UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOPEDIATRICS CORP.,

Petitioner,

v.

K2M, INC.,

Patent Owner

Inter Partes Case No. IPR2018-01547
Patent No. 9,655,664

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,655,664

TABLE OF CONTENTS

LIST OF EXHIBITS

ORT-1101	U.S. Pat. No. 9,655,664 ("the '664 Patent")
ORT-1102	Prosecution history of the '664 Patent
ORT-1103	U.S. Pat. No. 9,532,816 ("the '816 Patent")
ORT-1104	Prosecution history of the '816 Patent
ORT-1105	U.S. Pat. No. 8,961,523 ("the 523 patent")
ORT-1106	Prosecution history of the '523 patent
ORT-1107	OrthoPediatrics' opening claim construction brief, *K2M, Inc. v. OrthoPediatrics Corp., et al*., C.A. No. 17-61 (GMS) (D. Del. Oct. 27, 2017)
ORT-1108	K2M's opening claim construction brief, *K2M, Inc. v. OrthoPediatrics Corp*., C.A. No. 17-61 (GMS) (D. Del. Oct. 27, 2017)
ORT-1109	OrthoPediatrics' answering claim construction brief, *K2M, Inc. v. OrthoPediatrics Corp.*, C.A. No. 17-61 (GMS) (D. Del. Nov. 22, 2017)
ORT-1110	K2M's answering claim construction brief, *K2M, Inc. v. OrthoPediatrics Corp*., C.A. No. 17-61 (GMS) (D. Del. Nov. 22, 2017)
ORT-1111	Claim construction order, *K2M, Inc. v. OrthoPediatrics Corp., et al*., C.A. No. 17-61 (GMS) (D. Del. May 30, 2018)
ORT-1112	K2M's preliminary response, *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-00429 (June 28, 2018)
ORT-1113	K2M's preliminary response, *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-00521 (June 28, 2018)
ORT-1114	Decision of institution, *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-00429 (June 28, 2018)
ORT-1115	Decision of institution, *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-00521 (June 28, 2018)

LIST OF EXHIBITS

ORT-1116 Expert declaration of Ottie Pendleton

ORT-1117 U.S. App. Pub. No. 2006/0293692 ("Whipple")

ORT-1118 U.S. App. Pub. No. 2006/0079909 ("Runco")

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

I. INTRODUCTION

OrthoPediatrics Corp. ("Petitioner") petitions for *inter partes* review ("IPR") of claims 1, 3, 5, 6, 8-10, 12, and 15-19 (the "Challenged Claims") of U.S. Patent No. 9,655,664 (ORT-1101; "the '664 Patent"), which public records indicate is assigned to K2M, Inc. ("Patentee"). The Challenged Claims of the '664 Patent relate to "a manually operated device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw." ORT-1101 at 1:19-22. Each feature of the Challenged Claims is expressly or implicitly disclosed and/or rendered obvious by the prior art discussed below.

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

A. Real Parties-in-Interest under 37 C.F.R. §42.8(b)(1)

The real parties-in-interest are Petitioner OrthoPediatrics Corp. and OrthoPediatrics US Distribution Corp., a wholly owned subsidiary of OrthoPediatrics Corp.

B. Related Matters under 37 C.F.R. §42.8(b)(2)

Patentee has asserted the '664 Patent and related U.S. Patent No. 9,532,816 ("the '816 Patent") against OrthoPediatrics Corp. and OrthoPediatrics US Distribution Corp. in a civil action, Case No. 1:17-cv-00061-GMS, filed on January 20, 2017, in the U.S. District Court for the District of Delaware.

OrthoPediatrics Corp. has since petitioned for *inter partes* review of the '816 Patent in Case Nos. IPR2018-00429 and IPR2018-00521, both of which the Board instituted on June 28, 2018.

C. Lead and Back-up Counsel under 37 C.F.R. §42.8(b)(3)

Petitioner provides the following designation of counsel:

Lead Counsel	Back-up Counsel
Paul M. Ulrich (Reg. No. 46,404) ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202 Telephone: (513) 698-5156 Fax: (513) 698-5157 E-mail: pulrich@ulmer.com	Christopher A. Singh (Reg. No. 61,236) ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202 Telephone: (513) 698-5084 Fax: (513) 698-5085 E-mail: csingh@ulmer.com

D. Service Information under 37 C.F.R. §42.8(b)(4)

Please address all correspondence and service to the Lead and Back-up Counsel at the address provided above. Petitioner consents to electronic service by electronic mail.

III. POWER OF ATTORNEY UNDER 37 C.F.R. §42.10(b)

Pursuant to 37 C.F.R. §42.10(b), a Power of Attorney accompanies this petition. The above-identified Lead and Back-up Counsel are registered practitioners associated with Customer No. 69,082 listed in that Power of Attorney.

IV. PAYMENT OF FEES UNDER 37 C.F.R. §42.103

The fee set forth in 37 C.F.R. §42.15(a) for requesting IPR of the Challenged Claims was paid at the time of filing this petition. Petitioner authorizes the United States Patent and Trademark Office to charge Deposit Account No. 501884 for any additional fees that may be due in connection with this petition.

V. REQUIREMENTS FOR IPR UNDER 37 C.F.R. §42.104

A. Grounds for Standing under 37 C.F.R. §42.104(a)

Petitioner certifies that the '664 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the grounds identified herein.

B. Identification of Challenge under 37 C.F.R. §42.104(b) and Relief Requested

Petitioner requests IPR of the Challenged Claims based on the prior art and grounds set forth below and requests that the Board find each of these claims to be unpatentable. In support of this petition, the declaration of Ottie Pendleton (ORT-1116) also has been submitted.

Ground	Claims	Basis for Unpatentability
Ground 1	1, 3, 5, 6, 8-10, 12, and 15-19	Anticipated under 35 U.S.C. §102(e) by Whipple
Ground 2	1, 3, 5, 6, 8-10, 12, and 15-19	Anticipated under 35 U.S.C. §102(b) by Runco
Ground 3	6, 9, 15, and 17-19	Obvious under 35 U.S.C. §103(a) over Whipple in view of Runco

C. Claim Construction under 37 C.F.R. §42.104(b)(3)

Petitioner does not believe any specific claim term of the Challenged Claims requires construction for the purposes of this petition and that every claim term should be given its "broadest reasonable construction in light of the specification." 37 C.F.R. §42.100(b); *see also Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2144-45 (2016). Only terms in controversy need to be construed—and only to the extent necessary to resolve the controversy. *See, e.g., Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The Board instituted *inter partes* review of claims of related U.S. Patent No. 9,532,816 ("the '816 Patent"), also owned by Patentee. *See* ORT-1114; ORT-1115. In Patentee's preliminary responses to the two petitions for *inter partes* review, Patentee argued that two terms required construction: "grasping" and "extending through the housing." ORT-1112 9-19; ORT-1113 9-21. Patentee did not argue that any other claim term required construction.

In instituting *inter partes* review, the Board construed "extending through the housing" as "extending through the fixed portion of the rod reducing device that defines the body through passage." ORT-1114 10; ORT-1115 11. The Board did not construe "grasping," as its construction was not necessary to resolve the controversy. *See, e.g.*, ORT-1114 6 ("For purposes of this decision we need only construe 'extending through the housing.'") (citing *Vivid Techs.*, 200 F.3d at 803).

For purposes of this petition, Petitioner does not request that the Board construe "extending through the housing" differently than the Board construed the phrase in IPR2018-00429 or IPR2018-00521, which is consistent with Petitioner's understanding of the phrase's broadest reasonable interpretation.

The terms and phrases of the Challenged Claims are nearly identical to the terms and phrases of the claims challenged in IPR2018-00429 and IPR2018-00521. As no other terms or phrases are in dispute, the Board need not and should not construe any other terms or phrases. *See, e.g., Vivid Techs.*, 200 F.3d at 803. In essence, this petition is based on the claim constructions urged by Patentee in the related district court litigation.

Although Petitioner sought narrower claim constructions in the district court proceedings, the Federal Circuit has observed that the broadest reasonable interpretation of a claim term is often broader than the term's construction under the *Phillips* standard. *See, e.g., Facebook, Inc. v. Pragmatus AV, LLC*, 582 Fed. Appx. 864, 869 (Fed. Cir. 2014). Moreover, as the Board recognizes, "Our rules do not require positions consistent with related cases in different fora. Our rules require that the parties identify related matters. Various reasons may justify inconsistencies among fora, including differing legal or evidentiary standards, a change in litigation strategy, or a change in position." *Caterpillar Inc. v. Wirtgen*

America, Inc., IPR2017-02185, Paper 7, 11 (PTAB May 3, 2018) (citing 37 C.F.R. §42.8(b)(2)).

With respect to potential means-plus-function limitations, no Challenged Claim contains the word "means." As such, there is a presumption that none of the Challenged Claims invoke 35 U.S.C. §112, ¶6. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). Moreover, Patentee has not requested any construction under §112, ¶6, and Petitioner has no reason to believe that Patentee will do so now. The Board, therefore, need not and should not construe any terms or phrases under §112, ¶6. *Vivid Techs.*, 200 F.3d at 803 ("only those terms need be construed that are in controversy"). Nevertheless, should Patentee request any construction under §112, ¶6, Patentee would have the burden of overcoming the presumption against §112, ¶6 by a preponderance of the evidence. *See Apex Inc. v. Raritan Comp., Inc*., 325 F.3d 1364, 1372 (Fed. Cir. 2003).

VI. SUMMARY OF THE PATENT

A. Background of the Art

The '664 Patent is generally directed to orthopedic surgery and, more specifically, to devices for stabilizing and fixing bones, particularly vertebrae. ORT-1101 1:16-19.

The '664 Patent further explains that "it is ***common practice to place bone screws*** into the vertebral bodies and ***then connect a metal rod*** between adjacent

vertebral bodies" to immobilize the spinal column. *Id.* 1:48-53. That is, the surgeon uses a metal rod to connect multiple vertebrae by placing the rod into a "receiving slot" in the head of each of the bone screws already attached to the vertebrae. *Id.*

B. Alleged Invention of the '664 Patent

The '664 Patent relates to a device that is used to lower—or ***reduce***—such a metal rod into the receiving slot of a bone screw during an orthopedic surgery. These types of devices—conventionally called "rod reducers" or "rod approximators"—existed long before the named inventors of the '664 Patent filed their patent applications.

The rod reducer of the '664 Patent is a manually operated device that reduces a rod into a rod receiving slot of a bone screw head by the rotation of a screw shaft 16. *Id.* 1:19-22.

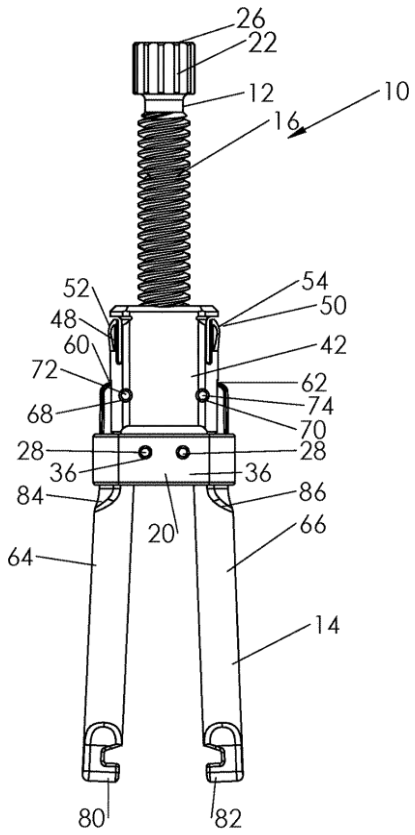


FIG 5

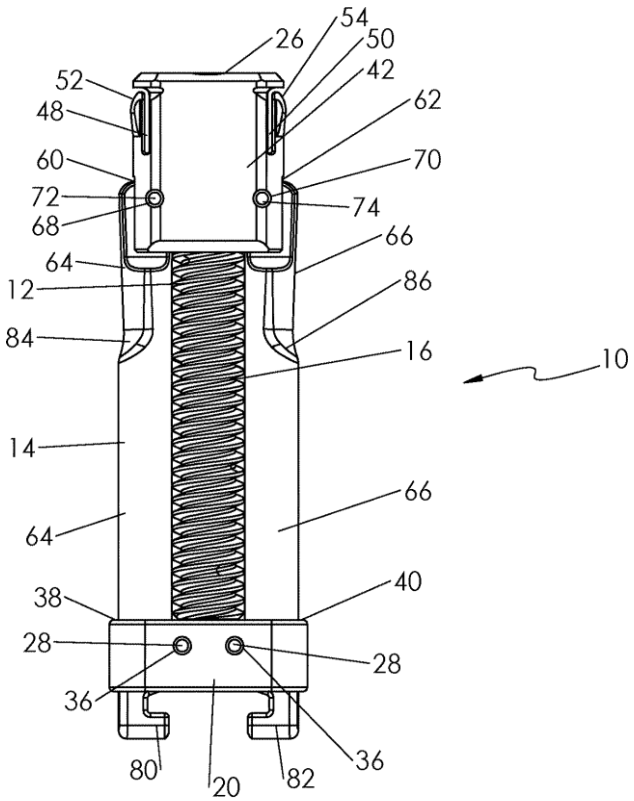


FIG 2

Figure 5 shows an embodiment of the device before rotation of the screw shaft 16. *Id.* 3:33-34. The device includes two opposed, elongated "grasping members" 64 and 66. *Id.* 5:58-67; FIGS. 2, 5. At the bottom (*i.e.*, distal end) of the screw shaft 16 is a "rod contact member" 20. *Id.* 4:41-44.

When a surgeon rotates the screw shaft 16, both it and the rod contact member 20 move downward. When a rod is positioned between the grasping members 64 and 66, rotation of the screw shaft 16 causes the rod contact member to push the rod downward into the receiving slot of the bone screw. *See, e.g., id.* 6:27-57. Figure 2 thus shows the device after rotation of the screw shaft 16. *Id.* 3:25-26.

C. Claim Key

In discussing limitations of the Challenged Claims, this petition refers to limitations according to the below "key":

Key	Listing of Claims
[1-PRE]	1. A method of advancing a rod into a housing of a bone anchor comprising:
[1-1]	coupling a rod reducing device to a bone anchor,
[1-2]	the bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom,
[1-3]	the rod reducing device including:
[1-4]	a rotatable member,
[1-5]	a rod contact member positioned at a distal end of the rotatable member, and
[1-6]	a body including first and second elongated grasping members extending therefrom,
[1-7]	each of the first and second elongated grasping members having a screw grasping element,
[1-8]	the rotatable member threadably coupled with the body,
[1-9]	the first and second elongated grasping members defining a plane,
[1-10]	the rotatable member and the rod contact member movable within the plane;
[1-11]	securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members; and
[1-12]	rotating the rotatable member thereby causing the rod contact member to move relative to the body within the plane to advance a rod disposed between the first and second elongated grasping members toward the rod-receiving housing.

Key	Listing of Claims
[3-1]	3. The method of claim 1, wherein securing the rod reducing device to the bone anchor includes coupling respective distal ends of the first and second elongated grasping members having at least one grasping feature to engage the rod-receiving housing of the bone anchor.
[5-1]	5. The method of claim 1, wherein coupling the rod reducing device includes coupling the rod reducing device in which a portion of the rod contact member is positioned between the first and second elongated grasping members.
[6-1]	6. The method of claim 1, wherein coupling the rod reducing device includes coupling the rod reducing device in which the rod contact member is attached to the distal end of the rotatable member.
[8-PRE]	8. A kit for reducing a rod, the kit comprising:
[8-1]	a bone anchor; and
[8-2]	a rod reducing device including:
[8-3]	a housing defining a longitudinal axis,
[8-4]	the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween,
[8-5]	the first and second grasping members defining a plane;
[8-6]	a rotatable member extending through the housing along the longitudinal axis; and
[8-7]	a rod contact member positioned at a distal end of the rotatable member,
[8-8]	the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis,
[8-9]	wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.
[9-1]	9. The kit according to claim 8, further comprising a plurality of bone anchors and a plurality of rod reducing devices.

Key	Listing of Claims
[10-1]	10. The kit of claim 8, further comprising at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device.
[12-PRE]	12. A system for reducing a connecting rod, the system comprising:
[12-1]	a bone anchor;
[12-2]	a connecting rod; and
[12-3]	a rod reduction device including:
[12-4]	a housing defining a longitudinal axis,
[12-5]	the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween,
[12-6]	the first and second grasping members defining a plane;
[12-7]	a rotatable member extending through the housing along the longitudinal axis; and
[12-8]	a rod contact member positioned at a distal end of the rotatable member,
[12-9]	the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis.
[15-1]	15. The system according to claim 12, further comprising a plurality of bone anchors and a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors.
[16-1]	16. The system of claim 12, further comprising an additional orthopedic tool or device selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device.
[17-PRE]	17. A surgical construct comprising:
[17-1]	a plurality of bone anchors;
[17-2]	a connecting rod; and

Key	Listing of Claims
[17-3]	a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices connectable to a bone anchor of the plurality of bone anchors,
[17-4]	each rod reduction device of the plurality of rod reduction devices including:
[17-5]	a housing defining a longitudinal axis,
[17-6]	the housing including first and second grasping members configured to grasp a portion of the bone anchor therebetween,
[17-7]	the first and second grasping members defining a plane;
[17-8]	a rotatable member extending through the housing along the longitudinal axis; and
[17-9]	a rod contact member positioned at a distal end of the rotatable member,
[17-10]	the rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis.
[18-1]	18. The construct of claim 17, wherein the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors,
[18-2]	whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors.
[19-1]	19. The construct of claim 17, wherein each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") at the time of the alleged invention would have at least a bachelor's degree in mechanical engineering or biomedical engineering combined with at least one year of post-graduate or industry work experience in orthopedic instruments or an equivalent. ORT-1116 ¶13.

VIII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '664 PATENT IS UNPATENTABLE

As detailed below, each Challenged Claim is anticipated and/or rendered obvious by at least one or more references, singularly or in combination (the "Grounds"). Each Ground independently shows a reasonable likelihood that one or more of the claims of the '664 Patent are unpatentable. The Grounds are not cumulative or redundant.

A. Ground 1: All the Challenged Claims Are Anticipated by Whipple

Whipple anticipates the Challenged Claims of the '664 Patent. Whipple was filed on June 2, 2005 and published on December 28, 2006. ORT-1117 1. Therefore, Whipple is prior art under at least 35 U.S.C. §§102(a) and 102(e).[1] Whipple was never cited nor considered by the Examiner during prosecution of the

[1] The 35 U.S.C. §102(e) critical reference date of Whipple is at least as early as its filing date of June 2, 2005.

'664 Patent or the parent patents—the '816 and '523 Patents. ORT-1101 1-2; *see, e.g.*, ORT-1104; ORT-1106; *see also* ORT-1102.

FIG. 2

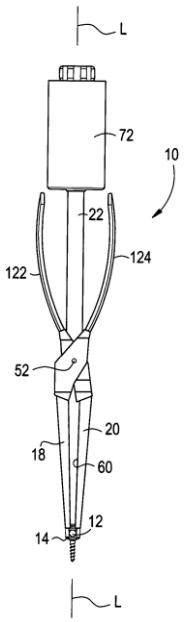


FIG. 4

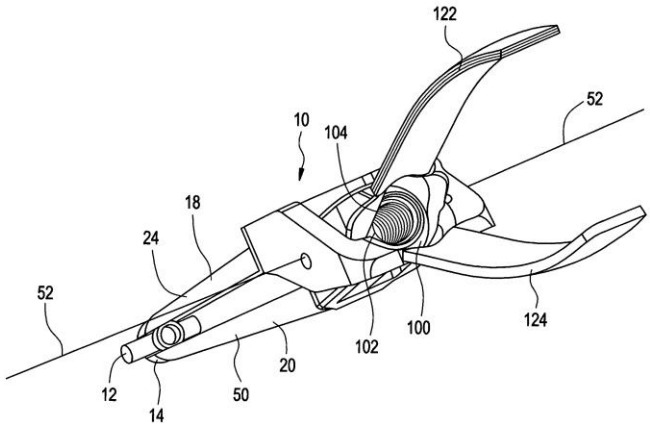
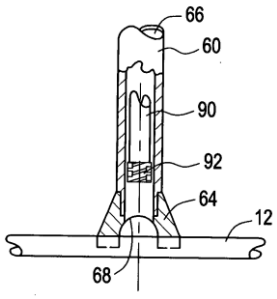


FIG. 11A



Whipple generally discloses instruments and methods for manipulating a spinal fixation element (*i.e.*, a spinal rod) relative to a bone anchor. ORT-1117 ¶5. For example, Whipple discloses an instrument 10 that includes first and second arms 24, 50 configured to releasably engage the instrument 10 with a bone anchor. *Id.* ¶¶28-32. The instrument 10 further includes an adjustment mechanism 22 coupled to the first arm 24 and/or the second arm 50. *Id.* ¶¶34-37. The adjustment mechanism 22 is configured to adjust a spinal fixation element 12 (*i.e.*, a spinal rod) relative to the bone anchor. *Id.* ¶34.

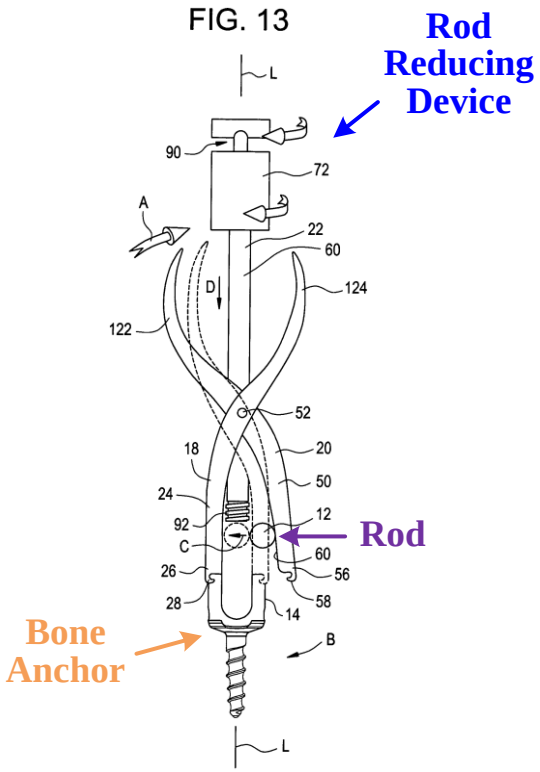
To facilitate analysis of the Challenged Claims, the below table provides a textual mapping of various claim elements of the '664 Patent to disclosed features of Whipple.

'664 Claim Element	Corresponding Feature(s) of Whipple[2]
bone anchor	bone anchor 14
(connecting) rod	spinal fixation element 12
rod reducing device / rod reduction device	instrument 10
housing / body	coupling mechanism 100
first (elongated) grasping member	first arm 24
second (elongated) grasping member	second arm 50
rotatable member	tube 60
rod contact member	distal end 64 [of tube 60]
grasping feature / screw grasping element	projection 28, 58
additional orthopedic tool	closure mechanism delivery instrument 90

[2] *See* ORT-1117, FIGS. 1-6, 11A, 13

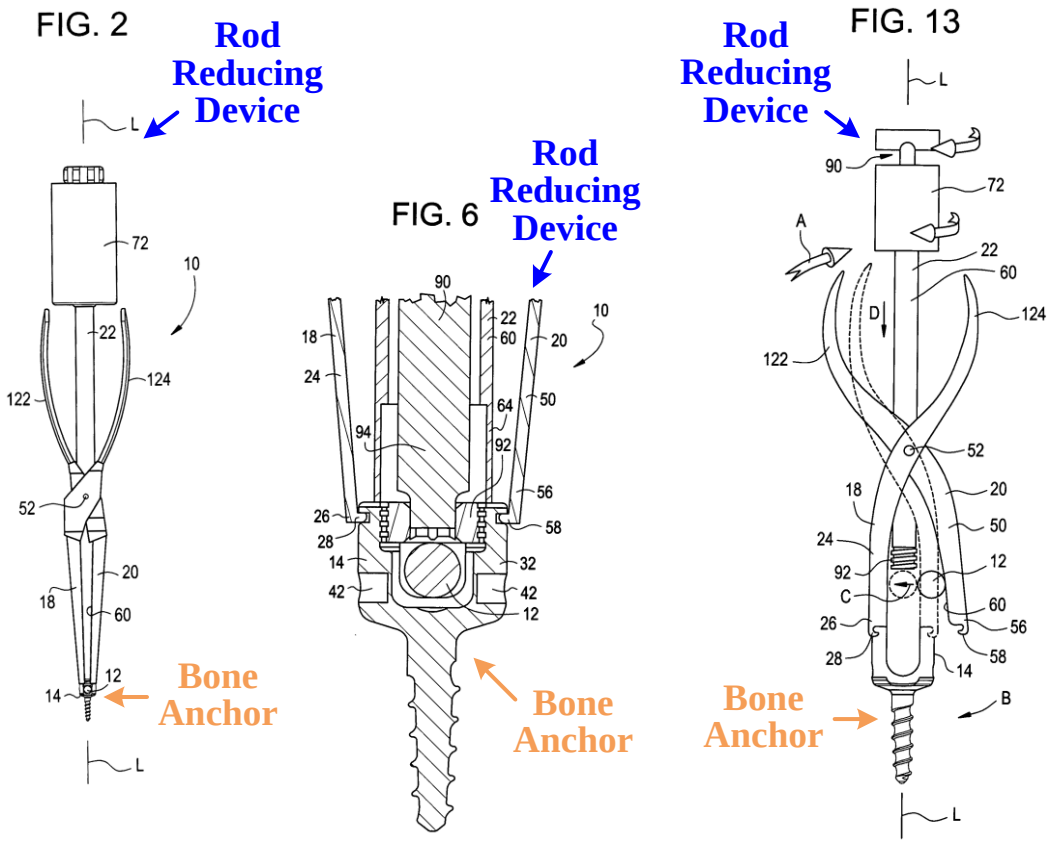
1. Independent Claim 1:

a. Limitation-[1-PRE]:



Whipple discloses the "method of advancing a rod into a housing of a bone anchor" of claim 1. For example, Whipple discloses "instruments and ***methods for manipulating a spinal fixation element, such as a spinal rod, relative to a bone anchor***, such as a polyaxial or monoaxial bone screw." *Id.* ¶5; FIG. 13 (annotated); ORT-1116 ¶¶40-41.

b. Limitation-[1-1]:

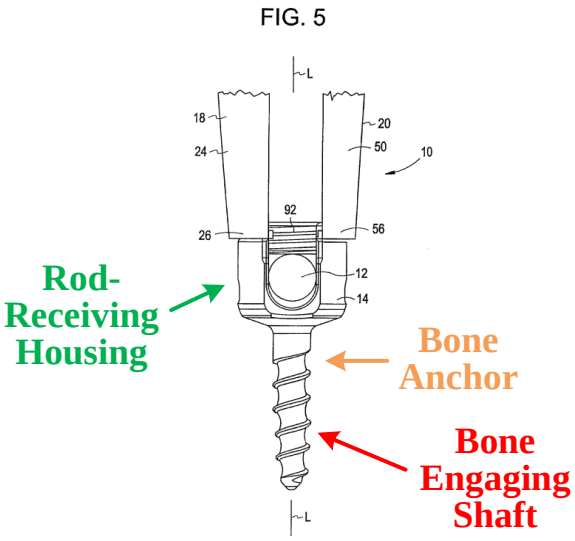


Whipple discloses the "rod reducing device" of claim 1. For example, Whipple discloses "***an instrument 10 for manipulating a spinal fixation element 12, such as, for example, a spinal rod***, a plate, a tether or cable or combinations thereof, relative to a bone anchor 14, such as, for example, a bone screw or hook." *Id*. ¶26; FIGS. 2, 13 (annotated). Whipple further discloses that "the exemplary instrument 10 is suited for . . . ***vertical adjustment of the spinal fixation element 12 relative to the bone anchor 14***." *Id*; ORT-1116 ¶43.

Whipple discloses claimed "coupling" of the rod reducing device to "a bone anchor." *Id*. FIGS. 2, 6, 13 (annotated). For example, Whipple discloses that "the

first arm 24 may be engaged to a bone anchor in a manner ***that allows*** the first arm 24, and thus ***the instrument 10, to be connected to the bone anchor 14 during use***." *Id.* ¶28; FIGS. 6, 13 (annotated); ORT-1116 ¶44.

c. Limitation-[1-2]:



Whipple discloses the "bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom" of claim 1. In particular, Whipple discloses "instruments and methods for manipulating a spinal fixation element, such as a spinal rod, relative to ***a bone anchor***, ***such as a polyaxial or monoaxial bone screw***." *Id.* ¶5. Whipple also discloses that "screws typically include ***a threaded shank*** that is adapted to be ***threaded into a vertebra***, and ***a head portion having a spinal fixation element receiving element***, which, in spinal rod applications, is usually in the form of a U-shaped slot formed in the head for receiving the rod." *Id.* ¶2. Furthermore, as depicted in FIG. 5, Whipple discloses

the claimed features of the bone anchor. *Id.* FIG. 5 (annotated); ORT-1116 ¶¶46-47.

d. Limitation-[1-3]:

As discussed below, Whipple discloses a rod reducing device including all of the recited features of claim 1.

e. Limitation-[1-4]:

FIG. 1

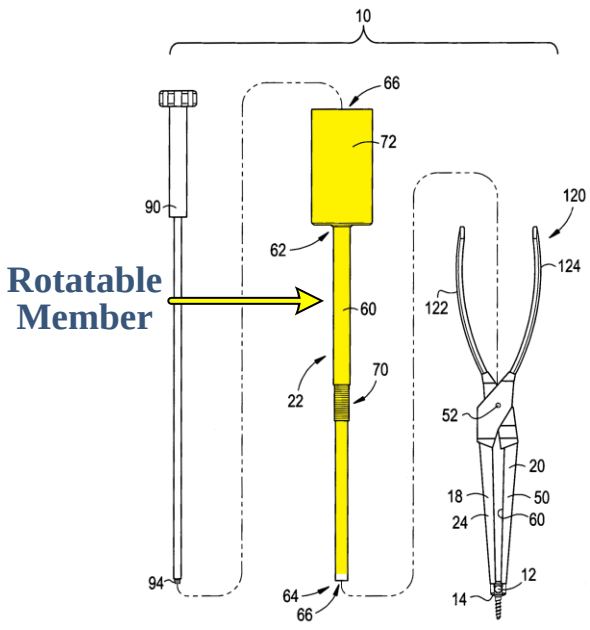
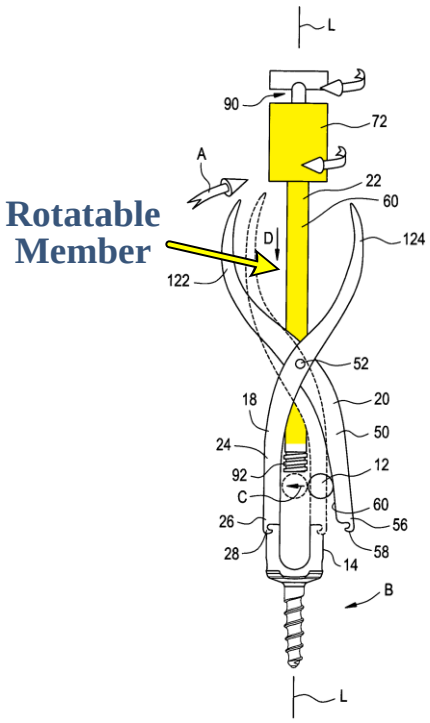


FIG. 13



Whipple discloses the "rotatable member" of claim 1. For example, Whipple states that "***[r]otation of the tube 60*** relative to the collar 102 causes ***the tube 60*** to advance distally or proximally, depending on the direction of rotation, relative to the first arm 24 and the second arm 50." *Id.* ¶36; FIGS. 1, 13 (annotated).

f. Limitation-[1-5]:

FIG. 1

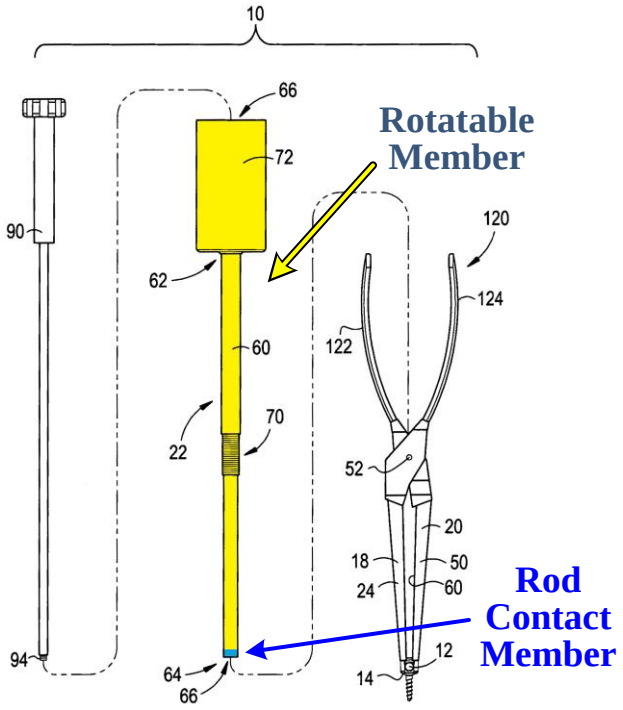
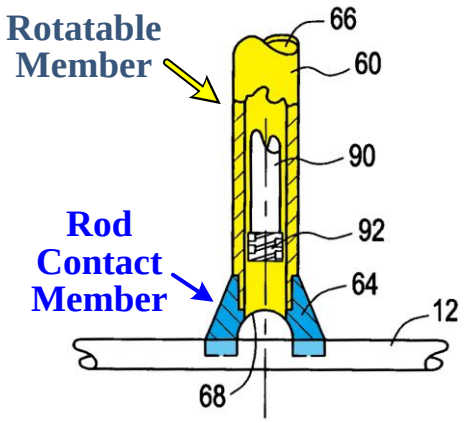


FIG. 11A



Whipple discloses "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 1. For example, Whipple discloses "***the distal end 64*** of ***the tube 60*** may ***directly contact*** the spinal fixation element 12 to effect adjustment of the spinal fixation element 12." *Id.* ¶35; FIG. 1 (annotated). Whipple also discloses "***the distal end 64*** of the tube [60] ***may be sized and shaped to facilitate contact with the spinal fixation element 12***." *Id.* For example, Whipple discloses "***the distal end 64*** may include ***an arcuate contact surface 68*** having a curvature approximate to the curvature of the spinal fixation element 12." *Id.*; FIG. 11A (annotated). As shown in FIG. 11A, the distal end 64 having the

accurate contact surface 68 (the claimed *rod contact member*) of Whipple is positioned at the distal-most end of the tube 60 (the claimed *rotatable member*).

g. Limitation-[1-6]:

FIG. 2

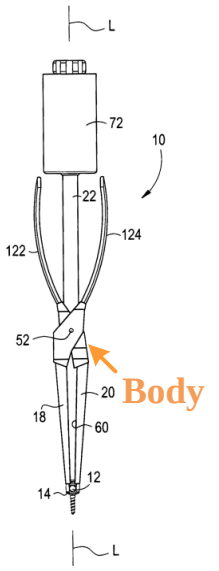


FIG. 3

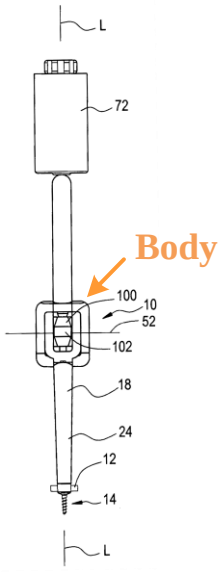
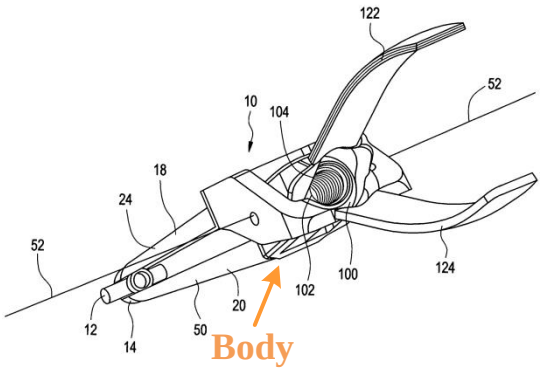
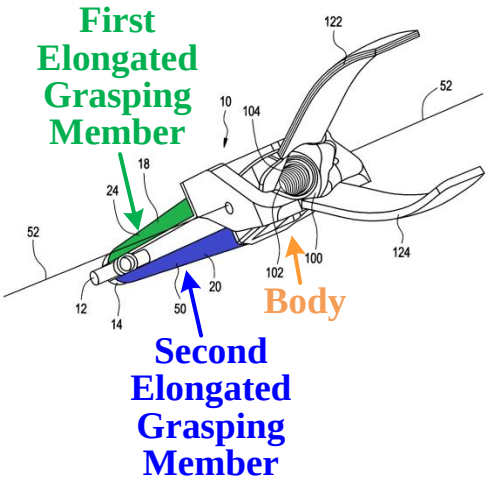


FIG. 4



Whipple discloses the "body" of claim 1. For example, Whipple discloses "***a coupling mechanism 100*** that is connected to the first arm 24 and/or the second arm 50 and is configured to receive the second adjustment mechanism 22, *e.g.*, tube 60." *Id.* ¶36; FIGS. 2-4 (annotated).

FIG. 4



Whipple also discloses that the claimed "body" includes "first and second elongated grasping members extending therefrom" as recited in claim 1. As discussed, Whipple discloses that the coupling mechanism 100 (the claimed *body*) "is connected to ***the first arm 24 and[ ] the second arm 50.***" *Id.* ¶36; FIG. 4 (annotated).

FIG. 6

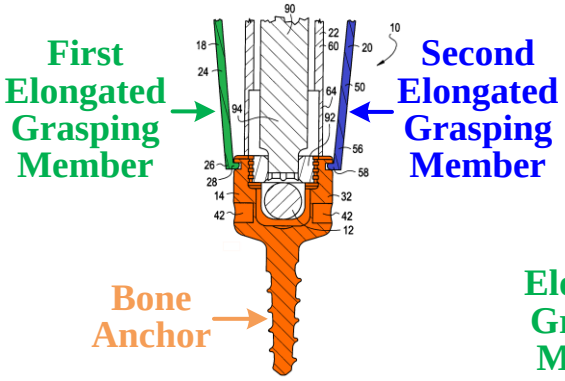
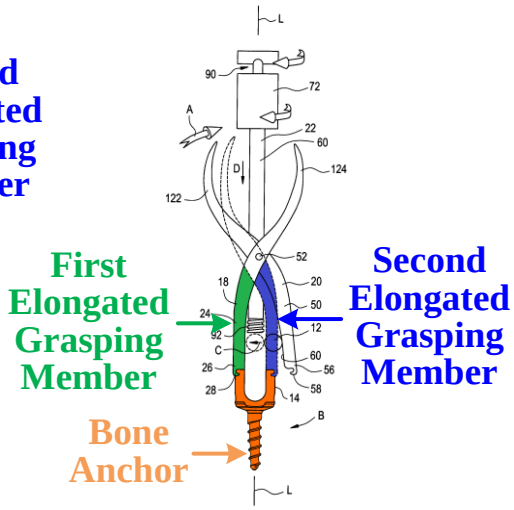


FIG. 13

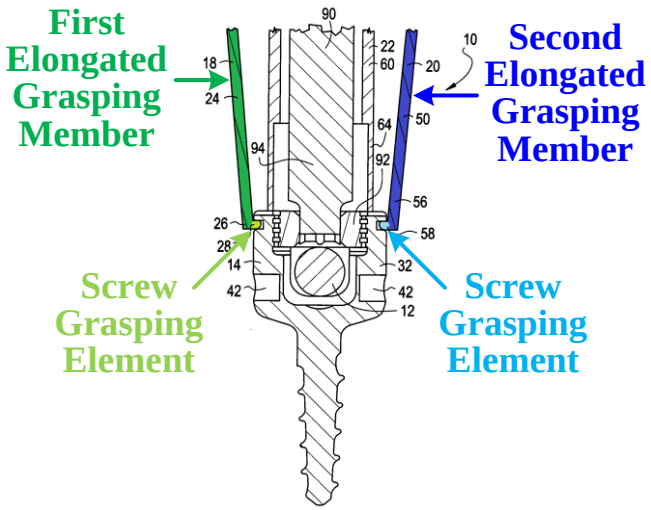


Additionally, Whipple discloses the "***first arm 24*** having a distal end 26 ***configured to releasably engage a bone anchor***" and the "***second arm 50*** . . .

hav[ing] a distal end 56 ***configured to releasably engage the bone anchor 14***." *Id.* ¶¶28, 32. Furthermore, annotated FIGS. 6 and 13 clearly show a portion of the bone anchor 14 grasped between the first and second arms 24 and 50, respectively.

h. Limitation-[1-7]:

FIG. 6



Whipple discloses "each of the first and second elongated grasping members having a screw grasping element" as recited in claim 1. For example, Whipple discloses that the first arm 24 (the claimed *first grasping member*) has "***a distal end 26*** configured to releasably engage a bone anchor" and the second arm 50 (the claimed *second grasping member*) has "***a distal end 56*** configured to releasably engage the bone anchor." *Id.* ¶¶28, 32; FIG. 6 (annotated). Whipple further discloses that the distal ends 26, 56 of the first and second arms 24, 50 include ***radially inward facing projections 28, 58*** sized and shaped to engage bone anchor openings. *See, e.g., id.* ¶¶29, 32.

i. Limitation-[1-8]:

FIG. 1

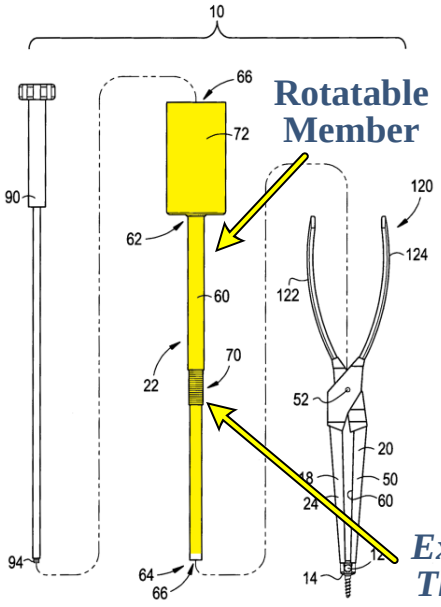
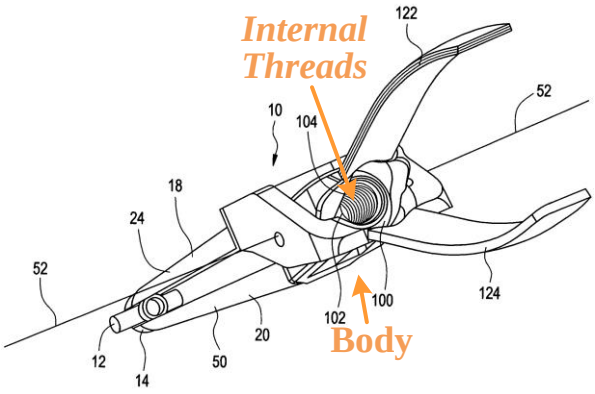


FIG. 4



Whipple discloses the "rotatable member threadably coupled with the body" of claim 1. In particular, Whipple discloses that ***the coupling mechanism 100*** (the claimed *body*) "is a collar or nut 102 ***having internal threads 104 that may engage external threads 70 provided on the tube 60*** between the proximal end 62 and the distal end 64 of the tube 60." *Id.* ¶36; FIGS. 1, 4 (annotated).

j. Limitation-[1-9]:

FIG. 2

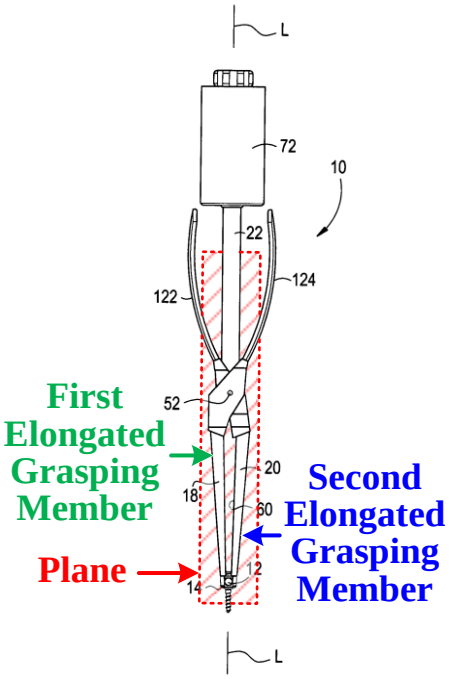
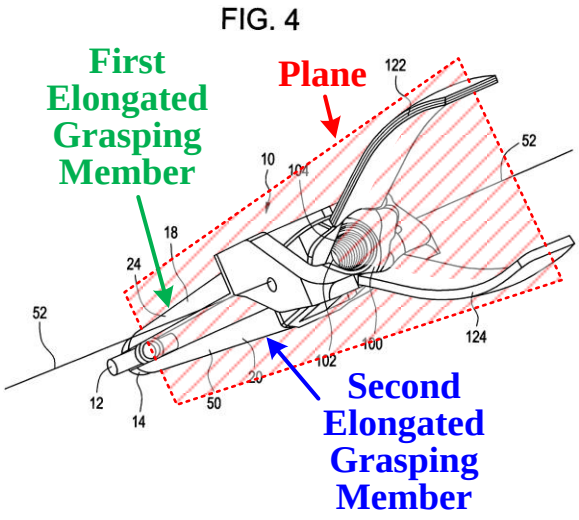
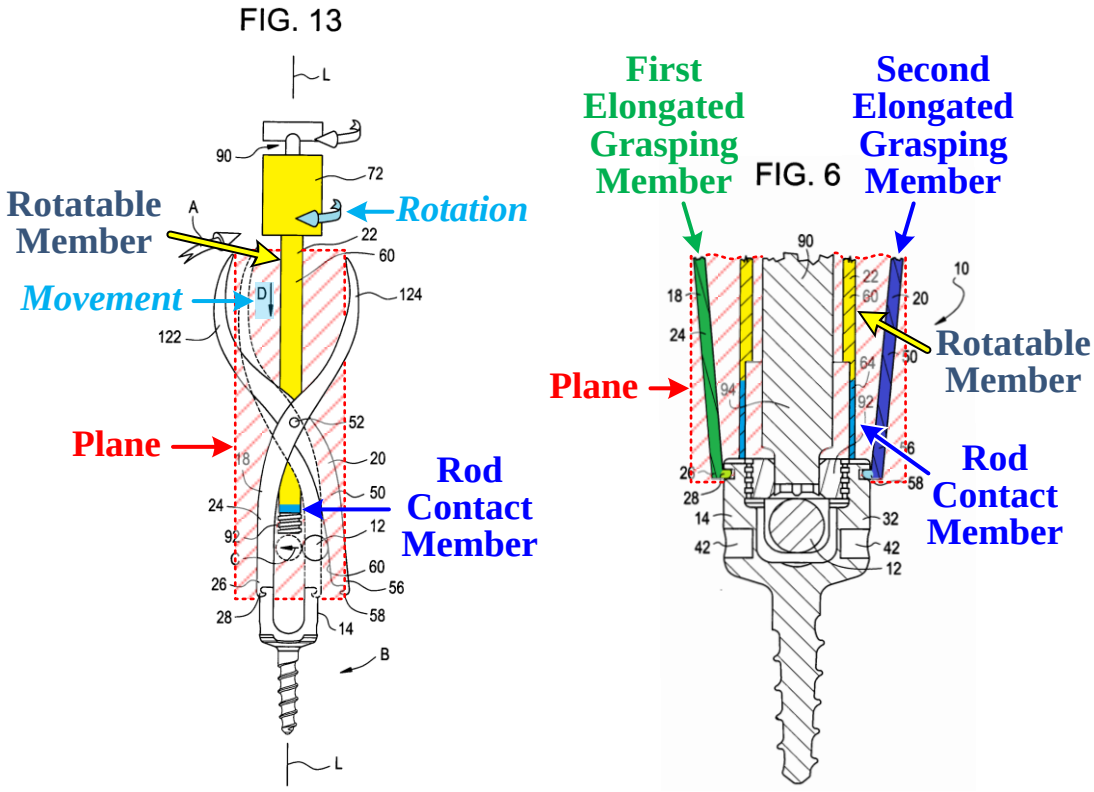


FIG. 4



Whipple discloses "the first and second elongated grasping members defining a plane" as recited in claim 1. As shown in FIGS. 2 and 4, the first and second arms 24, 50 (*i.e.*, the claimed *first and second grasping members*) of Whipple implicitly define a plane. *See also* ORT-1116 ¶¶67-68.

k. Limitation-[1-10]:



Whipple discloses the "the rotatable member and the rod contact member movable within the plane" of claim 1. As discussed, Whipple discloses that "***[r]otation of the tube 60*** . . . ***causes the tube 60 to advance distally*** . . . relative to the first arm 24 and the second arm 50." ORT-1117 ¶36; FIG. 13 (annotated). Whipple also discloses that "***the tube 60*** may be ***advanced distally in a second direction*** into contact with spinal fixation element 12, as indicated by arrow D." *Id.* ¶*46*; FIG. 13 (annotated).

Additionally, because ***the distal end 64*** (the claimed *rod contact member*) is positioned at the distal end of ***the tube 60*** (the claimed *rotatable member*), it too advances distally relative to the first and second arms 24, 50 (the claimed *first and*

second elongated grasping members). For example, annotated FIGS. 6 and 13 show that the distal end (the claimed *rod contact member*) and tube 60 (the claimed *rotatable member*) are disposed between and moveable within the first and second arms 24, 50 (the claimed *first and second elongated grasping members*).

Thus, both the distal end 64 (*i.e.*, the claimed *rod contact member*) and the tube 60 (*i.e.*, the claimed *rotatable member*) are moveable within the plane defined by the first and second arms 24, 50 (*i.e.*, the claimed *first and second elongated grasping members*).

l. Limitation-[1-11]:

FIG. 6

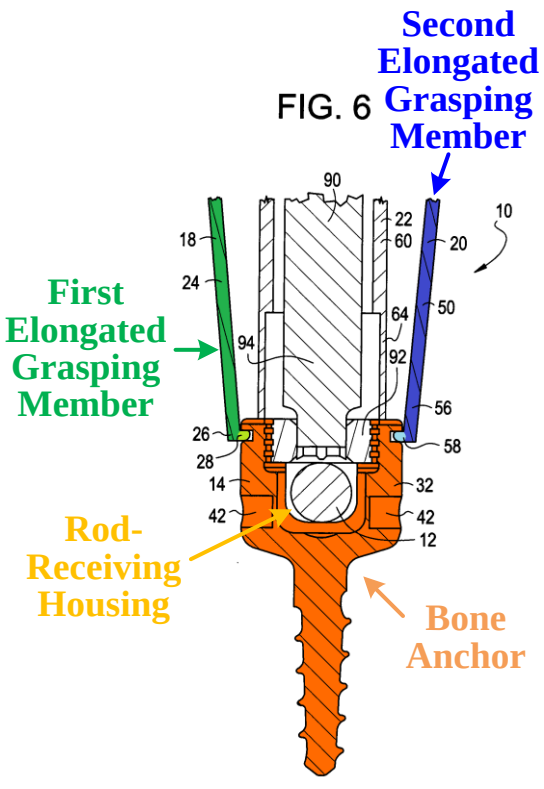
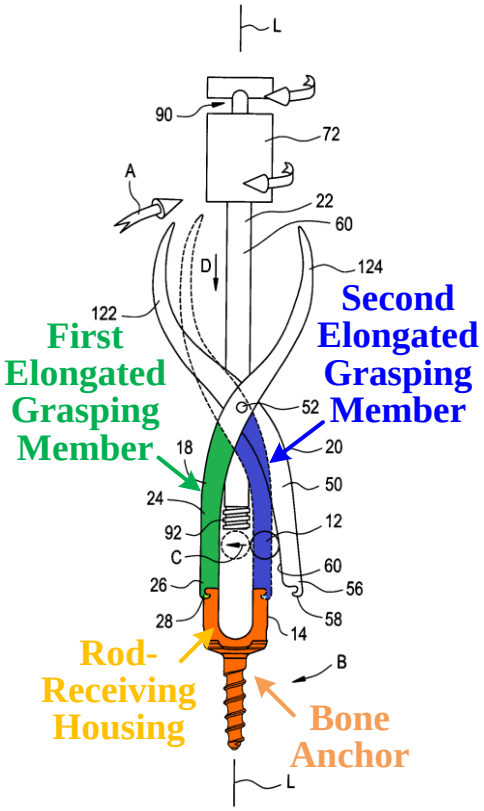


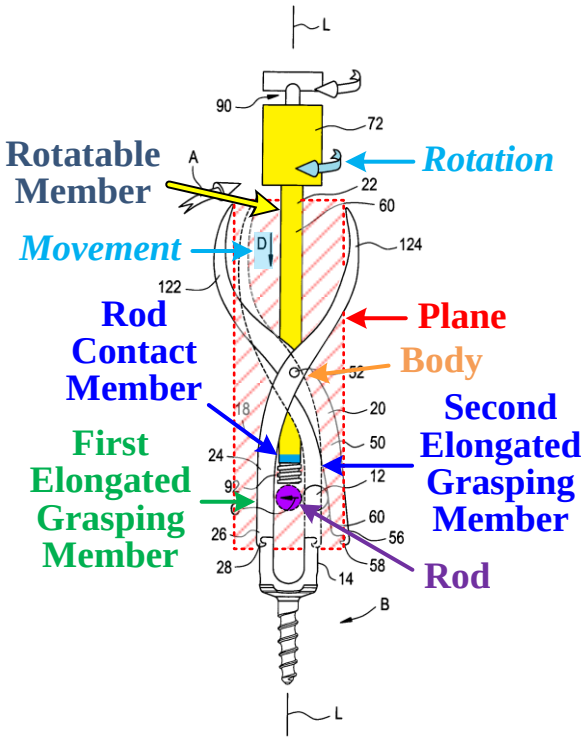
FIG. 13



Whipple discloses "securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members" as recited in claim 1. As discussed, Whipple discloses features that allow the ***instrument 10*** to be ***connected*** to ***a bone anchor 14***. *See, e.g., Id.* ¶28. For example, Whipple discloses that "the distal end 26 of ***the first arm 24 may be engaged with the bone anchor 14***" and "***[t]he second arm 50*** may have a distal end 56 configured to releasably ***engage the bone anchor 14***." *Id.* ¶¶28, 32; FIGS. 6, 13 (annotated). Whipple also discloses arrangements that include "a locking mechanism, such as a latch or a ratchet assembly, that is operable to lock the handles 122, 124 in position relative to one another, for example, in a closed position ***to retain the bone anchor between the distal ends 26, 56 of the arms 24, 50***." *Id.* ¶40.

m. Limitation-[1-12]:

FIG. 13

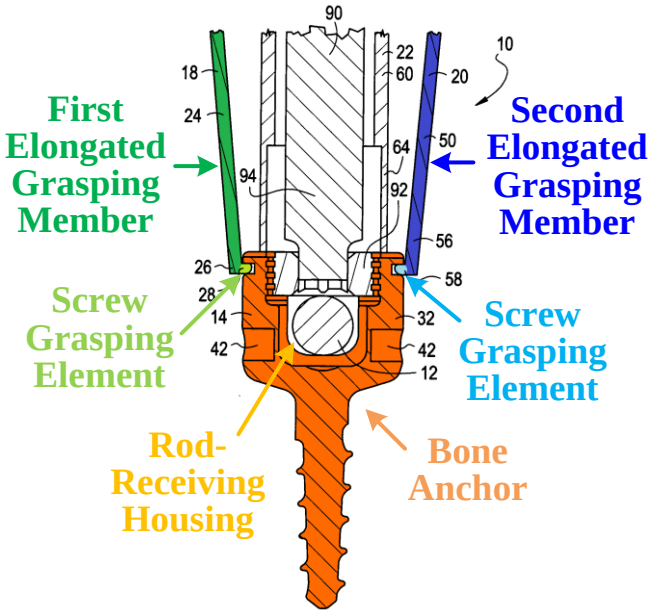


Whipple discloses "rotating the rotatable member thereby causing the rod contact member to move relative to the body within the plane to advance a rod disposed between the first and second elongated grasping members toward the rod-receiving housing" as recited in claim 1. In particular, Whipple discloses that "***[r]otation of the tube 60 . . . causes the tube 60 to advance distally*** . . . relative to the first arm 24 and the second arm 50." *Id.* ¶36; FIG. 13 (annotated). Whipple also discloses that "***advancement of the tube 60 toward the bone anchor 14 advances the spinal fixation element 12 toward the bone anchor 14*** until the spinal fixation element 12 is seated in the bone anchor 14." *Id.* ¶46.

As discussed, Whipple discloses that ***the tube 60*** (the claimed *rotatable member*) and ***the distal end 64*** (the claimed *rod contact member*) move within the plane. Annotated FIG. 13 shows that such movement within the plane is also movement relative to the body. Furthermore, FIG. 13 depicts ***the spinal fixation element 12*** (the claimed *rod*) positioned between the first and second arms 24, 50 (the claimed *first and second elongated grasping members*).

2. Dependent Claim 3:

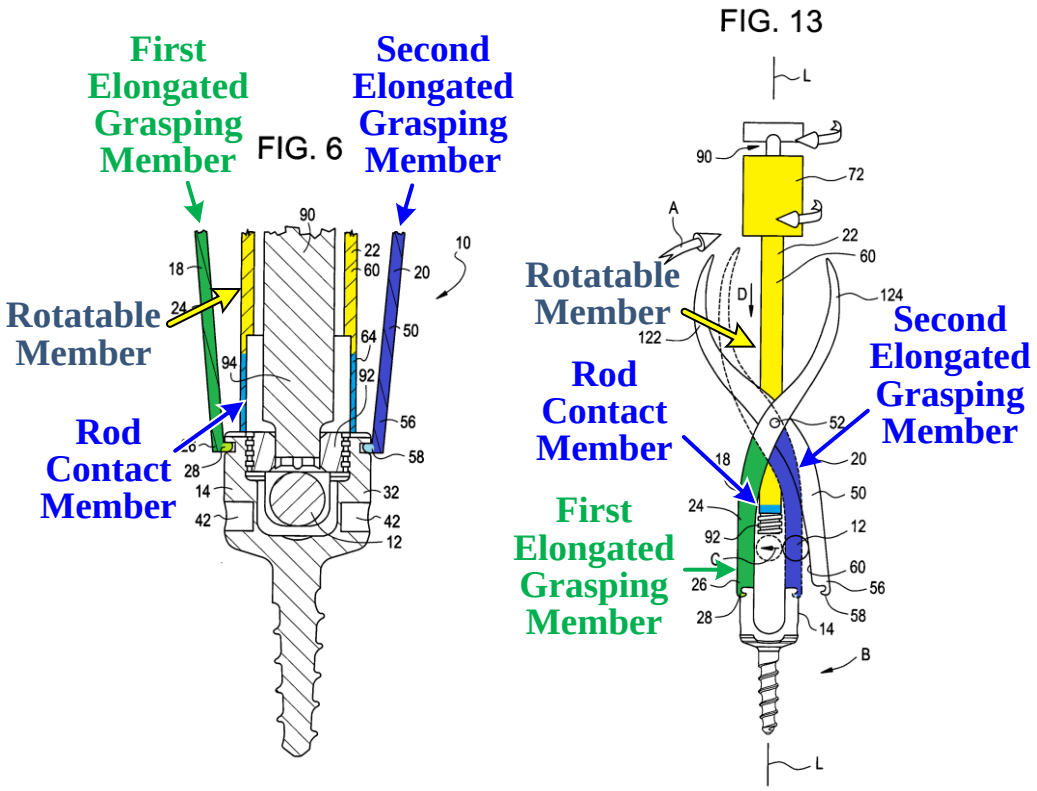
FIG. 6



Whipple discloses "securing the rod reducing device to the bone anchor includes coupling respective distal ends of the first and second elongated grasping members having at least one grasping feature to engage the rod-receiving housing of the bone anchor" as recited in claim 3. Whipple discloses that "the distal end 26

of ***the first arm 24 may be engaged with the bone anchor 14***" and "***[t]he second arm 50*** may have a distal end 56 configured to releasably ***engage the bone anchor 14***." *Id.* ¶¶28, 32; FIG. 6 (annotated). Whipple further discloses that the distal ends 26, 56 of the first and second arms 24, 50 include ***radially inward facing projections 28, 58*** sized and shaped to engage bone anchor openings. *See, e.g., id.* ¶¶29, 32; FIG. 6 (annotated).

3. Dependent Claim 5:

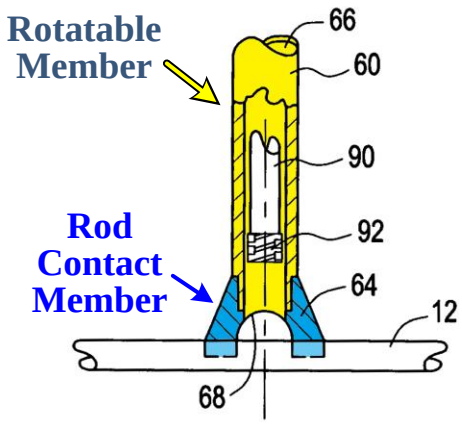


Whipple discloses "coupling the rod reducing device includes coupling the rod reducing device in which a portion of the rod contact member is positioned between the first and second elongated grasping members" as recited in claim 5.

As discussed, Whipple discloses that, in response to rotation, the tube 60 (the claimed *rotatable member*) advances distally relative to the first and second arms 25 and 50 (the claimed *first and second elongated grasping members*). *See id.* ¶36; FIG. 13 (annotated). Whipple further discloses that ***the distal end 64*** (the claimed *rod contact member*), which is positioned at the distal end of the tube 60 (the claimed *rotatable member*), directly contacts the spinal fixation element 12 (*e.g.*, the spinal rod). *See id.* ¶35; FIG. 11A. Additionally, FIGS. 6 and 13 of Whipple depict a portion of ***the distal end 64*** (the claimed *rod contact member*) of the tube 60 positioned between the first and second arms 24, 50 (the claimed *first and second elongated grasping members*).

4. Dependent Claim 6:

FIG. 11A



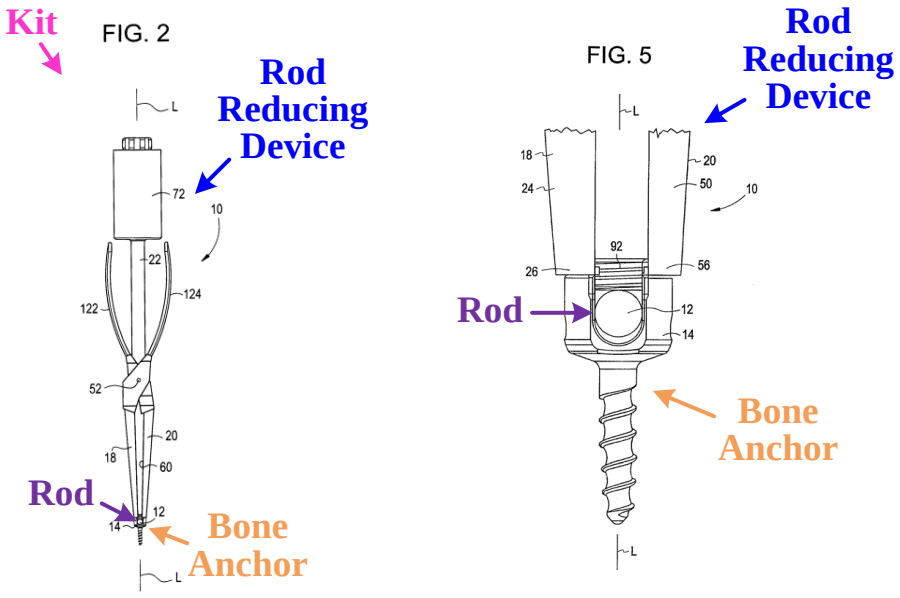
Whipple discloses "the rod contact member is ***attached*** to the distal end of the rotatable member" as recited in claim 6. More specifically, as discussed,

Whipple discloses that ***the distal end 64*** may be positioned at the distal-most end of ***the tube 60***. *See, e.g.*, FIG. 11A (annotated). Furthermore, ***the distal end 64*** (the claimed *rod contact member*) is joined to the distal-most end of ***the tube 60*** (the claimed *rotatable member*) by way of a receiver portion configured to cooperate with the distal-most end of the tube 60. *See id.*

Nothing in claim 6, or in any of the other Challenged Claims, requires the claimed *rod contact member* to be "fixedly" or "securely" attached to the distal end of the claimed *rotatable member*. As such, because ***the distal end 64*** (the claimed *rod contact member*) and ***the tube 60 (***the claimed *rotatable member*) are ***joined*** together by way of respective cooperating structures, ***the distal end 64*** is ***attached*** to the distal-most end of ***the tube 60***.

5. Independent Claim 8:

a. Limitation-[8-PRE]:



Whipple discloses "kit for reducing a rod" as recited in claim 8. In particular, Whipple discloses "***an instrument 10*** for ***manipulating a spinal fixation element 12***, such as, for example, a spinal rod, a plate, a tether or cable or combinations thereof, relative to ***a bone anchor 14***, such as, for example, a bone screw or hook." *Id.* ¶26; FIGS. 2, 5 (annotated). In doing so, Whipple discloses all of the recited features of claim 8, each of which is further discussed below.

b. Limitation-[8-1]:

FIG. 13

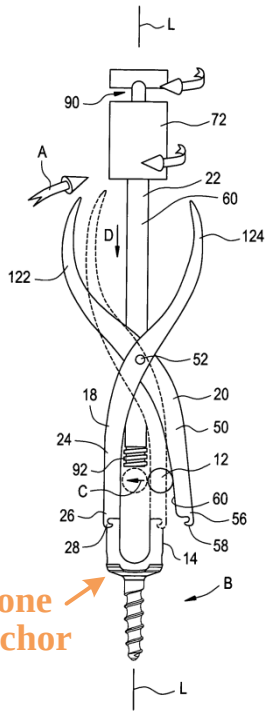
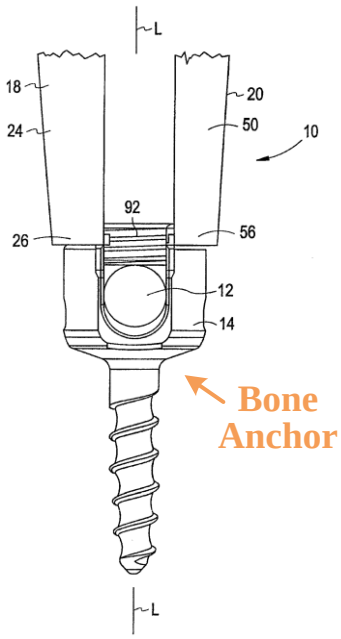


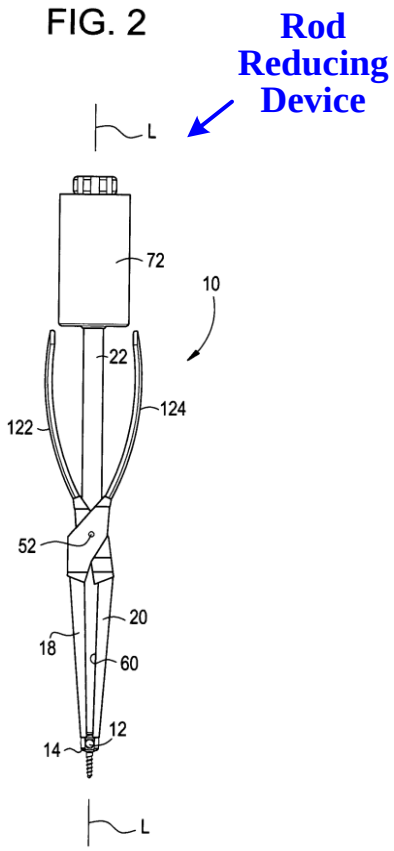
FIG. 5



Whipple discloses the "bone anchor" of claim 8. For example, as discussed, Whipple discloses "an instrument 10 for manipulating a spinal fixation element 12, such as, for example, a spinal rod, a plate, a tether or cable or combinations

thereof, relative to ***a bone anchor 14***, such as, for example, a bone screw or hook." *Id.* ¶26; FIGS. 5, 13 (annotated).

c. Limitation-[8-2]:



Whipple discloses the "rod reducing device" of claim 8. In particular, Whipple discloses "***an instrument 10 for manipulating a spinal fixation element 12, such as, for example, a spinal rod***, a plate, a tether or cable or combinations thereof, relative to a bone anchor 14, such as, for example, a bone screw or hook." *Id.* ¶26; FIG. 2, above. Whipple further discloses that "the exemplary instrument 10 is suited for . . . ***vertical adjustment of the spinal fixation element 12 relative to the bone anchor 14***." *Id.*

d. Limitation-[8-3]:

FIG. 2

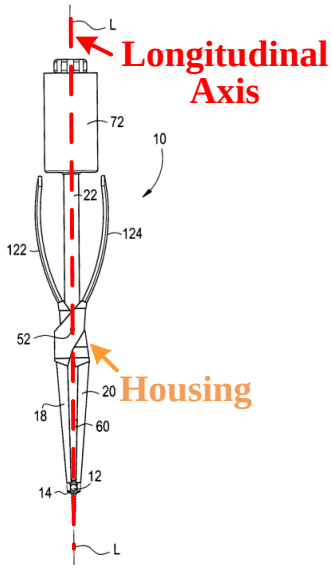


FIG. 3

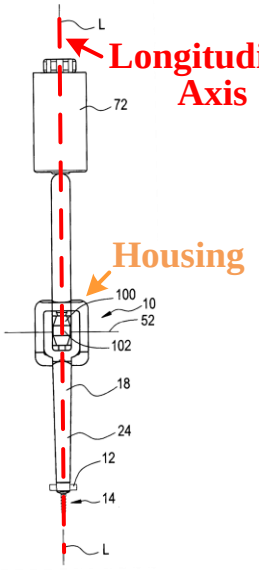
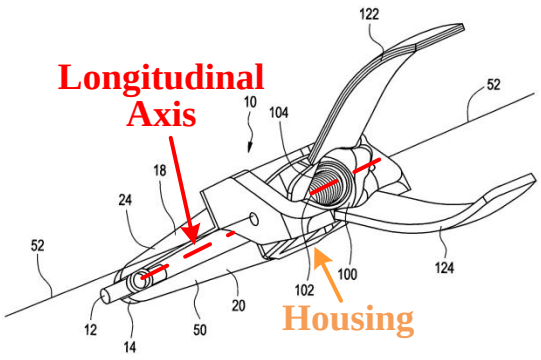
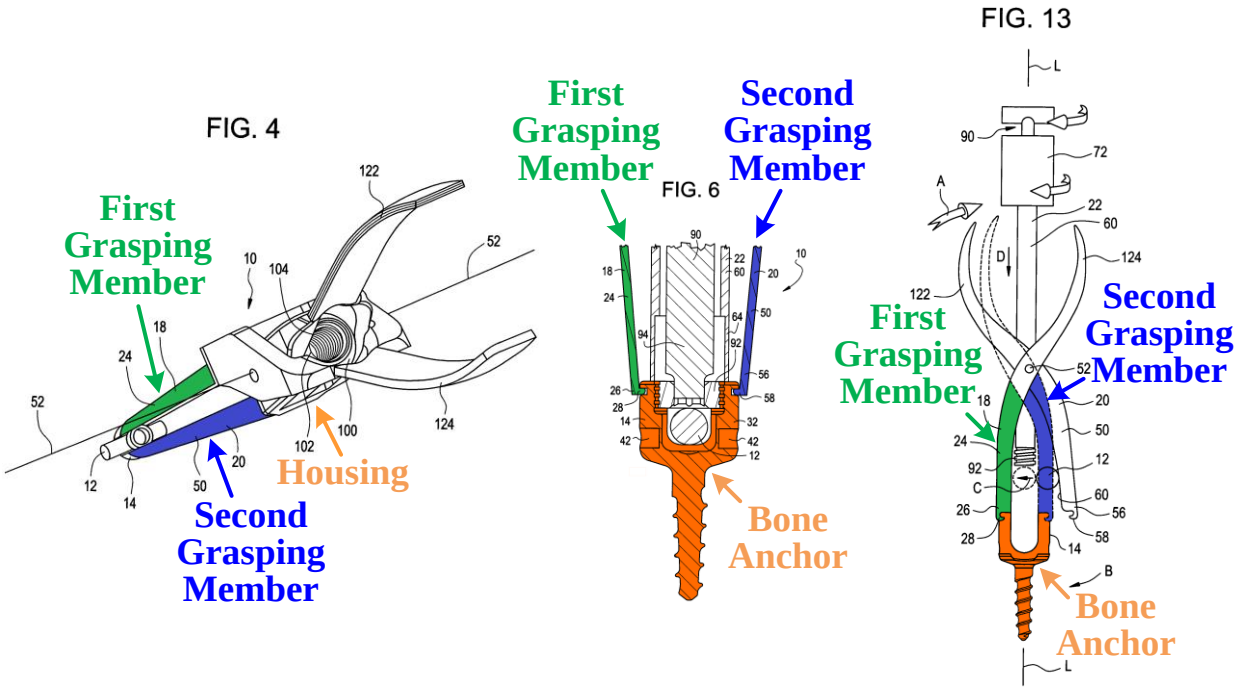


FIG. 4



Whipple discloses the "housing defining a longitudinal axis" of claim 8. For example, Whipple discloses "***a coupling mechanism 100*** that is connected to the first arm 24 and/or the second arm 50 and is configured to receive the second adjustment mechanism 22, *e.g.*, tube 60." *Id.* ¶36; FIGS. 2-4 (annotated). Whipple further discloses "the handles 122, 124 . . . are oriented generally in a direction parallel to ***the longitudinal axis L*** of the instrument 10." *Id.* ¶42; FIG. 2, above. Thus, Whipple discloses ***coupling mechanism 100*** (the claimed *housing*) defining the ***longitudinal axis L***.

e. Limitation-[8-4]:



Whipple discloses the claimed "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween." As discussed, Whipple discloses that ***the coupling mechanism 100*** (the claimed *housing*) "is connected to ***the first arm 24 and/or the second arm 50***." *Id.* ¶36; FIGS. 4, 13 (annotated). Additionally, Whipple discloses the "***first arm 24*** having a distal end 26 ***configured to releasably engage a bone anchor***" and the "***second arm 50*** . . . hav[ing] a distal end 56 ***configured to releasably engage the bone anchor 14***." *Id.* ¶¶28, 32; FIGS. 4, 6, 13 (annotated). FIGS. 6 and 13 clearly show a portion of the bone anchor 14 grasped between the first and second arms 24 and 50, respectively.

f. Limitation-[8-5]:

FIG. 2

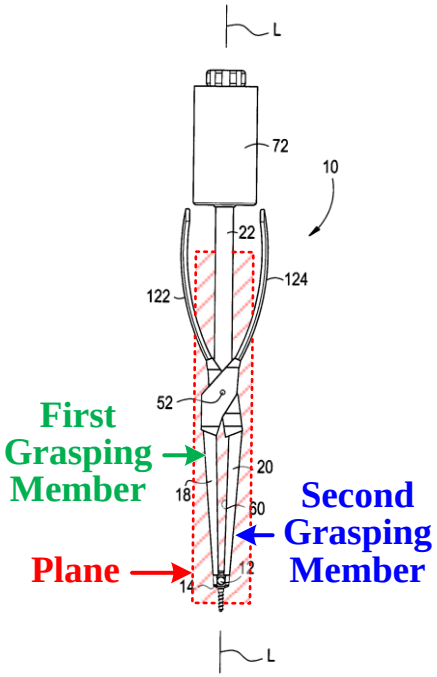
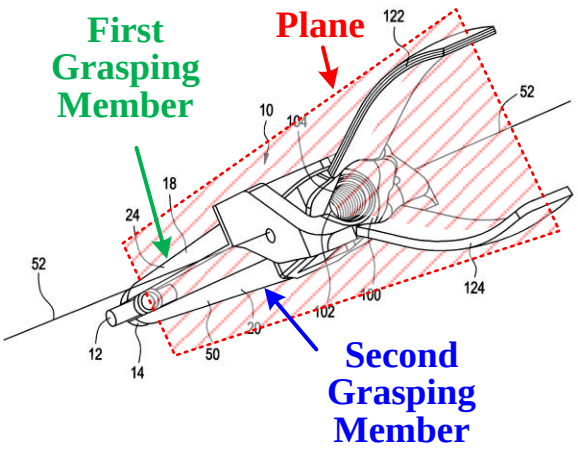
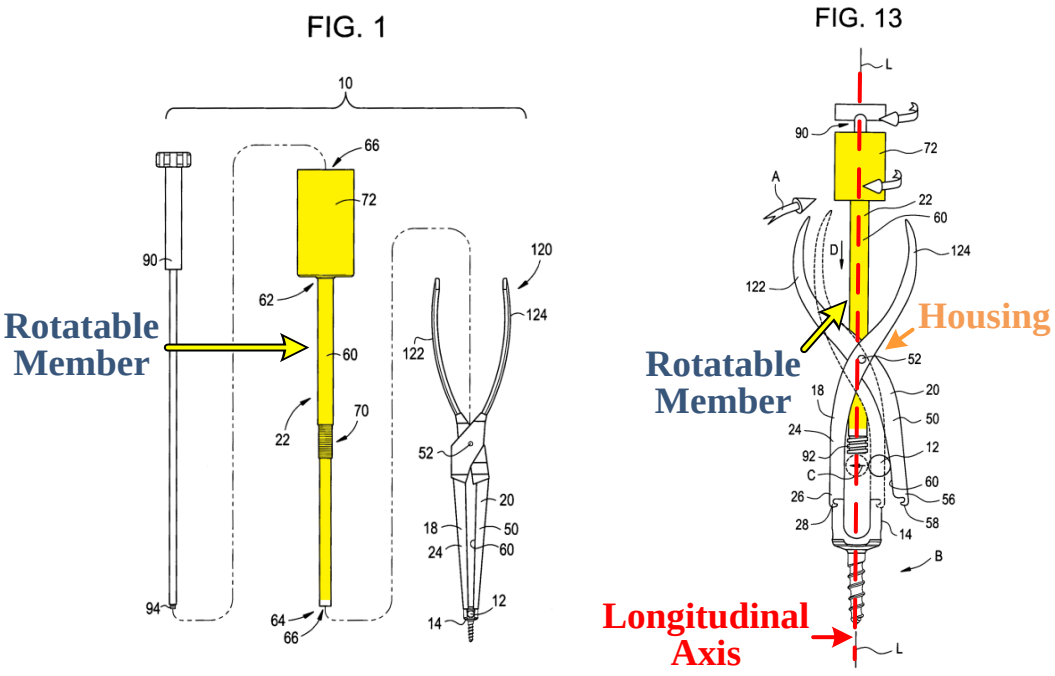


FIG. 4



Whipple discloses "first and second grasping members defining a plane" as recited in claim 8. As shown in FIGS. 2 and 4 above, ***the first and second arms 24, 50*** (*i.e.*, the claimed *first and second grasping members*) of Whipple implicitly define a plane.

g. Limitation-[8-6]:



Whipple discloses the "rotatable member extending through the housing along the longitudinal axis" of claim 8. For example, Whipple states that ***"[the] coupling mechanism 100 . . . is configured to receive the second adjustment mechanism 22, e.g., tube 60***, and permit motion of the second adjustment mechanism 22 relative to the first arm 24 and/or the second arm 50." ORT-1117 ¶36; FIGS. 1, 13 (annotated). Whipple further discloses that "***[r]otation of the tube 60*** relative to the collar 102 causes the tube 60 to advance distally or proximally, depending on the direction of rotation, relative to the first arm 24 and the second arm 50." *Id*. As shown in FIGS. 1 and 13 above, ***the tube 60***/second adjustment mechanism 22 extends ***through the coupling mechanism 100*** (the claimed *housing*) ***along the longitudinal axis L***. *See also* FIGS. 2-4.

h. Limitation-[8-7]:

FIG. 1

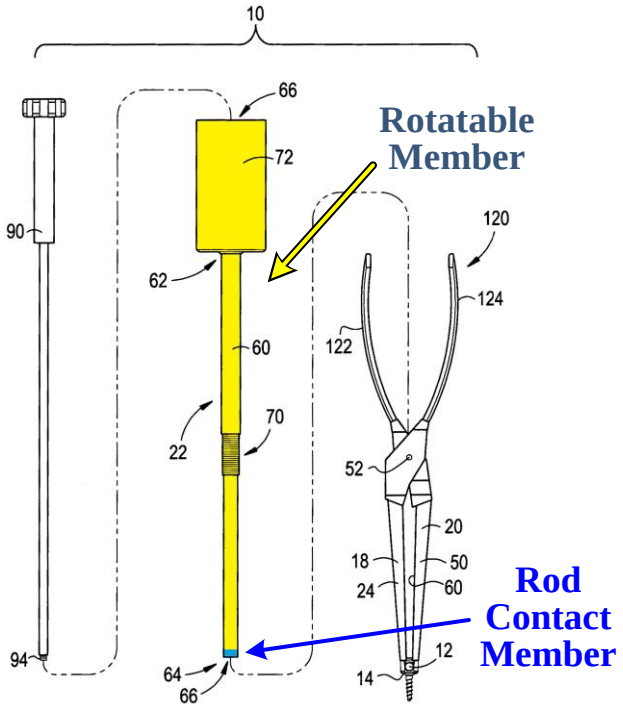
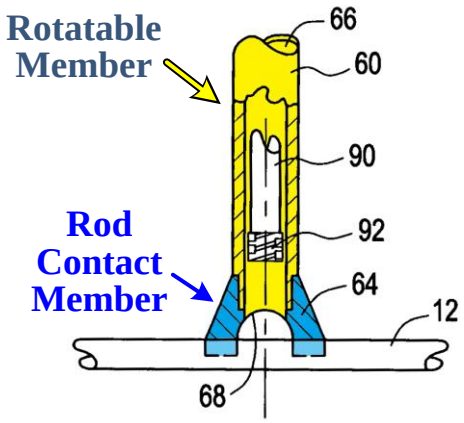


FIG. 11A

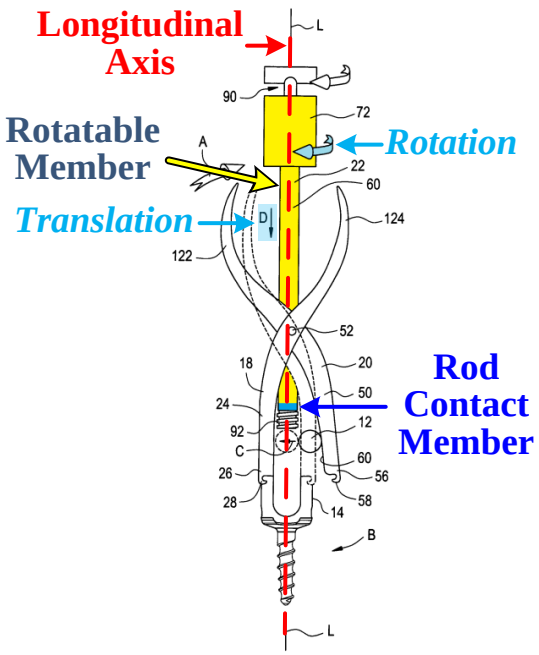


Whipple discloses "a rod contact member positioned at a distal end of the rotatable member" as recited in claim 8. For example, Whipple discloses "***the distal end 64*** of the tube 60 ***may directly contact the spinal fixation element 12*** to effect adjustment of the spinal fixation element 12." *Id.* ¶35; FIG. 1 (annotated). Whipple also discloses "***the distal end 64*** of the tube [60] ***may be sized and shaped to facilitate contact with the spinal fixation element 12***." *Id.* For example, Whipple discloses "***the distal end 64*** may include ***an arcuate contact surface 68*** having a curvature approximate to the curvature of the spinal fixation element 12." *Id.*; FIG. 11A (annotated). As shown in FIG. 11A, ***the distal end 64*** having the

accurate contact surface 68 (the claimed *rod contact member*) of Whipple is positioned at the distal-most end of ***the tube 60*** (the claimed *rotatable member*).

i. Limitation-[8-8]:

FIG. 13

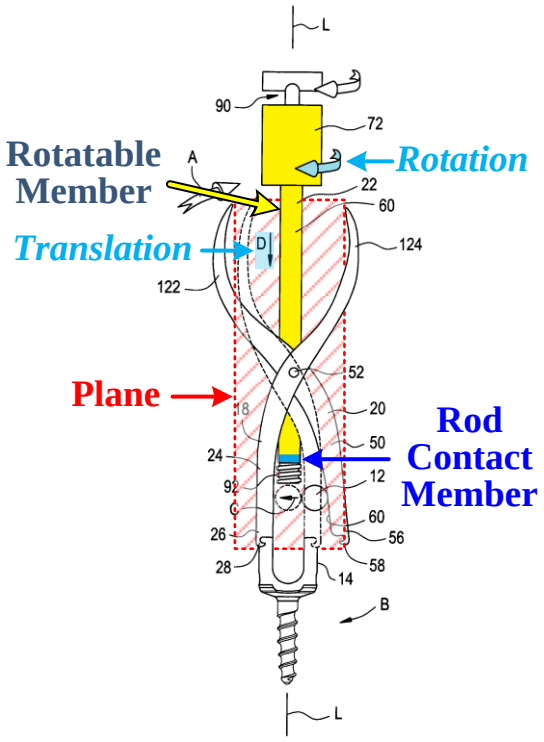


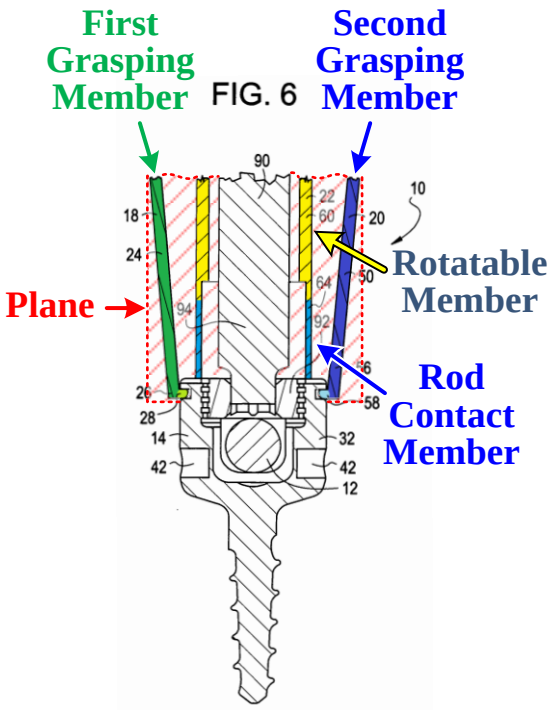
Whipple discloses the "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" of claim 8. For example, Whipple states that "***[r]otation of the tube 60*** relative to the collar 102 ***causes the tube 60 to advance distally . . . relative to the first arm 24 and the second arm 50***. *Id.* ¶36; FIG. 13 (annotated). Whipple also states that "[u]pon vertical alignment of the spinal fixation element 12 with ***the longitudinal axis L*** of the instrument and the bone anchor, ***the tube 60 may be advanced distally*** in a second direction into contact with spinal fixation element 12, as indicated by arrow D." *Id.* ¶46; FIG. 13. Because ***the distal end 64***

(the claimed *rod contact member*) is positioned at the distal end of ***the tube 60*** (the claimed *rotatable member*), it too advances distally along ***the longitudinal axis L*** in response to rotation of the tube 60 about the longitudinal axis L.

j. Limitation-[8-9]:

FIG. 13





Whipple discloses the "rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 8. As illustrated in FIGS. 6 and 13, the first and second arms 24, 50 (*i.e.*, the claimed *first and second grasping members*) of Whipple implicitly define a plane. As discussed, Whipple discloses that "***[r]otation of the tube 60*** . . .

causes the tube 60 to advance distally or proximally . . . relative to the first arm 24 and the second arm 50." *Id.* ¶36; FIG. 13.

Additionally, because ***the distal end 64*** (the claimed *rod contact member*) is positioned at the distal end of ***the tube 60*** (the claimed *rotatable member*) it too advances distally relative to ***the first and second arms 24, 50*** (the claimed *first and second grasping members*). For example, as shown in FIGS. 6 and 13***, the distal end 64*** (the claimed *rod contact member*) and ***the tube 60*** (the claimed *rotatable member*) are disposed between and translatable within the first and second arms 24, 50 (the claimed *first and second grasping members*).

Thus, both ***the distal end 64*** (*i.e.,* the claimed *rod contact member*) and ***the tube 60*** (*i.e.*, the claimed *rotatable member*) are translatable within this plane defined by the first and second arms 24, 50 (*i.e.*, the claimed *first and second grasping members*).

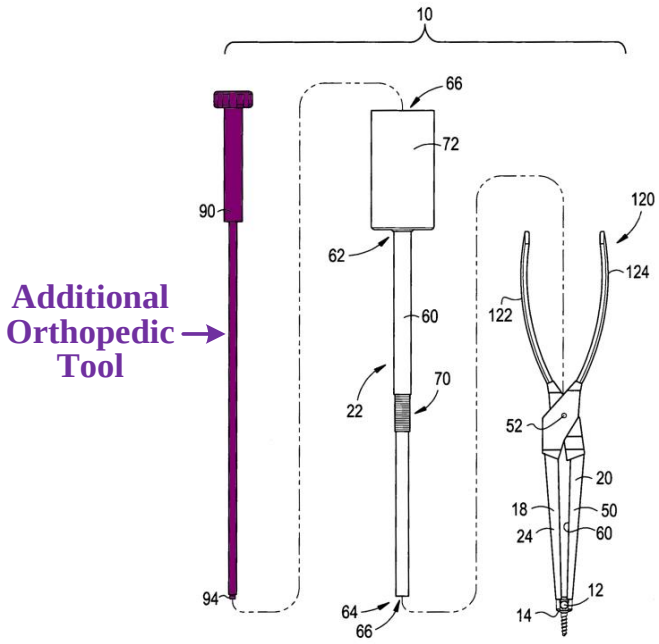
6. Dependent Claim 9:

Claim 9 recites "a plurality of bone anchors and a plurality of rod reducing devices." Claim 9 thus calls for the mere duplication of the bone anchor and the rod reducing device described in claim 8, but such duplications do not have any patentable significance because they produce no new or unexpected result. *See In re Harza*, 274 F.2d 669, 774 (CCPA 1960) ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected

result is produced, and we are of the opinion that such is not the case here."); MPEP §2144.04(VI)(B); ; ORT-1116 ¶¶116, 118-119.

7. Dependent Claim 10:

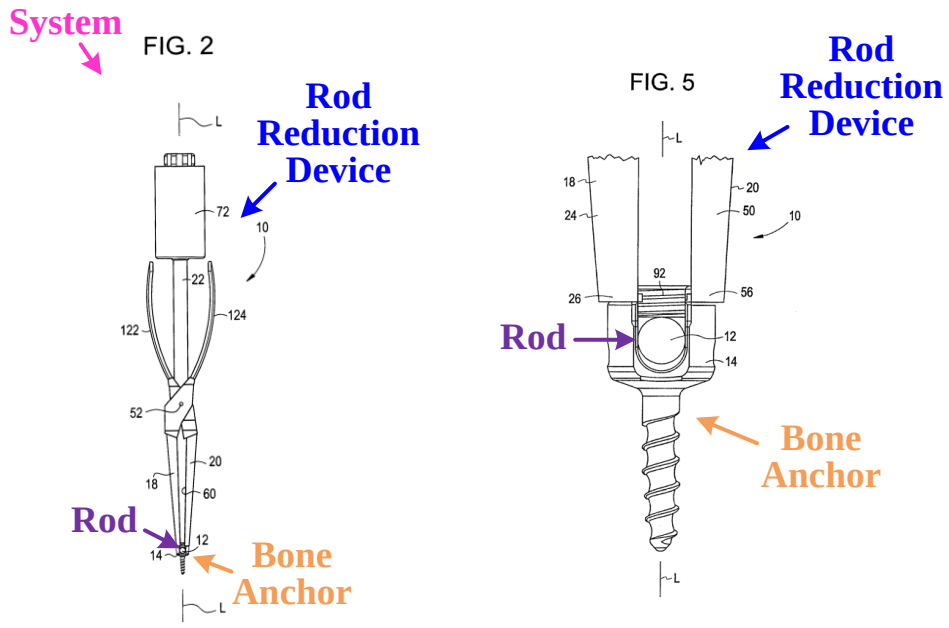
FIG. 1



Whipple discloses the "at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" of claim 10. In particular, Whipple discloses that "***the closure mechanism delivery instrument 90*** is a ***screwdriver*** having a distal end 94 with external threads for engaging the closure mechanism 92." ORT-1117 ¶34; FIG. 1 (annotated).

8. Independent Claim 12:

a. Limitation-[12-PRE]:

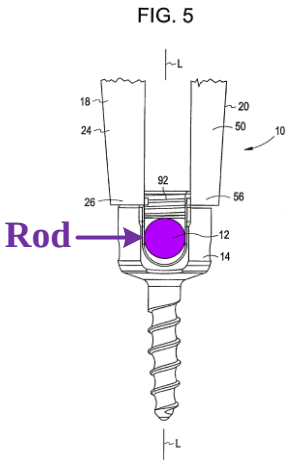


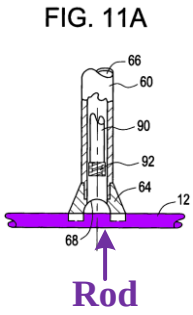
Whipple discloses the "system for reducing a connecting rod" of claim 12. In particular, Whipple discloses "***an instrument 10*** for ***manipulating a spinal fixation element 12***, such as, for example, a spinal rod, a plate, a tether or cable or combinations thereof, relative to ***a bone anchor 14***, such as, for example, a bone screw or hook." *Id.* ¶26; FIGS. 2, 5 (annotated). In doing so, Whipple discloses all of the recited features of the system of claim 12, each of which is further discussed below.

b. Limitations-[12-1], [12-4]-[12-8]:

Per §VIII(A)(5)(b), (d)-(h), Whipple discloses these identical limitations, respectively.

c. Limitation-[12-2]:





Whipple discloses the "connecting rod" of claim 12. In particular, Whipple discloses "***a spinal fixation element 12***, such as, for example, ***a spinal rod***." *Id.* ¶26; FIGS. 5, 11A (annotated).

d. Limitation-[12-3]:

Per §VIII(A)(5)(c), Whipple discloses "a rod reducing device"[3] and therefore likewise discloses limitation [12-3].

[3] As discussed, the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device.

e. Limitation-[12-9]:

FIG. 13

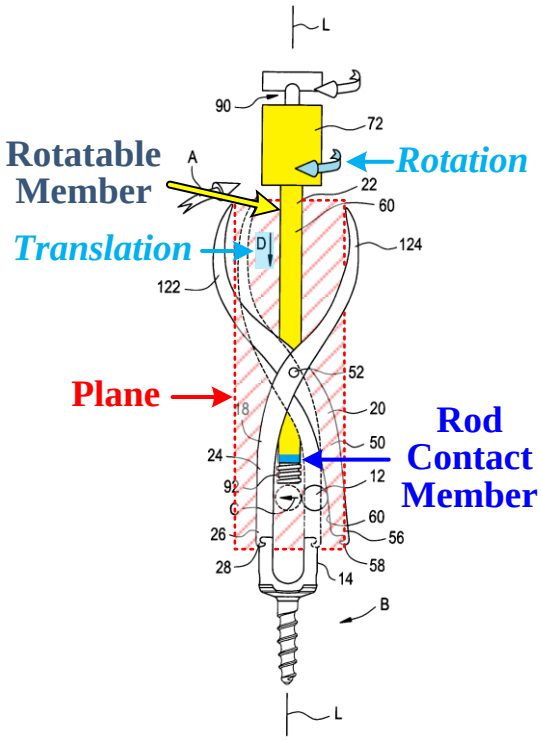
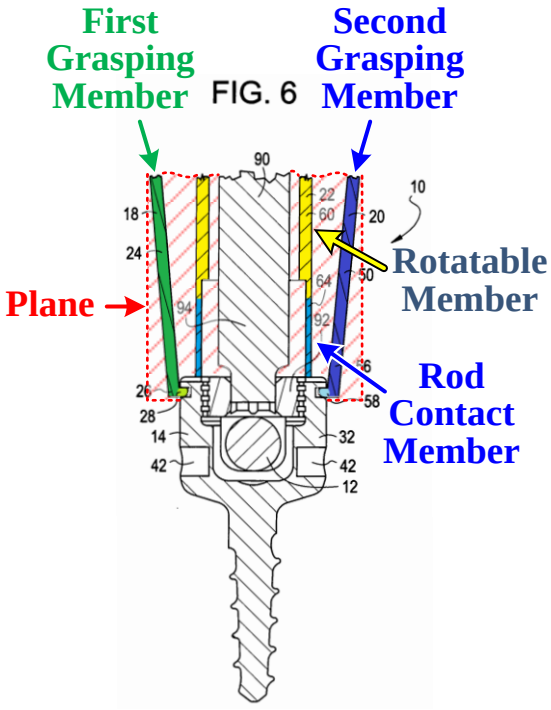


FIG. 6



Whipple discloses the "rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" as recited in claim 12. As illustrated in annotated FIGS. 6 and 13, the first and second arms 24, 50 (*i.e.*, the claimed *first and second grasping members*) of Whipple implicitly define a plane. As discussed, Whipple discloses that "***[r]otation of the tube 60*** . . . ***causes the tube 60 to advance distally*** or proximally . . . relative to the first arm 24 and the second arm 50." *Id.* ¶36; FIG. 13. As depicted in FIGS. 6 and 13, this distal advancement or translation of ***the tube 60*** (the claimed *rotatable member*) occurs within the plane defined by the ***first and second arms 24, 50*** and in response to rotation of ***the tube 60***.

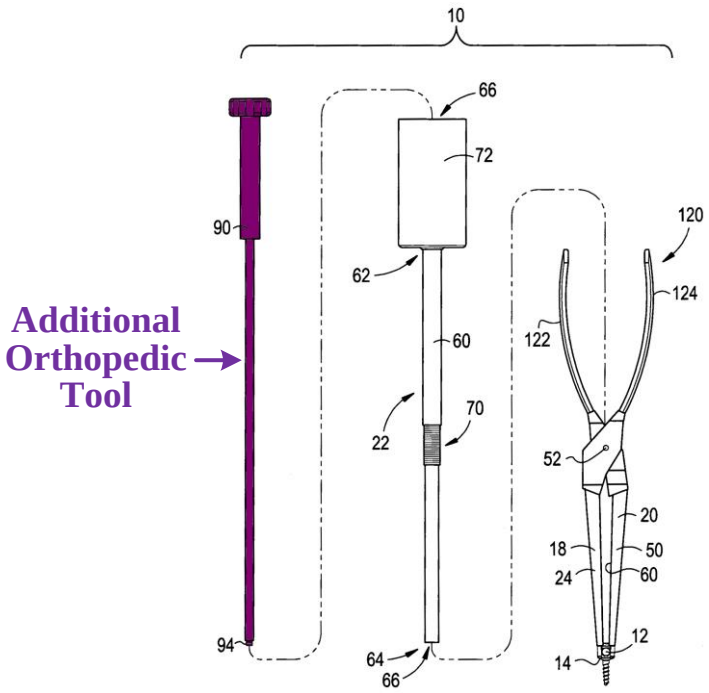
Additionally, because ***the distal end 64*** (the claimed *rod contact member*) is positioned at the distal end of ***the tube 60*** (the claimed *rotatable member*), it too advances relative to, and within the plane defined by, ***the first and second arms 24, 50*** (the claimed *first and second grasping members*) in response to rotation and translation of ***the tube 60***. For example, as shown in FIGS. 6 and 13, ***the distal end 64*** (the claimed *rod contact member*), like ***the tube 60*** (the claimed *rotatable member*), is disposed between and translatable within the plane defined by the first and second arms 24, 50 (the claimed *first and second grasping members*).

9. Dependent Claim 15:

Claim 15 recites "a plurality of bone anchors and a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors." Claim 15 thus calls for the mere duplication of the bone anchor and the rod reduction device described in claim 12, but such duplications do not have any patentable significance because they produce no new or unexpected result. *Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B); ORT-1116 ¶¶152, 154-155.

10. Dependent Claim 16:

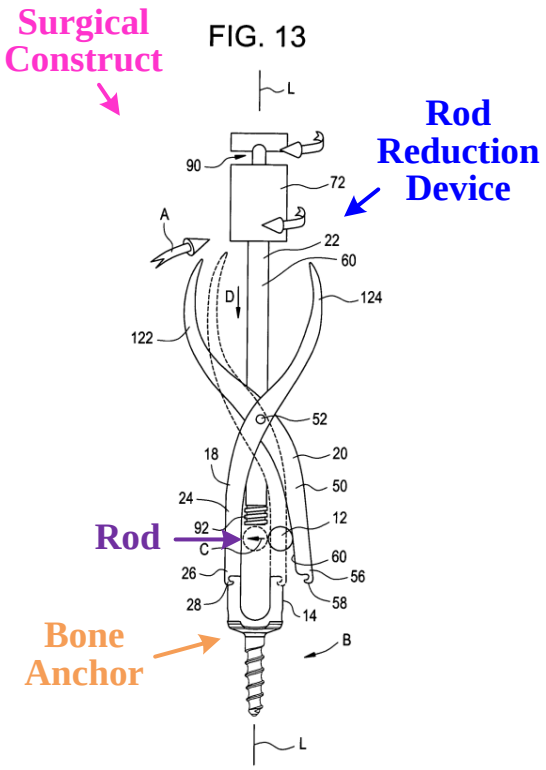
FIG. 1



Whipple discloses the "at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" of claim 16. In particular, Whipple discloses that "***the closure mechanism delivery instrument 90*** is a ***screwdriver*** having a distal end 94 with external threads for engaging the closure mechanism 92." ORT-1117 ¶34.; FIG. 1 (annotated).

11. Independent Claim 17:

a. Limitation-[17-PRE]:



Whipple discloses the "surgical construct" of claim 17. In particular, Whipple discloses ***an instrument 10*** (*i.e.*, the claimed *rod reduction device*) connected to ***a bone anchor 14*** and engaging ***a spinal fixation element 12*** (*i.e.*, the claimed *connecting rod*). *See, e.g.*, *id.* ¶¶26, 28, 45; FIG. 13 (annotated).

b. Limitation-[17-1]:

Per §VIII(A)(5)(b), Whipple discloses "a bone anchor." Limitation [17-1] recites "a plurality of bone anchors." Claim 17 thus calls for mere duplication of the bone anchor of claim 8, but such duplication does not have any patentable

significance because it produces no new or unexpected result. *Harza*, 274 F.2d at 774 ; MPEP §2144.04(VI)(B); ORT-1116 ¶¶162, 164-165.

c. Limitations-[17-2], [17-5]-[17-9], [17-10]:

Per §VIII(A)(8)(c), (5)(d)-(h), (8)(j), Whipple discloses these identical limitations, respectively.

d. Limitation-[17-3]:

Per §VIII(A)(5)(c), Whipple discloses "a rod reducing device."[4] Limitation [17-3] recites "a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices connectable to a bone anchor of the plurality of bone anchors." Therefore, claim 17 calls for mere duplication of the rod reducing device described in claim 8, but such duplication does not have any patentable significance because it produces no new or unexpected result. *Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B); ORT-1116 ¶¶170, 172-173.

e. Limitation-[17-4]:

As discussed, Whipple discloses rod reduction device(s)[5] including all of the recited features of claim 17. ORT-1116 ¶174.

---

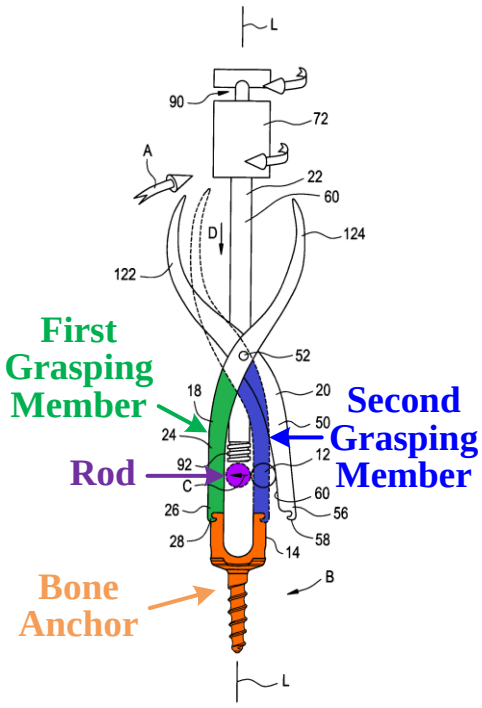
[4] *Supra* note 3.

[5] As discussed, the mere duplication of rod reduction devices in claim 17 (*i.e.*, the claimed *plurality of rod reduction devices*) does not have any patentable

12. Dependent Claim 18:

a. Limitation-[18-1]:

FIG. 13



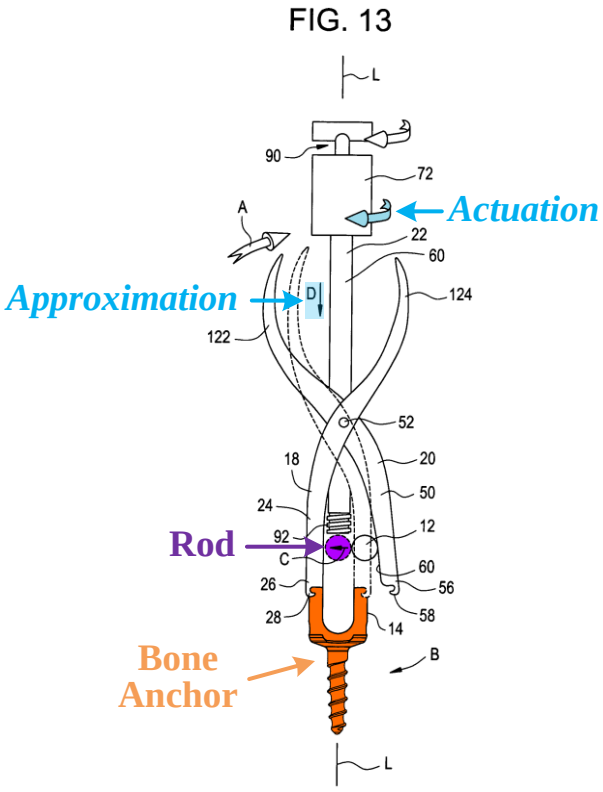
Whipple discloses "the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors" as recited in claim 18. In particular, Whipple discloses that "***the first arm 24*** may be ***engaged with the bone anchor 14***" and "***the second arm 50 engages*** the spinal fixation element 12 ***to move the spinal fixation element 12 . . . toward the bone anchor 14***." ORT-1117 ¶45. Additionally, FIG. 13 of

---

significance because it produces no new or unexpected result. *Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B).

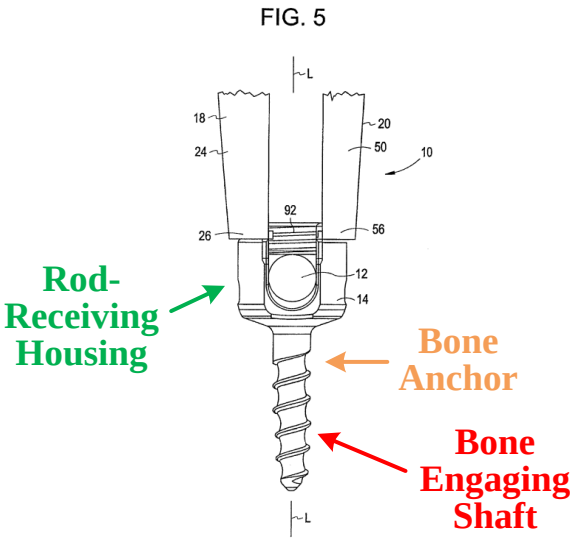
Whipple depicts a portion of ***the spinal fixation element 12*** (*i.e.*, the claimed *connecting rod*) positioned between the first and second arms 24, 50 (*i.e.*, the claimed *first and second grasping members*).

b. Limitation-[18-2]:



Whipple discloses "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18. In particular, Whipple discloses that "***advancement of the tube 60 toward the bone anchor 14 advances the spinal fixation element 12 toward the bone anchor 14*** until the spinal fixation element 12 is seated in the bone anchor 14." *Id.* ¶46; FIG. 13 (annotated).

13. Dependent Claim 19:



Whipple discloses "each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom" as recited in claim 19. In particular, Whipple discloses "***a bone anchor***, such as a polyaxial or monoaxial ***bone screw***." *Id.* ¶5. Whipple also discloses that "screws typically include ***a threaded shank*** that is adapted to be ***threaded into a vertebra***, and ***a head portion having a spinal fixation element receiving element***, which, in spinal rod applications, is usually in the form of a U-shaped slot formed in the head for receiving the rod." *Id.* ¶2. Furthermore, Whipple discloses the claimed features of the bone anchor. *Id.* FIG. 5 (annotated).

B. Ground 2: All Challenged Claims Are Anticipated by Runco

Runco anticipates the Challenged Claims of the '664 Patent. Runco was filed on September 26, 2005 and was published on April 13, 2006. ORT-1118 1.

Therefore, Runco is prior art under at least 35 U.S.C. §§102(a) and (e). Runco was never cited nor considered by the Examiner during prosecution of the '664 Patent. ORT-1101 1-2.

Runco discloses rod reduction instruments configured to position a spinal rod within a rod-receiving portion of a bone anchor. ORT-1118 ¶¶5-7. For example, Runco discloses "an instrument 400 for engaging an implant, such as a bone anchor, and positioning a fixation element, such as a spinal rod, relative to the bone anchor." *Id.* ¶100.

To facilitate analysis of the Challenged Claims, the Listing of Elements, below, provides a textual mapping of various claim elements of the '664 Patent to disclosed features of Runco.

Listing of Elements	
'664 Claim Element	**Corresponding Feature(s) of Runco**
bone anchor	"pedicle screw assembly" (¶3)[6]; "bone anchor" (¶100)
(connecting) rod	"spinal rod" (¶100)
rod reducing device / rod reduction device	"instrument 400" (¶100; FIG. 27A)
housing / body	"bone anchor engaging tool 412" (¶101; FIG. 27D)
first (elongated) grasping member	"first jaw member 418A" (¶101; FIG. 27D)

[6] All citations provided in the Listing of Elements refer to ORT-1118.

second (elongated) grasping member	"second jaw member 418B" (¶101; FIG. 27D)
rotatable member	"proximal component 423" (¶104; FIG. 27C)
rod contact member	"distal component 419" (¶104; FIG. 27C)
grasping feature / screw grasping element	"cylindrical pin 54A,B" (¶74)
additional orthopedic tool	"driver 70" (¶80)
[bone anchor] bone engaging shaft	"threaded shank" (¶3)
[bone anchor] rod-receiving housing	"head portion" (¶3)

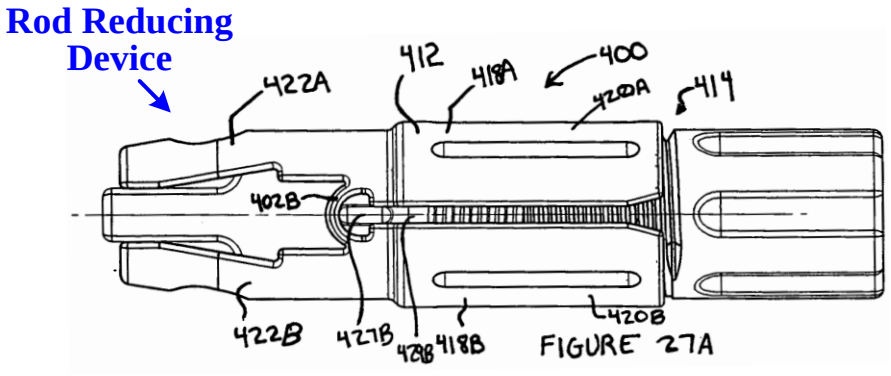
1. Independent Claim 1:

a. Limitation-[1-PRE]:

Runco discloses "a method of advancing a rod into a housing of a bone anchor" as recited in claim 1. Runco recites that "there is a need for an improved rod approximator and ***methods for seating a spinal rod in a rod-receiving portion of one or more spinal implants***." ORT-1118 ¶5. In meeting such need, Runco discloses that "the use of a spinal rod approximator, also referred to as a spinal rod reducer, is often required in order to grasp the head of the fixation device and ***reduce the rod into the rod-receiving portion of the fixation device***." *Id*. ¶4. Further, Runco describes that "[t]he exemplary bone anchor engaging tool 412 of the exemplary ***instrument 400*** may be constructed in manner analogous to the bone anchor engaging tool 12 and/or the bone anchor engaging tool 212." *Id*. ¶101. With respect to such bone anchor engaging tool 12, Runco recites that "[i]n

one exemplary method of operation, the bone anchor engaging tool 12 may be coupled to an exemplary bone anchor 100." *Id*. ¶84.

b. Limitation-[1-1]:



Runco discloses "coupling a rod reducing device to a bone anchor" as recited in claim 1. For example, Runco discloses the "***instrument 400*** for engaging an implant, such as a ***bone anchor***, and positioning a fixation element, such as a spinal rod, relative to the bone anchor." ORT-1118 ¶100. Runco recites that the device includes a "rod adjustment tool 414," which can be used "to reduce a spinal rod into the rod receiving portion of a pedicle screw." *Id*.

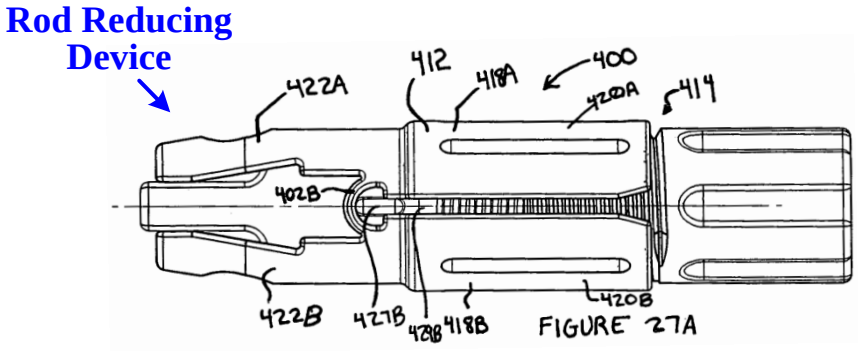
As discussed, Runco discloses that "[t]he exemplary bone anchor engaging tool 412 of the exemplary instrument 400 may be constructed in manner analogous to the bone anchor engaging tool 12 and/or the bone anchor engaging tool 212." *Id*. ¶101. Given this disclosure, it is significant to note that Runco also discloses that "[i]n one exemplary method of operation, ***the bone anchor engaging tool 12 may be coupled to an exemplary bone anchor 100***." *Id*. ¶84. Specifically, "the

bone anchor engaging tool 412 may include a first jaw member 418A and a second jaw member 418B which can cooperate to engage an implant such as a bone anchor." *Id*. ¶101; FIG. 27D (annotated). The first and second jaw members 418A, 418B employ distal ends 422A, 422B, respectively, to engage or grasp a portion of the bone anchor. *Id*.

c. Limitation-[1-2]:

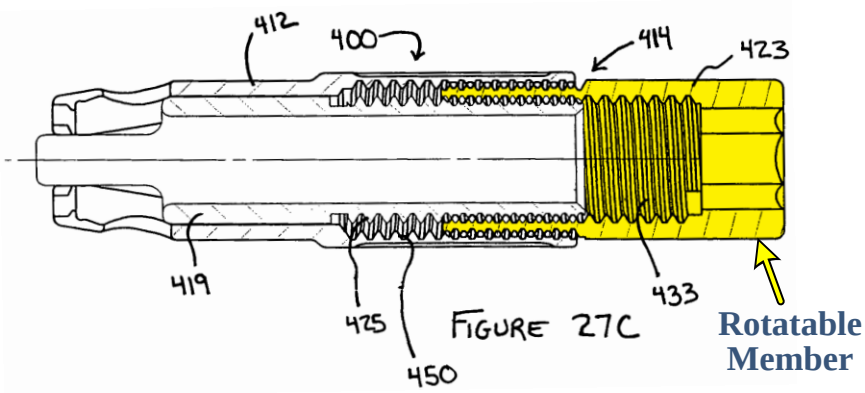
Runco discloses "the bone anchor having a rod-receiving housing and a bone engaging shaft extending therefrom" as recited in claim 1. For example, as discussed, Runco discloses the "***instrument 400*** for engaging an implant, such as a ***bone anchor***." ORT-1118 ¶100. Further, Runco also generally describes "***pedicle screw assemblies***," noting that "[s]uch screws typically include a ***threaded shank*** that is adapted to be threaded into a vertebra, and a ***head portion*** having a spinal fixation element receiving element, which, in spinal rod applications, is usually in the form of a U-shaped slot formed in the head for receiving the rod." *Id*. ¶3.

d. Limitation-[1-3]:



Runco discloses the "rod reducing device" of claim 1. As discussed, Runco discloses "***an instrument 400*** for engaging an implant, such as a bone anchor, and ***positioning a fixation element, such as a spinal rod, relative to the bone anchor***." ORT-1118 ¶100; FIG. 27A (annotated).

e. Limitation-[1-4]:



Runco discloses the "rotatable member" of claim 1. For example, Runco discloses "[t]he bone anchor engaging tool 412 may include an adjustment mechanism . . . such as, for example, the rod adjusting tool 414, along the longitudinal axis of the tool 412." ORT-1118 ¶104. Runco further teaches that "the rod adjusting tool 414 includes . . . ***a proximal component 423***" and that "[i]n operation, ***rotation of the proximal component 423*** causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id.*; FIG. 27C (annotated).

f. Limitation-[1-5]:

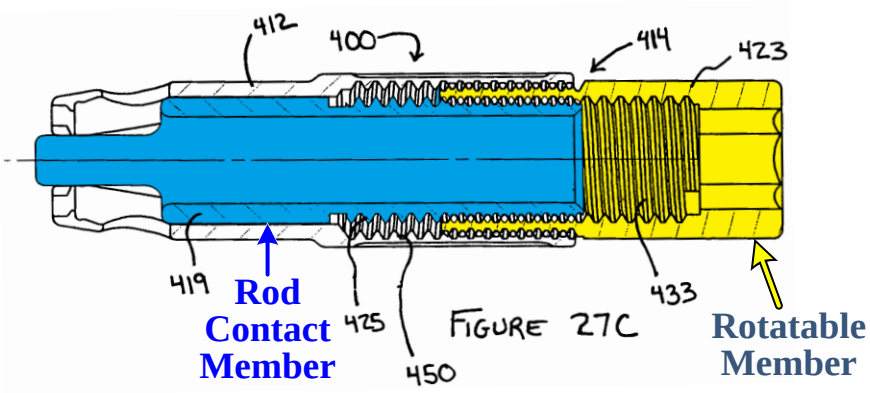


FIGURE 27C

Runco discloses the "rod contact member positioned at a distal end of the rotatable member" of claim 1. For example, Runco discloses "the rod adjusting tool 414 includes ***a distal component 419 having a rod engaging surface 421***." ORT-1118 ¶104; FIG. 27C (annotated). As shown, Runco discloses the proximal component 423 of the rod adjusting tool 414 having a rod engaging surface 421 of the distal component 419, which is clearly positioned at the distal end of such proximal component 423.

g. Limitation-[1-6]:

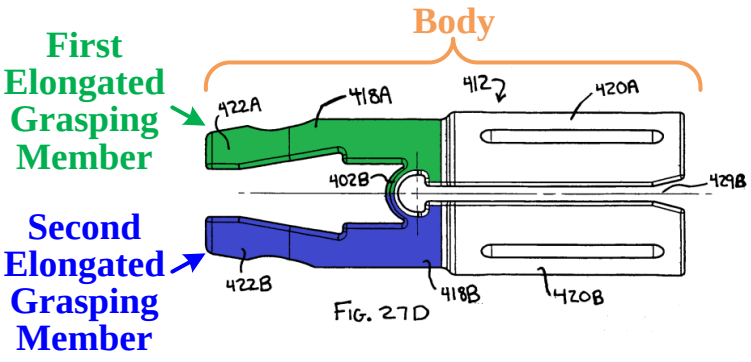


FIG. 27D

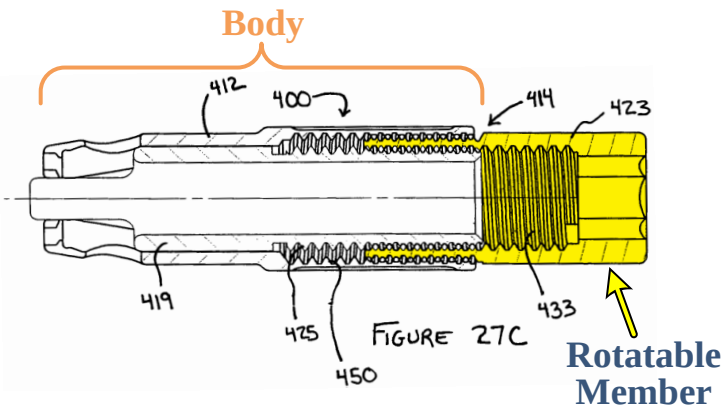
Runco discloses the "body including first and second elongated grasping members extending therefrom" of claim 1. In particular, Runco discloses "***the bone anchor engaging tool 412*** may include ***a first jaw member 418A and a second jaw member 418B*** which can cooperate to engage an implant such as a bone anchor." ORT-1118 ¶101; FIG. 27D (annotated).

h. Limitation-[1-7]:

Runco discloses "each of the first and second elongated grasping members having a screw grasping element" as recited in claim 1. As discussed, Runco recites that "[t]he exemplary bone anchor engaging tool 412 of the exemplary instrument 400 may be constructed in manner analogous to the bone anchor engaging tool 12." *Id.* In reference to the bone anchor engaging tool 12, Runco recites that "[t]he distal end 22A,B on one or both of the jaw members 18A,B may include ***an implant engagement mechanism*** that provides a releasable connection between the distal end(s) and the implant." ORT-1118 ¶74.

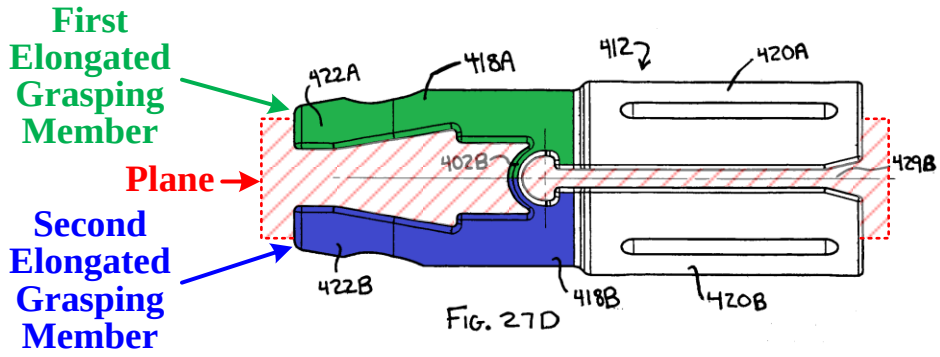
In a specific example of the implant engagement mechanism, Runco discloses that "each distal end 22A,B includes a ***cylindrical pin 54A,B*** extending from an interior surface thereof" and that "[t]he ***cylindrical pins 54A,B*** may be sized to engage swage holes provided in exterior surface of the rod receiving portion of a pedicle screw, for example." *Id.*;

i. Limitation-[1-8]:



Runco discloses the "rotatable member threadably coupled with the body" of claim 1. For example, Runco recites that "the proximal component 423 is generally tubular in shape and includes . . . an ***external thread 435 for engaging the internal threads 450A,B formed on the interior surface of the bone anchor engaging tool 412***." ORT-1118 ¶105; FIG 27C (annotated);

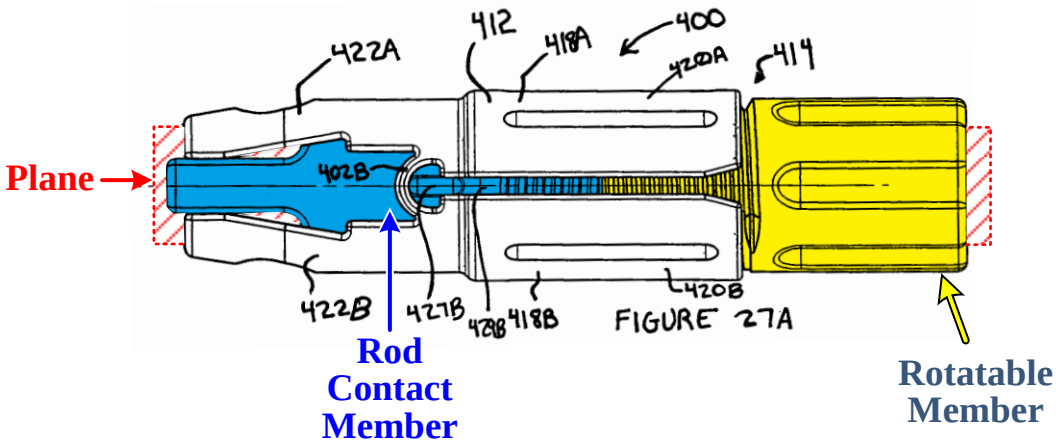
j. Limitation-[1-9]:



Runco discloses the "first and second elongated grasping members defining a plane" as recited in claim 1. In particular, the first and second jaw members

418A and 418B of Runco implicitly define a plane. ORT-1118 FIG. 27D (annotated);

k. Limitation-[1-10]:

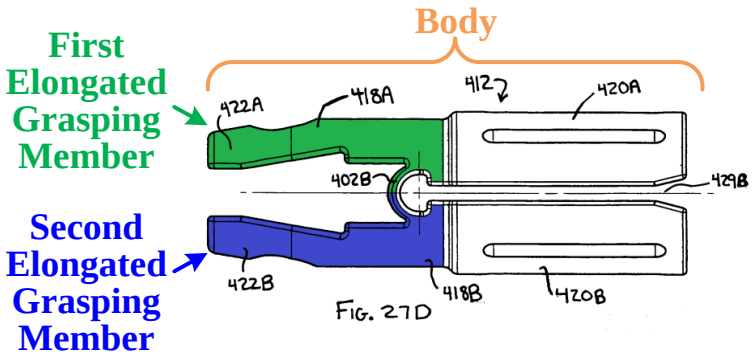


Runco discloses "the rotatable member and the rod contact member movable within the plane" as recited in claim 1. As discussed, Runco discloses that the rod adjustment tool 414 includes both the proximal component 423 and the distal component 419. ORT-1118 ¶104. Runco also discloses "***[t]he exemplary rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412***." *Id.* ¶100; FIG. 27A (annotated). Runco further discloses "[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id.* ¶104.

Such axial advancement of rod adjustment tool 414 relative to the bone anchor engaging tool 412, and thus first and second jaw members 418A and 418B,

clearly shows that both the proximal component 423 and the distal component 419 are movable within the plane, as shown in annotated FIG. 27A.

l. Limitation-[1-11]:



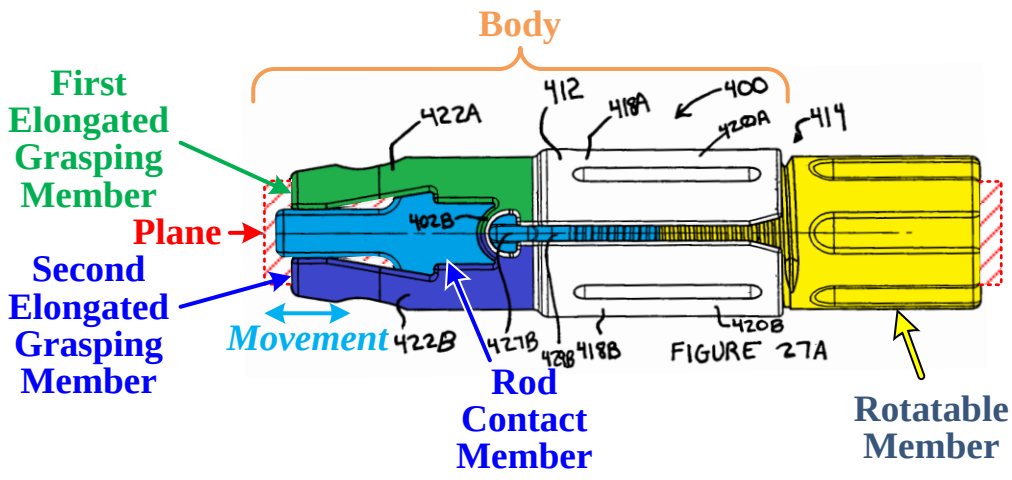
Runco discloses "securing the rod reducing device to the bone anchor by engaging the first and second elongated grasping members with the rod-receiving housing so that the rod-receiving housing is disposed between the first and second elongated grasping members" as recited in claim 1.

As discussed, Runco recites that "the bone anchor engaging tool 412 may include ***a first jaw member 418A and a second jaw member 418B which can cooperate to engage an implant such as a bone anchor***." ORT-1118 ¶101; FIG. 27D (annotated). Further, Runco recites that, "in the exemplary embodiment, ***compressing proximal ends 420A, 420B*** [of the first and second jaw members 418A, 418B] towards one another causes the distal ends 422A, 422B to rotate from an approximately closed position in which the jaw members are

proximate one another, as illustrated in FIG. 27D, to an open position in which the distal end 422A, 422B are displaced from one another." *Id*.

Moreover, Runco recites that "the use of a spinal rod approximator, also referred to as a spinal rod reducer, is often required in order to ***grasp the head of the fixation device and reduce the rod into the rod-receiving portion of the fixation device***." *Id*. ¶4.

m. Limitation-[1-12]:



Runco discloses "rotating the rotatable member thereby causing the rod contact member to move relative to the body within the plane to advance a rod disposed between the first and second elongated grasping members toward the rod-receiving housing" as recited in claim 1.

As discussed, Runco discloses "[i]n operation, ***rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412***." ORT-1118 ¶104. Further, as discussed, Runco recites that "***[t]he exemplary rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412***." *Id*. ¶100; FIG. 27A (annotated).

As shown in annotated FIG. 27A, such axial advancement of the distal component 419 relative to the bone anchor engaging tool 412, to position a spinal rod relative to a bone anchor, is clearly within the above-described plane and between the first and second jaw members 418A and 418B.

2. Dependent Claim 3:

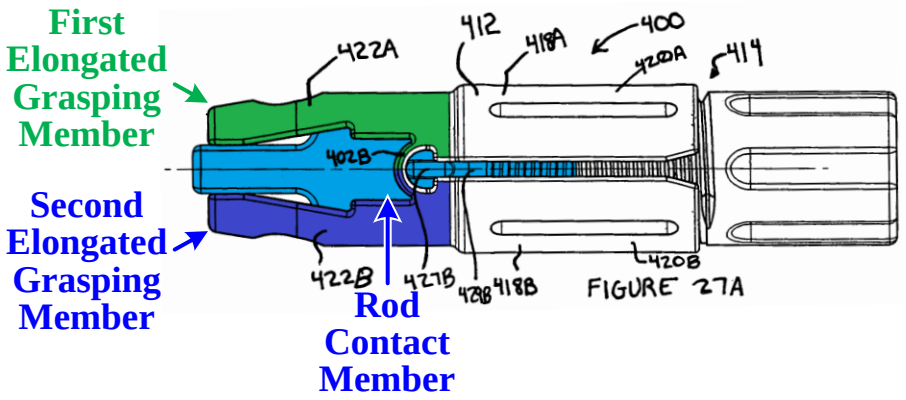
Runco discloses "securing the rod reducing device to the bone anchor includes coupling respective distal ends of the first and second elongated grasping members having at least one grasping feature to engage the rod-receiving housing of the bone anchor" as recited in claim 3.

As discussed, Runco recites that "[t]he exemplary bone anchor engaging tool 412 of the exemplary instrument 400 may be constructed in manner analogous to the bone anchor engaging tool 12." ORT-1118 ¶101. In reference to the bone anchor engaging tool 12, Runco recites that "***[t]he distal end 22A,B on one or both of the jaw members 18A,B may include an implant engagement mechanism that***

provides a releasable connection between the distal end(s) and the implant." *Id*. ¶74.

In a specific example of the implant engagement mechanism, Runco discloses that "each distal end 22A,B includes a ***cylindrical pin 54A,B*** extending from an interior surface thereof" and that "[t]he ***cylindrical pins 54A,B*** may be sized to engage swage holes provided in exterior surface of ***the rod receiving portion of a pedicle screw***, for example." *Id*.

3. Dependent Claim 5:



Runco discloses "wherein coupling the rod reducing device includes coupling the rod reducing device in which a portion of the rod contact member is positioned between the first and second elongated grasping members" as recited in claim 5.

For example, and as discussed, Runco recites "[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." ORT-1118 ¶104; FIG. 27A

(annotated). Even more importantly, however, FIG. 27A clearly shows that the distal component 419 is positioned between the first and second jaw members 418A and 418B.

4. Dependent Claim 6:

Runco discloses "wherein coupling the rod reducing device includes coupling the rod reducing device in which the rod contact member is attached to the distal end of the rotatable member" as recited in claim 6. Specifically, Runco recites that "[i]n the exemplary embodiment, the rod adjusting tool 414 includes a distal component 419 having a rod engaging surface 421 and ***a proximal component 423 connectable to*** and separable from ***the distal component 419***." ORT-1118 ¶104; FIG. 27C.

5. Independent Claim 8:

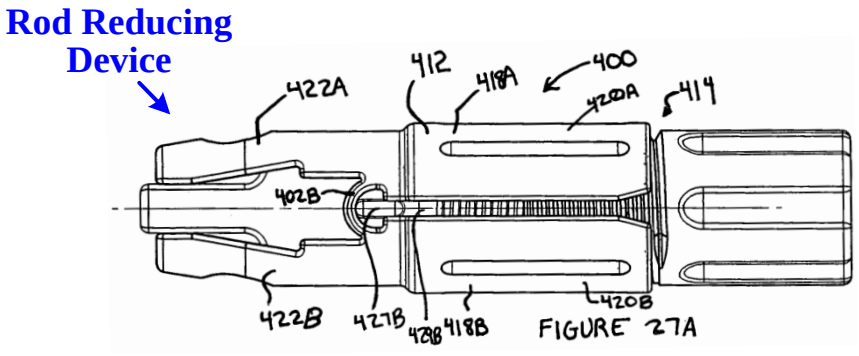
a. Limitation-[8-PRE]:

Runco discloses the "kit for reducing a rod" of claim 8. Runco discloses "the rod adjustment tool 414 [of instrument 400] may be employed ***to reduce a spinal rod*** into the rod receiving portion of a pedicle screw that is engaged by the bone anchor engaging tool 412." ORT-1118 ¶102. Further, Runco recites "[i]n procedures in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***," illustrating that a kit is disclosed. *Id*.

b. Limitation-[8-1]:

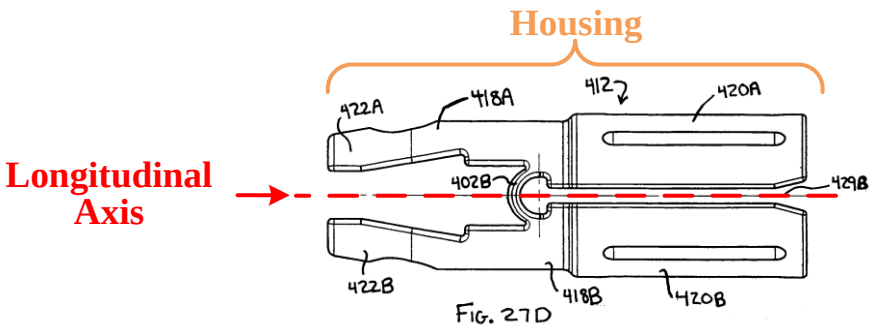
Runco discloses the "bone anchor" of claim 8. As discussed, Runco discloses that "FIGS. 27A-L illustrate another exemplary embodiment of an instrument 400 for engaging ***an implant, such as a bone anchor,*** and positioning a fixation element, such as a spinal rod, relative to the bone anchor." ORT-1118 ¶100.

c. Limitation-[8-2]:



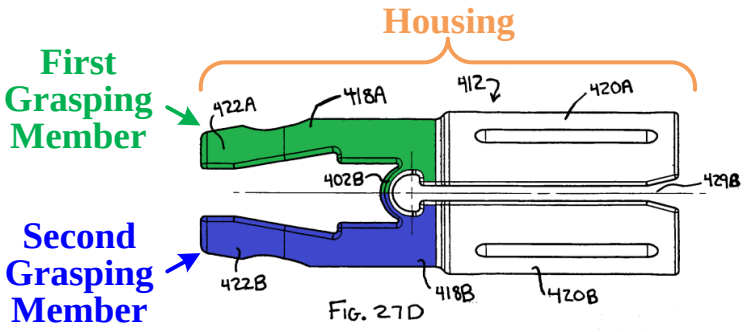
Runco discloses the "rod reducing device" of claim 8. As discussed, Runco discloses "***an instrument 400*** for engaging an implant, such as a bone anchor, and ***positioning a fixation element, such as a spinal rod, relative to the bone anchor***." ORT-1118 ¶100; FIG. 27A (annotated).

d. Limitation-[8-3]:



Runco discloses the "housing defining a longitudinal axis" of claim 8. For example, Runco discloses "***an implant (e.g., bone anchor) engaging tool 412*** for engaging at least a portion of an implant." ORT-1118 ¶100; FIG. 27A (annotated). Runco further discloses that "***[t]he bone anchor engaging tool 412*** may include an adjustment mechanism that facilitates the adjustment of a second instrument . . . ***along the longitudinal axis of the tool 412***." *Id*. ¶101; FIG. 27D (annotated).

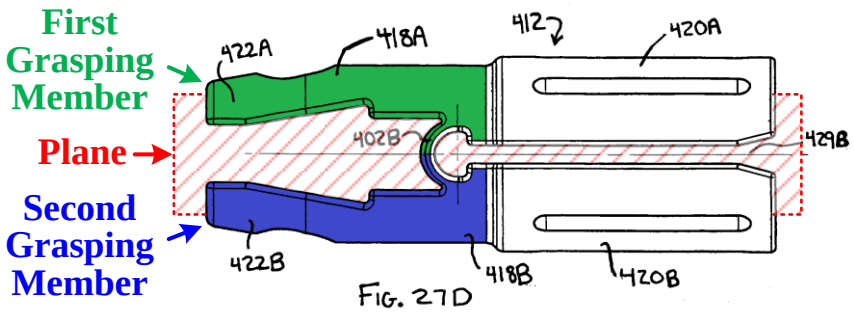
e. Limitation-[8-4]:



Runco discloses the "housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween" of claim 8. In particular, Runco discloses "***the bone anchor engaging tool 412*** may include ***a***

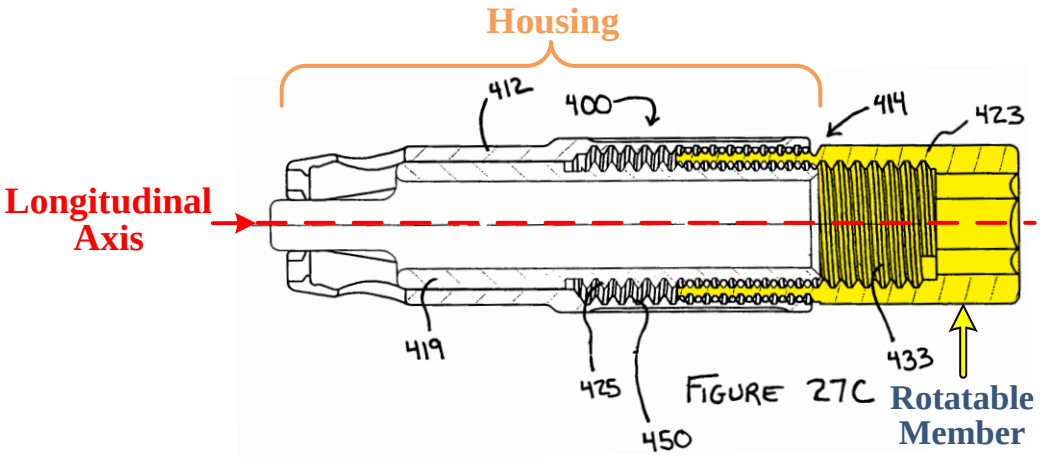
first jaw member 418A and a second jaw member 418B which can cooperate ***to engage an implant such as a bone anchor***." ORT-1118 ¶101; FIG. 27D (annotated).

f. Limitation-[8-5]:



Runco discloses the "first and second grasping members defining a plane" of claim 8. In particular, the first and second jaw members 418A and 418B of Runco implicitly define a plane as demonstrated above in annotated FIG. 27D.

g. Limitation-[8-6]:



Runco discloses the "rotatable member extending through the housing along the longitudinal axis" of claim 8. As discussed, Runco discloses "[t]he bone

anchor engaging tool 412 may include ***an adjustment mechanism*** . . . such as, for example, ***the rod adjusting tool 414, along the longitudinal axis of the tool 412***." ORT-1118 ¶104. Runco adds that "***the rod adjusting tool 414 includes . . . a proximal component 423***" and that "[i]n operation, ***rotation of the proximal component 423*** causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id*. Moreover, annotated FIG. 27C clearly shows that the proximal component 423 extends through the bone anchor engaging tool 412 along the longitudinal axis of the tool.

h. Limitation-[8-7]:

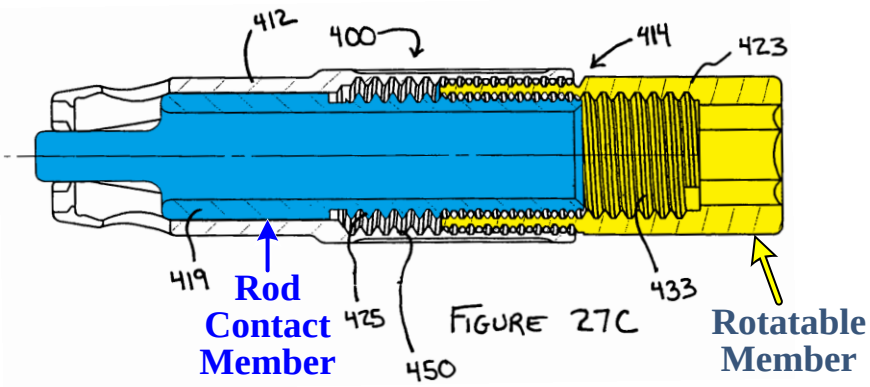
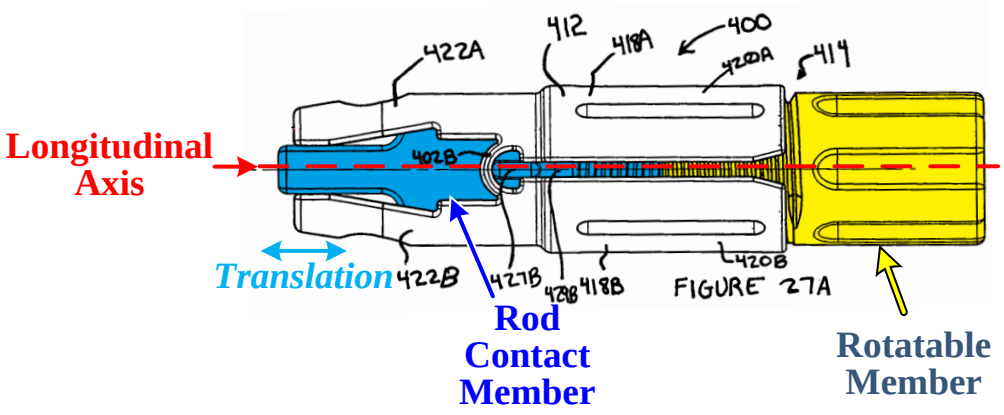


FIGURE 27C

Runco discloses the "rod contact member positioned at a distal end of the rotatable member" of claim 8. For example, Runco discloses "the rod adjusting tool 414 includes ***a distal component 419 having a rod engaging surface 421***." ORT-1118 ¶104; FIG. 27C (annotated). As shown, Runco discloses the proximal component 423 of the rod adjusting tool 414 having a rod engaging surface 421 of

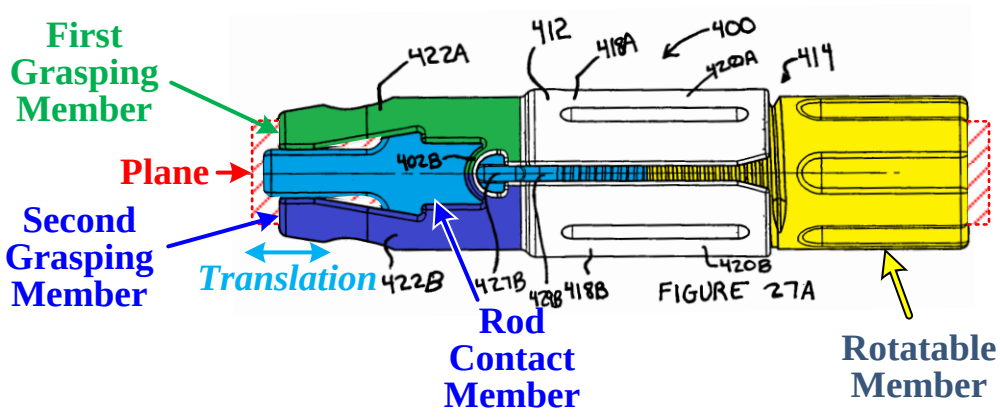
the distal component 419, which is clearly positioned at the distal end of such proximal component 423.

i. Limitation-[8-8]:



Runco discloses the "rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis" of claim 8. As discussed, Runco discloses "[i]n operation, ***rotation of the proximal component 423 causes the distal component 419 to advance axially*** relative to the bone anchor engaging tool 412." ORT-1118 ¶104. In view of such disclosure and annotated FIG. 27C, it is clear that the distal component 419 is translatable along the longitudinal axis in response to rotation of the proximal component 423 about the longitudinal axis.

j. Limitation-[8-9]:



Runco discloses "the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members" as recited in claim 8. As discussed, Runco discloses that the rod adjustment tool 414 includes both the proximal component 423 and the distal component 419. ORT-1118 ¶104. Runco also discloses "***[t]he exemplary rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412***." *Id.* ¶100; FIG. 27A (annotated). Runco further discloses "[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id.* ¶104.

Such axial advancement of rod adjustment tool 414 relative to the bone anchor engaging tool 412, and thus first and second jaw members 418A and 418B, clearly shows that both the proximal component 423 and the distal component 419

are translatable within the plane defined by the first and second grasping members, as shown in annotated FIG. 27A. ORT-1116 ¶¶288-290.

6. Dependent Claim 9:

Runco discloses a kit "further comprising a plurality of bone anchors and a plurality of rod reducing devices" as recited in claim 9. As discussed, Runco discloses that there are procedures "in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***." ORT-1118 ¶102; ORT-1116 ¶291.

Nevertheless, it has been established that Runco discloses each of a bone anchor and rod reducing device, singularly. *See supra* §§VIII(B)(5)(b)-(c). While claim 9, which depends from claim 8, calls for duplication of bone anchors and rod reducing devices, such duplication does not have any patentable significance because it produces no new or unexpected result. *Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B); ORT-1116 ¶¶292, 294-295.

7. Dependent Claim 10:

Runco discloses a kit "further comprising at least one additional orthopedic tool selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" as recited in claim 10. As discussed, Runco describes that "[t]he exemplary bone anchor engaging tool 412 of the exemplary ***instrument 400*** may be constructed in manner analogous to the bone anchor

engaging tool 12 and/or the bone anchor engaging tool 212." ORT-1118 ¶101. In association with the bone anchor engaging tool 12, Runco describes "***a driver 70 for securing a closure mechanism***," noting that "[t]he driver 70 may have a proximal end 72 including a handle and a distal end 74 for engaging the closure mechanism." *Id*. ¶80. It is clear the driver 70 is intended for use as at least a tightening tool or locking device for a closure mechanism, such that the kit further comprises an additional orthopedic tool. ORT-1116 ¶¶297-299.

8. Independent Claim 12:

a. Limitation-[12-PRE]:

Runco discloses the "system for reducing a connecting rod" of claim 12. Runco discloses "the rod adjustment tool 414 [of instrument 400] may be employed ***to reduce a spinal rod*** into the rod receiving portion of a pedicle screw that is engaged by the bone anchor engaging tool 412." ORT-1118 ¶102. Further, Runco recites "[i]n procedures in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***," illustrating that a system is disclosed. *Id*.

b. Limitation-[12-1], [12-4]-[12-8]:

Per §VIII(B)(5)(b), (d)-(h), Runco discloses these identical limitations, respectively.

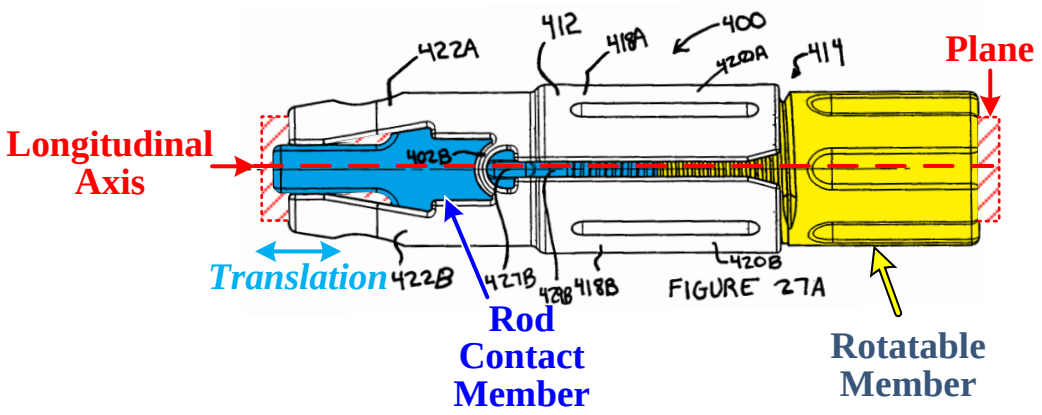
c. Limitation-[12-2]:

Runco discloses the "connecting rod" of claim 12. As discussed, Runco recites "an instrument 400 for engaging an implant, such as a bone anchor, and positioning **a fixation element, such as a spinal rod**, relative to the bone anchor." ORT-1118 ¶100.

d. Limitation-[12-3]:

Per §VIII(B)(5)(c), Runco discloses "a rod reducing device" and therefore likewise discloses limitation [12-3]. Limitation [8-2] recites "a rod ***reducing*** device" whereas limitation [12-3] recites "a rod ***reduction*** device." Petitioner submits that the specification of the '664 Patent uses "rod ***reducing*** device" and "rod ***reduction*** device" interchangeably to describe the *same* device. *See, e.g.*, ORT-1101 3:21-47, 3:65-66, 4:1-2, 7:24-50.

e. Limitation-[12-9]:



Runco discloses the "rod contact member translatable within the plane in response to rotation of the rotatable member about the longitudinal axis" of claim

12. As discussed, Runco discloses "[i]n operation, ***rotation of the proximal component 423 causes the distal component 419 to advance axially*** relative to the bone anchor engaging tool 412." ORT-1118 ¶104. In view of such disclosure and annotated FIG. 27C, it is clear that the distal component 419 is translatable within the above-described plane in response to rotation of the proximal component 423 about the longitudinal axis.

9. Dependent Claim 15:

Runco discloses a system "further comprising a plurality of bone anchors and a plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors" as recited in claim 15.

As discussed, Runco discloses that there are procedures "in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***." ORT-1118 ¶102; ORT-1116 ¶¶336.

Nevertheless, it has been established that, with respect to claim 12, Runco discloses each of a bone anchor and rod reducing device, singularly, in §§VIII(B)(8)(b) and VIII(B)(8)(d), respectively. While claim 15, which depends from claim 12, calls for the duplication of bone anchors and rod reducing devices, such a duplication does not have any patentable significance because it produces

no new or unexpected result. *Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B); ORT-1116 ¶¶337-338.

10. Dependent Claim 16:

Runco discloses a system "further comprising an additional orthopedic tool or device selected from the group consisting of: a tightening tool, a loosening tool, an alignment tube, and a locking device" as recited in claim 16. As discussed, Runco describes that "[t]he exemplary bone anchor engaging tool 412 of the exemplary ***instrument 400*** may be constructed in manner analogous to the bone anchor engaging tool 12 and/or the bone anchor engaging tool 212." ORT-1118 ¶101. In association with the bone anchor engaging tool 12, Runco describes "***a driver 70 for securing a closure mechanism***," noting that "[t]he driver 70 may have a proximal end 72 including a handle and a distal end 74 for engaging the closure mechanism." *Id*. ¶80. It is clear the driver 70 is intended for use as at least a tightening tool or locking device for a closure mechanism, such that the kit further comprises an additional orthopedic tool or device.

11. Independent Claim 17:

a. Limitation-[17-PRE]:

Runco discloses the "surgical construct" of claim 17. Runco discloses "the rod adjustment tool 414 [of instrument 400] may be employed to reduce a spinal rod into the rod receiving portion of a pedicle screw that is engaged by the bone

anchor engaging tool 412." ORT-1118 ¶101. Further, Runco recites that "[s]pinal fixation systems ***may be used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies***" and that "[s]uch systems typically include a spinal fixation element, such as a relatively rigid fixation rod or plate, that is coupled to adjacent vertebrae by attaching the element to various anchoring devices, such as hooks, bolts, wires, or screws." *Id*. ¶2.

Moreover, Runco recites "[i]n procedures in which multiple instruments 400 are used simultaneous [*sic*], for example, a plurality of instruments 200 [*sic*] each placed on separate bone anchor [*sic*], this configuration minimizes interference between adjacent instruments 400, ***facilitates visualization of the surgical field, and minimizes the need for the instruments 400 to be held by the surgeon to maintain the instruments 400 in position***." *Id*. ¶102. Thus, a surgical construct is disclosed.

b. Limitation-[17-1]:

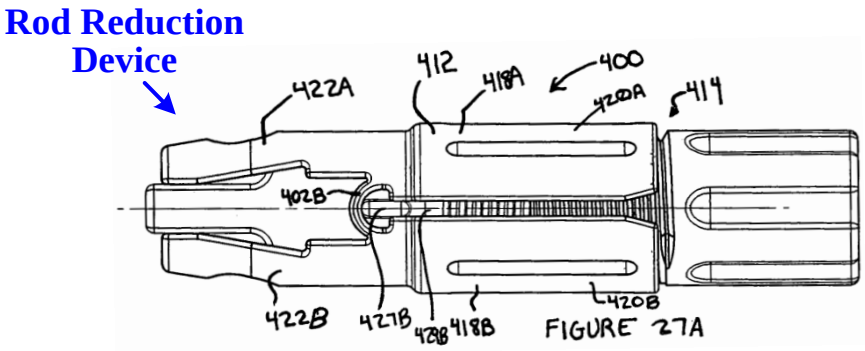
Runco discloses the "plurality of bone anchors" of claim 17. As discussed, Runco discloses that "FIGS. 27A-L illustrate another exemplary embodiment of an instrument 400 for engaging ***an implant, such as a bone anchor,*** and positioning a fixation element, such as a spinal rod, relative to the bone anchor." ORT-1118 ¶100. Also, as discussed, Runco recites "[i]n procedures in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of***

instruments 200 [sic] each placed on separate bone anchor [sic]" to indicate a plurality of bone anchors. *Id*. ¶102.

c. Limitations-[17-2], [17-5]-[17-10]:

Per §VIII(B)(8)(c), (5)(d)-(i), Runco discloses these identical limitations, respectively.

d. Limitation-[17-3]:



Runco discloses the "plurality of rod reduction devices, each rod reduction device of the plurality of rod reduction devices connectable to a bone anchor of the plurality of bone anchors," of claim 17. As discussed, Runco discloses "***an instrument 400*** for engaging an implant, such as a bone anchor, and ***positioning a fixation element, such as a spinal rod, relative to the bone anchor***." ORT-1118 ¶100; FIG. 27A (annotated).

Further, Runco recites that there are procedures "in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of***

instruments 200 [sic] each placed on separate bone anchor [sic]." *Id*. ¶102; ORT-1116 ¶351.

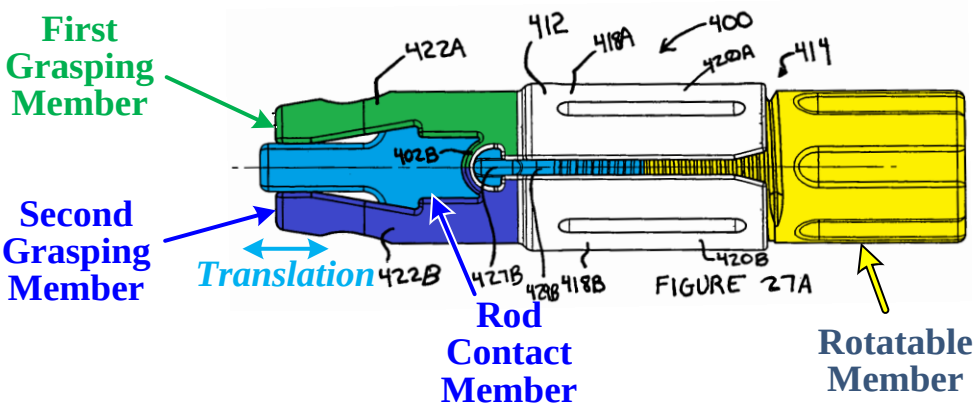
Nevertheless, it has been established that Runco discloses a rod reducing device,[7] singularly, in §VIII(B)(5)(c). Claim 17 calls for the duplication of rod reducing devices; however, such a duplication does not have any patentable significance because it produces no new or unexpected result. *See Harza*, 274 F.2d at 774; MPEP §2144.04(VI)(B); ORT-1116 ¶353.

e. Limitation-[17-4]:

As discussed, Runco discloses rod reduction devices including all of the recited features of claim 17.

12. Dependent Claim 18:

a. Limitation-[18-1]:



[7] *See supra* note 3.

Runco discloses "the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors."

Runco discloses "[t]he exemplary rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412," and that "***the rod adjustment tool 414 may be employed to reduce a spinal rod into the rod receiving portion of a pedicle screw that is engaged by the bone anchor engaging tool 412***." ORT-1118 ¶101. Further, Runco discloses "***the bone anchor engaging tool 412*** may include ***a first jaw member 418A and a second jaw member 418B*** which can cooperate ***to engage an implant such as a bone anchor***." *Id*. Runco recites "[i]n operation, rotation of the proximal component 423 causes the distal component 419 [of the rod adjustment tool 414] to advance axially relative to the bone anchor engaging tool 412." *Id*. ¶104; FIG. 27A (annotated). Runco also notes that the distal component 419 has "***a rod engaging surface 421***." *Id*.

Given that the first and second jaw members 418A and 418B engage a bone anchor therebetween, that the distal component 419 is positioned between the first and second jaw members 418A and 418B, and that the distal component engages

the spinal rod, it is clear that the connecting rod is disposed between the first and second jaw members 418A and 418B.

Moreover, and as discussed, Runco recites that there are procedures "in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***." *Id*. ¶102.

b. Limitation-[18-2]:

Runco discloses "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18. As discussed, Runco discloses "[t]he exemplary ***rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412***." ORT-1118 ¶100. Further, Runco recites that "[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id*. ¶104. And as discussed, Runco recites that there are procedures "in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***." *Id*. ¶102.

13. Dependent Claim 19:

Runco discloses "each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor" as recited in claim 19.

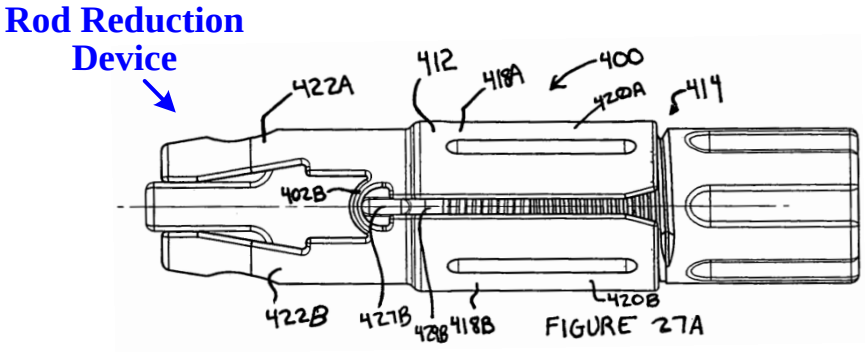
As discussed, Runco discloses the "***instrument 400*** for engaging an implant, such as a ***bone anchor***." ORT-1118 ¶100. Runco also generally describes "***pedicle screw assemblies***," noting that "[s]uch screws typically include a ***threaded shank*** that is adapted to be threaded into a vertebra, and a ***head portion*** having a spinal fixation element receiving element, which, in spinal rod applications, is usually in the form of a U-shaped slot formed in the head for receiving the rod." *Id*. ¶3.

Furthermore, Runco discloses "[t]he exemplary rod adjustment tool 414 may be advanced axially to position a spinal rod relative to a bone anchor engaged by the bone anchor engaging tool 412." *Id*. ¶100. Further, Runco recites that "[i]n operation, rotation of the proximal component 423 causes the distal component 419 to advance axially relative to the bone anchor engaging tool 412." *Id*. ¶104.

C. Ground 3: Claims 6, 9, 15, and 17-19 Are Rendered Obvious by Whipple in View of Runco

Claims 6, 9, 15, and 17-19 of the '664 Patent are rendered obvious by Whipple in view of Runco. ORT-1116 ¶¶397. As discussed, Whipple generally

discloses instruments and methods for manipulating a spinal fixation element (*i.e.*, a spinal rod) relative to a bone anchor. ORT-1117 ¶5. Similar to Whipple, Runco discloses rod reduction instruments configured to position a spinal rod within a rod-receiving portion of a bone anchor. *See, e.g.*, ORT-1118 ¶¶5-7; FIG. 27A (annotated).



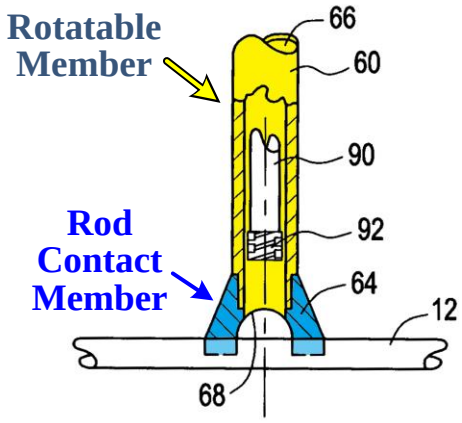
1. Dependent Claim 6:

Claim 6 of the '664 Patent is also rendered obvious by Whipple in view of Runco. ORT-1116 ¶¶398. Claim 6 depends from independent claim 1 and, as set forth in §VIII(A)(1), Whipple discloses each limitation of claim 1 (*i.e.*, limitations [1-PRE]-[1-12]).

Claim 6 recites, in part, "coupling the rod reducing device includes coupling the rod reducing device in which the rod contact member is ***attached*** to the distal end of the rotatable member." Per §VIII(A)(4), FIG. 11A of Whipple depicts the distal end 64 (the claimed *rod contact member*) ***joined*** to the distal-most end of the tube 60 (the claimed *rotatable member*) by way of respective cooperating

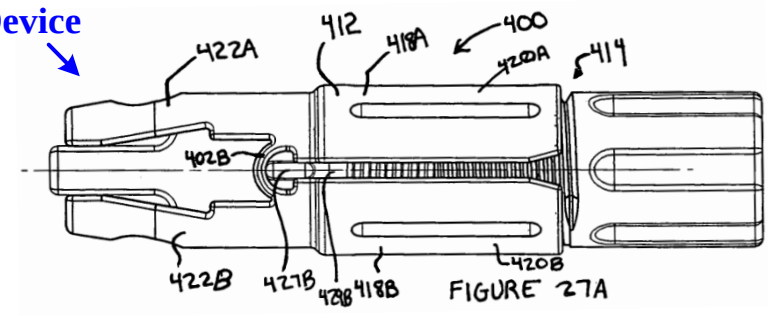
structures. *See* ORT-1117; FIG. 11A (annotated); ORT-1116 ¶399. Furthermore, nothing in claim 6, or in any of the other Challenged Claims, requires the rod contact member to be "fixedly" or "securely" attached to the distal end of the rotatable member. ORT-1116 ¶400. Therefore, since the distal end 64 is joined to the distal-most end of the tube 60, it is also ***attached*** to the distal-most end of the tube 60. *Id*.

FIG. 11A



Should the Board, however, conclude that the distal end 64 (the claimed *rod contact member*) shown in FIG. 11A of Whipple is not ***attached*** to the tube 60 (the claimed *rotatable member*), or that claim 6 requires the claimed *rod contact member* to be "fixedly" attached to the distal end of the claimed *rotatable member*, such features are disclosed by Runco. ORT-1116 ¶401.

Rod Reduction Device



As discussed, Runco discloses rod reduction instruments configured to position a spinal rod within a rod-receiving portion of a bone anchor. *See, e.g.*, ORT-1118 ¶¶5-7; FIG. 27 (annotated). More specifically, Runco discloses "an instrument 400 for engaging an implant, such as a bone anchor, and positioning a fixation element, such as a spinal rod, relative to the bone anchor." *Id.* ¶100. Runco discloses that the instrument 400 includes a rod adjusting tool 414. *Id.* ¶104. The rod adjusting tool 414 includes "***a distal component 419 having a rod engaging surface 421*** and a proximal component 423 ***connectable to . . . the distal component 419***." *Id.*; FIG. 27C; ORT-1116 ¶403. Runco explains that "the proximal component 423 . . . includes an internal thread 433 for engaging [an] external thread 425 of the distal component 419." *Id.* ¶105. That is, Runco discloses a distal component 419 (*e.g.*, a *rod contact member*) ***attached*** to a proximal component 423 (*e.g.*, a *rotatable member*) by way of cooperating external and internal threads 425 and 433. ORT-1116 ¶404.

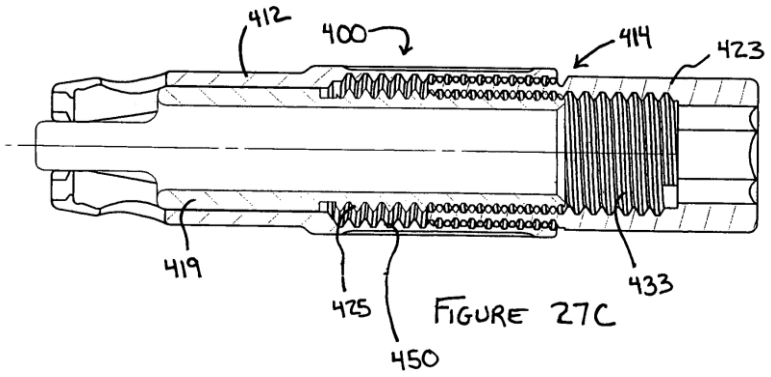


FIGURE 27C

It would have been obvious to a POSITA to ***attach the distal end 64*** (*i.e.*, the claimed *rod contact member*) shown in FIG. 11A of Whipple to the distal end ***of the tube 60*** (*i.e.*, the claimed *rotatable member*), as taught by Runco. ORT-1116 ¶405. Such an arrangement would enable the distal end 64 (*i.e.*, the claimed *rod contact member*) shown in FIG. 11A to remain proximate to (*i.e.*, does not separate from) the distal-most end the tube 60 (*i.e.*, the claimed rotatable member) during axial advancement and retraction of the distal end 64 and the tube 60. *See, e.g.*, ORT-1116 ¶405.

2. Dependent Claim 9:

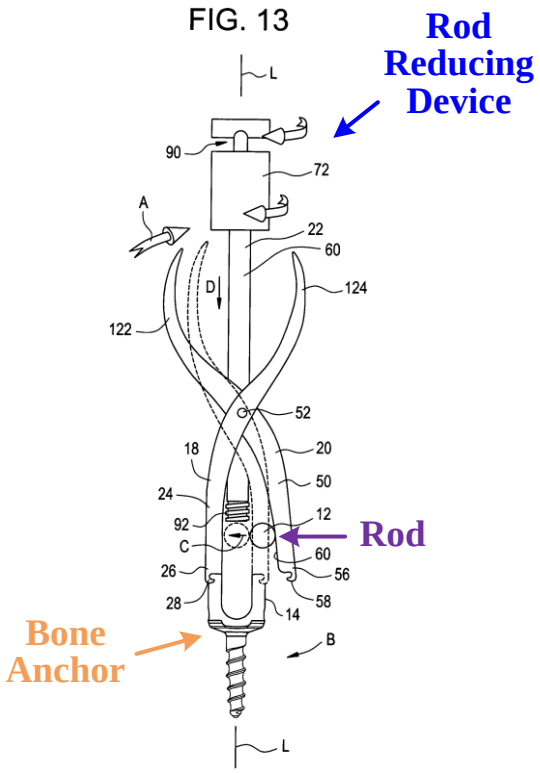
Claim 9 recites "a plurality of bone anchors and a plurality of rod reducing devices." Per §§VIII(A)(5)(b)-(c), Whipple discloses "a bone anchor" and "a rod reducing device," respectively. Should it be determined that a *plurality* of bone anchors and a *plurality* of rod reducing devices are not explicitly or implicitly disclosed by Whipple, and if the Board concludes that merely duplicating the bone anchor and rod reducing device of claim 8 provides patentable significance,

Petitioner submits that such features are disclosed by Runco. ORT-1116 ¶408. In particular, Runco discloses "[i]n procedures in which ***multiple instruments 400 are used simultaneous [sic]***, for example, ***a plurality of instruments 200 [sic] each placed on separate bone anchor [sic]***." ORT-1118 ¶102; *id*. ¶408.

Based on the teachings of Runco, it would have been obvious to a POSITA to use a plurality of the rod reducing devices and bone anchors of Whipple in a kit for reducing a rod. Such an arrangement enables a surgeon to separately adjust the position of the connecting rod relative to any one of the plurality of bone anchors. ORT-1116 ¶409.

3. Dependent Claim 15:

Per §VIII(C)(2), Whipple in view of Runco discloses "a plurality of bone anchors" and "a plurality of rod reduction devices" and, therefore, likewise discloses the identical limitations in claim 15.



Claim 15 recites that "each rod reduction device of the plurality of rod reduction devices mountable to a bone anchor of the plurality of bone anchors." Per §VIII(A)(5), and depicted in annotated FIG. 13, Whipple discloses a rod reducing device attached or mounted to a bone anchor.[8] *See also* ORT-1117 ¶28; FIGS. 2, 6. It therefore follows that, similar to Whipple's rod reduction device, each of the plurality of rod reduction devices disclosed by Whipple in view of Runco would likewise be mountable to a respective bone anchor. Therefore, Whipple and Runco teach every limitation of claim 15.

[8] *Supra* note 3.

4. Independent Claim 17:

Per §VIII(A)(11), Whipple discloses each limitation of claim 17 (*i.e.*, limitations [17-PRE]-[17-10]). With respect to limitations [17-1] and [17-3], it was asserted that Whipple discloses, at least singularly, "a bone anchor" and "a rod reduction device," where the rod reduction device is "connectable to a bone anchor of the plurality of bone anchors." *See also* §§VIII(A)(1)(b), VIII(A)(5)(c).

Further, for the same reasons discussed in §VIII(C)(2), it would have been obvious to a POSITA to use a plurality of the bone anchors and a plurality of the rod reducing devices of Whipple, as taught by Runco, for reducing a rod. ORT-1116 ¶¶417. Therefore, Whipple and Runco teach limitations [17-1] and [17-3], and thus, all the limitations of independent claim 17. *Id*. ¶¶413-417.

5. Dependent Claim 18:

a. Limitation-[18-1]:

Per §VIII(A)(12)(a), Whipple discloses "the connecting rod is disposed between the first and second grasping members of the plurality of the rod reduction devices with the plurality of rod reduction devices mounted to the respective bone anchors of the plurality of bone anchors" as recited in claim 18.

b. Limitation-[18-2]:

Per §VIII(A)(12)(b), Whipple discloses "whereby actuation of the rod reduction devices approximates the connecting rod to the plurality of bone anchors" as recited in claim 18.

6. Dependent Claim 19:

Per §VIII(A)(13), Whipple discloses "each bone anchor further comprises a rod receiving housing and a bone engaging shaft extending therefrom, each rod reduction device of the plurality of rod reduction devices approximating the connecting rod toward the rod receiving housing of the bone anchor" as recited in claim 19.

IX. CONCLUSION

As detailed above, each of the Challenged Claims of the '664 Patent is anticipated and rendered obvious by at least one or more prior art references. Petitioner has therefore established that there is a reasonable likelihood that one or more of the claims of the patent are unpatentable. Accordingly, Petitioner requests review of these claims.

Dated: August 21, 2018

Respectfully submitted,

/Paul M. Ulrich/

Paul M. Ulrich
Reg. No. 46,606
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Telephone: 513.698.5156
Facsimile: 513.698.5157

Attorney for Petitioner

CERTIFICATE OF COMPLIANCE

In accordance with 37 C.F.R. §42.24(d), Petitioner certifies that the word count for this petition totals 13,395 words, which is less than 14,000 allowed under 37 C.F.R. §42.24(a)(i).

/Paul M. Ulrich/
Paul M. Ulrich

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 21, 2018, a complete and entire copy of this petition for *inter partes* review and all supporting exhibits were provided by Federal Express, cost prepaid, to the Patentee by serving the correspondence address of record as follows:

Carter DeLuca Farrell & Schmidt LLP
445 Broad Hollow Road, Suite 420
Melville, NY 11747

/Paul M. Ulrich/
Paul M. Ulrich
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Telephone: 513.698.5156
Facsimile: 513.698.5157