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. No. 04-204-JJF **REDACTED – PUBLIC VERSION**

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S CLAIM CONSTRUCTION MEMORANDUM REGARDING KYPHON'S U.S. PATENT NOS. 6,241,734 (B1) AND 6,613,054 (B2)

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I. SUMMARY OF ARGUMENT

1. There are two key factors in the claim interpretation for the two patents addressed in this brief, referred to as the Bone Filler Patents: (1) material gets expelled into the bore and contacts the inner walls of the canula, because a nozzle instrument is withdrawn into a cannula as material is expelled; and (2) after the nozzle instrument is removed, all tamping operations are performed relative to the cannula in order to clear the residual material from the bore (and contacting the inner walls) of the cannula into the bone cavity.

2. The Bone Filler Patents disclose a distinct set of instruments: a nozzle instrument, a tamping instrument, a cannula, a stylet, and a delivery device. Even though the nozzle instrument and the cannula are both hollow tubes, they are distinct instruments with distinct purposes and operations.

3. All the tamping operations that are disclosed in the Bone Filler Patents are relative to the cannula – this is because the nozzle instrument has been withdrawn, leaving residual material contacting the inner walls of the cannula that needs to be cleared. Specifically, the Bone Filler Patents disclose two tamping operations that occur with respect to the cannula after the nozzle instrument is removed, leaving residual material in the bore and contacting the inner walls of the cannula: (1) tamping residual material from the cannula with a stylet and the nozzle instrument nested together; and (2) tamping residual material from the cannula with a tamping instrument that is separate and distinct from the nozzle instrument.

4. Because the tamping operations of the Bone Filler Patents are performed relative to the cannula, all markings on the instruments, and more specifically the nozzle instrument and tamping instrument, are also relative to the cannula.

II. FACTUAL BACKGROUND

A. Asserted Claims and General Background

Kyphon, Inc. alleges that DOT's pre-July 2004 Impactor device infringes claims 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, and 21 of U.S. Patent No. 6,241,734 B1, entitled "Systems and Methods for Placing Materials into Bone" ("the '734 Patent"); and Claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 42, 43, 44, 46, 47, 48, and 49 of U.S. Patent No. 6,613,054 B2 entitled "Systems and Methods for Placing Materials into Bone" ("the '054 Patent"). The '734 and '054 Patents are referred to collectively herein as the "Bone Filler Patents," and are attached as Exhibits A and B, respectively, to the Appendix in Support of Claim Construction of the Bone Filler Patents ("Appendix"), submitted herewith.

Kyphon also alleges that the Sky Bone Expander Device (the "SKy Device") infringes Claims 1, 3, 8, 9, 10, 12, and 15 of U.S. Patent No. 5,108,404 entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device" ("the '404 Patent"); Claims 1, 3, 7, 8, 9, 11, and 14 of U.S. Patent No. 4,969,888 entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device" ("the '888 Patent"); and Claims 2, 17, 20, 23, 24, 25, 26, and 28 of U.S. Patent No. 6,235,043 (B1) entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone" ("the '043 Patent"). This memorandum addresses the construction of claim terms in the '734 and '054 patents.[1] The construction of the claim terms of the '404, '888 and '043 Patents are

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1 Kyphon brought this suit against DOT alleging that the SKy Device infringes Claim 27 of the '043 Patent and certain claims of U.S. Patent No. 6,248,110 (B1) ("the '110 Patent"). Kyphon is no longer asserting any claims of the '110 Patent, or Claim 27 of the '043 Patent.

addressed in a separate memorandum (the "Balloon Bone Tamp Claim Construction Brief")[2] submitted concurrently with this memorandum.

The application which became the '734 Patent was filed on August 14, 1998; the '734 Patent issued on June 5, 2001. It generally describes an apparatus that delivers material into the bone by deploying a cannula to establish a subcutaneous path into the bone. More specifically, the '734 Patent describes the use of a delivery device to expel material into a nozzle instrument that is inserted through a cannula, the withdrawal of the nozzle instrument from the cannula as the material is being expelled so that material enters the bore (and contacts the inner walls) of the cannula, and the advancement of a tamping instrument through the cannula to clear the residual material from the bore (and inner walls) of the cannula into the bone.

The '054 Patent is entitled "Systems and Methods for Placing Materials into Bone." The application which became the '054 Patent was filed on March 12, 2001; the '054 Patent issued on September 2, 2003. The '054 Patent is a divisional of the '734 Patent, which was filed on August 14, 1998. The '054 Patent generally describes an apparatus that delivers material into the bone by deploying a cannula to establish a subcutaneous path into the bone. More specifically, the '054 Patent describes the use of a delivery device to expel material into a nozzle instrument that is inserted through a cannula, the withdrawal of the nozzle instrument from the cannula as the material is being expelled so that material enters the bore (and contacts the inner walls) of the cannula, and the advancement of a tamping instrument through the cannula to clear the residual material from the bore (and inner walls) of the cannula into the bone.

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2 The Balloon Bone Tamp Claim Construction Brief is titled Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043.

Because the '054 Patent is a divisional of the '734 Patent, the patents share the same specification, but have different (though substantially similar) claims.

B. The Relevant Anatomy

The human anatomy relevant to a full understanding of the patents-in-suit is discussed in full detail in the Balloon Bone Tamp Claim Construction Brief.

III. THE COURT'S ROLE IN CLAIM CONSTRUCTION

A. Intrinsic Evidence Is the Most Important Evidence

Claim construction is a matter of law for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384-391 (1996). To ascertain the meaning of claim terms, three sources of "intrinsic evidence" are used: the claims themselves; the patent specification; and, the prosecution history. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). These sources are referred to as intrinsic evidence because they include the public record of the patent and claims. Such intrinsic evidence is "the most significant source of the legally operative meaning of the disputed claim language." Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

To define the scope of the invention, a court first looks to the words of the claims themselves. Id. The words of the claims are to be given their ordinary meaning unless that meaning is inconsistent with the usage of the word in the specification and prosecution history. See Desper Prods., Inc. v. QSound Labs., Inc., 157 F.3d 1325, 1336 (Fed. Cir. 1998); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citations omitted) (the specification may require that a term be construed more narrowly than its dictionary

definition). "Throughout the construction process, it is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art." Interactive Gift Express, 256 F.3d at 1332.

Significantly, the court should also review the specification to determine the meaning of the claim terms. See id.; Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 979. Claims should not be interpreted "in a vacuum," but rather, should be consistent with the specification which provides content for the proper construction of the claims because it explains the nature of the patentee's invention. See Medrad, Inc. v. MRI Devices Corp., 2005 WL 605532, No. 04-1134 (Fed. Cir. Mar. 16, 2005); Interactive Gift Express, 256 F.3d at 1331; Renishaw, 158 F.3d at 1250.

The Federal Circuit has emphasized the importance of determining the overall context and intent of the invention:

> "[U]ltimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction. A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Renishaw, 158 F.3d at 1250. (emphasis added; citations omitted). The Federal Circuit re-affirmed these principles just weeks ago, in Medrad, quoting the emphasized language above, and further re-asserting that "[w]e cannot look at the ordinary meaning of the [claim] term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, 2005 WL 605532, at *6 (quoting DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1324 (Fed. Cir. 2001); see also Interactive Gift Express, 256 F.3d at 1331-32 (citing Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998))

(Because there is "a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification[,] . . . it is useful to remember that [the specification should be looked to in ascertain[ing] the meaning of the claim term as it is used by the inventor in the context of the entirety of [the] invention . . . .]") (emphasis added).

The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and claim the invention. C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (citing Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2003)). "Statements that describe the invention as a whole, rather than statements that describe only the preferred embodiments, are more likely to support a limiting definition of a claim term." Bard, 288 F.3d at 864 (citing Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998)). "Accordingly, other things being equal, certain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case by case basis." Bard, 288 F.3d at 864. The Federal Circuit noted that "[i]n relying on statements in the specification to limit claim terms, while the statement's location is not determinative of claim construction, the location can signal the likelihood that the statement will support a limiting definition of a patent claim term." Bard, 288 F.3d at 864 (citation omitted).

The prosecution history may also be of significance in determining the meaning of claim terms because. As the Federal Circuit has stated, "claims may not be construed one way [by the patentee] in order to obtain allowance and in a different way against accused infringers." Spectrum Int'l Inc. v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998) (citations omitted).

Because the claimed invention must be novel and non-obvious over the prior art, the prior art cited during prosecution also gives guidance as to what the claims do not cover. See Vitronics, 90 F.3d at 1583 (citing Autogiro Co. of America v. United States, 384 F.2d 391, 399 (Ct. Cl. 1967)).

Additionally, claims should not be construed so that they do not read on the prior art. As the Federal Circuit explained, "[w]hen claims are amenable to more than one construction, they should, when reasonably possible, be interpreted so as to preserve their validity." See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996), cert. denied sub nom., Showa Aluminum Corp. v. Modine Mfg. Co., 518 U.S. 1005 (1996); Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1153 (Fed. Cir. 1997) ("[C]laims should be read in a way that avoids ensnaring prior art if it is possible to do so.") (citing, inter alia, Modine, supra).

B. Extrinsic Evidence May Also Be Considered But May Not Be Used to Alter the Meaning of the Claims

Extrinsic evidence may be considered in determining the meaning of claim terms for the purpose of assisting in the Court's understanding of the underlying technology. Interactive Gift Express, 256 F.3d at 1332. Extrinsic evidence is all of the evidence outside of the patent and its prosecution history. Such evidence would include inventor and expert testimony, treatises and dictionaries. Markman, 52 F.3d at 980. Extrinsic evidence, however, must not be used to alter the meaning of claim terms as defined by the specification and prosecution history. Interactive Gift Express, 256 F.3d at 1332; Markman, 52 F.3d at 981, 986.

IV. CONSTRUCTION OF THE ASSERTED CLAIMS

A. Instruments Referenced in the Asserted Claims of the Bone Filler Patents

The Bone Filler Patents disclose systems for placing material into bone cavities. All claims of the Bone Filler Patents asserted by Kyphon are apparatus claims. These claims reference a number of instruments that are defined in the specification: a tamping instrument, a cannula, a nozzle instrument, a stylet and a delivery device. As will be demonstrated below, these instruments are explained and discussed in detail in the '734 and '054 patents.

Figure 5 of the Bone Filler Patents is a "perspective view of the material introducing instrument group." Figure 5 shows a syringe 104 (i.e., a delivery device), a nozzle instrument 106, and a material tamping instrument 108:

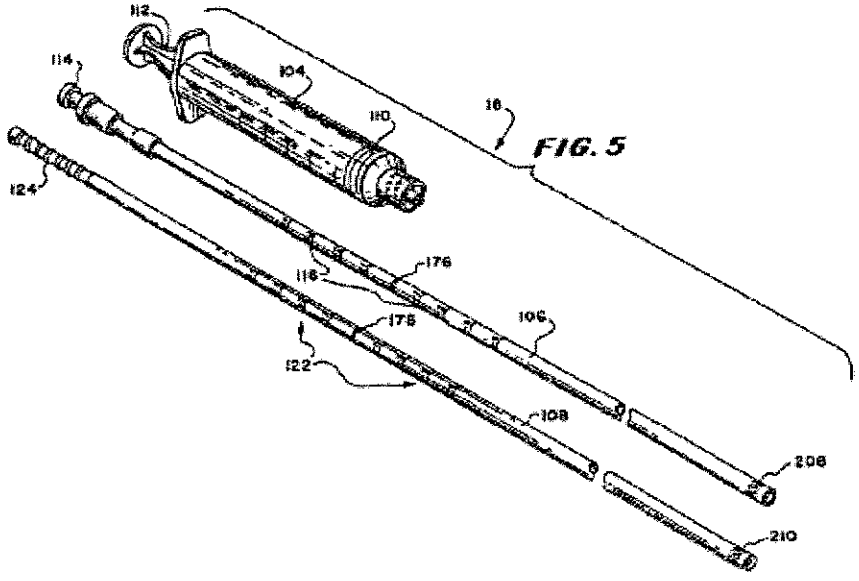


FIG. 5

(See Figure 5, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)[3] As shown, the nozzle instrument 106 is a hollow tube with a constant diameter. The body portion of the tamping instrument 108 has a constant diameter. Figure 3 below shows a cannula 30:

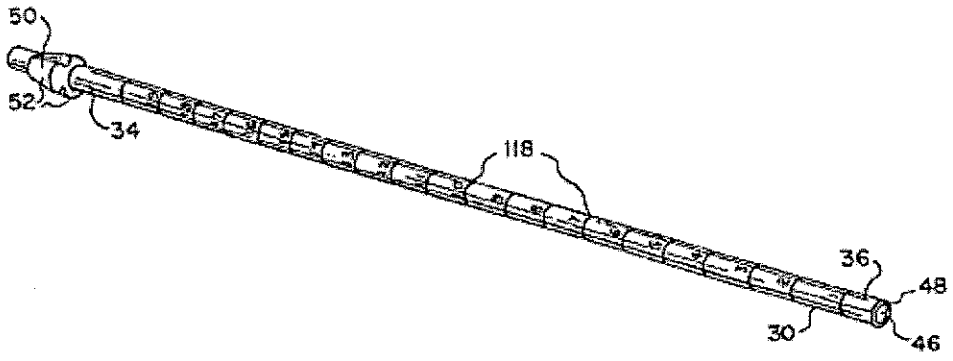
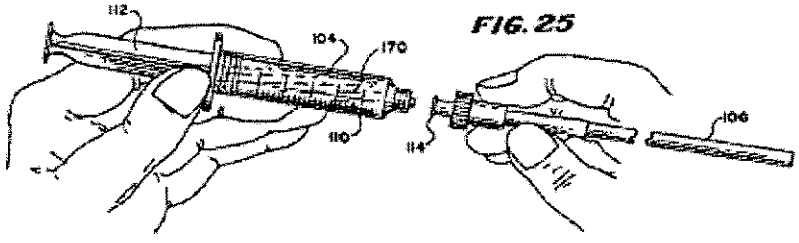


Figure 3

(See Figure 3, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.) The cannula 30 is a hollow tube with a constant diameter. Figure 25 is a "perspective view of the syringe . . . being joined to a nozzle":



(See Figure 25, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.) Figure 26 is a "perspective view showing the syringe and attached nozzle . . . being deployed though the cannula instrument in preparation of introducing material into the cavity":

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3 Exhibits cited herein are contained in the Appendix of Exhibits to Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Claim Construction Memoranda and Motions for Summary Judgment of Non-Infringement and Invalidity ("Appendix of Exhibits").

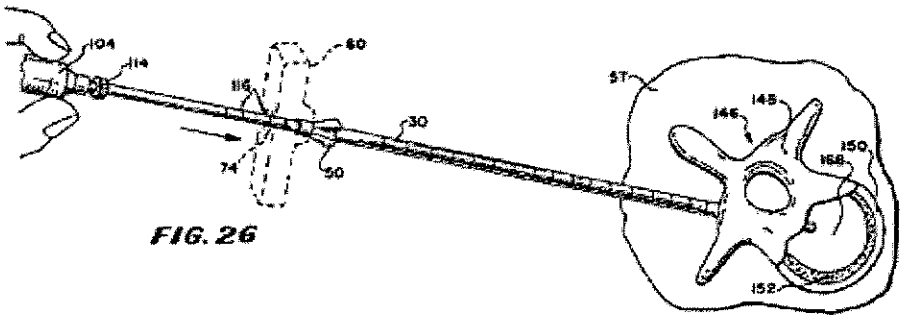


FIG. 26

(See Figure 26, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.) In Figure 26, the syringe 104 is joined to the threaded connector end 114 of the nozzle instrument; the nozzle instrument is inserted through the cannula 30.

A stylet, while not shown above, will be discussed in more detail below.

B. Disputed Claim Terms in the '734 and '054 Patents

Because of the similarities between the specifications of the two patents as well as the terms used in both patents, some of the disputed claim terms will be discussed together. DOT contends that those terms should be construed the same way. Claim terms which are specific to the '734 will be discussed separately. DOT's claim construction for each and every element of claims 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, and 21 of the '734 patent and claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 42, 43, 44, 46, 47, 48, and 49 of the '054 patent appears in a claim chart, attached hereto at Tabs A and B, respectively.

1. Similar Claim Terms in the '734 and '054 Patents

The disputed claim terms of independent claims 1, 12 and 15 and dependent claim 5 of the '734 Patent should be construed the same way as similar claim terms in the '054 Patent. The claims of the '734 Patent require (with disputed claim terms in bold):

> 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]**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.

12. 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 [c] **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.**

15. 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 [b]**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.**

5. Apparatus according to claim 1

wherein the [d] **tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.**

(See '734 patent, Exhibit B-1 to Appendix of Exhibits.) (emphasis added).

The claim terms of independent claims 26 and 36 and dependent claims 37 and 38 of the '054 Patent, which are similar to the above claim terms of the '734 Patent, require (with disputed claim terms in bold):

26. 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, [b] **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.

36. Apparatus for delivering material into bone comprising

a cannula for establishing a subcutaneous path into bone; and

[a] **a tamping instrument for advancement through the cannula** [d] **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.

37. Apparatus according to claim 36

[e]**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.**

38. Apparatus according to claim 36

wherein the [f] **tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula.**

(See '054 Patent, Exhibit B-2 to Appendix of Exhibits) (emphasis added).

DOT submits that the above disputed terms should be construed as follows.

(a) **a tamping instrument capable of advancement into the subcutaneous cannula** ('734 patent language)

a tamping instrument for advancement through the cannula ('054 patent language)

The above claim terms should be construed the same way. The tamping operation of the Bone Filler Patents is performed relative to the cannula in order to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity. These claim terms mean "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (See Rebuttal Expert Report of Dr. David Mitchell Regarding the Non-Infringement of U.S. Patent Nos. 6,241,734 (B1) and 6,613,054 (B2) ("Mitchell Bone Filler Patent Non-Infringement Report"), Exhibit D to Appendix of Exhibits at p. 16, ¶ 30.)

The specification for the Bone Filler patents compels this interpretation. The Bone Filler Patents disclose how these instruments described above are used to fill a cavity in the bone with material. Initially, the syringe is filled with material and then the filled syringe is attached to the nozzle instrument:

> Upon formation of the cavity 168, the physician acquires the syringe 104 and injection nozzle 106 from the kit 12. As FIG. 24 shows, the physician fills the syringe chamber 110 with the desired volume of filling material 170. As FIG. 25 shows, the physician attaches the nozzle 106 to the filled

> syringe 104. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 1-6.)

The nozzle instrument is then inserted through the cannula; initially, the distal end of the nozzle instrument is placed a select distance beyond the distal end of the cannula:

> In use, the distal end of the nozzle 106 is located beyond the distal end 36 of the cannula instrument 30 within the cavity formed in the targeted tissue region. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 11, lines 3-5.)
>
> As FIG. 26 shows, the physician inserts the nozzle 106 a selected distance beyond the distal end 36 of the cannula instrument 30 and into the cavity, guided by the markings 116. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 6-9.)

The syringe expels material into the bore of the nozzle instrument; while the material is being expelled from the nozzle instrument into the bone cavity, the distal end of the nozzle instrument is retracted from the bone cavity and withdrawn into the cannula:

> The syringe 104 ejects a predetermined volume of material into the nozzle 106 in a low pressure stream into the cavity. As the material fills the cavity, the nozzle (still ejecting material) is retracted from the cavity and into the cannula instrument 30 itself. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 11, lines 9-13; emphasis added.)
>
> As FIG. 27 shows, the physician manually advances the piston 112 to cause the material 170 to flow through and out of the nozzle 106 and into the cavity. As material 170 fills the cavity, the physician withdraws the nozzle from the cavity and into the cannula instrument 30. The cannula instrument 30 channels the material 170 flow toward the cavity 168. As FIG. 28 shows, the cement material 170 flows in a stream into the cavity 168. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 14-21; emphasis added.)
>
> As before explained, as the cavity 168 progressively fills with material, the nozzle 180 is withdrawn back into the cannula instrument 184. ('734 Patent, Exhibit B-1 to

> Appendix of Exhibits at Col. 18, lines 40-42; emphasis added.)
>
> The physician operates the syringe 104 to expel the cement material 170 from the chamber, through the nozzle 106, first into the cavity and then into the cannula instrument 30. . . .When a desired volume of cement is expelled from the syringe 104, the physician withdraws the nozzle 106 from the cannula instrument 30, as FIG. 29 shows. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 30-38; emphasis added)

Figure 27 is similar to Figure 26, and shows cement ejected from the syringe 104 into the bore of the nozzle instrument 106 and into the bone cavity; the nozzle instrument 106 is inserted through cannula 30:

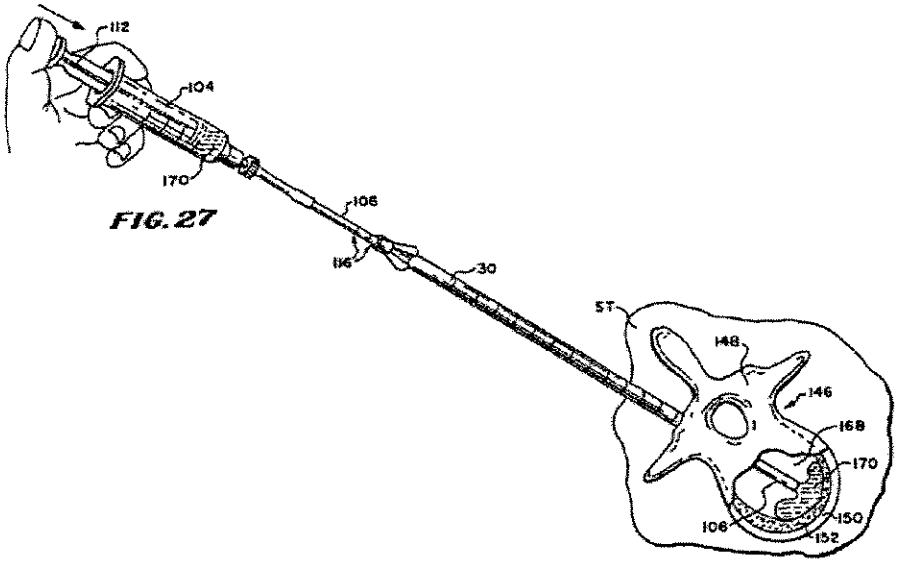
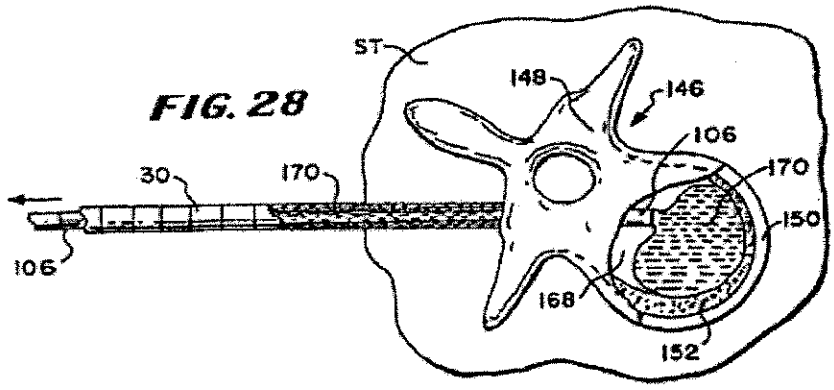


FIG. 27

(See Figure 27, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.) Figure 28 shows the withdrawal of the nozzle instrument 106 from the cannula 30 as the material 170 fills the cavity (note the arrow on the left side of the figure):

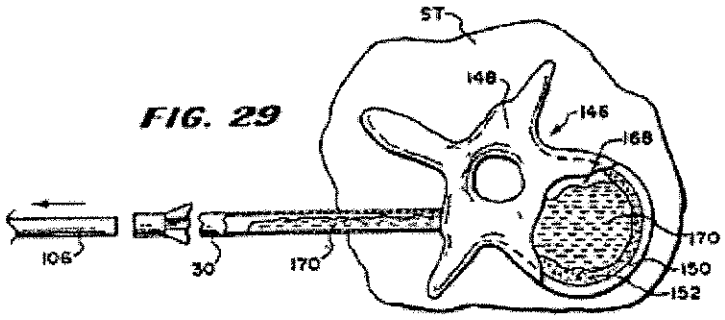


(See Figure 28, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)

As the nozzle instrument is withdrawn from the cannula, material is expelled into the bore of the cannula; this residual material contacts the inner walls of the cannula:

> After withdrawal of the nozzle 106 from the cannula instrument 30, residual material is left in the cannula instrument 30. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 11, lines 9-13 Col. 11, lines 43-45.)
>
> Typically, when the injection of material is completed, material extends from the cavity 168 and occupies about 40% to 50% of the cannula instrument 184. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 18, lines 41-44; emphasis added.)
>
> Typically, at the end of the syringe injection process, material 170 should extend from the cavity and occupy about 40% to 50% of the cannula instrument 30. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 33-35; emphasis added.)

Figure 29 depicts material 170 in the cavity as well as residual material 170 in the cannula 30:



(See Figure 29, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)

The arrow on the left side of the diagram shows the complete withdrawal of the nozzle instrument from the cannula; material is left in the bone cavity, and residual material is left in the bore (which material also touches the inner walls) of the cannula.

After removal of the nozzle instrument from the cannula, a tamping instrument is inserted into the cannula to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity:

> The physician acquires the tamping instrument 108 from the kit 12. As FIG 30 shows, the physician advances the tamping instrument 108 through the cannula instrument 30. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 43-45.)
>
> The purpose of the tamping instrument 108 is to displace the residual material out the distal end 36 of the cannula instrument 30 and into the cavity, to thereby fill the cavity without exerting undue pressure within the bone. The tamping instrument 108 thereby serves to clear residual material from the cannula instrument 30, to assure that the desired volume of material is delivered into the cavity. The removal of residual material from the cannula instrument 30 by the tamping instrument 108 also prevents seepage of the material into surrounding tissue regions upon removal of the cannula instrument 30. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 11, lines 45-55; emphasis added.)

> The distal end of the tamping instrument 108 contacts the residual volume of cement material 170 in the cannula instrument 30. As FIGS 30 and 31 show, advancement of the tamping instrument 108 displaces progressively more of the residual material 170 from the cannula instrument 30, forcing it into the cavity 168. The flow of material 170 into the cavity 168, propelled by the advancement of the tamping instrument 108 in the cannula instrument 30, serves to uniformly distribute and compact the material 170 inside the cavity 168, without the application of undue pressure. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 16, lines 50-59; emphasis added.)

In Figures 30 and 31, tamping instrument 108 is clearing the residual material 170 from the bore of the cannula into the bone cavity. Figure 30 shows the residual material 170 contacting the inner walls of the cannula:

FIG. 30

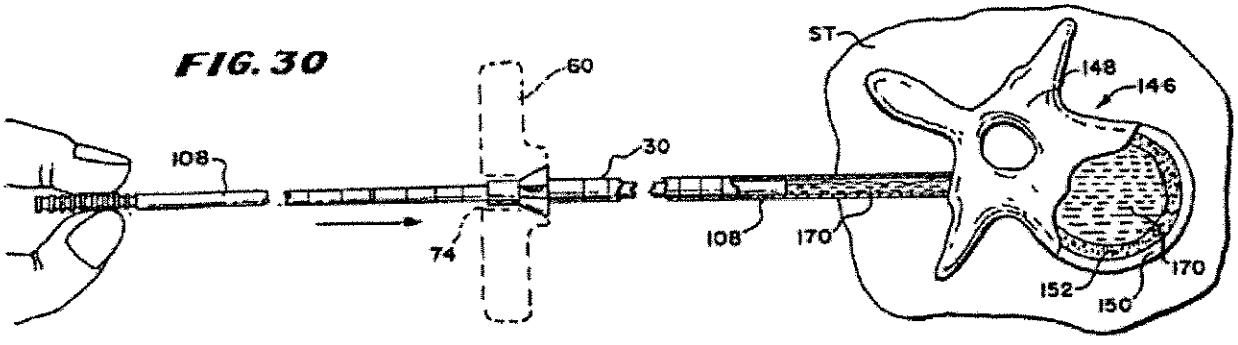
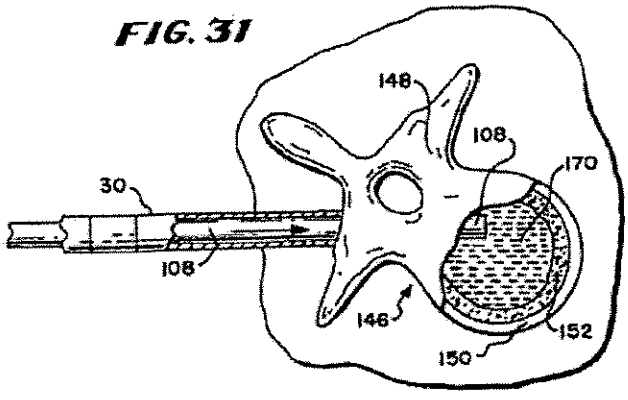


FIG. 31



(See Figures 30 and 31, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)

The tamping operation of the Bone Filler Patents is performed relative to the cannula in order to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity. The claim terms "a tamping instrument capable of advancement into the subcutaneous cannula" ('734 patent language) and "a tamping instrument for advancement through the cannula" ('054 patent language), therefore, mean "an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 16, ¶ 30.)

(b) **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 language)

advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone ('054 patent language)

The above claim terms should be construed the same way. The tamping operation of the Bone Filler Patents is performed relative to the cannula in order to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity.

The term "terminus" must be given its ordinary meaning, and as described in the specification of the '734 and '054 patents, it refers to the distal end of the tamping instrument. Therefore, these claim terms also mean "an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 16, ¶ 31.)

(c) **stylet . . .with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula** (claim 12 of the '734)

The above claim term means a "nested stylet/nozzle instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 16, ¶ 32.)

As an alternative to the tamping instrument described above, the stylet and the nozzle, when nested together, serve as a tamping instrument to clear the residual material 170 from the bore of the cannula into the bone cavity. Figure 33 of the Bone Filler Patents is a perspective view of syringe 104, nozzle instrument 180, cannula instrument 184, and stylet 182:

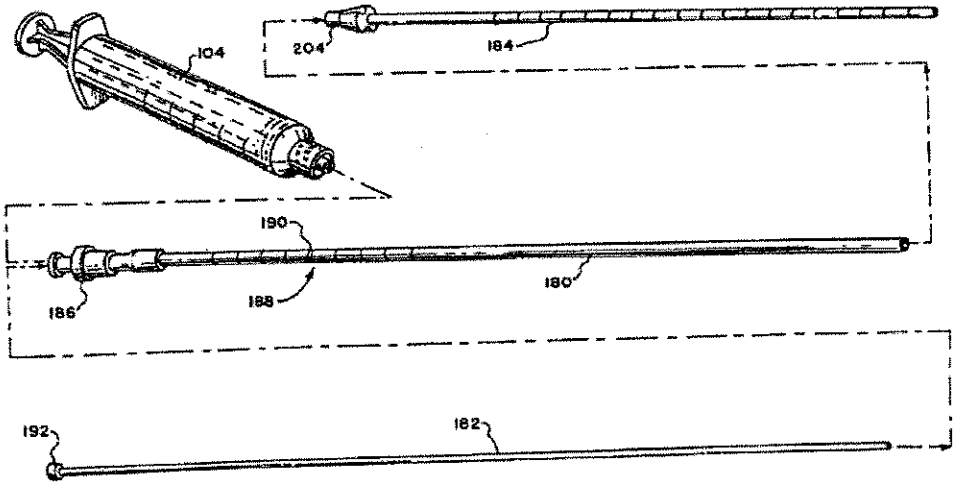


FIG. 33

(See Figure 33, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)

As in the procedure using the tamping instrument outlined above, the syringe expels material into the bore of the nozzle instrument that is inserted through the cannula, and the nozzle instrument is withdrawn from the cannula as the material is being expelled so that material enters the bore (and contacts the inner walls) of the cannula.

The nozzle 180 is nested with the stylet 182 to form, together, a tamping instrument that clears the residual material from the bore (and contacting the inner walls) of the cannula:

> The apparatus further includes a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument [sic]. Together, the nozzle and the stylet form a tamping instrument capable of advancement through the subcutaneous cannula to urge residual material from the subcutaneous cannula. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 2, lines 61-67; emphasis added.)
>
> At this point, the nozzle 180 can be fully withdrawn from the cannula instrument 184 and unthreaded from the syringe 104. The stylet 182 can be advanced into the nozzle 180, to bring the handle 192 at rest against the connector 186, thereby clearing residual material from the nozzle 180. The nozzle 180 and stylet can then be inserted as a nested unit into the cannula instrument 184. Nested together, the nozzle 180 and stylet 182 form a tamping instrument. Upon advancement through the cannula instrument 184, the nested nozzle 180 and the stylet 182 displace residual material from the cannula instrument 184 into the cavity 168, in generally the same manner as previously shown in FIGS. 30 and 31, thereby uniformly compacting material within the cavity 168 in a controlled fashion and without undue pressure. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 18, lines 45-59; emphasis added.)
>
> The other reduced-diameter instrument 182 comprises a stylet, which is sized to pass through the interior bore of the nozzle 180. The stylet 182 includes a handle 192, which rests on the proximal connector 186 of the nozzle 180 when the stylet 182 is fully inserted into the nozzle 180. When the handle 192 is rested, the distal ends of the stylet 182 and nozzle 180 align. The presence of the stylet 182 inside the nozzle 180 closes the interior nozzle bore. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 18, lines 26-30; emphasis added.)

When the stylet is inserted and advanced through the nozzle, the stylet does not clear material from the bore of the nozzle into the bone cavity. The stylet is inserted and advanced through the nozzle outside of the body.

As can be seen from the discussion above, when the stylet is nested with the nozzle, it forms a tamping instrument that acts in the same manner as described above. Therefore, a "stylet . . .with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula" means a "nested stylet/nozzle instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 16, ¶ 32.)

(d) tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula ('734 patent language)

a tamping instrument. . .including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula ('054 patent language)

The above claim terms should be construed the same way. The tamping operation of the Bone Filler Patents is performed relative to the cannula in order to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity. These claim terms mean "an instrument with [at least one marking/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." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 17, ¶ 33.)

Because the tamping operations of the Bone Filler Patents are performed relative to the cannula, the same kind of markings are placed on the nozzle instrument and tamping instrument. Figure 5 depicts the markings on tamping instrument 108 and nozzle instrument 106:

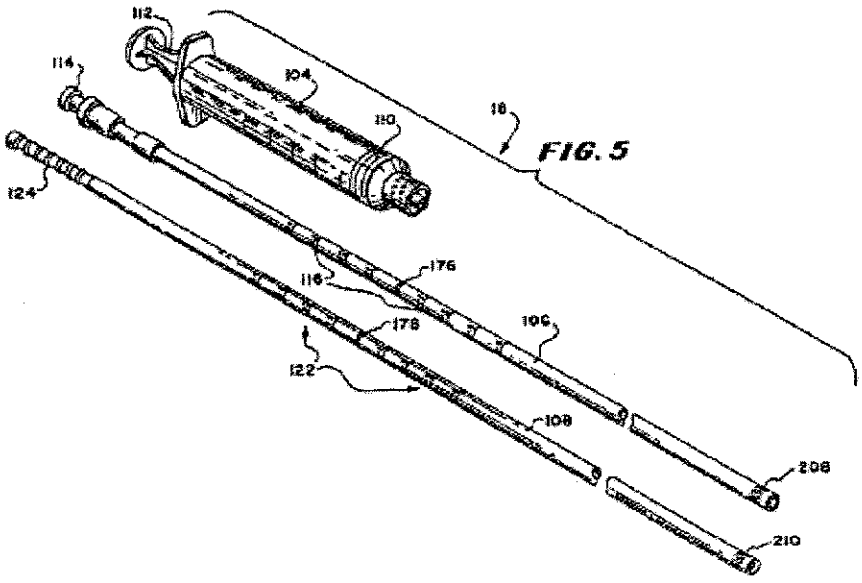


FIG. 5

(See Figure 5, '734 and '054 Patents, Exhibits B-1 and B-2 to Appendix of Exhibits.)

Thus, the tamping operation of the Bone Filler Patents is performed relative to the cannula in order to clear the residual material from the bore of the cannula (which material contacts the inner walls of the cannula) into the bone cavity. Because the tamping instrument's operation is relative to the cannula, the tamping instrument includes markings relative to the distal end of the cannula:

> The tamping instrument 108 includes measured markings 122 along its length. The markings 116 can be placed for example, at one centimeter intervals, to correspond with the markings 118 on the cannula instrument 30, so that the relative position of the tamping instrument 108 within the cannula instrument 30 can be gauged. Like the nozzle 106, the markings 122 on the tamping instrument 108 includes a set point 178, which indicates when the distal end of the tamping instrument 108 aligns with the distal end 36 of the cannula instrument 30. Also, like the nozzle 106, the

> markings 122 on the tamping instrument 108 are consecutively numbered with positive numbers proximally of the set point 178 and with negative numbers distally of the set point 178. The physician is thereby able to tell at a glance the location of the end of the tamping instrument 108 in terms of how far beyond or short of the distal end 36 of the cannula instrument 30 it is. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 11, lines 23-29; emphasis added.)

As previously discussed, the nozzle/stylet combination can be used in a tamping operation identical to the tamping instrument. Because the nozzle/stylet combination's tamping operation is relative to the cannula, the nozzle instrument includes markings relative to the distal end of the cannula:

> The nozzle 106 includes measured marking 116 along its length. The markings 116 can be placed, for example, at one centimeter intervals, to correspond with the markings 118 on the cannula instrument 30, so that the relative position of the nozzle 106 within the cannula instrument 30 can be gauged. The markings 118 can, e.g., include a set point 176. Alignment of the set point 176 at the proximal end 34 of the cannula instrument 30, indicates that the distal end of the nozzle 106 is located in an aligned relationship with the distal end 36 of the cannula instrument 30. In this arrangement, the markings 118 are consecutively numbered with positive numbers proximally of the set point 176 and with negative numbers distally of the set point 176. The physician is thereby able to tell at a glance the location of the distal end of the nozzle 106, in terms of how far beyond or short of the distal end 36 of the cannula instrument 30 it is. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 10, line 53 through Col. 11, line 2; emphasis added.)
>
> As FIG. 33 shows, the reduced–diameter nozzle 180 also includes measured markings 188 along its length, as previously described, the markings 188 include a set point 190, as previously described, which aligns with the proximal end of the cannula instrument 184 when the distal ends of the cannula instrument 184 and the nozzle 180 align. ('734 Patent, Exhibit B-1 to Appendix of Exhibits at Col. 18, lines 20-25.)

The claim language that "includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula" ('734 patent language) and a "tamping instrument. . . including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula" ('054 patent language) indicate that all movement of the tamping instrument and/or the stylet/nozzle combination is relative to the cannula, and are therefore marked as such. Therefore, these claim terms mean "an instrument with [at least one marking/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." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 17, ¶ 33.)

(e) **tamping 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**. (claim 37).

The above claim term means "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." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 17, ¶ 34.) As discussed in more detail above, all movement of the tamping instrument is relative to the cannula. This claim term describes a marking on tamping instrument to indicate when the instrument has completely cleared all residual material from the inner walls of the cannula.

(f) **tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula** (claim 38)

The above claim term means "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." (See Mitchell Bone Filler Patent Non-Infringement Report, Exhibit D to Appendix of Exhibits at p. 17, ¶ 35.) As discussed in detail above, all movement of the tamping instrument is relative to the cannula. This claim term describes a marking on the tamping instrument to indicate the instrument's progress in clearing residual material from the cannula.

2. Claim Terms Specific to the '734 Patent

Dependent claims 10 and 21 as well as independent claim 15 of the '734 patent (with disputed claim terms in bold) require:

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

21. Apparatus according to claim 15

[a] **wherein the cavity forming instrument includes an expandable structure.**

15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula, [b] **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.

(See '734 patent, Exhibit B-1 to Appendix of Exhibits.) (emphasis added).

(a) **a cavity forming instrument** capable of advancement through the subcutaneous cannula **to compress cancellous bone** (claim 10)

wherein the cavity forming instrument includes an expandable structure (claim 21)

The claim terms "a cavity forming instrument . . . to compress cancellous bone" and "wherein the cavity forming instrument includes an expandable structure" are limited to the inflatable devices disclosed in the '404 and '888 patents. In the "Cavity Forming Instrument" section ('734 patent, Exhibit B-1 to Appendix of Exhibits at col. 8, line 25 through col. 10, line 13) of the Bone Filler Patents, the cavity forming instruments comprise the inflatable devices disclosed in the '404 and '888 patents. A more detailed analysis of why these claim terms are limited to inflatable instructures can be found in the Balloon Bone Tamp Claim Construction Brief.

(b) **a delivery device to convey the material into the subcutaneous cannula**

As can clearly be seen from the specification, the claim term "a delivery device to convey the material into the subcutaneous cannula" means "a delivery device such as a syringe that expels material into the bore (which material contacts the inner walls) of the cannula." (See, e.g., Figure 25, '734 patent, Exhibit B-1 to Appendix of Exhibits; col. 10, ll. 33-51 (describing "injection" of material into nozzle from syringe)).

V. CONCLUSION

For the foregoing reasons, DOT requests that the disputed claim terms of the '734 and '054 Patents be be adopted by the Court and provided to the jury at trial in this matter.

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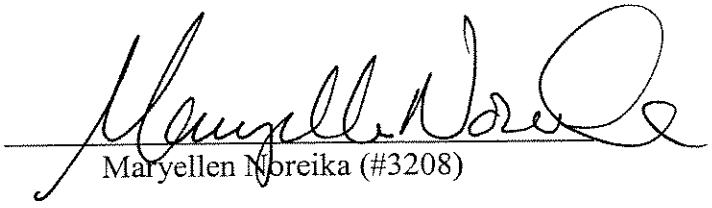
April 6, 2005

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 6h day of April, 2005 upon the following in the manner indicated:

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Maryellen Noreika (#3208)

A

U.S. PATENT NO. 6,241,734 (B1)
CLAIMS AND DOT'S CONSTRUCTION

'734 Patent Claim	DOT'S Construction
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.	an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
3. Apparatus according to claim 1 wherein the nozzle instrument is made of a generally rigid material.	
4. Apparatus according to claim 1 wherein the delivery device comprises a syringe.	
5. Apparatus according to claim 1 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	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
7. Apparatus according to claim 1 wherein the tamping instrument is made of a generally rigid material.	

'734 Patent Claim	DOT'S Construction
8. Apparatus according to claim 1 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus through the subcutaneous cannula.	
10. Apparatus according to claim 1 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	limited to inflatable devices disclosed in '404 and '888 patents
11. Apparatus according to claim 10 wherein the cavity forming instrument includes an expandable structure.	limited to inflatable devices disclosed in '404 and '888 patents
12. 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.	nested stylet/nozzle instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
13. Apparatus according to claim 12 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle instrument through the cannula.	

'734 Patent Claim	DOT'S Construction
14. Apparatus according to claim 12 wherein the delivery device comprises a syringe.	
15. 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.	a delivery device such as a syringe that expels material into the bore (which material contacts the inner walls) of the cannula. an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
16. Apparatus according to claim 15 wherein the delivery device comprises a syringe.	
17. Apparatus according to claim 15 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	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
19. Apparatus according to claim 15 wherein the tamping instrument is made of a generally rigid material.	
20. Apparatus according to claim 15 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	limited to inflatable devices disclosed in '404 and '888 patents

'734 Patent Claim	DOT'S Construction
21. Apparatus according to claim 15 wherein the cavity forming instrument includes an expandable structure.	limited to inflatable devices disclosed in '404 and '888 patents

B

U.S. PATENT NO. 6,613,054 (B2)
CLAIMS AND DOT'S CONSTRUCTION

'054 Patent	DOT's Construction
26. 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 withdrawal of the tamping terminus from the cannula.	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 an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
27. 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.	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
28. 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.	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
29. 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.	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

'054 Patent	DOT's Construction
36. 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.	an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity 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
37. 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.	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
38. 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.	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
39. 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.	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

'054 Patent	DOT's Construction
41. 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.	an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity 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
42. 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.	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
43. 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.	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
44. 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.	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

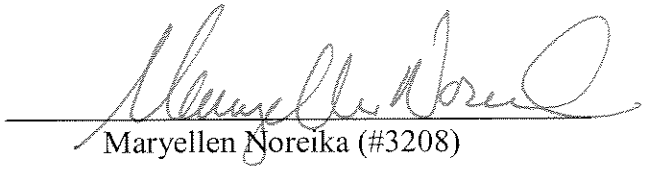
'054 Patent	DOT's Construction
46. Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone; and a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to 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.	an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity 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
47. 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 end of the cannula instrument.	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
48. 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.	an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity 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
49. 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.	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

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 13h day of April, 2005 upon the following in the manner indicated:

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