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Datasheet for the decision of 12 October 2015

Case Number: T 1773/11 - 3.2.02

Application Number: 06254008.3

Publication Number: 1752183

IPC: A61M5/32, A61M25/06

Language of the proceedings: EN

Title of invention:
Needle guard mechanism with angled strut wall

Applicant:
Smiths Medical ASD, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 1773/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 October 2015

Appellant: (Applicant)	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, NH 03431 (US)
Representative:	Findlay, Alice Rosemary Reddie & Grose LLP 16 Theobalds Road London WC1X 8PL (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 April 2011 refusing European patent application No. 06254008.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	P. L. P. Weber

Summary of Facts and Submissions

I. On 4 April 2011 the Examining Division posted its decision to refuse European patent application No. 06254008.3 under Article 113(2) EPC, having declined to admit the applicant's final and only request on the grounds that prima facie it was not in conformity with Article 123(2) EPC and not novel over D1.

II. An appeal was lodged against this decision by the applicant by notice received on 27 May 2011. The appeal fee was paid on 2 June 2011. The statement setting out the grounds of appeal was received on 29 July 2011.

III. By communication of 22 April 2015, the Board summoned to oral proceedings and informed the appellant about deficiencies under Article 84 and Rule 42(1)(b) EPC.

IV. With letter of 11 May 2015 the appellant submitted amended application documents.

V. By communication of 22 May 2015 the Board informed the appellant that the oral proceedings were cancelled.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claim 1 as filed with letter of 11 May 2015 and claims 2 to 20 as filed with letter of 28 July 2011; description pages 1, 4 and 4a as filed with letter of 11 May 2015, pages 2, 3 and 5 filed by telefax of 18 February 2011, page 6 filed by telefax of 11 September 2008, and pages 7 to 23 as originally filed; drawing sheets 1/9 to 9/9 as originally filed.

VII. The following documents are of importance for the present decision:

D1: WO-A-99/08742
D2: US-A-5 300 045
D3: EP-A-1 180 381
D4: US-A-5 584 810
D5: WO-A-01/10488
D6: EP-A-0 554 841
D7: US-A-2003/0100868
D8: WO-A-2006/047737
D9: US-A-2005/0075609
D10: WO-A-03/103757.

VIII. Claim 1 of the appellant's only request reads:

"A safety catheter device comprising
a catheter hub (220) and a catheter tube (226) extending therefrom;
a needle (52) having a needle shaft (56) terminating in a sharp tip (58); and
a rigid canted-plate clip (12) having a first wall (16) with an aperture (18) adapted to slidably receive the needle shaft (56) therethrough in a first state of the clip (12), the clip (12) having a second state in which the needle shaft (56) is gripped by the first wall aperture (18), the clip (12) having a second wall (20) with a portion (38) adapted to bear against the shaft (56) in the first state and being adapted to confront the tip (58) of the needle (52) in the second state, and a strut (24, 26) connecting the first and second walls (16, 20); and
a spring member (14) biasing the clip (12) towards the second state;

the needle (52) having a first position slidably received through the aperture (18) of the clip first wall (16), in bearing relationship with the clip second wall portion (38), and extending through the catheter tube (226) with the sharp tip (58) exposed in the first state of the clip (12), the needle having a second position in which the needle tip (58) has been pulled out of the catheter tube (226) past the clip second wall (20) so that in the needle second position the clip (12) moves towards the second state and grips the needle shaft (56) with the tip (58) blocked by the clip second wall;
the device being **characterised in that** the strut (24, 26) extends from the first wall (16) of the clip (12) at an included angle of less than 90 degrees relative to the first wall (16)."

Claims 2 to 20 are dependent claims.

IX. The appellant's arguments are essentially those on which the following reasons of this decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

Claim 1 is based on original claim 1. It has been cast in the two-part form and the term "rigid canted-plate" has been inserted before the word "clip", as disclosed in paragraph [0028] of the description as originally filed. Claims 2 to 10 and 11 to 20 correspond to original claims 2 to 10 and 16 to 25, respectively. The requirements of Article 123(2) EPC are complied with.

3. Novelty

Claim 1 is directed to a safety catheter device with a needle guard mechanism of the "canted-plate" type which is to be distinguished from the "spring-clip" type. In both cases, the construction of the device is generally such that the clip performs two functions: it moves to block the needle tip and, further, engages the shaft or some other part of the device so that it is retained on the needle tip when the needle is fully withdrawn. However, spring-clip and canted-plate needle guard clips achieve these two goals in different ways.

In a "spring-clip" type needle guard, a spring clip, usually of sheet metal, is held in a loaded condition by the presence of the needle shaft. When the needle tip is withdrawn, the spring-clip deforms so that a portion of the spring clip moves into a position where it blocks or covers the needle tip. Thus, in use, the shape of the spring-clip changes. The spring clip itself must therefore be flexible enough to deform to change the shape of the clip when the needle shaft is withdrawn.

A "canted-plate" clip, on the other hand, does not achieve blocking of the needle tip by deformation; rather, the clip, as a whole, moves in a pivoting or rotating manner as a rigid unit under the influence of a spring member which acts on the clip. The spring member acts to cant the clip (that is, generally, to pivot the clip about a fulcrum) and, hence, to rotate the clip into a position where one part (in the present case the second wall 20) blocks or covers the needle tip and another part (the first wall 16) grips the needle shaft within an aperture thereof, with both

parts moving in unison. This operation is described in paragraph [0033] of the present application and shown in Figures 2A and 2B, from which it can be seen that although spring member (14) flexes (and changes shape) between the first and second states shown in those drawings, the shape of clip (12) formed by first wall (16), strut (24) and second wall (20) remains unaltered; the clip simply pivots or cants, as a unit, about the fulcrum formed where it engages a ledge (72) formed on housing (60).

Document D1 relates to a device utilising a spring-clip, rather than a rigid canted-plate clip. It does not disclose that the aperture/opening (58, 76, 134, 170) has any gripping function, as required by claim 1. The gripping or clamping is always achieved by the "transverse segment", corresponding to the strut as claimed. Accordingly, this functional feature of the first wall aperture as defined in claim 1 is not directly and unambiguously derivable from D1. For this reason alone, D1 does not anticipate the subject-matter of claim 1.

None of the other documents D2 to D10 cited in the search report discloses in combination all the features of claim 1.

Accordingly, the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

4. Inventive step

Document D10 is the closest prior art. The canted-plate clip (termed "shield") depicted in Figures 4 and 5 of D10 is structurally and functionally the most similar to the claimed clip. Shield (28) has a first wall (42)

with an aperture (50) adapted to slidably receive the needle (21) and to grip the needle shaft in a second state (shown in Figure 5). It also has a second wall (48) adapted to bear against the shaft and to confront a tip of the needle in the second state shown in Figure 5. Finally, strut (46) connects the first and second walls. The device of D10 also includes a spring member (26). The functioning of the canted-plate clip shown in Figures 4 and 5 of D10 is analogous to that in the present invention.

Document D10 (Figures 4 and 5) discloses the features of the preamble of claim 1.

The technical effect underlying the distinguishing feature as defined in the characterising portion of claim 1 is that better blocking of the needle tip is achieved by allowing the clip to go through a greater degree of rotation (see paragraph [0034] of the present application as originally filed) than is generally possible with a clip employing a right-angle arrangement as in D10. A less-than-90-degrees angling between the first wall and the strut permits the clip to rotate further before it stops bringing the second wall fully into the position in which it blocks the needle tip. In that regard, it must be remembered that the tilting will cease as the edges of aperture (18) bite into the needle shaft. In order to make sure that the second wall goes far enough to block the needle fully, a greater degree of rotation is desired than can be achieved with a right angle.

The objective technical problem solved by the invention is to provide more reliable and complete blocking of the needle tip in the second state before the tilting stops due to the gripping of the needle by the first

wall. There is only a limited angle of cant possible inside these small devices and the right-angle wall is found to be insufficient.

The result is enhanced with the less-than-90-degrees angle as defined in the characterising portion of claim 1 which allows for a greater degree of rotation in the same physical space.

D10 contains no indication that the objective technical problem solved by the invention is recognised, nor does it contain any information about how to solve that problem which might prompt the skilled person to angle the strut joining the two walls of the clip so that the included angle between the strut and the first wall is less than ninety degrees.

Among the remaining cited documents, D5 is the only one also disclosing a rigid canted-plate clip (110 and 222 in Figures 5, 8A and 8B). As can be seen from these figures and mentioned at page 8, lines 10 to 12, the strut or base (120, 232) is perpendicular to the apertured first wall (112, 224), as in D10. Moreover, it is not derivable from D5 that the second wall (116, 228) comprises a portion adapted to bear against the shaft of the needle in the first state. D5 also gives no hint towards the objective technical problem as mentioned above and towards reducing the right angle in an effort to solve it.

As mentioned above, Dl does not disclose a canted-plate clip but, rather, relates to a device utilising a spring-clip. Looking at the clip (96) shown in Figure 8 (which comprises a proximal arm (106) and a vertical arm (112) with a portion (114) adapted to bear against the needle shaft) reveals an included angle of less

than 90 degrees between the sloping section (page 16, lines 1 to 4; reference numeral 102, not shown in the drawings) of the transverse segment (98) or strut and the proximal vertical arm (106). However, as mentioned above, the aperture (58) formed in the latter does not grip the needle shaft; the gripping is achieved by the transverse segment (98) and its locking tab (118), as explained in the third paragraph of page 17. Accordingly, the proximal vertical arm (106) cannot be equated to the first wall of the claim. Similar considerations apply to the clips (40, 120) of the other embodiments described in D1. Even if this distinction is ignored, it would not be obvious to modify the spring-clips (40, 96 or 120) of Dl by changing the angle between the "first wall" and the "strut" in order to improve blocking of the needle tip. Movement of the distal arm (42 or 112) across the line of the needle is not affected by the angle between that arm and the rest of the spring-clip. Rather, movement of the apertured arm equivalent to the "first wall" is influenced by the extent of compression of the spring-clip at the proximal end of the apertured arm where it meets arm (54) in Figures 1A and 1B of D1 or arm (126) in Figures 10 and 11. The skilled person would understand that to effect greater movement of the distal arm of the spring-clip it would be necessary to provide greater loading of the spring by compressing together the apertured arm and the proximal vertical arm (54 or 126). Accordingly, when starting from a canted-plate clip as disclosed in D10 or D5, the subject-matter of claim 1 is not obvious even taking into account the spring-clip disclosed in D1. The content of document D3 corresponds to that of D1.

Item 200 shown in Figures 17 and 18 of D4 is not a needle guard clip of the canted-plate type. Rather, it

is a trigger intended to maintain inner housing (12) wound with respect to outer housing (14) when the sharp distal end of the needle extends beyond the distal end of assembly (10). This trigger must allow the inner housing to unwind with respect to the outer housing when the distal end of the needle is withdrawn into the assembly (column 7, lines 30 to 32 and column 5, lines 21 to 28).

D6 relates to a spring-clip (58), rather than to a rigid canted-plate clip as claimed. D9 too relates to a spring-clip, having a ready position (Figure 3) and an activated position as shown in Figure 4 wherein the clip grips the needle shaft and blocks its tip. Neither document discloses an angle of less than 90° as claimed. Documents D2 and D7 are even more remote.

D8 is merely an intermediate document under Article 54(3) EPC.

Accordingly, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the following documents:

Claims, numbers:
1 as filed with letter of 11 May 2015;
2 to 20 as filed with letter of 28 July 2011;

Description, pages:
1, 4 and 4a as filed with letter of 11 May 2015;
2, 3 and 5 filed by telefax of 18 February 2011;
6 filed by telefax of 11 September 2008;
7 to 23 as originally filed;

Drawings, sheets:
1/9 to 9/9 as originally filed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated