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**Datasheet for the decision  
of 6 March 2018**

**Case Number:** T 0639/13 - 3.2.02

**Application Number:** 02775909.1

**Publication Number:** 1328199

**IPC:** A61B17/122, A61B17/128

**Language of the proceedings:** EN

**Title of invention:**

THROUGH THE SCOPE ENDOSCOPIC HEMOSTATIC CLIPPING DEVICE

**Applicant:**

Boston Scientific Limited

**Headword:**

**Relevant legal provisions:**

EPC Art. 56, 123(2)

**Keyword:**

Amendments - added subject-matter (no)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 0639/13 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 6 March 2018**

**Appellant:** Boston Scientific Limited  
(Applicant) Clarendon House  
2 Church Street  
Hamilton HM11 (BM)

**Representative:** Vossius & Partner  
Patentanwälte Rechtsanwälte mbB  
Siebertstrasse 3  
81675 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 19 October 2012  
refusing European patent application  
No. 02775909.1 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

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

## **Summary of Facts and Submissions**

- I. The applicant's appeal is against the decision of the Examining Division posted on 19 October 2012 to refuse its application. The subject-matter of claim 1 of the main request was held to lack inventive step in view of D1 (EP-A-738501) combined with D4 (US-A-4733664).
- II. The notice of appeal was filed on 4 December 2012 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 12 February 2013.
- III. In a communication pursuant to Article 15(1) RPBA, the Board informed the appellant that the subject-matter of claim 1 of the main request was inventive but that several formal deficiencies had to be dealt with before an order for grant could be issued.
- IV. The appellant filed amended specification documents on 15 January 2018 and on 28 February 2018.
- V. The appellant requested that a patent be granted on the basis of the main request filed on 15 January 2018, or, in the alternative, on the basis of either the first or the second auxiliary request filed with the statement setting out the grounds of appeal.
- VI. Claim 1 of the main request reads as follows:  
  
"A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising:  
  
a clip (2101), the clip having at least two clip legs (1801);

a control wire (1006; 1803; 2104), the control wire (1006; 1803; 2104) being coupled to the clip;

a frangible link (1005; 1804; 2105) coupling the control wire (1006; 1803; 2104) to the clip;

an axially rigid sheath (1806; 2103) enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire;

a handle coupled to the axially rigid sheath; and

an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip;

characterized in that

the control wire (1006; 1803; 2104) is reversibly operable both to open the at least two clip legs and to close the at least two clip legs;

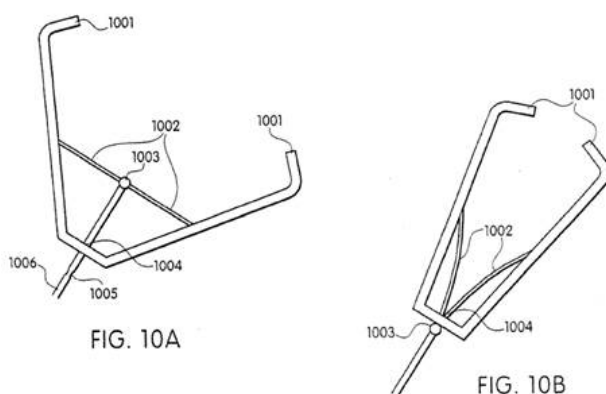
the frangible link (1005; 1804; 2105) is adapted to be broken by a first predetermined tensile force applied by the control wire (1006; 1803; 2104), wherein when the frangible link (1005; 1804; 2105) is broken, the control wire (1006; 1803; 2104) uncouples from the clip."

Claims 2 to 4 are dependent claims.

VII. The appellant's arguments are essentially those on which the following reasons for this decision are based.

## Reasons for the Decision

1. The appeal is admissible.
2. The invention is a clip for haemostasis which can be placed through an endoscope; the clip can be reversibly opened and closed for better positioning before definitive placing. Definitive placing is achieved by application of a force to break a frangible link between the clip and a control wire allowing opening and closing, the wire extending through the endoscope to the proximal end.



3. Claim 1 is a combination of claims 1 and 4 of the application as originally filed, and dependent claims 2 to 4 find support in dependent claims 2, 13 and 14 of the application as originally filed.

Therefore, the requirements of Article 123(2) EPC are fulfilled.

4. Inventive step

The Examining Division considered the subject-matter of claim 1 not to be inventive over a combination of D1 with D4. More precisely, the Examining Division

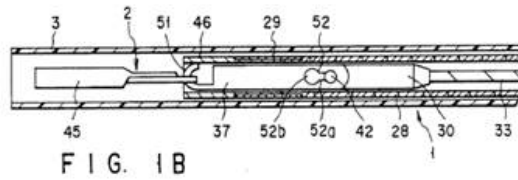
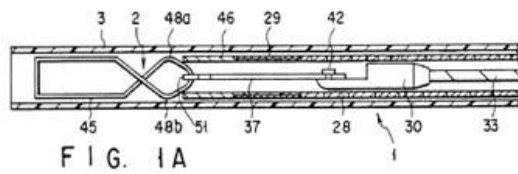
considered all features except the frangible link to be disclosed by D1.

- 4.1 D1 discloses a medical device which is able to deliver a clip for bonding tissue through an endoscope comprising all the features of the first part of claim 1. In this device the frangible link coupling the control wire 33 and the clip is constituted by a hook 51 which is straightened by pulling on the control wire 33 when the clip is to be freed.

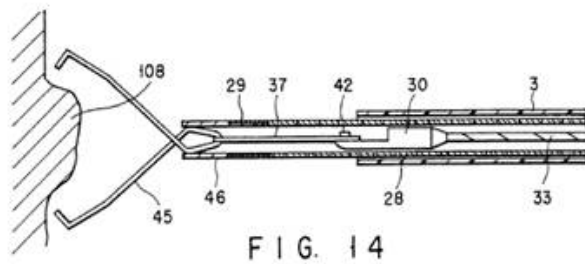
The Examining Division (paragraph 3.2 of its decision) considered that, since it was possible to move the operating wire 33 back and forth relative to the tube 28 and/or the endoscope 3 with the handle 36, this implied that the arms of the clip could be opened and closed at will, such that the feature "*the control wire is reversibly operable both to open [...] and to close the at least two clip legs*" of the characterising portion of claim 1 was disclosed in D1.

The Board finds that the Examining Division's opinion is not confirmed by a mechanical analysis of the disclosure.

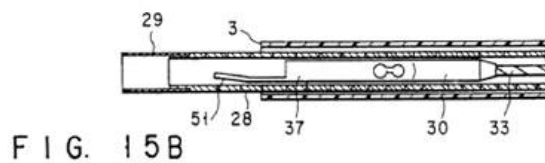
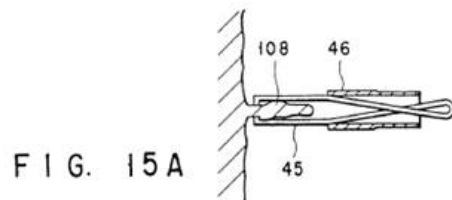
How the clip is placed in the patient's body is described from column 14, line 9, to column 15, line 40. The clip is brought to the desired location inside the patient's body with the endoscope 3 shown in Figures 1A and 1B.



After arrival at the desired location, the clip together with the ring 46 on the tube 28 is pushed out of the endoscope 3. The clip arms are then opened by pulling the clip portions 48a and 48b inside the ring 46 as shown in Figure 14.



When the clip is to be closed, it is pulled further inside the ring 46 until it is held completely closed as shown in Figure 15A. In that position the hook is straightened as shown in Figure 15B.





The ring 46 obviously has to be loosely fitted in the tube 28, otherwise it could not easily be freed from the tube 28 together with the clip. Moreover, as can be seen in Figures 1B and 3A, the clip is loosely attached to the hook 51, and the link 37 is attached to the hook 30 of the control wire 33 with a pin 42 in a longitudinal hole 52a including a larger opening 52b.

The mechanical consequence of the above is that, if the control wire is pushed distally, for instance, when the clip is in the position shown in Figure 14, before the clip can move distally, the length of the longitudinal hole 52a has to be compensated for and the longitudinal play at hook 51 has to be compensated for. Then, since the parts 48a and 48b are (frictionally) trapped within the ring 46, the latter would move distally because it is loosely fitted in the tube 28. Hence, once the parts 48a and 48b of the clip are trapped within the ring 46 it is no longer possible to push them distally out of it.

Therefore, in the Board's opinion, it is clear that, in the device of D1 it was not intended that the clip could be opened and closed reversibly before being definitively closed, as required by claim 1.

4.2 From the above it follows that this is a first differentiating feature.

The second differentiating feature is that the hook 51 is straightened, whereas claim 1 requires the frangible link to be broken.

4.3 The Examining Division considered that document D4 suggested a breakable link as an alternative to the hook used in D1 and, thus, would lead the skilled person in an obvious manner to the subject-matter of claim 1.

4.4 Document D4

This document discloses a tool (a clip applier) for use by a surgeon in order to place a clip to close a wound, in particular for vascular anastomoses (column 1, lines 9 to 20).

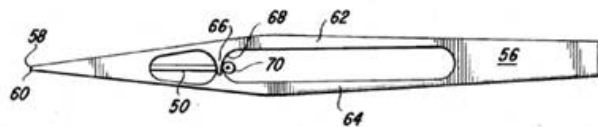


FIG. 5

As can be seen for instance in Figure 2, the clip with its tang 19 is placed in the tool with its curved arms spread apart in an open position. The clip is then placed on the wound sides with the tool deforming the arms into their closed position and breaking the clip away from the tang 19 at a frangible neck 21, as seen in Figures 3 and 4.

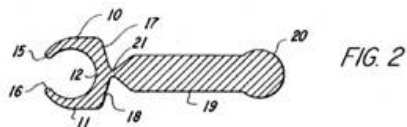


FIG. 2

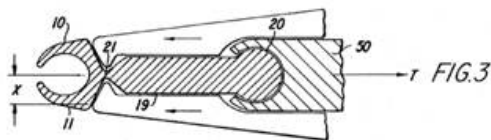


FIG. 3

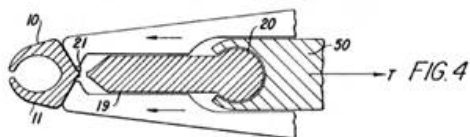


FIG. 4

From this method of operation, it is mechanically self-evident that the material of the clip is plastically deformed into the closed position, otherwise the clip would open again after having been separated from the tang 19. This in turn means that it is impossible to reversibly open and close the clip before placing it definitively. The plastic deformation is clearly mentioned in column 2, lines 35 to 42, and in claim 1 of D4.

- 4.5 It follows that this document does not suggest a reversibly openable and closable clip for improving placement.

Moreover, although this document shows the use of a clip to be broken away from a tang for vascular anastomosis, this is not done in the context of endoscopic surgery, the placing tool being held by the surgeon (column 2, lines 47 to 53). Hence, the tool is not intended for use in an endoscope, and would, in any case, need extensive adaptation in order to be usable in that context.

- 4.6 In the Board's opinion, this means that not only is it questionable whether the person skilled in the art, desiring to improve the endoscopic placement of clips, would consult D4, but also, even if he did so, he would not arrive at the solution of claim 1, because it is not obvious to adapt the device of D4 for use in an endoscope, and because the clip used in D4 is not suitable for opening and closing several times before definitive placing.

Therefore, the subject-matter of claim 1 is inventive starting from D1 in combination with D4.

- 4.7 None of the other documents in the search report discloses a "breakable" connection to a clip, meaning that they cannot suggest the claimed solution either.
- 4.8 Hence, the subject-matter of claim 1 is inventive pursuant to Article 56 EPC.
5. The description as filed on 28 February 2018 is properly adapted to the claims.
6. The Board is satisfied that the formal requirements for the issuance of a communication according to Rule 71(3) EPC are met.

## Order

### For these reasons it is decided that:

The case is remitted to the first-instance department with the order to grant a patent on the basis of:

Claims 1 to 4 of the main request as filed on 15 January 2018;

Description pages 1 to 23 as filed on 28 February 2018;

Drawing sheet 24/27 as filed on 15 January 2018, and drawing sheets 1/27 to 23/27 and 25/27 to 27/27 as originally filed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated