United States Patent [19]

Chapman

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[54] **STERILIZING PROCEDURES**

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[52] **U.S. Cl.** ..... **22/253 TP**

[51] **Int. Cl.** **G01n 31/22**

[58] **Field of Search** ..... 23/253 TP; 252/408; 73/356; 116/114 AM, 114 V

[56] **References Cited**

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[57] **ABSTRACT**

Indicator means for showing that a surgical material or appliance has been sterilized by steam and formaldehyde vapour, the indicator means comprising a carrier for a sulphite to react with the formaldehyde to produce an alkali, and an indicator for the alkali having a change point on the alkaline side of neutrality.

8 Claims, No Drawings

STERILIZING PROCEDURES

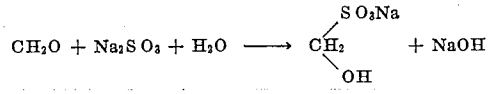
This invention relates to sterilising procedures, more particularly of surgical materials and appliances, the sterilisation of which is usually carried out by the use of steam under pressure, which destroys bacteria and their spores within periods of time dependent on the temperature (and hence pressure) of the steam.

There are, however, some surgical materials and appliances which are sensitive to steam at temperatures of, say, 120°–140°C and for which, therefore, alternative methods of sterilisation have to be employed. One such method is the employment of steam at less than atmospheric pressure (say equivalent to a temperature of 80°C) in association with formaldehyde vapour, which destroys the spores that are unaffected by the low temperature steam, which is only effective against vegetative bacteria.

It is, however, essential to be sure that the formaldehyde vapour reaches all parts of the material or appliance to be sterilised, and the object of the invention is, therefore, to provide some convenient test which can be introduced into the material or appliance to show that the desired penetration has been achieved.

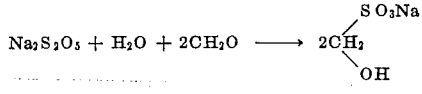
According to the present invention, indicator means for showing that a surgical material or appliance has been sterilised by steam and formaldehyde vapour comprises a carrier for a sulphite to react with the formaldehyde to produce an alkali and an indicator for the alkali having a change point on the alkaline side of neutrality.

A suitable sulphite is sodium sulphite, the reaction being as follows:

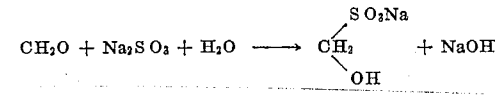


A suitable indicator is phenolphthalein.

The carrier may be a piece of paper or fabric of a porous nature, or other porous material of suitable form, e.g., a cord, on which the sulphite and the indicator are deposited, and the indicator means may be used as it stands by being located in the material or appliance at a position such that when the indicator changes colour all parts of the material or appliance must have been penetrated by the steam and formaldehyde vapour, or it may be enclosed in a cover having a permeability and thickness such as to delay contact by the steam and formaldehyde vapour, until such time as the material or appliance to be sterilised has had an ample treatment with the vapour, regardless of the position of the indicator means. Another method of delaying the colour change is to add to the sulphite a proportion, depending on the delay required, of a bisulphite, such as sodium or potassuim metabisulphite, the reaction being initially, e.g., as follows:



i.e., no alkali being produced until all the bisulphite has been reacted, the ensuing reaction—to produce alkali for changing the colour of the indicator — then being, e.g., as follows:



as before.

EXAMPLE

A piece of white filter paper is soaked in a 1 percent solution of phenolphthalein in ethyl or iso-propyl alcohol and dried. The paper is then immersed in a 25 percent aqueous solution of sodium sulphite until thoroughly wetted, and dried on a warm hot-plate. The paper may turn pink in the solution, but exposure to the air while drying provides enough CO_2 from the air to cause the paper to return to white.

The paper is now sensitive to formaldehyde vapour (in the presence of steam) which turns it red, the shade depending on the extent of exposure to formaldehyde and being comparable with an appropriate colour chart. It is used either as it stands, by placing it in the most inaccessible part of the material or appliance to be sterilised, or it is sealed in a polyethylene cover which is permeable to formaldehyde vapour, but requires a higher concentration of that vapour or a longer exposure to reach and produce an equal change in the colour of the paper, the covered paper preferably being placed in the most inaccessible part of the material or appliance.

Before use by a surgeon the material or appliance is subjected to a steam and formaldehyde vapour mixture, and when the paper has reached an appropirate shade of red the surgeons knows that it is safe for use.

The invention also embraces surgical materials and appliances fitted with indicator means as described above.

Indicator means in accordance with the invention can also be applied to the detection of formaldehyde in other circumstances than sterilisation.

What I claim is:

1. Steam and formaldehyde vapour sterilization indicator means comprising a carrier, a sulfphite deposited on the carrier which is capable of reacting with formaldehyde to form an alkali which can be detected by an indicator, and an indicator deposited on said carrier which will indicate the presence of the alkali by a change point on the alkaline side of neutrality.

2. Indicator means as in claim **1,** wherein the carrier having the sulphite and indicator deposited thereon is enclosed in a cover having sufficient permeability and thickness to delay contact by the steam and formaldehyde vapour with the carrier.

3. Indicator means as in claim **2,** wherein the cover is formed of polyethylene.

4. Indicator means as in claim **1,** wherein a sufficient proportion of a bisulphite is added to the sulphite to delay the color change.

5. Indicator means as in claim **4,** wherein the bisulphite is sodium or potassium metabisulphite.

6. Indicator means as in claim **1,** wherein the sulphite is sodium sulphite.

7. Indicator means as in claim **6,** wherein the indicator is phenolphthalein.

8. Indicator means as in claim **7,** wherein the carrier is a piece of paper or fabric of a porous nature.

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