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ALMANSOURI et al.(10) **Pub. No.: US 2015/0352318 A1**(43) **Pub. Date: Dec. 10, 2015**(54) **ULTRASOUND ASSISTED CATHETER
PLACEMENT SYSTEM**(52) **U.S. CL.**CPC *A61M 25/002* (2013.01); *A61M 25/09041*
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(57)

ABSTRACT

A deep vein intravenous introducer has a wheel located toward the front end of the device that can be rotated by the index finger of the user. After placement of the needle in the lumen of the vessel, the user rotates the wheel, which advances the wire guide through the center of the needle and into the patient. Once the guide wire is advanced into the vessel lumen the catheter can be advanced over the guide wire with a hub or finger tab on the catheter close to the index finger. The operation can be performed by one hand without moving the hand from its initial position. The user can then simultaneously use the other hand to operate an ultrasound detection device during insertion without the assistance of another person. A catheter is provided that can be visualized by ultrasound to enable confirmation of correct placement in a vessel. A probe cover is provided that is pre-sterilized and packaged in a cardboard with the top sides of the cover folded down over the cardboard. The cover is placed over the probe end, the sides of the cover are folded up, and the cardboard is removed. The sterile probe cover can be quickly and efficiently placed over the ultrasound's transducer end. Finally, a kit is provided that contains all of the medical devices needed to perform cannulation.

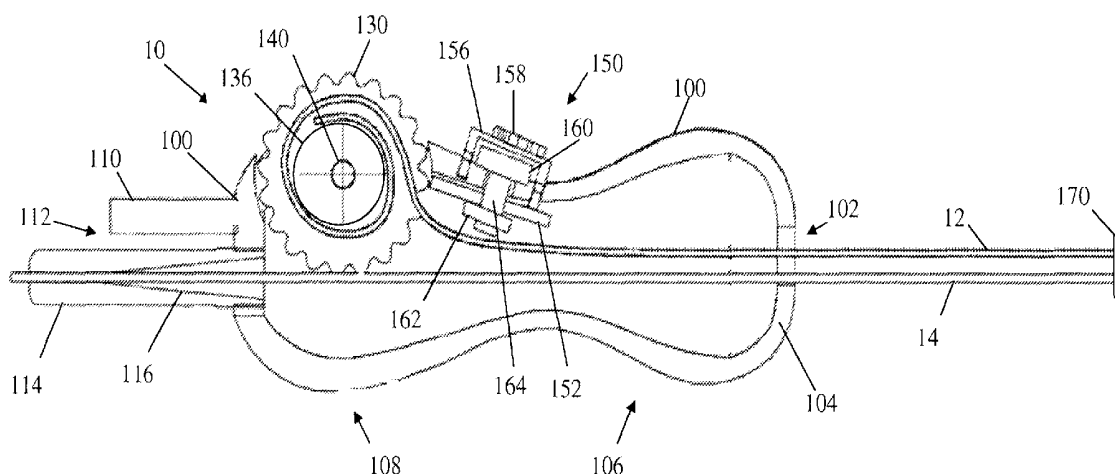
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(60) Provisional application No. 61/770,052, filed on Feb. 27, 2013.

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<i>A61M 25/06</i>	(2006.01)



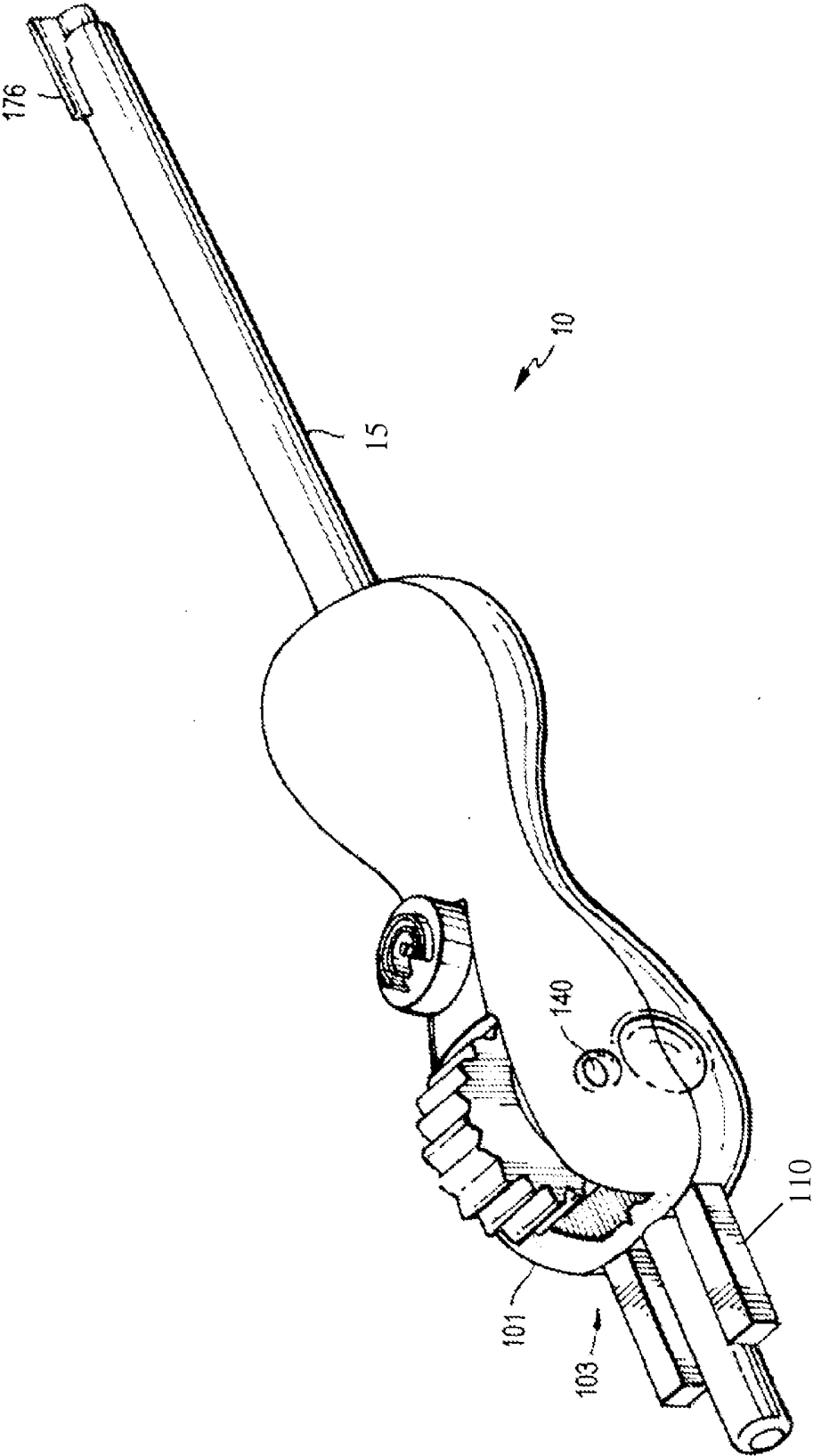


Figure 1

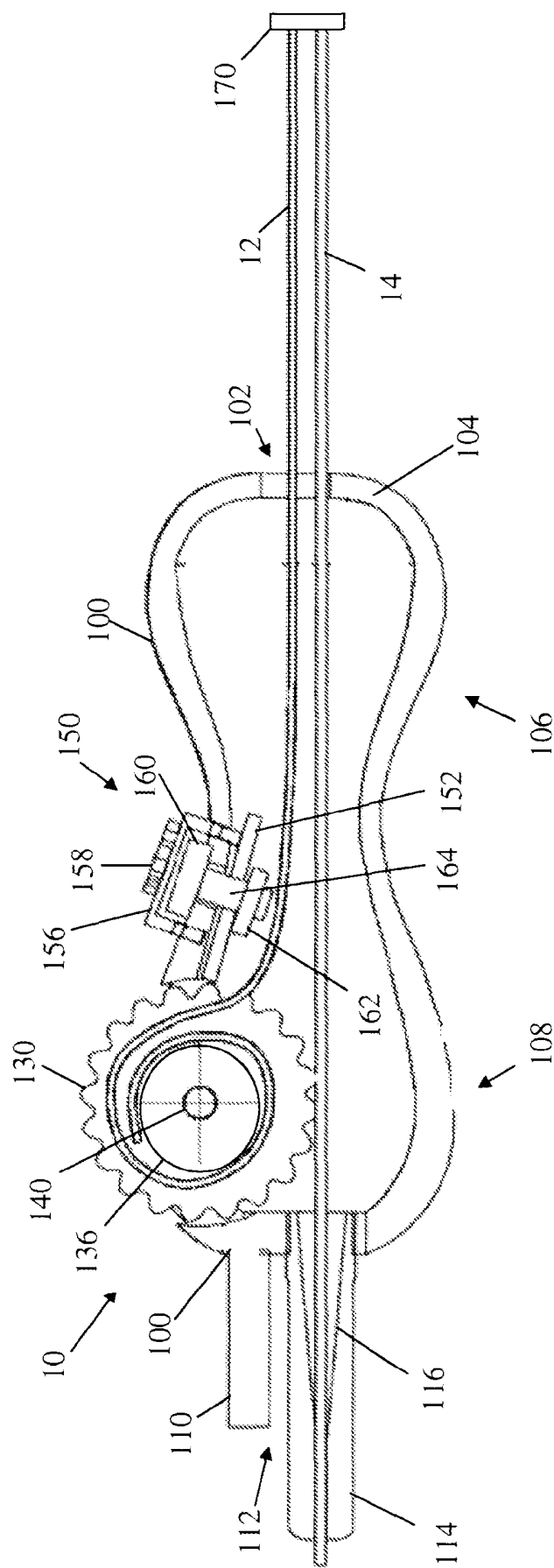


Figure 2

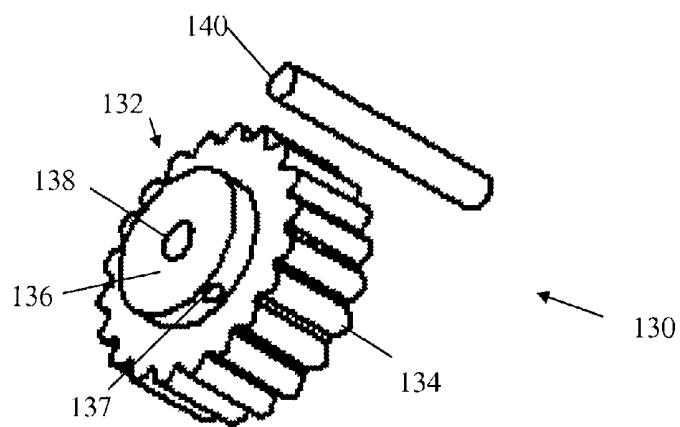


Figure 3

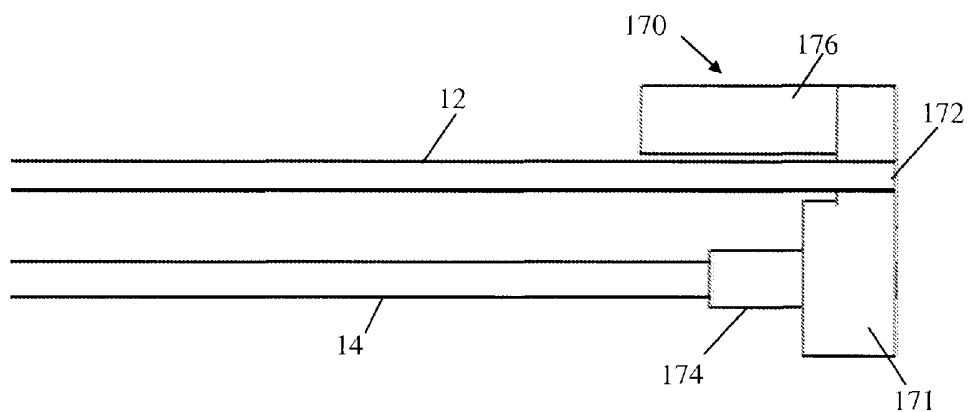


Figure 4

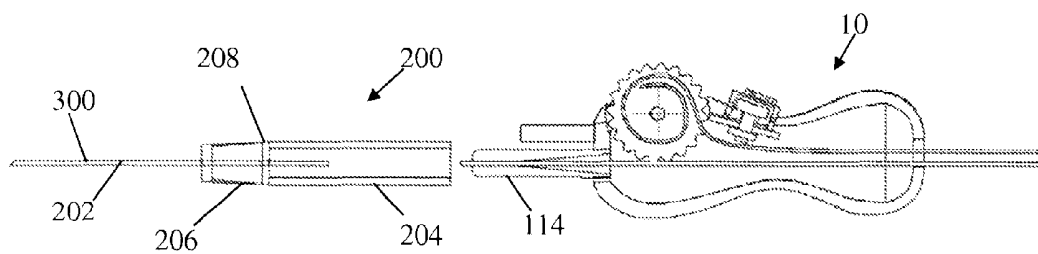


Figure 5

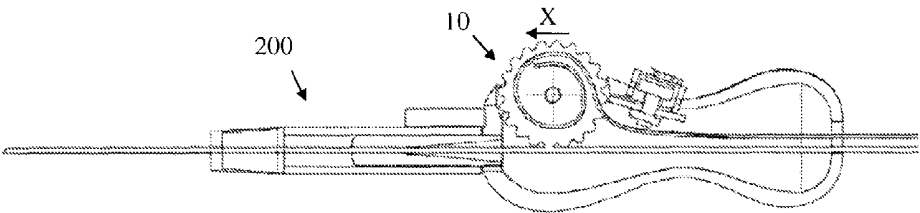


Figure 6

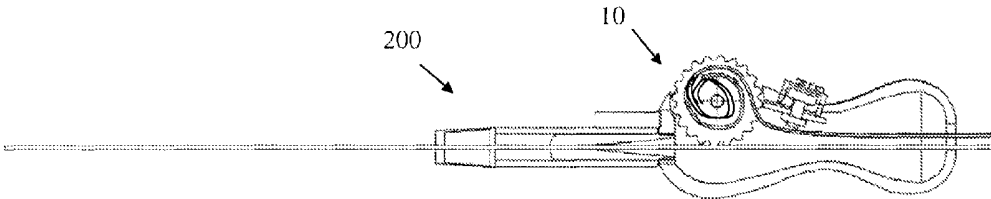


Figure 7

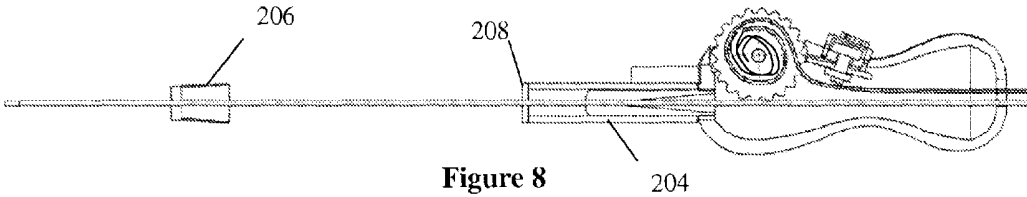


Figure 8

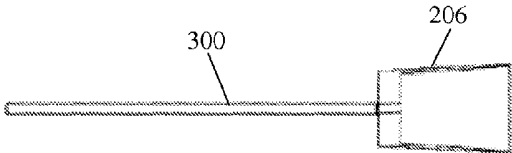


Figure 9

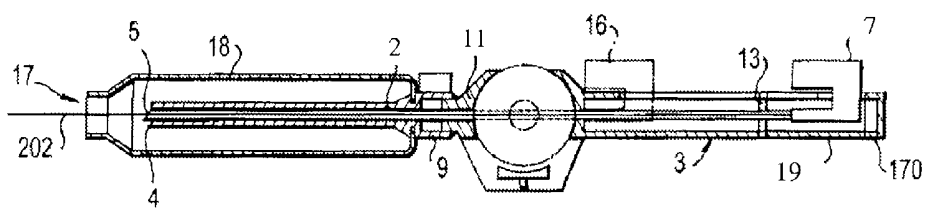


Figure 10A

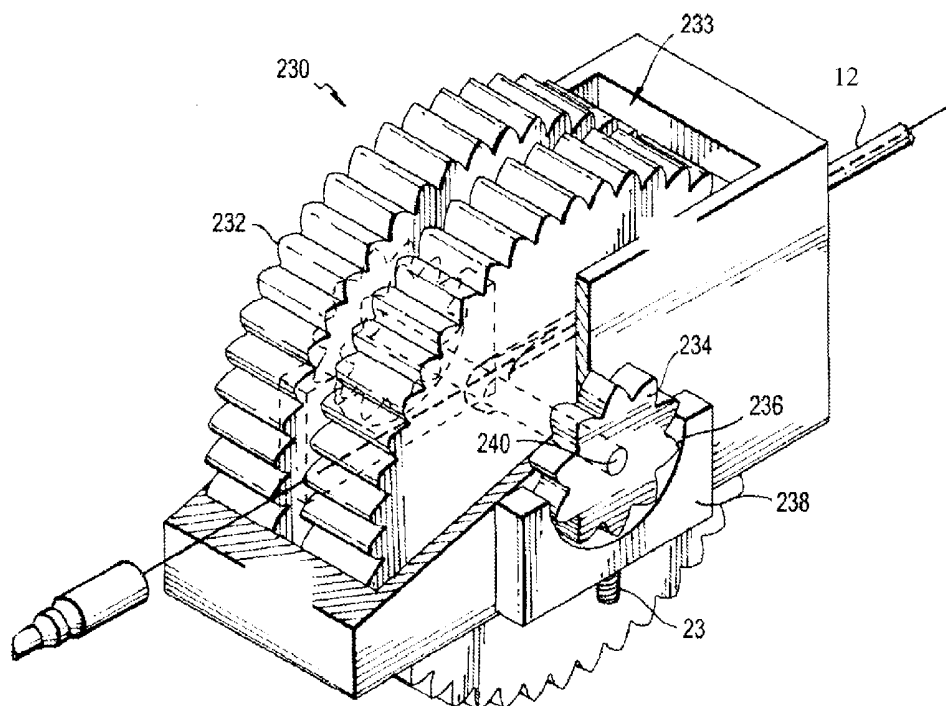


Figure 10B

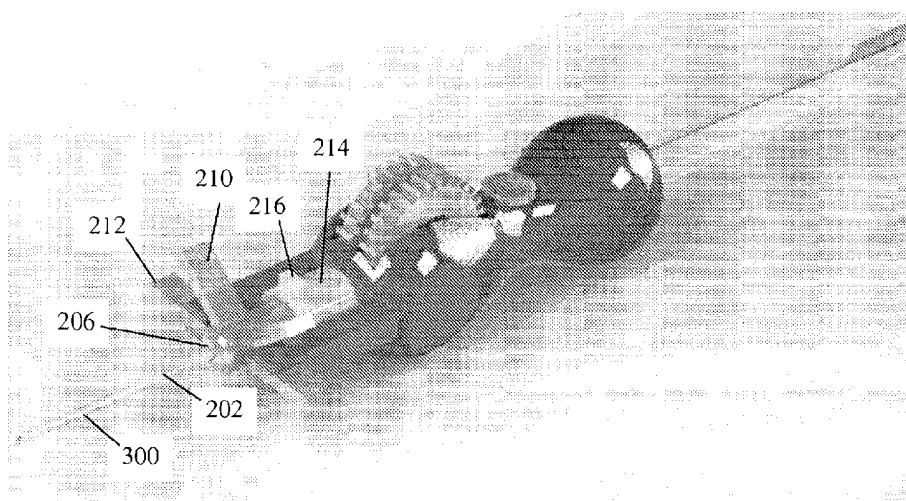


Figure 11A

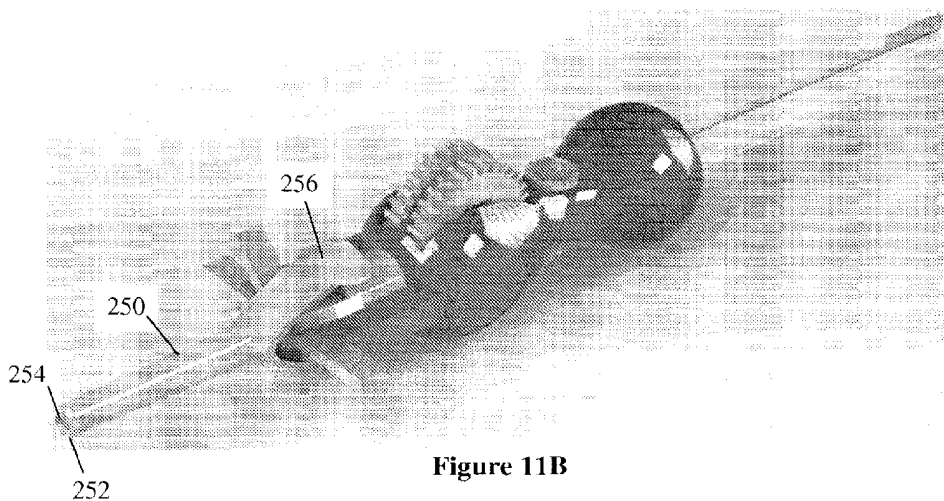


Figure 11B

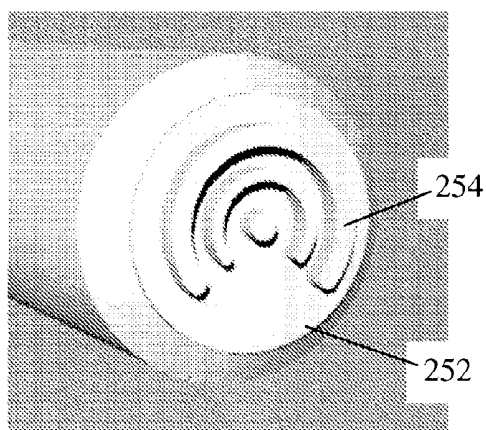


Figure 11C

COMPARISON OF DENSITY AND ACCOUSTIC PROPERTIES
OF CATHETER AND METALLIC MATERIAL

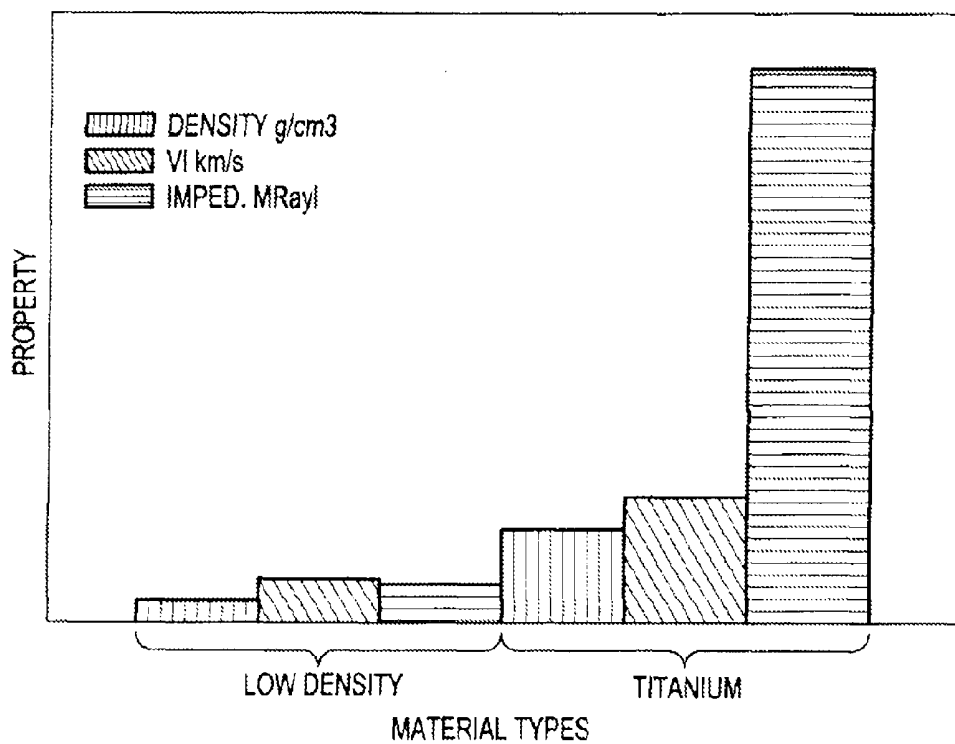


Figure 12

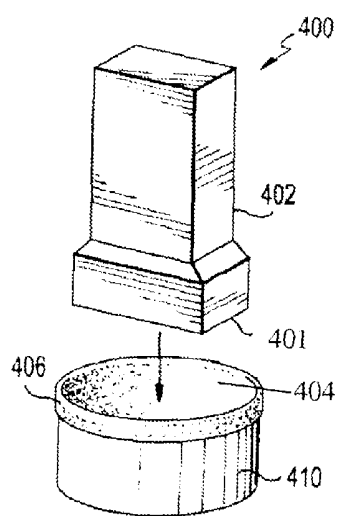


Figure 13

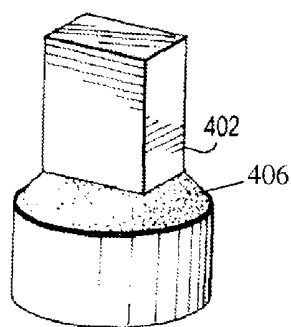


Figure 14

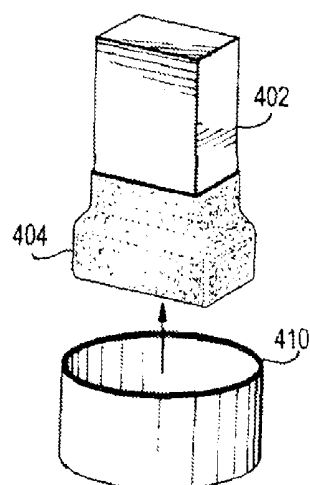


Figure 15

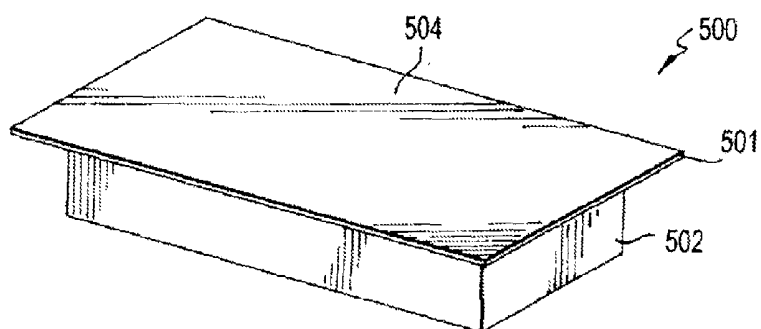


Figure 16

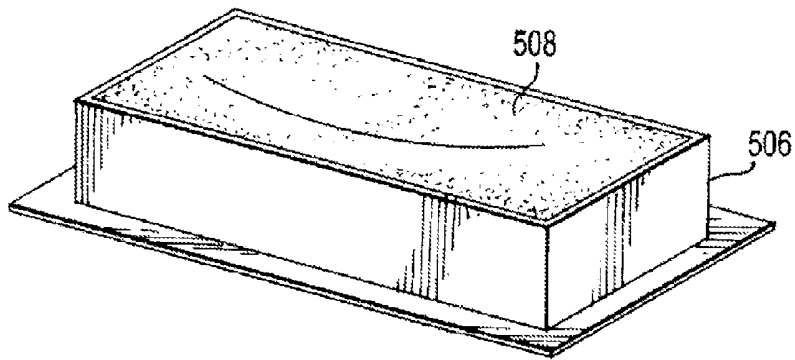


Figure 17

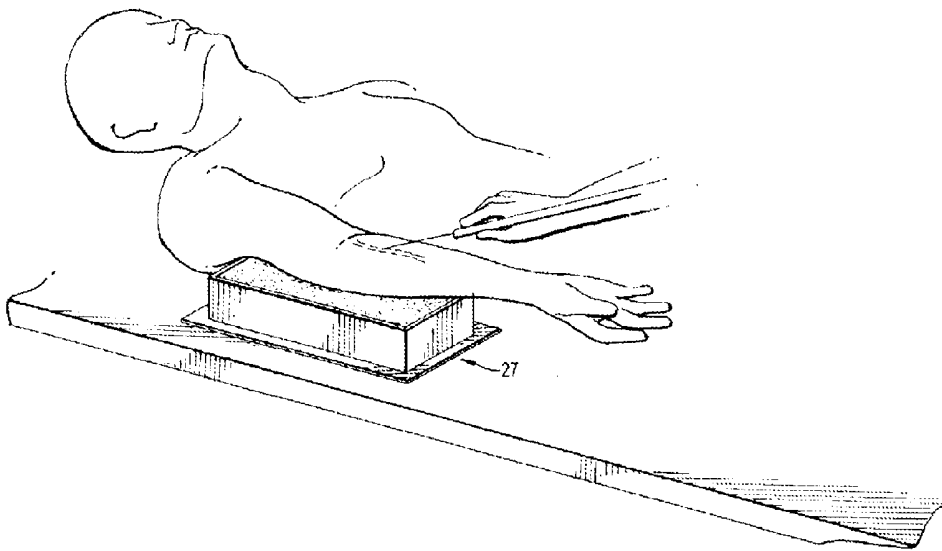


Figure 18

ULTRASOUND ASSISTED CATHETER PLACEMENT SYSTEM

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/770,052, filed Feb. 27, 2013, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to a system, device and method for the introduction of catheters and more particularly to the introduction of catheters into small diameter blood vessels, deep vessels, central veins, arteries, and those visualized by ultrasound.

[0004] 2. Background of the Related Art

[0005] Catheter introduction sets are generally known. For instance, U.S. Pat. No. 4,417,886 discloses a catheter introduction set having a needle, catheter, wire guide and wire guide feed device in which when the needle is positioned into a lumen of a blood vessel, a wire guide is first inserted into the vessel and the catheter is fed over the wire guide from the use of a radially extended handle into the lumen. This arrangement is similarly disclosed in U.S. Pat. No. 4,772,264 with the addition of a retaining finger for stabilization of the catheter on the skin.

[0006] However, these catheter introduction sets require the user to use two hands to operate the device. One hand is needed to insert the needle and catheter, and a second hand to feed the guide wire. This means that one hand has to be taken off the ultrasound probe to feed the guide wire. Consequently, a single user cannot visualize the guide wire directly while threading the vessel, which increases the possibility of misplacement of the guide wire.

[0007] Catheters, both central and peripheral, are not designed to be visualized under ultrasound and correct placement is essential for proper medication administration. A catheter can be placed into a vessel with an introducer needle with or without a guide wire. The guide wire and the introducer needle can be visualized under ultrasound, but the catheter itself cannot be visualized. Because the catheter cannot be visualized, sometimes catheters are placed incorrectly. Examples of incorrect catheter placement include: in an artery instead of a vein, in a vein instead of an artery, and in neither a vein nor an artery. Arteries flow next to veins and can be easily catheterized accidentally when aiming for a vein. Accidental placement of a catheter in an artery instead of a vein can lead to destruction of tissues receiving blood from that artery due to application of medications that damage arteries and are intended only for use in veins.

[0008] While placing an ultrasound guided IV catheter there are two directional variables the health care professional has to deal with: longitudinal and vertical. Without the use of a directional marker the physician can become disoriented to the longitudinal direction. There is a simple method to alleviate this complication by using a directional marker to orient the longitudinal direction of the catheter to the vessel, eliminating this variable and simplifying the ultrasound guidance technique. Two temporary points can be marked on the surface of the skin one at the point of planned initial entry of the catheter over the vessel and another small distance distal to this point. The ultrasound can be used to follow the vessel allowing the clinician to mark these two points above the

vessel on the skin. However, currently available catheter introduction sets do not incorporate a means to make directional markings on the skin.

[0009] Stable position of the body part to be catheterized is essential for both placement of the catheter and comfort of the patient. Catheter introduction kits are available manufactured by Arrow International for the radial artery. These kits include a case that both holds the kit contents and provides means to stabilize the wrist for the catheter insertion in the artery of the wrist. Currently there are no kits available for catheter introduction in the anti-cubital veins of the upper arm. Because no such kits are available, practitioners do not have readily available means to stabilize the arm for catheterization. Likewise, additional body parts that are catheterized besides the arm, also do not have kits available that provide body part stabilizing means.

[0010] Ultrasound guided vascular access and other procedures must be done in an expedited fashion for medical purposes. Often the speed of vascular access can be a matter of life or death. This procedure is invasive, meaning that there is the chance of bacteria being introduced from the skin into the vessel, which is why the procedure must be performed under sterile conditions. Ultrasound probes used repeatedly have a propensity to be contaminated. For this reason sterile probe covers are used to prevent infection. Current probe covers for probes used in ultrasound guided vascular access are large, bulky and time consuming to put on. These probe covers are very long in order to cover not only the transducer end of the probe, but also much of the cord.

[0011] A fast time to catheter placement is essential in the health care setting for the administration of medications especially in sick patients, and patients in pain, who have rapidly spreading medical conditions. When placing an ultrasound guided IV having all the supplies in one place is essential for placement to be time efficient in the application of medicine or performing blood draws. However, the necessary equipment is often scattered throughout the department or not available in the department, making the procedure even more difficult or impossible to perform. Oftentimes medical professionals resort to using surgical rectal lubrication and attempt to use alcohol swabs on dirty ultrasound probes instead of a sterile sheath.

[0012] Ultrasound guided catheters are more often in deeper vessels. This is because vessels closer to the surface are more easily visualized leading to greater success with the conventional technique. With the deep and small nature of the vessels used in the ultrasound guided IV catheter technique it can take more time and attention to place these catheters. More of the catheter is in the soft tissue between the skin surface and the deep vessel, which means that the deeper vessel has less of the catheter within its lumen. A slight slip of the catheter can cause displacement of the catheter from the lumen. In addition, sterile lubrication used for the ultrasound makes it difficult for tape and tegaderm to adhere to the skin. All of these factors make it difficult and essential to secure an ultrasound guided IV catheter.

[0013] The placement of an ultrasound guided IV catheter is often painful to the patient. The use of an anesthetic at the skin surface can make catheter placement much more comfortable for the patient. The placing of a catheter via ultrasound usually uses a large bore catheter, 18 gauge or larger. The large gauge is necessary for the rapid transfusion of medicines, fluids and IV contrast, and this can be quite painful, especially because the placement of ultrasound guided IV

catheters usually takes longer than the conventional method with a sharp needle being slowly manipulated beneath the skin. The use of local anesthetic at the site of entry can alleviate this pain.

[0014] Ultrasound guided catheter introduction kits are currently available for central venous access, but no kits are available for ultrasound guided peripheral venous access.

SUMMARY OF THE INVENTION

[0015] Accordingly, it is an object of the invention to provide a needle/catheter introduction apparatus that can be operated with one hand. It is a further object to provide an introduction apparatus that is reliable and easy to use. It is a further object of the invention to provide a catheter that can be visualized with ultrasound. It is yet another object of the invention to provide a probe cover that is easy to use, reliable, and sterile. It is still a further object of the invention to provide an assembly or kit with components needed for ultrasound guided catheter introduction to peripheral veins or arteries.

[0016] A needle/catheter introducer is provided that can be operated by one hand. The introducer has a wheel located toward the front end of the device that is rotated by the index finger of the user. After placement of the needle in the lumen of the vessel, the user rotates the wheel, which advances the wire guide through the center of the needle and into the patient. Once the guide wire is advanced into the vessel lumen the catheter can be advanced over the guide wire with a hub or finger tab on the catheter close to the index finger. The introducer fits in the palm of the user's hand and the wheel can be operated by the user's index finger. Because the actions needed to advance the guide wire and advance the catheter can both be comfortably performed by one hand without moving the hand from its initial position, the catheter introducer is easy to use and allows the user to also operate an ultrasound detection device during insertion without the assistance of another person.

[0017] In addition, a catheter is provided that is comprised of materials that make the catheter capable of being visualized by ultrasound to enable confirmation of correct placement in a vessel.

[0018] In addition, a probe cover is provided that is pre-sterilized and packaged in a cardboard with the top sides of the cover folded down over the cardboard. The cover is placed over the probe end, the sides of the cover are folded up, and the cardboard is removed. The sterile probe cover can be quickly and efficiently placed over the ultrasound's transducer end.

[0019] Still further, the invention includes a kit having components needed for ultrasound guided catheter introduction to peripheral veins or arteries. The kit has a sterile package with an ergonomic shape that can be used to stabilize the arm. The needle cover, in addition to protecting the needle, has a tip which can mark the skin to provide a directional marker. This allows the needle to be aligned to the direction of the vessel. The catheter introduction set allows a catheter tube to be introduced into blood vessels such as veins and arteries while keeping the ultrasound probe cover sterile. The introducer assembly is contained in a sterile package, which is designed to be converted into an ergonomic arm stand for assisting in stabilizing the arm while placing the catheter. The sterile package can also contain the sterile probe cover. The introducer assembly is removed as an entire unit including needle, catheter, wire guide, rotational wire guide feed device, needle cover with directional guide. The sterile probe cover is placed

on the transducer end of the ultrasound probe. Other items in the kit that one might need to locate separately (outside of peripheral kits) to perform ultrasound guided catheter insertion on peripheral veins or arteries include: lidocaine or other anesthetic, sterile gel (for ultrasound transduction), ultrasound probe cover for sterile patient contact, two rubber hands to secure the ultrasound probe cover, suture material to stabilize the catheter on the arm.

[0020] These and other objects of the invention, as well as many of the intended advantages thereof, will become more readily apparent when reference is made to the following description, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

[0021] FIG. 1 is a perspective view of the introducer in accordance with the preferred embodiment of the invention;

[0022] FIG. 2 is a side cross-sectional view of the introducer of FIG. 1;

[0023] FIG. 3 is an exploded view of the wheel apparatus of FIG. 2;

[0024] FIG. 4 is a side view of the wire connector used to couple the drive wire to the guide wire in FIG. 1;

[0025] FIG. 5 is a side cross-sectional view of the introducer just prior to a needle being placed on the introducer;

[0026] FIG. 6 is a side cross-sectional view of the introducer coupled with the needle;

[0027] FIG. 7 is a side cross-sectional view of the introducer with the guide wire extended;

[0028] FIG. 8 shows the hub extended forward on the guide wire;

[0029] FIG. 9 shows the hub and catheter that remains in a patient's body following removal of the introducer and introducer needle;

[0030] FIG. 10A is an alternative embodiment of the introducer;

[0031] FIG. 10B is a perspective view of the wheel assembly in accordance with an alternative embodiment of the invention;

[0032] FIG. 11A is a perspective view of the introducer device having needle handles and hub handles with the two-wheel assembly of FIG. 10B;

[0033] FIG. 11B is a perspective view of the introducer device of FIG. 11A having a needle cover;

[0034] FIG. 11C is a detailed view of the needle cover tip having projections;

[0035] FIG. 12 is a graph showing UV detectable materials;

[0036] FIG. 13 is a perspective view of a probe cover assembly prior to being applied to a probe in accordance with another embodiment of the invention;

[0037] FIG. 14 shows the cover assembly of FIG. 13 fitted to a probe;

[0038] FIG. 15 shows the container removed from the cover with the probe ready to be used;

[0039] FIG. 16 shows a UV assisted introducer kit in accordance with another embodiment of the invention;

[0040] FIG. 17 is a bottom view of the kit of FIG. 16; and

[0041] FIG. 18 shows the patient resting an arm on the kit of FIG. 16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0042] In describing a preferred embodiment of the invention illustrated in the drawings, specific terminology will be resorted to for the sake of clarity. However, the invention is not intended to be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents that operate in similar manner to accomplish a similar purpose. Several preferred embodiments of the invention are described for illustrative purposes, it being understood that the invention may be embodied in other forms not specifically shown in the drawings.

[0043] This catheter has several features which will improve medical treatment. With these added features, the catheter makes IV placement with ultrasound easier, more efficient, and more accurate, thus significantly decreasing pain experienced by the patient by reducing the number of IV sticks currently performed.

[0044] As shown in the drawings the invention comprises of multiple elements that have separate novel advantages and features, but also can be utilized together to improve medical treatment by making IV placement with ultrasound easier, more efficient and more accurate, and reducing pain. Those elements include a catheter introduction apparatus (FIGS. 1-11B), a UV-visible catheter (FIG. 12), a needle cover with marking means (FIG. 11A-11C), a probe cover (FIGS. 13-15), a sterile kit package (FIGS. 16-18), and a catheter having finger tabs (FIGS. 11A, 11B).

The Introducer Apparatus 10 (FIGS. 1-11)

[0045] Turning to FIGS. 1-10, an illustrative non-limiting embodiment of the introducer apparatus 10 is shown. As best shown in FIG. 2, the introducer 10 has a housing 100, wheel assembly 130, drive wire 12, and guide wire 14. The housing 100 is slightly elongated and ergonomically shaped to fit in the palm of a user's hand. The inside of the housing 100 is hollow, such that the housing 100 forms a wall 104. The housing 100 has a front end 108 and a rear end 106. An opening 102 is provided at the rear end 106.

[0046] An elongated coupling 114 extends forward from the distal front end 108 of the housing 100. The coupling 114 has the shape of an elongated post having a round cross-section. The coupling 114 has a central opening. At the front of the coupling 114, the central opening is sized to be slightly larger than the guide wire 14. At the middle of the coupling, the opening gets progressively larger to the rear end of the coupling 114. The tapered opening forms guide walls 116 that funnel the guide wire toward the smaller portion of the opening so that the guide wire 14 can be pushed through the coupling 114 and out of the coupling 114 without stubbing or damage.

[0047] A guide post 110 is also provided at the front end 108 of the housing 100. The guide post 110 extends forward from the front end 108. The post 110 is elongated, has a square-shaped cross-section (though any suitable shape can be utilized), and extends substantially parallel to and slightly spaced apart from the coupling 114. The post 110 is shorter than the coupling 114, but creates a channel 112 between the post 110 and the coupling 114. An injection needle can then be received over the coupling 14 and is further secured in the channel 110 by the post 110. There can be a single post 110 positioned above the coupling 114 (FIG. 2) or two posts on opposite sides of the coupling 114 (FIG. 1), or both a single

post 110 above the coupling and two posts on opposite sides of the coupling. It will be apparent that any number of posts 110 can be provided and positioned anywhere about the coupling 114 to reliably receive and retain the injection needle. In addition, other coupling means can be provided to reliably couple the needle to the housing 100.

[0048] As best shown in FIG. 1, the wheel assembly 130 is provided in an opening 103 located at the top of the housing 100 at the front end 108. As more fully shown in FIG. 3, the wheel assembly 130 includes a wheel 132 with teeth 134 that extend transversely along the outer circumferential edge of the wheel 132. The teeth 134 enable the user to more easily turn the wheel 132. A small circular post or drum 136 is provided on one side of the wheel 132. The circular drum 136 projects outward from the side of the wheel 132 and is concentrically aligned with the wheel 132. A through-hole 138 extends transversely through the center of the drum 136 and the wheel 132. A pin 140 extends through the through-hole 138 and engages openings in the two opposing sides 101 (FIG. 1) of the housing 100 so that the wheel 132 can rotate about the pin 130. The drum 136 is fixed to the wheel 132 so that the drum 136 rotates as the wheel 132 rotates.

[0049] Returning to FIG. 2, one end of the drive wire 12 is partly wrapped about the drum 136. For instance, the distal end of the drive wire 12 can be at least partially placed in a hole 137 (FIG. 3) that extends at least part way through the drum 136 to hold the drive wire 12 in place on the drum 136. Other suitable coupling methods can be used, such as adhesive, or a fastener. Thus, the user can wind the drive wire 12 to retract the drive wire 12. The drive wire 12 is sufficiently rigid to retain a straight form, but sufficiently flexible to wind about the drum 136 of the wheel 132.

[0050] Still referring to FIG. 2, a lock assembly 150 is located just behind the wheel assembly 130 on the housing 100. The lock assembly 150 includes a locking tab 152, cover 156, nut 162, bolt 164, and display area 158 that can be used to present a logo or directions to the user. The bolt 164 extends through an opening in the housing 100 and an opening in the locking tab 152. The head 160 of the bolt 164 is outside of the housing 100 and the bolt 164 attaches to a nut 162 located on the opposite side of the locking tab 152. The bolt 164 fastens the tab 152 in place on the housing 100 to engage the teeth 134 of the wheel 132. The locking tab 152 is a flat element that extends to the teeth 134 on the wheel 132. The tab 152 can be somewhat flexible, so that the user can operate the wheel 132. However, the tab 152 prevents the wheel 132 from moving when not be operated on by the user, and in particular prevents the wheel 132 from moving backwards to retract the drive wire 14. The tab 152 can also make a clicking noise as the wheel 132 is being moved forward, to provide an audible and/or tactile feedback that confirms to the user that the wheel 132 is being moved. Though a bolt and tab 152 are shown, it will be readily apparent that other mechanisms can be provided to prevent unintended operation of the wheel 132. For instance, the wheel 132 can be friction fit into the opening 103 so that a slight force is needed to move the wheel 132. The cover 156 extends over the bolt head 160 so that the user does not get injured by the bolt head 160. The cover 156 can be adhered or fastened to the housing 100.

[0051] A connector or plug 170 is provided at the distal ends of the drive wire 12 and the guide wire 14. As best shown in FIG. 4, the connector 170 is configured to engage both the drive wire 12 and the guide wire 14 so that the guide wire 14 moves when the drive wire 14 moves. The connector 170 has

a connector body 171 that includes a first opening 172 that receives the drive wire 12 by a friction fit. The body 171 also has a post 174 that extends forward and has an opening that receives the guide wire 14 by a friction fit. In addition, the body 171 includes a guide post or guide tab 176 that extends forward substantially parallel to the drive wire 12. A small channel is formed between the tab 176 and the drive wire 12 to receive and engage a tube or sheath 15 (FIG. 1) that surrounds the two wires 12, 14 to prevent injury to the user or patient. A slit extends the entire longitudinal length of the sheath 15, and the guide post 176 moves through the slit. This keeps the drive wire 12 and the guide wire 14 properly oriented with respect to each other during operation and so they do not become twisted. Instead of a sheath 15, the housing 100 can be extended to cover the two wires 12, 14.

[0052] Operation of the introducer 10 will now be discussed with respect to FIGS. 5-9. In these illustrative non-limiting embodiments, the introducer 10 is coupled with a conventional introducer needle assembly 200 having a standard catheter. One example of a suitable needle assembly is offered by Smiths-Medical, JELCO® I.V. Catheter, <http://www.smiths-medical.com/catalog/peripheral-catheters/conventional-catheters/jelco-conventional-catheters/jelco-v-catheter-radiopaque.html>. It will be recognized however, that the introducer 10 can be used with other suitable devices, such as Insite™ Autoguard™ Shielded IV Catheters by Becton Dickinson (<http://www.medline.com/product/Insite153-Autoguard153-Shielded-IV-Catheters-by-Becton-Dickinson/IV-Catheters/Z05-PF29088#.UwqiYfldWo0>), Introcath® IV Catheter Straight by B Braun (<http://www.medline.com/product/Introcath-Safety-IV-Catheter-Straight-by-B-Braun/IV-Catheters/Z05-PF70731#.UwqiufldWo0>), IV Catheters by Exel International (<http://www.medline.com/product/IV-Catheters-by-Exel-International/IV-Catheters/Z05-PF29139#.Uwqi-vldWo0>), and OPTIVA® IV Catheters by Smiths Medical (<http://www.medline.com/product/OPTIVA-IV-Catheters-by-Smiths-Medical/IV-Catheters/Z05-PF52843#.UwqjavldWo0>).

[0053] As shown in FIG. 5, the needle assembly 200 has a round tubular housing 204, needle 202, hub 206 and support member 208. The housing 204 has a first end that is open and mates with the coupling member 114. The support member 208 is fitted at an opposite end of the needle housing 204 and the hub 206 is placed about the support member 208. The needle 202 extends through openings in the hub 206 and support member 208 and partly into the front end of the interior of the housing 204. The coupling 114 of the introducer assembly 10 aligns the guide wire 14 with the needle 202 of the needle assembly 200. A catheter 300 extends over the outside of the needle 202 and terminates at and couples with the hub 206.

[0054] The operation starts with FIG. 5, where a needle assembly 200 is aligned with the introducer 10. The drive wire 12 and guide wire 14 are fully retracted at the rear of the introducer 10. Turning now to FIG. 6, the user places the needle assembly 200 on the introducer 10. The tubular housing 204 of the needle assembly 200 is slidably received over the coupling 114 of the introducer 10. The housing 204 wall enters the channel(s) 112 between the one or more post(s) 110 and the coupling 114. The needle housing 204 fits snugly about the coupling 114, so that the needle assembly 200 does not come free of the introducer 10 until operated on by the user. As shown, the guide wire 14 is aligned with the needle 202. It will be appreciated that though this is described as a

manual process, the introducer 10 can come pre-loaded with a needle assembly 200 already positioned on the introducer 10. Or the introducer 10 can have a needle integrally formed with the introducer 10.

[0055] At this point the user places the needle 202 into the patient, such as the vein or artery lumen. To do so, the needle cover 250 (14G, 11B) is first taken off of the needle and the needle cover tip 252 (FIGS. 11B, 11C) is used to mark the skin surface either with pressure or a marking ink in two spots to give directional marking for the direction of the cannulation. The needle cover tip 252 has one or more projections 254 that extend forward from the front surface of the tip 252. The projections 254 shown are concentric curves that form a company logo. However, the projection(s) 254 can have any shape, such as an arrow, line, or dot. Ink can be placed on the projections 254 and applied to the patient. Or, the projections 254 can be pushed into the patient's skin without ink, to cause pressure indentations on the patient. The user can use the inked cap to place directional markings on the patient. Without this it can be difficult to place cannula once it has entered under the skin. This can be especially useful with ultrasound guidance. Both marks are made at points along the vessel. The cannula (also called a catheter) 300 is placed in the direction of this guidance in line with the vessel and the needle 202 is inserted into the patient. For deep vessels and small vessels the directional marking is of particular advantage. To visualize smaller vessels ultrasound can be used. As further shown in FIG. 11B, the needle cover 250 has a main tube that extends the length of the needle 202, and one or more arms 256 at the rear end that extend outward and upward over the top of the hub 206. The arms 256 protect the hub 206 and make it easy for the user to remove the cover 250. The cover 250 can come pre-assembled over the needle 202, and protects the user from being injured by the needle 202.

[0056] Returning to FIG. 6, after the needle cover 250 is removed, the needle is aligned along the skin with the two points marked for direction and then inserted into the lumen of the vessel. Once the needle 202 is properly placed, the user turns the wheel 132 forward with an index finger in the direction X. This operation can be done using a single hand of the user. Since the needle 202 is already positioned in the vein, the user simply rotates the wheel 132, which is easy to reach because it is at the front end 108 of the housing body 100. Thus, the user can retain hold of the housing 100 in the palm of the hand and (without moving his hand) operate the wheel 132 with the index finger. In addition, the user holds the introducer 10 steady (i.e., it does not have to be moved forward) and allows the movement of the wheel 132 to advance the guide wire 12, so that single-handed operation is possible. Single-handed operation is further made possible by the contour shape of the hub. Thus, the user can hold an ultrasound probe in the other hand to assist placement of the guide wire 12 and catheter 300. The tab 152 prevents the wheel 132 from moving in reverse.

[0057] As the wheel 132 is moved forward, it draws the drive wire 12 further onto and around the wheel drum 136. This, in turn, causes the connector 170 to push the guide wire 14 forward (to the left in the embodiment of FIG. 7). The guide wire 14 enters the central opening in the needle 202 and continues through the needle 202 until it emerges from the distal tip of the needle 202 and enters the patient, as shown in FIG. 7. Accordingly, the guide wire 14 threads the vessel lumen.

[0058] The thin guide wire **14** is then ready to have the soft plastic catheter **300** slid over the guide wire **14** into the vessel lumen. As shown in FIG. 8, once the guide wire **14** has entered the user's vein (which is roughly one to two and a half inches depending on catheter length), the user pushes the hub **206** (or finger tabs on the catheter **300**, if used) forward to force the catheter off the needle **202** and into the patient. The support **208** keeps the needle **202** positioned on the introducer **10**. The catheter **300** can be pushed into the patient further than the needle **202** and/or guide wire **12** since it is more flexible and won't puncture the side of the vein or vessel. The user can then remove the needle **202** and guide wire **12** from the patient, leaving the catheter and hub **206** properly placed in the patient, as shown in FIG. 9. The user can then connect a syringe, intra venous (IV) device or other medical instrument at the rear end of the hub **206**.

[0059] Turning to FIG. 10A, an alternative embodiment of the invention is shown. Here, the needle **202** is an elongated shank portion having a beveled tip. The shank is hollow or cannulated and is joined at its rear or end to a hollow transparent hub **2** having a rounded front end. The catheter **300** is sized to be telescopically fitted over the shank of the needle **202**. As with FIGS. 1-9, the catheter **300** is slightly shorter than the needle **202** so that when it is fully pushed back against the needle hub **2** the beveled tip **5** of the needle projects outwardly from the catheter tip **4** by an amount sufficient to permit puncture of the blood vessel by the user of the device. A female luer-type fitting **9** is formed on the rear of the catheter and mates with and fits over a shoulder projection **11** on the front of the hub **2**. The wire guide assembly **3** includes an elongated tubular member **19** which is fitted into the counter bore at the end of hub **2**. The tubular member **19** can be formed of a transparent, semi-rigid plastic material, and have sufficient resilience to maintain its tubular configuration and use. A guidance tab **16** interfaces with the hollow, grooved tube **19**. The tab **16** is attached to the back of the guide wire, and slides through the groove, making sure that the wire does not tangle or twist. The shoulder projection **11** is a solid plastic piece that is part of the housing and holds the wheel. A flash guard **13** keeps blood from spilling or squirting out the back end of the device. A safety cap **18** is also provided that can be removed when the device is used.

[0060] In its preferred form, the tubular member **19** has a longitudinally extending slot running from a point adjacent the needle hub **2**. A plug or other suitable sealing means provides a seal for the end. An elongated flexible spring wire guide is housed within tubular member **19**. A wheel is provided that directly acts on the spring wire guide to advance the spring wire guide. This can be done, for instance, by a drum or shaft that is attached to the wheel. The outer surface of the drum can press the guide wire between a fixed surface on the housing to physically move the guide wire forward by friction. The drum can have a surface that grabs the guide wire.

[0061] A laterally or radially extending handle **7** is fastened to its rear end handle projects through the slot and is adapted to advance the spring wire guide through the lumen through needle and outwardly from the distal end into and through the lumen of the blood vessel. For facilitating this insertion with the use of one hand the index finger pushes one of the finger tabs on either side of the cannula **4**. Once in place the cannula **4** can be secured with the securing tabs. The securing tabs can be secured to the skin, either with an adhesive tape or sutured into place through the holes in these tabs.

[0062] The tabs **210** are best shown in FIG. 11A. The needle **202** is connected to a hub **206** having a rounded front end. Handles or tabs **212** are connected to the catheter, and handles or tabs **210** are connected to the hub **206**. The catheter handles **212** and the hub handles **210** are elongated and rectangular, and extend outward substantially transverse to the catheter **300** and hub **206**, respectively. The user can grab the tabs **202** to push the catheter **300** forward. And the user can grab the tabs **210** to push the hub **206** forward. Thus, the hub **206** has elongated slots to receive the hub handles **210**. The catheter handles **212** and the hub handles **210** are easier for the user to grab and operate.

[0063] As further shown in FIG. 11A, a flash chamber **214** can be provided behind the hub **206**. The flash chamber **214** allows the user to see blood and fluid. Once the vessel is pierced by the needle **202**, blood enters the flash chamber **214**. The flash chamber **214** is transparent, so that the user can visually confirm that the vessel has been pierced but to keep the blood from getting on the practitioner, patient or device. The chamber **214** has a tab **216** that can connect to a safety cap. In the present embodiment, the needle **202** is connected to the flash chamber **214**, but the flash chamber **214** is not connected with the hub **206**. The catheter **300** is connected to the hub **206**.

[0064] Turning to FIG. 10B, an alternative embodiment of the wheel assembly of FIGS. 1-9 is shown. Here, the wheel assembly **230** has two wheels **232** separated from each other by a slight gap **233**. The wheels **232** have an outer circumferential edge that can have transverse ridges, a roughened surface or an easy to grip surface (such as rubber), to make it easy for the user to operate the wheels **232**. A circular drum **234** is affixed to or integral with the side of one of the wheels **232**. The drum **234** has an outer circumferential edge with large transverse ridges or teeth **236** positioned thereabout. A locking structure **238** is coupled to the housing **100** of the introducer **10** and aligned with the drum **234**. The locking structure **238** has a top inner surface that is aligned with the drum **234**, and can optionally include at least one mating tooth that engages the drum teeth **236**. The drum teeth **236** are configured so that the wheel **232** can advance the guide wire **14** into the patient, but that the wheel **232** cannot be reversed. The inner surface of the locking structure **238** can also rub against the surface of the teeth **236** so that the wheel **232** does not move without being operated on by the user. A pin **240** extends through the center of the wheels **232** and drum **234** to permit the wheels **232** and pin **240** to rotate with respect to the housing **100**. The drive wire **12** extends into the gap **233** between the wheels **232** and the end of the drive wire **12** is wrapped about the pin **240**. Thus, as the user operates the wheels **232**, the drive wire **12** wraps around the pin **240** and advances the guide wire **14** into the patient. The pin **240** can optionally have a widened portion at the gap **233** to receive the drive wire **12**. Or, the two wheels **232** can be connected together as a single wheel that has a channel which receives the drive wire **12**, and the pin **240** need not move. It will be apparent that other suitable configurations can be provided within the spirit and scope of the invention.

[0065] Usually the wire guide **12** only needs to be fed forward, so the default state of the wire guide feed wheel assembly prevents backward feeding. To prevent backward feeding, the tab **152** (FIG. 2) or gear box **238** (FIG. 10B) unidirectional block movement of the drum teeth **236**. In order to allow backward feeding of the wire guide, a user can unscrew the bolt **164** (FIG. 2) or push down on the wheels **232**

(FIG. 10B) and rotate the wheels **232** in the direction opposite of that for forward feeding. Pushing down on the wheels **232** moves the drum **234** away from the gear box **238**, enabling backward rotation. A spring **23** can maintain the drum teeth **236** in contact with the gear box teeth in the default setting.

[0066] The entire introducer **10** can be made of a plastic medical grade polymers and UV cure adhesives), except that the tab **152**, bolt **164**, nut **162**, drive wire **12** and guide wire **14** are preferably made of metal (such as stainless steel, 300 series). The entire introducer can be sterilized and packaged in a sterilized container, such as being heat sealed in a plastic bag. A typical material for the catheter is Tecollex EG-80A polyurethane. Component materials are usually a polycarbonate like Lexan HP4 or an ABS like Cycolac HMG47MD.

[0067] In a non-limiting illustrative embodiment of the invention, the coupling element **114** is about 1cm long with a diameter of about 4 mm. The introducer **10** is about 6.2 cm long (including the coupling element **114**), and has a width of about 3.8 mm. The wheel **132** has a diameter of about 1.4 cm. The drive wire **12** has a length of about 20-29 cm, and the guide wire **14** has a length of about 18-27 cm so that the guide wire **14** can be advanced through the longest needle that is used. The coupling **114** can be sized to fit any needle, and the guide wire **14** can be sized to any size needle. Common site needles are 16-18 gauge, but larger gauges such as 14-15 would be suitable, and still larger or smaller needles may be suitable as well.

[0068] The Ultrasound-Guided IV Catheter has a number of features that make placement of the catheter in deep peripheral vessels easier. First, it has an inked cap that permits the user to mark the location and direction of the vessel as visualized by the ultrasound machine. This gives directional guidance to the catheter along the vessel for insertion. The cap can mark the skin for directional guidance. When placing an ultrasound guided IV catheter the medical professional placing that catheter can get lost as to the direction of the needle in relationship to the vessel. The Ultrasound gives a two dimensional image which does not show direction. The cap on the ultrasound guided IV marks the surface of the skin so the direction of the vessel can be marked on the skin. For instance, the marking can have an ink spot or directional arrow indentation into the skin, allowing the catheter to be aligned to the vessel. The medical professional can then align the needle/catheter which the markings and not miss the vessel.

[0069] Second, the catheter has a slender guide-wire that can easily thread smaller, deeper vessels. The guide-wire can easily thread deep vessels and advance the catheter without catching on the vessel walls. The ultrasound is used to find deeper vessels which cannot be visualized by the human eye. These deep vessels are difficult to thread with the soft large plastic catheters. The catheter can catch on the sides of the vessel and thus not slide easily into the lumen of the vessel. The Ultrasound guided IV catheter uses a thin guide wire to thread deep vessels. The guide-wire is placed within the lumen of the vessel first and then the catheter is threaded over the catheter, preventing the catheter from getting caught on the sides of the vessel wall.

[0070] The guide-wire and catheter can be advanced and placed with only one hand so that as one holds the catheter with one hand the other hand holds the ultrasound and visualizes correct entry into the vessel. The drive wheel advances the guide wire **14**, and the catheter tabs or hub advance catheter over the guide-wire. The other hand is free to manipulate

the ultrasound. When moving the guide-wire into the vessel a traditional catheter needs two hands for guide-wire placement: one hand placing the catheter and the other hand advancing the guide wire. The Ultrasound guided IV catheter advances the guide-wire and catheter with the same hand. This gives a unique advantage to ultrasound guidance because one person can use his spare hand to hold the ultrasound to visualize the guide-wire and catheter being advance ensuring placement in the vessel lumen.

[0071] The present introducer avoids potential complications with exposure to blood and fluid, and provides a tactile resistance. The drive wire also provides a spring-like behavior when wound about the wheel assembly to provide greater control of the advancement and retraction of the drive wire. However, it will be apparent that other configurations of the introducer may be possible within the spirit and scope of the invention. For instance, the drive wire can be eliminated and the guide wire directly connected to the wheel assembly to push the guide wire.

The Visible Catheter **300** (FIGS. 11-12)

[0072] Another object of the invention is to provide a catheter, both central and peripheral, that can be visualized by ultrasound, to enable correct placement to be determined and recorded by ultrasound visualization. Catheters, both central and peripheral, which are easily visualized by ultrasound, enable correct placement to be determined and recorded by ultrasound visualization.

[0073] It is noted that current catheter materials cannot be detected by ultrasound. In the present embodiment of the invention, the catheter **300** is constructed of materials that can be easily visualized under ultrasound. For instance metals, ceramics, or compounds (like barium sulfate or titanium), can be integrated within the stricture of the catheter material allowing for direct visualization of catheter placement with the ultrasound. As an example, one could confirm by ultrasound that a catheter intended to be placed in a vein is in fact located in a vein and not in an artery or outside any blood vessel.

[0074] Ultrasound properties are material dependent. The sound velocities and impedance values of typical catheter materials such as plastics, urethanes or rubbers are very low (0.959-2.06 km/s and 1.41-2.00 MRayl) compared to metals such as, aluminum, copper and Titanium (5.01-6.3 km/s and 17.0-44.6 MRayl). The properties for low density polyethylene and Titanium are compared in FIG. 12. This demonstrates that as the density of a material changes, so do it's acoustic properties. Materials of different densities will appear as distinct and different in an ultrasound image.

[0075] In yet another embodiment of the invention, the outer surface **304** of the catheter is coated with metallic material such as Titanium, the catheter. This makes the catheter **300** detectable by ultrasound, because the high impedance surface will reflect some of the sound. A specific length of the catheter to be detected by ultrasound is coated with a metallic coating, such as by using sputtering. Thus, only a portion (the front end) of the catheter **300** can be coated or made of UV visible materials. Sputtering is a Physical Vapor Deposition vacuum process used to deposit very thin films onto a substrate for a wide variety of commercial and scientific purposes. Sputtering occurs when an ionized gas molecule is used to displace atoms of a specific material. These atoms then bond at the atomic level to a substrate and create a thin film. Several types of sputtering can be used, including: ion

beam, diode, and magnetron sputtering. Sputtering units are available commercially and not only they can help in coating a variety of metallic materials, but the thickness of the coating can also be measured during the sputtering process. The coating thickness is typically in Angstroms. Preferably, Titanium is used best mode, because of its biocompatibility and excellent corrosion resistance to a broad range of possible corroding media that may be encountered in the field of medicine.

[0076] It is noted that the catheter 300 and the introducer 10 (FIGS. 1-10) of the invention have separate utility and need not be utilized together. For instance, the catheter 300 can be utilized with any catheter introduction set, and not only the introducer 10 of the present invention. In addition, the introducer 10 can be used to place any conventional catheter, and need not be utilized with the catheter 300 of the present invention. Notwithstanding those separate uses, the catheter 300 and introducer 10 of the invention have certain advantages when utilized together (FIGS. 1-10). Because the catheter 300 is visible to UV detection and the introducer 10 allows the user to perform IV insertion with a single hand, the user can perform UV detection at the same time he/she is inserting an IV into the patient. Thus, the user can confirm proper placement of the needle 202, as well as the catheter 300, during and immediately after insertion. The user can perform the catheter 300 placement with a single hand using the introducer 10, and with the other hand can track placement of the needle 202 and the catheter 300 in the patient.

Probe Cover 400

[0077] Another embodiment of the invention is shown in FIGS. 13-15. A sterile cover set 400 is provided that can be placed over the transducer end of a piece of medical equipment, such as an ultrasound probe 402. The sterile probe cover set 400 includes a sterile probe cover 404 and a container 410. The cover 404 is open at the top (i.e., no lid or cover) and can be made of rubber or latex for instance, can have the general shape of the probe 402 and is sized to fit snugly over the probe 402. In the embodiment shown, the cover 404 is shaped like a bag, with a bottom and sides and can optionally match the shape of the probe end 401. The container 410 can have a similar shape as the cover 404 and is slightly wider than the cover 404. The container 410 is shorter than the cover 404 so that the tops 406 of the sides extend beyond the top of the sides of the container 410. In the current embodiment, the container 410 can be a circular piece, with a bottom and sides, or can be a tube with no bottom, or can have a rectangular shape. The container 410 can optionally match the shape of the probe end 401. The container 410 can be made of cardboard or from hard plastic or other material which can maintain its shape and the shape of the rubber sterile probe cover 404. The container 410 is wider than the probe and the cover 404, so that the cover 404 is stretched and can be easily fit over the end 401 of the probe 402.

[0078] The cover 404 is pre-assembled to be inside the container 410, and the top sides 406 of the cover 404 are stretched and folded down over the top sides of the container 410. The container 410 and cover 404 are packaged in a sealed plastic bag, and the entire packaging is sterilized.

[0079] When the probe 402 is ready to be used, the user opens the sealed plastic bag and removes the container 410 with the cover 404 positioned inside of the container 410. The user should preferably hold the assembly by the container 410. However, only the inside of the cover 404 is exposed

(since the cover is turned inside-out at the top sides 406), so the user can touch the cover 404 without contaminating the outside of the cover 404.

[0080] As shown in FIG. 13, the user then pushes the container 410 and cover 404 over the end of the probe 402, so that the sterile probe cover 404 is wrapped around the probe 402. Optionally, ultrasound gel can be placed on the surface of the sterile probe cover prior to placing it on the ultrasound probe. Referring to FIG. 14, the cover 404 and container 410 are positioned over the probe 402. The top sides 406 of the cover 404 are then folded up, off of the container 410 and onto the probe 410. Because the top sides 406 were stretched to fit over the container 410, the top sides 406 will retract inward and form a snug fit on the probe end 401. At this point, the cover 404 is on the probe 402. Referring to FIG. 15, the container 410 is then removed from the probe 402, leaving the sterile probe cover 404 on the probe transducer end 402. During the process, the sterile probe cover remains sterile, because the operator only touches the container 410. The sterile probe cover 404 is never touched by the operator.

[0081] It should be appreciated that the assembly 400 can be preassembled so that the top portion 406 is folded downward over the top of the container 410. The cover 404 may need to be stretched in order to do so, and so that the cover 404 fits the probe. In accordance with one embodiment of the invention, the probe cover is less than 3 inches deep, 4 inches in width and 4 inches in height. It will be appreciated that while a snug fitting cover 404 is provided in the current embodiment, a longer and looser fitting cover 404 can be provided that is secured to the probe 402 by rubber bands or the like.

The Ultrasound Introducer Kit

[0082] One object of the invention is to provide a catheter introduction set that is particularly well suited for use with a single hand. The catheter introduction set includes a proximal end and a distal end, with the proximal end able to couple with a needle. The introducer device can either come packaged and mated with a catheter and introducer needle, or be mated by the user with another prepackaged needle. To enable single-handed use, the means to control the guide-wire is located within the proximal two-thirds of the catheter introduction set. An additional inventive step enabling single-handed use is the introduction of cannula progression means that are located within the proximal two-thirds of the catheter introduction set.

[0083] Turning to FIGS. 16-18, another embodiment of the invention is shown. Here, an introducer kit 500 is provided. The kit 500 includes a case or box 501 having a base 502 and a lid or top 504. The box 501 is rectangular in shape and the top 504 is larger than the base 502 so that it is easy to remove the top 504. As best shown in FIG. 17, the box also has a bottom 506. A pad 508 is provided at the exterior surface of the bottom 506. The pad 508 can be at a portion of the bottom 506 or extend the entire width and height of the bottom 506. Referring to FIG. 18, the patient can rest his/her arm on the pad 508 during IV placement or other medical procedure. The pad 508 stabilizes a body part that is to be catheterized. In the embodiment shown, the pad 508 of the kit case 500 stabilizes the patient's arm at the elbow to assist in catheterization of the anti-cubital veins. In an alternative embodiment of the invention, the bottom 506 can have a concave shape instead of a pad 508.

[0084] The box 501 has an interior space that is used to retain medical equipment that is useful for a medical practitioner to perform a medical process, in particular an ultrasound assisted vessel cannulation. Thus, the kit 500 includes all the single-use components necessary for ultrasound assisted vessel cannulation, including: catheter introducer 10 (FIGS. 1-10); catheter tubing 300 (FIG. 11); probe cover set 400 (FIGS. 13-15); lidocaine solution; sterilizing solution and applicator; suture material; suturing needle; gauze pads; scalpel; drape with adhesive; towel; sterile US gel packet; two rubber bands; directional marker; normal saline flush; and tourniquet. It will be appreciated, however, that the kit 500 need not include every single element listed here, and still be within the spirit and scope of the invention. In particular, the introducer 10, catheter tubing 300, and probe cover set 400 of the invention need not be provided with the kit 500, and any conventional introducer, catheter tubing and probe cover can be provided. The box 501 and its contents can be placed in a heat-sealed plastic bag and sterilized.

[0085] For use in vessel cannulation, the patient is first placed in a recumbent position. After the contents are removed from the sterile package the box 501 is flipped so that the ergonomically designed bottom faces up and the elbow is placed on this surface to facilitate stabilization for cannulation. The kit keeps all necessary materials located in a single convenience place in a sterile manner. The box 501 provides arm stabilization for sale and successful cannulation.

[0086] The foregoing description and drawings should be considered as illustrative only of the principles of the invention. The invention may be configured in a variety of shapes and sizes and is not intended to be limited by the preferred embodiment. Numerous applications of the invention will readily occur to those skilled in the art. Therefore, it is not desired to limit the invention to the specific examples disclosed or the exact construction and operation shown and described. Rather, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

1. A wire introduction device for introducing a guide wire into a body of a patient, the device comprising:

a housing body; and

a wheel rotatably coupled with said housing body, said wheel connected to the guide wire and configured to advance the guide wire into the patient body upon rotation of said wheel.

2. The wire introduction device of claim 1, further comprising a drive wire connected to the wheel, and a connector connecting said drive wire to the guide wire, wherein rotation of said wheel advances the drive wire which in turn advances the guide wire.

3. The wire introduction device of claim 2, further comprising a drum connected to said wheel, wherein the drive wire is coupled with said drum.

4. The wire introduction device of claim 2, further comprising a rear opening located at a rear end of said housing, wherein said drive wire and the guide wire extend through the rear opening.

5. The wire introduction device of claim 4, further comprising a sheath positioned about the drive wire and guide wire at the rear opening of said housing.

6. The wire introduction device of claim 1, further comprising an opening at a front end of said housing body, wherein the guide wire extends through the opening.

7. The wire introduction device of claim 6, further comprising an elongated coupling projecting outward from said housing body about said opening and configured to receive a needle having a central opening, wherein the guide wire extends through the central opening of the needle.

8. The wire introduction device of claim 1, wherein said wheel has an outer circumferential edge with ridges, and further comprising a tab coupled to said housing and configured to engage the ridges and prevent said wheel from backward rotation while allowing forward rotation of said wheel.

9. The wire introduction device of claim 1, wherein said device is configured for single-handed operation, whereby the user can hold the device in a single hand and operate said wheel with an index finger of said hand.

10. A catheter comprising a tube for insertion into a human body, and a tab extending from said tube, said tab coupled to said tube and configured to facilitate insertion of said tube into the human body.

11-17. (canceled)

18. A sterile probe cover assembly comprising:

a container having a top edge; and

a probe cover having one or more sides, said one or more sides having a top portion, whereby said one or more sides are received in said container and the top portion of said one or more sides is folded down over the top edge of said container.

19. The probe cover assembly of claim 20, wherein the cover is configured to fit over an ultrasound probe.

20. The probe cover assembly of claim 20, wherein said assembly can slide over the ultrasound probe, the top portion of said one or more sides folded up and onto the probe, and the container removed.

21. (canceled)

22. A intravenous deep vein kit comprising: a box, and one or more intravenous medical devices contained within the box.

23. The kit of claim 22, said box having a bottom configured to stabilize a body part to be catheterized.

24. The kit of claim 23, further comprising a cushion affixed to the bottom of said kit.

25. The kit of claim 23, wherein said bottom has a concave form to stabilize an elbow and arm to facilitate alignment of the arm for catheter placement.

* * * * *

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摘要(译)

深静脉静脉导入器具有朝向装置前端定位的轮子，该轮子可以通过使用者的食指旋转。在将针放置在血管的内腔中之后，使用者旋转轮，使导丝器穿过针的中心并进入患者体内。一旦导丝推进到血管腔中，导管就可以在导丝上前进，导管上的鞍或指状突片靠近食指。可以用一只手进行操作而不用将手从其初始位置移开。然后，用户可以在插入期间同时使用另一只手来操作超声检测设备而无需另一个人的帮助。提供了一种导管，其可以通过超声波可视化，以确认在血管中的正确放置。提供探针盖，其被预先灭菌并包装在纸板中，盖的顶侧向下折叠在纸板上。将盖子放在探头末端上，将盖子的侧面折叠起来，然后取下纸板。无菌探头盖可以快速有效地放置在超声波换能器端。最后，提供了一个套件，其中包含执行插管所需的所有医疗设备。

