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(54) **VASCULAR ACESS DEVICE ULTRASOUND GUIDANCE SYSTEM**

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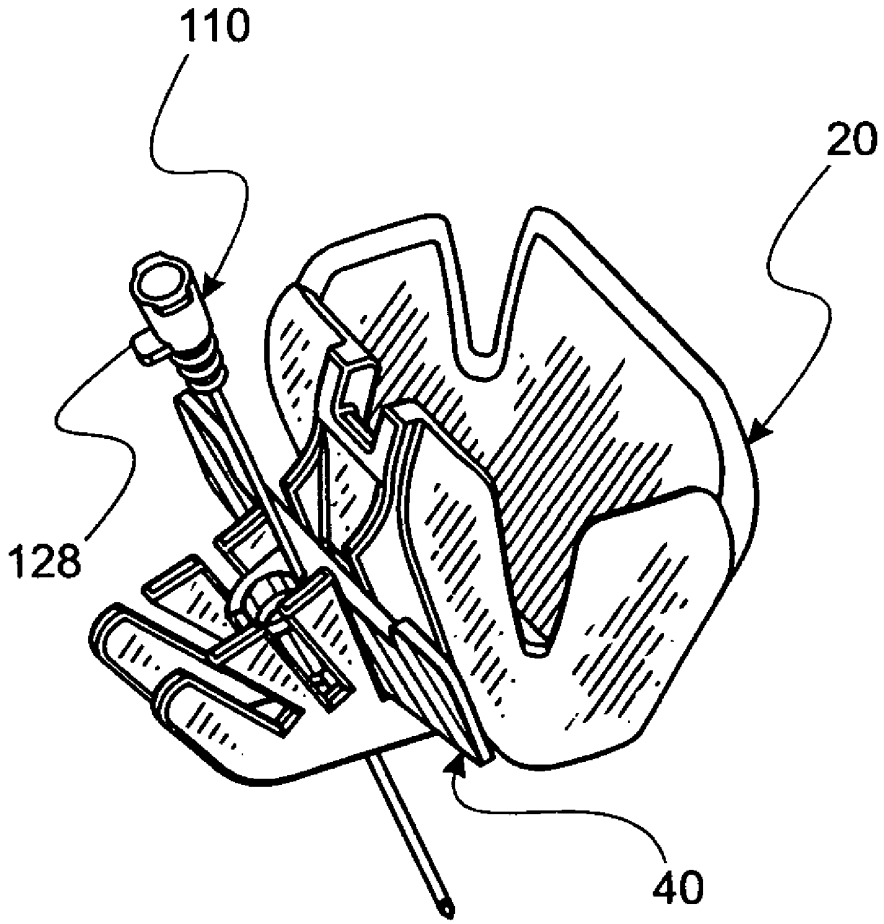
(57) **ABSTRACT**

A vascular access device ultrasound guidance system which provides a novel ultrasound imaging head interface for vessel access. The system comprises a fitted basket/VAD guide for attachment to a hand held ultrasound transducer. The VAD guide, being integrally molded to the fitted basket, comprises a releasible guide assembly for a VAD needle guide. In addition, the needle guide assembly comprises means for anchoring the VAD to a patient's skin following successful insertion. A magnetic needle guide system is disclosed. A fluid sampling device which integrates needle guidance and, safety needle capture in a single guide head is also disclosed.



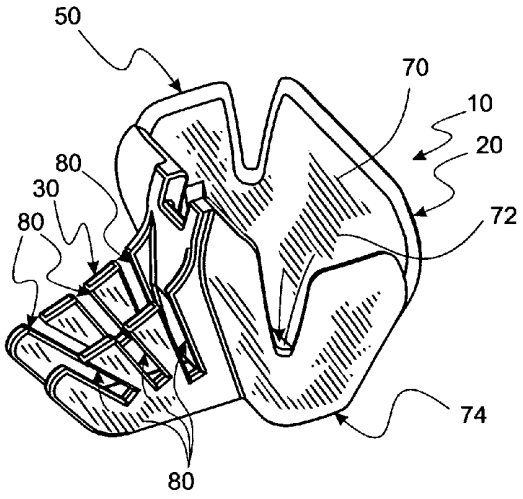


FIGURE 1

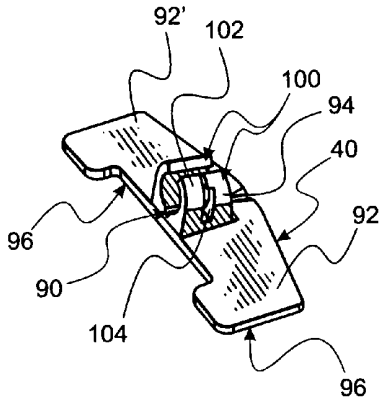


FIGURE 2

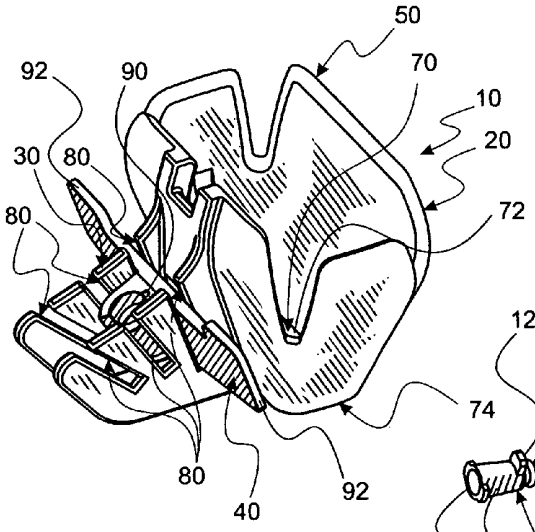


FIGURE 3

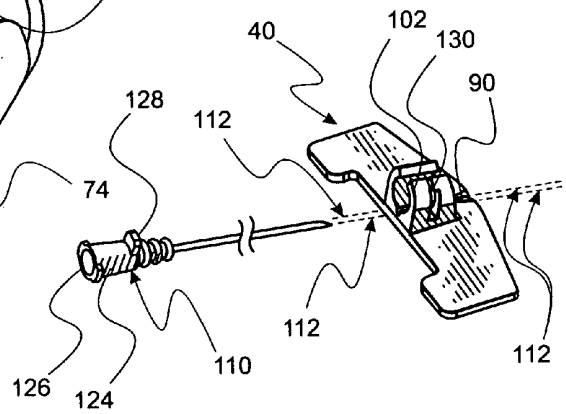


FIGURE 4

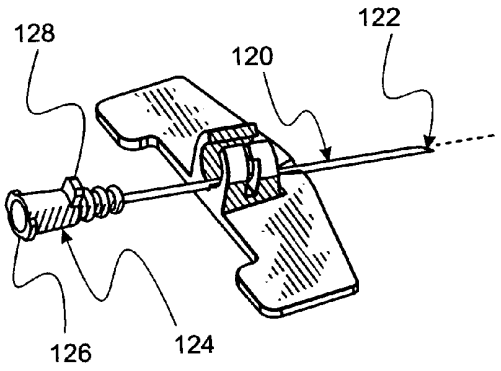


FIGURE 5

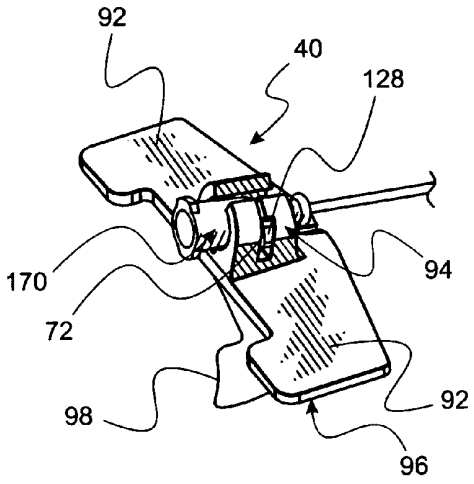


FIGURE 6

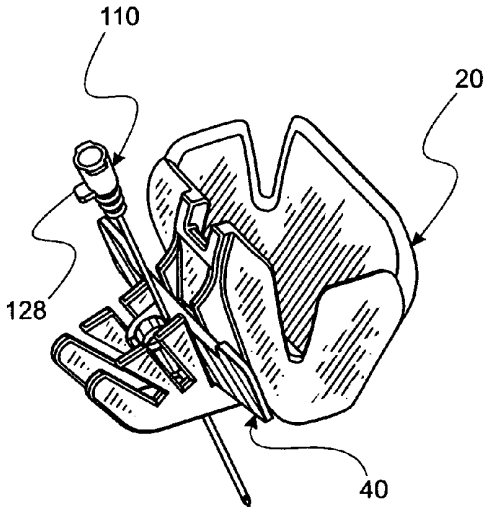


FIGURE 7

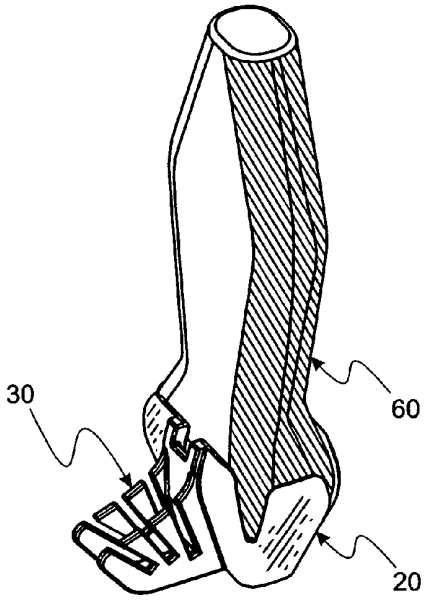


FIGURE 8

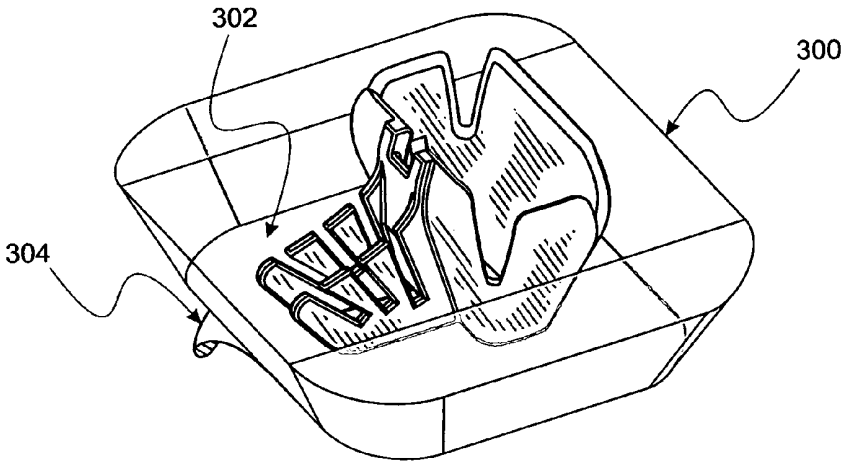


FIGURE 9

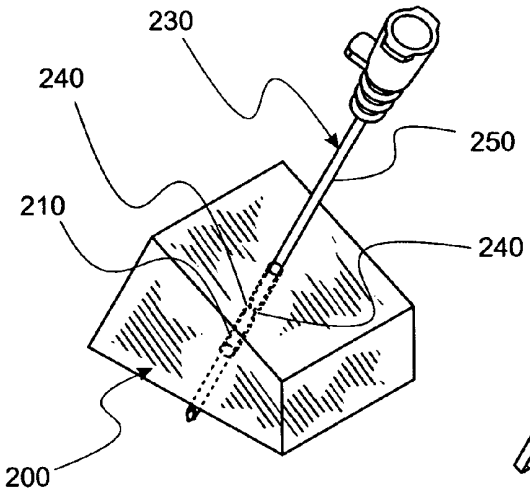


FIGURE 15

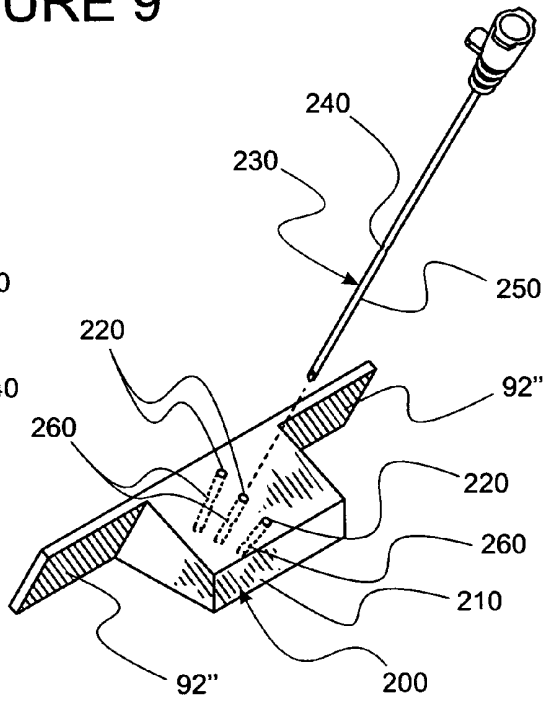


FIGURE 13

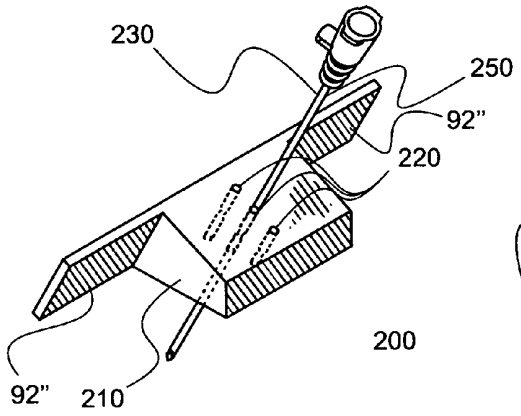


FIGURE 14

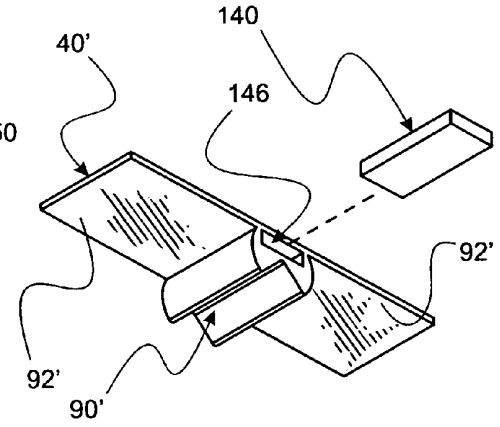


FIGURE 10

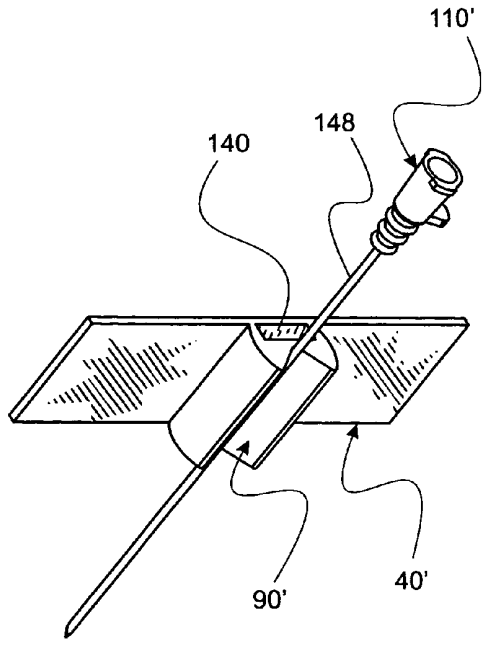


FIGURE 11

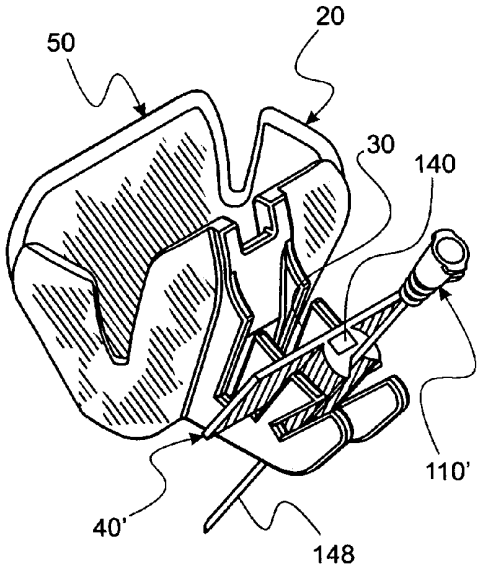


FIGURE 12

VASCULAR ACESS DEVICE ULTRASOUND GUIDANCE SYSTEM

CONTINUATION-IN-PART

[0001] This U.S. Patent application is a Continuation-in-Part of a U.S. Provisional Application Ser. No. 61/630,491 titled VASCULAR ACCESS ULTRASOUND GUIDANCE SYSTEM (VADUGS) and filed Dec. 13, 2011.

FIELD OF INVENTION

[0002] This instant invention is directly related to ultrasound imaging systems and associated devices which are employed in aiding needle access to veins and arteries.

BACKGROUND AND RELATED ART

[0003] Use of ultrasound imaging is well known in medical art. Ultrasound guided vascular access devices (VAD) are being used with increasing frequency, particularly in patients with difficult-to-access veins and arteries. Use of ultrasound guidance, including using a needle guide is the most safe, accurate and effective method for VAD insertion currently available and is proven to increase first-stick success and decrease complications such as infiltration, hematoma and nerve damage. Ultrasound needle guides have been in use for many years. A common example of such being the Bard Access Systems' SiteRite® needle guide, commonly used in ultrasonic placement of central venous catheters (CVC), especially peripherally inserted central catheters (PICC). However, current needle guides are designed primarily for use with full barrier procedures where masks, gowns and full bed drapes are employed. Sterile draping is expensive, time consuming and used almost exclusively by vascular access specialists. Current needle guides are discarded after achieving vascular access and another device is used to secure the VAD to a patient's skin.

[0004] Also, there is no device known to Applicants which is currently available for combining a needle guide with a catheter securement device as a single unit. Combining an easy-to-use, systematized, drape-free sterile needle guide and VAD securement feature in single, dual-function device would offer distinct advantages including: 1) lower cost; 2) easier use; 3) more rapid procedure; 4) result in less waste material; 5) promotion of sterile technique when draping is not used; 6) convenient use of a needle guide that will reduce VAD insertion complications; and 7) better stabilization and securement of inserted VADs immediately after insertion in order to prevent inadvertent movement and/or removal of a VAD.

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

[0005] In brief summary, this novel invention provides novel apparatus and methods for vascular access and VAD securement. The VADUGS is comprised of two primary components: 1) a basket-like fitted transducer cover which includes a needle guide holder; and 2) a needle guide device, referenced by the term "guide and anchor assembly", disclosed in detail hereafter. For brevity and clarity, the transducer cover and needle holder unit is identified by the term "basket" hereafter.

[0006] The basket may be designed to fit or snap onto an ultrasound transducer head. The basket has a sealed opening in the bottom that provides a lens which enables the transducer to "see" through and into adjoining tissue. The basket and sealed opening operate much like current practice of using a sterile sheath to cover a transducer head during VAD guidance. The basket, being sterile, assures sterile insertion of a needle/cannula used therewith.

[0007] The basket also includes a needle guide holder. The holder may comprise as plurality of slots molded into the basket to assure the needle guide is releasibly affixed onto the basket at a pre-desired position for achieving a proper angle and depth for tissue entry of an associated needle/cannula. As such, the needle guide holder permits multiple angles of VAD insertion to meet an objective of more facile and accurate targeting of vessels at varying depths. As an example, one embodiment of the instant invention, provides three slots at varying angles to achieve the objective.

[0008] The guide and anchor assembly comprises a flexible and close fitting needle guide channel into which a needle/cannula is fitted. Further, the guide and anchor assembly has wings which are then fitted into the needle guide holder of the basket. For such, the needle guide holder may comprise slots for positioning an associated guide and anchor assembly channel and needle/cannula into a desired position and angle for advancing the needle/cannula through the skin and into a target vessel.

[0009] The guide and anchor assembly comprises three parts which may be constructed as a single unit: 1) a needle guide channel; 2) a "hub'lock" device into which a VAD hub can be releasibly affixed; and 3) a surface (preferably winged) having an applied adhesive for adhering to a patient's skin. The guide and anchor assembly is shaped and sized to securely attach to the needle guide holder. For example, the guide and anchor assembly may be so attached by a friction fit to assure no movement relative to the needle holder without substantial removal force, once attached.

Method of Use

[0010] 1. A predetermined ultrasound probe is affixed to the basket.

[0011] 2. A desired slot in the basket is selected for target vessel depth.

[0012] 3. The guide and anchor assembly is secured into the selected slot.

[0013] 4. The VAD is loaded into the needle guide channel of the guide and anchor assembly.

[0014] 5. The associated ultrasound probe, guide and anchor assembly and VAD are displaced to be over a target vessel.

[0015] 6. Once so disposed as determined by ultrasound imaging, the VAD is advanced until the target vessel is cannulated.

[0016] 7. Then the VAD is removed from the needle guide channel and the Basket/guide and anchor assembly, permitting the basket/guide and anchor assembly to be set aside.

[0017] 8. The VAD is fully advanced and correct placement is confirmed.

[0018] 9. The guide and anchor assembly is retrieved from a holder on the basket and secured to a hub on the VAD via a locking mechanism (such as a bayonet locking mechanism) to securely retain the VAD.

[0019] 10, Adhesive upon the winged surface of the guide and anchor assembly is exposed by removing

protective strips, permitting the guide and anchor assembly to be adhesively affixed to skin of the associated patient.

[0020] In another embodiment, a magnetic needle guide is fitted into the Basket in the place of the guide and anchor assembly. To provide for a variety of needle sizes, a V-shaped channel is disposed within the effective lines of force of a magnet used as part of the needle guide. Noting that there is only moderate force required to move the needle parallel to a magnet, a needle is easily displaced along the V-channel. For like reasons, a needle/cannula is easily removed by gentle linear displacement along the V-channel. As such, no integrated securement system, similar to that of the guide and anchor assembly is required for the magnetic needle guide.

[0021] Yet another embodiment which is associated with the instant invention is an integral needle block. The integral needle block also fits into the basket in the same manner as other needle guide devices. In this embodiment, the needle, typically used for a single vessel access as in blood sampling, is not removable from the needle guide. As such, the needle guide block performs as a needle lock-out safety device once desired material is obtained and the needle is no longer needed.

[0022] Accordingly, it is a primary object to provide a novel ultrasound needle guide and associated catheter securement unit.

[0023] It is an important object to provide an integrally molded transducer basket and needle guide holder which has a plurality of guide slots for achieving various angles and depths of penetration for accessing a vessel.

[0024] It is a chief object to provide a needle holder and guide for both providing a vascular access device guide and an anchor at a patient skin penetration site.

[0025] It is an object to provide a basket which can be mechanically affixed to a selected ultrasound transducer head.

[0026] It is another important object to provide a needle guide device which is securely affixed to a vascular access device for assured containment.

[0027] It is another object to provide a needle guide to which a needle is affixed by magnetic force.

[0028] It is yet another object to provide apparatus and method for applying gel to an ultrasound head and to an ultrasound communication site of a basket.

[0029] It is a basic object to provide a vascular access device ultrasound guidance system which provides a needle safety enclosure for a needle.

[0030] These and other objects and features of the present invention will be apparent from the detailed description taken with reference to accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] FIG. **1** is a perspective of a transducer basket and needle guide.

[0032] FIG. **2** is a perspective of a needle guide and anchor assembly made according to the instant invention and which may be used in conjunction with the transducer basket and needle guide seen in FIG. **1**.

[0033] FIG. **3** is a perspective of the needle guide and anchor assembly seen in FIG. **2** disposed for use in the transducer basket and needle guide seen in FIG. **1**.

[0034] FIG. **4** is a perspective of the needle guide and anchor assembly seen in FIG. **2** and a mode of insertion of a VAD into the needle guide and anchor assembly.

[0035] FIG. **5** is a perspective of the parts seen in FIG. **4** wherein the VAD is partially displaced into the guide.

[0036] FIG. **6** is a perspective of the parts seen in FIGS. **4** and **5** with the VAD fully inserted and locked in position and a backing strip partially removed from wings of the needle guide and anchor assembly for adhesing the needle guide anchor assembly to a patient's skin.

[0037] FIG. **7** is a perspective of the transducer basket and needle guide, needle guide and anchor assembly and VAD assembled preparatory to an insertion procedure.

[0038] FIG. **8** is a perspective of the transducer basket and needle guide seen in FIG. **1** with a schematic of an ultrasound transducer head disposed within the basket.

[0039] FIG. **9** is a perspective of a basket disposed within a gel dip basin displayed in schematic format, this basin having an adhesive strip affixed to the bottom.

[0040] FIG. **10** is a perspective of an exploded view of a magnet guide for the instant invention.

[0041] FIG. **11** is a perspective of an assembled magnet guide seen in FIG. **10** with a needle inserted and magnetically held therein.

[0042] FIG. **12** is a perspective of the magnet guide seen in FIG. **10** disposed in a transducer basket and needle guide seen in FIG. **1**.

[0043] FIG. **13** is a perspective of an integral needle block guide with hidden line paths for needle insertion.

[0044] FIG. **14** is a perspective of the integral needle block guide with a VAD inserted through a path thereof.

[0045] FIG. **15** is a perspective of the combination seen in FIG. **15** with a needle of the VAD locked to prevent removal.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENT

[0046] In this description, the term proximal is used to indicate the segment of the device normally closest to the object of the sentence describing its position. The term distal refers to the other end. Reference is now made to the embodiments illustrated in FIGS. **1-15** wherein like numerals are used to designate like parts throughout. Primes of numbers are used to identify parts being similar in form and function, but not identical to parts numbered without primes.

[0047] VADUGS **10**, a portion of which is seen in FIG. **1**, comprises two primary components, 1) a transducer basket **20** and a needle guide holder **30**, and a second portion, seen by example in FIG. **2**, comprising a needle guide device, an example of which is a guide and anchor assembly **40**. Within the scope of the instant invention, a needle guide device may take a plurality of forms and functions. This example of such a needle guide device is guide and anchor assembly guide **40**, disclosed in detail hereafter. As disclosed supra, an integral combination of the transducer basket **20** and needle guide holder **30** is further identified as basket **50**.

Basket **50**

[0048] Transducer basket **20** is shaped and sized to conform to a predetermined ultrasound transducer head **60** (see FIG. **8**) such that transducer basket **20** snugly fits or snaps onto ultrasound head **60**, permitting basket **20** and head **60** to be used as a single unit. Basket **50** has a lens portion **70** which is formed to provide sealed containment for head **60** while being substantially transparent to ultrasound impulses emitted from head **60**. Basket **20** and lens portion **70** perform in similar fashion to a sterile sheath used to cover a transducer head

during VAD guidance in conventional ultrasound imaging procedures. Of course, any surface of basket **20** which contacts any part associated with skin penetration should be sterile.

[0049] Needle guide holder **30** seen by example in FIG. **1** is preferably integrally molded with transducer basket **20**. Holder **20** comprises a plurality of slots (generally numbered **80**) disposed at varying predetermined angles to achieve proper angles and depths of needle/cannula tissue entry. As such, needle guide holder **30** allows for multiple angles of VAD insertion to better target vessels at varying depths per arrangement of slots **80**. The embodiment of slots **80**, seen in FIG. **1**, provides three slots of varying angles for needle guide device **40**.

[0050] A variety of needle guides have been defined for use with basket **50**. While the number is not limited to those disclosed herein, three such guides are hereafter disclosed in detail. They are: 1) a guide and anchor assembly; 2) magnetic needle guide; and 3) a guide and capture needle block.

Guide and Anchor Assembly **40**

[0051] Guide and anchor assembly **40** combines an ultrasound needle guide channel and a VAD securement feature in a single device. As seen in FIG. **2**, guide and anchor assembly **40** comprises a needle guide channel **90** sized and shaped to provide controlled guidance for a needle/cannula of a VAD. When disposed within channel **90** a needle/cannula may be freely moved longitudinally within the channel without being dislodged, unless thrust out by undue force. A pair of opposing planar wings (generally numbered **92**) are sized and shaped to snugly fit within guide slots **80**. Note that so positioning wings **92** determines position and direction of channel **90**.

[0052] Other than channel **90**, two primary parts of guide and anchor assembly **40** are wings **92** and a hub-lock **94**. Wings **92** not only provide for guidance when inserted into slots **80**, but, being planar, are fitted with an adhesive on the under surface **96** thereof (see FIG. **6**). By providing adhesive on underside **96** of wings **92**, once a needle has been threaded into a target vessel, guide and anchor assembly **40** may be displaced from slots **80** and disposed as a butterfly adhesively affixed to a patients skin to construct an anchor for the associated VAD. Of course, prior to affixing under surface **96** to a patients skin to anchor guide and anchor assembly **40**, the adhesion on under surface **96** must be protected. For such, a removable backing strip **98** should be provided as seen in FIG. **6**.

[0053] Hub-lock **94** provides a hub securing member **100** for releasibly affixing a VAD hub to assembly **40**. As an example, a bayonet-style locking member **102** is seen in FIG. **2**. In summary, assembly **40** is designed for two modes of use: 1) to be securely affixed to a needle guide channel in an insertion mode and 2) to be securely affixed to a patients skin in an anchoring mode.

Method of Use of Guide and Anchor Assembly **40**

[0054] Following are a series of exemplary steps for using assembly **40**:

[0055] 1. Affix a transducer head **60** into transducer basket **20** (See FIG. **8**). (Note: prior to inserting head **60** into basket **20**, both sides (interior side **72** and exterior side **74**, as seen in FIG. **3**) of lens **70** should be coated with gel as prescribed by manufacturer of head **60** to assure clarity of ultrasound signal transmission.)

[0056] 2. Choose a desired slot **80** for angle of entry and target vessel depth for a selected VAD. (See slot examples in FIG. **3**.)

[0057] 3. Insert an assembly **40** into the chosen slot **80**. (See FIG. **3**.)

[0058] 4. Insert the selected VAD (generally **110**) into guide channel **90** (See FIG. **4**.)

[0059] 5. Displace head **60** and lens **70** to a site above a target vessel.

[0060] 6. Cannulate the target vessel by displacing VAD **110** inferiorly (See FIG. **7**.).

[0061] 7. Detach the VAD **110** from VADUGS **10** and assembly **40**.

[0062] 8. Fully advance VAD **110** and check for appropriate placement.

[0063] 9. Retrieve assembly **40** (see FIG. **2**).

[0064] 10. Secure VAD **110** into hub-lock **94**. (See FIG. **6**)

[0065] 11. Remove backing strip **98** from adhesive side of wings **92**. (See FIG. **6**) Note: Backing strip should not be removed from wings **92** until after VAD is secured into bayonet lock.

[0066] 12. Anchor assembly **40** to patient skin (Not shown in figures as such is well known in catheter anchoring art.)

[0067] Reference is now made to FIGS. **4-6** wherein a VAD **110** is seen in various stages of displacement through a guide channel **90** into assembly **40**. As seen in FIG. **4**, a VAD **110** is displaced in direction of dashed lines **112** toward engagement in assembly **40**. Once partially engaged, as seen in FIG. **5**, a portion **120**, having a sharpened entry end **122** protrudes distally from assembly **40** for ultimate skin entry.

[0068] A needle hub **124** generally comprises a luer fitting **126** for upstream fluid communication and an outwardly protruding locking member **128**. Locking member **128** is sized and shaped to latch in bayonet fashion within slots **130** of locking member **102**. Note: Affixing VAD **110** in slots **130** is performed only after VAD **110** is fully advanced and in appropriate placement within a target vessel. VAD **110** is so disposed in FIG. **6**.

Magnetic Needle Guide **40'**

[0069] Reference is now made to FIGS. **10-12** wherein a magnetic needle guide **40'** is variously seen. As seen in FIG. **10**, guide **40'** comprises a pair of wings, generally numbered **92'** and a "V" groove **90'** which acts as a guide for a VAD **110'**. Guide **40'** also comprised an imbedded magnet **140** which is sized and shaped to be imbedded in an enclosing housing **142** in a centrally disposed guide element **144** which longitudinally disposed relative to V groove **90'**. VAD **110'** is like VAD **110**, except for a needle which is made of material which can be magnetized by magnet **140**.

[0070] Magnet **140** (see FIG. **10**) is seen inserted into slot **146** (see FIG. **10**) in assembly **40'**, as seen in FIG. **11**. Form of V groove **90'** permits a magnetizable needle **148** of a VAD **110'** of varying size to be affixed by magnetic force thereat. VAD **110'** is seen disposed for penetration by needle **148** in FIG. **12**.

Guide and Capture Needle Block **200**

[0071] A guide and capture needle block, generally numbered **200**, is seen in various stages of use in FIGS. **13-15**. Block **200** generally comprises a pair of wings **92"** and a block part **210** all of which are integrally molded to form a needle guide for use with VADUGS **10**. Note that wings **92"** may perform the same skin securing function as wings **92** and **92'**. Block part **210** comprises a plurality of through holes, generally numbered **220**. Each hole **220** is varied in size from each of the other holes **220** in diameter to permit, by selection, an appropriate hole **220** sized for a selected VAD needle. Note that all holes **220** are preferably disposed to guide each selected needle to a common penetration site.

[0072] Further, for each VAD **110** used with block part **210**, a specially formed needle **230** having a notch **240** circumferentially disposed about the exterior **250** of needle **230**. Also, each hole **220** has a molded latch, commonly numbered **260**, disposed therein. Such notches and latches are well known in the plastics molding art. It should be noted that latches **260** are formed to be permissive to displacement of needle **230** in a distal direction of insertion, but made to effectively latch against notch **240** when needle **230** is displaced proximally toward a user. Such provides a needle safety mechanism for needles after use.

Gel Dip Basin

[0073] As seen in FIG. **9**, associated with VADUGS **10** is a dip basin **300** for gel **302**, (deposited therein) to be applied to a surface to facilitate ultrasound transmission. Such gels are commonly used in ultrasound imaging procedures. As sterility of gel is very important in such applications, it is anticipated that dip basin **300** is usually pre-molded, filled, sealed with a removable cover and sterilized before use.

[0074] As such, with a protective cover removed, a sterile transducer head **60** can be first dipped into gel provided within basin **300**. Thereafter, head **60** can be inserted into basket **20**, as seen in FIG. **8**. Basket **50** is seen disposed in basin **300** to affix gel to lens **70** exterior side **74** in FIG. **9**. Note that the above disclosed operation associated with basin **300** may be performed with a single hand, simplifying associated procedures and lessening risk of contamination if securely affixed to a work surface. For single handed operation, basin **300** may best be secured at a dipping site by adhesive applied to an underside. A backing **304** is seen partially removed in FIG. **9**. Using adhesive protected by backing **304**, basin **300** may be securely affixed to a planar surface prior to application of gel to either transducer head **60** or basket **50**.

[0075] The inventions disclosed herein may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of inventions being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

1. A vascular access device ultrasound guidance system for imaging vessels by providing guidance for vascular access devices and for providing for vascular access device securement, said system comprising:

an integrally molded transducer basket and needle guide holder which comprises a plurality of guide slots for an associated needle guide device;

the needle guide device comprising a pair of wings and structure for affixing and guiding direction of insertion for a vascular access device;

said wings comprising sufficient rigidity, thickness and expanse to assure proper direction of needle insertion when disposed within said slots;

said wings further comprising sufficient flexibility and planarity for skin adhesion and an adhesive applied to contacting surfaces such that, when disposed upon a patients skin, said wings and associated needle guide provide an anchor for the associated vascular access device after vessel penetration.

2. A vascular access device ultrasound guidance system according to claim **1** wherein said basket comprises a molded form by which said basket is securely bur releasibly, mechanically affixed to a predetermined ultrasound head.

3. A vascular access device ultrasound guidance system according to claim **1** wherein said structure comprises a guidance channel which provides directional control for vascular access device insertion and containment when wings are affixed to a patients skin to thereby anchor the vascular access device after successful vascular access device insertion.

4. A vascular access device ultrasound guidance system according to claim **3** wherein said structure comprises a bayonet lock about the guidance channel for securing the associated vascular access device to the needle guide device.

5. A vascular access device ultrasound guidance system according to claim **3** wherein said structure comprises a magnet disposed to hold a needle which can be held in place by magnetic force within the channel.

6. A vascular access device ultrasound guidance system according to claim **1** wherein said wings comprise a removable cover placed over said adhesive for protection until removed for purposed of anchoring the associated vascular access device.

7. A vascular access device ultrasound guidance system according to claim **1** further comprising a dip basin for covering a lens of said basket for clarity of ultrasound transmission.

8. A vascular access device ultrasound guidance system for imaging vessels by providing guidance for needle based vascular access devices and for providing for needle securement, said system comprising:

an integrally molded transducer basket and needle guidance device which comprises a guide block comprising a portion having a predetermined thickness opposing direction of insertion of the vascular access device and at least one guide hole through the portion;

each at least one guide hole comprising a latch proximally disposed a predetermined distance from an associated exit orifice for the needle;

the needle comprising a sharpened end and an exterior diameter in which an annular notch is proximally disposed thereto;

said latch and said notch being disposed to permit distal displacement of the vascular access device but to catch and hold the needle of the access device thereby providing a needle safety device.

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专利名称(译)	血管通路装置超声引导系统		
公开(公告)号	US20130150714A1	公开(公告)日	2013-06-13
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摘要(译)

一种血管进入装置超声引导系统，其为血管通路提供新颖的超声成像头接口。该系统包括用于连接到手持式超声换能器的配合篮/ VAD引导件。 VAD导向器整体模制到配合的篮子上，包括用于VAD针导向器的可释放的导向组件。另外，针引导组件包括用于在成功插入后将VAD锚固到患者皮肤的装置。公开了一种磁针引导系统。还公开了一种流体取样装置，其将针引导和安全针捕获集成在单个引导头中。