

** NOT FOR PRINTED PUBLICATION **

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

MARK BARRY, M.D.,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

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CIVIL ACTION No. 1:14-cv-104

JUDGE RON CLARK

BRC

**ORDER CONSTRUING CLAIM TERMS OF
UNITED STATES PATENT NOS. 7,670,358 AND 8,361,121**

Dr. Mark Barry, M.D. filed suit against Medtronic, Inc., claiming infringement of United States Patent Nos. 7,670,358 (‘358 Patent) and 8,361,121 (‘121 Patent). Having carefully considered the patents, the parties’ briefs, and the arguments of counsel at the *Markman* hearing,¹ the court now makes the following findings and construes the disputed claim terms.

I. CLAIM CONSTRUCTION STANDARD OF REVIEW

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc. (Markman II)*, 517 U.S. 370, 388–91 (1996). “Because the patentee is required to ‘define precisely what his invention is,’ . . . it is ‘unjust to the public, as well as an evasion of the law, to construe it in a

¹ The transcript of the November 10, 2015 *Markman* hearing [Dkt. # 119] contains a number of representations by and agreements of the parties, as well as answers by their experts to technical questions from the court, all of which will not be repeated here, but which may assist in understanding the issues presented. This order governs in the event of any conflict between the order and the court’s preliminary analysis at the hearing. Court’s Exhibit Nos. 1–21 were discussed at the hearing and are part of the record. [Dkt. # 117-1]. These exhibits will be cited in this order as “Ct.’s Ex. __.” The transcript of the November 10, 2015 claim construction hearing, [Dkt. # 119], will be cited as “*Barry Tr.* at page:line.”

manner different from the plain import of its terms.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *White v. Dunbar*, 119 U.S. 47, 52 (1886)).

Words in a claim are generally given their ordinary and customary meaning as understood by a person having ordinary skill in the art (“PHOSITA”) in question as of the effective filing date of the patent application. *Phillips*, 415 F.3d at 1313. However, a patentee may demonstrate an express intent to impart a novel meaning by redefining a term “with reasonable clarity, deliberateness, and precision” in the patent specification or prosecution history. *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). A patentee may also limit scope by an express disclaimer or disavowal. *Phillips*, 415 F.3d at 1316.²

The intrinsic evidence, that is, the patent’s specification and, if in evidence, the prosecution history, is important in claim construction. *Phillips*, 415 F.3d at 1315–17. A court may also review extrinsic evidence, such as dictionaries, inventor testimony, and learned treatises. *Id.* at 1317. However, extrinsic evidence should be considered in the context of the intrinsic evidence in order to result in a reliable interpretation of claim scope. *Id.* at 1319.

A claim term may take the form of a means-plus-function limitation under 35 U.S.C. § 112(6). The first step in construing a means-plus-function limitation is to identify the function of the limitation. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351 (Fed. Cir. 2015) (en banc). The next step is to identify the corresponding structure in the written description necessary to perform that function. *Id.* Structure disclosed in the specification is

² Following its standard practice, the court required both parties to have an expert present to answer questions about the technology. The court considers such testimony with care because of the potential bias of such witnesses. But there have been many occasions in the past where the opposing experts will agree on basic facts and on elements of a claim when the lawyers would argue *ad infinitum*. And construction may depend on determination of certain facts by the court. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837–38 (2015).

“corresponding” structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. *Id.*

II. PATENT BACKGROUND AND TECHNOLOGY

Dr. Barry is the owner of the '358 Patent and the '121 Patent. Both claim a priority date of December 30, 2004, the day that the '358 Patent was filed. Each patent bears the same title, “System and Method for Aligning Vertebrae in the Ameliorating of Aberrant Spinal Column Deviation Conditions.”

The invention relates to an improved method of aligning vertebrae of the spinal cord, involving pedicle screws and a derotation tool. Importantly, the invention permits rotation of the spinal column as a whole by a single surgeon while reducing the risk that damaging force will be applied to individual vertebrae. *See* '358 Patent, 2:39–67. Generally, the method involves inserting pedicle screws into to-be-rotated vertebrae, correcting the alignment of the vertebrae with a “pedicle screw cluster derotation tool” that engages the pedicle screws, and setting the spine by fixing the pedicle screws to pre-contoured spinal rods. *See* '358 Patent, 3:34–4:4.

III. PERSON HAVING ORDINARY SKILL IN THE ART

During the *Markman* hearing, the parties agreed to the following definition of a person having ordinary skill in the art (“PHOSITA”):

A person of ordinary skill in the art related to the technology of the patents would have had an undergraduate degree in Mechanical or Biomedical Engineering or the equivalent, and at least two to three years of experience with fixation implants and methods and systems for scoliosis or spinal deformity correction and the like; or a medical degree or the equivalent, and at least two to three years of experience with fixation implants and methods and systems for scoliosis or spinal deformity correction and the like. Sufficient experience in design of medical devices used in this field might substitute for some formal education, while advanced degree work might substitute for some of the years of experience.

Ct.’s Ex. 1; *Barry Tr.* at 5:1–18.

IV. CONSTRUCTION OF '358 AND '121 PATENT CLAIM TERMS

Undisputed Term

[Ref. 1]³ “Handle Means.” ’358 Patent, Claims 1–5.

The parties have agreed that:

“handle means” as used in the ’358 Patent shall be construed to mean **“a part that is designed especially to be grasped by the hand.”**

[Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 1]; *Barry Tr.* at 5:19–6:7 (discussing Ct.’s Ex. 2).

This definition comports with the ordinary use of the term and with the specification and figures.

Disputed Terms

A. [Ref. 2] “Pedicle Screw Cluster Derotation Tool.” ’358 Patent, Claims 1–2 and ’121 Patent, Claims 1–2.

During the *Markman* hearing, the parties agreed that the term “pedicle screw cluster derotation tool” carries the same meaning in the ’358 Patent and the ’121 Patent. *Barry Tr.* at 52:24–53:9. An exemplar use of the term is found in ’358 Patent, Claim 1, with the disputed terms in bold:

A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:

selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment;

selecting a first **pedicle screw cluster derotation tool**, said first **pedicle screw cluster derotation tool** having first handle means and a first group of pedicle screw engagement members which are mechanically linked

³ The “[Ref. _]” before each term is the numbering the parties applied to the disputed claim terms in the Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I).

with said first handle means, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws.

Plaintiff argued that no construction was necessary. [Opening Brief, Dkt. # 93, at 20–21]. Defendant proposed the following construction for this term:

Tool for engaging a plurality of screws on one side of the spine.

[Opp. Brief, Dkt. # 108, at 10].

The patents identify item 30 in Fig. 1 as an example of a “pedicle screw cluster derotation tool.” ’358 Patent, at 4:67–5:2; ’121 Patent, at 5:9–11.

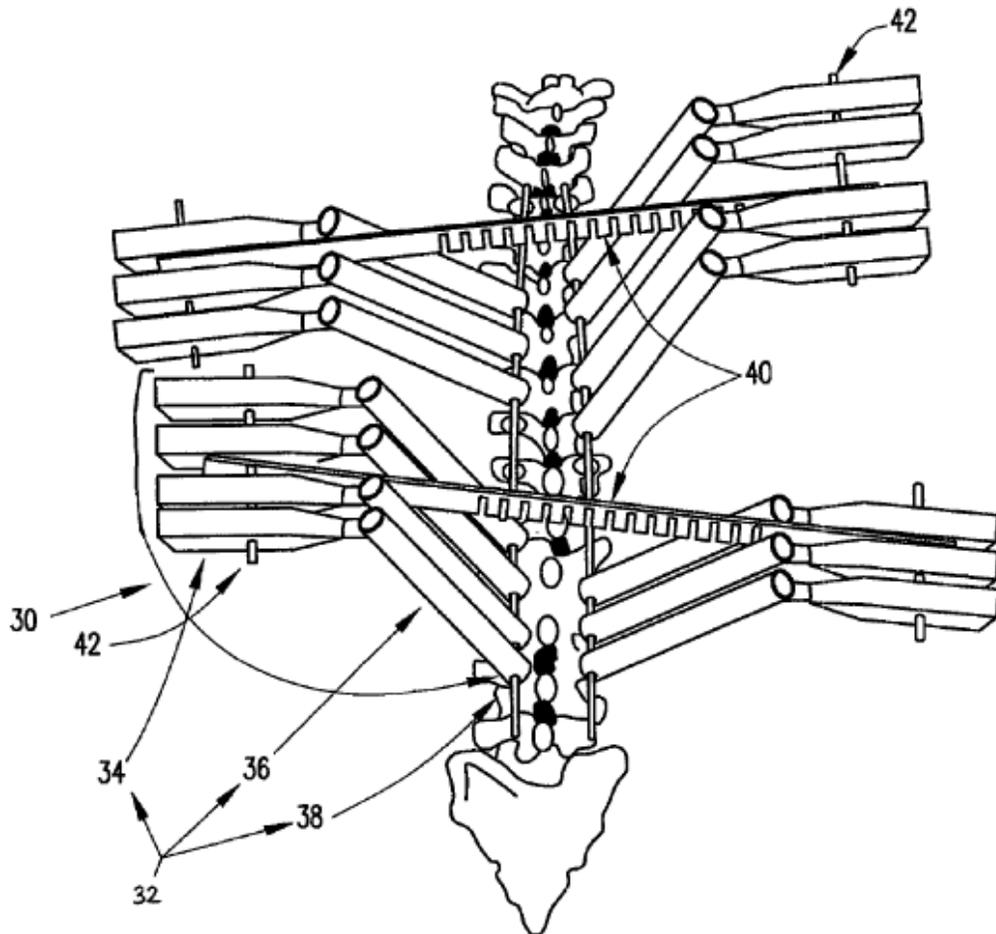


FIG. 1

Each tool “is configured from a grouping of pedicle screw wrenches 32, joined together by pedicle screw wrench linking members 42 to act in unison during use.” ’358 Patent, at 5:2–4; ’121 Patent, at 5:11–13. The individual pedicle screw wrenches are made up of “a handle 34, a shaft 36, and a distal end 38 which is configured to reversibly engage the head segment 14 of a pedicle screw 10.” ’358 Patent, at 5:12–14; ’121 Patent, at 5:14–16. “Ordinarily, two tools 30 will be involved on either side of the spinal column Wrench cross linking members 40 are used to coordinate forces applied to screw clusters on either side of the spinal column.” ’358 Patent, at 5:7–11.

During the *Markman* hearing, the court proposed the following construction for this term:

“pedicle screw cluster derotation tool” means “a tool for engaging a plurality of pedicle screws implanted in a plurality of vertebrae of a spinal column.”

Barry Tr. at 78:15–19 (discussing Ct.’s No. 13). Plaintiff agreed with the construction. *Id.* at 78:20–25. Defendant argued that a construction should require that the tool be on one side of the spine. *Id.* at 79:3–18.

The Claims Do Not Require that the Tool Be on Only One Side of the Spine.

Plaintiff’s expert testified that two pedicle screw cluster derotation tools on opposite sides of the spine (’358 Patent, Fig. 1, item 30) joined by a wrench cross linking member (’358 Patent, Fig. 1, item 40) could also qualify as a tool. *Barry Tr.* at 40:11–20 (discussing Ct.’s Ex. 10). The court would not put great weight on the testimony, taken by itself. But it was not contradicted by the claim language or the specification, nor by any factual testimony of Defendant’s expert.

The claim language does not limit the location of a pedicle screw cluster derotation tool to only one side of the spine. Claims 1 and 2 of the ’358 Patent describe a pedicle screw cluster

derotation tool with a handle means and a group of pedicle screw engagement members which are mechanically linked with the handle means. '358 Patent, at 6:14–17 (Claim 1), 6:59–62 (Claim 2). Claims 1 and 2 of the '121 Patent state that each pedicle screw cluster derotation tool has a “handle means for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means.” '121 Patent, at 6:36–40 (Claim 1), 8:3–7 (Claim 2). Nothing in the language of either claim requires that the pedicle screw cluster derotation tool be on one side of the spine. Under the claim language screws could be placed in pedicles on each side of the spine.

Likewise, the specification does not limit the pedicle screw cluster derotation tool to being on one side of the spine. There are embodiments where each individual tool is located on only one side of the spine. *See* '358 Patent, at 5:7–11 (“Ordinarily, two tools 30 will be involved on either side of the spinal column”); *id.* at 5:36 (describing Figure 1 as a “preferred mode”). But these embodiments are specifically described as “ordinary” or “preferred.”

Even if there was only one embodiment, the court could not import the “on one side of the spine” limitation absent clear disavowal or the patentee acting as his own lexicographer by providing a definition of the term that is different from the plain and ordinary meaning. *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 719 (2014). The patents contain no such disavowal regarding whether the tool must be located on one side of the spine and the parties have pointed to no instances where Plaintiff acted as his own lexicographer.

Defendant’s counsel argued that Plaintiff limited itself to a “one side of the spine” embodiment during prosecution. Disavowal requires “that the specification or prosecution

history make clear that the invention does not include a particular feature or is clearly limited to a particular form of the invention.” *Hill-Rom*, 755 F.3d at 1372 (internal citations and quotations omitted). This can occur when the preferred embodiment is described as being “the invention” or when a step or feature of the invention is described as “required” or “important.” *Id.* Disavowal does not occur merely because the specification only contains one embodiment. *See Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004).

To support its disavowal theory, Defendant argued that Plaintiff’s use of the phrase “cross-tool connector” in his original application implies that there are two separate tools on opposite sides of the spine and limits the pedicle screw cluster derotation tool to being on one side of the spine. *Barry Tr.* at 65:24–67:1. In the original application, the actual phrase used was as follows: “Ordinarily, two tools 30 will be involved on either side of the spinal column, with two pedicle screws 10 being implanted in each vertebrae, as shown. A **cross-tool linkage member** 31 is used to coordinate forces applied to screw clusters on either side of the spinal column.” [Original Application of ’358 Patent, Dkt. # 108-2 (Ex. A), at 14–15] (emphasis added). Use of the word “[o]rdinarily” in the sentence preceding “cross-tool linkage member” suggests that “two tools . . . on either side of the spinal column” is merely describing a preferred embodiment. Even if “a cross-tool linkage member” is required structure for this preferred embodiment, it does not follow that the recitation of this structure for a preferred embodiment somehow disavows a pedicle screw cluster derotation tool that exists on both sides of the spine.

The court construes this term as follows:

“pedicle screw cluster derotation tool” means “a tool for engaging a plurality of pedicle screws implanted in a plurality of vertebrae of a spinal column.”

B. [Ref. 3] **“pedicle screw engagement members which are mechanically linked with said [first/second] handle means”** (’358 Patent, Claims 1–2); and

[Ref. 11] **“a [first/second] group of three or more pedicle screw engagement members which are mechanically linked with said [first/second] handle means”** (’121, Claims 1–2)

An exemplar use of the term is found in ’358 Patent, Claim 1, with the disputed terms in bold:

A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:

selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment;

selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having first handle means and a first group of **pedicle screw engagement members which are mechanically linked with said first handle means**, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws.

Although Defendant urges construction of two long phrases (Plaintiff argues ordinary meaning), each actually consists of three terms: 1) “handle means;” 2) “mechanically linked;” and 3) “pedicle screw engagement members.” The parties agree that “handle means” in the ’358 Patent means “a part that is designed especially to be grasped by the hand.” [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 1]; *Barry Tr.* at 5:19–6:7 (discussing Ct.’s Ex. 2). During the *Markman* hearing, the parties expressed no objection to construing “handle means” in this term according to their agreed construction. *Barry Tr.* at 107:17–22, 108:19–23 (discussing Ct.’s Ex. 17). The remaining terms to be construed are “pedicle screw engagement members” and “mechanically linked.”

Pedicle Screw Engagement Members.

The patents state that “[e]ach pedicle screw wrench 32 includes a handle 34, a shaft 36, and a distal end 38 which is configured to reversibly engage the head segment 14 of a pedicle screw” ’358 Patent, at 5:12–14; ’121 Patent, at 5:14–16. During the *Markman* hearing, Plaintiff argued, and Defendant did not dispute, that the “pedicle screw engagement members” were the part of the “pedicle screw wrench” that extends from the handle, which includes the “shaft 36” and “distal end 38” that “engage the head[]” of the pedicle screw. *Barry Tr.* at 102:16–23, 103:22–104:6. Ultimately, the parties agreed to the following construction:

“pedicle screw engagement members” means “the shaft and the shaft distal end that engages the pedicle screw.”

Barry Tr. at 107:17–22, 108:19–23 (discussing Ct.’s Ex. 17).

Mechanically Linked.

Although agreeing on “handle means” and “pedicle screw engagement members,” the parties still had a dispute over “mechanically linked.” The Patent Trial and Appeal Board had previously construed the term “mechanically linked” in both patents to mean “physically joined.” [Dkt. # 93-2 (Ex. A), at 9 (Decision Granting Institution of *Inter Partes Review* of the ’358 Patent)]; [Dkt. # 93-6 (Ex. E), at 10 (Decision Denying Institution of *Inter Partes Review* of the ’121 Patent)]. Plaintiff agreed to this construction during the *Markman* hearing. *Barry Tr.* at 107:17–22 (discussing Ct.’s Ex. 17).

Defendant argued that a construction of this term should specify that the “pedicle screw engagement members” and “handle means” cannot be linked through “intervening structures.” *Barry Tr.* at 109:18–110:11 (discussing Ct.’s Ex. 17). According to Defendant, a proper construction should include “directly connected or physically touching.” *Id.* at 109:24–25.

Defendant could not explain why these proposals were not a distinction without a difference. The proposals merely appear to add some potential confusion.

The problem with Defendant's argument is that neither the claims nor the specification limit the connection between the "handle means" and the "pedicle screw engagement members" to a "direct connection," whatever that is. While the Figure 1 embodiment discloses a single member or bar between the pedicle screw engagement members, the claims are in no way limited to such a connection. The components only need to be physically joined. Defendant stated that the invention would not exclude a unitary handle with shafts extending from it. *Barry Tr.* at 112:2–12. Defendant also acknowledged that there are "other ways" to mechanically link the shaft and handle. *Barry Tr.* at 106:14–20. For example, they could be screwed together, joined by a ferrule, or the socket could be connected to the handle with a socket and detent similar to the detent at the end of a socket wrench extension. A PHOSITA would be familiar with these, and probably other, means of joining two or more parts of a member that is used to connect two parts of a mechanical device, or two devices.

The court construes "**mechanically linked**" to mean "**joined by a physical connection.**"

To sum up, the court construes the terms in the phrases "**pedicle screw engagement members which are mechanically linked with said handle means**" and "**a [first/second] group of three or more pedicle screw engagement members which are mechanically linked with said [first/second] handle means**" as follows:

"pedicle screw engagement members" means "**the shafts and the shaft distal ends that engage the pedicle screws,**"

"mechanically linked" means "**joined by a physical connection,**" and

"handle means" means "**a part that is designed especially to be grasped by the hand.**"

C. [Ref. 5] “amelioration of aberrant spinal column deviation conditions,” ’358 Patent, Claims 1, 2, 4, and 5, and ’121 Patent, Claims 1–2

Defendant argues that this term is indefinite and Plaintiff argues that no construction is necessary. [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 9].

This term is found in the following claim preambles:

- “A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the step of” ’358 Patent, at 6:7–9 (Claim 1); ’121 Patent, at 6:24–26 (Claim 1).
- “A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising” ’121 Patent, at 7:57–58.

It is also found as a claim limitation in several claims of the two patents. ’358 Patent, at 6:35–36 (Claim 1), ’358 Patent, at 7:14–15 (Claim 2), and ’121 Patent, at 7:55–56 (Claim 1) (“to achieve an amelioration of an aberrant spinal column deviation condition”); ’358 Patent, at 8:15–17 (Claim 4) and ’358 Patent, at 8:21–23 (Claim 5) (“to cooperatively achieve an amelioration of an aberrant spinal column deviation condition”).

“Amelioration of Aberrant Spinal Column Deviation Conditions” Is Not Indefinite.

The sole issue is whether this term is indefinite. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014) (*Nautilus II*). Where a claim uses a word of degree, “the court must determine whether the patent provides some standard for measuring that degree.” *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015) (*Nautilus III*). “Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the

context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014), *cert. denied*, 14-1362, 2015 WL 2338493 (U.S. Oct. 5, 2015).

In *Nautilus III*, the Federal Circuit held that the term “spaced relationship” was not indefinite because the claim language and specification “provide[d] sufficient clarity to skilled artisans as to the bounds of [the] disputed term,” even though the patent “[did] not specifically define ‘spaced relationship’ with actual parameters.” 783 F.3d at 1382–83 (internal citations and quotations omitted).⁴

By contrast, in *Interval Licensing*, the Federal Circuit held that the term “unobtrusive manner that does not distract a user” was indefinite because the term was “highly subjective” and “offer[ed] no objective indication of the manner in which content images [were] to be displayed to the user.” 766 F.3d at 1371.⁵ The “unobtrusive manner that does not distract a user” term was also equally tied to two very different embodiments, “leaving one unsure of whether the ‘unobtrusive manner’ phrase ha[d] temporal dimensions as well as spatial dimensions.” *Interval Licensing*, 766 F.3d at 1372.

The present case is more analogous to the *Nautilus III* case than to *Interval Licensing*. The specifications of the patents in suit provide reasonable certainty as to the scope of the term and give guidance as to what kind of improvement. According to the patents, “[t]he effect of practice of the present invention is three-dimensional correction which provides, not only spinal correction to near normal configuration, but corrects ‘rib humps.’” ’358 Patent, 3:64–67; ’121

⁴ The disputed term appeared in two phrases: “a [first/second] live electrode and a [first/second] common electrode mounted on said [first/second] half *in spaced relationship* with each other.” *Nautilus III*, 783 F.3d at 1376 (emphasis in original).

⁵ The disputed term appeared in the claim phrase: “a set of instructions for enabling the content display system to selectively display, **in an unobtrusive manner that does not distract a user . . .**” *Interval Licensing*, 766 F.3d at 1368 (emphasis in original).

Patent, at 4:3–6. The invention also “facilitates a successful entire-spine, 3D derotation of a scoliosis patient to near normal parameters.” ’358 Patent, at 5:33–35; ’121 Patent, at 5:36–37. The ’121 Patent describes rotating a pre-contoured spinal rod “to achieve a substantial correction of the scoliosis in the first two of three axes,” ’121 Patent, at 5:53–54, followed by a “final correction” in the third axis. ’121 Patent, at 5:66–6:3. Furthermore, a PHOSITA would understand that the ordinary use of the word “amelioration” is “to improve.” See DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) (“improvement, as of the condition of a patient”); WEBSTER’S INTERNATIONAL DICTIONARY (3d ed. 2002) (“to make better, improve”).

Improvement of an aberrant spinal condition like scoliosis to a “near normal” configuration provides some standard for measuring the improvement and provides a PHOSITA reasonable certainty regarding the scope of the invention. Unlike the “unobtrusive manner that does not distract a user” term in *Interval Licensing*, “amelioration of aberrant spinal column deviation conditions” is not “highly subjective” in the context of a patent directed to curing scoliosis. The “amelioration” term is not indefinite.

No PHOSITA would expect a medical device to claim an exact degree of improvement. As acknowledged by Defendant’s expert, it is impossible to predict the results of a surgery or to guarantee perfect results. *Barry Tr.* at 18:14–19:17. Defendant’s expert also stated: “[W]e do not promote giving any advice in terms of how far to correct the patient. A lot of that is solely based on the surgeon’s experience.” *Barry Tr.* at 19:11–13. That does not mean that no medical device aimed at achieving some benefit to a patient can be patented because the precise result or level of improvement is not specified or guaranteed.

Contrary to Defendant’s arguments, to avoid a holding of indefiniteness, the patentee is not required to set an end point when employing a term of degree. In *Nautilus III*, “spaced

relationship” was held not indefinite, even though the spacing was not defined, because the bounds would be clear to a PHOSITA. Courts have also held that the term “effective amount” is not indefinite in pharmaceutical patents, even though the “effective amount” may vary from patient to patient, “provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation.” *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383–84 (Fed. Cir. 2003). The fact that the ’358 and ’121 Patents do not specify the exact amount of required derotation or define a “near normal” spinal configuration is no basis to hold this term indefinite.

The term “amelioration of aberrant spinal column deviation conditions” is not indefinite. The term will be accorded its normal, customary meaning.

D. [Ref. 6] “Spinal Rod Engagement Means,” ’358 Patent, Claims 1, 3 and ’121 Patent, Claims 1, 3

An exemplar use of the term is found in ’358 Patent, Claim 1, with the disputed term in bold:

A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of: . . .

selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes: . . .

spinal rod engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

. . . .

The Parties Propose the Same Function.

Because this claim limitation uses the word “means,” there is a rebuttable presumption that it is a means-plus-function limitation. *Media Rights Techs., Inc. v. Capital One Fin. Corp.*,

800 F.3d 1366, 1371 (Fed. Cir. 2015). The first step in construing a means-plus-function term is to identify the function. *Williamson*, 792 F.3d at 1351.

The court agrees with the parties that this is a means-plus-function term governed by § 112 ¶ 6 and that the function of this term is “to secure the pedicle screw and spinal rod in a substantially fixed position and orientation.” [Opp. Brief, Dkt. # 108, at 18]. Plaintiff’s originally proposed function contained the phrase “and equivalents thereof,” but Plaintiff stated during the *Markman* hearing that “and equivalents thereof” should have been at the end of the proposed structure, not the proposed function. *Barry Tr.* at 116:14–19.

The patents identify item 20 in Fig. 4 as an example of a “spinal rod engagement means.” ’358 Patent, at 4:63, 5:51; ’121 Patent, at 5:5.

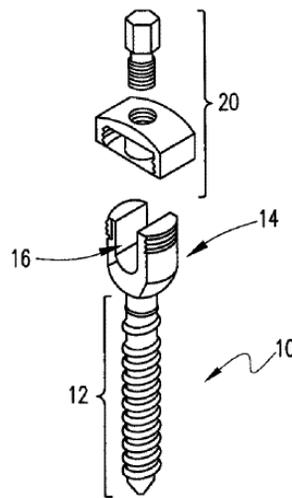


FIG. 4

According to the specifications:

pedicle screws 10 will include a threaded shank segment 12 and a head segment 14. Head segment 14 will be configured with a spinal rod conduit (or channel) 16 or interfacing with a spinal rod 18 (shown in FIG. 3). Spinal rod engagement means 20 serve to fix pedicle screw 10 and spinal rod 18 in relative position and orientation, once a spinal column derotation is complete.

'358 Patent, at 4:59–65; '121 Patent, at 5:1–7. Once the spinal rod is in place and the forces are applied to the pedicle screw cluster derotation tool, “the spinal rod engagement means 20 is tightened to fix pedicle screw 10 and spinal rod 18 in relative position and orientation to secure the corrected spinal column configuration.” '358 Patent, at 5:51–54. The specifications also say that “[p]edicle screws 10 may be of a variety of designs” and state that pedicle screws in four specifically-listed patents are incorporated by reference. '358 Patent, at 4:62–67; '121 Patent, at 4:62–67.

Patent law allows for incorporation by reference to a U.S. Patent to “[d]escribe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by 35 U.S.C. 112(f).” 37 C.F.R. § 1.57(c)(3) (citing to 35 U.S.C. § 112 ¶ 6 in the version in effect during the filing of the patents at issue). Because the applications for these patents were filed before March 16, 2013, the pre-AIA § 112 ¶ 6 applies. Pub. L. No. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

A court “cannot look to the prior art, identified by nothing more than its title and citation in a patent, to provide corresponding structure for a means-plus-function limitation.” *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir. 2010). That would be the case where a patent gives a generic “laundry list of prior art references” without describing the structures in the specification. *Id.* However, a reference to a specific device described in a patent is sufficient. In *Otto Bock HealthCare LP v. Ossur HF*, the following language was sufficient to incorporate a “weight-actuated vacuum pump” as a means-plus-function structure: “To maintain the vacuum in the cavity . . . a weight-actuated vacuum pump and shock absorber as disclosed in [the '274 application], may be employed.” 557 F. App'x. 950, 955 (Fed. Cir. 2014) (quoting U.S. Patent No. 6,726,726).

Likewise, in the present case, the patentee has properly incorporated four embodiments of a pedicle screw by referring to “pedicle screws” described in specific patents. The specification states:

Pedicle screws 10 may be of a variety of designs, such as, for example, are generally depicted in U.S. Pat. Nos. 6,743,237 (Gray, et al), 6,827,719 (Ralph, et al), 6,652,526 (Arafiles), 6,375,657 (Doubler, et al), the disclosures of which are incorporated herein by reference.

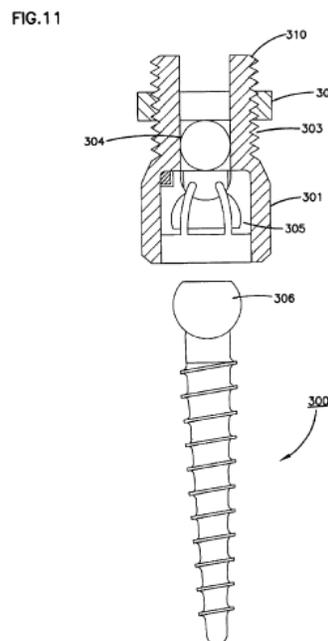
’358 Patent, at 4:62–67; ’121 Patent, at 4:62–67. Each of these patents discloses an embodiment of a pedicle screw that fixes a spinal rod. ’231 Patent, at 7:54–58; ’526 Patent, at 1:44–45; ’719 Patent, at 12:25–27; ’657 Patent, at 3:31–40. This is not a situation where the specification merely catalogs prior art references without stipulating what structure is disclosed. *See Pressure Prods.*, 599 F.3d at 1317. Here, the patentee specifically stated that alternative pedicle screws were being incorporated by reference and listed four patents specifically directed to the alternative structures. This is sufficient to incorporate these structures.

There Are Four Disclosed Structures For This Means-Plus-Function Term.

The ’358 and ’121 Patents incorporate by reference four alternative designs of pedicle screws. ’358 Patent, at 4:54–58; ’121 Patent, at 4:62–67. One of the listed patents was U.S. Pat. No. 6,743,237 (Gray et al.). But the ’237 Patent is directed to an invention entitled “Endoscopic Stone Extraction Device With Improved Basket” to inventor Avtar S. Dhindsa. The parties agreed the reference to the ’237 Patent was a typo—and that the court could correct it to refer to U.S. Pat. No. 6,743,231, as listed on the front page of both patents. *Barry Tr.* at 137:21–138:4. The error was evident from the face of the patent. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1333 (Fed. Cir. 2014). From the viewpoint of one skilled in the art, the correction is

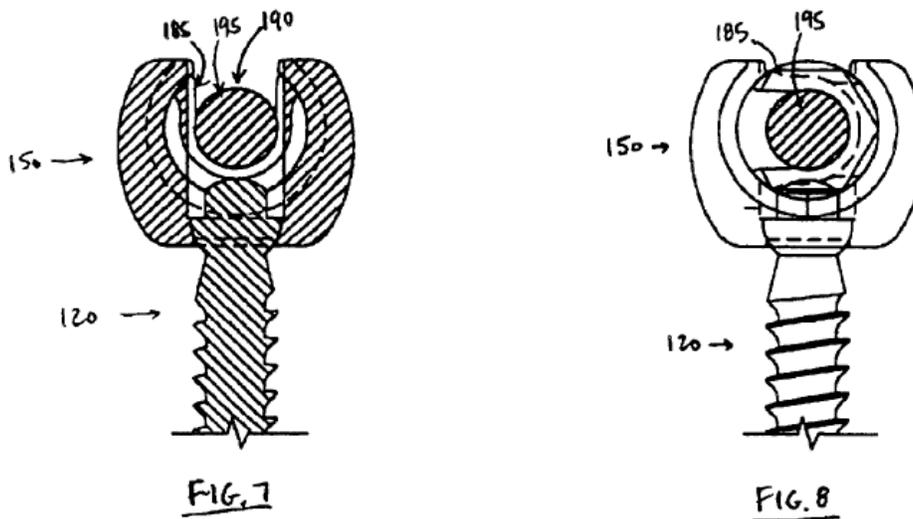
not subject to reasonable debate and the prosecution history does not support a different interpretation. *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009). Accordingly, the court corrects the specification of the '358 Patent (4:55–56) to read “6,743,231 (Gray, et al.)”

“Figure 11 [of the '231 Patent] illustrates a pedicle screw with a polyaxial head that can be set according to one embodiment of the invention.” '231 Patent, at 2:58–60.



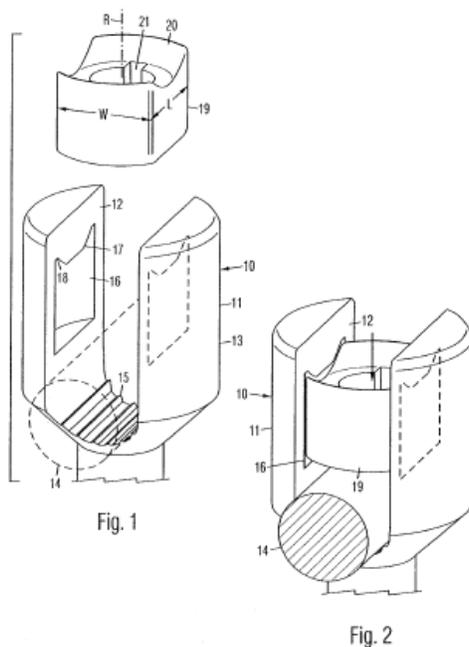
According to the '231 Patent, “[t]ypically, the mobility of polyaxial head 301 is set when **locking nut 302** is advanced distally along distal threads 303 **to force rod 304 against insert 305** which tightens around screw head 306 to set polyaxial head 301 in a fixed position.” '231 Patent, at 7:56–60 (emphasis added). According to this disclosure, it is the “locking nut 302” structure that performs the function of “secur[ing] the pedicle screw and spinal rod in a substantially fixed position and orientation.”

The second incorporated-by-reference patent, U.S. Patent No. 6,827,719, is entitled “Polyaxial Pedicle Screw Having a Rotating Locking Element.” In this patent, “[t]he screws [120] are provided with upper portions which comprise coupling elements [150], for receiving and securing an elongate rod [195] therethrough.” ’231 Patent, at 2:20–22. The patent shows images of the coupling mechanism 150 in the open (Fig. 7) and closed (Fig. 8) positions around a rod 195 in the rod-receiving channel 190.



There is a locking element 185 that is disposed within the coupling element 150. ’719 Patent, at 8:30–31. “Once the rods are in the rod receiving channels, the surgeon proceeds to move each locking element 185 into the locked position show in Fig. 8.” ’719 Patent, at 12:25–27. “[O]nce the locking element 185 is moved to the locked position, the screw 120, the coupling element 150, the locking element 185, and the rod 195 are all fixed relative to one another and to the bone.” ’719 Patent, at 13:9–12. Based on this disclosure, the rotatable locking element embedded within the spinal rod conduit is the structure in the ’719 Patent that performs the function of “secur[ing] the pedicle screw and spinal rod in a substantially fixed position and orientation.”

The third incorporated-by-reference patent, U.S. Patent No. 6,652,526, is entitled “Spinal Stabilization Rod Fastener.” The “spinal stabilization rod fastener is arranged to effectively secure a spinal stabilization rod.” ’526 Patent, at 3:60–61. This patent discloses a pedicle screw head that can receive a bridge 19 (’526 Patent, at 2:43), as shown in Figures 1 and 2.



Item 14 is a “bone stabilization rod.” ’526 Patent, at 2:42. According to these figures, the bone stabilization rod 19 is secured after the bridge structure is rotated into place. Based on this disclosure, the rotatable bridge structure that can fasten to the inner walls of the spinal rod conduit is the structure in the ’526 Patent that performs the function of “secur[ing] the pedicle screw and spinal rod in a substantially fixed position and orientation.”

The fourth patent, U.S. Pat. No. 6,375,657, is for a pedicle screw 10 “with a bore 18 through which a rod . . . is placed in order to support the spine.” ’657 Patent, at 3:39–40. Figure 1 of the ’657 Patent provides an image of this pedicle screw 10 and the bore 18 through which the spinal rod is threaded.

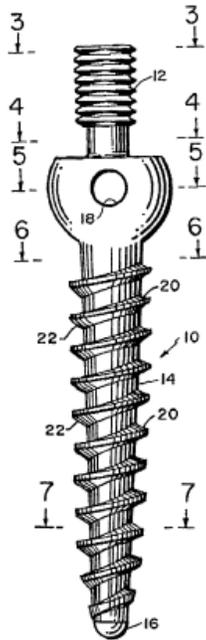


FIG. 1

The pedicle screw in this patent contains no structure for a spinal rod engagement means.

Construction of This Term.

“**Spinal Rod Engagement Means**” is a means-plus-function limitation.

The function is: **“to secure the pedicle screw and spinal rod in a substantially fixed position and orientation.”**

The structures corresponding to this function are the following structures and equivalents thereof:

1. **a two-piece nut and screw**, as described in '358 Patent, at 4:59–65, '121 Patent, at 5:1–7, and Figure 4 of both patents;
2. **locking nut**, as described in '231 Patent, at 7:56–60 and Figure 11;
3. **rotatable locking element embedded within a spinal rod conduit**, as described in '719 Patent, at 8:28–35 and Figures 7–8; and
4. **a rotatable bridge structure that can fasten to the inner walls of the spinal rod conduit**, as described in '526 Patent, at 2:66–3:11, and Figures 1–2.

E. [Ref. 7] “The Claimed Steps Must be Carried Out in the Recited Order.” ’358 Patent, Claims 1–5.

The last three steps of Claim 1 of the ’358 Patent read as follows:

A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of: . . .

selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes: . . .

extending said first length of said spinal rod member through said spinal rod conduits of one or more of said pedicle screws of said first set of pedicle screws; and

after applying said manipulative force to said first handle means, actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.

Defendant argues that these three steps must be carried out in the recited order.

Specifically, the spinal rod must be inserted into the pedicle screws and the spinal rod must then be rotated before the spinal rod engagement means are employed to secure the vertebrae. *See Barry Tr.* at 142:11–22.

Neither the Specification nor the Prosecution History Require That the Steps Be Performed in the Order Proposed by Defendant.

“As a general rule, ‘[u]nless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one.’” *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398-99 (Fed. Cir. 2014) (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001)). “However, a claim requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires an order of steps.” *Mformation*, 764 F.3d at 1398 (internal citation and quotation omitted). In

Mformation, the Federal Circuit upheld a district court decision that an “establish a connection” step must be performed before a “transmit” step. *Id.* One reason for the required order was that the “establish a connection” sub-step would be superfluous if a connection was not required before transmission. *Id.* A second reason was that the sole disclosed embodiment stated that transmission occurred “[u]pon connection . . . being established.” *Id.* (internal citation omitted). In another case, the Federal Circuit held that an order of steps was required based on a clear disclaimer during prosecution. *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1321 (Fed. Cir. 1999).

For the ’358 Patent, neither the specification nor the prosecution history require that steps be carried out in the order proposed by Defendant. During the *Markman* hearing, the court specifically asked Defendant to point out some lines in the specification or statements in the prosecution history that would require the seventh step of the claim, as listed in the claim itself, to be performed first or for steps seven, eight, and nine to be performed in order. *Barry Tr.* at 153:10–15. Defendant pointed to no such statement, arguing instead that under *Mformation* a court will require steps be performed in a particular order when the order is required for the invention to work. *See Barry Tr.* at 155:14–156:11.

There are two problems with Defendant’s argument. First, the *Mformation* holding was not based on whether the order of steps was required for the invention to work. Rather, the required order of steps was based on the claim language and the only embodiment of the “establishing a connection” sub-step in the specification. Second, the argument ignores cases where the Federal Circuit will accord claims their clear meaning even when the invention will not work as intended under that construed meaning. *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (affirming a district court’s construction requiring that

“dough be heated to a temperature range of 400° F. to 850° F,” even though the baked product would be unusable if the dough was heated to that temperature).

Defendant has pointed to nothing in the claims, specification, or prosecution history of the '358 Patent that “directly or implicitly requires an order of steps.” *Mformation*, 764 F.3d at 1398. That is the standard, not whether or not the invention will function according to a given construction. “[C]ourts may not redraft claims, whether to make them operable or to sustain their validity.” *Chef Am.*, 358 F.3d at 1374.

The claimed steps do not need to be carried out in the recited order.

F. [Ref. 10] “Handle Means,” ’121 Patent, Claims 2–4.

An exemplar use of the term is found in ’121 Patent, Claim 2, with the disputed terms in bold:

A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:

a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment; and

a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first **handle means** for facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first **handle means**, said first **handle means** having a handle linked to each pedicle screw engagement member

So Claim 2 of the ’121 Patent contains not only the term “handle means” but also the phrase “handle means for facilitating.” ’121 Patent, at 8:3, 8:25. Nevertheless, the court concludes that “handle means” and “handle means for” as used in the ’121 Patent are not means-plus-function terms and that they should be construed in the same manner as “handle means” in the ’358 Patent.

The Presence of the Phrase “Means For” Raises a Rebuttable Presumption That the Term “Handle Means” in the ’121 Patent Is a Means-Plus-Function Term.

Because the applications for these patents were filed before March 16, 2013, the pre-AIA § 112 ¶ 6 applies. Pub. L. No. 112-29, § 3(n), 125 Stat. 284, 293 (2011). Use of the word “means” in a claim limitation invokes a rebuttable presumption that § 112 ¶ 6 applies. *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015). The same presumption arises when the words “means for” are used. *Elbex Video, Ltd. v. Sensormatic Electrs. Corp.*, 508 F.3d 1366, 1370 (Fed. Cir. 2007).

The Means-Plus-Function Presumption Is Rebutted Because the Claims Recite Sufficient Structure to Perform the Function.

The means-plus-function presumption can be rebutted “if the claim recites sufficient structure for performing the described functions in their entirety.” *TecSec, Inc. v. Int’l Bus. Machs. Corp.*, 731 F.3d 1336, 1347 (Fed. Cir. 2013), *cert. denied sub nom. Cisco Sys., Inc. v. TecSec, Inc.*, 134 S. Ct. 2698 (2014). The court must first evaluate how the term “is used in the specification and the intrinsic record” before considering whether the limitation “contains additional structure to rebut the means-plus-function presumption.” *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1262 (Fed. Cir. 2010). One reason to consult the specification is to determine whether the patent “defines [the term at issue] as a particular structure.” *Id.* at 1263.

In the specification, there is only one instance of the phrase “handle means:” “The engagement between the pedicle screw cluster derotation tool and the individual pedicle screws is such that, as manipulative forces are applied to the **handle means** of pedicle screw cluster derotation tool, forces are transferred and dispersed simultaneously among the engaged vertebrae.” ’121 Patent, at 3:60–65 (emphasis added). This part of the specification

characterizes the “handle means” as a part of the “pedicle screw cluster derotation tool” to which forces are applied. The ’121 Patent, like the patent at issue in *Becton*, “defines [the term at issue] as a particular structure.” 616 F.3d at 1263.

Looking next at the claim itself, “the claim recites sufficient structure for performing the described functions in their entirety.” *TecSec*, 731 F.3d at 1347. Claim 2 of the ’121 Patent states that the handle means has “**a handle** linked to each pedicle screw engagement member of the [first/second] group of three or more pedicle screw engagement members and **a linking member to join together the handles** linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member.” ’121 Patent, at 8:7–13, 8:30–36 (emphasis added). This is sufficient structure for performing the claimed function of “facilitating simultaneous application of manipulative forces to said first set of pedicle screws and a [first/second] group of three or more pedicle screw engagement members which are mechanically linked with said [first/second] handle means.” ’121 Patent, at 8:3–7, 8:25–29. The presence of such structure in the claim language is sufficient to rebut the presumption that “handle means” is a means-plus-function term.

“Handle Means” Will Be Construed Identically for Both the ’358 and ’121 Patents.

The “handle means” term in the ’121 Patent will be accorded the same construction as the “handle means” term in the ’358 Patent. This is consistent with the presumption that “unless otherwise compelled, . . . the same claim term in the same patent or related patents carries the same construed meaning.” *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1380 (Fed. Cir. 2013) (quoting *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003)). In *Aventis Pharm.*, the Federal Circuit held that “substantially pure” should be construed differently as relating to an intermediate chemical product and a chemical end product.

“Substantially pure” was only used to describe the intermediate product in the patent at issue. In related patents it was only used to describe the end product. “Further, a person of ordinary skill in the art would recognize that an intermediate of the claimed chemical reaction would not be required to have the same purity as the end product.” *Aventis Pharm.*, 715 F.3d at 1374.

The present case is distinguishable from *Aventis Pharm.* because “handle means” has an essentially identical structure in both patents. The specifications of both patents contain identical language characterizing the “handle means” as a part of the “pedicle screw cluster derotation tool” to which forces are applied. ’358 Patent, at 3:54–59; ’121 Patent, at 3:60–65. The “handle means” in Claim 2 of the ’121 Patent is described as having “a handle linked to each pedicle screw engagement member of the [first/second] group of three or more pedicle screw engagement members.” ’121 Patent, at 8:7–10, 8:30–32. In the ’358 Patent, there are “pedicle screw engagement members which are mechanically linked with said [first/second] handle means.” ’358 Patent, at 6:15–17, 6:60–62. The difference is that the “handle means” in the ’121 Patent gives a specific number, three, for the quantity of “pedicle screw engagement members.” This difference is not sufficient to justify construing the terms differently in the two patents.

The court construes this term as follows:

“handle means” as used in the ’121 Patent shall be construed to mean “a part that is designed especially to be grasped by the hand.”

This is the same construction to which the parties agreed for “handle means” in the ’358 Patent. [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 1]; *Barry Tr.* at 5:19–6:7 (discussing Ct.’s Ex. 2).

G. [Ref #9] “wherein the steps of applying manipulative force to said first handle means and applying manipulative force to said second handle means are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition” (’358 Patent, Claims 4–5).

In response to a request by the court to list the most important disputed claim terms, this term was identified by Plaintiff as first and Defendant as second. It is closely related to Reference 4, which will be the next term to be discussed.

The parties propose the following constructions for this term:

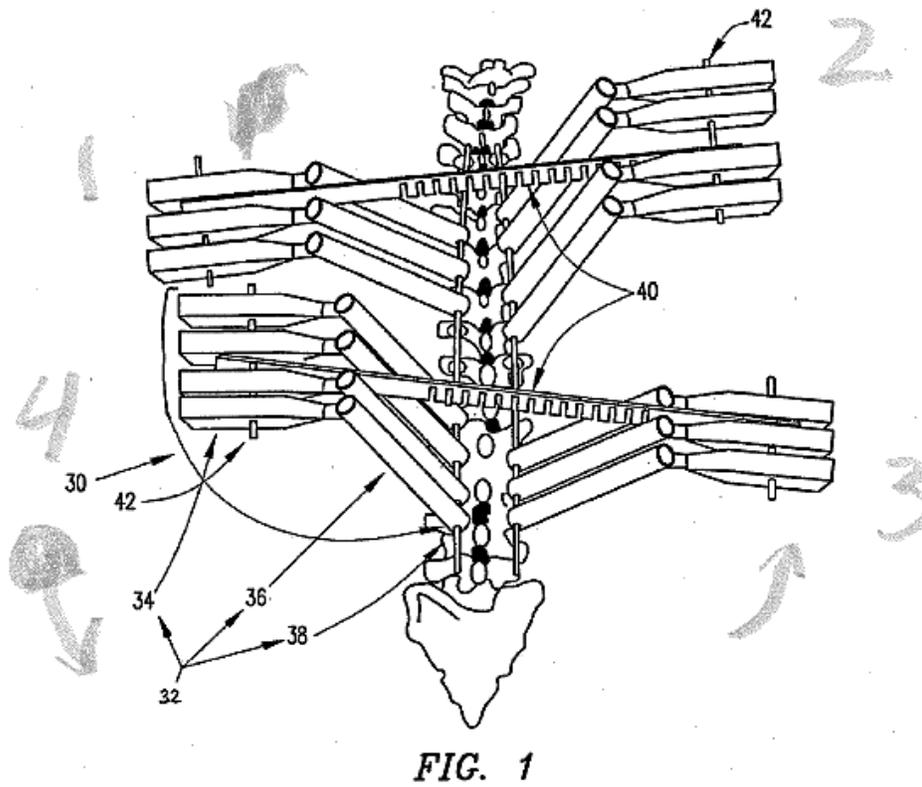
Plaintiff’s Construction	Defendant’s Construction
Further using wrench cross linking members to coordinate forces applied to screw clusters on either side of the spinal column to correct an aberrant spinal column deviation condition. [Opening Brief, Dkt. # 93, at 10].	Applying an external single action force to each of the handle means of the respective tools at about the same time. [Opp. Brief, Dkt. # 108, at 22].

The first issue is whether this term requires the use of wrench cross linking members, as argued by Plaintiff. [Opening Brief, Dkt. # 93, at 10]. The ’358 Patent shows a wrench cross linking member (item 40) in Figure 1 (see below) and describes the use of the wrench cross linking member as follows: “Ordinarily, two tools 30 will be involved on either side of the spinal column, with two pedicle screws 10 being implanted in each vertebrae, as shown. Wrench cross linking members 40 are used to coordinate forces applied to screw clusters on either side of the spinal column.” ’358 Patent, at 5:7–11. Use of the phrase “ordinarily” indicates that the use of a wrench cross linking member is merely a preferred embodiment.

During the *Markman* hearing, the court asked if Plaintiff really wanted to define the wrench cross linking member as part of its method claim. *Barry Tr.*, at 31:23–32:10. The

Federal Circuit has “held that reciting both an apparatus and a method of using that apparatus renders a claim indefinite under section 112, paragraph 2.” *Rembrandt Data Techs., LP v. AOL, LLC*, 641 F.3d 1331, 1339 (Fed. Cir. 2011) (internal citations and quotations omitted). Plaintiff argued that the tools must be linked by the wrench cross linking member in order for the doctor to apply forces “substantially simultaneously.” *Barry Tr.* at 33:4–13. However, Plaintiff’s expert at the hearing, Dr. Barry, testified that the method described in the patent can be performed without a wrench cross linking member. *Barry Tr.* at 39:9–40:2.

Ct.’s Ex. 10 is a copy of Figure 1 from the ’358 Patent with the four tools numbered, with arrows indicating the forces applied to the handles. *Barry Tr.* at 33:17–22, 35:20–36:3, and 38:20–39:6 (discussing Ct.’s Ex. 10).



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Court Ex # 10

After discussing Ct.'s Ex. 10 with Dr. Barry, the court discussed Ct.'s Ex. 11 with him. Ct.'s Ex. 11 is a modified version of Ct.'s Ex. 10, based on Figure 1 of the '358 Patent, in which the top two tools (tools 1 and 2 of Ct.'s Ex. 10) and the wrench cross linking member 40 between tools 3 and 4 of Ct.'s Ex. 10 were whited out:

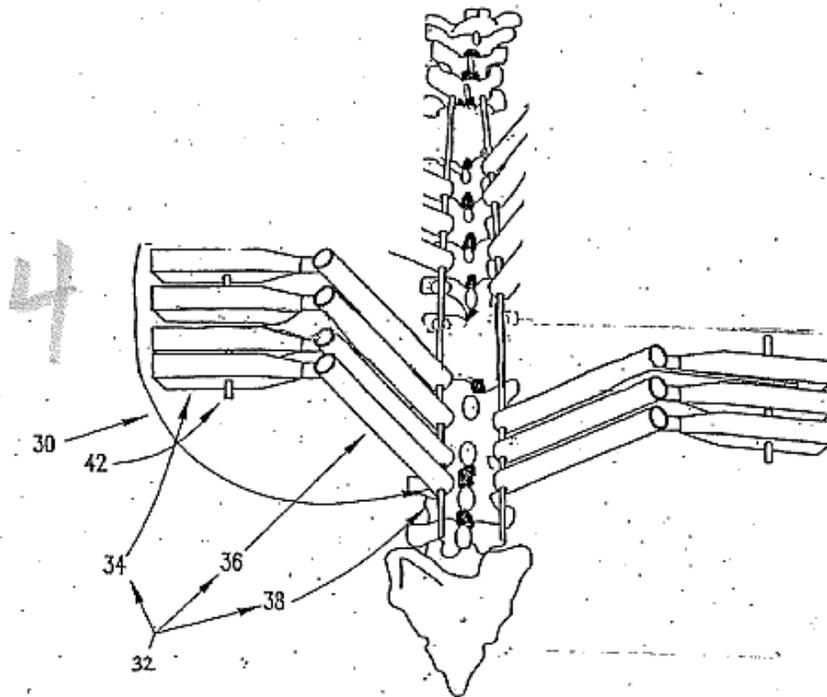


FIG. 1. (Modified)

Court Ex. # 11

Specifically, the court had the following conversation with Dr. Barry regarding Ct.'s Ex. 11:

THE COURT: All right. Here is Figure 1 modified, and it will be Court's Exhibit 11. And I think, doctor, I've already got the answer because I think you indicated this before. But it would be technically possible for a surgeon not to use the cross-linking member 40. And I guess it would be technically possible for the surgeon . . . to simply grasp what we have numbered as the handles for Tool 4 and the handle for Tool 3, twist again to the left, and achieve some derotation?

DR. BARRY: Yes.

THE COURT: Probably not as good as with the Number 40 cross-linking member because then the surgeon is going to have to be much more careful, I assume, to try to provide pretty equal force on the two handles, right?

DR. BARRY: Yes.

Barry Tr. at 39:9–40:2 (discussing Ct.’s Ex. 11).

Consistent with Dr. Barry’s testimony, Plaintiff’s counsel (Mr. DeBruine) argued that the preferred or ordinary way to apply forces “substantially simultaneously” was with a wrench cross linking member. But he did not state that the claim language required the use of a wrench cross linking member.

MR. DeBRUINE: Now, it’s possible that a surgeon, much better hands than I have, can actually get these two things to move together free-handing. It’s very likely that that wouldn’t occur.

THE COURT: All right.

MR. DeBRUINE: So, what does the patent tell us? It tells us the importance of moving these together, distributing force. And, ordinarily, the way to get these two tools to move together is to link them.

Barry Tr. at 44:23–45:6.

The Federal Circuit has cautioned that “even if ‘all of the embodiments discussed in the patent’ included a specific limitation, it would not be ‘proper to import from the patent’s written description limitations that are not found in the claims themselves.’” *Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) (quoting *Flo Healthcare Solns., LLC v. Kappos*, 697 F.3d 1367, 1375 (Fed. Cir. 2012)). Under this rule, even though Figure 1 of the ’358 Patent shows tools linked by wrench cross linking members 40, absent claim language or specification support limiting the invention to the use of wrench cross linking members, it is inappropriate to include this limitation in the construction.

This is especially true given the statements of Dr. Barry and his attorney. Dr. Barry and his attorney argued strenuously that using a wrench cross linking member such as item 40 in Fig. 1 was a better way or the best way to equalize force between two tools. *Barry Tr.* at 41:13–45:14. The court agrees that a wrench cross linking member tool is likely to make the method and the tools work better. *See e.g., Barry Tr.* at 43:6–22. But the court may not import limitations from the specification into the claim—not even limitations described for the best mode or the preferred embodiment. The court concludes that the claim language does not require the presence of a wrench cross linking member.

Defendant raised two concerns. The first related to its contention that “amelioration” was indefinite, thus making the whole term indefinite. The court has dealt with this issue above in discussing Reference 5. Defendant’ proposed construction also sought to include the language “single action force.” [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 15]. During the *Markman* hearing, the court asked Defendant how this added anything to the “single motion” limitation in Claim 1, from which Claim 4 depends. *Barry Tr.* at 46:2–22. Defendant agreed that “single action force” was covered by the “single motion” limitation in Claim 1. *Barry Tr.* at 48:18–21, 50:14–20, 51:17–52:7.

Construction

The court construes the terms in this claim phrase as follows:

“wherein the steps of applying manipulative force to said first handle means and applying manipulative force to said second handle means are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition” means “applying manipulative force to both of the handle means of the respective tools at substantially the same time so that tools attached to these handles work together to cooperatively achieve an amelioration of an aberrant spinal column deviation condition,” and

“handle means” means **“a part that is designed especially to be grasped by the hand,”** and

“amelioration of an aberrant spinal column deviation condition” carries its normal, customary meaning.

H. [Ref #4] **“applying manipulative force to said [first/second] handle means in a manner for simultaneously engaging said [first/second] group of pedicle screw engagement members and [first/second] set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said [first/second] group of multiple vertebrae”** (’358 Patent, Claims 1 and 2)

This dispute is closely related to the dispute over Reference 9, which dealt with very similar terms in ’358 Patent, Claims 4 and 5. An exemplar use of the term is found in ’358 Patent, Claim 1, with the disputed term in bold:

A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of: . . .

applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition

Plaintiff argued that no construction was necessary and Defendant proposed the following construction:

“Applying an external single action force to the handle means that rotates all of the vertebrae of the claimed group of multiple vertebrae.”

[Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 5–6].

The problem with Defendant’s construction is that it merely restates two claim limitations and leaves out two others. *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) (“Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.”).

The phrase “applying an external single action force to said first handle means” in the proposed construction [Dkt. # 93-10, at 5–6] is virtually identical to the claim limitation “applying manipulative force to said first handle means.” ’358 Patent, at 6:29. Likewise, “rotates all of the vertebrae of the claimed group of multiple vertebrae” in the proposed construction [Dkt. # 93-10, at 5–6] merely restates the claim limitation “rotating said vertebrae of said first group of multiple vertebrae.” ’358 Patent, at 6:33–34.

Defendant’s proposed construction leaves out the claim limitations “simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws” and “in a single motion simultaneously rotating.” ’358 Patent, at 6:30–33.

The court agrees with Plaintiff that the words and phrases of this lengthy element of Claim 1 and Claim 2 should be accorded their customary meaning. In light of the claim language and the specification, the meaning would be apparent to a PHOSITA and readily apparent to a jury. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (recognizing that “district courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims”).

In this term, “handle means” will carry the meaning that the parties have agreed to:

“handle means” means “a part that is designed especially to be grasped by the hand.”

Otherwise, the term carries its plain and ordinary meaning.

I. [Ref #8] “Second Group of Multiple Vertebrae.” ’358 Patent, Claims 2 and 3.

An exemplar use of the term is found in ’358 Patent, Claim 2, with the disputed terms in bold:

The method of claim 1 further comprising the steps of:

selecting a second set of pedicle screws; . . .

implanting each pedicle screw in a pedicle region of each of a **second group of multiple vertebrae** of a spinal column which exhibits an aberrant spinal column deviation condition;

engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said second set of pedicle screws; and

applying manipulative force to said second handle means in a manner for simultaneously engaging said second group of pedicle screw engagement members and said second set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said **second group of multiple vertebrae** in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition.

Plaintiff argues that the words should be given their ordinary meaning. [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 13]. Defendant proposes that this term should be construed to mean:

“A separate and different group of vertebrae from the ‘first’ group that does not include any vertebra in the first group.”

Id. Defendant’s support for its construction is based in part on the following sentence in the specification:

For example, as depicted in FIG. 5, in the case of a single curvature case of scoliosis, both derotative forces (illustrated by the central force vector arrow of FIG. 5) to vertebrae involved in scoliotic curvatures, as well as of balancing, or offsetting forces to contiguous spinal segments cephalad and caudad (illustrated by the lateral arrows of FIG. 5) are applied.

’358 Patent, at 5:40–46 (emphasis added).

During the *Markman* hearing, the court repeatedly asked Defendant why one group of vertebrae could not be a subset of a second group, as shown in Ct.’s Ex. 10, where tool 3 engages a subset of the vertebrae engaged by tool 4. *Barry Tr.* at 158:3–16, 159:10–11. Defendants have

not explained why in this case the court should construe a claim term so as to exclude an embodiment described in the specification. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) (rejecting claim construction that would exclude embodiments illustrated in the drawings).

Defendant first responded by stating that under the ordinary rules of English grammar, “first group” and “second group” refer to different groups. *Barry Tr.* at 158:17–25, 159:12–13. Defendant also argued that one group could not be a subset of a second group because the spinal groups have to be contiguous in the ’358 Patent. *Barry Tr.* at 161:16–25, 163:14–18. According to Defendant, the ’358 Patent “really is only talking about where you have a tool at the top left and a tool at the bottom left or a tool at the top right and a tool at the bottom right” such that the vertebrae are “separate and distinct groups that don’t overlap.” *Barry Tr.* at 164:22–165:3. This is based on the presence of the word “contiguous” in the ’358 Patent (col. 5, l. 44), a word that was changed to “lateral” in ’121 Patent (col. 5, l. 45). Defendant asserts that this change in wording means that it is only in the ’121 Patent that “two tools . . . could be across from each other” and “multiple groups of vertebrae could overlap.” *Barry Tr.* at 165:6–8.

Defendant’s argument is undermined by the fact that its specification support begins with the phrase “[f]or example,” which implies that Figure 5 is merely an illustrative embodiment. Absent clear claim language to the contrary, it is error for a court to limit a claim construction to a preferred embodiment. *See Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”).

Also, as noted by the court during the *Markman* hearing, this section of the specification is referring to applying forces, not tools. ’358 Patent, at 41–46 (“[B]oth derotative **forces** [and]

balancing, or offsetting **forces** . . . are applied.”) (emphasis added); *Barry* Tr. at 162:7–11.

Defendant did not respond to this argument. Because Defendant’s specification support refers to a preferred embodiment only directed to forces, not tools, it does not support a construction for which the “second group of multiple vertebrae” does not include any vertebrae in the “first group of multiple vertebrae.” ’358 Patent, at 6:23 (Claim 1, “first group . . .”), 7:2 (Claim 2, “second group . . .”).

3M Innovative Props. Co. v. Avery Dennison Corp. is not to the contrary. 350 F.3d 1365 (Fed. Cir. 2003). In that case, the court held that the use of the claim terms “first . . . pattern” and “second . . . pattern” referred to different patterns. *Id.* at 1371. But those terms were described as having different characteristics in both the claim language and the specification. *Id.* at 1368. In the present case, there is no language that requires the two groups of vertebrae be non-overlapping.

This term will carry its ordinary meaning.

J. [Ref #12] “a linking member (or handle linking member) to join together the handles linked to the pedicle screw engagement members” (’121 Patent, Claim 2).

This term is found in Claim 2 of the ’121 Patent and highlighted below in bold:

A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising: . . .

said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and **a linking member to join together the handles linked to the pedicle screw engagement members**, wherein the handle means is configured to move simultaneously each pedicle screw engagement member;

Plaintiff asserts that the term needs no construction. [Joint Claim Construction Chart, Dkt. # 93-10 (Ex. I), at 22]. Defendant proposes the following construction for this term:

“A single rod that joins all of the handles of the group of three or more unitary pedicle screw wrenches (i.e., Item 42 of Figure 1).”

Id.

The '121 Patent describes Item 42 as follows: “As depicted in FIG. 1, each pedicle screw cluster derotation tool 30 is configured from a grouping of pedicle screw wrenches 32, by a pedicle screw wrench linking member 42 joined together to act in unison during use.” '121 Patent, at 5:10–13. During the *Markman* hearing, Defendant stated that “the point is it’s a single piece, and that’s all that’s disclosed in the specification of the patent. *Barry Tr.* at 171:24–172:1.

Neither the Claims nor the Specification Require that the “Linking Member to Join Together the Handles Linked to the Pedicle Screw Engagement Members” Be a Single Piece.

The claim language itself suggests that the “linking member to join together the handles linked to the pedicle screw engagement members” can be more than one structure. The term is preceded by the indefinite article “a,” which the Federal Circuit has held means “one or more” in a claim term containing the word “comprising,” absent a clear intent to limit the claim to “one.” *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342–43 (Fed. Cir. 2008). The claims contain no indication that Plaintiff intended to limit the invention to only one “linking member to join together the handles linked to the pedicle screw engagement members.”

The specification does not limit the “linking member to join together the handles linked to the pedicle screw engagement members” to a single piece. It is true that it is shown as a single rod in the Figure 1 embodiment. The Federal Circuit has cautioned “even if ‘all of the embodiments discussed in the patent’ included a specific limitation, it would not be ‘proper to import from the patent’s written description limitations that are not found in the claims themselves.’” *Cadence Pharm.*, 780 F.3d at 1369 (quoting *Flo Healthcare*, 697 F.3d at 1375). Under this rule, absent claim language limiting the “linking member to join together the handles

linked to the pedicle screw engagement members” to a single piece, it is inappropriate to include such a limitation in the construction.

There Is No Prosecution Disclaimer.

Plaintiff’s statements during the prosecution of U.S. Patent Application No. 13/645,589 (“’589 App”) are not a clear and unmistakable disavowal of claim scope. The ’589 App has the same seven figures as the ’121 Patent and has shares much of the same specification. But the ’589 App does not claim priority to the ’358 Patent or the ’121 Patent.

“When a patentee makes a clear and unmistakable disavowal of scope during prosecution, a claim’s scope may be narrowed under the doctrine of prosecution disclaimer.” *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1341 (Fed. Cir. 2012). The purpose of this doctrine is to “preclud[e] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). There is no such disavowal where statements “do not unambiguously focus on the characteristics of the [element]” or “distinguish it from the prior art.” *Grober*, 686 F.3d at 1342. Statements made during the prosecution of a later-filed application can limit the scope of an earlier-filed application in the same patent family. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004).

But there was no clear and unmistakable disavowal of claim scope in the prosecution statements identified by Defendant. Defendant’s basis for prosecution disclaimer involves a limitation (emphasized below) in Claim 13 of the ’589 App, which reads as follows:

A system for aligning human vertebrae comprising:

, said first pedicle screw cluster derotation tool having a first set of at least three pedicle screw engagement members configured to engage the heads

of the corresponding first set of at least three pedicle screws, **said first set of pedicle screw engagement members being interconnected by a first linking member** such that application of the rotative force in the single motion to said pedicle screw engagement members simultaneously moves all of the interconnected pedicle screw engagement members;

[Patentee's Amendments and Response, Dkt. # 108-13 (Ex. L), at 5]. During prosecution of the '589 App, Plaintiff distinguished a piece of prior art by stating that it failed to teach the limitation of "said first set of pedicle screw engagement members being interconnected by a *first linking member*." [Patentee's Amendments and Response, Dkt. # 108-13 (Ex. L), at 9] (emphasis in original). According to Plaintiff, the prior art required "multiple linking members . . . to link together three guides." *Id.*

There is no clear, unmistakable disavowal of scope because the linking members in the '589 App and the '121 Patent connect different structures. In Claim 13 of the '589 App, the linking member directly connects pedicle screw engagement members that do not have handles. [Patentee's Amendments and Response, Dkt. # 108-13 (Ex. L), at 5]. In the '121 Patent, the linking member is used "to join together **the handles linked to** the pedicle screw engagement members." '121 Patent, at 8:10–12 (Claim 2) (emphasis added). In other words, in the '589 App the linkage members connect pedicle screw engagement members lacking handles and in the '121 Patent the linkage members connect handles linked to pedicle screw engagement members. Because the linking members in the '589 App do not connect handles, any potential disclaimer there does not limit the characteristics of the handle-connecting linking members of the '121 Patent.

No Construction Needed.

In light of the claim language and the specification, the meaning of “a [handle] linking member to join together the handles linked to the pedicle screw engagement members” would be apparent to a PHOSITA and would be readily understandable to the jury. *See O2 Micro*, 521 F.3d at 1362 (recognizing that “district courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims”). Defendant’s proposed construction reciting “a single piece” or “a single rod” would import claim limitations that are not required by the claim language or the intrinsic record. No construction is necessary for this term.

K. [Ref #13] “cross-linking member that links the first handle means to the second handle means” (’121 Patent, Claim 2).

An exemplar use of the term is found in ’121 Patent, Claim 2, with the disputed term in bold:

A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising: . . .

a cross-linking member that links the first handle means to the second handle means.

Plaintiff argues ordinary meaning. [Opening Brief, Dkt. # 93, at 23]. Defendant proposes the following construction:

A cross-tool connector (i.e., Item 40 of Figure 1) that connects the first handle means of the first pedicle screw cluster derotation tool on one side of the spine to the second handle means of the second pedicle screw cluster derotation tool on the other side of the spine.

[Opp. Brief, Dkt. # 108, at 26].

Having already construed “handle means” in the ’121 Patent, the only remaining part of this term requiring construction is “a cross-linking member.” The claims of the ’121 Patent only

describe the “cross-linking member” as connecting the first and second handle means of the pedicle screw cluster derotation tools. ’121 Patent, at 7:41–42 (Claim 1); ’121 Patent, at 8:44–45 (Claim 2). The specification mentions the cross-linking member in the following sentence only: “For example, the multiple wrenches 32, linked by wrench cross linking members 40, depicted in FIG 1” ’121 Patent, at 5:22–24.

In light of the claim language and the specification, the meaning of “a cross-linking member” would be apparent to a PHOSITA and would be readily understandable to the jury. *See O2 Micro*, 521 F.3d at 1362 (recognizing that “district courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims”). Defendant’s proposal to replace “a cross-linking member” with “a cross-tool connector,” a term that does not appear in the ’121 Patent Specification, would not clarify the meaning of this term.

Defendant offers two reasons that “cross-tool connector” should be included in the construction of this term. [Opp. Brief, Dkt. # 108, at 26–27]. The first reason is that in Figure 1 the object is shown connecting two tools. This is no reason to replace the claim term “cross linking member” with “cross-tool connector,” a phrase that does not occur in the patent. Second, Defendant points out that the original patent application used the term “cross-tool linkage member,” [Original Application of ’358 Patent, Dkt. # 108-2 (Ex. A), at 15], which was changed to “wrench cross linking members” in the issued patent. ’358 Patent, at 5:9. But Defendant provides no explanation for why this change was made and no legal argument as to why Plaintiff is somehow bound by the term “cross tool connector” because it decided to change “cross-tool linkage member” to “wrench cross linking members.”

Defendant also argues that the construction should stipulate that the handle means are located on both sides of the spine. The whole point of claims 2–4 is that there is a second tool

working together with the first tool to provide derotative force. If the tools are on the same side, the cross-linking member connecting handle means becomes the linking member that joins together individual handles. '121 Patent, at 8:10–11. The presence of handle means on opposite sides of the spine is consistent with the ordinary meaning of this term.

In this term, “handle means” will carry the same meaning stated in reference 10:

“handle means” means “a part that is designed especially to be grasped by the hand.”

Otherwise, the term carries its plain and ordinary meaning.

L. [Ref #14] “wherein the rod is precontoured” ('121 Patent, Claim 4).

This term is found in '121 Patent, Claim 4, with the disputed term in bold:

The system of claim 3 **wherein the spinal rod is precontoured.**

During the *Markman* hearing, the parties agreed to a construction of this term. *Barry Tr.* at 183:14–23 (discussing Ct.’s Ex. 21). In keeping with the parties’ agreement, the court construes this term as follows:

“wherein the rod is pre-contoured” means “the spinal rod is bent to the approximate desired curvature of the spine before being extended through the spinal rod conduits.”

V. CONCLUSION

The jury will be instructed in accordance with the court’s interpretation of the disputed claim terms in the '358 and '121 Patents.

So **ORDERED** and **SIGNED** this **22** day of **December, 2015**.



Ron Clark, United States District Judge