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(54) **ORTHOPEDIC IMPLANT AND METHODS OF IMPLANTING AND REMOVING SAME**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

321,389 A 6/1885 Schirmer
1,095,054 A 4/1914 Wiesenfeld
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2551021 A1 3/2005
CA 2243699 C 1/2006
(Continued)

OTHER PUBLICATIONS

Pietrzak WS, et al., "A bioabsorbable fixation implant for use in proximal interphalangeal joint (hammer toe) arthrodesis: Biomechanical testing in a synthetic bone substrate". J Foot Ankle Surg. Sep.-Oct. 2006;45(5):288-94. doi: 10.1053/j.jfas.2006.05.004. PMID: 16949524. 7 pgs. [Exhibit No. 1007 to Petition for Inter Partes Review of U.S. Pat. No. 9,168,074].

(Continued)

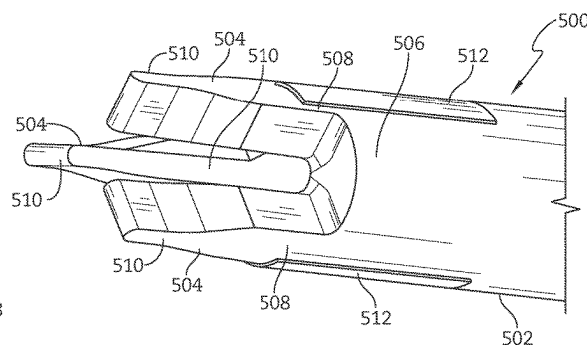
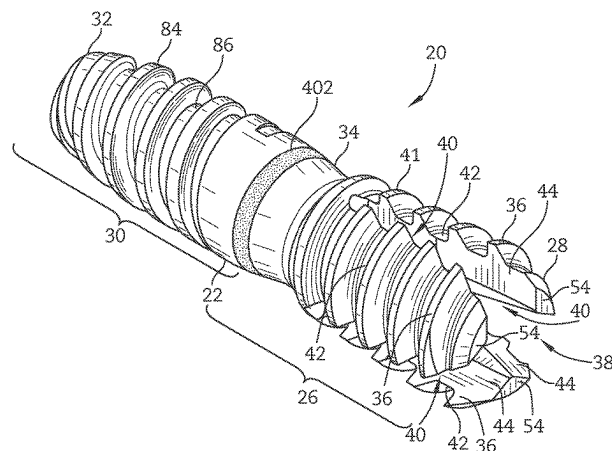
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(57) **ABSTRACT**

Illustrative embodiments of orthopedic implants and methods for surgically repairing hammertoe are disclosed. According to at least one illustrative embodiment, an orthopedic implant includes a proximal segment comprising a number of spring arms forming an anchored barb at a first end of the implant, a distal segment extending between the proximal segment and a second end of the implant, and a central segment disposed between the proximal and distal segment.

20 Claims, 11 Drawing Sheets



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(56)**References Cited**

U.S. PATENT DOCUMENTS

1,517,334	A	12/1924	Young	5,207,712	A	5/1993	Cohen
1,893,864	A	1/1933	Kocher	5,326,364	A	7/1994	Clift, Jr. et al.
2,128,005	A	8/1938	Lombard	5,360,450	A	11/1994	Giannini
2,208,848	A	7/1940	Jorgensen	5,382,251	A	1/1995	Hood et al.
2,531,911	A	11/1950	Johnson	5,405,400	A	4/1995	Linscheid et al.
2,580,821	A	1/1952	Nicola	5,405,401	A	4/1995	Lippincott, III et al.
2,984,248	A	5/1961	Sidelman	5,417,692	A	5/1995	Goble et al.
3,338,689	A	8/1967	Hetzel et al.	5,425,776	A	6/1995	Cohen
3,462,765	A	8/1969	Swanson	5,425,777	A	6/1995	Sarkisian et al.
3,466,669	A	9/1969	Flatt	5,454,814	A	10/1995	Comte
3,593,342	A	7/1971	Niebauer et al.	5,464,427	A	11/1995	Curtis et al.
3,646,654	A	3/1972	Cervenka et al.	5,474,557	A	12/1995	Mai
3,681,786	A	8/1972	Lynch	D366,114	S	1/1996	Ohata
3,739,403	A	6/1973	Nicolle	5,480,447	A	1/1996	Skiba
3,805,302	A	4/1974	Mathys	5,484,443	A	1/1996	Pascarella et al.
3,824,631	A	7/1974	Burstein et al.	D369,412	S	4/1996	Morgan
3,875,594	A	4/1975	Swanson	5,507,822	A	4/1996	Bouchon et al.
D243,716	S	3/1977	Treace et al.	5,522,903	A	6/1996	Sokolow et al.
4,091,806	A	5/1978	Aginsky et al.	5,554,157	A	9/1996	Errico et al.
4,158,893	A	6/1979	Swanson	5,578,036	A	11/1996	Stone et al.
4,204,284	A	5/1980	Koeneman	5,634,925	A	6/1997	Urbanski
4,237,875	A	12/1980	Terminini	5,674,297	A	10/1997	Lane et al.
4,276,660	A	7/1981	Laure	5,690,631	A	11/1997	Duncan et al.
4,364,382	A	12/1982	Mennen	5,702,472	A	12/1997	Huebner
4,367,562	A	1/1983	Gauthier et al.	D388,877	S	1/1998	Morgan
4,485,816	A	12/1984	Krumme	5,725,585	A	3/1998	Zobel
D277,509	S	2/1985	Lawrence et al.	5,779,707	A	7/1998	Bertholet et al.
D277,784	S	2/1985	Sgarlato et al.	5,782,927	A	7/1998	Klawitter et al.
4,522,200	A	6/1985	Stednitz	5,824,095	A	10/1998	Di Maio, Jr. et al.
D284,099	S	6/1986	Laporta et al.	5,876,434	A	3/1999	Flomenblit et al.
4,634,382	A	1/1987	Kusano et al.	5,881,443	A	3/1999	Roberts et al.
D291,731	S	9/1987	Aikins	5,882,444	A	3/1999	Flomenblit et al.
4,759,768	A	7/1988	Hermann et al.	5,919,193	A	7/1999	Slavitt
4,871,367	A	10/1989	Christensen et al.	5,951,288	A	9/1999	Sawa
4,905,679	A	3/1990	Morgan	5,958,159	A	9/1999	Prandi
4,955,916	A	9/1990	Carignan et al.	5,984,970	A	11/1999	Bramlet
4,969,909	A	11/1990	Barouk	5,984,971	A	11/1999	Faccioli et al.
5,011,497	A	4/1991	Persson et al.	6,011,497	A	1/2000	Tsang et al.
5,047,059	A	9/1991	Saffar	6,017,366	A	1/2000	Berman
5,062,851	A	11/1991	Branemark	6,093,188	A	7/2000	Murray
5,074,865	A	12/1991	Fahmy	6,123,709	A	9/2000	Jones
5,092,896	A	3/1992	Meuli et al.	6,146,387	A	11/2000	Trott et al.
5,108,443	A	4/1992	Branemark	6,162,234	A	12/2000	Freedland et al.
5,133,761	A	7/1992	Krouskop	6,187,008	B1	2/2001	Hamman
5,179,915	A	1/1993	Cohen et al.	6,193,757	B1	2/2001	Foley et al.
5,190,546	A	3/1993	Jervis	6,197,037	B1	3/2001	Hair
				6,200,330	B1	3/2001	Benderev et al.
				6,248,109	B1	6/2001	Stoffella
				6,261,289	B1	7/2001	Levy
				6,319,284	B1	11/2001	Rushdy et al.
				6,325,805	B1	12/2001	Ogilvie et al.
				6,342,076	B1	1/2002	Lundborg
				6,348,052	B1	2/2002	Sammarco
				6,352,560	B1	3/2002	Poeschmann et al.
				6,383,223	B1	5/2002	Baehler et al.
				6,386,877	B1	5/2002	Sutter
				6,395,031	B1	5/2002	Foley et al.
				6,413,260	B1	7/2002	Berrevoets et al.
				6,423,097	B2	7/2002	Rauscher
				6,428,634	B1	8/2002	Besselink et al.
				6,454,808	B1	9/2002	Masada
				6,458,134	B1	10/2002	Songer et al.
				6,475,242	B1	11/2002	Bramlet
				6,517,543	B1	2/2003	Berrevoets et al.
				6,554,833	B2	4/2003	Levy et al.
				6,689,169	B2	2/2004	Harris
				6,692,499	B2	2/2004	Tormala et al.
				6,699,247	B2	3/2004	Zucherman et al.
				6,699,292	B2	3/2004	Ogilvie et al.
				6,706,045	B2	3/2004	Lin et al.
				6,736,818	B2	5/2004	Perren et al.
				6,773,437	B2	8/2004	Ogilvie et al.
				6,811,568	B2	11/2004	Minamikawa
				6,827,741	B2	12/2004	Reeder
				6,833,006	B2	12/2004	Foley et al.
				6,869,449	B2	3/2005	Ball et al.
				6,896,177	B2	5/2005	Carter
				6,981,974	B2	1/2006	Berger
				7,025,789	B2	4/2006	Chow et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,037,342 B2	5/2006	Nilsson et al.	9,492,215 B2	11/2016	Augoyard et al.
7,041,106 B1	5/2006	Carver et al.	9,498,266 B2	11/2016	McCormick et al.
7,044,953 B2	5/2006	Capanni	9,498,273 B2	11/2016	Thoren et al.
7,052,498 B2	5/2006	Levy et al.	9,554,914 B2	1/2017	Taylor et al.
7,182,787 B2	2/2007	Hassler et al.	9,724,140 B2	8/2017	McCormick
7,240,677 B2	7/2007	Fox	9,757,168 B2	9/2017	Seavey et al.
7,291,175 B1	11/2007	Gordon	9,775,630 B2	10/2017	Leavitt et al.
7,537,664 B2	5/2009	O'Neill et al.	10,022,167 B2	7/2018	Augoyard et al.
7,588,603 B2	9/2009	Leonard	10,111,690 B2	10/2018	Anderson et al.
7,600,956 B2	10/2009	McDuff et al.	2001/0025199 A1	9/2001	Rauscher
7,601,152 B2	10/2009	Levy et al.	2001/0049529 A1	12/2001	Cachia et al.
7,655,042 B2	2/2010	Foley et al.	2002/0019636 A1	2/2002	Ogilvie et al.
7,670,339 B2	3/2010	Levy et al.	2002/0055785 A1	5/2002	Harris
7,674,426 B2	3/2010	Grohowski, Jr.	2002/0065561 A1	5/2002	Ogilvie et al.
7,780,737 B2	8/2010	Bonnard et al.	2002/0068939 A1	6/2002	Levy et al.
7,794,483 B2	9/2010	Capanni	2002/0082705 A1	6/2002	Bouman et al.
7,837,738 B2	11/2010	Reigstad et al.	2002/0099395 A1	7/2002	Acampora et al.
7,842,091 B2	11/2010	Johnstone et al.	2002/0133156 A1	9/2002	Cole
7,909,880 B1	3/2011	Grant	2002/0169066 A1	11/2002	Cassidy et al.
7,918,879 B2	4/2011	Yeung et al.	2002/0189622 A1	12/2002	Cauthen et al.
7,922,765 B2	4/2011	Reiley	2003/0040805 A1	2/2003	Minamikawa
7,955,388 B2	6/2011	Jensen et al.	2003/0069645 A1	4/2003	Ball et al.
7,976,580 B2	7/2011	Berger	2003/0120277 A1	6/2003	Berger
7,993,403 B2	8/2011	Foley et al.	2003/0130660 A1	7/2003	Levy et al.
8,048,173 B2	11/2011	Ochoa	2004/0002759 A1	1/2004	Ferree
8,100,983 B2	1/2012	Schulte	2004/0093081 A1	5/2004	Nilsson et al.
8,162,942 B2	4/2012	Coati et al.	2004/0102853 A1	5/2004	Boumann et al.
8,202,305 B2	6/2012	Reiley	2004/0138756 A1	7/2004	Reeder
8,262,712 B2	9/2012	Coilard-Lavirotte et al.	2004/0172031 A1	9/2004	Rubecamp et al.
8,308,779 B2	11/2012	Reiley	2004/0220574 A1	11/2004	Pelo et al.
8,388,667 B2	3/2013	Reiley et al.	2004/0220678 A1	11/2004	Chow et al.
8,394,097 B2	3/2013	Peyrot et al.	2004/0230193 A1	11/2004	Cheung et al.
8,414,583 B2	4/2013	Prandi et al.	2005/0065589 A1	3/2005	Schneider et al.
8,414,648 B2	4/2013	Reiley	2005/0119757 A1	6/2005	Hassler et al.
8,425,570 B2	4/2013	Reiley	2005/0124990 A1	6/2005	Teague et al.
8,444,693 B2	5/2013	Reiley	2005/0216015 A1*	9/2005	Kreidler B25B 15/007 606/104
8,470,004 B2	6/2013	Reiley	2005/0251265 A1	11/2005	Calandrucchio et al.
8,475,456 B2	7/2013	Augoyard et al.	2005/0261768 A1	11/2005	Trieu
8,529,611 B2	9/2013	Champagne et al.	2005/0283159 A1	12/2005	Amara
8,597,337 B2	12/2013	Champagne	2006/0015181 A1	1/2006	Elberg
8,608,785 B2	12/2013	Reed et al.	2006/0036322 A1	2/2006	Reiley
8,685,024 B2	4/2014	Roman	2006/0052725 A1	3/2006	Santilli
8,715,325 B2	5/2014	Weiner et al.	2006/0052878 A1	3/2006	Schmieding
8,728,387 B2	5/2014	Jones et al.	2006/0074492 A1	4/2006	Frey
8,734,462 B2	5/2014	Reiley et al.	2006/0084998 A1	4/2006	Levy et al.
8,734,491 B2	5/2014	Seavey	2006/0085075 A1	4/2006	McLeer
8,834,483 B2	9/2014	Cheney et al.	2006/0147332 A1	7/2006	Jones et al.
8,834,572 B2	9/2014	Averous et al.	2006/0247787 A1	11/2006	Rydell et al.
8,840,623 B2	9/2014	Reiley	2007/0038303 A1	2/2007	Myerson et al.
8,840,651 B2	9/2014	Reiley	2007/0123993 A1	5/2007	Hassler et al.
8,858,601 B2	10/2014	Reiley	2007/0142920 A1	6/2007	Niemi
8,864,804 B2	10/2014	Champagne et al.	2007/0156241 A1	7/2007	Reiley et al.
8,920,477 B2	12/2014	Reiley	2007/0162018 A1	7/2007	Jensen et al.
8,986,348 B2	3/2015	Reiley	2007/0185584 A1	8/2007	Kaufmann et al.
8,992,703 B2	3/2015	O'Neill et al.	2007/0198088 A1	8/2007	Biedermann et al.
8,998,999 B2	4/2015	Lewis et al.	2007/0213831 A1	9/2007	de Cubber
9,011,504 B2	4/2015	Reed	2007/0233110 A1	10/2007	Muhanna et al.
9,039,743 B2	5/2015	Reiley	2007/0239158 A1	10/2007	Trieu et al.
9,044,287 B2	6/2015	Reed et al.	2008/0039949 A1	2/2008	Meesenburg et al.
9,056,014 B2	6/2015	McCormick et al.	2008/0132894 A1	6/2008	Coilard-Lavirotte et al.
9,072,562 B2	7/2015	Weiner et al.	2008/0154385 A1	6/2008	Trail et al.
9,072,564 B2	7/2015	Reed et al.	2008/0177262 A1	7/2008	Augoyard et al.
9,089,427 B2	7/2015	Grohowski, Jr.	2008/0177291 A1	7/2008	Jensen et al.
9,089,431 B2	7/2015	Grohowski, Jr.	2008/0195219 A1	8/2008	Wiley et al.
D738,504 S	9/2015	Weiner et al.	2008/0221697 A1	9/2008	Graser
9,125,698 B2	9/2015	Miller	2008/0221698 A1	9/2008	Berger
9,125,704 B2	9/2015	Reed et al.	2008/0234763 A1	9/2008	Patterson et al.
9,135,374 B2	9/2015	Jones et al.	2008/0269908 A1	10/2008	Warburton
9,161,789 B2	10/2015	Peyrot et al.	2009/0005821 A1	1/2009	Chirico et al.
9,168,074 B2	10/2015	Prandi et al.	2009/0012564 A1	1/2009	Chirico et al.
9,180,010 B2	11/2015	Dong et al.	2009/0018556 A1	1/2009	Prandi
9,282,977 B2	3/2016	Penzimer et al.	2009/0138096 A1	5/2009	Myerson et al.
9,283,007 B2	3/2016	Augoyard et al.	2009/0254189 A1	10/2009	Scheker
9,403,213 B2	8/2016	Lapszynski	2009/0254190 A1	10/2009	Gannoe et al.
9,452,002 B2	9/2016	Roman et al.	2010/0010637 A1	1/2010	Pequignot
			2010/0016905 A1	1/2010	Greenhalgh et al.
			2010/0016982 A1	1/2010	Solomons
			2010/0057214 A1	3/2010	Graham et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2010/0121390	A1	5/2010	Kleinman	EP	0340159	A1	11/1989
2010/0131014	A1	5/2010	Peyrot	EP	0420794	A1	4/1991
2010/0131072	A1	5/2010	Schulte	EP	0454645	A1	10/1991
2010/0161068	A1	6/2010	Lindner et al.	EP	1300122	A2	4/2003
2010/0185295	A1	7/2010	Emmanuel	EP	1356794	A3	11/2003
2010/0228301	A1	9/2010	Greenhalgh et al.	EP	1582159	A1	10/2005
2010/0249942	A1	9/2010	Goswami et al.	EP	1923012	A1	5/2008
2010/0256731	A1	10/2010	Mangiardi	EP	2228015	A3	3/2011
2010/0256770	A1	10/2010	Hakansson et al.	EP	2471477	A1	7/2012
2010/0262254	A1	10/2010	Lawrence et al.	EP	2471478	A1	7/2012
2011/0004317	A1	1/2011	Hacking et al.	EP	2544633	A1	1/2013
2011/0093084	A1	4/2011	Morton	EP	2749236	A3	10/2014
2011/0093085	A1	4/2011	Morton	FR	2663838	A1	1/1992
2011/0144644	A1	6/2011	Prandi et al.	FR	2725126	A1	4/1996
2011/0208304	A1	8/2011	Justin et al.	FR	2783702	A1	3/2000
2011/0301652	A1	12/2011	Reed et al.	FR	2787313	A1	6/2000
2011/0301653	A1	12/2011	Reed et al.	FR	2794019	A1	12/2000
2012/0029579	A1	2/2012	Bottlang et al.	FR	2801189	A1	5/2001
2012/0065692	A1	3/2012	Champagne et al.	FR	2846545	A1	5/2004
2012/0083791	A1	4/2012	Cheney et al.	FR	2856269	A1	12/2004
2012/0089197	A1	4/2012	Anderson	FR	2884406		10/2006
2012/0197311	A1	8/2012	Kirschman	FR	2927529	A1	8/2009
2012/0259419	A1	10/2012	Brown et al.	FR	2935601	A1	3/2010
2013/0053975	A1	2/2013	Reed et al.	FR	2957244	A1	9/2011
2013/0060295	A1	3/2013	Reed et al.	GB	2119655	A	11/1983
2013/0066435	A1	3/2013	Averous et al.	GB	2430625	B	4/2007
2013/0123862	A1	5/2013	Anderson et al.	JP	S60145133	A	7/1985
2013/0131822	A1	5/2013	Lewis et al.	JP	03001854	A	8/1991
2013/0150965	A1	6/2013	Taylor et al.	JP	H7303662	A	11/1995
2013/0190761	A1	7/2013	Prandi et al.	JP	2004535249	A	11/2004
2013/0190831	A1	7/2013	Ek et al.	JP	3648687	B2	5/2005
2013/0231744	A1	9/2013	Taylor et al.	JP	2007530194	A	11/2007
2013/0317559	A1	11/2013	Leavitt et al.	JP	2008188411	A	8/2008
2013/0325077	A1	12/2013	Champagne et al.	JP	2008537696	A	9/2008
2014/0005219	A1	1/2014	Foster et al.	JP	4695511	B2	6/2011
2014/0039630	A1	2/2014	Peyrot et al.	JP	5631597	B2	11/2014
2014/0058462	A1	2/2014	Reed et al.	JP	5645826	B2	12/2014
2014/0107712	A1	4/2014	Fallin et al.	KR	20070004513	A	1/2007
2014/0142715	A1	5/2014	McCormick	KR	20070022256	A	2/2007
2014/0180428	A1	6/2014	McCormick	KR	101004561	B1	1/2011
2014/0188239	A1	7/2014	Cummings	KR	101235983	B1	2/2013
2014/0257509	A1	9/2014	Dacosta et al.	WO	9116014	A1	10/1991
2014/0276827	A1	9/2014	Roman et al.	WO	9625129	A1	8/1996
2014/0277554	A1	9/2014	Roman et al.	WO	9641596	A1	12/1996
2014/0309747	A1	10/2014	Taylor et al.	WO	9726846	A1	7/1997
2014/0316474	A1	10/2014	Graham	WO	9733537	A1	9/1997
2014/0343615	A1	11/2014	Cheney et al.	WO	0117445	A1	3/2001
2015/0011998	A1	1/2015	McCormick et al.	WO	03084416	A1	10/2003
2015/0066097	A1	3/2015	Biedermann	WO	2005020830	A1	3/2005
2015/0073413	A1	3/2015	Palmer et al.	WO	2005020831	A2	3/2005
2015/0094778	A1	4/2015	McCormick et al.	WO	2005063149	A1	7/2005
2015/0112341	A1	4/2015	Penzimer et al.	WO	2005104961	A1	11/2005
2015/0112342	A1	4/2015	Penzimer et al.	WO	2006109004	A1	10/2006
2015/0112446	A1	4/2015	Melamed et al.	WO	2007135322	A1	11/2007
2015/0150607	A1	6/2015	Chen et al.	WO	2008057404	A2	5/2008
2015/0164563	A1	6/2015	Lewis et al.	WO	2008112308	A1	9/2008
2015/0223848	A1	8/2015	McCormick	WO	2008129214	A2	10/2008
2015/0223849	A1	8/2015	McCormick et al.	WO	2009055952	A1	5/2009
2015/0223850	A1	8/2015	Reed	WO	2009103085	A1	8/2009
2015/0223853	A1	8/2015	Appenzeller et al.	WO	2010029246	A1	3/2010
2015/0342655	A1	12/2015	Reed et al.	WO	2011082343	A1	7/2011
2016/0058484	A1	3/2016	McCombs-Stearnes et al.	WO	2011110784	A1	9/2011
2016/0338751	A1	11/2016	Kellar et al.	WO	2011116078	A1	9/2011
2017/0065310	A1	3/2017	Girod et al.	WO	2011130229	A1	10/2011
2017/0239059	A1	8/2017	Boublil et al.	WO	2012089330	A1	7/2012
2017/0252084	A1	9/2017	Anderson et al.	WO	2012089331	A1	7/2012
2017/0333081	A1	11/2017	Cordier et al.	WO	2013164819	A1	11/2013
2018/0021145	A1	1/2018	Seavey et al.	WO	2014031947	A1	2/2014
2018/0161170	A1	6/2018	Petranto	WO	2014165123	A1	10/2014
					2015136212	A1	9/2015

FOREIGN PATENT DOCUMENTS

CA	2836654	A1	6/2014
CA	2837497	A1	6/2014
EP	0042808	A1	12/1981

OTHER PUBLICATIONS

The American Heritage College Dictionary, Fourth Edition, Houghton Mifflin Company (Apr. 2007). 3 pgs. [Exhibit No. 1008 to Petition for Inter Partes Review of U.S. Pat. No. 9,168,074].

(56)

References Cited

OTHER PUBLICATIONS

Cross section, <<https://byjus.com/maths/cross-section/>> (last visited Jan. 26, 2022). 4 pgs. [Exhibit No. 1009 to Petition for Inter Partes Review of U.S. Pat. No. 9,168,074].

Declaration of Michael Sherman (Jan. 28, 2022). 119 pgs. [Exhibit No. 1002 to Petition for Inter Partes Review of U.S. Pat. No. 9,168,074].

Petition for Inter Partes Review of U.S. Pat. No. 9,168,074 , *OsteoMed LLC v. Stryker European Operations Holdings LLC*. (Jan. 28, 2022). 98 pgs.

Patent Owner's Preliminary Response and Exhibits List, IPR2022-00486 of U.S. Pat. No. 9,168,074 , *OsteoMed LLC v. Stryker European Operations Holdings LLC*. (Filed May 16, 2022), 77 pages. [Including Appendices at Exhibits 2003 and 2004].

Collins English Dictionary Excerpt (Jun. 2007), 6 pages. [Exhibit No. 2001 to Patent Owner's Preliminary Response, IPR2022-00486 of U.S. Pat. No. 9,168,074 filed May 16, 2022].

Excerpt from Tool.com—File and Rasp Tools, (Copyright 2022), 6 pages. [Exhibit No. 2002 to Patent Owner's Preliminary Response, IPR2022-00486 of U.S. Pat. No. 9,168,074 filed May 16, 2022].

Jung, H. J. et al., JJ., Decision Denying Institution of Inter Partes Review, IPR2022-00486 of U.S. Pat. No. 9,168,074 , *OsteoMed LLC v. Stryker European Operations Holdings LLC*. (Aug. 12, 2022). 42 pages.

HammerFix IP Fusion System, Hammertoe Deformity Surgical Technique, designed by Extremity Medical, published Mar. 31, 2014 (8 pages).

Intraosseous Fixation System, Hammertoe Surgical Technique, designed by OrthoHelix, published Aug. 23, 2012 (16 pages).

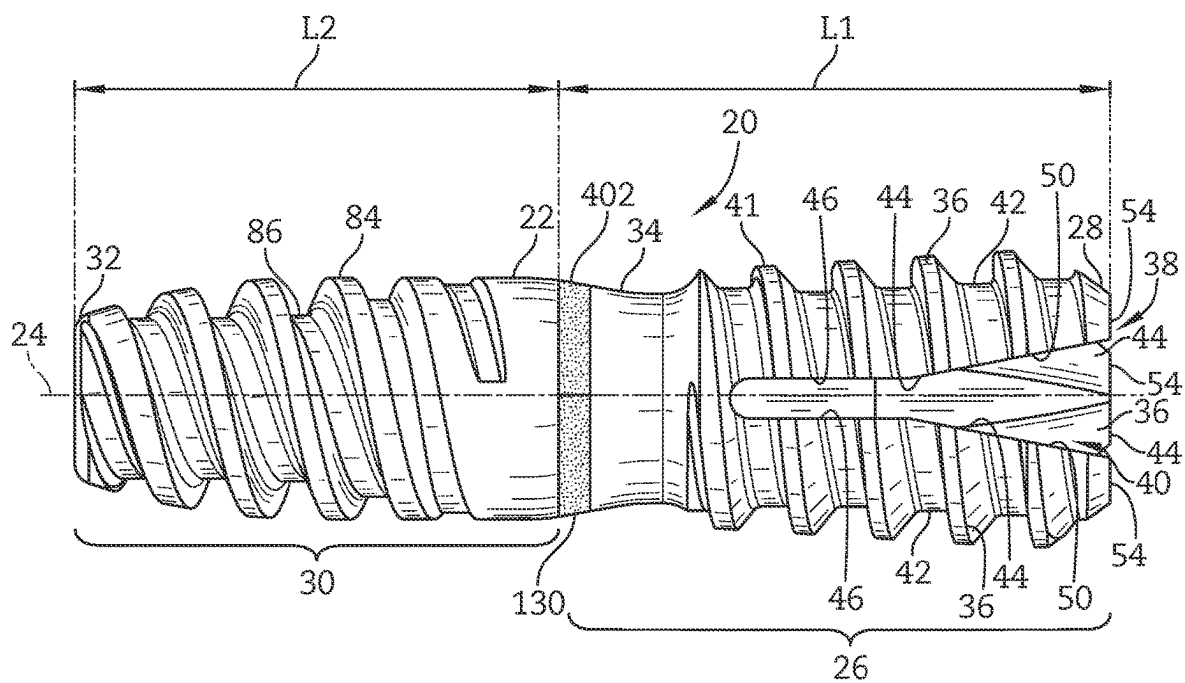
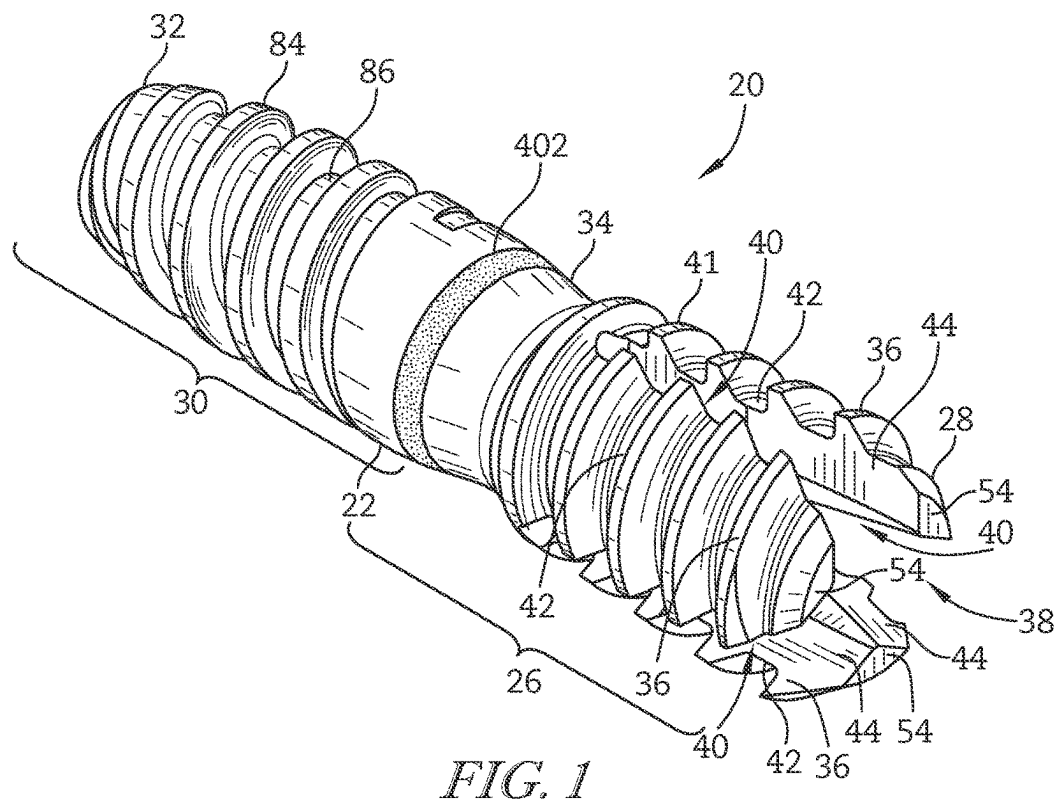
International Search Report for PCT/FR2008/050453 dated Nov. 4, 2008, 4 pages.

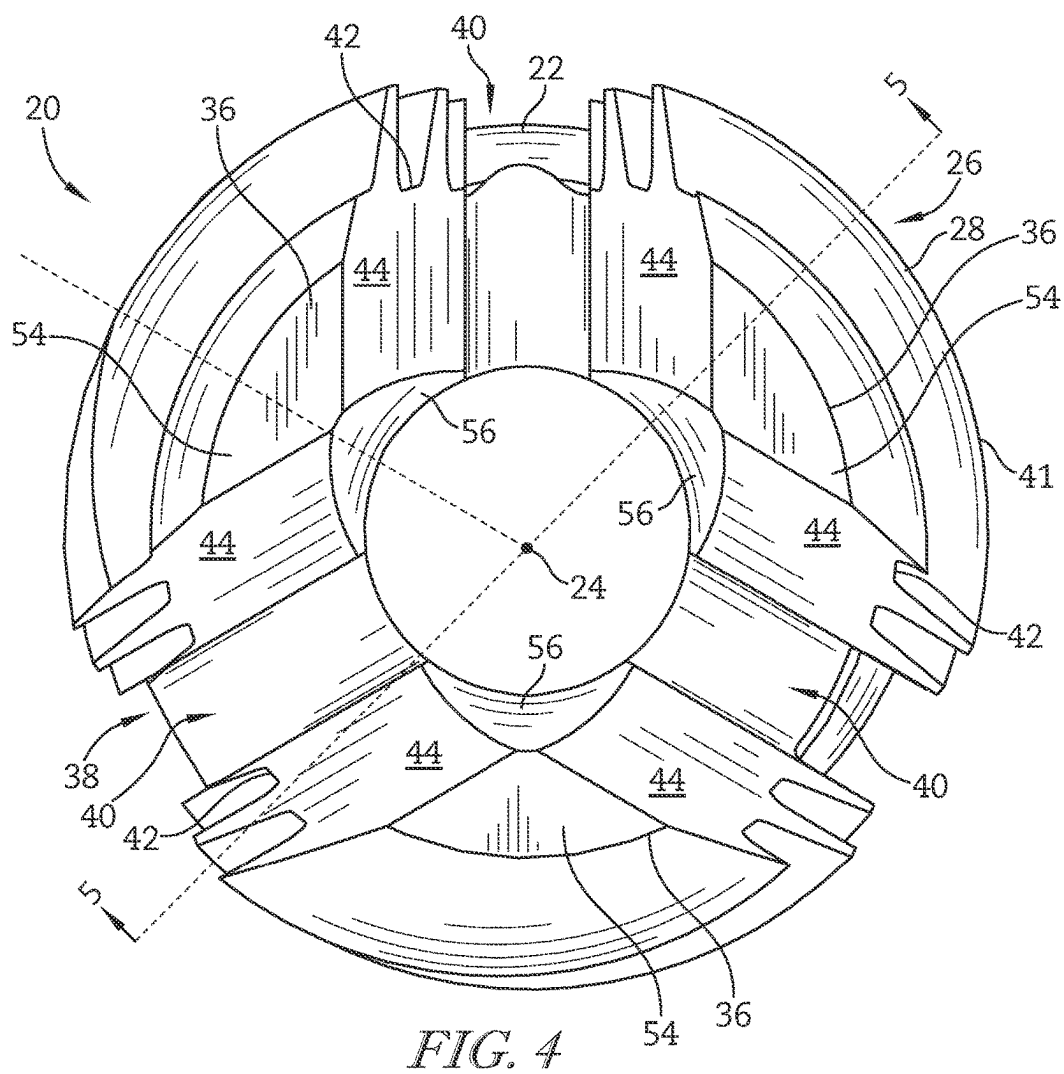
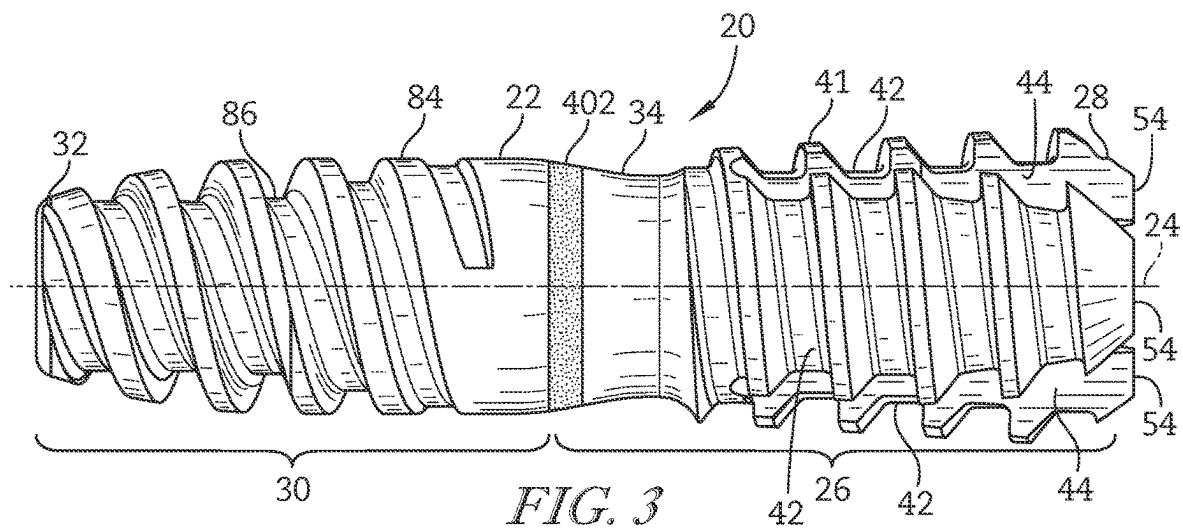
International Search Report, PCT/FR2006/050345, dated Aug. 30, 2006, 3 pages.

Japanese Office Action for Application No. 2011-526540 dated Aug. 13, 2013, 3 pages.

EP Notification for Application No. 09741356.1 dated Feb. 12, 2015, 4 pages.

* cited by examiner





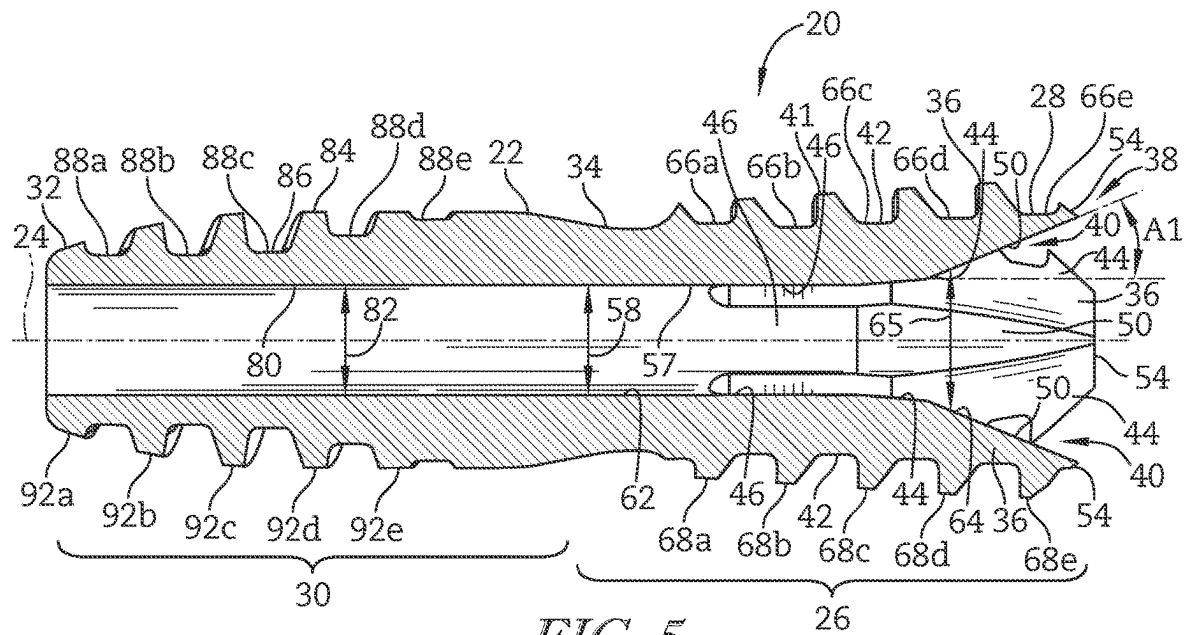


FIG. 5

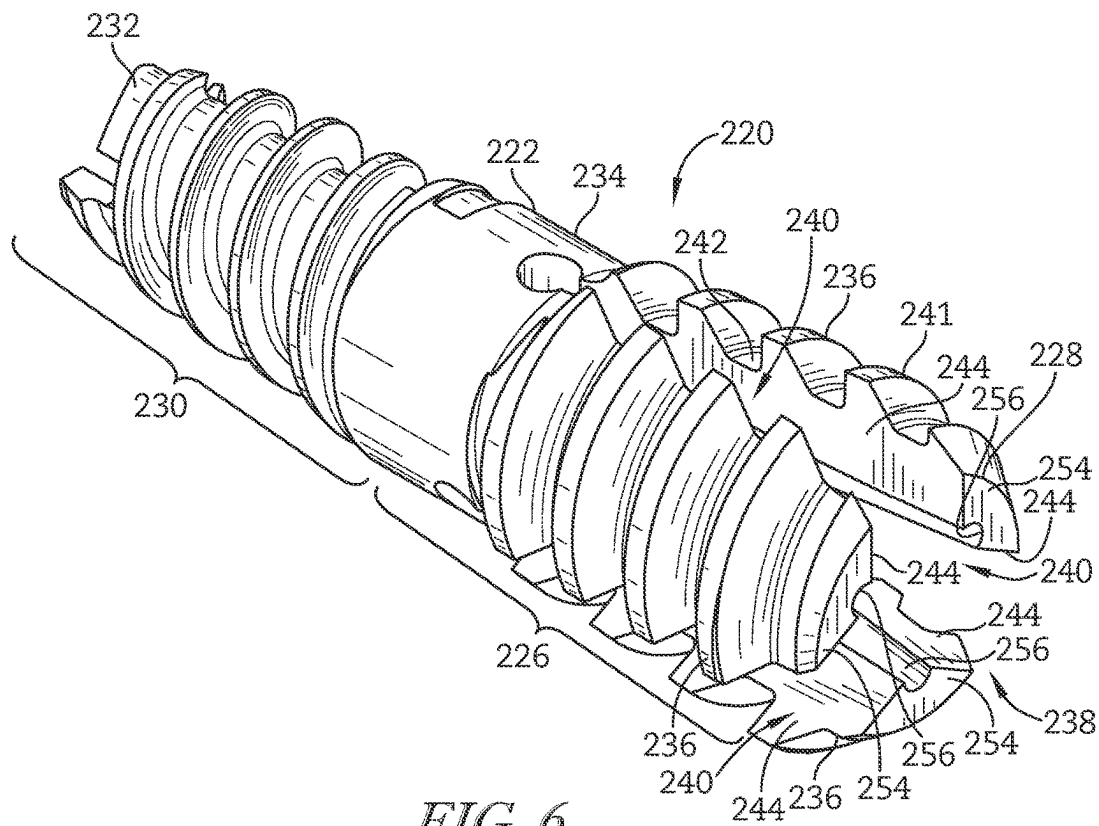


FIG. 6

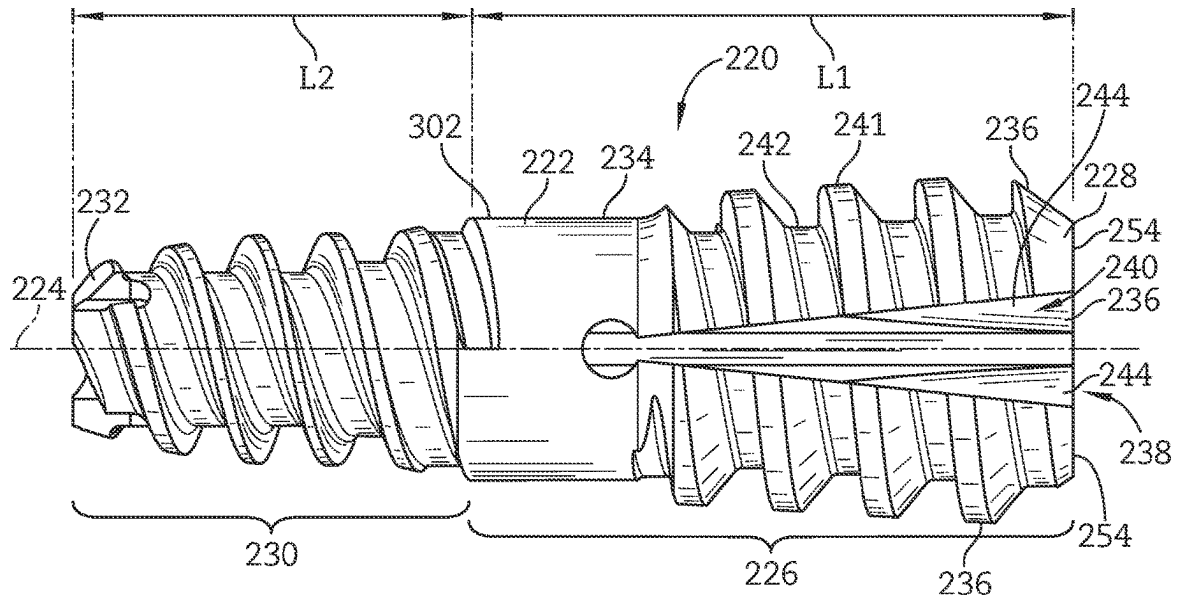


FIG. 7

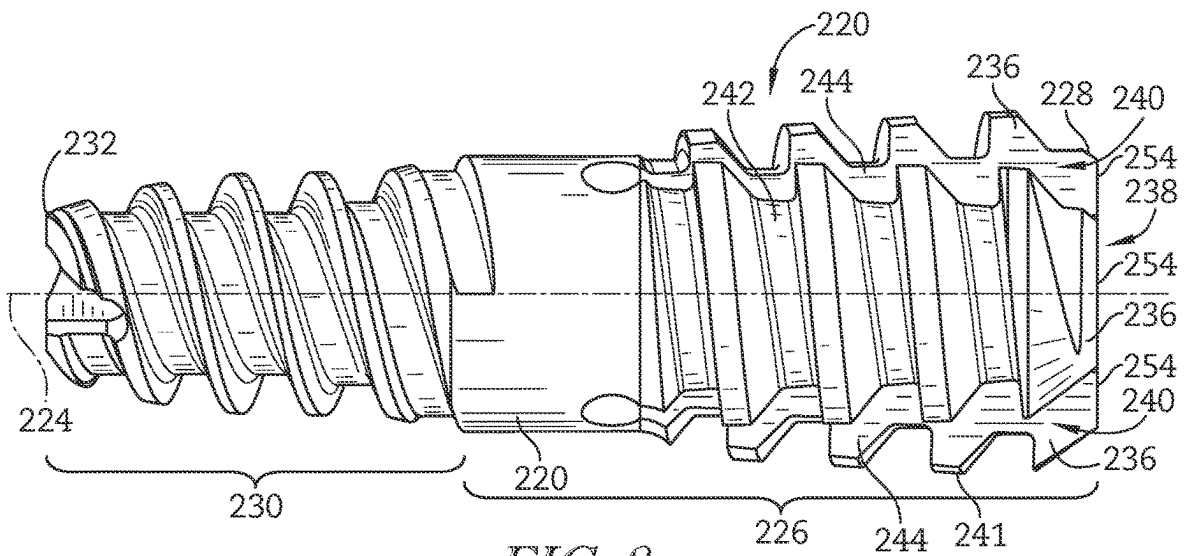


FIG. 8

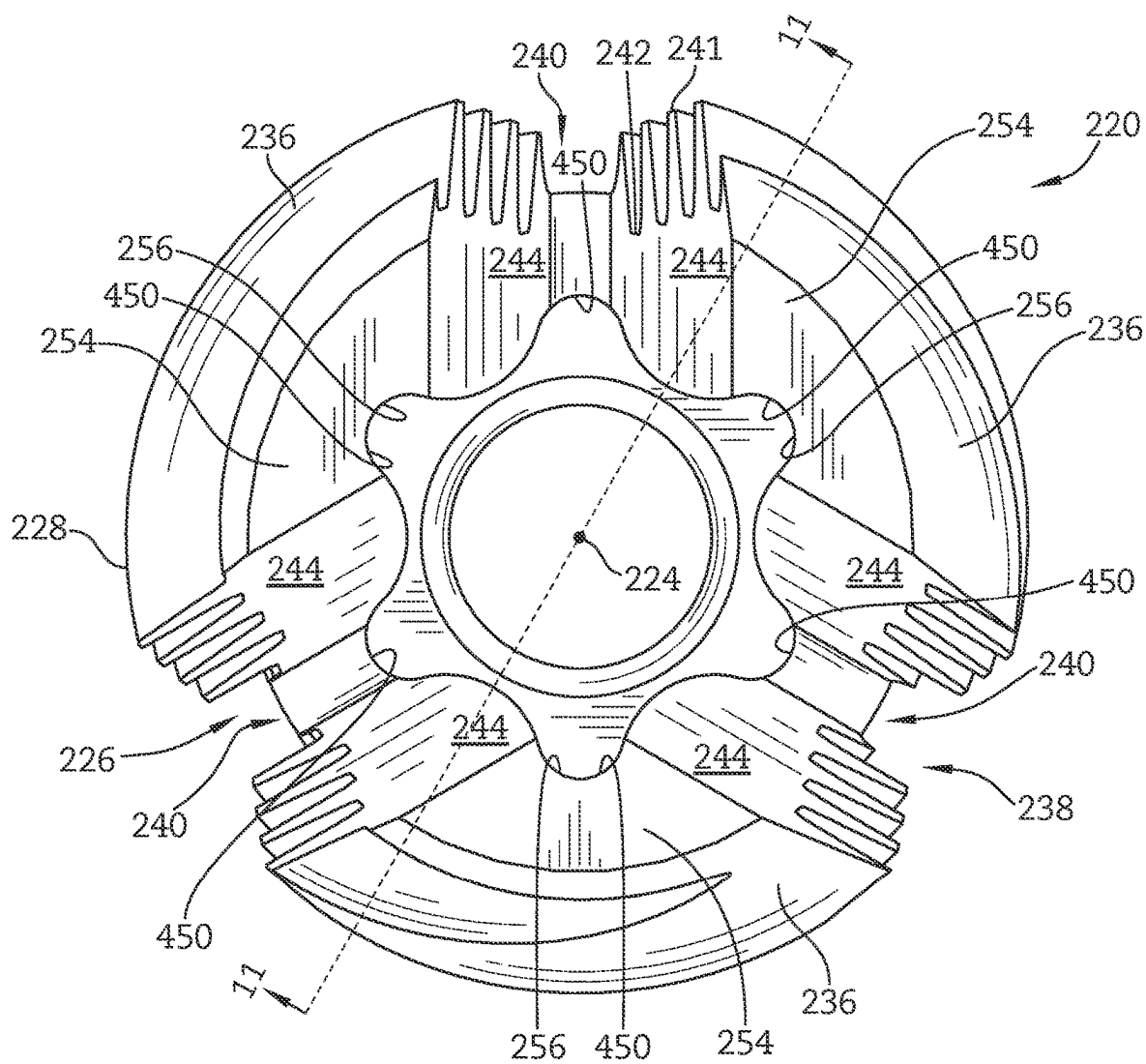


FIG. 9

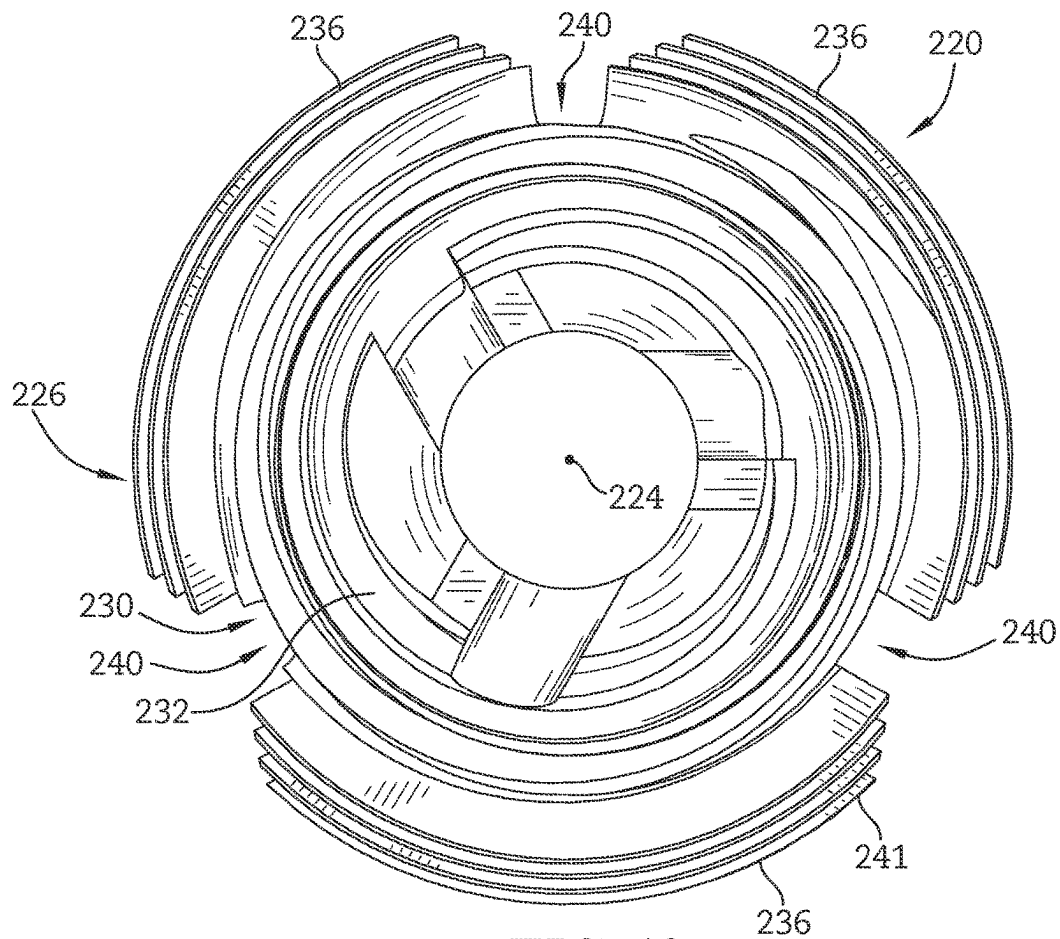


FIG. 10

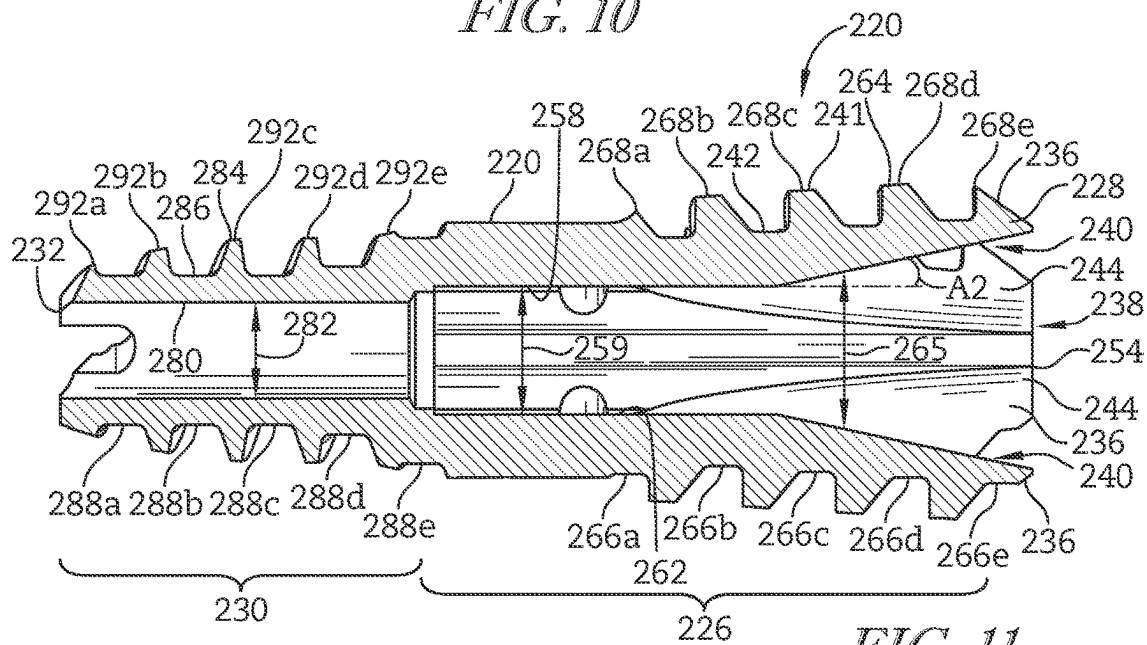


FIG. 11

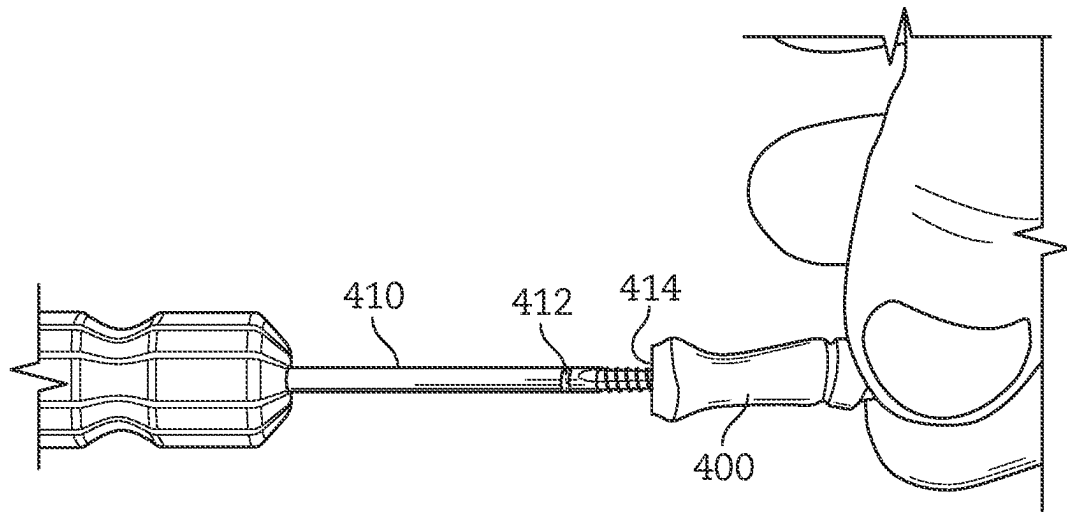


FIG. 12

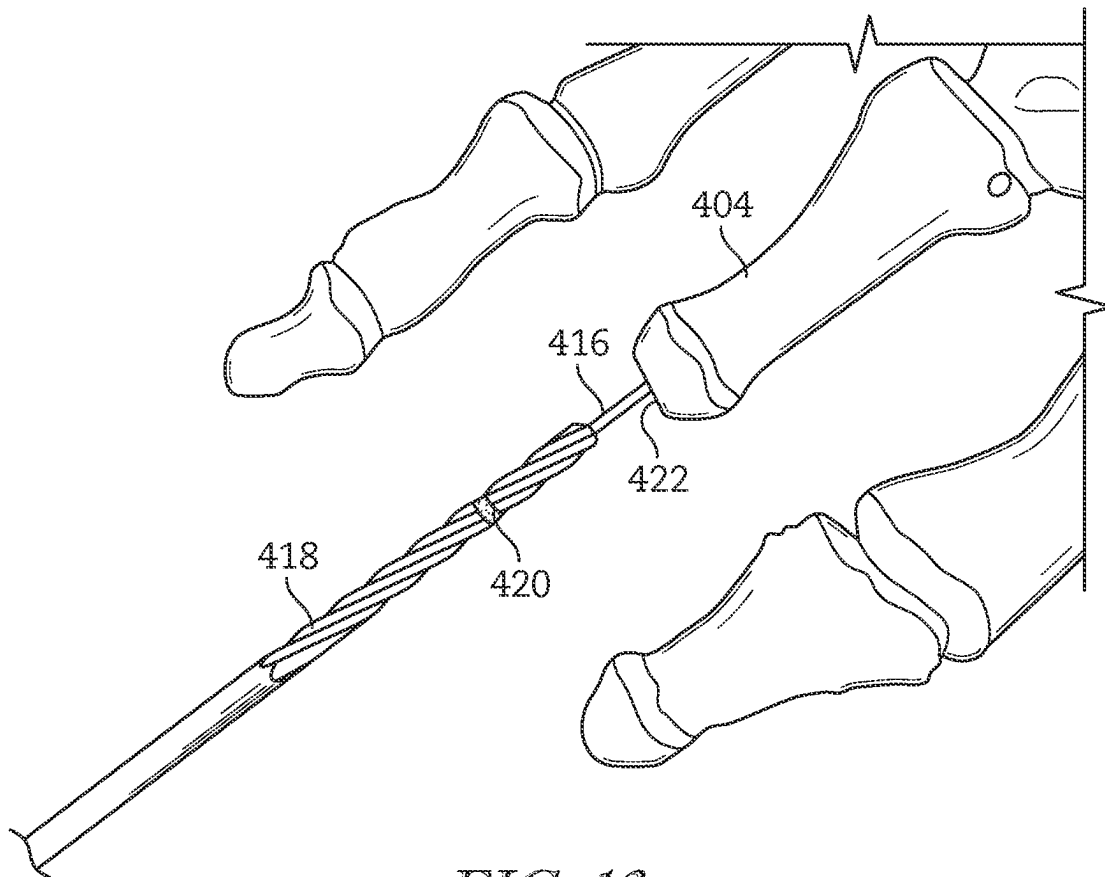


FIG. 13

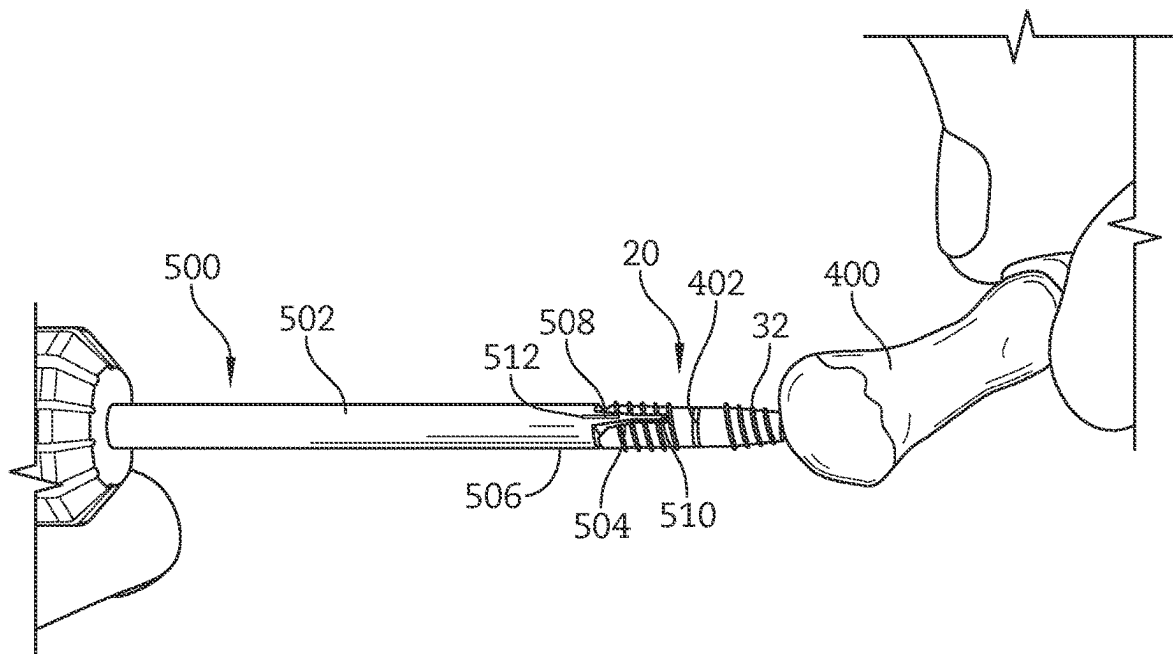


FIG. 14A

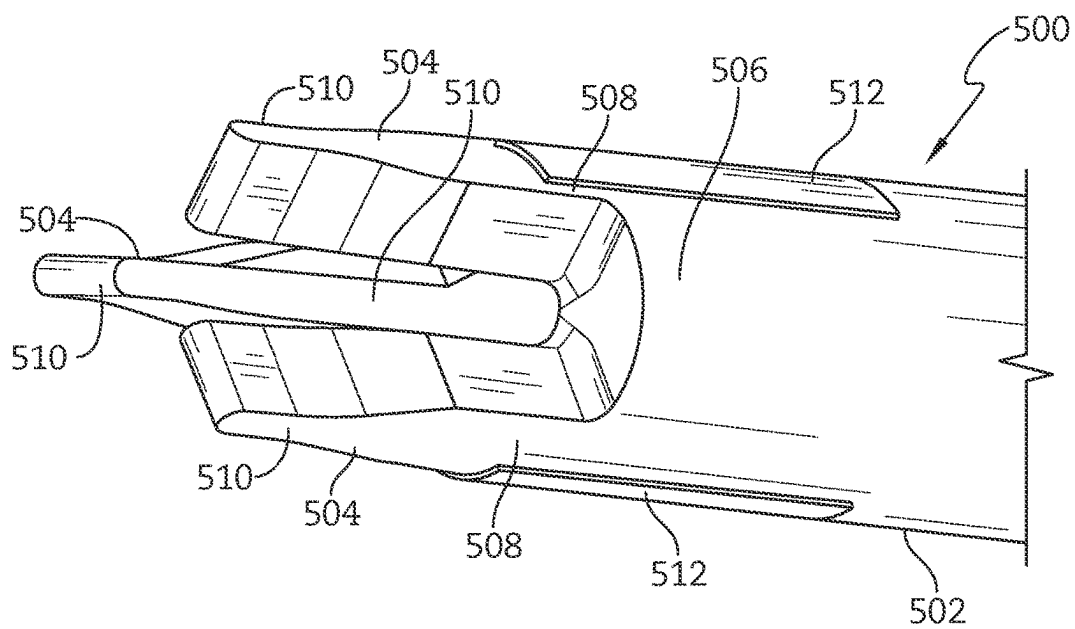
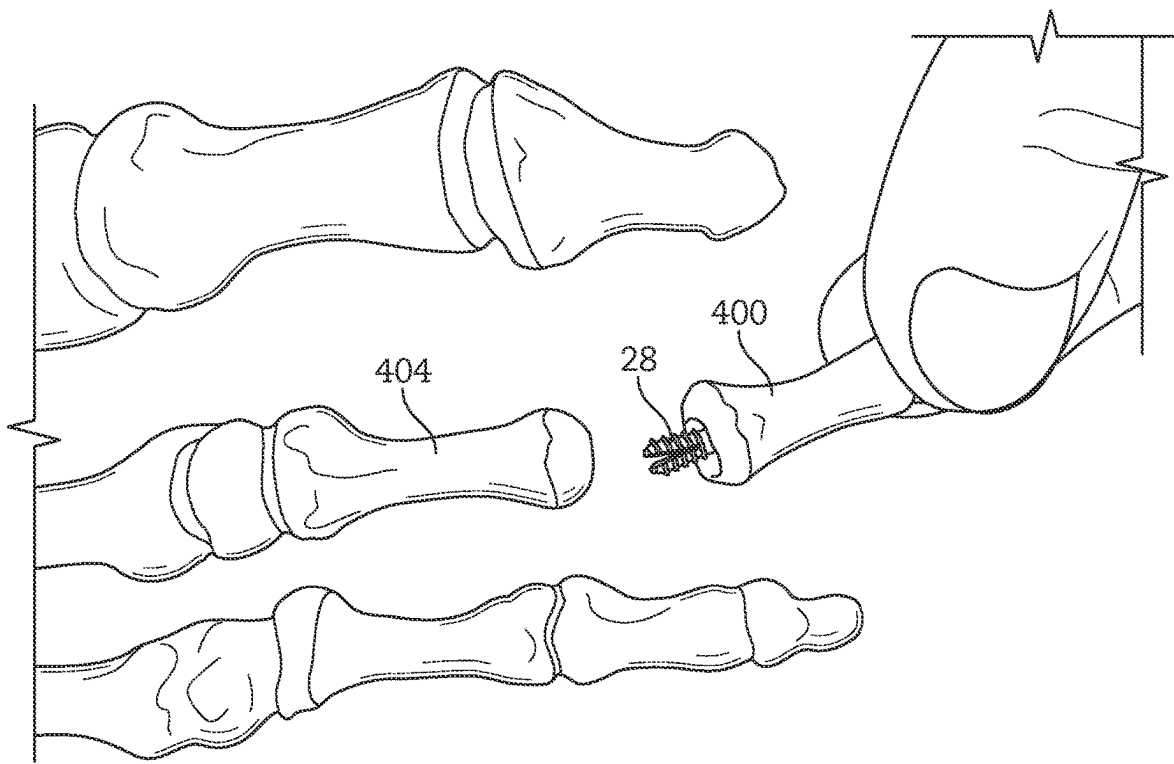
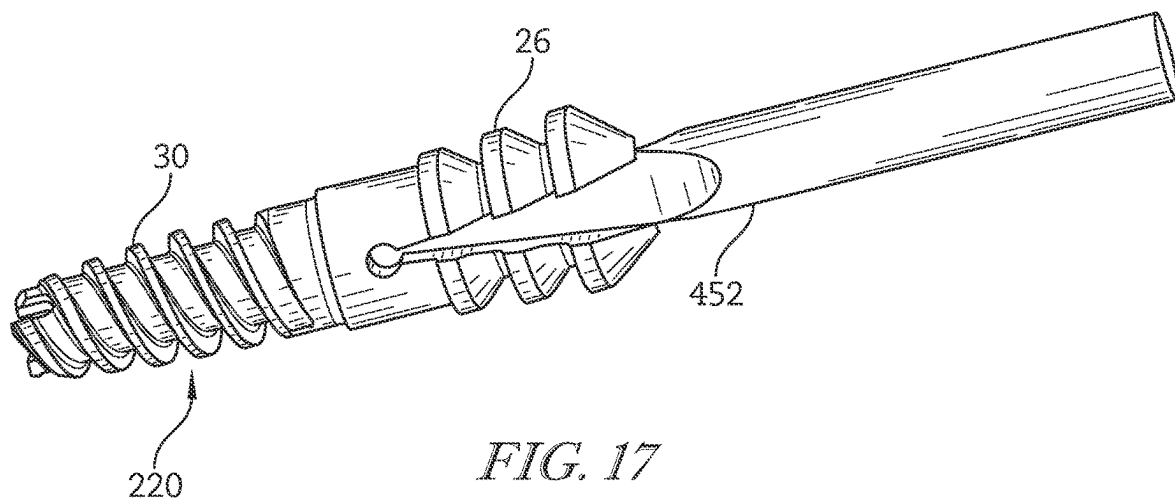
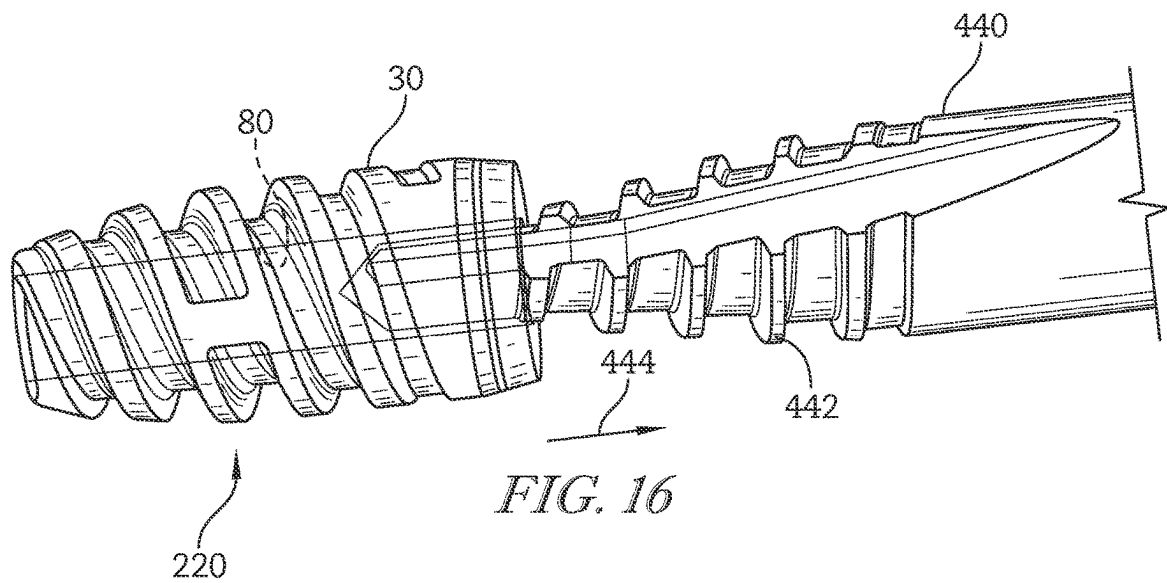


FIG. 14B

*FIG. 15*



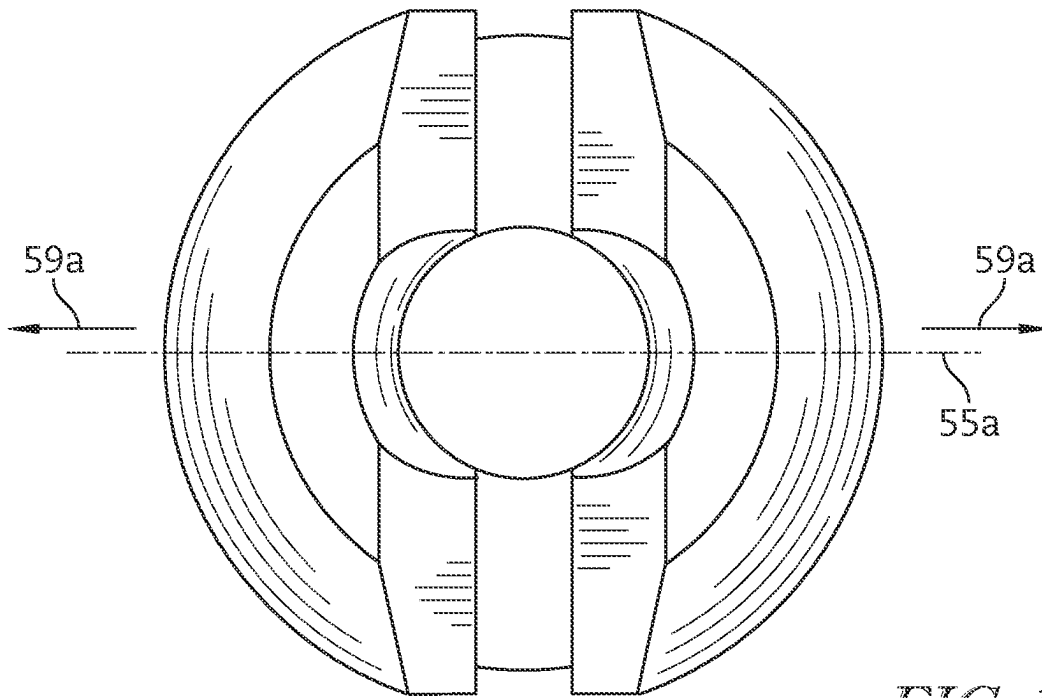


FIG. 18A

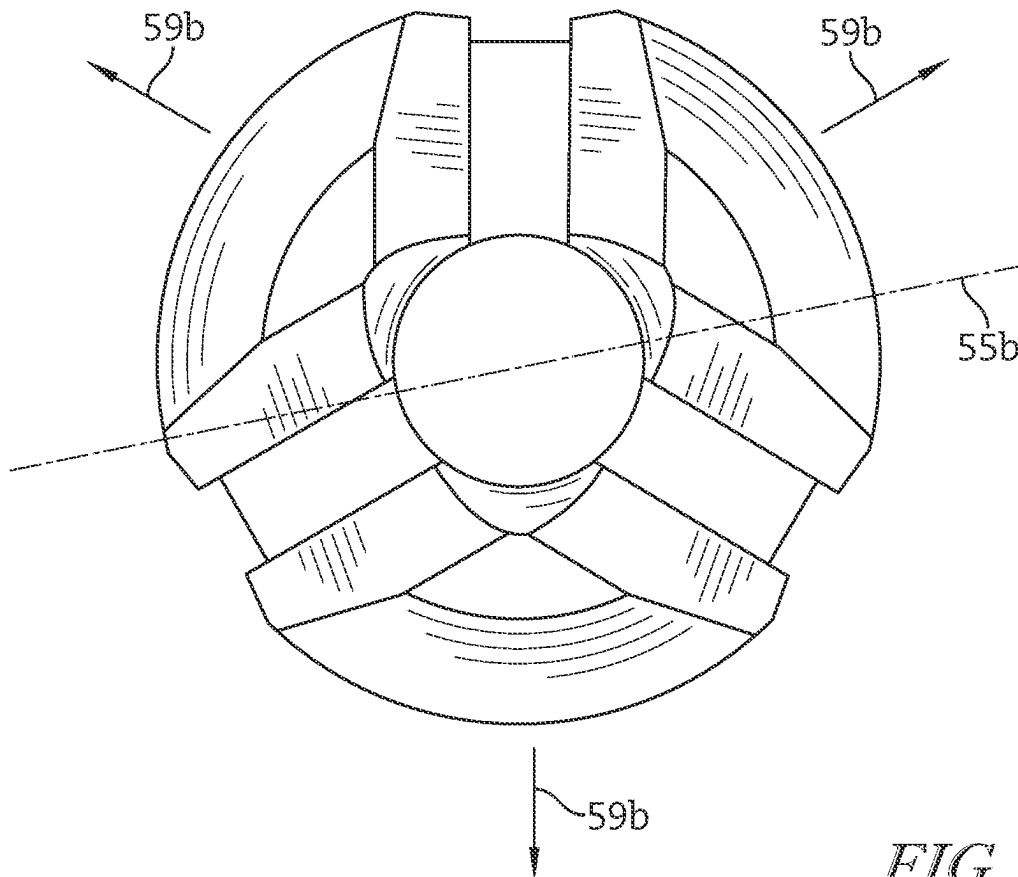


FIG. 18B

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ORTHOPEDIC IMPLANT AND METHODS OF IMPLANTING AND REMOVING SAME

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 16/891,732, filed on Jun. 3, 2020 which is a divisional of U.S. patent application Ser. No. 15/669,370, filed on Aug. 4, 2017, which is a divisional of U.S. patent application Ser. No. 14/637,032 (now U.S. Pat. No. 9,757,168) filed Mar. 3, 2015, the disclosures of which are incorporated herein by reference.

TECHNICAL FIELD

The present disclosure relates generally to orthopedic implants. More particularly, the present disclosure relates to orthopedic implants for surgically repairing joints and methods of implanting and removing same.

BACKGROUND OF THE INVENTION

A hammertoe is condition in which the proximal interphalangeal joints of the second, third, fourth, or fifth toe has become deformed, thereby causing the toe to be permanently bent. Hammertoe occurs from a muscle and ligament imbalance around the joints between the toes, which causes the joints to bend and become stuck in a bent position. Hammertoe oftentimes causes painful rubbing and irritation on the top of the bent toe. If caring for any callouses or corns, changing ones footwear, and/or utilizing cushions, supports, or comfort devices in ones shoes do not alleviate the pain associate with hammertoe, surgical intervention may be required to alleviate the pain. A procedure may be utilized to anatomically correct the joint using a pin, screw, or other implant. After anatomical correction, fusion or bony consolidation of the joint area occurs.

SUMMARY OF THE INVENTION

The present application discloses one or more of the features recited in the appended claims and/or the following features which alone or in any combination, may comprise patentable subject matter.

According to a first aspect of the present disclosure, an orthopedic implant may include a proximal segment comprising at least three spring arms forming an anchored barb at a first end of the implant, wherein first threading extends around outer surfaces of at least a portion of each spring arm and the first threading includes minor and major diameters. The surgical implant may further include a distal segment extending between the proximal segment and a second end of the implant and including second threading extending along at least a portion of the distal segment.

In some embodiments, at least two of the major diameters of the first threading may increase between the distal segment and the first end of the implant.

In some embodiments, each of the major diameters of the first threading may increase between the distal segment and the first end of the implant.

In some embodiments, the proximal segment may be configured to be implanted within a proximal phalanx of a patient and the distal segment may be configured to be threaded into a middle phalanx of the patient.

In some embodiments, the surgical implant may include a marking disposed on the surgical implant between the proxi-

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mal and distal segments, wherein the marking may be configured to identify an optimal depth for implantation of the distal segment of the implant into a middle phalanx of a patient.

5 In some embodiments, the implant may be manufactured of polyetheretherketone (PEEK).

In some embodiments, the second threading may include minor diameters and major diameters and at least two of the minor diameters may increase between the second end and the proximal segment.

10 In some embodiments, each of the minor diameters of the second threading may increase between the second end and the proximal segment.

In some embodiments, the proximal segment may include a drive feature formed in an end thereof that is configured to accept a tool for removal of the implant from a phalanx.

According to a second aspect of the present disclosure, an orthopedic implant may include a proximal segment comprising at least two spring arms forming an anchored barb at a first end of the implant, wherein first threading may extend around outer surfaces of at least a portion of each spring arm and the first threading may include minor and major diameters. The surgical implant may further include a distal segment extending between the proximal segment and a second end of the implant and include second threading extending along at least a portion of the distal segment, wherein the second threading may include minor and major diameters and at least two of the minor diameters may increase between the second end and the proximal segment.

25 In some embodiments, each of the minor diameters of the second threading of the distal segment may increase between the second end and the proximal segment.

In some embodiments, each of the major diameters of the first threading of the proximal segment may increase between the distal segment and the first end of the implant.

35 In some embodiments, the proximal segment may be configured to be implanted within a proximal phalanx of a patient and the distal segment may be configured to be threaded into a middle phalanx of the patient.

40 In some embodiments, a marking may be disposed on the surgical implant between the proximal and distal segments, wherein the marking may be configured to identify an optimal depth for implantation of the distal segment of the implant into a middle phalanx of a patient.

45 In some embodiments, the implant may be manufactured of polyetheretherketone (PEEK).

In some embodiments, the proximal segment may include at least three spring arms forming the anchored barb at the first end of the implant.

50 In some embodiments, the proximal segment may include a drive feature formed in an end thereof that is configured to accept a tool for removal of the implant from a phalanx.

According to a third aspect of the present disclosure, a method of removing an orthopedic implant from a patient may include the step of severing an orthopedic implant in a central segment of the orthopedic implant that is disposed between a proximal segment configured for implantation within a proximal phalanx of the patient and a distal segment opposite the proximal segment and configured for implantation within a middle phalanx of the patient. The method may further include the steps of inserting a tool into the proximal or distal segment of the orthopedic implant and rotating the tool to remove the proximal or distal segment from the proximal or middle phalanx, respectively.

65 In some embodiments, the method may include one or more of the steps of severing the implant, inserting the tool, which is made of a high-strength stainless steel, into the

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distal segment, which is made of a polymeric material, to thereby tap the tool into the distal segment, and removing the distal segment from the middle phalanx.

In some embodiments, the method may include one or more of the steps of inserting the tool into an end of the proximal segment, mating a portion of the tool with a drive feature in the proximal segment of the implant, and rotating the tool to remove at least a portion of the surgical implant.

In some embodiments, the drive feature may include a plurality of semi-cylindrical channels.

According to a fourth aspect, a tool for implantation of an orthopedic implant having a proximal segment with at least three arms spaced from one another by recesses, the three arms configured for implantation with a proximal phalanx of a patient and a distal segment opposite the proximal segment and configured for implantation within a middle phalanx of the patient is disclosed. The implantation tool may include a body and at least three arms extending from an end of the body, wherein each of the arms is sized and shaped to fit within one of the recesses disposed between the three arms in the proximal segment of the implant.

In some embodiments, the arms may have an outer diameter that is less than an outer diameter of the arms of the proximal segment of the implant.

In some embodiments, the tool may be configured to retain the proximal segment of the implant on the end of the body.

BRIEF DESCRIPTION OF THE DRAWINGS

The concepts described in the present disclosure are illustrated by way of example and not by way of limitation in the accompanying figures. For simplicity and clarity of illustration, elements illustrated in the figures are not necessarily drawn to scale. For example, the dimensions of some elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, the same or similar reference labels have been repeated among the figures to indicate corresponding or analogous elements.

FIG. 1 is an isometric view of a first embodiment of an orthopedic implant taken generally from a first end of the implant;

FIG. 2 is an elevational view of a first side of the implant of FIG. 1;

FIG. 3 is an elevational view of a second side of the implant of FIG. 1, wherein the second side is opposite the first side depicted in FIG. 2;

FIG. 4 is an elevational view of the first end of the implant of FIG. 1;

FIG. 5 is a cross-sectional view of the implant of FIG. 1 taken generally along the lines 5-5 of FIG. 4;

FIG. 6 is an isometric view of a second embodiment of an orthopedic implant taken generally from a first end of the implant;

FIG. 7 is an elevational view of a first side of the implant of FIG. 6;

FIG. 8 is an elevational view of a second side of the implant of FIG. 6, wherein the second side is opposite the first side depicted in FIG. 7;

FIG. 9 is an elevational view of the first end of the implant of FIG. 6;

FIG. 10 is an elevational view of a second end of the implant of FIG. 7, wherein the second end is opposite the first end;

FIG. 11 is a cross-sectional view of the implant of FIG. 6 taken generally along the lines 11-11 of FIG. 9;

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FIG. 12 is a view depicting a tap advanced over a distal Kirschner wire (K-wire) into a middle phalanx of a patient during a first method of implantation of an orthopedic implant disclosed herein;

FIG. 13 is a view depicting a proximal K-wire inserted into a center of a proximal phalanx of a patient and a drill advanced over the K-wire during the first method of implantation of an orthopedic implant;

FIG. 14A is a view depicting a second end of a distal segment of an orthopedic implant threaded into the middle phalanx of a patient during the first method of implantation of an orthopedic implant utilizing an implantation tool;

FIG. 14B is a perspective view of a drive end of the implantation tool shown in use in FIG. 14A, wherein the implantation tool is utilized to thread the distal segment of the orthopedic implant into the middle phalanx;

FIG. 15 is a view depicting insertion of a barbed anchor disposed at a first end of a proximal segment of an orthopedic implant into a pre-drilled hole in the proximal phalanx of the patient during the first method of implantation of an orthopedic implant;

FIG. 16 is a view depicting a method of removing a distal segment of an orthopedic implant in which a threaded tool is utilized to tap an inner surface of the distal segment;

FIG. 17 is a view depicting a method of removing an orthopedic implant in which a tool having a drive features is utilized in combination with a complementary drive feature within a proximal segment of an orthopedic implant to remove the implant; and

FIGS. 18A and 18B are views depicting bending axes for orthopedic implants having two and three arms, respectively.

DETAILED DESCRIPTION

While the concepts of the present disclosure are susceptible to various modifications and alternative forms, specific exemplary embodiments thereof have been shown by way of example in the figures and will herein be described in detail. It should be understood, however, that there is no intent to limit the concepts of the present disclosure to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present disclosure.

A first embodiment of an orthopedic implant 20 suitable for treatment and correction of hammertoe is depicted in FIGS. 1-5. The implant 20 generally includes a pin-shaped body 22 extending along a longitudinal axis 24 and further includes a proximal segment 26 terminating in a first end 28 and a distal segment 30 terminating in a second end 32. The proximal and distal segments 26, 30 may be integral with one another and joined at a central, narrowed segment 34 of the implant 20. The proximal segment 26 of the body 22 may generally comprise the central, narrowed segment 34 and three spring arms 36 that form a barbed anchor 38 and which extend away from the central, narrowed segment 34. While the segment 34 is depicted as being narrowed, the segment 34 may alternatively not be narrowed or may have a constant outer diameter.

As seen in FIGS. 1, 2, and 4, each of the arms 36 is separated from adjacent arms 36 by a channel 40. Helical threading 41 may be disposed about outer edges or surfaces 42 of each of the arms 36 and may continue between arms 36 (despite the existence of channels 40 therebetween). Each of the arms 36 is formed by opposing side edges 44 that, with side edges 44 of adjacent arms 36, form the channels 40. As seen in FIGS. 2 and 6, each side edge 44 is formed of a straight segment 46 that is generally parallel to a

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longitudinal axis **24** of the implant **20** and a tapered segment **50** that tapers outwardly from the straight segment **46** at an angle **A1** of greater than 0 degrees to a tip forming a flattened edge **54**. In an illustrative embodiment, the angle **A1** may be between about 1 degree and about 15 degrees. In another illustrative embodiment, the angle **A1** may be between about 3 degrees and about 10 degrees. In a further illustrative embodiment, the angle **A1** may be about 7 degrees. As seen in FIG. 4, each arm **36** further includes a generally cylindrical inner edge **56** (FIG. 4) that tapers outwardly from an inner, generally cylindrical surface **57** of the proximal segment **26**. The tapered segment **50** and the inner edge **56** are tapered to thin out the arms **36** to provide a desired stiffness and even stress distribution for each of the arms **36**.

The use of three arms **36** provides more resistance to bending of the arms **36** along various axes that are perpendicular to the longitudinal axis **24**. Less bending equates to higher contact forces and improved fixation. Three arms **36** also stabilize the bone in which implantation occurs more than two arms, since two arms leave a weak bending axis.

Currently, a number of hammertoe implant designs incorporate two spring arms for retention in the proximal phalanx, the middle phalanx, or both. Designs with two arms are intrinsically easier to manufacture through machining and may be easier to insert into the bone, as well. It has been discovered in the present invention that designs with multiple arms, for example, those with an odd number of arms, impart a strong advantage to implant fixation in the bone. Implant fixation into the bone is a common failure mode because bone in older hammertoe patients is oftentimes osteopenic and poorly supports an interface with the implant. The key to implant stability is the ability of the implant to uniformly impart stresses to the underlying bone. The loading vector for a hammertoe implant is predominantly in the dorsal-plantar direction as the foot moves through the gait cycle, however, complex tri-axial stresses also occur in all planes as the foot pushes laterally or moves over uneven surfaces. The objective of the implant designer should be to create a design that retains strength and fixation even in a tri-axial stress state.

A two-arm implant design, as seen in FIG. 18A, has a weak bending axis **55a** on a plane of symmetry between the two arms. This weak axis **55a** imparts a deficiency to the design in resisting tri-axial stresses, particularly when the dorsal-plantar loading vector is aligned perpendicularly to a vector of the arm spring force **59a**. In this case, the spring arms contribute little to the stability of the implant in the bone.

As seen in FIG. 18B, a three-arm implant design still has weak bending axis **55b**, but the weak bending axis **55b** is not as weak as the weak bending axis **55a** of the two-arm design since there are now arms at more angular positions along a diameter of the implant. Even if a weak axis **55b** of the implant is aligned with the dorsal-plantar loading vector, there are portions of the adjacent spring arms that directly contribute to resistance on the loading vector. This advantage is shared by all arm designs having three or more arms, although odd-numbered arm designs convey a particular evenness between the strong and weak axes. Additionally, with odd-numbered arm designs, the dorsal-plantar loading vector is not aligned perpendicularly to the vector of the arms spring force **59b**. An additional advantage of a three-arm design is that it self-centers in a center of a hole in the bone in which it is implanted.

Referring to FIG. 6, the inner surface **57** of the proximal segment **26** has an inner diameter **58** that does not vary along a first section **62** that includes both the central, narrowed

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segment **34** and a portion of the arms **36**. The inner surface **58** further includes a second section **64** that includes the generally cylindrical surface **57** of the arms **36** and which has a diameter **65** that increases along the longitudinal axis **24** from the central segment **34** toward the first end **28**. The arms **36**, as seen in FIG. 6, include outer edges **42** that, due to the helical threading **41**, have minor diameters **66a-66e** and major diameters **68a-68e**. The minor diameters **66a-66e** of the helical threading **41** may be constant in that the diameters thereof do not vary along a length of the threading **41**. The major diameters **68a-68e** of the helical threading **41** may increase from a first major diameter **68a** closest the central segment **34** toward the first end **28** of the proximal segment **30**. More particularly, a major diameter **68a** of the threading **41** may be smaller than each of the other major diameters **68b-68e** and the major diameters **68b-68e** may each increase between the central segment **34** and the first end **28**. An increasing major diameter **68a-68e** maximizes bony contact during insertion of the second end **28** of the implant **20** into a proximal phalanx, as discussed in more detail below. In other illustrative embodiments, two or more consecutive or non-consecutive major diameters **68a-68e** may be increasing between the major diameter **68a** and the major diameter **68e** and/or two or more consecutive or non-consecutive major diameters **68a-68e** may be the same.

Referring again to FIG. 6, the distal segment **30** includes an inner cylindrical surface **80** having an inner diameter **82**. The inner diameter **82** may be the same or different than the inner diameter **58** of the proximal segment **26**. Helical threading **84** may be disposed on an outer surface **86** of all or a portion of the distal segment **30**. As seen in FIG. 6, the helical threading **84** includes minor diameters **88a-88e** and major diameters **92a-92e**, wherein the minor diameters **88a-88e** may increase along the longitudinal axis **24** of the implant **20** between the second end **32** and the first end **28**. More particularly, a minor diameter **88a** of the threading **84** may be smaller than each of the other minor diameters **88b-88e** and the minor diameters **88a-88e** may increase between minor diameter **88a** and minor diameter **88e**. Increasing minor diameters **88a-88e** provide tactile feedback when implanting the distal segment **30** of the implant **20** into a middle phalanx, as discussed in greater detail below. In alternative illustrative embodiments, two or more consecutive or non-consecutive minor diameters **88a-88e** may increase between minor diameter **88a** and minor diameter **88e** and/or two or more consecutive or non-consecutive minor diameters **88a-88e** may be the same. Major diameters **92a-92e** of the helical threading **84** may increase in diameter from the major diameter **92a** to the major diameter **92e** or the major diameters **92a-92e** may be the same. Still alternatively, two or more consecutive or non-consecutive major diameters **92a-92e** may be increasing between the major diameters **92a** and the major diameter **92e** and/or two or more consecutive or non-consecutive major diameters **92a-92e** may be the same.

While a particular number of threads are depicted for the threading **41** and **84**, any number of threads may be present depending on a particular application for the implant **20**.

A second embodiment of an orthopedic implant **220** suitable for treatment and correction of hammertoe is depicted in FIGS. 6-11. The implant **220** generally includes a pin-shaped body **222** extending along a longitudinal axis **224** and further includes a proximal segment **226** terminating in a first end **228** and a distal segment **230** terminating in a second end **232**. The proximal and distal segments **226**, **230** may be integral with one another and joined at a central, cylindrical flattened segment **234** of the implant **220**. The

proximal segment 226 of the body 222 may generally comprise the central flattened segment 234 and three arms 236 that form a barbed anchor 238 and which extend away from the central, flattened segment 234.

As seen in FIGS. 5, 6, 7, and 9, each of the arms 236 is separated from adjacent arms 236 by a channel 240. Helical threading 241 may be disposed about outer edges or surfaces 242 of each of the arms 236 and may continue between arms 236 (despite the existence of channels 240 therebetween). Each of the arms 236 is formed by opposing side edges 244 that, with side edges 244 of adjacent arms 236, form the channels 240. As seen in FIGS. 7 and 12, each side edge 244 tapers outwardly at an angle A2 of greater than 0 degrees to a tip forming a flattened edge 254. In an illustrative embodiment, the angle A2 may be between about 1 degree and about 15 degrees. In another illustrative embodiment, the angle A2 may be between about 3 degrees and about 10 degrees. In a further illustrative embodiment, the angle A2 may be about 7 degrees. As seen in FIGS. 6 and 10, each arm 236 further includes an inner, generally cylindrical edge 256 that tapers outwardly from an inner, generally cylindrical surface 258 of the proximal segment 226.

Referring to FIG. 11, the inner surface 258 of the proximal segment 226 has an inner diameter 259 that may not vary along a first section 262 and that may include both the central segment 234 and a portion of the arms 236. The inner diameter 258 may further include a second section 264 that includes at least a portion of the arms 236 and which has a diameter 265 that increases along the longitudinal axis 224 from the central segment 234 toward the first end 228. The arms 236, as seen in FIG. 11 include helical threading 241 that has minor diameters 266a-266e and major diameters 268a-268e. The minor diameters 266a-266e of the helical threading 41 may be constant in that the diameters thereof do not vary along a length of the threading 241 or the minor diameters 266a-266e may have different or varying diameters. The major diameters 268a-268e of the helical threading 41 may be constant in that the diameters thereof do not vary along a length of the threading 241 or the major diameters 268a-268e may have different or varying diameters. In illustrative embodiments and similar to the embodiment of FIGS. 1-5, the major diameters 268a-268e may increase from a first major diameter 268a closest the central segment 234 toward the first end 228 of the proximal segment 230. In other illustrative embodiments, two or more consecutive or non-consecutive major diameters 268a-268e may be increasing between the major diameter 268a and the major diameter 268e and/or two or more consecutive or non-consecutive major diameters 268a-268e may be the same.

Referring again to FIG. 11, the distal segment 230 includes an inner cylindrical surface 280 having an inner diameter 282. The inner diameter 282 may be constant or may vary along the longitudinal axis 224. The inner diameter 282 may be the same as or less than the inner diameter 259 of the proximal segment 226. Helical threading 284 may be disposed on an outer surface 286 of all or a portion of the distal segment 230. As seen in FIG. 11, a minor diameter 288a-288e of the helical threading 284 may be the same for each thread or may increase along the longitudinal axis 224 of the implant 220 from the second end 232 toward the first end 228, as discussed above with respect to the embodiment of FIGS. 1-5. In other illustrative embodiments, two or more consecutive or non-consecutive minor diameters 288a-288e may be increasing between the minor diameter 288a and the

minor diameters 288e and/or two or more consecutive or non-consecutive minor diameters 288a-288e may be the same.

Major diameters 292a-292e of the helical threading 284 may increase in diameter from the major diameter 292a to the major diameter 292e or the major diameters 292a-292e may be the same. Still alternatively, two or more consecutive or non-consecutive major diameters 292a-292e may be increasing between the major diameters 292a and the major diameter 292e and/or two or more consecutive or non-consecutive major diameters 292a-292e may be the same.

While a particular number of threads are depicted for the threading 241 and 284, any number of threads may be present depending on a particular application for the implants 20, 220.

Implantation of the implants 20, 220 will now be discussed in detail. Prior to implantation, the proximal interphalangeal (PIP) joint of the patient is opened using, for example, a dorsal approach. A head of a proximal phalanx 104 of the patient is prepared by reaming until bleeding bone is reached, for example, using a proximal phalanx reamer and a base of a middle phalanx 100 of the patient is also reamed until bleeding bone is reached, for example, using a middle phalanx reamer. Once the middle phalanx 400 is reamed, a distal K-wire may be inserted into a center of the middle phalanx 400. As seen in FIG. 12, tap 410 of the appropriate size 410 is selected for the desired implant size and, using firm axial pressure, the tap 410 is advanced over the distal K-wire into the middle phalanx 100 until a laser line 412 on the tap 410 is level with an outer surface 414 of the middle phalanx 400. A proximal K-wire 416 may be inserted into a center of the proximal phalanx 404, as seen in FIG. 13. In an illustrative embodiment, the K-wire 416 may be introduced at a 10 degree angle plantar to a medial axis of the proximal phalanx 404. An appropriate drill size may be selected and advanced over the K-wire 416 into the proximal phalanx 404 until a laser line 420 on the drill 418 is level with an outer surface 422 of the proximal phalanx 404, as seen in FIG. 13, and the proximal K-wire 416 may be removed after drilling.

The second end 32, 232 of the distal segment 30, 230 of either implant 20, 220 is threaded into the middle phalanx 400 of the patient, as seen in FIG. 14A, using an implantation tool 500, until an increase in torque indicates firm seating of the implant 20, 220. Additionally, an outer edge of the middle phalanx 400 may be aligned with a laser line 402 positioned between the proximal and distal segments 26 or 226, 30 or 230 and should be facing dorsally. The laser line 402 is formed of one or more of a black burn, engraving, one or more dyes, or any other suitable substance capable of creating a line, marker, or other indicator. The laser line 402 provides guidance to a surgeon or other healthcare professional such that the distal segment 30, 230 of the implant 20, 220 is threaded into the middle phalanx 400 to an optimal or ideal depth. The laser lines on the tap 410 and the drill 418 additionally prepare the bone for insertion of the implant 20, 220 to an appropriate depth.

The implantation tool 500, as best seen in FIG. 14B, may include a generally cylindrical body 502, although, the body 502 need not be cylindrical. Three arms 504 extend outwardly from a first end 506 of the body 502. Each of the arms 504 includes a wider based 508 that tapers into a narrowed tip 510. The arms 504 are sized and shaped to be complementary to and fit within the channels 40, 240 formed by the arms 36, 236 of the implant 20, 220, as seen in FIG. 14A. In illustrative embodiments, the implantation tool 500 may retain the implant 20, 220 on the first end 506 by, for

example, an interference fit. In other illustrative embodiments, the implantation tool **500** may fit within the implant **20**, **220**, but may not retain the implant **20**, **220** on the first end **506**.

As may be seen in FIG. **14A**, an outer diameter of the arms **504** of the implantation tool **500** is fully within an outer or major diameter of the threads **68a-68e**, **268a-268e**. Each of the arms **504** may also include a laser mark **512** that denote which way the implant arms **36**, **236** are oriented. As one skilled in the art will understand, if an implant includes more than three arms/three recesses, the implantation tool **500** may include a similar number of arms.

After the distal segment **30**, **230** is implanted within the middle phalanx **400** and the distal K-wire **416** is removed, the proximal segment **26**, **226** of the implant **20**, **220** is aligned with a proximal phalanx **404** of the patient. More specifically, the barbed anchor **38**, **238** at the first end **28**, **228** of the proximal segment **26**, **226** is aligned with and inserted into the pre-drilled hole in the proximal phalanx **404**, as seen in FIG. **15**. The proximal segment **26**, **226** is thereafter pressed into the proximal phalanx **404**. Once both the proximal and distal segments **26** or **226**, **30** or **230** are implanted within the proximal and middle phalanges **404**, **400**, respectively, a typical surgical procedure is used to close the patient.

Ofentimes, implants, such as implant **20**, **220** or any of the implants disclosed herein, must be removed and replaced (during, for example, a revision surgical procedure). It can be very difficult to remove the distal and/or proximal segments **30** or **230**, **26** or **226** from the middle and proximal phalanges **400**, **404**, respectively. The implant **20**, **220** may be provided with features that allow for easier removal of the implant **20**, **220** from the middle and proximal phalanges **400**, **404**. More particularly, in illustrative embodiments, the implant **20**, **220** may be manufactured of a polymeric material, for example, ultra-high molecular weight polyethylene (UHMWPE), polyetheretherketone (PEEK), or any other suitable polymeric material. The central segment **34**, **234** of the implant **20**, **220** may be cut to sever the proximal and distal segments **26** or **226**, **30** or **230** from one another. In illustrative embodiments, the central segment **34**, **234** may be cut at a point **130** adjacent the distal segment **30**, **230**.

In illustrative embodiments, once the implant, for example, the implant **20**, is severed, a tool **440** that is made of a high-strength material, for example, stainless steel, having threading **442** may be threaded into the distal segment **30**. In illustrative embodiments, the threading **442** on the tool **440** taps out the inner cylindrical surface **80** of the distal segment **30** such that opposing threads are created therein. Once the tool **440** is threaded a sufficient distance into the distal segment **30**, the tool **440** may be threaded or pulled in a direction **444** opposite the direction of threading to remove the distal segment **30** from the middle phalanx **400**. In a similar manner, the tool **440** may be threaded into the proximal segment **26**, for example, such that the threading **442** on the tool **440** taps out an inner surface **446** of the central segment **34** and/or the proximal segment **26**, thereby creating opposing threads therein. Once the tool **440** is threaded a sufficient distance into the proximal segment **26**, the tool **440** may be threaded or pulled in a direction opposite the direction of threading to remove the proximal segment **26** from the proximal phalanx **404**.

In other illustrative embodiments, the implant, for example, the implant **220**, may include a proximal segment **226** having an internal drive feature **450** (see FIG. **9**) that mates with a tool **452** such that, upon rotation of the tool

452, the distal segment **230** may be threaded out of the bore in which it was implanted. In the illustrative embodiment, the drive feature **450** may be comprised of a hexalobe bore formed by the cylindrical inner edge **256** that form semi-cylindrical channels and portions of the central segment **34** that form semi-cylindrical channels. Alternatively or additionally, the drive feature **450** may include any suitable feature(s) or geometr(ies) configured to accept a tool and allows for rotation of the implant **220** using the tool **452**. While six semi-cylindrical channels are depicted in FIG. **9**, any suitable number of semi-cylindrical channels may be utilized.

Any of the implants disclosed herein may be manufactured in different sizes, for example, for differently-sized phalanges of the same foot or phalanges of persons with differently-sized feet, toes, and/or phalanges. In an illustrative embodiment, three or more differently-sized implants may be provided, for example, small, medium, and large implants or small, medium, large, and extra-large implants. In an illustrative embodiment with small, medium, and large implants, an overall length of the small implant may be 13 millimeters, a proximal length **L1** may be 7 millimeters, and a distal length **L2** may be 6 millimeters. Similarly, an overall length of the medium implant may be 14 millimeters, the proximal length **L1** may be 7 millimeters, and the distal length **L2** may be 7 millimeters. Still further, an overall length of the large implant may be 15 millimeters, the proximal length **L1** may be 7 millimeters, and the distal length may be 8 millimeters. In other embodiments, the overall length of one or more implants may be between about 5 millimeters and about 20 millimeters.

Any of the implants disclosed herein may be manufactured of one or more of metal, ultra-high molecular weight polyethylene (UHMWPE), ceramic, polyetheretherketone (PEEK), or any other suitable material or materials.

While the implants disclosed in detail herein are discussed as being suitable for treatment and correction of hammertoe, the implants disclosed herein may be utilized for treatment and/or correction of other conditions, for example, other conditions in the foot or hand and/or conditions related to other joints.

Any one or more features of any of the implant disclosed herein may be incorporated (alone or in combination) into any of the other implants disclosed herein.

While certain illustrative embodiments have been described in detail in the figures and the foregoing description, such an illustration and description is to be considered as exemplary and not restrictive in character, it being understood that only illustrative embodiments have been shown and described and that all changes and modifications that come within the spirit of the disclosure are desired to be protected. There are a plurality of advantages of the present disclosure arising from the various features of the apparatus, systems, and methods described herein. It will be noted that alternative embodiments of the apparatus, systems, and methods of the present disclosure may not include all of the features described yet still benefit from at least some of the advantages of such features. Those of ordinary skill in the art may readily devise their own implementations of the apparatus, systems, and methods that incorporate one or more of the features of the present disclosure.

The invention claimed is:

1. An orthopedic implantation kit, comprising:
an orthopedic implantation tool including:
a body defining a longitudinal axis;
three circumferentially spaced apart tool arms extending from the body, each of the tool arms including:

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- a first surface extending from the body and within a first plane parallel to the longitudinal axis; and
 a second surface distal to and extending distally from the first surface, the second surface being within a second plane transverse to the longitudinal axis, wherein each of the first and the second surfaces extends across a full width of the arm defined within a plane extending radially from the longitudinal axis; and
 an orthopedic implant defining respective recesses configured to receive the three circumferentially spaced tool arms of the orthopedic implantation tool, wherein the tool arms are configured for moving and thereby causing implantation of the orthopedic implant when the tool arms are received by the recesses of the orthopedic implant.
2. The orthopedic implantation kit of claim 1, wherein the orthopedic implant includes a laser line configured to indicate alignment of the orthopedic implant with a surface of the bone.
3. The orthopedic implantation kit of claim 1, wherein each of the tool arms is inserted between respective sets of two circumferentially spaced apart implant arms of the orthopedic implant when recesses of the orthopedic implant receive the tool arms.
4. The orthopedic implantation kit of claim 3, wherein each of the tool arms includes a base and a tip that is attached to and thinner than the base, wherein the respective sets of two circumferentially spaced apart implant arms of the orthopedic implant each define a semi-cylindrical channel, and wherein the tip of each implant arm is complementary to each semi-cylindrical channel and the base is complementary to a surface wider than each semi-cylindrical channel.
5. The orthopedic implantation kit of claim 1, wherein the orthopedic implant extends between a first end and a second end opposite the first end, wherein the recesses of the orthopedic implant are positioned at the first end, and wherein the second end is threaded.
6. The orthopedic implantation kit of claim 1, wherein each of the implant arms includes a third surface within a third plane, the third plane being transverse to the second plane and the third surface being distal to the second surface, the third surface further extending from the second surface along a full width of the second surface.
7. The orthopedic implantation kit of claim 1, wherein the tool arms of the orthopedic implantation tool are configured to rotate the orthopedic implant when the recesses of the orthopedic implant receive the tool arms of the orthopedic implantation tool.
8. An orthopedic implantation kit, comprising:
 an orthopedic implantation tool including:
 a body;
 three tool arms extending from the body,
 wherein each of the tool arms defines a central plane that extends radially from the center of the implantation tool,
 wherein a distal end of each of the tool arms is spaced apart from the distal ends of each of the other tool arms, and
 wherein each of the tool arms includes a side having a plurality of surfaces defining a set of planes, each of the planes of the set of planes of the side being parallel to or forming a different angle with respect to the central plane of the respective tool arm than the other planes of the set of planes; and

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- an orthopedic implant defining respective recesses configured to receive the three tool arms of the orthopedic implantation tool, wherein the tool arms are configured for moving and thereby causing implantation of the orthopedic implant when the tool arms are received by the recesses of the orthopedic implant.
9. The orthopedic implantation kit of claim 8, wherein the tool arms of the orthopedic implantation tool are configured to rotate the orthopedic implant when the recesses of the orthopedic implant receive the tool arms of the orthopedic implantation tool.
10. The orthopedic implantation kit of claim 8, wherein each of the tool arms of the implantation tool is sized and shaped to be a complementary fit within a channel formed between adjacent implant arms on a first end of the implant.
11. The orthopedic implantation kit of claim 10, wherein each of the tool arms of the implantation tool has a base at a proximal end of the tool that tapers in a distal direction to a tip narrower than the base.
12. The orthopedic implantation kit of claim 8, wherein each of the tool arms includes a first surface extending from the tool body along a plane parallel to a longitudinal axis defined by the tool body, each of the tool arms further including a second surface distal to the first surface and extending along a plane parallel to the longitudinal axis, the first and the second surface spanning a full width of each of the respective tool arms.
13. The orthopedic implantation kit of claim 8, wherein each of the tool arms defines a respective tip spanning a full width of the respective tool arm.
14. An orthopedic implantation kit, comprising:
 an orthopedic implant extending from a first end to a second end and including:
 a central segment; and
 three circumferentially spaced bendable implant arms at the first end extending from the central segment and defining a channel between adjacent ones of the implant arms; and
 an orthopedic implantation tool including:
 tool arms sized and shaped to complementarily fit into the first end of the implant,
 wherein a surface of each of the tool arms contacts first and second surfaces of corresponding ones of the implant arms and each of the tool arms contacts at least two of the implant arms, and
 wherein the first and second surfaces of each of the implant arms define planes extending in transverse directions to each other.
15. The orthopedic implantation kit of claim 14, wherein the first surface of each of the tool arms defines a plane parallel to a longitudinal axis of the tool arm and the second surface of each of the tool arms defines a plane transverse to the respective first surface.
16. The orthopedic implantation kit of claim 14, wherein the orthopedic implant is configured to be implanted into a middle phalanx.
17. The orthopedic implantation kit of claim 14, wherein the first end of the orthopedic implant is configured to be implanted into a proximal phalanx and the second end of the orthopedic implant is configured to be threaded into a middle phalanx.
18. The orthopedic implantation kit of claim 14, wherein the second end of the implant includes an outer surface having a helical threading.

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19. The orthopedic implantation kit of claim **14**, wherein the orthopedic implant includes a marking configured to indicate alignment of the orthopedic implant with a surface of a bone.

20. The orthopedic implantation kit of claim **14**, wherein each of the implant arms includes a barb at the first end of the implant for anchoring the implant.

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