(12) PATENT **(11)** Application No. **AU 199920204 B2**
(19) AUSTRALIAN PATENT OFFICE **(10)** Patent No. **736637**

(54) Title
Antimicrobial composition delivery system with an integrated filter

(51)[7] International Patent Classification(s)
A61L 002/18 **A61L 002/26**

(21) Application No: **199920204** (22) Application Date: **1998.12.23**

(87) WIPO No: **WO99/34840**

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/070930	**1997.12.23**	**US**

(43) Publication Date : **1999.07.26**
(43) Publication Journal Date : **1999.09.30**
(44) Accepted Journal Date : **2001.08.02**

(71) Applicant(s)
Steris Corporation

(72) Inventor(s)
David E. Minerovic; Todd A. Christopher; Brian E. Schindly; Christopher M. Fricker; Karen Thomas

(74) Agent/Attorney
WATERMARK PATENT and TRADEMARK ATTORNEYS,Locked Bag 5,HAWTHORN VIC 3122

20204/99

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61L 2/18, 2/26 — A1

(11) International Publication Number: WO 99/34840

(43) International Publication Date: 15 July 1999 (15.07.99)

(21) International Application Number: PCT/US98/27772

(22) International Filing Date: 23 December 1998 (23.12.98)

(30) Priority Data:
60/070,930 23 December 1997 (23.12.97) US

(71) Applicant: STERIS CORPORATION [US/US]; 5960 Heisley Road, Mentor, OH 44060 (US).

(72) Inventors: MINEROVIC, David, E.; 6168 Cheryl Drive, Concord, OH 44077 (US). CHRISTOPHER, Todd, A.; 4060 South Kelly Drive, New Palestine, IN 46163 (US). SCHINDLY, Brian, E.; 8404 Nowlen Street, Mentor, OH 44060 (US). FRICKER, Christopher, M.; 7960 Fieldstone Court, Mentor, OH 44060 (US). THOMAS, Karen; 145 Pinehurst Boulevard, Eastlake, OH 44095 (US).

(74) Agent: KOCOVSKY, Thomas, E., Jr.; Fay, Sharpe, Beall, Fagan, Minnich & McKee, 7th floor, 1100 Superior Avenue, Cleveland, OH 44114-2518 (US).

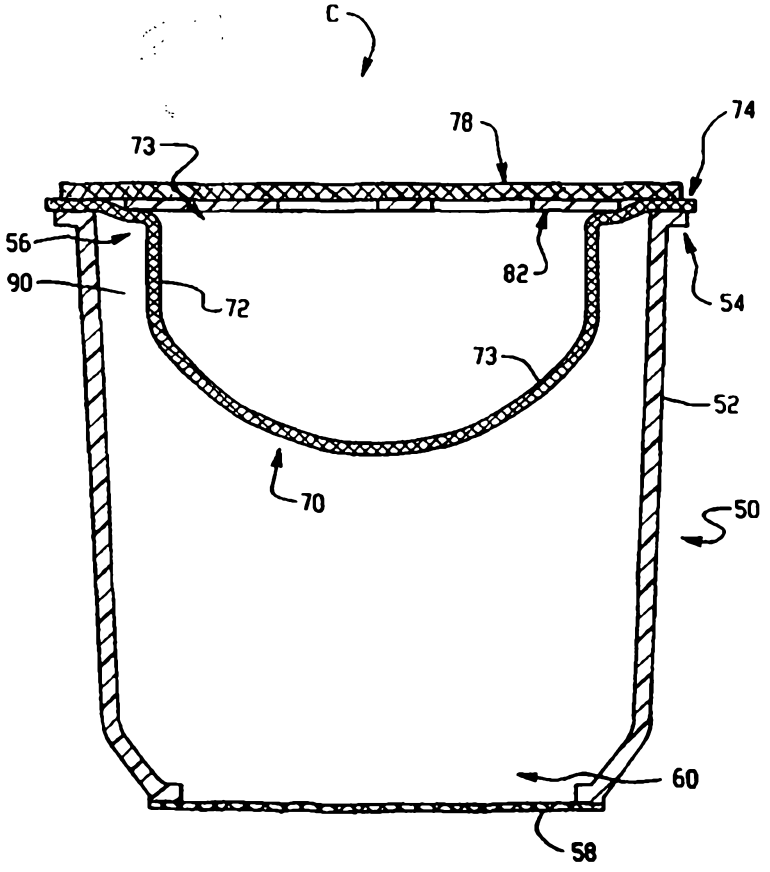
(81) Designated States: AU, CA, CN, JP, KR, MX, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ANTIMICROBIAL COMPOSITION DELIVERY SYSTEM WITH AN INTEGRATED FILTER

(57) Abstract

An outer, first container portion (50, 50', 90, 120) has a cylindrical peripheral wall (52, 122) which has an opening at a first end (56) and at a second end (60). A porous filter (58) covers the second end. An inner, second container portion (70, 70', 94) has a peripheral wall (72) with a region which is formed from a first material which is impermeable to the powdered reagents but is permeable to water and to solutions containing dissolved reagents. The first and second container portions are configured such that the second container portion peripheral wall abuts and is connected to the first end of the outer first container portion. The first and second container portions define a first powdered reagent receiving chamber in the first container portion for receiving a first reagent, such as acetyl salicylic acid, and a second powdered reagent receiving chamber in the second container portion for receiving a second reagent, such as sodium perborate. The porous filter is impermeable to the first reagent but permeable to water and to solutions containing dissolved reagents.



ANTIMICROBIAL COMPOSITION DELIVERY SYSTEM WITH AN INTEGRATED FILTER

Background of the Invention

The present invention relates to the decontamination arts. It finds particular application in conjunction with powdered reagents which are reacted in situ to form a liquid sterilant solution for sterilizing or disinfecting medical instruments and equipment and will be described with particular reference thereto. It should be appreciated, however, that the invention is also applicable to a wide variety of technologies in which at least two components or reagents are kept separate until time of use and then combined through dissolution in a common solvent.

Disinfection connotes the absence of pathogenic life forms. Sterilization connotes the absence of all life forms, whether pathogenic or not. The term decontamination is used herein to connote sterilization, disinfection or other antimicrobial treatments.

Heretofore, medical equipment and instruments have often been decontaminated in a steam autoclave. Autoclaves kill life forms with a combination of high temperature and pressure. However, steam autoclaves have several drawbacks. The high temperature pressure vessels tend to be bulky and heavy. The high temperature and pressure tends to curtail the useful life of endoscopes, rubber and plastic devices, lenses, and portions of devices made of polymeric materials and the like. Moreover, a typical autoclave decontaminating and cool down cycle is sufficiently long that multiple sets of the medical instruments are commonly required.

Instruments which cannot withstand the pressure or temperature of the oven autoclave are often decontaminated

with ethylene oxide gas, particularly in larger medical facilities or hospitals. However, the ethylene oxide decontamination technique also has several drawbacks. First, the ethylene oxide decontamination cycle tends to be even longer than the steam autoclave cycle. Another drawback is that ethylene oxide decontamination is sufficiently sophisticated that trained technicians are commonly required, making it unsuitable for physician and dental offices and for other smaller medical facilities. Moreover, some medical equipment can not be decontaminated with ethylene oxide gas.

Liquid decontamination systems have also been utilized for equipment which could not withstand the high temperatures of steam decontamination. Commonly, a technician mixes a liquid disinfectant composition immediately prior to use and manually immerses the items to be decontaminated. The high degree of manual labor introduces numerous uncontrolled and unreported variables into the process. There are quality assurance problems with the weakening of the decontaminant chemicals due to aging on the shelf, and technician errors in the mixing of decontaminant, control of immersion times, rinsing of residue, exposure to the ambient atmosphere after the rinsing step, and the like. On occasion, powdered reagents are carried away from the mixing region and deposited in undesired locations before they dissolve or react. When systems are used for decontaminating medical instruments, undissolved reagent particles remaining on the medical instruments after a decontamination cycle are considered undesirable.

U.S. Patent No. 5,662,866 to Siegel, et al. discloses a two-compartment cup for powdered sterilant reagent components. An outer cup holds a first reagent while an inner cup, disposed within the outer cup, holds a second reagent. Peripheral walls of inner and outer cups are affixed together at their open ends at flanges. A permeable sheet is affixed to the inner cup portion flange for ventedly sealing both cups. The outer cup is closed at its base by a first detachable base and the inner cup similarly closed by a second detachable base. In use, the two bases are opened to allow

mixing of the two reagents. The two-compartment cup ensures sterilization or disinfection with a reproducible, pre-measured dose of reagents, while also facilitating handling and shipping of the reagents.

The present invention provides for a new and improved two compartment package which does not require detachment of first and second compartment bases and which is ideal for storing powdered reagents which are retained separately until time of use and are released in solution when a solvent is passed through both compartments.

Summary of the Invention

In accordance with one aspect of the present invention, a multi-compartment package for holding powdered reagents which interact with water to form an anti-microbial solution is provided. The package includes an outer, first container portion and at least one inner, second container portion. The first and second container portions are configured such that a first powdered reagent receiving chamber is defined in the first container portion for receiving a first reagent and at least a second powdered reagent receiving chamber is defined in the second container portion for receiving a second reagent. The package is characterized by the first container portion including a region which is formed from a first material which is impermeable to the first reagent but is permeable to water and to solutions containing dissolved reagents, and the second container portion including a region which is formed from a second material which is impermeable to the first and second reagents but is permeable to water and to solutions containing dissolved reagents.

In accordance with another aspect of the present invention, a method is provided. The method includes metering a preselected volume of a first powdered reagent into a first container, inserting a second container into the first container, connecting the second container to the first container, metering a preselected volume of the second powdered reagent into the second container, and closing the

first and second containers. The method is characterized by the first container including a region of a first porous material which is impermeable to the first reagent but is permeable to water and to aqueous solutions containing dissolved reagents, and the second container including a region of a second porous material which is impermeable to the first reagent and to a second reagent but is permeable to water and to solutions containing dissolved reagents.

In accordance with yet another aspect of the present invention, a decontamination system is provided. The system includes a powdered reagent container receiving well. A first fluid flow path is defined between a water receiving inlet and the reagent container receiving well to bring water from the inlet to the well to mix with powdered reagents and form a decontaminant solution. A second fluid flow path is defined for the decontaminant solution from the reagent container receiving well to a decontamination region for receiving items to be decontaminated. The system also includes a fluid circulator for selectively circulating fluid through the first and second fluid flow paths and among the inlet, the decontamination region, and the reagent container receiving well, and a multi-chamber powdered decontamination reagent holding container for insertion into the well. The container includes a) an outer, first container portion including a first peripheral flange adjacent a first end which defines an inlet opening and a second end which defines an outlet opening, and b) an inner, second container portion including a second peripheral flange which defines a first end with an inlet opening and a second end with an outlet opening, the first and second container portions being nested, and c) a top cover covering the first and second container portion inlets. The system is characterized by the first container portion outlet opening being closed with a material which is impermeable to undissolved reagents held in the container and is freely permeable to aqueous solutions, and the second container portion second end outlet opening being defined by a porous portion of the second peripheral wall.

One advantage of the present invention is that it facilitates materials handling.

It is preferable that the present invention simplifies filling and sealing of two reagents in separate compartments.

It is also preferable that the present invention promotes thorough mixing of the reagents and complete dissolution of the reagents.

It is also preferable that undissolved particles of reagent remain trapped within the cartridge until dissolved.

Another preferred feature of the present invention is that it enables release of dissolved reagents from the package without first opening the package.

A further preferred feature of the present invention is that it permits introduction of reagents at different rates.

Further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is an exterior view of a decontamination unit according to the present invention.

FIGURE 2 is a plumbing diagram of the decontamination unit of FIGURE 1 including a cross-sectional view of a reagent cartridge receiving well and one embodiment of a two-compartment reagent package according to the present invention;

FIGURE 3 is a plumbing diagram of a second embodiment of the decontamination unit of FIGURE 1 according to the present invention;

FIGURE 4 is a side sectional view of a first embodiment of the two compartment package in accordance with the present invention;

FIGURE 5 is an expanded perspective view of the two-compartment package of FIGURE 4;

FIGURE 6 is another alternate embodiment of the package of FIGURE 3;

FIGURE 7 is an expanded view of yet another alternate embodiment of the package of FIGURE 3;

FIGURE 8 is an expanded view of yet another alternate embodiment of the package of FIGURE 3;

FIGURE 9 is yet another alternate embodiment of the package of FIGURE 3;

FIGURE 10 is an expanded view of yet another alternate embodiment of the package of FIGURE 3;

FIGURE 11 is a detailed illustration of a preferred weld joint configuration;

FIGURE 12 is an expanded view of yet another alternate embodiment of the package of FIGURE 3; and,

FIGURE 13 is an expanded view of yet another alternate embodiment of the package of FIGURE 3.

Detailed Description of the Preferred Embodiments

With reference to FIGURES 1 and 2, a microbial decontamination apparatus **A** is configured to sit on a counter top or other convenient work surface. A door or lid **10** is manually openable to provide access to a tray **12** which defines a receiving region **14** for receiving items to be microbially decontaminated. In the illustrated embodiment, the tray **12** is configured to receive endoscopes or other long, coilable items. Other trays with item receiving regions of different configurations for receiving the items themselves or item holding containers are also contemplated. A well **16** receives a unit dose of reagents for forming a sterilant, disinfectant, other microbial decontaminating solution, detergent or cleaning solution, or the like.

With particular reference to FIGURE 2, a reagent containing package or cartridge **C** is inserted into the well

16. Once the items are loaded into the tray and the reagent carrying package C is inserted into the well 16, the lid 10 is closed and latched. A fill valve 20 passes water through a microbe removing HEPTA filter 22 in flow paths of a fluid circulating system. The microbe removing filter 22 provides a source of sterile water by passing water and blocking the passage of all particles the size of microbes and larger. The incoming water which has been sterilized by the filter 22 passes through a spray or distribution nozzle 24 and fills the item receiving region 14 in the tray 12. As additional water is received, it flows into the well 16 dissolving powdered, crystalline, encapsulated, or other non-flowing reagents in the package C, forming an anti-microbial solution. Filling is continued until all air is forced through an air system 26 and an entire interior volume is filled with the sterile water. After the fill valve 20 is closed, a pump 28 circulates the fluid through a heater 30, the item receiving region 14 of the tray 12, and the well 16. The pump also forces the anti-microbial solution through the filter 22 to a check valve 32, thereby sterilizing the filter. Further, the pump forces the anti-microbial solution through another microbe filter 34 in the air system 26 to a check valve 36.

After the anti-microbial solution has been brought up to temperature and circulated over the items to be microbially decontaminated for a selected duration, a drain valve 38 is opened, allowing the solution to drain. Air is drawn through the microbe filter 34 such that sterile air replaces the fluid within the system. Thereafter, the drain valve is closed and the fill valve 20 opened again to fill the system with a sterile rinse fluid. It will be noted, that because the pump 28 circulated the anti-microbial solution over all surfaces of the flow paths including all surfaces leading from the sterile rinse source, microbe removing filter 22, the rinse cannot bring microbial contaminants into the item receiving region 14.

With reference to FIGURE 3, an alternative embodiment of the decontamination apparatus A is shown. In this embodiment, incoming water passes from the microbe

removing filter **22** to the well **16**, without first passing through the receiving region **14**. Optionally, the reagent containing package **C** includes the microbe removing filter **22**, as will be discussed later.

With reference to FIGURES 4 and 5, a first embodiment of the package **C** includes a first, or outer container portion **50**. The outer container **50** is constructed of a light weight, rigid polymeric material. The outer container **50** includes a cylindrical peripheral wall **52** that has a flange **54** at a first, open end **56** thereof. A fluid-permeable base, or porous filter **58** covers a second, opposite, or lower end **60** of the peripheral wall **52**. The porous filter **58** is ultrasonically welded or otherwise adhered to the peripheral wall **52** covering the lower end **60** in the outer container. The outer container is then filled with reagent components, such as sodium perborate, corrosion inhibitors, pH buffers, detergents and wetting agents. The filter **58** is preferably formed from a material that is impermeable to the dry reagents that are contained within the first container portion, yet is permeable to water with dissolved reagents.

A second, or inner container portion **70** is received in the first container portion **50**. The second container portion includes a thermally molded, peripheral wall **72** which defines a generally hemispherical cup with a top opening **73**, and an integrally molded flange **74**. Alternatively, the second container peripheral wall is cone or cylindrically shaped. The inner container **70** is filled with a second reagent component, preferably an acetyl donor such as acetylsalicylic acid.

The peripheral wall **72** of the second container portion **70** is formed from a filter material that is impermeable to the dry reagents contained within the first and second container portions, yet is permeable to water and to the dissolved reagents. Suitable filter materials include polypropylene, polyethylene, nylon, rayon, rigid porous media, such as POREX™ expanded plastic, or other porous plastic, fabric, felt, mesh, and analogous materials. Alternatively the peripheral wall **72** includes only a limited region that is

formed from a material which is impermeable to the powdered reagents but which is permeable to water and to the dissolved reagents.

A top cover **78** covers the top opening **73** of the second container portion. Any particles of reagent in the second container portion **70** that are not dissolved are therefore trapped within the second container portion. Preferably, the top cover is also formed from a similar filter material to that of the peripheral wall **72**, or includes a porous region. Dissolved reagents pass through the layers of porous material and are transported to the items to be decontaminated.

With particular reference to FIGURE 5, the inner container flange **74** is pressed against the top flange **54** for ultrasonic or heat welding. Preferably, an outer edge of the top cover **78** is sealed to the inner container flange **74** in the same welding operation. Analogously, the porous filter **58** is pressed against the flange on the outer container peripheral wall **52** around the opening **60** for ultrasonic or heat welding. Under heat or ultrasonic vibration, the plastic melts and flows into the fibers or the voids of other porous filter materials, forming a unitary seal. Alternatively, other methods of sealing such as gluing, fusion bonding, clamping with a clamping ring, or the like replace the heat or ultrasonic welding as a means of joining the various components.

Optionally, as shown in FIGURE 4, a stiffener **82**, such as an annular ring with a pair of x-shaped cross members, is positioned between the inner container **70** and the top cover **78** to ensure that the top cover lays flat. Preferably, the stiffener **82** is of smaller diameter than the weld rings **80** and is not incorporated into the weld. Rather, it is held in place by frictional or mechanical force.

The two compartment package **C** is alternatively constructed according to a variety of different embodiments which serve to keep the dry reagents in separate compartments during transportation and storage, yet allow the reagents to

leave the package when dissolved in water, or other suitable solvent, that flows into the package.

In the embodiment of FIGURE 6, the inner container **70** is constructed in whole or part of a porous filter material. The inner container and filter layer **58** are welded or otherwise affixed to a lower end of the outer container peripheral wall **52** to cover the lower open end **60**. One of the reagents such as acetylsalicylic acid or multiple components, is held in the inner container, and other reagents, such as a perborate, are held in the outer container **50**. Upper filter layer **78** is welded across the top opening **56** of the outer container.

In the embodiment of FIGURE 7, an outer container **90** is formed of a porous filter material. The outer container includes an upper flange **92**. An inner container **94** is also formed of the filter material and, again, has an upper flange **96**. The flanges of the inner and outer containers are pressed together along with a top filter layer **98** and are welded or otherwise adhered together to form sealed inner and outer container portions.

Optionally, for stiffness, an annular ring of rigid plastic **100** is welded or otherwise adhered to one or both of the flanges **92, 96**. For additional stability, a retainer, such as a second annular ring **102** of rigid plastic is inserted into the bottom of the outer container to hold the bottom in a circular configuration. Alternatively, the inner and outer containers **90, 94** are formed, at least in part, from a rigid porous material, such as POREX™ expanded plastic, which retains its rigid structure when wet. Again, one or more of the powdered reagents is loaded into the inner container and the other into the outer container.

With reference to FIGURE 8, an outer container **50'** is formed of the filter material with an upper flange **54'**. An inner container **70'** is formed of the porous material with a flange **74'**. A retainer, such as a frame member **104**, constructed from a rigid material such as plastic, defines an upper shaping ring **106** and a bottom shaping ring or surface **108**. The bottom shaping surface **108** is received into the

outer filter material container **50'** to force its base into a preselected shape. Sides **110** of the frame member **104** have large openings **112** separated by ribs **114** to assure adequate liquid flow paths. The upper ring **106** of the retainer **104** is held adjacent the flanges **74', 54'** of the inner and outer containers when they are affixed together with an upper filter layer **78'**. Again, the flanges may be welded, glued, fusion bonded, clamped with a clamping ring, or the like.

In the embodiment of FIGURE 9, an outer container **120** includes a peripheral wall **122** constructed of a rigid plastic which defines the shape of a tube having upper and lower flanges **124** and **126**, adjacent upper and lower openings **128** and **130**, respectively. A horizontal dividing wall, or partition **132** separates the outer container **120** into two compartments. The dividing wall **132** is constructed of a porous plastic or filter material. A porous or rigid top cover **134** is sealed to the upper flange **124**. A porous base **136** is sealed to the lower flange. One of the reagents is placed in a first compartment **138** defined on one side of the partition **132** and the other reagent is loaded into a second compartment **140** defined on the other side of the partition **132**.

In the embodiment of FIGURE 10 an outer container **150** of a rigid plastic material defines the shape of a tube having an upper flange **152** and a lower flange **154** adjacent upper and lower openings **156** and **158** in the container, respectively. A vertical dividing wall, or partition **160** separates the outer container **150** into two compartments. In the illustrated embodiment, the dividing wall **160** is constructed of rigid plastic, although porous plastics or filter material are also contemplated. One or more of the reagents is placed in a first compartment **162** defined on one side of the partition **160** and the other reagent(s) is loaded into a second compartment **164** defined on the other side of the partition **160**. Other components, such as corrosion inhibitors, wetting agents, pH buffers, and the like are optionally loaded into one of the two compartments.

While the embodiments have been described with reference to two containers or compartments, alternately, one or more additional partitions are provided to divide the outer container into three or more compartments to receive the other components.

A top cover **170** formed from a layer of filter material or rigid plastic is welded or otherwise adhered to the upper flange **152** and the upper edge of the partition **160**. Analogously, a base **172** formed from a layer of filter material is welded or otherwise adhered to the lower flange **154** and the bottom surface of the partition **160**.

Alternatively, the base comprises two portions **172a** and **172b** which serve as a base for the first and second compartments, **162,164,** respectively. The material of each of the portions is selected according to the particle size of the reagent to be loaded into the compartment, or according to a desired rate of solubilization of the reagent, as will be discussed later.

Preferably, the upper flange **152** of the outer container **150** of this, or any of the other embodiments includes a plurality of positioning tabs **174**. The positioning tabs **174** are located radially outward beyond the top cover **170** and the weld. The tabs **174** extend upward a sufficient distance to engage a structure on the lid **10** of the decontamination apparatus **A**, or other internal lid, which presses against the tabs when the lid is closed at the commencement of a cycle. The tabs are spaced and sufficiently long that a fluid flow between the lid structure **10** and the cartridge **C** is assured.

With continued reference to FIGURE 10 and reference also to FIGURE 11, the upper flange **152** of the outer container **150** or of any of the other embodiments with a rigid outer container or a rigid annular ring includes an upward projecting energy director **180**. The energy director **180** includes an upward projecting annular rib **182** extending around the flange **152**. The rib is relatively narrow with a narrowing upper edge. A top cover **184** and, where present, a flange **186** of an inner container (such as for the embodiments of FIGURES

4, 5, or 7) are pressed against the energy director **180**. The flange **186**, and optionally the top cover **184**, are formed from a porous filter material. A welding horn **188** presses the filter layers against the energy director with a significant force and concurrently applies ultrasonic vibrations and optionally heat. The ultrasonic vibrations are preferentially attracted to the raised energy director. The combination of pressure, heat, and vibration causes the energy director to fluidize, flowing into and through the filter material **186** to the top cover **184**, forming a tight, unitary seal.

When the two compartments are formed by a vertical barrier, or dividing wall, as shown in FIGURE 10, a top **190** of the barrier **160** also includes an energy director **192** for sealing the top cover to the barrier. Analogously, similar energy directors on the lower flange **154** of the outer container and on a lower end of the barrier assist in welding on the porous base **172**.

The flow-through design of the package allows for integration of filters with absolute ratings into the package which allows for segregation of the components and prevents sifting of particles due to particle size exclusion. The preferred design uses polypropylene, polyethylene, blended polyolefin non-woven material, or a porous media for one or more of the filters. The filter optimizes solubility by increasing flow through the package and prevents any material from escaping the filter package without being solubilized. The flow-through filter design allows for complete segregation of the materials during shipment and storage. It further provides for complete retention of the particles and the chemistry while the delivery system is being flooded. Further, the design allows the constituents to be released and reacted together without opening, or puncturing, the cartridge. The filter layer further provides a gross filter for any particles that might be washed off the instruments being decontaminated in the tray **12**.

The inner container can take various shapes including truncated cones, cones, and the like. It can be constructed totally of filter material or only partially of

a filter material. For example, the inner compartment can have peripheral walls and a flange of solid plastic with the filter material supported across the bottom of the inner container. A lower flange on the inner container facilitates welding or bonding and crossing ribs can provide structural support to the filter layer at the bottom of the inner container. Optionally, one or more of the filter layers can be replaced with an openable or severable barrier. For example, the bottom of the inner container can be constructed of a film which breaks when water is introduced into the system. The film may be constructed of a water-soluble material, or of a material which becomes sufficiently weakened in the presence of the water or water and powdered reagents that it ruptures under the pressure applied by the pump **28**. As another alternative, the bottom of the inner container may open in response to pressure applied to the peripheral walls of the outer container. Other release mechanisms for releasing the bottom of the inner container are also contemplated.

Alternately, the bottom of the inner container can be a filter material, and the bottom opening of the outer container can be a releasable member. When the bottom of the outer container is releasable, it is preferred that the most soluble reagents be positioned in the outer container and the less soluble reagents positioned in the inner container.

In another embodiment, the top cover is impermeable to water and may be integrally formed with the outer container. Water enters the cartridge through an opening which is pierced in the top cover at the commencement of the decontamination cycle.

In yet another embodiment shown in FIGURE 12, one of the compartments is defined by a filter bag **200**, formed from a porous material, which encloses one of the dry reagents and which is impermeable to dry reagents yet allows water and dissolved reagents to pass freely through the cartridge **C**. Preferably the bag is retained in the cartridge such that water flowing through the cartridge must pass through the filter bag. Optionally, the bag is supported within the outer

compartment **202** on an open support **204**, such as a mesh screen. The outer compartment is covered at inlet and outlet ends **206** and **208**, respectively, by sheets of porous material **210** and **212**.

Alternatively, as shown in FIGURE 13, each of the reagent compartments is defined by a filter bag, **214** and **216**, respectively, disposed within an outer container **218**. Preferably, these are retained within an outer container **220** such that water flowing through the container passes through both compartments.

The choice of filter material depends on the particle size of the reagents. For reagents having a particle size of about 50 microns, a non-woven polypropylene web or felt keeps the dry reagents from penetrating the material, while allowing the water and dissolved reagents to pass freely through the cartridge. When the material is a polypropylene web, the top cover is readily sealed to the second container portion by ultrasonically welding or other heat sealing the flange of the second container portion to the top cover.

Moreover, the choice of filter material affects the rate of solubilization of the reagents. By selecting the dimensions of the pores appropriately, turbulence is created within and adjacent the pores, assisting in solubilization of the reagents.

Particularly when the construction of the cartridge permits separate water flow through each of the two compartments, as in the embodiment of FIGURE 10, the filter material of one of the compartments is optionally selected to delay the rate of introduction of the reagent contained within that compartment to the flow of water passing through the cartridge. By limiting the pore size or increasing the thickness of the filter material, the rate of introduction is slowed. Alternatively, an additional barrier that slowly dissolves in water covers the filter material of one of the compartments and delays the introduction of the reagent into the flow of water. In one embodiment, surfactants and buffers are released into the flow of water ahead of sterilizing or disinfecting reagents. This improves the rate

of dissolution of the sterilizing or disinfecting reagents in the water. In another embodiment, cleaning compounds are introduced ahead of disinfecting or sterilizing reagents. The cleaning agents begin the removal of adhered organic deposits from the surfaces of instruments to be decontaminated, rendering the surfaces more accessible to the sterilants or disinfectants.

In another embodiment, the cartridge includes a microbial filter **190**, as shown in FIGURE 3. The microbial filter **190** replaces or supplements the microbe removing filter **22** of the decontamination apparatus **A**. The incorporation of the microbial filter into a disposable cartridge **C** ensures that a fresh microbial filter is used for every cycle. The microbial filter **190** is positioned such that all water flowing through the well **16** passes through the microbial filter. The microbial filter preferably filters particles of 2μ and above from the fluid passing through the cartridge. Optionally, the filter material of one of the compartments of the cartridge **C** provides the microbial filter.

Optionally, the microbial filter **190** is impregnated with an antimicrobial composition which is slowly released into the water throughout the cycle. In one embodiment, an encapsulated source of chlorine impregnated into the microbial filter **190** slowly releases active chlorine into the water. A minute quantity of chlorine is sufficient to ensure that any pathogenic microbes entering with the rinse water are killed. Alternatively, the microbial filter **190** is electrically charged. Antimicrobial agents are bound to the filter at charged sites within pores and on surfaces of the filter. These agents are slowly released into solution throughout the cycle. Alternatively, an electrical potential is selectively applied across the microbial filter **190** which causes the agents to be released.

Electrical potentials applied to the filter material of one or other of the compartments may also be employed to control the rate of introduction of the reagents into the fluid.

The filter material is preferably free of additives, such as binders or surfactants, that could be dissolved in the water and contaminate the items to be decontaminated. The material is also preferably lint free, so that small particles of the material do not come away from the second container and become trapped within items to be decontaminated. Further, the material preferably has a fairly high tensile strength and does not disintegrate when it is subjected to a fairly high pressure of water. The material is also preferably unreactive toward the reagents and other additives used in the decontamination unit. A polypropylene nonwoven web having an absolute pore size of under 50 microns, and preferably around 10 microns, is a preferred material because it is virtually lint-free. It also has a high tensile strength, even when under a moderately high water pressure.

The porous nature of the inner container portion and top cover **78** or porous base **58** allows gases formed from the reagents during transit to outgas from the cartridge **C**.

The preferred reagents include an acid precursor, preferably acetylsalicylic acid and a persalt, preferably sodium perborate. These two reagents are supplied in a sufficient amount to generate peracetic acid in a concentration of 1500 ppm or better with the volume of water used to fill the system and the tray **12**. The sodium perborate generates hydrogen peroxide, which, in combination with acetylsalicylic acid as an acetyl donor, forms peracetic acid.

It is also contemplated using powdered reagents which react in a common solvent to generate chlorine gas, hydrogen peroxide, hypochlorous acid, hypochlorites, or other strong oxidants which have biocidal effects.

Preferably, additional corrosion inhibitors, buffers, and a wetting agent are added to these powders. Preferred copper and brass corrosion inhibitors include azoles, benzoates, other five-membered ring compounds, benzotriazoles, tolytriazoles, mercaptobenzothiazole, and the like. Other anti-corrosive buffering compounds include phosphates, molybdates, chromates, dichromates, tungstates, vanadates, other borates, and combinations thereof. These

compounds are effective for inhibiting steel and aluminum corrosion. For hard water in which calcium and magnesium salts may tend to precipitate, a sequestering reagent, such as sodium hexametaphosphate is also included.

To assemble the cartridge C of the embodiments shown in FIGURES 4 and 5, the base 58 is first attached to the outer container portion 50. The first reagent is then disposed within the outer container portion. The inner container portion 70 is then placed within the outer container portion with the flange 74 of the inner container portion resting on the flange 54 of the outer container portion. The second reagent is disposed within the inner container portion and the top cover 78 disposed so that it rests on the flange of the inner container portion. The top cover, inner container portion and outer container portion are then sealed together at the flanges of the inner and outer container portions. Thus, the first reagent is sealed within the outer container, while the second reagent is sealed within the inner container. Other methods of assembly are also contemplated. Similar methods of assembly are employed for the other embodiments.

"Comprises/comprising" when used in this specification is taken to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A multi-compartment package (C) for holding powdered reagents which interact with water to form an anti-microbial solution, the package including an outer, first container portion (50, 50', 90, 120), at least one inner, second container portion (70, 70', 94), the first and second container portions being configured such that a first powdered reagent receiving chamber is defined in the first container portion for receiving a first reagent and at least a second powdered reagent receiving chamber is defined in the second container portion for receiving a second reagent, the package characterized by:

the first container portion including a region which is formed from a first material which is impermeable to the first reagent but is permeable to water and to solutions containing dissolved first and/or second reagents; and

the second container portion including a region which is formed from a second material which is impermeable to the first and second reagents but is permeable to water and to solutions containing dissolved first and/or second reagents.

2. The package of claim 1, further characterized by:

the first container portion defining a base (58, 136) extending to a continuous peripheral wall (52) with an opening at an end (56); and,

the second container portion having a peripheral wall with an opening at an end (73), the first and second container portions being configured such that the second peripheral wall abuts and is connected to the outer first container portion adjacent the end of the first peripheral wall, a top cover (78, 98, 134) covering the openings in the first and second container portions.

3. The package of claim 2, further characterized by the first container portion end (56) defining a first flange (54, 54', 92) and the second container portion end

(73) defining a second flange (74, 74', 96), the first flange being sealed to the second flange.

4. The package of claim 3, further characterized by the top cover (78, 98) being sealed to the second flange (74).

5. The package of any of preceding claims 2-4, further characterized by:

the top cover (78) including a porous region which is formed from a cover material which is impermeable to the second reagent received in the second container but is permeable to water and to solutions containing dissolved first and/or second reagents.

6. The package of any of preceding claims 2-5, further characterized by:

the first peripheral wall defining a second opening at a lower end (60); and,

the base (58) of the first container portion being formed from the first material which is sealed to the side of the first peripheral wall adjacent the lower end to cover the second opening.

7. The package of any of preceding claims 1-6, further characterized by:

the second container portion (70) being molded substantially of the second material.

8. The package of claim 7, further characterized by:

a stiffening member (82, 100, 102, 104, 204) for adding rigidity to portions of the second container.

9. The package of any one of preceding claims 3 and 4, further characterized by:

alignment means (174) for facilitating alignment of the flanges during assembly.

10. The package of any one of preceding claims 1-8, further characterized by:

the second material including a microbial filter (190) which filters particles having a size of 2μ or greater from fluids passing through the package.

11. The package of any one of preceding claims 1-10, further characterized by:

the first reagent including acetylsalicylic acid and the second reagent including sodium perborate.

12. The package of any one of preceding claims 1-11, further characterized by:

the first container portion being substantially formed from a non-rigid porous material; and,

the package further including a stiffening member (82, 100, 102, 104) which retains a shape of the package when the package is wet.

13. A method for preparing a multi-compartment package for holding powdered reagents which interact with water to form an anti-microbial solution comprising:

metering a preselected volume of a first powdered reagent into a first container (50, 50', 90, 120), inserting a second container (70, 70', 94) into the first container, connecting the second container to the first container, metering a preselected volume of the second powdered reagent into the second container, and closing the first and second containers, the method characterized by:

the first container including a region of a first porous material which is impermeable to the first reagent but is permeable to water and to aqueous solutions containing dissolved reagents; and,

the second container including a region of a second porous material which is impermeable to the first reagent and to a second reagent but is permeable to water and to solutions containing dissolved reagents.

14. The method of claim 13, further characterized by:

transporting the containers and the contained powdered reagent to a site **(A)** at which decontamination is to be performed;

flowing water along a fluid flow path through the first and second containers to dissolve the first and second powdered reagents with water and form a decontamination solution, the fluid flow path including the porous regions of the first and second containers; and,

immersing items to be decontaminated in the decontamination solution.

15. The method of either of claims 13 and 14, further characterized by:

the first container including a flange **(54, 54', 92)** connected to the end of the first container **(50, 50', 90, 120)** and the second container **(70, 70', 94)** including a flange **(74, 74', 96)** connected to the end of the second container, the first and second containers being configured such that when the second container is inserted into the first container, the second container flange abuts the first container flange; and,

the step of connecting the second container to the first container including:

connecting the second container flange to the first container flange; and,

the step of closing the first and second containers including:

sealing a top cover **(78)** to the second container flange.

16. The method of any one of preceding claims 13-15, further characterized by the first peripheral wall being formed from a non-rigid porous material, the method further including:

disposing a retainer **(82, 100, 102, 104)** within the first container to prevent the peripheral wall from collapsing inward.

17. A decontamination system **(A)** comprising a powdered reagent container receiving well **(16)**, a first fluid flow path defined between a water receiving inlet **(20)** and the reagent container receiving well to bring water from the inlet to the well to mix with powdered reagents and form a decontaminant solution, a second fluid flow path being defined for the decontaminant solution from the reagent container receiving well to a decontamination region **(12)** for receiving items to be decontaminated, a fluid circulator **(28)** for selectively circulating fluid through the first and second fluid flow paths and among the inlet, the decontamination region, and the reagent container receiving well, a multi-chamber powdered decontamination reagent holding container **(C)** for insertion into the well, the container including a) an outer, first container portion **(50, 50', 90, 120)** including a first peripheral flange **(54)** adjacent a first end **(56)** which defines an inlet opening and a second end **(60)** which defines an outlet opening, b) an inner, second container portion **(70, 70', 94)** including a second peripheral flange **(74)** which defines a first end with an inlet opening **(73)** and a second end with an outlet opening, the first and second container portions being nested, and c) a top cover **(78)** covering the first and second container portion inlets, the system characterized by:

the first container portion outlet opening being closed with a material which is impermeable to undissolved reagents held in the container and is freely permeable to aqueous solutions; and,

the second container portion second end outlet opening being defined by a porous portion of the second peripheral wall.

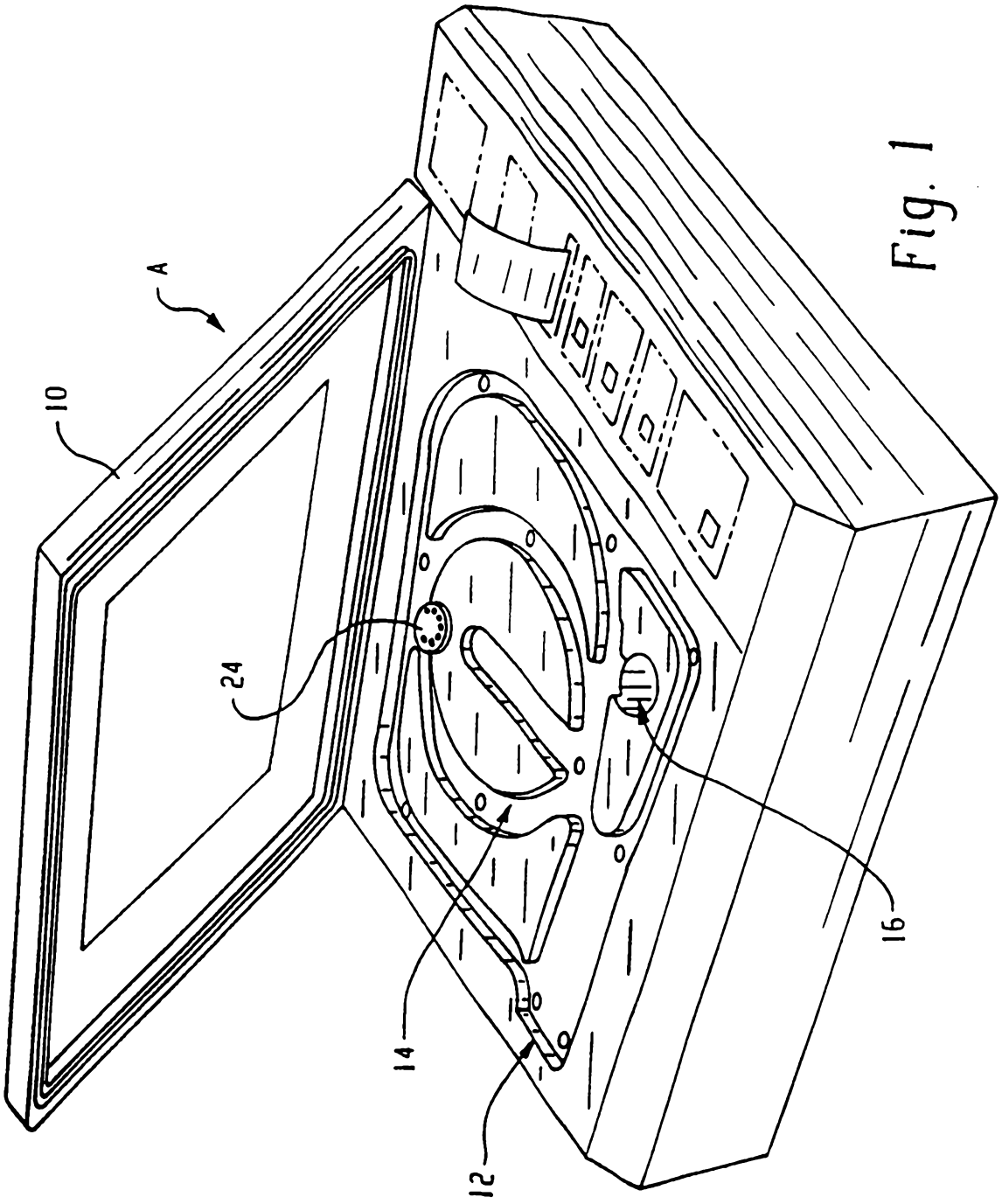


Fig. 1

Fig. 2

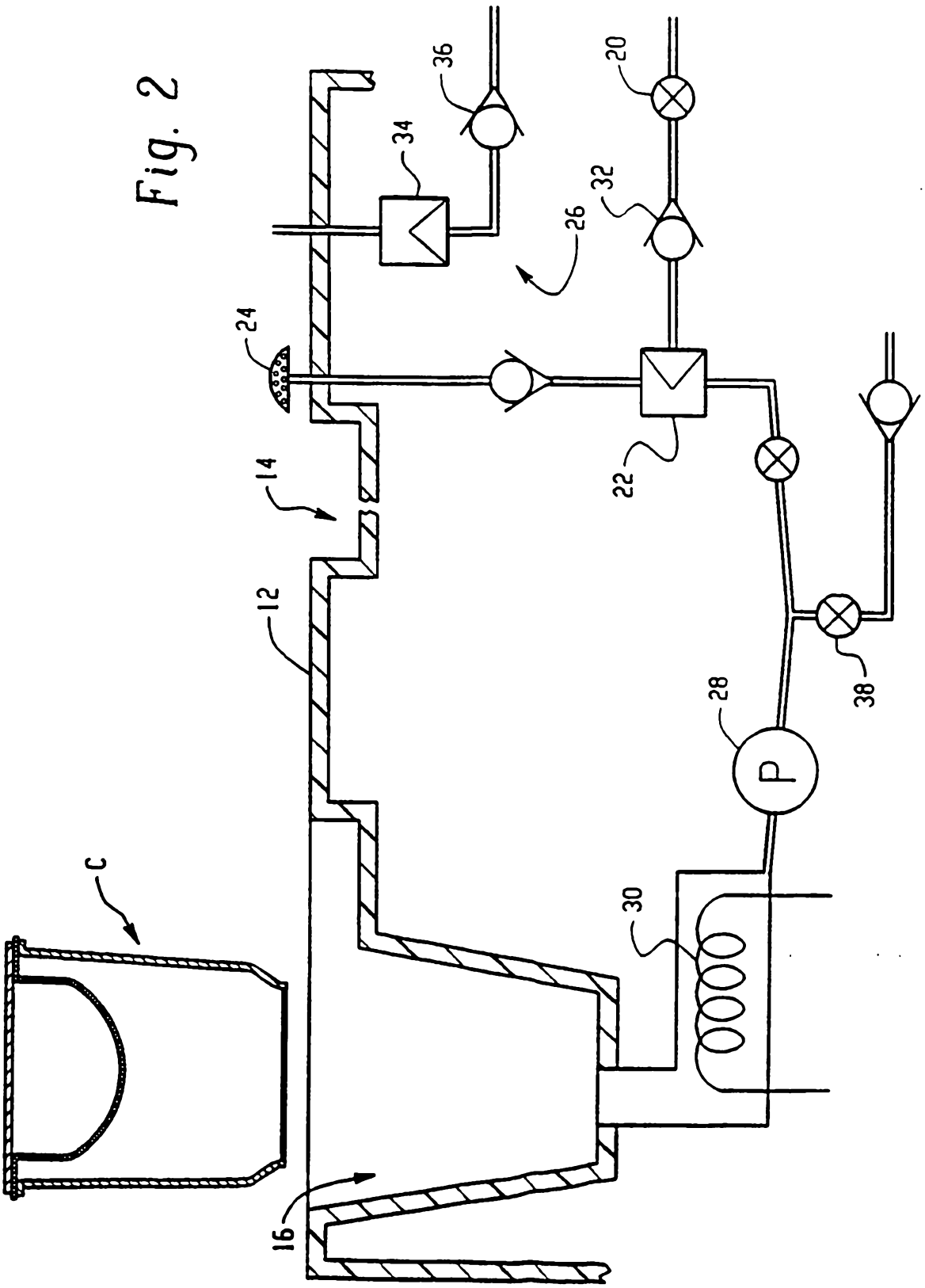
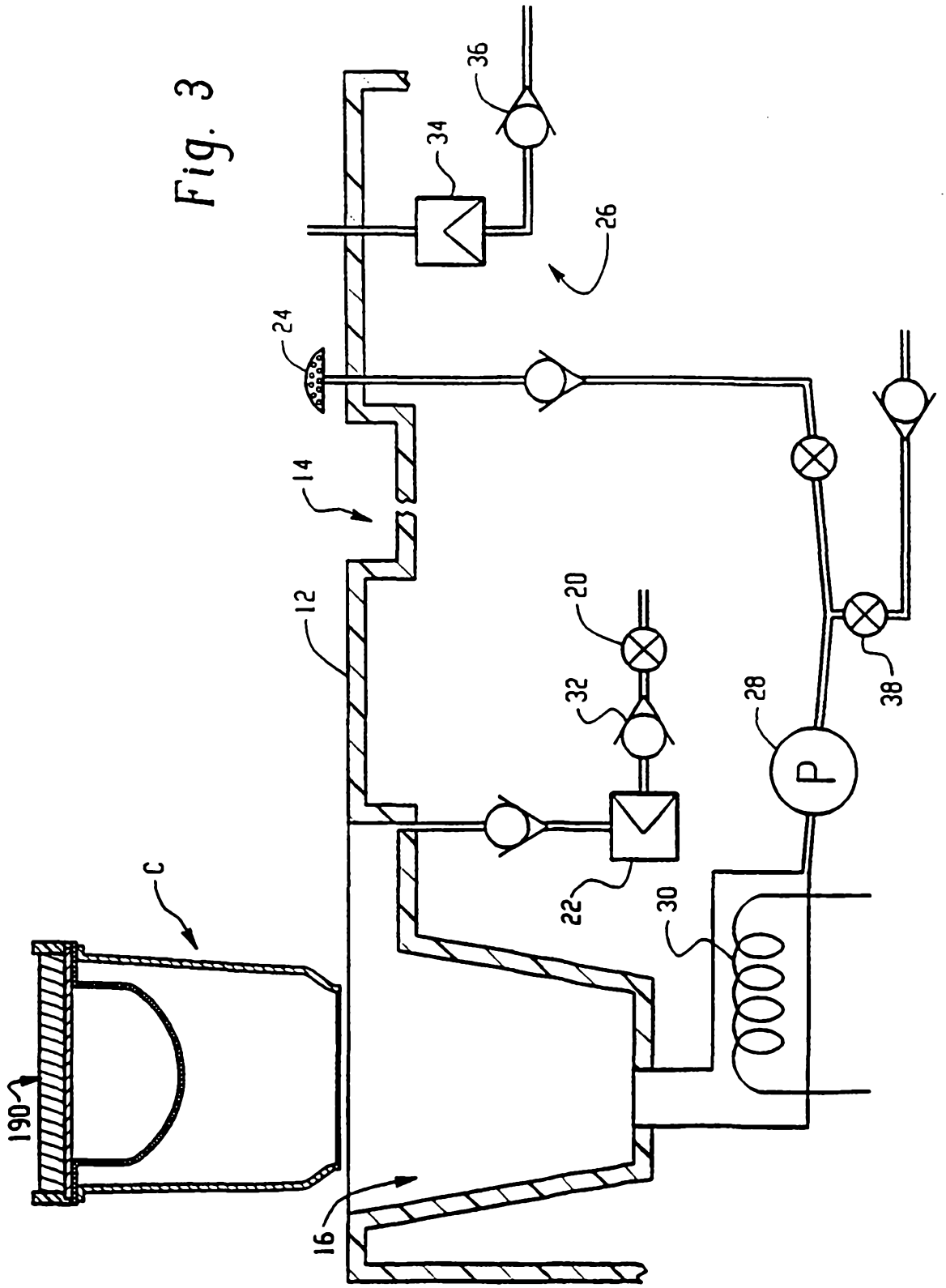


Fig. 3



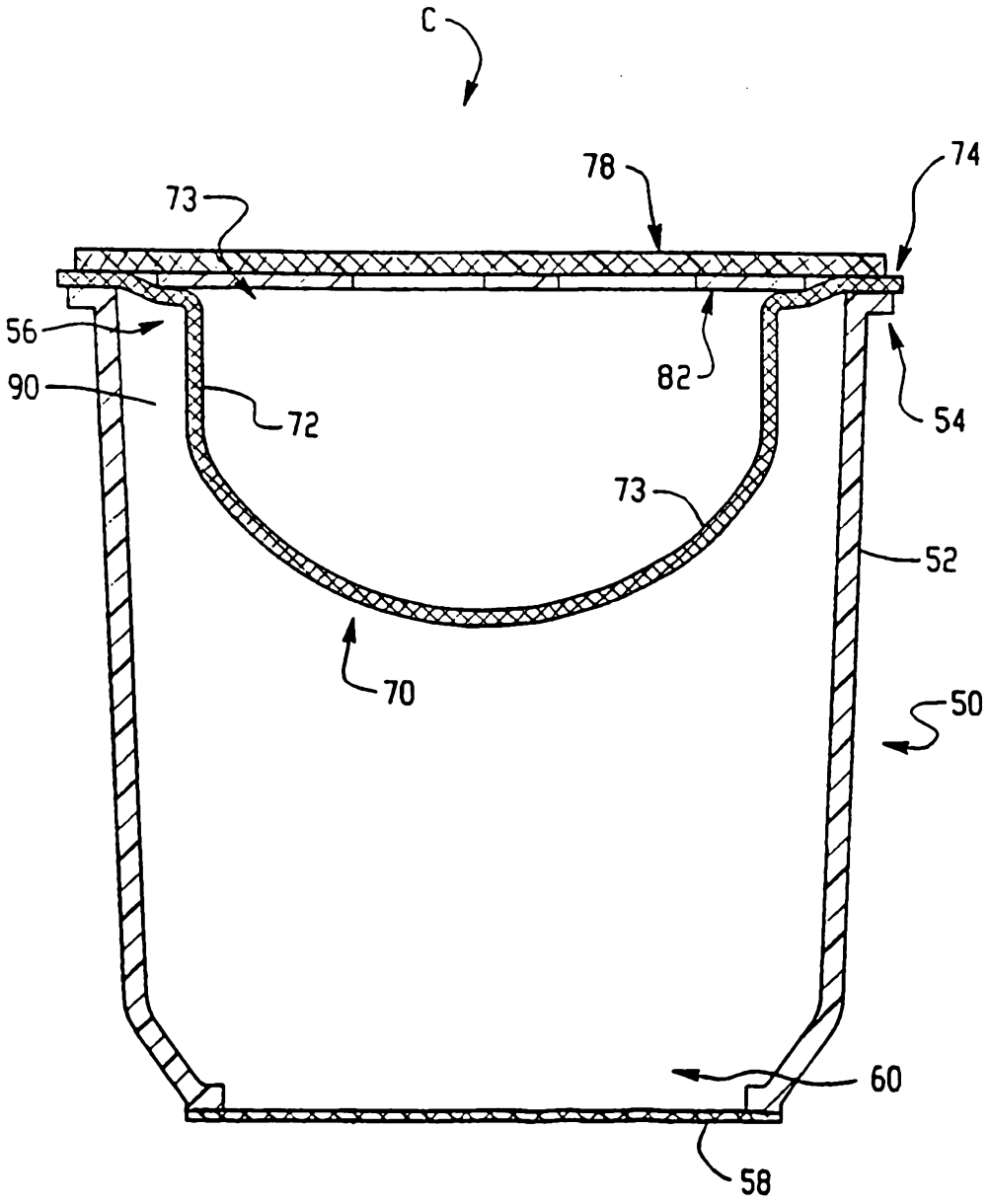


Fig. 4

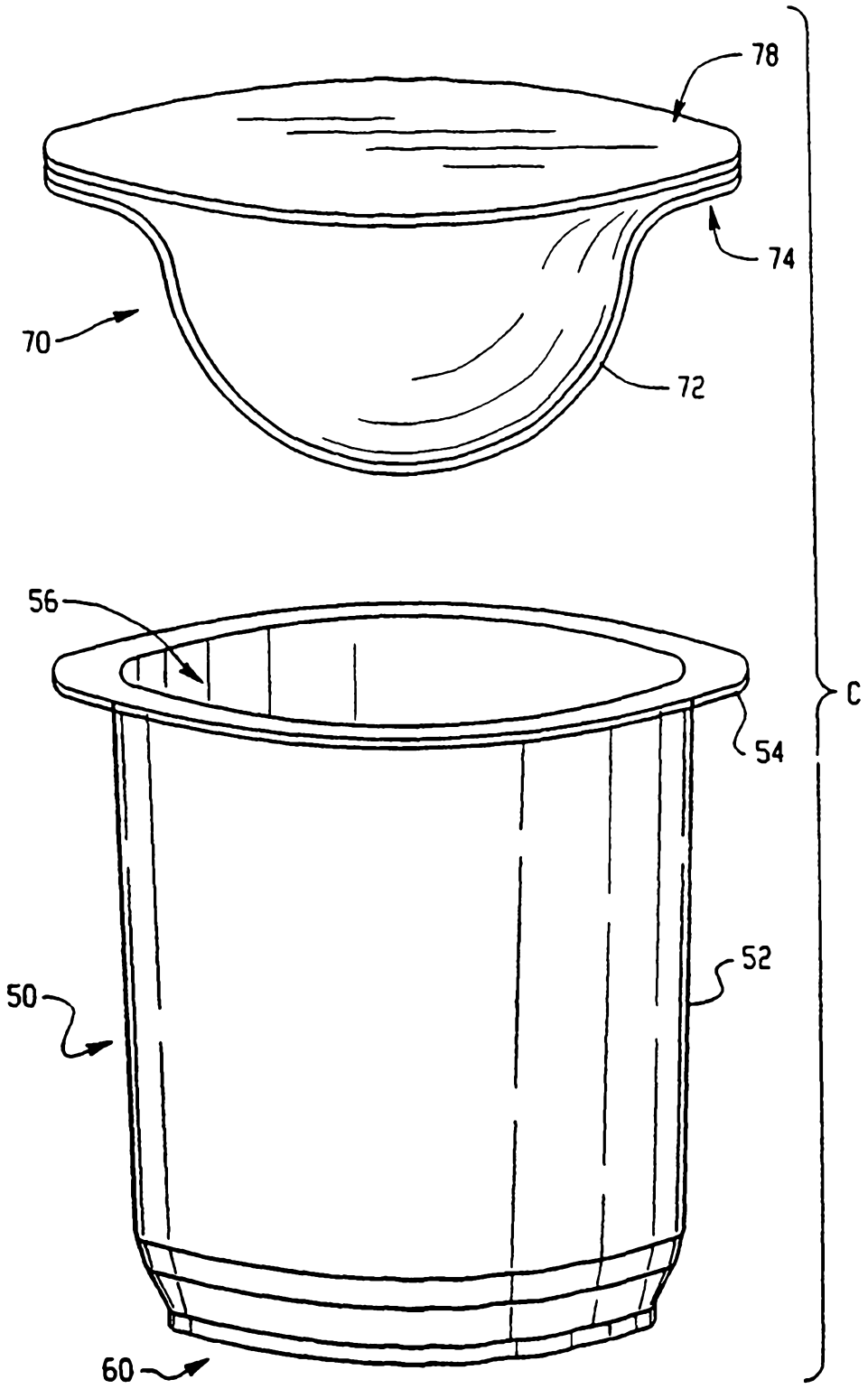


Fig. 5

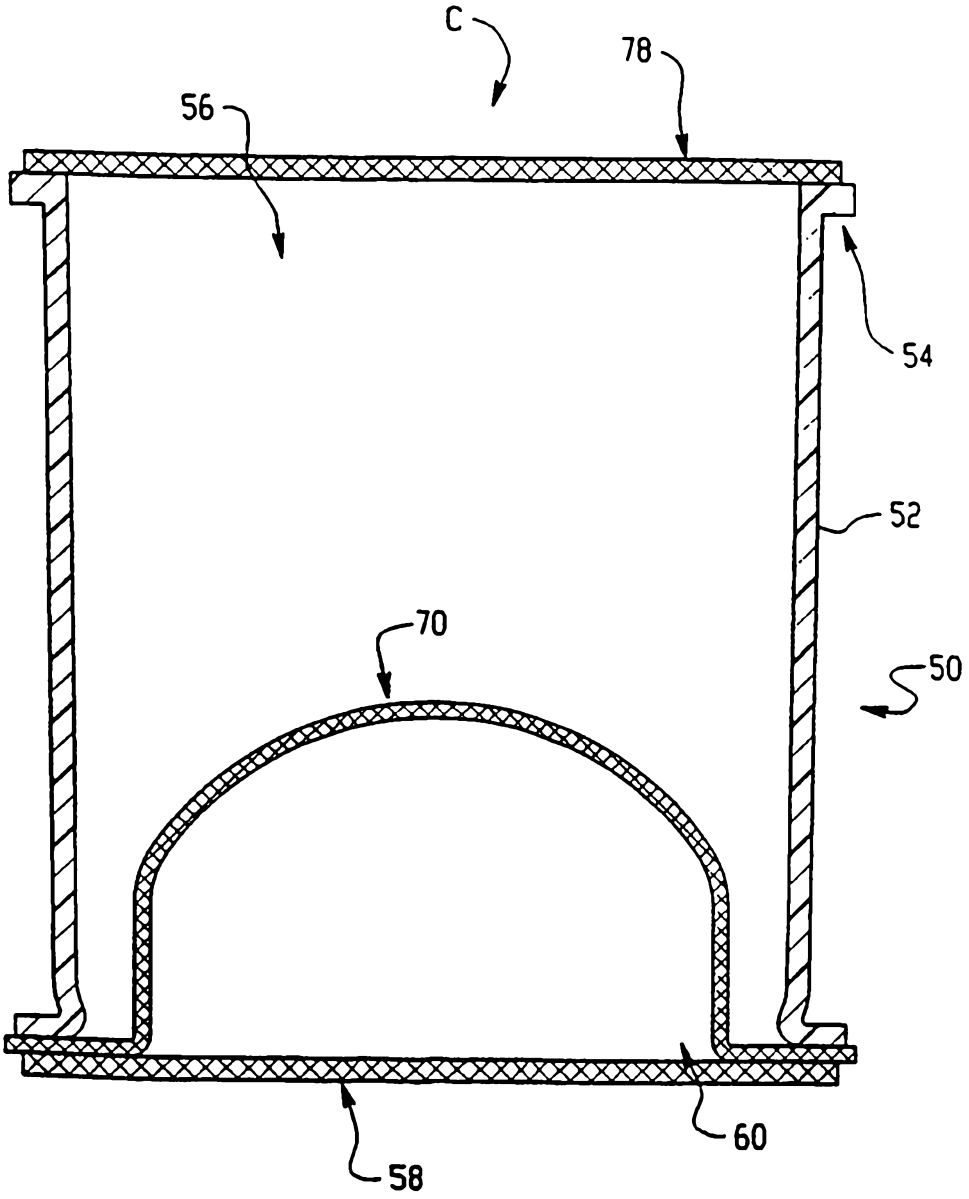


Fig. 6

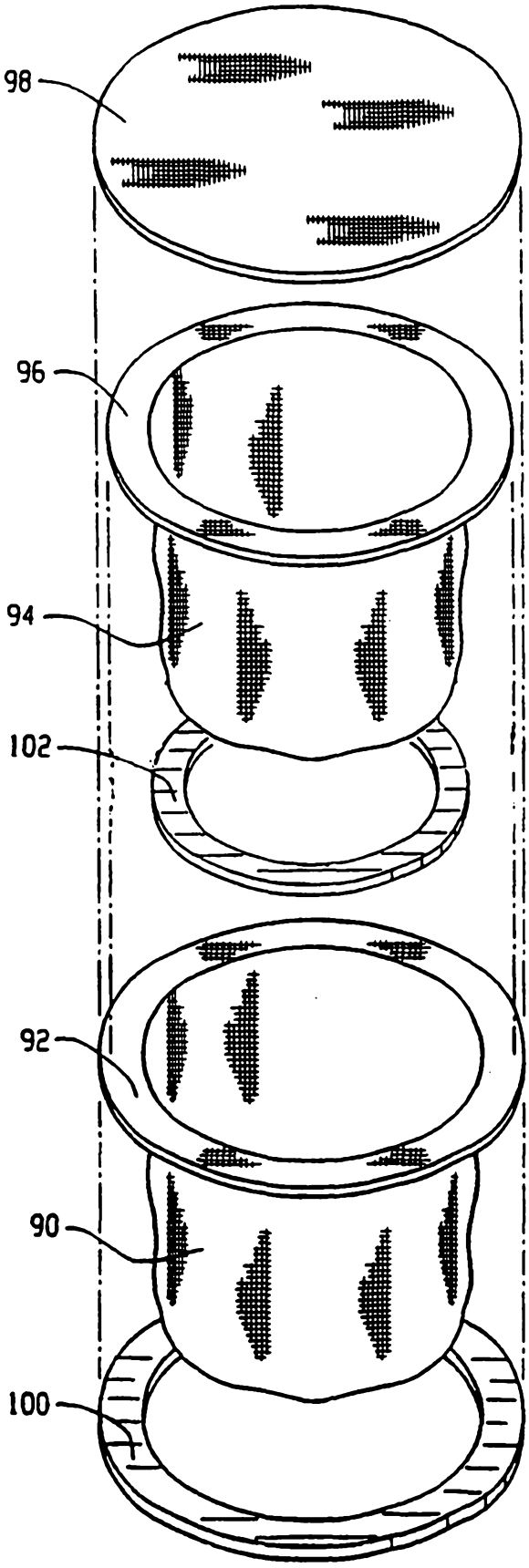


Fig. 7

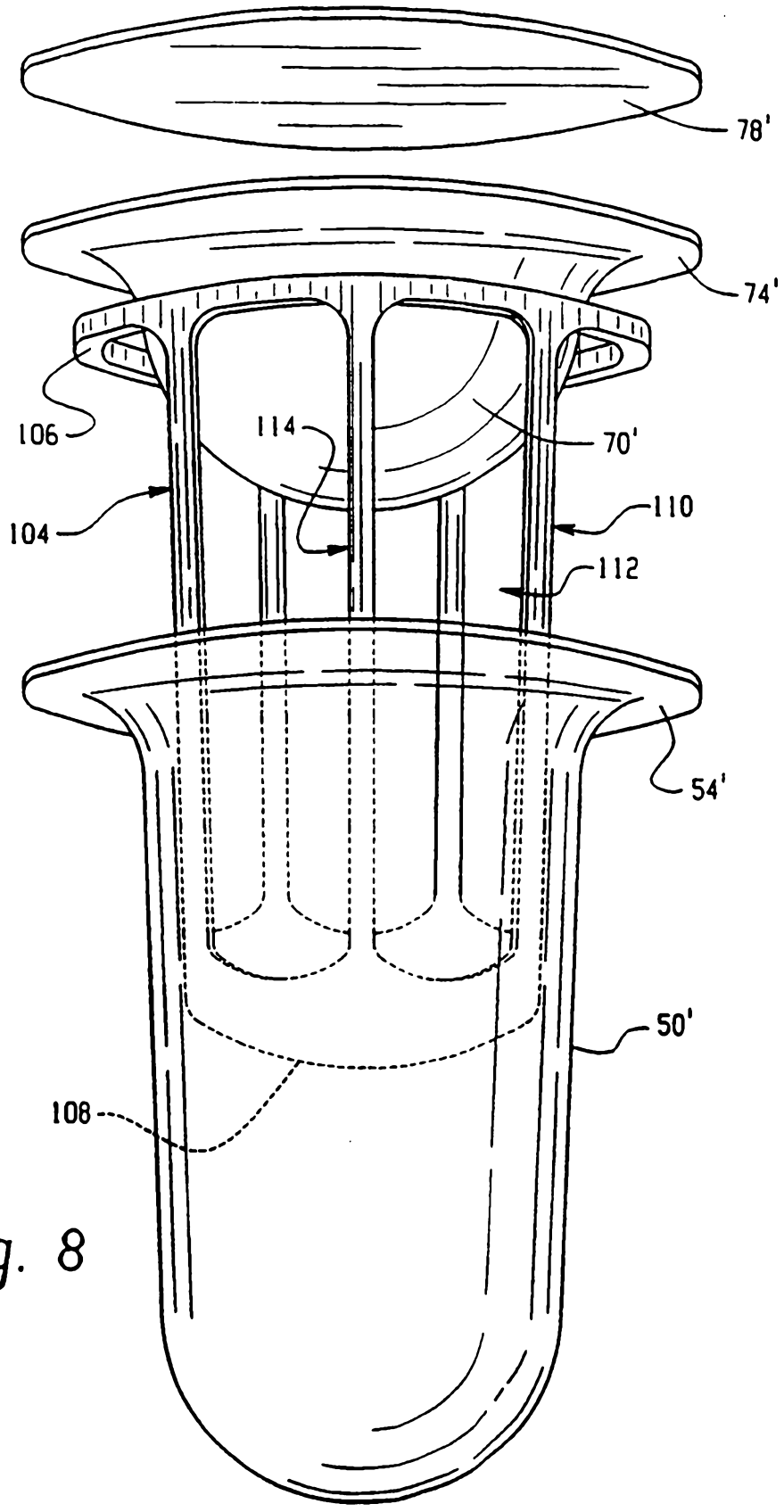


Fig. 8

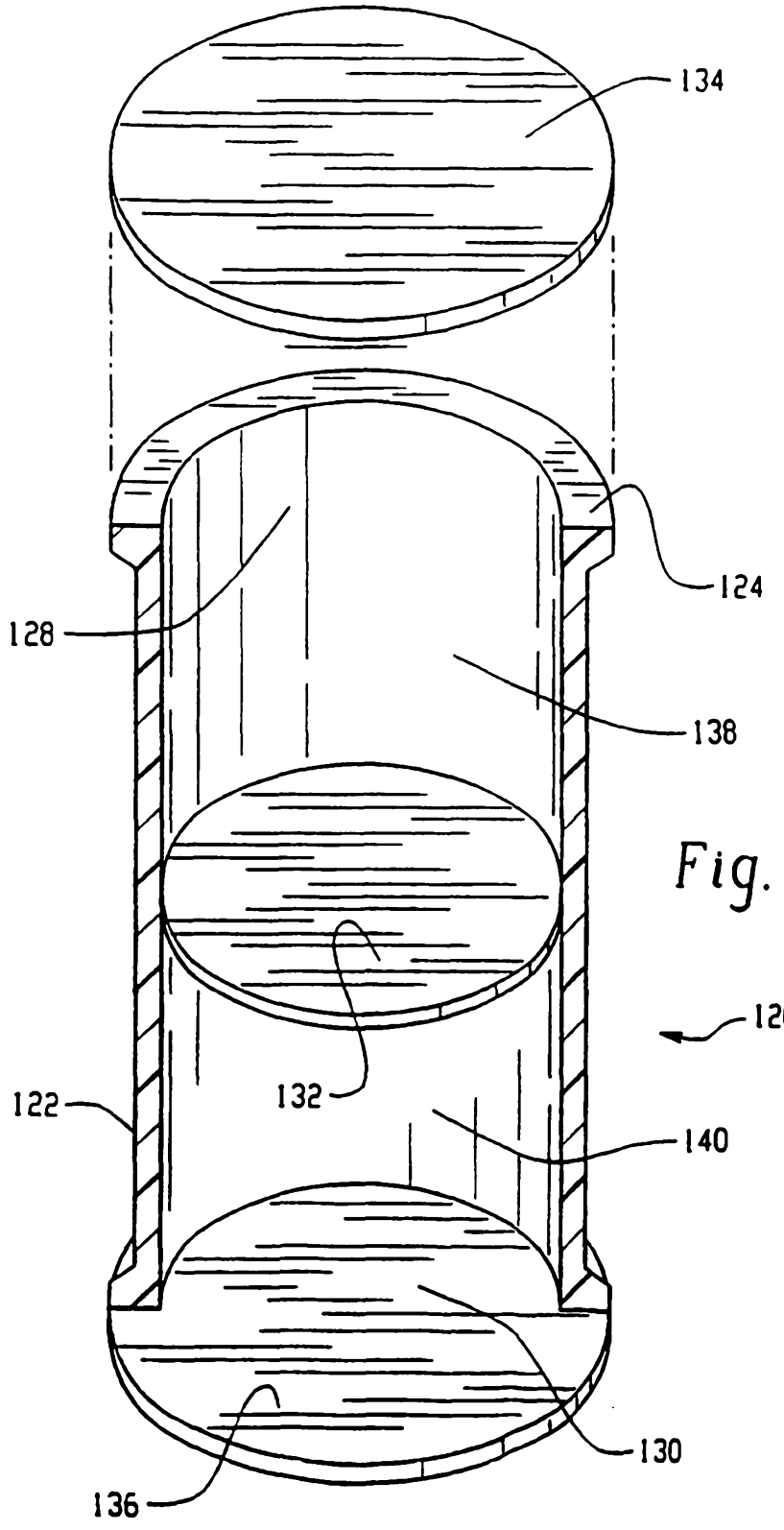


Fig. 9

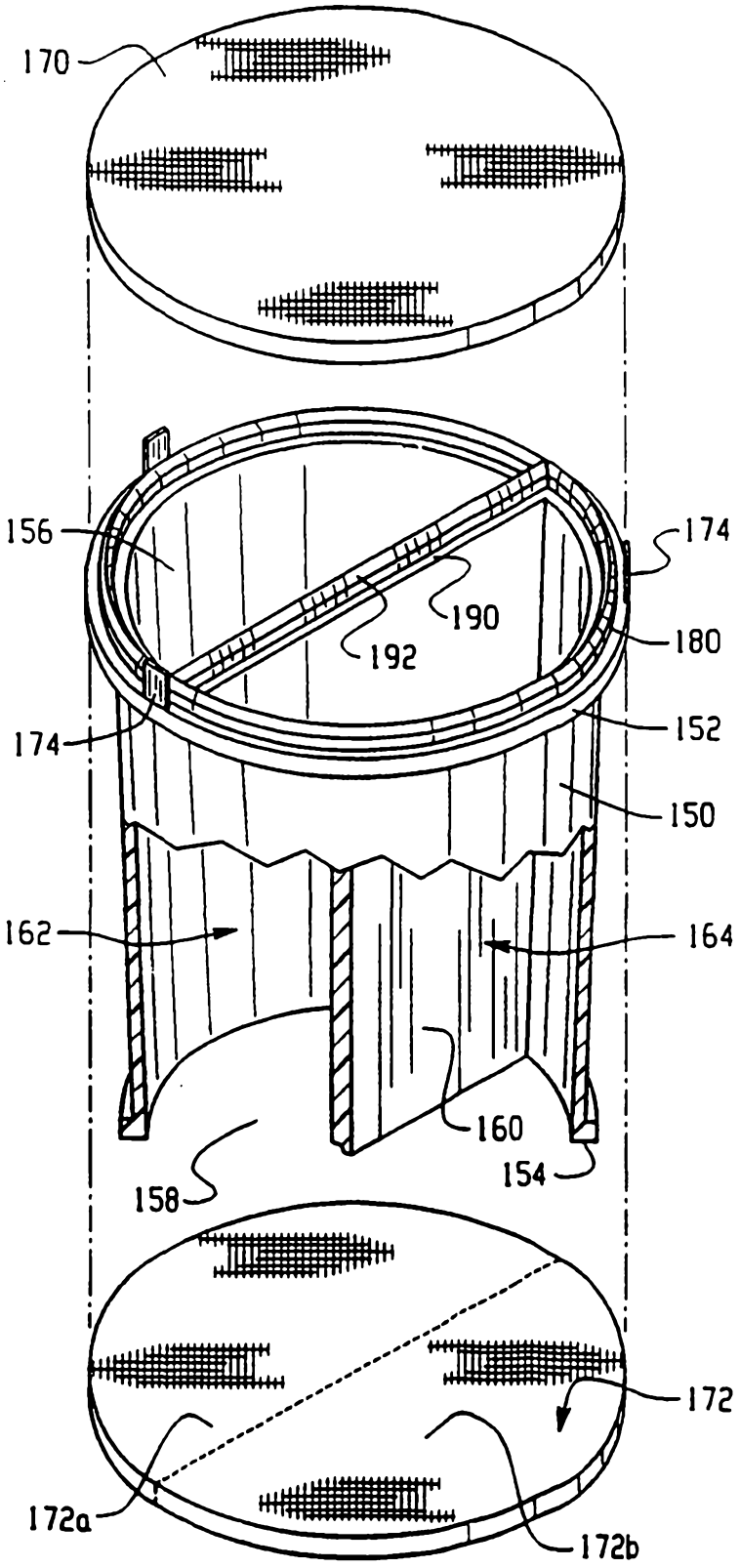

170
156
174
190
192
180
174
152
150
162
164
160
158
154
172
172a
172b

Fig. 10

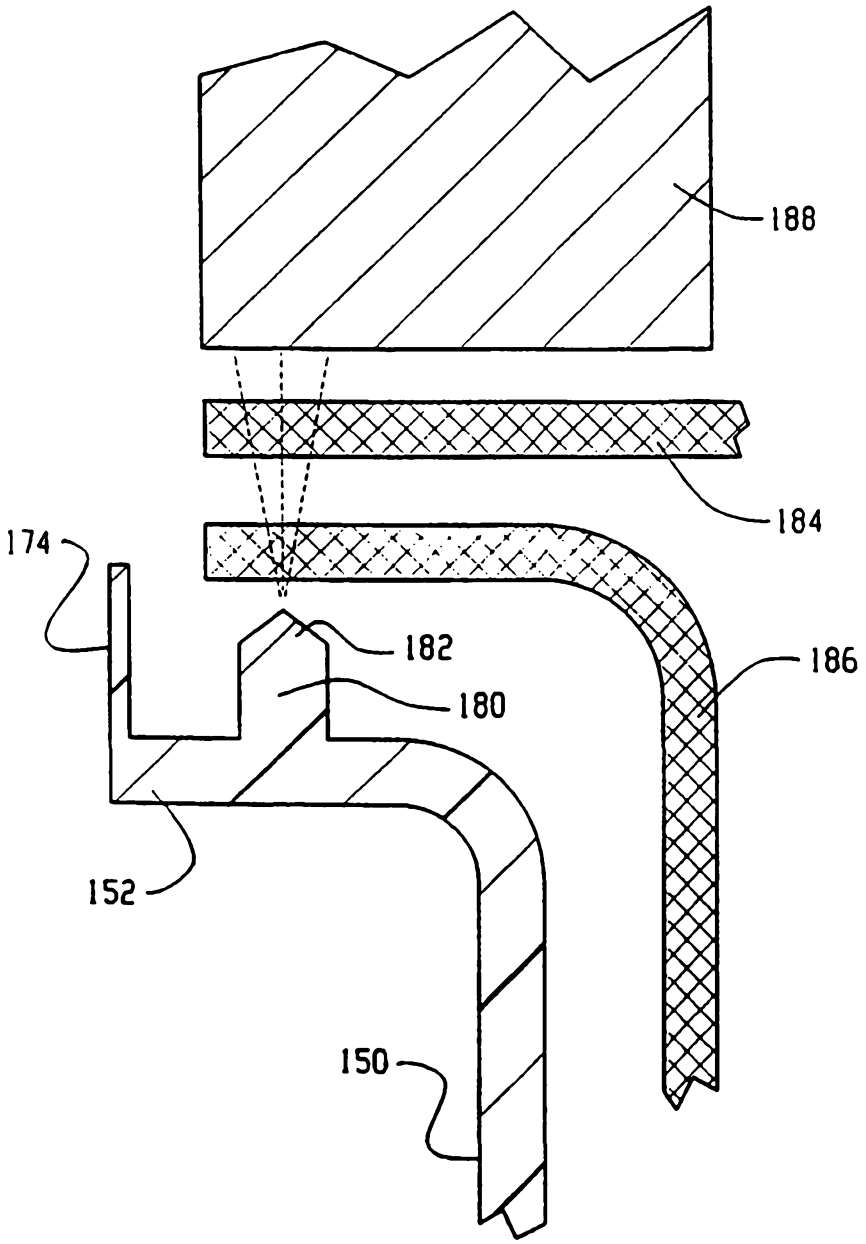


Fig. 11

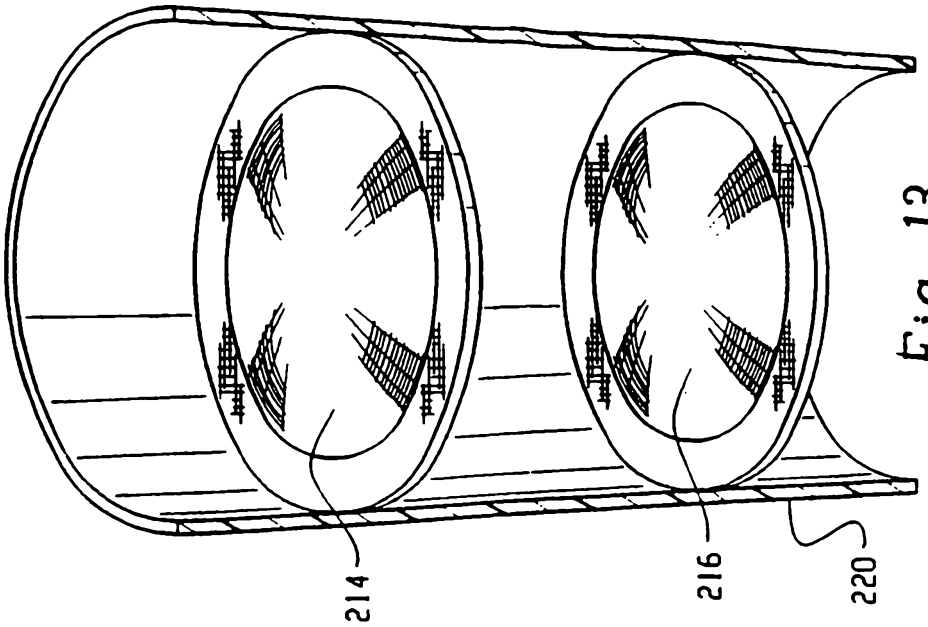


Fig. 13

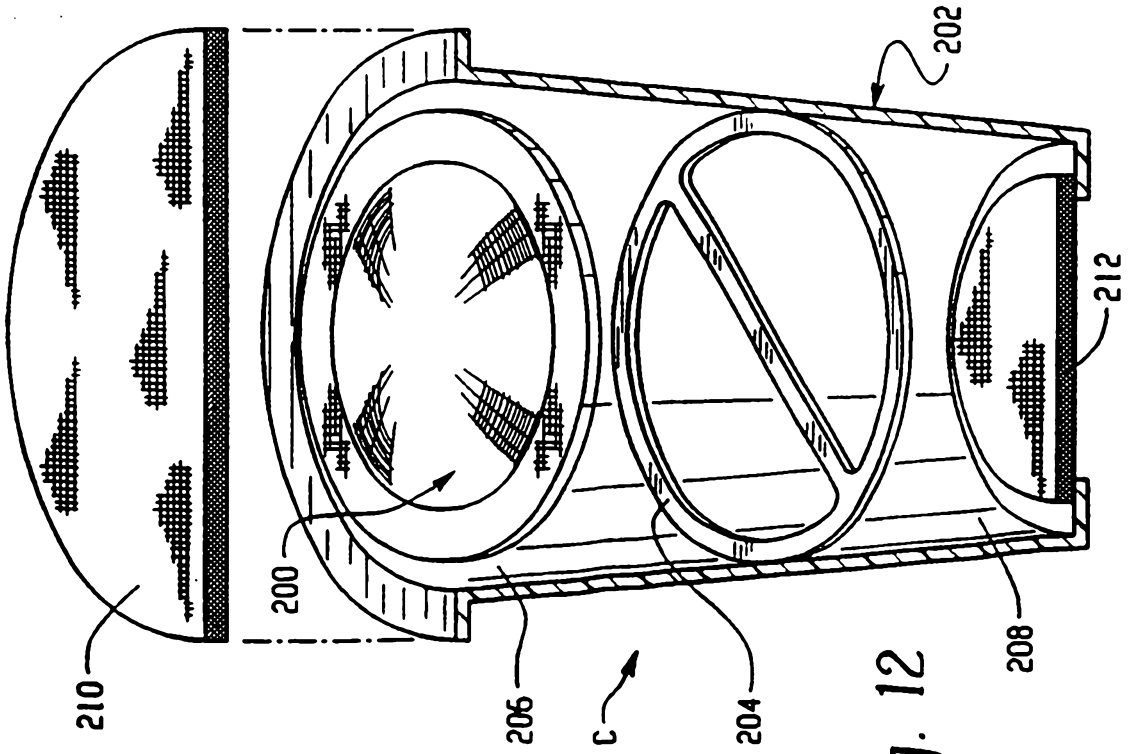


Fig. 12