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**D E C I S I O N**  
**of 18 January 2006**

**Case Number:** T 1016/03 - 3.2.02

**Application Number:** 96938622.6

**Publication Number:** 0955933

**IPC:** A61B 19/00

**Language of the proceedings:** EN

**Title of invention:**

A device, system and method for interstitial transvascular intervention

**Applicant:**

Transvascular, Inc.

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 84, 123(2)

**Keyword:**

"New subject-matter (no, after amendment)"

"Clarity (yes)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 1016/03 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 18 January 2006

**Appellant:** Transvascular, Inc.  
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Menlo Park, CA 94025 (US)

**Representative:** Whitaker, Iain Mark  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 20 March 2003  
refusing European application No. 96938622.6  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
E. Dufrasne

## Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 20 March 2003 to refuse European patent application No. 96 938 622.6.

The ground of refusal was that claim 1 of the main and auxiliary requests was objectionable under Article 123(2) EPC and further did not meet the clarity requirement of Article 84 EPC.

II. On 30 May 2003 the appellant (applicant) lodged an appeal against the decision having already paid the prescribed fee on the previous day. On 30 July 2003 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of claims 1 to 7 filed on 23 December 2005.

IV. Claim 1 of the main request reads as follows:

"A catheter device for affecting tissues beyond the lumen of a blood vessel comprising;

(a) a catheter (5) with proximal and distal ends, a distal portion of the catheter being adapted to be positioned within the lumen of a blood vessel while the proximal end remains outside of the body to allow for control by an operator;

(b) a tissue penetrating member (26, 27), provided on the distal portion of the catheter said tissue penetrating member being advanceable from the distal portion of the catheter to create a penetration tract

that extends from the blood vessel lumen to a target location outside of that blood vessel lumen; and characterized by

(c) a passive or active orientation detection means provided on the distal portion of the catheter for allowing the operator to determine the rotational orientation of the catheter within the blood vessel lumen prior to advancement of the penetrating member, thereby enabling the operator to adjust the rotational orientation of the distal portion of the catheter relative to a predetermined target location outside of the blood vessel lumen such that subsequent advancement of the tissue penetrating member (26, 27) will create a penetration tract that extends from the blood vessel lumen to that predetermined target location."

Claims 2, 3 and 7 are dependent on claim 1. Claims 4 to 6 are directed to a system comprising a catheter device according to any one of claims 1, 2, or 3.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Article 123(2) EPC - Claim 1*
  - 2.1 The decision under appeal objected to the use of the expression "imaging apparatus" in claim 1. This expression is not used in the present claims, which meet the objections of the examining division under Article 84 EPC and Article 123(2) EPC, accordingly.

2.2 Claim 1 now on file is based on claim 3 of the application as originally filed (WO-A-97/13471), which claim has been amplified in order to define the orientation means as being an active or passive orientation detection means, and the expression "penetrating access means" in the original claim has been replaced by "a tissue penetrating member". The new claim also describes the use of this member and the orientation detection means.

It is clear from the description, especially that part on pages 6 and 7 referring to Figure 2, that the orientation means may be an active or a passive orientation detection means, and these pages also describe details of and the manner of use of these elements, as featured in claim 1. Further, the above change of terminology is allowable since the present terminology more clearly describes the member (26, 27), see page 7. All the amendments to original claim 3 are based on the application as originally filed and comply with Article 123(2) EPC, accordingly.

3. *Claims 2 to 7*

Claims 2 and 3 are also fairly based on the disclosure of pages 6 and 7 of the original application and are allowable under Article 123(2) EPC. These claims define further features of the passive or active orientation detection means which are supported by page 6 of the description.

Claims 4 to 6 define combinations of a catheter as claimed in claims 1 to 3 and penetration tract

modifying apparatus, which combination are described with reference to Figures 5 to 29.

Claim 7 defines a combination of a catheter and a blocker apparatus for blocking a blood vessel, which combination is supported by the description of Figures 3 and 12, for example.

Claims 2 to 7 also meet the requirement of Article 123(2) EPC, accordingly.

4. *Article 84 EPC*

The claims, although directed to a catheter device, include some use features. This is not objectionable in the context since they provide further information as to the construction of the device. For example, the feature in claim 1 that the passive or active orientation detection means provided on the distal portion of the catheter are for allowing the operator to determine the rotational orientation of the catheter within the blood vessel is a functional feature which informs the reader that the orientation detection means may not possess circular symmetry and must be directional.

The Board has no other objections under Article 84 EPC.

5. The application was refused on grounds under Articles 84 and 123(2) EPC only. The examining division, in its communications dated 3 December 2001 and 26 November 2002, had made only tentative attacks against the claims under Article 52(1) EPC, based on a broad interpretation of the claims, and the Board

considers it appropriate to remit the case to the first instance for further prosecution.

## **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 resume the examination procedure on the basis of the claims 1 to 7 filed on 23 December 2005.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner