No. 2019-1583

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

WARSAW ORTHOPEDIC INC.; MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK, INC.,

Plaintiffs-Appellants,

v.

RICK C. SASSO,

Defendant-Appellee.

On Appeal from the United States District Court for the Northern District of Indiana, No. 3:18-cv-437-JD-MGG, Judge Jon E. DeGuilio

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March 15, 2019

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CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Warsaw Orthopedic Inc.; Medtronic, Inc.; and Medtronic Sofamor Danek, Inc. certifies the following:

1. The full name of every party or *amicus* represented by me is:

Warsaw Orthopedic Inc.; Medtronic, Inc.; and Medtronic Sofamor Danek, Inc.

2. The name of the real party in interest represented by me is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Medtronic plc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not entered or will not enter an appearance in this case) are:

SOUTHBANK LEGAL: LADUE | CURRAN | KUEHN: Daniel J. VeNard, Paul E. Harold, Stephen M. Judge, Timothy M. Curran

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

Warsaw Orthopedic, Inc., et al. v. Sasso, No. 19A-PL-00378 (Ind. Ct. App.)

Warsaw Orthopedic, Inc., et al. v. Sasso, No. 50C01-1806-PL-000027 (Circuit Court of Marshall Cty., Ind.)

Dated: March 15, 2019

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STATEMENT OF RELATED CASES

No appeal from this action has previously been before this or any other appellate court.

Related litigation is currently pending before the Indiana Court of Appeals and may be affected by the Court's decision in this appeal. *Warsaw Orthopedic, Inc., et al. v. Sasso*, No. 19A-PL-00378 (appeal docketed Feb. 19, 2019). On March 13, 2019, Plaintiff-Appellee Dr. Rick Sasso filed a subsequent related complaint in Indiana state court demanding additional royalties beyond those awarded in the judgment currently before the Indiana Court of Appeals. Compl., *Sasso v. Warsaw Orthopedic, Inc., et al.*, No. 43D01-1903-PL-000020 (Ind. Cir. Ct., Kosciusko County).

Counsel for Plaintiffs-Appellants Medtronic, Inc.; Medtronic Sofamor Danek, Inc.; and Warsaw Orthopedic Inc. (together, "Medtronic"[1]) is unaware of any other case pending in this or any other appellate court that may directly affect or be directly affected by the Court's decision in this appeal.

[1] This brief uses "Medtronic" to refer interchangeably to Plaintiffs-Appellants Medtronic, Inc.; Medtronic Sofamor Danek, Inc.; and Warsaw Orthopedic Inc. and to Medtronic Sofamor Danek's predecessor, Sofamor Danek (previously Danek). The corporate distinctions among these entities are not relevant to the appeal.

INTRODUCTION

Medtronic filed this declaratory judgment action to obtain federal court resolution of a dispute that, though disguised as a breach of contract action, necessarily turns on substantial issues of federal patent law. Although the district court assumed—correctly—that it had exclusive jurisdiction over the case, it committed legal error in declining to exercise that jurisdiction. This Court should reverse that determination so that the parties' controversy can be resolved as Congress directed: in federal district court.

In 1999, Medtronic and Dr. Rick Sasso agreed that Medtronic would pay Dr. Sasso a 2.5% royalty on sales of specific, identified medical devices—Facet Screw Instrumentation and a Headless Facet Screw Fixation System—if those devices included Dr. Sasso's invention. As Dr. Sasso does not dispute, Medtronic has always paid that royalty on the facet screw devices mentioned in that contract (the "Agreement"). Nonetheless, Dr. Sasso sued Medtronic in Indiana state court, demanding royalties on other products not identified in the Agreement, on the theory that they were covered by certain patents that he had assigned to Medtronic as part of the Agreement. In effect, Dr. Sasso reconceptualized the Agreement to entitle him to royalties not just on the products that the Agreement identifies, but also on *any* products covered by the patents he had assigned.

Dr. Sasso's breach-of-contract claim cannot be decided without adjudicating the scope and validity of the asserted patent claims. The contract itself explicitly provides that it expires seven years after the first sale of the relevant device—which occurred in 2002—"if no patent application(s) issue into a patent having ***valid claim coverage*** of the Medical Device." Appx600.[2] Thus, if the patent claims on which Dr. Sasso relies are not valid or do not cover Medtronic products, there is no enforceable contract at all because it terminated in 2009. (Indeed, the Patent and Trademark Office has already held certain of the claims to be invalid.) And even if the contract were enforceable, and even if Dr. Sasso were correct that he could be entitled to royalties on products covered by the patents he assigned, there could be no breach—and no damages—unless the patent claims are valid and actually cover the products at issue.

Congress has directed that federal district courts and this Court have exclusive jurisdiction in cases "arising under" federal patent law. 28 U.S.C. §§ 1295(a)(1), 1338(a). The Supreme Court and this Court have recognized that, even if patent law does not create the cause of action, a case arises under patent law—and falls within the exclusive jurisdiction of the federal district courts and this Court—if "the plaintiff's right to relief necessarily depends on resolution of a

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[2] Emphases are added except where otherwise noted.

substantial question of federal patent law." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988); *see also, e.g.*, *Gunn v. Minton*, 568 U.S. 251, 256-258 (2013). And this Court has squarely held that a breach-of-contract case necessarily depends on resolution of a substantial question of patent law where—as here—it turns on the scope and validity of the relevant patents. *Jang v. Boston Sci. Corp.*, 767 F.3d 1334, 1336-1338 (Fed. Cir. 2014) (*Jang III*). Thus, faced with ongoing litigation in Indiana state court—and with the Indiana courts' refusal to recognize their lack of jurisdiction—Medtronic was left with no choice but to bring this declaratory judgment suit to resolve Dr. Sasso's claims in the only forum with jurisdiction to provide a resolution: a federal district court.

At the same time, the Indiana state court—over Medtronic's objection—proceeded to a trial that only confirmed the centrality of federal patent law issues to Dr. Sasso's claims. The state court held a *Markman* hearing, issued a claim construction order, and instructed the jury on the patent law. (In fact, patent issues were so central to Dr. Sasso's case that his counsel at one point threatened to move for a mistrial based on a single answer by one of Medtronic's experts regarding the interpretation of a phrase in a patent claim.) The state court ultimately entered judgment against Medtronic for over $112 million, more than $79 million of which rests explicitly on the 1999 Agreement. Medtronic has appealed that judgment to the Indiana Court of Appeals.

The district court here did not deny that Dr. Sasso's claims raised substantial patent issues within the federal courts' exclusive jurisdiction; on the contrary, it assumed that to be the case. Nonetheless, it refused to exercise its exclusive jurisdiction, dismissing the action under the doctrine of *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995), and *Brillhart v. Excess Insurance Co. of America*, 316 U.S. 491 (1942). Those decisions recognize that federal courts may abstain from exercising declaratory judgment jurisdiction where the issues at stake "can better be settled in [a] proceeding pending in … state court." *Brillhart*, 316 U.S. at 495; *see also Wilton*, 515 U.S. at 283 (reiterating *Brillhart*'s instruction for courts to consider "'whether the claims of all parties in interest can satisfactorily be adjudicated in [the state-court] proceeding'"). But the district court failed to account for the crucial fact that—by its own correct assumption—the issues in this action *cannot* be resolved by the Indiana courts, because those courts lack jurisdiction over claims raising substantial issues of patent law. Neither the district court nor Dr. Sasso has pointed to a single decision holding that federal district courts have free rein to decline the exercise of declaratory judgment jurisdiction, in favor of a parallel state-court proceeding, where the state court has no authority to decide the relevant issues because federal jurisdiction is exclusive.

The district court's core rationale for declining jurisdiction was that it cannot disturb the Indiana trial court's judgment against Medtronic. But that is legally

irrelevant for several reasons. First, if the federal courts have exclusive jurisdiction over this case—as Medtronic argues and as the district court correctly assumed—then the Indiana judgment was rendered without jurisdiction and is a nullity. Second, while Medtronic is challenging the Indiana judgment through the proper avenues of appeal, it should not have to wait until those appeals have been completed in order to have a court of competent jurisdiction resolve Dr. Sasso's claims. Medtronic brought this action to do just that. Third, a declaratory judgment in this case would address *all* claims Dr. Sasso might bring on the basis of the relevant patent claims and contract, not only those resolved by the state-court judgment. That difference is not hypothetical: Dr. Sasso has already filed a further complaint in state court demanding additional royalties beyond those awarded in the state-court judgment. *See supra* p. 1.

Although district courts have discretion to decline declaratory judgment jurisdiction, that discretion is not boundless, and it cannot be exercised for a legally erroneous reason. There was no legally sound basis for the district court's refusal to hear this case. To the contrary, this case lies in the heartland of the federal courts' exclusive jurisdiction over cases arising under the patent law, and the district court's failure to adjudicate it—if affirmed by this Court—would require Medtronic to wait years before having the opportunity to defend itself before any jurisdictionally proper court, contrary to Congress's clear directive. Because the

district court legally erred by refusing to hear this case, the dismissal should be reversed and the case remanded for the district court to address the merits.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1338(a) because this is a "civil action arising under any Act of Congress relating to patents." This Court has jurisdiction under 28 U.S.C. § 1295(a)(1) for the same reason. Jurisdiction is discussed more fully below (at 24-37).

This appeal is from a final judgment of dismissal entered by the district court on February 4, 2019 (Appx10) pursuant to an opinion and order dated January 31, 2019 (Appx1-9). Medtronic timely appealed on February 13, 2019. Appx2221.

STATEMENT OF ISSUE

Whether the district court erred by declining to exercise its exclusive jurisdiction and dismissing this action under the *Wilton-Brillhart* doctrine.

STATEMENT OF THE CASE

The following statement assumes the truth of the factual allegations in the Complaint (Appx17-37), as appropriate on appeal from the dismissal of an action. *See, e.g.*, *Mid-America Reg'l Bargaining Ass'n v. Will Cty. Carpenters Dist. Council*, 675 F.2d 881, 883 (7th Cir. 1982).

A. The Facet Screw Agreement

This case concerns a purchase agreement dated December 1, 1999, known as the Facet Screw Agreement (or "Agreement").

Under the Agreement, Dr. Sasso assigned to Medtronic all rights to an "Invention and the Intellectual Property Rights relating to the Medical Device," in exchange for 2.5% of the worldwide net sales of the "Medical Device." Appx598-599. The Agreement defines the "Invention," in turn, as "any product, method or system relating to a facet screw instrumentation and a headless facet screw fixation system as described in Schedule A," and "Medical Device" as "any device, article, system, apparatus or product including the Invention." Appx596-597. It is undisputed that Medtronic paid all royalties owed on the devices specifically mentioned in the Agreement.[3]

The Agreement defines "Intellectual Property Rights" as "any patent and/or patent application, improvement, modification, enhancement, any and all know-how and technology, and any other intellectual property right with respect to the

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[3] Schedule A describes a "Facet Screw Instrumentation and a Headless Facet Screw Fixation System consisting of bone screws and associated instruments for installation thereof." Appx604. The Agreement provides that the Medical Devices containing the Invention—in other words, the devices on which royalties were to be paid—were to "be listed … in Schedule B." Appx597. Schedule B lists "Facet Screw Instrumentation, and A Headless Facet Screw Fixation System." Appx605. Medtronic undisputedly paid all royalties owed on its facet screw instrumentation products (Appx52); the parties dispute whether Medtronic owes royalties on other products ***not*** listed in Schedules A or B.

Invention." Appx597. Consistent with the Agreement and its definition of "Intellectual Property Rights," Dr. Sasso assigned to Medtronic the patent application that eventually issued as U.S. Patent No. 6,287,313 ("the '313 patent") and to which U.S. Patent No. 6,562,046 ("the '046 patent") claims priority. Appx18; Appx24; *see also* Appx606-620 ('313 patent); Appx621-635 ('046 patent). Dr. Sasso interprets the Agreement to entitle him to royalties on not only the products specified in the Agreement but also *any* product covered by the patents he assigned to Medtronic.

The part of the Agreement that is most relevant to this appeal is the "Term of Agreement" provision, which states in relevant part: "Unless sooner terminated, this Agreement shall expire upon the last to expire of the patents included in Intellectual Property Rights, or ***if no patent application(s) issue into a patent having valid claim coverage of the Medical Device***, then seven (7) years from the Date of First Sale of the Medical Device." Appx600. The Agreement's provision requiring the payment of royalties to Dr. Sasso (Appx598-599) does not survive the termination of the Agreement. Appx602.

B. The State-Court Litigation

1. Initial complaint, removal, and remand of the Vertex Agreement claims

In August 2013, Dr. Sasso sued Medtronic in Indiana state court on breach-of-contract claims related to a *different* licensing agreement known as the Vertex Agreement.

Medtronic removed the action to the U.S. District Court for the Northern District of Indiana, on the ground that the federal court had exclusive jurisdiction under 28 U.S.C. § 1338(a), which provides that federal district courts "shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents" and that "[n]o State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents." Medtronic argued that Dr. Sasso's claims regarding the Vertex Agreement arose under the patent law because his claim for relief turned on whether certain Medtronic products were covered by certain patents. Appx847-848.

Dr. Sasso moved to remand the case to state court. Appx853-861. At the beginning of the hearing on that motion, the district court stated its tentative view that Seventh Circuit decisions had "held that the federal courts don't have subject matter jurisdiction over suits involving patent licensing agreements unless the validity of the patent is brought into question." Appx865. The court further expressed the view that *Gunn v. Minton*, 568 U.S. 251 (2013), did not require a

different result. Appx865-867. The court reasoned that "patent law [was not] necessarily raised by the complaint," that any issue of patent construction presented by Dr. Sasso's claims was "not substantial," and that "an exercise of federal jurisdiction over a suit filed in an Indiana court concerning a contract between Indiana citizens would disrupt the federal/state balance embodied in federal law." *Id.* After the hearing, the court issued an order remanding the case to state court "for the reasons stated in open court." Appx885; *Sasso v. Warsaw Orthopedic, Inc.*, No. 13-cv-1031 (N.D. Ind. Apr. 2, 2014).[4]

2. Dr. Sasso amends the state-court complaint to add claims concerning the '313 and '046 patents under the Facet Screw Agreement

Following remand, Dr. Sasso amended his complaint to add claims based on the patents assigned through the Facet Screw Agreement. Appx19; *see* Appx49-53; Appx62-63. Dr. Sasso asserted that the '313 and '046 patents have valid

[4] The district court's remand was unappealable. 28 U.S.C. § 1447(d). Medtronic disagrees with the district court's decision but does not contest it here, as only the Facet Screw Agreement (not the Vertex Agreement) is at issue in this case. *See* Appx20 n.1. On remand, however, Medtronic vigorously contested the Indiana state court's jurisdiction over the substantial questions of patent law raised by Dr. Sasso's claims regarding the Vertex Agreement. Those claims were nonetheless tried on the merits and are now the subject of an appeal in which Medtronic continues to dispute the state courts' jurisdiction. *See infra* pp. 13-14, 17-18.

claims that cover Medtronic products and that he was accordingly entitled to royalties on those products during the life of those patents. Appx19.[5]

After adding the Facet Screw Agreement claims, Dr. Sasso repeatedly confirmed what was already clear from the amended complaint: his claims turn on whether valid patent claims covered Medtronic's products. For example, in 2016, Dr. Sasso served interrogatory responses confirming his belief that he was entitled to additional royalties on his theory that the '313 and '046 patents included valid claims covering Medtronic products. In particular, his response to Interrogatory No. 5—requiring him to identify the products for which he claimed a right to royalties—stated: "My entitlement to royalties derive[s] from my Patent Nos. 5,287,313 and 6,542,046 … , the relevant coverage of which is described in my response to Interrogatory No. 30"—which, in turn, identified devices supposedly "covered by claim 26 of the '313 patent" and related claims. Appx762-763; Appx777-778.

[5] Because Medtronic's attempt to remove the Vertex Agreement claims based on patent issues had been unsuccessful, Medtronic did not attempt to remove the case after addition of the Facet Screw Agreement claims. Notably, this Court's decision in *Jang III*—which clarified the propriety of federal jurisdiction in this case, *see supra* p. 4—did not issue until after the 30-day deadline to remove the Facet Screw Agreement claims had passed. 28 U.S.C. § 1446(b)(3); *compare* Appx40-69 (amended complaint dated June 9, 2014), *with Jang III*, 767 F.3d 1334 (dated Sept. 16, 2014).

Dr. Sasso's expert disclosures further confirmed the centrality of federal patent law to his claims. For instance, Dr. Sasso proffered an expert, Dr. T. Keith Parnell, to testify regarding "coverage of the '046 patent" and "coverage of the '313 patent," while another expert, Irving Rappaport, would testify that "independent claims 9 and 25 of [the '046 patent] cover … products sold by Medtronic" and that "independent claim 26 and dependent claim 34 of [the '313 patent] cover[] many different products and instruments and methods." Appx1103.

The interrogatory responses and expert disclosures confirmed that Dr. Sasso intended to litigate a patent case. Medtronic therefore moved to dismiss the state-court action for lack of jurisdiction. It explained that the interrogatory responses showed Dr. Sasso's Facet Screw Agreement claims turned on the scope and validity of the '313 and '046 patents, and thus arose under patent law, which rendered them subject to exclusive federal jurisdiction under 28 U.S.C. § 1338(a). Appx962-984. Medtronic relied on this Court's intervening decision in *Jang III*, which had not been issued at the time of the district court's remand of the Vertex Agreement claims or, indeed, when the deadline to remove Dr. Sasso's new Facet Screw Agreement claims expired. *See supra* p. 12 n.5. The state trial court denied the motion in January 2017, ruling that "an analysis of the current patent issues results in the same decision as that made by [the federal district court] in 2013," even though the federal district court had never previously examined whether Dr.

Sasso's Facet Screw Agreement claims (as opposed to his Vertex Agreement claims) arose under federal patent law and did not have the benefit of *Jang III*. Appx1289-1290. Recognizing the importance of the question, the trial court certified its decision for interlocutory review by the Indiana Court of Appeals, but that court declined to accept jurisdiction. Appx1602.

3. Pretrial litigation regarding construction of the '313 and '046 patent claims

Throughout the litigation—and emboldened by the trial court's denial of Medtronic's motion to dismiss—Dr. Sasso continued advancing his argument that he was entitled to additional royalties because the '313 and '046 patents covered certain Medtronic products. He litigated the state-court action precisely as one would litigate a patent case in federal court.

For example, Dr. Sasso sought extensive discovery regarding claim coverage, including a Rule 30(b)(6) deposition of Medtronic that was almost entirely devoted to claim coverage. *See* Appx785-799 (deposition notice); Appx792 (inquiring whether a certain surgical technique "is or is not covered by claims 9-32 of [the '046 patent] … and/or claims 17-25 of [the '313 patent]"); *id.* (inquiring whether a certain surgical technique "is or is not covered by claims 9-32 of [the '046 patent]"). Dr. Sasso's expert reports, moreover, offered detailed opinions on claim coverage. *See* Appx639-716 (report of Dr. Parnell, offering

extensive claim interpretations and charts examining how "various products across Medtronic's product line" correspond with the '313 and '046 patents).

The state trial court likewise treated the litigation as a patent case. It acknowledged that the parties "dispute[d] the interpretation of certain terms in" the '313 and '046 patents, conducted a *Markman* hearing, and issued a claim construction order construing the scope of claims in both the '313 and '046 patents. Appx1878-1880. Throughout the state court proceedings, Medtronic repeatedly renewed its objection that the state court lacked jurisdiction over Dr. Sasso's claims.

C. Patent Office Proceedings

In March and May 2018, Dr. Sasso's expert disclosed claim interpretations in the state-court litigation specifying how he believed the '313 and '046 patents should be construed to cover certain Medtronic products. Appx639-716. Shortly thereafter, Medtronic filed requests for ex parte reexaminations of some of the claims of the '313 and '046 patents. Appx328-429 ('313 patent); Appx430-585 ('046 patent).

In late November 2018—shortly before the conclusion of the state-court trial—the Patent Office issued notices of intent to issue reexamination certificates canceling the challenged claims of both patents. Notice of Intent to Issue Ex Parte Reexamination Certificate, No. 90/014,131 (Nov. 26, 2018) (claims 26-34 of the

'313 patent); Notice of Intent to Issue Ex Parte Reexamination Certificate, No. 90/014,171 (Nov. 20, 2018) (claims 9 and 11-32 of the '046 patent). The Patent Office then issued reexamination certificates canceling the challenged claims. Reexamination Certificate, No. 90/014,131 (issued Jan. 4, 2019); Reexamination Certificate, No. 90/014,171 (issued Jan. 24, 2019).[6] Other claims of the '313 and '046 patents were not challenged during the reexaminations and currently remain in force.

D. This Declaratory Judgment Action

In June 2018, shortly after receiving Dr. Sasso's broad claim constructions in the state-court litigation, Medtronic filed this declaratory judgment action in the district court. Appx17-37. Medtronic's complaint explained that "[a] substantial sum of money may hinge on the answer to [a] question of patent law" over which the federal courts have exclusive jurisdiction—namely whether the '313 and '046 patents "contain any valid claim that covers any of Medtronic's products." Appx18. Medtronic sought a declaratory judgment that it did not breach the Facet Screw Agreement for two reasons: (1) no valid claim of the '313 and '046 patents

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[6] These filings are available at the U.S. Patent & Trademark Office's Public Patent Application Information Retrieval website, https://portal.uspto.gov/pair/PublicPair, and are judicially noticeable in this appeal. *See, e.g.*, *Old Reliable Wholesale, Inc. v. Cornell Corp.*, 635 F.3d 539, 549 (Fed. Cir. 2011) ("[T]his court can take judicial notice of the fact that the PTO, after assessing the relevant prior art, issued a notice of intent to issue a reexamination certificate confirming the patentability of all claims of the '950 patent.").

covers the products for which Dr. Sasso sought royalties and (2) to cover any of the products for which Dr. Sasso sought royalties, the claims must be construed so broadly as to render them invalid. Appx30-32. The complaint explained that "[a]n actual dispute exists" because Dr. Sasso and Medtronic disagree on the answers to those questions. Appx18. And it asserted that, because the federal courts have exclusive jurisdiction to answer the questions, "it would be an abuse of discretion to decline jurisdiction." Appx22.

In August 2018, three months before the state-court trial, Dr. Sasso filed a motion asking that the district court abstain from hearing Medtronic's claims or stay the proceedings until the completion of the state-court action. Appx806-836. Dr. Sasso did not invoke the *Wilton-Brillhart* doctrine. He relied only on the doctrines of *Colorado River Water Conservation District v. United States*, 424 U.S. 800 (1976); *Rooker v. Fidelity Trust Co.*, 263 U.S. 413 (1923); and *District of Columbia Court of Appeals v. Feldman*, 460 U.S. 462 (1983).

Briefing on Dr. Sasso's motion was complete by the end of August 2018 (Appx1834-1848), with two months left before the state-court trial, but the district court did not rule on the motion or otherwise act on the complaint.

E. The State-Court Trial, Verdict, And Appeal

In November 2018, the Indiana trial court held a four-week jury trial. From the beginning of the trial—indeed, in his opening statement—Dr. Sasso made clear

that claim coverage was critical to his case. *See* Appx1947 ("the system that was developed" based on the Facet Screw Agreement included "five things" that "are the elements of" claim 26 of the '313 patent). To support his claim-coverage arguments, Dr. Sasso presented testimony from two experts on issues of patent law, including Dr. Parnell, whose entire testimony related to patent claim coverage. *See* Appx2059 (Q.: "Dr. Parnell, if a doctor uses all of these five elements, would that be covered by the claim 26 of the '313 patent?" A.: "Yes, it would."); *see also* Appx1972-2052 (testimony of Irving Rappaport). And Dr. Sasso himself testified that the invention he assigned to Medtronic under the Facet Screw Agreement was covered by claim 26 of the '313 patent, which he characterized as "really really broad." *See* Appx2125; Appx2128. The trial ended with detailed jury instructions regarding patent law, patent claim coverage, and the court's construction of terms in the '313 patent claims. Appx2141-2145.

As relevant here, the jury found that Medtronic breached the Facet Screw Agreement and awarded $79,794,721 in damages; it separately awarded $32,657,548 in damages for breach of the Vertex Agreement, which has never been part of this federal action and is not at issue in this appeal. Appx1911-1912; Appx1916-1917. The trial court entered judgment against Medtronic for over $112 million. Appx1917. Medtronic has appealed that judgment to the Indiana Court of Appeals.

F. Decision Below

After the conclusion of the state-court trial, Dr. Sasso asked the district court for leave to submit supplemental briefing on the effect of the state-court judgment. Appx1906-1909. The next day, the district court granted the request for supplemental briefing and—sua sponte—ordered the parties to "address the effect, if any, of the fact that this is a declaratory judgment action, and that the Declaratory Judgment Act grants courts discretion over whether to grant declaratory relief" under the *Wilton-Brillhart* doctrine, a doctrine Dr. Sasso had not invoked. Appx1918.

After receiving the supplemental briefing, the district court dismissed this action under the *Wilton-Brillhart* doctrine. Appx1-9. The court recognized that the 2014 decision to remand Dr. Sasso's Vertex Agreement claims to state court was "not res judicata as to whether [federal] jurisdiction exists in this case," both because "an unappealable ruling is not res judicata" and because "Medtronic's claim in this case addresses only the Facet Screw Agreement, which was not [at the time of the remand] at issue in that case." Appx1 n.2. The court then explained it would "assum[e] but not decid[e]" that Medtronic's complaint raised patent issues subject to exclusive federal jurisdiction. Appx3-4. It nonetheless concluded that, even on that assumption, "dismissal is appropriate under *Wilton* and *Brillhart*." Appx3.

The court ruled that "there is no purpose to be served by the declaratory judgment Medtronic seeks, at least at this time." Appx5. The court did not deny that there remains an actual controversy between Medtronic and Dr. Sasso on the question whether Medtronic breached the Facet Screw Agreement and owed Dr. Sasso royalties, nor did it deny that that controversy arises under the patent law. Instead, it declined to hear the case because the Indiana court "has already entered judgment in Dr. Sasso's favor on that claim," and "[n]o order or judgment of [a federal district court] can undo that judgment." *Id.* For the same reason, the court opined, "Medtronic would not stand to benefit from the declaratory judgment it seeks." *Id.*

The court rejected Medtronic's "argument that a court has no authority to abstain from hearing a claim that is within its exclusive jurisdiction." Appx6-8. In a footnote, the court recognized that "[t]he existence of exclusive federal jurisdiction can still be a relevant factor to consider in deciding whether to exercise that jurisdiction," but it opined that that factor would not affect its conclusion, on the theory that "a declaratory judgment here" would serve no "legitimate purpose." Appx7 n.5.

SUMMARY OF ARGUMENT

I. Because jurisdictional issues are central to this case, Medtronic begins by addressing this Court's appellate jurisdiction. Since this case falls within the

exclusive original jurisdiction of the district court, Medtronic's appeal is within this Court's exclusive appellate jurisdiction under 28 U.S.C. § 1295(a)(1). Cases "aris[e] under" the patent laws, and thus fall within exclusive federal jurisdiction, not only where a patent statute supplies the cause of action, but also where an issue of patent law is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013). All four factors are present here.

First, this case necessarily raises patent-law issues, because it turns on the scope and validity of certain patent claims. If the claims in question are invalid (as the Patent Office has already held as to certain claims), or if they do not cover Medtronic products, then the contract—by its express terms—has expired. And even if it had not, and even if Dr. Sasso were correct that it entitles him to royalties for products covered by the relevant patent claims, there would be no breach or damages if the patent claims are invalid or do not cover the products at issue.

Second, the patent-law issues raised by this case are manifestly disputed. Indeed, they were the subject of a trial in Indiana state court, though they should not have been.

Third, the issues are "substantial" within the meaning of *Gunn*, in that allowing the state courts to adjudicate them would undermine the uniformity of

patent law by creating the risk of inconsistent judgments as to the scope and validity of the relevant patent claims.

Fourth, resolution of this case in the federal courts would not disrupt the allocation of judicial responsibilities between the federal and state courts. To the contrary, adjudicating the scope and validity of patent claims is a core function of the federal district courts and, of course, this Court.

II. The district court committed legal error, thus abusing its discretion, by refusing to exercise its exclusive jurisdiction to decide this case. *Wilton* and *Brillhart*, on which the court relied, do not remotely suggest that the pendency before a state court of issues within the exclusive jurisdiction of the federal courts—that is, issues over which the state courts lack jurisdiction—is a basis for a federal court to decline to exercise its declaratory judgment jurisdiction. To the contrary, Congress's judgment that "[n]o state court shall have jurisdiction over" the issues at stake (28 U.S.C. § 1338(a)) weighs heavily in favor of ***exercising*** jurisdiction.

Several district courts have explicitly declined to abstain under *Wilton* and *Brillhart* when faced with declaratory judgment suits (like this one) that present questions within the exclusive jurisdiction of the federal courts. And neither the district court nor Dr. Sasso has identified any decision—before the district court's

ruling in this case—that abstained under *Wilton/Brillhart* in favor of a parallel state court proceeding involving issues subject to exclusive federal jurisdiction.

The district court committed several errors of law in declining to exercise declaratory judgment jurisdiction, and those errors of law necessarily constitute an abuse of discretion. The court misinterpreted Medtronic's authorities as addressing the *Colorado River* abstention doctrine, when in fact they squarely address the *Wilton-Brillhart* doctrine. Rather than addressing Medtronic's authorities, the district court instead relied on cases that did not involve parallel state-court proceedings or exclusive federal jurisdiction—most of which, at any rate, did not approve a district court's decision to decline jurisdiction. Indeed, the court cited two decisions of this Court that support Medtronic's position, by recognizing that district courts must have a "sound basis" to refuse to decide controversies within their jurisdiction. *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1357-1358 (Fed. Cir. 2004); *see also Teva Pharms. USA, Inc. v. EISAI Co.*, 620 F.3d 1341, 1349 (Fed. Cir. 2010), *vacated as moot*, 564 U.S. 1001 (2011).

The district court refused to decide this case on the ground that it could not disturb the state-court judgment against Medtronic. But the court failed to recognize that, under its own (correct) assumption that it possessed exclusive federal jurisdiction, the state-court judgment was rendered without authority and has no legal effect. And it failed to recognize that the purpose of this action is for

Medtronic to seek a resolution of the parties' merits dispute in the ***only*** forum with jurisdiction to decide it. There is no basis for the district court's apparent view that Medtronic should have to wait years—until the conclusion of all appellate review of the state-court judgment—before it can obtain resolution of the federal controversy between the parties in the forum Congress intended would hear it: a federal district court.

STANDARD OF REVIEW

The district court's application of the *Wilton-Brillhart* doctrine is reviewed for abuse of discretion. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 288-289 (1995). "A district court abuses its discretion when its decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." *iLOR, LLC v. Google, Inc.*, 631 F.3d 1372, 1376 (Fed. Cir. 2011) (internal quotation marks omitted).

ARGUMENT

I. THIS COURT HAS APPELLATE JURISDICTION BECAUSE THIS IS A PATENT CASE WITHIN THE EXCLUSIVE JURISDICTION OF THE FEDERAL COURTS

Although this Court docketed this appeal on February 25, Dr. Sasso has not challenged this Court's appellate jurisdiction. *See* Fed. Cir. R. 27(f) (a motion to dismiss for lack of jurisdiction "should be made as soon after docketing as the grounds for the motion are known"). But because this Court has an independent

obligation to evaluate its own appellate jurisdiction, Medtronic addresses this issue affirmatively.

Cases fall within the exclusive original jurisdiction of the district courts, and within the exclusive appellate jurisdiction of this Court, when they "***aris[e] under … any Act of Congress relating to patents***." 28 U.S.C. § 1295(a)(1) (this Court's jurisdiction); *see* 28 U.S.C. § 1338(a) (district courts' jurisdiction). The Supreme Court has held that cases "aris[e] under" the patent laws not only where a patent statute supplies the cause of action, but also where an issue of patent law is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013). Although *Gunn* interpreted district court jurisdiction under 28 U.S.C. § 1338(a), this Court has applied the same analysis to the determination of its own jurisdiction under § 1295(a)(1), which uses similar phrasing. *See, e.g.*, *Jang v. Boston Sci. Corp.*, 767 F.3d 1334, 1336 (Fed. Cir. 2014) (*Jang III*).

Under the *Gunn* standard, as applied by this Court in *Jang* and other cases, the district court possessed exclusive jurisdiction to resolve the issues of patent law presented by this case. For the same reason, this Court has appellate jurisdiction to review the district court's erroneous decision dismissing the case.

A. This Case Necessarily Raises Patent-Law Issues

To evaluate jurisdiction in declaratory judgment suits, courts generally "look[] to the 'mirror image' suit the declaratory defendant might bring if and when it seeks coercive relief." *AbbVie Inc. v. MedImmune Ltd.*, 881 F.3d 1334, 1336 (Fed. Cir. 2018). Here, the "mirror-image" suit is not hypothetical; the claims that Dr. Sasso actually brought make clear that this case necessarily raises issues of patent law.

Dr. Sasso's state-court action seeks to hold Medtronic liable for allegedly breaching the Facet Screw Agreement. Appx174-175. The Agreement is governed by Tennessee law. Appx601. To establish breach of contract under Tennessee law, "claimants must prove [1] the existence of a valid and enforceable contract, [2] a deficiency in the performance amounting to a breach, and [3] damages caused by the breach." *Federal Ins. Co. v. Winters*, 354 S.W.3d 287, 291 (Tenn. 2011). Dr. Sasso cannot make it past the first element without resolution of substantial issues of patent law.

The first element of breach of contract—whether the Facet Screw Agreement is in force or has expired—depends on whether the '313 and '046 patents contain valid patent claims that cover Medtronic devices. As explained above, the Agreement's term provision states that, "[u]nless sooner terminated, this Agreement shall expire upon the last to expire of the patents included in

Intellectual Property Rights, or ***if no patent application(s) issue into a patent having valid claim coverage of the Medical Device***, then seven (7) years from the Date of First Sale of the Medical Device." Appx600. The first sales of the Medical Device occurred in 2002 (Appx166), so by its express terms, the Agreement terminated in 2009 unless the '313 or '046 patents have "valid claim coverage of the Medical Device" (Appx600).

Dr. Sasso's breach-of-contract theory also depends on the resolution of additional questions of patent law. Dr. Sasso relied on the Agreement's reference to "Intellectual Property Rights," defined to include "any patent and/or patent application … with respect to the Invention" (Appx597), to argue that Medtronic owes royalties not just on the facet instrumentation products expressly included in the contractual definitions of "Medical Device" and "Invention"—royalties Medtronic has undisputedly paid (Appx52)—but also on products he contends are covered by claim 26 of the '313 patent. Those products, according to Dr. Sasso, are included in the "Invention" by virtue of their coverage by the patents. *See, e.g.*, Appx164-167; Appx2184 ("Claim 26 of the '313 patent demonstrates what 'the Invention' is." (emphasis omitted)). Under that theory, the breach and damages elements of his claim turn on the scope and coverage of claim 26 of the '313 patent.

Breach-of-contract claims present patent law issues when they raise questions regarding the validity or construction of patent claims—both of which are present here. As the Supreme Court has held, a case falls within exclusive federal jurisdiction if "a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988).

This Court and other courts have repeatedly held that the patent law is a "necessary element" of a claim in cases involving royalty agreements that turn on a patent's validity or coverage. This Court's decision in *Jang III* is on point: the inventor of two medical device patents assigned the patents to Boston Scientific in exchange for a one-time $50 million payment and ongoing royalties based on any sale of medical devices covered by the assigned patents. *Jang v. Boston Sci. Corp.*, 532 F.3d 1330, 1332 (Fed. Cir. 2008). After Boston Scientific failed to make royalty payments, the inventor sued in federal court, alleging that Boston Scientific breached the contract by selling medical devices "covered by either or both of the … patents" without paying royalties. *Id*. After the district court denied summary judgment, Boston Scientific appealed to this Court rather than the Ninth Circuit. *Jang III*, 767 F.3d at 1335. This Court held that the suit necessarily raised patent

issues because the inventor's "right to relief on the contract claim as asserted in the complaint depend[ed] on an issue of federal patent law—whether the stents sold by [Boston Scientific] would have infringed [the inventor's] patents." *Id*. at 1336 (internal quotation marks omitted). That issue was "substantial and neither entirely backward-looking nor hypothetical," the Court concluded. *Id.* at 1337. The Court further explained that, when the "resolution of [a] contract claim … requires resolution of underlying issues of infringement," including the scope and validity of the relevant patents, "there exists the possibility that" those issues could arise in subsequent infringement litigation and could create divergent judgments unless this Court maintains appellate jurisdiction "to avoid such conflicting rulings." *Id.* at 1337-1338.

Additional precedents of this Court, which predate *Gunn* but are consistent with it, confirm *Jang*'s holding. For example, in *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999), the Court held that federal jurisdiction was proper where a state-law claim that the defendants had "committed an injurious falsehood" turned on whether patent claims were invalid or unenforceable. *Id.* at 1329. In *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc.*, 986 F.2d 476 (Fed. Cir. 1993), the Court likewise held that federal jurisdiction was proper where a state-

law business disparagement claim turned on whether a given patent was infringed. *Id.* at 478.

Other circuits have reached similar conclusions. For example, in *U.S. Valves, Inc. v. Dray*, 190 F.3d 811 (7th Cir. 1999), the Seventh Circuit held—on facts quite similar to those here—that a breach-of-contract claim necessarily raised an issue of patent law where the existence of a breach "depend[ed] on whether [the defendant] sold valves which infringed on the licensed patents," and "[t]he only way to tell whether a valve [was] covered by the licensed patents [was] to apply substantive patent law." *Id.* at 814. It therefore transferred the appeal to this Court. *Id.* The Fifth Circuit did the same in *Scherbatskoy v. Halliburton Co.*, 125 F.3d 288 (5th Cir. 1997), holding on equally comparable facts that a breach-of-contract claim arose under patent law where it turned on whether one party infringed the other's patents. *Id.* at 291-292.

Likewise, in *Alexsam, Inc. v. WildCard Systems, Inc.*, 2015 WL 13688558 (S.D. Fla. Nov. 20, 2015)—another breach-of-contract case—the contract provided that it "remain[ed] in full force and effect for the life of the Licensed Patent" or until "the claims of the Licensed Patents are held invalid or unenforceable by a court of competent jurisdiction." *Id.* at *1. The district court held that, because the relevant counterclaim and defenses "require[d] the Court to determine whether the Licensed Patents are valid" and "to apply patent claim terms to the accused

services to determine if they are subject to the [contract]," the case necessarily raised federal patent issues under *Gunn*. *Id*. at *7. The Eleventh Circuit transferred the appeal to this Court, likewise finding that the case arose under patent law. Appx1903-1905. This Court summarily affirmed, and the Supreme Court denied certiorari. *Alexsam, Inc. v. WildCard Sys., Inc.*, 708 F. App'x 680 (Fed. Cir. 2018) (Rule 36 judgment), *cert. denied*, 139 S. Ct. 320 (2018).

In short, Dr. Sasso's state-court claims regarding the Facet Screw Agreement—and thus the mirror-image claims for declaratory relief that Medtronic brought in this case—turn on issues of patent law, namely the scope and validity of the relevant claims of the '313 and '046 patents and whether they cover any Medtronic products. As a result, "patent law is a necessary element" of Dr. Sasso's claims regarding the Facet Screw Agreement. *Christianson*, 486 U.S. at 809.

B. The Patent-Law Issues Raised By This Case Are Disputed

The issues of patent law raised by this case are "actually disputed," *Gunn*, 568 U.S. at 259—indeed they were so central to the state-court jury trial that Dr. Sasso's counsel threatened at one point to move for a mistrial based on a single answer by one of Medtronic's experts regarding the interpretation of a phrase in claim 26 of the '313 patent. Appx2133. Dr. Sasso contends that the '313 and '046 patents are valid and cover products on which he claims Medtronic failed to pay

royalties. *E.g.*, Appx166-167 (complaint in state-court litigation); Appx2184 (Dr. Sasso stated in post-trial briefing that "'[he] needed to prove and did prove the nature of 'the Invention,'" demonstrated by "'[c]laim 26 of the '313 patent'" (emphasis omitted)). Medtronic seeks a declaratory judgment to the contrary, because it believes that the relevant products are not covered by the patents and, moreover, that any claims that Dr. Sasso alleges cover Medtronic's products are not valid under Dr. Sasso's construction. Appx30-32.

C. The Patent-Law Issues Raised By This Case Are Substantial

The issues of patent law raised by this case are also "substantial" within the meaning of *Gunn*, 568 U.S. at 258.

The substantiality inquiry focuses not on the significance of an issue of patent law "to the particular parties in the immediate suit," *Gunn*, 568 U.S. at 260, but rather "on the broader significance of the federal issue," *Vermont v. MPHJ Technology Investments, LLC*, 803 F.3d 635, 646 (Fed. Cir. 2015). The relevant question is "whether allowing state courts to resolve [the case] undermines the development of a uniform body of patent law." *Id*. (internal quotation marks and alteration omitted). That analysis reflects that "[o]ne of the fundamental purposes behind the Patent and Copyright Clauses of the Constitution was to promote national uniformity in the realm of intellectual property"—which is why, "since the Patent Act of 1800, Congress has lodged exclusive jurisdiction of actions

'arising under' the patent laws in the federal courts" and why it has more recently "conferred exclusive jurisdiction of all patent appeals" on this Court. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989).

This Court has recognized that issues of patent law are significant within the meaning of *Gunn* when allowing state courts to adjudicate them "could result in inconsistent judgments between state and federal courts," *Forrester Envtl. Servs., Inc. v. Wheelabrator Techs., Inc.*, 715 F.3d 1329, 1334 (Fed. Cir. 2013), or when allowing regional courts of appeals to adjudicate them "could result in inconsistent judgments between a regional circuit and the Federal Circuit," *Jang III*, 767 F.3d at 1338. In *Jang*, for example, the Court explained that the adjudication of a state-law contract claim required "resolution of underlying issues of infringement," and therefore that if the patentee were to "file suits alleging infringement by others," there might well be "conflicting rulings particularly as to validity." *Jang III*, 767 F.3d at 1337-1338. That would create a risk of "serious uncertainty for parties facing similar infringement charges." *Id.* at 1338. "[A]void[ing] such conflicting rulings," the Court explained, "is important to 'the federal system as a whole' and not merely 'to the particular parties in the immediate suit.'" *Id.*; *see also Hunter Douglas*, 153 F.3d at 1330 (holding, before *Gunn*, that issues of "infringement," "validity," and "enforceability," among others, were sufficiently substantial under *Christianson* to support federal jurisdiction).

That holding is controlling here. As in *Jang*, Dr. Sasso's breach-of-contract claim concerning the Facet Screw Agreement requires determining both the validity and the construction of the relevant patent claims to resolve whether they cover the products for which Dr. Sasso seeks royalties. Allowing the Indiana courts to determine those issues creates a serious risk of inconsistency with determinations that might be rendered by a federal court—and heard on appeal by this Court—in litigation concerning the same patents.

Jang also explains why it is irrelevant to this jurisdictional analysis that, after this action was filed, the PTO canceled certain claims of the '313 and '046 patents. Exactly the same thing had happened in *Jang*, but the Court rejected the argument that the substantial patent issues were somehow rendered insubstantial by that development. 767 F.3d at 1338. Federal subject-matter jurisdiction, the Court explained, "is predicated on the cause of action and the basis of the facts as they existed at the time the complaint or any compulsory counterclaim was filed." *Id.* What matters, therefore, is "whether the four-part *Gunn* test is met on the basis of the cause of action pled and the facts as they existed at the time the complaint or any compulsory counterclaim is filed." *Id.* Here, as in *Jang*, the PTO's cancellation of certain claims occurred well after Medtronic brought this action, and it is therefore irrelevant to the question of federal jurisdiction.

Even if the cancellation of certain claims were relevant to the jurisdictional analysis, moreover, the viability of Dr. Sasso's claim for breach of the Facet Screw Agreement depends on whether *any* valid patent claim covers Medtronic products. *See* Appx18 (Complaint) (defining the dispositive question in this case as whether "two patents assigned by Dr. Sasso to Medtronic …. contain *any* valid claim that covers any of Medtronic's products"); Appx600 (Facet Screw Agreement) (Agreement has expired "if no patent application(s) issue into a patent having valid claim coverage of the Medical Device"). Prior to trial in the state-court litigation, Dr. Sasso focused on the scope of several claims that he ultimately did not address at trial. *See, e.g.*, Appx785-799 (deposition notice); Appx792 (inquiring whether a certain surgical technique "is or is not covered by claims 9-32 of [the '046 patent] … and/or claims 17-25 of [the '313 patent]"); *id*. (inquiring whether a certain surgical technique "is or is not covered by claims 9-32 of [the '046 patent]"). Dr. Sasso's strategic decision at the state-court trial to narrow his evidence to a limited set of claims does not change the fact that the viability of his cause of action for breach depends on claims that the PTO has *not* deemed unpatentable.

D. Federal Court Resolution Of The Patent-Law Issues Raised By This Case Would Not Disrupt The Federal-State Balance

The final *Gunn* factor "is concerned with the appropriate 'balance of federal and state judicial responsibilities.'" *Gunn*, 568 U.S. at 264. In *Gunn*, the Supreme

Court held that the issue presented by that case—legal malpractice—was properly left for the state courts to resolve, given the states' "'special responsibility for maintaining standards among members of the licensed professions.'" *Id*. The Court found "no reason to suppose that Congress—in establishing exclusive federal jurisdiction over patent cases—meant to bar from state courts state legal malpractice claims simply because they require resolution of a hypothetical patent issue." *Id.*

Here, by contrast, the federal patent issues are not hypothetical; as previously discussed, they are real and substantial. And unlike in *Gunn*, they fall within the heartland of those issues Congress reserved to the exclusive jurisdiction of federal courts: questions of claim construction, claim coverage of products, and patent validity. Resolution of these questions in federal court would therefore advance the federal-state balance approved by Congress; indeed, it was the state court's assumption of jurisdiction over Dr. Sasso's claims that disrupted Congress's allocation of jurisdiction.

* * *

At bottom, this is a patent case: Dr. Sasso's claim for breach of the Facet Screw Agreement turns entirely on whether the relevant claims of the '313 and '046 patents are valid and whether they cover the Medtronic products for which Dr. Sasso seeks royalties. Under the *Gunn* factors and as a matter of common

sense, this case is subject to exclusive federal jurisdiction, and this Court accordingly has appellate jurisdiction.

II. THE DISTRICT COURT LEGALLY ERRED, AND THUS ABUSED ITS DISCRETION, IN REFUSING TO EXERCISE ITS EXCLUSIVE JURISDICTION

As noted above, the district court assumed, without deciding, that this case arises under federal patent law and therefore that the federal courts possess exclusive jurisdiction. Appx4. But the district court then incorrectly refused to exercise its exclusive jurisdiction, instead dismissing the case under the *Wilton-Brillhart* doctrine. That was legal error and thus an abuse of discretion. *Wilton* and *Brillhart* provide no basis for dismissing this case.

A. The *Wilton-Brillhart* Doctrine Provides No Basis For Dismissal In Favor Of Parallel State Proceedings Where Federal Jurisdiction Is Exclusive

1. *Wilton* and *Brillhart* do not remotely suggest that the pendency before a state court of federal-law issues within the exclusive jurisdiction of the federal courts—that is, issues over which the state courts lack jurisdiction—is a basis for a federal court to decline to exercise its declaratory judgment jurisdiction. To the contrary, those decisions suggest that a state court's inability to adjudicate the issues at stake in the federal action weighs strongly, or even decisively, in favor of the federal court's exercising its jurisdiction.

In *Brillhart*, an insurer sought a declaratory judgment in federal court that it was not liable under state law on a policy it had issued. The Supreme Court held

that, in determining whether to hear a declaratory judgment action, a district court "should ascertain whether the questions in controversy between the parties to the federal suit, and which are not foreclosed under the applicable substantive law, *can better be settled in the proceeding pending in the state court*." *Brillhart*, 316 U.S. at 495. That analysis, the Court explained, "may entail inquiry into the scope of the pending state court proceeding and the nature of defenses open there"—including such questions as "whether the claims of all parties in interest can satisfactorily be adjudicated in that proceeding, whether necessary parties have been joined, whether such parties are amenable to process in that proceeding, etc." *Id.*

Brillhart thus provides no basis to believe a district court has discretion to dismiss declaratory judgment claims in favor of a state-court action where the issues at stake *cannot* possibly be adjudicated in the state court because federal jurisdiction is exclusive. To the contrary, by singling out the availability of state-court adjudication as the central factor in the exercise of discretion, *Brillhart* indicates that a state court's inability to adjudicate the issues at stake in a federal declaratory judgment action should weigh heavily—arguably decisively—in favor of the federal court's exercising its discretion to decide the case.

Wilton bolsters that conclusion. Like *Brillhart*, *Wilton* involved a state-law dispute regarding insurance coverage. And like *Brillhart*, *Wilton* emphasized that

a district court's determination whether to entertain a declaratory judgment action should turn largely on the suitability of the state forum to adjudicate the mirror-image claim. *Wilton* reiterated *Brillhart*'s instruction for courts to consider "'whether the claims of all parties in interest can satisfactorily be adjudicated in [the state-court] proceeding.'" 515 U.S. at 283 (quoting *Brillhart*, 316 U.S. at 495). And it summarized *Brillhart* as having concluded "that, at least where another suit involving the same parties and *presenting opportunity for ventilation of the same state law issues* is pending in state court, a district court might be indulging in '[g]ratuitous interference' if it permitted the federal declaratory action to proceed." *Id.* (citation omitted). Thus, *Wilton* does not suggest—any more than *Brillhart* does—that a district court has unfettered discretion to dismiss declaratory judgment claims in favor of a parallel state-court action where the state court *cannot* lawfully adjudicate the issues at stake because they are subject to exclusive federal jurisdiction.

Indeed, *Wilton* goes further than *Brillhart* in emphasizing the need for federal courts to consider "'the functions and extent of federal judicial power'"—as well as the limits of state judicial power—in determining whether to exercise their jurisdiction over declaratory judgment suits. *Wilton*, 515 U.S. at 287. At least two other circuits have accordingly held that, where a declaratory judgment suit presents a question of federal law—as opposed to questions of state law, as in

Wilton and *Brillhart*—that feature should weigh heavily in favor of the federal court's exercise of jurisdiction. In *Youell v. Exxon Corp.*, 74 F.3d 373 (2d Cir. 1996), for example, the Second Circuit reversed the dismissal on *Wilton-Brillhart* grounds of a declaratory judgment suit that presented "'a novel issue of federal admiralty law'"—the "[f]ederal adjudication of" which, it held, would "not constitute 'gratuitous interference with the orderly and comprehensive disposition of the state court litigation.'" *Id.* at 376 (alterations omitted; quoting *Brillhart*, 316 U.S. at 495).[7] And in *Verizon Communications, Inc. v. Inverizon International, Inc.*, 295 F.3d 870 (8th Cir. 2002), the Eighth Circuit reversed a district court's decision to stay a declaratory judgment suit, on the ground that "the presence of a federal question that is not present in the state court action"—a factor that "was not at issue in either *Brillhart* or *Wilton*"—was "very significant" and "should have been given significant weight" in the exercise of the district court's discretion. *Id.* at 873.

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[7] The district court attempted to distinguish *Youell* (Appx7 n.5) on the ground that, in this case, "there is no broader federal question of first impression that demands resolution in federal court." But nothing in *Youell* suggests the court would have reached a different conclusion had the issue in question not been one "of first impression." To the contrary, the *Youell* court "adhere[d] to" its prior view that any case in which "'federal law supplies a rule of decision'" is "'fundamentally distinct from *Wilton*,'" which "'involved state law only.'" 74 F.3d at 376 (quoting *Youell v. Exxon Corp.*, 48 F.3d 105, 109 n.1 (2d Cir. 1995)).

Several district courts have explicitly declined to abstain under *Wilton* and *Brillhart* when faced with declaratory judgment suits (like this one) that present questions within the exclusive jurisdiction of the federal courts. In *Carlin Equities Corp. v. Offman*, 2007 WL 2388909 (S.D.N.Y. Aug. 21, 2007), for example, the district court held that abstention would be inappropriate because one of the issues presented by the case—one party's liability to the other under the Securities Exchange Act—could not "be resolved in the state-court proceedings … because federal courts have exclusive jurisdiction over suits brought pursuant to the Securities Exchange Act." *Id.* at *4. In *Sabre Oxidation Technologies, Inc. v. Ondeo Nalco Energy Services LP*, 2005 WL 2171897 (S.D. Tex. Sept. 6, 2005), the district court reached the same conclusion in a suit presenting a question of inventorship under patent law, reasoning that "because the issue arises under federal law and cannot be resolved in the state court proceeding, *Brillhart* abstention is not available." *Id.* at *4. And in *Epling v. Golden Eagle/Satellite Archery, Inc.*, 17 F. Supp. 2d 207 (W.D.N.Y. 1998), the court concluded that "abstention [was] inappropriate" in a case "involv[ing] solely issues of federal patent law, which are committed to the exclusive jurisdiction of" the federal courts. *Id.* at 210.

Notably, neither the district court nor Dr. Sasso has pointed to any decision holding that a district court may decline to exercise declaratory judgment

jurisdiction in favor of a parallel state-court proceeding where federal jurisdiction is exclusive. To the contrary, the cases recognize the profound importance of ensuring that *some* jurisdictionally proper forum is available to adjudicate cases and controversies. If a state court is the most sensible forum, then *Wilton* and *Brillhart* counsel that the federal court may abstain from exercising jurisdiction. But where a state court *lacks* jurisdiction, a federal court should not abstain from exercising jurisdiction without some exceptionally compelling reason, since abstaining leaves *no* court of competent jurisdiction to resolve the dispute.

2. The district court failed to take account of that concern. To the contrary, after suggesting in a footnote that "[t]he existence of exclusive federal jurisdiction" is "a relevant factor to consider," the district court asserted without explanation that "that factor [did] not alter" its conclusion. That would on its own be the sort of "unreasonable" or "arbitrary" decision that constitutes an abuse of discretion. *iLOR*, 631 F.3d at 1376. And to the extent the district court separately explained its reasoning, its explanations reveal legal errors that, by definition, are also abuses of discretion. *Id.*

First, the district court misconstrued the authorities on which Medtronic relied as addressing not "*Wilton-Brillhart* abstention, but *Colorado River* abstention—a distinct doctrine that is not analogous." Appx6. In fact, Medtronic

pointed the district court to *Youell*, *Carlin*, *Sabre*, and *Epling*, all of which consider *Wilton* and *Brillhart* as discussed above. *See* Appx1938-1940.[8]

The district court also opined that "courts have commonly considered *Wilton-Brillhart* abstention even in patent cases over which federal courts have exclusive jurisdiction." Appx8. But none of the cases on which the district court based that assertion involved abstention in favor of *state-court* proceedings in the face of exclusive federal jurisdiction, as the district court's ruling did here. Indeed, none of the cases so much as mentioned the exclusive nature of federal jurisdiction. Rather, they all involved the question whether a district court should entertain a declaratory judgment action at a particular time or whether the action should be heard in a federal court at some future time.[9] That is a different issue

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[8] *See Youell*, 74 F.3d at 375-376 (applying *Wilton* and *Brillhart* to consider the propriety of abstention, after the Supreme Court remanded for consideration in light of *Wilton*); *Carlin*, 2007 WL 2388909, at *4 ("Assuming arguendo that *Brillhart* and *Wilton* apply here, this Court will not exercise its discretion to stay or dismiss this suit."); *Sabre*, 2005 WL 2171897, at *4 ("[B]ecause the issue arises under federal law and cannot be resolved in the state court proceeding, *Brillhart* abstention is not available."); *Epling*, 17 F. Supp. 2d at 209-211 (extensively discussing *Wilton* and *Brillhart*). Medtronic ***also*** cited two cases that discussed *Colorado River* abstention, but it identified them specifically as such. Appx1938; Appx1940.

[9] *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 120-121 (2007) (issue was "whether Article III[] … requires a patent licensee to terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed"); *Teva Pharms. USA, Inc. v. EISAI Co.*, 620 F.3d 1341, 1343 (Fed. Cir. 2010) (addressing generic drug maker's request for a declaratory judgment that its drug did not infringe relevant

altogether because, in that situation, a district court's decision not to entertain a declaratory judgment action at a given time does not mean an issue of patent law will be determined in state court; it simply means the issue will be determined in a (correct) federal forum at the appropriate time.

Moreover, only two of the cases on which the district court relied—just one of which was from this Court—actually approved a district court's decision not to exercise jurisdiction, and they did so for reasons inapplicable here. In *EMC Corp. v. Norand Corp.*, 89 F.3d 807 (Fed. Cir. 1996), the Court noted that "serious negotiations to sell or license" the patent in question made exercising jurisdiction less important than it is in cases—like this one—where "there is no real prospect of a non-judicial resolution of the dispute." *Id.* at 814. And in *Trost v. Bauer*, 2001 WL 845477 (N.D. Ill. July 24, 2001), the district court found that the plaintiffs had filed the declaratory action in order to "race[] to the courthouse to Defendants'

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patents), *vacated as moot*, 564 U.S. 1001 (2011); *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1354 (Fed. Cir. 2004) (addressing request for "a declaration of noninfringement of … design patents" where patentholder had sued in federal court for trade dress infringement and unfair competition); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 809 (Fed. Cir. 1996) (addressing request for a declaratory judgment of invalidity and noninfringement by manufacturer that had been approached for license negotiations by holder of various patents); *Trost v. Bauer*, 2001 WL 845477, at *1 (N.D. Ill. July 24, 2001) (request for declaratory judgment of noninfringement by manufacturer who had been contacted by patentholder alleging potential infringement).

detriment" by depriving the patentholders of their chosen (federal) forum for a patent infringement action. *Id.* at *5. Neither rationale for abstaining applies here.

Two of the other cases on which the district court relied, both from this Court, strongly suggest that the district court abused its discretion by refusing to resolve this case—even aside from the fact that federal jurisdiction is exclusive.[10] In *Capo, Inc. v. Dioptics Medical Products, Inc.*, 387 F.3d 1352 (Fed. Cir. 2004), this Court held that the district court abused its discretion by refusing to adjudicate a declaratory judgment action. It explained that district courts must have "***a sound basis*** for refusing to adjudicate an actual controversy, for the policy of the [Declaratory Judgment] Act is to enable resolution of active disputes. 'When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, ***in the usual circumstance the declaratory judgment is not subject to dismissal***.'" *Id.* at 1357 (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993)). Because the resolution of a live patent dispute was "within the [district] court's capability," this Court held, "it [was] the district court's responsibility to resolve it." *Id.* at 1358. And in *Teva Pharmaceuticals USA, Inc. v. EISAI Co.*, 620 F.3d

[10] The fifth case, *MedImmune*, does not address whether an exercise of jurisdiction was proper or improper; the Supreme Court simply remanded for the district court to exercise its *Wilton-Brillhart* discretion "'in the first instance.'" 549 U.S. at 136-137.

1341 (Fed. Cir. 2010), *vacated as moot*, 564 U.S. 1001 (2011), the Court likewise held that the district court had abused its discretion by refusing to exercise jurisdiction, where "no 'sound basis' for refusing to adjudicate [the] case ha[d] been shown" and where "the validity or infringement of the" relevant patents would otherwise "not be litigated." *Id.* at 1349-1350. As discussed below, the district court offered no more "sound basis" for refusing to exercise jurisdiction here than in *Capo* or *Teva*.

B. The District Court's Reliance On The State-Court Judgment Was Incorrect

The district court's stated rationale for not exercising its jurisdiction to decide this case was that, because "the state court has already entered judgment in Dr. Sasso's favor" and "[n]o order or judgment of this Court can undo that judgment," a declaratory judgment would serve "no purpose" and "Medtronic would not stand to benefit from" it. Appx5. That is legally erroneous for several reasons.

First, since the district court expressly "assum[ed]" that this case fell within its exclusive jurisdiction, *see supra* p. 19, the corollary is that the state court judgment is a nullity. *See* 28 U.S.C. § 1338(a) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents[.]"); *Hickey's Lessee v. Stewart*, 44 U.S. 750, 762 (1845) (if a court "acts without authority, its judgments and orders are regarded as nullities"). Indiana

courts apply that rule to their own judgments. *See, e.g.*, *Emmons v. State*, 847 N.E.2d 1035, 1038 (Ind. Ct. App. 2006) ("'It is a universal principle as old as the law that the proceedings of a court without jurisdiction are a nullity and its judgment void.'"). The district court was therefore wrong to decline to exercise its exclusive jurisdiction simply because the state court issued a judgment that the district court (correctly) assumed the state court was powerless to issue. That is a legal error and thus automatically an abuse of the district court's discretion. *See, e.g.*, *iLOR*, 631 F.3d at 1376.

Second, and relatedly, the district court misunderstood the purpose of Medtronic's declaratory judgment claims. Medtronic did not file this action to "collaterally attack the state court's orders" or to "undo" the judgment of the Indiana state courts. Appx4-5. Rather, Medtronic brought this case to obtain resolution of the actual merits controversy between Dr. Sasso and Medtronic in the only forum with jurisdiction to decide it: a federal district court. Denying Medtronic the ability to defend itself against Dr. Sasso's claims in federal court means denying it the ability to defend itself in *any* court of competent jurisdiction.

Third, the district court was wrong to believe that "Medtronic would not stand to benefit from the declaratory judgment it seeks," Appx5. Completely apart from any effect on the current state-court judgment, a declaratory judgment in Medtronic's favor would certainly resolve *other* claims Dr. Sasso might try to

bring concerning the same contracts or patent claims. That is not merely a hypothetical concern: Dr. Sasso recently filed a new state-court suit demanding additional royalties under the Facet Screw Agreement. *See supra* p. 1.

The district court's view boils down to this: *Even assuming this case falls within the exclusive jurisdiction of the federal courts*, the issuance of a jurisdictionally defective state-court judgment on the same claim deprives Medtronic of the right to have the claim decided by a jurisdictionally proper court, unless and until the state-court judgment is vacated by the state appellate courts or the Supreme Court of the United States. There is no sound basis for that conclusion. As this Court held in *Capo*: "Resolution of this dispute is within the [district] court's capability, and it is the district court's responsibility to resolve it. Declining to do so is an abuse of discretion." 387 F.3d at 1358.

CONCLUSION

The Court should reverse the dismissal of this action and remand for the district court to adjudicate Medtronic's claims for declaratory relief on the merits.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

WARSAW ORTHOPEDIC, INC., et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 3:18-CV-437 JD
	)	
RICK C. SASSO, M.D.,	)	
	)	
Defendant.	)	

OPINION AND ORDER

This case is an offshoot of a long-running licensing dispute between Dr. Rick Sasso and Medtronic.[1] Dr. Sasso licensed to Medtronic certain inventions used in spinal surgeries, for which he also received patents. A dispute later arose over the scope and duration of the licensing agreements. Dr. Sasso sued Medtronic in August 2013 in state court, seeking damages for breach of an agreement referred to as the "Vertex Agreement." Medtronic removed the action to federal court, contending that the claim fell within the federal courts' exclusive jurisdiction over patent claims. 28 U.S.C. § 1338. Though the claim itself was for breach of a licensing agreement, Medtronic argued that the claim depended on the scope of the patent covering the invention, so it actually arose under federal patent law. Judge Miller disagreed and remanded the action to state court.[2] *Sasso v. Warsaw Orthopedic, Inc.*, No. 3:13-cv-1031 (N.D. Ind. Apr. 2, 2014).

[1] The plaintiffs here are actually three separate entities, but the parties refer to them collectively as Medtronic and do not otherwise distinguish between them. The Court likewise refers only to Medtronic.

[2] That decision is not res judicata as to whether jurisdiction exists in this case. First, Medtronic's claim in this case addresses only the Facet Screw Agreement, which was not at issue in that case. Second, an unappealable ruling is not res judicata, and an order remanding a case to state court for lack of jurisdiction is not appealable. *Health Cost Controls of Ill., Inc. v. Washington*, 187 F.3d 703, 709 (7th Cir. 1999).

After remand, Dr. Sasso filed an amended complaint in June 2014, asserting an additional claim for breach of a separate agreement, which Medtronic refers to as the "Facet Screw Agreement." Medtronic did not try to remove the case again, but it argued to the state court that the claims fell within the federal courts' exclusive jurisdiction, thus depriving the state court of jurisdiction. The state court disagreed and declined to dismiss the case. Litigation thus continued for years in state court.

Shortly before trial was scheduled to commence in November 2018, Medtronic filed this action in federal court.[3] Medtronic seeks a declaratory judgment that it did not breach the Facet Screw Agreement, on the basis that the patents related to that agreement are invalid and do not cover any of Medtronic's products. Medtronic forthrightly characterizes this claim as the mirror image of Dr. Sasso's claim for damages under that same agreement in state court. (Medtronic's claims in this action do not address the Vertex Agreement, which the federal and state courts have already held do not support federal jurisdiction.)

Dr. Sasso responded by moving to dismiss or stay this action. He argued that Medtronic's claim does not support federal jurisdiction, that it is barred by the *Rooker–Feldman* doctrine, and that the Court should abstain under *Colorado River*. Medtronic disagreed on all counts. In the meantime, the state court held a month-long trial, at the conclusion of which the jury returned a verdict in favor of Dr. Sasso as to both agreements. It awarded damages of over $112 million—over $32 million on the Vertex Agreement, and nearly $80 million on the Facet Screw

[3] Medtronic also turned to the United States Patent and Trademark Office and took the unusual position that its own patents are invalid. In response, the patent office apparently invalidated the patents in relevant part. That action is not relevant here, but it could call into question whether any patent issues are "substantial" in the sense required to invoke federal patent jurisdiction. *See Gunn v. Minton*, 568 U.S. 251, 260 (2013) (holding that "substantial" refers to "the importance of the issue to the federal system as a whole," not its role in the immediate case).

Agreement—and the state court entered judgment accordingly. Dr. Sasso then requested permission in this case to file supplemental briefs to argue that this action is barred by res judicata now that judgment has been entered in state court. The Court granted that permission, and directed the parties to address another issue as well: whether the Court should exercise its discretion to entertain this action under the Declaratory Judgment Act, which permits but does not require courts to enter declaratory judgments. [DE 27 (citing *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) and *Brillhart v. Excess Ins. Co. of Am.*, 316 U.S. 491 (1942))].

Having considered all of the parties' filings, the Court concludes that dismissal is appropriate under *Wilton* and *Brillhart*, as a declaratory judgment would serve no legitimate purpose here. Initially, the Court notes that it has the authority to reach that issue without first addressing the question of whether Medtronic's claim invokes federal jurisdiction. Subject matter jurisdiction is typically a threshold issue, as it concerns a court's authority to hear a case. Courts thus cannot assume the presence of jurisdiction in order to decide a case on the merits, even if that would promote judicial economy. *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 101–02 (1998). That does not mean, however, "that a federal court must consider subject matter jurisdiction over all other threshold matters." *Meyers v. Oneida Tribe of Indiana of Wis.*, 836 F.3d 818, 821 (7th Cir. 2016). "To the contrary, 'a federal court has leeway to choose among threshold grounds for denying audience to a case on the merits." *Id.* (quoting *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007)); *see also Washington v. Sevier*, 717 F. App'x 622, 623 (7th Cir. 2018) ("[T]here is no priority among non-merits-based reasons for dismissing a case."); *Kromrey v. U.S. Dep't of Justice*, 423 F. App'x 624, 626 (7th Cir. 2011) ("There is no priority among grounds for *not* addressing the merits; thus

a district judge may with equal propriety dismiss a suit for lack of subject-matter jurisdiction, lack of personal jurisdiction, or improper venue.").

Because abstaining under *Wilton* and *Brillhart* means the Court does not reach the merits of Medtronic's claim, the Court has the authority to rule on that basis without first addressing subject matter jurisdiction. *Meyers*, 836 F.3d at 823 ("[T]here are numerous circumstances in which a court appropriately accords priority to a non-merits threshold inquiry other than subject matter jurisdiction, such as pendent jurisdiction, forum non conveniens, abstention, and others."). That approach is particularly appropriate here. As discussed below, Medtronic filed this action in large part to collaterally attack the state court's orders, and to use an opinion from this Court to try to convince the state courts that they lack jurisdiction. Instead of taking that bait, the Court confines its analysis to the discretion provided by the Declaratory Judgment Act, assuming but not deciding that jurisdiction exists.

Under the Declaratory Judgment Act, a court "*may* declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). The Declaratory Judgment Act "has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." *Wilton*, 515 U.S. at 286. The Supreme Court has "repeatedly characterized the Declaratory Judgment Act as an enabling Act, which confers a discretion on the courts rather than an absolute right upon the litigant." *Id.* at 287 (quotation omitted). "[T]he propriety of declaratory relief in a particular case will depend upon a circumspect sense of its fitness informed by the teaching and experience concerning the functions and extent of federal judicial power." *Id.* (quotation omitted); *Envision Healthcare, Inc. v. PreferredOne Ins. Co.*, 604 F.3d 983, 986 (7th Cir. 2010) ("Under what is known as the *Wilton/Brillhart* abstention doctrine,

district courts possess significant discretion to dismiss or stay claims seeking declaratory relief, even though they have subject matter jurisdiction over such claims." (quotation omitted)).

Here, there is no purpose to be served by the declaratory judgment Medtronic seeks, at least at this time. Medtronic is asking for a declaratory judgment that it did not breach the Facet Screw Agreement and does not owe Dr. Sasso any damages. But the state court has already entered judgment in Dr. Sasso's favor on that claim. No order or judgment of this Court can undo that judgment—only the Indiana courts of appeals and the United States Supreme Court have authority to review that judgment. *Exxon Mobil Corp. v. Saudi Basic Indus. Corp.*, 544 U.S. 280, 291–92 (2005). Similarly, Medtronic would not stand to benefit from the declaratory judgment it seeks. *See BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 981 (Fed. Cir. 1993) ("A court may decline to exercise declaratory judgment jurisdiction if it would not afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding."), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). Even if this Court found that it had jurisdiction and held that Medtronic was not liable on Dr. Sasso's claim, that would not change the fact that the state court has entered judgment against Medtronic. Medtronic will be bound by that judgment unless and until the judgment is vacated by the state courts or the United States Supreme Court.

Medtronic surely understands that, yet it never articulates what purpose would be served by a declaratory judgment, leading to the conclusion that it is seeking a declaratory judgment solely because it believes an order in its favor in this Court would strengthen its hand in the state courts. That is plainly not the purpose of the Declaratory Judgment Act. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 814–15 (Fed. Cir. 1996) (explaining that the purpose of declaratory judgments in patent cases is to prevent parties from being coerced by threats of litigation with no

ability determine their rights, noting that the Act frees competitors from the "*in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises"); *Ford Motor Co. v. United States*, 811 F.3d 1371, 1378 (Fed. Cir. 2016) ("Trial courts must determine whether hearing the case would serve the objectives for which the Declaratory Judgment Act was created, namely, allowing a party who is reasonably at legal risk because of an unresolved legal dispute to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side." (quotation and alterations omitted)). Medtronic's quest for a more sympathetic ear for its arguments, or for an advisory opinion for use in another court, does not justify a declaratory judgment action.

Of course, it is possible that the state judgment will be vacated at some point. Medtronic has vowed to appeal, and perhaps it will convince the appellate courts that the state court lacked jurisdiction over Dr. Sasso's claims.[4] If that happens, though, the case before this Court would no longer be only a declaratory judgment action; Dr. Sasso would be seeking damages as well. If the parties return to federal court at that time, the Court can evaluate its own jurisdiction and proceed to the merits if appropriate. Until then, there is no use in proceeding with a declaratory judgment action.

In opposing abstention, Medtronic relies almost entirely on its argument that a court has no authority to abstain from hearing a claim that is within its exclusive jurisdiction. The Court disagrees. The cases Medtronic cites for that proposition were not addressing *Wilton–Brillhart* abstention, but *Colorado River* abstention—a distinct doctrine that is not analogous. *Colorado River* abstention is a judge-made doctrine that created a very narrow exception to the general rule

[4] It is also possible that the appellate courts will reject Medtronic's jurisdictional argument but rule in its favor on the merits.

that courts have a "'virtually unflagging obligation' to exercise the jurisdiction conferred on them." *Wilton*, 515 U.S. at 284. *Colorado River* permits a court to abstain in "exceptional circumstances" when parallel litigation is ongoing in state court. *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 818–20 (1976).

In contrast, *Wilton–Brillhart* abstention derives from the text of the Declaratory Judgment Act itself, which grants discretion by stating that district courts "may" enter declaratory judgments. *Envision*, 604 F.3d at 986. Thus, as the Supreme Court held in *Wilton*, *Colorado River* does not govern a court's discretion under the Declaratory Judgment Act. *Wilton*, 515 U.S. at 286. Medtronic's argument that courts "must" enter declaratory judgments upon request in cases over which they have exclusive jurisdiction finds no support in the text of the statute.[5] *MedImmune*, 549 U.S. at 136 ("The Declaratory Judgment Act provides that a court '*may* declare the rights and other legal relations of any interested party,' not that it *must* do so."); *see EMC Corp.*, 89 F.3d at 814 ("[S]pecial flexibility is called for in the declaratory judgment context, where 'the normal principle that federal courts should adjudicate claims within their jurisdiction yields to considerations of practicality and wise judicial administration.'" (quoting *Wilton*, 515 U.S. at 288)). In addition, unlike *Colorado River* abstention, *Wilton–Brillhart* abstention does not depend on whether another action is pending or could be brought in another forum. *Envision*, 604 F.3d at 986 ("[T]he classic example of when [*Wilton–Brillhart*] abstention is proper occurs

[5] The existence of exclusive federal jurisdiction can still be a relevant factor to consider in deciding whether to exercise that discretion. But given the lack of any legitimate purpose of a declaratory judgment here, as already explained, that factor does not alter the Court's conclusion. Nor is the Court abstaining because one party won a race to the courthouse. There was no race—Medtronic waited for over four years after Dr. Sasso asserted his claim in state court before filing this declaratory judgment action on the eve of trial. And unlike *Youell v. Exxon Corp.*, 74 F.3d 373 (2d Cir. 1996), there is no broader federal question of first impression that demands resolution in federal court.

where . . . solely declaratory relief is sought and parallel state proceedings are ongoing. That does not mean that abstention is limited to parallel proceedings."); *Teva Pharm. USA, Inc. v. EISAI Co.*, 620 F.3d 1341, 1349 (Fed. Cir. 2010), *vacated on other grounds sub nom. EISAI Co. v. Teva Pharm. USA, Inc.*, 131 S. Ct. 2991 (2011).

Moreover, courts have commonly considered *Wilton–Brillhart* abstention even in patent cases over which federal courts have exclusive jurisdiction. The Federal Circuit has acknowledged on multiple occasions that courts have discretion whether to entertain a declaratory judgment action for patent noninfringement. *Teva*, 620 F.3d at 1348–49; *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1357 (Fed. Cir. 2004) (stating, in an action for a declaration of noninfringement, that "[t]here is indeed discretion in the district court with respect to declaratory actions."); *EMC Corp.*, 89 F.3d at 814–15; *see also Trost v. Bauer*, No. 01 C 2038, 2001 WL 845477 (N.D. Ill. July 24, 2001) (declining to exercise jurisdiction over a declaratory judgment action for noninfringement). Likewise, in *MedImmune*, the Supreme Court held that an "actual controversy" existed sufficient to support a declaratory judgment action by a patent licensee that sought a declaration that the patent was invalid and did not cover the licensee's product. After reaching that holding, the Supreme Court remanded the case to the lower courts with instructions to exercise discretion under *Wilton* and *Brillhart* in deciding whether to entertain the declaratory judgment action. 549 U.S. at 136. That holding is irreconcilable with Medtronic's argument that no such discretion exists.

For those reasons, the Court concludes that it has discretion to decide whether to entertain this declaratory judgment action. And since Medtronic has not identified any legitimate purpose that would be served by, or any way in which it stands to benefit from, a declaratory judgment in light of the judgment in state court, the Court declines to exercise jurisdiction. The Court

therefore DISMISSES this action without prejudice. The Clerk is DIRECTED to enter judgment accordingly and close the case. The pending motions—the initial motion to stay, a motion for oral argument, and two motions to supplement that addressed issues not pertinent to this analysis—are DENIED as moot. [DE 17, 20, 23, 31].

SO ORDERED.

ENTERED: January 31, 2019

/s/ JON E. DEGUILIO
Judge
United States District Court

AO 450 (Rev. 01/09) Judgment in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Indiana

WARSAW ORTHOPEDIC INC;
MEDTRONIC, INC;
MEDTRONIC SOFAMOR DANEK, INC;

Plaintiff(s)

v. **Civil Action No.** 3:18cv437

RICK C SASSO;

Defendant(s)

JUDGMENT IN A CIVIL ACTION

The court has ordered that (*check one):*

☐ the plaintiff _____
recover from the defendant _____ the amount of _____
_____ dollars $_____, which includes prejudgment interest at the rate of _____% plus post-judgment interest at the rate of _____ % along with costs.

☐ the plaintiff recover nothing, the action is dismissed on the merits, and the defendant _____ recover costs from the plaintiff _____.

X Other: This case is DISMISSED WITHOUT PREJUDICE. The Clerk is DIRECTED to enter judgment accordingly and close the case.

This action was (*check one):*

☐ tried to a jury with Judge _____ presiding, and the jury has rendered a verdict.

☐ tried by Judge _____ without a jury and the above decision was reached.

X decided by Judge Jon E. DeGuilio.

DATE: 2/4/2019 ROBERT TRGOVICH, CLERK OF COURT

by S/ J. Darrah
Signature of Clerk or Deputy Clerk

US006287313B1

(12) **United States Patent**
Sasso

(10) **Patent No.: US 6,287,313 B1**
(45) **Date of Patent: Sep. 11, 2001**

(54) **SCREW DELIVERY SYSTEM AND METHOD**

(75) Inventor: **Rick Sasso**, Indianapolis, IN (US)

(73) Assignee: **SDGI Holdings, Inc.**, Wilmington, DE (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/448,361**

(22) Filed: **Nov. 23, 1999**

(51) **Int. Cl.**[7] **A61B 17/56**

(52) **U.S. Cl.** **606/96**; 606/80; 606/98

(58) **Field of Search** 606/80, 96, 97, 606/98, 104

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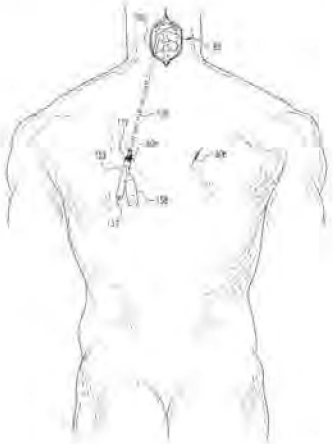
Primary Examiner—Nicholas D. Lucchesi
(74) *Attorney, Agent, or Firm*—Woodard, Emhardt, Naughton Moriarty & McNett

(57) **ABSTRACT**

A screw delivery system and method are disclosed for use in a variety of surgical indications. The screw delivery system generally comprises an outer cannula, a guide, and various interventional devices such as bone drill bits and taps as well as an implant driver for inserting a screw. The method disclosed varies by indication, but is ordinarily intended for use as a minimally invasive procedure which is a combination of percutaneous and open techniques wherein a small midline incision is made over a surgical site and the screw delivery system provides a percutaneous portal through an incision distant from the small midline incision over the surgical site.

34 Claims, 6 Drawing Sheets



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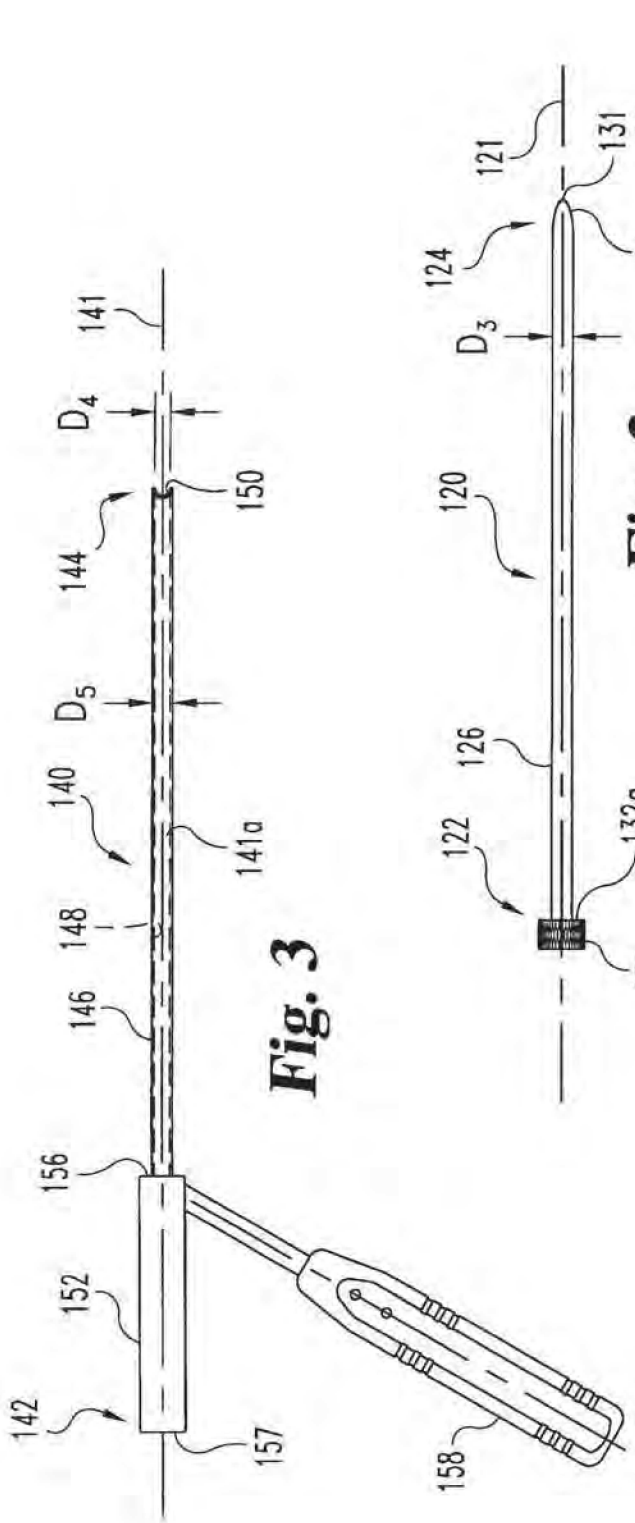

Fig. 3

Fig. 2

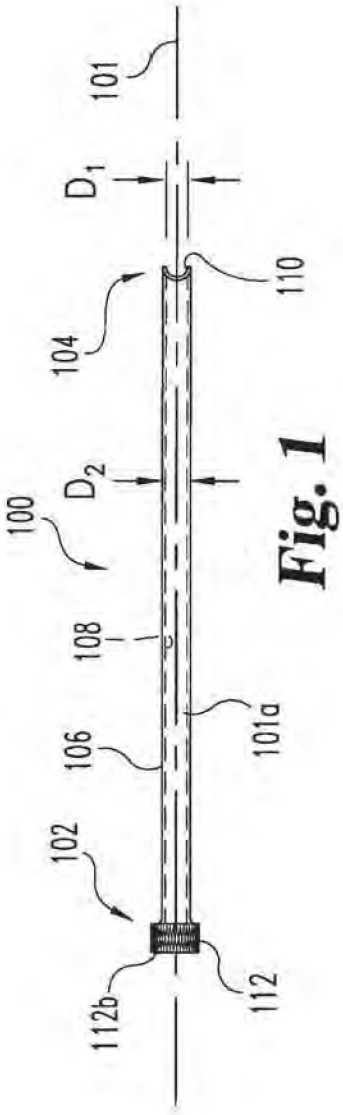

Fig. 1

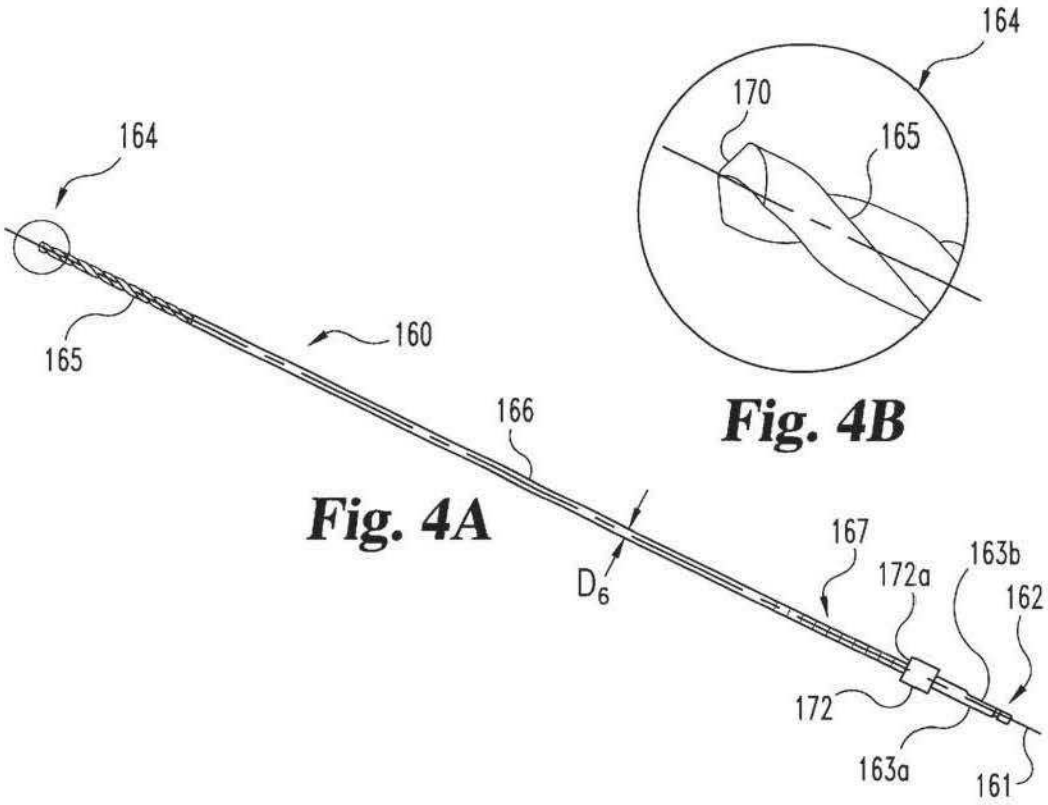

Fig. 4A

Fig. 4B

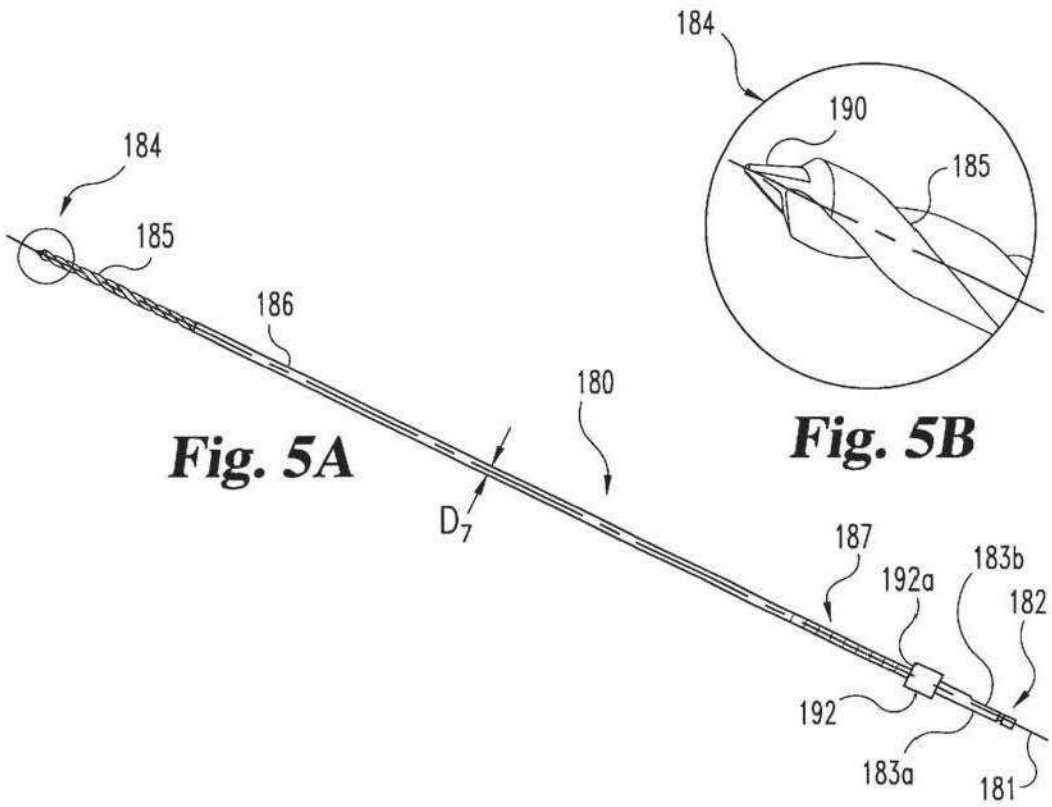

Fig. 5A

Fig. 5B

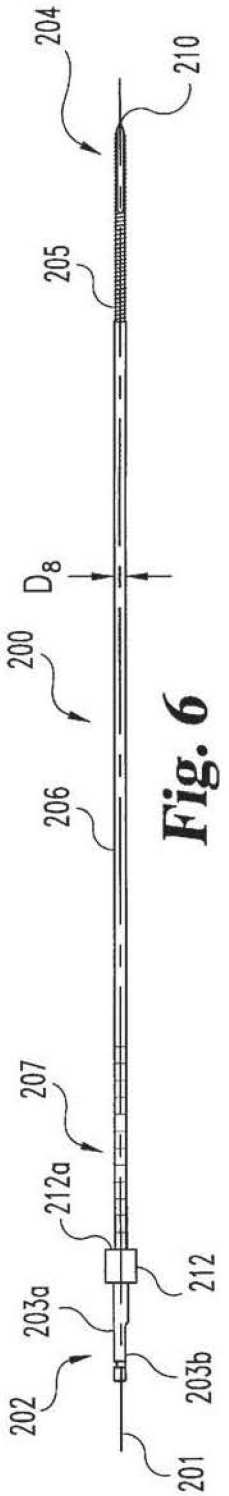

Fig. 6

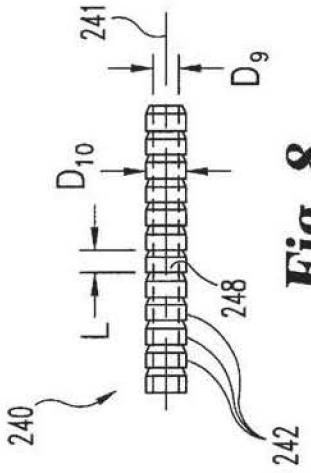

Fig. 8

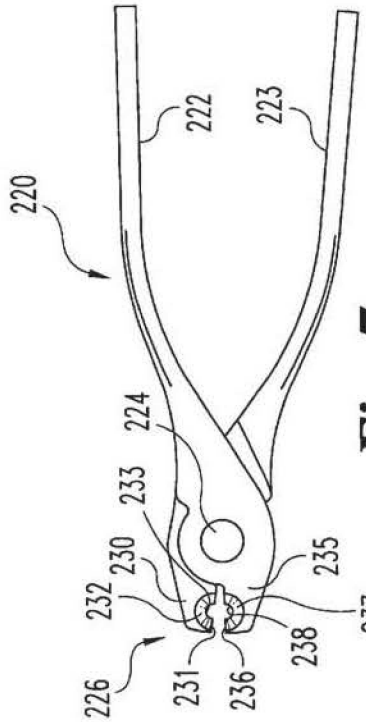

Fig. 7

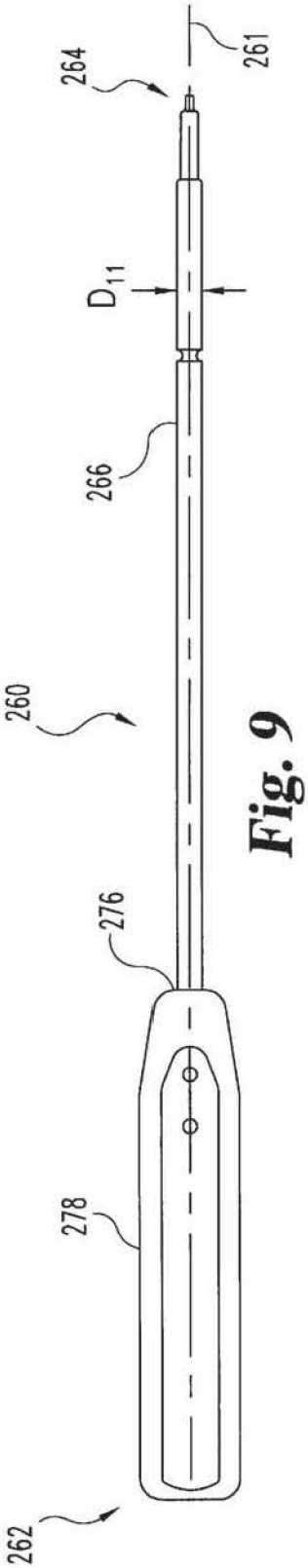

Fig. 9

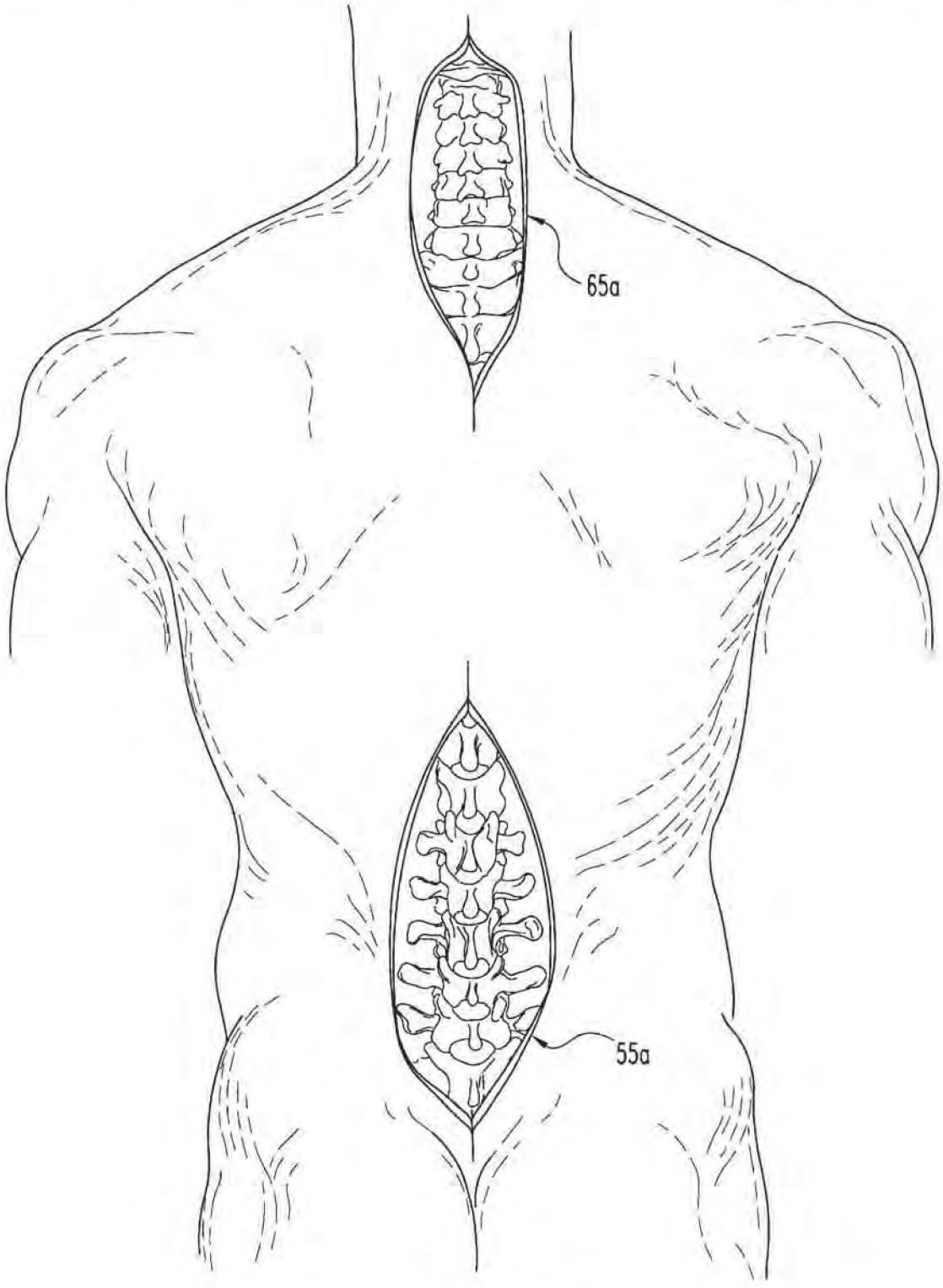

Fig. 10
(PRIOR ART)

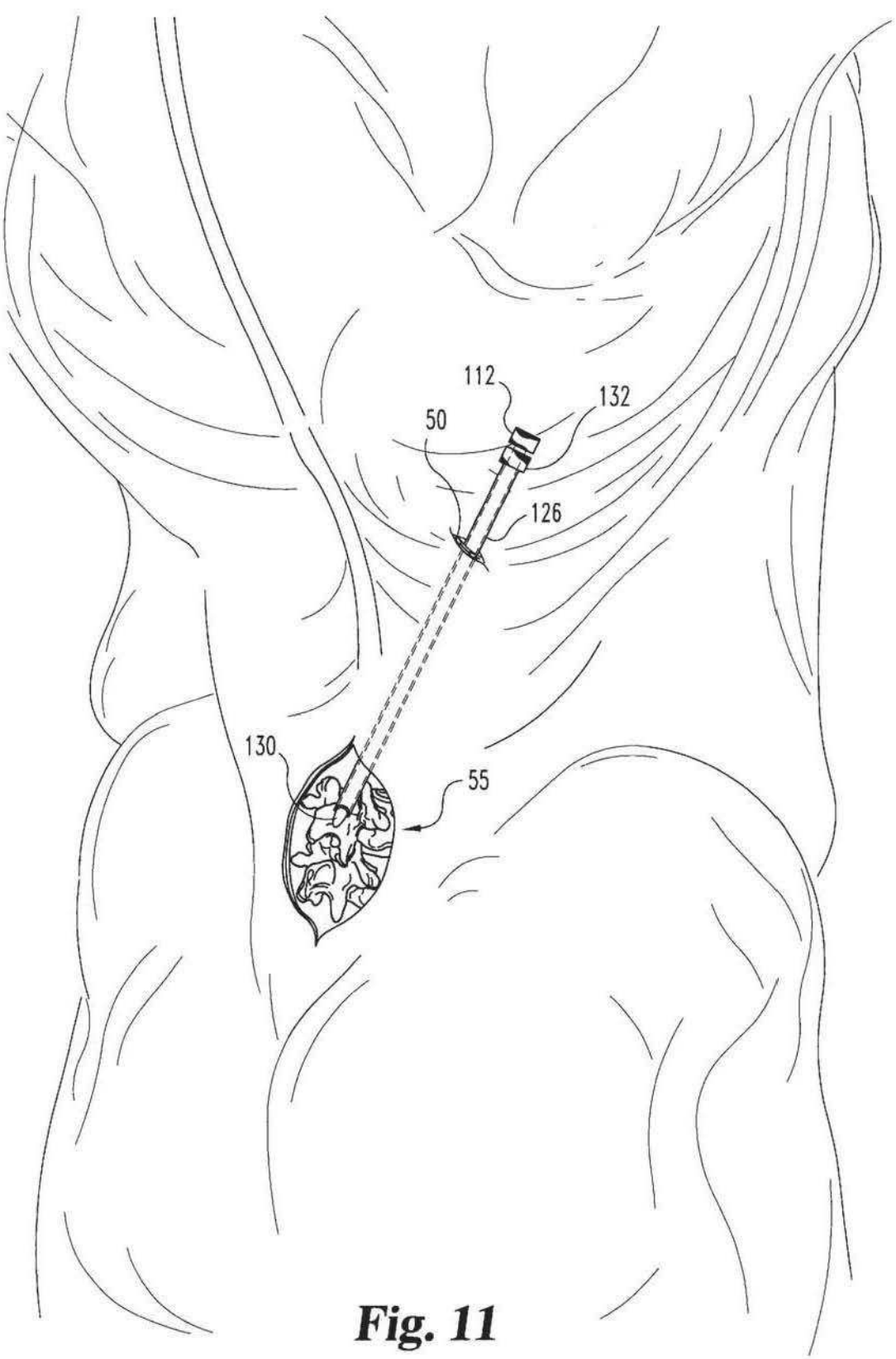

Fig. 11

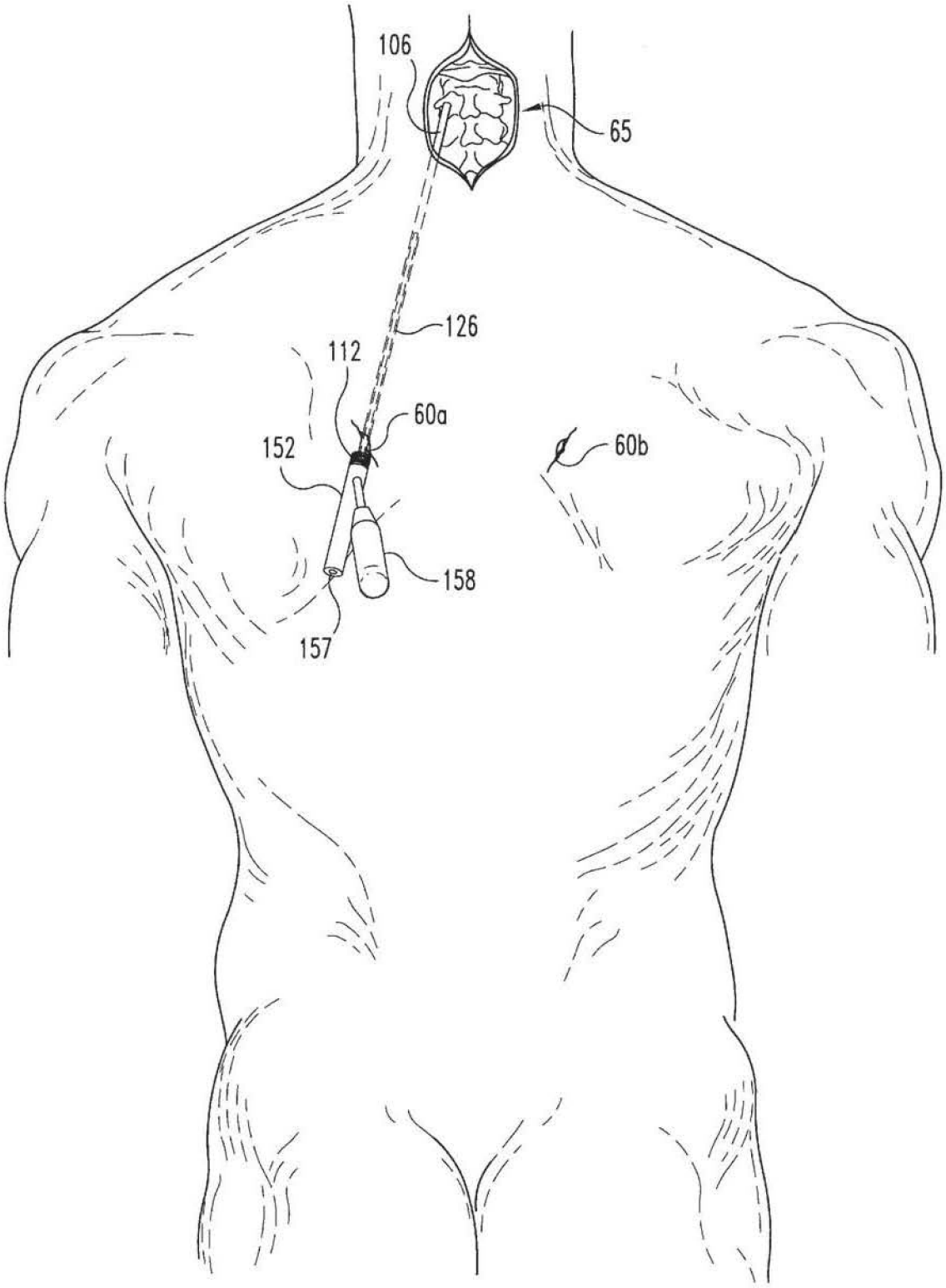

Fig. 12

SCREW DELIVERY SYSTEM AND METHOD

BACKGROUND

The human spine is a flexible weight bearing column formed from a plurality of bones called vertebrae. There are 33 vertebrae which are named based on which of five regions (cervical, dorsal, lumbar, sacral, and coccygeal) in which they are found. Going from the top of the spine down, in general there are seven cervical vertebra, twelve dorsal vertebra, five lumbar vertebra, five sacral vertebra, and four coccygeal vertebra. The vertebra of the cervical, dorsal, and lumbar regions of the spine are separate throughout the life of an individual, but the vertebra of the sacral and coccygeal regions in an adult are fused to form two bones, the five sacral vertebra entering into the formation of the sacrum and the four coccygeal vertebra into the coccyx. In general, each vertebra contains an anterior, solid segment or body and a posterior segment or arch. The arch is generally formed of two pedicles and two laminae, supporting seven processes—four articular, two transverse, and one spinous. There are exceptions to these general characteristics of a vertebra. For example, the first cervical vertebra (atlas vertebra) has neither a body nor spinous process. Also, the second cervical vertebra (axis vertebra) has an odontoid process, which is a strong, prominent process, shaped like a tooth, rising perpendicularly from the upper surface of the body of the axis vertebra. Further details regarding the construction of the spine are known to those of ordinary skill in the art and may be found in such common references as *Gray's Anatomy,* Crown Publishers, Inc., 1977, pp. 33–54, which is herein incorporated by reference.

The past two decades have seen greatly increased use of implants for the stabilization of fractures and/or fusion of various portions of the spine. These implant devices include a variety of longitudinal elements such as rods or plates which span two or more vertebra and are affixed to the vertebra by various fixation elements such as wires, staples, and screws (often inserted through the pedicles of the vertebra). These systems may be affixed to either the posterior or the anterior side of the spine. In many cases, these implant systems are prominent beneath the skin and have a higher profile than more simple fixation devices. One such simpler fixation device is in the stable posterior fusion of the atlas and axis vertebra by transarticular screw fixation using the technique of Magerl et al. disclosed in Stable Posterior Fusion of the Atlas and Axis by Transarticular Screw Fixation, F. Magerl, P-S. Seeman, *Cervical Spine,* Volume 1, Springer-Verlag, Copyright 1987, pp. 322–327; Primary Posterior Fusion 1–2 in Odontoid Factors; Indications, Technique, and Results of Transarticular Screw Fixation, B. Jeanneret and F. Magerl, *Journal of Spinal Disorders,* Volume 5, No. 4, pp. 464–475, 1992, Raven Press, Ltd., New York; (also see Atlanto-Axial Fusion With Transarticular Screw Fixation, D. Grob, B. Jeanneret, M. Aebi, and T. M. Markwalder, *The Journal of Bone and Joint Surgery* Volume 73-B, No. 6, 1991, pp. 972–976 all of which are herein incorporated by reference.

The use of transarticular screw fixation in both fusion procedures and stabilization procedures for fractures has undergone increasing use. However, due to the small entry angle of the screw with respect to the back of a patient lying prone on the operating table, procedures making use of transarticular screw fixation have required extremely long and wide midline incisions in order to place the screws as necessary in various procedures in both the cervical and lumbar spine regions. These large incisions result in

increased operating time with consequent increase in blood loss as well as enlarging the size of the scar left on the patient. It should be understood that while reduction of pain and maintaining range of motion are the surgical goal, the size of the incision and the scar it leaves behind are often the only visible measure a patient will have to judge the quality of the surgeon's work. Thus, it is preferable if the incision is made in a manner not only to preserve the skin's contour, but of a minimum length and size to increase patient satisfaction.

SUMMARY OF THE INVENTION

One embodiment of the present invention is a screw delivery system kit for providing a minimally invasive portal with a small entry angle to a surgical site, comprising an outer cannula, a trocar, a guide and a bone drill bit. The outer cannula has a first exterior surface and a first interior surface defining a bore. The first interior surface has a first inner diameter and the first exterior surface has a first outer diameter. The surfaces extend along a first length on a first axis between a first proximal end having a first stop and a first distal end. The trocar has a second exterior surface with a second outer diameter. The second exterior surface extends along a second length on a second axis between a second proximal end having a second stop defined thereon and a second distal end defining a blunt tip. The guide has a handle and a tube. The tube has a third exterior surface and a third interior surface defining a passageway. The third interior surface has a third inner diameter and the third exterior surface has a third outer diameter. The third interior surface extends between a third proximal end and a third distal end. The third exterior surface extends along a third length on a third axis between a third stop at the third proximal end and the third distal end. The handle is connected to the tube at an angle to the third axis. The bone drill bit has a fourth exterior surface with a fourth outer diameter extending along a fourth length on a fourth axis between a fourth stop located near a fourth proximal end and a plurality of drilling flutes defined on a fourth distal end.

Another embodiment of the invention is a method of inserting a screw through a minimally invasive portal comprising making a first incision for viewing over a surgical site and making a second incision spaced apart from the first incision. Then an outer cannula having a bore defined between a proximal end and a distal end and a trocar through the bore are inserted into the second incision. The outer cannula and trocar are advanced toward the surgical site until the distal end contacts the surgical site at which time the trocar is withdrawn from the outer cannula. An opening in the bone is then drilled followed by screwing a screw into the opening in the bone.

Yet another embodiment of the present invention is a screw delivery system kit for providing a minimally invasive portal to a surgical site comprising: an outer cannula; a trocar; means for drilling an opening in a bone at the surgical site; means for aiming said means for drilling; and means for screwing a screw into the opening in the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of the outer most cannula of a screw delivery system of the present invention.

FIG. **2** is a trocar for use with the outer cannula of FIG. **1** for initial insertion of the screw delivery system into the patient.

FIG. **3** is a side view of a guide for insertion into the outer cannula of FIG. **1** for more accurately directing the bone drill bits and taps of FIGS. **4–6**.

FIG. **4**A is a standard bone drill bit for use in a screw delivery system of the present invention.

FIG. **4**B is an enlarged portion of the bone drill bit tip of FIG. **4**A.

FIG. **5**A is a side view of an improved bone drill bit for use with the screw delivery system of the present invention.

FIG. **5**B is an enlarged view of the tip of the bone drill bit of FIG. **5**A.

FIG. **6** is a side view of a bone tap for use with the present invention.

FIG. **7** is a side view of a cutter for adjusting the length of the adjustable length stop of FIG. **8**.

FIG. **8** is a side view of an embodiment of an adjustable length stop of the present invention.

FIG. **9** is a side view of a screwdriver for use in the screw delivery system of the present invention.

FIG. **10** is a top view of the back of a patient lying prone illustrating the size of the prior art incision made in the cervical and lumbar regions for transarticular screw fixation.

FIG. **11** is an illustration of the insertion of the bullet-shaped trocar of FIG. **2** through the outer cannula of FIG. **1** creating a percutaneous portal in the back distal from a lumbar vertebra surgical site.

FIG. **12** is a top view of the use of the screw delivery system of the present invention on a patient lying prone with the surgical site in the cervical vertebra region.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

With respect to FIG. **1** there is illustrated outer cannula **100** extending along longitudinal axis **101**. Outer cannula **100** provides the primary passageway for screw implantation to a surgical site through a percutaneous portal (as discussed further below) distant from the surgical site. Many of the spinal surgeries for which the screw delivery system and method of the present invention will find use in involve very small entrance angles for the screw with respect to the spine of a patient lying prone. The outer cannula **100** has a bore **101***a* extending between the near end **102** and far end **104** of the outer cannula **100**. Outer cannula **100** has an exterior surface **106** and an interior surface **108**, interior surface **108** defining bore **101***a*. The far end **104** of outer cannula **100** terminates in a tip **110**. Tip **110** is shown as having serrations with a crescent moon-like shape for ease of contacting the surgical site (i.e., bone of a vertebra). It should be understood, however, that the tip **110** may take a variety of shapes and forms other than the crescent moon illustrated.

The near end **102** of outer cannula **100** has an annular flange or stop **112**. Bore **101***a* also extends through the annular flange **112**. The stop **112** acts in combination with the stops on other devices inserted through the bore **101***a* of the outer cannula to prevent over-insertion of the various bone drill bits, taps, and other probes and interventional devices and prevents possible damage to the surgical site resulting from over-insertion. It should be understood that stop **112** need not be in the shape of an annular flange, but may simply be a plurality of projections extending from the exterior surface **108** of outer cannula **100**. It should be further understood that the stop **112** of outer cannula **100** may also be simply the circumference of the exterior surface **108** of outer cannula **100** at the near end **102**. This is because the stops of the other probes or interventional devices (e.g., bone drill bits, bone taps, guides) will contact the circumference of the near end **102** of the exterior surface **106** of outer cannula **100**. It should also be understood that the preferred embodiment is for outer cannula **100** to possess an annular flange **112**. Outer cannula **100** has an inner diameter D1 for bore **101***a* and an outer diameter D2 as illustrated in FIG. **1**.

With respect to FIG. **2** there is illustrated a trocar **120** extending along a longitudinal axis **121** between a proximal end **122** and a distal end **124**. Trocar **120** is preferably, but not necessarily, a solid shaft having an exterior surface **126** between the proximal end **122** and the distal end **124**. The distal end **124** of trocar **120** has a bullet-shaped head **130** with a blunt tip **131** for minimizing the trauma to the tissue as the combination of the trocar **120** and the outer cannula **100** are used as a soft tissue penetrator or introducer from a distal incision SO on the back to the surgical site **55** of the vertebra (see FIG. **11**). Trocar **120** has an annular flange or stop **132** at the proximal end **122**. The exterior surface **126** of trocar **120** has an outer diameter D**3**. The outer diameter D3 of trocar **120** is less than the inner diameter D1 of outer cannula **100** which is in turn less than the outer diameter D2 of outer cannula **100**. Since the outer diameter D3 is less than the inner diameter D1, the exterior surface **126** of trocar **120** may be inserted through the bore **101***a* of outer cannula **100**. It should be understood that to act as a soft tissue penetrator, the trocar **120** need merely have an unbroken surface at bullet-shaped head **130** and whatever other portion extends beyond the far end **104** of outer cannula **100**. Thus, while FIG. **2** illustrates trocar **120** as a solid shaft, variations as would occur to a person of ordinary skill in the art for the connection between the distal end **124** and the proximal end **122** of trocar **120** are contemplated as within the scope of the invention.

The trocar **120** has a length such that when inserted through the bore **101***a* of outer cannula **100**, the bullet-shaped head **130** will extend past the tip **110** of outer cannula **100**. When the trocar **120** is inserted as far as possible through the bore **101***a* of outer cannula **100**, the front face **132***a* of the annular flange **132** will contact the rear face **112***b* of stop **112** of outer cannula **100** (see FIG. **11**). At or near this point the bullet-shaped head **130** will extend past the tip **110** of outer cannula **100** thus permitting the trocar **120** and outer cannula **100** to be percutaneously inserted through an incision **50** distal from the surgical site **55**. Thus, despite the fact that the desired entry angle for transarticular screw fixation is very small, the large midline incision of current techniques is unnecessary. Only a small midline incision directly over the surgical site is necessary, as the passageway provided by bore **101***a* of outer cannula **100** of the screw delivery system permits the introduction of all the tools, implants, and interventional devices necessary to stabilize the spine using transarticular screw fixation. It should be understood that while the illustration of FIG. **11** demonstrates the applicability of the soft tissue penetrator combination of trocar **120** with outer cannula **100** in the lumbar vertebra of the spine, the screw delivery system of the present invention is equally useful for avoiding the necessity of a large midline incision when a surgical site is,

for example, in a cervical vertebra as is the case in a transarticular screw fixation across the atlanto-axial joint (see FIG. **12**).

The devices used through the bore **101***a* of outer cannula **100** in various embodiments of the present invention are illustrated in FIGS. **3–9** and are discussed in more detail below. After the details of the individual components of various embodiments of the present invention are outlined, the method of their use will be discussed in further detail. With reference to FIG. **3**, there is illustrated one embodiment of a device for more accurately aiming various embodiments of bone drill bits and bone taps to the appropriate lengths. The guide **140** generally extends along a longitudinal axis **141** (with the exception of the handle **158**). The guide **140** has a bore **141***a* defined by an interior surface **148** extending between the proximal end **142** and the distal end **144**. The guide **140** has an exterior surface **146** defined between the proximal end **142** and the distal end **144** which terminates in a tip **150**. The proximal end **142** of the guide **140** has an annular flange or stop **152** with a front face **156** and a rear face **157**. The exterior surface **146** has an outer diameter D5 and the interior surface **148** has an inner diameter D4.

The guide **140** has a handle **158** which is connected at an angle to the stop **152**. It should be understood, however, that the handle **158** may be located/connected at a variety of locations. The handle **158** is at an angle transverse to the longitudinal axis **141**. The angle of the handle is relevant to many of the applications with small entry angles as it should not be perpendicular to the longitudinal axis **141**. It should also be understood that the angle that the handle **158** makes with respect to the longitudinal axis **141** is preferably less than 60 degrees. The outer diameter D5 is greater than the inner diameter D4, but is less than the inner diameter D1 of the outer cannula **100**. Thus, the exterior surface **146** may be inserted through the bore **101***a* of outer cannula **100** until the front face **156** of guide **140** contacts the rear face **112***b* of stop **112** of outer cannula **100**. As discussed further below, when the front face **156** is in contact with the rear face **112***b* of a stop **112** of outer cannula **100**, various other instruments are inserted through the bore **141***a* as well as the bore **101***a* such as the bone drill bits **160**, **180**, and tap **200** discussed below.

With reference to FIG. **4**A, there is illustrated a side view of a standard bone drill bit **160** extending along an axis **161** between a proximal end **162** and a drilling end **164**. The proximal end **162** has a surface adapted for the application of force to rotate the bone drill bit **160**. In one embodiment, as illustrated in FIG. **4**A, the standard bone drill bit **160** has a half solid cylinder **163***a* and a flattened portion **163***b* at the proximal end **162** to permit rotation of the standard bone drill bit **160**. With reference to FIGS. **4**A and **4**B, the drilling end **164** has a plurality of flutes **165** and a standard drill tip **170**. Standard bone drill bit **160** has an exterior surface **166** extending between the front face **172***a* of annular flange or stop **172** and the beginning of the flutes **165** making up the drilling end **164** of standard bone drill **160**. The exterior surface **166** of standard bone drill **160** has an outer diameter D6. Additionally, the portion of exterior surface **166** near annular flange or stop **172** preferably has a plurality of length markings **167**.

With reference to FIGS. **5**A and **5**B, there is illustrated the preferred embodiment of a bone drill bit **180** for use in the screw delivery system and method of the present invention. It should be understood that due to the small entry angle between the bone drill bit and the bone in the spine/vertebra of the surgical site, that a standard bone drill bit **160** has a blunt end that is difficult to get started. The tip **170** of the bone drill bit **160** has a tendency to walk along the surface, making accurate placement difficult. Thus, the more preferred embodiment is bone drill bit **180** which extends along an axis **181** between a proximal end **182** and drilling end **184**. Similar to the standard bone drill bit, the preferred bone drill **180** has a half solid cylinder **183***a* and a flattened portion **183***b* at proximal end **182** for use in rotating the bone drill bit **180**. The drilling end **184** of bone drill bit **180** has a plurality of flutes **185**. Bone drill bit **180** has an exterior surface **186** extending between the front face **192***a* of annular flange or stop **192** and the beginning of the plurality of flutes **185** on the drilling end **184**. Bone drill bit **180** has a sharper angled drill tip **190** at the end of drilling end **184** which permits ease of insertion when beginning to drill even at the small entry angles preferably less than 45° (not perpendicular to bone) for the methods of use of the screw delivery system discussed further below. The exterior surface **186** of bone drill bit **180** has an outer diameter D7. Both outer diameter D7 and outer diameter D6 are less than the inner diameter D4 of guide **140**. In a preferred embodiment, the guide **140** has an inner diameter D4 which is only slightly larger than the outer diameter D6 or outer diameter D7 of bone drills **160**, **180**, respectively. This permits more accurate placement of the drill tips **170**, **190** and minimizes deviations from side to side of the axis **161**, **181**, respectively when drilling.

With reference to FIG. **6** there is illustrated a side view of a bone tap **200** for use with a screw delivery system of the present invention. Bone tap **200** extends along axis **201** between proximal end **202** and tapping end **204**. Similar to the bone drill bits **160**, **180**, the proximal end **202** of tap **200** has a solid half cylinder **203***a* and a flattened portion **203***b* to permit rotation of the bone tap **200**. As is understood by those of ordinary skill in the art, the tapping end **204** of bone tap **200** has threading **205** thereon and a tip **210** for creating threading in the opening or bore in the bone created by a bone drill bit **160**, **180**. Bone tap **200** has an exterior surface **206** extending between the front surface **212***a* of annular flange or stop **212** and the beginning of the threading **205** at the tapping end **204**. The exterior surface **206** has an outer diameter D8 which is less than the inner diameter D4 of the guide **140** to permit the bone tap **200** to be inserted through the bore **141***a* of guide **140**. As with the bone drill bits **160**, **180**, the exterior surface **206** of bone tap **200** preferably has a plurality of length markings **207** on the portion of exterior surface **206** adjacent the annular flange or stop **212**.

With reference to FIGS. **7** and **8** there are illustrated side views for the cutter (FIG. **7**) and the adjustable length stop (FIG. **8**). In particular with reference to FIG. **7**, cutter **220** has handles **222**, **223** which are pivotally connected around hinge **224**. The cutting end **226** of cutter **220** is made up of a first cutting element **230** and a second cutting element **235**. The first cutting element **230** has a first sharp edge **231** adjacent a circular depression **232** which has its own cutting edge **233**. Similarly, second cutting element **235** has a second sharp edge **236** adjacent another circular depression **237** having its own cutting edge **238**. It should be understood that cutter **220** is intended for use on the adjustable length stop **240** as illustrated in FIG. **8**.

The adjustable length stop **240** has integrally connected individual cylindrical elements **242** with a length L and an inner diameter D9 and an outer diameter D10. The individual cylindrical elements **242** of adjustable length stop **240** extend along a longitudinal axis **241**. The individual cylindrical elements **242** of the adjustable length stop **240** define a bore **248** extending along the axis **241**. In one embodiment, the length L of the individual cylindrical elements **242**

corresponds to the distance between the length markings such as length markings **207** on bone tap **200**, length markings **187** on bone drill bit **180**, and/or length markings **167** on bone drill bit **160**. It is contemplated as within the scope of the invention, however, that the length of the individual cylindrical elements may be different than that of the markings on the respective bone drill bits and taps, and that the length of each individual cylindrical element may vary on a single adjustable length stop **240**. It should be understood that the inner diameter D9 of bore **248** of the adjustable length stop **240** should be greater than diameters D8, D7, D6, but is less than D5 which in turn is less than D1 which is less than D2. It should also be understood that the outer diameter D10 should be greater than either the outer diameter D5 of the guide **140** or at least of a sufficient diameter so that the adjustable length stop **240** will act as a contact mechanism to prevent further insertion of the bone drills or bone taps upon contacting the rear face **157** of annular flange or stop **152** of the guide **140**. Similarly, in those embodiments of the device where a guide **140** is not utilized, but instead only the outer cannula **100** is, the outer diameter D10 should be such that the adjustable length stop **240** will contact the rear surface **112***b* of annular flange or stop **102** of outer cannula **100**.

With reference to FIG. **9**, there is illustrated a side view of an implant driver in the form of a screwdriver **260** for use with the screw delivery system of the present invention. Screwdriver **260** extends generally along axis **261** between a proximal end **262** and distal end **264**. Screwdriver **260** comprises a handle **278** which has a front face **276**. Front face **276** of handle **278** could act as a stop, but in general the length of the screwdriver **260** is made deliberately long so that whatever screw used may be screwed in as deep as may be deemed necessary. Screwdriver **260** has an exterior surface **266** with an outer diameter D11 extending between the front face **276** of handle **278** and the tip **270** at distal end **264**. The tip **270** of screw driver **260** is configured so as to fit within the screw head of the screw used for transarticular screw fixation and other surgeries as contemplated within the scope of the invention. In general the tip **270** of screwdriver **260** will define a polygonal shape which will mate with a polygonal socket of the same shape in the screw head of the screw used. For ease of reference, the relationship among diameters of various components is summarized below:

$D_3 < D_1$
D_8
$D_7 < D_4 < D_5 < D_1 < D_2$
D_6
D_8
$D_7 < D_9 < D_{10}$
D_6
$D_{11} < D_2$

Having now described the individual elements of the screw delivery system, the general method of use will now be described. The screw delivery system of the present invention is particularly useful for three primary surgical indications. The first indication is use in repair of a odontoid fracture. The second indication is transarticular screw fixation across the first and second cervical vertebrae. The third indication is transarticular screw fixation across the lumbar facet joint. All of these indications will be discussed with more specificity below. The general procedure, however, essentially entails seizing the joint between the vertebrae and immobilizing it until either the fracture heals (as in the first indication) or until fusion occurs (as in the second or third indications). It should be understood that the first indication is an anterior procedure while the second and third indications are posterior procedures.

In the generalized method of use, the soft tissue penetrator or introducer in the form of the outer cannula **100** with the trocar **120** having a bullet-shaped head **130** is introduced through an incision **50** in the skin on the back and directed toward the surgical site (in FIG. **11** the surgical site is across lumbar vertebra) viewed through incision **55**. The tip **110** of the outer cannula **100** is then seated on the portion of the bone or vertebra at the appropriate angle for the introduction of the screw for fixation. The bullet-shaped head **130**, and indeed the entire trocar **120**, are then removed from the outer cannula **100**. Then, the distal end **144** of the drill guide **140** is inserted through the near end **102** of outer cannula **100** until the front face **156** of stop **152** of guide **140** contacts the rear face **112***b* of annular flange or stop **112** of outer cannula **100**. Next, the drilling end **184** of bone drill bit **180** is inserted through the bore **141***a* of guide **140** past the distal end **144** and then on into the bore **101***a* of outer cannula **100**. It should be understood that the surgeon could use a high speed burr to mark the point of insertion of the screw, but this generally weakens the fixation of the screw's strength because of the loss of cortical bone on the outside surface of the vertebra. Instead, it is preferable, as mentioned above, to use the improved drill bit **180** of the present invention which has a sharper angled drill tip **190** which permits easier insertion during the beginning of the drilling process despite the very small entry angle commonly encountered in transarticular screw fixation across vertebral joints.

As previously mentioned, the bone drill bit **180** has a plurality of length markings **187** adjacent the annular flange or stop **192**. The length markings **187** allow the surgeon to know the distance the drill has been drilled into the bone at a glance by examining the length markings **187** of the bone drill bit **180**. The screws (not shown) to be used are of a fixed length which can be measured. Based on this fixed length, an adjustable length stop **240** is inserted onto either the bone drill bit **180** or tap **200** as appropriate. The exterior surface **186**, **206** of the bone drill bit **180** or tap **200**, respectively, is inserted through the bore **248** of the adjustable length stop **240**. In general, both the bone tap **200** and the bone drill bit **180** will be marked with 30 mil projections in 5 mm increments. Similarly, the length L of the individual cylindrical elements **142** of the adjustable length stop **140** will generally be equal to these 5mm increments of the length markings **207** and **187**. The adjustable length stop **240** is simple and does not change the lengths of the guide **140** permitting the use of one standard guide **140** and of standard length bone drill bits **180** and bone taps **200**. The variable is the adjustable length stop **240**, which is generally constructed of plastic, allowing the use of a cutter **220** to trim the total length of the adjustable length stop **240**, thus permitting the desired length of insertion of the bone drill bit **180** and bone tap **200**. The cutter **220** may either cut off individual cylindrical elements **242** to alter the length L of adjustable length stop **240** or may even be used to cut through an individual cylindrical element **242**. It should be understood that it is generally preferable if the cutter **220** is used to cut to total length the adjustable length stop **240** by trimming through the weakened portion between the individual cylindrical elements which is intended to break off.

After trimming the adjustable length stop **240** to the desired total length, the bone drill bit **180** is inserted through the bore **141***a* of the guide **140** and the bore **101***a* of the

concentric outer cannula **100** and the drill is rotated and an opening in the bone is created by advancing the bone drill bit **180** along axis **181** until the adjustable length stop **240** contacts the rear face **157** of stop **152** of the guide **140** which prevents further advancement of the bone drill bit **180** into the bone. The bone drill bit **180** is then removed from both the guide **140** and outer cannula **100**. Next, the bone tap **200** is introduced through the bores **141***a* and **101***a*. The bone tap **200** will have an adjustable length stop **240** of the same total length as that used on the guide **140**. The opening in the bone created by the bone drill bit **180** is then threaded by rotating and advancing bone tap **200** until the adjustable length stop **240** on bone tap **200** contacts the rear face **157** of stop **152** on guide **140**.

After the opening in the bone portion has been drilled and tapped, the entire inner sleeve in the form of the bone tap **200** and guide **140** is removed from the outer cannula **100**. Next, a screw and implant driver are introduced through the near end **102** of outer cannula **100**. The implant driver will generally be a standard screwdriver **260** having a tip **270** with a polygonal head which will mate with a same shaped polygonal socket in the head of the screw (not shown) to be driven into the bone. The screw and screwdriver **260** are inserted through the bore **101***a* of outer cannula **100** until they have reached the opening located beyond the tip **110** of the far end **104** of outer cannula **100**. The location of this opening will vary depending on the indication as described further below.

As mentioned above, the first indication of particular use for the screw delivery system and method of the present invention is for use with an odontoid fracture. An odontoid fracture is a special type of C**2** (second cervical vertebra) or axis vertebra. As mentioned in the background section, the odontoid is a prominent process, tooth-like in form, projecting perpendicularly upward from the axis vertebra toward the atlas vertebra. In the past, odontoid fractures were treated by the use of halo. The alternative treatment mechanism is to insert a screw across the fracture site. This will be an anterior procedure through the neck, so that operating through the bore **101***a* of the outer cannula **100** aids in protecting important structures in the neck as well as providing a minimally invasive procedure generally.

Odontoid screw fixation is a technically demanding procedure that requires thorough preoperative planning and adequate surgical training. The entry point is critical at the anterior margin of the inferior endplate. If started more cephalad, the angle of inclination for fracture fixation cannot be achieved and anterior gapping of the fracture is a common result. Also, poor proximal fragment purchase with subsequent screw cut-out may occur. It is important to engage the far cortex of the odontoid tip to ensure adequate purchase and it is mandatory to lag the fracture fragments either through screw design or by creating a gliding hole through the body fragment. AP and lateral fluoroscopy is essential for constant monitoring during all stages of this procedure.

Odontoid screw fixation using the screw delivery system of the present invention is a combination of percutaneous and open technique to make a minimally invasive approach. The surgeon actually views the entry site of the screw and through a separate incision places the screw delivery system while viewing where the far end **104** of the outer cannula **100** is going to dock. The technique is generally done using biplanar fluoroscopy, which allows viewing of the fracture on TV screens as you place the drill, tap and screw, respectively, across it during the procedure. The entirety of drilling, tapping, and screw insertion is done through the working sleeve in the form of the outer cannula **100** and drill guide **140**, as previously discussed.

The specifics of the screw entry angle and placement for the second indication, transarticular screw fixation of the C**1** and C**2** (atlas and axis) vertebra are described in the articles previously incorporated by reference and will not be discussed in any detail here. Suffice it to say that the desired result is the fusion of C**1** and C**2** together using a posterior approach wherein the screw goes across the C**1**/C**2** joint in the back. Using the standard technique generally requires a very long incision in order to get the appropriate trajectory. The incision would have to be made all the way into the thoracic area of the spine in order to get the correct entry angle since it is a very steep shot for the drill, tap, and screw, respectively. Indeed, the articles describing the standard technique recommend making an incision from C**1** all the way down to C**7** (see incision **65***a* of FIG. **10**). In contrast, the use of the screw delivery system and method of the present invention requires only a small midline incision **65** (see FIG. **12**) at the C**1**/C**2** region and two percutaneous incisions **60***a* and **60***b* (see FIG. **12**) around the upper thoracic area through which the screw delivery system of the present invention is introduced and directed toward the surgical site at the joint between C**1** and C**2**. This surgical site is viewed directly through the small midline incision **65** made.

The third indication mentioned above as deriving particular benefit through use of the screw delivery system of the present invention is placing a screw across a lumbar facet joint to fuse the joint between two lumbar vertebra. This may be done rather than putting pedicle screws in and then attaching those anchors (the pedicle screws) to a rod, plate or other longitudinal element spanning the intervertebral disc or the space left behind after it is excised. Instead, in this procedure, the surgeon simply places two screws in the shape of an X (when viewed from above a prone patient) across the lumbar facet joint. This is usually done in combination with an anterior interbody fusion which has more recently undergone an upsurge in popularity with the use of devices known as cages. The benefits of simply putting screws across the lumbar facet joint as to the more complex apparatus involving insertion of pedicle screws and attaching longitudinal elements to the anchors is that putting screws across the lumbar facet joint results in a very, very low profile implant.

Again, this third indication is a minimally invasive procedure which is a combination of percutaneous and open techniques. As with the cervical fusion described in the second indication, a small midline incision **55** (see FIG. **11**) is made over the two vertebra to be fused which goes right down to the facet joint. Each screw goes across the lamina from the posterior spinous process, being driven across the facet joint which is out laterally and downstream. The entry point for the drill bit (and the tap and screw) is again out and aside, up in the flank. The joint between the lumbar vertebrae is fairly deep and the exit point of the drill bit and the screw is intended to be fixed deep into the joint. The screw's entry point is the posterior spinous process on the contralateral side. The screw travels between the anterior and posterior cortices of the laminae to enter the inferior articular process. The screw then crosses the facet joint—entering the superior articular process and then exiting at the base of the transverse process and pars interarticularis.

The screw delivery system of the present invention is beneficial, both in the three indications described above, as well as in other procedures known to those of ordinary skill in the art. The screw delivery system of the present invention

permits the making of one or more small percutaneous portals through which the implant and interventional devices are introduced. After making an incision at midline or otherwise permitting viewing of the surgical site, the docking part of the multi-sleeve device of the screw delivery system of the present invention is introduced and directly abuts the surgical site as desired. Then a surgeon may drill, tap, and insert the screw through the percutaneous portal provided by the screw delivery system of the present invention.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed:

1. A screw delivery system kit for providing a minimally invasive portal with a small entry angle to a surgical site, comprising:

an outer cannula having a first exterior surface and a first interior surface defining a bore, the first interior surface having a first inner diameter and the first exterior surface having a first outer diameter, the surfaces extending along a first length on a first axis between a first proximal end having a first stop and a first distal end;

a trocar having a second exterior surface with a second outer diameter, the second exterior surface extending along a second length on a second axis between a second proximal end having a second stop and a second distal end defining a blunt tip;

a guide having a handle and a tube, the tube having a third exterior surface and a third interior surface defining a passageway, the third interior surface having a third inner diameter and the third exterior surface having a third outer diameter, the third interior surface extending between a third proximal end and a third distal end, the third exterior surface extending along a third length on a third axis between a third stop at the third proximal end and the third distal end, the handle being connected to the tube at an angle to the third axis; and

a bone drill bit having a fourth exterior surface with a fourth outer diameter extending along a fourth length on a fourth axis between a fourth stop located near a fourth proximal end and a plurality of drilling flutes defined on a fourth distal end.

2. The kit of claim **1**, further including a bone tap having a fifth exterior surface with a fifth outer diameter extending between a fifth stop located near a fifth proximal end and a fifth distal end having threading thereon for tapping an opening in bone created by said bone drill bit.

3. The kit of claim **2**, wherein the fifth exterior surface has a plurality of length markings adjacent the fifth stop, the length markings being located on the fifth exterior surface between the fifth stop and the fifth distal end of said bone tap.

4. The kit of claim **1**, wherein the fourth exterior surface has a plurality of length markings adjacent the fourth stop, the length markings being located on said fourth exterior surface between the fourth stop and the fourth distal end.

5. The kit of claim **1**, further including an adjustable length stop having a length.

6. The kit of claim **5**, wherein said adjustable length stop is a series of interconnected cylindrical elements.

7. The kit of claim **6**, further including a cutter for adjusting the length of said adjustable length stop.

8. The kit of claim **5**, wherein said adjustable length stop has an outer surface and an inner surface defining a bore with a bore diameter, the bore diameter of said adjustable length stop being greater than the fourth outer diameter.

9. The kit of claim **1**, wherein the first distal end defines a plurality of serrations.

10. The kit of claim **9**, wherein the serrations have a crescent moon shape.

11. The kit of claim **1**, further including an implant driver for inserting a screw.

12. The kit of claim **11**, wherein said implant driver is a screwdriver, said screwdriver having a handle at a first end and a tip at a second end of said screwdriver.

13. The kit of claim **12**, wherein the tip of said screwdriver has a polygonal head matching a polygonal socket in the screw.

14. The kit of claim **1**, wherein the first stop of said outer cannula is the circumference of the exterior surface of said outer cannula at the first proximal end.

15. The kit of claim **1**, wherein the first stop of said outer cannula is an annular flange.

16. The kit of claim **1**, further including a bone tap and an adjustable length stop, said bone tap having a fifth exterior surface with a fifth outer diameter extending between a fifth stop located near a fifth proximal end and a fifth distal end having threading thereon for tapping an opening in bone created by said bone drill bit, said adjustable length stop having an outer surface and an inner surface defining a bore with a bore diameter, the bore diameter of said adjustable length stop being greater than the fourth outer diameter and the fifth outer diameter.

17. A method of inserting a screw into a bone through a minimally invasive portal comprising:

making a first incision for viewing over a surgical site;

making a second incision spaced apart from the first incision;

inserting an outer cannula having a bore defined between a proximal end and a distal end and a trocar through the bore into the second incision;

advancing the outer cannula and trocar toward the surgical site until the distal end contacts the surgical site;

removing the trocar from the outer cannula;

drilling an opening in the bone;

screwing a screw into the opening in the bone.

18. The method of claim **17**, further including tapping the opening in the bone before screwing the screw into the opening in the bone.

19. The method of claim **17**, wherein said bone includes a pair of spinal vertebrae, and wherein said act of screwing comprises screwing at least one screw through one vertebra and into a second vertebra.

20. The method of claim **19**, herein said act of screwing screws into vertebral bone is done in combination with at least one interbody fusion implant between the vertebrae.

21. The method of claim **20**, wherein said act of screwing comprises screwing at least one screw across a facet joint of the vertebrae.

22. The method of claim **20**, wherein said act of screwing comprises transarticular screw fixation of the C1 and C2 cervical vertebrae.

23. The method of claim **17**, wherein said act of screwing comprises screwing a vertebral odontoid fracture.

24. The method of claim **17**, wherein said act of screwing comprises screwing at least one screw across a facet joint of the vertebrae.

25. The method of claim **17**, wherein said act of screwing comprises transarticular screw fixation of the C**1** and C**2** cervical vertebrae.

26. A screw delivery system kit for providing a minimally invasive portal to a surgical site comprising:

an outer cannula;

a trocar;

means for drilling an opening in a bone at the surgical site;

means for aiming said means for drilling; and

means for screwing a screw into the opening in the bone.

27. The kit of claim **26**, further including means for tapping the opening in the bone of the surgical site, wherein said means for aiming said means for drilling is also means for aiming said means for tapping.

28. The kit of claim **26**, further including a screw adapted for transarticular screw fixation of the C**1** and C**2** cervical vertebrae.

29. The kit of claim **28**, further comprising at least one interbody fusion implant.

30. The kit of claim **26**, further including a screw adapted for screwing at least one screw across a facet joint of the vertebrae.

31. The kit of claim **30**, further comprising at least one interbody fusion implant.

32. The kit of claim **26**, further including a screw adapted for screwing a vertebral odontoid fracture.

33. The kit of claim **32**, further comprising at least one interbody fusion implant.

34. The kit of claim **26**, further comprising at least one interbody fusion implant.

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(12) **United States Patent**
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(54) **SCREW DELIVERY SYSTEM AND METHOD**

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This patent is subject to a terminal disclaimer.

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(52) **U.S. Cl.** **606/96**; 606/80; 606/98
(58) **Field of Search** 606/80, 96, 97, 606/98, 104

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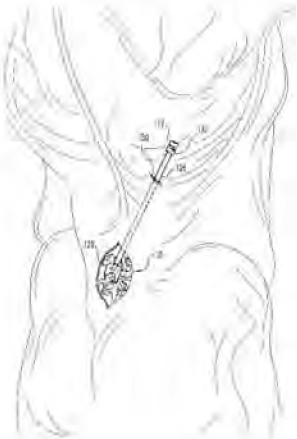
(57) **ABSTRACT**

A screw delivery system and method are disclosed for use in a variety of surgical indications. The screw delivery system generally comprises an outer cannula, a guide, and various interventional devices such as bone drill bits and taps as well as an implant driver for inserting a screw. The method disclosed varies by indication, but is ordinarily intended for use as a minimally invasive procedure which is a combination of percutaneous and open techniques wherein a small midline incision is made over a surgical site and the screw delivery system provides a percutaneous portal through an incision distant from the small midline incision over the surgical site.

32 Claims, 6 Drawing Sheets



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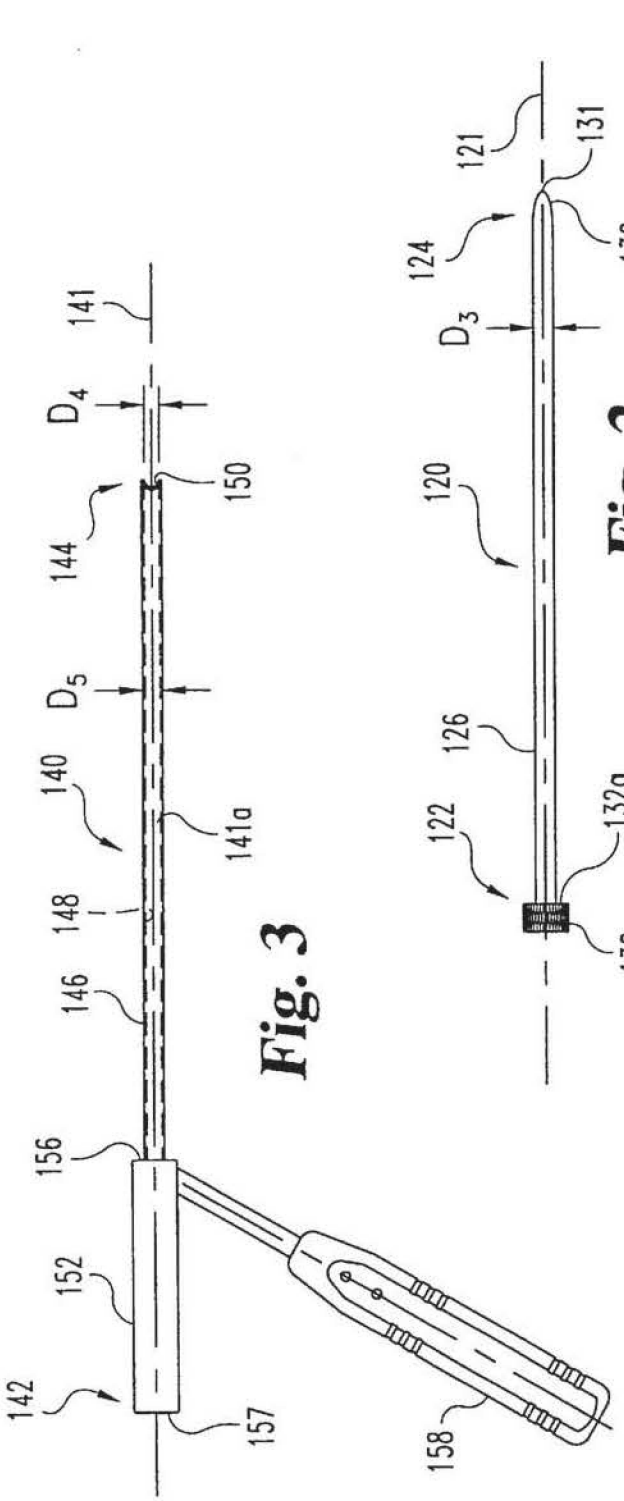

Fig. 3

Fig. 2

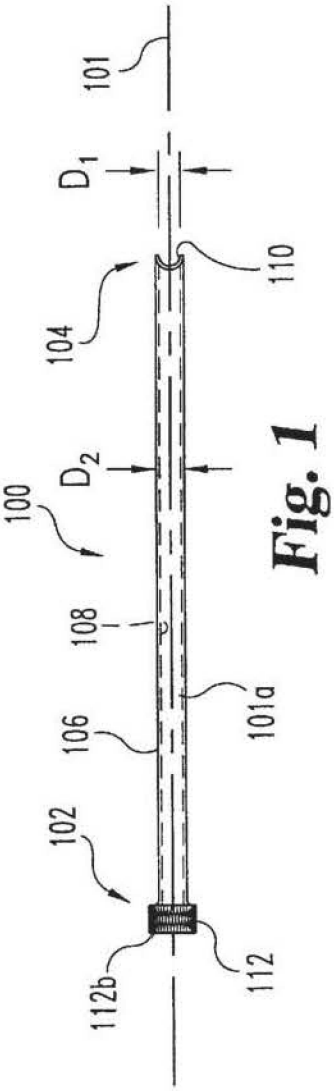

Fig. 1

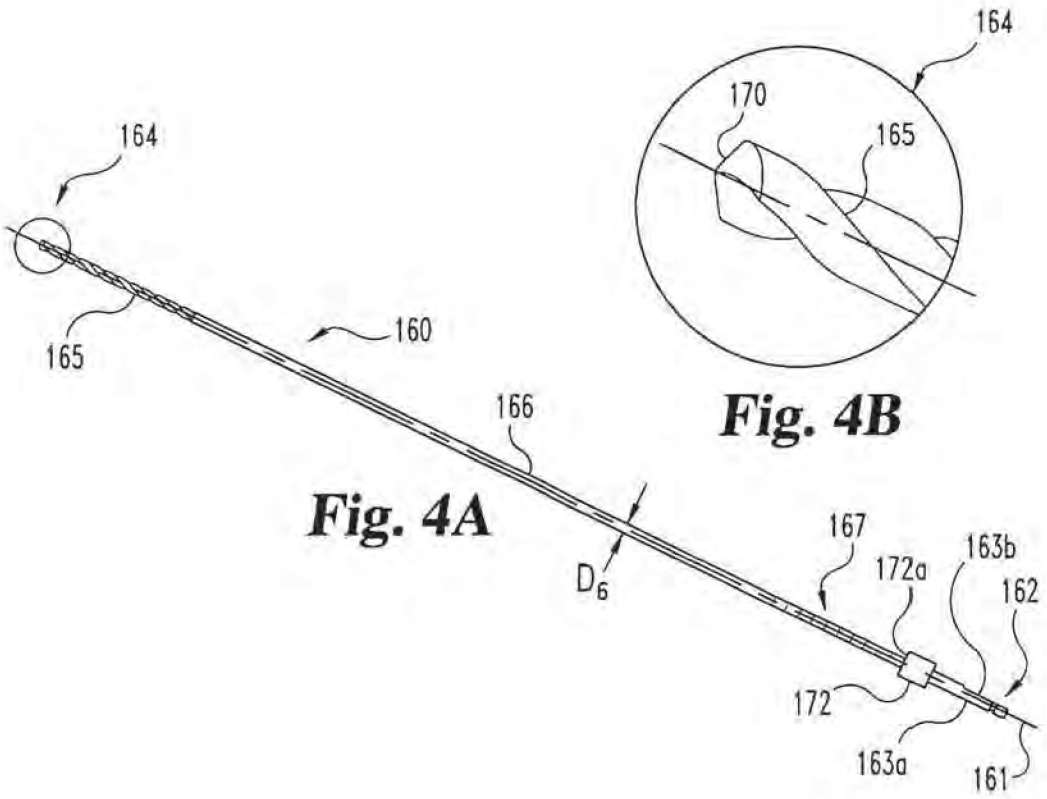

Fig. 4A

Fig. 4B

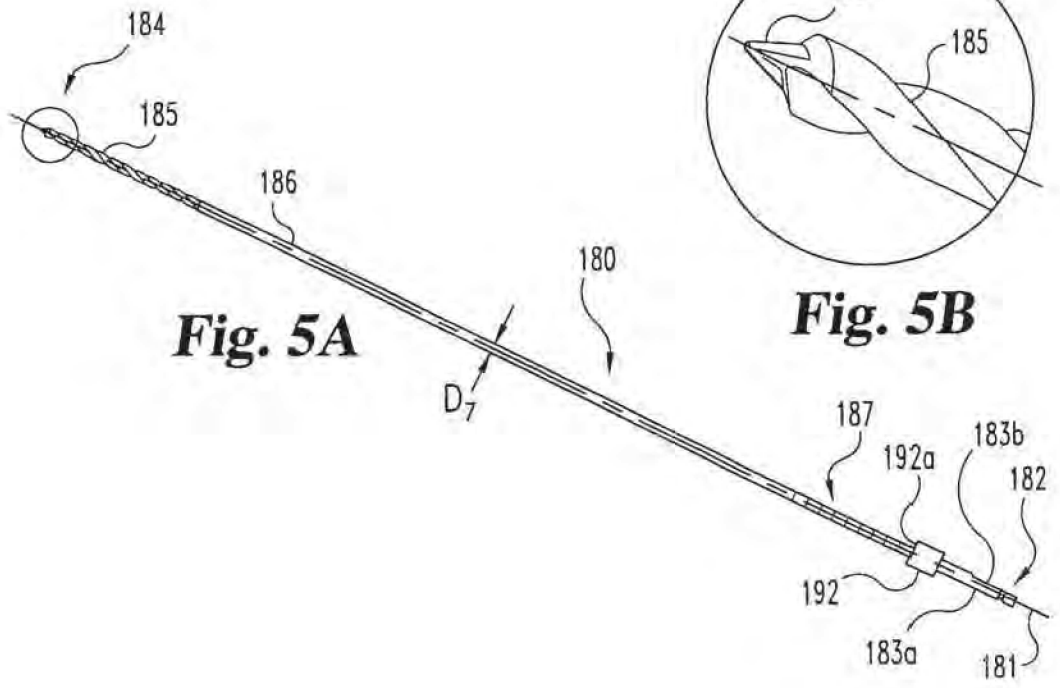

Fig. 5A

Fig. 5B

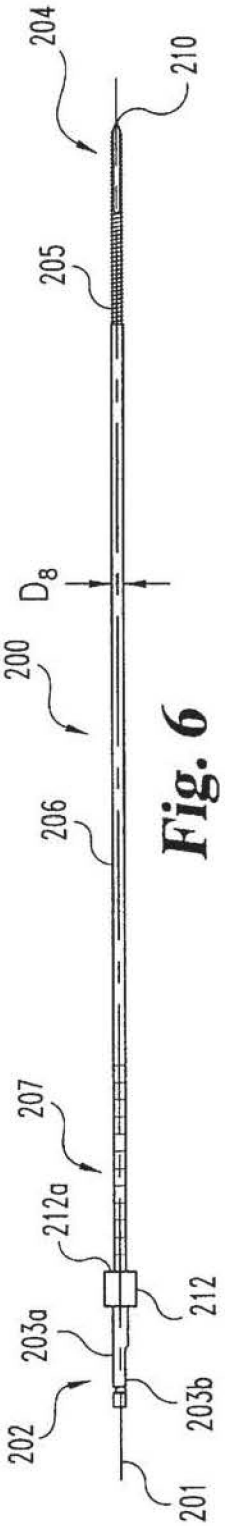

Fig. 6

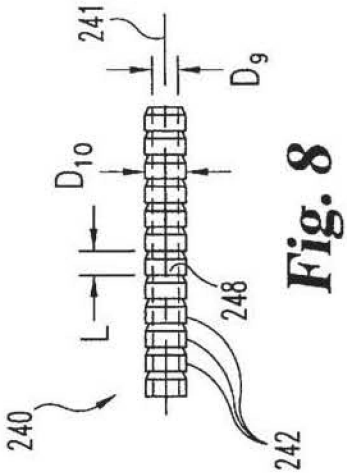

Fig. 8

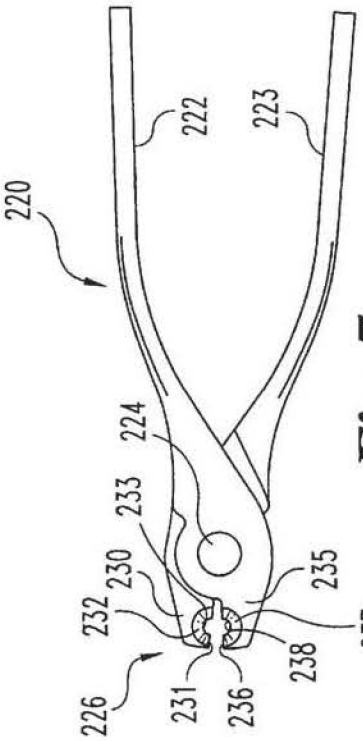

Fig. 7

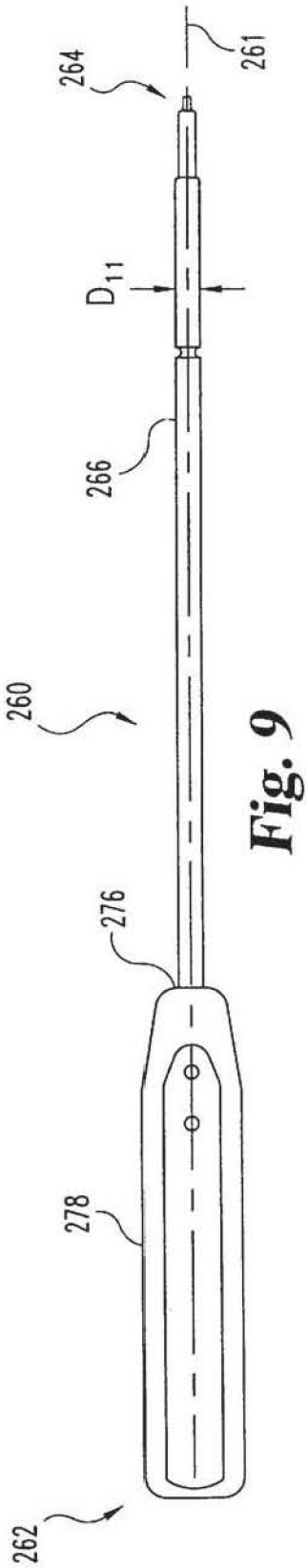

Fig. 9

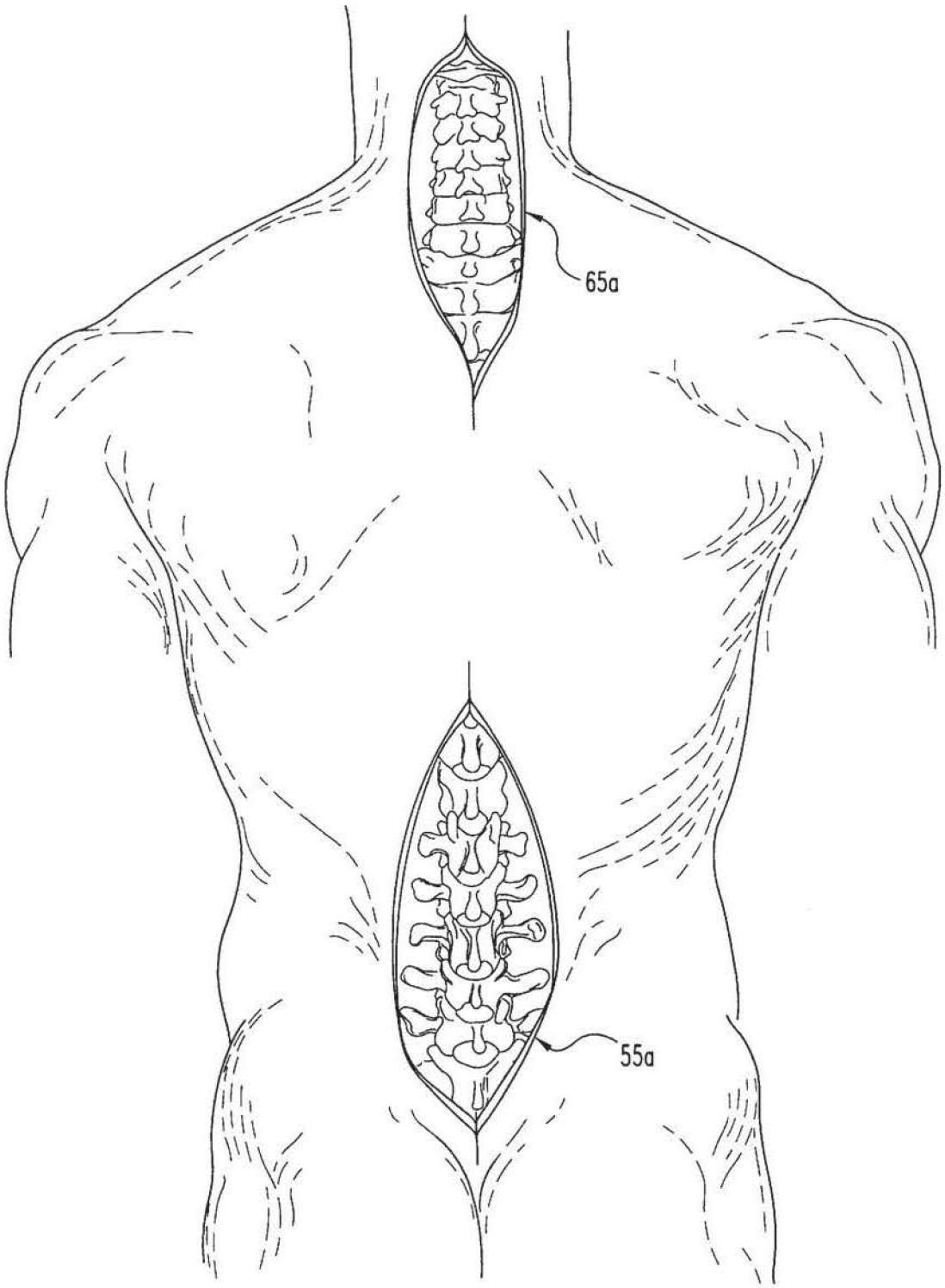

Fig. 10
(PRIOR ART)

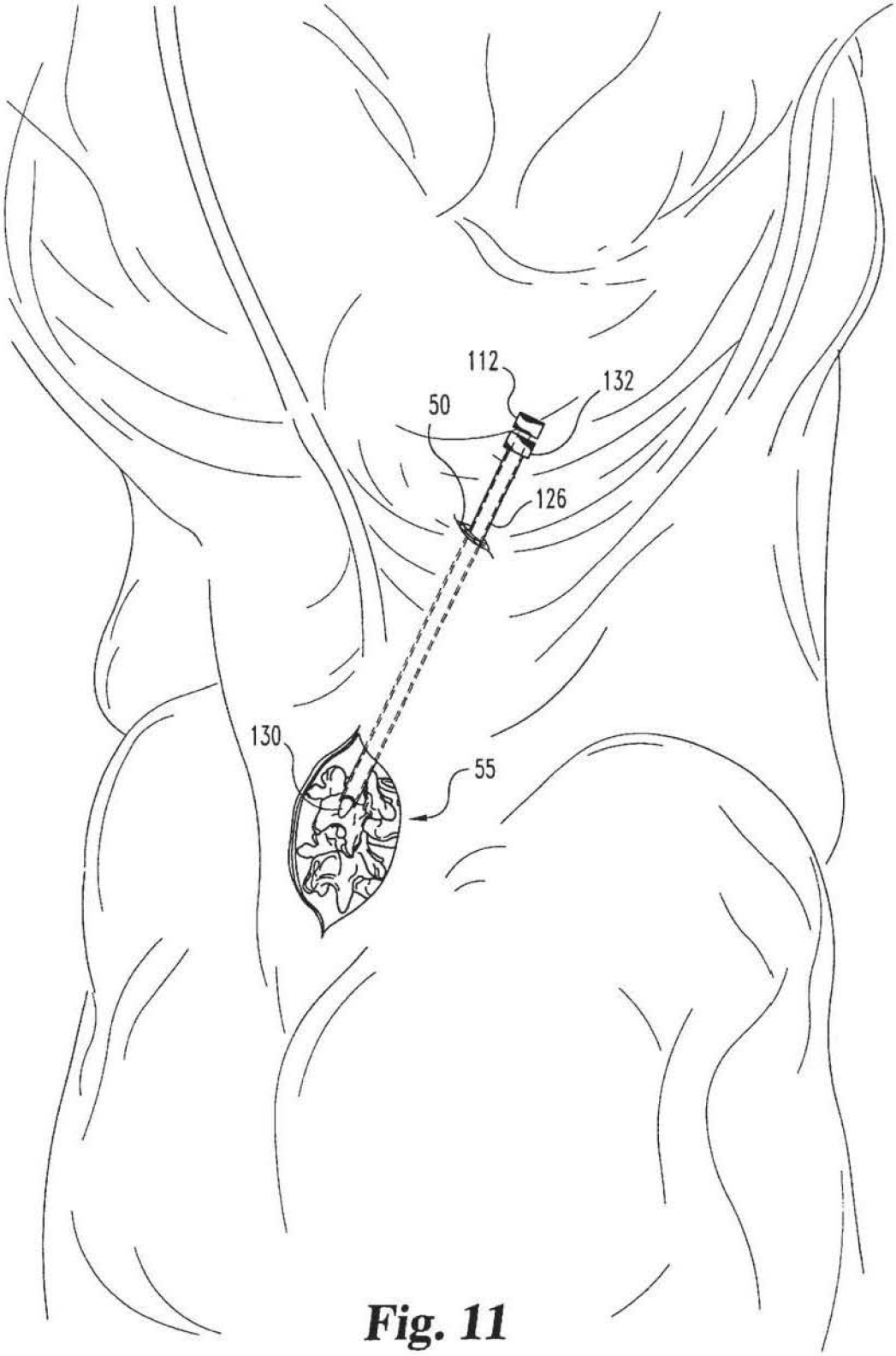

Fig. 11

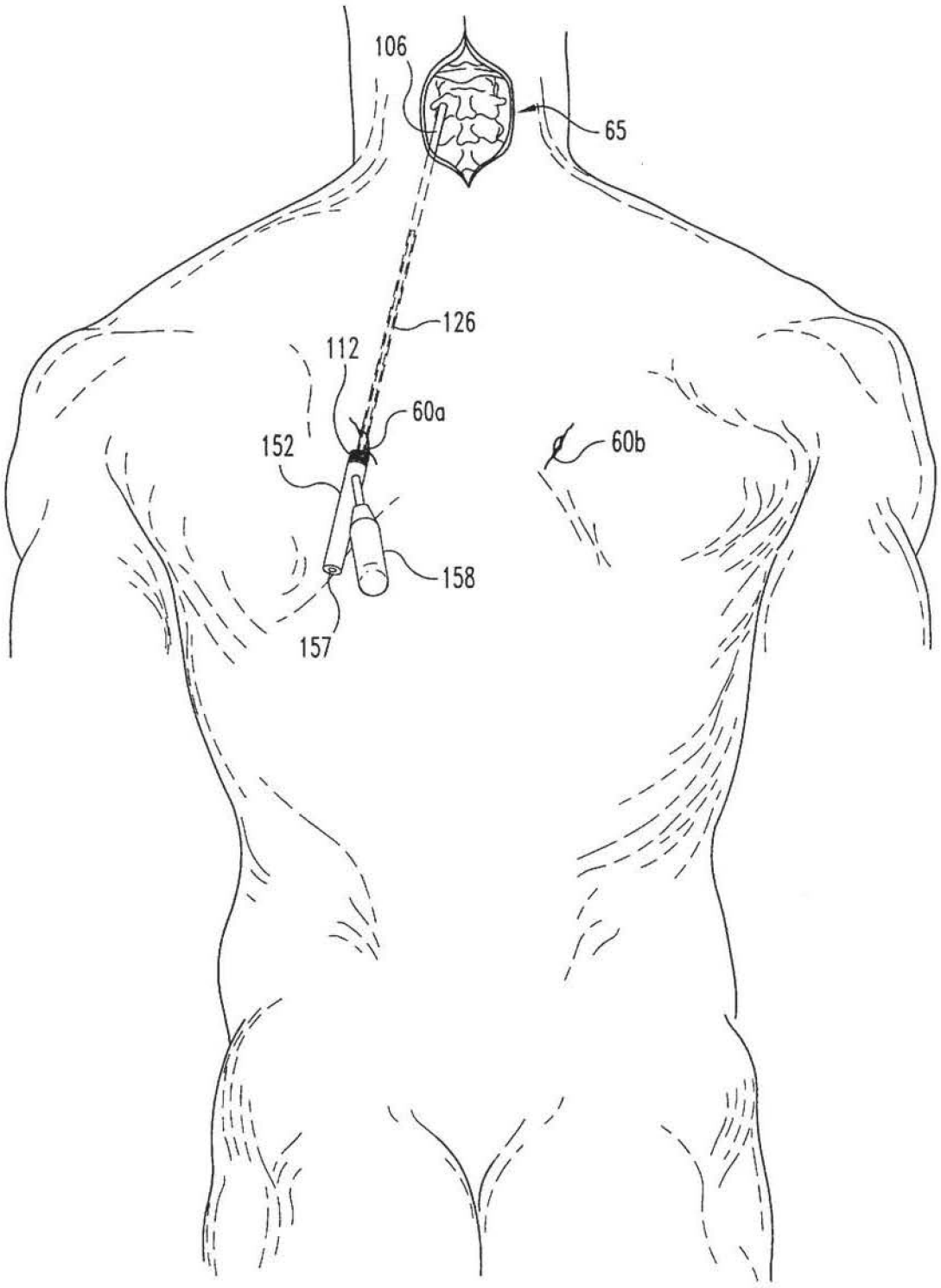

Fig. 12

SCREW DELIVERY SYSTEM AND METHOD

This is a continuation of application Ser. No. 09/448,361, filed Nov. 23, 1999.

BACKGROUND

The human spine is a flexible weight bearing column formed from a plurality of bones called vertebrae. There are 33 vertebrae which are named based on which of five regions (cervical, dorsal, lumbar, sacral, and coccygeal) in which they are found. Going from the top of the spine down, in general there are seven cervical vertebra, twelve dorsal vertebra, five lumbar vertebra, five sacral vertebra, and four coccygeal vertebra. The vertebra of the cervical, dorsal, and lumbar regions of the spine are separate throughout the life of an individual, but the vertebra of the sacral and coccygeal regions in an adult are fused to form two bones, the five sacral vertebra entering into the formation of the sacrum and the four coccygeal vertebra into the coccyx. In general, each vertebra contains an anterior, solid segment or body and a posterior segment or arch. The arch is generally formed of two pedicles and two laminae, supporting seven processes—four articular, two transverse, and one spinous. There are exceptions to these general characteristics of a vertebra. For example, the first cervical vertebra (atlas vertebra) has neither a body nor spinous process. Also, the second cervical vertebra (axis vertebra) has an odontoid process, which is a strong, prominent process, shaped like a tooth, rising perpendicularly from the upper surface of the body of the axis vertebra. Further details regarding the construction of the spine are known to those of ordinary skill in the art and may be found in such common references as *Gray's Anatomy*, Crown Publishers, Inc., 1977, pp. 33–54, which is herein incorporated by reference.

The past two decades have seen greatly increased use of implants for the stabilization of fractures and/or fusion of various portions of the spine. These implant devices include a variety of longitudinal elements such as rods or plates which span two or more vertebra and are affixed to the vertebra by various fixation elements such as wires, staples, and screws (often inserted through the pedicles of the vertebra). These systems may be affixed to either the posterior or the anterior side of the spine. In many cases, these implant systems are prominent beneath the skin and have a higher profile than more simple fixation devices. One such simpler fixation device is in the stable posterior fusion of the atlas and axis vertebra by transarticular screw fixation using the technique of Magerl et al. disclosed in *Stable Posterior Fusion of the Atlas and Axis by Transarticular Screw Fixation*, F. Magerl, P-S. Seeman, *Cervical Spine*, Volume 1, Springer-Verlag, Copyright 1987, pp. 322–327; *Primary Posterior Fusion* 1-2 *in Odontoid Factors; Indications, Technique, and Results of Transarticular Screw Fixation*, B. Jeanneret and F. Magerl, *Journal of Spinal Disorders*, Volume 5, No. 4, pp. 464–475, 1992, Raven Press, Ltd., New York; (also see *Atlanto-Axial Fusion With Transarticular Screw Fixation*, D. Grob, B. Jeanneret, M. Aebi, and T. M. Markwalder, *The Journal of Bone and Joint Surgery*, Volume 73-B, No. 6, 1991, pp. 972–976) all of which are herein incorporated by reference.

The use of transarticular screw fixation in both fusion procedures and stabilization procedures for fractures has undergone increasing use. However, due to the small entry angle of the screw with respect to the back of a patient lying prone on the operating table, procedures making use of transarticular screw fixation have required extremely long and wide midline incisions in order to place the screws as necessary in various procedures in both the cervical and lumbar spine regions. These large incisions result in increased operating time with consequent increase in blood loss as well as enlarging the size of the scar left on the patient. It should be understood that while reduction of pain and maintaining range of motion are the surgical goal, the size of the incision and the scar it leaves behind are often the only visible measure a patient will have to judge the quality of the surgeon's work. Thus, it is preferable if the incision is made in a manner not only to preserve the skin's contour, but of a minimum length and size to increase patient satisfaction.

SUMMARY OF THE INVENTION

One embodiment of the present invention is a screw delivery system kit for providing a minimally invasive portal with a small entry angle to a surgical site, comprising an outer cannula, a trocar, a guide and a bone drill bit. The outer cannula has a first exterior surface and a first interior surface defining a bore. The first interior surface has a first inner diameter and the first exterior surface has a first outer diameter. The surfaces extend along a first length on a first axis between a first proximal end having a first stop and a first distal end. The trocar has a second exterior surface with a second outer diameter. The second exterior surface extends along a second length on a second axis between a second proximal end having a second stop defined thereon and a second distal end defining a blunt tip. The guide has a handle and a tube. The tube has a third exterior surface and a third interior surface defining a passageway. The third interior surface has a third inner diameter and the third exterior surface has a third outer diameter. The third interior surface extends between a third proximal end and a third distal end. The third exterior surface extends along a third length on a third axis between a third stop at the third proximal end and the third distal end. The handle is connected to the tube at an angle to the third axis. The bone drill bit has a fourth exterior surface with a fourth outer diameter extending along a fourth length on a fourth axis between a fourth stop located near a fourth proximal end and a plurality of drilling flutes defined on a fourth distal end.

Another embodiment of the invention is a method of inserting a screw through a minimally invasive portal comprising making a first incision for viewing over a surgical site and making a second incision spaced apart from the first incision. Then an outer cannula having a bore defined between a proximal end and a distal end and a trocar through the bore are inserted into the second incision. The outer cannula and trocar are advanced toward the surgical site until the distal end contacts the surgical site at which time the trocar is withdrawn from the outer cannula. An opening in the bone is then drilled followed by screwing a screw into the opening in the bone.

Yet another embodiment of the present invention is a screw delivery system kit for providing a minimally invasive portal to a surgical site comprising: an outer cannula; a trocar; means for drilling an opening in a bone at the surgical site; means for aiming said means for drilling; and means for screwing a screw into the opening in the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of the outer most cannula of a screw delivery system of the present invention.

FIG. **2** is a trocar for use with the outer cannula of FIG. **1** for initial insertion of the screw delivery system into the patient.

FIG. **3** is a side view of a guide for insertion into the outer cannula of FIG. **1** for more accurately directing the bone drill bits and taps of FIGS. **4–6**.

FIG. **4**A is a standard bone drill bit for use in a screw delivery system of the present invention.

FIG. **4**B is an enlarged portion of the bone drill bit tip of FIG. **4**A.

FIG. **5**A is a side view of an improved bone drill bit for use with the screw delivery system of the present invention.

FIG. **5**B is an enlarged view of the tip of the bone drill bit of FIG. **5**A.

FIG. **6** is a side view of a bone tap for use with the present invention.

FIG. **7** is a side view of a cutter for adjusting the length of the adjustable length stop of FIG. **8**.

FIG. **8** is a side view of an embodiment of an adjustable length stop of the present invention.

FIG. **9** is a side view of a screwdriver for use in the screw delivery system of the present invention.

FIG. **10** is a top view of the back of a patient lying prone illustrating the size of the prior art incision made in the cervical and lumbar regions for transarticular screw fixation.

FIG. **11** is an illustration of the insertion of the bullet-shaped trocar of FIG. **2** through the outer cannula of FIG. **1** creating a percutaneous portal in the back distal from a lumbar vertebra surgical site.

FIG. **12** is a top view of the use of the screw delivery system of the present invention on a patient lying prone with the surgical site in the cervical vertebra region.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

With respect to FIG. **1** there is illustrated outer cannula **100** extending along longitudinal axis **101**. Outer cannula **100** provides the primary passageway for screw implantation to a surgical site through a percutaneous portal (as discussed further below) distant from the surgical site. Many of the spinal surgeries for which the screw delivery system and method of the present invention will find use in involve very small entrance angles for the screw with respect to the spine of a patient lying prone. The outer cannula **100** has a bore **101***a* extending between the near end **102** and far end **104** of the outer cannula **100**. Outer cannula **100** has an exterior surface **106** and an interior surface **108**, interior surface **108** defining bore **101***a*. The far end **104** of outer cannula **100** terminates in a tip **110**. Tip **110** is shown as having serrations with a crescent moon-like shape for ease of contacting the surgical site (i.e., bone of a vertebra). It should be understood, however, that the tip **110** may take a variety of shapes and forms other than the crescent moon illustrated.

The near end **102** of outer cannula **100** has an annular flange or stop **112**. Bore **101***a* also extends through the annular flange **112**. The stop **112** acts in combination with the stops on other devices inserted through the bore **101***a* of the outer cannula to prevent over-insertion of the various bone drill bits, taps, and other probes and interventional devices and prevents possible damage to the surgical site resulting from over-insertion. It should be understood that stop **112** need not be in the shape of an annular flange, but may simply be a plurality of projections extending from the exterior surface **108** of outer cannula **100**. It should be further understood that the stop **112** of outer cannula **100** may also be simply the circumference of the exterior surface **108** of outer cannula **100** at the near end **102**. This is because the stops of the other probes or interventional devices (e.g., bone drill bits, bone taps, guides) will contact the circumference of the near end **102** of the exterior surface **106** of outer cannula **100**. It should also be understood that the preferred embodiment is for outer cannula **100** to possess an annular flange **112**. Outer cannula **100** has an inner diameter D1 for bore **101***a* and an outer diameter D2 as illustrated in FIG. **1**.

With respect to FIG. **2** there is illustrated a trocar **120** extending along a longitudinal axis **121** between a proximal end **122** and a distal end **124**. Trocar **120** is preferably, but not necessarily, a solid shaft having an exterior surface **126** between the proximal end **122** and the distal end **124**. The distal end **124** of trocar **120** has a bullet-shaped head **130** with a blunt tip **131** for minimizing the trauma to the tissue as the combination of the trocar **120** and the outer cannula **100** are used as a soft tissue penetrator or introducer from a distal incision **50** on the back to the surgical site **55** of the vertebra (see FIG. **11**). Trocar **120** has an annular flange or stop **132** at the proximal end **122**. The exterior surface **126** of trocar **120** has an outer diameter D**3**. The outer diameter D3 of trocar **120** is less than the inner diameter D1 of outer cannula **100** which is in turn less than the outer diameter D2 of outer cannula **100**. Since the outer diameter D3 is less than the inner diameter D1, the exterior surface **126** of trocar **120** may be inserted through the bore **101***a* of outer cannula **100**. It should be understood that to act as a soft tissue penetrator, the trocar **120** need merely have an unbroken surface at bullet-shaped head **130** and whatever other portion extends beyond the far end **104** of outer cannula **100**. Thus, while FIG. **2** illustrates trocar **120** as a solid shaft, variations as would occur to a person of ordinary skill in the art for the connection between the distal end **124** and the proximal end **122** of trocar **120** are contemplated as within the scope of the invention.

The trocar **120** has a length such that when inserted through the bore **101***a* of outer cannula **100**, the bullet-shaped head **130** will extend past the tip **110** of outer cannula **100**. When the trocar **120** is inserted as far as possible through the bore **101***a* of outer cannula **100**, the front face **132***a* of the annular flange **132** will contact the rear face **112***b* of stop **112** of outer cannula **100** (see FIG. **11**). At or near this point the bullet-shaped head **130** will extend past the tip **110** of outer cannula **100** thus permitting the trocar **120** and outer cannula **100** to be percutaneously inserted through an incision **50** distal from the surgical site **55**. Thus, despite the fact that the desired entry angle for transarticular screw fixation is very small, the large midline incision of current techniques is unnecessary. Only a small midline incision directly over the surgical site is necessary, as the passageway provided by bore **101***a* of outer cannula **100** of the screw delivery system permits the introduction of all the tools, implants, and interventional devices necessary to stabilize the spine using transarticular screw fixation. It should be understood that while the illustration of FIG. **11** demonstrates the applicability of the soft tissue penetrator

combination of trocar **120** with outer cannula **100** in the lumbar vertebra of the spine, the screw delivery system of the present invention is equally useful for avoiding the necessity of a large midline incision when a surgical site is, for example, in a cervical vertebra as is the case in a transarticular screw fixation across the atlanto-axial joint (see FIG. **12**).

The devices used through the bore **101***a* of outer cannula **100** in various embodiments of the present invention are illustrated in FIGS. **3–9** and are discussed in more detail below. After the details of the individual components of various embodiments of the present invention are outlined, the method of their use will be discussed in further detail. With reference to FIG. **3**, there is illustrated one embodiment of a device for more accurately aiming various embodiments of bone drill bits and bone taps to the appropriate lengths. The guide **140** generally extends along a longitudinal axis **141** (with the exception of the handle **158**). The guide **140** has a bore **141***a* defined by an interior surface **148** extending between the proximal end **142** and the distal end **144**. The guide **140** has an exterior surface **146** defined between the proximal end **142** and the distal end **144** which terminates in a tip **150**. The proximal end **142** of the guide **140** has an annular flange or stop **152** with a front face **156** and a rear face **157**. The exterior surface **146** has an outer diameter D5 and the interior surface **148** has an inner diameter D4.

The guide **140** has a handle **158** which is connected at an angle to the stop **152**. It should be understood, however, that the handle **158** may be located/connected at a variety of locations. The handle **158** is at an angle transverse to the longitudinal axis **141**. The angle of the handle is relevant to many of the applications with small entry angles as it should not be perpendicular to the longitudinal axis **141**. It should also be understood that the angle that the handle **158** makes with respect to the longitudinal axis **141** is preferably less than 60 degrees. The outer diameter D5 is greater than the inner diameter D4, but is less than the inner diameter D1 of the outer cannula **100**. Thus, the exterior surface **146** may be inserted through the bore **101***a* of outer cannula **100** until the front face **156** of guide **140** contacts the rear face **112***b* of stop **112** of outer cannula **100**. As discussed further below, when the front face **156** is in contact with the rear face **112***b* of a stop **112** of outer cannula **100**, various other instruments are inserted through the bore **141***a* as well as the bore **101***a* such as the bone drill bits **160**, **180**, and tap **200** discussed below.

With reference to FIG. **4**A, there is illustrated a side view of a standard bone drill bit **160** extending along an axis **161** between a proximal end **162** and a drilling end **164**. The proximal end **162** has a surface adapted for the application of force to rotate the bone drill bit **160**. In one embodiment, as illustrated in FIG. **4**A, the standard bone drill bit **160** has a half solid cylinder **163***a* and a flattened portion **163***b* at the proximal end **162** to permit rotation of the standard bone drill bit **160**. With reference to FIGS. **4**A and **4**B, the drilling end **164** has a plurality of flutes **165** and a standard drill tip **170**. Standard bone drill bit **160** has an exterior surface **166** extending between the front face **172***a* of annular flange or stop **172** and the beginning of the flutes **165** making up the drilling end **164** of standard bone drill **160**. The exterior surface **166** of standard bone drill **160** has an outer diameter D6. Additionally, the portion of exterior surface **166** near annular flange or stop **172** preferably has a plurality of length markings **167**.

With reference to FIGS. **5**A and **5**B, there is illustrated the preferred embodiment of a bone drill bit **180** for use in the screw delivery system and method of the present invention. It should be understood that due to the small entry angle between the bone drill bit and the bone in the spine/vertebra of the surgical site, that a standard bone drill bit **160** has a blunt end that is difficult to get started. The tip **170** of the bone drill bit **160** has a tendency to walk along the surface, making accurate placement difficult. Thus, the more preferred embodiment is bone drill bit **180** which extends along an axis **181** between a proximal end **182** and drilling end **184**. Similar to the standard bone drill bit, the preferred bone drill **180** has a half solid cylinder **183***a* and a flattened portion **183***b* at proximal end **182** for use in rotating the bone drill bit **180**. The drilling end **184** of bone drill bit **180** has a plurality of flutes **185**. Bone drill bit **180** has an exterior surface **186** extending between the front face **192***a* of annular flange or stop **192** and the beginning of the plurality of flutes **185** on the drilling end **184**. Bone drill bit **180** has a sharper angled drill tip **190** at the end of drilling end **184** which permits ease of insertion when beginning to drill even at the small entry angles preferably less than 45° (not perpendicular to bone) for the methods of use of the screw delivery system discussed further below. The exterior surface **186** of bone drill bit **180** has an outer diameter D7. Both outer diameter D7 and outer diameter D6 are less than the inner diameter D4 of guide **140**. In a preferred embodiment, the guide **140** has an inner diameter D4 which is only slightly larger than the outer diameter **D6** or outer diameter D7 of bone drills **160**, **180**, respectively. This permits more accurate placement of the drill tips **170**, **190** and minimizes deviations from side to side of the axis **161**, **181**, respectively when drilling.

With reference to FIG. **6** there is illustrated a side view of a bone tap **200** for use with a screw delivery system of the present invention. Bone tap **200** extends along axis **201** between proximal end **202** and tapping end **204**. Similar to the bone drill bits **160**, **180**, the proximal end **202** of tap **200** has a solid half cylinder **203***a* and a flattened portion **203***b* to permit rotation of the bone tap **200**. As is understood by those of ordinary skill in the art, the tapping end **204** of bone tap **200** has threading **205** thereon and a tip **210** for creating threading in the opening or bore in the bone created by a bone drill bit **160**, **180**. Bone tap **200** has an exterior surface **206** extending between the front surface **212***a* of annular flange or stop **212** and the beginning of the threading **205** at the tapping end **204**. The exterior surface **206** has an outer diameter D8 which is less than the inner diameter D4 of the guide **140** to permit the bone tap **200** to be inserted through the bore **141***a* of guide **140**. As with the bone drill bits **160**, **180**, the exterior surface **206** of bone tap **200** preferably has a plurality of length markings **207** on the portion of exterior surface **206** adjacent the annular flange or stop **212**.

With reference to FIGS. **7** and **8** there are illustrated side views for the cutter (FIG. **7**) and the adjustable length stop (FIG. **8**). In particular with reference to FIG. **7**, cutter **220** has handles **222**, **223** which are pivotally connected around hinge **224**. The cutting end **226** of cutter **220** is made up of a first cutting element **230** and a second cutting element **235**. The first cutting element **230** has a first sharp edge **231** adjacent a circular depression **232** which has its own cutting edge **233**. Similarly, second cutting element **235** has a second sharp edge **236** adjacent another circular depression **237** having its own cutting edge **238**. It should be understood that cutter **220** is intended for use on the adjustable length stop **240** as illustrated in FIG. **8**.

The adjustable length stop **240** has integrally connected individual cylindrical elements **242** with a length L and an inner diameter D9 and an outer diameter D10. The individual cylindrical elements **242** of adjustable length stop **240**

extend along a longitudinal axis **241**. The individual cylindrical elements **242** of the adjustable length stop **240** define a bore **248** extending along the axis **241**. In one embodiment, the length L of the individual cylindrical elements **242** corresponds to the distance between the length markings such as length markings **207** on bone tap **200**, length markings **187** on bone drill bit **180**, and/or length markings **167** on bone drill bit **160**. It is contemplated as within the scope of the invention, however, that the length of the individual cylindrical elements may be different than that of the markings on the respective bone drill bits and taps, and that the length of each individual cylindrical element may vary on a single adjustable length stop **240**. It should be understood that the inner diameter D9 of bore **248** of the adjustable length stop **240** should be greater than diameters D8, D7, D6, but is less than D5 which in turn is less than D1 which is less than D2. It should also be understood that the outer diameter D10 should be greater than either the outer diameter D5 of the guide **140** or at least of a sufficient diameter so that the adjustable length stop **240** will act as a contact mechanism to prevent further insertion of the bone drills or bone taps upon contacting the rear face **157** of annular flange or stop **152** of the guide **140**. Similarly, in those embodiments of the device where a guide **140** is not utilized, but instead only the outer cannula **100** is, the outer diameter D10 should be such that the adjustable length stop **240** will contact the rear surface **112***b* of annular flange or stop **102** of outercannula **100**.

With reference to FIG. **9**, there is illustrated a side view of an implant driver in the form of a screwdriver **260** for use with the screw delivery system of the present invention. Screwdriver **260** extends generally along axis **261** between a proximal end **262** and distal end **264**. Screwdriver **260** comprises a handle **278** which has a front face **276**. Front face **276** of handle **278** could act as a stop, but in general the length of the screwdriver **260** is made deliberately long so that whatever screw used may be screwed in as deep as may be deemed necessary. Screwdriver **260** has an exterior surface **266** with an outer diameter D11 extending between the front face **276** of handle **278** and the tip **270** at distal end **264**. The tip **270** of screw driver **260** is configured so as to fit within the screw head of the screw used for transarticular screw fixation and other surgeries as contemplated within the scope of the invention. In general the tip **270** of screwdriver **260** will define a polygonal shape which will mate with a polygonal socket of the same shape in the screw head of the screw used. For ease of reference, the relationship among diameters of various components is summarized below:

$D_3<D_1$
D_8
$D_7<D_4<D_5<D_1<D_2$
D_6
D_8
$D_7<D_9<D_{10}$
D_6
$D_{11}<D_2$

Having now described the individual elements of the screw delivery system, the general method of use will now be described. The screw delivery system of the present invention is particularly useful for three primary surgical indications. The first indication is use in repair of a odontoid fracture. The second indication is transarticular screw fixation across the first and second cervical vertebrae. The third indication is transarticular screw fixation across the lumbar facet joint. All of these indications will be discussed with more specificity below. The general procedure, however, essentially entails seizing the joint between the vertebrae and immobilizing it until either the fracture heals (as in the first indication) or until fusion occurs (as in the second or third indications). It should be understood that the first indication is an anterior procedure while the second and third indications are posterior procedures.

In the generalized method of use, the soft tissue penetrator or introducer in the form of the outer cannula **100** with the trocar **120** having a bullet-shaped head **130** is introduced through an incision **50** in the skin on the back and directed toward the surgical site (in FIG. **11** the surgical site is across lumbar vertebra) viewed through incision **55**. The tip **110** of the outer cannula **100** is then seated on the portion of the bone or vertebra at the appropriate angle for the introduction of the screw for fixation. The bullet-shaped head **130**, and indeed the entire trocar **120**, are then removed from the outer cannula **100**. Then, the distal end **144** of the drill guide **140** is inserted through the near end **102** of outer cannula **100** until the front face **156** of stop **152** of guide **140** contacts the rear face **112***b* of annular flange or stop **112** of outer cannula **100**. Next, the drilling end **184** of bone drill bit **180** is inserted through the bore **141***a* of guide **140** past the distal end **144** and then on into the bore **101***a* of outer cannula **100**. It should be understood that the surgeon could use a high speed burr to mark the point of insertion of the screw, but this generally weakens the fixation of the screw's strength because of the loss of cortical bone on the outside surface of the vertebra. Instead, it is preferable, as mentioned above, to use the improved drill bit **180** of the present invention which has a sharper angled drill tip **190** which permits easier insertion during the beginning of the drilling process despite the very small entry angle commonly encountered in transarticular screw fixation across vertebral joints.

As previously mentioned, the bone drill bit **180** has a plurality of length markings **187** adjacent the annular flange or stop **192**. The length markings **187** allow the surgeon to know the distance the drill has been drilled into the bone at a glance by examining the length markings **187** of the bone drill bit **180**. The screws (not shown) to be used are of a fixed length which can be measured. Based on this fixed length, an adjustable length stop **240** is inserted onto either the bone drill bit **180** or tap **200** as appropriate. The exterior surface **186**, **206** of the bone drill bit **180** or tap **200**, respectively, is inserted through the bore **248** of the adjustable length stop **240**. In general, both the bone tap **200** and the bone drill bit **180** will be marked with 30 mil projections in 5 mm increments. Similarly, the length L of the individual cylindrical elements **142** of the adjustable length stop **140** will generally be equal to these 5 mm increments of the length markings **207** and **187**. The adjustable length stop **240** is simple and does not change the lengths of the guide **140** permitting the use of one standard guide **140** and of standard length bone drill bits **180** and bone taps **200**. The variable is the adjustable length stop **240**, which is generally constructed of plastic, allowing the use of a cutter **220** to trim the total length of the adjustable length stop **240**, thus permitting the desired length of insertion of the bone drill bit **180** and bone tap **200**. The cutter **220** may either cut off individual cylindrical elements **242** to alter the length L of adjustable length stop **240** or may even be used to cut through an individual cylindrical element **242**. It should be understood that it is generally preferable if the cutter **220** is used to cut to total length the adjustable length stop **240** by trimming through the weakened portion between the individual cylindrical elements which is intended to break off.

After trimming the adjustable length stop **240** to the desired total length, the bone drill bit **180** is inserted through

the bore **141***a* of the guide **140** and the bore **101***a* of the concentric outer cannula **100** and the drill is rotated and an opening in the bone is created by advancing the bone drill bit **180** along axis **181** until the adjustable length stop **240** contacts the rear face **157** of stop **152** of the guide **140** which prevents further advancement of the bone drill bit **180** into the bone. The bone drill bit **180** is then removed from both the guide **140** and outer cannula **100**. Next, the bone tap **200** is introduced through the bores **141***a* and **101***a*. The bone tap **200** will have an adjustable length stop **240** of the same total length as that used on the guide **140**. The opening in the bone created by the bone drill bit **180** is then threaded by rotating and advancing bone tap **200** until the adjustable length stop **240** on bone tap **200** contacts the rear face **157** of stop **152** on guide **140**.

After the opening in the bone portion has been drilled and tapped, the entire inner sleeve in the form of the bone tap **200** and guide **140** is removed from the outer cannula **100**. Next, a screw and implant driver are introduced through the near end **102** of outer cannula **100**. The implant driver will generally be a standard screwdriver **260** having a tip **270** with a polygonal head which will mate with a same shaped polygonal socket in the head of the screw (not shown) to be driven into the bone. The screw and screwdriver **260** are inserted through the bore **101***a* of outer cannula **100** until they have reached the opening located beyond the tip **110** of the far end **104** of outer cannula **100**. The location of this opening will vary depending on the indication as described further below.

As mentioned above, the first indication of particular use for the screw delivery system and method of the present invention is for use with an odontoid fracture. An odontoid fracture is a special type of C**2** (second cervical vertebra) or axis vertebra. As mentioned in the background section, the odontoid is a prominent process, tooth-like in form, projecting perpendicularly upward from the axis vertebra toward the atlas vertebra. In the past, odontoid fractures were treated by the use of halo. The alternative treatment mechanism is to insert a screw across the fracture site. This will be an anterior procedure through the neck, so that operating through the bore **101***a* of the outer cannula **100** aids in protecting important structures in the neck as well as providing a minimally invasive procedure generally.

Odontoid screw fixation is a technically demanding procedure that requires thorough preoperative planning and adequate surgical training. The entry point is critical at the anterior margin of the inferior endplate. If started more cephalad, the angle of inclination for fracture fixation cannot be achieved and anterior gapping of the fracture is a common result. Also, poor proximal fragment purchase with subsequent screw cut-out may occur. It is important to engage the far cortex of the odontoid tip to ensure adequate purchase and it is mandatory to lag the fracture fragments either through screw design or by creating a gliding hole through the body fragment. AP and lateral fluoroscopy is essential for constant monitoring during all stages of this procedure.

Odontoid screw fixation using the screw delivery system of the present invention is a combination of percutaneous and open technique to make a minimally invasive approach. The surgeon actually views the entry site of the screw and through a separate incision places the screw delivery system while viewing where the far end **104** of the outer cannula **100** is going to dock. The technique is generally done using biplanar fluoroscopy, which allows viewing of the fracture on TV screens as you place the drill, tap and screw, respectively, across it during the procedure. The entirety of drilling, tapping, and screw insertion is done through the working sleeve in the form of the outer cannula **100** and drill guide **140**, as previously discussed.

The specifics of the screw entry angle and placement for the second indication, transarticular screw fixation of the C**1** and C**2** (atlas and axis) vertebra are described in the articles previously incorporated by reference and will not be discussed in any detail here. Suffice it to say that the desired result is the fusion of C**1** and C**2** together using a posterior approach wherein the screw goes across the C**1**/C**2** joint in the back. Using the standard technique generally requires a very long incision in order to get the appropriate trajectory. The incision would have to be made all the way into the thoracic area of the spine in order to get the correct entry angle since it is a very steep shot for the drill, tap, and screw, respectively. Indeed, the articles describing the standard technique recommend making an incision from C**1** all the way down to C**7** (see incision **65***a* of FIG. **10**). In contrast, the use of the screw delivery system and method of the present invention requires only a small midline incision **65** (see FIG. **12**) at the C**1**/C**2** region and two percutaneous incisions **60***a* and **60***b* (see FIG. **12**) around the upper thoracic area through which the screw delivery system of the present invention is introduced and directed toward the surgical site at the joint between C**1** and C**2**. This surgical site is viewed directly through the small midline incision **65** made.

The third indication mentioned above as deriving particular benefit through use of the screw delivery system of the present invention is placing a screw across a lumbar facet joint to fuse the joint between two lumbar vertebra. This may be done rather than putting pedicle screws in and then attaching those anchors (the pedicle screws) to a rod, plate or other longitudinal element spanning the intervertebral disc or the space left behind after it is excised. Instead, in this procedure, the surgeon simply places two screws in the shape of an X (when viewed from above a prone patient) across the lumbar facet joint. This is usually done in combination with an anterior interbody fusion which has more recently undergone an upsurge in popularity with the use of devices known as cages. The benefits of simply putting screws across the lumbar facet joint as to the more complex apparatus involving insertion of pedicle screws and attaching longitudinal elements to the anchors is that putting screws across the lumbar facet joint results in a very, very low profile implant.

Again, this third indication is a minimally invasive procedure which is a combination of percutaneous and open techniques. As with the cervical fusion described in the second indication, a small midline incision **55** (see FIG. **11**) is made over the two vertebra to be fused which goes right down to the facet joint. Each screw goes across the lamina from the posterior spinous process, being driven across the facet joint which is out laterally and downstream. The entry point for the drill bit (and the tap and screw) is again out and aside, up in the flank. The joint between the lumbar vertebrae is fairly deep and the exit point of the drill bit and the screw is intended to be fixed deep into the joint. The screw's entry point is the posterior spinous process on the contralateral side. The screw travels between the anterior and posterior cortices of the laminae to enter the inferior articular process. The screw then crosses the facet joint—entering the superior articular process and then exiting at the base of the transverse process and pars interarticularis.

The screw delivery system of the present invention is beneficial, both in the three indications described above, as well as in other procedures known to those of ordinary skill

in the art. The screw delivery system of the present invention permits the making of one or more small percutaneous portals through which the implant and interventional devices are introduced. After making an incision at midline or otherwise permitting viewing of the surgical site, the docking part of the multi-sleeve device of the screw delivery system of the present invention is introduced and directly abuts the surgical site as desired. Then a surgeon may drill, tap, and insert the screw through the percutaneous portal provided by the screw delivery system of the present invention.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed:

1. A screw delivery system kit, comprising:

an outer cannula having a first exterior surface and a first interior surface defining a bore, the first interior surface having a first inner diameter and the first exterior surface having a first outer diameter, the surfaces extending along a first length on a first axis between a first proximal end having a first stop and a first distal end;

a trocar having a second exterior surface with a second outer diameter, the second exterior surface extending along a second length on a second axis between a second proximal end having a second stop and a second distal end defining a blunt tip;

a guide having a handle and a tube, the tube having a third exterior surface and a third interior surface defining a passageway, the third interior surface having a third inner diameter and the third exterior surface having a third outer diameter, the third interior surface extending between a third proximal end and a third distal end, the third exterior surface extending along a third length on a third axis between a third stop at the third proximal end and the third distal end, the handle being connected to the tube at an angle to the third axis;

a bone drill bit having a fourth exterior surface with a fourth outer diameter extending along a fourth length on a fourth axis between a fourth stop located near a fourth proximal end and a plurality of drilling flutes defined on a fourth distal end;

a bone tap having a fifth exterior surface with a fifth outer diameter extending between a fifth stop located near a fifth proximal end and a fifth distal end having threading thereon for tapping an opening in bone created by said bone drill bit;

an adjustable length stop having a length, the adjustable length stop being a series of interconnected cylindrical elements;

a cutter for adjusting the length of said adjustable length stop; and,

an implant driver for inserting a screw.

2. The kit of claim **1**, further comprising at least one interbody fusion implant.

3. The kit of claim **1**, further including a screw adapted for screwing at least one screw across a facet joint of the vertebrae.

4. The kit of claim **3**, further comprising at least one interbody fusion implant.

5. The kit of claim **1**, wherein the fifth exterior surface has a plurality of length markings adjacent the fifth stop, the length markings being located on the fifth exterior surface between the fifth stop and the fifth distal end of said bone tap.

6. The kit of claim **1**, wherein the fourth exterior surface has a plurality of length markings adjacent the fourth stop, the length markings being located on said fourth exterior surface between the fourth stop and the fourth distal end.

7. The kit of claim **1**, wherein said adjustable length stop has an outer surface and an inner surface defining a bore with a bore diameter, the bore diameter of said adjustable length stop being greater than the fourth outer diameter.

8. The kit of claim **7**, further comprising at least one interbody fusion implant.

9. A method of inserting a screw into vertebral bone in the lumbar region or the spine, comprising:

making an incision for percutaneous access to a surgical site;

inserting an outer cannula having a bore defined between a proximal end and a distal end and a trocar through the bore into the incision;

advancing the outer cannula and trocar toward the surgical site until the distal end of the outer cannula is positioned adjacent the surgical site;

removing the trocar from the outer cannula;

forming an opening through a first lumbar vertebra and into a second lumbar vertebra;

delivering a screw through the bore of the outer cannula to the surgical site; and

screwing the screw into the opening through the first lumbar vertebra and into the second lumbar vertebra.

10. The method of claim **9**, further comprising tapping the opening before screwing the screw into the opening.

11. The method of claim **9**, further comprising positioning at least one interbody fusion implant between the first and second lumbar vertebrae.

12. The method of claim **9**, wherein the screwing comprises engaging the screw across a joint of the first and second lumbar vertebrae.

13. The method of claim **12**, wherein the joint is a lumbar facet joint.

14. The method of claim **13**, wherein the screwing comprises transarticular screw fixation across the lumbar facet joint.

15. The method of claim **13**, wherein the engaging of the screw across the lumbar facet joint facilitates fusion between the first and second lumbar vertebrae.

16. The method of claim **13**, wherein two of the screws are engaged across the lumbar facet joint.

17.The method of claim **16**, wherein the two screws are engaged across the lumbar facet joint in a cross-over configuration.

18. The method of claim **13**, wherein the opening through the first lumbar vertebra extends from the posterior spinous process and through the lamina to the lumbar facet joint.

19. The method of claim **18**, wherein the opening through the first lumbar vertebra extends from the contralateral side of the posterior spinous process.

20. The method of claim **18**, wherein the opening through the first lumbar vertebra extends across the anterior and posterior cortices of the lamina to the inferior articular process.

21. The method of claim **20**, wherein the opening into the second lumbar vertebra extends from superior articular process.

22. The method of claim **21**, wherein the opening extends through the second lumbar vertebra from the superior articu-

lar process to the base of the transverse process and pars interarticularis.

23. The method of claim **13**, wherein the screwing comprises transarticular screw fixation cross the lumbar facet joint.

24. The method of claim **9**, wherein the access incision is remote from the surgical site; and

wherein the method further comprises making a second incision over the surgical site for viewing the surgical site.

25. A method of facilitating interbody fusion between a first vertebra and a second vertebra, comprising:

making an incision for percutaneous access to a surgical site;

inserting an outer cannula having a bore defined between a proximal end and a distal end and a trocar through the bore into the incision;

advancing the outer cannula and trocar toward the surgical site until the distal end of the outer cannula is positioned adjacent the surgical site;

removing the trocar from the outer cannula;

forming an opening through the first vertebra and into the second vertebra;

delivering a screw through the bore of the outer cannula to the surgical site;

screwing the screw into the opening through the first vertebra and into the second vertebra; and

positioning at least one interbody fusion implant between the first and second vertebrae.

26. The method of claim **25**, further comprising tapping the opening before screwing the screw into the opening.

27. The method of claim **25**, wherein the screwing comprises engaging the screw across a joint of the first and second vertebrae.

28. The method of claim **27**, wherein the first and second vertebrae are lumbar vertebrae.

29. The method of claim **27**, wherein the joint is a lumbar facet joint.

30. The method of claim **27**, wherein the screwing comprises transarticular screw fixation across the joint.

31. The method of claim **27**, wherein two of the screws are engaged across the joint.

32. The method of claim **25**, wherein the access incision is remote from the surgical site; and

wherein the method further comprises making a second incision over the surgical site for viewing the surgical site.

* * * * *

CERTIFICATE OF SERVICE

I hereby certify that, on this 15th day of March, 2019, I filed the foregoing Brief for Plaintiffs-Appellants Warsaw Orthopedic Inc.; Medtronic, Inc.; and Medtronic Sofamor Danek, Inc. with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Federal Circuit Rule 32(a).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b), the brief contains 11,098 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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