Title: SYSTEMS AND METHODS FOR APPLYING AN ANTIMICROBIAL COATING TO A MEDICAL DEVICE

Abstract: Methods for applying an antimicrobial coating to a medical device is disclosed. Generally, the methods comprise providing a medical device, dispensing an antimicrobial coating onto the device, flushing excess coating from the device, and curing the coating onto the device. In one aspect, the coating includes a UV-curable, antimicrobial composition. In this aspect, the medical device can be coated and the coating can be cured with UV light in a manner of seconds. In another aspect, the coating includes an antimicrobial solution that contains an acrylate-type monomer or copolymer. In this aspect, the medical device can be coated and the coating can be heat-cured in a manner of minutes. Both the UV-curable composition and the antimicrobial solution can also include rheological modifiers, as necessary. Additionally, the compositions include one or more antimicrobial agents, which may be selected from a wide array of agents.
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SYSTEMS AND METHODS FOR APPLYING AN ANTIMICROBIAL COATING TO A MEDICAL DEVICE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to systems and methods for using antimicrobial coatings in various medical applications. One of the major challenges of modern medical treatment is control of infection and the spread of microbial organisms.

[0002] One area where this challenge is constantly presented is in infusion therapies of various types. Infusion therapy is one of the most common healthcare procedures. Hospitalized, home care, and other patients receive fluids, pharmaceuticals, and blood products via a vascular access device inserted into the patient's vascular system. Infusion therapy may be used to treat an infection, provide anesthesia or analgesia, provide nutritional support, treat cancerous growths, maintain blood pressure and heart rhythm, or for many other clinically significant uses.

[0003] Infusion therapy is facilitated by a vascular access device. The vascular access device may access a patient's peripheral or central vasculature. Additionally, the vascular access device may be indwelling for a short term (e.g., days), a moderate term (e.g., weeks), or a long term (e.g., months to years). The vascular access device may also be used for continuous infusion therapy or for intermittent therapy.

[0004] A common vascular access device is a plastic catheter that is inserted into a patient's vein. Generally, the length of such a catheter may vary from a few centimeters, for peripheral access, to many centimeters, for central access. The catheter may be inserted transcutaneously or may be surgically implanted beneath the patient's skin. The catheter, or any other vascular access device attached thereto, may have a single lumen or multiple lumens for infusion of many fluids simultaneously.

[0005] The vascular access device commonly includes an adapter (e.g., a Luer adapter) to which other medical devices may be attached. For example, an administration set may be attached to a vascular access device at one end while an intravenous (IV) bag is attached at the other. The administration set is a fluid conduit for the continuous infusion of fluids and pharmaceuticals. Commonly, an IV access device is a vascular access device that attaches to another vascular access device, closes the vascular access device, and allows for intermittent infusion or injection of fluids and pharmaceuticals. An IV access device may include a housing and a septum for closing the system. The septum may be opened with a blunt cannula or a male Luer of a medical device.
When the septum of a vascular access device fails to operate properly or has inadequate design features, certain complications may occur. Complications associated with infusion therapy may cause significant morbidity and even mortality. One significant complication is catheter related blood stream infection (CRBSI). An estimate of 250,000 - 400,000 cases of central venous catheter (CVC) associated blood stream infections (BSIs) occur annually in US hospitals.

Current vascular access devices prevent complications, such as infection resulting in CRBSIs, by providing a septum that functions properly during attachment and/or access of the vascular access device by other medical devices. Septa that function properly will act, in part, as infection barriers between the internal and external environments of the vascular access device during attachment and/or access by other medical devices. By functioning properly as infection barriers, septa minimize CRBSIs and other complications.

In some cases, a vascular access device may serve as a nidus of infection, resulting in a disseminated BSI. This may be caused by failure to regularly flush the device, a non-sterile insertion technique, or by pathogens that enter the fluid flow path through either end of the path subsequent to catheter insertion. When a vascular access device is contaminated, pathogens adhere to the vascular access device, colonize, and form a biofilm. Many such biofilms are resistant to a variety of biocidal agents and provide a replenishing source for pathogens to enter a patient's bloodstream and cause a BSI.

Over the past few decades, it has been a common practice to use a thermoplastic polyurethane solution as the carrier for an antimicrobial coating. The solvent is usually tetrahydrofuran (THF), dimethylformamide (DMF), or a blend of both. Because THF can be oxidized very quickly and tends to be very explosive, an expensive explosion-proof coating facility is necessary when THF is used as the solvent. Harsh solvents, such as THF and DMF, are also highly toxic and environmentally hazardous. Additionally, the harsh solvents tend to attack most of the polymeric materials (i.e., polyurethane, silicone, polyisoprene, butyl rubber polycarbonate, polyvinyl chloride, PET, and acrylics) that are used to produce medical devices (e.g., vascular access devices). Therefore, medical devices that are made with these materials can become distorted and/or form micro-cracks on their surfaces. Another issue with coatings comprising harsh solvents is that such coatings generally require a relatively long period of time (e.g., about 24 hours) for the solvent to be completely heat evaporated. Still another issue with coatings comprising a harsh solvent is that such solvents are difficult to apply uniformly across the surface of a medical device.
Accordingly, conventional technologies using harsh solvents have persistent problems with processing and performance.

Another conventional method for providing medical devices with antimicrobial characteristics involves the use of silver salts and elemental silver. Silver salts and elemental silver are well known antimicrobial agents in both the medical surgical industry and general industries. They are usually incorporated into the polymeric bulk material or coated onto the surface of the medical devices by plasma, heat evaporation, electroplating, or by conventional solvent coating technologies. These technologies, however, are often very tedious, expensive, time consuming, and environmentally hazardous.

In addition, the performance of silver coating medical devices is mediocre at best. For example, it can take up to 8 hours before the silver ion, ionized from the silver salts or silver element, can reach certain efficacy as an antimicrobial agent. As a result, substantial microbial activity can occur prior to the silver coating even becoming effective. Furthermore, the silver compound or silver element has an unpleasant color, from dark amber to black.

Accordingly, there is a need in the art for improved coatings for providing antimicrobial capability to medical devices of various types, and particularly to devices related to infusion therapy. There is also a need for improved methods of applying such antimicrobial coatings to medical devices.

**BRIEF SUMMARY OF THE INVENTION**

The present invention has been developed in response to problems and needs in the art that have not yet been fully resolved by currently available systems and methods for applying antimicrobial coatings to medical devices. Thus, the described methods, systems, and compositions are developed to reduce complications (e.g., the occurrence of CRBSIs, damage to medical devices caused by harsh solvents, environmental damage caused by harsh solvents, etc.) by providing improved methods and systems for coating medical devices with an improved antimicrobial coating.

Generally, the present invention includes coating a medical device with an antimicrobial coating. The described methods can be used to coat a medical device made from a variety of materials. In some preferred implementations, however, the described methods are used to coat medical devices that comprise one or more polymeric substrates, which include, but are not limited to, polycarbonate, polyurethane, polyvinyl chloride, acrylic, and combinations thereof.
The described methods can be performed with one or more of a wide variety of coatings. Nevertheless, the preferred coating is selected from an ultraviolet light- (UV) curable, antimicrobial composition and an antimicrobial solution.

Where the coating comprises the UV-curable, antimicrobial composition, the UV-curable composition can comprise any suitable ingredient. In some implementations, the UV-curable composition comprises a UV-curable material comprising one or more urethane- or polyester-type oligomers with at least one acrylate-type functional group, acrylate-type monomers, and photoinitiators. Additionally, in some implementations, the UV-curable composition further comprises one or more rheological modifiers and antimicrobial agents.

Where the coating comprises the antimicrobial solution, the solution can comprise any suitable ingredient. Indeed, in some implementations, the solution comprises one or more solvents, coating resins, rheological modifiers, and antimicrobial agents.

The described methods generally include providing a medical device, dispensing an antimicrobial coating onto a surface of the device, flushing excess coating from the device, and curing the coating onto the device. Of course, the methods can be modified in any suitable manner. In one example of a modification, the methods include masking a portion of the device to prevent the coating from being deposited on the portion of the medical device that is covered by the masking.

In the described methods, the coating can be dispensed onto a surface of the device in any suitable manner. In one example, a machine injects a calculated amount of the coating into the device.

After the antimicrobial coating has been applied to the medical device, excess coating, if any, can be removed from the device in any suitable manner. For example, the excess coating can be removed by blowing the excess coating from the device with an inert gas, spinning the medical device in a centrifuge, by wiping the device with a material, through gravity, etc. In some presently preferred implementations, however, nitrogen gas is used to blow the excess coating from the medical device.

With the excess coating removed from the medical device, the coating can be cured in any suitable manner. For example, the UV-curable composition can be rapidly cured through exposure to UV light. For instance, after the UV-curable composition is applied to the medical device, the composition can be cured within seconds or minutes, depending on the formulation and curing conditions. In another example, the antimicrobial solution can be cured relatively quickly by exposure to heat (e.g., infrared heat). Indeed, under certain
circumstances, the solution can be heat-cured at about 100° Celsius (C) in about 5 minutes or less.

[0022] While the methods of the present invention have proven to be particularly useful in the area of coating IV access devices, those skilled in the art will appreciate that the described methods can be used for a variety of different applications in a variety of different areas of manufacture that include coating an object with an antimicrobial coating.

[0023] These and other features and advantages of the present invention will be set forth or will become more fully apparent in the description that follows and in the appended claims. The features and advantages may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. Furthermore, the features and advantages of the intention may be learned by the practice of the invention or will be obvious from the description, as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] In order that the manner in which the above-recited and other features and advantages of the invention are obtained and will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof, which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not, therefore, to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0025] Figure 1 illustrates a block diagram of a representative embodiment of a method for coating a medical device with an antimicrobial coating;

[0026] Figure 2 illustrates a block diagram of a representative embodiment of the method for coating a medical device with an antimicrobial coating;

[0027] Figure 3 illustrates a perspective view of a representative embodiment of an IV access device;

[0028] Figure 4A illustrates a perspective view of a representative embodiment of a system for applying an antimicrobial coating to a medical device; and

[0029] Figure 4B illustrates a perspective view of a representative pallet for holding a medical device during operation of the system shown in Figure 4A.

DETAILED DESCRIPTION OF THE INVENTION

[0030] The described invention relates to methods and compositions for coating one or more surfaces of a medical device with an antimicrobial coating. Once the antimicrobial
coating is cured onto the medical device, an antimicrobial agent in the coating can gradually diffuse out of the coating when the coating is softened by IV fluids or other types of fluids. Accordingly, microbes that come into contact with the coated surface of the medical device can be killed and the medical device may remain sanitary for a prolonged period of time.

[0031] Figure 1 illustrates a representative embodiment of the described coating methods. Specifically, Figure 1 shows that the method 10 for coating a medical device with an antimicrobial coating generally comprises providing a medical device 12, dispensing an antimicrobial coating onto the device 14, flushing excess coating from the device 16, and curing the coating to the device. In order to provide a better understanding of the described coating method, the following disclosure provides a more detailed disclosure of medical devices and antimicrobial coatings that can be used with the coating method, the various stages of method, and systems for performing the method.

[0032] With respect to the types of medical devices that can be used with the described coating methods, the methods can be used with any suitable medical device, including, but not limited to, an IV access device, medical tubing, a catheter assembly, and any other viable medical-grade instrument that contacts fluids flowing into or out of a patient.

[0033] The medical device can comprise any material that is suitable for use with the described methods. In some typical embodiments, however, the medical device comprises one or more polymeric substrates. For instance, the medical device can comprise one or more polycarbonates, polyurethanes, polyvinyl chlorides, silicones, PET plastics, styrene-butadiene rubbers, acrylics, and combinations thereof.

[0034] The antimicrobial coating can comprise any suitable antimicrobial composition that is suitable for use on the medical device. Nevertheless, in preferred embodiments, the antimicrobial coating is selected from a UV-curable, antimicrobial composition and an antimicrobial solution. To provide a better understanding of the UV-curable composition and the antimicrobial solution, each is discussed below in more detail.

[0035] In some currently preferred embodiments, the antimicrobial coating comprises the UV-curable, antimicrobial composition. In such embodiments, the UV-curable composition may comprise any suitable ingredient. In one aspect of the invention, the UV-curable coating comprises materials (referred to herein the UV-curable material) that are capable of forming a UV-curable polymer composition. While the UV-curable material may comprise any suitable ingredient, in some preferred embodiments, the UV-curable material comprises one or more oligomers, monomers, and photoinitiators. In addition to the UV-
curable material, the UV-curable composition further comprises an effective antimicrobial agent. The various ingredients that are added together to form the UV-curable composition are described below. In the following discussion, the UV-curable material will comprise 100 parts by weight. Additionally, the ingredients added to the UV-curable material to form the UV-curable composition will be defined in parts by weight added to 100 parts by weight of the UV-curable material.

The UV-curable material may comprise any oligomer that is compatible with the other components of the UV-curable composition and that is usable within the scope of the present invention. Nevertheless, the oligomer is generally selected from one or more acrylated aliphatic urethanes, acrylated aromatic urethanes, acrylated polyesters, unsaturated polyesters, acrylated polyethers, acrylated acrylics, and the like, or combinations thereof. Indeed, in some embodiments, the UV-curable coating comprises a urethane- or polyester-type acrylate, such as 7104, 7101, 7124-K, 7105-5K from Electronic Materials Inc. (EMI) (EM Breckenridge, Co.), 1168-M, 1-20781 from Dymax Corporation (Torrington, CT.), or UV 630 from Permabond Engineering Adhesives (Somerset, NJ). Where the oligomer comprises an acrylated functional group, the functional group is preferably selected from a mono-functional, di-functional, tri-functional, tetra-functional, penta-functional, and hexa-functional acrylate.

The oligomer may account for any suitable portion of the UV-curable material. Typically, however, the oligomer will comprise from about 10% to about 90% of the UV-curable material. In some preferred embodiments, the oligomer comprises from about 20% to about 80% of the UV-curable material. In certain other embodiments, however, the oligomer comprises from about 30% to about 70% of the UV-curable material.

While the monomer in the UV-curable material can be selected from any monomer that is compatible with the other components of the UV-curable composition and that is usable within the scope of the invention, the monomer is preferably selected from 2-ethyl hexyl acrylate, isoctyl acrylate, isobornylacrylate, 1,6-hexanediol diacrylate, diethylene glycol diacrylate, Methyleneglycol diacrylate, pentaerythritol tetra acrylate, pentaerythritol tri acrylate, dimethoxy phenyl acetophenone hexyl methyl acrylate, 1,6 hexanidiol methacrylate, and the like, or combinations of these compounds.

In typical embodiments, the monomer comprises from about 5% to about 90% of the UV-curable material. In other embodiments, however, the monomer comprises from
about 10% to about 75% of the UV-curable material. In still other embodiments, the monomer comprises from about 20% to about 60% of the UV-curable material.

[0040] The photoinitiator can comprise any photoinitiator that is compatible with the other components of the UV-curable composition (i.e., the UV-curable material) and that is usable within the scope of the invention. Generally, the photoinitiator is selected from either a single molecule cleavage type photoinitiator, such as one or more benzoin ethers, acetonphenones, benzoyl oximes, and acyl phosphine oxides; or a hydrogen abstraction type of photoinitiator, such as Michler's ketone, thioxanthone, anthroguionone, benzophenone, methyl diethanol amine, and 2-N-butoxyethyl-4-(dimethylamino) benzoate.

[0041] The photoinitiator typically comprises from about 0.5% to about 10% of the UV-curable material. Indeed, in some embodiments, the photoinitiator comprises from about 1% to about 8.5% of the UV-curable material. In still other embodiments, the photoinitiator comprises from about 2% to about 7% of the UV-curable material.

[0042] The antimicrobial agent can comprise any antimicrobial agent that is compatible with the other components of the UV-curable composition and that is usable within the scope of the invention. Additionally, in some embodiments, the antimicrobial agent comprises an agent that either dissolves in the UV-curable composition or can be uniformly distributed therein. Accordingly, in such embodiments, sufficient antimicrobial agent can migrate within the UV-curable composition to contact the location of microbial activity. In any event, it is preferred that the antimicrobial agent not react chemically with the other components of the UV-curable composition. Some examples of antimicrobial agents that are suitable for use with the UV-curable composition include one or more aldehydes, anilides, biguanides, silver, silver compound, bis-phenols, and quaternary ammonium compounds.

[0043] The antimicrobial agent is generally present in the UV-curable composition in the amount of from about 0.5 to about 50 parts, by weight, in comparison to 100 parts by weight of the UV-curable material. In other embodiments, the antimicrobial agent is present in the UV-curable composition in the amount of from about 0.5 to about 30 parts, by weight, in comparison to 100 parts of the UV-curable material. In further embodiments of the UV-curable composition, the antimicrobial agent is present in the amount of from about 0.5 to about 20 parts, by weight, in comparison to 100 parts of the UV-curable material.

[0044] In addition to the aforementioned materials, the UV-curable composition can comprise any other suitable component. Indeed, in certain embodiments, the UV-curable
composition also includes a rheological modifier to improve the composition's flow characteristics and to help components be uniformly distributed throughout the composition. In such embodiments, the rheological modifier is preferably selected from organic clay, castor wax, polyamide wax, polyurethane, and fumed silica. Additionally, in such embodiments, the rheological modifier generally comprises from about 0.1 to about 30 parts, by weight, added to 100 parts, by weight, of the UV-curable material (i.e. the UV-curable material is 100 weight units, while the rheological modifier comprises from about 0.1 to about 30 parts of additional weight that is added to the 100 parts of the UV-curable material). In other embodiments, the rheological modifier comprises from 0.1 to about 20 parts by weight compared to 100 parts by weight of the UV-curable material. In certain further embodiments, the rheological modifier comprises from about 0.2 to about 10 parts by weight compared to 100 parts by weight of the UV-curable material.

[0045] The UV-curable composition may also have any other suitable characteristic. For instance, in some embodiments, the UV-curable composition has a viscosity that is less than about 10,000 centipoises (cps). In other embodiments, the viscosity of the UV-curable composition is below about 5,000 cps. In some presently preferred embodiments, the UV-curable composition has a viscosity that is between about 20 and about 1,000 cps.

[0046] While the UV-curable composition has been described above with specificity, a more detailed description of the UV-curable composition is found in U.S. Patent Application No. 12/397,760, filed March 4, 2009, and entitled "Antimicrobial Compositions;" the entire disclosure of which is hereby incorporated by reference.

[0047] Where the antimicrobial coating comprises an antimicrobial solution, the solution may comprise any suitable ingredient. In some embodiments, the antibacterial solution comprises an acrylate polymer or copolymer, a solvent, and an antimicrobial agent. To provide a better understanding of the antimicrobial solution, each of its aforementioned ingredients is described below in more detail.

[0048] The acrylate polymer or copolymer can comprise any acrylate polymer and/or copolymer that is compatible with the other components of the antimicrobial solution and that is usable within the scope of the invention. In some embodiments, the acrylate-type polymer, copolymer, or polymer resin is insoluble in water while being soluble in one or more of the solvents that are discussed hereinafter. For example, the acrylate polymer or copolymer is generally selected from one or more alkyl acrylates, alkyl methacrylates, alkyl hydroxyl (meth) acrylates, and alkyl methoxycinnamate acrylates. In this example, the acrylate can be
alkyl acrylate, alkyl hydroxyl (meth) acrylate, or alkyl methacrylate. Additionally, in this example, the alkyl group can have a carbon number from 0 to 22, wherein 0 means hydrogen, 1 means a methyl group, 2 means an ethyl group, 3 means a propyl group, etc.), but preferably a number from 0 to 6, and more preferably from 0 to 3.

[0049] The solvent in the antimicrobial solution can comprise any solvent that is compatible with the other components of the antimicrobial solution and that allows the solution to function as intended. For instance, the solvent may comprise one or more of a variety of solvents that are capable of dissolving the aforementioned acrylate polymer or copolymer. Some examples of suitable solvents include one or more low molecular weight alcohols, low molecular weight alkanes, simple ketones, and combinations thereof. Some examples of suitable low molecular weight alcohols comprise alcohols having from 1 to 6 carbons (e.g., methanol, ethanol, propanol, isopropanol, and butanol). Because methanol evaporates relatively quickly, however, methanol may not be preferred in all embodiments. Instead, in some currently preferred embodiments, the solvent comprises ethanol or isopropanol. Some suitable examples of suitable low molecular weight alkanes comprise alkanes having from 5 to 7 carbons (e.g., pentane, hexane, heptane, and isomers thereof). Indeed, in some preferred embodiments the solvent comprises hexane and/or heptane. Additionally, an example of a suitable simple ketone is acetone. It should be noted, however, that in some embodiments that comprises acetone, the solvent preferably also comprises another solvent, such as an alcohol or an alkane.

[0050] While the solvent may comprise any suitable amount of the antimicrobial solution, in some embodiments, the solvent comprises less than about 67% of the dry weight of the antimicrobial solution. For instance, where the polymer accounts for about 60% ± 10% of the antimicrobial solution, the solvent can account for less than about 40% ± 10% of the solution. In other embodiments, however, the solvent comprises less than about 50% of the dry weight of the composition. In still other embodiments, the solvent comprises less than about 40% of the dry weight of the composition.

[0051] The antimicrobial agent in the antimicrobial solution can comprise any antimicrobial agent that is compatible with the other components of the solution and that allows the solution to function as intended. Indeed, the antimicrobial agent for the antimicrobial solution is generally selected from one or more aldehydes, anilides, biguanides, silver, silver compounds, bis-phenols, and quaternary ammonium compounds. In certain
instances, the antimicrobial agent is preferably selected from cetyl pyridium chloride, cetrimide, benzalkonium chloride, alexidine, chlorexidine diacetate, and o-phthalaldehyde.

[0052] While the antimicrobial agent may comprise any suitable amount of the antimicrobial solution, in some embodiments, the antimicrobial agent comprises less than about 50% of the dry weight of the solution. In other embodiments, the antimicrobial comprises less than about 30% of the dry weight of the antimicrobial solution. In still other embodiments, the antimicrobial agent comprises about 0.5% and about 20% of the dry weight of the antimicrobial solution.

[0053] In addition to the aforementioned ingredients, the antimicrobial solution may comprise any other suitable ingredient. Indeed, in some embodiments, the antimicrobial solution comprises a rheological modifier that is generally selected from organic clay, castor wax, polyamide wax, polyurethane, and fumed silica. In such embodiments, the rheological modifier is generally present in an amount of from about 0.2% to about 30% of the dry weight of the antimicrobial solution. That is, the weight of the composition once the solvent has evaporated. In certain other embodiments, the rheological modifier is present in the amount of from about 0.2% to about 20% of the dry weight of the antimicrobial solution. In certain other embodiments, the rheological modifier is present in an amount of from about 0.2% to about 10% of the dry weight of the antimicrobial solution.

[0054] While the antimicrobial solution has been described above with specificity, a more detailed description of the antimicrobial solution is found in U.S. Patent Application No. 12/476,997, filed June 2, 2009, and entitled "Antimicrobial Coating Compositions;" the entire disclosure of which is hereby incorporated by reference.

[0055] The described methods can be performed or modified in any suitable manner. By way of example, Figure 2 illustrates one presently preferred embodiment of the described method for coating a medical device. Specifically, Figure 2 shows an example in which the method 11 begins at 12 by providing a medical device.

[0056] Next, at 13, Figure 2 shows the method 10 optionally includes masking one or more desired portions of the medical device to prevent the antimicrobial coating from contacting the masked portion(s). By way of illustration, Figure 3 shows that where the medical device comprises a portion of an IV access device 100 (e.g., BECTON DICKINSON'S Q-SYTE® IV access device) having a Luer component 102, the Luer component 102 can be inserted into a medical-grade tube 104 so that the external surface of the Luer 102 is prevented from being coated with the antimicrobial coating.
Returning back to Figure 2, box 14 shows that the method 10 continues by dispensing the antimicrobial coating (e.g., the UV-curable composition or the antimicrobial solution) onto the medical device. Any suitable amount of the antimicrobial coating can be dispensed onto the desired surface(s) of the medical device. For example, where the medical device comprises the IV access device of Figure 3, between about 0.01 and about 0.05 grams of the antimicrobial coating can be dispensed into the device's inner lumen 106. In still another example, where the medical device comprises the IV access device of Figure 3, between 0.02 and about 0.04 grams of antimicrobial coating are dispensed into the device's inner lumen.

After the antimicrobial coating has been dispensed onto the medical device, box 16 of Figure 2 shows that any excess coating on the device is flushed or otherwise removed from the medical device. In this manner, the antimicrobial coating can be caused to have a uniform thickness across the coated surface. The excess coating can be removed in any suitable manner, including by blowing an inert gas across the coated surface of the medical device, spinning the medical device in a centrifuge, by allowing excess material to drip from the device due to the pull of gravity, etc. Nevertheless, in some presently preferred embodiments, a pressured inert gas, such as nitrogen, helium, or argon, is blown across the coated surface. By way of example, where the medical device comprises the IV access device 100 of Figure 3, an insert gas, such as nitrogen, with an air pressure of between about 5 and about 25 pounds per square inch (psi) (e.g., 10 psi ± 5psi) is preferably blown past the coated surface.

In order to reduce the amount of antimicrobial coating that is wasted during the described method, box 17 of Figure 2 shows that the excess antimicrobial coating that is flushed from the medical device is optionally collected and recycled. In other words, the excess antimicrobial coating can be collected and be used to coat another medical device.

With the excess antimicrobial coating removed from the medical device, boxes 20 and 22 show that the coating left on the device is cured. While the antimicrobial coating can be cured in any suitable manner, box 20 shows that in some embodiments where the antimicrobial coating comprises the UV-curable composition, the UV-curable composition is cured by being exposed to UV light. In such embodiments, the UV-curable composition can be exposed to any suitable wavelength of UV light. In one example, the UV-curable composition is exposed to UV light with a wavelength of between about 320 to
about 500 nm. In another example, the UV-curable composition is cross-linked by being exposed to light with a wavelength of between about 350 and about 450 nm.

[0061] Additionally, the UV-curable composition can be exposed to the UV light for any amount of time that allows the UV-curable composition to dry and be cured to the medical device. Indeed, in one example, the UV-curable composition is cured after less than about 1 minute of exposure to the UV light. In another example, the UV-curable coating is cured after less than about 30 seconds of exposure to the UV light. In still another example, the UV-curable coating is cured after less than about 10 seconds of exposure to the UV light. In a final example, the UV-curable coating is cured after less than about 4 seconds of exposure to the UV light.

[0062] Referring now to box 22, Figure 2 shows that in some embodiments where the antimicrobial coating comprises the antimicrobial solution, the solution is cured through exposure to heat from a heat source (e.g., an infrared heater, a convectional heater, a conventional heater, etc.). In such embodiments, the antimicrobial solution coating the device can be cured at any suitable temperature. In one example, the solution is cured at a temperature of less than about 120° C. In another example, the antimicrobial solution is cured at a temperature of less than about 100° C. In still another example, the antimicrobial solution is cured at a temperature of less than about 60° C.

[0063] While the antimicrobial solution can be cured in any suitable amount of time, under certain conditions, the solution is cured after less than about 10 minutes of exposure to a temperature of less than about 60° C. Similarly, under certain conditions, the antimicrobial solution is cured after less than about 5 minutes of exposure to a temperature of less than about 100° C.

[0064] Once the antimicrobial coating is cured, box 24 of Figure 2 shows that any masking material is optionally removed from the medical device. At that point, the medical device can be used and the antimicrobial coating can be effective almost immediately after being exposed to a fluid (e.g., an IV fluid).

[0065] The described methods can be performed by any suitable system and/or apparatus that is capable of performing one or more of the features illustrated in Figure 2. Indeed, in some embodiments, at least a portion of the described methods are performed by medical device coating system. While such a system can comprise any suitable component or characteristic, Figure 4A illustrates a representative embodiment in which the medical device coating system 200 comprises a medical device pallet 202, a top slide 204 having
coating-dispensing heads 206 and gas-dispensing heads 208, coating valves 210, gas valves 212, a gas reservoir 214, excess funnels 216, and a pressurized coating reservoir 218.

While the medical device coating system may be used in any suitable manner, in order to provide a better understanding of the system, a typical example of its use is provided herein. Specifically, Figure 4B shows that one or more medical devices, such as the IV access device 100, can be placed on the medical device pallet 202 so that an opening 108 to the inner lumen 106 of the device 100 is facing towards a coating-dispensing head 206 (shown in Figure 4A).

In order to ensure that the medical device stays in a proper orientation through the coating process, the pallet may secure the medical device in a desired orientation, in any suitable manner. By way of illustration, Figure 4B shows an embodiment in which the IV access device 100 is secured to the pallet 202 when a lip 110 on the access device 100 is slid into a groove 220 on the pallet 202.

With the medical devices secured to the pallet 202, Figure 4A shows that the pallet 202 is placed beneath the top slide 204. At this point, the top slide 204 may move with respect to the pallet 202 so that a coating dispensing head 206 is disposed above the opening of each device (not shown in Figure 4A).

Once the dispensing heads are aligned with the surface of the medical device that is to be coated, the coating valves 210 are opened to allow a predetermined amount (e.g., between about 0.01 and about 0.05 g) of antimicrobial coating to be squirt from the pressurized coating reservoir 218, through the coating-dispensing heads 206, and onto the medical device. While this dispensing process can take any suitable amount of time, in some instances, the dispensing process takes as little as 4 seconds or less (e.g., about 2 seconds ± 1 second).

After the coating has been dispensed, the top slide 204 moves in the direction of arrow 222 so that a gas-dispensing head 208 is disposed above the coated surface of each medical device. Once the gas-dispensing heads are properly aligned, the top slide 204 moves in the direction of arrow 224 so that the gas-dispensing heads 208 form a seal against the medical device's opening (not shown in Figure 4A). Once a seal is formed, the gas valves 212 open to allow a controlled amount of the inert gas, at a controlled pressure, to flush any excess coating from the medical device. This excess coating is then collected in the excess funnels 216, which direct the excess coating back to the pressurized coating reservoir 218 for future use.
With the excess coating removed from the medical devices, the pallet 202 can be removed from beneath the top slide 204 and be placed in a curing chamber (not shown), such as a UV-light chamber or a heated chamber—depending on composition of the antimicrobial coating.

Following the curing process, the medical devices are removed from the pallet and new batch of uncoated medical devices can be placed in the pallet so that the process can be repeated.

The described system can be modified in any suitable manner. In one example, while Figure 4A shows an embodiment in which the system 200 is configured to coat 4 medical devices simultaneously, the system can modified to simultaneously coat any suitable number of medical devices. For instance, the system can be modified to coat 1, 2, 3, 5, 6, 7, 8, or more medical devices, simultaneously. In another example, instead of comprising a coating-dispensing head and a separate gas-dispensing head, the antimicrobial coating and the inert gas may be dispensed to a medical device through single head so as to speed the time between the dispensing and flushing portions of the method. In yet another embodiment, the pallet, the gas dispensing head, or some other component in proximity to the medical devices can comprise a UV light source. In such embodiments, the system can cure the medical devices without requiring the pallet to be removed from a location beneath the top slide.

As discussed above, the described methods, apparatus, and compositions have several beneficial characteristics. In one example, the described methods allow a medical device to be coated with an antimicrobial coating (e.g., the UV-curable composition) in a relatively short period of time. For instance, instead of taking several hours (e.g., 24) to cure a harsh solvent (e.g., THF or DMF) onto a medical device, the UV-curable coating and the antimicrobial solution can be cured onto a medical device in a few second or minutes, respectively. Indeed, in some embodiments in which the antimicrobial coating comprises the UV-curable composition, the composition can be dispensed, flushed, and cured within about 30 seconds. In some preferred embodiments, the UV-curable composition can be dispensed, flushed, and cured within about 10 seconds. Similarly, in some embodiments in which the antimicrobial coating comprises the antimicrobial solution, the solution is dispensed, flushed, and cured within about 10 minutes. In some presently preferred embodiments, however, the antimicrobial solution is dispensed, flushed, and cured in less than about 5 minutes.
In another example of a beneficial characteristic of the described methods, the methods can allow the antimicrobial coating to be applied to the medical device with a substantially uniform coating thickness. In still another example, because the described methods allow for excess antimicrobial coating to be recycled, the described methods may use less antimicrobial coating, overall, than certain conventional coating techniques.

In yet another example, the described UV-curable and antimicrobial solutions provide several advantages over certain known antimicrobial coatings. For instance, the UV-curable and antimicrobial solutions can be less toxic, less expensive, more environmentally friendly, cause less deformation or cracking to a medical device, be more aesthetically pleasing, and require less-expensive equipment than do several competing antimicrobial coatings (e.g., THF and DMF).

The present invention may be embodied in other specific forms without departing from its structures, methods, or other essential characteristics as broadly described herein and claimed hereinafter. The described embodiments and examples are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.
CLAIMS

1. A method for applying an antimicrobial coating to a medical device, the method comprising:
   - providing a first medical device;
   - dispensing an antimicrobial coating onto the first device, wherein the coating is selected from:
     a) a UV-curable, antimicrobial composition, and
     b) an antimicrobial solution comprising an acrylate polymer or copolymer;
   - flushing an excess amount of the coating from the first device; and
   - curing the coating.

2. The method of claim 1, wherein the UV-curable composition comprises:
   - a photoinitiator;
   - an oligomer;
   - a monomer;
   - a rheological modifier; and
   - an antimicrobial agent.

3. The method of claim 2, wherein the photoinitiator is selected from the group consisting of benzoin ether, acetophenone, benzoyl oxime, acyl phosphine oxide, Michler's ketone, thioxanthone, anthroguionone, benzophenone, methyl diethanol amine, 2-N-butoxyethyl-4-(dimethylamino) benzoate, and combinations thereof.

4. The method of claim 2, wherein the oligomer is selected from an acrylated aliphatic urethane, an acrylated aromatic urethane, an acrylated polyester, an unsaturated polyester, an acrylated polyether, an acrylated acrylic, and combinations thereof.

5. The method of claim 2, wherein the monomer is selected from the group consisting of 2-ethyl hexyl acrylate, isoctyl acrylate, isobornylacrylate, 1,6-hexanediol diacrylate, diethylene glycol diacrylate, Methylene glycol diacrylate, Pentaerythritol tetra acrylate, pentaerythritol tri acrylate, dimethoxy phenyl acetophenone hexyl methyl acrylate, 1,6 hexanidio methacrylate, and combinations thereof.

6. The method of claim 1, wherein the antimicrobial solution further comprises:
   - a solvent selected from an alcohol having from 1 to 6 carbons, an alkane having from 1 to 6 carbons, acetone, and combinations thereof;
   - a rheological modifier; and
   - an antimicrobial agent.
7. The method of claim 6, wherein the acrylate polymer or copolymer is selected from the group consisting of an alkyl acrylate, an alkyl methacrylate, an alkyl hydroxyl (meth)acrylate, an alkyl methoxycinnamate, and combinations thereof.

8. The method of claim 1 wherein the flushing of the excess coating comprises blowing the excess coating from the device with a pressurized, inert gas.

9. The method of claim 8, wherein the excess coating is recycled and dispensed onto a second medical device.

10. The method of claim 1, wherein the curing of the coating comprises exposing the first device having the UV-curable composition disposed thereon to UV light.

11. The method of claim 1, wherein the curing comprises exposing the first device having the antimicrobial solution to heat.

12. A method for applying an antimicrobial coating to a medical device, the method comprising:
   - providing a medical device;
   - dispensing a UV-curable, antimicrobial composition onto the medical device, wherein the coating comprises an oligomer, a monomer, a photoinitiator, a rheological modifier, and an antimicrobial agent;
   - flushing an excess amount of the composition from the device; and
   - curing the composition by exposing the composition to UV light.

13. The method of claim 12, wherein the dispensing, flushing, and curing of the composition is completed in less than about 30 seconds.

14. The method of claim 12, wherein the dispensing, the flushing, and the curing of the composition is completed in less than about 10 seconds.

15. A method for applying an antimicrobial coating to a medical device, the method comprising:
   - providing a medical device;
   - dispensing an antimicrobial solution onto the medical device;
   - flushing an excess amount of the composition from the device; and
   - curing the composition with a heat source,
   wherein the antimicrobial solution comprises an acrylate polymer or acrylate copolymer.
16. The method of claim 15, wherein the antimicrobial solution further comprises a solvent selected from an alcohol having from 1 to 6 carbons, an alkane having from 1 to 6 carbons, acetone, and combinations thereof.

17. The method of claim 15, wherein the antimicrobial solution further comprises a rheological modifier and an antimicrobial agent.

18. The method of claim 15, wherein the dispensing, flushing, and curing of the composition are completed in less than about 10 minutes.

19. The method of claim 15, wherein the dispensing, flushing, and curing of the composition are completed in less than about 5 minutes.

20. The method of claim 17, wherein the antimicrobial agent is selected from cetyl pyridium chloride, cetrimide, benzalkonium chloride, alexidine, chlorhexidine diacetate, phthalaldehyde, and combinations thereof.
FIG. 1

1. Provide Medical Device
2. Dispense Antimicrobial Coating onto Device
3. Flush Excess Coating from Device
4. Cure the Coating onto the Device
FIG. 2

1. Provide Medical Device
2. Mask Medical Device
3. Dispense Antimicrobial Coating onto Device
4. Flush Excess Coating from Device
5. Recycle Excess Coating
6. Expose Coating to UV Light
7. Expose Coating to Heat Source
8. Remove Masking
FIG. 3