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(57) **ABSTRACT**

A system provides for high level disinfection or sterilization of an endoscope having a first portion adapted for immersion and a second portion not adapted for immersion. The system includes a container having a first basin sized and adapted to receive the first portion of the endoscope for immersion, a separate and adjacent second basin sized and adapted to receive the second portion of the endoscope, a wall between the first basing and the second basin, and a trough in an upper portion of the wall between the first basin and second basin through which a tube connecting the first portion of the endoscope and the second portion of the endoscope may extend.

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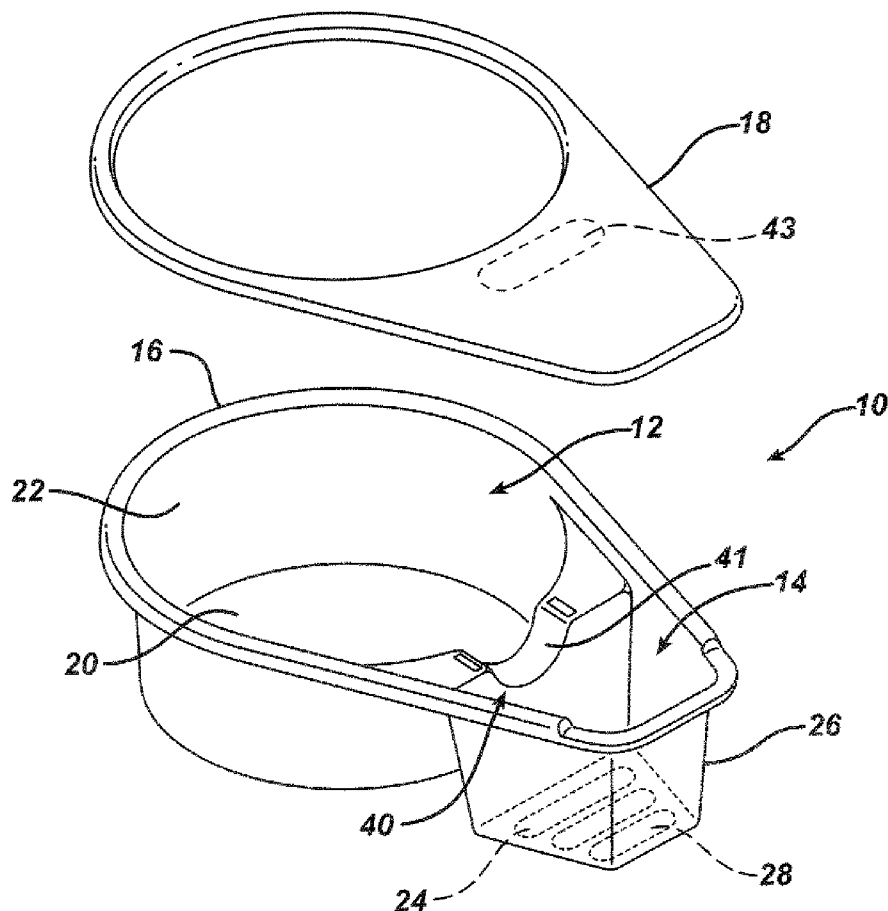


FIG. 1

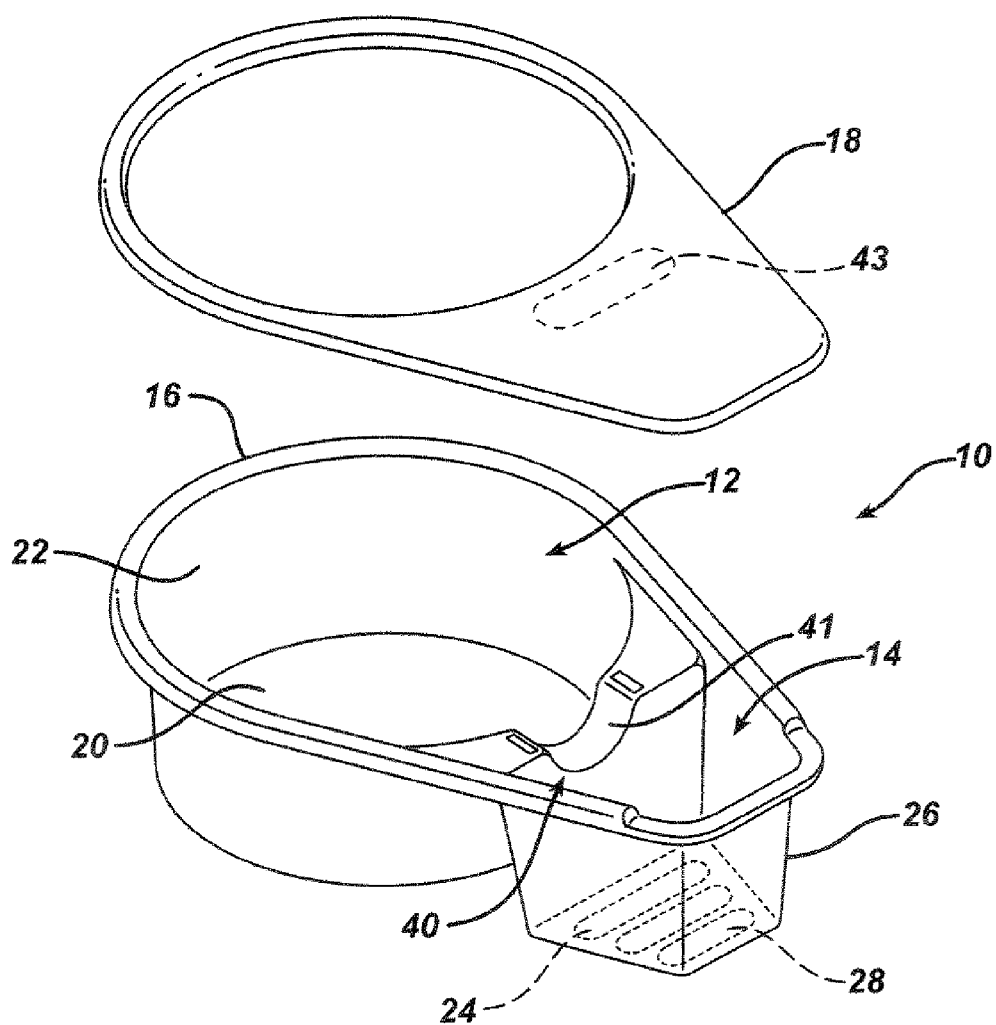


FIG. 2

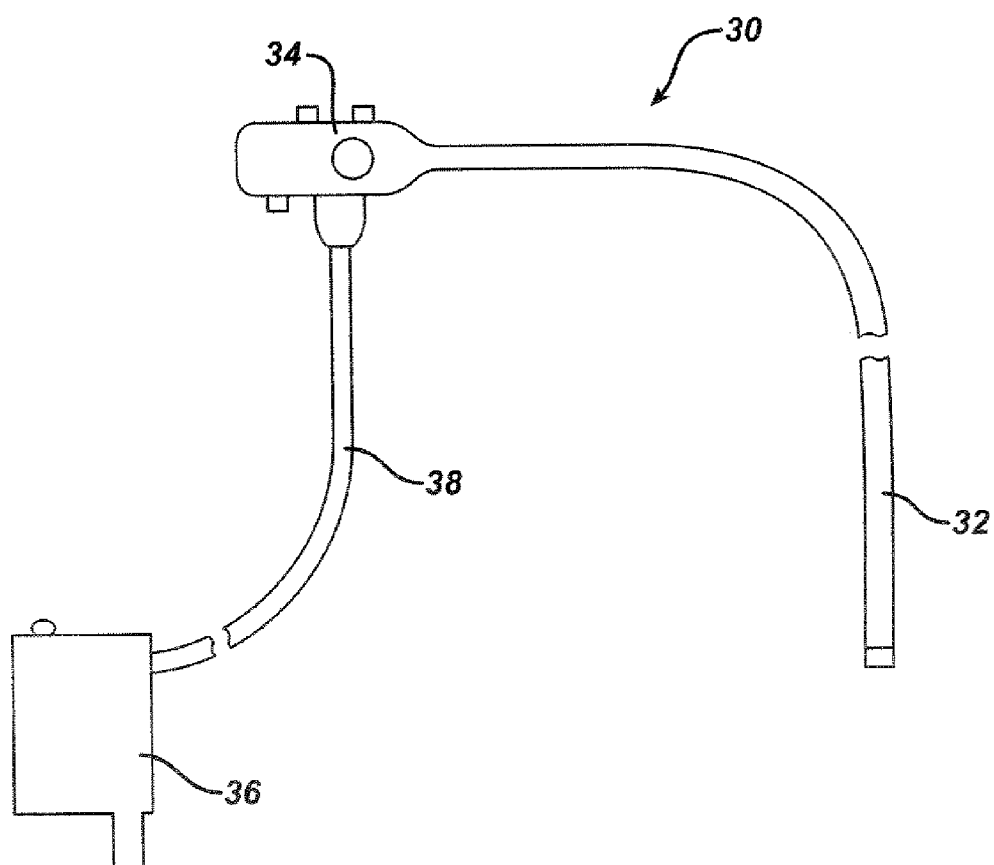


FIG. 3

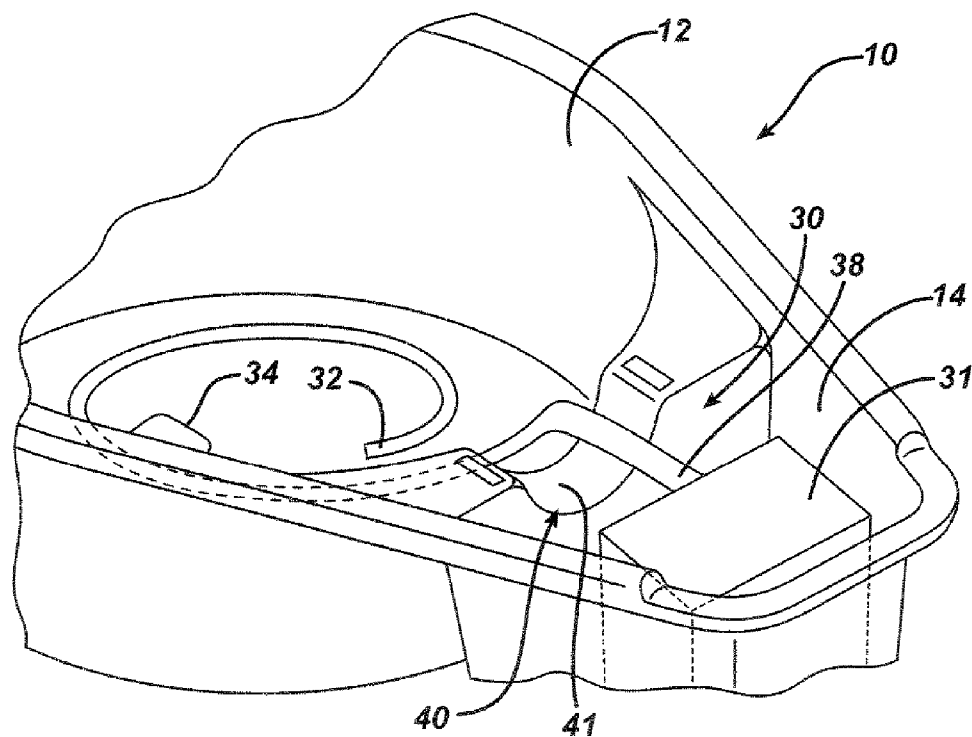
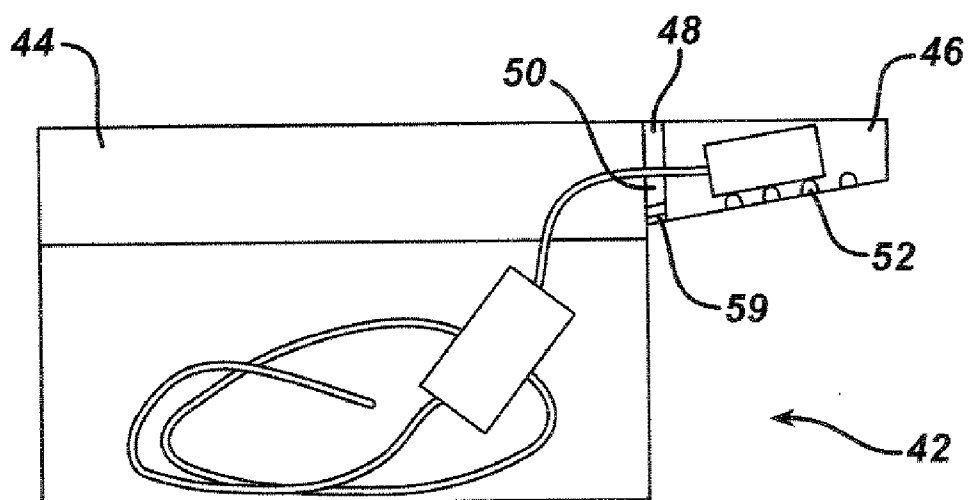


FIG. 4



ENDOSCOPE IMMERSION TRAY

BACKGROUND OF THE INVENTION

[0001] The present invention relates to systems and methods for high level disinfection or sterilization of endoscopes through immersion into disinfecting or sterilization liquids and more particularly to the immersion of endoscopes having liquid sensitive portions.

[0002] After a thorough cleaning, high level disinfection or sterilization of an endoscope employing a liquid disinfectant or sterilant solution is frequently performed in a basin. The basin is filled with the solution and the solution is tested to ensure it is of sufficient concentration. The endoscope is immersed within the solution and all of the endoscope channels are filled with the solution. Typically, the basin is covered with a lid. The endoscope then soaks within the solution for a time period sufficient to achieve the desired level of disinfection or sterilization. After the immersion, the endoscope is processed to remove the sterilant and any rinsing liquids.

[0003] While many endoscopes are designed to be completely immersed, some endoscopes, such as those having ultrasonic scanners, have sensitive electronics which are not completely sealed from moisture. These electronics would be damaged through immersion and thus at least this portion of the endoscope is not suitable for immersion within the disinfecting or sterilization solution. Current immersion practice with such endoscopes involves leaving that sensitive portion outside of the basin and immersing the remainder of the endoscope. However, some of the disinfecting or sterilization solution may leak out along the flexible tubes of the endoscope to reach electronic portion and to reach surfaces upon which it has been placed. Since this solution by its very nature tends to be hazardous, such releases of solution from the basin are to be discouraged.

SUMMARY OF THE INVENTION

[0004] A method, according to the present invention, provides high level disinfection or sterilization of an endoscope having a first portion adapted for immersion and a second portion not adapted for immersion. The method includes the steps of: placing the first portion of the endoscope into a first basin of a container; placing the second portion of the endoscope into a separate second basin of the container; immersing the first portion of the endoscope in a disinfecting or sterilization solution in the first basin; and not immersing the second portion of the endoscope.

[0005] Preferably, the method further includes the step of covering at least the first basin, but more preferably both the first and second basins, with a lid.

[0006] Preferably, the first basin is sealed from the second basin, such as by interposing a conformable seal between the lid and the container, with the seal conforming around the endoscope where it passes between the first basin and the second basin.

[0007] Preferably, the method further includes the step of resting that portion of the endoscope within the second basin upon upwardly extending protrusions so as to elevate it above a lower surface of the second basin and thereby prevent immersion in any solution accidentally carried over into the second basin.

[0008] Preferably, a tube connecting the first portion of the endoscope and second portion of the endoscope is passed through a trough in a wall between the first basin and second basin.

[0009] Preferably, the method includes the step of draining any fluid from the second basin to the first basin to keep the second basin essentially free of fluid.

[0010] Suitable disinfection or sterilization solutions preferably include one or more active ingredients selected from the group of glutaraldehyde, ortho-phthalaldehyde, peracetic acid, hydrogen peroxide, performic acid, chlorine or hydrochloride generating solutions, and ozone containing or generating solutions, most preferably from glutaraldehyde and ortho-phthalaldehyde.

[0011] A system, according to the present invention, provides for high level disinfection or sterilization of an endoscope having a first portion adapted for immersion and a second portion not adapted for immersion. The system comprises a container having a first basin sized and adapted to receive the first portion of the endoscope for immersion, a separate and adjacent second basin sized and adapted to receive the second portion of the endoscope, a wall between the first basin and the second basin; and a trough in an upper portion of the wall between the first basin and second basin through which a tube connecting the first portion of the endoscope and the second portion of the endoscope may extend.

[0012] Preferably, the system includes instructions for use which thereof, said instructions including directions for immersing the first portion of the endoscope in a disinfecting or sterilization solution in the first basin and placing the second portion of the endoscope into the second basin and not immersing the second portion of the endoscope.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a perspective view of a container system according to the present invention for high level disinfection or sterilization of an endoscope having a non-immersible portion thereof;

[0014] FIG. 2 is a perspective view of an endoscope for disinfection or sterilization within the container system of FIG. 1;

[0015] FIG. 3 is a detail view of a portion of the container system of FIG. 1; and

[0016] FIG. 4 is an alternative embodiment of a container system according to the present invention for high level disinfection or sterilization of an endoscope having a non-immersible portion thereof.

DETAILED DESCRIPTION

[0017] FIG. 1 illustrates a container 10 according to the present invention. It comprises a large first basin 12 for receiving an endoscope (not shown in FIG. 1) for immersion and an adjacent smaller second basin 14 for receiving non-submersible portions of the endoscope. A lip 16 encircles an upper portion of the container 10 and provides a sealing surface against which a cover 18 may seal. The large basin comprises a circular bottom wall 20 and a side wall 22 extending upwardly therefrom. Of course other shapes are possible. The smaller basin 14 comprises a

bottom wall **24** having the shape of a truncated pyramid and side walls **26** extending upwardly therefrom. A series of ribs **28** extend upwardly from the bottom wall **24** and serve to elevate that portion of the endoscope in the small basin **14** above the bottom wall **24** to prevent immersion thereof in any carryover liquid which may travel into the small basin **14**.

[0018] FIG. 2 illustrates an endoscope **30** of a type which might be processed in the container **10**. It comprises a flexible insertion portion **32** connected to a control head **34**. It also comprises a scanner unit **36** connected via a flexible tube **38** to the control head **34**. It is the scanner **36** which generally is not susceptible to an immersion during the disinfection process. The endoscope **30** illustrated in FIG. 2 is but one example of an endoscope having a portion not susceptible to immersion. Many other designs carry this limitation.

[0019] FIG. 3 illustrates how the endoscope **30** sits within the container **10**, with the scanner **36** in the smaller basin **14** and the insertion tube **32** and control head **34** in the large basin **12**. The flexible tube **38** between the scanner **36** and control head **34** passes through a trough **40** between the side walls **22** of the large basin **12** and **26** of the small basin **14**.

[0020] As shown in FIGS. 1 to 3, the arrangement of the container **10** with one basin **12** for the bulk of the endoscope **30** and a separate basin **14** for liquid sensitive portions of the endoscope **30** allows efficient high level disinfection or sterilization of those portions of the endoscope **30** susceptible to immersion while simultaneously protecting those portions of the endoscope **30** not susceptible to immersion and preventing carryover of disinfecting solution out of the container **10**. The trough **40** substantially aids in preventing solution from transferring into the smaller basin **14** and the ribs **28** protect the scanner section **36** even if solution gets into the small basin **14**. An elastomeric seal or seals **41** can be provided at the trough **40** to seal the trough **40** and flexible tube **38** to further limit fluid carryover from the large basin **12** to the small basin **14**. Adding an additional seal **43** on the lid **18** in registry with the trough **40** enhances the sealing.

[0021] FIG. 4 illustrates an alternative embodiment of a container **42**. In this embodiment, a large basin **44** holds the bulk of the endoscope and a small basin **46** connected thereto holds the scanner **36** a wall **48** separates the large and small basins **44** and **46** and has a trough **50** therethrough as in the previous embodiment. Upwardly extending protrusions **52** elevate the scanner **36** in the small basin **46**. Departing from the prior embodiment, drainage, as through apertures **54** or deep troughs is allowed from the small basin **46** to the large basin **44**. Thus, any fluid which makes its way into the small basin **46** will drain back into the large basin.

[0022] The container **10** is preferably formed of materials not susceptible to long or short term degradation by the desired disinfection/sterilization solution. Suitable materials include, without limitation, polyethylene (either high density or low density), polypropylene, polyvinyl chloride (PVC), acrylonitrile-butadiene-styrene (ABS), polycarbonate (PC), polyether imide (PEI), polysulfone (PS), polyether sulfone (PES), polyphenyl sulfone (PPS), liquid crystal polymers (LCP), and polytetrafluoroethylene (PTFE). Some materials can be more desirable when designing the con-

tainer **10** to be compatible with multiple disinfection and sterilization solutions, particularly polypropylene, PEI, PS, PC and PPS.

[0023] The material chosen to some degree determines the preferred forming techniques as will be understood by those of skill in the art. Preferred construction methods include injection molding, thermoforming and transfer molding. Other primary polymer processing methods, such as rotomolding and casting, may be employed. Secondary polymer processing methods, such as machining, drilling, cutting, melt bonding and gluing, can be use to complete the construction and connect various portions of the tray or to attach the seal or seals **41**.

[0024] The following description of operation refers to FIGS. 1 to 3. However, operation with the embodiment of FIG. 4 is similar. After a medical procedure the endoscope **30** is thoroughly cleaned according to the manufacturers instructions and prepared for immersion in the container **10**. Typically the cleaning will involve block and leak testing of the endoscope channels, a manual cleaning, as with an enzymatic detergent, of the exterior as well as a manual cleaning of any endoscope channels suitable to receive a cleaning brush. Remaining channels are flushed with cleaning detergent and the entire endoscope and channels are then rinsed.

[0025] The endoscope **30** is then immersed in a suitable disinfecting or sterilization solution such as glutaraldehyde (available from Advanced Sterilization Products Division Ethicon Inc., Irvine, Calif. under the trademark CIDEX®) or ortho-phthalaldehyde (available from Advanced Sterilization Products Division Ethicon Inc., Irvine, Calif. under the trademark CIDEX®-OPA). Other possible disinfection or sterilization liquids includes without limitation, peracetic acid, hydrogen peroxide, performic acid, chlorine or hydrochloride generating chemical solutions, such as hypochlorite, hypochlorous acid and chlorine dioxide, and ozone containing or generating chemical solutions. Combinations of any of these liquids can be used, either together or sequentially.

[0026] Typically the solution is tested with a test strip to ensure that it is of the required potency. Then all of the endoscope **30** with the exception of the scanner section **36** is placed into the large basin **12** in such a fashion as to maximize filling of the lumens of the endoscope. The scanner portion **36** is placed into the smaller basin **14** with the flexible tube **38** extending through the trough **40**. Additional solution is manually squirted into the endoscope lumens (not shown) as for example via a syringe. The scanner portion **36** is typically treated by wiping it with the solution which does not effect the same level of disinfection as immersion, yet suffices as this part of the endoscope **30** is not inserted into a patient and in fact should not contact the patient.

[0027] The lid **18** is placed onto the container **10** and the endoscope **30** remains immersed for a sufficient period of time to effect the desired level of cleaning or disinfection. After that time has passed the endoscope is removed from the container **10** and rinsed with sterile water, the channels flushed with alcohol and purged with air to ensure that they are dry. The endoscope **30** is now ready for its next use.

[0028] While the invention has been particularly described in connection with specific embodiments thereof, it is to be

understood that this is by way of illustration and not of limitation, and that the scope of the appended claims should be construed as broadly as the prior art will permit.

1-10. (canceled)

11. A system for high level disinfection or sterilization of an endoscope having a first portion adapted for immersion and a second portion not adapted for immersion, the system comprising:

a container comprising:

a first basin sized and adapted to receive the first portion of the endoscope for immersion;

a separate and adjacent second basin sized and adapted to receive the second portion of the endoscope;

a wall between the first basin and the second basin; and

a trough in an upper portion of the wall between the first basin and second basin through which a tube connecting the first portion of the endoscope and the second portion of the endoscope may extend.

12. A system according to claim 11 and further comprising a lid for covering at least the first basin.

13. A system according to claim 11 wherein the lid covers both the first and second basins.

14. A system according to claim 11 and further comprising a conformable seal at the trough adapted to conform about the tube and seal the first basin from the second basin.

15. A system according to claim 11 and further comprising a plurality of upwardly extending protrusions whereby to elevate the second portion of the endoscope above a lower surface of the second basin and prevent immersion in any solution accidentally carried over into the second basin.

16. A system according to claim 11 and further comprising a drainage path between a lower surface of the second basin and the first basin whereby to drain any fluid accidentally entering the second basin to the first basin to keep the second basin essentially free of fluid.

17. A system according to claim 11 wherein the materials of the container are resistant to degradation by or absorption of the disinfection or sterilization solution when it comprises an active ingredient selected from the group of glutaraldehyde and ortho-phthalaldehyde.

18. A system according to claim 11 and further comprising instructions for use thereof, said instructions including directions for immersing the first portion of the endoscope in a disinfecting or sterilization solution in the first basin and placing the second portion of the endoscope into the second basin and not immersing the second portion of the endoscope.

19. A system according to claim 11 and further comprising an elastomeric seal for sealing the lid, container and endoscope at the trough.

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