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Datasheet for the decision of 5 November 2020

Case Number: T 0971/16 - 3.2.02

Application Number: 13185438.2

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Title of invention:
Methods and devices for threading sutures

Applicant:
DePuy Mitek, LLC

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
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Catchword:

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Case Number: T 0971/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 November 2020

Appellant: (Applicant)	DePuy Mitek, LLC 325 Paramount Drive Raynham, MA 02767 (US)
Representative:	Tunstall, Christopher Stephen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 November 2015 refusing European patent application No. 13185438.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	Y. Podbielski
Members:	M. Stern
	S. Dennler

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division refusing European patent application No. 13 185 438.2. The application was refused on the grounds that the subject-matter of claim 1 of the main request then on file lacked an inventive step (Article 56 EPC) over document D1 in combination with document D4, where:

D1: EP-A2-2 455 003
D4: US-A-5 906 624

II. Oral proceedings took place on 5 November 2020.

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 with the statement setting out the grounds of appeal on 29 March 2016.

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

"1. A surgical kit comprising:
a suture (100) comprising a biocompatible elongate weave of fibers having a first length (112) with a first pick count and a second length (114) with a second pick count that is greater than the first pick count, wherein the first length (112) defines a first pattern and the second length (114) defines a second pattern that differs from the first pattern and wherein the first length (112) has a reduced bending stiffness as compared with the second length (114) such that, upon application of a bending force, the first length (112) of the suture (100) will more readily deform,

resulting in a reduced cross-section of the first length (112); and

a cannulated anchor (600) having an inner lumen (622) configured to receive the weave of fibers;

characterized in that a doubled over portion of the first length (112) of the weave of fibers is received in the inner lumen (622)."

IV. The arguments of the appellant that are relevant for the present decision may be summarised as follows:

The subject-matter of claim 1 differed from that of D1, particularly the embodiment of Figure 41, in that a doubled over portion of the first length of the weave of fibers is received in the inner lumen of the cannulated anchor, as defined in the characterising portion of the claim. As a consequence, the objective technical problem should be formulated as providing an alternative way of threading the suture of Figure 41 of D1 into the lumen of the anchor. The skilled person would not be motivated to introduce the sleeve 560 of D1 into the anchor in a doubled-over configuration, precisely because of the presence of the stiffening core element described in paragraph [0074]. One of the functions of the stiffening core element was to facilitate the threading of the sleeve 560. However, the stiffening core element was there mainly to resist deformation of the sleeve 560, so that the latter remained open after it had been threaded through the anchor - a key requirement in the device of D1, enabling the filament 564, after the stiffening core element has been removed, to be threaded within the sleeve 560 using a needle-type insertion device as disclosed in paragraph [0074]. On the other hand, a suture threader of the type disclosed in D4 required the suture to double over and hence deform. These two

requirements of D1 and D4, respectively, were fundamentally incompatible. In other words, if the skilled person were to remove the stiffening core element from the sleeve and use a suture threader, tension would be applied to the sleeve as it was pulled through the lumen of the anchor, and as a consequence it would stretch longitudinally and collapse diametrically because there was no longer anything there to prevent this from happening. Owing to this collapse, it would no longer be possible to thread the filament 564 within the sleeve 560 using a needle-type insertion device as disclosed in paragraph [0074] of D1. Even if one were to consider it possible then the threading of filament 564 into sleeve 560 would be much more time-consuming.

Moreover, starting from D1 it was not possible to address the problem that is mentioned in paragraph [0005] of the application, i.e. to utilise an anchor having a small diameter so as to avoid unnecessary trauma.

Reasons for the Decision

1. The claimed subject-matter

The application relates to the threading of sutures through a suture anchor for re-attaching ligaments, tendons or other soft tissue to bone in which the anchor is deployed.

Claim 1 of the sole (main) request is in substance identical to claim 1 underlying the decision under

appeal (merely reference signs and a two-part claim formulation were introduced).

The claimed subject-matter concerns a surgical kit (see Figure 7) comprising, in essence, a suture (100) comprising a biocompatible elongate weave of fibers and a cannulated anchor (600) having an inner lumen configured to receive the weave of fibers, the weave of fibers having a first length (112) with a first pick count and a second length (114) with a second pick count that is greater than the first pick count, wherein the first length has a reduced bending stiffness as compared with the second length such that, upon application of a bending force, the first length will more readily deform, resulting in a reduced cross-section of the first length.

The surgical kit is characterised in that a doubled over portion of the first length of the weave of fibers is received in the inner lumen. The defined pick count refers to the setting used during manufacture of the suture and defines the number of picks (i.e., the number of times the fibers cross) per inch of material (paragraph [0028]).

The doubling-over of the suture as claimed in the characterising portion of claim 1 is a configuration of the suture as it is threaded through the anchor. As depicted in Figures 6 and 7, the first portion (112) is doubled over to be threaded by the threader loop (700), taking advantage of the fact that the first portion's lower pick count and associated lower bending stiffness allows it to deform and/or compress when bent around the loop portion (742) of the threader loop (700) (paragraph [0048]).

2. Inventive step

2.1 Document D1 is considered as the closest prior art. The embodiment of Figure 41, described in paragraph [0073], discloses a snare assembly (540) comprising a braided filament (542) received within an inner lumen of a cannulated anchor (548), the filament having a first length (sleeve 560) with a first pick count and a second length (555) with a second pick count that is greater than the first pick count (column 22, lines 23 to 27).

2.2 One technique for attaching the suture to the anchor is disclosed in paragraph [0074] making reference to Figures 42A to 42D (column 22, lines 31 to 32). It is described, in particular, that sleeve 560 carries a core element which is removed after it has been threaded through the anchor (column 22, lines 40 to 44). As correctly ascertained by the appellant in their letter filed on 14 July 2020 (point 5.5) and during the oral proceedings, it is clear that the core element has the function of resisting deformation of the sleeve, thereby providing it with the necessary stiffness to be threaded into and out of the anchor lumen, in particular around the filament engagement feature 550, of anchor 548 of Figure 41. It can thus directly be inferred that, once the core element has been removed, the first length (sleeve 560) "has a reduced bending stiffness as compared with the second length (555) such that, upon application of a bending force, the first length will more readily deform, resulting in a reduced cross-section of the first length", as claim 1 defines. There is no compelling reason for equating the "first length" as claimed with a combination of sleeve 560 *and* the core element, an interpretation initially advanced

by the appellant in the statement of grounds of appeal, but no longer relied on during the oral proceedings.

2.3 Hence, the subject-matter of claim 1 differs from D1 in its characterising feature, i.e., that a doubled over portion of the first length of the weave of fibers is received in the inner lumen.

This feature defines the (transient) state or condition of the claimed surgical kit in which a portion of the first length of the weave of fibers is doubled over within the inner lumen of the anchor. Although the suture-anchor kit of Figure 41 of D1 is suited for being in such a state or condition, the latter has not been disclosed.

2.4 This differentiating feature vis-à-vis D1 results from threading the suture of Figure 41 of D1 through the lumen of the anchor with a technique different from that described in connection with Figures 42A to 42D. Consequently, the objective technical problem may be formulated as finding an alternative way of threading the suture into the lumen of the anchor. The appellant agreed (during the oral proceedings and in their letter filed on 14 July 2020, point 5.3) that this is indeed the objective technical problem derived from the differentiating feature vis-à-vis D1.

2.5 In search of a solution for the problem posed, the skilled person would resort to document D4. In D4, the free ends of a suture (300) are threaded through the loop (35) of a threader (25), the loop engaging a doubled-over portion of the suture and pulling it through the bore (125) of an anchor (100) (as shown in Figures 12 to 14 and described in column 5, lines 1 to 7). D4 discloses, moreover, that the threader may also

be used with a suture anchor having a suture-receiving bore extending in a longitudinal direction along the length of the anchor (column 5, lines 60 to 65).

2.6 Hence, the person skilled in the art would employ the aforementioned threader of D4 to thread each of filament limbs 545 and 546 of the suture of Figure 41 of D1 through the inner lumen of the cannulated anchor 548. The use of a threader is generally known to be an effective means for passing filaments through narrow passages. This is all the more so when, as in the case of D1, two separate filament limbs (545 and 546) need to be passed through an anchor lumen. Applying the teaching of D4, the skilled person would double-over a portion of each of the filament limbs 545 and 546 around the threader loop. It would be obvious to double-over that portion of filament limb 545 having the lower bending stiffness, that is, sleeve 560 ("the first length" of claim 1), after having removed the core element from within the sleeve. In fact, as mentioned above, one of the purposes of the removable core element is to stiffen the bendable sleeve for threading it through the anchor when using the threading technique of D1 (paragraph [0074]; Figures 42A to 42D). The skilled person would hence recognise that the core element used for poking the sleeve through the lumen of the anchor in the threading method of D1 is no longer necessary when using a threader according to D4 around which the filament limbs are doubled-over.

2.7 The appellant disputed, however, that the skilled person would be motivated to introduce the sleeve 560 of D1 into the anchor using a suture threader as that of D4 in a doubled-over configuration. The stiffening core element had primarily the function to resist

deformation of the sleeve 560, so that the latter remained open after it had been threaded through the anchor. If the skilled person were to remove the core element from the sleeve and use a suture threader for threading the sleeve through the anchor, tension would be applied to the sleeve as it was pulled through the lumen of the anchor, and as a consequence the sleeve would stretch longitudinally and collapse diametrically because there was no longer anything there to prevent this from happening. Owing to this collapse, it would then no longer be possible to thread the filament 564 within the sleeve 560 using a needle-type insertion device as disclosed in paragraph [0074] of D1 (column 22, lines 40 to 46). Even if one were to consider it possible then the threading of filament 564 into sleeve 560 would be much more time-consuming.

2.8 The Board agrees with the appellant that when the sleeve engages the threader loop in a doubled-over configuration and is then threaded through the anchor lumen, the bendable sleeve will be compressed to a certain extent.

However, the Board is not convinced that this compression extends significantly beyond the limited length of the sleeve that engages the threader loop. Moreover, the portion of the sleeve engaging the threader loop will obviously be located at a certain distance from the proximal point of the sleeve where filament end 564 is to be inserted using a needle-type device after having passed through the anchor lumen. Also no reason was given for the assumption that the doubled-over portion of the sleeve remains collapsed after having been threaded through the anchor lumen - D1 is entirely silent concerning the resilience properties of the sleeve. The Board, therefore,

disagrees with the appellant's contention that by using a threader, the sleeve would diametrically collapse so that it would no longer be possible to thread the filament end 564 within the sleeve 560 using a needle-type insertion device, as disclosed in paragraph [0074] of D1 (column 22, lines 40 to 46). Likewise, the Board is not convinced by the appellant's speculation on the increased and time-consuming difficulties the skilled person would face when inserting the filament end 564 into the allegedly collapsed sleeve.

As indicated above, the use of a threader is known to be an effective means for passing filaments through narrow passages. Hence, when the threading technique of D4 is employed for the surgical kit of Figure 41 of D1, the skilled person is enabled to thread sutures through anchors with small diameters, as described in paragraph [0005] of the application.

2.9 As a consequence, the subject-matter of claim 1 of the sole (main) request lacks an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

D. Hampe Y. Podbielski

Decision electronically authenticated