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(71) Applicant: MEDICAL SAFETY PRODUCTS, INC. [US/ USI; 2696 South Colorado Blvd., Suite 500, Denver, CO 80222 (US).

(72) Inventors: SAGSTETTER, William, E.; 2217 Grove, Denver, CO 80221 (US). COOKE, John, E.; 2295 Willow Lane, Lakewood, CO 80215 (US).

(74) Agent: SAGSTETTER, William, E.; Medical Safety Products, Inc., 2696 South Colorado Blvd., Suite 500, Denver, CO 80222 (US).

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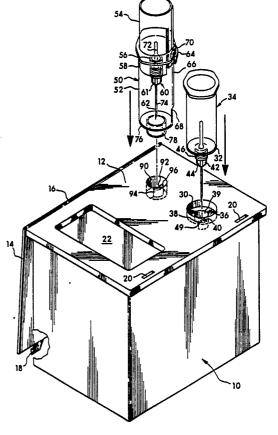
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(54) Title: DISPOSAL FOR DISENGAGING AND RECEIVING NEEDLES

#### (57) Abstract

A receptacle includes a first recess (130) for receiving the anterior end (32) of the barrel of a conventional double ended needle blood collection tube holder (34) to stabilize the holder during threaded disengagement of the needle. A post (138) is disposed within the recess (130) to prevent rotation of the hub (44) while the holder (34) is rotated to unthread the hub. Upon threaded disengagement, the needle (62) drops into the receptacle (10), which drop may be augmented by a pair of leaf springs (142, 144). A second recess (172) in the receptacle receives the collar (78) of a guard (52) supporting a translatable blood collection tube holder (54), which holder threadedly engages the hub (60) of a double ended needle (62). A post (198) within the recess (172) can extend within the collar (78) to engage a rib (61) of the hub (60) to prevent rotation of the double ended needle upon rotation of the guard (52) to threadedly disengage the hub (60) from the holder (54). Upon threaded disengagement, the double ended needle (62) drops into the receptacle (10), which drop may be augmented by a pair of leaf springs (178, 180).



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blood samples.

# DISPOSAL FOR DISENGAGING AND RECEIVING NEEDLES

#### Background of the Invention

## 1. Field of the Invention

The present invention relates to disposals and, more particularly, to disposals for needles and related devices.

#### 2. Description of the Prior Art

To obtain a blood sample for diagnostic purposes, blood is drawn into an evacuated blood collection tube through a double ended needle. The needle includes a hub, an anterior needle for tissue penetration into a blood vessel and a posterior needle having an exterior elastomeric valve. The posterior end of the needle is penetrably inserted within a barrel having female threads for threadedly engaging the hub to retain the double ended needle positionally fixed with respect to the barrel. The proximal end of the barrel is to open to receive an evacuated blood collection tube having a stopper for penetrably receiving the posterior needle. Upon venipuncture, blood will flow through the anterior needle and the posterior needle into Upon removal of the the collection tube. collection tube, the elastomeric valve recovers the posterior needle to prevent spontaneous blood flow from the needle. A phlebotomist can then insert a second or more blood collection tubes into the barrel to receive additional

Upon completion of the venipuncture procedure, the anterior needle is withdrawn

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from the patient. While the barrel is often reused, the double ended needle must be safely removed from the barrel without causing needle stick and while avoiding contact with any

residual body fluids of the patient to prevent transmission of infectious disease. Typically, a conventional biohazard receptacle for needles is provided with a lid having various shaped slots to engage the needle hub. To dispose of a used needle, the phlebotomist must carefully place the exposed needle hub into the slot, grip and rotate the barrel to unthread the needle and cause the disengaged needle to drop completely through the slot into the underlying container.

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Since the barrels are often opaque, it is difficult to know when the double ended needle has become completely threadedly disengaged from the barrel. A further danger arises from the upstanding exposed posterior needle until the

hub has become sufficiently disengaged from the slot to permit the needle to drop into the receptacle. Aside from hub engaging slots, other devices have been developed including the use of fixed and moveable jaws to engage the needle hub. Mechanized devises for unthreading

a double ended needle are also known.

A recently available reusable safety blood collection device includes a holder for engaging the double ended needle, which holder is translatable within a guard to fully enclose and shield both the anterior and posterior needles of the double ended needle. The guard includes an anterior collar for shielding the end of the anterior needle upon retraction of the holder and for supporting therewithin the hub engaging boss of the holder during use. Known syringe

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disposal devices are not well suited for receiving and disposing needles of such devices since the hub of the double ended needle is shielded by the collar and is not accessible for griping by the opposed edges of a slot, jaws or the like.

#### Summary of the Invention

within receptacle post mounted a interferingly engages a rib of a conventional double ended needle hub to prevent rotation of the hub upon engagement of a rib. A sloping upper surface of the post encourages downward needle movement of the into receptacle upon threaded disengagement of the In a second embodiment, a partial annular slot receives the collar of a guard for an enclosed double ended needle supporting holder and a post extending from the slot interferingly engages with a hub rib. Rotation of the guard with commensurate rotation of the enclosed holder will threadedly disengage the double ended needle from the holder whereafter the into the receptacle. needle will drop encourage drop of the double ended needle, a pair of vertical diametrically opposed leaf springs may be incorporated, which leaf springs includes a lip for preventing upward withdrawal of the double ended needle. In a variant, the hub engaging and supporting post assembly along with a downwardly directed chute for guiding a double ended needle into a receptacle may be of modular construction attachable to an aperture of any container.

It is therefore a primary object of the present invention to provide apparatus for receiving and disengaging a double ended needle

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from a blood collection tube holder on completion of a venipuncture procedure.

Another object of the present invention is to provide a post for threadedly disengaging a double ended needle from a blood collection tube holder.

Still another object of the present invention is to provide a post for engaging a rib of the hub of a double ended needle to permit unthreading the needle from a blood collection tube holder in combination with a pair of lead springs to encourage dropping of the needle into an underlying receptacle.

Yet another object of the present invention is to provide an annular slot for receiving a collar of a blood collection tube holder supporting guard, which collar is concentric with a post for interferingly engaging a rib of a double ended needle hub threadedly engaged with the holder.

A further object of the present invention is to provide a receptacle mounted post for engaging a rib of a double ended needle hub to a permit threaded disengagement of the hub from a supporting blood collection tube holder and to encourage drop of the needle into the post supporting receptacle.

A still further object of the present invention is to provide a method for unthreading a used double ended needle prior to disposal.

A yet further object of the present invention is to provide a method for converting any receptacle to a disposal unit for double ended needles.

A yet further object of the present invention is to provide apparatus and method

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for safely disengaging a double ended needle from a blood collection holder while shielding a clinician from exposure to each end of the needle.

A yet further object of the present invention is to provide a transparent disposal for receiving a double ended needle from a transparent blood collection tube holder to permit visual inspection of the separation and disposal of the needle.

10 These and other objects of the present invention will become apparent to those skilled in the art as the description thereof proceeds.

## Brief Description of the Drawings

The present invention will be described with greater clarity and specificity with reference to the following drawings, in which:

Figure 1 is an isometric view of a container supporting posts for engaging the hubs of double ended needles threadedly engaged with different types of blood collection tube holders;

Figure 2 is a partial top view of two types of post assemblies mounted in a container for receiving used doubled needles;

Figure 3 is a partial sectional view illustrating the relationships between needle hub engaging devices and the respective types of blood collection tube holders;

Figure 4 illustrates a variant of the hub engaging post structure;

Figure 5 is a partial cross sectional view illustrating operation of the variant shown in Figure 4;

Figure 6 is an isometric view of a variant of the needle hub engaging post and associated structure;

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Figure 7 is a cross sectional view taken along lines 7-7, as shown in Figure 6;

Figure 8 is a cross sectional view taken along lines 8-8, as shown in Figure 7;

Figure 9 is a top (bottom) view taken along lines 9-9, as shown in Figure 8;

Figure 10 is a top isometric view of a further variant;

Figure 11 is a top view of the further variant;

Figure 12 is a cross sectional view taken along lines 12-12, as shown in Figure 11; and

## Description of the Preferred Embodiment

Receptacles for used blood collection tube

15 holders with double ended needles of the type
associated with venipuncture procedures have
been in existence for a period of years. Such
receptacles tend to reduce the likelihood of
needle stick and spread of infectious disease

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resulting from contact with the needles and body fluids disposed upon and within the needles. When blood collection tube holders used with the needles are not to be disposed, various problems arise in attempting to separate the double ended needle from the holder without requiring a phlebotomist to touch the needle. A number of devices for this purpose have been developed but each suffers from actual or potential problems which preclude repetitive fail safe operation.

Referring to Figure 1, there is illustrated a receptable 10 for receiving and housing used double ended needles. The receptable includes a top surface 12 and a cover 14. The cover may be himged along hinge line 16. Prongs, such as

prong 18 may extend from cover 14 for locking engagement with slots, such as slots 20 formed

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in top surface 12. An opening 22 may be formed in the top surface to permit insertion into the receptacle of various items for disposal.

Referring jointly to Figures 1, 2 and 3, a circular recess 30 is formed in top surface 12 to receive and nestingly support cylindrical 32 conventional anterior end of a tube holder 34. An apertured collection supporting surface 36, which may be partially or completely annular, is disposed at the bottom end of recess 30 to support anterior end 32 of the blood collection tube holder. A post 38, oriented off center within recess 30, includes a slot 40 for receiving a rib 42 formed in hub 44 of a conventional double ended needle threadedly engaged with boss 46 formed in anterior end 32 of the blood collection tube holder.

eliminate the possibility of needle stick by phlebotomists during a conventional venipuncture procedure, a more complex blood holder device 50 has collection tube This device includes a barrel 52 for developed. receiving and supporting a holder 54. holder includes a boss 56 disposed at anterior end 58 for threadedly engaging hub 60 of a conventional double ended needle 62. A spring loaded tab 64 extends from anterior end 58 of holder 54 for penetrable engagement with and translation along a slot 66 formed longitudinally in barrel 52. Preferably, the

longitudinally in barrel 52. Preferably, the slot includes laterally expanded anterior segment 68 and posterior segment 70 for lockingly receiving the tab to retain holder 54 locked in the anterior or posterior position.

35 The axial length of holder 54 is sufficient to fully enclose posterior needle 72 to prevent

inadvertent contact with the needle. Upon translation of holder 54 to its posterior position, anterior needle 74 is enclosed within the anterior portion of barrel 52. Anterior end 76 of barrel 52 includes a collar 78 for accommodating penetration therethrough of anterior needle 74 and at least a portion of hub 60 of double ended needle 62. Upon retraction of holder 54 to its posterior position, the end of anterior needle 74 may be located within the confines of collar 78.

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To accommodate disengagement of double ended needle 62 from holder 54 on completion of a venipuncture procedure, receptacle 10 may be

- used. A cylindrical passageway 90 is sized and configured to receive and guide collar 78 through top surface 12 of the receptacle. The passageway also serves the function of stablizing device 50 during the process of
- unthreading double ended needle 62 from holder 54. After placement of collar 78 within passageway 90, tab 64 is translated along slot 66 to position hub 60 within collar 78. Simultaneously, a rib 61 of the hub will
- slidingly engage slot 92 disposed in post 94 (92) located within passageway 90. The size and orientation of post 94 permits the post to extend into collar 78 of device 50 to accommodate engagement with the hub 60.
- To disengage the double ended needle from blood collection tube holder 34, the holder is inserted into recess 30, guiding the anterior needle 48 through aperture 39 downwardly into adjacent slot 40 until rib 42 of hub 44
- slidingly engages the slot. In this position, anterior end 32 (34) of the holder will rest upon

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and be supported by supporting surface 36. Upon counterclockwise rotation of holder. the hub 44 will commensurate rotation of be procluded by interference between rib 42 and slot 40, resulting in unthreading of the hub from the holder. Upon subsequent raising of the holder out of the recess, the hub, will slide downwardly into the receptacle through the space between post 38 and supporting surface 36. downward sliding movement is encouraged if top surface 49 of the post is canted downwardly toward slot 40.

To separate double ended needle 62 from holder 54 of device 50, collar 78 is inserted within passageway 90 until anterior end 76 of top surface 12 rests upon barrel 52 Thereafter, tab 64 is brought receptacle 10. out of detent or expanded segment translated along passageway 66 until rib 61 of hub 60 engages slot 92 in post 94. Subsequent counterclockwise rotation of barrel 52 will result in commensurate rotation of holder 54 due to interference therebetween provided by tab 64 and slot 66 or further detent or expanded The counterclockwise movement will segment 68. unthread hub 60 from boss 56. Prior to or upon lifting of device 50, disengaged double ended will drop through the space 62 intermediate post 94 and passageway 90.

30 Downward sliding movement of the double ended needle will be enhanced if top surface 96 of post 94 cants downwardly toward the slot.

Referring jointly to Figures 2 and 3, further details attendant the needle receiving elements of receptacle 10 will be described. Post 38 attendant recess 30 depends from a segment of supporting surface 36. By

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incorporating recess 30, anterior end 32 of holder 34 reasonably well is guided supported during rotation of the holder prevent skewing of the double ended needle upon 5 partial unthreading and the act of unthreading will be enhanced. Moreover, the recess will maintain the holder in axial alignment with slot 40 to ensure continuing engagement of rib 42 of the hub with the slot. Top surface 49 of post 10 necessarily dropped below supporting 38 is surface 36 to an extent sufficient accommodate the extending axial dimension of boss 46 and the axial positioning of a band 47 normally found in hub 44, which band segregates the ribbed portion of the hub from the threaded 15 portion of the hub. As noted above, a downward canting of top surface 49 is preferable to encourage sideways movement of a freed double ended needle to assist the hub in clearing the 20 post prior to dropping into the receptacle 10. As particularly noted in Figure 2, post 38 may extend across a chord of aperture 39 defined by supporting surface 36. Such configuration will assist in locating the hub of the needle with respect to slot 40 and minimize the likelihood 25 of the hub missing or not engaging the post in the manner intended.

Passageway 90 includes and is defined by a depending annular skirt 98, which skirt guides and stabilizes collar 78 upon mounting of device 30 50. Α shelf 100 extends centrally into passageway 90 from skirt 98, which shelf supports post 94. The post may include a curved side 102 concentric with passageway 90 to define therebetween an annular slot 104 for receiving a 35 segment of collar 78 of device 50. Slot 92 may extend inwardly from a flat surface 106

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interconnecting opposed edges of curved side 102.

As will be evident by inspection, annular slot 104 in combination with the remaining surface area of skirt 98 defining passageway 90 will permit unimpeded rotation of device 50 about its longitudinal axis (and double ended needle 62) but generally impede pivoting or lateral displacement of the device. The limited permissible movement of the device encourage non binding interference between the rib engaged with slot 92 and permit ready disengagement upon dropping of the double ended needle after threaded disconnection between hub 60 and boss 56.

Referring to Figure 4 there is shown a variant structure for either or each of posts 38, 94. Under abnormal conditions, a double ended needle may not disengage from the supporting post and drop into receptacle 10 as intended and expected. To encourage lateral movement of the hub of the respective double ended needle off of the top surface of the respective post and to totally eliminate any basis for support for the double ended needle, bias means may be incorporated to force the needle out of engagement with the post. A bias means of this type is illustrated in Figure 4.

A leaf spring 110 is disposed at the rear of a slot, such as slot 40, of one of the posts, such as post 38. This leaf spring may be formed as part of the post with its lower end extending upwardly from the lower part of the post. As illustrated, the leaf spring may replace the

wall portion of the post directly rearwardly of the respective slot; the leaf spring may be

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formed in place of a part of the wall portion depicted in Figures 2 and 3; or, the leaf spring may be separate from the post. By having leaf spring 110 extend forwardly in its relaxed state, it will be forced rearwardly upon

state, it will be forced rearwardly upon engagement of a double ended needle hub with the post. Accordingly, the leaf spring will bear against and bias the hub out of the slot. Upon disengagement of the double ended needle from

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- the blood collection tube holder, the double ended needle will no longer be positionally restrained and the bias urged by the leaf spring will be exercised. Such exercise will cause the double ended needle to be urged out of
- engagement with the slot. Leaf spring 110 thereby contributes to release of the double ended needle to permit it to drop under force of gravity into the underlying receptacle; the drop may be augmented by the leaf spring. As
- depicted in Figure 4, top surface 49 may be canted to further encourage disengagement between the double ended needle and the post.

Conventional double ended needles include a band disposed about the hub intermediate the threaded segment and the ribbed segment, as illustrated in Figure 3. Under certain circumstances, despite threaded disengagement between a blood collection tube holder and a double ended needle, the double ended needle

- may remain attached to the boss of the blood collection tube holder, the double ended needle may inadvertently be withdrawn from receptacle 10 and later drop somewhere else. To prevent this from happening, leaf spring 110, as shown
- in Figure 4, includes a lip 112 for bearing against the upper edge of the band attendant the hub of the double ended needle. Because of

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the bias provided by the leaf spring, the lip will be urged toward the hub for such engagement. To permit passages of the band past the lip upon insertion of the double ended needle, a ramp 114 may be formed to force the lip laterally as the band passes therepast. The resulting sharp edge 116 will assist repositioning of the lip adjacent the top edge of the band of the hub upon initially unthreading of the hub. Upon upward movement of the holder due to threaded release of the double ended needle, the lip, bearing against the upper edge of the band about the hub, will then move over the top surface of the band and restrain upward movement of the double ended Such restraint will be enough needle. completely disengage the needle from the blood Once collection tube holder. complete disengagement is effected and with the aid of the leaf spring mounted lip, the double ended needle is free to drop into the receptacle, as discussed above.

A further structural configuration of leaf spring 110 with its lip 122 is depicted in Figure Post 94, as also shown in Figure 3, includes a slot 92 for receiving rib 61 of hub 60 in threaded engagement with boss 56 of device 50. The hub includes an annular band 69 disposed intermediate the plurality of ribs and threaded segment 67. Bias means, which may be a leaf upwardly from post 94 spring 120, extends laterally of slot 92. The upper end of the leaf spring includes a lip 122 extending from the leaf spring toward the slot. The vertical position of lip 122 is set to permit band 69 to be placed intermediate the top of post 94 and the lip. Furthermore, the orientation of the leaf spring, in combination with the extent

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of lip 122, is established to ensure overlap of the lip with the band upon engagement of hub 60 with post 94. Upon such initial engagement, the band may cause the <u>leaf</u> (lead) spring to spring

- rearwardly (laterally) to permit the band to clear the lip. Upon further downward movement of the band, the leaf spring will cause the lip to translate forwardly (laterally) into an overlying engagement with the band. Subsequent
- upward movement of hub 60 would result in interference between band 69 and lip 122 to discourage further upward movement. Thereby, lip 122 in combination with its supporting leaf spring 120, will encourage complete
- disengagement between double ended needle 62 and boss 56. Alternatively, a single bendable lip or lips may extend radially inwardly to engage the hub and prevent withdrawal of the needle.

Referring jointly to Figures 6, 7, 8 and 9,
20 a cylindrical wall 130 depends from top surface
12 to define a cylindrical recess for receiving
end 32 of a blood collection tube holder, such
as holder 34 shown in Figure 1. An annular base
132 extends radially inwardly from the

- cylindrical wall to support the holder. A cylindrical skirt 134 depends from the annular base proximate aperture 136 formed centrally of the annular base. The interior diameter defined by cylindrical wall 130 is approximately
- equivalent to that of end 32 of the blood collection tube holder. The interior diameter of cylindrical skirt 134 is approximately that defined by hub 44 (see Figure 1) double ended needle 62. As discussed above, hub 44 includes
- a plurality of ribs, usually equiangularly spaced, extending longitudinally along the hub. A longitudinally oriented post 138 extends

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radially inwardly from cylindrical skirt 134. The extent of radial inward extension of post 138 is sufficient to interferingly engage with one of the ribs on hub 44 upon insertion of end 32 of the blood collection tube holder within the recess defined by cylindrical wall 130. Thus, post 138 will interferingly engage a rib of the hub to prevent rotation of the hub commensurate with rotation of the holder; thereby, threaded disengagement of the hub from

thereby, threaded disengagement of the hub from the holder may be effected.

To encourage drop of double ended needle 62 (Figure 1) into receptacle 10 upon threaded disengagement with the holder, the end of the post may be canted inwardly downwardly to serve in the manner of a ramp 140 to encourage downward sliding movement of the double ended Sometimes, due to manufacturing needle. tolerances or for other reasons, disengagement between the double ended needle and the holder may require application of a force more positive than that of gravity. To ensure disengagement after unthreading, a pair of diametrically opposed leaf springs 142, 144 may be formed in cylindrical skirt 134. These leaf springs may be defined by a pair of slots 146, 148 joined at the upper end by a third slot 150. Thus, the lower end of each leaf spring is formed as a part of the cylindrical skirt while the upper end is free to flex. The interior upper end of leaf spring 142 includes an inwardly directed lip 152. The radial inward extension of lip 152 is sufficient to engage the top edge of the needle hub and interfere with upward withdrawa 1 of the hub upon upward movement of the holder. Leaf spring 144 includes a similar lip 154. Upper surfaces 156, 158 may be canted

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inwardly downwardly to accommodate passage therepast of the hub upon insertion of the blood collection tube holder within cylindrical wall 130. During such insertion, the leaf springs will cant radially outwardly to accommodate transport of the hub past lips 152, 154.

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Referring jointly to Figures 10, 11 and 12, there is shown a further variant for receiving a more complex blood collection tube holder device 50, as shown in Figure 1. A cylindrical wall 170 extends downwardly from top surface 12 and defines an aperture 172. A base 174 extends radially inwardly from a part of the lower end of the cylindrical wall. In particular, the

- 15 base defines a semi annular segment for supporting an upwardly extending semi cylindrical flange 176. The flange is radially inwardly displaced from the interior surface of cylindrical wall 172 to form a slot having a
- radial width commensurate with the radial width of collar 78 of blood collection tube device 50 (see Figures 1 and 3). The longitudinal extremities of the semi cylindrical flange include lead springs 178, 180. These leaf
- springs may be formed as part of the semi cylindrical flange and defined by slots 182, 184. The upper ends of the leaf springs may include radially inwardly oriented lips 186, 188. The top of these lips may be canted
- downwardly inwardly to define ramps 190, 192.

  Base 174 may be terminated by edges 194, 196, which edges extend tangentially from leaf springs 178, 180 to cylindrical wall 170. A post 198 extends radially inwardly from semi
- cylindrical flange 176 at its approximate mid point. The upper end of the post may be canted inwardly downwardly to define a ramp 200.

In operation, collar 78 (see Figure 3) of blood collection holder device 50 is inserted within the slot defined by cylindrical wall 170 and semi cylindrical flange 176. Support for the blood collection tube holder device may 5 provided by the holder resting on surface 12 and by collar 78 resting upon base 174 or either one. The inward extension of post 198 is sufficient to extend adjacent the body of hub 60 and intermediate ribs 61 of the hub to interferingly 10 engage a rib in the event of rotation of the collection tube device about blood longitudinal axis. Thereby, rotation of blood collection tube device will result in 15 unthreading and disengagement supported double ended needle from the blood Upon withdrawal of the collection tube device. blood collection tube device, the hub and its needle will drop into receptacle 10. To ensure disengagement of the hub, lips 186, 188 of leaf 20 springs 178, 180 are vertically positioned and radially inwardly extended to contact the upper end of the hub. With such contact, a resistive force will be exerted upon the hub to prevent 25 upward translation of the hub in response to upward movement of the blood collection tube device. Thereby, disengagement of the supporting needle will be assured. By forming ramp 200 upon the post, the upper end of the post will have little support for the hub and the hub 30 will slide off the post. By forming the upper surfaces of leaf springs 186, 188 with ramps 190, 192, lateral outward displacement of the leaf springs to accommodate downward passage therepast 35 of the hub is assured.

By inspection, it will be evident that the retention and positioning of the collar of the

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blood collection tube holder device intermediate semi cylindrical flange 176 and the interior wall of cylindrical wall 172, little lateral movement of the blood collection tube holder device will result; thus, interfering engagement by post 198 with the ribs of the hub is assured.

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therethrough.

Figure 13 illustrates a variant of the present invention usable in conjunction with any container or receptacle having a lid, which receptacle is to be employed for receiving used double ended needles. A module 230 includes a plate 232 having a recess 234 formed therein; this recess may be of the type shown in Figure 3 for use with a blood collection device 50 or of the type shown in either of Figure 6 or 10. described above, a post 236 having a slot 238 is disposed within recess 234. Top surface 240 of post 236 may be horizontal, as depicted, or may be canted, as shown in Figure 3; alternatively, the post may be of the type described with respect to Figure 6 to 10. A circular shroud 242 extends downwardly from plate 232. shroud serves in the manner of a guide or chute direct disengaged double ended needles

Module 230 is to be used in conjunction with a receptacle having an apertured top for penetrably receiving shroud 242. Thereby, any receptacle can be used as a disposal unit for double ended needles upon attachment of module 230. The means for retaining the module in place may be permanent or temporary.

A top 250 of a presently widely used receptacle is depicted. The top includes an aperture 252 of sufficient size to permit penetrable engagement by shroud 242. The length and width of plate (place) 232 supports module 230 upon

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top 250 after penetration of shroud 242. The lower end of the shroud may include a plurality of outwardly biased resilient wings 254 extending downwardly from a groove 256 formed in the shroud. Locking means, such as plate 260, includes an aperture 262 dimensioned to be seated in groove 256.

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In operation, module 230 is penetrably engaged with aperture 252 of top 250.

10 Protruding wings 254 are forced radially inwardly to pass through aperture 262 in plate 260 and the plate is translated upwardly along shroud 242 until aperture 262 seats within groove 256. Thereafter, wings 254 will tend to

spread radially outwardly to prevent disengagement of plate 260. The module will now be locked in place. Plate 260 may include upwardly extending sidewalls 264, 266, 268 and 270 to provide dimensional correspondence

20 between the extent to which groove 256 is below top 250 with the position of aperture 262 of plate 260 to preclude vertical movement of the module and to frictionally maintain the module at a predetermined location within aperture 252.

Even though top 250 having a particularly configured aperture 252 corresponds with a widely used type of receptacle, it is to be understood that module 260 may be used with any receptacle having an aperture sufficient in size to penetrably receive shroud 242 and permit locking the module in place with a plate, such as plate 260.

Blood collection holder device 50, illustrated in Figures 1, 3 and 5, was developed by Medical Safety Products, Inc. for the purpose of eliminating exposure of both the anterior and posterior needles of a double ended needle while

handling of the holder other than during the venipuncture procedure itself. That is, after attachment of a conventional double ended needle, the device may be immediately used for

- venipuncture; alternatively, the double ended needle may be retracted within the guard of the device in the event there will be a time lapse prior to use. After withdrawal of the needle on completion of a venipuncture procedure, the
- anterior needle is retracted within the guard to prevent needle stick and to contain any body fluids of the patient which may be on or about the needle. Prior to retraction, the posterior needle is shielded by both the holder and the
- guard. Upon retraction of the double ended needle, the posterior needle remains shielded within the holder to prevent needle stick or contact therewith by a clinician. Passageway 90 (Figure 3) or the slot adjacent cylindrical wall
- 20 170 (Figure 10) receives the collar extending anteriorly from the barrel, which collar may partly house and shield the end of the anterior needle. Prior to and during the act of mating the collar with the passageway or the slot, the
- anterior needle remains shielded and accidental contact therewith by a clinician will be precluded. During extension of the double ended needle prior to segregation of the needle from the holder, the anterior needle is interior of
- receptacle 10 (Figure 1), which receptacle shields the needle against accidental contact by the clinician. After unthreading of the double ended needle from the holder, the needle will drop into the receptacle with little possibility
- that the clinician can contact either the anterior or posterior needle of the double ended needle. Accordingly, the combination of device

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50 and receptacle 10 provides apparatus which will completely safeguard a clinician from contact with a double ended needle during the time subsequent to a venipuncture procedure to final disposal of the double ended needle.

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Single ended needles attached to hypodermic needles have similar ribbed hubs. Accordingly, the present invention can be used to disengage such needles from their syringes.

while the principles of the invention have now been made clear in an illustrative embodiment, there will be immediately obvious to those skilled in the art many modifications of structure, arrangement, proportions, elements,

materials and components used in the practice of the invention which are particularly adapted for specific environments and operating requirements without departing from those principles.

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#### **CLAIMS**

We claim:

holder:

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- 1. A disposal for receiving double ended needles, said disposal comprising in combination:
- a) a receptacle for housing the needles;
- b) a means disposed in said receptable for receiving the anterior end of a blood collection tube holder and for accommodating rotation of the holder about its longitudinal axis, which holder includes a boss for threadedly engaging a ribbed hub disposed upon the double ended needle, said receiving means including means for supporting at least a part of the anterior end of the blood collection tube
- c) a stationary post for preventing rotation of the hub about the longitudinal axis of the needle by interferingly engaging a rib of the hub upon attempted rotation of the hub during rotation of the holder, thereby
  - d) an urging means to urge the unthreaded needle into said receptacle; and
- e) an aperture disposed in said receiving means for accommodating passage of the needle upon threaded disengagement of the needle from the holder resulting from rotation of the holder relative to the hub.

unthreading needle from said holder;

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2. The apparatus as set forth in Claim 1 wherein said post includes an upper end and a ramp disposed at said upper end.

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- 3. The apparatus as set forth in Claim 1 wherein said supporting means includes a segment of an annular surface.
- The apparatus as set forth in Claim 1
   wherein said receiving means includes a recess.
  - 5. The apparatus as set forth in Claim 1 with an urging means comprising of a leaf spring disposed in said recess for urging disengagement of the needle from the holder after rotation of the holder relative to the needle.
  - 6. The apparatus as set forth in Claim 5 wherein said leaf spring includes a lip for engaging the hub to prevent rise of the needle upon withdrawal of the holder from said recess.
- 7. The apparatus as set forth in Claim 4 wherein said recess includes a side wall and wherein said post extends radially inwardly from said side wall.
- 8. A disposal for receiving a double ended
  needle having a ribbed hub threadedly engaged
  with a blood collection tube holder, which holder
  is translatable within a guard having a collar
  disposed at the anterior end for receiving the
  hub, said disposal comprising in combination:

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- a) a receptacle for housing the
  needle;
- b) means for supporting the anterior end of the collar with respect to said receptacle;

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- c) a post extending into the guard for preventing rotation of the hub about the longitudinal axis of the needle by interferingly engaging a rib of the hub upon attempted rotation of the hub; and
- d) means for accommodating passage of the needle into said receptacle upon threaded disengagement of the needle from the holder resulting from rotation of the guard relative to the hub.
- 9. The apparatus as set forth in Claim 8 wherein said post includes an upper end and a ramp disposed at said upper end.
- 10. The apparatus as set forth in Claim 8
  20 including means for urging separation between the needle and the holder after threaded disengagement therebetween.
- 11. The apparatus as set forth in Claim 10 wherein said urging means comprises a pair of leaf springs.
  - 12. The apparatus as set forth in Claim 11 wherein each of said leaf springs includes a lip for engaging the hub to prevent rise of the needle upon withdrawal of the holder.

- 13. The apparatus as set forth in Claim 8 including a recess for receiving the collar and wherein said supporting means comprises the top of said receptacle for supporting the holder.
- 5 14. The apparatus as set forth in Claim 8 including a skirt depending from said top for defining said recess.
  - 15. The apparatus as set forth in Claim 14 including a shelf extending radially inwardly from said skirt.

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- 16. The apparatus as set forth in Claim 15 including a semicylindrical flange extending upwardly from said shelf to define a segment of an annular slot disposed between said semi cylindrical flange and said skirt for receiving the collar.
  - 17. The apparatus as set forth in Claim 16 wherein said post extends radially inwardly of said semi cylindrical flange.
- 20 18. A method for disposing double ended needles, said method comprising the steps of:
  - a) providing a receptacle for housing the needles;
- b) receiving the anterior end of a
  25 blood collection tube holder in a recess
  associated with the receptacle, which recess
  accommodates rotation of the holder about its
  longitudinal axis and supports as least a part
  of the anterior end of the holder, the holder
  30 including a boss at the anterior end for

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threadedly engaging a ribbed hub disposed upon the needle;

- c) interferingly engaging a rib of the ribbed hub upon attempted rotation of the hub with a stationary post disposed in the recess to prevent rotation of the hub about the longitudinal axis of the needle during rotation of said holder, thereby unthreading the needle from said holder, including the step of urging the unthreaded needle into said receptacle by an urging means; and
  - d) passing the needle through an aperture disposed in the recess and into the receptacle upon threaded disengagement of the needle from the holder.
  - 19. The method as set forth in Claim 18 including the step of restraining rise of the needle upon withdrawal of the holder.
- 20. A method for disposing double ended
  20 needles having a ribbed hub threadedly engaged
  with a blood collection tube holder translatable
  within a guard having a collar disposed at the
  anterior end for receiving the hub, said method
  comprising the steps of:
- 25 a) providing a receptacle for housing the needles;
  - b) receiving the collar of the guard in a recess of the receptacle;
- c) supporting the anterior end of the collar within the recess;
  - d) engaging a rib of the hub upon attempted rotation of the hub with a post disposed in the recess to prevent rotation of the hub about the longitudinal axis of the
- 35 needle; and

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- e) passing the needle through a passageway and into the receptacle upon threaded disengagement of the needle from the holder resulting from rotation of the holder relative to the hub.
- 21. The method as set forth in Claim 20 including the step of restraining rise of the needle upon withdrawal of the holder.
- 22. A disposal for receiving double ended 10 needles, said disposal comprising in combination:
  - a) a receptacle for housing the needles;
- b) a means disposed in said

  receptacle for receiving the anterior end of a blood collection tube holder and for accommodating rotation of the holder about its longitudinal axis, which holder includes a boss for engaging a hub disposed upon the double ended needle;
  - c) a stationary means disposed within said receiving means for engaging the hub to prevent rotation of the hub about the longitudinal axis of the needle during rotation of said holder and thereby separate the needle from the holder;
  - d) an urging means to urge the separated needle into said receptacle; and
- e) an aperture disposed in said
  receiving means accommodating passage of the
  needle upon disengagement of the needle from the
  holder resulting from rotation of the holder
  relative to the hub and withdrawal of the holder
  from the recess.

- 23. The apparatus as set forth in Claim 22 wherein said engaging means comprises a slot disposed in a post of said stationary means for engaging a rib of the hub.
- 5 24. The apparatus as set forth in Claim 22 wherein said receiving means is comprised of a recess including a means for supporting at least a part of the anterior end of said holder, said supporting means including a segment of an annular surface.
  - 25. The apparatus as set forth in Claim 22 wherein said urging means is comprised of a leaf spring.
- 26. The apparatus as set forth in Claim 25 wherein said urging means comprises more than one leaf spring.
  - 27. The apparatus as set forth in Claim 25 wherein said leaf spring extends from said post.
- 28. The apparatus as set forth in Claim
  20 25 said leaf spring includes a lip for engaging the hub to prevent rise of the needle upon withdrawal of the holder from said recess.
- 29. The apparatus as set forth in Claim 22 wherein said holder is transparent to permit viewing disengagement of the needle from the holder.

- 30. The apparatus as set forth in Claim 29 wherein said receptacle includes means to permit viewing drop of the needle into said receptacle.
- 31. A disposal for receiving double ended needles having a ribbed hub threadedly engaged with a blood collection tube holder translatable within a guard having a collar disposed at the anterior end for receiving the hub, said disposal comprising in combination:
- 10 a) a receptacle for housing the needles;
  - b) a passageway in communication with the interior of said receptacle for receiving the collar of the guard;
- c) means for supporting the anterior end of the guard upon placement of the collar within said passageway;
  - d) a post disposed within said passageway, said post including means for engaging a rib of the ribbed hub to prevent rotation of the hub about the longitudinal axis of the needle; and
- e) means for accommodating passage of the needle into said receptacle upon threaded
  25 disengagement of the needle from the holder resulting from rotation of the guard relative to the hub and withdrawal of the collar from said passageway.
- 32. The apparatus as set forth in Claim 31 wherein said engaging means comprises a slot disposed in said post for engaging a rib of the ribbed hub.

- 33. The apparatus as set forth in Claim 31 including means for actively urging the unthreaded needle into said receptacle.
- 34. The apparatus as set forth in Claim 33 wherein said urging means comprises a leaf spring.
  - 35. The apparatus as set forth in Claim 34 wherein said leaf spring extends from said post.
- 36. The apparatus as set forth in Claim 34
  wherein said leaf spring includes a lip for engaging the hub to prevent rise of the needle upon withdrawal of the holder from said recess.
  - 37. The apparatus as set forth in Claim 31 wherein said supporting means comprises said top.
- 15 38. The apparatus as set forth in Claim 31 including a skirt depending from said top for defining said passageway.
- 39. The apparatus as set forth in Claim 38 including a shelf extending from said skirt for supporting said post.
  - 40. The apparatus as set forth in Claim 39 including a segment of an annular slot disposed between said post and said skirt for receiving the collar.

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41. The apparatus as set forth in Claim 31 wherein said holder is transparent to permit viewing disengagement of the double ended needle from the holder.

42. The apparatus as set forth in Claim 41 wherein said receptacle includes means to permit viewing drop of the needle into the receptacle.

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- 43. A method for disposing double ended needles, said method comprising the steps of:
- a) providing a receptacle for housing the needles, which receptacle includes a top;
- b) receiving the anterior end of a blood collection tube holder in a recess disposed in the receptacle, which recess accommodates rotation of the holder about its longitudinal axis and supports at least a part of the anterior end of the holder, the holder including a boss for threadedly engaging a
- ribbed hub disposed upon the needle;

  20 c) engaging a rib of the ribbed hub
  with a stationary post disposed in the recess to
  prevent rotation of the hub about the
  longitudinal axis of the needle during rotation
  of said holder thereby unthreading the needle
- from said holder, including the step of urging the unthreaded needle into said receptacle by an urging means; and
  - d) passing the needle through an aperture disposed in the recess and into the receptacle upon threaded disengagement of the needle from the holder resulting from rotation of the holder relative to the hub and withdrawal of the holder.

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44. The method as set forth in Claim 43 including the step of urging the unthreaded needle into said receptacle by an urging means comprised of a leaf spring.

- 5 45. The method as set forth in Claim 44 including the step of restraining rise of the needle commensurate with withdrawal of the holder.
- 46. A method for disposing double ended

  needles having a ribbed hub threadedly engaged with a blood collection tube holder translatable within a guard having a collar disposed at the anterior end for receiving the hub, said method comprising the steps of:
- a) providing a receptacle for housing the needles, which receptacle includes a top;
  - b) receiving the collar of the guard in a passageway in communication with the interior of the receptacle;
- c) supporting the anterior end of the guard upon placement of the collar within the passageway;

- d) engaging a rib of the ribbed hub with a post disposed in the passageway to prevent rotation of the hub about the longitudinal axis of the needle; and
  - e) passing the needle through the passageway and into the receptacle upon threaded disengagement of the needle from the holder
- resulting from rotation of the holder relative to the hub and withdrawal of the holder.

- 47. The method as set forth in Claim 46 including the step of urging disengagement of the needle with the post upon threaded disengagement of the needle from the holder.
- 5 48. The method as set forth in Claim 47 including the step of restraining rise of the needle commensurate with withdrawal the holder.
- 49. A method for disposing used 10 conventional double ended needles, said method comprising the steps of:
  - a) housing the used needles within a receptacle;
- stabilizing and supporting the b) 15 anterior end of a blood collection tube holder in single position in said receptacle accommodate rotation of the holder about its longitudinal axis while precluding movement of the holder, which holder includes a 20 for threadedly engaging a ribbed hub boss
- disposed upon the needle;
  - engaging the ribbed hub with a stationary engaging means to prevent rotation of the hub about the longitudinal axis of the needle while said holder is rotating in said single position in said receptacle; and
  - accommodating passage of the needle into the receptacle upon threaded disengagement of the needle from the holder resulting from
- 30 rotating the holder relative to the hub and withdrawing the holder.

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- 50. The method as set forth in Claim 49 including the step of urging passage of the needle into the receptacle.
- 51. A disposal for receiving used conventional double ended needles, said disposal comprising in combination:

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- a) means for housing the used needles;
- b) means for stabilizing and supporting the anterior end of a blood collection tube holder to accommodate rotation of the holder about its longitudinal axis while precluding lateral movement of the holder, which holder includes a boss for threadedly engaging a ribbed hub disposed upon the needle;
- c) a stationary means for engaging the ribbed hub to prevent rotation of the hub about the longitudinal axis of the needle;
  - d) an urging means comprised of a leaf spring to urge the needle into said receptacle; and
  - e) means for accommodating passage of the needle into said housing means upon threaded disengagement of the needle from the holder resulting from rotation of the holder relative to the hub.
  - 52. The apparatus as set forth in Claim 51 wherein said engaging means comprises a slot for receiving a rib of the ribbed hub.
- 53. The apparatus as set forth in Claim 51
  wherein said stabilizing and supporting means comprises a recess for receiving the anterior end of the holder.

- 54. The apparatus as set forth in Claim 53 wherein said engaging means is disposed within said recess.
- 55. The apparatus as set forth in Claim 51 wherein said stabilized and supporting means includes a cylindrical skirt extending into said housing means.
- 56. The apparatus as set forth in Claim 55 wherein said engaging means is disposed within said skirt.
  - 57. The apparatus as set forth in Claim 51 including means for urging disengagement between said engaging means and the needle.
- 58. A disposal for receiving double ended

  15 needles, said disposal comprising in
  combination:
  - a) a receptacle for housing the needles;
- b) a recess disposed in said

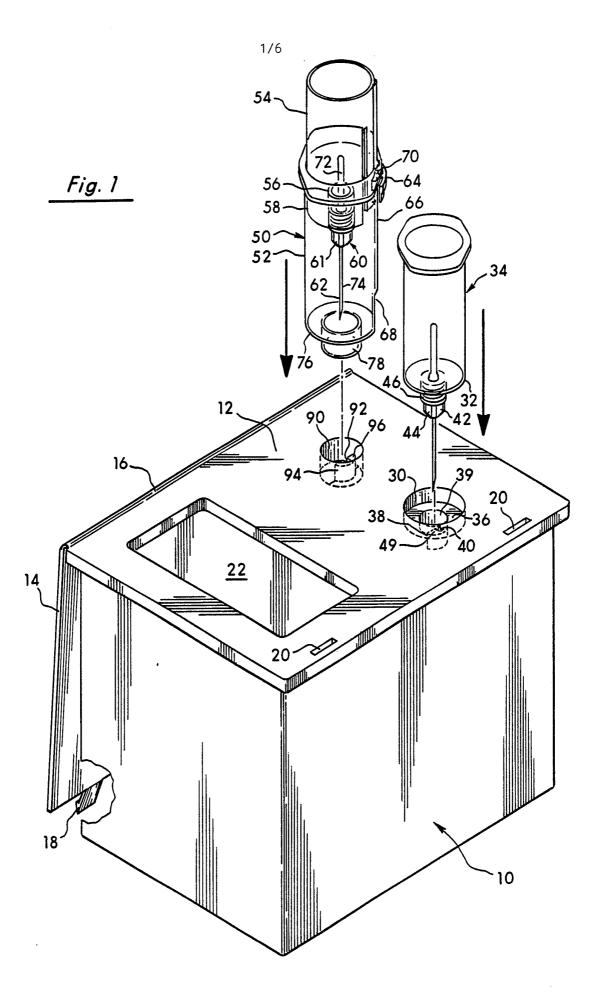
  receptacle for accommodating rotation of the blood collection tube holder about its longitudinal axis, which holder includes a boss for threadedly engaging a ribbed hub disposed upon the double ended needle, said recess
- 25 including means for supporting at least a part of the anterior end of the blood collection tube holder;
  - c) a stationary post disposed within said recess, said post including means for engaging a rib of the ribbed hub to prevent

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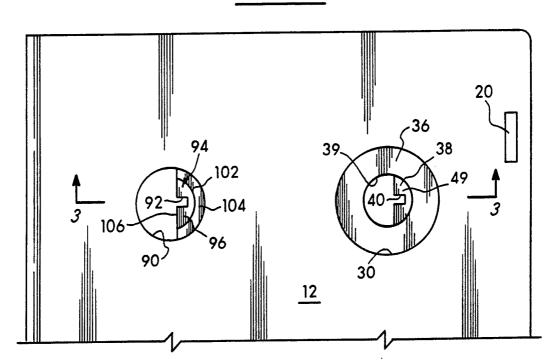
rotation of the hub about the longitudinal axis of the needle; and

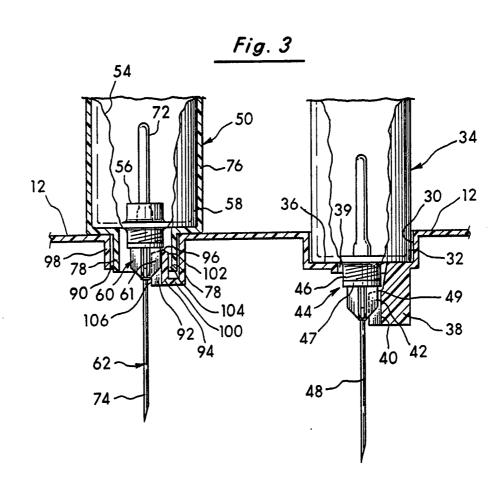
- d) an aperture disposed in said recess for accommodating passage of the needle upon threaded disengagement of the needle from the holder resulting from rotation of the holder relative to the hub and withdrawal of the holder from the recess.
- 59. A disposal for receiving double ended needles, said disposal comprising in combination:
  - a) a receptacle for housing the needles, said receptacle including a top;
- b) a single position disposed in said receptacle for supporting at least a part of the anterior end of a blood collection tube holder and for accommodating rotation of the holder about its longitudinal axis, which holder includes a boss for threadedly engaging a ribbed hub disposed upon the double ended needle;
  - c) a stationary engaging means disposed within said single position in said receptacle for engaging a rib of the ribbed hub to prevent rotation of the hub about the
- 25 longitudinal axis of the needle; and
  - d) an aperture disposed in said single position of said receptacle accommodating passage of the needle upon threaded disengagement of the needle from the holder
- resulting from rotation of the holder relative to the hub and withdrawal of the holder from said single position of said receptacle.



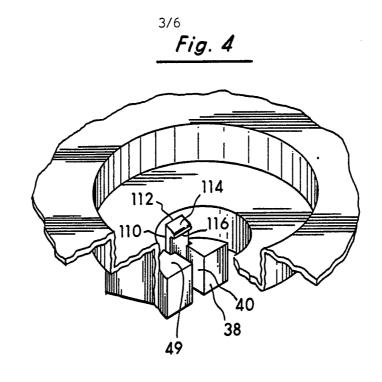
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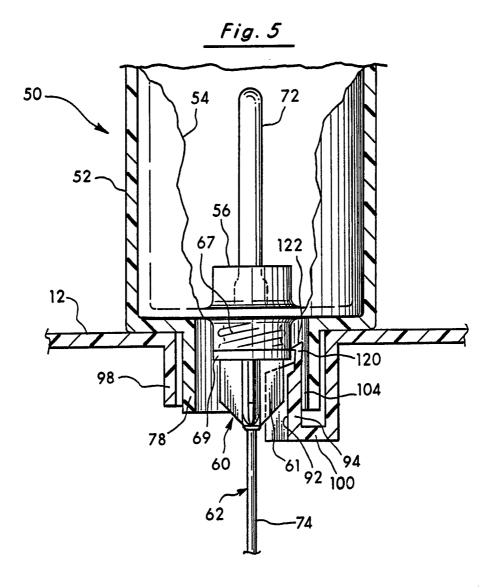
<sup>2/6</sup> Fig. 2



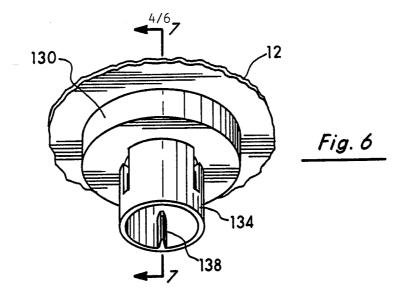


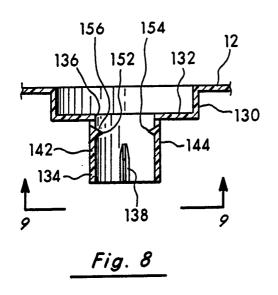
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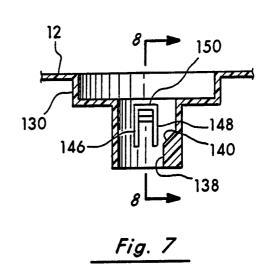


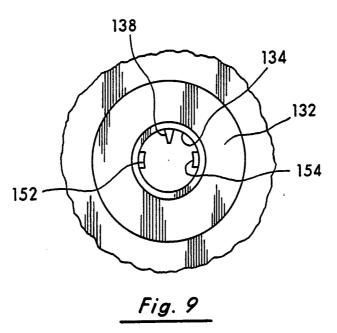


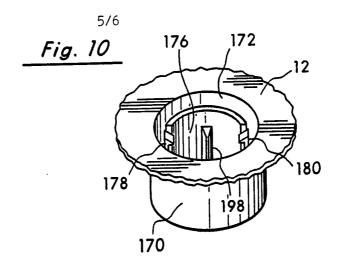
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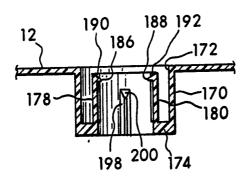
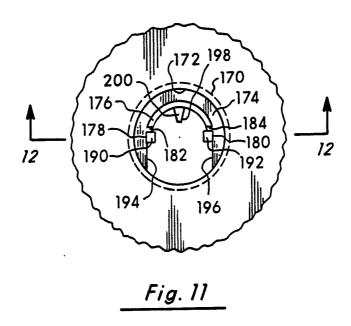


Fig. 12



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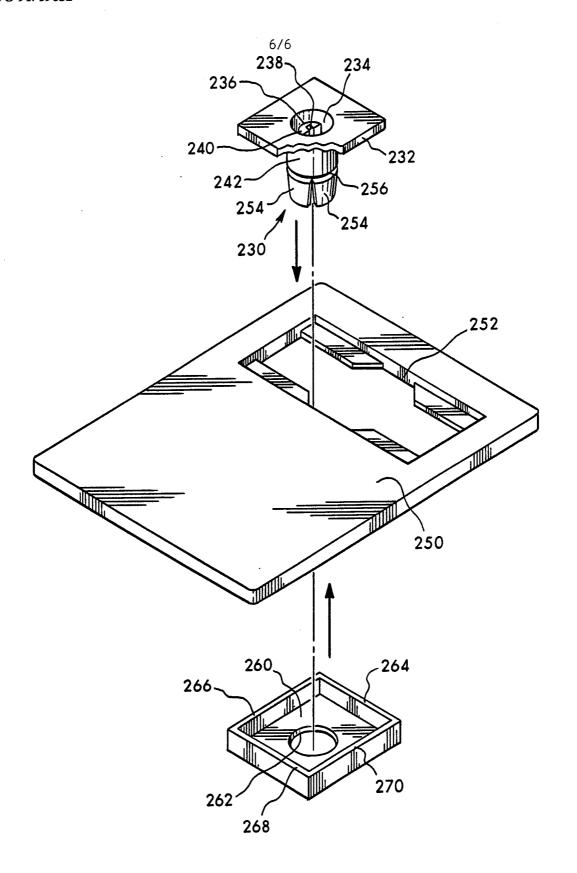


Fig. 13

## INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/04084

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 6						
IPC(5	5): B6	ional Patent Classification (IPC) or to both Nati 5D 83/10; B65D 85/24; A61M 6/366 604/198		·		
	S SEARCE					
		Minimum Documen	ntation Searched 7			
Classification System			Classification Symbols			
US		206/365,366; 604/192,198				
		Documentation Searched other t to the Extent that such Documents	han Minimum Documentation are Included in the Fields Searched <sup>8</sup>			
III. DOCU		ONSIDERED TO BE RELEVANT				
Category *	Citat	ion of Document, 11 with indication, where app	ropriate, of the relevant passages 12	Relevant to Claim No. 13		
A, P		A, 4,995,871 (SASKI et al	-			
A, P		A, 5,024,327 (SHILLINGTON				
A,P	US,	A, 5,031,767 (BRUNO) 16 J	uly 1991			
A	FR,	Al, 2,624,023 (BRUNET) 09	June 1989			
A	US,	A, 4,923,447 (MORGAN) 08	May 1990			
A	US,	A, 4,917,243 (ABRAMS et a	1.) 04 April 1990			
A	US,	A, 4,986,811 (THEAD et al	.) 22 January 1991			
A	US,	A, 4,807,344 (KELSON et a	1.) 28 February 1989			
A	US,	A, 4,798,587 (WILLOUGHBY)	17 January 1989			
A	US,	A, 4,738,362 (BURNS et al	.) 19 April 1988			
A	US,	A, 4,801,013 (BRUNO) 31 Ja	anuary 1989			
A	US,	A, 4,494,652 (NELSON et al	1.) 22 January 1985			
<ul> <li>Special categories of cited documents: 10</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filing date</li> <li>"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)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> <li>"T" later document published after the international filing or priority date and not in conflict with the application cited to understand the principle or theory underly invention</li> <li>"X" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> <li>"Y" document of particular relevance; the claimed involve an inventive step</li> </ul>						
		mpletion of the International Search	Date of Mailing of this International Se	arch Report		
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		g Authority	Signature of Authorized Officer	of Noregue		
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FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET						
A US, A, 4,802,579 (HALL et al.) 07 February 1989						
A US, A, 4,667,821 (SHILLINGTON) 26 May 1987						
A US, A, 4,466,538 (GIANNI) 21 August 1984						
A US, A, 4,375,849 (HAMIFL) 08 March 1983						
V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE						
This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:						
1. Claim numbers , because they relate to subject matter 12 not required to be searched by this Authority, namely:						
2. Claim numbers, because they relate to parts of the international application that do not comply with the prescribed require-						
ments to such an extent that no meaningful international search can be carried out 13, apecifically:						
3. Claim numbers, because they are dependent claims not drafted in accordance with the second and third sentences of						
PCT Rule 6.4(a).						
VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING?						
This International Searching Authority found multiple inventions in this international application as follows:						
1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims						
of the international application.						
2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:						
3. 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 claim numbers:						
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did no invite payment of any additional fee.						
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did no invite payment of any additional fee.  Remark on Protest						
invite payment or any additional fee.						

Form PCT/ISA/210 (supplemental sheet (2) (Rev. 11-87)