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MICROWAVE REACTOR AND PROCESS FOR ASEPSIS

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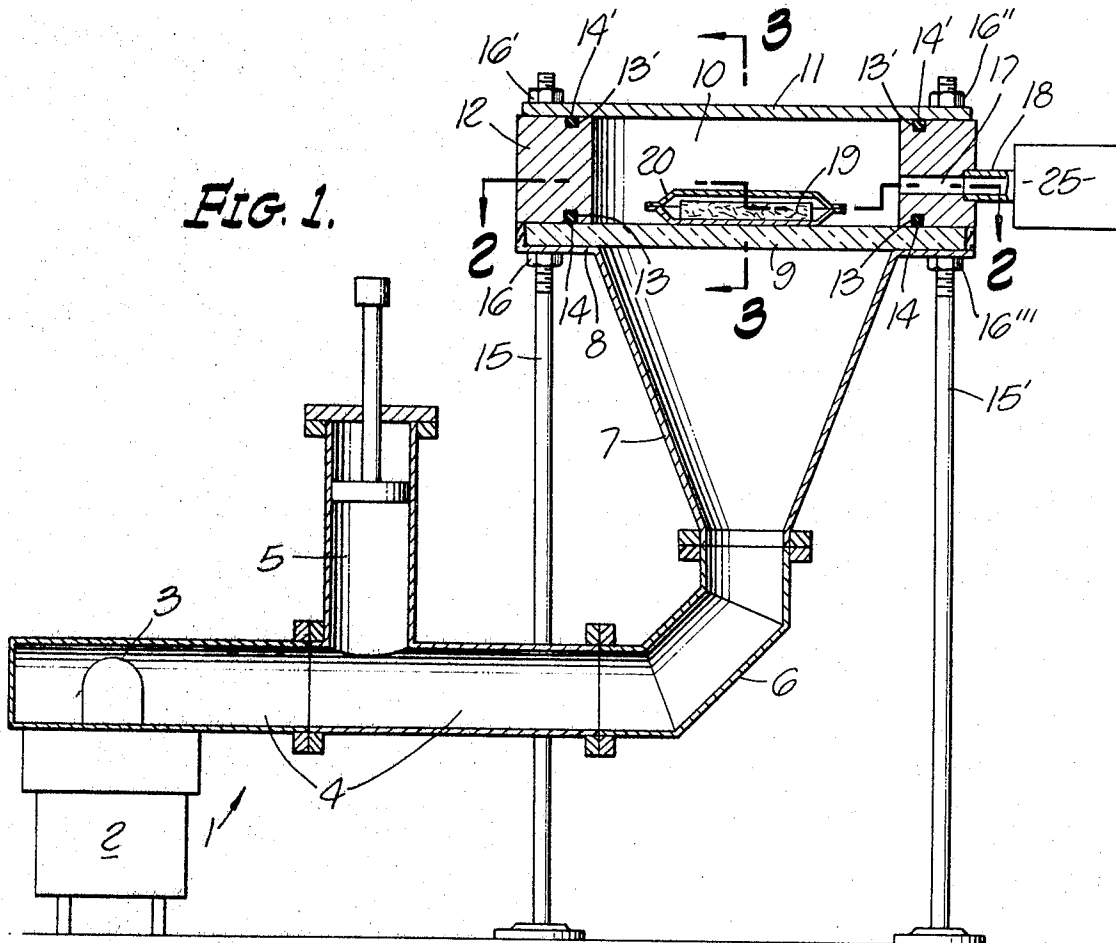


FIG. 1.

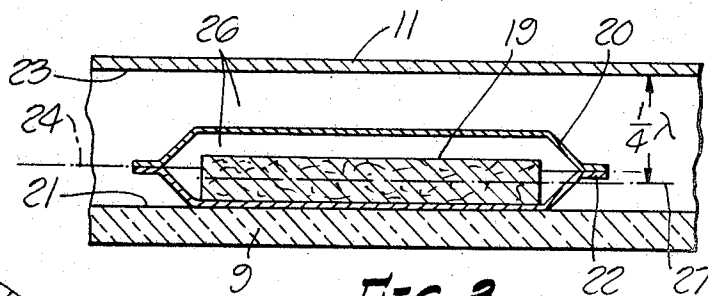


FIG. 3.

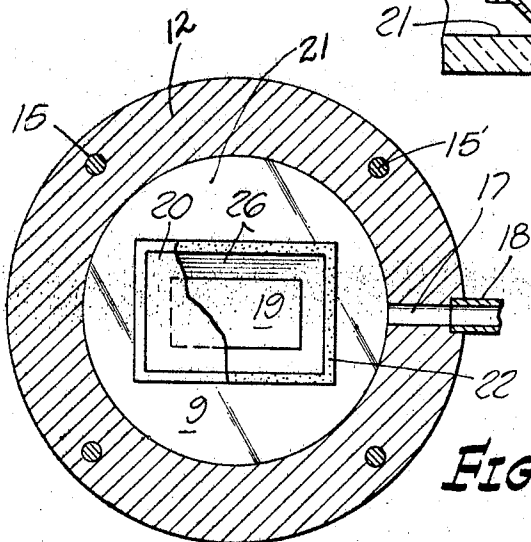


FIG. 2.

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1

2

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**MICROWAVE REACTOR AND PROCESS  
FOR ASEPSIS**

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5 Claims

**ABSTRACT OF THE DISCLOSURE**

A process and apparatus providing sterilization of medical dressing products, such as bandages, gauzes, sponges, sutures and the like, using microwave energy to generate a low pressure gaseous glow discharge in and around the medical dressing products, providing aseptic products. The products may be pre-packaged in microporous containers, prior to sterilization.

**BACKGROUND OF THE INVENTION**

There has been a continuing commercial requirement for aseptic medical products which are pre-packaged and sealed in disposable packages prior to sterilization. The package container means and the sterilizing process must be cooperatively adapted to both contain and not deteriorate the medical product, and also to provide aseptic product protection in storage after the sterilization process. The steam sterilization process is well known in the prior art; however, the standard minimum sterilization temperature of 121° C. associated with the process is destructive to many packaging or container materials which can be used for the medical products. The steam sterilization process is also notably time consuming and slow.

Cold sterilization of the medical products can also be accomplished using ethylene oxide gas as the sterilant gas. Again this is a comparatively slow process, requiring removal of air from the vessel containing the product packages and the introduction of the ethylene oxide gas at atmospheric pressure. Typically, the asepsis process requires 3 hours at 85° F. ambient temperature and 48 minutes at 140° F. ambient temperature in a relatively humid atmosphere.

Both of the above described common processes require extensive time periods to produce an effectively aseptic product. The invention taught in this application produces an aseptic product in a few seconds, representing a marked advance over the prior art. The combustible hazard of ethylene oxide and the high pressure hazard of a steam autoclave are also eliminated.

**SUMMARY OF THE INVENTION**

This improvement in apparatus and process for preparing unpackaged or pre-packaged aseptic medical products, or the like, utilizes microwave energy to generate a low gas pressure glow discharge in the low pressure gas, air or the like, inside a cavity containing the unpackaged or pre-packaged product. The microwave energy is generated at 2450 mHz. or other suitable frequency, channeled through a required waveguide at atmospheric pressure, thence through a window transparent to the high frequency energy into an evacuated chamber holding the medical dressing, packaged or unpackaged. If a commercial storage container surrounds the medical dressing, the storage container has a major area of microporous thin paper sheet, allowing rapid exchange of gas molecules through the paper, but not the exchange of living organisms, such as bacteria, yeasts, molds, spores, viruses or the like.

Included in the objects of this invention are:

First, to provide an apparatus for producing an aseptic medical dressing product, utilizing microwave frequency energy as a source to generate a low gas pressure glow discharge in and around the product.

Second, to provide an apparatus for generating a low pressure gaseous glow discharge in sealed containers, which are only porous to air, and the like molecular weight gases, utilizing microwave frequency energy to generate the glow discharge inside the sealed container.

Third, to provide a process for producing an aseptic medical dressing product, utilizing microwave frequency energy to generate a low gas pressure glow discharge capable of sterilizing the dressing product.

Fourth, to provide a process for generating a low pressure gaseous discharge inside a sealed container having a package wall porous to air and the like molecular weight gases, said process generating said gaseous discharge in a vacuum chamber, wherein the glow discharge is generated by conversion of impinging microwave energy inside the container.

Fifth, to provide an apparatus for sterilizing medical dressings and the like, utilizing microwave energy to generate a low pressure gaseous discharge in and around the medical dressings.

Sixth, to provide a very rapid process for producing an aseptic medical dressing by exposure of the dressing to a low pressure gaseous discharge generated by microwave energy absorbed by the ambient low pressure gas.

Other objects and advantages of this invention are taught in the following description and claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The description of this invention is to be read in conjunction with the following drawings:

FIG. 1 is an elevational sectional view of the microwave sterilizing reactor suitable for producing aseptic medical dressing products.

FIG. 2 is a cross sectional plan view through 2—2 of FIG. 1.

FIG. 3 is a detailed sectional view through 3—3 of FIG. 1, further illustrating the operation of the asepsis process in the apparatus.

**DESCRIPTION OF THE PREFERRED EMBODIMENT**

Referring to FIG. 1 in detail, the microwave sterilizing reactor 1 is shown in a sectional elevational view, having a magnetron generator 2, terminating in a RF input probe 3 located in a flanged wave guide 4. A tuning stub means 5 provides exact tuning of the wave length to the 2450 mHz. band, or the like desired frequency, on introduction of power to the power pack. One wave guide 4 terminates at the flanged 90° wave guide bend 6, and the bend 6 is connected to the flanged expanding wave guide transition horn 7. The horn 7 is terminated at the flange 8 and a glass, quartz or the like, flat window 9 seals the flange 8 face. The window plate 9 provides one wall of the cavity 10, in which a low pressure gaseous glow discharge can be formed by the microwaves which pass through the window plate 9. The window plate 9 is specifically transparent to the microwaves, except for the known usual losses. The metal surface plate 11 of the cavity 10, paralleled and opposed to the window plate 9, is typically aluminum, although steel, copper, brass and the like metals can be used. Plate 11 functions as a microwave reflector. An annular ring 12 cooperatively spaces the plates 9 and 11 parallel and apart. The O-ring grooves 13, 13' are formed in the opposed faces of the ring 12 and hold the sealing O-rings 14 and 14'. The threaded securing and positioning rods 15 and 15' together with the nuts 16, 16', 16'', 16''' provide locating and quick clamping means for the

3

cavity 10. By clamping plates 9 and 11 to the ring 12, sealing the O-rings 14 and 14', a vacuum tight cavity 10 is constructed. An opening 17 normally extending through ring 12 is connected to a pipe 18, providing an exit opening through which gas may be pumped from cavity 10 by evacuation means 25, providing low pressure gas atmosphere of the desired value in cavity 10. A medical dressing 19 is shown in sectional view in the cavity 10, the dressing 19 being sealed in a pouch 20 made of microporous paper.

In FIG. 2 the sealed pouch or container 20 is shown in plan partial sectional view supported on the interior face 21 of the window plate 9. The window plate face 21 is partially coextensive with and contiguous to one face of the annular ring 12. The normal opening 17 in the ring 12 has a pipe 18 connected to opening 17, providing an evacuation orifice for the cavity 10. The pouch or container 20 has a perimeter sealed rim 22, sealing the two microporous paper sheets of container 20 together.

As illustrated in elevational sectional view in FIG. 1 and in plan partial section view in FIG. 2, the medical dressing 19, which can be a gauze pad, sponge, bandage, suture or the like, is sealed inside a flat pouch or container 20 made of microporous paper in accordance with known teachings. The pouch perimeter sealed rim 22 is a hermetic seal, providing no rim opening. The microporous paper utilized in the pouch surface construction has microscopic sized channel openings which traverse from a first face of a paper sheet to the second face of the sheet, providing gas transpiration openings in the paper sheet which are about 5 microns in size or the like. The microporous openings in the 35 pound white kraft paper sheet have a Gurley air porosity minimum of 80 sec./100 cc. air leak. The paper sheet is free of dirt, holes and the like, and does not permit the larger sized bacteria, yeast, molds, spores or virus particles to move through the paper openings.

Utilizing the microporous paper sheets described above, the sealed pouch 20 is constructed around the medical dressing 19. A sterilization process which requires transpiration of air or other low molecular weight gas into and out of the pouch interior can then be utilized to prepare an aseptic medical dressing 19, without then exposing the prepackaged dressing 19 to fresh inoculation of bacteria, yeasts, molds, spores or viruses after the asepsis process. The ethylene oxide sterilization process is now typically commercially used with the pouch 20 construction.

FIG. 3 illustrates a detailed sectional view through 3-3 of FIG. 1, relating the position of the micro-wave reflector plate 11 with respect to the sealed pouch or container 20 and the medical dressing 19 during the asepsis process taught in this application. Preferably, the interior face 23 of reflector plate 11 is located ¼ micro-wave length distance from and parallel to the center line 27 of the dressing 19. The container 20 placed in the cavity 10 will tend to distend when the cavity 10 is evacuated by evacuation means 25 to 10 mm. Hg. or lower air pressure, due to the slow rate of gas passage outward through the container micro-porous paper gas channels. When the microwaves of frequency 2450 mHz. are generated by the magnetron microwave generator subsystem and transmitted through the glass window plate 9, the microwaves impinge upon and are reflected by the metal reflector plate 11. Applying the wave length  $\lambda$  Formula 1 below

$$\lambda = v_c / f \quad (1)$$

where  $v_c$  = microwave velocity and  $f$  = microwave frequency, the microwave length  $\lambda$  is approximately 12.3 cm. and the ¼ wave length is approximately 3.1 cm. At the ¼ wave length distance of 3.1 cm. from the interior face 23, the constructive interference of the microwaves is a maximum and the microwave field strength voltage reinforcement is a maximum, due to the standing waves. Hence, at this distance, one quarter wave length, there is a maximum field voltage available to initiate low pres-

4

sure gaseous glow discharge inside the container 20, due to electron avalanching in the ionized low pressure gas.

A low pressure gaseous glow discharge can be excited inside the sealed pouch 20 using air at a pressure 26 range of 10 to 0.01 mm. Hg. At the higher air pressure the glow discharge must be less than ½ second long, to avoid ignition of the package and dressing. At 0.05 mm. Hg pressure, the glow discharge can proceed for up to 10 seconds without package ignition and sterilization is produced in 2-3 seconds. Typically in a cavity 10 which has the area dimension 6 x 8 inches x 1½ inch thick, the microwave power input into the cavity is 800 watts for 2-3 seconds at 2450 mHz. frequency.

The several bands of frequencies commercially available for microwaves, ranging from 890 to 22,250 mHz., may be used. The higher microwave frequencies can be used to more precisely position the ¼ wave length voltage reinforcement zone used to generate the low pressure glow discharge, since the thinner zone can be more easily located inside a thin flat package of medical dressing. Since the ¼ wavelength voltage reinforcement zone is formed by reflection off a flat plate, the plane of the reinforcement zone should be parallel to the center line 27, in order to provide maximum voltage reinforcement zone location inside the container 20 or the like.

In commercial production of medical dressing products, product control containers of gauze medical sponges of construction typical of container 20 are placed in the sterilization apparatus and subjected to the sterilization process, along with the commercial production, to measure sterilization effectiveness. The control samples of gauze sponges are inoculated with the organism *Bacillus pumilis*, a bacteria having a very resistant spore. After sterilization of the commercial production lot, the control samples are removed and incubated for a period of up to three weeks on a broth of thio-glycollate. If the spores are not killed in the sterilization process, there is heavy growth of *Bacillus pumilis* in 24 hours.

Samples of gauze sponges inoculated with *Bacillus pumilis*, were sealed in container 20 and used as test samples for this invention. The containers 20 were placed in the cavity 10 of reactor 1 and evacuated to 100 micron air pressure, the containers 20 lying on the window plate 9 at the face 21. Each dressing center line 27 was ¼ distance from the inside reflector plate face 23, for the microwave frequency 2450 mHz. Approximately one kw. of generated microwave energy was transmitted down the wave guides 4, 6 and the expander horn 7, for a period of 1 sec. A second set of dressing samples were likewise irradiated for 2 secs. Both irradiated sets of samples had low pressure glow discharges generated inside each container. The treated gauze sponges when used to inoculate a thio-glycollate broth, showed 100% bacterial kill after a period of three weeks incubation.

Many modifications and variations of our improvements in a microwave reactor and process for asepsis may be made in the light of our teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

We claim:

1. A sterilization apparatus comprising: a magnetron microwave generator subsystem; a wave guide transmission subsystem containing said microwave generator and electrically matched to transmit the generated microwaves; a window plate transparent to said microwaves, said window plate terminating said wave guide transmission system and the window plate surface secured normal to the microwave transmission direction; a low pressure gaseous glow discharge cavity coplanarly contiguous to said window plate, a metal microwave reflecting plate forming the cavity wall opposed to said window plate, and a cooperatively sized vacuum sealing spacer means separating said window plate and said microwave reflecting plate, said spacer means adapting said cavity to evacuation and sized

5

to separate said window plate and said reflecting plate at least the distance of one-quarter microwave length; and evacuation means for said cavity adapted to produce the required gas pressure.

2. A sterilization apparatus comprising: a microwave transmission means; a window plate transparent to said microwaves terminating said microwave transmission means, the plate surface of said window plate disposed normal to the direction of microwave transmission; a low pressure gaseous glow discharge cavity having the window plate as one wall and an opposed parallel microwave metal plate reflecting wall, together with a vacuum sealable evacuable spacer means adapted to separate and secure together said window plate and said reflecting wall, said spacer means separating said window plate and said reflecting wall at least one-quarter microwave length; and evacuation means adapted to provide the desired gas pressure.

3. A method of sterilizing a medical dressing comprising: irradiating said medical dressing by disposing same within a low pressure gaseous glow discharge contained in a cavity at a gas pressure in the range of 0.01 to 10 mm. Hg absolute of air and for a time period of less than 5 seconds, said glow discharge being produced by ionizing said air in said cavity by the absorption of microwave energy of a frequency range of 900 to 22,250 mHz. transmitted into said cavity, said time period being selected to produce asepsis of said medical dressing.

4. The method of claim 3 in which the medical dressing is completely enveloped in a microporous paper container prior to irradiation, all joint of said container being hermetically sealed.

5. The method of claim 3 wherein said medical dressing is completely enveloped in a microporous paper container prior to irradiation with said microwave frequency energy, said container is disposed on the interior face of

6

a microwave frequency transparent wall of said cavity, and said interior face of said transparent wall disposing said container interior within a one-quarter wave microwave wavelength distance of a voltage reinforcement loop, thereby providing increased exposure to said microwave energy on initial passage and reflection of said microwaves.

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U.S. Cl. X.R.

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