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## (54) Sterilant concentrate injection system.

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## Description

### Background of the Invention

The present invention relates to ampule systems for maintaining components, particularly reactive components and reagents, separated until immediately prior to use. It finds particular application in conjunction with sterilant systems in which a peracetic sterilant as well as buffers and corrosion inhibitors are diluted or dissolved immediately prior to a sterilizing operation. However, it is to be appreciated that the present invention will find utility in other multi-component systems which are intermixed in preparation for use, such as photographic systems, coating systems, medications, and the like.

Heretofore, most medical facilities have used steam autoclave sterilization systems. Commonly, medical instruments and equipment were transported to a central sterilizing facility where they were sterilized under the supervision of sterilizing room technicians. In a steam autoclave, which typically has a cycle time of one to two hours, the equipment was subject to superheated steam at high pressures. After an appropriate sterilizing duration, the autoclave was depressurized and cooled.

Instruments and equipment which could not withstand the temperature of an autoclave were commonly sterilized with ethylene oxide gas. After the equipment was sealed in a sterilizing chamber, the highly toxic ethylene oxide gas was introduced under pressure and allowed to remain for a couple of hours, as was appropriate to the selected sterilizing cycle. After the sterilizing cycle, the equipment could not be utilized until absorbed ethylene oxide was removed. This generally required about 12 to 16 hours in a vacuum or about 72 hours in ambient atmospheric conditions.

Liquid sterilization systems were also available for equipment which could not withstand the autoclave or the ethylene oxide systems. However, most were manually performed. That is, the equipment was immersed in a vat or tank that had been filled with a sterilizing solution, such as stabilized hydrogen peroxide or glutaraldehyde. However, because long immersion times on the order of 6 to 10 hours, were commonly required for sterilization, the liquid systems were more commonly used for disinfecting. Because the liquid sterilizing or disinfecting agents were toxic to human tissue, the equipment had to be rinsed before it could be used with human patients. Frequently, non-sterile tap water was used as the rinse.

Sterilization connotes the absence of all life forms including bacterial endosphores which are the living organisms most resistant to known sterilants. By contrast, disinfection only connotes the absence of pathogenic life forms. As is to be appreciated, establishing the absence of all life forms for sterilization is more readily documented and controlled than the elimination of pathogenic but not all life forms for disinfection.

Because bacterial spores are the life form which is most resistant to sterilants, they are commonly used as a reproducible, stable indicators of the effectiveness of a sterilization product. For medical sterilizers, a sterility assurance level (SAL) of less than or equal to one chance in one million of having an item contaminated by a bacteria spore is generally regarded as the minimum acceptable level for medical devices. In practice, this level of assurance is obtained by a establishing the exposure time required to sterilize a given quantity of bacterial endosphores known to be resistant to the sterilant. The destruction rate of the spore is commonly logarythmic. From the logarythmic destruction rate, commonly denoted by a D value, the exposure time required for an insurance level of one in a million ($10^{-6}$) can be readily calculated. Because pathogenic microorganisms, which are mostly vegetative forms of bacteria, do not have the stability to derive a D value or its equivalent, there is no readily available biological indicator to show the effectiveness of a disinfectant.

In accordance with the present invention, a new and improved reactive agent dispensing system is provided which overcomes the above referenced sterilizer problems and analogous problems and other equipment in which reactive agents are released contemporaneously with use.

### Summary of the Invention

In accordance with one aspect of the present invention, a spill resistant, vented ampule is provided. A vent passage defines an vent aperture at one end. A sealed exterior wall defines an interior volume surrounding the vent aperture such that the vent aperture is generally centrally located in the interior volume. The exterior wall is sealed to the vent passage such that the vent aperture provides the ocily ingress and egress to the interior volume.

DE-B-1 216 770 (Hans Dohse) discloses a sealable, vacuum-pack container which comprises a cannister and a co-operating deformable lid therefor, the cannister including an integral vent passage that extends co-axially the length of the cannister from a first end to a second end adjacent the lid, the second end being formed with an aperture which is sealed by the lid when the latter is deformed. The vent passage provides a means of pumping air from the cannister to provide a vacuum therein which inwardly deforms the lid, thereby bringing it into sealing contact with the

aperture.

The operation of the Dohse structure is quite different from the ampule of this invention; in the latter the vent aperture is spaced apart from the exterior wall by an amount such that it is substantially at the volumetric or geometric centre of the ampule.

In accordance with more limited aspects of the invention, a gas permeable, fluid blocking membrane is mounted across the vent aperture. In this manner, gas is vented from the interior volume but the leakage of fluid is retarded. A volume of a liquid reagent which is less than half of the interior volume is contained within the ampule. The liquid volume is selected such that a top surface of the liquid is below the vent aperture with the ampule disposed in any orientation.

In accordance with another aspect of the present invention, a siphon extraction system is provided for drawing the liquid from the ampule. A small bore tubular member is passed through the vent passage and into the interior volume. The tubular member is connected with an aspirator for withdrawing the liquid from the ampule and intermixing it with a second reagent. In the preferred embodiment, the first reagent is a strong sterilant concentrate such as peracetic acid and the second reagent is a dilutant such as water.

In accordance with another more limited aspect of the present invention, the water and aspirated sterilant concentrate are circulated through a container holding an item to be sterilized and through a tubing system which interconnects the container with a source of sterile rinse water until the item, the interior of the container, and the tubing system are all sterilized. In this manner, the sterile rinse solution cannot carry bacterial contaminants from the tubing into contact with the sterilized item during a rinse portion of the sterilizing cycle.

One advantage of the present invention is that a sterilizing system is provided that assures sterility.

Another advantage of the present invention is that a one dose sterilant cartridge is provided to assure proper reagent formulation and eliminate operator error.

Yet another advantage of the present invention is that it provides a vented, liquid containing ampule which may be disposed in any orientation without leaking liquid.

Still further advantages of the present invention will become apparent upon reading and understanding of the following detailed description.

## Brief Description of the Drawings

The invention may take form in various parts and arrangements of parts or 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 a perspective view of a sterilizing apparatus in accordance with the present invention;

FIGURE 2 is a tubing diagram of the sterilizer of FIGURE 1;

FIGURE 3 is a detailed cross sectional view of the aspirator sterilant withdrawal assembly of FIGURE 1;

FIGURE 4A, 4B, and 4C are detailed cross sectional views of the ampule of FIGURE 3 in a range of orientations;

FIGURES 5A, 5B, 5C, and 5D illustrate a preferred method of loading sterilant and powered reagents into the sterilizing apparatus;

FIGURE 6 illustrates an alternate embodiment of a sterilant ampule in accordance with the present invention;

FIGURE 7 is another alternate embodiment of the sterilant ampule;

FIGURE 8 is a top view of yet another alternate embodiment of the sterilant ampule; and,

FIGURE 9 illustrates an alternate reagent discharging apparatus.

## Detailed Description of the Preferred Embodiments

With reference to FIGURES 1 and 2, a dilutant or water source **10** supplies water or other fluid reagents. In the preferred sterilizer embodiment, the water source includes a length of tubing **12** connected with a water spigot or other building plumbing and a control valve **14** for selectively preventing and permitting the flow of water to a water sterilizing means **16**. In the preferred embodiment, the water sterilizing means is a filter which removes particulates which are as large or larger than bacteria.

A tubing system connects the filter with a container or module **20** for receiving an item to be sterilized. In the preferred embodiment, the container is defined by a removable tray **22** configured in accordance with the item to be sterilized, e.g. an endoscope. A lid **24** is sealed to the tray by a resilient gasket **26** to complete the container. Optionally, a transparent window **28** is defined the in the lid.

During a fill cycle, sterile water flows through the tubing system filling itself and the container **20**. The water flows through a spray nozzle **30** and a container distribution manifold **32** into the container and a reagent receiving well **34**. As more water is introduced, vent lines **36** are filled with excess water and discharged through a check valve **38** into a drain **40**.

A reagent introduction system **42** selectively supplies sterilant, buffer, detergent, and corrosion inhibitors to the dilutant. More specifically, an aspirator **44** selectively withdraws sterilant concentrate from an ampule **46**. Powdered reagent received in the well **34** is dissolved as water flows in from the container.

After the system is filled, pump **50** selectively draws water from the container **20** through the well **34** and aspirator **44**. Recirculating the water dissolves the powdered reagents and aspirates the sterilant from the ampule and circulates the sterilant and reagents through the tubing system **18**. Preferably, the vent line **36** is very short and of a substantial diameter such that the solution is circulated over exposed services of the drain check valve **38** and a vent check valve **52**. A heating coil **54** adjusts the temperature of the solution. Recirculation continues until the item, the interior of the container, and all exposed surfaces of the tubing system and valves are sterilized.

As the sterilant solution is drained through drain valve **56**, sterile air is drawn into the system through an air sterilizing means - preferably a filter that removes any particles the size of a bacteria or larger. The fill valve **14** is opened and the drain valve **56** is closed such that the sterile filter **16** provides a source of sterile rinse. Note that the sterile rinse passes only along sterilized surfaces to assure sterility. The pump **50** circulates the sterile rinse throughout the system. Sterile rinse is drained by opening drain valve **56** again. By closing a valve **60**, the pump **50** functions to pump liquid from the system out the drain **40**. Additional drain lines (not shown) and aspirators or pumps (not shown) may be provided for removing liquid from all regions of the system.

With particular reference to FIGURE 3, the sterilant aspirator system **42** includes a hollow, tubular needle or tube **70** which is inserted into the ampule to withdraw the sterilant. The needle **70** is connected with arm **72** which selectively swings the needle into and out of alignment with the ampule **46**. A vertical tubular portion **74** is telescopically received in a stationary tubular portion **86**. A coil spring **78** biases the arm tubular portion upward, hence, the needle **70** out of contact with the ampule. When the arm is locked into proper alignment with the ampule, closing the lid **24** biases the arm downward against the coil spring **78** forcing the needle **70** into the ampule. Water pumped through the aspirator **44** aspirates the sterilant from the ampule into the fluid flow. Preferably, the aspiration rate is selected such that the sterilant is aspirated gradually over the time required to circulate the water around the system one time.

With reference to FIGURES 4A, 4B, and 4C, the sterilant ampule **46** has an exterior wall **80** which defines an interior volume **82** therein. A linear vent passage **84** integral with the exterior wall defines a passage extending linearly from the exterior to a vent aperture **86**. In the preferred embodiment, the vent passage extends linearly along a first axis **88** to act as a guide for the needle **70**. In this manner, the needle **70** passes through the vent aperture **86** into the interior volume.

In the illustrated embodiment, the exterior wall includes a circularly cylindrical peripheral wall **90** a minimum radius **r** from the first axis. End walls **92** and **94** extend generally transverse to the axis **88** and are integrally sealed to the peripheral wall. The vent aperture **86** is centrally disposed in the volume. More specifically, the vent aperture **86** is disposed a minimum radial distance **r** from the peripheral wall and generally a height **h** from each end wall. The ampule is charged less than half full with a fluid sterilant **96** such that its upper surface **98** is disposed below the vent aperture **86**. More specifically, the interior volume **82** is configured relative to the volume of the sterilant such that the sterilant depth is always less than **h** and **r** regardless of the orientation of the ampule. In this manner, the liquid does not leak from the vent aperture **86** regardless of the orientation of the ampule **46**.

To protect against leakage due to splashing, a porous membrane **100** is disposed across the vent aperture **86**. The membrane is a fine woven material which has a median pore size sufficiently small compared to the drop size and wetting ability or surface tension of the liquid sterilant on the fiber material that the sterilant is effectively blocked from passing therethrough. Similarly, water is prevented from flowing freely into the ampule. When the needle **70** passes the vent aperture **86**, its cambered end distorts the woven porous material moving the fibers out of its way. The natural resiliency of the fibers tends to return them to their original position when the needle is withdrawn. Any sterilant residue is held in the ampule by the position of the vent aperture **86** and the membrane **100**. In this manner, after the sterilization cycle is complete, the operator is protected from contacting the full strength sterilant concentrate directly. Analogously, no dilution of the sterilant concentrate occurs if a sterilizing cycle is aborted before aspiration starts.

With reference again to FIGURE 1 and particular reference to FIGURES 5A-D, in operation, the ampule **46** is disposed in the bottom of a see-through larger container **110**. The container **110** has a peel-off top **112** which provides access to its contents. The container is shaped such that the ampule **46** fits snugly in the bottom and other powdered reagents **114** are disposed on top.

In FIGURE 5B, the sterilizer arm **72** is swung out of the way and the powdery agents are poured into the well **34**. The ampule **46** is supported by rods or other ampule supporting means **116** in a preselected position in the well. In the illustrated embodiment, the ampule is symmetric, thus assuring a central position of the vent aperture **86**. Alternately, the support means **126** may include a key or key means which interacts with a selected portion of the ampule to assure proper alignment and positioning.

In FIGURE 5C, the aspirator arm **72** is swung and locked until the needle **70** is directly over the vent aperture **86**. Because the ampule is accurately positioned in the well, the aspirator arm is adjusted to lock itself in the aligned position without hand aligning by the operator. When the lid **24** is closed as in FIGURE 5D, the lid cams the aspirator arm against the coil spring **78** moving the tip of the needle **70** through the vent aperture into the proper position within the ampule. Optionally, the ampule may have a small well directly in line with the vent to accommodate the tip of the aspirator needle and assure more complete emptying of the ampule.

In the preferred embodiment, the powdered materials include buffers, detergents, and anti-corrosive agents. The anti-corrosive agents are selected in accordance with the selected sterilant and the nature of the materials in the sterilized items, such as brass fittings, that might be subject to corrosion. Further to the preferred embodiment, the sterilant is peracetic acid. Peracetic acid tends to liberate small quantities of oxygen during transportation and storage. Accordingly, the vent **86** insures that the pressure within the ampule does not become so great that it ruptures. High pressure could also cause spraying of the sterilant upon entry by the needle **70**. Once the peracetic acid is diluted and mixed with the buffers, detergents, and corrosion inhibitors, its efficacy as a sterilant is lost after a relatively short duration. The loss of efficacy is much slower than a normal sterilizing cycle, but too short for an ampule containing all the ingredients to have a satisfactory shelf life.

With reference to FIGURES 6, 7, and 8, the ampule may take various shapes. For example, as shown in FIGURE 6, the exterior wall **80** may be spherical. The vent aperture is still disposed in the center of the sphere and the fill level is such that the depth of the sterilant is smaller than the radius of the spherical interior volume. Alternately, as illustrated in FIGURE 7, the vent aperture may be disposed eccentrically. However, the vent aperture is still disposed sufficiently close to the center of the interior volume that for the volume of sterilant provided, the upper surface of the sterilant always remains below the vent aperture. As yet another alternative, as shown in FIGURE 8, the ampule may have a groove or key way **120** in the exterior wall or a groove or aperture **122** in an exterior flange to assure that the ampule is disposed in a preselected alignment. By selecting a sufficiently fanciful or arbitrary exterior shape or key pattern, protection can be had against inserting generally round ampules from other equipment which might contain substances other than sterilants.

With reference to FIGURE 9, the sterilant, buffer, detergent, anti-corrosives, and other reagents may be retrieved from a two compartment container in other ways. For example, the liquid containing ampule **46** may be mounted in the upper portion of a clear plastic cup **110** with the powdered components or reagents **114** in the lower portion. The powdered components are selected to include a material which changes color upon exposure to the liquid components. In this manner, a visual check is provided that the liquid components have not leaked into the powdered components. A vent **124** in the outer cup provides communication between the ampule and the atmosphere. Rather than siphoning out the liquid sterilant, a first puncturing ram **130** can extend into the lower part of the cup to introduce water or other dilutant into the cup and dissolve the powdered reagents. Additional water flow into the cup may be had when a first cutter **132** cuts the cup allowing water pumped into the well to circulate through the powder region of the cup. Movement of additional cutters **134** pierce both the cup and the sterilant ampule. In this manner, the powdered ingredients can be dissolved and mixed with recirculating water or other dilutant before the sterilant is released. In the illustrated embodiment, cutters **132** and **134** are mounted on a common shaft **136** which is incrementally rotated to cause staged cutting of the cup and the ampule.

The invention has been described with reference to the preferred embodiment. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such alterations and modifications insofar as they come within the scope of the appended claims.

## Claims

1. An ampule which comprises:

an exterior wall (80) defining an interior volume (82);

a vent passage (84) sealed to the exterior wall and defining a vent aperture (86) at one end of the vent passage, the vent aperture being surrounded by the exterior wall;

characterised in that:

the vent aperture (86) is disposed substan-

tially at a volumetric or geometric centre of said interior volume; and the ampule contains a fluid reagent (96) that partially fills said interior volume and whose upper surface remains below the vent aperture (86) regardless of the orientation of the ampule, whereby gases are vented from said interior volume while the liquid reagent is retained in said interior volume.

2. An ampule according to Claim I, which includes a gas-permeable, fluid-blocking membrane (100) mounted across the vent aperture.

3. An ampule according to Claim 1 or 2, wherein the vent passage is linear and of relatively small diameter and, in use, acts as a guide for a hollow tube (70) passing along the vent passage and through the vent aperture for withdrawing fluid reagent from the ampule, whereby any fluid reagent retained in the ampule after the hollow tube has been withdrawn is inhibited by the position of the vent aperture from being discharged from the ampule.

4. An ampule according to Claim 1, 2 or 3, wherein the liquid reagent comprises peracetic acid.

5. An ampule according to any of the preceding claims, wherein the ampule is disposed in a well (34) having a vent aperture therein, the well further including a powdered reagent including at least one of a buffer, a detergent and an anti-corrosive agent.

6. A microbial decontaminating system comprising:

an ampule (46) as claimed in any of the preceding claims;

a source of water (10);

a container (20) for holding an item to be microbially decontaminated;

a tubing system (12) for providing a fluid flow path for received water from the water source to the container;

a reservoir (34) for receiving powdered reagents including at least one of a buffer, a detergent, and anti-corrosive, and for receiving the ampule;

the reservoir (34) being connected with the tubing system (12) such that the received water dissolves said powdered reagent to provide an antimicrobial solution; and

discharging means for selectively discharging said antimicrobial solution from the ampule into the water.

7. A system according to Claim 6, wherein the ampule contains an antimicrobial solution in an amount such that the ampule is less than half-filled with the solution.

8. A system as claimed in Claim 6, wherein the tubing system includes a valve for preventing the inflow of additional water after the tubing system and container are filled with water and a pump connected with the tubing system for recirculating antimicrobial solution containing water through the tubing system and the container such that the container and the tubing system are both microbially decontaminated; and,

further including a means for supplying a sterile rinse liquid into the tubing system for selectively rinsing antimicrobial solution and powdered reagent residue from the microbially decontaminated item such that microbially decontaminating the tubing system assures that the sterile rinse fluid passes only over microbially decontaminated surfaces as it flows to the container, whereby contamination of the microbially decontaminated item with bacteria from the tubing system is prevented.

**Patentansprüche**

1. Ampulle, die aufweist:
eine äußere Wand (80), die ein inneres Volumen (82) abgrenzt;
einen Entlüftungsdurchgang (84), der zu der äußeren Wand dicht ist und eine Entlüftungsöffnung (86) an einem Ende des Entlüftungsdurchgangs festlegt, wobei die Entlüftungsöffnung von der äußeren Wand umgeben wird;
dadurch gekennzeichnet, daß:
die Entlüftungsöffnung (86) im wesentlichen in einer volumetrischen oder geometrischen Mitte des inneren Volumens angeordnet ist; und die Ampulle ein Fluidreagenz (96) enthält, welches das innere Volumen teilweise füllt und dessen obere Oberfläche unterhalb der Entlüftungsöffnung (86) verbleibt, unabhängig von der Orientierung der Ampulle, wodurch Gase von dem inneren Volumen abgegeben werden, während das Flüssigreagenz in dem inneren Volumen zurückgehalten wird.

2. Ampulle nach Anspruch 1, welche eine gaspermeable, fluid-zurückhaltende Membran (100) einschließt, die über der Entlüftungsöffnung angeordnet ist.

3. Ampulle nach Anspruch 1 oder 2, wobei der Entlüftungsdurchgang linear und von relativ kleinem Durchmesser ist und, im Gebrauch,

als eine Führung für eine hohles Rohr (70) wirkt, welches entlang des Entlüftungsdurchgangs und durch die Entlüftungsöffnung hindurch geht, um Fluidreagenz von der Ampulle abzuziehen, wodurch jegliches Fluidreagenz, das in der Ampulle verbleibt, nachdem das hohle Rohr entfernt worden ist, durch die Position der Entlüftungsöffnung daran gehindert wird, aus der Ampulle abgegeben zu werden.

4. Ampulle nach Anspruch 1, 2 oder 3, wobei das Flüssigreagenz Peracetatsäure enthält.

5. Ampulle nach einem der vorhergehenden Ansprüche, wobei die Ampulle in einem Schacht (34) mit einer Entlüftungsöffnung darin angeordnet ist, wobei der Schacht außerdem ein pulverförmiges Reagenz enthält, das wenigstens einen Puffer, einen Detergenz oder ein Antikorrosionsmittel enthält.

6. Ein Mikrobielles Dekontaminiersystem mit:
einer Ampulle (46) nach einem der vorhergehenden Ansprüche;
einer Wasserquelle (10);
einem Behälter (20) zum Halten eines mikrobiell zu dekontaminierenden Gegenstandes;
einem Rohrsystem (12) zur Schaffung eines Fluidströmungsweges für aufgenommenes Wasser von der Wasserquelle zu dem Behälter;
einem Reservoir (34) zur Aufnahme pulverförmiger Reagenzien, die wenigsten ein wenigstens einen Puffer, einen Detergenz oder ein Antikorrosionsmittel aufweisen, und zur Aufnahme der Ampulle;
wobei das Reservoir (34) mit dem Rohrsystem (12) derart verbunden ist, daß das aufgenommene Wasser das pulverförmige Reagenz auflöst, um eine antimikrobielle Lösung zu erzeugen; und
Abgabemittel zur wahlweisen Abgabe der antimikrobiellen Lösung von der Ampulle in das Wasser.

7. System nach Anspruch 6, wobei die Ampulle eine antimikrobielle Lösung in einer solchen Menge enthält, daß die Ampulle weniger als halb mit der Lösung gefüllt ist.

8. System nach Anspruch 6, wobei das Rohrsystem ein Ventil zur Verhinderung des Einströmens von zusätzlichem Wasser, nachdem das Rohrsystem und der Behälter mit Wasser gefüllt sind, und eine Pumpe aufweist, die mit dem Rohrsystem verbunden ist, um antimikrobielle Lösung enthaltendes Wasser durch das Rohrsystem und den Behälter derart zu rezirkulieren, daß der Behälter und das Rohrsystem jeweils mikrobiell dekontaminiert werden; und
außerdem mit Mitteln zur Zugabe einer sterilen Spülflüssigkeit in das Rohrsystem zur wahlweisen Spülung von antimikrobieller Lösung und pulverförmigem Reagenzrückstand von dem mikrobiell dekontaminierten Gegenstand derart, daß das mikrobielle Dekontaminieren des Rohrsystems sicherstellt, daß das sterile Spülfluid nur über mikrobiell dekontaminierte Oberflächen hinweggeht, wenn es zu dem Behälter fließt, wodurch eine Kontaminierung des mikrobiell dekontaminierten Gegenstandes mit Bakterien von dem Rohrsystem verhindert wird.

**Revendications**

1. Ampoule qui comprend :
une paroi extérieure (80) définissant un volume intérieur (82);
un passage d'évent (84) fermé par rapport à la paroi extérieure et définissant une ouverture d'évent (86) à une extrémité du passage d'évent, l'ouverture d'évent étant entourée par la paroi extérieure;
caractérisé en ce que
l'ouverture d'évent (86) est disposée sensiblement au centre volumétrique ou géométrique dudit volume intérieur; et l'ampoule contient un réactif fluide (96) qui remplit partiellement ledit volume intérieur et dont la surface supérieure reste au-dessous de l'ouverture d'évent (86) quelle que soit l'orientation de l'ampoule, de sorte que les gaz sont évacués dudit volume intérieur tandis que le réactif liquide est retenu dans ledit volume intérieur.

2. Ampoule selon la revendication 1, qui comprend une membrane (100) perméable aux gaz, arrêtant les fluides, montées en travers de l'ouverture d'évent;

3. Ampoule selon la revendication 1 ou 2, dans laquelle le passage d'évent est linéaire et de diamètre relativement petit et se comporte, en utilisation, comme un guide pour un tube creux (70) qui passe le long du passage d'évent et à travers l'ouverture d'évent pour extraire le réactif fluide de l'ampoule, de sorte que tout réactif fluide retenu dans l'ampoule après que le tube creux a été retiré est empêché de sortir de l'ampoule par la position de l'ouverture d'évent.

4. Ampoule selon la revendication 1, 2 ou 3, dans laquelle le réactif liquide comprend de l'acide peracétique.

5. Ampoule selon l'une quelconque des revendications précédentes, dans laquelle l'ampoule est disposée dans un puits (34) présentant intérieurement une ouverture d'évent, le puits contenant en outre un réactif pulvérulent comprenant au moins l'un parmi un tampon, un détersif ou un agent anticorrosif.

6. Système de décontamination microbienne, comprenant :

une ampoule (46) selon l'une quelconque des revendications précédentes;

une source d'eau (10);

un récipient (20) destiné à contenir un article en vue d'une décontamination microbienne;

un réseau de tubes (12) destiné à établir un trajet d'écoulement de fluide pour l'eau reçue allant de la source d'eau au récipient;

un réservoir (34) destiné à recevoir des réactifs pulvérulents comprenant l'un parmi un tampon, un détersif ou un anticorrosif, et à recevoir l'ampoule;

le réservoir (34) étant connecté au réseau de tubes (12) de telle manière que l'eau reçue dissolve le réactif pulvérulent pour former une solution antimicrobienne; et

des moyens de déchargement servant à décharger sélectivement ladite solution antimicrobienne de l'ampoule dans l'eau.

7. Système selon la revendication 6, dans lequel l'ampoule contient une solution antimicrobienne en une quantité telle que l'ampoule soit moins d'à demi remplie avec la solution.

8. Système selon la revendication 6, dans lequel le réseau de tubes comprend une vanne servant à empêcher l'entrée d'une quantité d'eau additionnelle après que le réseau de tubes et le récipient ont été remplis d'eau, et une pompe reliée au réseau de tubes pour faire recirculer la solution antimicrobienne contenant de l'eau à travers le réseau de tubes et le récipient, de manière que le récipient et le réseau de tubes subissent tous deux la décontamination microbienne; et,

comprenant en outre un moyen pour introduire un liquide de rinçage stérile dans le réseau de tubes pour rincer sélectivement le résidu de solution antimicrobienne et de réactif pulvérulent de l'article qui a subi la décontamination microbienne, de sorte que la décontamination microbienne du réseau de tubes garantit que le fluide de rinçage stérile passe uniquement sur des surfaces qui ont subi la décontamination microbienne lorsqu'il s'écoule vers le récipient, de sorte qu'on évite que l'article qui a subi la décontamination microbienne ne soit contaminé par des bactéries provenant du réseau de tubes.

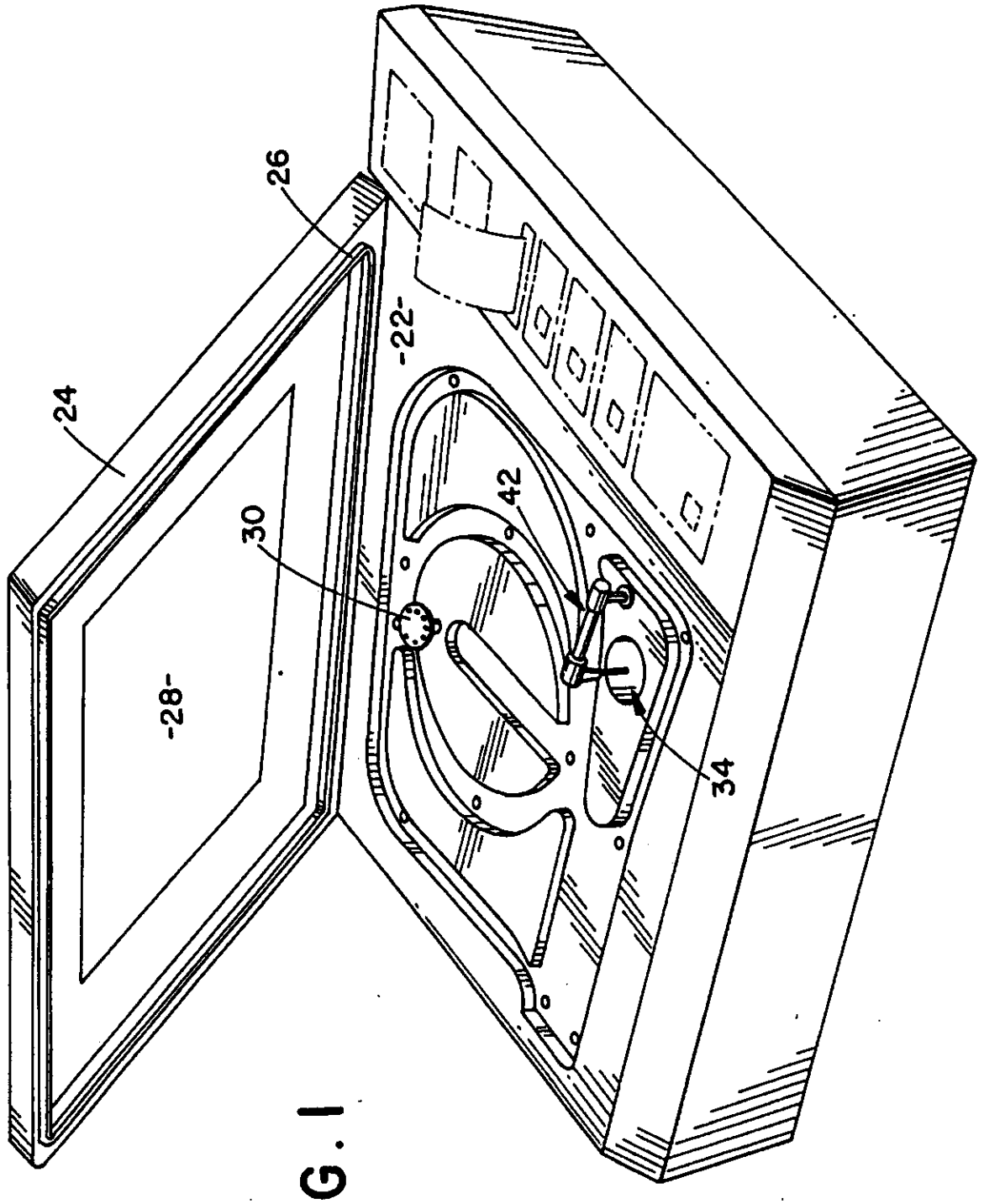



FIG. 1

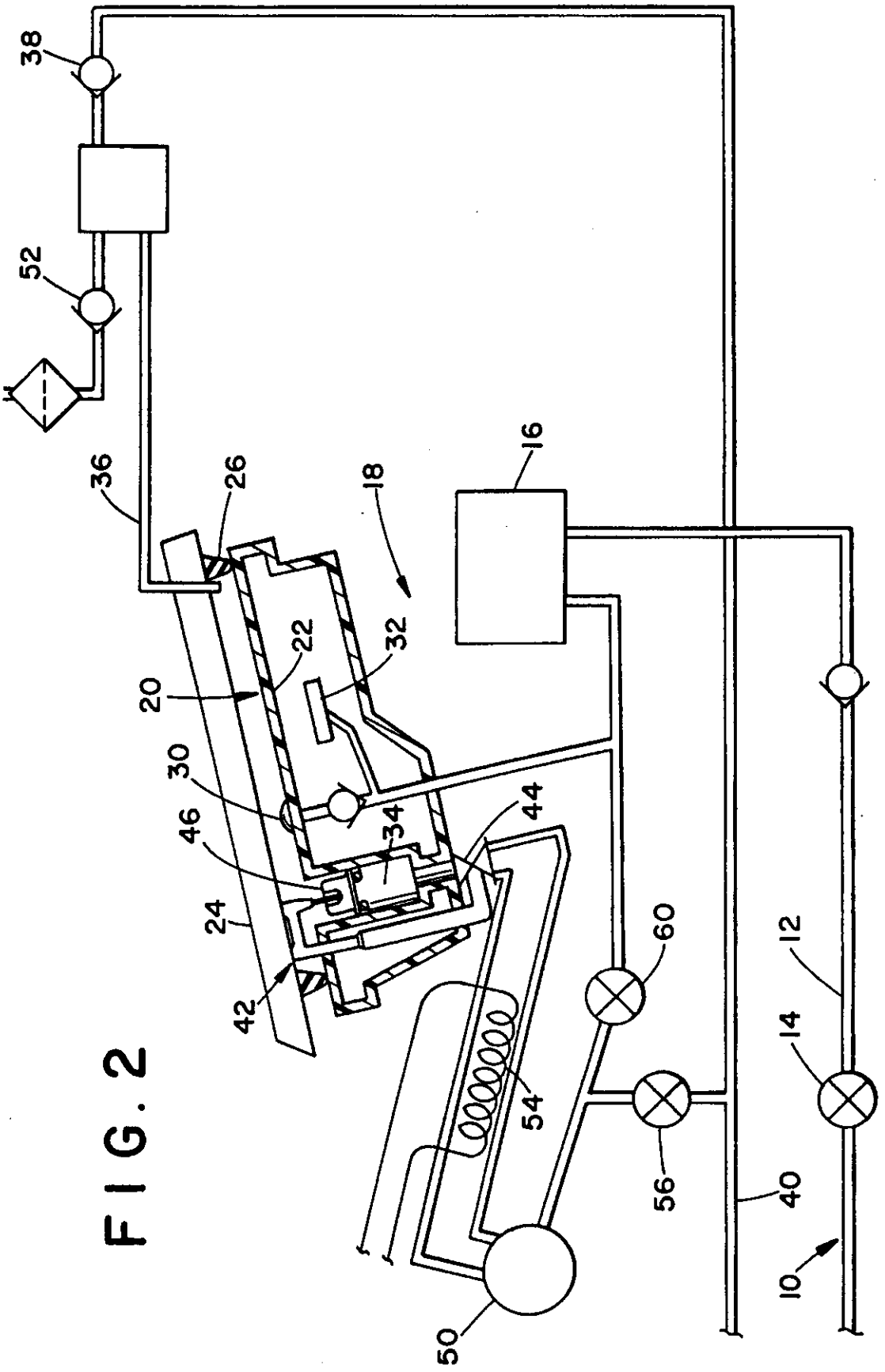



FIG. 2

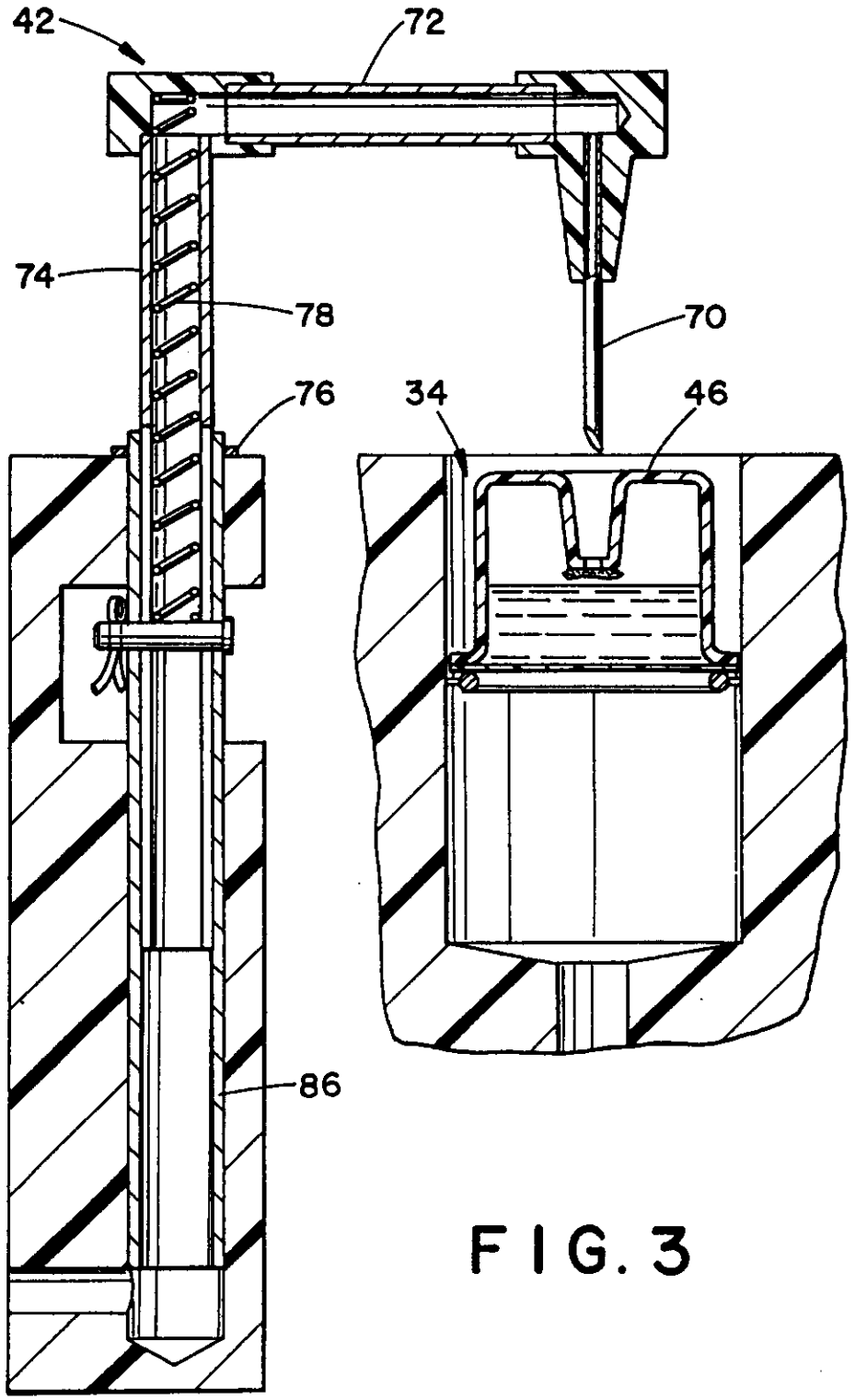



FIG. 3

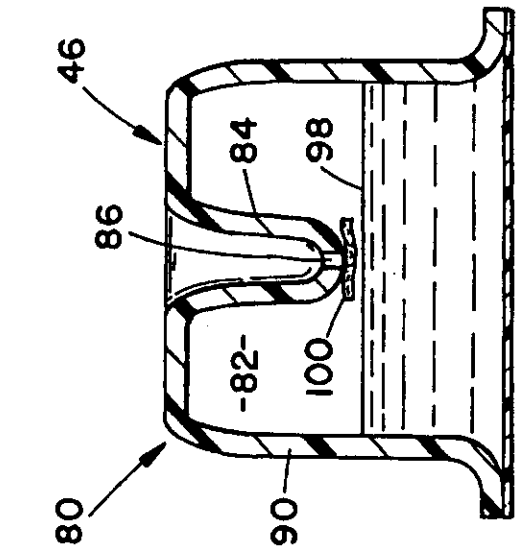



FIG. 4C

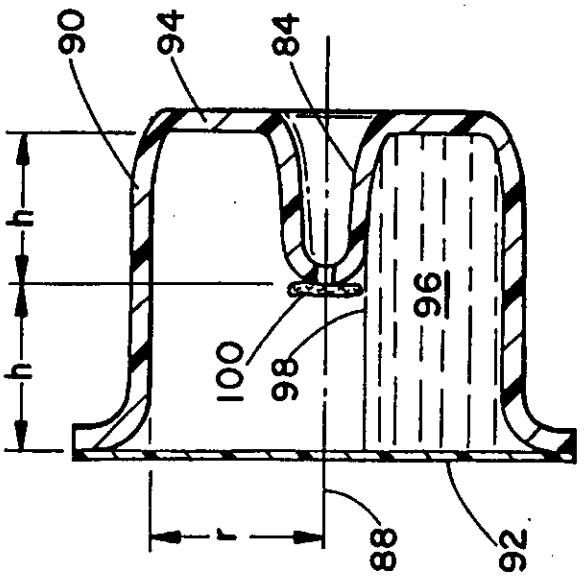



FIG. 4B

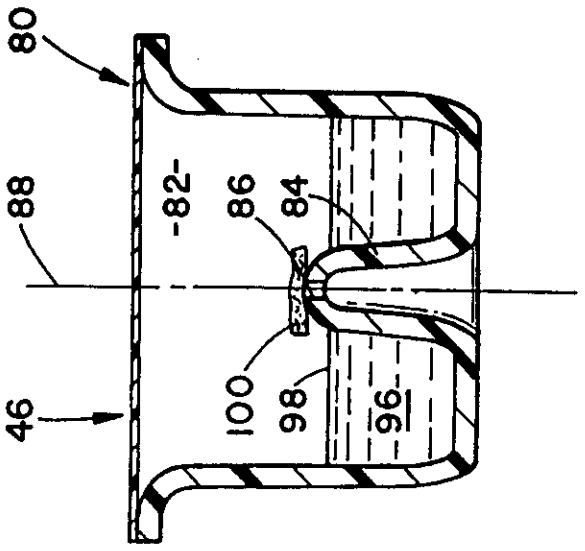



FIG. 4A

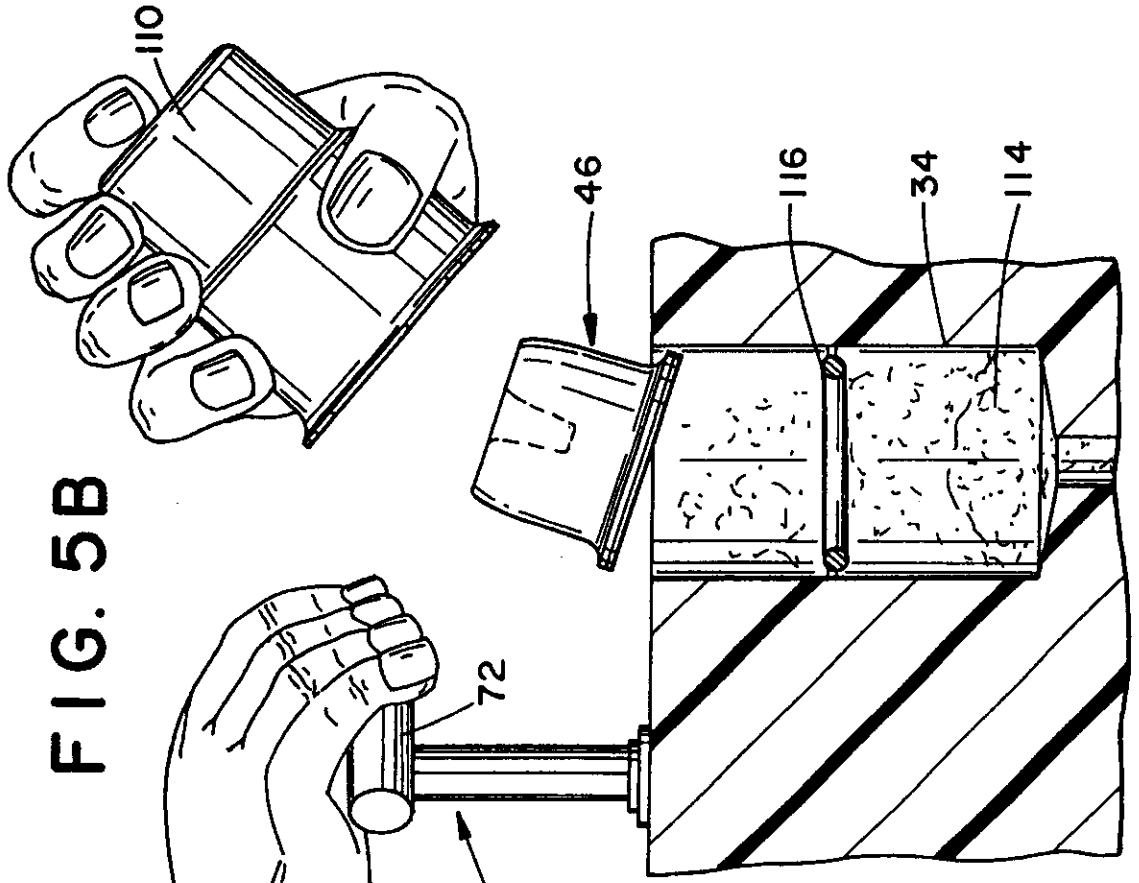



FIG. 5B

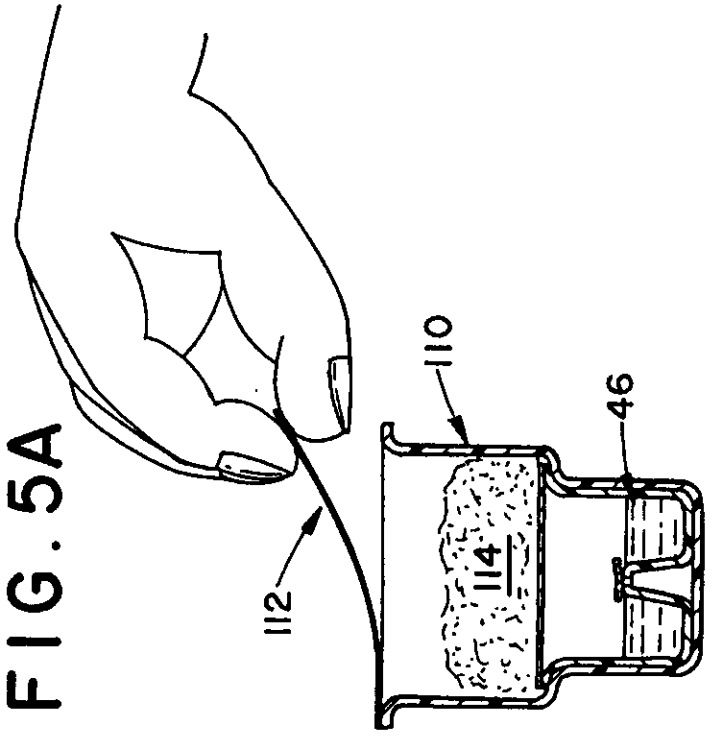



FIG. 5A

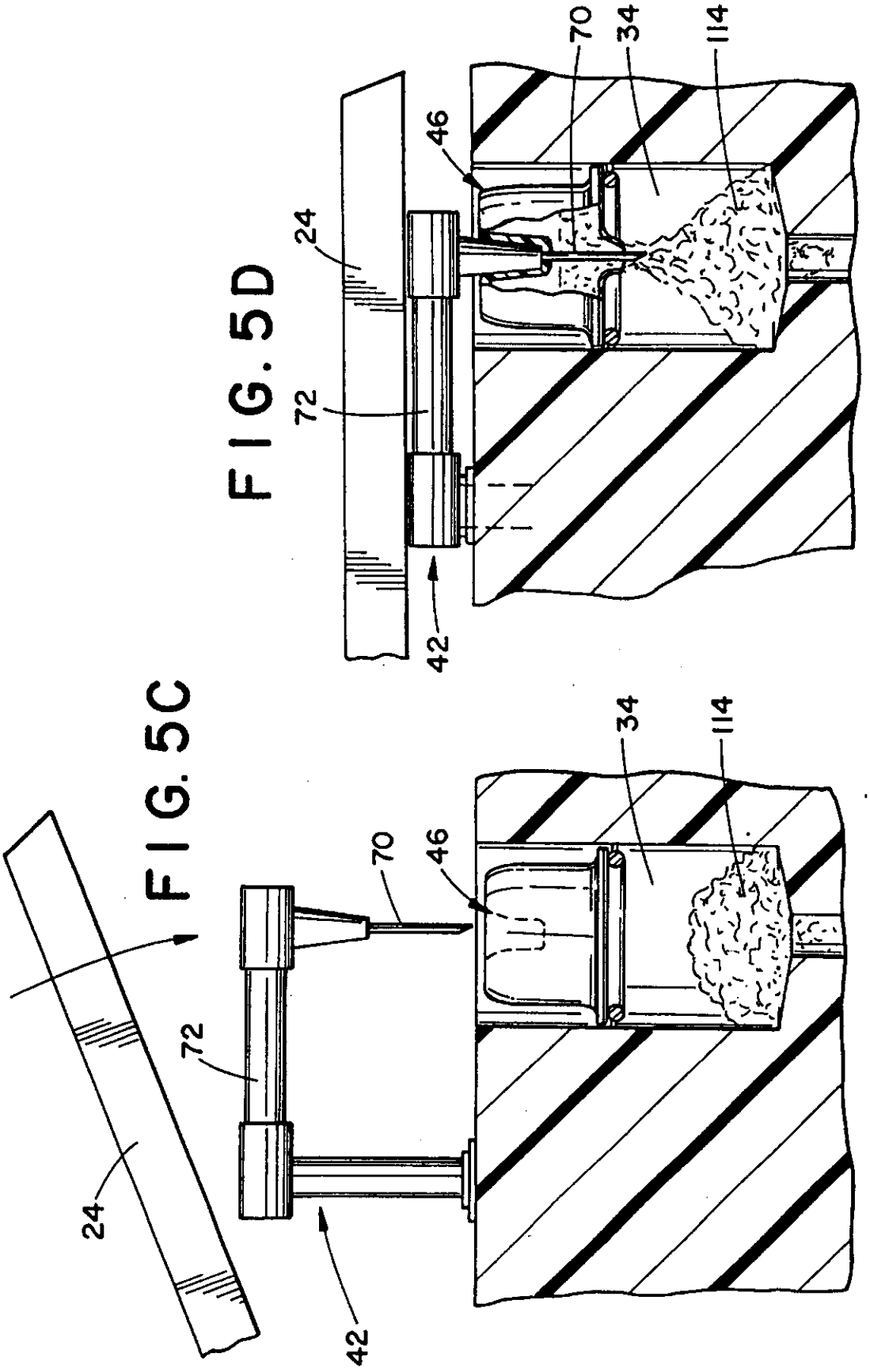
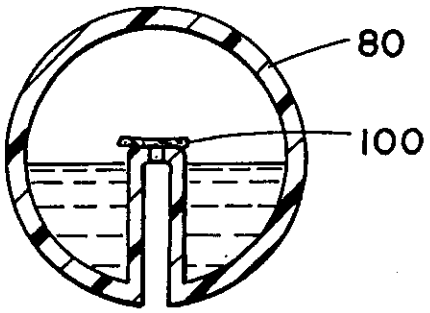



FIG. 5D

FIG. 5C

FIG. 6



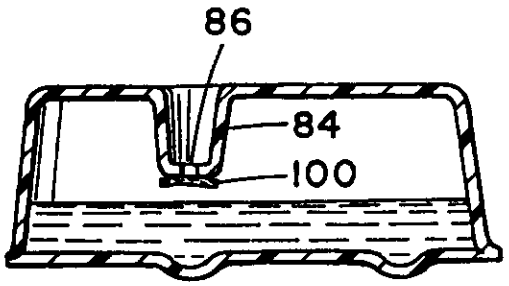




FIG. 7

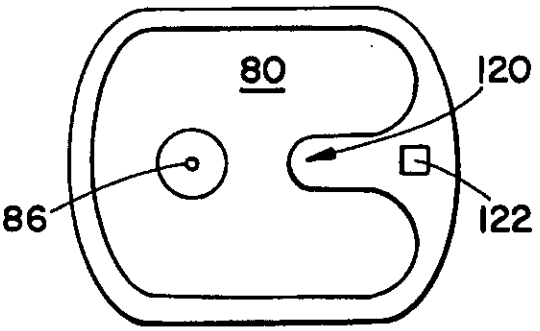
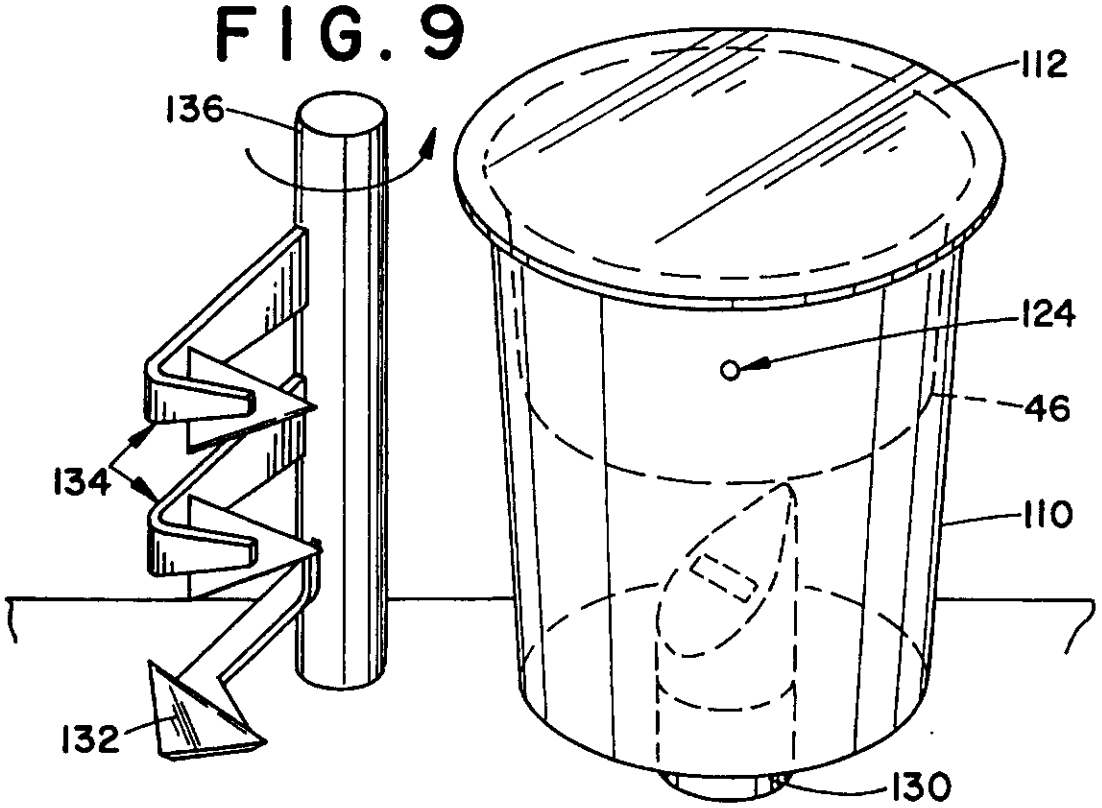



FIG. 8

FIG. 9



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