PUBLISHED
MAY 11, 1943.
BY A. P. C.

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Filed Nov. 14, 1939

Serial No. 304,428
2 Sheets-Sheet 1

Fig. 1

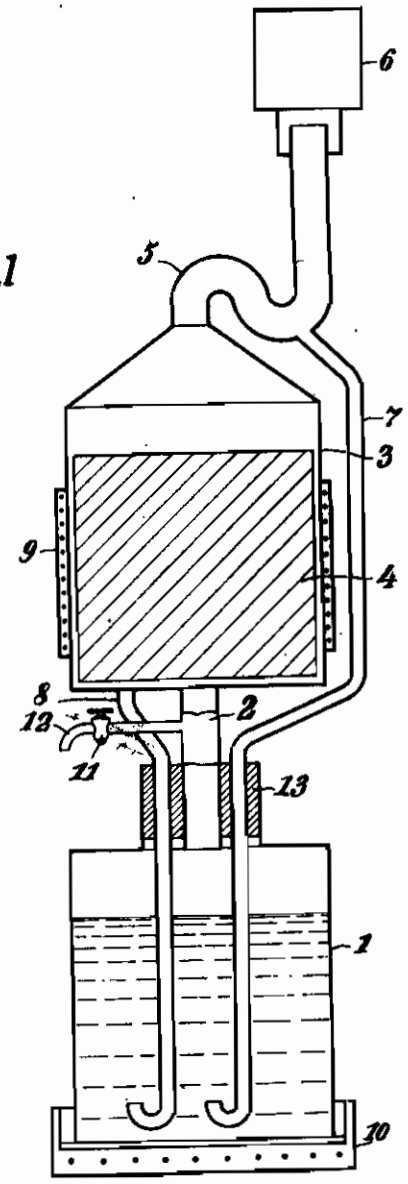

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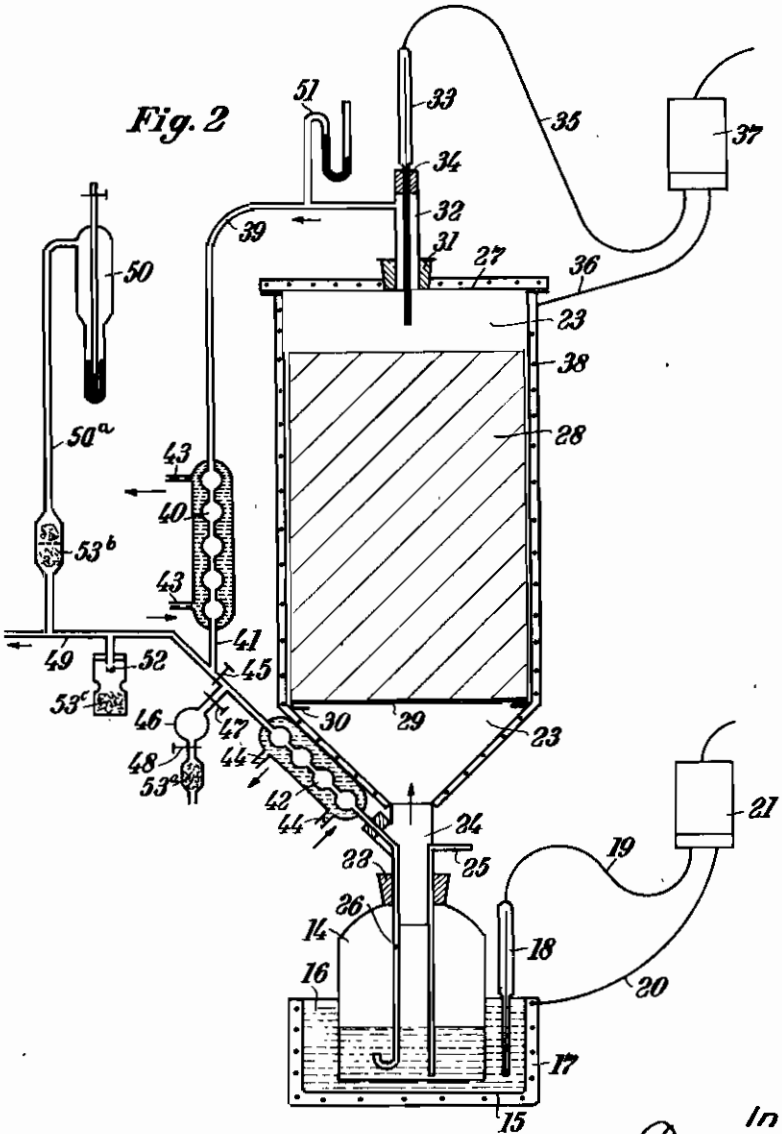
Fig. 2



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Published May 11, 1943 Serial No. 304,428

ALIEN PROPERTY CUSTODIAN

METHOD OF, AND APPARATUS FOR, STERILISING ORGANIC OR SYNTHETIC MATERIALS, ESPECIALLY CHIRURGICAL SEWING THREADS

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Application filed November 14, 1939

Organic or synthetic substances and materials which cannot be sterilised by water or steam from water, especially chirurgical sewing threads, have been sterilised up to now in the majority of cases in a chemical way, in that the respective substances or materials have been subjected to the action of aequeous or alcoholic solutions of chemical bodies said to exert a bactericidal effect. The action of these chemical bodies is due to the fact that they form together with the albuminous bodies, of which the bacteria and the spores consist, compounds which entail dying away of the bacteria and the spores. These chemical methods cannot, however, be employed selectively solely with the bacteria and the spores but they exert an action also upon the chemically very kindred albuminous bodies of the substance or material to be sterilised. When treating the respective substances or materials in a manner suitable to the object in view it is possible to sterilise them, say, for instance, the starting material of catgut, i. e., the submucosa of the mutton gut, in an aqueous solution of iodide of potassium without a far-going chemical change of the albuminous bodies of the tissue.

In the further working-up of the catgut threads made of that sterile material and transforming them into the usual commercial packages it is, however, extraordinarily difficult to protect them from a re-infection and to kill by an after-sterilisation in an alcoholic solution the air bacteria, especially the spores thereof, which have found aceess to them by the indispensably necessary manipulations. Treating the threads with an aqueous solution is out of the question, as the catgut threads swell in such a solution already after a short time of storing and lose thereby their shape.

It would be possible to attain sterility by a suitably high concentration of the chemical agents and a suitably long period of action of the same, but that would entail also such a chemical change of the albuminous bodies of the catgut that the tensile strength thereof would be reduced very considerably, in such a degree, that the threads would become practically useless.

In order to remove this uncertainty as to the sterility it has been endeavored to effect the sterilisation in a physical manner by rendering the catgut sterile by means of heat. As, however, at that temperature at which absolute sterility is warranted again the tensile strength of the catgut is impaired in consequence of its chemical consistency, it has again been endeavored to heat it in high-boiling anhydrous liquids, such as toluol, xylol, cumol, and the like, but also these methods entail likewise a reduction of the tensile strength of the catgut and can be carried out only if the catgut has been deprived of its entire content of moisture prior to that treatment.

Thus, sterility and tensile strength have up to now been two conditions contradicting one another. Another way to sterilise catgut has been the use of gases exerting a detrimental effect upon the breathing ferments of the bacteria and of the spores and killing them thereby without, in fact, reducing the tensile strength of the catgut threads. As it is, however, on the one hand, possible that spores are present also in the interior of the dried threads and cannot, therefore, be killed by the respective gases, and as, on the other hand, some of the gases suitable for the purpose in view are highly poisonous, also this method of sterilising has been abandoned.

It has, furthermore, been suggested to sterilise the catgut in vapors produced from a mixture of alcohol and phenol in the proportion of 10:0.5, but as the boiling point of phenol lies at 182° C and, therefore, the heat requisite to evaporate it is such at which the tensile strength of the catgut is again reduced and, besides, also the sterilising effect of such a mixture is not strong enough to kill the several sorts of bacteriae, especially the spores thereof, present in the raw gut, also this procedure could not be successful. Besides, the apparatus designed for carrying out that procedure has been proved as unsuited, in that a part of the condensed vapor could drop down upon the catgut whereby certain portions in the same were rendered fragile by reason of the non-uniform action of the vapor as such and of the drops formed by the condensed vapor.

Counter to all known methods of sterilising chirurgical sewing threads the present improved method is chiefly characterised by the feature that the substance or material to be sterilised is subjected to the action of a continuous current of vapor formed by volatile organic compounds, especially halogenised, nitrated or/and sulphurised ones. These organic compounds, as, for instance, methyl-iodide or ethyl-iodide, have in vaporised state such a high bactericidal effect that sterilisation can be effected not only in their pure atmosphere, but also in a mixture thereof with, or solution in, other organic solvents in a certain distinct concentration, for instance 96%-ethyl alcohol.

In a suitably designed apparatus the vaporised sterilising agent can be condensed by return-cooling and be thereafter again vaporised so that

it flows in a circuit, its efficiency is increased and the operating costs are reduced.

For determining the effect of the sterilisation carried out in the just mentioned manner, silk threads have been infected with a mud of highly resistent garden soil whereafter they were subjected to the action of the sterilising agent. In a bacteriologic examination 14 days after the incubation in an aerobic and an anareobic broth no growth could be ascertained.

The height of the temperature used while carrying out the process with a normal content of moisture in the catgut threads should, according to experience, not exceed 70° C. in order to prevent a reduction of the tensile strength of the threads. If the catgut threads are more strongly drained prior to the sterilisation, higher degrees of temperature (up to 150° C.) can be employed, but in this case the completely brittle threads must be immersed in a 90% alcohol so as to give them again the normal content of moisture. To generate the vapor, preferably volatile organic compounds are used, the boiling point of which remains within admissible limits, but it is, anyhow, possible to make use also of compounds having a higher boiling point, provided, the pressure within the apparatus is reduced, as is, therefore, also the boiling point of the respective organic compound, so that also in this case the higher temperature cannot exert any detrimental action upon the tensile strength and the elasticity of the catgut. Owing to this uniform manner of treating the material at a moderate temperature the threads become softer and more supple than has been attainable with the sterilising methods known up to now. According to the present improved method not only raw catgut or preliminarily sterilised catgut can be securely sterilised, but also heat-proof materials, such, for instance, as silk, thread or twine and synthetic sewing materials. Furthermore, laminaria pins and animal bladders per se and in finished packs enveloped with paper or enclosed in glass tubes can be securely sterilised and finished, the invention presenting, therefore, obviously a highly improved method warranting sterile packing of the sterilised materials.

Two constructional forms of apparatuses for carrying out this improved method are illustrated diagrammatically and by way of example on the accompanying drawings, on which Figure 1 is a vertical section through the one of said apparatuses and Figure 2 is likewise a vertical section through the other thereof.

Referring to Fig. 1, 1 denotes a vessel consisting of glass and containing the evaporable liquid sterilising mixture. Above the vessel 1 is a receptacle 3 likewise consisting of glass and containing the substance or material 4 to be sterilised.

The vessel 1 and the receptacle 3 are connected with one another by a tube 2. On the top of the receptacle 3 is an S-shaped tube 5, the upper end of which terminates in a return-flow cooler 6. From the lowest portion of the tube 5 extends downwardly a pipe 7, by which the liquid collecting in the cooler 6 is conducted back into the vessel 1. Another return-flow pipe 8 extends downwardly from the bottom of the receptacle 3 likewise into the vessel 1.

The receptacle 3 is surrounded with an electric heating jacket 9 for heating said receptacle and its contents, and also the vessel 1 and the contents thereof can be heated by an electric heating plate 10. We wish it, however, to be understood that also any other heating means, for instance a gas-heated water-bath, can be used instead of said plate 10.

The vessel 1 is closed by a stopper 13 through which pass the tube 2 and the pipes 7 and 8. From the tube 2 extends laterally a pipe 12 provided with a cock 11. The lower ends of the pipes 7 and 8 are bent upwardly so as to prevent the vapor produced in the vessel 1 from passing into said pipes. The tube 2 is assumed to consist of a piece of rubber-hose drawn at its ends upon short branches (not shown) provided at the vessel 1 and the receptacle 3. This piece of rubber-hose may be interiorly stiffened by a piece of glass tube (not shown). Anyhow, also the tube 2 may consist of glass and a shut-off cock (not shown) may be inserted thereinto below the place where the pipe 12 is branched off. Also the pipes 7 and 8 may be provided with such cocks (not shown).

The practical employment of the apparatus is about as follows: About 200 ccm of ethyl-iodide are introduced into the vessel 1 together with about 5 liters of 96%-ethyl-alcohol or another, easily boiling, liquid substance and the mixture is then heated until it evaporates. The vapor escapes through the tube 2 into the receptacle 3 and penetrates therein the material 4 to be sterilised. Then the vapor passes through the tube 5 into the cooler 6 from which the condensed steam flows back into the vessel 1 through the tube 7. Condensed vapor forming in the receptacle 3, for instance, at the commencement of the sterilising procedure passes likewise into the vessel 1 through the pipe 8.

When the material 4 has been subjected to the action of the vapor for a sufficiently long time, the tube 2 is closed. If this tube consists of rubber, closing the passage can be effected simply by a clamp or the like. Now the cooler 6 is removed and instead of it an air-filtering device (not shown) is connected up to the tube 5. Now the cock 11 is opened and a vacuum pump or the like is connected up to the pipe whereby the receptacle 3 will be evacuated. At the same time sterile air flows through the above-mentioned filtering device into said receptacle and penetrates into and through the material 4. This procedure is repeated until the material 4 has been completely freed from the smell of the sterilising agent, whereafter the packs can be closed and made ready for despatch.

Referring now to Fig. 2, 14 denotes the vessel containing the sterilising agent and 15 is a vat containing glycerine and being heated by an electric heating shell 17 whereby also the sterilising agent will be heated. The temperature of the glycerine bath can be read at a thermometer 18 inserted into a circuit comprising, besides said thermometer, also the thermic regulator 21 and wires 19 and 20, as shown. The regulation is such that the sterilising liquid is continually kept at boiling temperature.

The vessel 14 is closed air-tight by a stopper 23 through which passes a tube 24, as well as a pipe 25 provided with means for shutting it and serving for introducing the sterilising agent into the vessel 14 and withdrawing it therefrom, and a pipe 26 which is more fully dealt with hereinafter.

The vapor generated in the vessel 14 rises through the tube 24 into the receptacle 23 which is closed by a removable cover 27 and contains the material 28 to be sterilised. This material is supported by a grate 29 supported in turn by a ring 30 preventing the vapor from streaming

along the inner wall of the receptacle **23** so that it is compelled to pass through the material **28** over the entire sectional area of the same.

Into the cover **27** is inserted an outlet tube **32** and held fast therein by a stopper **31**; into said tube extends a thermometer **33** which is retained in place by means of a stopper **34**. The thermometer is inserted into a circuit comprising a thermic regulator **37** and wires **35** and **38**, of which the wire **35** is connected with said thermometer and the wire **36** with a heating wire **38** embedded in the wall of the receptacle **23**. The regulation is effected in this way so that the temperature of the vapor streaming through the receptacle **23** is maintained at such a height that condensation of the vapor within the receptacle is prevented.

The outlet tube **32** is connected with a vapor return pipe **39** to which is connected up a cooling device **40**, a short pipe **41**, another cooling device **42** and a pipe **26** which extends down into the vessel **14** and leads the condensed vapor back into said receptacle. The cooling devices are preferably formed by bulged portions **40** and **42** of the pipes passing through them and by casings enclosing said bulged portions and being connected up to water pipes **43** and **44**. Between the two cooling devices is inserted a cock **45**, and between this cock and the cooling device **42** there is established, by a short pipe, a communication between the pipe **41** and a small vessel **46** to which a small filtering device **53**^{a} is attached. The two branches extending from this device are provided with cocks **47** and **48**. The cock **45** is open while the sterilisation procedure is going on and the cock **47** is closed during this time. The vessel **46** serves for making tests as to the chemical composition of the condensed vapor which finds access into said vessel when both the cocks **47** and **48** are open, the condensed vapor being then drawn off through the device **53**^{a} in filtered state. It is not necessary to interrupt the sterilisation procedure during this time.

The pipe **41** is also connected with a pipe **49** establishing a communication between the pipe **41** and some means, especially a vacuum pump, for producing an air-pressure below atmospheric pressure so as to render possible the employment of a liquid organic compound, the boiling point of which is higher than admissible for the material to be sterilised, and to reduce, thus, the temperature of the vapor to a degree not detrimental to that material. The measure of the reduction can be adjusted by a pressure regulator **50** connected up to the pipe **48** by a pipe **50**^{a} into which a filtering device **53**^{b} is inserted. The height of the reduced pressure can be read at a pressure gauge **51** connected up to the pipe **39**. Besides the regulation made possible by the pressure regulator **50**, a fine regulation is made possible by a lipped valve **52** located in a filtering device **53**^{c}. The three filtering devices are able to free the eventually entering air from bacteria carried along with it.

When the sterilising procedure has been finished the sterilised material is dried and freed from the adhering smell of the sterilising agent. For this purpose first this agent is sucked off from the vessel **14** through the pipe **25** whereby any further generation of vapor is prevented and now the filtering device **53**^{a} is attached to the small test vessel **46**, the cock **45** is closed and the cocks **47** and **48** are opened. Now the air under reduced pressure will pass from the pipe **25** through the vessel **14**, the sterilised material **28**, the tube **32**, the pipe **39**, the cooling device **40**, and the pipe **49** which is connected up to a vacuum pump or the like, as already mentioned. This last phase of the procedure is continued until the material **28** has been perfectly dried and freed from the smell of the sterilising agent. Finally, the cover **27** is removed whereafter the completely finished material **28** can be withdrawn from the receptacle **23**.

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