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(54) **MEDICAL FLUID ACCESS SITE WITH ANTISEPTIC INDICATOR**

(76) Inventors: **Shmuel Sternberg**, Palatine, IL (US); **Kent L. Lurvey**, Grayslake, IL (US); **Robin G. Pauley**, Lake Villa, IL (US); **Dustin C. Cawthon**, Crystal Lake, IL (US); **Ton That Hai**, Round Lake, IL (US); **Lecon Woo**, Libertyville, IL (US); **Ashok K. Khanna**, Lake Zurich, IL (US); **Birendra K. Lal**, Lake Zurich, IL (US); **Michael Tung-Kiung Ling**, Vernon Hills, IL (US); **Vadim V. Krongauz**, Bartlett, IL (US); **Rosa H. Yeh**, Libertyville, IL (US); **William S. Hoerle**, Cary, IL (US); **Craig L. Sandford**, Buffalo Grove, IL (US)

Correspondence Address:
BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY, DF2-2E
DEERFIELD, IL 60015

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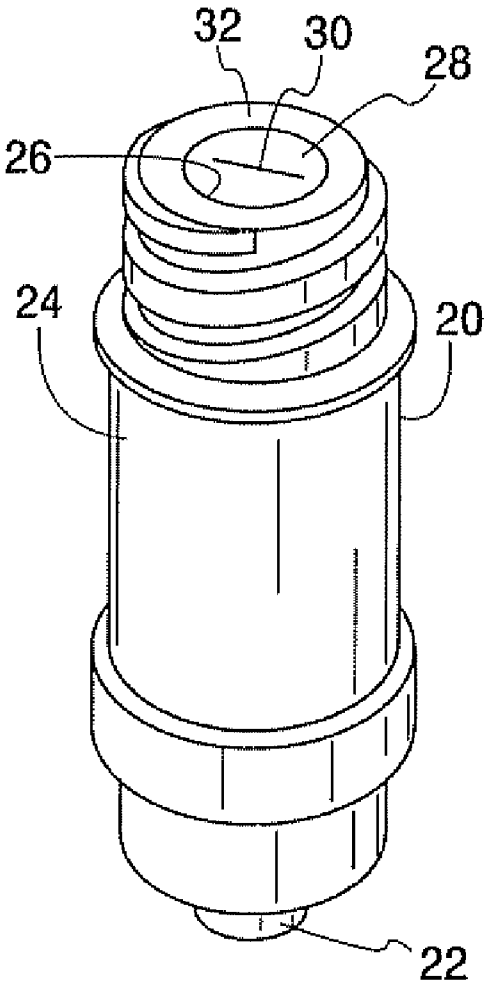
(57) **ABSTRACT**

An access device including access site is disclosed for providing access to a medical fluid flow path for the introduction or withdrawal of medical fluids to and from the flow path. The access device includes an indicator for providing a visual indication when the access device has been exposed to an antiseptic agent.



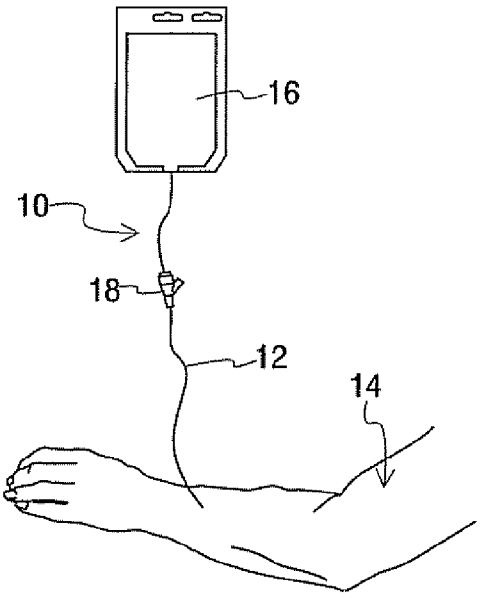


Fig. 1

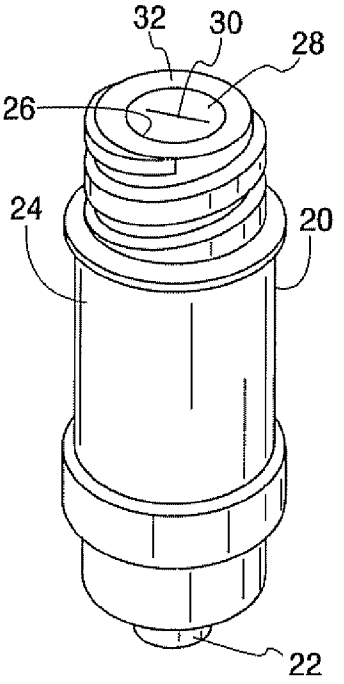


Fig. 2

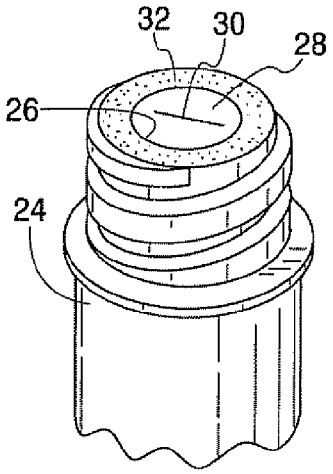


Fig. 3

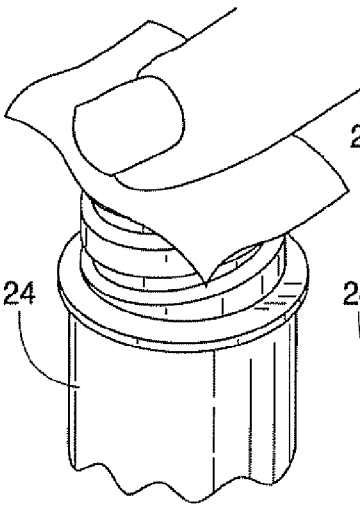


Fig. 4

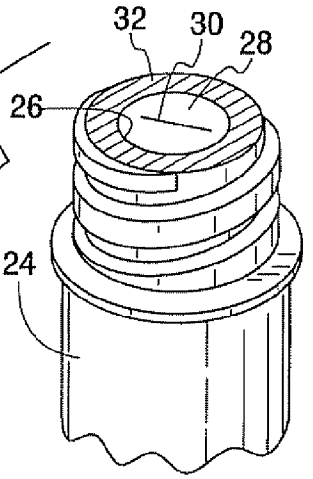


Fig. 5

Fig. 6

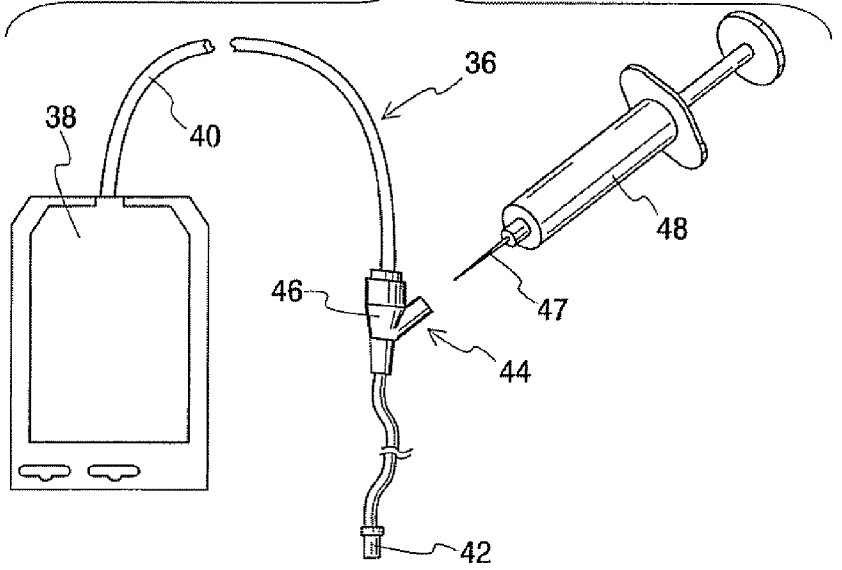


Fig. 7

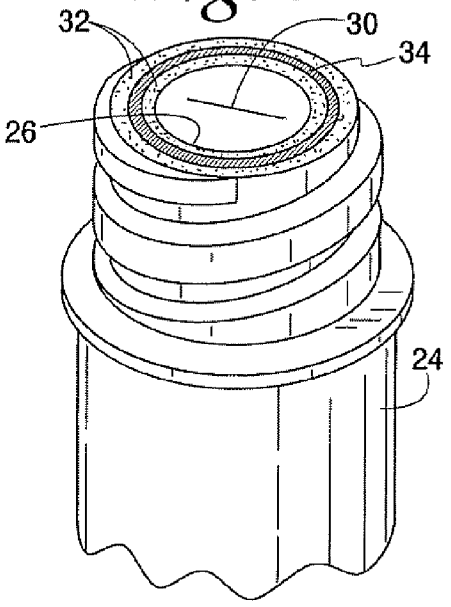
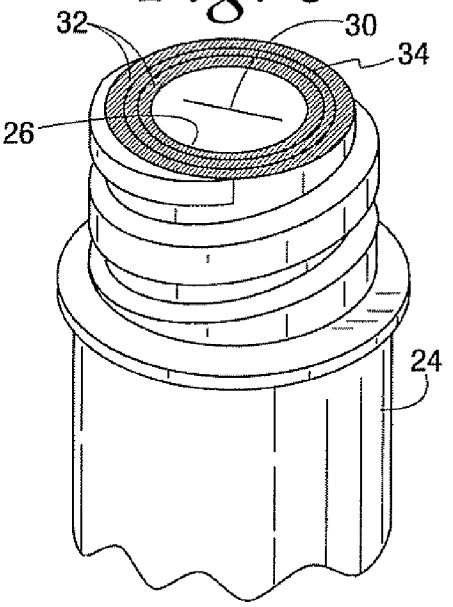


Fig. 8



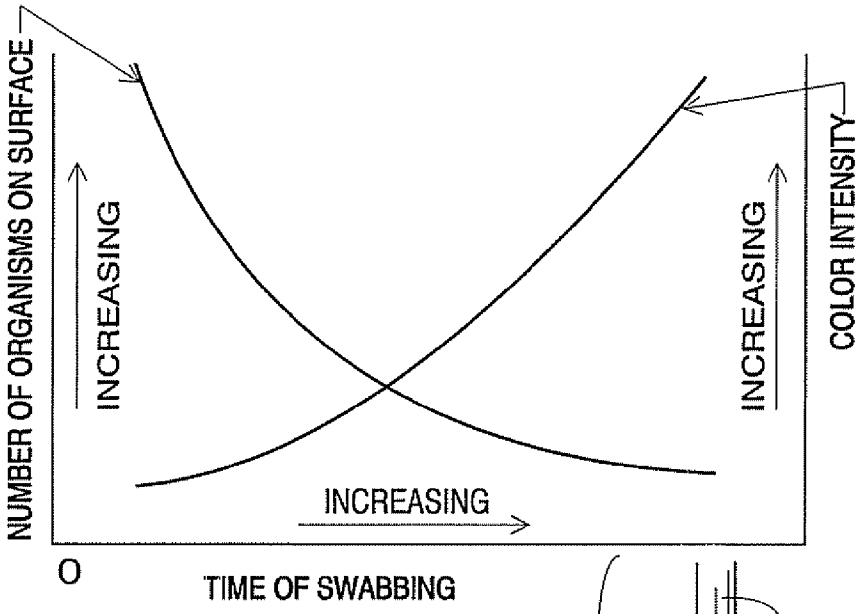


Fig. 12

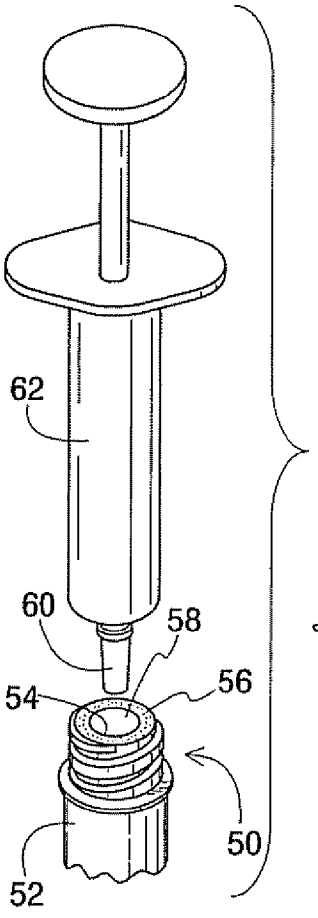


Fig. 10

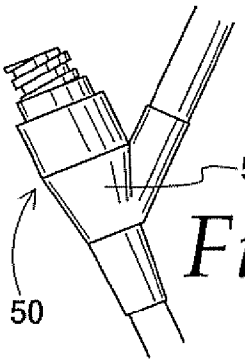


Fig. 9

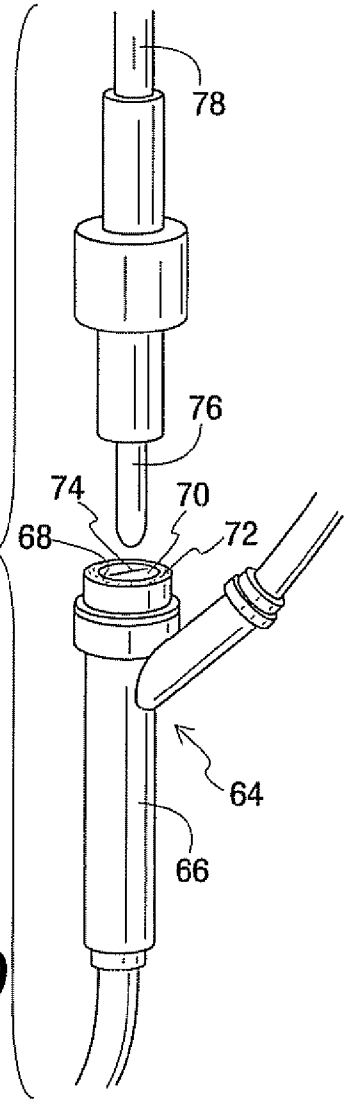


Fig. 11

Fig. 13

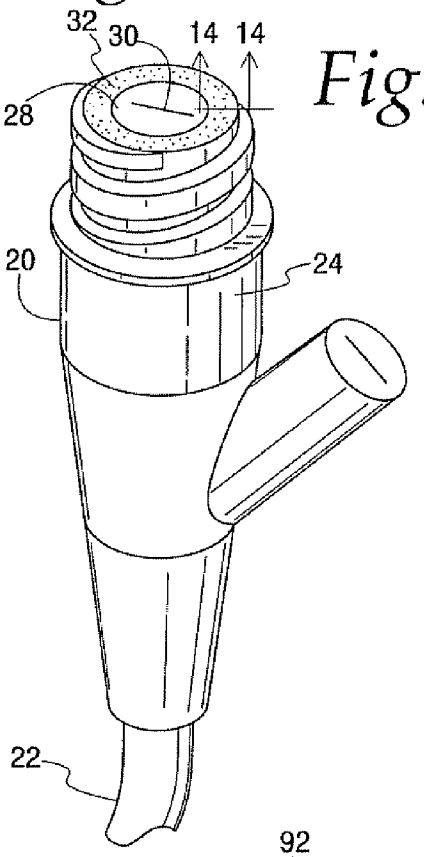


Fig. 14a

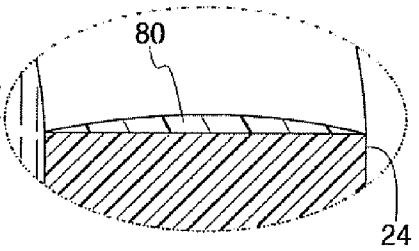


Fig. 14b

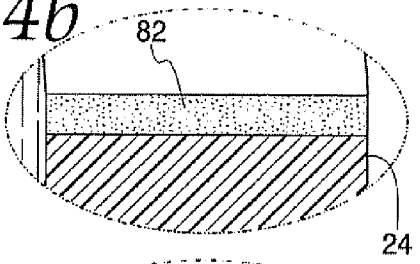


Fig. 14c

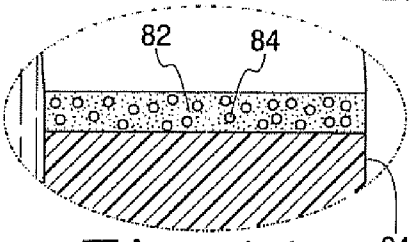


Fig. 14d

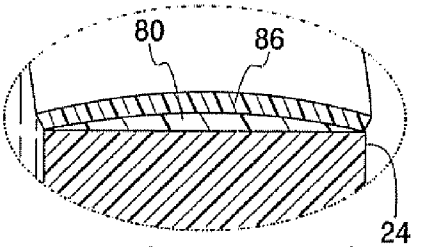


Fig. 14e

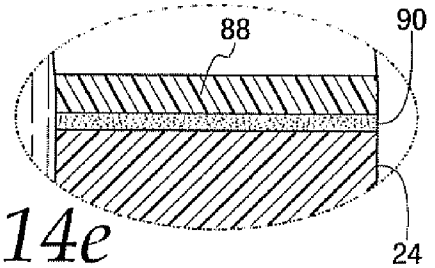
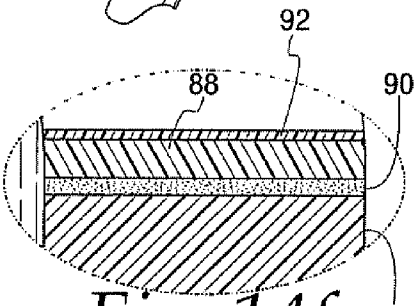


Fig. 14f



MEDICAL FLUID ACCESS SITE WITH ANTISEPTIC INDICATOR

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical fluid access devices for the addition or withdrawal of fluid to or from medical fluid flow systems.

BACKGROUND OF THE INVENTION

[0002] Medical fluid access devices are commonly used in association with medical fluid containers and medical fluid flow systems that are connected to patients or other subjects undergoing diagnostic, therapeutic or other medical procedures. The access devices simplify the addition of fluids to or withdrawal of fluids from the container or the subject connected to the fluid flow system.

[0003] Within the medical field there are a wide variety of medical fluid flow systems, serving a variety of functions. One of the more common fluid flow systems is used for the intravenous administration of fluids, such as saline, antibiotics, or any number of other medically-related fluids, to a patient. These flow systems are commonly referred to as intravenous or "IV" fluid administration sets, and use plastic tubing to connect a phlebotomized subject to one or more medical fluid sources, such as intravenous solution or medicament containers.

[0004] Typically, such intravenous administration sets include one or more access devices providing access to the fluid flow path to allow fluid to be added to or withdrawn from the IV tubing. For example, an access device may allow for the introduction of medication, antibiotics, chemotherapeutic agents, or a myriad of other fluids to a previously established IV fluid flow system. Alternatively, the access device may be used for withdrawing fluid from the subject for testing or other purposes. The presence of one or more access devices in the IV tubing sets eliminates the need for phlebotomizing the subject repeatedly and allows for immediate administration of medication or other fluids directly into the subject.

[0005] Several different types of access devices are well known in the medical field. Although varying in the details of their construction, these devices usually include a housing that defines an access opening or site for the introduction or withdrawal of medical fluids through the housing, and a resilient gland that normally closes the access site. Beyond those common features, the design of access sites varies considerably. For example, the gland may be a solid rubber or latex septum or be made of other elastomeric material that is pierceable by a needle, so that fluid can be injected into or withdrawn from the access device. Alternatively, the gland may comprise a septum or the like with a preformed but normally closed aperture or slit that is adapted to receive a specially designed blunt cannula therethrough. Other types of access devices are designed for use with connecting apparatus employing standard male luers. Such an access device is commonly referred to as a "luer access device" or "luer-activated device," or "LAD." LADS of various forms or designs are illustrated in U.S. Pat. Nos. 6,682,509, 6,669,681, 6,039,302, 5,782,816, 5,730,418, 5,360,413, and 5,242,432, and U.S. Patent Application Publications Nos. 2003/0208165 and 2003/0141477, all of which are hereby incorporated by reference herein.

[0006] Access devices may also be fashioned as a part of a larger device or structure. For example, stop-cocks or the like used in medical fluid flow control may include access ports normally closed by septums or other elastomeric gland structures. Access devices or access sites may also be part of containers, such as vials or bags that have an opening closed by an elastomeric stopper or septum or other gland.

[0007] Before an access device is actually used to introduce or withdraw liquid from a container or a medical fluid flow system or other structure or system, good medical practice dictates that the gland and surrounding housing be contacted, usually by wiping or swabbing, with a disinfectant or sterilizing agent such as isopropyl alcohol or the like to reduce the potential for contaminating the fluid flow path and harming the patient. It will be appreciated that a medical fluid flow system, such as an IV administration set, provides a direct avenue into a patient's vascular system. Without proper aseptic techniques by the physician, nurse or other clinician, microbes, bacteria or other pathogens found on the surface of the access device could be introduced into the IV tubing and thus into the patient when fluid is introduced into or withdrawn through the access device. Accordingly, care is required to assure that proper aseptic techniques are used by the healthcare practitioner.

[0008] As described more fully below, the fluid access device of the present invention provides an important advance in the safe and efficient administration or withdrawal of medical fluids to or from a patient.

SUMMARY OF THE INVENTION

[0009] In accordance with one aspect of the present invention, a medical fluid access device is provided, either alone or in combination with a medical fluid flow system, which includes a housing defining an access site for introduction or withdrawal of medical fluid through the housing and an indicator that provides a visual indication when the access site has been exposed to an antiseptic agent, such as by directly wiping or swabbing the access device pursuant to accepted aseptic practices. The access device preferably also comprises a gland made of a resilient or other suitable elastomeric or other material and of any suitable design that normally closes the access site. For example, the gland may be solid so as to normally close the access site and be pierceable by a sharp cannula or needle to allow the introduction or withdrawal of medical fluid through the access device. Alternatively, the gland may have an aperture that is normally closed and is adapted to receive a blunt cannula therethrough for introduction or withdrawal of fluid. Still further the gland may be movable, such as upon pressure from a male luer or other flow member, between a normally closed position and an open position for introduction or withdrawal of medical fluid. In one embodiment, the visual indication of exposure to an antiseptic agent comprises a color change that is preferably but not necessarily of limited time duration. For example, the access device may have an original color, such as blue, before exposure to an antiseptic agent. The original color may serve as a reminder to the clinician that the access site needs to be swabbed with antiseptic before accessing the site. When the access device is exposed to antiseptic agent, such as by direct swabbing by the clinician, the indicator will change color, such as to red to indicate that swabbing has taken place. The indicator may remain the changed color indefinitely or, more preferably, remain the changed color only for a limited time to indicate

that antiseptic swabbing has taken place. After a limited time duration, the access device may return to the original color, reminding the clinician to re-swab the access device before it is used again.

[0010] In a related aspect of the present invention, the indicator may be located on a portion of the housing that generally circumscribes the access site. The indicator may be one or more of several types of indicators that operate on different principles.

[0011] In one embodiment, the exposure indicator may comprise a material disposed on the housing, on the gland, or both, for providing a visual indication of exposure to an antiseptic agent. The material may be, for example, an agent coated on a portion of the housing, such as a dye including a dye including a solvatochromic dye that changes color in the presence of a solvent in an antiseptic agent or that is otherwise responsive to exposure to an antiseptic agent to visually indicate such exposure.

[0012] Alternatively, the indicator may comprise a dye including a solvatochromic dye that changes color as a result of temperature change from the exposure to the antiseptic agent. Temperature change may occur during swabbing, for example, as a result of the cooler temperatures that occur as the antiseptic agent evaporates from the surface of the access device.

[0013] It will be appreciated that the dye may include a solvatochromic dye and be selected from a variety of commercially available dyes or may be specially manufactured or synthesized. For example, the dye may comprise Nile Red, or Reihert's dye or a salt, such as Nile Red and its derivatives. Alternatively, the dye may be incorporated into a hydrogel material. The dye may also comprise a combination of acid and dye such as a product of Nile Red reaction with poly(acrylic acid) that are incorporated in a solvent-absorbing polymer matrix for example a hydrogel material. The dye may be attached or affixed to the housing by various means, including adhesive or covalent or Van der Waals bonding.

[0014] The selected dye may maintain the visual indication of exposure to an antiseptic agent for a selected period of time after exposure. The visual indication of exposure to an antiseptic agent may be indefinite, or more preferably, the visual indication may be for a limited time duration. It should be appreciated that the visual indication is preferably a clear and conspicuous indication to the clinician that antiseptic swabbing has taken place. For example, as previously noted, the visual indication may comprise a change in color of the dye. In this way, the indicator may also serve as an indication of the degree of exposure or contact of the access device with an antiseptic agent. For example, the color change or the degree or amount of color change may serve as an indication to the clinician as to whether the access site has been actively swabbed, including using deliberate pressure, mechanical agitation, and duration of application in accordance with accepted aseptic practices. For example, the more intense color change may indicate a greater degree of active swabbing or contact with the antiseptic agent.

[0015] In another embodiment, the exposure indicator may comprise a membrane that is disposed on the surface of the housing of a medical fluid access device. The membrane may be incorporated with dye, or as an alternative to this embodiment that will be described in further detail below, the membrane may be layered with various dye containing materials or impregnated with dye-containing gels, beads, micro-capsules.

[0016] For example, the exposure indicator may comprise a substrate and a membrane carried on the substrate. The membrane can provide a visual indication of exposure of the membrane to an antiseptic agent. It should be appreciated that the membrane may be solid or porous. A porous membrane with a particular pore size may be used, such as, for example, a microporous membrane or an ultrafiltration membrane. The dye may be incorporated in the membrane during manufacture or the membrane may otherwise be constructed to carry a dye that is responsive to exposure to an antiseptic agent to provide a visual indication of such exposure.

[0017] The exposure indicator within the membrane may produce a color change upon exposing the membrane to an antiseptic agent. Preferably, the color change is for a limited time duration. For example, the membrane may have an original apparent color before exposure to an antiseptic agent, change apparent color upon exposure to an antiseptic agent, and then return substantially to the original color thereafter. The visual indication also may serve to indicate to a clinician the degree of exposure of the membrane to an antiseptic agent or amount of swab pressure applied or the coverage of the swab. "Color" and "apparent color" are used interchangeably herein to take into account and include the situation where the actual color does not change, but the perceived appearance changes, for example as a result of change in diffraction or other properties that change the viewer's perception of the appearance of the membrane

[0018] In accordance with another embodiment, the exposure indicator for indicating exposure to an antiseptic agent may comprise a substrate, a membrane carried on the substrate, and an indicator incorporated in the membrane. The indicator incorporated in the membrane is adapted to provide a visual indication of exposure of the membrane to an antiseptic agent. In this embodiment, the membrane may comprise for example, a microporous membrane or an ultrafiltration membrane. The indicator may be a dye impregnated in the membrane or, alternatively, a dye encapsulated in a poymer dispersed material or hydrogel material. Such hydrogel material can be a crosslinked polymer such as, for example, "[2-(methacryloyloxy)ethyl]trimethylammonium chloride or other suitable material.

[0019] As with the previous embodiment, the visual indication may include a color change of the indicator upon exposure to an antiseptic agent, and preferably the color change is of a limited time duration. For example, the indicator may have an original apparent color before exposure to an antiseptic agent, change apparent color upon exposure to an antiseptic agent, and then return substantially to the original color thereafter. As previously mentioned the indicator may also indicate a degree of exposure to an antiseptic agent. For example, the degree of color change may be indicative of the degree of exposure to an antiseptic agent.

[0020] In a still further embodiment, the exposure indicator for indicating exposure to an antiseptic agent may comprise a substrate, and an indicator material carried on the substrate which is responsive by visible change upon exposure to the antiseptic agent, and a membrane disposed over the indicator material. The substrate may include, for

example, the housing of the medical fluid access device, and may be comprised of a polycarbonate material or other suitable material.

[0021] The indicator material may comprise a dye layer disposed on the surface of the housing of the access device, a membrane disposed on the surface of the housing of the access device, or a dye incorporated in a solvent-absorbing polymer matrix material that is impregnated in the dye layer or membrane layer. The dye may be comprised of a material such as a combination of acid and dye. The indicator material may be affixed to the housing by various methods including, solvent bonding, adhesive, glue, and sonic welding.

[0022] Again, the visual indication may include a color change of the indicator upon exposure to the antiseptic agent, which preferably, is of a limited time duration. As with the previously described embodiments, the indicator may have an original color before exposure to an antiseptic agent, change color upon exposure to an antiseptic agent, and then return substantially to the original color thereafter. The indicator also indicates a degree of exposure to an antiseptic agent. For example, the degree of color change may be indicative of the degree of exposure to an antiseptic agent.

[0023] In this embodiment, an additional membrane may be disposed over the layer of exposure indicator material. It may be a porous and/or permeable membrane layer, disposed directly on the exposure indicator material. As such, the layer of indicator material is "sandwiched" between the housing and the top membrane layer. The top membrane layer may serve various purposes, such as, for example, a protective layer over the exposure indicator to protect the indicator and thereby increase durability and shelf life, and/or to control the rate of ingress and/or evaporation of antiseptic agent after swabbing has taken place to control the time of visual indication.

[0024] In still another embodiment, the visual indication may comprise a change in transparency. In this embodiment, the exposure indicator for indicating exposure to an antiseptic agent may comprise a substrate and an indicator material disposed on the substrate. The indicator disposed on the substrate may comprise a substantially non-transparent material that is responsive by a change in transparency upon exposure to an antiseptic agent.

[0025] For example, an indicator may be disposed on a portion of the housing, the gland, or both, and undergo a change in transparency upon contact with an antiseptic agent. The indicator may change, for example, from a substantially non-transparent state to at least a partially transparent state. More specifically, such an indicator may be comprised of a substantially non-transparent material, such as a layer of microporous fibers. For example, the exposure indicator can be selected from various materials, such as polytetrafluoroethylene, ethylene tetrafluoroethylene, polychlorotrifluoroethylene, polydimethyl siloxane, polyvinylidene fluoride, polyvinyl acetate, cellulose acetate, ethylene vinyl acetate copolymer, poly methyl methacrylate, polypropylene, polyethylene, polyacrylic acid, polyvinyl chloride and polycarbonate.

[0026] The indicator may generally have a refractive index that is substantially different from the refractive index of air. Therefore, in a dry state, the indicator material appears to be substantially non-transparent, or generally white in appearance. Upon exposure to an antiseptic agent, the indicator material preferably changes from a substantially non-transparent state to at least partially transparent state due to the fact that the refractive index of the indicator material is closer to the refractive index of the antiseptic agent than it is to the refractive index of air. The change in transparency is preferably for a limited time duration. This may be the result of the fact that the antiseptic agent evaporates from the membrane, allowing the membrane to return to its original dry and substantially non-transparent state.

[0027] Generally, the substrate on which the exposure indicator material is disposed upon may be constructed of various materials. These substrate materials include, for example, polyester, polyvinyl chloride, polypropylene, polyethylene, cellulose acetate, ethylene vinyl acetate, cyclic olefin copolymer, PET—polyethylenetetraflouride, polyurathane, nylon, polyacrylamide and any other suitable materials. Preferably, the exposure indicator is affixed to a substrate, rather than being affixed directly to the surface of the housing of an access device. This mechanical affixation of the exposure indicator to a substrate may aid in securing or attaching the indicator more securely to the housing, and can be achieved by methods such as heat bonding, laser welding, adhesive, and ultrasonic welding. The substrate can then, in turn, be affixed to the surface of a medical fluid flow control device housing by methods such as mechanical attachment, heat staking, laser welding, adhesive, decorative molding and ultrasonic welding. Adhesives can include synthetic rubber adhesive, UV cured adhesive, cyanoacrylate adhesive, hot melt, epoxy or solvent bonding. Alternatively, the substrate may include the housing of the access device, and adhesive bonding, double sided adhesive tape or other suitable attachment technique such as those described above may be used to affix the exposure indicator directly to the housing.

[0028] Further, the exposure indicator material may be used in combination with a visual signal source that is obscured until the material becomes transparent upon contact with an antiseptic agent. When in a dry state, the non-transparent material may, for example, be generally non-transparent so as to obscure the visual signal source. Upon contact with an antiseptic agent, the indicator may undergo a change in transparency to become at least partially transparent, allowing the visual signal source to become visible to the user. Such visual signal source may take a variety of forms, such as a particular color, a text message, an icon, or other visually communicative tool that provides a visual indication to the user that the access site has been exposed to antiseptic agent. Alternatively, the exposure indicator material may include a visible pattern in the substantially non-transparent state, wherein the pattern becomes substantially invisible when the indicator material is contacted by an antiseptic agent.

[0029] In a still further embodiment, which is a variation of the previously described embodiment, an exposure indicator for indicating exposure to an antiseptic agent comprises a substrate, and an indicator disposed on the substrate. The indicator comprises a substantially non-transparent material that is responsive by a change in transparency upon exposure to the antiseptic agent. Further, a permeable membrane is disposed over the indicator. As an example, the substrate may comprise an adhesive layer and the indicator may comprise a porous material. Further, the permeable membrane disposed on the indicator may also comprise a porous material. It is preferable that the pore size of the

indicator is different than the pore size of the permeable membrane disposed over the indicator.

[0030] Generally, the substrate on which the exposure indicator material is disposed upon may be constructed of various materials. For example, substrate materials may include polyester, polyvinyl chloride, polypropylene, polyethylene, cellulose acetate, ethylene vinyl acetate, cyclic olefin copolymer, polyethyleneterathalate, polyurethane, nylon, and polyacrylamide. The exposure indicator can then be affixed to the substrate. The substrate can then, in turn, be affixed to the surface of a medical fluid flow control device housing. The affixation of the exposure indicator to the substrate may aid in securing or attaching the indicator more securely to the housing.

[0031] The exposure indicator of the present embodiment may be selected from a variety of materials, including, for example, polytetrafluoroethylene, ethylene tetrafluoroethylene, polychlorotrifluoroethylene, polydimethyl siloxane, polyvinylidene fluoride, polyvinyl acetate, cellulose acetate, ethylene vinyl acetate copolymer, poly methyl methacrylate, polypropylene, polyethylene, polyacrylic acid, polyvinyl chloride, and polycarbonate.

[0032] In the present embodiment, the exposure indicator preferably changes from substantially non-transparent to at least partially transparent upon exposure to an antiseptic agent. It is preferable that the change in transparency is for a limited time duration. Further, the exposure indicator material may be used in combination with a visual signal source that is obscured until the material becomes transparent upon contact with an antiseptic agent. When in a dry state, the non-transparent material may, for example, be white in color, and generally non-transparent so as to obscure the visual signal source. Upon contact with an antiseptic agent, the indicator may undergo a change in transparency to become at least partially transparent, allowing the visual signal source to become visible to the user. Such visual signal source may take a variety of forms, such as a particular color, a text message, an icon, or other visually communicative tool that provides a visual indication to the user that the access site has been exposed to antiseptic agent. Alternatively, the exposure indicator material may include a visible pattern in the substantially non-transparent state, wherein the pattern becomes substantially invisible when the indicator material is contacted by an antiseptic agent.

[0033] The top permeable membrane layer of the present embodiment may serve various purposes, such as, for example, a protective layer over the exposure indicator to increase durability and shelf life, and/or to control the rate of ingress and/or evaporation of antiseptic agent after swabbing has taken place to control the time of visual indication.

[0034] In yet another aspect of the present invention, the access device may further include a fixed reference color that can be used by the clinician as a comparison to the color of the indicator. The reference color could be, for example, a ring of color disposed around the access site, such as in a "bulls eye" fashion, so that the clinician can compare the color change of the adjacent gland and/or housing to the fixed reference color after swabbing has taken place. This may help the clinician to determine when a complete color change has occurred, and consequently, if a swab had been conducted and/or indicate that active, deliberate swabbing has taken place.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Turning now to a more detailed description of the various embodiments of the present invention illustrated in the attached drawings, of which:

[0036] FIG. **1** is a perspective view of a medical fluid flow system in flow communication with a phlebotomized human subject, that includes a fluid access device in accordance with the present invention for adding fluid to or withdrawing fluid from the medical fluid flow system.

[0037] FIG. **2** is a perspective view of one embodiment of a medical fluid access device embodying the present invention particularly well suited for attachment to a terminal end of fluid flow tubing, such as at the end of a catheter going into a patient.

[0038] FIGS. **3-5** are a sequence of perspective views of the access device of FIG. **2**. FIG. **3** shows the access device prior to exposure to an antiseptic agent. FIG. **4** shows the access device being exposed to an antiseptic agent by swabbing the access site with an antiseptic cloth. FIG. **5** shows the access device providing a visual indication, such as by a change of color or transparency, that the access site has been exposed to an antiseptic agent.

[0039] FIG. **6** is a perspective view of another embodiment of the access device of the present invention as part of a medical fluid flow system, with fluid about to be added to or withdrawn from the flow system through the access device by a syringe with a needle.

[0040] FIG. **7** is a perspective view of another embodiment of a medical fluid access device of the general type shown in FIG. **2**, and comprising a ring of a fixed reference color disposed on the access device for comparison by the user to evaluate a color change of the indicator when exposed to antiseptic agent.

[0041] FIG. **8** is a perspective view of the access device of FIG. **7** after the access device has undergone swabbing or other contact or exposure to an antiseptic agent and after the indicator has become substantially identical in color to the fixed reference color to indicate to the user that the access site has been disinfected in accordance with proper medical practice.

[0042] FIG. **9** is a side view of another embodiment of the access device of the present invention particularly suited for mounting in-line or mid-line in association with a fluid flow system.

[0043] FIG. **10** is a perspective view of the access device of FIG. **9** about to receive a male luer end of a syringe for introduction or withdrawal of medical fluid.

[0044] FIG. **11** is a perspective view of yet another embodiment of the fluid access device of the present invention located mid-line in a fluid flow path and adapted to receive a specially designed blunt cannula for introduction or withdrawal of medical fluid.

[0045] FIG. **12** is a graph generally showing a correlation between the time of swabbing the surface of an access device of the present invention with antiseptic agent, the reduction in the number of organisms on the surface of the access device, and the change in color intensity of a visual indicator that changes color upon exposure to an antiseptic agent.

[0046] FIG. **13** is an enlarged perspective view of the access device of FIG. **2**, with a cross-section taken along line **14-14** where an exposure indicator surrounds the access site.

[0047] FIG. **14***a* is an enlarged view of the cross section taken along line **14-14** generally showing an exposure indicator in the form of a layer of dye or other suitable indicator disposed on the surface of the housing of an access device.

[0048] FIG. **14***b* is an enlarged view of the cross section taken along line **14-14** generally showing an alternative embodiment of an exposure indicator, such as a membrane layer impregnated with a color changing material disposed on the surface of the housing of an access device.

[0049] FIG. **14***c* is a variation of the embodiment shown in FIG. **14***b*, wherein a membrane is disposed on the surface of the housing of an access device and is impregnated with a hydrogel material containing a dye or other suitable indicator.

[0050] FIG. **14***d* is an enlarged view of the cross section taken along line **14-14**, generally showing a layer of an exposure indicator material disposed on the housing of an access device, and a membrane disposed over the indicator material.

[0051] FIG. **14***e* is an enlarged view of the cross section taken along line **14-14** generally showing an intermediate substrate layer disposed on the housing of an access device and an exposure indicator layer disposed on the substrate layer.

[0052] FIG. **14***f* is a variation of the embodiment shown in FIG. **14***e*, wherein a permeable membrane layer is disposed on the exposure indicator layer.

DETAILED DESCRIPTION OF THE INVENTION

[0053] FIG. **1** generally illustrates a medical fluid flow system, generally at **10**. The fluid flow system **10** is illustrated for exemplary purposes only as is an intravenous (IV) administration set. The present invention is not limited to IV flow systems and may be used in association with any apparatus, or container or flow system where fluid flow access is useful, such as but not limited to administering fluid to or withdrawing fluid from a subject (e.g. patient) or container (e.g. vial or bag).

[0054] As illustrated in FIG. **1**, the set comprises a length of flexible plastic tubing **12**, one end of which is connected via needle or other access means to a phlebotomized patient (i.e., subject) **14**, and the other end is connected to a container **16** of medical fluid, such as intravenous solution or any other medically-related liquid. The tubing **12** of the IV administration set provides a fluid passageway allowing fluid communication between the donor **14** and the container medical fluid source **16**.

[0055] For introducing fluid into or withdrawing fluid from the flow path, the illustrated IV set **10** includes one or more access devices **18** in accordance with the present invention. The fluid access device **18** (or additional such devices) may be provided at any convenient location along the length of the tubing **12**, and FIG. **1** illustrates a generally mid-line entry location. The access device **18** in FIG. **1** may take the form, for example, of the access devices shown in larger view in FIGS. **6**, **9** and **11**. Such access devices are commonly referred to as V-sites or Y-sites, in reference to their shape, and are typically but not exclusively used for mid-line entry points into fluid flow systems. Again, this is for purposes of illustration only. The fluid access device **18** of the present invention may be a permanent component of a fluid flow set or may be removably attached to a connector member or to tubing branch, without departing from the present invention—which is not limited to the general form or location of the access device. The fluid access device of the present invention may also be part of another structure such as a container, e.g., as a vial or bag, into which medical fluid is introduced or from which fluid is withdrawn.

[0056] Other shapes and forms of the access device may also be used. For example, FIG. **2** shows another access device **20** in accordance with the present invention that may be located at the terminal end of tubing **22**, such as at the external end of an indwelling catheter inserted into a patient's blood vessel. Of course, the access device **20** could also be located at the end of any branch tubing associated with a fluid flow system **10**. The illustrated fluid access device **20** has a generally elongated rigid or semi-rigid plastic housing **24** that includes a flow path (not shown) therethrough. The housing **24** material may be constructed of a semi-rigid or rigid medical grade material, such as polycarbonate material for ease of molding and bonding to common medical grade tubing, such as PVC tubing. The housing material may also be constructed of, for example, acrylic (PMMA), acrylonitrile butadiene styrene (ABS), methyl acrylonitrile butadiene styrene (MABS), polypropylene (PP), cyclic olefin copolymer (COC), polyurethane (PU), polyvinyl chloride (PVC) or other suitable material. The housing may be connected at its bottom or distal end to tubing **22** or to an intermediate connector as part of a fluid flow set. The top or proximal end of the housing **24** has a generally central circular opening or aperture **26** that defines an access site for introduction or withdrawal of medical fluid through the housing. As noted previously, such medical fluid may include, without limitation, IV solutions, blood and blood components, medications, chemotherapeutic agents, and various other fluids used for various diagnostic, therapeutic or other procedures.

[0057] In the illustrated access device, the aperture **26** is closed by a gland **28** that is preferably made of resilientlelastomeric material, such as rubber, silicone or latex. The gland normally closes and seals the aperture **26** when it is not being accessed. As used herein, "gland" is intended to have a broad and generic meaning directed to any member or members for normally closing or sealing the access site and which, in cooperation with an accessing member, allows for entry or access into the access site for introduction or withdrawal of medical fluid therethrough.

[0058] The gland **28** may be mounted or carried on or in the housing in a variety of ways that are known in the medical field. For example, as noted earlier, the gland may be a solid rubber, silicone or latex septum that spans the aperture and is pierceable by a needle, or the gland may include a pre-formed aperture or slit, which is adapted to receive or be opened by a blunt cannula, such as a male luer or specially designed cannula, for introducing or withdrawing fluid, or the gland may be moveable between the normally closed position and an open position, such as a "luer activated valve" or "luer access device" (LAD), for introduction or withdrawal of medical fluid. This is not an exclusive listing, but merely an indication of the wide variety of gland constructions that may be employed in an access site employing the present invention.

[0059] For purposes of illustration, FIGS. **2-5** show an access device in which the gland **28** has a preformed opening or slit **30** which is normally in a closed or sealed condition, but which can be forced open by penetration or compression by a blunt cannula or male luer. In this regard, the gland is preferably of resilient material so that it can be displaced or pierced in any suitable manner to allow access and return to a closed position sealing the aperture **26** and access site when the needle, cannula or luer is removed from the access site.

[0060] It will be appreciated that a fluid access device of the type described herein is, in normal usage, exposed to various contaminants or pathogens, such as airborne microorganisms, or by human contact by medical staff or patients. This may cause the surface of the access device to become contaminated with microbes such as bacteria or other harmful microorganisms. To reduce the risk of introducing such microorganisms or other pathogens into the subject, potentially resulting in infection, sickness, or even worse, good medical practice dictates that the clinician clean the access device with an antiseptic agent to kill or reduce the number of pathogens on the access site before administering fluid into or withdrawing fluid through the access site.

[0061] In accordance with the present invention, the access device **18** includes an indicator **32** that provides a visual indication when the access device has been exposed to an antiseptic agent. The indicator (or absence of a visual indication) serves as a deterrent to a clinician who might otherwise fail to observe proper aseptic techniques before introducing or withdrawing fluid through the access device.

[0062] As shown in FIGS. **2-5**, the indicator **32** is located on the portion or edge of housing **24** that immediately surrounds the gland **28**. Accordingly, when the medical personnel swab the surface of the gland, the indicator is also contacted by the antiseptic agent. In accordance with this aspect of the present invention, the indicator generates a visual indication to the user that such swabbing has occurred. The visual indication may be achieved in any suitable manner. It is preferable that the visual indication of exposure to the antiseptic agent be generated immediately upon disinfecting or shortly thereafter, for example, within several seconds.

[0063] As illustrated in FIGS. **2-5**, the visual indication is a color change. The indicator has an original color before it has been exposed to an antiseptic agent, such as blue or purple, and may change to another color, such as red or pink or become transparent from opaque, upon exposure of the indicator to an antiseptic agent, such as by contacting the indicator by swabbing with an antiseptic agent. Where the original color of the indicator is red, orange or the like, it serves as a convenient and conspicuous warning or reminder to the clinician that the surface of the access device has not been properly treated with an antiseptic agent and that the access device should not be used until proper aseptic technique has been carried out. The changed color, such as red or white or other, indicates that the access site has been swabbed with disinfectant agent.

[0064] Referring to FIGS. **3-5**, the clinician may treat the surface of the access device with an antiseptic agent by direct contact such as spraying, wetting, wiping or swabbing the gland and surrounding housing with a disinfectant or sterilizing agent. The antiseptic agent is typically contained in a cloth, tissue, cotton swab or the like, and by swabbing. Suitable sterilizing agents may include standard rubbing alcohol (isopropyl alcohol), or any other suitable antiseptic agents for killing bacteria or other pathogens.

[0065] A visual indication in the form of a color change may also serve as an indication to the clinician of the quality and thoroughness of the antiseptic treatment, such as proper swabbing surface coverage, proper swabbing force and/or pressure to the surface. For example, if aggressive antiseptic treating has taken place, the color change of the indicator may be of greater difference or intensity. More specifically, for example, if the indicator changes to red upon exposure to an antiseptic agent, the vividness or shade of the red color could indicate the extent of exposure. Dark or bright red could indicate that the access site has been aggressively treated with antiseptic agent or contacted with antiseptic agent over an extended period of time. A lighter or paler red might indicate a less aggressive treatment and signal the nurse or other clinician that further swabbing or wiping is necessary or would be useful.

[0066] It will be appreciated that the effectiveness of the antiseptic agent is only temporary, as the access device may become re-contaminated from exposure to the air or from human contact. As such, it is preferable that the visual indication, such as a color change, be temporary and of limited time duration, and that the access site return to its original or another color at some time after disinfecting—for example, several minutes, such as 3-10 or 5-10 minutes or such other time as may be desired after disinfecting. By reverting to the original condition or color, the indicator serves to remind the clinician to re-swab the access device with antiseptic agent before it is used again.

[0067] As seen in FIGS. **7** and **8**, which are a variation on the embodiment of FIGS. **2-5**, it may also be desirable to include a fixed reference indicator, such as a color, disposed on the gland or housing or both of the access device. As shown in detail in FIG. **7**, the fixed reference may be a color in the form of a ring **34** or other similar marking of color on the access device. The reference color preferably is a color that is substantially similar to the color of the indicator after exposure to an antiseptic agent. In the illustrated access device, if the indicator turns red upon exposure to an antiseptic agent, the fixed reference color may be a red ring disposed near the access site, although the reference color could be at a location elsewhere on housing **24** significantly spaced from the access site. As shown in FIGS. **7** and **8**, indicator **32** is a pair of rings flanking the reference ring **34** so that the colors may be easily compared and the indicator rings will be simultaneously contacted with antiseptic agent during swabbing. Swabbing is typically directed primarily at the gland and surrounding housing portions which may be contacted by the luer, cannula or needle for adding or withdrawing fluid through the access site. Thus, when the indicator is located on the housing, it is preferably located closely adjacent to the gland so as to contact the antiseptic agent to the same general degree as the gland.

[0068] With the above arrangement, if the indicator rings are, for example, red before the access device is swabbed with antiseptic agent, and the reference ring were red, the access device would have red, red and red rings around the gland prior to swabbing, thereby alerting the user to the need to disinfect the access site. After swabbing with an antiseptic agent, the red rings would turn red and the visual indication would appear as generally a single, wide red ring around the gland—until such time as the indicator rings **34** returned to their original red color or other non-red color.

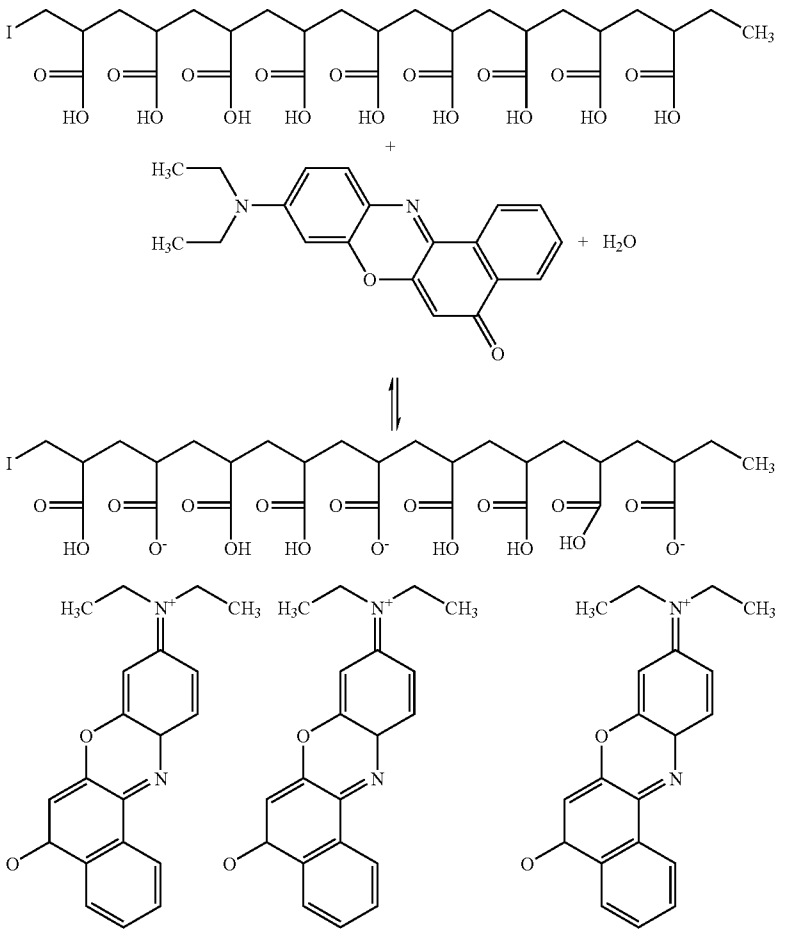
[0069] The visual indicator of the present invention may also include a feature or aspect that facilitates visual indication to a clinician who is color-blind or otherwise color-sight impaired. For example, if the visual indicator is a change of color, the change of color may have associated with it a pattern or arrangement that is visible to a color-impaired clinician. For example, the color change may be from a solid color to a color of having a pattern discernible to the impaired clinician, or vice versa. Alternatively, colors may be specially selected such that the color change employed by the indicator are detectable even by a person who is color-sight impaired.

[0070] The indicator of the present invention may be made in a number of different ways. In an optimal configuration, the indicator would actually be sensitive or reactive to presence of micro-organisms or other contaminants and would generate a visual indication when the surface of the gland and surrounding housing are substantially free of contaminants or microbes. In combination with an indicator of the present invention, one or more of the housing, gland or indicator may also include an anti-microbial coating, or an anti-infective agent attached, coated, or impregnated therein. Alternatively, or in addition to an anti-microbial coating on the housing, chlorhexidine gluconate can be added to the antiseptic agent used in the swabbing or included in the housing or gland or membrane of the access device as an additional antiseptic precaution.

[0071] As indicated earlier, the indicator may be one or more of several types of indicators that operate on different principles. Preferably, the indicator will generate a visual indication in response to contact with an antiseptic agent, such as isopropyl alcohol.

FIG. **14***a*

[0072] In one embodiment, as seen in FIG. **14***a*, the indicator may comprise a polyacrylic coating **80** or film that changes color in the presence of an antiseptic agent and is bonded, for example, by covalent or Van der Waals attraction, to the polycarbonate housing **24** of the access device. The polyacrylic coating **80** may be, for example a solvatochromic dye that reacts to the polarity of the antiseptic solution. The molecular structure of one example of an exposure indicator comprising a dye coating that may be disposed on the surface of an access device includes:



[0073] For a coating application of an exposure indicator **80** to polycarbonate substrates such as the housing of an access device **24**, for example, the use of a combination of an acid and a salt such as polyacrylic acid and Nile Red and

its derivatives may be incorporated in a antiseptic solvent-absorbing polymer matrix which has yielded a blue to pink color shift in the presence of a polar solvent such as isopropanol.

[0074] Alternatively, a color changing dye could actually be incorporated into at least a portion of the material that comprises the access device during manufacture. This is achieved, for example, by saturating the material that is used to construct the gland or "boot" portion of the fluid access device with dye that is reactive to exposure with an antiseptic agent. As discussed previously, the gland may be comprised of silicone, rubber, or similar elastomeric material, which is disposed within the housing of a fluid access device. The dye may be incorporated into the silicone, for example, during molding of the material, or alternatively, the silicone boot may be stained or "imbibed" with dye by placing the boot in a dye containing solution. The housing of the access device is then assembled with the dye-containing boot disposed within the housing.

[0075] To extend or control the length of time that the visual indication takes place, the dye may be incorporated in a antisceptic solvent-absorbing polymer matrix material. The antiseptic solven-absorbing polymer matrix absorbs the antiseptic agent and prolongs contact between the agent and dye so that the visual indication may continue for a more extended time than otherwise. Binding the Nile Red and its derivatives with polyacrylic acid, helps to prevent the unintentional removal of the dye as a result of swabbing of the access site. Potential variants of this approach include the use of agents in the exposure indicator that detect a pH shift or chemical change from the antiseptic agent during swabbing to produce a color change.

FIG. **14***b*

[0076] In another embodiment, as shown in FIG. **14***b*, the exposure indicator may comprise a dye encapsulated in or carried by a porous structure **82**, such as a membrane. The membrane **82** may be for example, a micro-porous membrane or an ultra-filtration membrane. The pores of the membrane can absorb and retain antiseptic agent during swabbing, thus increasing the duration of contact between the antiseptic agent and the dye that is encapsulated within the membrane. Pore size, pore structure, surface tension, skin layer thickness and density are factors to control absorption, evaporation rate and retention of the antiseptic agent allowing the membrane to therefore serve as a permeable selective layer. The longer the antiseptic agent is retained within the membrane **82**, the longer the duration of color or other visual change of the indicator will be maintained.

[0077] The membrane **82** may be constructed in various ways. In one embodiment, the membrane is formed separately from the manufacture of the housing of the access device. For example, a microporous polycarbonate membrane embedded with dye may be formed by a phase inversion process. In this method, the membrane is cast as a separate film or grown on a solid surface such as a glass plate or a liquid surface in several steps. First, a polymer and a dye are dispersed in a solvent. The solvent can be, for example, cyclohexane, toluene, THF, acetone, cyclohexanone, methylene chloride, NMP (N-methylpyrrolidone), ethylene chloride, and/or water. The solvent is then evaporated by various methods, including, increasing the temperature of the solvent or by increasing the gradient of vapor pressure. This causes the polymer to coagulate and solidify into a substantially solid porous structure. By controlling the evaporation rate of the solvent and the coagulation rate, characteristics of the porous membrane, such as skin layer thickness and density, pore size, and pore structure can be controlled. Once the membrane **82** is formed, it can then be attached to the surface of the housing **24** (or the gland **28** if desired). Such attachment may be achieved by various means, including, for example, sonic welding or adhesive. The attachment may also be formed using decorative or insert molding techniques which include introducing the membrane **82** into the mold for the housing **24** prior to the molding of the housing.

[0078] Alternatively, the membrane may be directly formed on the housing of the access device **24**. This is accomplished by preparing a membrane as described above by the phase inversion process. Dye is added to a polymer solution containing a solvent. The polymer solution is preferably made with the same polymer that is used for the construction of the housing. The housing of the access device can be contacted with the solution, such as by "dipping" into the solution, and the solvent contained in the polymer solution will dissolve the surface of the housing. The membrane with encaptured dye will thus be formed on and bonded directly on the surface of the housing.

FIG. **14***c*

[0079] In another embodiment, as seen in FIG. **14***c*, the active agent in the indicator, such as a dye or other agent, can be encapsulated in another material **84** which is embedded in a membrane, or chemically cross-liked to other materials. For example, dye can be captured in a antiseptic solvent-absorbing polymer matrix during the polymerization of the antiseptic solvent-absorbing polymer matrix. For non-reactive dyes, the dye can be trapped in the antiseptic solvent-absorbing polymer matrix after the antiseptic solvent-absorbing polymer matrix is polymerized. For reactive dye, the dye structure can become part of the polymer segment itself. Potential dye containing materials include, for example, crosslinked co-polymer of urethane acrylates with polyvinyl pyrolidone or dimethyl acrylamide

[0080] Again, as described above, the antiseptic solvent-absorbing polymer matrix is a generally absorbent material, that can absorb and "swell" with antiseptic agent. A membrane that includes a hydrogel material will provide a longer retention of antiseptic agent. This, in turn, increases the duration of contact of the antiseptic agent with the exposure indicator, thus increasing the duration of the visual indication.

[0081] Alternatively, hydrogel beads with encaptured dye can be mixed into a polymer solution such as polycarbonate or PVDF when synthesizing a porous membrane. In this way, dye-containing beads **84** can be embedded in the membrane **82** during the synthesis and formation of the membrane.

Other Variations

[0082] Other variations may include cross-linked solvent-absorbent polymers, placing the dye in an acrylic polymer, using thermal cure types of emulsion carriers for the dye, or employing lacquer carriers for the dye or employing substrates (such as silicone) to hold the dye in the substrate matrix. The dye could potentially also be suspended in a

matrix of adhesive or secured by two-shot molding of film to a polycarbonate substrate of the access device.

[0083] The indicator of the present invention could also include a liquid crystal material that changes color upon a temperature change from contact with the antiseptic agent. The liquid crystal material may be suspended between layers of film, such as polyester film, to capture the material. Such material may be present in the form of mirco-capsules. The film may then be attached to the access device housing, which may be of polycarbonate material, by cyanoacrylate adhesive or other bonding agent or method. Alternatively, the liquid crystal material may be suspended in an impregnated substrate or contained in a coating applied to the access device. An alternative to liquid crystal materials are thermochromic dyes, which change color due to a temperature change. Such dyes could be employed as described above. Such an indicator allows for quick color change which is also reversible back to the original color in minutes.

[0084] Yet a further variation of the indicator is the use of a pressure-sensitive material, such as liquid crystal microcapsules, which change color as a result of pressure exerted by the clinician during swabbing. The microcrystals may be suspended between layers of film, such as polyester film, to capture the material. Such microcapsules may exhibit a single color change and may not be reversible. Accordingly if reversibility of the color change is desired, other pressure sensitive materials or mechanisms may be employed.

FIG. **14***d*

[0085] In another embodiment, as seen in FIG. **14***d*, a layer **86**, which may be porous or permeable, may be disposed over the exposure indicator. In this embodiment, the exposure indicator may comprise a layer of dye **80** or other suitable indicator material disposed on the housing **24**, including a dye-containing membrane **82** disposed on the housing **24**. A permeable layer **86** or cover is then disposed over the indicator material. In one example the layer **86** could be a clear porous material such as cellulose acetate or thin polycarbonate film disposed over the exposure indicating material. The exposure indicator would therefore be "sandwiched" between the surface of the housing of the access device **24** and the permeable layer **86**. Attachment of the permeable layer **86** to the layer of exposure indicator may be achieved by solvent bonding, heat, adhesive, or sonic welding.

[0086] Such a coating over the indicator may serve various purposes, such as to provide a protective layer over the indicator, control absorption and evaporation of antiseptic agent and/or provide a layer of selective permeability, without unduly interfering with a visual indication of swabbing with an antiseptic agent. in fact, a permeable membrane may actually encourage a more effective antiseptic swab technique by a clinician for the reason that the clinician may be required to swab with greater deliberate and consistent pressure across the surface of the access device so that antiseptic agent from the swab permeates the membrane and reaches the exposure indicator thereunder.

[0087] In the event that the exposure indicator layer comprises a dye-containing membrane, it may be desirable to provide a permeable layer with a pore size different than the pore size of the underlying membrane layer of exposure indicator, creating a "differential porosity" between the exposure indicator and the overlying permeable layer. For example, the pore size of the overlying permeable layer may be smaller than the pore size of the underlying layer of exposure indicator. Thus, evaporation of antiseptic agent from the exposure indicator would be slowed and the time of contact between the exposure indicator and the antiseptic agent would be increased. This will generally provide a longer duration of visual indication, for example, a change in color of the exposure indicator would be maintained for a longer period of time. This would ensure a clear and conspicuous indication of a proper antiseptic swab to the clinician. A covering membrane of substantially smaller pore size may also retard escape or extraction of dye or other material from the underlying indicator.

FIG. **14***e*

[0088] In another embodiment, the visual indication may comprise a change in transparency. For example, as seen in FIG. **14***e*, an exposure indicator **88** may be disposed on a portion of the housing, the gland, or both, and undergo a change in transparency upon exposure to an antiseptic agent. For example, dry (air filled) microporous structures appear white to the observer even when the strands comprising the microporous structures are transparent. The reason for this is the mismatch between the refractive index of the solid strand of material and the surrounding air. If the air is replaced by another fluid with a refractive index identical to or very close to that of the strand, the structure will appear transparent to the observer. Various polymeric materials can be used as an exposure indicator in which a noticeable change in transparency will occur upon wetting with an antiseptic agent. Preferably, such materials have a refractive index within a range approaching or approximating that of the typical antiseptic agent. For example, polymeric materials having a refractive index in the range of 1.25 to 1.6 may be particularly suited to this embodiment. Materials having a refractive index in this range include, but are not limited to: polytetrafluoroethylene, ethylene tetrafluoroethylene, polychlorotrifluoroethylene, polydimethyl siloxane, polyvinylidene fluoride, polyvinyl acetate, cellulose acetate, ethylene vinyl acetate copolymer, poly methyl methacrylate, polypropylene, polyethylene, polyacrylic acid, polyvinyl chloride, and polycarbonate.

[0089] In use, it is desired that the antiseptic fluid penetrate the structure thoroughly if it is to wet all strands. One can use this phenomenon as a visual signal of good wetting by a known fluid. For example ePTFE and 70% IPA have almost identical refractive indices. Thus, when a microporous ePTFE membrane which is white or opaque to the eye when dry, is wetted by swabbing with a 70% IPA, the membrane becomes transparent, and the underlying color or predetermined visual signal, such as a color or printed message, will be visually discernible. If the user tries to swab with a fluid which does not provide effective swabbing, which by way of example may be water, blood, infusion solutions or drugs, the ePTFE membrane will not wet, and will remain white. Such fluids may interfere with the indicating properties or provide a medium for the growth of infectious agents. In this regard, it also may be desirable to provide a hydrophobic coating on or over the exposure indicator layer to substantially prevent a change in transparency in the presence of water. Such hydrophobicity can be described for purposes of this description as any material which is wettable by alcohol, and not wettable by water. In this way, water may be rejected or segmented out by the

hydrophobic coating, while only the antiseptic agent will wet the microporous membrane.

[0090] The visual indication provided by the above-described change in transparency has particular advantages. First, it is purely physical in nature and does not rely on incorporated dyes or pigments and is not subject to extractables of any kind. Also, the swabbing fluid that includes 70% isopropyl alcohol can be used effectively to create a visual indication of swabbing with materials that have a long history of use in medical deices. Alternatively, materials which have a refractive index similar to chlorhexidine in 70% IPA which is also used as a swabbing agent.

[0091] Such a microporous structure may be carried or mounted on the gland or housing or both in any desired manner. If provided as a separate member, the microporous structure could be in the form of a membrane or other structure, with an adhesive backing **90** that may be attached to the housing or gland using ultrasound, adhesive, heat binding or other techniques. The structure may also be applied to the housing using decorative molding techniques.

[0092] In an embodiment, the microporous material may be an ePTFE material having a polyester, polyethylene or polypropylene mesh support which facilitates attachment to the housing. In particular such mesh facilitates sonic welding or attachment by liquid adhesive of the material to the surface. Additional layers of polyester mesh may be used to aid in the attachment of the microporous material to the housing. Membranes having a polyester mesh support are commercially available.

[0093] The change in transparency may itself be a visual indication to the user, or the microporous structure may be used in combination with a visual signal source. When in a substantially non-transparent state, the microporous structure may serve to obscure the visual signal source, such as a source that is situated therebelow. Such a visual signal source may be, for example, a particular color, a text message, a bar code or other computer readable image, an icon, or other visual indicator that, when revealed, would provide an indication to the clinician that the access device has been exposed to antiseptic agent. Conversely, when the visual signal source is obscured by the non-transparent state of the indicator, the clinician will be alerted to the fact that the surface of the access device has not been treated with antiseptic agent. Accordingly, as the microporous structure dries, it returns to a non-transparent state, alerting the clinician to swab the access device before using it again. The reading of the visual signal source by a reader may then produce a signal which is fed into a medical information system or database to verify and produce a historical record of the swabbing before administration. For purposes of the present invention, it is not necessary that the refractive indexes of the antiseptic agent and the membrane be so close that complete transparency occurs (although that may be preferred). It is sufficient if the change in transparency is sufficiently noticeable to the user to permit its use as an indicator or contact with an antiseptic agent.

[0094] In a further embodiment a layer of the microporous structure may be applied to a layer of the indicating material which also displays a visual signal when coming into contact with the swabbing fluid. Thus the outer layer becomes transparent and an intermediate layer visually indicates that the swabbing has occurred.

[0095] In a further embodiment the degree of transparency exhibited may be controlled such that the desired degree of transparency only occurs upon a desired level of swabbing. By way of example, a visual indicator such as a bar code may not be visible with a required degree of readability without the membrane being sufficiently wetted or swabbed, this required degree being imposed by the bar code reader. One method of achieving this control is to provide two or more layers of the membrane which require the desired swabbing before the needed transparency is achieved. Another method is to select a membrane with a specific pore size which affect the degree of transparency and also may provide a sterilizing membrane by filtering out pathogens from penetrating through the membrane prior to or after use of the device.

FIGS. **14***f*

[0096] In an alternative embodiment, as seen in FIG. **14***f*, an additional permeable layer **92** may be disposed over the exposure indicator **88** shown FIG. **14***e*. In an example, the layer **92** may be porous or permeable and disposed on the indicator layer **88** would be a clear porous material such as cellulose acetate or polycarbonate film. As in FIG. **14***e*, the exposure indicator **88** of this alternative embodiment preferably undergoes a change in transparency upon exposure to an antiseptic agent. The entire structure of this embodiment would generally include four layers—the uppermost layer being the permeable layer **92**, which may be disposed on the exposure indicator layer **88**, which, in turn, may be disposed on a substrate layer **90**, which, in turn, may be disposed on the surface of the access device **24**. The substrate layer **90** and the exposure indicator **88** would therefore be "sandwiched" between the surface of the housing of the access device **24** and the permeable layer **92**. Attachment of the permeable layer **92** to the layer of exposure indicator **88** may be achieved by various means such as sonic welding.

[0097] Such a permeable layer **92** over the indicator **88** may serve various purposes, such as to provide a protective layer over the indicator, control absorption and evaporation of antiseptic agent and/or provide a layer of selective permeability. For example, the permeable layer **92** may comprise a polycarbonate, having a 0.20-micron pore size. The surface of the permeable layer **92** is preferably generally smooth in texture, so that it may substantially deter harmful microbes or bacteria from collecting on the surface of the access device near the access site. It will be appreciated that such a permeable layer **92** would not hinder the indication of proper swabbing from being verifiable. In fact, it may actually promote a more effective antiseptic swab technique by a clinician for the reason that the clinician may be required to swab with greater deliberate and consistent pressure across the surface of the access site so that antiseptic agent from the swab can permeate the permeable membrane **92** and reach the exposure indicator **88** thereunder.

[0098] The accompanying drawings show other types of access sites in which the present invention also may be employed. FIG. **6**, for example, illustrates a medical fluid flow system, generally at **36**, having a medical fluid container **38** and flexible plastic tubing **40** extending between the container **38** and a terminal connector **42**. The system **36** includes an access device **44** embodying the present invention and including a housing **46** and gland (not visible) with an indicator for indicating exposure to an antiseptic agent. The access device **44** is of the type that employs a solid septum, such as rubber, latex, or silicone, that is accessed by

piercing with a needle, such as needle **47** attached to syringe **48**. Examples of such an access site may be seen in U.S. Pat. Nos. 4,048,995 and 4,219,912, which are hereby incorporated by reference herein.

[0099] FIGS. **9** and **10** illustrate an access device **50** having a substantially rigid housing **52** having an opening or aperture **54** defining an access site and an indicator **56** for indicating exposure to an antiseptic agent. The device may further include a gland **58** for normally closing or sealing the aperture **54**. There may be certain circumstances where the access site is not closed by a gland, but in most typical applications, a gland will be employed.

[0100] The access device of FIGS. **9** and **10** is a LAD-type device, for access by a male luer, and the gland **58** is depressed by contact with a standard male luer, such as the luer **60** illustrated on syringe **62**, to open the access device to flow therethrough. Examples of this type of access site may be found in U.S. Pat. No. 6,682,509, where depression of a seal causes it to be pierced by an internal spike; U.S. Pat. No. 5,360,413, where depression of a piston accesses fluid passageways for flow through the access device; and U.S. Pat. No. 5,782,816, where compression of the valve element causes it to cant, permitting fluid flow through the device. All of the above patents are incorporated by reference herein and are intended to demonstrate that the present invention is not limited to the particular internal design or construction of a given access device, and that it has utility across the entire spectrum of access devices that are now or may later be employed in medical fluid access or flow systems.

[0101] In this regard, FIG. **11** illustrates a fluid access device **64** in accordance with another embodiment of the present invention and including a housing **66**, an aperture or opening **68** in the housing defining an access site, a gland **70**, normally closing and sealing the aperture, and a visual indicator **72**. This access device has a preformed but normally closed opening or slit **74** for receiving a blunt cannula **76** of a connecting fluid flow system **78**. The blunt cannula may be a specially designed cannula, such as described in U.S. Pat. No. 5,135,489, incorporated by reference herein, or may be a standard male luer or other member as illustrated, for example, in U.S. Pat. No. 6,669,681, also incorporated by reference herein.

[0102] Finally, it should be noted that the access device of the present invention does not need to be a separate device, and the access device housing may also be formed as part of another structure, such as in the form of the neck end of a medical fluid vial, a port on a stopcock or any other structure that defines an access opening into a container, a fluid flow system or other structure for the introduction or withdrawal of medical fluid therethrough. For example, the present invention may be particularly useful on medical vials.. Such vials are commonly glass or plastic containers with an open top or neck defining an opening or access site that is sealed by an elastomeric gland such as a rubber or silicone stopper or septum. The visual indicator of the present invention may be employed on the gland, or on a surrounding portion of the vial or closure structure, or both, so as to indicate to the user when the stopper or septum has been properly swabbed with disinfectant before the stopper or septum is punctured or otherwise accessed for withdrawal of contents from or introduction of fluid into the vial.

[0103] While the present invention has been described in terms of certain preferred and alternative embodiments for purposes of illustration, it is not limited to the precise embodiments shown or to the particular features, shapes or sizes illustrated. A variety of changes may be made without departing from the present invention as defined by the appended claims.

1. A medical fluid access device including an exposure indicator for indicating exposure to an antiseptic agent, the access device comprising:
- a housing defining an access site for the introduction or withdrawal of medical fluid through the housing,
- a material disposed on the housing for providing a visual indication of exposure to an antiseptic agent, the material comprising a dye that is responsive to exposure to an antiseptic agent to visually indicate such exposure.

2. The medical fluid access device of claim **1** wherein the material comprises a salt.

3. The medical fluid access device of claim **1** wherein the material comprises a solvent-absorbing polymer matrix material.

4. The medical fluid access device of claim **1** wherein the material is bonded to the housing by decorative molding.

5. The medical fluid access device of claim **1** wherein the material maintains the visual indication of exposure for a selected period of time after exposure.

6. The medical fluid access device of claim **1** wherein the visual indication comprises a change in color of the dye.

7. The medical fluid access device of claim **1** wherein the visual indication is for a limited time duration.

8. The medical fluid access device of claim **1** wherein said material comprises a salt and an acid.

9. The medical fluid access device of claim **1** wherein said dye is incorporated in a hydrogel material.

10. A medical fluid access device in accordance with claim **1** wherein the material comprises a salt of Nile Red and poly(acrylic acid) incorporated in a crosslinked antiseptic solvent-absorbing polymeric material.

11. An exposure indicator for indicating exposure to an antiseptic agent comprising:
- a substrate and a membrane carried on the substrate, the membrane providing a visual indication of exposure of the membrane to an antiseptic agent.

12. The exposure indicator of claim **11** wherein the membrane comprises a microporous membrane.

13. The exposure indicator of claim **11** wherein the membrane comprises an ultrafiltration membrane.

14. The exposure indicator of claim **11** wherein the visual indication comprises a color change.

15. The exposure indicator of claim **11** wherein the visual indication is for a limited time duration.

16. The exposure indicator of claim **11** wherein the membrane carries a dye that is responsive to exposure to an antiseptic agent to provide a visual indication of such exposure.

17. The exposure indicator of claim **16** wherein the dye is incorporated in the membrane.

18. The exposure indicator of claim **11** wherein the membrane has an original apparent color before exposure to an antiseptic agent, changes apparent color upon exposure to an antiseptic agent, and returns substantially to the original color thereafter.

19. The exposure indicator of claim **11** wherein the visual indication also indicates one of a degree of exposure to an antiseptic agent, the amount of swabbing motion of the antiseptic agent, and the pressure and control of the swabbing of the antiseptic agent.

20. The exposure indicator of claim **11** wherein the membrane is solid or porous.

21. An exposure indicator for indicating exposure to an antiseptic agent comprising:

a substrate

a membrane carried on the substrate,

an indicator incorporated in the membrane and adapted to provide a visual indication of exposure of the membrane to an antiseptic agent.

22. The exposure indicator of claim **21** wherein the membrane comprises a microporous membrane.

23. The exposure indicator of claim **21** wherein the membrane comprises an ultrafiltration membrane.

24. The exposure indicator of claim **21** wherein the visual indication comprises a color change.

25. The exposure indicator of claim **21** wherein the indicator indicates a degree of exposure to an antiseptic agent.

26. The exposure indicator of claim **24** wherein the degree of color change is indicative of the degree of exposure to an antiseptic agent.

27. The exposure indicator of claim **21** wherein the visual indicator is for a limited time duration.

28. The exposure indicator of claim **21** wherein the indicator comprises a dye impregnated in the membrane.

29. The exposure indicator of claim **21** wherein the indicator comprises a dye encapsulated in a solvent-absorbent polymer.

30. The exposure indicator of claim **29** wherein the solvent-absorbent polymer comprises a crosslinked polymer.

31. The exposure indicator of claim **21** wherein the solvent-absorbent polymer comprises a hydrogel.

32. The exposure indicator of claim **21** wherein the indicator has an original apparent color before exposure to an antiseptic agent, changes apparent color upon exposure to an antiseptic agent, and returns substantially to the original color thereafter.

33. An exposure indicator for indicating exposure to an antiseptic agent comprising:

a substrate,

an indicator material carried on the substrate, the indicator material being responsive by visible change upon exposure to the antiseptic agent, and

a membrane disposed over the indicator material.

34. The exposure indicator of claim **33** wherein the indicator material comprises a dye.

35. The exposure indicator of claim **33** wherein the indicator material comprises a salt.

36. The exposure indicator of claim **33** wherein the indicator material is incorporated in a solvent-absorbent polymer.

37. The exposure indicator of claim **33** wherein the indicator material comprises an acid.

38. The exposure indicator of claim **33** wherein the indicator material comprises a salt of an acid.

39. The exposure indicator of claim **33** wherein the visible change comprises a color change.

40. The exposure indicator of claim **39** wherein the color change is for a limited time duration.

41. The exposure indicator of claim **39** wherein the indicator material has an original apparent color before exposure to an antiseptic agent, changes apparent color upon exposure to an antiseptic agent, and returns substantially to the original color thereafter.

42. The exposure indicator of claim **33** wherein the indicator material indicates a degree of exposure to an antiseptic agent.

43. The exposure indicator of claim **39** wherein the degree of color change is indicative of the degree of contact with an antiseptic agent

44. The exposure indicator of claim **33** wherein the substrate comprises a polycarbonate.

45. The exposure indicator of claim **33** wherein the indicator material is affixed to the housing by one of solvent bonding, adhesive, glue, and sonic welding.

46. The exposure indicator of claim **33** wherein the membrane is porous.

47. The exposure indicator of claim **33** wherein the membrane controls the one of the rate of evaporation and ingress of the antiseptic agent from the indicator material after contact therewith.

48. An exposure indicator for indicating exposure to an antiseptic agent comprising:

a substrate,

a indicator material disposed on the substrate, the indicator comprising a substantially non-transparent material, said material being responsive by a change in transparency upon exposure to an antiseptic agent.

49. The exposure indicator of claim **48** wherein the substrate comprises a medical fluid access device housing.

50. The exposure indicator of claim **48** wherein the substrate is selected from the group consisting of polyester, polyvinyl chloride, polypropylene, polyethylene, cellulose acetate, ethylene vinyl acetate, cyclic olefin copolymer, PET-polyethylenetetraflouride, PU-polyurathane, nylon, and polyacrylamide.

51. The exposure indicator of claim **48** wherein the indicator is selected from the group consisting of polytetrafluoroethylene, ethylene tetrafluoroethylene, polychlorotrifluoroethylene, polydimethyl siloxane, polyvinylidene fluoride, polyvinyl acetate, cellulose acetate, ethylene vinyl acetate copolymer, poly methyl methacrylate, polypropylene, polyethylene, polyacrylic acid, polyvinyl chloride, and polycarbonate.

52. The exposure indicator of claim **48** wherein the indicator material is affixed to the substrate.

53. The exposure indicator of claim **48** wherein the indicator material is affixed to the substrate by one of laser welding, adhesive, and ultrasonic welding.

54. The exposure indicator of claim **48** wherein the substrate comprises a medical fluid access device housing and an adhesive bonding the indicator to the housing.

55. The exposure indicator of claim **48** wherein the substrate is affixed to a medical fluid flow control device housing by one of laser welding, adhesive, and ultrasonic welding.

56. The exposure indicator of claim **48** wherein the indicator material changes from substantially non-transparent to at least partially transparent upon exposure to an antiseptic agent.

57. The exposure indicator of claim **56** wherein the indicator material includes a visible pattern in the substantially non-transparent state, and wherein the pattern becomes substantially invisible when the indicator material is contacted by an antiseptic agent.

58. The exposure indicator of claim **56** wherein the change in transparency is for a limited time duration.

59. The exposure indicator of claim **56** wherein the indicator further includes a visual signal source that becomes visible upon a change in transparency when the indicator material is contacted by an antiseptic agent.

60. The exposure indicator of claim **59** wherein the visual signal source is selected from a group consisting of a color, a text message, and an icon.

61. The exposure indicator of claim **48**, wherein the indicator material comprises a microporous structure and has a refractive index that is substantially different from the refractive index of air.

62. The exposure indicator of claim **61** wherein the refractive index of the indicator material is closer to the refractive index of the antiseptic agent than it is to the refractive index of air.

63. An exposure indicator for indicating exposure to an antiseptic agent comprising:

a substrate,

an indicator disposed on the substrate, said indicator comprising a substantially non-transparent material, said material being responsive by a change in transparency upon exposure to the antiseptic agent

a permeable membrane disposed over the indicator.

64. The exposure indicator of claim **63** wherein the substrate comprises an adhesive layer.

65. The exposure indicator of claim **63** wherein the indicator comprises a porous material.

66. The exposure indicator of claim **63** wherein the permeable membrane comprises a porous material.

67. The exposure indicator of claim **65** wherein the pore size of the indicator is different than the pore size of the permeable membrane.

68. The exposure indicator of claim **63** wherein the substrate is selected from the group consisting of polyester, polyvinyl chloride, polypropylene, polyethylene, cellulose acetate, ethylene vinyl acetate, cyclic olefin copolymer, polyethyleneterathalate, polyurethane, nylon, and polyacrylamide.

69. The exposure indicator of claim **63** wherein the indicator is selected from the group consisting of polytetrafluoroethylene, ethylene tetrafluoroethylene, polychlorotrifluoroethylene, polydimethyl siloxane, polyvinylidene fluoride, polyvinyl acetate, cellulose acetate, ethylene vinyl acetate copolymer, poly methyl methacrylate, polypropylene, polyethylene, polyacrylic acid, polyvinyl chloride, and polycarbonate.

70. The exposure indicator of claim **63** wherein the indicator changes from substantially non-transparent to at least partially transparent.

71. The exposure indicator of claim **63** wherein the indicator includes a visible pattern in the substantially non-transparent state, and wherein the pattern becomes substantially invisible when the indicator is contacted by an antiseptic agent.

72. The exposure indicator of claim **70** wherein the change in transparency is for a limited time duration.

73. The exposure indicator of claim **70** wherein the indicator further includes a visual signal source that becomes visible upon a change in transparency when the indicator is contacted by an antiseptic agent.

74. The exposure indicator of claim **73** wherein the visual signal source is selected from a group consisting of a color, a text message, and an icon.

75. The exposure indicator of claim **63** wherein the indicator includes a second substrate, the second substrate being attached to the substrate and material and comprising a double sided adhesive tape.

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