IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH CENTRAL DIVISION

| GUIDE FLOW LLC | § | |
|-----------------------------------|---|---------------------|
| | § | |
| Plaintiff, | § | |
| | § | |
| v. | § | CIVIL ACTION NO |
| | § | |
| ANGIODYNAMICS, INC., BARD ACCESS | § | JURY TRIAL DEMANDED |
| SYSTEMS, INC., BECTON, DICKINSON | § | |
| AND COMPANY, MEDICAL | § | |
| COMPONENTS, INC., NAVILYST | § | |
| MEDICAL, INC., AND SMITHS MEDICAL | § | |
| ASD, INC., | § | |
| | § | |
| Defendants. | | |

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff Guide Flow LLC files this Original Complaint against the above-named Defendants, alleging as follows:

I. THE PARTIES

- 1. Plaintiff Guide Flow LLC ("Guide Flow") is a Delaware limited liability company with its principle place of business in Newport Beach, California.
- 2. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business in Queensbury, New York. This Defendant may be served with process through its registered agent, Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.
- 3. Defendant Bard Access Systems, Inc. ("Bard") is a Utah corporation with its principal place of business in Salt Lake City, Utah. This Defendant may be served with process

through its registered agent, C T Corporation System, 136 East South Temple, Suite 2100, Salt Lake City, Utah 84111.

- 4. Defendant Becton, Dickinson and Company ("BD") is a New Jersey corporation with its principal place of business in Franklin Lakes, New Jersey. This Defendant may be served with process through its registered agent, C T Corporation System, 111 8th Avenue, New York, New York 10011.
- 5. Defendant Medical Components, Inc. ("MedComp") is a Pennsylvania corporation with its principal place of business in Harleysville, Pennsylvania. This Defendant may be served with process through its President, Timothy M. Schweikert, 1499 Delp Drive, Harleysville, Pennsylvania 19438.
- 6. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business in Marlborough, Massachusetts. This Defendant may be served with process through its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.
- 7. Defendant Smiths Medical ASD, Inc. ("Smiths Medical") is a Delaware corporation with its principal place of business in Brooklyn Park, Minnesota. This Defendant may be served with process through its registered agent, Registered Agent Solutions, Inc., 32 W. Loockerman Street, Suite 201, Dover, Delaware 19904.

II. JURISDICTION AND VENUE

8. This is an action for infringement of a United States Patent arising under 35 U.S.C. §§ 271, 281, and 284-285, among others. This Court has subject matter jurisdiction of this action under 28 U.S.C. §1331 and §1338(a).

- 9. This Court has general and specific personal jurisdiction over each Defendant, and venue is proper, pursuant to 28 U.S.C. §§ 1391 and 1400(b).
- 10. Each Defendant is subject to the Court's general and specific jurisdiction consistent with the principles of due process and/or the Utah Long Arm Statute. Upon information and belief, each Defendant has substantial contacts with this forum as a result of substantial business activities conducted within the State of Utah and within this District: (a) Each Defendant regularly solicits business in Utah and derives substantial revenue from products, systems and/or services sold or provided to individuals and entities residing in Utah and, particularly, this District; (b) Further, each Defendant has committed and continues to commit acts of patent infringement in Utah and within this District through its making, using, selling and/or offering to sell products, systems and/or services that infringe or contribute to the infringement of the claims of the patent-in-suit; (c) At least Defendant Bard maintains a physical presence within this District, including commercial premises, where it manufactures products that are used to commit patent infringement and/or from which it conducts extensive business with customers residing in this District and beyond concerning products, systems and/or services that are the subject of this Complaint.

III. BACKGROUND

- 11. On October 25, 1994, United States Patent No. 5,357,961 ("the '961 patent") was duly and legally issued for a "Catheter Guidewire and Flushing Apparatus and Method of Insertion." A true and correct copy of the '961 patent is attached hereto as Exhibit "A."
- 12. Plaintiff Guide Flow is the assignee of the '961 patent and owns all right, title, and interest in and to the '961 patent, including the right to prosecute this action and recover past, present and future damages for the infringements alleged herein.

13. The inventions of the '961 patent are generally directed to, among other things, particular methods for inserting catheters within a patient.

IV. PATENT INFRINGEMENT

- 14. Defendants import, make, use, sell and/or offer for sale Peripherally Inserted Central Catheter ("PICC") products in the United States. These products are sold in kits that contain detailed explanations, instructions, and information regarding how to insert Defendants' respective PICC products into a patient. These publications and instructions are often referred to as Instructions for Use ("IFUs"). Defendants' IFUs are directed toward and written for Defendants' customers, which include doctors, nurses, and other medical personnel. In addition to being included in the PICC kit, Defendants make their IFUs available over the publicly-shared Internet.
- 15. Upon information and belief, Defendants directly infringe (now and in the past) at least claim 7 of the '961 patent by testing (i.e., using), in the United States, the methods disclosed in Defendants' respective IFUs for inserting PICCs into patients.
- 16. Upon information and belief, Defendants directly infringe (now and in the past) at least claim 7 of the '961 patent by demonstrating to and/or teaching Defendants' United States customers how to insert Defendants' respective PICC products using the methods described in their respective IFUs.
- 17. Defendants induce infringement (now and in the past) of the '961 patent by knowingly advertising, teaching, publishing, instructing and providing their respective customers (and others) with detailed explanations, instructions, and information regarding methods for inserting Defendants' respective PICC products into a patient in an infringing manner. Defendants supply their United States customers (and others) with IFUs related to Defendants'

respective PICC products. These IFUs instruct and actively induce Defendants' customers to directly infringe the claimed methods of the '961 patent, including at least claim 7.

- 18. Defendants contributorily infringe (now and in the past) the '961 patent by importing, selling, and offering to sell their respective PICC products in the United States. Defendants' PICC products are a material component of, at least claim 7 of the '961 patent, which claim is "[a] method of installing a catheter in a patient...." Defendants' PICC products are specialized medical devices. They are not staple articles suitable for substantial non-infringing uses. This is evident in the fact that Defendants' PICC products are not made available to the general public. Rather, federal law restricts Defendants' PICC products for sale by or on the order of a physician. See 21 C.F.R. § 801.109(b). Defendants' PICC products are designed for use in a manner that infringes at least claim 7 of the '961 patent, as evidenced by the incorporation of side ports, sidearms and/or luer attachments to aid in the use of a syringe to flush the supplied catheter. Defendants include such side ports, side arms and/or luer attachments, as well as relevant IFUs, with their PICC products to facilitate their customers' direct infringements.
- 19. With respect to Defendant AngioDynamics, the aforementioned infringements involve one or more of AngioDynamic's PICC products, including, but not limited to its: (1) Morpheus CT PICC and (2) Morpheus SMART CT PICC.
- 20. With respect to Defendant Bard the aforementioned infringements involve one or more of Bard's PICC products, including, but not limited to its: (1) Poly Per Q Cath Triple Lumen; (2) Poly Per Q Cath; (3) Power Per Q Cath; (4) Power PICC Solo, and (5) Polyurethane PICC with MicroEZ Universal Microintroducer.

- 21. With respect to Defendant BD, the aforementioned infringements involve one or more of BD's PICC products, including, but not limited to its: (1) First PICC; (2) First MidCath PICC; and (3) L-Cath.
- 22. With respect to Defendant MedComp, the aforementioned infringements involve one or more of MedComp's PICC products, including, but not limited to its 1.9F Peripherally Inserted Central Vein Access Catheter.
- 23. With respect to Defendant Navilyst, the aforementioned infringements involve one or more of Navilyst's PICC products, including, but not limited to its Xcela Power Injectable PICC.
- 24. With respect to Defendant Smiths Medical, the aforementioned infringements involve one or more of Smiths Medical's and Smith Medical North's PICC products, including, but not limited to its CliniCath product.
- 25. All Defendants have knowledge of the '961 patent as a result of, at a minimum, the filing and serving of this Complaint.
- 26. Defendant AngioDynamics has had knowledge of the '961 patent since at least 2000, when it marketed and sold its Seldinger V-Cath PICC with a "Patented Ultra E-Z Flush stylet system." The Ultra E-Z Flush stylet system was manufactured by the original '961 patent assignee, HDC Corporation ("HDC"). Marketing materials for the Seldinger V-Cath PICC specifically referenced the '961 patent.
- 27. Defendant Bard has had knowledge of the '961 patent since at least April 2006 when HDC Corporation expressly disclosed the '961 patent to Bard in connection with discussions concerning the two companies.

- 28. Defendant BD has had knowledge of the '961 patent since at least September 28, 1999, the date that BD's U.S. Patent No. 5,957,893 issued. The '961 patent was cited in connection with the prosecution of BD's patent and appears in the patent itself among other prior art references.
- 29. Defendant MedComp has had knowledge of the '961 patent since at least January 14, 2009, when it received written correspondence from Guide Flow's predecessor-in-interest, Neo Medical, Inc., specifically identifying and discussing the '961 patent.
- 30. Defendant Navilyst has had knowledge of the '961 patent since at least April 7, 2009, the date that Navilyst's U.S. Patent No. 7,513,892 issued. The '961 patent was cited in connection with the prosecution of Navilyst's patent and appears on its face among other prior art references.
- 31. Upon information and belief, each Defendant has had additional knowledge of the '961 patent since 2001 through their familiarity with HDC marketing materials pertaining to HDC's V-Cath PICCs, which incorporated the "E-Z Flush guidewire system" and specifically referenced the '961 patent.
- 32. Each Defendant's infringements have been willful since it began knowingly engaging in the infringing activities referenced in this Complaint.
- 33. Plaintiff Guide Flow has been damaged as a result of Defendants' infringements. Defendants are, thus, liable to Plaintiff in an amount that adequately compensates Plaintiff for their respective infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

IV. JURY DEMAND

Plaintiff hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

IV. PRAYER FOR RELIEF

Plaintiff requests that the Court find in its favor and against Defendants, and that the Court grant Plaintiff the following relief:

- a. Judgment that one or more claims of United States Patent No. 5,357,961 have been infringed, either literally and/or under the doctrine of equivalents, by one or more Defendants and/or by others to whose infringements Defendants have contributed and/or by others whose infringements have been induced by Defendants;
- b. Judgment that Defendants account for and pay to Plaintiff all damages to and costs incurred by Plaintiff because of Defendants' infringing activities and other conduct complained of herein;
- c. That Defendants' infringements be found to be willful as alleged in this Complaint or, otherwise, from the time that Defendants became aware of the infringing nature of their respective products and services, and that the Court award treble damages for the period of such willful infringement pursuant to 35 U.S.C. § 284;
- d. That Plaintiff be granted pre-judgment and post judgment interest on the damages caused by Defendants' infringing activities and other conduct complained of herein:
- e. That this Court declare this an exceptional case and award Plaintiff its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and
- f. That Plaintiff be granted such other and further relief as the Court may deem just and proper under the circumstances.

Dated: September 29, 2010. Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF GUIDE FLOW LLC

Exhibit "A"

US005357961A

United States Patent [19]

Fields et al.

[11] Patent Number:

5,357,961

[45] Date of Patent:

Oct. 25, 1994

[54] CATHETER GUIDEWIRE AND FLUSHING APPARATUS AND METHOD OF INSERTION

| [75] | Inventors: | Charles B. Fields, Pittsburg; Gretchen K. Marchesani, San Jose, both of Calif. |
|------|------------|--------------------------------------------------------------------------------|
| | | Cant. |

| [73] Assignee: HDC Corp | oration, San Jose, Calif. |
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[21] Appl. No.: 61,481

[22] Filed: May 12, 199

| [22] | Fued: | May 12, 1993 | |
|------|-----------|-----------------------------------------|-------------------|
| [51] | Int. Cl.5 | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | A61B 5/0 |
| [52] | U.S. Cl. | | 128/658; 604/9 |
| [58] | Field of | Search | 128/657, 658, 772 |
| | | | |

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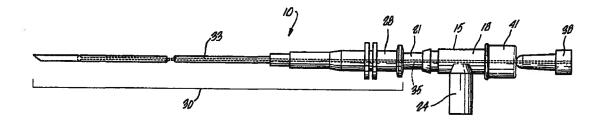
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Primary Examiner—Max Hindenburg Attorney, Agent, or Firm—Lyon & Lyon

[7] ABSTRACT

A flushing device comprises a catheter guidewire flushing apparatus comprising a connector having an insertion port, an outlet port and a flushing port. The invention allows a clinician to adjust the length of a catheter, to insert the catheter while flushing to maneuver the catheter through a tortuous blood vessel, and to easily remove the guidewire for safe disposal. The catheter can then be left in place in the blood vessel.

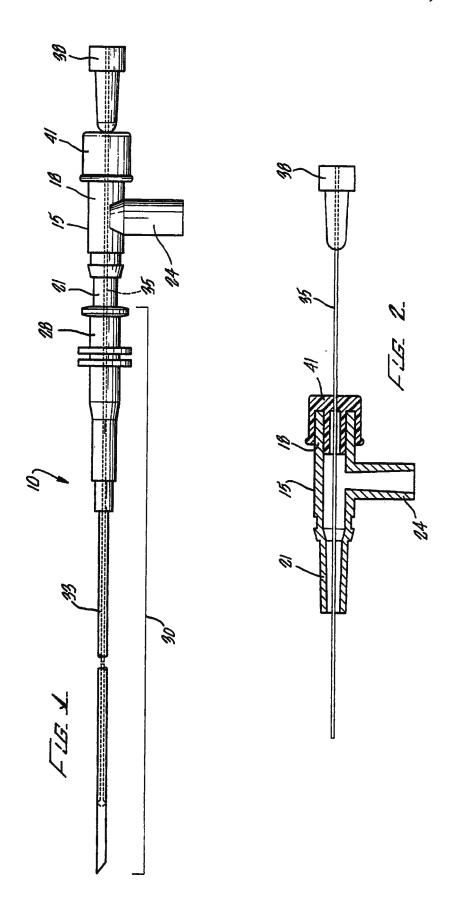
18 Claims, 2 Drawing Sheets



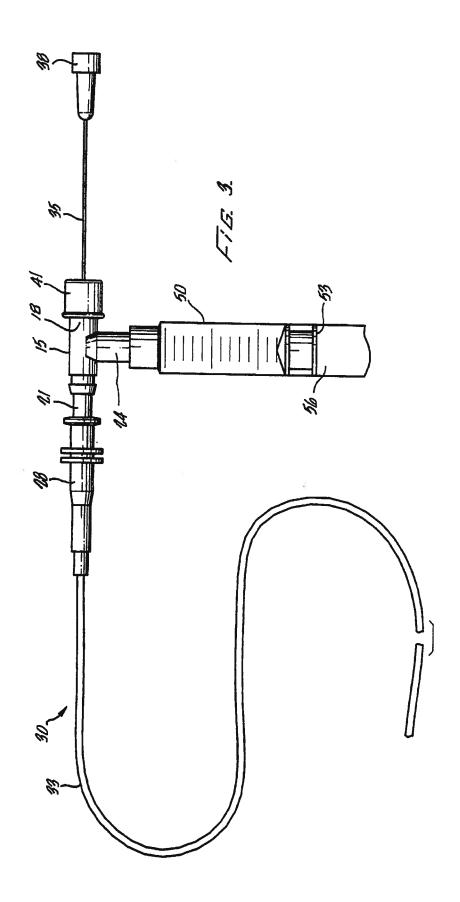
U.S. Patent

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CATHETER GUIDEWIRE AND FLUSHING APPARATUS AND METHOD OF INSERTION

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to the field of medical devices, and more particularly pertains to the field of catheter guidewire and flushing apparatus.

2. Description of the Prior Art

Peripherally inserted catheters have long been used to access the vascular system because they provide a means of repeated access without causing trauma or pain to the patient. Additionally, when long term vascular access is required (greater then two weeks) a cathe- 15 ter should be used because the alternative, multiple injections, can cause patient discomfort and lead to vein deterioration. When peripheral catheters are installed in a patient's extremity, they are left in the vein and therefore a portion protrudes through the skin for access. 20 These prior art catheters were short (approximately one to one and one-half inches). Their short length results in migration into and out of the vein, an undesired occurrence. This migration provides an opening for infectious agents to enter the vascular system which has led to 25 serious complications. Because of this, peripheral intravascular catheters were usually changed every two to three days. In certain circumstances, they were replaced daily.

Peripherally inserted central catheters, or PICCs, 30 were developed to alleviate some of the problems associated with long-term vascular access using short-term peripheral catheters. The PICC is a much longer catheter designed to be inserted percutaneously such that it reaches deep into the vascular system. The end of the 35 catheter is usually placed in the superior vena cava of the heart to utilize the larger blood volume in that chamber as a diluent for the medication being administered. PICCs are becoming the device of choice for providing access to a patient's vascular system for therapeutic support such as chemotherapy, antibiotic treatment, chemical environment monitoring and intravenous medication.

To place the end of the PICC in the heart, one must be able to navigate the tortuous venous path, which 45 includes many natural blockades (e.g., venous valves). The catheter must be soft and pliable for navigation and comfort. It must also be constructed of biocompatible materials because of the long indwelling period. Catheters having these characteristics are usually manufactured of medical grade polyurethane or silicone rubber, both of which can be made very soft and pliable.

PICC lines made of these soft pliable materials are very difficult and time consuming to install. Their pliant construction allows them to collapse and bend making 55 insertion tedious. Often, it can take up to one hour to insert one catheter, time most clinicians do not have. This also increases the cost of health care.

To ease the difficulty of installation, a flexible metal stylet, or guidewire, is used as a means of stiffening the 60 catheter for insertion. Once the catheter is inserted, the guidewire is removed, leaving the soft, pliable, catheter in the desired position. The two most common guidewire types are of a coiled spring or twist-braided wire construction.

The use of guidewires, however, causes their own problems. A first problem is that friction between the guidewire and catheter inner-wall increases the diffi-

culty of removing the guidewire. The tortuous route the catheter takes in order to reach its final destination causes bends in the catheter guidewire apparatus forcing the guidewire against the inner wall. To reduce this friction, some manufacturers have coated their guidewires with a teflon (PTFE) material, adding some lubricity and thereby reducing the friction between the guidewire and the catheter inner-wall. A second approach to reducing friction is to coat the guidewire with hydrophilic silicone. Such coatings provide lubricating surfaces when they become wet. Both of these methods, which require coating the guidewire, are useful on either the coiled spring or the twist-braided guidewire.

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A second problem involved with the use of guidewires is the potential for vessel perforation if the end of the guidewire is forced against the vessel wall. To reduce this danger, coiled spring wires use a soft flexible tip while twist-braided wires have a spherical ball affixed to their ends.

No matter what type of guidewire is used, it is recommended that the catheter be flushed with an aqueous solution before, during, and after catheter insertion. The catheter guidewire apparatus is flushed prior to patient installation in order to check for catheter patency. The catheter is flushed during installation to help maneuver it through the tortuous venous path and to prevent blood from entering the PICC and clotting (an occurrence which makes guidewire removal difficult or in order to facilitate removal of the guidewire. Therefore, there is a need for an apparatus that allows for safe, convenient and economical flushing of catheter guidewire systems before, during and after insertion.

Prior art catheter guidewire apparatus' recommended that the user install the guidewire so that it emerges a little, approximately one-half of one centimeter beyond the end of the catheter. This is for flushing purposes and to provide the user with a portion to hold when removing the guidewire. Traditionally, when flushing a catheter that has a guidewire installed therein, a syringe is connected to the catheter by placing the exposed portion of the guidewire into the tip of the syringe and fastening the syringe to the catheter's fitting. While this method provides a way to supply liquid a interface between the catheter and the guidewire, it has several disadvantages. With this method, the exposed portion of the guidewire is actually inserted inside the syringe's barrel. During flushing, the syringe's plunger naturally moves further into the barrel. A major disadvantage of this system is that the depressing plunger is prone to striking that portion of the guidewire that is within the syringe's barrel. In such a situation, the plunger then may push the guidewire further into the catheter causing the guidewire to actually emerge from the end of the catheter that is deep within a patient. When this occurs, the guidewire, which is now exposed in the patient, can puncture vital organs of the patient such as a lung or a major vein.

This traditional method also does not work well when the catheter is trimmed to length (catheters are made to standard lengths which may be longer than needed to ensure that the tip is installed at the most desirable site). Since the guidewire has a special tip on its end, as discussed above, it is usually not cut and therefore the guidewire must be partially withdrawn prior to trimming. In this situation, there will be considerably more than the normal length of guidewire

emerging from the end of the catheter. This excess length of guidewire cannot be inserted in the syringe barrel, thereby preventing the syringe from being placed over the syringe's female luer for flushing. This is a major disadvantage of the prior art.

Some manufacturers suggest that post-catheter shortening flushing when excess guidewire emerges from the female hub can be accomplished by forcing the syringe tip alongside the wire in the end of the catheter, thereby bending the guidewire to the side of the catheter end. A 10 major disadvantage to forcing the syringe in the catheter's end with the guidewire bent away from the syringe's luer is that in such an arrangement there will be no seal between the catheter and the syringe. An incomplete seal will lead to leaks which will prevent adequate 15 flushing. Therefore, since prior art devices are extremely difficult to flush once the catheter has been shortened, guidewire removal, which is a critical requirement of catheter guidewire systems, has been very difficult and a better system and method is needed.

The present invention overcomes the problems associated with prior art catheter guidewire flushing apparatus. The invention allows the user to flush the catheter before using it to check catheter patency, to flush the catheter during insertion to help maneuver around 25 venous obstructions, to flush the catheter after placement for guidewire removal, to leave the guidewire in place to help visibility when checking placement position radio graphically and to be able to trim a catheter and still maintain a seal between a syringe and the cathe-

SUMMARY OF THE INVENTION

The present invention overcomes the problems and disadvantages of the prior art through the use of a 35 unique catheter assembly comprising a connector. The preferred connector comprises a three-way connector that comprises an insertion port, a outlet port and a flushing port. The insertion port is preferably collinear with the outlet port and preferably a reclosable septum 40 covers the insertion port.

The assembly of the present invention preferably comprises a peripherally inserted catheter that is connected to the outlet port. A hydrophilic stylet is slidably disposed such that it extends through the insertion port 45 and outlet port so that the stylet enters the catheter, thereby stiffening it for venous introduction. A plastic handle may be affixed to the distal end of the stylet to provide a means for stylet manipulation and to prevent stylet migration.

A preferred method of using the catheter assembly comprises preparing the assembly for insertion, inserting the catheter and removing the stylet. If desired, the method may include the step of verifying the position of the catheter. The method of preparation comprises the 55 attaching of a syringe filled with a heparin or normal saline solution to the flushing port of the connector, flushing the catheter to check for patency and to remove excess air, adjusting, if desired, the length of the catheter by withdrawing a portion of the stylet from the 60 catheter such that only the desired length of catheter has the stylet within it, and removing the unwanted portion of the catheter.

After any necessary trimming, the catheter is ready for installation in a patient. The method of insertion 65 comprises flushing with the syringe (which is still attached to the flushing port) if undue resistance is felt due to any venous obstructions. This flushing helps to

deflect the tip of the catheter to help ease it past the obstruction. The verification step comprises leaving the guidewire in place, radiographically detecting the stylet, and flushing the catheter by simply depressing the 5 syringe's plunger as needed. The method of removal of the guidewire comprises pulling the guidewire handle to move the guidewire out of the catheter. The catheter is flushed if resistance is met when removing the guidewire by depressing the syringe's plunger.

The above and other features of the invention, including various novel details of construction and combination of parts, will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular devices embodying the invention are shown by way of illustration only and not as limitations of the invention. The principles and features of this invention may be employed in various and numerous embodiments without departing from the scope of the invention

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the accompanying drawings in which are shown illustrative embodiments of aspects of the invention, from which its novel features and advantages will be apparent to those skilled in the art.

FIG. 1 is a side view of an embodiment of a vascular catheter guidewire flushing apparatus in accordance with the present invention.

FIG. 2 is an enlarged sectional view of the embodiment of FIG. 1 which shows the catheter guidewire flushing apparatus' three-way connector, septum, and guidewire.

FIG. 3 is a view of catheter trimming technique.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, and in particular FIGS. 1 and 2, there is seen an embodiment of a catheter guidewire flushing apparatus 10 of the invention. The guidewire flushing apparatus comprises a three-way connector 15 that comprises an insertion port 18, a outlet port 21 and a flushing port 24. The insertion port 18, outlet port 21 and flushing port 24 are preferably integral to each other and form a cavity.

A peripherally inserted central catheter, or PICC, 30 comprises a female hub 28 and a catheter 33. The female hub 28 and catheter 33 are fastened together to form a continuous and leakless assembly. The catheter 33 can be constructed of any suitable material, such as medical grade polyurethane or silicone rubber. The PICC 30 is connected to the three-way connector 15 by sliding its female hub 28 over the three way connector's 15 outlet port 21. The size of the female hub 28 is selected so that it fits snugly on the outlet port 21 of the three-way connector 15 creating a seal. It will not slide off without application of a substantial force. The outlet port 21 provides communication between the three-way connector 15 and the proximal end of the PICC 30. Disposed on the insertion port 18 is a reclosable septum 41.

In order to make installation of the PICC 30 easier, a guidewire 35 is run through the length of catheter 33. The guidewire 35 stiffens catheter 33, which makes pushing it through a patient's venous system easier. The guidewire 35 preferably comprises a hydrophilically coated, twist-braided stylet. The guidewire 35 preferably has a handle 38 at its distal end. The handle 38 provides a gripping surface that is larger than the guidewire

35. The large gripping surface makes guidewire handling easier, which simplifies guidewire 35 movement and manipulation, which reduces the amount of time it takes to install the catheter. The handle 38 also acts as a stop to fix the position of the guidewire 35 in relation to 5 the tip of the catheter 33.

The guidewire 35 passes through the reclosable septum 41 disposed on the insertion port 18. The resilient nature of the latex rubber reclosable septum 41 is such that it makes a water tight seal around the guidewire 35. 10 The guidewire 35 then travels through the three-way connector 15 and into the catheter 30. When completely inserted, the guidewire handle 38 will rest against the reclosable septum 41. Initial guidewire 35 length is selected such that when completely inserted, its proximal 15 tip rests approximately one-half to one centimeter from the catheter's 30 proximal tip. This provides additional protection from vein puncture or irritation by the guidewire 35. Once guidewire 35 is completely inserted in PICC 30, the catheter 33 is stiff enough to allow it to 20 move through a vein without being impeded by any venous obstructions.

once the guidewire 35 is placed through the three-way connector 15, it can slide its full length through the reclosable septum 41. The reclosable septum 41 pro- 25 vides a slight resistance to movement of the guidewire 35. This resistance prevents the guidewire 35 from being moved too quickly through the three-way connector 15 and PICC 30. This is advantageous since moving too quickly can cause patient discomfort and 30 may result in puncturing the vein. Once the wire is removed, the reclosable septum 41 forms a watertight barrier.

The flushing port 24 provides a means for connecting a syringe 50, as shown in FIG. 3, to the three-way con-35 nector 15. The lateral port 24 is preferably disposed perpendicular to the insertion port 18 and outlet port 21. Experimentation has shown that maintaining the lateral port 24 perpendicularly to the insertion port 18 and outlet port 21 provides many advantages. These advantages include insuring that the full force of the injected flushing solution is absorbed by the side wall of the three-way connector 15.

The syringe 50 is filled with flushing solution. Flushing solutions that provide the necessary characteristics 45 include heparin and saline. Once attached to the flushing port 24, the syringe 50 and its contents (the flushing solution) can be left attached until the PICC 30 is installed in its desired position. The normal operation of the syringe 50 will prevent any of the flushing fluid 50 from entering the three-way connector 15 until the syringe's plunger 53 is forced into the syringe's barrel 56.

With reference to FIG. 3, the method of installing a PICC 30 in a patient will be discussed. In this discussion, the adjustability advantages of the invention will be described. Prior to installation, the catheter guidewire flushing apparatus 10 must be prepared. The first step in preparing for installation is the flushing of the catheter guidewire flushing apparatus 10. The manner 60 in which the syringe 50 is used to flush the catheter guidewire apparatus 10 has been described above. Flushing prior to installation allows the user to check for patency. The user will know that the PICC 30 has been successfully flushed when drops of flushing solution begin to emerge from the catheter 33 tip.

The next preparation step is to determine how long the PICC 30 needs to be in order for its tip to reach the desired location within the patient. In order to determine this length, the user measures the distance between the insertion site and the desired tip location. If the length necessary for proper catheter 33 tip location is shorter than the length of the catheter 33, the catheter 33 of the PICC 30 must be trimmed to the proper length.

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The method of trimming the PICC 30 will now be discussed. It is noted that prior to trimming, the guidewire 35 is placed in the PICC 30 such that the guidewire's 35 handle 38 rests against the reclosable septum 41. The first step in trimming the catheter 33 is to withdraw the guidewire 35 through the reclosable septum 41 so that the guidewire 35 is only within the necessary length of the PICC 30. After the proper length of guidewire 35 has been withdrawn, the catheter 33 portion of the PICC 30 can be trimmed using sterile scissors and being careful to avoid cutting the guidewire. Approximately one centimeter of catheter 33 should remain that has no guidewire within it. The resulting catheter guidewire flushing apparatus 10 has a PICC 30 with a catheter 33 of proper length. Because the guidewire 35 has been withdrawn from the PICC 30, the guidewire 35 handle 38 will no longer rest against the reclosable septum 41 and a portion of the guidewire 35 will no longer be within either the three-way connector 15 or the PICC 30. This is clearly shown in FIG. 3.

After trimming the catheter 33, but immediately prior to installation, the catheter guidewire apparatus 10 may be flushed again. Flushing prior to installation allows the user to recheck catheter patency and can remove any residue created during catheter 33 trimming.

As discussed above, traditional catheter guidewire flushing apparatus' were difficult, if not impossible, to flush when excess guidewire emerged from the PICC 30. In the catheter guidewire flushing apparatus 10 of the invention, however, the provision of flushing port 24 allows the catheter guidewire apparatus 10 to be flushed even though the guidewire 35 has been slightly withdrawn from the PICC 30. Thus, even after trimming, the peripherally inserted catheter can be installed in a patient with the flush feature intact.

It may be necessary to flush the catheter guidewire flushing apparatus 10 during insertion to aid in installation. When the PICC 30 is flushed during installation, the flushing solution will act to slightly move the catheter 33, thereby allowing it to move past any venous obstruction. Flushing during installation can also remove any blood that may accumulate inside the lumen of the PICC 30.

Once installed in the patient, the guidewire 35 can be left in the PICC 30 to verify its placement. This verification will take place radiographically. After this verification, if it was desired, the guidewire 35 must be removed from the PICC 30. In order to remove the guidewire 35, the guidewire's 35 handle 38 is pulled. If any resistance is felt, the PICC 30 should be flushed. As discussed above, the flushing solution lubricates the guidewire 35, thereby making removal much easier. The provision of a separate flushing port 24, unlike traditional guidewire flushing apparatus, allows the flushing to take place without any guidewire 35 manipulation, allows for flushing to take place at any time, without having to reattach a syringe containing flushing solution, and avoids the possibility of puncturing a patient's vein or organ.

We claim:

1. A method of installing a peripherally installed central catheter comprising:

attaching a connector to a catheter;

inserting a guidewire through the connector and into the catheter;

filling a syringe with a flushing solution;

attaching the syringe to a port on the connector;

depressing a plunger in the syringe such that an amount of the flushing solution from the syringe enters the connector and the catheter, thereby flushing the catheter;

determining the catheter's desired length;

withdrawing the guidewire from the catheter such that the guidewire resides in a majority of the catheter's desired length without detaching the syringe; trimming the catheter so that only the catheter's desired length remains;

advancing the catheter into a patient;

depressing the plunger in the syringe again such that an additional amount of the flushing solution from the syringe enters the catheter, thereby flushing the catheter and lubricating the guidewire; and

withdrawing the guidewire from the catheter and the connector.

- 2. The installation method of claim 1 further comprising the step of depressing the plunger in the syringe while advancing the catheter into the patient such that an additional amount of the flushing solution from the syringe enters the catheter to help ease the guidewire 30 past an obstruction in the patient.
- 3. The installation method of claim 1 further comprising the step of depressing the plunger in the syringe after trimming the catheter such that an additional amount of the flushing solution from the syringe enters 35 the catheter.
 - 4. A method of installing a catheter comprising: attaching a connector to a catheter;

inserting a guidewire through the connector and into the catheter;

filling a syringe with a flushing solution;

attaching the syringe to a port on the connector;

depressing a plunger in the syringe such that an amount of the flushing solution from the syringe flushing the catheter;

determining the catheter's desired length;

withdrawing the guidewire from the catheter such that the guidewire resides in a majority of the catheter's desired length without detaching the syringe; 50 trimming the catheter so that only the catheter's desired length remains;

advancing the catheter into a patient;

depressing the plunger in the syringe again such that an additional amount of the flushing solution from 55 the syringe enters the catheter, thereby flushing the catheter and lubricating the guidewire; and

withdrawing the guidewire from the catheter and the connector.

- 5. The installation method of claim 4 further compris- 60 ing the step of depressing the plunger in the syringe while advancing the catheter into the patient such that an additional amount of the flushing solution from the syringe enters the catheter to help ease the guidewire past an obstruction in the patient.
- 6. The installation method of claim 4 further comprising the step of depressing the plunger in the syringe after trimming the catheter such that an additional

amount of the flushing solution from the syringe enters the catheter.

7. A method of installing a catheter in a patient comprising:

connecting a syringe containing flushing solution to a flushing port of a connector, said connector attached to said catheter at an outlet port and having a guidewire passing through said connector and through said catheter's length;

depressing a plunger in said syringe such that an amount of said flushing solution from said syringe enters said connector and said catheter, thereby flushing said catheter;

determining said catheter's desired length;

withdrawing said guidewire from said catheter such that said guidewire resides in a majority of said catheter's desired length without detaching said

trimming said catheter so that only said catheter's desired length remains; and

inserting said catheter into the patient.

- 8. The method of claim 7 wherein said inserting said catheter step further comprises the steps of depressing said plunger in said syringe such that an additional 25 amount of said flushing solution enters said connector and said catheter, thereby floating said catheter past an obstruction in said patient.
 - 9. The method of claim 7 further comprising the step of removing said connector from said catheter.
 - 10. The method of claim 7 further comprising the steps of:

withdrawing said guidewire from said catheter and from said connector after inserting said catheter;

removing said connector from said catheter.

- 11. The method of claim 7 further comprising the step of withdrawing said guidewire from said catheter and said connector.
- 12. The method of claim 11 further comprising the 40 steps of:

removing said syringe from said flushing port; and connecting a fluid infusing device to said flushing

- 13. The method of claim 12 further comprising the enters the connector and the catheter, thereby 45 step of administering fluid from said fluid infusing device to said patient.
 - 14. A method of installing a catheter in a patient comprising:

depressing a plunger of a syringe containing flushing solution, said syringe connected to a flushing port of a connector, said connector attached to said catheter and having a guidewire passing through said connector and through said catheter's length such that an amount of said flushing solution from said syringe enters said connector and said catheter, thereby flushing said catheter;

determining said catheter's desired length;

withdrawing said guidewire from said catheter such that said guidewire resides in a majority of said catheter's desired length without detaching said syringe;

trimming said catheter so that only said catheter's desired length remains; and

inserting said catheter into the patient.

15. The method of claim 14 wherein said inserting said catheter step further comprises the step of depressing said plunger in said syringe such that an additional amount of said flushing solution enters said connector

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and said catheter, thereby floating said catheter past an obstruction in said patient.

16. The method of claim 14 further comprising the steps of:

withdrawing said guidewire from said catheter and said connector after inserting said catheter; and removing said connector from said catheter.

17. The method of claim 14 further comprising the step of withdrawing said guidewire from said catheter 10 and said connector.

18. A method of installing a catheter in a patient comprising:

determining said catheter's desired length, said catheter attached to a three-way connector at an outlet 15 port of said catheter and having a guidewire pass-

10 ing through said three-way connector and said catheter;

withdrawing said guidewire from said catheter such that said guidewire resides in a majority of said catheter's desired length;

trimming said catheter so that only said catheter's desired length remains;

connecting a syringe containing flushing solution to a flushing port of said three-way connector;

inserting said catheter into the patient; and depressing a plunger in said syringe such that an amount of said flushing solution from said syringe enters said connector and said catheter, thereby flushing said catheter and floating said catheter past an obstruction in said patient.

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