ADHESIVE PATCH WITH ANTIMICROBIAL COMPOSITION

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Patent Applicant No. 13/757,423 filed on February 1, 2013 entitled "Adhesive Patch with Antimicrobial Composition" which claims priority to U.S. Provisional Patent Application No. 61/595,635 filed on February 6, 2012 entitled "Antiseptic Applicators and Protective Devices," both of which are hereby incorporated by reference in their entirety.

BACKGROUND

[0002] Healthcare acquired infection (HAI) has been recognized as a significant cause of preventable mortality and morbidity. In the United States, HAI annually costs nearly 99,000 lives and billions of dollars in additional treatment and hospitalization. Klevens, et al., *Estimating Health Care-Associated Infection and Deaths in U.S. Hospitals, 2002*, Public Health Reports, Vol. 122, p. 160, 2007. Contamination of intravascular catheters, surgical sites and invasive procedure sites, frequently leads to device removal and replacement, prolonged parenteral antimicrobial therapy, and extended hospitalizations and rehabilitation.

[0003] The spread of multi-antimicrobial resistant organisms frequently are spread by healthcare providers' hands or medical equipment, from one colonized or infected patient to other susceptible patients. Surgical site infections may result from inadequate antiseptic preparations of the skin. Widespread use of chlorhexidine

gluconate (CHG) for routine washing and wiping of pre-operative sites, has led to the increased incidence of resistant Staphyloccus aureus, both to methicillin (MRSA) and CHG, in some hospital environments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] The detailed description is set forth with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the reference number first appears. The use of the same reference numbers in different figures indicates similar or identical items or features.

[0005] FIG. 1A illustrates a cross-sectional view of an example adhesive patch.

[0006] FIG. 1B illustrates an adhesive side view of an example adhesive patch.

[0007] FIG. 2 illustrates an example adhesive patch as used on the arm of a human.

[0008] FIG. 3 is a flow diagram showing an example process for operating an example adhesive patch.

DETAILED DESCRIPTION

Overview

[0009] This disclosure describes medical applicators and patches designed to reduce and/or prevent infections. In one embodiment, the disclosure describes example patches comprising an impermeable backing having an adhesive located around a perimeter of the backing. The adhesive configured to allow the backing to removably

attach to a surface (e.g., human skin or animal tissue). The impermeable backing further coupled to a permeable layer located interior to the adhesive and saturated with an antimicrobial agent.

[0010] The detailed discussion below begins with a section entitled "Example Antimicrobial Composition", which describes in detail an example antimicrobial composition that may be included in the adhesive patches described herein. Next, the disclosure describes "Example Adhesive Patch". Next, an "Example Process" for operating an example adhesive patch is described. Finally, the disclosure concludes with a brief "Conclusion."

[0011] This overview, including section titles, is provided to introduce a selection of concepts in a simplified form that are further described below. The overview is provided for the reader's convenience and is not intended to limit the scope of the claims, nor the proceeding sections.

Example Antimicrobial Composition

[0012] In one example implementation, antimicrobial compositions that may be used in connection with the approaches described herein may include those described in, for example, International Patent Application No. PCT/US2011/022150, filed January 21, 2011, to Tennican et al., and, U.S. Non-Provisional Patent Application No. 13/688,078, filed November 28, 2012, to Tennican, which are incorporated herein by reference. For example, the antimicrobial compositions may include water (H_2O), a strong and non-toxic chelating agent such as ethylenediaminetetraacetic acid (EDTA)(e.g., disodium

EDTA, calcium disodium EDTA, magnesium EDTA, potassium EDTA, gallium EDTA) or sodium citrate (or acids, salts, derivatives, or other forms of EDTA or sodium citrate), a short-chain monohydric alcohol (e.g., ethanol with a molecular formula of C_2H_5OH and an empirical formula of C_2H_6O), and a strong, small molecule oxidizing agent such as hydrogen peroxide (H_2O_2). In one specific example, the compositions may consist essentially of water, EDTA, ethanol, and hydrogen peroxide. Additional ingredients can include thickeners, gellants, surfactants, foamers and/or foam stabilizers. However, in other examples, other antimicrobial compositions may be used in combination with the applicators and patches described in this disclosure.

[0013] The antimicrobial compositions may be in a liquid form or a gel form, and may be combined with one or more carriers or diluents, depending on the needs of a specific application. For example, if the antimicrobial composition is used as a cleaning agent the antimicrobial composition may be in a liquid form. In that case, the concentration of the various constituents may depend on, for example, a desired level of sanitation and/or disinfection, whether the composition is being applied directly to living tissue or to a medical device, and/or to avoid irritation of tissue to which the composition will be applied directly or indirectly (e.g., via a medical device to which the composition is or was applied).

[0014] In addition to providing disinfection at the time of the application, the antimicrobial compositions may also provide a lasting barrier against contamination. For example, even after volatile constituents of the composition (e.g., water, alcohol, hydrogen peroxide, etc.) have evaporated, the chelating agent may remain on the treated

surfaces (e.g., multiple use vial or port cleaning/protecting device, stethoscope, fingers, surrounding tissue, etc.) as a barrier that will provide antibacterial, antifungal or sporicidal (e.g., preventing germination of the spores), anti-parasitic, spermicidal or spermiostatic (e.g., decrease the motility of spermatozoon) and antiviral qualities. By robbing the environment of components (e.g., iron, magnesium, and manganese) that are needed for the bacteria (e.g., methicillin-resistant Staphylococcus aureus (MRSA), Pseudimonas aeruginosa and other resistant bacteria), spores, parasites, fungus and viruses to reproduce, the chelating agent provides a lasting defense to contamination even after other constituents of the antimicrobial composition have evaporated. Furthermore, the hydrogen peroxide in the antimicrobial compositions may induce a charge on a surface of materials (e.g., silicone materials) to which the antimicrobial compositions are applied, which make the materials more resistant to bacteria or other microorganisms.

[0015] The antimicrobial composition described above may also provide a visual indication of contamination when applied to a surface or material, such indication may allow users to identify and clean surfaces to prevent infection.

[0016] The term "about" or "approximate" as used in context of describing the example antimicrobial composition is to be construed to include a reasonable margin of error that would be acceptable and/or known in the art.

Example Adhesive Patch

[0017] Various adhesive patches are describes herein. Example adhesive patches are described generally with reference to FIGS. 1A, 1B, and 2.

[0018] FIG. 1A illustrates a cross-section view of an embodiment of an example adhesive patch that may be used to prepare and/or protect a site or surface. In this embodiment, an adhesive patch 100 may be applied to an area of skin prior to the beginning of a medical procedure, thus creating, and/or maintaining an uncontaminated skin zone while simultaneously allowing surgical entry and visibility. In some embodiments, the example adhesive patch 100 comprises an impermeable backing layer 102 having an adhesive material 104 located around the perimeter of the backing. The impermeable backing may further be coupled to a permeable layer 106 which may contain an antimicrobial agent. The permeable layer 106 may be located interior from the adhesive material on the impermeable backing.

[0019] In some embodiments, the impermeable backing 102 and permeable layer 106 of the example adhesive patch 100 may be composed of a sterile, translucent/semi-transparent, radiolucent, hypoallergenic, waterproof, and/or elastic material. For example material of the impermeable backing 102 of patch 102 may include, but not limited to, polyethylene, aluminum oxide, silicon oxide coated polymeric films, polypropylene, polysilicone, polytetrafluoroethylene, polyvinyl chloride, mylar, urethane polymer, acrylate polymer, or mixtures thereof. Where example materials for the permeable layer 106 include, but are not limited to, starch polymer, cellulosic gel, polyethylene foam, polyurethane foam, silicone open cell foam, or mixtures thereof. A level of transparency may allow a user to monitor a site while the patch is in place and also may allow a medical procedure (e.g., a radiological exam, an arthroscopic procedure, or the like) to proceed while the patch remains in place over the site. In some

embodiments, elasticity may allow the patch to conform to various contours of the application surface (e.g., a human knee, arm, chest, or the like).

[0020] FIG. 1B illustrates an adhesive side view of an example adhesive patch 100. The example adhesive patch 100 is shown as having a rectangle shape, although alternative shapes are contemplated such as, for example, a round shape, a rectangular shape, an oval shape, a polygon shape, or any other shape to accommodate the contours of human or animal skin.

[0021] In some embodiments, example adhesive patch 100 may have an adhesive material positioned around the exterior perimeter of the patch 100 and a permeable layer 106 positioned interior to the adhesive material 104. The adhesive material 104 may comprise any one or more of hypoallergenic, medical grade adhesives. Additionally, adhesive material 104 may be positioned on the perimeter of the impermeable backing layer in any width suitable to secure the patch to a surface. For example, a greater amount of adhesive material may be necessary to affix a larger patch or to affix a patch to a surface prone to movement (e.g., a knee, elbow, shoulder, or the like).

[0022] In some embodiments, the permeable layer may contain or be at least partially coated with the antimicrobial composition described in the preceding section. In some embodiments, the antimicrobial composition may be formulated as a liquid or a gel in any number of concentrations. In some embodiments, where the antimicrobial composition is a gel, the adhesive patch 100 may be constructed without the permeable layer 106,

[0023] In other embodiments, the antimicrobial composition may be combined with the adhesive material. In yet other embodiments, the adhesive material 104 may cover the entire underside shown in FIG. 1B. In this embodiment, the patch 100 may be constructed with or without the permeable layer 106.

[0024] The adhesive patch 100 may establish the uncontaminated zone by antimicrobial action when the patch is placed on a desired surface. In some embodiments, the adhesive patch could be applied at a sufficient time before the medical procedure to allow the antimicrobial action to work more thoroughly. The adhesive patch may additionally or alternatively be placed on the skin to maintain the uncontaminated zone after the skin is otherwise prepared for the medical procedure. In some embodiments, placing the adhesive patch over a desired incision site and allowing the patch to remain on the site for an extended period of time may permit the antimicrobial composition to penetrate skin and tissue layers more so than would be possible by using a simple topical application of a very strong antimicrobial before starting the incision.

[0025] As illustrated in FIG. 1B, the adhesive patch 100 may comprise one or more removable windows 108 at positions corresponding to incision and/or penetration sites. The adhesive patch 100 may be placed/aligned over a desired site so that the one or more removable windows 108 correspond with one or more incision and/or penetration sites. At the time of incision and/or penetration, a user may peel or otherwise remove the one or more windows to expose the site. For example, as illustrated in FIG. 1B, a user may peel away the three removable windows 108 which may correspond to the three incision or penetration sites for a common arthroscopic knee surgery.

[0026] FIG. 2 illustrates an example adhesive patch 200 that may be manufactured to comprise one or more pattern markings 202 on the adhesive patch to act as a template for the incision and/or penetration sites for a particular medical procedure. For example, the adhesive patch may be manufactured with a marking to designate the needle puncture site for the placement of a central venous catheter, or other IV components. In this embodiment, a user or health practitioner may place the adhesive patch over a human arm 204 so the marking on the patch aligns with the needle puncture site. In other embodiments, the adhesive patch 200 (or any other patch described herein) may allow a user to make any marking to designate one or more personalize or specific penetration site(s).

[0027] Details of the medical device described with respect to FIGS. 1A, 1B, and 2 may additionally or alternatively be applied to the example protective devices described in U.S. Pat. App. No. 12/874,188, filed September 1, 2010 to Tennican et al., which is incorporated herein by reference.

Example Process

[0028] FIG. 3 illustrates an example process 300 for execution of the techniques described above of operating an example adhesive patch. The process 300 is illustrated as a logical flow graph. The order in which the operations are described is not intended to be construed as a limitation, and any number of the described operations can be combined in any order and/or in parallel to implement the process.

[0029] At operation 302, an area to be sanitized or disinfected may be identified. For example, a user may identify an area of such as human skin that needs to be sanitized prior to beginning a medical procedure.

[0030] At operation 304, an adhesive patch having an antimicrobial composition may be applied to the area by aligning one or more removable windows of the adhesive patch with one or more access sites on the area to be sanitized or disinfect. In the context of FIG. 1B, a user may align the removable windows 108 of adhesive patch 100 with one or more incision sites corresponding to the incision sites for a particular medical procedure.

[0031] At operation 306, the aligned adhesive patch may be placed on the area to be sanitized or disinfected. As described in the context of adhesive patch 100, placing the adhesive patch over the area may allow the antimicrobial composition to come into contact with the area and one or more contaminants.

[0032] At operation 308, the adhesive patch may be allowed to remain on the area to be sanitized or disinfected. As described in the context of adhesive patch 100, allowing the adhesive patch to remain over the area may, for example, allow the antimicrobial composition to penetrate deeper into the skin and tissue layers and/or allow the antimicrobial composition to continue disinfecting or sanitizing.

[0033] At operation 310, the one or more removable windows aligned with the one or more access sites on the area may be removed. In the context of FIG. 1B, a user may peel away the three removable windows 108 to expose the one or more access sites on the area.

[0034] Finally at operation 312, the one or more access sites on the area may be accessed through the removed one or more windows of the adhesive patch.

Conclusion

[0035] Although the disclosure describes embodiments having specific structural features and/or methodological acts, it is to be understood that the claims are not necessarily limited to the specific features or acts described. Rather, the specific features and acts are merely illustrative some embodiments that fall within the scope of the claims of the disclosure.

CLAIMS

1. A medical patch for creating or maintaining an area of human tissue free of one or more contaminants comprising:

an adhesive fixed to a perimeter of an impermeable backing, the impermeable backing comprising one or more removable windows, wherein each of the one or more removable windows is removable to expose one or more access sites on the area;

a permeable layer coupled to the impermeable backing interior to the adhesive; and

an antimicrobial agent located within the permeable layer, the antimicrobial agent comprising at least one or more of hydrogen peroxide, carbamide peroxide, a chelator, or an alcohol.

2. The patch as recited in claim 1, wherein the one or more contaminants comprises at least one of bacteria, spores, parasites, viruses, bodily fluids, fungi or a combination thereof.

3. The patch as recited in claim 2, wherein the one or more bacteria includes methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa or other resistant bacteria.

4. The patch as recited in any one of claims 1-3, wherein the each of the one or more access sites corresponds to one or more locations on the human tissue where penetration is desired for a medical procedure.

5. The patch as recited in any one of claims 1-4, wherein the chelator comprises one of ethylenediaminetetraacetic acid (EDTA), salts of EDTA, sodium citrate, or another biocompatible chelator.

6. The patch as recited in claim 5, wherein the antimicrobial agent comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

7. A method of creating an area free of one or more contaminants comprising:

identifying the area to be sanitized or disinfected;

applying an adhesive patch to the area, the adhesive patch comprising:

an impermeable backing layer, the impermeable backing layer including one or more removable windows, wherein each of the one or more removable windows is removable to expose one or more access sites on the area;

an adhesive boundary fixed around an exterior edge of the impermeable backing layer;

a permeable layer coupled to the impermeable backing layer and interior to the adhesive boundary; and

an antimicrobial composition retained by the permeable layer.

8. The method as recited in claim 7, wherein the one or more contaminants includes methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa or other resistant bacteria.

9. The method as recited in claim 7 or 8, wherein the area to be sanitized or disinfected comprises a portion of human skin.

10. The method as recited in any one of claims 7-9, wherein applying the adhesive patch to the area further comprises:

aligning the one or more removable windows of the adhesive patch with the one or more access sites on the area to be sanitized or disinfected;

placing the aligned adhesive patch on the area to be sanitized or disinfected allowing the antimicrobial agent to come in contact with the one or more contaminants;

allowing the adhesive patch to remain on the area:

removing the one or more removable windows aligned with the one or more access sites; and

accessing the one or more access sites.

11. The method as recited in any one of claims 7-9, wherein the impermeable backing layer further comprises one or more markings, wherein each of the one or more markings represents the one or more access sites on the area, and wherein applying the adhesive patch to the area further comprises:

aligning the one or more markings with the one or more access sites on the area to be sanitized or disinfected;

placing the aligned adhesive patch on the area to be sanitized or disinfected allowing the antimicrobial agent to come in contact with the one or more contaminants;

allowing the adhesive patch to remain on the area;

accessing the one or more access sites through the one or more markings.

12. The method as recited in any one of claims 7-11, wherein the antimicrobial agent comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

13. A medical patch comprising:

a transparent impermeable backing layer, wherein the transparent impermeable backing layer includes one or more removable windows wherein each of the one or more removable windows is removable to expose one or more access sites;

an adhesive attached to a perimeter of the impermeable backing layer; and

an antimicrobial gel located interior to the adhesive perimeter on the impermeable backing layer, the antimicrobial gel comprising at least one or more of hydrogen peroxide, carbamide peroxide, a chelator, or an alcohol.

14. The medical patch as recited in claim 13, wherein each of the one or more access sites corresponds to an incision site or a penetration site for a predetermined medical procedure.

15. The medical patch as recited in claim 13 or 14, wherein the antimicrobial gel comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

16. The medical patch as recited in any one of claims 13-15, wherein the antimicrobial gel is effective to disinfect an area of human skin of one or more of a bacterium, a spore, a parasite, a virus, a fungus, a bodily fluid or a combination thereof.

17. The medical patch as recited in claim 16, wherein the one or more bacterium include methicillin-resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa or other resistant bacteria.

18. The medical patch as recited in any one of claims 13-17, wherein the transparent impermeable backing layer comprises polyethylene, silicon oxide coated polymeric films, polypropylene, polysilicone, polytetrafluoroethylene, polyvinyl chloride, mylar, urethane polymer, acrylate polymer, or mixtures thereof.