# UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA ORLANDO DIVISION

# BONUTTI SKELETAL INNOVATIONS LLC,

#### Plaintiff,

v.

Case No: 6:13-cv-620-Orl-22TBS

**ARTHREX, INC.,** 

Defendant.

## ORDER

This cause comes before the Court for construction of twelve terms across seven patents.<sup>1</sup> Plaintiff Bonutti Skeletal Innovations LLC ("Bonutti") filed a claim construction brief (Doc. No. 54) to which Defendant Arthrex, Inc. ("Arthrex") filed a Response brief (Doc. No. 64). On January 24th, the Court held a joint claim construction hearing for this case and a highly related action in which Bonutti sued another medical device company for infringement of many of the same patents. All of the patents-in-suit were invented by Dr. Peter Bonutti, and pertain to devices and methods for inserting and anchoring sutures in the course of surgical procedures.

## I. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

The Court construes a patent claim as a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). To construe claims, the Court begins with the words of the claims themselves. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally, the Court accords the words of a claim "their ordinary and customary meaning," which is "the

<sup>&</sup>lt;sup>1</sup> The patents-in-suit include U.S. Patent Nos. 5,782,862 (the "'862 Patent"); 5,921,986 (the "'986 Patent"); 5,980,559 (the "'559 Patent"); 6,569,187 (the "'187 Patent"); 7,087,073 (the "'073 Patent"); 5,814,072 (the "'072 Patent"); and 8,147,514 (the "'514 Patent").

meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Persons of ordinary skill in the art do not read the claim term in isolation, but in the context of the entire patent. *Id.* at 1313. If the ordinary meaning of claim language is "readily apparent even to lay judges," then claim construction requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. But because the meaning of a claim term as understood by a person skilled in the art is often not immediately apparent, the Court looks to both intrinsic evidence (the words of the claims themselves, the specification, and the prosecution history) and extrinsic evidence (sources like dictionaries and expert testimony). *Id.* at 1314 (internal citations and quotation marks omitted); *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1328 (Fed. Cir. 2008).

The patent's specification is "the single best guide to the meaning of a disputed term," as it may reveal that the patentee intended a special definition to apply to a claim term that differs from its ordinary meaning or that the patentee intentionally disclaimed, or disavowed, the claim's scope. *Phillips*, 415 F.3d at 1315-16 (internal citations and quotation marks omitted). The Court also considers the prosecution history, which is created by the patentee in an attempt to explain and obtain the patent. *Id.* at 1317. The prosecution history consists of the complete record of proceedings before the Patent and Trademark Office ("PTO") and the prior art cited during the examination of the patent. *Id.* Unlike the specification, which is a final product, the prosecution history is less useful in claim construction because it represents the ongoing negotiations between the PTO and applicant. *Id.* (internal citations and quotation marks omitted).

The Court also looks at the prosecution history to determine whether the applicant "clearly and unambiguously" disclaimed an interpretation of claim scope in order to obtain the patent grant. Middleton, Inc. v. Minn. Mining and Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985)). A patentee disclaims an interpretation by "clearly characterizing the invention in a way to try to overcome rejections based on prior art," as opposed to simply describing features of the prior art without distinguishing the claimed invention based on those features. Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374-75 (Fed. Cir. 2008) (citations omitted). Thus, the Court protects the public's reliance on the definitive statements made during the prosecution by precluding the patentee from "recapturing" through claim construction an interpretation disclaimed during prosecution. Id. at 1374 (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003)). However, "if the specification expressly defines a claim term, and remarks made to distinguish claims from the prior art are broader than necessary to distinguish the prior art, the full breadth of the remark is not a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term provided in the written description." Computer Docking, 519 F.3d at 1375 (internal quotation marks omitted) (quoting 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1373 (Fed. Cir. 2003)).

Extrinsic evidence, such as expert testimony and dictionary definitions, is helpful but "less significant than the intrinsic record."<sup>2</sup> *Phillips*, 415 F.3d at 1317 (citations and quotation marks

<sup>&</sup>lt;sup>2</sup> Courts accord extrinsic evidence less weight because (1) it is not part of the patent and was not created at the time of patent prosecution; (2) the court construes claims with reference to a hypothetical person of skill in the art, and extrinsic publications may not be written by or for skilled artisans; (3) expert reports and testimony generated at the time and for the purpose of litigation can suffer from bias, unlike intrinsic evidence; (4) the universe of potential extrinsic evidence is "virtually unbounded," and each party is likely to choose the pieces of extrinsic evidence most favorable to its case; and (5) "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of the claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Phillips*, 415 F.3d at 1318-19 (internal citations

omitted). However, expert testimony about claim terms that is conclusory, unsupported or "clearly at odds" with the intrinsic evidence is not useful. *Id.* at 1318. While dictionaries and treatises are relevant, the Court must ensure that the dictionary definition does not contradict a definition "found in or ascertained by a reading of the patent documents." *Id.* at 1322-23 (quoting *Vitronics*, 90 F.3d at 1584 n.6). "In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319. Finally, while the Court construes the claim in light of the intrinsic evidence, it is also appropriate for the Court to consider the accused device when determining what aspect of the claim should be construed. *Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1309 n.10 (Fed. Cir. 2006) (internal citations and quotation marks omitted).

Several other principles guide the Court's construction of claim terms. First, the Court presumes that the same terms appearing in different portions of the claims have the same meaning, unless the specification and prosecution history clearly demonstrate that the terms have different meanings at different portions of the claims. *Fin Control Sys. Pty, Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1318 (Fed. Cir. 2001). While the "[i]nterpretation of a disputed claim term requires reference to the other claims," *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1331 (Fed. Cir. 1999), "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (citation omitted). Finally, "a construction that renders the claimed invention inoperable should be viewed with extreme skepticism." *Talbert Fuel* 

and quotation marks omitted).

*Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002) (citation omitted), vacated and remanded on other grounds, 537 U.S. 802, 123 S. Ct. 70 (2002).

A handful of terms appear in means-plus-function limitations of the asserted patents. A means-plus function limitation is governed by 35 U.S.C. §  $112 \ \mbox{0.6}\ 6$ ,<sup>3</sup> which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Determining whether claim language articulates a means-plus-function limitation is a matter of law. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008) (citation omitted). Claim language that uses the word "means" "creates a presumption that § 112 ¶ 6 applies." *Id.* (citation omitted). "If, in addition to the word 'means' and the functional language, the claim recites sufficient structure for performing the described functions in their entirety, the presumption of § 112 ¶ 6 is overcome—the limitation is not a means-plus-function limitation." *Id.* (citation omitted). However, sufficient structure exists only when "the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *Id.* at 1259-60.

## **II. '072 PATENT TERMS**

The '072 Patent (Doc. No. 54-8) discloses an improved suture anchor inserter that facilitates positioning of the suture anchor within the body and includes an end shaped to pierce

<sup>&</sup>lt;sup>3</sup> Although the recently enacted America Invents Act amended 35 U.S.C. § 112, the old version of the statute applies to the patents asserted in this suit. Regardless, subsection (f) of the new version of the statute is not materially different from paragraph 6 of the old version. *See* Pub. L. No. 112-29, § 4(c)(6), 125 Stat. 284, 296 (2011).

body tissue. Bonutti alleges that Arthrex infringed ten claims of the '072 Patent and/or the reexamined '072 Patent.

## A. "Pierce / Piercing"

Bonutti	Arthrex
Pass through or force a way into or through	to make a hole in or through a surface without a pre-formed opening

The first issue is whether the terms "pierce" and "piercing" require formation of a hole or merely moving through a pre-formed opening. The terms appear in several dozen of the 237 claims in the '072 Patent and the reexamined '072 Patent.

On at least four occasions, the Specification specifically links the terms at issue with forming a hole or opening. *See* '072 Patent at 3:44-45 ("By piercing the body tissue with the point 76, an opening is initially formed"); 7:1-8 ("Manual force is applied to the handle 22 to cause the point 76... to pierce the surface 130. As this occurs, a circular opening is formed in the skin by the point"); 7:26-28 ("The point 76 pierces the flesh 134 ahead of the anchor 30 to initiate the formation of an opening in the flesh for the anchor"); 10:22-26 ("A downward force is then manually applied[,] .... [which] causes the point 76*a* on the shaft 24*a* to pierce the outer side surface 130*a* of the skin 132*a*... As this occurs, an opening is formed by the point 76*a* in the skin 132*a*"). The Specification also contrasts using the inserter "to pierce soft body tissue." '072 Patent at 3:53-55.

Bonutti references the Specification for a passage indicating that the suture anchor inserter could pierce with a pointed tip or a "blunt end," but fails to note that in the latter circumstance, the inserter shaft would have a "cross sectional size" that is "so small as to enable the shaft to pierce

body tissue with a blunt end." '072 Patent at 3:35-43. Bonutti also cites dictionary definitions that include the phrase "pass through" in their definitions of "pierce," but these references are inconsistent and in any event less relevant to the Court's construction than the overwhelming Specification evidence.

Bonutti argues that the doctrine of claim differentiation works in its favor because certain claims in the '072 Patent specifically mention forming an opening in the context of piercing. *See* '072 Patent at 13:17-19, 16:16-17, and 27:23-25. The doctrine of claim differentiation creates a presumption that dependent claims are of narrower scope than the independent claims from which they depend. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) (citation omitted). Therefore, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1314-15 (citation omitted). However, the claim differentiation presumption is "not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history." *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1375 (Fed. Cir. 2008) (quoting *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005)).

In addition to the above-mentioned Specification evidence, the prosecution history in this case clearly supports a construction of "pierce" that requires making a hole. In written remarks to his amended '072 Patent application, Dr. Bonutti distinguished prior art by noting that "there is nothing in the patent to DiPoto et al. which even remotely suggests that the guide wire and anchor will be moved <u>together</u> into an opening formed in body tissue during <u>piercing</u> of the body tissue." (Doc. No. 64-17 at p. 37 (emphasis in original).) In this case, the written description and the

prosecution history overcome the three claims (out of more than 200) that create a potential claim

differentiation presumption.

For these reasons, the Court will construe "pierce" as "make a hole in or through."<sup>4</sup>

## B. "End surface means for piercing body tissue ahead of the first surface area on the anchor

## during insertion of the anchor into body tissue"

Bonutti	Arthrex
Plain Meaning: alternatively.	Function: Piercing body tissue
	(as construed above) ahead of
Function: Passing through	the first surface area on the
body tissue ahead of the first	anchor during insertion of the
surface area on the anchor	anchor into body tissue.
during insertion of the anchor	
into body tissue.	Structure: A point (e.g., 76 in
	'072 Patent drawings, or as
Structure: An end surface and	otherwise described in '072
equivalents.	Patent) on the leading end of
	the shaft that is movable in a
	passage in the anchor.

Arthrex claims that a mean-plus-function limitation arises in Claims 78, 90, 104, and 122 of the '072 Patent. When a patentee uses the word "means" in a claim, a presumption arises that he did so in order to invoke 35 U.S.C. § 112 ¶ 6. *TriMed*, 514 F.3d at 1259. The presumption may be rebutted in one of two ways: "(1) if a claim term uses the word 'means' but recites no function which corresponds, or (2) if the claim recites a function but also recites sufficient structure or material for performing the claimed function." *Bausch & Lomb Inc. v. Moria S.A.*, 222 F. Supp. 2d 616, 630 (E.D.P.A. 2002) (citing *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999)).

 $<sup>^4</sup>$  Arthrex agreed to drop the words "a surface" from its construction. (Doc. No. 64 at 23 n.11.)

Bonutti admits that the claims use functional language, but argues that the term "end surface" specifies sufficient structure to take the limitation outside the scope of § 112, ¶ 6. This is not the case. A claim term might specify sufficient structure if it is itself a structural term or if the claim provides a detailed description of the purported structure. See Envirco Corp. v. Clestra Cleanroom, Inc., 209 F.3d 1360, 1364-65 (Fed. Cir. 2000) (holding that claims containing the phrase "second baffle means . . ." were not means-plus-function claims because the term "baffle" is a technical term with a specific meaning to a person skilled in the art and the claims went on to describe the second baffle as "having inner surfaces for directing airflow . . . ."). In this case, Bonutti does not argue that "end surface" is a technical term known to those skilled in the art to imply a particular structural element, nor is there any further description of the "end surface" in the asserted claims. In contrast, claim 78 uses the term "surface" to refer to multiple different structural components of the shaft that is part of the suture anchor inserter apparatus. See '072 Patent at 22:9-18 (disclosing "end surface means," "pusher surface means," and "positioning surface means"). As such, the Court construes the term "end surface means" as a means-plusfunction limitation under § 112,  $\P$  6.

The first step in construing a means-plus-function limitation is to determine the claimed function. Here, the parties agree that the function is to pierce body tissue ahead of the first surface area on the anchor during insertion of the anchor into body tissue. The Court will cross-apply its construction of "pierce" to this function. The second step is to "ascertain[] the corresponding structure in the written description that is necessary to perform that function." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed. Cir. 2003) (citation omitted). "Corresponding structure" is limited to that which "the specification or prosecution history clearly links or

associates" with the function recited in the claim. *Id.* (quoting *B. Braun Med. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

The dispute over the corresponding structure centers on whether the "end surface" must be pointed or whether it can also be a blunt end, rounded, or flat. Reference to Figure 2 helps to resolve this issue:



'072 Patent at p. 2 (highlights added by the Court). Where the Specification mentions a rounded or flat configuration, it is referring to the "leading end portion 72," which may or may not have "a point 76." '072 Patent at 3:22-34. But according to the Specification, it is the "point 76 on the leading end of the shaft," not the leading end portion 72, that is used to "pierce body tissue." '072 Patent at 3:36-39. Thus, the structure cannot include any "end surface and equivalents" that is mentioned in the Specification, as Bonutti suggests. The Specification does support treating a "blunt end" of the leading end of the shaft as a piercing structure, but only if the blunt end is "so small as to enable the shaft to pierce body tissue." '072 Patent at 3:41-43. This caveat is important, and does not fit under Bonutti's construction of the "end surface" structure. Accordingly, the Court adopts the following constructions of the function and structure:

Function: "Piercing body tissue (as construed above) ahead of the first surface area on the anchor during insertion of the anchor into body tissue."

Structure: A point (e.g., 76 in '072 Patent drawings, or as otherwise described in '072 Patent) on the leading end of the shaft that is movable in a passage in the anchor.

C. "Changing the orientation of the anchor relative to [various elements of the device or body tissue]"

Bonutti	Arthrex
Plain meaning	Changing the axis of the anchor with respect to the axis of the [applicable device element or body tissue]

The suture anchor inserter described in the '072 Patent is designed to facilitate "chang[ing] the orientation" of the anchor relative to the inserter, one of the components of the inserter, or body tissue. The dispute is whether that change in orientation requires changing the axis of the anchor with respect to the axis of the device component or body tissue, or whether any change in the orientation of the anchor (such as rotating the anchor around the inserter shaft or moving the anchor along the shaft) is sufficient.

Importing a limitation from particular embodiments disclosed in the Specification into the claims is typically disfavored. *Phillips*, 415 F.3d at 1323. However, when the embodiments "define the outer limits of the claim term," they may limit the invention as a whole. *Id.* "Claim terms are properly construed to include limitations not otherwise inherent in the term only 'when a patentee sets out a definition and acts as his own lexicographer,' or 'when the patentee disavows the full scope of a claim term either in the specification or during prosecution.'" *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1283 (Fed. Cir. 2012) (quoting *Thorner v. Sony Computer* 

*Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). An inventor acts as his own lexicographer when he "clearly set[s] forth a definition of the disputed claim term other than its plain and ordinary meaning." *Thorner*, 669 F.3d at 1365 (citation and quotation marks omitted). Bonutti argues that limiting the change in orientation to changing the axis of the anchor would amount to importing limitations from the Specification, while Arthrex claims that the limitations it advocates are discussed in the context of the invention, not just preferred embodiments.

In this case, neither the claim language nor the Specification supports Arthrex's proposed limitation. Exemplary claim 46, on which several subsequent claims depend, discloses a "method of positioning a suture anchor in body tissue" that includes a step of "changing the orientation of the anchor relative to the member while the end portion of the member is disposed in the passage in the anchor along with the suture." '072 Patent at 18:31-33. Independent claim 62 also fails to limit how "changing the orientation" must be accomplished. In contrast, the dependent claims following Claims 46 and 62 propose specific methods of changing the orientation: transmitting force from the suture to the anchor by tensioning the suture (claim 53) and/or applying force against an inner side surface of the passage in the anchor with the inserter shaft (claim 54). *Id.* at 19:1-6. Although these dependent claims suggest changing the orientation of the suture by pivoting it around the inserter shaft, the Specification makes clear that a surgeon can "change the orientation of the anchor relative to the body tissue by pivoting or otherwise moving the anchor relative to body tissue." *Id.* at 1:16-20.

Arthrex references prior art that seems to disclose one form of "changing the orientation" that is not specifically taught in the '072 Patent, but this argument is more appropriate as an invalidity defense. Similarly, Arthrex claims that a "screw-in" technique would not infringe, even

under Bonutti's construction of "changing the orientation," but this is, obviously, a noninfringement argument not suitable for claim construction.

The Court adopts the plain meaning of "changing the orientation" because it has no specialized meaning to a person of ordinary skill in the art and neither the claim language nor the written description mandates a more limited construction.

D. "Positioning surface means for engaging an inner surface of the passage in the anchor to position the anchor relative to [said pusher surface means / said shaft] and said end surface means"

Bonutti	Arthrex
Plain meaning; alternatively,	Function: For engaging an inner surface of the passage in
Function: For engaging an inner surface of the passage in the anchor to position the anchor relative to [said pusher surface means / said shaft] and said end surface means.	the anchor to position the anchor relative to said pusher surfaces means and said end surface means [construed to require changing the axis as defined in the previous term].
Structure: A surface and equivalents.	Structure: Outer side surface on the inner member, e.g., 120 in '072 Patent.

This term, which appears in several claims in the '072 Patent, purportedly presents another means-plus-function limitation. Arthrex argues that the term "positioning surface" does not identify sufficient structure to overcome the presumption that § 112, ¶ 6 applies. However, unlike the limitation of "end surface means" discussed in Part II. B. of this Order, the "positioning surface" is well-defined in the applicable claims. "Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function." *Phillips*, 415 F.3d at 1311. Here, the noun before "means" is not a "purely functional placeholder,"

*id.*, and there is a sufficient description of the positioning surface following the function clause to preclude the need to consult the Specification for the appropriate structure. Claim 78 describes the "positioning surface" as follows:

[S]aid positioning surface means extends through the passage in the anchor during insertion of the anchor into body tissue to position the anchor relative to said pusher surface means and said end surface means, said positioning surface means having an axial extent along a longitudinal central axis of said shaft equal to a distance between the first and second surface areas on the anchor.

'072 Patent at 22:18-24. Thus, Claim 78 identifies the location of the "positioning surface" relative to the other key components of the inserter and describes its length and shape.

Given the adequate description of the claimed structure, the Court declines to construe

"positioning surface" as a means-plus-function limitation. Instead, the Court will construe the term

according to the plain meaning disclosed in Claim 78.

## III. '559 PATENT TERM

The '559 Patent discloses new suture anchors, and methods of using sutures together with suture anchors, to secure body tissue. Specifically, the suture anchor expands in the body in order to allow greater tension to be placed on the suture. '559 Patent (Doc. No. 54-5) Abstract.

A. "Material which expands while said s	uture anchor means is disposed in bo	ody tissue"
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Bonutti	Arthrex
Plain meaning	Material which increases in overall size or volume to retain the suture anchor [means] in body tissue, which does not include non- expanding material such as resorbable lactide/glycolide polymers

The primary dispute with respect to the '559 Patent is whether Bonutti disclaimed an anchor made of "resorbable lactide/glycolide polymers" when prosecuting U.S. Patent No. 6,572,635 (the "635 Patent"). The '635 Patent is not asserted in this case, but it is a continuation patent that claims priority to the '559 Patent. Arthrex also supplies a construction of "expands" in the context of the '559 Patent.

A clear and unambiguous disavowal of claim scope during prosecution of a later patent supports a limiting construction in an earlier patent when the patents are directly related in a familial relationship. *Capital Mach. Co., Inc. v. Miller Veneers, Inc.,* 524 F. App'x 644, 649 (Fed. Cir. 2013) (citing *Microsoft Corp. v. Multi-Tech Sys., Inc.,* 357 F.3d 1340, 1350 (Fed. Cir. 2004)).

In this case, the Examiner rejected several claims of the '635 Patent as being unpatentable over U.S. Patent No. 5,021,059 to Kensey (the "Kensey '059 Patent"). (Doc. No. 65-10 at p. 50.) In response, Bonutti distinguished the Kensey '059 Patent by arguing that it "does not disclose or suggest an anchor that expands upon contact with body fluid, as claimed in the present invention." (*Id.*) Bonutti described the "anchoring component 202" of the Kensey '059 Patent as a "thin, narrow, strip of material, such as a resorbable lactide/glycolide that is resistant to deformation." (*Id.*) Crucially, Bonutti argued that, "based on the function and the material from which it is made," the anchoring component disclosed in the Kensey '059 Patent "could not be an expandable material." (*Id.* at pp. 50-51.) Bonutti also noted that the "anchor [disclosed in the Kensey '059 Patent] does not take up fluid." (*Id.* at p. 51.) Finally, in remarks to a subsequent Amendment to the '635 Patent, Bonutti again claimed that "Kensey does not teach or suggest any anchoring component that expands." (*Id.* at p. 67.)

This disavowal is clear and unambiguous. In repeated attempts to distinguish the '635 Patent from Kensey, Bonutti expressly listed an anchoring component made of "resorbable lactide/glycolide" as one that "could not be an expandable material" based in part on the "the material from which it is made." (Doc. No. 65-10 at pp. 50-51.) The point of applying prosecution history disclaimers is to protect the public's reliance on the definitive statements made during prosecution by preventing the patentee from "recapturing" through claim construction an interpretation disclaimed during prosecution. *Computer Docking*, 519 F.3d at 1374 (citation omitted). Therefore, the Court will adopt the following construction of "material which expands": "material that increases in overall size or volume to retain the suture anchor [means] in body tissue, but not including non-expanding material such as resorbable lactide/glycolide polymers."

## IV. '073 PATENT TERM

This patent teaches methods for securing a first body tissue to a second body tissue using a suture that connects two suture anchors inserted into the body tissues. '073 Patent (Doc. No. 54-7) 1:38-54; 2:1-6.

Bonutti	Arthrex
Plain meaning	Measuring when a specific magnitude of tension chosen in advance is present

A. "Determining when a predetermined tension is present"

The parties dispute whether this term requires ascertaining that a specific magnitude of tension, chosen in advance, is present. Bonutti vaguely argues that "the predetermined tension may be a tension that the surgeon selects based on knowledge of the amount of tension that can be exerted on a particular suture or anchor or other experience," and that the tension "need not be a specific measured tension and may be a tension within a general range or of a general amount sufficient to achieve or avoid a specific result." (Bonutti Br. (Doc. No. 54) p. 12.) Bonutti fails to cite the Specification or any other intrinsic evidence for its position with respect to this term.

The claim language, which requires the "determining" at issue here to occur during performance of a separate "tensioning" step, suggests that a specific tension must have been predetermined and subsequently verified as being "present" during the tensioning step. '073 Patent at 65:3-10. The Specification states that "the suture 24 may be tensioned with a force application assembly 60" that "applies a predetermined force," which "has a magnitude which is a function of the size and strength of the suture," and is "indicated schematically by an arrow 62." '073 Patent at 6:22-29. This embodiment also includes "a transducer or load cell 344 [that] is provided to measure the amount of force, indicated by the arrow 62, which is utilized to tension the leg portions ... of the suture." '073 Patent at 29:42-44.



'073 Patent at p. 9 (highlights added by the Court). Another embodiment discussed in the Specification references a different "force measuring device 112" that detects when the desired

tension is present, further suggesting that the tension should be assigned a measurable magnitude. '073 Patent at 8:21-9:34; 36:51-37:48.

The parties agree that the "determining" portion of the term at issue does not require measurement using a specific device. *See* Greenleaf Decl. (Doc. No. 64-1) ¶ 39. The major disagreement occurs over how specific the "predetermined tension" must be, and whether it must be measured at all. The problem with Bonutti's construction, as interpreted by its expert, Dr. Belkoff, is that it does not distinguish the method at issue here from the basic prior art—general surgical practice. If the "predetermined tension" can be nothing more than "a tension within a general range or a general amount sufficient to achieve a specific result," Belkoff Decl. (Doc. No. 54-26) ¶ 72, then any tensioning performed according to any method could conceivably infringe, as long as it is done in approximately the correct amount to achieve the surgeon's desired result. Thus, the Court agrees with Arthrex and adopts the following construction: "measuring when a specific magnitude of tension chosen in advance is present."

#### V. '986 PATENT TERM

The '986 Patent relates to a new method for securing sections of a fractured bone and/or securing body tissue to bone. '986 Patent (Doc. No. 54-4) 1:19-21. A suture extending through a passage in a fractured bone holds sections of the bone against movement relative to each other; alternatively, body tissue may be held against movement relative to bone by a suture extending through a passage in the bone. '986 Patent at 1:21-27. Figure 2 of the '986 Patent demonstrates how this might occur:



'986 Patent at p. 3.

Bonutti	Arthrex
Plain meaning	The [anchor/retainer] is pressed against another side of the fracture of the fractured bone. The 'bone' is the same bone with the first anchor on a first side of the fracture of the fractured bone

Δ	"Transmitting	force from	[anchor/suture	retainer	to hone"
А.	Transmitting	lorce from	Lanchor/suture	retainer	· · · to bolle

Bonutti asserts that the plain meaning of this term is "to cause force to pass from the second anchor/suture retainer to bone on a second side of the fracture." (Bonutti Br. at p. 13.) Arthrex seeks to import two limitations, purportedly from the Specification, into the claim language: (1) that "transmitting" force requires "pressing"; and (2) that the "bone" tied to the transmitting terms is the same bone referenced throughout the claims.<sup>5</sup> In other words, Arthrex claims that the anchor / suture retainer has to press two sides of the same fractured bone together. Although this seems to be the purpose of the invention, Bonutti suggests that the Specification permits a construction that

<sup>&</sup>lt;sup>5</sup> Bonutti suggested in its brief that Arthrex's construction required direct contact between the anchor or retainer and the bone/body tissue to which force is to be transmitted. Arthrex does not pursue such a limitation. (*See* Arthrex Br. (Doc. No. 64) p. 17.)

would allow the "bone" referenced in the claim to be a different bone from the one that is fractured and on which one of the anchors / suture retainers is located.

The claim language is dispositively in favor of Arthrex's construction. The "transmit[ting] force" term appears in four key independent claims: 1, 24, 64, and 76. Claims 1 and 24 teach a method of

treating a fractured bone . . . [by] moving a first anchor connected with a suture through bone disposed on opposite sides of the fracture, tensioning the suture to transmit force from the first anchor to bone on a first side of the fracture with the suture extending across the fracture, and transmitting force from a second anchor to bone on a second side of the fracture.

'986 Patent at 20:6-12. Claim 24 teaches the same method, except the second anchor is replaced by a suture retainer. The claim language plainly describes an invention in which a suture pulls two anchors (or an anchor and a retainer) toward each other, which presses together two sides of a fractured bone. Claims 64 and 76 are even more specific, describing a similar method of "transmitting force from the second anchor to the body tissue to press the body tissue against a second side of the bone under the influence of the force transmitted from the first anchor through the suture to the second anchor." '986 Patent at 25:57-61.

It is also clear that the claimed method applies to a single fractured bone, a bone and a fragment of the same bone, or a bone and body tissue. There is no evidence that the invention applies to transmitting force to "one or more" bones, as Bonutti suggests. The claims would not refer to "bone on a first [/second] side of the fracture" if not referring to opposite sides of the same bone. *See* '986 Patent at 20:6-12. Claim 64 is even clearer, referring to "a passage extending between opposite sides of a bone," "the first anchor on a first side of the bone" and "the second anchor" pressing body tissue against "a second side of the bone." '986 Patent at 25:55-59. Nothing in this claim or any other suggests that a second bone is somehow involved.

The plain language of the claims compels the Court to adopt the following construction: "The [anchor/retainer] is pressed against another side of the fracture of the fractured bone. The 'bone' is the same bone with the first anchor on a first side of the fracture of the fractured bone."

## VI. '862 PATENT TERMS

The '862 Patent discloses a device and method for "accurate[ly] positioning" a suture anchor in soft or hard body tissue. '862 Patent (Doc. No. 54-3) 1:9-20. Claim 69 teaches "[a] method of positioning a suture anchor relative to body tissue" that includes steps of "selecting a depth of insertion of an anchor into body tissue," "moving the anchor into body tissue . . . and effecting relative movement between the inner and outer members," and "blocking relative movement between the inner and outer members," and "blocking relative of the anchor into the body tissue through a distance corresponding to the selected depth of insertion of the anchor into body tissue." '862 Patent at 31:5-18.

A. "Depth of insertion of the anchor into body tissue"<sup>6</sup>

Bonutti	Arthrex
Plain meaning	The "depth" is the measured distance at which an anchor is positioned inside the body tissue that receives the anchor

There are two issues regarding this construction: whether the "depth" must be a measured distance, and whether the anchor must be inserted "inside" body tissue. Bonutti argues that the plain meaning of "depth of insertion of the anchor into body tissue" is the distance the anchor is inserted into the body tissue. Bonutti disputes that the depth must be a measured distance to the

<sup>&</sup>lt;sup>6</sup> The Court's discussion of this term takes care of the disputed means-plus-function claim term—"means for limiting the depth to which the anchor is inserted into body tissue"—because the parties only dispute the function component of the term, not the structure.

extent that the depth must be pre-determined; instead, Bonutti claims that the distance to which the anchor is inserted may be one the surgeon selects based on indicia or markings on the anchor inserter, or one selected based on the surgeon's experience.

The claim language is dispositive as to whether the "depth" must be a "measured distance." The method claim, number 69, does not require the surgeon to measure a distance, nor do the device claims, numbers 147, 153, 158, 164, 167, and 168, disclose a measuring structure or function. Instead, the method claim includes a step of "selecting a depth of insertion," '862 Patent at 31:6-7, and the device claims disclose a feature allowing the surgeon "to select a desired depth of insertion of the anchor into body tissue," '862 Patent at 43:54-56. Thus, the appropriate adjective for "distance" should be "selected," not "measured." Since the claims already provide that the depth will be "selected" by the surgeon prior to inserting the anchor, no additional construction is necessary for this part of the term.

The claims also provide that the anchor is inserted "into body tissue" to a selected depth, but do not specify whether the anchor must be inserted all the way into the body tissue such that it is "inside" the tissue. At least in the context of inserting an anchor into bone, the Specification plainly supports Arthrex's construction, as it describes a suture anchor 40 being inserted through an opening 322 and secured completely inside of bone 324. '862 Patent at 16:11-60. Figures 18-22 show this process:



'862 Patent at p. 10. Although this is just an embodiment of the invention, there do not appear to be any disclosed embodiments in which the anchor is left on the surface of the applicable bone or body tissue. There are also no disclosed embodiments for which the invention would work properly if it were not completely inserted inside of the receiving body tissue. The Court is mindful that "a construction that renders the claimed invention inoperable should be viewed with extreme skepticism." *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002), vacated and remanded on other grounds, 537 U.S. 802, 123 S. Ct. 70 (2002).

The Court construes "depth of insertion of the anchor into body tissue" and "depth to which the anchor is inserted into body tissue" as "distance to which the anchor is inserted inside the body tissue that receives the anchor."

#### B. "Movement relative" / "Relative movement"

Bonutti	Arthrex
Plain meaning	Any and all axial movement between the inner and outer members

Bonutti asserts that the plain meaning of "relative movement" is simply "movement relative to something else." The suture anchor inserter disclosed in the '862 Patent includes both an inner member and an outer member that can move relative to each other. The parties agree that a retainer assembly can, when engaged, restrain axial movement of the inner member relative to the outer member, and vice versa. '862 Patent at 5:4-15. Figures 3 and 4 confirm the Specification, indicating a cylindrical inner member 66 and a cylindrical outer member 68 that are restrained from axial movement when the retainer assembly 92 is engaged:



'862 Patent at p. 4 (highlights added by the Court).

The key issue is not whether the movement is axial or not. Instead, Bonutti claims that Arthrex is attempting to read an "any and all" modifier onto the "relative movement" terms in the Patent that is not present in the claim language. The proposed "any and all" language is not necessary to define the type of "relative movement" that the retainer prohibits; if anything, the proposed language looks suspiciously like a noninfringement argument clothed as claim construction. Had he so desired, the inventor could have claimed a retainer that prohibited "any and all" relative movement. There being no clear reason to limit the term in either the claim language or the Specification, the Court construes "relative movement" according to its plain meaning.

#### **VII. REMAINING TERMS**

Bonutti	Arthrex
Plain meaning	A strand or fiber used to sew
	parts of the living body,
	which is distinct from bone or
	body tissue including muscle,
	ligament, cartilage or other
	tissue

#### A. "Suture" ('986, '514 Patents)

The issue here is whether the "suture" disclosed in these patents must be separate and distinct from bone and body tissue. Although the relevant Specifications state that the suture "may be formed of any desired natural or artificial material," '514 Patent (Doc. No. 54-9) 4:24-28, there is nothing to suggest that the meaning of the term "suture," in the context of the asserted patents, could include ligaments or other forms of body tissue. The patents distinguish sutures from body tissue throughout the Specification and claims; e.g., by stating that "[b]ody tissue may be held

against movement relative to bone by a suture." '986 Patent 1:24-27. Different terms in the same claim are presumed to have different meanings. *Helmsderfer v. Bobrick Washroom Equip., Inc.,* 527 F.3d 1379, 1382 (Fed. Cir. 2008) (citing *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006)).

Additionally, the Court is aware that the Patent Trial and Appeal Board ("PTAB") recently granted petitions to institute *inter partes* review of the '514 Patent and the '986 Patent, and in so doing interpreted "suture" to mean "a thread or wire used for joining of the edges of a wound or incision by stitching" based on its common medical definition. *See Bonutti Skeletal Innovations LLC v. Linvatec Corp.*, No. 6:12-cv-1379-ACC-TBS, Doc. No. 115 (M.D. Fla. Mar. 10, 2014). The PTAB interprets a claim term according to "its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b).<sup>7</sup>

Here, Bonutti provides no evidence that is sufficient to overcome the presumption that different terms in the same claim have different meanings. The Court cannot construe "suture" in such a way as to allow it to mean the same thing as the bone and body tissue that it sews together. The Court adopts the following construction for "suture": "A strand or fiber used to sew parts of the living body, which is distinct from bone or body tissue including muscle, ligament, cartilage or other tissue."

<b>D.</b> Flexible Member (514 Faten	ent)	Pa	4	('51	ber"	Men	xible	<b>"Flex</b>	B.
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Bonutti	Arthrex
Plain meaning	A bendable structure arranged to connect said first anchor and said second anchor, wherein the structure is distinct from a body segment

<sup>&</sup>lt;sup>7</sup> The Court is not bound by the PTAB's construction of a term and does not rely on it here.

# including bone or body tissue

Construction of "flexible member" presents the same dispute as "suture"—whether the term encompasses bone or body tissue. The Court will construe the term in order to clarify that the disclosed "flexible member" in the '514 Patent is distinct from bone or body tissue, but there is no reason to insert synonyms for common words like "flexible" and member." Accordingly, the Court construes "flexible member" as "flexible member, which is distinct from a body segment including bone or body tissue."

Bonutti	Arthrex
Plain meaning; alternatively, a device that retains a suture	A device that grips a suture configured to retain suture that is not implantable into soft or hard tissue, which is distinct from a suture anchor

C. "Suture retainer" ('187, '986, '073 Patents)

The parties dispute two points: whether the "suture retainer" at issue is implantable in body tissue, and whether a suture anchor could be a "suture retainer." The latter issue is easy to resolve, because the various claims and Specifications for the patents-in-suit consistently distinguish between suture retainers and suture anchors. *See, e.g.,* '986 Patent at 22:1-10; 26:52-61. Because different terms in the same claim are presumed to have different meanings, *Helmsderfer*, 527 F.3d at 1382, the Court has no trouble concluding that a "suture retainer" is distinct from a suture anchor.

Bonutti also objects to Arthrex's inclusion of a limitation that a suture retainer is "not implantable." Although this seems to be a consistent limitation in the various embodiments of the asserted patents, the Court does not see the necessity in importing such a broad limitation in its construction of an otherwise simple term. Distinguishing suture retainers from suture anchors should be enough to put the jury on notice that the devices are different. The Court adopts the following construction of "suture retainer": "a device—distinct from a suture anchor—that retains a suture."

## **IX. CONCLUSION**

The Court adopts the following constructions:

Patent	Claim Term	Construction
'072	"pierce / piercing"	"Make a hole in or through"
,072	"End surface means for piercing body tissue ahead of the first surface area on the anchor during insertion of the anchor into body tissue"	<u>Function</u> : "Piercing body tissue (as construed above) ahead of the first surface area on the anchor during insertion of the anchor into body tissue" <u>Structure</u> : "A point (e.g., 76 in '072 Patent drawings, or as otherwise described in '072 Patent) on the leading end of the shaft that is movable in a passage in the anchor"
'072	"Changing the orientation of the anchor relative to [various elements of the device or body tissue]"	Plain meaning
,072	"Positioning surface means for engaging an inner surface of the passage in the anchor to position the anchor relative to [said pusher surface means / said shaft] and said end surface means"	Plain meaning
'559	"Material which expands while said suture anchor means is disposed in body tissue"	"Material that increases in overall size or volume to retain the suture anchor [means] in body tissue, but not non-expanding material such as resorbable lactide / glycolide polymers"
'073	"Determining when a predetermined tension is present"	"Measuring when a specific magnitude of tension chosen in advance is present"
'986	"Transmitting force from [anchor/suture retainer] to bone"	"The [anchor/retainer] is pressed against another side of the fracture of the fractured bone. The 'bone' is the same bone with the first anchor

		on a first side of the fracture of the fractured bone"
'862	"Depth of insertion of the anchor into body tissue"	"Distance to which the anchor is inserted inside the body tissue that receives the anchor"
'862	"Movement relative" / "Relative movement"	Plain meaning
'986, '514	"Suture"	"A strand or fiber used to sew parts of the living body, which is distinct from bone or body tissue including muscle, ligament, cartilage or other tissue"
'514	"Flexible member"	"Flexible member, which is distinct from a body segment including bone or body tissue"
'187, '986, '073	"Suture retainer"	"A device—distinct from a suture anchor—that retains a suture"

DONE and ORDERED in Chambers, in Orlando, Florida on March 25, 2014.

ANNE C. CONWAY United States District Judge

Copies furnished to:

Counsel of Record Unrepresented Parties