Oct. 31, 1967 W. F. BLANFORD 3,349,765

SURGICAL DRAPE

Filed Oct. 7, 1965 2 Sheets-Sheet 1

Fig. 1.

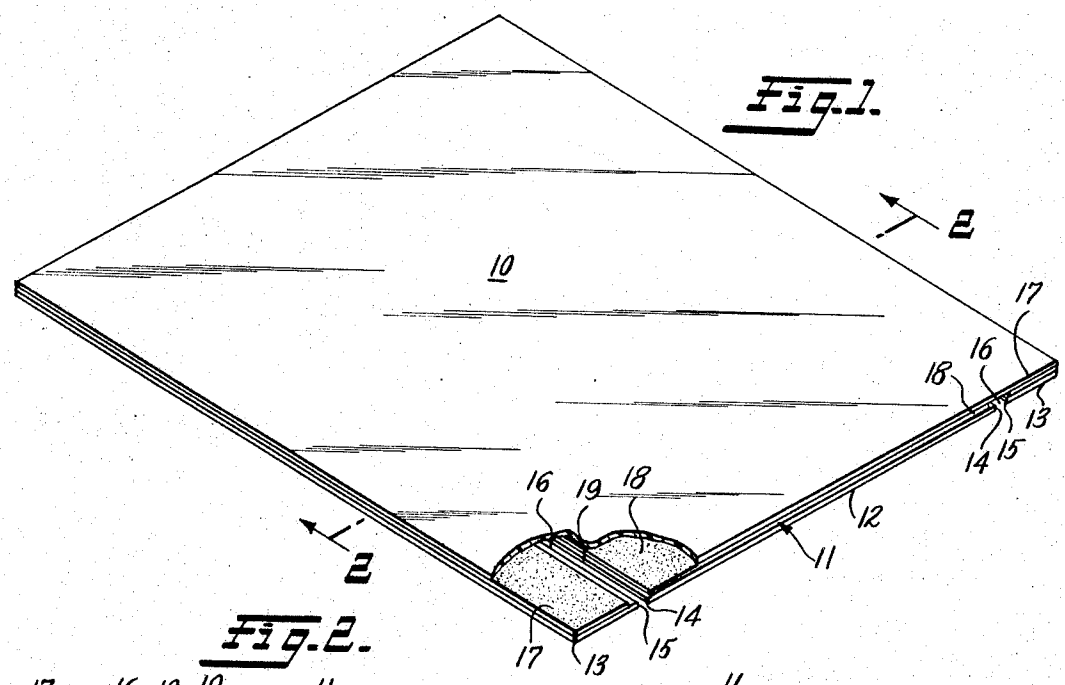


Fig. 2.

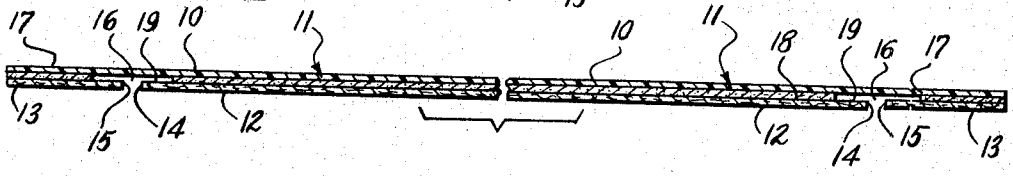
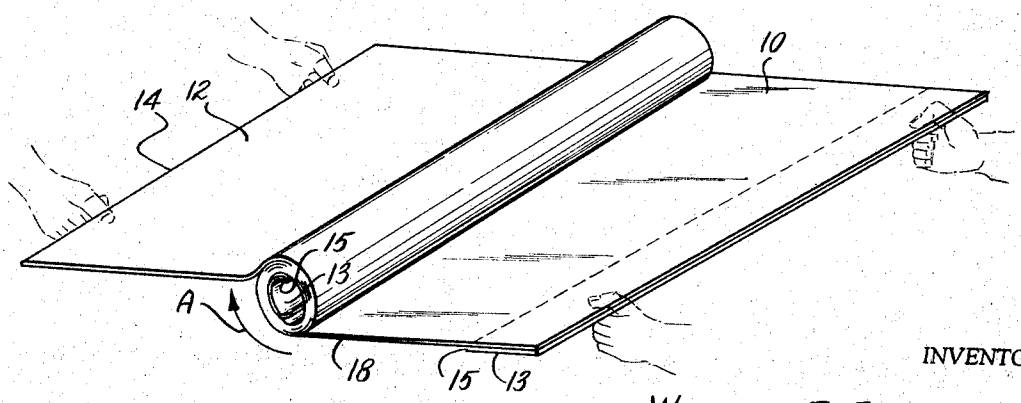


Fig. 3.



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SURGICAL DRAPE

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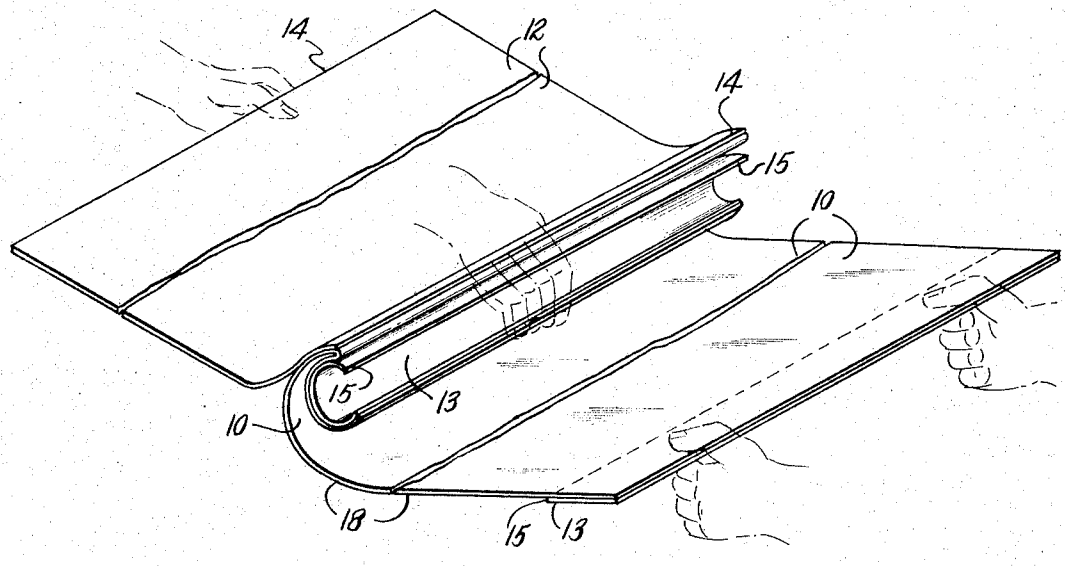

Fig. 4.

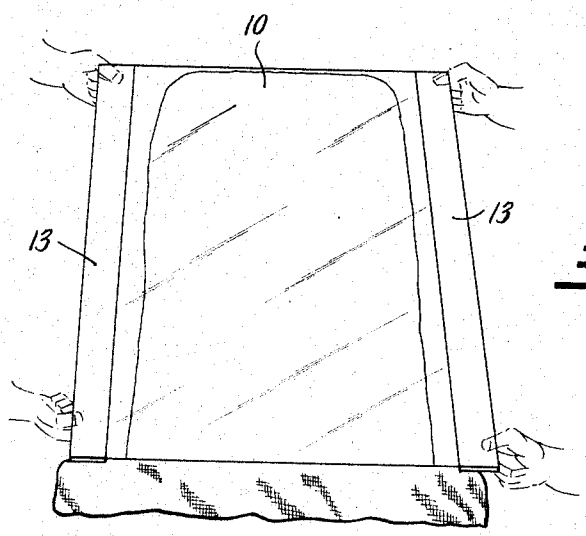

Fig. 5.

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SURGICAL DRAPE

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Filed Oct. 7, 1965, Ser. No. 493,847
13 Claims. (Cl. 128—132)

This invention relates to thin transparent plastic surgical drapes provided with pressure sensitive temporary adhesive on the back thereof for adhering the drape to the skin of a patient to be operated upon and to the provision of a drape in rolled form having an adhesive protective backing and marginal edge reinforcements which allows the adhesive protective backing to be easily removed in a manner which provides for improved aseptic handling.

In the present field of surgery, thin transparent plastic films are applied to the skin of the patient over the area where the incision is to be made. The film is of an extremely thin and flexible nature and is provided with a pressure sensitive adhesive backing for adhering the film to the skin of the patient. To prevent adherence of the adhesive to other portions of the film during packaging and shipping, a paper backing is applied to the pressure sensitive adhesive so that the drape may be rolled up and delivered for use in a convenient rolled form. In the use of these surgical drapes, it is necessary that the drape be sterilized prior to use, and the adhesive protective backing must be removed and the drape applied to the patient in a manner which does not destroy asepsis.

The backing is removed from the rolled drape by sterile gloved hands in the operating room and applied directly to the patient. Two persons accomplish this operation, one holding the drape while the other pulls at the backing to remove the same, the drape unrolling as the backing is removed. To facilitate this operation, workers have provided rolled drapes with nonadhesive marginal edge portions of approximately four to six inches on the outer end of the roll and on the inner end of the roll so that a gloved hand will have a convenient place to hold the drape during backing removal and during application of the drape to the patient.

Due to the necessary adherent quality of the adhesive, the removal of the protective backing prior to applying the drape to the patient necessitates a certain amount of force to be applied to the backing to remove the same. Difficulty has arisen in the removal of the backing from the drape in its roll form in that the inner non-adhesive marginal edge is hidden by the protective backing and no indication is given to the persons removing the backing as to where the adhesive ends and the non-adhesive marginal edge begins. When the inner non-adhesive marginal edge is reached, the drape in some cases suddenly falls away from the backing leaving no opportunity for a person to grasp the inner marginal edge of the drape. This is disadvantageous from two standpoints. First, and in falling away, the adhesive surfaces of the drape have a good chance of adhering to themselves, thereby necessitating the use of another drape. Second, and most important, this falling away allows the drape to fall below the waist of one of the handlers of the drape. Since it is present surgical practice to consider as unsterile anything which falls below the waist, the drape would have to be thrown out as being no longer aseptic.

Even if the beginning of the inner non-adhesive area were known, the drapes known heretofore have no provision for the grasping of the inner marginal edge in a manner which is easily accomplished thereby making the use of the drape extremely difficult.

Also, and due to the force necessary for removal of the backing, the drape has a tendency to wrinkle during backing removal and become adhered to itself. In order to overcome this difficulty, workers have provided for marginal reinforcement of the plastic drape by adhering thereto a narrow heavy plastic strip. While this has overcome the difficulties of the drape without marginal reinforcement, nevertheless, the use of the heavy plastic strip makes the drape relatively expensive and difficult to manufacture thereby reducing its commercial desirability.

In accordance with the present invention, these difficulties are overcome by providing a marginally reinforced surgical drape in rolled form having a pressure sensitive adhesive layer covering the major central portion of one surface of the drape and a protective backing for the adhesive substantially coextensive with the adhesive and substantially coterminous with at least the end of the central adhesive layer at the inner end of the drape in its rolled form, and removably adhered thereto. In this way, two persons separating the backing from the rolled drape can visually note when the end of the adhesive area has been reached during the unrolling operations to provide an opportunity to grasp the inner marginal edge reinforcement before the backing is completely removed and while the partially attached backing still supports one end of the drape. Thus, and in this way, when removal of the backing is completed, the drape cannot fall away to endanger asepsis.

A feature of the present invention is the manner in which the inner marginal edge reinforcement is rolled relative to the rest of the drape. By rolling the inner marginal edge reinforcement in a direction opposite the direction of the remainder of the roll, the inner marginal edge when it is reached during backing removal tends to move out from the roll to make it easier to grasp. This feature provides for easier handling especially for gloved hands.

As will be discussed more fully hereinafter, the invention also contemplates the accomplishment of the above invention in a simple and inexpensive manner to thereby increase product desirability by keeping manufacturing costs low.

The invention will be discussed more fully in connection with the drawings illustrating a preferred embodiment of the invention in exaggerated scale in which:

FIG. 1 is a perspective view of the drape in unrolled form and in partial section to show the adhesive areas, the marginal edge reinforcements and the adhesive protective backing;

FIG. 2 is a cross-sectional view of the drape of FIG. 1 taken along the lines 2—2;

FIG. 3 illustrates the manner in which the removal of the backing is begun;

FIG. 4 illustrates the manner in which the inner end of the backing comes to view and how the inner marginal edge may be easily grasped; and

FIG. 5 illustrates the manner in which the reinforced marginal edges assist in handling and applying the drape to the patient.

Referring more particularly to the drawings, and especially to FIGS. 1 and 2, thin transparent plastic film, generally indicated by **10**, has applied hereto an adhesive layer **11**, which layer is covered with protective backing **12** and marginal reinforcements **13**. The marginal edge reinforcements are preferably on the same side of the drape as the backing and the interior edges **15** of the marginal reinforcements **13** are preferably substantially juxtaposed to the opposite side edges **14** of the protective backing **12**. A small non-adhesive area **16** is provided beneath the juncture of marginal reinforcements **13** and the protective backing **12** to facilitate backing removal and for ease of manufacture. The term "small" is used to denote an area having a width of not over one inch.

The adhesive layer 11 comprises adhesive layers 17 for adhering the marginal edge reinforcements to the drape, preferably permanently, and a pressure sensitive adhesive layer 18 for adhering the drape to the patient, which layer 18 has temporarily adhered thereto backing 12 substantially coextensive and coterminous with the adhesive layer.

The term "temporarily adhered" indicates that the backing may be easily removed or separated. Temporary adherence may be accomplished by using a pressure sensitive adhesive coated with a release agent or a backing coated with a release agent or a backing formed of material which is releasable due to its composition as will be discussed hereinafter.

The term "permanently adhered" indicates that the marginal edge reinforcement may not be easily removed. This may be accomplished by a permanent type adhesive but preferably, the marginal edge areas are coated with the same pressure sensitive adhesive as the central portion, the marginal edge reinforcing material having no release agent coating thereon so that they will be permanently adhered to the drape.

The specific types of adhesive which may be used and specific types of the preferred pressure sensitive adhesives are well known and do not form part of this invention.

While it is preferred that the backing be temporarily adhered and the marginal edge reinforcements be permanently adhered to the drape, it is understood that the marginal edge reinforcements may be temporarily adhered to the drape though this is less desirable since the marginal edge reinforcements could thereby be easily removed.

To the central adhesive layer 18 is removably adhered an adhesive protective backing 12 substantially coextensive with the adhesive and substantially coterminous with at least the inner end of the central adhesive layer 18 of the drape in its rolled form so that the inner marginal edge reinforcement may be grasped before the backing is completely removed from the adhesive layer. Preferably, the backing is substantially coterminous with both ends of the central adhesive layer as set forth in the drawings. This backing may be of any material such as paper, waxed or coated paper, glassine paper, plastic, etc. When a pressure sensitive adhesive is used to constitute the central adhesive layer 18, it is preferred to use an adhesive releasable paper such as waxed paper or glassine paper as the backing though any coated paper or plastic film which does not become permanently adhered to the pressure sensitive adhesive may be used.

The protective backing sheet 12 is preferably provided with a small non-adhered lip 19 of not over approximately ½ inch to provide the person removing the backing with a place to grasp the backing without the necessity of having to peel the edge of the backing away from the adhesive.

The lip 19 is intended to be included within the language "substantially coextensive and coterminous with" which is used to describe the length of the backing in relation to the central adhesive layer.

The edges of the backing 12 are preferably juxtaposed to the edges of the marginal edge reinforcements 13. The term juxtaposed is not to be limited to the meaning abutting but also includes embodiments of the invention where the backing may slightly overlap the marginal edge reinforcements, or where a small gap is left between the backing and the marginal edge reinforcement. In a commercial embodiment of the invention, the backing overlaps the marginal edge reinforcements by ¼ inch. The drawings showing this juxtaposition have been exaggerated to facilitate discussion and for clarity of the drawing.

Also adhered to the adhesive layer 11 is the marginal edge reinforcements 13. These reinforcements may be of any material such as paper, waxed paper, glassine paper,

plastic, etc. though it is preferred that these be of paper which is non-releasable from the pressure sensitive adhesive of the type used in the central adhesive portion 18. It is understood that the marginal edge reinforcements may be of a different material than the protective backing 12, but it is preferred that they be of the same material.

The main requirement of both the backing material and the reinforcement material is that they be of sufficient strength to resist tearing or excessive wrinkling when force is applied thereto. A further requirement is that the material and any coatings thereon be able to withstand sterilization conditions as the drape must be supplied in sterile form.

The thin transparent plastic drape is made of lightweight plastic sheeting which is soft and flexible to have a good draping effect, preferably stretchable so as to be readily molded for adherence over the contours of the patient's body, and heat resistant to withstand sterilization, polyvinyl chloride sheeting being a preferred material. Other materials which may be used are illustrated in Pereny et al. Patent 3,060,932.

The drapes of the present invention are easily and inexpensively manufactured by first applying two narrow bands of adhesive to the marginal edges and a wide band of adhesive to the central portion of the draping material preferably using the same pressure sensitive adhesive. A non-adhesive area of less than one inch width and preferably of one-half an inch width is left between the narrow bands and the wide band. To this adhesive layer (includes both the narrow and wide adhesive bands) is applied the material which forms the backing and the marginal edge reinforcements. This material, preferably paper, can take the form of a single sheet which is cut after being adhered to the drape to form the backing sheet and the marginal edge reinforcements though the use of separate strips of paper is preferred. In the preferred form of the invention, thin strips of paper having no release agent thereon would be used for the marginal edge reinforcements and a wide sheet of paper coated with a release agent would be used for the backing. The non-adhesive area between the narrow adhesive bands and the wide adhesive band allows the backing to be applied without fear of contacting the narrow adhesive band. The drapes are then cut to a desirable length and rolled for packaging.

The drapes are rolled so that one marginal edge reinforcement is on the inside of the roll and the other on the outside. Though all parts of the drape may be rolled in one direction, it is preferred that the inner marginal edge reinforcement be rolled or caused to assume a rolled configuration opposite the remainder of the roll. By rolling the inner marginal edge reinforcement in such a manner, the inner marginal edge reinforcement when reached during backing removal tends to move out from the remainder of the roll to make it easier to grasp. This is illustrated in FIG. 4.

A simple manner of accomplishing this opposite rolled configuration is to fold the inner marginal edge reinforcement over the central portion of the drape (the plastic film side of the edge contacting the plastic film of the central portion of the drape) and then rolling the drape in one direction. This folding can be seen in FIG. 4. While it is preferred to fold the inner marginal edge reinforcement over the central plastic film portion of the drape, the reinforcement may also be folded over the paper backing with the same effect.

The rolled drape is preferably rolled so that the paper backing is on the outside, the plastic being on the inside, as illustrated in FIGS. 3 and 4. However, the drape of the present invention will provide similar properties if the drape is rolled in the opposite direction so that the plastic film is on the outside and the backing is on the inside.

The roll is preferably cylindrical in form without folds

or creases though a folded roll having the end configuration of an ellipse or flattened cylinder may also be used.

The rolled drapes are inserted into special packages which are designed to maintain sterility of the drape once it is sterilized and to provide for removal of the drape from the package without destroying asepsis. The drapes may then be sterilized by any known technique, steam sterilization being illustrative. Such packaging and sterilizing techniques are described in my copending application Ser. No. 424,663, filed Jan. 11, 1965, now issued as Patent No. 3,279,595, dated Oct. 18, 1966.

By way of specific example, a commercial embodiment of the present invention is illustrated by a polyvinyl chloride plastic sheet 26½ inches long and 24 inches wide. A coating of pressure sensitive adhesive is applied to the marginal edges and has a width of approximately two inches measured from the marginal edges and has a width of approximately two inches measured from the marginal edge of the drape. A 21½ inch coating of the same pressure sensitive adhesive, is applied to the central portion of the drape leaving a non-adhesive area of approximately ½ inch between the two adhesive areas. The permanent adhesive area is covered with thin sheets of uncoated, non-releaseable paper approximately 2¼ inches wide and the temporary adhesive is covered by a sheet of the same type paper 22 inches wide which has been coated with a release agent such as wax. The drape is then rolled and packaged as described hereinbefore.

The removal of the protective backing is easily accomplished according to the following procedure. After the drape has been aseptically removed from its package, a pair of sterile hands grasps the outer marginal reinforcement of the rolled drape with the paper side of the reinforcement down, the pressure sensitive adhesive down and the plastic film up. Another pair of hands grasps the lip on the backing and begins to pull the backing away from the pressure sensitive adhesive surface. The placement of the hands and the direction the backing is moved (arrow A) is illustrated in FIG. 3.

When the backing is almost completely removed, the end of the backing can be observed and, in this position, the marginal edge reinforcement will tend to move away from the roll as shown in FIG. 4. The person removing the backing then moves one of his hands to the center of the edge of the backing while the other hand grasps the inner marginal edge reinforcement at the center thereof, the positioning of the hands being shown in FIG. 4. After the inner marginal edge has been grasped with one hand, the other hand pulls the backing completely off. Since the inner marginal edge reinforcement has been grasped before the backing has been completely removed, the drape is prevented from falling below the waist of the person holding the outer marginal edge reinforcement which would destroy asepsis. The drape with the pressure sensitive adhesive side down is then applied to the patient as is shown in FIG. 5. Should the drape be provided in a rolled form with the plastic film on the outside and the paper on the inside of the roll, the backing removal technique would be essentially the same.

The invention is defined in the claims which follow.

I claim:

1. A marginally reinforced surgical drape adapted for improved aseptic handling comprising in rolled form:
(1) a sheet of thin transparent flexible plastic material having a central pressure sensitive adhesive layer thereon covering the major central portion of one surface of said sheet for adhering the drape to a patient;
(2) reinforcing strips adhered to said sheet along the marginal edges thereof at the outer and inner ends of the rolled sheet, said strips being out of contact with said adhesive layer; and
(3) a protective backing removably adhered to said adhesive layer, said backing being substantially co-

extensive with said adhesive layer and substantially coterminous with at least the end of the central adhesive layer at the inner end of the drape in its rolled form so that, in removing the backing from the drape in its rolled form, the inner end of said backing may be noted before said backing has been completely removed from said adhesive layer.

2. A marginally reinforced surgical drape as recited in claim 1 in which said reinforcing strip at the inner end of said rolled sheet is rolled in a direction opposite the remainder of said rolled sheet.

3. A marginally reinforced surgical drape as recited in claim 2 in which said drape is rolled in a direction so as to position said backing on the outside of the roll and the plastic sheet material on the inside of the roll.

4. A marginally reinforced surgical drape as recited in claim 1 in which said sheet is polyvinyl chloride sheeting material.

5. A marginally reinforced surgical drape as recited in claim 1, in which said protective backing is formed of paper having an adhesive release agent coating thereon.

6. A marginally reinforced surgical drape adapted for more aseptic handling comprising in rolled form:
(1) a sheet of thin transparent flexible plastic material having two marginal edge adhesive layers on opposing end edges and a central adhesive layer thereon;
(2) reinforcing strips permanently adhered to said marginal edge adhesive layers; and
(3) a protective backing removably adhered to said central adhesive layer and substantially coextensive and coterminous therewith, opposite side edges of said backing being in juxtaposition with inner edges of said marginal edge reinforcing strips so that, in removing the backing from the drape in its rolled form, the inner end of said backing may be noted before said backing has been completely removed from said central adhesive layer.

7. A marginally reinforced surgical drape as recited in claim 6 in which small non-adhesive layers are provided between each of said marginal adhesive layers and said central adhesive layer.

8. A marginally reinforced surgical drape as recited in claim 6 in which said sheet is polyvinyl chloride sheeting material.

9. A marginally reinforced surgical drape as recited in claim 6 in which said adhesive layers are of the same pressure sensitive adhesive material.

10. A marginally reinforced surgical drape as recited in claim 6 in which said backing is formed of paper having an adhesive release agent coating thereon.

11. A marginally reinforced surgical drape as recited in claim 6 in which said reinforcing strip at the inner end of said rolled sheet is rolled in a direction opposite the remainder of said rolled sheet.

12. A marginally reinforced surgical drape adapted for more aseptic handling comprising in rolled form:
(1) a sheet of thin flexible transparent polyvinyl chloride material having two marginal adhesive layers at the outer and inner ends of the rolled sheet and a central adhesive layer thereon separated by small non-adhesive areas, said adhesive layers being composed of the same pressure sensitive adhesive material;
(2) marginal edge reinforcing strips of non-release agent coated paper adhered to said outer and inner marginal adhesive layers, said reinforcing strip adhered to said inner adhesive layer being rolled in a direction opposite the remainder of said rolled sheet; and
(3) a protective backing including a non-adherent lip at the edge thereof to facilitate manipulation of the backing from the adhesive layer, said backing comprising paper coated with an adhesive release agent removably adhered to said central adhesive layer and

substantially coextensive and coterminous therewith, opposite side edges of said backing being in juxtaposition with inner edges of said marginal edge reinforcing strips, so that, in removing the backing from the drape in its rolled form, the inner end of said backing may be noted before said backing has been completely removed from said central adhesive layer.

13. The drape as recited in claim 12 treated to render it sterile and individually packaged in said sterile condition.

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