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(71) Applicant: RYAN MEDICAL, INC. [US/US]; 7106 Crossroads Blvd., Suite 201, Brentwood, TN 37027 (US).

(72) Inventor: RYAN, Dana, Wm. ; 1711 New Highway 96 NW, Franklin, TN 37604 (US).

(74) Agent: GORDON, David, P.; 65 Woods End Road, Stamford, CT 06905 (US).

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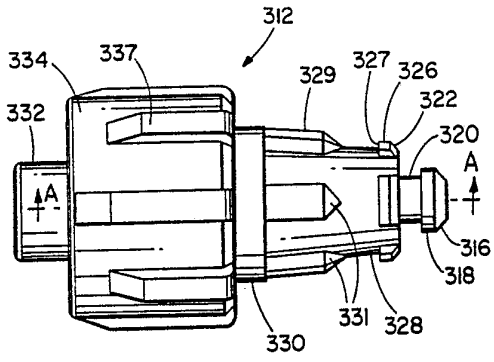

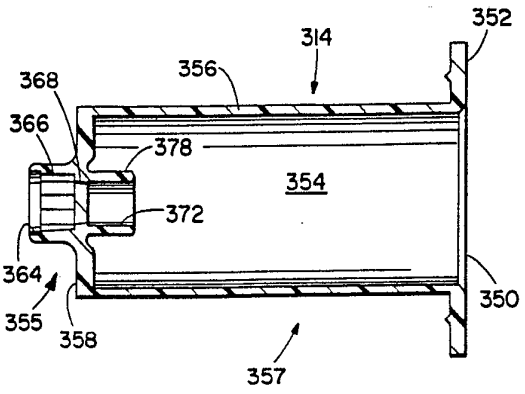

(57) Abstract

Safety multiple sample rear adapter assemblies utilizing one or two molded components are provided. A preferred arrangement (Figs. 9 and 10) includes a male connector (312) and a rear blood tube holder (314) each of which is provided with cooperative locking and anti-rotational devices. The locking device of the male connector is a ramp (322) which terminates in a shoulder (326) which in turn terminates in a groove (328), while the locking device of the rear blood tube holder is a ramp (368) terminating in a seat (376). The anti-rotational device of the male connector comprises protrusions (329) on the middle portion of the male connector, while the anti-rotational device of the rear blood tube holder comprises notches (399) in a front cylindrical portion (366) of the rear blood tube holder.

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SAFETY MULTIPLE SAMPLE REAR ADAPTER ASSEMBLY

BACKGROUND OF THE INVENTION

This invention relates to medical devices for drawing blood samples, and more particularly to a safety multiple sample rear adapter assembly that makes it easier to draw blood samples from patients, and at the same time, provides substantial protection against needlesticks.

Drawing blood samples from patients is often a difficult task especially if a patient has small veins as is frequently the case with children, small women or the elderly. It is not unusual for a patient with small veins to be stuck more than once using standard blood collection needles before the needle is positioned properly in the vein to draw the blood sample. This problem can cause the patient physical distress and considerable anxiety. Under such conditions, the medical staff is also subjected to increased stress because of the patient's reaction to the difficulty of the procedure.

Winged needle devices, which give the phlebotomist greater control of the venipuncture procedure, can be helpful in solving the problem of taking blood samples from patients with small veins. The smaller winged needle device, because of its reduced size, allows the medical staff to position the needle more accurately, which significantly reduces the number of times a patient must be stuck with the needle to produce satisfactory blood sampling. However, standard winged needle devices do not have means for accepting blood collection vacuum tubes which provide negative pressure for drawing blood and in which the drawn blood is collected.

In order to permit the use of a winged needle device with a blood collection vacuum tube, it was proposed in U.S. Patent #4,140,108 issued to Nugent to provide a blood collection assembly with a rear needle adapter for use in taking blood samples. The blood collection assembly of Nugent is comprised of several parts, including a rear needle adapter, and flexible tubing with hubs and needles on each end (one venipuncture needle and one rear needle for puncturing a stopper on a vacuum tube). The venipuncture needle is in open communication with the tubing and is held in the tubing by attachment to the hub. The rear needle is attached to the flexible tubing via the rear hub. The rear hub has external male helical threads which permit it to be screwed to and unscrewed from the forward hub portion of a standard rear blood tube holder which has reciprocating internal female helical threads. The standard rear blood tube holder also includes a receiving cylinder which is open at one end for receiving blood collection vacuum tubes.

In using the device disclosed by the Nugent patent, the rear needle attached to the male threaded hub is placed in the forward hub portion of a standard rear blood tube holder, and the rear hub on the flexible tubing is mated with the forward hub portion of a standard rear blood tube holder by screwing the two together. The assembly is then ready to have standard blood collection vacuum tube(s) inserted in the receiving cylinder of the rear blood tube holder, such that the rear needle will puncture the stopper of the blood collection vacuum tube and blood will be collected. When the blood sampling procedure is finished, the venipuncture needle is

removed from the patient's vein, and the rear needle is removed from the standard rear blood tube holder by unscrewing the hub holding the rear needle. The rear blood tube holder is then saved for subsequent uses. However, upon disassembly, the venipuncture and rear needles are contaminated and left completely exposed increasing the possibility of unwanted needlesticks occurring.

SUMMARY OF INVENTION

It is therefore the primary object of the invention to provide a safety multiple sample rear adapter blood collection assembly which can be used with standard or safety winged needle venipuncture devices and which shields a rear needle which is permanently locked inisde a rear blood tube holder, thereby significantly reducing the possibility of needlesticks and/or blood borne contaminates.

According to a first aspect of the invention, the safety rear adapter assembly of the invention preferably comprises a male connector and a hollow rear blood tube holder. The male connector has hollow first and second ends and a hollow needle, the hollow first and second ends defining a throughbore that is connected with the needle. The first end of the male connector holds the needle and includes a first locking means for locking with reciprocal means of the hollow rear blood tube holder. The second end of the male connector has a coupling such as a luer lock for coupling to a standard female luer lock adapter which is typically connected to a winged needle device. The hollow rear blood tube holder has an outer wall which forms a receiving cylinder with an open rear end for receiving blood collection vacuum tubes, and a

front end having an opening for accepting the hollow front end of the male connector, the front end having locking means that mates to the male adapter.

The locking configuration on the male connector uses a ramp portion of increasing diameter and an increased diameter shoulder, while the locking configuration on the rear tube holder uses a ramp of decreasing diameter which terminates in an increased diameter seat. The ramp and shoulder of the male connector are slid past the ramp at the front end of the rear blood tube holder such that the shoulder passes the ramp, rests in the seat, and cannot be removed from the rear blood tube holder because of the back face of the rear blood tube holder ramp. To expedite the movement of the increased diameter shoulder past the decreasing diameter ramp, the shoulder may be notched. To prevent rotation of the male connector and the rear blood tube holder, at least portions of the outer surface of the first end of the male connector and corresponding portions (in the mated position) of the inner surface of the front end of the rear blood tube holder are reciprocally notched.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross section through a first embodiment of an assembled asafety multiple sample rear adapter assembly of the invention having a male connector and a rear blood tube holder.

Fig. 2a is a cross section through the male connector of Fig. 1.

Fig. 2b is an end view of the first end of the male connector of Fig. 1.

Fig. 3a is a cross section through the rear blood tube holder of Fig. 1.

Fig. 3b is an end view of the front end of the rear blood tube holder of Fig. 1.

Fig. 3c is an end view of the rear end of the rear blood tube holder of Fig. 1 showing a flange.

Fig. 4 is an enlarged cross section showing the mating portions of the male connector and rear blood tube holder of Fig. 1.

Fig. 5 is a cross section showing a standard size blood collection vacuum tube in place in a safety multiple sample rear adapter assembly of Fig. 1.

Fig. 6 is a cross section showing a pediatric adapter in place in the rear blood tube holder of Fig. 1.

Figs. 7a-1 and 7a-2 are a cross section through and a front view of a male connector of a locking thread embodiment of the invention.

Figs. 7b-1 and 7b-2 are a partial cross section through and a partial front view of the rear blood tube holder of the locking thread embodiment of the invention.

Fig. 7c is a partial cross section through the male connector and rear blood tube holder of Figs. 7a-1 and 7b-1 illustrating how th male connector and rear blood tube holder mate by means of the locking thread system.

Fig. 8 is a cross section through a third embodiment of the invention which is a one piece molded safety multiple sample rear adapter.

Fig. 9a is an enlarged perspective of the male connector of a fourth embodiment of the invention.

Fig. 9b is a cross section along axis A-A through the male connector of Fig. 9a.

Fig. 9c is an enlarged front view of the male connector of Fig. 9a.

Fig. 10a is a cross section through the rear blood tube holder of the fourth embodiment of the invention.

Fig. 10b is an enlarged view of the cross section through the front end of the rear blood tube holder of Fig. 9.

Fig. 10c is a partial front end view of the rear blood tube holder of Fig. 10b.

DETAILED DESCRIPTION OF THE INVENTION

As seen in Fig. 1, the safety multiple sample rear adapter assembly 10 of the invention comprises a male connector 12 and a rear blood tube holder 14. The male connector 12 as shown in Fig. 2a and Fig. 2b has a hollow front end with a nose 18 having a bevel 16 on the end of the nose, a groove 20 of reduced outer diameter relative to the outer diameter of the nose 18, a ratcheted ramp 22 which is of greater diameter than the diameter of the nose 18, which increases in diameter as it extends away from the nose, and which terminates in a ratcheted locking shoulder 26 of relatively constant diameter. A locking shoulder in turn terminates with a rear abutment surface 27. Rearward of the front end of the male connector 12 is a hollow middle portion

with a stop member 30, and a generally cylindrical section 28 which lies between the abutment surface 27 of the ratcheted shoulder and the stop member 30. The generally cylindrical section 28 is provided with a reduced diameter relative to the shoulder 26. Rearward of the hollow middle portion is a rear end which comprises a standard male luer 32 as shown with an outer surface which tapers according to standard male luer specifications. As aforestated, the front end, middle portion, and rear end are hollow, and they together provide a continuous throughbore 36 of varying size. The portion of tapered bore 36 that begins at the nose 18 is arranged to permit a hollow needle 44 to be permanently attached therein, such as by gluing or bonding.

Fig. 4 shows the resilient self-sealing sleeve 48 covering the needle 44. The self-sealing sleeve 48 has an open end 49 which is arranged to fit over and grip the nose 18 while terminating in groove 20, and in this manner the self-sealing sleeve 48 is held in place. A closed end 51 of the self-sealing sleeve 48 extends slightly beyond the sharp end 53 of needle 44. As will be described in more detail hereinafter, self-sealing sleeve 48 permits multiple blood samples to be taken using the safety assembly by sealing off needle 44 between the taking of multiple blood samples.

Turning to Figures 3a-3d, the rear blood tube holder 14 is seen to have a front mating portion 55 and rear receiving cylindrical portion 57. The receiving cylindrical portion 57 has a circular opening 50 surrounded by a flange 52, and a chamber 54 formed by receiving cylinder wall 56. Receiving cylinder portion 57 terminates with a front end wall 58 which

supports and is closed around front mating portion 55 which extends outward from the front wall 58. The front end of the front mating portion begins with a hollow cylinder 64 which has an inside diameter substantially equal to the diameter of the male connector stop member 30 shown in Fig. 2a, and with a depth substantially equal to the length of the stop member. Adjacent to hollow cylinder 64 is a reduced diameter cylinder 66 with an inside diameter substantially equal to the diameter of the male connector ratcheted shoulder 26 which is also substantially equal to the tooth apex diameter 34 shown in Fig. 2b. The reduced diameter cylinder 66 terminates in a ramp 68. Ramp 68 of the rear blood tube holder terminates at an annular ratchet 70, which has a root diameter 72 which is larger than the diameter 74 at the termination of the tapered bore 68 as shown in Fig. 3d. The difference in these two diameters forms a seat 76. The interior cylindrical wall 72 of collar 78 surrounds the annular ratchet and the collar extends beyond the annular ratchet protruding into the hollow middle portion 54 of the rear blood tube holder 14. The horizontal distance between seat 76 and seat 82 formed by the hollow cylinders 64 and 66 of the rear blood tube holder is substantially the same as the horizontal distance between the termination of the male connector ratcheted shoulder 27 and stop member 30 shown in Fig. 2a.

In connecting the male connector to the rear blood tube holder to make up the invention assembly as shown in Fig. 1 and Fig. 4, the male connector nose 18 is inserted in the rear blood tube holder front mating portion hollow cylinder 64. The nose 18 of the male connector is slid past the hollow

cylinder 64 and into the reduced diameter cylinder 66 and then into ramp 68. At this point the male connector ratcheted ramp 22 is slid along rear blood tube holder ramp 68. The ratchet teeth of the male connector are flexible enough to permit them to deform to the contour of the rear blood tube holder ramp 68, which permits the male connector to be slid along rear blood tube holder ramp 68. When the male connector ratcheted ramp 22 reaches the beginning of the annular ratchet 70 it self-aligns and the male connector 12 self-rotates slightly so that the teeth of the male connector ratchet line up with the spaces between the teeth of the rear blood tube holder annular ratchet. In Fig. 2b the ratchet teeth 24 can be seen. The male connector ratchet locking diameter (apex to apex diameter 34 seen in Fig. 2b), and the rear blood tube holder ratchet root diameter (valley to valley diameter 72 seen in Fig. 3b) are substantially the same as are the shape of the teeth which permits them to be interleaved. When the teeth are lined up the male connector ramp is slid forward so the teeth of the two ratchets do interleave. The male connector is slid as far into the rear blood tube holder as possible; the sliding distance being controlled by the male connector stop member 30 coming into contact with rear blood tube holder seat 82. The longitudinal movement of the male connector into the rear blood tube holder is sufficient to allow the male connector ratcheted ramp 22 to deform sufficiently to permit ratcheted shoulder 26 to slide past rear blood tube holder seat 76 as shown in Fig. 4. As ratcheted shoulder 26 clears seat 76 the deformed ratcheted ramp and shoulder return substantially to their original shape. If an attempt is made to pull the male

connector out of the rear blood tube holder, the ratcheted shoulder 26 is restrained from being pulled out by rear tube holder seat 76 bearing on abutment surface 27. Since the male connector ratchet teeth are interleaved with the rear blood tube holder annular ratchet teeth no rotation of the male connector relative to the rear tube holder is possible. In this manner the male connector is permanently installed in the rear blood tube holder.

In use, the male connector is attached to the rear blood tube holder as described. A venipuncture needle which is part of a winged needle assembly (not shown) such as described in U.S. Patent application #07/416,927 assigned to the assignee hereof, is placed in the vein of a patient. Blood flows from the vein of the patient through a flexible tube (not shown), through a female luer (not shown) attached to the flexible tube, through the male connector 12, and into the needle 44. Because the needle 44 is covered by sleeve 48, the blood can go no farther as the sleeve seals off the needle. At this point a blood collection vacuum tube 86 is pushed into the receiving chamber 54 with the rubber stopper 88 at the end of the collection tube pushing back the resilient self-sealing sleeve 48 and exposing the hollow needle 44 which penetrates the rubber stopper 88 all as shown by Fig. 5. The blood will then flow into the collection tube easily through the hollow needle aided by the presence of the vacuum in the collection tube 86.

When the vacuum blood collection tube is removed from receiving chamber 54, the resilient self-sealing sleeve 48 returns to its original shape covering and resealing the

hollow needle so that it again appears as shown in Fig. 4, and so that blood does not continue to flow out of the needle 44. Another vacuum blood collection tube may then be introduced as aforedescribed to collect further blood samples. When all blood samples have been collected, the safety multiple sample rear adapter assembly 10 should not be reused. In disposal of the assembly, the needle 44 remains secure inside the receiving cylinder 54 of the rear blood tube holder 14 and is well shielded by resilient sleeve 48 and by cylindrical wall 56 to significant reduce the probability of accidental needlesticks. If the assembly is used with the preferred winged needle device of Serial No. 07/416,927, then the venipuncture needle is withdrawn into the protective sheath of the winged needle device and no danger is presented from needlesticks from that source either.

If a smaller sample of blood is required as is the case in some pediatric and other situations, then a special reduced diameter blood collection vacuum tube adapter 90 (hereinafter referred to as a "pediatric adapter") is provided as shown in Fig. 6. The outside diameter of the pediatric adapter is substantially the same as the inside diameter of the receiving chamber walls 56. The inside "diameter" of the pediatric adapter 90 is formed by longitudinal ribs 94 that preferably run the length of the pediatric adapter. The pediatric adapter also includes a small beveled flange 92 at one end. The pediatric adapter 90 is installed in the rear blood tube holder 14 by pushing the pediatric adapter into the chamber 54 of the receiving cylinder until the beveled flange 92 of the pediatric adapter contacts the beveled edge 84 of the rear

blood tube holder. A smaller diameter blood vacuum collection tube (not shown) may then be introduced into the pediatric adapter 90, with the ribs 94 of the pediatric adapter making contact with the tube which is guided and loosely supported thereby. The entire assembly then functions exactly as described above with relation to the standard blood collection vacuum tubes.

Figures 7a-1, 7a-2, 7b-1, 7b-2 and 7c illustrate an embodiment of the invention utilizing a locking thread system to permanently mate a male connector 112 to a rear blood tube holder 114. As seen in Fig. 7a, the male connector is hollow and substantially cylindrical, and defines a male luer on one end 132. The other end of male connector has a nose with ramp 116, shoulder 118, and a groove 120 rearward of the shoulder 118. The middle portion (which may be considered an extension of the nose end) of male connector 112 has a helical type male thread 161a around a portion of its circumference followed by a section 129 of increased diameter which is followed by a tabbed stop section 130 of even greater diameter. Tabbed stop 130, as seen in Fig. 7a-2, preferably includes two tabs 125a which are used as locking means as is more completely described below. The tabs 125a extend beyond the outer diameter of the remainder of stop 130, but are provided with bending flexibility by undercuts 199 in the stop member 130.

The rear blood tube holder 114 of the second embodiment shown in Fig. 7b has first and second ends. The first end (not shown) is substantially identical to the receiving cylinder of Figure 1, and is of sufficient diameter to receive a standard blood collection vacuum tube. The first end

terminates at a front end wall 158. Extending forward from the front end wall 158 is a front mating portion 155. The front end of the front mating portion 155 has a tapered hollow opening 164 which starts with an inside diameter slightly larger than the outside diameter of the tabbed stop member 130 of the male connector 112, and which terminates in a ratcheted seat 162 with ramped teeth 125b (seen in Fig. 7b-2). The ratcheted seat 162 in turn terminates in a reduced inner diameter cylinder 166 which terminates in wall 165 having a female threaded opening 161b. Extending rearward from wall 165 is a collar 178 which acts as a stop for blood collection vacuum tubes inserted into the rear blood tube holder 114.

As will be appreciated by reference to Figure 7c, the threaded opening 161b in wall 165 of the rear blood tube holder 114 is arranged with an inner diameter which matches the outer diameter of the male threaded middle portion of male connector 112. Similarly, ratcheted seat 162 and the ramped ratchet teeth 125b of the rear blood tube holder 114 are arranged with inner diameters which match that of the outer diameter of stop member 130 and tabs 125b respectively. Further, it will be appreciated that the outer diameter of the shoulder 118 of the nose of the male connector 112 is smaller than the inner diameter of threaded opening 161b in wall 165 of the rear blood tube holder 114, and that the axial distance between threaded opening 161b and seat 162 of the rear blood tube holder 114 is substantially equal to the axial distance between the thread 161a and the stop 130 of the middle portion of the male connector 112.

In mating the male connector 112 with the rear blood tube holder 114, the nose portion of the male connector 112 and needle 144 (as well as a self-sealing sleeve not shown) are inserted through the threaded hole 161b in wall 165 of the blood tube holder, until the male threaded section 161a of the male connector contacts wall 165 of the rear blood tube holder. Then, the male threaded section 161a is screwed into the female opening 161b until enlarged cylindrical portion 129 of the male connector contacts wall 165 of the rear blood tube holder. As the male connector and rear blood tube holder 114 are being screwed together, the tabbed stop 130 of the male connector 112 rotates in the ratcheted seat 162 of the rear blood tube holder, with the flexible tabs 125a flexing inwardly as they ride over ramped teeth 125b.

If rotational force is applied to the male connector in an attempt to remove the male connector 112 from the rear blood tube holder 114, the tabs 125a on the shoulder 130 of the of the male connector catch on the blunt portions of teeth 125b of seat 162 of the the blood tube holder 114 and deform. With tabs 125a deformed between the teeth 125b, the male connector 112 is locked into the rear blood tube holder 114 and cannot be removed by rotation. Also, if axial force is applied to the male connector in an attempt to remove the male connector 112 from the rear blood tube holder 114, the threads of threaded portion 161a of the male connector, and the threads of threaded opening 161b of the female connector act as stops, and prevent axial movement without rotation.

Turning to Fig. 8, a safety multiple sample rear adapter assembly fabricated as a one piece molding is seen. The adapter 210 is comprised of a hollow receiving cylinder 256, a male luer 232 of substantially reduced outer diameter relative to the outer diameter of the cylinder 256, and a dividing wall 255 through which a throughbore 236 provides fluid communication between the receiving cylinder and male luer. The hollow receiving cylinder 256 has a circular open end 250 and a bevel 284 around the circular opening, and is of sufficient diameter to receive standard blood collection vacuum tubes 286 with front stoppers 288. The male luer 232 is sized and tapered according to standard luer specifications. The dividing wall 255 is effectively the front wall of the hollow receiving cylinder 256. Extending from the front wall 255 of the receiving cylinder 256 and back into the receiving cylinder 256 is a hollow rear extension which includes nose portion 218 and a groove 220 of reduced diameter relative to the nose portion 218. The hollow rear extension serves two purposes. First, it holds in place a needle 244 which is used to puncture the stoppers 288 of the vacuum tubes 286. Second, it holds in place a resilient self-sealing needle covering sleeve 248 which as shown in Fig. 8 is punctured by the needle 244 and collapsed by the stopper 288 when the needle 244 punctures the stopper 288, but which as shown in Fig. 4 covers the sharp end of the needle 244 and stops blood flow after the vacuum tube is pulled off of the needle.

Another embodiment 300 of the safety multiple sample luer adapter assembly of the invention comprises a male connector 312 shown in Figs. 9a-9c and a rear blood tube holder 314 shown in Figs. 10a-10c. The male connector 312 as shown in Figs. 9a-9c has a hollow front end with a nose 318 having a bevel 316 on the end of the nose, a groove 320 of reduced outer diameter relative to the outer diameter of the nose 318 (the nose and groove for purposes described in the parent application hereto), a segmented ramp 322 which is of greater diameter than the diameter of the nose 318, which increases in diameter as it extends away from the nose, and which terminates in a segmented locking shoulder 326 of relatively constant diameter. The segmented locking shoulder 326 in turn terminates with a rear abutment surface 327. Rearward of the front end of the male connector 312 is a hollow middle portion which starts with a groove 328 of diameter smaller than segmented locking shoulder 326, continues with preferably ramped anti-rotational protrusions or ribs 329, and terminates with stop collar 330. The anti-rotational protrusions 329 preferably start in an arrow configuration 331 (best seen in Fig. 9a and 9c) for self-centering purposes, and the protrusions 329 preferably increase in diameter as they extend from groove 328 toward the stop collar 330.

Rearward of the hollow middle portion of the male connector is a rear end which comprises a standard male luer lock. The male luer lock has a male luer section 332 with an outer surface which tapers according to standard male luer specifications, and a threaded locking section 334 according to luer lock specifications. The threaded locking section 334

preferably includes outwardly extending ribs 337 which permits a user of the assembly to more easily grip the assembly while mating the assembly with a female luer lock mechanism.

As aforestated, the front end, middle portion, and rear end of the male connector 312 are hollow, and they together provide a continuous throughbore 336 of varying size. The portion of tapered bore 336 that begins at the nose 318 is arranged to permit a hollow needle (not shown) to be permanently attached therein, such as by gluing or bonding. Of course, the needle may be permanently attached via injection molding of the assembly.

Turning to Figures 10a-10c, the rear blood tube holder 314 is seen to have a front mating portion 355 and rear receiving cylindrical portion 357. The receiving cylindrical portion 357 has a circular opening 350 surrounded by a flange 352, and a chamber 354 formed by receiving cylinder wall 356. Receiving cylinder portion 357 terminates with a front end wall 358 which supports and is closed around front mating portion 355 which extends outward from the front wall 358. The front end of the front mating portion begins with a hollow cylinder 364 which has an inside diameter substantially equal to the diameter of the male connector stop collar 330 shown in Figs. 1a and 1b, and with a depth substantially equal to the length of the stop collar. Adjacent to hollow cylinder 364 is a grooved reduced diameter cylinder 366 with an inside diameter substantially equal to the outside diameter of the male connector segmented shoulder 326. As indicated in Figs. 2b and 2c, grooves or notches 399 are formed in reduced diameter cylinder 366. The grooves 399 increase the inner

diameter of the reduced diameter cylinder 366 at certain locations and are sized to receive the anti-rotational protrusions 329 of the male connector; i.e. the inner diameter of grooves 399 is substantially equal to the outer diameter of protrusions 329 and is preferably appropriately tapered.

The notched reduced diameter cylinder 366 of the rear blood tube holder terminates in a ramp 368. Ramp 368 decreases in diameter as it extends toward chamber 354 and terminates in a seat 376 which is also defined by the interior cylindrical wall 372 of collar 378. The collar 378 protrudes into the hollow middle portion (chamber) 354 of the rear blood tube holder 314. The horizontal distance between seat 376 and the notched seat 382 formed by hollow cylinder 364 and notched hollow cylinder 366 of the rear blood tube holder is substantially the same as the horizontal distance between the termination of the male connector ratcheted shoulder 27 and the beginning of stop collar 330 shown in Figs. 1a and 1b. Also, the horizontal length of stop collar 330 is preferably approximately equal to the horizontal length of hollow cylinder 364.

In connecting the male connector to the rear blood tube holder to make up the invention assembly 300 shown as Figs. 9a and 10a, the male connector nose 318 is inserted in the rear blood tube holder front mating portion hollow cylinder 364. The nose 318 of the male connector is slid past the hollow cylinder 364 and into the reduced diameter cylinder 366 and then past ramp 68. At approximately that time, or some time before, the male connector 312 and the rear blood tube holder 314 are rotationally aligned such that the protrusions 329 on

the middle portion of the male connector will properly slide into the grooves 399 in the reduced hollow cylinder 364 of the blood tube holder 314. Rotational alignment is expedited by the arrow configuration 331 of the front end of the anti-rotational protrusions 329. In fact, depending on the circumferential size of the protrusions 399 relative to the entire circumference, rotational alignment may be automatic, as at least one protrusion 329 may always partly engage a groove 399 and cause rotation of the male connector relative to the rear blood tube holder during assembly. With the male connector and blood tube holder aligned (or during alignment), the segmented ramp 322 and shoulder 326 of the male connector is slid along rear blood tube holder ramp 368 while protrusions 329 slide in grooves 399. Because the ramp 322 and shoulder 326 of the male connector are segmented, they deform to the contour of the rear blood tube holder ramp 368 as they slide therethrough. As the segmented shoulder 326 clears seat 376 of the rear blood tube holder, the deformed segmented ramp 322 and shoulder 326 return substantially to their original shape. If an attempt is made to pull the male connector out of the rear blood tube holder, the ratcheted shoulder 326 is restrained from being pulled out by rear tube holder seat 376 bearing on abutment surface 327. Since the male connector protrusions 329 are sitting in the rear blood tube holder grooves 399, no rotation of the male connector relative to the rear tube holder is possible. In this manner the male connector is permanently installed in the rear blood tube holder.

In use, the male connector is attached to the rear blood tube holder as described. The assembly is then used as described with reference to Figs. 1-6, except that a female luer lock is used to connect to the male luer lock (332 and 334) of the male connector 312.

There have been described and illustrated herein safety multiple sample rear adapter assemblies. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereby, as it is intended that the invention be as broad in scope as the art will allow. Thus, it will be understood by those skilled in the art that means other than ratcheted ramps and shoulders, and particular threaded arrangements could be utilized to establish permanent connection between two pieces of the assembly. For example,
permanent connection could be accomplished by welding or gluing the two plastic parts together. Or, if desired, connecting pieces with locking threads having different thread widths, thread root diameters or thread pitch could be utilized to establish permanent connection upon screwing the pieces together. Further, while the male connectors of the two piece embodiments were described as having a male luer on one end, it will be appreciated that a male luer-lock could be utilized in lieu of the male luer. In fact, even a female luer or other connection means such as means which could connect directly to tubing could be utilized if the winged needle device terminates with tubing or a reciprocating mating connection means. Also, it should be appreciated that while the male connectors of the two piece embodiments were

described as having a hollow needle inserted and glued into the nose of the connector, the needle could be insert molded or even formed in the molding process from plastic.

It will further be appreciated that while the locking shoulder and ramp of the male connector were described as segmented for purposes of deformation, depending on the tolerances and materials used, the locking shoulder and ramp could be continuous. Also, while self-aligning protrusions were described for aligning the protrusions of the male connector in the notches of the rear blood tube holder, it will be appreciated that alignment could be obtained by other means. Therefore, it will be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

I claim:

1. A safety rear adapter assembly for coupling a fluid conduit means to a fluid collection means, said safety rear adapter assembly comprising:

a) a male connector having hollow first and second end portions and a hollow needle, said hollow first and second end portions defining a throughbore in fluid communication with said hollow needle, said first end portion having on its outer surface a first locking means, and said second end portion having coupling means for coupling to the fluid conduit means, and said outer surface of said first end portion of said male connector comprising a first ramp of increasing diameter as it extends from said first end portion toward said second end portion, and a shoulder of relatively constant outer diameter, said first ramp terminating in a first end of said shoulder, said shoulder having a second end terminating in portion of reduce diameter relative thereto; and

b) a hollow rear blood tube holder with an outer wall defining a receiving cylinder with an open rear end for receiving the fluid collection means, and a front end having an opening therein for accepting at least a portion of said hollow first end portion of said male connector, said front end of said hollow rear blood tube holder having on its inner surface a second locking means, said inner surface of said front end of said hollow rear blood tube holder comprising a second ramp of decreasing inner diameter as it extends from said front end to said open rear end, said second ramp terminating in a chamber of inner diameter at least as large as said outer diameter of said shoulder, and said shoulder

being of larger outer diameter than the inner diameter of said second ramp termination such that said termination of said second ramp and said shoulder form abutting locking surfaces,

wherein in assembling said safety rear adapter assembly said first and second locking means are brought into permanent locking engagement.

2. A safety rear adapter assembly according to claim 1, wherein:

said first ramp and said shoulder of said male connector are ratcheted with a plurality of teeth, and said chamber of said rear blood tube holder has a ratcheted front end section with a plurality of grooves to mate with said plurality of teeth, thereby preventing rotation of said male connector relative to said rear blood tube holder.

3. A safety rear adapter assembly according to claim 1, wherein:

said male connector further includes a hollow middle portion between said hollow first and second end portions, said hollow middle portion having an outwardly extending stop member, said outwardly extending stop member having an outer perimeter of larger radial distance than said opening in said front end of said rear blood tube holder,

the axial distance between said stop member and said second end of said shoulder along a longitudinal axis of said male connector being substantially equal to the axial distance between said opening and said increased diameter chamber of said rear blood tube holder.

4. A safety rear adapter assembly according to claim 2, wherein:

said male connector further includes a hollow middle portion between said hollow first and second end portions, said hollow middle portion having an outwardly extending stop member, said outwardly extending stop member having an outer perimeter of larger radial distance than said opening in said front end of said rear blood tube holder,

the axial distance between said stop member and said second end of said shoulder along a longitudinal axis of said male connector being substantially equal to the axial distance between said opening and said increased diameter chamber of said rear blood tube holder.

5. A safety rear adapter assembly according to claim 1, wherein:

said hollow first end portion of said male connector includes a nose portion and a groove forward of said first ramp, said groove being between said nose portion and said first ramp and of an outer diameter smaller than said nose portion, and said nose portion being of outer diameter smaller than said outer diameter of said ramp.

6. A safety rear adapter assembly according to claim 5, further comprising:

c) a resilient self-sealing sleeve, said resilient self-sealing sleeve being closed at a first end and open at a second end and of a length and diameter such that said first end fits over a sharp end of said hollow needle, and said second end fits over said nose and engages said groove of said first end of said male connector.

7. A safety rear adapter assembly according to claim 4, wherein:

said hollow first end portion of said male connector includes a nose portion and a groove forward of said first ramp, said groove being between said nose portion and said first ramp and of an outer diameter smaller than said nose portion, and said nose portion being of outer diameter smaller than said outer diameter of said ramp, said safety rear adapter assembly further comprising

c) a resilient self-sealing sleeve, said resilient self-sealing sleeve being closed at a first end and open at a second end and of a length and diameter such that said first end fits over a sharp end of said hollow needle, and said second end fits over said nose and engages said groove of said first end of said male connector.

8. A safety rear adapter assembly according to claim 1, wherein:

said coupling means of said second portion of said male connector comprises a male luer.

9. A safety rear adapter assembly according to claim 8, wherein:

said coupling means of said second portion of said male connector comprises a male luer.

10. A safety rear adapter assembly according to claim 1 where said fluid collection means is a smaller diameter blood collection vacuum tube, further comprising:

c) a cylindrical pediatric adapter having open first and second ends, an outer surface having a diameter substantially equal to the inside diameter of the said rear blood tube holder, and an inner surface having a diameter substantially

equal to the outside diameter of the smaller diameter blood collection vacuum tube.

11. A safety rear adapter assembly according to claim 1, wherein:

said male connector has first anti-rotational means,

said hollow rear blood tube holder has second anti-rotational means,

wherein in assembling said safety rear adapter assembly, said first and second anti-rotational means are brought into engagement to prevent rotation of said male connector relative to said hollow rear blood tube holder.

12. A safety rear adapter assembly according to claim 11, wherein:

said first ramp of said male connector is a first segmented ramp, and said shoulder of said of said male connector is a segmented shoulder,

said male connector further includes a hollow middle portion between said hollow first and second end portions, said hollow middle portion having at least one outwardly extending protrusion which constitutes said first anti-rotational means, and

at least a portion of said front end of said hollow rear blood tube holder comprises a notched member with at least one notch arranged to receive and hold said at least one outwardly extending protrusion when said male connector and said hollow rear blood tube holder are in permanent locking engagement.

13. A safety luer adapter assembly according to claim 12, wherein:

said at least one outwardly extending protrusion comprises a plurality of outwardly extending protrusions, and said at least one notch comprises a plurality of notches.

14. A safety luer adapter assembly according to claim 13, wherein:

said outwardly extending protrusions taper in two directions to form self-aligning protrusions.

15. A safety luer adapter assembly according to claim 11, wherein:

said hollow first end portion of said male connector includes a nose portion and a groove forward of said first ramp, said groove being between said nose portion and said first ramp and of an outer diameter smaller than said nose portion, and said nose portion being of outer diameter smaller than said outer diameter of said ramp.

16. A safety luer adapter assembly according to claim 11, wherein:

said coupling means of said second portion of said male connector comprises a male luer lock having a male luer portion and a threaded locking portion.

17. A safety luer adapter assembly according to claim 16, wherein:

said threaded locking portion of said male luer lock has an outer surface, and said outer surface has a gripping means.

18. A safety luer adapter assembly according to claim 17, wherein:

said gripping means comprises a plurality of ribs extending axially parallel to a long axis of said male connector.

19. A safety rear adapter assembly for coupling a fluid conduit means to a standard or smaller diameter blood collection vacuum tube having a resilient stopper thereon, said safety rear adapter comprising:

a) a hollow needle having a first sharp end for piercing the
resilient stoppers of standard or smaller diameter blood collection vacuum tubes;

b) a hollow receiving cylinder having an open first end, a dividing wall having an opening for said hollow needle or for fluid communication with said hollow needle, and a hollow holding means extending into said hollow receiving cylinder from said dividing wall, wherein a first end of said hollow needle extends into said hollow holding means and a second sharp end of said hollow needle extends into said hollow receiving cylinder, and said hollow receiving cylinder is of sufficient diameter to receive said standard blood collection vacuum tube;

c) a luer means extending from said dividing wall opposite said hollow receiving cylinder, said luer means for coupling said safety rear adapter to said fluid conduit means, said luer means having an outer diameter substantially smaller than the outer diameter of said hollow receiving cylinder;

d) a resilient self-sealing needle covering sleeve having a closed end and an open end, said sleeve being of a length sufficient to couple with said holding means and to cover said first sharp end of said needle with its closed end, wherein

said hollow receiving cylinder with said dividing wall and said hollow holding means, and said luer means constitute a single molded unit, and

a fluid path is established from said luer means to said needle via said opening in said dividing wall and said hollow holding means.

20. A safety rear adapter assembly according to claim 19, wherein:

said hollow needle is insert molded into said holding means.

21. A safety rear adapter assembly according to claim 19, wherein:

said hollow needle with said sharp second end is plastic and is formed simultaneously with and integral with said receiving cylinder and luer means in a molding process.

22. A safety rear adapter according to claim 19, wherein:

said holding means includes a nose portion and a groove forward of said dividing wall on the receiving cylinder side of said dividing wall, said groove being between said nose portion and said dividing wall and of an outer diameter smaller than said nose portion, and said nose portion being of an outer diameter smaller than said inner diameter of said dividing wall.

FIG. 1

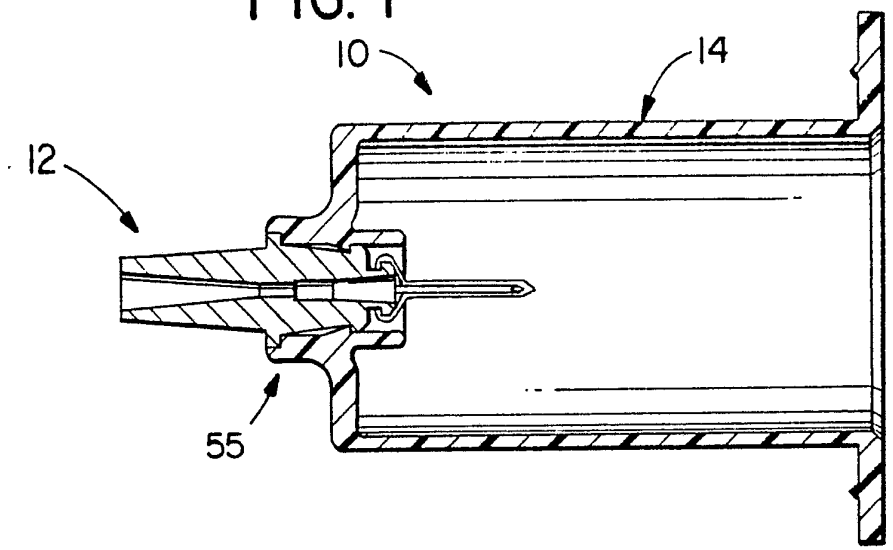

FIG. 2A

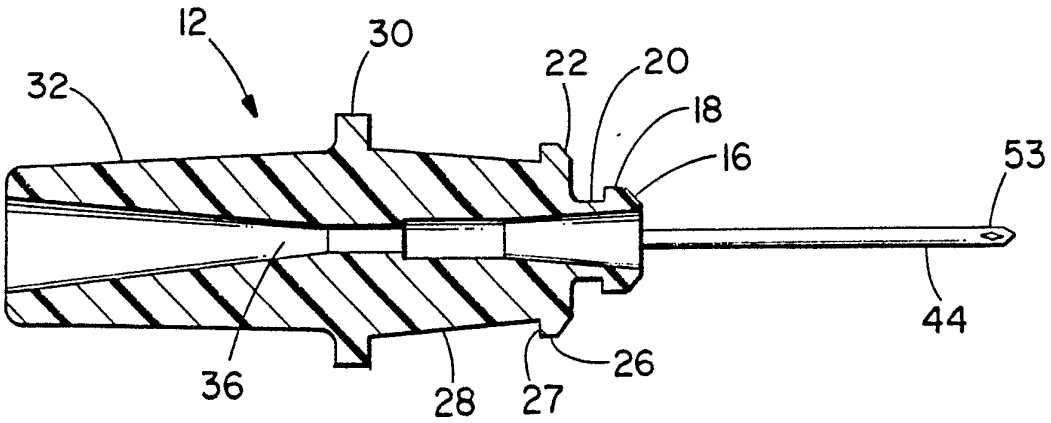

FIG. 2B

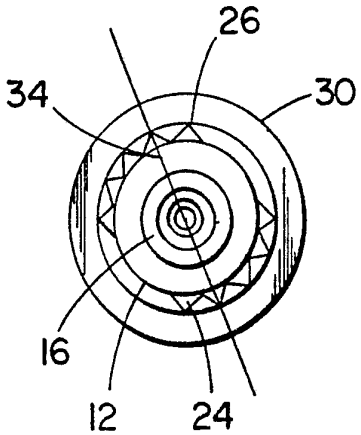

FIG. 3A

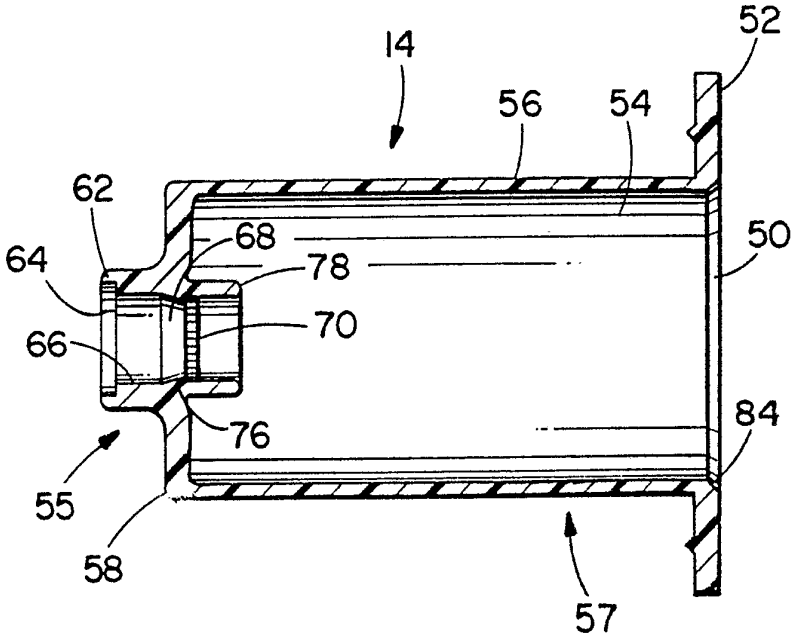

FIG. 3B

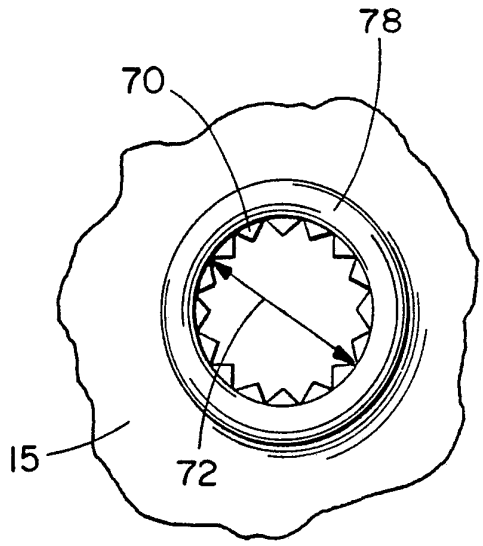

FIG. 3D

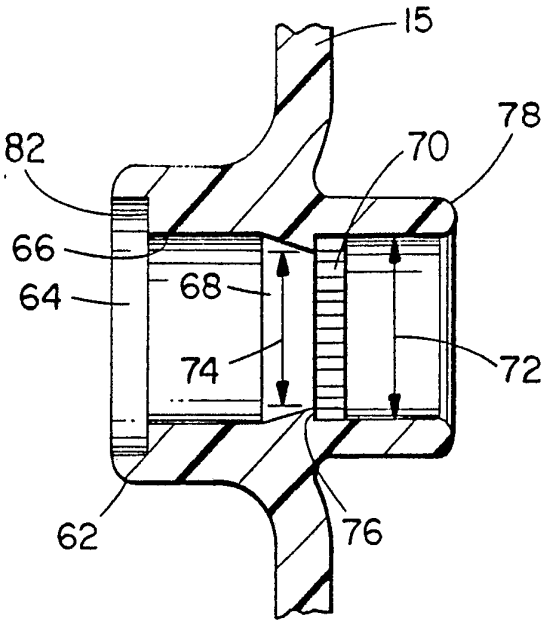

FIG. 3C

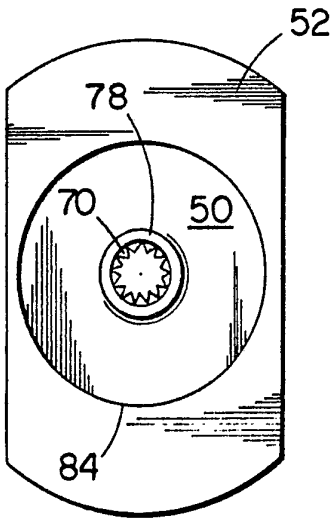

FIG. 4

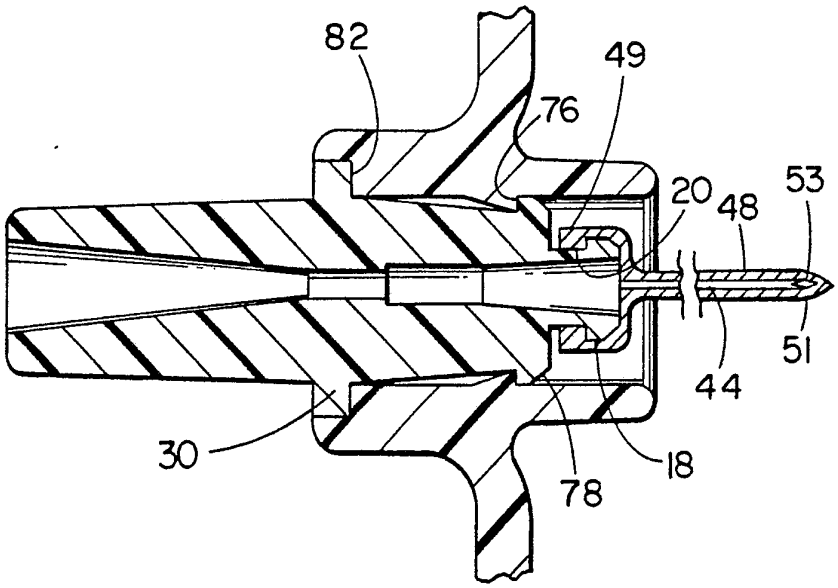

FIG. 5

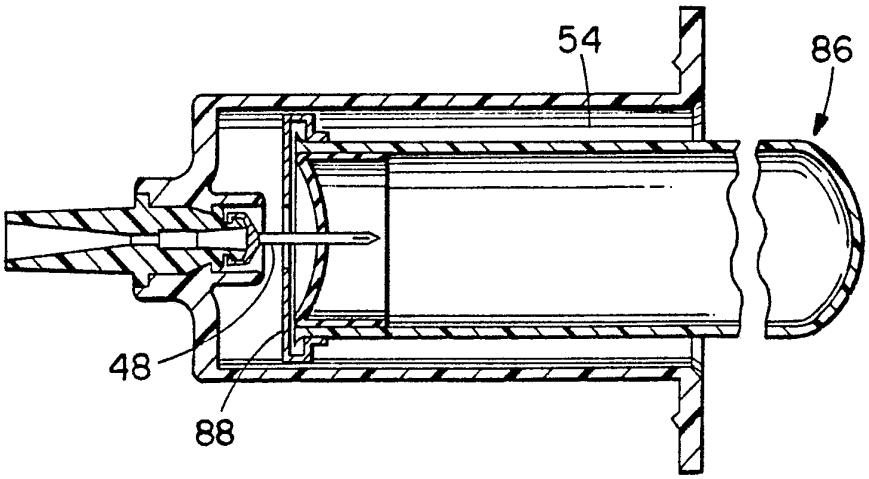

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FIG. 6

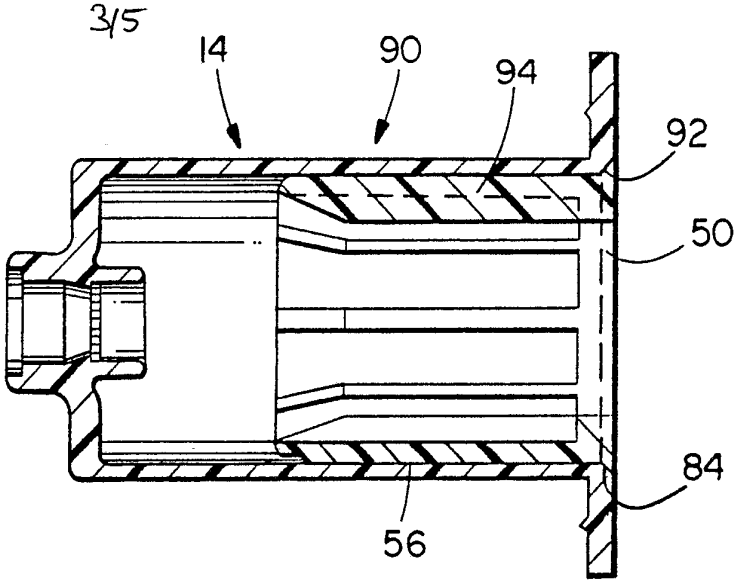

FIG. 7A-2

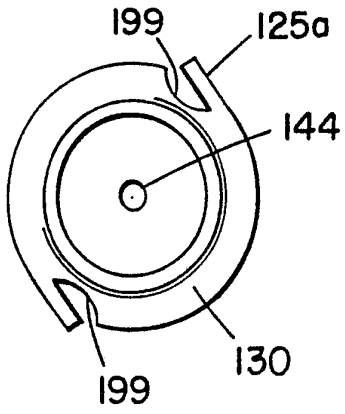

FIG. 7A-1

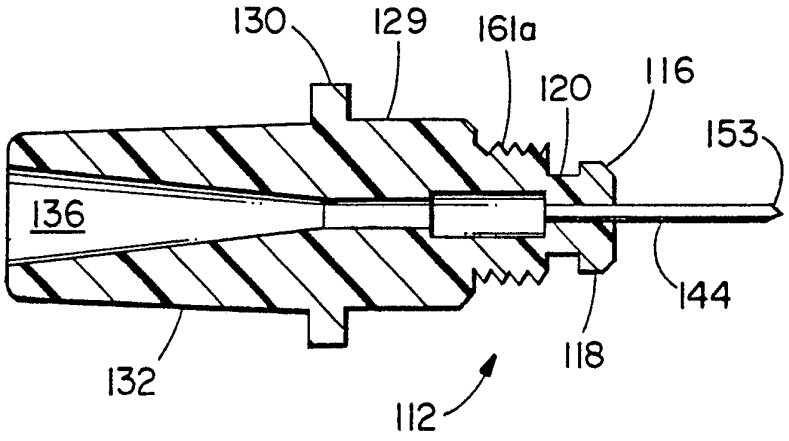

FIG. 7B-2

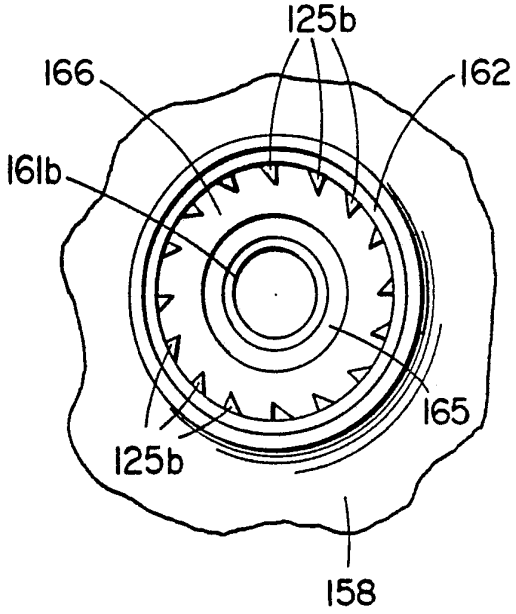

FIG. 7B-1

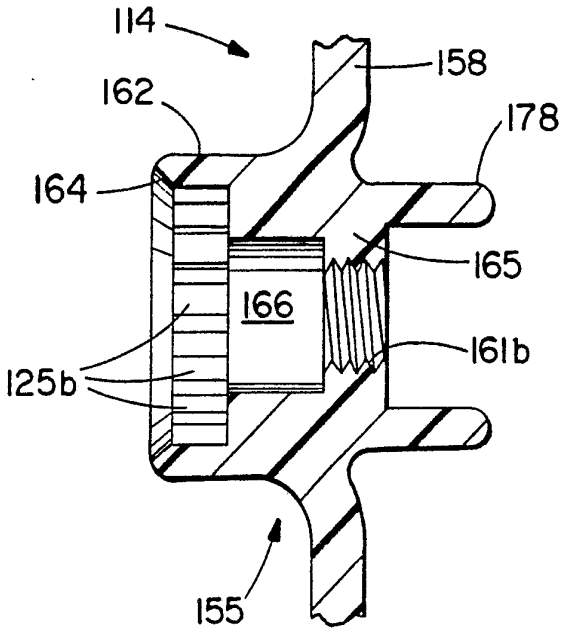

FIG. 7C

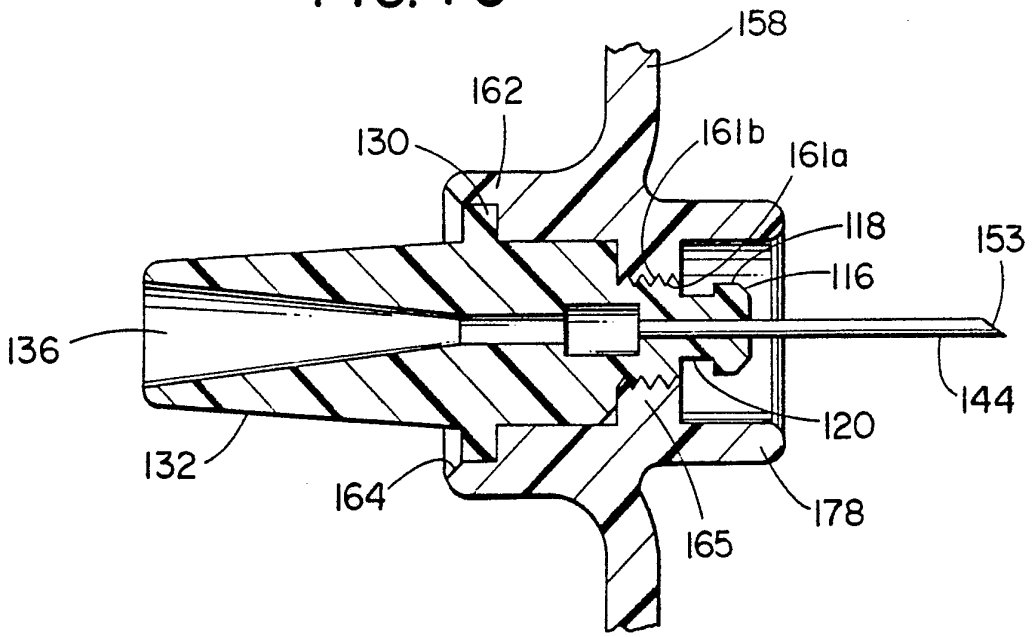
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FIG. 8

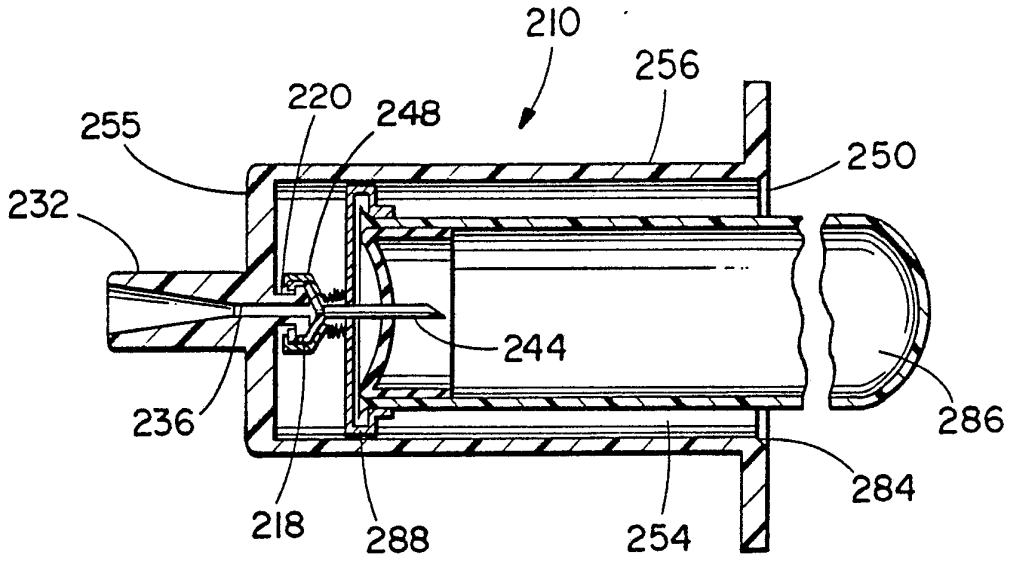
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FIG. 9A.

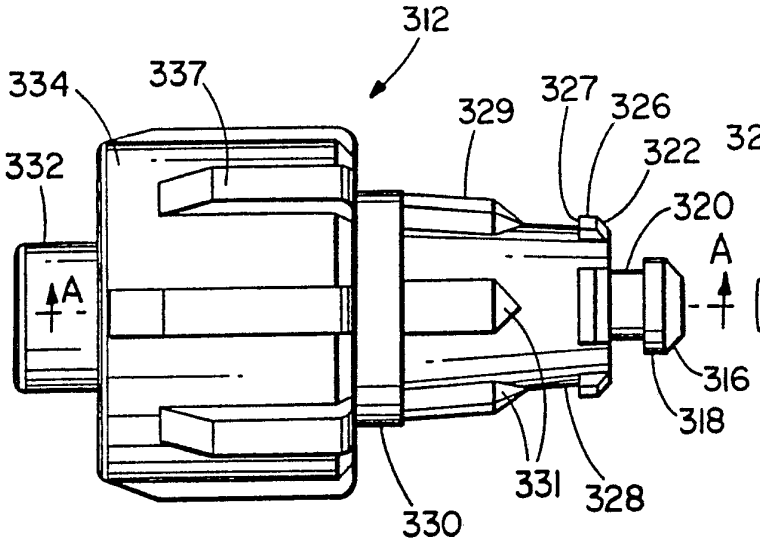


FIG. 9C.

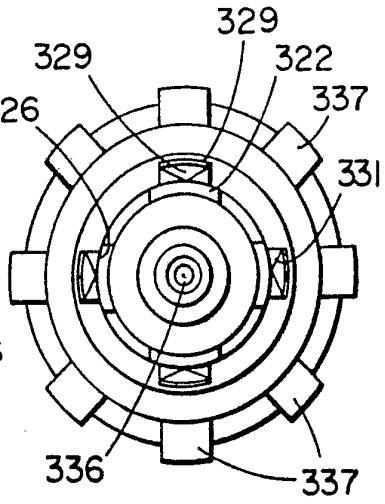


FIG. 9B.

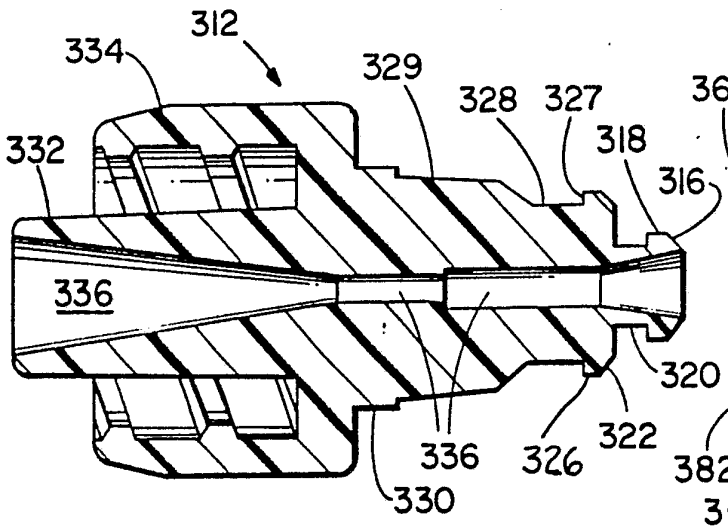


FIG. 10B.

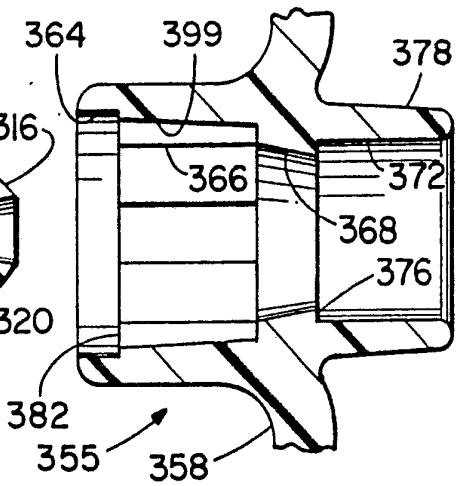


FIG. 10A.

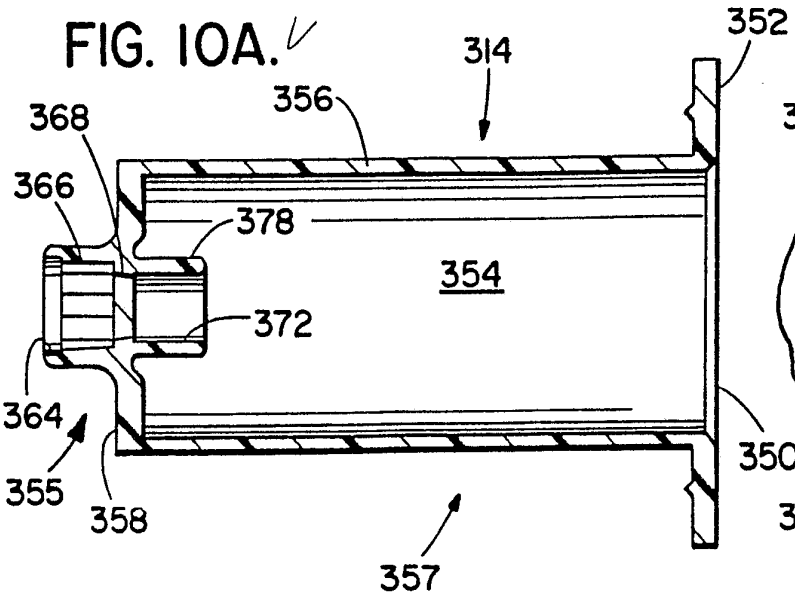
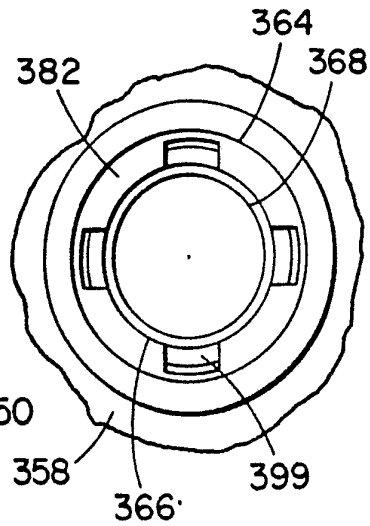


FIG. 10C.



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/03150

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 5/00
US CL : 604/240

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	604/240,241,242,195,187,232 128/763,764,765

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 3,884,229 (RAINES ET AL.) 20 MAY 1975 See entire document.	1-22
A	US, A, 4,398,544 (NUGENT ET AL.) 16 AUGUST 1983 See entire document.	1-22
A	US, A, 4,418,703 (HOCH ET AL.) 06 DECEMBER 1983 See entire document.	1-22
A	US, A, 4,679,571 (FRANKEL ET AL.) 14 JULY 1987 See entire document.	1-22

* Special categories of cited documents: [10]

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

"E" earlier document 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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
18 JULY 1991	12 AUG 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	JOHN D. YASKO

Form PCT/ISA/210 (second sheet) (Rev.11-87)