

United States District Court,
S.D. New York.

LABORATOIRES PEROUSE, S.A.S,
Plaintiff.

v.

W.L. GORE & ASSOCIATES, INC,
Defendant.

No. 06 Civ. 5276(RJH)

Dec. 10, 2007.

Background: Owner of patent for self-expanding stent and implantation tool brought patent infringement action against fluoropolymer manufacturer. Manufacturer filed counterclaim for declaratory judgment that patent was invalid under the patent laws, and that it had not infringed any claim of the patent. Patent owner moved to exclude newly proposed claim constructions.

Holdings: The District Court, Richard J. Holwell, J., held that:

- (1) owner was not prejudiced by manufacturer's proposed claim constructions in reply brief;
- (2) court could not construe phrase "for fitting a self-expanding stent" in preamble of patent;
- (3) use of term "tool" in preamble of patent was substantive limitation requiring construction; and
- (4) phrase "tool for fitting a self-expanding stent" meant an instrument.

Motion denied; claims construed.

6,019,787. Construed.

MEMORANDUM OPINION AND ORDER

RICHARD J. HOLWELL, District Judge.

BACKGROUND

I. Procedural History

This is an action for patent infringement brought by Plaintiff Laboratoires Perouse, S.A.S. ("Perouse") against Defendant Plaintiff W.L. Gore & Associates, Inc. ("Gore"). Perouse alleges that Gore has infringed U.S. Patent No. 6,019,787 ("the '787 patent") by making, using, selling, and/or offering for sale in the United States products including Gore's TAG(R) thoracic endoprosthesis devices and EXCLUDER(R) bifurcated endoprosthesis devices. (Compl.para.para. 9-10.) Gore has filed a counterclaim for a declaratory judgment

that (1) the '787 patent is invalid under the patent laws, and (2) that Gore has not infringed any claim of the '787 patent. (Answer para. 22-45.)

The parties identified claim language requiring construction, completed simultaneous briefing on claim construction, and submitted their opening and reply briefs to the Court on August 15, 2007. On September 21, 2007, Perouse filed a "Motion to Exclude Defendant/Counterclaim Plaintiff's Newly Proposed Claim Constructions" ("Motion to Exclude"), in which Perouse requested that this Court exclude and refuse to consider claim constructions allegedly presented for the first time in connection with Gore's reply brief on claim construction. (Perouse Mot. to Exclude Br. 1.) On October 23 and 29, 2007, the Court held Markman hearings at which the parties argued their proposed constructions of the disputed claim terms in the '787 patent.

II. The '787 Patent FN1

FN1. The '787 patent is reproduced in the Appendix to the Court's opinion.

The '787 patent is entitled "Fitting tool for use of an expansible endoprosthesis for a human or animal tubular organ." The specification of the '787 patent describes a self-expanding stent FN2 (also known as an "auto-expansible endoprosthesis") and a tool for implanting a self-expanding stent in a desired location within a blood vessel in the body. The claims of the '787 patent cover only the "tool" invention. Claim 1, the only independent claim in the '787 patent, recites "[a] tool for fitting a self-expanding stent." The tool of claim 1 includes three elements: (1) a "guide tube," which allows the tool to follow a guide wire through a blood vessel to an appropriate location in the body; (2) a "housing part," which is located at the distal end of the guide tube and houses the self-expanding stent prior to deployment at the treatment site; and (3) a "housing part opener," which "opens" the housing part once positioned, allowing the stent to expand radially and hold open the walls of the blood vessel.

FN2. A stent is a vascular implant that is used to hold open a blood vessel or other body lumen, used in the treatment of vascular aneurysms and dilations. A "self-expanding stent" can expand by itself from a compressed configuration to a fully expanded one.

The specification of the '787 patent describes two embodiments of the invention. The two embodiments differ only in the "means for opening the ... housing part" used by each. The first embodiment includes a set of wires attached to an actuation handle. When the handle is pulled, the wires cut the housing part (shown in the patent drawings as a cylindrical structure) and allow the self-expanding stent to expand. In the second embodiment, the housing part is slit longitudinally. The opposing edges of the slit are each lined with "gussets," which are drawn as small tubular structures oriented parallel to the slit. (*See* '787 patent Fig. 8.) A cord, connected at its proximal end to an actuation handle, is threaded through these gussets, holding the edges of the housing part together. When the handle is pulled, the cord is withdrawn from the gussets, allowing the stent to expand.

The '787 patent issued on February 1, 2000 from U.S. Patent Application No. 08/946,657 ("the '657 application"), a divisional application of U.S. Patent Application No. 08/146,137 ("the '137 application"), which included eight claims.FN3 During prosecution of the '137 application, the patent examiner determined that the claims were drawn to two separate inventions, "an expansible endoprosthesis" (claims 1-

5) and "a tool for fitting an expansible endoprosthesis" (claims 6-8), and issued a restriction requirement, which required the applicants to elect one of these inventions for further examination.FN4 (*See* Gallagher Opening Decl. Ex. B at 354-57.) The applicants elected the "endoprosthesis" claims and the examiner withdrew the "tool" claims from the application. (*See* Gallagher Opening Decl. Ex. B at 354-57.) The applicants refiled the "tool" claims on October 7, 1997 as the ' 657 application. (*See* Gallagher Opening Decl. Ex. B at 2-20.)

FN3. The '137 application was filed on April 21, 1994 and later issued as U.S. Patent No. 5,755,769, entitled "Expansible endoprosthesis for a human or animal tubular organ, and fitting tool for use thereof."

FN4. "The Patent Office can issue a restriction requirement if it finds that two or more inventions claimed in a patent application are 'independent and distinct.' 35 U.S.C. s. 121 (1994).... In response to a restriction requirement, an applicant must elect one invention for examination. *See* 37 C.F.R. s. 1.142(a) (1999). Claims to the non-elected invention(s) are withdrawn from consideration and must be canceled before the application is allowed to issue as a patent. *See* 37 C.F.R. s. 1.142(b) (1999)." *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1348 (Fed.Cir.2000); *see also* Manual of Patent Examining Procedure s. 802.02 ("Restriction is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.").

DISCUSSION

I. Perouse's Motion to Exclude

[1] In its Motion to Exclude, Perouse contends that the Court should refuse to consider several of the proposed claim constructions in Gore's reply brief because these constructions are either worded differently from the corresponding constructions proposed in Gore's opening brief or are constructions of claim terms that Gore did not construe at all in its opening brief.FN5 (Perouse Mot. to Exclude Br. 4-5.)

FN5. The alleged differences between the claim constructions proposed in Gore's opening brief and reply brief are based on a comparison between the claim constructions listed in the proposed order accompanying Gore's reply brief and those listed in bullet points in the "Conclusion" section of Gore's opening brief. (*See* Gore Opening Br. 39; Gore Reply Br. Attach. # 1.) When construing terms for which Gore has provided different constructions, the Court has assumed that the construction proposed in connection with Gore's reply brief is Gore's final and intended proposed construction.

Perouse complains that it is prejudiced by Gore's "newly proposed" constructions because Perouse has been denied the opportunity to respond. (Perouse Mot. to Exclude Br. 2, 10.) Furthermore, because Gore has proposed two different constructions for certain claim terms, Perouse alleges it was forced to "chas[e] a moving target" as it prepared for expert depositions and the Markman hearing. (Perouse Mot. to Exclude Br. 2.) Finally, Perouse alleges that Gore's conduct forced Perouse to waste time and money preparing its Motion to Exclude. (Perouse Mot. to Exclude Br. 2.) FN6 However, Perouse did not request leave to file a supplemental response to Gore's reply brief, nor did Perouse request postponement of the Markman hearing.

FN6. Perouse notes that it also wasted time and money due to Gore's failure, in its opening brief, to provide

constructions of numerous claim terms that Gore had previously maintained required construction. (Perouse Reply Br. 3-5; Perouse Mot. to Exclude Br. 3.) Perouse states that it agreed to construe numerous terms that it did not believe were in dispute because Gore insisted that these terms required construction, only to find, after receiving Gore's opening brief, that Gore had chosen not to construe many of these terms. (Perouse Reply Br. 3-5; Perouse Mot. to Exclude Br. 3.) Gore's conduct was prejudicial, Perouse claims, because Perouse incurred substantial attorneys' fees and wasted limited briefing space construing terms that were in fact not in dispute. (Perouse Mot. to Exclude Br. 3.)

The Court finds that, with respect to most of the constructions challenged by Perouse, there is no meaningful difference in scope between Gore's original and "newly proposed" constructions. With respect to these constructions, the Court believes Perouse has suffered no prejudice because it had a full opportunity to respond to the substance of each "newly proposed" construction, if not the precise language. In other cases, these new constructions conform to Perouse's proposed constructions, thereby eliminating unnecessary disputes. (Gore Opp. to Mot. to Exclude Br. 8, Ex. 1.) In a few cases, however, Gore's "newly proposed" constructions are in fact new, or include "clarifications" that assert arguments not made in Gore's opening brief and to which Perouse therefore did not have an opportunity to respond in writing. The Court has not relied upon any of Gore's constructions from this last category, and therefore need not consider whether Perouse has been prejudiced by Gore's late advancement of its constructions and arguments.

II. Claim Construction

A. Legal Standard

[2] [3] The claims of a patent define the limits of the patentee's statutory right to exclude. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005). The meaning and scope of the claim language is a question of law for the court's decision. *See Markman v. Westview Instruments*, 52 F.3d 967, 976-79 (Fed.Cir.1995).

[4] Because patents are addressed to practitioners in the field of the patented invention, a court should usually construe claim language consistent with its "ordinary and customary meaning" to a person of ordinary skill in the relevant art on the effective filing date of the patent application. FN7 *Phillips*, 415 F.3d at 1312-13. "Such a person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field." *Id.* at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)).

FN7. Perouse contends that the effective filing date for claims 1, 2, 4, 5, 7, 8, 10, and 11 is March 12, 1992, and that the relevant date for claims 3, 6, 9, and 12 is March 11, 1993. (Golds Decl. para. 16.) Gore disputes that the '787 patent is entitled to an effective filing date of March 12, 1992 (the filing date of the inventors' French patent application No. 92 02 971 (*See, e.g.,* Gallagher Decl. Ex. B at 1, 13-14, 189, 229-249)), but apparently does not dispute that the '787 patent is entitled to an effective filing date of March 11, 1993 (the filing date of international patent application PCT/FR93/00246 (*See, e.g.,* Gallagher Decl. Ex. B at 1, 13-14, 189, 210-222)). (Gore Opening Br. 4 n. 4, 13.) Because neither party argues otherwise, the Court assumes that the ordinary meaning of all disputed claim terms to a person of ordinary skill in the relevant art was the same on March 12, 1992 and March 11, 1993.

[5] [6] To determine the "ordinary and customary meaning" of a claim term, a court should first consult the

intrinsic evidence, which consists of the claims, the specification, and the prosecution history. *See, e.g.,* Primos, Inc. v. Hunter's Specialties, Inc. 451 F.3d 841, 847-48 (Fed.Cir.2006) ("In ascertaining the ordinary and customary meaning of a claim term, a court's primary focus should be on the intrinsic evidence of record, viz., the claims, the specification, and, if in evidence, the prosecution history."); Kinik Co. v. Int'l Trade Comm'n, 362 F.3d 1359, 1365 (Fed.Cir.2004) ("The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history."). Prior art cited to the examiner during prosecution is considered part of the prosecution history. *See* Phillips, 415 F.3d at 1317.

[7] "A fundamental rule of claim construction is that terms ... are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification" Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1370 (Fed.Cir.2003) (citations omitted). Therefore, the patent specification has been called the most important guide to claim construction. *See, e.g.,* Vitronics Corp. v. Conceptor, Inc., 90 F.3d 1576, 1582 ("[The specification] is always highly relevant to the claim construction analysis. Usually, it is dispositive."); Phillips, 415 F.3d at 1315-16 ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." (quoting Multiform Desiccants, 133 F.3d at 1478)).

[8] [9] The specification may show that a patentee has provided its own definitions for claim terms or has narrowed the scope of the claims through disclaimer. *See* Phillips, 415 F.3d at 1316. In such cases, the claim is construed according to the patentee's expressed intent even if the resulting construction departs from the ordinary meaning of the claim language. *See, e.g.,* id.; Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 493 F.3d 1358, 1361 (Fed.Cir.2007) ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term.") A patentee may redefine a term either explicitly or implicitly. *See, e.g.,* Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed.Cir.2003) ("The applicant may also act as his own lexicographer and use the specification to implicitly or explicitly supply new meanings for terms"); Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1268 (Fed.Cir.2001) ("[T]he specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.' ").

[10] [11] Though claims should be interpreted in light of the specification, it is not generally appropriate to import limitations from the specification into the claims. *See, e.g.,* N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1348 (Fed.Cir.2005) ("[U]nless required by the specification, limitations that do not otherwise appear in the claims should not be imported into the claims."); Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 412 F.3d 1284, 1289 (Fed.Cir.2005) ("We have repeatedly made clear that limitations cannot be imported from the specification into the claims."); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340 (Fed.Cir.2001) (describing the reading of a limitation from the written description into the claims as "one of the cardinal sins of patent law"). For example, the scope of a claim is usually not limited to the particular embodiment or embodiments described in the specification. *See, e.g.,* Resonate Inc. v. Alteon Websystems, Inc., 338 F.3d 1360, 1364-65 (Fed.Cir.2003) ("[A] particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.") In order to determine whether the limitations of an embodiment should be applied to a claim, a court must determine whether a person of skill in the art would consider the embodiments to be merely exemplary, or whether they are intended to define the scope of the claim. *See* Phillips, 415 F.3d at 1323; Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290 (Fed.Cir.2006) ("[I]mport[ing] limitations from the specification into the claims ... should be avoided unless the patentee clearly 'intends for the claims and the embodiments in the specification to be strictly coextensive.' " (quoting Phillips, 415 F.3d at 1323)).

[12] The prosecution history, also part of the intrinsic evidence, may "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. However, the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

[13] [14] [15] "Extrinsic evidence is that evidence which is external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles." Vitronics, 90 F.3d at 1584. While a district court may consult extrinsic evidence as part of the claim construction analysis, such evidence is considered less reliable than the intrinsic evidence. *See, e.g.,* Phillips, 415 F.3d at 1317-19 ("[T]he court should keep in mind the flaws inherent in each type of [extrinsic] evidence and assess that evidence accordingly.") While the testimony of expert witnesses may be useful in some cases, a court should disregard expert testimony that is merely conclusory or that is inconsistent with the intrinsic evidence. *See id.* at 1318.

[16] A court may use general purpose dictionaries as an aid to claim construction, so long as the dictionary definition relied upon does not contradict the definition indicated by the intrinsic evidence. *See id.* at 1322-23 (stating that courts "may ... rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents."). The Federal Circuit has specifically noted that dictionaries may be useful in the construction of ordinary, non-technical terms, which often involves "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314; *see also* Agfa Corp. v. Creo Prods. Inc., 451 F.3d 1366, 1376 (Fed.Cir.2006) (affirming district court construction of "stack" based on dictionary definition); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1306 (Fed.Cir.2006) (using dictionary definition in construction of claim term "geometry"). However, excessive reliance on dictionary definitions is improper because the "ordinary meaning" of a claim term is not the abstract dictionary definition, but the "meaning to the ordinary artisan after reading the entire patent." Phillips, 415 F.3d at 1321. The correct approach is to "focus at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down." *Id.*

[17] Despite the guidelines outlined above, "there is no magic formula or catechism for conducting claim construction," and a court is not "barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324. Instead "what matters is for the court to attach the appropriate weight ... to those sources in light of the statutes and policies that inform patent law." *Id.*

B. Construction of disputed claim language in the '787 patent

1. Claim 1

Claim 1 is the only independent claim in the '787 patent. All other claims in the patent are dependent claims, that is, they incorporate by reference all the elements of an earlier claim in the patent. *See* 35 U.S.C. s. 112 para. 4. Claim 1 reads as follows:

A tool for fitting a self-expanding stent comprising:

a guide tube having a distal end;

a housing part for housing a self-expanding stent, said housing part provided at said distal end of said guide tube; and

a housing part opener for opening said housing part independent of the selfexpanding stent.

a. "A tool for fitting a self-expanding stent"

The parties' first dispute concerns whether "A tool for fitting a self-expanding stent," is a substantive limitation on claim 1 that requires construction, and, if so, how it should be construed.

[18] The language at issue appears in the preamble to claim 1 of the '787 patent.FN8 "The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties," but may in some cases constitute a limitation. *See* 3-8 Chisum on Patents s. 8.06 (2007). No "litmus test" exists for determining whether a preamble acts as a substantive limitation on a claim. In *re* Paulsen, 30 F.3d 1475, 1479 (Fed.Cir.1994). Instead, "a claim preamble has the import that the claim as a whole suggests for it." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed.Cir.1995). As the Federal Circuit has explained,

FN8. A patent claim is typically drafted in three parts: the preamble, the transition; and the body. 3-8 Chisum on Patents s. 806[1] [b] (2007). In the '787 patent, as in many patents, the preamble consists of the language preceding the transition phrase "comprising." *See, e.g.*, *Bicon, Inc. v. The Straumann Co.*, 441 F.3d 945, 949 (Fed.Cir.2006).

If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999) (quoting *Kropa v. Robie*, 38 C.C.P.A. 858, 187 F.2d 150, 152 (Cust. & Pat.App.1951)) (internal citations omitted).

[19] [20] Therefore, preamble language does not limit the scope of a claim when it merely states a "purpose or intended use of the invention." In *re* Paulsen, 30 F.3d at 1479. However, "when the claim drafter chooses 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*, 55 F.3d at 620.

[21] Perouse argues that this entire phrase should be disregarded because it "is a claim preamble which merely states an intended use of the invention and does not limit the claim." (Perouse Opening Br. 16.) Gore concedes that "for fitting a self-expanding stent" is a non-limiting statement of intended use, but maintains that "tool" is a substantive limitation requiring construction. (Gore Reply Br. 3.) The Court agrees that "for fitting a self-expanding stent" describes an intended use of the claimed apparatus, and will not construe this portion of the preamble. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed.Cir.2002) ("[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.").

[22] With respect to "tool," however, the Court finds that this is a substantive limitation requiring construction. The body of claim 1 merely recites three elements. Standing alone, the body does not "fully ... set [] forth the complete invention" of the '787 patent because the invention is not a set of three unassembled constituents, but a tool that includes these three elements and that can be used to implant a self-expanding stent within the body. (*See* '787 patent col.2 ll.46-47 ("Another aspect of the invention is a tool for fitting an auto-expansible endoprosthesis").) *Pitney Bowes*, 182 F.3d at 1305. In the context of claim 1, "tool" is clearly necessary for "life, meaning, and vitality," and will be construed as a substantive limitation. *Id.*

[23] Gore argues that "tool" should be construed to mean "a single instrument having the three constituents recited in the body of the claim (a guide tube, a housing part, and a housing part opener), none of which may be a part of the object to be fitted." (Gore Proposed Order.) Perouse contends that, if the Court should find that the term "tool" requires construction, the proper construction is "instrument." (Perouse Opening Br. 17.)

With respect to Gore's proposed limitation, "having the three constituents recited in the body of the claim (a guide tube, a housing part, and a housing part opener)," Perouse argues that this construction is redundant, unnecessary, and confusing. (Perouse Reply Br. 10.) The Court agrees. The body of claim 1 already includes the "guide tube," "housing part," and "housing part opener" limitations. It would add nothing to the construction of the claim to read these limitations into the preamble word "tool" as well. Even if it were not redundant, Gore's proposed limitation would be rejected as improper claim construction. None of these three constituents are part of the ordinary meaning of "tool," and their inclusion would improperly import limitations from the specification into the claims. *See Phillips*, 415 F.3d at 1323-24.

Gore's proposed construction includes a further limitation-that "none of [the guide tube, housing part, and housing part opener] may be a part of the object to be fitted." In other words, Gore's proposed construction of "tool" requires that the "tool" and the "object to be fitted," i.e., the stent, are physically distinct, separate structures. (*See* Gore Opening Br. 21-25.)

Gore argues that the stated purpose of the tool, "for fitting a self-expanding stent," implies that the tool and the stent must be physically separate structures. (Gore Opening Br. 21.) Gore further notes that the drawings in the '787 patent depict the endoprosthesis and tool as separate objects, and that the specification describes an endoprosthesis that is "inserted" into the tool. (Gore Opening Br. 22.) However, while it is true that the specification and drawings describe a tool that is physically separate from the object to be fitted, it is improper claim construction to import limitations from the specification to the claims unless there is a clear disclaimer of claim scope. *See, e.g., Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed.Cir.2005) ("This court declines to import limitations to the claims from the specification absent a 'manifest' or 'explicit' exclusion."); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed.Cir.2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.' "). There is no disclaimer, clear or otherwise, of "tools" that incorporate the object to be fitted, and therefore no justification for this Court to deviate from the ordinary meaning of the term "tool."

Gore also argues that its proposed limitation is appropriate in light of the prosecution history of the '787 patent, in which a restriction requirement was issued against the '137 application (the parent application to

the '787 patent) and the applicants responded by electing to pursue the "tool" and "stent" claims in separate applications. Gore apparently contends that the restriction requirement and the applicant's election in compliance with this requirement somehow invoked a limitation of physical separateness between the tool and stent upon the patent claims that issued following this election. Gore has cited no case law, and the Court is aware of none, that suggests that a restriction requirement limits the construction of claims in a later filed divisional application in the manner suggested by Gore. (See Gore Opening Br. 24-25; Gore Reply Br. 6.) Most courts that have considered similar issues have noted that a restriction requirement is primarily an administrative tool. See, e.g., Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., 2000 WL 34204509, at (N.D.Cal. Feb.28, 2000) (noting that restrictions are made "[f]or the purpose of case management and to control filing and search fees"); Michaels of Or. Co. v. Clean Gun, LLC, 2002 WL 31496414, at (D.Or. July 9, 2002) (noting that restriction requirements "(1) facilitate [] administration in the PTO; and (2) allow[] the PTO to obtain additional filing and maintenance fee revenue that would be lost if an applicant were always permitted to obtain a patent covering any number of distinct inventions.") Therefore, courts have questioned whether it is appropriate to use a restriction requirement to substantively limit claims. See, e.g., Michaels of Or., 2002 WL 31496414, at *8 ("Restriction requirements do not constitute a substantive claim construction doctrine."); Amersham, 2000 WL 34204509, at *15-16 ("[T]he applicants' compliance with an administrative requirement (i.e., the restriction requirement) ... in the parent application, is entitled to little weight as against the applicants' claims as amended, and the Examiner's allowance of those claims, in the issued '648 patent."); but see R2 Med. Sys., Inc. v. Katecho, Inc., 931 F.Supp. 1397, 1437-40 (N.D.Ill.1996) (noting that "the court has not identified any precedent using prosecution history of the election of a species in order to restrict or otherwise interpret the scope of a patent claim" but proceeding to consider restriction requirement and applicant's response as part of the prosecution history to aid in discerning meaning of claim).

Even assuming that a restriction requirement may be considered as part of the claim construction analysis, this Court rejects Gore's argument. The examiner's restriction requirement simply requires an applicant to segregate its "tool" and "stent" claims into separate patent applications. 35 U.S.C. s. 121. While the '137 applicants' election in response to the restriction requirement might arguably be viewed as an admission that the elected "stent" invention is not an *element* of the non-elected "tool" invention, it did not impose an additional limitation on any claims so as to exclude products that include a "tool" and a "stent" in combination or physical contiguity.

[24] "Tool" is a common, familiar term, and neither party contends that it has any specialized meaning in the relevant art. Construction of ordinary, non-technical terms can involve "little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. There is no indication that the word "tool," in the context of the intrinsic evidence, includes the limitation of physical separateness proposed by Gore. The specification describes how the tool operates and the elements that it includes, not those that it excludes. Likewise, there is no indication that the "tool" and "stent" must be distinct, unconnected, or physically separate. Gore does not dispute that its proposed "none of which may be part of the object to be fitted" limitation is not part of the ordinary meaning of "tool." In fact, Gore's own expert stated that "most generally, a tool is a surgical instrument or implement for accomplishing a task." (Matsumura Decl. para. 26.)

Furthermore, because claim 1 includes the transitional word "comprising," there is a presumption that this claim is drafted in "open-ended" form, meaning that its scope includes the listed elements (i.e., a "guide tube," "housing part," and "housing part opener") but does not exclude additional elements. See, e.g., Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1327-28 (Fed.Cir.1999) ("The

transitional term 'comprising' ... is inclusive or open-ended and does not exclude additional, unrecited elements or method steps."); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed.Cir.2001) ("In the parlance of patent law, the transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements."). This presumption is overcome only by "evidence of a clear intent to limit the claims." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp., N.V.*, 365 F.3d 1299, 1305-06 (Fed.Cir.2004). Gore's proposed construction is inconsistent with this presumption, as it would define claim 1 (and all claims dependent therefrom) so as to specifically exclude a self-expanding stent element. Gore does not provide evidence of the "clear intent" necessary to overcome this presumption.

Perouse's proposed construction of "tool" to mean "instrument" reflects the meaning of this term as used in the '787 patent. This construction is also supported by dictionary definitions of "tool." For example, the dictionary definitions of "tool" provided by Gore include "an instrument ... used or worked by hand" and "something (as an instrument or apparatus) used in performing an operation." (Matsumura Opening Decl. Ex. E.) The invention described in the '787 patent is a physical instrument used to perform an operation-fitting an endoprosthesis within a vessel in the body. (*See, e.g.*, '787 patent Abstract, col.1 ll.46-47, col.3 ll.33-43.)

The Court construes "a tool for fitting a self-expanding stent" to mean "an instrument."

b. "a guide tube having a distal end"

i. "guide tube"

[25] It is not clear whether the parties dispute the construction of the term "guide tube." Perouse, in its opening brief, construed "guide tube" to mean "a hollow cylinder through which a guide can pass." (Perouse Opening Br. 23-24.) Gore did not construe "guide tube" in its opening brief but stated that the term "may not be in dispute." (Gore Opening Br. 26 n. 12.) In its reply brief, Gore alleged that the parties were in agreement that "guide tube" was to be construed as "a tubular structure with a central lumen." (Gore Reply Br. 27.) Similarly, Perouse asserted in its reply brief that Gore agreed with Perouse's proposed construction. (Perouse Reply Br. 13-14.) At the Markman hearing, Gore again stated that the parties did not dispute the construction of "guide tube." (*See* Oct. 23, 2007 Tr. 78:10-24.) Perouse, however, asserted that there was a disagreement concerning whether the claim language required a lumen positioned exactly in the center of the tube or whether it permitted a guide tube with an off-center lumen.

The Court finds that the lumen need not be positioned exactly in the geometric center of the guide tube. There is no indication in the specification that the precise positioning of the lumen is important, and neither expert contends that a person of ordinary skill would interpret "guide tube" to include this limitation. Gore did not brief this issue. At the Markman hearing, Gore's only argument in support of the limitation was that the specification and drawings consistently depict a tube with a lumen that is centered within the tube. This argument merely proposes importing a limitation from the specification into the claims, which is improper. *See* Phillips, 415 F.3d at 1323-24. The Court rejects this limitation.

The Court does not believe there is any other difference between the constructions proposed by the parties, and construes "guide tube" to mean "a hollow cylinder or tubular structure through which a guide can pass." This is the ordinary meaning of the term as understood by a person of ordinary skill in the art at the relevant time, and is supported by the intrinsic evidence. For example, the specification discloses that "the tool is threaded onto a guide, inserted through the skin, and conveyed endoluminally as far as the desired location."

(787 patent col.3 ll.32-35.) This construction is further confirmed by extrinsic evidence, including dictionary definitions and patents for similar devices. (Golds Opening Decl. para. 63-67.)

The Court construes "a guide tube" to mean "a hollow cylinder or tubular structure through which a guide can pass."

ii. "distal end"

[26] The parties provide identical constructions of "distal end," as it appears in the phrase, "guide tube having a distal end." Both parties construe this phrase as "the extremity of the guide tube away from the operator." (Perouse Opening Br. 22; Gore Proposed Order 2.) The Court agrees and adopts this construction.

Accordingly, the Court construes "a guide tube having a distal end" to mean "a hollow cylinder or tubular structure through which a guide can pass, having an extremity away from the operator."

c. "a housing part for housing a self-expanding stent, said housing part provided at said distal end of said guide tube"

i. "a housing part for housing a self-expanding stent"

[27] Perouse's proposed construction of "a housing part for housing a self-expanding stent" is "a piece that covers a self-expanding stent." (Perouse Opening Br. 20.) Gore's proposed construction is "a case or enclosure that is capable of temporarily holding a self-expanding stent in a compressed state until placement in the desired location, regardless of whether the housing part actually covers the entirety of the stent or is even capable of doing so." (Gore Proposed Order 2.)

With respect to the ordinary meaning of "housing," the Court does not detect any meaningful difference between the parties' proposed language. "A piece that covers" and "a case or enclosure" are both acceptable constructions that accurately reflect the meaning of "housing" as understood by a person of skill in the art in light of the intrinsic evidence. As explained in the specification, the "housing part" provides housing for the self-expanding stent during endoluminal delivery to the treatment site, until the housing part is "opened" and the stent expands. (*See* '787 patent col.3 ll.1-4, ll.33-43, col.3 l.57-col.4 l.4). The specification makes clear that the "housing part" fits around and covers the outside of the stent. For example, a stent is described as being "inserted" into the housing part of one embodiment. ('787 patent col.3 ll.1-4.)

Gore has not objected to Perouse's proposed language, "a piece that covers." In fact, Gore has indicated that it believes the parties are in agreement with respect to this aspect of the construction. (Gore Reply Br. 6.) Perouse's objection to Gore's definition is apparently that "case or enclosure" is too narrow. (Perouse Reply Br. 11.) "Enclosure" is arguably narrower in scope than "a piece that covers." For example, the dictionary definition of "housing" provided by Perouse's expert is "something that covers or protects, as a case or enclosure." (Gold Opening Decl. Ex. 5 at 585.)

There is no indication in the intrinsic evidence that "housing part" requires or excludes any particular type of housing or covering. Therefore, though the parties' constructions may not be substantively different, the Court will incorporate both parties' proposed language into its construction in order to ensure that it captures the full scope of the ordinary meaning of "housing." The Court construes "a housing part" to mean "an enclosure or covering." FN9

FN9. As discussed *infra*, the Court has used the word "covering" instead of "piece that covers" to avoid any implication that the piece only infringes when it is "actually" covering a self-expanding stent. *See infra* note 10.

The parties also dispute Gore's proposed limitation that the "housing part" must be "*capable of* temporarily holding a self-expanding stent until placement in the desired location" (emphasis added). Gore's proposed construction is rejected because the ordinary meaning of "housing" does not include the requirement that the "housing" must constrain the housed object from expansion. While the specification of the '787 patent describes a delivery device that constrains a self-expanding stent, this description does not demonstrate the patentee's intent to implicitly or explicitly redefine "housing," and therefore the ordinary meaning applies.

Finally, Gore has raised an issue regarding whether the "housing part" is required to "cover the entire stent or even [be] capable of doing so." (Gore Reply Br. 9.) Gore apparently interprets Perouse's proposed construction as requiring a housing part that "completely cover[s] the self-expanding stent." (Gore Reply Br. 7.) It is not at all clear, however, that Perouse even advances this "complete coverage" limitation, which is not apparent from Perouse's proposed claim language, "a piece that covers a self-expanding stent." Perouse did not argue for this limitation in its briefs, and addressed the issue only perfunctorily at the Markman hearing. (*See* Oct. 23, 2007 Tr. 70:12-18.)

Assuming this issue requires resolution, the Court finds that the "housing part" element does not require complete coverage of the self-expanding stent nor does it require that the "housing part" be capable of complete coverage. While the drawings of the '787 patent depict a housing part that completely covers a self-expanding stent, there is no indication that this is a significant or necessary detail. The Court finds that a person of ordinary skill in the art would not interpret the "housing part" element as necessarily capable of completely covering a self-expanding stent. Nothing in the intrinsic evidence indicates that partial coverage is excluded from the scope of this element or that the degree of coverage provided by the "housing part" is an important aspect of the invention.

ii. "for housing a self-expanding stent "

[28] The "housing part" of claim 1 is not a housing part for any object, but a housing part "*for housing a self-expanding stent.*" In the context of the '787 patent, this means a "housing part" that fits a self-expanding stent. A person of ordinary skill would understand that a "housing" is designed to house a particular object or structure. In the context of the '787 patent, the "housing part" element houses a self-expanding stent. That is, the housing part provides a covering, case, or enclosure for a self-expanding stent. Therefore the housing part must be of a size and shape that *fit* a self-expanding stent.FN10

FN10. Gore interprets Perouse's construction, "a piece that covers" as requiring a structure that "*actually covers* a self-expanding stent." (Gore Reply Br. 7 (emphasis added)) and asserts that this construction is improper because it "implicitly requires a stent to be part of the claimed tool" (Gore Reply Br. 9). Gore seems to be suggesting that Perouse's proposed construction would only cover "housing parts" while they are being used to cover stents. If this is Perouse's contention, this would be an improper functional limitation on a claim addressed to structure, because the scope of an apparatus claim does not depend upon whether it is actually used for its intended purpose or not. *See, e.g., Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed.Cir.2002) ("[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure."); *In re Gardiner*, 36

C.C.P.A. 748, 171 F.2d 313, 315-16 (Cust. & Pat.App.1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof."). However, it is not clear that Perouse makes this argument. To clear up any potential confusion, the Court emphasizes that its construction of "housing part" means that the housing part must "fit" a stent if and when the stent is inserted, not that the tool only infringes when the stent is *actually* fit inside the tool.

Accordingly, the Court construes "a housing part for housing a self-expanding stent" to mean "an enclosure or covering that fits a self-expanding stent."

iii. "said housing part provided at said distal end of said guide tube"

[29] The final dispute between the parties regarding the "housing part" element concerns the location of the housing part along the guide tube. The "housing part" of claim 1 is "provided at said distal end of said guide tube." ('787 patent col.4 ll.9-10.) Gore construes this phrase to mean "provided at or in contact with the tip end of a guide tube," while Perouse contends that it means "located at the extremity of a guide tube away from the operator." (Gore Proposed Order 2; Perouse Opening Br. 22.) The primary point of dispute between the parties is whether, as Gore asserts, the housing part must be *in contact with* the distal tip of the guide tube, FN11 or whether, as Perouse asserts, the housing part must simply be located in the area *near* the distal extremity of the guide tube. (*See* Gore Opening Br. 26-27; Gore Reply Br. 9-11; Perouse Opening Br. 22-23 & n. 16; Perouse Reply Br. 12-13.)

FN11. While the language of Gore's construction is ambiguous, Gore's reply brief makes clear that Gore contends that the "housing part" must be "in contact with" the distal tip of the guide tube. (Gore Reply Br. 9, 11 (characterizing proposed construction as requiring that "the housing part of the tool is provided at, *i.e.*, in contact with, the tip end of a guide tube") (emphasis added).)

Gore construes "distal end" to mean "distal tip." Gore's construction is not consistent with the ordinary meaning of "distal end" as informed by the intrinsic evidence. "End" is used ambiguously in the '787 specification. For example, "end" and "end parts" are used interchangeably in the specification (alternately describing the "flared" portions of the endoprostheses as "ends" and "end parts"), indicating that "end" is not used as a synonym for "tip." ('787 patent col.1 ll.40-42, col.3 ll.44-45.) However, "end" is arguably used to mean "tip" when describing the open "distal end" of the housing part or the "cord ... connected, at its proximal end, to the actuation handle." ('787 patent col.3 ll.5-7, col.3 l.67-col.4 l.2.) However, other intrinsic evidence indicates that "distal end" is not used as a synonym for "tip end." Specifically, patents cited during prosecution of the '787 patent use "end" or "distal end" to refer to the area near the extremity of a device. (*See* Golds Reply Decl. Ex. 16, col.8 ll.26-27; Ex. 17, col.4 ll.24-30.); *see also* V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1311 (Fed.Cir.2005) (stating that prior art references cited in patent or prosecution history are considered intrinsic evidence).

[30] Finally, extrinsic evidence also refutes Gore's proposed construction of "distal end" to mean "distal tip." U.S. Patent No. 4,950,228, a patent issued in 1990 that was not cited during prosecution but nevertheless sheds light on the meaning of the disputed language to a person of ordinary skill in the art at the relevant time, clearly distinguishes between the "distal end" and "distal tip" of a ureteral stent. (Golds Reply Decl. Ex. 18, col.3 l.41-col.4 l.15.) Because both the intrinsic and extrinsic evidence indicate that "distal end" was used by persons of skill in the relevant art to mean either the distal tip or the area near the

distal tip, the Court adopts Perouse's construction of this claim term.FN12

FN12. Gore's construction of "distal end" as it appears in this claim element is also inconsistent with Gore's construction of the same claim language in the previous element, "a guide tube having a distal end." "[S]aid distal end," in the "housing part" element of claim 1, refers to the same "distal end" that is recited in the "guide tube element." *See, e.g., Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1333 (Fed.Cir.2007) ("The use of the word 'said' in a claim refers to an earlier use of the term in the claim."). Yet Gore did not construe "distal end" in the "guide tube" element to mean "distal tip," but instead proposed "the extremity of the guide tube away from the operator of the tool." *See supra* Discussion B.1.b.2. A claim term in a patent should be construed consistently wherever it appears. *See, e.g., Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir.2001).

Accordingly, the Court construes the phrase "a housing part for housing a selfexpanding stent, said housing part provided at said distal end of said guide tube," to mean "an enclosure or covering that fits a self-expanding stent, regardless of whether the housing part actually covers the entirety of the stent or is even capable of doing so, said housing part located at the extremity of a guide tube away from the operator."

d. "a housing part opener for opening said housing part independent of the self-expanding stent"

i. Applicability of 35 U.S.C. s. 112 para. 6

[31] The parties first dispute whether "a housing part opener for opening said housing part independent of the self-expanding stent" should be construed as a "means-plus-function" element under 35 U.S.C. s. 112 para. 6.

[32] Under 35 U.S.C. s. 112 para. 6, "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. s. 112. Thus, this provision "operates to restrict claim limitations drafted in such functional language to those structures, materials, or acts disclosed in the specification (and their equivalents) that perform the claimed function." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed.Cir.1998). A claim limitation drafted in this manner is called a "means-plus-function" (or "step-plus-function") limitation. *See, e.g., Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed.Cir.2003). The question of whether s. 112 para. 6 applies is a question of law for the court. *Personalized Media*, 161 F.3d at 702.

[33] [34] To determine whether a limitation is drafted in "means-plus-function" format, the Court looks to the language of the claim. In particular, "the term 'means' is central to the analysis." *Id.* at 703. Claim language that includes the word "means" triggers a presumption that the claim is drafted according to s. 112 para. 6, as a "means-plus-function" claim. *Id.* Conversely, a claim limitation that does not use the word "means" triggers a presumption that s. 112 para. 6 does not apply, and that the claim should be construed in the ordinary fashion. *See, e.g., LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1372 (Fed.Cir.2006).

[35] [36] [37] It is possible to rebut the presumption triggered by the absence of the word "means" "by showing that the claim element recite[s] a function without reciting sufficient structure for performing that function." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed.Cir.2000). However, "sufficient structure" does not mean "specific structure." *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1359

(Fed.Cir.2004) "Instead ... it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their functions." Id. at 1359-60. As a result, "the presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." Id. at 1358. The Federal Circuit has "seldom held" that claim language not drafted using the word "means" is to be construed under s. 112 para. 6, as a means-plus-function claim. Id. at 1363 (identifying only one opinion in which s. 112 para. 6 was invoked without the word "means"); *but see* Mass. Inst. of Tech. v. Abacus Software, 462 F.3d 1344, 1353-55 (Fed.Cir.2006) (construing "colorant selection mechanism" as "means-plus-function" element).

Gore contends that the "housing part opener" element is drafted as a "means-plus-function" limitation and should be limited to the specific embodiments disclosed in the specification. (Gore Opening Br. 27-31; Gore Reply Br. 12-13.) Perouse contends that because this element does not include the word "means" and because "housing part opener" is "inherently structural" language, it is not a "means-plus-function" element and should be construed according to its ordinary meaning, "a device that opens the housing part." (Perouse Reply Br. 14-15.) Gore's expert concedes that "opener" does not have a specialized meaning in the relevant art and that the dictionary definition of "opener" is "one that opens." (Matsumura Decl. para. 41-43).

Applying the analysis outlined above, the Court first notes that this element was not drafted using the word "means." As a result, there is a presumption that the element is not drafted in "means-plus-function" format. *See, e.g.,* DePuy Spine Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1023 (Fed.Cir.2006). To determine whether this presumption is rebutted, the Court must determine whether the "housing part opener" element merely "recites a function without reciting sufficient structure for performing that function." *Watts*, 232 F.3d at 880.

Neither "housing part opener" nor "opener" appears in the '787 specification. Therefore, the specification does not help to determine whether "opener" constitutes structural language.FN13

FN13. Gore argues that the use of "means" in the specification indicates that "housing part opener" should be construed as a "means-plus-function" element. (Gore Opening Br. 28.) However, "means" must be used in the *claim* to trigger the presumption that s. 112 para. 6 applies. *See, e.g.,* 911EP v. Whelen Eng'g Co., 512 F.Supp.2d 713, 726-27 (E.D.Tex.2007) (not applying presumption though specification used the word "means").

In *Lighting World, Inc. v. Birchwood Lighting, Inc.*, the Federal Circuit reversed a district court finding that a claim element for a "connector assembly" was a "means-plus-function" element. 382 F.3d at 1359. In doing so, the court explicitly rejected the premise, relied upon by the district court, that the presumption arising from the absence of the word "means" was rebutted because the claim language "does not bring to mind a particular structure." Id. at 1360. Instead, "what is important is whether the term is one that is understood to describe structure, as opposed to a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term 'means for.'" Id. The "pertinent distinction" is whether or not the term at issue is "a generic structural term such as 'means,' 'element,' or 'device' ... [or] a coined term lacking a clear meaning such as 'widget' or 'ram-a-fram.'" Id. The court held that a term may be structural even if "the term may encompass a multitude of structures" and "may in the end include any structure that performs the [function]." Id. at 1361. It found that "connector" was a noun denoting structure based in part on dictionary definitions including "something that connects" and "one who or that which connects ... any of various devices for connecting one object to another." Id. at

The claim term at issue here, "housing part opener," is similar to "connector assembly," the term at issue in *Lighting World*. The relevant dictionary definition of "opener" is "one who or that which opens." *The Oxford English Dictionary* (2d Ed.), vol.10 p. 843. As noted above, the *Lighting World* court found that "connector assembly" was a structural term based in part on a dictionary definition of "connector" that used similarly functional terms.

[38] Expert testimony may be relevant to the determination of whether a claim element is drafted in "means-plus-function" format as long as the testimony is consistent with the intrinsic evidence. *Lighting World*, 382 F.3d at 1359. Perouse's expert states that the term "opener" indicates structure both in common parlance and to a person of skill in the art. (Golds Reply Decl. para. 6-7.) In support of this claim, she notes phrases like "can opener" and "bottle opener," and cites several pre-1992 patents in which "opener" was used "to indicate structures which opened something." (Golds Reply Decl. para. 6-7.) While these "openers" identified by Perouse's expert obviously are not suitable "housing part openers" for purposes of the '787 patent, these examples confirm that "opener" denotes structure and that the drafter of the patent intended "housing part opener" to refer by analogy to structures that open a housing part. Though "housing part opener," like "connector assembly," may not "bring to mind a particular structure," it is not a generic structural term like "mechanism," "means," "element," or "device." *See Lighting World*, 382 F.3d at 1360; *Mass. Inst. of Tech.*, 462 F.3d at 1354 ("The generic terms 'mechanism,' 'means,' 'element,' and 'device' typically do not connote sufficiently definite structure."). Instead, "housing part opener" would be understood by a person of skill in the art to be a structural term defined by its function, like "connector." "Housing part opener" is therefore structural for the purposes of the s. 112 para. 6 analysis. *See, e.g., Lighting World*, 382 F.3d at 1361 (finding "connector" to be a name for structure "defined in terms of the function it performs"); *see also Personalized Media*, 161 F.3d at 705 ("[T]he fact that a 'detector' is defined in terms of its function ... does not detract[] from the definiteness of structure. Even though the term 'detector' does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures known as 'detectors.' ").

Evidence from the prosecution history of the applicant's *intent* in drafting the "housing part opener" element also supports the Court's finding that this element should not be construed according to s. 112 para. 6. *See, e.g., Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed.Cir.1996) (finding s. 112 para. 6 not applicable in part because "nothing cited to us from the prosecution history or elsewhere suggests that the patentee intended to claim in that fashion"); *Markman*, 52 F.3d at 985 ("The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (*except as documented in the prosecution history*).") (emphasis added). The goal of the analysis used to determine whether s. 112 para. 6 applies appears to be ascertaining whether or not the drafter intended to take advantage of this provision. For example, the use of the word "means" is a significant factor in the analysis because it is considered a reliable indicator that a drafter intended to draft a "means-plus-function" limitation. *See, e.g., Masco Corp. v. U.S.*, 303 F.3d 1316, 1326 (Fed.Cir.2002) ("The use of the word 'means' to describe a claim limitation 'gives rise to "a presumption that the inventor used the term advisedly to invoke the statutory mandates for means-plus-function clauses." ' "); *Unidynamics Corp. v. Automatic Prods. Int'l, Ltd.*, 157 F.3d 1311 (Fed.Cir.1998) ("The use of the term 'means' generally (but not always) shows that the patent applicant has *chosen* the option of means-plus-function format") (emphasis added); *DESA IP, LLC v. EML Techs., LLC*, 211 Fed. Appx. 932, 936 (Fed.Cir.2007) ("[T]he claims use both means-plus-function language ... and structural language ..., which suggests that the patentee *intentionally* used 'means' language to invoke s. 112, para. 6.") (emphasis added).

The '657 application was filed with three claims, numbered 6 through 8. (Gallagher Decl. Ex. B at 5-11, 19, 139.) Claim 6 was the only independent claim. (Gallagher Decl. Ex. B at 10-11.) During prosecution of the '657 application, the examiner rejected claim 6 as "clearly anticipated" by U.S. Patent No. 4,447,222, issued to Santinoranont ("Santinoranont").FN14 In response to the rejection, the applicants canceled claims 6-8 and substituted claims 9-20, which are identical to claims 1-12 of the ' 787 patent. (Gallagher Decl. Ex. B at 150-53; ' 787 patent col. 4 ll.5-col.6 l.3.) Claim 9, the only independent claim among the new claims, was similar to claim 6.FN15 (Gallagher Decl. Ex. B at 150-53.) While the last element of claim 6 recited "means [] for opening the tulip-shaped part longitudinally," this language was replaced in claim 9 by "a housing part opener for opening said housing part independent of the self-expanding stent." (Gallagher Decl. Ex. B at 10, 150.) FN16

FN14. Santinoranont is a patent for a "tampon inserter" device. The Santinoranont device includes an outer tube with a closed forward end and a tampon that is releasably attached to the forward end of an inner insertion tube. (*See* Gallagher Decl. Ex. B at 106-11.) The forward end of the insertion tube (with the tampon attached) is inserted into the outer tube and the tampon is pushed into through the closed forward end of the outer tube, rupturing it and permitting the tampon to be inserted into the vagina. (*See* Gallagher Decl. Ex. B at 106-11.)

FN15. Claim 6 of the '657 application claimed:

[A] [t]ool for fitting an auto-expansible endoprosthesis, characterized in that it comprises:

- a guide tube [] provided at its distal end with a tulip-shaped part [] for housing the endoprosthesis [] in the contracted state; and

- means [] for opening the tulip-shaped part longitudinally.

(Gallagher Decl. Ex. B at 10.) Claim 9 of the '657 application claimed:

A tool for fitting a self-expanding stent comprising:

a guide tube having a distal end;

a housing part for housing a self-expanding stent, said housing part provided at said distal end of said guide tube; and

a housing part opener for opening said housing part independent of the self-expanding stent.

(Gallagher Decl. Ex. B at 150.)

FN16. To distinguish claim 9 from Santinoranont and overcome the examiner's rejection, the applicants argued:

The objects to be fitted by the present invention (e.g., a self expanding stent) have very little, if any, strength in the longitudinal direction. Therefore, these objects can not be pushed or otherwise used in order to open the housing part because, even if successful (which is doubtful), the objects would probably be damaged. Consequently, the tool of the present invention provides a housing part opener for opening the housing part *independent* of the objects housed therein.

The Santinoranont reference discloses a tampon inserter including an outer tube housing a tampon. The forward end of the outer tube ruptures when the tampon contained therein is pushed against the forward end. This reference does not disclose a housing part with a housing part opener for opening the housing part *independent* of the object to be fitted (i.e., a tampon).

As discussed above, a tool with a housing part opener for opening the housing part *independent* of the object to be fitted is critical in order to prevent damage to the object.

(Gallagher Decl. Ex. B at 153-54.)

The applicants' response to the rejection of claim 6 clearly indicates that the "housing part opener" element in claim 9 of the '657 application (which issued as claim 1 of the '787 patent) was not intended as a "means-plus-function" claim. The corresponding element in claim 6 ("means ... for opening the tulip-shaped part longitudinally") is clearly drafted as in "means-plus-function" format-it includes the word "means" without any additional structure capable of performing the "opening" function. *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed.Cir.2007) (noting that presumption arising from use of the word "means" can be rebutted if "the claim, in addition to the functional language, recites structure sufficient to perform the claimed function in its entirety" (quoting *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed.Cir.2003))). In drafting claim 9, the applicants did not simply add "independent of the self-expanding stent" to the existing language of claim 6. Instead, they replaced "means" in claim 6 with "housing part opener" in claim 9. (Gallagher Decl. Ex. B at 10, 150.) The "means for opening" language of claim 6 demonstrates that the applicants knew how to draft a "means-plus-function" element and could have done so if they had intended. But the applicants reworded the claim without "means" language, signaling their intent to avoid construction of the "housing part opener" element under s. 112 para. 6.

The Court concludes based on the intrinsic and extrinsic evidence that "housing part opener" was not drafted as a means-plus-function element, and construes this language according to its ordinary meaning, "a device that opens."

ii. "for opening said housing part independent of the self-expanding stent"

[39] [40] Gore addresses the "independent of the self-expanding stent" limitation by asserting that, during prosecution of their patent, the applicants disclaimed all "tools that move the housing part by the action of the stent." (Gore Reply Br. 14.) Gore's argument is based on the fact that, after the examiner rejected claim 6 of the '657 application as anticipated by Santinoranont, the applicants amended their claims to add the limitation "for opening said housing part independent of the self-expanding stent" to the "housing part opener" element of new independent claim 9. (Gore Opening Br. 14-16; Gallagher Decl. Ex. B 139-55.) The

applicants argued that this limitation rendered the amended claims patentable over the prior art, including Santinoranont:

As discussed above, a tool with a housing part opener for opening the housing part independent of the object to be fitted is critical in order to prevent damage to the object. The Santinoranont reference does not disclose a tool with such a feature. Therefore, it is respectfully submitted that the rejection raised by the Examiner is not applicable to new independent claim 9, and the claims that depend therefrom, with the additional limitation discussed above.

(Gallagher Decl. Ex. B. at 153.); *see also supra* note 14-16.

Gore is correct that the scope of a claim "may be limited by a disclaimer in the specification or prosecution history." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 997 (Fed.Cir.2006) (citing *Phillips*, 415 F.3d at 1316-17); *see also Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."); *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1326 (Fed.Cir.2003) (stating that disclaimer requires a "clear and unmistakable" disavowal during prosecution). However, the applicants did not disclaim housing parts that "spread out" or "unfold" by operation of the self-expanding stent, as Gore contends. (Gore Opening Br. 31-32; Gore Reply Br. 13-17.) As the amended claim language indicates, the applicants at most disclaimed all tools in which the housing part opener is not "independent of the object to be fitted."

Gore's argument is based on an incorrect construction of "open" to mean "spread out" or "unfold." FN17 Indeed, Gore clarified during the Markman hearing that its construction required that the self-expanding stent may not "push" the housing part apart when it expands. Instead, the housing part must expand "all by itself, automatically.... In other words, if the stent were constrained in some way ... the housing part would still open up." (Oct 23, 2007 Tr. at 88:22-96:25.) Under Gore's interpretation, the housing part is "opened" when it expands radially outward, as it must in order to release the self-expanding stent.

FN17. Though neither party construed "open" or "opener" in its claim construction briefs, it is apparent from the parties' arguments in support of their proposed constructions of the "housing part opener" element that Gore interprets "open" to mean "spread out" or "unfold" (Gore Reply Br. 13-17), while Perouse interprets this term to mean "create[] a separation" (Perouse Reply Br. 18-19).

[41] While "spreading out" is undoubtedly one of many permissible definitions of "opening" in common parlance, a person of ordinary skill would understand that a different meaning is used in the context of the '787 patent. The ordinary meaning of a claim term for purposes of claim construction is the meaning that is used by the applicant in the patent and prosecution history. *See Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed.Cir.2005) ("We cannot look at the ordinary meaning of the term ... in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history."); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1351 (Fed.Cir.2004), *rev'd on other grounds*, 546 U.S. 394, 126 S.Ct. 980, 163 L.Ed.2d 974 (2006) (proper definition is the "definition that one of ordinary skill in the art could ascertain from the intrinsic evidence in the record").

The specification makes clear that "opening" of the housing part does not refer to the outward expansion of the housing part. For example, the abstract of the '787 patent describes "[c]utting threads [that] cause the

housing to open longitudinally." ('787 patent Abstract.) The phrase "to open longitudinally" makes no sense if, as Gore maintains, "open" means "spread out" or "unfold," because these actions require motion that is directed radially outward, not longitudinally.

Furthermore, the '787 patent describes two embodiments, which differ only in the "means for opening" employed by each. In one embodiment, the housing part is "opened" using "wires for separating, such as by cutting, the ... housing part, into several petal-like parts, or sections." ('787 patent col.1 ll.54-57.) In another embodiment, "longitudinal opening" of the housing part occurs when a cord is withdrawn from the series of gussets through which it passes. ('787 patent col.1 ll.58-63, col.3 l.57-col.4 l.4.) In neither embodiment does "opening" refer to the expansion, "spreading out," or "unfolding" of the housing part. Instead, a person of ordinary skill in the art would understand that, in the context of the '787 patent, "opening" refers to the creation of an opening or separation in the housing part, a step which necessarily precedes and is distinct from the expansion of the housing part and stent.

Furthermore, the construction of "opening" relied upon by Gore to support its disclaimer argument is entirely inconsistent with its argument that the "cutting wires" and "interpenetrating gussets and longitudinal cord" are the structures that correspond to the "housing part opener" element that Gore contends is drafted as a means-plus-function element. In support of this argument, Gore argued that "cutting" and "longitudinal opening" (as performed by the cord and gussets) satisfy the "opening" function. Both "cutting" and "longitudinal opening" create an opening or separation in the housing part, but do not spread it out or unfold it.

Gore's proposed construction is also undermined by the fact that the '787 patent describes no mechanism by which the housing part might undergo radial expansion without the assistance of the self-expanding stent. For the tool of the '787 patent to operate according to Gore's proposed construction, something other than the self-expanding stent must provide the force that expands the housing part. Yet Gore does not dispute the fact that the '787 patent discloses no such mechanism, nor does Gore provide any explanation of its own. A person of ordinary skill in the art would be unlikely to interpret the patent so as to leave such an important aspect of the invention's operation mysterious and unexplained. This is especially true in this case, where an alternative explanation, that the self-expanding stent is the element that expands the housing part, is disclosed in the patent and is entirely consistent with the intrinsic evidence.

The prosecution history also confirms that "opening" does not mean "spreading out." The applicants argued that claim 9 in the '657 application was patentable over Santinoranont because the opener of claim 9 was *independent* of the object to be fitted, while the opener of Santinoranont *was* the object to be fitted, i.e., a tampon, which "opened" the device when it was pushed through the end of an outer tube, creating a separation or opening in the device. (*See* Gallagher Decl. Ex. B at 154.); *see also supra* notes 14, 16. The applicants noted that self-expanding stents had very little longitudinal strength and therefore could be damaged if "pushed or otherwise used in order to open the housing part." (Gallagher Decl. Ex. B at 106-111, 154.) It is clear that "opening," as used by the applicants in the prosecution history, does not refer to the radial expansion or "spreading out" of the stent and/or housing part because these actions do not implicate the *longitudinal* strength of the stent. Instead, the use of "opening" in the prosecution history is entirely consistent with the use of this term in the specification of the '787 patent. In the prosecution history, as in the specification, an "opener" is something that creates a separation or opening. As described in the prosecution history, the "opening" of the outer tube in Santinoranont does not involve "spreading out." In fact, the outer tube of the Santinoranont invention does not expand or "spread out" at all-it is "opened" when its forward end is ruptured, permitting the release of the object to be fitted.

Therefore, even if Gore is correct that the applicants expressly disclaimed any tool in which the self-expanding stent is used to open the housing part, Gore's proposed limitation is not consistent with this disclaimer.FN18 If the applicants disclaimed any claim scope during prosecution, such disclaimer was incorporated explicitly into the amended claim language, which requires an opener that is "independent of the self-expanding stent." (*See* Gallagher Decl. Ex. B at 154 ("[T]he tool of the present invention provides a housing part opener for opening the housing part independent of the objects housed therein.")) That is, the effect of any disclaimer on the resulting claim scope is coextensive with the effect of the "independent of the self-expanding stent" limitation that is now part of claim 1 of the '787 patent. Indeed, the applicants indicated that this limitation was added to claim 9 of the '657 application for the purpose of distinguishing the amended claims from Santinoranont. The applicants distinguished their claims by pointing out that the object to be fitted in the applicants' invention "can not be pushed or otherwise used in order to open the housing part," in contrast to the tampon of the Santinorant device, which "opens" the device when it is pushed through the outer tube, rupturing it. (*See* Gallagher Decl. Ex. B at 154.) Therefore, when the correct construction of "open" is applied, the language of the amended claim limits the scope of the element to "housing part openers" that do not use the self-expanding stent to create an opening or separation in the housing part.

FN18. Perouse correctly points out that "independent," as used in the claims and the prosecution history, is an adjective modifying the noun "opener" (Perouse Opening Br. 26; Perouse Reply Br. 14 n. 6), not an adverb modifying the verb "opening" ("independently" is the adverb form), as Gore maintains (Gore Reply Br. 13-14 & n. 11). However, neither interpretation supports Gore's position. Even if the limitation requires that the "opening" of the housing part must be performed independently, without using the self-expanding stent, the stent may still be involved in the housing part's *expansion*, because this is distinct from the "opening" of the housing part.

During the Markman hearing, Gore argued that Figures 6 and 8 of the '787 patent disclose a housing part that expands without the assistance of the self-expanding stent. These figures depict the stent and housing part of the tool in mid-expansion, after partial cutting of the housing part (in the case of the first embodiment) or partial withdrawal of the cord from the gussets (in the case of the second embodiment). Gore's argument is based on the fact that these figures show a gap between the stent and the housing part, indicating that the stent is not in contact with the housing part during expansion. (Oct. 23, 2007 Tr. 90:17-95:9.) The Court rejects Gore's argument. It would be obvious to a person of ordinary skill in the art that these figures were merely schematic in nature and were not intended to faithfully reflect every detail of the expansion process. Indeed, the patent explicitly states that Figure 8 is a "diagrammatic[]" representation of the second embodiment. ('787 patent col.3 ll.57-58.) Furthermore, as discussed above, Gore's interpretation of these figures is inconsistent with the interpretation that emerges from the remainder of the specification and prosecution history. In light of the intrinsic evidence, it is far more likely that the separation between the stent and the housing part shown in these figures is not significant-it simply contributes to a cleaner diagram in which the reader can easily distinguish the elements.

However, even if Figures 6 and 8 were interpreted as literal representations of the operation of the invention, they would not support Gore's argument, which is based on an incorrect and unsupported construction of "opener." The drawings do not purport to represent "opening." In fact, the patent refers to Figure 6 as illustrating "release" or "expan[sion]." ('787 patent col.3 ll.39-40.) Even if the drawings did show release or expansion of the housing part occurring independently of the self-expanding stent (and they

do not), this would be irrelevant to this discussion. No such limitation was made part of claim 1 and limitations found only in patent drawings do not alter the scope of otherwise unambiguous claim language.

Regardless what the drawings show, the claim term "housing part opener" is used consistently throughout the intrinsic evidence to refer to something that creates a separation or opening in the housing part, not something that spreads out, unfolds, or expands the housing part. The Court therefore rejects Gore's argument that the applicants' characterization of their invention as "a tool with a housing part opener for opening the housing part independent of the object to be fitted" disclaimed all tools in which the stent is used to spread out, unfold, or expand the housing part.

The Court therefore construes "independent of the self-expanding stent" to exclude from the scope of the "housing part opener" element any housing part opener that uses the self-expanding stent to create an opening or separation in the housing part.

Accordingly, the Court construes the phrase, "a housing part opener for opening said housing part independent of the self-expanding stent," to mean "a device that creates an opening or separation in the housing part, the device not using the self-expanding stent to create an opening or separation in the housing part."

2. Claim 2

Claim 2 reads as follows:

"The tool of claim 1, wherein said housing part opener includes an actuation handle and wires for cutting said housing part into several sections, said wires being connected to said actuation handle."

a. "wires for cutting said housing part into several sections"

i. "wires"

[42] The parties first dispute whether the claim term "wires" should be limited to structures made of metal. Gore argues that the ordinary meaning of "wires" requires a metallic structure and cites dictionary definitions that support this interpretation. (Gore Opening Br. 33; Matsumura Decl. para. 51-55.) Perouse argues that "wires" are not limited to metal structures because the term "wires," as used in the relevant art, refers to both plastic and metal structures. (Perouse Opening Br. 22.)

The intrinsic evidence does not resolve this dispute. As Gore correctly notes, the specification is silent regarding the material or materials used to make the "wires." (Gore Opening Br. 33.) Because the intrinsic evidence gives no indication that the material of the wires is significant, this would seem to support Perouse's broader construction. However, because the intrinsic evidence is somewhat ambiguous, it is appropriate to consult extrinsic evidence. *See* *Pickholtz v. Rainbow Techs., Inc.*, 284 F.3d 1365, 1373 (Fed.Cir.2002) ("Only if a disputed claim term remains ambiguous after analysis of the intrinsic evidence should the court rely on extrinsic evidence."); *see also* *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed.Cir.1999) ("[I]t is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.")

The dictionary definitions cited by Gore support its contention that "wires" are metal structures. However, Perouse's expert suggests that "wires" has a particular meaning to persons of skill in the art that may differ from its dictionary definition. *See* Phillips, 415 F.3d at 1322 (" [A] general usage dictionary cannot overcome art-specific evidence of the meaning' of a claim term.... Even technical dictionaries ... may suffer from some of these deficiencies." (quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1321 (Fed.Cir.2004))). The Court is persuaded by the extrinsic evidence cited by Perouse's expert that a person of skill in the art would not interpret "wires" as being limited to structures made from metal. In particular, Perouse's expert cites a number of patents from the 1980s and 1990s relating to implantable medical devices in which "wires" is used to include both metal and plastic structures. (Golds Decl. para. 14, Ex. 25, 26, 27, 28.) While the Federal Circuit has cautioned that expert testimony may be unreliable because it is prepared for the purpose of litigation, the Court believes this concern is minimized here where the expert testimony is supported by the patent literature. *See* Phillips, 415 F.3d at 1318 ("[E]xtrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias....").

Therefore, the Court's construction of "wires" is not limited to structures made of metal.

The Court also adopts Perouse's proposed construction of "wires" to mean "threads." Gore's proposed construction of "structures" is obviously too broad and inconsistent with any reasonable definition of "wires." The specification appears to use the terms "wires" and "threads" interchangeably. The abstract of the '787 patent states that "cutting threads cause the housing to open longitudinally into several petal-like parts" ('787 patent Abstract), while in the body of the patent, these "cutting" elements are referred to as "wires." ('787 patent Abstract, col.1 ll.54-55, col.3 ll.19-39). This construction is also consistent with dictionary definitions cited by Gore, several of which refer to a wire as a "slender, flexible structure" or "thread." (Matsumura Decl. para. 54.)

The Court construes "wires" to mean "threads."

ii. "for cutting said housing part"

[43] "Cutting" is a common, nontechnical term used in the '787 patent consistent with its ordinary meaning, "to penetrate with an edged instrument which severs the continuity of the substance." *The Oxford English Dictionary*, v.4 at 172. The specification uses "cutting" to refer to the creation of separations in the housing part by the wires of the first embodiment. ('787 patent col.1 ll.54-57, col.3 ll.5-43.) The operator induces tension in the wires by pulling on the actuation handle and these wires then cut the housing part into sections. ('787 patent col.1 ll.54-57, col.3 ll.5-43.) There is nothing in the intrinsic evidence to warrant departure from the ordinary meaning of this term.

[44] Gore construes "cutting" to mean "severing." FN19 (Gore Reply Br. 19-20.) Because "severing" ordinarily requires the complete separation of a part from the whole, Gore's construction is too narrow. "Cutting" does not require complete severance, nor does the intrinsic evidence describe a housing part from which a portion has been severed. Gore's construction would therefore exclude the "wires" embodiment described in the '787 patent, because the wires of this embodiment do not necessarily "sever" the housing part from the tool. A construction that does not include preferred embodiments within its scope is "rarely, if ever, correct." *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996).

FN19. While the language of Gore's proposed construction (as worded in Gore's proposed order) was

"cutting or severing," Gore's reply brief clarifies that the intended construction is "cutting, i.e., severing." (Gore Proposed Order 2; Gore Reply Br. 20.)

Perouse construes "cutting" to mean "dividing." This construction is too broad because there are ways to "divide" a housing part that do not involve "cutting." For example, removal of the cord in the '787 patent's "gussets" embodiment divides but does not cut the housing part.

Therefore, the Court cannot accept either party's proposed construction and instead adopts its own construction that is more consistent with the ordinary meaning of the word. The Court construes "wires for cutting said housing part" to mean "threads that can penetrate and completely or partially divide said housing part."

iii. "into several sections"

[45] Finally, the parties dispute the construction of the claim term "several." Perouse contends that "several" means "more than one," while Gore proposes "more than two." The Court believes that "several" is typically used to mean "more than two," but will review the evidence to determine whether a different construction is appropriate.

The specification and drawings depict a housing part that is cut into three sections, which is consistent with either proposed definition. Because the intrinsic evidence is ambiguous, the Court will consider extrinsic evidence. Perouse's expert states that "several" does not have a particular meaning in the art, but contends that the ordinary meaning is "more than one." (Golds Decl. para. 88.) The dictionary on which Perouse's expert relies is ambiguous, however, as it includes definitions for "several" as both "more than one" and "more than two but fewer than many." (Golds Decl. para. 88, Ex. 5 at 1078.) Gore's expert assumes without discussion that "several" is defined as "more than two." (Matsumura Decl. para. para. 51-52, 55.) In its reply brief, Gore notes an additional dictionary definition that defines "several" as "[a]s a vague numeral: Of an indefinite (but not large) number exceeding two or three; more than two or three but not very many." (Gore Reply Br. 20 n. 14.) The parties cite no additional extrinsic evidence in support of their constructions.

While each construction finds some support from dictionary definitions, there is slightly more support for Gore's proposed construction of "more than two." The Court also believes "more than two" is more consistent with the use of "several" in common parlance. The Court therefore construes "several" to mean "more than two."

[46] Accordingly, the Court construes the phrase, "wires for cutting said housing part into several sections," to mean "threads that can penetrate and divide said housing part into more than two sections." FN20

FN20. Perouse provided a construction for "sections" in its opening brief. (Perouse Opening Br. 28-29.) However, Gore did not construe this term in its briefing or address its construction during the Markman hearing. Therefore, the Court presumes this claim term is not in dispute and does not require construction.

3. Claim 3

Claim 3 reads as follows:

The tool of claim 1, wherein said housing part includes a longitudinal slit forming edges in said housing part, said housing part having a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together; and

Said housing part opener including an actuation handle and a cord, said cord passing through said gussets along each of said edges such that said cord holds said edges together, said cord being connected to said actuation handle.

a. "a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together"

i. "a series of"

It does not appear that the parties dispute the construction of the claim phrase, "a series of." Perouse construed "series" in its opening brief to mean that the "gussets" "come one after another in spatial succession." (Perouse Opening Br. 29.) However, Gore did not construe this term either in its briefs or during the Markman hearing. Therefore, the Court will assume that this term is not in dispute. If the term should require construction, the Court adopts Perouse's proposed construction.

ii. "gussets"

[47] The parties dispute the construction of "gussets." Perouse's proposed construction is "housing part portions through which something passes." Gore's proposed construction is "several sequential, cylindrical structures that protrude from opposing edges of the housing part."

The parties agree that the ordinary meaning of "gussets" is not applicable in the context of this invention.FN21 Therefore, "gussets" is a term coined for use in the ' 787 patent and has no ordinary meaning to a person of skill in the art. In this circumstance, the construction is determined by the disclosure in the specification. *MyMail, Ltd. v. Am. Online, Inc.*, 476 F.3d 1372, 1376 (Fed.Cir.2007) ("Both parties agree that the term NSP is a coined term, without a meaning apart from the patent.... We therefore look to the specification to determine what the NSP must do...."); *J.T. Eaton & Co., Inc. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1570 (Fed.Cir.1997) ("In this case, the dispositive claim limitation is a term unknown to those of ordinary skill in the art at the time the patent application was filed. It thus fell to the applicants, as a duty, to provide a precise definition...."); *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 991 (Fed.Cir.2007) ("Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning."); *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed.Cir.2004) (" '[I]f a disputed term has "no previous meaning to those of ordinary skill in the prior art"[,] its meaning, then, must be found [elsewhere] in the patent.' ... absent such an accepted meaning, we construe a claim term only as broadly as provided for by the patent itself. The duty thus falls on the patent applicant to provide a precise definition for the disputed term.").

FN21. Gore's expert cites the following dictionary definitions for "gusset": "1: A usu. diamond-shaped or triangular insert in a seam (as of a sleeve, pocketbook, or shoe upper) to provide expansion or reinforcement 2: A plate or bracket for strengthening an angle in framework (as in a building or bridge)." (Matsumura Decl. Ex. E at 543.)

The intrinsic evidence provides very little guidance regarding the structure of the gussets. The second

embodiment is described as having "a series of projecting, cylindrical gussets" that "interpenetrate" when the housing part is in its closed state. ('787 patent col.3 ll.62-66.) In this embodiment, a "cord ... passes through all the gussets, holding the housing part together". ('787 patent col.3 l.67-col.4 l.1.) Figure 8, which represents this embodiment "diagrammatically," depicts the "gussets" as cylindrical structures lining the edges of the slitted housing part. ('787 patent Fig. 8.)

Gore asserts that its construction is supported by the reference in the specification to the second embodiment's "projecting, cylindrical gussets" and by Figure 8. ('787 patent col.3 ll.62-63, Fig. 8.) In fact, the patentee's choice of language refutes Gore's construction. If "gussets" were inherently projecting (or "protrud[ing]"), cylindrical structures, it would be unnecessary to specify that the gussets of the second embodiment had these qualities. *See, e.g.,* *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 807 (Fed.Cir.2007) (stating that where specification describes "a plurality of transverse holes, each of which is ... perpendicular to the ... nail axis [t]his implies that a 'transverse' hole need not be 'perpendicular.' "); *Phillips*, 415 F.3d at 1314 ("The claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel."). Also, the depiction of the gussets in Figure 8 is a representation of the second embodiment. Therefore, the specific features of this representation are not to be imported as a limitation on the claims. *See Phillips*, 415 F.3d at 1323.

In fact, the only limitation imposed by the specification is that the gussets must have a structure such that a cord can be passed through them. Given this lack of detail regarding this term, it would be clear to a person of ordinary skill that "gussets" is used to refer to any structure through which a cord can pass.

Therefore, the Court construes "a series of gussets" to mean "a series of structures through which a cord can pass."

iii. "said gussets along each of said edges being fitted together"

[48] The parties also dispute the construction of the claim term "fitted together." Perouse's proposed construction is "positioned in one place or group." Gore's proposed construction is "interlock[ing] and contact[ing] each other."

In common parlance, two items that are "fitted together" have structures that conform to or complement one another, as evidenced by the relevant dictionary definition of "fit," "[t]o fashion, modify, or arrange so as to conform or correspond to something else," *The Oxford English Dictionary* (2d Ed.), vol.5 p. 975, and the relevant dictionary definition of "together" (used following a transitive verb), "each other." *The Oxford English Dictionary* (2d Ed.), vol.18 p. 190. The '787 specification does not explicitly define the phrase "fitted together." However, it is clear that "fitted together" is being used in the patent according to its ordinary meaning. The gussets are described as "being fitted into each other" ('787 patent col.1 ll.60-61) and "interpenetrat [ing]" ('787 patent col.3 l.66), and Figure 8 depicts a zipper-like arrangement of gussets, in which each gusset fits into the space between gussets on the opposing edge.

Perouse's construction of "fitted together" as "positioned in one place or group" is therefore too broad and inconsistent with the ordinary meaning and intrinsic evidence. "Gussets" that are merely "positioned in one place or group" are not "fitted together," as this term is used in the '787 patent.

The Court cannot accept Gore's proposed construction either. Gore construes "fitted together" to mean "interlock[ing] and contact[ing] each other." This construction is too narrow and improperly imports

limitations from the specification into the claim. *See, e.g.*, Phillips, 415 F.3d at 1323. Gore's "interlocking" limitation is easily dismissed, as there is no suggestion in the patent that opposing gussets lock together in any sense. While Figure 8 does depict gussets that contact each other, a drawing of a single embodiment does not limit the ordinary meaning of "fitted together," which does not require contact. *See, e.g.*, *id.*; *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1342-43 (Fed.Cir.2001) ("Such a construction would improperly add a limitation appearing in the specification and the drawings, but not appearing in the unambiguous language of the claim.").

Accordingly, the Court construes the phrase, "said gussets along each of said edges being fitted together," to mean "said gussets along each of said edges having an arrangement that conforms to the arrangement of gussets on the opposite edge, such as an arrangement in which the gussets on one edge can occupy the spaces between the gussets on the opposing edge."

a. "said cord passing through each of said gussets along each of said edges such that said cord holds said edges together"

[49] It is not clear whether any part of this claim language is in dispute. Perouse provided constructions of "cord," "holds," and "edges" in its opening brief. (Perouse Opening Br. 32-33.) Gore did not address this claim language in either its opening or reply brief. However, in the proposed order accompanying its reply brief, Gore construed this phrase to mean "a single cord extends through a conduit formed by all of the 'gussets' and holds the opposing edges of the housing part in contact with one another." (Gore Proposed Order 3.). Neither party addressed this claim language during the Markman hearing.

There appears to be no dispute regarding the claim terms "cord" and "edges." Therefore, the Court will not construe these terms.

Gore apparently construes "passing through each of said gussets" to require that "all of the 'gussets' " form a "conduit." The ordinary meaning of "passing through" does not require that "all of the 'gussets' " form a conduit. While Figure 8 depicts gussets that are arranged so as to form a single conduit, this limitation from the specification will not be imported into the claims. *See Phillips*, 415 F.3d at 1323. Because Perouse does not object to Gore's construction of "passing through" to mean "extending," the Court will adopt this portion of Gore's proposed construction.

Finally, Gore's proposed construction apparently construes "holds said edges together" to require that the opposing edges of the housing part contact one another. Figure 8 depicts the two edges of the housing part in contact with one another. Again, however, this is a limitation from the specification that should not be imported into the claim. *See Phillips*, 415 F.3d at 1323. Furthermore, this limitation is not consistent with the ordinary meaning of the non-technical term, "holds together," and is rejected. "Holds said edges together," in ordinary usage, means "holds said edges near or in contact with one another." *See, e.g., The Oxford English Dictionary* (2d Ed.), vol.18 p. 189 ("Of two persons or things: Into companionship, union, proximity, contact, or collision"). Nothing in the intrinsic evidence warrants departure from this ordinary meaning.

The Court construes the phrase "said cord passing through each of said gussets along each of said edges such that said cord holds said edges together" to mean "said cord extending through each of said gussets along each of said edges such that said cord holds said edges near or in contact with one another."

4. Claim 4

Claim 4 reads as follows:

The tool of claim 1, wherein said housing part comprises a tulip-shaped housing part.

a. "tulip-shaped housing part"

[50] The parties dispute the construction of "tulip-shaped housing part." Gore's proposed construction is "a tulip (bell-shaped) structure with a closed hub end and an open tip end, and having a diameter substantially larger than the guide tube." (Gore Reply Br. 25-27; Gore Proposed Order 3.) Perouse's proposed construction is "[a] housing part [that] in its closed state is a cylinder having a diameter larger than the guide tube, and in its opened state has at least one linear separation." (Perouse Opening Br. 33-34.)

There is no indication that "tulip-shaped" has a "technical or specialized meaning" in the relevant art. (Gore Opening Br. 35.) Though "tulip" is a common word with a well defined meaning, "tulip-shaped" is too vague to have any clear ordinary meaning to one of skill in the art. Without context, it is unclear whether this language refers to an open or closed tulip, and it is unclear which specific aspects of the tulip shape the housing part must possess.

The Court looks to the specification to determine how a person of ordinary skill would interpret this term. *See, e.g., Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 991 (Fed.Cir.2007) ("Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning.") Even if "tulip-shaped" were deemed to have an ordinary meaning to one of skill in the art, claim terms are construed "in the context of the entire patent, including the specification" and "a patent applicant may use the words in the specification, prosecution history, or both 'in a manner inconsistent with [their] ordinary meaning.'" *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed.Cir.2005). Therefore, the Court must also examine the patent specification "to determine whether the patentee has given the term an unconventional meaning." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 955 (Fed.Cir.2000).

The Court finds that the patentee has implicitly provided its own definition of "tulip-shaped" in the '787 patent. The specification repeatedly refers to element number 4 in the drawings as "tulip-shaped" (*see, e.g., '787 patent col. 3 ll. 1-42, 61-67*), and explicitly states that the "housing part" is "shown in the drawings as shaped like a tulip." ('787 patent col.1 l.50, col.3 ll.5-6). The patentee thus defines "tulip-shaped" to mean the shape of the closed housing part in the drawings.FN22

FN22. The patentee makes clear that "tulip-shaped" refers to the shape of the *closed* housing part by stating that the stent is inserted into the "tulip-shaped" end of the tool. ('787 patent col.3 ll.1-4.)

Gore's "bell-shaped" and "closed hub end" limitations are easily dismissed because the drawings show a housing part that is not bell-shaped, but cylindrical (*see '787 patent Figs. 3, 4*), and with a proximal ("hub") end that is not closed, but open and continuous with the guide tube (*see '787 patent Fig. 4*).FN23 Even if Gore's proposed construction reflected the "ordinary meaning" of "tulip-shaped," the construction is inconsistent with the patentee's use of the term and must be rejected. *See Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364 (Fed.Cir.2003) ("After identifying the ordinary meaning of a disputed claim term, we turn to the patent's written description and drawings to determine whether that

meaning is inconsistent with the patentee's use of the term.").

FN23. Because Gore's proposed construction is inconsistent with the drawings, it would also exclude both of the embodiments represented by these drawings. A construction that does not include preferred embodiments within its scope is "rarely, if ever, correct." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed.Cir.1996).

The parties originally agreed that a "tulip-shaped housing part" has a diameter larger than that of the guide tube. (Perouse Opening Br. 33-34; Gore Opening Br. 35-36.) However, in its reply brief, Gore offered a different construction that required a housing part "having a diameter *substantially larger* than [that of] the guide tube." (Gore Opening Br. 35-36.) Gore offers no support for this new limitation and the Court finds that it is not consistent with the intrinsic evidence. For example, the drawings in the '787 patent do not show a "tulip-shaped" housing part that is "substantially larger" in diameter than the guide tube. (*See* '787 patent Figs. 3, 4, 6.)

The "tulip-shaped" features of the housing part depicted in the drawings are the cylindrical structure, open distal end, and larger diameter relative to the guide stem. In combination, these features roughly suggest the shape of a tulip flower attached to a stem.

Accordingly the Court construes "tulip-shaped housing part" to mean a "cylindrical housing part with an open distal end and a diameter larger than that of the guide tube."

5. Claim 7

Claim 7 reads as follows:

The tool of claim 4, wherein said guide tube includes at least one longitudinal channel for injecting fluids.

a. "channel for injecting fluids"

[51] The parties have two disputes regarding this claim element. First, the parties dispute whether the "channel" element may be satisfied by the channel inherently provided by the lumen of the guide tube. Gore's proposed construction requires that the "channel for injecting fluids" must be "*in addition to* the lumen which is inherent in the guide tube" (emphasis added).

Gore's "in addition to the lumen which is inherent in the guide tube" limitation is not supported by the ordinary meaning of the claim language, interpreted in light of the intrinsic evidence. The claim requires a "channel," not an "additional" channel. Nothing in the specification warrants a departure from the ordinary meaning of the claim language. Gore correctly observes that the only channel described in the specification is an additional channel provided within the wall of the guide tube. However, the limitations of an embodiment are not read into the claims, even if the specification describes only one embodiment. *See Phillips*, 415 F.3d at 1323. The specification does not suggest that this embodiment is intended to define the scope of the "channel" element or that the physical location of the channel is a significant detail. To the contrary, the only requirement found in the specification is that the channel must allow for the injection of fluids. Therefore, if the central lumen of the guide tube is a "channel" and permits the injection of fluids, it is within the scope of the claim language.

This construction is also confirmed by extrinsic evidence. Perouse cites a 1994 patent that describes administration of liquids through a guide tube lumen to the site of stent placement. (Golds Reply Decl. para. 18, Ex. 29.) Though this reference postdates the filing of the patent, it nevertheless provides some support for Perouse's argument that a person of ordinary skill in the art would not have interpreted this claim term to exclude the central lumen from the scope of the "channel" element.

Gore argues that the "channel for injecting fluids" of claim 7 cannot be the central lumen because, under this construction, claim 1 and claim 10 would have the same scope. *Cf. Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998) ("While we recognize that the doctrine of claim differentiation is not a hard and fast rule of construction, it does create a presumption that each claim in a patent has a different scope."). The Court does not agree. Claim 10 requires a channel "for injecting fluids." Under Perouse's proposed construction, the central lumen is a "channel for injecting fluids" *only* if it can be used for injecting fluids. The central lumen of a guide tube may or may not be suitable for injection of fluids. While the central lumen of any guide tube falls within the scope of claim 1, only those which allow for the injection of fluids are within the scope of claim 10.

The parties also dispute whether "fluids" should be construed to mean "liquids" or "liquids and gases." The specification refers to a "liquid-tight" stent. ('787 patent col.2 l.52). However, the patentee used the word "fluids," not "liquids," in claim 10. If the patentee had wanted to claim a channel for injecting *liquids*, it clearly was capable of doing so without ambiguity. The fact that the patentee used the term "fluids" instead indicates that "fluids" was chosen intentionally and was not intended to be synonymous with "liquids,"

Accordingly, the Court construes "channel for injecting fluids," to mean "lengthwise running conduit or passageway (including the central lumen of the guide tube) through which liquids or gases can be forced."

CONCLUSION

The Court construes the disputed claim terms in the '787 patent as set forth in this Memorandum Opinion and Order. Perouse's Motion to Exclude Defendant/Counterclaim Plaintiff's Newly Proposed Claim Constructions [45] is DENIED.

SO ORDERED.

APPENDIX



US006019787A

United States Patent [19]

(11) Patent Number: **6,019,787**

Richard et al.

(43) Date of Patent: **Feb. 1, 2000**

- [54] **FITTING TOOL FOR USE OF AN EXPANSIBLE ENDOPROSTHESIS FOR A HUMAN OR ANIMAL TUBULAR ORGAN**
- [75] Inventors: **Thierry Richard, Paris; Eric Perouse, L'Isle Adam, both of France**
- [73] Assignee: **Laboratoire Perouse Implants, Borneol, France**
- [31] Appl. No.: **08/946,657**
- [32] Filed: **Oct. 7, 1997**

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Related U.S. Application Data

[62] Division of application No. 08/146,337, filed as application No. PC12/R93/00246, Mar. 11, 1993, Pat. No. 5,755,769.

Foreign Application Priority Data

Mar. 12, 1992 [FR] France 92 02931

- [51] Int. Cl.⁷ **A61F 2/06**
- [52] U.S. Cl. **623/1; 606/194**
- [58] Field of Search **623/1, 11, 12; 606/194, 195**

Primary Examiner—Michael J. Milano
Attorney, Agent, or Firm—Wenderoth, Lind & Ponack, L.L.P.

[57] ABSTRACT

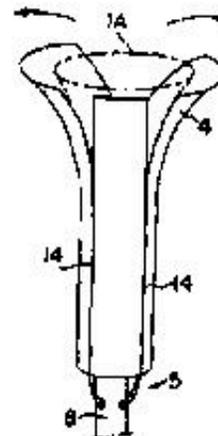
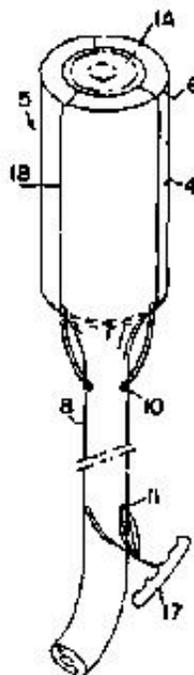
An endoprosthesis includes an extensible tubular mesh embedded in a plastic or elastomer extensible film. A tool for positioning the endoprosthesis includes a tube-shaped guide provided at its distal end with a whip-shaped housing. Cutting threads cause the housing to open longitudinally into several petal-like parts. Application is to endoluminal treatment of aneurysms and dilations.

12 Claims, 3 Drawing Sheets

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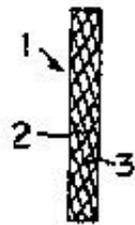


FIG. 1

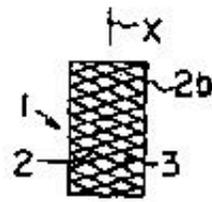


FIG. 2

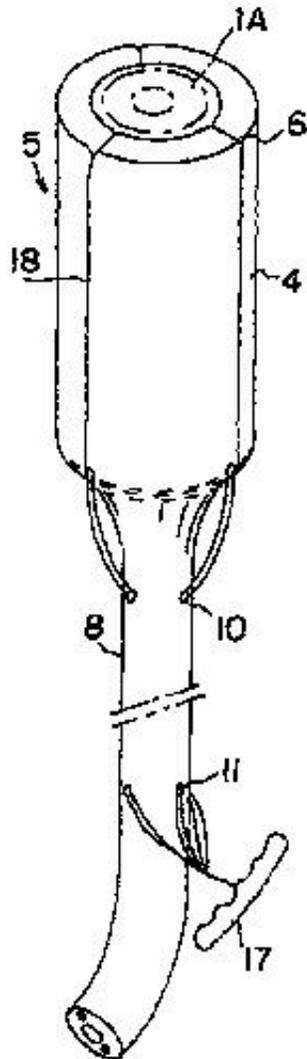


FIG. 3

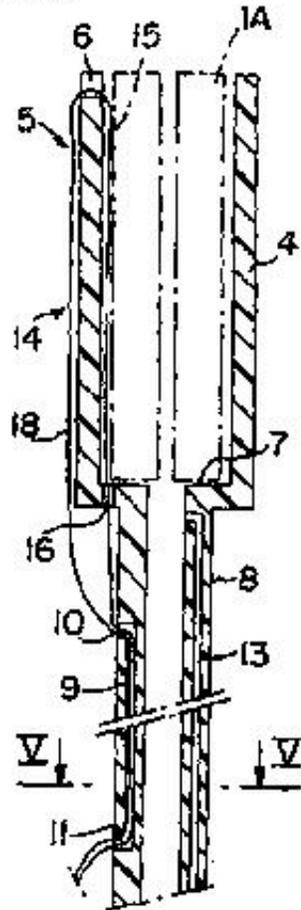


FIG. 4

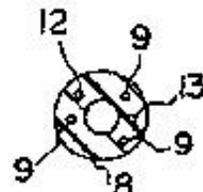


FIG. 5

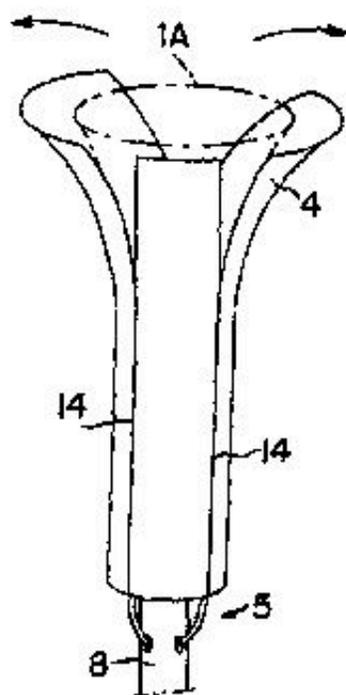


FIG. 6

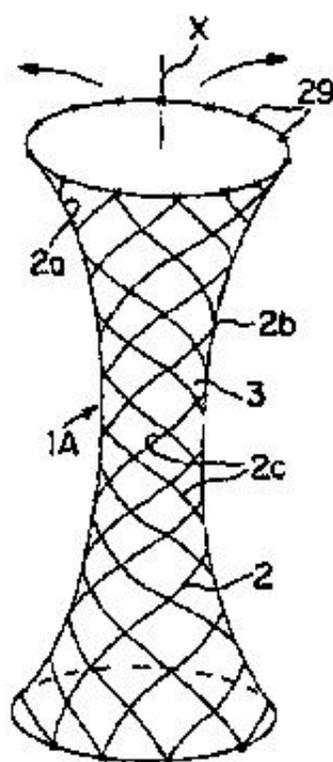


FIG. 7A

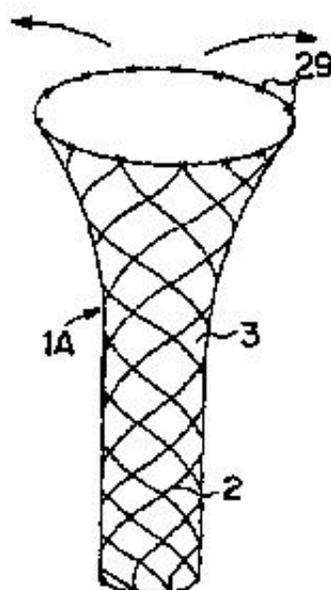


FIG. 7

***400**

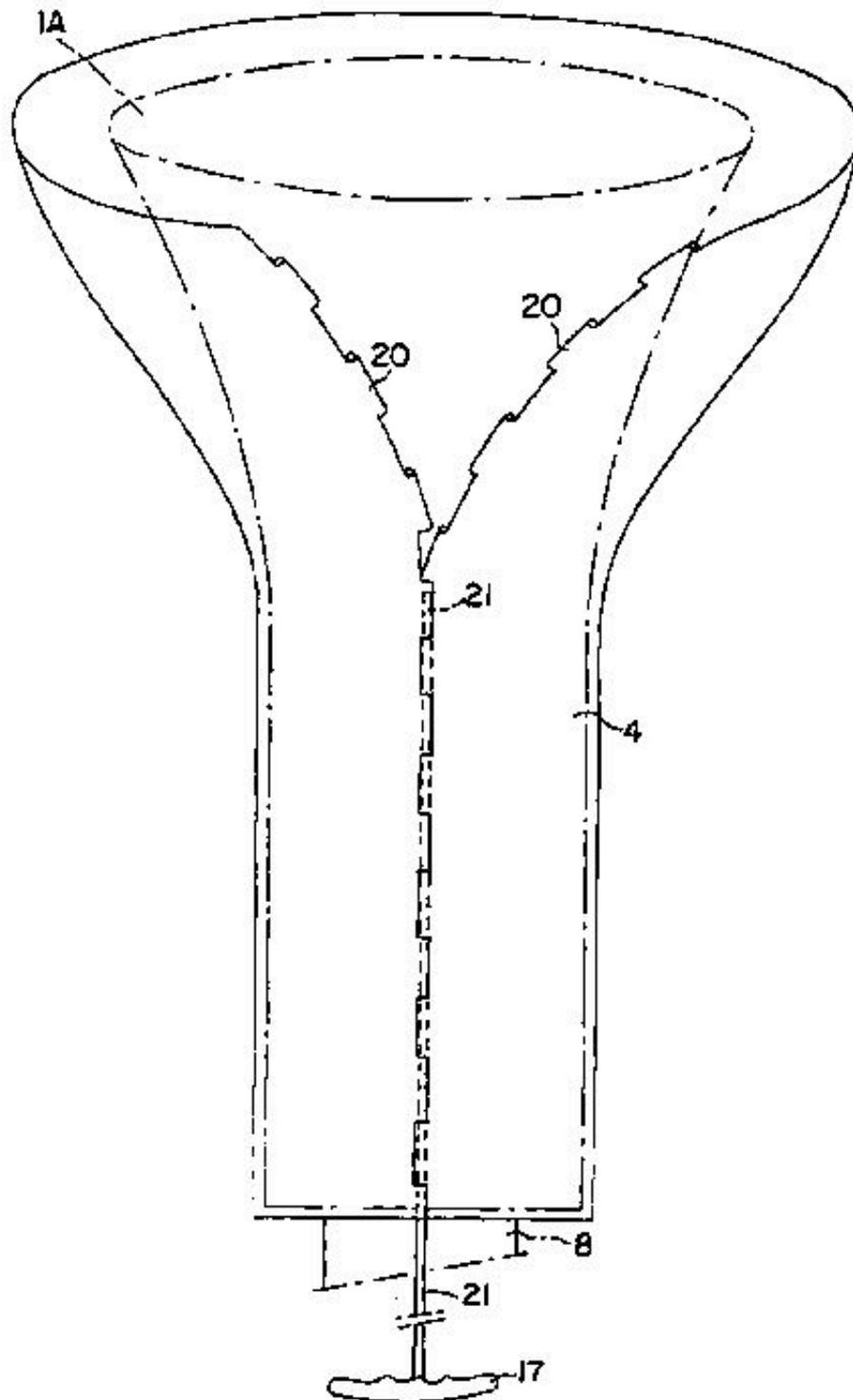


FIG. 8

FITTING TOOL FOR USE OF AN EXPANSIBLE ENDOPROSTHESIS FOR A HUMAN OR ANIMAL TUBULAR ORGAN

This is a divisional application of Ser. No. 08/146,137, filed Apr. 21, 1994 now U.S. Pat. No. 5,755,769, which is a 371 of PCT/FR93/00246, filed Mar. 11, 1993.

BACKGROUND OF THE INVENTION

The present invention relates to an expansible endoprosthesis for a human or animal tubular organ, of the type comprising an expansible mesh of cylindrical general shape, and is useful in particular for the endoluminal treatment of aneurysms and to dilations.

Endoprostheses of this type generally consist of a stent metal mesh which can be expanded using a balloon, or are auto-expansible, i.e. self-expanding. After a transluminal dilation, they are inserted endoluminally using a probe, then expanded or released.

These known endoprostheses are not entirely satisfactory, because the tissues penetrate the cavities of the mesh and are traumatized and, in addition, the endoprosthesis creates turbulence in the blood flow.

Furthermore, these endoprostheses cannot be used for treating aneurysms, or more generally for connecting two healthy segments of a tubular organ such as a vessel, since they are not liquid-tight.

SUMMARY OF THE INVENTION

The object of the invention is to provide an expansible endoprosthesis which eliminates these drawbacks. For this purpose, the invention provides an endoprosthesis of the aforementioned type, but wherein a mesh is embedded in an extensible and biocompatible plastic or elastomer film, this film filling the cavities of the mesh and covering the entire surface of the mesh substantially throughout the whole extent of the endoprosthesis.

According to other characteristics:

the film consists of a polymer such as polyurethane or a natural or synthetic rubber;

the endoprosthesis is of the auto-expansible or self-expanding type, and the end parts of the endoprosthesis are flared when it is in its expanded state;

the mesh is made of stainless steel or of a relatively rigid plastic such as polytetrafluoroethylene which has been made radiopaque.

Another aspect of the invention is a tool for fitting an auto-expansible endoprosthesis as defined above. This tool comprises:

a guide tube provided at its distal end with a housing part (shown in drawings as shown like a tulip) for housing the endoprosthesis in the contracted state; and means for opening the tulip-shaped housing part longitudinally.

According to one embodiment, such means comprise wires for separating, such as by cutting, the tulip-shaped housing part into several petal-like parts, or sections such wires being connected to an actuation handle.

According to another embodiment, such means comprise a longitudinal opening of the tulip-shaped housing part, each edge of which has a series of gussets, the gussets of the two edges being fitted into each other and being held by a cord which passes through them and which is connected to an actuation handle.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described with reference to the attached drawings, in which:

FIG. 1 diagrammatically represents an endoprosthesis according to the invention in a retracted state;

FIG. 2 diagrammatically represents the same endoprosthesis in an expanded state;

FIG. 3 represents, on a greatly enlarged scale, in perspective, a tool for fitting an auto-expansible endoprosthesis according to the invention;

FIG. 4 is a view in longitudinal section of the tool in FIG. 3;

FIG. 5 is a view taken in section along the line V—V in FIG. 4;

FIG. 6 illustrates the use of the tool in FIGS. 3 to 5; FIG. 7 represents the corresponding expansion of the endoprosthesis; and

FIG. 8 diagrammatically represents, on a greatly enlarged scale and in perspective, another tool for fitting an auto-expansible endoprosthesis according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

The endoprosthesis 1 represented in FIGS. 1 and 2 consists of a tubular mesh 2 embedded in a film 3.

The mesh 2 consists of stainless steel of biocompatible grade. Mesh 2 can be made by weaving or knitting of a yarn, axial spreading of a tube, or by any other suitable technique. It is plastically deformable, that is to say that it has a first stable shape of small diameter, represented in FIG. 1, in which the cavities form diamonds elongated parallel to its axis, and a second stable shape of greatly enlarged diameter and shorter length, represented in FIG. 2, in which the cavities form diamonds elongated in the circumferential direction. Mesh 2 has opposite ends or end portions and a body or main portion extending between said end portions, as clearly illustrated.

The mesh 2 is entirely embedded in film 3 of an extensible and liquid-tight material which fills its cavities. Film 3 covers and is attached to the entire exposed surface of mesh 2 including portions thereof defining the cavities therein. The extensibility of this material is sufficient for the film 3 to be able to follow the deformation of the mesh 2 from its contracted state to its expanded state without tearing or detachment, despite the deformation of the cavities of the mesh. Appropriate materials are a biocompatible elastomer, which may be a natural or synthetic rubber, or alternatively a biocompatible polymer such as polyurethane.

The coating of the mesh 2 with the film 3 may be carried out by techniques of co-extrusion or immersion, after degreasing of the metal and its treatment with a primary adhesion substance.

In the expanded state (FIG. 2), a liquid-tight tubular segment is then obtained which can be used as an endoprosthesis or "stent" after a transluminal dilation. This endoprosthesis does not traumatize the tissues and creates practically no turbulence in the blood flow, since the tissues and the blood are in contact with a practically smooth elastomer or polymer surface.

Because of its leaktightness, the endoprosthesis can be used for endoluminal treatment of an aneurysm, by making it bridge the aneurysm, each of its ends being applied radially against the inner wall of a healthy artery segment adjacent to the aneurysm.

In another embodiment, illustrated in FIGS. 3 to 7, the mesh 2 of the endoprosthesis 1A is auto-expansible, which is obtained conventionally by using stainless steel with spring properties.

For fitting the endoprosthesis 1A, it is compressed radially into its configuration in FIG. 1, which is not stable, and is inserted into a tulip-shaped end 4 of a tool 3 represented in FIGS. 3 to 5.

The distal end of the housing part 4 (shown in the drawings as shaped like a tulip) is open and has three notches 6 spaced at angles of 120° from each other. Its proximal end forms an inner shoulder 7 from which extends a guide tube 8. In the plane of each notch 6, a channel 9 formed in the thickness of the wall of the tube 8 emerges outwardly through radial orifices 10, 11, on the one hand near the shoulder 7, and on the other hand near the proximal end of the tube 8.

It is also possible to provide in the thickness of the wall of the tube 8, as shown, longitudinal channels 12, 13 for injecting fluids, which channels start from the proximal end of tube 8 and emerge into a space inwardly of the tube 8 near the shoulder 7.

In each of the three aforementioned planes, a flexible wire 14 passes through the respective notch 6. An inner strand 15 of wire runs along the inner wall of the tulip-shaped part 4, passes through an orifice 16 provided in the shoulder 7, penetrates the orifice 10, extends along the channel 9, leaves through the orifice 11 and rejoins an actuation handle 17 (FIG. 3). An outer strand 18 of the wire 14 runs along the outer wall of the tulip-shaped part, follows the same path 19, 11 as the strand 15, and also rejoins the handle 17. This handle is therefore connected to six wire strands, and the three inner strands 15 are pressed flat against the inner wall of the tulip-shaped part by the tendency of the endoprosthesis 1A to expand.

Before using the endoprosthesis, after a transluminal dilation or for treating an aneurism, the tool 3 is threaded into a guide, inserted through the skin and conveyed endoluminally as far as the desired location.

The operator then pulls on the handle 17. This tensions the three wires 15, and these wires each cut the tulip-shaped housing part 4 along one generatrix. The tulip-shaped housing part then progressively releases the endoprosthesis, which expands by itself, as illustrated in FIG. 6. When the tulip-shaped housing part is completely open, the tool is withdrawn by pulling on the tube 8.

In the expanded state (FIG. 7), it is seen that the two ends of the endoprosthesis are automatically flared, which provides two advantageous effects: on the one hand, the tightness of the endoprosthesis and the artery is reinforced, and, on the other hand, the ends 19 of the wires of the mesh 2 extend slightly beyond the film 3 and form as many points for anchoring the endoprosthesis in the artery. The endoprosthesis is thus positionally stabilized.

Other materials may be used to form the mesh 2. For example, in order to produce an auto-expansible endoprosthesis, a yarn of a relatively rigid polymer with spring properties, such as polytetrafluoroethylene (PTFE), which has been made radiopaque, may be used.

Another embodiment of the tool 3 has been represented diagrammatically in FIG. 8. This tool differs from that described hereinabove by the means for longitudinal opening of the tulip-shaped housing part.

The tulip-shaped housing part is actually slit longitudinally over its entire height. Each edge of the slit includes a series of projecting cylindrical gussets 20. When the tulip-shaped housing part is in its closed cylindrical state, and holds an auto-expansible endoprosthesis 1A in the contracted state, the gussets 20 of the two edges interpenetrate, and the whole is held by a cord 21 which passes through all

the gussets and is connected, at its proximal end, to the actuation handle 17.

The endoprosthesis is released simply by pulling on the handle 17.

We claim:

1. A tool for fitting a self-expanding stent comprising:
 - a guide tube having a distal end;
 - a housing part for housing a self-expanding stent, said housing part provided at said distal end of said guide tube; and
 - a housing part opener for opening said housing part independent of the self-expanding stent.
2. The tool of claim 1, wherein said housing part opener includes an actuation handle and wires for cutting said housing part into several sections, said wires being connected to said actuation handle.
3. The tool of claim 1, wherein said housing part includes a longitudinal slit forming edges in said housing part, said housing part having a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together; and
 - said housing part opener including an actuation handle and a cord, said cord passing through said gussets along each of said edges such that said cord holds said edges together, said cord being connected to said actuation handle.
4. The tool of claim 1, wherein said housing part comprises a tulip-shaped housing part.
5. The tool of claim 4, wherein said housing part opener includes an actuation handle and wires for cutting said housing part into several sections, said wires being connected to said actuation handle.
6. The tool of claim 4, wherein said housing part includes a longitudinal slit forming edges in said housing part, said housing part having a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together; and
 - said housing part opener including an actuation handle and a cord, said cord passing through said gussets along each of said edges such that said cord holds said edges together, said cord being connected to said actuation handle.
7. The tool of claim 4, wherein said guide tube includes at least one longitudinal channel for injecting fluids.
8. The tool of claim 7, wherein said housing part opener includes an actuation handle and wires for cutting said housing part into several sections, said wires being connected to said actuation handle.
9. The tool of claim 7, wherein said housing part includes a longitudinal slit forming edges in said housing part, said housing part having a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together; and
 - said housing part opener including an actuation handle and a cord, said cord passing through said gussets along each of said edges such that said cord holds said edges together, said cord being connected to said actuation handle.
10. The tool of claim 1, wherein said guide tube includes at least one longitudinal channel for injecting fluids.
11. The tool of claim 10, wherein said housing part opener includes an actuation handle and wires for cutting said housing part into several sections, said wires being connected to said actuation handle.
12. The tool of claim 10, wherein said housing part includes a longitudinal slit forming edges in said housing

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part, said housing part having a series of gussets disposed along each of said edges, said gussets along each of said edges being fitted together; and

said housing part opener including an actuation handle and a cord, said cord passing through said gussets along

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each of said edges such that said cord holds said edges together, said cord being connected to said actuation handle.

* * * * *