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Datasheet for the decision of 18 December 2023

Case Number: T 0368/19 - 3.2.08

Application Number: 11801410.9

Publication Number: 2588026

IPC: A61F2/01, A61B17/12

Language of the proceedings: EN

Title of invention:
LEFT ATRIAL APPENDAGE OCCLUSION DEVICE

Applicant:
PFM Medical AG

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

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

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Case Number: T 0368/19 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 18 December 2023

Appellant: (Applicant)	PFM Medical AG Wankelstrasse 60 50996 Köln (DE)
Representative:	Hohendorf Kierdorf Patentanwälte PartGmbB Hohenzollernring 79-83 (Capitol) 50672 Köln (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 September 2018 refusing European patent application No. 11801410.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	G. Buchmann
Members:	A. Björklund
	F. Bostedt

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the patent application.

The examining division decided that the subject-matter of claim 1 of the main request was not novel over D3 and that auxiliary request I then on file did not involve an inventive step in view of D3 in combination with D5.

II. 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 by letter of 30 October 2023.

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

"A left atrial appendage occlusion device (1, 100, 200) comprising:
(i) an occluder disk (2, 102, 202), configured to substantially prevent blood from at least one of entering and exiting the left atrial appendage;
(ii) a middle portion (97, 197, 297) that includes a coiled element (5, 105, 205), wherein the coiled element (5, 105, 205) connects to the occluder disk (2, 102, 202), has a substantially constant cross section and allows for at least one of variable length, variable orientation, and varied angles of the occlusion device (1,100,200); and
(iii) a first anchoring element (6, 106, 206) that connects to the coiled element characterized in that the first anchoring element (6, 106, 206) includes scalloped edges (96, 196, 296) that are configured to anchor the occlusion device (1, 100, 200) to inner

walls of the left atrial appendage and reduce the risk of one of penetration and perforation of walls of the left atrial appendage.

IV. The following documents are relevant to the decision:

D1 US 2004/044361 A1
D2 WO 01/30267 A1
D3 US 2009/099647 A1
D4 WO 00/72909 A1
D5 EP 1 982 655 A1

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

Novelty

The device disclosed in Figure 8 of D3 was not suitable as a left atrial appendage (LAA) occlusion device due to the size of the anchoring disk 64. Furthermore, it did not have an anchoring element with a scalloped edge.

The subject-matter of claim 1 was thus novel.

Inventive step

The closest prior art was an LAA occlusion device as disclosed in e.g. Figures 14A and 14B of D3 or D1 or D5. The skilled person would not start from another kind of occlusion device.

None of the available prior art disclosed an anchoring portion with scalloped edges suitable for anchoring an occlusion device.

The subject-matter of claim 1 thus involved an inventive step.

Reasons for the Decision

1. Article 123(2) EPC

The main request fulfils the requirements of Article 123(2) EPC. The subject matter of the claims of the main request is disclosed in the application as filed as shown in the following table.

Main request	Published international application
Claim 1	Claim 1
Claim 2	Claims 2 + 3, Paragraph [0047]
Claim 3	Claim 4
Claim 4	Claim 5
Claim 5	Claims 6 + 7, Paragraph [0060]
Claim 6	Claim 8
Claim 7	Claim 9
Claim 8	Claim 10
Claim 9	Claims 11 + 12
Claim 10	Claim 13
Claim 11	Claim 14
Claim 12	Claim 15
Claim 13	Claim 16
Claim 14	Claim 17
Claim 15	Claim 18

2. Article 54 EPC

The subject-matter of claim 1 is novel.

2.1 D3

Figure 8 of D3 discloses a left atrial appendage (LAA) occlusion device.

2.1.1 Neither this figure nor the description explicitly discloses that disk 64 of this occluder has a scalloped edge. Additionally, the fact that it is made of a braided fabric does not necessarily mean that the edges are scalloped, in particular since Paragraph [0069] describes that the fabric is deformed in a mould which re-orients the configuration of the strands.

2.1.2 The decision of the examining division states that "depending on the shape of the LAA which varies considerably from patient to patient, the device of D3, Figure 8 may very well be suited for occluding an LAA" (sentence bridging pages 3 and 4 of the decision).

The examining division regarded reference 62 as the occluder disk, reference 64 as an anchoring element and reference 66 as a middle portion including a coiled element.

It is true that Paragraph [0006] of D3 mentions closure of a left atrial appendage as an example of selective occlusion and that the dimensions of the LAA vary between patients. However, the dimensions of the LAA vary within a certain range and an occluder for the LAA must have suitable dimensions for anchoring within the LAA and occluding the opening of the LAA.

D3 is silent about the intended use of the occluder in Figure 8. The dimensions of the occluder in Figure 8 are also not disclosed. It is thus not directly and unambiguously disclosed that the occluder in Figure 8 of D3 is suitable for occluding a left atrial appendage.

2.2 D1 and D2

In the European search opinion, an objection was raised as to lack of novelty in view of the occlusion devices disclosed in Figures 3 and 4 of D1 and Figures 5 to 8 and 10 to 12 of D2. These objections were not maintained by the examining division.

2.2.1 Figures 3 and 4 of D1 disclose a left atrial appendage occlusion device. This has an occluder disk ("occlusion member 11") connected via a middle portion including a coiled element ("hinge 206") to a "stabilizing element 194". This stabilising element is intended to resist compression and volume changes of the LAA to minimise leakage past the occlusion member 11 (see paragraph [0067]). It is not disclosed that it is provided with an anchoring element which includes scalloped edges as required by the characterising portion of the claim of the main request.

2.2.2 Figures 5 to 8 and 10 to 12 of D2 disclose two embodiments of a left atrial appendage occlusion device. Both embodiments have an occluder disk ("membrane 40") and a middle portion including a coiled portion ("spring 90").

The embodiment of Figures 5 to 8 has an anchoring element ("disk 130") which is positioned outside of the wall of the LAA. It does not, therefore, anchor to the

inner walls of the left atrial appendage. Nor does it have scalloped edges.

The embodiment of Figures 10 to 12 has an anchoring element in the form of umbrella struts. While it anchors to the inner walls of the LAA, it does not have scalloped edges.

The subject-matter of claim 1 thus differs from these occlusion devices in the characterising portion of the claim.

3. Article 56 EPC

The subject-matter of claim 1 involves an inventive step.

3.1 According to established case law, a suitable starting point for assessing inventive step is a prior art document disclosing subject-matter conceived for the same purpose and having the most relevant technical features in common.

3.2 In the present case, the left atrial appendage occlusion device in Figures 3 and 4 of D1, or alternatively in Figures 10 to 12 of D2 may be considered a suitable starting point for the assessment of inventive step, since they comprise a middle portion that includes a coiled element which connects to the occluder disk, and an anchoring element configured to anchor the occlusion device to inner walls of the left atrial appendage.

3.3 As set out above, the subject-matter of claim 1 differs from these occlusion devices at least in the features of the characterising portion.

The effect of these features is that complications due to anchoring are avoided. This is in accordance with paragraph [0053] of the application. Therefore, the objective technical problem is to provide an LAA occlusion device which may avoid complications (due to anchoring).

3.4 None of the available prior art documents suggests that anchoring elements which include scalloped edges could be used to reduce complications due to anchoring.

The subject-matter of claim 1 is thus not obvious to the skilled person and therefore involves an inventive step.

4. The appellant filed an adapted description and requested deletion of Figures 19A and B, 20A and B, 21 A and B, and 22 of the application as filed. The Board finds the amended documents to be in line with 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 examining division with the order to grant a patent on the basis of the following documents:

Claims 1 to 15 of the main request filed by letter of 30 October 2023,
Description pages 1 to 23 filed by letter of 10 November 2023, and

Figures 1 to 18 as published.

Figures 19A and B, 20A and B, 21 A and B, and 22 of the application as filed are to be deleted.

The Registrar: The Chairman:

C. Moser G. Buchmann

Decision electronically authenticated