

[54] **FENESTRATED SURGICAL DRAPE** 3,693,618 9/1972 Madden..... 128/132 D
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 [22] Filed: **Apr. 17, 1972**
 [21] Appl. No.: **244,437**
 [52] U.S. Cl..... **128/132 D**
 [51] Int. Cl..... **A61f 13/00**
 [58] Field of Search..... 128/132 R, 132 D, 128/292

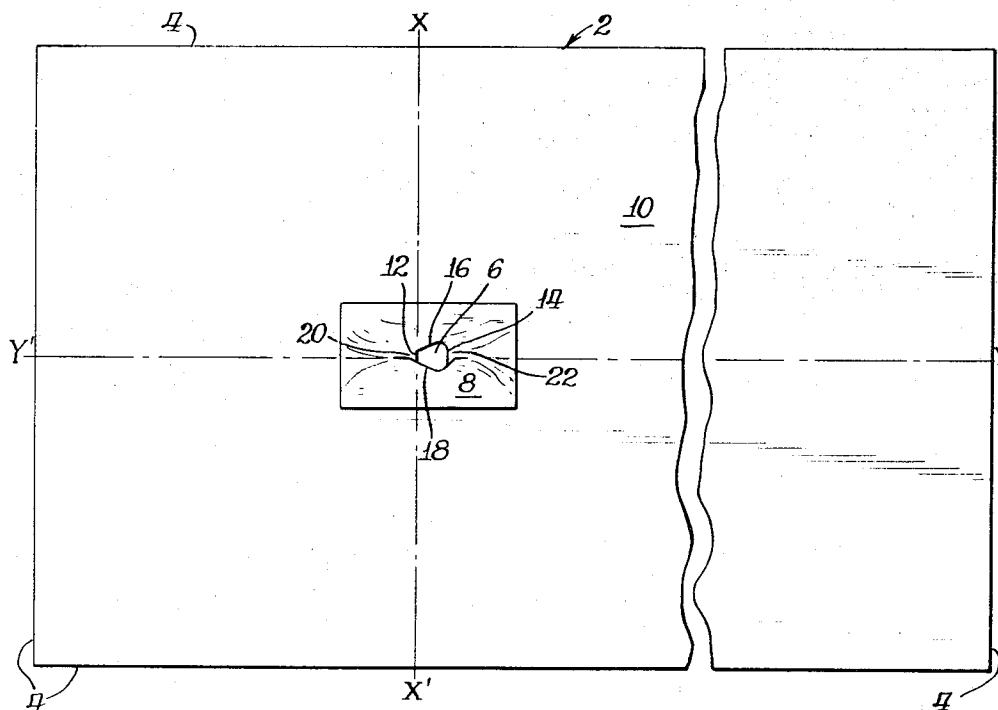
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[57] **ABSTRACT**

A surgical drape including, a sheet of material having a fenestration disposed within an area intermediate the outer peripheral edges of the sheet. The fenestration is positioned over a surgical site on a patient, and is conformable to an irregular contoured surface of the patient's body without excessive bunching, buckling or overlapping of the sheet material adjacent the fenestration. The fenestration thus remains sufficiently open during an operative procedure to provide access to the surgical site.

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19 Claims, 5 Drawing Figures



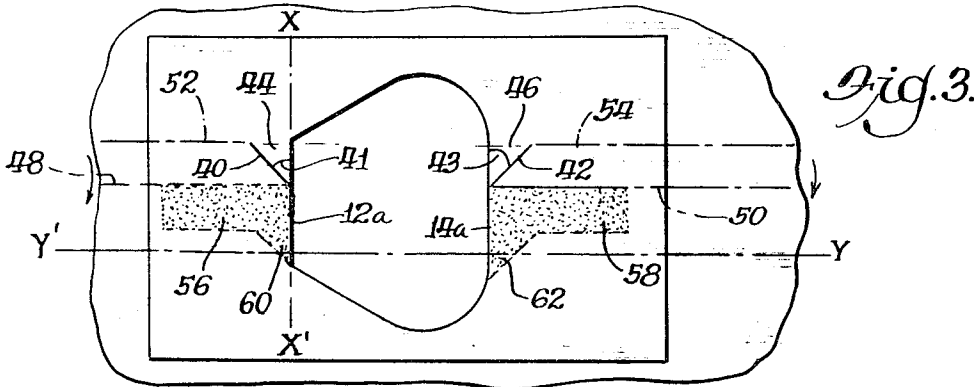
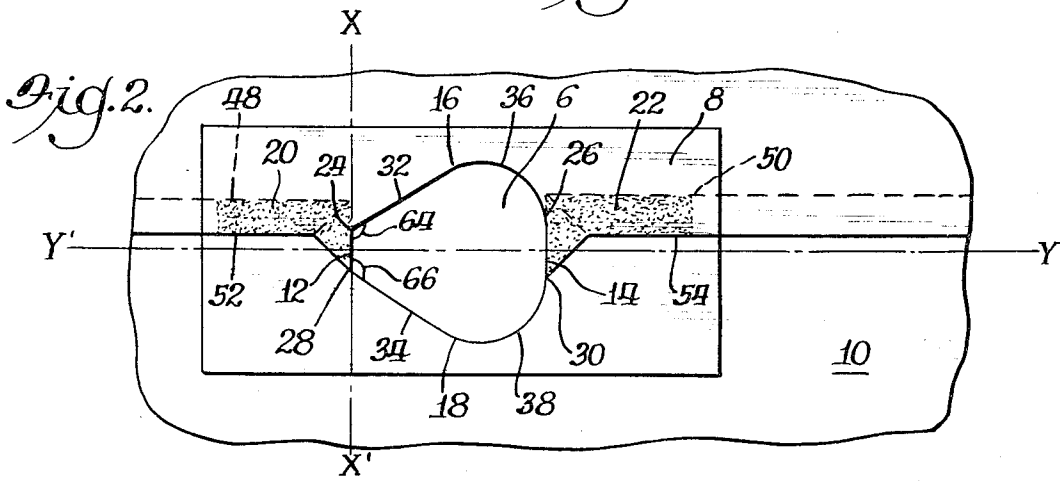
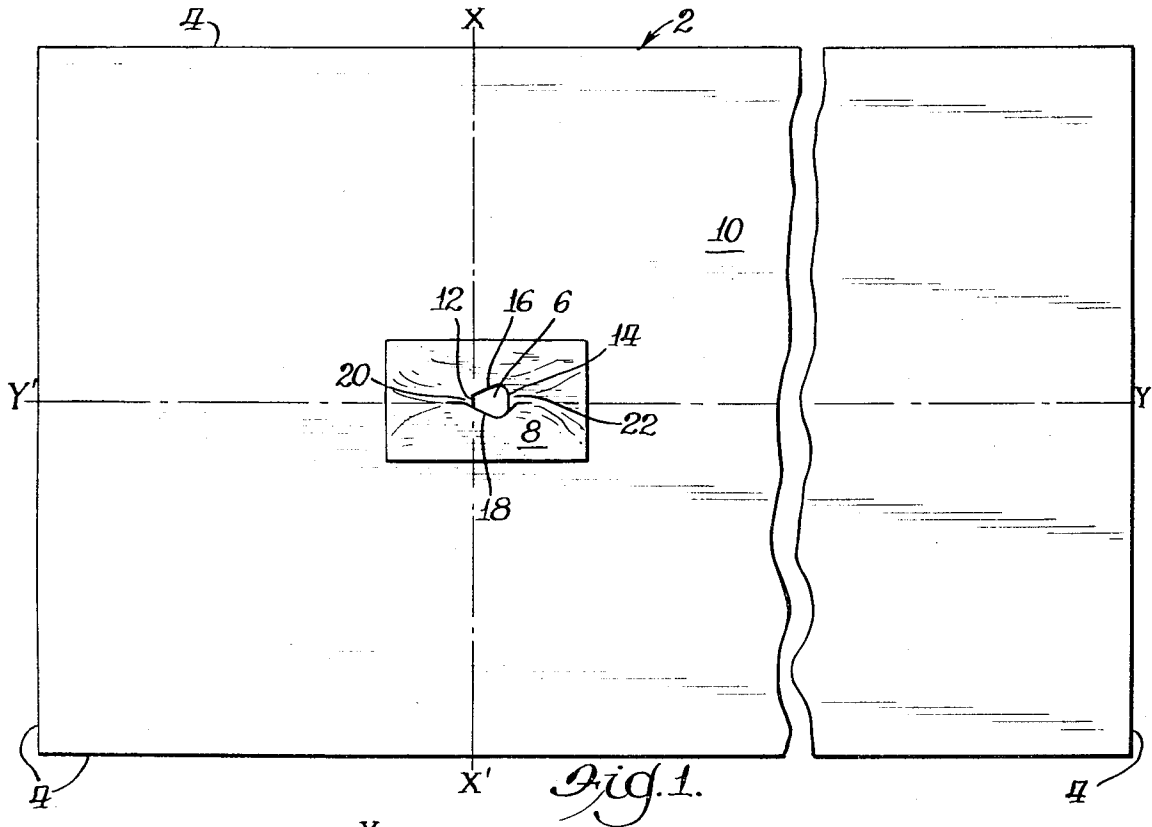


Fig. 4.

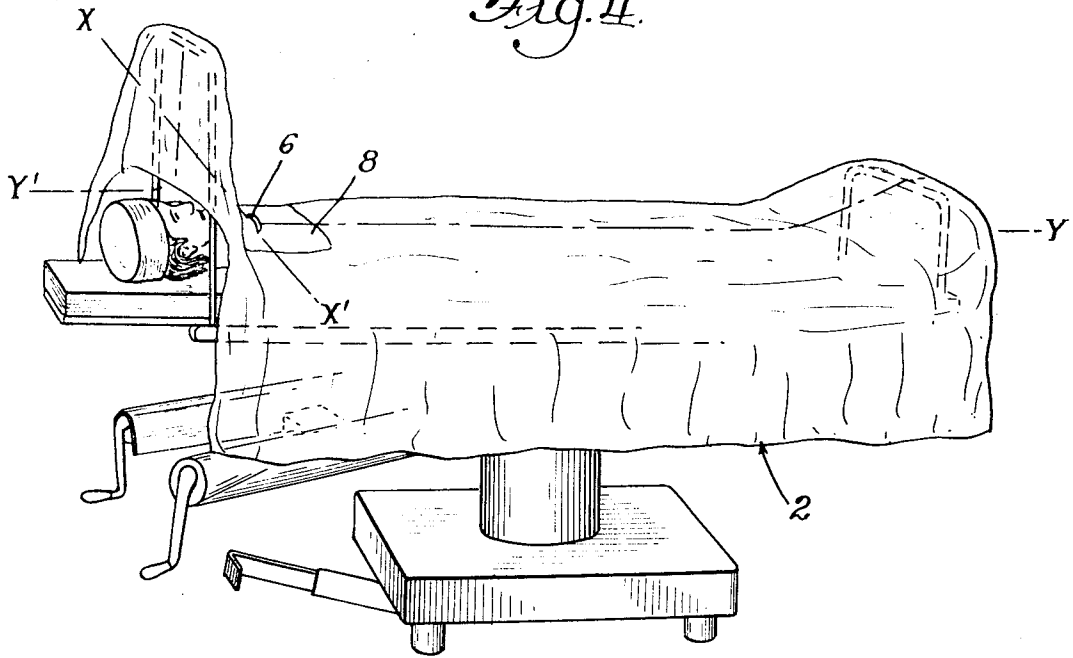
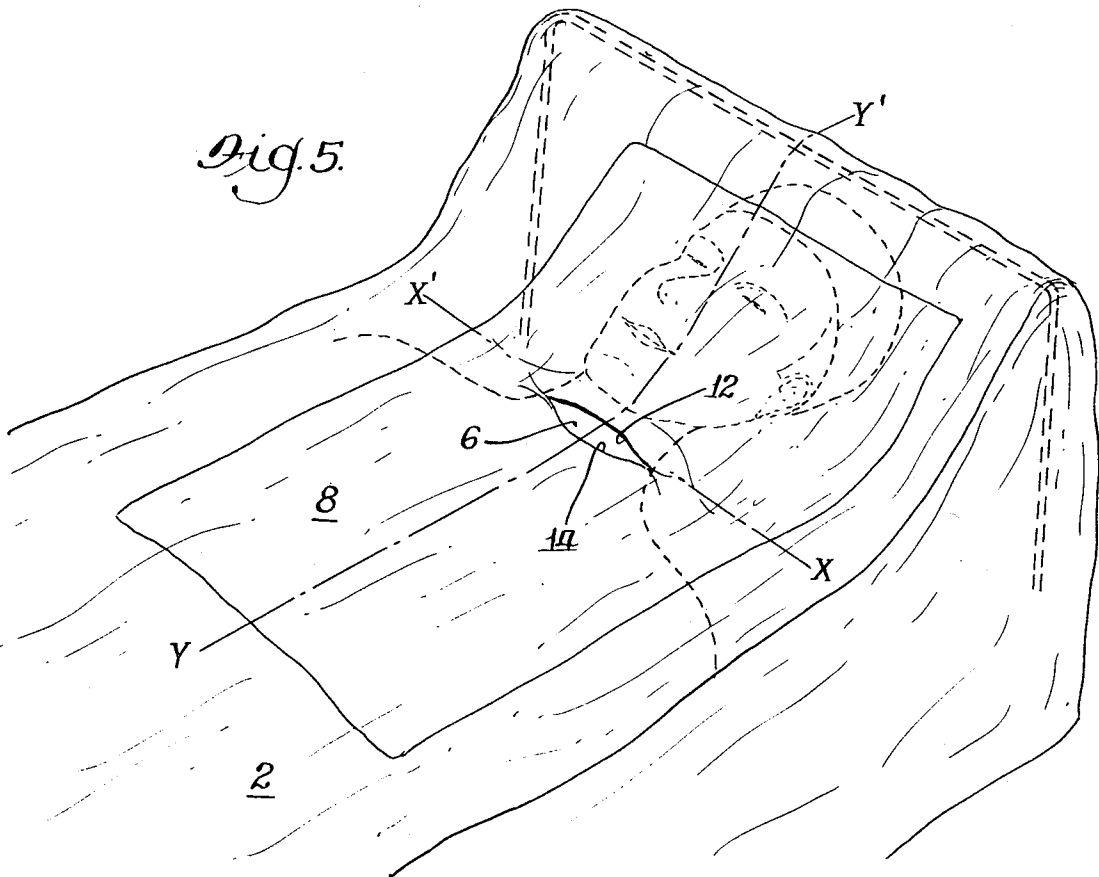


Fig. 5.



FENESTRATED SURGICAL DRAPE

BACKGROUND OF THE INVENTION

Surgical drapes are employed to cover portions of the body of a medical patient during an operative procedure. Commonly, a surgical drape may include a fenestration for access therethrough to a surgical site. Fenestrated drapes are intended to cover the body of a patient around a surgical site while allowing a doctor to operate at the site through the fenestration with his hands and instruments. Accordingly, the opening provided by the fenestration in such drapes should be appropriately sized and otherwise suitably adapted for providing access to the surgical site without hindrance by the drape material adjacent the fenestration to the activity of the doctor, while permitting the drape to cover a sufficient area of the patient's body around the surgical site to prevent contamination of other portions of the patient's body by fluids draining from the site.

Typically, convention surgical drapes are made from sheets of flexible, relatively soft, and drapable material. Fenestrated drapes often are reinforced around the fenestration by an additional ply of material, such as by a layer of fluid impervious plastic sheet material. Such reinforcement strengthens the drape material and provides additional protection against strike-through of blood and other body fluids in the area around the fenestration. Such reinforcement also tends to stiffen the drape, making it somewhat "boardy" in the area around the fenestration.

Conventional surgical drapes generally conform fairly well to surface areas of the human body where the body contour is flat, gently sloping, or broadly curved and not sharply angular. However, certain regions of the body have irregularly shaped contours which include sharp corners or extremely concave or convex surfaces. One such irregularly contoured region extends from the shoulders or upper chest to the chin. The contour of the body surface of a patient lying on his back on a flat table or bed is substantially horizontally flat or gently sloping in the area of the chest but drops off sharply in a substantially vertical direction at the shoulders, narrows to a generally tubular, concave surface at the neck, and bends up in a sharp convex angle to the chin, forming a somewhat saddle-shaped surface between the upper part of the chest and the chin. When a surgical site is located within this irregularly contoured area, such as in a thyroid operation, it has proven difficult to properly drape the patient with conventional surgical drapes.

Conventional surgical drapes do not conform well to irregularly contoured surfaces. Conventional drapes tend to buckle and bunch up at sharply angular surfaces, and the drape material overlaps itself. Also, sizeable gaps form between the drape and the surface of the patient's body. Therefore, when an attempt is made to conform a conventional fenestrated drape to a body surface with the fenestration positioned over a surgical site in an irregularly contoured region thereof, such as over an incision in the neck for a thyroid operation, the drape material buckles or bunches up and overlaps itself, causing the opening provided by the fenestration to be substantially reduced in size or completely closed by the drape material. Closing of the fenestration in this manner prevents ready access therethrough to the surgical site and seriously inhibits activity at the site. Also, because the drape material tends to gap from body sur-

face around the surgical site, blood and other body fluids drain under the drape and contaminate other areas of patient's body. If a conventional fenestrated drape is reinforced by an additional layer of material around the fenestration, these problems are increased because of the greater stiffness, or "boardiness," of the reinforced drape material.

As mentioned, the area on and adjacent to the neck has a particularly irregular contour. Thus, draping with conventional fenestrated drapes has been particularly difficult to achieve satisfactorily in thyroid operations. Conventional fenestrated drapes do not conform well to the contour of the body surface in this area. Instead, when applied with the fenestration over a site on the neck, the material of a conventional fenestrated drape bunches up so that the fenestration is substantially narrowed or completely closed. Also, the drape material adjacent the fenestration becomes spaced, or gaps, from the body surface so that fluids from the surgical site may drain under the drape. Bunching of the drape material also interferes with the activity of a doctor attempting to operate at the surgical site.

To avoid these problems, some doctors follow the practice of stitching or clipping the drape material to the skin of the patient adjacent the surgical site to maintain the fenestration in a properly open condition during a thyroid operation. Such practice is both time consuming and generally undesirable.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a fenestrated surgical drape which is suitably adapted for covering irregularly contoured surfaces.

It is also an object of this invention to provide a surgical drape having a fenestration therein which is adapted to be placed on a patient with the fenestration over a surgical site on his neck, such as for a thyroid operation, and is readily conformable to the contour of the patient's body adjacent the surgical site without excessive bunching, buckling, or overlapping of the drape material adjacent the fenestration and with the fenestration sufficiently open to provide access therethrough for operative procedures.

Briefly described, the surgical drape of this invention comprises a sheet of drapable material having a fenestration therein to provide access to a surgical site when the drape is applied over the body of a patient. The sheet may be made of any material suitable for draping hospital patients during an operative procedure. Such materials are usually somewhat soft and flexible, and may be impervious or resistant to the passage of body fluids and other liquids. The sheet may be either reusable or disposable. Suitable materials for the sheet include woven and nonwoven cotton or cellulosic materials, linen, paper, plastic films, and combinations of these materials, which may also be reinforced by materials such as nylon fibers, if desired.

The outer periphery of the sheet may have any shape and size suitable for the intended purpose of the drape. Typically, the outer peripheral edges of the sheet define a generally rectangularly shaped drape.

The sheet has a fenestration therein in an area intermediate the outer peripheral edges of the sheet. The fenestration is adapted to provide an opening for a doctor to operate therethrough, particularly at a surgical site located in an irregularly contoured portion of a patient's body. The sheet has interior edges which define

the periphery of the fenestration. With reference to an imaginary X — X' axis and an imaginary Y — Y' axis which lie in the plane of the fenestration and intersect each other perpendicularly in the area of the drape in which the fenestration is located, the interior edges are described as follows: a substantially straight first interior edge extending along a portion of X — X' axis and being intersected at its approximate midpoint by said Y — Y' axis; a second interior edge spaced from and generally parallel to said X — X' axis and intersected at its approximate midpoint by the Y — Y' axis; a third interior edge extending from one end of the first interior edge to the end of the second interior edge which is on the same side of the Y — Y' axis as said one end; and a fourth interior edge extending from the other end of the first interior edge to the end of the second interior edge which lies on the same side of the Y — Y' axis as said other end; the third and fourth interior edges extending for a first portion of their lengths away from the ends of the first interior edge in substantially straight lines tapering away from the Y — Y' axis and extending from that first portion along a second portion which curves inwardly toward the Y — Y' axis to join the ends of the second interior edge.

As an additional feature of this invention, the drape includes compacting means which compact the sheet in areas adjacent the fenestration at the first and second interior edges. The compacting means may comprise one or more pleats along the first and second interior edges which draw in the material of the sheet along those edges. Such pleats are formed by overlapping portions of the sheet along those interior edges and securely bonding those portions in such overlapping relationship by adhering means such as glue or adhesive. Compacting means other than pleats may also be employed in accordance with this invention to compact the sheet along those interior edges adjacent the fenestration. Examples of other satisfactory compacting means include elastic strips affixed along those interior edges to draw in the sheet material and accordian folding of the sheet material along those edges. Also, such compacting could be achieved by cutting a notch from the sheet along those interior edges and securely closing the opposing edges of the notched portion against each other in abutting or overlapping relationship.

The fenestrated drape of this invention provides a solution to the problem of draping the irregularly contoured surface of the body on and around the neck. When applied over a patient with the fenestration positioned above a surgical site on his neck such that said first interior edge is located at that end of fenestration nearest his head and with the imaginary Y — Y' axis aligned generally lengthwise with the patient's body, this drape will conform to the contour of body surfaces around the surgical site without excessive bunching, buckling, overlapping or gapping, and will provide an opening through the fenestration of sufficient size to operate therethrough, without requiring stitching or clamping of the drape to the patient's body adjacent the site to maintain the fenestration in such a condition. Thus, this invention provides an excellent fenestrated drape for thyroid operations.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects, details, and exact nature of this invention will be better understood upon reading the following portions of the specification detailed in reference to the accompanying drawings, in which:

FIG. 1 is a plan view of a flat fenestrated drape in accordance with this invention having a portion of the length of the drape cut out therefrom;

FIG. 2 is an enlarged plan view of a cutaway portion of the drape of FIG. 1 which includes the fenestration;

FIG. 3 is a plan view showing the cutaway portion of the drape illustrated by FIG. 2 at an unfolded preliminary stage in its formation;

FIG. 4 is a perspective view showing the drape of FIG. 1 placed over a patient with the fenestration in position to provide access through the drape to a surgical site on the patient's neck; and

FIG. 5 is a perspective view of the draped patient of FIG. 4 from a different angle illustrating the opening through the drape to the patient's neck provided by the fenestration.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a drape having a fenestration therein in accordance with this invention. The drape comprises a sheet 2 of drapable material defined by peripheral edges 4 and having a fenestration 6 disposed therein within an area intermediate the peripheral edges 4. The sheet 2 may comprise any sheet material suitable for draping hospital patients during an operative procedure. Such drapes are usually somewhat soft, flexible, and impervious or resistant to the passage of body fluids and other liquids therethrough, at least in areas thereof which are likely to be contacted by such liquids while covering a patient's body. As shown in FIG. 1, the sheet 2 defined by peripheral edges 4 has a generally rectangular shape. While this shape is suitable for many purposes, it is not an essential element of the invention, and other shapes may be employed equally well so long as the drape adequately covers and protects the area to which it is applied.

The sheet 2 of FIG. 1 includes a reinforcing layer 8 in an area adjacent the fenestration 6. Such reinforcement also is optional with a drape in accordance with this invention. When employed, it strengthens the sheet and increases protection against fluid strike-through in the area around the fenestration 6. Where the major portion 10 of sheet 2 comprises a fluid permeable or absorbent material, such as nonwoven cellulosic fabric, reinforcing layer 8 may preferably comprise a fluid impervious layer of plastic film.

As shown in FIG. 1, the fenestration 6 passes through sheet 2 in the area reinforced by layer 8. The fenestration 6 is defined by interior edges 12, 14, 16, and 18. To facilitate description of the interior edges 12, 14, 16, 18 defining the fenestration 6 and to indicate the alignment of the sheet 2 relative thereto, an imaginary X — X' axis and an imaginary Y — Y' axis which intersects the X — X' axis at an angle of 90° at a point intermediate the peripheral edges 4 of sheet 2 have been included in FIGS. 1 — 4. As shown in FIG. 1, the Y — Y' axis runs longitudinally down the approximate center of the sheet 2 parallel to two of the four peripheral edges 4. The X — X' axis runs across the sheet perpendicular to the Y — Y' axis and parallel to the other two

of the four peripheral edges 4 and extends along interior edge 12 at the fenestration 6. The material of sheet 2 is compacted at interior edges 12 and 14 by pleats 20 and 22 adjacent the fenestration.

FIG. 2 shows an enlarged view of a cutaway portion of the drape of FIG. 1 which includes the fenestration 6. Interior edge 12 lies along the X — X' axis and is intersected at its approximate midpoint by the Y — Y' axis. Interior edge 14 is spaced a distance from the X — X' axis and generally parallel thereto and is also intersected at its approximate midpoint by the Y — Y' axis. Interior edge 16 extends from an end 24 of interior edge 12 to the end 26 of interior edge 14 which lies on the same side of the Y — Y' axis as end 24 of interior edge 12. Similarly, interior edge 18 extends from the other end 28 of interior edge 12 to the end 30 of interior edge 14 which lies on the same side of the Y — Y' axis as end 28 of interior edge 12. Interior edges 16 and 18 have first portions, 32 and 34 respectively, which extend from opposite ends of interior edge 12 in substantially straight lines tapering away from the Y — Y' axis. Second portions 36 and 38 of interior edges 16 and 18 extend from first portions 32 and 34 respectively along lines which curve inwardly toward the Y — Y' axis and join opposite ends of interior edge 14.

Pleats 20 and 22 are located at interior edges 12 and 14 respectively to compact the material of the sheet 2 along those edges adjacent the fenestration 6. To better understand the construction of pleats 20 and 22, FIG. 3 should be considered in conjunction with FIG. 2. FIG. 3 shows the portion of sheet 2 shown in FIG. 2 prior to the formation of pleats 20 and 22. Since edges 12a and 14a of FIG. 3 have not yet been compacted by the formation of pleats 20 and 22, they are longer than their pleated counterparts, edges 12 and 14 of FIG. 2. Slits 40 and 42 extend at angles 41 and 43 away from edges 12a and 14a respectively creating tabs 44 and 46. Fold lines 48 and 50 extend generally perpendicularly away from edges 12a and 14a respectively. Fold lines 52 and 54 extend in directions generally parallel to fold lines 48 and 50 away from the ends of slits 40 and 42 respectively. Adhering means 56 and 58, comprising material such as adhesive or glue, is positioned at the fenestration 6 along edges 12a and 14a. To securely form pleat 20, sheet 2 is folded back upon itself along fold line 48 and back in the reverse direction along fold line 52 in a pleating fashion such that an area between fold lines 48 and 52 and under tab 44 is brought into contact with adhering means 56 and bonded thereby to the underlying portion of the sheet. Similarly, sheet 2 is folded back upon itself along fold line 50 and back in the reverse direction along fold line 54 in a pleating fashion such that an area between fold lines 50 and 54 and under tab 46 is brought into contact with adhering means 58 and bonded thereby to the underlying portion of the sheet to securely form pleat 22.

Tabs 44 and 46 are provided for attachment to areas 60 and 62 by adhering means 56 and 58 respectively in order to strengthen the bond of pleats 20 and 22 adjacent the fenestration. Such tabs are optional, however. This invention also contemplates the compacting of sheet 2 along these interior edges by creating pleats without such tabs simply by extending fold lines 52 and 54 to edges 12a and 14a respectively and not providing slits 40 and 42. In fact, as previously mentioned, other means of compacting the sheet adjacent these edges could be employed in accordance with this invention,

the important feature being the removal or drawing in of an amount of the sheet material in areas adjacent interior edges 12 and 14 at the fenestration. Removal of the sheet material in these areas has the effect, when combined with a fenestration of the general shape shown in the drawings, of eliminating that portion of the sheet material which tends to buckle, bunch, and overlap to close the fenestration when the sheet is draped over a patient with the fenestration positioned over a surgical site on the patient's neck. When properly placed, the drape of this invention conforms well to the irregularly contoured body surfaces adjacent such a surgical site and provides a fenestration which remains sufficiently open, naturally and without clamping or stitching to the patient's skin, so that a doctor may conveniently operate therethrough at the surgical site.

FIG. 4 shows a patient covered with the drape of FIG. 1 with the fenestration 6 positioned over his neck and providing an opening through the sheet 2 appropriate for a thyroid operation. FIG. 5 shows another view of a portion of the draped patient of FIG. 4 taken at a different angle to better illustrate the opening provided by the fenestration 6. When the drape of FIG. 1 is properly positioned on a patient, as shown in FIGS. 4 and 5, the imaginary Y — Y' axis lies substantially parallel to the lengthwise body dimension of the patient. Interior edge 12 is at that end of the fenestration 6 nearest the patient's head. As illustrated, sheet 2 is in general conformity with the contour of the patient's body at and around the surgical site at the neck, and the fenestration is in a properly open condition.

The size and precise configuration of the fenestration of a drape in accordance with this invention may vary within practical limits and according to the size of the body to which it is applied. In one embodiment of the structure of the fenestration 6 shown in FIG. 2 suitably adapted for a drape to be used in thyroid operations on most human neck sizes, interior edges 12 and 14 are each approximately 1½ inches in length and are spaced apart a perpendicular distance of approximately 6 inches, substantially straight line portions 32 and 34 of interior edges 16 and 18 are each approximately 3 inches in length and extend away from interior edge 12 at angles 64 and 66 respectively of approximately 120°, and curved line portions 36 and 38 extend from the ends of straight line portions 32 and 34 respectively to opposite ends 26 and 28 of interior edge 14 along arcs of circles which have a radii of approximately 2 inches. Prior to the formation of pleats 20 and 22, the perpendicular distance between fold lines 48 and 52 and between fold lines 50 and 54 is approximately 1½ inches (half the amount of the sheet material taken up by pleats 20 and 22 in compacting the sheet along the interior edges 12 and 14), and slits 40 and 42 are approximately 1¾ inches long and extend away from interior edges 12a and 14a to fold lines 52 and 54 at angles 41 and 43, respectively, of approximately 45°. Adhering means 56 and 58 extend a distance of approximately 4 inches from interior edges 12 and 14 respectively.

As indicated, these specific dimensions define but one preferred structure of a fenestration in accordance with this invention. Each of these dimensions may be varied within practical range limitations depending on the size of the body to which the drape is to be applied, the personal preferences of the user, the size of the opening desired, and a natural range of sizes for these

dimensions which will form acceptable openings in the drape applied to a patient. As previously pointed out, tabs 44 and 46 may be eliminated altogether without departing from the essence of this invention. It has also been found that the perpendicular distance between interior edges 12 and 14 may vary from 3½ inches to 9 inches and provide a functional thyroid drape for a normal sized (15½ inch) human neck. Also, interior edges 12 and 14 may each vary in length up to a maximum of approximately 4 inches, and edges 12 and 14 do not necessarily have to be exactly the same length. Furthermore, edge portions 32 and 34 may be gently curved rather than precisely straight lines, and may extend from interior edge 12 at angles 64 and 66 of from approximately 100° to approximately 150°, while edge portions 36 and 38 need not follow precisely circular arcs (although generally circular arcs are preferred). Likewise, it has been found that the adhering means 56 and 58 may range in size to provide narrow line bonds (bonds extending only approximately ¼ inch from interior edges 12 and 14 respectively) to bonds extending a distance of approximately 8 inches from interior edges 12 and 14 respectively. Also, it is not essential that such bonding extend for exactly the same distance at each end of the fenestration.

Furthermore, it has been found that a functionally operable fenestrated drape can be produced with a drape having a fenestration with a peripheral shape as defined by interior edges 12, 14, 16, and 18 of FIG. 2, but including compacting means, i.e. a pleat, only along interior edge 12 adjacent the fenestration. It should be pointed out, however, that while such a drape is functional, it is not as satisfactory for a neck operation as the previously described embodiment having compacting means along both interior edges 12 and 14.

Thus, it is apparent that the specific parameters may vary within given ranges and according to different conditions, it being only essential that the fenestration have the general shape shown in FIG. 2. Pleats at one or both ends of the fenestration add to the operability of a drape with a fenestration of that shape, especially when used as a thyroid drape. Such a drape conforms naturally and well to the irregularly contoured surfaces of the body at and adjacent the neck, without excessive bunching, buckling, and gapping around the fenestration or closing of the opening provided by the fenestration.

Other variations and modifications will be apparent to persons skilled in the art upon reading this disclosure. All such variations and modifications are included within this invention except as limited by the scope of the following claims.

I claim:

1. A surgical drape comprising:

a sheet of drapable material defined by peripheral edges and having a fenestration disposed therein within an area intermediate said peripheral edges, said fenestration being defined by interior edges of said sheet described with reference to an imaginary X — X' axis and an imaginary Y — Y' axis which intersects said X — X' axis at an angle of 90° in said area as follows:

a substantially straight first interior edge extending along a portion of said X — X' axis and intersected at its approximate midpoint by said Y — Y' axis; a substantially straight second interior edge parallel to and spaced from said X — X' axis and inter-

sected at its approximate midpoint by said Y — Y' axis;

a third interior edge extending from one end of said first interior edge to an end of said second interior edge which lies on the same side of said Y — Y' axis as said one end; and

a fourth interior edge extending from the other end of said first interior edge to an end of said second interior edge lying on the same side of said Y — Y' axis as said other end;

said third and fourth interior edges having first portions thereof which extend from opposite ends of said first interior edge in substantially straight lines tapering away from said Y — Y' axis.

2. The surgical drape of claim 1 wherein said third and fourth interior edges include second portions thereof which extend from said first portions and curve inwardly toward said Y — Y' axis to join opposite ends of said second interior edge.

3. The surgical drape of claim 2 wherein said second portion of each of said third and fourth interior edges comprises an edge which follows a circular arc from said first portion to an end of said second interior edge.

4. The surgical drape of claim 2 including a first compacting means for compacting said sheet adjacent said first interior edge.

5. The surgical drape of claim 4 including a second compacting means for compacting said sheet adjacent said second interior edge.

6. The surgical drape of claim 5 wherein said first compacting means comprises a pleat in the material of said sheet along said first interior edge and said second compacting means comprises a pleat in the material of said sheet along said second interior edge.

7. The surgical drape of claim 6 wherein each of said pleats comprises a first fold of the sheet along a first fold line extending outwardly from the fenestration bringing the sheet adjacent the fenestration over onto itself and a second fold in the opposite direction as said first fold along a second fold line extending parallel to said first fold line bringing said sheet back over upon itself over said first fold.

8. The surgical drape of claim 6 including means bonding each of said pleats in the material of the sheet adjacent the fenestration.

9. The surgical drape of claim 8 wherein said means comprises adhesive material.

10. The surgical drape of claim 8 wherein each of said pleats includes a tab adjacent the edge of the fenestration, said tab being bonded to an underlying portion of the sheet by said means to secure said pleat in said sheet.

11. The surgical drape of claim 8 wherein said first and second interior edges are spaced apart a perpendicular distance of from approximately 3.5 to approximately 9 inches.

12. The surgical drape of claim 11 wherein each of said first and second interior edges has a length of from 0 to approximately 4 inches.

13. The surgical drape of claim 12 wherein said first portion of each of said third and fourth interior edges extends away from an end of said first interior edge and forms an angle therewith of from approximately 100° to approximately 150°.

14. The surgical drape of claim 13 wherein said first and second interior edges are substantially the same length.

15. The surgical drape of claim 13 wherein said means provides bonds extending from the first and second interior edges of the fenestration a distance of from approximately 1/8 inch to approximately 8 inches.

16. The surgical drape of claim 15 wherein said pleats compact the sheet by taking up approximately 2.5 inches of the sheet material along said first and second interior edges.

17. The surgical drape of claim 16 wherein said means provides bonds extending from the first and second interior edges of the fenestration a distance of approximately 4 inches, said first and second interior

edges are each approximately 1 1/4 inches in length, and said first and second interior edges are spaced apart a perpendicular distance of approximately 6 inches.

18. The surgical drape of claim 17 wherein said first portion of each of said third and fourth interior edges extends away from an end of said first interior edge and forms an angle therewith of approximately 120°.

19. The surgical drape of claim 18 wherein said second portion of each of said third and fourth interior edges extends along the arc of a circle having a radius of approximately 2 inches.

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