

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

TISSUE ANCHOR INNOVATIONS
LLC,

Plaintiff,

CIVIL NO. 2:15CV473

v.

ASTORA WOMEN'S HEALTH, LLC,

Defendant.

OPINION AND ORDER

This case concerns alleged infringements of a single patent owned by Doctor Christopher J. Walshe (“Dr. Walshe”) and for which Tissue Anchor Innovations LLC (“TAI”) is the exclusive licensee. This patent, titled “Tissue Anchor System,” was issued on January 14, 2003 as United States Patent No. 6,506,190 (“the ’190 Patent”). Presently before the Court is the claim construction of several terms found within the claims of the ’190 patent. After careful consideration of the briefs submitted by the parties and the arguments advanced at the *Markman* hearing held on June 20, 2016, the Court issues the following Opinion and Order detailing the claim constructions in this case.

I. FACTUAL AND PROCEDURAL HISTORY

The ’190 patent’s abstract describes the invention at issue in this case as “a tissue-anchoring system, including a tissue-anchoring device and tissue anchors.” Compl., Ex. 1 at Abstract, ECF No. 1-1. The patent discloses a system that “relates to a tissue anchor and applicator for supporting a suture, sling member, or other device for use in a surgical procedure.

In particular, this invention relates to tissue anchors for use in surgical treatment of urinary incontinence.” *Id.* at 1:7-11. TAI filed suit against defendant ASTORA Women’s Health, LLC (“ASTORA”) for patent infringement on October 28, 2015 alleging that a number of the medical devices ASTORA designs and sells addressing women’s health concerns (collectively “ASTORA Systems”) directly and indirectly infringe the ’190 patent. *See* Compl. ¶¶ 11-15, ECF No. 1. On January 13, 2016, after an extension of time granted by the United States Magistrate Judge upon a consent motion filed by ASTORA, ASTORA filed its Answer, denying any infringement and asserting several affirmative defenses, including non-infringement, invalidity of the ’190 patent, prosecution history estoppel, and other legal and equitable defenses. *See* Answer ¶¶ 19-42, ECF No. 25. Additionally, ASTORA alleges two counterclaims in its Answer, seeking declaratory judgment that it has not infringed the ’190 patent and that the ’190 patent is invalid. *Id.* at ¶¶ 10-20.

On April 20, 2016, the parties filed a Joint Statement regarding claim construction that identified claim terms which one or both parties deemed necessary to construe. Joint Statement, ECF No. 33. After the parties fully briefed their positions with respect to claim construction, the Court held a *Markman* hearing on June 20, 2016 at which it heard argument concerning the construction of the disputed claim terms.

II. LEGAL STANDARDS

The United States Supreme Court has explained that “a patent must describe the exact scope of an invention and its manufacture to ‘secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.’” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (quoting *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891)). To that end, a patent “contains a specification describing the invention ‘in such full, clear, concise,

and exact terms as to enable any person skilled in the art . . . to make and use the same” and “one or more claims, which ‘particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.’” *Id.* (quoting 35 U.S.C. § 112). The claims identified in a patent define the scope of a patent grant and are central to resolving patent infringement suits as “[v]ictory [for the Plaintiff] . . . requires a finding that the patent claim ‘covers the alleged infringer’s product or process,’ which in turn necessitates a determination of ‘what the words in the claim mean.’” *Id.* at 374 (quoting H. Schwartz, *Patent Law and Practice* 80 (2d ed. 1995)). “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innoval Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Construing the meaning of the words contained in a claim is a matter of law to be determined by the Court. *Id.* at 388. The purpose of such claim construction is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d* 517 U.S. 370 (1996).

When construing patent claims “there is a heavy presumption that a claim term carries its ordinary and customary meaning.” *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1370 (Fed. Cir. 2003). “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. Moreover, “the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*; *see also Thorner v. Sony Computer Entm’t Am.*

LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (“The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.”) (internal citations omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. As the Federal Circuit has repeatedly held, “a district court is not obligated to construe terms with ordinary meanings, lest trial courts be inundated with requests to parse the meaning of every word in the asserted claims.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (footnote omitted); *see also id.* at 1362 (“[D]istrict courts are not (and should not be) required to construe *every* limitation present in a patent’s asserted claims Claim construction ‘is not an obligatory exercise is redundancy.’”) (quoting *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)) (emphasis in original).

In other cases, however, “determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.” *Phillips*, 415 F.3d at 1314. In such cases, the Court must look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* (internal quotation marks omitted).

When determining the meaning of disputed terms or phrases, the Court must begin with the intrinsic record, which consists of the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. The Court looks first to the claim language, then “to the rest of the intrinsic evidence, beginning with the specification and concluding with the prosecution history, if in evidence.” *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). “Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.” *Vitrionics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The Court, when examining the intrinsic record, first looks “to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention.” *Vitrionics*, 90 F.3d at 1582. Both asserted and nonasserted claims can be “valuable sources of enlightenment as to the meaning of a claim term” because “claim terms are normally used consistently throughout the patent.” *Phillips*, 415 F.3d at 1314. Superfluity is to be avoided if possible when construing claim language. *See Marine Polymer Technologies, Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1368 (Fed. Cir. 2012) (“Where a particular construction of an independent claim would nullify claims that depend from it, the doctrine of claim differentiation creates a presumption that such a construction is improper.”); *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); *Comark Comme'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (recognizing that while “the doctrine of claim differentiation is not a hard and fast rule of construction, it does create a presumption that each claim in a patent has a different scope”). “If the claim language is clear on its face, then [the Court’s] consideration of the rest of the intrinsic evidence is restricted to determining if a

deviation from the clear language of the claims is specified.” *Interactive Gift Express*, 256 F.3d at 1331. As the Federal Circuit has reiterated, there are only two circumstances in which claim interpretation may deviate from the ordinary and customary meaning of the claim terms: “1) when a patentee sets out a definition and acts as its own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); *see also Phillips*, 415 F.3d at 1316–17; *Interactive Gift Express*, 256 F.3d at 1331. An “exacting” standard must be met in order for an inventor to disavow the full scope of a claim. *Thorner*, 669 F.3d at 1366. “If however the claim language is not clear on its face, then our consideration of the rest of the intrinsic evidence is directed to resolving, if possible the lack of clarity. *Interactive Gift Express*, 256 F.3d at 1331.

The Court looks next to the specification to resolve unclear claim language and to “determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning.” *Vitrionics*, 90 F.3d at 1582. “The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention.” *Markman*, 52 F.3d at 979. The specification, as required by statute, describes the claimed invention in “full, clear, concise, and exact terms.” 35 U.S.C. § 112(a). “For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims.” *Markman*, 52 F.3d at 979, *aff’d*, 517 U.S. 370. The specification “may [also] reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.” *Id.* “[A]lthough the specification often

describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments.” *Id.* at 1323.

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive.

Id. “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* at 1315 (quoting *Vitrionics*, 90 F.3d at 1582).

In addition to the claim terms themselves and the specification, the Court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history “consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317; *Vitrionics*, 90 F.3d at 1582. “Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent,” but “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips*, 415 F.3d at 1317. “Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

Finally, the Court may also examine extrinsic evidence, which includes “all evidence

external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. “[W]hile extrinsic evidence ‘can shed useful light on the relevant art,’ [the Federal Circuit has] explained that it is ‘less significant than the intrinsic record in determining the legally operative meaning of the claim.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)) (internal quotations omitted).

With these principles in mind, the Court proceeds with construction of the disputed claim terms.

III. CLAIM CONSTRUCTION

Prior to the *Markman* hearing conducted by the Court, the parties filed a Joint Statement Regarding Claim Construction, ECF No. 33, that included two agreed-upon claim term constructions, an agreement that an element found in Claim 1 should be divided into two phrases and construed separately, and ten disputed claim terms. The Court adopts the parties’ stipulated construction of the agreed-upon terms and the agreed-upon division of an element found in Claim 1 as the Court only need construe claims “to the extent necessary to resolve . . . [a] controversy.” *Vivid Techs., Inc. v. Am. Science Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (internal citations omitted). Accordingly, the term “shaft” as used in Claim 2 is construed to mean “a structure attached to the barb end of the tissue anchor”; the phrase “on said shaft distal from said barb end” as used in Claim 2 is construed to mean “located on the shaft in a direction opposite or away from the barb end”; and the element “said anchor having a barb end and a barb with a tip shaped to penetrate soft tissue position thereon” is interpreted separately as an anchor having a “barb end . . . with a tip shaped to penetrate soft tissue . . .” and a “barb” positioned on the barb end. *See* Joint Statement at 1, ECF No. 33.

Of the remaining ten disputed claim terms, TAI argues six do not require construction. Although the Court may make a determination based on the intrinsic and extrinsic evidence that a claim term needs no construction and should be understood by its plain and ordinary meaning, such a determination “may be inadequate when a term has more than one ‘ordinary’ meaning or when reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). If such a situation arises, the Court will follow the Federal Circuit’s instruction to construe claims “that are in controversy, and only to the extent necessary to resolve the controversy.” *Vivid Techs., Inc. v. Am. Science Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (internal citations omitted); *see also O2 Micro*, 521 F.3d at 1362 (noting that when “the parties present a fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.”). The ten disputed terms are addressed individually herein.

A. “tissue anchor” (Claims 1-8)

The ’190 patent discloses a tissue anchoring system, which includes a tissue anchoring device and tissue anchors. *See* ’190 Patent at Abstract. The parties contest the construction of a key part of this system – the “tissue anchor” used in Claims 1-8 of the ’190 patent.

TAI contends that the proper construction of the term “tissue anchor” is “a rigid device to be inserted into soft tissue to fixedly retain a separate item with respect to the soft tissue.” Joint Statement at 2, ECF No. 33. In support of this construction, TAI argues its proposed construction is consistent with the ordinary meaning of the term “anchor as a device inserted into something to retain a separate item to it” and that this ordinary meaning is evident in the use of the term throughout the ’190 patent. Pl.’s Opening Brief at 7-8, ECF No. 38 (internal quotations omitted). For example, TAI notes that the ’190 patent provides that the tissue anchor “has a tip 130

adapted to penetrate soft tissue,”¹ that the “[t]ip 130 should be fairly rigid to ease tissue penetration,”² that the anchor may be “inserted in or thorough a tissue and anchored by [the] barb,”³ and that “the attachment member [may include] holes[] for attaching sutures or other suitable items,” such as “synthetic mesh [or] graft for later suspension of the vaginal vault to the sacrum.”⁴

In contrast, ASTORA proposes the following construction for “tissue anchor”: “a device capable of independently piercing intact soft tissue and being retained after piercing.” Joint Statement at 2, ECF No. 33. In support of its construction, ASTORA first contends that the ’190 patent describes “tissue anchors” that are capable of independently piercing into or through intact soft tissue⁵ and that the prosecution history demonstrates Dr. Walshe, through counsel, disclaimed or disavowed embodiments of the tissue anchor that were not capable of independently piercing soft tissue by amending the claim language to overcome prior art.⁶

Based on the arguments presented by the parties and a review of the intrinsic and extrinsic record, the Court finds that the ordinary meaning of the term “tissue anchor,” as used in the ’190 Patent, is not readily apparent on the face of the ’190 Patent claim language and requires more than application of widely accepted meanings of commonly understood words. “Tissue anchor” may be subject to multiple ordinary meanings or ordinary meanings that would not resolve the dispute between the parties. Accordingly, the Court finds it necessary to construe the term “tissue anchor.”

The claims and specification indicate, and the parties agree, that the “tissue anchor” is a

¹Pl.’s Opening Brief at 8, ECF No. 38 (quoting ’190 Patent at 13:14-18).

²*Id.* (quoting ’190 Patent at 13:14-18).

³*Id.* (quoting ’190 Patent at 6:55-57).

⁴*Id.* (quoting ’190 Patent at 9:13-19; 11:5-16).

⁵’190 Patent at 7:19-23 (“[p]ortions of anchors 20, however, should be sufficiently rigid to insure that anchor 20 cleanly and precisely penetrates the tissue at the desired location and that a deployed barb will resist removal from tissue.”).

⁶Def.’s Opening Br. at 7-13, ECF No. 40 (discussing Dr. Walshe’s amendments to the ’190 patent claims).

device that is inserted in or through soft tissue. '190 Patent at Abstract (“The tissue-anchoring device includes a housing and a tissue anchor . . . that will be inserted into a tissue or secured onto a tissue.”); *Id.* at 3:14-15 (. . . a tissue-anchoring device that may insert completely through a tissue or partially through a tissue; *Id.* at 6:55-57 (“Viewing FIG. 4a, barb end 21 is adapted to resist removal of anchor 20 after anchor 20 has been inserted in or through a tissue and anchored by barb 40”). As a result, the Court will include “inserted in or through soft tissue” as a feature of the ordinary and plain meaning of the term “tissue anchor.” Although the parties agree on this element of the “tissue anchor,” the parties have at least three primary disputes regarding the remaining construction of the claim centered on whether the device: (1) must be rigid; (2) must be capable of independently piercing the tissue; and (3) fixedly retains a separate item with respect to the soft tissue.

First, in support of the inclusion of the word “rigid” in the construction of “tissue anchor,” TAI argues that the '190 patent specifically describes the “tissue anchor” as rigid. For example, 7:18-23 of the '190 patent reads that “[p]ortions of the anchors 20, however, should be *sufficiently rigid* to insure that anchor 20 cleanly and precisely penetrates the tissue at the desired location” and later, at 13:14-18, “[t]ip 130 should be *fairly rigid* to ease tissue penetration.” (emphases added). In addition, TAI argues that the '190 patent claims are limited to rigid embodiments of the tissue anchor because Dr. Walshe attempted to avoid prior art during the prosecution of the patent by drawing a distinction between his “tissue anchor” and a device constructed of a fibrous absorbable suture material. In opposition to the inclusion of the term rigid, ASTORA argues that the term fails to provide any specific parameter or guidance to the rigidity of the “tissue anchor” and notes that the patent also indicates that though “[t]ip 130 should be fairly rigid to ease tissue penetration,” a “flexible tip 130 is preferred for certain

procedures” ’190 Patent at 13:17-18.

The Court finds it unnecessary and incorrect to include the term “rigid” in the construction of “tissue anchor.” The specification uses two separate qualifiers, “sufficiently” and “fairly,” when describing the rigidity of the tissue anchor and does not describe how to differentiate between the two adjectives. This ambiguity provides little guidance for a person with ordinary skill in the art to determine what level of rigidity is required to fall within the scope of the claim. While the specification does describe embodiments of the tissue anchor that require the device to be sufficiently or fairly rigid, the specification also indicates that, in some contexts, a flexible tissue anchor tip is preferred. *Id.* Thus, the embodiments and descriptions describing a rigid tissue anchor should not be interpreted as universal limitations on the device, but rather as one or more embodiments of the device. Finally, the Court finds that Dr. Walshe did not disavow, disclaim, or limit the scope of “tissue anchor” during the prosecution of the patent. An exacting standard must be met in order for an inventor to disavow the full scope of a claim and although Dr. Walshe did distinguish his claimed tissue anchor from prior art during prosecution by noting the prior art was constructed of a fibrous absorbable suture material, he did not disclaim, disavow, or limit the claim to tissue anchors that were rigid. *See Thorner*, 669 F.3d at 1366. Instead, the prosecution history merely indicates that Dr. Walshe disclaimed any embodiment of the tissue anchor that was made of fibrous absorbable suture material. Accordingly, the Court declines to include the term “rigid” in its construction of “tissue anchor.”

Second, ASTORA claims TAI disavowed or disclaimed any tissue anchor that is not capable of independently piercing soft tissue during the prosecution of the patent. It is clear from the prosecution history that, after having all claims rejected in a non-final Office Action issued on March 28, 2002, TAI amended claims to distinguish the device disclosed in the ’190 patent

from prior art, particularly United States Patent No. 5,948,001 (“Larsen”) and United States Patent No. 5,976,127 (“Lax”). The relevant portion of the prosecution history indicates Dr. Walshe amended the original claims to recite a feature of the tissue anchor “with a tip shaped to penetrate soft tissue.” Decl. of Jonathan Caplan, Ex. 8 at ASTORA 0000195, ECF No. 41-8. In further explanation of the amendment, Dr. Walshe argued during prosecution:

As would be expected, the bone anchor [of Larsen] has a rather blunt or rounded tip which obviously is not shaped to penetrate soft tissue. This is an entirely different concept from a soft tissue penetrating tip such as the 1-3mm needle disclosed at the top of page 12 of the specification or the sharp end 125a in Figure 7a or the sharp tip 130 seen in Figure 8b. Applicant submits that there is no fair reading of Larsen which discloses an anchor with a tip shaped to penetrate soft tissue. Nor is there any suggestion in Larsen to modify its bone anchor to include a sharp tip.

Id. at ASTORA 0000196. In addition to distinguishing the claims from Larsen, Dr. Walshe also distinguished the amended claim from Lax by arguing:

In regards to claim 3, applicant submits that the tip shaped to penetrate soft tissue on the anchor also distinguishes the present invention from Lax. While Lax does in fact disclose a method of securing together two pieces of soft tissue with an anchor device, *Lax does not employ the anchor itself to penetrate the tissue.* Rather, Lax utilizes the sharp edge of tractor 22 (see Figure 11) to penetrate tissue while the distal end 66 of anchor 50 appears to be comparatively rounded. There is no detailed disclosure regarding the tip shape of anchor 50 and Lax only describes anchor 50 as being constructed of a fibrous absorbable material. *It appears nothing in the Lax disclosure suggests that the anchor itself has a tissue penetrating tip.* Therefore, applicant submits that Lax cannot anticipate claim 3 as amended.

Id. at ASTORA 0000196-97 (emphasis added).

Based primarily on this amendment and these explanations, ASTORA argues the Court should include “independently piercing” in its construal of the term “tissue anchor.” At the *Markman* hearing, TAI conceded that the prosecution history, through this amendment, disclaims embodiments of the tissue anchor system where the housing alone is responsible for penetrating soft tissue. However, TAI contends that no such disclaimer applies to embodiments where the

barb end of the tissue anchor is alone responsible for penetrating soft tissue, *see* '190 Patent at 9:47-55, or where the tissue anchor and the shaft both penetrate soft tissue. *See* '190 Patent Figures 3c, 8b, 13:11-15, 6:30-31.

After a thorough review of the claim language, specification, and prosecution history, the Court finds the record does not support the inclusion of “independently piercing” in the construction of the term “tissue anchor.” The claim language and specification of the '190 do not require the tissue anchor itself to be capable of piercing tissue independently. Instead, the claim language and specification describe or depict embodiments where the tissue anchors designed to penetrate soft tissue may be aided in penetrating the soft tissue by other parts or devices. *See* '190 Patent at 5:66-6:11, 8:49-62, 13:4-18, 15:58-19:9, Figs. 13-17. For example, dependent Claim 7 includes an embodiment of the tissue anchor system in which the hollow portion of the housing “has a tip end . . . being shaped to allow said tip end to penetrate tissue” and that also has a tissue anchor with a “barb end . . . with a tip shaped to penetrate soft tissue” as described in Claim 1. '190 Patent at Claims 1, 7. Finally, the prosecution history makes clear that Dr. Walshe disclaimed or disavowed embodiments of the tissue anchor that do not have a tip shaped to penetrate soft tissue; however, the prosecution history does not meet the exacting standard for disavowal or disclaimer for limiting the claim to tissue anchors that are capable of independently piercing soft tissue. There is no indication in the prosecution history that the tip shaped to penetrate soft tissue must itself be used independently or without the aid of other parts or devices when penetrating tissue. Accordingly, the Court declines to include “independently piercing” in its construction of “tissue anchor.”

Finally, ASTORA contends that there is no basis in the claim or specification language for including the term “fixedly retain a separate item” in the construction of “tissue anchor.”

ASTORA argues that this portion of TAI's proposed construction is more appropriately directed to the claim term "attachment member," which is construed separately herein. As previously noted, a "claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co., Inc.*, 395 F.3d at 1372. As a result, the Court agrees with ASTORA's arguments and finds it unnecessary to include "fixedly retain a separate item" in the construction of "tissue anchor," as the claims and specification indicate the attachment member is the portion of the tissue anchor which is used for retaining a separate item and it is construed separately herein.

Having addressed the primary disputes between the parties regarding the construction of this disputed claim term, the Court **FINDS** that, in the context provided by the claim language, specification, and prosecution history, the ordinary and customary meaning of "tissue anchor," as used in Claims 1-8 and as understood by a person of skill in the art at the time of the invention, is "a device capable of being inserted in or through soft tissue and being retained after insertion."

B. "barb end . . . with a tip shaped to penetrate soft tissue . . ." (Claims 1-3)

The parties agree that for purposes of claim construction the phrase "with a tip shaped to penetrate soft tissue" should be construed as modifying the "barb end" of the tissue anchor and not the barbs themselves, although the phrase appears immediately after the term "barb" in Claim 1. *See* Joint Statement at 1, ECF No. 33. As previously noted, the Court adopts this interpretation of the structure of this phrase.

In the Joint Statement, ASTORA proposes that the construction of this phrase should be "leading portion of the tissue anchor for independently piercing soft tissue and having at least one outward projection, and this leading portion of the tissue anchor is sharp and designed to independently pierce intact soft tissue." *Id.* at 4. TAI proposes "the end portion of the tissue

anchor having one or more barb positioned thereon, the end being sufficiently sharp or pointed to easily penetrate soft tissue when being inserted therein.” *Id.*

Although described somewhat differently by the parties in their proposed constructions, the parties appear to generally agree that the “barb end” is the “end” or “leading” portion of the anchor that has “at least one” “or more barbs positioned thereon.” *Id.* ASTORA’s construction of “barb end” needlessly includes a portion of its proposed construction for the term “barb,” which is discussed and construed *infra* at III.C, and inserts the contested notion that the tissue anchor is designed “for independently piercing soft tissue,” which the Court addressed *supra* in III.A. *Id.* Based on the numerous descriptions and figures found within the ’190 patent,⁷ the Court **FINDS** that the ordinary and customary meaning of “barb end,” as understood by a person of ordinary skill in the art at the time of the invention, is “the leading portion of the tissue anchor having at least one or more barbs positioned thereon.”

The parties’ primary dispute regarding the remainder of this claim term arises from the portion of the claim describing the “barb end” as having a “tip shaped to penetrate soft tissue.” ’190 Patent at Claim 1. TAI argues that the barb end with a tip shaped to penetrate soft tissue should be construed as having an end “sufficiently sharp or pointed to easily penetrate soft tissue when being inserted.” In support of this construction TAI claims the ’190 patent describes and depicts tissue anchors with sharp or pointed barb ends and indicates it is designed to “allow easy penetration into tissue,” ’190 Patent at 8:60-62, or “is easily insertable into tissue.” ’190 Patent at 13:30-33. ASTORA contends that TAI’s use of “sufficiently” and “easily” in its construction are overly ambiguous and that reading “easily” into the claim language would be reading in an unsupported limitation to the claim. Def.’s Opening Br. at 14-16, ECF No. 40. While there exists

⁷ See ’190 Patent at 6:31-65; 7:24-35; 9:37-43; 13:25-33; 15:57-67; 18:42-45; Figs. 3c, 4a-h, 5a-5c, 7a-b, 8a-c, 13, and 16a-16g.

some support in the specification in at least two embodiments for including the term “easily” in the construction, the Court finds that TAI’s use of both “sufficiently” and “easily” are overly ambiguous and potentially unnecessary limitations.

In contrast to TAI’s construction, ASTORA, as it did with respect to the construction of the term “tissue anchor,” argues the specification and prosecution history require the “barb end . . . with a tip shaped to penetrate soft tissue” to be capable of independently penetrating soft tissue. As previously detailed in this Order and Opinion *infra* at III.A, the Court finds that while the prosecution history supports the assertion that Dr. Walshe disclaimed embodiments of the device that did not have a tip shaped to penetrate soft tissue, it does not support ASTORA’s claim that the “tissue anchor” or its “barb end . . . with a tip shaped to penetrate soft tissue” need to be capable of doing so independently or without the aid of other parts or devices. Therefore, after thorough review of the record, the Court believes both proposed constructions for “with a tip shaped to penetrate soft tissue” suffer from deficiencies. The Court finds no other intrinsic or extrinsic evidence revealing a meaning different from the plain and ordinary meaning of “with a tip shaped to penetrate soft tissue” and therefore the Court **FINDS** that the term does not need construction as it carries only its ordinary and customary meaning.

Accordingly, the Court **FINDS** that the ordinary and customary meaning of “barb end,” as understood by a person of skill in the art at the time of the invention, is “the leading portion of the tissue anchor having at least one or more barbs positioned thereon.” The Court **DECLINES** to construe “with a tip shaped to penetrate soft tissue” as found in Claims 1-3 of the ’190 patent as the phrase carries only its plain and ordinary meaning.

C. “barb . . . adapted to resist removal from a tissue once inserted” (Claim 1)

The primary dispute between the parties regarding this claim term is whether the patentee

acted as a lexicographer and whether he disavowed the full scope of the claim term. TAI contends the term should be construed to mean “a sharp rigid projection extending backward from the barb end (as from the point of an arrow or fishhook) to prevent easy extraction of the anchor from soft tissue after the anchor has been inserted in or through the tissue.” Joint Statement at 5, ECF No. 33. TAI argues this construction accounts for the dictionary definition that Dr. Walshe provided the Patent Office during prosecution of the ’190 patent, which it asserts evidenced Dr. Walshe’s intent to limit the claims to embodiments meeting the definition proffered during prosecution. *See* Pl.’s Opening Brief at 15-16, ECF No. 38. ASTORA disagrees, arguing that the claimed limitation made during prosecution through Dr. Walshe’s citation of the dictionary definition was made in connection with a different claim element and, in any event, does not amount to a clear disavowal of the full scope of the claim. *See* Def.’s Opening Br. at 17, ECF No. 40. As a result, ASTORA’s proposed construction is “the outward projection at the barb end portion of the anchor resists removal of the anchor once placed in or through a tissue.” *Id.* at 16.

A patentee may act as a lexicographer; however, to do so the patentee “must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning,” *Thorner*, 669 F.3d at 1365 (internal quotations omitted), and indicate an “express intent to impart a novel meaning.” *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000) (internal quotations omitted). Such a meaning should appear with “reasonable clarity, deliberateness, and precision” in the specification or prosecution history.” *Abbott Labs. V. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1354 (Fed. Cir. 2003) (emphasis omitted). While it is undisputed that Dr. Walshe recited the definition of a barb as found in Merriam Webster’s Online Dictionary during the prosecution of the ’190 patent, it is equally clear that Dr. Walshe did not endeavor to set forth a

definition that differed from the plain and ordinary meaning of the term “barb.” Rather, Dr. Walshe recited the dictionary definition in an effort to persuade the Patent Office that its earlier interpretation finding a prior art to disclose a “barbed housing” was incorrect and did not align with the plain and ordinary meaning of “barb.” Decl. of Seth Ostrow, Ex. I at 9-10, ECF No. 39-9. As a result, the Court finds that Dr. Walshe’s use of the dictionary definition in the prosecution history as it relates to this claim term did not evidence intent to impart a novel meaning to the term “barb.” Therefore, the Court finds that Dr. Walshe did not act as a lexicographer in relation to this term.

In addition to arguing Dr. Walshe acted as a lexicographer of this term, TAI contends Dr. Walshe’s quotation of the dictionary definition acted as a disavowal of the full scope of the claim term. In order for the patentee to disclaim a particular construction of a term during prosecution, he or she must make “a clear and unmistakable disavowal of scope during prosecution” by, for example, “explicitly characteriz[ing] an aspect of his invention in a specific manner to overcome prior art.” *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004). An “exacting” standard must be met in order for an inventor to disavow the full scope of a claim. *Thorner*, 669 F.3d at 1366. After thorough review of the prosecution history and specification, the Court finds that Dr. Walshe’s recitation of the Merriam Webster’s Online Dictionary definition of “barb” did not amount to a clear and unmistakable disavowal of the scope of the claim term. As previously discussed, the context of Dr. Walshe’s use and discussion of the Merriam Webster’s Online Dictionary definition of “barb” demonstrates an intent to classify a prior art’s disclosure as falling outside the plain and ordinary meaning of the term “barb,” as opposed to limiting the scope of the ’190 patent. While it is clear that Dr. Walshe did

characterize an aspect of his invention regarding “barbs” during this portion of the prosecution, the characterization was consistent with the plain and ordinary meaning of the term.

Accordingly, the Court **FINDS** that Dr. Walshe did not act as a lexicographer or make disavowals with respect to this term. In addition, the Court finds no other intrinsic or extrinsic evidence revealing a meaning different from the plain and ordinary meaning of this term and believes ASTORA’s proposed construction primarily rephrases or paraphrases the plain meaning of the term. Therefore, the Court **FINDS** that the term does not need construction as it carries only its ordinary and customary meaning to someone with ordinary skill in the art and the Court **DECLINES** to construe “barb . . . adapted to resist removal from a tissue once inserted” as found in Claim 1 of the ’190 patent.

D. “attachment member” (Claims 1-2)

The parties agree that construction of this term is necessary and their primary disputes center on 1) whether the proposed constructions adequately encompass both general embodiments of the attachment members depicted and described in the specification and 2) which construction provides language most helpful for a jury. ASTORA’s proposed construction defines an attachment member as an “engageable structure on the tissue anchor for engaging other items.” Joint Statement at 6, ECF No. 33. TAI proposes “a structure on or connected to the tissue anchor to which one or more other items are attached or such structure adapted to attach one or more other items thereto.” *Id.* at 6-7.

Claims 1 and 2 provide little description of the attachment member, describing it as “an attachment member” in Claim 1 and “said attachment member being positioned on said shaft distal from said bar end” in Claim 2. ’190 Patent at 19:42, 47-49. In contrast, the specification provides depictions and descriptions of a number of embodiments of the attachment member. *See*

'190 Patent at Figures 4a, 4c, 4e, 6a-6g, 10a-10b, 17; 6:46-55; 7:52-67; 8:1-13, 30-34, 49-67; 9:13-19; 10:26-27; 11:14-16; 15:42-44. In particular, the specification indicates, viewing Figures 6a-6g:

attachment member 23 is a structure generally located on shaft 120 for engaging a material, such as a suture or tissue sample, a second barb end, or a tissue-retaining device 23 Tissue-retaining device 27 may comprise a disk-like washer or button . . . or simply a lip that operates in conjunction with attachment member 23 and reversibly mates with attachment member 23. Viewing FIGS. 6a-g, attachment member 23 comprises one or more openings 50a in shaft 120 . . . a ring . . . a tissue clamp . . . ratcheting devices, such as a series of projection figures . . . or annular projections . . . extending radially from shaft 120, or a series of indentations 58 in shaft 120.

'190 Patent at 7:52-67. These depictions and descriptions illustrate at least two principle configurations of the attachment member, one where the attachment member is formed on the tissue anchor and one where the attachment member is a separate structure connected to the tissue anchor.

The Court finds that TAI's proposed construction, while comprehensive, falls short in clarity to ASTORA's construction. However, ASTORA's construction fails to adequately address both embodiments described in the specification. The Court, therefore, **FINDS** that the ordinary and customary meaning of the term "attachment member" as found in Claims 1 and 2 of the '190 Patent, as understood by a person of skill in the art at the time of the invention, is "engageable structure on or connected to the tissue anchor for attaching one or more other items."

E. "tip shaped to penetrate soft tissue" (Claim 1)

"tip end being shaped to allow said tip end to penetrate soft tissue" (Claim 7)

As an initial matter in the construction of these claims, TAI objects to the grouping of these two claim terms together for two reasons: (1) the claim terms refer to different and distinct

claim elements and (2) the excerpt from Claim 1 is already addressed separately as a part of the term “a barb end . . . with a tip shaped to penetrate soft tissue,” construed *supra* at III.B. Joint Statement at 7-8, ECF No. 30. ASTORA concedes in its brief that the limitation “tip shaped to penetrate soft tissue” in Claim 1 was already addressed and agrees, in anticipation that the Court would adopt its previously proposed construction, that “[n]o further construction is necessary” beyond its previous construal. Def.’s Opening Br. at 21, ECF No. 40. In addition, ASTORA concedes that the element in Claim 7, while similar to the element in Claim 1, relates to the housing element of the device – while the relevant excerpt from Claim 1 relates to the barb end of the tissue anchor. *Id.* For these reasons, the Court **DECLINES** to group these two claim terms together and further **DECLINES** to construe “tip shaped to penetrate soft tissue,” as used in Claim 1, beyond the construction previously set forth in this Order and Opinion at III.B.

With regard to the phrase contained in Claim 7, ASTORA argues that the terms should be construed similarly to its proposed construction of the tip of the “tissue anchor,” as previously detailed *supra* at III.A. For the same reasons set forth in that analysis, ASTORA proposes that this term be construed to mean that “the hollow barrel of the fixed exterior portion of the delivery device is sharp and designed to independently pierce intact tissue.” Joint Statement at 8, ECF No. 33. In the event that the Court does not adopt ASTORA’s proposed construction, ASTORA contends the terms are indefinite and that the record does not inform a person skilled in the art with sufficient information to determine what shape and what design can penetrate tissue within the scope of the purported invention. Def.’s Opening Br. at 21, ECF No. 40. In contrast, TAI argues that no construction is necessary and that, in the event construction is deemed necessary, the proper construction is “an end being sufficiently sharp or pointed to easily penetrate soft tissue.” Joint Statement at 8, ECF No. 33.

After thorough review of the intrinsic record, the Court believes both proposed constructions suffer from the addition of unnecessary or unsupported qualifiers. As detailed previously in this Order and Opinion, the terms “independently,” “sufficiently,” and “easily,” are either unsupported by the intrinsic record or overly ambiguous and unnecessary. In addition, the Court finds no other intrinsic or extrinsic evidence revealing a meaning different from the plain and ordinary meaning of this term and believes the parties’ constructions, without the proposed qualifiers, tend to rephrase the plain meaning of the term. Therefore, the Court **FINDS** that the term does not need construction as it carries only its ordinary and customary meaning. Accordingly, the Court **DECLINES** to further construe “tip end being shaped to allow said tip end to penetrate soft tissue” as found in Claim 7 of the ’190 patent.

F. “said anchor being advanced away from said housing upon operation of said plunger” (Claim 1)

ASTORA’s proposed construction for this term is “the anchor moves forward and away from the fixed exterior portion of the delivery device when the plunger is advanced forward.” Joint Statement at 9, ECF No. 30. ASTORA also contends that if its construction is not adopted, the term should be found to be indefinite. *Id.* TAI, in contrast, argues no construction is necessary and, should the Court deem construction necessary, proposes a construction of “the anchor is released from the housing when the plunger is moved within the housing.” *Id.*

The specification explicitly describes the act reflected in this term on multiple occasions. *See* ’190 Patent 6:9-11 (“Anchor end 10 can have any structure engaging anchor 20 that allows plunger 5 to advance anchor 20 into a tissue and uncouple therefrom, leaving anchor 20 in tissue.”); 9:33-36 (“When hollow barrel portion 7 has advanced so that sharp end 125a clears the tissue or is embedded therein, plunger 5 is advanced, releasing anchor 20.”); 9:41-46 (“In this

embodiment, hollow barrel portion 7 is placed against the tissue, and plunger 5 is advanced, forcing anchor 20 into tissue. When anchor 20 has advanced sufficiently into tissue or through tissue, delivery device 1 is withdrawn, leaving barb 40 embedded into tissue.”); 10:68–11:1 (“Plunger 5 is depressed and advances anchor 20 into the space . . . [d]elivery device 1 is withdrawn into the endoscope.”); 19:12-14 (“Generally, anchor 20 will be placed against the desired placement location, and advanced through the scope, using a rigid or flexible plunger 5 (not shown).”). In the context provided by the specification, the Court **FINDS** that the ordinary and customary meaning of this disputed claim term found in Claim 1, as understood by a person of skill in the art at the time of the invention, is “the anchor is advanced and released from the housing when the plunger is moved within the housing.”

G. “housing” (Claims 1, 3-7)

TAI asserts that this disputed term requires no construction and should be afforded its plain and ordinary meaning. In the alternative, should construction be deemed necessary, TAI contends that the proper construction should be “an enclosure for at least a portion of the plunger.” Joint Statement at 10, ECF No. 33. ASTORA, in contrast, proposes the proper construction of this term as: “a fixed exterior portion of the delivery device.” *Id.* In its opening claim construction brief, TAI further alleges that 1) its proposed construction is consistent with the claims and specification as a “common characteristic of the housing in . . . various embodiments is that it encloses a plunger to ensure directed application of said plunger” and 2) ASTORA’s proposed construction introduces ambiguity because the patent does not require the housing to be “fixed” and the term “delivery device” is vague. Pl.’s Opening Br. at 24-25, ECF No. 38. ASTORA contends in its brief that: 1) the ’190 repeatedly describes and depicts the housing as an exterior portion of the delivery device; 2) the housing is fixed and unitary, that is,

it is not collapsible or slidable into any other portions of the delivery device and that the term “fixed” does not exclude embodiments where the housing is “flexible” or “detachable”; and 3) TAI’s construction reads in unnecessarily limitations regarding what the housing encloses. Def.’s Opening Br. at 25-26, ECF No. 40.

The Court declines to adopt ASTORA’s proposed construction for several reasons. First, the term “fixed,” as used in ASTORA’s proposed construction, is itself prone to several interpretations regarding its ordinary and customary meaning and the ’190 patent does not require the “housing” to be “fixed.” As both parties note, the specification depicts or describes embodiments where the housing has portions that may be flexible or detachable and, despite ASTORA’s contentions, the Court believes the term “fixed” could potentially be understood to exclude these embodiments. *See* ’190 Patent at 6:16-31; Figure 3b. Second, ASTORA’s use of the term “delivery device” is redundant and circular, as applied in Claim 1. The Court also declines to adopt the construction proposed by TAI for the reasons set forth by ASTORA in its briefing and arguments at the *Markman* hearing. In particular, although a number of the embodiments of the housing depict or describe it enclosing the plunger, the specification also describes or depicts embodiments where a portion of the anchor may be enclosed in the housing. ASTORA argues, and the Court agrees, that a construction of the term “housing” should not selectively identify features to the housing limitation.

Having addressed the parties’ proposed constructions, the Court **FINDS** that the disputed term does not need to be construed as it carries its ordinary and customary meaning and claim construction regarding this term “involves little more than the application of the widely accepted meaning of [a] commonly understood word[].” *Accumed LLC v. Stryker Corp.*, 483 F.3d 800, 805 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1314). There is nothing in the

claims or specification to suggest that the inventor intended the term to mean anything other than what it says, read in context. Therefore, the Court **DECLINES** to construe the term “housing” as found in Claims 1, 3-7.

H. “plunger” (Claims 1, 3-4)

In the Joint Statement on claim construction, ASTORA contends that the proper construction for “plunger” is: “a member adapted to slide forward and backward within the housing of the delivery device when a force is directly applied to the member.” Joint Statement at 11, ECF No. 33. In contrast, TAI argues that the term does not require construction and, if construction is deemed necessary, that the proper construction is: “a member adapted to slide within the housing.” *Id.*

The Court finds that the jury will be aided by construction of this disputed term as it may be understood to have more than one ordinary meaning. At the *Markman* hearing the parties agreed that if construction is necessary, the proper construction is: “a member adapted to slide forward within the housing of the delivery device when a force is applied to the member.” *See Markman Hr’g Tr.*, ECF No. 68, at 80:14-22 (Mr. Ostrow: “So if we said, ‘a member adapted to slide within the housing’ – or we could say ‘forward’ – ‘of the delivery device when a force is applied to the member,’ yeah, that’s fine with us. The Court: Thank you. Let me hear from Mr. Caplan. Mr. Caplan: Your Honor, I believe that last proposal from Your Honor probably would be acceptable, you know, in terms of modification of our construction for ‘plunger.’”). Because the Court need only construe claims “that are in controversy, and only to the extent necessary to resolve the controversy,” the Court **ADOPTS** the construction agreed upon by the parties at the *Markman* hearing on June 20, 2016, with a minor adjustment reflecting the Court’s understanding of counsels’ comments as reflected in the transcript. Therefore, the construction of

the claim term “plunger” as used in Claims 1, 3, and 4 is “a member adapted to slide forward within the housing of the delivery device when a force is applied to the member.” If either party objects to the construed term as set forth by the Court, that party is **ORDERED** to submit its objection and supporting brief with seven (7) days of the issuance of the Opinion and Order.

I. “said hollow portion of said housing has an axial slot” (Claim 5)

“said axial slot in said housing” (Claim 6)

Again, TAI contends that the two claim phrases do not require construction and, if construction is deemed necessary, that the proper construction is “a lengthwise slot in the hollow portion of the housing.” Joint Statement at 12, ECF No. 33. ASTORA proposes the following construction: “a narrow lengthwise slit on the tip portion of the hollow barrel of the fixed exterior portion of the delivery device.” *Id.*

The parties agreed at the *Markman* hearing that the ordinary meaning of the term axial, as understood by a person with ordinary skill in the art, is “lengthwise” and that the axial slot is understood as being located on the hollow portion of the housing. However, the substantive areas of the parties’ dispute relate to the location and width of the axial slot described in Claims 5 and 6. ASTORA contends that a construction failing to address the shape and location of the slot is overly broad and accordingly contends that the axial slot should be construed as being “narrow” and located “on the tip” of the housing. In contrast, TAI contends that “while the ’190 Patent discloses embodiments where the axial slot is located primarily on the tip . . . it also discloses embodiments wherein the axial slot extends throughout the entire hollow barrel portion.” Pl.’s Opening Br. at 27, ECF No. 38. TAI also noted at the hearing that the claims themselves make no mention of the axial slot being located at the “tip” of the housing and that the word “tip” could potentially be interpreted to refer to at least two areas of the housing.

Because the relevant language used in the Claims 5 and 6 may evoke multiple interpretations, the Court also considers the “remainder of the specification,” *Am. Piledriving Equip. Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1332 (Fed. Cir. 2011), including the “drawings and corresponding discussion in the written description.” *Desper Prods. v. QSound Labs, Inc.*, 157 F.3d 1325, 1336 (Fed. Cir. 1998). The remainder of the specification is limited in its portrayal and discussion of the axial slot referred to in Claims 5 and 6 to Figures 3c, 7a, 8b, and 13 and descriptions found on 6:28-34 and 7:31-42. The specification describes Figure 3c, in part, as follows: “tip 8 has a knife-edge 13 to penetrate tissue. Tip 8 may have a slot 9 starting at the edge 8a of tip 8 and extending down tip 8, substantially along the longitudinal axis” ’190 Patent at 6:31-34. The specification also describes the axial slot depicted in Figure 7a as having a portion of shaft 120 extending “through slot 9 configured in housing sidewalls 9a.” *Id.* at 7:34-36. Based primarily on Figure 3c and its description in the ’190 patent, ASTORA argues the construction of the term should include “narrow” and “on the tip portion.”

As the Federal Circuit has noted, “the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice.” *Phillips*, 415 F.3d at 1323. The Court believes that ASTORA’s inclusion of “narrow” and “on the tip portion” in its proposed construction impose a limitation on the claims stemming solely from limited embodiments portrayed and described in the specification. The specification and claims themselves never describe or define the axial slot as narrow, and while some figures in the ’190 may arguably depict a narrow slot or contain a description of the axial slot being located on and extending down the tip of the housing, the Court heeds the warning of the Federal Circuit “against confining the claims to [specific] embodiments” described in the specification. *Phillips*, 415 F.3d at 1323 (citation omitted). The

Court finds that the claim terms at issue are described rather broadly in the claims themselves and accordingly the Court construes the terms broadly, consistent with the claims, patent specification, and arguments made by the Plaintiff at the *Markman* hearing. Therefore, the Court **FINDS** that the ordinary and customary meaning of the disputed claim terms found in Claims 5 and 6, as understood by a person of skill in the art at the time of the invention, is “a lengthwise slit in the hollow portion of the housing.”

J. “a portion of said anchor partially extends through said axial slot in said housing” (Claim 6)

TAI contends that no construction is necessary for this term beyond the construction of the parts of this phrase that have been set forth elsewhere in this Order and Opinion. In contrast, ASTORA argues that construction is necessary “because the term’s ordinary meaning does not resolve the parties’ dispute.” Def.’s Opening Br. at 30, ECF No. 40. Accordingly, ASTORA proposes that the term should be construed as “at least some portion of the anchor exits through the narrow lengthwise slit on the hollow barrel of the fixed exterior portion of the delivery device.” *Id.* at 29.

Notably, the Court has already addressed construction questions regarding a number of the terms found in this phrase. The only remaining substantive terms which the Court has not addressed are “portion” and “partially extends through,” which ASTORA construes as “at least some portion” and “exits through.” *Id.* The Court finds no indication in the claim terms, specification, prosecution history, or extrinsic evidence that the remaining substantive terms of the phrase have multiple ordinary meanings or an ordinary meaning that would not resolve the dispute between the parties. Therefore, the Court **FINDS** that the phrase as a whole and the individual terms therein do not need to be construed beyond the constructions previously set

forth in this Order and Opinion. Accordingly, the Court **DECLINES** to further construe these terms and **FINDS** the remaining substantive terms to carry only their ordinary and customary meaning.

The Clerk is **DIRECTED** to forward a copy of this Order to all Counsel of Record.

IT IS SO ORDERED.


Robert G. Donnar
Senior United States District Judge
UNITED STATES DISTRICT JUDGE

Norfolk, VA
July 4, 2016