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[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR AUTOMATED ACTIVE STERILIZATION OF FULLY IMPLANTED DEVICES

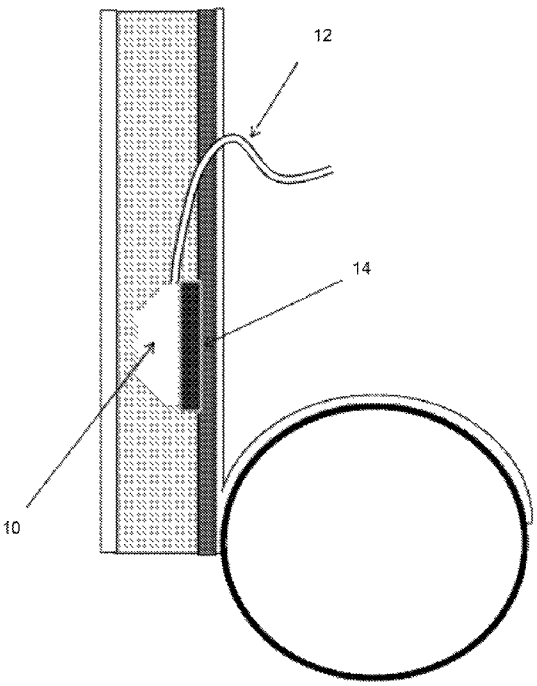

FIG. 1

(57) Abstract: The current invention provides this advance in infection control via its unique application of active sterilization to a catheter or implant. While most catheters, and many implants, are passive devices, the current invention will provide an active component as a integral part of the implanted catheter or device to continuously or intermittently sterilize the exposed surfaces/areas of the device. This active sterilization may be accomplished by a variety of mechanisms, including, application of heat, RF, microwave, ultrasound, ultraviolet radiation or other energy capable of sterilizing the device or dislodging any problematic biofilm that may form. The active sterilization may also employ the pumping of a sterilizing chemical from an attached drug reservoir, the use of electricity or freezing temperatures or any other mechanism for either inhibiting, killing or dislodging any infection material in contact with the implant.

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METHOD AND APPARATUS FOR AUTOMATED ACTIVE STERILIZATION OF FULLY IMPLANTED DEVICES

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CROSS-REFERENCE TO RELATED APPLICATIONS

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[0001] This application claims the benefit of priority to U.S. Prov. Pat. App. 60/964,822 filed August 15, 2007, which is incorporated herein by reference in its entirety.

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FIELD OF THE INVENTION

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BACKGROUND OF THE INVENTION

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[0003] In the last few decades, there has been incredible progress in a variety of medical fields. At the same time, though, many fields have stymied and remained stagnant. Once such field is the treatment and prevention of catheter and implant infections. Despite many of the issues associated with indwelling catheters and implants, the primary of which is infection in many cases, there has been little effort put forth to solve these problems and the medical community at large just accepts these complications as a fact of life. What effort has been put forth to combat this problem has been directed at the sterilization of externalized catheters and devices. These devices typically are highly prone to infection, but they can be sterilized through the external application of anti-infective measures. The prior art in this field, then, mostly consists of devices and methods for sterilizing indwelling catheters and devices through the external application of bactericidal measures.

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[0004] Fully implantable devices for the prevention of infection, though, have been limited to bactericidal and bacteriostatic coatings or the application of a small current/voltage to prevent bacterial adhesion. The use of an electronegative field to prevent bacterial adhesion, though, has been in development for quite some time and there is still no device that has been successfully commercialized with this feature due to the energy demands and poor cost-efficacy. The present innovation, then, provides a fully implantable novel device and method capable of actively preventing and treating infection of an indwelling catheter or implant.

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SUMMARY OF THE INVENTION

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[0005] e applic The current invention provides this advance in infection control via its unique application of active sterilization to a catheter or implant. While most catheters, and many implants, are passive devices, the current invention will provide an active component as a integral part of the implanted catheter or device to continuously or intermittently sterilize the exposed surfaces/areas of the device. This active sterilization may be accomplished by a variety of mechanisms, including, application of heat, RF, microwave, ultrasound, ultraviolet radiation or other energy capable of sterilizing the device or dislodging any problematic biofilm that may form. The active sterilization may also employ the pumping of a sterilizing chemical from an attached drug reservoir, the use of electricity or freezing temperatures or any other mechanism for either inhibiting, killing or dislodging any infectious material in contact with the implant. One major advantage of this design is that through the use of a small, battery powered or inductively powered sterilization element, the implanted catheter or device can be effectively sterilized without requiring the standard removal surgery, waiting period, then replacement of the infected device. This is expected to translate into greatly improved outcomes (particularly for devices where infection may be catastrophic, ie a prosthetic knee or hip), greatly improved costs, and greatly improved longevity of susceptible devices (ie IV ports, etc.).

[0006] In its preferred catheter (or any device with no moving parts) embodiment, an ultrasonic energy generator (including batter, circuit board, etc.) may incorporated into the base of an intravascular injection port and the port and catheter may be intermittently subjected to a vigorous ultrasonic wave to break free any potential biofilm that may have formed in the interim. This wave may, preferably, be powered by an internal battery and run on a programmed schedule. The device may also alert the user or healthcare practitioner that the battery charge is low by simple vibration or other communication mechanisms. Other sources of energy may be utilized, as well, including ultraviolet radiation, temperature extremes (ie freezing/heating), EMF, RF, microwave (or other energy source) and/or actively pumped drug. In its ideal and most practical embodiments, the internally powered sterilization device may also be transcutaneously activated and/or recharged (ie inductive recharging through the use of an external coil providing pulsed magnetic fields) so that it need not be removed simply due to battery depletion. This is a critical feature for devices with long-term implantation and not as essential for devices with short-term residence. As long-term implants are the most susceptible to infection, though, these are also the devices that will need this protection the most, so in its preferred hough.

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embodiment the device will incorporate an inductive recharging element. The device may also be capable of communicating to the user the status of the device and/or usage statistics for the device i.e. number of times the port has been accessed, pressure inside the port (an indication of clogging, etc.)

[0007] In its preferred fluid pumping embodiment, the device of the present invention may entail one or more sterilization features. In its ideal embodiment, the device of the present invention provides for an in-line sterilization element capable of sterilizing fluid that passes through its conduits to prevent spread of infection. This may entail ultrasonic energy, mechanical energy (i.e. a rapidly spinning wire), ultraviolet radiation, temperature extremes (ie freezing or heating by liquid nitrogen, Peltier junction, or other means), EMF, RF, microwave (or other energy source) and/or actively pumped drug. The outside of the conduit may also be sterilized continuously or intermittently via one or more of these mechanisms. In its ideal embodiment, the tubing of the fluid pump may be exposed to an ultraviolet LED that has low current draw but which is capable of sterilizing stagnant fluid or low volume flow. This design is optimal when used to prevent retrograde spread of infection (ie when a pump is parked or is in line with a backcheck valve).

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Figure 1- Side view of the catheter sterilizing element.

[0009] Figure 2- Side view of the fluid flow sterilization with pump apparatus.

DETAILED DESCRIPTION OF THE INVENTION

[0010] Figure 1- Side view of the catheter sterilizing element 14. In this illustration, a modification to a typical subcutaneous peritoneal port 10 is shown. In this instance, though, the device is shown equipped with an implanted sterilization element 14 (optionally inductively rechargeable) which contains all the circuitry, etc. required to provide effective sterilization of the catheter 12 and/or port 10. In this illustration the sterilization element is shown as manufactured into the device. In addition the sterilization element 14 may also be a device which may be coupled with the implantable device at the time of implantation. In this illustration, as well, an intra peritoneal catheter 12 is shown connected to a subcutaneous port 10, but may include: an IV catheter port, a CNS catheter port, a bladder catheter port, a PICC catheter, a central venous catheter, etc. There may be elements within the catheter 12, as well, to transmit energy, etc., for example, fiberoptics to

transmit sterilizing UV or wires to transmit mechanical, ultrasonic or electrical energy.

The devices illustrated in this Figure may all be inductively rechargeable.

[0011] Figure 2 - Side view of the fluid flow sterilization embodiment with pump apparatus. In this illustration, the sterilization element 14 is shown inside of the pump 20 and it may transmit anti-infective to one or both catheters (e.g., ultrasound) or apply anti-infective directly to fluid in the pump 20, e.g., UV sterilization of fluid flow or direct ultrasound to fluid flow or sterilize the surface of the device itself. In this embodiment, as well, the peritoneal catheter 22 may receive active sterilization along with the bladder catheter 26 or on its own or indirectly via the pump 20. The bladder catheter 26 may also receive active sterilization along with the peritoneal catheter 22 or on its own or indirectly via the pump 20. Any of the aforementioned sterilization methods or devices may be used to sterilize the fluid flow and the surface of the device, as well. In this embodiment, the sterilization element 14 may preferably be inductively rechargeable as the implantable pump 20, itself, will likely be rechargeable.

[0012] These are but some of the potential embodiments and should not restrict the scope of the invention. The invention described here may be utilized in any implant that requires intermittent or continuous active sterilization to prevent colonization and/or spread of infection from the implant. Other devices for which this technology may be utilized include: pacemakers, Implantable Cardioverter Defibrillators, CNS shunts, bladder catheters, suprapubic catheters, cardiovascular valves, mechanical valves, stents, prosthetic joints (knee, hip, etc), plates, screw or other orthopedic devices, electrical stimulators, neuromodulators or other devices.

CLAIMS

What is claimed is:

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What is claimed is: A sterilization system for sterilizing an implanted prosthesis, comprising a housing sized for implantation within a patient body and having an energy generator therewithal, wherein the energy generator is configured to deliver anti-infective energy or agents through one or more catheters fluidly coupled to the housing.

1. A sterilization system for sterilizing an implanted prosthesis, comprising a housing sized for implantation within a patient body and having an energy generator therewithal, wherein the energy generator is configured to deliver anti-infective energy or agents through one or more catheters fluidly coupled to the housing.

2. The system of claim 1 wherein the one or more catheters comprise an intra-peritoneal catheter.

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3. The system of claim 2 further comprising a catheter fluidly coupled to a bladder within the patient body.

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4. The system of claim 1 further comprising a subcutaneous port fluidly coupled to the housing.

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5. The system of claim 1 further comprising fiberoptics optically coupled to the energy generator.

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6. The system of claim 1 wherein the energy generator is configured to generate energy in a form selected from the group consisting of ultrasound, ultraviolet radiation, temperature, electromagnetic energy, radio frequency, microwave, and anti-infective agents.

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7. The system of claim 1 further comprising a pump coupled to the energy generator.

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8. The system of claim 1 further comprising a charging coil for inductively charging the energy generator.

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9. The system of claim 1 further comprising a battery electrically coupled to the energy generator.

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10. A method of sterilizing an implanted prosthesis, comprising:

10. A method of sterilizing an implanted prosthesis, comprising:

activating an energy generator implanted within a patient body, and

activating an energy generator implanted within a patient body; and the body such that th applying energy from the generator to a prosthesis implanted within the body such that the prosthesis is sterilized.

11 The method of claim 10 wherein activating comprises generating energy in a

11. The method of claim 10 wherein activating comprises generating energy in a form selected from the group consisting of ultrasound, ultraviolet radiation, temperature, electromagnetic energy, radio frequency, microwave, and anti-infective agents

12 The method of claim 10 wherein applying energy comprises applying the

12. The method of claim 10 wherein applying energy comprises applying the energy to one or more catheters coupled to the energy generator.

13 The method of claim 12 wherein applying the energy comprises applying

13. The method of claim 12 wherein applying the energy comprises applying energy to fluid passing through the one or more catheters.

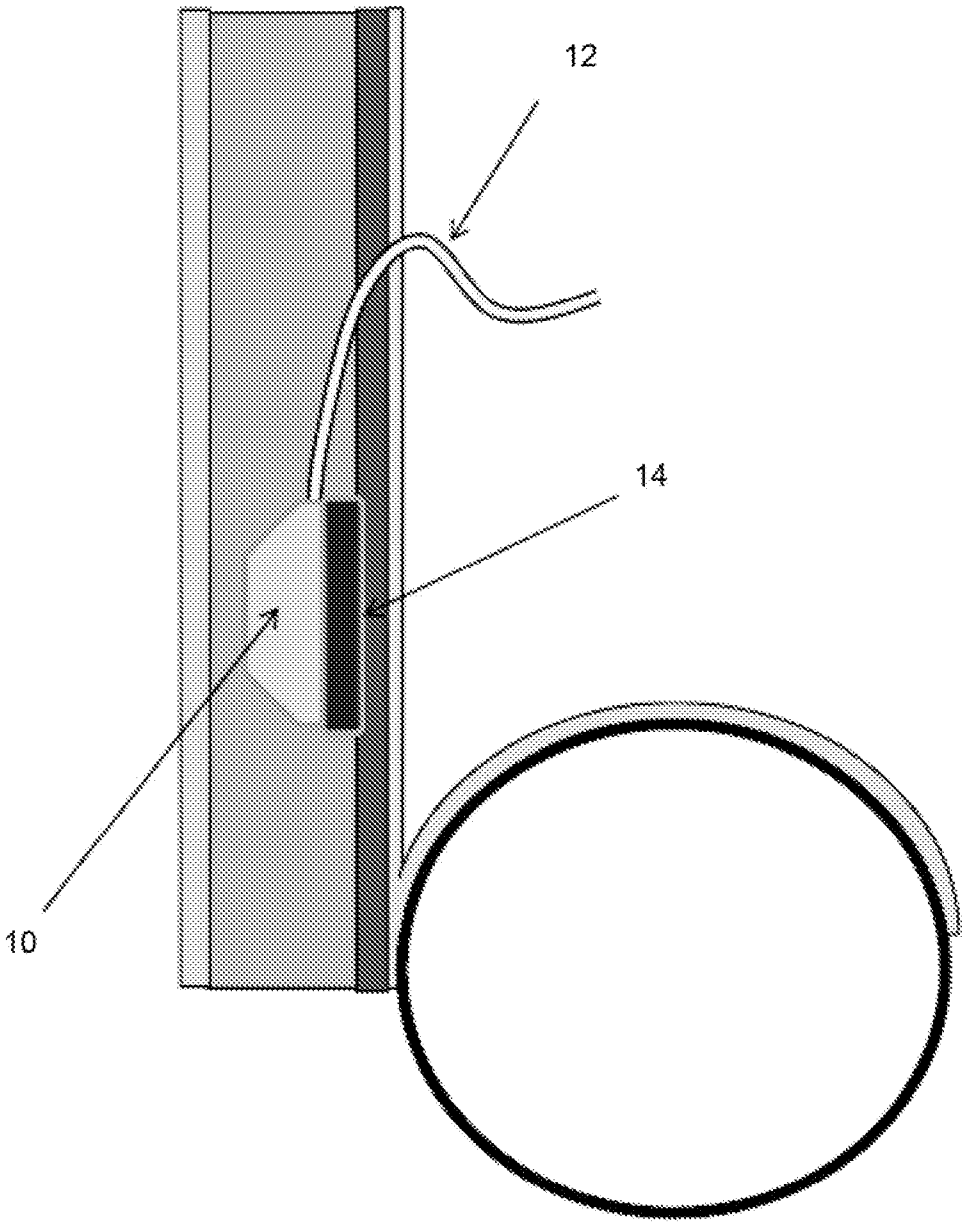

FIG. 1

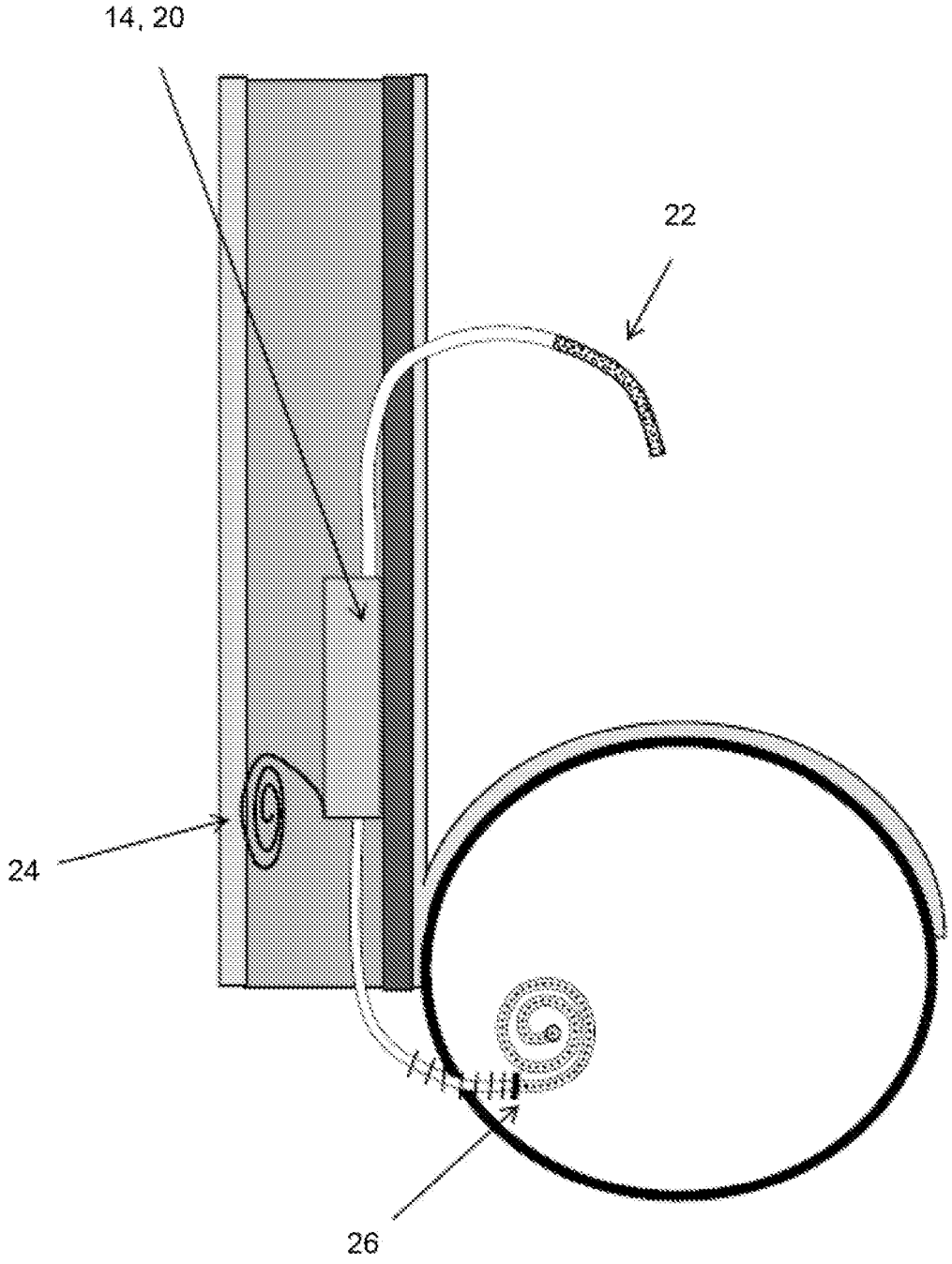

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/73279

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61L 2/00 (2008.04)
USPC - 422/20, 422/21, 422/22
According to International Patent Classification (IPC) or to both national classification and IPC

B. . FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC - 422/20, 422/21 , 422/22
IPC{8) - A61L 2/00 (2008.04)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 422/20, 422/21 , 422/22 (text delimited)
IPC(8) - A61L 2/00 (2008.04)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Google Patents; Google
Search Terms Used: implant implanted prosthesis medical device sterilization sterilizing energy generator generating catheter housing in vivo UV ultraviolet radiation pump inductive charge charging battery pump

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0191356 A1 (MORECI) 09 October 2003 (09.10.2003), entire document especially para [0024]-[0027], [0035], [0042]	1-6, 9-13
Y		7, 8
Y	US 2006/0282175 A1 (HAINES et al.) 14 December 2006 (14.12.2006), para [0106], [01 16]	7, 8

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

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