Description

This invention relates to X-ray detectable fabrics and, more particularly, to surgical swabs and sponges which include a printed X-ray detectable marker as an integral component of the sponge fabric.

Various absorbent fabric materials are used in surgical procedures for packing, wiping, and cleansing in or around the operating site. Typical products include surgical sponges such as 4x4 inch folded surgical gauze of nonwoven fabric, and woven, nonwoven and knitted laparotomy pads. Although standard operating room procedures require all materials brought into the operating area to be accounted for upon completion of the procedure, an occasional sponge may inadvertently be left in the patient. It is accordingly common practice in the medical field to include a radiopaque marker on all surgical sponges so that the presence or absence of a sponge in a patient experiencing difficulty after an operation can be determined by X-ray examination rather than by reoperating on the patient.

A common X-ray detectable marker used in conjunction with surgical sponges is a polymeric filament or ribbon loaded with an X-ray opaque filler material such as barium sulfate. Suitable polymeric materials include polyisobutylene, polyvinyl chloride and copolymers of vinyl acetate and vinyl chloride. Such X-ray detectable elements have been incorporated into sponge material by a variety of techniques. In the case of gauze swabs, a filament has been interwoven into the fabric of the gauze or fused to the surface of the fabric and folded into the sponge construction. In the case of laparotomy pads, an X-ray detectable ribbon has been enclosed in a seam stitched along one end of the pad, or an X-ray detectable filament has been incorporated into the woven handle strap of the pad or into the body of the pad fabric. In the case of nonwoven fabric sponges, the filament has been either heat fused onto the surface of the fabric or incorporated into the fabric by introducing the radiopaque element during the fabric manufacturing process.

GB-A- Patent 858787 discloses a sponge into which is injected a dense X-ray opaque body generally having a globoid shape. In most cases, however, the X-ray detectable element has been preformed as a ribbon, yarn or monofilament, and it has been essential to securely attach the element to the sponge fabric since if the element is separated from the fabric during use, not only is the fabric no longer visible by X-ray, but the separated element is easily lost in the surgical field. For manufacturing considerations, it is desirable that the X-ray detectable marker be secured to the sponge in a continuous and reliable manner with a minimum of labor. A final consideration is that the X-ray detectable marker be easily identified in an X-ray image.

It is accordingly an object of the present invention to provide an improved X-ray detectable marker on a surgical sponge. It is a further object of this invention to provide a surgical sponge having a distinctive and easily detected radiopaque marker. It is a yet further object to provide a method for applying a radiopaque marker to the surface of a fabric in a rapid, continuous and economical manner. These and other objects of the present invention will be apparent from the ensuing description and claims.

Summary of the Invention

A surgical sponge in accordance with the present invention comprises a fabric and a radiopaque marker bonded to said fabric in a visually distinctive pattern. The radiopaque marker is applied to the surface of the fabric by extruding or printing a radiopaque polymeric suspension or melt onto the surface of the fabric in such a way that the surface fibers of the substrate fabric are encapsulated. Upon heat-setting, curing or coalescing, the radiopaque material is securely bound to the fabric so that it becomes an integral part of the fabric and cannot be readily removed. Emulsion polymers such as plastisols and latexes which are soft, rubbery materials even when heavily loaded with barium sulfate or other radiopaque salt are well suited for use in the present invention.

The pattern of the X-ray detectable marker is determined by the structure of the underlying fabric and the nature of the application means. The marker may be applied to the surface of the fabric in a continuous process at a high rate of speed by printing with a gravure roll. Suitable compositions for the marker comprise biocompatible polymers containing an effective amount of a radiopaque filler such as barium sulfate and having a viscosity suitable for printing or other application means.

Description of the Drawings

Fig. 1 is a view in perspective of a folded surgical sponge having an X-ray detectable marker in accordance with the present invention.

Fig. 2 is a print of an X-ray image of a double thickness of a nonwoven fabric having two narrow X-ray detectable bands printed thereon.

Fig. 3 is a photograph of a nonwoven fabric having a radiopaque marker applied to the surface thereof.

Fig. 4 is a print of an X-ray image of the fabric of Fig. 3 illustrating the pattern of the X-ray marker.

Fig. 5 is a photograph of another nonwoven fabric having a radiopaque marker applied to the surface thereof.

Fig. 6 is a print of an X-ray image of the fabric of Fig. 5 illustrating the pattern of the X-ray marker.

Fig. 7 is a photograph of a surgical gauze having a radiopaque marker applied to the surface thereof and also containing a conventional X-ray detectable monofilament.

Fig. 8 is a print of an X-ray image of the fabric of Fig. 7.

Description of the Invention

The present invention consists of applying a polymeric material containing from 15 percent up to 70 percent by weight of a heavy metal radiopaque salt such as barium sulfate onto the surface of surgical sponge fabrics. The polymeric material may be applied as a hot melt extrusion, or by printing or cold extruding a latex emulsion or a plastisol onto the surface of the fabric in a continuous or intermittent pattern. Upon heat-setting, curing or coalescing, the upper layer of fibers of the underlying fabric are encapsulated by the radiopaque material so that the marker is securely bound to the surface of the fabric and will not separate during normal handling or use.

The radiopaque marker is applied to the surface of the fabric in a distinctive pattern which is readily identified in an X-ray image. In the case of those fabrics having an open structure such as woven gauze and certain nonwoven fabrics, the radiopaque material may be applied to the fabric in such a way as to preserve the open spaces in the fabric whereupon the fabric structure itself becomes the distinctive pattern of the X-ray marker.

In the case of fabrics having no distinguishable pattern such as closely knit or tightly-woven fabrics or nonapertured nonwoven fabrics, it is preferable to apply the radiopaque material to the surface of the fabric in a predetermined pattern which is controlled by the configuration of the printing roll or other application means. Latex emulsions and plastisol formulations may be applied to the fabric by padding, gravure printing, screen printing, or other convenient method.

Patterned nonwoven fabrics useful in the practice of the present invention may be prepared according to conventional hydraulic entanglement methods. In brief, these methods consist of providing a fibrous web of randomly oriented staple length fibers, positioning the web on a patterned, apertured belt, and subjecting the web to a plurality of high pressure hydraulic jets to entangle the fibers into a pattern conforming to that of the supporting belt. The entangled fibers are thereupon separated from the belt and dried on hot drums to produce a patterned nonwoven fabric. This method of manufacturing is described in detail in U.S.-A-3,068,547; 3,129,466; 3,485,706; 3,494,821; and 3,681,184 and is well known to those skilled in the art.

The nonwoven fabric may comprise any suitable combination of natural and/or synthetic textile materials including cotton, rayon, acrylics, polyester and nylon. A particularly preferred fiber composition is a blend of 70% rayon (1.5 denier, approximately 3 cm staple length) and 30% polyester (1.5 denier, approximately 3 cm staple length). The staple fibers are blended and converted to a fibrous web on conventional textile processing equipment such as a Rando-Webber which produces a web having random fiber orientation.

The nonwoven fabric preferably has a dry weight of from about 1.0 to 3.0 ozs per square yard (30 to 100 g/m^2), with the lighter weights limited by the processability of the fibrous web and the heavier weights limited by the desired utility and construction of the sponge or swab, although higher weights may be preferred for some product applications such as laparotomy pads.

The radiopaque composition is preferably dyed or pigmented blue or other suitable color which contrasts sharply with blood. The color permits ready identification of the X-ray detectable element in the sponge, facilitates sponge counting in the operating room and further helps locate the sponge when saturated with blood during use. As a characteristic of the sponges of the present inventin, the radiopaque material may be applied primarily to one surface of the fabric, and is consequently visually more apparent from that side. This increased visibility may be capitalized on when folding the sponge by placing the radiopaque material to the outside of the sponge.

Turning now to Figure 1 there is illustrated a surgical sponge, indicated generally by the numeral 10, which consists of folded fabric 11 having a radiopaque marker consisting of a pair of lines 12 and 13. The radiopaque marker lines are continuous over the length of the folded sponge and applied to the fabric during manufacture by, for example, printing a radiopaque plastisol directly onto the surface of the fabric. While lines 12 and 13 appear generally as two continuous lines of uniform width and depth, closer inspection reveals that the lines conform to the open pattern of the fabric and have a variable thickness on

the surface of the fabric. The pattern of the radiopaque material on the fabric of the sponge results in the formation of a distinctive X-ray image of the radiopaque marker. Figure 2 is a print of the X-ray image of a double thickness of a fabric having two narrow X-ray detectable bands printed thereon. While the X-ray pattern is created entirely by the pattern of the underlying fabric, the fabric pattern itself is not apparent from the X-ray image due to the narrow width of the radiopaque lines.

Figure 3 is a photograph of an open patterned nonwoven fabric which is characterized by a series of small, widely-spaced fiber masses interconnected by radial threads in what is commonly referred to as a "rosebud" pattern. A radiopaque material applied uniformly to the fabric over a width of from about 1 to 2 cm, appearing as dark bands in Figure 3, encompasses a sufficient area of fabric to make the actual pattern of the fabric visible in the X-ray image as illustrated in Figure 4. Where such a side band of radiopaque material is applied to the fabric, it will usually be sufficient to apply the material in a discontinuous line so that one or two bands of material appear in each sponge. For example, if the length of the fabric comprising each folded sponge is 0.5 m, it would be sufficient to apply the radiopaque material in bands of 2 cm wide by 10 cm long at a frequency of four bands per meter of fabric, thus assuring that each sponge would include two radiopaque markers, at least one of which would be a continuous 10 cm length.

Figures 5 is a photograph of another nonwoven fabric having a radiopaque marker applied to the surface thereof. The X-ray image of the fabric as illustrated in Figure 6 clearly shows the pattern of the fabric to be different than that of Figure 4.

Figure 7 illustrates a conventional 20x8 woven surgical gauze printed with a band of radiopaque plastisol material which appears as the dark bands in the photograph of Figure 7. The radiopaque material uniformly coats each yarn of the gauze within the area of the coating and the pattern of the gauze is readily identified in an X-ray image of the fabric as illustrated in Figure 8. Figures 7 and 8 also include a conventional monofilament marker which is clearly visible as the wavy line in the X-ray image of Fig. 8, and less evident in the photograph of the fabric of Fig. 7. It should also be noted that while the photograph and the X-ray are of the same fabric, the displayed areas are not precisely the same.

As illustrated in Figures 1-8, the radiopaque material may be applied to an open mesh fabric over an area sufficient to reveal the actual pattern of the underlying fabric in an X-ray image, or over an areas which is too narrow to disclose the repeating pattern of the fabric, but nevertheless displays a distinctive pattern of its own in an X-ray image as a result of the underlying fabric pattern.

In the case of closely knit or woven fabric, the radiopaque material is applied in a predetermined pattern controlled by the application means. For example, a plastisol may be applied to the surface of the fabric by screen printing or by gravure system in a continuous line or in discontinuous bands and in any desirable pattern. An infinite variety of patterns is, of course, possible and may be utilized in the practice of the present invention. One desirable pattern would be in the name or initials of the supplier of the surgical product and perhaps the order number of the product, which would not only provide X-ray detectability but also indicate the source of the product to the surgeon during the operating procedure. Since the surgical sponges are usually wadded up during use, it is unlikely that this information would be fully legible in an actual X-ray image, but even a single letter of the alphabetwould be distinctive and easily recognized as a foreign object in an X-ray following a surgical procedure.

The method of the present invention is further illustrated in the following examples where all parts and percentages are by weight unless otherwise indicated.

Example 1

A plastisol printing composition is prepared from polyvinyl chloride resin according to the following formulation:

100 parts	Geon 125-A® PVC resin
100 parts	Dioctyl phthalate plasticizer
328 parts	$BaSO_4$
5 parts	blue pigment

Geon® 125-A PVC resin is a low molecular weight, low viscosity polyvinylchloride powder available from B.F. Goodrich, Avon Lake, Ohio. The $BaSO_4$ is suitably No. 1 Barytes® HP available from Pfizer, Inc., Easton, Pennsylvania. The blue pigment is suitably Ultramarine Blue available from Sun Chemical Co., Cincinnati, Ohio. The PVC resin is sifted with stirring into the dioctyl phthalate plasticizer containing the blue dye, followed by addition of the $BaSO_4$. The resulting composition contains 61.5% $BaSO_4$ and has a

viscosity of about 20,000 cps which is suitable for printing. Desirable viscosities for printing are generally in the range of 5,000 to 20,000 cps although higher or lower viscosities may be utilized in some applications.

Example 2

An emulsion latex printing composition is prepared according to the following formulation:

25 parts	water
10 parts	blue pigment
2 parts	antifoam
4 parts	rheology modifier
3 parts	ammonia (28%)
200 parts	Rhoplex® K-3 (48%)
501 parts	$BaSO_4$

The latex printing composition is prepared by first combining the water, ammonia, antifoam, rheology modifier, pigment and Rhoplex® K-3, then slowly adding the $BaSO_4$ with stirring to obtain a mix with 67% $BaSO_4$ solids. The ammonia functions to increase the pH to about 8, the antifoam may be Colloids® 999 available from Colloids, Inc., Newark, NJ, and the rheology modifier may be a poly (ethylene oxide) such as Poly-ox® available from Union Carbide, Danbury, CN. Rhoplex® K-3, is a 46% aqueous acrylic emulsion available from Rohm & Haas, Philadelphia, PA. After application to the fabric and removal of volatiles, the $BaSO_4$ content in the resulting polymeric composition is approximately 80 percent.

The radiopaque polymeric composition with $BaSO_4$ is naturally white, but may be pigmented blue or other color for enhanced visibility, or left uncolored except for some indication of its presence such as a thin blue line printed onto the marker after curing. A wide, unpigmented band of radiopaque material with a narrow blue line or the logo of the manufacturer printed thereon, may be more aesthetically pleasing to the surgeon and still provide all the advantages of a wide, X-ray detectable marker as described herein.

The plastisol or latex printing composition is applied to the surface of the surgical fabric using conventional printing equipment and techniques as, for example, by gravure rolls. The printed fabric is passed through a heating station to polymerize the resin and remove volatile components. The resulting polymeric deposit is securely adhered to the underlying fabric and typically comprises from 60-90% $BaSO_4$ solids in the resin binder. We have found that at least 10% resin binder is desirable to assure the integrity of the polymeric mass and its adhesion to the fabric.

The $BaSO_4$ used in the printing formulations of the present invention preferably has an average particle size of at least 5 microns, and most preferably 10 microns or greater, in order to obtain printing compositions having the desired flow characteristics when containing up to 70% $BaSO_4$ solids. We have found that when the average particle size is substantially less than 5 microns, as for example 2 microns, formulations containing such high levels of $BaSO_4$ solids are essentially dry mixes not suitable for application to fabric by conventional printing means. In the case of the No. 1 Barytes HP used in the preceding examples, the average particle size is 10 microns with 75 percent of the particles being 5 microns or greater.

We have also found that the X-ray detectability of a cured latex or plastisol containing from 60 to 70 percent barium sulfate compares favorably with that of a conventional monofilament marker which usually contains about 60 percent barium sulfate. Moreover, the X-ray visibility of the radiopaque material is greater in the case of the present invention, since if the X-ray is taken in plan view, the pattern of the marker stands out while if the X-ray is taken in side view, the effective thickness of the marker is increased and the brightness of the marker in the X-ray image is enhanced.

The fabric may be printed on one or both sides with the radiopaque material and superimposed printing on both sides has the advantage of presenting thinner layers with greater surface area to speed drying or curing of the radiopaque material. Wide lengths of fabric may be printed with parallel bands of radiopaque material spaced to conform to the desired final width of the sponge so that the fabric may be slit within the bands. The radiopaque material thereby performs the dual function of stabilizing the cut edges of the fabric against loose yarns or linting, while at the same time imparting X-ray detectability to the fabric.

Claims

1. A method of preparing a surgical sponge comprising an absorbent fabric having an X-ray detectable

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Claims

1. A method of preparing a surgical sponge comprising an absorbent fabric having an X-ray detectable

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marker associated therewith, the method comprising applying a flowable, radiopaque polymeric composition to the surface of said fabric in a visually distinctive pattern and securely bonding said polymeric composition to said fabric.

2. The method of claim 1, wherein the polymeric composition has a printable viscosity.

3. The method of claim 2, wherein the polymeric composition is applied to the fabric by printing means.

4. The method of claim 3, wherein said printing means is gravure or screen printing.

5. The method of any one of claims 1 to 4, wherein the polymeric composition is a plastisol or latex emulsion containing a heavy metal salt.

6. The method of claim 5, wherein the heavy metal salt is barium sulphate having an average particle size greater than 5 micrometers.

7. The method of claim 5 or claim 6, wherein the polymeric composition contains from 15 to 70% by weight of the heavy metal salt.

8. The method of any one of claims 1 to 7, wherein said polymeric composition comprises a PVC plastisol or an acrylic latex emulsion.

9. A surgical sponge comprising an absorbent fabric having a radiopaque polymeric composition bonded to the surface thereof in a visually distinctive patterns which conforms to the structure of the underlying fabric.

10. A surgical sponge comprising a substantially non-apertured fabric having a radiopaque polymeric composition printed onto the surface of said fabric and bonded thereto in a visually distinctive pattern.

Patentansprüche

1. Verfahren zur Herstellung eines chirurgischen Schwamms aus einem absorbierenden Stoff mit einer durch Röntgenstrahlen nachweisbaren Markierung, gekennzeichnet durch das Aufbringen einer fließfähigen, für Röntgenstrahlen undurchlässigen, polymeren Zusammensetzung auf die Oberfläche des genannten Stoffs in einem deutlich sichbaren Muster und das sichere Verbinden der genannten polymeren Zusammensetzung mit dem genannten Stoff.

2. Verfahren nach Anspruch 1, bei dem die polymere Zusammensetzung eine druckfähige Viskosität hat.

3. Verfahren nach Anspruch 2, bei dem die polymere Zusammensetzung auf den Stoff mit einem Druckmittel aufgebracht wird.

4. Verfahren nach Anspruch 3, bei dem das genannte Druckmittel Tiefdruck oder Siebdruck ist.

5. Verfahren nach einem der Ansprüche 1 bis 4, bei dem die polymere Zusammensetzung ein Plastisol oder eine Latex-Emulsion ist, die ein Schwermetallsalz enthalten.

6. Verfahren nach Anspruch 5, bei dem das Schwermwetallsalz Bariumsulfat mit einer mittleren Teilchengröße über 5 µm ist.

7. Verfahren nach Anspruch 5 oder 6, bei dem die polymere Zusammensetzung von 15 bis 70 Gew.-% des Schwermetallsalzes enthält.

8. Verfahren nach einem der Ansprüche 1 bis 7, bei dem die genannte polymere Zusammensetzung ein PVC-Plastisol oder eine Acryl-Latex-Emulsion umfasst.

9. Chirurgischer Schwamm, umfassend einen absorbierenden Stoff mit einer für Röntgenstrahlen undurchlässigen, polymeren Zusammensetzung, die mit seiner Oberfläche als ein visuell unterscheidbares

Muster verbunden ist, und das sich an den darunter liegenden Stoff anpasst.

10. Chirurgischer Schwamm, umfassend einen im wesentlichen keine Öffnungen aufweisenden Stoff, mit einer für Röntgenstrahlen undurchlässigen, polymeren Zusammensetzung, die auf seine Oberfläche aufgedruckt und mit ihr als einem visuell unterscheidbaren Muster verbunden ist.

Revendications

1. Une méthode de préparation des compresses chirurgicales comprenant un tissu absorbant comportant un marqueur détectable aux rayons X, ladite méthode comportant l'application d'une composition fluide polymérique opaque aux rayons X sur ladite surface dudit tissu selon un motif distinctif visible à l'oeil nu, ainsi que l'adhésion ferme de ladite composition polymérique audit tissu.

2. La méthode de la revendication 1, selon laquelle la composition polymérique a une viscosité d'impression.

3. La méthode de la revendication 2, selon laquelle la composition polymérique est appliquée sur le tissu par un moyen d'impression.

4. La méthode de la revendication 3, selon laquelle ledit moyen d'impression est une impression par gravure ou par sérigraphie.

5. La méthode de l'une quelconque des revendications 1 à 4, selon laquelle la composition polymérique est une émulsion de plastisol ou de latex contenant un sel métallique lourd.

6. La méthode de la revendication 5, selon laquelle le sel métallique lourd est du sulphate de baryum ayant des particules de dimension moyenne supérieure à 5 microns.

7. La méthode de la revendication 5 ou de la revendication 6, selon laquelle la composition polymérique a une teneur en sel métallique lourd de 15% à 70% en poids.

8. La méthode de l'une quelconque des revendications 1 à 7, selon laquelle ladite composition polymérique renferme une émulsion de plastisol PVC ou de latex acrylique.

9. Une compresse chirurgicale comprenant un tissu absorbant ayant une composition polymérique opaque aux rayons X adhérant à la surface dudit tissu selon un motif distinctif visible à l'oeil nu qui épouse la structure dudit tissu sous-jacent.

10. Une compresse chirurgicale comprenant un tissu essentiellement non ajouré et comprenant une composition polymérique opaque aux rayons X imprimée sur la surface dudit tissu et adhérant à celle-ci selon un motif visible à l'oeil nu.