

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner

IPR2025-00225
Patent No. 9,730,805

PETITION FOR INTER PARTES REVIEW

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,730,805 (“the ’805 Patent”)
1002	Declaration of Technical Expert Brad Culbert
1003	Prosecution History of the ’805 Patent
1004	U.S. Patent 8,172,854 (“Blain”)
1005	U.S. Provisional Application No. 60/950,801 (“Blain-Provisional”)
1006	U.S. Patent No. 7,985,255 (“Bray”)
1007	Excerpts from Webster’s New World College Dictionary (4 th Ed., 1999)
1008	Excerpts from The Oxford American Desk Dictionary (1998)
1009	Excerpts from The American Heritage Dictionary (2 nd College Ed., 1982)
1010	Redline Comparison of Abstracts of Blain and Blain-Provisional
1011	Redline Comparison of Specification of Blain and Blain-Provisional
1012	Redline Comparison of Claims of Blain and Blain-Provisional
1013	Patent Owner’s Infringement Contention Claim Chart for ’805 Patent Against Globus Hendron AI Interbody Spacer
1014	U.S. Patent No. 8,535,353
1015	U.S. Patent No. 5,766,253
1016	U.S. Patent No. 4,790,303 (“Steffee”)
1017	U.S. Patent No. 9,358,127 (“Duffield”)
1018	U.S. Patent No. 7,942,903

Exhibit No.	Description
1019	U.S. Patent No. 8,075,593
1020	U.S. Patent Application Publication No. 2006/0265076
1021	Spinelogik's Preliminary Identification of Proposed Terms for Construction in <i>Spinelogik, Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-529-JRG-RSP, served October 30, 2024
1022	Globus's Preliminary Claim Constructions in <i>Spinelogik, Inc. v. Globus Medical, Inc.</i> , No. 2:23-cv-529-JRG-RSP, served October 30, 2024
1023	U.S. Patent No. 7,918,891
1024	U.S. Patent No. 8,328,851
1025	U.S. Patent No. 7,846,210
1026	U.S. Patent No. 8,673,005
1027	U.S. Patent No. 6,923,814
1028	U.S. Patent Application Publication No. US 2007/0270806
1029	U.S. Patent No. 6,613,091
1030	U.S. Patent No. 8,273,127
1031	Globus Marketing Video for Hendron IA Interbody Spacer
1032	U.S. Patent No. 7,662,186
1033	U.S. Patent No. 8,100,955
1034	U.S. Patent No. 7,041,135
1035	U.S. Patent No. 6,447,546
1036	U.S. Patent Application Publication No. US 2009/0112261
1037	U.S. Patent No. 8,105,382

Exhibit No.	Description
1038	U.S. Patent Publication No. 2005/0085913 (“Fraser”)
1039	<i>Curriculum Vitae</i> of Brad Culbert
1040	Machinery Handbook, 28th Ed. (Excerpts)

MANDATORY NOTICES (37 C.F.R. § 42.8)**42.8(b)(1)-RPI**

The real party in interest is Globus Medical, Inc. (“Globus”).

42.8(b)(2)–Related Matters

- *Spinelogik, Inc. v. Globus Medical, Inc.*, C.A. No. 2:23-cv-00529 (E.D. Tex.) filed November 17, 2023.
- *Spinelogik, Inc. v. Choice Spine, LLC*, No. 2:23-cv-00296 (E.D. Tex.) filed June 22, 2023.
- *Spinelogik, Inc. v. Genesys Orthopedics Systems, LLC*, No. 2:23-cv-00297 (E.D. Tex.) filed June 22, 2023.
- *Spinelogik, Inc. v. Camber Spine Techs., LLC*, 2:24-cv-00873 (E.D. Tex.) filed October 29, 2024.
- *Globus Medical, Inc. v. Spinelogik, Inc.*, IPR2025-00226 (PTAB) filed November 21, 2024.

42.8(b)(3)-Counsel

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Globus has filed a Power of Attorney concurrently with this petition.

42.8(b)(4)-Service

Service via mail or hand-delivery may be made on Globus at: Cabello Hall Zinda, PLLC 801 Travis Suite 1610, Houston, Texas 77002. The fax number for Globus's counsel is (832) 631-9991. Globus consents to electronic service by e-mail sent to all of the following e-mail addresses: stephen@chzfirm.com; james@chzfirm.com; and paralegal@chzfirm.com.

Proof of service of this petition and exhibits is provided in the appended certificate of service.

I. INTRODUCTION

Globus Medical, Inc. (“Petitioner” or “Globus”) requests *inter partes* review of claims 1–6, 11, 12, and 15–17 of U.S. Patent No. 9,730,805 (“the ’805 Patent”), which, according to PTO records, is assigned to Spinelogik, Inc. (“Patent Owner” or “Spinelogik”). As demonstrated below, the challenged claims are unpatentable and should be cancelled.

II. STANDING (37 C.F.R. §§ 42.101 & 42.104(A))

Globus certifies that the ’805 Patent is available for IPR and Globus is not barred or estopped from requesting IPR of any of the challenged claims.

III. FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Commissioner to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Acct. No. 603139, referencing attorney docket number 231-111. Any additional fees which may be required or credits for overpayment may be deducted or added to the same account.

IV. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))**A. § 42.104(b)(1), (b)(2) Statement of Requested Relief**

Globus requests institution and cancellation of claims 1–6, 11, 12 and 15–17 in view of Grounds 1–3 below. Because the latest possible priority date of the ’805 Patent is its filing date of October 18, 2012, the America Invents Act (“AIA”) is inapplicable. Any reference to the patent statute herein is pre-AIA.

Ground	Claims	Basis	References
1	1–6, 11, 12, 15–17	§ 102/103 ¹	U.S. Patent 8,172,854 (“Blain”)
2	1–6, 11, 12, 15–17	§ 103	Blain and U.S. Patent No. 7,985,255 (“Bray”)
3	5, 16	§ 103	Blain (with or without Bray) and U.S. Patent No. 4,790,303 (“Steffee”)

B. § 42.104(b)(4): Unpatentability

Claims 1–6, 11, 12, and 15–17 are unpatentable as detailed in Section V–VII.

C. § 42.104(b)(5): Supporting Evidence

The relevance of Globus’s evidence including identification of specific evidence that support this challenge is found in Sections V–VII below.

V. THE ’805 PATENT

A. Overview

The ’805 Patent claims priority to provisional applications filed on March 27, 2008 and October 28, 2008. Ex. 1001, 1. The earliest possible date of priority of the ’805 Patent is thus March 27, 2008.

The patent is directed to interbody implants used in spinal fusion and delivery

¹ All obviousness grounds include the general knowledge of a person having ordinary skill in the art.

tools for installing the same. *Id.*, 1:20–21. When disc between adjacent vertebral bodies in the spine degenerate and conservative treatments fail to treat the resulting pain, surgical fusion of the vertebrae using spinal implants is performed for pain relief. *Id.*, 1:27–35. This generally involves removing (or “dissecting”) the degenerated disc between two vertebral bodies to replace the disc with a fusion implant, which provides stability and support while also facilitating bone growth. Ex. 1002 ¶64.

One embodiment involves a fusion member (e.g., a fusion implant) configured to be positioned between two vertebral bodies, a delivery mechanism, and anchoring members. Ex. 1001, 6:41–51. The delivery mechanism allows the surgeon to deliver and position the fusion member between adjacent vertebral bodies after the degenerated cartilage has been dissected. *Id.* The anchoring members secure the fusion member to the vertebral bodies. *Id.* The delivery mechanism may include a delivery housing having channels that house and guide the anchoring members (e.g., needles). *Id.*, 6:62–7:7. Each of the channels aligns with a respective channel of the fusion member so that the anchors may be driven to and through the implant, into the vertebral bodies. *Id.*, 7:39–44.

Figure 1A shows delivery mechanism 130 coupled to fusion member 120, and anchoring mechanisms 140 inserted into fusion member channels (unlabeled):

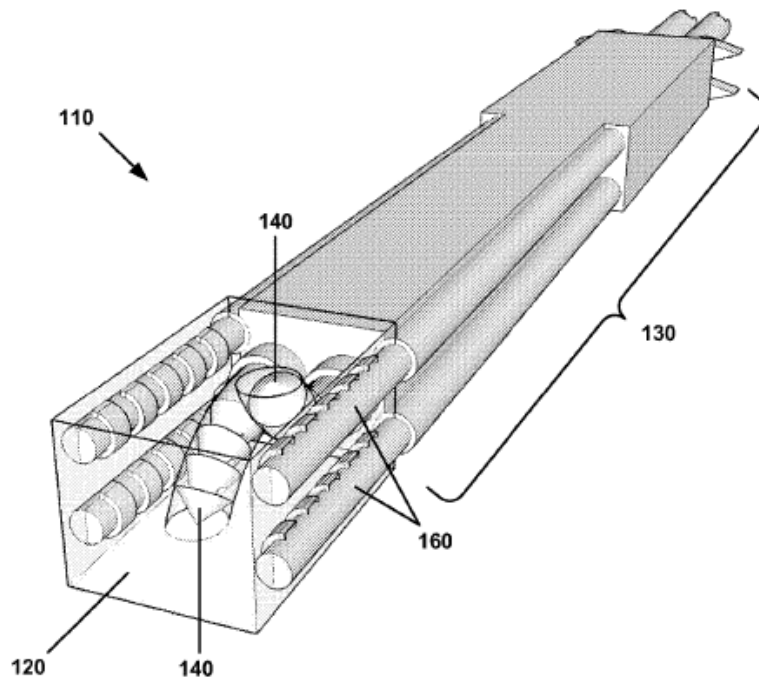
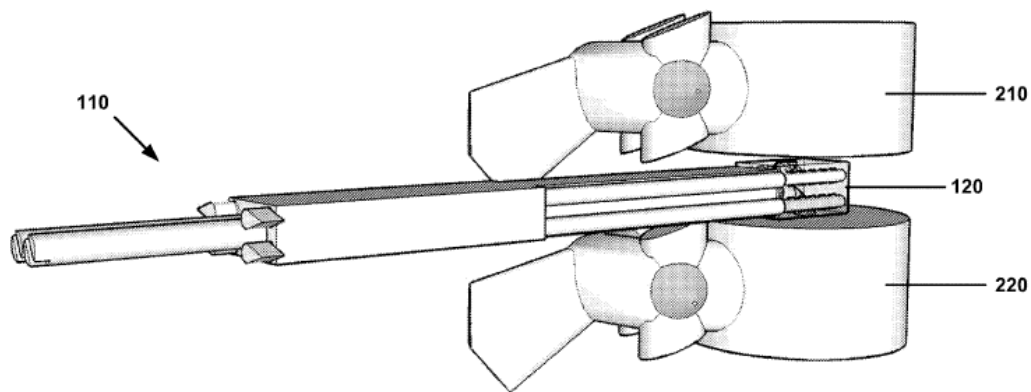


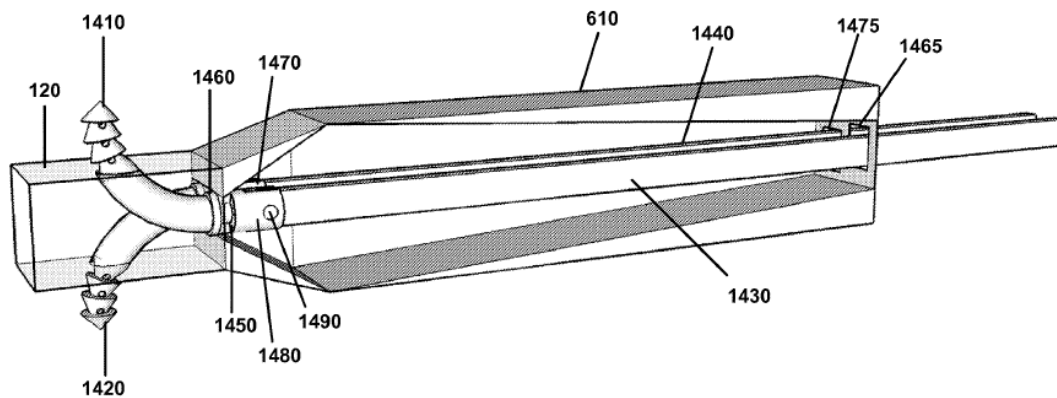
Figure 1A

Id., 9:29–37. Once the surgeon has positioned the fusion member between the vertebral bodies, driving members can push anchoring members through channels in the delivery mechanism and through the corresponding, aligned channels in the fusion member. *Id.*, 2:35–42, 3:26–29. Each anchoring member then penetrates one vertebral body to couple the fusion member with the vertebral bodies. *Id.*, 2:60–66, 3:10–15.

Figure 2 shows the fusion member 120 positioned between two vertebral bodies 210, 220 and Figure 15 shows two anchoring members 1410, 1420 after driving members 1430, 1440 have driven them through the channels of fusion member 120:

**Figure 2**

Id., 9:25–27.

**Figure 15**

Id., 14:21–30.

The delivery mechanism may also include a retention mechanism that couples the delivery mechanism to the fusion member. *Id.*, 2:35–39. The retention mechanism allows the surgeon to attach and detach the delivery mechanism from

the fusion member to facilitate its delivery. *Id.*, 2:60–3:39; 7:1–5; 7:22–28. In these embodiments, the delivery mechanism may include channels that guide retention rods. *Id.*, 7:1–7. Figure 6 shows retention rods 160 extending through delivery mechanism 130 and to fusion member 120:

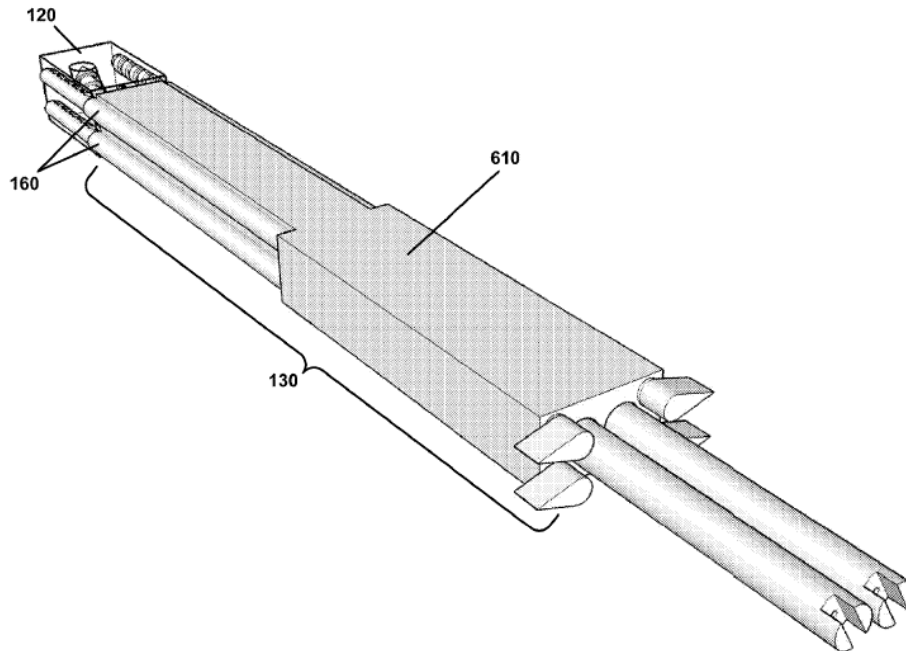
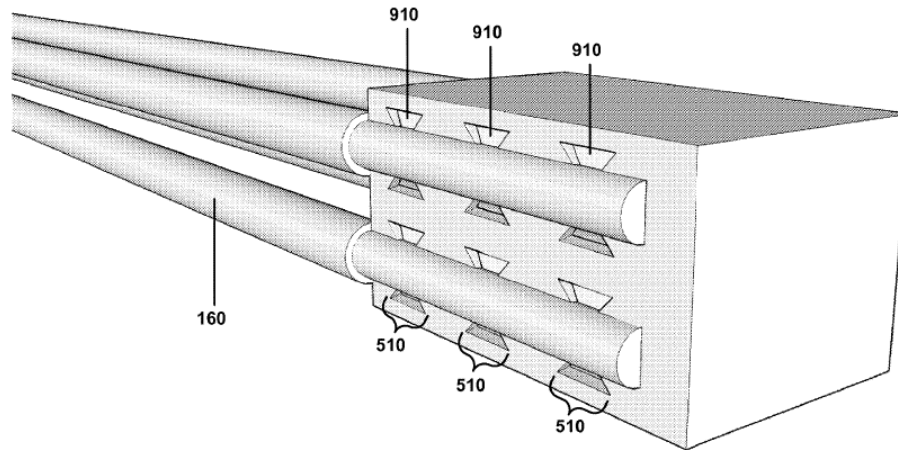


Figure 6

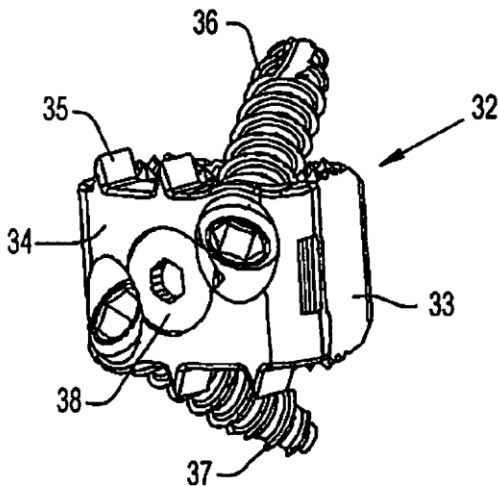
Id., 11:24–32.

As pictured in Figure 11 below, the retention rods 160 may also have retention teeth 910 that mate with retention grooves 510 of the fusion member upon rotation of the rods (via handles) by the surgeon. *Id.*, 12:51–60. This allows the retention mechanism to attach and detach from the fusion member, as discussed above. *Id.*

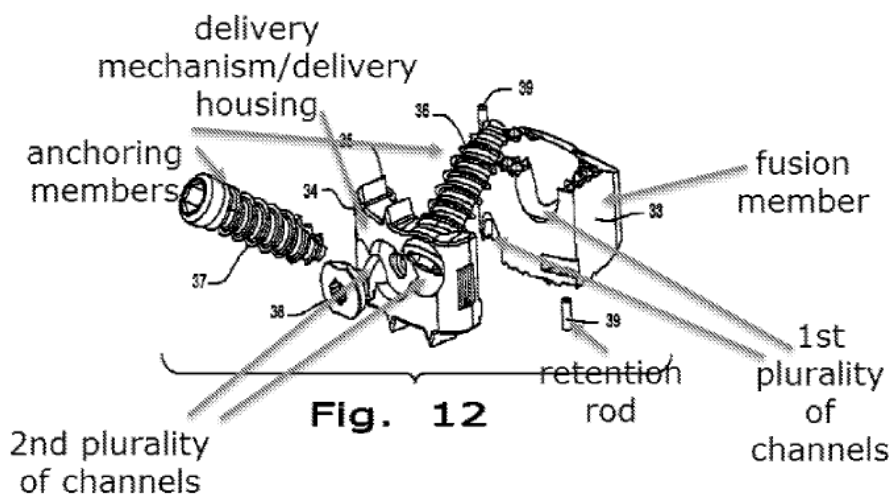
**Figure 11**

B. Prosecution History

During prosecution, the Examiner rejected then-pending claims 11–13, 15, 22–27, 29, 31, and 33–36 as anticipated by U.S. Patent No. 9,358,127 (“Duffield”). Ex. 1003, 110–111. Duffield is directed towards a “stand alone interbody fusion device for implementation in the spine,” which as shown in Figure 9 below, includes interbody implant 32 for insertion between two vertebral bodies. Ex. 1017, 1:15–16. The implant 32 includes, among other things, plate portion 34 and spacer portion 33. *Id.*, 4:43–48.

**Fig. 9**

In rejecting the claims, the Examiner considered plate portion 34 to be the *delivery mechanism* and spacer portion 33 to be the *fusion member*, as shown below:²



Ex. 1003, 111. In other words, the Examiner arbitrarily considered one portion of the implant 32 itself to be the *delivery mechanism*, rather than identifying the actual

² Claim language is italicized throughout this Petition.

delivery tool used to insert the implant into the patient (e.g., the “implant holder” used to deliver Duffield’s implant). Ex. 1002 ¶72 (citing Ex. 1017, 4:23–25).

An examiner-initiated interview was held, where the Examiner suggested that Duffield may be overcome if the claims were amended to require that the delivery mechanism *extend outside a patient’s body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies*. Ex. 1003, 116. Applicant amended the claims as proposed. *Id.*, 85–93. A Notice of Allowance then issued. *Id.*, 69–73.

The Examiner thus allowed the claims over Duffield because it allegedly did not disclose this limitation. However, this determination was based on the Examiner’s erroneous correlation of one portion of Duffield’s implant to the *delivery mechanism*—rather than relying on actual prior art delivery tools used with such implants, which did extend outside a patient’s body as claimed. Ex. 1002 ¶75. In fact, the ’805 Specification never discloses that its delivery mechanism extends outside a patient’s body to a medical practitioner, demonstrating that this claim limitation is so uninventive and trivial that even the inventor did not believe it merited disclosure. Ex. 1002 ¶76 (citing *generally* Ex. 1001).

C. Level of Ordinary Skill in the Art

A person having ordinary skill in the art (“POSA”) would have had a bachelor’s or equivalent degree in mechanical engineering or a related discipline

(e.g., biomedical engineering, metals and materials engineering), and at least five years of experience with a) designing, developing, evaluating and/or using spine devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. *Id.* ¶¶77-78. More education can supplement practical experience and vice versa. *Id.* Globus relies on the declaration of technical expert, Brad Culbert, who exceeds the qualification of a POSA. *Id.* ¶¶2-16; Ex. 1039.

D. Claim Construction (37 CFR § 42.104(B)(3))

Patent claims are construed in accordance with their ordinary and customary meanings as understood by a POSA. 37 C.F.R. § 42.100(b). Petitioner addresses the construction of certain terms that may be relevant to the application of the prior art. Petitioner reserves the right to respond to any claim construction issues raised by Spinelogik.³

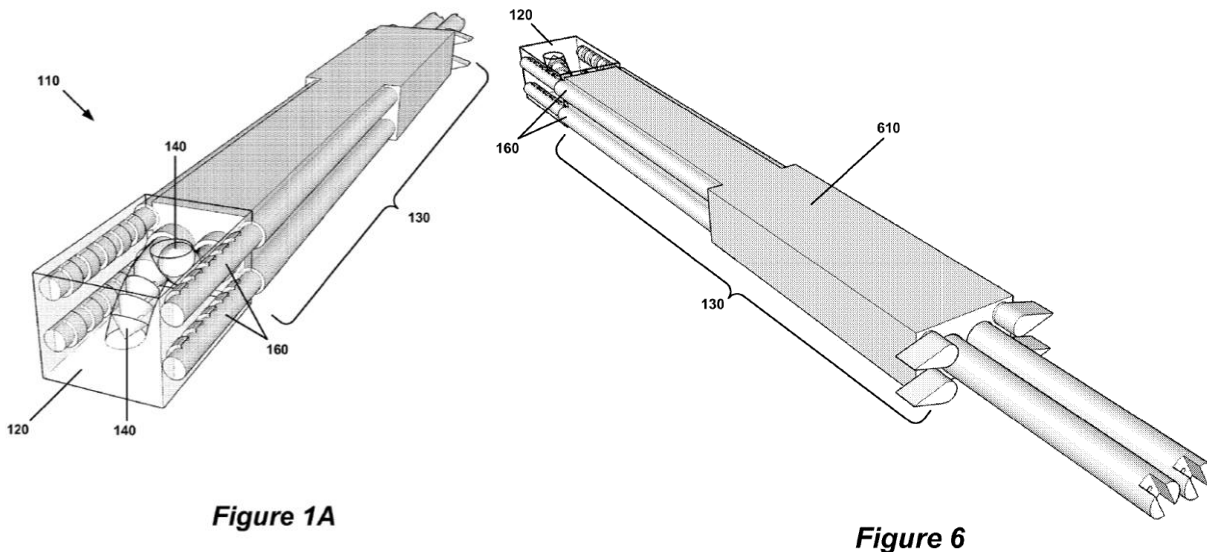
1. *housing* (claims 2–4)

POSAs understood a *housing* to be a component that protects, covers, supports, or contains another component. Ex. 1002 ¶81 (citing Ex. 1009, 5 (defining “housing” as “[s]omething that covers, protects, or supports”); Ex. 1007, 5 (defining “housing” as “a frame, box, etc. for containing some part, mechanism etc.”); Ex.

³ Petitioner reserves its right to challenge any claim for failure to comply with 35 U.S.C. § 112 in any other proceeding.

1008, 5 (defining “housing” as “rigid casing, esp. for machinery, etc.”)). This is consistent with the usage of “housing” in the Specification. *Id.* ¶82.

Figures 1A and 6 (below) provide an example of a delivery housing 610, which has tubular channels through which anchoring members 140 are inserted and driven to fusion member 120:



Ex. 1001, 11:24-32. POSAs understood that the delivery housing 610 houses anchoring members/mechanisms 140⁴ because each anchor is supported, contained, and protected within delivery housing as each anchor is guided to the implant, just as each retention rod 160 is supported, contained, and protected within housing 610.

Ex. 1002 ¶83. The Specification itself teaches that “the delivery housing channels

⁴ “Anchoring members” are also referred to as “anchoring mechanisms.” See Ex. 1001, 19:64-66, 9:29-37.

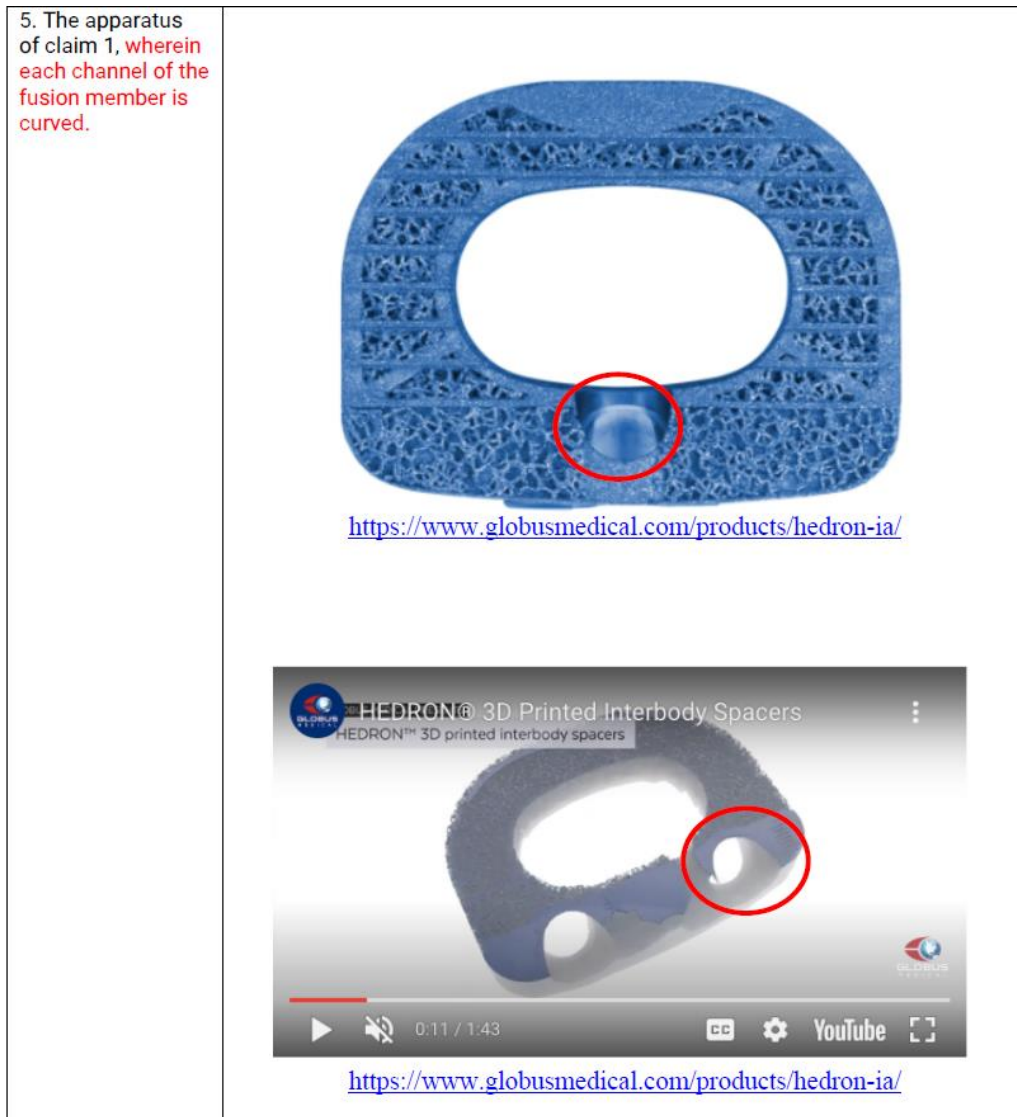
house and guide the anchoring mechanism to the proper location in the fusion member.” Ex. 1001, 13:25–27; *see also id.*, 2:37, 7:1–7, 11:27–28.⁵ Consequently, the ’805 Patent uses the term *housing* in accordance with its customary meaning of a component (e.g., housing 610) that protects, covers, supports, or contains another component (e.g., anchoring members 140, retention rods 160). Ex. 1002 ¶84.

2. *each channel of the fusion member is curved* (dependent claims 5, 16)

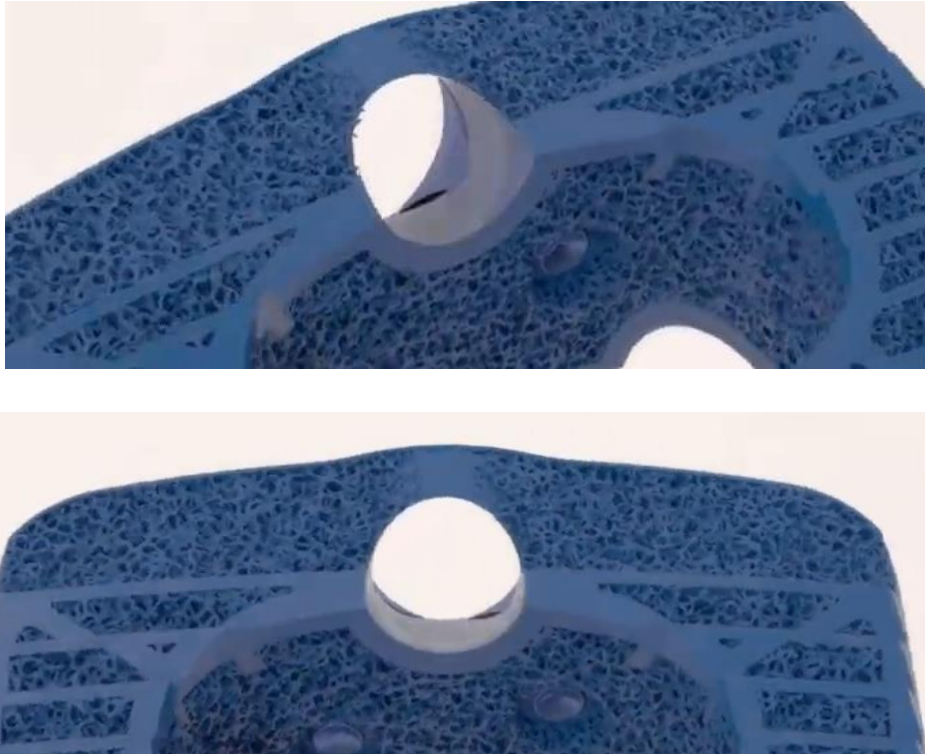
Petitioner applies the claim construction for *curved* urged by Spinelogik in the co-pending litigation. *See Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-00084, Paper No. 14, 11 (P.T.A.B. April 25, 2018) (explaining “37 C.F.R. § 104(b)(3) does not require Petitioner to express its subjective agreement regarding correctness of its proffered claim constructions or to take ownership of those constructions” and a “[p]etitioner complies with our rules by identifying claim constructions it proposes as the basis for requesting review of the challenged claims,” even where that construction is based on the constructions proposed by a patent owner upon which the petitioner ultimately disagrees); *see also Gen. Elec. Co. v. Vestas Wind Sys. A/S*, IPR2018-00928, Paper 9, 12–17 (PTAB Nov. 5, 201811/5/2018); *10x Genomics, Inc., v. Bio-Rad Labs, Inc.*, IPR2020-00086, Paper 8, 17–22 (PTAB April, 27, 2020).

⁵ All bold emphasis herein is added, unless indicated otherwise.

In the co-pending litigation, Spinelogik alleges that the anchor openings of Globus's accused interbody implants have *curved* channels. A representative example from Spinelogik's infringement contentions is provided below:



Ex. 1013, 11. Screenshots from around the 23-second mark of the cited video (Ex. 1031) are provided below, showing that accused products have channels that follow a straight—not curved—path.



Ex. 1002 ¶85. Although the accused channels have a circular opening on each end, a tubular-inner wall, and anchor seats for the head of the anchors, the channels only follow a straight (or linear) path. Spinelogik is thus applying the term *channel...is curved* as encompassing any channel having a curvature, regardless of whether the channel follows a curved path (e.g., like channels 4610, 4620 from Figures 46 and 47). *Id.* ¶86 (citing Ex. 1001, 23:26–31).⁶

Pursuant to Spinelogik’s application, a *channel* would thus qualify as *curved* when it has an: (1) opening with a curvature (e.g., round opening); (2) an inner wall

⁶ Spinelogik proposed plain and ordinary meaning for this term in the litigation and would not agree to Globus’s proposed construction in the litigation. Ex. 1021; Ex. 1022.

with a curvature (e.g., tubular inner-wall); (3) a radially inward curvature in the inner wall (e.g., a concave surface that forms a spherical anchor head seat); and/or (4) follows a curved path (e.g., an arc-shaped path). *Id.* ¶87. Petitioner demonstrates that the claims are unpatentable under each qualification.

VI. OVERVIEW OF APPLIED REFERENCES

A. Blain

1. Blain is Prior Art

Neither Blain nor its published application (US 2009/0024132) was before the Office during examination. *See* Ex. 1001, 1 (“References Cited”). Blain qualifies as prior art under 35 U.S.C. § 102(e) based on its July 18, 2008 non-provisional filing date, which is before the actual filing date of the ’805 Patent (October 18, 2012) and the continuation filing date (January 28, 2009) to which it claims priority. Ex. 1004, 1. Blain also qualifies as prior art under § 102(e) as of the July 19, 2007 filing date of its provisional, U.S. Application No. 60/950,801 (Ex. 1005, “Blain-Provisional”), which is before the earliest possible priority date of the ’805 Patent. *Id.*⁷

A patent is prior art as of the filing date of its provisional application if the provisional provides § 112 support for at least one claim in the patent, and the

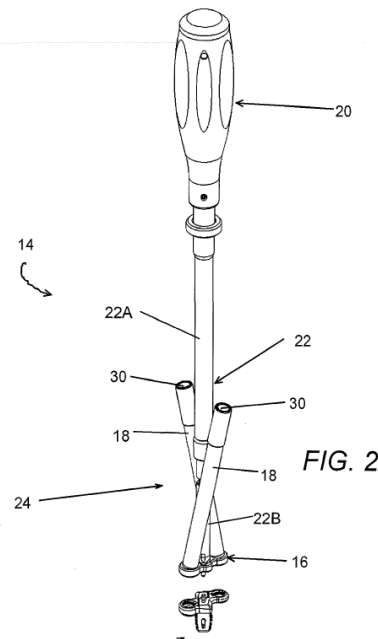
⁷ Globus does not believe that the ’805 Patent is entitled to its earlier priority dates. However, Blain qualifies as prior art regardless. Globus reserves the right to rebut any effort by Spinelogik to antedate any asserted prior art.

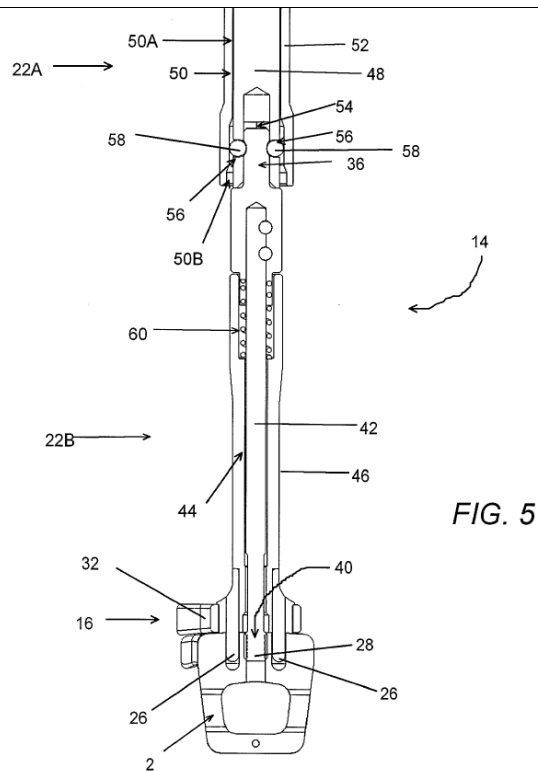
provisional describes the subject matter relied upon as prior art. *Dynamic Drinkware LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1381–82 (Fed. Cir. 2015).

Petitioner provides redline comparisons of the abstract (Ex. 1010), specification (Ex. 1011), and claims (Ex. 1012) of Blain and the Blain-Provisional. The redline comparisons demonstrate that the abstract and specification are substantively identical, and in fact, even some of the claims are identical. The figures of Blain and the Blain-Provisional are likewise identical. *Compare* Ex. 1004, Figs. 1–6 *with* Ex. 1005, 25–34. Consequently, the Blain-Provisional describes the subject matter relied upon as prior art from Blain.⁸

Petitioner further demonstrates that the Blain-Provisional provides written description support for at least claims 1 and 22 of Blain. Ex. 1002 ¶89.

⁸ The Petition also provides dual citations to Blain and the Blain-Provisional throughout.

Blain Claims (Ex. 1004) 1. An instrument guide, comprising:	Blain-Provisional (Ex. 1005) Instrument guide 14 (Figs. 2A to 2C). <i>See e.g.</i>, ¶¶[0004], [0020].  FIG. 2A
a releasable lock assembly comprising a movable outer tubular member having a lumen, the outer tubular member being movable in the longitudinal direction between a distal configuration and a proximal configuration;	Releasable lock assembly comprising a movable outer tubular member (movable outer shaft 52) having a lumen (proximal tubular lumen 50). <i>See</i> ¶¶[0006], [0029].



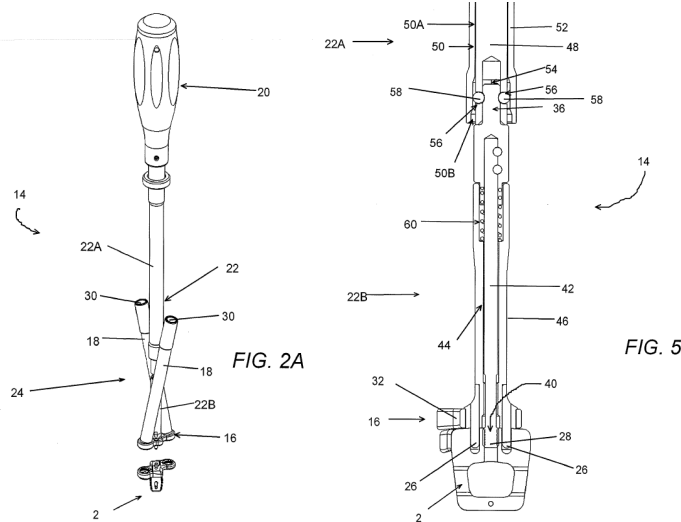
The outer shaft 52 is movable in the longitudinal direction between a distal configuration where it is “extended to lock the bearings 58 into the groove or recess 38” (as shown in Fig. 5) and a proximal configuration where the shaft 52 is “retracted relative to handle 20 and inner proximal shaft 48, thereby permitting the ball bearings 58 to displace outward into the larger lumen section 50B.” See ¶[0038]; see also ¶[0006].

a shaft having a proximal end and a distal end, wherein the shaft is partially in the lumen of the releasable lock assembly;

A shaft (inner proximal shaft 48) having a proximal end (end closer to handle 20) and a distal end (the end opposite of proximal end), wherein the shaft is partially in the lumen (proximal tubular lumen 50) of the releasable lock assembly. *See* ¶¶[0020], [0038]; *see also* ¶¶[0005]–[0006]. Moreover, when the outer shaft 52 is in the proximal (or retracted) configuration (not shown in Fig. 5), the inner proximal shaft 48 protrudes even further outside of the outer shaft 52.

a handle at the proximal end of the shaft;

Handle 20 is at the proximal end of the shaft (inner proximal shaft 48, within shaft 22A). See ¶¶[0004], [0006], [00020], [0029].



a device coupler comprising a coupling base with a through lumen and an elongate coupling member comprising a proximal end and a distal end, wherein the distal end is configured with a least one mechanical interfit structure, wherein at least a portion of the elongate coupling member is configured so as to move in the through lumen of the coupling base; and

The Blain-Provisional discloses a “a device coupler comprising a coupling base with a through lumen and an elongate coupling member comprising a proximal end and a distal end, wherein the distal end is configured with a least one mechanical interfit structure, wherein at least a portion of the elongate coupling member is configured so as to move in the through lumen of the coupling base.” ¶[0006].

Figure 5 also depicts a device coupler 16 having a coupling base 32 with a through lumen, through which elongate coupling member (distal inner shaft 42 and engagement member 36) passes. ¶¶[0029]–[0030]. The coupling member has a proximal end (the end closer to the handle 20) and a distal end 40, and the distal end 40 is configured with at least one mechanical interfit structure (movable coupling member 28). *Id.* At least a portion of the elongate coupling member (the portion

	containing movable coupling member 28) is configured so as to move through the lumen of the coupling base 32. <i>Id.</i>
at least one drill guide member joined to the device coupler;	The Blain-Provisional discloses “at least one drill guide member joined to the means for detachably coupling an implantable device” (¶[0005]) and “at least one drill guide member joined to the device coupler” (¶[0006]). Figures 2A–2C also depict drill guide (guide members/tubes 18) joined to the device coupler 16. <i>See</i> ¶¶[0020], [0035] (“The guide members 18 may comprise any shape suitable for accurately guiding a drilling device or other instrument, or fastener.”).
wherein the releasable lock assembly is configured to releasably lock the proximal end of the elongate coupling member of the device coupler to the distal end of the shaft when the outer tubular member is in a distal configuration.	When the releasable lock assembly is in the “distal configuration” (as shown in Fig. 5) it forces ball bearings 58 into recesses of engagement member 36, thereby releasably locking the proximal end of the elongate coupling member (engagement member 36 and distal inner shaft 42) of the device coupler 16 to the distal end of the shaft (inner proximal shaft 48). <i>See</i> ¶¶[0029]–[0030]; <i>See also</i> ¶¶[0005]–[0006].
22. A method for treating a patient, comprising:	“[A] method for treating a patient is provided.” ¶[0007]; <i>See also</i> Claim 22 of Blain-Provisional, identical in all respects to Claim 22 of Blain.
attaching an instrument guide with respect to an implantable device, wherein the instrument guide comprises a detachable handle and at least one instrument guide lumen;	“[A]ttaching an instrument guide with respect to an implantable device, wherein the instrument guide comprises a detachable handle and at least one instrument guide lumen.” ¶[0007]; <i>See also</i> ¶¶[0020]–[0022] (describing instrument guide 14 having detachable handle 20 and at least one instrument guide lumen 18)
inserting the implantable device to an implantation site;	“inserting the implantable device to an implantation site” ¶[0007]; <i>see also</i> ¶¶[0045] (explaining that instrument guide 14 may be

	attached to implant 2 prior to insertion, so that the instrument guide 14 can be used as the implant delivery tool).
separating the handle from the instrument guide;	“separating the handle from the instrument guide” ¶[0007]; <i>See also</i> ¶[0038] (explaining that the handle 20 is detached after insertion so that it does not interfere with insertion of the fasteners through guide tubes 18).
passing a component through the at least one instrument guide lumen to the implantable device to the implantation site;	“passing a component through the at least one instrument guide lumen to the implantable device to the implantation site.” ¶[0007]; <i>See also</i> ¶[0038] (explaining that, after the implant is in the desired location and the handle has been removed to avoid interference, the fasteners are inserted through guide tubes to the implantation site)
reattaching a handle to the instrument guide; and	“reattaching a handle to the instrument guide.” ¶[0007]. <i>See also</i> ¶[0038] (explaining that the handle 20 is reattached to the instrument guide 14 once the fasteners have been secured).
releasing the instrument guide with respect to the implantable device.	“releasing the instrument guide with respect to the implantable device.” ¶[0007]; <i>See also</i> ¶[0038] (explaining that the instrument guide 14 is detached from the implant once the handle 20 has been reattached)

2. Overview

Blain teaches an instrument guide that detachably couples to an interbody fusion implant. Ex. 1004, Abstract; Ex. 1005, 24. The instrument guide has two key purposes: (1) deliver the implant between two adjacent vertebral bodies; and (2) facilitate delivery of bone fasteners to and through the implant and into the vertebral bodies. Ex. 1002 ¶90.

Fig. 1 of Blain (below) illustrates an implant 2 having fastener apertures 4.

Ex. 1004., 4:26–39; Ex. 1005 ¶[0019]. Fasteners 6 are inserted through the apertures 4 to secure the implant 2 to bone. *Id.*

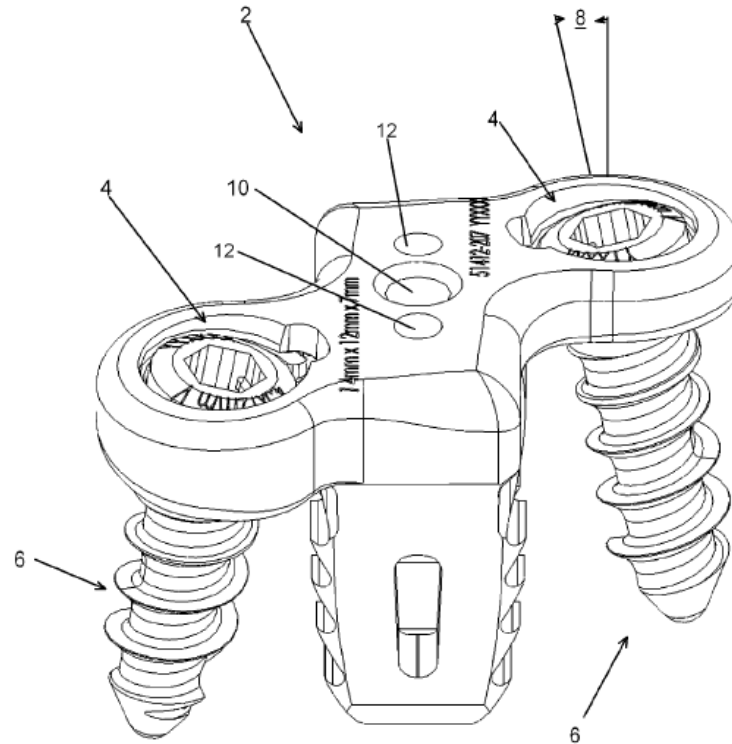
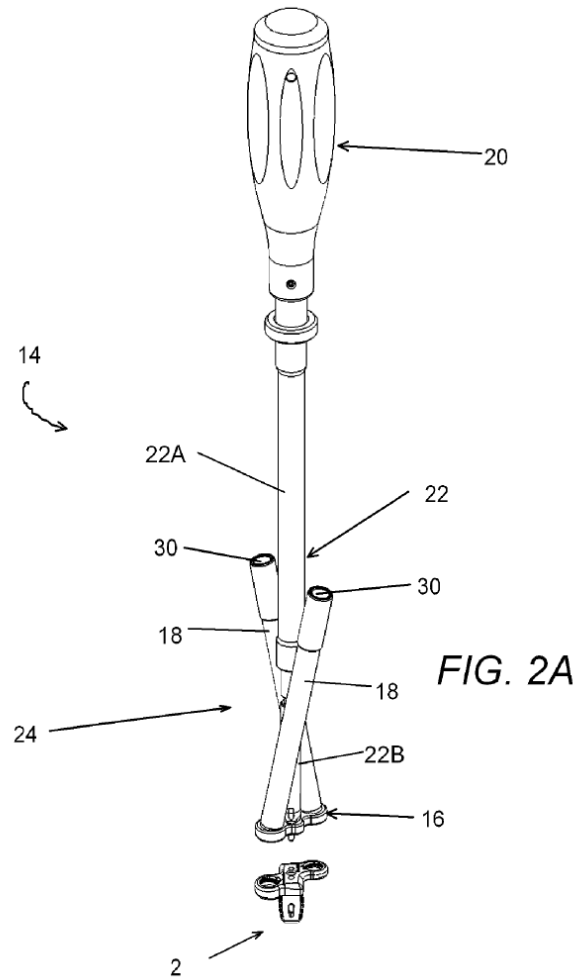


FIG. 1

The implant also has openings 10, 12 for coupling with an instrument guide 14. Ex. 1004, 4:44–54, 5:17–22; Ex. 1005 ¶¶[0019], [0022].

As shown in Figure 2A below, the instrument guide 14 comprises device coupler 16, handle 20 attached to corresponding shaft 22, and guide members/tubes 18. Ex. 1004., 4:55–61; Ex. 1005 ¶[0020].



Handle 20 is attached to handle shaft 22 (comprising proximal shaft 22A and distal shaft 22B), which has a distal end coupled to device coupler 16. Ex. 1004, 4:59–61; Ex. 1005 ¶[0020].⁹ The guide members/tubes 18 have proximal openings 30 of a tubular channel leading to distal openings (not shown), which are coupled to corresponding openings (also not shown) in device coupler 16. Ex. 1004, 8:5–8; Ex. 1005 ¶[0035]. Instrument guide is coupled to implant 2 via device coupler 16,

⁹ “Proximal” refers to the side of a device closer to the physician performing the surgery, whereas “distal” refers to the side furthest from the physician. Ex. 1002 ¶93.

thereby aligning channels of guide tubes 18 with fastener apertures 4 so that fasteners 6 can be driven through the guide tube channels, device coupler openings, implant apertures 4 and then into the bone of the vertebral bodies. Ex. 1004, 1:55–57, 5:18–33, 6:1–8, 8:50–54; Ex. 1005 ¶¶[0022], [0038].

Figures 3A and 6A show instrument guide 14 attached to implant 2 via device coupler 16. Ex. 1004, 8:46–54; Ex. 1005 ¶[0038]. Once the instrument guide delivers the implant between the vertebral bodies, the proximal shaft can be removed so that screw driver 66 can be inserted through guide tubes 18 (as shown in Figure 6A) to drive each anchor into a vertebral body. *Id.*

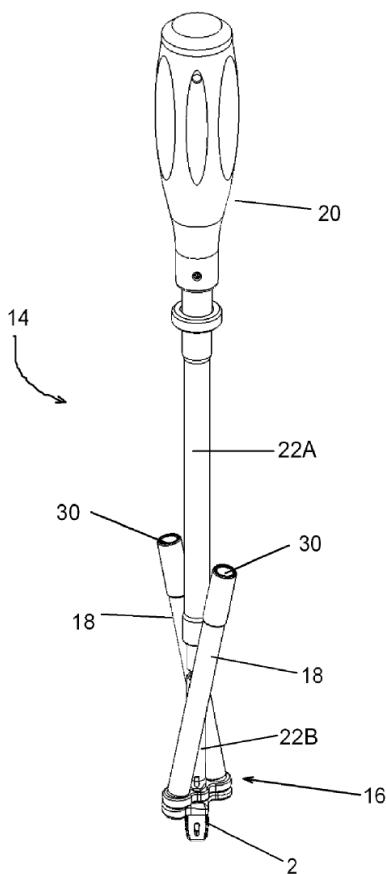


FIG. 3A

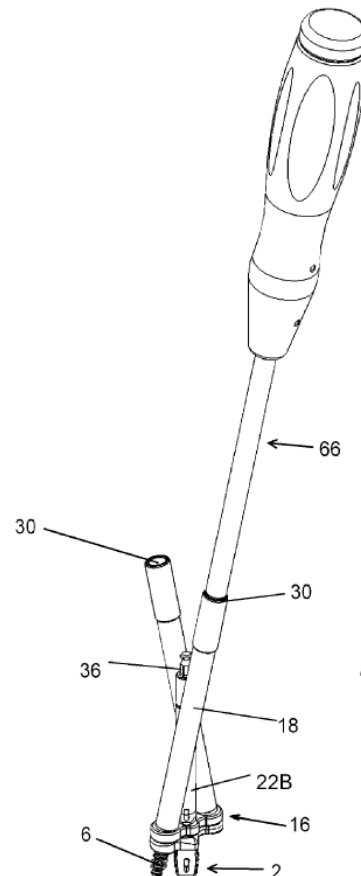
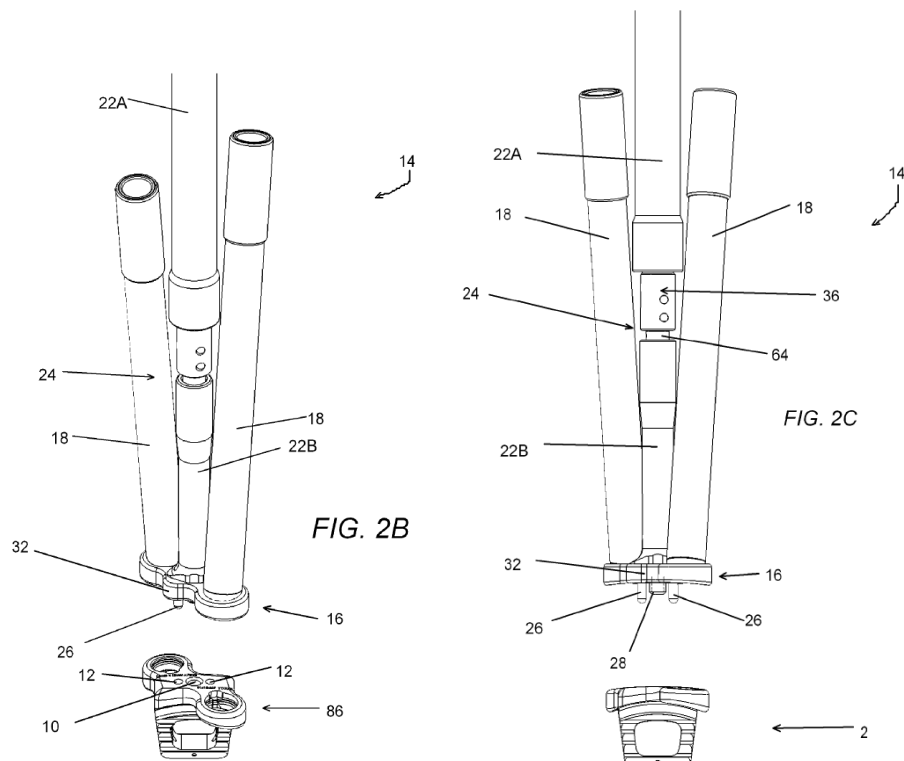
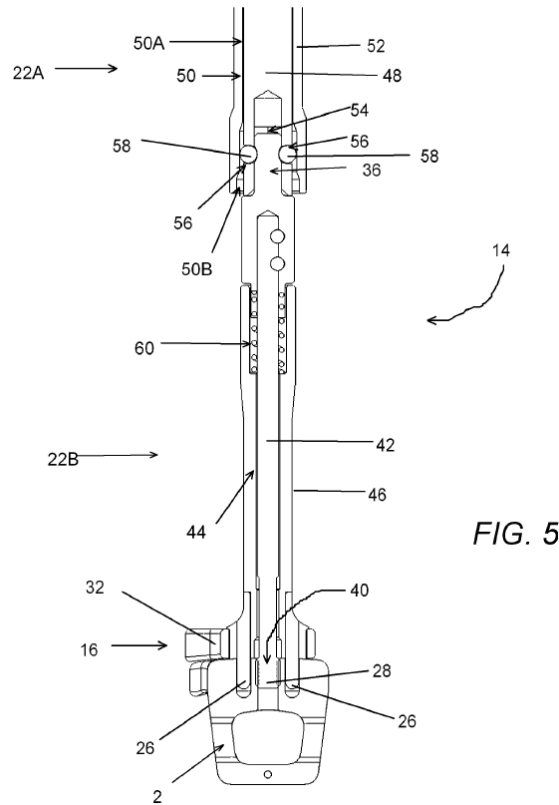


FIG. 6A

As shown in Figures 2B–2C (below), device coupler 16 comprises two fixed coupling members 26 and one movable coupling member 28. Ex. 1004, 5:19–22; Ex. 1005 ¶[0022]. The movable coupling member has a locking configuration (e.g., via threading or an interlocking fit) that detachably engages the coupling opening 10 of the implant 2. Ex. 1004, 5:44–50; Ex. 1005 ¶[0024]. The fixed coupling structures 26 also insert into coupling sites 12 on implant 2 to limit rotational movement between implant 2 and instrument guide 14. Ex. 1004, 6:1–8; Ex. 1005 ¶[0025].





As shown in Figures 2C and 5, movable coupling member 28 is at the distal end of inner shaft 42, which is itself within a distal tubular lumen 44 of distal outer shaft 46 of distal shaft 22B. Ex. 1004, 6:47–52; Ex. 1005 ¶[0029]. Handle 20 is used to cause axial translation of the distal engagement member 36, which in turn causes movable coupling member 28 to move axially. Ex. 1004, 7:11–17; Ex. 1005 ¶[0030]. Movable coupling member 28 may comprise a locking structure comprising “any of a variety of complementary mechanical interfits with the coupled implant, such as a threaded lock, snap-on fitting, or an interlocking fit.” Ex. 1004, 5:44–57; Ex. 1005 ¶[0024]. This locking structure allows instrument guide 14 to be detachably coupled to implant 2 prior to implantation, so that the instrument guide can be used as a

delivery instrument to insert the implant between the vertebral bodies and then detach from the implant. Ex. 1004, 10:4–11; Ex. 1005 ¶[0045].

B. Bray

1. Bray is Prior Art

Neither Bray nor its prior publication (US 2006/0030851) or parent (U.S. Patent No. 6,984,234) was before the Office during examination. *See* Ex. 1001, 1 (“References Cited”).

Bray is prior art under §§ 102(a) and (b) based on its February 9, 2006 publication date, which is more than a year before the earliest possible priority date of the ’805 Patent. Ex. 1006, 1. Bray is also prior art under § 102(e) based on its October 12, 2005 filing date. *Id.*

2. Overview

Bray is directed towards an interbody implant that is implanted between two adjacent vertebrae for fixation and support of the vertebrae. *Id.*, Abstract. As shown by Figures 1, 4 and 5 below, device 10 (i.e., interbody implant) includes base member 20 comprising a primary member 100 with two bone screw holes 140 and a secondary member 110 with bone screw hole 180. *Id.*, 4:37-40, 7:15–18, 7:40–42.

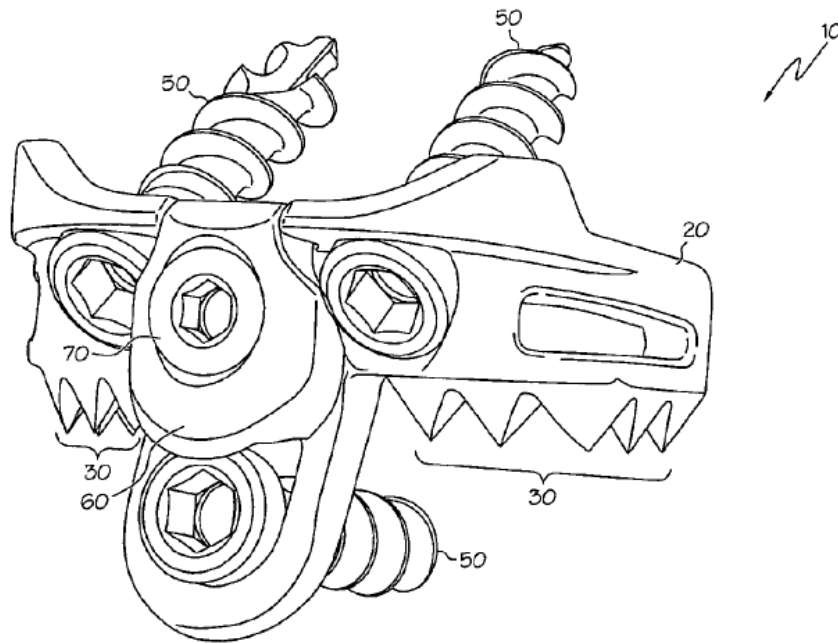


FIG. 1

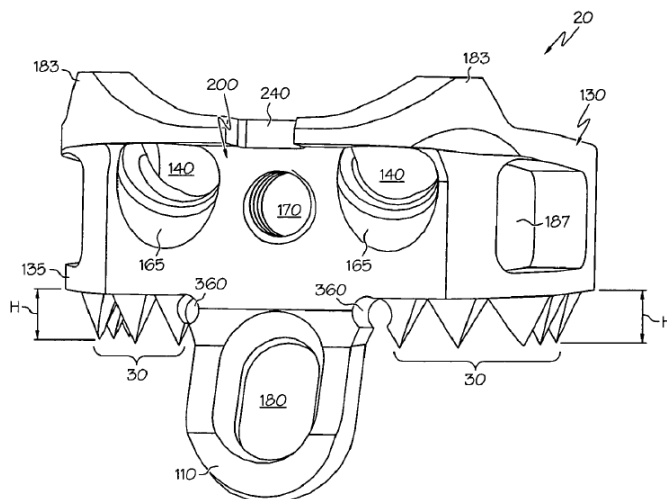


FIG. 4

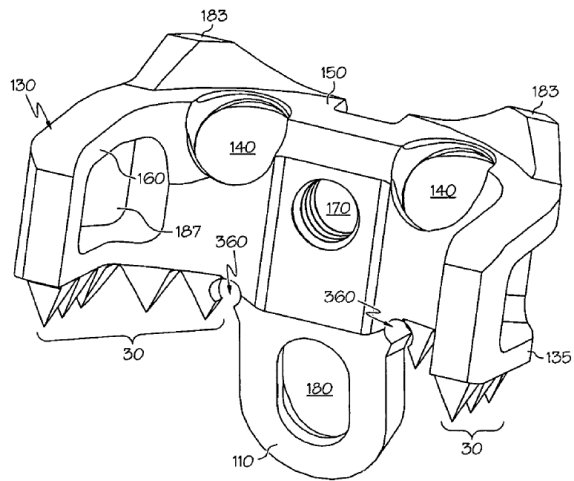


FIG. 5

Each screw hole 140 has seat 165 on which the retaining portion of a bone screw rests, and each seat has a concave, spherical shape, while the portion of the screw in contact with the seat has a complementary convex spherical shape. *Id.*, 7:30–36.

The implant also has a restraining feature “for securely covering at least a part

of each of the bone fasteners 50 so that the bone fasteners 50 cannot back out from the bone bodies once screwed in through the base member 20 of the device 10.” *Id.*, 4:49–57. In Figure 1, the restraining feature comprises restraining plate 60 and restraining plate fixing means 70. *Id.* Figures 9 and 10 are front and back perspectives, respectively, of the restraining plate. *Id.*, 3:46–51.

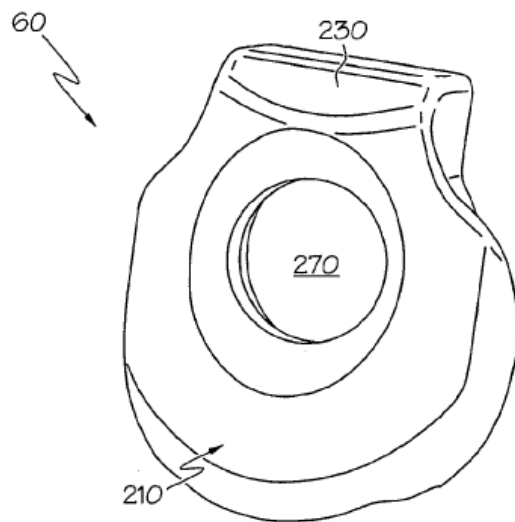


FIG. 9

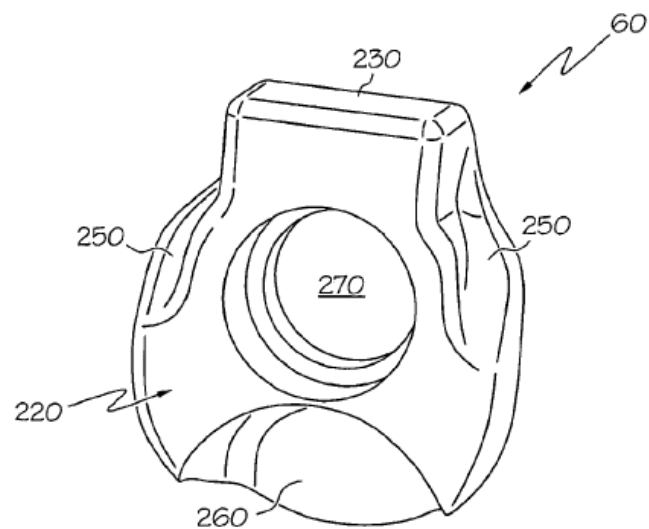


FIG. 10

In Figure 13 below, Bray further discloses guide tool 310 for delivering base member 20 between the vertebral bodies:

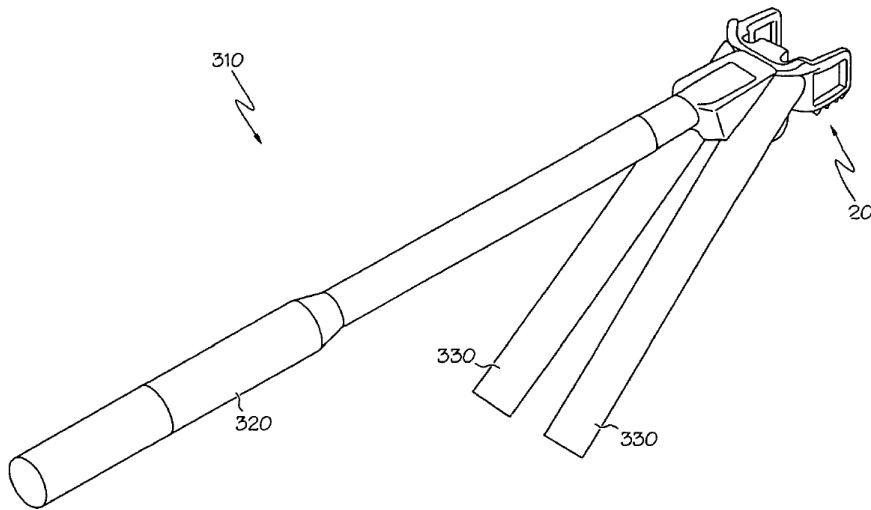


FIG. 13

Id., 9:61–10:14. The guide tool 310 has handle 320 and a pair of guide tubes 330, which the surgeon can drill through and then insert the bone screws 50 through (not depicted) to anchor the screws into the bone. *Id.*

C. Steffee

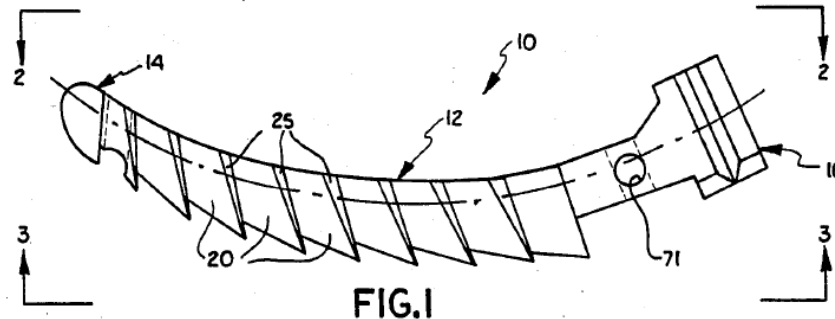
1. Steffee is Prior Art

Steffee was not before the Office during examination. *See* Ex. 1001, 1 (“References Cited”). Steffee is prior art under §§ 102(a) and (b) based on its December 13, 1988 issuance date, which is more than a year before the earliest possible priority date of the ’805 Patent. Ex. 1016, 1.

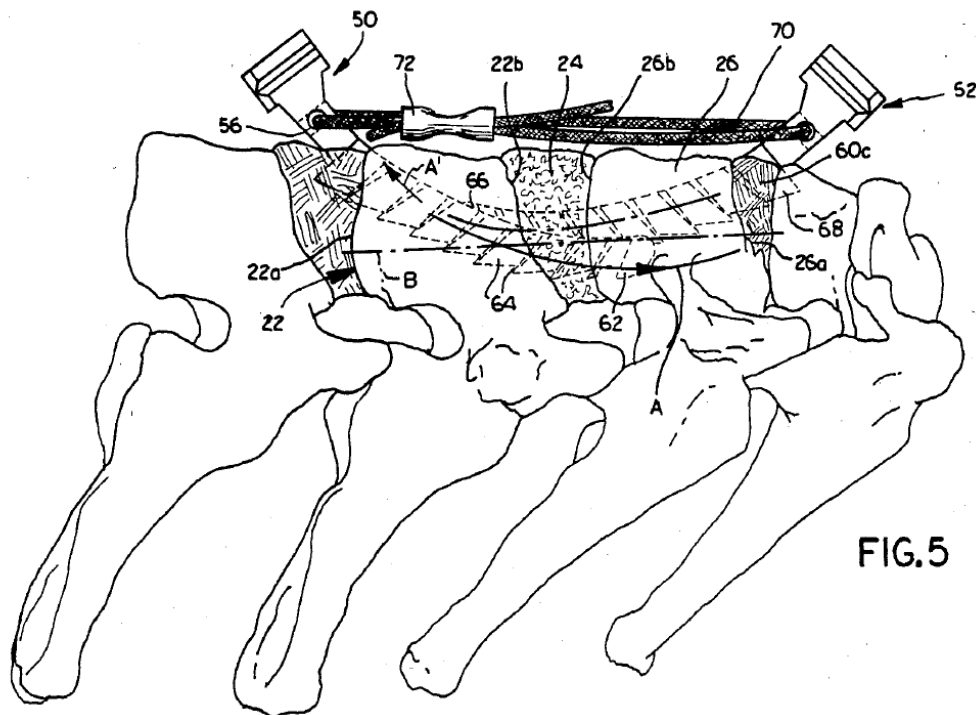
2. Overview

Steffee is directed toward interbody fusion using bone graft material. *Id.*, Abstract. In Figure 1, Steffee discloses a rigid (e.g., titanium or steel) bone fastener comprising “elongated curved fastener 10” which “includes a shank portion 12”

having “a pointed end 14 and at its opposite end has a driving head portion 16.” *Id.*, 2:33–43. Barbs 20 project along the shank portion 12. *Id.*



In reference to Figure 5 below, “[a]s the fastener 10 is driven into the bone portion [22], due to its curved configuration, it progresses along a curved path A through the bone graft 24 and into bone portion 26.” *Id.*, 2:45–48.

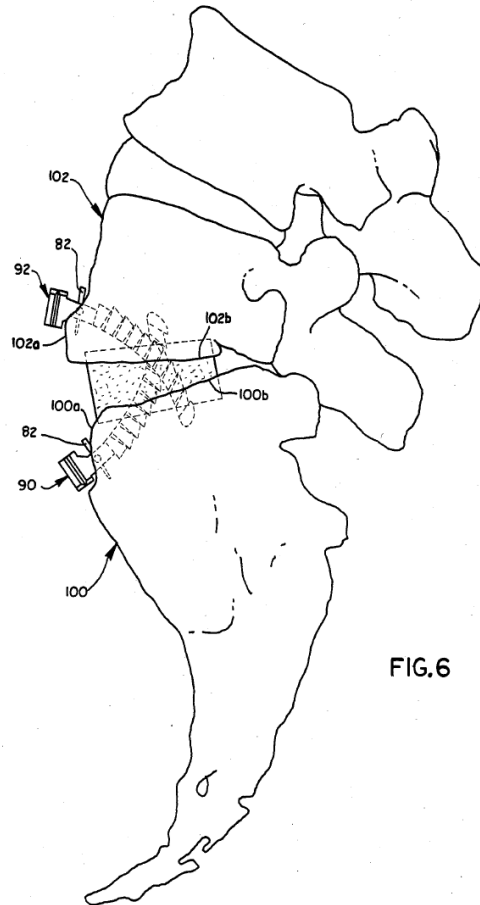


POSAs understood that bone portion 22 is one vertebral body and bone portion 26 is an adjacent vertebral body, and that bone graft 24 resides between those adjacent

bodies. Ex. 1002 ¶102.

Steffee teaches that it was known that “bone graft contracts as it resorbs.” Ex. 1016, 1:11–14. In other words, the bone graft material breaks down and forms the substrate for new bone growth. Ex. 1002 ¶103. This “resulted in difficulties in securing bone graft between spaced apart bone portions which are to be connected by the bone graft.” Ex. 1016, 1:11–14. Steffee explains that staples were used to secure bone graft between the bodies but as bone graft resorbs, it applies a force that “acts through a moment arm and causes the leg to pivot relative to a portion of the staple base,” causing the staple “to loose (*sic*) its effectiveness.” *Id.*, 1:14–20. Steffee’s curved fastener, on the other hand, “extends through the bone graft in a direction along a line extending through the bone graft and bone portions and along which the bone graft resorbs. Thus, the force applied to the shank by the bone graft as it resorbs acts generally along the longitudinal extent of the shank. Thus, the force does not act through a moment arm nor does it have a detrimental effect on the fastener.” *Id.*, 1:28–35. Stated another way, the curvature of the fasteners helps reduce the movement associated with graft reabsorption, thereby inhibiting movement of the fasteners due to migration. Ex. 1002 ¶103.

Steffee discloses an alternative embodiment in Figure 6:



Each fastener 90, 92 is driven into the side of a corresponding vertebral body 100, 102, respectively, and curves into bone graft between those bodies and into the opposing body. Ex. 1016, 4:23–34. Thus, Steffee is directed towards interbody fusion using bone graft held between the vertebral bodies by rigid curved fasteners. Although Steffee does not expressly disclose the use of interbody implants to provide structural support (e.g., like those disclosed in Blain and Bray), bone graft was commonly packed in and around such implants to facilitate bone fusion of vertebral bodies, which would exhibit the same behavior as the bone fusion that occurs in Steffee. Ex. 1002 ¶¶104-105 (citing Ex. 1006, 4:31–37; Ex. 1004, 1:32–

34).

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

This section demonstrates that all elements of the challenged claims are anticipated and/or obvious. Although the analyses of dependent claims may not explicitly reference the analysis of claims from which they depend, the analyses of the claims from which they depend are incorporated therein by reference.

**A. GROUND 1: BLAIN ANTICIPATES OR RENDERS
OBVIOUS CLAIMS 1–6, 11, 12 AND 15–17**

Claim 1

1.0 [Preamble] “An apparatus comprising:”

Blain discloses the preamble as shown below.

1.1 “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;”

In reference to Figure 1 (annotated below), Blain discloses an “interbody fusion implant 2” (*a fusion member for positioning between two vertebral bodies*):

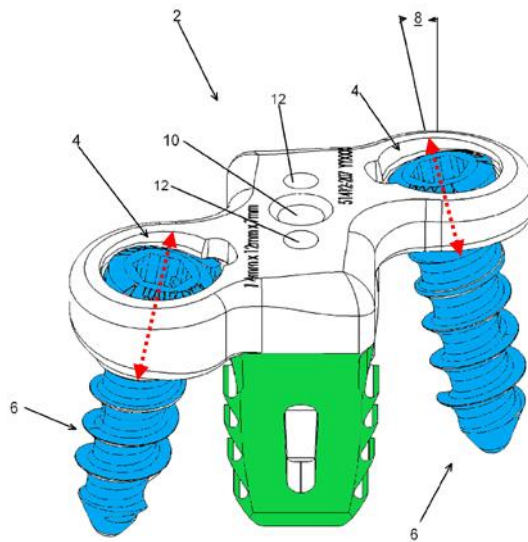


FIG. 1

Ex. 1004, 4:26–28; Ex. 1005 ¶[0019]. POSAs understood that the term “interbody fusion” in “interbody fusion implant” refers to how the implant is specifically designed to be inserted between two adjacent vertebral bodies to facilitate fusion,

providing structural support and stability. Ex. 1002 ¶¶108-109 (citing *e.g.*, Ex. 1001, 2:19–23 (referring to implant as “**interbody fusion** member” because it is used to fuse two adjacent vertebral bodies); Ex. 1014, 4:12–13 (“Spinal fusion involves removal of the spinal disc and fusing or joining the **two adjacent vertebrae.**”), 4:52–55 (“[i]n **all** interbody surgical approaches” disc (“nuclear material”) is removed and the end plates of the vertebral bodies are decorticated to facility bony fusion); Ex. 1015, 1:32–43; Ex. 1017, 1:13–17)). Blain itself teaches that spinal fusion “surgery involves removal of the affected disc and fusion of the **adjacent vertebrae.**” Ex. 1004, 1:30–34. POSAs thus understood that Blain’s interbody fusion implant is *for positioning between two vertebral bodies*. Ex. 1002 ¶109.

In reference to Figure 1 above, the cage portion (green) would be inserted in the disc space between two adjacent vertebral bodies. *Id.* ¶110. One fastener 6 (blue) would be inserted through implant opening 4 and fastened to one vertebral body, and the other fastener 6 (blue) would be inserted into the other opening 4 and fastened to the other vertebral body. *Id.* The fusion would then occur around and through the cage openings. *Id.*

The interbody implant 2 further comprises *a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the*

fusion member.¹⁰ *Id.* ¶111. As shown above, there are two channels identified generally by a red-dashed arrow (*a first plurality of channels*). *Id.* Each channel has an opening 4 on the proximal (top) side (*same side*) of the implant and an opening on the distal (bottom) side (not visible). *Id.* (citing Ex. 1004, 4:28–39, Fig. 2B (showing channels without fasteners 6 inserted); Ex. 1005 ¶[0019]). Each fastener 6 (blue) is inserted through a channel from the proximal side. *Id.* (citing Ex. 1004, 8:5–18; Ex. 1005 ¶[0035]).

1.2.1 “a delivery mechanism for delivering the fusion member between the two vertebral bodies,”

In the litigation, Spinelogik proposed ordinary meaning for *delivery mechanism*, and Globus proposed “insertion tool separate from the driving member.” Ex. 1021; Ex. 1022, 2. Blain satisfies either proposal.

Referring to Figure 3A (below), instrument guide 14 is *a delivery mechanism for delivering the fusion member between the two vertebral bodies*:

¹⁰ *Channel* refers to a passage through which something moves or is conveyed. Ex. 1002 ¶111 (citing Ex. 1007, 4; Ex. 1008, 4; Ex. 1009, 4). The Specification places no limits (e.g., length, diameter) on the ordinary meaning of *channel* and in fact teaches “channels of different shapes and sizes.” Ex. 1001, 13:32-33.

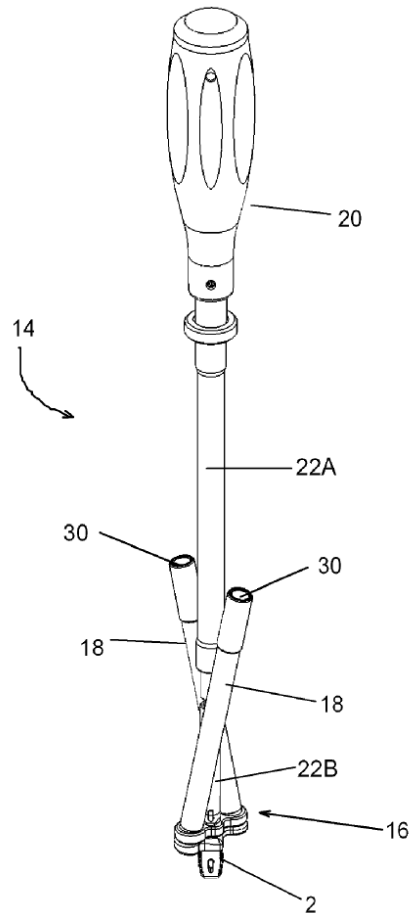


FIG. 3A

Ex. 1002 ¶113. Blain explains that “instrument guide 14 comprises one or more guide members 18 and a device coupler 16 with one or more coupling structures 26, 28 engageable to the implant 2.” Ex. 1004, 4:55–58; Ex. 1005 ¶[0020]. In an embodiment, “the instrument guide 14 is attached to the orthopedic device 2 prior to implantation, and the instrument guide 14 is also used **as a delivery instrument** used to insert and fix the orthopedic device 2 to the spine.” Ex. 1004, 10:6–13; Ex. 1005 ¶[0045]. POSAs thus understood that handle 20 of instrument guide 14 would be used by the medical practitioner to deliver the attached implant 2 between the vertebral bodies. Ex. 1002 ¶114. Screw driver 66 (a *driving member* as discussed

regarding claim 15) is separate from the instrument guide 14. *Id.* (citing Ex. 1004, 8:50–54, Figs. 6A–B (showing screw driver 66 as a separate tool inserted into guide tubes 18)); Ex. 1005 ¶[0038]. Consequently, the instrument guide meets this limitation.

Notably, Blain’s delivery mechanism is comprised of very similar structure for delivering the implant 2 as compared to the delivery mechanism disclosed in the ’805 Patent. Ex. 1002 ¶¶115-117. The ’805 Patent discloses one or more housed rotatable retention rods 160, each having a handle 820 and retention teeth 910, “male/female structures,” a “clamp,” or “expandable clasps” for attaching and detaching to the implant. *See e.g.*, Ex. 1001, 11:60–12:2, 12:7–16, 13:8–24.

Similarly, in reference to Figure 5 (annotated below), Blain’s *delivery mechanism* includes distal inner shaft 42 (housed in distal outer shaft 46 and coupling base 32), distal engagement member 36 (housed in distal outer shaft 46 and movable outer shaft 52), and proximal inner shaft 48 (housed partially in movable outer shaft 52 and distal outer shaft 46), each of which is highlighted yellow, below. Ex. 1004, 6:47–67; Ex. 1005 ¶[0029].

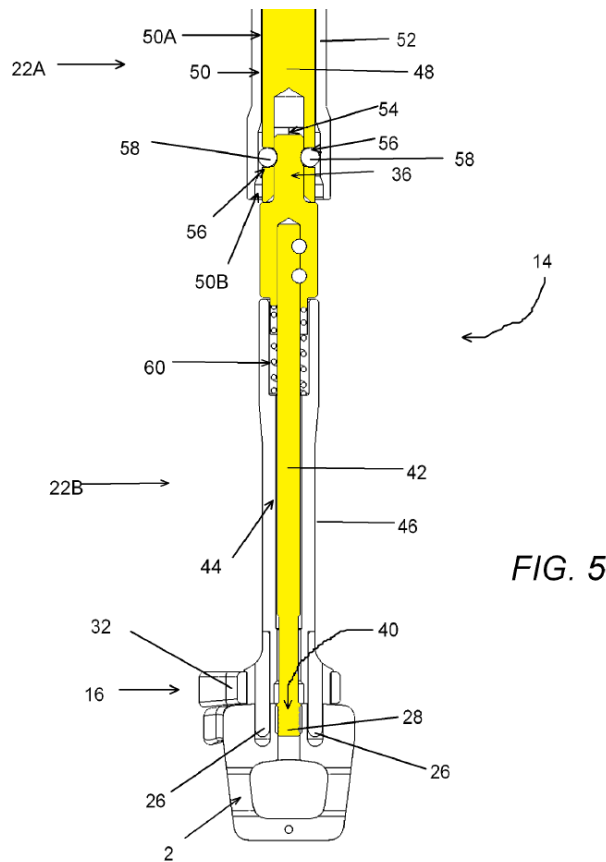


FIG. 5

The combination of these components mirrors each housed rotatable retention rod 160 disclosed in Figure 10A of the '805 Patent. Ex. 1002 ¶115.

Blain's *delivery mechanism* further comprises handle 20 on the proximal end of the retention rod, which is rotatable to couple the coupling member 28 to the coupling opening 10 of implant 2. Ex. 1004, 4:55–61, 5:44–62; Ex. 1005 ¶[0020]. This handle 20 mirrors handle 820 from the '805 Patent, which is used to rotate retention rods 160 to couple/decouple them with the implant. Ex. 1002 ¶116.

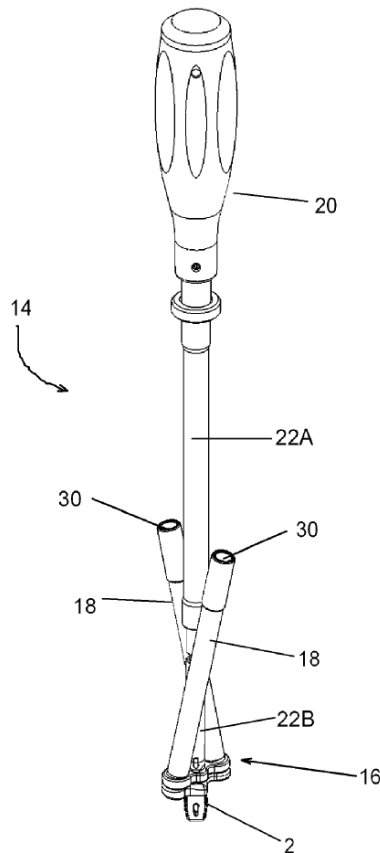


FIG. 3A

Blain's *delivery mechanism* further comprises retention teeth, male/female structures, or a clamp for attaching and detaching to the implant. Specifically, Blain teaches that the movable coupling member 28 (at the distal end of the retention rod) preferably comprises a "locking configuration or structure to detachably engage the implant" and may comprise "any of a variety of complementary mechanical interfits with the coupled implant, such as threaded lock, snap-on fitting, or an interlocking fit." Ex. 1004, 5:44–54, 6:28–38; Ex. 1005 ¶[0024]. Blain also teaches that coupling member 28 may comprise "a hook that engages a recess or pin on the implantable device, or a pivot or clamp member that retain the components by grasping onto the sides of the components." Ex. 1004, 6:25–28; Ex. 1005 ¶[0027]. Thus, the coupling

member's 28 "interlocking fit" feature correlates to the retention teeth or male/female structures in the '805 Patent (e.g., 910 in Fig. 10B), and the coupling member's 28 pivot or clamp member correlates to the '805 Patent's clamp. Ex. 1002 ¶117.

1.2.2. "the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,"

Blain does not explicitly state that instrument guide 14 *extend[s] outside a patient's body to a medical practitioner* as claimed. While this limitation was the basis for the Examiner allowing the claims over Duffield (*see* Section V.B above), this limitation is so trivial and un inventive that the Specification of the '805 patent does not discuss it. In any event, a POSA would understand this limitation to be disclosed by Blain. Ex. 1002 ¶118.

The instrument guide 14 of Blain has a handheld handle 20 (e.g., like a screwdriver handle), which POSAs readily understood to be designed so that the physician can manipulate the positioning of the implant from outside the patient's body and rotate the inner shaft 48 to attach to, and detach from, the implant 2 once the implant is inserted. *Id.* ¶119 (citing Ex. 1004, 4:57–62, 7:11-17, 10:6-13). This understanding is supported by numerous other prior art references showing that such handles for spinal fusion implant delivery were specifically designed for this purpose. *Id.* ¶120 (citing *e.g.*, Ex. 1027, 5:43–56 (explaining that interbody implant

insertion tool shaft 15 is “generally cylindrical of a length sufficient to allow the device to span **from the surgical target site to a location sufficiently outside the patient’s body** so the handling feature 14 can be easily accessed by a clinician or a complimentary controlling device.”); Ex. 1029, 9:55–56, 10:45–54 (explaining that implant delivery tool 50 “includes a shaft 91, having a length sufficient to reach **into the intradiscal space from outside the patient.**”); Ex. 1023, 7:6–9, 31–43; Ex. 1024, 15:28–37; Ex. 1026, 7:18–29; Ex. 1025, 5:8–13; Ex. 1028 ¶¶[0012], [0022])). Indeed, a POSA understood that the handle is designed to be outside the patient’s body, because a physician would otherwise be required to insert his or her hand into the patient’s body during deployment, impairing the ability of the physician to maneuver, position and manipulate the implant. *Id.*¹¹

Moreover, based on the dimensions of the implant 2 relative to the dimensions of instrument guide 14, POSAs understood that during surgery, at least the handle 20 and part of proximal shaft 22A of the instrument guide 14 would extend outside of the patient’s body through the surgical access channel. *Id.* ¶122. The implant 2 is sized to fit between two vertebral bodies, and thus, the size of the implant’s cage corresponds generally to the size of the disc space that the cage is designed to be

¹¹ Mr. Culbert has considerable spinal fusion surgery experience from before March 2008. He has never seen a fusion implant delivery tool that did not extent outside the patient’s body when the implant is between the vertebral bodies. Ex. 1002 ¶121.

inserted into. *Id.* Even assuming surgery were to be performed on an extraordinarily large patient, based on the relative dimensions of the implant 2 to the instrument guide 14 and the size of space between vertebral bodies, it is apparent to POSAs that shaft 22A and handle 20 would still extend outside the patient's body. *Id.*

To the extent Spinelogik argues that this limitation is not disclosed in Blain, it would have nevertheless been obvious based on common sense and the general knowledge of POSAs to make the length of the shaft of instrument guide 14 sufficiently long so that the physician would not have to stick his or her hand inside the incision location to insert the implant between the vertebrae. *Id.* ¶123. The numerous prior art references discussed above (Exs. 1023-1028) demonstrate that it was common knowledge for delivery tools to extend outside a patient's body to the physician once the implant was inserted, including for the purpose of allowing the physician to easily access the tool handle and control coupling (e.g., via a thumb wheel). *Id.*

It was nothing more than common sense that the combined length of the shafts of Blain should be sufficiently long for this purpose, providing the known benefit of allowing the physician to maneuver and manipulate the delivery tool without having to insert his or her hand into the patient's body to deliver and position the implant. *Id.* ¶124. It was also understood by POSAs, again based on common sense, that by designing the handle to extend outside of the patient's body, the incision in the

patient could be smaller. *Id.* This resulted in a more minimally invasive procedure, which was strongly desired. *Id.* (citing *e.g.*, Ex. 1014, 1:35–36; Ex. 1018, 2:26–28; Ex. 1020 ¶[0008]; Ex. 1037, 2:31–36).

Further, POSAs understood that during spinal fusion surgeries, an x-ray imaging process (e.g., fluoroscopy) helped physicians guide and insert the implant between the vertebrae. *Id.* ¶125 (citing Ex. 1023, 3:3–13; Ex. 1024, 18:7–12; Ex. 1027, 1:48–51). It was understood that inserting the physician’s hand into the patient would partially obscure the imaging, resulting in the physician delivering the implant with his or her vision obscured. *Id.* Further, it was known that a physician would not want his or her hand in the patient’s body during imaging due to unwanted exposure to radiation from the fluoroscopy. *Id.* This is another reason it was obvious to have the guide instrument’s handle extend outside the patient’s body.

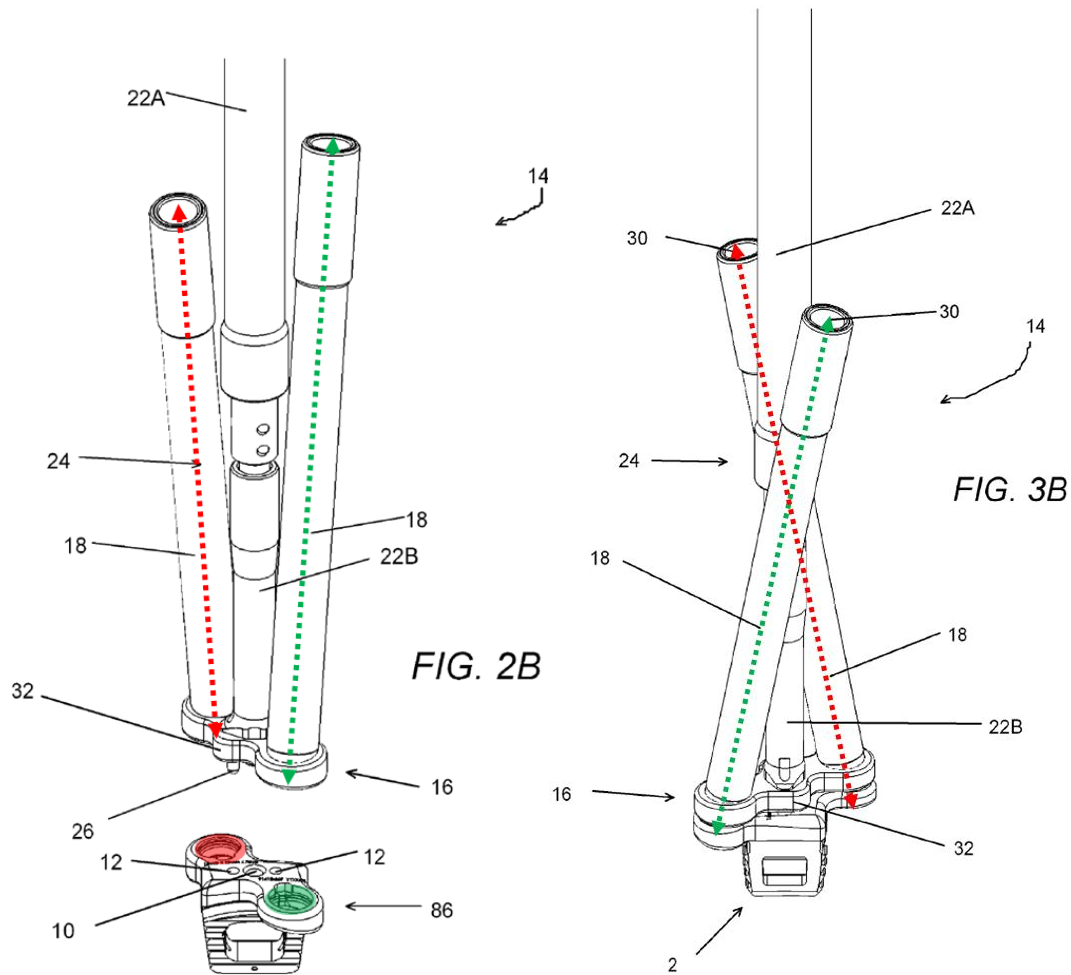
POSAs had a reasonable expectation of success in modifying the instrument guide 14 such that its handle 20 and shaft 22 extends outside the patient’s body, as this involved nothing more than lengthening the proximal shaft 22A and/or distal shaft 22B. *Id.* ¶126. Indeed, Blain itself expressly teaches that “the relative lengths between the proximal shaft 22A and the distal shaft 22B can vary” and the prior art discussed above shows that such a length was common place. Ex. 1004, 5:4–6; Ex. 1005 ¶[0021].

1.2.3. “the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured

to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and”

Blain teaches that the instrument guide 14 has *a second plurality of channels*, which are the tubular passages of the guide tubes 18. Ex. 1002 ¶127. In reference to Figures 2B and 3B (annotated below), one guide tube 18 has a proximal opening 30 of a channel that extends to the opposing end of the guide tube (as indicated by red-dashed arrow) and to a channel opening (not shown) in device coupler 16. Ex. 1004, 8:5–16; Ex. 1005 ¶ [0035]). Likewise, the other guide tube 18 has a proximal opening 30 of a channel that extends to that guide tube’s opposing end (as indicated by green-dashed arrow). *Id.*¹²

¹² Figures 2B and 3B show the same embodiment from different perspectives.



Blain discloses that *each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies*. Ex. 1002 ¶128. The guide instrument channel (red-dashed line) aligns with the implant fastener channel (red circle), and the other guide instrument channel (green-dashed line) aligns with a different implant fastener channel (green circle). Ex. 1004, 4:55–58, 5:17–33, 6:1–9; Ex. 1005 ¶¶[0020], [0022], [0025]. Figure 2B shows the instrument guide 14 before it has coupled to the implant 2, while Figure

3B shows the instrument guide 14 after coupling to the implant 2. Ex. 1004, 5:17–18, 5:29–33; Ex. 1005 ¶¶[0022]. As discussed in element 1.2.1, this alignment exists *when the delivery mechanism delivers the fusion member between the two vertebral bodies* because the instrument guide 14 is already coupled to the implant 2 when the surgeon inserts the implant between the vertebral bodies. Ex. 1002 ¶129 (citing Ex. 1004, 10:6–13; Ex. 1005 ¶[0045]).

1.3 “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing through a different channel of the fusion member, (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.”

Blain discloses *a plurality of independent anchoring members* (bone fasteners 6) *configured to secure the fusion member to the vertebral bodies*. *Id.* ¶130. Blain explains that “[a]fter the implant 2 is positioned in its desired location and orientation, self-tapping or self-drilling bone fasteners 6 may be inserted into the proximal openings 30 of the guide tubes 18 and **fastened to bone using a screw driver 66.**” Ex. 1004, 8:50–54; Ex. 1005 ¶[0038]. Figures 1 and Figure 6A (partial) are both annotated below to identify the bone fasteners 6 (blue):

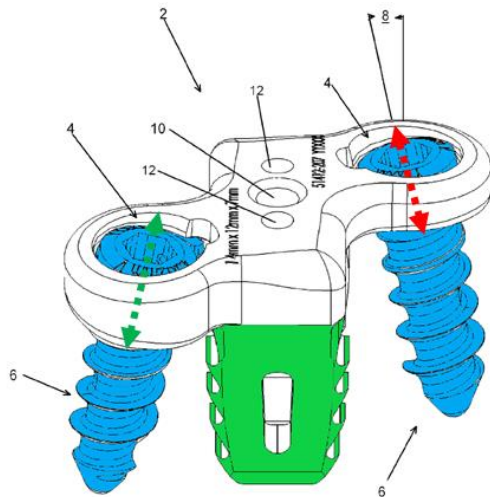


FIG. 1

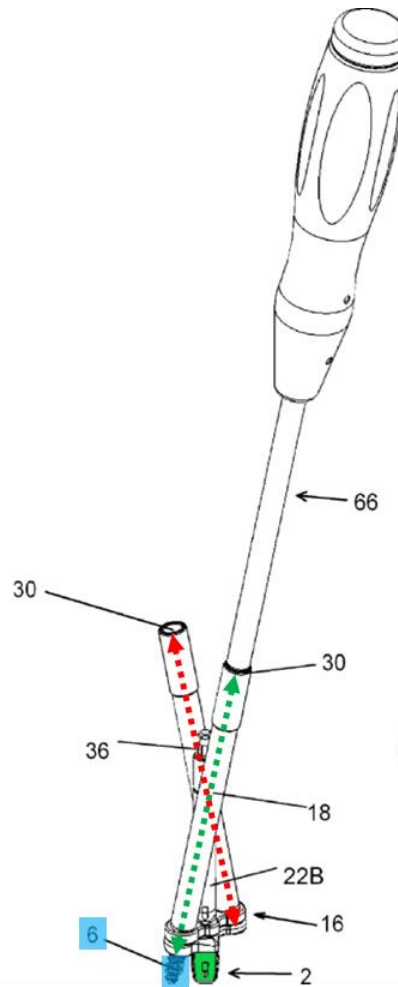


FIG. 6A

Figure 6A shows how screw driver 66 engages with one fastener 6 through guide tube 18 so that the fastener can be driven into a vertebral body (*i.e.*, bone). The other fastener 6 would then be inserted into the other guide member 18 and screw driver 66 is used to drive and couple it into to the other vertebral body. Ex. 1002 ¶131.

Blain also discloses that *each independent anchoring member is for (i) traversing through a different channel of the fusion member. Id. ¶132.* As shown in the figures above, Blain teaches that each *anchoring member* (blue fastener 6) is inserted into a *different channel* (red-dashed or green-dashed channel) of implant 2.

Ex. 1004, 8:46–56; Ex. 1005 ¶[0038]; *supra* claim element 1.1, 1.2.3.

Blain further discloses that *each independent anchoring mechanism is for (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.* Ex. 1002 ¶133. Blain teaches that the fasteners 6 are “**fastened to** bone using a screw driver 66,” which refers to how the fastener is screwed into the vertebral body to secure the fusion implant to and between the vertebral bodies. *Id.* (citing Ex. 1004, 8:50–54); Ex. 1005 ¶[0038]. In so doing, each fastener 6 of the fusion implant *penetrates* the vertebral bodies and *couples* and *prevents decoupling* of the implant from the vertebral bodies via threaded engagement with its respective vertebral body. Ex. 1002 ¶133. Indeed, the ’805 Patent teaches that “variations for the anchoring tip contours *prevent* the anchoring members from being easily withdrawn from the bone.” Ex. 1001, 4:1–4. The threading of Blain’s fasteners 6 likewise *prevent* them from being easily withdrawn from the bone. Ex. 1002 ¶133.

Blain also discloses an anti-rotation mechanism to further *prevent decoupling*. *Id.* ¶134. In reference to Figures 1 and 2B (annotated below), Blain depicts an anti-rotation mechanism comprising a lobe (blue) on each fastener head and a recess (red) adjacent the threading (pink) of each implant channel, which prevents the fasteners from rotating counter-clockwise to unthread. *Id.*

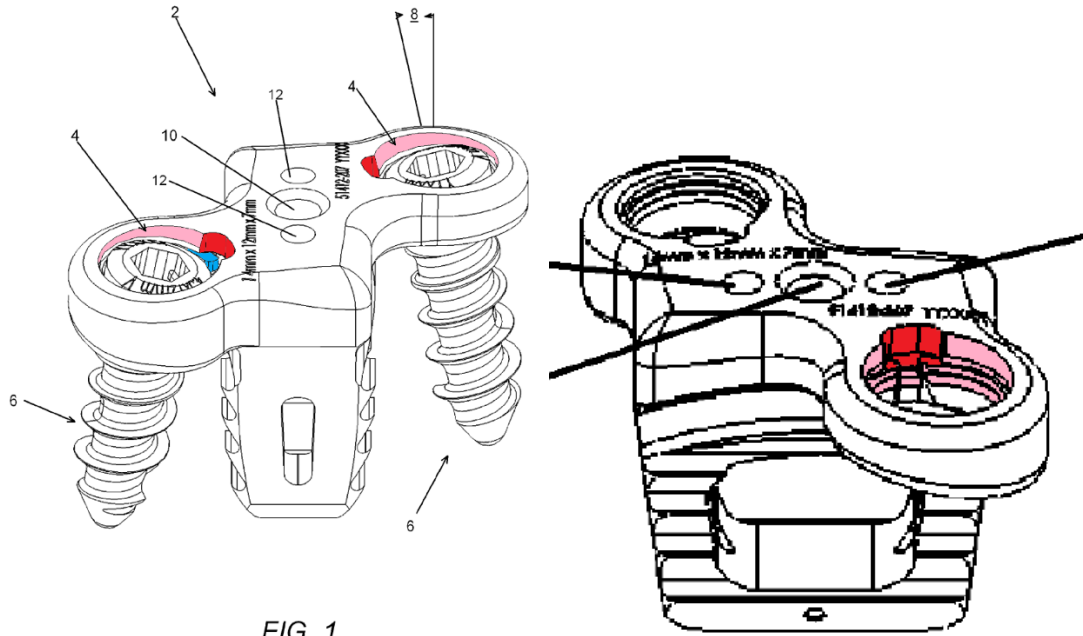


FIG. 1

While Blain does not explicitly discuss this anti-rotation mechanism, a POSA understood this to be a “locking” feature that helps prevent the fasteners 6 from “backing out” of the vertebral bodies and/or implant channel due to reverse-rotation. *Id.* ¶135.

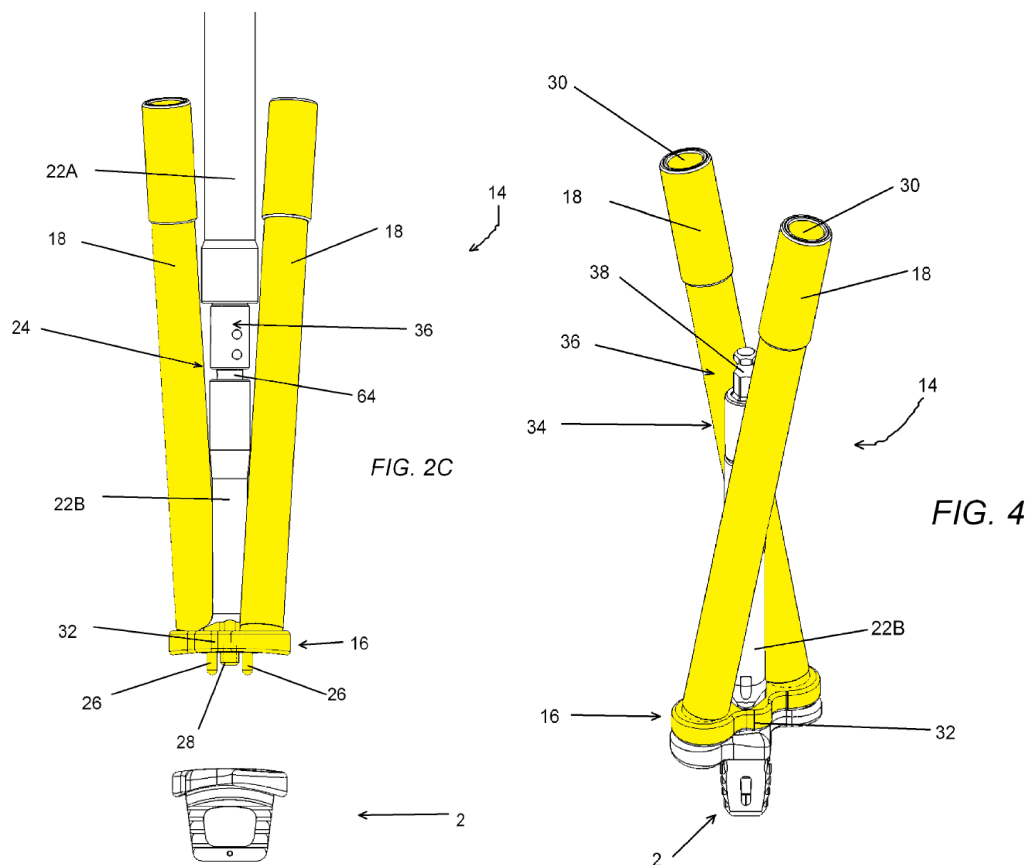
The fasteners 6 screw into the threading (pink) of the implant channels. Once the lobe (blue) of the fastener head bottoms out in the recess (red), the screw head and the implant are securely coupled together. *Id.* ¶¶136-137. The recess (red) then prevents the screw head (fastener 6) from rotating counter-clock wise due to the lobe (blue), meaning the screw cannot back out of the penetrated bone or implant channel due to reverse-rotation. *Id.* The recess (red) also prevents the screw head from advancing all the way through the implant, acting as a seat for the head. *Id.* Thus, each fastener 6 is not only threaded to a vertebral body—it is threaded to the

respective implant channel through which it passes and is “locked” via the anti-rotation mechanism. *Id.*

Claim 2: “The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member.”

Blain’s instrument guide 14 (*delivery mechanism*) comprises a *delivery housing for guiding each independent anchoring member into the fusion member.*

Ex. 1002 ¶138. Specifically, in Figures 2C and 4 (annotated below), instrument guide 14 has two guide tubes 18 (yellow) attached to device coupler 16 (yellow):



Ex. 1004, 8:5–20; Ex. 1005 ¶¶[0036]–[0037].

Guide tubes 18 constitute a *delivery housing* because they are part of the *delivery mechanism* and house fasteners 6 (*anchoring members*) as they pass from the proximal openings 30, through the guide tube channels, to the openings of the device coupler 16. Ex. 1002 ¶139 (citing Ex. 1004, 5:30-33, 8:5-11, 8:48-54); Ex. 1005 ¶¶[0022], [0035], [0038].

The device coupler 16 likewise constitutes a *delivery housing* because it is part of the *delivery mechanism* and houses the fasteners 6 as they pass through the openings in the device coupler 16 on their way to the proximal openings 4 in the fusion implant 2. Ex. 1002 ¶140 (citing Ex. 1004, 8:5-11, 8:50-54); Ex. 1005 ¶¶[0035], [0038]. Both the device coupler 16 and guide tubes 18 are *for guiding each independent anchoring member into the fusion member*, as each provides anchor channels leading to the fastener openings 4 of the implant 2. Ex. 1002 ¶141.

The instrument guide 14 also comprises a *retention mechanism for fixedly coupling the delivery housing to the fusion member*.¹³ *Id.* ¶142. In reference to Figures 2C and 5 (annotated below), instrument guide 14 includes inner shaft 42 (green) that resides in outer shaft 46 (pink) and has coupling members 26 (red) and coupling members 28 (at distal end 40 of green shaft 42). Ex. 1004, 6:47-57; Ex. 1005 ¶[0029].

¹³ In the litigation, both parties proposed that this term be given its ordinary meaning. Exs. 1021, 1022.

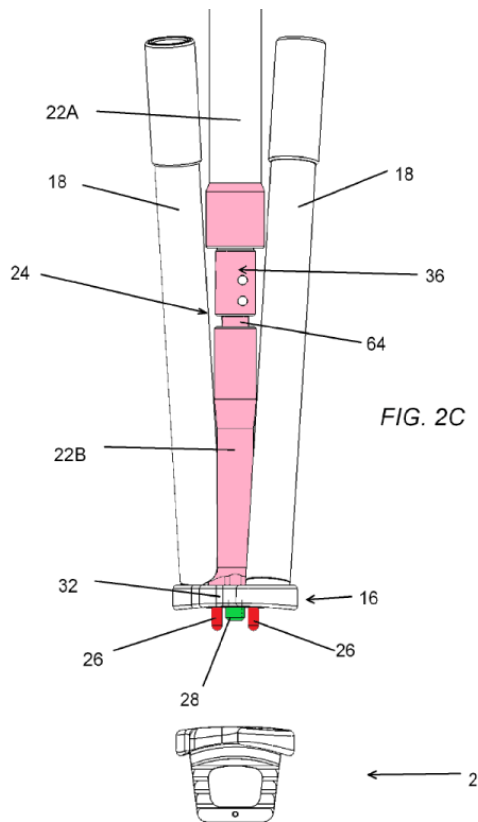


FIG. 2C

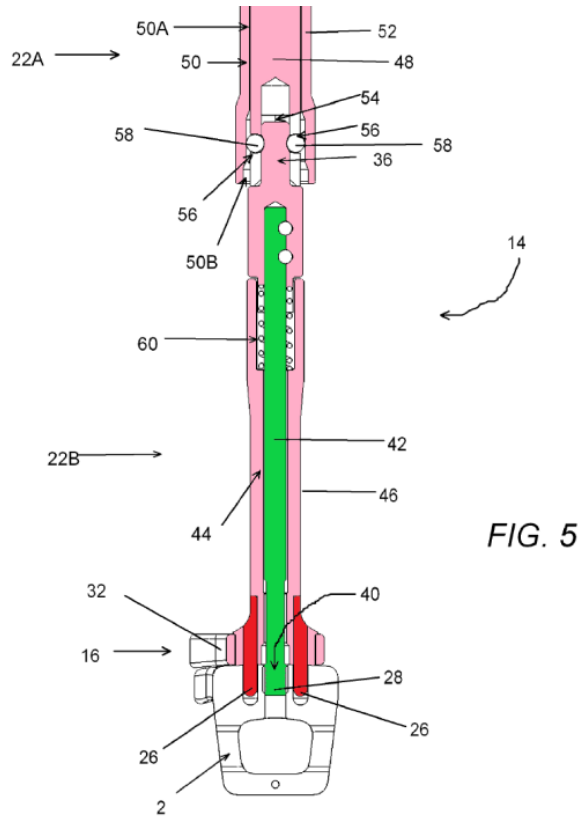


FIG. 5

The distal end 40 of the distal inner shaft 42 includes a movable coupling member 28 that “may comprise, for example, any of a variety of complementary mechanical interfits with the coupled implant, such as a ***threaded lock, snap-on fitting, or an interlocking fit.***” Ex. 1004, 5:44–50; Ex. 1005 ¶[0024]. This allows the instrument guide to be coupled to the implant 2 in a “locking configuration...to detachably engage the implant (2)” *Id.* Thus, the inter-locking fit between the coupling member 28 and the coupling opening 10 of the implant 2 results in the instrument guide 14 (including the device coupler 12 and guide tubes 18) being fixedly coupled to the fusion implant 2. Consequently, the inner shaft 42 (along with its coupling member 28) qualifies as the claimed *retention mechanism*. Ex. 1002 ¶¶143-144.

Notably, Blain's disclosed *retention mechanism* is comprised of very similar structure as the retention mechanism disclosed in the '805 Patent. *Id.* ¶145. The '805 Patent discloses a retention rod 160 with one or more of retention teeth 910, male/female structures, a clamp, or expandable clasps. Ex. 1001, 10:46–57, 12:31–39. Blain's coupling member 28 is likewise part of a retention rod (inner shaft 42) and has mechanical interfits (e.g., like retention teeth 910 of the '805 Patent) or a clamp member (like the clamp referenced in the '805 Patent) to fixedly couple the delivery housing to the implant. Ex. 1002 ¶145.

Claim 3: “The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member.”

As shown above regarding claim 2, the *retention mechanism* includes a *retention rod* in the form of inner shaft 42 (green), which has a distal end 40 with coupling member 28 that couples to the coupling opening 10 of fusion implant 2. Ex. 1002 ¶146. Additionally, the *retention mechanism* comprises coupling members 26, which are also rods used to couple the instrument guide 14 to the implant 2 via coupling openings 12 in the implant. *Id.* (citing Ex. 1004, 6:1-8).

Claim 4: “The apparatus of claim 2, wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.”

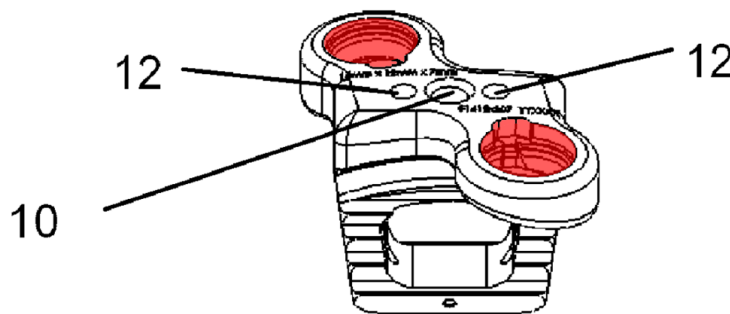
The analysis of claim element 1.2.3 above shows how coupling the instrument guide 14 (including the device coupler 16 and guide tubes 18) to the implant 2,

causes each channel (red-dashed channel and green dashed-channel) of the instrument guide 14 to be aligned with a different channel (red circle and green circle, respectively) of the implant 2. Ex. 1002 ¶147. Indeed, Blain specifically teaches that “[t]he **aligned** coupling between the instrument guide 14 and implant 2 **matches** the guide lumens 18 of the instrument guide 14 with the fastener apertures 4 of the implant 2.” Ex. 1004, 5:30–33; Ex. 1005 ¶[0022].

Claim 5: “The apparatus of claim 1, wherein each channel of the fusion member is curved.”

Blain discloses that *each of the plurality of first channels is curved* under the interpretation advanced by Spinelogik in the litigation. Under that interpretation, *each channel* of the fusion implant 2 is *curved* in two ways. Ex. 1002 ¶148.

First, as shown in Figure 2B (annotated below) of Blain, *each channel* has a round proximal opening (red) on the side that a fastener 6 is inserted into and a round distal opening (not visible) that the fastener protrudes out of.



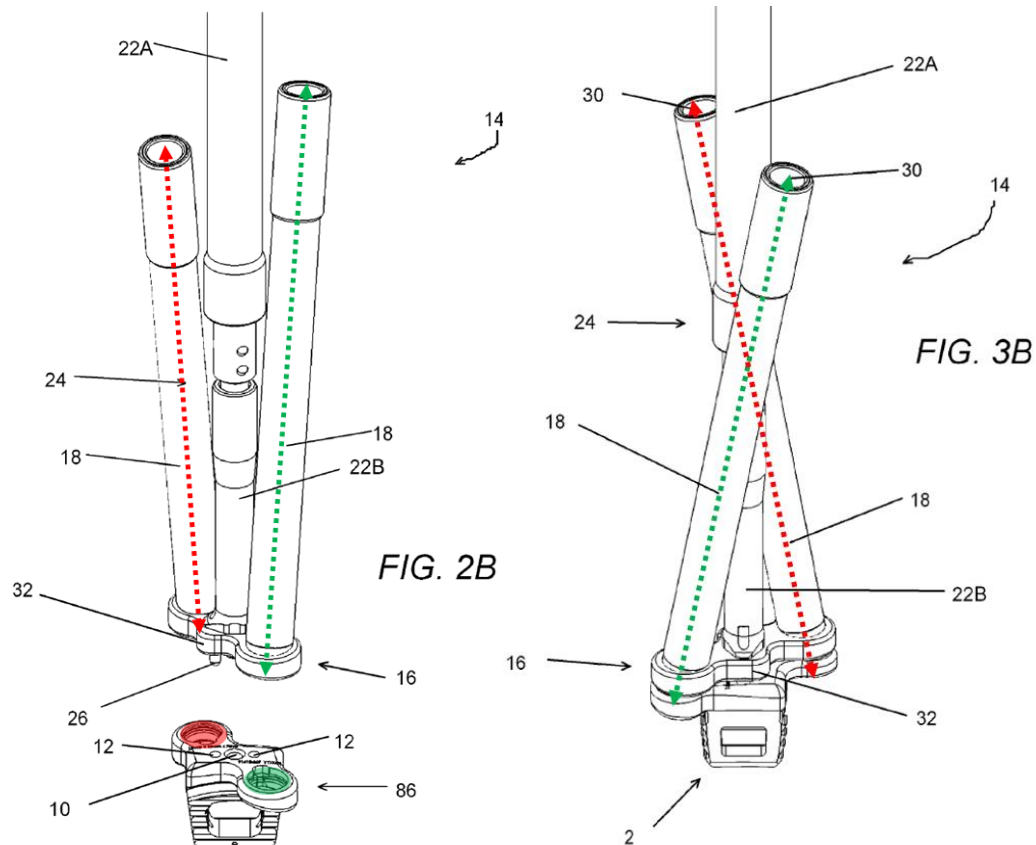
Because the openings of the channels are round, the *channels* would be *curved* pursuant to Spinelogik’s interpretation. Ex. 1002 ¶149. Notably, during prosecution,

the Examiner considered Duffield's implant channels to be curved based solely on them purportedly having a cross-section that is circular. *See e.g.*, Ex. 1003, 111-112 ("Each channel of the fusion member is curved (circular curved cross section).") (citing Ex. 1017, Fig. 12).

Second, *each channel* has a tube-like inner wall extending from one opening to the other opening. Because the inner wall is tube-like, *each channel is curved* under Spinelogik's interpretation. Ex. 1002 ¶150.

Claim 6: "The apparatus of claim 1, wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism."

As explained in claim element 1.2.3 using the annotated figures below, each fastener 6 traverses through a different channel of the implant (e.g., red circle or green circle) through a corresponding channel of a guide rod 18 (e.g., as indicated by red-dashed or green-dashed line) of the instrument guide 14:



Ex. 1002 ¶¶151 (citing Ex. 1004, 4:55-58, 5:17-33, 6:1-9, 8:50-54).

Claim 11

11.0 [Preamble] “A fusion device comprising:”

Blain discloses the preamble as shown below.

11.1 “a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;”

See claim element 1.1 above. *Id.* ¶153.

11.2.1 “a delivery mechanism for delivering the fusion member between the two vertebral bodies,

See claim element 1.2.1 above. *Id.* ¶154.

11.2.2. “the delivery mechanism extending outside a patient’s body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,”

See claim element 1.2.2 above. *Id.* ¶155.

11.2.3 “the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and”

See claim element 1.2.3 above. *Id.* ¶156.

11.3 “a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) coupling the fusion member to the vertebral body, and (ii) preventing decoupling of the fusion member from the vertebral body.”

This claim element is identical to claim element 1.3, except this element omits *(i) traversing through a different channel of the fusion member and (ii) penetrating into one of the vertebral bodies*. Thus, this claim element is broader than claim element 1.3 and the discussion of claim element 1.3 demonstrates that claim element 11.3 is satisfied by Blain. *Id.* ¶157.

Claim 12: “The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member.”

As discussed with respect to claim element 1.3 above, in reference to Figures 1 and 2B (annotated below), Blain’s fasteners 6 threadingly engage the threading (pink) of the implant channels. Additionally, the proximal openings include recesses

(red) that lobes (blue) of the fastener heads seat into once fully threaded into the openings, locking the fasteners to the implant, thereby preventing their counter-clockwise rotation to back out of the penetrated bone or implant.

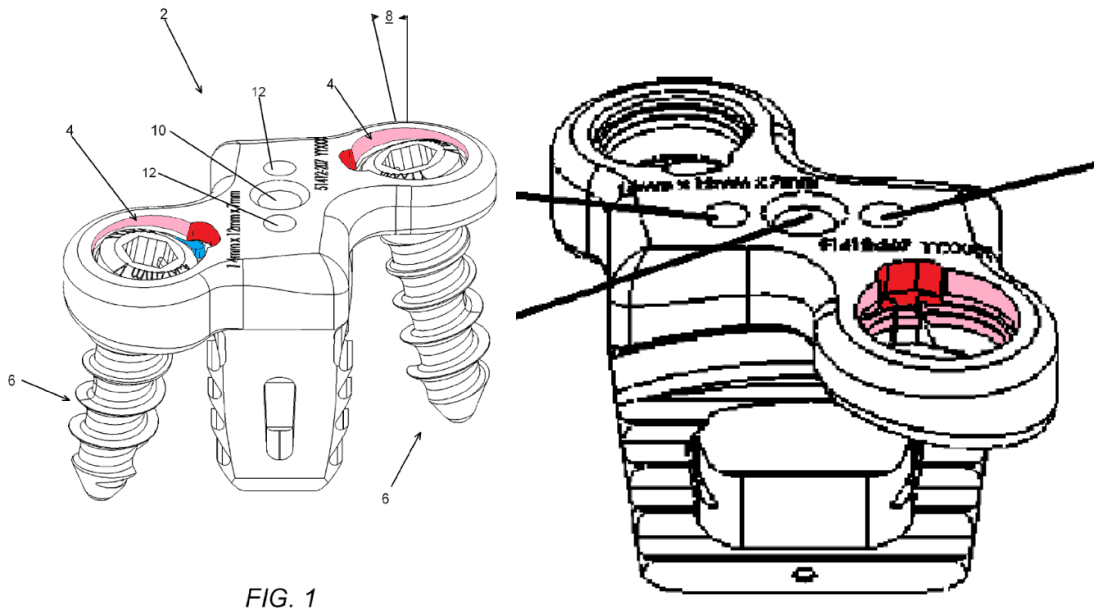


FIG. 1

A POSA understood that the threaded engagement of the fasteners 6 to the implant openings 4 and the anti-rotation mechanism “lock” each fastener to the implant once the fasteners are fully advanced through the implant channels, which helps further prevent decoupling of the implant from the vertebral body. Ex. 1002 ¶158.

Notably, the '805 Patent describes “locking” a fusion member and anchoring member together. In reference to Figures 16 and 17 (below), flanges 1645-1650 of the anchoring members 1410-1420 fit into recesses 1685-1690 of the fusion member channels “locking the anchoring members 1410-1420 to the fusion member 120 once the anchoring members are fully advanced through the fusion member’s channels.”

Ex. 1001, 15:63–16:5.

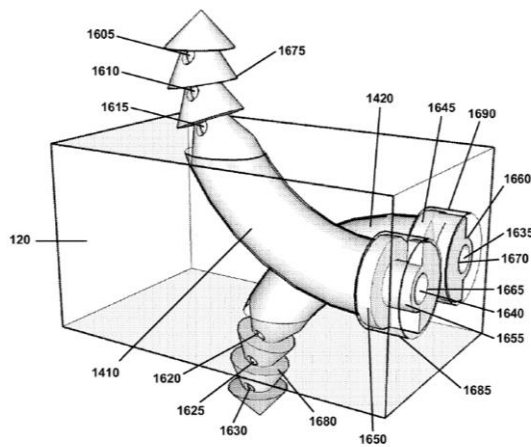


Figure 16

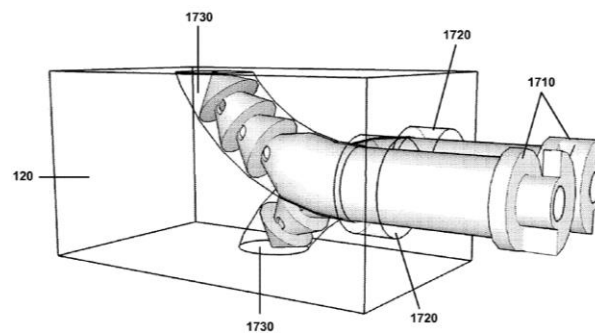


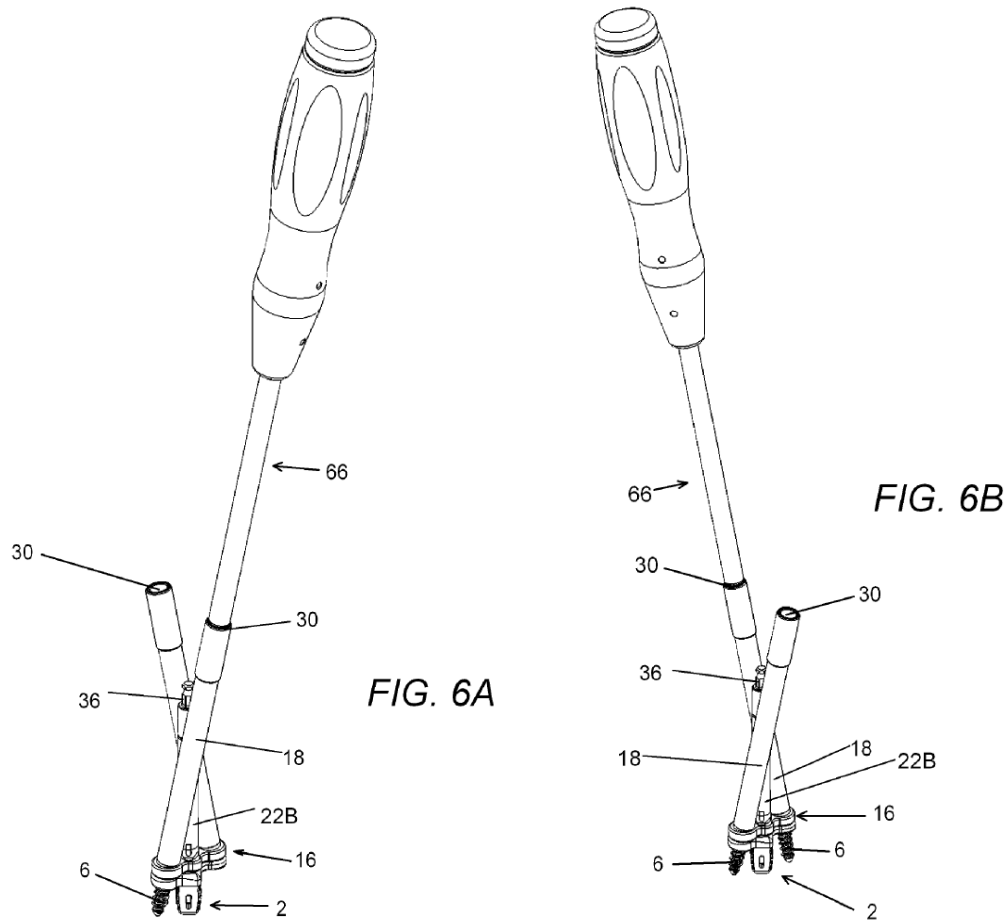
Figure 17

The '805 Patent thus characterizes fitting a head of an anchoring member into a recess of an anchor channel of the fusion implant after the anchors have been coupled to the vertebrae as “locking” the anchoring member and fusion implant together. Ex. 1002 ¶¶159-160. Just as the anchoring members of Figures 16 and 17 are “locked” to the fusion implant by fully advancing the surface contours into the vertebral bodies and the head of the anchoring members residing in recesses of the fusion implant, the *anchoring members* (fasteners 6) of Blain are likewise *locked* to the *fusion member* (implant 2) by virtue of their surface contours (threading) being fully advanced into the vertebral bodies and each fastener having a head that fits within a recess of the fusion member. *Id.* ¶161.

Claim 15: “The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism.”

Blain discloses *a driving member configured to drive each independent*

anchoring member through the delivery mechanism comprising at least a separate screw driver 66. Ex. 1002 ¶162. In reference to Figures 6A and 6B (below), Blain teaches that bone fasteners are “fastened to bone using a **screw driver 66.**” Ex. 1004, 8:50–54; Ex. 1005 ¶[0038]. These figures show the shaft of the screw driver 66 inserted through each of the guide tubes 18 to perform the described fastening.



A POSA understood that the screw driver drives each fastener 6 through a guide tube 18 and, when it screws each fastener 6 into the vertebral bodies, each fastener 6 is driven further through its guide tube 18 and through the opening of coupling device 16 of the instrument guide 14 as the fastener penetrates further and

further into the vertebral body. Ex. 1002 ¶163.

Claim 16: “The fusion device of claim 11, wherein each channel of the fusion member is curved.”

See claim 5 above.

Claim 17: “The fusion device of claim 11, wherein each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism in order to couple the fusion member to the penetrated vertebral body.”

The discussion of claim 6 above explains how Blain discloses that each *independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.*

Further, as explained in claim element 1.3, Blain teaches that “fasteners 6 may be inserted into the proximal opens 30 of the guide tubes 18 and fastened to bone using a screw driver 66.” Ex. 1004, 8:50–54; Ex. 1005 ¶[0038]. Each fastener 6 is thus inserted into a respective guide tube 18 of the instrument guide 14 *in order to couple the fusion implant 2 to the penetrated vertebral body.* Ex. 1002 ¶¶165-166.

**B. GROUND 2: BLAIN AND BRAY RENDER OBVIOUS
CLAIMS 1–6, 11, 12 AND 15–17**

To the extent Spinelogik argues that certain limitations are not anticipated or obvious based on Blain, it would have been obvious to modify Blain to incorporate Bray’s (1) anti-backout mechanism (i.e., restraining plate) and (2) spherical anchor

seat and anchor head, as further explained below. Ex. 1002 ¶167.¹⁴

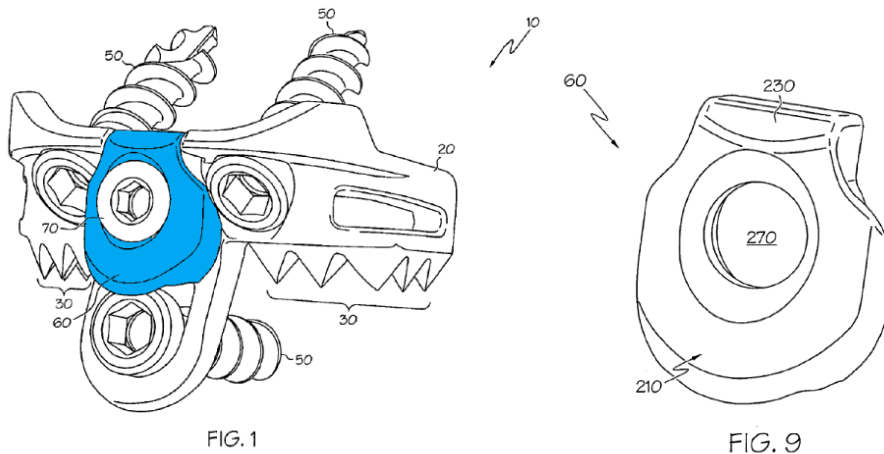
Blain and Bray are from the same field of endeavor as the claimed invention, as both references are directed toward interbody fusion implants and delivery tools for delivering and securing such implants between vertebral bodies. *See supra* Sections VI.A.2, VI.B.2. Both references are also reasonably pertinent to the problems faced by the inventor of the '805 Patent, namely problems associated with effectively and efficiently delivering fusion implants and their associated anchors between vertebral bodies. *Id.* Thus, Blain and Bray are analogous art. Ex. 1002 ¶168.

Claims 1, 11

Blain teaches all elements of independent claims 1 and 11. To the extent Spinelogik argues that Blain does not disclose *preventing decoupling of the fusion member from the penetrated vertebral body* as recited in claim elements 1.3 and 11.3, it would have been obvious to modify Blain in view of Bray.

Bray teaches the use of a restraining feature so that its bone fasteners 50 “cannot back out from the bone bodies once screwed in” through the implant 10. Ex. 1006, 4:49–57. Restraining feature in the form of a restraining plate 60 (blue) is depicted in Figures 1 (annotated below) and 9 of Bray:

¹⁴ This ground incorporates by reference the analysis discussed in Ground 1 as to all challenged claims.



The restraining plate 60 is fixed in place using restraining member fastener 70, which can be a screw. *Id.*, 9:2–6. Thus, Bray teaches the use of a restraining plate 60 to “lock” its anchors 50 to the implant, thereby helping to prevent decoupling of the fusion member from the penetrated vertebral body. Ex. 1002 ¶¶170-171.

It would have been obvious to use Bray’s restraining plate as a simple, yet improved, alternative to the anti-rotation-mechanism of Blain. *Id.* ¶172. POSAs recognized that overlay-type “locking” mechanisms were well-known and effective, which is why they were commonly used in prior art implants. *Id.* (citing Ex. 1030, 4:43-53; Ex. 1017, 4:62-5:13). A POSA would have understood that the restraining plate would prevent the fasteners 6 backing out from Blain’s implant under any scenario, whereas the anti-rotation mechanism only prevents backing out due to reverse rotation. Ex. 1002 ¶172.

POSAs understood Blain’s anti-rotation mechanism to be more complex to machine and somewhat more complex in practice to effectuate, as it requires the

interaction of several machined parts (lobe, recess, channel threading) and a somewhat precise degree of engagement to “lock” the lobe into the recess to prevent anti-rotation. *Id.* ¶173. The restraining plate, on the other hand, is easily coupled to the implant to effectuate its locking. *Id.*

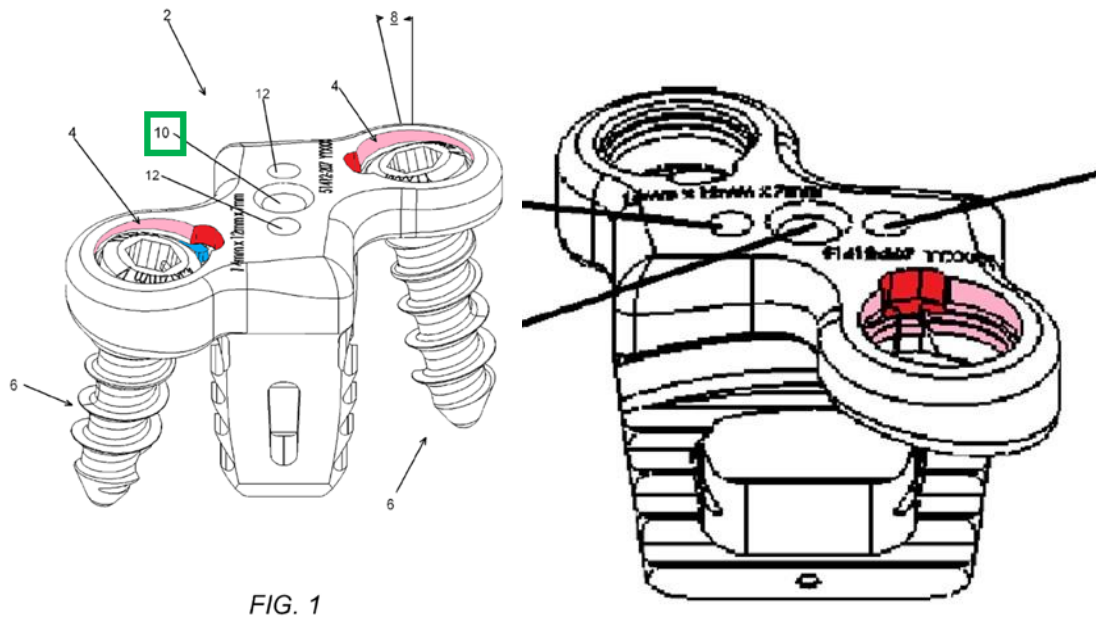
POSAs also understood that using Bray’s restraining plate eliminates the need for the anti-rotation mechanism—namely the lobes on the anchor heads, the recesses in the anchor channels, and the threading in the anchor channels. *Id.* Replacing Blain’s anti-rotation mechanism with Bray’s anti-backout restraining plate would thus reduce the complexity of machining the implant while providing a more reliable and robust anti-backout mechanism. *Id.* A POSA would have also recognized Bray’s restraining plate to be an improvement over Blain’s anti-rotation mechanism because the plate can easily be removed if the anchors need to be unthreaded, whereas Blain’s design makes this more difficult. *Id.* ¶174.

POSAs had an additional motivation to use the restraining plate of Bray to retain anti-backout/locking functionality when Blain’s implant relies on impact driven curved anchors, as proposed in the combination of Ground 3. Specifically, Blain’s anti-rotation mechanism would not work with an impact driven (i.e., unthreaded) anchor. Thus, a POSA would have been motivated to use Bray’s restraining plate with a non-threaded curved anchor to prevent the anchor from backing out. *Id.* ¶175.

The proposed modification would have also been obvious because incorporating the restraining plate of Bray into Blain involved nothing more than applying a known technique (preventing an anchor from backing out of an implant using a restraining plate) to improve a similar device (e.g., Blain's implant) in an entirely predictable way. *Id.* ¶176.

A POSA had a reasonable expectation of success in making this modification. Referring to Figure 1 and Figure 2B (annotated below) of Blain, the modification simply required: (1) eliminating the anchor head lobe (blue), anchor channel threading (pink), and channel recess (red), while maintaining a seat for the anchor head to rest on;¹⁵ and (2) taking the restraining plate 60 of Bray and modifying it to conform to the shape of the proximal side of Blain's implant 2, such that at least part of the plate overlaps with the proximal openings 4 to prevent the fasteners 6 from backing out. *Id.* ¶177.

¹⁵ As discussed below with respect to claims 5 and 16, it would have been obvious to further modify Blain to incorporate the convex anchor head and concave anchor seat of Bray into Blain's implant, thereby providing a bearing seat surface to support the anchor head.



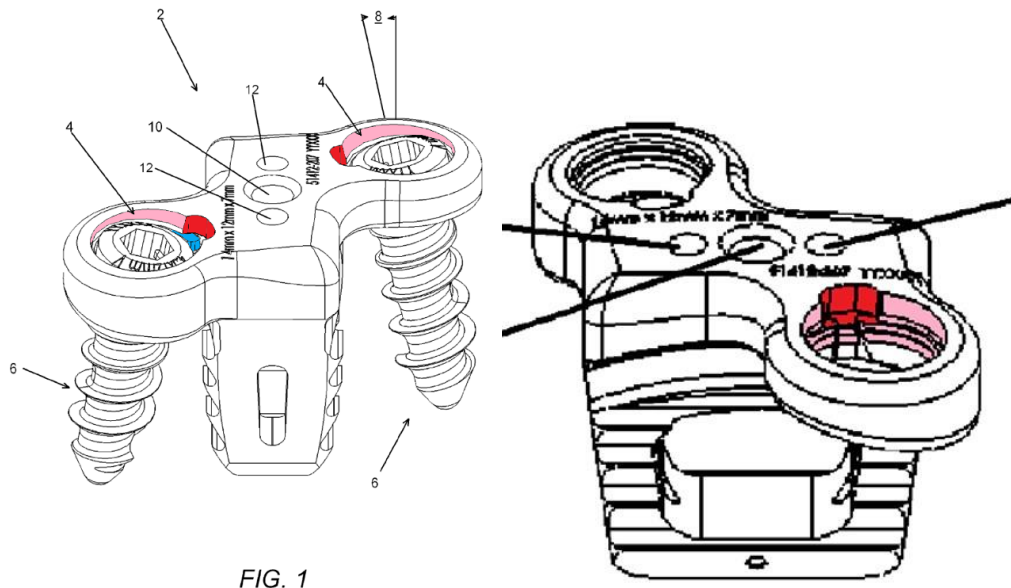
As shown in Figure 1, Blain's implant already has a coupling opening 10 that may be threaded so that the coupling member 28 of the instrument guide 14 can be fixedly coupled to the fusion implant 2. Ex. 1004, 5:57-67. POSAs understood that the coupling opening 10 could also be used for threading a restraining member fastener (e.g., screw) after the delivery guide 14 is removed, just like the restraining plate 60 of Bray is coupled to its implant using a restraining screw 70. Ex. 1002 ¶178.

Claims 5, 16

To the extent Spinelogik argues Blain does not disclose *wherein each channel of the fusion member is curved*, it would have been obvious to modify the anchor channels of Blain's implant to include a spherical anchor head and corresponding spherical seat for the head to sit in (as taught by Bray), resulting in channels that not only have circular openings and tube-like walls, but also radially inward curvatures

that form a concave, spherical anchor head seat. Ex. 1002 ¶179.

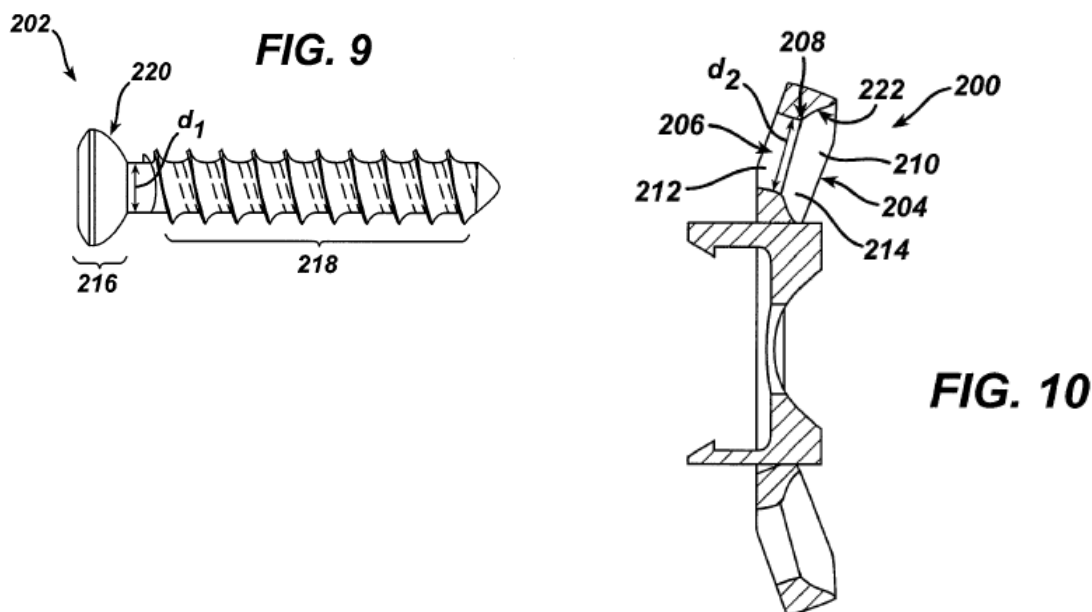
POSAs understood that an anchor must contain a surface, such as a lip or seat, to engage a bearing surface of the implant, or the anchor would not affix the implant to the bone. *Id.* ¶180 (citing Ex. 1040, 8-10). Blain does not explicitly discuss its anchor seats, which are obscured by the head of the anchors 6 in several of Blain's figures. However, Figure 1B (annotated below) appears to show that the recess (red) and/or threading (pink) is used as a seat upon which the anchor head sits. *Id.* ¶181. As discussed with respect to claims 1 and 11, it would have been obvious to modify Blain to incorporate the restraining plate of Bray, which would result in the anchor lobe (blue), recess (red) and threading (pink) being removed.



A POSA would have thus been motivated to incorporate the concave anchor seat and

convex anchor head of Bray into Blain to provide a bearing surface for the anchor head.

The use of such anchor heads and seats is disclosed in multiple prior art implants, in addition to being a well-known way by which screws and other fasteners affix implants to bone. *Id.* ¶183. For example, Fraser teaches the use of an inner lumen 210 (channel) having “a shape and size adapted to receive the head 216 of a bone screw 202” as shown in Figs. 9 and 10 below. Ex. 1038 ¶ [0061].



Fraser explains that the “generally spherical recess [is] formed in the plate for rotatably seating a head of a bone screw.” *Id.*, ¶ [0014]. POSAs understood that such seats both prevent the screw from advancing through the implant and allow the penetration angle of the screw to be slightly adjusted. Ex. 1002 ¶184.

Likewise, as shown in Figures 3 and 5 of Bray (below), each bone screw extends through holes 140 (channels), which “are sufficiently large to allow a portion of a respective bone screw to pass therethrough, but not large enough to allow a retaining portion of the bone screw through, such as the head of the bone screw.” Ex. 1006, 7:24–30; Ex. 1002 ¶185. “[E]ach of the first bone screw holes 140 has a seat 165 on which the retaining portion of a respective bone screw rests. Each seat 165 has a **generally concave spherical** shape and the surface of the retaining portion of the bone fastener in contact with the seat 165 has a complementary **convex spherical** configuration,” which means “the bone screws are free to pivot on the seats.” Ex. 1006, 7:30–37. Blain teaches that this pivotability provides the benefit of allowing “the interbody [implant] to migrate and self-center after it has been implanted.” Ex. 1006, 10:51-55.

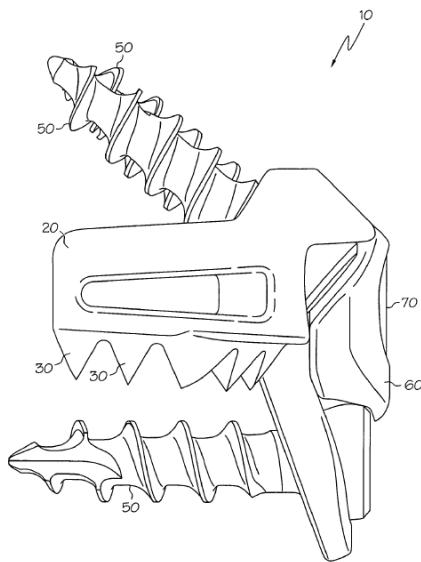


FIG. 3

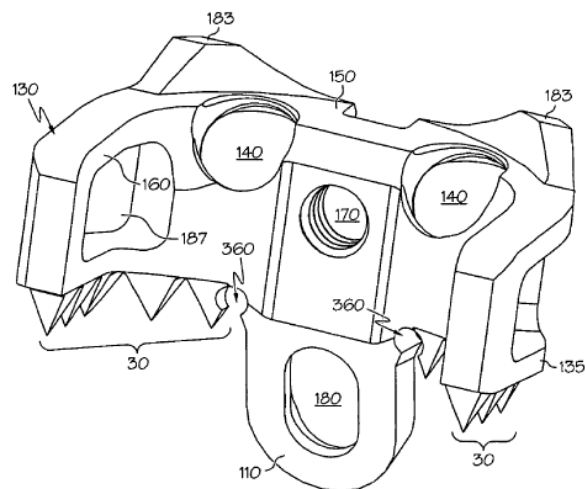


FIG. 5

POSAs were motivated to modify the proximal openings 4 of Blain to include a concave spherical seat and modify the anchor head to have a complementary convex shape, so that the “bone screws are free to pivot on the seats” as expressly taught by Bray. Ex. 1002 ¶186. This would provide the benefit of allowing the penetration angle of the screw to be adjusted by pivoting so that the anchor can be slightly adjusted, as well as provide the implant the ability to “migrate and self-center” as expressly taught by Bray. *Id.* This would also ensure that the anchor heads have a bearing surface to engage and that they cannot advance all the way through their respective anchor channels, while maintaining close conformity between the anchor head and seat due to their complementary shapes. *Id.*

The proposed modification was also nothing more than an obvious, alternative design choice to rely on an anchor with a spherical head, rather than a planar head, and to design the seat to have a complementary shape to provide for close conformity. *Id.* ¶187. A POSA would have recognized no appreciable difference in using a spherical anchor head and seat as compared to a planar head and seat, aside from the benefits previously discussed. *Id.*

A POSA would have also understood that modifying Blain to incorporate a convex anchor head and concave seat (as taught by Bray) was nothing more than combining known prior art elements according to known methods to yield entirely predictable results. *Id.* ¶188. The use of convex anchor heads and concave seats was

known, as evidenced by Bray and Fraser. *Id.* Methods of machining such heads and seats was also well-known using simple machining principles. *Id.* A convex anchor head and concave seat perform the same function when incorporated into Blain as they do in Bray. *Id.* Consequently, a POSA easily could have made this modification and the results of doing so were entirely predictable. *Id.*

POSAs had a reasonable expectation of success in using an anchor head and seat, such as that in Bray, because such designs were standard screw seat designs for engaging with screw heads to allow the screw to affix the seat-containing component to whatever material the screw was designed to penetrate. *Id.* ¶189. A POSA would have a reasonable expectation of success in using such a seat or lip, because such designs had been successfully implemented in similar spinal fusion implants, as evidenced by Bray and Fraser. *Id.* The bone screw holes in Bray extend through the implant in the exact same way as in Blain, and it would have required minimal modifications to machine an anchor with a spherical head and a corresponding spherical anchor seat for the implant. *Id.* A POSA would recognize that minor dimension changes may be needed so that the anti-rotation mechanism operates using a concave lip or seat, although as previously explained it was also obvious to modify Blain to use Bray's restraining plate rather than the anti-rotation mechanism. *Id.*

A POSA would have also recognized that providing the benefit of pivotability

via a spherical anchor seat would require eliminating the threading of Blain's anchor channels and machining the channels with a slightly larger diameter than the shaft of the anchor, which would provide a certain degree of freedom for the screw shaft to pivot. *Id.* ¶190. While this could affect the effectiveness of Blain's "as is" anti-rotation locking feature, Ground 2 also proposes substituting Blain's anti-rotation mechanism with Bray's anti-backout restraining plate (as discussed with regards to Claims 1 and 11 in Ground 2 above), which does not require a threaded channel.

Claim 12

To the extent Spinelogik argues that Blain does not teach the limitations of claim 12, they would have been obvious based on the combination of Blain and Bray. As explained with respect to claims 1 and 11 in Ground 2, it would have been obvious to modify Blain to include the restraining plate of Bray as an alternative to Blain's anti-rotation mechanism. Because the restraining plate prevents the fasteners 6 of Blain from backing out of (or separating from) the fusion implant 2, the restraining plate *locks* each fastener 6 to the fusion implant 2. Ex. 1002 ¶191. Bray specifically teaches that the restraining plate 60 is fixed into place after the bone screws 50 have been "inserted into the bone screw holes 140 and the bone screw slot 180" and threaded to the vertebral bodies. Ex. 1006, 10:35–50. Thus, the *locking* occurs *once the anchoring member is fully advanced through the channel of the fusion member*. Ex. 1002 ¶191.

The Other Challenged Claims

Claims 2–4, 6, 15 and 17 are disclosed by Blain as discussed with respect to Ground 1. *See supra* Section VII.A. Consequently, those claims are also satisfied by Blain as modified by Bray.

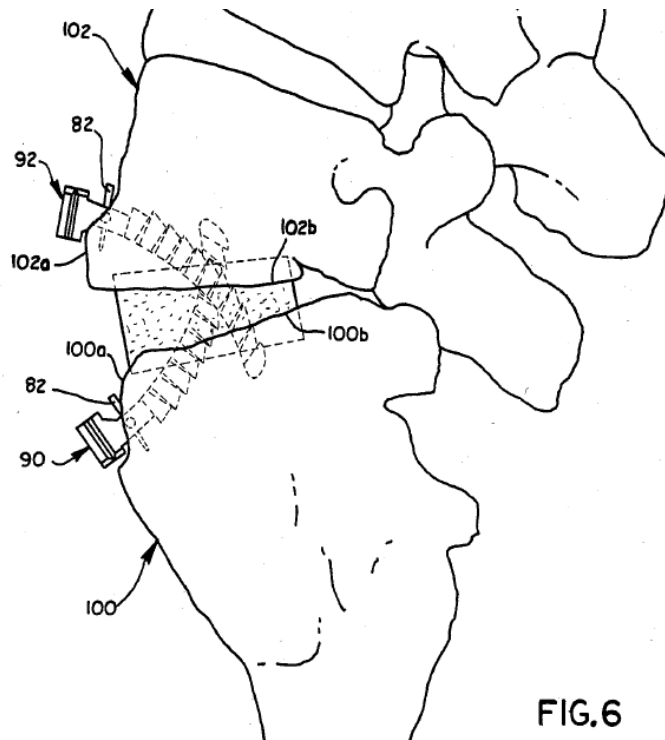
C. GROUND 3: BLAIN (WITH OR WITHOUT BRAY) AND STEFFEE RENDER OBVIOUS CLAIMS 5 AND 16.

This ground incorporates by reference the analysis discussed in Grounds 1 and 2 with respect to all challenged claims. To the extent *each channel ... is curved* is determined to require each channel to follow a curved path, it would have been obvious to use rigid curved anchors (as taught by Steffee) with Blain's implant to minimize post-surgery migration of the implant and anchors. Ex. 1002 ¶192. This modification would also entail modifying the implant's anchor channels to be curved to accommodate the shape of the curved anchors.

Steffee is analogous art. First, Steffee is from the same field of endeavor as the claimed invention, as Steffee relates to interbody fusion and anchors used for interbody fusion. Ex. 1002 ¶193; *Supra* Section VI.C.2. Second, Steffee is reasonably pertinent to the problems confronted by the inventor of the '805 Patent. Ex. 1002 ¶194. Steffee is focused on improving the reliability of fusion between vertebral bodies to avoid the considerable medical and economic impact of failed spinal fusions. *Id.* (citing Ex. 1001, 2:1-5). It was understood that one reason fusion implants fail was due to migration of the implant. *Id.* (citing Ex. 1033, 23:48-50; Ex.

1032, 4:61-64; Ex. 1034, 13:15-30; Ex. 1030, 1:31-39). It was also understood that one reason migration occurred was due to forces acting on the implant, including through its anchors or fasteners. *Id.* ¶195 (Ex. 1016, 1:11-20). Steffee uses a rigid curved anchor to address anchor migration caused by the forces resulting from bone graft resorption, because these anchors are not as susceptible to the same forces that affect straight anchors and cause sagittal and lateral movement. *Id.* ¶¶196-198 (citing Ex. 1016, 1:29-36). Steffee is thus reasonably pertinent to the problem facing the inventor—increasing the reliability and success rate of spinal fusion procedures—because it relates to minimizing the forces causing migration of spinal fusion implants, which was detrimental to the success of spinal fusion procedures. *Id.* ¶198.

A POSA would have found it obvious to modify Blain to incorporate Steffee's rigid curved anchors in order to prevent migration, which can cause an implant and its anchors to backout of the vertebral bodies. *Id.* ¶199. Steffee expressly teaches that migration results in bone graft staples coming out. *Id.* ¶200. In reference to Figure 6 of Steffee (below), Steffee mitigates migration by using a curved rigid anchor that traverses the vertebral body at an angle quasi-perpendicular to the angle upon which it entered the bone. For example, anchor 92 exits body 102 (adjacent 102b) at an angle quasi-perpendicular to the angle at which the anchor entered that body (adjacent 102a):



This inhibits lateral (or sagittal) migration ordinarily caused by side-to-side movement, because the path of the anchor is both non-linear and quasi-perpendicular to the forces that cause sagittal (or lateral) movement. *Id.*

While Steffee addresses migration relating to staples used to affix bone graft between vertebral bodies, migration was a well-known and understood problem with interbody implants with anchors as well. *Id.* ¶201 (citing Ex. 1034, 13:17–30; Ex. 1030, 1:31–39; Ex. 1032, 4:61–64; Ex. 1033, 23:48–50). A POSA would have readily recognized that, just as the curved anchor of Steffee inhibits migration that causes staples to come out, a curved anchor would provide the same benefit of inhibiting migration that causes straight implant anchors (like Bray's) to come out or loosen. *Id.* ¶¶201-202. In other words, POSAs understood that a non-linear anchor

would minimize the lateral forces acting on the anchor and the implant, thereby minimizing lateral movement (or migration) of the implant. *Id.* ¶202.

POSAs would have also recognized that having two curved fasteners that curve in non-identical directions (as taught by Steffee) would further resist migration. *Id.* ¶203. POSAs also understood that anchor screws could strip (e.g., due to over-torquing), but rigid barbed anchors such as those in Steffee do not have that risk. POSAs would thus have viewed curved barbed anchors as providing this additional advantage over threaded anchors. *Id.*

In addition to these motivations, Steffee even teaches that its curved fastener is “simple yet extremely effective” for interbody fusion. Ex. 1016, 2:29-33. This is an express teaching, motivation, or suggestion to use such anchors with interbody implants used for fusion, particularly given that the same or similar forces are present during interbody fusion regardless of whether an implant is used. Ex. 1002 ¶204.

POSAs recognized that the use of curved anchors was suitable for use with an implant device such as that shown in Blain. Indeed, the use of curved anchors with spinal implants was not novel. *Id.* ¶206 (citing Ex. 1035, 2:57–61; Ex. 1019, 7:14–25). POSAs further understood that the shape of the implant channels should match the shape of the anchor shaft to facilitate guiding the anchors into the vertebral bodies, as the curved anchors are rigid and cannot deform to conform to anchor channels that follow a straight path. *Id.* ¶205. POSAs were thus motivated to modify

Blain to rely on rigid curved anchors (as taught by Steffee), and to further modify Blain's guide tubes and channels to have curved shape that corresponds to the shape of the curved anchors.

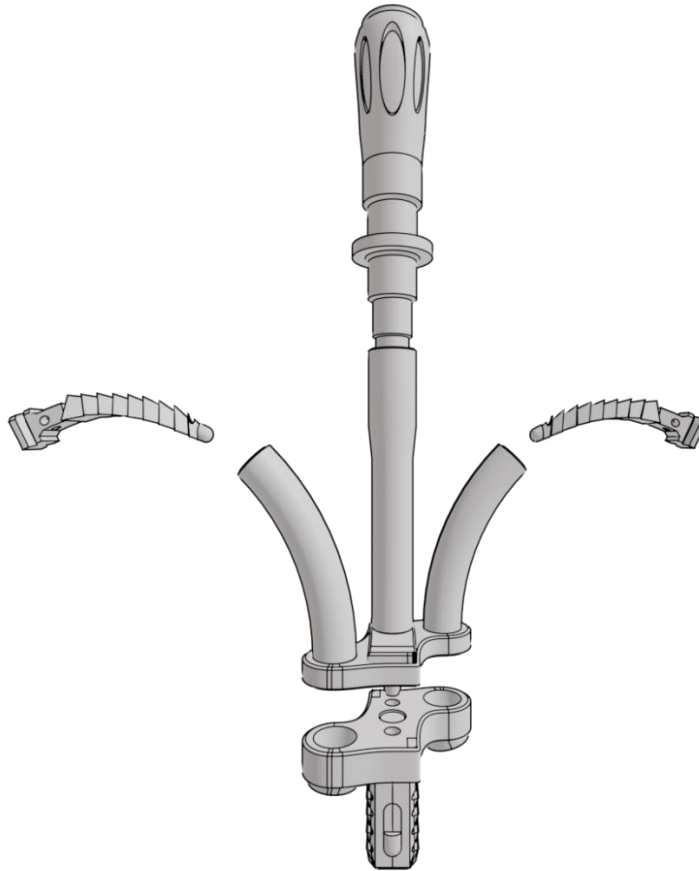
A POSA understood that modifying Blain to incorporate a curved anchor would have required simply replacing the anchoring screws 6 of Blain with curved barbed anchors similar to those of Steffee and modifying the fastener channels (of implant 2) and guide tube 18 channels (of guide instrument 14) to have shapes complementary to the curved anchors, such that the fastener channels are curved. *Id.* ¶206. In fact, Blain teaches that its guide tubes 18 “may have a tubular or trough-like configuration and may be linear or **non-linear**” and further that “non-linear guide members may facilitate access to difficult anatomical sites.” Ex. 1004, 8:8–16; Ex. 1005 ¶[0035]. Thus, Blain contemplates and suggests using guide tubes with curved channels, and POSAs understood that the anchor channels of the implant 2 and guide tubes 18 should be at least slightly curved to accommodate the curvature of the anchors. Ex. 1002 ¶206.

It was understood that curved channels would have been necessary to ensure that the rigid anchors did not become stuck or trapped when attempting to drive them through the screw/drill guides during surgery. *Id.* It was also understood that curved channels would also make it easier to drive the anchors to the desired location by

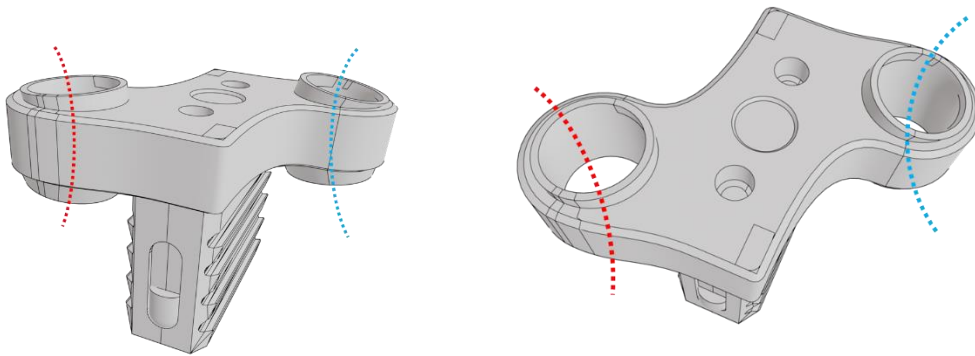
reducing the amount of friction between the anchors and inner-wall of the channels.

Id.

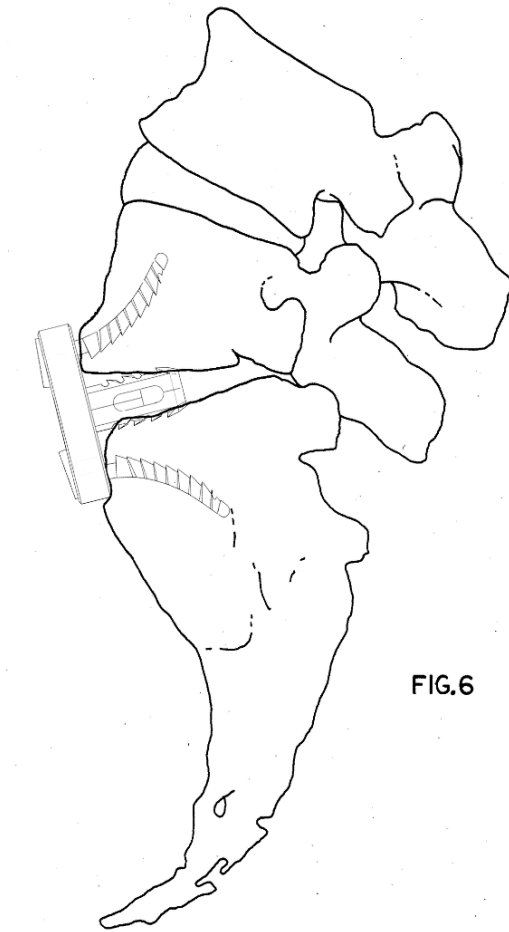
Petitioner provides figures below showing how simple it would be to modify Blain's implant and guide instrument:



The above figure depicts the instrument guide, implant, and fasteners of Blain as modified as proposed based on Steffee. *Id.* ¶207. The below figures depict the implant at various angles, and show that the anchor channels (red-dashed, blue dashed lines) are slightly curved to accommodate the shape of the curved anchor. *Id.*



A conceptual mock-up is also provided below based on Figure 6 of Steffee, to generally show how the Blain-Steffee implant would be situated between the vertebral bodies:



Id. ¶208. POSAs understood and found it obvious that, once these minor modifications are made, an impact driving tool (e.g., surgical hammer) would be used to drive the barbed anchors into their respective vertebral bodies as taught by Steffee. *Id.* ¶209 (citing Ex. 1016, 3:4–13). Blain itself teaches, “other [driving] tools are known in the art and may be used with the non-linear guide members.” Ex. 1004, 8:14–16. Impact driving tools for anchors were common, and hammers were a commonly used impact driving tool, as demonstrated by Steffee. Ex. 1002 ¶209 (citing Ex. 1036 ¶[0142]; Ex. 1004, 8:13-16).

A POSA would have had a reasonable expectation of success in making these proposed modifications, which would only entail modifying Blain’s anchors to be curved and barbed and modifying the contours of the guide tubes and fusion member channels to fit the concave surface of Steffee’s fasteners along the curved path taken by the fastener. *Id.* ¶210. This would require only the use of basic machining principles well known to a POSA. *Id.* In this obvious combination, the implant of Blain as modified by Steffee comprises channels that follow a curved path (like the “curved channels” discussed in the ’805 Patent) to accommodate the curved anchors.

VIII. THERE IS NO BASIS FOR DISCRETIONARY DENIAL

Petitioner stipulates that if the PTAB institutes this IPR petition, then Petitioner will not pursue in the co-pending district court proceeding (*Spinelogik, Inc. v. Globus Medical, Inc.*, No. 2-23-cv-00529) any grounds that were raised or

reasonably could have been raised in this IPR. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to §II.A).

IX. CONCLUSION

Globus respectfully requests that trial be instituted and claims 1–6, 11, 12 and 15–17 be cancelled.

Dated: November 21, 2024

Respectfully submitted,

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Stephen D. Zinda
Registration No. 67,272

APPENDIX: CHALLENGED CLAIM LISTING

Claim Element	Limitation
1.0	An apparatus comprising:
1.1	a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;
1.2.1	a delivery mechanism for delivering the fusion member between the two vertebral bodies,
1.2.2	the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,
1.2.3	the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and
1.3	a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent anchoring member for (i) traversing through a different channel of the fusion member, (ii) penetrating into one of the vertebral bodies, (iii) coupling the fusion member to the penetrated vertebral body, and (iv) preventing decoupling of the fusion member from the penetrated vertebral body.
2	The apparatus of claim 1, wherein the delivery mechanism comprises: a delivery housing for guiding each independent anchoring member into the fusion member; and a retention mechanism for fixedly coupling the delivery housing to the fusion member.

Claim Element	Limitation
3	The apparatus of claim 2, wherein the retention mechanism comprises at least one retention rod for coupling with the fusion member.
4	The apparatus of claim 2, wherein the coupling of the delivery housing to the fusion member causes each channel of the fusion member to be aligned with a different channel of the delivery mechanism.
5	The apparatus of claim 1, wherein each channel of the fusion member is curved.
6	The apparatus of claim 1, wherein traversing through the different channel of the fusion member comprises entering the different channel of the fusion member through a corresponding channel of the delivery mechanism.
11.0	A fusion device comprising:
11.1	a fusion member for positioning between two vertebral bodies, the fusion member having a first plurality of channels, each channel of the first plurality of channels having an opening on a same side of the fusion member;
11.2.1	a delivery mechanism for delivering the fusion member between the two vertebral bodies,
11.2.2	the delivery mechanism extending outside a patient's body to a medical practitioner while the delivery mechanism is coupled to the fusion member and the fusion member is positioned between the two vertebral bodies,
11.2.3	the delivery mechanism having a second plurality of channels, wherein each channel of the first plurality of channels is configured to be aligned with a different channel of the second plurality of channels when the delivery mechanism delivers the fusion member between the two vertebral bodies; and
11.3	a plurality of independent anchoring members configured to secure the fusion member to the vertebral bodies, each independent

Claim Element	Limitation
	anchoring member for (i) coupling the fusion member to the vertebral body, and (ii) preventing decoupling of the fusion member from the vertebral body.
12	The fusion device of claim 11, wherein preventing decoupling of the fusion member comprises locking each independent anchoring member to the fusion member once the anchoring member is fully advanced through the channel of the fusion member.
15	The fusion device of claim 11 further comprising a driving member configured to drive each independent anchoring member through the delivery mechanism.
16	The fusion device of claim 11, wherein each channel of the fusion member is curved.
17	The fusion device of claim 11, wherein each independent anchoring member is further for entering the different channel of the fusion member through a corresponding channel of the delivery mechanism in order to couple the fusion member to the penetrated vertebral body.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS

Pursuant to 37 C.F.R. § 42.24 *et seq.*, the undersigned certifies that this document complies with the type-volume limitations. This document, excluding those portions identified under § 42.24 (a)(1) (table of contents, table of authorities, mandatory notices under § 42.8, certificates of service and compliance with word count, appendix of exhibits, and claim listing) contains 13,990 words as calculated by the word processing program used in creating it.

/Stephen D. Zinda/

Stephen D. Zinda

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of November 2024, a copy of this Petition for Inter Partes Review and Exhibits 1001–1040 were served pursuant to Priority Mail Express (Next Day) on the following correspondence address of record with the United States Patent and Trademark for Patent Owner Spinelogik Inc.’s attorney/agent of record for the challenged patent:

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