April 28, 1970 P. E. WALTERS ET AL 3,508,551

DRESSINGS AND PRODUCTION THEREOF

Filed June 20, 1968

Fig. 1.

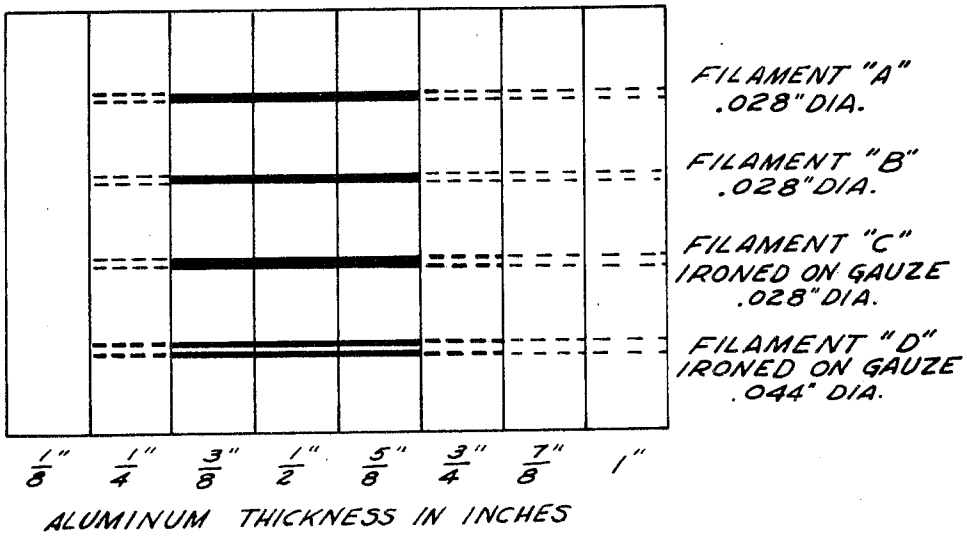


Fig. 2.

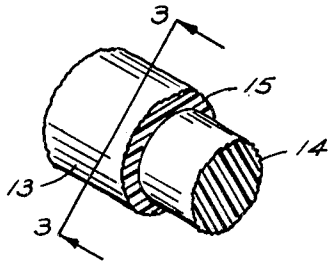


Fig. 3.

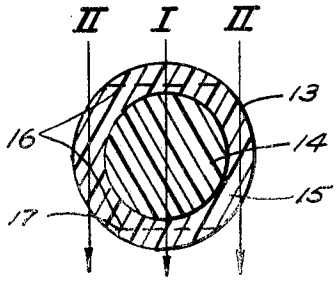
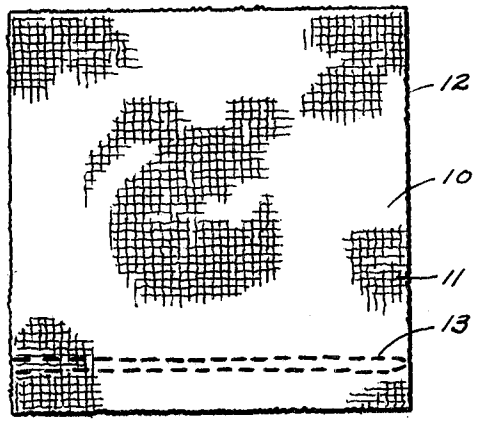


Fig. 4.



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DRESSINGS AND PRODUCTION THEREOF

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Continuation-in-part of application Ser. No. 472,467, July 16, 1965. This application June 20, 1968, Ser. No. 738,665

Int. Cl. A61f *13/00*

U.S. Cl. 128—296 6 Claims

ABSTRACT OF THE DISCLOSURE

X-ray detectable surgical dressings are provided having an improved X-ray opaque filament locked in place by thermoplastic adhesion induced by ironing with heat and pressure. This filament has a radio transparent core which is relatively non-compressible at ironing heat and pressure but which is surrounded by a thermoplastic radiopaque layer which during ironing softens and is preferentially compressed and imbedded across the face of the dressing. The filament affords a saving in the amount of X-ray opaque material required and can be designed to provide, as desired, either a single-line image or parallel double-line image for detection purposes.

SUMMARY AND DETAILED DESCRIPTION

This application is a continuation-in-part of our copending application Ser. No. 472,467 filed July 16, 1965.

The present invention relates to surgical dressings and the production thereof. More particularly, the invention relates to surgical sponges or dressings of the type including an X-ray detectable filament to permit postoperative discovery of any such dressing accidentally left within the surgical cavity. Prior art sponges of this general type are exemplified by the article described in U.S Patent No. 3,133,538.

In the prior art sponges, the detectable filament of choice is a solid plastic strand or thread containing an X-ray opaque filler. The filament is held in place by pressing with heat (i.e., "ironing" at pressures of the order of one p.s.i. and temperatures of about 300–350° F.) onto the textile layer to cause the filament and the textile layer to be fused together at random points. Federal specifications DDD–P–0054*a*, General Services Administration, Federal Supply Service, Aug. 8, 1962) provide that the filament should be inserted and so anchored between the layers of gauze that the filament will not fall out of the pad when the pad is completely unfolded and vigorously shaken. The specifications also provide that the filament should be capable of withstanding sterilization by live steam at a temperature of 250° F. for one hour without bleeding, becoming tacky, or showing any other signs of deterioration.

One difficulty with the prior art filaments is that they are unduly expensive. Also, they are dimensionally unstable and subject to unwanted stretching and breaking. Moreover, in connection with the production, handling and general treatment of the article during packing and shipping, or when the dressing is subjected to substantial temperature change or kept in inventory for long periods, the filament may embrittle, shrink and pull loose, or break into fragments. These fragments, if not fused to the gauze, can fall away from the sponge into the open wound or onto other areas of the surgical site.

It is therefore an object of the present invention to provide improved X-ray detectable surgical dressings.

Another object of the invention is to provide a surgical dressing with X-ray detectable filament means as an integral, non-extensible unit bonded to the dressing so

that fragments or portions of the filament means cannot unintentionally become separated or removed from the dressing.

A further object is to provide a surgical dressing with X-ray detectable means having the required opacity to X-rays but using a smaller quantity of radiopaque filler-resin raw material and therefore more economical.

Still another object is to provide a surgical dressing with X-ray detectable filament means in which the radiopaque material is disposed in an external circumferential layer encasing a central radiotransparent core, the thickness of the layer being subject to selection so as to permit the choice of detection either as a single-line or parallel double-line X-ray image, as desired.

These and other objects, features and advantages will be seen in the following description and drawings in which:

FIGURE 1 is a representation of different X-ray opaque filaments, side-by-side for comparison, when viewed radiographically through the various standard thicknesses of aluminum according to the opacity test conditions set forth in section 4.4.4 of the aforementioned Federal specifications;

FIGURE 2 is a view of a length of X-ray detectable filament according to the invention, with the reinforcing core exposed at one end;

FIGURE 3 is a cross-sectional view, taken on line 3—3 of FIGURE 2, of a filament; and

FIGURE 4 is a plan view of a surgical dressing in the conventional folded form illustrating the placement of the X-ray detectable filament.

The X-ray detectable dressing of the invention is generally depicted by the numeral **10** in FIGURE 4, which dressing like that of the above-mentioned patent, comprises a sheet or web of gauze **11** or other suitable dressing material folded along rectilinear fold lines to provide edges **12**. The dressing **10** includes an X-ray detectable filament shown by the dotted line **13**. In its unfolded, open condition (not shown), the dressing is a square or rectangular sheet or blank of gauge having the filament **13** disposed across its face from opposite edges. Thus, when a first fold is made of the sheet to enclose the filament, on a fold line bisecting the sheet and filament, and a second mid-fold is then made of the resulting half-shape, there is produced a 4-ply quarter-shape of the kind represented by FIGURE 4. It will be realized that the number of folds, plies, etc. is not a critical feature and can be varied as desired.

The filament **13** is more clearly seen in FIGURE 2 where the numeral **14** represents a generally cylindrical radiotransparent core **14** of reinforcing material covered or encased by a circumferential layer **15** of thermoplastic resin having uniformly dispersed and embedded therein a radiopaque substance. The makeup of the filament **13** is subject to wide variation according to individual choice or preference. For example, the core **14** may be any of the various materials, filaments, fibers, threads, etc., which can undergo ironing and sterilization without appreciable stretching or compression and without structural deterioration. Cotton, rayon, nylon, Orlon and other commonly used natural or synthetic fibers, or mixtures thereof, will ordinarily be satisfactory. The size can also be varied so long as the core is substantially non-stretchable and non-compressible (under the conditions required to manufacture the finished dressing containing the filament) and so long as the radiopaque material density is sufficient to be easily detected and present a prominent and conspicuous appearance during X-ray photography. Furthermore, the size of the core as compared with the overall size of the filament can be varied over a wide range of conditions. Configurations wherein the core accounts for as little as about 10% of the cross-sectional area to as much as about

75% of the cross-sectional area may be used to accomplish the objectives of our invention. The thermoplastic layer **15** in its original state prior to fusing to the gauze may have an annular cross-section, as shown in FIGURE 3, for ease in handling. This layer **15** may be concentric, as indicated in FIGURE 3, or it may be of a non-uniform nature, with the core **14** either centrally located, as in FIGURES 2 and 3, or otherwise positioned within the confines of the filament thereby producing a filament of any of many geometric cross-sectional configurations commensurate with good handling techniques.

The thermoplastic layer **15** comprises a base material which is solid and substantially non-deformable at room temperature but which softens and flows at ironing temperature so that under influence of ironing heat and pressure it can be made to attach to gauze or other fibrous textile dressing material and to move between the fibers and become anchored there in solid form as an integral fiber-base material unit, upon cooling. Any of a wide variety of resins, polymers or copolymers may be satisfactory for the purpose, as examples of which may be mentioned the polyolefins such as polyethylene and polypropylene, the vinyls such as polyvinyl chloride (PVC) and polyvinylidene chloride, the polyamides such as nylon 6, the cellulosics such as cellulosic acetate and ethyl cellulose, the styrene polymers such as polystyrene, and the acrylics such as ethyl acrylate. Polyvinylchloride is a preferred thermoplastic resin for the purpose. The thermoplastic layer **15** includes a uniform dispersion of fine radiopaque particles. The particles may be any radiopaque substance, preferably but not necessarily inorganic, such as barium sulfate, thorium dioxide and bismuth oxide. The thickness of the layer **15** and the content of radiopaque material are important factors governing the degree of opacity of the filament **13**. Without intending to limit the invention to any specific structure, there may be mentioned as an illustration of a suitably opaque filament a synthetic fiber core **14** having an average diameter of about 0.008–0.010 inch covered by a thermoplastic layer **15** containing 60% by weight of barium sulfate, the layer being of sufficient depth to result in an average outside filament diameter of about 0.026–0.031 inch. A preferred filament for purposes of the invention is a cylindrical filament having a cylindrical orlon or nylon core about .010 inch in average diameter covered by a PVC annular layer about .010 inch thick. The filament **15** of the invention is conveniently produced by drawing the fiber core **14** through orifices in an extrusion head containing the thermoplastic resin in molten condition whereby the core **14** emerges with the layer **15** encasing it. The plastic layer can be made to solidify by air cooling or other suitable cooling means. It is an unexpected feature of the invention that such a filament is not perceptibly different, with respect to opacity, from prior art filaments of the same diameter but lacking the fiber core and therefore containing substantially more radiopaque material. In other words, by eliminating the radiopaque material from the center or core of the filament, not only is there a saving of an expensive material but also there is no loss of radiopaque response.

In the production of the surgical dressings of the invention, the filament **13** is first positioned across the surface of the unfolded gauze sheet, as indicated above. It is then locked or ironed into position there by application of heat and pressure means, preferably by passing between complementary opposed heat shoes or rolls, so that the thermoplastic layer **15** softens and moves between and even surrounds the fibers, assuring pervasive contact with the gauze sheet along the line of the filament. The heat and pressure are finally discontinued whereupon the thermoplastic solidifies upon cooling so that a solid locking engagement is provided between the gauze and the filament. This ironing step, which precedes the folding sequence, is accomplished in a short period, of the order of about one second. Unlike the prior art dressings, the filament is so firmly embedded as an integral unit with the gauze that any attempt to remove the filament by stretching results in tearing or distortion of the gauze fibers with consequent destruction of the dressing and not merely the pulling away of a short section of the filament. Thus, there is no danger that fragments of the filament or the filament itself will unknowingly become dislodged during storage or use of the dressing. On the other hand, and it is a significant advantage of the invention, the core **14** of the filament is sufficiently inert to heat and pressure so that during the ironing step it desirably limits the extent to which the filament becomes embedded and locked in the web of the dressing. In this regard, it is found with prior art solid plastic filament sponges or dressings that excessive locking can cause embrittlement and fragmentation of the filament; thus, fragments and particles are undesirably subject to breaking off, flaking, and falling away from the web. Also, it is found that the ironing pressure if excessive can cause cutting and physical separation of the filament of the prior art type.

The Federal specifications prescribe a test, mentioned above, for measuring the performance of the X-ray opaque materials. In this test, the filament is placed on an unexposed X-ray film and is covered with an aluminum ladder ranging in ⅛ inch thickness increments (steps) upward to at least ¾ inch. The exposure is made in the conventional way at a distance of about 36–40 inches from the film. Using an exposure to X-rays such that the steps of at least ¼ inch, ⅜ inch, ½ inch and ⅝ inch are clearly delineated from each other, the filament must, to pass the test, appear prominent and conspicuous when covered by at least ⅝ inch of aluminum. FIG. 1 illustrating an X-ray positive exposure represents the kind of results seen with this test. Since the degree of contrast in the radiograph is often less pronounced at each end (e.g., at the ⅛, ⅞ and 1 inch steps) of the thickness spectrum, FIG. 1 shows such lack of contrast either as dotted lines or as a void. Thus, the different thickness steps appear first as transparent (⅛) and then range step-by-step from ¼ to 1 as increasingly darker gray bands with the degree of contrast between the filaments and the steps being generally the greatest at the central portion overlying the ⅜, ½ and ⅝ steps. Filament A represents a conventional filament consisting of an opaque-filled ($BaSO_4$) PVC resin; it does not have a fiber core. Filament B is a filament of the same size and has the same filled resin but it includes an Orlon fiber core about .008 inch in diameter. Filament C is the same as Filament B except that it has been ironed on gauze. Filament D is the same as Filament C but it is larger (.008 inch Orlon fiber core surrounded by a .018 inch PVC, $BaSO_4$-filled, layer). Filament D also has been ironed on gauze. As shown, Filament D appears not as a single line but rather as two parallel lines. The reason for the presence of two lines instead of one is that the geometry of the exposure, as is seen from the filament cross-section of FIG. 3, favors two lines occurring in the areas impinged upon by the two arrows II which by comparison with arrow I must traverse a relatively much thicker depth of radiopaque material in the layer **15**; also, the ironing step tends to flatten and deform the layer **15** to cause it to follow the more elliptical profile indicated by the dotted lines **17** thereby further contrasting the relative distances traversed through the radiopaque layer **15** by X-ray (arrows II versus arrow I). The center line of the filament is therefore transparent instead of opaque to X-rays. This novel structural arrangement provides a useful, unexpected advantage as regards the ease of detection of the surgical dressing. In the event a dressing with a filament of this type is accidentally misplaced within the surgical cavity, X-ray exposure will unequivocally establish its presence by means of the characteristic, closely-spaced parallel image, an image which is readily distinguished from the occasional chance image, usually monolinear, of muscle or organ structures.

We claim:

1. A surgical dressing comprising a folded gauze web having a plurality of plies, and an X-ray responsive filament affixed in solid locking engagement across one face of the web by ironing under heat and pressure, the filament comprising an X-ray transparent core material having an average diameter of about 0.008–0.010 inch covered with an X-ray opaque thermoplastic resin extruded onto the core in a continuous uniform layer while hot to provide an average outside filament diameter of at least about 0.026–0.031 inch, the thermoplastic resin being solid and substantially non-deformable at room temperature but softening, flowing and being adhesive at ironing temperature, the core material being substanstantially non-stretchable and non-compressible at room temperature and ironing temperature, the layer being embedded into the gauze web along the line of the filament to a depth not greater than the thickness of the layer to provide locking engagement such that attempted removal of the filament by stretching results in tearing of the fibers of the gauze web and destruction of the dressing.

2. A surgical dressing according to claim 1 wherein the filament is radiographically responsive in the form of a single-line image.

3. A surgical dressing according to claim 1 wherein the filament is radiographically responsive in the form of a parallel double-line image.

4. A surgical dressing according to claim 1 wherein the gauze web is folded along rectilinear fold lines to provide a rectangular sponge structure having multiple plies.

5. A surgical dressing according to claim 4 wherein the filament is radiographically responsive in the form of multiple loops, each loop presenting a single-line image.

6. A surgical dressing according to claim 4 wherein the filament is radiographically responsive in the form of multiple loops, each loop presenting a double-line image.

References Cited

UNITED STATES PATENTS

2,698,270	12/1954	Mesek	128—296 X
3,133,538	5/1964	Pratt et al.	128—296

FOREIGN PATENTS

333,980	8/1930	Great Britain.
839,451	6/1960	Great Britain.

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