IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MEDTRONIC SOFAMOR DANEK	:	CIVIL ACTION
USA, INC., et al.,	:	
	:	
Plaintiffs,	:	NO. 06-4248
	:	
V.	:	
	:	
GLOBUS MEDICAL, INC.,	:	
	:	
Defendant.	:	

MEMORANDUM AND ORDER

Giles, J.

March 18, 2008

This is a patent infringement case in which Medtronic Sofamor Danek USA, Inc.,

Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf, GmbH (collectively "Medtronic") seeks, *inter alia*, to enjoin Globus Medical, Inc. ("Globus") from marketing products that Medtronic contends infringe on its patents. Nine patents are in dispute:

- 1. U.S. Patent No. 7,008,422 (filed Mar. 7, 2006) ("the '422 patent");
- 2. U.S. Patent No. 6,530,929 (filed Mar. 11, 2003) ("the '929 Patent");
- 3. U.S. Patent No. 7,188,626 (filed Mar. 13, 2007) ("the '626 Patent");
- 4. U.S. Patent No. 7,011,660 (filed Mar. 14, 2006) ("the '660 Patent");
- 5. U.S. Patent No. 6,793,656 (filed Sep. 21, 2004) ("the '656 Patent");
- 6. U.S. Patent No. 6,485,491 (filed Nov. 26, 2002) ("the '491 Patent");
- 7. U.S. Patent No. 6,916,320 (filed Jul. 12, 2005) ("the '320 Patent");

8. U.S. Patent No. 7,066,961 (filed Jun. 27, 2006) ("the '961 Patent"); and

9. U.S. Patent No. 7,063,725 (filed Jun. 20, 2006) ("the '725 Patent").

Medtronic filed its original Complaint on September 22, 2006, asserting claims challenging six patents. This court subsequently granted Medtronic leave to amend its Complaint three times, and a total of nine patents are contested. Globus has filed counterclaims seeking, *inter alia*, declaratory judgments of non-infringement and invalidity of all claims of the asserted patents and non-enforceability of the '656 patent. The parties briefed the claim terms to be construed in the patents in suit, and the court held a <u>Markman</u> hearing on February 4, 2008.

I. <u>Background</u>

A. The '422 patent.

1. Overview of the invention.

The '422 patent, titled "Instruments and Methods for Stabilization of Bony Structures," relates to minimally invasive "percutaneous" surgeries. The '422 patent describes "devices and methods for insertion of an orthopedic brace to one of more anchors secured to an animal subject." '422 Patent, col.2 ll.1-3.

2. Relevant claims.

The parties dispute claims 26, 29, 42, 48, and 49 of the '422 patent. All the disputed claims relate to surgical methods. The relevant claims read as follows:

26. A method of installation of a connecting element in an animal subject, comprising: placing first and second anchors in first and second bony parts of the body; mounting an installation instrument on the first and second anchors, the installation instrument having the connecting element secured thereto; and moving the installation instrument to position the connecting element more proximate the first and second anchors.

29. A method of installation of a brace in an animal subject, comprising: placing

first and second anchors mounted on first and second anchor extensions, respectively, in first and second bony parts of the body; mounting a brace inserter on the first and second anchor extensions; and guiding the brace into a desired position relative to the anchors with the brace inserter.

42. A minimally invasive surgical method, comprising: positioning at least a pair of anchors within a body of a patient; contacting a connecting element with an insertion instrument; referencing a position of the connecting element relative to a position of the pair of anchors; and percutaneously inserting the connecting element into a desired subcutaneous position relative to the pair of anchors.

48. A minimally invasive surgical method for spinal stabilization, comprising: positioning at least a pair of anchors within at least a corresponding pair of vertebral bone portions; contacting a connecting element with an insertion instrument referenced to the pair of anchors; and percutaneously inserting the connecting element into a desired subcutaneous position relative to the pair of anchors.

49. A minimally invasive surgical method, comprising: positioning at least a pair of anchors within a body of a patient, where each of the pair of anchors comprises an anchor portion and a receiver member movably connected to the anchor portion, where each receiver member comprises a body having a passageway therethrough; and percutaneously controlling a position of the passageway of each respective receiver member.

3. Terms in Dispute.

The parties dispute the following terms from the '422 Patent:

- a. installation instrument (claim 26)
- b. mounting (claims 26 and 29)
- c. brace inserter (claim 29)
- d. referencing a position of the connecting element relative to a position of the pair of anchors (claim 42)
- e. percutaneously inserting the connecting element (claims 42 and 48)

B. The '929 Patent.

1. Overview of the invention.

The '929 patent and the '422 patent share a common patent specification. The common

specification describes instruments and methods for inserting a connecting element into the spine in minimally invasive "percutaneous" surgeries.

2. Relevant claims.

The parties dispute claims 45, 47, 74, 95, 96, and 98 of the '929 patent. The disputed

claims focus on surgical devices and systems that can be used in percutaneous surgeries. Claims

45, 74, 95, and 96 are independent claims. Claim 47 is dependent upon claim 45, and claim 98 is

dependent upon claim 97.

The relevant claims read as follows:

45. A minimally invasive surgical device, comprising: at least a pair of anchors positionable within a body of a patient; a connecting element positionable within the body; and an instrument associated with the connecting element, the instrument being operable to percutaneously place the connecting element in a predetermined location relative to the pair of anchors.

47. The minimally invasive surgical device of claim 45, wherein the instrument comprises a mechanical guide for directing the connecting element along a predetermined path.

74. A minimally invasive surgical system, comprising: at least a pair of anchors positionable within a body of a patient; a connecting element having a geometry configured for connection with the pair of anchors, the connecting element movable between a first position corresponding to a percutaneous insertion position of the connecting element with respect to the body, and a second position within the body, the second position having a predetermined relationship with respect to the position of the pair of anchors; and an inserter referenced to the pair of anchors, the inserter being operable to move the connecting element along a predetermined path between the first position and the second position.

95. A minimally invasive surgical system for spinal stabilization, comprising: at least a pair of anchors positionable within at least a corresponding pair of vertebral bone portions; a connecting element, the connecting element being positionable to a predetermined location relative to the pair of anchors; and an instrument associated with the connecting element, the instrument being operable to percutaneously place the connecting element in the predetermined location.

96. A minimally invasive surgical system for spinal stabilization, comprising: at

least a pair of anchors positionable within at least a corresponding pair of vertebral bone portions within a body; a connecting element having a geometry configured for connection with the pair of anchors, the connecting element having a first position corresponding to a percutaneous insertion position of the connecting element with respect to the body, and a second position within the body, the second position having a predetermined relationship with respect to the position of the pair of anchors; and an inserter referenced to the pair of anchors, the inserter being operable to move the connecting element along a predetermined path between the first position and the second position.

97. A minimally invasive surgical system, comprising: at least a pair of anchors positionable within a body of a patient; at least a pair of receiver members movably connectable to a corresponding one of the pair of anchors, each of the pair of receiver members comprising a body having a passageway therethrough; and an alignment mechanism percutaneously extendable within the body and connectable with the pair of receiver members, the alignment mechanism operable for controlling a position of the passageway of each respective receiver member.

98. The minimally invasive surgical system of claim 97, further comprising: a connecting element positionable within the body to a predetermined location relative to each of the passageways; and an instrument associated with the connecting element, the instrument being operable to percutaneously place the connecting element in the predetermined location.

3. Terms in Dispute.

The parties dispute the following terms from the '929 Patent:

- a. an instrument associated with the connecting element (claim 45)
- b. the instrument being operable to percutaneously place the connecting element (claims 45, 95, and 98)
- c. in a predetermined location relative to the pair of anchors (claim 45)
- d. mechanical guide for directing the connecting element along a predetermined path (claim 47)
- e. percutaneous insertion position (claims 74 and 96)
- f. the inserter being operable to move along a predetermined path (claims 74 and 96)

g. positionable to a predetermined location (claim 95)

C. The '626 Patent.

1. Overview of the invention.

The '626 patent is a continuation-in-part of the application of the '929 patent. The '626 patent shares a common patent specification with the '422, '929, and '660 patents, and it likewise describes instruments and methods for inserting a connecting element into the spine in a minimally invasive "percutaneous" procedure.

2. Relevant claims.

The parties dispute claims 17, 19, 35, 39, and 50. The disputed claims relate to methods for inserting a connecting element into anchors. Claims 17, 35, 39, and 50 are independent

claims, and claim 19 is dependent upon claim 17. The relevant claims read as follows:

17. A minimally invasive surgical method, comprising: positioning through a single incision at least a pair of anchors within a body of a patient; providing a connecting element; referencing a position of the connecting element relative to a position of an extension extending proximally from at least one of the pair of anchors through the incision; and percutaneously inserting the connecting element into a desired position relative to the pair of anchors.

19. The method of claim 17, further comprising coupling the connecting element with an insertion instrument mountable on the at least a [sic] pair of anchors.

35. A minimally invasive surgical method, comprising: making an incision in a patient; placing a first anchor through the incision; engaging the first anchor to a first bony element, the first anchor including a first anchor extension extending therefrom through the incision; placing a second anchor through the incision; engaging the second anchor to a second bony element, the second anchor including a second anchor extension extending therefrom through the incision; percutaneously guiding a connecting element to a position relative to the first anchor and the second anchor; and securing the connecting element to the first anchor and to the second anchor.

39. A minimally invasive surgical method, comprising: making an incision in a patient; positioning a first anchor with a first anchor extension through the

incision; engaging the first anchor to a first bony element; positioning a second anchor with a second anchor extension through the incision; engaging the second anchor to a second bony element; referencing a connecting element to at least one of the anchor extensions; and percutaneously positioning the connecting element to the first anchor and the second anchor.

50. A minimally invasive surgical method, comprising: making an incision in a patient; positioning a first anchor with a first anchor extension through the incision; engaging the first anchor to a first bony element; positioning a second anchor with a second anchor extension through the incision; engaging the second anchor to a second bony element; referencing a connecting element to at least one of the anchor extensions; and percutaneously positioning the connecting element adjacent to the first anchor and the second anchor.

3. Terms in Dispute.

The parties dispute the following terms from the '626 Patent:

- a. percutaneously inserting the connecting element (claim 17)
- b. percutaneously guiding the connecting element (claim 35)
- c. percutaneously positioning the connecting element (claims 39 and 50)
- d. insertion instrument (claim 19)

D. The '660 Patent.

1. Overview of the invention.

The '660 patent is a continuation-in-part of the application of the '929 patent. The '660 patent shares a common patent specification with the '422, '929, and '626 patents, and it likewise describes instruments and methods for inserting a connecting element into the spine in a minimally invasive "percutaneous" procedure.

2. Relevant claim.

The parties dispute claim 1 of the '660 patent. Claim 1 is an independent claim that reads as follows:

1. A brace installation instrument, comprising: at least one anchor extension including a proximal end and a distal end mountable with a corresponding anchor securable to a bony structure; and a brace inserter having a proximal end and a distal end, the proximal end mounted adjacent the proximal end of said at least one anchor extension and said brace inserter extending to a brace mounting portion at the distal end thereof, said brace inserter being movable relative to said at least one anchor extension, and further comprising a second anchor extension including a proximal end coupled to the proximal end of said brace inserter.

3. Terms in Dispute.

The parties dispute the following terms from the '660 patent:

- a. brace installation instrument (claim 1)
- b. brace inserter (claim 1)
- c. mounted (claim 1)
- d. said brace inserter being movable relative to said at least one anchor extension (claim 1)
- e. coupled (claim 1)

E. The '656 Patent.

1. Overview of the invention.

The '656 patent, titled "Systems and Methods for Fixation of Adjacent Vertebrae,"

describes a method for internal fixation of vertebra via minimally invasive surgery using

specially sized and shaped tissue dilators to implant bone screws into vertebral bones while

minimizing damage to the patient's skin and muscle. '656 patent abstract.

2. Relevant claims.

The parties dispute claims 8 and 12 of the '656 patent. Both are independent claims, and they read as follows:

8. A minimally invasive surgical system for fusing adjacent vertebrae, comprising: at least three tissue dilators each including a bore therethrough, said

bores being of increasing diameter wherein said at least three tissue dilators are positionable one over the other to sequentially dilate tissue to provide access through tissue to at least one of the adjacent vertebrae; at least one bone screw engageable to each of the adjacent vertebrae; and an elongated fixation element extendable between the adjacent vertebrae when implanted and engageable to each bone screw engaged to the adjacent vertebrae.

12. A three component dilator system for use in implantation of a bone screw into a vertebra, comprising: a first tubular dilator having a tapered end, a first length and a first diameter; a second tubular dilator having a tapered end, a second length and a second diameter; a third tubular dilator having a tapered end, a third length and a third diameter; a bone screw, wherein said first diameter is sized to receive said bone screw therethrough; and wherein said first length is shorter than said second length which is shorter than said third length.

3. Terms in Dispute.

The parties dispute the following terms from the '656 Patent:

- a. bone screw (claims 8 and 12)
- b. elongated fixation element extendable between the adjacent vertebrae when implanted engageable to each bone screw (claim 8)

F. The '491 Patent.

1. Overview of the invention.

The '491 patent, titled "Posterior Fixation System," describes a screw assembly to be

used with spinal surgery tools.

2. Relevant claim.

The parties dispute claim 1 of the '491 patent, which reads as follows:

1. A multi-axial bone attachment assembly, comprising: a saddle member having a plurality of upright portions that define a channel through said saddle member, said saddle member further having a hole therethrough bounded by an inner wall, said hole forming a lower opening in said saddle member; a bone anchoring member extending through said opening, said bone anchoring member including a head portion and an anchoring portion; and a washer having a recessed portion for accommodating an orthopedic rod and said washer having an alignment member to minimize misalignment between the rod and said recessed portion, said washer being fitted within said hole of said saddle member and atop said bone anchoring member.

3. Terms in Dispute.

The parties dispute the following terms from the '491 Patent:

- a. alignment member to minimize misalignment (claim 1)
- b. washer being fitted within said hole of said saddle member and atop said bone anchoring member (claim 1)

G. The '320 Patent.

1. Overview of the invention.

The '320 patent, titled "Anterior Cervical Plate System," describes an anatomically

contoured plate fusion of the human cervical spine from the anterior side.

2. Relevant claim.

The parties dispute claim 1 of the '320 patent. It reads as follows:

1. A plate adapted to be applied to the anterior human cervical spine for contacting the anterior aspects of at least two cervical vertebral bodies to be fused together, said plate comprising: a mid-longitudinal axis, a lower surface being concave along a substantial portion of the mid-longitudinal axis of said plate and adapted to contact the cervical vertebral bodies, and an upper surface opposite said lower surface; at least two bone screw receiving holes extending through said plate from said upper surface through said lower surface, each of said bone screw receiving holes having a central longitudinal axis and a radius, each of said bone screw receiving holes being adapted to receive a bone screw for engaging said plate to the cervical spine; and opposite first and second ends along the mid-longitudinal axis of said plate, at least said first end having one of said bone screw receiving holes on each side of the mid-longitudinal axis of said plate, at least said first end having an end wall extending from said upper surface to said lower surface, said end wall being proximate to a straight line connecting the central longitudinal axes of each bone screw receiving hole at said first end, said end wall being located a distance from the line that is less than a distance of the radius of either of said bone screw receiving holes at said first end to form an indentation at said first end, said indentation having a maximum width transverse to the mid-longitudinal axis that is greater than the minimum distance separating said bone screw receiving holes at said upper surface and along the straight line.

3. Terms in Dispute.

The parties dispute the following term from the '320 Patent:

a. each of said bone screw receiving holes being adapted to receive a bone screw for engaging said plate to the cervical spine (claim 1)

H. The '961 Patent.

1. Overview of the invention.

The '961 patent, titled "Spinal Implant," describes a spinal implant "which when placed

within the spinal disc space stabilizes the spinal segment." '961 Patent abstract.

2. Relevant claims.

The parties dispute claims 1, 12, 24, 36, 47, and 86 of the '961 patent.

1. spinal fusion implant comprising: a leading end and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end, said trailing end having a perimeter, said trailing end having a hole therein, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end; opposite sides between said leading and trailing ends, said implant having a width from one of said sides to the other of said sides, said implant having a height; and an opening through said implant and oriented along the height, said opening being between said opposite sides and between said leading and trailing ends.

12. A spinal implant comprising: a leading end and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end, said trailing end having a perimeter, said trailing end having a hole therein, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end; opposite sides between said leading and trailing ends, said implant having a height perpendicular to the length of said implant; and said implant having a generally rectangular cross section along at least a portion of the length of said implant.

24. A spinal implant comprising: a leading end and a trailing end opposite said

leading end, said implant having a length from said leading end to said trailing end, said trailing end having a perimeter, said trailing end having a hole therein, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end, said trailing end being convex; and opposite sides between said leading and trailing ends, said implant having a height perpendicular to the length of said implant.

36. A spinal implant comprising: a leading end and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end, said trailing end having a perimeter, said trailing end having a hole therein, said hole having a diameter, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end, said slot portion and said another slot portion being opposite ends of a slot having a length, said slot having a width transverse to the length of said slot, the width of said slot being greater than the diameter of said hole; and opposite sides between said leading and trailing ends, said implant having a height perpendicular to the length of said implant.

47. A spinal implant comprising: a leading end and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end, said trailing end having a perimeter, said trailing end having a hole therein, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end, said slot portion and said another slot portion being opposite ends of a slot having a length, said slot having a width transverse to the length of said slot, said slot having a depth perpendicular to the length and the width of said slot, the width of said slot being greater than the depth of said slot; and opposite sides between said leading and trailing ends, said implant having a height perpendicular to the length of said slot;

86. An artificial spinal fusion implant comprising: a leading end and a trailing end opposite said leading end, said implant having a length from said leading end to said trailing end; opposite sides between said leading and trailing ends, each of said sides and said trailing end having an upper portion, said implant having a maximum width from one of said sides to the other of said sides, said implant having a central vertical axis perpendicular to the length and width of said implant, said implant having a height, said implant having a maximum height less than the maximum width of said implant; and an opening through said implant and oriented along the height, said opening being between said opposite sides and between said leading and trailing ends, said opening having an upper portion between said upper portions of said opposite sides, said upper portion of said opening having a minimum dimension transverse to the central vertical axis of said implant that is greater than the maximum height of said implant.

3. Terms in Dispute.

The parties dispute the following terms from the '961 Patent:

- a. perimeter (claims 1, 12, and 24)
- b. slot portion intersecting one portion of the perimeter of said trailing end (claims 1, 12, 24, 36, and 47)
- c. another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end (claims 1, 12, 24, 36, and 47)
- d. an opening through said implant and oriented along the height (claims 1 and 86)

I. The '725 Patent.

1. Overview of the invention.

The '725 patent, titled "Systems and Techniques for Restoring and Maintaining Intervertebral Anatomy," describes implants "that can be sequentially inserted and withdrawn from a spinal disc space to restore the disc space to a desired disc space height and to postoperatively maintain the desired spinal disc space height when a selected implant is left in the spinal disc space." '725 Patent col.1 ll.50-54. It also describes implants "that can have the same height and leading end portion configuration of at least some trial instruments of a set of trial instruments. Each trial instrument of the set has a trial body providing a restored disc space height and a leading end portion configured to distract the disc space to the restored disc space height." <u>Id</u>. at col.1 ll.59-64. Additionally, "[i]mplants are provided that have a self-distracting lead end configuration." <u>Id</u>. at col.1 ll.65-66.

2. Relevant claims.

The parties dispute claims 14 and 25 of the '725 Patent. Claim 14 is an independent

claim. Claim 25 is dependent upon claim 23. The relevant claims read as follows:

14. An implant for the spinal column, comprising: a body positionable in a spinal disc space, said body including a leading end portion and an opposite proximal end, an upper surface orientable toward an endplate of an upper vertebra and a lower surface orientable toward an endplate of a lower vertebra, said body having a height between said upper and lower surfaces corresponding to a desired disc space height between the upper vertebra endplate and the lower vertebra endplate, wherein said leading end portion is adapted for insertion into the disc space in a collapsed condition to restore the collapsed disc space to the desired disc space height as the body is inserted in the collapsed disc space, wherein said body includes convexly curved upper and lower surfaces and said leading end portion includes a convexly curved leading end nose extending between said convexly curved upper and lower surfaces, wherein said body includes: a first lateral surface extending between said upper surface and said lower surface; a second lateral surface opposite said first lateral surface extending between said upper surface and said lower surface; and said leading end nose is convexly curved between and first and second lateral surfaces.

23. An implant insertable in a disc space between adjacent vertebrae, comprising: a body having a distal leading end portion sized for insertion into a non-distracted, collapsed disc space, said implant having a height between an upper surface and a lower surface thereof adapted to restore said non-distracted, collapsed disc space to a desired disc space height as said body is impacted into said non-distracted collapsed disc space, wherein said body is implantable in the restored disc space to post-operatively maintain said desired disc space height, wherein said body includes convexly curved upper and lower surfaces and said leading end portion includes a convexly curved leading end nose extending between said convexly curved upper and lower surfaces, wherein said body further includes: a first lateral surface extending between said upper surface and said lower surface; a second lateral surface opposite said first lateral surface extending end nose is convexly curved between said lower surface; and said leading end nose is convexly curved between said first and second lateral surfaces.

25. The implant of claim 23, wherein said body includes: a proximal end surface extending between said first and second lateral surfaces and also extending between said upper and lower surfaces of said body; a first notch in said first lateral surface recessed relative to said proximal end surface and said first lateral surface; and a second notch in said second lateral surface recessed relative to said proximal end surface recessed relative to said proximal end surface recessed relative to said second lateral surface recessed relative to said proximal end surface and said second lateral surface.

Additional details about the '725 patent are included as necessary in the court's discussion of the parties' arguments.

3. **Terms in Dispute.**

The parties dispute the following terms from the '725 Patent:

- a. convexly curved (claims 14 and 23)
- b. convexly curved upper and lower surfaces (claims 14 and 23)
- c. a convexly curved leading end nose extending between said convexly curved upper and lower surfaces (claims 14 and 23)

II. <u>Claim Construction Principles</u>

The court will construct the disputed claims according to several controlling principles of law. First, "the claims of a patent define the invention to which the patentee is entitled the right to exclude." <u>Phillips v. AWH Corp.</u>, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting <u>Innova/Pure</u> <u>Water, Inc. v. Safari Water Filtration Systems, Inc.</u>, 381 F.3d 1111, 1115 (Fed. Cir. 2004). <u>See</u> <u>also Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"). Second, claim terms "are generally given their ordinary and customary meaning." <u>Phillips</u>, 415 F.3d at 1313 (quoting <u>Vitrionics</u>, 90 F.3d at 1582). Third, "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." <u>Phillips</u>, 415 F.3d at 1313. Fourth, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the paticular claim in which the disputed term appears, but in the context of the entire patent, including the specification." <u>Id</u>. Fifth, the claims "do not stand alone. . . . [They] must be read in view of the specification, of which they are a part." <u>Id</u>. (quoting <u>Markman</u>, 52 F.3d at 978, 979). The court

will discuss claim construction principles further as it considers the parties' arguments.

III. <u>Claim Construction</u>

A. <u>The '422, '929, '626, and '660 Patents.</u>

The '422, '929, '626, and '660 patents share a common specification, and the parties agree that claim terms common to the four patents should be construed consistently. (See Globus Reply Br. at 49; Medtronic Second Suppl. Cl. Const. Br. at 1.) See also NTP, Inc. v. Research in Motion, Inc., 418 F.3d 1282, 1293 (Fed. Cir. 2005) ("Because [the] patents[-in-suit] all derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents."). For purposes of the Markman hearing, the parties organized the claims of these four patents by category. The court organizes its claim construction in the same manner. All proposed claim constructions are from the parties' reply briefs unless otherwise noted.

1. <u>The Instrument Terms</u>

a. installation instrument

The first term construed is "installation instrument." This term is found in claim 26 of the '422 patent. Medtronic contends that the term can be understood by its plain meaning and needs no construction. Alternatively, Medtronic contends that it should be construed as "an instrument for installing something." Globus contends that the term should be construed as "a unitary device for implanting a rod or brace ('connecting element') that includes a brace inserter, and which has a pivot axis relative to the anchors that is located outside the body."

The central dispute regarding this term is whether it should be limited to the disclosed embodiment. Globus attempts to so limit the term. (<u>See, e.g.</u>, Globus' Reply Br. at 33 ("As

depicted in [Figures 8 and 21 of the specification], the disclosed embodiment consists of two arms, or anchor extensions, which are mounted on the top of two anchor screws embedded in adjacent vertebral segments to be fused.").) There is no authority to limit the term in this way. As the Federal Circuit has noted, "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." <u>Phillips</u>, 413 F.3d at 1323 (internal citations omitted).

The Federal Circuit further noted that "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." <u>Id</u>. at 1314. This is one of those instances.

The court construes installation instrument to mean "an implement for installing something."

b. insertion instrument

The court next construes the term "insertion instrument." This term is found in claim 19 of the '626 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "an instrument for inserting something." Globus contends that the term should be construed as "a unitary device for implanting a rod or brace that includes a brace inserter and a pivot axis relative to the anchors that is located outside the body."

For the reasons discussed above, the court construes "insertion instrument" to mean "an

implement for inserting something."

c. brace installation instrument

The court next construes the term "insertion instrument," found in claim 1 of the '660 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends the term should be construed as "an instrument for installing a brace." Globus contends that the term should be construed as "a unitary device for implanting a rod or brace that includes a brace inserter and a brace, and which has a pivot axis relative to the anchors that is located outside the body."¹

For the reasons discussed above, the court construes "brace insertion instrument" to mean "an implement for inserting a brace."

d. an instrument associated with the connecting element

The last of the instrument terms is "an instrument associated with the connecting element." This term is found in claim 45 of the '929 patent. Medtronic contends that the term can be understood by its plain meaning and needs no construction. Alternatively, Medtronic contends that "instrument" should be construed as "a tool or implement that can be used, for example, for performing surgeries" and that the larger phrase should be construed as "an instrument that can be used to implant the connecting element." Globus contends that the term should be construed as "a unitary device for implanting a rod or brace that includes a brace inserter and a brace, and which has a pivot axis relative to the anchors that is located outside the

¹ The court considers the construction argued in Globus' reply brief. (<u>See</u> Globus' Reply Br. at 46.) Globus proposes a slightly different construction in the chart it submitted to the court. (<u>See</u> Globus' Reduced List of Claims in Dispute at 11 (proposing that "brace installation instrument" be construed as "a unitary device for implanting a rod or brace that includes a brace inserter, and which has a pivot axis relative to the anchors that is located outside the body").)

body."

In the context of claim 45, this term refers to an implement operable so as to place the connecting element in a predetermined location. '929 Patent col.18 ll.44-52. For this reason and the reasons discussed above, the court construes "an instrument associated with the connecting element" to mean "an implement for maneuvering the connecting element."

<u>2.</u> The Percutaneous Terms

a. percutaneously inserting the connecting element

The first percutaneous term the court construes is "percutaneously inserting the connecting element." This term is found in claims 42 and 48 of the '422 patent and claim 17 of the '626 patent. Medtronic contends that "percutaneously" means "through a small incision or small puncture in the skin" and that the larger phrase can be understood by its plain meaning. Alternatively, Medtronic contends the term should be construed as "inserting the connecting element through a small incision or small puncture in the skin." Globus contends that the term should be construed as "placing the connecting element through a small hole or puncture in the skin which is separate from the incisions or holes through which the anchors are inserted."

The court credits the numerous declarations and exhibits that demonstrate the consistent understanding of the term "percutaneous" in the spinal surgery field.² Consistent with these

² (See 1st Declaration of Scott Tromanhauser ("Tromanhauser 1st Decl.") at ¶ 6 ("In the spinal surgery field "percutaneous" refers to surgeries performed through a small incision or small puncture in the skin.") See also 1st Declaration of Gregory H. Lantier ("Lantier 1st Decl."), Ex. 28, STEDMAN'S MEDICAL DICTIONARY (27th ed. 2000) (percutaneous: "Denoting the passage of substances through unbroken skin, as in absorption by inunction; also passage through the skin by needle puncture, including introduction of wires and catheters by Seldinger technique [used in heart surgeries]); <u>id</u>. at Ex. 29, R.W. Obray, R.W. Filice & D.P. Beall, MR Imaging and Osseous Spinal Intervention and Intervertebral Disk Intervention, 15 MAGNETIC RESONANCE IMAGING CLINICS 257 (2007) ("Percutaneous spine intervention, a wide range of invasive spine procedures performed through a puncture hole or through a small incision not requiring soft tissue closure

declarations and exhibits, the court construes "percutaneous" to mean "through a small incision or small puncture in the skin."

Globus' dispute with the phrase "percutaneously inserting the connecting element" centers on whether the connecting element must be inserted through a separate incision from the incision through which the anchors are inserted. Again, there is no authority for such a limitation. "Claim terms are generally given the meaning those terms would have to a person of ordinary skill in the art." Phillips, 415 F.3d at 1313. A person skilled in the art would not interpret "percutaneously inserting the connecting element" to require a separate entry point for the connecting element. "[A]sserted claims can be assigned a narrower scope only if there is some indication in the patent or the prosecution history that the term [...] was meant to have a more restrictive meaning as used in the patent, or a broader meaning was disclaimed during prosecution." Saunders Group Inc. v. Comfortrac, 492 F.3d 1326, 1331 (Fed. Cir. 2007). An inventor's intention to deviate from the ordinary meaning of a claim term must be clear. Conoco, Inc. v. Energy & Envtl Int'l, L.C., 460 F.3d 1349, 1357 (Fed. Cir. 2006). Globus points to nothing in the '422 specification or prosecution history that shows that the inventors intended to limit the meaning of the phrase under consideration. It directs the court's attention to one place in the '422 patent specification that refers to a surgical procedure using four entry holes. (See Globus' Reply Br. 40.) See also '422 Patent col.15 ll.20-23 ("Thus, a minimally invasive

and with few or no skin sutures or staples, is rapidly emerging as an effective alternative to open surgery."); <u>id</u>. at Ex. 30, SPINE UNIVERSE,

www.spineuniverse.com/displayarticle.php/article1530.html (When a screw is placed through a very small incision in the skin, it is called a percutaneous procedure."); <u>id</u>. at Ex. 31, BC Heath Guide, www.bchealthguide.org/kbase/topic/detail/surgical/hw225848/detail.html ("Percutaneous means 'through the skin' or using a very small incision . . . There are several percutaneous procedures. All of them involve inserting small instruments between the vertebrae and into the middle of the disc.").)

surgical procedure of the present invention contemplates interbody fusion and stabilization of the adjacent vertebrae to be accomplished with four entry holes or punctures through skin S."). Importantly, the portion of the specification that refers to four entry holes is only one of several procedures contemplated and disclosed in the '422 patent. See '422 Patent col.12 1.4 to col.16 1.7. Although Globus refers to other examples in the specification where connecting elements are inserted through different entry points than the anchors, (see Globus' Reply Br. at 41), nothing in the specification limits the invention in the way it suggests. Therefore, the court construes "percutaneously inserting the connecting element" to mean "inserting the connecting element through a small incision or small puncture in the skin."

b. percutaneous insertion position

The next term the court construes is "percutaneous insertion position." This term is found in claims 74 and 96 of the '929 patent. Medtronic contends that "percutaneous" has the same meaning as "percutaneously" and that the larger phrase can be understood by its plain meaning and needs no construction. Alternatively, if the court construes the larger phrase, Medtronic contends that it should be construed as "a position for insertion into the body through a small incision or small puncture in the skin." Globus contends that the term should be construed as "a location where the connecting element is inserted through a small hole or puncture in the skin which is separate from the holes or incisions through which the anchors are inserted."³

³ The court considers the construction argued in Globus' reply brief. (See Globus' Reply Br. at 45.) Globus proposes a slightly different construction in its attached chart. (See Globus' Reduced List of Claims in Dispute at 9 (proposing that "percutaneous insertion position" be construed as "a location where the connecting element is inserted through a small hole or puncture in the skin, which is separate from the hole(s) or incision(s) through which the anchors are inserted").)

For the reasons discussed above, the court construes "percutaneous insertion position" to mean "a position for insertion into the body through a small incision or small puncture in the skin."

c. percutaneously guiding the connecting element

The next term the court construes is "percutaneously guiding the connecting element." This term is found in claim 35 of the '626 patent. Once again, Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that the phrase should be construed as "guiding the connecting element through a small incision or small puncture in the skin." Globus contends that the term should be construed as "guiding a rod or brace (the connecting element) through a small hole or puncture in the skin which is separate from the incision through which the anchors are inserted."

For the reasons discussed above, the court construes "percutaneously guiding the connecting element" to mean "guiding the connecting element through a small incision or small puncture in the skin."

d. percutaneously positioning the connecting element

The next term the court construes is "percutaneously positioning the connecting element." This term is found in claims 39 and 50 of the '626 patent. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that the phrase should be construed as "positioning the connecting element through a small incision or small puncture in the skin." Globus contends that the term should be construed as "positioning a rod or brace through a small hole or puncture in the skin which is separate from the incision through which the anchors are inserted." For the reasons discussed above, the court construes "percutaneously positioning the connecting element" to mean "positioning the connecting element through a small incision or small puncture in the skin."

3. <u>The Inserter Terms</u>

a. brace inserter

The only inserter term that remains in dispute is "brace inserter." This term is found in claim 29 of the '422 patent and claim 1 of the '660 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that it should be construed as "a device for inserting a brace." Globus contends that the term should be construed as "a pivot arm which is part of the brace installation instrument."⁴

Globus does not contend that the ordinary meaning of "brace inserter" requires a pivot arm, and nothing in the specification or the prosecution history indicates the inventors intended to limit brace inserters to pivot arms. Furthermore, the doctrine of claim differentiation indicates that brace inserters need not have pivot arms. "Independent claims are presumed to have broader scope than their dependents." <u>Acumed LLC v. Stryker Corp.</u>, 483 F.3d 800, 806 (Fed. Cir. 2007). "That presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." <u>Id</u>. (quoting <u>SunRace Roots Enter. Co. v. SRAM Corp.</u>, 336 F.3d 1298, 1303 (Fed. Cir. 2003)). The asserted

⁴ Globus proposes two different constructions of "brace inserter." For the '422 patent, it proposes the term be construed as "a pivot arm which is part of the installation instrument." (See Globus' Reply Br. at 33.) For the '660 patent, Globus proposes the same term be construed as "a pivot arm which is part of the <u>brace</u> installation instrument." (See Globus' Reply Br. at 47 (emphasis added).)

claim of the '422 patent, claim 29, is an independent claim that refers simply to "brace inserters," while its dependant claim, claim 30, specifies that the brace inserter has a "pivot axis." <u>Compare</u>, '422 Patent claim 29 ("mounting a brace inserter on the first and second anchor extensions") with '422 Patent claim 30 ("The method of claim 29, wherein the brace is curved, <u>the brace inserter has a pivot axis</u>, and guiding the brace includes swinging the brace through an arc in a plane containing the brace and perpendicular to the axis of curvature of the brace.") (emphasis added). In the '422 patent, the only meaningful difference between the brace inserter clause of the independent claim and that of the dependent claims is the pivot axis. That indicates that the pivot axis limitation should not be read into the independent claim.⁵ Globus has failed to rebut the presumption that "brace inserter" should not be limited in the manner it advocates.

The court construes "brace inserter" to mean "a device for inserting a brace."

4. The Mounting Terms

a. mounting

The court next construes the term "mounting." This term is found in claims 26 and 29 of the '422 patent. During the <u>Markman</u> hearing, the parties agreed to construe mounting as "setting securely in position." Having found this to be the proper construction of "mounting," the court so construes the term.

⁵ Also, the asserted claim of the '660 patent, claim 1, refers simply to "brace inserters," while several of its dependent claims specify that the brace inserter is "pivotably secured." <u>Compare</u>, '660 Patent claim 1 ("a brace inserter having a proximal end and a distal end . . . said brace inserter being movable relative to said at least one anchor extension, and further comprising a second anchor extension including a proximal end coupled to the proximal end of said brace inserter") <u>with, e.g.</u>, '660 Patent claim 3 ("The instrument of claim 1, wherein said brace inserter includes a support arm pivotably secured to said anchor extension."). <u>See also</u> '660 Patent claims 2, 5, 9, 13, 16, 20, 23, and 24.

b. mounted

The court next construes the term "mounted." This term is found in claim 1 of the '660 patent. Consistent with the court's construction of the "mounting" term, the court construes "mounted" to mean "set securely in position."

5. The Referencing Terms

a. referencing a position of the connecting element relative to a position of the pair of anchors

The only referencing term that remains in dispute is "referencing a position of the connecting element relative to a position of the pair of anchors." This term is found in claim 42 of the '422 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "establishing the position of the connecting element relative to the position of the pair of anchors." Globus contends that the term should be construed as "fixing a geometric relationship between the pivot axis of the installation instrument and the position of the pair of anchors."

Globus' suggested construction has no basis in the plain meaning of the claim language. It attempts to limit the term to the proposed embodiment by citing two passages from the many alternative disclosed forms of the invention. (See Globus Reply Br. at 39-40.) This argument is legally incorrect. The court construes "referencing a position of the connecting element relative to a position of the pair of anchors" to mean "establishing the position of the connecting element relative to the position of the pair of anchors."

B. Additional '929 Terms

1. the instrument being operable to percutaneously place the connecting element [in a predetermined location]

The next term the court construes is "the instrument being operable to percutaneously place the connecting element [in a predetermined location]." This term is found in claims 45, 95, and 98 of the '929 patent. Once again, Medtronic contends that the phrase can be understood by its plain meaning and needs no construction. Alternatively, Medtronic contends that "operable" should be construed as "capable of being operated," "percutaneously" should be construed as above, "predetermined location" should be construed as "a location that is determined in advance," and the larger phrase should be construed as "the instrument is capable of being operated to guide the connecting element, though a small incision or small puncture in the skin, into a location relative to the pair of anchors that is determined in advance." Globus contends that the term "instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument" should be construed as above and the larger phrase should be construed as "the instrument places the connecting element through a small hole or small puncture in the skin which is separate from the incision(s) or holes through which the anchors are inserted."

Consistent with the court's constructions above, the court construes "the instrument being operable to percutaneously place the connecting element in a predetermined location" to mean "the instrument can be operated to guide the connecting element, though a small incision or small puncture in the skin, into a location that is determined in advance."

2. mechanical guide for directing the connecting element along a predetermined path

The next term the court construes is "mechanical guide for directing the connecting element along a predetermined path." This term is found in claim 47 of the '929 patent. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that "mechanical guide" should be construed as "a mechanical device that guides the motion of something," "predetermined path" should be construed as "a path that is determined in advance," and the larger phrase should be construed as "a mechanical guide for directing the connecting element along a path that is determined in advance." Globus contends that the phrase should be construed as "a pivot arm which is part of the instrument associated with the connecting element."

This term can only be construed in light of the entire dependent claim: "The minimally invasive surgical device of claim 45, wherein the instrument comprises a mechanical guide for directing the connecting element along a predetermined path." '929 Patent claim 47. Claim 45 reads as follows:

A minimally invasive surgical device, comprising: at least a pair of anchors positionable within a body of a patient; a connecting element positionable within the body; and an instrument associated with the connecting element, the instrument being operable to percutaneously place the connecting element in a predetermined location relative to the pair of anchors."

^{'929} Patent claim 45. Nothing in the asserted claim or the independent claim to which the asserted claim refers limits the "mechanical guide" to a "pivot arm." According to the Federal Circuit, "[i]n the absence of any evidence to the contrary, we must presume that the use of . . . different terms in the claims connotes different meanings." <u>CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG</u>, 224 F.3d 1308, 1317 (Fed. Cir. 2000). The court is not persuaded by Globus' attempts to rebut that presumption. Nothing in the claims or written description of the '929 patent indicates that the term "mechanical guide" is used in any sense other than its ordinary meaning. <u>See THE AMERICAN HERITAGE COLLEGE DICTIONARY</u> (3d ed. 1997) (mechanical: "1. Of or relating to machines or tools"); WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (2002) (mechanical: "1 a: of, relating to, or concerned with machinery or tools"); TABER'S

CYCLOPEDIC MEDICAL DICTIONARY (18th ed. 1997) (guide: "A mechanical aid or device which assists in setting a course or directing the motion either of one's hand or of an instrument one holds.").

In light of claim 45, the meaning of claim 47 is clear: the instrument includes an apparatus that can mechanically guide the connecting element along a path to its ultimate location rather than simply placing the connecting element in the predetermined location. The court construes "mechanical guide for directing the connecting element along a predetermined path" to mean "a mechanical device that assists in setting the course of the connecting element along a path that is determined in advance."

3. the inserter being operable to move the connecting element along a predetermined path

The next term the court construes is "the inserter being operable to move the connecting element along a predetermined path." This term is found in claims 74 and 96 of the '929 patent. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that "operable" should be construed as "capable of being operated," "predetermined path" should be construed as "a path that is determined in advance," and the larger phrase should be construed as "the inserter has an established position relative to the pair of anchors, and is capable of being operated to move the connecting element along a path, determined in advance, between the first position and the second position." Globus contends the phrase should be construed as "the insertion path of the brace inserter is predetermined by fixing the geometric relationship between the pivot axis of the installation instrument and the position of a pair of anchors."6

Consistent with the court's constructions above, the court construes "the inserter being operable to move the connecting element along a predetermined path" to mean "the inserter is capable of being operated to move the connecting element along a path, determined in advance, between the first position and the second position."

4. positionable to a predetermined location

The last disputed term from the '929 patent is "positionable to a predetermined location." This term is found in claim 95. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that "positionable" should be construed as "capable of being positioned," "predetermined location" should be construed as "a location that is determined in advance," and the larger phrase should be construed as "capable of being positioned to a location that is determined in advance." Globus contends the phrase should be construed as "positionable to a final location that is predetermined by fixing the geometric relationship between the pivot axis of the installation instrument and the position of a pair of anchors."

For the reasons discussed above, the court construes "positionable to a predetermined location" to mean "capable of being positioned to a location that is determined in advance."

C. Additional '660 Terms

1. said brace inserter being movable relative to said at least one anchor extension

The disputed term "said brace inserter being movable relative to said at least one anchor

⁶ This construction is taken from Globus' Reduced List of Claims in Dispute. Globus does not directly address this term in its reply brief.

extension" is found in claim 1 of the '660 patent. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "the brace inserter is capable of being moved relative to at least one anchor extension." Globus contends the phrase should be construed as "the brace inserter moves along a path that is predetermined by fixing the geometric relationship between the pivot axis of the instrument and at least one anchor extension."

For the reasons discussed above, the court construes "said brace inserter being movable relative to said at least one anchor extension" to mean "the brace inserter is capable of being moved relative to at least one anchor extension."

2. coupled

The disputed term "coupled" is found in claim 1 of the '660 patent. Medtronic contends that the phrase can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "connected together, linked, or joined." Globus contends the term should be construed as "tied, joined, linked, or associated together."

The parties agree that "coupled" should be construed according to its ordinary meaning, as evidenced by general purpose dictionaries. <u>See</u> Lantier 3d Decl., EX. 13, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (2002) (couple: "2 : to fasten together: JOIN LINK"); THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE (2d ed. 1987) (couple: "9. to fasten, link, or associate together in a pair or pairs. 10. to join; connect.").

The court construes "coupled" to mean "joined, linked, or fastened together."

D. <u>The '656 Terms</u>

1. bone screw

The disputed term "bone screw" is found in claims 8 and 12 of the '656 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "a screw for use in bone." Globus contends the term should be construed as "a bone screw configured to maintain the position of the fixation element within the suprafascial subcutaneous space."

Claims 8 and 12 of the '656 patent describe surgical systems with several elements. The bone screw portion of the each claim is one of many elements that describe the system as a whole. Nothing in the '656 specification indicates that the bone screws must be configured in a certain way to maintain the position of the fixation element within the suprafascial subcutaneous space. As the patent abstract plainly states, "In <u>an important aspect of the invention</u>, the fixation plates, engagement nuts and linking members are supported suprafascially but subcutaneously so that the fascia and muscle tissue are not damaged. The bone screw is configured to support the fixation hardware above the fascia." '656 Patent abstract (emphasis added). The patent is not limited to that one aspect. Therefore, the court construes bone screw to mean "a screw for use in bone."

2. elongated fixation element extendable between the adjacent vertebrae when implanted and engageable to each bone screw

The disputed term "elongated fixation element extendable between the adjacent vertebrae when implanted and engageable to each bone screw" is found in claim 8 of the '656 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that "elongated fixation element extendable between the adjacent vertebrae when implanted" should be construed as "an elongated element that fixes or secures something and which is capable of being extended between adjacent vertebrae when implanted" and that "engageable to each bone screw" should be construed as "can be engaged to each bone screw." Globus contends the term should be construed as "elongated plate attachable to each bone screw, and spanning adjacent vertebrae within the suprafascial subcutaneous space."

Reading the specification as a whole, it is clear that the fixation instrument described in claim 8 need not be a plate. Claim 11 of the '656 patent reads as follows: "11. The system of claim 8, wherein the elongated fixation element is a plate." Thus "fixation instrument" in claim 8 must be construed more broadly than "plate."

Medtronic has not proposed a construction of the term "engageable." Globus has proposed that "engageable" be construed as "attachable." The definition of "engage" is "to interlock or cause to interlock; mesh." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2004). In the context of this patent, where "engageable" refers to a bone screw's connection to a fixation element, the dictionary definition is appropriate and is consistent with the term "attach."

The court construes "elongated fixation element extendable between the adjacent vertebrae when implanted and engageable to each bone screw" to mean "an elongated element that fixes or secures something and is capable of being extended between adjacent vertebrae when implanted and that attach to each bone screw."

E. <u>The '491 Terms</u>

1. alignment member to minimize misalignment

The disputed term "alignment member to minimize misalignment" is found in claim 1 of

the '491 patent. Medtronic contends that the term should be construed as "the washer has a projection that minimizes misalignment between the rod and the recess on the washer." Globus contends the term should be construed as "two structures that extend from the crown member which function to prevent rotation of the crown member."

The claim language and the prosecution history clearly show that the purpose of the alignment member is to minimalize misalignment between the rod and the recessed portion of the washer. (See Lantier 4th Decl., Ex. 18, '491 File History ('491 File History) at MSD 0634140-42.) In the original '491 patent application, the disputed portion of claim 1 read as follows: "a washer having a recessed portion for accommodating an orthopedic rod and a radially extending projection. . . ." (Globus Reply Br., Ex. J, '491 File History at 94.) The patent examiner initially rejected claim 1 as obvious because prior art disclosed "the use of a washer with radially extending projections to facilitate the insertion of the washer into the saddle," and it would have been obvious to incorporate that invention with another patented bone anchoring member. ('491 File History at MSD 0634141.) The inventors subsequently amended claim 1 to its current form by removing the "radially extending projection" term and including the currently contested term. (Id. at MSD 0634154, 0634162-63.) The patent examiner allowed the amended claim. (Id. at MSD 0634178.) Nothing in the prosecution history indicates that the "alignment member" must be two structures that extend from the crown member. Moreover, the claim language, the specification, and the prosecution history all demonstrate that the alignment member can be one or more projections. Though the term "alignment member" is singular, some of the disclosed embodiments describe two projections that serve as alignment members, see, e.g., '491 Patent figs. 9 & 12; id. col.6 ll.45-52, and claim 19 of the '491 patent describes "[t]he assembly of claim

1, wherein said upright portions each have a trough defined therein, <u>said washer including a</u> <u>plurality of projections</u> with each provided in one of said troughs," <u>id</u>. claim 19 (emphasis added).

The intended purpose of the alignment member is clear from the language of claim 1, where the disputed term is part of the following phrase: "a washer having a recessed portion for accommodating an orthopedic rod and said washer having an alignment member to minimize misalignment between the rod and said recessed portion." <u>Id</u>. col.12 ll.25-27.

The court construes "alignment member to minimize misalignment" to mean "a projection or projections to minimize misalignment between the rod and the recessed portion of the washer."

2. washer being fitted within said hole of said saddle member and atop said bone anchoring member

The disputed term "washer being fitted within said hole of said saddle member and atop said bone anchoring member" is also in claim 1 of the '491 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "the washer is sized such that it can fit within the hole of the saddle member and on top of the bone anchoring member." Globus contends the term should be construed as "a crown member, fitted within an opening of the saddle member, which directly contacts the bone anchoring member."

While the parties agree that the term "atop" includes "above," the court finds that construction is not sufficiently definitive. Dictionaries define "atop" as "on the top of," RANDOM HOUSE UNABRIDGED DICTIONARY (2006), or "on top of," THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2006). Contrary to Globus' arguments, (<u>see</u> Globus Reply Br. at 22-23), it would be improper for the court to rely on the figures of certain disclosed embodiments of the '491 patent to require direct contact between the washer and the bone anchoring member. Nonetheless, the definitions of "atop" do include the word "on" – not simply "above." Both the dictionary definitions of "atop" and the use of the term in the '491 patent specification connote either direct or indirect touching. That is, either the washer directly touches the bone anchoring member or it may be separated by some other object that enables the purpose of a washer resting on the bone anchoring member.

The court construes "washer being fitted within said hole of said saddle member and atop said bone anchoring member" to mean "the washer is fitted within the hole of the saddle member and on top of the bone anchoring member, with the washer either in direct or indirect contact with the bone anchoring member ."

<u>F.</u> <u>The '320 Term</u>

1. each of said bone screw receiving holes being adapted to receive a bone screw for engaging said plate to the cervical spine

The disputed term "each of said bone screw receiving holes being adapted to receive a bone screw for engaging said plate to the cervical spine" is found in claim 1 of the '320 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "the hole is sized to permit the shaft of the screw to pass through the hole and engage the bone." Globus contends the term should be construed pursuant to 35 U.S.C. § 112, ¶ 6, the means-plus-function provision of the Patent Act, and in any case should be construed as "bone screw receiving holes that (i) are specially configured to accommodate rotatable locking elements that, in the locked position, lock the bone screws to the plate and the cervical spine; (ii) are internally threaded to receive a locking cap; or

(iii) are specially configured with offset threaded openings for receiving a locking element such as a set screw, cap or screw."

The court finds that the disputed '320 patent term is not means-plus-function language that invokes 35 U.S.C. § 112, ¶ 6. Section 112, paragraph 6 provides that "[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 claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2007). In other words, "means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function." Phillips, 415 F.3d at 1311 (citing Watts v. XL Sys., Inc., 232 F.3d 877, 880-81 (Fed. Cir. 2000)). The disputed '320 term clearly describes a structure – a hole. Therefore Section 112, paragraph 6 does not apply. Furthermore, the Federal Circuit has held repeatedly that the absence of the term "means" creates a rebuttable presumption that Section 112, paragraph 6, does not apply. See, e.g., Personalized Media Comm'ns, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 703-04 (Fed. Cir. 1998); CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002). "The presumption that a limitation lacking the term 'means' is not subject to section 112 ¶ 6 can be overcome if it is demonstrated that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function. [Federal Circuit] cases make clear, however, that the presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." Lighting World, Inc. v. Birchwood Lighting, Inc., 382 F.3d 1354, 1358 (Fed. Cir. 2004) (internal citations omitted). With the disputed '320 term, there is no evidence whatsoever to overcome the

presumption.

Although Globus correctly points out that a bone screw receiving hole must be sized to permit the shaft of a screw to pass through the hole, (Globus Reply Br. at 15), the court disagrees with its argument that the phrase "adapted to receive a bone screw for engaging said plate to the cervical spine" must refer to screw locking elements, (<u>id</u>.).

The court construes "each of said bone screw receiving holes being adapted to receive a bone screw for engaging said plate to the cervical spine" to mean "each bone screw receiving hole is sized to permit the shaft of the bone screw to pass through the hole and attach the plate to the cervical spine."

G. <u>The '961 Terms</u>

1. perimeter

The disputed term "perimeter" is found in claims 1, 12, and 24 of the '961 patent. Medtronic contends that the term should be construed as "the outer limits or boundary of a surface or area." Globus contends the term should be construed as "a continuous line forming the boundary of a closed geometric figure."

Dictionaries define "perimeter" in various ways, and the parties have cited a few definitions in their pleadings. <u>See, e.g.</u>, Globus' Reply Br. Ex. E, OXFORD ENGLISH DICTIONARY ONLINE (2d. ed. 1989) (perimeter: "1.a. "A continuous line forming the boundary of a closed geometrical figure or of any area or surface; a circumference; a periphery, outline."); Lantier 1st Decl., Ex. 60, TABER'S CYLOPEDIC MEDICAL DICTIONARY (14th ed. 1981) (perimeter: "1. The outer edge or periphery of a body or measure of the same."); <u>id</u>. at Ex. 61, AMERICAN HERITAGE DICTIONARY (2d college ed. 1985) (perimeter: "1.a. Math, A closed curve bounding a plane area"; "1.b. [t]he length of such a boundary"; or "3. [t]he outer limits of an area."). "Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor. If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." <u>Texas Digital Sys., Inc. v. Telegenix, Inc.</u>, 308 F.3d 1193. 1203 (Fed. Cir. 2002) (citations omitted).

The United States Court of Federal Claims construed the term "perimeter" in Paymaster

Techs., Inc. v. United States, 54 Fed. Cl. 579 (Fed. Cl. 2002), and that court's conclusions are

instructive here. After citing nine definitions of "perimeter,"⁷ the court wrote the following:

Of the nine definitions of "perimeter" quoted above, only three require a perimeter to surround a closed figure. In two of the three cases, the dictionary in question annotated the definitions as mathematical terms, suggesting that those definitions differ from the non-mathematical, non-technical meaning of the word (indeed, one of the sources was a dictionary of scientific and technical terms).

<u>Id</u>. at 588. This court agrees with the Court of Federal Claims' conclusion that the ordinary meaning of "perimeter" embraces broken plane characters. <u>Id</u>.

⁷ <u>Id</u>. at 588 ("One dictionary offers the following definition: '1. a: the boundary of a closed plane figure b: the length of a perimeter 2: a line or strip bounding or protecting an area 3: outer limits.' WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY [(3d ed.1981)]. Alternatively, 'perimeter' is defined as: '1. a. Math. A closed curve bounding a plane area. b. The length of such a boundary. 2. A fortified strip or boundary usually protecting a military position. 3. The outer limits of an area.' AMERICAN HERITAGE DICTIONARY [(2d ed.1982)]. A final dictionary defines 'perimeter' as: '[Math] The total length of a closed curve; for example, the perimeter of a polygon is the total length of its sides.' MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS (2d ed.1978).")

All uses of the term "perimeter" is the disputed '961 patent claims refer to the perimeter of the trailing end of a spinal fusion implant. As in Paymaster, nothing in the '961 patent indicates that the patentee intended to use the term "perimeter" in its mathematical sense. Indeed, the mathematical sense is inconsistent with the disclosed embodiments of the invention. The '961 patent specifically discloses implants with trailing ends that are not simple planes. See, e.g., '961 Patent col.10 ll.24-30 ("said trailing end having a perimeter, said trailing end having a hole therein, said trailing end having a slot portion intersecting one portion of the perimeter of said trailing end, said trailing end having another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end"). Likewise, nothing in the '961 patent specification or prosecution history indicates the trailing end portion of the implant must be a closed geometric figure. The court will not read such a limitation into the claim. As the Court of Federal Claims wrote, "While the perimeter of a character can be drawn around closed or open plane figures, it merely must bind the outer limits of the figure. The effect would be the same even if the character surface were uneven; the perimeter would bind the outer limits of the character . . . [A] perimeter can exist around either a broken or closed plane character." Paymaster Techs., 54 Fed. Cl. at 590. The same logic applies to leading end portions of the '961 patent implants: they need not be closed geometric figures.

The court rejects Globus' attempt to limit the '961 patent to the figures disclosed in U.S. Patent Application No. 29/023,922 (later issued as Patent No. Des. 425,989) ("the design patent"). (See Globus' Reply Br. at 8-14.) The '961 patent prosecution history addresses how the design patent affects the <u>priority</u> of certain claims in the '961 patent; the prosecution history does not support Globus' contention that the '961 patent may encompass no implants other than

those in the '922 design patent. (Globus' Reply Br. Ex. C, '961 Patent File History, at 285-87.) The court construes "perimeter" to mean "the outer boundary of a surface or area."

2. slot portion intersecting one portion of the perimeter of said trailing end

The disputed term "slot portion intersecting one portion of the perimeter of said trailing end" is found in claims 1, 12, 24, 36, and 47 of the '961 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "the slot portion intersects one portion of the perimeter of the trailing end." Globus contends the term should be construed as "portion of the vertical groove or depression which cuts through or across the perimeter of the trailing end of the implant, as depicted in Figures 1, 1a-e and 2 of the '961 Patent and Figures 1-7 of the U.S. Design Patent No. D 425,989 ('the Design Patent')."

Dictionaries define "intersect" to mean cut through, pass through, or cross. <u>See</u>, e.g., AMERICAN HERITAGE DICTIONARY (4th ed. 2000) (intersect: "1. To cut across or through. 2. To form an intersection with; cross."); RANDOM HOUSE UNABRIDGED DICTIONARY (2006) (intersect: to cut or divide by passing through or across). Medtronic points out that the preferred embodiments depicted in the drawings of the '961 patent show a slotted portion that <u>reaches</u> or <u>meets</u> the perimeter of the trailing end of the implant and does not cross it. (Medtronic Opening Br. at 58.) <u>See</u>, e.g., '961 Patent fig. 1. The court agrees with Medtronic that, in the drawings of the '961 patent, the slot portion does not extend across the perimeter of the trailing end. The court must construe the disputed claim in view of the entire specification, <u>Markman v. Westview</u> <u>Instruments, Inc.</u>, 52 F.3d 967, 979 (Fed.Cir.1995), including the drawings. Therefore, the court must construe "intersecting" to encompass the embodiments depicted in the drawings of the '961 patent. The court construes "intersecting" to mean "cutting through, crossing, or meeting."

For the reasons stated above, the disputed term is not limited to the diagrams in the Design Patent. Furthermore, nothing in the '961 patent specification supports Globus' argument that the slot portion must be vertical. (See Globus' Reply Br. at 12.) Globus' attempt to limit the patent to the embodiments depicted in the figures directly contradicts controlling law. <u>See</u> Phillips v. AWH Corp., 413 F.3d 1308, 1323 (Fed. Cir. 2005).

The court construes "slot portion intersecting one portion of the perimeter of said trailing end" to mean "the slot portion cuts through, crosses, or meets one portion of the perimeter of the trailing end."

3. another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end (claims 1, 12, 24, 36, and 47)

The disputed term "another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end" is found in claims 1, 12, 24, 36, and 47 of the '961 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "another slot portion intersects another portion of the perimeter of the trailing end, at a point opposite where the first slot portion intersects the perimeter of the trailing end." Globus contends the term should be construed as "a second portion of the vertical groove or depression which cuts through or across the perimeter of the trailing end of the implant, as depicted in Figures 1, 1a-e and 2 of the '961 Patent and Figures 1-7 of the Design Patent."

For the reasons stated above, the court construes "another slot portion intersecting another portion of the perimeter of said trailing end opposite said one portion of the perimeter of said trailing end" to mean "a second slot portion intersects a second portion of the perimeter of the trailing end, at a point opposite where the first slot portion intersects the perimeter of the trailing end."

4. an opening through said implant and oriented along the height

The disputed term "an opening through said implant and oriented along the height" is found in claims 1 and 86 of the '961 patent. Medtronic contends that the term can be understood by its plain meaning. Alternatively, Medtronic contends that the term should be construed as "at least one opening through the implant that is oriented along its height." Globus contends the term should be construed as "a hole or opening, oriented along the height of the implant, that extends through the upper wall of the implant but not through the bottom wall of the implant, which has a plurality of holes, as depicted in Figures 1, 1a-e and 2 of the '961 Patent and Figures 1-7 of the Design Patent."

For the reasons stated above, the disputed term is not limited to the diagrams in the Design Patent. Nothing in the '961 patent specification or the plain meaning of the disputed term limits the opening to one that extends through the upper wall of the implant but not through the bottom wall of the implant. The court construes "an opening through said implant and oriented along the height" to mean "a hole or opening through the implant that is oriented along the height of the implant."

H. <u>The '725 Terms</u>

- 1. convexly curved;
- 2. convexly curved upper and lower surfaces; and
- 3. leading end portion includes a convexly curved leading end nose extending between said convexly curved upper and lower surfaces

The court considers all three disputed terms from the '725 patent together because the longest term includes the two shorter terms. All three disputed terms are found in claims 14 and 23 of the '725 patent. Medtronic contends that "convexly curved" should be construed as "outwardly curved," while Globus contends the term should be construed as "continuously outwardly curved." Medtronic contends that "convexly curved upper and lower surfaces" should be construed as "the upper and lower surfaces are outwardly curved," while Globus contends the term should be construed as "the upper and lower surfaces are outwardly curved," while Globus contends the term should be construed as "continuously outwardly curved top and bottom sections that do not include any flat and planar portions." Medtronic contends that "leading end portion includes a convexly curved leading end nose extending between said convexly curved upper and lower surfaces" should be construed as "the leading end portion includes a leading end nose that is convexly curved and that extends between the convexly curved upper and lower surfaces," while Globus contends the term should be construed as "the leading end of the implant has a nose portion that is continuously outwardly curved, without any flat or planar portions, and extends between the convexly curved upper and lower surfaces."

In both disputed claims, the term "convexly curved" is used to describe two different portions of the spinal implant: 1) the upper and lower surfaces of the body and 2) the leading end portion of the implant's leading end nose. Globus argues that the term should be construed as "continuously outwardly curved" because the Examiner's statement in the prosecution history that none of the prior art taught or made obvious "spinal implants as claimed including a continuously outwardly curved surface on the leading end between both the upper and lower surfaces and the lateral surfaces." <u>See</u> Globus Opening Br., Ex. H(1), '725 patent File History, at 280. Although the meaning of this statement is arguable, <u>see</u> Medtronic Reply Br. at 71 ("[The

Examiner's statement] is inherently confusing because it could be read to suggest that either the convexity of the leading end nose, or the curve of the nose, must be continuous."), the statement clearly applies to the leading end nose and not to the upper and lower surfaces of the body. Nothing in the specification indicates that "convexly curved" should be construed differently for the leading end nose than for the upper and lower surfaces of the body, and there is no evidence that the upper and lower surfaces must be "continuously outwardly curved." There is no basis for construing the term "convexly curved" to require a continuous curve. <u>See</u> Lantier 1st Decl., Ex. 62, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (2002) (convex: "2: arched up: bulging out; bow outward in a convex curve"). The court construes "convexly curved" to mean "outwardly curved," and "leading end portion includes a convexly curved leading end nose extending between said convexly curved upper and lower surfaces" to mean "the leading end nose extending between that is convexly curved and that extends between the convexly curved upper and lower surfaces."

IT IS SO ORDERED.

BY THE COURT:

S/ James T. Giles J.