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(54) **MEDICATED PATCH FOR PREVENTING EXIT SITE INFECTIONS DURING PERITONEAL DIALYSIS**

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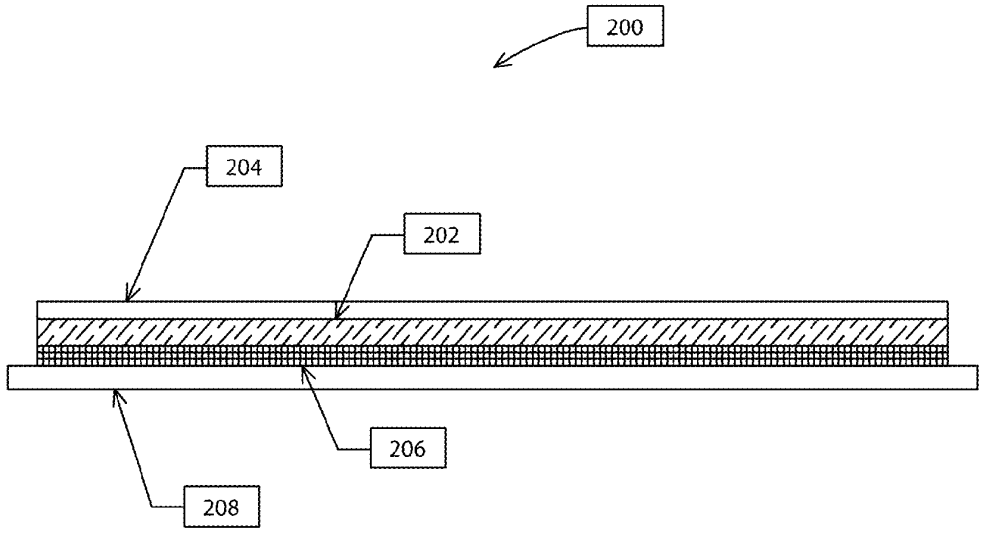
(57) **ABSTRACT**

A medicated apparatus including a medicated patch for use onto a subject undergoing peritoneal dialysis is disclosed, according to an embodiment of a present invention. The patch includes a medication layer containing a medication therein, and a backing film disposed on one side of the medication layer. The patch also includes a skin adhesive layer disposed beneath the medication layer; and a protective liner disposed beneath the skin adhesive layer. The patch is placed on a catheter by applying pressure to skin of a subject after insertion of the catheter therein, thereby holding the catheter and the medication diffusing into the skin prevents an exit site of infection.



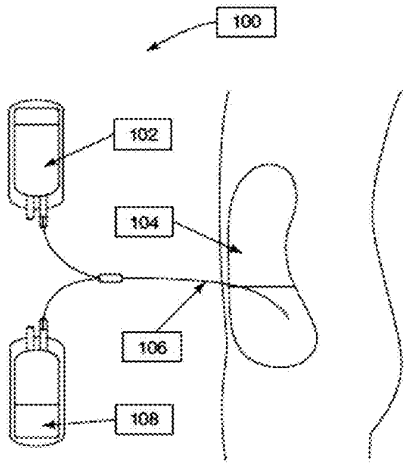


Figure 1A

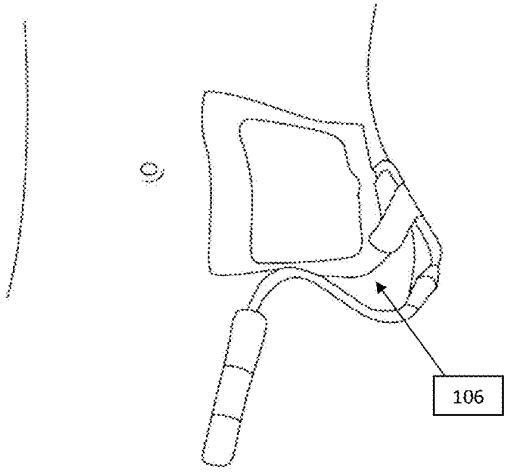


Figure 1B

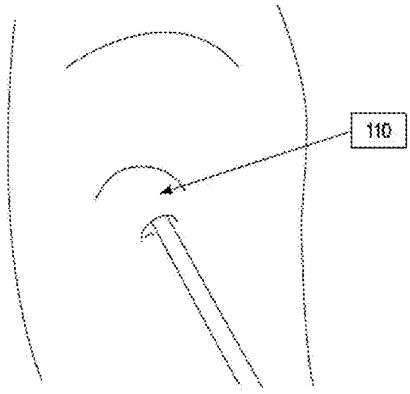


Figure 1C

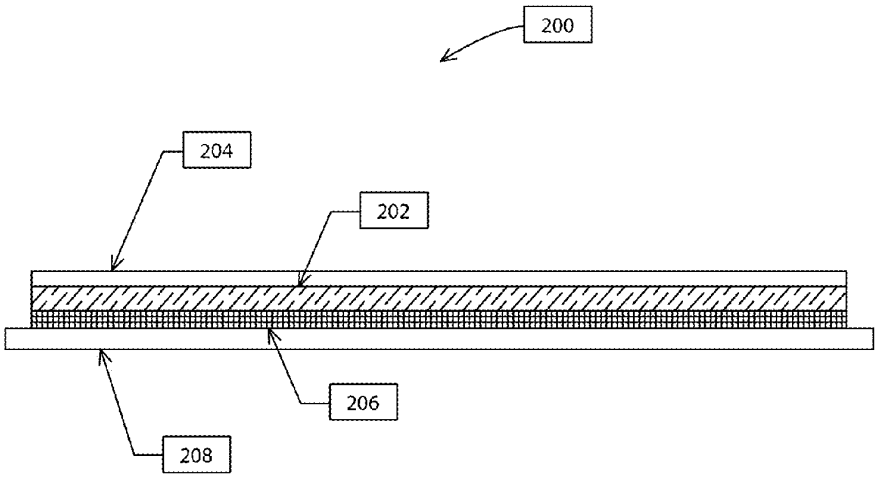
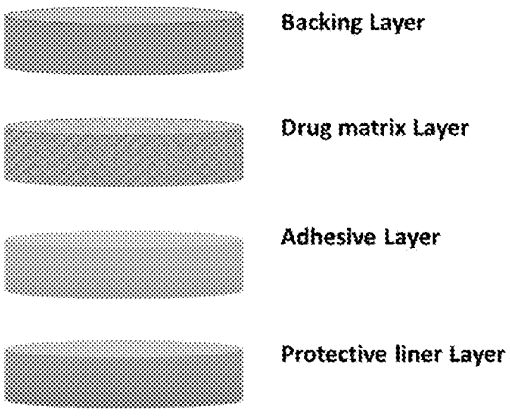

200
204
202
206
208

Figure 2


Backing Layer
Drug matrix Layer
Adhesive Layer
Protective liner Layer

MEDICATED PATCH FOR PREVENTING EXIT SITE INFECTIONS DURING PERITONEAL DIALYSIS

RELATED APPLICATION

[0001] This application claims the benefit of Brunei Application No. BN/N/2016/0060 filed on Aug. 8, 2016 and entitled "A Medicated Tape for Preventing Exit Site Infections During Peritoneal Dialysis, the content of which is incorporated in its entirety herein by reference.

FIELD OF INVENTION

[0002] The present invention relates generally to a medicated patch and more particularly, the present invention relates to a medicated surgical patch for preventing exit site infections during peritoneal dialysis. Such infections can otherwise lead to serious infection of peritonitis. Moreover, the present invention also relates to a medicated surgical patch for preventing infections which can occur laparascopic surgical incisions or other incisions.

BACKGROUND OF THE INVENTION

[0003] Patients with severe chronic kidney disease require dialysis e.g. Peritoneal Dialysis (PD). PD involves exchange of fluids and dissolved substances from the blood using the patient's peritoneum in the abdomen. The PD requires access to the peritoneal cavity where the peritoneal dialysis catheter is inserted which acts as a permanent pathway into the peritoneal cavity. The permanent catheter involves exchange of fluids and dissolved substances from the blood. The catheter is usually placed just below the side of the belly button. The catheter exit site is usually covered with a dressing and the catheter is taped to the skin to avoid infections and pulling on the exit site. However, frequent changing of the catheter involves repetitive adhering and removing tape from the skin, which may lead to serious skin inflammation. In addition, increased duration of PD may cause morphological changes in the peritoneal membrane. For example, inadequate solute clearance, ultrafiltration failure (UFF) and changes in peritoneal membrane transport properties may cause progressive damage to the peritoneal membrane, thereby leading to inability of the membrane to function properly. Such changes may also lead to Exit Site Infections (ESIs) and peritonitis.

[0004] In another instance, the catheter and the surgical dressing can also be contaminated by bacteria such as *S. aureus* or fungi, which can lead to an infection of the peritoneum thereby leading to ESIs and peritonitis.

[0005] Conventional arts such as topical mupirocin can reduce the risk of *S. aureus* induced ESIs and peritonitis. However, the topical mupirocin has a poor bioavailability 0.24% and has a short half-life of about 20-40 minutes, requiring repeated administration. Thus, such administration may lead to the development of antibiotic resistance in patients. In addition, the ointment contains alcohol which can degrade the catheter, leading to cracks in the catheter. Therefore, catheter needs to be changed frequently which can cause inconvenience to patients and skin inflammations.

[0006] Therefore, there exists a need for developing an alternative over the conventional arts which can prevent ESIs and peritonitis.

SUMMARY OF THE INVENTION

[0007] In an aspect, a medicated apparatus including a medicated patch for use onto a subject undergoing peritoneal dialysis is disclosed. According to an embodiment of a present invention. The patch includes a medication layer containing a medication therein, and a backing film disposed on one side of the medication layer. The patch also includes a skin adhesive layer disposed beneath the medication layer; and a protective liner disposed beneath the skin adhesive layer. The patch is placed on a catheter by applying pressure to skin of a subject after insertion of the catheter therein, thereby holding the catheter and the medication diffusing into the skin prevents the infection of exit site.

[0008] In another aspect of the present invention, a method for preventing transdermal infections during transdermal drug delivery procedures is disclosed. The method includes loading a medicated patch with a medication. The patch includes a medication layer containing a medication therein, and a backing film disposed on one side of the medication layer. The patch also includes a skin adhesive layer disposed beneath the medication layer; and a protective liner disposed beneath the skin adhesive layer. The patch is placed on a catheter by applying pressure to the medicated patch on skin of a subject after insertion of the catheter therein. The medication gets diffused into the skin for treating an exit site infection of peritonitis during peritoneal dialysis.

BRIEF DESCRIPTION OF DRAWINGS

[0009] Other objects, features, and advantages of the invention will be apparent from the following description when read with reference to the accompanying drawings. In the drawings, wherein like reference numerals denote corresponding parts throughout the several views:

[0010] FIG. **1**A depicts a schematic diagram of a peritoneal dialysis already known in the art; FIG. **1**B depicts an image of a medicated patch from the art during peritoneal dialysis; and FIG. **1**C depicts an image of an exit site infection using medicated patch of the art.

[0011] FIG. **2** depicts a schematic of a medicated patch, according to an embodiment of a present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0012] Reference will now be made in detail to the preferred embodiments of the present invention, examples of which are illustrated in the accompanying drawings.

[0013] In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be understood by those or ordinary skill in the art that the invention may be practiced without these specific details. In other instances, well known methods, procedures and/or components have not been described in detail so as not to obscure the invention.

[0014] The embodiment will be more clearly understood from the following description of the methods thereof, given by way of example only with reference to the accompanying drawings.

[0015] PD for patients with severe chronic kidney diseases requiring peritoneal dialysis involves access to the peritoneal cavity wherein the catheter is inserted. As shown in FIG. **1**A, PD **100** involves insertion of a catheter **106** into a

peritoneal cavity **104**. Dialysis fluid **102** is introduced through the catheter **106** in the peritoneal cavity **104** and waste fluid **108** is flushed out through the catheter **106**.

[0016] As shown further in FIG. **1**B, the catheter **106** exit site is covered with a dressing and the catheter **106** is taped to the skin to avoid infections. However, frequent changing of catheter **106** can lead to ESIs and peritonitis as shown in FIG. **1**C.

[0017] As already known in the art, topical mupirocin can reduce the risk of *S. aureus* induced ESIs and peritonitis. However, the topical mupirocin has a poor bioavailability of 0.24% and has a short half-life of about 20-40 minutes, requiring repeated administration. Thus, such administration may lead to the development of antibiotic resistance in patients. In addition, the ointment contains alcohol which can degrade the catheter leading to cracks in the catheter. Therefore, catheter needs to be changed frequently which can cause inconvenience to patients and skin inflammations.

[0018] However, if a self-adhesive medicated patch having mupirocin is applied on the exit site, then ESI can not only be used to prevent entry of bacteria but also can be applied nearest to the site of action. As already known in the art, mupirocin is an ideal drug candidate to formulate topical delivery because it has characteristics as log P: 2.45, PKa: 4.83, molecular weight: 500.6 Da, and has less half-life: 20-40 minutes. Therefore, such characteristics favor the mupirocin to formulate as a self-adhesive matrix patch.

[0019] Therefore, the present invention discloses a self-adhesive medicated patch that can prevent exit site infections during peritoneal dialysis.

[0020] As shown in FIG. **2**, the present invention discloses the self-adhesive medicated patch **200** that can prevent exit site infections during peritoneal dialysis. In some embodiments, the patch **200** can be used for topical and other transdermal drug delivery applications/procedures. The patch **200** can cure medical conditions also. The patch **200** is configured to be a medicated patch having a medication which can prevent medical condition such as ESI and peritonitis. In some embodiments, the patch **200** can cure impetigo (school sores); Folliculitis; Furunculosis (boils); Ecthyma; Infected dermatoses such as eczema, psoriasis, atopic dermatitis, epidermolysis bullosa, and ichthyosis; and Infected traumatic lesions such as ulcers, minor burns, abrasions, cuts, wounds.

[0021] As shown in FIG. **2**, the patch **200** includes a medication layer **202** having the medication contained therein. Examples of the medication may include, but are not limited to mupirocin, or any other prophylactic antibiotics, curcumin or any other antibiotics of natural product origin, and so on. The medication layer **202** provides an adhesive matrix into which the medication is embedded. In an embodiment, the medication that is used in the patch is a natural substance or chemical compound produced by a living organism. In another embodiment, the medication used in the patch is an antibiotic compound that inhibits the growth of or destroys microorganisms. In another embodiment, the medication is mixture of natural origin and of chemical origin.

[0022] In some embodiments, the medication layer **202** can be made from materials which include but are not limited to polymers, adhesive polymer, and so on. Examples of the polymers may include but are not limited to Ethyl cellulose, Hydroxy propyl methyl cellulose, Methyl methacrylate, and so on.

[0023] In some embodiments, the patch **200** includes a backing layer **204** disposed on one side of the medication layer **202**. In some embodiments, the backing layer **204** may be defined as an uppermost layer of the patch **200** which is visible and can be made from materials such as including but are not limited to polyethylene, polypropylene, ethyl vinylacetate copolymer film, and so on.

[0024] In some embodiments, the patch **200** provides a protective barrier preventing bacteria to enter therein. For Instance, as the microbes—bacteria or fungi reach inner to the patch **200**, the medication starts killing not only *S. aureus* but also against Methicillin-resistant *Staphylococcus aureus* (MRSA). Mupirocin reversibly binds to the isoleucyl t-RNA synthetase in *Staphylococcus aureus*, thereby inhibiting bacterial protein synthesis. Curcumin, a natural product, disrupts the bacterial membrane leading to prevention of biofilm formation. Moreover, the combination of antibiotic with curcumin produces synergistic effect and increases the antibiotic effect.

[0025] In some embodiments, the patch **200** has another layer—skin adhesive layer **206** which allows the patch to stick onto the skin, as well as holding the catheter firmly. In some embodiments, the adhesive layer **206** can be made from materials such as including but are not limited to medical-grade adhesives, such as low viscosity dimethylsiloxane, silicone, acrylates, and so on.

[0026] The patch **200** further has a protective liner **208** disposed beneath the skin adhesive layer **206**. The protective liner **208** is configured to protect the patch **200** from various damages such as contamination from dust and other avoidable contamination. The liner **208** needs to be removed immediately before the application of the patch **200** to the skin. The liner **208** is a primary packaging material and is in intimate contact with the delivery system. Thus, the liner **208** should be chemically inert to the materials used in the patch **200**. Cross-linking between adhesion layer **206** and the liner **208** can increase the amount of force needed to remove the liner **208**.

[0027] In some embodiments, the liner **208** can be made with materials such as including but are not limited to special medical grade, fluorocarbon polyester or siliconized polyester or polyester liner.

[0028] In some embodiments, the patch **200** includes chemical enhancers such as menthol or eugenol which can trigger the permeation of the medication into the site of application. For Example, the matrix of the medication layer **202** allows the medication to diffuse into the site of application area i.e. exit site area. The medication is allowed to diffuse from the matrix of the medication layer **202** to the adhesive layer **206**, followed by passing into the site of application. The diffusion of the medication release behavior/characteristics is controlled by the optimization of the matrix and adhesive layer **206**. Thus controlled release of medication is obtained.

[0029] In some embodiments, the patch **200** can be thick as 0.2 mm and diameter can vary in the range of 5-8 cm as per the patient's requirement. In some embodiments, the backing layer **204**, the medication layer **202**, and the adhesive layer **206** can be as thick as 0.1 mm, and diameter in the range of 5-8 cm, while the liner **208** can be as thick as 0.05 mm and diameter in the range of 5-8 cm.

[0030] In some embodiments, a method for manufacturing the patch **200** is disclosed in accordance with the present invention. The method involves dissolving polymer, adhe-

sive and plasticizer in chloroform, forming a solution. Examples of polymers may include but are not limited to Ethyl cellulose polymer, Hydroxy propyl methyl cellulose, Methyl methacrylate, and so on. Examples of adhesives may include but are not limited to medical-grade silicone adhesives, such as low viscosity dimethylsiloxane, silicone, acrylates, and so on. Examples of plasticizers may include but are not limited to triethylcitrate, dibutyl sebacate, propyleneglycol, and so on. The method further includes dissolving the medication into the solution i.e. embedding, forming a final viscous mass. The mass is coated onto the backing layer **204** using film applicator, incorporating the medication layer **202**. Thus, the medication is coated such that the medication is distributed uniformly in between the polymer chains of the matrix of the medication layer **202** and is not released from the matrix. The method further includes providing an unmedicated adhesive layer **206** on top of the medication layer **202** for stronger adhesion of the patch **200** onto the catheter and the skin.

[0031] In some embodiments, the patch **200** is placed on the catheter by applying pressure to skin of the patient after insertion of the catheter therein, thereby holding the catheter and the medication diffusing into the skin prevents the exit site of infection.

[0032] While the preferred embodiment of the present invention and its advantages has been disclosed in the above description, the invention is not limited there to but only by the scope of the appended claim.

[0033] As will be readily apparent to those skilled in the art, the present invention may easily be produced in other specific forms without departing from its essential characteristics. The present embodiments are, therefore, to be considered as merely illustrative and not restrictive, the scope of the invention being indicated by the claims rather than the foregoing description, and all changes which come within therefore intended to be embraced therein.

I/We claim:

1. A medicated apparatus comprising of a medicated surgical patch for use onto a subject undergoing peritoneal dialysis, the medicated surgical patch further comprising:
- a backing film disposed on one side of a medication layer;
- a medication layer containing a medication therein;
- a skin adhesive layer disposed beneath the medication layer; and
- a protective liner disposed beneath the skin adhesive layer;
- wherein the tape is placed on a catheter by applying pressure to skin of a subject after insertion of the catheter therein, thereby holding the catheter and the medication diffusing into the skin prevents an exit site infection and prevents incision related infection.

2. The medicated apparatus of claim **1**, wherein the medicated surgical patch is self-adhesive.

3. The medicated apparatus of claim **1**, wherein the medication is embedded into an adhesive matrix of the medication layer.

4. The medicated apparatus of claim **1**, wherein the medicated surgical patch prevents infections at exit site in peritoneal dialysis.

5. The medicated apparatus of claim **1**, wherein the medicated surgical patch prevents peritonitis in the patients.

6. The medicated apparatus of claim **1**, wherein the medicated surgical patch prevents infections at exit site in drainage tubes.

7. The medicated apparatus of claim **1**, wherein the medicated surgical patch prevents infections at exit site in laparascopic surgical incisions or due to other incisions.

8. The medicated apparatus of claim **3**, wherein the medication is coated on the medication layer using a film applicator.

9. The medicated apparatus of claim **3**, wherein the medication is a drug, a natural substance, antibiotic, or any medication or combination thereof for prevention of infection.

10. A method for preventing infections by topical drug delivery, the method comprising:
- loading a medicated patch with a medication, the medicated patch comprising:
  - a backing film disposed on one side of the medication layer;
  - a medication layer containing a medication therein;
  - a skin adhesive layer disposed beneath the medication layer; and
  - a protective liner disposed beneath the skin adhesive layer;
- placing the medicated patch on a catheter by applying pressure to the medicated patch on skin of a subject after insertion of the catheter therein; and
- diffusing the medication into the skin for preventing an exit site infection of peritonitis during peritoneal dialysis.

11. The method of claim **10**, wherein the medication is loaded using film coating method.

12. The method of claim **10**, wherein the infection is peritonitis.

13. The method of claim **10**, wherein the peritoneal dialysis is performed.

14. The method of claim **10**, wherein the medicated surgical patch prevents infections at exit site in drainage tubes.

15. The method of claim **10**, wherein the medicated surgical patch prevents infections at exit site in laparascopic surgical incisions.

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