

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 September 2008 (25.09.2008)

PCT

(10) International Publication Number
WO 2008/115244 A1

(51) International Patent Classification:

A61M 5/32 (2006.01) A61M 39/02 (2006.01)
A61M 39/04 (2006.01) A61M 39/26 (2006.01)

(21) International Application Number:

PCT/US2007/070086

(22) International Filing Date: 31 May 2007 (31.05.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

11/687,533 16 March 2007 (16.03.2007) US

(71) Applicant (for all designated States except US): **SMITHS MEDICAL ASD, INC.** [US/US]; 2231 Rutherford Road, Carlsbad, CA 92008-8820 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BAXTER, Charles, S.** [US/US]; 5839 Westchester Court, Worthington, OH 43805 (US). **GALLOGLY, Dale, Marvin** [US/US]; 12001 Pleasant Valley Road, Moun Vernon, OH 43050

(US). **MOSLER, Theodore, J.** [US/US]; 5433 Alafia Court, Raleigh, NC 27616 (US). **PATZER, Charles, R.** [US/US]; 5388 Cherry Bud Court, Columbus, OH 43228 (US).

(74) Agents: **GROSSMAN, Kurt, L.** et al.; Wood, Herron & Evans, L.L.P., 441 Vine Street, 2700 Carew Tower, Cincinnati, OH 45202 (US).

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: BLUNT CANNULA FOR ACCESSING A SLIT SEPTUM

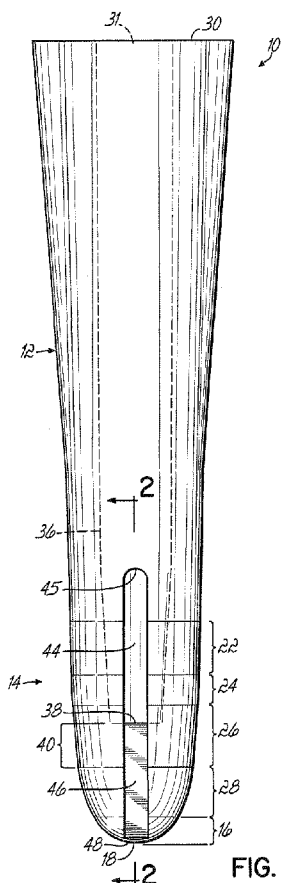


FIG. 1

(57) Abstract: A blunt cannula (10) includes a distal portion (12) and a proximal portion (14). The distal portion (14) has a non-uniform taper defined by a plurality, such as four, differently tapered segments (22, 24, 26, 28). The proximal portion (12) may additionally or alternatively have a non-circular, such as oval, cross-section. At least the major diameter (DMAJ) of the proximal portion (12) may taper toward the distal portion (14).

WO 2008/115244 A1



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

BLUNT CANNULA FOR ACCESSING A SLIT SEPTUM

FIELD OF THE INVENTION

[0001] The present invention relates to medical devices in the form of blunt cannulas used to access a slit septum and adaptors having blunt cannulas to access slit septums of medical sites, such as sample sites or injection sites. In another aspect, the present invention relates to a sample site.

DESCRIPTION OF PRIOR ART

[0002] Sample sites and injections sites typically comprise a plastic housing with one or more ports for fluid ingress or egress relative to the interior cavity of the housing. The housing also typically has a cylindrical portion defining a large aperture adjacent the cavity but which is closed off by a solid septum. A sharp needle may be inserted through the material of the septum to bring the distal opening of the needle at the sharp tip into communication with fluid within the housing to facilitate fluid flow through the lumen of the needle. To reduce needle-stick risks, the needle is contained within a shroud that is generally sized and shaped to prevent fingers from touching the needle tip. The shroud fits over the cylindrical portion of the housing as the needle extends into and through the septum into the

cavity. In some arrangements, the shroud may also include slots positioned and sized to fit over the port(s) of the housing, and further may be shaped, such as to define a J-shape, so as to be rotatable relative to the port(s) to lock the shroud to the site.

[0003] In an effort to reduce or eliminate needles, the solid septum is replaced with a slit septum through which a blunt cannula is to be inserted. Typically, the blunt cannula may form part of an adaptor having luer mating structure to connect with the luer structure of a standard medical device, such as a syringe by way of example, in order to fluidically couple into the site cavity via the central lumen of the blunt cannula. The blunt cannula typically has an upper or proximal circular cross-section cylindrical portion, and a lower or distal portion that tapers to a tip, with the tip defining or including a distal opening for fluid flow relative to the central lumen of the blunt cannula. It has been proposed to control the taper of the distal portion so that it is gradual and uniform between the proximal portion and the tip, which uniform taper is said to reduce insertion forces necessary to insert the cannula through the slit. Also, the proximal portion is intended to be a cylinder without any significant taper, other than perhaps a nominal taper due to draft in the molding process, to reduce the tendency for kick back of the cannula (i.e., the septum material and cannula surface interacting in a manner which would urge the cannula back out of the slit) when the cannula is inserted far enough into the slit to reach the proximal portion of the cannula as is typically desired.

[0004] There are various drawbacks with these blunt cannulas. By way of example, the slit may not seal against the proximal portion of the cannula extending therein, thus creating an area for possible fluid leakage. Further, some of the tip ends of the blunt cannula have been found to be quite sharp. While that "sharp" end allows the cannula to make initial entry into the slit, a shroud is still necessary therewith to prevent finger-touching of the tip as was done with the sharp needles these blunt cannula were intended to replace. Alternatively,

the tip end or surface of the cannula may be flat and so is desirably blunt rather than sharp. But the flat end can impede initial entry of the cannula into the slit.

SUMMARY OF THE INVENTION

[0005] The present invention provides an improved blunt cannula design with a uniquely shaped distal portion so as not to require a tip end that is either essentially sharp or flat while advantageously reducing insertion resistance. In accordance with the principles of the present invention, the distal portion of the blunt cannula presents a rounded tip end or surface, which may be solid, and a plurality of tapered segments having different tapers extending between the proximal portion and the tip end. The differently-tapered segments present a non-uniformly tapering distal portion which is believed to provide the advantage of reduced insertion forces, but without the disadvantage of a tip end that is so sharp as to have need for a protective shroud nor so flat as to impede entry into the septum slit.

[0006] The distal portion advantageously includes at least a conically tapered segment and a generally arcuately tapered segment. Further advantageously, there are four differently-tapered segments (by type and/or size). The four segments may alternate between conical and arcuate tapers. A first tapered segment adjacent the proximal portion may extend with a conical taper, followed by a second tapered segment having a generally arcuate taper with a radius of curvature. A third tapered segment may extend with a conical taper, which may advantageously be greater than the conical taper of the first tapered segment, and a fourth tapered segment may lead into the solid, rounded tip and may have a generally arcuate taper with a radius of curvature less than that of the second segment.

[0007] In accordance with a further aspect of the present invention, the central lumen of the blunt cannula extends distally through the proximal portion and only partially into the distal portion. Advantageously, the central lumen does not extend into the distal portion so far

as to reach the solid, rounded tip end and further advantageously not so far as to reach even the lowermost tapered segment. To that end, some aspect of the tapered segment adjacent the tip (or that entire segment and possibly some aspect of the next, proximally adjacent segment) is solid. The fluid opening(s) of the distal portion coupling to the central lumen pass through one or more of the tapered segments, excluding the solid aspect(s) of the tapered segment. As a result, the fluid path to and from the central lumen via the fluid opening(s) advantageously will not extend into or through the tip so as not to interfere with the solid, rounded tip. A groove(s) may extend distally from the fluid opening(s) along some or all of the solid aspect(s) of the tapered segments toward, but not necessarily all the way, to the tip end. The fluid opening(s) may also extend through aspects of the proximal portion of the blunt cannula, particularly the aspect thereof closely adjacent to the distal portion of the blunt cannula.

[0008] The present invention may also or alternatively provide an improved blunt cannula design with a uniquely shaped proximal portion by which to enhance the seal between the septum slit and the blunt cannula during use. To that end, and in accordance with the principles of the present invention, the proximal portion of the blunt cannula may have a non-circular cross-section instead of a circular cross-section. Advantageously, the proximal portion is not a cylinder. In that regard, the cross-section of the proximal portion, at least along a substantial length thereof, is generally oval and tapers distally such that the major diameter of the oval cross-section decreases therealong to merge into the first tapered portion of the distal portion. It is believed that the shape created upon opening of the slit is not circular. The shaping of the proximal portion to have a generally oval cross-section is thus believed to afford a more complete seal between the surfaces of the slit and the blunt cannula during use. Yet, while the tapering of the major diameter of the proximal portion, along with the non-uniform taper of the distal portion, results in a blunt cannula that has a

significant taper along substantially its entire length, it is believed that kickback is not problematic.

[0009] The blunt cannula of the present invention may form part of an adaptor to be used with a medical site, for example. In that regard, the medical site may be a sample site with oppositely disposed fluid ports extending from a central housing containing the septum to define a T-shape to the medical site. With such a T-shaped construction, fluid flows between the ports and across the septum. The central housing may be cylindrical, and support the septum at the top thereof adjacent the flow path. The adaptor has a plate with luer mating structure, such as a male luer lock, associated with one surface thereof and the blunt cannula extending from the opposite surface thereof with the central lumen of the cannula in fluid communication with the luer mating structure. Depending from opposite edges of the plate to either side of the blunt cannula is a pair of oppositely disposed, generally flat guide walls. The guide walls may have lateral edges extending into the area below the intermediate edges of the plate. Advantageously, the cannula may be spaced equidistant from the two guide walls. Further advantageously, the guide walls are spaced apart a distance approximating the diameter of the central housing such that the guide walls and housing cooperate to align the tip of the cannula with the slit of the septum for proper insertion therewith. One or more of the outboard or lateral edges of the guide walls may be provided with a rib aimed toward the blunt cannula and which further cooperates to align the blunt cannula to the slit.

[0010] The flat guide walls may be spaced apart enough to provide a distal mouth that is large enough not to preclude finger touching. The lateral edges of the flat guide walls may extend into the area below the intermediate edges of the plate sufficient to define a gap that conforms to the width of the port(s) so as to reduce the likelihood of rotation of the adaptor relative to the housing with the cannula inserted into the septum. While the guide walls could be shaped and positioned differently to provide a shroud and/or the ability to lock same to the

site, it is not believed necessary to do so with the blunt cannula of the present invention and/or the adaptor containing same.

[0011] The outboard walls of the housing between the ports of the medical site could be generally flat rather than arcuate, such as by thickening the plastic thereat. The generally flat sides of the housing would cooperate with the generally flat guide walls to further enhance alignment and/or resist rotation. Advantageously, one or more of the lateral edges of the flat side walls of the housing define a groove edge to receive the rib(s) of the guide walls therealong to still further enhance alignment and/or resist rotation.

[0012] Where the proximal portion of the blunt cannula has a generally oval-cross-section, the cannula is advantageously inserted into the slit with the major diameter of the generally oval cross-section proximal portion aligned with the slit. To that end, the septum is generally affixed to the site housing aperture with the slit in a fixed orientation relative to the flow path between the ports. The blunt cannula and guide walls of the adaptor are fixed in relationship such that the major diameter of the proximal portion of the blunt cannula extends at an orientation thereto corresponding to the orientation of the slit of the septum relative to the fluid ports. Advantageously for the present invention, the slit orientation may be transverse to that flow path, in which case the blunt cannula is oriented in the adaptor with the major diameter transverse to the guide walls (i.e., with the minor diameter thereof parallel to the guide walls). The gap(s) between the lateral edges of the guide walls and/or the interaction of the rib(s) of the adaptor and the groove edge(s) of the site housing resist rotation of the blunt cannula aligned into the slit.

[0013] By virtue of the foregoing, there is thus provided an improved blunt cannula design with a uniquely shaped distal portion so as not to require a tip that is either essentially sharp or flat while advantageously reducing insertion resistance. There is thus also provided an improved blunt cannula design with a uniquely shaped proximal portion by which to

enhance the seal between the septum slit and the blunt cannula during use. There is further also provided an adaptor with the improved blunt cannula design(s) for use in accessing the slit septum of medical sites. There is still further provided a medical site configured to advantageously mate with the adaptor. These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with the general description of the invention given above and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0015] Fig. 1 is a front elevation view of a medical device in the form of a blunt cannula in accordance with the principles of the present invention;

[0016] Fig. 2 is a cross-sectional view of the blunt cannula of Fig. 1 taken along line 2-2;

[0017] Fig. 3 is a top or proximal plan view of the blunt cannula taken of Fig. 1;

[0018] Fig. 4 is a bottom or distal plan elevation view of the blunt cannula of Fig. 1;

[0019] Figs. 5A and 5B are a partial perspective views of the blunt cannula of Fig. 1 and a slit septum showing the blunt cannula out of and within the slit, respectively;

[0020] Fig. 6 is a side elevation view of a medical device in the form of an adaptor including the blunt cannula of Fig. 1 in accordance with the principles of the present invention;

[0021] Fig. 7 is a top plan view of the adaptor of Fig. 6;

[0022] Fig. 8 is bottom perspective view of the adaptor of Fig. 6;

[0023] Fig. 9 is a perspective view of one embodiment of a medical device in the form of a sample site for use with the adaptor of Fig. 6 in accordance with the principles of the present invention;

[0024] Fig. 10 is a cross-sectional view of the sample site of Fig. 9 taken along line 10-10;

[0025] Fig. 11 is a transverse cross-sectional view of the sample site of Fig. 9 with the adaptor of Fig. 6 mounted thereon;

[0026] Fig. 12 is a perspective view of another embodiment of a medical device in the form of a sample site for use with the adaptor of Fig. 1 in accordance with the principles of the present invention; and

[0027] Fig. 13 is a transverse cross-sectional view of the sample site of Fig. 12 with the adaptor of Fig. 6 mounted thereon.

DETAILED DESCRIPTION OF THE DRAWINGS

[0028] With reference to Figs. 1 through 4, there is shown an embodiment of a medical device in the form of a blunt cannula 10 in accordance with the principles of the present invention. Cannula 10 includes a proximal or upper portion 12 and a distal or lower portion 14, the latter terminating in a tip segment 16 including a rounded tip end or surface 18. In accordance with one aspect of the present invention, the distal portion 14 is tapered non-uniformly. To that end, distal portion 14 includes a plurality of tapered segments 22, 24, 26, 28 each progressively closer to tip end 18 and each having a different taper as will be described hereinafter. First tapered segment 22 is adjacent proximal portion 12, second tapered segment 24 is adjacent first tapered segment 22, third tapered segment 26 is adjacent second tapered segment, and fourth tapered segment 28 is adjacent third tapered segment and tip segment 16 so as to be closer to tip end 18 than tapered segments 22, 24, or 26.

[0029] Advantageously, the tapered segments 22, 24, 26, 28 alternate between conical and arcuate tapers. To that end, first and third tapered segments 22, 26 have conical tapers and second and fourth tapered segments 24, 28 have arcuate tapers. The taper of the third tapered segment 26 is advantageously larger than that of the first tapered segment 22. By way of example, the taper of the first tapered segment 22 may be about 1° while that of the third tapered segment may be about 5° . The arcuate tapers of the second and fourth tapered segments 24 and 28 may also differ, with the radius of curvature of the latter smaller than that of the former. To that end, the radius of curvature of the second tapered segment 24 may be about 1/4 inch while that of the fourth tapered segment may be slightly greater than 1/16 inch. The tip segment 16 may have a radius of about 1/36 inch to define rounded end 18.

[0030] In accordance with a further aspect of the present invention, the proximal portion 12 advantageously has a non-circular cross-section such as an oval cross section as seen particularly in Figs. 3, 4, 5A, and 5B. The proximal portion 12 may taper from its upper end 30 and opening 31 thereat toward the distal portion 14 such that the major diameter (D_{MAJ}) thereof decreases to facilitate merger of the proximal and distal portions 12, 14. The minor diameter (D_{MIN}) of the proximal portion 12 may also taper along its length if desired.

[0031] A fluid lumen 36 extends centrally from the upper end opening 31 of cannula 10 through proximal portion 12 and partially into distal portion 14, but terminates as at 38 spaced away from tip end 18. Advantageously, lumen 36 extends through the first and second tapered segments 22, 24 but only partially into third tapered segment 26, such that the rest 40 of tapered segment 26, and all of fourth tapered segment 28 and tip segment 16 are solid. Fluid communication is established with central lumen 36 via one or more fluid openings 44 extending through an aspect of proximal portion 12 as at 45 and the portions of first, second and third tapered segments 22, 24, 26 coextensive with lumen 36, excluding the solid portion 40 of tapered segment 26 and all of solid tapered segment 28 and solid tip segment 16, such

that the fluid path to and from the central lumen 36 via the fluid opening 44 does not extend into or through tip end 18. As shown in Fig. 4, there may be three fluid openings 44 circumferentially and equidistantly spaced about cannula 10. Fluid openings 44 each communicate with a respective groove 46 extending from lumen 36 at 38, distally along solid aspect 40 of tapered segment 26 and solid segment 28 formed in the solid aspects thereof. Each groove 46 may also extend partially along solid tip segment 16, but the grooves 46 advantageously do not extend so far into the material of cannula 10 as to reach all the way to tip end 18 (as exemplified by the area 48 in Fig. 2).

[0032] With reference to Fig. 5A, there is shown a perspective view of the blunt cannula 10 and a septum 50 held by a rigid structure 51 and having a slit 52. Septum 50 is held in position by structure 51 so as to close off an aperture 53 to a fluid path as at 54 below septum 50. Cannula 10 is oriented relative to slit 52 such that the major diameter (D_{MAJ}) of cannula proximal portion 12 is aligned therewith. In use, blunt cannula is inserted into slit 52 with tip end 18 impacting against septum 50 thereat to begin to open slit 52. The distal portion 12 enters into slit 52 with what is believed to be acceptably low insertion forces until proximal portion 12 resides within slit 52 and fluid opening(s) 44 are in the fluid path 54 as seen in Fig. 5B. It is believed that slit 52 does not normally open into a circular shape but instead more of a shape compatible with an oval such that with proximal portion 12 aligned and extending therein as seen in Fig. 5B, an effective seal is achieved with blunt cannula 10 thereat. End 30 may be coupled to or integrally formed with other structure for fluidic communication with lumen 36 via opening 31, such as a male or female luer lock, a syringe end, or other medical fluid connections.

[0033] The tapering of proximal and distal portions 12 and 14 presents a significant taper along substantially the entire length of cannula 10, but it is believed that with the foregoing arrangement, kickback is not problematic.

[0034] In accordance with yet another aspect of the present invention, the blunt cannula with the non-circular cross-section proximal portion 12 and/or the non-uniform tapered distal portion 14 may form part of a medical device in the form of an adaptor 60 for accessing a medical site 62 (Fig. 9). To that end, and as shown in Figs. 6 through 8, adaptor 60 includes a plate 64 having an upper surface 66 with which is associated luer mating structure such as a male luer lock 68, and a lower surface 70 with which a blunt cannula, such as cannula 10, is associated. Plate 64 includes oppositely disposed edges 72, 74 extending between surfaces 66 and 70 and from which extend a pair of generally flat guide walls 76, 78. Walls 76, 78 are to either side of blunt cannula 10 and may extend distally slightly past tip end 18, but may be spaced far enough apart to define a distal mouth 80 that is large enough not to preclude a finger from touching blunt cannula 10, and particularly tip end 18 thereof. Advantageously, walls 76, 68 may be spaced equidistant from cannula 10 such that cannula 10 is in the center of adaptor 60. Central lumen 36 of cannula 10 fluidically couples into the luer cavity 82 of male luer lock 68 as at opening 84 coupled to opening 31 of cannula 10 as best shown in Fig. 6.

[0035] Guide walls 76, 78 have lateral edges as at 85, one or more of which may be provided with a rib 86 along a radial of the centerline of cannula 10 so as to be aimed toward cannula 10. Further, lateral edges 85 may extend as at 87 into the area 90 below the intermediate edges 92, 94 of plate 64, but if they do so extend, may advantageously form a gap 96 therebetween.

[0036] The adaptor 60 may be used with a medical site such as a sample site 62 shown in Figs. 9, 10, and 11. To that end, sample site 62 has a central, cylindrical and circular cross-section housing 102 with oppositely disposed ports 104 extending therefrom to define a T-shape to site 62 (Fig. 9). Fluid normally flows (as at 54) between ports 104 and through cavity 106 within housing 102 and may be as shown in U.S. Patent No. 5,221,271.

Housing 102 includes an aperture 108 adjacent cavity 106 which is closed off by septum 50 with slit 52 thereof in a fixed orientation relative to the path of flow between ports 104, such as tangent or perpendicular thereto as shown in Fig. 9. Septum 50 may be secured in aperture 108 by a cap 110 bonded to housing 102 thereat. Adaptor 60 is sized to cooperate with sample site 62. To that end, guide walls 76, 78 are spaced apart a distance approximating the width or diameter of central housing 102 transverse to the ports 104 (see Fig. 11) so as to fit closely thereover with tip end 18 of cannula 10 aimed at slit 52. Further, cannula 10 may be held in adaptor 60 at a fixed orientation such that the major axis (D_{MAJ}) of proximal portion 12 of cannula 10 is aligned with slit 52. To that end, the major axis (D_{MAJ}) advantageously extends transversely between guide walls 76 and 78. The rib(s) 86 also help to align cannula 10 with slit 52. The gap(s) 96 are sized to receive a respective port 104 therethrough so as not to impede insertion of cannula 10 into septum 50, while also advantageously reducing the likelihood of rotation of adaptor 60 relative to housing 102.

[0037] Housing 102 may be supported on struts 120 which extend and are coupled to outboard support walls 122, each having an elongated flat portion 124 and lateral arcuate edges 126, the latter being secured to bracket 128. The flat portions 124 each define an inner surface 130 confronting housing 102 and an outer surface 136 facing away from housing 102. One or more ridges 138 are disposed on the outer surface(s) 136 of flat portion(s) 124 to facilitate gripping site 62. Ridges 138 each extend in a line in the same direction as the elongated flat portion on to which they are disposed so as not to form radially inwardly or outwardly curvatures thereof relative to housing 102.

[0038] An alternative sample site 62' is shown in Figs. 12 and 13 in which at least the outboard aspects of housing 102 between ports 104 are generally flat side walls 140 such as by thickening the plastic of housing 102 thereat. Side walls 140 matingly align with guide walls 76, 78 and further resist rotation therebetween (see Fig. 13). In the embodiment of Fig.

12, one or more of the lateral edges 142 of walls 140 define a groove edge to receive a respective rib 86 therealong to still further enhance alignment and/or resist rotation.

Alternatively, or additionally, the adjacent side walls 144 could also be thickened so as to cooperate with walls 140 to define grooves 146 therebetween bounded by groove edges 142 for receiving the rib(s) 86. Also, septum 50 may be held to housing 102 by swaging the upper end of the housing thereover as at 148.

[0039] In use, ports 104 of site 62 typically are connected to tubing such as in a closed blood sampling system. The cavity 106 of site 62 may be accessed by blunt cannula 10 to withdraw fluid from cavity 106. To that end, a syringe (not shown) may be coupled to luer connector 68 and adaptor 60 is positioned with guide walls 76, 78 to either side of housing 102 and ports 104 aligned with gaps 96. The user (not shown) may grip site 62 by support walls 122 and push adaptor 60 down over housing 102 to insert cannula 10, tip end 18 first, into slit 52 with the major diameter (D_{MAJ}) of proximal portion 12 aligned with slit 52. The adaptor 60 may be pushed into place until the guide walls 76, 78 hits against struts 120 whereat portion 12 extends into slit 52 and distal portion 14 is in the cavity 106 so as to communicate with fluid path 54 extending therein as seen in Fig. 11 (or Fig. 13 when used with site 62'). Septum 50 seals to cannula 10 for withdrawal of fluid into lumen 36 (or expulsion of fluid from lumen 36 were adaptor 60 or blunt cannula 10 coupled to an injection site such as a heparin lock (not shown)). The resiliency of the elastomeric material of septum 50 about cannula 10 holds adaptor 60 in place without the need for locking structure, although such could be added or included if desired. After use, adaptor 60 is pulled off from site 62 whereupon slit 52 closes to maintain the closure of aperture 108.

[0040] While the present invention has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not intended to restrict or in any way limit the scope of the appended claims to such

detail. Additional advantages and modifications will readily appear to those skilled in the art.

The invention in its broader aspects is, therefore, not limited to the specific details, representative apparatus and method, and illustrative examples shown and described.

Accordingly, departures may be made from such details without departing from the spirit or scope of the general inventive concept.

[0041] Having described the invention, what is claimed is:

1. A medical device in the form of a blunt cannula (10) comprising a proximal portion (12) and a distal portion (14) terminating in a tip end (18), a central lumen (36) extending through the proximal portion (12) and into the distal portion (14), and at least one fluid opening (44) communicating through an aspect (48) of the distal portion (14) with the central lumen (36), characterized in that the distal portion (14) has a non-uniform taper defined by a plurality of tapered segments (22, 24, 26 and/or 28) having different tapers.
2. A medical device in the form of a blunt cannula (10) comprising a proximal portion (12) and a distal portion (14) terminating in a tip end (18), a central lumen (36) extending through the proximal portion (12) and into the distal portion (14), and at least one fluid opening (44) extending through an aspect (48) of the distal portion (14) into fluid communication with the central lumen (36), characterized in that the proximal portion (12) has a non-circular cross-section.
3. A medical device as claimed in claim 2, the distal portion (14) being tapered between the proximal portion (12) and the tip end (18).
4. A medical device as claimed in claim 1, the proximal portion (12) having a non-circular cross-section.
5. A medical device as claimed in claim 3 or claim 4, the proximal portion (12) having a generally oval cross-section.

6. A medical device as claimed in claim 5, the proximal portion (12) tapering toward the distal portion (14) such that the major diameter of the generally oval section decreases toward the distal portion.
7. A medical device as claimed in claim 1 or claim 4, one of the tapered segments (26 or 28) being closer to the tip end (18) than at least another of the tapered segments (22 or 24), an aspect (40) of the one tapered segment (26 or 28) being solid, the central lumen (36) extending into the distal portion (14) short of the solid aspect (40).
8. A medical device as claimed in claim 7, the one tapered segment (28) being closer to the tip end (18) than any other of the tapered segments (22, 24, or 26), the one tapered segment (28) being completely solid, the central lumen (36) extending into the distal portion (14) short of the one tapered segment (28).
9. A medical device as claimed in any of claims 1, 4, 7 and 8, at least one of the tapered segments (22 or 26) having a conical taper and at least another of the tapered segments (24 or 28) having an arcuate taper.
10. A medical device as claimed in any of claims 1, 4, 7 and 9, the distal portion (14) having a non-uniform taper defined by four tapered segments, a first segment (22) adjacent the proximal portion (12), a second segment (24) adjacent the first segment (22), a third segment (26) adjacent the second segment (24), and a fourth segment (28) adjacent the third segment (26) and closer to the tip end (18) than the other three segments (22, 24, 26).

11. A medical device as claimed in claim 10, at least an aspect of the fourth tapered segment (28) being solid.
12. A medical device as claimed in claim 11, the central lumen (36) extending into the distal portion (14) short of the solid aspect of the fourth tapered segment (28).
13. A medical device as claimed in claim 10, the fourth tapered segment (28) being solid and at least an aspect (40) of the third tapered segment (26) adjacent the fourth tapered segment (28) being solid.
14. A medical device as claimed in claim 13, the central lumen (36) extending into the distal portion (14) short of the solid aspect (40) of the third tapered segment (26).
15. A medical device as claimed in any of claims 10 through 14, the central lumen (36) extending through at least the first and second tapered segments (22, 24) of the distal portion (14).
16. A medical device as claimed in any of claims 10 through 15, the at least one fluid opening (44) extending into the distal portion (14) coincident with the central lumen (36) therein but not extending into the distal portion (14) coincident with the fourth tapered segment (24) or the tip end (18).

17. A medical device as claimed in any of claims 10 through 16, the first and third tapered segments (22, 26) being conically tapered, the conical taper of the third segment (26) being greater than the conical taper of the first segment (22).
18. A medical device as claimed in any of claims 10 through 17, the second and fourth tapered segments (24, 28) being arcuate each with a respective radius of curvature, the radius of curvature of the arcuate taper of the fourth tapered segment (28) being less than the radius of curvature of the arcuate taper of the second tapered segment (24).
19. A medical device as claimed in any preceding claim further comprising at least one groove (46) extending along the distal portion (14) between the fluid opening (44) and the tip end (18).
20. A medical device as claimed in any preceding claim, the tip end (18) being solid.
21. A medical device as claimed in claim 20, the central lumen (36) extending into the distal portion (14) short of the tip end (18).
22. A medical device as claimed in claim 19, or either of claims 20 and 21 when dependent on claim 19, the at least one groove (44) stopping short of the tip end (18).
23. A medical device as claimed in any preceding claim further comprising a plurality of circumferentially spaced fluid openings (44) extending into the distal portion (14) coincident with the central lumen (36) therein.

24. A medical device as claimed in claim 23 further comprising a plurality of circumferentially spaced grooves (46) extending along the distal portion (14) from a respective fluid opening (46) toward the tip end (18).
25. A medical device as claimed in any of claims 1 through 5 and 7 through 24, the proximal portion (12) tapering toward the distal portion (14).
26. A medical device as claimed in any preceding claim, the distal portion (14) extending from the proximal portion (12).
27. A medical device as claimed in any preceding claim further comprising a plate (64) having an upper surface (66) and a lower surface (70) and oppositely disposed side edges (72, 74) therebetween, luer mating structure (68) associated with the plate upper surface (66), the proximal portion (12) of the blunt cannula (10) associated with the lower surface (70), and a pair of guide walls (76, 78) extending from the oppositely disposed edges (72, 74) to either side of the blunt cannula (10).
28. A medical device in the form of an adaptor (60) comprising a plate (64) having upper and lower surfaces (66, 70), and oppositely disposed side edges (72, 74) therebetween, luer mating structure (68) associated with the plate upper surface (66), and a blunt cannula (10) associated with the plate lower surface (70), the blunt cannula (10) having a proximal portion (12) extending from the plate lower surface (66) and a distal portion (14) extending from the proximal portion (12) to a

tip end (18), characterized by a pair of generally flat guide walls (76, 78) extending from the plate side edges (72, 74) to either side of the blunt cannula (10).

29. A medical device in the form of an adaptor (60) comprising a plate (64) having upper and lower surfaces (66, 70), the plate (64) having four corners, luer mating structure (68) associated with the plate upper surface (66), and a blunt cannula (10) associated with the plate lower surface (70), the blunt cannula (10) having a proximal portion (12) extending from the plate lower surface (70) and a distal portion (14) extending from the proximal portion (12) to a tip end (18), characterized by four ribs (86) extending from the plate lower surface (66) generally parallel to the blunt cannula (10), each associated with a respective one of the four corners of the plate (64), each rib (86) being aimed toward the blunt cannula (10).

30. A medical device as claimed in claim 28, the guide walls (76, 78) having lateral edges (85).

31. A medical device as claimed in claim 30 further comprising a rib (86) running along at least one of the lateral edges (85).

32. A medical device as claimed in claim 31, the rib (86) being aimed at the blunt cannula (10).

33. A medical device as claimed in any of claims 29, 31 and 32, each rib (86) being along a radial of a centerline of the blunt cannula (10).

34. A medical device as claimed in claim 30, the plate (64) having intermediate edges (92, 94) between the side edges (72, 74), at least one of the lateral edges (85) of one of the guide walls (76) extending into an area (90) below at least one of the intermediate edges (92).
35. A medical device as claimed in claim 34, at least one of the lateral edges (85) of the other guide wall (78) extending into the area (90) and defining a gap (96) between the lateral edges (85).
36. A medical device as claimed in claim 34 or claim 35, the other lateral edge (85) of the one guide wall (76) extending into another area (90) below another of the intermediate edges (94).
37. A medical device of claim 36, the other lateral edge (85) of the other guide wall (78) extending into the other area (90) and defining a gap (96) between the other lateral edges (85).
38. A medical device as claimed in any preceding claim in combination with a medical site (62) including a slit septum (50) for receiving the blunt cannula (10) therethrough.
39. A combination as claimed in claim 38, the medical site being a sample site (62).
40. A medical assembly comprising a blunt cannula (10) including a proximal portion (12) and a distal portion (14), the distal portion (14) terminating in a tip end (18), and a medical site (62) including a housing (102) having a flow path (54), and a septum (50) bounding a portion of the flow path, the septum having a slit (52) therein, the blunt cannula (10) insertable through the slit (52) in the septum (50), characterized in that the proximal portion (12) has a non-circular cross section that

defines a major diameter and the slit (52) in the septum (50) is oriented so that the major diameter of the proximal portion (12) is substantially aligned to the slit (52) when the proximal portion (12) is disposed in the septum (50).

41. A medical assembly as claimed in claim 40, the proximal portion (12) being an oval cross-section.

42. A medical assembly as claimed in claim 40 or claim 41, the proximal portion (12) tapering along at least the major diameter.

43. A medical assembly as claimed in any of claims 40 through 42 further comprising a plate (64) having an upper surface (66) and a lower surface (70) and oppositely disposed side edges (72, 74) therebetween, the proximal portion (12) of the blunt cannula (10) associated with the lower surface (66), and a pair of guide walls (76, 78) extending from the oppositely disposed edges (72, 74) to either side of the blunt cannula (10).

44. A medical assembly as claimed in claim 43, the guide walls (76, 78) engaging the housing (102) of the medical site (62) so that the major diameter of the blunt cannula (10) is substantially aligned to the slit (52) in the septum (50).

45. A medical assembly comprising an adaptor (60) having a plate (64) with upper and lower surfaces (66, 70) and oppositely disposed side edges (72, 74) therebetween, a blunt cannula (10) associated with the lower surface (66), the blunt cannula (10) having a proximal portion (12)

extending from the plate lower surface (66) and a distal portion (14) extending from the proximal portion (12) to a tip (16), the medical assembly further comprising a medical site (62) comprising a housing (102) having a flow path (54) and a septum (50) bounding a portion of the flow path, the blunt cannula (10) insertable through the septum (50), characterized in that the adaptor (60) also has a pair of generally flat guide walls (76, 78) extending from the plate side edges (72, 74) to either side of the blunt cannula (10), at least one of the guide walls (76 or 78) having a lateral edge (85) including a rib (86) running therealong and aimed at the blunt cannula (10), the housing (102) having a pair of opposed generally flat side walls (140), at least one of the side walls (140) having a lateral edge (142) defining a groove edge running therealong and oriented so that the rib (86) engages along the groove edge (142) when the blunt cannula (10) is disposed in the septum (50).

46. A medical site comprising a housing (102) having a flow path (54) and a septum (50) bounding a portion of the flow path and characterized by a pair of spaced support walls (122) coupled to the housing (102) and configured such that the housing is disposed between the support walls to define a gap therebetween, each support wall (122) having an elongated flat portion (124) extending in a direction astride the housing such that an inner surface (130) thereof confronts the housing (102) and an outer surface (136) thereof faces away from the housing (102), and at least one elongated ridge (138) disposed on the outer surface (136) of at least one of the support walls for gripping the site, the elongated ridge (138) extending along a line in the same direction as the flat portion (124) of the support wall (122).

47. A medical site as claimed in claim 46, each of the support walls (122) including a plurality of said elongated ridges (138).

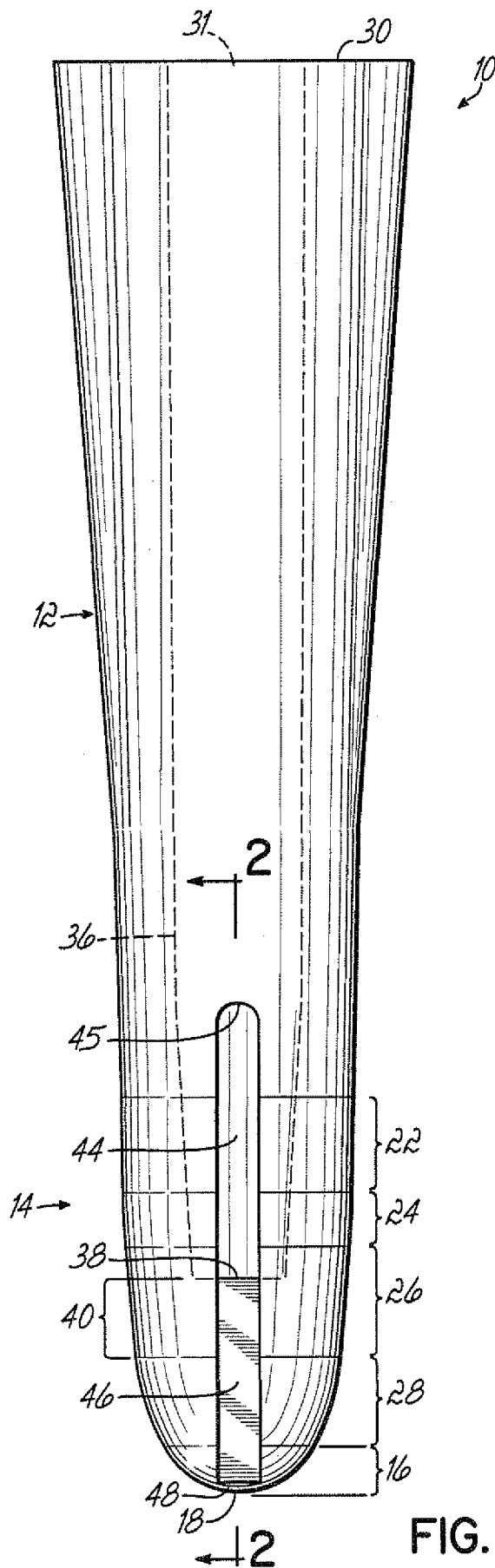


FIG. 1

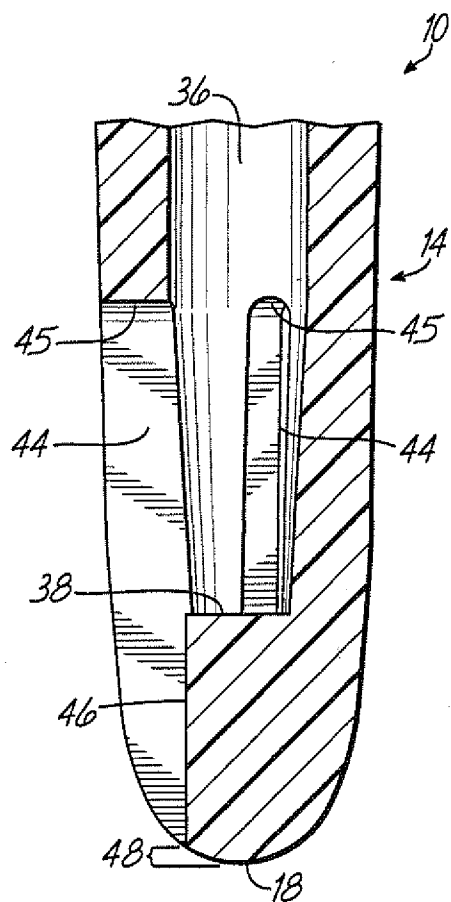


FIG. 2

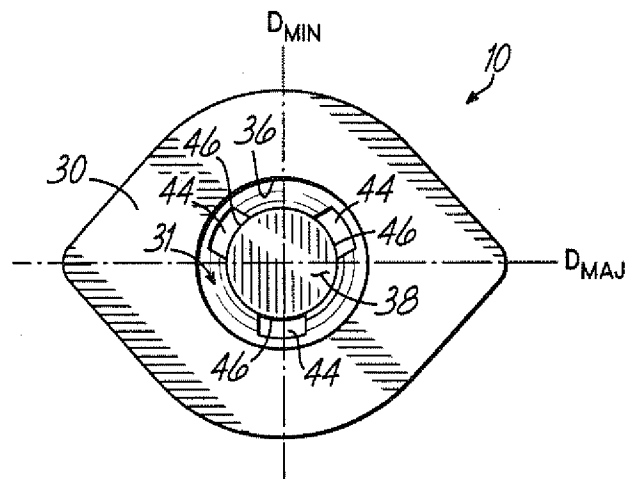


FIG. 3

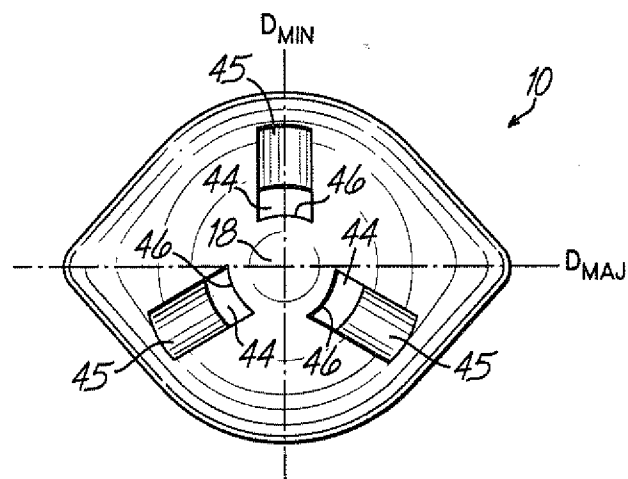


FIG. 4

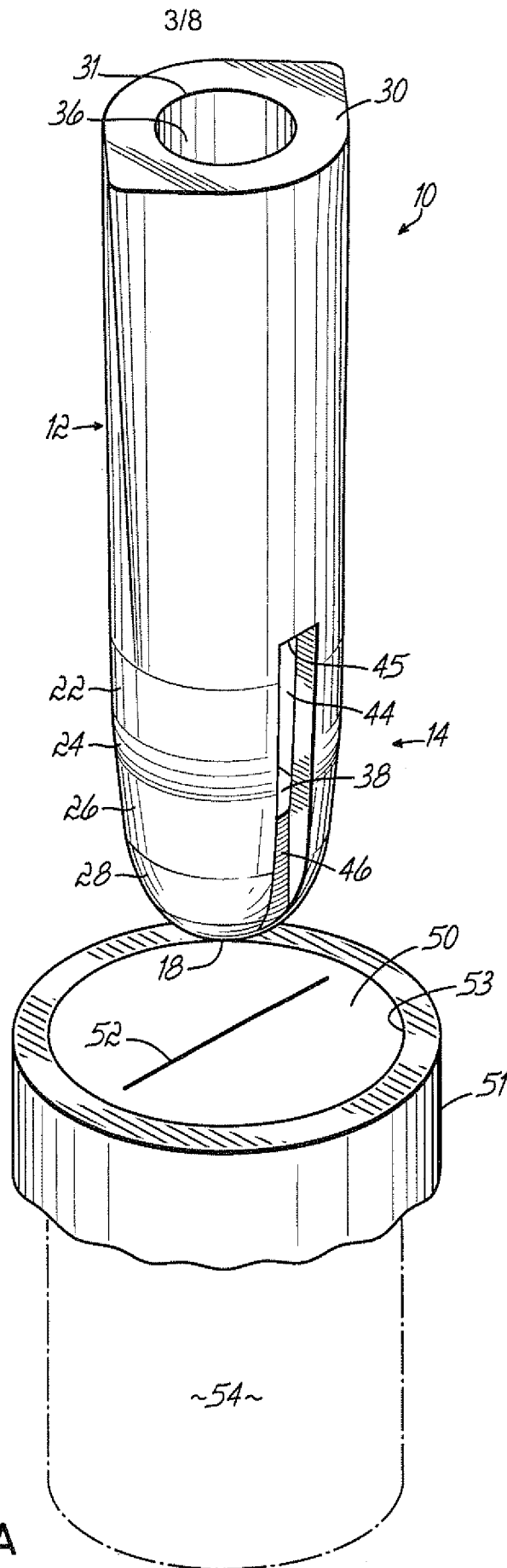


FIG. 5A

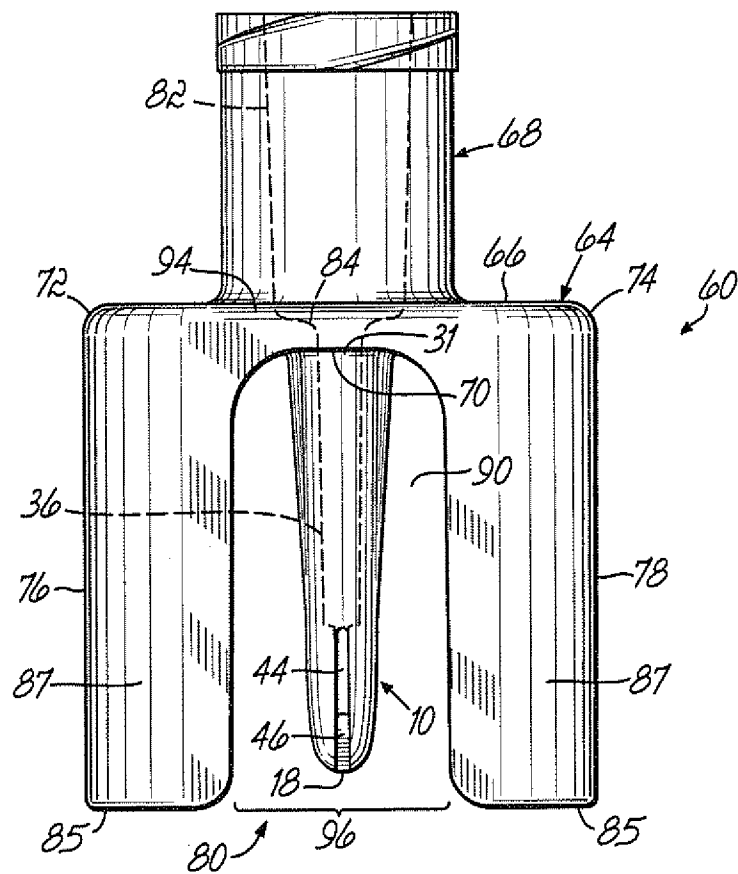


FIG. 6

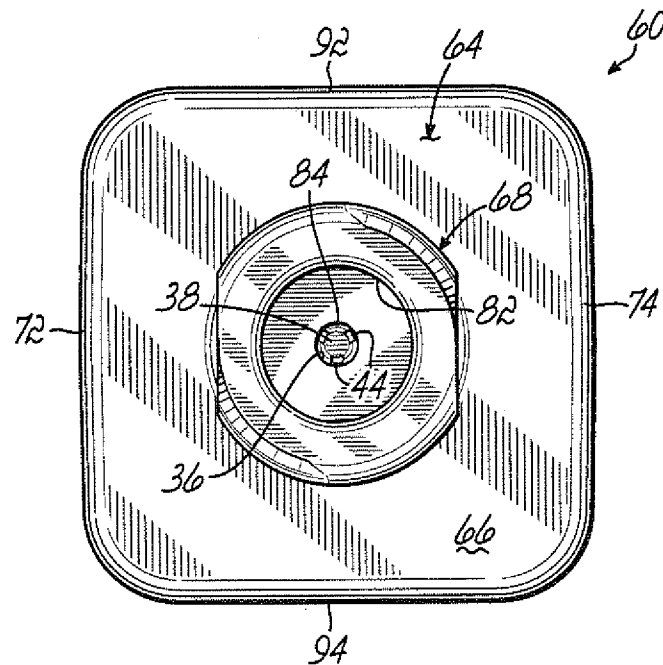


FIG. 7

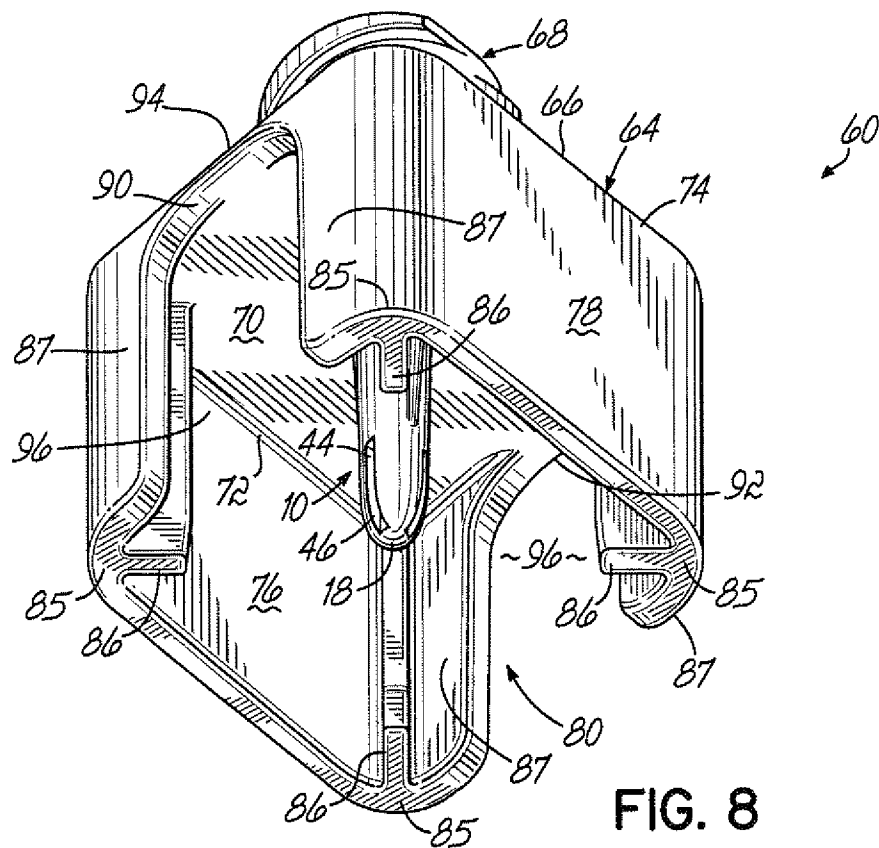


FIG. 8

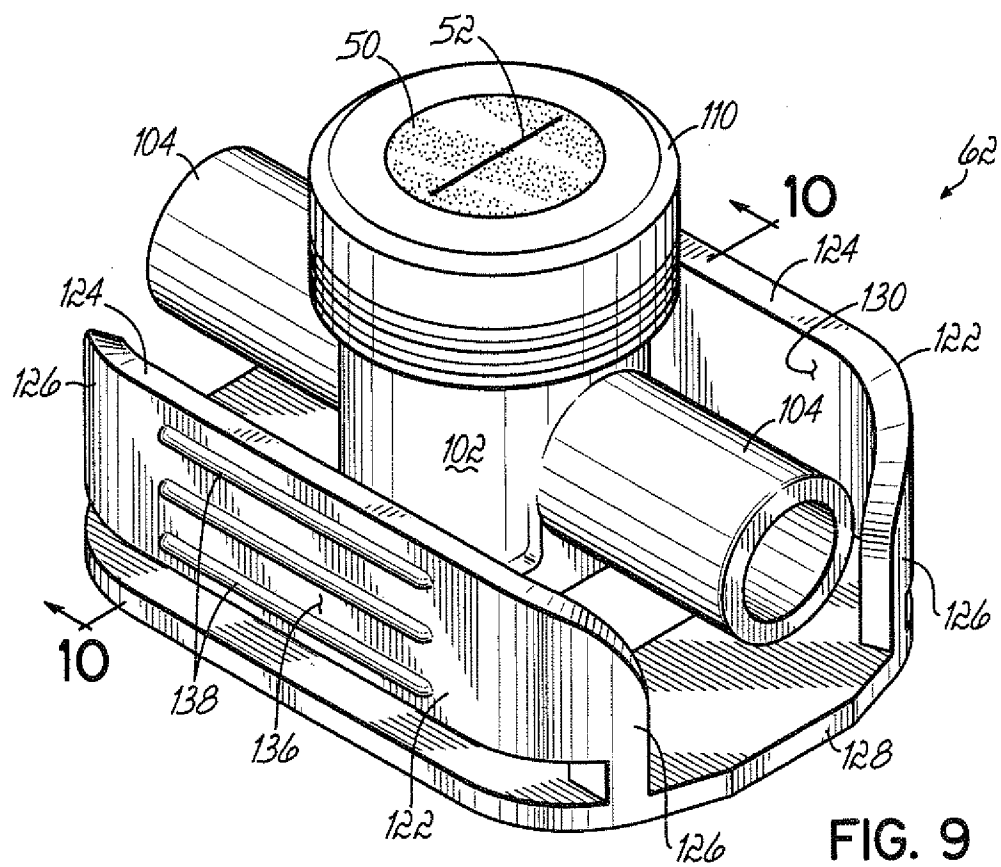


FIG. 9

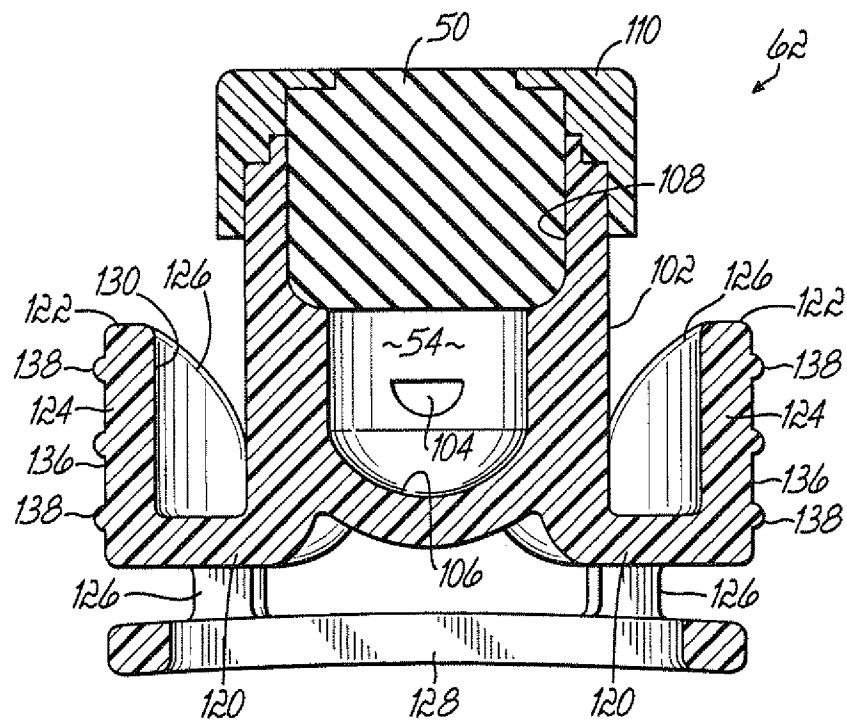


FIG. 10

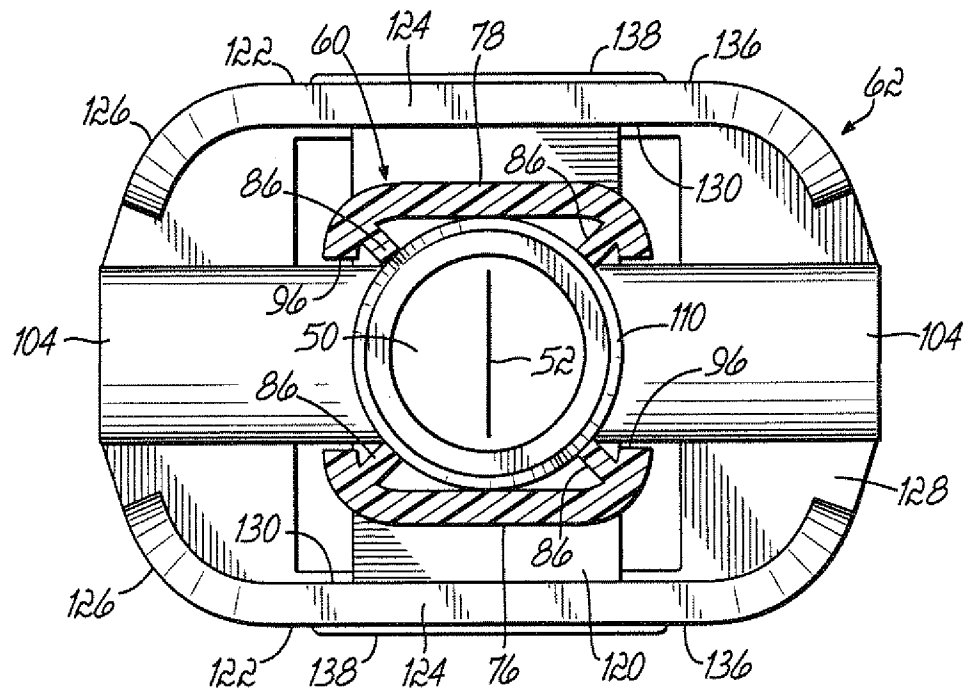


FIG. 11

8/8

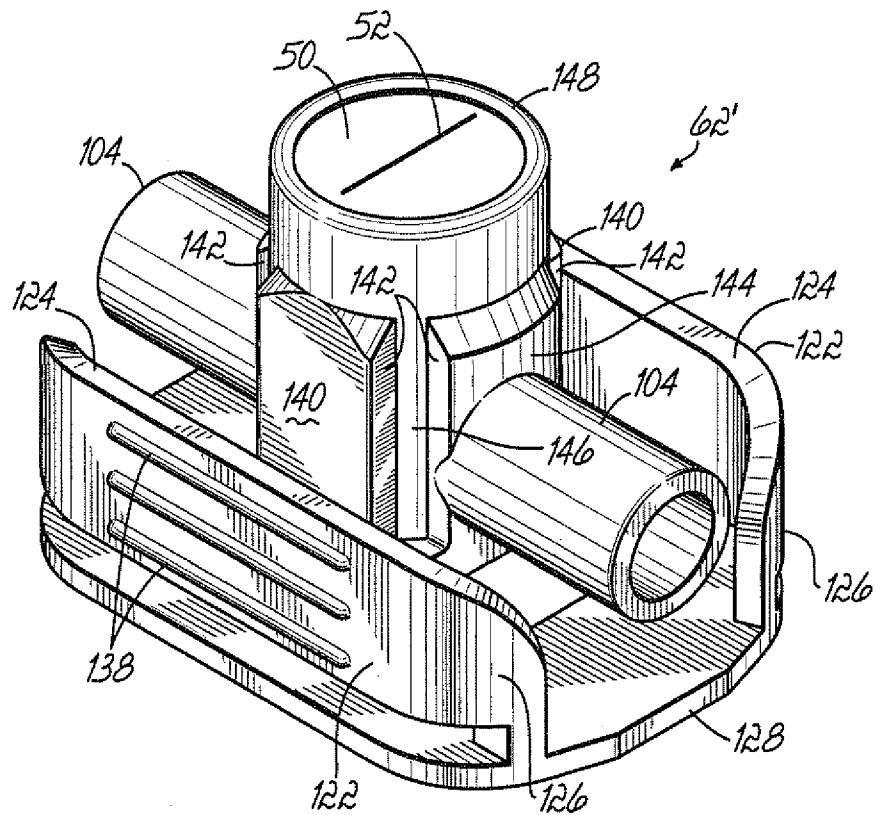


FIG. 12

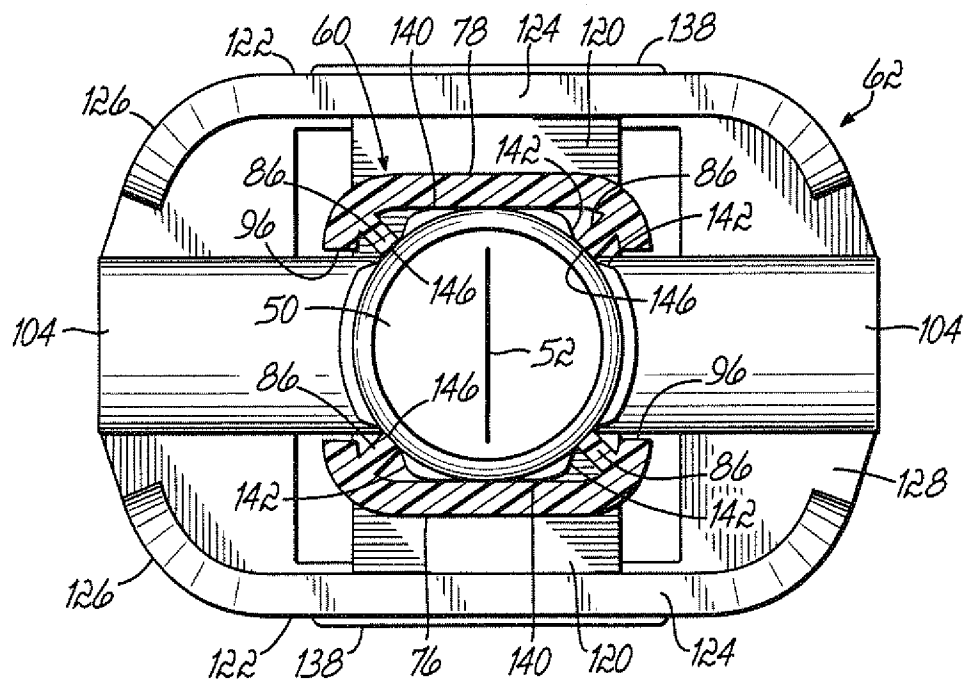


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/070086

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/32 A61M39/04 A61M39/02 A61M39/26

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)

A61M A61J

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)

EP0-Internal

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 5 135 489 A (JEPSON STEVEN C [US] ET AL) 4 August 1992 (1992-08-04) abstract figures 34-37, 59 column 14, line 1 - line 41 column 23, line 63 - column 24, line 7 -----	1, 7-27, 38, 39 2-6, 40-44
Y	US 5 322 516 A (BRUGGER JAMES M [US]) 21 June 1994 (1994-06-21) the whole document -----	2-6, 40-44
X	WO 91/19462 A (UTTERBERG DAVID S [US]) 26 December 1991 (1991-12-26) abstract figures 1-4 page 12, line 8 - page 15, line 24 ----- -/--	1, 7-27

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

☒ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier 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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

25 February 2008

Date of mailing of the international search report

04/03/2008

Name and mailing address of the ISA/

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

Authorized officer

GUIDOIN, M

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/070086

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/254541 A1 (WONG K C [TW] ET AL) 16 December 2004 (2004-12-16) abstract figures 1a-1b -----	1,7-26
X	US 2004/220542 A1 (CISE DAVID [US] ET AL) 4 November 2004 (2004-11-04) abstract figure 14a -----	1,7-26
A	US 5 833 674 A (TURNBULL CHRISTOPHER J [US] ET AL) 10 November 1998 (1998-11-10) the whole document -----	1,27
A	US 5 188 593 A (MARTIN GEOFFREY S [CA]) 23 February 1993 (1993-02-23) abstract figures 3-7 -----	1,4-27
X	WO 90/11103 A (BAXTER INT [US]) 4 October 1990 (1990-10-04) abstract figures 5a,49,53-56 page 17, line 27 - page 18, line 7 -----	28-39,45
X	US 5 632 735 A (WYATT PHILIP [US] ET AL) 27 May 1997 (1997-05-27) abstract figures 8d,36 column 7, line 4 - line 52 column 11, line 33 - column 12, line 30 -----	28,38,39
X	WO 98/50106 A (BECTON DICKINSON CO [US]) 12 November 1998 (1998-11-12) abstract figure 2 -----	28,30
X	US 2005/261637 A1 (MILLER PAVEL T [US]) 24 November 2005 (2005-11-24) the whole document -----	46,47
A	EP 1 391 219 A (BAXA CORP [US]) 25 February 2004 (2004-02-25) abstract paragraph [0023] - paragraph [0046] -----	46,47
A	EP 1 391 220 A (BAXA CORP [US]) 25 February 2004 (2004-02-25) figures 1a-5c -----	46,47
A	US 4 908 018 A (THOMSEN JOHN [US]) 13 March 1990 (1990-03-13) abstract figure 6 -----	46

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/070086

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an 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 reportcovers 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1,4-18,19-27 (in parts), 38-39 (in parts)

Blunt cannula having a plurality of tapered segments.

2. claims: 2,3,19-27 (in parts), 38-39 (in parts),40-44

Blunt cannula having a non-circular proximal portion and a system disclosing the use of this cannula with a medical site.

3. claims: 28-37, 38-39 (in parts),45

Adaptor having a plate, a cannula and a luer mating structure, and a system comprising the use of this adaptor with a medical site.

4. claims: 46,47

A housing having support walls with elongated flat portions and an elongated ridge.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/070086

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5135489	A	04-08-1992	NONE	
US 5322516	A	21-06-1994	US 5453089 A	26-09-1995
WO 9119462	A	26-12-1991	AT 123958 T	15-07-1995
			CA 2064749 A1	14-12-1991
			DE 69110623 D1	27-07-1995
			DE 69110623 T2	11-01-1996
			DK 486670 T3	21-06-1995
			EP 0486670 A1	27-05-1992
			ES 2076535 T3	01-11-1995
			JP 5500767 T	18-02-1993
			JP 3103938 B2	30-10-2000
			US 5071413 A	10-12-1991
US 2004254541	A1	16-12-2004	NONE	
US 2004220542	A1	04-11-2004	US 2005283121 A1	22-12-2005
			US 2006058740 A1	16-03-2006
US 5833674	A	10-11-1998	NONE	
US 5188593	A	23-02-1993	NONE	
WO 9011103	A	04-10-1990	AU 3022195 A	23-11-1995
			AU 666181 B2	01-02-1996
			AU 3718393 A	01-07-1993
			AU 681317 B2	21-08-1997
			AU 3796095 A	25-01-1996
			AU 634532 B2	25-02-1993
			AU 5333290 A	22-10-1990
			AU 678071 B2	15-05-1997
			AU 8022294 A	16-03-1995
			CA 2027591 A1	18-09-1990
			DE 69009131 D1	30-06-1994
			DE 69009131 T2	19-01-1995
			DE 69019170 D1	08-06-1995
			DE 69019170 T2	30-11-1995
			DE 69023926 D1	11-01-1996
			DE 69023926 T2	14-08-1996
			EP 0419620 A1	03-04-1991
			ES 2057546 T3	16-10-1994
			ES 2083247 T3	01-04-1996
			ES 2074909 T3	16-09-1995
			IE 62767 B1	22-02-1995
			JP 3411984 B2	03-06-2003
			JP 8243092 A	24-09-1996
			JP 7110284 B	29-11-1995
			JP 3504571 T	09-10-1991
			JP 2002191583 A	09-07-2002
			JP 2003126269 A	07-05-2003
			JP 2006055670 A	02-03-2006
			MX 173202 B	08-02-1994
US 5632735	A	27-05-1997	NONE	
WO 9850106	A	12-11-1998	AU 6977398 A	27-11-1998
			US 6050978 A	18-04-2000

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/070086

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005261637	A1	24-11-2005	AU 2005247373 A1 08-12-2005
			CA 2567273 A1 08-12-2005
			EP 1778333 A2 02-05-2007
			JP 2008500131 T 10-01-2008
			WO 2005115504 A2 08-12-2005
EP 1391219	A	25-02-2004	US 2004039374 A1 26-02-2004
			US 2007078443 A1 05-04-2007
EP 1391220	A	25-02-2004	US 2005245883 A1 03-11-2005
			US 2004039346 A1 26-02-2004
US 4908018	A	13-03-1990	NONE