IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

SNYDERS HEART VALVE LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Case No. 4:16-cv-00812-ALM-KPJ**
	§	
ST. JUDE MEDICAL S.C., INC., ET AL.,	§	
	§	
Defendant.	§	

CLAIM CONSTRUCTION MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiff Snyders Heart Valve LLC's ("Plaintiff" or "Snyders'") Opening Claim Construction Brief (Dkt. 163), Defendants St. Jude Medical S.C., Inc., St. Jude Medical, LLC, and St. Jude Medical, Cardiology Division Inc.'s (collectively, "Defendants" or "St. Jude") Responsive Claim Construction Brief (Dkt. 168)[1] and Plaintiff's Reply Claim Construction Brief (Dkt. 172). Also before the Court are the parties' July 24, 2017, Joint Claim Construction and Prehearing Statement (Dkt. 153) and the parties' September 15, 2017, Joint Patent Local Rule 4-5(d) Claim Construction Chart (Dkt. 174). The Court held a claim construction hearing on September 28, 2017 (the "September 28 Hearing"), to determine the proper construction of the disputed claim terms in United States Patents No. 6,540,782 ("the '782 Patent") and 6,821,297 ("the '297 Patent").

The Court issues this Claim Construction Memorandum Opinion and Order and hereby incorporates by reference the claim construction hearing and transcript, as well as the

[1] Some of the exhibits to Defendants' Responsive Claim Construction Brief are filed under the docket entry numbered 169.

demonstrative slides presented by the parties during the hearing. For the following reasons, the Court provides the constructions set forth below.

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I. BACKGROUND

Plaintiff brings suit alleging infringement of the '782 Patent and the '297 Patent. The '782 Patent, titled "Artificial Heart Valve," issued on April 1, 2003, and the Abstract of the '782 Patent states:

> An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region. The artificial valve includes a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region. The frame has a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors. The valve also includes a flexible valve element attached to the frame and to the central portion of the frame having an upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves to an open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the upstream region to the downstream region. The valve element moves to a closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region.

The '297 Patent, titled "Artificial Heart Valve, Implementation Instrument and Method Therefor," issued on November 23, 2004, and the Abstract of the '297 Patent states:

> An artificial valve for repairing a damaged heart valve having a plurality of cusps separating upstream and downstream regions. The artificial valve includes a flexibly resilient frame with a plurality of peripheral anchors for anchoring the frame in position between the regions. The frame includes a central portion located between the anchors. The valve includes a flexible valve element attached to the central portion of the frame having an upstream side and a downstream side opposite the upstream side. The valve element moves to an open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow. The valve element moves to a closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal. The valve may be used in beating heart procedures, avoiding cardiopulmonary bypass and cardioplegia.

Both the ’782 Patent and the ’297 Patent claim priority to a provisional application filed February 2, 2000. Plaintiff submits that “[t]his case focuses on the aortic valve, which is the valve that is replaced by the accused products.” Dkt. 163 at 1.

Plaintiff has asserted: Claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the ’782 Patent; and Claims 1–3, 8, 9, 17, 18, 20, 22, 23, 31–35, 37–39, and 45 of the ’297 Patent. *See* Dkt. 174, Ex. 1 at 6–22.

II. LEGAL STANDARD

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). The purpose of claim construction is to resolve the meanings and technical scope of claim terms. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). When the parties dispute the scope of a claim term, “it is the court’s duty to resolve it.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The Court examines a patent’s intrinsic evidence to define the patented invention’s scope. *Id.* at 1313–14; *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). Intrinsic evidence includes the claims, the rest of the specification, and the prosecution history. *Phillips*, 415 F.3d at 1312–13; *Bell Atl. Network Servs.*, 262 F.3d at 1267. The Court gives claim terms their ordinary and customary meaning as understood by one of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

Claim language guides the Court's construction of claim terms. *Phillips*, 415 F.3d at 1314. "[T]he context in which a term is used in the asserted claim can be highly instructive." *Id.* Other claims, asserted and unasserted, can provide additional instruction because "terms are normally used consistently throughout the patent." *Id.* Differences among claims, such as additional limitations in dependent claims, can provide further guidance. *Id.*

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex. Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). In the specification, a patentee may define his own terms, give a claim term a different meaning than it would otherwise possess, or disclaim or disavow some claim scope. *Phillips*, 415 F.3d at 1316. Although the Court generally presumes terms possess their ordinary meaning, this presumption can be overcome by statements of clear disclaimer. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir. 2001). This presumption does not arise when the patentee acts as his own lexicographer. *See Irdeto Access, Inc. v. EchoStar Satellite Corp.*, 383 F.3d 1295, 1301 (Fed. Cir. 2004).

The specification may also resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex*, 299 F.3d at 1325. For example, "[a] claim interpretation that excludes a preferred embodiment from the scope of the claim 'is rarely, if ever, correct.'" *Globetrotter Software, Inc. v. Elan Computer Group Inc.*, 362 F.3d 1367, 1381 (Fed. Cir. 2004) (quoting *Vitronics*, 90 F.3d at 1583). But, "[a]lthough the specification may aid

the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988); *accord Phillips*, 415 F.3d at 1323.

The prosecution history is another tool to supply the proper context for claim construction because a patentee may define a term during prosecution of the patent. *Home Diagnostics Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) ("As in the case of the specification, a patent applicant may define a term in prosecuting a patent."). The well-established doctrine of prosecution disclaimer "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). "Indeed, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover." *Spectrum Int'l v. Sterilite Corp.*, 164 F.3d 1372, 1378–79 (Fed. Cir. 1988) (quotation omitted). "As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Omega Eng'g*, 334 F.3d at 1324. However, the prosecution history must show that the patentee clearly and unambiguously disclaimed or disavowed the proposed interpretation during prosecution to obtain claim allowance. *Middleton Inc. v. 3M Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002). Statements will constitute disclaimer of scope only if they are "clear and unmistakable statements of disavowal." *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1358 (Fed. Cir. 2003). An "ambiguous disavowal" will not suffice. *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1285 (Fed. Cir. 2010) (citation omitted).

Although "less significant than the intrinsic record in determining the legally operative meaning of claim language," the Court may rely on extrinsic evidence to "shed useful light on the relevant art." *Phillips*, 415 F.3d at 1317 (quotation omitted). Technical dictionaries and treatises may help the Court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but such sources may also provide overly broad definitions or may not be indicative of how terms are used in the patent. *Id.* at 1318. Similarly, expert testimony may aid the Court in determining the particular meaning of a term in the pertinent field, but "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful." *Id.* Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.*

III. ANALYSIS

A. AGREED CLAIM TERMS

Apart from terms presented in their briefing, the parties have reached agreement upon the following constructions:

Term	Agreed Construction
"having a plurality of cusps" ('782 Patent, Claims 1, 10, 17, 18, 28, 29, 30; '297 Patent, Claims 1, 22, 31, 38)	**modifies "damaged heart valve," not "artificial valve"**
"an artificial valve as set forth in claim 1" ('297 Patent, Claims 17, 18, 20)	**"an artificial valve that meets all of the limitations of claim 1 of the 297 Patent"**

Dkt. 153 at 1; *see* Dkt. 174, Ex. 1 at 1.

B. DISPUTED CLAIM TERMS

1. "upstream region" and "downstream region"

"upstream region" ('782 Patent, Claims 1, 10, 17–20, 28–30; '297 Patent, Claims 1, 8, 22, 28, 31, 34, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a region from which fluid flows to a downstream region"	"side of the native heart valve leaflets from which blood flows"
"downstream region" ('782 Patent, Claims 1, 10, 17–20, 28–30; '297 Patent, Claims 1, 8, 22, 28, 31, 34, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a region to which fluid flows from an upstream region"	"side of the native heart valve leaflets to which blood flows"

Dkt. 153 at 2; Dkt. 163 at 7; Dkt. 174, Ex. 1 at 1.

Plaintiff argues that "[t]he patents-in-suit use 'upstream' and 'downstream' in their ordinary sense to mean two regions that have a relative relationship: fluid flows from the upstream region to the downstream region." Dkt. 163 at 7. In response, "St. Jude accepts Plaintiff's constructions of these terms." Dkt. 168 at 42. Plaintiff's reply brief acknowledges this agreement. Dkt. 172 at 1; *see* Dkt. 174 at 1.

The Court therefore hereby construes these terms as set forth in the following chart:

Term	Construction
"upstream region"	**"a region from which fluid flows to a downstream region"**
"downstream region"	**"a region to which fluid flows from an upstream region"**

2. "frame"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"a structure designed to shape or support"	"a conical geodesic birdcage-shaped wire structure"

Dkt. 153 at 2; Dkt. 163 at 9; Dkt. 168 at 22; Dkt. 174-1, Ex. 1 at 2. The parties submit that this term appears in Claims 1–14, 17–22, and 25–30 of the '782 Patent and Claims 1–4, 8–11, 16, 22–24, 28–32, 36, 38–40, and 46 of the '297 Patent. *Id.*

a. The Parties' Positions

Plaintiff argues that Defendants' proposed construction is unwarranted because it "comes from a description of a particular embodiment, that was contained in an appendix, that was submitted with Dr. Snyders' provisional patent application, and that ultimately led to the patents-in-suit." Dkt. 153 at 9. Plaintiff also argues that Defendants' proposal is inconsistent with the prosecution history. *Id.*

Defendants respond that "the patentee identified the birdcage-shaped structure as 'fundamental' and 'needed,' and all embodiments show this specific frame." Dkt. 168 at 23; *see id.* at 24. Defendants also cite the prosecution history, in particular the provisional patent application, as well as testimony of the named inventor. *Id.* at 24–25.

Plaintiff replies that "Dr. Snyders specifically chose not to include th[e] alleged disclaimer in his non-provisional applications." Dkt. 172 at 2. Moreover, Plaintiff argues, "[t]he alleged disclaimers on which Defendants rely would not support Defendants' proposed construction of 'frame' even if they had been included in Dr. Snyders' patent specifications." *Id.* at 3. For example, Plaintiff argues that the patentee's reference to a conical geodesic birdcage-shaped wire structure "refers to a specific embodiment of Dr. Snyders' invention." *Id.* Plaintiff further argues that Defendants are attempting to take Dr. Snyders' deposition testimony out of context because

Defendants' counsel asked Dr. Snyders about specific embodiments rather than about the claims. *Id.* at 5–6.

At the September 28 Hearing, Plaintiff also noted that a specific limitation as to the shape of the claimed artificial valve is set forth in Claim 8 of the '782 Patent, which explicitly recites "a plurality of U-shaped elements joined together at a junction of the elements."

b. Analysis

Claim 1 of the '782 Patent, for example, recites in relevant part (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient *frame* sized and shaped for insertion in a position between the upstream region and the downstream region, the *frame* having a plurality of peripheral anchors for anchoring the *frame* in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors;
>
> . . . .

Defendants have not shown that this claim, or any of the other claims at issue, expressly recites any limitation of a "conical geodesic birdcage-shaped wire structure." Defendants have emphasized Appendix B to the provisional application, which is incorporated by reference and to which the patents-in-suit claim priority. *See* Dkt. 169-3, Ex. 3 at B-1; *see also Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1365–66 (Fed. Cir. 2016) ("provisional applications incorporated by reference are 'effectively part of the' specification as though it was 'explicitly contained therein'") (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)); *X2Y Attenuators, LLC v. ITC*, 757 F.3d 1358, 1362–63 (Fed. Cir. 2014) ("The incorporated patents are effectively part of the host [patents] as if [they] were explicitly contained therein. . . . As a result, the disclaimers of the incorporated patents are a part of the asserted patents.") (citations and internal quotation marks omitted).

On one hand, the patentee referred to a "funnel" valve implemented with a "bird-cage," which the patentee also referred to as "the cage," "the frame cage," "the wire cage housing," "the wire cage framing apparatus," or "the enclosing conical wire frame cage." *See, e.g.*, Dkt. 163-3, Ex. 3 at B-5:12–14, B-6:2–8, B-7:1, B-9:17–21 & B-11:21–22. The patentee also explained that such a shape can be advantageous:

> This internal flexible funnel member when opened after exiting the introducer at the native A-V valve site then presents itself in a geometric conical or "inverted funnel" configuration in a close conforming relationship with the externally supporting wire cage. Thus it is essentially congruent with that cage and with which it is in contact in its greater circumferential surface. Such a congruency between the outer wire cage and the internal flexible funnel element thus affords a certain reinforcing effect from the flat wire caging to oppose excessive strain effects on the flexible internal funnel member during its pressurized "open" mode of filling in the functional state, and such a reinforcement will reduce the potential of stress related fatigue problems for that flexing member.

Id. at B-7:8–20.

On the other hand, Appendix B discloses that "[*i*]*n one embodiment*, the valve is a self-seating stented atrioventricular *funnel* valve. . . ." *Id.* at B-1:6–7 (emphasis added). Thus, although the patentee then described that "[t]he fundamental design of the stented funnel valve prosthesis consists of a conical geodesic 'bird- cage' [*sic*] styled external supporting wire framework" (*id.* at B-5:12–14), these details regarding the "funnel" valve embodiment are fairly read as describing just that, an "embodiment." *See id.* at B-1:6–7; *see also id.* at A-3:17–18 ("[t]he presently described *device*") (emphasis added). Indeed, the patentee also referred to specific wire shape, size, and material, but these are plainly just examples as well. *See id.* at B-6:12–30.

On balance, the "conical geodesic birdcage-shaped wire structure" proposed by Defendants would improperly import limitations from disclosed embodiments. *See Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323.

Alternatively, even assuming for the sake of argument that a disclaimer were present, "it is certainly possible that a clear and unmistakable disavowal in an incorporated patent is no longer so when placed in the context of the disclosure of the host patent." *Id.*; *see MPHJ Tech. Invs., LLC v. Ricoh Ams. Corp.*, 847 F.3d 1363, 1369, 1376 (Fed. Cir. 2017) (even where the "specification incorporates in full the . . . provisional application," "it is the deletion from the . . . [p]rovisional application that contributes understanding of the intended scope of the final application"); *see also id.* at 1369 (regarding "the deleted one-step operation," noting that "the . . . Patent describes the single-step operation as 'optional,'" but stating that "[t]hese statements that single-step operation is 'optional' *accord* with the change from the . . . [p]rovisional to the final patent") (emphasis added).

Also of note, the word "geodesic" appears in the provisional application without elaboration (*see* Dkt. 169-3, Ex. 3 at p. B-5:13) and does not appear in the specifications of the patents-in-suit. Indeed, even the named inventor referred to "geodesic" as "kind of an architectural term" and stated that his invention is "kind of like that." Dkt. 168-33, Ex. 46, Deposition of Robert Snyders taken August 1, 2017 (August 1, 2017 Snyders Depo.), at 138:13–24. At the September 28 Hearing, Defendants did not concede that "geodesic" would be confusing but did state that other words could be used so long as the frame is required to come to a point. The potential for confusion regarding the significance and meaning of the word "geodesic" demonstrates at least one reason why "incorporation by references does not convert the invention of the incorporated patent into the invention of the host patent." *X2Y*, 757 F.3d at 1363 (citation and internal quotation marks omitted).

Further, Defendants have argued that in the provisional application, in the specifications of the patents-in-suit, and during prosecution of the patents-in-suit, the patentee distinguished the

"stent-like" structures disclosed in "Bessler" (*see* Dkt. 169-3, Ex. 3 at A-3:9–13), "Andersen" (*see* '782 Patent at 2:5–19; '297 Patent at 2:9–23), "Teitelbaum" (*see* Dkt. 169-5, Ex. 5, Nov. 24, 2003 Amendment Under 37 C.F.R. § 1.111 at 14–15 (SJM00106556–57)), and "Stevens" (*see* Dkt. 169-4, Ex. 4, July 10, 2002 Amendment in Response to Office Action Mailed April 10, 2002 at 10–11 (SJM00106436–37)).

In none of these instances, however, did the patentee make any definitive statement that the claimed invention is limited to a "birdcage" shape, let alone a "conical geodesic birdcage-shaped wire structure." *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added). For example, Defendants have noted that the patentee stated: "The fundamental design of the stented funnel valve prosthesis consists of a conical geodesic 'bird- cage' [sic] styled external supporting wire framework fabricated of any biocompatible metallic material (*e.g.*, stainless steel, titanium, Nitinol, etc.) with an internally disposed and congruently fabricated unitary flexible funnel-shaped member located within this cage. . . ." Dkt. 169-3, Ex. 3 at B-5:12–17 (emphasis added). Defendants emphasized at the September 28 Hearing that whereas the patentee used "e.g." when referring to the "biocompatible metallic material," no "e.g." (or similar signal or language) appears in relation to the "conical geodesic 'birdcage'" framework. *See id.* This proposed inference, however, does not rise to the level of a "definitive statement[]." *See Omega Eng'g*, 334 F.3d at 1324. As discussed above, these details regarding the "funnel" valve embodiment are fairly read as describing just that, an "embodiment." *See* Dkt. 169-3, Ex. 3 at B-1:6–7.

As another example, in the "Background of the Invention" section of the specification, the patentee explained that Andersen "must be implanted by direct abdominal aortic incision and

entry" and Bessler "does not describe the specific valve construction" but "[t]he Bessler procedure includes excision, vacuum removal of the native valve, cardio pulmonary bypass and backflushing of the coronary arterial tree." '782 Patent at 2:6–10 and 2:14–19. No relevant disclaimer is apparent. *See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) ("Such general statements, without more, will not be interpreted to disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent.").

As to the Teitelbaum reference discussed by the parties in their briefing and at the September 28 Hearing, Defendants have not shown that the patentee ever distinguished Teitelbaum based on the absence of a "birdcage-shaped" frame. *See, e.g.*, Dkt. 169-5, Ex. 5, Nov. 24, 2003 Amendment Under 37 C.F.R. § 1.111 at 14–15 (SJM00106557) ("Teitelbaum does not disclose or suggest a frame having a plurality of peripheral anchors, or a flexible valve element attached to the frame.").

Further, Defendants have cited testimony of the named inventor, Dr. Snyders, agreeing that his valve used a geodesic birdcage design. *See* Dkt. 168-33, Ex. 46, Aug. 1, 2017 Snyders Depo. at 138:14–139:5. In general, inventor testimony may be considered. *See Phillips*, 415 F.3d at 1317 ("Although we have emphasized the importance of intrinsic evidence in claim construction, we have also authorized district courts to rely on extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.") (citation and internal quotation marks omitted); *see also Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1371 (Fed. Cir. 2014) (considering inventor testimony as to "the ordinary meaning of 'programmable device'").

Here, however, the cited testimony is of little, if any, relevance in these claim construction proceedings. *See Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346–

47 (Fed. Cir. 2008) (noting that inventor testimony is "limited by the fact that an inventor understands the invention but may not understand the claims, which are typically drafted by the attorney prosecuting the patent application"). Moreover, Defendants have not demonstrated that Dr. Snyders was testifying about the claimed invention as opposed to a particular embodiment. The same is true regarding other similar characterizations of the inventor's "funnel valve." *See, e.g.*, Dkt. 168-31, Ex. 44, Questionnaire at 6.

Finally, Defendants urged at the September 28 Hearing that the intrinsic and extrinsic evidence consistently demonstrate that "there was 'nothing in the context to indicate that the patentee contemplated any alternative' embodiment to the one presented." *Phillips*, 415 F.3d at 1323 (quoting *Snow v. Lake Shore & M.S. Ry. Co.*, 121 U.S. 617, 630 (1887)); *see Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1355 (Fed. Cir. 2006) ("Although claims need not be limited to the preferred embodiment when the invention is more broadly described, neither do the claims enlarge what is patented beyond what the inventor has described as the invention.") (citation and internal quotation marks omitted); *see also Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) ("In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention.") (citing *Phillips*, 415 F.3d at 1323–24).

Defendants argued that what Dr. Snyders has referred to as the "funnel valve" is coextensive with the claimed invention. *See, e.g.*, Dkt. 168-16, Ex. 29 at 2 and 4; *id.*, Dkt. 168-1, Ex. 14 at 3. Nonetheless, "although the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those

embodiments. In particular, [the Federal Circuit has] expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323. At the September 28 Hearing, Defendants repeatedly urged that all that the named inventor ever invented or described was a "funnel" valve with a "birdcage-shaped" frame. Although these arguments may perhaps bear upon requirements of enablement or written description, Defendants have not persuasively demonstrated that these arguments warrant limiting the claim scope to the specific features of particular disclosed embodiments. *See id.*; *see also id.* at 1327 ("we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction").[2]

Based on the foregoing, the Court hereby expressly rejects Defendants' proposed construction. No further construction is necessary. *See U.S. Surgical*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro*, 521 F.3d at 1362 ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015).

The Court accordingly hereby construes **"frame"** to have its **plain meaning**.

[2] Defendants also argued at the September 28 Hearing that the frame must be birdcage-shaped so as to be able to house a unitary valve element. The parties' disputes as to the "valve element" terms are addressed separately below.

3. "frame element," "u-shaped elements," and "u-shaped frame elements"

"frame element" ('782 Patent, Claims 18–22, 25, 26, 29; '297 Patent, Claims 8–11, 16, 28–30)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a part of a frame"	"one distinct component of the frame"
"u-shaped elements" ('782 Patent, Claims 8, 13)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"parts that are generally shaped like a 'U'"	"distinct components of the frame in the shape of the letter U"
"u-shaped frame elements" ('782 Patent, Claims 18, 29)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"parts of a frame that are generally shaped like a 'U'"	"distinct components of the frame in the shape of the letter U"

Dkt. 153 at 2 and 3; Dkt. 163 at 10; Dkt. 168 at 29; Dkt. 174, Ex. 1 at 2.

a. The Parties' Positions

Plaintiff submits that the '297 Patent expressly discloses that "[t]he frame 20 may be of unitary construction." Dkt. 163 at 10 (citing '297 Patent at 5:51-52).

Defendants respond that the disclosure that Plaintiff relies upon "was new matter added for the first time in the '297 patent," and "[a] patentee cannot use new matter in a continuation-in-part application to broaden the meaning of claim terms in a parent patent." Dkt. 168 at 29. Defendants argue that their proposed construction "is consistent with both the plain meaning and the relevant intrinsic record," including the prosecution history. *Id.* at 30; *see id.* at 30–31. Further, as to "u-

shaped," Defendants argue that Plaintiff's proposal of "generally" should be rejected because "[t]he patentee did not claim 'generally u-shaped,'" and "every embodiment in the patent shows frame members that are clearly u-shaped." *Id.* at 31.

Plaintiff replies: "The fact that the claimed frame elements are 'elements' indeed means that they must be separate 'parts' of the frame. But it does not mean that [*sic*, they] must be separate 'components' in the sense that they could not be formed from the same piece of material as specifically described in the 297 Patent." Dkt. 172 at 7.

b. Analysis

The parties present two disputes: (1) whether "elements" refers to distinct components; and (2) whether "u-shaped" requires the shape of the letter "u" or instead encompasses shapes that are "generally" shaped like the letter "u."

The specification of the '297 Patent discloses details regarding a possible "unitary" construction:

> In addition, the frame 20 may be of unitary construction. For instance, a small diameter tube of Nitinol or other appropriate material may have longitudinal slits extending from one end of the tube nearly to the opposite end, thereby forming multiple portions cantilevered from one end. Such cantilevered portions may be bent outward to form the frame of the artificial valve.

'297 Patent at 5:51–57.

Defendants argue that "the fact that new matter regarding 'unitary' frames was added to the '297 patent confirms that the invention as originally disclosed was a non-unitary frame." Dkt. 168 at 30; *see Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1168 (Fed. Cir. 2004) ("[N]ew-matter content of the [continuation-in-part] patent is not available to construe the claims of the [parent] patent, and the district court erred in relying on [it].").

The absence of this "unitary" disclosure in the earlier '782 Patent does not demonstrate that the '782 Patent necessarily excluded unitary structures. *See, e.g., Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) ("The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. . . . There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.") (citing *Phillips*, 415 F.3d at 1313). Defendants have thus failed to demonstrate that the '782 Patent is limited to non-unitary embodiments. *See Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323.

Defendants have also submitted dictionary definitions of "element" as referring to "a distinct part" or "irreducible constituent" of a "composite" device. Dkt. 169-15, Ex. 49, MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 373 (1995) ("a distinct part of a composite device"); Dkt. 169-16, Ex. 50, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 594 (3d ed. 1992) ("A fundamental, essential, or irreducible constituent of a composite entity."). In general, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). Yet, "heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Phillips*, 415 F.3d at 1321. Here, Defendants have not identified any persuasive indication in the intrinsic evidence that the claims use the word "elements" to require non-unitary "distinct components."

As to the provisional patent application, the patentee stated:

> The fundamental design of the stented funnel valve prosthesis consists of a conical geodesic "bird- cage" [*sic*] styled external supporting wire framework fabricated of any biocompatible metallic material (e.g., stainless steel, titanium, Nitinol, etc.) with an internally disposed and congruently fabricated unitary flexible funnel-shaped member located within this cage also to be described later. This external flat wire construction consists of any reasonable number of individual wire elements crossing in their mid-length at the apical site of the framing cage to develop into a curvilinear patterned series of equally spaced stents (i.e., 2 stents derived from each wire length) to terminate at the expanding base of the device. Thus a wire cage composed of 4 wire lengths would result in there being 8 separate stenting elements, and these elements would then terminate individually in an enclosed laminating treatment between the wrappings of a common encircling stabilizer band fabricated of some type biocompatible flexible polymeric material (e.g., silicone rubber, polyurethane, ePTFE, etc.).

Dkt. 169-3, Ex. 3 at B-5:12–29 (emphasis added); *see id.* at B-9:19–21 (joining of the distinct components of the frame "is needed . . . to insure that [the valve element] does not collapse. . . .").

This disclosure contemplates that the word "elements" does not require physically separate components because "2 stents [are] derived from *each wire length*" such that "a wire cage composed of *4 wire lengths* would result in there being *8 separate stenting elements*." *Id.* at B-5:22–24. In other words, each single wire comprises two "elements." *See id.*

Further, even assuming for the sake of argument that these statements necessarily support Defendants' proposal of requiring distinct components, these details regarding the "funnel" valve embodiment are fairly read as pertaining to a specific "embodiment" that should not be imported into the claims. *Id.* at B-1:6–7; *see Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323.

Finally, Defendants have argued that the patentee distinguished the "Johnson," "Stevens," and "Teitelbaum" references based on the disputed terms requiring distinct components. *See* Dkt. 169-4, Ex. 4, July 10, 2002 Amendment in Response to Office Action Mailed April 10, 2002 at 9–12 (SJM00106435–38)). Upon review, no relevant definitive statements are apparent. *See, e.g.*, *id.* at 9 (SJM00106435) ("Johnson does not disclose a plurality of U-shaped valve elements or a band surrounding the frame and extending between adjacent elements to limit spacing between the

adjacent elements."); *see also Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added).

Therefore, the Court hereby expressly rejects Defendants' proposed construction for "frame elements." No further construction is necessary as to that term. *See U.S. Surgical*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro*, 521 F.3d at 1362 ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); *Summit 6*, 802 F.3d at 1291.

As to Plaintiff's proposal of "generally u-shaped," however, Plaintiff has not sufficiently justified introducing "generally," which would tend to obscure rather than clarify the scope of the disputed terms.

The Court therefore hereby construes these disputed terms as set forth in the following chart:

Term	Construction
"frame element"	**Plain meaning**
"u-shaped elements"	**"elements that are shaped like the letter U"**
"u-shaped frame elements"	**"elements of the frame that are shaped like the letter U"**

4. "peripheral anchor(s)" and "anchor"

"peripheral anchor(s)" ('782 Patent, Claims 1, 10, 28, 29; '287 Patent, Claims 1, 22, 31, 38, 45)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
anchor(s): structure(s) that secure or stabilize something in place *an anchor can be integrated with a frame* *peripheral:* located on the periphery	"distinct structure(s) formed outside the general shape of the frame and used to attach the frame to the native anatomy"
"anchor" ('782 Patent, Claims 1, 6, 10, 19, 20, 28, 29; '297 Patent, Claims 1, 22, 31, 38, 45)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a structure that secures or stabilizes something in place" *an anchor can be integrated with the frame*	"distinct structure used to attach the frame to the native anatomy"

Dkt. 153 at 2; Dkt. 163 at 10–11; Dkt. 168 at 32; Dkt. 174-1, Ex. 1 at 2.

a. The Parties' Positions

Plaintiff argues that Defendants' proposed constructions should be rejected because "separate dependent claims add these requirements to the more broadly claimed 'anchors.' . . ." Dkt. 163 at 12. Plaintiff also argues that its proposed interpretation is consistent with the prosecution history. *See id.* at 12–13.

Defendants respond that the patents-in-suit "define and claim 'peripheral anchors'/'anchors' separately from the 'stenting' (outward radial force) provided by the frame itself." Dkt. 168 at 33. Defendants also cite testimony of the named inventor. *Id.* Defendants

contend that "one cannot call the same piece of metal both the 'frame' and the 'peripheral anchor.'" *Id.*

Plaintiff replies that, during prosecution, the examiner found that the term "peripheral anchors" encompassed a stenting frame disclosed in a prior art reference, and "[a]fter the Examiner rejected his argument, [Dr. Snyders] acquiesced in the examiner's broader construction, and thus amended his claims to give up other, unrelated claim scope." Dkt. 172 at 7–8. Plaintiff also submits that "SJM's own documents describe stenting as anchoring." *Id.* at 8. Finally, Plaintiff argues that Defendants' reliance on inventor deposition testimony and purported disclaimers should be rejected for the same reasons discussed as to the term "frame" (addressed separately above). *Id.* at 8.

b. Analysis

As a threshold matter, the parties have discussed the prosecution history, as well as the examiner and the patentee's respective interpretations of the "anchor" terms, but no definitive statement is apparent (or, as the parties put it at the September 28 Hearing, there was no "meeting of the minds"). *See* Dkt. 163-9, Ex. 9, Feb. 11, 2004 Office Action at 2 (SNYDERS_0000309) ("Applicant's arguments . . . have been fully considered but they are not persuasive. Applicant contends Teitelbaum lacks a frame having a plurality of anchors. . . . Examiner disagrees because frame element 12 is comprised of a plurality of self-expanding anchors."); *see* Dkt. 163-9,, Ex. 10, May 11, 2004 Amendment and Response to Office Action Under 37 C.F.R. § 1.116 at 14 ("Applicant appreciates the broad interpretation of the claims the Examiner has obviously chosen."); *see also Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added).

Turning to the claim language, Claim 1 of the ’782 Patent, for example, recites in relevant part (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of *peripheral anchors* for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of *peripheral anchors*;
>
> a band attached to the frame limiting spacing between adjacent *anchors* of said plurality of *peripheral anchors*; . . .

In general, “[w]here a claim lists elements separately, the clear implication of the claim language is that those elements are distinct component[s] of the patented invention.” *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (citations and internal quotation marks omitted). Examples of “anchors 34” are illustrated in Figure 1 of the patents-in-suit. *See* ’782 Patent at 5:14–17. As Defendants emphasized at the September 28 Hearing, the specification separately refers to “stenting elements 30” and “frame elements 30.” *See id.* at 4:48–5:29.

Nonetheless, separately recited limitations do not necessarily require “wholly separate structures.” *See Powell v Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231–32 (Fed. Cir. 2011) (Finding that “the disclosure in the specification cuts against Home Depot’s argument that the [recited] ‘cutting box’ and ‘dust collection structure’ must be separate components” because “the specification teaches that the cutting box may also function as a ‘dust collection structure’ to collect sawdust and wood chips generated during the wood cutting process.”).

Defendants' reliance on Claims 1 and 8 of the '297 Patent is unpersuasive.[3] Although dependent Claim 8, which depends from Claim 1, adds a requirement of frame elements "biased outward" to hold the frame in position in an expanded configuration, Defendants have not shown that any inconsistency arises when interpreting the "anchors" terms as encompassing anchors that are integrated with the frame. Further of note, the specification discloses that "the stenting elements 30 preferably are sufficiently resilient to *hold the artificial valve 10M in position* between the cusps C of the native heart valve M after implantation. . . ." '782 Patent at 4:65–5:1. Plaintiff has also submitted that "SJM's own documents describe stenting as anchoring." Dkt. 172 at 8; *see* Dkt. 173-1, Ex. 2 and Dkt. 173-2, Ex. 3.

As to the provisional patent application, Defendants have cited disclosures that "critical fabrication requirements" include "secure fixation," and "[i]t is proposed that the everting hooks (estimated 110°–135° eversion) developed at the terminal end of each stenting arm beyond the stabilizer band will be adequate for engaging the adjacent native valve structures . . . for such a requisite fixation and stabilization." Dkt. 169-3, Ex. 3 at B-13:21–31; *see id.* at B-6:12–16 ("The terminal ends of each stent element just beyond the stabilizer band will be developed into a series of everted hooklets for attachment to their designated sites of implantation (2-3 mm tissue penetration depth) at the native valve location. . . ."). Upon review, no relevant definitive statements are apparent. *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added). Further, the details provided regarding the "funnel" valve embodiment are fairly read as part of just that, an "embodiment." *See* Dkt. 169-3, Ex. 3. at B-1:6–7.

[3] Claims 22 and 28 of the '297 Patent are similarly presented by Defendants. Dkt. 168 at 33 n.8.

Defendants have also cited testimony of the named inventor. *See* Dkt. 168, Ex. 46, August 1, 2017 Snyders Depo. at 85:14–17 and 91:10–14; *see also* Dkt. 168-34, Ex. 47 at 432:21–24. Here, however, the cited testimony is of little, if any, relevance in these claim construction proceedings. *See Howmedica*, 540 F.3d at 1346–47 (noting that inventor testimony is "limited by the fact that an inventor understands the invention but may not understand the claims, which are typically drafted by the attorney prosecuting the patent application"). To whatever extent this testimony is relevant, it is noteworthy that Dr. Snyders' explained that "[t]he critical anchoring mechanism is still the Superelastic Nitinol material. That's what gives the stability." Dkt. 172-1, Ex. 1, Aug. 1, 2017 Snyders Depo. at 82:16–18. Defendants urged, at the September 28 Hearing, that the claimed invention requires *both* an expanding stent *and* anchors. Any dispute between the parties' as to the meaning of Dr. Snyders' testimony in this regard is of no apparent consequence, however, because the claims here at issue expressly recite "anchor" limitations.

On balance, Defendants have not shown that the disputed terms necessarily refer to structures that are separate from the frame. *See Powell*, 663 F.3d at 1231–32 (quoted above).

As to where the "anchors" are anchored, the parties do not appear to dispute that the "anchors" are used to anchor the frame either to damaged native anatomy or to a damaged artificial heart valve. At the September 28 Hearing, Plaintiff was amenable to a construction along the lines of "structure on the periphery of the frame used to secure the frame" to the existing anatomy. To whatever extent Defendants are arguing that the claim scope is limited to anchoring directly to native anatomy (rather than potentially to a damaged artificial valve), Defendants have not demonstrated that such a limitation is warranted. In short, surrounding claim language is sufficiently clear regarding the structure to which the anchors are anchored.

Finally, at the September 28 Hearing, the parties were unable to agree on whether an anchor "secures," as Plaintiff has proposed, or "attaches," as Defendants have proposed. Defendants cited disclosure of "attach" in the specification. *See* '782 Patent at 5:14–15; *see also id.* at 5:59–62. On balance, Defendants' proposal of "attach" is more consistent with these disclosures as well as the intrinsic evidence as a whole.

The Court therefore hereby construes these disputed terms as set forth in the following chart:

Term	Construction
"peripheral anchor(s)"	**"structure(s) on the periphery of the frame that are used to attach the frame"**
"anchor"	**"structure used to attach the frame"**

5. "central portion located along a centerline extending between the plurality of peripheral anchors," "central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region," and "central portion of the frame/central portion located between the plurality of peripheral anchors"

"central portion located along a centerline extending between the plurality of peripheral anchors" ('297 Patent, Claims 1, 31)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"apex of the frame located along the central axis of the valve"
"central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region" ('297 Patent, Claim 1)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"apex of the frame located along the central axis of the valve"
"central portion of the frame/central portion located between the plurality of peripheral anchors" ('782 Patent, Claims 1, 6, 28, 30; '297 Patent, Claims 1, 2, 4, 31, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"apex of the frame"

Dkt. 153 at 2; Dkt. 163 at p. 13; Dkt. 168 at 26; Dkt. 174, Ex. 1 at 3.

a. The Parties' Positions

Plaintiff argues: "Although the specific embodiments disclosed in the patent specification show frames with apexes, *see, e.g.*, ['782 Patent] at 7:1-3, nothing in the language of the asserted claims, or what is taught in the specification, *requires* the frame to have an apex, let alone *requires*

the 'central portion' to be the apex. Quite the contrary; the patents include dependent claims—not asserted in this case—that specifically add the requirement that the artificial valve have an apex." Dkt. 163 at 14 (citing '782 Patent at Cl. 9). Plaintiff also cites the prosecution history. *See id.* at 14–15.

Defendants respond that these disputed terms necessarily refer to structure because of "the plain meaning of the term, the fact that every embodiment in the patents expressly defines the 'central portion' as the structure at the apex of the frame, the patentee's explanation that such apical structure is 'needed,' and the patentee's clear disclaimer of tube-like stents during prosecution." Dkt. 168 at 26.

Plaintiff replies that Defendants improperly attempt to limit this disputed term to specific disclosed embodiments. Dkt. 172 at 9. Plaintiff also argues that Defendants' reliance on purported disclaimers should be rejected for the same reasons discussed as to the term "frame" (addressed separately above).

b. Analysis

Claim 1 of the '782 Patent, for example, recites (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a *central portion located between the plurality of peripheral anchors*;
>
> a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the *central portion of the frame* and adjacent the band, said valve element being substantially free of connections to the frame except at the *central portion of the frame* and adjacent the band, said valve element having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region

> when the frame is anchored in the position between the upstream region and the downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

As a threshold matter, the parties appear to agree that whereas some claims require that the "central portion" must be "along a centerline," others (such as above-reproduced Claim 1 of the '782 Patent) do not. Plaintiff also "does not dispute that the claimed 'centerline' is the central axis of the valve." Dkt. 163 at 14; *see id.* ("Although replacing 'centerline' with 'central axis' does not seem particularly helpful.").

Plaintiff has cited prosecution history in which, Plaintiff argues, the examiner interpreted "central portion" to mean "any centrally located portion of the frame 12" (*see* Dkt. 163-9-163-11, Exs. 9–11), but regardless of how the examiner's statements are interpreted, the applicability of that prosecution history to the present dispute is not sufficiently clear, particularly in light of the broader claim construction standard applied during prosecution. *See, e.g., In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004) ("During prosecution, . . . the PTO gives claims their broadest reasonable interpretation.") (citation and internal quotation marks omitted); *see Phillips*, 415 F.3d at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.").

Plaintiff has also argued claim differentiation as to dependent Claim 9 of the '782 Patent, which depends from Claim 8, which in turn depends from Claim 1. Claim 9 of the '782 Patent explicitly recites an "apex" (emphasis added):

> 9. An artificial valve as set forth in claim 8 wherein said upstream side of the *flexible valve element* is convex and has an *apex* which is attached to the frame at the junction of the elements.

Claim 9 thus recites that "the flexible valve element . . . has an apex," not that the frame must have an apex. Also, Claims 8 and 9 recite additional limitations other than merely the apex. The doctrine of claim differentiation thus carries little if any weight as to the present disputed terms. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("Claim differentiation, while often argued to be controlling when it does not apply, is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims.").

Nonetheless, turning to the Figures, the specification states that a "central portion" is "*generally* designated by [reference numeral] 36" in Figure 2. '782 Patent at 5:26–29 (emphasis added). Indeed, Figures 2 and 3 illustrate reference numeral 36 using a lead line with an arrow at the end thereof, which thus "indicate[s] the entire section towards which it points" rather than being a "[l]ead line[] . . . between the reference character[] and the detail[] referred to." 37 C.F.R. § 1.84(q) and (r); *see* MANUAL OF PATENT EXAMINING PROCEDURE § 608.02 at 600-90 (8th ed. Aug. 2001) (same). This intrinsic evidence weighs at least somewhat against limiting the disputed "portion" to necessarily being an "apex."

As to the provisional patent application, Defendants have cited disclosures regarding the "apex of the cage." Dkt. 169-3, Ex. 3 at B-6:2–8 and B-9:17–21. Upon review, no relevant

definitive statements are apparent. *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added). Again, the details provided regarding the "funnel" valve embodiment are fairly read as part of just that, an "embodiment." *See* Dkt. 169-3 at B-1:6–7.

Defendants have also cited testimony of the named inventor. *See* Dkt. 168-33, Ex. 46, Aug. 1, 2017 Snyders Depo. at 136:13–19, 200:24–201:18 and 221:2–14. Here, however, the cited testimony is of little, if any, relevance in these claim construction proceedings. *See Howmedica*, 540 F.3d at 1346–47 (noting that inventor testimony is "limited by the fact that an inventor understands the invention but may not understand the claims, which are typically drafted by the attorney prosecuting the patent application"). Moreover, Defendants have not demonstrated that Dr. Snyders was testifying about the claimed invention as opposed to a particular embodiment. *See* Dkt. 168-33, Ex. 46, Aug. 1, 2017 Snyders Depo. at 136:13–19, 200:24–201:18 and 221:2–14.

The apparent dispute instead turns upon the meaning of the constituent term "portion" as used in the claims, such as above-reproduced Claim 1 of the '782 Patent. In particular, the claim recites "the frame *having* . . . a central portion located between the plurality of peripheral anchors." A fair reading of this recital is that, as Defendants have argued, the "central portion" must be part of the structure of the frame rather than merely an empty space surrounded by the frame. *See Phillips*, 415 F.3d at 1314 ("the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words").

Likewise, this claim also recites that the flexible valve element is attached to the central portion of the frame, thus again implying that the "central portion" must be structure rather than empty space. '782 Patent at Cl. 1 ("a flexible valve element *attached to the central portion of the frame* and adjacent the band, said valve element being substantially *free of connections to the frame except at the central portion of the frame* and adjacent the band") (emphasis added); *Phillips*, 415 F.3d at 1314 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms.").

Finally, interpreting "central portion" as structure rather than empty space is also consistent with the specification. *See* '782 Patent at 7:3–6 ("As illustrated in FIG. 3, the flexible valve element 22 is *attached to the central portion 36 of the frame 20* at a position substantially centered between the anchors 34.") (emphasis added); *see also id.* at '782 Patent at 5:26–29 and Figs. 2 and 3.

Indeed, at the September 28 Hearing, Plaintiff acknowledged that the "central portion" must be structural. Nonetheless, Plaintiff asserted that a dispute may remain because Defendants are interpreting "along a centerline" as meaning "on" a centerline. Plaintiff argued that the phrase "along a centerline" can encompass "parallel" to a centerline. Plaintiff analogized that a road can be understood as running "along a beach" without actually running on top of the sand of the beach. Instead, Plaintiff analogized, the road could follow "along" the shoreline at some distance.

Claim 1 of the '297 Patent, for example, recites in relevant part (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a *central portion located along a centerline extending between the plurality of peripheral anchors* and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region; . . .

Plaintiff's proposed interpretation of "along" as "parallel" is vague and lacks support in either intrinsic or extrinsic evidence. Instead, the specification supports Defendants' proposal that "along a centerline" means at a position "on" the centerline (and Plaintiff "does not dispute that the claimed 'centerline' is the central axis of the valve" (Dkt. 163 at 14). *See, e.g.*, '782 Patent at 7:3–6 ("As illustrated in FIG. 3, the flexible valve element 22 is attached to the central portion 36 of the frame 20 at a position substantially *centered* between the anchors 34.") (emphasis added) and Fig. 3.

The Court therefore hereby construes these disputed terms as set forth in the following chart:

Term	Construction
"central portion located along a centerline extending between the plurality of peripheral anchors"	**"central structural frame portion that is located at a position on the central axis of the valve between the plurality of peripheral anchors"**
"central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region"	**"central structural frame portion that is located at a position on the central axis of the valve, between the plurality of peripheral anchors, and between the upstream region and the downstream region"**
"central portion of the frame/central portion located between the plurality of peripheral anchors"	**"central structural frame portion that is located between the plurality of peripheral anchors"**

6. "band"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a structure generally in the shape of a circular strip or ring" *a band can be integrated with the frame*	"tissue or material that encircles the frame and binds the frame elements"

Dkt. 153 at 2–3; Dkt. 163 at 15; Dkt. 168 at 35; Dkt. 174, Ex. 1 at 3. The parties submit that this term appears in Claims 1, 10, 15–18, 23, 24, 27, 28, and 30 of the '782 Patent and Claims 9, 10, 29, and 30 of the '297 Patent. Dkt. 174-1, Ex. 1 at 3.

a. The Parties' Positions

Plaintiff argues: "A band is a structure that has a circular strip or ring. Not every tissue or material that surrounds something is a band." Dkt. 163 at 15. Further, Plaintiff argues that "not all 'bands' bind," and "[w]hat the 'band' of the asserted claims is required to do is addressed by other claim language that has not been proposed for construction." *Id.*

Defendants respond that the "band" cannot be merely a portion of the frame because, for example, the claims require that the "band" is "surrounding" or "attached to" the frame. Dkt. 168 at 35–36. Defendants submit that this interpretation is consistent with the specification and the prosecution history. *See id.* at 36–37.

Plaintiff replies that "there is no logical reason why the claimed 'band' could not be part of the frame." Dkt. 172 at 10.

b. Analysis

Defendants have cited testimony of the named inventor as to whether the accused instrumentality "has th[e] band." *See* Dkt. 168, Ex. 46, Aug. 1, 2017 Snyders Depo. at 126:7–22. On balance, however, the cited testimony is of little, if any, relevance in these claim construction proceedings. *See Howmedica*, 540 F.3d at 1346–47 (noting that inventor testimony is "limited by the fact that an inventor understands the invention but may not understand the claims, which are typically drafted by the attorney prosecuting the patent application"). Moreover, the testimony cited by Defendants does not clearly demonstrate that Dr. Snyders was testifying about the claimed invention as opposed to a particular embodiment.

Turning to the claims, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Claim 1 of the '782 Patent, for example, recites in relevant part (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors;
>
> a *band* attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the central portion of the frame and adjacent the *band*, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the *band*. . . .

The claim thus expressly recites "a band *attached* to the frame," which implies that the band is not part of the frame.[4] *See Becton, Dickinson*, 616 F.3d at 1254 ("Where a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention."); *see also id.* at 1255–56 (regarding "spring means connected to said hinged arm": "If the hinged arm and the spring means are one and the same, then the hinged arm must be 'connected to' itself and must 'extend between' itself and a mounting means, a physical impossibility. A claim construction that renders asserted claims facially nonsensical cannot be correct.") (citation and internal quotation marks omitted). It is also noteworthy that this interpretation is consistent with the specification. *See* '782 Patent at 5:30–6:23.

[4] Defendants properly submit that the other Claims at issue are similar in this respect: "The Claims of the '782 patent recite a 'band attached to the frame' (Claims 1 and 28), a 'band . . . positioned inside and attached to the frame' (Claim 10), a 'first band surrounding and attached to the frame' (Claim 17), a 'band surrounding the frame and extending between adjacent [frame] elements' (Claim 18), and a 'first band surrounding the frame' (Claim 30). The '297 patent similarly claims a 'band extending around the frame elements' (Claim 9). From this claim language, it is apparent that the 'band' must be a structure separate from the frame." Dkt. 168 at 36.

Plaintiff's reliance upon the *Powell* case, discussed above as to the "peripheral anchor(s)" and "anchor" terms, is unavailing. 663 F.3d 1221. Here, the specification does not teach that the "band" could be both integral with the frame *and* attached to the frame. *See id.* at 1231–32 (Fed. Cir. 2011) (finding that "the disclosure in the specification cuts against Home Depot's argument that the [recited] 'cutting box' and 'dust collection structure' must be separate components" because "the specification teaches that the cutting box may also function as a 'dust collection structure' to collect sawdust and wood chips generated during the wood cutting process"). The above-discussed context provided by surrounding claim language is therefore persuasive.

Also, the above-noted context provided by the claim language is more persuasive than the prosecution history cited by Plaintiff, in which the examiner described the "Teitelbaum" reference. Dkt. 163-9, Ex. 9, Feb. 11, 2004 Office Action at p. 3 (SNYDERS_0000310) ("Note the frame is a wire mesh, which inherently includes a band (one of the wires) extending around the other frame elements."). No lexicography or clear interpretation is apparent in this prosecution history. *See Phillips*, 415 F.3d at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."); *see also Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003) ("The court correctly viewed the prosecution history not for the examiner's or the applicant's subjective intent, but as an official record that is created in the knowledge that its audience is not only the patent examining officials and the applicant, but the interested public.").

On balance, the context provided by the claims is controlling. *See Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) ("In claim construction, this court gives primacy to the language of the claims, followed by the specification."); *see also Aria Diagnostics, Inc. v.*

Sequenom, Inc., 726 F.3d 1296, 1300 (Fed. Cir. 2013) ("Claim construction focuses primarily on the language of the claims.") (citing *Phillips*, 415 F.3d 1303); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[T]he claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.").

The Court therefore hereby expressly rejects Plaintiff's interpretation that "a band can be integrated with the frame."

As to the remainder of the parties' proposals, surrounding claim language specifies the relevant configuration of the recited "band." In other words, the parties' proposals do not appear to have any further incongruity that is not already addressed by other claim language. To whatever extent Defendants are arguing that the "band" must encircle the outside of the frame rather than the inside, such an interpretation would be inconsistent with Claim 10 of the '782 Patent, which recites "a band comprising an internal strip positioned inside and attached to the frame. . . ." The submitted extrinsic dictionary definition of "band" does not compel otherwise. Dkt. 169-16, Ex. 50, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 143 (3d. ed. 1992) ("A thin strip of flexible material used to encircle and bind one object or to hold a number of objects together"); *see Phillips*, 415 F.3d at 1321 ("heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification"). The Court therefore hereby expressly rejects any limitation that the "band" is limited to being positioned on

the outside of the frame.[5] Likewise, Defendants have not adequately supported their proposal of "binds," particularly in light of the context already provided by surrounding claim language.

Thus, in light of the foregoing findings, no further construction is necessary. *See U.S. Surgical*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro*, 521 F.3d at 1362 ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); *Summit 6*, 802 F.3d at 1291.

The Court therefore hereby construes **"band"** to have its **plain meaning**.

[5] Also, Defendants themselves have stated that "'encircle' does not necessarily mean encircle the exterior." Dkt. 168 at 37. At the September 28 Hearing, Defendants confirmed their position that the recited "band" can go around the inside of the frame, the outside of the frame, or both.

7. "valve element," "flexible valve element," and "flaps"

"valve element" ('782 Patent, Claims 1, 6, 7, 9, 10, 14, 17, 18, 24, 28–30; '297 Patent, Claims 1, 2, 22, 31, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary *alternative*: a part of the valve	"unitary piece of tissue or material that collapses inwardly away from the frame to allow forward fluid flow between the frame and the unitary piece of tissue or material"
"flexible valve element" ('782 Patent, Claims 1, 6, 7, 9, 10, 14, 17, 18, 24, 28–30; '297 Patent, Claims 1, 2, 22, 31, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary *alternative*: a flexible part of the valve	"unitary piece of tissue or material that collapses inwardly away from the frame to allow forward fluid flow between the frame and the unitary piece of tissue or material"
"flaps" ('782 Patent, Claims 7, 24)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"reversing cusps that collapse inwardly away from the frame to allow forward fluid flow between the frame and the reversing cusps"

Dkt. 153 at 3; Dkt. 163 at 16; Dkt. 168 at 14; Dkt. 174, Ex. 1 at 4.

a. The Parties' Positions

Plaintiff argues: "The Court should not import that very detailed description of a specific reversing-cusp design into the simple claim terms 'valve element,' 'flexible valve element,' and 'flaps.' The asserted claims simply do not include these requirements." Dkt. 163 at 17.

Defendants respond that "both the intrinsic and extrinsic records . . . provide that the valve element *must* be a unitary piece of material that opens by collapsing inwardly." Dkt. 168 at 15. For example, Defendants submit that "[t]here is no embodiment that does not have a unitary, inwardly collapsing valve element having reversing cusps." *Id.* Defendants also argue that "[t]he provisional patent application—to which almost all independent claims claim priority and which is incorporated into the specifications by reference—repeatedly emphasizes the importance of this 'unitary' valve to the invention." *Id.* at 16. Defendants urge that "[t]he patentee also expressly distinguished and disparaged native-like multi-leaflet valves." *Id.* at 17. Further, Defendants argue that their proposed construction is consistent with the prosecution history as well as the testimony of the named inventor. *Id.* at 18–21. Finally, Defendants argue: (1) "[a]s used in the claims, 'valve' refers to the whole implant;" (2) "the patents make it clear that the 'valve element' refers to the entire valve member that alternately allows and blocks flow;" and (3) "[b]oth the claims and the specifications show that what the patentee meant by 'flaps' was 'reversing cusps.'" *Id.* at 21–22.

Plaintiff replies: "[W]hat 'element' describes in this context is the relationship between the 'valve element' and the overall claimed artificial valve: the 'valve element' is a particular part of the claimed artificial valve. Nothing about 'valve element' talks about what the valve element itself must be made of, let alone requires that it be made from a single piece of tissue or material." Dkt. 172 at 10. As to disclosures in the specification cited by Defendants, Plaintiff argues that "[n]othing about these statements disavows unitary or reversing-cusp valve elements." *Id.* at 11. Further, Plaintiff argues that Defendants' reliance on purported disclaimers should be rejected for the same reasons discussed as to the term "frame" (addressed separately above). *Id.*

b. Analysis

Defendants submit: "The specifications of the patents, not just the provisional application, state that the figures, including Figure 1, show 'the present invention . . . in their entireties'—not merely an embodiment of the invention." Dkt. 168 at 15. Defendants have taken these words out of context. The full statement is:

> Referring now to the drawings and in particular to FIG. 1, artificial heart valves of the present invention are designated in their entireties by the reference numbers 10A and 10M.

'782 Patent at 4:25–27; '297 Patent at 4:61–63 (same). This passage does not state that Figure 1 illustrates the artificial heart valves of the present invention in their entireties. Rather, this passage states that, in Figure 1, the entireties of the illustrated artificial heart valves are identified by the reference numerals 10A (which indicates an artificial heart valve specifically configured for repairing a damaged aortic valve "A") and 10M (which indicates an artificial heart valve specifically configured for repairing a damaged mitral valve "M"). *See* '782 Patent at 4:25–31.

The specification also discloses, for example:

> [T]he flexible valve element 22 is attached to the frame 20, and more particularly to the band 40, at several attachment points 56 around the frame. Thus, the valve element 22 forms flaps 58 extending between adjacent attachment points 56. Each of the flaps 58 and a corresponding portion of the band 40 extending between adjacent attachment points 56 defines an opening 60 though the valve when the valve element 22 moves to the open position.

'782 Patent at 7:10–17. This disclosure regarding the flexible valve elements, and flaps formed thereby, does not specify that the flexible valve element is necessarily of unitary construction, let alone that unitary construction is an essential aspect of the disclosed invention. Even if such disclosure were apparent, Defendants have not shown that those specific features should be imported into the claims. *See Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323.

Further, although the patentee distinguished prior art artificial heart valves (*see* '782 Patent at 2:5–19), Defendants have not shown that the patentee necessarily relied upon a "unitary" valve element or "reversing cusps" in order to do so. *See Retractable*, 653 F.3d at 1305 (noting that "the specifications do not disclose a body that consists of multiple pieces or indicate that the body is anything other than a one-piece body," but also noting that "[i]n distinguishing prior art syringes comprised of multiple pieces, the specifications state that the prior art had failed to recognize a retractable syringe that 'can be molded as one piece outer body'").

As to the provisional patent application, Defendants have cited disclosures regarding a "unitary" valve element and a "reversed cusp" design:

> The presently described device, to the contrary, derives its novel diminutive features from the very elemental use of a *unitary* flap type flexible *funnel member* that presents virtually no impaction of free forward flow mechanics for the *funnel valve* prosthesis as pertains in the bulkier valve constructions as described above. Its simplified method of providing an innovative *"reversed cusp"* enhancement for device functionality is the essence of its capability for the diminutive fabrication dimensions needed for transluminal or endothoracoscopic implantation procedures.

Dkt. 169-3, Ex. 3 at A-3:9–26 (emphasis added); *id.* at A-4:10–15, A-7:13–20, B-5:12–18, B-6:31–B-7:1, B-7:20–27, B-8:13–30 (discussing "'reversing cusp' flaps"), B-9:17–24 and B-20:24–28.

Defendants have argued that what Dr. Snyders has referred to as the "funnel valve" is coextensive with the claimed invention. *See, e.g.*, Dkt. 168-16, Ex. 29 at 2 and 4; Dkt. 168-1, Ex. 14 at 3. Nonetheless, "although the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments. In particular, [the Federal Circuit has] expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323. At the September 28 Hearing, Defendants

repeatedly urged that all that the named inventor ever invented or described was a "funnel" valve with a unitary valve member. Although these arguments may perhaps bear upon requirements of enablement or written description, Defendants have not persuasively demonstrated that these arguments warrant limiting the claim scope to the specific features of particular disclosed embodiments. *See id.*; *see also id.* at 1327 ("we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction").

On balance, the patentee's statements pertained to particular "unitary," "reversed cusp" embodiments, and no relevant definitive statements are apparent that would justify imposing the limitations proposed by Defendants. *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added). Again, the details provided regarding the "funnel" valve embodiment are fairly read as part of just that, an "embodiment." *See* Dkt. 169-3, Ex. 3 at B-1:6–7.

Alternatively, even assuming for the sake of argument that a disclaimer were present, "it is certainly possible that a clear and unmistakable disavowal in an incorporated patent is no longer so when placed in the context of the disclosure of the host patent." *X2Y*, 757 F.3d at 1363; *see MPHJ*, 847 F.3d at 1369, 1376 (even where the "specification incorporates in full the . . . provisional application," "it is the deletion from the . . . [p]rovisional application that contributes understanding of the intended scope of the final application"); *see also id.* at 1369 (regarding "the deleted one-step operation," noting that "the . . . Patent describes the single-step operation as 'optional,'" but stating that "[t]hese statements that single-step operation is 'optional' *accord* with the change from the . . . [p]rovisional to the final patent") (emphasis added).

Defendants have further cited prosecution history of the '782 Patent in which the patentee distinguished the "Stevens" reference:

> Stevens discloses a prosthetic valve comprising a cylindrical element (100) and at least one cusp (95). However, Stevens does not disclose an artificial valve comprising a band attached to a frame limiting spacing between adjacent anchors of the frame or a flexible valve element attached to a central portion of the frame and adjacent the band as recited in the claims.

Dkt. 169-4, Ex. 4, July 10, 2002 Amendment in Response to Office Action Mailed April 10, 2002 at 10 (SJM00106436). The prosecution history cited by Defendants contains no relevant definitive statement that would support Defendants' proposed "unitary" or "reversing cusps" limitations. *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on *definitive* statements made during prosecution.") (emphasis added).

Defendants have also cited testimony of the named inventor. *See* Dkt. 168-33, Ex. 46, Aug. 1, 2017 Snyders Depo. at 120:10–14, 120:19–121:10, 127:6–14, 143:16–25, 146:12–21 and 264:5–11. Here, however, the cited testimony is of little, if any, relevance in these claim construction proceedings. *See Howmedica*, 540 F.3d at 1346–47 (noting that inventor testimony is "limited by the fact that an inventor understands the invention but may not understand the claims, which are typically drafted by the attorney prosecuting the patent application"). Moreover, Defendants have not demonstrated that Dr. Snyders was testifying about the claimed invention as opposed to a particular embodiment.

Defendants have also submitted dictionary definitions of "element" as referring to "a distinct part" or "irreducible constituent" of a "composite" device. Dkt. 169-15, Ex. 49, MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 373 (1995) ("a distinct part of a composite device"); Dkt. 169-16, Ex. 50, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 594 (3d ed.

1992) ("A fundamental, essential, or irreducible constituent of a composite entity."). In general, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck*, 395 F.3d at 1372. Yet, "heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Phillips*, 415 F.3d at 1321. Here, Defendants have not identified any persuasive indication in the intrinsic evidence that the claims use the word "element" to preclude a "valve element" from having constituent parts.

Likewise, Defendants noted at the September 28 Hearing that whereas the preambles of the claims recite "a plurality of cusps" as plural, the disputed terms recite "valve element" and "flexible valve element" as singular. Although the disputed terms "valve element" and "flexible valve element" are singular, these disputed terms appear in "comprising" claims that do not prohibit the presence of additional elements. *See, e.g., Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.").

Based on all of the foregoing, the Court hereby expressly rejects Defendants' proposed constructions. No further construction is necessary, particularly in light of the context provided by surrounding claim language. *See U.S. Surgical*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro*, 521 F.3d at 1362 ("[D]istrict

courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); *Summit 6*, 802 F.3d at 1291.

The Court accordingly hereby construes **"valve element," "flexible valve element,"** and **"flaps"** to have their **plain meaning**.

8. "opening extending through at least one of said frame and said flexible valve element/opening extending through at least one of said frame and the flexible valve element" and "opening extends through the central portion of the frame and the flexible valve element"

"opening extending through at least one of said frame and said flexible valve element / opening extending through at least one of said frame and the flexible valve element" ('297 Patent, Claims 1, 22, 31, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"small aperture in the structure of the frame and/or the flexible valve element"
"opening extends through the central portion of the frame and the flexible valve element" ('297 Patent, Claim 2)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary	"small aperture in the structure of the frame and the flexible valve element"

Dkt. 153 at 3; Dkt. 163 at 17–18; Dkt. 168 at 39; Dkt. 174, Ex. 1 at 4.

a. The Parties' Positions

Plaintiff argues: (1) "nothing in the claim language speaks about the size of the opening;" (2) "[c]hanging 'opening' to 'aperture' merely replaces a well-known word with a less-well known word for no apparent reason, and would not be helpful to the jury;" and (3) "[t]he 297 patent

describes a frame having an opening (212) that extends between (but not through) the frame elements (230)." Dkt. 163 at 18–19. Plaintiff also cites the prosecution history. *See id.* at 19–20.

Defendants respond that "Plaintiff's construction would cover any physical 'opening' in an artificial heart valve implant—including the opening formed when the valve element opens to allow blood flow." Dkt. 168 at 39.

Plaintiff replies that "[a]s confirmed by the prosecution history," the claimed "opening" "covers the opening in the Teitelbaum frame." Dkt. 172 at 13.

b. Analysis

As a threshold matter, Plaintiff has cited prosecution history in which the examiner described the "Teitelbaum" reference:

> Teitelbaum discloses in figures 3-4B an artificial heart valve comprising a flexibly resilient frame (12) comprising anchors for maintaining the frame in position, a flexible valve element (20) having convex upstream and concave downstream sides, and an *opening through the frame* for receiving an implement such as a guide (see Fig 2).

Dkt. 163-9, Ex. 9, Feb. 11, 2004 Office Action at 3 (SNYDERS_0000310) (emphasis added). On balance, this prosecution history is not sufficiently clear so as to create any inconsistency with Defendants' proposed constructions. *See Phillips*, 415 F.3d at 1317 ("Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."). Also of note, a broader claim construction standard was applied during prosecution than is applicable here. *See, e.g.*, *In re Bigio*, 381 F.3d at 1324 ("During prosecution, . . . the PTO gives claims their broadest reasonable interpretation.") (citation and internal quotation marks omitted).

The specification discloses:

> An opening extends through at least one of the frame and the valve element for receiving an implement.
>
> * * *
>
> In one embodiment, the post 310 mounts on the frame 220 (FIGS. 8, 14, 16 and 17) and includes an opening 212 (FIG. 14) to allow an implement 214, such as a guide, or guidewire, as depicted in FIG. 16 and described in detail below, to pass through the valve 210. The opening 212 extends through at least one of the frame 220 and the valve element 222 for receiving the implement 214 (FIGS. 8 and 16). Although the opening 212 of the illustrated embodiment extends through the central portion 236 of the frame 220 and the valve element 222, it is envisioned that the opening 212 could extend through other portions of the artificial valve 210 without departing from the scope of the present invention. After removal of the implement 214, it is envisioned the opening 212 may provide surface washing to reduce a potential for blood to coagulate adjacent the downstream side (i.e., the concave side 252) of the valve element 222. It is further envisioned the opening 212 may be used even where an implement 214 is not needed to reduce potential for blood to coagulate adjacent the valve element 222. Although this opening 212 may have other dimensions without departing from the scope of the present invention, in one embodiment the opening has a width of between about 0.5 mm and about 1 mm, and more preferably a width of about 1 mm.

'297 Patent at 3:1–3 and 13:1–24. On balance, these disclosures in the specification pertain to specific features of particular disclosed embodiments that should not be imported into the claims. *See Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323. Also, this disclosure expressly notes that "it is envisioned that the opening 212 could extend through other portions of the artificial valve 210 without departing from the scope of the present invention." *Id.* at 13:10–13.

Moreover, Defendants' proposal of a "small aperture in the structure" lacks sufficient support in the intrinsic evidence and would tend to confuse rather than clarify the scope of the claims. At the September 28 Hearing, Defendants argued that the specification explains these disputed terms refer to an opening for a guide wire. Claim 1 of the '297 Patent, for example, recites: "an opening extending through at least one of said frame and said flexible valve element *for receiving an implement*" (emphasis added). Nonetheless, Defendants' proposal remains

unclear and also is seemingly superfluous, at least in the case of the express recital in Claim 1 of '297 Patent of "for receiving an implement."

Defendants' proposal would also appear to read out, for example, the embodiment illustrated in Figure 14 of the '297 Patent, in which "opening 212" is positioned between frame elements rather than through any frame element. *See* '297 Patent at 13:1–6 and Fig. 14.[6] Further, as to the term "opening extends through the central portion of the frame and the flexible valve element," the constituent term "central portion of the frame" is a separately disputed term (addressed above). Finally, Defendants have argued that the usage of the phrase "not shown" in the '782 Patent ('782 Patent at 8:40–53) means that "'openings' that were shown in the '782 Patent are not the 'opening' subsequently claimed in the '297 Patent" (Dkt. 168 at 39–40), but the passage cited by Defendants does not demonstrate any such disclaimer, and Defendants have not identified any legal precedent to support their proposition. Moreover, what is disclosed as being "not shown" is an "alternative embodiment," not the "opening." *See* '782 Patent at 8:40–53.

The Court therefore hereby expressly rejects Defendants' proposed constructions. No further construction is necessary, particularly in light of the context provided by surrounding claim language. *See U.S. Surgical*, 103 F.3d at 1568 ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro*, 521 F.3d at 1362 ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims."); *Summit 6*, 802 F.3d at 1291.

[6] At the September 28, 2017 Hearing, Defendants clarified that Defendants are not seeking an interpretation that would require the "openings" to be formed in a particular frame element.

The Court accordingly hereby construes **"opening extending through at least one of said frame and said flexible valve element/opening extending through at least one of said frame and the flexible valve element"** and **"opening extends through the central portion of the frame and the flexible valve element"** to have their **plain meaning**.

9. "releasable fastener" and "releasably attachable"

"releasable fastener" ('297 Patent, Claims 3, 23)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a fastener that is designed to be released non-destructively"	"device that allows selective disengagement and reengagement"
"releasably attachable" ('297 Patent, Claims 34, 38)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"attached in a manner that can be unattached nondestructively"	"allows selective disengagement and reengagement"

Dkt. 153 at 3 and 4; Dkt. 163 at 20; Dkt. 168 at 40; Dkt. 174, Ex. 1 at 5.

a. The Parties' Positions

Plaintiff argues: (1) "[i]nherent in the concept of 'releasable' is the idea that something is designed to be unattached in a non-destructive manner;" (2) the ability to "reengage" after a release "is not found in the terms 'releasable fastener' or 'releasably attachable;'" and (3) although "one form of 'engaging' something is to push against it," "that X pushes against Y does not mean that X is 'fastened' or 'attached' to Y." Dkt. 163 at 21.

Defendants respond that surrounding claim language demonstrates that "releasable" requires a capability of reengagement. Dkt. 168 at 40–41.

Plaintiff replies that "SJM presents no argument that destructive releasing should count." Dkt. 172 at 14. Plaintiff also argues that, as to the separate recital that the fastener is "for selectively connecting," "[i]f anything, the fact that separate claim language adds this limitation means that the 'releasable fastener' does not inherently include it." *Id.*

b. Analysis

Claims 3 and 34 of the '297 Patent, for example, recite (emphasis added):

> 3. An artificial valve as set forth in claim 2 further comprising a *releasable fastener* mounted on the frame for *selectively connecting* the valve to an instrument.
>
> * * *
>
> 34. A combination as set forth in claim 33 further comprising an installer received within the hollow interior of the holder and *releasably attachable* to the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

The specification likewise discloses "releasable fastener[s]" and "releasably attachable" installers:

> The post 318 may additionally include a releasable fastener 314. For example, the post 318 may include threads 320 (FIG. 16) for attaching the valve 210 to the instrument 306. Either the inside or outside of the post 318 may be threaded, but is preferably externally threaded, as shown in FIGS. 8 and 16. Preferably, the post 318 has an inner diameter ID of about 1.0 mm (FIG. 16) and an outer diameter OD of about 2.0 mm. The post 318 is also preferably right-hand threaded, although left-hand threads are contemplated as being within the scope of the present invention.
>
> * * *
>
> The elongate manipulator 344 further includes a hollow interior 348 shaped and sized to receive the installer 328. The installer is *releasably attachable* to the artificial heart valve 210 for maneuvering the artificial heart valve from the hollow interior 332 of the holder 276 into position between the upstream region and the downstream region of the damaged heart H. In one embodiment, an end 352 of the installer 328 includes an internally threaded portion 354 for threadably receiving the externally threaded post 310 of the valve 210. This allows the user to push the valve 210 from the holder 276 and *selectively release* the installer 328 from the post 310 of the valve by rotating the installer, thereby unscrewing the installer from the

> post. The installer 328 and elongate manipulator 344 may then be removed from the surgical field. Preferably, the internally threaded portion 354 would have an inner dimension ID" of about 2.0 mm to match the outer dimension OD of the externally threaded post 310. In one embodiment, the end 352 of the installer 328 preferably has an outer dimension OD' of about 2.5 mm while the remaining portion of the installer has an outer dimension OD" of about 2.0 mm.
>
> * * *
>
> Alternately, access to the aortic valve A is possible in a retrograde configuration (e.g., from the femoral artery), as described above with respect to FIG. 5. *Such an installation would not include the use of a releasable fastener*, but would incorporate a plunger tip 80 and push rod 82 as set forth above.

'297 Patent at 13:25–35, 14:45–65 and 16:53–58 (emphasis added); *see id.* at 14:66–15:11 (disclosing "a different installer and post embodiment" that "includes a bayonet fastener 360 as depicted in FIG. 17"); *see also id.* at Cls. 5 and 7.

These particular types of fasteners, however, are disclosed as examples. To the extent that these examples might be implemented so as to enable both "disengagement and reengagement," as Defendants have proposed, such specific features from particular disclosed embodiments should not be imported into the claims. *See Constant*, 848 F.2d at 1571; *see also Phillips*, 415 F.3d at 1323. Further, the extrinsic evidence cited by Defendants is of minimal, if any, weight in these claim construction proceedings and is unpersuasive. *See* Dkt. 168-1, Ex. 14 at 23; *see also Phillips*, 415 F.3d at 1317 ("while extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language) (citation and internal quotation marks omitted).

Nonetheless, Plaintiff has not adequately supported its proposal of requiring releasing "non-destructively." Plaintiff's suggested analogy that "a page of a book is not 'releasable' because it can be ripped out" (Dkt. 163 at 20) is unpersuasive because its applicability to the present dispute is unclear. For example, under Plaintiff's apparent reasoning, a page of a

perforated notebook might not be considered "releasable" because removing the page would destroy the perforation. On balance, Plaintiff has not sufficiently explained or supported its assertion that "[i]nherent in the concept of 'releasable' is the idea that something is designed to be unattached in a non-destructive manner." *Id.* The Court therefore hereby expressly rejects Plaintiff's proposal in that regard.

The Court accordingly hereby construes the disputed terms as set forth in the following chart:

Term	Construction
"releasable fastener"	**"fastener that allows for selectively releasing"**
"releasably attachable"	**"attachable in a manner that can be selectively released"**

10. "incision"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a cut"	"surgical cut using a knife or scalpel"

Dkt. 153 at 3; Dkt. 163 at 21. The parties submit that this term appears in Claims 17, 18, and 20 of the '297 Patent. Dkt. 174 at 1.

Plaintiff argues that Defendants' proposed limitation should be rejected because the specification "specifically describe[s] making an 'incision' in the context of a percutaneous, transluminal method of implanting an artificial valve. . . ." Dkt. 163 at 21. Plaintiff also submits that Defendants' own documents refer to implanting a heart valve through an "incision" in the femoral artery or a "puncture." *Id.* at 22. In response, "St. Jude accepts Plaintiff's construction of

'a cut.'" Dkt. 168 at 42. Plaintiff's reply brief acknowledges this agreement. Dkt. 172 at 14; *see* Dkt. 174, Ex. 1 at 1.

The Court therefore hereby construes **"incision"** to mean **"a cut."**

11. "end of [an] instrument"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
no construction necessary *alternative*: the end of the elongate [flexible] instrument	"furthest extremity of the instrument"

Dkt. 153 at 3; Dkt. 163 at 23. The parties submit that this term appears in Claims "17, 28 [*sic*, 18], [and] 20" of the '297 Patent. Dkt. 174, Ex. 1 at 2.

Plaintiff submits that "SJM's own documents confirm that in the context of TAVR,[7] 'end of [an] instrument' does not mean the 'furthest extremity' of the instrument." Dkt. 163 at 23. In response, "St. Jude accepts Plaintiff's proposal of no construction necessary." Dkt. 168 at 42. Plaintiff's reply brief acknowledges this agreement. Dkt. 172 at 14.

As agreed-upon by the parties, therefore, the Court hereby finds as to **"end of [an] instrument"**: **"no construction necessary."**

12. "ejecting"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"causing to come out" *this can be from any frame of reference*	"causing to come out"[8]

[7] "TAVR" appears to be an abbreviation for "transcatheter aortic valve replacement."

[8] Defendants previously proposed: "completely expelling, removing." Dkt. 153 at 4.

Dkt. 153 at 4; Dkt. 163 at 24; Dkt. 168 at 41; Dkt. 174-1, Ex. 1 at 5. The parties submit that this term appears in Claims 28 and 29 of the '782 Patent and Claims 17, 18, and 20 of the '297 Patent. *Id.*

a. The Parties' Positions

Plaintiff argues that "nothing in the patents suggests that 'ejecting' requires 'complete' ejection," and the specification "explain[s] that the valve can be 'ejected' and then recaptured by the delivery instrument for re-positioning if necessary." Dkt. 163 at 24 (citing '297 Patent at 3:37–50 and 20:42–21:25).

Defendants "accept[] Plaintiff's construction, 'causing to come out.' But St. Jude does not accept Plaintiff's confusing and ambiguous gloss that '[t]his can be from any frame of reference,' which Plaintiff evidently does not even offer as part of its proposed construction." Dkt. 168 at 41.

Plaintiff replies that "[a]lthough it disagrees with this aspect of Snyders' proposed construction, SJM presents no argument responding to the reasons why Snyders' position is correct." Dkt. 172 at 14.

b. Analysis

Defendants appear to no longer argue that "ejecting" requires causing to come out *completely*. The only potential remaining issue might arise from Plaintiff's assertion that "this can be from any frame of reference." Dkt. 174-1, Ex. 1 at 5. Plaintiff asserted, in its opening brief:

> SJM's proposed construction could arguably require the delivery instrument to be held in place relative to the patient so that when the valve is ejected it moves with respect to the patient. Snyders' proposed construction would allow for that, but would also allow the valve (instead of the instrument) to be held in place relative to the patient, so that the valve could be ejected by withdrawing the end of the instrument.

Dkt. 163 at 24.

At the September 28 Hearing, Defendants did not articulate any substantive objection to Plaintiff's proposed interpretation. Rather, Defendants simply maintained that the additional language proposed by Plaintiff is superfluous.

To resolve any confusion in this regard, the Court hereby finds that "ejecting" does not exclude withdrawing an instrument while the valve remains stationary. Such a reading is supported by the specification. *See* '782 Patent at 7:65–8:1 and Fig. 4.

With that understanding, the Court hereby construes **"ejecting"** to mean **"causing to come out."**

13. "flexibly resilient"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"able to spring back to its original shape, on its own, after being compressed"	"able to regain an original shape after being compressed"

Dkt. 153 at 4; Dkt. 163 at 26; Dkt. 168 at 31. The parties submit that this term appears in Claims 1–5, 8, 10–13, 17, 21, and 28–30 of the '782 Patent and Claims 1, 8, 22, 28, 31, 36, 38, and 46 of the '297 Patent. Dkt. 174-1, Ex. 1 at 31.

a. The Parties' Positions

Plaintiff argues that Defendants' proposal, which would encompass frames that must be mechanically reopened, is inconsistent with disclosure "distinguish[ing] prior-art valves that must be mechanically reopened (and that require the heart to be stopped while the valve is being re-opened)." Dkt. 163 at 26 (citing '782 Patent at 2:6–10). Plaintiff submits that "[t]he patents-in-suit explain that the resiliency of the claimed valves means that they have a springiness that causes them to expand outward on their own." Dkt. 163 at 26 (citing '782 Patent at 4:65–5:2, 5:51–52 and 9:48–49).

Defendants respond that "[t]here is nothing in the specification, much less in the passages Plaintiff cites, that says a flexibly resilient frame *has* to 'spring back' to its original shape 'on its own.'" Dkt. 168 at 32. Defendants argue that their proposed construction "is consistent with the intrinsic record and aligns with the ordinary meaning for the term, and does so without introducing extraneous limitations." *Id.*

Plaintiff replies that "Dr. Snyders actually distinguished Anderson [on the ground] that it must be expanded mechanically by inflating a balloon," and "Dr. Snyders' distinguishing of Anderson confirms the plain meaning of 'resilient,' which refers to something that is *itself* able to bounce back to its original shape after being compressed." Dkt. 172 at 15.

b. Analysis

Claim 1 of the '782 Patent, for example, recites in relevant part (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a *flexibly resilient* frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors; . . .

The parties have not submitted any intrinsic evidence that defines or otherwise explains the meaning of "resilient" as used here.

Defendants have submitted dictionary definitions of "resilient" as meaning "[c]apable of returning to an original shape or position, as after having been compressed," or "[t]he property of a material that enables it to regain its original shape or position after being bent, stretched, or compressed." Dkt. 169-16, Ex. 50, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1535 (3d ed. 1992); Dkt. 169-17, Ex. 51, WEBSTER'S II NEW COLLEGE DICTIONARY

943 (1999). Neither of these definitions demands that something "resilient" must be able to regain its original shape "on its own."

Plaintiff has emphasized that the specification refers to enabling "'beating heart' procedures" ('782 Patent at 9:32-37), but Plaintiff has not identified any intrinsic evidence demonstrating that such procedures necessarily require that the frame must regain its original shape "on its own." Instead, this disclosure refers to "the relatively small size of the valves and instruments." *Id.*

In the specification, the patentee distinguished the "Andersen" reference:

> The Andersen device includes a heterologous pig valve mounted in an annular ring. Due to the size of this device, it must be implanted by direct abdominal aortic incision and entry. Further, *the Andersen device requires a separate inflating balloon for its deployment*.

'782 Patent at 2:6–10 (emphasis added). The specification also discloses that a valve can expand to fit a growing child:

> It is envisioned that the valves of the present invention may be suitable for implant in pediatric patients due to their small size and substantially unrestricted flow characteristics. Further, *because the valves adaptively expand, they are capable of expanding to fit the growing child*.

Id. at 9:45–49 (emphasis added).

On balance, however, Plaintiff has not demonstrated any disclaimer or lexicography or any other sufficiently persuasive support for Plaintiff's proposal of "on its own." *See, e.g., Thorner*, 669 F.3d at 1365. In particular, neither distinguishing the use of a balloon nor providing an ability of the frame to expand to fit a growing child necessarily precludes the use of any instrument or device for returning the frame to an original shape. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 908 (Fed. Cir. 2004) ("The fact that a patent asserts that an invention achieves

several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.").

Nonetheless, the parties' proposed constructions contain some common ground, in particular as to being able to return to an "original shape" "after being compressed." In light of this, "some construction of the disputed claim language will assist the jury to understand the claims." *TQP Dev., LLC v. Merrill Lynch & Co., Inc.*, No. 2:08-CV-471, 2012 WL 1940849, at *2 (E.D. Tex. May 29, 2012) (Bryson, J.).

The Court therefore hereby construes **"flexibly resilient"** to mean **"able to return to an original shape after being compressed."**

14. "junction of the elements / junction of the frame elements"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"a structure where the elements come together" / "a structure where the frame elements come together"	*Plain and ordinary meaning* Alternatively: "place where the frame elements are joined"

Dkt. 153 at 4; Dkt. 163 at 27. The parties submit that this term appears in Claims 8, 9, 13, 14, and 18 of the '782 Patent. Dkt. 174-1, Ex. 1 at 1.

"Snyders accepts SJM's proposed alternative construction." Dkt. 163 at 27; *see* Dkt. 172 at 15; *see also* Dkt. 174-1, Ex. 1 at 1.

The Court therefore hereby construes **"junction of the elements / junction of the frame elements"** to mean **"place where the frame elements are joined."**

15. "valve element having a . . . concave downstream side" and "valve element having a convex upstream side / valve element . . . having a convex upstream side"

"valve element having a . . . concave downstream side" ('782 Patent, Claims 10, 17, 18, 29; '297 Patent, Claim 22)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"valve element having a downstream side that bulges away from the downstream direction"	*Plain and ordinary meaning* Alternatively "the downstream side of the valve element is shaped like the inside surface of a bowl"
"valve element having a convex upstream side / valve element . . . having a convex upstream side" ('782 Patent, Claims 10, 17, 18, 29; '297 Patent, Claim 22)	
Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
"valve element having an upstream side that bulges out in the upstream direction"	*Plain and ordinary meaning* Alternatively "the upstream side of the valve element is shaped like the exterior surface of a bowl"

Dkt. 153 at 4; Dkt. 163 at 27; Dkt. 168 at 38; Dkt. 174-1, Ex. 1 at 5. Defendants submit that these terms appear in Claims 10, 17, 18, and 29 of the '782 Patent and Claim 22 of the '297 Patent. Dkt. 168 at 38 n.12.

a. The Parties' Positions

Plaintiff argues that "[t]he claims of the patents-in-suit use the words 'concave' and 'convex' to describe the claimed artificial valve in the same way those terms are used to describe the curvature of native heart valves, and in the same way that those terms are generally used." Dkt. 163 at 28. Plaintiff argues that Defendants' alternative proposed constructions should be rejected

because "not all concave and convex surfaces are shaped like the interior or exterior of a bowl." *Id.* at 29.

Defendants respond that "[t]here is no need to construe these terms" because "[t]he terms 'convex' and 'concave' are easily understood." Dkt. 168 at 38. Defendants also argue that "it is unclear how much complexity Plaintiff's construction would allow for," and Defendants submit that Plaintiff cites no intrinsic evidence to support "leaving room for 'more complicated surfaces.'" *Id.* at 39 (quoting Dkt. 163 at 29).

Plaintiff replies that "SJM does not dispute that native heart valves have convex upstream sides and concave downstream sides. . . . That is exactly what the claims require, not the opposite." Dkt. 172 at 15.

b. Analysis

On balance, the terms "concave" and "convex" are readily understandable in the context of the claims and need not be construed. *See* Dkt. 169-16, Ex. 50, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 390 (3d. ed. 1992) (defining "concave" as "[c]urved like the inner surface of a sphere"); *id.* at 412 (defining "convex" as "[h]aving a surface or boundary that curves or bulges outward, as the exterior of a sphere"); Dkt. 169-17, Ex. 51, WEBSTER'S II NEW COLLEGE DICTIONARY 232 (1999) (defining "concave" as "[c]urved like the inner surface of a ball"); *id.* at 247 (defining "convex" as "[h]aving a surface or boundary that curves or bulges outward, as the exterior of a sphere"); Dkt. 169-18, Ex. 52, TABER'S CYCLOPEDIC MEDICAL DICTIONARY 426 (18th ed. 1997) (defining "concave" as "[h]aving a spherically depressed or hollow surface"); *id.* at 439 (defining "convex" as "[c]urved evenly; resembling the segment of a sphere").

In other words, construction would not serve to clarify the scope of the claims, as demonstrated by the parties' proposals of phrases such as "bulges away" and "shaped like the inside surface of a bowl." Further, the parties have not identified any intrinsic evidence that provides any special meaning. In sum, no construction is appropriate or necessary as to these terms. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) ("The resolution of some line-drawing problems . . . is properly left to the trier of fact.") (citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact")); *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1318–19 (Fed. Cir. 2016) (citing *PPG*, 156 F.3d at 1355).[9]

The Court therefore hereby construes **"valve element having a . . . concave downstream side"** and **"valve element having a convex upstream side / valve element . . . having a convex upstream side"** to have their **plain meaning**.

16. Preambles

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
The preambles are limiting	The preambles are not limiting

Dkt. 153 at 4; Dkt. 163 at 29; Dkt. 174, Ex. 1 at 5. The parties submit that this dispute applies to "all claims." *Id.*

[9] At the September 28 Hearing, the parties presented arguments regarding whether native heart valves have surfaces that are "convex" or "concave," which Defendants argued was significant because the patentee purportedly distinguished the shape of the claimed invention from the shape of native heart valves. *See, e.g.*, Dkt. 169, Ex. 3 at B-20:23–28. For substantially the same reasons discussed as to Defendants' other disclaimer arguments in the present Claim Construction Memorandum Opinion and Order, Defendants have not persuasively demonstrated any disclaimer in this regard. As a result, no relevant significance has been demonstrated as to whether native heart valves can be characterized as having "concave" and "convex" surfaces.

a. The Parties' Positions

Plaintiff argues that the preambles are limiting because the bodies of the claims rely upon the preambles for antecedent basis and for "essential structure." Dkt. 163 at 30 (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)).

Defendants respond that "[a]t most, . . . the preambles are limiting only to the extent necessary to provide antecedent basis for ['upstream region' and 'downstream region']." Dkt. 168 at 42.

Plaintiff replies that "[e]verything included in the preambles is implicated by the antecedent basis and essential structure arguments made by Snyders, such that the Court should rule that the preambles as a whole are limiting." Dkt. 172 at 15.

b. Analysis

> In 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. *Pitney Bowes*[*, Inc. v. Hewlett-Packard Co.*], 182 F.3d [1298,] 1305 [(Fed. Cir. 1999)]. Conversely, a preamble is not limiting "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." *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Catalina Mktg., 289 F.3d at 808; *see, e.g.*, *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention."). Also, "the purpose or intended use of the invention . . . is of no significance to claim construction. . . ." *See Pitney Bowes*, 182 F.3d at 1305. This principle has sometimes been characterized as "the presumption against reading a statement of purpose in the preamble as a claim limitation." *Marrin v. Griffin*, 599 F.3d 1290, 1294-95 (Fed. Cir. 2010); *see Allen Eng'g*

Corp. v. Bartell Indus., 299 F.3d 1336, 1346 (Fed. Cir. 2002) ("Generally, the preamble does not limit the claims.").

Plaintiff appears to submit that Claim 1 of the '782 Patent is representative of the present dispute. Claim 1 of the '782 Patent recites (emphasis added):

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating *an upstream region* from *a downstream region*, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between *the upstream region* and *the downstream region*, the frame having a plurality of peripheral anchors for anchoring the frame in the position between *the upstream region* and *the downstream region* and a central portion located between the plurality of peripheral anchors;
>
> a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band, said valve element having an upstream side facing *said upstream region* when the frame is anchored in the position between *the upstream region* and *the downstream region* and a downstream side opposite the upstream side facing *said downstream region* when the frame is anchored in the position between *the upstream region* and *the downstream region*, said valve element moving in response to a difference between fluid pressure in *said upstream region* and fluid pressure in *said downstream region* between an open position in which the element permits downstream flow between *said upstream region* and *said downstream region* and a closed position in which the element blocks flow reversal from *said downstream region* to *said upstream region*, wherein the valve element moves to the open position when fluid pressure in *said upstream region* is greater than fluid pressure in *said downstream region* to permit downstream flow from *said upstream region* to *said downstream region* and the valve element moves to the closed position when fluid pressure in *said downstream region* is greater than fluid pressure in *said upstream region* to prevent flow reversal from *said downstream region* to *said upstream region*.

On one hand, recital of structure in a preamble does not necessarily mean that the preamble is limiting. *See, e.g.*, *Marrin*, 599 F.3d at 1294 ("the mere fact that a structural term in the preamble is part of the claim does not mean that the preamble's statement of purpose or other description is also part of the claim"). For example, "it is generally not appropriate to limit claim language to exclude particular devices because they do not serve a perceived purpose of the invention."

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1325 (Fed. Cir. 2008) (citation and internal quotation marks omitted).

Thus, at first blush, the recital of "[a]n artificial valve for repairing a damaged heart valve" might be read as a non-limiting statement of purpose. *See TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015) ("That the phrase in the preamble . . . provides a necessary structure for [the] claim . . . does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention."); *see also id.* at 1314 ("It was therefore error for the district court to use an antecedent basis rationale to justify converting this independent part of the preamble into a new claim limitation."); *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1236–37 (Fed. Cir. 2017) ("In the context of the entire patent, it is apparent that the term 'mounted on a vehicle for movement along the railroad track' is meant to describe the principal intended use of the invention but not to import a structural limitation or to exclude from the reach of the claims an assembly that does not include a vehicle mount.").

Here, however, the preamble language is necessary to understand the structures recited in the bodies of the claims. *Deere & Co. v. Bush Hog, LLC* is analogous:

> Unlike non-limiting preamble terms, "rotary cutter deck" does not merely state a name or a use for the claimed box section. Rather, the term describes a "fundamental characteristic of the claimed invention" that informs one of skill in the art as to the structure required by the claim. *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004). For example, that the claim is drawn to a "rotary cutter deck" informs the meaning of the "torsional stiffness" limitation—the claimed structure must possess sufficient stiffness to withstand the torsional loads imposed by the operation of a rotary cutter.

703 F.3d 1349, 1358 (Fed. Cir. 2012).

Here, the body of the claim refers to "the upstream region" and "the downstream region," which have their antecedent basis in the preamble's recital of "an upstream region" and "a downstream region." Importantly, these regions are recited in the preamble not in isolation but

rather with reference to "a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region." In turn, this phrase is intertwined with the recital of "[a]n artificial valve *for repairing* a damaged heart valve. . . ." Thus, because "the claim drafter cho[se] to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995).

The preamble of Claim 1 of the '782 Patent is therefore limiting in its entirety. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1373 (Fed. Cir. 2014) ("The phrase 'the image data' clearly derives antecedent basis from the 'image data' that is *defined in greater detail in the preamble* as being 'representative of at least one sequential set of images of a spray plume.'") (emphasis added).

Claims 10, 17, 18, and 30 of the '782 Patent, as well as Claims 1 and 22 of the '297 Patent, are similar to above-discussed Claim 1 of the '782 Patent for purposes of this dispute as to the preambles. Claims 28 and 29 of the '782 Patent and Claims 31 and 38 of the '297 Patent are also similar to above-discussed Claim 1 of the '782 Patent with respect to those preambles' recitals of "[a]n artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region."[10] Claims 17, 18, and 20 of the '297 Patent are also similar because the preambles of those claims refer to "an artificial valve as set forth in claim 1."

The Court accordingly hereby finds that **the preambles of Claims 1, 10, 17, 18, and 30 of the '782 Patent and the preambles of Claims 1 and 22 of the '297 Patent are limiting.**

[10] Plaintiff does not appear to have argued that any other portions of the preambles of these claims are limiting. *See* Dkt. 163 at 29–30. Although Plaintiff asserts in its reply brief that "the preambles as a whole are limiting," Plaintiff has not presented any specific arguments other than as to the above-discussed recitals of "a damaged heart valve having a plurality of cusps." For example, Plaintiff has not presented any argument as to the recitals of "an instrument for inserting the artificial valve between the upstream region and the downstream region" in Claims 28 and 29 of the '782 Patent.

The Court also hereby finds that **the preambles of Claims 28 and 29 of the '782 Patent and Claims 31 and 38 of the '297 Patent are limiting as to the recitals of "[a]n artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region."**

The Court further hereby finds that **the preambles of Claims 17, 18, and 20 of the '297 Patent are limiting as to the recitals of "an artificial valve as set forth in claim 1."**

IV. CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the patents-in-suit. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

It is SO ORDERED.

SIGNED this 27th day of October, 2017.

KIMBERLY C. PRIEST JOHNSON
UNITED STATES MAGISTRATE JUDGE