections of the sheet 15a, in successively superimposed relationship to the folded-in sections of the sheet 15 (FIGS. 12–13) and tucking the double folded flap 60 of section 24b behind the free edges of the sections 21b and 22a as shown in FIG. 14.

Kit 20, of any of these adaptations, after being sterilized, may be stored in any convenient place for instant use as occasion may require. When the occasion does arise, for the use of such a sterile field surgical kit 20, the procedure for opening and making the intended use thereof as follows, for the respective adaptations:

**Adaptation of FIGS. 2–3.** Following the removal of the kit 20 from the envelope 25, the doctor or nurse first grips the tab 53 and lays the glove compartment section 22 back substantially into the plane of the interior part 16. The glove compartment tabs 54 are thus exposed to permit lifting of the portions 33 to 49 and 49 to remove the gloves from the compartments 32, only the cuffed portions of the gloves being touched by the bare hands. These tabs 53 and 54 are the only inside parts of the kit that are subject to contamination by reason of contact with unprotected hands.

With the sterilized gloves on the hands of the doctor or nurse subsequent contact with any other parts of the kit incurs no likelihood of contamination. Hence, the doctor or nurse proceeds to successively unfold the sections 26", 24, 23, and 21, in that order, to completely spread out the sheet 15, as shown in FIG. 1, to serve as a sterile field and afford access to the accessories—such as listed above—and permit use thereof in the conventional manner.

**Adaptation of FIGS. 5–6.** Upon removal of the kit from its envelope 25, the sterile gloves in the compartment 52 are immediately exposed for removal therefrom, merely by the lifting of the tabs 54. With the gloves on the doctor or nurse proceeds to successively unfold the sections 22, 24, 23, and 21 so as to spread out the sheet 15, in the same manner as shown in FIG. 2, to serve as a sterile field and afford access for use in the conventional manner.

**Adaptation of FIGS. 10–14.** Following removal of the kit 20 from its envelope 25, the doctor or nurse successively grips the tabs 58 on the respective sections 24b,
21b, 22b, and 23b to lay out the sheet 15 as shown in FIG. 11. Thereupon the sterile gloves are accessible. After putting on the gloves the doctor or nurse successively lays back the sections 21a and 22a and successively unfolds the section 24a and the portions 49a and 51a and finally the section 23a and the portions 48a and 50a resulting in a completely spread-out sterile sheet 15, as shown in FIG. 10, to serve as a sterile field or work area. Thereupon access is had to the sterile accessories on the tray 31 for their conventional use.

The adaptations of this invention shown in FIGS. 2 and 5 are particularly designed for use as catheterization kits for use at the patient’s bed and for that reason the sheet portion 21 serves as a drape to cover the abdomen and inner surfaces of the patient’s thighs and is provided with the opening 36 for access and insertion of the catheter into the urinary canal. Thus the kit is opened in situ, being first set in position between the patient’s legs and then unfolded, as above described with the drape portion 21 spread over the adjacent parts of the patient’s body. With male patients the organ can be inserted through the opening 36, it then being fully exposed for cleansing and insertion of the catheter. For female patients the opening 36 is enlarged by tearing away the margin 36, so as to provide sufficient room for cleansing the meatus and surrounding area and then inserting the catheter. It will thus be seen that no more area of the patient’s body than is necessary is exposed for possible contact by the doctor or nurse and a sterile work field can be maintained during the entire procedure.

A particular advantage of the present invention resides in its simple construction and arrangement whereby it can be made of relatively low cost materials for one-time use, the construction being such that when use is completed the sterile field will provide a complete wraper for the used and soiled accessories thereby making disposal a matter that can be quickly and easily accomplished.

Other advantages which ensue from the use of sterilized kits of this kind are many. The major ones are:

1. Eliminating making out requisitions to the central supply center of a hospital for needed accessories.

2. A greatly increased storage life.

3. Avoids necessity of major investment for reusable accessories separately stored and repeatedly sterilized periodically whether used or not.

4. A considerable saving of labor otherwise needed to put up sets of accessories at hospital central supply.

Although several embodiments of this invention have been herein shown and described it will be understood that details of the constructions and arrangements shown may be altered or omitted without departing from the spirit of the invention as defined by the following claims.

I claim:

1. A disposable sterile catheterization kit comprising, a sheet of flexible water impervious material of predetermined dimensions sufficient for the sheet to overhang the thighs and the abdomen of the patient when the sheet is spread and having four individual sections bordering an integral interior part, a strip of flexible water impervious material smaller in size than the said interior part of the sheet overlaid on and sealed to the said interior part of the sheet to form a compartment for subsequent use to collect liquid, the said four sections of the sheet bordering the interior part being folded over into successive superimposed relationship onto the interior part to form a closed kit encasing the said compartment, said kit being enclosed in an envelope and sterilized for subsequent uncontaminated opening for access to the interior thereof whereupon the sheet may be spread for one-time use as a sterile field for a catheterization procedure.

2. A disposable sterile catheterization kit comprising a sheet of flexible material of predetermined dimensions sufficient for the sheet to overhang the thighs and abdomen of a patient when the sheet is spread and having four individual sections bordering respective edges of an interior rectangular part, a strip of material smaller in size than the said interior part of the sheet overlaid on and sealed along three edges of its margin to the said interior part to form a pocket for receiving a container made of flexible material for subsequent use to collect liquid in a flexible container in said pocket, said individual sections of the sheet bordering the interior part being folded over into successive superimposed relationship onto the interior part to form a closed kit encasing said pocket, said kit being enclosed in an envelope and sterilized for subsequent uncontaminated opening for access to the interior thereof whereupon the sheet may be spread for one-time use as a sterile field for a catheterization procedure.

3. A disposable sterile catheterization kit as claimed in claim 2, wherein the portion of said sheet which overhangs the patient’s abdomen, when the sheet is spread, is provided with an aperture for access to the patient’s body therethrough to perform a catheterization procedure.

4. A disposable sterile catheterization kit comprising a sheet of flexible material of predetermined dimensions sufficient for the sheet to overhang the thighs and abdomen of a patient when the sheet is spread and having four individual sections bordering respective edges of an interior rectangular part, a strip of material smaller in size than the said interior part of the sheet overlaid on and sealed along its perimeter to the said interior part to provide an integral pocket to form a container, said container being suitably apertured for subsequent use to collect liquid therein, said individual sections of the sheet bordering the interior part being folded over into successive superimposed relationship onto the interior part to form a closed kit encasing said pocket, said kit being enclosed in an envelope and sterilized for subsequent uncontaminated opening for access to the interior thereof whereupon the sheet may be spread for one-time use as a sterile field for a catheterization procedure.

5. A disposable sterile catheterization kit as claimed in claim 4, wherein the apertures in said container are provided with stem portions and through which liquid is introduced to said container.

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