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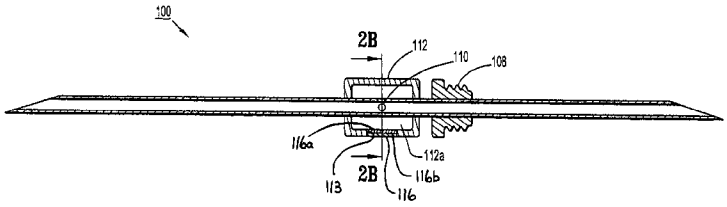
(54) **Title:** VENTED PHLEBOTOMY NEEDLE WITH FLASHBACK CHAMBER



(57) **Abstract:** A phlebotomy needle is disclosed which includes structure to facilitate visualization of flashback. In one embodiment, a central portion of the needle includes a hole or opening which communicates with a flow channel defined by the needle and a transparent housing is positioned about the opening to facilitate visualization of blood flow through the needle. A material which allows passage of air and provides an indication of blood flow through the needle is positioned over the opening. In one embodiment, the material is in the form of a plug or, alternately, in the form of a patch or collar. The material can be encased in or provide a window in the transparent housing. In another embodiment, the phlebotomy needle includes a needle and a housing having a passive vent and a viewing region for visualizing blood flow in the housing.

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VENTED PHLEBOTOMY NEEDLE WITH FLASHBACK CHAMBER

BACKGROUND

1. Technical Field

The present disclosure relates to medical needles having structure to facilitate visualization of flashback. More specifically, the present disclosure relates to vented phlebotomy needles including structure to facilitate visualization of flashback.

2. Background of Related Art

Medical devices are well known for drawing blood from patients. These devices include standard needle-syringes, butterfly needle sets and phlebotomy needles. Typically, a butterfly needle set includes a hollow needle having a sharpened distal end and a proximal end which is secured to a needle hub. A proximal portion of the needle hub is connected to flexible tubing. The needle hub defines a fluid conduit communicating with the tubing and includes a pair of flexible, radially extending wings which facilitate grasping of the butterfly needle set by medical personnel. Generally, the flexible tubing is formed of a transparent material which allows medical personnel to visualize blood flow, i.e, flashback, through the tubing immediately proximal to the needle hub. Visualization of flashback allows medical personnel to confirm that the needle has been properly inserted into a patient.

Some clinicians utilize hypodermic needle-syringes with transparent needle hubs to obtain blood samples. During insertion, those clinicians typically observe flashback in the needle hubs.

Generally, phlebotomy needles have not included structure for visualizing flashback. Although the lack of structure for visualizing flashback in phlebotomy

needles is not a major drawback for more experienced medical personnel, for those having little experience drawing blood with phlebotomy needles, the lack of any means to confirm that the needle has been properly positioned within a patient may increase the time required to draw blood and add to the discomfort of a patient.

In an attempt to overcome the above disadvantages, U.S. Patent No. 5,450,856 to Norris discloses a phlebotomy needle which is attachable to a blood collection tube and includes an outboard needle, an inboard needle and a bulb therebetween. The bulb is clear and allows medical personnel to visualize blood within the bulb when the outboard needle has been properly positioned within the vein of a patient. The bulb also includes a button which can be depressed by medical personnel to vent air from within the needle. Air within the needle prevents blood from flowing through the needle and must be vented.

Although the Norris phlebotomy needle facilitates visualization of flashback, a less expensive, less complex phlebotomy needle which facilitates visualization of flashback is desired.

SUMMARY

The present disclosure is directed to a phlebotomy needle which includes a distal needle portion having a sharpened distal end configured to pierce tissue, a proximal needle portion having a sharpened proximal end configured to pierce a stopper of a blood collection tube, and a central needle portion defining an opening. The distal needle portion, the proximal needle portion and the central needle portion define a fluid channel which communicates with the opening. A material is positioned adjacent the opening. The material is of a type to permit passage of air through the opening to exit

the fluid channel while preventing passage of blood. In one embodiment, the material provides a visual indication of blood flow adjacent the opening, i.e., flashback.

In one embodiment, the material includes a hydrophobic material. In an alternate embodiment, the material includes a hydrophilic wicking material. In yet another embodiment, the material includes a hydrophobic plug. Alternately, the material can define a collar positioned about the opening.

In one embodiment, the opening is circular. Alternately, it is envisioned that the opening can assume a variety of configurations, e.g., rectangular or slot-shaped.

In one embodiment, a transparent housing is positioned about the opening to facilitate visualization of flashback. The housing can also be positioned to encompass the material and can include a vent for venting air from the needle.

In one embodiment, the phlebotomy needle includes engagement structure which is configured to engage a needle holder.

In one embodiment, a check valve is provided to inhibit passage of air through the opening into the fluid channel. In yet another embodiment, the phlebotomy needle includes a needle holder.

Brief Description Of Embodiments

Embodiments of the presently disclosed vented phlebotomy needle with flashback chamber are disclosed herein with reference to the drawings, wherein:

FIG. 1 is a perspective view with parts separated of a "Prior Art" phlebotomy needle with a needle holder, protective needle covers and a blood collection tube shown in phantom;

FIG. 1A is a side cross-sectional view of the "Prior Art" phlebotomy needle, the needle holder, and the blood collection tube shown in phantom, assembled, with a distal portion of the phlebotomy needle positioned within a vein;

FIG. 2 is a side perspective view of one embodiment of the presently disclosed phlebotomy needle;

FIG. 2A is a cross-sectional view of the phlebotomy needle shown in FIG. 2;

FIG. 2B is a cross-sectional view taken along section lines 2B-2B of FIG. 2A;

FIG. 2C is a side cross-sectional view of another embodiment of the presently disclosed phlebotomy needle;

FIG. 3 is a side cross-sectional view of an alternate embodiment of the presently disclosed phlebotomy needle;

FIG. 3A is a cross-sectional view taken along section lines 3A-3A of FIG. 3;

FIG. 4 is a side perspective cutaway view of another embodiment of the presently disclosed phlebotomy needle;

FIG. 4A is a cross-sectional view taken along section lines 4A-4A of FIG. 4;

FIG. 5 is a side perspective cutaway view of another embodiment of the presently disclosed phlebotomy needle;

FIG. 6 is a side cross-sectional view of another embodiment of the presently disclosed phlebotomy needle; and

FIG. 7 is a cross-sectional view taken along section lines 7-7 of FIG. 6.

Detailed Description Of Embodiments

Embodiments of the presently disclosed vented phlebotomy needle with flashback chamber will now be described in detail with reference to the drawings

wherein like reference numerals designate identical or corresponding elements in each of the several views.

FIG. 1 illustrates a known phlebotomy needle 10, a needle holder 12, and needle covers 14 and 16. A blood collection tube 17 is shown in phantom. Phlebotomy needle 10 includes a distal needle portion 20, a proximal needle portion 22 and an intermediate needle hub 23 with engagement portion 24. Engagement portion 24 is provided to facilitate connection of phlebotomy needle 10 to needle holder 12. In one embodiment, the engagement portion includes a male fitting 24a which is configured to engage a female fitting or engagement member 26 provided on the distal end of needle holder 12. Alternately, other engagement structures including screw threads, snap-type connectors, etc., can be used. An elastomeric shield 28 is positioned over proximal needle portion 22 to seal the proximal needle portion 22 as will be described in further detail below.

Needle holder 12 includes a substantially cylindrical body 30 having a distal end including engagement member 26 and a proximal end including a pair of flange members 32. Flange members 32 facilitate gripping and insertion of a blood collection tube 17 by medical personnel. Cylindrical body 30 defines a cavity 34 (FIG. 1A) for receiving blood collection tube 17. Typically, blood collection tube 17 is sealed with a pierceable stopper 17a and defines a cavity 17b (FIG. 1A) of low pressure. The distal end of holder 12 defines an opening 36 through engagement member 26 which is dimensioned to receive proximal needle portion 22.

As shown in FIG. 1A, in use, needle 10 is secured to the distal end of needle holder 12 via engagement portion 24 and engagement member 26. When needle 10 is

secured to needle holder 12, proximal needle portion 22 is positioned within cavity 34 of body 30 of needle holder 12 with elastomeric shield 28 positioned over proximal needle portion 22. Next, a blood collection tube 17 (shown in phantom) which includes pierceable stopper 17a is positioned within cavity 34. When collection tube 17 is inserted into cavity 34, proximal needle portion 22 engages stopper 17a and pierces through shield 28. Shield 28 is compressed downwardly (FIG. 1A) such that proximal needle portion 22 pierces stopper 40 and enters cavity 17b of collection tube 17. Typically, collection tube 17 is maintained at a vacuum such that when distal needle portion 20 is properly positioned in a vein 38 of a patient and collection tube 17 is positioned within cavity 34, blood will flow through needle 10 into blood collection tube 17. When blood collection tube 17 is removed from needle holder 12, elastomeric shield 28, which is resilient, returns to its original configuration and covers the proximal needle portion 22 to seal proximal needle portion 22.

FIGS. 2 and 2A illustrate one embodiment of the presently disclosed phlebotomy needle with flashback chamber shown generally as 100. Needle 100 includes a distal end 102, a proximal end 104 and a central portion 106. Distal end 102 has a sharpened end 102a configured to pierce tissue of a patient and proximal end 104 has a sharpened end 104a configured to pierce the stopper 17a of a blood collection tube 17 (see FIG. 1A). Central portion 106 includes an engagement member 108 as discussed above, configured to engage a needle holder (FIG. 1). Central portion 106 also includes an opening or hole 110 and a translucent or transparent housing 112 positioned about the portion of central portion 106 defining opening 110. Although opening 110 is illustrated as circular other configurations are envisioned e.g., rectangular, square, oval, an

elongated slot 39 (FIG. 5), etc. Transparent housing 112 defines a blood reservoir 112a. A vent opening 113 preferably is formed in transparent housing 112. The vent opening 113 facilitates venting of needle 100 to permit blood flow through needle 100. Vent opening 113 in housing 112 can be covered by a material which allows passage of air but does not permit passage of liquid, e.g., blood, as discussed below.

Referring to FIGS. 2A and 2B, vent opening 113 can be covered with a filter 116. Filter 116 preferably includes an inner layer 116a of hydrophilic material and an outer layer of hydrophobic material 116b. Preferably, at least one of layers 116a, 116b has a pore size of less than 0.45 microns. Such a pore size prevents entry of bacteria into housing 112 while allowing for passage of air.

Referring to FIG. 2C, in an alternate embodiment, filter 116 can be replaced with a hydrophobic check valve, e.g., flap valve 150. Flap valve 150, as illustrated, is constructed to bend outwardly from housing 112 to uncover vent opening 113 to vent housing 112 when blood flow into housing112 is initiated. A hydrophobic sheet 152 is positioned over opening 113 to prevent blood from exiting vent opening 113 when the check valve is open. Prior to the initiation of blood flow into housing 112, flap valve 150 seals opening 113 to prevent entry of material into housing 112. Alternately, flap valve 150 can be formed from a hydrophilic material if the pore size of the hydrophilic material is of a size to occlude passage of blood components.

Transparent housing 112 allows a medical practitioner to visualize the flow of blood through needle 100 when distal end 102 of needle 100 has been properly positioned within the vein of a patient, i.e., as blood flows through needle 100, air will be vented and blood will flow through opening 110 into reservoir 112a. This allows the

medical practitioner to confirm that the distal end 102 of needle 100 has been properly positioned within a patient's vein to draw blood. This provides a great benefit to medical practitioners attempting to draw blood from a patient, especially those practitioners having a limited amount of experience drawing blood from a patient with a phlebotomy needle.

FIG. 3 illustrates an alternate embodiment of the presently disclosed vented phlebotomy needle with flashback chamber shown generally as 200. Needle 200 is substantially similar to needle 100 except as will be described below. Needle 200 includes a distal end 202, a proximal end 204 and a central portion 206. Distal end 202 has a sharpened end 202a configured to pierce tissue of a patient and proximal end 204 has a sharpened end 204a configured to pierce the stopper of a blood collection tube (see FIG. 1A). Central portion 206 includes an opening or hole 210 and an engagement member 212a. A material 214 is positioned over hole 210. The material 214 can be a hydrophilic material that wicks blood into the material such that medical personnel can readily identify blood flow through needle 200. The material 214 can also be a hydrophilic material which is permeable to air but not to liquid, e.g., blood, to facilitate venting of needle 200. In one embodiment, the hydrophilic material can be of the type which turns color when it is contacted by blood. The material can be in the form of a collar 250 (FIG. 3) or a plug 252 (FIG. 4). Further, the material can be positioned within a transparent housing or hub 212 or, alternately, positioned adjacent opening 210 without any housing. In an alternate embodiment, the material is a hydrophobic material which passes air but not blood. It is noted that a vent opening 226 can be provided in housing 212 to facilitate venting of the housing. The vent can be in the form

of an opening in housing 212 which allows for air to flow from housing 212 as blood enters.

In an alternate embodiment also shown in FIGS. 3 and 3A, material 214 can be formed of a swellable material which prior to contacting blood allows for the passage of air through vent opening 226. Upon contacting blood, material 214 can swell to close the vent opening 226.

Although only hydrophilic and hydrophobic materials have been discussed herein, other materials which facilitate passage of air while preventing passage of blood and which provide an indication of blood flow can be used with the presently disclosed phlebotomy needle. The material can have other configurations not disclosed herein, e.g., the material may define a pad which covers the opening.

FIGS. 6 and 7 illustrate another embodiment of the presently disclosed phlebotomy needle with flashback chamber shown generally as device 398. Phlebotomy needle 398 includes a needle 400 and a stepped housing 408 Needle 400 includes a distal end 402, a proximal end 404 and a central portion 406. Distal end 402 has a sharpened end 402a configured to pierce tissue of a patient and proximal end 404 has a sharpened end 404a configured to pierce the stopper (not shown) of a blood collection tube (not shown).

A stepped housing 408 has a distal portion 408a and a larger-diameter proximal portion 408b. Stepped housing 408 is supported on central portion 406. Distal portion 408a defines a throughbore 412 dimensioned to receive needle central portion 406. Distal portion 408a is sealingly secured to needle 400 using, for example, an adhesive 410. Alternately, other known techniques can be used to secure needle 400 to housing

408, e.g., crimping, clamps, screws, welding etc. Proximal portion 408b is formed of a transparent or translucent material to facilitate visualization within proximal portion 408b of housing 408. Proximal portion 408b also defines throughbore 414 which communicates with the throughbore 412 but is larger in diameter than throughbore 412. Proximal portion 408b defines an annular recess 416 between portion 408b and proximal end 404 of needle 400. Recess 416 is dimensioned to receive a hydrophilic material 418 and an inner fluted member 420. Inner fluted member 420 is positioned about proximal end 404 of needle 400 and defines a plurality of channels 422 which communicate with hydrophilic material 418. A vent opening 409 is provided through housing 408.

An elastomeric shield 428 is positioned over proximal end 404 of needle 400. As discussed above, elastomeric shield 428 is resilient and functions to seal proximal end 404 of needle 400 when proximal end 404 of needle 400 is not connected to a blood collection tube (not shown). Elastomeric shield 428 includes a closed proximal end 428a and an open distal end 428b. Open distal end 428b includes an annular flange 430 which is positioned adjacent material 418 within recess 416 of housing 408. Proximal portion 408b of housing 408 includes an inwardly extending annular rib 432 which is positioned to engage flange 430 of elastomeric shield 428 to retain distal end 428b of shield 428 within recess 416 of housing 408. As illustrated by arrows 434, a flow path 436 is defined between elastomeric shield 428 and proximal end 404 of needle 400. Flow path 436 directs blood from proximal end 404 of needle 400 into fluted channels 422 of fluted member 420 into contact with hydrophilic material 418. In

use, when blood contacts material 418, material 418 provides a visual indication of blood flow which is visible through proximal portion 408b of housing 408.

The vent openings 113 defined in connection with filter 116, FIGS. 2A-2B, with filer 252, FIGS. 4-4A, or with filter 39, FIG. 5, or with check valve 150, FIGS. 2C as well as opening 226, FIGS. 3-3A and opening 409, FIG. 6, all may be described as passive vent openings which automatically enable gases at greater than atmospheric pressure within the needle cannula to escape into the atmosphere. These passive vent openings do not require any action by a user of devices according to the present invention.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS

1. A phlebotomy needle comprising:

a distal needle portion having a sharpened distal end configured to pierce tissue, a proximal needle portion having a sharpened proximal end configured to pierce a stopper of a blood collection tube, and a central needle portion defining an opening, the distal needle portion, the proximal needle portion and the central needle portion defining a fluid channel which communicates with the opening; and

a material positioned adjacent the opening, the material being of a type to permit passage of air through the opening to exit the fluid channel while preventing passage of blood, the material further enabling a visual indication of blood flow.

2. The phlebotomy needle according to Claim 1, wherein the material includes a hydrophobic material.

3. The phlebotomy needle according to Claim 1, wherein the material includes a hydrophilic wicking material.

4. The phlebotomy needle according to Claim 1, wherein the material includes an inner layer of hydrophilic material toward the opening and an outer layer of hydrophobic material.

5. The phlebotomy needle according to Claim 1, wherein the opening is circular.

6. The phlebotomy needle according to Claim 1, wherein the opening defines an elongated slot.

7. The phlebotomy needle according to Claim 1, further including a transparent housing positioned about the opening.

8. The phlebotomy needle according to Claim 1, further including engagement structure supported on the phlebotomy needle, the engagement structure being configured to engage a needle holder.

9. The phlebotomy needle according to Claim 1, wherein the material defines a collar positioned about the needle over the opening.

10. The phlebotomy needle according to Claim 9, further including a transparent housing positioned about the collar of material.

11. The phlebotomy needle according to Claim 1, further including a check valve for inhibiting passage of air through the opening into the fluid channel.

12. The phlebotomy needle according to Claim 1, further including a needle holder.

13. The phlebotomy needle according to Claim 1, wherein the material provides the visual indication of blood flow through the opening.

14. A phlebotomy needle comprising:

a distal needle portion having a sharpened distal end configured to pierce tissue, a proximal needle portion having a sharpened proximal end configured to pierce a stopper of a blood collection tube and a central needle portion defining an opening, the distal needle portion, the proximal needle portion and the central needle portion defining a fluid channel which communicates with the opening;

a hydrophobic material positioned adjacent the opening, the material being of a type to permit passage of air through the opening to exit the fluid channel while preventing passage of blood, the material further enabling a visual indication of blood flow;

a transparent housing positioned about the opening; and

engagement structure supported on the phlebotomy needle, the engagement structure being configured to engage a needle holder.

15. The phlebotomy needle according to Claim 14, further including the needle holder.

16. A phlebotomy needle comprising:

a distal needle portion having a sharpened distal end configured to pierce tissue, a proximal needle portion having a sharpened proximal end configured to pierce a stopper of a blood collection tube and a central needle portion defining an opening, the distal needle portion, the proximal needle portion and the central needle portion defining a fluid channel which communicates with the opening;

a hydrophilic wicking material positioned adjacent the opening, the hydrophilic wicking material being of a type to permit passage of air through the opening to exit the fluid channel while preventing passage of blood, the material further enabling a visual indication of blood flow;

a transparent housing positioned about the opening; and

engagement structure supported on the phlebotomy needle, the engagement structure being configured to engage a needle holder.

17. The phlebotomy needle according to Claim 16, further including the needle holder.

18. A phlebotomy needle comprising:

a needle including a distal needle portion having a sharpened distal end configured to pierce tissue and a proximal needle portion having a sharpened proximal

end configured to pierce a stopper of a blood collection tube, the distal needle portion and the proximal needle portion defining a fluid channel; and

a housing supported on the needle, the housing including a passive vent;

wherein the housing defines a viewing region for visualizing blood in the housing.

19. The phlebotomy needle according to Claim 18, further including an elastomeric shield positioned about the proximal needle portion the elastomeric shield and the proximal needle portion defining a fluid flow path into the housing;

20. The phlebotomy needle according to any of Claims 18 and 19, further including a fluted member positioned within the housing, the fluted member defining a plurality of fluid channels.

21. The phlebotomy needle according to any of Claims 18-20, further including a hydrophilic material supported within the housing.

22. The phlebotomy needle according to any of Claims 18-21, wherein the needle has a central portion defining an opening into the housing.

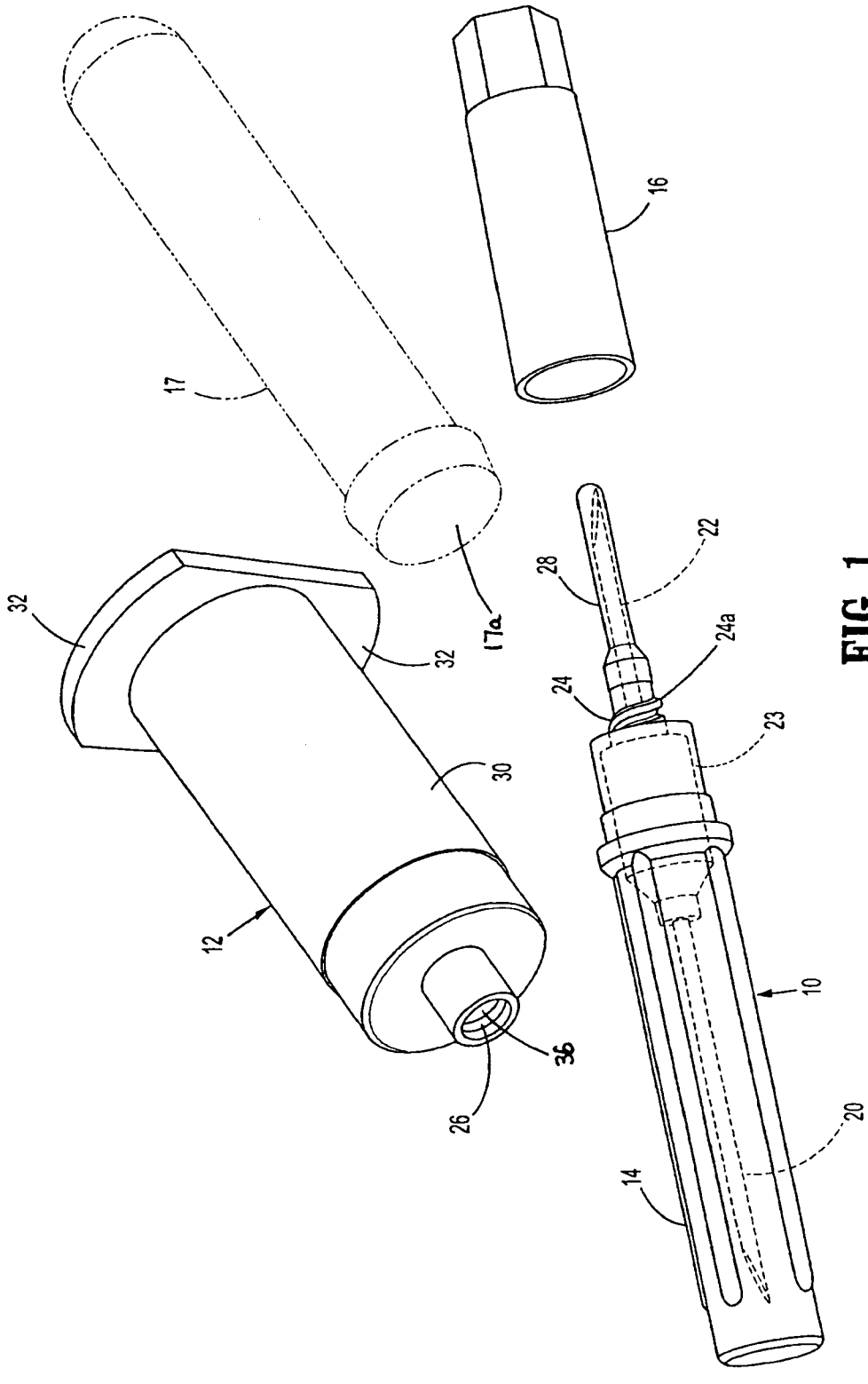


FIG. 1

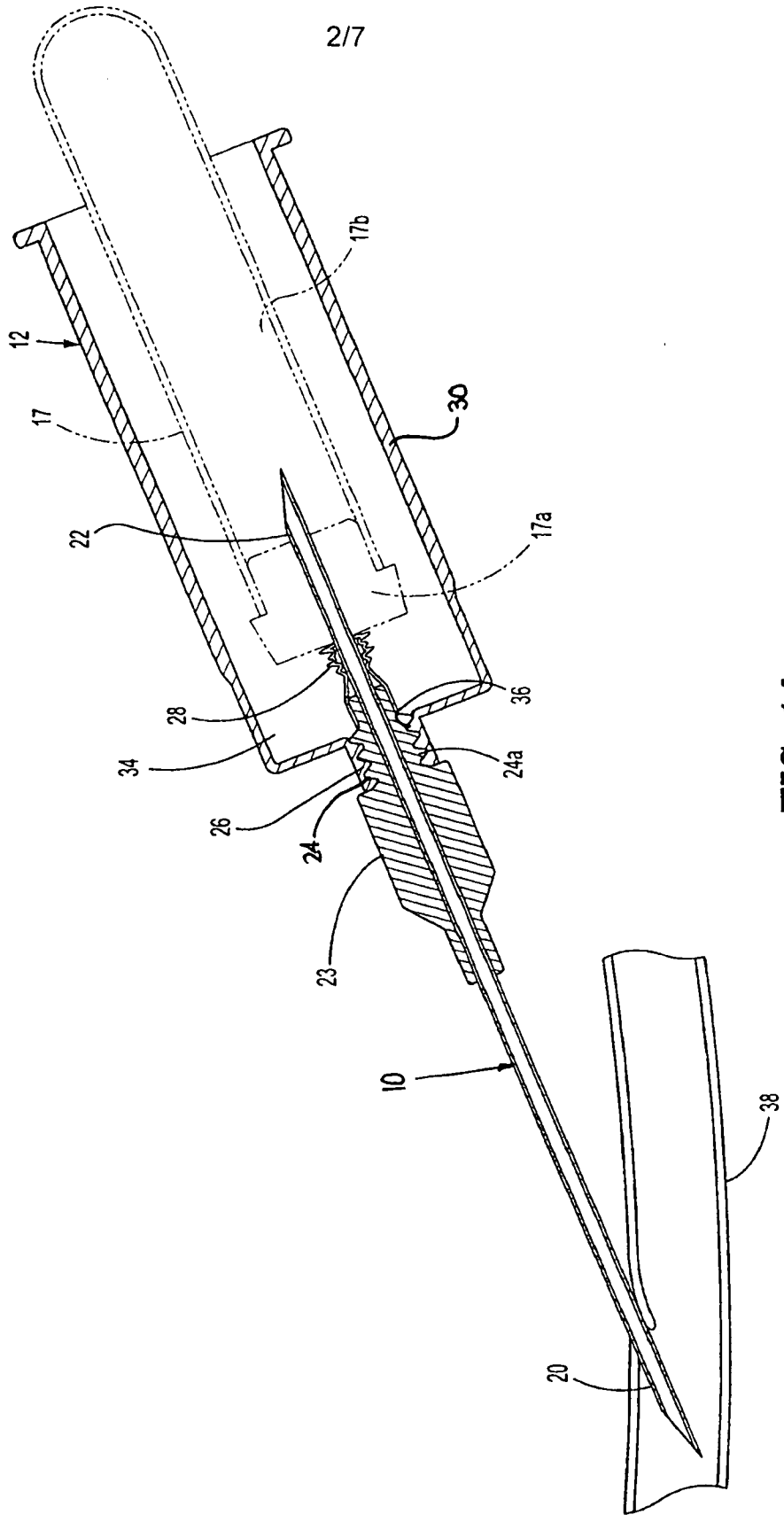


FIG. 1A

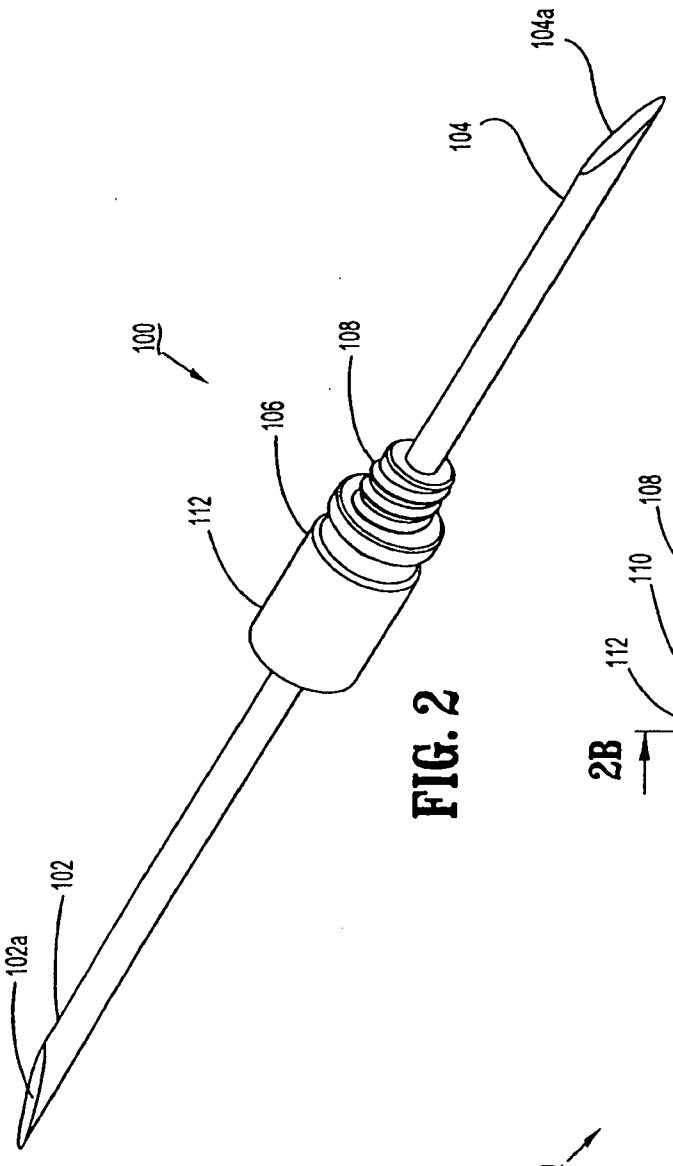


FIG. 2

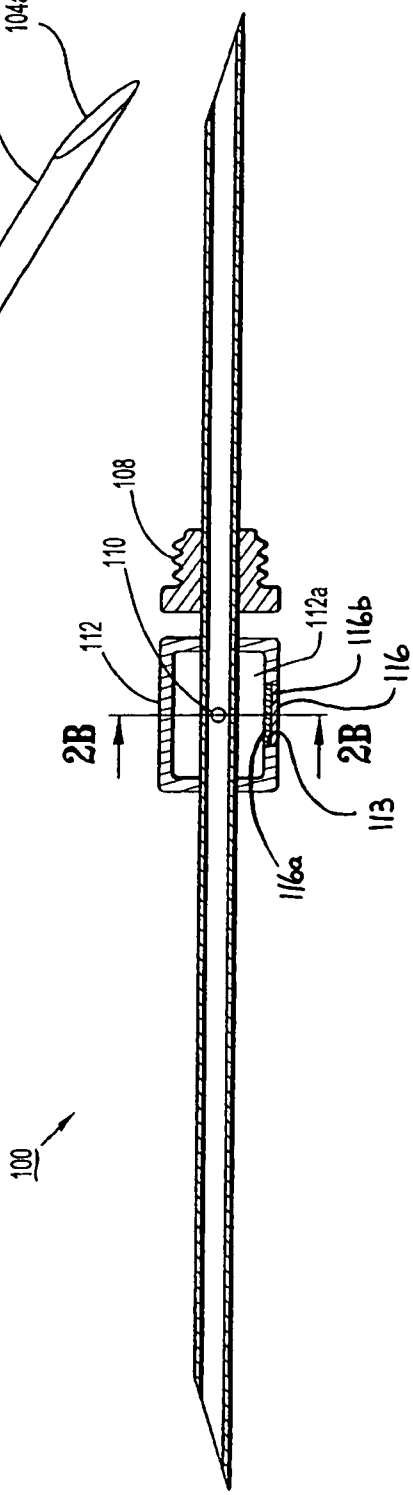


FIG. 2A

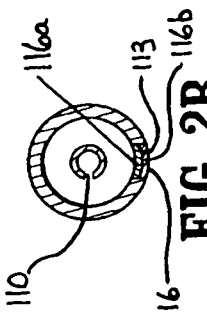


FIG. 2B

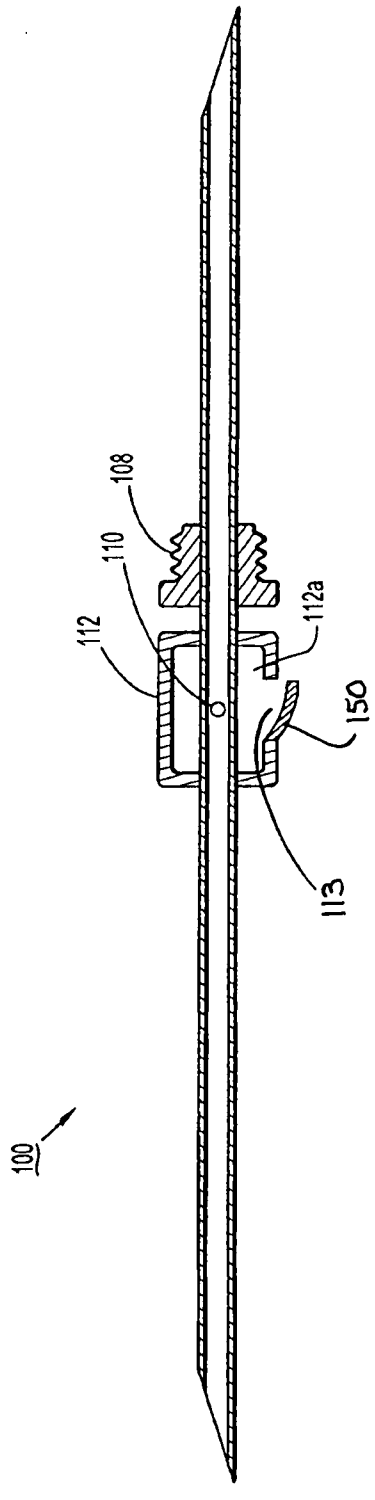
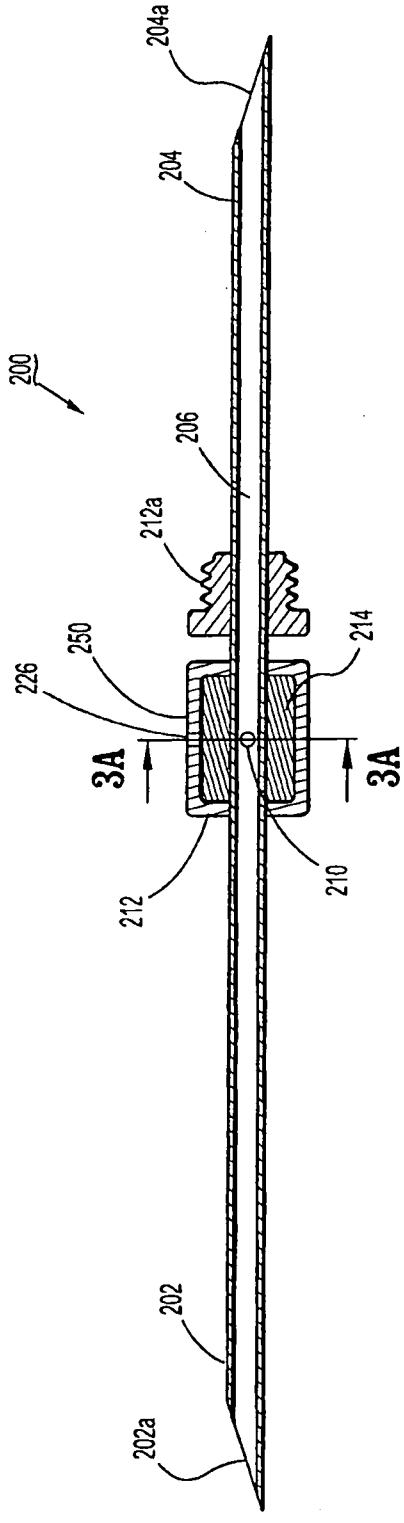


FIG. 2C


204a
204
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212a
214
250
226
3A
3A
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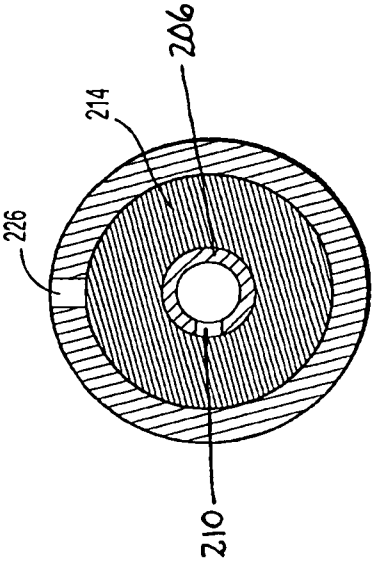
202
202a

FIG. 3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226
210

FIG. 3A

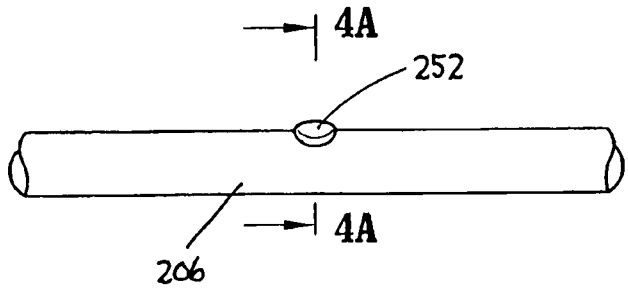


FIG. 4

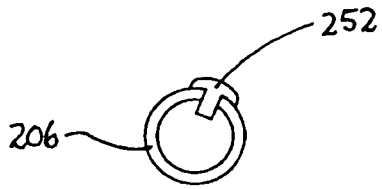


FIG. 4A

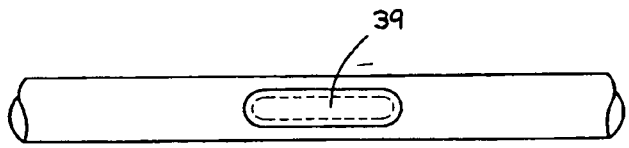
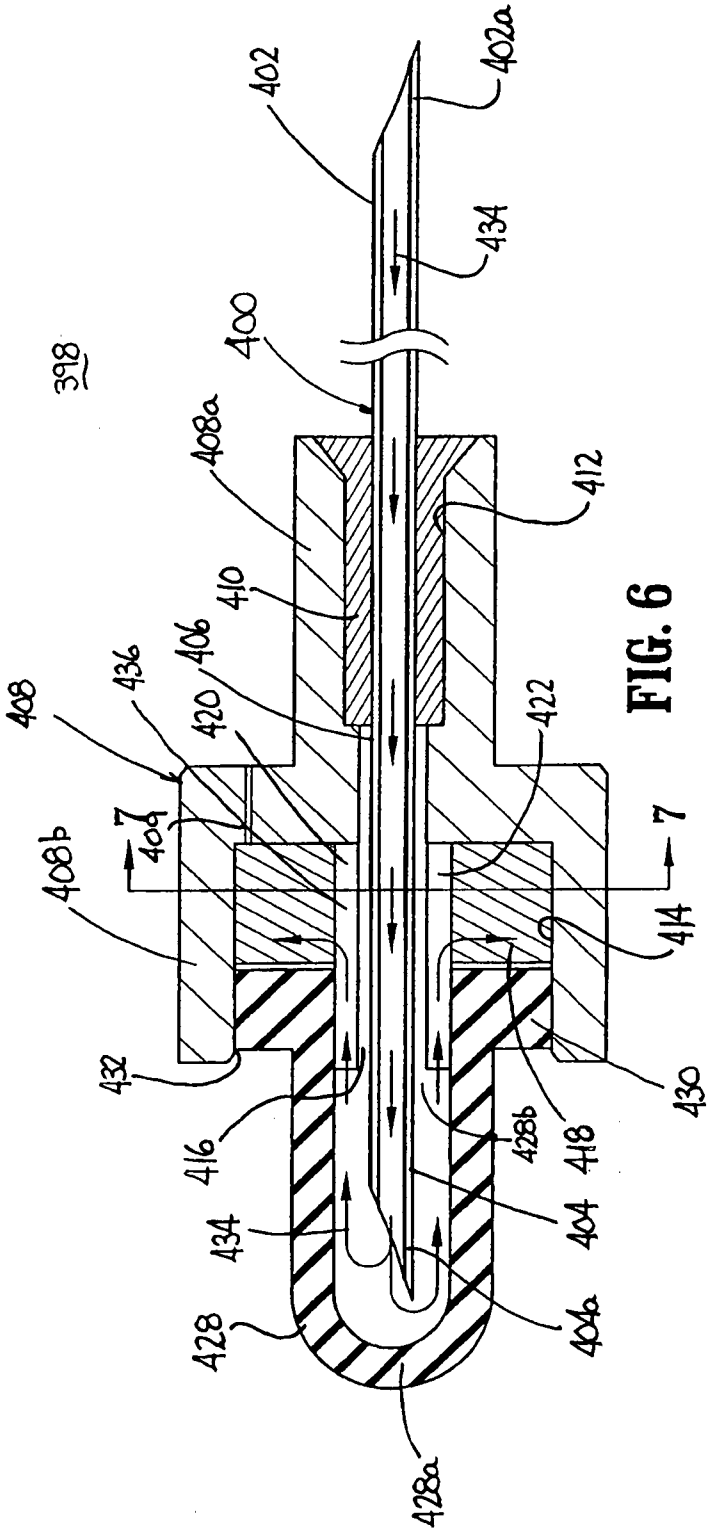


FIG. 5


398
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420
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416
428b
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434
404
428
404a
428a

FIG. 6

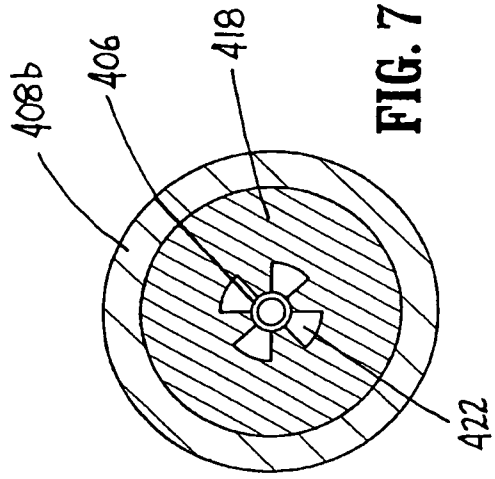
408b
406
418
422

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/26111

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 3/00 (2008.04)
USPC - 604/45
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 3/00 (2008.04)
USPC - 604/45

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/576, 577; 604/168.01, 122, 403, 405

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST - DB=PGPB,USPT,USOC,EPAB,JPAB; PLUR=NO; OP=ADJ; Google
Search Terms: needle, needles, phlebotomy, syringe, venesection, venepuncture, venipuncture, draw, draws, drawing, take, takes, taking, blood, visualize, flashback, flash back, transparent, translucent, visual, visualizing, visualized, visualizes, stopper, plug, etc

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2005/0283093 A1 (CONWAY et al.) 22 December 2005 (22.12.2005) para [0011]; para [0012]; para [0014]; para [0015]; para [0016]; para [0054]; para [0056]; para [0057]; para [0068]; abstract; Fig. 27A.	1-19 ----- 20
Y	US 4,365,630 A (MCFARLANE) 28 December 1982 (28.12.1982) col. 1, ln 30-35; col. 3, ln 54-60.	20
A	US 6,905,483 B2 (NEWBY et al.) 14 June 2005 (14.06.2005), entire document.	1-20

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 June 2008 (03.06.2008)	16 JUN 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/26111

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

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

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

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

3. ☒ Claims Nos.: 21 and 22
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.