IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPEYSIDE MEDICAL, LLC, Plaintiff, v. MEDTRONIC COREVALVE, LLC and MEDTRONIC, INC., Defendants.	))))))))))	Civil Action No. 20-361-GBW-CJB

REPORT AND RECOMMENDATION

In this patent action filed by Plaintiff Speyside Medical, LLC ("Speyside" or "Plaintiff") against Defendants Medtronic Corevalve, LLC and Medtronic, Inc. ("Medtronic" or "Defendants"), Speyside alleges infringement of United States Patent Nos. 8,377,118 (the "'118 patent"), 9,510,941 (the "'941 patent"), 10,449,040 (the "'040 patent") and 9,445,897 (the "'897 patent" and collectively with the '118 patent, the '941 patent and the '040 patent, "the asserted patents" or the "patents-in-suit").[1] Presently before the Court is the matter of claim construction. (D.I. 177; D.I. 178) The Court recommends that the District Court adopt the constructions set forth below.

I. BACKGROUND

Speyside commenced this action on March 13, 2020. (D.I. 1) The case was thereafter referred to the Court to hear and resolve all pretrial matters up to and including expert discovery matters (but not including summary judgment motions, *Daubert* motions, pretrial motions in limine or the pretrial conference). (D.I. 103; D.I. 165)

[1] While Speyside previously also asserted United States Patent No. 9,603,708 (the "'708 patent"), (*see* D.I. 119 at 1), it no longer asserts the '708 patent, (D.I. 175 at 1).

Speyside alleges that Medtronic's Evolut R, Evolut Pro, Evolut Pro+ and Evolut FX transcatheter aortic valve replacement ("TAVR") systems infringe the asserted patents. (D.I. 74 at ¶ 7; D.I. 160 at 1; D.I. 209 at 1; D.I. 223) The '118 patent, '941 patent and '040 patent share a common specification and recite methods for delivering a replacement heart valve. (D.I. 100, exs. A, C, E; Speyside's Markman Presentation, Slide 2) The '897 patent is a member of a different family and recites methods of positioning a prosthetic valve using a delivery catheter with an introducer catheter that is preassembled. (D.I. 100, ex. G; Speyside's Markman Presentation, Slide 2)[2] Further details regarding the asserted patents will be provided below in Section III.

On July 28, 2021, the parties filed their joint claim construction brief. (D.I. 119) On September 30, 2021, the case was stayed pending completion of *inter partes review* ("IPR") proceedings involving the '118 patent, the '897 patent and the '708 patent. (D.I. 155) In August 2022, the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") issued Final Written Decisions affirming the patentability of all asserted claims of the '118 patent, affirming the patentability of six out of 17 claims of the '897 patent and finding the two asserted claims of the '708 patent unpatentable. (D.I. 162 at 1) On October 14, 2022, the Court lifted the stay of the case. (D.I. 166)

The parties then filed supplemental claim construction opening briefs on November 22, 2022 to address the impact of the IPRs on certain of the disputed claim terms, (D.I. 170; D.I.

[2] The asserted patents appear on the docket in this action more than once. Further citations to the patents will simply be to their patent number. The '118 patent is entitled "Unstented Heart Valve With Formed In Place Support Structure." ('118 patent, Title) The '941 patent and '040 patent are entitled "Method of Treating a Patient Using a Retrievable Transcatheter Prosthetic Heart Valve." ('941 patent, Title; '040 patent, Title) The '897 patent is entitled "Prosthetic Implant Delivery Device With Introducer Catheter." ('897 patent, Title)

171), and supplemental claim construction responsive briefs on December 6, 2022, (D.I. 173; D.I. 174). The Court conducted a *Markman* hearing on January 10, 2023. (D.I. 183 (hereinafter, "Tr.")) On May 26, 2023, Defendants submitted a notice of supplemental authority, and Speyside submitted a response on May 30, 2023. (D.I. 276; D.I. 278)

II. STANDARD OF REVIEW

The Court has often set out the relevant legal standards for claim construction, including in *Vytacera Bio, LLC v. CytomX Therapeutics, Inc.*, Civil Action No. 20-333-LPS-CJB, 2021 WL 4621866, at *2-3 (D. Del. Oct. 7, 2021). The Court hereby incorporates by reference its discussion in *Vytacera Bio* of these legal standards and will follow them herein. To the extent consideration of the disputed terms here necessitates discussion of other, related legal principles, the Court will address those principles in Section III below.

III. DISCUSSION

The parties set out seven disputed terms for the Court's review.[3] The Court takes up the first six terms in the order in which they were argued, and lastly addresses the remaining term that was submitted on the papers.

A. "substantially equal to or less than"

The first disputed term, "substantially equal to or less than[,]" appears in claim 1 of the '118 patent. Claim 1 recites a method for replacing a patient's native aortic heart valve, which requires the delivery of "an implantable expandable carrier element and an implantable replacement valve[.]" ('118 patent, col. 79:24-27) Pursuant to the method, *inter alia*: (1) the "carrier element" that brings the replacement valve to the heart is positioned "proximate" to the

[3] The parties originally presented three additional disputed terms from the claims of the '708 patent. (D.I. 119 at 63-80) However, the Court need not take up these terms since the '708 patent is no longer being asserted. (D.I. 175 at 1)

native aortic heart valve; (2) the carrier element is expanded "from a collapsed delivery configuration to a first expanded configuration"; (3) the position of the carrier element is evaluated; and (4) the carrier element is then "at least partially collapse[ed] . . . from the first expanded configuration to a moveable configuration, a length of the carrier element in the moveable configuration being *substantially equal to or less than* a length of the carrier element in the first expanded configuration" so that the carrier element can be repositioned in the vicinity of the native aortic heart valve. (*Id.*, col. 79:34-54 (emphasis added))

The parties' competing proposed constructions for "substantially equal to or less than" are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
"substantially equal to or less than"	"approximately equal to or less than"	"equal to or less than" Or, in the alternative, indefinite.

(D.I. 119 at 2; D.I. 170 at 1; Speyside's Markman Presentation, Slide 5) Speyside wants a construction for this term that would allow for the length of the carrier element in the moveable configuration to be, at least in certain circumstances, some amount longer than the length of the carrier element in the first expanded configuration. (Tr. at 51-52) In other words, Speyside contends that the patentee—by stating that the length of the carrier element in the movable configuration is "*substantially equal to* or less than" the length of the carrier element in the first expanded configuration—was allowing for the length of the carrier element in the movable configuration to be equal to, less than, or *insignificantly longer* than the length of the carrier element in the movable configuration. (*Id.* at 87; *see also id.* at 77 (Speyside's counsel asserting that "substantially" allows for "some variation from precisely equal"))

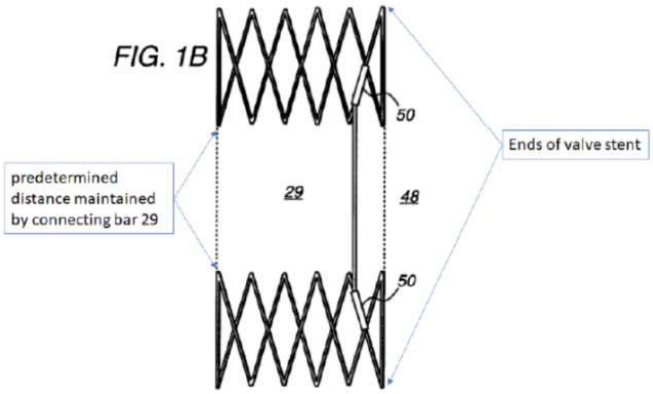
Meanwhile, Medtronic argues that during the IPR proceedings, Speyside disclaimed any construction of the term that would allow for the length of the carrier element in the moveable configuration to be longer than the length of the carrier element in the first expanded configuration. (D.I. 170 at 1; Tr. at 6, 12) Thus, Medtronic argues that the claim term should be construed to mean "equal to or less than." (D.I. 170 at 1) Alternatively, Medtronic argues that the claim term is indefinite, because the intrinsic record provides no guidance as to how much longer the carrier element in the moveable configuration can be and still fall within the scope of the claim. (D.I. 119 at 5-9, 12-14; Medtronic's Markman Presentation, Slide 2)

"The doctrine of prosecution disclaimer precludes . . . patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005) (brackets and citation omitted). Statements made by a patentee during an IPR proceeding can be considered for prosecution disclaimer, though in order to invoke the doctrine, such statements must be "both clear and unmistakable." *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1361 (Fed. Cir. 2017) (internal quotation marks and citation omitted). The United States Court of Appeals for the Federal Circuit has explained that "when a prosecution argument is subject to more than one reasonable interpretation, it cannot rise to the level of a clear and unmistakable disclaimer." *Id.* at 1363 (internal quotation marks and citation omitted).

Here, the Court concludes that during the IPR proceedings, Speyside made a clear and unmistakable argument that "substantially equal to or less than" should be limited in the manner

suggested by Medtronic.[4] To explain why, the Court will begin by discussing the IPR proceedings at issue.

In those proceedings, Medtronic had argued that the claims of the '118 patent were obvious over, *inter alia*, a prior art reference called "Leonhardt." (D.I. 170, ex. 1 at 8) Leonhardt, as shown in the annotated figure below, discloses a carrier element (i.e., a stent)[5] with top and bottom portions that define a zig-zag shape and that are connected by a connecting bar 29; collectively, these parts form a cylinder. (*See* D.I. 170 at 1)



In the IPR, with respect to the "substantially equal to or less than" claim limitation, Medtronic had asserted that the length of Leonhardt's stent in the "repositioning" (i.e., moveable) configuration was "substantially equal to" its length in the fully deployed (i.e., first expanded) configuration. (D.I. 173, ex. 1 at 47) Medtronic's expert opined that this was so because the connecting bar in the structure maintained a "predetermined distance" between the

[4] In light of this conclusion, the Court need not address Medtronic's indefiniteness argument.

[5] Because a carrier element can mean the same thing as a stent, the Court will use the terms interchangeably. (*See* Tr. at 9)

ends of the valve/stent. (*Id.*; *id.*, ex. 2 at ¶ 137)[6] In Speyside's written IPR Response ("POR"), it retorted that Medtronic had failed to demonstrate that Leonhardt met the "substantially equal to or less than" claim limitation of the '118 patent claims because Medtronic's argument "only addressed *a portion* of the length of the carrier." (*Id.*, ex. 3 at 23 (emphasis added)) Speyside pointed out that the connecting bar did not extend through the zig-zag portions at the top and bottom of the stent, and that Medtronic failed to address the impact of the "expansion of the zig-zag portions at either end of the carrier on the length of the carrier." (*Id.* at 25) As the stent in Leonhardt expanded, the shape changed substantially, with the zig-zag ends of the stent flaring outwards. (*Id.* at 26-27) Speyside argued that even though the flaring of the stent impacts the length thereof, Medtronic did not confront this, and instead had focused solely on the length of the connecting bar in asserting that Leonhardt met the claim limitation. (*Id.* at 28)

During the IPR hearing held on May 16, 2022, Speyside's counsel discussed this issue with the PTAB. Speyside's counsel first explained that:

> [T]he only dispute appears to be whether [Medtronic has] shown that the length of the valve carrier in Leonhardt in the mov[e]able configuration is substantially equal to the length in the first expanded configuration. In other words, when the valve in Leonhardt is collapsed, does its length stay substantially the same.

(D.I. 170, ex. 2 at 37) Speyside's counsel then continued that:

> [T[he fact that Leonhardt's stent can't become shorter when it's collapsed does not mean that the length stays substantially the same or substantially equal.

[6] It was undisputed that the connecting bar precluded the length of the stent in the movable configuration from becoming "less than" (i.e., shorter than) a length of the carrier element in the first expanded configuration. (*See* Tr. at 11; D.I. 170, ex. 2 at 38) Thus, the issue was whether the length of Leonhardt's carrier element in the moveable configuration was "substantially equal to" the length of the carrier element in the first expanded configuration (such that it met the "substantially equal to or less than" claim limitation from the claims of the '118 patent).

> To the contrary, the length of the stent in Leonhardt *becomes longer* when it's collapsed as compared to when it's expanded, and *that change in the length, that lengthening of Leonhardt*, is not addressed by [Medtronic] in [its IPR] Petition and *is, in fact*, *the opposite of what the claims require.*
>
> *The claims require that when it's collapsed, it becomes—it stays the same length or becomes shorter.* In Leonhardt, it necessarily will *become longer* when it's collapsed.

(*Id.* at 38-39 (emphasis added)) And Speyside's counsel then again reiterated that:

> When [the stent in Leonhardt is] then collapsed to the movable configuration, those [zig-zag shaped] tips again compress down and expand back outwards, causing it to *become longer* when it's in the compressed configuration. *That's exactly the opposite of what's required by the claims.*
>
> And because the distensible fingers at the ends of the Leonhardt valve lengthen when the valve is collapsed and shorten when the valve is expanded, [Medtronic hasn't] shown that the length of the carrier element in the movable configuration is substantially equal to or less than a length in the first expanded configuration.

(*Id.* at 42-43 (emphasis added))[7]

Speyside contends that Medtronic's disclaimer argument wrongly focuses on a "few out-of-context statements" made by Speyside's counsel during the PTAB hearing that, when placed in the context of the full record, do not amount to a clear and unmistakable disclaimer. (D.I. 173 at 3; Tr. at 61, 63) Speyside points to the times in the hearing where its counsel used the "substantially equal to" language in order to demonstrate that it did not disclaim "substantially[,]" (D.I. 173 at 4); Speyside asserts that it "never argued that . . . because [the stent in Leonhardt] becomes longer, it can't meet the claim limitation[,]" (Tr. at 64; *see also* D.I. 173 at 3 ("Speyside, however, never argued that Leonhardt failed to meet the claim language simply

[7] The PTAB's Final Written Decision noted Speyside's argument during the hearing "that the length of Leonhardt's stent becomes longer when it is collapsed as compared to when the stent is expanded." (D.I. 170, ex. 1 at 21)

because Leonhardt's valve gets longer when it is collapsed.")). Instead, Speyside's counsel asserted that while he "did say [during the IPR hearing that the claims require that the stent] stays the same length [or become shorter when it is collapsed]" after he[8] utilized the "substantially equal to" language, he did so only because "you're in the middle of a hearing and you're talking, and . . . saying 'substantially equal to or less than' over and over again becomes a little bit tiresome." (Tr. at 61, 67)[9]

The Court is not persuaded. It is true that in its POR and in its initial comments at the hearing, Speyside used the "substantially equal" language in arguing that Medtronic had not addressed the amount of lengthening of the Leonhardt stent (and whether that amount fell within the scope of the claim language). But then at the hearing, Speyside's counsel argued repeatedly that the length of the stent in Leonhardt becomes longer in the movable configuration, and stated that this falls outside the scope of the claim limitation. (*Id.* at 12-15, 99) That is, Speyside told the PTAB—clearly and unmistakably—that the claims require that when the carrier element is collapsed, it "stays the same length or becomes shorter" than the length of the carrier element in the first expanded configuration. (D.I. 170, ex. 2 at 39) And its counsel then twice—again, clearly and unmistakably—emphasized this same point in a different way. Counsel stated that

[8] The same attorney that argued at the IPR hearing on behalf of Speyside argued this term at the *Markman* hearing.

[9] The Court understands Speyside to be suggesting that its position on Leonhardt during the PTAB hearing was something like the following: (1) the patent's claims require that the length of the carrier element in the movable configuration must be "substantially equal to or less than" its length in the expanded configuration; (2) this can mean that, in order to read on the claims, the length in the movable configuration can be *somewhat* (or *insubstantially*) greater than in the expanded configuration (just not *substantially* greater); but (3) since Medtronic did not address the amount of length that the Leonhardt stent had in the movable configuration; then (4) Medtronic did not show that Leonhardt invalidated the claims, since it is possible that the Leonhardt stent may have been of *substantially* greater length in the movable configuration, as opposed to in the expanded configuration. (Tr. at 53-55, 58-59)

when the stent of Leonhardt is collapsed, it "become[s] longer" than the length of the stent in the first expanded configuration, which is "exactly the opposite of what[is] required by the claims." (*Id.* at 38-39, 42-43) In other words, Speyside's counsel was surely conveying that the claims at issue do not allow for the length of the carrier element to become "longer" in the movable configuration—they allow for the "opposite" of that (i.e., claims where this length becomes shorter, or at most, stays the same).[10] In light of these statements, a claim construction reflecting Speyside's disclaimer (i.e., "equal to or less than") is warranted here. *See, e.g.*, *CliniComp Int'l, Inc. v. Cerner Corp.*, Case No.: 17-cv-02479-GPC (DEB), 2022 WL 3006343, at *7 (S.D. Cal. July 28, 2022) (agreeing with the defendant that the plaintiff's several statements made during the IPR hearing "to distinguish claim 1 of the '647 patent from the Johnson prior art reference" constituted a clear and unmistakable disclaimer).[11]

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[10] Speyside likens the circumstances here to those in *M2M Sols., LLC v. Sierra Wireless Am., Inc.*, Civil Action No. 14-cv-01102-RGA, Civil Action No. 14-cv-01103-RGA, 2019 WL 6328119, at *3-4 (D. Del. Nov. 26, 2019), where the Court declined to find that a single statement made during an IPR hearing constituted disclaimer. (D.I. 173 at 4 n.1) In that case, the defendants argued that a statement made "only during oral argument and not in Plaintiffs' papers" constituted a disclaimer with respect to the "programmable interface" limitation. *M2M Sols, LLC*, 2019 WL 6328119, at *3. In rejecting the defendants' position, the Court noted that the single statement at issue was not specific and was made once in a "back-and-forth between the [PTAB] Judge and [plaintiffs'] counsel" about a *different* claim limitation. *Id.* at *4. The Court concluded that "[t]he lack of specificity of the statement and the fact that it is out of context mean that the statement is subject to more than one reasonable interpretation and is therefore not clear and unmistakable disclaimer." *Id.* The circumstances are not the same here. Speyside's repeated statements to the PTAB were specific and clear. And those statements concerned the very same claim limitation that is at issue here ("substantially equal to or less than"), not a different claim limitation (as was the case in *M2M*). *See, e.g.*, *Pact XPP Schweiz AG v. Intel Corp.*, Case No. 1:19-cv-01006-JDW, 2023 WL 2631503, at *3 (D. Del. Mar. 24, 2023) (finding prosecution disclaimer based on statements made during oral argument in an IPR proceeding).

[11] The Court's conclusion here is not impacted by the fact that the PTAB did not expressly adopt Speyside's disclaimer in its Final Written Decision. (D.I. 170 at 3-4); *see also Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1374 (Fed. Cir. 2005) ("An applicant's argument made during prosecution may lead to a disavowal of claim scope even if the Examiner

Therefore, the Court recommends that "substantially equal to or less than" be construed to mean "equal to or less than."[12]

B. "[a]/[in the] vicinity of the native heart valve" (Speyside) / "vicinity" (Medtronic)

The next disputed term (the "vicinity term") (which Speyside views as "[a]/[in the] vicinity of the native heart valve" and Medtronic views as "vicinity") appears, *inter alia*, in claims 1, 17 and 28 of the '941 patent. These claims each recite a method for replacing a patient's native heart valve requiring the delivery of "an expandable first carrier element and a first replacement valve endovascularly to *a vicinity of the native heart valve*" and expanding the carrier element from a collapsed delivery configuration to an expanded configuration "*in the vicinity of the native heart valve*." ('941 patent, cols. 81:22-24, 81:29-31, 83:7-13, 84:5-14 (emphasis added)) Claim 1 further requires expanding a "second carrier element from a collapsed delivery configuration to an expanded configuration to secure the second carrier element in *the vicinity of the native heart valve*[.]" (*Id.*, col. 81:57-60 (emphasis added))

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did not rely on the argument."). Nor does it alter the Court's conclusion that adoption of Speyside's disclaimer would essentially read "substantially" out of the claim term. (D.I. 170 at 4); *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 429 (Fed. Cir. 2016) ("The preference for giving meaning to all terms, however, is not an inflexible rule that supersedes all other principles of claim construction."); *ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1286 (Fed. Cir. 2010) (finding prosecution history disclaimer even though it resulted in some claim limitations being "surplusage"). Moreover, construing the claim term to mean "equal to or less than" would not be inconsistent with the specification of the '118 patent, which does not depict any carrier elements that are longer in a moveable configuration than in a first expanded configuration. (*See* D.I. 119 at 6, 13; Tr. at 26, 93)

[12] Medtronic further briefly suggests that the Court should find that Speyside is judicially estopped from arguing infringement based on its statements to the PTAB. (D.I. 170 at 4-5) The Court declines to consider Medtronic's estoppel argument at the claim construction stage of the case. (*See* D.I. 173 at 5)

The parties' competing proposed constructions for the vicinity term are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
"[a]/[in the] vicinity of the native heart valve" (Speyside) / "vicinity" (Medtronic)	"proximate to the native heart valve"	indefinite

(D.I. 119 at 14) As Medtronic contends that this term is indefinite, the Court will first set out the law as to definiteness. It will then discuss the merits.

Section 112 of the Patent Act requires that a patent claim "particularly point[ ] out and distinctly claim[ ] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). If it does not, the claim is indefinite and therefore invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 902 (2014). The primary purpose of the definiteness requirement is to ensure that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling interested members of the public (e.g., competitors of the patent owner) to determine whether they infringe. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). Even so, "absolute precision is unattainable" and is not required. *Nautilus*, 572 U.S. at 910. In the end, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 901. As long as claims satisfy the test for definiteness, "relative terms and words of degree do not render patent claims invalid." *One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1063 (Fed. Cir. 2017). Definiteness is to be

evaluated from the perspective of a person of ordinary skill in the art ("POSITA") at the time the patent was filed. *Nautilus*, 572 U.S. at 908.[13]

For its part, Speyside argues that the ordinary meaning of "vicinity" is "proximate"—and that this would be well known and understood by a POSITA. (D.I. 119 at 15 (citing D.I. 120, ex. K at 2550); *id*. at 19; Tr. at 111; *see also, e.g.*, D.I. 121, ex. JJ at 2 (noting that "proximity" and "vicinity" are synonyms)) Because the '941 patent uses the term "vicinity" interchangeably with its ordinary meaning—"proximate"—Speyside argues that there is no indefiniteness issue, and the term should be construed as such. (D.I. 119 at 15-16) In support, Speyside notes that the specification describes embodiments in which the "prosthetic valve" (which seems to be synonymous with the claimed "replacement valve") is advanced to a position "proximate a native valve of the heart." (*Id.* at 20 (citing '941 patent, col. 5:19-22, 5:26-30, 5:34-38, 5:41-45, 5:48-51); Tr. at 112)[14] The specification also discloses Figures 2, 2A and 2D which depict the replacement valve as being in physical contact with or "spanning" the native heart valve. ('941 patent, FIGS. 2, 2A, 2D; *id.*, cols. 8:1-5, 8:12-13, 11:47-50; Medtronic's Markman Presentation, Slide 23) It is undisputed that these embodiments constitute examples of the replacement valve being in the vicinity of the native heart valve. (Tr. at 107, 113)

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[13] Like claim construction, definiteness is a question of law for the court. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1332 (Fed. Cir. 2014). The Federal Circuit has stated that "[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

[14] The specification explains that the prior art "percutaneous valve replacement devices [did] not provide a means for testing the function of the valve before committing to the position of the valve." ('941 patent, col. 75:4-6) Speyside contends that delivering the replacement valve proximate to the native heart valve is important to the "'unique deployment procedure'" claimed by the patent, which "'consist[s] of the steps of position, enable, test, and reposition or deploy.'" (D.I. 119 at 15 (quoting '941 patent, col. 75:14-16))

Nevertheless, Medtronic asserts that the term "vicinity" is indefinite because the intrinsic record provides no guidance as to the scope of "vicinity," leaving it "impossible for a doctor performing a TAVR procedure to know at which locations the claims are and are not practiced." (D.I. 119 at 16 (citing D.I. 120, ex. U at ¶ 29)) Medtronic's argument in this regard really hinges on two figures in the patent: Figures 52A and 57E. The embodiments depicted in those two figures are described in the patent as ones where *temporary* valves are implanted in the ascending and descending aorta, in locations that are *not* in physical contact with the native heart valve. ('941 patent, FIGS. 52A, 57E; *id.*, cols. 54:55-57, 64:17-40) Medtronic contends that the intrinsic record provides no guidance as to whether these Figure 52A- and 57E-related embodiments would satisfy the "vicinity" term. (D.I. 119 at 16-17; Tr. at 107) And even though these disclosures relate to the delivery of a *temporary* valve, Medtronic argues that it is possible that they could still be captured by the claim language at issue here because: (1) the "replacement valve" recited in the claims could be a temporary valve; and (2) a POSITA would be aware of replacement valves that were actually described in the art at the relevant time as being deployed in the aorta, such as in United States Patent No. 9,125,739 (the "'739 patent"). (D.I. 119 at 22; Tr. at 107-08) So Medtronic asserts that because the specification fails to shed light on whether the embodiments depicted in Figures 52A and 57E practice the "in the vicinity" claim limitation, it is unclear whether such valves (i.e., valves placed in a location that is "not contiguous to" the native heart valve) would be "in the vicinity" of that native valve or not. (D.I. 119 at 16-17)

Medtronic's argument is not persuasive. That is because the "temporary valves" referenced in the patents cannot be understood to be examples of the claimed "replacement valve." While Medtronic argues to the contrary that "[t]here's nothing in the body of Claim 1

that talks about the [replacement] valve that's [recited therein] being a permanent valve[,]" (Tr. at 108), in fact the claimed invention seems to be all about permanently replacing a patient's native heart valve, (D.I. 119 at 19 n.1; Tr. at 116-17). After all, the relevant claim language requires the delivery of a *replacement* valve to a vicinity of the native heart valve. And the specification clearly differentiates temporary valves from replacement valves (which it also refers to as "prosthetic valve[s,]"), explaining that:

> [I]n order to preserve outflow from the heart, between the time that the native aortic valve is excised or debulked and the time that a *prosthetic valve* is implanted, a *temporary valve* **520** (see Fig. **52A**) can be installed. The *temporary valve* **520** can be placed in the aorta **36** in the arch or in the descending or ascending aorta.

('941 patent, col. 54:53-57 (emphasis added)) The placement of a temporary valve is an optional (unclaimed) additional step that may be performed as part of the process for delivering a replacement valve. To that end, the specification further describes Figures 57A-57O, which include "the steps of placing a *temporary valve* . . . implanting a *permanent prosthetic valve*, and then removing the *temporary valve*[.]" (*Id.*, col. 64:3-11 (emphasis added)) The specification does not refer to a replacement valve being placed in the ascending or descending aorta, nor does it ever disclose a temporary valve being delivered to a vicinity of the native heart valve. (*See* D.I. 119 at 20; Tr. at 114) Instead, it simply refers to placement of a temporary valve "at a cardiovascular site in fluid communication with a native valve" or "in series fluid flow with a native valve" or "in the ascending or descending aorta." ('941 patent, cols. 6:22-24, 29-30, 64:26-28) And it discloses that replacement valves (i.e., prosthetic valves) are delivered "to a position proximate a native valve of the heart." (*Id.*, col. 5:19-22, 5:26-30, 5:34-38, 5:41-45,

5:48-51) Therefore, because the claims at issue are about installing replacement valves (not temporary valves), Figures 52A and 57E do not have relevance to the vicinity terms.[15]

Medtronic also asserts that Speyside's position (that "vicinity" means "proximate") is wrong because dependent claim 21 (which depends from claim 17) and dependent claim 39 (which depends from claim 28) of the '941 patent recite the proximal and distal ends of the carrier element forming a seal with "respective native anatomical features *proximate* opposing sides of the native valve." (*Id.*, cols. 83:35-38, 85:7-10 (emphasis added) (cited in D.I. 119 at 18)) Now, it is true as a general matter, as Medtronic points out, (D.I. 119 at 18 (citing cases)), that the use of different terms in a patent typically signals that the terms mean different things. But that assumption "is overcome where . . . the evidence indicates that the patentee used the two terms interchangeably." *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, as discussed above, there *is* evidence that the patentee used "vicinity" and "proximate" synonymously. (Tr. at 112)

For these reasons, the Court recommends that "[a]/[in the] vicinity of the native heart valve" be construed to mean "proximate to the native heart valve."[16]

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[15] The Court is also not moved by Medtronic's citation (referenced above) to the fact that the '739 patent—an unrelated, prior art patent—includes a figure depicting a "replacement heart valve device" as "implanted within an artery." (D.I. 119 at 22) The '941 patent's disclosure is what really matters here, and it does not suggest that the claimed replacement valve is or should be implanted in the aorta. (*See id.* at 20)

[16] The Court notes that both sides cited to expert declarations in support of their competing positions regarding the vicinity term. (*See, e.g.*, D.I. 119 at 16 (citing D.I. 120, ex. U at ¶ 29); *id.* at 19 (citing D.I. 120, ex. Y at ¶¶ 48-49)) However, with the intrinsic evidence unambiguous regarding the meaning of "[a]/[in the] vicinity of the native heart valve[,]" the Court need not consider the parties' expert testimony. *See, e.g.*, *Intex Recreation Corp. v. Team Worldwide Corp.*, 42 F. Supp. 3d 80, 98 (D.D.C. 2013) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996)).

C. "prior to expanding the proximal end of the [] carrier element / prosthetic valve"

The next disputed term, "prior to expanding the proximal end of the [] carrier element / prosthetic valve" (the "prior to expanding term") appears, *inter alia*, in claims 1, 17 and 28 of the '941 patent and claim 7 of the '040 patent. The term's use in claim 17 of the '941 patent is representative, and it discloses a method for replacing a patient's native heart valve with steps comprising:

> delivering an expandable carrier element and a replacement valve endovascularly to a vicinity of the native heart valve; and
>
> expanding the carrier element from a collapsed delivery configuration to an expanded configuration to secure the carrier element in the vicinity of the native heart valve, wherein during expansion of the carrier element, a distal end of the carrier element is expanded prior to a proximal end of the carrier element being expanded, the proximal end of the carrier element being expanded without urging the proximal end of the carrier element toward the distal end of the carrier element,
>
> wherein the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction during the expansion of the carrier element, after expanding the distal end of the carrier element, and *prior to expanding the proximal end of the carrier element*.

('941 patent, col. 83:5-25 (emphasis added))[17] The parties' competing proposed constructions for the prior to expanding term are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
"prior to expanding the proximal end of the [] carrier element / prosthetic valve"	"before the proximal end of the carrier element is expanded at all"	"before the proximal end of the carrier element is expanded to a very significant

[17] "Distal" refers to the end of the valve that is closer to the heart, while "proximal" refers to the end that is further from the heart. (D.I. 119 at 1 n.2; *see also* '118 patent, col. 11:58-60)

		degree, but less than full expansion"

(D.I. 119 at 22; Tr. at 149, 156)

The parties' dispute regarding the prior to expanding term did not crystalize until the *Markman* hearing. That was likely due in part to the fact that, during the briefing process, Speyside's proposed construction was "before the proximal end of the carrier element is expanded" while Medtronic was asserting that no construction was necessary. (D.I. 119 at 22) Thus, there was no real comparison of competing constructions in the briefs, which typically sheds light on the parties' dispute(s). Moreover, in the briefing, Medtronic (as it turns out, wrongly) at times characterized the dispute as being about whether the claim language required either a "full[]" or "first" expansion of the proximal end before the occurrence of a one-way flow of blood. (*Id.* at 27, 33-34)[18]

During the hearing, however, the parties' conflict eventually became clearer. Everyone agrees that the claimed replacement valve becomes functional when the blood is flowing in one direction through the replacement valve. (*Id.* at 26; Tr. at 120) But what the parties dispute is whether the valve must become functional *before* the proximal end of the carrier element has expanded *at all* (that is Speyside's position)—or instead whether the valve can become functional even after there has first been some amount of expansion of the proximal end (that is

[18] In the briefing, Medtronic also suggested that there was a dispute about whether the *distal* end of the carrier element must be fully (as opposed to only partially) expanded, before an expansion of the proximal end (with Medtronic arguing that there was no such requirement). (D.I. 119 at 27-28; *see also* Medtronic's Markman Presentation, Slides 32-33 (pointing to prosecution history excerpts making clear that the claim does not require full expansion of the distal end prior to expanding the proximal end)) However, during the *Markman* hearing, Speyside clarified that it did not dispute that the distal end need be only partially expanded before an expansion of the proximal end. (Tr. at 126, 133) And so this is no longer a disagreement that the Court must take up here.

Medtronic's position). (Tr. at 136, 140-41, 147-48, 152)[19] The Court sides with Speyside here, for a few reasons.

First, and most importantly, the plain language of the claims aligns with Speyside's position. Claim 17, for instance, requires that the replacement valve allows the flow of blood in one direction "after expanding the distal end of the carrier element, and *prior to expanding* the proximal end of the carrier element[.]" ('941 patent, col. 83:19-25 (emphasis added)) "[P]rior to expanding" connotes prior to *any* expansion, since something is "expanding" even if it is only expanding a little bit. (*See* Tr. at 141, 155)[20]

The specification also supports Speyside's position. (D.I. 119 at 23, 25; Tr. at 127) The specification teaches that known replacement valves at the time of the invention did not function "until the valve was fully deployed" (i.e., until after the proximal end had been expanded). ('941 patent, col. 75:45-51 ("A self-expanding support structure of a length sufficient only to support and retain the valve would not allow testing of the valve function, until the valve was fully deployed. This is because the *proximal portion* of the support structure contained within the device would prevent normal function of the valve.") (emphasis added)) As a result, the prior art devices did not allow "for testing the function of the valve before committing to the position of the valve." (*Id.*, col. 75:4-6) The patentees specifically referenced Leonhardt and another prior art patent, explaining that the valves therein did not function (i.e., no blood flowed through in

[19] In light of this crystallized dispute, the parties agreed to amended proposed constructions during the hearing. (*See* Tr. at 149, 156)

[20] Medtronic's position in its briefing regarding the distal end of the carrier element seemed to only confirm this natural reading of the claim language. There, Medtronic asserted that there is no requirement "that the distal end of the carrier element must be *fully* (as opposed to being only *partially*) expanded before an expansion of the proximal end[.]" (D.I. 119 at 27 (emphasis in original)) As Speyside agreed, that is correct; "expanding the distal end" means expanding the distal end in any way, even if less than full expansion is achieved.

one direction) when the proximal end of the device "is still restrained within the deployment catheter, preventing the valve from opening." (*Id.*, col. 74:1-12) The inventors set out to solve this problem by allowing for the replacement valve to function and be tested before the proximal end of the carrier element has been expanded. (*Id.*, col. 74:46-49 ("The distal end of the inflatable cuff is inflated. The sheath is retracted far enough that the deployment control wires allow the prosthetic valve to function."); *see also id.*, cols. 75:26-29, 77:49-51)[21]

Finally, the prosecution history also demonstrates that Speyside's proposal is the correct one. During prosecution of the '941 and '040 patents, the Examiner had rejected certain claims as anticipated by Leonhardt. (D.I. 100, ex. D at SPEYSIDE006108; *id.*, ex. F at SPEYSIDE0000650) The applicants responded that Leonhardt does not disclose a method of replacing a patient's native heart valve where the replacement valve becomes functional "after expanding the distal end of the first carrier element and prior to expanding the proximal end of the first carrier element[,]" as "the replacement valve in Leonhardt is *not* operational until it fully exits the deployment catheter 100 to expand the proximal end." (*Id.*, ex. D at SPEYSIDE006108 (certain emphasis omitted); *see also id.*, ex. F at SPEYSIDE0000724 ("Leonhardt teaches a method using an expansion balloon which *occludes* the flow of blood through the prosthetic

[21] Medtronic's briefing pointed to some of these same portions of the specification too. It did so as part of an argument that these portions disclose the deployment of a "replacement valve with an inflatable cuff in which the distal end is inflated . . . and the valve functions both before *and after* the proximal end of the device is inflated (whether fully or partially), and discloses that this process can occur in several rounds in which the valve is 'partially deflated, and advanced or retracted, and then reinflated.'" (D.I. 119 at 27, 30 (citing '941 patent, cols. 74:39-51, 75:16-36) (emphasis added)) It is not clear enough to the Court, though, that the cited portions of the specification actually disclose that the "valve functions both before *and after* the proximal end of the device is inflated[.]" (*Id.* (emphasis added)) Nor did Medtronic sufficiently explain to the Court why this was so.

valve in the second direction during the expansion of the prosthetic valve.") (emphasis in original))[22]

In sum, the intrinsic record makes clear that the claimed method requires the valve to become functional (such that blood is flowing unidirectionally through the valve) before the proximal end of the carrier element has expanded *at all*.[23] Thus, the Court recommends that "prior to expanding the proximal end of the [] carrier element / prosthetic valve" be construed to mean "before the proximal end of the carrier element is expanded at all."

D. "wherein the prosthetic valve does not include an interlocking locking mechanism" (Speyside) / "an interlocking locking mechanism" (Medtronic)

The next disputed term, "wherein the prosthetic valve does not include an interlocking locking mechanism" (Speyside) / "an interlocking locking mechanism" (Medtronic) (the "interlocking locking mechanism term") is found in claim 7 of the '040 patent. Claim 7 recites a method of implanting a prosthetic valve "wherein the prosthetic valve does not include an

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[22] Some of the parties' arguments with respect to this term centered on whether the invention disclosed in Leonhardt would fall within the scope of the prior to expanding term. (*See* D.I. 119 at 24-25; Tr. at 143-44, 146) However, the Court will be making no determination at this stage as to whether Leonhardt does or does not fall within the scope of the claims. That is not a proper inquiry for claim construction. (Tr. at 154); *see also, e.g.*, *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, Civil Action No. 17-1612-MN-CJB, 2022 WL 605357, at *10 (D. Del. Jan. 13, 2022) (citing cases), *report and recommendation adopted*, 2022 WL 855518 (D. Del. Mar. 23, 2022).

[23] During the *Markman* hearing, the parties pointed to certain figures in support of the respective positions. Speyside contended that Figures 45A, 45B and 45C depict an embodiment in which blood is flowing through the valve after the distal end has expanded but before the proximal end has expanded. (Tr. at 124; Speyside's Markman Presentation, Slide 40) Meanwhile, Medtronic asserted that Figures 45B, 46B, 46C and 47A-C demonstrate that the replacement valve can be functional after the proximal end has been expanded. (Tr. at 137-39, 148, 158-59) However, in the Court's view, these figures are just not clear enough, one way or the other, to really help either side. In other words, it is hard to know for sure whether certain of these figures actually depict the proximal end of the valve as being expanded (or not), and it is hard to know whether the figures depict uni-directional blood flow occurring at any particular given time. (*Id.* at 160)

interlocking locking mechanism[.]" ('040 patent, col. 82:25-26) The parties' competing proposed constructions for the interlocking locking mechanism term are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
"wherein the prosthetic valve does not include an interlocking locking mechanism" (Speyside) / "an interlocking locking mechanism" (Medtronic)	"the prosthetic valve does not include portions that fit together to lock the prosthetic valve"	"a part that fits into another part to lock"

(D.I. 119 at 34; Tr. at 176-77, 183) The dispute regarding this term is whether the interlocking locking mechanism (that is excluded from the claimed method) must be entirely located on the prosthetic valve, or whether instead one part may be located on the prosthetic valve that can lock together with another part that is not on the prosthetic valve. (D.I. 119 at 36, 39; Tr. at 164, 190)[24]

The parties agree that "interlocking locking mechanism" is not a term of art that would have a particular meaning to a POSITA in the relevant field. (D.I. 119 at 37; Tr. at 170, 176) Therefore, to assess the meaning of the term, a POSITA would need to rely on the intrinsic evidence. *See, e.g.*, *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, Civil Action No. 16-905-JFB-CJB Consolidated, 2018 WL 4776372, at *11 (D. Del. June 18, 2018).

The interlocking locking mechanism term was added during prosecution of the '040 patent. Certain claims of the patent were rejected as being anticipated by a prior art reference

[24] While the parties initially appeared to dispute whether the interlocking locking mechanism could be used to "fasten" as opposed to "lock," (D.I. 119 at 34, 37; Tr. at 163-64), during the *Markman* hearing, Medtronic confirmed that this was no longer a dispute and that "lock" could be substituted for "fasten" in its proposed construction, (Tr. at 176-77, 183).

called "Salahieh," and claim 7 (prosecution claim 13) was rejected as being anticipated by Leonhardt. (D.I. 100, ex. F at SPEYSIDE0000649-50) The applicants then amended claim 7, in part to specify that the claimed prosthetic valve "does not include an interlocking locking mechanism[.]" (*Id.* at SPEYSIDE0000719) The Examiner allowed the claim, explaining that:

> [T]he closest prior art is Salahieh[.] . . . However, Salahieh includes an interlocking locking mechanism (e.g., para. 102) and thus is excluded by the claims. Examiner notes that the negative limitation "wherein the prosthetic valve does not include an interlocking locking mechanism" has basis in the original disclosure because locking elements are positively recited as alternative elements in the specification (e.g., element 181), and thus may be explicitly excluded in the claims (see MPEP 2173.05(i)).

(*Id.* at SPEYSIDE0000738-39)[25]

There is no dispute that in Salahieh, the interlocking locking mechanism consisted of interlocking elements that (1) were both on the valve and (2) fit together to lock the valve in an expanded configuration. (D.I. 119 at 35-36, 39-40, 41; Tr. at 170) The question is whether the interlocking locking mechanism that is excluded from the claims here must be a "Salahieh-type mechanism"—i.e., one located entirely on the valve. Or can it lock into another part of a different structure that is not located on the valve? (D.I. 119 at 37, 39) The intrinsic record suggests that the former is the correct interpretation.

First, the plain language of the claims supports Speyside's position. (*Id.* at 36, 41; Tr. at 170, 191) The claim term specifies that it is the "*prosthetic valve*" that "does not include an interlocking locking mechanism." This language does not suggest that part of such a mechanism

[25] MPEP § 2173.05(i) provides that "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." MPEP § 2173.05(i); *see also Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015).

is on the valve, while another part is located elsewhere. (D.I. 119 at 41) Instead, it is talking about what is or is not located *on the valve itself*—full stop.

Second, the prosecution history supports Speyside's view. (*Id.* at 40-41); *see also Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) ("The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history."). The applicants and the Examiner clearly viewed Salahieh as having an interlocking locking mechanism. And so it makes sense to have a construction "that is consistent with the use of that term in Salahieh because distinguishing Salahieh was the very basis for the addition of this claim term." (D.I. 119 at 41; Tr. at 166, 169)

Finally, the '040 patent specification comports with Speyside's position. The Examiner cited to element 181 as an example of a locking element that could be excluded by the claims. (D.I. 100, ex. F at SPEYSIDE0000739) And the parties agree that in the specification, an example of an interlocking locking mechanism is shown at element 181 (which is depicted in Figures 17A-B and 18A-C). (D.I. 119 at 39, 42, 43; Tr. at 178-79, 190, 192) Figures 17A and 18C (with the interlocking locking mechanism depicted at 181) are shown below:

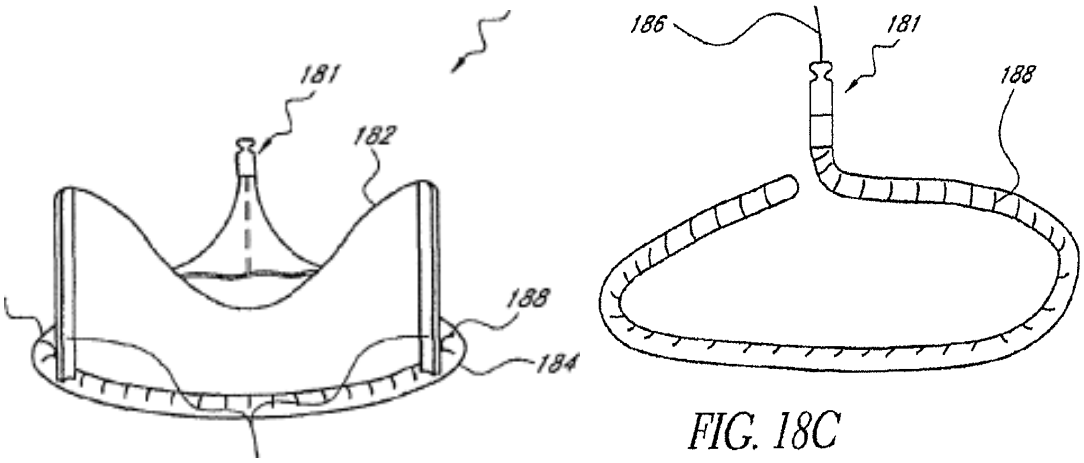

FIG. 18C

The specification explains that:

> A latch or lock mechanism **181** maintains the tension in the wire or locks the distal end to a location near the proximal end. This tension mechanism may be driven from the handle through a tension wire, a hydraulic system, a rotational member to drive a screw. Furthermore the tensioning members may utilize a locking means to maintain the desired circular shape, such as a suture, an adhesive, or a mechanical snap together type lock actuated by the tension wire. . . . A wire **186** located inside the tube is tensioned providing a bias to shape the device . . . . into a circular shape as shown in FIG[]. . . . 18C.

('040 patent, cols. 25:59-26:11) Medtronic's counsel points to this excerpt and to element 181 as supporting a "broad meaning" for the interlocking locking mechanism (such that it could encompass a mechanism with one part on the valve that can lock together with another part that is not on the valve). (D.I. 119 at 37-38; Tr. at 180; Medtronic's Markman Presentation, Slide 40) During the *Markman* hearing, Medtronic's counsel argued that this was so because element 181 is shown in Figure 17A as one piece on the valve, and "[t]here's not a second piece that's on the valve that [that one piece] fits into[,]" which necessarily means that element 181 "has to meet [] something else that's not on the valve" in order to lock. (Tr. at 179-80, 182-83, 185-87)

However, the specification does not bear this out. (D.I. 119 at 42) As shown above, it tells us that interlocking locking mechanism 181 maintains the tension in the wire (the wire is

shown as 186 in Figure 18C) or locks the distal end to a location near the proximal end. In other words, you can pull on that wire and it will lock the distal end of the valve to a location near the proximal end. (Tr. at 171-72, 188-89) Nothing regarding this embodiment suggests that "mechanism 181 fits together with an undisclosed part not on the prosthetic valve" or that mechanism 181 is "mating with something else"; instead, the "entirety of the interlocking locking mechanism is on the valve." (D.I. 119 at 42; Tr. at 188-89, 190-91; *see also* D.I. 119 at 36; Tr. at 173, 188, 192)[26]

For these reasons, the Court recommends that the term to be construed is "an interlocking locking mechanism" and that this term be construed to mean "portions that lock the prosthetic valve, and that are entirely located on the prosthetic valve."[27]

E. "hemostasis valve assembly" (Speyside) / "valve assembly" (Medtronic)

The next disputed term, **"**hemostasis valve assembly" (Speyside) / "valve assembly" (Medtronic) is found in claim 1 of the '897 patent, which recites a method of positioning a prosthetic implant within a heart. This method includes the step of "advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system . . . the introducer catheter comprising a *hemostasis valve assembly* at a proximal end of the introducer catheter[.]" ('897 patent, col. 33:19-32 (emphasis added)) The

[26] Medtronic's counsel asserted that while the wire may apply to Figures 18A-C, it does not apply to Figure 17A, which does not depict a wire, such that "whatever [element 181 is] mating to is not on the valve." (Tr. at 194-95) However, the specification states that "[t]hese slots 188 and tension wire 186 cause the device to form a circular shape as shown in FIGS. 17A and 18C[.]" ('040 patent, col. 26:9-11) This reference clearly links the wire to Figure 17A (even if it may not be seen in that particular figure).

[27] The Court is not certain about the accuracy of the portion of Speyside's construction requiring that the mechanism includes portions that "fit together" to lock. Indeed, it is not clear that the depiction of such a mechanism in Figure 18C would qualify as such. And so the Court leaves out this portion of Speyside's proposal.

parties' competing proposed constructions for "hemostasis valve assembly" / "valve assembly" are set out in the chart below:

Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"hemostasis valve assembly" (Speyside) / "valve assembly" (Medtronic)	"a valve assembly configured to minimize blood loss during percutaneous procedures"	"a part that selectively controls the flow of blood"

(D.I. 119 at 56) The dispute regarding this term is whether a hemostasis valve should be limited to a structure that selectively controls the flow of blood (as Medtronic proposes), or whether it could possibly also encompass a structure that blocks the flow of blood, such as a seal (as Speyside contends). (*Id.* at 58-59; Tr. at 196, 200) The Court agrees with Speyside here, as its proposal is supported by the intrinsic and extrinsic evidence.[28]

Most importantly, as Speyside points out, its proposed construction comes straight from the specification of the '897 patent. (D.I. 119 at 56-57, 61; Tr. at 198) The specification teaches that "[i]n some embodiments, the seal assembly **1042** comprises a *hemostasis seal/valve configured to minimize blood loss during percutaneous procedures*." ('897 patent, col. 24:59-61 (emphasis added)) According to the specification, "the seal assembly **1042** can include a seal member **1046** configured to form a seal around the delivery catheter **900**" or, in some embodiments, can "comprise a flush port **1044**." (*Id.*, col. 24:54-56, 61-62)

[28] In its supplemental opening claim construction brief, Speyside contends that Medtronic's proposed construction "directly contradicts Medtronic's positions in the '897 Patent IPR" where Medtronic purportedly treated "seal" and "valve" interchangeably. (D.I. 171 at 2-5; Tr. at 198-99) In light of this, Speyside argues that Medtronic should be judicially estopped from advancing the narrow construction that it proposes here. (D.I. 171 at 4; Tr. at 200) Medtronic retorts that Speyside could have and should have raised this argument earlier, in the parties' joint claim construction brief. (D.I. 174 at 1-3; Tr. at 202-03) However, because the Court agrees with Speyside on the merits, it need not decide whether Medtronic is judicially estopped from advancing its proposed claim construction.

Additionally, Speyside's proposal is supported by the plain meaning of "hemostasis." (D.I. 119 at 57; Tr. at 197) The term has been defined in medical dictionaries to mean: (1) "[t]he arrest of bleeding[;]" (2) "[s]tagnation of blood[;]" and (3) "arrest of bleeding, either by the physiologic properties of vasoconstriction and coagulation or by surgical means[.]" (D.I. 120, ex. M at 873; *id.*, ex. N at 854; *see also id.*, ex. L at 1056)

Medtronic's arguments—i.e., that the proper term for construction is simply "valve assembly[,]" and that this phrase must be defined differently than "seal assembly" (with the former selectively controlling blood flow and the later passively blocking blood flow)—are not persuasive. (D.I. 119 at 58) For example, Medtronic asserts that the specification discloses "seal assembl[ies]" and a "hemostasis seal" that "passively block[] blood flow without selective control over whether blood flows or the direction of blood flow." (*Id.* (citing '897 patent, cols. 20:26-31, 24:58-62 (describing a "hemostasis seal" that can be "provided between the inner and outer tubular members" and "disposed in outer sheath handle" and the "seal assembly **1042**" described above); Tr. at 201-02) And that may be so. But Medtronic cites to nothing from the patent that supports the idea that a "hemostasis valve assembly" *cannot also* seal off blood flow.[29]

Medtronic also cites to portions of the specification that it contends refer to valves as "involving selective control of blood flow"—in contrast to the specification's description of "seals." (D.I. 119 at 59 (citing '897 patent, cols. 1:39-43 (explaining that the "valves of the heart . . . function to ensure that blood flows in only one direction through the heart"), 7:3-9 (noting

[29] Medtronic also points to the specification's disclosure of a prosthetic implant with a "soft seal . . . and spherical ball . . . to create a sealing mechanism" whereby the "ball . . . ca[n] move against the soft seal . . . and halt any fluid communication[.]" ('897 patent, cols. 9:62-63, 10:21-22 (cited in D.I. 119 at 59)) However, this portion of the specification does not seem particularly relevant to the definition of the claimed "hemostasis valve assembly."

that a tissue valve can be configured with an "'open'" configuration where blood can flow through the implant in a first direction and a "'closed'" configuration whereby blood is prevented from back flowing through the valve in a second direction), 8:62-9:2 (referring to "valve systems that allow for pressurization without leakage or passage of fluid in a single direction"))) Yet while these cited portions of the specification refer to a "valve" or "valves," the portion of the claim at issue here is not "valve"—it is "hemostasis valve assembly." And, as noted above, when the patent actually discusses a "hemostasis valve" it: (1) refers to it as a hemostasis "seal/valve"; and (2) never says anything about this "seal/valve" minimizing blood loss only by selectively controlling the flow of blood. By referring to the structure as a "seal/valve" in the specification, the patentees are clearly indicating that, at least in the context of the claimed hemostasis assembly structure, "seal" and "valve" could well mean the same thing.[30]

Medtronic also argues that the prosecution history confirms the correctness of its construction. More specifically, Medtronic asserts that the prosecution history shows why the Court must distinguish a "valve assembly" (one that selectively controls the flow of blood) from a "seal assembly" (one that passively blocks the flow of blood)—i.e., because the prosecution record demonstrates that everyone understands the terms "valve" and "seal" to have distinct meanings. (D.I. 119 at 59-60, 62-63; Tr. at 200-01) But a close look at the prosecution history in question does not bear that out. (D.I. 119 at 61-62; Speyside's Markman Presentation, Slide 79)

[30] Indeed, even the extrinsic evidence that Medtronic points to confirms that this is the right outcome. (D.I. 119 at 60) Medtronic cites to a dictionary that defines "seal" to mean "a tight and perfect closure" and "valve" to mean "any of numerous mechanical devices by which the flow of liquid . . . may be started, *stopped*, or regulated by a movable part that opens, shuts, or partially obstructs one or more ports or passageways[.]" (D.I. 120, ex. W at 1049, 1301 (emphasis added)) Thus, Medtronic's own evidence tells us that even a "valve" *could* be a structure that *stops* the flow of liquid. (D.I. 119 at 62)

The original claims had recited "advancing an introducer catheter positioned over and together with a delivery catheter . . . the introducer catheter comprising a *hemostasis seal assembly* at a proximal end of the introducer catheter[.]" (D.I. 100, ex. H at SPEYSIDE0003271 (emphasis added)) The Examiner rejected the claims as anticipated over a prior art patent application referred to as "Dwork" that taught, *inter alia*, an introducer catheter comprising a "hemostasis seal assembly at a proximal end of the introducer catheter." (*Id.* at SPEYSIDE0003460-61; *see also id.* at SPEYSIDE0003464 ("Dwork clearly teaches establishing a low friction hemostasis seal at a proximal end of the introducer catheter[.]")) The Examiner cited to paragraph 54 of Dwork in support, (*id.* at SPEYSIDE 0003461, -3464), which recites an "introducer valve [that] frictionally contacts the stability tube [], thereby establishing a low friction hemostasis seal around the stability tube[,]" (*id.* at SPEYSIDE0080843). Following an interview with the Examiner, the applicants then amended the claim to recite, *inter alia*, "advancing . . . an introducer catheter that is preassembled over the delivery catheter . . . the introducer catheter comprising a *hemostasis valve assembly* at a proximal end of the introducer catheter." (*Id.* at SPEYSIDE0003271, -3274 (emphasis added)) The applicants explained that "[t]o advance prosecution, the Applicant agreed to amend [the pending claims] along the lines suggested by [the Examiner] so as to positively claim[] the preassembled configuration of the introducer catheter and delivery catheter." (*Id.* at SPEYSIDE0003274) In allowing the amended claims, the Examiner reported that "[t]he novelty of this invention is that [by] having a preassembled introducer catheter over a proximal portion of the delivery catheter, a reduced outer diameter combined delivery system is created which is useful in minimally invasive surgeries" while noting that Dwork "fails to teach a preassembled configuration and teaches away from preassembly." (D.I. 121, ex. II at SPEYSIDE0003209)

In the end, while it is true that the applicant did change the term "seal" to "valve" during prosecution (in the manner highlighted by the Court above via the use of italics), that does not mean that the Court must construe the claim term at issue to require only the selective control of blood flow. In explaining the reasons for the claim alterations, neither the applicants nor the Examiner appeared to comment on or put any emphasis on the change from "seal" to "valve." (D.I. 119 at 62) Therefore, nothing in the prosecution history provides a clear enough statement sufficient to undercut the Court's conclusion above that: (1) the patent specification clearly indicates that the claimed hemostasis valve assembly can encompass a structure that seals off or blocks the flow of blood; and (2) the patent does not otherwise suggest that such an assembly must only "selectively control[] the flow of blood."

Accordingly, the Court recommends that the term "hemostasis valve assembly" be construed to mean "a valve assembly configured to minimize blood loss during percutaneous procedures."

F. "vascular system"

The next disputed term, "vascular system[,]" is found in claim 1 of the '897 patent, which recites a method of positioning a prosthetic implant within a heart. This method includes the step of "advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's *vascular system*[.]" ('897 patent, col. 33:19-23 (emphasis added)) The delivery catheter comprises a prosthetic valve and a distal tip that can be inserted into the access vessel, and the prosthetic valve is then "translumenally advanc[ed] to a position proximate a native valve of the heart[.]" (*Id.*, col. 33:23-34) The parties' competing proposed constructions for "vascular system" are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**

"vascular system"	"circulatory system of blood vessels"	"circulatory system including the heart and blood vessels"

(D.I. 119 at 44) While there is no dispute between the parties that a "vascular system" is a circulatory system that includes blood vessels, the parties dispute whether "vascular system" also includes the heart. (*Id.* at 44, 45; Tr. at 204, 206) Medtronic posits that "vascular system" includes the heart, while Speyside contends that "vascular system" does not (and contrasts it to the *cardio*vascular system, which does include the heart). (D.I. 119 at 44) While there is material for both sides to work with here, the Court ultimately agrees with Speyside that "vascular system" does not include the heart—but instead is a pathway (made up of blood vessels) *to* the heart. (*Id.*)

Both sides suggest that the ordinary meaning of "vascular system" supports their construction. And they both point to dictionary definitions in support. (*See* Speyside's Markman Presentation, Slide 58; Medtronic's Markman Presentation, Slide 47) Speyside, for its part, highlights medical dictionaries that define "vascular system" to mean "[t]he blood vessels: the arteries, capillaries, and veins" and "vascular" to mean "relating to or containing blood vessels." (D.I. 119 at 44 (citing D.I. 120, ex. L at 2440; *id.*, ex. M at 2092)) Medtronic, meanwhile, cites to a medical dictionary that defines "vascular system" as "[t]he cardiovascular and lymphatic systems collectively" and defines "cardiovascular" as "[r]elating to the heart and the blood vessels or the circulation." (*Id.* at 47 (citing D.I. 120, ex. U at ex. 1)) And another medical dictionary cited by Medtronic directs the reader to "[s]ee circulatory system" for "vascular system"; it there defines "circulatory system" as "[t]he system of structures, consisting of the heart, blood vessels, and lymphatics, by which blood and lymph are circulated throughout the body." (*Id.* (citing D.I. 120, ex. U at ex. 2) (emphasis in original)) So which meaning is consistent with the '897 patent?

Medtronic's position (that "vascular system" includes the heart) stems from its view that claim 1 of the '897 patent is "broadly directed" to any approach for delivering a prosthetic implant to the heart—including inserting the introducer catheter into a blood vessel, *or* inserting the introducer catheter directly into the heart's left ventricle and advancing it to the aortic valve (with the latter approach being known as a "transapical approach"). (*Id.* at 46, 50; Medtronic's Markman Presentation, Slide 51; D.I. 120, ex. U at ¶ 34)[31] In support, Medtronic points to the specification's note that "[t]he implant **800** and various modified embodiments thereof will be described in detail below. As will be explained in more detail below, the implant **800** can be delivered minimally invasively using an intravascular delivery catheter **900** or trans[]apical approach with a trocar." ('897 patent, col. 5:48-52) Thus, according to Medtronic, the transapical approach is an "expressly disclosed embodiment[,]" and nothing in the intrinsic record suggests that it should be excluded from the claims. (D.I. 119 at 48, 50; Tr. at 213; D.I. 120, ex. U at ¶ 35)

In the Court's view, this is a strained reading of the patent. The title of the cited section of the specification is "Inflatable Prosthetic Aortic Valve Implant[,]" in which the implant at issue is referred to as "**800**." ('897 patent, col. 5:44-46) And the passage tells us that generally, the implant 800 can be delivered: (1) minimally invasively using an intravascular delivery catheter 900; *or* (2) via a transapical approach with a trocar. (D.I. 119 at 48; Tr. at 208-09; D.I. 120, ex. Y at ¶ 56) Turning to claim 1, its language matches up with delivery approach number (1)—a method of positioning the implant by, *inter alia*, "advancing together a *delivery catheter*

[31] One of Medtronic's primary prior art references in the IPR proceedings was United States Patent Pub. 2011/0319989 to Lane ("Lane"), which recites a transapical delivery of a replacement valve in which the catheter is inserted directly into the heart. (D.I. 119 at 45; *see also* D.I. 120, ex. O at 32-36)

and an introducer catheter that is preassembled over the delivery catheter *into a patient's vascular system*[.]" ('897 patent, col. 33:21-23 (emphasis added)) Even though the specification additionally refers to a transapical delivery of the implant, that does not mean that claim 1 must necessarily claim that approach. *See, e.g.*, *Apple Inc v. Andrea Elecs. Corp.*, 949 F.3d 697, 708 (Fed. Cir. 2020) ("As we have held, [when] the patent describes multiple embodiments, every claim does not need to cover every embodiment. This is particularly true [when] the plain language of a limitation of the claim does not appear to cover that embodiment.") (internal quotation marks and citation omitted).[32]

Beyond the patent's reference to a transapical approach, Medtronic relies on another piece of intrinsic evidence in support of its position. This is the specification's teaching that "[t]he circulatory system is a closed loop bed of arterial and venous vessels supplying oxygen and nutrients to the body extremities through capillary beds. The *driver of the system is the heart* providing correct pressures to the circulatory system and regulating flow volumes as the body demands." (D.I. 119 at 45 (citing '897 patent, col. 1:22-26) (emphasis added); *see also* Tr. at 210; Medtronic's Markman Presentation, Slide 48) According to Medtronic, this passage confirms that the vascular system (which, again, everyone agrees is synonymous with "circulatory system") includes the heart—because the heart is described as the "driver" of the

[32] Medtronic points to dependent claims 3 and 4 (which recite, respectively "wherein the step of advancing the . . . prosthetic valve into the patient's vascular system comprises inserting the introducer catheter into a femoral artery" and "advancing the prosthetic valve through an aorta"); it argues that these claims demonstrate that claim 1 is more broadly directed to delivery of the implant via, *inter alia*, a transapical approach (i.e., with the "catheter [] inserted into the heart without proceeding through an artery or vein[)]." (D.I. 119 at 46) The Court agrees with Speyside, however, that another logical reading of claims 1, 3 and 4 is that claim 1 refers to delivery of the implant to the heart through *any blood vessel*, whereas the vascular system in claims 3 and 4 are limited to doing so via *specific blood vessels*. (*Id.* at 50) This is the reading that is most consistent with the rest of the evidence with respect to this term.

circulatory system. (D.I. 119 at 45-46; *see also* Tr. at 210 (Medtronic's counsel asserting that this passage "really should be the end of the inquiry"))

Yet in truth, this passage reads as if it is more in line with Speyside's position. (Tr. at 206) It explicitly states that the circulatory system (i.e., the vascular system) is a "closed loop bed" of vessels. And while it does note that the heart is the driver of that system, it tells us that the heart provides correct pressures "*to the* circulatory system[,]" which suggests that the heart is separate and apart from that system. (*Id.* at 206-07)[33]

Other parts of the intrinsic record confirm that the "vascular system" recited in the claims of the '897 patent does not include the heart—and instead constitutes a pathway *to* the heart. For instance, claim l recites advancing the delivery catheter and introducer catheter "*into* a patient's vascular system," and then separately requires "translumenally advancing the prosthetic valve *to a position proximate* a native valve of *the heart*[.]" ('897 patent, col. 33:21-23, 33-34 (emphasis added)) Speyside's expert opines that a person of ordinary skill in the art would understand "translumenally advancing" to mean "advancement through a patient's blood vessel." (D.I. 120, ex. Y at ¶ 58; D.I. 121, ex. CC at 2360 (medical dictionary defining "transluminal" to mean "[w]ithin or through the internal bore or cylindrical channel within a blood vessel")) The claim language thus suggests that the catheter is advanced into and through the blood vessels (i.e., the vascular system) *to* the heart, which is separate and different from the vascular system. (D.I. 119 at 44)

[33] Medtronic also points to the teaching in the specification that "[t]hus, in general, distal means closer to the heart while proximal means further from the heart with respect to the circulatory system." ('897 patent, col. 6:12-14 (cited in D.I. 119 at 47)) While this statement might be read to suggest that the heart is a part of the circulatory system, it really is not that clear on the point. It certainly is not so conclusive in Medtronic's favor that it overrides the other portions of the intrinsic record, cited herein, that suggest that the heart is not a part of the vascular system.

Moreover, the specification notes that at the time of the patent, "transcatheter valve replacement has been attempted via percutaneous method such as a catheterization or delivery mechanism *utilizing the vasculature pathways*." ('897 patent, col. 1:59-61 (emphasis added)) This tells us that "vascular" relates to the body's pathways—i.e., the blood vessels. (D.I. 119 at 45) Another portion of the specification explains that "the combined delivery system **1000** carrying the *cardiovascular prosthetic implant **800*** can be translumenally advanced. . . . to a position proximate a native valve." ('897 patent, cols. 26:56-27:5 (emphasis added); *see also id.* at Abstract ("A delivery system and a method for deploying a cardiovascular prosthetic implant")) The prosthetic implant is implanted in the heart, (*see id.*, col. 33:19-20), and so the patentee calls it a "cardiovascular" implant, *not* a vascular implant, (D.I. 119 at 45, 48).

For these reasons, the Court recommends that the term "vascular system" be construed to mean "circulatory system of blood vessels."

G. "access vessel" (Speyside) / "vessel" (Medtronic)

The final disputed term, "access vessel" or "vessel," is found in claim 1 of the '897 patent; claim 1, as seen above, recites a method of positioning a prosthetic implant within a heart.[34] Claim 1 requires that, *inter alia*, a delivery catheter and an introducer catheter be advanced together into a patient's vascular system, "the delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the *access vessel* such that the distal tip dilates the *access vessel* for the introducer catheter[.]" ('897 patent, col. 33:19-27 (emphasis added)) The delivery catheter is then advanced "to a position proximate a native valve of the

[34] The parties submitted this term on the papers. (D.I. 175 at 2)

heart" and deployed. (*Id.*, col. 33:33-38) The parties' competing proposed constructions for "access vessel"/"vessel" are set out in the chart below:

Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
"access vessel" (Speyside) / "vessel" (Medtronic)	"blood vessel providing access to the heart"	"a structure conveying or containing blood"

(D.I. 119 at 51) The parties' dispute with respect to this term mirrors the dispute they had regarding "vascular system." Medtronic contends that "vessel" includes the heart, such that the claims cover the transapical approach; Speyside argues that "access vessel" is limited to vessels that provide access to the heart (and does not include the heart itself). (*Id.* at 52, 54) The Court reaches the same conclusion that it did for "vascular system": "access vessel" does not include the heart (and instead is a blood vessel providing access *to* the heart).

With regard to this term, Medtronic advances similar arguments to those it put forward for "vascular system." (*See id.* at 54) It first argues that claim 1 of the '897 patent requires that the "vascular system" (which Medtronic asserts includes both the heart and blood vessels) to be accessed, such that the claim does not exclude the heart from the scope of "vessel." (*Id.* at 53, 56) But, as explained above, "vascular system" does not include the heart.

Then Medtronic argues that since the specification discloses the transapical approach, the construction for "access vessel" must not exclude such an approach. (*Id.*) However, as discussed above, while the specification references the transapical approach, the Court is not persuaded that claim 1 actually claims that approach.

Medtronic also criticizes Speyside's construction for equating an "access vessel" with a "blood vessel." (*Id.* at 54) Medtronic points out that the specification also uses the phrase "blood vessel," and argues that since claim 1 recites "access vessel," the latter must mean something different than the former. (*Id.*) Speyside retorts that it is not *equating* "access vessel"

and "blood vessel[;]" rather, it views the claimed "access vessel" as "a *specific* blood vessel that provides *access* to the heart for delivery of the prosthetic implant." (*Id.* at 55 (certain emphasis added))

The specification aligns with Speyside's position. It does use the term "blood vessels" at certain points. However, when it does so, it is typically in a generic sense "and not in the context of providing access to the heart for delivery of an implant." (*Id.*) For example, the specification describes Figure 1 as a "cross-sectional schematic view of a heart and its major blood vessels." ('897 patent, col. 4:11-12; *see also id.*, cols. 5:8-9; 15:32-38 (explaining that natural tissue valves can be obtained from "heart valves, aortic roots, aortic walls, aortic leaflets, pericardial tissue . . . bypass grafts, blood vessels . . . and the like")) Meanwhile, when the specification is discussing the claimed delivery system, it refers to the "access vessel," explaining that the system can be "translumenally advanced" over a guidewire that "can be inserted directly into the access vessel . . . such that the guidewire tip dilates the access vessel for the introducer catheter[.]" (*Id.*, col. 26:56-64) The delivery system is then "advanced to a position proximate a native valve" of the heart. (*Id.*, cols. 26:67-27:2) This is consistent with the idea that an "access vessel" for the delivery catheter is a specific blood vessel that provides access to the heart. (D.I. 119 at 51-52, 55) And importantly, the specification does use "blood vessel" once in describing the claimed method of delivery, which further underscores Speyside's view that an access vessel is a *particular type of blood vessel* (one that provides access to the heart). (*Id.* at 55 (citing '897 patent, col. 29:53-56) ("The smooth transition can help prevent the distal end **1034** of the introducer catheter **1030** from damaging the blood vessel as the introducer catheter is removed from the patient."))

For the foregoing reasons, the Court recommends that the term to be construed is "access vessel" and that this term be construed to mean "blood vessel providing access to the heart."

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "substantially equal to or less than" should be construed to mean "equal to or less than"

2. "[a]/[in the] vicinity of the native heart valve" should be construed to mean "proximate to the native heart valve"

3. "prior to expanding the proximal end of the [] carrier element / prosthetic valve" should be construed to mean "before the proximal end of the carrier element is expanded at all"

4. "an interlocking locking mechanism" should be construed to mean "portions that lock the prosthetic valve, and that are entirely located on the prosthetic valve"

5. "hemostasis valve assembly" should be construed to mean "a valve assembly configured to minimize blood loss during percutaneous procedures"

6. "vascular system" should be construed to mean "circulatory system of blood vessels"

7. "access vessel" should be construed to mean "blood vessel providing access to the heart"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the

loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: June 16, 2023

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE