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**Datasheet for the decision  
of 15 February 2018**

**Case Number:** T 0993/13 - 3.2.02

**Application Number:** 05704344.0

**Publication Number:** 1709924

**IPC:** A61B18/16

**Language of the proceedings:** EN

**Title of invention:**  
ABLATION CATHETER

**Applicant:**  
Japan Lifeline Co., Ltd

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 123(2)

**Keyword:**  
Amendments - extension beyond the content of the application  
as filed (no)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 0993/13 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 15 February 2018**

**Appellant:** Japan Lifeline Co., Ltd  
(Applicant) 2-20, Higashi-shinagawa 2chome, Shinagawa-ku  
Tokyo 140-0002 (JP)

**Representative:** Gille Hrabal  
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40593 Düsseldorf (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 23 November  
2012 refusing European patent application  
No. 05 704 344.0 pursuant to Article 97(2) EPC**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** D. Ceccarelli  
P. L. P. Weber

## Summary of Facts and Submissions

I. The applicant has appealed against the Examining Division's decision, dispatched on 23 November 2012, to refuse European patent application No. 05 704 344.0. The subject-matter of claim 1 of the main and the auxiliary request was found to lack novelty over document:

D1: US-A-2003/0004506.

II. Notice of appeal was received on 22 January 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 21 March 2013.

III. Oral proceedings took place on 15 February 2018.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed during the oral proceedings.

All other requests were withdrawn.

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

"Radio-frequency electric current ablation catheter, comprising a tip electrode (1; 3), a means for detecting temperature of the tip electrode, a catheter shaft (4) and a portion (5) for operation at proximal end, characterized in that, the tip electrode (1;3) has a smooth and smoothly undulated shape with a surface without holes for passing cooling water formed by connecting three or more spherical surfaces having centers on a same straight line to each other with a curved surface."

Claims 2 to 4 are dependent claims.

V. The appellant's arguments may be summarised as follows:

Claim 1 was based on claim 1 and paragraphs [0016] and [0020] of published application EP-A1-1 709 824. More particularly, paragraph [0016] provided a basis for the "smooth and smoothly undulated shape" and paragraph [0020], last sentence, provided a basis for disclaiming the "holes for passing cooling water". The disclaimer introduced had therefore been implicitly disclosed.

There was novelty over D1. In particular, the embodiment of figure 5 of D1 comprised a tip electrode with apertures for supplying cooling fluid, and the tip electrode of the embodiment of figure 2 did not have a shape formed by connecting three or more spherical surfaces having centres on a same straight line to each other with a curved surface.

Considering the embodiment of figure 5 of D1 to be the closest prior art, the skilled person would not close the apertures, since the particular undulated shape of that embodiment was intended to push tissue away from the apertures to create tissue cooling areas which increased the cooling of the surrounding tissue (paragraph [0042] of D1). Closing the apertures would render the undulated shape useless in view of the teaching of D1. If the skilled person wanted to implement internal irrigation, as in the embodiment of figure 2 of D1, for example, he would use the whole electrode tip of that latter embodiment. It followed that the subject-matter of claim 1 was inventive too.

## Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention relates to an ablation catheter with a tip electrode for providing electric current at a radio frequency in order to perform myocardial cautery. This is typically performed to treat cardiac arrhythmia, resulting from regions of the heart having damaged tissue cells which wrongly propagate the electric wave impulses steering heart contractions. The treatment is performed by a catheter driven through the vasculature to those regions inside the heart, to which electric current is delivered in order to create scarring lesions blocking the wrong propagation of the electric waves.

The invention as defined in claim 1 proposes a particular shape for the tip of the catheter, namely "a smooth and smoothly undulated shape [...] formed by connecting three or more spherical surfaces having centers on a same straight line to each other with a curved surface", as shown in figures 1 to 3.

Fig. 1

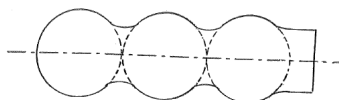


Fig. 2

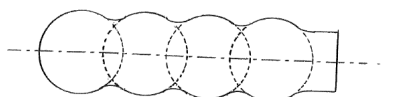
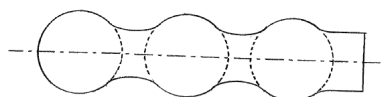


Fig. 3



According to the application, the claimed shape achieves better cooling of the catheter tip by the circulating bloodstream, which makes it possible to apply currents of higher power in order to cauterise larger regions at a greater depth, without exceeding the acceptable temperature at the treatment site (paragraphs [0003], [0004] and [0034], and Table 1).

3. Basis in the original application - Article 123(2) EPC

The present application derives from an international application filed and published in Japanese. Upon entry into the European phase, that application was published as EP-A1-1 709 924, in accordance with Article 158(3) EPC 1973. For the assessment of compliance with Article 123(2) EPC, reference is made to this latter publication, hereinafter "the original application as published".

As the appellant argued, the subject-matter of claim 1 derives from claim 1 and paragraphs [0016] and [0020] of the original application as published.

More particularly, paragraph [0016] discloses a tip electrode with a "smooth" (second sentence) and "smoothly undulated" (first sentence) shape.

As far as the "surface without holes for passing cooling water" is concerned, the Board notes that the description of the original application as published repeatedly states that the catheter can be easily cooled by the circulating bloodstream (paragraphs [0001], second sentence; [0005]; [0016], third sentence; and [0035], first sentence). The figures and examples do not show or describe any holes in the exterior surface of the tip electrode. Paragraph

[0020], which deals with the structure of the catheter in general and with the interior of the catheter shaft in particular, states (last sentence) that "a lumen for passing cooling water may be disposed" inside the ablation catheter. In the Board's view all this amounts to the disclosure of a first (ordinary) alternative of a catheter tip with no provision for cooling irrigation and a second alternative with the provision of an internal lumen in the catheter shaft for cooling irrigation. In this second alternative it is not specified whether the cooling water is to provide flushing irrigation, by exiting the catheter tip through dedicated apertures, or internal irrigation, by circulating within the catheter shaft. In any case, in the first alternative no holes for passing cooling water can be present on the exterior surface of the tip electrode because there is no internal lumen for cooling irrigation and consequently also no opening for bringing cooling fluid around that exterior surface.

For these reasons, the Board is satisfied that a "surface without holes for passing cooling water" is directly and unambiguously disclosed in the application as originally filed, thereby fulfilling the requirements of Article 123(2) EPC.

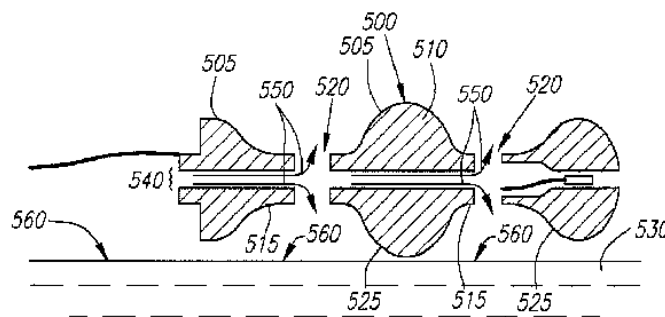
4. Novelty and inventive step - Articles 54 and 56 EPC

4.1 D1 is concerned with ablation catheters with electrodes that are capable of efficiently dissipating heat during an ablation procedure (paragraph [0009]).

The Board agrees with the Examining Division that the embodiment of figure 5 of D1 (reproduced below) discloses a radio-frequency ablation catheter (paragraphs [0001] and [0004]) with a tip electrode



(500), a means for detecting the temperature of the tip electrode (within most distal convex section 525; corresponding to sensor 430 described in paragraph [0040], last sentence), a catheter shaft and a portion for operation at the proximal end (implicit), the tip electrode having a shape formed by connecting three approximately spherical surfaces (undulating outer surface 505).



**FIG. 5**

This embodiment comprises exit ports 520 through which irrigating fluid can exit the electrode for cooling (paragraph [0043]). Hence, it does not disclose a tip electrode surface without holes for passing cooling water as defined in claim 1.

D1 also discloses other embodiments: of catheters with a tip electrode that may have an external surface without holes for passing cooling water (described with reference to figures 2 and 7 in particular). In these embodiments, however, the shape of the tip electrode is not formed by connecting three or more spherical surfaces having centres on a same straight line to each other with a curved surface.

It follows that the subject-matter of claim 1 is novel

over D1 (Article 54(1) and (2) EPC).

- 4.2 In the Board's view the embodiment of figure 5 of D1 is the closest prior art, since the shape of the tip electrode is closest to the one defined in claim 1.

As explained above, the subject-matter of claim 1 differs from that embodiment in particular in that the surface of the tip electrode does not have holes for passing cooling water.

The technical effect associated with this distinguishing feature is that the ablation catheter does not provide flushing irrigation for cooling the surrounding tissue, which makes the catheter easier to manufacture and to operate, as, in particular, no control of the flow rate of a fluid to be delivered to the body is required.

The objective technical problem solved by the distinguishing feature is therefore to simplify the device of D1 and facilitate ablation treatment while maintaining reliable cooling of the surrounding tissue.

As mentioned above, D1 discloses other embodiments: of ablation catheters having a tip electrode with an external surface without holes for passing cooling water. However, for the embodiment of figure 5, D1 stresses the advantages of having the undulated surface exclusively in order to improve the cooling of surrounding tissue when flushing irrigation is employed. More particularly, according to paragraph [0043]:

*"As the irrigating fluid exits the electrode 500 it cools the surrounding tissues 530, e.g., at cooling*

*areas 560. Thus, cooling fluid that may otherwise be blocked by direct tissue contact when using a level irrigated catheter tip, is delivered to the pertinent tissue substantially unimpeded."*

Faced with the objective technical problem and in view of that specific teaching of D1, the skilled person would not have any motivation to modify the embodiment of figure 5 by closing the holes. Rather, if flushing irrigation was to be dispensed with for any reason, it would be obvious for the skilled person to use the whole configuration of the external surface of the tip electrode according to the embodiments of figure 2 or figure 7.

Hence, the subject-matter of claim 1 involves an inventive step in view of the teaching of D1 (Article 56 EPC).

- 4.3 The other documents cited in the international and in the supplementary European search report are less relevant, since none of them teaches the specific shape of the tip electrode as defined in claim 1, in particular with a view to improving its cooling, in operation, by the circulating bloodstream.
- 4.4 For these reasons, the Board is satisfied that the subject-matter of claim 1, and its dependent claims 2 to 4, is patentable in view of the available prior art.
5. The description has been brought into conformity with the amended claims.

## 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:
  - claims 1 to 4 of the main request filed during the oral proceedings;
  - pages 1 to 21 of the adapted description filed during the oral proceedings; and
  - figures 1 to 14 of the original application.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated