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(71) Applicant (for all designated States except US): **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417 (US).

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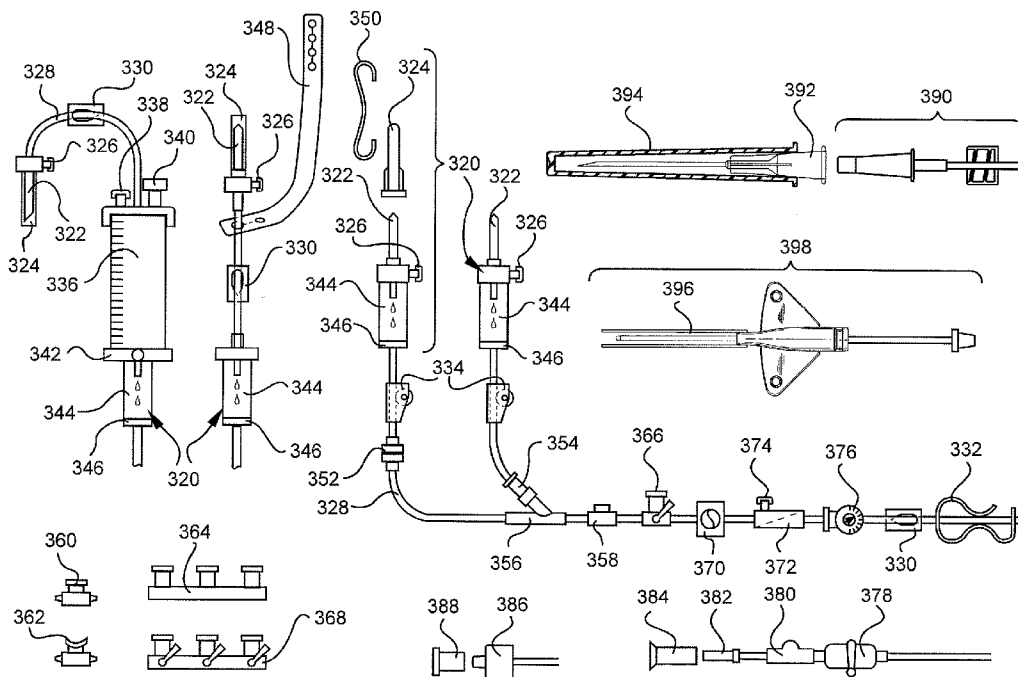
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **CRAWFORD, Mark, A.** [US/US]; 1057 Pineridge Road, Sandy, Utah 84094 (US). **HARDING, Weston, F.** [US/US]; 2421 North 910 West, Lehi, Utah 84043 (US).

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(74) Agent: **METCALF, Craig**; 15 West South Temple, Suite 1200, Salt Lake City, Utah 84101 (US).

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(54) Title: VASCULAR ACCESS DEVICE PATHOGENIC STATUS INDICATION



(57) Abstract: A vascular access device for communicating with the vascular system of a patient may include a status indicator. The status indicator may detect and signal that a pathogen is in communication with the vascular access device.

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VASCULAR ACCESS DEVICE PATHOGENIC STATUS INDICATION

BACKGROUND OF THE INVENTION

[0001] The present disclosure relates to infusion therapy with vascular access devices. Infusion therapy is one of the most common health care procedures. Hospitalized patients as well as home care patients receive fluids, pharmaceuticals and blood products via a vascular access device (VAD) that may be inserted at least partially into the 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 many other clinically significant uses.

[0002] Infusion therapy is facilitated by a vascular access device. The vascular access device may access a patient's peripheral or central vasculature. The vascular access device may be indwelling for short term (days), moderate term (weeks), or long term (months to years). The vascular access device may be used for continuous infusion therapy or for intermittent therapy. A vascular access device is commonly a plastic catheter that is inserted into a patient's vein, but may include any device employed to access the vasculature, such as a catheter, a syringe, a Luer adapter, an intravenous (IV) set, bag, or devices attached thereto, a needle, or other related devices. The catheter may be from a few centimeters in length for peripheral access to many centimeters long for central access. A vascular access device may be inserted transcutaneously or may be surgically implanted beneath the patient's skin. A vascular access device may have a single lumen or multiple lumens for infusion of many fluids simultaneously.

[0003] The proximal end of the vascular access device commonly includes a Luer adapter to which other vascular access devices may be attached in order to form an extravascular system. For example, an administration set of one or more vascular access devices may be attached to a vascular access device at one end and an intravenous bag at the other. The administration set is a fluid conduit for the continuous infusion of fluids and pharmaceuticals. Commonly, an intravenous access device is a vascular access device that may be attached to another vascular access device. The IV access device closes the vascular access device and allows for intermittent infusion or injection of fluids and pharmaceuticals. An IV access device may comprise 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.

[0004] 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 BSIs occur annually in US hospitals. Attributable mortality is an estimated 12% - 25% for each infection and a cost to the health care system of \$25,000 - \$56,000 per episode.

[0005] Vascular access device infection resulting in CRBSIs may be caused by a non-sterile insertion technique or by pathogens entering the fluid flow path subsequent to catheter insertion. Studies have shown the risk of CRBSI increases with catheter indwelling periods. This is due to a risk of contamination with every access of the vascular access device via an upstream port or IV access device. When contaminated, pathogens adhere to the vascular access device or IV access device, colonize, and form a biofilm. The biofilm is resistant to most biocidal agents and provides a replenishing source for pathogens to enter a patient's bloodstream and cause a BSI.

[0006] Recent studies have shown a potential correlation between the use of IV access devices and CRBSI rates. An IV access device is designed to close another vascular access device lumen between uses. Closure of the vascular access device supposedly prevents pathogens from infecting the vascular access device and causing a CRBSI. Contamination of an IV access device during use may originate from a variety of sources including a non-cleaned septum, a contaminated male Luer, or a contaminated infusion fluid. The contamination may result in pathogen colonization and biofilm formation which may cause a CRBSI if the pathogens enter the bloodstream. The risk of IV device contamination increases over time and with each use of the device.

[0007] Before accessing an IV access device, the top surface of the septum or valve should be swabbed with an alcohol pad or other pad containing an antimicrobial agent. The swabbing cleans the surface of foreign material and disinfects the surface. If the top surface is not swabbed and allowed to fully dry prior to use, foreign matter and pathogens may be introduced to the interior of the device. The pathogens may colonize the device and catheter leading to biofilm formation. The pathogens of the biofilm may breakaway and enter the patient's bloodstream resulting in a CRBSI. To ensure the highest ratio of foreign matter and pathogens are killed, the alcohol or antimicrobial agent must be first applied and then allowed to fully dry. Unfortunately, a large percentage of accesses of IV access devices are completed without swabbing and drying the septum or valve top surface. Thus, what is needed are

indicators to remind the operator to clean or replace the vascular access device to reduce the risk and occurrence of CRBSI.

BRIEF SUMMARY OF THE INVENTION

[0008] 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 vascular access devices and intravenous (IV) access devices. Thus, these developed systems and methods provide a vascular access device, or IV access device, with a status indicator capable of communicating a passage of time from when the vascular access device was first placed into service, an amount of usage of the vascular access device while in service, and/or disinfection of the vascular access device.

[0009] A vascular access device for introducing a substance into a blood vessel of a patient, includes a body with a lumen, and a status indicator. The vascular access device may also include a second vascular access device with a proximal end and a distal end. The distal end of the second vascular access device is introduced into the blood vessel, and the vascular access device is a connector affixed to the proximal end of the second vascular access device. The status indicator provides an indication of elapsed time that the device has been in use, usage of the device, and/or disinfection, i.e., the presence, absence, and/or extent to which a pathogen is present on, in, and/or near the device.

[0010] These and other features and advantages of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0011] In order that the manner in which the above-recited and other features and advantages of the invention are obtained 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. These drawings depict only typical embodiments of the invention and are not therefore to be considered to limit the scope of the invention.

[0012] Figure 1 is a perspective view of a vascular access device with a status indicator.

- [0013] Figure 2 is a cross section view of a status indicator with a time-sensitive adhesive.
- [0014] Figure 3 is a cross section view of a status indicator with snap arms.
- [0015] Figure 4 is a cross section view of a status indicator with a clamp.
- [0016] Figure 5 is a cross section view of a set and unset adhesive status indicator.
- [0017] Figure 6 is a cross section view of a set and unset spring anchored status indicator.
- [0018] Figure 7 is a cross section view of a compression spring status indicator.
- [0019] Figure 8 is a cross section view of a status indicator with a wick and dye.
- [0020] Figure 9 is a cross section view of the wick and dye of Figure 8.
- [0021] Figure 10 is a side view of the status indicator of Figure 8 on the surface of a vascular access device.
- [0022] Figure 11 is a side view of a status indicator with a reservoir of colored liquid on a vascular access device.
- [0023] Figure 12 is a cross section view of the reservoir of Figure 11.
- [0024] Figure 13 is a side view of a strip status indicator on a vascular access device.
- [0025] Figure 14 is a close up side view of the strip status indicator of Figure 13.
- [0026] Figure 15 is a cross section view of the strip of Figure 14 taken along lines 146-146 of Figure 14.
- [0027] Figure 16 is a perspective view of a lightened photochromic vascular access device as a status indicator.
- [0028] Figure 17 is a perspective view of a darkened photochromic vascular access device as a status indicator.
- [0029] Figure 18 is a perspective view of a lightened photochromic disk as a status indicator attached to a vascular access device.
- [0030] Figure 19 is a perspective view of a darkened photochromic disk as a status indicator attached to a vascular access device.
- [0031] Figure 20 is a perspective view of a label as a status indicator attached to a vascular access device.
- [0032] Figure 21 is a side view of a label with multiple chemical reservoirs as a status indicator.
- [0033] Figure 22 is a timing diagram of the visual change of a status indicator.
- [0034] Figure 23 is a cross section view of a status indicator on the slit of a septum.

- [0035] Figure 24 is a side view of a ratchet status indicator of a vascular access device.
- [0036] Figure 25 is a top view of the ratchet status indicator of Figure 24.
- [0037] Figure 26 is a cross section view of a multi-layered status indicator.
- [0038] Figure 27 is a close up cross section view of the multi-layered status indicator of Figure 26.
- [0039] Figure 28 is a perspective view of the top of a septum having a multi-layered status indicator.
- [0040] Figure 29 is a perspective view of the top of a septum having a multi-layered status indicator after use.
- [0041] Figure 30 is a side view of a bar code status indicator of a vascular access device.
- [0042] Figure 31 is a side view of a radio frequency identification chip status indicator of a vascular access device.
- [0043] Figure 32 is a side view of a piezoelectric crystal status indicator of a vascular access device.
- [0044] Figure 33 is a perspective view of a thermochromic status indicator layer on the top of a septum.
- [0045] Figure 34 is a perspective view of a pH sensor status indicator layer on the top of a septum.
- [0046] Figure 35 is a perspective view of an alcohol sensor status indicator layer on the top of a septum.
- [0047] Figure 36 is a perspective view of a textured surface status indicator layer on the top of a septum.
- [0048] Figure 37 is a perspective view of a moisture sensitive status indicator layer on the top of a septum.
- [0049] Figure 38 is a cross section and top view of a dye transport reservoir status indicator before and after use.
- [0050] Figure 39 is a perspective view of a piezochromic status indicator layer on the top of a septum.
- [0051] Figure 40 is a cross section view of a loaded dual-chamber syringe status indicator.

[0052] Figure 41 is a cross section view of a partially ejected dual-chamber syringe status indicator.

[0053] Figure 42 is a cross section view and a close up cross section view of a status indicator of the inner surface of a vascular access device.

[0054] Figure 43 is a cross section view of a status indicator on the surface of a vascular access device.

[0055] Figure 44 is a schematic of various vascular access devices.

DETAILED DESCRIPTION OF THE INVENTION

[0056] The presently preferred embodiments of the present invention will be best understood by reference to the drawings, wherein like reference numbers indicate identical or functionally similar elements. It will be readily understood that the components of the present invention, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description, as represented in the figures, is not intended to limit the scope of the invention as claimed, but is merely representative of presently preferred embodiments of the invention.

[0057] Referring now to Figure 1, an intravenous (IV) access device and/or vascular access device 10 is used to introduce a substance into a blood vessel of a patient. As described herein, a vascular access device includes any device employed to access the vasculature, such as a catheter, a syringe, a Luer adapter, an IV set, bag, or devices attached thereto, a needle, or other related devices. The vascular access device 10 includes a body 12 with a lumen 14 and a septum 16 placed within the lumen 14. The septum 16 may have a slit 18 through which a device may introduce a substance into the lumen 14 of the vascular access device 10. The device 10 also includes a status indicator 20 which will be described with further detail in the following figures.

[0058] Referring now to Figure 2, a status indicator 22 includes a time sensitive adhesive 24 attached to a movable member 26 and to the body 12 of a vascular access device 10. The movable member 26 is attached to the first end of a spring 28, and the second end of the spring 28 is attached to the body 12 of a vascular access device 10. The vascular access device 10 includes a window 30 through which the movable member 26 may be seen by an operator of the device 10 when the device 10 is in use.

[0059] An operator of the status indicator 22 may use the status indicator 22 to learn how long the device 10 has been in use. When the device 10 is first attached to another

vascular access device, such as a catheter or other structure that is placed within the blood vessel or vein of a patient, an operator, such as a patient, a physician, a clinician, a nurse, or other healthcare professional, may allow the movable member 26 to be pulled away from a stationary member 32 towards the spring 28. Eventually, the time sensitive adhesive 24 will permit the movable member 26 to detach from the stationary member 32, causing the movable member 26 to shift its position towards the spring 28. When the movable member 26 is shifted from a first position to a second position, a red tag 34 will be placed within the viewing area of the window 30 through which the operator can see the red flag 34. Upon viewing the red flag 34, an operator will know that the device 10 has been in use for a specific period of a lapsed time.

[0060] Referring now to Figure 3, a status indicator 36 has one or more snap arms 38 attached to the head 40 of a movable member 42. The movable member 42 is in turn attached at its tail to a first end of a spring 44, and the second end of the spring 44 is attached to a body 12 of a vascular access device 10. The plastic snap arms 38 engage the head 40 such that the movable member 42 is secured by the snap arms 38 for a predetermined amount of time. After a predetermined amount of time, the tension of the extended spring 44 causes the movable member 42 to pull upon the snap arms 38, which in turn causes the snap arms 38 to creep in a direction 46 opposite the head 40 of the movable member 42. Ultimately, the snap arms 38 will creep far enough such that the movable member 42 will be released from the snap arms 38 and will move from a first position in the snap arms 38 to a second position towards the spring 44 and away from the snap arms 38. In the second position, the movable member exposes a colored flag 48 through a window 50 of the body 12. When an operator of the vascular access device 10 sees that the flag 48 is exposed within the window 50, the operator will know that a given period of time has elapsed, indicating that the device 10 may need to be cleaned or replaced.

[0061] Referring now to Figure 4, a status indicator 52 includes a clamp 54 which may be removed by an operator to initiate the sequence of steps illustrated in Figure 2. Once the clamp 54 is removed from the status indicator 52, a spring 56 which is connected to the body 12 of a vascular access device 10 can pull a movable member 58 from a stationary member 60 over a period of time. After an elapsed, predetermined amount of time, an adhesive 62 holding the movable member 58 to the stationary member 60 will release, and the movable member 58 will move from a first position to a second position towards a spring 56. When the movable member 58 moves into the second position, a flag 64 or other visible,

colored structure, will be exposed through a window 66. When the flag 64 is exposed through the window 66 of the device 10, an operator will know that a given period of time has elapsed, indicating that the device 10 may need to be cleaned or replaced.

[0062] The clamp 54 shown in Figure 4 permits an operator to initiate the timing sequence of the status indicator 52 at any point in time. By permitting the operator to have control over when the status indicator is engaged by removing the clamp 54, an operator may choose to either engage the status indicator 52 upon first removing the device 10 from its sterile packaging, upon first attaching the device 10 to another vascular access device, or upon first using the attached device 10 by inserting a needle or other member to introduce a substance through the device 10 into a blood vessel of a patient.

[0063] Referring now to Figure 5, a status indicator 68 may be delivered to an operator within its packaging such that an adhesive 70 is not yet attached to a stationary member 72. At any point after removing the device 10 from its packaging, an operator may engage or set the status indicator by pressing or otherwise placing a movable member 74 containing the time sensitive adhesive 70 against the surface of the stationary member 72. When the status indicator 68 is set by the operator, the operator initiates a time sequence by which the movable member 74 is pulled with a spring 76 in a direction opposite the bound surfaces of the movable member 74 and the stationary member 72.

[0064] Referring now to Figure 6, a status indicator 78 may come disengaged on a vascular access device 10 when the device 10 is still in its sterile packaging. Similar to the status indicator 68 of Figure 5, a user may engage the status indicator 78 of Figure 6 at any desired point of device 10 operation. A spring 80 is compressed in a state where no tension or force is placed upon the spring 80. The spring 80 is attached on a first end to a movable member 82 and on a second end to an anchor 84. The movable member 82 is attached to a stationary member 86 by means of a time sensitive adhesive 88. The anchor 84 may be set by an operator by moving the anchor 84 in a direction 90 opposite the direction of the movable member 82. Upon moving the anchor 84 along a certain distance in the direction 90, the anchor 84 is engaged with a notch 92. When the anchor 84 is fully engaged with the notch 92, an appropriate amount of tension and force is placed upon the spring 80 such that the movable member 82 will detach from the stationary member 86 after an appropriate predetermined amount of time, which indicates that the device 10 has been in operation for an appropriate amount of time.

[0065] Referring now to Figure 7, a status indicator 94 includes a compression spring 96 attached on a first end to the body 12 of the device 10 and on a second end to a movable member 98. The movable member 98 is attached on a bottom surface 102 to a top surface 104 of the body 12 of the device 10. The compression spring 96 is compressed while the movable member 98 is adhered to the body 12. After a predetermined amount of time, the adhesive 100 will release the movable member 98 from the body 12 under the pressure and force of the compression spring 96. When moved, the movable member 98 will expose a flag 106 within a window 108 through which an operator may see the flag 106. When the operator sees the flag 106 through the window 108, the operator will know that the device 10 has been in use for the predetermined amount of time.

[0066] Any one of the status indicators of Figures 2 through 7 can be initiated by an operator in any number of ways when the device 10 is put into service. In one embodiment, the members may start together with a clamp that takes the load from the adhesive. The clamp is then removed at the start of service. In another embodiment, the members start together, but a spring is not loaded until the start of service. In another embodiment, an operator presses the two members together at the start of service.

[0067] Any of these actions initiating the start of service for any of the status indicators discussed above can be coupled to other actions which are commonly performed with a vascular access device. For example, a dust cover protecting certain structures on the vascular access device 10 may be removed after the device 10 is removed from its sterile packaging or after the vascular access device 10 is attached to another device. The dust cover may be removed by pulling the dust cover from a surface of the body 12 of the vascular access device 10 or by twisting and pulling the dust cover from the device 10. The device 10 may also be removed from the package, and a portion of the package may cause a status indicator to begin the time sequence that places it in service. Further, as the dust cover is removed, a clamp may be removed with the dust cover, a spring may be loaded with the dust cover, or a movable member may be placed into contact with a stationary member. Any other action performed by an operator of the device 10 can be combined to engage or disengage a status indicator.

[0068] The status indicators of Figures 2 through 7 may include any form of visual or mechanical indication as shown by example with the red flag 34 of Figure 2. The flag 34, or form of visual or mechanical indication, may be any size, shape, or color and may include any mechanical structure capable of indicating any lapsed period of time to an operator. In

addition, multiple status indicators or multiple flags may be used in a single device 10. In one embodiment, a device 10 includes a movable member with multiple flags indicating multiple periods of time that have elapsed.

[0069] In another embodiment, multiple movable members are attached to one or more stationary members using multiple time sensitive adhesives of varying strengths and or amounts. The multiple adhesives release at different time intervals, causing each of the multiple movable members to be released in sequence and thus illustrating that certain time periods have elapsed to an operator. For example, a first movable member with a weak adhesive or an adhesive in a small amount, may first disengage from a stationary member to show an operator that 12 hours have elapsed since the device 10 was placed in service. A second movable member attached to a stationary member with a stronger adhesive than the first movable member or attached to a stationary member with a greater amount of adhesive may later detach from the stationary member indicating to an operator that 24 hours have elapsed since the device 10 was placed in service. This sequence may occur for a third and subsequent movable members to indicate to an operator that various periods of time have elapsed.

[0070] Referring now to Figures 8 through 10, a status indicator 110 includes a fluid absorbing material or a wick 112 and a series of separated dye 114. The wick 112 is in contact with the dye 114 as shown in the cross section view of the status indicator 110 which is placed on the body 12 of the vascular access device 10. The status indicator 110 also includes an open port 116 to which a catheter or other fluid delivery system or device is attached. For example, a catheter attached to an IV bag delivers water or saline to the open port 116, delivering a constant supply of saline or water to the wick 112. In the alternative, the device may include an exterior fluid reservoir which is activated upon usage of the device. As time passes, the capillary forces of the wick 112 draw water further along the length of the wick 112. As the water is drawn along the wick 112, the dye 114 core is wetted, and the color of the water soluble dye 114 leaches through the wall of the wick 112 such that it is visible on the outer surface of the wick 112. The wetted dye is visible through a viewing window 118 to an operator. As used above and as mentioned throughout this description and the claims, "usage" includes any use of a vascular access device or any structure in communication with the device, including any use of or interaction with the device, including disinfection, by a healthcare provider or other individual or with the environment after the vascular access device is removed from its manufacturer packaging.

[0071] Referring now to Figure 9, a cross section view of the wick 112 and water soluble dye 114 is shown. As the wicking material or wick 112 is wetted, the dye 114 is dissolved and color migrates to the wicking material in a direction 120.

[0072] Referring now to Figure 10, the status indicator 110 of Figure 8 is shown embodied on the surface of a vascular access device 10. The status indicator 10 shows the port 116 that is open to receive a fluid supply. The status indicator 110 also shows a serpentine path 122 through which the wicking material 112 and dye 114 travel. The entire length, or any portion, of the path 122 may be viewable through the body 12 of the device 10 to an operator. The viewing window 118 of the status indicator 110 as shown in Figure 10, permits the operator to see when the dye 114 at the end of the path 122 has been dissolved and has migrated to the wick 112 in the viewing window 118. When the dye 114 is seen in the viewing window 118, an operator will know that a predetermined amount of time has elapsed. The operator will then know that the operator should clean and/or replace the device 10.

[0073] In one embodiment, the wicking material 112 is a weave of fabric or a paper wick with a water soluble dye core. In another embodiment, the path 122 of the wick 112 and the dye 114 is not serpentine. Rather, the path 122 is a straight line. The serpentine path 122 is preferably spaced and has an adequate length to cover an entire desired predetermined time period for the status indicator 110. The path may also wrap around the entire device 10 in multiple revolutions. In another embodiment, the wick 112 is visible along the entire length of its path. In another embodiment, the wick 112 is visible at discreet points along the length of the path. In the preceding two embodiments, the status indicator preferably includes marks on the surface of the body 12 of the device 10 which indicate that various amounts of time have elapsed since the device 10 was placed in service. As the dye dissolves along the path, the various time indicator points are reached and are visible to an operator. In another embodiment, the dye 114 comes in various shapes, sizes, and colors. For example, along the path 122 a first series of dye 114 may be colored green to indicate a first 12 hour period, a second series of dye 114 are colored yellow to indicate a second 12 hour period from hour 12 to 24 and a third series of dye may be colored red to indicate a third 12 hour period from hour 24 to 36. When the path turns red, an operator will know that the device should soon or immediately be cleaned or replaced. The thickness and width of the wick material and dye and the size and spacing of the channel or path in which the wick and dye are placed may be

varied in order to adjust the rate and visibility at which the dye is dissolved and displayed to an operator along the path.

[0074] Referring now to Figure 11, a status indicator 124 of a vascular access device 10 includes a colored liquid 126 and a material 128 placed in a channel 130 through which the colored liquid 126 is transferred.

[0075] Referring now to Figure 12, a cross section of the reservoir of colored liquid 126 of Figure 11 is shown located on the exterior surface of the body 12 of the device 10. A seal 132 prevents the colored liquid 126 from being absorbed by the material 128 until an operator exerts pressure upon the reservoir of liquid 126. When an operator places pressure upon the colored liquid 126, the seal 132 is broken and the colored liquid 126 is permitted to travel in a direction 134 along the material 128 until the colored liquid 126 is visible in a window 136 to an operator.

[0076] As shown in Figure 12, the status indicator 124 is integrated into the device 10. In another embodiment, the status indicator 124 is a label having a colored ink or colored oil as the colored liquid 126, and the label is attached to the device 10. In this embodiment, the colored ink or oil 15 initially contained in a reservoir that is obscured from view via a mask of the label. The ink or oil is then exposed to a porous or absorbent material. The material is designed to wick the ink or oil at a specified rate. Activation of the wicking may be accomplished by an operator compressing the reservoir as discussed above. The compression, however, may not be accomplished by the operator's fingers. Rather, the compression of the reservoir may be initiated in conjunction with use of the device 10 as it is placed in service or upon any other event capable of acting upon the reservoir. For example, the compression is caused by removing a dust cover from the device 10. As another example, the compression is caused when the device 10 is attached to another vascular access device providing access to a blood vessel of the patient. By twisting the device 10 onto another device, the force required to twist and attach the two devices together may also simultaneously compress the reservoir to initiate the travel of the colored ink or oil along the absorbent material. At at least one point equivalent to a desired elapsed time of wicking, the colored material is exposed to view in at least one viewing window to an operator. In this manner, the material changes color and the operator is able to visualize the time based color change.

[0077] Referring now to Figure 20, a label 162 as previously discussed, is attached to a vascular access device 10. The label 162 shows an elapsed time period in numbers of days

by advancing a strip of color across the label 162. In one embodiment, the label may be integrated into the device 10.

[0078] Referring now to Figure 13, a status indicator 138 is a label adhered to the exterior surface of the device 10.

[0079] Referring now to Figure 14, the status indicator 138 is shown in further detail. The label, or strip, of the status indicator 138 indicates various time periods 140 along its length. The time periods 140 are divided as follows: 12 hours, 24 hours, 36 hours, and 72 hours. When any of these given periods of time have elapsed as displayed by the status indicator 138 to an operator, the operator may either clean or remove and replace the device 10 depending on the specific needs of the patient and the environment in which the device 10 is used. The strip 142 is a multi-layered strip that is sensitive to light. When exposed to light, the strip 142 slowly begins to change color initially at a first end and then the color change advances to a second end of the strip 142 in a direction 144. The rate at which the color travels in the direction 144 may be modulated or adjusted or tuned, by overlaying a semi-transparent layer over a color changing substrate as shown in Figure 15.

[0080] Referring now to Figure 15, a cross section of the strip 142 of Figure 14 is shown along lines 146-146. The cross section of the strip 142 reveals a color changing substrate 148 and a variably transmissive insulating layer 150 on top of the color changing substrate 148. The variably transmissive layer 150 has a higher degree of transmissivity to light at its first end 152 and a lower amount of transmissivity to light at its second end 154. Between end 152 and end 154, the degree of transmissivity to light of the layer 150 is graded from a higher to a lower amount of transmissivity. Thus the transmissive layer 150 permits light to communicate with the color changing layer 148 at a faster rate at end 152 than the light would communicate at the end 154. This permits the status indicator 148 to show an earlier color change at end 152 than the color change at end 154. The earlier color change is shown in Figure 14 as a colored band beginning at end 152 and traveling through the 12 hour, 24 hour, 36 hour marks. However, because end 154 of Figure 14 has a lower level of transmissivity to light the light has not yet been permitted to communicate with the color changing substrate 148, and the strip 142 does not yet show a color change at end 154.

[0081] In one embodiment, as shown with reference to Figures 13 through 15 above, the status indicator 138 is sensitive to light. In another embodiment, the status indicator is sensitive to oxygen. When exposed to oxygen, the strip of the status indicator begins to slowly change color. In this embodiment, rather than having a semi-transparent layer 150, the

strip includes a semi-permeable layer over the color changing substrate 148. The semi-permeable layer is permeable to oxygen. The semi-permeable layer is variably permeable such that the first end of the strip will change color before a second end of the strip changes color, indicating a change in time during the use of the device 10. The color change will begin at one end of the strip, and proceed along the length of the strip during the period of elapsed time. In this manner, the position of the boundary between the colored and the non-colored portions of the strip becomes an indicator of how long the strip has been exposed to oxygen.

[0082] In one embodiment, a light or oxygen sensitive strip is mounted on an adhesive backing and applied to any time sensitive device 10. The device is stored in a light or oxygen proof package to ensure that the strip does not initiate its time sequence until after the package is opened. Many of the embodiments discussed with reference to Figures 13 through 15 appear much like a temperature-sensitive strip used in a fish tank. However, the colored band or strip indicates the passage of time rather than a change in temperature. The principals discussed in these embodiments may be applied to indicate the passage of time, an amount of use of the device 10, or the disinfection of the device 10.

[0083] The oxygen sensitive material discussed above, may be an oxidizable compound that is covered by a substrate. The oxidizable compound may be a metal such as aluminum, silver, or magnesium. When oxidized, the metal may turn a dark color or exhibit some other visual change. In one embodiment, a layer that is semi-permeable to oxygen may cover the oxidizable compound. In another embodiment, the compound is compounded directly into the layer. The layer is designed to have an oxygen permeability rate controlling the timing of the oxidation of the metal. The layer and/or oxidative compound may contain an anti-oxidant to control the timing of oxidation. The anti-oxidant will delay the oxidation reaction until the anti-oxidant is consumed. The oxidative compound and layer may be incorporated directly into the device 10. Alternately, the oxidative compound and layer may be attached by adhesive to the device 10. Alternatively, the oxidative compound and layer may be incorporated into a disk or other structure that can be attached to the exterior surface of the device 10. Multiple labels, disks, and/or bands of varying lengths may be used in combination on a single device 10 to indicate the passage of multiple periods of time.

[0084] Referring now to Figure 16, a status indicator 156 includes a photochromic material forming the body 12 of a device 10. The photochromic material 156 is a visual status indicator that shows a distinct change in color from when the device 10 is first placed

into service at initial use to a specific lapse of time as mentioned above. For example, the photochromic material 156 starts as a clear or white color upon initial use of the device 10. After the device 10 has been attached to a vascular access device or otherwise placed in service for 24 hours, the photochromic material 156 changes to a dark color 158 as shown in Figure 17.

[0085] Referring now to Figure 17, the dark photochromic material 158 of the device 10 indicates to an operator that the device 10 has been placed in service for at least 24 hours and has reached an infection risk threshold. The operator may then clean or replace the device 10.

[0086] The color change of the photochromic material 156 and 158 of Figures 16 and 17 may be accomplished in a variety of embodiments. In one embodiment, a photochromic dye is incorporated directly into the device 10, to any portion thereof, or to any structure attached thereto. Photochromic materials may be used to, for example, indicate a passage of time during which a photochromic material has been exposed to light or the lack thereof, indicate whether and to what extent a photochromic material has been disinfected, and/or indicate whether and to what extent a photochromic material has been properly cleaned. Photochromic dyes are commonly used compounds for non-medical device applications such as eyeglasses and printing. When sunlight or ultraviolet (UV) radiation is applied, the dye becomes excited and the molecular structure is changed allowing a color to appear.

[0087] Photochromic materials include a colorless isomer that contains a spiro carbon atom. This carbon atom is SP^3 -hybridized and serves to separate the molecule into two halves. Because of the highly localized pi systems that are separated by a SP^3 -hybridized carbon, all absorption is in the UV part of the spectrum with none in the visible part of the spectrum, and hence the molecule appears colorless. When the molecule absorbs UV light, the spiro carbon atom opens. The molecular structure then changes to one of extended conjugation and the molecule absorbs light in the visible region. Many colors are possible through the mixing of four base colors: blue, yellow, purple and orange/red. UV absorbing compounds may be used in conjunction with the photochromic dyes to extend the time of color shift.

[0088] The sensitivity of the ultraviolet material 158 may be modified and/or modulated in order to provide a material that only changes color when in the presence of an ultraviolet light of very high intensity. Thus an ultraviolet light wand or other light source may be applied to the high intensity UV sensitive material 158 in order to change its color.

After the color is changed and the intense light source is removed, it may return back to an original color after a predetermined amount of time. The intense source of ultraviolet light may be applied to the material just prior to, during, or after disinfection of the material.

[0089] A light source may be provided not only to change the color or provide some other visual change of a vascular access device, but a UV light source may additionally or alternatively be used to sterilize or disinfect the device. UV rays or various intensities and wavelengths may be used to kill or harm bacteria or pathogens on the device in order to disinfect the device. In such an embodiment, a UV wand or other device may be placed by a healthcare provider into communication with at least a portion of a vascular access device in order to disinfect the device. The wand may remain in communication with the vascular access device until the device is disinfected. After disinfection occurs, the healthcare provider may remove the UV wand.

[0090] A light source may also be used to confirm whether all or a significant number of pathogens have been killed. For example, a photochromic material may require a completion of a color change in order to indicate that all or a significant number of bacteria and pathogens have been completely killed on the light sensitive material. An operator is then able to confirm whether the operator remembered to sterilize or disinfect the device 10. For example, the absence of a bright or other color in the material indicates that the operator has forgotten the vital sterilization or disinfection step.

[0091] As shown in Figure 17, the color change may also occur in another embodiment where the photochromic dye is incorporated into the device 10 through addition of the dye to the polymer making the body 12 and/or septum 16. The preferred housing polymer is polycarbonate but may be other clear or translucent polymers such as acrylic, polyvinylchloride, polypropylene, and polyurethane. The addition of the dye may occur at the time the polymer is polymerized or during a subsequent compounding operation. The dye may also be added at the time of injection molding of the body 12 or septum 16.

[0092] In another embodiment, the photochromic dye may also be applied as a coating to the body 12 or septum 16. The dye may be mixed with a solvent and the mixture sprayed, poured, atomized, printed, or dipped onto the appropriate surface. The solvent will evaporate leaving the dye on the surface. The photochromic dye may also be printed onto a label and the label attached to the device 10.

[0093] Referring now to Figure 18, a disk 160, as previously discussed, is attached to the exterior surface of the device 10. Referring now to Figure 19, the disk 160 has changed from a light color to a dark color consistent with the principles discussed herein.

[0094] In another embodiment, a status indicator may communicate an elapsed period of time to an operator through a transparency or refractive index change of a material forming the body 12 of the device 10. The change of transparency of the substrate of the material may be initiated by oxidation, moisture absorption, or polymer crystallization. In this embodiment, the substrate includes a compound that is sensitive to oxidation, and when oxidized, changes the substrate's refractive index. In another embodiment, the substrate is a material that absorbs moisture. When the moisture content of the substrate reaches a specified amount, the substrate swells, causing a change in optical properties of the material. In another embodiment, a substrate polymer may crystallize, causing an optical change such as a change in clarity of the material. In the embodiments above, the substrate may form the body 12 of the device 10, may be a separate disk as shown in Figures 18 and 19, or may be a label as shown in Figure 20.

[0095] Referring now to Figure 21, a status indicator 164 is a label that may be attached to a device 10. The label includes a first chemical 166 and a second chemical 168. The chemicals 166 and 168 are contained in separate reservoirs that are obscured from view of an operator via a mask of the multi-layer label 164. The status indicator 164 is activated by compressing the reservoirs using either an operator's fingers or an action that is performed in conjunction with installation, cleaning, attachment of the device 10 to another device, or other use of the device 10. Upon activation, the two chemicals 166 and 168 are mixed in a chamber 170. Upon mixing, the chemicals react with each other and change colors. The chamber 170 is viewable to an operator. When the operator sees a change of color in the window of the chamber 170, the operator will know that a predetermined amount of time has elapsed. The two chemicals 166 and 168 may travel from their separate reservoirs into the chamber 170 by means of a porous or absorbent material or by means of micro fluid channels 172 and 174. In another embodiment, a change of pH when the two chemicals 166 and 168 are mixed results in a color change within the chamber 170. In another embodiment, the reservoirs containing the chemicals 166 and 168 are separated from each other and/or from the chamber 170 using a breakable seal similar to seal 132 described earlier with reference to Figure 12.

[0096] In another embodiment, a device 10 package is resistant to the environmental factors that initiate a time sequence of any of the status indicators discussed herein. Depending on the particular status indicator, the package includes a barrier to light, oxygen and/or other gasses, and moisture, as appropriate. The package may also include a mechanism to initiate the time sequence of the particular status indicator upon removal from the package.

[0097] The status indicator time sensitive signals, discussed above, that are communicated to an operator, correlate with the risk level that has been shown to result in catheter related blood stream infections (CRBSIs) if exceeded. The activation time for the signal may be different, depending upon device 10 application. As stated previously, the risk of contamination and pathogen colonization increases with device 10 usage. For devices used in a high use application such as an intensive care unit (ICU), a short (24 hours) time sensitive status indicator will be used. For medium use applications, the activation time may be 48 hours. And, for minimal use applications the signal activation time may be 72 hours to 96 hours, or greater.

[0098] Referring now to Figure 22, as discussed above, a status indicator may be a color change or may be a change of other visual properties, such as transparency. In one embodiment, the visual change timing will follow an s-shaped curve 176. As shown in Figure 22, there will be no, or minimal, change for a specified period of time 178, and then the visual change will be quick, intense, and non-reversible for a separate period of time 180. The activation of the visual change 182 may be delayed to the desired time frames discussed herein. Initiation of the time sensitive status indicator may occur by exposing the status indicator to environmental factors such as light, air, and moisture as discussed herein. Initiation may also occur upon removing the device 10 from its sterile package, initial usage or actuation of the device 10 through normal or deliberate use, or by manual or other actuation of the operator.

[0099] Referring now to Figure 23, the septum 16 of the vascular access device 10 of Figure 1 is shown. The septum 16 includes a slit 18 through which a needle, catheter, or male Luer may be inserted into the device 10. The surface of the slit 18 may be coated with a lube or adhesive 184. The lube or adhesive 184 as shown in Figure 23 is a cross-linking silicone lube that glues or otherwise adheres the slit 18 shut after a given amount of time. The silicone cross-linking of the silicone material that forms the body of the septum 16 can be initiated, initialized, or catalyzed by enzymes produced by a bacteria or other pathogen. After

a period of time, the septum 16 of the device 10 is colonized by bacteria or other pathogen, and the slit 18 is glued shut by the lube 184, thus blocking access of a needle, catheter, male Luer, or other device that an operator may desire to insert through the septum 16. Thus, in the embodiment of Figure 23, a status indicator 186 is a mechanical indicator that prevents an operator from further accessing the septum 16 after a predetermined amount of time. The type and amount of adhesive or lube 184 that is used and the location at which the lube or adhesive 184 is applied along the length of the slit 18 may be varied to adjust the speed or rate at which the slit is sealed.

[0100] Alternatively, the adhesive may be time sensitive due to moisture sensitivity. The adhesive gradually absorbs moisture over a predetermined period of time. Once moisture is absorbed to a specific level the slit 18 may be glued shut as discussed above.

[0101] In addition to the embodiments discussed above with reference to Figures 1 through 23, a status indicator can indicate an amount of use by an operator in addition to or in place of an elapsed period of time. Embodiments of status indicators which can communicate usage of a device 10 to an operator are discussed with reference to the following figures.

[0102] Referring now to Figure 24, a status indicator 188 provides an indication of usage of a vascular access device 10. The status indicator 188 includes a ratcheting mechanism 190 that includes a ratchet 192 that communicates with multiple sequential teeth 194 of the ratcheting mechanism 190. As the ratchet 192 articulates between the multiple sequential teeth 194, the ratchet 192 is advanced from a first position to a second position in a direction 196 along the device 10.

[0103] Referring now to Figure 25, a top view of the status indicator 188 is shown. The device 10 is often accessed by another device from a direction shown in the view of Figure 25. When another device, such as a needle, catheter, or male Luer, accesses the device 10, the ratchet 192, which is spring loaded, is moved from a first elevation to a second elevation and articulated from a first tooth 194 to a second tooth 194 causing the ratcheting mechanism 190 to rotate the pointer 198 of the ratchet 192 to move along in a direction 196 as shown in Figure 24. Thus, the ratcheting mechanism 190 may be used to sense an amount of usage of the device 10 as it is mated, combined, or otherwise accessed by other devices. Each time a device accesses device 10, the pointer 198 of the ratchet 192 will advance in a direction 196 to indicate that the device 10 has been accessed again. As shown in Figure 24, a counter 200 illustrates to an operator the number of times the device 10 has been accessed by an operator. By viewing the counter 200 and the location of the pointer 198 in relation to

the counter 200, any operator viewing the device 10 can understand the history of the usage of the device 10 without ever having seen the device or interacted with the patient during the life of the device. The status indicator 188 and ratcheting mechanism 190 of Figures 24 and 25 functions very similarly to the clicking mechanism of a pen. Any similar mechanism capable of indicating the usage of the device 10, including the ratcheting mechanism of a pen, may come within the scope of the status indicator 188 as described herein. The ratchet 192 and/or the pointer 198 may be any size, shape or color and may become visible in any window, or series of windows, or may be visible along the entire body 12 of the device 10.

[0104] Referring now to Figure 26, a septum 16 of a vascular access device 10 includes a status indicator 204 on the top external surface 202 of the septum 16. The status indicator 204 includes at least one removable layer of colored material on the external surface 202 of the septum 16.

[0105] Referring now to Figure 27, an exploded cross-section view of the status indicator 204 of the septum 16 of Figure 26 is shown. The status indicator 204 includes multiple layers 206 of different colored materials. A first layer 208 is colored green, a second layer 210 is colored yellow, and a third layer 212 is colored red.

[0106] Referring now to Figure 28, initially, the surface 202 of the septum 16 is coated with all three layers of soft and easily abraded colored material. The material may also be slightly alcohol soluble. Thus, the status indicator 204 of Figure 28, shows a top green layer 208 of material at its most external surface.

[0107] Referring now to Figure 29, after an operator abrades, actuates, swabs, or otherwise disturbs the top surface 202 of the septum 16, the top green layer 208 will be removed and the middle yellow layer 210 will be exposed. After further access and use of the device 10, the yellow layer 210 will be removed, exposing the red bottom layer 212. When any or all of the top surface 202 is shown as a red 212 color to the operator, the operator will know that the device 10 has received a certain amount of usage. The operator may then choose to clean and/or replace the device 10.

[0108] In one embodiment, the status indicator 204 of Figures 26 through 29 includes a material that is soluble to alcohol. Operators often swab alcohol on the exterior surface 202 of the septum 16 in order to clean the device 10 and kill any bacteria or other pathogens that are on the surface 202 of the septum 16 or within the slit 18 of the septum 16. By allowing the layered material to be slightly alcohol soluble, the material can change color, texture, and/or shape in order to visually communicate to an operator that the device 10 has been

swabbed one or more times. In another embodiment, the material may be an easily abraded colored material which when touched, swabbed, or otherwise accessed or disturbed, changes color or shape. In another embodiment, multiple layers 206 having multiple characteristics including alcohol solubility, saline solubility, water solubility, and abrasion, may be stacked upon each other to achieve a variety of affects in order to tailor the septum 16 and the status indicator 204 to a particular use within a hospital.

[0109] Referring now to Figure 30, a status indicator 214 includes a bar code label 216 secured to a vascular access device 10. When the device 10 is put into service, and each time the device 10 is accessed, an operator scans the bar code 216 with a bar code scanner to keep track of the time the device 10 is in use and the number of times the device 10 has been accessed. A database within the bar code scanner or other device capable of receiving data from the bar code scanner provides an alarm when either time or access limits are reached. For example, after 24 hours after the device 10 was initially scanned in a first time, a device may provide an alarm to the operator which indicates that the device 10 has been in use for at least 24 hours. Alternately or additionally, an alarm which indicates that a maximum number of accesses has been reached may also be communicated to an operator. The bar code 216 may come in the form of a label or hang tag or other structure that it is attached, affixed, or otherwise secured or connected to the device 10.

[0110] Referring now to Figure 31, a status indicator 218 includes a radio frequency identification (RFID) chip 220. The RFID chip 220 is placed on the external surface of a vascular access device 10. The RFID chip 220 permits the device 10 to store information relative to the amount of time the device 10 has been in service and/or the number and frequency of accesses or uses of the device 10. A scanner is used to signal the chip 220 when the device 10 is put into service, and each time the chip 220 is accessed, so that the chip 220 can record the data. The scanner can also read the start time and the number of accesses from the chip 220. Thus, the embodiment of Figure 31 of a status indicator 218 provides an advantage over the status indicator 214 of Figure 30, because the information is stored in the chip 220 of the device 10 and not in remote database of a bar code scanner or other device. A number of different scanners can access and manipulate the information on the device 10 without requiring a single scanner to follow the device 10 or without requiring a link to a central remote database. Thus, each of a number of different operators who come into contact with the device 10 may have their own separate scanner and can learn about the history of the device 10 independently.

[0111] Referring now to Figure 32, a status indicator 222 includes a piezoelectric crystal 224 in series with an RFID chip 220. The piezoelectric crystal 224 senses when the device 10 is activated and produces a small amount of electrical charge when the crystal is compressed by use of the device 10. The charge produced by the crystal 224 is detected by the RFID chip 220, and the RFID chip increments the counter based on the number of accesses or uses. Thus, the embodiment of the status indicator 222 of Figure 32 does not require a separate scanner to indicate whether or not the device 10 has been used. Rather, the RFID chip 220 senses each use of the device 10 upon compression of the device by the handling of an operator. A scanner is only required to be used in order to retrieve the collected information of the RFID chip 220. Various other circuits and electrical components in addition to those illustrated in Figures 30 through 32 are possible.

[0112] In addition to the multiple embodiments discussed herein directed to detecting the time and usage of a device 10, other embodiments of status indicators described herein can provide an indication of disinfection, sterility, cleanliness, or the presence or absence of a bacteria or other pathogen in or on a device 10.

[0113] Referring now to Figure 33, a status indicator 226 includes a thermochromic material 228 on an external, swabbable surface 230 of a septum 16 of a vascular access device 10. The thermochromic material 228 is applied as a coating on the septum 16. In another embodiment, the material 228 is applied as a compound into the material of the septum 16 itself. The thermochromic material 228 is a status indicator 226 that provides a reversible indication of cleaning and disinfecting. Upon swabbing the surface 230 with alcohol or another rapidly evaporating liquid, the surface 230 changes color temporarily to another color indicating that the device 10 has been cleaned. After accessing the device 10, and after the alcohol or other liquid is fully evaporated, the color of the thermochromic material 228 will change to its original color.

[0114] The color change may be accomplished via thermochromism which is the ability of a substance to change color due to a change in temperature. Two thermochromic approaches are based upon liquid crystals and leuco dyes. Liquid crystals are capable of displaying different colors at different temperatures. The crystalline structure of the material changes as the temperature changes resulting in selective reflection of certain wavelengths. The crystals will assume the original structure upon return of temperature to the starting point. Therefore, the color of thermochromic liquid crystals is changeable and reversible. Liquid crystals may be encapsulated in microcapsules.

[0115] A leuco dye is a dye whose molecules can acquire two forms, one of which is colorless. For example, the spiro form of an oxazine part of the molecule is separated by a SP^3 -hybridized, or spiro, carbon. An illustrative example includes microcapsules with crystal violet lactone, weak acid, and a dissociable salt dissolved in dodecanol are encapsulated. When the solvent melts, the salt dissociates, the pH inside the microcapsule lowers, the dye becomes protonated, its lactone ring opens, and its absorption spectrum shifts drastically causing the dye to become deeply violet.

[0116] Another thermochromic material is polythiophene. Chains of a polycrylamide derivative are attached to a polythiophene backbone. At lower temperatures the chains are irregular and stretched out. As the temperature is increased the chains and backbone pull into a compact spherical structure. This conformational change causes a color change of orange-red to yellow.

[0117] As shown in Figure 33, in use, an operator prepares to access the device 10 by swabbing the top surface of the septum 16 with an alcohol wipe or similar disinfecting tool. Following swabbing, the alcohol applied to the surface 230 begins to evaporate. As the alcohol evaporates, the surface temperature decreases, causing the thermochromic material 228 to change color. The color change may be a status indicator 226 to the operator that the septum 16 disinfected and the device 10 is ready for access. As the temperature of the septum surface returns to room temperature, the color change reverses, returning to the original color or no color.

[0118] 70% isopropyl alcohol evaporating from a stainless steel surface may cause a temperature shift of 20 degrees F. The septum 16 and coating may be made from a polymer. However, polymers do not have good thermal conductivity. Therefore, the temperature change caused by the evaporation of alcohol from a polymer surface may not be as large as that from stainless steel. Thus, metal nanoparticles may be added to the septum 16 material or coating to improve thermal conductivity.

[0119] Referring now to Figure 34, a status indicator 232 includes at least one pH sensor 234. The pH sensor 234 is located on the exterior surface 230 of the septum 16 of a device 10. The pH shift can indicate whether or not the septum 16 has been swabbed with a substance containing a pH within a specific range. The pH of 70% isopropyl alcohol in water is between five and six. A reversible pH sensor 234 sensitive to a pH range of five to six is integrated into the swabbing surface 230 by a coating or by compounding the sensor 234 into the material of the septum 16. Upon swabbing the surface 230, the alcohol solution causes

the pH sensor 234 to change colors indicating that the device 10 has been disinfected and is ready for access. Following evaporation of the alcohol solution, the pH of the swabbing surface 230 will shift outside the sensor range of five to six, and the sensor 234 will return to a baseline color.

[0120] Referring now to Figure 35, a status indicator 236 includes an alcohol sensor 238 on the surface 230 of a septum 16 of a vascular access device 10. The alcohol sensor 238 initiates a color change caused by a chemical reaction between a chemochromic compound and alcohol solution or other disinfecting agent. The chemochromic compound of the alcohol sensor 238 may be integrated into the swabbing surface 230 via coating or may be compounded into the material of the septum 16 itself. Upon swabbing the surface 230 with alcohol, the alcohol solution reacts with the chemochromic compound, causing a color change and indicating that the device 10 has been disinfected and is ready for access. Following evaporation of the alcohol solution, the reaction would reverse and the chemochromic compound of the sensor 238 would return to a baseline color. An alcohol indicator consisting of a carrier matrix with an alcohol oxidase enzyme which catalyzes a reaction converting alcohol to an oxidizing agent, and a hydrogen donor indicator which changes color when oxidized, may be used. Examples of hydrogen donors include 2,2'-azinodi-(3-ethylbenzthiazoline sulfonic acid); 3-methyl-2-benzothiazolinone hydrazone and 3-dimethylaminobenzoic acid; 3,4-dichlorophenol and 4-aminophenazone, o-tolidine; and o-tolidine and dianisidine.

[0121] Several other additional or alternative chemicals may be identified or developed to exhibit a reversible or irreversible color change when exposed to alcohol, chlorhexadine gluconate (CHG), or other common disinfectants. Several companies currently produce test strips that react to the alcohol that is present in saliva after alcohol has been consumed. One such strip is produced by Chematics and is named the ALCO-SCREEN™ test strip. The ALCO-SCREEN™ test strip will turn green or blue when exposed to saliva containing alcohol. With higher concentrations of alcohol than that found in saliva, the strip will turn, through a chemical reaction, to a dark brown or black color. Such a strip in another embodiment, may be applied to the surface of the septum 16 or any portion of the device 10.

[0122] Referring now to Figure 36, a status indicator 240 includes a textured surface 242 on the surface 230 of a septum 16. Beneath the textured surface 242, lies a colored substrate 244. When the textured surface 242 is swabbed with alcohol, water, or another disinfectant or liquid, the liquid is absorbed by the textured surface 242 and the contact

surface 242 becomes nearly transparent. In its transparent state, surface 242 provides a window through which an operator may view the colored substrate 244. In this manner, a surface which is nearly frosted, opaque, or otherwise obscured when a surface finish is applied, becomes a transparent window to a more visible colored substrate when the surface is wetted. Thus, when the surface 242 is wetted, it will appear to take on the color of the submerged surface or colored substrate 244. After the liquid evaporates fully, the surface 242 will again appear frosted, opaque, or otherwise obscured.

[0123] Referring now to Figure 37, a status indicator 246 includes a moisture sensitive layer 248 on the surface 230 of a septum 16. The moisture sensitive layer 248 may also be a moisture sensitive compound fully integrated with the material of the septum 16. Upon swabbing the surface of the moisture sensitive layer 248, the water of an alcohol solution may be absorbed by the moisture sensitive layer 248 causing a change in color and indicating that the device 10 has been disinfected and is ready for access. Following evaporation of the water of any liquid, the moisture sensitive layer 248 returns to a baseline color. Desiccants are an example of moisture sensitive layers or compounds. Many desiccants change to a blue color upon absorption of water and then return to a baseline color when the moisture is removed.

[0124] Referring now to Figure 38, a status indicator 250 includes a reservoir of colored liquid 252 with an elastomeric septum 16 of a vascular access device 10. The reservoir contains either an opaque white liquid or a colored dye. When properly designed, the reservoir is partially or fully evacuated when exposed to pressure on a surface 230 of the septum 16 during normal cleaning and use. The fluid 252 is then displaced into a storage reservoir under pressure. When the pressure is released, the fluid 252 will slowly flow back from the holding reservoir 254 into the original reservoir 256. Figure 38 shows a top view 258 of the original reservoir 256 prior to use of the septum 16. The original reservoir 256 is shown in a dark color. After cleaning or use of the septum 16, a top view 260 shows the original reservoir 256 evacuated of the colored dye 252, thus leaving the original reservoir 256 as a lighter color than the original reservoir 256 of top view 258.

[0125] As shown in Figure 38, the device 10 has a surface 230 that changes color when exposed to temperature change, alcohol, or other disinfectant. The device 10 then changes color back to the original color after an appropriate amount of time that would correspond to the time required for the disinfectant to evaporate and completely kill a bacteria or other pathogen. This would enforce two important behaviors for operators: first, proper

and full disinfection, and second, waiting an appropriate amount of time before inserting a device into the septum 16. The rate at which the surface 230 is changed from a dark color to a light color may be adjusted by varying the type of liquid or other material placed within the reservoir, the size of the reservoir, the color of the material, and/or the dimensions and materials of the body of the septum 16.

[0126] Referring now to Figure 39, a status indicator 262 includes a piezochromic material 264. The piezochromic material 264 is a material which will change color when exposed to pressure. The material 264 may be coated as a layer on a surface 230 of a septum 16. In another embodiment, the material 264 may be embedded into the surface of the septum. In yet another embodiment, the material 264 may be integrated into the material of the septum 16 as a compound. When proper disinfective swabbing occurs on the surface 230, the pressure caused from the swabbing action would cause the surface 230 to change color. As the pressure is removed, the surface 230 would return to its original color. This approach, like many other surface contact approaches described herein, encourages an operator to disinfect the entire surface of the corresponding status indicator.

[0127] Referring now to Figure 40, a status indicator 263 includes a pathogen staining solution 265 or other reagent. The solution 265 is placed within a dual chamber syringe 266 containing both the solution 265 and a cleaning saline solution 268 divided by a movable stopper 270. The syringe 266 includes a plunger 272 and at least one notch 274 into which the movable stopper will collide as the plunger 272 is advanced through the lumen of the syringe 266.

[0128] Referring now to Figure 41, the plunger 272 of Figure 40 is shown advanced through the syringe 266 such that the movable stopper 270 has advanced and collided with the notches 274. In its advanced state, the plunger 272 has expelled the solution 265 into a vascular access device 10 and the leakage 276 caused by the collision of the movable stopper 270 with the notches 274 has permitted a saline solution 264 to leak past the movable stopper 270 and into the device 10.

[0129] An operator may attach the syringe 266 of Figures 40 and 41 to a device 10 and flush the syringe 266 as the operator would with any normal syringe. A main stopper 278 attached to the end of the plunger 272 pushes the saline 268, which pushes on the movable stopper 270, which in turn pushes the pathogen staining solution 265 into the device 10. The pathogen staining solution 265 stains all the microorganisms and pathogens as it passes them. When the staining solution 265 is fully flushed into the device 10, the movable stopper 270

reaches the notches 274 in the barrel of the syringe 266 allowing the saline 268 to leak past the movable stopper 270 and into the device 10. The saline 268 then flushes the staining solution 265 from the device 10 leaving the device 10 clear. Any microorganisms in the device 10 will now be stained and visible to an operator. In this manner, a device 10 and any other device to which the device 10 is attached may be checked for disinfection and the absence of pathogens each time the status indicator 263 is employed. As another embodiment, notches 274 may be supplemented or replaced by grooves or other recesses within the material of the barrel of the syringe 266. Fluid, such as saline 268, may flow through the grooves or recesses when the movable stopper 270 is in communication with the grooves or recesses.

[0130] Referring now to Figure 42, a close-up view shows a status indicator 280 disposed on the inner surface 282 of the body 12 of a vascular access device 10. The status indicator 280 includes a fluid activated dye 284 substrate beneath a degradable membrane 286. The chamber 288 within the device 10 fills with fluid 290 when the device 10 is placed in service. The fluid 290 in the chamber 288 comes into contact with the inner surface 282, causing the degradable membrane 286 to dissolve or degrade over a controlled period of time, thus exposing the fluid activated dye 284 to the fluid 290. When the fluid activated dye 284 changes color or otherwise causes the fluid 290 to change color, an operator will know that the device 10 has been exposed to fluid 290 and placed into service for a given period of time. The rate at which the degradable membrane 286 degrades or dissolves may be adjusted to produce the desired timing effect by varying the material properties, thickness, and location of application of the membrane 286 to the device 10.

[0131] In one embodiment, the status indicator 280 of Figure 42 includes a color or other mechanism to alert an operator that the device 10 has expired. In another embodiment, the status indicator 280 of Figure 42 includes a moisture sensitive layer or other fluid activated indicator in place of the fluid activated dye 284. When the moisture sensitive layer is exposed to the fluid 290, the layer will indicate to an operator that a given period of time has elapsed. In another embodiment, the status indicator 280 includes a lube or adhesive similar or identical to the lube or adhesive 184 discussed with reference to Figure 23. In this embodiment, the lube or adhesive and the degradable membrane 286 are placed on the exposed surface of the slit 18 of the septum 16. After the degradable membrane 286 is removed, the lube or adhesive will cause the slit 18 to seal, thus blocking further use and access of the device 10 to an operator.

[0132] The embodiments set forth above are merely illustrative of any vascular access device capable of detecting the passage of time, an amount of usage, or the disinfection, e.g., the presence or absence of a pathogen on, in, or near the device. As used in the embodiments of this disclosure, a vascular access device may be any device capable of accessing the vascular system of a patient, including a closed-luer access device, an adapter, a catheter, a needle, a syringe, an IV access device, and/or any other similar device.

[0133] Vascular access devices capable of sensing and/or responding to a passage of time may include any embodiment discussed in this disclosure, including any of the following elements: migrating ink, photochromic dye activated by light, silver zeolite activated by light, an oil migration time strip, an air activated flexplay, a moisture activated silver zeolite, moisture activated color change desiccants, mechanical pressure capsules, a mechanical rotation ratchet, a mechanical axial wire tie, electrical light emitting polymers, an electrical microchip clock, and/or a delayed mixing chemical reaction. Vascular access devices capable of sensing and/or responding to usage of the device may include any embodiment discussed in this disclosure, including any of the following elements: pressure sensitive pigment bands, a pressure sensitive carbonless paper, a mechanical color wear change, a mechanical nanoskin, polyvinyl alcohol (PVO), a chemical nanoskin, reuse prevention (RUP), and/or an electrical cycle counter. Vascular access devices capable of sensing and/or responding to disinfection, e.g., the presence, absence, and/or extent to which a pathogen is present may include any embodiment discussed in this disclosure, including any of the following elements: radiopharmaceutical visualization, fluorescent visualization, chameleon material, proteins and other substances that detect pathogen secretion, bioreporters, antigens and/or antibodies, plasmids, polyamines, DNA, eNose electric biosensor sniffing technology, perfume, carbohydrates, analytes, and/or impedance. Many of the elements in this paragraph have been discussed previously in this disclosure. Others of these elements will be discussed below.

[0134] Referring now to Figure 43, a status indicator 292 is disposed on the inner surface 294 of the body 12 of a vascular access device 10. The status indicator 292 may be disposed on, in, or near any surface or structure of the device 10. The status indicator will preferably sense the presence of a pathogenic colony within a range of 100 to 100,000 colony-forming units (CFUs), and may sense the presence of a pathogenic colony below 100 CFUs.

[0135] The status indicator 292 is any one or any combination of the following elements: a protein and/or other substance that detects pathogen secretion, such as

EXPRESSDETECT™ Diagnostics by ECI Biotech of Expressive Constructs, Inc., set forth in the article at <http://ecibiotech.com/index.php?id=detection> and in all currently published patents and patent applications by Expressive Constructs, Inc.; a bioreporter, such as any bioreporter and/or similar substance set forth in the article at www.ceb.utk.edu/bioprimer.pdf and in all currently published patents and patent applications by the Center for Environmental Biotechnology at the University of Tennessee and/or the Oak Ridge National Laboratory; a DNA array detection chip, such as the chip set forth in the article at <http://fis.com/fis/techno/newtechno.asp?1=e&id=14633&ndb=1> and in all currently published patents and patent applications by Japan's Fisheries Research Agency; a polymerized diacetylene (PDA) chemosensor for pathogenic detection (including PDA-based and other chemosensors for the detection of biologically important small and medium sized molecules) set forth in Chemistry Letters, Vol. 32, No. 3 (2003) by Jae-Taek Cho, et. al and all currently published patents and patent applications by the Department of Chemical and Biochemical Engineering of the Korea University; and/or an electric nose biosensor capable of detecting a pathogen, such as the Cyranose set forth in the article at http://www.clevelandclinic.org/media/release.asp?Press_Releases_No=513 of the Cleveland Clinic Lerner Research Institute and manufactured by Smiths Detection Inc. of Pasadena, California and all currently published patents and patent applications by the Cleveland Clinic and Smiths Detection Inc. The Cyranose 320 portable hand-held electronic nose has been successfully demonstrated to detect six different bacteria in a study described in the article at <http://www.biomedical-engineering-online.com/content/1/1/4>. The subject matter of all of the articles and published patents and patent applications referred to specifically and/or generally herein is incorporated herein by reference in its entirety.

[0136] Pathogenic status indication will enable an operator of a device 10 to rapidly identify whether one or more pathogens are in communication with the device 10 and to understand specifically which type of pathogen is in communication with the device 10. For example, a status indicator 292 may include a substance that detects a host specific secretion and turns a specific color upon detection of the specific secretion. When the substance turns the specific color, an operator will understand that a specific pathogen corresponding with that specific color is in communication with the status indicator 292 of the device 10. By rapidly identifying specific pathogens, operators of the device 10 will be able to provide specific treatment aimed at protecting the patient and all healthcare givers from the specific harm caused by such specific pathogens.

[0137] More specifically, and by way of example, the status indicator 292 is capable of detecting the presence or absence of a prokaryotic microorganism by identifying a bacterial-specific protein (such as a protease that characterizes the presence of a specific prokaryotic microbe and thereby provides a marker for that microbe), detecting the protease that is a marker for the presence of a specific prokaryotic microbe by cleaving a substrate when the protease is present, and signaling the presence of that protease when cleavage has occurred. The status indicator 292 may identify a bacterial-specific protein by identifying at least one outer membrane protein or a secreted protein that is unique to a particular microbial pathogen and that is substrate specific. An example of a microbial pathogen that may be detected using the method above may include *Listeria monocytogenes*, as described in United States Patent Application Number 11/036,761, entitled "Device for detecting bacterial contamination and method of use", and filed January 14, 2005, which patent application is incorporated herein by reference in its entirety.

[0138] In embodiments where a substrate is cleaved, the substrate may be covalently bound to a label and thus has a detection signal that upon proteolysis of the substrate-label bond indicates the presence of the pathogen. The biosensor is made by first determining the specific substrate of a specific protease characteristic of the bacteria to be detected. The determined specific substrate is labeled with a plurality of chromatogenic or fluorescent leaving groups. The labeling group may provide a latent signal that is activated only when the signal is proteolytically detached from the status indicator 292. Chromatogenic leaving groups are, for example, para-nitroanalide groups.

[0139] As previously indicated, labeled substrate molecules may be coupled to the interior surface of the device 10. Should the device 10 become colonized by bacteria or other pathogen, the microbial pathogen produces protease which acts on the labeled substrate that is attached to the device 10, liberating the leaving group. When a visually detectable calorimetric signal is released, this results in a visible color change at the site where the status indicator 292 is located.

[0140] As previously mentioned, a status indicator 292 may also include a bioreporter. As set forth in the article at www.ceb.utk.edu/bioprimer.pdf, bioreporters include intact, living microbial cells that have been genetically engineered to produce, display, indicate, or otherwise signal a measurable signal in response to a specific chemical or physical agent in their environment. Bioreporters may include two genetic elements, a promoter gene and a reporter gene. The promoter gene is turned on, or transcribed, when a

target agent, such as a pathogen or related substance, is present in the cell's environment. The promoter gene in a normal bacterial cell is linked to other genes that are then likewise transcribed and then translated into proteins that help the cell in either combating or adapting to the agent to which it has been exposed. In the case of a bioreporter, these genes, or portions thereof, have been removed and replaced with a reporter gene. Consequently, turning on the promoter gene now causes the reporter gene to be turned on. Activation of the reporter gene leads to production of reporter proteins that ultimately generate some type of a detectable signal. Therefore, the presence of a signal indicates that the bioreporter of the status indicator 292 has sensed a particular target agent, such as a pathogen, in its environment.

[0141] Bioreporters as status indicators may produce a variety of signals to indicate the present of target agents such as pathogens. For example, bioreporters can produce either colorimetric, fluorescent, luminescent, chemiluminescent, or electrochemical signals. Some bioreporters, such as luxAB bioreporters, firefly luciferase, or aequorin, require an additional substrate to be added to the bioassay containing the bioreporter in order to produce a measurable signal. Other bioreporters, such as green fluorescent protein or uroporphyrinogen III methyltransferase, require the presence of a light source in order to produce a measurable signal. Still other bioreporters, such as luxCDABE bioreporters, require no additional substrate or external activation in order to produce a measurable signal. The bioreporters mentioned above, in addition to other bioreporters, are described in more detail in the article referenced herein. In addition, any bioreporter capable of producing a signal to a health care provider may be used as a status indicator.

[0142] As discussed herein, a vascular access device, such as device 10, may include any device capable of providing therapy to the vascular system of a patient. Various examples of vascular access devices are provided herein. By way of further example and with reference to Figure 44, a vascular access device may include any one or more of the following structures, taken alone or in any combination, and any other structure in communication with any of the following structures: an IV and/or drip chamber assembly 320 including a spike 322, a spike cover 324, a vent such as a spike vent 326, a cannula or catheter 328, a clamp including a slide clamp 330, a snap clamp 332, or a roller clamp 334, a burette 336, a burette vent 338, a burette fill port 340, a drug run prevention barrier 342, a drip chamber 344, a filter 346, a safety strap 348, an IV hook 350, a valve such as a check valve 352, an injection site and/or Luer connector 354, a Y-port 356, an access port including a needle access port 358, a

blunt can access port 360, a Luer access port 362, a T-site manifold 364, a stop cock 366, or a stop cock manifold 368, a pump including a pump cartridge 370, an air or particulate filter 372 including a vent 374, a flow regulator 376 such as a precision flow regulator, a flash bulb 378, an air trap 380, a slip Luer 382, a cap such as a dust cap 384, a Luer lock 386, a vent cap 388, a universal Luer 390, a needle tip cannula 392 or catheter tip cannula, a needle tip guard or shield 394 or catheter tip guard or shield 396, and/or a needle set such as a wing needle set 398.

[0143] Hundreds, if not thousands, of vascular access devices exist or may be developed in the future. The vascular access devices described herein form merely an abbreviated list of some vascular access devices to which the principles and elements of the claimed invention may be applied. The principles and elements of the claimed invention may be applied to any structure discussed above, to its equivalents, or to similar, after-arising technology. Specifically, a status indicator may be placed in communication with any vascular access device to detect and/or communicate an event or passage of time helpful to a caregiver, such as the passage of time during which the device has been in use, an amount of usage of the device, whether or not the device has been cleaned, disinfected, or sterilized, and/or whether and to what extent one or more pathogens reside at or near the device.

[0144] Many of the embodiments discussed above have been described to include either reversible or non-reversible changes of status indicators. For example, a color change from a first color to a second color may reverse from the second color to the first color after a period of time or the occurrence of a certain event. Although not every example of reversible status indicators has been provided here, any claimed embodiment, whether described as reversible or non-reversible, or described without respect to reversibility, may be capable of reversing from a second state back to a first state or from a second state to an additional third state and is intended to come within the scope of the claimed invention.

[0145] 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. For example, the elements discussed above may be combined in any number and orientation in an enabling manner with any number and orientation of any of the other elements discussed above to produce a status indicator for a vascular access device. The described embodiments 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 medical device, comprising:
a vascular access device for communicating with the vascular system of a patient, wherein the vascular access device comprises:
a body with a lumen, and
a status indicator, wherein the status indicator provides an indication of the presence of a pathogen in communication with the vascular access device.
2. The medical device of claim 1, further comprising:
a second vascular access device with a proximal end and a distal end, wherein the distal end of the second vascular access device is introduced into the vascular system, and wherein the vascular access device is a connector affixed directly or indirectly to the proximal end of the second vascular access device.
3. The medical device of claim 1, wherein the status indicator provides an indication of the extent of pathogenic presence or absence.
4. The medical device of claim 3, wherein the status indicator senses a pathogenic culture within a range of 100 to 100,000 colony-forming units.
5. The medical device of claim 3, wherein the status indicator senses a pathogenic culture of less than about 100 colony-forming units.
6. The medical device of claim 4, wherein the status indicator produces at least one of colorimetric, fluorescent, luminescent, chemiluminescent, and electrochemical signals.
7. The medical device of claim 4, wherein the status indicator requires radiopharmaceutical visualization or fluorescent visualization.
8. The medical device of claim 1, wherein the status indicator includes a protein that detects pathogen secretion.
9. The medical device of claim 1, wherein the status indicator includes at least one of a bioreporter, an antigen, an antibody, a plasmid, and a polyamine.
10. The medical device of claim 1, wherein the status indicator includes a DNA array detection chip.
11. The medical device of claim 1, wherein the status indicator includes electric biosensor technology.
12. The medical device of claim 1, wherein the status indicator includes at least one of a perfume, a carbohydrate, and an analyte.

13. The medical device of claim 1, wherein the status indicator includes an impedance sensor.

14. A method of using a medical device, comprising:

attaching a status indicator to a vascular access device, said status indicator being active during usage of the device;

detecting with the status indicator the presence of a pathogen; and

signaling with the status indicator the presence of the detected pathogen.

15. The method of claim 14, wherein signaling with the status indicator the presence of the detected pathogen includes signaling in response to a specific chemical or physical agent within the environment of the status indicator.

16. The method of claim 15, further comprising:

transcribing a promoter gene when the pathogen is present in the environment of the status indicator;

transcribing a reporter gene during or after transcribing the promoter gene;

producing reporter proteins during or after transcribing the reporter gene; and

generating a detectable signal as a result of the production of reporter proteins.

17. The method of claim 16, wherein signaling with the status indicator the presence of the detected pathogen includes signaling through at least one of a colorimetric, fluorescent, luminescent, chemiluminescent, and electrochemical signal.

18. A medical device, comprising:

means for accessing the vascular system of a patient;

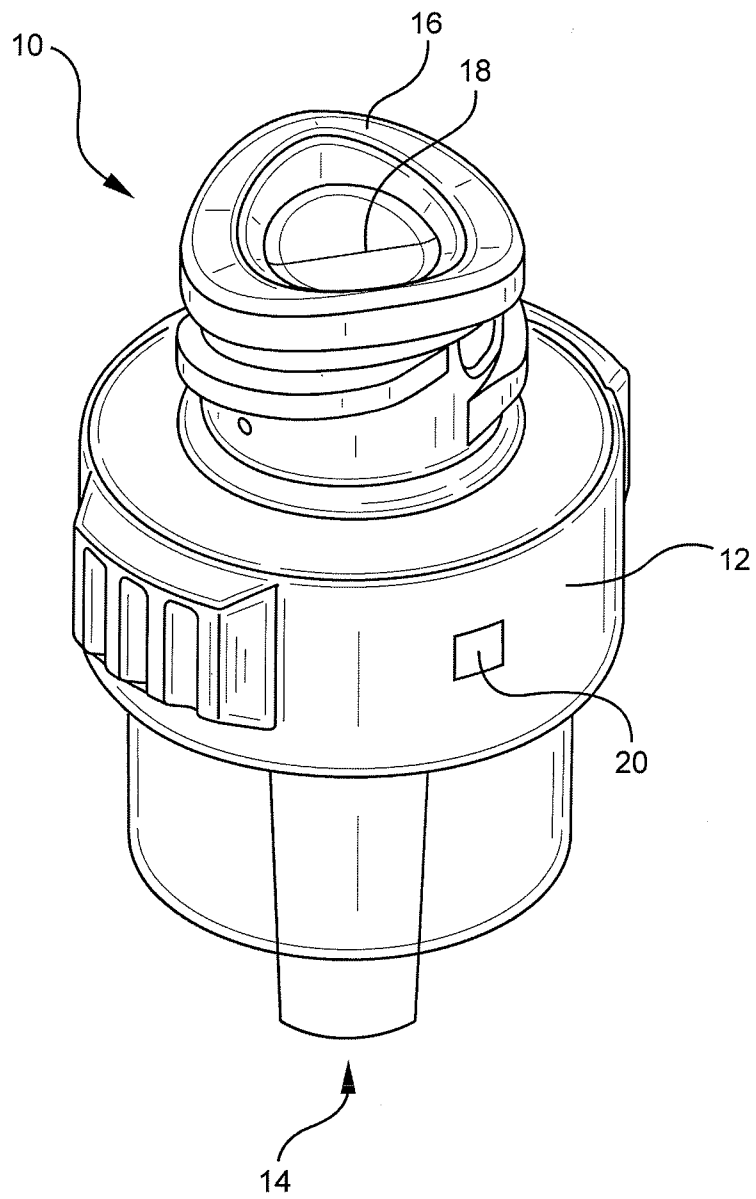
means for detecting a pathogen in communication with the means for accessing the vascular system of a patient; and

means for signaling a status change of the means for accessing the vascular system after or during detecting a pathogen in communication with the means for accessing the vascular system of a patient.

19. The medical device of claim 18, wherein means for detecting a pathogen in communication with the means for accessing the vascular system of a patient and means for signaling a status change of the means for accessing the vascular system after or during detecting a pathogen in communication with the means for accessing the vascular system of a patient include the same structure.

20. The medical device of claim 19, wherein means for detecting a pathogen in communication with the means for accessing the vascular system of a patient and means for signaling a status change of the means for accessing the vascular system after or during detecting a pathogen in communication with the means for accessing the vascular system of a patient include a pathogen staining solution.

FIG. 1



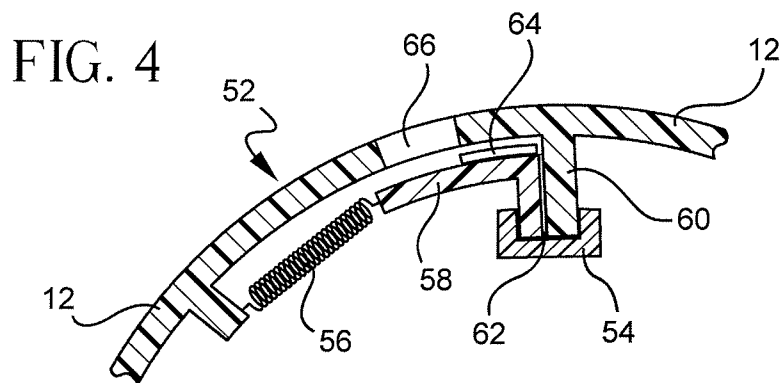
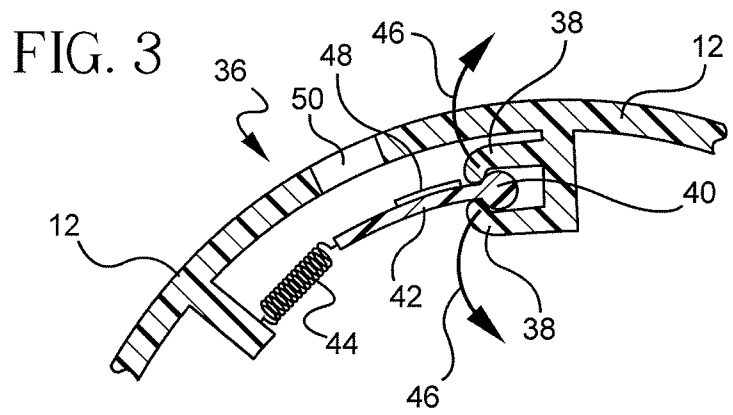
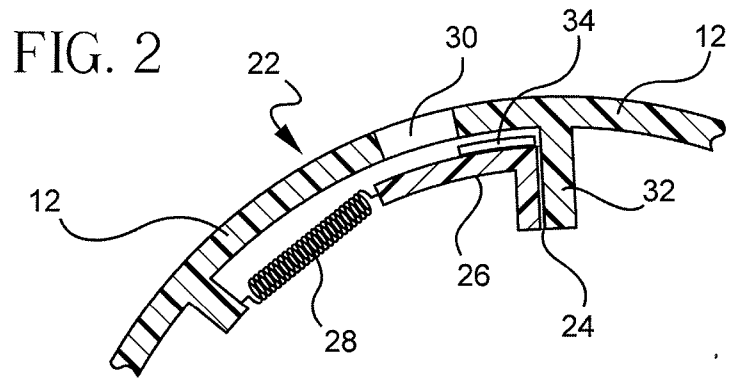


FIG. 5

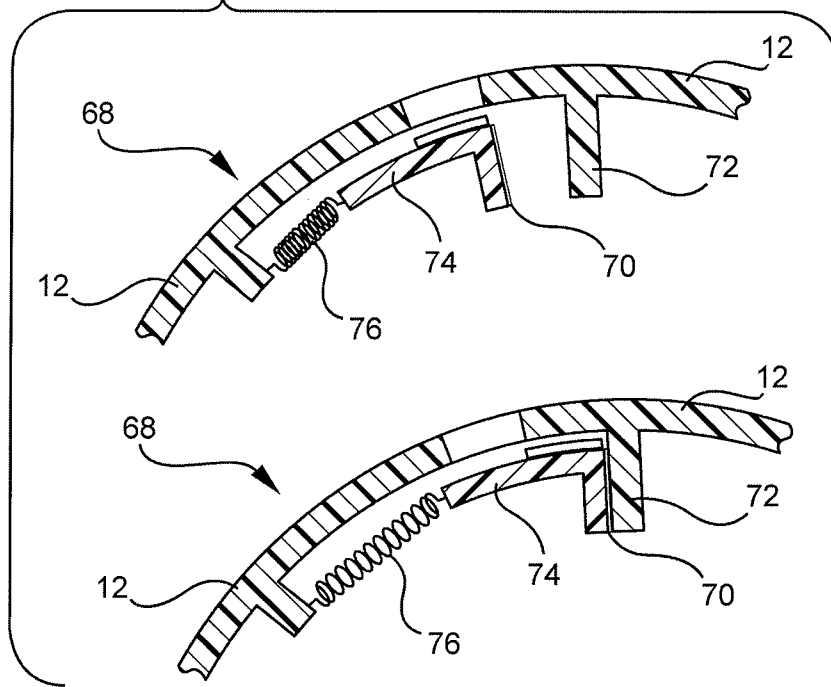
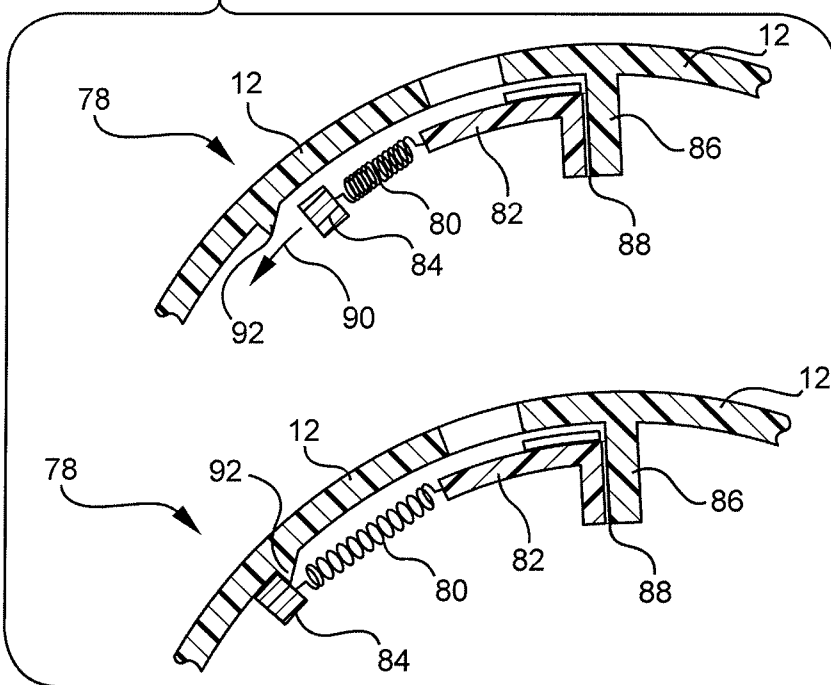


FIG. 6



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FIG. 7

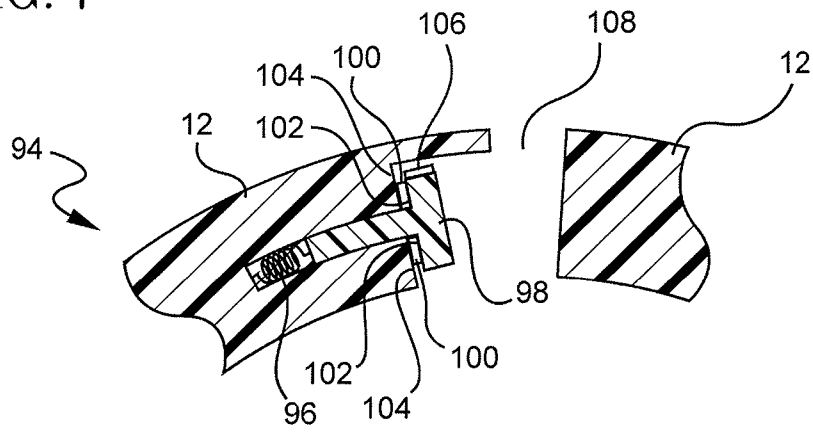


FIG. 8

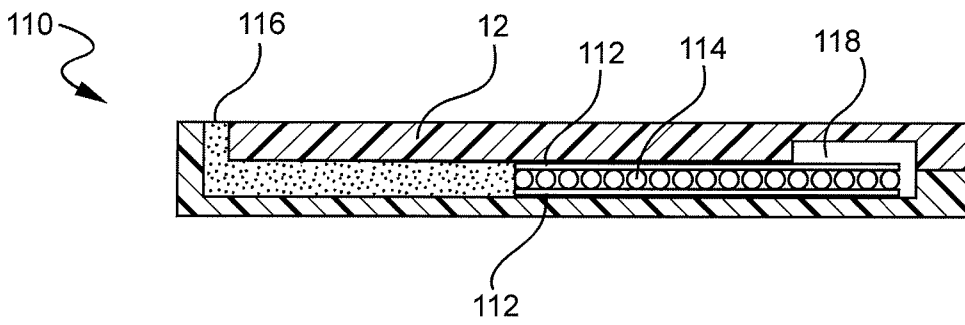


FIG. 9

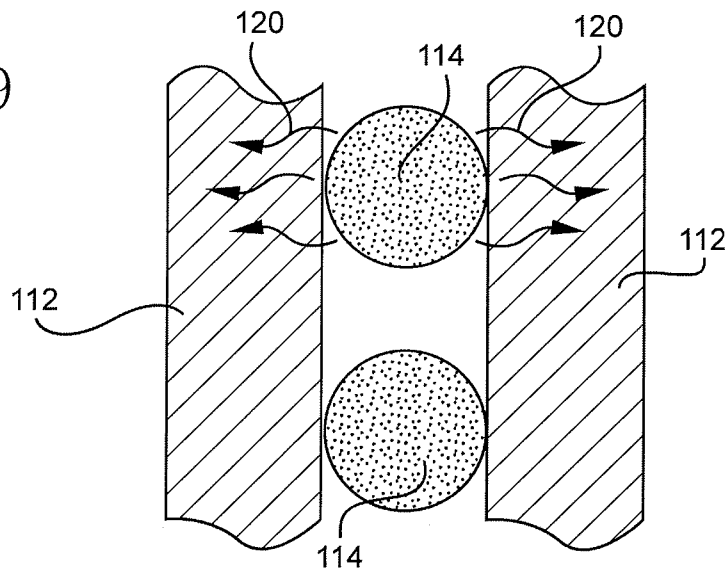
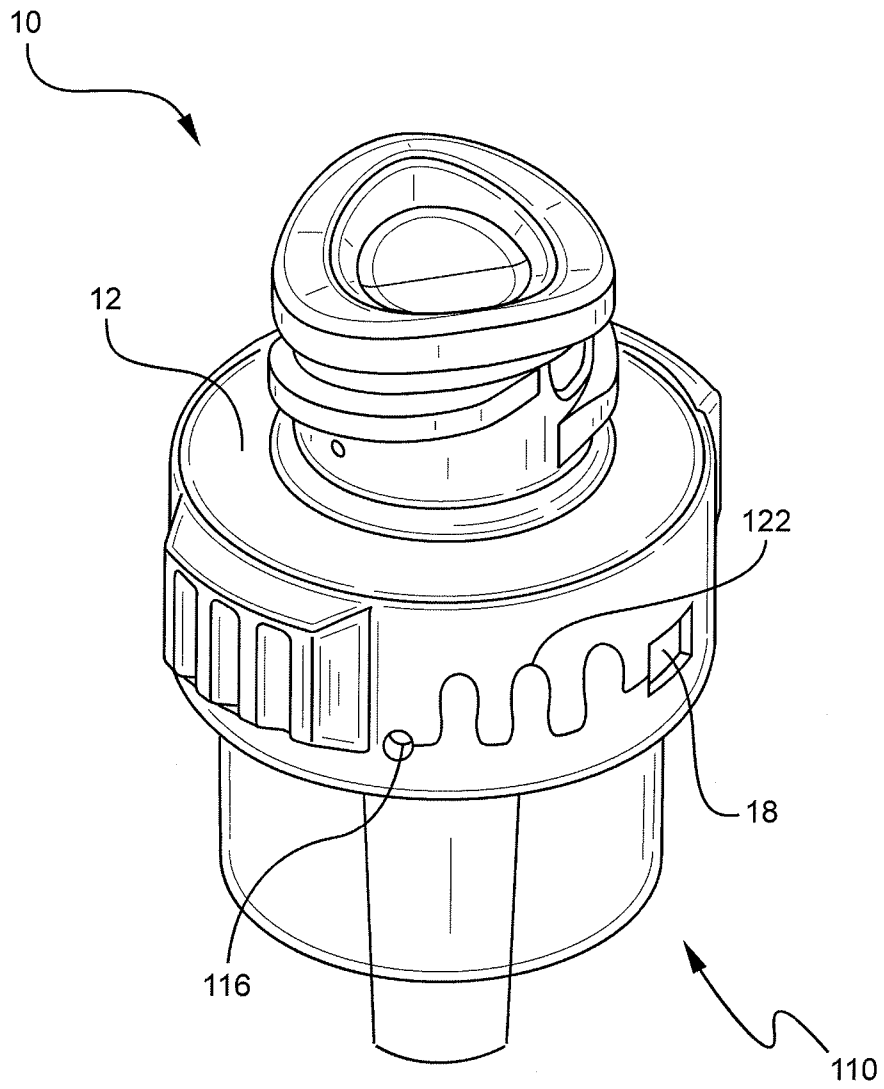


FIG. 10



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FIG. 11

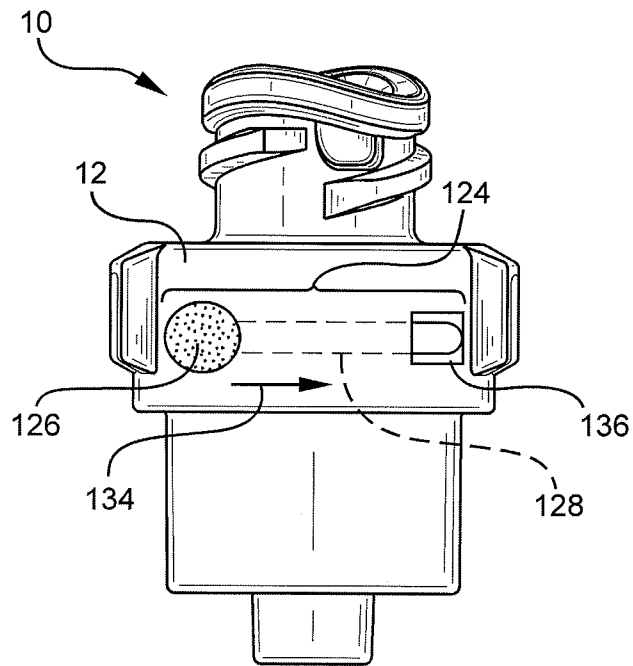
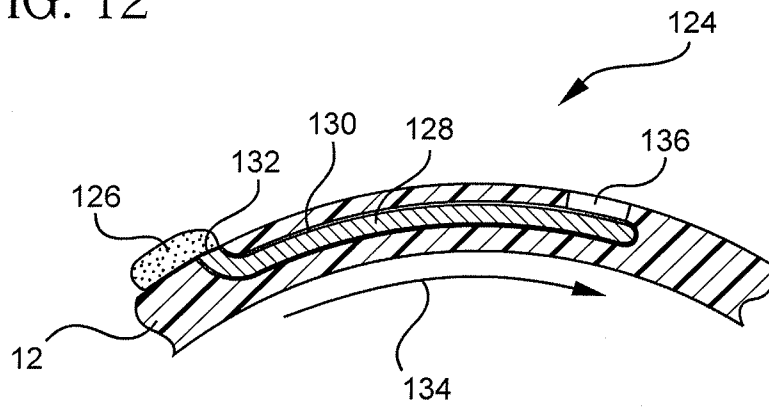
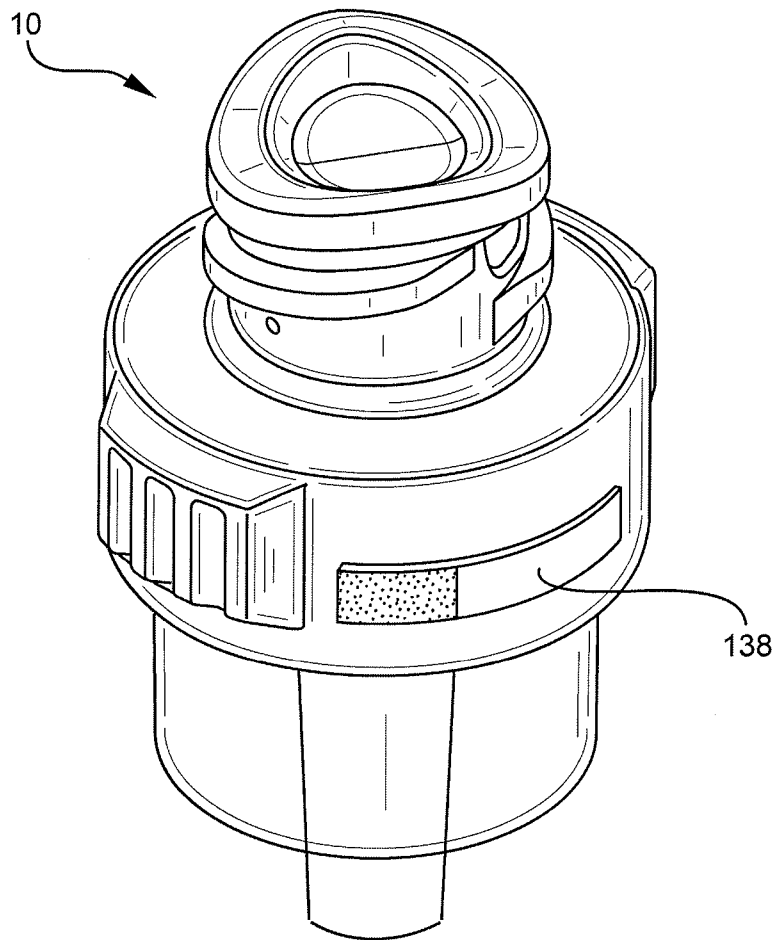


FIG. 12



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FIG. 13



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FIG. 14

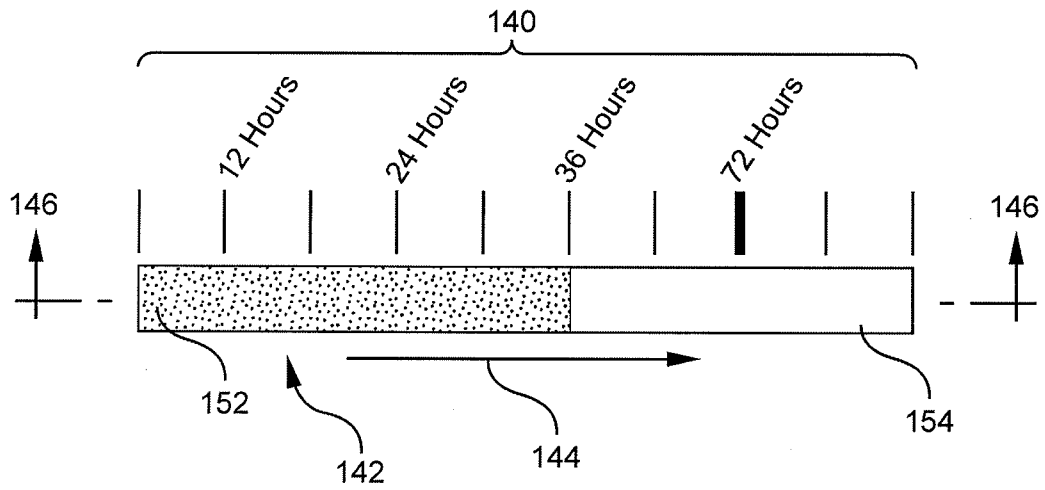
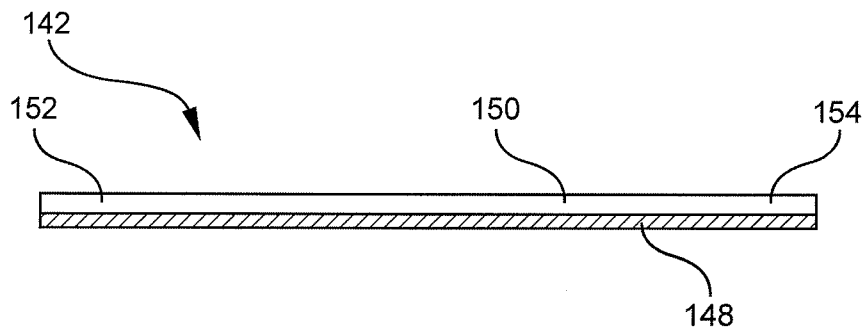
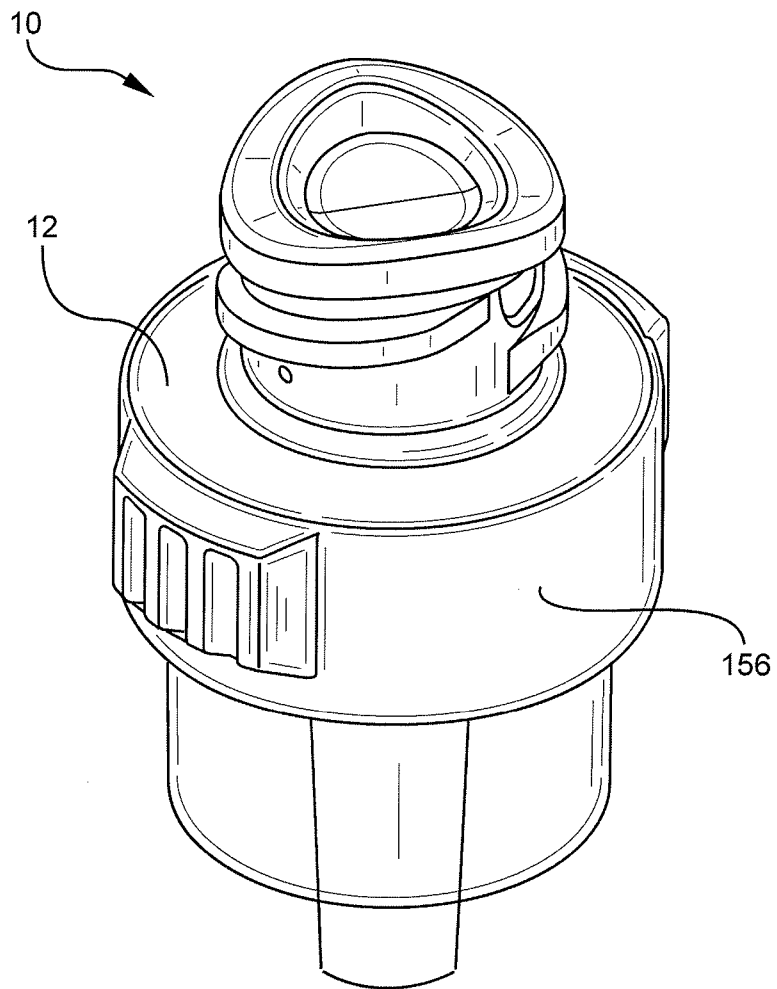


FIG. 15



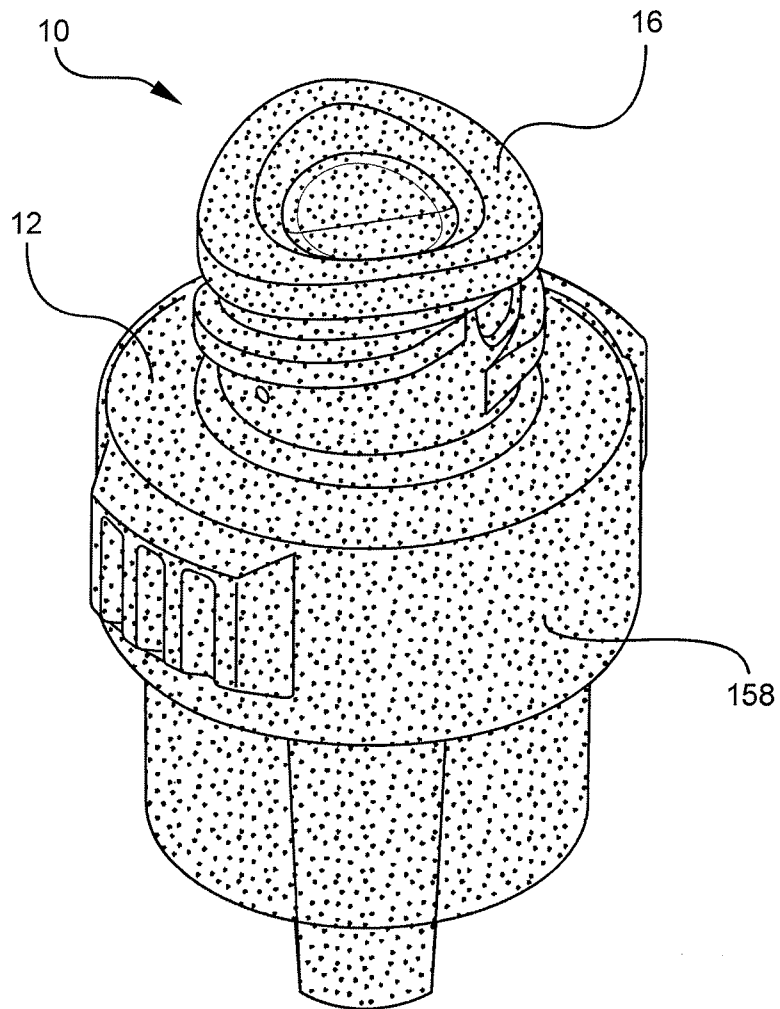
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FIG. 16



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FIG. 17



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FIG. 18

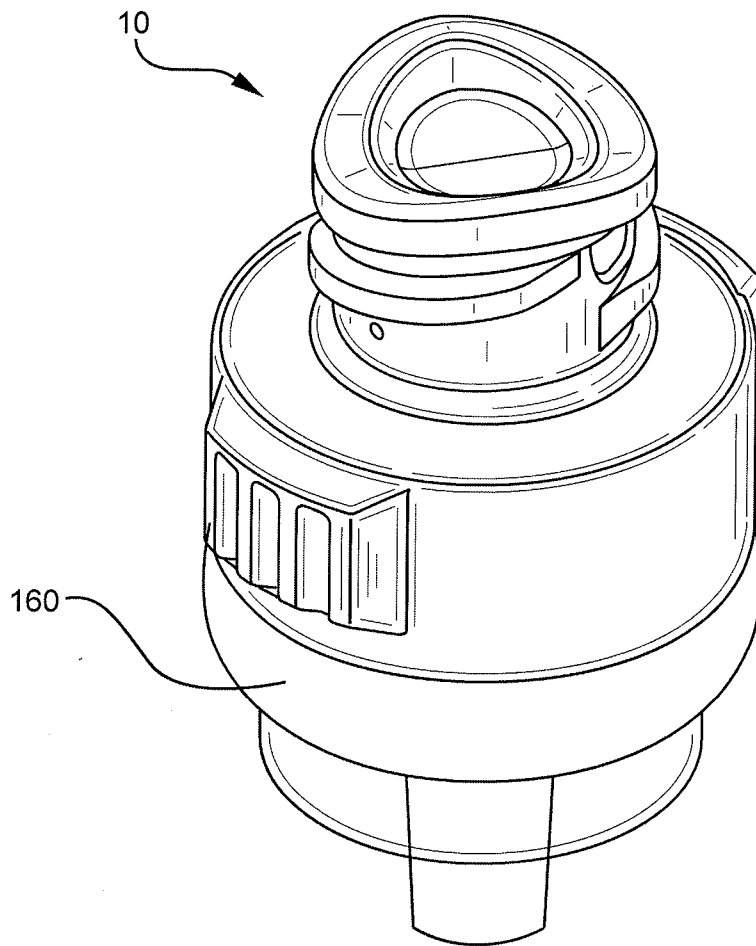


FIG. 19

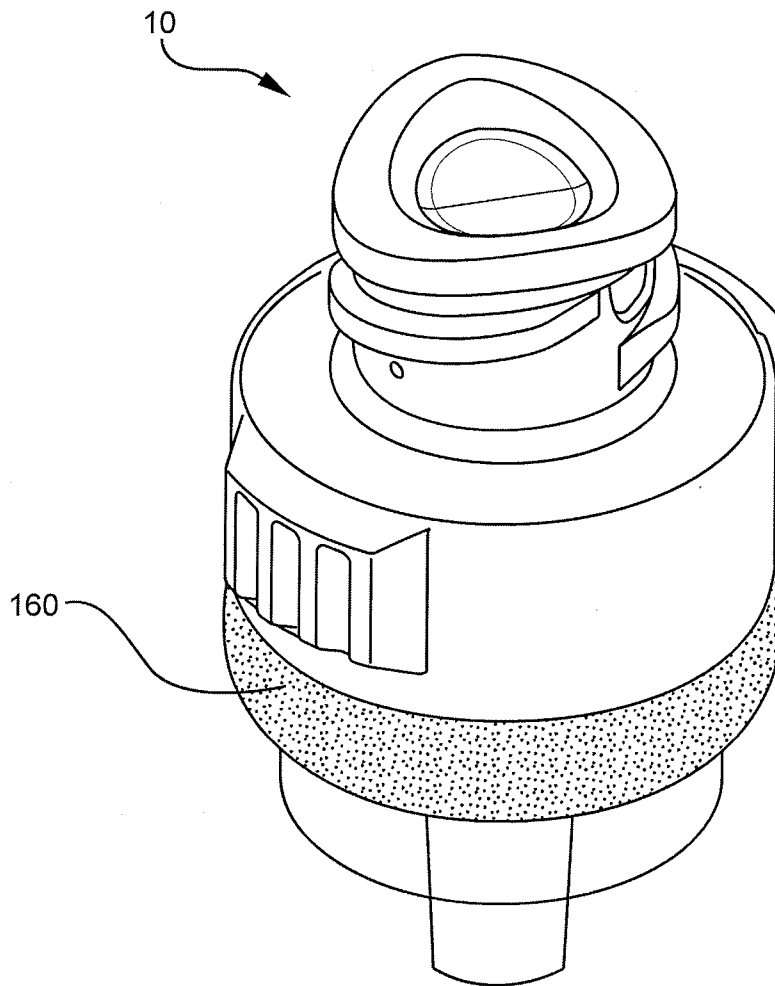


FIG. 20

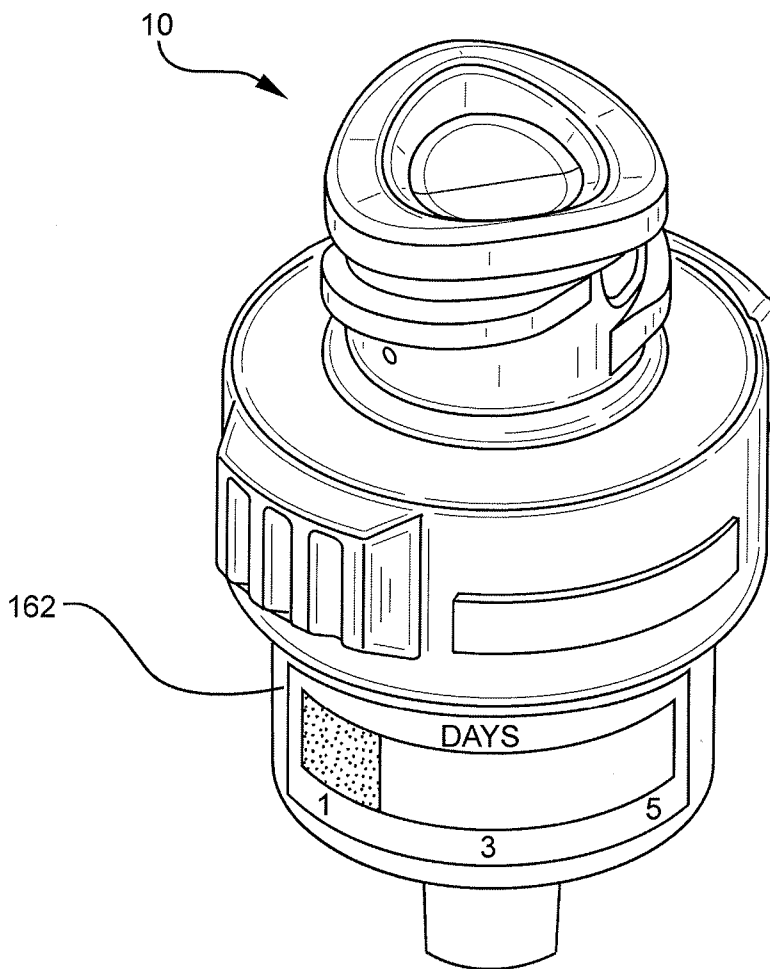


FIG. 21

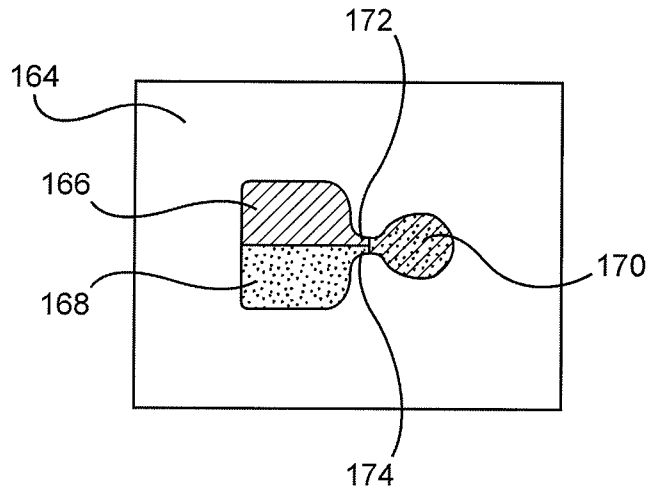


FIG. 22

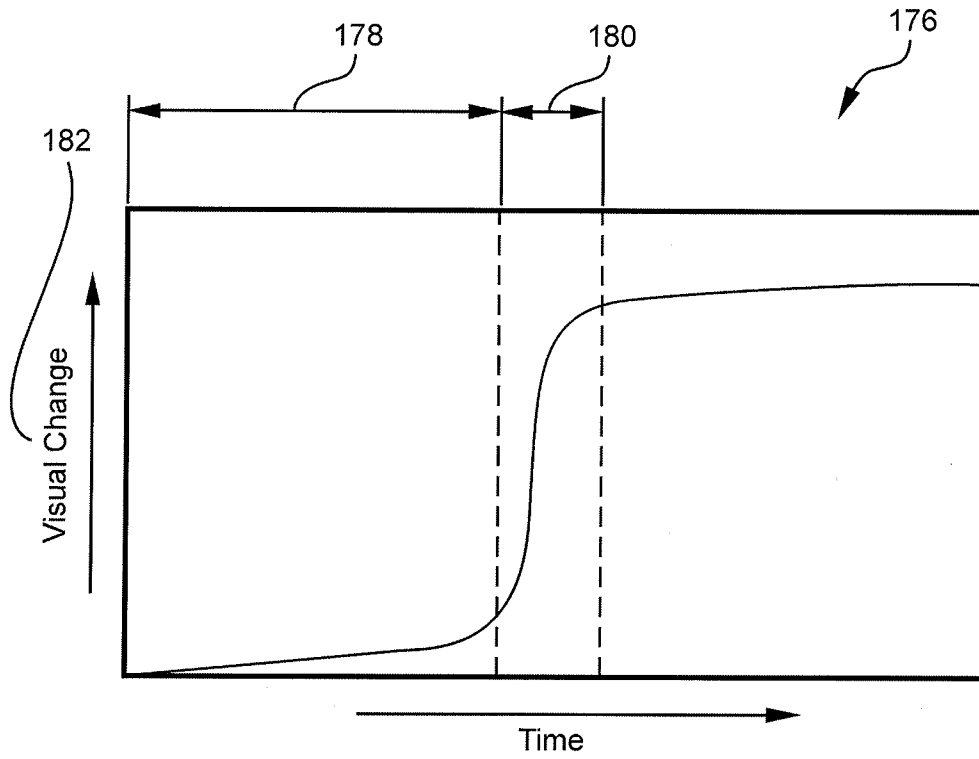


FIG. 23

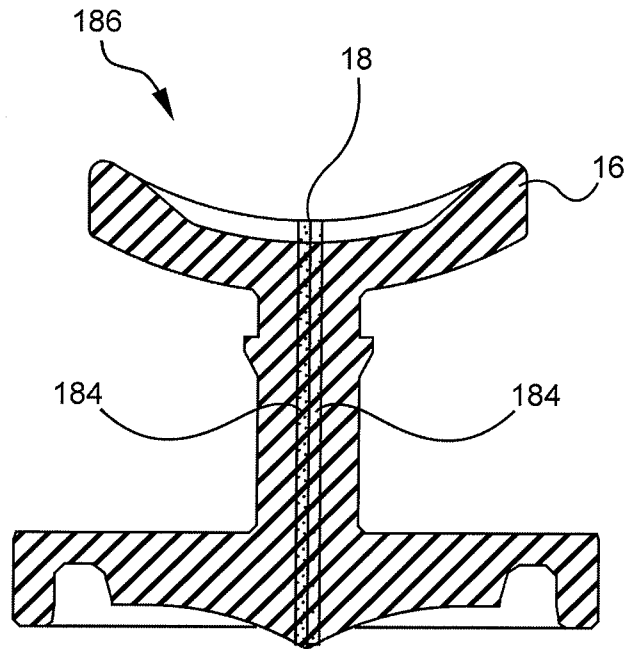


FIG. 24

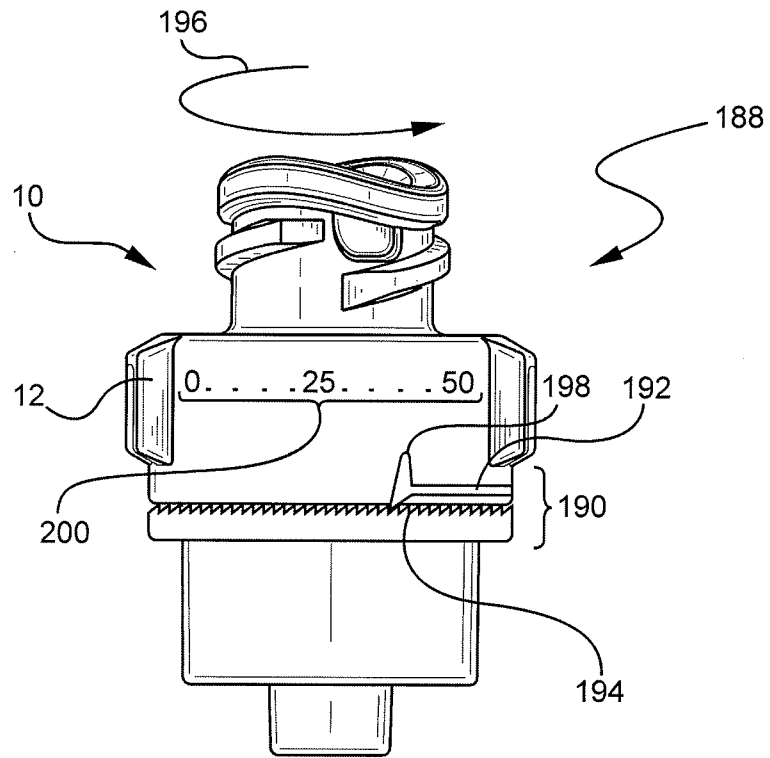


FIG. 25

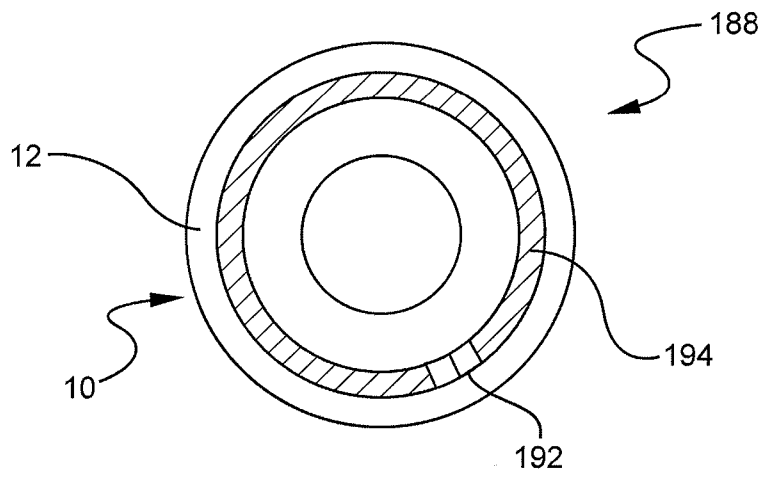


FIG. 26

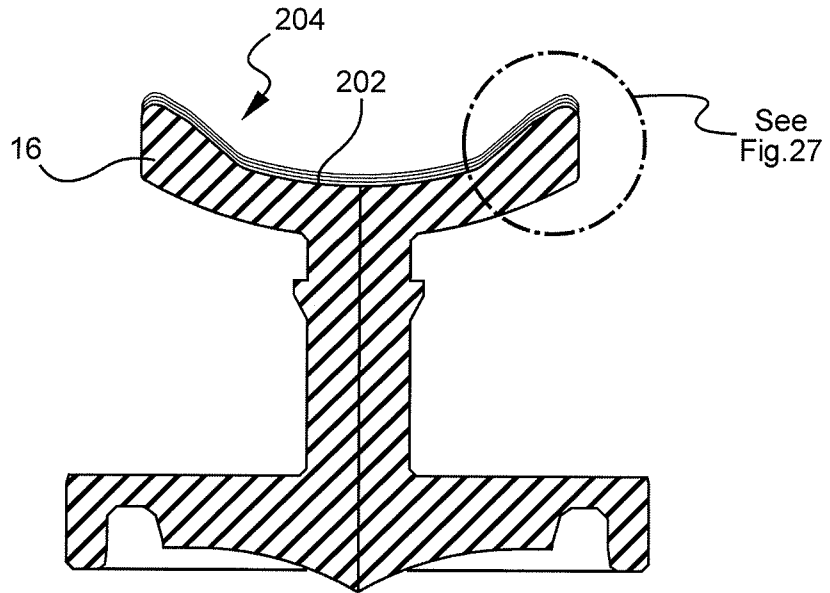


FIG. 27

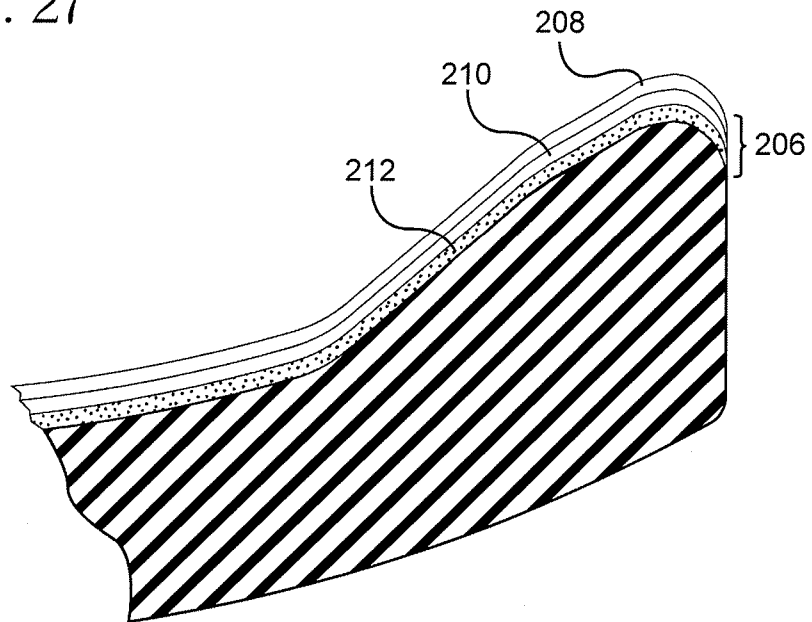


FIG. 28

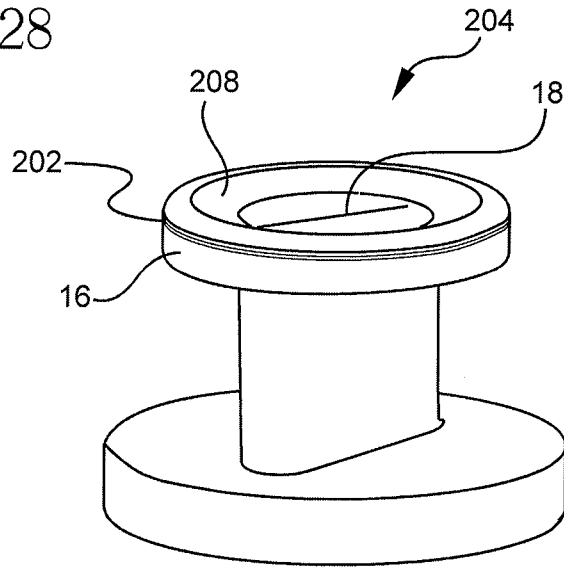


FIG. 29

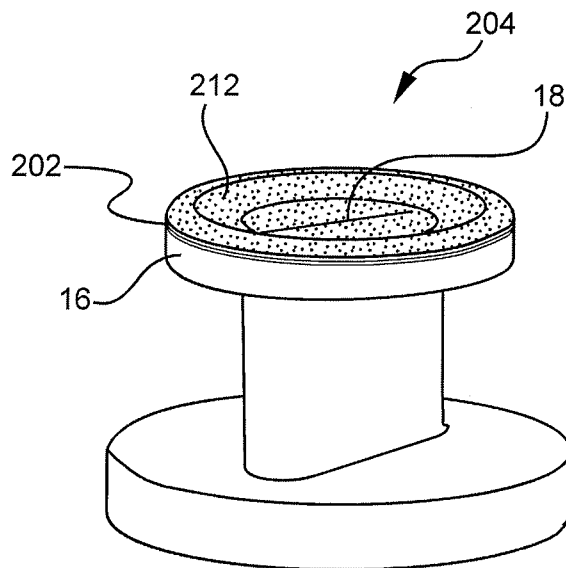


FIG. 30

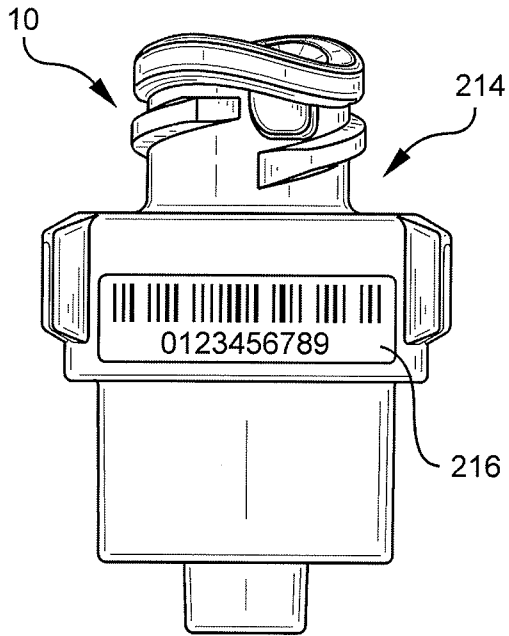


FIG. 31

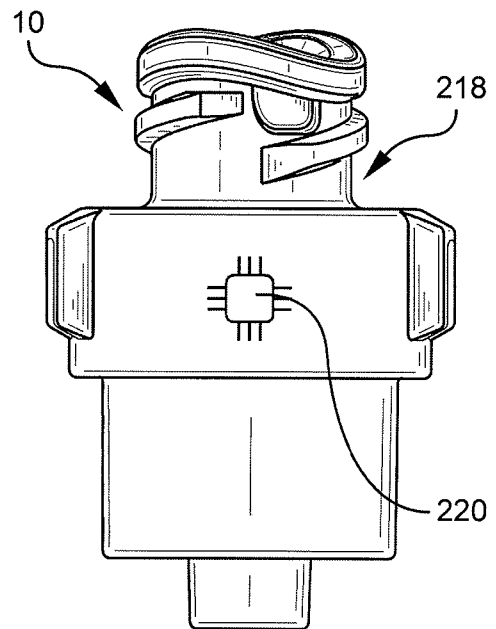


FIG. 32

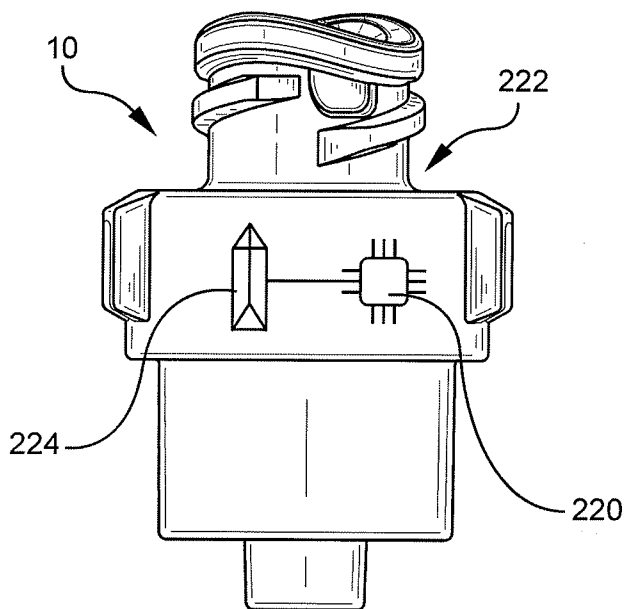


FIG. 33

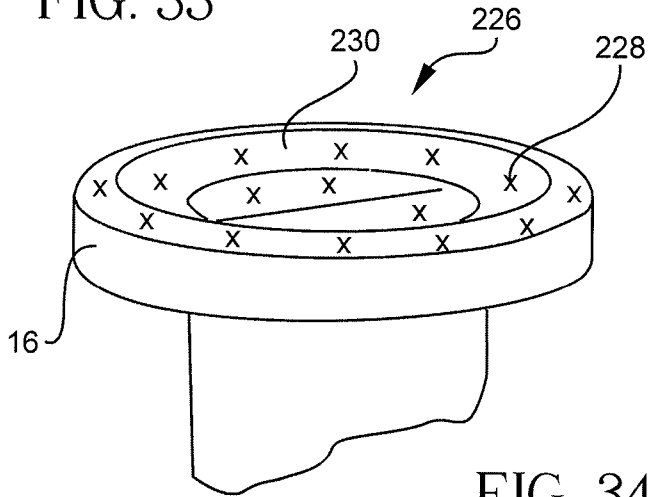


FIG. 34

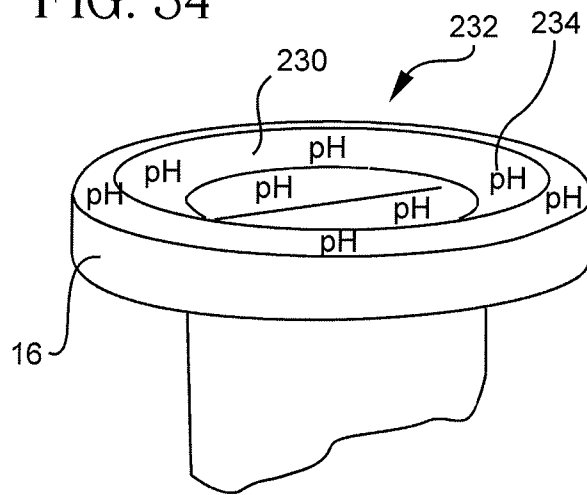


FIG. 35

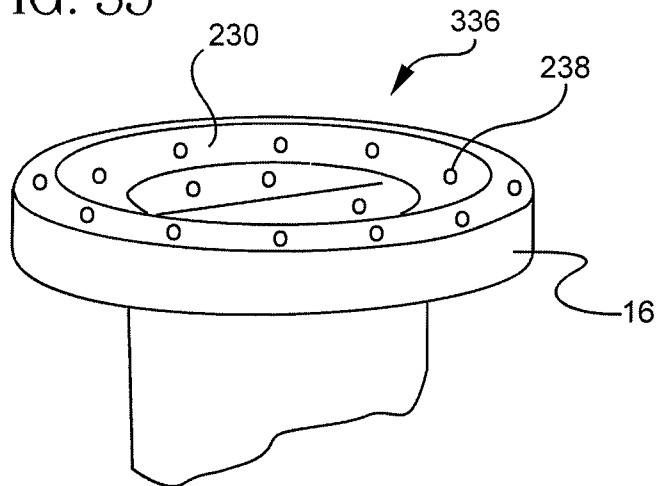


FIG. 36

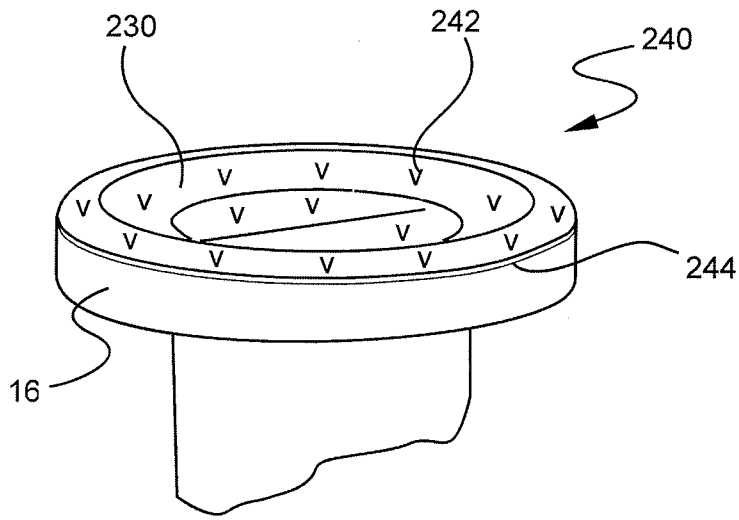


FIG. 37

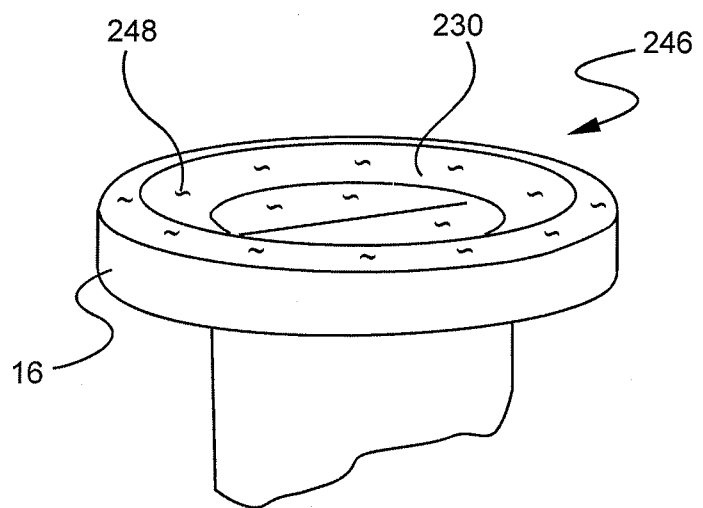


FIG. 38

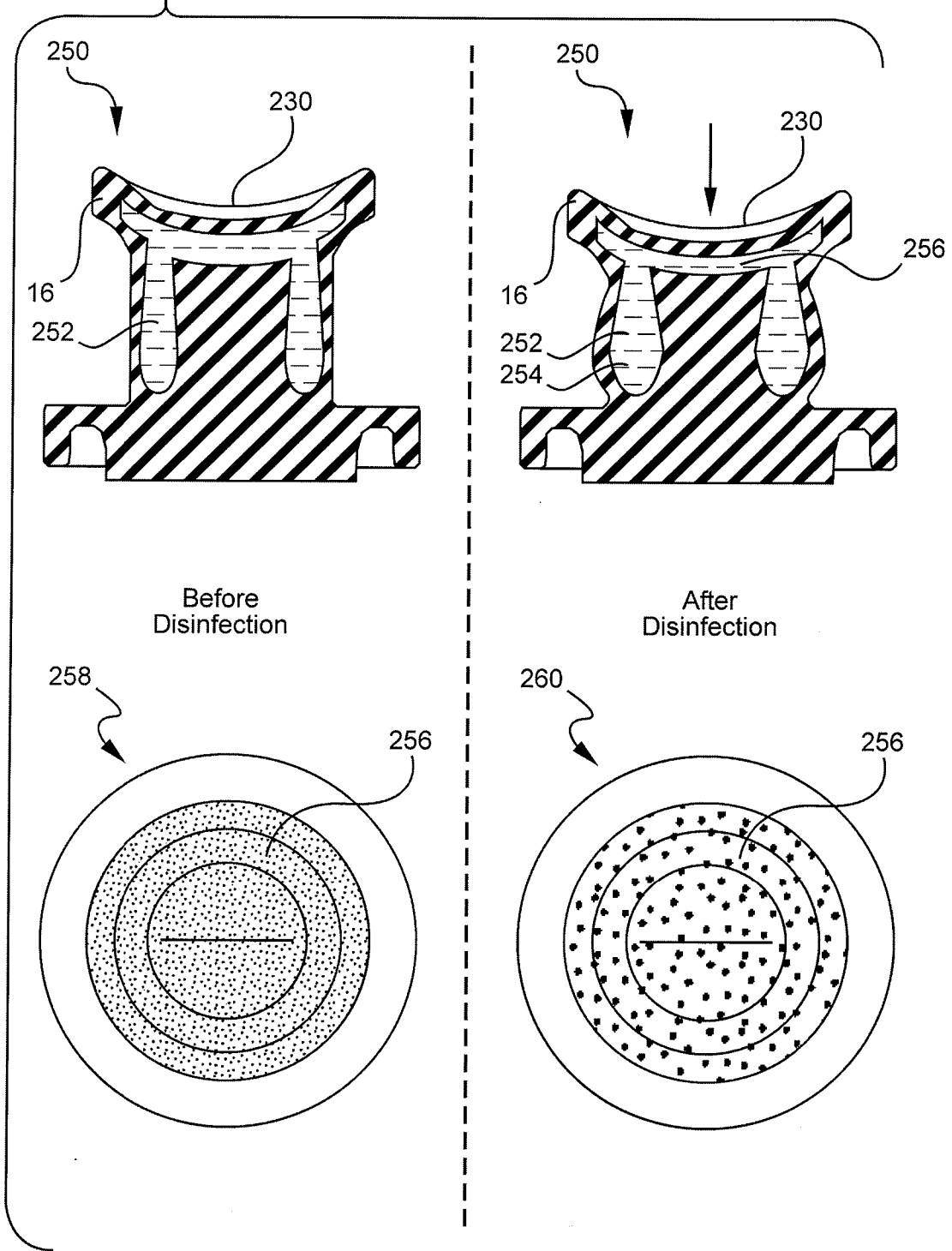


FIG. 39

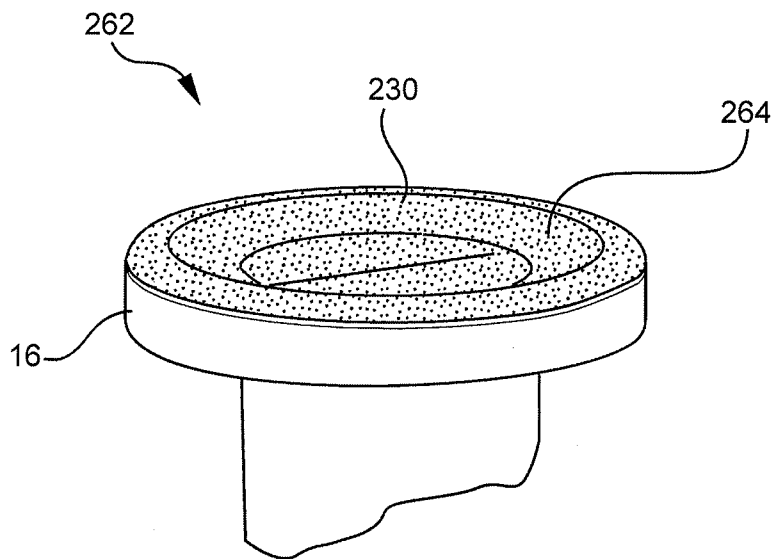


FIG. 40

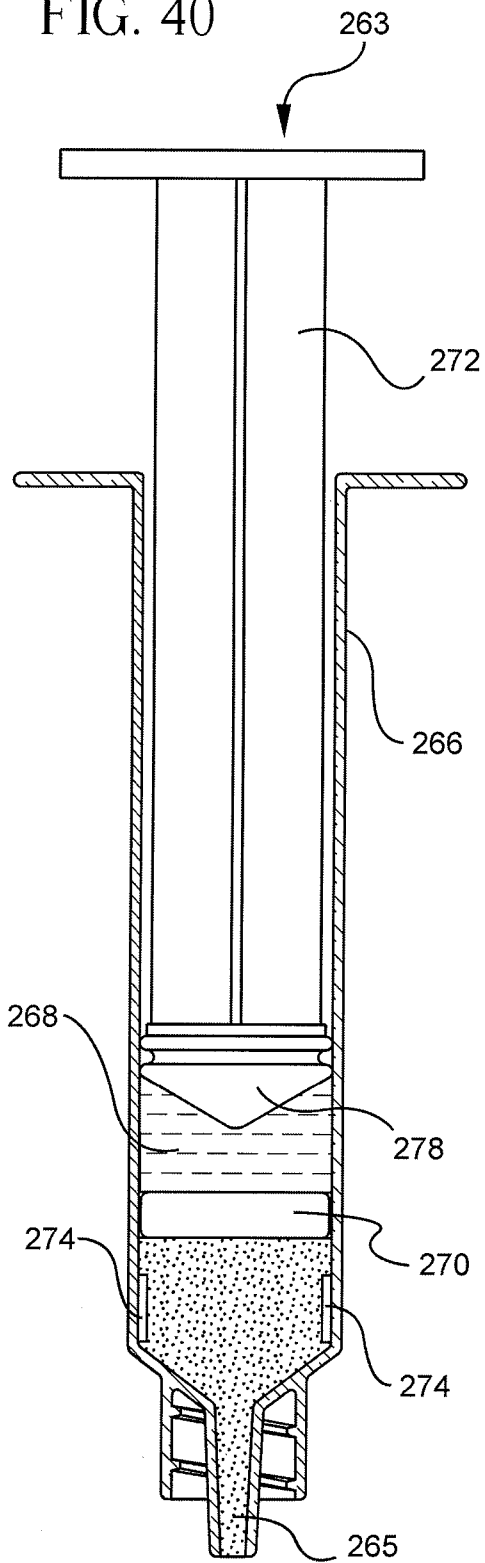
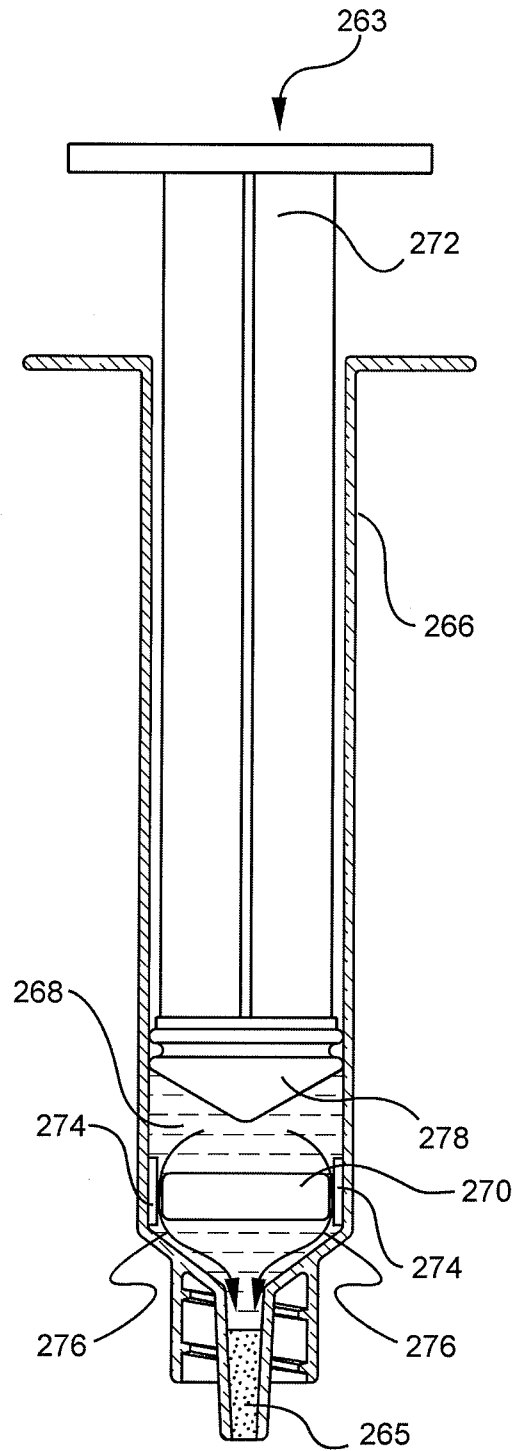


FIG. 41



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FIG. 42

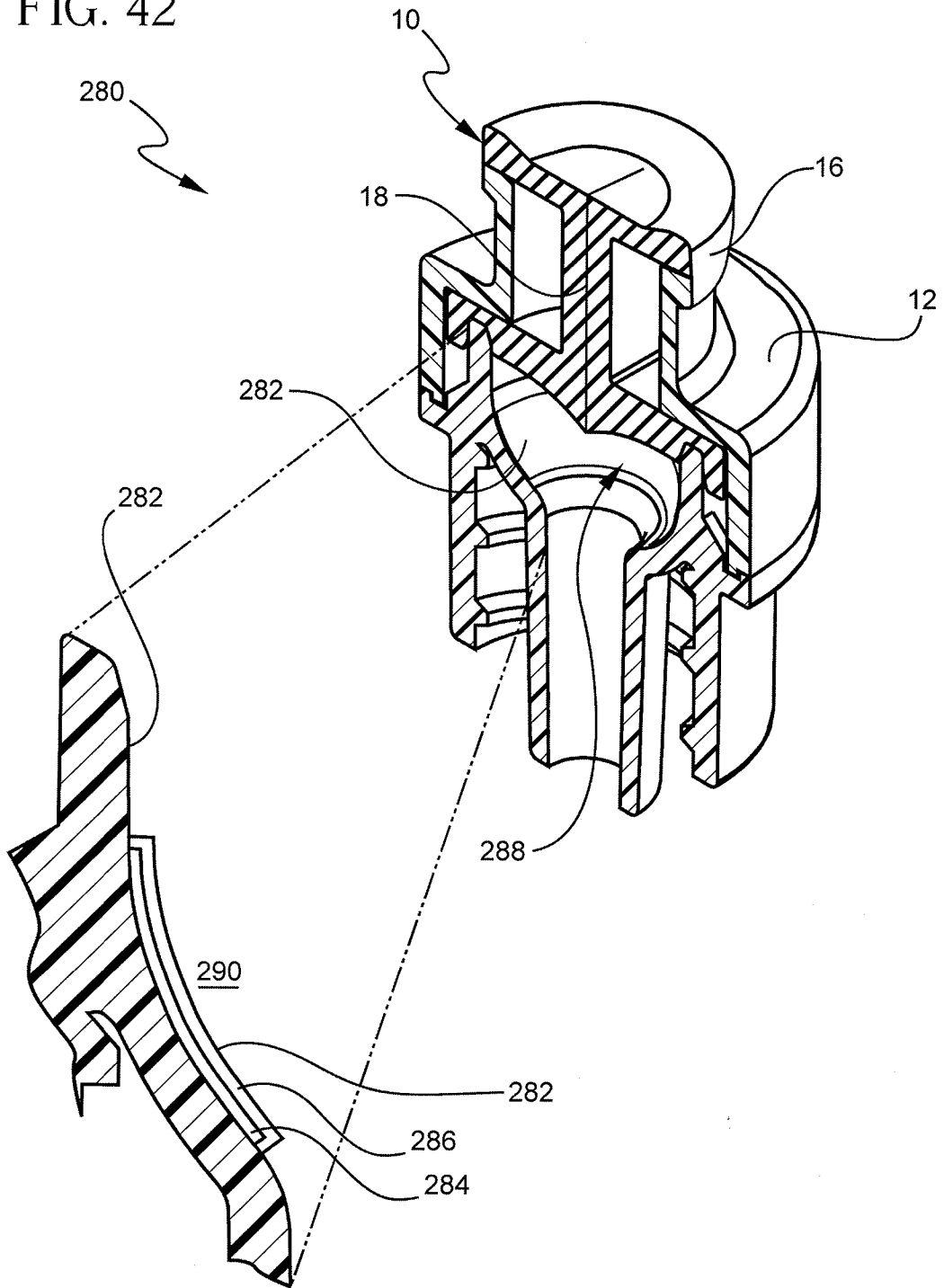


FIG. 43

