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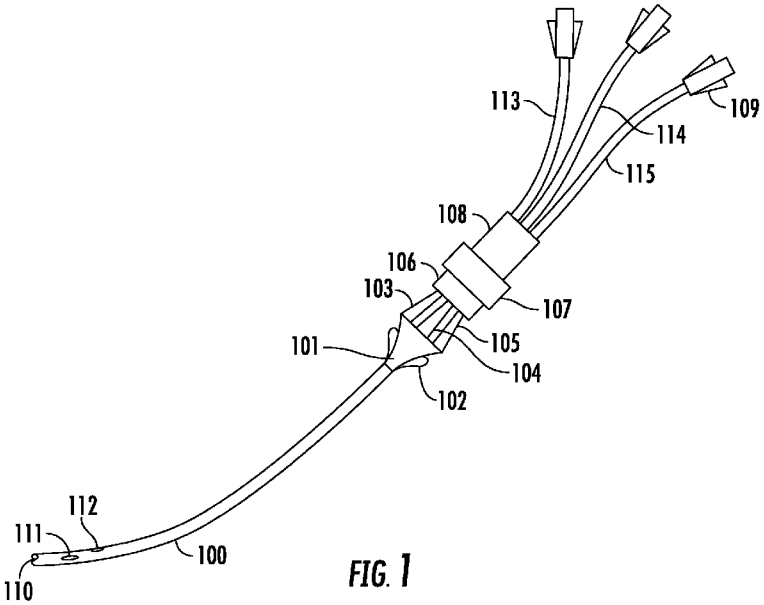


FIG. 1

(57) Abstract: The present invention relates to a novel interchangeable lockable catheter having a cap, the cap locking onto a junction hub or base, and encasing at least one lumen proximally to the junction hub of a multi-lumen catheter, PICC line and the like. The interchangeable lockable catheter's cap and base may be made of more than one piece, and provide a locking mechanism sufficient to deter tampering, while providing a low profile, comfortable, sanitary, and efficient means of closing off lumens for patients leaving the treatment area.

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INTERCHANGEABLE LOCKABLE CATHETER

This application claims priority to a US non-provisional application number 15/593,012 filed on May 11, 2017 which claims priority to a provisional application number 62/334,482 filed on May 11, 2016 and which is incorporated herein in its entirety by reference.

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BACKGROUND OF THE INVENTION

Field of the Invention

[001] The present invention relates to a novel interchangeable venous lockable catheter having a cap, the cap locking onto a junction hub or base, and encasing at least one lumen proximally to the junction hub of a multi-lumen venous catheter, peripherally inserted central catheters (PICC) line and the like. The interchangeable lockable catheter's cap and base may be made of more than one piece and provide a locking mechanism sufficient to deter tampering while providing a low profile, comfortable, sanitary, and efficient means of closing off lumens for patients leaving the treatment area.

Description of Related Art

[002] Intravenous (IV) access is essential in hospital medicine. IV access provides methods for fluid resuscitation, drug administration, and nutritional support in some patients. Peripheral IV access is appropriate for most patients; however, PICC and central venous catheters are needed for long term IV access and infusion of certain medications.

[003] PICCs provide a common means of maintaining IV access in hospitalized patients and are now commonly placed for discharge purposes. The utilization of PICC lines have increased significantly. According to the idata research, the PICC market was valued at $413 million in 2011 and is expected to reach $583 million in 2017. PICC use is expected to increase with the increase in the aging population and in conjunction with Medicare payment bundling which demands shorter length of stay and improved outcomes.

[004] Current PICC line apparatus are fixed one-piece devices. The number of lumens can vary from single to triple lumen for each catheter. The number of lumens is fixed, there is no technology that allows for manipulation of that number by either increasing or decreasing, without exchanging the entire catheter. Where the number of lumens must be changed, the patient is subjected to new catheter placement, increased medical spending, inconvenience, discomfort, and risk of complications.

[005] The complications and limitations with PICC lines are well documented. Infections with traditional PICCs are well known, allowing bacteria to be introduced directly into the bloodstream (known as central line-associated infections (CLABSI)). After infection has taken hold, the incidence of morbidity and mortality are high, and concomitantly, the cost of care where infection has occurred is very high. These infections, as well as thrombotic catheter occlusions, are well-known critical issues in

healthcare. Central lines also put patients at risk for thrombosis (forming of blood clots), including both upper and lower extremity deep vein thrombosis. Moreover, venous catheters placed in the chest increase the patient's risk for a pneumothorax. Other complications include misplacement, embolisms, hemorrhage, and venous fusion among many others.

[006] Many advances have been made to combat risk of infection including valves, caps, and antimicrobial and antithromboic devices. Antimicrobial coatings used in the manufacture of PICC lines reduce infection risk, but it cannot eliminate it. Moreover, current venous catheters allow lumens to hang at significant length from the hub junction with a plastic cap for each lumen extending therefrom.

[007] Despite advances in the functionality of the venous catheter, the general structure of the product has not changed. The device is large, bulky, fixed in regards to number of lumens, and accessible to the patient. Currently, the junction hub terminates in the lumen, or multiple lumens. Those lumens hang from the junction hub and are closed off by a cap having at least one piece. These hang from the junction hub as the patient is discharged. Each cap, in one embodiment, measures approximately 1 cm in width and 4.0-4.5 cm in height. When a three-lumen port is prepared, the result is three tubes hanging from the outlet, each with its own cap hanging therefrom. These aspects cause inconvenience and discomfort for the patient, complicate management for the physician which result in unnecessary healthcare expenditures.

[008] Additionally, large and bulky nature of the traditional device has the added disadvantage of supplying a larger surface area. While this obviously complicates the ability to secure the device to the patient, it also increases the probability of contact with harmful bacteria and subsequent catheter associated infections.

[009] The large PICC line device also increases the risk of both intentional and accidental device movement. Decannulation is a common occurrence among patients with impaired cognition (either medically induced or otherwise). The bulky device provides a large target for such patients to remove their catheter entirely. Decannulation has its highest incidence in the morning and evening. This timing, unfortunately, provides a logistic conundrum, in that this coincides with the most difficult time to regain venous access. Thus, decannulation can result in prolonged hospital stay, wasted hospital resources, and cause unnecessary risk for the patient. It may also result in unnecessary and inconvenient short-term venous catheter placement before long-term venous access can be regained.

[010] While posing a particular problem for the impaired patient, the large surface area increases the risk of accidental movement of the catheter by the daily activities of the patient. The dangling lumens with their stops/end caps can impact the patient's activities of daily living (ADLs), at the very least, they are inconvenient. For instance, when bathing, the dangling lumens must be covered and secured, often necessitating a caregiver to assist. Lastly, the large dangling device is tedious for the outpatient to keep for long-term access and is inconvenient for working professionals or those patients attempting to work towards their rehabilitation goals.

[011] A common issue in the inpatient setting is the number of lumens needed for the patient. Patients are commonly discharged with single lumen catheters. The amount of access can change on a daily basis depending on the patient's clinical status. A patient who receives a single lumen PICC, which is commonly placed for hospital discharge, may medically decompensate during the hospital stay or outpatients may require admission into a hospital that may require an increased lumen need if they are not clinically stable. This scenario could result in repeated

unnecessary procedures, delay in care, and increases healthcare expenditures. Some have provided systems that allow for a hub with dual lumens (U.S. Patent No. 7,901,396), or systems allowing for the manipulation of components within the hub (U.S. Patent Application Publication No. 20130204206). Others have created hub systems that are detachable, such as in U.S. Patent Application Publication NO. 20080214991. None of these systems, however, allow for the locking of one or more lumens while allowing access to desired lumens for flushing and the like. Moreover, these systems do not provide a low-profile, compact design for outpatient use, and use with impaired patients.

[012] Accessibility to the venous catheter is a very common clinical conundrum. The recent increase in intravenous drug abuse (IVDA) among the general population has only highlighted and exacerbated the issue. Patients who abuse intravenous drugs through accessing their venous catheter are at an increased risk for complications such as catheter-associated infections and detrimental impacts on outcomes. This unnecessarily results in a large waste of healthcare dollars and places added stress on providers and patients as well as their caregivers. Few documents contemplate a locking mechanism on venous catheters. For instance, U.S. Patent Application Publication No. 20050055012 describes a multi-lumen stoppage device with a locking mechanism. That lock is a leur lock, and locks the lumen separately, does not aggregate the lumens together, or provide any low-profile system.

[013] A common and controversial topic includes the discharge of the patient with a history of IVDA with a placed venous catheter. Easy access to the bloodstream can prove irresistible, resulting in the patient removing the stop to a lumen and inputting non-prescribed/illicit drugs. Access to lumens by the patient carries a

significant risk of infection through the central line. Common infections include endocarditis, osteomyelitis, and discitis, treatment of which commonly requires weeks to months of antibiotics. Patients contracting these infections as a result of IVDA commonly are admitted throughout the entirety of their treatment because of their need for continued intravenous access for antibiotic therapy. This is a significant strain on healthcare resources as well as the patient and their loved ones.

[014] Inappropriate patient access of the PICC is not only an issue for patients with venous catheters in their home environment. IVDA is a common occurrence even in the hospitalized patient. Patients are commonly found to be accessing their own venous catheters while admitted into hospital to self-administer non-prescribed/illicit drugs inappropriately. This commonly results in patients being placed in monitored beds which utilizes scarce resources within the hospital and impairs overall performance of hospital staff thus impacting care for other patients.

[015] There is a need for the significant reduction in size of dangling lumen stops and lumens from the traditional multi-lumen venous catheter which is also tamper-proof and significantly inhibits detrimental bacterial colonization. The present apparatus meets such needs and provides further related advantages.

BRIEF SUMMARY OF THE INVENTION

[016] The present invention describes a low profile and low surface area device that caps a/the lumen(s) extending from a catheter (referred to here as an interchangeable lockable catheter, or "ILC"). The device is more convenient for the patient, provides a smaller target for patient for self-removal, and is less cumbersome for continuation of the patient's ADLs upon discharge. The cap of the

ILC gives providers the chance to modulate number of lumens based on the patient's clinical status and need. The low profile cap of the ILC decreases accessibility for inappropriate use, decreases rate of infections, decreases length of hospital stay with patients with a history of IVDA, and is less prone to accidental removal. The tamper resistant and tamper evident cap decreases the need for inpatient observation thus freeing resources within staff, decreasing monitored bed use, and improving overall care.

[017] The ILC of the present invention offers a significant financial benefit when used as it includes the catheter itself, the lumen exchange, and the tamper-resistant caps.

[018] In one embodiment, the interchangeable lockable catheter offers a user the ability to up or down regulate the number of lumens at any time based on the patient's current medical need. Changing accessibility to lumens is simple and efficient, being accomplished by a nurse at bedside in a matter of minutes.

[019] In another embodiment, the ILC has a two-piece design. In this embodiment, the ILC includes the catheter itself that is inserted into the vessel in a standard PICC line fashion with the junction hub sutured or secured onto the skin. The base of the ILC has four points of contact, or each side of the device, to ensure good contact and to form a proper seal with a cap.

[020] In yet another embodiment, the four points of contact from the interchangeable portion of the ILC rely on a hooking device and three levers on the base that lock with the cap to provide a tamper-resistant and tamper-evident cap.

[021] In most embodiments, the ILC has a locking, tamper-resistant, and tamper-evident cap.

[022] In one embodiment, interchangeable portion of the ILC houses male inserts based on the number of lumens required.

[023] In another embodiment, the ILC is a tamper resistant/evident cap having a push insert base comprising a pull-tab and breakaway twist cap attachment.

[024] In another embodiment, the ILC is manufactured using a medical grade plastic that is either antiseptic in nature or coated to be antiseptic.

[025] In these embodiments, the ILC is applied after the junction hub and allows for traditional dressing to be untouched (i.e., lumens extend beyond the junction hub before ILC placement).

[026] In an alternate embodiment, the ILC is applied and is in contact with the junction hub.

[027] In one embodiment, the ILC has a tubing carriage capable of attaching lumens to the ILC for access to lumens by a health professional.

[028] In another embodiment, the ILC comprises a female receiving piece for each lumen capable of accepting a male insert with raised knots to form a seal with the female piece and residing within the cap of the ILC.

[029] In another embodiment, the ILC has a plastic binder which secures the male inserts and provides a contact point for a screw cap. Wherein the ILC is substantially flat in nature, as in yet another embodiment, the male inserts are in the cap which has perforated clips for break away, one-time use.

[030] In some embodiments, the screw cap of the ILC has a sliding screw cap which forms a seal with the base. The sliding screw cap, in some embodiments, may allow for at least one lumen to egress from the cap while capping at least one other lumen and those capped lumens may have a capped end within the screw cap that allows for penetration for flushing purposes.

[031] In further embodiments, the base of the ILC has a threaded female accepting base having a plurality of openings adequate to accept at least one lumen and having at least one flange to further secure the screw cap of the ILC.

[032] In yet other embodiments, the ILC can be configured for use with one, two, three, four, or five lumens extending from the junction hub.

[033] These and other aspects of the present invention will become evident upon reference to the following detailed description and attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[034] FIG. 1 is an illustration of the ILC with a detachable tubing carriage, as in one embodiment.

[035] FIG. 2 is an illustration of the ILC with detachable tubing carriage, as in one embodiment.

[036] FIG. 3 is an illustration of the screw cap of the circular ILC, as in one embodiment.

[037] FIG. 4 is an illustration of the male inserts connecting to the extension lumen, as in one embodiment of the ILC.

[038] FIG. 5 is an illustration of the female receiving piece from the lumen, as in one embodiment of the ILC.

[039] FIG. 6 is a lateral view of the base of the ILC, as in one embodiment.

[040] FIG. 7 is a cut-away lateral view of the base of the ILC, as in one embodiment.

[041] FIG. 8 is a posterior view of the base of the ILC, as in one embodiment.

[042] FIG. 9 is a view of the flat embodiment of the ILC.

[043] FIG. 10 is a lateral view of the base portion of the ILC, as in one embodiment.

[044] FIG. 11 is a lateral view of the cap portion of the ILC, as in one embodiment.

[045] FIG. 12 is an alternate lateral view of the cap portion of the ILC, as in one embodiment.

[046] FIG. 13 is another view of the base portion of the ILC, as in one embodiment.

[047] FIG. 14 is an alternate lateral view of the cap of the ILC, as in one embodiment.

[048] FIG. 15 is a view of yet another lateral view of the cap of the ILC, as in one embodiment.

[049] FIG. 16 is a lateral view of the cap portion of the ILC, as in one embodiment.

[050] FIG. 17 is a view of yet another alternate embodiment of the ILC.

[051] FIG. 18 is a view of the cap of the ILC, as in one embodiment.

[052] FIG. 19 is a lateral view of the base of the ILC, as in one embodiment.

[053] FIG. 20 is a perspective view of an embodiment of an ILC with quick release function.

[054] FIG. 21 is a perspective view of the device of FIG. 20 apart.

[055] FIG. 22 is a cross section of the connector in FIG. 20.

[056] FIG. 23 is a perspective view of a safety plug inserted into a PICC base.

[057] FIG. 24 is a cutaway perspective view of the base and catheter.

[058] FIG. 25 is a cutaway perspective of the base.

DETAILED DESCRIPTION OF THE INVENTION

[059] Provided herein is a description of multiple configurations of an ILC capable of locking at least one lumen, providing antiseptic support, and, relative to a traditional PICC line, a small, singular extension from the catheter.

[060] Throughout this application, references are made to various embodiments relating to the apparatus and its method of use. The various embodiments described are meant to provide a variety of illustrative examples and should not be construed as descriptions of alternative species. Rather, it should be noted that the descriptions of various embodiments provided herein may be of overlapping scope. The embodiments discussed herein are merely illustrative and are not meant to limit the scope of the interchangeable lockable catheter.

[061] In the present description, any concentration range, percentage range, ratio range or other integer range is to be understood to include the value of any integer within the recited range and, when appropriate, fractions thereof (such as one tenth and one hundredth of an integer), unless otherwise indicated. As used herein, "about" or "comprising essentially of" means +/- 15%. The use of alternative (i.e., or) should be understood to mean one, both, or any combination thereof of the alternatives. As used herein, the use of an indefinite article, such as "a" or "an," should be understood to refer to the singular and the plural of a noun or noun phrase.

[062] The term "comprising" is not intended to limit inventions to only claiming the present invention with such comprising language. Any invention using the term comprising could be separated into one or more claims using "consisting" or

“consisting of” claim language and is so intended.

[063] Reference throughout this document to "one embodiment", "certain embodiments", and “an embodiment" or similar terms means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearances of such phrases or in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments without limitation.

[064] The term "or" as used herein is to be interpreted as an inclusive or meaning any one or any combination. Therefore, "A, B or C" means any of the following: "A; B; C; A and B; A and C; B and C; A, B and C". An exception to this definition will occur only when a combination of elements, functions, steps or acts are in some way inherently mutually exclusive.

[065] The drawings featured in the figures are for the purpose of illustrating certain convenient embodiments of the present invention, and are not to be considered as limitation thereto. Term “means” preceding a present participle of an operation indicates a desired function for which there is one or more embodiments, *i.e.*, one or more methods, devices, or apparatuses for achieving the desired function and that one skilled in the art could select from these or their equivalent in view of the disclosure herein and use of the term “means” is not intended to be limiting.

[066] As used herein the term “interchangeable lockable catheter (ILC)” refers to a PICC line catheter which can attach one or more different tubes by means of

interchangeable tubing cartridges having 1 to 190 or more tubes connecting to the single line catheter.

[067] As used herein the term "subject" refers to a patient, normally human, but in one embodiment, the subject is a mammal in need of a single venous catheter for peripheral insertion into a vessel of the subject.

[068] As used herein the term "a single venous catheter for peripheral insertion into a vessel" refers to having a proximal end for insertion into a vessel of the subject as a single venous catheter. The distal end is connected to a junction hub.

[069] As used herein the term "junction hub" refers to a connect device which attaches one or more lumens to the single venous catheter distal end. In one embodiment, it is a plurality of lumens. By attaching a tubing cartridge, one or more tubes can be connected to the single line by replacement of the tubing cartridge.

[070] As used herein the term "base" refers to a device which is removable or attached which is configured to receive the one or more lumens in the junction hub. The lumens will extend through the base to attach to one or more tubes for delivery of liquids to the single venous catheter. The base can be any shape, such as circular, rectangular, or, in one embodiment, essentially flat (rectangular looking).

[071] As used herein the term "tubing cartridge" refers to a device which attaches to the base for attaching the one or more tubing to the one or more lumens in the system thus allowing multiple sources to be fed to the single line catheter. The tubing cartridge can attach by any means but in one embodiment it attaches with a pin and spring mechanism as shown in the figures.

[072] As used herein the term "cap" refers to a device for attaching to the base to seal the base when a tubing cartridge is not attached. The cap can be screwed or snapped on or by any means. as desired. In one embodiment, it is constructed to be tamper resistant, as shown in the drawings, or otherwise. The cap can also be fitted with a penatratable layer such that tubing can be inserted through the penatratable layer.

[073] Throughout the description of the ILC, materials to manufacture the device are described as "medical grade plastics." Medical grade plastics include polymers with capability of sterilization, long-term durability, low leaching and extractability, and long shelf life and aging. Medical grade plastics include polymers either alone or in combination of, but not limited to: polyethylene, polypropylene, polystyrene, polyester, polycarbonate, polyvinyl chloride, polyethersulfone, polyacrylate, hydrogel, polysulfone, polyetheretherketone, thermoplastic isomers, thermoset elastomers, poly-p-xylylene, and fluoropolymers. Blends of polymers include, but are not limited to: polystyrene and polyphenylene oxide, polyethylene terephthalate and polybutylene terephthalate, and PMMA and polyvinylidene fluoride. Medical grade plastics include compositions including fillers, reinforcement and composites (such as glass), mineral powders, or carbon. Medical grade plastics include compositions described above and have been treated with biocidal or biofilm resistant materials as either coatings or as permeated within the polymer itself (i.e., halogens, plasmas, etc.).

DRAWINGS

[074] Now referring to the drawings, **FIG. 1** is a lateral view of the ILC with detachable tubing carriage. The catheter **100** is inserted into a patient's vessel. The most anterior end has openings **110, 111, 112**. These openings correspond to

lumens **103, 104, 105** which are connected to the catheter **100** at the junction hub **101**. Each opening **110, 111, 112** corresponds with its own lumen **103, 104, 105**. The junction hub **101 is** configured to connect the catheter **100** with a set of lumens, and as shown, three lumens **103, 104, 105** are shown. In other embodiments, fewer or more lumens may be provided (i.e., one, two, or up to ten lumens may be provided). The openings always correspond to the number of lumens provided in any configuration.

[075] The junction hub **101** provides connection between the catheter **100** and lumen(s) **103, 104, 105.** The junction hub 101 may also have at least one suture hook **102**. As shown**,** two suture hooks **102** may be provided. The suture hooks **102** provide an anchor to the patient by sutures to the patient's skin. As is well known to those in the art, the junction hub **101** may be sutured to the patient through the use of the suture hooks **102**. At the posterior end of the junction hub **101**, lumens **103, 104, 105** protrude therefrom, the lumens being received by a base **106**. The base **106** is configured to receive the lumens **103, 104, 105**. In some embodiments, the base **106** may receive between one and ten lumens. In this embodiment, as shown, three lumens **103, 104, 105** come from the junction hub **101** to the base **106**.

[076] The lumens **103, 104, 105** extend from the posterior end of the junction hub **101** through the base **106**. The base **106** is adapted to receive a screw cap **107**. The screw cap **107** terminates at its posterior end in a tubing carriage **108**. The tubing carriage **108,** shown in this embodiment, is used when desired but is not necessary in other embodiments. The tubing carriage **108** houses connections to the extension lumens **113, 114, 115**. The extension lumens connect to and correspond with their associate lumens **103, 104, 105**. The extension lumens **113, 114, 115** terminate at their posterior end in a lumen stop

109. Lumen stops **109** are well known in the art, and are a means of terminating a lumen with closure.

[077] FIG. 2 is an illustration of the ILC cap with detachable tubing carriage illustrating positioning of the extension lumens. The most anterior portion of this illustration shows the lumen junction **117** that connects the lumens (**103, 104, 105** in **FIG. 1**) with the lumen extensions **113, 114, 115**. The lumen junction **117** includes male inserts **116** that serve as a connection point by inserting into the posterior end of the lumens **103, 104, 105**. The anterior portion of the extension lumens **113, 114, 115** are fitted with the male inserts **116** and the lumen junction **117** and then secured within the screw cap **107** by a capped end with a penetrable layer **118**. The screw cap **107** is connected posteriorly to the tubing carriage **108**. In one embodiment, the diameter of the capped end with a penetrable layer **118** is of approximately 2.5 cm. In some embodiments, the capped end with a penetrable layer is constructed of a sterile medical grade plastic. The screw cap **107**, in one embodiment, is approximately 3 cm in diameter and is constructed of medical grade plastics, thermoset polymers, antibacterial coated, or permeated plastics and the like. In other embodiments, the tubing carriage **108** is approximately 5-6 cm in diameter and may be constructed of any number of durable impermeable plastics, such as medical grade plastics.

[078] FIG. 3 is a close up view of an embodiment of the screw cap **107** of the ILC. This illustration further depicts the male inserts **116** and the lumen junction **117** that connects the extension lumens **113, 114, 115** to the lumens (not shown in this illustration). The extension lumens are secured in placement by the capped end with penetrable layer **118** and fit within the screw cap **107**. Note, thought **FIG. 3** depicts a configuration using three extension lumens, it is

contemplated that between one and ten lumen extensions may be housed within the capped end with penetrable layer **118** and the screw cap **107**. The anterior end of the screw cap **107** also shows threading **139** that is adapted to receive and connect with the flanges and threading on the base **106** (see **FIG. 8**).

[079] **FIG. 4** depicts a male insert connecting to an extension lumen. The male insert **116** has at least one protrusion serving to anchor the male insert **116** within the female insert **119** (**FIG. 5**). The male insert **116** has a lumen junction **117** which is a raised portion adapted to meet with and be flushed with the female insert **119** (**FIG. 5**) when connected. The male insert **116** has a posterior end that fits within the extension lumen **113, 114, or 115**. In some embodiments, the interior diameter of the male insert **116** is approximately 5 mm. In those embodiments, the height of the flange from the male insert **116** is approximately 1 mm. The outer diameter of the lumen junction **117** is approximately 10 mm and the width of the lumen junction **117** is approximately 8 mm. The length of the male insert **116** is approximately 12 mm, wherein 5 mm extends within the female insert **119**, and 5 mm extends within the extension lumen **113, 114, 115**. In most embodiments, the male insert **116** and lumen junction **117** are constructed in one piece and are made of impermeable plastics such as medical grade plastics.

[080] **FIG. 5** shows the connection point between the lumens **103, 104, 105** and the extension lumens **113, 114, 115**. The female insert **119** extends from an anterior end that is anchored within the lumen to a posterior end that may be received by a male insert **116** (**FIG. 4**). The female insert **119**, in one embodiment, is approximately 5 mm in diameter at its anterior end and approximately 5 mm at its

posterior end. The female insert **119** may be constructed in one piece and made of impermeable plastics, such as medical grade plastics.

[081] **FIG. 6** is a lateral view of the base of the ILC, as in one circular embodiment. The junction hub **101** is shown with the lumens **103, 104, 105** extending from the posterior edge.. As has been stated, any number of lumens between one and ten may extend from the junction hub **101**. The lumens **103, 104, 105** extend to the base **106** which houses and secures the lumens **103, 104, 105**. In some embodiments, the base is circular in shape and is approximately 5 cm in diameter. The base **106**, as in other elements of the ILC, may be made of impermeable, medically advantageous plastics and synthetics, such as medical grade plastics (see above). The base **106** has a posterior end that has threading **120** adapted to receive the screw cap **107** (see **FIG. 2** and **FIG. 3**).

[082] **FIG. 7**, similar to **FIG. 6**, shows a lateral view of the base of the ILC, as in one circular embodiment, while showing a cut-away of the lumen **103** within the base **106**. Each lumen, no matter the number in any embodiment, terminates within the base **106**. The lumen **103**, as depicted in **FIG. 6**, terminates within the base **106** with the female insert **119** described in detail by **FIG. 5**. The threading **120** is also shown in this illustration, as described further in **FIG. 6.**

[083] **FIG. 8** is a posterior view of the base of the ILC, as in one circular embodiment. This posterior view shows the lumens **103, 104, 105** within the base **106** and fitted with the female insert **119**. A plurality of flanges **121** exist on the base **106**. Whereas **FIG. 8** depicts four flanges **121** on the outside of the base **106**, it is contemplated and well within the knowledge of someone of skill in the art to provide anywhere between three and twenty flanges to provide a secure fitting between the base **106** and the screw cap **107**.

[084] FIG. 9 is an alternate configuration of the ILC. This configuration is substantially flat in nature, thus providing further advantages to patients in terms of comfort and profile (being lower in profile). As in the first embodiment described in **FIGs. 1-8**, the catheter **100** is placed within the vessel of a patient. The openings **110, 111, 112,** as shown in **FIG. 1**, will be present in the most anterior end of the catheter **100** of the embodiment of **FIG. 9.** Those openings correspond to lumens **103, 104, 105** which are connected to the catheter **100** at the junction hub **101**. Each opening **110, 111, 112** corresponds with its own lumen **103, 104, 105**. The junction hub **101** is configured to connect the catheter **100** with a set of lumens, in **FIG. 1**, three lumens **103, 104, 105**. In other embodiments, fewer or more lumens may be provided (i.e., one, two, or up to ten lumens may be provided). The openings always correspond to the number of lumens provided in any configuration.

[085] Still in **FIG. 9,** the junction hub **101** provides connection between the catheter **100** and lumen(s) **103, 104, 105.** The junction hub **101** may also have at least one suture hook **102**. As shown in **FIG. 1,** two suture hooks **102** may be provided. The suture hooks **102** provide an anchor to the patient. As is well known to those in the art, the junction hub **101** may be sutured to the patient through the use of the suture hooks **102**. At the posterior end of the junction hub **101**, lumens **103, 104, 105** protrude therefrom, the lumens being received by a base **127**. The base **127** is configured to receive the lumens **103, 104, 105**. In some embodiments, the base **127** may receive between one and ten lumens. In this embodiment, **FIG. 1** shows three lumens **103, 104, 105** come from the junction hub **101** to the base **127.** Unseen in this illustration is a lower flange **128** (see **FIG. 13**) that will connect with the lower hook like extension in the base (not shown but mirroring **131** in **FIG. 11**).

[086] The base **127** is configured to receive a cap **130**. The cap **130**, in this embodiment, is tamper evident and tamper resistant. The cap **130** has multiple points of contact, including an upper hook like extension (and lower) **131** and multiple perforated clips **134** for break-away use. A lower hook like extension **131** is not shown but mirrors the upper hook like extension both in shape and position. In this embodiment, the posterior position of the cap **130** is impermeable and does not house extension lumens, as in the previous embodiment. However, the presence of a similar tubing carriage is contemplated and may be used in this embodiment with adjustments to the cap, including an opening to receive the tubing carriage.

[087] **FIG. 10** illustrates a close up lateral view of the flat base **127**, as in one embodiment of the ILC. The anterior end of the base **127** receives the lumens **103, 104, 105**. In some embodiments, the base **127** may receive between one and ten lumens. The base **127** is equipped with a plurality of flanges **128, 129**. The lateral flanges **129** will connect with the cap **130** and anchor the ILC such that it is tamper resistant and tamper evident. There is also an upper flange **128** further anchoring the cap **130** to the base **127** in this embodiment of the ILC. In some embodiments, the base **127** is approximately 5 cm wide (lateral), 2 cm in length (anterior/posterior), and 10 mm thick. The lateral flanges **129** protrude 2 mm from the base **127** at their highest point and are generally shaped as an inclined rhombus with the posterior portion flushed with the base **127.** The lateral flanges 129 protrude outward to a highest point located most anterior to the base **127**. The upper and lower flange **128** may be trapezoidal in shape and similarly are flushed with the base **127** at its posterior end and extend outward from the base **127** to a measurement of approximately 2 mm at its anterior end. Unseen in this illustration is a lower flange **128** (see **FIG. 13**) that will connect with the lower hook like extension in the base

(not shown but mirroring **131** in **FIG. 11**). As is well known in the art, other shapes that allow for the secure application of the cap are contemplated for use in the ILC.

[088] **FIG. 11** depicts a lateral view of the cap **130** of the ILC in a flat embodiment. The cap **130** has two lateral (side) extensions terminating in a hook like extensions **132** and capable of connecting and latching to the flanges **128** and **129** of the base **127** (see **FIG. 10**). The cap **130** also has an upper hook like extension **131** capable of receiving and locking to the upper flange **128** on the base **127**, as well as a lower hook like extension not depicted but mirroring the upper hook like extension **131**. Male inserts **133** protrude from the middle portion of the cap **130** and fit within the lumens **103, 104, 105** housed within the base **127**. A plurality of male inserts **133** may be used and should be of the same number as the number of lumens present (as stated, anywhere between one and ten). The cap **130** also has two notches **135** that may serve as insertion points for a clamp removal device (not shown). On the same plane as the two lateral hook-like extensions **132** and upper and lower hook-like extensions **131** are perforated edges **134**. These perforated edges **134** allow for the cap **130** to be excised from the base **127** through a break-away of the perforated edges **132**. In this embodiment, the lateral perforated edges extend from the hook-like extension **132** posterior to the edge of the cap **130** near the notches **135**. The medial and upper and lower hook like extensions **131** have perforated edges posterior about three quarters of the length of the entire cap **130** (as measured from the lateral hook like extensions **132** to the most posterior edge of the cap).

[089] In some embodiments, the length of the cap **130** from the most anterior edge of the lateral hook-like extension **132** to the posterior edge is approximately 1 cm. The approximate distance between the anterior edge of the lateral hook-like

extension **132** to the medial edge where the male inserts **133** are housed is 4 mm. The male inserts **133** protrude approximately 1 mm from the medial edge. While the shape of the medial and upper hook and lower like extensions **131** are shown terminating in a point, it is well known to those skilled in the art that the shape may be anything adapted to receive and connect with the upper flange **128** on the base **127** (i.e. circular, rectangular, trapezoidal, rhomboid and the like). A third center lumen cap **138** is provided.

[090] FIG. 12 is an alternate lateral view of the cap portion, as in another embodiment of the ILC. In this embodiment, the lateral hook-like extensions **132** protrude from the cap **130** and two male inserts **140** are shown. In this embodiment, two lumens would be present in the base for fitting with the cap **130**. The male inserts **140** are shown with two lateral protrusions **141** which serve to further anchor the inserts **140** into the lumens. This configuration is illustrated in **FIG. 4**, and may be employed in any male insert in any of the embodiments. Also note, in this embodiment, no medial and upper hook like extension **131** (see **FIG. 11**) is present. An edge **138** provides further contact and structural support to the cap **130** in this embodiment. Dimensions of this embodiment are similar to that depicted in **FIG. 11**. For example, the length of the cap **130** from the most anterior edge of the lateral hook-like extension **132** to the posterior edge is approximately 1 cm. Moreover, the approximate distance between the anterior edge of the lateral hook-like extension **132** to the medial edge where the male inserts **133** are housed is 5 mm. Similarly, the male inserts **133** protrude approximately 5 mm from the medial edge.

[091] FIG. 13 is a posterior view of the base portion of the ILC in a flat embodiment. In this view, positioning of the lumens **103, 104, 105** is shown within the base **127**. The lateral flanges **129** and upper and lower flanges **128** are shown protruding from

the base **127** reaching their highest point near the anterior edge of the base **127**. As shown in this embodiment, the flange **128, 129** shape is rectangular in nature, and may have either sharp or curved edges. As described, the flanges **128,129** may be rhomboid in shape and serve to secure the cap **130** to the base **127**.

[092] FIG. 14 is a lateral view of the cap of yet another embodiment of the ILC. In this embodiment, the cap **125** has a break away twist cap attachment allowing for a twisting motion to loosen the cap **125**. A pull tab **123** allows for access to pull away from the push insert base **122** that would house the lumens **103, 104, 105.** The cap **125** would house male inserts for the capping of the lumens in this configuration. In this embodiment, the cap **125** is substantially circular in shape, wherein the diameter of the cap is approximately 5 cm and the length is approximately 3 cm. The cap **125** is constructed of medical-grade plastics or synthetics that harbor microbially resistant elements. The insert base **122** is approximately 1 cm wide and 5 cm in length and being constructed of the same materials as the cap **125**.

[093] FIG. 15 is yet another embodiment of the cap of the ILC as viewed laterally. In this embodiment, the cap **125** has a removable portion **124** at its anterior end which may be accessed by pulling a protruding tab **123** that will then be stripped from the main body of the cap **125** through two perimeters of the cap **125**. The cap **125** is adaptable to receive a push insert base **122** (see **FIG. 14**) that houses the lumen(s). Not shown are the male inserts within the cap **125** for filling and capping the lumen(s) in this embodiment. In this embodiment, the cap **125** is substantially circular in shape, wherein diameter of the cap is approximately 5 cm. The cap **125** is constructed of medical grade plastics or synthetics that harbor microbially resistant elements. The tab **123** and removable portion **124** are approximately 10 mm in length.

[094] **FIG. 16** shows the embodiment as in **FIG. 15**, wherein the tab **123** has been pulled and a portion of the anterior end of the cap **125** has been removed, thus revealing the male inserts **126** contained therein. While this illustration depicts the inserts **126** in a conical and sloped type shape which can be used in any of the embodiments described herein, the inserts **126** may be adjacent and lateral to one another. Whatever configuration is chosen for the male inserts **126,** the cap **125** will be mirrored by the corresponding push insert base **122**.

[095] **FIG. 17** is an alternate embodiment of the ILC. In this embodiment, the catheter **100** is within the vessel of the patient and the dashed line represents the insertion point into the skin. The junction hub **101** is shown with two lateral suture hooks **102**. The lumens are not visible and would be positioned by a push insert base (see **FIG. 14**) to be received by the cap **125** (having male inserts **126** to cap off the lumens). This embodiment shows the pull tab **123** removal system, where the tab may be pulled to expose the anterior end of the cap for removal by a medical caregiver.

[096] **FIG. 18** is a cap of a circular embodiment of the ILC. The cap **107** is circular and constructed of medical grade plastics. The interior of the cap has a recessed portion **139** capable of receiving threading located on the base (see **FIG. 19**). In one preferred embodiment, the diameter is approximately 5 cm. As will be understood by those skilled in the art, this embodiment will receive a base **106** (see **FIG. 19**) housing three lumens. As different numbers of lumens are used, the diameter may change (i.e., where ten lumens are contemplated the diameter will necessarily larger, by proportion).

[097] As shown in **FIG. 19**, the base **106** houses the lumens **103, 104, and 105**, and has threading **120** on the exterior and posterior end of the base **106**. A ridge is

shown delineating the threaded portion of the base **106** in this embodiment of the ILC. As has been stated, the number of lumens housed within the base **106** will vary in many embodiments and contain between one and ten lumens. The base **106** is constructed of medical grade plastics and is of similar diameter to the cap **107** thus creating a seamless piece when the base **106** is connected to the cap **107**.

[098] As shown in **FIG. 20,** the base **106** is a two-piece **201** and **202** connection that is spring operated by pressing button **203**. In other embodiments, fewer or more lumens may be provided as taught herein (i.e. one, two, or up to ten lumens or more may be provided). Lumen openings correspond, as in other embodiments shown herein.

[099] **FIG. 21** is a perspective view of the two piece base separated showing locking pin **210** which inserts into hole **210a** and locks, as shown in **FIG. 22**. Lumen connections **212** fit into holes **211** for making a connection with extension lumens **113**, **114**, **115**.

[0100] **FIG. 22** is an x-ray view of the base in **FIG. 20** in the locked position. In this view, one can see that spring **220** operates locking pin **221** which holds the locking pin **210** in place via hole **210a** thus locking the two-piece pins **201** and **202** connection together unless button **203** is pressed compressing spring **220** and releasing locking pin **221** so that the base can be separated into two pieces.

[0101] **FIG. 23** is a perspective view of a safety plug **231** inserted into a PICC base **230** holding catheter tube **232**.

[0102] **FIG. 24** is a cutaway perspective view of a base **240** and catheter **241**. In this view, an adjustable valve **242** is shown having three valve positions. It is held in

place via stainless steel retainer **243**. The valves allow for opening and closing each valve.

[0103] **FIG. 25** is a cutaway perspective view of the base. In this view, base **250** has adjustable valve **252** to open and close anything coming from each of tubes **253**. A metal tube **254** connects tubing **253** to the adjustable valve **252.**

[0104] While the compositions and methods of this disclosure have been described in terms of particular embodiments, it will be apparent to those of skill in the art that variations may be applied to the structures and/or methods and in the steps or in the sequence of steps of the method described herein without departing from the concept, spirit, and scope of the disclosure. All such similar substitutes and modifications apparent to those skilled in the art are deemed to be within the spirit, scope, and concept of the disclosure as defined by the appended claims. It will be understood that particular embodiments described herein are shown by way of illustration and not as limitations of the disclosure.

[0105] The principal features of this disclosure can be employed in various embodiments without departing from the scope of the disclosure. Those skilled in the art will recognize, or be able to ascertain using no more than routine study, numerous equivalents to the specific structures described herein. Such equivalents are considered to be within the scope of this disclosure and are covered by the claims. All publications and patent applications mentioned in the specification are indicative of the level of skill of those skilled in the art to which this disclosure pertains. All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

What I Claim is:

1. An interchangeable lockable catheter (ILC) for use with a subject comprising:
    a) a single central catheter for peripheral insertion having a proximal end for insertion into a vessel of the subject and a distal end in communication with a junction hub;
    b) a junction hub configured to connect one or more lumens to the distal end of the central catheter;
    c) a base configured to receive the one or more lumens in the junction hub wherein the lumens extend through the base; and
    d) a tubing cartridge which attaches one or more tubes to the lumen in the base.
2. The ILC according to claim 1 wherein the base is adapted to receive a cap.
3. The ILC according to claim 1 wherein the cap is designed to be tamper resistant.
4. The ILC according to claim 2 wherein the cap is fitted with a penetrable layer.
5. The ILC according to claim 2 wherein the tubing cartridge is attached to the cap.
6. The ILC according to claim 1 wherein a plurality of tubes are attached to the lumen in the base.
7. The ILC according to claim 1 wherein there are one or more suture securing device.
8. The ILC according to claim 1 wherein the base is circular.
9. The ILC according to claim 1 wherein the base is substantially flat in nature.

10. The ILC according to claim 1 wherein the base removably attaches to the tubing cartage via a spring loaded pin attachment.

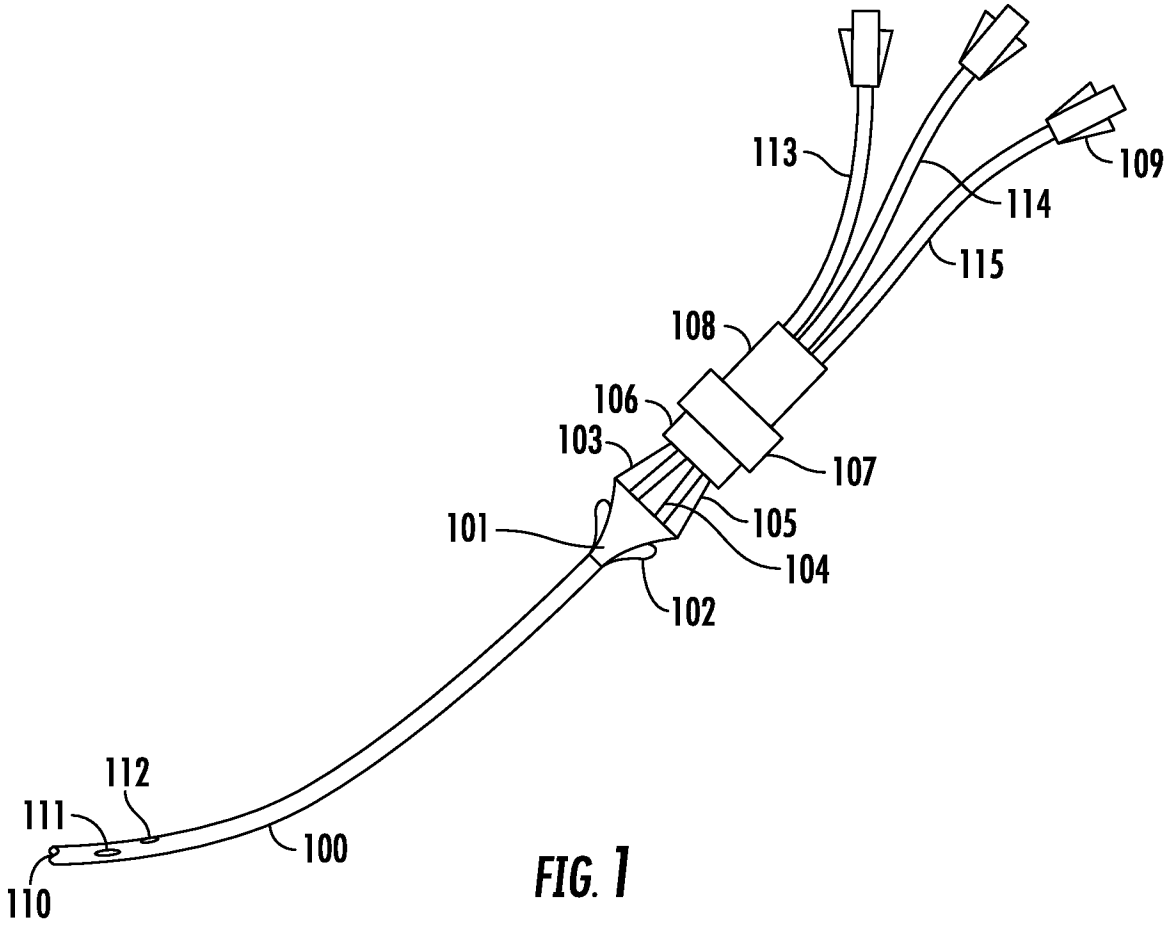

113
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101
105
104
102
112
111
100
110

FIG. 1

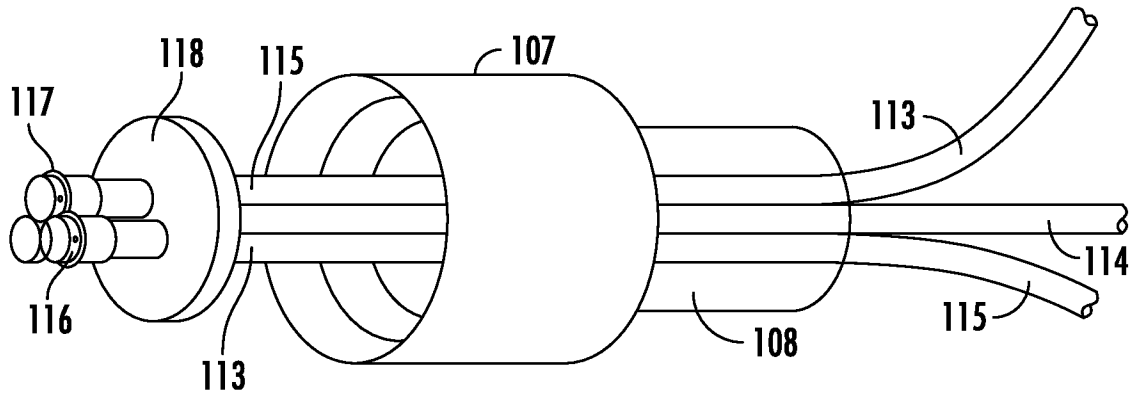

118
115
107
117
113
114
116
115
113
108

FIG. 2

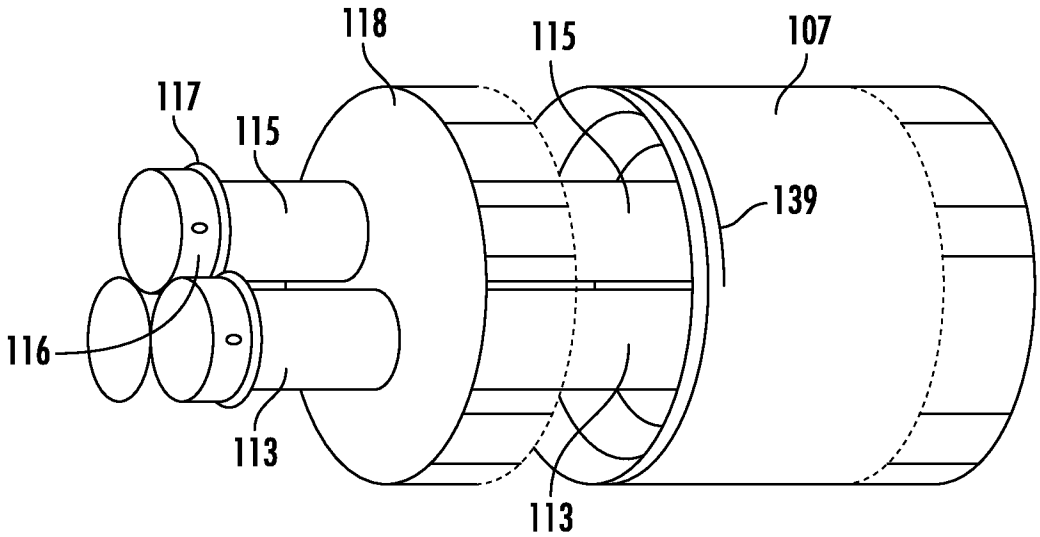


FIG. 3

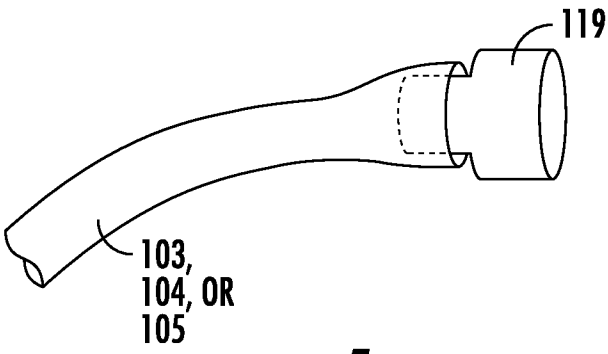


FIG. 5

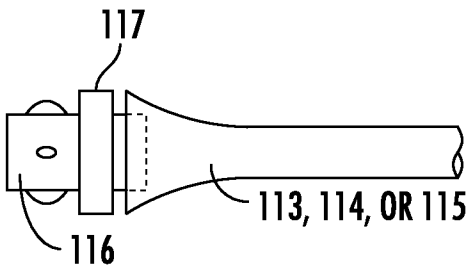


FIG. 4

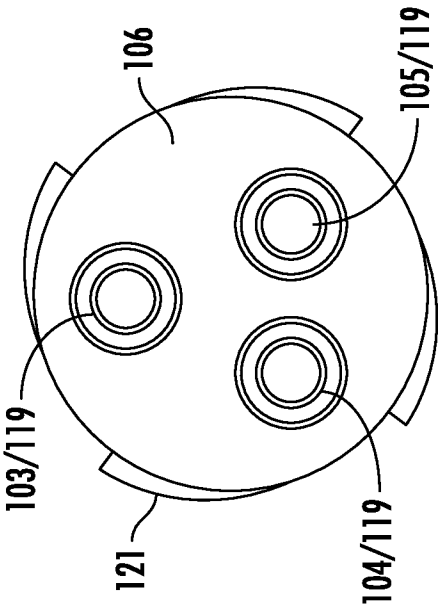


FIG. 8

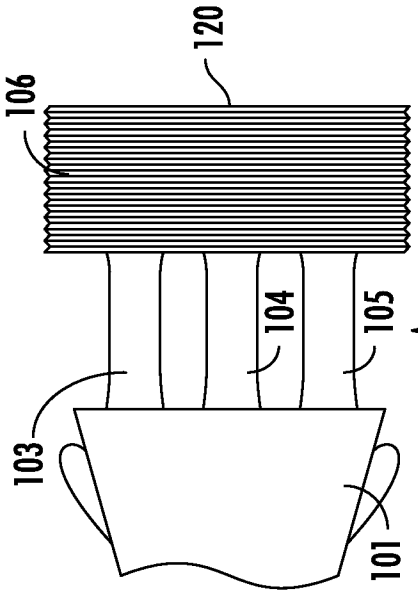


FIG. 6

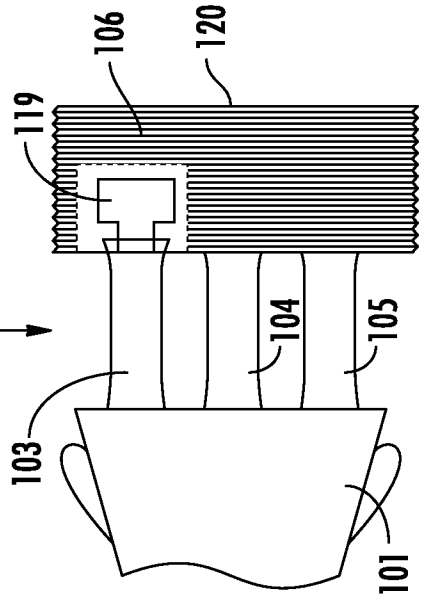


FIG. 7

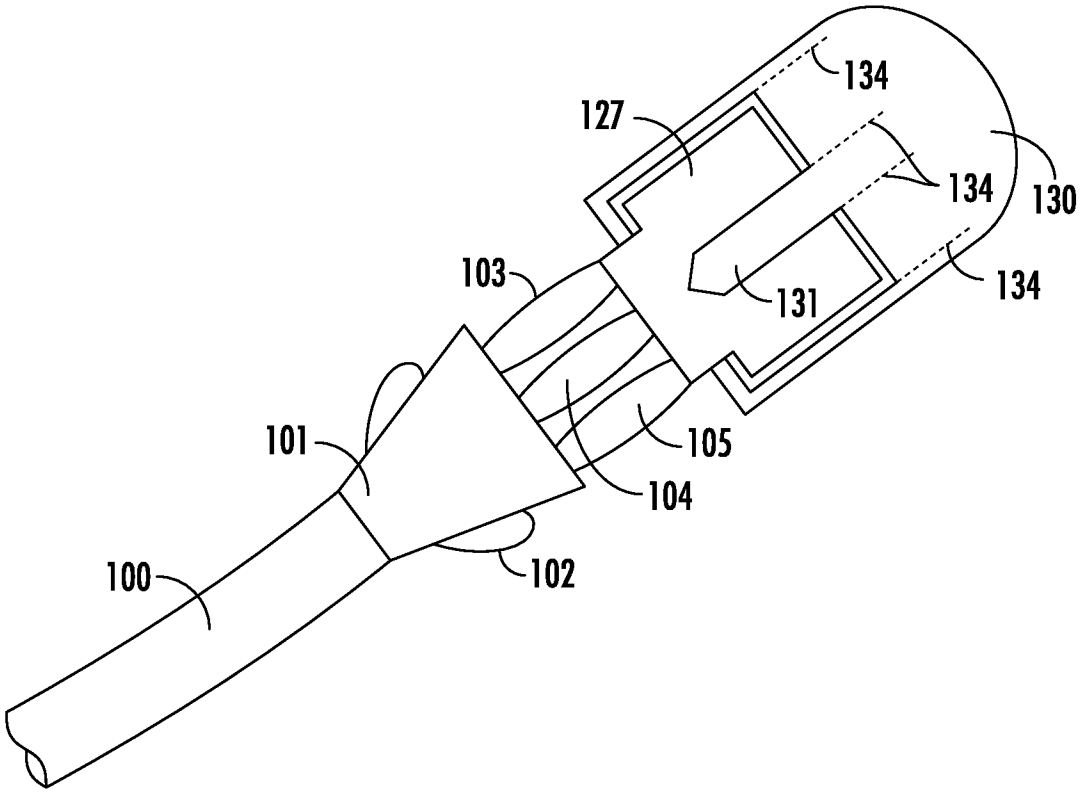


FIG. 9

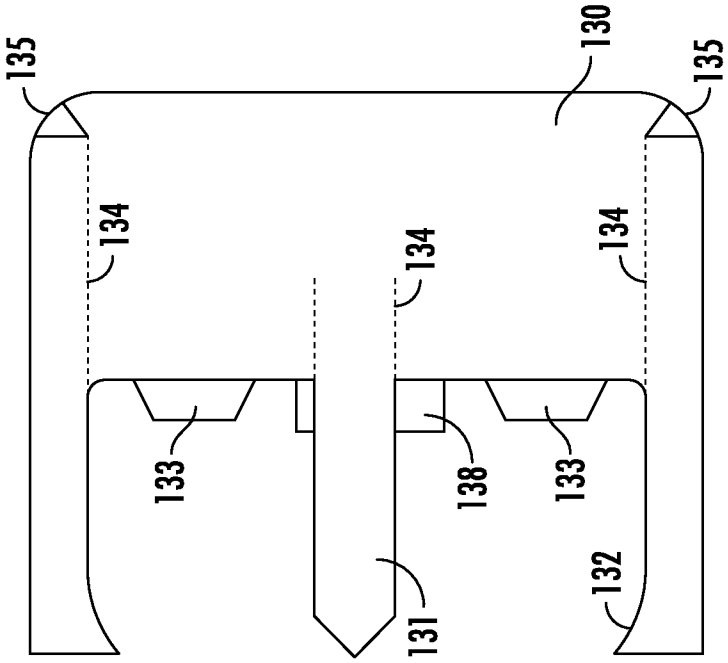

135
130
135
134
134
134
133
138
133
132
131

FIG. 11

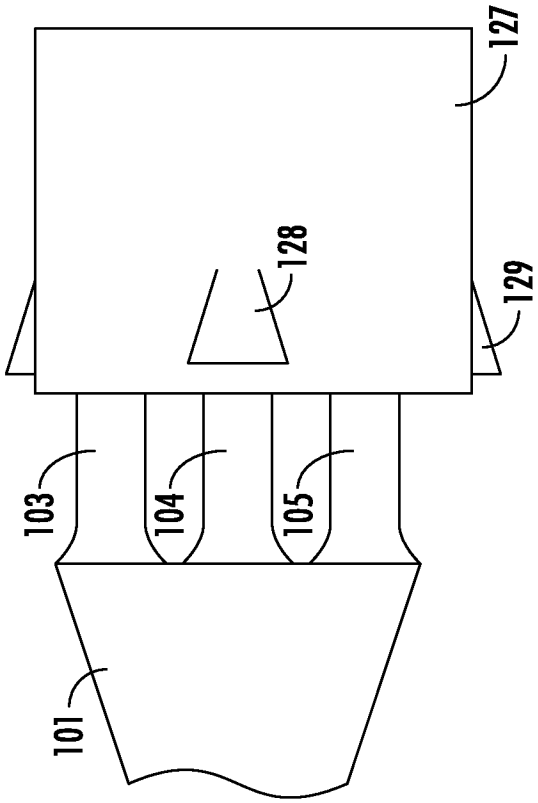

127
128
129
103
104
105
101

FIG. 10

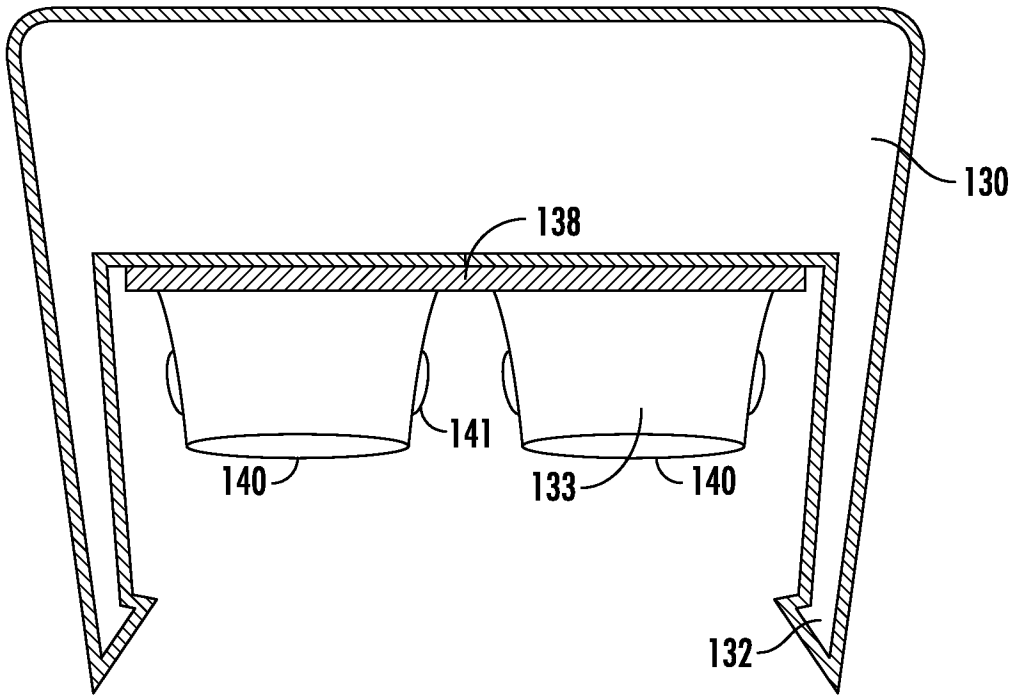


FIG. 12

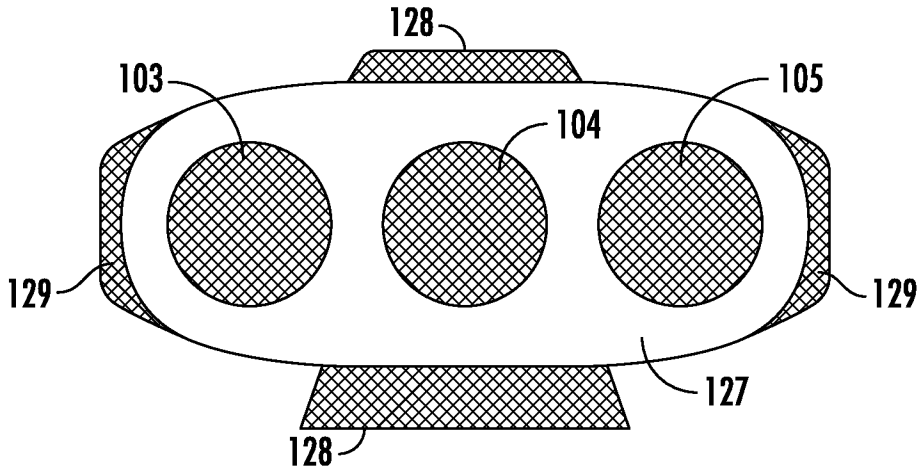


FIG. 13

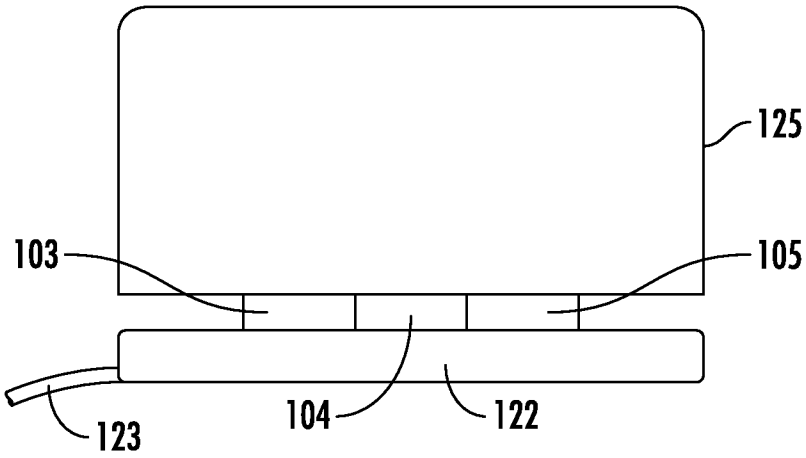


FIG. 14

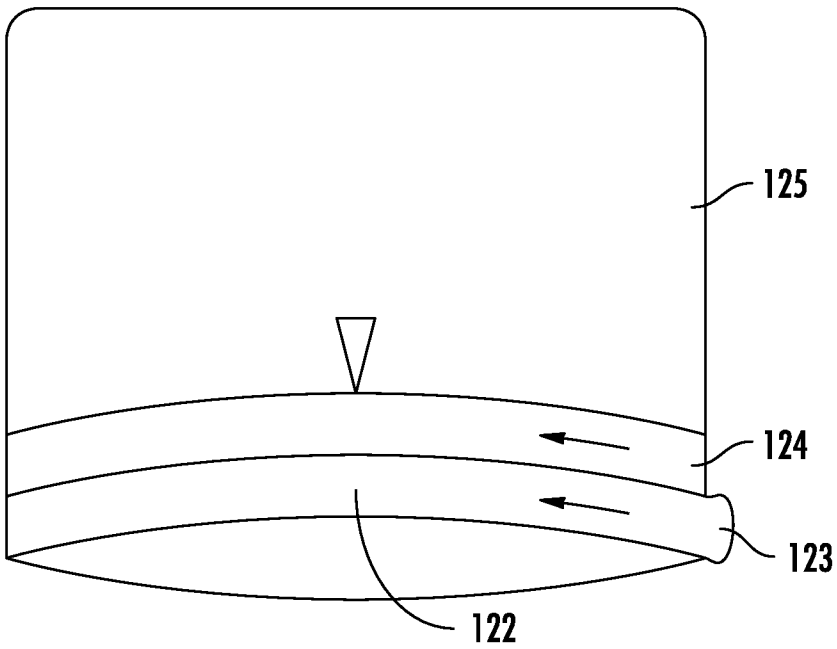


FIG. 15

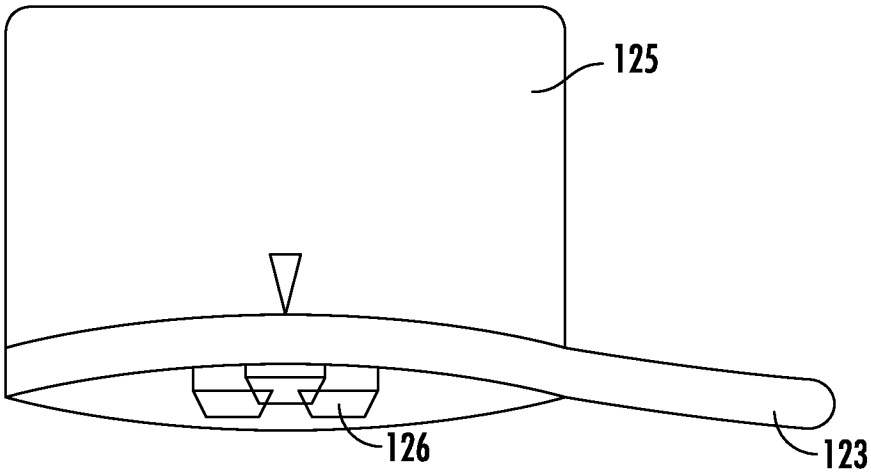


FIG. 16

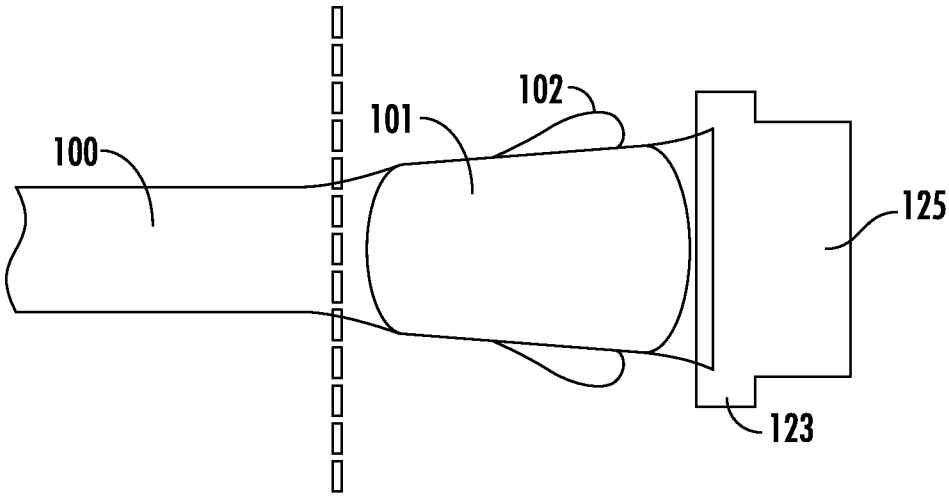


FIG. 17

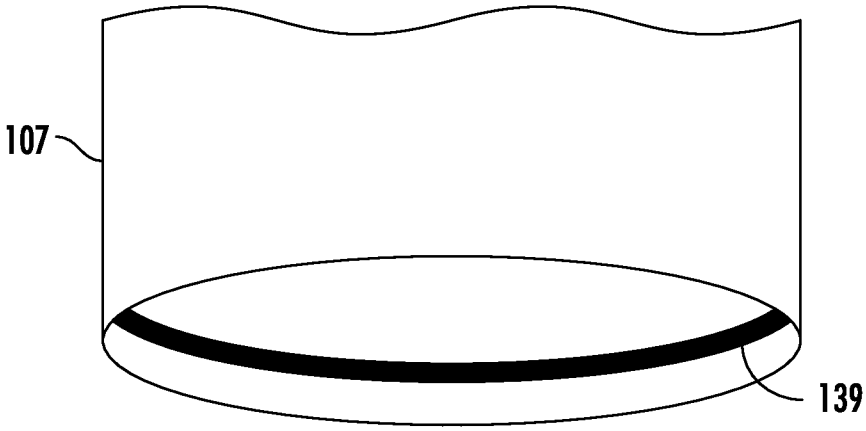


FIG. 18

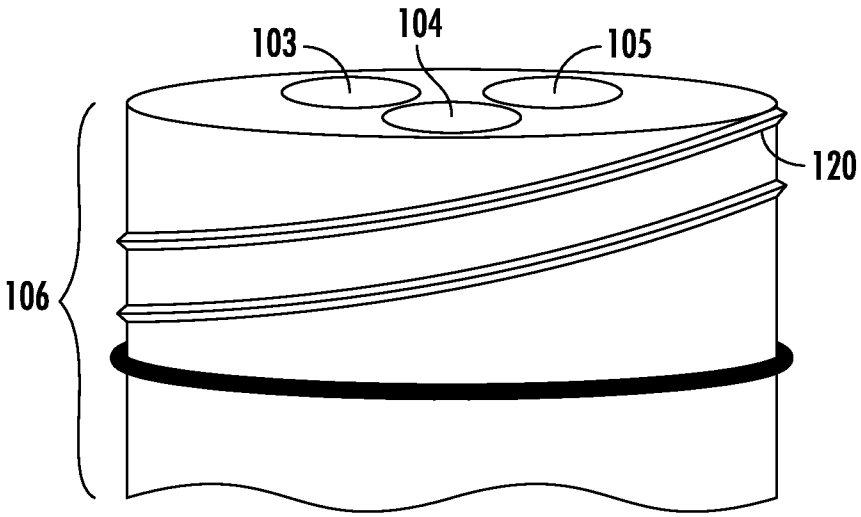


FIG. 19

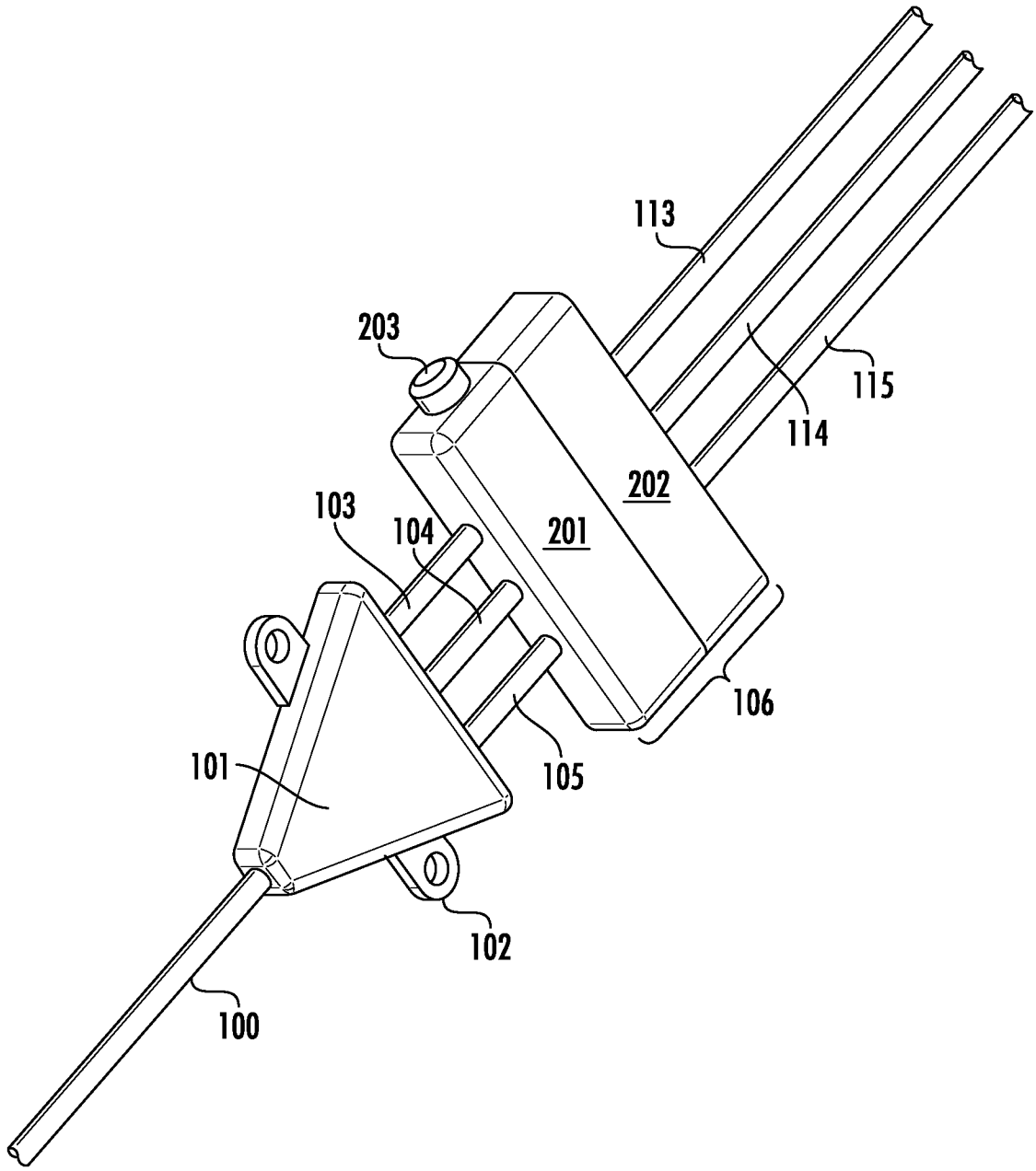


FIG. 20

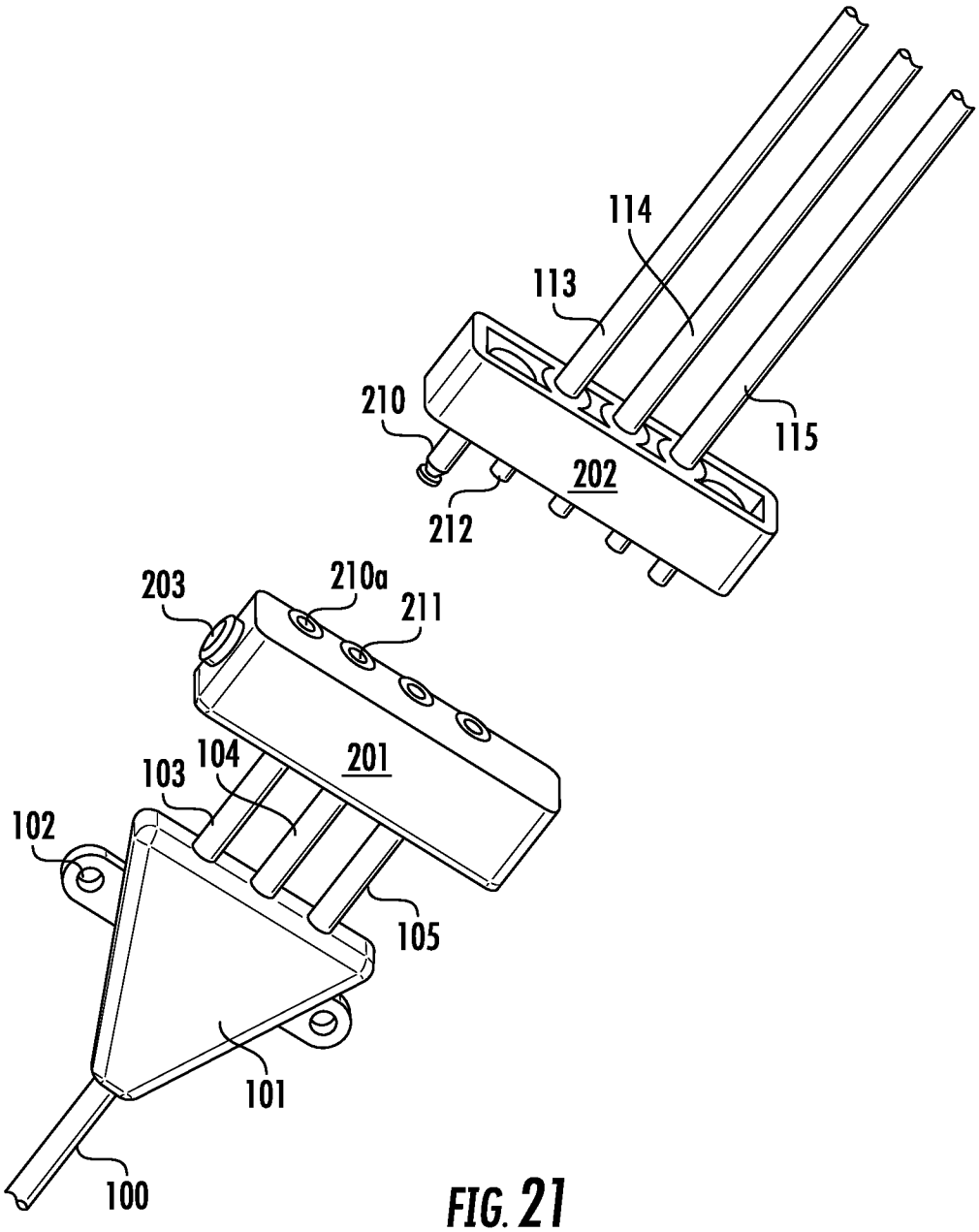


FIG. 21

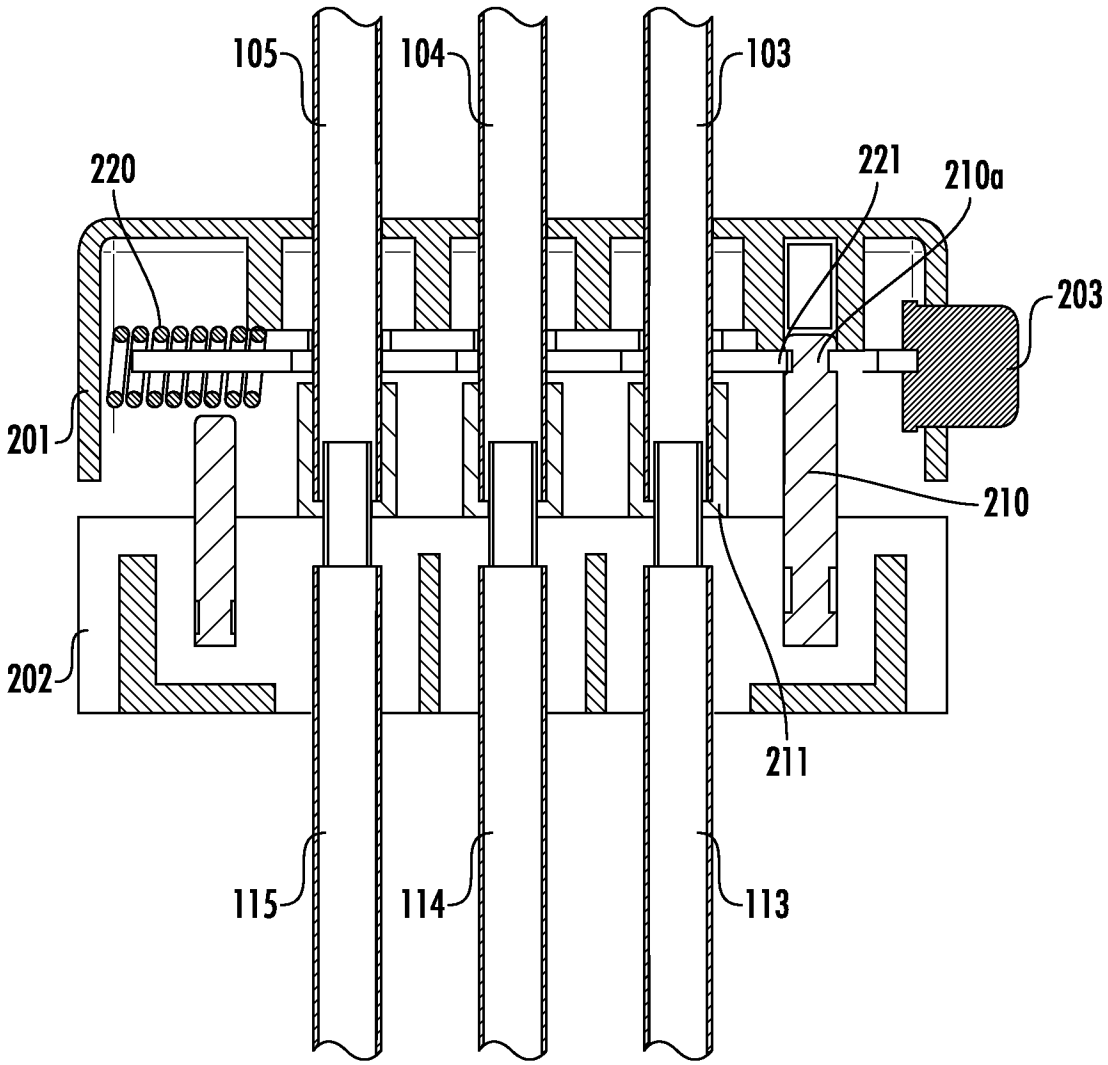


FIG. 22

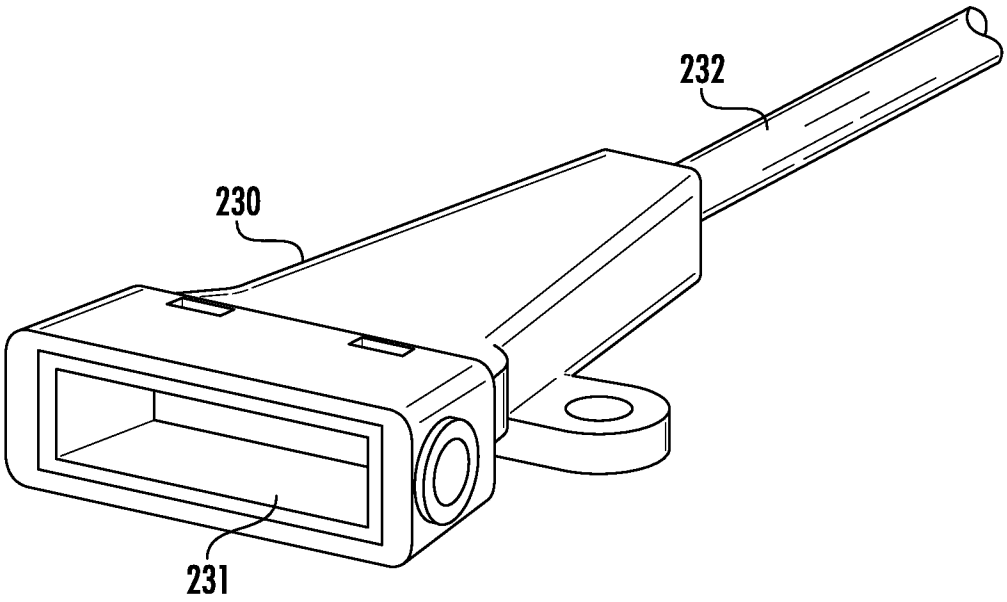


FIG. 23

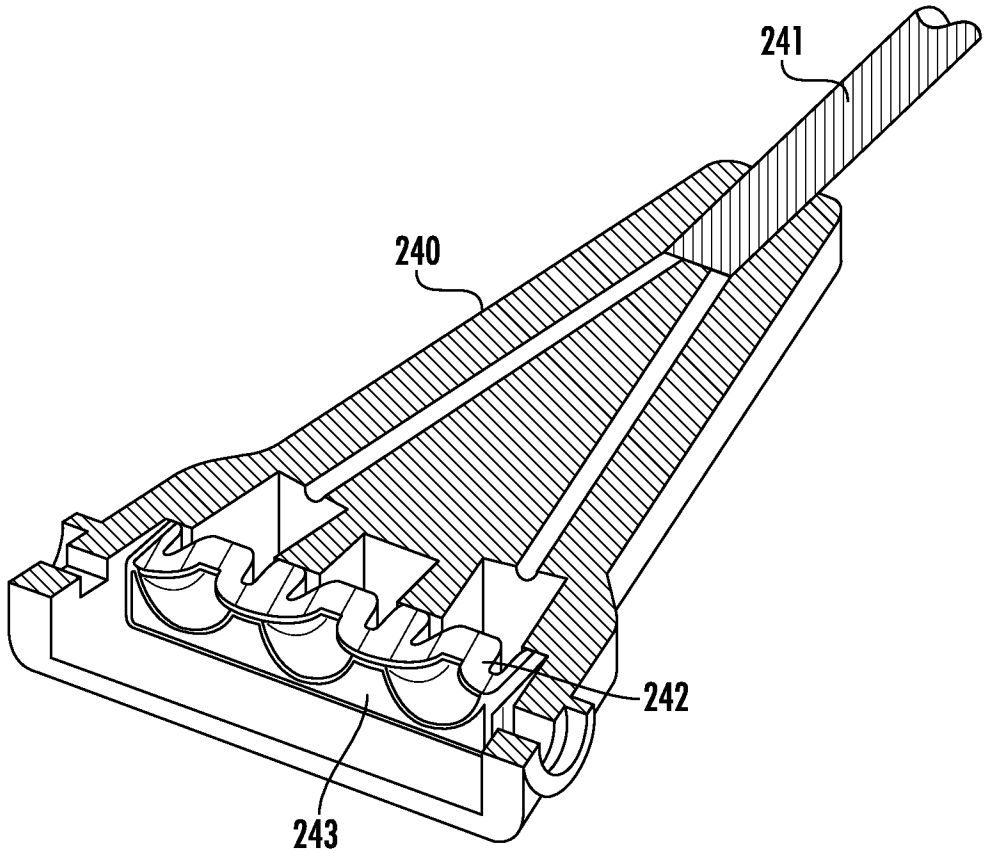


FIG. 24

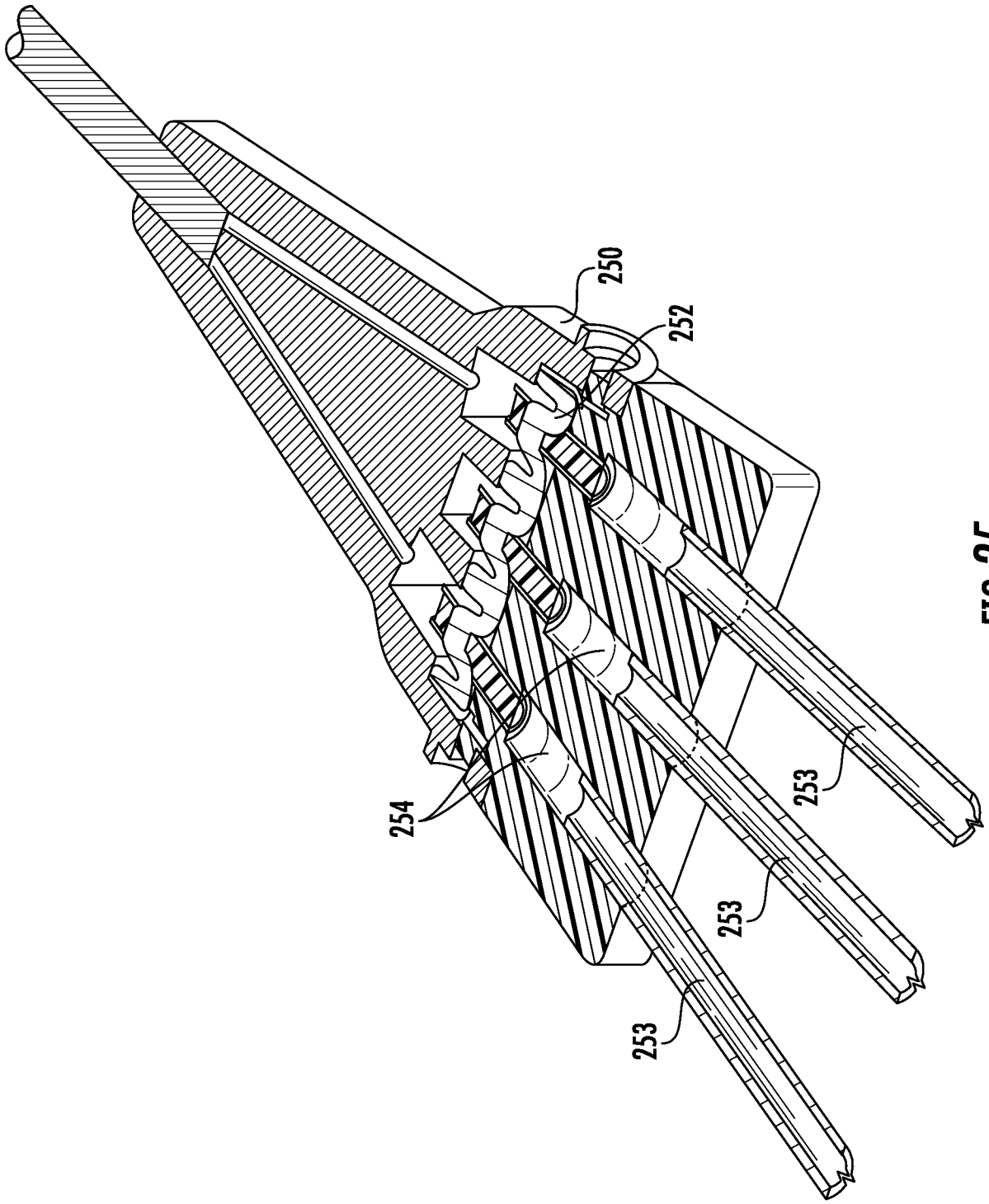


FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/032236

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/00; A61M 25/01; A61M 25/06; A61M 39/00; A61M 39/02; A61M 39/10 (2017.01)

CPC - A61M 25/0097; A61M 39/1011; A61M 39/105; A61M 2025/0286; A61M 2039/1072; A61M 2039/1077 (2017.05)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 600/247; 604/43; 604/246; 604/256; 604/264; 604/523; 604/533 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/123689 A1 (THE JOHNS HOPKINS UNIVERSITY) 20 August 2015 (20.08.2015) entire document	1-10
A	US 2005/0256461 A1 (DIFIORE et al) 17 November 2005 (17.11.2005) entire document	1-10
A	US 2003/0088213 A1 (SCHWEIKERT et al) 08 May 2003 (08.05.2003) entire document	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 July 2017	03 AUG 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774