

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS
TEXARKANA DIVISION

ST. JUDE MEDICAL, INC., a Minnesota)
Corporation, and ST. JUDE MEDICAL)
PUERTO RICO LLC, a Puerto Rico Limited)
Liability Company,)

Plaintiffs)

v.)

ACCESS CLOSURE, INC., a Delaware)
Corporation,)

Defendant.)

Case No. 4:08-cv-04101-HFB

JURY TRIAL DEMANDED

CLAIM CONSTRUCTION ORDER

I INTRODUCTION

This claim construction opinion construes the disputed terms in U.S. Patent Nos. 5,275,616 (“the ‘616 patent”), 5,601,602 (“the ‘602 patent”), 5,716,375 (“the ‘375 patent”), 5,725,498 (“the ‘498 patent”) and 7,008,439 (“the ‘439 patent”). Plaintiffs are St. Jude Medical, Inc. and St. Jude Medical Puerto Rico LLC (hereinafter collectively, “St. Jude,” “Plaintiffs”). Defendant is Access Closure, Inc. (hereinafter “Defendant” or “ACI”).

The parties have submitted a number of claim terms for construction and filed claim construction briefs (Doc. Nos. 56, 68, 69, 71, 94, 95, and 96). A tutorial and claim construction hearing was held on January 19 and 20, 2010. Tr. January 19-20, 2010.

For the reasons stated herein, the Court adopts the constructions set forth below.

II SUMMARY OF THE TECHNOLOGY

Catheterization procedures are commonly performed medical events that result in holes in blood vessels. Doc. 56 at 2. A patient’s comfort may vary depending upon the medical treatment applied to promote healing of those holes. Prior to the purported inventions discussed herein, one such medical treatment required patients to endure hours of uncomfortable manual pressure on the skin over the opening in the artery (often involving heavy sand bags) to prevent bleeding. *Id.* The patents at issue in this case describe devices and methods intended to facilitate faster and more comfortable recovery using procedures and tools for sealing the hole in the blood vessel.

There are two distinct patent families at issue in this case. One family emanates from an inventor named “Fowler” and includes the ‘616 patent, the ‘602 patent, and the ‘375 patent (collectively, the “Fowler patents”), all entitled “Insertion Assembly and Method of Inserting a Vessel Plug into the Body of a Patient.” The Fowler patents share a common written description and Plaintiffs are asserting claim 14 of the ‘616 patent; claims 38, 40, and 44 of the ‘602 patent; and claim 21 of the ‘375 patent. Fowler discloses vascular closure devices and methods for positioning a plug to seal a hole in a blood vessel. Among other things, Fowler describes closing or sealing the wound in a blood vessel by using a positioning element to locate a plug “adjacent to the outer surface of the blood vessel duct or lumen.” ‘375 patent, 2:51-66. In one

embodiment, the positioning element is an inflatable balloon that is inserted into the hole in the blood vessel and is expanded. *Id.*, Fig. 3 (shown). The vessel plug is then inserted until encountering resistance from the expanded balloon. *Id.*, 4:64-67. Once the plug is properly positioned, the balloon may be deflated and withdrawn. *Id.*, 5:2-6.

The second patent family involved in this case originates with an inventor named Janzen. The Janzen family comprises the '498 patent, and the '439 patent (collectively, the "Janzen patents"), both entitled "Device and Method for Sealing Puncture Wounds." Like the previous family, the Janzen patents share a common written description. Plaintiffs are asserting claims 7-10 of the '439 patent and claim 1 of the '498 patent against Defendant, ACI.

The Janzen specification also discloses vascular closure devices and methods for positioning a plug to seal the hole in a blood vessel. *See, e.g.*, '439 patent, 1:14-16. In one exemplary embodiment, a guide wire is used in positioning a sheath containing the plug into the tissue tract created during a catheterization procedure. *Id.*, 2:45-54; 7:40-46; Fig. 14. The guide wire guides the plug towards the hole. *Id.*, 7:40-50. Once the end of the plug "is near to or abuts" the hole in the blood vessel, the sheath is withdrawn, leaving the plug next to the hole. *Id.*, 2:45-54; 7:22-29. The plug seals the flow of blood sufficiently so that the blood can, for example, clot. *Id.*, 3:37-43. The plug is later absorbed by the body. *Id.*, 2:21-25.

III LEGAL PRINCIPLES

"A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999) (*quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)). Claim construction is an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996).

In construing patent claims, the court looks to three primary sources: the claims, the specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (*quoting Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). Under the patent law, the specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the

invention. 35 U.S.C. § 112; *id.* at 978. A patent's claims "must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979. "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." *Id.* "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nevertheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's claims. Otherwise, there would be no need for claims. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*en banc*). "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*, 415 F.3d at 1312 (internal quotes omitted). "The claim construction inquiry...begins and ends in all cases with the actual words of the claim." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). There is "a heavy presumption that claim terms carry their full ordinary and customary meaning, unless . . . the patentee expressly relinquished claim scope." *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009). "[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." *Phillips*, 415 F.3d at 1313. Claim construction is not always difficult—it often "involves little more than the application of the widely accepted meaning of commonly understood words." *Id.*, at 1314.

The primacy of claim terms notwithstanding, the Federal Circuit has made clear that "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." See *Phillips*, 415 F.3d at 1313. The Federal Circuit has emphasized the role of the specification as follows:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction. *Phillips*, 415 F.3d at 1316.

Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

While the specification is prominent in claim construction, courts cannot 'import limitations into claims from examples or embodiments appearing only in a patent's written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment.' *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005). The rationale for this rule is straight-forward: '[i]f everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims.' *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Thus, "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect.

Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004).

The court "should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1317. Because the prosecution represents an "ongoing negotiation" rather than the "final product" of the negotiation, "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* The prosecution history only limits the claims when the patentee's intent to surrender claim scope was "clear and unmistakable." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1358 (Fed. Cir. 2003) (finding that a statement "amenable to multiple reasonable interpretations" did not constitute "a clear and unmistakable surrender"). This is a high standard, and generally is met only when the patentee "explicitly characterizes an aspect of his invention in a specific manner to overcome prior art." *Purdue Pharma L.P. v. Endo Pharma, Inc.*, 438 F.3d 1123, 1136-37 (Fed. Cir. 2006) (finding no disavowal of claim scope where inventors touted a feature to overcome the prior art, but that feature was not described as a "necessary feature" of the claimed formulations).

"Extrinsic evidence," on the other hand, "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. *Phillips* made clear that extrinsic evidence is "less

significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (internal cites omitted). A court may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Id.* at 1322-23. Although dictionaries sometimes present difficulties because they collect many different definitions and may describe terms more generally or simply than would one skilled in the art, this is redressed by reading their definitions not as abstract pronouncements, but with the claim language and specification in mind. *Id.* at 1322-24; *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1349 (Fed. Cir. 2005) (in choosing between dictionary definitions, "the task is to scrutinize the intrinsic evidence in order to determine the most appropriate definition").

IV CONSTRUCTION OF THE TERMS

a. *Preambles of Asserted Claims*

i. The Parties' Positions

Defendant makes a blanket request for this Court to hold that all of the preambles of all of the claims at issue are limitations to those claims. Doc. 68 at 7-8; Tr. January 19-20, 2010 at 44-45. Plaintiffs oppose this request. Doc. 69 at 4-5. The preamble issue for each and every claim is not reflected in the Joint Claim Construction Chart Pursuant to Patent Rule 4-5(d). *See* Doc. 72-1.

ii. Analysis

"Generally, the preamble does not limit the claims." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). While claim preambles are not always limiting, "[i]n general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Eaton Corp. v. Rockwell Intern. Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). As such, a preamble is limiting where it is necessary to understand limitations in the body of the claim. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305-06 (Fed. Cir. 1999). However, there is "[n]o litmus test [that] defines when a preamble limits claim scope." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Even a preamble that provides an antecedent basis is not always limiting. *See, e.g., Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 18, 22

(Fed. Cir. 2000) (preamble held not limiting even though it provided an antecedent basis for “said plurality of windows”).

As suggested by the legal authorities cited by the parties and recast above by the Court, the inquiry regarding whether a preamble is a claim limitation, is subtle and claim-specific. This inquiry necessarily involves examination of specifically chosen claim words and the relationship between those words and other items throughout the intrinsic record. During the January 20 hearing, Plaintiffs’ counsel made light of that exact point: “The preamble, the Federal Circuit has told us ‘[t]he preamble does not limit the claims unless it is ‘necessary to give life, meaning and vitality’ to the claims. Well, now there’s the standard for you. So what does this really mean for the preamble to give life and meaning to the claims?’” Tr. January 19-20, 2010 at 45.

Defendant’s blanket request regarding the claim preambles invites the Court to examine each and every asserted claim in five patents to evaluate the possibility that the preamble is a limitation of the claim. Since no specifics regarding that request have been identified in the Rule 4-5 chart, this examination would involve an exploration into each preamble and whether the particularities of the claim body, specification, or file history impact one or more unidentified words in that preamble. In other words, the Court has been asked to find specific issues, assume a dispute, and resolve those issues without understanding the parties’ positions regarding those specific issues.

iii. Holding

The Court declines to undertake the requested analysis. The Court will address preambles as limitations to the extent those issues are relevant to determination of the specific disputes raised by the parties, for example in the Rule 4-5 statement.

b. *“operatively associated with”*

i. The Parties’ Positions

The term “operatively associated with” occurs in claims 38 and 40 of the Fowler ‘602 patent. Plaintiffs propose that no construction is necessary, although alternatively offer the following: “functionally joined, combined or linked.” Defendant asserts that the term is indefinite.

In support of its indefiniteness assertion, Defendant shows that similar or identical phrases were rejected during prosecution of patent applications related to the '602 Patent.¹ Doc. 68 at 8. Defendant asserts that “the examiners rejected the phrase because Fowler failed to disclose the location and structural relationship of the claimed elements. Fowler did not dispute the legitimacy of the three examiners’ rejections. Instead, Fowler either amended the language of the claim in an attempt to cure the indefiniteness or dropped the indefinite claims entirely.” *Id.* Defendant cites *Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1115 (Fed. Cir. 2002) to support its conclusion that applicant acquiesced to the rejections in the related patent applications causing the subject term of the '602 patent to be indefinite as well.

Plaintiffs argue in response to Defendant that in various unrelated cases, both the Courts and the Patent Office have approved the use of the subject words, so the term is not inherently indefinite. Doc. 69 at 5-6 *citing Innova/Pure Water, Inc., v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1120-21 (Fed. Cir. 2004); *also citing* (Faber (Formerly Landis) *On Mechanics Of Patent Claim Drafting* § 3:24 (6th. ed. 2009)) (“[T]he Federal Circuit and the leading treatise on patent drafting both endorse use of the claim terms ‘operatively’ and ‘associated with’ to denote the joining of the recited elements ‘in some kind of relationship’ that allows them to ‘perform the function.’”). Plaintiffs also cite section 2173.02 of the Manual of Patent Examining Procedures (MPEP) for the proposition that “[p]atent examiners make judgments on indefiniteness on a claim by claim basis, not on the kind of scattershot basis that ACI proposes.” Doc. 69 at 6. Plaintiffs note that with respect to the prosecution of the '602 patent, the Patent Office examiner rejected the phrase “operatively associated with” in pending claim 25, but not in pending claim 33, demonstrating that the examiner was properly performing his diligence in reviewing the language across all the claims. Doc. 71 at 6. Finally, Plaintiffs point out alleged inaccuracies in Defendant’s assessment regarding the indefinite rejections in the related patent applications. *Id.*

Defendant disagrees with Plaintiffs’ allegation regarding inaccuracies and contends that those perceived inaccuracies actually support Defendant’s view. Doc. 69 at 2-3.

¹ Defendant's Supplemental Sur-Reply identifies similar material. Doc. 94 at 4.

ii. Analysis

The second paragraph of 35 U.S.C § 112 requires that the “specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C § 112, ¶ 2. Claims that do not meet those requirements are considered *indefinite* “when they are not amenable to construction or are insolubly ambiguous. Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning. Indefiniteness requires a determination whether those skilled in the art would understand what is claimed.” *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1367 (Fed. Cir. 2010). The purpose of the definiteness requirement is to ensure that “the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the scope of the patentee’s right to exclude.” *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1339 (Fed. Cir. 2003).

Claims 38 and 40 are reproduced below with the subject claim language in bold.

38. An assembly for sealing or closing an incision or puncture in the body of a living patient wherein the incision or puncture extends into a blood vessel or an organ of the patient, the assembly comprising:

an elongate shaft member having a proximal end and a distal end and having an expandable member disposed at said distal end, said expandable member constructed to be positioned alternatively in a relaxed condition and an expanded condition;

said shaft member and said expandable member dimensioned to be inserted within the puncture so that said expandable member is positioned within a target organ or blood vessel of the patient;

control member operatively connected to said expandable member and associated with said shaft member for selectively positioning said expandable member between said expanded condition and said relaxed condition; and

a vessel plug ***operatively associated with*** said shaft member for insertion into the puncture, said expandable member configured to cooperate with said plug when said expandable member is in said expanded condition to prevent said vessel plug from entering the vessel or the organ of the patient, and said vessel plug, when sealingly positioned within the puncture, extends proximally of the target organ or blood vessel without extending into said vessel or said organ.

40. An apparatus for sealing or closing an incision or puncture in the body of a living patient wherein the incision or puncture extends into a blood vessel or an organ of the patient, the apparatus comprising:

a tubular member having a proximal end and a distal end and having an expandable member disposed at said distal end of said catheter, said expandable member constructed to be positioned alternatively in a relaxed condition and an expanded condition;

said expandable member dimensioned to be positioned within a target organ or blood vessel of the patient and constructed to permit blood and other body fluids to pass through the target organ or blood vessel while said expandable member is positioned therein;

a control member operatively attachable at one end thereof to control expansion of said expandable member through said tubular member; and

a vessel plug *operatively associated with* said tubular member and said expandable member, said vessel plug dimensioned to close the puncture or incision, said expandable member, when in said expanded condition within said blood vessel or said target organ, preventing said vessel plug from extending into said vessel or said organ.

Reading the claims in light of the specification, the Court finds that the term “operatively associated with” is readily understood in describing both the relationship between the vessel plug and the “tubular member and said expandable member” (claim 40) and the relationship between the vessel plug and “said shaft member for insertion into the puncture” (claim 38). For example, referring to claim 38, there is “operative association” in that the shaft is positioned with respect to the plug so that the expandable member (*e.g.*, a balloon) prevents the plug from entering the blood vessel. The relative position of the components is a structural relationship and the way the plug and vessel work together is a functional relationship. The specification describes this well: “The vessel plug 20 is then inserted into the incision along the shaft of the balloon catheter 22 until the distal end 32 of the vessel plug 20 contacts the inflated balloon 24 on the distal end 26 of the balloon catheter 22. In this position, the distal end 32 of the vessel plug 20 is aligned with the outer lumen of the artery 10 and the balloon 24 prevents the vessel plug 20 from extending into the artery 10.” ‘602 patent, 4:66-5:5.

The Court is not persuaded by Defendant’s arguments regarding Patent Office rejections of similar language on related patent applications. As Plaintiffs point out, indefiniteness is considered for a particular claim as a whole. MPEP § 2173.02 (“In reviewing a claim for

compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 U.S.P.Q. 2d 1279, 1283 (Fed. Cir. 2000).” When considered as a whole, the phrase “operatively associated with” is readily understandable in claims 38 and 40 of the ‘602 patent.

iii. Construction

The Court construes the term “operatively associated with” to mean “functioning in combination with,” because this best describes the claimed interaction of the vessel plug and the items respectively claimed to be “operatively associated” therewith.

c. *“lumen” as occurring in the Fowler ‘616 patent*

i. The Parties’ Positions

The term “lumen” occurs in the ‘616 and ‘498 patents. At the outset, the parties disagree regarding whether the term should have the same construction with respect to both patents. For example, in the ‘616 patent the term “lumen” only occurs in the preamble of claim 9 so there is some dispute regarding whether construction of the term is necessary. To the extent a construction is necessary, Plaintiffs propose the construction “space within a vessel or organ and the walls surrounding the space.” Alternatively, Defendant proposes the construction “open space within a vessel or organ.”

Plaintiffs argue that “as a general matter, ‘lumen’ refers just to the space within a vessel or organ, [but] St. Jude’s proposed definition of ‘lumen’ acknowledges Fowler’s particular use of the word in the claims and specification, referring to a space within a vessel *and also the walls surrounding that space.*” Doc. 56 at 11 (emphasis in original). In support of its contention that vessel walls are part of the “lumen,” Plaintiffs note the legal principle that a patentee may be his own lexicographer and point to places in the specification and claims where the alleged usage of “lumen” includes the vessel wall. First, Plaintiffs cite the claim language, which states “through the lumen of a blood vessel and into the blood vessel of a patient.” Plaintiffs reason that, “[t]o get into the blood vessel the device needs to go ‘through the lumen,’” which would have to be

the vessel wall. Doc. 56 at 11-12. Plaintiffs bolster this point stating that “Fowler’s specification refers to the exterior of the arterial wall as the ‘outer lumen of the artery’ and the interior of the arterial wall as the ‘inner lumen of the artery.’” Doc. 56 at 12, *citing* ‘375 patent, 4:37-40; 4:60-63. Lastly, Plaintiffs object to Defendant’s suggestion that the “lumen” constitutes “open space.” Doc. 056 at 12. Plaintiffs contend that the specification is clear that blood may fill the vessel so the lumen need not be “open space.” *Id. citing* ‘375 patent, 4:37-40.

Defendant argues that the term “lumen” must be construed because it is a key part of the claimed incision and affects both the length and location of that incision, which determines the dimensions and position of the vessel plug. Defendant also argues ordinary meaning must govern this term and that the “burden to overcome the ordinary meaning of ‘lumen’ is a high one—the Federal Circuit requires that a patentee ‘must clearly express’ the intent to redefine a term. *Merck & Co. v. Teva Pharms., Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005).” Doc. 68 at 10. Defendant contends that the high burden cannot be met, because Plaintiffs’ citations show only a lack of clarity. *Id.* Further, Defendants press that if a term is unclear, this Court must adopt its most narrow construction. *Id., citing, Genentech, Inc. v. Wellcome Found.*, 29 F.3d 1555, 1564 (Fed. Cir. 1994). Defendant also argues that including vessel walls in the construction of “lumen” would exclude the preferred embodiment as shown in figures 3-4 and 6-9. *Id.* Finally, Defendant argues that claim 9’s preamble phrase “through the lumen and into the blood vessel” is not redundant because it may refer to a “double-wall technique” shown in the prior art.

ii. Analysis

Claim 9 of the ‘616 reads as follows:

9. A method of sealing an incision formed in the body of a patient ***wherein the incision extends generally from the skin of the patient; through the lumen of a blood vessel and into the blood vessel of a patient***, the method including the steps of:

forming a vessel plug of a material which is absorbable in the body of the patient and wherein the vessel plug is formed to include distal and proximal ends therein and is dimensioned to be received in the ***incision***; and

positioning the vessel plug in the *incision* such that the distal end of the vessel plug is located proximally of the blood vessel to seal the *incision* from the flow of blood passing through the blood vessel.

‘616 Patent, claim 9 (emphasis added).

The Court agrees with Defendant regarding the importance of the preamble relative to the body of claim 9. The preamble defines the “incision” that is a primary frame of reference in the body of the claim. In general, a preamble is construed as a limitation “if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc.*, 182 F.3d at 1305). “A preamble is not limiting, however, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Symantec Corp. v. Computer Assocs. Int’l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (citations and quotations omitted). Here, a phrase of the preamble serves as antecedent basis for the “incision” term in the body of the claim: “wherein the incision extends generally from the skin of the patient; through the lumen of a blood vessel and into the blood vessel of a patient.” In particular, the quoted preamble phrase defines the incision that is referenced in the claim body as “the incision.” Thus, the Court finds the entire phrase is a limitation of the claim.

The parties dispute the meaning of the term “lumen” within that phrase. The Court finds that the term must be given its ordinary meaning because there is no clear expression that the patentee redefined that term. The Court acknowledges that the patent’s use of the phrases “inner lumen” and “outer lumen” introduce ambiguity as to whether the patentee was referring to vessel walls or some portion of the lumen adjacent the vessel walls. However, this potential ambiguity does not clearly redefine the term lumen to include the vessel wall. Indeed, to the extent the patentee was defining anything with those terms, he was discussing the phrasal terms “inner lumen” and “outer lumen,” which are irrelevant to our inquiry because those phrasal terms are not used in the claims. In sum, the Court construes the term “lumen” consistent with its ordinary meaning.

Having found that the term “lumen” should have its ordinary meaning, the Court now turns to claim 9’s larger preamble phrase, “the incision extends generally from the skin of the patient; through the lumen of a blood vessel and into the blood vessel of a patient.” On its face, this preamble phrase requires that the incision must be “from the skin . . . through the lumen . . . and into the blood vessel of a patient.” So the preamble defines the starting point of the incision as “the skin” and the end point as in “the blood vessel of a patient.” The intermediate phrase “through the lumen” designates that the incision extends past the vessel wall “through” some portion of the lumen. This intermediary phrase is not redundant of the final phrase (“into the blood vessel of the patient”) because the final phrase defines the end point and the intermediary phrase does not. The intermediary phrase “through the lumen” provides no indication regarding how much of the lumen is traversed by the incision. It is the final phrase, “into the blood vessel,” that defines the termination of the incision as some point within the lumen. Thus, the preamble does not provide for the incision to go “completely” or “entirely” through the lumen. Finally, in view of the foregoing, the Court finds that the “double-wall” technique (as described by Defendant) is clearly inconsistent with teachings of the ‘616 patent and the body of claim 9. *See* Doc. 71 at 3-4. The claim 9 preamble is not describing the double-wall technique.

iii. Construction

For claim 9 of the ‘616 patent, the Court construes “lumen” to mean “space within a vessel or organ.” Further, with respect to the preamble of claim 9, the parties are instructed to tailor their trial arguments to be consistent with this Order.

d. *“lumen” as occurring in the Janzen ‘498 patent*

i. The Parties’ Positions

As noted above, Plaintiffs propose that the construction of the term “lumen” should differ between the Fowler and Janzen patents. For Janzen, Plaintiffs propose that the claim have its ordinary meaning, which Plaintiffs propose as “space within a vessel or organ.” Doc. 56 at 17. Defendant also applies the plain and ordinary meaning of the term, which it proposes is “open space within a vessel or organ.” Thus, on the briefing, the only disagreement between the parties is whether the word “open” should be included to describe the “space within a vessel or organ.” Doc. 68 at 9.

Plaintiffs object to the use of the word “open” because it “adds the confusing limitation that the vessel space must be ‘open,’ rather than full of blood.” Doc 56 at 17. At the hearing, Defendant’s counsel defended use of the term “open” by pointing to extrinsic evidence, but effectively agreed that the presence of blood or fluid does not mean that a vessel is not open:

Now, as you can see, Your Honor, for Janzen the parties basically agree on the construction with respect to everything except our use of the word “open” in there, and we’ve highlighted that in green. St. Jude has objected and they did this in their brief that a blood filled space within the lumen of a vessel is not open. Our point is, and I think we made this in our brief, that dictionaries cited in our claim construction briefing describe lumen with the word “open” and we’re not saying that the lumen or vessel is empty. There is definitely blood in it, but the point is it’s still open. Having said all of that, we’re willing, Your Honor, if it will take a dispute away to say that the term should be defined as a “blood filled or fluid filled space within a vessel or organ,” as long as the court makes clear that the surrounding walls are not part of the construction. So rather than saying an open space within a vessel or organ, we would be happy with blood filled or fluid filled space within a vessel or organ. I think that would respond to the objection that St. Jude has made with respect to that claim term.²

ii. Analysis

The Court agrees with the parties that the ordinary meaning applies to this term. The parties only dispute the use of the word “open” in the construction, and the Court is not persuaded by Defendant’s arguments. Defendant asserts that an “open” vessel may be filled with blood or fluid. While the Court does not opine on the merits of that argument, the Court believes the argument demonstrates why a juror may be confused by including the word “open” in the construction. Thus, the Court declines to construe the term “lumen” using the word “open” to describe the vessel.

iii. Construction

The Court construes the term “lumen” in the Fowler patents to mean “space within a vessel or organ.”

² Tr. January 19-20, 2010 at pp. 81-82.

e. *vessel plug*

i. The Parties' Positions

This term occurs in claim 9 of the Fowler '616 patent, claims 38, 40 and 43 of the Fowler '602 patent, and claim 21 of the Fowler '375 patent. Plaintiffs cite extrinsic evidence to argue that the term's ordinary meaning is "a mass obstructing a hole or intended for closing a hole." Doc. 56 at 13, *citing* Exh. J. Defendant similarly relies upon extrinsic evidence in submitting an ordinary meaning proposal of "an item that occupies and fills a hole in a vessel." Doc. 68 at 11, *citing* Exhs. K, L, M, and N. Therefore, the principle dispute between the parties is whether a plug must fill the hole or merely obstruct the opening. *See, e.g., id.* at 11 ("A plug does not merely obstruct a hole—it occupies and fills it so that nothing may pass through.").

Defendant argues that by merely requiring obstruction, Plaintiffs' proposal is far too broad and would encompass many items that are clearly not plugs: "SJM's construction would include, for example, a bottle-cap or even a finger placed over part of, or near to, the opening in a bottle. It similarly would include a sheet wrapped around a punctured vessel or a finger placed over part of, or near to, the puncture in a vessel, which no one would understand to be a 'vessel plug.'" Doc. 68 at 11-12. Plaintiffs respond that Defendant's proposal is too narrow because by requiring the plug to seal the hole, embodiments of the patents are excluded:

ACI is simply wrong that Fowler is limited to a plug that occupies and fills a hole in a blood vessel. The specification makes it clear that the plug need not extend into the blood vessel. 375 patent, 2:32-37. Instead, the plug generally conforms to the outside of the artery: "the vessel plug 20 is preferably contoured to conform to the outer lumen of the artery 10." *Id.*, col. 4:38-40. In operation, it could very well be that part of the plug dips slightly into the puncture and perhaps mates with part of the balloon, especially since the blood vessel is flexible and both the plug and balloon expand. But this does not mean that the plug must "occupy and filly [*sic*] a hole."

Doc. 69 at 8.

ii. Analysis

As discussed above, the primary dispute between the parties relates to the ultimate function of a vessel plug, not its structure or nature. The Court finds that each and every relevant

claim speaks extensively to the function, use and positioning of the vessel plug. Claim 9 of the '616 patent requires,

positioning the vessel plug in the incision with an elongate member to position the vessel plug in the incision such that the distal end of vessel plug is located proximally of the blood vessel without extending into the blood vessel to seal the incision from the flow of blood passing through the blood vessel, such that the blood vessel is free of obstruction.

Claim 38 of the '602 patent requires,

a vessel plug operatively associated with said shaft member for insertion into the puncture, said expandable member configured to cooperate with said plug when said expandable member is in said expanded condition to prevent said vessel plug from entering the vessel or the organ of the patient, and said vessel plug, when sealingly positioned within the puncture, extends proximally of the target organ or blood vessel without extending into said vessel or said organ.

Claim 40 of the '602 patent requires,

a vessel plug operatively associated with said tubular member and said expandable member, said vessel plug dimensioned to close the puncture or incision, said expandable member, when in said expanded condition within said blood vessel or said target organ, preventing said vessel plug from extending into said vessel or said organ.

Claim 43 of the '602 patent requires,

inserting a vessel plug into said incision or puncture, said expandable member operating in said expanded condition to prevent said vessel plug from extending into said vessel or target organ of said patient;

positioning said expandable member in said relaxed condition; and

retracting said elongated tubular member and said expandable member from said incision or puncture while retaining said vessel plug within said incision or puncture.

Finally, claim 21 of the '375 patent requires,

a vessel plug which is constructed of a material that is absorbable within the body of a patient and which seals the incision from the flow of blood therethrough; and

an elongate positioning member having a passage way therein for the receipt of said vessel plug therein, and at least a portion of said positioning member is expandable so that it has an outer diameter in use which is greater than the diameter of the incision to position said vessel plug in the incision proximally of the blood vessel such that said vessel plug obstructs the flow of blood through the incision without extending into the blood vessel.

As shown in the quoted claim limitations above, the claims themselves speak in great detail regarding the use and positioning of a vessel plug. The Court thus finds that construction of the term “vessel plug” should not include a necessary function and position of the plug. Including the function of the “vessel plug” in the construction would make other language in the claims redundant and unnecessary. Furthermore, in this instance, how a particular plug is used does not speak to its characteristics which make it a plug. For example, a vessel plug would still be a vessel plug if it sits on a shelf and is never used. The ordinary meaning of a vessel plug cannot require the plug to actually do something, like seal or fill a hole. A vessel plug is a structure and the Court’s construction should primarily reflect a structural description. Functional language may be necessary to describe the structure, but the structure itself does not mandate an actual use of the plug. The structure of the vessel plug is discussed in the patents as follows:

As shown in FIGS. 3-5, the vessel plug 20 of the present invention is preferably a cylindrical rod-shaped member which is constructed of a porous, biodegradable and expandable hemostatic collagen sponge such as the collagen cuff 35 sold by Vitaphore Corporation under the name VITACUFF, or a polymerized polylactic acid, or polyglycolic acid matrix. The distal end 32 of the vessel plug 20 is preferably oriented at an angle of approximately 25 to 45 degrees with respect to the lengthwise dimension of the vessel plug 20 and, as shown in FIG. 5, the distal end 32 of the vessel plug 20 is preferably contoured to conform to the outer lumen of the artery 10. The proximal end 34 of the vessel plug 20 may be excised after placement in the patient and positioned at or slightly below the epidermal layer of the patient’s skin as described more fully hereinafter.

‘602 patent, 4:31-45.

That description is a statement of alternative embodiments and may therefore inform our construction. Furthermore, the parties have submitted a number of extrinsic dictionary

definitions for the Court’s consideration. For example, Plaintiff submits the definition “[A] mass obstructing a hole or intended to close a hole.” Doc. 56, Exh. J. Defendant submits and discusses several extrinsic definitions:

A plug occupies and fills a hole, as in the case of a bottle’s cork or a test-tube’s stopper. *See* Ex. K (“An object, such as a cork or wad of cloth, used to stop a hole or gap.”); Ex. L (“a piece used to fill a hole”). Medical dictionaries indicate that the term “plug” has no more specialized usage in that field. *See* Ex. N (“Any mass filling a hole or closing an orifice.”); Ex. M (“Something that stops up an orifice or opening, especially when inserted for that purpose or if [*sic?*] removable.”). The Federal Circuit has held in another medical device case that the “plug” at issue in that case filled the hole it was designed to plug. *See C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 860 (Fed. Cir. 2004) (“The conformable surface allows the plug to fill irregularly shaped hernia defects more completely than other plugs.”).

Doc. 68 at 11.

In view of the entirety of the specifications and the extrinsic evidence, the Court finds that a vessel plug must be a structure that is designed or configured to close a hole in a vessel. Plaintiffs’ extrinsic definition is most instructive in this regard: “mass obstructing a hole or *intended for closing a hole.*” Doc. 056 at 13, *citing* Exhibit J (emphasis added). That definition comports most closely with all the extrinsic and intrinsic evidence presented by the parties. Defendant’s argument would confine the meaning of a plug essentially to that of a cork in a wine bottle (filling and sealing a specific hole). While the embodiments may conjure this analogy, none of the intrinsic or extrinsic evidence supports confining the definition of a plug in this way. Even Defendant’s submitted definitions acknowledge that a plug might simply “close an orifice.” The term is entitled to be given its full breadth.

iii. Construction

The Court construes the term “vessel plug” to mean “a mass designed or configured to close a hole in a vessel.” The Court provides the following guidance to ensure that the parties’ dispute is resolved. “To close” does not require a seal or fit that is completely fluid-tight. Rather it requires only that the plug is designed or configured to close the hole well enough to substantially stem liquid flow in a way that is consistent with improved healing. On the other hand, for example, if a mass is designed or configured to merely partially close the vessel and

allow fluid flow beyond minor amounts that would be consistent with healing the hole in the vessel, then that mass is not a plug within the meaning of these patents.

f. “puncture” and “incision”

i. The Parties’ Positions

The term “puncture” occurs in claims 38, 40 and 43 of the ‘602 patent. The term “incision” occurs in: claim 9 of the ‘616 patent; claims 38, 40 and 43 of the ‘602 patent; and claim 21 of the ‘375 patent. Plaintiffs contend that these terms do not require construction, but if they are construed they should be given their common meaning of a “hole or slit opening created during a procedure.” Doc. 56 at 13. Defendant argues that the ordinary meanings of “incision” and “puncture” are distinctly different. Doc. 68 at 13-14. Thus, Defendant proposes that “incision” means “cutting wound” and “puncture” means “piercing wound.”

Defendant supports its proposal first with extrinsic dictionary definitions. *Id.* Plaintiffs respond to Defendant’s dictionaries saying they “would result in a construction divorced from the disclosures in the intrinsic record.” Doc. 69 at 10. Plaintiffs cite to the following portions of the intrinsic record to show that the words “‘puncture’ and ‘incision’ refer interchangeably to an opening in the artery or elsewhere:

During catheterization procedures, the nurse or physician will create an opening into an artery or other vessel...” ‘375, col. 1:22-25 (emphasis added). Further: ‘The puncture of the artery 10 by the needle is then confirmed by the physician and a small diameter guide wire (not shown) is inserted through the needle for approximately 15 to 20 cm. The needle is then withdrawn over the guidewire while pressure is applied to the artery 10 to limit the bleeding and prevent the formation of a hematoma at the incision site. ‘375, col. 4:2-8 (emphasis added).

Doc. 69 at 10. Defendant replies arguing that the specification actually supports different definitions for the subject terms because “‘incision’ and ‘puncture’ are connected seven different times in the Fowler specification by the disjunctive ‘or,’ indicating a choice between alternatives.” Doc. 71 at 6, citing *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 995 F. Supp. 1229, 1236 (D. Kan. 1998) (“‘Or’ typically is defined as ‘a choice of available alternatives.’ An ‘alternative’ is defined as ‘a proposition or situation offering a choice between two things wherein if one thing is chosen the other is rejected.’”) (internal quotations and citations omitted). Defendant further notes that the terms “incision” and “puncture” appear in the same Fowler

claims at least three times. Doc. 71 at 6. Defendant’s criticism of Plaintiffs’ proposal is that Plaintiffs’ common definition does “not reflect the plain meaning of the terms to one of skill in the art or to anyone else.” Doc. 71 at 7.

Finally, Defendant notes that its proposals are affirmatively supported by words in the specification and claims: “The Fowler patents state that a ‘needle pierc[ing] the femoral artery’ creates a ‘puncture’ and use ‘said wound or incision’ to refer to the antecedent ‘incision or puncture’). *See* col. 3:67 – 4:3; ‘602 cl. 45.’” Doc. 71 at 7 (emphasis in Doc. 71).

ii. Analysis

The Court finds the following dictionary definitions of interest in examining these terms³:

“Puncture – 1. To pierce with a pointed object. 2. To make (a hole) by piercing. 3. To cause to collapse by piercing.” Doc. 68, Exh. K.

“Puncture – 1. To pierce with or as if with a pointed instrument or object.” Doc. 68, Exh. L.

“Incision – A surgical cut with a sharp instrument into the body that results in a division of tissue and creation of a wound.” Doc. 68, Exh. M.

“Incision – A cut made with a knife, esp. for surgical purposes.” Doc. 71, Exh. JJ.

“Puncture – 1. A hole or wound made by a sharp pointed instrument. 2. To make a hole with such an instrument.” *Id.*

“Incision – [to cut open, to cut through] 1. A cut, or a wound produced by cutting with a sharp instrument.” Doc. 71, Exh. KK.

“Puncture – 1. The act of piercing or penetrating with a pointed object or instrument. 2. a wound so made.” Doc. 71, Exh. KK.

“Incision – A cut; a surgical wound; a division of the soft parts made with a knife.” Doc. 71, Exh. LL.

“Puncture – 1. To make a hole with a small pointed object , such as a needle. 2. A prick or small hole made with a pointed instrument.” Doc. 71, Exh. LL.

³ The Court notes that some Exhibits contained illegible material.

The Court finds that the extrinsic evidence supports Defendant’s conclusion that a skilled artisan would interpret an “incision” differently from a “puncture.”⁴ The vast majority of the intrinsic evidence supports the same conclusion. As Defendant points out, the Fowler specifications use the term disjunctively and many claims also use both words. For example, claims 40 and 43 of the ‘602 patent disjunctively use the terms in both the claim preamble and body. Since the nature of patent claims is precise, the Court finds this disjunctive use as strong evidence that the patentee distinguished between these terms. Indeed, the Court finds that the majority of the specification and the plethora of disjunctive claim usage show that the intrinsic record supports distinct meanings for the two terms.

There are two items in the intrinsic record that may be interpreted to create ambiguity. First, claim 38 of the ‘602 patent use “incision” and “puncture” disjunctively in the preamble: “an assembly for sealing or closing an incision or puncture in the body of a living patient wherein the incision or puncture extends” Oddly, however, in the body of claim 38, only the “puncture” term is referenced. Further, there is a single specification passage where the terms appear to be used interchangeably:

The puncture of the artery 10 by the needle is then confirmed by the physician and a small diameter guide wire (not shown) is inserted through the needle for approximately 15 to 20 cm. The needle is then withdrawn over the guidewire while pressure is applied to the artery 10 to limit the bleeding and prevent the formation of a hematoma at the incision site.

‘375, col. 4:2-8 (emphasis added). In the first portion of the quoted passage, the patentee refers to the wound as a puncture, but later in the passage, when referring back to the same wound, the patentee uses the word “incision.” While there may be meaning to glean from this passage, the Court finds that this is not a re-definition of both terms, such that they have the same meaning. *See CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1367 (Fed. Cir. 2002) (“First, the claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.”). In the overall context of the extrinsic and intrinsic evidence, the Court finds that this

⁴ This is consistent with the testimony of Mr. Wolvek submitted in Defendant's Supplemental Sur-Reply and distinguishing between cutting wounds and those caused by a needle. Doc. 94 at 4.

particular specification quote and the unusual term usage in '602 claim 38 (disjunctive use in the preamble and using only "puncture" in the claim body) do not clearly indicate that a puncture and an incision are the same. Rather, like the entirety of the evidence, these two potentially ambiguous uses indicate that the nature of a wound as a puncture or incision is not material to the application of the inventive ideas.

Without a clear indication from the patentee that he intended those terms to have the same meaning, and given the many other uses of those terms which indicate they are intended to have different meanings, the Court declines to construe "puncture" and "incision" as having the same meaning.

iii. Construction

The Court generally agrees with Defendant's evidence that incisions are cutting wounds and punctures are piercing wounds. However, for clarity and certainty regarding resolving the parties' disputes, the Court construes "puncture" to mean "piercing wound or opening such as that made by piercing with a needle or other pointed object." The Court further construes "incision" to mean "cutting wound or opening such as that made by a knife or scalpel or other bladed object." The Court also clarifies that the constructions of "puncture" and "incision" are not intended to limit the appearance of the wound created. For example, the Janzen '439 patent suggests that after removal of instruments, punctures may appear as "slits." '439 patent, 3:43-48. Regardless of appearance, a puncture remains a puncture.

g. *"relaxed" and "expanded"*

At the hearing, the parties reported that there was no longer a dispute regarding these terms.

In the Joint Claim Construction Chart at page 3 the parties had been disputing the claim terms "relaxed" and "expanded" and yesterday afternoon after the tutorial, the parties reached an agreement that the court need not construe the terms "relaxed" or "expanded" as they appear in the Fowler 602 patent. So that one is off the table. The parties are fine with the court not construing either of those terms.

Tr. Jan. 19 – 20, 2010 at 72. In view of the parties’ agreement, the Court declines to define these terms.

h. “(located / extends) proximally of”

i. The Parties’ Positions

These terms are used in claim 9 of the ‘616 patent, claim 38 of the ‘602 patent and claim 21 of the ‘375 patent. Plaintiffs contend that the terms use the word “proximally” for its general meaning, which Plaintiffs contend is “close to” based primarily upon extrinsic evidence. Doc. 56 *citing* Exh. K. Defendant proposes a different meaning for “proximally” based upon the parties’ agreement for the term “proximal end” and the medical meaning of that term. In particular, Defendant proposed the construction “away from the midline.” Doc. 68 at 16-17. Thus, the primary issue presented by the parties is whether the terms use the word “proximally” to indicate closeness (general meaning) or away from the patient (medical meaning).

ii. Analysis

When construing claims, we look first “to the words of the claims themselves . . . to define the scope of the patented invention.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Furthermore, it is fundamental that we give due weight to the specification when construing the claim term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). In this instance, the parties have proposed constructions that appear to have only a very subtle difference when applied to the relevant claims. The Court examines the claims to determine whether either or both proposals may be applied to the claims and remain faithful to the specification.

Claim 9 of the ‘616 patent states:

9. A method of sealing an incision formed in the body of a patient wherein the incision extends generally from the skin of the patient; through the lumen of a blood vessel and into the blood vessel of a patient, the method including the steps of:

forming a vessel plug of a material which is absorbable in the body of the patient and wherein the vessel plug is formed to include distal and proximal ends therein and is dimensioned to be received in the incision; and

positioning the vessel plug in the incision with an elongate member to ***position the vessel plug in the incision such that the distal end of vessel plug is located proximally of the blood vessel without extending into the blood vessel*** to seal the incision from the flow of blood passing through the blood vessel, such that the blood vessel is free of obstruction (emphasis added).

Claim 38 of the '602 patent states:

38. An assembly for sealing or closing an incision or puncture in the body of a living patient wherein the incision or puncture extends into a blood vessel or an organ of the patient, the assembly comprising:

an elongate shaft member having a proximal end and a distal end and having an expandable member disposed at said distal end, said expandable member constructed to be positioned alternatively in a relaxed condition and an expanded condition;

said shaft member and said expandable member dimensioned to be inserted within the puncture so that said expandable member is positioned within a target organ or blood vessel of the patient;

control member operatively connected to said expandable member and associated with said shaft member for selectively positioning said expandable member between said expanded condition and said relaxed condition; and

a vessel plug operatively associated with said shaft member for insertion into the puncture, said expandable member configured to cooperate with said plug when said expandable member is in said expanded condition to prevent said vessel plug from entering the vessel or the organ of the patient, and ***said vessel plug, when sealingly positioned within the puncture, extends proximally of the target organ or blood vessel without extending into said vessel or said organ*** (emphasis added).

Claim 21 of the '375 patent states:

Claim 21 (asserted). An insertion assembly for sealing an incision in the body of a patient wherein the incision extends from the skin of the patient into a blood vessel of the patient, said insertion assembly comprising the combination:

a vessel plug which is constructed of a material that is absorbable within the body of a patient and which seals the incision from the flow of blood therethrough; and

an elongate positioning member having a passage way therein for the receipt of said vessel plug therein, and at least a portion of said positioning member is expandable so that it has an outer diameter in use which is greater than the diameter of the incision to position ***said vessel plug in the incision proximally of the blood vessel such that said vessel plug obstructs the flow of blood through the incision without extending into the blood vessel*** (emphasis added).

All three of those claims use the term “proximally” in referring to the position of the vessel plug with respect to a blood vessel (or organ). All three claims also expressly require that the plug does not extend into the blood vessel. Further, the Court notes that the purpose of all three claims is to recite an assembly for sealing or closing a wound such as an incision or puncture. With that context, if the Plaintiff’s definition is applied to the relevant phrase of claim 21, it would state, “said vessel plug in the incision [*close to*] the blood vessel such that said vessel plug obstructs the flow of blood through the incision without extending into the blood vessel.” This application of the claim is consistent with the embodiments of the specification in that it places the vessel plug close to the opening in the vessel without extending into the blood vessel. The Plaintiff’s proposal applies similarly to the other relevant claims.

Applying the Defendant’s proposal results in the relevant part of claim 21 stating as follows: “said vessel plug in the incision *away from the midline* of the blood vessel such that said vessel plug obstructs the flow of blood through the incision without extending into the blood vessel.” While far less clear, this application of the claim phrase also appears consistent with the specification in that it would place the vessel plug in the incision without extending into the blood vessel. However, while the Defendant’s proposal is consistent with the specification, the Court finds that it may confuse the fact finder by suggesting that plug should be “away” from the vessel. Indeed, “away from the midline” does not connote any proximity to the vessel. The outside surface of the skin is “away from the midline.” That is confusing because the entire intrinsic record discusses only embodiments that place the plug close to the vessel. Furthermore, the reference to the vessel midline may also be confusing because that midline is a new reference point that would require independent explanation to the fact finder. The potential for confusion and putative need for further definition is verified with certainty in view of Defendant’s Supplemental Claim Construction Sur-Reply-Brief, where Defendant argues that very old testimony of inventor Fowler defines “proximally” as “the direction away from the midline of the patient.” Doc. 94 at 2. This reference to Mr. Fowler’s testimony is confusing because, according to the same testimony, the “midline of the patient” is “an imaginary line that runs through from the top of the head down between the legs right through the center of the patient.”

Id. With respect to the claims at issue here and discussed above, such a construction would not make sense.⁵

Finally, even if Defendant's proposal is adopted, the only reasonable interpretation of the contextually relevant portions of the claims will place the plug close to the vessel without extending into the vessel. Thus, the Court finds that, in context, both the general meaning and the medical meaning of the term "proximally" lead to the same result.

iii. Construction

The Court construes the term "proximally of" in the referenced claims to mean "close to."

- i. *"threading a plug over said guide wire . . . [and] moving the plug inwardly along the guide wire"*

- i. The Parties' Positions

This term occurs in claim 10 of the '439 patent, which is a method claim. The term requires two distinct steps of the method claim – the "threading" step and the "moving" step. Plaintiffs argue that both of these steps refer to "movement of the plug in the tissue channel" requiring both that the plug pass "over" the guide wire and that the plug move inwardly "along" the guidewire. Doc. 56 at 17. Plaintiffs reason that the two steps differ because the second step "simply requires that the plug move toward the puncture using the guide wire as a guide." Doc. 56 at 18. Thus, Plaintiffs propose that the "threading" step be construed as "passing a plug over the guide wire," and that the "moving" step be construed as "advancing the plug from the proximal end of the guide wire toward the patient." Doc. 69 at 14.

Defendant disagrees with Plaintiffs only regarding the "threading" step, which Defendant proposes be construed as "feeding the proximal end of the guide wire into and through the lumen in the plug." Doc. 71 at 12. Defendant argues that "threading" is a commonly understood word as in the context of putting thread through the eye of a needle. Tr. Jan. 19-20, 2010 at 112.

⁵ In their Supplemental Sur-Reply, Defendant's also note a related and abandoned patent application where claims use the word "distal" in a similar context. Doc. 94 at 2-3. Whatever inference may be gained from this usage is insufficient to persuade this Court to read the "proximally" limitation outside of the clear context of the claims at issue in this case.

Further, Defendant notes that Plaintiffs' proposal conflates both claimed method steps into the single action of moving the plug. Doc. 71 at 12.

ii. Analysis

The crux of the parties' disagreement regards the term "threading" and whether the claim's threading step merely indicates the position of the plug with respect to the guide wire, or whether that step requires placing the guide wire through the lumen of the plug. Claim 10 of the '439 patent is a four-step method claim that states:

10. A method of closing a puncture in a wall of an artery comprising the steps of:

inserting a removable guide wire through said puncture into the artery;

threading a plug over said guide wire so that the guide wire extends from the plug through said puncture,

moving the plug inwardly along the guide wire into blocking relation with said puncture, and

withdrawing the guide wire from the plug so as to leave the plug sealed in blocking relation with said puncture (emphasis added).

A brief review of the claim shows it bears a strong resemblance to the description in the '439 patent specification at column 7:

FIG. 12e shows yet another form of plug, similar to the plug of FIG. 12d, but with a lumen 85. This form of plug is designed for use by physicians who prefer not to remove the guide wire immediately after a procedure. The proximal end of the guide wire 15 can be fed through lumen 85 and through the collagen membrane 81. The plug is slid down along the guide wire through tissue channel 9 until its front end reaches the wall of the femoral artery. Indeed, the plug of FIG. 12e could even be inserted without the use of a sheath. When the wire 15 is withdrawn, the collagen membrane automatically reseals itself.

'439 patent, 7:39-50.

In view of the strong association of the claim with this specification passage and the common meaning of the word "threading," the Court agrees with Defendants that the claim term "threading" is embodied in the statement "the proximal end of the guide wire 15 can be fed

through lumen 85” The inquiry does not end here because the term “threading” may have a broader meaning than that expressed in a preferred embodiment.

The “threading” step of this method claim states “*threading a plug over said guide wire so that the guide wire extends from the plug through said puncture.*” On its face, this step requires that the “threading” of the plug over the wire result in the wire extending from the plug to the puncture. In relevant part, this indicates that the “threading” verb is an action that brings the plug and the wire together. The common use of the word “threading” would bring those items together in a particular way – moving the wire through the lumen of the plug.

In addition, when the threading step is viewed in the context of the “moving” step, the Court finds that “threading” is something other than “moving” the plug along the wire.

iii. Construction

The Court construes the term “threading a plug over said guide wire” to mean “feeding the proximal end of the guide wire into and through the lumen of the plug.” Furthermore, the Court adopts the parties’ agreement and defines “moving the plug inwardly” to mean “advancing the plug towards the puncture.”

- j. *“means for ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture”*

i. The Parties’ Positions

This term occurs in claim 1 of the ‘439 patent. The parties agree that the term should be interpreted under 35 U.S.C. § 112(6). Further, the parties agree that the function of the clause is “ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture.” The parties disagree only on the structure that corresponds to the claimed function. Plaintiffs propose that the structure requires a plug pusher and a retracting sheath, but rather than list all the embodiments for those items, Plaintiffs state their proposal as “a plug pusher (for example, plug pusher 33, fig. 1) and retracting sheath (for example, sheath 45, fig. 16), and equivalents thereof.” Doc. 69 at 29. In view of the partial agreement discussed above, Defendant updated its proposal at the hearing, proposing “items 33 and 23 in Fig. 1, col. 3:49-60, 4:1-13, and

equivalents thereof.” Tr. Jan. 19-20, 2010 at 103-105 (discussing slides 79 and 80 of Defendant’s presentation).

ii. Analysis

Section 112, ¶ 6, provides that “a patentee may express an element in a claim as a means for performing a specified function without reciting the particular structure that performs the recited function . . . the ‘means-plus-function’ limitation must be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” *Commonwealth Sci. & Indus. Research Org. v. Buffalo Tech., Inc.*, 542 F.3d 1363, 1383 (Fed. Cir. 2008) (internal cites and quotes omitted). The Court construes a means-plus-function limitation by a two-step process: (1) “identify[ing] the function of the means-plus-function limitation;” and (2) “identify[ing] the corresponding structure in the written description necessary to perform that function.” *Minks v. Polaris Indus.*, 546 F.3d 1364, 1377 (Fed. Cir. 2008) (internal cites and quotes omitted).

The parties have agreed on a function, which is stated as “ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture.” The Court agrees with the parties regarding the function, so the Court must now determine the structure that is necessary to perform that function. The Court notes that the parties have some level of agreement regarding the structure as well. In particular, at the core of both proposals is a plug pusher (for example, item 33 of figure 1) and a sheath (for example, item 23 of Figure 1). In this respect, the Court agrees with the parties. The function requires ejecting the plug into a certain position and such function necessarily requires a plug pusher to push the plug through a necessary sheath (the placement of which will result in the ultimate position of the plug).

The parties appear to disagree on two primary points. First, as indicated by the parties’ respective proposals, Plaintiffs disagree with Defendant’s proposal to add the following paragraphs of the written description to the required structure:

In order to insert the plug to assure that it is properly located and to be able to hold it in place until a good seal is established, a special insertion apparatus has been designed. One embodiment (FIG. 1) of an insertion apparatus according to the instant invention is comprised of a sheath assembly 23, a plug holder 29 and

a plug pusher 33. Sheath assembly 23, in turn, is comprised of an elongated tubular sheath 45 and a collar 35. At its rear end, collar 35 is provided with an external thread 37. In addition, sheath assembly 23 is provided with a sheath channel 27, which runs through the entire assembly, from front end 25, through sheath 45 and through collar 35.

'439 Patent, 3:48-60.

Like the other two components, the plug pusher 33 is also comprised of two parts, an elongated piston 49, and a stop knob 43. Piston 49 has a cross sectional size and configuration so as to permit sliding passage into channels 31 and 27 with only minimal clearance. The length of piston 49 is such that when sheath assembly 23 and plug holder 29 are screwed tightly together, shoulder 51 of knob 43 will abut rear end 53 of plug holder 29 as front end 55 of piston 49 is aligned with front end 25 of sheath 45.

Id., 4:1-13.

As evident from the quoted portions, the first excerpt is a component-level description of the sheath 23 of Figure 1 and the second excerpt is a component-level description of the plug pusher 33. Thus, Defendant is proposing that the means be limited to the specific component-level description of the embodiment of Figure 1's sheath and plug pusher. The Court agrees that sheath 23 and plug pusher 33 are structural elements underlying the means, but disagrees that the structure is limited to described component-level descriptions. The number and nature of pieces that make up the plug pusher and the sheath are not "necessary" to the function. To be clear, the Court is not creating a vague amalgamation of the disclosed structures -- they are limited to what is disclosed. However, the Court is holding that a plug pusher or sheath would meet this limitation if composed of more or less components having varying characteristics, as long as the assembled or manufactured plug pusher and sheath are the same or equivalent to the disclosed items.

Next, the parties disagree regarding whether the plug pusher embodiment of Figure 1 is the only embodiment where the means may derive associated structure. In this respect, Defendant argues that "[t]his structure is the only structure disclosed in the specification that can perform the function as claimed because it is the only plug pusher that includes a channel to receive the guide wire required by other claim limitations. *See* col. 4:1-13. Notably, this plug pusher is what the '439 patent specification says forces the plug out of the device because the

front end 55 of piston 49 is aligned with front end 25 of sheath 45. *See* col. 4:8-9; *see also* col. 5:39-47.” Doc. 68 at 33. Defendant is proposing that the structural plug is limited to the plug having a channel to accommodate a guide wire. The Court disagrees with Defendant because, notwithstanding the guide wire requirement of the claim, all the disclosed plug pushers are linked with the agreed function that does not involve the channel or the guide wire. The skilled artisan would link any of the plug pushers with the claimed ejecting function.

iii. Construction

The Court construes the term “means for ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture” under § 112(6) and finds that the function is as agreed by the parties, “ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture.” Furthermore, the Court construes the corresponding structure as “a plug pusher (items 33, 69 or 95 of the ‘439 patent) and a sheath (items 23 or 45 of the ‘439 patent) and equivalents thereof.”

k. *“ejecting mechanism for ejecting said plug member from said distal end of said elongated member so as to place said plug member in a blocking relation with said puncture, so as to seal said puncture”*

i. The Parties’ Positions

This term occurs in claim 8 of the ‘439 patent. The parties primarily dispute whether §112(6) applies to this term. Doc. 72-1 at 17. The parties agree that, if §112(6) applies, the Court should refer to the parties’ positions for the “means for ejecting” term in claim 1 of the ‘439 patent. *Id.* Thus, to the extent §112(6) applies, the parties agree that the function of this term is “ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture.” To the extent that §112(6) applies, the parties disagree only on the structure that corresponds to the claimed function. Plaintiffs proposed that the structure requires a plug pusher and a retracting sheath, but rather than list all the embodiments for those items, Plaintiffs state their proposal as “a plug pusher (for example, plug pusher 33, fig. 1) and retracting sheath (for example, sheath 45, fig. 16), and equivalents thereof.” Doc. 69 at 29. In view of the partial agreement discussed above, Defendant updated its proposal at the hearing, proposing “items 33 and 23 in

Fig. 1, col. 3:49-60, 4:1-13, and equivalents thereof.” Tr. Jan. 19-20, 2010 at 103-105 (discussing slides 79 and 80 of Defendant’s presentation). Finally, to the extent that §112(6) does not apply, the Defendant offers the following construction: “a plunger with a front end that does not extend past the front end of the elongate member.” Doc. 72-1 at 17.

ii. Analysis

A limitation that does not use the word “means” triggers a rebuttable presumption that the limitation does not require construction as a “means plus function” term. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1023 (Fed. Cir. 2006). A limitation, like the “ejecting mechanism” term, that lacks the term “means” may overcome the presumption against means-plus-function treatment if it is shown that “the claim term ‘fails to recite sufficiently definite structure’ or else recites a ‘function without reciting sufficient structure for performing that function.’” *CCS Fitness*, 288 F.3d at 1369 (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)); see also *Depuy*, 469 F.3d at 1023 (the presumption that such terms are not means plus-function terms “can be rebutted by showing that the claim element recites a function without reciting sufficient structure for performing that function.”) (Citation omitted).

The Federal Circuit has specifically commented on “generic structural terms” such as “mechanism” or “element” and determined that these terms do not recite “sufficient structure to avoid 112 ¶ 6.” For example, the court holds that “generic terms ‘mechanism,’ ‘means,’ ‘element,’ and ‘device,’ typically do not connote sufficiently definite structure.” *MIT v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) (holding that the term “colorant selection mechanism for receiving said modified appearance signals” is a means-plus-function term). See also, *Widevine Techs., Inc. v. Verimatrix, Inc.*, Civil Action No. 2-07-cv-321, 2009 WL 3734106, at *14 (E.D. Tex. Nov. 4, 2009) (holding that “first device” and “second device” were means plus function limitations since the “claim provides no structural context and describes each ‘device’ by the functions that it performs”).

As used in the “ejecting mechanism” term, the word “ejecting” is purely functional stating only the function of the “mechanism.” Furthermore, as discussed above, the word “mechanism” does not, itself, recite sufficient structural content to avoid treatment under §112(6). Moreover, the remainder of the limitation (“ejecting said plug member from said distal

end of said elongated member so as to place said plug member in a blocking relation with said puncture, so as to seal said puncture”) contributes nothing to the structure of the “ejecting mechanism.” As a result, the Court finds this term does not recite sufficient structure to avoid treatment under §112(6).

Like the parties, the Court refers to the analysis for the “ejecting means” term for further discussion regarding the determination of the “function” and corresponding structure for this term.

iii. Construction

The Court construes the term “ejecting mechanism for ejecting said plug member from said distal end of said elongated member so as to place said plug member in a blocking relation with said puncture, so as to seal said puncture” under § 112(6). The Court finds that the function is as agreed by the parties, “ejecting said plug means from said distal end of said elongated member so as to place said plug means in a blocking relation with said puncture, so as to seal said puncture.” Furthermore, the Court construes the corresponding structure as “a plug pusher (items 33, 69 or 95 of the ‘439 patent) and a sheath (items 23 or 45 of the ‘439 patent) and equivalents thereof.

1. *“separable plug means for plugging said puncture being disposed in said elongate member.”*

i. The Parties’ Positions

This term occurs in claim 1 of the ‘439 patent. Defendant asserts that this term should be interpreted under §112(6) due to the presumption created by use of the word “means” in the claim. Doc. 68 at 29. Plaintiffs disagree arguing that the term recites sufficient structure to rebut the presumption. Doc. 56 at 28.

ii. Analysis

Defendant asserts that “The limitation itself merely says “plug means,” and the specification of the ‘439 patent states that the shape and composition of the plug “may vary widely.” Col. 6:65-73. “That the plug means must be separable’ does not rebut the presumption; it simply indicates that whatever structure the ‘plug means’ has, it must be detachable from the

insertion apparatus.” Doc. 68 at 29-30. The Court disagrees with Defendant. The term “plug” is recited in the claim as a noun and it is a reference to a well-known structure. This is particularly true with respect to the specific claim words that place the plug structure in a clear contextual framework. The fact that an embodiment’s shape may vary does not bear on whether the claim recites structure. In claim 1 of the ‘439 patent, the plug means recites a well-known structure that is a plug, and as such is not subject to interpretation under §112(6). *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 1365 (Fed. Cir. 2000); (“[t]he term ‘baffle’ itself is a structural term...[and] the claims describe the particular structure of this particular baffle.”); *see also TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1121 (Fed. Cir. 2001) (holding that “radial positioning means” and “compressed spring means” do not invoke § 112, ¶ 6 because “the claim recites sufficient structure to overcome the presumption.”).

iii. Construction

The Court does not construe the “plug means” term under §112(6).

m. *“movable guide means extending longitudinally through said elongated member and said plug means for extension through said puncture for guiding said plug means to said puncture” and “movable guide element extending longitudinally through said elongated member and said plug member for extension through said puncture for guiding said plug member to said puncture.”*

i. The Parties’ Positions

The “guide means” term occurs in claim 1 and the “guide element” term occurs in claim 8, both in the ‘439 patent. Defendant asserts that both these limitations are subject to §112(6) because the “guide means” term uses the word “means” and because the “guide element” term has no more structure than the means term. Doc. 68 at 34. Plaintiffs respond stating “that the ‘means’: (1) must be a ‘guide means’ (‘guide’ is addressed separately above with the terms ‘guide wire’ / ‘guide element’); (2) must be ‘movable’ independent from the rest of the device; and (3) must pass through the elongate member and plug.” Doc. 56 at 28.

ii. Analysis

As used in the “guide means” term, the word “guide” is employed in the sense of action without evoking any particular structure. For example, viewing the claim language alone, the guide means could be a wire, a finger, a pipe, a string or virtually anything that would fulfill the function. In essence, the word “guide” does not connote any structure, which (semantically) is only limited by the function. Plaintiffs effectively makes this point in suggesting that the structure is defined by the functional limitations, *e.g.*, “movable” or “pass through an elongate member.” Doc. 56 at 28. Claim 8’s substitution of the word “element” for “means” does nothing to change this analysis. *See Bausch & Lomb, Inc. v. Moria S.A.*, 222 F. Supp. 2d 616, 632-36 (E.D. Pa. 2002) (finding no structure in the “guide element” limitation to distinguish it from the “guide means” claim and analyzing both under § 112, ¶ 6).

Having determined that §112(6) applies, the Court must determine the appropriate function and structure. Furthermore, the parties and the Court agree that the claimed function is “guiding said plug means/element to said puncture.” Doc. 72-1 at 14 and 17. The parties, however, disagree subtly as to structure. Defendant would simply state the structure as “a guide wire.” Plaintiffs, alternatively propose “a guide wire (for example, guide wire 15) capable of movement independent from said elongated member and said plug means and extending longitudinally through said elongated member and said plug means for extension through said puncture and equivalents thereof.” *Id.*

The Court disagrees with the Plaintiffs’ illustrative and exemplary structural recitation because it may be confusing to the jury and does not find the suggested verbiage clearly linked to the function through the specification.

iii. Construction

The Court construes the “guide means” and “guide member” limitations under §112(6). For both terms, the function is as agreed, “guiding said plug means to said puncture” for claim 1 and “guiding said plug element to said puncture” for claim 8. Additionally for both terms, the structure is a guide wire and equivalents thereof.

n. “plug”

i. The Parties’ Positions

The term “plug” as discussed here occurs in claims 9 and 10 of the ‘439 patent. While the term bears a strong resemblance to the “vessel plug” term discussed above, the Court notes that term is distinguishable because it occurs in the Janzen family of patents.

While the Janzen patents are independent of the Fowler patents, the parties’ arguments with respect to the term “plug” ring familiar to their respective positions regarding Fowler’s “vessel plug” term. In particular, Plaintiffs assert that a “plug” is a “mass that obstructs a hole” and Defendant counter-proposes an “item that occupies and fills a hole.” Once again, both parties argue the use of ordinary meaning. Doc. 56 at 22 (“it should be given its common meaning”); Doc. 68 at 35 (“Fowler used “plug” consistently with its commonly-understood meaning”). Furthermore, both parties cite to the specification to support their positions. In particular, Plaintiffs state:

The specification describes using “a plug, preferably a collagen plug or plug of some other resorbable material, to seal the artery along its outside wall.” ‘439, col. 2:22-24. Janzen specifically notes that “[t]he physical form of the plug may vary widely, with the one selected by the physician being dependent upon the circumstances of the case.” *Id.*, col. 6:65-7:3. . . . [T]he plug can form a “bandage-like covering *over* puncture.” ‘439, col. 7:54-57 (emphasis added); Figs. 10, 11, 18-19, and 21

Doc. 56 at 22.

In response, Defendant points to figures 10, 11 and 17-22 and states that the “specification unambiguously shows the plug occupying and filling the incision.” Doc. 68 at 35.

ii. Analysis

The Court agrees with the parties that the Janzen patents apply the ordinary meaning of the term “plug.” Furthermore, like the parties, the Court does not find the language of the Janzen specification casting a different construction for “plug.” A “plug” as claimed by Janzen is a structure that the Court construes for what it is, not what it does. The parties may refer to the Court’s discussion of the term “vessel plug” for further discussion on this point.

Finally, regarding the Janzen version of “plug,” the parties pointedly dispute the notion of whether a plug must fill the void or recess that is created in a vessel wall by a puncture, incision or wound. On this point, in addition to the discussion of “vessel plug,” the Court notes its agreement with Plaintiffs regarding the persuasiveness of Figure 11 (showing no plug portion in the vessel hole) and the cited “bandage” portion of the specification:

As noted earlier, the sheath is substantially larger in cross section than is arterial puncture 13. Consequently, when plug 57, which fills the entire cross section of the sheath channel, reaches the artery, even in its compressed state it overlaps puncture 13 on all sides. Obviously, then, when it exits the sheath and is permitted to expand, a full bandage-like covering over puncture 13 is assured.

‘439 Patent, 7:50-56. These passages of the Janzen patent reinforce the Court’s earlier conclusion that the common meaning of a plug is not limited to a cork-like structure.

iii. Construction

The Court construes the term plug to mean “a mass designed or configured to close a hole.” The Court provides the following guidance to ensure that the parties’ dispute is resolved. “Closing” does not require fluid-tight sealing or filling the hole. The Court also refers the parties to the discussion above regarding “closing” and the term “vessel plug.”

o. *“plug member being disposed in said elongate member”*

i. The Parties’ Positions

The term “plug member being disposed in said elongate member” occurs in claim 8 of the ‘439 patent. The parties disagree whether this term requires construction. Plaintiffs assert that no construction is necessary, but offer a contingent construction. Doc. 56 at 22; Doc. 69 at 15. In sum, Plaintiffs assert that Defendant seeks to add limitations to the term improperly. *Id.* Defendant disagrees and argues that the specification and prosecution history of the Janzen patents make clear “the applicants claimed only plugs that were larger than the arterial puncture when in the ‘elongate member.’” Doc. 68 at 36. In particular, Defendant argues as follows:

The plug must completely fill the tissue channel leading to the puncture in the artery. In order to do so, and ensure “a full bandage-like covering over [the] puncture,” it must be larger than the puncture. ‘439 col. 7:55-57. In the only passage from the specification that describes the physical dimensions of a plug

disposed in an elongate member, Janzen states that “plug 57, which fills the entire cross section of the sheath channel, ... even its compressed state it overlaps puncture 13 on all sides.” *Id.*, col. 7:53-55. The specification repeatedly explains that the plug must “overlap[] the arterial puncture on all sides.”

Id., col. 2:50-54; *see also id.* Figs. 9-10. The specification supports ACI’s proposed construction.

Indeed, Janzen explicitly stated about his specification that “it is clear to a person skilled in the art that the plug or charge must cover the area of the puncture together with a portion of the surrounding perimeter.” Ex. MM at JM0046626. The Australian examiner stated that every claim supported by that specification needed to “explicitly include” the “essential” feature of the invention “that hemostatic material is placed against the outside wall of a punctured artery (or blood vessel) and that the hemostatic material covers the entire puncture site.” Ex. OO. SJM cannot be permitted to read out this “essential” feature of the invention that “is clear to a person skilled in the art” based on one non-enabling sentence at the end of the specification. The plug must, at all times, be larger than the puncture in the vessel.

Doc. 71 at 18-19

ii. Analysis

The parties disagree whether this claim term speaks to the relative sizing of the plug and the puncture. In context, this claim term is referring to the plug while inside of the elongate member. Thus, references to embodiments where the plug is not within the elongate member have minimal relevance. Similarly, the foreign prosecution cited by Defendant does not bear on the instant term in the ‘439 patent. The term carries no size restriction and Defendant offers insufficient basis for the Court to otherwise import such a limitation into the claim term.

iii. Construction

The Court declines to define the instant term but instructs the parties to tailor their trial arguments in accord with this Order.

p. *“puncture” in the Janzen patents*

i. The Parties’ Positions

The term “puncture” occurs in claim 1 of the ‘498 patent and claims 1, 8, 9 and 10 of the ‘439 patent. As with “puncture” in the Fowler patents, Plaintiff proposes “hole or slit.” Defendant proposes “piercing wound.”

ii. Analysis

The Janzen patents are independent of the Fowler patents and therefore require independent evaluation of the term. While the Court’s earlier definition of “puncture” (Fowler patents) was informed by the intrinsic record, the Court also concluded that the specification coincided with the ordinary meaning of the term puncture as provided in extrinsic sources.

Here, Plaintiffs offer one intrinsic description that was absent in consideration of the Fowler patents:

In accordance with one embodiment of the instant invention, wounds of this type are closed by inserting a plug into tissue wound or channel 9, and holding it against the outside of the artery wall over arterial puncture 13 for a short period of time until a good self-sustaining hemostatic seal is established. Although punctures of the sort made by percutaneous procedures will generally, after removal of all cannulas and catheters, be in the nature of slits, for ease of understanding, they are depicted in the drawings herein more as holes. The shape of the puncture, however, is not critical.

‘439 Patent, 3:37-48.

The Court finds this quotation informative in that, according to Janzen, a “puncture” may appear as a slit. However, the Court finds no reason to define the term puncture differently from Fowler.

iii. Construction

The Court construes “puncture” in the Janzen patents to mean “piercing wound or opening such as that made by piercing with a needle or other pointed object.” As with the Fowler construction, the Court clarifies that the construction of “puncture” is not intended to

limit the appearance of the wound created. Regardless of appearance, a puncture remains a puncture.

q. “*guide wire*”

i. The Parties’ Positions

The term “guide wire” is used in claims 9 and 10 of the ‘439 patent. Plaintiffs propose that the term should be construed as a “wire used to assist in positioning.” Doc. 72-1 at 18. Defendant proposes a construction of “a wire for guiding and exchanging catheters.” *Id.* As evident, the dispute relates to whether the essence of a guide wire requires guiding and exchanging catheters.

Defendant supports its construction arguing that a “guide wire” is a “specialized instrument used in intravascular medical procedures for guiding and exchanging catheters.” Doc. 68 at 38. After arguing at length, Defendant requests entry of its proposal “[b]ecause the exchange function of a guide wire is not readily obvious to a lay person” *Id.* at 39.

Plaintiffs rebut Defendant’s suggestion asserting that Defendant “seeks a radical narrowing of the claims, proposing that the claimed guide wires are only used “for guiding and exchanging catheters,” even though the specification discloses that guide wires are used for multiple purposes (*e.g.*, positioning the plug, the plug sheath, or a tissue dilator). Doc. 56 at 23-24. Plaintiffs further note that the specification “discloses that the guide wire used for the catheterization procedure need not be used for plug placement. Instead, a guide wire just for the placement of the vascular closure device can be used: “[i]f no guide wire has been employed, prior to the removal of the catheter and cannula, a guide wire may be inserted.” *Id.*, col. 4:17-18. Doc. 56 at 24.

ii. Analysis

The Court has examined Defendant’s citations to the intrinsic and extrinsic evidence and, while the Court finds that a guide wire may be commonly used to “exchange” catheters, the Court is otherwise not persuaded. The Court agrees with Plaintiffs that both the specification and extrinsic evidence do not confine a guide wire to the function of “exchanging catheters.”

At the hearing on January 20, 2010, Defendant also argued as follows:

Your Honor, as we saw yesterday during the tutorial, a guide wire is a device used commonly in these sorts of procedures. It's designed to reach from the surface of the patient's skin down through the puncture in the vessel and into the puncture of the vessel, so that when the doctor is exchanging one device for another, a catheter or other device, you maintain access to the puncture in the vessel the whole time. You want the guide wire in that hole or puncture in the vessel so that when you're taking different devices back up and over, the doctor doesn't have to go back in through the vascular structure and find the puncture in the vessel. So that's the function of a guide wire. It's maintaining access to the vessel interior and it's allowing a doctor to guide catheters to that area. Maintaining access and guiding. Your Honor, St. Jude's proposed construction actually ignores both of those functions, in our opinion. It only requires that a guide wire be used in positioning. It would not even require that a guide wire actually guide. It simply says a guide wire is "a wire used to assist in positioning." But it makes common sense that if you're talking about a guide wire, you're talking about guiding something over that wire.

Tr. January 19-20, 2010 at 108-109.

In arguing as quoted, Defendant raised the issue that the guide wire must "guide." The Court agrees and finds the Plaintiffs are in agreement as well. Doc. 56 at 23 ("a guide wire is a wire that guides"). But "guiding" is not exchanging catheters, which is a very specific activity. In effect, Defendant's proposal would limit the use of Plaintiffs' invention to situations where an exchange of catheters has occurred on the wire. The claims are not so limited by reference to the guide wire. Claim 9 is a method claim that actually speaks to the use and withdrawal of a catheter that is not necessarily exchanged over the guide wire. Claim 10 does not speak to catheters at all. Thus, the patentee was aware of the potential placement of catheters in the claims, but chose to make claims without requiring an exchange over a guide wire. Defendant does not present sufficient evidence or argument to justify inserting this limitation, which the Court finds outside the ordinary meaning of the term.

iii. Construction

The Court construes the term "guide wire" as "a wire used to assist in positioning by guiding."

r. “sheath introducer” and “exterior guide tube”

i. The Parties’ Positions

The term “sheath introducer” occurs in claim 44 of the ‘602 patent. The term “exterior guide tube” occurs in claim 9 of the ‘439 patent. The Court notes that the two terms are from two different patent families so their contextual support may differ. Plaintiffs propose that both “sheath introducer” and “exterior guide tube” should be construed to mean “hollow tube through which other objects are inserted.” Doc. 72-1 at 9 and 18. Defendant argues that “sheath introducer” means “hollow tube through which catheters are inserted” and that “exterior guide tube” means “outermost hollow tube through which catheters are inserted.” *Id.* Thus, with respect to these terms, the parties dispute whether the “exterior guide tube” must be outermost, and with respect to both terms, whether they necessarily must carry catheters. Defendant clarified its position as merely requiring that the tubes carry “at least” catheters, but not exclusively catheters. Doc. 71 at 9.

Defendant argues that catheters are always used with sheaths so the terms should be interpreted as such:

In each patent family, the “sheath introducer” or “exterior guide tube” is a tube placed into the vessel to aid insertion of catheters into the vessel. The Fowler specification repeatedly describes a “catheter sheath” through which catheters are inserted into the vessel. *See, e.g.*, col. 4:8-16, 4:44- 53. In fact, the claim in which “sheath introducer” appears requires that the tubular member is inserted through the sheath introducer into the vessel or target organ. *See* ‘602 patent, cl. 9. The Janzen specification similarly describes a sheath (or cannula) through which catheters are inserted into the vessel. *See, e.g.*, col. 1:28-35, 3:30-32 (“as seen in FIG. 5, a catheter or other device 7 is inserted, often over a guide wire 15, through a guide cannula 3 into an artery 11”). Claim 9 of the ‘439 patent similarly requires that “the catheter” go “through the guide tube and into the artery” before being removed so that the puncture can be closed.

Doc. 68 at 18.

In discussing Fowler, Plaintiffs respond stating that, “The claim does not recite “catheter introducer,” ‘catheter sheath’ or even anything similar relating to catheters. Moreover, Fowler specifically discloses that the sheath introducer can be used to insert objects other than a catheter: for example, it may be used to insert the balloon and vessel plug. ‘375, col. 4:12-16.”

Doc. 69 at 12-13. With respect to Janzen, Plaintiff states, “The specification confirms that an exterior guide tube can be a hollow tube through which other objects are inserted – not just a hollow tube through which catheters are inserted, as ACI would have it. ‘439, col. 1:32-35 (‘catheter *or other device* can be inserted through the cannula’) (emphasis added).” Doc. 69 at 24.

ii. Analysis

Assuming, arguendo, that every embodiment in the patents instructs on the use of catheters, the law would not allow this Court to narrow these terms as suggested without something more. “Generally speaking, we indulge a ‘heavy presumption’ that a claim term carries its ordinary and customary meaning.” *CCS Fitness*, 288 F.3d at 1366 (quoting *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)); *Wasinger v. Levi Strauss & Co.*, 106 Fed. Appx. 34, 38 (Fed. Cir. 2004). “[A] claim term will not receive its ordinary and customary meaning only in limited situations.” *CCS Fitness*, 288 F.3d at 1366-67. “Those situations include: where the patentee has acted as his own lexicographer and clearly provided an alternate definition for the term; where the intrinsic evidence shows that the patentee distinguished his invention from a prior art reference, expressly disclaimed subject matter, or highlighted a particular feature as important to the invention; or, where the term chosen makes the scope of the claim so unclear as to require resort to the intrinsic evidence for meaning.” *W.E. Hall Co. v. Atlanta Corrugating, LLC*, 2004 U.S. App. LEXIS 11122 (Fed. Cir. 2004) (citations omitted). “While clear indications in the intrinsic evidence communicating an intent to depart from an ordinary customary meaning will be respected, those that fall short must be disregarded.” *Id.*

With respect to the catheter limitation, Defendant simply fails to meet any recognized legal standard for altering the plain meaning of the claim. Furthermore, as Plaintiffs indicate, the specifications at least suggest, if not specify, that “sheaths” may be employed for purposes other than catheters.

The parties provide little discussion with respect to Defendant’s proposal regarding the word “outermost” as applied to the term “exterior guide tube.” The Court must apply meaning to the word “exterior” and accepts Defendant’s suggestion.

iii. Construction

The Court construes the term “sheath introducer” to mean “hollow tube through which other objects are inserted.” The Court construes the term “exterior guide tube” to mean “outermost hollow tube through which other objects are inserted.”

s. “*blocking relation*”

i. The Parties’ Positions

This term occurs in claims 1, 8, 9 and 10 of the ‘439 patent. Plaintiffs propose that “blocking relation” be defined as “positioned to impede the passage through.” Doc. 72-1 at 15. Defendant proposes the construction “covering a hole and its perimeter to prevent passage therethrough.” *Id.*

Plaintiffs argue that “the claim’s own language says it best, this language requires that the plug impede the flow of blood, through either the puncture or the tissue channel, sufficiently to allow the puncture to seal.” Doc. 56 at 24. Plaintiffs further assert that the specification supports their proposed construction by “disclosing that the plug may ‘fill that section of channel 9 which is adjacent puncture 13’ thereby resulting in sealing of the puncture. ‘439, 9:2-3.” *Id.* In addition, Plaintiffs argue that the extrinsic evidence is similarly supportive because “to ‘block’ is ‘to stop or impede passage.’” *Id. citing* Ex. H.

Defendant counters Plaintiffs, stating that [t]he central purpose of the ‘439 patent is ‘to stop bleeding from the puncture wound.’ *See* ‘439 Patent, col. 2:32-33. It accomplishes this purpose by placing a large plug against the outside wall of the vessel to cover the entire puncture. This complete covering of the puncture is what is meant by placing a plug in “blocking relation” with the puncture.” Doc. 68 at 27. Defendant also argues that the claims make clear that the plug is placed in a “blocking relation” with the puncture in order to seal the puncture. *Id.* Defendant reasons that the plug can only perform this function if it covers the entire puncture. *Id.* For further support, Defendant cites to an embodiment in the patent:

As noted earlier, the sheath is substantially larger in cross section than is arterial puncture 13. Consequently, when plug 57, which fills the entire cross section of the sheath channel, reaches the artery, even in its compressed state it overlaps puncture 13 on all sides. Obviously, then, when it exits the sheath and is

permitted to expand, a full bandage-like covering over puncture 13 is assured.
'439, 7:51-57(emphasis supplied).

Doc. 68 at 27.

ii. Analysis

The parties essentially argue about the construction of the common word “blocking.” The Court agrees with Defendant that the embodiments of the invention indicate that the plug covers the perimeter of the puncture. However, the Court also finds that the patentee chose not to claim the invention with that detail. Instead the patentee claimed “a blocking relation” “so as to seal” the puncture (or similar words). The Court declines to impose limitations from the embodiments when, as here, the claim language does not encompass those limitations.

The Court also agrees with Defendant that the Plaintiffs’ proposal (“positioned to impede the passage through”) is too broad. In the context of the specification, the term “blocking” requires a physical barrier. As this term is used in the claims, it requires a physical “blocking” to accomplish the claimed “seal.” Assuming support in the written description, the patentee could have claimed sealing by other mechanisms such as gluing, clamping or “covering a hole and its perimeter.” Instead, the patentee claimed “blocking” and that term is readily understood for its ordinary meaning in view of the specification. Perhaps “covering a hole and its perimeter” is a type of blocking, but there is no reason to limit the term to this type.

iii. Construction

The Court construes the term “blocking relation” to mean “positioned to physically impede the passage through.”

t. *“sized to be fitted through a passageway leading to said puncture so that said distal end is disposed near said puncture in said artery.”*

i. The Parties’ Positions

This term occurs in claims 1 and 8 of the ‘439 patent. Plaintiffs propose the construction “having a size that fits through the passageway towards the puncture so as to put the distal end near the puncture in the artery.” Doc. 72-1 at 12. Defendant proposes, “wider than the puncture in the artery.” Doc. 72-1 at 12.

Plaintiffs largely support their proposal by pointing to the claim language and an embodiment that Plaintiffs assert contradicts Defendant's proposal. Doc. 56 at 25. Plaintiffs state:

The claim language says nothing about the width of the elongate member in relation to the hole in the vessel. ACI ignores the disclosure that "it would be within the scope of the instant invention to use the procedure cannula as the delivery sheath through which hemostatic material is passed." '439, col. 9:52-56. Because the existing "procedure cannula" enters the arterial puncture, and the plug sheath in turn fits into the procedure cannula, this embodiment calls for a plug sheath that fits into, *i.e.*, is not *wider* than, the puncture.

Id. (emphasis in original).

Defendant makes a variety of arguments. First, Defendant argues that the file history requires its interpretation. Doc. 68 at 23. Next Defendant points to the specification's abstract and summary where "Janzen unambiguously states that the claimed invention's elongated member . . . is larger than the puncture in the artery." *Id.* Defendant further dismisses Plaintiffs' exemplary embodiment as "boilerplate" or "throw-away." *Id.* at 24. Finally, Defendant argues that the claim words themselves require the size limitation because the sizing is "so as to put the distal end near the puncture in the artery." Doc. 71 at 11.

ii. Analysis

The Court agrees with Plaintiffs that the term does not require the "elongated member" to be "wider than the puncture in the artery." The Court has reviewed Defendant's U.S.-based file history citations and finds them unpersuasive because they relate to other patents where relative size limitations were included in the pending claims. *See* Doc. 68, Exhs. V, P, and Q. In other words, those citations are directed at different claims with different limitations. The Court also finds the citations to the foreign prosecution unpersuasive for similar reasons. Thus, the cited statements are not persuasive as to the construction of the instant limitation because those statements are directed at different claims, with different limitations and in other prosecution.

The Court also disagrees that the Summary and Abstract statements (or other specification statements) should limit the ordinary meaning of this claim term. As Plaintiffs note, the specification states that the scope of the invention provides for delivery of the

hemostatic material in the procedure cannula, which was inside of the hole in the artery. *See* ‘439 patent, 9:52-56. Defendant argues that the Court should ignore this embodiment as boilerplate, but the Court finds that it is not a boilerplate statement but rather a specific potential alteration of the previously disclosed embodiments.⁶ However, at the January 20 hearing, Defendant also suggested the embodiment should be ignored because the specification does not say how to use the cannula and still keep the hemostatic material out of the hole in the artery. Tr. January 19-20, 2010 at 98 and 99. Defendant’s argument is unpersuasive because the relevant claims (1 and 8) do not require that the hemostatic material be kept out of the hole. In sum, the Court will not ignore the cited embodiment.

Finally, Defendant argues that the claim wording itself requires the greater width of the elongated member because it must be “sized to be fitted . . . so that said distal end is disposed near said puncture.” The Court disagrees. Even assuming that the “sized to be fitted” words modify the “so as . . .” clause, the claim merely would require that the elongated member “fit” in a way to deposit the material as claimed. The language simply does not require a specific relative width limitation as Defendant suggests.

iii. Construction

The Court construes the term “sized to be fitted through a passageway leading to said puncture so that said distal end is disposed near said puncture in said artery” to mean “having a size that fits through the passageway towards the puncture so as to put the distal end near the puncture in the artery.”

u. “without extending into” and “preventing . . . from extending into”

i. The Parties’ Positions

The term “without extending into” occurs in claim 9 of the ‘616 patent, claim 38 of the ‘602 patent and claim 21 of the ‘375 patent. The term “preventing . . . from extending into” occurs in claims 40 and 43 of the ‘602 patent. Defendant proposes the construction “without extending into the open space within a vessel or organ.” Plaintiffs suggest no construction for

⁶ Boilerplate language is general in nature, thus making the language “boilerplate.” In contrast, the specification language discusses a specific relative use of hemostatic material and a procedure cannula.

either of these terms, and criticizes Defendant's offering because it "oddly repeats the claim language, but adds 'open space,' adding limitations where none exist." Doc. 56 at 16.

Defendant supports its construction by noting the ambiguity it wishes to clarify: "The issue is whether the terms prevent the vessel plug from entering into the vessel wall. ACI's proposed construction eliminates this ambiguity by making clear that, consistent with the intrinsic evidence, the vessel plug may extend into the wall of the vessel or organ, but not the space within the wall." Doc. 68 at 12-13. Defendant further argues that:

The Fowler specification repeatedly states that the vessel plug does not extend into the lumen and, as such, does not disrupt the flow of blood therethrough. *See, e.g.*, Abstract, col. 2:52-57, col. 3:3-8. Specifically, Fowler states at col. 5:1-6 that "the distal end of the vessel plug contacts the inflated balloon on the distal end of the balloon catheter. In this position, the distal end of the balloon prevents the vessel plug from extending into the artery." Figures 3-4, depicting Fowler's balloon catheter embodiment, show a plug extending into the vessel wall, but not into the space within that wall (*i.e.*, the lumen). Figures 6-9 show that the same is true for the winged embodiment—each figure shows the vessel plug extending into the vessel wall but no further.

Doc. 68 at 13.

ii. Analysis

The claim language in every claim at issue is very clear that the claimed plug may not extend into the blood vessel. The Court agrees with Defendant that, to be consistent with the specification, this term must be construed to allow the plug to enter the void or opening (*i.e.*, the wound) in the vessel wall. The Court, however, rejects Defendant's wording regarding "open space," and instead adheres to terminology consistent with the Court's construction of "lumen."

iii. Construction

The Court declines to construe these terms, but clarifies for the parties that the terms "without extending into" and "preventing . . . from extending into" should not be interpreted to prevent the plug from extending into the wall of the vessel, but only to prevent the plug from extending into the lumen. The parties are instructed to tailor their motion and jury arguments in accord with this holding.

v. “*seal(ed)*” and “*seal(ing)(ly)*”

i. The Parties’ Positions

The “seal” terms occur in claim 9 of the ‘616 patent, claim 38 of the ‘602 patent and claims 1, 8, 9 and 10 of the ‘439 patent. While the parties have not argued any distinction, the Court notes that the ‘439 patent is a Janzen patent and both the ‘616 and ‘602 patents are Fowler patents. Thus, the Court presumes that the same specification teachings do not apply across the patent families.

Defendant asks the Court to construe the “seal” terms to mean “close in a manner that prevents passage of liquid.” Doc. 72-1 at 1. Plaintiffs assert that no construction is necessary, although provides a provisional proposal of “close or effect closure.” *Id.* Thus, the parties disagree regarding whether the claimed “seal” prevents passage of liquid.

Defendant argues that “[b]oth Fowler and Janzen chose to use the common term ‘seal’ and variants of that term to claim the manner in which the vessel wound is repaired. They did not use the broader term “close,” choosing “seal” to reflect the special type of “closure” they were claiming—to close in a manner that prevents passage of liquid.” Doc. 71 at 8. Defendant argues further that:

Every dictionary definition of “seal” supports ACI’s construction. *See, e.g.*, Ex. K (“airtight closure”); Ex. L (“a tight and perfect closure (as against the passage of gas or water)”). Nowhere do Janzen or Fowler ever indicate that they are using the term in some other or broader sense than is reflected in the dictionaries. In fact, both specifications repeatedly emphasize the importance of preventing the passage of blood: Fowler explicitly states that the purpose of his invention is to more quickly “seal[] an incision” so as to “decrease the likelihood that a hematoma will form” (‘375 col. 2:43-46); and Janzen states that the “hemostatic seal is formed so as to stop bleeding from the puncture wound.” ‘439 col. 2:32-33 (emphasis added). This interpretation is further supported by the special plug Janzen describes for working with a guide wire, which includes a “collagen membrane [that] automatically reseals itself” after the guide wire is removed.

Id. at col. 7:49-50. Doc. 71 at 8-9.

Plaintiffs’ respond that Defendant’s proposal is adding limitations to the claim. Doc. 69 at 12. Plaintiffs state that “[t]he patents do not require that all passage of liquid is prevented,”

but “only that a seal be formed.” *Id.* Plaintiffs plainly assert that “[s]ome liquid may indeed still pass, or at least for some time, until clotting occurs. *See* ‘375, col. 7:43-46.” *Id.* Thus, Plaintiff’s position is that the term seal simply requires “the promotion of closure: ‘the vessel plug 52 of the present embodiment may include a clotting agent incorporated therein to promote localized hemostasis in the incision’” *Id.* Finally, in support of its provisional construction using the word “close,” Plaintiff points to the Fowler specification which states “None of the prior art devices teach the use of a simple and relatively inexpensive means for effecting the closure of a puncture or incision in the wall of a blood vessel” ‘375 patent, 2:32-36.

ii. Analysis

The Court has been asked to interpret the word “seal” in the medical context provided in the subject patents discussing the healing of wounds in living organisms. The Court finds Plaintiffs’ statement at the January 19-20 hearing relevant in this regard:

The fact of the matter is that blood vessels are permeable. The fact of the matter is that all sorts of substances permeate through the blood vessels, perhaps not blood, but water permeates, lymphocytes permeate, all sorts of cells permeate. You cannot just completely seal it and prevent all passage of anything therethrough. It doesn’t make any sense from an anatomical point of view.

Tr. January 19-20 at 57.

Indeed, the Court must agree that high school biology teaches us about a myriad of molecular movement in and out of cells and that cells themselves can be the primary ingredient of a fluid (*e.g.*, blood). If the Court adopts a construction proscribing the “passage of fluids,” a sub-question arises then regarding what, if anything, can pass (*e.g.*, cells, molecules). The Court finds that the term “seal” does not, and in context, cannot address the question of micro-movements of anatomical agents, including fluids. None of the patents are discussed in that context and at that level of detail.

Nevertheless, the parties dispute whether the movement of fluid past the plug is proscribed by the word “seal.” The Court can best answer this question by reference to the specifications. Janzen speaks most voluminously regarding the nature of a “seal” through his contextual comments. In particular, Janzen analogizes “closure” to a “sealing” when after

discussing a prior art problem of “closing” a wound, he refers back to the discussion as one regarding “sealing”:

After a procedure, for example, counterpulsation, has been completed, the sheath must be removed and *the wound closed*. Often, this can be accomplished simply by the application of digital pressure, generally augmented by the use of a pressure dressing. Customarily, pressure must be applied for at least 1/2 hour, and frequently for much longer than that. While pressure dressings often suffice, it is not uncommon for additional devices, such as sandbags, to be needed. In addition, during this period the patient must be immobilized, lest movement interfere with *the closing process*. Because of the pressure required, the time during which it must be applied and the need for immobilization, the procedure is painful and uncomfortable. It also requires prolonged personal attention of a health care professional. Finally, *wound closures* accomplished in this manner are prone to reopen unexpectedly long after closure appears to have been completed. Patients are therefore often required to remain in the hospital for 24 hours or longer.

Because sealing can be such a problem, cardiologists tend to use the smallest caliber catheters

‘439 patent, 1:47-67 (emphasis added).

Janzen several times discusses the notion of a “good seal” being achieved by the invention only after a waiting period for the assertion of pressure:

After the plug has been inserted, the upstream clamping pressure is maintained for a very short period of time, and then gently removed. Slight pressure may be maintained on the plug to *hold it against the artery wall until a good seal has been established*. ‘439 patent, 2:40-44 (emphasis added).

In accordance with one embodiment of the instant invention, wounds of this type are closed by inserting a plug into tissue wound or channel 9, and holding it against the outside of the artery wall over arterial puncture 13 for a short period of time *until a good self-sustaining hemostatic seal* is established. *Id.* at 3:37-43 (emphasis added).

Minimal axial pressure is thereafter continued while clamping pressure is slowly released *until a good self-sustaining hemostatic seal* has been confirmed. The sheath, holder, and pusher can all then be removed.’ *Id.* at 5:52-57 (emphasis added).

As was described in connection with the embodiment of FIG. 1, pressure is then maintained *until a good self-sustaining hemostatic seal has been established*. *Id.* at 6:47-50 (emphasis added).

In practice it has been found that when using a collagen plug in accordance with the subject invention, *a good hemostatic seal can be achieved in five minutes or less*. With larger wounds, for example, ones left after removal of 14 Fr. or larger catheters, or after the use of anticoagulants and heparin, sealing may take somewhat longer. *Id.* at 7:57-64 (emphasis added).

While not as replete with references, Fowler also analogized closure to sealing by using the words apparently interchangeably.

By positioning the distal end 32 of the vessel plug 20 at or near the outer lumen of the artery 10, there is no disruption of the fluid flow through the artery 10 at the incision site and the risk of thrombosis is minimized as compared to prior devices which *include a closure or sealing member* which is positioned along the inner lumen of the artery 10. It is anticipated that the vessel plug 20 will degrade and be absorbed within a few weeks or months so that there is no need to remove the vessel plug 20 from the incision at a later date.

‘616 patent, 5:47-58 (emphasis added).

None of the above references expressly define or re-define the term “seal.” However, the Court finds that, with regard to the dispute between the parties, the construction of the term “seal” must be informed by these references to the specification. Most prominently, the references reveal that in the parlance of the Janzen patent, a “good” seal (perhaps still less than perfect) is not achieved upon placement of the plug, but rather over time. Also, the references reveal that both patents, however loosely, sometimes equate “sealing” and “closing.”

Defendant’s proposal would exclude these statements and embodiments by potentially requiring a perfect seal upon placement of the plug. Furthermore, while Plaintiffs’ proposal is consistent with the disclosure, the Court finds it is potentially too broad because the term “close” may not sufficiently connote a substantial fluid barrier to the fact finder. The patentee chose the word “seal,” which is at least technically different than “close.” The Court gives meaning to that difference by interpreting “seal” more narrowly than the broadest reasonable meaning a juror might ascribe to the word “close.” In view of all the foregoing, the Court finds that a “seal” may allow fluid passage as follows: any amount of passage that is normal and consistent with the

healing of a plugged wound (*e.g.*, one that is corked and/or completely covered by the plug); and only other types of fluid passage that are insignificant to the healing of the wound. Lastly, the parties are cautioned that the Court’s use of the words “completely covered” is exemplary and bears only on the “seal terms” and not on the “blocking relation” terms.

iii. Construction

Having resolved the parties’ dispute, the Court declines to construe these terms and instructs the parties to tailor their motion and jury arguments in accord with this Order.

w. “*device*”

i. The Parties’ Positions

The term “device” occurs in the preambles of claims 1, 7 and 8 of the ‘439 patent. The Court notes that, in each case, the term is used as a generic recitation in an apparatus claim. Defendant argues that statements in the specification and file history require that the generically claimed “device” is limited to “the device may not enter the blood vessel.” Doc. 72-1 at 12. Plaintiffs argue that the term is not limiting in any way. Doc. 69 at 23.

Defendant argues its position based upon two sets of statements from the patentee. Defendant asserts the following regarding the specification:

The ‘439 specification repeatedly states that the crucial aspect of the invention is that it does not enter the blood vessel. *See* col. 2:11-14, 2:45-54, 4:53-56, 5:14-15, 7:51-57. Specifically, the ‘439 specification states that the “special device” is sized so as to prevent it from ever entering the blood vessel. Col. 2:46. Therefore, “device” must be construed to exclude any devices that enter the blood vessel from the scope of the ‘439 patent’s asserted claims.

Doc. 68 at 19 (footnote omitted).

In addition, Defendant quotes a variety of file history statements, but admits those statements are merely from related patents. Doc. 68 at 20.

Plaintiffs reply stating that “ACI’s suggestion that nothing of the “device” of claims 1, 7 and 8 of the ‘439 patent can enter the blood vessel, is wrong on its face” because “[t]here clearly are parts of the claimed device that enter the blood vessel.” Doc. 69 at 23. Plaintiffs assert, for

example, that claims 1, 7 and 8 recite a “guide means” or a “guide element,” as part of the described device, which expressly extends through the puncture and therefore into the blood vessel. *Id. citing* ‘439 patent, Figs. 6-8, 13-15, 17.

ii. Analysis

As discussed above, “[g]enerally, the preamble does not limit the claims.” *Allen Eng’g Corp.*, 299 F.3d at 1346. A preamble may limit the invention “if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Eaton Corp.*, 323 F.3d at 1339. As such, a preamble is limiting where it is necessary to understand limitations in the body of the claim. *See Pitney Bowes, Inc.*, 182 F.3d at 1305-06. A preamble is also limiting where the preamble is the basis for a distinction over the prior art made during prosecution. *See In re Cruciferous Sprout Lit.*, 301 F.3d 1343, 1347 (Fed. Cir. 2002).

Thus, whether the term “device” should be considered a limitation at all depends upon whether it breathes life into the claim or otherwise qualifies as a limitation under the law. As stated above, Defendants advance two sets of evidence in this regard. First, Defendants suggest that the “specification repeatedly states that the crucial aspect of the invention is that it does not enter the blood vessel.” Doc. 68 at 19. The Court has examined Defendant’s citations closely and finds no words indicating that the feature is necessary to the device. All of the citations refer to either normal suggestive language or recitation of embodiments. Second, Defendant points to file history statements of other, but related, patents. In this regard, Defendant emphasizes the general nature of the patentee’s comments regarding the device’s exclusion from the vessel. The Court finds that those comments are not relevant to claims 1, 7 and 8 of the ‘439 patent. As Plaintiffs point out, claims 1, 7 and 8 recite a “guide means” or a “guide element,” as part of the described device, which expressly extend through the puncture and therefore into the blood vessel.

In view of the foregoing, the Court does not apply the quoted file history statement to the subject claims. Thus, the Court finds that the term “device” does not limit the claims in any way. The Court recognizes that file history statements may alter and contradict the ordinary meaning of claim terms. If the statements cited by Defendant were in the ‘439 patent file history and clearly tied to the subject claims, this result may be different. Here, there are no statements by

the patentee or Patent Office that tie the statements to the claims. The Court will not imply a relationship merely because the statements are general and unequivocating. The Court finds that the quoted statements do not apply to the subject claims. Given the differing contexts between these related patent applications and the stark contradiction between the statements and the express claim language, the Court finds that it is unreasonable to believe the two relate to each other.

iii. Construction

The Court finds that the term “device” is not a limitation.

x. “*method comprising the steps of*”

i. The Parties’ Positions

This dispute applies to claims 9 and 10 of the ‘439 patent. The parties disagree regarding whether the claimed method steps must be performed in order. The Defendant asserts that “the ‘439 patent’s claim language, specification, and prosecution history all require that the steps of claims 9 and 10 be performed sequentially.” Doc. 68 at 37. In substance, Plaintiffs argue that the file history makes clear that there is no order to the steps.

ii. Analysis

The steps of method claims must be performed in order when the language of the claims requires ordering the steps or something in the intrinsic record suggests they must occur sequentially. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1321-22 (Fed. Cir. 1999) (“Although not every process claim is limited to the performance of its steps in the order written, the language of the claim, the specification and the prosecution history support a limiting construction in this case.”); *see also Mantech Envtl. Corp. v. Hudson Envtl. Svcs., Inc.*, 152 F.3d 1368, 1375-76 (Fed. Cir. 1998) (finding sequential limitation implicit in claim language).

The Court reproduces the claims below and labels the method steps so that the discussion may contain reference thereto.

9. A method of closing a puncture in a wall of an artery made for the purpose of moving an elongated cardiac catheter into the artery in which an exterior guide tube is extended through a passage leading to the puncture and through the

puncture in the wall of the artery and into the artery so as to enable the catheter to be guidingly moved through the guide tube and into the artery, the method comprising the steps of:

- (a) withdrawing the cardiac catheter and moving the guide tube outwardly so that it no longer extends within the puncture,
- (b) extending a plug having a removable guide wire extending longitudinally therethrough so that the guide wire extends from the plug through said puncture,
- (c) moving the plug inwardly along the guide wire into blocking relation with said puncture, and
- (d) withdrawing the guide wire from the plug so as to leave the plug sealed in blocking relation with said puncture.

10. A method of closing a puncture in a wall of an artery comprising the steps of:

- (a) inserting a removable guide wire through said puncture into the artery,
- (b) threading a plug over said guide wire so that the guide wire extends from the plug through said puncture,
- (c) moving the plug inwardly along the guide wire into blocking relation with said puncture, and
- (d) withdrawing the guide wire from the plug so as to leave the plug sealed in blocking relation with said puncture.

With reference to claim 9, the first recited method step is the withdrawing of the cardiac catheter and moving the guide tube outwardly. This step was the subject of discussion in the prosecution history. Doc. 69, Exh. EE at 4 and 5. Prior to the amendments made during the cited prosecution document, the part of step (a) requiring “moving the guide tube outwardly” was recited after the current step (b) (“extending the plug”) *Id.* at 1 and 2. At the time of the cited amendment, the patentee effectively changed the position of the “moving the guide tube” substep from its original position after step (b), to its current position prior to step (b). *Id.* While the exact purpose of this amendment may be debatable, there is no doubt that it was performed to

overcome the examiner's rejections (“[a]pplicants have now amended claim 103 in a manner which is believed to fully overcome the latest objection under §112”). *Id.* at 4-5. As a result, the patentee may not now argue that claim step may be performed in its original position, *i.e.*, any time after step (b).

Thus, with respect to claim 9, step (a) must occur before step (b). Furthermore, step (b) must occur before step (c) because the plug may not be moved along the guide wire until the guide wire has been extended. Finally, step (c) must be performed prior to step (d) because the guide wire cannot be withdrawn from the plug until after the plug has been moved inwardly along the guide wire.

With respect to claim 10, step (a) must occur before or simultaneous with step (b) because step (b) requires the “threading” step “so that the guide wire extends from the plug through the puncture.” This “so that” clause could not occur prior to (a)’s insertion of the guidewire into the puncture (*i.e.*, the guidewire cannot extend from the plug to the puncture unless the guidewire extends to the puncture). Step (b) must be performed before step (c) because, consistent with the disclosure, the plug may not be guided into a blocking relation with the puncture, unless the plug has been threaded and the guidewire is in place. Finally, step (d) must occur after step (c) because the guide wire cannot be withdrawn from the plug until after the plug has been moved inwardly along the guide wire.

iii. Construction

The method steps as labeled above must be performed in order from (a) to (d).

V ORDER

This is the Court’s Claim Construction Order with respect to the ‘616, ‘602, ‘375, ‘498, and ‘439 patents. The Order is based on the current record before the Court.

IT IS SO ORDERED, this 19th day of July, 2010.

/s/ Harry F. Barnes
Hon. Harry F. Barnes
United States District Judge