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3,396,419

DISPOSABLE SURGICAL SCRUB SPONGE AND DISPENSER

Filed June 2, 1966

3 Sheets-Sheet 1

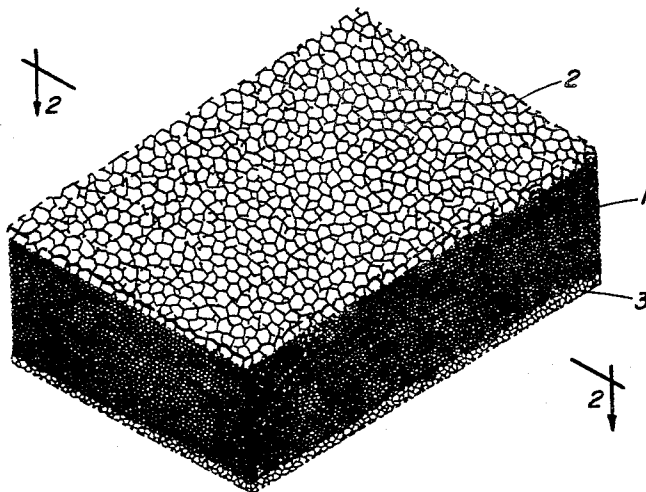


FIG - 1

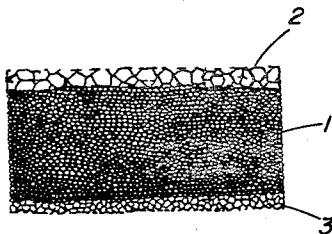


FIG - 2

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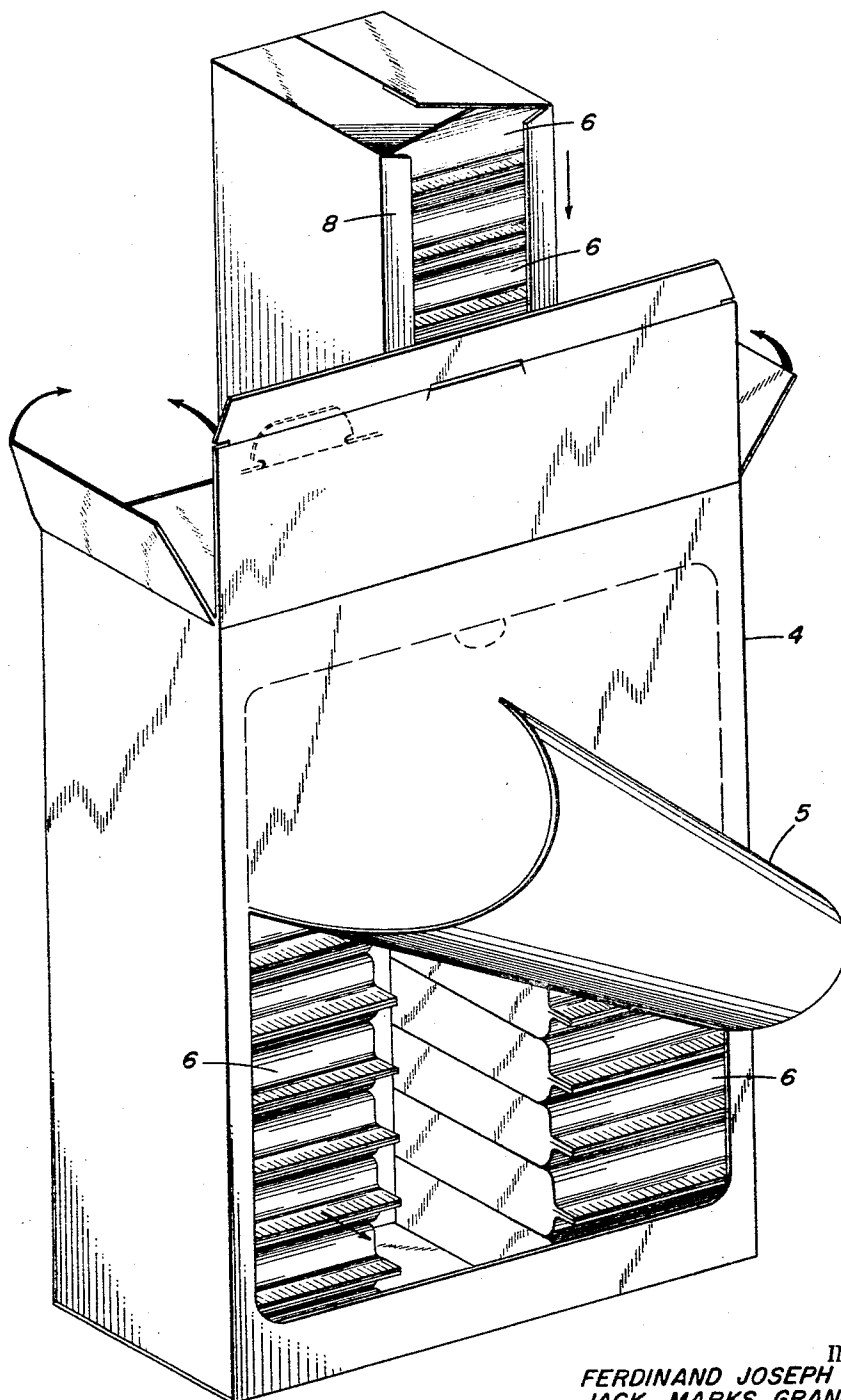
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3 Sheets-Sheet 2



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FIG - 3

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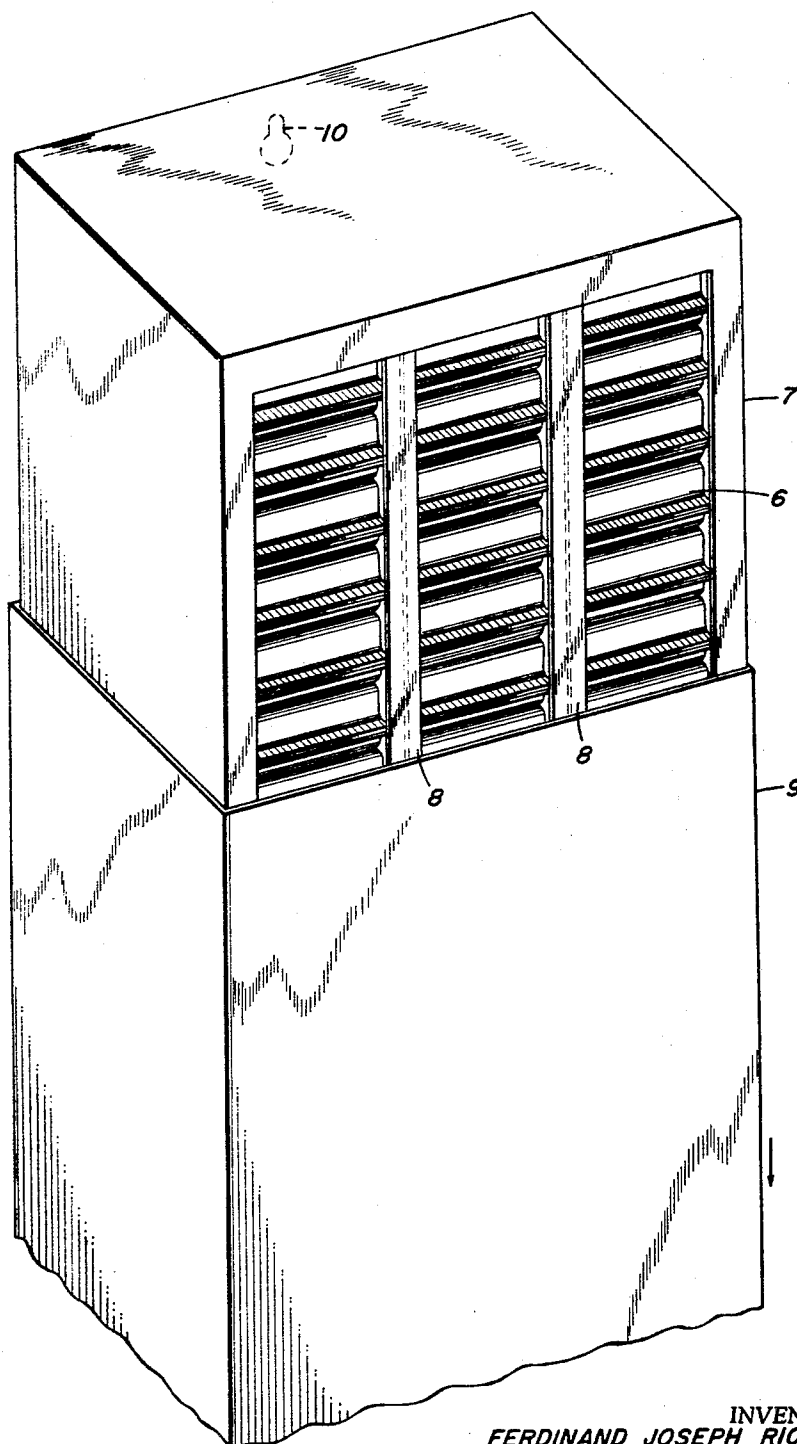
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DISPOSABLE SURGICAL SCRUB SPONGE AND DISPENSER

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3 Sheets-Sheet 3



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FIG - 4

1

2

3,396,419 DISPOSABLE SURGICAL SCRUB SPONGE AND DISPENSER

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6 Claims. (Cl. 15—104.93)

ABSTRACT OF THE DISCLOSURE

A surgical scrub sponge is described which has two or more zones, one fine pored polyurethane foam the pores being interconnecting and impregnated with a liquid detergent composition containing antibacterial agents. Another zone or preferably two zones on either side of the fine pored foam containing the detergent dispersion have coarser pores of polyurethane so that they exert a scrubbing action when a sponge is used for surgical scrubbing. The detergent dispersion is free from abrasive materials and is of low alkalinity and nonirritating to the human skin. The zone or layer having impregnated detergent dispersion contains sufficient detergent for a surgical scrubbing of five minutes or more.

Background of the invention

The problem of eliminating bacteria and other microorganisms from the skin of a surgeon's hand or of a sterile nurse or other person in the operating room requiring similar standards for skin flora is a very serious one. It is standard practice in all hospitals for surgeons, sterile nurses, and the like to scrub their hands and forearms intensively before putting on sterile rubber gloves. Throughout the remainder of this specification reference will be made to surgeons as a typical example of persons requiring the scrubbing without intending it to be limited. A surgeon ordinarily scrubs his hands and forearms, usually in at least two stages, using sterilized scrub brushes and an antibacterial soap, the most common of which is one containing 2,2'-dihydroxy-3,5,6,3',5',6'-hexachloro diphenyl methane. This compound is normally referred to as hexachlorophene and the short common name will be used in the further description of the present invention. Hexachlorophene and related halogenated dihydroxy diphenyl methanes or biphenols have the property of forming a very thin coating on the skin of the surgeon's hands which does not wash off easily with water and detergent. The mechanism by which this resistant film is formed or its exact nature is not known, but it is an advantage because it maintains a low bacterial count on the surgeon's hands and forearms for a considerable time. It is also common to use a soap which contains an iodine complex, and for certain purposes this is desired because there are certain microorganisms which are much more easily attacked by iodine than by hexachlorophene. Other antibacterial agents have been used in soaps and the present invention is not limited to the two typical ones referred to above, although in a more specific aspect scrub sponges having antiseptic or antibacterial soaps containing either of the two compounds referred to above are preferred.

Another problem is the irritation of the surgeon's skin, for the scrubbing is quite vigorous and prolonged, typical scrubbing rituals involving 50 strokes of the brush on the hands and 30 across the nails and other more sensitive parts, followed by rinse and repeated again. If the surgeon's skin is irritated by mechanical irritation or by irritating detergents, this is not only uncomfortable and unpleasant but may result in the surgeon's skin picking up infecting agents more readily than it would have if it

had not been irritated or otherwise damaged. The seriousness of skin irritation from scrub brushes is emphasized in an article in "The Lancet," vol. 269, 1955, p. 791. It is customary to use very gentle soaps and detergents, staying away from high alkalinity and providing sufficient emollients to be gentle on the skin. Not too much can be done for the brushes except to provide bristles with somewhat rounded ends, such as nylon bristles. The protection of the surgeon's skin by using non-irritating, low alkaline soap is just as important in the present invention as in the normal scrubbing of the prior art and, as will be pointed out below, nonirritating soaps should be used in the sponges of the present invention.

No matter how good the soaps or brushes, there are still serious problems of bacterial and other contaminations and the elimination of such contaminations is one of the most important features of the present invention. It should be realized that in scrubbing there are several sources of contamination. Under the pressure of hospital operation scrub brushes sometimes are not completely sterilized before they are reused, although theoretically this is planned. A far more serious source of contamination lies in the fact that soap dispensers cannot be maintained sterile even though the dispensers are cleaned and autoclaved once a day, which is the procedure in the best hospitals.

It might be thought that since the soap contains an antibacterial agent and the surgeon scrubs off a large part of the bacterial contamination on his hands and forearms during scrubbing that this would not be a serious problem. However, it has turned out to be a very serious problem because most antibacterial agents, such as hexachlorophene, are not complete bactericides in the concentrations in which they can be practically used in soaps. This is particularly serious with the resistant strains of many microorganisms which tend to develop in hospitals by reason of the extended use of antibiotics and other antibacterial agents. Such organisms are particularly bad when they get on the surgeon's skin, as they can be the result of serious infections in patients. This problem is well brought out in an article by Dr. Kresky, American Journal of Diseases of Children, vol. 107, April 1964, pp. 363-369. In spite of daily cleaning and sterilization, dispensers for hexachlorophene detergent were found to be contaminated with dangerous, resistant forms of germ-negative bacilli about 60% of the time.

Summary of the invention

The present invention by using disposable sponges completely eliminates cross contamination and contamination from such pieces of equipment as detergent dispensers. At the same time daily cleaning and sterilization of such equipment, including scrub brushes, is eliminated, together with waste of discarded detergent, so that with the preferred cheap multilayer sponges of the present invention the overall cost is not significantly greater and in some cases may actually represent a saving. Of course the elimination of contamination is far more important in surgery than any small saving in cost.

The present invention cannot use just any sponge; for example, ordinary regenerated cellulose sponges are completely unsuitable. They can be impregnated with germicidal soaps all right, but they do not have a texture permitting satisfactory scrubbing, and this is essential because the surgeon does not reduce the flora on his skin merely by the application of materials which, as hexachlorophene does, spread a thin film on the skin. It is also necessary to remove the major portion of microorganisms physically by washing off in a good detergent lather, and this requires considerable mechanical scrubbing regardless of the nature of the detergent used. It is possible to utilize certain special, very expensive, fine textured regenerated

cellulose sponges, and in its broadest aspect such sponges are included in the present invention. However, it is preferred to use laminated sponges of polyester based polyurethane, such as those sold by the Foam Division of the Scott Paper Company under the designation of open-pore polyester polyurethane sponges. Preferably these sponges are made in the form of a multi-layered sandwich with a relatively thick layer of fairly fine pore sponge, for example 60 pores to the inch, which retains the antiseptic soap solution by capillary attraction and acts as a reservoir, maintaining sufficient material for a complete scrubbing ritual with, of course, a sufficient excess to provide a margin of safety. This thicker layer of fine pored polyurethane is softened by heat and one or more thin layers of much coarser polyurethane foam are laminated on one or both sides using suitable pressure, such as squeeze rolls. Preferably both sides of the relatively thicker, fine pored polyurethane are laminated with the coarser layers, one layer being considerably coarser than the other. For example, one layer may have pores averaging 10 to the inch and the other 20. Having two different degrees of pore size is a definite advantage because the coarser material is useful for removing greater amounts of dirt, for example from the palm of the hand when the surgeon has been working outdoors over a weekend, and the finer for parts of the hand which are more sensitive, such as the fingertips or where the hands are less heavily soiled.

It should be noted that the present invention requires very definite characteristics for the sponge, or more properly for the combination of the sponge and the soap. The sponge must be stiff enough, it must be compatible with the soap, and it must be capable of being sterilized, for example by so-called cold sterilization with ethylene oxide gas or electron beam radiation, which is effected at temperatures not exceeding the temperatures which the scrub sponge will stand. Most polyether based polyurethanes are not suitable as they are not sufficiently stiff and in many cases tend to deteriorate on storage when in contact with the detergent. So long as it has the proper physical characteristics and compatibility with the soap and method of sterilization it is not necessary to use only a single or a particular material. Thus, for example, the center portion of a laminate may be of a material which would not be suitable for the scrubbing surfaces as it need not be as stiff since it merely has to serve as a reservoir for the detergent.

It should be noted that the present invention is not directed to the broad idea of a detergent impregnated sponge or even a sponge having more than one layer. In Patent 3,112,219, Nov. 26, 1963, there is described a regenerated cellulose sponge to which a resin bound non-woven fabric layer has been fastened by adhesive, the layer containing abrasive material. The sponge is then impregnated with a melted soap gel in which a polyhydric alcohol is used as the gelling agent for the soap. After impregnation the gel is permitted to set and the sponge can be used for some time as a scouring pad to replace steel wool pads, which have also been impregnated with detergents. The scouring pad, of course, is not useful for purposes of the present invention. It is not a surgical sponge and there is not the combination of a sponge having a layer which is not abrasive but capable of scrubbing action combined with impregnation of a detergent which has antibacterial components and which is soft and gentle on the human skin. It is this combination, which is essential to the performance and proper functioning of the present invention, to which the present invention is limited.

The sponge has at least the following definite limitations: It must have surfaces which are capable of scrubbing without being abrasive; it must be impregnated with a soap which is non-irritating to the skin and which contains antibacterial agents; the soap and the sponge must be compatible with each other and capable of extended storage, and the combination must be capable of com-

plete cold sterilization. If any of these factors is absent, the sponge is not useful for the purposes of the present invention and of course is not included therein.

The present invention is directed to a surgical scrub sponge, and in some more specific aspects to a sponge in a dispensing container and wrapped to maintain its initial sterility. It is of course true that if desired the sponge can be used on surfaces other than the human skin, and it is an advantage of the invention that the sponge can be used occasionally for cleaning surfaces in an operating room. This additional function, while quite apart from its primary use and primary function, constitutes an additional practical advantage.

The sponges of the present invention after impregnation with the detergent are then cold sterilized and placed in containers. It is also desirable, although not always absolutely essential, that the sponge be wrapped so as to protect it from contamination after it is removed from its container. Preferably, however, such a wrap is provided which should be of a nature to prevent the penetration by microorganisms while at the same time to permit passage of cold sterilizing agents, such as ethylene oxide gas, and/or be transparent to radiation when radiation sterilization, such as for example electron beam sterilization, is used. So long as these characteristics are present, the particular composition of the wrapper is not any particular concern of the present invention, except of course that obviously it must not be something that is either itself toxic or which is capable of adverse reaction with the sponge itself. A typical wrap which is illustrative of the requirements is a multi-wall wrap of glassine paper with a thin polyethylene liner.

Brief description of the drawings

FIG. 1 is an isometric view of an unwrapped sponge; FIG. 2 is a section through FIG. 1 along the lines 2—2; FIG. 3 is an isometric view of a dispensing container with wrapped sponges with tear front partly opened, and FIG. 4 is a similar view of a modified dispensing rack for dispensing sponges from the top of piles.

Description of the preferred embodiments

FIGS. 1 and 2 illustrate a preferred laminated sponge of the present invention. The center section 1 is of polyester polyurethane foam of about 60 pores to the inch of the open pore type sold by the Foam Division of the Scott Paper Company. Laminated on two sides of the sponge are two thin layers of polyester based polyurethane sponge 2 and 3, the layer 2 having coarse pores, for example about 10 to the inch and the layer 3 finer pores, about 20 to the inch. The two thin layers are laminated on the center layer by heating the former to the point where it softens and passing the composite layers through squeeze rolls. A sheet is thus formed which is then cut into sponges of suitable size. A typical desirable size is a rectangle 2 x 3 inches and 1.25 inches thick. Laminate 2 is $\frac{3}{16}$ inch and laminated $\frac{3}{16}$ inch thick. Section 1 contains 10 to 15 ml. of a soap solution, which will be described in more detail in conjunction with the examples to follow.

It will be seen from the drawing that the three layers all have interconnecting pores, that is to hollow spaces surrounded by walls, the only difference between the layers being in the pore size. It will be seen that in the fine-pored layer 1 the thickness of the walls surrounding the pores as compared to the cross-section of the open spaces is greater than with the much coarser pores in layers 2 and 3. The layers with interconnecting pores are not to be confused with reticulated structures formed of a large number of filaments.

FIG. 3 shows a dispenser 4 in the form of a box with a tear strip opening 5 on the face shown partly opened from which wrapped sponges 6 can be removed from columns formed by a flanged separating wall 8. As has been stated above, the wrapping is preferably of a glassine paper and polyethylene. Their exact construction is not

shown as the wrappings are applied and heat sealed in the conventional manner, the whole wrapped sponge then being cold sterilized with ethylene oxide, electron beam irradiation or other means which do not injure the sponge or its wrapping.

FIG. 4 shows a somewhat different form of dispenser with an outer sheath 9 around an inner dispenser proper 7 which can be hung on the wall by means of the opening 10. The dispenser is also provided with flanged separating walls 8 forming columns for the wrapped sponges 6. The figure shows the outer sheath 9 only partly removed. In practice of course it is completely removed and the inner dispenser hung on the wall. Sponges are removed from the top of each column. In the case of either dispenser when the surgeon or nurse requires a sponge it is removed and opened and is kept free from contamination other than the microorganisms which are already on the surgeon's hands and which are of course to be scrubbed away by use of the sponge.

It has been emphasized above that the present invention is a combination of a particular kind of sponge with surfaces which are stiff enough for scrubbing but non-abrasive, with a soap which is gentle on the skin, of low alkalinity and provide with an antibacterial constituent. Two specific formulations are shown in the first two examples which are illustrative of the invention although the latter is of course not in any sense limited to the exact formulations therein set forth. Parts are by weight.

EXAMPLE 1

A solution of soap is formed in warm water with the following formulation:

Glycerine	8.00
Lauric acid	7.00
Triethanolamine	5.00
Sodium lauryl sulfate	14.00
Ethylene diamine tetrasodium acetate	2.00
Lanoline alcohols	3.00
Hexachlorophene	3.00
Water (70° C.)	58.00
	100.00

It will be seen that the soap is of low alkalinity and is provided with emollients, such as glycerine, and lanoline alcohols. In order to prevent unwanted deposition of curds by hard water the ethylene diamine tetrasodium acetate is present as a sequestering agent which prevents formation of insoluble calcium and magnesium soaps.

The various soap ingredients perform the following functions. Glycerine is a stabilizing agent which keeps the fatty acid ester amide and the synthetic detergent in a single aqueous phase. The lauric acid and triethanolamine react together to form a fatty acid ester amide which is a neutral non-irritating soap. Sodium lauryl sulfate is a mild synthetic detergent, and the lanoline alcohols act as emollients to replace skin oils that otherwise would be removed during washing. The pH of the formulation is between 7 and 8.

EXAMPLE 2

An iodine formulation is prepared as follows using water at room temperature:

Water	60.0
Citric acid	0.5
Condensation product of ethylene oxide and nonyl phenol	16.0
Glycerine	5.5
Adduct of lanoline alcohols and ethylene oxide	10.0
Ethylene diamine tetrasodium acetate	2.0
Iodine complex of ethylene oxide linear alkyl phenol product (20% avail. I ₂)	6.0
	100.0

The ingredients in the above example have the following functions. The glycerine, lanoline alcohol-ethylene oxide adduct and the synthetic detergent, which is the condensation product of ethylene oxide and nonyl phenol, perform the same functions as the corresponding ingredients in Example 1, which have been described above. The ethylene diamine tetrasodium acetate is a sequestrant and in both formulations sequesters calcium and magnesium salts which may be present in hard water. The iodine complex is of course the antibacterial component in the formulation. The pH of the formulation is approximately 4.0.

Example 2 represents a typical surgical soap containing iodine as the antibacterial component. The iodine has stronger germicidal activity against many pathogens than does hexachlorophene but it is sometimes a little harder on the skin. It may be used wherever the problem of unwanted pathogens is particularly severe.

EXAMPLE 3

A one inch thick sheet of 60 pore per inch polyurethane-polyester foam of the open pore type was laminated first to a 1/8 inch thick sheet of 20 pore material and then to a 3/16 inch thick sheet of 10 pore material by softening the 60 pore foam by heat until it softened, applying the coarser mesh materials over the 60 pore foam and bonding the layers firmly by passing them through squeeze rolls. Sheets of laminated foam were then cut into 2" x 3" blocks by conventional means and 11 ml. of the antibacterial soap formulation shown in Example 1 was placed in a shallow tray and drawn up into each sponge by the suction action created when the sponge was first compressed and then released. The sponges were then placed in a drying oven at 80° C. until the volatile materials were removed.

These nonsterile sponges containing the antibacterial soap were then subjected to an actual scrubbing test using the Blank modification of the Price technique as described in Surgical & Gynecological Obstetrics, vol. 91, 1950, page 577. In addition to the test on the scrub sponge, tests were also conducted with the conventional surgeon's brush using the soap formulation presented in Example 1, and a second brush test in which the popular commercial scrubbing agent, pHisoHex, was used as the antibacterial agent. Both the scrub index and residual activity were determined with all three systems. Twenty-five separate sets of observations were made on each test. Each individual washed hands with nonmedicated bar soap for 2 minutes and then the hands were rinsed in two basins according to the Blank technique. Samples were taken and the bacterial counts determined. The individual next scrubbed his hands with one of the test agents for five minutes and samples were again taken from the rinse basins. Two hours after the five minute scrub the procedure was followed once again. The scrub indices found for the three types of materials are shown in the following table.

TABLE I

	Scrub index
Standard nylon brush with pHisoHex antibacterial soap solution	25
Standard nylon brush with solution of Example 1	23
Polyurethane sponge with 11 ml. of soap solution of Example 1	24

The percentage reduction in counts and the effect of a repeat test two hours after the initial scrub are shown in Table 2.

TABLE 2

	Average Percent Reduction in Colonies	
	Immediate Post Scrub	Two Hours Post Scrub
pHisoHex plus brush	73.5	89.5
Example 1 plus brush	75.0	89.3
Example 1 impregnated in sponge	74.6	89.9

These results show that the impregnated sponge provides the same removal of bacteria as does a scrub with a conventional brush and separate liquid soap.

EXAMPLE 4

The unsterilized impregnated sponge described in Example 3 was placed in a vapor tight pouch made of 30 lb. greaseproof glassine paper laminated to 1 mil thickness of polyethylene film. The polyethylene was on the inside of the pouch and the pouch was then heat sealed by conventional means. Pouches containing sponges were packed loosely in cardboard containers and then exposed to ethylene oxide gas, 100% concentration, at a temperature of 100°-125° F. and a pressure slightly under atmosphere for about 6 hours. Samples of the sterilized sponges were then taken and tested for sterility in the following manner.

Sponges were opened in a sterile room under aseptic conditions and each sponge was placed in 500 ml. of a solution containing 0.7% lecithin and 1.0 Tween 80 in a 2000 ml. Erlenmeyer flask in order to neutralize the hexachlorophene. They were kept in this solution under aseptic conditions overnight. The sponges were then transferred aseptically into thioglycollate medium contained in a 2000 ml. wide mouth Erlenmeyer flask and incubated for two weeks. No growth was obtained in any of the sample flasks indicating that sterility had been obtained. A similar batch of material was sterilized by exposure to electron beam radiation from a 3 million volt Van de Graaff generator at a dose of 5 megarads—2½ on one side and 2½ on the other. Samples of sponges sterilized by this method were tested as described above and found to be sterile.

Sponges sterilized by both methods were then subjected to the Blank modification of the Price scrub index described in Example 3. No significant differences in scrub indices and residual activities were found between the nonsterile product tested in Example 3 and the scrub sponges sterilized by the techniques of this example. This test showed that the sterilization procedure had no effect on the efficacy of the scrub sponge in reducing the bacteria count of the hands. Physical observation of the sponges showed no evidence of change in package seal, laminate bond strength, appearance or odor when compared with the nonsterile product.

EXAMPLE 5

The procedure of Example 4 was repeated, replacing the soap formulation of Example 1 with the detergent formulation of Example 2. When tested for scrub index as described above, the index was found to be 19. This somewhat higher effectiveness in removal of contaminants is, at least in part, due to the somewhat greater antibacterial activity of the iodine activity.

The sponges of Examples 4 and 5 were used by a number of persons without any sign of skin irritation. In general the coarse pore lamination 2 was used for scrubbing the more soiled and tougher portions of the hands and arms and the finer surface 3 for the fingernails and fingertips and in some cases by nurses where their skin was softer and more delicate and the gentler scrubbing of layer 3 was found more acceptable. In all of the tests made by practical users the sponges retained sufficient detergent so that a full scrubbing routine was possible with a small amount of excess detergent remaining in the sponge after scrubbing was completed. Disposal of the sponges presented no problem as they could be disposed of in the same way as any other surgical material which was no longer sterile.

Compatibility of the detergent with the sponge material was shown by a test where the wrapped sterilized sponges

were stored for about a year. No deterioration took place and when used after this storage period excellent lather was produced and the sponges were completely satisfactory for scrubbing purposes.

We claim:

1. A surgical scrub sponge-antibacterial detergent combination comprising in combination:

(a) a multizonal sponge of sufficient stiffness for effective scrubbing, said sponge having one zone having fine pore sizes, the pores being intercommunicating and capable of retaining liquids by capillary attraction as a reservoir storage, the zone being impregnated with sufficient detergent of low alkalinity and nonirritating to the intact human skin, the detergent being in a dispersion which is liquid and flowable and in amounts sufficient for a surgical scrub lasting at least five minutes;

(b) a zone on at least one side of the impregnated zone having larger interconnecting pore size, too large to retain liquid by capillary attraction as a reservoir, the large pore sized zone being of a stiffness suitable for scrubbing but non-abrasive to the intact human skin;

(c) all of the pores in each of the zones consisting of a central open space surrounded by walls; and

(d) a detergent dispersion containing an antibacterial agent and being compatible with the fine pored zone and a non-solvent therefor, whereby the fine pored zone is not degraded during storage and retains the liquid detergent as a reservoir and the zone having large pore size being substantially free from impregnated liquid detergent dispersion during storage but being capable of receiving detergent dispersion from the finer pored zone during scrubbing.

2. A surgical scrub sponge according to claim 1 in which the thermoplastic is polyester based polyurethane foam.

3. A surgical scrub sponge according to claim 2 in which the detergent dispersion contains hexachlorophene.

4. A surgical scrub sponge according to claim 1 in which the detergent dispersion contains hexachlorophene.

5. A surgical scrub sponge according to claim 1 in which the detergent dispersion contains an iodine liberating antibacterial agent.

6. A surgical scrub sponge according to claim 1 in which the sponge is composed of three laminations constituting the zones, a central lamination of fine pore size, one surface lamination of very coarse pore size, and a second surface lamination of finer pore size but still large enough to provide scrubbing properties.

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