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**D E C I S I O N**  
**of 3 May 2005**

**Case Number:** T 0532/04 - 3.2.2

**Application Number:** 97914904.4

**Publication Number:** 0929337

**IPC:** A61M 25/01

**Language of the proceedings:** EN

**Title of invention:**  
Intravascular Guidewire

**Applicant:**  
SCIMED LIFE SYSTEMS, INC.

**Opponent:**

-

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 52, 56, 84

**Keyword:**

"Clarity inventive step - yes (after amendments)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0532/04 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 3 May 2005

**Appellant:** SCIMED LIFE SYSTEMS, INC.  
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**Representative:** Kirschner, Klaus Dieter, Dipl.-Phys.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 22 October 2003  
refusing European application No. 97914904.4  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. K. H. Kriner  
**Members:** D. Valle  
E. J. Dufrasne

## Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 22 December 2003 against the decision of the examining division, posted on 22 October 2003, refusing the European patent application 97914904.4. The fee for the appeal was paid simultaneously and the statement setting out the grounds of appeal was received on 1 March 2004.
- II. The examining division held that the application did not meet the requirements of Article 84 EPC (lack of clarity) and of Articles 52 and 56 EPC (lack of inventive step).
- III. The following documents have been considered:
- D1 = EP-A-0 519 604
- D2 = US-A-5 171 232
- D3 = WO-A-95/31244
- D4 = EP-A-0 407 965
- D5 = EP-A-0 661 073
- D6 = US-A-5 368 048.
- IV. Oral proceedings took place on 3 May 2005.

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

claims: 1 to 5 filed during the oral proceedings on 3 May 2005;

description: pages 1 to 3 and 5 to 15 filed with letter dated 1 March 2004, and page 4 filed during oral proceedings on 3 May 2005;

Figures: 1 to 6 filed with letter dated 1 March 2004.

V. Claim 1 reads as follows:

"A guidewire comprising: an elongated core (118) having a length, a width, proximal end, distal end, and an axial surface extending the length of said elongated core; a plastic jacket (120) extending around said axial surface of said elongated core (118), said plastic jacket including a proximal jacket portion (122) and a distal jacket portion (142; 242) distal of said proximal jacket portion (122), said portions formed of a plastic material, wherein said distal jacket portion (142; 242) incorporates means for enhancing the radiopaque properties of said distal jacket portion (142; 242) relative to said proximal jacket portion (122); said distal jacket portion (142; 242) having a distal jacket section (108; 208) and a proximal jacket section (106; 206), wherein said means for enhancing the radiopaque properties of said distal jacket portion (142; 242) relative to said proximal

jacket portion (122) include loading said distal jacket section and said proximal jacket section with radiopaque material by incorporation of a radiopaque material within said plastic of said distal jacket portion (142; 242); wherein the distal portion of the core (118) includes a first region (24) immediately adjacent to, and distal of, the proximal portion (122) and tapering in diameter from the diameter of the proximal portion (20) of the core, the core includes a second region (28) immediately adjacent, and distal of the first region (24), the second region (28) having a uniform diameter, a third region (30) immediately adjacent to, and distal of the second region (28) and tapering in diameter from the diameter of the second region (28), a fourth region (32) in which the core (18) is flattened towards a distal end (34) thereof to form a ribbon shape, and characterized in that the distal jacket section (108, 208) extending from the third region (30) to the distal end of the core (118), said distal jacket section (108; 208) having a greater radiopacity than said proximal jacket section (106; 206) in that said distal jacket section (108; 208) is more heavily loaded with radiopaque material than said proximal jacket section (106; 206); said distal jacket section (108; 208) is loaded about 80% to 90% by weight with radiopaque material and said proximal jacket section (106; 206) is loaded about 40% to 65% by weight with radiopaque material; said distal jacket section (108; 208) includes a softer material than said proximal jacket section (106; 206); and said distal jacket section (108; 208) has a Durometer value in the range of about 80 A to about 85 A, and said proximal jacket section (106; 206) has a Durometer value of about 93 A."

VI. In support of his request the appellant relied essentially on the following submissions.

The present patent application met all requirements of the EPC, in particular claim 1 was clear, and the subject-matter of claim 1 involved an inventive step. No document of the available state of the art contained any hint to combine the specific range of values of the softness and the content in weight of radiopaque material of two end sections of the plastic cover with a tapered core of a guidewire as defined in claim 1 of the patent application.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*

Claim 1 is based on claims 1, 2, 6, 7, 9 and 12, on the description, page 7, line 12, to page 8, line 20, page 19, line 21 to page 20, line 1, and on Figure 7 of WO-A-97/32625. Claim 2 is based on claim 4 of the published application (WO-A-97/32625), claim 3 is based on page 19, lines 4 to 12 of WO-A-97/32625, and claims 4 and 5 are based on claims 10 and 11 of WO-A-97/32625.

The description has been adapted to the newly filed claims.

Figures 1 to 6 are based on Figures 1 to 3 and 5 to 7 of WO-A-97/32625.

Therefore the amendments to the application meet the requirements of Article 123(2) EPC.

3. *Clarity*

Contrary to the findings in the decision under appeal, the proximal portion, the proximal section and the distal section of the plastic jacket are sufficiently defined in claim 1, so that they can clearly be distinguished from each other.

According to claim 1 the plastic jacket comprises a proximal jacket portion and a distal jacket portion having a proximal jacket section and a distal jacket section. Moreover, claim 1 describes that the proximal and the distal jacket sections are loaded with radiopaque material by incorporation of a radiopaque material within the plastic of the distal jacket portion for enhancing the radiopaque properties of the distal jacket portion relative to the proximal jacket portion. Since this implicitly means that no radiopaque material is incorporated within the plastic of the proximal jacket portion, the distal and proximal jacket portions can unequivocally be distinguished from each other. Additionally claim 1 requires that the distal jacket section has a greater radiopacity than the proximal jacket section (80% to 90% compared to 40% - 65%) Therefore the proximal and the distal jacket sections can also clearly be distinguished from each other.

In the light of these findings, claim 1 is clear and therefore meets the requirements of Article 84 EPC.

4. *Novelty*

4.1 D1, which is considered to contain the closest state of the art, discloses a device according to the preamble of claim 1, or in other words a guidewire comprising an elongated core (18) having a length, a width, proximal end, distal end, and an axial surface extending the length of said elongated core; a plastic jacket (38) extending around said axial surface of said elongated core, said plastic jacket including a proximal jacket portion (40) and a distal jacket portion (42) distal of said proximal jacket portion, said portions formed of plastic material, wherein said distal jacket portion incorporates means for enhancing the radiopaque properties of said distal jacket portion relative to said proximal jacket portion (see description, column 5, lines 49 to 51); said distal jacket portion having a distal jacket section and a proximal jacket section wherein said means for enhancing the radiopaque properties of said distal jacket portion relative to said proximal jacket portion include loading said distal jacket section and said proximal jacket section with radiopaque material by incorporation of a radiopaque material within said plastic of said distal jacket portion (see description, column 5, lines 51 to 54); wherein the distal jacket portion of the core includes a first region (24) immediately adjacent to, and distal of, the proximal portion and tapering in diameter from the diameter of the proximal jacket portion of the core, the core includes a second region (28) immediately adjacent, and distal of the first



region, the second region having a uniform diameter, a third region (30) immediately adjacent to, and distal of the second region and tapering in diameter from the diameter of the second region, a fourth region (32) in which the core is flattened towards a distal end thereof to form a ribbon shape.

However, D1 does not disclose any of the characterizing features of claim 1.

4.2 All further documents are less relevant.

D2 discloses a plastic catheter having three different sections with different softness and radiopacity, but it does not disclose a guidewire having a core and a plastic cover.

D3 does not disclose a tapered core, nor that the radiopaque properties of the distal jacket portion relative to the proximal jacket portion are enhanced, that said distal jacket section radiopacity is greater than said proximal jacket section radiopacity, that said distal jacket section is more heavily loaded with radiopaque material than said proximal jacket section; and that said distal jacket section includes a softer material than said proximal jacket section.

D4 discloses a guidewire having a plastic (resin) jacket incorporating means for enhancing its radiopaque properties (see claim 1 and page 3 of the description, lines 35 to 37) However, D3 neither discloses two sections of a distal portion of the plastic jacket, nor a tapered core as defined in claim 1 of the present application.

D5 discloses a guidewire comprising a core member, a X-ray opaque metal coil attached to the distal section of the core member, and a synthetic resin envelope covering the core member and the metal coil.

D6 does not disclose a plastic jacket with differentiated radiopacity, but a guidewire having one overall jacket (5, see Figure 1) and an overhanging sleeve at the distal end having enhanced radiopacity.

5. *Inventive step*

Starting from D1, the object underlying the present application may be regarded as to optimize the trade-off between the flexibility of the distal end of the guidewire and the radiographic signature of the guidewire (see WO-97/32625, page 2, lines 11 to 15).

This object is achieved by the subject-matter of claim 1 and in particular by the provision of a guidewire, wherein the distal jacket section extends from the third region to the distal end of the core, said distal jacket section has a greater radiopacity than said proximal jacket section, said distal jacket section is more heavily loaded with radiopaque material than said proximal jacket section, said distal jacket section is loaded about 80% to 90% by weight with radiopaque material and said proximal jacket section is loaded about 40% to 65% by weight with radiopaque material, said distal jacket section includes a softer material than said proximal jacket section, and said distal jacket section has a Durometer value in the

range of about 80 A to about 85 A, and said proximal jacket section has a Durometer value of about 93 A.

Since none of the available documents suggests choosing a specific range of values for the Durometer and the load in weight of the two section of the plastic cover, together with associating the distal jacket section with a specific tapered part of the core, the claimed invention cannot be regarded as being obvious.

6. *Conclusions*

From the above considerations, it follows that the subject-matter of claim 1 meets the requirements of the EPC.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of:

claims: 1 to 5 filed during the oral proceedings on 3 May 2005;

description: pages 1 to 3 and 5 to 15 filed with the letter dated 1 March 2004, and page 4 filed during the oral proceedings on 3 May 2005;

figures: 1 to 6 filed with letter dated 1 March 2004.

The Registrar:

The Chairman:

V. Commare

T. Kriner