

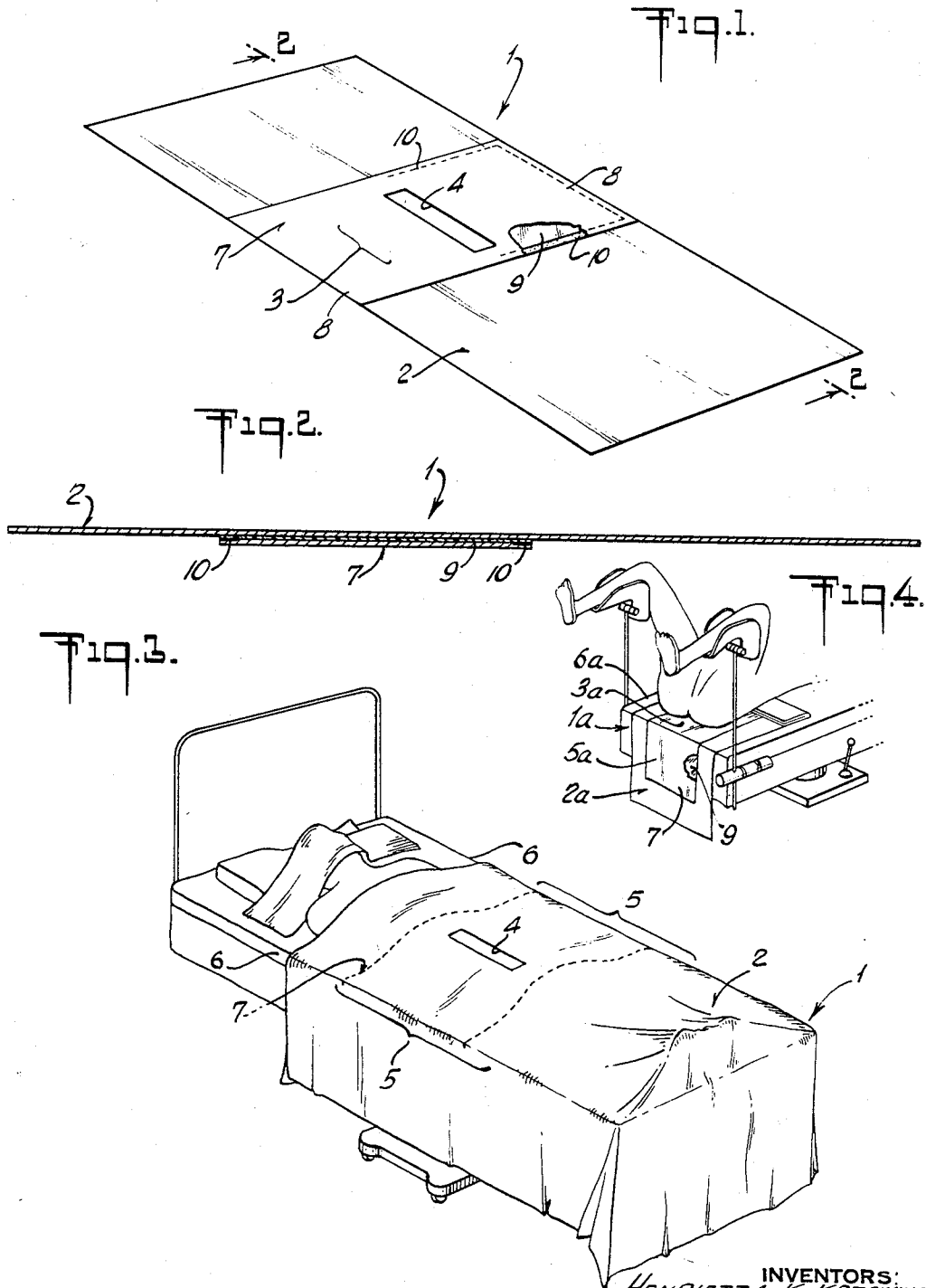
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SURGICAL APPAREL

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3,410,266

SURGICAL APPAREL

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This invention relates to surgical apparel and in particular to surgical drapes, gowns, and the like which are fluid repellent.

Surgical gowns, drapes, and the like are an important instrument in surgical and obstetrical procedures. Surgical drapes not only protect surgically prepared areas of the skin from contamination, but in addition protect the gowns of the surgeons and nurses against contamination through contact with unprepared or contaminated areas of the skin which may be a source of infection. The surgical gown presents a sterile barrier surface to protect the patient from contamination through contact with the surgeon.

The fluid imperviousness of the gown or drape has been long recognized as an important property in assuring that the gown or drape presents a sterile or relatively germ free outer surface and acts as an effective barrier to the passage of bacteria. If the blood and other fluids strike through the surgical drape and thus contact the skin of the patient, or the operating table, which is not considered sterile, not only may bacteria which are sometimes deposited on the surface of the drape be wicked through the capillary channels to the skin of the patient, but any bacteria present on the skin of the patient or operating table may be wicked outward through capillary channels to the surface of the drape whereby the surgeon's gown may become contaminated by contact with the drape. In the case of the surgical gown, if fluids are wicked through the same to the skin of the surgeon, bacteria present on the skin may be wicked outward to the desired sterile outer surfaces of the gown.

Surgical gowns and drapes have usually been made of linen, muslin or other similar woven fabrics or of laminated disposable sheet materials, for example, of the type proposed in U.S. Patent 2,900,980 to Harwood. In rendering general purpose gowns and drapes made of these fabrics impervious to fluids, one approach has been to alter the surface tension characteristics of the fabric by treating the drape or gown with a water repellent agent. In our assignees' copending application Ser. No. 364,707, an alternate approach for providing a fluid impervious drape is disclosed and a surgical drape construction proposed in which a fluid impervious sheet of organic film is sandwiched between two absorbent nonwoven fibrous sheets.

Until now, no one has ever thought of providing a drape or gown fabric of laminated construction utilizing an impervious organic film sandwiched between normally fluid repellent fibrous sheets. The interposing of a fluid impervious film between two absorbent sheets and the treatment of the surfaces of a sheet material with a water repellent were until now thought of as alternate solutions to the same problem and therefore no advantage was seen in combining the use of the film with the repellent treatment.

We have recently discovered that while for most areas

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of the drapes and gowns a repellent treatment is sufficient to render the fabric essentially impervious to the passage of fluids, certain areas of the drapes and gowns are subjected to a substantial amount of pressure during operative or obstetrical procedures, and this pressure tends to force fluids through the pores of the otherwise repellent drape or gown. These areas of the drape and gown will often hereinafter be referred to as the primary operative areas. These areas which are subjected to increased pressure include, for example, the central portion of the under buttocks drape used for obstetrical procedures, or the area surrounding the fenestration in a laparotomy sheet, and the central front portion of the surgical gown.

We first attempted to eliminate this fluid strike through by providing a double thickness of repellent material in these primary operative areas of the drapes and gowns and/or treating these areas of the drape or gown with additional amounts of repellent agent. However, these approaches to solving the problems have been found to be generally inadequate, neither the extra repellent agent or the second layer of repellent treated material acting to provide an effective barrier to the passage of fluids under increased pressure.

In the case of the construction utilizing the impervious film and wherein the outer plies of material are absorbent, although the film does provide an effective barrier to the passage of fluids and bacteria, due to the absorbency of its outer layers, the area of the outer surface of the sheet adjacent portions of the body where fluid flow is heaviest becomes quickly saturated with fluids. This was considered by many to be an advantage of this construction. However, we have recently realized that in cases where fluid flow is very heavy, when using absorbent drapes, the fluid is absorbed locally where it is first deposited on the outer drape surface and the patient is soon lying in his own exudate or the surgeon working in the exudate. For this reason, we consider these absorbent drapes to have primary usefulness as a local drape which is placed over the main drape in areas where substantial fluid flow is expected where these areas are so located that the drape may be easily replaced periodically during the operation. They are not generally satisfactory for use as a main drape since the same should not be changed once the operation begins.

We now provide a material for surgical apparel comprising a normally fluid repellent main sheet having a primary operative area, a secondary sheet of material overlying at least the primary operative area of said main sheet, and a fluid impervious film interposed between the primary operative area of said main sheet and the secondary sheet and secured to at least one of said main sheet and said secondary sheet preferably only at the edges of the film.

By virtue of the fluid impervious film, a barrier is provided against the striking through of fluids in the primary operative area and by virtue of the normally repellent outer layer, fluids which are deposited in large amounts on the outer surface will not be absorbed in a localized area but will flow along the contours of the drape and spread out over a much larger area of the drape where they will dry and coagulate more rapidly. Thus, it is surprisingly found that the use of the impervious film

and the repellent treatment may be combined to provide a drape having definite advantages.

The inventive concept will be more easily understood by referring to the attached drawings which are hereinafter described. In the drawings,

FIG. 1 is a view in perspective of a surgical drape utilizing the concepts of this invention;

FIG. 2 is a cross section of the drape illustrated in FIG. 1 taken along line 2—2;

FIG. 3 is a representation of a drape utilizing the concepts of this invention as applied to laparotomy procedures;

FIG. 4 is a representation of a drape utilizing the concepts of this invention as applied to obstetrical procedures.

Referring specifically to the figures, there is illustrated a surgical drape 1 comprising a main sheet 2 having a primary operative area 3 which is subjected to increased pressure due to the surgical activity around the fenestration 4 and due to the pressure created by the surgeon leaning against the area of the drape 5 overlying the edge 6 of the operating table. The main sheet 2 consists of a sheet of laminated fabric comprising two plies of tissue paper with a nonwoven scrim interposed between the plies of tissue paper, in the manner described in U.S. Patent 2,900,828 to Harwood. The material has been impregnated to a weight of 10% pick-up with a fluorocarbon stearate-chromium complex fluid repellent, this repellent treatment being adequate to provide a fabric having a saline repellency of greater than 24 hours. Saline repellency is the time required for a 1% saline solution at a four inch fluid head to strike through the fabric.

A secondary sheet 7 of the same repellent treated laminated reinforced fabric overlies the primary operative area 3 of the main sheet 2 and is essentially coextensive therewith, the secondary sheet being secured to the main sheet at edges 8 and edges 10 outward of the central operative field. A 0.5 mil thick ethylene-propylene copolymer (90% propylene) film 9 having a melting point of about 335° F. is interposed between the primary operative area 3 of the main sheet 2 and the secondary sheet 7 and is secured by glueing with a polyvinyl acetate-acrylate copolymer glue along the edges 10 of the film.

In use as illustrated in FIG. 3, the fluid repellent main sheet 2 provides the drape with its basic fluid repellent characteristics. The heavy fluid flow onto the outer drape surface in the area surrounding the fenestration 4, rather than being absorbed locally, will, due to the contours of the patient's body, spread out toward the edges 6 of the table and thus over a large portion of the drape where it dries and coagulates. Thus, the surgeon will not be working in the exudate. In the primary operative area 3 surrounding the fenestration 4 and in the area 5 along the edge 6 of the table, the copolymer film acts as a fluid barrier.

In FIG. 4, a drape of this invention is shown in use as the under buttocks drape during a delivery. In this case, the film 9a provides a bacteria barrier between the patient and the operating table, which is not considered sterile. The pressure on the primary operative area 3a of the drape 1a is due both to the weight of the patient and the surgeon leaning against the edge 6a of the table. When "breaking of the water" occurs, due to the repellency of the sheet 7a the fluid will spread out and flow over the end of the slightly sloping operating table and thus to a large extent is effectively removed from the operative area.

The main sheet of the drape, as previously mentioned, must be fluid repellent. By the term "fluid repellent" it is meant that fluids having a surface tension approximating that of water which contact the surface of the material initially tend to form puddles on the surface of the sheet without penetrating the same, i.e., the sheets are nonwetttable.

The organic film may be any fluid impervious film which can withstand the minimum temperatures of sterilization, i.e., about 160° F. for chemical sterilization and

about 270° F. for steam sterilization. For these purposes, polypropylene and copolymers of ethylene and propylene have been found to be particularly suitable.

The purpose of the secondary sheet is to enclose the film and thus prevent static discharge problems from arising. These thermoplastic films tend to carry a substantial quantity of electrical charge and this charge is increased when the gown or drape is opened by shaking or similar motions, the charge build-up due to the film being large compared to the charge build-up caused by the repellent agent on the fabric. Thus, sparking may occur between the stationary charges on the surface of the film and grounded objects in the operating room. Since the operating room often has a flammable atmosphere, sparking must be avoided.

In order for the charge to be dissipated, the electrons must be absorbed by either another body or the air, or the charge on one of the sheets must be neutralized. In order for either of these phenomena to occur, the sheet must be made conductive so that the charges are mobile. By conductive, it is not necessarily meant conductive with respect to rapid current flow but rather with respect to the movement of charges across the surface of the same. Since charges migrate to the surface, it is conductivity of the outer plies of the fabric which is important.

The secondary sheet serves to sandwich the film between two layers of the fabric and thus provides essentially a capacitor construction, both outer surfaces of the drape being able to dissipate readily any charges which may form on the thermoplastic film. The charges are not prevented from forming but only increased in mobility so that they are more easily dissipated.

The secondary sheet need not be repellent since it is anticipated that the same will face inward toward the patient or operating table. However, it is preferred that the sheet be repellent so that a reversible drape is provided.

The thermoplastic film may be secured to either the main sheet or the secondary sheet over its entire surface if desired although it is preferable to secure the film to the main sheet or secondary sheet or both only at its outer edges to retain the desired drape in the surgical product. The extrusion of an impervious film on the drape or gown tends to substantially decrease the drape and flexibility of the material. In addition, the rate of shrinkage of the film and of the underlying substrate are somewhat different and therefore undesirable buckling of the material occurs.

While several specific examples of the inventive concept have been described with particularity, they are provided only for the purposes of illustration and the invention should not be construed to be limited to the same. The inventive concept may be applied not only to all types of surgical drapes but to surgical gowns and the like and to any surgical fabric product wherein certain areas of the same are subjected to increased pressure during use.

What is claimed is:

1. An article of surgical apparel comprising a normally fluid repellent main fibrous sheet having a primary operative area, a secondary fibrous sheet overlying said main sheet in at least a portion of the primary operative area of said main sheet and secured to said main sheet, a fluid impervious organic film which is stable to heat at temperatures above about 160° F. interposed between said main sheet and said secondary sheet in at least a portion of the primary operative area of said main sheet and secured to at least one of said main sheet and said secondary sheet, said secondary sheet overlying essentially the entire fluid impervious film.

2. The article of surgical apparel of claim 1 in which said secondary sheet is essentially coextensive with the primary operative area of said main sheet and in which said fluid impervious film is essentially coextensive with the primary operative area of said main sheet.

3. The article of surgical apparel of claim 2 in which

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said fluid impervious film is secured to at least one of said main sheet and said secondary sheet only in an area at the periphery of the film.

4. The article of surgical apparel of claim 3 in which said film is chosen from the group consisting of polypropylene and copolymers of propylene and ethylene.

5. The article of surgical apparel of claim 3 in which said secondary sheet is also fluid repellent.

6. The article of surgical apparel of claim 3 in which said main sheet has a saline repellency of at least 24 hours.

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