



(51) International Patent Classification:

G09B 23/28 (2006.01) G09B 23/00 (2006.01)

(21) International Application Number:

PCT/US2017/030559

(22) International Filing Date:

02 May 2017 (02.05.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/330,404 02 May 2016 (02.05.2016) US
15/296,680 18 October 2016 (18.10.2016) US

(71) Applicants: GREENVILLE HEALTH SYSTEM

[US/US]; 701 Grove Road, Greenville, South Carolina 29605 (US). SEALEVEL SYSTEMS, INC. [US/US]; 2779 Greenville Hwy., Liberty, South Carolina 29657 (US).

(72) Inventors: CULL, David, L.; 172 Ridgeland Drive, #300,

Greenville, South Carolina 29601 (US). O'HANLAN, Thomas Booker; 100 Edgemont Avenue, Liberty, South Carolina 29657 (US).

(74) Agent: MANGELSEN, Christina, L. et al.; Dority &

Manning, P.A., P O BOX 1449, Greenville, South Carolina 29602-1449 (US).

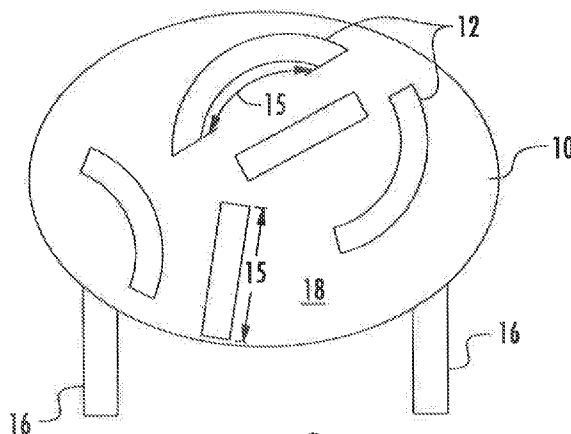
(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: FISTULA CANNULATION SIMULATOR



(57) **Abstract:** A cannulation simulation device and methods for using the device are described. The device is designed to teach dialysis technicians/nurses or patients to cannulate arteriovenous (AV) fistulas for hemodialysis. The simulator includes one or more artificial fistulas. The simulator includes a pad of simulated flesh that can cover the artificial fistula(s). The pad can be reversed, rotated, and replaced with thicker or thinner pads. A personal simulation device for teaching self-cannulation can include a sleeve for a limb that can carry an artificial fistula. A clinical simulation device can include a plurality of artificial fistulas held in a support. Optionally, the artificial fistulas can vibrate to simulate an actual fistula.

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

FISTULA CANNULATION SIMULATOR

Cross Reference to Related Application

[0001] This application claims filing benefit of United States Provisional Patent Application Serial Number 62/330,404 having a filing date of May 2, 2016, which is incorporated herein by reference in its entirety.

5

Background

[0002] To cannulate an arteriovenous (AV) fistula for hemodialysis, it is necessary to insert two large gauge (usually 15 g to 17 g) needles through a patient's skin and into a vessel having high blood flow rate. AV fistula cannulation is an almost entirely tactile skill that requires locating the AV fistula in the subcutaneous tissue and proper assessment of the fistula orientation and depth followed by accurate placement of the needle end within the lumen of the vessel. Fistulas are identified in practice by the tactile pressure difference of the vessel longitude and circumference and by local area vibration caused by the mixed venous and arterial blood flow. The procedure is performed in clinical settings by dialysis nurses and technicians and requires great skill in correctly identifying the proper location and orientation of the fistula as well as obtaining proper needle insertion into the vessel lumen. Patients who opt for home dialysis treatment must learn how to perform this skill themselves, generally without any prior experience in vascular access.

[0003] To improve the dialysis capabilities of medical personnel, nurses and technicians are trained on simulators. Unfortunately, no such simulators exist that have been designed for patients to train for self-cannulation. Moreover, even existing simulators offer only limited training effectiveness. Typical existing cannulation simulators are formed in shapes that mimic human or animal body parts (e.g., arms) and include a fixed artificial fistula covered with an artificial flesh material. While the anatomical form of the simulators can add to the perceived realism of the devices, the fixed placement and materials of the components decreases realism. Repeated piercing of the surface material to access the artificial fistula fixed beneath the surface material can reveal previous students' attempt locations and decrease effectiveness of the training. Movement or replacement of the surface material can be carried out at added expense, but the

gel-like artificial flesh can be difficult to replace and the replacement procedure can be messy if the simulator includes synthetic blood.

[0004] Due to such issues, the skills gained by use of existing simulators provide fairly limited proficiency in real-world application. Difficulties can arise following training not only due to the fixed, static nature of existing simulators but also because it is difficult to capture in existing training simulators the large degree of variation in fistula depth, orientation, skin thickness and size between patients that will be faced by clinicians.

[0005] Patients wishing to self-cannulate away from the clinical setting may have the opportunity to use existing simulators, but the insufficiencies described for clinical settings still apply. Currently, estimates show that only 0.8% of hemodialysis patients choose to engage in home treatment. However, it is commonly held that outcomes are better when patients choose home treatment and nephrologists prefer patients be on home dialysis. The major barrier to home dialysis is patient fear of needle sticks, but proper training could alleviate such fears. As technology improves and the pool of hemodialysis patients expands, this market is expected to grow, as will the need for better training options.

[0006] What is needed in the art are cannulation simulators that more closely mimic an AV fistula cannulation experience. For instance, a cannulation simulator that addresses the real-world variables that may be encountered by health-care workers during actual dialysis practice such as little or no visual cues as to the location of the fistula could be of great benefit. A cannulation simulator that provides for patients to safely train for self-cannulation that can closely represent an actual AV fistula cannulation experience would also be of great benefit.

Summary

[0007] A cannulation simulation device is disclosed. The cannulation simulation device includes an artificial fistula that can include an upper barrier, a lower barrier, and an opening there between that simulates the lumen of a fistula blood vessel. The upper barrier can define a radial curvature and an axial length that can simulate the radial curvature and longitudinal length of a blood vessel. The lower barrier can include a conductive material, e.g., a metal. During use, the conductive material can be utilized to register the passage of the conductive tip of a needle tip

and provide information with regard to the exit of the needle tip out of the fistula opening and through the lower barrier. This feature can be used to register to a trainee that the needle has passed out of the fistula opening.

[0008] An artificial fistula can be associated with a vibration motor and a controller. The controller can be utilized to vibrate an artificial fistula via the associated vibration motor. An artificial fistula can optionally include a sensor that can be in communication with the open lumen area of the artificial fistula and function to register and communicate the presence of a needle tip within the opening of the artificial fistula.

[0009] In one embodiment, a device can include a support surface that defines a plurality of cut-outs in the surface, and each cut-out can retain an artificial fistula therein.

[0010] A device can also include a pad that can be removably located over the upper barrier of an artificial fistula. For instance, in one embodiment a pad can be removably located on a support surface that defines a plurality of cut-outs in the surface. In this embodiment, the pad can cover all of the cut-outs and the artificial fistulas retained therein and can function as an artificial flesh over the fistulas.

Optionally, a device can include several different pads of different thickness, compression characteristics, etc. so as to provide a different “feel” to the simulator surface and provide for cannulation simulations of a variety of difficulties.

[0011] In one embodiment, a support surface and a pad can both have a same surface area shape and size, such as a circle. As such, the pad can be removed, rotated and/or reversed, and replaced on the support surface to again fully cover the support surface and artificial fistulas. This can minimize the presence of visual and tactile cues on the pad that could designate the locations of the underlying fistulas and can extend the useful life of the pad.

[0012] In one embodiment, the support surface can rotate about an axis, which can be utilized to vary the location of the artificial fistulas underneath the pad and prevent memorization by trainees of fistula locations on a simulator.

[0013] According to another embodiment, a personal cannulation simulation device is disclosed. A personal cannulation simulation device can include a sleeve that is configured for temporary attachment to a subject, for instance by having a

shape that generally conforms to a human arm. In one embodiment, the sleeve can be of a closed and substantially cylindrical construction and can be configured to be slipped over the hand and onto the arm. In another embodiment the sleeve can include an opening along a length of the sleeve and can include a closure. In this embodiment, a sleeve can be configured to wrap around an arm and optionally be held in place by use of the closure. A sleeve can be impenetrable to a needle (e.g. include a metal or a hard plastic) and can protect a wearer from accidental needle puncture during training.

[0014] A personal cannulation simulation device can also include an artificial fistula and a pad as described above. The artificial fistula can be between the sleeve and the pad, and can be separable from the pad and/or sleeve or of unitary construction with the pad and/or sleeve.

[0015] In one embodiment, a personal cannulation simulation device can include multiple removably attachable components so as to be assembled to mimic an individual's fistula depth, orientation, size, etc.

[0016] A cannulation simulation device can also include a flesh simulant material located on either side of the artificial fistula. The flesh simulant material can be a unitary component of a pad (e.g., the pad can include one or more channels of the flesh simulant material for location of the artificial fistula), or may be removably attachable to the pad, a sleeve, and/or the artificial fistula.

[0017] Also disclosed are methods for utilizing the cannulation simulation devices. For instance, following assembly of a device, a vibration motor can be turned on causing an artificial fistula to vibrate. A trainee (either a clinician or a patient) can then use tactile interaction to explore the upper surface of the pad and locate this vibrating artificial fistula. The trainee can then insert a dialysis needle into the fistula opening following determination of the direction and side edges of the fistula. Successful entrance of the needle tip into the fistula opening can be ascertained by use of sensors within the fistula openings. Should the trainee pass the needle tip through the fistula opening and out of a lower barrier of the artificial fistula, contact between the needle tip and a conductive surface on the lower barrier can be registered to signify that the needle tip has gone too far.

Brief Description of the Drawings

[0018] A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth in the specification, which makes reference to the appended figure, in which:

5 [0019] FIG. 1 is a top view of a support surface.

[0020] FIG. 2 is a perspective view of a support surface.

[0021] FIG. 3 is a side view of components of a cannulation simulator.

[0022] FIG. 4 is a top view of an opening of a support surface and an artificial fistula retained therein.

10 [0023] FIG. 5 is an end view of an artificial fistula.

[0024] FIG. 6 illustrates several components of an artificial fistula.

[0025] FIG. 7 illustrates a fistula needle and hub.

[0026] FIG. 8 illustrates a method of utilizing a cannulation simulator.

[0027] FIG. 9 illustrates a personal cannulation simulator in cross section.

15 [0028] FIG. 10 illustrates a personal cannulation simulator located on an arm.

Detailed Description

[0029] It is to be understood by one of ordinary skill in the art that the present discussion is a description of exemplary embodiments only, and is not intended as limiting the broader aspects of the present disclosure. Each example is provided
20 by way of explanation of the invention, not limitation of the invention. In fact, it will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope or spirit of the invention. For instance, features illustrated or described as part of one embodiment can be used with another embodiment to yield a still further
25 embodiment. Thus, it is intended that the present invention covers such modifications and variations as come within the scope of the appended claims and their equivalents.

[0030] A cannulation simulation device and methods for using the device are disclosed herein. The device can be used as an instructive instrument designed to
30 teach dialysis technicians/nurses/patients to cannulate arteriovenous (AV) fistulas for hemodialysis. The simulator facilitates cannulation training by use of a more realistic experience as compared to existing cannulation simulators and can

include real-time feedback to the trainee to indicate successful as well as unsuccessful cannulation of the lumen of the artificial fistula. Moreover, the simulator has been designed to provide for long life without development of visual or eidetic indicators as to the location of the artificial fistulas, so as to improve the capabilities of individuals trained by use of the device. While the present disclosure is primarily directed to description of arteriovenous cannulation, it will be readily understood by the person skilled in the art that the invention is not so limited but extends to techniques such as cannulation of arteriovenous grafts for hemodialysis.

[0031] In one embodiment, the simulator comprises a support, multiple artificial fistulas held in various locations in conjunction with the support, and a removable pad of synthetic flesh overlaying the upper surface of the support and the artificial fistulas. By way of example, FIG. 1 illustrates a top view of a support 10 and FIG. 2 illustrates a perspective view of a support 10. The support 10 includes a series of cut-outs 12 within the support 10. The cut-outs 12 can generally have a cross-sectional dimension 14 of about 0.5 inches, for instance from about 0.25 inches to about 1 inch. In addition, the cut-outs 12 can have a length 15 of several inches, for instance from about 5 inches to about 12 inches or from about 7 inches to about 10 inches in some embodiments. As shown, the cut-outs 12 can define curvature(s) or can be generally straight along the length 15.

[0032] As shown in FIG. 2, the support 10 can be supported by legs 16. The legs 16 can be of any suitable length. For instance, the legs 16 can be designed such that the device can be held on a table or bench top, in which case the legs 16 can be relatively short, e.g., about 8 inches to about 14 inches, or about 12 inches in one embodiment. Alternatively, the device can be self-standing, in which case the legs 16 can be long enough (e.g., about 24 inches to about 40 inches) to locate the upper surface 18 of support 10 at a convenient height for use. In any case, the legs 16 can be of a height such that device components, e.g., wiring, controllers, motors, etc. can be retained beneath the support 10.

[0033] In general, the device can be portable. As such, the support 10 can generally be about 36 inches or less in width as measured from one side to an opposite side of the upper surface 18 of the support 10, e.g., from about 15 inches

to about 24 inches in some embodiments. In addition, the support 10 and legs 16 can be formed of any suitable material, e.g., wood, plastic, or combinations of materials.

[0034] In the embodiment of FIG. 1 and FIG. 2, the support 10 has a generally round upper surface 18. The round surface 18 can be of benefit in some embodiments as by placing the artificial fistulas in conjunction with a round support 10, there can be few or no spatial reference points for students, ensuring that students will rely on tactile sensing to determine the location and the size of the target fistula held in conjunction with the support 10. A round upper surface 18 can also enable instructors to rotate and flip a flesh-simulation pad (described further herein) that is held on the upper surface 18 of the support 10 and has a size and shape that corresponds to the upper surface 18 of the support 10 while maintaining alignment between the upper surface 18 of the support 10 and the pad held thereon. This can prevent the formation of visual cues on the flesh-simulator pad that could indicate underlying fistula locations and can also extend the life of the flesh-simulator pad.

[0035] FIG. 3 presents a side-view of components of a device including a support 10 an artificial fistula 20 held in conjunction with the support 10 and a flesh-simulation pad 22 that can be removably located so as to align with the upper surface 18 of support 10 and can cover the artificial fistula 20.

[0036] The pad 22 can be a flesh-simulation material as is generally known in the art. For instance, the pad 22 can include an opaque gel-like or foam filler to simulate subcutaneous tissue and an outer cover to simulate skin. The pad 22 can generally be from about 0.5 inches to about 1 inch in total thickness. In one embodiment, the device can include multiple pads of varying thicknesses or various degrees of hardness (e.g., Shore A hardness) that can provide varying degrees of difficulty to a trainee. For instance, a relatively thin pad of about 0.5 inches can be used in an easier or beginning training session and a higher degree of difficulty can be obtained by substituting a thicker pad, e.g., about 1 inch, on the support 10. Alternatively, multiple thin pads can be combined to provide a more difficult simulation experience.

[0037] As mentioned previously, the temporary fixation of the pad 22 on the upper surface 18 of the support 10 can also be used to extend the life of the pad 22 and prevent the formation of visual cues on the pad 22 with regard to the location of the underlying fistula 20. In particular, the pad 22 can be lifted, rotated and/or flipped and replaced on the upper surface 18 of the support 10.

Beneficially, such changes can be carried out without creating a mess as the device need not include an artificial blood in the simulated flesh, as is the case for previously known cannulation simulators (though inclusion of an artificial blood in the device is certainly not prohibited). By changing the orientation of the gel pad the previous attempts at cannulation are obfuscated, preventing students from following needle marks to find a fistula. Further, the difficulty of the cannulation can be increased by increasing the thickness, density, and/or hardness of the pad 22, simulating difference in the depth and tenacity of the flesh.

[0038] An artificial fistula 20 can be held in conjunction with each of the openings 12 in the support 10. FIG. 4 presents a top view of an artificial fistula 20 held in a cut-out 12. Each fistula 20 is suspended within a cut-out 12, for instance by use of rubber bushings 24 and the like. The suspension mechanism can at least partially isolate the fistula 20 from the support 10 that surrounds the cut-out 12. As such, vibration of the fistula 20 can be better confined to the fistula and minimal vibration can transfer to the support 10. Partial isolation of the vibrations of the fistula 20 can better simulate the vibrations of an actual fistula in real-world practice.

[0039] FIG. 5 presents an end-view of an artificial fistula 20. The fistula 20 includes an upper barrier 26 and a lower barrier 28 that define a cannulation opening 27 there between. In the illustrated embodiment, the upper barrier 26 and the lower barrier 28 can be formed of different materials, but this is not a requirement of the devices. For instance, the upper barrier 26 can be a portion of a rubber or silicone tube that has a cross sectional width w similar to that of a typical fistula. For instance, the side-to-side width (e.g., diameter) of the upper barrier 26 can be from about 6 millimeters to about 10 millimeters, or about 8 millimeters in one embodiment. The semi-circular cross-sectional shape of upper barrier 26 defining a radial curvature can also be beneficial as it can more closely

resemble the shape of a natural fistula for the trainee. A fistula 20 can be held in a cut-out 12 such that a portion of the upper barrier 26 extends above the upper surface 18 of the support 10. For instance the upper barrier 26 of a fistula 20 can protrude above the upper surface 18 of the support 10 by a distance of from about 2 millimeters to about 4 millimeters.

[0040] The lower barrier 28 can be of any suitable shape and material. In one embodiment, the lower barrier 28 can be formed of an electrically conductive material, such as a metal mesh. In this embodiment penetration of the lower barrier 28 of the fistula 20 can be noted by a closed electrical circuit created between the conductive material of the lower barrier 28 and a conductive material of the needle tip. A signal (e.g., visual and/or auditory) can then be generated when the needle passes through the fistula opening 27 and makes physical contact with the charged mesh on the other side. Of course, alternatively, the electric signal generator and detector may be reversed, with the needle providing an electric potential and the mesh acting as a detector. As illustrated in FIG. 8, if the tip of the needle 42 passes through the opening 27 and through the lower barrier 28, a signal (e.g., an optical and/or auditory sound) can be emitted; signifying cannulation failure because the lower barrier 28 of the fistula 20 has been penetrated. For instance, the signal can be generated when the metal tip of the needle 42 contacts the charged wire mesh forming the lower barrier 28 of the fistula 20.

[0041] Referring again to FIG. 5, the fistula 20 can include a cradle 25 that can be utilized to suspend the fistula 20 in a cut-out 12 of a support 10 and to support the other components of the fistula 20, including the upper barrier 26 and the lower barrier 28, as shown.

[0042] The cradle 25 can also support a component of a sensor 30 that can be utilized to detect successful penetration of the tip of a needle 42 into the opening 27. By way of example, the cradle 25 can support a strip 34 of IR-light emitting diodes (LEDs) 30 spaced along the length 15 of the fistula 20 that radiate emission within the opening 27. Proper positioning of a cannulation needle 42 with the tip within the opening 27 of the simulated fistula 20 can be determined by an infrared (IR) detector 40 (FIG. 7) attached to the needle 42 that can detect emission from

the IR-LEDs 30 placed beneath the fistula opening 27 in the cradle 25. The emission from the IR-LEDs 30 cannot permeate beyond the fistula opening 27 as the upper barrier 26 and the overlying pad 22 can be opaque. When the tip of the needle 42 pierces the upper barrier 26, the detector 40 can create a signal upon
5 detection of the IR emission from the IR-LEDs 30. For example, the detector 40 in the end of the cannulation needle 42 can create a signal 44 (e.g., optical and/or auditory signal) when the student successfully inserts the needle tip within the cannulation opening 27 of the fistula 20.

[0043] Of course, the detection method is not limited to IR and other optical or
10 other detection systems may be utilized. Moreover the location of the various sensor components may be reversed. For instance an IR-LED can be attached to the tip of a fistula needle, and an IR detector can be located under or within the fistula opening. Missed cannulations of the fistula can thus be noted by the absence of a signal generation by the IR detector.

[0044] In the real-world cannulation of a fistula, the proper alignment of a
15 needle in a vessel is evidenced by the “flashback” of blood within the IV tubing of the cannulation set that includes a large gauge needle, IV tubing with connectors, and flow arrestor. Previously known simulation systems include tubes filled with simulated blood that are connected to external reservoirs, allowing the simulator to
20 “bleed”. Cannulated synthetic veins in such systems can continue to leak between simulations and can lead to wet, messy simulators as the artificial blood will not coagulate a puncture as would living tissue. The presently disclosed systems can avoid such problems as proper cannulation of a fistula can be determined by signal generation without the need for synthetic blood.

[0045] Signals generated or received by the cannulation needle can be used to
25 generate an indication for immediate user feedback, an indication only revealed to the instructor, and/or a recording of the trainee’s attempts. These indications can be of any type, e.g., visual, tactile, and/or auditory, and recordings can be catalogued by computer program.

[0046] In addition to other components, a device can include vibration motors
30 32 in communication with each of the artificial fistulas 20. For example, one or more vibration motors 32 can be in mechanical communication with a cradle 25 or

some other component of each fistula 20 so as to vibrate the upper barrier 26 of the fistula 20 and provide a tactile cue through the pad 22 to a trainee of the location, width, and direction of the underlying fistula 20.

[0047] Any suitable vibration motor 32 is encompassed, such as those

5 commonly found in cell phones that can be used to mimic the vibrations of fistula.

The vibration motor(s) 32 can be in communication with a control system (not shown) as is known in the art. Each motor 32 can be separately controlled or alternatively multiple motors 32 can be in communication with a single controller.

10 For instance multiple vibration motors 32 of a single fistula 20 can be controlled together. As shown in FIG. 8, in one embodiment a series of vibration motors 32 can be located beneath the fistula opening 27, for instance in mechanical communication with the cradle 25 of a fistula 20. During use, the vibration motor(s) 32 of only one fistula 20 of the device can be activated at a time to denote a single fistula that the trainee will then attempt to locate and cannulate. This is
15 not a requirement, however, and in other embodiments, multiple fistulas can be activated at one time.

[0048] According to one embodiment, a simulator can be designed as a personal simulation device for use in training a patient for self-cannulation.

20 According to this embodiment, a simulator can include a support in the form of a removable sleeve that is held in conjunction with a single artificial fistula. Similar to the multiple-fistula device described above, a personal simulation device can also include a pad of synthetic flesh overlaying the upper surface of the sleeve and the artificial fistula.

[0049] One embodiment of a personal simulation device 101 is illustrated in
25 FIG. 9. As shown, a simulation device 101 can include a sleeve 128 as a support for the artificial fistula. In one embodiment, a portion of the sleeve 128 can function as a lower barrier for the artificial fistula 120. In other embodiments, the lower barrier can be applied to the sleeve 128 during assembly. In the cross sectional view of FIG. 9, the device is illustrated as covering a portion of a patient's
30 limb 130, e.g., a forearm, leg, etc.

[0050] The sleeve 128 can be of a material that can prevent puncture by the trainee (generally a person wearing the device on their limb 130) with the training

needle. For instance, the sleeve 128 can include a metal or a relatively hard plastic (e.g., a polyvinyl chloride, a polypropylene, etc.) The sleeve can be formed so as to be pulled over or wrapped around a patient's limb. For instance, one embodiment of a sleeve can be in the form of a generally cylindrical tube that can slide over a wearer's hand and into place on the limb. In another embodiment, the sleeve is not in the form of a closed tube, but rather is open along the length of the cylinder. In this embodiment, the sleeve can be wrapped around the arm.

Optionally, and depending upon the flexibility of the sleeve material, etc., a sleeve can include a closure such as a buckle, snap, button, or other commonly used

securing techniques. As such, following location around a patient's limb, the sleeve can be secured in place. Currently available products on the market may also be used as a sleeve of a simulation device such as, without limitation, the Needle Resistant Arm Sleeves AG8TW by HexArmor®. Optionally, the sleeve 128 can include a conductive material, such as a metal mesh as described above for the lower barrier so as to aid in training when a portion of the sleeve serves as the lower barrier of the artificial fistula.

[0051] A personal fistula cannulation simulation device 101 can include an artificial fistula 120 that includes an upper barrier 126 as described previously and a portion of the sleeve 128 as a lower barrier that define a cannulation opening 127 there between. Alternatively, the lower barrier can be formed of a different material that is applied to the sleeve. For instance, in one embodiment, the upper and lower barriers can be formed from a unitary tube that is assembled on the sleeve 128. The artificial fistula 120 can generally be of a size and shape as described previously.

[0052] A personal simulation device 101 can optionally include penetration sensors and vibrational components as described above for a larger, clinical-type device. For instance, a device 101 can be electrically connectable to a motor as described above that can vibrate all or a portion of the upper barrier 126 or a portion of the sleeve 128 so as to provide a vibration in the area of the artificial fistula 120 similar to what will be encountered by the patient during self-cannulation.

[0053] In one embodiment a personal simulation device can include separable components that can provide for the device to be personalized for a user. For instance, the artificial fistula 120 can be separable from the sleeve 128 so as to be securable thereto in a variety of orientations. During formation, a technician that is familiar with a patient's fistula can locate the artificial fistula 120 on the sleeve 128 so as to mimic the orientation of the patient's actual fistula. Placement can be carried out with temporary attachment, for instance by use of a temporary adhesive or hook and pile attachments (e.g., Velcro®) or alternatively by use of a more permanent adhesive.

[0054] The personal device 101 can also include a pad 122 that can cover the artificial fistula and function as a flesh simulation. For instance, the pad can have a thickness of from about 0.25 inches to about 1 inch and be formed of materials as discussed previously.

[0055] In order to create a generally uniform upper surface on the device 101 and thereby offer minimal tactile cues as to the location of the fistula below the flesh simulant pad, a device can provide for the artificial fistula 120 to be generally surrounded on the top and sides with an artificial flesh such as the pad 122. For instance, the pad 122 can be formed with a channel or cavity within which the artificial fistula 122 can be located. Alternatively, multiple pieces of pad materials can be located on the sleeve 128 so as to surround the artificial fistula 120 and provide a uniform upper surface with little or no visual cues as to the location of the underlying fistula 120.

[0056] The channel or cavity formed in a pad 122 that can be adjacent to the top and sides of the fistula 120 may be formed by the manufacturer or may be custom designed by a nurse/technician removing material from a pad 122 to mimic a patient's specific fistula orientation. The pad 122 with imbedded artificial fistula 120 can then be located on the sleeve 128.

[0057] FIG. 10 illustrates a perspective view of a personal simulation device 101 following location on a patient's limb 130. As can be seen, in this embodiment, the sleeve 128 can be formed so as to be wrapped around the limb 128, following which it can be secured with buckles, snap closures, buttons, hook and loop closure, or other commonly-used temporary securing techniques. A

sleeve 128 that is open along the side and includes a closure can be preferred in some embodiments, as this can provide for a device with a variable cross sectional size.

[0058] As shown, during use, a trainee can target a needle 142 to the artificial
5 fistula 120. In the illustrated embodiment, the pad 122 is not shown. In one
embodiment, during use a trainee can locate the device on their own limb and over
their own fistula. The trainee can then be taught to locate the artificial fistula 120
that lies beneath the pad by tactile exploration of the pad following which the
trainee can be taught to penetrate the pad with a needle 142 and successfully
10 locate the tip of the needle within the lumen 127 of the artificial fistula 120.

[0059] This written description uses examples to disclose the invention,
including the best mode, and also to enable any person skilled in the art to practice
the invention, including making and using any devices or systems and performing
any incorporated methods. The patentable scope of the invention is defined by the
15 claims, and may include other examples that occur to those skilled in the art. Such
other examples are intended to be within the scope of the claims if they include
structural elements that do not differ from the literal language of the claims, or if
they include equivalent structural elements with insubstantial differences from the
literal languages of the claims.

WHAT IS CLAIMED IS:

1. A cannulation simulation device comprising:
a support;
an artificial fistula held in conjunction with the support, the artificial fistula including an upper barrier having a radial curvature and an axial length and further
5 including a lower barrier, the artificial fistula defining a lumen between the upper barrier and the lower barrier; and
a pad configured to be removably located on an upper surface of the support such that the pad overlays the upper barrier of the artificial fistula.
2. The cannulation simulation device of claim 1, further comprising a vibration motor in mechanical communication with the upper barrier.
3. The cannulation simulation device of claim 1, further comprising a first sensor configured to detect the presence of a needle tip within the lumen of the artificial fistula.
4. The cannulation simulation device of claim 1, further comprising a second sensor configured to detect contact of a needle tip with the lower barrier of the artificial fistula.
5. The cannulation simulation device of claim 1, wherein the support defines a plurality of cut-outs and a plurality of the artificial fistula, one of the plurality of the artificial fistulas being retained in each of the plurality of cut-outs.
6. The cannulation simulation device of claim 1, further comprising a plurality of pads.
7. The cannulation simulation device of claim 1, the pad defining a cut-out configured to retain the artificial fistula.

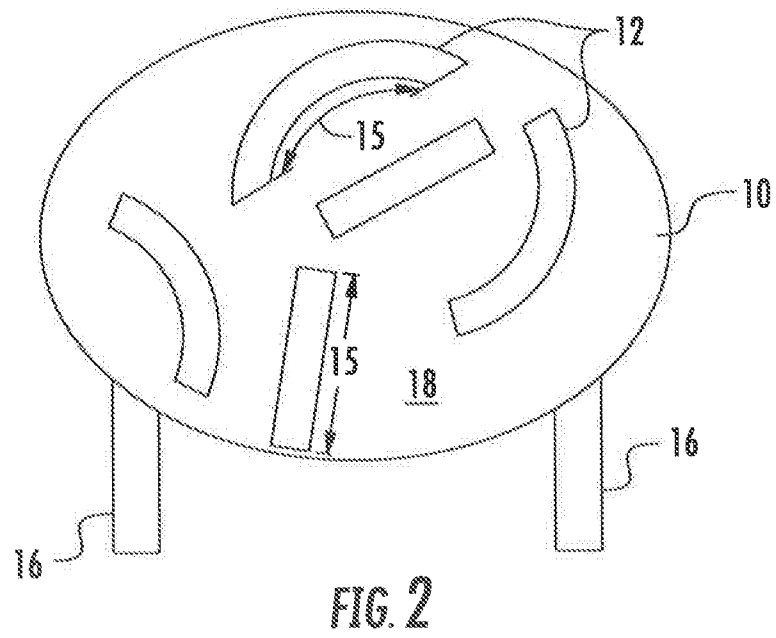
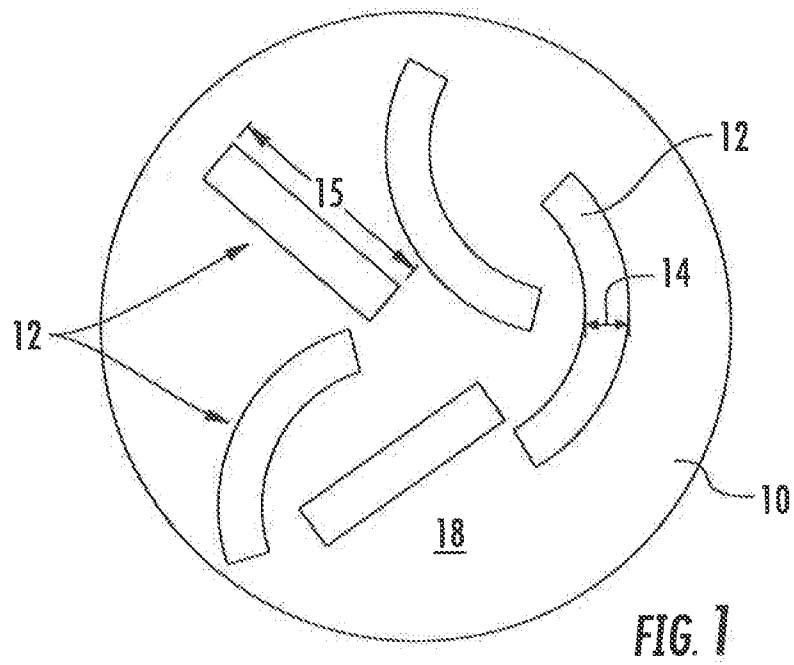
8. The cannulation simulation device of claim 1, wherein a portion of the support is the lower barrier.
9. The cannulation simulation device of claim 1, wherein the support is in the form of a sleeve configured for temporary attachment to a subject.
10. A method for cannulation training comprising:
 - inserting a dialysis needle through a pad, the pad overlying an artificial fistula, the artificial fistula including an upper barrier having a radial curvature and an axial length and further including a lower barrier, the artificial fistula defining a
 - 5 lumen between the upper barrier and the lower barrier;
 - passing the dialysis needle through the upper barrier; and
 - detecting the presence of the dialysis needle within the lumen of the fistula by use of a first sensor in communication with the lumen.
11. The method of claim 10, wherein the first sensor is in optical communication with the lumen.
12. The method of claim 10, the method further comprising detecting contact of the dialysis needle with the lower barrier.
13. The method of claim 12, wherein the contact is detected by formation of an electrical contact between the dialysis needle and the lower barrier.
14. The method of claim 10, further comprising engaging a vibration motor in communication with the artificial fistula such that the upper barrier of the artificial fistula vibrates.
15. The method of claim 10, wherein the pad overlays a plurality of artificial fistulas, the method further comprising reorienting the pad from a prior orientation prior to inserting the dialysis needle.

16. The method of claim 10, the artificial fistula being retained on a sleeve, the method further comprising temporarily attaching the sleeve to a subject.

17. The method of claim 10, further comprising prior to inserting the dialysis needle, assembling the artificial fistula with the pad.

18. The method of claim 17, wherein the artificial fistula is assembled on a support with an orientation to mimic the fistula of a subject.

1/4



2/4

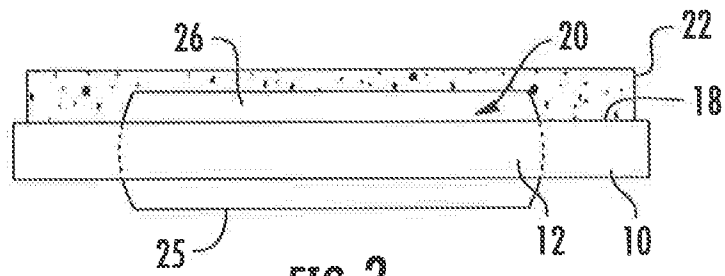


FIG. 3

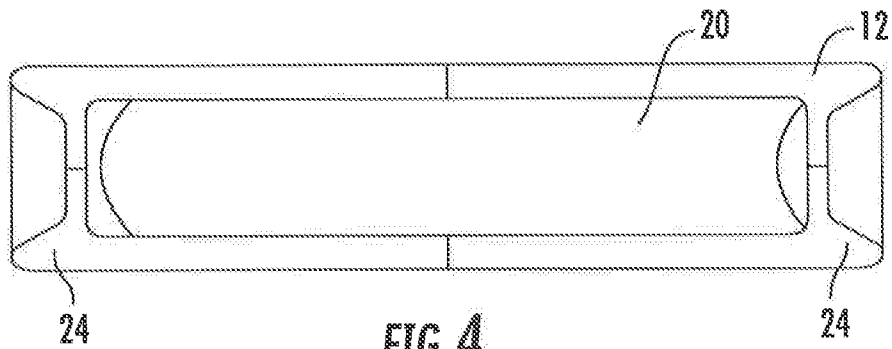


FIG. 4

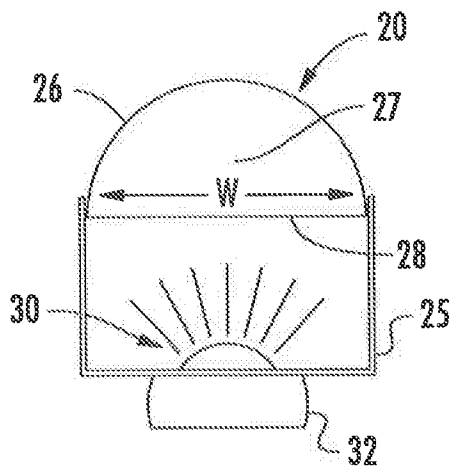


FIG. 5

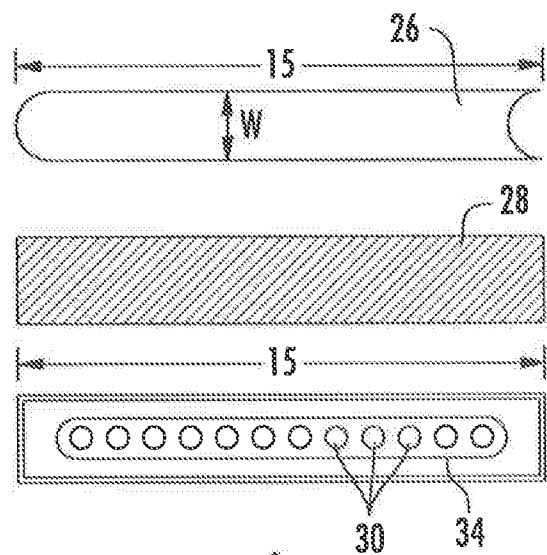


FIG. 6

3/4

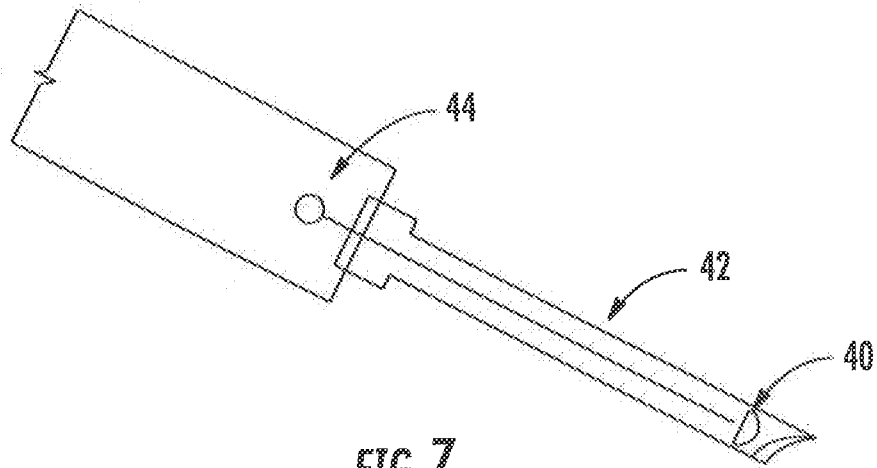


FIG. 7

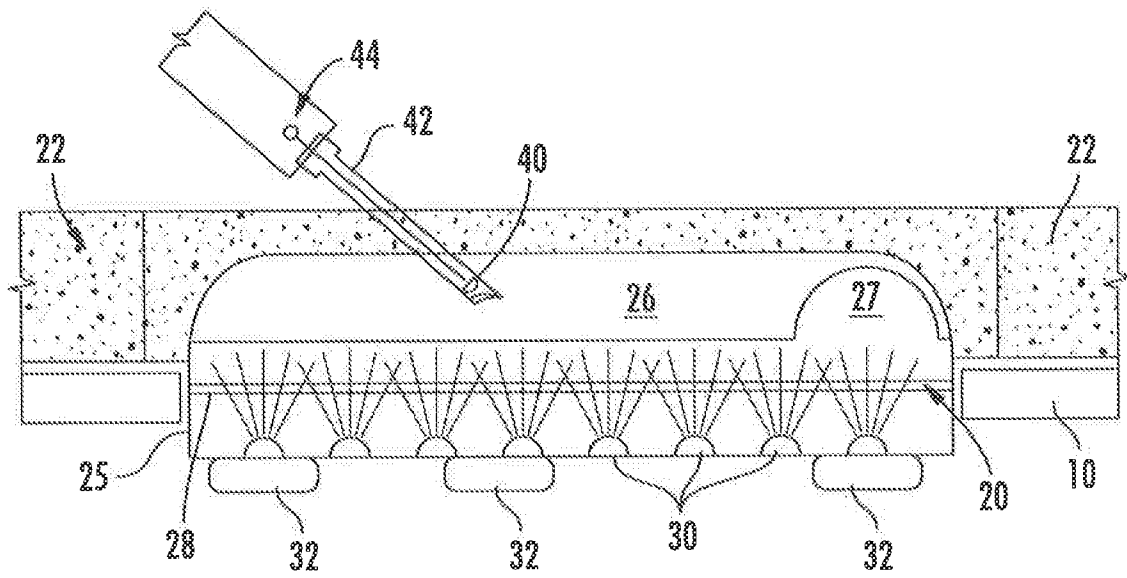


FIG. 8

4/4

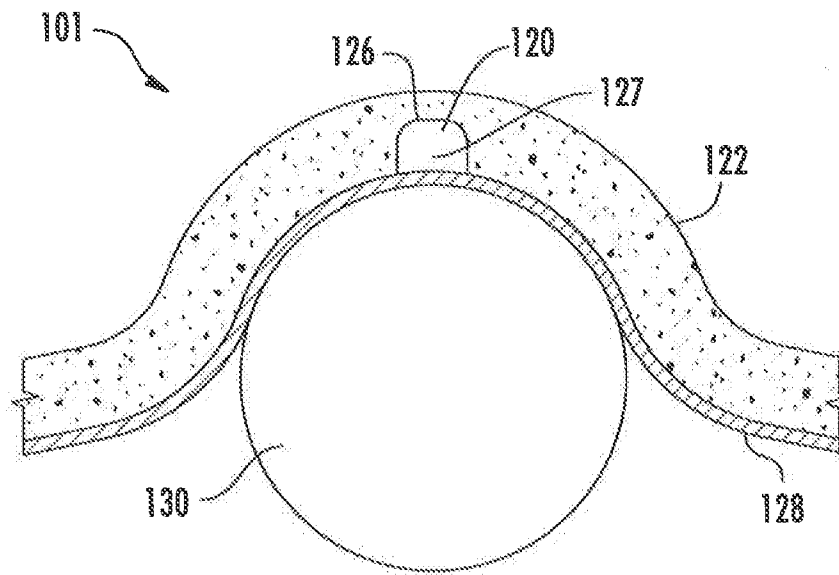


FIG. 9

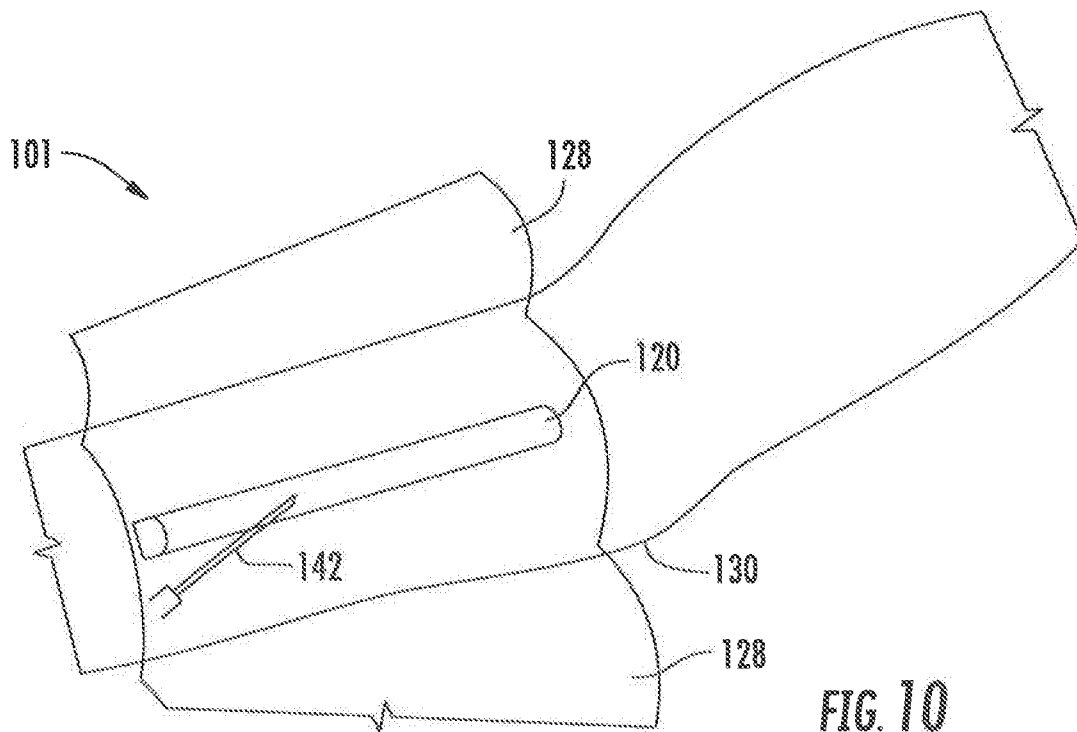


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/30559

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - G09B 23/28, G09B 23/00 (2017.01)
 CPC - G09B 23/285, G09B 23/30, G09B 23/303

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- A	US 2011/0200977 A1 (PARONEN) 18 August 2011 (18.08.2011) fig 1, para[0018]-[0019]	1 ----- 2, 4, 7-8
X ----- A	WO 2016/028821 A1 (THE GENERAL HOSPITAL CORPORATION) 25 February 2016 (25.02.2016) fig 2, 4, para [0033], [0051]	1, 3 ----- 2, 4, 7-8
X ----- A	JP 2013/246393 A2 (TERUMO CORP) 09 December 2013 (09.12.2013) fig 1, 2, 4	1, 5-6 ----- 2, 4, 7-8
X ----- A	US 5,839,904 A (BLOOM) 24 November 1998 (24.11.1998) fig 3-6, col 3, ln 36-39, col 5, ln 6-9	1, 9 ----- 2, 4, 7-8
A	US 5,112,228 A (ZOURAS) 12 May 1992 (12.05.1992) entire document	1-9

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

22 August 2017

Date of mailing of the international search report

18 SEP 2017

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
 P.O. Box 1450, Alexandria, Virginia 22313-1450
 Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/30559

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-9 directed to a cannulation simulation device.

Group II: Claims 10-18 directed to a method for cannulation training.

----See Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-9

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/30559

Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features

The invention of Group II includes the special technical feature of method for cannulation training comprising:

inserting a dialysis needle through a pad;

and detecting the presence of the dialysis needle within the lumen of the fistula by use of a first sensor in communication with the lumen, not required in Group I.

Common Technical Features

Groups I and II are related as an apparatus (group I) and a method of using the apparatus (group II). The apparatus is known in prior art as shown in US 2011/0200977 A1 (PARONEN).

Regarding claim 1, Paronen discloses a cannulation simulation device comprising:

a support (1, fig 1);

an artificial fistula (5) held in conjunction with the support (fig 1), the artificial fistula including an upper barrier (upper wall of 5) having a radial curvature (tube is curved, fig 1) and an axial length and further including a lower barrier (lower wall of 5, fig 1), the artificial fistula defining a lumen between the upper barrier and the lower barrier (5 is a tube which has a lumen, fig 1); and

a pad (4) configured to be removably located on an upper surface of the support such that the pad overlays the upper barrier of the artificial fistula (fig 1, para [0018]-[0019]).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.