

Nov. 29, 1966

L. PERENY ETAL

3,288,135

DRAPE

Filed Nov. 22, 1963

2 Sheets-Sheet 1

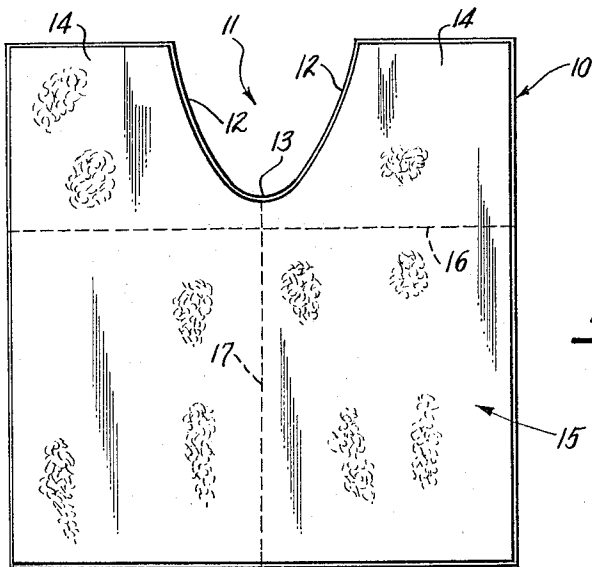


Fig. 1.

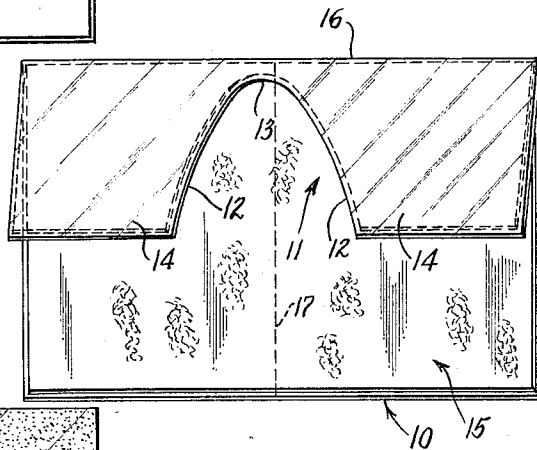


Fig. 2.

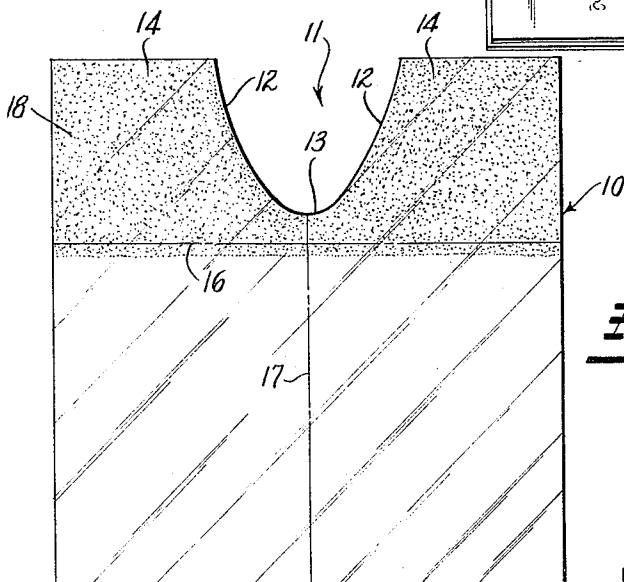


Fig. 3.

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2 Sheets-Sheet 2

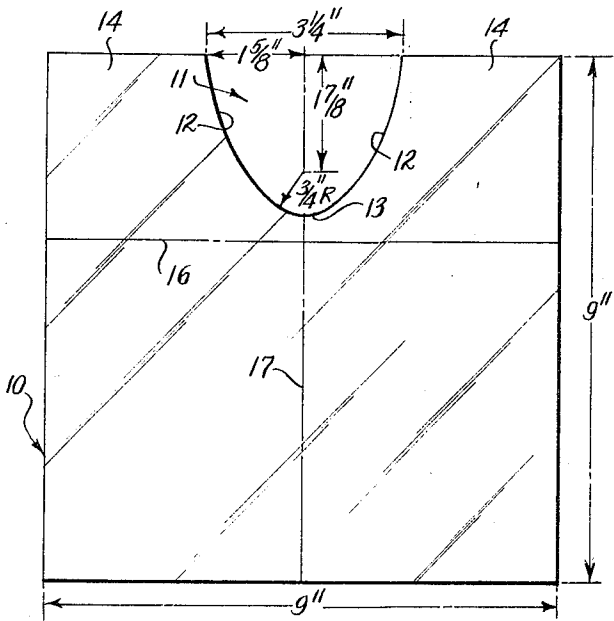


Fig. 4.

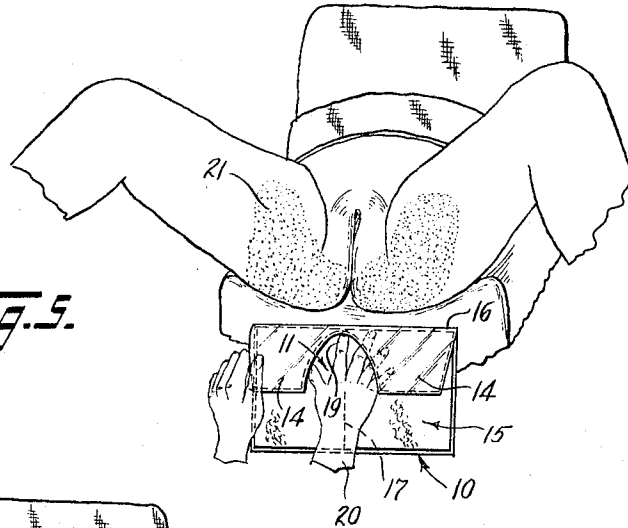


Fig. 5.

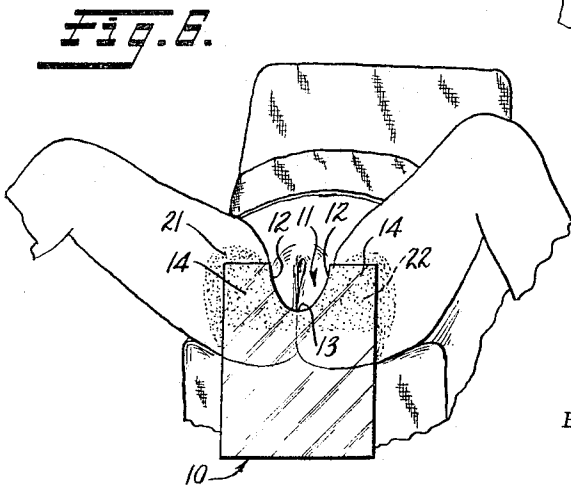


Fig. 6.

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3,288,135
DRAPE

Louis Pereny, deceased, late of Dayton, Ohio, by Evelyn Pereny, executrix, Dayton, Ohio, and Paul Creager, Jr., and Thomas N. Zinck, Dayton, Ohio, assignors to Protective Treatments, Inc., Dayton, Ohio, a corporation of Ohio

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9 Claims. (Cl. 128-132)

The present invention relates to a bifurcated plastic surgical drape which is adhesively secured below the vaginal area to aseptically wall off this area from the anal area and which is especially adapted to tolerate the extensive stretching of the vaginal area which takes place during an obstetrical delivery.

During any surgical operation conducted in the vaginal area, and especially during delivery, contamination of the surgeon's hands from the anal area, including any fecal extrusion which may occur during the operation, is a serious problem. The danger of such contamination is significantly reduced by the use of the surgical drape of the invention.

The adhesive application of plastic drapes over a surgical area to prevent contamination of the operative site is now known and is well illustrated in Pereny et al. Patent 3,060,932. However, when the operation performed in the vaginal area is an obstetrical delivery, a plastic drape adhesively secured around the vaginal area does not adequately tolerate the extensive expansion in the vaginal area which occurs during delivery and the drape may tear or become separated from the skin to destroy asepsis.

According to the invention, the hazard of contamination from the anal area is effectively eliminated despite extensive expansion in the vaginal area by aseptically walling off the anal area from the vaginal area with a bifurcated plastic drape adhesively secured to the patient and which extends across the space between the vaginal and anal areas. The bifurcated configuration of the drape tolerates the extensive expansion in the vaginal area which occurs during delivery without destroying asepsis.

The surgical drape of the present invention comprises a sheet of flexible plastic material, preferably a clear vinyl film, having a central arcuate cut-out portion in one end thereof defining a pair of upper end portions (the bifurcation) adapted to be adhesively secured to the thighs of the patient adjacent to the buttocks, the arcuate bottom of the cut-out portion being adapted to be adhesively secured across the space between the vaginal area and the anal area. When the thighs are referred to, it should be understood that the upper end portions may also, in part, be secured to part of the perineal area and, indeed, off center application of the drape is also contemplated.

The curved configuration of the cut-out portion in combination with the upper end portions is especially designed to tolerate the extensive expansion in the vaginal area during delivery without tearing the drape and without imposing nonuniform stresses on the edges of the cut-out portion of the drape which causes the drape to be separated from the skin. As will be evident, the tearing and separation referred to are undesirable since either of them will destroy asepsis.

The cut-out portion of the drape is defined by a curved bottom smoothly joined with two side portions which flare outwardly from the cut-out portion to the upper edge of the drape. The curved configuration of the bottom of the cut-out permits the drape to tolerate expansion in the vaginal area and to uniformly distribute the stresses imposed by such expansion so that the expansion will be

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tolerated without destroying asepsis as will appear more fully hereinafter.

A further feature of the present invention is the utilization of a relatively stiff paper liner of approximately the same size and shape as the drape which facilitates the handling and application of the drape which, without the liner, is difficult to handle and apply due to the flexible and limp nature of the plastic material. To facilitate convenient and accurate application of the drape, it is desirable that the drape be combined with the liner to facilitate application of the drape to the patient with one hand while the other hand holds the drape, the paper liner, or the combination of drape and paper liner.

The invention will be more fully understood in connection with the accompanying drawings in which:

FIG. 1 is a plan view showing the configured drape of the invention having a paper liner positioned thereon; FIG. 2 shows the combination of FIG. 1 in a folded position;

FIG. 3 shows the bottom of a drape provided with a preferred portion of its surface coated with an adhesive;

FIG. 4 shows the preferred dimensions of the cut-out portion of the drape;

FIG. 5 shows the manual application of the drape to a patient; and

FIG. 6 shows the drape in position on a patient.

Referring more particularly to FIG. 1 which shows a preferred construction, the drape 10 is rectangular, preferably square, and formed from a single sheet of limp and flexible polyvinyl chloride plastic material. Cut-out portion 11 is formed in the upper end of the drape 10 and is defined by the flared out sides 12 joined at the bottom by a curved or arcuate bottom 13 which merges with the flared out sides 12 tangentially. The sides 12 of the cut-out portion 11 define the inner edge of two upper end portions 14 which, together, form the bifurcated upper end which is adapted for adhesive securement to the patient.

Overlying the configured plastic drape is a stiff paper liner 15 which is preferably of exactly the same size and shape as the drape but, for clarity of representation, is shown in a less preferred form in which the liner is of slightly smaller size. This paper liner facilitates handling of the drape as has been noted.

As a feature of the invention, the stiff paper liner 15 is temporarily and removably adhesively secured to the upper surface of the drape 10, at least over the upper portion thereof. This temporary securement is easily achieved by a thin coating of wax applied to the contacting surface of the paper liner. The wax coated paper liner is then lightly heat-sealed to the drape. This temporary securement is not shown in the drawing because of the difficulty of illustration.

The drape and the paper liner are preferably folded in a particular manner to facilitate application of the drape to the patient. As can be seen in FIGURES 1 and 2, the drape and liner are folded along the line 16 which parallels the upper end of the drape and extends across the drape a short distance beneath the bottom 13 of the cut-out 11 so that the paper liner is between the plastic drape in the folded state as can be seen in FIGURE 2. This folded structure is highly useful in the application of the drape to the patient as will appear more fully hereinafter. The drape may, optionally, be folded vertically along line 17 for packaging purposes.

Various techniques, not shown, may be used to facilitate separation of the paper liner after the drape has been adhesively secured to the patient including tabs, upward folding of the lower end of the drape 10 beneath the downwardly folded upper end of the drape 10 shown in FIG. 2, inwardly folded corners, etc.

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The drape of the invention is adhesively secured to the patient with a pressure sensitive adhesive which holds the drape securely in place. Adhesive specially adapted for application to the patient are shown in United States Patent 3,090,694.

An adhesive may be applied to the bottom or patient contacting surface of the drape during its manufacture or just prior to its use, though these applications are less preferred. Appropriate areas for adhesive application are shown in FIGURE 3 and identified by numeral 18. When the adhesive is applied to the drape during manufacture, and as is well known, the adhesive is a pressure sensitive adhesive and is protected by a relatively non-adherent paper liner which is removed during application or just prior to application. This non-adherent paper liner may be coextensive with the drape and serve in place of the paper line referred to hereinbefore in which event, it would be applied to the bottom or patient contacting surface of the drape instead of the top surface of the drape.

When the adhesive is applied directly to the patient, it is desirably sprayed onto the region where the thighs join the buttocks and across the space between the vaginal and anal areas. The adhesive is applied uniformly so that the upper portion of the drape 10 is uniformly adhered to the patient in the areas which have been noted. These areas are pictured in FIGURE 5 and identified by numeral 21. Application of the adhesive to the patient avoids any problem of inadvertent adhesion prior to application.

The adhesive is desirably applied as an aerosol spray since spray application is quite convenient as is disclosed in United States Patent 3,090,694. When using spray application, the vagina is preferably sealed off by the insertion therein of a surgical sponge or like material.

The application of the drape is preferably accomplished using the folded structure previously noted to assist guiding the drape to its proper location with one hand. This is shown in FIGURE 5, the forefinger 19 of the hand 20 being placed at the center of the drape at the fold line 16 to facilitate accurate placing of the drape. The thumb and the other fingers remain beneath the fold to support the drape and the other hand may be used, as shown, to hold and position the combination of drape and liner.

The applicator directs his forefinger to a point beneath the vagina and presses the drape to adhesively secure it at this point. The hands are then moved upwardly to smoothly adhere the end portions 14 on the thighs adjacent the buttocks. The areas covered by adhesive on the patient are shown by shading and identified by numeral 21 in FIGS. 5 and 6.

The paper liner 15 assists in this operation by making the plastic drape stiff enough for easy handling. It can be readily understood that the paper liner is preferably not larger than the drape itself as the liner would then adhere to the adhesive on the patient. The paper liner is pulled away from the drape and discarded once the drape is adhered in its desired position.

FIG. 6 shows the drape in position on the patient. As is shown by the shaded portion 22, the adhesive secures the upper bifurcated portion of the drape completely to the patient's thighs, buttocks and perineal area to thereby aseptically wall off the anal area.

The cut-out portion 11 of the drape 10 is shaped, as previously indicated, to include outwardly tapering side margins 12 and an arcuate or curved bottom 13 which merges therewith. Of particular importance to optimum performance is the curvature at the bottom 13 which can vary from a curve corresponding to a circle having a radius from $\frac{1}{2}$ inch to 1 inch, but which is preferably about $\frac{3}{4}$ inch. While circles are referred to, it is not essential that the curve used correspond precisely with the arc of a circle, though this is preferred. The outwardly flaring side margins 12 are also desirably curved so that the entire cut-out portion 11 resembles one-third of an ellipse severed across its shorter diameter. The depth of the cut-

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out portion 11 is roughly the same as its width where it joins the upper margin of the drape 10. While overall dimensions are not of prime significance, these dimensions of depth and width of the cut-out 11 may vary between $\frac{1}{2}$ inch to 4 inches, the particular dimensions preferred being based upon the size and shape of the average patient. A preferred cut-out depth is $2\frac{3}{8}$ inches and a preferred width at the top of the cut-out is $3\frac{1}{4}$ inches. The preferably curved side margins 12 of the cut-out 11 are preferably curved to correspond with a circle having a radius of $3\frac{1}{4}$ inches with its center at the opposite juncture of the cut-out portion and the upper margin of the drape. Preferred dimensions for the cut-out portion are shown in FIGURE 4.

While it is preferred to utilize a rectangular drape, variations of the lower portion of the drape may be made without changing the utility of the drape such as a rounded drape, triangular drape, trapazoidal drape, etc. Indeed, and in normal practice, the lower portion of the drape merely hangs freely as is shown in FIG. 6.

Further, the bottom portion of the drape can be modified to include an inner pouch for receiving any fecal extrusion during the operation without departing from the scope of the invention, though this is not necessary.

The invention is not limited to the specially folded structure as the drape may also be provided in roll form with or without a paper liner.

Since the drape is utilized in surgical operations, each drape is preferably separately packaged under sterile conditions to provide an immediately usable product, though it is not essential that the product be supplied in a sterile condition, since its primary use is in child birth where the portion of the patient covered by the drape of the invention is not subjected to surgery.

The invention is defined in the claims which follow.

We claim:

1. A bifurcated obstetrical drape comprising a sheet of flexible plastic material having its upper end configured to define a central arcuate cut-out portion separating a pair of upwardly extending upper end portions, the said cut-out portion being defined by a curved bottom smoothly joined with outwardly flaring sides defining the inner edges of said upper end portions, said upper end portions being adapted for adhesive securement to the thighs of a patient adjacent the buttocks with the arcuate bottom of said cut-out portion being adapted to be adhesively secured across the space between the vaginal area and the anal area of the patient, and one surface of said drape being temporarily secured to a stiff sheet.

2. A drape as recited in claim 1 in which said sheet of paper is substantially coextensive with said drape and the combination of drape and paper sheet is folded with the paper on the inside, the fold extending across the drape along a line parallel with the upper margin of the drape and positioned a short distance below the bottom of the cut-out portion.

3. A drape as recited in claim 1 in which the bottom of said cut-out portion is curved to correspond with the arc of a circle having a radius of from $\frac{1}{2}$ inch to 1 inch.

4. A drape as recited in claim 1 in which said stiff sheet is temporarily secured to said one surface of said drape with a pressure sensitive adhesive.

5. A drape as recited in claim 4 in which said cut-out portion has a depth of from $1\frac{1}{2}$ inches to 4 inches, and a width which generally corresponds with its depth.

6. A generally rectangular folded bifurcated obstetrical drape comprising a sheet of limp flexible plastic material having its upper end configured to define a central arcuate cut-out portion separating a pair of upwardly extending upper end portions, the said cut-out portion being defined by a curved bottom smoothly joined with outwardly flaring sides defining the inner edges of said upper end portions, the bottom of said cut-out portion being curved to correspond with the arc of a circle having a radius of from $\frac{1}{2}$ inch to 1 inch, and said cut-out portion

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having a depth of from 1½ inches to 4 inches, and a width which generally corresponds with said depth; and a stiff paper liner substantially coextensive with said drape, said liner being removably secured to one surface of said drape; the said drape with its paper liner being folded with the paper on the inside, the fold extending across the drape along a line parallel with the upper margin of the drape and poistioned a short distance below the bottom of said cut-out portion.

7. A drape as recited in claim 6 in which the surface of said paper liner facing said drape is thinly coated with wax and said wax coated paper liner is lightly heat sealed to said drape.

8. A drape as recited in claim 6 in which the bottom of said cut-out portion is curved to correspond with the arc of a circle having a radius of about ¾ inch, and said

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cut-out portion has a depth of about 2½ inches, and a shape which corresponds generally to about ⅓ of an ellipse which has been bisected across its smaller diameter.

9. The drape structure defined in claim 8 treated to render it sterile and individually packaged in said sterile condition.

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