material inside the cavity" in a controlled manner. '734 Patent [D.I. 146, Ex. H], at col. 16:57-59. DOT's bone filler devices, like the preferred method described in the patent specification, also slide a tamp through a cannula tube to achieve precisely the same low pressure delivery of material into a bone. At the root of DOT's claim construction argument, however, is DOT's desire to avoid infringement of the asserted patents by limiting the claims to the best mode described in the specification. The specification of the patent describes the preferred method of using the claimed device as including the sliding of a nozzle tube out of a cannula tube, and then the sliding a tamp through ***one*** cannula tube to push material into a bone. DOT, however, contends that its device pushes material into the bone by sliding a tamp through the nozzle tube while the nozzle tube is still resting within the cannula tube (i.e., the tamp is slid thru ***two*** concentric tubes).

Specifically, the method employed by those using DOT's bone filler device is purportedly, as follows:

[1] a cannula tube establishes subcutaneous access to a bone;

[2] a nozzle tube slides into the cannula, forming a second concentric subcutaneous access into the bone;

[3] a syringe delivers material into the nozzle (while the nozzle is inside the cannula); and

[4] a tamping instrument pushes any material left in the nozzle tube out into the bone.

The specification of the '734 (and '054) describes essentially the same method. One difference is that just prior to step 4 the nozzle tube is slid out of the cannula and the

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polymer sleeve, and thereby results in a constrained expansion and forces the body to expand radially to compact the bone.

tamping instrument then pushes any material left in the single cannula tube into the bone. Because DOT allegedly does not slide the nozzle tube out before tamping – and instead, DOT pushes its tamp through the interior of the cannula while the nozzle tube is still resting inside the cannula tube – DOT asserts that it does not infringe the claims of the '734 and '054 patents. DOT, not surprisingly, demands that every asserted claim in the two bone filler device patents, the '734 and '054 patents, must be limited to requiring the use of a tamp directly vis-à-vis the cannula for clearing "residual material", and that the "material" itself must be in direct contact with the inner walls of the outer cannula.

DOT's claim construction limits all the claims to the single best method described in the specification for using the claimed device. Yet nothing in any of the claims requires that the claimed device must be used in the particular method that the patentees described as being the best way of using the device. These are apparatus claims, not method of use claims. For example, nothing in any claim requires that the nozzle tube must first be slid out of the cannula before a tamp is pushed through the cannula to tamp material into a bone. Likewise, no term in any of the claims even mentions, much less requires, that the tamp or the material being pushed into bone must be in "direct contact" with the inner walls of the outer cannula. The plain language chosen by the patentees for the claims merely describe a device that includes a tamp that is capable of being slid "into" "in" or "through" a cannula. Further still, nothing in the specification requires that the subcutaneous path into the bone be formed only with a single tube, as opposed to a double-tube. Simply put, the claims are broad, and deliberately cover all these alternatives.

Why then must the claims be "interpreted" to require the particular method of using a tamp on material that is in "direct contact" with the inner walls of the outer

cannula? The only answer from DOT is that the specification says so. But, DOT identifies no passage in the specification where the patentees set forth a "clear disavowal" of the full plain and ordinary scope of the claims. *See Teleflex* 299 F.3d at 1324. Instead, DOT merely provides a lengthy recitation of the description provided by the patentees of the best method for using the claimed device. Thus, because the claim constructions demanded by DOT ignore the basic roles played by the specification vis-à-vis the claims, they must be rejected.

1. **a tamping instrument capable of advancement into the subcutaneous cannula**

   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

For each of these limitations, DOT argues that they should be interpreted as requiring an instrument "that when it advances clears the residual material from the inner walls of the cannula into the bone cavity." Other than a lengthy recitation of the method described in the patent as being the patentee's best mode for carrying-out the invention, DOT provides no support for the additional requirements it seeks to add to the claims. *SRI*, 775 F.2d at 1121 ("The district court correctly described the specification, but the difficulty is this: claims are infringed, not specifications."). Indeed, DOT fails to identify any aspect of the patent specification or prosecution history that even purports to show that the patentee clearly disavowed or unmistakably intended to deviate from the full plain and ordinary meaning of the claims.

Moreover, because the claims of the '734 patent describe an apparatus, as opposed to a particular method of using a device, DOT's limitation of the claims to a specific method for *using* the tamp to push material through the interior of a cannula is especially

lacking in merit. Indeed, by focusing exclusively on the best mode method described in the specification, and then seeking to limit the apparatus claims of the '734 patent to a particular method of using the device, DOT invites the Court to commit the same error recognized by the Federal Circuit in *SRI*:

> Focusing exclusively on the way the structure of the Figure 1 embodiment in the specification operates, the district court allowed that focus to control its claim interpretation and its grant of summary judgment. In so doing, it erred.

Id. at 1117. In *SRI*, the invention concerned a filter for a camera that had grids placed at angles to one another. The preferred, and only, embodiment describing the best mode for practicing the invention with the grids constituted a device having one grid that was vertical and the other that was set at a 45-degree angle away from vertical. Based on the specification, and other factors, the trial court interpreted the claims as requiring that one of the grids must be vertical. Yet, claim 1 had no such limitation; it merely required that the grids be "relatively angularly superimposed." Thus, the trial court's claim construction was found to be in error. In correcting the trial court's claim construction, the Federal Circuit emphasized:

> If everything in the specification were required to be read into the claims, or **if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims.** Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with "claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. **It is the claims that measure the invention.**

Id. at 1121 (citing *Aro Mfg. Co., Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336, 339 (1961); *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d

903, 922 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed. Cir. 1984)) (emphasis added).

As noted above, the specification of the '734 details the best method for using the claimed bone filler device as including the step of sliding the nozzle tube out of the cannula and then tamping material through the cannula and into the bone. DOT seeks to import this particular method of using the claimed device into all the claims of the '734 patent. However, DOT's interpretations depart from the plain and ordinary meaning of the simple claim terms "into" and "in". As explained in Kyphon's Opening Brief, the ordinary meaning of these terms are "to the inside or interior of" and "within the limits, bounds, or area of". The tamp and the material that is pushed into the body, therefore, need only be within the interior, or limits of, the cannula tube. Nothing in the plain terms of the claims specifically requires that the material, and the tamp, be inside ***and*** also be in direct contact with the inner walls of the outer cannula, as opposed to, for example, in contact with the inner walls of a second tube which is "in" the cannula. Thus, DOT's effort to limit the plain meaning of the claims to the specific method described in the specification must be rejected.

2. 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

For the same reasons as noted above, DOT's effort to import a limitation from the specification – to require that "material" be in direct contact with the "inner walls" of the cannula and that a tamp act directly upon the cannula surface to clear the "material" – must be rejected.

3. **tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula**

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 tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula

DOT seeks to impose two additional limitations for each of these claim terms. First, as with DOT's interpretations of all of the terms from the '734 patent, it seeks to import from the specification a limitation that requires "material" to be in direct contact with the "inner walls" of the cannula and that a tamp act directly upon the cannula surface to clear the "material." For the reasons set forth above, DOT's effort to import such limitations from the specification must be rejected.

Second, DOT also seeks to change the plain meaning of these claims terms by requiring the additional limitation that all the markings somehow be "relative to the cannula." In doing so, DOT again is attempting to use the specification in an effort to escape liability for infringement.

As indicated above, DOT's bone filler devices include a plunger that is capable of sliding into the nozzle tube, while the nozzle is resting inside the cannula, and thereby allowing the plunger to tamp material simultaneously through the nozzle and cannula and into bone. DOT does not dispute that the nozzle tube has markings that allow the user to determine the precise location of the nozzle tube vis-à-vis the cannula tube. Therefore, when DOT's plunger is slid into the nozzle (while the nozzle is resting inside the cannula), the markings on the plunger allow the user to, among other things: (i) gauge advancement of the plunger as it slides into both the nozzle and the cannula; and (ii) determine when the

distal end of all three components are aligned, including the plunger and the cannula. Thus, while DOT has asserted that the markings on the plunger are not directly "relative to the cannula," the markings on the plunger clearly meet the plain language of the claim terms of allowing a user to gauge advancement of the plunger into the cannula and to determine when the plunger's distal end is aligned at the same point as the distal end of both the cannula and the nozzle.

To avoid infringement, DOT cites various excerpts from the specification that explain that the patentee's best method for using the claimed device involved the use of markings on the tamping instrument that could, for example, "correspond with the markings on the cannula instrument." While a direct correspondence of markings between the cannula and the tamping instrument is described by the patentee as being the best approach, nothing in the plain meaning of the claims requires that the markings on the tamping instrument must be directly "relative to the cannula" as demanded by DOT. Thus, DOT's effort to import from the specification a limitation that requires that the "markings" in all the asserted claims must be directly "relative to the cannula" should be rejected along with all of DOT's other efforts to deviate from the plain meaning of the claims by limiting them to the best mode described in the specification.

4. a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone

wherein the cavity forming instrument includes an expandable structure

DOT seeks to limit these claim terms to "inflatable devices." DOT's only basis for advancing this interpretation is that the specification of the '734 patent describes the best mode of the invention as including a cavity-forming instrument that is an inflatable device.

For the same reasons noted with regard to the '888 and '404 patents, DOT's effort to limit these terms of the '734 patent to inflatable devices must be rejected.[20]

5. a delivery device to convey the material into the subcutaneous cannula

DOT, again, seeks to add limitations to the plain meaning of a claim, by requiring that the "delivery device" "expels material into the bore" of the cannula, and that the material "contacts the inner walls" of the cannula. Neither of these additional limitations is required by the actual terms of the claims.[21] As noted above, the plain meaning of the term "into" simply means "to the inside or interior of." DOT has identified nothing in the specification or prosecution history that evidences a clear disavowal of this plain meaning. Thus, the material need only be conveyed to any point within the cannula, including a point that is within a nozzle tube that itself is resting within the cannula. DOT's effort to otherwise deviate from the plain meaning of this element should be rejected.

D. Construction of Claim Terms Disputed by DOT re '054 Patent

1. a tamping instrument for advancement through the cannula

advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone

As with DOT's interpretations of all of the terms from the '734 patent, DOT seeks to import limitations from the specification to require that "material" be in direct contact with the "inner walls" of the cannula and that a tamp act directly upon the cannula surface to clear the "material." DOT again ignores the plain meaning of the term "through" as

[20] Moreover, the specification of the '734 patent, itself, states that the cavity-forming instrument "can be constructed in various ways." '734 Patent, at col. 8: 31.

[21] Moreover, even the specification cited by DOT arguably does not show that material is expelled from the syringe directly "into the bore" of the cannula. Rather the best mode of the invention is described as having the delivery device attached to the nozzle and having the material pushed into the nozzle (material ultimately gets put into the cannula indirectly when the nozzle is slid out of the cannula).

referencing the movement of an object in another component (where "in" is commonly defined as being "within the limits, bounds or area of"), and "into" as being "to the inside or interior of." *See* D.I. 147, Ex. V, at 1266 (definition of "through"). Therefore, the plain meaning of the claims merely requires that the tamp be advanced through any point within the cannula, and that the material simply be located at any point within the cannula. Thus, for all the reasons previously set forth, DOT's effort to deviate from the plain meaning of the claims and to import limitations from the specification into the above terms of the '054 claims must be rejected.

2. a tamping instrument ... including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula

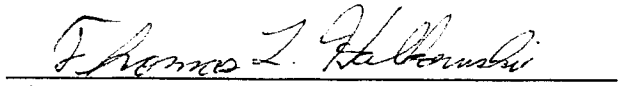
DOT seeks to impose two additional limitations onto this claim element. First, as with DOT's interpretations of all of the terms from the '734 patent, it seeks to import a limitation from the specification to require that "material" be in direct contact with the "inner walls" of the cannula and that a tamp acts directly upon the cannula surface to clear the "material." Second, DOT also seeks to add to the plain meaning of this claim element the additional limitation that all the markings somehow be "relative to the cannula." For all the reasons previously set forth, DOT's effort to deviate from the plain meaning of the claims and to import limitations from the specification into the above element of the '054 claims must be rejected.

IV. CONCLUSION

For the foregoing reasons, Kyphon respectfully requests that the Court reject DOT's efforts to deviate from the plain meaning, and to adopt the constructions of the disputed claim terms proposed by Kyphon as set forth in the attached addendum.

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Appendix A

Disputed Claim Construction Terms

* **Claim terms** requested for construction by **Kyphon** are in **bold font style**;
claim terms requested for construction by DOT are underlined

U.S. Patent No. 4,969,888

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 1		
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	the viscous liquid material contained within the interstices (spaces) of the cancellous bone
forming a passage in the bone marrow;	forming a path or channel into the interior of the bone through the bone marrow	forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone
compacting the bone marrow to increase the volume of said passage and	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	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 the interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage
filling the passage with a flowable material capable of setting to a hardened condition.	filling the passage with a material that is at some point in a fluid state (i.e., capable of flowing on its own)	bone filler material capable of flowing and setting to a hardened condition

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U.S. Patent No. 4,969,888 (*cont'd*)

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.][1]	forcing the bone marrow outwardly of the central portion of the bone
Claim 7		
A method as set forth in claim 1		
wherein said forming step includes **drilling said osteoporotic bone marrow** to form said passage.	rotating a shaft with one or more cutting edges to bore a hole into and through the osteoporotic bone marrow in the interior of the bone	using a drill to break through the cortical wall of the bone

[1] Kyphon also notes that DOT's proposed construction simply eliminates the term "osteoporotic" from the claim.

U.S. Patent No. 5,108,404

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 1		
A method of fixation of a fracture or impending fracture of a bone having **bone marrow** therein comprising:	a combination of the connective tissue and the cancellous bone framework inside a bone	the viscous liquid material contained within the interstices (spaces) of the cancellous bone
forming a passage in the bone marrow;	forming a path or channel into the interior of the bone through the bone marrow	forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone
compacting the bone marrow to increase the volume of said passage; and	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	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 the interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage
filling the passage with a flowable material capable of setting to a hardened condition.	filling the passage with a material that is at some point in a fluid state (i.e., capable of flowing on its own)	bone filler material capable of flowing and setting to a hardened condition
Claim 3		
A method as set forth in claim 1,		
wherein said compacting step includes forcing the **bone marrow** outwardly of the central portion of the bone.	[No further clarification of these claim terms is required.]	forcing the bone marrow outwardly of the central portion of the bone
Claim 8		
A method as set forth in claim 1,		
wherein said forming step includes **drilling said bone marrow** to form said passage.	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	using a drill to break through the cortical wall of the bone

U.S. Patent No. 6,235,043

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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,	a body adapted to be inserted into bone and to undergo an increase in size while in cancellous bone	an inflatable body that can be inserted into bone and expanded
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,	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal walls of the inflatable body
causing constrained expansion of the body in cancellous bone, and	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	constraining the expansion of the inflatable body
compacting cancellous bone by the constrained expansion.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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

U.S. Patent No. 6,235,043 (*cont'd*)

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 17		
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, 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,	*see claim 2 for Kyphon's proposed construction*	*see claim 2 for DOT's proposed construction*
causing constrained expansion of the body in cancellous bone, and	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 2 for DOT's proposed construction*
compacting cancellous bone by the constrained expansion.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 2 for DOT's proposed construction*

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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**	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	an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
and having a tamping terminus which, during the advancement, urges **material residing in the subcutaneous cannula** into bone.	material located at any point within the subcutaneous 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
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 10		
Apparatus according to claim 1		
and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	limited to inflatable devices disclosed in '404 and '888 patents
Claim 11		
Apparatus according to claim 10		
wherein the cavity forming instrument includes an expandable structure.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	limited to inflatable devices disclosed in '404 and '888 patents
Claim 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.	*See claim 1 for Kyphon's proposed construction re bolded terms* [Kyphon also objects to DOT's proposal re the remainder of the terms. No further clarification of these claim terms is required.]	nested stylet/nozzle instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity

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Claim 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,		a delivery device such as a syringe that expels material into the bore (which material contacts the inner walls) of the 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.	*See claim 1 for Kyphon's proposed construction* [Kyphon also objects to DOT's proposal re the remainder of the terms. No further clarification of these claim terms is required.]	an instrument with a terminus that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 5 for DOT's proposed construction*
Claim 20		
Apparatus according to claim 15		
and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 10 for DOT's proposed construction*
Claim 21		
Apparatus according to claim 15		
wherein the cavity forming instrument includes an expandable structure.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 11 for DOT's proposed construction*

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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,	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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 cannula into the bone cavity
the **tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula,**	a tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument through any point within the cannula, where the tamp and the cannula may consist of one or more components	
advancement of the tamping terminus in the cannula to urge **material residing in the cannula** into bone, and	[a tamping instrument] for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components material located at any point within 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
withdrawal of the tamping terminus from the cannula		

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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
Claim 29		
Apparatus according to claim 27		
wherein the tamping instrument includes at least one additional marking to visually gauge advancement of the terminums relative to the distal end of the cannula.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	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

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U.S. Patent No. 6,613,054 (*cont'd*)

CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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,	a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components [Kyphon objects to DOT's proposal with regard to the remainder of the terms. No further clarification of these claim terms is required.]	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 to the instrument as it clears the residual material from the inner walls of the cannula into the bone cavity
the handle portion having a cross-sectional area greater than the cross-sectional area of the body portion.		
Claim 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	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 27 for DOT's proposed construction*

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 28 for DOT's proposed construction*
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 29 for DOT's proposed construction*
Claim 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,	*see claim 36 for Kyphon's proposed construction* [Kyphon objects to DOT's proposal with regard to the remainder of the terms. No further clarification of these claim terms is required.]	*see claim 36 for DOT's proposed construction*
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.		

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 27 for DOT's proposed construction*
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 28 for DOT's proposed construction*
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 29 for DOT's proposed construction*

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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	*see claim 36 for Kyphon's proposed construction* [Kyphon objects to DOT's proposal with regard to the remainder of the terms. No further clarification of these claim terms is required.]	*see claim 36 for DOT's proposed construction*
comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.		
Claim 47		
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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 27 for DOT's proposed construction*

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CLAIM	KYPHON'S PROPOSED CONSTRUCTION	DOT'S PROPOSED CONSTRUCTION
Claim 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	*see claim 36 for Kyphon's proposed construction* [Kyphon objects to DOT's proposal with regard to the remainder of the terms. No further clarification of these claim terms is required.]	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
a body portion and a handle portion, the body portion having a substantially constant diameter along its length.		
Claim 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.	[Kyphon objects to DOT's proposal. No further clarification of these claim terms is required.]	*see claim 29 for DOT's proposed construction*

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