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(71) Applicant *(for all designated States except US)*: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **TAN CHEE LEONG, Alvin** [SG/SG]; 225 Pasir Ris Street 21 #08-60, Singapore 510225 (SG).

(74) Agent: **HIGHET, David, W.**; Becton Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).

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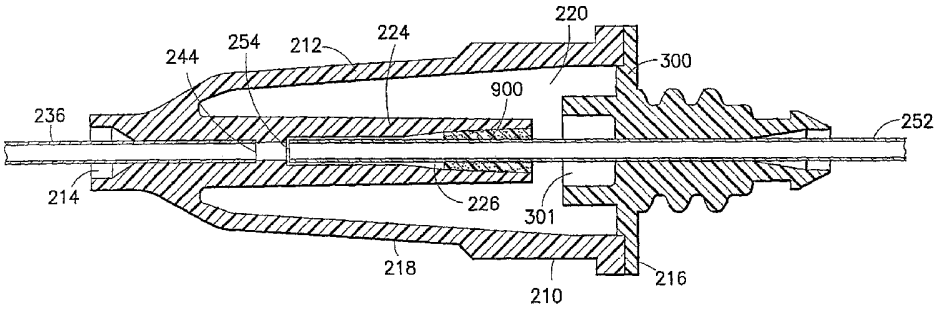
(54) Title: FLASHBACK BLOOD COLLECTION NEEDLE



(57) Abstract: A needle assembly includes a transparent or translucent housing with a fluid inlet end, a fluid outlet end, a flashback chamber and a venting mechanism therebetween. Substantially axially aligned inlet and outlet cannulas extend from the housing and communicate with the chamber. A sealable sleeve covers the external end of the outlet cannula. Relative volumes of the cannulas, the chamber and the sleeve are selected to provide rapid reliable flashback indicative of venous entry with an internal vent plug over the outlet of the flashback chamber to inhibit leakage of blood from the needle on withdrawal from the patient.

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FLASHBACK BLOOD COLLECTION NEEDLE

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to a device for collecting blood samples by performing venipuncture on a patient. More particularly, the present invention relates to a needle assembly for multiple sample blood collection that allows a phlebotomist to determine whether vein entry has occurred when collecting a blood sample from a patient into an evacuated blood collection tube.

2. Description of Related Art

[0002] Venipuncture is the primary method used for acquiring blood samples for laboratory testing. In performing venipuncture procedures, a phlebotomist must follow several steps simultaneously. Such steps include assessing the patient's overall physical and psychological condition so as to properly select a venipuncture site and technique. The phlebotomist must also select the proper corresponding equipment, perform the technique so as to control bleeding, and properly collect and identify fluid specimens for testing. The phlebotomist must ascertain all of these coinciding factors, as such factors may adversely affect the distension of the vein and the length of the venipuncture procedure.

[0003] Various venipuncture devices have been developed to address the above-described problems. These devices include products intended to assist the phlebotomist in confirming that vein entry has been made see e.g. U.S. Patent Nos. 5,222,502 and 5,303,713. Such a device contains a needle assembly with a housing that defines a chamber therein. A single cannula pointed at both ends, is affixed to the housing. The intravenous (IV) end of the cannula is adapted for penetration of a

patient's vein. The non-patient end of the cannula has a sealable sleeve and is adapted for penetration of a penetrable stop positioned within an evacuated container.

[0004] Upon vein entry with the intravenous end of the cannula, blood will flow through the cannula, into the sealable sleeve and into the housing chamber, which is clear or translucent for visualization ("flashback"). Once air is vented from the flashback chamber, the blood therein is pressurized each time the sealable sleeve is pushed toward the housing chamber upon activation of an evacuated container.

[0005] Due to the length of time between vein entry and flashback, the phlebotomist may erroneously believe that satisfactory vein entry has not been achieved since there is no immediate indication of vein entry in the see-through chamber. The phlebotomist may therefore unnecessarily repeat the venipuncture procedure, requiring replacement of the evacuated container and/or the needle assembly itself. Such a repetitive process prolongs the physical and emotional discomfort endured by the patient. In such cases, a phlebotomist may use a blood collection set to provide some entry indication, and will then incur the cost of the blood collection set, as well as the cost of a discard tube.

[0006] It would therefore be desirable to provide an improved blood collection device that permits blood flow through a relatively short needle directly into a flashback chamber, thereby providing immediate indication of successful vein entry.

SUMMARY OF THE INVENTION

[0007] The invention provides a needle assembly for the extraction of at least one fluid sample into an evacuated container for laboratory testing. The needle assembly provides a clear or translucent housing with sufficient dead space for blood to flow into a flashback chamber for visualization by the user to confirm

successful vein entry, with an internal vent mechanism over the outlet of the flashback chamber to inhibit leakage of blood from the IV needle on withdrawal from the patient. As used herein vent mechanism indicates one or more features or elements that provide venting of air, but which, typically, prevent fluid from passing through. The actual element that vents the air in the venting mechanism may be for example a vent plug or a one-way valve. At the same time there will be very little residual blood in the housing after use as the vent mechanism retains the blood within the relatively small flashback chamber.

[0008] According to the invention a needle assembly includes a housing which in turn is comprised of a housing interior, a flashback chamber in communication with the housing interior, and either (i) a first cannula mounted in the housing in communication with the flashback chamber and a second cannula mounted in the housing in communication with the flashback chamber, or (ii) a single cannula mounted in the housing with an opening in communication with the flashback chamber. These elements are configured such that the sole communication path between the housing interior and the external environment is via the flashback chamber. A vent mechanism is located in the communication path between the flashback chamber and the housing interior; so that upon contact with blood, this venting mechanism seals against the flow of air from the housing interior into the flashback chamber.

[0009] In use, the intravenous (IV) cannula (or IV portion of a single cannula) punctures the patient's skin to make a vein entry. Upon satisfactory vein entry, air that is at atmospheric pressure within the lumen of the IV cannula, flashback chamber, housing interior and the lumen of the non-patient cannula (or non-patient portion of a single cannula) experiences compression due to the influence of venous pressure and therefore flows through the IV cannula into the flashback chamber and through the vent plug into housing interior. Because the venous pressure exceeds

the atmospheric pressure within flashback chamber, blood flows into the chamber. Blood flow into the housing interior is prevented by the vent mechanism, which while allowing air to flow through it, seals on contact with blood thereby trapping the compressed air at venous pressure in the housing interior. This inhibits leakage of the blood or fluid sample from the IV cannula on removal from the patient, which might otherwise occur due to decompression of the air from the housing interior through the IV cannula.

[0010] The volumes defined by the lumens through the cannulas, the chamber, the housing interior and the sleeve are selected to achieve a very rapid indication of vein entry. The first and second cannulas are typically in axial alignment with one another to provide an axial fluid flow path therebetween along a length of the housing. The second cannula typically includes a sealable sleeve.

DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a cross-sectional view of a typical embodiment of the needle assembly of the present invention.

[0012] FIG. 2 is a cross-sectional view of a second embodiment.

[0013] FIG. 3 is a cross-sectional view of a third embodiment.

[0014] FIG. 4 is a cross-sectional view of a fourth embodiment.

[0015] FIG. 5 is a schematic view of the needle assembly of FIG. 1 prior to use.

[0016] FIG. 6 is a schematic view similar to FIG. 5, but showing the first sign of venous entry.

[0017] FIG. 7 is a schematic view of a fifth embodiment.

DETAILED DESCRIPTION

[0018] The invention provides a needle assembly for blood collection that provides a visual indication of vein entry ("flashback") upon collection of a blood or other fluid sample from a patient into one or more evacuated blood collection tubes and inhibits leakage of the blood or fluid sample from the IV cannula on removal from the patient.

[0019] Various embodiments of the present invention are shown in FIGS. 1-7, With reference to FIG. 1, this embodiment is directed to a needle assembly **210** with a housing **212** having a fluid inlet end **214**, a fluid outlet end **216** and a frustum-shaped exterior wall **218** extending between the ends. Exterior wall **218** defines the housing interior **220**. Housing **212** further includes a cylindrical interior wall **224** that extends in the housing interior **220** from fluid inlet end **214** substantially concentrically with cylindrical exterior wall **218** to a vent plug **900**. Cylindrical interior wall **224** and vent plug **900** define a flashback chamber **226**.

[0020] Needle assembly **210** also includes a fluid inlet cannula **236** having an exterior end that defines a sharpened bevel and an interior end **244** that is mounted fixedly in fluid inlet end **214** of housing **212**. Fluid inlet cannula **236** is characterized further by a substantially cylindrical lumen extending between the ends and communicating with the interior of housing **212**.

[0021] Needle assembly **210** further includes a fluid outlet cannula **252**. Outlet cannula **252** concludes a blunt interior end **254**, an exterior end defining a sharpened bevel and a substantially cylindrical lumen extending between the ends. Portions of outlet cannula **252** between the ends are securely affixed in outlet end **216** of housing **212**. Outlet cannula **252** is mounted so that interior end **254** passes substantially coaxially into interior wall **224** and so that interior end **254** of outlet cannula **252** substantially aligns axially with interior end **244** of inlet cannula **236**.

Additionally, interior end **254** of outlet cannula **252** is spaced only a small distance from interior end **244** of inlet cannula **236**. An axial gap between interior end **254** of outlet cannula **252** and interior end **244** of inlet cannula **236** that is less than 0.5mm may result in a flashback that is inconsistent.

[0022] Cylindrical interior wall **224** is dimensioned relative to outlet cannula **252** to achieve both desirable flow of blood through assembly **210** and to achieve effective flashback indication. In particular, cylindrical interior wall **224** preferably is dimensioned to provide a radial gap around outlet cannula **252** of about 0.2mm, as indicated by dimension "c" in FIG. 1. This gap achieves a substantially laminar blood flow within flashback chamber **226** and prevents blood hemolysis. Additionally, the small radial gap between cylindrical inner wall **224** and outlet cannula **252** enables a drop of blood to be spread thinly across the radial gap in flashback chamber **226** to provide a magnified flashback indication with a very small volume of blood. Thus, an easily visualized flashback indication is achieved quickly at the first appearance of blood from interior end **244** of inlet cannula **236**.

[0023] Needle assembly **210** further includes a sealable sleeve **261** mounted to fluid outlet end **216** of housing **212** and covering exterior end **258** of outlet cannula **252** when sealable sleeve **261** is in an unbiased condition. However, sealable sleeve **261** can be collapsed in response to pressure exerted by the stopper of an evacuated tube for urging exterior end **260** of outlet cannula **252** through both sealable sleeve **261** and stopper of an evacuated tube, as known in the art.

[0024] The above embodiment is described in terms of a vent plug. However, any vent mechanism is suitable. The vent mechanism may be, for example, a porous vent plug formed from a matrix or carrier material, typically hydrophobic, that is coated with, impregnated with, or otherwise, contains a hydrophilic material that swells on contact with aqueous or water containing substances. The hydrophobic carrier material can be but is not limited too, high-density polyethylene,

polytetrafluoroethylene, ultra-high molecular weight polyethylene, Nylon 6, polypropylene, polyvinylidine fluoride and polyethersulfone. The swellable nature of the hydrophilic material thereby provides the sealing function in the vent upon contact with blood. It is also possible to use a porous vent plug that becomes sealed upon contact with blood using biological phenomena, e.g., by clotting and/or cell agglutination that blocks the vent; a superabsorbant material to seal the vent by swelling on contact with an aqueous fluid; or a one-way valve, (e.g., a thin flap such as plastic film covering a vent, a deformable seal such as a rubber or plastic duckbill valve, or a deformable wrap over a vent). Is should be noted that any combination of these various mechanisms is also possible.

[0025] FIGS 2-4 show embodiments with varying vent plugs. FIG. 2 shows a vent plug **900a,** which is located at the end of the cylindrical inner wall **224a** and fitted into a recess **301** in the housing interior non-patient wall **300**. FIG. 3 shows a vent plug in a similar location to that of FIG. 2 however Vent plug **900b** has a shoulder **901b. FIG. 4** shows a vent plug **900c** that is located both within the cylindrical inner wall **224c** and the recess **301** in the housing interior non-patient wall **300**, and has a shoulder **901c**. The vent plug location in each of these embodiments is such that no air can flow out of the flashback chamber **226** into the housing interior **220** without passing through the vent mechanism (**900 a,b,c**).

[0026] FIGS. 5 and 6 provide schematic representations of the needle assembly **210** of FIG. 1 before and after a conventional venipuncture, in which, the needle assembly **210** is connected to a holder (not shown) and punctures the patient's skin to make a vein entry. Upon vein entry, blood enters the IV cannula **236** and flows toward the flashback chamber **226**. The blood flows from inlet cannula **236** into the space between inlet and outlet cannula, such that blood flows both into the outlet cannula **252** and into flashback chamber **226**. At this point in time, Flashback chamber **226** indicates successful vein entry and reduces the volume of air present

in housing **212** shown in FIG. 6. Air that was at atmospheric pressure within the lumen of the IV cannula **248**, flashback chamber **226** housing interior **220** and the lumen of the non-patient cannula **262** prior to vein entry. Thus experiences compression due to the influence of venous pressure and this air is therefore forced through the IV cannula **236** shown in FIG. 6 into the flashback chamber **226** and through the vent plug into chamber **220**. Blood flow into housing interior **220** is prevented by the vent plug **900**, which allows the pressurized air to flow through it, but seals on contact with blood, thereby trapping the compressed air (at venous pressure) in housing interior **220**. Blood flow in the entire needle assembly ceases once the pressure within chamber **226** and the venous pressure are equal.

[0027] Once the steps set forth in the previous paragraph occur, and venous entry is visually confirmed by the phlebotomist, an evacuated container (not shown), is then inserted into the holder such that exterior end **260** of second cannula **252** penetrates stopper of the container, as known in the art. Upon penetration of the stopper by second cannula **252**, a negative pressure gradient is transmitted to chamber **226**, causing blood to flow from chamber **226** into the container.

[0028] The needle assemblies described above desirably should be small for convenient use, but should be constructed to ensure reliable and rapid flashback. The occurrence of flashback in the needle assemblies described and illustrated above operate pursuant to the ideal gas law. In particular, at very low densities all gases and vapors approach ideal gas behavior and closely follow the Boyle's and Charles' laws given by:

$$P_1 V_1 = P_2 V_2$$

where:

P_1 denotes the pressure of air within the needle assembly before needle insertion,

P_2 denotes the pressure of air within the needle assembly after vein entry;

V_1 denotes the volume of air within the needle assembly before vein entry; and

V_2 denotes the volume of air within the needle assembly after vein entry.

[0029] Design parameters should keep the needle device as small as possible for easy use, while ensuring an appropriate volume as specified by the preceding equation. FIGS. 5 and 6 provide schematic representations of the needle assembly **210** of FIG. 1 for purposes of depicting the application of the ideal gas law. In this regard, **A** identifies the volume of lumen **248** through inlet cannula **236**. **B** denotes the total volume of the housing interior **220**, flashback chamber **226**, lumen **242** through outlet cannula **252** and sealable sleeve **261**. Referring again to the preceding equation, P_1 is the pressure within needle assembly **210** before use, and hence substantially equals atmospheric pressure. Atmospheric pressure will vary slightly from time to time and from location to location. However, for purposes of this analysis, atmospheric pressure P_1 will be assumed to be 760mm Hg. P_2 in the preceding equation is the volume of the dead space in needle assembly **210** after vein entry. More particularly, after vein entry, blood will fill lumen **248** of inlet cannula **236**, thereby reducing the volume to be occupied by gas in remaining portions of needle assembly **210** and hence increasing the pressure of air in the remaining portion of needle assembly **210**. A needle assembly with dimensions approximately as shown in FIG. 1 will have a pressure P_2 of about 790mm Hg at venous pressure (with tourniquet). V_1 in the preceding equation defines the volume of the total dead spaced in needle assembly **210** before use, and hence will equal **A** + **B** as shown in FIG. 5. V_2 defines the dead space in the device after vein entry, and with lumen **248** of inlet cannula **236** filled with blood. Hence, V_2 in the preceding equation will equal **B**. These input parameters can be employed to define

a minimum desired size for the respective components of needle assembly **200** as shown in the following application of the ideal gas law equation.

$$P_1 V_1 = P_2 V_2$$

$$P_1/P_2 = V_2/ V_1$$

$$760/790 = B/(A+B)$$

$$0.962 = B/(A+B)$$

$$0.962(A+B) = B$$

$$0.038B = 0.962A$$

$$B=25.3A$$

Therefore, dead space in housing **212**, outlet cannula **252** and sleeve **261** advantageously is at least 25.3 times the volume defined by lumen **248** through inlet cannula **236**, and most advantageously is about 26 times the volume of lumen **248**. However, other configurations are possible and will function as described herein.

[0030] The immediate response when an evacuated tube is placed in communication with outlet cannula **252** is to draw blood from the vein into tube (not shown). The highest-pressure gradient is always maintained between the vein and the evacuated tube. An axially aligned inlet cannula **236** and outlet cannula **252,** therefore provide an unobstructed path for blood flow from the vein into evacuated tube.

[0031] When the requisite tubes are filled with blood, the needle assembly is removed from the vein. The sealed nature of the vent plug **900** inhibits the pressurized air within housing interior **220** from then moving into the flashback chamber **226** and into the inlet cannula **236**, which could promote dripping of blood from the IV cannula tip.

[0032] The preceding embodiments show structurally separate inlet and outlet cannulas that are axially aligned with one other and placed in close end-to-end relationship with one another. However, the principals of the invention described above also can be achieved with a single cannula formed with a transverse slot or aperture within the flashback chamber. For example, FIG. 7 schematically shows a needle assembly **310** with a housing **312** that is substantially identical to housing **212** described and illustrated above. Needle assembly **310** differs from needle assembly **210** in that a single double end needle cannula **336** is provided and passes entirely through housing **312**. More particularly, needle cannula **336** includes a venous entry end **338**, a non-patient end **340** and a lumen **342** extending therebetween. Portions of cannula **336** within inner wall **324** include a slot or aperture **344** to provide communication between lumen **342** and flashback chamber **336** within inner wall **324**. Needle assembly **310** functions substantially in the same manner as needle assembly **210** described and illustrated above.

[0033] The relative dimensional calculations, volumes and pressures apply to both illustrated and unillustrated embodiments of the invention. Accordingly, the scope of the as defined by the appending claims is not limited to the specific illustrated embodiments. Various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention, and it is intended to claim all such changes and modifications as fall within the scope of the invention.

WHAT IS CLAIMED IS:

1. A needle assembly comprising:

a housing comprising

(a) a housing interior,

(b) a chamber in communication with the housing interior,

(c) a first cannula mounted in the housing in communication with the chamber, and a second cannula mounted in the housing in communication with the chamber, or a single cannula mounted in the housing with an opening in communication with the chamber,

wherein the sole communication path between the housing interior and the external environment is via the chamber;

a vent mechanism located in the communication path between said chamber and said housing;

wherein upon contact with blood, said venting mechanism seals against the flow of air from the housing interior into the chamber.

2. The needle assembly of claim 1, further comprising;

a sealable sleeve mounted over portions of said second cannula disposed externally of said housing.

wherein said sealable sleeve, said lumen of said second cannula and said chamber of said housing and said housing interior define a combined volume approximately 26 times greater than a volume defined by said lumen of said first inlet cannula.

3. The needle assembly of Claim 2, wherein said lumen of the said first cannula is substantially axially aligned with said lumen of said second cannula.

4. The needle assembly of Claim 1, wherein an exterior wall of said housing and wall of said chamber is formed from a transparent or translucent plastic

5. The needle assembly of Claim 1, wherein an exterior wall of said housing comprises a transparent or translucent window region and the wall of said chamber is formed from a transparent or translucent plastic.

6. The needle assembly of claim 1 wherein said vent mechanism is a porous plug formed from a hydrophobic carrier material or a one-way valve.

7. The needle assembly of claim 6 wherein said vent mechanism is a porous plug and wherein said porous plug further comprises a hydrophilic material that swells on contact with blood.

8. The needle assembly of claim 6 wherein said vent mechanism is a porous plug and wherein said porous plug further comprising a biological agent, which induces said seal against the flow of air via a biological phenomena.

9. The needle assembly of claim 6 wherein said vent mechanism is a porous plug and wherein said hydrophobic carrier material is selected from a group consisting of high-density polyethylene, polytetrafluoroethylene, ultra-high molecular weight polyethylene, Nylon 6, polypropylene, polyvinylidine fluoride and polyethersulfone.

10. The needle assembly of claim 1;

wherein said first cannula comprises an inlet cannula having opposite external and internal ends and a lumen extending between said ends, said inlet cannula being mounted to said housing such that said external end of said inlet cannula is externally of said housing and such that said lumen through said inlet cannula communicates with said chamber; and

wherein said second cannula comprises an outlet cannula having opposite internal and external ends and a lumen extending between said ends, said outlet cannula being mounted to said housing such that said external end of said outlet cannula is externally of said housing and such that said lumen of said outlet cannula communicates with said chamber.

11. The needle assembly of claim 1 wherein the housing comprises said single cannula.

12. The needle assembly of claim 1 wherein said vent mechanism is located completely within the chamber.

13. The needle assembly of claim 1 wherein said vent mechanism is located partially within the chamber.

14. The needle assembly of claim 1 wherein said vent mechanism is located within a recess in the outlet wall of the housing interior such that the vent mechanism abuts the outlet of the chamber.

12. A method of flashback visualization for a blood collection needle assembly comprising the steps;

a) providing a needle assembly for blood collection, said needle assembly comprising a housing comprising a housing interior, a chamber in

communication with the housing interior, a first inlet cannula mounted in the housing in communication with the chamber, and a second outlet cannula mounted in the housing in communication with the chamber, wherein the sole communication path between the housing interior and the external environment is via the chamber, and a vent mechanism located in the communication path between said chamber and said housing;

wherein upon contact with blood, said venting mechanism seals against the flow of air from the housing interior into the chamber.

b) providing a blood flow into the first inlet cannula and into the chamber such that air is pushed out of the cannula into the chamber, through the vent mechanism and into the housing interior; and

c) continuing the blood flow such that the blood contacts the vent mechanism, thereby sealing the vent mechanism against flow of air from said housing interior back into said chamber or out to the surrounding atmosphere.

13. A needle assembly comprising:

a housing comprising

(d) a housing interior,

(e) a chamber in communication with the housing interior,

(f) a first cannula mounted in the housing in communication with the chamber, and a second cannula mounted in the housing in communication with the chamber, or a single cannula mounted in the housing with an opening in communication with the chamber,

wherein the sole communication path between the housing interior and the external environment is via the chamber;

a vent mechanism located in the communication path between said chamber and said housing;

a sealable sleeve mounted over portions of said second cannula disposed externally of the outlet end of said housing;

wherein said sealable sleeve, said lumen of said second outlet cannula and said chamber of said housing and said housing define a combined volume which is greater than a volume defined by said lumen of said first cannula.

wherein upon contact with blood, said venting mechanism seals against the flow of air from the housing interior into the chamber.

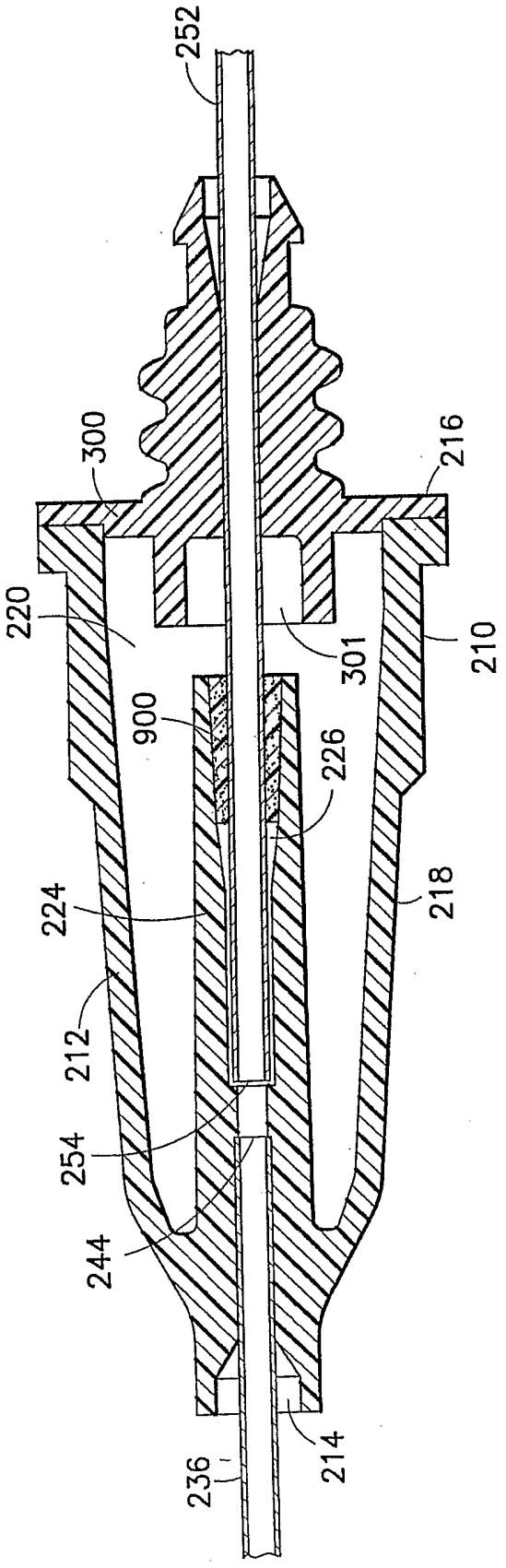

FIG. 1

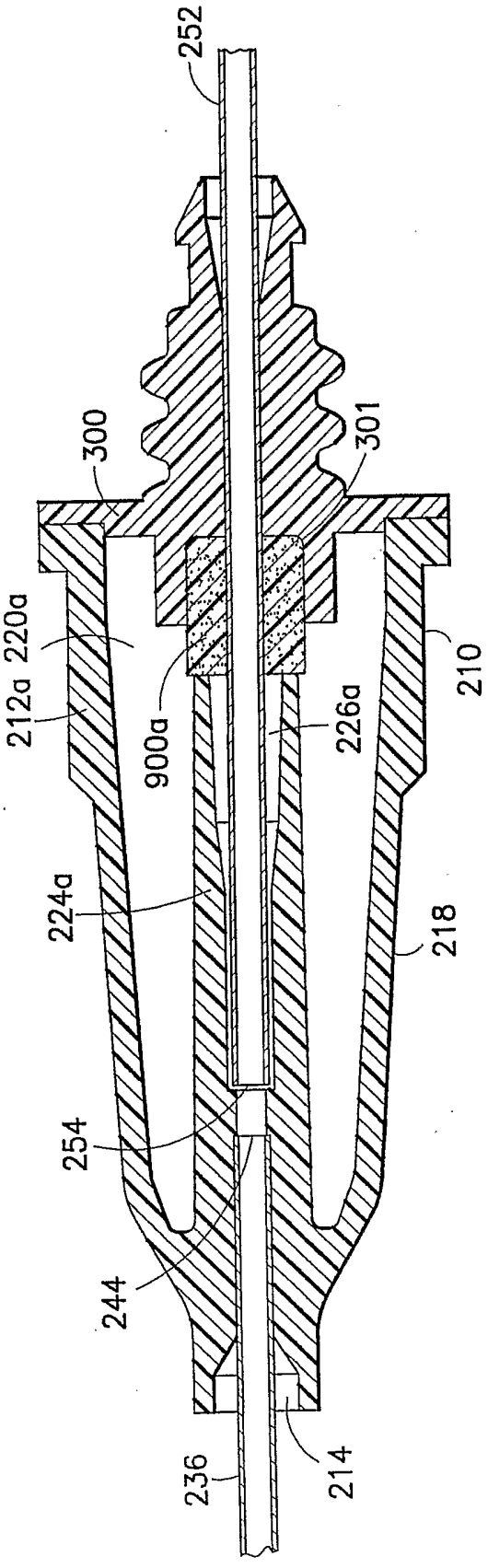

FIG.2

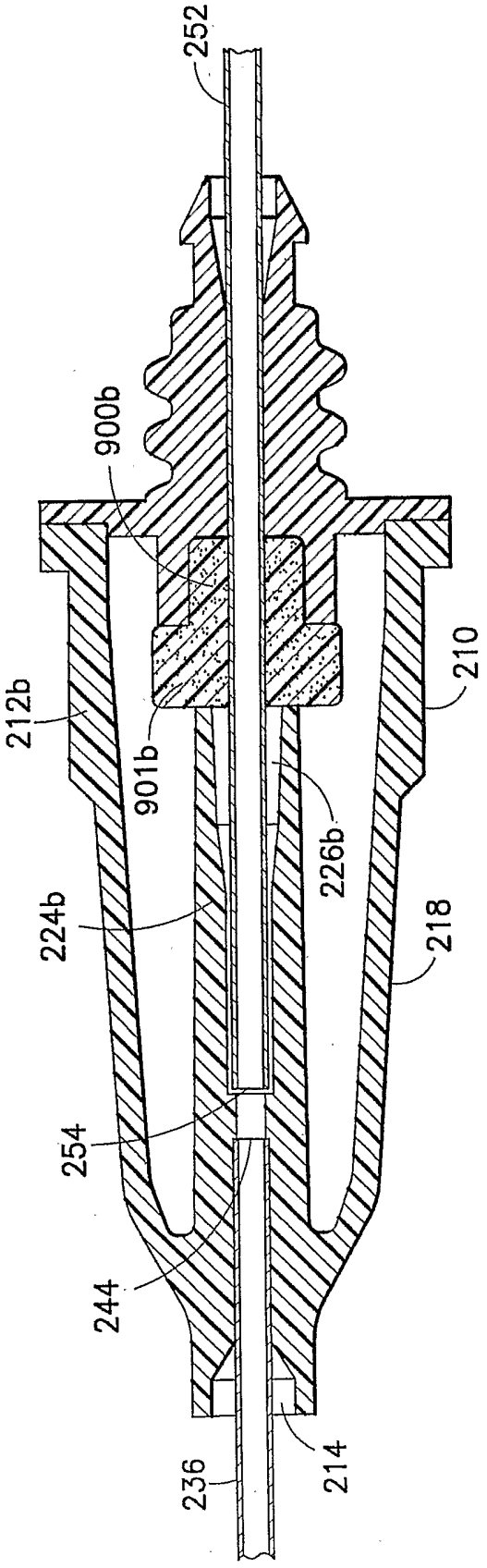

FIG.3

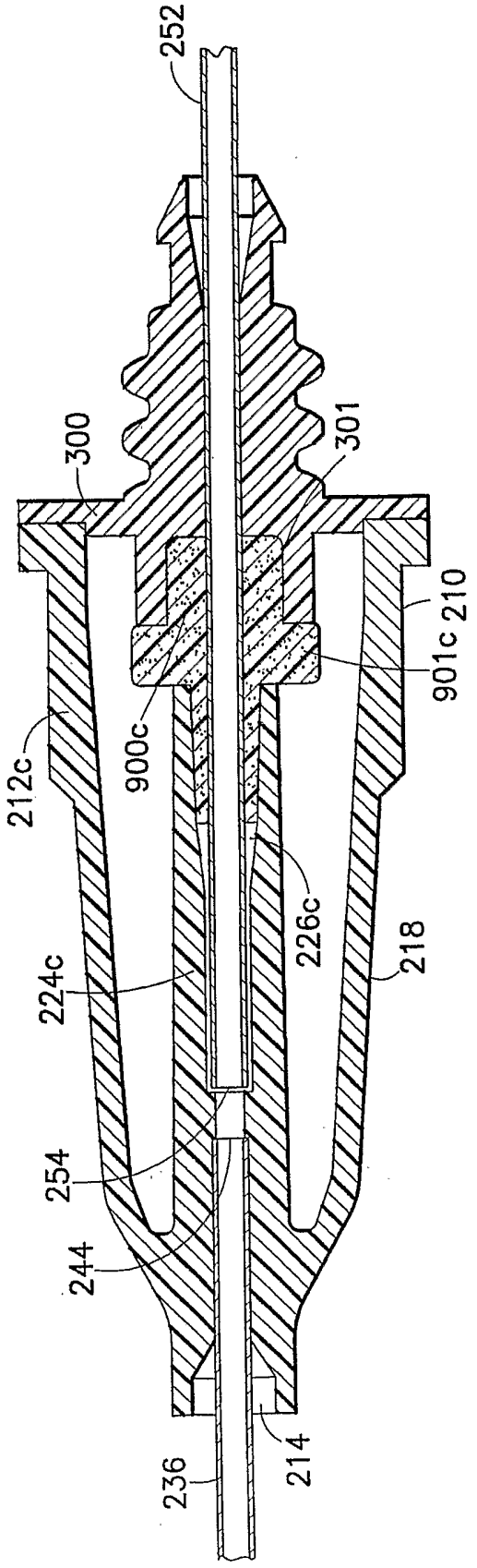

FIG.4

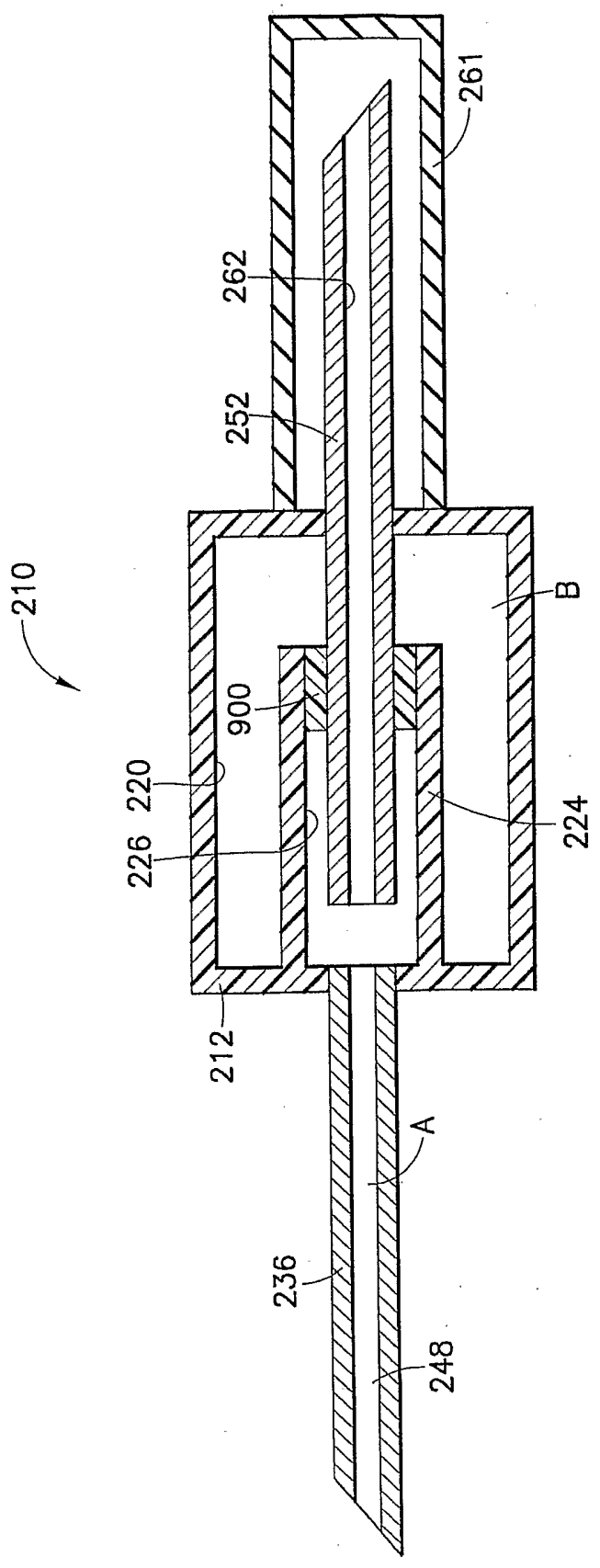

FIG.5

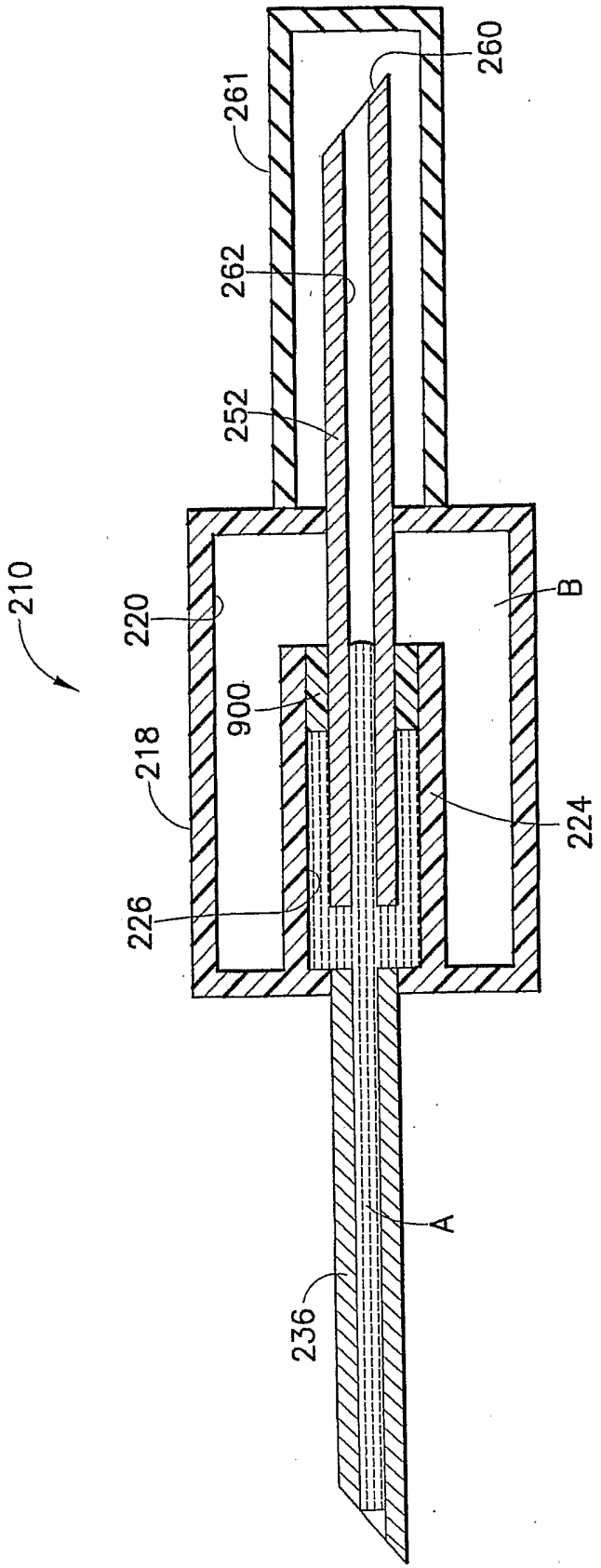

FIG.6

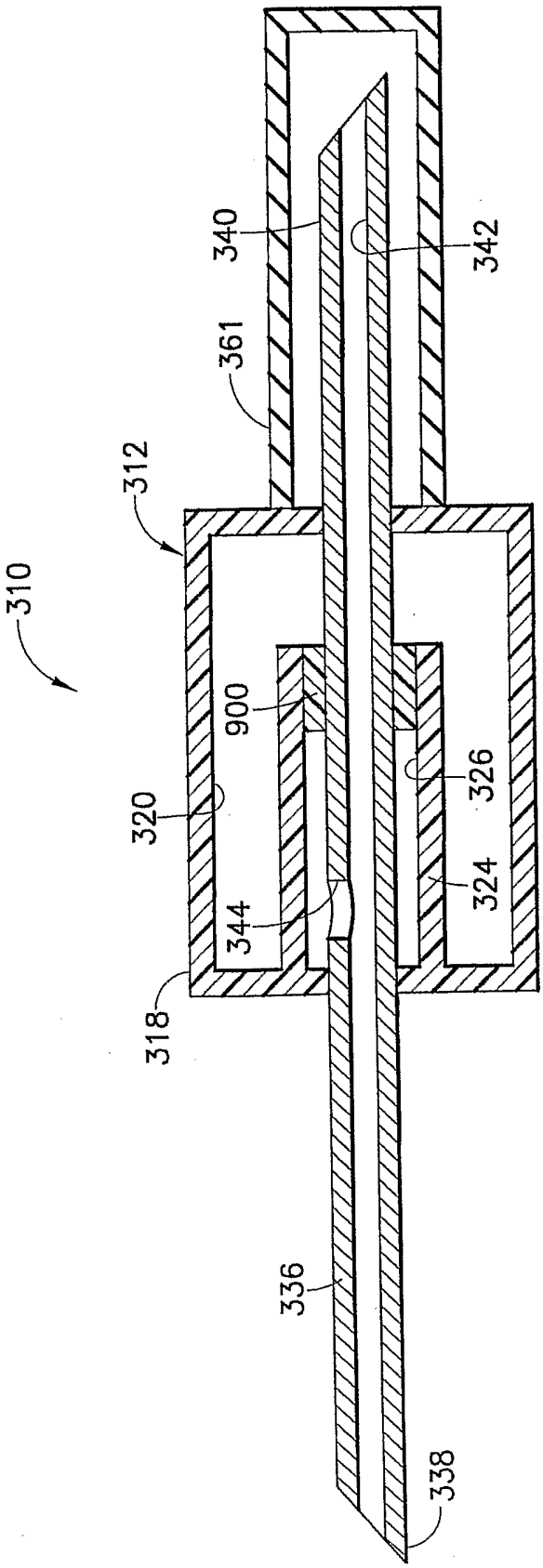

FIG.7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/026543

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15

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 7 A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/105414 A1 (LEONG ALVIN TAN CHEE) 5 June 2003 (2003-06-05) claim 1; figures 10,11	1,13
A	EP 0 060 385 A (BECTON, DICKINSON AND COMPANY) 22 September 1982 (1982-09-22) claim 1; figure 2	1,13
A	US 4 886 072 A (PERCARPIO ET AL) 12 December 1989 (1989-12-12) claim 1	1,13

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

☒ Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step 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
5 April 2005	13/04/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hooper, M

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/026543

Box 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. [X] Claims Nos.: 12
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery, as the term "providing a blood flow" is seen in light of the description as including a step performed on the human or animal body which necessitates the insertion of a needle into said body.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box 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 an additional fee, this Authority did not invite payment of any additional fee.

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.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/026543

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