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(54) Title: METHOD OF REMOVING A BIOFILM FROM A SURFACE

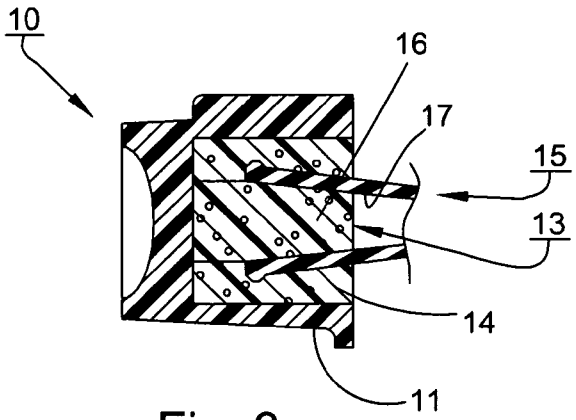

Fig. 3

(57) Abstract: A scrub brush housing a swab of foam material impregnated with an anti bacterial disinfectant is first placed over a female luer with an annular portion of the swab compressed against the luer and a central portion of the swab passed into the passage of the luer to effect a full contact with the surfaces of the swab. The swab is then rotated on the female luer for a time sufficient to substantially remove the biofilm on the surfaces of the luer that are contacted by the swab.

Method of Removing A Biofilm From a Surface

This invention relates to a method of removing a biofilm from a surface. More particularly, this invention relates to a method of removing a biofilm from a catheter.

Almost all micro-organisms subsist in elaborate colonies that are embedded in biofilms of self-produced exopolymer matrices. The biofilm allows the micro-organisms to adhere to any surface, living or nonliving. The adaptive and genetic changes of the micro-organisms within the biofilm make them resistant to all known antimicrobial agents. Thus, the diagnostic and therapeutic strategies used to fight acute infections are not effective in eradicating medical device biofilm-related infections or chronic biofilm diseases. Today, vascular catheter-related bloodstream infections are the most serious and costly healthcare-associated infections.

Catheter-related bloodstream infection originates from biofilm formation on either extra-or intra-luminal surfaces of the catheter. Microbial points of entry are the skin (extra-luminal) and any access port or disconnection site of the administration system.

The disinfection of access sites is a preventative intervention for microbial entry to the intra-luminal catheter surface. Currently, an alcohol (I.P.A.) prep pad is used in clinical practice for this purpose although no standard applies to address the optimal antiseptic, method of application or duration of application. The surfaces of the access ports and needle less connectors are highly variable in configuration.

Accordingly, it is an object of the invention to disinfect the surface of any type of access system prior to entry.

It is another object of the invention to substantially remove a biofilm from a surface and particularly the surfaces of a female luer or similar catheters.

Briefly, the invention provides a method of removing a biofilm from a surface comprising the steps of providing a substrate characterized in having a roughness sufficient to scrape a biofilm on a surface, a plurality of cavities or pores for capturing scrapings of biofilm and an antibacterial disinfectant therein; and moving the substrate across the surface having a biofilm thereon for a number of times sufficient to substantially remove the biofilm.

During the times that the substrate is moved across the biofilm-containing surface, a pressure is applied to facilitate the scrubbing action of the substrate on the biofilm.

The substrate is particularly useful on catheters, such as female luers, that have surfaces that can become the site for the growth of bacteria and, in particular, the growth of a biofilm.

The substrate that is preferably used is a semi-closed hydrophilic polyurethane medical grade foam.

In one embodiment, use is made of a scrub brush as described in pending United States Patent Application No. 11/732,075, filed April 2, 2007 the disclosure of which is incorporated by reference herein. In this respect, the scrub brush includes a housing that defines a cavity, a swab of foam material disposed in the cavity and an anti-bacterial disinfectant in the swab. In addition, a lid is

removably mounted on the housing for sealing over the cavity in order to maintain the cavity and swab therein in a sterile condition until ready for use.

In accordance with the invention, the scrub brush is placed concentrically over the outer surface of a female luer with the swab compressed circumferentially between the housing and the luer in order to effect a full contact of the swab with the outer surface. Thereafter, the scrub brush is rotated relative to the outer surface of the female luer for a time sufficient to substantially remove the biofilm on the outer surface.

Experiments have shown that for a female luer of conventional size, the number of rotations of the scrub brush relative to the female luer is in the range of from 6 to 10 rotations and, preferably, 8 rotations in order to substantially remove the biofilm.

It is understood that the action of the scrub brush is such as to effectively remove bacteria on the surface of a biofilm and, upon subsequent rotations, to scrape into the biofilm thereby removing scrapings of the biofilm into the cavities (pores) of the swab. Upon completion of the number of rotations, substantially all of the biofilm is scraped off the luer surface contacted by the swab and held within the cavities (pores) of the swab.

After the swab has been rotated on the female luer, the swab may be slid off the female lure and discarded.

In an embodiment in which the swab of a scrub brush includes an annular portion for enveloping the outer surface of a female luer and an inner central portion for insertion within the central passage of the female luer, a similar

method is carried out as described above. In this case, the scrub brush is again placed concentrically over the outer surface of the female lure with the annular portion compressed circumferentially between the housing of the scrub brush and the luer to effect a full contact of the swab with the outer surface while the central portion of the swab is compressed within the central passage of the female luer. After a sufficient number of rotations have been effected to remove or substantially remove the biofilm, the scrub brush can be removed from the female luer and discarded.

Where the female luer has an external thread, the scrub brush is threaded onto the outer surface and conforms to the shape of the external thread in order to contact the surfaces thereof. In this way, all the nooks and crannies on the outer surface of the female luer can be scrubbed by the swab.

Use may be also be made of a microbial scrub brush that has a pair of cavities on opposite sides of a housing with each cavity housing a swab of foam material with an antibacterial disinfectant therein. As above, a lid is removably mounted on the housing for sealing over each respective cavity in order to maintain the cavity and swab therein in a sterile condition until ready for use.

This embodiment is particularly useful in removing multiple layers of biofilm from a female luer that has been in use for an extended period of time. In such cases, it has been known that multiple layers will build up on the surfaces of the female luer.

The use of the multi-cavity housing allows the user to apply one of the swabs to the female luer to remove at least some of the biofilm layers followed by use of the second swab to remove the remaining layers of biofilm.

One advantage of the multi-cavity scrub brush is that the swabs may be made of different compositions. For example, one swab may be a low density hydrophilic polyurethane medical grade foam of high porosity while the other swab is a medium density hydrophilic polyurethane medical grade foam of low porosity. Further, one swab may be provided with a higher concentration of disinfectant than the other swab. Using the swab with the greater roughness first allows most of the biofilm layers to be removed. Follow-up swabbing with the less rough swab should result in the removal of the remaining biofilm layer or layers.

These and other objects and advantages of the invention will become more apparent from the following detailed description taken in conjunction with the accompanying drawings wherein:

Fig. 1 illustrates a perspective view of a microbial scrub brush utilized in accordance with the invention;

Fig. 2 illustrates a cross sectional view of the scrub brush of Fig. 1;

Fig 3 illustrates a cross sectional view of the scrub brush on the end of a female luer during scrubbing thereof in accordance with the invention;

Fig. 4 schematically illustrates a biofilm on a catheter surface; and

Fig 5 illustrates a cross sectional view of a scrub brush with a pair of oppositely disposed cavities and swabs in accordance with the invention.

Referring to Fig. 1, the scrub brush 10 is constructed in a manner as described in pending US Patent Application 11/732,075, which is incorporated by reference herein.

Referring to Fig. 2, the scrub brush 10 includes a housing 11 that defines a cavity 12, a swab 13 of foam material disposed in the cavity 12 and an anti-bacterial disinfectant in the swab 13.

The swab 13 includes an annular portion 14 for enveloping an outer surface of a female luer 15 (see Fig. 3) and a central portion 16 within the annular portion 14 for insertion within a central passage 17 of the female luer 15.

The swab 13 is a substrate characterized in having a roughness sufficient to scrape a biofilm on a surface and a plurality of cavities (pores) for capturing scrapings of biofilm therein. By way of example, the foam material may be a low to medium to density foam having a density of up to 5 pounds per cubic foot with an average core size of 0.013 inch.

The antibacterial disinfectant which is employed may be any suitable solution, such as, an aqueous solution containing from 2% to 5% chlorhexidine gluconate (CHG) and, in particular, a 3.15 % CHG Solution, a 4 % CHG Solution and a 5 % CHG Solution.

Referring to Fig. 4, the surface of the female luer 15 is shown with a biofilm 17 thereon. In this respect, the biofilm 17 covers over a layer of bacteria 18 formed directly on the surface of the female luer 15 and is it self covered by a layer of bacteria 19.

Referring to Fig. 3, in order to render the surfaces of the female luer 15 antiseptic, the scrub brush 10 is placed concentrically over the outer surface of the female luer 15 with the annular portion 14 of the swab 13 compressed circumferentially between the housing 11 and the luer 15 to effect a full contact of the swab 13 with the outer surface and the central portion 16 of the swab 13 is compressed within the central passage 17 of the female luer 15. Thereafter, the scrub brush 10 is rotated relative to the female luer 15 from 6 to 10 times, and preferably 8 times, in order to remove the exposed layer of bacteria 19, substantially all of the biofilm 17 and the covered-over layer of bacteria 18 on the outer surface of the luer 15 as well as the layers of bacteria and biofilm from the central passage 17 within the luer 15 that is contacted by the swab 13.

During rotation of the scrub brush 13 on the female luer 15, a scrubbing action takes place under compression. During the first turns of the scrub brush 13, the layer of bacteria 19 on top of the biofilm is removed. Subsequent turning of the scrub brush 13 scrapes into and removes the biofilm 17. The final turns of the scrub brush 13 remove the layer of bacteria 18 located below the now removed biofilm 17.

The combination of the roughness and the compression of the foam material of the swab 13 serves to scrape the biofilm 17 along the edges of the pores or cavities of the foam while capturing the scrapings in the pores or cavities of the foam.

Where the luer 15 has an external thread, or an internal thread, the compression of the foam material of the swab 13 serves to insure a full contact of

the swab 13 with the surfaces to be rendered antiseptic. Thus, the foam material yields to conform to the threaded surfaces to be cleaned so that all nooks and crannies can be swabbed.

As indicated in Figs 1 and 2, a lid 20 is removably mounted on the housing 11 for sealing over the cavity 12 in order to maintain the cavity 12 and swab 13 therein in a sterile condition until ready for use.

Referring to Fig 5, wherein like reference characters indicate like parts as above, the scrub brush 10' includes a housing 11' that defines a pair of oppositely disposed cavities 12, 12', each of which contains a swab 13, 13'. As indicated, each swab 13, 13' has an annular portion 14, 14' and a central portion 16, 16' as described above.

The swab 13 on one side of the housing 11' is made of a different porosity than the swab 13' on the opposite side of the housing 11'.

For example, the swab 13 is a semi-closed low density hydrophilic polyurethane medical grade foam of high porosity while the oppositely disposed 13' is a semi-closed medium density hydrophilic polyurethane medical grade foam of low porosity. The high porosity swab 13 would be used initially as a rough grain sandpaper to remove "chunks" of built-up biofilm layers and the lower porosity swab 13 used thereafter as a fine grain sandpaper to remove any remaining biofilm.

Further, the swab 13 may contain a different concentration of disinfectant from the other swab 13'. For example, the swab 13 may have a higher concentration of chlohexidine gluconate than the other swab 13'.

When placed into use, the lid 20 on one side of the scrub brush 10' is removed to expose the swab 13. The scrub brush 10' is then placed concentrically over the outer surface of a female luer in a manner as described above with respect to Fig. 3. After several rotations, e.g. 6 to 8 rotations, of the scrub brush 10' on the female luer, the scrub brush 10' is removed from the luer and the removable lid 20' removed to expose the second swab 13'. This swab 13' is then placed over the female luer, again as indicated in Fig 3, and rotated a similar number of times, e.g. 6 to 8 times, in order to remove any remaining biofilm layers on the female luer.

By using a swab with a greater roughness, several layers of biofilm may be removed from the female luer. Following with a swab that is less rough, serves to remove any remaining layer or layers of biofilm. In this respect, if only one swab were used, there is a risk that the one swab would become saturated with scraped off biofilm and would not remove all the biofilm layers from the female luer. The use of the second swab reduces this risk.

The invention thus provides a method of removing biofilm from a female luer and like catheters.

Further, the invention provides a method of reducing the risk of catheter-related blood stream infections originating from biofilm formation.

The invention further provides a method that is able to disinfect the surface of any type of access system prior to entry.

What is Claimed is:

1. A method of removing a biofilm from a surface comprising the steps of

providing at least one substrate characterized in having a roughness sufficient to scrape into a biofilm on a surface, a plurality of cavities for capturing scrapings of biofilm therein and an antibacterial disinfectant therein; and

moving said substrate across a surface having a biofilm thereon for a time sufficient to substantially remove said biofilm.

2. A method as set forth in claim 1 wherein said step of moving a substrate is characterized in a pressure being applied by said substrate onto said surface.

3. A method as set forth in claim 1 wherein said substrate is a semi-closed hydrophilic polyurethane medical grade foam.

4. A method as set forth in claim 3 wherein said antibacterial disinfectant is an aqueous solution containing from 2% to 5% chlorhexidine gluconate.

5. A method of removing a biofilm from a female luer having an outer peripheral surface and a central passage comprising the steps of

providing a scrub brush including a housing defining at least one cavity, a swab of foam material disposed in said cavity and an anti-bacterial disinfectant in said swab;

placing said scrub brush concentrically over said outer surface of said female luer with said swab compressed circumferentially between

said housing and said luer to effect a full contact of said swab with said outer surface; and

thereafter rotating said scrub brush relative to said outer surface of said female luer for a time sufficient to substantially remove the biofilm on said outer surface.

6. A method as set forth in claim 5 wherein said outer surface of said female luer has an external thread thereon and wherein said scrub brush is threaded onto said outer surface and conforms to the shape of said external thread to contact the surfaces thereof.

7. A method as set forth in claim 6 further comprising the step of sliding said swab off said female luer after said step of rotating said scrub brush.

8. A method of removing a biofilm from a female luer having an outer peripheral surface and a central passage comprising the steps of

providing a scrub brush including a housing defining a cavity, a swab of foam material disposed in said cavity said and including an annular portion for enveloping said outer surface of said female luer and a central portion within said annular portion for insertion within said central passage of said female luer, and an anti-bacterial disinfectant in said swab;

placing said scrub brush concentrically over said outer surface of said female luer with said annular portion of said swab compressed circumferentially between said housing and said luer to effect a full contact

of said swab with said outer surface and said central portion of said swab compressed within said central passage of said female luer; and

thereafter rotating said scrub brush relative to said female luer for a time sufficient to substantially remove the biofilm on said outer surface and from said central passage contacted by said swab.

9. A method as set forth in claim 8 wherein said swab is rotated from six to ten times relative to said female luer.

10. A method as set forth in claim 8 wherein said swab is rotated eight times relative to said female luer.

11. A method as set forth in claim 8 wherein said swab has a surface characterized in having a roughness sufficient to scrape into the biofilm on said substrate and to remove scrapings of the biofilm therefrom and further characterized in having a plurality of cavities for capturing said scrapings therein.

12. A method as set forth in claim 11 wherein said swab is a semi-closed hydrophilic polyurethane medical grade foam.

13. A method as set forth in claim 8 wherein said antibacterial disinfectant is an aqueous solution containing 2% chlorhexidine gluconate.

14. A microbial scrub brush comprising

a housing defining a first cavity on one side thereof and a second cavity on an opposite side thereof;

a first swab of foam material disposed in said first cavity;

a second swab of foam material disposed in said second cavity;

an anti-bacterial disinfectant in each said swab;

a first lid removably mounted on said housing for sealing over said first cavity and said first swab therein; and

a second lid removably mounted on said housing for sealing over said second cavity and said second swab therein.

15. A microbial scrub brush as set forth in claim 14 wherein said first swab includes an annular portion for enveloping an outer surface of a female luer and a central portion concentrically within said annular portion for insertion within a central passage of the female luer and said second swab includes an annular portion for enveloping an outer surface of a female luer and a central portion concentrically within said annular portion for insertion within a central passage of the female luer.

16. A microbial scrub brush as set forth in claim 14 wherein said first swab is a semi-closed low density hydrophilic polyurethane medical grade foam of high porosity and said second swab is a semi-closed medium density hydrophilic polyurethane medical grade foam of low porosity.

17. A microbial scrub brush as set forth in claim 14 wherein said anti-bacterial disinfectant is an aqueous solution containing from 2% to 5% chlorhexidine gluconate.

18. A microbial scrub brush as set forth in claim 17 wherein said anti-bacterial disinfectant in said first swab has a higher concentration of chlorhexidine gluconate than said anti-bacterial disinfectant in said second swab.

19. A method of removing multiple layers of biofilm from a female luer having an outer peripheral surface comprising the steps of

providing a scrub brush including a housing defining a pair of oppositely disposed cavities, a swab of foam material disposed in each said cavity of said pair of cavities and an anti-bacterial disinfectant in each said swab;

placing said scrub brush concentrically over said outer surface of said female luer with said swab in one of said cavities compressed circumferentially between said housing and said luer to effect a full contact of said swab with said outer surface;

thereafter rotating said scrub brush relative to said outer surface of said female luer for a time sufficient to remove at least one layer of biofilm from said outer surface;

thereafter placing said scrub brush concentrically over said outer surface of said female luer with said swab in the other of said cavities compressed circumferentially between said housing and said luer to effect a full contact of said swab with said outer surface; and

thereafter rotating said scrub brush relative to said outer surface of said female luer for a time sufficient to remove any remaining layers of biofilm from said outer surface.

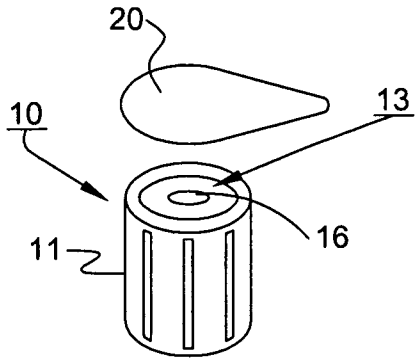

Fig. 1

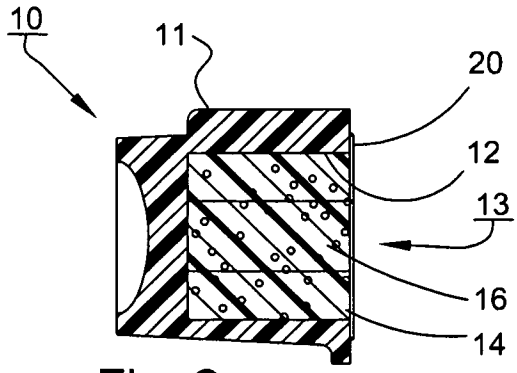

Fig. 2

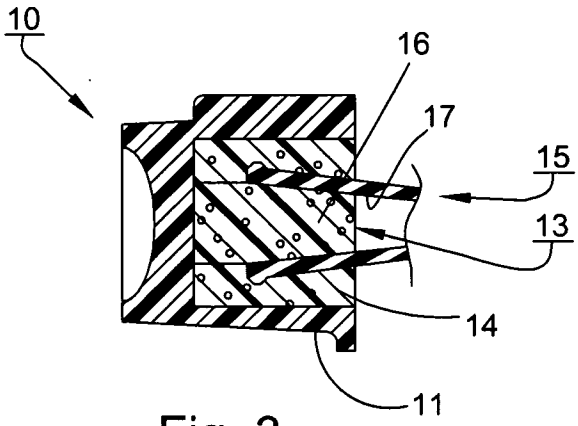

Fig. 3

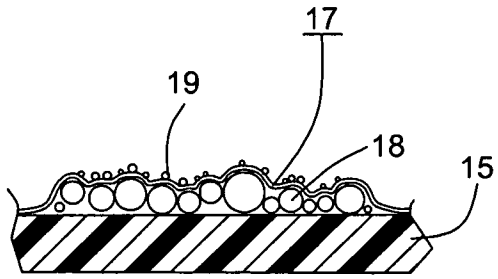

Fig. 4

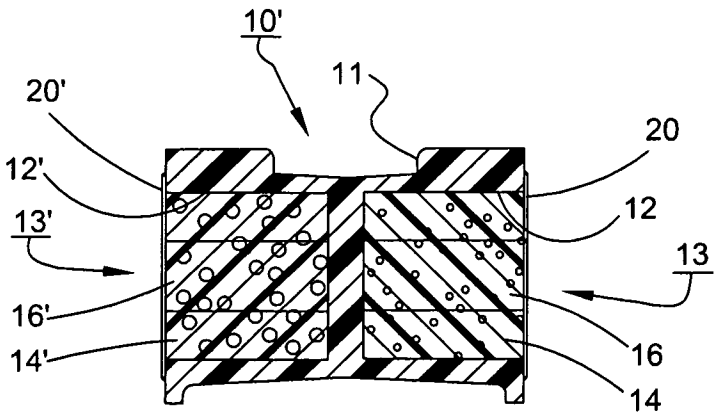

Fig. 5