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**Datasheet for the decision
of 15 December 2011**

Case Number: T 1202/09 - 3.2.02

Application Number: 04000853.4

Publication Number: 1421969

IPC: A61M 25/06, A61M 5/32

Language of the proceedings: EN

Title of invention:
Spring clip as needle protection for a safety IV catheter

Applicant:
B. Braun Melsungen AG

Headword:
-

Relevant legal provisions:
EPC Art. 76(1), 123(2)

Keyword:
"Extension beyond parent application (no, after amendment)"

Decisions cited:
-

Catchword:
-



Case Number: T 1202/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 15 December 2011

Appellant:
(Applicant) B. Braun Melsungen AG
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Representative: Klingseisen, Franz
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 13 January 2009
refusing European patent application
No. 04000853.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: C. Körber
Members: P. L. P. Weber
J. Geschwind

Summary of Facts and Submissions

I. The appeal is against the decision of the Examining Division posted on 13 January 2009 to refuse the application because it did not comply with Article 76(1) EPC.

Claim 1 as refused by the Examining Division reads as follows:

An IV-catheter comprising

- a catheter hub (26) attached to the proximal end of a tubular catheter (24),
- a needle (16) having a large diameter segment (138), a needle shaft and a needle tip,
- a needle guard (120) retained in a ready position in the catheter hub (26),
- wherein the needle guard (120) is provided with distal guard walls (130) which are positioned on the shaft of the needle (16) in the ready position and overlap each other in the front of the needle tip when the needle guard is in a blocking position, wherein the needle guard (120) is in the form of two resilient arms (122, 124) which are urged apart by the needle shaft (16) in the ready position, each arm (122, 124) terminating at a respective one of the distal guard walls (130) and each being joined at the proximal end of the needle guard (120) which includes an opening (134) through which the needle shaft (16) passes, and wherein the diameter of the large diameter segment (138) is greater than that of said opening (134), characterized in that

said resilient arms (122, 124) are intersecting, and the needle guard (120) is in retaining contact with the inner wall of the catheter hub (26).

II. The application in suit is a divisional application of the parent application WO 99/08742 and concentrates on the embodiment according to figure 10a, 10b and 11 of the parent application.

III. A notice of appeal was filed on 13 March 2009 and the appeal fee paid on the same day. A statement setting out the grounds of appeal was filed on 13 May 2009.

With the statement of the grounds of appeal the appellant filed a main request and two auxiliary requests.

Claim 1 of the main request reads as follows (feature subdivision added):

a) a catheter hub (26) attached to the proximal end of a tubular catheter (24),

b) a needle (16) having a needle tip and a needle shaft with a large diameter segment (138), and

c) a needle guard (120) retained in a ready position in the catheter hub (26) by contact with the inner wall of the catheter hub,

d) wherein the needle guard is provided with distal guard walls (130) which are positioned on the shaft of the needle (16) in the ready position and overlap each

other in front of the needle tip when the needle guard is in a blocking position,

e) wherein the needle guard (120) is in the form of two resilient intersecting arms (122, 124), which are urged apart by said needle shaft in the ready position, each arm terminating at a respective one of the distal guard walls (130) and each extending from a rear wall (126)

f) which includes an opening (134) through which the needle shaft passes, and wherein the diameter of the large diameter segment (138) is greater than that of said opening (134).

IV. In the communication annexed to summons to oral proceedings the Board raised several objections under Article 76(1) EPC in relation to the main request (and the auxiliary requests).

In particular the Board had the following objections against claim 1 (the passages referred to are of the application in suit as published):

Concerning Feature b): in the paragraphs of the description the element 138 was designated as a "bulge 138" see col.10 lines 28, 29. A needle having any kind of "large diameter segment" had not been disclosed in relation with the embodiment according to figures 10A, 10B, 11.

Concerning Feature c): The "contact with the inner wall" was not any kind of inner contact. In the embodiment at stake it was "an annular groove or ring 136 formed in the inner wall of the catheter hub", and

it was not any part of the needle guard which was in contact with the inner wall of the hub, but "curved protrusions 128 in each of the arms 122, 124" see col.10, lines 18 to 22.

Concerning Feature d): The distal guard walls 130 had lips 132 which were in engagement with the needle shaft, so as to urge the curved protrusions 128 of each of the arms 122, 124 into the annular groove 136, see col.10, lines 33 to 39.

Concerning Feature e): the resilient intersecting arms were not simply "extending from the rear wall", but the description mentioned that "they are respectively joined at their proximal ends in a hinged arrangement at 125 to the ends of the rear wall 126", see col.10 lines 5 to 9.

The arms each further included a narrow portion that extended between a distal wide portion and a proximal wide portion (see col.10 lines 12 to 15) and the shaft of the needle that passed through the needle guard frictionally engaged the inner edges of the narrow portions so as to further retain the needle in its ready position (see col.10, lines 40 to 43).

Concerning Feature f): see remark concerning the bulge 138 under feature b). Further it was not sufficient to mention that the diameter of the bulge 138 was greater than that of the opening 134 because then the bulge could have any diameter. The increased diameter bulge had to be sufficiently small to allow the needle to move axially along the catheter (see col.10, lines 28 to 32), but greater in diameter than opening 134 to avoid any further axial movement of the needle out of

the needle guard once the needle guard was in the blocking position (see col.11, lines 3 to 10).

The Board therefore considered that claim 1 according to the main request was far too general to be supported by the divisional application as originally filed (Article 123(2) EPC) or the parent application as originally filed (Article 76 EPC).

V. Oral proceedings took place on 15 December 2011.

The appellant withdrew its previous requests and requested as main and only request, that the decision be set aside and a patent granted on the basis of claims 1 to 5 as filed during the oral proceedings and the description and drawings as filed with the statement of the grounds of appeal.

Claim 1 according to the only request reads as follows:

An IV-catheter comprising

- a) a catheter hub (26) attached to the proximal end of a tubular catheter(24),
- b) a needle (16) having a needle tip and a needle shaft with a bulge (138) and
- c) a needle guard (120) retained in a ready position in the catheter hub (26), comprising
- d) first and second resilient arms (122, 124), intersecting in the ready position, respectively joined at their proximal ends in a hinged arrangement to the ends of a rear wall (126),
- e) the distal ends of each arm (122, 124) extend to a distal guard wall (130) which in turn terminates in a lip (132), each arm (122, 124) including a narrow

portion (142) that extends between a proximal wide portion (140) and a distal wide portion (144),
f) whereby the needle shaft passes through the needle guard (120) in the ready position and applies an outward radial force on arms (122, 124) by means of its engagement with lips (132), so as to urge the distal ends of the arms (122,124) into an annular groove or ring (136) formed in an inner wall of the catheter hub (26),
g) and the distal guard walls (130) overlap one another at a location distally in front of the needle tip in a protected position,
h) whereby the rear wall (126) includes an opening (134) through which the needle shaft passes and wherein the diameter of the bulge (138) is sufficiently small to allow the needle (16) to move axially along the catheter (24), but greater than the diameter of the opening (134).

VI. The arguments of the appellant can be summarized as follows:

The wording of claim 1 took into consideration all the objections raised by the Board in its communication annexed to the summons. It was however considered that the man skilled in the art would understand that the curved protrusions 128 at the distal ends of the arms were not necessary for the retaining function, so that this feature had not been taken over into claim 1. The feature that the shaft of the needle that passed through the needle guard frictionally engaged the inner edges of the narrow portions of the arms had not been introduced into claim 1 either because in the description this measure was presented as optional to

further retain the needle in its ready position.
Finally the wording "protected position" was taken from the paragraph "brief description of the drawings".

Therefore the requirements of Article 76(1) EPC were fulfilled.

Reasons for the Decision

1. The appeal is admissible.
2. The Board will refer to the A1 publication of the present divisional application since the description and drawings are identical to those of the parent application.
3. The invention is about a protection guard for the needle tip of a so called safety IV catheter. This type of catheters is used to administer fluids directly into the patient's vascular system. The catheter is introduced into the vein of the patient with the help of a needle. Once in the vein the needle is withdrawn and the catheter remains in place. The invention is about a protection guard for the needle tip once the needle is withdrawn from the catheter and catheter hub. The protection guard is within the hub of the catheter and it gets into a so called protected position when the needle is withdrawn.

The embodiment intended to be protected is shown in figures 10A, 10B and 11. The description paragraphs [0048] to [0052] relate to this embodiment. In the introductory part of the description paragraph [0014]

combined with [0018] introduces the embodiment shown in the above mentioned figures.

4. The appellant overcame the objections raised by the Board in its annex to the summons (see point VI above).

The only two features not taken over by the appellant are the following:

- (i) the distal ends of the arms include curved protrusions received in the annular groove or ring
- (ii) the shaft of the needle that passes through the needle guard frictionally engages the inner edges of the narrow portions of the arms

Finally (iii) the wording "blocking position" has been replaced by "protected position".

- 4.1 The feature of the claim in which feature (i) is included is feature f) whereby the needle shaft passes through the needle guard (120) in the ready position and applies an outward radial force on arms (122, 124) by means of its engagement with lips (132), so as to urge the distal ends of the arms (122,124) into an annular groove or ring (136) formed in an inner wall of the catheter hub (26). In this feature it is mentioned that the distal ends of the arms are urged into an annular groove or ring formed in an inner wall of the catheter hub. This feature is thus more general than the description of the embodiment in paragraph [0048] or than the embodiment shown in Figures 10A, 10B and 11. In these parts of the specification the ends of the arms are said or shown to include curved protrusions and these protrusions are received in the annular groove. It is clear that the reason for these

protrusions being urged into the groove is to retain the needle guard in the catheter hub (see paragraph [0050]: ... *so as to retain needle guard 120 in a fixed position within the inner wall of catheter hub 26.*), another function of the curved protrusions is not described and not immediately apparent. The Board considers that it is self evident for the skilled man reading the originally filed application that the curvature of the protrusions does not play any role for the retaining function but what is important is that the distal ends of the arms have a shape which is able to be urged into the groove and fulfil this retaining function.

The Board therefore considers that the generalisation in present claim 1 is directly and unambiguously derivable from the originally filed divisional application and from the originally filed parent application.

4.2 Concerning feature (ii) it is clearly expressed in col.10, lines 40 to 43 that the frictional engagement of the edges of narrow portions of the arms on the needle shaft is to further retain the needle in its ready position (emphasis added). In other words it is clear for the man skilled in the art that this frictional engagement on the needle shaft is not essential for the retaining function but is a possible enhancement.

4.3 Finally the wording "protected position" to designate the position of the needle guard in front of the needle tip is unambiguously disclosed in the paragraph "brief description of the drawings" where it is stated in relation with figure 10A and 10B that these figures are

views in partial cross-section of a safety IV catheter in accordance with still a further embodiment of the invention shown in the ready and protected positions, respectively; (emphasis added).

- 4.4 The specification, the claims and drawings according to the main request thus fulfil the requirements of Article 76(1) and 123(2) EPC.
5. As the Examining Division already issued a communication under Rule 71(3) EPC in relation with the then valid auxiliary request, the Examining Division had already examined the conformity with other requirements of the EPC for a patent to be granted and considered them as fulfilled. Present claim 1 being more restricted than claim 1 of the then valid auxiliary request, the Board has no reason to question the finding of the Examining Division.

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 the first instance with the order to grant a patent on the basis of the following application documents:

Claims 1 to 5 as filed during the oral proceedings of 15 December 2011,
Description Pages 1 to 3, 3a and 4 to 11 as filed with letter of 12 May 2009,
Drawings sheets 1/2 - 2/2 as filed with letter of 12 May 2009.

The Registrar:

The Chairman:

D. Hampe

C. Körber