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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

[Continued on next page]

(54) Title: NEEDLE ASSEMBLIES AND METHODS OF MANUFACTURE

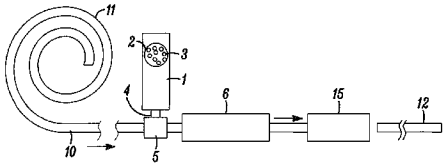

FIG. 1

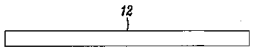

FIG. 1A

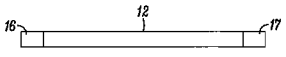

FIG. 1B

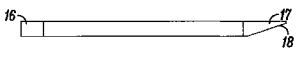

FIG. 1C

FIG. 1D

(57) Abstract: A needle assembly of a metal shaft (10, 10') and an outer plastics sleeve (12) is made by extruding the sleeve onto the outside of the shaft. The sleeve contains gas bubbles (13), preferably with a size in the range 5μ to 10μ, to increase the ultrasound visibility of the assembly. A sharp, penetrating tip (18) may be formed on the shaft either before or after the sleeve is extruded on the shaft. The metal shaft (10) may be supplied to the extruder 1 to 5 in a continuous length and cut to the size of the needle assemblies after extrusion of the sleeve (12). Alternatively, pre-cut lengths of metal shafts (10') could be supplied to the extruder 1' to 5', the sleeve being cut between the shafts after extrusion.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

NEEDLE ASSEMBLIES AND METHODS OF MANUFACTURE

This invention relates to needle assemblies of the kind including a hollow needle shaft.

Ultrasound scanners are used increasingly to help direct or check placement of catheters and other devices inserted in the body. Some of these devices are not normally very visible under ultrasound because of their shape, size or the fact that the material from which they are made has similar reflectance acoustic impedance to the tissue or body fluid within which they are inserted. Attempts have been made to increase the visibility of medico-surgical devices under ultrasound observation in various ways. Where the device is of a metal within the body it may reflect ultrasound but the reflected energy tends to be highly directional so it does not necessarily produce a very visible image on the scanner.

The usual way of increasing the visibility of a metal needle is by modifying its surface, such as by forming grooves or indentations in its surface. A reflective liquid coating may be applied to the device, such as incorporating bubbles, as described in WO98/19713. Discrete echogenic markings may be deposited on a device, as described in EP0624342. US8398596 describes a metal needle with a bubble-filled stylet or a removable outer sleeve of a bubble-filled material. Where the device is of a plastics material, such as a catheter of the kind described in GB2379610 the wall may include gas bubbles or a bubble-containing material may be incorporated in a stripe occupying only a part of the circumference. GB2400804 describes a similar catheter with several layers. US7258669 describes a catheter with a helical, gas-filled lumen extending along its length. WO9822022 describes an instrument with an inner stylet that may have an air void or a solution containing microbubbles. DE102006051978 describes a bubble-filled rod inserted along the bore of a flexible plastics catheter to enhance visibility under ultrasound observation.

The ultrasound visibility of a catheter in a body can also be enhanced by supplying a fluid containing bubbles along the bore of the catheter. These arrangements, however, are not suitable in all cases. It may, for example, be undesirable to paint a substance onto a device because of the risk of detachment. Also, some arrangements do not provide visibility

along the length of the device. Altering the surface of a metal device by forming grooves or the like may reduce the smoothness of the device. A sleeve of a bubble-filled material on a needle may be effective but such sleeves can be difficult to manufacture, handle and assemble on a needle where the sleeve has a relatively thin wall.

It is an object of the present invention to provide an alternative needle assembly and method of manufacture.

According to one aspect of the present invention there is provided a needle assembly of the above-specified kind, characterised in that the assembly includes a plastics sleeve extruded onto and extending along the outside of the needle shaft, and that the extruded sleeve contains a plurality of gas bubbles within the thickness of the sleeve such that the sleeve is visible under ultrasound observation and such that the ultrasound visibility of the assembly with the sleeve is greater than that of the needle alone.

The assembly preferably includes a hub joined at one end with the needle shaft and a sharp, penetrating tip at the opposite end. The gas bubbles may have a size range of 0.1μ to 300μ and preferably in the range 1μ to 50μ, more preferably in the range 5μ to 10μ. The sleeve may have a thickness between 0.01mm and 2mm and preferably a thickness between 0.01mm to 0.1mm.

According to another aspect of the present invention there is provided a method of manufacture of a needle assembly including the steps of providing a metal shaft and extruding on the outside of the shaft a sleeve of a plastics material containing gas bubbles within its thickness, wherein the metal shaft is formed with a sharp, penetrating tip and the gas bubbles are effective to increase ultrasound visibility of the assembly.

The sharp, penetrating tip may be formed before or after the plastics sleeve is extruded on the shaft.

According to a second aspect of the present invention there is provided a method of manufacture of a needle assembly including the steps of providing a metal shaft and

extruding on the outside of the shaft a sleeve of a plastics material containing gas bubbles within its thickness, the metal shaft being formed with a sharp, penetrating tip.

The sharp, penetrating tip may be formed before or after the plastics sleeve is extruded on the shaft.

According to a third aspect of the present invention there is provided a method of manufacture of needle assemblies including the steps of supplying a hollow metal shaft to extruder apparatus, extruding around the outside of the shaft in the extruder apparatus a sleeve of a plastics material containing gas bubbles, subsequently cutting the shaft into discrete lengths, and forming a sharp, penetrating tip (18) at one end to form needle assemblies.

According to a fourth aspect of the present invention there is provided a method of manufacture of needle assemblies including the steps of supplying to extruder apparatus a plurality of pre-cut lengths of metal shafts, extruding around the outside of the shafts in the extruder apparatus a sleeve of a plastics material containing gas bubbles, subsequently cutting through the extruded sleeve to form separate shafts, each shaft being formed with a sharp, penetrating tip at one end either before or after supply to the extruder machine.

The method according to the above second, third or fourth aspect of the present invention may include the step of attaching a hub to each shaft at the end opposite the sharp, penetrating tip.

According to a fifth aspect of the present invention there is provided a needle assembly made by a method according to the above other second, third or fourth aspect of the present invention.

A needle assembly and its method of manufacture, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 illustrates a first form of apparatus for use in manufacture of the needle assemblies and illustrates various stages in the manufacture;

Figure 2 is a side elevation view of a needle assembly after manufacture;

Figure 3 is an enlarged cross-sectional side elevation view of a part of the needle assembly shown in Figure 2; and

Figure 4 illustrates an alternative apparatus for use in manufacturing the needle assemblies.

With reference first to Figures 1 to 3 there is shown extruder apparatus for use in manufacturing needle assemblies including an extruder 1 with a hopper 2 or other supply of a thermoplastics material 3 such as in pellet form. The plastics material is preferably PEBA, nylon, PVC, polyethylene, polypropylene, polyester or polyurethane and includes a suitable foaming agent. It will be appreciated that there are other ways of forming gas bubbles or interstices such as by including gas-filled polymer or glass microparticles into the plastics material. The gas within the bubbles or interstices could be of any kind and could be a vacuum. The outlet 4 of the extruder connects with a cross-head extrusion head 5, which is supplied with a hollow metal shaft or tube 10, such as of stainless steel, which typically has a diameter of between about 0.5mm and 2.0mm. The shaft 10, if sufficiently flexible, may be supplied from a coiled reel 11, as shown, or, if too stiff to be coiled, may be supplied in straight lengths, such as of between about 1m and 2m, exceeding the length of the individual needle assemblies.

The extruder 1 heats and pumps the plastics material 3 with its foaming agent to an outer die of the cross-head extrusion head 5 so that the foamed plastics material is flowed about and deposited on the outer surface of the shaft 10. The shaft 10 emerging from the head 5 is, therefore, coated with the plastics material 3, which cools and solidifies as it passes through a cooling tank 6 to form a smooth outer layer or sleeve 12 of a plastics material containing gas bubbles 13 (Fig 3). The size and density of the bubbles 13 are selected to ensure that the layer 12 is highly echogenic. Typically the gas bubbles 13 have a

size in the range 0.1μ to 300μ, preferably having a size in the range 1μ to 50μ and most preferably having a size in the range 5μ to 10μ. Because the outer layer 12 is formed directly on the shaft 10 and does not need to be manually handled, the outer layer can be relatively thin, such as between 0.01mm and 2mm, and preferably between 0.01mm and 0.1mm.

A haul-off and cutter unit 15 pulls the coated shaft 10 through the extrusion head 5 and severs it into lengths equal to that of the desired needle assemblies, typically being 50 – 150mm long, as shown in Figure 1A. A short length of the plastics outer layer 12 is then removed from both ends of the cut shafts to form opposite end regions 16 and 17 where the metal is exposed, as shown in Figure 1B. The plastics may be removed by any conventional technique, such as by cutting a ring around the layer and stripping off the end pieces. Alternatively, techniques involving grinding, milling, laser, thermal or chemical methods may be used. One exposed end 17 is then ground to form a sharp, bevelled penetrating tip 18, as shown in Figure 1C. A hub 19 is then attached to the opposite exposed end 16, as shown in Figure 1D to form the finished needle assembly shown in Figure 2. It will be appreciated that the hub 19 could be attached to the shaft10 before forming the sharp tip 18, instead of after forming the tip.

The plastics extrusion could include two or more layers as a co-extrusion. These could include an inner layer against the metal shaft acting as a bonding layer for the bubble-filled layer. The extrusion could include an outer layer without bubbles to provide a smooth layer on top of the bubble layer and, hence, a smooth outer surface to the needle assembly. Sections of the bubble layer could be removed to give distance/depth markings.

With reference now to Figure 4 there is shown an alternative manufacturing arrangement identical with that shown in Figure 1 except that, instead of the metal tube or shaft being supplied to the extrusion head 5' in lengths greater than that of the formed needle assembly, the metal shaft is pre-cut into discrete lengths 10' equal to that of the needle assemblies before supply to the extruder. These pre-cut lengths 10' could be supplied on a web 30 from which the shaft lengths are peeled off adjacent the extrusion head 5. Alternatively, the pre-cut lengths could be supplied in a cassette or some other temporary holder. The pre-cut lengths 10' could either be supplied preformed with a sharpened bevelled

tip or these could be formed after the extrusion process in the manner described above with reference to the extruder shown in Figure 1. The extruded product emerging from the extrusion head 5' consists of a plastics sleeve 12' encasing separate lengths of the metal shafts 10' so it is just necessary to cut the sleeve between the shafts and trim the plastic from both ends to enable the hub to be attached at one end and to expose the sharp tip at the opposite end, or to enable the sharp tip to be formed at the opposite end.

CLAIMS

1. A needle assembly including a hollow needle shaft (10, 10'), characterised in that the assembly includes a plastics sleeve (12) extruded onto and extending along the outside of the needle shaft (10, 10'), and that the extruded sleeve (12) contains a plurality of gas bubbles (13) within the thickness of the sleeve (12) such that the sleeve is visible under ultrasound observation and such that the ultrasound visibility of the assembly with the sleeve is greater than that of the needle (10, 10') alone.

2. A needle assembly according to Claim 1, characterised in that the assembly includes a hub (19) joined at one end with the needle shaft (10, 10') and a sharp, penetrating tip (18) at the opposite end.

3. A needle assembly according to Claim 1 or 2, characterised in that the gas bubbles (13) in the sleeve (12) have a size range of 0.1μ and 300μ.

4. A needle assembly according to Claim 3, characterised in that the gas bubbles (13) have a size range of 1μ to 50μ.

5. A needle assembly according to Claim 4, characterised in that the gas bubbles (13) have a size range of 5μ to 10μ.

6. A needle assembly according to any one of the preceding claims, characterised in that the sleeve (12) has a thickness between 0.01mm and 2mm.

7. A needle assembly according to Claim 6, characterised in that the sleeve (12) has a thickness between 0.01mm and 0.1mm.

8. A method of manufacture of a needle assembly including the steps of providing a metal shaft (10, 10') and extruding on the outside of the shaft a sleeve (12) of a plastics material containing gas bubbles (13) within its thickness, wherein the metal

shaft (10, 10') is formed with a sharp, penetrating tip (18) and the gas bubbles (13) are effective to increase ultrasound visibility of the assembly.

9. A method according to Claim 8, characterised in that the sharp, penetrating tip (18) is formed before the plastics sleeve (12) is extruded on the shaft (10, 10').

10. A method according to Claim 8, characterised in that the sharp, penetrating tip (18) is formed after the plastics sleeve (12) is extruded on the shaft (10, 10').

11. A method of manufacture of needle assemblies including the steps of supplying a hollow metal shaft (10) to extruder apparatus (1 to 5), extruding around the outside of the shaft (10) in the extruder apparatus a sleeve (12) of a plastics material containing gas bubbles (13), subsequently cutting the shaft into discrete lengths, and forming a sharp, penetrating tip (18) at one end to form needle assemblies.

12. A method of manufacture of needle assemblies including the steps of supplying to extruder apparatus (1' to 5') a plurality of pre-cut lengths of metal shafts (10'), extruding around the outside of the shafts (10') in the extruder apparatus (1' to 5') a sleeve (12) of a plastics material containing gas bubbles (13), subsequently cutting through the extruded sleeve to form separate shafts, each shaft being formed with a sharp, penetrating tip (18) at one end either before or after supply to the extruder machine.

13. A method according to any one of Claims 8 to 12, characterised in that the method includes the step of attaching a hub (19) to each shaft (10, 10') at the end opposite the sharp, penetrating tip (18).

14. A needle assembly made by a method according to any one of Claims 8 to 13.

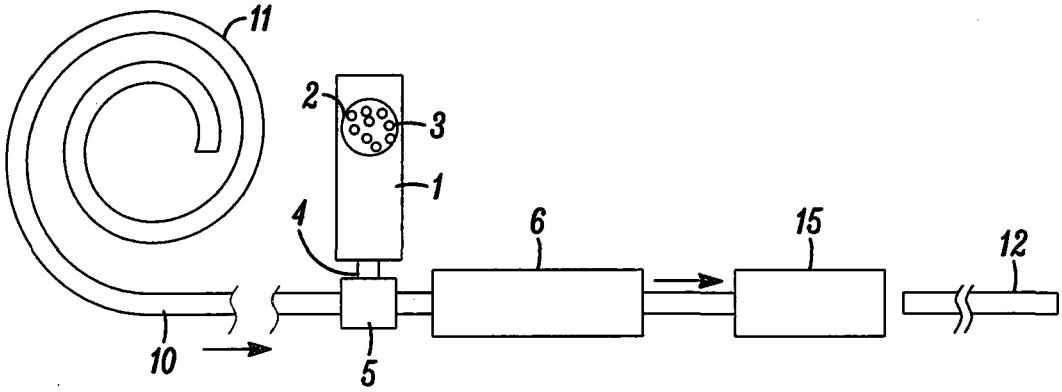

FIG. 1

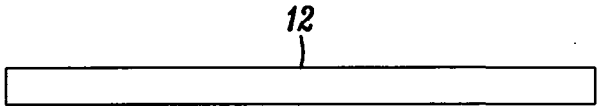

FIG. 1A

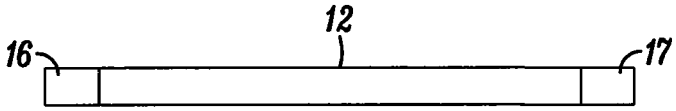

FIG. 1B

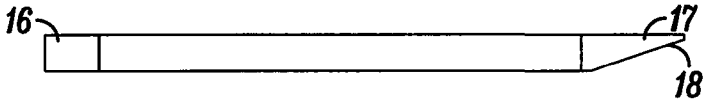

FIG. 1C

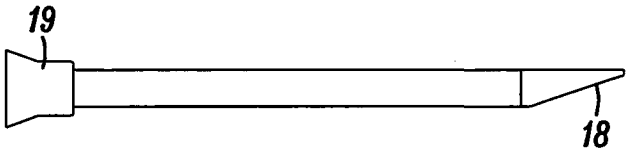

FIG. 1D

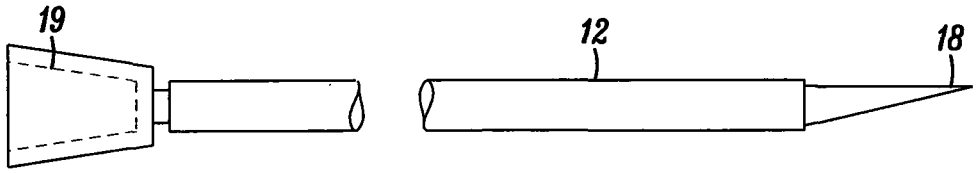

FIG. 2

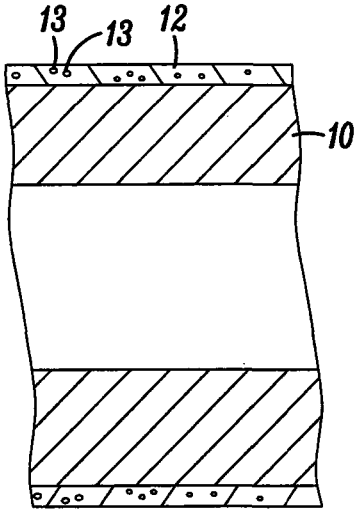

FIG. 3

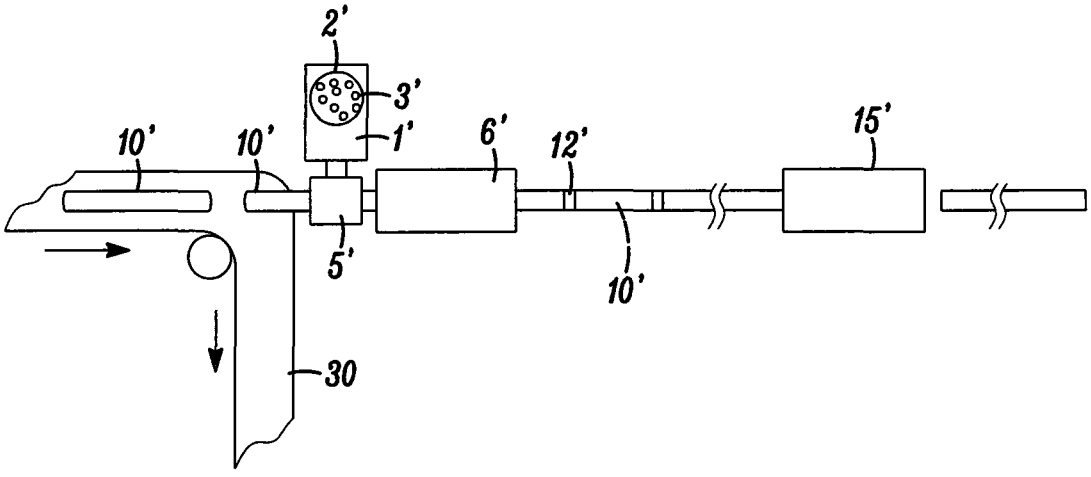

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000237

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 B29C47/02
ADD. A61B17/00 A61B19/00

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)
A61B B29C

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/148265 A1 (ENCAPSON B V [NL]; VRIEZEMA DENNIS MANUEL [NL]; AYRES LEE [NL]; KEEREW) 1 November 2012 (2012-11-01) page 7, line 28 - page 9, line 5 page 10, line 10 - page 11, line 14 page 13, line 29 - page 14, line 33 figure 1	1-7
X	EP 0 624 342 A1 (BECTON DICKINSON CO [US]) 17 November 1994 (1994-11-17) cited in the application column 4, line 20 - column 6, line 23; figures 3,4	1-7
X	DE 20 2009 001974 U1 (RUEGER MEDICAL GMBH [DE]) 19 August 2010 (2010-08-19) paragraphs [0013] - [0021], [0037] - [0041]; figure 1	1-7

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[X] Further documents are listed in the continuation of Box C.

[X] 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 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
11 November 2014	17/11/2014

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, Fax: (+31-70) 340-3016	Maier, Christian

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000237

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 400 804 A (SMITHS GROUP PLC [GB]) 27 October 2004 (2004-10-27) cited in the application page 4, line 1 - page 5, line 12; figures 1-4 -----	1,3-7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2014/000237

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012148265 A1	01-11-2012	EP 2701625 A1	05-03-2014
		US 2014207000 A1	24-07-2014
		WO 2012148265 A1	01-11-2012
EP 0624342 A1	17-11-1994	CA 2122682 A1	15-11-1994
		EP 0624342 A1	17-11-1994
		JP 3049179 U	02-06-1998
		JP H06327671 A	29-11-1994
		US 5383466 A	24-01-1995
DE 202009001974 U1	19-08-2010	DE 102010000599 A1	23-09-2010
		DE 202009001974 U1	19-08-2010
		US 2010239505 A1	23-09-2010
GB 2400804 A	27-10-2004	AT 485771 T	15-11-2010
		AU 2004201146 A1	14-10-2004
		CA 2462166 A1	29-09-2004
		DK 1462056 T3	31-01-2011
		EP 1462056 A1	29-09-2004
		ES 2350578 T3	25-01-2011
		GB 2400804 A	27-10-2004
		JP 4724372 B2	13-07-2011
		JP 2004298632 A	28-10-2004
		US 2004193055 A1	30-09-2004
		US 2013281835 A1	24-10-2013

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2014/000237

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 all searchable claims.

2. ☐ As all searohable 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 report covers only those claims for which fees were paid, specifically claims Nos.:

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

1-7

Remark on Protest

☐ The additional search fees were acccmpanied 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: 1-7

A needle assembly including a needle shaft and a plastics sleeve extending along the outside of the needle shaft, wherein the sleeve contains a plurality of gas bubbles within the thickness of the sleeve, and wherein the needle shaft is hollow, so that fluids can be introduced into or removed from a patient's body through the needle shaft.

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2. claims: 8-14

A method of manufacture of a needle assembly including the steps of providing a metal shaft and extruding on the outside of the shaft a sleeve of a plastics material containing gas bubbles, and forming a sharp, penetrating tip at one end of the metal shaft, so that the needle assembly can be inserted into a patient's body by piercing a tissue wall.
A needle assembly made by the above method.

专利名称(译)	针组件和制造方法		
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申请号	EP2014734533	申请日	2014-06-17
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摘要(译)

金属轴（10,10'）和外塑料套管（12）的针组件通过将套管挤压到轴的外侧而制成。套管包含气泡（13），优选地具有5μ至10μ的尺寸，以增加组件的超声可见度。在套筒挤压在轴上之前或之后，可在轴上形成尖锐的穿透尖端（18）。金属轴（10）可以连续长度供给挤出机1至5，并在挤出套管（12）后切割成针组件的尺寸。或者，可以将预切长度的金属轴（10'）供应到挤出机1'至5'，在挤出之后在轴之间切割套筒。