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SURGICAL SPONGES

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This invention relates to improved surgical sponges and the preparation thereof.

The location and recovery of surgical sponges (i.e., sterile pads of absorbent material used to absorb body fluids which tend to collect and thus interfere with the performance of successful operative procedures) is a problem which is as old as the operative procedures themselves. The problem is made more difficult by the tendency of the sponges to become camouflaged through absorption of the colored body fluids thereby diminishing the usefulness of the visual faculties in detecting them. Attempts have been made to solve the problem by maintaining a careful count of the sponges that are used and comparing it with the count of the sponges which are discarded. Further attempts at solution have been made by using metal-wired sponges which can be located by X-ray. Neither the tally method, nor the X-ray method has been an ideal solution since in the case of the former human frailty often leads to improper counts, and in the case of the latter, the use of X-rays results in unwanted delays towards the completion of operative procedures while awaiting the developed X-ray pictures, and necessitates the presence in the operating room of the cumbersome and expensive X-ray equipment.

It is the object of this invention to overcome the deficiencies of the art by the provision of surgical sponges having affixed thereto with sufficient permanence to resist leaching by the body fluids, a non-toxic quantity of a radioactive labeling agent sufficient to render the labeled sponge easily detectable by conventional scintillation counters.

In accordance with the method of this invention, the labeled sponges are prepared by contacting pieces of absorbent material of suitable size to be useful as surgical sponges, with a radioactive labeling agent, and subjecting them to conditions of heat and pressure for a time sufficient to assure sterilization.

Unexpectedly it has been found that the single step of autoclaving the impregnated sponge until it is sterilized yields, not only a sponge which is surgically sterile, but one which contains a labeling agent affixed with such permanence that it remains affixed to the sponge even in the presence of body fluids in which the labeling agents per se are soluble. The sterilized labeled sponge thus prepared can be used in the manner prescribed for ordinary unlabeled surgical sponges.

The absorbent material suitable for use herein can be any substance which is normally used as a surgical sponge. Cotton gauge pads, being readily available and highly economical, are preferred.

The labeling agents suitable for the practice of this invention must contain, preferably in chemically combined form, a metallic or non-metallic radioactive isotope which is non-toxic in quantities which are sufficiently radioactive to perceptibly register on conventional crystal scintillation counting equipment. Thus, in the proper amount, it must be able to register a count which is at least two, and optimally at least five times the count being continually registered by the ambient radiation normally existing in the atmospheric background. Preferred isotopes are those which have a half life greater than one week and less than two months and emit primarily gamma radiation.

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The isotopes may form, or be a part of, either the anion or the cation of the compound which constitutes the labeling agent. The isotope may be chemically combined as a simple ion resulting from the loss or gain of electrons, or in the form of a complex ion such as the chromate ion. Among the preferred radioactive isotopes may be mentioned inter alia: radioactive halogens such as I^{131} ; radioactive alkaline earth metals such as Ba^{140} and Ca^{47} ; radioactive alkali metals such as Rb^{86} ; and radioactive heavy metals such as those of the iron period (e.g. Cr^{51} , Mn^{52} , Zn^{65} and Fe^{59}); and those of the silver period (e.g. Ag^{105} , Ag^{108} and Cd^{115}).

The labeling agent is most conveniently applied to the surgical sponge in the form of a dilute solution of the radioactive chemical compound in a liquid medium. The liquid medium may be chosen from a wide range of organic solvents and inorganic solvent which will dissolve the radioactive compound to be used as the labeling agent. Since water is the most readily available and useful solvent it is preferred as the liquid medium for water soluble labeling agents. To prepare the solution it is only necessary to dissolve the radioactive material in the water. This may in most cases be accomplished at room temperatures, but may be hastened in others by the application of heat. Among the labeling agents which may be formed with the foregoing radioactive isotopes there may be named *sodium chromate (* indicates the radioactive moiety), *calcium iodide, *barium carbonate, zinc *chloride, ferrous *sulfate, ferric *chloride, cadmium *sulfate and silver *nitrate. The proper concentration of the radioactive material in the solution will depend on the amount of solution to be used in treating each sponge. Sufficient solution should be used for each sponge to assure that the sponge will be sufficiently radioactive to register a count of at least twice, and optimally between five and ten times the background count on a crystal scintillation counter.

In order to prepare the labeled surgical sponges of this invention a conventional sponge is treated with a quantity of a solution of the radioactive labeling agent, as defined above. The labeling agent is then affixed to the sponge by subjecting it to heat and/or pressure (e.g. autoclaving) for a time sufficient to at least sterilize the sponge. Conventional hospital autoclaving equipment is suitable for the performance of this step. Suitable results are obtained by heating the sponge at 250° F. and 15 p.s.i. for a period of 15 minutes. Temperature, pressure and length of heating step may be varied so long as the selected conditions will yield properly sterilized sponges.

The sponges thus produced are used as the conventional unlabeled sponges. They should be used within a short period following preparation in order to insure that decay of the labeling agent does not proceed to the point at which the labeled sponges are not sufficiently radioactive to energize the conventional crystal scintillation counting equipment which is to be used to locate the sponge.

After use, the sponges may be discarded through the usual radioactive waste disposal facilities.

The following example is presented to more fully illustrate the invention.

EXAMPLE

A. Preparation of Sodium Chromate Solution

A glass vessel containing dilute solution of chromic chloride (10 ml.) having a specific activity of 10 millicuries/mg. is immersed in an ice-salt water bath and chilled to below 4° C. 2 N. sodium hydroxide is added to the chilled solution dropwise, with stirring until a light blue opalescent precipitate appears. The dropwise

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addition is continued until the precipitate dissolves. Hydrogen peroxide (30%) is added dropwise until the light blue-green color changes to yellow and the solution is removed from the water bath and boiled to remove the excess hydrogen peroxide. The sodium chromate solution is filtered to remove any suspended material. The filtrate is adjusted to pH 7.4 by the addition of dilute hydrochloric acid and then diluted with water until a solution having a specific activity of 12 microcuries/ml. is obtained.

B. Preparation of Labeled Surgical Sponges

A conventional cotton gauze surgical sponge measuring 2" x 2" is treated with 0.1 ml. of the solution prepared in step A. The treated sponge is wrapped in absorbent paper and placed in an autoclave which is adjusted to maintain a pressure of 15 p.s.i. at a temperature of 250° F. The sponge is removed from the autoclave and tested for specific activity. It shows a radioactivity of 1.2 microcuries.

In order to show the usefulness of the sponges of this invention a sponge prepared as in step B was implanted in a large dog. The sponge exhibited sufficient radioactivity to be easily detectable by a conventional crystal scintillation counter. The urine of the dog tested negative 24 hours for radioactive material, and gross scintillation scanning of the animal indicated no translocation of radioactivity throughout the animal. The tests show that the radioactive moiety had been permanently fixed to the sponge by autoclaving.

Following the exemplified procedure, surgical sponges

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bearing other radioactive labeling agents affixed thereto are prepared, which upon implantation can be readily located by crystal scintillation counting equipment.

The invention may be otherwise embodied within the scope of the appended claims.

What is claimed is:

1. A process of preparing a surgical sponge having a radioactive labeling agent permanently affixed thereto and impregnated thereon, which comprises treating an absorbent material with a solution of a radioactive labeling agent until a non-toxic quantity of said agent is absorbed and then heating the absorbent material for a time and under conditions sufficient to permanently affix the radioactive labeling agent to the absorbent material and to assure sterilization.

2. A process of affixing a radioactive labeling agent to a surgical sponge, which comprises treating a surgical cotton sponge with a solution of a radioactive labeling agent until a non-toxic quantity of said agent is absorbed on said sponge and then autoclaving the sponge for a time sufficient to permanently affix the radioactive labeling agent to the sponge and to assure sterilization of the sponge.

3. The process of claim 2 in which the labeling agent is sodium radioactive chromate.

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