A61M 5/34 (2006.01)

The inserted ded

(26) o n the boss i s also used t o orient the needle shaft (10) while a bevel (12) i s formed a t the patient end (13).

The place.

(30) Priority Data:
1520043.9 13 November 2015 (13. 11.2015) GB


(32) Inventors: BATEMAN, Timothy; 31 High Knocke, Dymchurch, Hythe, Kent TN25 0QD (GB). DAVEY, Andrew Bernard; Smiths Medical, Technical & Development Centre, Boundary Road, Hythe, Kent CT21 6LJ (GB). HINGLEY, Richard; 141 Dymchurch Road, Hythe, Kent CT21 6LJ (GB). VEASEY, Neil Steven; 33 Cypress Avenue, Ashford, Kent TN23 3JS (GB).


Declarations under Rule 4.17:
— as to the identity of the inventor (Rule 4.1.7(i))
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.1.7(ii))
— if inventorship (Rule 4.1.7(iv))

Published:
— with international search report (Art. 21(3))

(54) Title: NEEDLE ASSEMBLIES AND METHODS OF MANUFACTURE

(57) Abstract: An oocyte needle assembly has a metal needle shaft (10) and small boss (21) of plastics material moulded onto the shaft. The rear end of the needle shaft and the boss are inserted into a receptacle (34, 36) at one end of an outer sleeve (22) and bon ded in place. The other end of the outer sleeve (22) has a tapered female coupling recess (31) into which the nose of a syringe can be inserted to make fluid connection with the needle. The boss has a key (26) that extends in a keyway (35) in the receptacle (34, 36). The key (26) on the boss is also used to orient the needle shaft (10) while a bevel (12) is formed at the patient end (13).

FIG. 5

WO 2017/081431 A1
NEEDLE ASSEMBLIES AND METHODS OF MANUFACTURE

This invention relates to needle assemblies of the kind including a hollow metal needle shaft and a hub assembly attached with the shaft, the hub assembly including a coupling by which fluid connection can be made to the needle assembly.

There are many different types of needles used in medical and surgical applications. Usually, medico-surgical needles comprise a metal shaft with a bevelled cutting tip at one end and a hub at the opposite end by which connection is made to the bore of the needle. The hub has some form of coupling, such as a female tapered bore into which a male coupling can be inserted. Alternatively, the coupling could take the form of a male connection adapted to be inserted into a mating female connection such as at the end of tubing. Examples of needle assemblies are described in, for example, EP109657, US2989053, US5149328, US4795445, US8672892, US6673440, EP356774, US5342309, US3720210, US2740192, US7736337, US2012179113, GB894653, US3093134, US6024727 and GB1 151222.

Although it is possible for a plastics hub to be moulded onto the shaft of a metal needle there can be problems with the plastics shrinking or deforming and leading to a poor connection of the hub on the needle shaft. Reliable assembly and quality checks can be difficult. Also, the material of the hub needs to be compatible with the fluid or other material supplied through the needle but this material may not be suitable for forming a secure connection with the needle shaft.

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 hub assembly includes a first part of a plastics material moulded about the shaft and a second part preformed of a plastics material providing the coupling and a receptacle into which the first part is inserted and secured.

The first part is preferably secured in the receptacle by bonding. The first part and the receptacle may be formed with cooperating surface formations to define an angular
orientation between the first and second parts. The cooperating surface formations preferably include a projecting key on one part and a cooperating keyway on the other part. The needle shaft may have a bevel at its patient end and the second part may include an externally-visible marking to indicate the orientation of the bevelled end of the needle shaft. The coupling may be a female tapered recess adapted to receive a mating male coupling. The needle assembly may be an oocyte recovery needle assembly.

According to another aspect of the present invention there is provided a method of manufacturing a needle assembly including the steps of providing a hollow, metal needle shaft, moulding onto the shaft towards its machine end a first part of a plastics material, providing a preformed second part including a coupling at one end by which connection can be made to the needle assembly and at its opposite end a receptacle adapted to receive the first part, inserting the needle shaft and first part into the receptacle and securing the first part in the receptacle so as thereby to provide a hub at the machine end of the needle shaft.

The first part may be secured in the receptacle by bonding. The first part may be moulded with a surface formation to define the orientation of a bevel at the patient end of the shaft. The method may include the step of forming a bevel at the patient end of the shaft after moulding the first part and using the surface formation on the first part to orientate the shaft while forming the bevel.

According to a further aspect of the present invention there is provided needle assembly made by a method according to the above other aspect of the present invention.

An oocyte recovery 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 is a cross sectional side elevation view of the assembly;

Figure 2 shows a needle shaft at a preliminary step in manufacture;
Figures 3 and 4 show subsequent steps in manufacture;

Figure 5 is a perspective view showing a final step in manufacture; and

Figure 6 is a perspective view of a modified form of a part of a needle assembly.

With reference first to Figures 1 and 5 the oocyte needle assembly comprises a hollow, metal shaft 10 and a plastics hub assembly 20 securely attached to the machine end 11 of the shaft. The needle shaft 10 is formed with a bevelled cutting tip 12 at its forward, patient end 13. The hub 20 is formed in two parts namely a first part or boss 21 of a plastics material moulded onto the needle shaft 10 a short distance from the machine end 11 and a second part or sleeve 22 premoulded of a plastics material in which the first part 21 is securely attached.

The boss 21 is shown most clearly in Figure 5 and has a forward, patient end portion 23 of cylindrical shape and a central portion 24 of circular section and with a larger diameter than the forward portion. The boss 21 also has a rear portion 25 of about the same diameter as the forward portion 23 and of circular section apart from a surface formation in the form of a projecting rib or key 26 extending longitudinally externally along the rear portion. The boss 21 is spaced from the rear end 11 of the shaft 10 by a distance approximately equal to the length of the boss.

The sleeve 22 has a larger bulk than the boss 21 and has a generally cylindrical shape with a waisted outer surface 30 to enable the hub 20 to be gripped firmly between finger and thumb. Internally, the sleeve 22 provides a female coupling formed by a recess 31 of circular section that tapers along its length from a larger diameter at the rear end to a slightly smaller diameter at the forward end of the recess. The recess 31 is shaped to receive a tapered male coupling (not shown) such as the nose of a syringe, in a sealing mating engagement. The forward end of the recess 31 communicates with an axially-aligned passage 32 extending along the forward half of the sleeve 22. The passage 32 is divided into three parts. The rear part 33 opens into the coupling recess 31 and has a diameter equal to the outer diameter of
the needle shaft 10. The central section 34 has a larger diameter than the rear part 33 and is of circular section apart from a longitudinally-extending channel or keyway 35. The central section 34 and the forward section 36 together provide a receptacle for the rear and central portions 25 and 24 of the boss 21 on the needle shaft. More particularly, the shape and size of the central section 34 is arranged to receive the rear portion 25 of the boss 21, with the key 26 on the boss being received in the keyway 35 in the central section. The forward, patient end section 36 of the passage 32 is circular and larger in diameter than the central section 34. More particularly, the patient end 36 section opens on the forward, patient end face 37 of the sleeve 22 and is the same size as the central portion 24 of the boss 21 received in the patient end section. The boss 21 is secured into the sleeve 22 by means of an adhesive or solvent applied to the outside of the boss and the outside of that part 11 of the needle shaft 10 rearwardly of the boss, with the forward facing surface 38 of the central portion 24 lying level with the forward face 37 of the sleeve 22.

The hub 20 has some form of marking visible on its external surface to indicate the orientation of the bevel 12 at the patient end 13 of the needle shaft 10 so that the user can identify the orientation when the patient end tip is inserted in patient tissue. As shown in Figure 5 this marking takes the form of a printed mark 50 in line with the keyway 35 in the passage 32 and hence in line with the key 26 on the boss 21 and the axis of the bevel 12. Alternatively, the marking could be provided by a surface formation on the hub 20, such as a groove or a raised marking.

The needle assembly is made by first providing a hollow metal needle shaft 10 cut square at both ends, as shown in Figure 2. The shaft 10 may be treated such as by roughening or grooving towards its patient end 13 to enhance its echogenic properties. It may also be similarly treated in the region where the boss 21 is to be moulded so as to improve the grip of the boss on the shaft 10.

One end of the shaft 10 is then inserted in a mould tool 60 so that the end 11 of the shaft projects a short distance beyond the tool, as shown in Figure 3. A molten thermoplastic is then injected through an inlet 61 to fill a cavity 62 around the shaft 10 that defines the
external shape of the boss 21. The boss 21 has a relatively low bulk and wall thickness, making it less likely to deform or shrink after removal from the mould tool.

After the shaft 10 has been removed from the tool 60 with the boss 21 in place it is mounted in a grinding machine 70 so that its patient end 13 is located adjacent a grinding tool 71, as shown in Figure 4. The key formation 26 on the boss 21 is used to retain the shaft 10 in the machine 70 in the appropriate orientation so that the grinding tool 71 grinds the tip 13 of the shaft 10 to form a bevel 12 aligned with the key. Alternatively, the bevel 12 could be formed before moulding the boss 21.

The next step is to apply a suitable bonding solution such as an adhesive, cement, solvent or the like to the outside of the rear part of the boss 21 and to the outside of the rear part 11 of the shaft 10 where it projects from the rear end of the boss. As shown in Figure 5, the key 26 on the boss 21 is aligned with the keyway 35 in the sleeve 22, the rear end 11 of the shaft 10 and the boss being pushed 22 into the passage 32 at the rear end of the sleeve. After the bonding solution has cured the needle shaft 10 will be securely attached with the sleeve to provide a finished hub 20.

Needle assemblies according to the present invention can have various advantages. Connection to the outside of the shaft is made by the boss, which is a relatively small, low bulk item and is, therefore, less susceptible to shrinkage and deformation during moulding. There is, therefore, less risk that it will shrink away from the shaft and form a poor connection. It is also easier to inspect the joint of the boss with the shaft and detect any preassemblies that may not be secure before they are assembled into the sleeve to complete the hub. The material of the boss and of the hub sleeve could be the same or could be different. The boss need not come into contact with any materials flowing along the bore of the shaft so could be of a material that provides the best bond with the needle shaft even if it is not biocompatible with the material supplied along the needle shaft. The sleeve of the hub can be made of a different material less suitable for bonding to the metal shaft but that does have suitable biocompatibility.
The fit of the boss in the hub sleeve could be chosen to be a tight fit so that the sleeve applies a compressive inwardly-directed force around the boss. This would help keep the boss in close contact with the outside of the needle shaft and resist any shrinkage. This effect can be enhanced by the arrangement shown in Figure 6. This shows a modified form of the boss 121 where the rear portion 125 is extended beyond the key 126 to provide a chuck section 225 divided into a number of parallel fingers 226 separated from one another by slots 227 through the thickness of the chuck section. The sleeve (not shown) is modified by the inclusion of an internal ramp portion positioned to engage the outside of the chuck section 225. The fingers 226 make the rear portion 125 more flexible in the region of the chuck section 225 so that, when the needle and boss assembly 100, 121 is pushed into the passage through the sleeve the ramp engages the outside of the fingers and pushes them radially inwardly against the outside of the needle shaft to improve retention with the shaft.

The invention is not confined to use in oocyte recovery needle assemblies but could be used in other medico-surgical needle assemblies. The needle assemblies could be made in other ways than the method described above.
CLAIMS

1. A needle assembly including a hollow metal needle shaft (10) and a hub assembly (20) attached with the shaft, the hub assembly including a coupling (31) by which fluid connection can be made to the needle assembly, characterised in that the hub assembly (20) includes a first part (21) of a plastics material moulded about the shaft (10) and a second part (22) preformed of a plastics material providing the coupling (31) and a receptacle (34, 36) into which the first part (21) is inserted and secured.

2. A needle assembly according to Claim 1, characterised in that the first part (21) is secured in the receptacle (34, 36) by bonding.

3. A needle assembly according to Claim 1 or 2, characterised in that the first part (21) and the receptacle (34, 36) are formed with cooperating surface formations (26 and 35) to define an angular orientation between the first and second parts (21 and 22).

4. A needle assembly according to Claim 3, characterised in that the cooperating surface formations include a projecting key (26) on one part (21) and a cooperating keyway (35) on the other part (22).

5. A needle assembly according to any one of the preceding claims, characterised in that the needle shaft (10) has a bevel (12) at its patient end (13) and the second part (22) includes an externally-visible marking (50) to indicate the orientation of the bevelled end (12) of the needle shaft (10).

6. A needle assembly according to any one of the preceding claims, characterised in that the coupling is a female tapered recess (31) adapted to receive a mating male coupling.

7. A needle assembly according to any one of the preceding claims, characterised in that the needle assembly is an oocyte recovery needle assembly.
8. A method of manufacturing a needle assembly including the steps of providing a hollow, metal needle shaft (10), moulding onto the shaft towards its machine end a first part (21) of a plastics material, providing a preformed second part (22) including a coupling (31) at one end by which connection can be made to the needle assembly and at its opposite end a receptacle (34, 36) adapted to receive the first part (21), inserting the needle shaft (10) and first part (21) into the receptacle (34, 36) and securing the first part (21) in the receptacle so as thereby to provide a hub (20) at the machine end of the needle shaft (10).

9. A method according to Claim 8, characterised in that the first part (21) is secured in the receptacle (34, 36) by bonding.

10. A method according to Claim 8 or 9, characterised in that the first part (21) is moulded with a surface formation (26) to define the orientation of a bevel (12) at the patient end (13) of the shaft (10).

11. A method according to Claim 10, characterised in that the method includes the step of forming a bevel (12) at the patient end (13) of the shaft (10) after moulding the first part (21) and using the surface formation (26) on the first part to orientate the shaft (10) while forming the bevel.

12. A needle assembly made by a method according to any one of Claims 8 to 11.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/34

ADD.

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

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

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 4 266 543 A (BLUM ALVIN S) 12 May 1981 (1981-05-12) column 3, line 10 - line 32; figure 3</td>
<td>1,2,6,7</td>
</tr>
<tr>
<td>A</td>
<td>DE 14 91 743 AI (GEORG A HENKE GMBH) 26 June 1969 (1969-06-26) page 4, line 23 - page 5, line 15</td>
<td>1,2-6-12</td>
</tr>
<tr>
<td>Y</td>
<td>Wo 2009/150399 AI (SMITHS MEDICAL INTERNAT LTD [GB]; LODGE STEPHEN JAMES [GB]) 17 December 2009 (2009-12-17) page 2, line 30 - page 3, line 24</td>
<td>8-11</td>
</tr>
</tbody>
</table>

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

**B** 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 novel or 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

**A** document member of the same patent family

Date of the actual completion of the international search

5 January 2017

Date of mailing of the international search report

18/01/2017

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax. (+31-70) 340-3016

Authorized officer

Dai nti th, Ni chol a
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>US 4266543 A 12-05-1981</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>US 3093134 A 11-06-1963</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>DE 1491743 A1 26-06-1969</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>WO 2009150399 A 1 17-12-2009</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>US 2013138047 A 30-05-2013</td>
<td>CN 103096953 A 08-05-2013</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EP 2623144 A    07-08-2013</td>
<td></td>
</tr>
<tr>
<td></td>
<td>JP 2016144745 A 12-08-2016</td>
<td></td>
</tr>
<tr>
<td></td>
<td>US 2013138047 A 30-05-2013</td>
<td></td>
</tr>
<tr>
<td></td>
<td>US 2016271848 A 22-09-2016</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WO 2012043544 A 05-04-2012</td>
<td></td>
</tr>
</tbody>
</table>