IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC.,

Plaintiff,

v.

DISC-O-TECH MEDICAL TECHNOLOGIES, LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC.,

Defendants.

C.A. 04-204-JJF

SPECIAL MASTER'S OPINION AND ORDER ON CLAIM CONSTRUCTION

This is an action for patent infringement brought by plaintiff Kyphon Inc. ("Kyphon") against defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "Disc-O-Tech").

The matter is presently before the Special Master on the parties' respective requests for the construction of disputed claim language – in accordance with *Markman v. Westview Instruments, Inc.*, 52 F. 3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996) – of U.S. Patent No. 4,969,888 issued November 13, 1990 (the '888 patent); U.S. Patent No. 5,108,404 issued April 28, 1992 (the '404 patent); U.S. Patent No. 6,235,043 B1 issued May 22, 2001 (the '043 patent); U.S. Patent No. 6,241,734 B1 issued June 5, 2001 (the '734 patent); and U.S. Patent No. 6,613,054 B2 issued September 2, 2003 (the '054 patent).[1] The parties have fully briefed their respective positions on the construction of disputed terms, and argued them before the Special Master at a *Markman* hearing held on April 19, 2005. Jurisdiction is proper under 28 U.S.C. § 1338.

[1] Although Kyphon's Amended Complaint also asserts that Disc-O-Tech infringes U.S. Patent No. 6,248,110 B1 issued June 19, 2001 (the '110 patent), Kyphon is not asserting any claims of the '110 patent.

I. LEGAL STANDARD FOR CLAIM CONSTRUCTION

The legal standard governing claim construction was recently summarized by this Court as follows:

> Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*. 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed. 2d 577 (1996). A claim term should be construed to mean "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." *Markman*, 52 F.3d at 986.
>
> The starting point for a claim construction analysis is the claims themselves. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (stating that "[t]he starting point for any claim construction must be the claims themselves."). Generally, there is a strong presumption in favor of the ordinary meaning of claim language as understood by those of ordinary skill in the art. *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001). However, "[t]he intrinsic record, comprising the claims, the written description, and the prosecution history if in evidence 'must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted.'" *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1325-26 (Fed. Cir. 2003) (quoting *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1393, 1204 (Fed. Cir. 2002)).
>
> If the meaning of a claim term is clear from the totality of the intrinsic evidence, then the claim may be construed. If, however, the meaning of a claim term is "genuinely ambiguous" after examining the intrinsic evidence, then a court may consult extrinsic evidence. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997).

Lucent Technologies, Inc. v. Extreme Networks, Inc., No. CIV. A. 03-508, slip op. at **1-2 (D.Del. Apr. 14, 2005) (Farnan, J.) [available as 2005 WL 859255].

II. CLAIM CONSTRUCTION

The patents-in-suit collectively describe methods and/or apparatus for the internal fixation of bones weakened by disease or damaged by injury. The '888 patent and the '404 continuation patent are both directed to the basic method of bone fixation known as kyphoplasty. The '888 and '404 patents describe a method of internal fixation of bones that includes the surgical formation of a passage in bone marrow, the compaction of the bone marrow to increase the volume of that passage, and the filling of the passage with a flowable material that will set to a hardened condition, to create what Kyphon describes as an internal cast. The '043 patent is directed to methods for achieving the controlled expansion of the devices used in kyphoplasty for compacting the bone marrow. The '734 and '054 patents are directed to the instruments, systems and methods used in the kyphoplasty procedure for internally filling the bone.

A. Threshold Construction Issue

The parties' proposed claim constructions for all of the patents-in-suit derive from their disagreement as to whether the "compacting" step described in the '888 and '404 patents requires compaction by an inflatable (balloon) device. Disc-O-Tech argues that the '888 and '404 patents describe only inflatable (balloon) devices and compaction by such devices. Kyphon argues that, although its preferred embodiment is an inflatable device, its patents are not so limited and therefore claim a method of compaction by expandable devices. Thus, before construing the disputed claim language, the Special Master must address the threshold question of whether the claims of the '888 and '404 patents are limited only to inflatable (balloon) devices and the compaction of bone marrow by such devices.

The parties agree that the starting point for the analysis of claim construction is the claims themselves. *See, e.g., Vitronics*, 90 F. 3d at 1582; *Pitney Bowes*, 182 F. 3d at 1305;

Lucent Technologies, 2005 WL 859255, slip. op. at *1. Ground zero for the parties' dispute is the language of claim 1 of both the '888 and '404 patents. The language of claim 1 is identical for both patents, except that claim 1 of the '888 patent describes a method for treating osteoporotic bone, and claim 1 of the '404 patent deletes the descriptive word "osteoporotic" and claims a method for treating all bone.[2] The language of claim 1 of both the '888 and '404 patents (except for the descriptive word "osteoporotic") is as follows:

> 1. A method of fixation of a fracture or impending fracture of an [osteoporotic] bone having [osteoporotic] bone marrow therein comprising:
>
> forming a passage in the bone marrow;
>
> compacting the bone marrow to increase the volume of said passage and
>
> filling the passage with a flowable material capable of setting to a hardened condition.

('888 patent at 9:21-28) and ('404 patent at 9:33-40). On its face, this language does not include any reference to a balloon and/or inflatable.

Disc-O-Tech urges that the strong presumption in favor of the ordinary meaning of claim language, as it would be understood by someone skilled in the art, is inapplicable to the language of claim 1. In this regard, Disc-O-Tech points to the intrinsic record as support for its contentions that the '888 and '404 patents describe only inflatable (balloon) devices and compaction by inflation, and that the patentee has excluded other devices and methods of compaction.

First, Disc-O-Tech points to the titles of the '888 patent ("Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device") and the '404 patent ("Surgical Protocol for

[2] The parties agree that the claim terms and specifications of the '888 and '404 patents are substantially identical and, because the '404 is a continuation of the '888 patent, that their claim terms should be similarly construed.

Fixation of Bone Using Inflatable Device"). However, the language used in patent titles has been held to have little relevance to the construction of a patent's claims. *See, e.g., Pitney Bowes,* 182 F. 3d at 1312 ("The near irrelevancy of the patent title to claim construction is further demonstrated by the dearth of case law in which a patent title has been used as an aid to claim construction").

Disc-O-Tech also points out that the Abstracts for both the '888 and '404 patents reference inflatable devices ("The method of the present invention includes a series of steps including penetrating the bone having the fracture with a guide pin, drilling the [osteoporotic] bone marrow of the bone to enlarge the cavity to be treated, following which a bone specific inflatable device is inserted in the cavity and inflated."). Abstract, '888 patent and '404 patent (without descriptive term "osteoporotic"). However, like the language of a title, the language of an Abstract does not weigh heavily in claim construction. *See, e.g., Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F. 3d 1111, 1121 (Fed. Circuit 2004) ("Nor does this statement [in the Abstract] weigh heavily when considering whether the applicant has acted as his own lexicographer. To begin, this statement is in the Abstract of the patent. This section of a patent speaks generally to the invention and, much like the syllabus of an opinion, sets forth general information about the document's content, which is described in more detail in the remainder of the document.").

Disc-O-Tech then turns to the claims, specifications, and what it asserts is prosecution history to argue that the patentee has restricted the ordinary and otherwise broad meaning of the claim language by defining only inflatable (balloon) devices and compaction by such devices. In so arguing, Disc-O-Tech relies primarily upon *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F. 3d 858 (Fed. Cir. 2004). *See* April 19, 2005 Hearing Transcript, D.I. 193 at 70:5-6 ("[W]e're going

to show you that this case is just like *Bard*.").

In *C.R. Bard*, the Federal Circuit examined the intrinsic record as it related to claim 20 of the patent-in-suit, which claimed an implantable plug for use in hernia repair. Specifically, the Federal Circuit examined the language of the claim, the specifications, and the prosecution history. The Federal Circuit concluded that, based on the intrinsic record, the patentee clearly defined the scope of the patent claim to be a "pleated" plug, even though the claim language did not expressly describe the plug as pleated. *Id.* at 869 ("Bard clearly defined the plug in claim 20 as having pleats in both the specification and the prosecution history.") See also, *id.* at 870 ("In this case, the inventors clearly and deliberately disclaimed any coverage of non-pleated plugs . . . when they stated during reexamination that 'the surface of the inventive plug is pleated' in an attempt to overcome the prior art-based rejections of claims 19 and 20.") (Prost, J., concurring).

In examining the intrinsic record in the instant case, the Special Master concludes that it is clearly distinguishable from that set forth in *C.R. Bard*. First, the language of claim 1 of the '888 and '404 patents does not claim or describe or limit any device or structure. See claim 1, *supra* at p. 4. In contrast, the language of claim 20 that was at issue in *C.R. Bard* contained a detailed description of the invention's structure, as well as precise modifying terms that specifically limited the structure:

> 20. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising: a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect and which is ***radially compressible*** upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, ***the surface of said hollow plug being conformable to irregularities*** in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect, ***said hollow plug being extremely pliable, allowing localized portions of the hollow***

plug to adapt to irregularities in the tissue or muscle wall defect.

C.R. Bard, 388 F. 3d at 860 (quoting U.S. Patent No. 5,356,432).

Second, the Special Master has reviewed the specifications of the '888 and '404 patents, mindful that "Specifications teach. Claims claim." *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (en banc). See also, *Smith v. Snow*, 294 U.S. 1, 11 (1935) ("We may take it that, as the statute requires, the specifications just detailed show a way of using the inventor's method and that he conceived the particular way described was the best one. But he is not confined to that particular mode of use since the claims of the patent, not its specifications, measure the invention."); *C.R. Bard*, 388 F.3d at 865 ("a patent claim term is not limited merely because the embodiments in the specification all contain a particular feature"); and *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d. 1313, 1327 (Fed. Cir. 2002) (claims of patent will not be read restrictively unless patentee has demonstrated clear intention to limit claim scope using "words or expressions of manifest exclusion or restriction.").

The Special Master is satisfied that this patentee has not, by describing the best mode as inflatable (balloon) devices in the specifications, made a clear disavowal of other devices. *See e.g.*, '888 patent at 2:3-11 ("The method of the present invention includes a series of steps including forming an incision in the body and penetrating the bone having the fracture with instruments including a guide pin and a cannula, drilling the bone marrow of the bone to enlarge the cavity or passage to be treated, following which an inflatable device, such as an expandable balloon, is inserted in the cavity and inflated."). This is true no matter how frequently an inflatable (balloon) device is mentioned in the specifications. *C.R. Bard*, 388 F.3d at 864 ("the holding . . . did not depend on the number of times the term "pressure jacket" was used or on details of preferred embodiments.") (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898

(Fed. Cir. 2004)).

Finally, in contrast to the prosecution history in *C.R. Bard*, the Special Master is satisfied that this patentee did not disclaim anything in order to overcome prior-art rejections. Disc-O-Tech has not adduced evidence of anything in the prosecution history of either the '888 or '404 patent to support the view that the patent applicant manifestly disavowed or disclaimed the unambiguous language of claim 1. Disc-O-Tech improperly references the extrinsic record (in the absence of any ambiguity) by pointing to the following language from the prosecution history of the '043 patent – a patent-in-suit filed years after the '888 and '404 patents were filed – that references claims 1 and 16 of the '404 patent, and allegedly supports Disc-O-Tech's argument that the applicant had limited claim 1:[3]

> Claim 16, like claim 1, recites the step of inflating the device to force the bone marrow outwardly of the recess and against the bone to form a void in the bone.

Claim 16, however, is not like claim 1. Its language is easily distinguishable from the language of claim 1. Claim 16 expressly provides:[4]

> A method of fixation of a fracture of a bone containing bone marrow therein comprising:
>
> drilling said bone to form a recess therein;
>
> inserting **an inflatable device** in said recess;
>
> **inflating the device in the recess to increase the volume** thereof and to force the bone marrow outwardly of the recess to form a void in the bone; and
>
> filling the void in the bone with a flowable material capable of setting to a hardened condition.

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[3] This argument was not raised by Disc-O-Tech until the *Markman* hearing on April 19, 2005.

[4] Claim 15 of the '888 patent contains similar language to claim 16 of the '404 patent. Both specifically claim inflatable devices.

Compare claim 16 ('404 patent at 10:22-30) (emphasis added) *with* claim 1, *supra* at p. 4. To argue that the language of claim 1 should be construed in the same manner as the different language of claim 16 ignores the presumption under the doctrine of claim differentiation that there is a difference in meaning and scope when different words or phrases are used in separate claims. *See, e.g., Comark Communications, Inc. v. Harris Corp.*, 156 F. 3d 1182, 1187 (Fed. Cir. 1998) (finding that, although "the doctrine of claim differentiation is not a hard and fast rule of construction, it does create a presumption that each claim in a patent has a different scope.").

Disc-O-Tech's argument also ignores the '043 patent applicant's language that immediately preceded the portion cited by Disc-O-Tech – language that clearly negates the interpretation urged by Disc-O-Tech:

> Claim 16 recites the same combination of elements as allowable Claim 1 and **is distinguished over claim 1 by reciting the step of inserting an inflatable device** in the recess.

In conclusion, the Special Master holds that the claim language of the '888 and '404 patents do not explicitly limit the invention to inflatable (balloon) devices or to the compaction of bone marrow by such devices; and that there is no clear disavowal of other embodiments in the patents' specifications and/or prosecution histories. Therefore, the Special Master concludes that the claims of the '888 and '404 patents are not limited to inflatable (balloon) devices or to the compaction of bone marrow by such devices, and the Special Master will construe the disputed claim language that follows in accordance with this holding.

B. Construction of Disputed Terms

1. THE '888 and '404 PATENTS

The '888 patent is entitled Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device. Kyphon has asserted claims 1, 3, 7, 8, 9, 11 and 14 of the '888 patent against

Disc-O-Tech in this litigation. The disputed terms are contained in claims 1, 3 and 7.

a. **Claim 1** of the '888 patent claims:

> 1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:
>
> forming a passage in the bone marrow;
>
> compacting the bone marrow to increase the volume of said passage and
>
> filling the passage with a flowable material capable of setting to a hardened condition.

('888 patent at 9:21-28).

The '404 patent is entitled Surgical Protocol for Fixation of Bone Using Inflatable Device. Kyphon has asserted claims 1, 3, 8, 9, 10, 12 and 15 of the '404 patent against Disc-O-Tech in this litigation. The disputed terms are contained in claims 1, 3 and 8.

Claim 1 of the '404 patent – which is a continuation of the '888 patent – claims:

> 1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:
>
> forming a passage in the bone marrow:
>
> compacting the bone marrow to increase the volume of said passage; and
>
> filling the passage with a flowable material capable of setting to a hardened condition.

('404 patent at 9:33-40). Claim 1 of the '404 patent is identical to Claim 1 of the '888 patent, except that it does not use the term "osteoporotic" to describe the bone and/or bone marrow.

(1) **Parties' Contentions**

Kyphon asserts that the term *bone marrow* means "a combination of the connective tissue and the cancellous bone framework inside a bone" in all asserted claims of both the '888 patent

and the '404 patent which is a continuation of the '888 patent. Disc-O-Tech initially asserted that *bone marrow* should be defined as "the viscous liquid material contained within the interstices (spaces) of the cancellous bone." By its Response dated April 14, 2005, and by its positions taken at the April 19, 2005 *Markman* hearing, Disc-O-Tech concedes that it is no longer contesting Kyphon's interpretation of *bone marrow* as including cancellous bone. Disc-O-Tech Response, D.I. 163 at p. 6.

Kyphon asserts that the language *forming a passage in the bone marrow* should be interpreted as "forming a path or channel into the interior of the bone through the bone marrow." Disc-O-Tech asserts that this language should be construed as "forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone," or "forming an opening, hole or perforation in the bone marrow."

Kyphon asserts that the language *compacting the bone marrow to increase the volume of said passage* should be interpreted to mean "compacting the bone marrow to increase the volume of the passage created by the surgeon, so that the resulting cavity can then be safely filled with a flowable material." Disc-O-Tech asserts that this language should be interpreted as "using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage."

Kyphon asserts that the step of *filling the passage with a flowable material capable of setting to a hardened condition* should be interpreted to mean "filling the passage with a material that is at some point in a fluid state (i.e., capable of flowing on its own) that is capable of setting to a hardened condition." In its briefing, Disc-O-Tech asserts that this language should be construed as "bone filler material capable of flowing and setting to a hardened condition." At the

Markman hearing, Disc-O-Tech amplified its proposed construction to define *flowable material* as "a nonsolid substance that tends to conform to the shape of a container."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 1 of U.S. Patent No. 4,969,888 and claim 1 of U.S. Patent No. 5,108,404 are construed as follows:

'888 and '404 Patent Claim 1	Special Master's Construction
A method of fixation of a fracture or impending fracture of an [osteoporotic] bone having [osteoporotic] **bone marrow** therein comprising:	a combination of the connective tissue and the cancellous bone framework inside a bone
forming a passage in the bone marrow;	forming a channel in the bone marrow
compacting the bone marrow to increase the volume of said passage and	compacting the bone marrow to increase the volume of the created channel
filling the passage with a **flowable material capable of setting to a hardened condition**.	filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition

b. **Claim 3** of both the '888 and '404 patents claims:

> 3. A method as set forth in claim 1, wherein said compacting step includes forcing the [osteoporotic] bone marrow outwardly of the central portion of the bone.

('888 patent at 9:33-35) and ('404 patent at 9:45-47). Claim 3 of the '404 patent again differs from claim 3 of the '888 patent only by its deletion of the descriptive term "osteoporotic."

(1) Parties' Contentions

Kyphon has not submitted a proposed claim construction of the phrase *forcing the osteoporotic bone marrow outwardly of the central portion of the bone*, other than to urge a construction consistent with its plain meaning and to urge rejection of any construction that would require the use of an inflatable device. Disc-O-Tech asserts that this language should be

construed as "forcing the bone marrow outwardly of the central portion of the bone."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 3 of both U.S. Patent No. 4,969,888 and U.S. Patent No. 5,108,404 is construed as follows:

'888 and '404 Patent Claim 3	Special Master's Construction
A method as set forth in claim 1, wherein said compacting step includes **forcing the** [osteoporotic] **bone marrow outwardly of the central portion of the bone.**	compacting the bone marrow so as to force it outwardly from the central portion of the bone

c. **Claim 7** of the '888 patent and **claim 8** of the '404 patent claims:

> 7./8. A method as set forth in claim 1, wherein said forming step includes drilling said [osteoporotic] bone marrow to form said passage.

('888 patent at 9:47-49) and ('404 patent at 9:64-66). Claim 8 of the '404 patent again deletes the descriptive term "osteoporotic."

(1) Parties' Contentions

Kyphon asserts that the step of *drilling said . . . bone marrow to form said passage* should be interpreted to mean "rotating a shaft with one or more cutting edges to bore a hole into and through the bone marrow in the interior of the bone." Disc-O-Tech asserts that this language should be interpreted as "using a drill to break through the cortical wall of the bone."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 7 of U.S. Patent No. 4,969,888 and claim 8 of U.S. Patent No. 5,108,404 are construed as follows:

'888 Patent Claim 7/'404 Patent Claim 8	Special Master's Construction
A method as set forth in claim 1, wherein said forming step includes **drilling said** [osteoporotic] **bone marrow to form said passage**.	using a drill to form a channel into and through the bone marrow

Charts summarizing all of the Special Master's claim constructions for the '888 and '404 patents are attached at Exhibits **A** and **B**, respectively, and incorporated herein by reference.

2. THE '043 PATENT

The '043 patent is entitled an Inflatable Device for Use in Surgical Protocol Relating to the Fixation of Bone. Kyphon has asserted claims 2, 17, 20, 23, 24, 25, 26 and 28 of the '043 patent against Disc-O-Tech in this litigation.[5] The disputed language is contained in claims 2 and 17.

a. **Claim 2** of the '043 patent claims:

> 2. A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, including the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.

('043 patent at 14:38-49).

(1) Parties' Contentions

Kyphon asserts that all claims of the '043 patent that contain the language that *a body adapted to be inserted into bone and undergo expansion in cancellous bone* – including claims 2

[5] Kyphon is no longer asserting claim 27 of the '043 patent against Disc-O-Tech.

and 17 – should be construed as "a body adapted to be inserted into bone and to undergo an increase in size while in cancellous bone." Kyphon rejects any proposed construction that would limit the claims of the '043 patent to inflatable devices. Disc-O-Tech asserts that this language should be construed as "an inflatable body that can be inserted into bone and expanded."

Kyphon asserts that the language *includes an internal restraint coupled to an interior of the body to constrain the expansion* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal walls of the inflatable body."

Kyphon asserts that the language *causing constrained expansion of the body* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "constraining the expansion of the inflatable body."

Finally, Kyphon asserts that the language *compacting cancellous bone by the constrained expansion* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 2 of U.S. Patent No. 6,235,043 B1 are construed as follows:

'043 Patent Claim 2	Special Master's Construction
A method for treating bone comprising the steps of	
inserting inside bone a devise comprising **a body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, including the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further	a body adapted so as to be capable of insertion into bone and of expansion in cancellous bone
includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone,	includes an internal restraint coupled to the interior of the body, that constrains the expansion of the body in cancellous bone
causing constrained expansion of the body in cancellous bone,	causing constrained expansion of the body
and **compacting cancellous bone by the constrained expansion**.	compacting cancellous bone by the body's constrained expansion

b. **Claim 17** of the '043 patent claims:

> 17. A method for treating bone comprising the steps of inserting into bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone,
>
> causing constrained expansion of the body in cancellous bone, and
>
> compacting cancellous bone by the constrained expansion.

('043 patent at 15:30-37 to 16:1-4).

(1) **Parties Contentions**

Kyphon asserts that the language *a body to be inserted into bone and undergo expansion*

in cancellous bone should be construed, like the same language in claim 2, as "a body adapted to be inserted into bone and to undergo an increase in size while in cancellous bone." Disc-O-Tech asserts that this language should be construed as "an inflatable body that can be inserted into bone and expanded."

Kyphon asserts that the language *causing constrained expansion of the body* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "constraining the expansion of the inflatable body.

Finally, Kyphon asserts that the language *compacting cancellous bone by the constrained expansion* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 17 of U.S. Patent No. 6,235,043 B1 are construed as follows:

'043 Patent Claim 17	Special Master's Construction
A method for treating bone comprising the steps of	
inserting inside bone a devise comprising **a body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone,	a body adapted so as to be capable of insertion into bone and of expansion in cancellous bone
causing constrained expansion of the body in cancellous bone, and	causing constrained expansion of the body
compacting cancellous bone by the constrained expansion.	compacting cancellous bone by the body's constrained expansion

The Special Master's claim construction of the disputed terms of U.S. Patent No. 6,235,043 B1 are summarized in Exhibit **C**, and incorporated herein by reference.

3. THE '734 PATENT

The '734 patent is entitled Systems and Methods for Placing Materials into Bone. Kyphon has asserted claims 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20 and 21 of the '734 patent against Disc-O-Tech in this litigation. The disputed terms are contained in claims 1, 5, 10, 11, 12, 16, 17, 20 and 21.

a. **Claim 1** of the '734 patent claims:

> 1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi, a nozzle instrument capable of advancement into the subcutaneous cannula and

> comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure, and a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.

('734 patent at 19:63-67 to 20:1-8).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument capable of advancement into the subcutaneous cannula* should be construed as "a tamping instrument capable of advancing through any point within the subcutaneous cannula, where the tamp and the cannula may consist of one or more components." Kyphon further asserts that the language *material residing in the subcutaneous cannula* should be construed as "material located at any point within the subcutaneous cannula."

Disc-O-Tech asserts that the language *a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone* should be, in its entirety, construed as "an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 1 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 1	Special Master's Construction
Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi, a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure,	
and **a tamping instrument capable of advancement into the subcutaneous cannula** and having a tamping terminus which, during the advancement, urges **material residing in the subcutaneous cannula into bone**.	a tamping instrument that is capable of advancing through any point into the subcutaneous cannula, where the tamp and the cannula may consist of one or more components, and having a tamping terminus that urges material from any point in the subcutaneous cannula into bone

b. **Claim 5** of the '734 patent claims:

> Apparatus according to claim 1 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.

('734 patent at 20:17-20).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with markings relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula

into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 5 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 5	Special Master's Construction
Apparatus according to claim 1 wherein the **tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.**	the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula

c. Claim 10 of the '734 patent claims:

> Apparatus according to claim 1 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.

('734 patent at 20:35-38).

(1) Parties' Contentions

Kyphon asserts that the language *a cavity forming instrument* does not require further clarification. Disc-O-Tech asserts that the language should be construed to limit said instrument to "inflatable devices disclosed in the '404 and '888 patents."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 10 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 10	Special Master's Construction
Apparatus according to claim 1 and further including **a cavity forming instrument** capable of advancement through the subcutaneous cannula to compress cancellous bone.	a cavity forming instrument

d. **Claim 11** of the '734 patent claims:

> Apparatus according to claim 10 wherein the cavity forming instrument includes an expandable structure.

('734 patent at 20:39-41).

(1) Parties' Contentions

Kyphon asserts that the language *cavity forming instrument includes an expandable structure* does not require further clarification. Disc-O-Tech asserts that this language should limit said instrument to "inflatable devices disclosed in the '404 and '888 patents."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 11 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 11	Special Master's Construction
Apparatus according to claim 10 wherein the **cavity forming instrument includes an expandable structure.**	cavity forming instrument includes an expandable structure

e. **Claim 12** of the '734 patent claims:

> Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi, a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to

> the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure, and a stylet capable of advancement into the nozzle bore through the nozzle fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.

('734 patent at 20:42-55).

(1) Parties' Contentions

Kyphon asserts that the language *stylet . . . with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula* requires no further clarification. Disc-O-Tech asserts that this language should be construed as "nested stylet/nozzle instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 12 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 12	Special Master's Construction
Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi, a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure, and a **stylet** capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, **with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula**.	stylet [capable of advancing into the nozzle bore . . .] that, with the nozzle instrument, forms a tamping instrument capable of advancing into any point of the subcutaneous cannula to urge residual material from the subcutaneous cannula

f. **Claim 15** of the '734 patent claims:

> Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula, a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi, and a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone.

('734 patent at 20:62-66 to 21:1-3).

(1) Parties' Contentions

Kyphon asserts that the language *a delivery device to convey the material into the subcutaneous cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "a delivery device such as a syringe that expels material into the bore (which material contacts the inner walls) of the cannula."

Kyphon asserts that the language *a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone* should be construed, like claim 1, as "a tamping instrument capable of advancing through any point within the subcutaneous cannula, where the tamp and the cannula may consist of one or more components, and having a tamping terminus which, during the advancement, urges material located at any point in the subcutaneous cannula into bone." Disc-O-Tech asserts that this language should be construed as "an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 15 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 15	Special Master's Construction
Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula,	
a **delivery device to convey the material into the subcutaneous cannula**, at a delivery pressure of no greater than about 360 psi,	a delivery device to convey the material into the subcutaneous cannula
and **a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone**.	a tamping instrument having a tamping terminus that, as it advances through any point within the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone

g. **Claim 17** of the '734 patent claims:

Apparatus according to claim 15 wherein the tamping instrument includes markings to visually gauge the advancement of the

tamping terminus through the subcutaneous cannula.

('734 patent at 21:6-9).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with markings relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 17 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 17	Special Master's Construction
Apparatus according to claim 15 wherein the **tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula**.	the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula

h. **Claim 20** of the '734 patent claims:

> Apparatus according to claim 15 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.

('734 patent at 22:4-7).

(1) Parties' Contentions

Kyphon asserts that the language *a cavity forming instrument* does not require further clarification. Disc-O-Tech asserts that this language should be construed to limit said instrument

to "inflatable devices disclosed in the '404 and '888 patents."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 20 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 20	Special Master's Construction
Apparatus according to claim 15 and further including **a cavity forming instrument** capable of advancement through the subcutaneous cannula to compress cancellous bone.	a cavity forming instrument

i. **Claim 21** of the '734 patent claims:

> Apparatus according to claim 15 wherein the cavity forming instrument includes an expandable structure.

('734 patent at 22:8-11).

(1) Parties' Contentions

Kyphon asserts that the language *cavity forming instrument includes an expandable structure* does not require further clarification. Disc-O-Tech asserts that this language should limit said instruments to "inflatable devices disclosed in the '404 and '888 patents."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 21 of U.S. Patent No. 6,241,734 B1 is construed as follows:

'734 Patent Claim 21	Special Master's Construction
Apparatus according to claim 15 wherein the **cavity forming instrument includes an expandable structure**.	cavity forming instrument includes an expandable structure

The Special Master's claim construction of the disputed terms of U.S. Patent No. 6,241,734 B1 are summarized in Exhibit **D**, and incorporated herein by reference.

4. THE '054 PATENT

The '054 patent discloses systems and methods for delivering material into bone that deploy a cannula through soft tissue to establish a subcutaneous path into bone. ('054 patent, Abstract). Kyphon has asserted claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 42, 43, 44, 46, 47, 48 and 49 of the '054 patent against Disc-O-Tech in this litigation. The disputed language is contained in claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 46 and 47.

a. **Claim 26** of the '054 patent claims:

> Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone, and a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula, the tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and to withdrawal of the tamping terminus from the cannula.

('054 patent at 20:58-67 to 21:1-4).

(1) Parties' Contentions

Kyphon asserts that the language *a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

Kyphon asserts that the language *advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone* should be construed as "a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components, to urge material located at any point within the cannula into bone." Disc-O-Tech asserts that this language should be construed as "an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 26 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 26	Special Master's Construction
Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone,	
and **a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula**,	a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula
the tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula, **advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone**, and withdrawal of the tamping terminus from the cannula.	advancement of the tamping terminus through any point within the cannula, to urge material located at any point within the cannula into bone

b. **Claim 27** of the '054 patent claims:

> Apparatus according to claim 26 wherein at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument.

('054 patent at 21:5-8).

(1) Parties' Contentions

Kyphon asserts that the language *at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument* requires no further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula indicating when the distal end of the instrument and cannula are aligned, where the tamping instrument clears residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 27 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 27	Special Master's Construction
Apparatus according to claim 26 wherein the **at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument**.	at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument

c. Claim 28 of the '054 patent claims:

> Apparatus according to claim 26 wherein the tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula.

('054 patent at 21:9-12).

(1) Parties' Contentions

Kyphon asserts that the language tamping instrument includes a set point marking spaced

from the terminus at a distance generally equal to the length of the cannula does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with a set point marking relative to the cannula spaced from the terminus at a distance generally equal to the length of the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 28 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 28	Special Master's Construction
Apparatus according to claim 26 wherein the **tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula**.	tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula

d. **Claim 29** of the '054 patent claims:

> Apparatus according to claim 27 wherein the tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.

('054 patent at 21:13-16).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least marking relative to the cannula to visually gauge the advancement

of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 29 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 29	Special Master's Construction
Apparatus according to claim 27 wherein the **tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula**.	tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula

e. **Claim 36** of the '054 patent claims:

> Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone; and a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula and comprising a body portion and a handle portion, the handle portion having a cross-sectional area greater than the cross-sectional area of the body portion.

('054 patent at 22:1-11).

(1) Parties' Contentions

Kyphon asserts that the language *a tamping instrument for advancement through the cannula* should be construed as "a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components." Disc-O-Tech asserts that this language should be construed as "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

Kyphon asserts that the language *including at least one marking to visually gauge the*

advancement of the terminus relative to the distal end of the cannula does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the advancement of the terminus to the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 36 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 36	Special Master's Construction
Apparatus for delivering material into bone comprising	
a cannula for establishing a subcutaneous path into bone; and	
a tamping instrument for advancement through the cannula	a tamping instrument for advancement through any point within the cannula, where the tamp and cannula may consist of one or more components
including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula and comprising a body portion and a handle portion,	including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula
the handle portion having a cross-sectional area greater than the cross-sectional area of the body portion.	

f. Claim 37 of the '054 patent claims:

> Apparatus according to claim 36 wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument.

('054 patent at 22:12-15).

(1) Parties' Contentions

Kyphon asserts that the language *wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula indicating when the distal ends of the instrument and cannula are aligned, where the tamping instrument clears residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 37 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 37	Special Master's Construction
Apparatus according to claim 36 **wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument**.	wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument

g. **Claim 38** of the '054 patent claims:

> Apparatus according to claim 36 wherein the tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula.

('054 patent at 22:16-19).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes a set point marking spaced*

from the terminus at a distance generally equal to the length of the cannula does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with a set point marking relative to the cannula spaced from the terminus at a distance generally equal to the length of the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 38 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 38	Special Master's Construction
Apparatus according to claim 36 wherein the **tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula**.	tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula

h. **Claim 39** of the '054 patent claims:

> Apparatus according to claim 38 wherein the tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.

('054 patent at 22:20-23).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the

advancement of the terminus of the instrument as it clears the residual material form the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 39 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 39	Special Master's Construction
Apparatus according to claim 38 wherein the **tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula**.	tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula

i. **Claim 41** of the '054 patent claims:

> Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone; and a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula, and comprising a body portion and a handle portion, the body portion being sized and configured to substantially fill the cannula when the tamping instrument is fully inserted into the cannula.

('054 patent at 22:34-44).

(1) Parties' Contentions

Kyphon asserts that the language *a tamping instrument for advancement through the cannula* should be construed as "a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components." Disc-O-Tech asserts that this language should be construed as "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

Kyphon asserts that the language including at least one marking to visually gauge the

advancement of the terminus relative to the distal end of the cannula does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 41 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 41	Special Master's Construction
Apparatus for delivering material into bone comprising	
a cannula for establishing a subcutaneous path into bone; and	
a tamping instrument for advancement through the cannula	a tamping instrument for advancement through any point within the cannula, where the tamp and cannula may consist of one or more components
including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula, and comprising a body portion and a handle portion, the body portion being sized and configured to substantially fill the cannula when the tamping instrument is fully inserted into the cannula.	including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula

j. Claim 42 of the '054 patent claims:

Apparatus according to claim 41 wherein the at least one marking indicates when the distal end of the tamping instrument is aligned

with the distal end of the cannula instrument.

('054 patent at 22:45-48).

(1) Parties' Contentions

Kyphon asserts that the language *at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument* requires no further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula indicating when the distal ends of the instrument and cannula are aligned, where the tamping instrument clears residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 42 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 42	Special Master's Construction
Apparatus according to claim 41 wherein the **at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument**.	at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument

k. **Claim 43** of the '054 patent claims:

> Apparatus according to claim 41 wherein the tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula.

('054 patent at 22:49-52).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes a set point marking spaced*

from the terminus at a distance generally equal to the length of the cannula requires no further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with a set point marking relative to the cannula spaced from the terminus at a distance generally equal to the length of the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material form the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 43 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 43	Special Master's Construction
Apparatus according to claim 41 wherein the **tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula**.	tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula

l. **Claim 44** of the '054 patent claims:

> Apparatus according to claim 43 wherein the tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.

('054 patent at 22:53-56).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula* requires no further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the

advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity.

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 44 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 44	Special Master's Construction
Apparatus according to claim 43 wherein the **tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula**.	tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula

m. **Claim 46** of the '054 patent claims:

> Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone; and a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula and comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.

('054 patent at 22:65-66 to 23:1-8).

(1) Parties' Contentions

Kyphon asserts that the language *a tamping instrument for advancement through the cannula* should be construed as "a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components." Disc-O-Tech asserts that this language should be construed as "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

Kyphon asserts that the language *including at least one marking to visually gauge the*

advancement of the terminus relative to the distal end of the cannula does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 46 of U.S. Patent No. 6,613,054 B2 are construed as follows:

'054 Patent Claim 46	Special Master's Construction
Apparatus for delivering material into bone comprising	
a cannula for establishing a subcutaneous path into bone; and	
a tamping instrument for advancement through the cannula	a tamping instrument for advancement through any point within the cannula, where the tamp and cannula may consist of one or more components
including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula and comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.	including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula

n. **Claim 47** of the '054 patent claims:

Apparatus according to claim 46 wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with distal end of the cannula instrument.

('054 patent at 23:9-12).

(1) Parties' Contentions

Kyphon asserts that the language *at least one marking indicates when the distal end of the tamping instrument is aligned with distal end of the cannula instrument* requires no further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least one marking relative to the cannula indicating when the distal ends of the instrument and cannula are aligned, where the tamping instrument clears residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 47 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 47	Special Master's Construction
Apparatus according to claim 46 wherein the **at least one marking indicates when the distal end of the tamping instrument is aligned with the distal of the cannula instrument**.	at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument

o. **Claim 48** of the '054 patent claims:

> Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone; and a tamping instrument for advancement through the cannula including a set point marking spaced from the terminus at a distance generally equal to the length of the cannula and comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.

('054 patent at 23:13-22).

(1) Parties' Contentions

Kyphon asserts that the language *a tamping instrument for advancement through the cannula* should be construed as "a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components." Disc-O-Tech asserts that this language should be construed as "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity."

Kyphon asserts that the language *including a set point marking spaced from the terminus at a distance generally equal to the length of the cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with a set point marking relative to the cannula spaced from the terminus at a distance generally equal to the length of the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed terms of claim 48 of U.S. Patent No. 6,613,054 B2 are construed as follows:

'054 Patent Claim 48	Special Master's Construction
Apparatus for delivering material into bone comprising	
a cannula for establishing a subcutaneous path into bone; and	
a tamping instrument for advancement through the cannula	a tamping instrument for advancement through any point within the cannula, where the tamp and cannula may consist of one or more components
including a set point marking spaced from the terminus at a distance generally equal to the length of the cannula and comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.	including a set point marking spaced from the terminus at a distance generally equal to the length of the cannula

p. **Claim 49** of the '054 patent claims:

> Apparatus according to claim 48 wherein the tamping instrument includes at lease one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.

('054 patent at 23:23-28).

(1) Parties' Contentions

Kyphon asserts that the language *tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula* does not require further clarification. Disc-O-Tech asserts that this language should be construed as "an instrument with at least marking relative to the cannula to visually gauge the advancement of the terminus of the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity."

(2) Special Master's Construction

It is hereby ordered that the disputed term of claim 49 of U.S. Patent No. 6,613,054 B2 is construed as follows:

'054 Patent Claim 49	Special Master's Construction
Apparatus according to claim 48 wherein the **tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.**	tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula

The Special Master's claim construction of the disputed terms of U. S. Patent No. 6,613,054 B2 are summarized in Exhibit **E**, and incorporated herein by reference.

SO ORDERED:

/s Vincent J. Poppiti
Vincent J. Poppiti (DSBA No. 100614)
Special Master

Dated: May 16, 2005