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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	F. Barry Bays
Art Unit	
Examiner Name	
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4159716	A	1979-07-03	BORCHERS	
	2	4187840	A	1980-02-12	Watanabe	
	3	4338927	A	1982-07-13	Volkov et al.	
	4	4570624	A	1986-02-18	Wu	
	5	4627425	A	1986-12-09	Reese	
	6	4628919	A	1986-12-16	Clyburn	
	7	4757810	A	1988-07-19	Reese	
	8	4952214	A	1990-08-28	Comparetto	

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	9	4978347	A	1990-12-18	Ilizarov	
	10	4895141	A	1990-01-23	Koeneman et al.	
	11	4988349	A	1991-01-29	PENNIG	
	12	5021056	A	1991-06-04	Hofmann et al.	
	13	5112334	A	1992-05-12	Alchermes et al.	
	14	5207676	A	1993-05-04	Canadell et al.	
	15	5254119	A	1993-10-19	SCHREIBER	
	16	5312412	A	1994-05-17	WHIPPLE	
	17	5358504	A	1994-10-25	Paley et al.	
	18	5364402	A	1994-11-15	Mumme et al.	
	19	5413579	A	1995-05-09	TOM DU TOIT	

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	20	5449360	A	1995-09-12	SCHREIBER	
	21	5620442	A	1997-04-15	BAILEY et al.	
	22	5788695	A	1998-08-04	RICHARDSON	
	23	5803924	A	1998-09-08	Oni et al.	
	24	5810822	A	1998-09-22	MORTIER	
	25	5893553	A	1999-04-13	PINKOUS	
	26	5935128	A	1999-08-10	Carter et al.	
	27	5941877	A	1999-08-24	Viegas et al.	
	28	5951556	A	1999-09-14	FACCIOLI et al.	
	29	6030391	A	2000-02-29	Brainard et al.	
	30	6162223	A	2000-12-19	Orsak et al.	

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	31	6171309	B1	2001-01-09	Huebner	
	32	6719773	B1	2004-04-13	Boucher et al.	
	33	6743233	B1	2004-06-01	Baldwin et al.	
	34	7033361	B2	2006-04-25	Collazo	
	35	7182766	B1	2007-02-27	Mogul	
	36	7241298	B2	2007-07-10	Nemec et al.	
	37	7377924	B2	2008-05-27	Raistrick et al.	
	38	7465303	B2	2008-12-16	Riccione et al.	
	39	7641660	B2	2010-01-05	Lakin et al.	
	40	D 610257	S	2010-02-16	Horton	
	41	7686811	B2	2010-03-30	Byrd et al.	

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	42	D 629900	S	2010-12-28	Fisher	
	43	7972338	B2	2011-07-05	O'Brien	
	44	D 646389	S	2011-10-04	Claypool et al.	
	45	8057478	B2	2011-11-15	Kuczynski et al.	
	46	8080010	B2	2011-12-20	Schulz et al.	
	47	D 651316	S	2011-12-27	May et al.	
	48	D 651315	S	2011-12-27	Bertoni et al.	
	49	8123753	B2	2012-02-28	Poncet	
	50	8137406	B2	2012-03-20	Novak et al.	
	51	8147530	B2	2012-04-03	Strnad et al.	
	52	8167918	B2	2012-05-01	Strnad et al.	

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	53	8172848	B2	2012-05-08	Tomko et al.	
	54	8192441	B2	2012-06-05	Collazo	
	55	8197487	B2	2012-06-12	Poncet et al.	
	56	8231663	B2	2012-07-31	Kay et al.	
	57	8231623	B1	2012-07-31	Jordan	
	58	8246561	B1	2012-08-21	Agee et al.	
	59	D 666721	S	2012-09-04	Wright et al.	
	60	8262664	B2	2012-09-11	Justin et al.	
	61	8282645	B2	2012-10-09	Lawrence et al.	
	62	8282644	B2	2012-10-09	Edwards	
	63	8292966	B2	2012-10-23	Morton	

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	64	8313492	B2	2012-11-20	Wong et al.	
	65	8323289	B2	2012-12-04	Re	
	66	8337503	B2	2012-12-25	Lian	
	67	8343159	B2	2013-01-01	Bennett	
	68	8377105	B2	2013-02-19	Bscher	
	69	D 679395	S	2013-04-02	Wright et al.	
	70	8435246	B2	2013-05-07	Fisher et al.	
	71	8475462	B2	2013-07-02	Thomas et al.	
	72	8523870	B2	2013-09-03	Green, II et al.	
	73	D 694884	S	2013-12-03	Mooradian et al.	
	74	D 695402	S	2013-12-10	Dacosta et al.	

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	75	8652142	B2	2014-02-18	Geissler	
	76	8672945	B2	2014-03-18	Lavallee et al.	
	77	D 701303	S	2014-03-18	Cook	
	78	8696716	B2	2014-04-15	Kartalian et al.	
	79	8715363	B2	2014-05-06	Ratron et al.	
	80	8728084	B2	2014-05-20	Berelsman et al.	
	81	D 705929	S	2014-05-27	Frey	
	82	8758354	B2	2014-06-24	Habegger et al.	
	83	8764763	B2	2014-07-01	Wong et al.	
	84	8771279	B2	2014-07-08	Philippon et al.	
	85	8784457	B2	2014-07-22	Graham	

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	86	8784427	B2	2014-07-22	Fallin et al.	
	87	8795286	B2	2014-08-05	Sand et al.	
	88	8801727	B2	2014-08-12	Chan et al.	
	89	8808303	B2	2014-08-19	Stemniski et al.	
	90	8828012	B2	2014-09-09	May et al.	
	91	8858602	B2	2014-10-14	Weiner et al.	
	92	8882778	B2	2014-11-11	Ranft	
	93	8998904	B2	2015-04-07	Zeetser et al.	
	94	8998903	B2	2015-04-07	Price et al.	
	95	9023052	B2	2015-05-05	Lietz et al.	
	96	9044250	B2	2015-06-02	Olsen et al.	

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	97	9060822	B2	2015-06-23	Lewis et al.	
	98	9089376	B2	2015-07-28	Medoff et al.	
	99	9101421	B2	2015-08-11	Blacklidge	
	100	9107715	B2	2015-08-18	Blitz et al.	
	101	D 765844	S	2016-09-06	DaCosta	
	102	D 766439	S	2016-09-13	DaCosta	
	103	D 766438	S	2016-09-13	DaCosta	
	104	D 766437	S	2016-09-13	DaCosta	
	105	D 766434	S	2016-09-13	DaCosta	
	106	9750538	B2	2017-09-05	Soffiatti et al.	
	107	H001706	H	1998-01-06	Mason	

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	108	5529075	A	1996-06-25	CLARK	
	109	4995875	A	1991-02-26	COES	
	110	5601565	A	1997-02-11	HUEBNER	
	111	6511481	B2	2003-01-28	VON HOFFMANN et al.	
	112	5417694	A	1995-05-23	MARIK et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020198531	A1	2002-12-26	Millard et al.	
	2	20040039394	A1	2004-02-26	Conti et al.	
	3	20040097946	A1	2004-05-20	Dietzel et al.	
	4	20050004676	A1	2005-01-06	Schon et al.	

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	5	20050075641	A1	2005-04-07	Singhatat et al.	
	6	20050101961	A1	2005-05-12	Huebner et al.	
	7	20050149042	A1	2005-07-07	Metzger	
	8	20050228389	A1	2005-10-13	Stiernborg	
	9	20050273112	A1	2005-12-08	McNamara	
	10	20060206044	A1	2006-09-14	Simon	
	11	20060217733	A1	2006-09-28	Plassky et al.	
	12	20060229621	A1	2006-10-12	Cadmus	
	13	20060241608	A1	2006-10-26	Myerson et al.	
	14	20060241607	A1	2006-10-26	Myerson et al.	
	15	20060264961	A1	2006-11-23	Murray-Brown	

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	16	20070123857	A1	2007-05-31	Deffenbaugh et al.	
	17	20070233138	A1	2007-10-04	Figueroa et al.	
	18	20070265634	A1	2007-11-15	WEINSTEIN	
	19	20070276383	A1	2007-11-29	Rayhack	
	20	20080091197	A1	2008-04-17	Coughlin	
	21	20080140081	A1	2008-06-12	Heavener et al.	
	22	20080208252	A1	2008-08-28	Holmes	
	23	20080262500	A1	2008-10-23	Collazo	
	24	20080269908	A1	2008-10-30	Warburton	
	25	20090036893	A1	2009-02-05	Kartalian et al.	
	26	20090093849	A1	2009-04-09	Grabowski	

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	27	20090105767	A1	2009-04-23	Reiley	
	28	20090118733	A1	2009-05-07	Orsak et al.	
	29	20090198279	A1	2009-08-06	Zhang et al.	
	30	20090198244	A1	2009-08-06	Leibel	
	31	20090222047	A1	2009-09-03	Graham	
	32	20090254126	A1	2009-10-08	Orbay et al.	
	33	20090254092	A1	2009-10-08	ALBIOL LLORACH	
	34	20090287309	A1	2009-11-19	Walch et al.	
	35	20100069910	A1	2010-03-18	Hasselman	
	36	20100121334	A1	2010-05-13	Couture et al.	
	37	20100130981	A1	2010-05-27	Richards	

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	38	20100152782	A1	2010-06-17	Stone et al.	
	39	20100168799	A1	2010-07-01	Schumer	
	40	20100185245	A1	2010-07-22	Paul et al.	
	41	20100249779	A1	2010-09-30	Hotchkiss et al.	
	42	20100256687	A1	2010-10-07	Neufeld et al.	
	43	20100324556	A1	2010-12-23	Tyber et al.	
	44	20110093084	A1	2011-04-21	Morton	
	45	20110245835	A1	2011-10-06	Dodds et al.	
	46	20110288550	A1	2011-11-24	Orbay et al.	
	47	20110301648	A1	2011-12-08	Lofthouse et al.	
	48	20120016426	A1	2012-01-19	Robinson	

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	49	20120065689	A1	2012-03-15	Prasad et al.	
	50	20120078258	A1	2012-03-29	Lo et al.	
	51	20120123484	A1	2012-05-17	Lietz et al.	
	52	20120123420	A1	2012-05-17	Honiball	
	53	20120130383	A1	2012-05-24	Budoff	
	54	20120130376	A1	2012-05-24	Loring et al.	
	55	20120184961	A1	2012-07-19	Johannaber	
	56	20150045801	A1	2015-02-12	AXELSON JR et al.	
	57	20120239045	A1	2012-09-20	Li	
	58	20120253350	A1	2012-10-04	ANTHONY et al.	
	59	20120265301	A1	2012-10-18	Demers et al.	

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	60	20130012949	A1	2013-01-10	Fallin et al.	
	61	20130035694	A1	2013-02-07	Grimm et al.	
	62	20130085499	A1	2013-04-04	Lian	
	63	20130150903	A1	2013-06-13	Vincent	
	64	20130158556	A1	2013-06-20	Jones et al.	
	65	20130165938	A1	2013-06-27	Chow et al.	
	66	20130165936	A1	2013-06-27	MYERS	
	67	20130172942	A1	2013-07-04	LEWIS et al.	
	68	20130184714	A1	2013-07-18	Kaneyama et al.	
	69	20130190766	A1	2013-07-25	Harris et al.	
	70	20130190765	A1	2013-07-25	Harris et al.	

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	71	20130204259	A1	2013-08-08	Zajac	
	72	20130231668	A1	2013-09-05	Olsen et al.	
	73	20130237989	A1	2013-09-12	Bonutti	
	74	20130237987	A1	2013-09-12	Graham	
	75	20130267956	A1	2013-10-10	Terrill et al.	
	76	20130310836	A1	2013-11-21	Raub et al.	
	77	20130325076	A1	2013-12-05	Palmer et al.	
	78	20130331845	A1	2013-12-12	HORAN et al.	
	79	20130338785	A1	2013-12-19	Wong	
	80	20140005672	A1	2014-01-02	Edwards et al.	
	81	20140025127	A1	2014-01-23	Richter	

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	82	20140039561	A1	2014-02-06	Weiner et al.	
	83	20140039501	A1	2014-02-06	Schickendantz et al.	
	84	20140046387	A1	2014-02-13	Waizenegger	
	85	20140074101	A1	2014-03-13	Collazo	
	86	20140074099	A1	2014-03-13	Vigneron et al.	
	87	20140094924	A1	2014-04-03	Hacking et al.	
	88	20140094861	A1	2014-04-03	Fallin	
	89	20140163563	A1	2014-06-12	Reynolds et al.	
	90	20140171953	A1	2014-06-19	GONZALVEZ et al.	
	91	20140180342	A1	2014-06-26	Lowery et al.	
	92	20140194884	A1	2014-07-10	Martin et al.	

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	93	20140207144	A1	2014-07-24	LEE et al.	
	94	20140249537	A1	2014-09-04	WONG et al.	
	95	20140257509	A1	2014-09-11	Dacosta et al.	
	96	20140277214	A1	2014-09-18	Helenbolt et al.	
	97	20140277176	A1	2014-09-18	Buchanan et al.	
	98	20140276853	A1	2014-09-18	Long et al.	
	99	20140276815	A1	2014-09-18	Riccione	
	100	20140296995	A1	2014-10-02	Reiley et al.	
	101	20140303621	A1	2014-10-09	Gerold et al.	
	102	20140336658	A1	2014-11-13	Luna et al.	
	103	20150032168	A1	2015-01-29	Orsak et al.	

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	104	20150045839	A1	2015-02-12	DACOSTA et al.	
	105	20150051650	A1	2015-02-19	VERSTREKEN et al.	
	106	20150066094	A1	2015-03-05	Prandi et al.	
	107	20150112446	A1	2015-04-23	Melamed et al.	
	108	20150119944	A1	2015-04-30	Geldwert	
	109	20150142064	A1	2015-05-21	Perez et al.	
	110	20150150608	A1	2015-06-04	Sammarco	
	111	20150182273	A1	2015-07-02	Stemniski et al.	
	112	20150223851	A1	2015-08-13	Hill et al.	
	113	20150245858	A1	2015-09-03	Weiner et al.	
	114	20170079669	A1	2017-03-23	Bays et al.	

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	115	20160022315	A1	2016-01-28	SOFFIATTI et al.	
	116	20160151165	A1	2016-06-02	Fallin et al.	
	117	20160175089	A1	2016-06-23	Fallin et al.	
	118	20160192950	A1	2016-07-07	Dayton et al.	
	119	20160199076	A1	2016-07-14	Fallin et al.	
	120	20160213384	A1	2016-07-28	Fallin et al.	
	121	20160235414	A1	2016-08-18	Hatch et al.	
	122	20160242791	A1	2016-08-25	Fallin et al.	
	123	20160256204	A1	2016-09-08	PATEL et al.	
	124	20160354127	A1	2016-12-08	Lundquist et al.	
	125	20160015426	A1	2016-01-21	Dayton et al.	

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	126	20020107519	A1	2002-08-08	DIXON et al.	
	127	20040010259	A1	2004-01-15	KELLER et al.	
	128	20130325019	A1	2013-12-05	THOMAS et al.	
	129	20120277745	A1	2012-11-01	LIZEE et al.	
	130	20050059978	A1	2005-03-17	SHERRY et al.	
	131	20080009863	A1	2008-01-10	BOND et al.	
	132	20140257308	A1	2014-09-11	JOHANNABER	
	133	20020099381	A1	2002-07-25	MARONEY	
	134	20080172054	A1	2008-07-17	CLAYPOOL et al.	
	135	20120330135	A1	2012-12-27	MILLAHN et al.	
	136	20130096563	A1	2013-04-18	MEADE et al.	

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	137	20180344334	A1	2018-12-06	KIM et al.	

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	1	2009227957	AU	B2	2014-07-10	Boutin, et al.		
	2	2491824	CA	A1	2005-09-08	Grimm, et al.		
	3	2854997	CA	A1	2013-05-16	Leslie, et al.		
	4	695846	CH	A5	2006-09-29	Roland, et al.		
	5	2930668	CN	Y	2007-08-08	Lin		
	6	201558162	CN	U	2010-08-25	Xiaojian, et al.		
	7	201572172	CN	U	2010-09-08	Xiaojian, et al.		
	8	201586060	CN	U	2010-09-22	Xiaojian, et al.		

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	Filing Date	
	First Named Inventor	F. Barry Bays
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	Attorney Docket Number	71212.4.8.6

	9	201912210	CN	U	2011-08-03	Xing, et al.		
	10	202801773	CN	U	2013-03-20	Tang, et al.		
	11	103462675	CN	A	2013-12-25	Tang, et al.		
	12	103505276	CN	A	2014-01-15	Wang, et al.		
	13	203458450	CN	U	2014-03-05	Wang, et al.		
	14	203576647	CN	U	2014-05-07	Huang, et al.		
	15	102860860	CN	B	2014-05-21	Xia, et al.		
	16	104490460	CN	A	2015-04-08	Xu		
	17	104510523	CN	A	2015-04-15	Xu		
	18	104523327	CN	A	2015-04-22	Ma, et al.		
	19	104546102	CN	A	2015-04-29	Ma, et al.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	F. Barry Bays
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	20	204379413	CN	U	2015-06-10	Xu		
	21	204410951	CN	U	2015-06-24	Xu		
	22	204428145	CN	U	2015-07-01	Xu		
	23	204428144	CN	U	2015-07-01	Xu		
	24	204428143	CN	U	2015-07-01	Xu		
	25	204446081	CN	U	2015-07-08	Ma, et al.		
	26	200904479	IN	P2	2010-05-21	Auger, et al.		
	27	685206	EP	B1	2000-09-06	Ellis		
	28	1897509	EP	B1	2009-07-08	Arnould		
	29	2124772	EP	A1	2009-12-02	Richards		
	30	2124832	EP	B1	2012-08-08	Collins, et al.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	31	2632349	EP	A1	2013-09-04	Iannotti, et al.		
	32	2665428	EP	A1	2013-11-27	Johannaber		
	33	2742878	EP	A1	2014-06-18	Reynolds, et al.		
	34	2750617	EP	A1	2014-07-09	Gaudin		
	35	2849684	EP	A1	2015-03-25	Neal, et al.		
	36	2362616	FR	A1	1978-03-24	Duyck		
	37	2764183	FR	B1	1999-11-05	Afriat, et al.		
	38	3030221	FR	A1	2016-06-24	Boniface et al.		
	39	2154144	GB	A	1985-09-04	De Bastiani, et al.		
	40	2154143	GB	A	1985-09-04	De Bastiani, et al.		
	41	4134243	JP	B2	2008-08-20	Nishiyama, et al.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	42	4162380	JP	B2	2008-10-08	Michael, et al.		
	43	2011092405	JP	A	2011-05-12	Sato		
	44	2011523889	JP	A	2011-08-25	Saravuia, et al.		
	45	4796943	JP	B2	2011-10-19	Yoshimura, et al.		
	46	5466647	JP	B2	2014-04-09	Fox		
	47	2014511207	JP	A	2014-05-15	Webber		
	48	2014521384	JP	A	2014-08-28	Iannotti, et al.		
	49	5628875	JP	B2	2014-11-19	Matsugaritei, et al.		
	50	100904142	KR	B1	2009-06-15	Warburton, et al.		

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	1	2098036	RU	C1	1997-12-10	Skvortsov, et al.		
	2	2195892	RU	C2	2003-01-10	Kotel, et al.		
	3	2320287	RU	C1	2008-03-27	Ezhov		

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	Filing Date	
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	4	2321369	RU	C1	2008-04-10	Valiakhmetov, et al.		
	5	2321366	RU	C2	2008-04-10	Kotel, et al.		
	6	2346663	RU	C2	2009-02-20	Barinov, et al.		
	7	2412662	RU	C1	2011-02-27	Zyrjanov, et al.		
	8	1333328	SU	A2	1987-08-30	Nadgertsev, et al.		
	9	2008051064	WO	A1	2008-05-02	Jose		
	10	0166022	WO	A1	2001-09-13	Pinczewski et al.		
	11	2009032101	WO	A2	2009-03-12	Simon		
	12	2011037885	WO	A1	2011-03-31	Sand, et al.		
	13	2012029008	WO	A1	2012-03-08	Herzog et al.		
	14	2004/KOLNP/2013	IN	P2	2013-11-01	Stemniski, et al.		

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	Attorney Docket Number	71212.4.8.6

	15	200903719	IN	P1	2009-06-08	Hasselman		
	16	2013090392	WO	A1	2013-06-20	Sammarco		
	17	2013134387	WO	A1	2013-09-12	Elghazaly		
	18	2013169475	WO	A1	2013-11-14	Neal, et al.		
	19	2014022055	WO	A1	2014-02-06	O'Connell, et al.		
	20	2014020561	WO	A1	2014-02-06	Honiball		
	21	2014035991	WO	A1	2014-03-06	Lang		
	22	2014085882	WO	A1	2014-06-12	Angeli		
	23	2014152535	WO	A1	2014-09-25	Mcginley, et al.		
	24	2014152219	WO	A2	2014-09-25	Dacosta, et al.		
	25	2014147099	WO	A1	2014-09-25	Claes, et al.		

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	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	26	2014177783	WO	A1	2014-11-06	Leemrijse, et al.		
	27	2014200017	WO	A1	2014-12-18	Tanji		
	28	2015105880	WO	A1	2015-07-16	Montoya, et al.		
	29	2015127515	WO	A2	2015-09-03	Verstreken, et al.		
	30	140/DELNP/2012	IN	P1	2013-02-01	Johnson, et al.		
	31	2009029798	WO	A1	2009-03-05	ACUMED LLC		

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	1	ALBANO et al., "Biomechanical Study of Transcortical or Transtrabecular Bone Fixation of Patellar Tendon Graft wih Bioabsorbable Pins in ACL Reconstruction in Sheep," Revista Brasileira de Ortopedia (Rev Bras Ortop.) Vol. 47, No. 1, 2012, pp. 43-49.	
	2	ANDERSON et al., "Uncemented STAR Total Ankle Prostheses," The Journal of Bone and Joint Surgery, Vol. 86(1, Suppl 2), September 2004, pp. 103-111, (Abstract Only).	
	3	DAYTON et al., "Is Our Current Paradigm for Evaluation and Management of the Bunion Deformity Flawed? A Discussion of Procedure Philosophy Relative to Anatomy," The Journal of Foot and Ankle Surgery, Vol. 54, 2015, pp. 102-111.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	4	DAYTON et al., "Observed Changes in Radiographic Measurements of the First Ray after Frontal and Transverse Plane Rotation of the Hallux: Does the Hallux Drive the Metatarsal in a Bunion Deformity?," The Journal of Foot and Ankle Surgery, Vol. 53, 2014, pp. 584-587.	
	5	DAYTON et al., "Relationship Of Frontal Plane Rotation Of First Metatarsal To Proximal Articular Set Angle And Hallux Alignment In Patients Undergoing Tarsometatarsal Arthrodesis For Hallux Abducto Valgus: A Case Series And Critical Review Of The Literature," The Journal of Foot and Ankle Surgery, Vol. 52, No. 3, May/June 2013, pp. 348-354.	
	6	DAYTON et al., "Quantitative Analysis of the Degree of Frontal Rotation Required to Anatomically Align the First Metatarsal Phalangeal Joint During Modified Tarsal-Metatarsal Arthrodesis Without Capsular Balancing," The Journal of Foot and Ankle Surgery, 2015, pp. 1-6.	
	7	DE GEER et al., "A New Measure of Tibial Sesamoid Position in Hallux Valgus in Relation to the Coronal Rotation of the First Metatarsal in CT Scans," Foot and Ankle International, March 26, 2015, 9 pages.	
	8	DiDOMENICO et al., "Correction of Frontal Plane Rotation of Sesamoid Apparatus during the Lapidus Procedure: A Novel Approach," The Journal of Foot and Ankle Surgery, Vol. 53, 2014, pp. 248-251.	
	9	DOBBE et al. "Patient-Tailored Plate For Bone Fixation And Accurate 3D Positioning In Corrective Osteotomy," Medical and Biological Engineering and Computing, Vol. 51, No. 1-2, February 2013, pp. 19-27, (Abstract Only).	
	10	EBI Extra Small Rail Fixator, Biomet Trauma, retrieved December 19, 2014, from the Internet: <http://footandanklefixation.com/product/biomet-trauma-ebi-extra-small-rail-fixator>, 7 pages.	
	11	GARTHWAIT, "Accu-Cut System Facilitates Enhanced Precision," Podiatry Today, Vol. 18, No. 6, June 2005, 6 pages.	
	12	GONZALEZ DEL PINO et al., "Variable Angle Locking Intercarpal Fusion System for Four-Corner Arthrodesis: Indications and Surgical Technique," Journal of Wrist Surgery, Vol. 1, No. 1, August 2012, pp. 73-78.	
	13	GRONDAL et al., "A Guide Plate for Accurate Positioning of First Metatarsophalangeal Joint during Fusion," Operative Orthopädie Und Traumatologie, Vol. 16, No. 2, 2004, pp. 167-178 (Abstract Only).	
	14	'HAT-TRICK Lesser Toe Repair System," Smith & Nephew, Brochure, August 2014, 12 pages.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	15	"Hoffmann II Compact External Fixation System," Stryker, Brochure, Literature Number 5075-1-500, 2006, 12 pages.	
	16	"Hoffmann II Micro Lengthener," Stryker, Operative Technique, Literature Number 5075-2-002, 2008, 12 pages.	
	17	"Hoffmann Small System External Fixator Orthopedic Instruments," Stryker, retrieved December 19, 2014, from the Internet: <http://www.alibaba.com/product-detail/Stryker-Hoffmann-Small-System-External-Fixator_1438850129.html>, 3 pages.	
	18	KIM et al., "A New Measure of Tibial Sesamoid Position in Hallux Valgus in Relation to the Coronal Rotation of the First Metatarsal in CT Scans," Foot and Ankle International, Vol. 36, No. 8, 2015, pp. 944-952.	
	19	"Lag Screw Target Bow," Stryker Leibinger GmbH & Co. KG, Germany 2004, 8 pages.	
	20	MAC (Multi Axial Correction) Fixation System, Biomet Trauma, retrieved December 19, 2014, from the Internet: <http://footandanklefixation.com/product/biomet-trauma-mac-multi-axial-correction-fixation-system>, 7 pages.	
	21	Michelangelo Bunion System, Surgical Technique, Instratek Incorporated, publication date unknown, 4 pages.	
	22	Mini Joint Distractor, Arthrex, retrieved December 19, 2014, from the Internet: <http://www.arthrex.com/foot-ankle/mini-joint-distractor/products>, 2 pages.	
	23	MiniRail System, Small Bone Innovations, Surgical Technique, 2010, 24 pages.	
	24	Modular Rail System: External Fixator, Smith & Nephew, Surgical Technique, 2013, 44 pages.	
	25	MONNICH et al., "A Hand Guided Robotic Planning System for Laser Osteotomy in Surgery," World Congress on Medical Physics and Biomedical Engineering Vol. 25/6: Surgery, Nimimal Invasive Interventions, Endoscopy and Image Guided Therapy, September 7-12, 2009, pages 59-62, (Abstract Only).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	26	MOORE et al., "Effect Of Ankle Flexion Angle On Axial Alignment Of Total Ankle Replacement," Foot and Ankle International, Vol. 31, No. 12, December 2010, pp. 1093-1098, (Abstract Only).	
	27	MORTIER et al., "Axial Rotation of the First Metatarsal Head in a Normal Population and Hallux Valgus Patients," Orthopaedics and Traumatology: Surgery and Research, Vol. 98, 2012, pp. 677-683.	
	28	OKUDA et al., "Postoperative Incomplete Reduction of the Sesamoids as a Risk Factor for Recurrence of Hallux Valgus," The Journal of Bone and Joint Surgery, Vol. 91-A, No. 1, July 2009, pp. 1637-1645.	
	29	Rx-Fix Mini Rail External Fixator, Wright Medical Technology, Brochure, August 15, 2014, 2 pages.	
	30	SCANLAN et al. "Technique Tip: Subtalar Joint Fusion Using a Parallel Guide and Double Screw Fixation," The Journal of Foot and Ankle Surgery, Vol. 49, Issue 3, May-June 2010, pp. 305-309, (Abstract Only).	
	31	SCRANTON JR. et al, "Anatomic Variations in the First Ray: Part I. Anatomic Aspects Related to Bunion Surgery," Clinical Orthopaedics and Related Research, Vol. 151, September 1980, pp. 244-255.	
	32	SIDDIQUI et al. "Fixation Of Metatarsal Fracture With Bone Plate In A Dromedary Heifer," Open Veterinary Journal, Vol. 3, No. 1, 2013, pp. 17-20.	
	33	SIDEKICK STEALTH Rearfoot Fixator, Wright Medical Technology, Surgical Technique, December 2, 2013, 20 pages.	
	34	SIMPSON et al., "Computer-Assisted Distraction Ostegogenesis By Ilizarov's Method," International Journal of Medical Robots and Computer Assisted Surgery, Vol. 4, No. 4, December 2008, pp. 310-320, (Abstract Only).	
	35	Small Bone External Fixation System, Acumed, Surgical Technique, Effective date September 2014, 8 pages.	
	36	Stableloc External Fixation System, Acumed, Product Overview, Effective date September 2015, 4 pages.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

	37	STAHL et al., "Derotation Of Post-Traumatic Femoral Deformities By Closed Intramedullary Sawing," Injury, Vol. 37, No. 2, February 2006, pp.145-151, (Abstract Only).
	38	TALBOT et al.," Assessing Sesamoid Subluxation: How Good is the AP Radiograph?," Foot and Ankle International, Vol. 19, No. 8, August 1998, pp. 547-554.
	39	TempFix Spanning the Ankle Joint Half Pin and Transfixing Pin Techniques, Biomet Orthopedics, Surgical Technique, 2012, 16 pages.
	40	WEBER et al., "A Simple System For Navigation Of Bone Alignment Osteotomies Of The Tibia," International Congress Series, Vol. 1268, January 2004, pp. 608-613, (Abstract Only).
	41	WHIPPLE et al., "Zimmer Herbert Whipple Bone Screw System: Surgical Techniques for Fixation of Scaphoid and Other Small Bone Fractures," Zimmer, 2003, 59 pages.
	42	YAKACKI et al. "Compression Forces of Internal and External Ankle Fixation Devices with Simulated Bone Resorption," Foot and Ankle International, Vol. 31, No. 1, January 2010, pp. 76-85, (Abstract Only).
	43	YASUDA et al., "Proximal Supination Osteotomy of the First Metatarsal for Hallux Valgus," Foot and Ankle International, Vol. 36, No. 6, June 2015, pp. 696-704.
	44	International Patent Application No. PCT/US2016/046953, International Search Report and Written Opinion mailed December 27, 2016, 13 pages.
	45	European Patent Application No. 16837624.2, Extended European Search Report dated April 17, 2019, 8 pages.

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	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	F. Barry Bays
	Art Unit	
	Examiner Name	
	Attorney Docket Number	71212.4.8.6

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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2019-06-19
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Application Number	Not Yet Assigned
Filing Date	Filed Herewith
First Named Inventor	F. Barry Bays
Title	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	71212.4.8.6

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul J. LaVanway, Jr./	Date (Optional)	2019-06-19
Name	Paul J. LaVanway, Jr.	Registration Number	64610
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Treace Medical Concepts, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

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SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/John T. Treace/	Date (Optional)	10/19/16
Name	John T. Treace		
Title	Chief Executive Officer		

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

RELATED APPLICATIONS

[0001] This application is a divisional of US Patent Application No. 15/236,464, filed August 14, 2016, which in turn claims the benefit of US Provisional Application No. 62/293,189, filed February 9, 2016, and is a continuation-in-part of US Patent Application No. 14/981,335, filed December 28, 2015, now US Patent No. 9,622,805, issued April 18, 2017, which claims the benefit of US Provisional Application No. 62/205,338, filed August 14, 2015. The entire contents of all these applications are incorporated herein by reference.

TECHNICAL FIELD

[0002] This disclosure relates generally to devices and methods for positioning and/or preparing bones.

BACKGROUND

[0003] Bones, such as the bones of a foot, may be anatomically misaligned. In certain circumstances, surgical intervention is required to correctly align the bones to reduce patient discomfort and improve patient quality of life.

SUMMARY

[0004] Embodiments of the present invention include methods for fixing an orientation of a bone or bones. In general, the method of positioning a bone includes the steps of moving a bone from an anatomically misaligned position to an anatomically aligned position with respect to another bone and preparing an end of the bone and a facing end of another bone. In some embodiments, at least one bone end is prepared after the bone is moved into the aligned position. In some embodiments, the bone is anatomically aligned in more than one plane such that the bone both translates and rotates in response to a moving force.

[0005] One embodiment includes a method of correcting a bunion deformity. The method includes inserting a fulcrum between a first metatarsal and a second metatarsal, where the first metatarsal is anatomically misaligned with respect to the second metatarsal. The method further includes preparing an end of the first metatarsal and preparing an end of a medial cuneiform

opposing the end of the first metatarsal. In addition, the method involves moving a distal portion of the first metatarsal toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing the intermetatarsal angle between the first metatarsal and the second metatarsal.

[0006] In one example, a fulcrum is described for use in a bone realignment procedure. The fulcrum includes a body and a handle. The body is configured to be inserted in an intermetatarsal space between adjacent metatarsals. The handle is operatively connected to the body. The example specifies that the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

[0007] In another example, a multidimensional fulcrum is described that includes a fulcrum body having a length extending from a first end to a second end, a width, and a thickness. The first end of the fulcrum has a first thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a first size. The second end of the fulcrum has a second thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a second size. The example specifies that the second thickness is greater than the first thickness.

[0008] The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The following drawings are illustrative of particular embodiments of the present invention and, therefore, in no way limit the scope of the invention. The drawings are not necessarily to scale (unless otherwise stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the invention will hereinafter be described with respect to the appended drawings, wherein like numerals denote like elements.

[0010] FIG. 1 is a side perspective view of a bone positioning guide in accordance with an embodiment of the invention.

[0011] FIG. 2 is a side perspective view of a bone engagement member of a bone positioning guide in accordance with an embodiment of the invention.

[0012] FIG. 3A is a side perspective view of a tip of a bone positioning guide in accordance with an embodiment of the invention.

[0013] FIG. 3B is a side view of a bone positioning guide with a straight tip in accordance with an embodiment of the invention.

[0014] FIG. 3C is a side view of a bone positioning guide with a nonlinear tip in accordance with an embodiment of the invention.

[0015] FIG. 4 is an end view of an actuator of a bone positioning guide in accordance with an embodiment of the invention.

[0016] FIG. 5 is a top plan view of a bone preparing guide in accordance with an embodiment of the invention.

[0017] FIG. 6A is a perspective view of a bone preparing guide, a spacer, and a tissue removing instrument location check member in accordance with an embodiment of the invention.

[0018] FIG. 6B is a perspective view of another embodiment of a tissue removing instrument check location member engaged with a bone preparing guide.

[0019] FIG. 7 is a perspective view of a bone preparing guide engaged with a spacer in accordance with an embodiment of the invention.

[0020] FIG. 8 is a perspective view of a bone preparing guide engaged with a tissue removal instrument location check member in accordance with an embodiment of the invention.

[0021] FIG. 9A is a front view of a bone positioning guide on a deformed foot in accordance with an embodiment of the invention.

[0022] FIG. 9B is a front view of a bone positioning guide on a foot with a corrected alignment in accordance with an embodiment of the invention.

[0023] FIG. 10A is a top view of a bone positioning guide on a deformed foot in accordance with an embodiment of the invention.

[0024] FIG. 10B is a top view of a bone positioning guide on a foot with a corrected alignment in accordance with an embodiment of the invention.

[0025] FIGS. 11A-C depict a sequence of a bone positioning operation using a bone positioning guide on a foot at first, second, and third positions in accordance with an embodiment of the invention.

[0026] FIG. 12A is a front view of a foot with a normal first metatarsal position.

[0027] FIG. 12B is a front view of a foot with an isolated first metatarsal rotation bunion deformity.

[0028] FIG. 13A is a top view of a foot with a normal first metatarsal position.

[0029] FIG. 13B is a top view of a foot with an isolated first metatarsal transverse plane bunion deformity.

[0030] FIG. 14A is a side view of a foot with a normal first metatarsal position.

[0031] FIG. 14B is a side view of a foot with an isolated first metatarsal sagittal plane bunion deformity.

[0032] FIG. 15A is a perspective view and an enlarged view of a foot.

[0033] FIG. 15B is a perspective view of a first metatarsal.

[0034] FIG. 16 is a side perspective view of a foot depicting a bone preparation instrument inserted into a joint.

[0035] FIG. 17 is a perspective view of a foot depicting a bone positioning guide on the foot prior to an alignment of a first metatarsal.

[0036] FIG. 18 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal.

[0037] FIG. 19 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and an insertion of a spacer into a joint space.

[0038] FIG. 20 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide.

[0039] FIG. 21A is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide with pins.

[0040] FIG. 21B is another perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide with pins.

[0041] FIG. 22 is a perspective view of a foot depicting a bone preparation instrument preparing a bone of the foot guided by a guide surface of a bone preparation guide.

[0042] FIG. 23 is a perspective view of a foot depicting a bone positioning guide on the foot and a removal of a bone preparation guide.

[0043] FIG. 24 is a perspective view of a foot depicting a bone positioning guide on the foot and pins.

[0044] FIG. 25 is a perspective view of a foot depicting a bone positioning guide on the foot and a compression pin.

[0045] FIG. 26A is a side perspective view of a foot depicting bone plates across a joint between first and second bones and a compression pin in accordance with an embodiment of the invention.

[0046] FIG. 26B is a side perspective view of a foot depicting bone plates across a joint between first and second bones and a compression pin in accordance with an embodiment of the invention.

[0047] FIG. 27 is a side perspective view of a foot depicting bone plates across a joint between first and second bones in accordance with an embodiment of the invention.

[0048] FIG. 28A and FIG. 28B depict examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention.

[0049] FIG. 29A and FIG. 29B depict examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention.

[0050] FIG. 30A illustrates a portion of a foot having a bunion caused by a misaligned first metatarsal relative to a second metatarsal.

[0051] FIG. 30B shows an example base compression that can be caused after the foot of FIG. 30A is anatomically aligned.

[0052] FIG. 31 illustrates an example bone positioning operation in which a fulcrum is positioned at an intersection between a first bone and a second bone.

[0053] FIG. 32 is a perspective view of one example fulcrum.

[0054] FIG. 33 illustrates an example system of different sized fulcrums.

[0055] FIG. 34 is a perspective view of another bone positioning guide according to an embodiment of the invention.

[0056] FIG. 35 illustrates an example configuration of a joint spacer that can allow a bone preparation guide to rotate around the spacer.

[0057] FIG. 36A is a perspective view of an example configuration of a bone positioning guide having an opening with circular cross-sectional shape.

[0058] FIG. 36B is a perspective view of the example bone positioning guide of FIG. 36A shown with the joint spacer from FIG. 35 inserted into the guide.

[0059] FIG. 37 is a block flow diagram of an example bone correction technique utilizing a fulcrum.

[0060] FIG. 38 is a perspective view of a foot showing an example position of a fulcrum during a bone correction procedure according to the method of FIG. 37.

[0061] FIGS. 39A and 39B are different perspective views of another example fulcrum that can be used during a bone correction procedure.

[0062] FIG. 40 is an image of the example fulcrum of FIGS. 39A and 39B inserted between a first metatarsal and a second metatarsal.

[0063] FIG. 41 illustrates an alternative arrangement of surface features that may be used on the example fulcrum of FIGS. 39A and 39B.

[0064] FIGS. 42A and 42B are perspective and side views, respectively, of an example fulcrum having two fulcrum bodies.

[0065] FIGS. 43A and 43B are perspective and side views, respectively, of an example multidimensional fulcrum having ends of different dimensions and a unitary body.

DETAILED DESCRIPTION

[0066] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention. Rather, the following description provides practical illustrations for implementing exemplary embodiments of the disclosure. Examples of constructions, materials, and dimensions are provided for selected elements, and all other elements employ that which is known to those of ordinary skill in the field of the invention. Those skilled in the art will recognize that many of the noted examples have a variety of suitable alternatives.

[0067] Embodiments of the invention include a bone positioning guide and method of positioning bones in a medical procedure. In an exemplary application, embodiments of the bone positioning guide can be useful during a surgical procedure, such as a bone alignment, osteotomy, fusion procedure, and/or other procedures where one or more bones are to be prepared (e.g., cartilage or bone removal and/or cut). Such a procedure can be performed, for example, on bones (e.g., adjacent bones separated by a joint or different portions of a single

bone) in the foot or hand, where bones are relatively smaller compared to bones in other parts of the human anatomy. In one example, a procedure utilizing an embodiment of the bone positioning guide can be performed to correct an alignment between a metatarsal (e.g., a first metatarsal) and a second metatarsal and/or a cuneiform (e.g., a medial, or first, cuneiform), such as in a bunion correction surgery. An example of such a procedure is a Lapidus procedure (also known as a first tarsal-metatarsal fusion). In another example, the procedure can be performed by modifying an alignment of a metatarsal (e.g., a first metatarsal). An example of such a procedure is a basilar metatarsal osteotomy procedure.

[0068] FIG. 1 shows a side perspective view of a bone positioning guide 10 in accordance with an embodiment of the invention. The bone positioning guide 10 can be useful for positioning a bone (e.g., orientating and/or translating) during a medical procedure. In some embodiments, the bone positioning guide includes a bone engagement member, a tip, a mechanism to urge the bone engagement member and the tip towards each other (e.g. moving the bone engagement member towards the tip, moving the tip towards the bone engagement member, or moving both simultaneously), and an actuator to actuate the mechanism. When the mechanism is actuated it causes a first bone engaged with the bone engagement member to move to correct an alignment in more than one plane with respect to a second bone in contact with the tip. In some embodiments, the correction in more than one plane includes a correction about an axis in a frontal plane.

[0069] In the embodiment of FIG. 1, bone positioning guide 10 includes a main body member 20 and a shaft 30, and the bone engagement member 40 is connected to the shaft and the tip 50 is connected to the main body member. In general, the main body member 20 can be sized and shaped to clear anatomy or other instrumentation (e.g., pins and guides) while positioned on a patient. In the embodiment of FIG. 1, the main body member 20 includes a generally C-shaped configuration with a first end 60 and a second end 70. In some embodiments, the main body is sized and configured to engage bones of a human foot. In addition, although bone positioning guide 10 is illustrated as being formed of two components, main body member 20 and shaft 30, the guide can be fabricated from more components (e.g., 3, 4, or more) that are joined together to form the guide.

[0070] A shaft 30 can be movably connected to the main body member 20 proximate its first end 60. In some embodiments, the shaft 30 includes threads 80 that engage with the main body

member 20 such that rotation of the shaft translates the shaft with respect to the main body member. In other embodiments, the shaft can slide within the main body member and can be secured thereto at a desired location with a set screw. In yet other embodiments, the shaft can be moved with respect to the main body by a ratchet mechanism. In the embodiment shown, the shaft moves along an axis that intersects the tip 50. In other embodiments, such as that described with respect to FIG. 34, the shaft 30 and/or bone engagement member 40 is offset from tip 50.

[0071] As shown in FIG. 2, embodiments of the bone positioning device can have a bone engagement member 40. In some embodiments, the bone engagement member includes a surface 90 configured to contact a bone, such as a metatarsal or a cuneiform. In the embodiment shown, the surface 90 is concave. Such a surface is adapted to promote surface contact with a generally cylindrical bone, such as a metatarsal. Other embodiments of surface shapes include planar surfaces and V-shaped surfaces. When using a concave or V-shaped bone engagement member 40, the sidewalls of the concavity or V-shaped groove may be symmetrical or asymmetrical. In a symmetrical configuration, the bottom of the concavity or groove can be centered between upwardly extending sidewalls configured to receive a bone. Each sidewall can extend upwardly to the same height and/or at the same slope. In the asymmetrical configuration, one sidewall can have a different configuration than the opposing sidewall. For example, one of the sidewalls may extend upwardly from the bottom of the concavity or groove to a lower height than the opposing sidewall. As another example, one sidewall may extend upwardly at a different angle than the opposing sidewall. The asymmetrical configuration can be useful for applying a force that is biased laterally instead of only being linear toward tip 50.

[0072] In some embodiments, bone engagement member 40 includes a pin or a clamp. Independent of whether bone engagement member 40 includes such pin or clamp, the bone engagement member can engage an anatomical feature of a bone, such as a ridge (e.g., a medial ridge of a first metatarsal). In such embodiments, the engagement generally prohibits rotational movement of the bone with respect to the bone engagement member. In other embodiments, bone may be allowed to rotate with respect to the bone engagement member.

[0073] In the embodiment shown, the bone engagement member 40 is provided on an end of the shaft 30. In the embodiment of the shaft shown having threads 80, the bone engagement member 40 can be rotatably coupled to the shaft 30. In such embodiments, as the shaft is rotated relative to the main body member the bone engagement member 40 may or may not rotate with respect

to the main body member even as it translates with respect to the main body member along with the shaft 30 and rotates with respect to the shaft. The bone engagement member may oscillate about the shaft 30, but generally does not rotate with respect to bone after contact with the bone.

[0074] FIGS. 3A-C depict a tip 50 of bone positioning guide 10, which can be at a second end 70 of the main body member opposite the first end. The tip 50 can be useful for contacting a bone, generally a bone distinct from a bone contacting the bone engagement member. For example, if the bone engagement member is in contact with a first metatarsal, the tip can be in contact with a metatarsal other than the first metatarsal (e.g., the second, third, fourth, or fifth metatarsal). In some embodiments, the tip is tapered to facilitate percutaneous insertion and contact with bone. The tip can also include a textured surface 100, such as serrated, roughened, cross-hatched, knurled, etc., to reduce slippage between the tip and bone. In the embodiment shown, the tip further includes a stop 110 to limit a depth of insertion. The shape of the tip can be configured to stably contact bone. For example, FIG. 3B shows a side view of the bone positioning guide with a generally straight tip 50, while FIG. 3C shows a side view of the bone positioning guide with a nonlinear tip 50 (e.g., a tip that is angled or curved). In some embodiments, the tip is configured to restrict translational movement between it and a bone, but to allow rotational movement between it and the bone.

[0075] As shown in FIG. 4, bone positioning guide 10 can also include an actuator (e.g., a knob or a handle) 120 to actuate the mechanism, in this embodiment associated with the shaft. In the embodiment shown, the actuator can be useful for allowing a user to rotate the shaft with respect to the main body member 20. Also as shown in FIG. 4, the actuator, shaft, and bone engagement member may include a cannulation 130 to allow the placement of a fixation wire (e.g., K-wire) through these components and into contact with or through a bone engaged with the bone engagement member. For example, the fixation wire can be placed into the bone engaged with bone engagement member 40 to fix the position of the bone engagement member with respect to the bone. In another example, the fixation wire can be placed through the bone in contact with the bone engagement member and into an adjacent bone to maintain a bone position of the bone in contact with the bone engagement member and the adjacent bone.

[0076] In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a tenaculum or tong structure. In such embodiments, the guide can include a first shaft pivotably connected to a second shaft. A first end of each shaft can

include an actuator, such as a handle. A second end of the first shaft can include a bone engagement member, as described above. And a second end of the second shaft can include a tip, as described above. In use, the actuator can be actuated (e.g., squeezed together) to move the bone engagement member and the tip closer together to position bone. Other embodiments of this type may include another set of shafts and another pivoting connection such that the bone engagement member and tip translate towards each other when the actuator is actuated.

[0077] In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a rack and pinion structure. In such embodiments, the rack can include a tip, as described above. And the pinion can include a bone engagement member, as described above, and an actuator (e.g., a knob). In use, the actuator can be actuated (e.g., turned about an axis generally perpendicular to a direction of travel) to move the bone engagement member and the tip closer together to position bone.

[0078] Embodiments of the bone positioning guide may include any suitable materials. In certain embodiments, the bone positioning guide is fabricated from a radiolucent material such that it is relatively penetrable by X-rays and other forms of radiation, such as thermoplastics and carbon-fiber materials. Such materials are useful for not obstructing visualization of bones using an imaging device when the bone positioning guide is positioned on bones.

[0079] Embodiments of the bone positioning guide can be useful in operation for positioning a bone or bones during a medical procedure. Bone positioning can be useful, for instance, to correct an anatomical misalignment of bones and maintain an anatomically aligned position, such as in a bone alignment and/or fusion procedure. In some embodiments, the bone positioning guide is capable of reducing an angle between the first metatarsal and the second metatarsal from over 10 degrees (e.g., up to about 35 degrees) to about 10 degrees or less (e.g., to about 1-5 degrees), including to negative angles of about -5 degrees. In some embodiments, the bone positioning guide is also capable of rotating the first metatarsal about its long axis with respect to the medial cuneiform from a rotational angle of over 4 degrees to a rotational angle of less than 4 degrees (e.g., to about 0 to 2 degrees).

[0080] In some embodiments, a bone preparation guide may be provided to facilitate the preparation of a bone. The bone preparation guide can be provided with a bone positioning guide, or either device can be provided or used independently. An example of a bone preparation guide 150 is shown in FIG. 5. In some embodiments, the bone preparation guide 150

includes a body 154 defining a first guide surface 160 to define a first preparing plane and a second guide surface 164 to define a second preparing plane. A tissue removing instrument (e.g., a saw, rotary bur, osteotome, etc., not shown) can be aligned with the surfaces to remove tissue (e.g., remove cartilage or bone and/or make cuts to bone). The first and second guide surfaces 160, 164 can be spaced from each other by a distance, (e.g., between about 2 millimeters and about 10 millimeters, such as between about 4 and about 7 millimeters). In the embodiment shown, the first and second guide surfaces are parallel, such that cuts to adjacent bones using the guide surfaces will be generally parallel.

[0081] In some embodiments, as shown in FIG. 5, a first facing surface 166 is positioned adjacent the first guide surface 160 and/or a second facing surface 168 is positioned adjacent the second guide surface 164. In such embodiments, the distance between the first guide surface and the first facing surface defines a first guide slot, and the distance between the second guide surface and the second facing surface defines a second guide slot. Each slot can be sized to receive a tissue removing instrument to prepare the bone ends. The first and second slots may be parallel or skewed. In the illustrated embodiment, the facing surfaces each contain a gap, such that the surface is not a single, continuous surface. In other embodiments, the facing surfaces can be a single, continuous surface lacking any such gap.

[0082] An opening 170 can be defined by the body 154 between the first and second guide surfaces. The opening can be an area between the guide surfaces useful for allowing a practitioner to have a visual path to bones during bone preparation and/or to receive instruments. In the embodiment shown, the opening extends across the body and a distance from a surface 172 opposite of the first facing surface 166 to a surface 174 opposite of the second facing surface 168.

[0083] The embodiment shown also includes a first end 176 extending from the body 154 in a first direction and a second end 178 extending from the body in a second direction. The second direction can be different than the first direction (e.g., an opposite direction). As shown, each of the first end and the second end can include at least one fixation aperture 180 configured to receive a fixation pin (not shown in FIG. 5) to secure the guide to a bone. As shown, such apertures may extend through the end at a vertical or skewed angle relative to a top surface of the guide.

[0084] The bone preparation guide 150 can also include a first adjustable stabilization member 182 engaged with the first end 176. In some embodiments, the bone preparation guide can include a second adjustable stabilization member 184 engaged with the second end 178. Each of the members can be threaded and engage a threaded aperture defined by the ends. The elevation of each end can be adjusted with respect to a bone by adjusting the stabilization member. In some embodiments, as shown, the stabilization members are cannulated such that they can receive a fixation pin.

[0085] As shown in FIGS. 6A and 7, the bone preparation guide can also include a spacer 188 extending downward from the body 154 and configured to be placed into a joint. In some embodiments, the spacer 188 is selectively engageable with the body. The spacer can have a first portion 190 configured to extend into a joint space and a second portion 192 engageable with the body 154. In the embodiment shown, the spacer can be received within opening 170, such that the spacer extends from the body in between the first and second guide surfaces. Such a spacer can be useful for positioning the body at a desired position with respect to a joint and for properly positioning the guide with respect to bones to be cut in more than one plane (e.g., three planes selected from more than one of a frontal plane, a transverse plane, and a sagittal plane). The distance between the spacer and the first guide surface can define a length of tissue removal (e.g., bone or cartilage to be cut) from a first bone, and the distance between the spacer and the second guide surface can define a length of tissue removal (e.g., bone or cartilage to be cut) from a second bone.

[0086] As shown in FIGS. 6A/B and 8, the bone preparation guide can also include a tissue removal location check member 194 engageable with the body 154 and configured to extend to a first bone and a second bone. The tissue removal location check member can have a first portion 196 configured to extend into contact with first and second bones and a second portion 198 engageable with the body. In the embodiments shown in FIGS. 6A and 8, the tissue removal location check member extends from the body at both the first and second guiding surfaces. In other embodiments, such as the embodiment shown in FIG. 6B, separate tissue removal location check members are provided for independent insertion into respective slots of the guide. Accordingly, embodiments of tissue removal location check members are useful for allowing a practitioner to see where a tissue removing instrument guided by the surfaces will contact the bone to be prepared.

[0087] Embodiments of the bone preparation guide can be useful in operation for guiding a preparation of a bone or bones at a targeted anatomy. Bone preparation can be useful, for instance, to facilitate contact between leading edges of adjacent bones, separated by a joint, or different portions of a single bone, separated by a fracture, such as in a bone alignment and/or fusion procedure. A bone may be prepared using one or more bone preparation techniques. In some applications, a bone is prepared by cutting the bone. The bone may be cut transversely to establish a new bone end facing an opposing bone portion. Additionally or alternatively, the bone may be prepared by morselizing an end of the bone. The bone end can be morselized using any suitable tool, such as a rotary bur, osteotome, or drill. The bone end may be morselized by masticating, fenestrating, crushing, pulping, and/or breaking the bone end into smaller bits to facilitate deformable contact with an opposing bone portion.

[0088] Embodiments of the present invention also include methods for temporarily fixing an orientation of a bone or bones, for example, prior to or in conjunction with permanently fixing the orientation of the bone or bones. In general, the method of positioning a bone includes the steps of moving a bone from an anatomically misaligned position to an anatomically aligned position with respect to another bone and preparing an end of the moved bone and a facing end of another bone. In some embodiments, the end of at least one of the moved bone and the other bone is prepared after moving the bone into the aligned position. In certain embodiments, the bone is anatomically aligned in more than one plane with respect to another bone by applying a force to one bone at a single location, such that the bone both translates and rotates in response to the force. In certain embodiments, the moving step can be accomplished with a bone positioning device and/or the preparing step can be accomplished with a bone preparation guide, as described herein. In other embodiments, the moving step can be accomplished by a clinician physically grasping a bone, either through direct contact with the bone or indirectly (e.g., by inserting a K-wire, grasping with a tenaculum, or the like), and moving his hand to move the bone. In these applications, a fulcrum may be used to control movement of the bone, as also described herein.

[0089] FIGS. 9A-B depict fontal views of a bone positioning guide 10 on a foot 200 having a first metatarsal 210, a medial cuneiform 220, a second metatarsal 292, and a third metatarsal 294. FIG. 9A depicts a foot 200 with an uncorrected bunion deformity, while FIG. 9B depicts the foot 200 with an alignment corrected by the bone positioning guide 10. Solid line L1 represents the

starting location of the bone positioning guide 10 and dotted line L2 represents the finishing location of the bone positioning guide. As shown, as the bone positioning guide 10 is actuated it rotates with the first metatarsal 210 about an axis extending through the frontal plane as it pushes the first metatarsal 210 laterally in the transverse plane and plantarly in the sagittal plane. Accordingly, in this example, the position of the first metatarsal 210 is corrected with respect to the second metatarsal 292 generally in three planes by actuating a single bone positioning guide 10 to urge a bone engagement member 40 toward a tip 50. FIG. 10A shows a top view of a foot 200 with an uncorrected bunion deformity, while FIG. 10B shows a top view of the foot 200 with an alignment corrected by the bone positioning guide 10, emphasizing the rotational correction in the frontal plane and the lateral correction in the transverse plane.

[0090] FIGS. 11A-C show three sequential images of a bone positioning guide 10 on a foot 200 positioning a first metatarsal 210 with respect to a second metatarsal 292. FIG. 11A represents the beginning of the procedure, FIG.11B the middle, and FIG. 11C the end. The orientation of the pins 270 is useful for visualizing the amount of rotation of the first metatarsal 210 in each image. With respect to FIGS. 11A-C, it can be seen the bone positioning guide 10 and the first metatarsal 210 are rotating in the frontal plane in response to actuation of bone positioning guide 10. Further, the angle between the first metatarsal 210 and second metatarsal 292 is reduced, as the space that can be seen between the first and second metatarsals in FIG. 11A is eliminated in FIG. 11C.

[0091] Each of the three potential planes of deformity will now be described in isolation. FIGS. 12A and 12B show frontal plane views of a foot 200. In FIG. 12A, the foot 200 is normal, while in FIG. 12B the foot is depicted with an uncorrected bunion deformity showing an isolated axial rotation of the first metatarsal 210. Solid line L3 indicates the alignment of the first metatarsal 210 relative to ground, while dotted line L4 in FIG. 12B indicates the extent of axial rotation in the frontal plane.

[0092] FIGS. 13A and 13B show transverse plane views of a foot 200. In FIG. 13A, the foot 200 is normal, while in FIG. 13B the foot is depicted with an uncorrected bunion deformity showing an isolated transverse plane first metatarsal 210 deviation. Solid line L5 indicates the alignment of the second metatarsal 292 and solid line L6 indicates the proper alignment of the first metatarsal 210 relative to the second metatarsal 292. The angle between these two lines

forms the intermetatarsal angle (IMA). Dotted line L7 in FIG. 13B indicates the extent of transverse deviation.

[0093] FIGS. 14A and 14B show sagittal plane views of a foot 200. In FIG. 14A, the foot 200 is normal, while in FIG. 14B the foot is depicted with an uncorrected bunion deformity showing an isolated sagittal deviation of the first metatarsal 210. Solid line L8 indicates the proper alignment of the first metatarsal 210, while dotted line L9 in FIG. 14B indicates the extent of sagittal deviation.

[0094] A specific embodiment of a method in accordance with an embodiment of the invention includes the steps of engaging a bone engagement member with a first bone, placing a tip of the bone positioning guide in apposition to a second bone, the second bone being different from the first bone, and moving the bone engagement member with respect to the tip to change the position of the first bone with respect to the second bone in more than one plane. In some embodiments, after alignment, at least one of an end of the first bone and a facing end of a third bone are prepared (e.g., only the end of the first bone or both the end of the first bone and the end of the second bone), optionally using a preparation guide.

[0095] In some embodiments, the method includes the step of mobilizing a joint for a corrective procedure. For example, after creating surgical access to the joint and before moving the bones into an aligned position, tissue can be released to allow a bone, such as a metatarsal, to rotate freely. In some embodiments, obstructing bone may be excised (e.g., a dorsolateral flare of the metatarsal base, a plantar flare of the metatarsal base (sometimes referred to as a plantar condyle), part of an end of a metatarsal facing a cuneiform, or osteophyte) to further promote free rotation by creating relatively flat surfaces with respect to a frontal plane. An example of a dorsolateral flare F on a first metatarsal 210 of a foot 200 is shown in FIG. 15A. An example of a plantar flare PF on a first metatarsal 210 is shown in FIG 15B. FIG. 15B also depicts a medial ridge MR, which, in some embodiments, can be engaged by the bone engaging member of a bone positioning guide.

[0096] Embodiments of methods in accordance with the invention can also include steps performed after preparing the ends of the bones. For example, the ends of the bones may be placed in apposition and optionally compressed together and the position of the bones can be fixed with one or more bone fixation devices (e.g., compressing bone screw, bone plate, bone

staple, external fixator, intramedullary implant or nail) prior to a closing of the surgical access to the joint.

[0097] An exemplary method will now be described with respect to FIGS. 16-27 depicting a foot 200 having a first metatarsal 210, a medial cuneiform 220, and a second metatarsal 292. Note, unless otherwise indicated, the steps described need not be carried out in the order described.

[0098] After customary surgical preparation and access, a bone preparation instrument 296 can be inserted into the joint (e.g., first tarsal-metatarsal joint) to release soft tissues and/or excise the plantar flare from the base of the first metatarsal 210, as shown in FIG. 16. Excising the plantar flare may involve cutting plantar flare off the first metatarsal 210 so the face of the first metatarsal is generally planar. This step helps to mobilize the joint to facilitate a deformity correction. In some embodiments, the dorsal-lateral flare of the first metatarsal may also be excised to create space for the deformity correction (e.g., with respect to rotation of the first metatarsal). In certain embodiments, a portion of the metatarsal base facing the medial cuneiform can be removed during this mobilizing step.

[0099] An incision can be made and a tip 50 of a bone positioning guide 10 can be inserted on the lateral side of a metatarsal other than the first metatarsal 210, such as the second metatarsal 292. As shown in FIG. 17, the tip can be positioned proximally at a base of the second metatarsal 292 and a third metatarsal 294 interface. A surface of a bone engagement member 40 can be placed on the proximal portion of the first metatarsal 210. In some embodiments, the bone engagement member engages a medial ridge of the first metatarsal 210. As shown, the body 20 of the positioning guide can be generally perpendicular to the long axis of the second metatarsal 292.

[0100] As depicted in FIG. 18, the actuator 120 can be actuated to extend the shaft 30 to reduce the angle (transverse plane angle between the first metatarsal and the second metatarsal) and rotate the first metatarsal about its axis (frontal plane axial rotation). The first metatarsal 210 can be properly positioned with respect to the medial cuneiform 220 by moving the bone engagement member 40 with respect to the tip 50. In some embodiments, such movement simultaneously pivots the first metatarsal with respect to the cuneiform and rotates the first metatarsal about its longitudinal axis into an anatomically correct position to correct a transverse plane deformity and a frontal plane deformity. In certain embodiments, body 20 rotates in a generally lateral direction during this step. In some embodiments, fixation pins (not shown in

FIG. 18) can be inserted into the bones prior to the positioning step (e.g., freehand or using apertures in the guide as a template), and can be used to impart additional force (transverse, sagittal, and/or frontal plane rotational) to the first metatarsal 210, if desired. The bone positioning guide 10 can hold the desired position of the first metatarsal 210 with respect to the second metatarsal 292. After the desired correction is achieved, a fixation wire 298 can be inserted through a cannulation in the shaft 30 and driven into the first metatarsal 210 and the second metatarsal 292 to hold the corrected position.

[0101] As depicted in FIG. 19, a joint spacer 188 can be positioned within the joint between the first metatarsal and the medial cuneiform.

[0102] As shown in FIG. 20, a bone preparation guide 150 can be placed over the joint spacer 188 and engaged with the joint spacer to set a position and orientation of the bone preparation guide relative to the joint. As shown, the bone preparation guide 150 can be positioned proximal to the bone positioning guide 10 in longitudinal alignment with the long axis of the first metatarsal 210 and the medial cuneiform 220, generally on the dorsal or dorsal-medial surface. In other embodiments, the spacer 188 is positioned after the guide 150 is provisionally placed on the bones. In yet other embodiments, bone preparation guide 150 and joint spacer 188 are placed simultaneously. In still other embodiments, bone preparation guide 150 is placed on the bones without using joint spacer 188 to aid with positioning.

[0103] As depicted in FIGS. 21A and 21B, one or more fixation pins 270 can be inserted into apertures of the bone preparation guide 150 to secure the guide to the first metatarsal 210 and the medial cuneiform 220. As shown, some pins 270 can be inserted at an angle or in a converging orientation to help prevent movement of the bone preparation guide 150 during a tissue removing step. As shown, two of the pins 270, one on the first metatarsal and one on the medial cuneiform, are parallel to allow the bone preparation guide 150 to be removed from the foot without removing all the pins. After insertion of the pins 270, the spacer 188 can optionally be removed in embodiments having a selectively engageable spacer (e.g., a joint spacer 188 that is physically removable from bone preparation guide 150).

[0104] In some embodiments, the location of the intersection of the tissue removing instrument and the bone to be prepared is confirmed before bone preparation. In one embodiment, a tissue removing instrument location check member can be engaged with the preparation guide to visually confirm where a tissue removal instrument will contact the bone. In another

embodiment, a tissue removal instrument is engaged with the preparation guide to visually confirm where the instrument will contact the bone. In either embodiment, such visual confirmation can include the use of an imaging device, such as an X-ray. If the position of the preparation guide is correct, additional fixation pins may be inserted through the apertures (e.g., angled apertures) to further fix the position of the preparation guide with respect to the first metatarsal and the medial cuneiform. In some embodiments, the spacer is reattached prior to further bone preparation steps.

[0105] In some embodiments, the end of the first metatarsal 210 facing the medial cuneiform 220 can be prepared with a tissue removing instrument 296 guided by a guide surface of bone preparation guide 150 (e.g., inserted through a slot defined by a first guide surface and a first facing surface). Additionally or alternatively, the end of the first metatarsal 210 facing the medial cuneiform 220 can be prepared by morselizing the end of the first metatarsal. In some embodiments, the first metatarsal 210 end preparation is done after the alignment of the bones, e.g., by actuating bone positioning guide 10 before preparing the end of first metatarsal 210. In other embodiments, the first metatarsal 210 end preparation is done before the alignment of the bones, e.g., by preparing the end of the first metatarsal 210 before actuating bone positioning guide 10.

[0106] In addition, as shown in FIG. 22, the end of the medial cuneiform 220 facing the first metatarsal 210 can be prepared with the tissue removing instrument 296 guided by a guide surface of bone preparation guide 150 (e.g., inserted through a slot defined by a second guide surface and a second facing surface). Additionally or alternatively, the end of the medial cuneiform 220 facing the first metatarsal 210 can be prepared by morselizing the end of the medial cuneiform. In some embodiments, the medial cuneiform 220 end preparation is done after the alignment of the bones. In yet other embodiments, the medial cuneiform 220 end preparation is done before the alignment of the bones. In embodiments that include cutting bone or cartilage, the cuneiform cut and the metatarsal cut can be parallel, conforming cuts. In the specific embodiment shown in FIG. 22, a saw blade can be inserted through a first slot to cut a portion of the medial cuneiform and the saw blade can be inserted through a second slot to cut a portion of the first metatarsal (e.g., in some embodiments the medial cuneiform can be cut before the first metatarsal). Accordingly, in the embodiment shown, the cuts to both the first metatarsal and the medial cuneiform were preformed after the first metatarsal was positioned.

[0107] Any angled/converging pins can be removed and the bone preparation guide 150 can be lifted off the parallel pins 270, as shown in FIG. 23. The parallel pins can be referred to as "reference pins" which can serve as a reference in later steps to ensure that the corrected alignment of the first metatarsal 210 has been maintained. The joint spacer can also be removed before, after, or simultaneously with the bone preparation guide. In some embodiments, the bone positioning guide 10 is also removed from the foot.

[0108] The tissue (e.g., bone or cartilage slices) from the first metatarsal and the medial cuneiform can be removed from the joint site and the joint surfaces can be fenestrated, if desired. If the bone positioning guide was taken off the foot, it can be put back on, as shown in FIG. 24, before the additional steps discussed below.

[0109] After preparation, the ends of the two bones can be placed in apposition and optionally compressed together by provisionally fixating the joint. For example, the two bones may be placed in apposition by placing the cut and/or morselized end of the first metatarsal 210 in abutment with the cut and/or morselized end of the medial cuneiform 220. In some examples, the cut and/or morselized end of the first metatarsal 210 is placed adjacent to, and optionally in contact with, the cut and/or morselized end of the medial cuneiform 220.

[0110] As shown in FIG. 25, a compression pin, such as a threaded olive pin 300 can be inserted through the first metatarsal 210 and into the medial cuneiform 220 to provide compression and provisional fixation between the first metatarsal and the medial cuneiform. Additional compression pins can be inserted to provide additional stability. As shown, the parallel reference pins should be aligned during this step. In some embodiments, a practitioner checks for alignment of the parallel reference pins prior to insertion of the compression pin, and, if they are not aligned, adjusts the position of the first metatarsal until desired alignment is achieved.

[0111] Although they can be left in place, in some embodiments the parallel reference pins and bone positioning guide can be removed and a bone fixation device (e.g., two bone plates positioned in different planes, as shown) can be applied to stabilize the joint for fusion. FIG. 26A shows a first bone plate 310 positioned on a dorsal-medial side of the first metatarsal and medial cuneiform and a second bone plate 320 positioned on a medial-plantar side of the first metatarsal and the medial cuneiform. In other embodiments, such as the embodiment shown in FIG. 26B, the second bone plate 320 can be a helical bone plate positioned from a medial side of the cuneiform to a plantar side of the first metatarsal across the joint space. The plates can be

applied with the insertion of bone screws. Example bone plates that can be used as first bone plate 310 and/or second bone plate 320 are described in US Patent Publication No. US2016/0192970, titled "Bone Plating System and Method" and filed January 7, 2016, which is incorporated herein by reference.

[0112] As shown in FIG. 27, the compression pin can be removed and the incision can be closed.

[0113] FIGS. 28 A/B and 29A/B include examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention. FIG. 28A shows a left foot pre-operation and post-operation, while FIG. 28B shows a right foot pre-operation and post-operation. As can be seen from a comparison of the pre-operative images to the post-operative images, the patients' intermetatarsal angle (IMA) was significantly reduced. FIGS. 29A and 29B show the correction of an axial rotation in a frontal rotational plane. FIG. 29A shows a pre-operative image and a post-operative image of a right foot. Drawings of a metatarsal 210 are also provided to illustrate the rotation. The rotation of the metatarsal can be seen by the position of sesamoid bones 400, which are depicted as having been rotated under the first metatarsal 210 in the post-operative drawing. FIG. 29B shows pre-operative views of a left foot 200 and a right foot 200. Again, by comparing the location of the sesamoid bones 400 with respect to a reference location, such as ground, the planter surface of the foot, and/or a cuneiform, it can be seen this patient's metatarsal is rotated out of alignment.

[0114] Methods in accordance with embodiments of the invention can be useful for positioning a bone or bones. Bone positioning can be useful, for instance, to correct an anatomical misalignment of bones and maintain an anatomically aligned position, such as in a bone alignment and/or fusion procedure. In some embodiments, an "anatomically aligned position" means that an angle of a long axis of a first metatarsal relative to a long axis of a second metatarsal is about 10 degrees or less in the transverse plane or sagittal plane. In certain embodiments, anatomical misalignment can be corrected in both the transverse plane and the frontal plane. In the transverse plane, a normal intermetatarsal angle ("IMA") between a first metatarsal and a second metatarsal may be less than about 9 degrees (e.g., less than 6 degrees). An IMA of between about 6 degrees and about 13 degrees (e.g., between about 9 degrees and about 13 degrees) may be considered a mild or moderate misalignment of the first metatarsal relative to the second metatarsal. An IMA of greater than about 16 degrees may be considered a severe misalignment of the first metatarsal relative to the second metatarsal. In some

embodiments, methods in accordance with the invention are capable of anatomically aligning the bone(s) by reducing the IMA from over 10 degrees to about 10 degrees or less (e.g., to an IMA of less than 6 degrees, such as to an IMA of about 1-5 degrees), including to negative angles of about -5 degrees or until interference with the second metatarsal, by positioning the first metatarsal at a different angle with respect to the second metatarsal.

[0115] With respect to the frontal plane, a normal first metatarsal will be positioned such that its crista prominence is generally perpendicular to the ground and/or its sesamoid bones are generally parallel to the ground and positioned under the metatarsal. This position can be defined as a metatarsal rotation of 0 degrees. In a misaligned first metatarsal, the metatarsal is axially rotated between about 4 degrees to about 30 degrees or more. In some embodiments, methods in accordance with the invention are capable of anatomically aligning the metatarsal by reducing the metatarsal rotation from about 4 degrees or more to less than 4 degrees (e.g., to about 0 to 2 degrees) by rotating the metatarsal with respect to the medial cuneiform.

[0116] While various embodiments of bone positioning and preparing guide systems and methods have been described, it should be appreciated that the concepts of the disclosure can be altered in practice, e.g., based on the needs of the clinician, the patient undergoing the bone repositioning procedure, the specific anatomy being treated, and/or the target clinical outcome. As one example, the described systems and techniques may be modified to utilize a fulcrum about which rotation and/or pivoting of one bone relative to another bone occurs, e.g., with or without use of bone positioning guide 10. The fulcrum can establish and/or maintain space between adjacent bones being moved, e.g., compressed between bone engagement member 40 and tip 50 when using bone positioning guide 10, preventing lateral translation or base shift of the bones during rotation and/or pivoting.

[0117] FIG. 30A illustrates a portion of a foot having a bunion caused by a misaligned first metatarsal 210 relative to second metatarsal 292. FIG. 30B shows the foot of FIG. 30A after being anatomically aligned to correct the misalignment using bone positioning guide 10. As shown, first metatarsal 210 has been rotated counterclockwise in the frontal plane (from the perspective of a patient, clockwise from the perspective of a frontal observer) and also pivoted in the transverse plane (e.g., such that the angle 350 between the first metatarsal 210 and second metatarsal 292 is reduced). Rotation and pivoting of first metatarsal 210 can cause the base 352 of first metatarsal 210 to shift relative to medial cuneiform 220. In general, it is desirable that

the offset 354A between first metatarsal 210 and medial cuneiform 220 be reduced to zero (e.g., such that there is substantially no offset) after rotation and pivoting. As shown in the illustrated application of FIG. 30B, however, the base 352 of first metatarsal 210 abutting medial cuneiform 220 has shifted toward second metatarsal 292. This results in a transverse offset 354B of first metatarsal 210 toward second metatarsal 292, causing base compression between first metatarsal 210 and second metatarsal 292.

[0118] To help avoid the base shift and offset 354B observed in FIG. 30B, a clinician can insert a fulcrum in the notch between first metatarsal 210 and second metatarsal 292 at the base of the metatarsals (e.g., adjacent respective cuneiform) before actuating bone positioning guide 10. The fulcrum can provide a point about which first metatarsal 210 can rotate and/or pivot while helping minimize or avoid base compression between the first metatarsal and the second metatarsal. In addition, use of the fulcrum may cause first metatarsal 210 and medial cuneiform 220 to be better angled relative to the guide slots of bone preparation guide 150 (once installed), providing a better cut angle through the guide slots than without use of the fulcrum. This can help reduce or eliminate unwanted spring-back, or return positioning, of first metatarsal 210 after removing bone positioning guide 10 (in instances in which bone positioning guide 10 is used with the fulcrum).

[0119] FIG. 31 illustrates a bone positioning operation in which a fulcrum 356 is positioned at an intersection between a first bone and a second bone, where the first bone is being realigned relative to the second bone. In particular, FIG. 31 illustrates fulcrum 356 being positioned between first metatarsal 210 and second metatarsal 292. Fulcrum 356 may be positioned distally of bone preparation guide 150 between first metatarsal 210 and second metatarsal 292 as shown in FIG. 31 or, in other applications, proximally of the guide (e.g., at the ends of the first and second metatarsals abutting the medial and intermediate cuneiform bones, respectively). In still other examples, fulcrum 356 can be positioned in the intermetatarsal space between first metatarsal 210 and second metatarsal 292 without using bone preparation guide 150.

[0120] When used, the clinician can insert fulcrum 356 between first metatarsal 210 and second metatarsal 292 (or other adjacent bones, when not performing a metatarsal realignment) at any time prior to moving the first metatarsal (e.g., by actuating bone positioning guide 10 or other means of manipulating the bone). In different embodiments, fulcrum 356 can be inserted between first metatarsal 210 and second metatarsal 292 before or after inserting joint spacer 188

and/or placing bone preparation guide 150 over the joint being operated upon. In one embodiment, the clinician prepares the joint being operated upon to release soft tissues and/or excise the plantar flare from the base of the first metatarsal 210, as discussed above. Either before or after installing bone positioning guide 10 over adjacent bones, for example with bone engagement member 40 positioned in contact with the medial ridge of the first metatarsal 210 and tip 50 positioned in contact with second metatarsal 292, the clinician inserts fulcrum 356 at the joint between the first metatarsal and the second metatarsal. The clinician can subsequently actuate bone positioning guide 10 (e.g., rotate knob 120). In the case of a left foot as shown in FIG. 31, actuation of bone positioning guide 10 causes the first metatarsal 210 to rotate counterclockwise in the frontal plane (from the perspective of a patient) and also pivot in the transverse plane about the fulcrum. In the case of a right foot (not shown), actuation causes the first metatarsal to rotate clockwise in the frontal plane (from the perspective of a patient) and also pivot in the transverse plane about the fulcrum. Thus, for both feet, actuation of bone positioning guide 10 can supinate the first metatarsal in the frontal plane and pivot the first metatarsal in the transverse plane about fulcrum 356. While use of fulcrum 356 can minimize or eliminate base compression between adjacent bones being operated upon, in other embodiments as discussed above, the described systems and techniques can be implemented without using the fulcrum.

[0121] In instances in which fulcrum 356 is used, any suitable mechanical instrument that maintains a spacing between adjacent bones can be used for the fulcrum. FIG. 32 is a perspective view of one example instrument that can be used as fulcrum 356. In this embodiment, fulcrum 356 has a generally rectangular shape and tapers in thickness along at least a portion of the length from the trailing end 358 to the leading end 360. Fulcrum 356 may be sized sufficiently small so that it does not interfere with placement of bone preparation guide 150 on the joint being worked upon. In some embodiments, the clinician is provided a system containing multiple different size and/or shape fulcrums and allowed to choose the specific size and/or shape fulcrum desired for the specific procedure being performed. FIG. 33 illustrates an example kit or system of different sized fulcrums, labeled with exemplary "width x thickness" sizes, that may be provided to a clinician in such an embodiment. In some examples, fulcrum 356 has a width ranging from 5 millimeters to 15 millimeters (e.g., about 6 millimeters to about

10 millimeters) and a thickness ranging 1 millimeter to 12 millimeters (e.g., about 2 millimeters to about 3 millimeters), although fulcrums with different dimensions can be used.

[0122] While FIGS. 32 and 33 illustrate one example style of fulcrum, other mechanical instruments providing a fulcrum functionality can be used without departing from the scope of the disclosure. For instance, as alternative examples, a surgical pin or rod, a screw driver head/shaft, an osteotome, or a retractor may be used as fulcrum 356. Depending on the instrument used as a fulcrum, the fulcrum may have a variety of cross-sectional shapes, such as a generally polygonal shape (e.g., square, hexagonal), a generally arcuate shape (e.g., circular, elliptical), or combinations of polygonal and arcuate shapes.

[0123] As discussed above, bone positioning guide 10 can have a variety of different configurations, including a configuration in which bone engagement member 40 is laterally offset from tip 50. FIG. 34 is a perspective view of bone positioning guide 10 showing an example arrangement in which bone engagement member 40 is laterally offset from tip 50. In this embodiment, the first end 60 of main body member 20 is laterally offset from an axis 362 extending through shaft 30 and a geometric center of bone engagement member 40. In particular, in the illustrated configuration, tip 50 is offset laterally in the direction of the cuneiform relative to bone engagement member 40. As a result, when bone positioning guide 10 is actuated, e.g., by rotating knob 120, a moment can be created by the offset tip. This can cause the end of the first metatarsal 210 adjacent the proximal phalange to pivot toward the second metatarsal 292 and close angle 350, e.g., while the opposite end of the first metatarsal adjacent the medial cuneiform pivots away from the second metatarsal. This can also help avoid base compression between the first and second metatarsals.

[0124] As discussed above with respect to FIGS. 19 and 20, a joint spacer 188 can be positioned in a joint between a first metatarsal and a medial cuneiform before placing bone preparation guide 150 over the joint spacer. Bone preparation guide 150 can have an opening 170 (FIG. 5) sized to receive joint spacer 188. In some examples, opening 170 of bone preparation guide 150 is size and/or shaped indexed to joint spacer 188 such that there is substantially no, or no, relative movement between the guide and spacer (once bone preparation guide 150 is placed over joint spacer 188). This arrangement can ensure that bone preparation guide 150 is positioned precisely at the location where guided by joint spacer 188.

[0125] In practice, once bone preparation guide 150 is placed over joint spacer 188, the guide slots of the bone positioning guide may not be perfectly aligned with the ends of the bones (e.g., first metatarsal 210 and medial cuneiform 220) to be cut through the guide slots. Accordingly, in other configurations, opening 170 of bone preparation guide 150 may not be sized and/or shaped and/or indexed to joint spacer 188. In other words, opening 170 of bone preparation guide 150 may have a different cross-sectional size and/or shape than the cross-sectional size and/or shape of joint spacer 188. In these configurations, bone preparation guide 150 may actuate or rotate about an axis extending through the length of joint spacer 188. As a result, after the clinician places bone preparation guide 150 over joint spacer 188, the clinician may rotate bone preparation guide 150 around joint spacer 188 until the guide slots of the bone preparation guide are better aligned with the ends of the bones to be cut (e.g., first metatarsal 210 and medial cuneiform 220). Depending on the configuration of opening 170 of bone preparation guide 150 and the configuration of joint spacer 188, the guide may rotate freely (e.g., 360 degrees) around the joint spacer (e.g., seeker) or within a bounded angular range (e.g., from plus 20 degrees to minus 20 degrees from a normal position).

[0126] FIG. 35 illustrates one example configuration of a joint spacer 188 that can allow bone preparation guide 150 to rotate around the spacer (e.g., seeker). As shown in the illustrated example, joint spacer 188 has a proximal portion 370 having a cylindrical cross-section and a distal portion 372 having a rectangular cross-section. A leading edge of the distal portion 372 is insertable into the joint between the first metatarsal 210 and the medial cuneiform 220. Once bone preparation guide 150 is inserted over joint spacer 188, body 154 of the guide (FIG. 5) may be positioned about the proximal portion 370. This can allow the guide to be rotated around the proximal portion.

[0127] In other configurations, opening 170 of bone preparation guide 150 may be size and/or shape indexed to the cross-sectional size and/or shape of joint spacer 188 but still provide relative rotation between the two components. For example, opening 170 may have a circular cross-section sized and shaped to receive proximal portion 370 of joint spacer 188 from FIG. 35. Because both opening 170 of bone preparation guide 150 and proximal portion 370 of joint spacer 188 have circular cross-sections in such an embodiment, the two components may rotate relative to each other. FIG. 36A is a perspective view of an example configuration of bone preparation guide 150 having an opening 170 with circular cross-sectional shape. FIG. 36B is a

perspective view of the example bone positioning guide of FIG. 36A shown with joint spacer 188 from FIG. 35 inserted into the guide.

[0128] In embodiments where bone preparation guide 150 can rotate relative to joint spacer 188, the bone positioning guide and/or joint spacer may include a locking mechanism that is engageable to lock the rotational angle of the bone positioning guide relative to the joint spacer. For example, bone preparation guide 150 may include a set screw with thumb wheel that can be rotated, causing a distal end of the set screw to bear against or retract away from joint spacer 188. In use, a clinician can rotate bone preparation guide 150 around joint spacer 188 until the guide slots of the bone preparation guide are best aligned with the ends of the bones to be cut (e.g., first metatarsal 210 and medial cuneiform 220). The clinician can then engage the locking mechanism to prevent further rotation of bone preparation guide 150 relative to joint spacer 188 before performing further steps of the procedure.

[0129] A bone correction procedure can be accomplished using one or more instruments according to the disclosure. In some applications, a bone correction procedure, such as a tarsal-metatarsal joint fusion procedure to correct a bunion deformity, is performed utilizing a fulcrum as a pivot point. The first metatarsal is moved relative to a second metatarsal about the fulcrum without utilizing bone positioning guide 10. In these applications, the clinician can insert the fulcrum into an intermetatarsal space between the first and second metatarsals and physically grasp the first metatarsal and move the metatarsal about the fulcrum. For example, the clinician may directly grasp the first metatarsal with his hand or indirectly grasp the first metatarsal through an intermediate tool, such as a K-wire or pin inserted into the first metatarsal, a tenaculum or tongs, or other grasping instrument. Thereafter, the clinician may translate his hand relative to the foot of the patient being operated upon to move the first metatarsal about the fulcrum and relative to the second metatarsal, e.g., to anatomically align the first metatarsal with respect to the second metatarsal.

[0130] FIG. 37 is a block flow diagram of an example bone correction technique utilizing a fulcrum. Specific steps of the technique of FIG. 37 can be performed utilizing techniques and/or instruments discussed above. As shown, the example technique of FIG. 37 includes mobilizing a tarsal-metatarsal joint by releasing soft tissue and/or obstructing bone (500). After customary surgical preparation and access, the clinician may mobilize the tarsal-metatarsal joint by inserting a cutting instrument (e.g., saw, rotary bur, osteotome) at least partially between the first

metatarsal and medial cuneiform. The clinician may use the cutting instrument to release soft tissues and/or excise the plantar flare from the base of the first metatarsal. Excising the plantar flare may involve cutting plantar flare off the first metatarsal so the face of the first metatarsal is generally planar. In some applications, the dorsal-lateral flare of the first metatarsal may also be excised to create space for the correction procedure.

[0131] The technique of FIG. 37 further involves inserting a fulcrum between the first metatarsal and the second metatarsal (502). The fulcrum may be inserted from the dorsal side of the foot toward the plantar side of the foot in the intermetatarsal space between the first metatarsal and the second metatarsal. Although the fulcrum may be positioned at any desired location in the intermetatarsal space, in some applications, the fulcrum is positioned adjacent to, and optionally in contact with, a proximal portion of the first metatarsal and/or the second metatarsal. For example, the fulcrum may be positioned adjacent to, and optionally in contact with, a proximal-most half of the first metatarsal and/or proximal-most half of the second metatarsal, such as the proximal-most third or proximal-most quarter of the first metatarsal and/or the second metatarsal. In one application, the fulcrum is positioned in the intermetatarsal space adjacent to, and optionally in contact with, the base of the first metatarsal facing the medial cuneiform and the base of the second metatarsal facing the intermediate cuneiform. This positioning can help prevent or minimize lateral translation of the base of the first metatarsal toward the base of the second metatarsal during alignment of the first metatarsal. In some applications, the clinician inserts the fulcrum from the dorsal toward the plantar side of the foot in the intermetatarsal space and then translates the fulcrum proximally in the intermetatarsal space.

[0132] The technique of FIG. 37 also involves preparing the end of the first metatarsal and/or the opposed end of the medial cuneiform (504). Typically, bone preparation is performed after inserting the fulcrum in the intermetatarsal space (502), although bone preparation can be performed prior to inserting the fulcrum. To prepare the end of the first metatarsal and the end of the medial cuneiform, a tissue removing instrument can be applied to the ends of the bones. In one example, a cutting instrument is applied to transect each bone and thereby form a new end surface, e.g., by inserting the cutting instrument through a slot defined bone preparation guide 150. Additionally or alternatively, the tissue removing instrument can be applied to the end face of each bone to morselize at least a portion of the end face.

[0133] Independent of the specific technique used to prepare the end of the first metatarsal and/or the opposed end of the medial cuneiform (504), the technique of FIG. 37 includes moving the first metatarsal to help correct the anatomical misalignment (506). The first metatarsal can be moved relative to the second metatarsal before and/or after preparing the end of the first metatarsal and/or the opposed end of the medial cuneiform. To move the first metatarsal relative to the second metatarsal, the clinician may directly or indirectly grasp the first metatarsal and translate a distal portion of the first metatarsal toward the second metatarsal (e.g., a distal portion of the second metatarsal) in the transverse plane. As the distal end of the first metatarsal moves toward the second metatarsal in the transverse plane, the proximal portion of the first metatarsal can pivot about the fulcrum. For example, the fulcrum can function as a central point around which the proximal portion of the first metatarsal turns as the distal portion of the first metatarsal translates laterally. Accordingly, moving the distal portion of the first metatarsal toward the second metatarsal can reduce the intermetatarsal space, and hence intermetatarsal angle, between the first metatarsal and the second metatarsal.

[0134] As the first metatarsal pivots in the transverse plane toward the second metatarsal, closing the intermetatarsal space, a proximal portion of the first metatarsal may contact and press against the fulcrum, thereby causing the fulcrum to contact and press against a proximal portion of the second metatarsal. The fulcrum may function to maintain spacing between the proximal portion of the first metatarsal and proximal portion of the second metatarsal, e.g., such a spacing equal to the width of the fulcrum. This may help reduce or eliminate shifting or translation of the base of the first metatarsal toward the base of the second metatarsal during pivoting.

[0135] In some applications of the technique of FIG. 37, the clinician may rotate the first metatarsal in the frontal plane in addition to or in lieu of translating the first metatarsal in the transverse plane. For example, either before, after, or concurrent with moving the distal portion of the first metatarsal toward the second metatarsal in the frontal plane, the clinician can directly or indirectly grasp the first metatarsal and rotate the metatarsal in the frontal plane. The clinician may rotate the first metatarsal about its longitudinal axis into an anatomically correct frontal plane position to correct a frontal plane deformity. Rotating the first metatarsal in the frontal plane may further rotate the sesamoid bones (e.g., tibial sesamoid bone and fibular sesamoid bone) from a misaligned position to an aligned position under the first metatarsal. In some

examples, the clinician additionally or alternatively moves the first metatarsal in the sagittal plane to correct a misalignment in the sagittal plane.

[0136] In some applications of the technique of FIG. 37, the clinician moves the first metatarsal in at least one plane from an anatomically misaligned position with respect to the second metatarsal to an anatomically aligned position. The at least one plane may be one or more planes selected from the frontal plane, the transverse plane, and the sagittal plane. For example, the clinician may move the first metatarsal in any two of the three planes or even in all three of the planes to adjust the first metatarsal from an anatomically misaligned position to an anatomically aligned position.

[0137] After suitably moving the first metatarsal relative to the second metatarsal, the joint between the first metatarsal and medial cuneiform may be provisionally fixated (508). In one example, a fixation wire is driven into the first metatarsal and the medial cuneiform to provisionally fixate the joint. In another example, a compression pin, such as a threaded olive pin, is inserted through the first metatarsal and into the medial cuneiform to provide compression and provisional fixation between the first metatarsal and the medial cuneiform. The fulcrum can be removed from the intermetatarsal space before or after provisionally fixating the joint.

[0138] Following optional provisional fixation, the corrected position of the first metatarsal can be permanently fixated by fixing the position of the first metatarsal with respect to the medial cuneiform (510). One or more bone plates can be applied across the tarsal-metatarsal joint and the provisional fixation hardware removed. For example, a first bone plate may be positioned on a dorsal-medial region of the first metatarsal and on the medial cuneiform while a second bone plate is positioned on a medial-plantar region of the first metatarsal and on the medial cuneiform. In these applications, the second bone plate may or may not be a helical-shaped bone plate extending from a medial region of the medial cuneiform to a plantar region of the first metatarsal across the joint.

[0139] FIG. 38 is a perspective view of a foot showing an example position of a fulcrum during a bone correction procedure according to the method of FIG. 37. As shown, fulcrum 356 is positioned in the intermetatarsal space between the first metatarsal 210 and the second metatarsal 292. In particular, fulcrum 356 is illustrated as being positioned between a proximal portion of first metatarsal 210 adjacent base 352 and an opposed proximal portion of second metatarsal 292. An optional pin 512 is inserted into the first metatarsal 210, providing a structure that a

clinician can grab to move and manipulate the first metatarsal relative to the second metatarsal. As discussed with respect to FIG. 37, the clinician may pivot the first metatarsal 210 about fulcrum 356 toward the second metatarsal 292, reducing the intermetatarsal angle 350 between the first and second metatarsals. The clinician may also rotate the first metatarsal 210 in the frontal plane. The use of fulcrum 356 can provide a pivot surface that also maintains a defined spacing between first metatarsal 210 and second metatarsal 292, potentially leading to a more anatomically correct realignment than when moving first metatarsal 210 without using the fulcrum.

[0140] As discussed above with respect to FIGS. 32 and 33, fulcrum 356 can have a variety of different configurations that provide a fulcrum functionality. FIGS. 39A and 39B illustrate another example configuration of fulcrum 356 that can be used according to the disclosure. FIG. 39A is a perspective view of one side of fulcrum 356, while FIG. 39B is a perspective view of the fulcrum from the opposite side. In the illustrated configuration, fulcrum 356 includes a body 380 and a handle 382 operatively connected to the body. Typically, body 380 and handle 382 will be formed as a unitary structure, e.g., by milling, casting, or molding the components to be permanently and structurally integrated together. However, body 380 and handle 382 may be fabricated as separate components that are subsequently joined together.

[0141] Body 380 can be configured (e.g., sized and shaped) to be inserted into an intermetatarsal space between adjacent metatarsals. For example, body 380 may be configured to be inserted between a first metatarsal and a second metatarsal. Body 380 is illustrated as having a rectangular shape with a length 383 greater than its width 384 and thickness 386. Moreover, in this configuration, body 380 has a constant width 384 across its length but has a thickness 386 that that tapers along at least a portion of the length from the leading end 388 to the trailing end 390. For example, body 380 may have a tapered leading end 388 to facilitate insertion of fulcrum 356 in a space between adjacent metatarsals. In other configurations, body 380 may have a constant thickness across is length or may define a different generally polygonal shape (e.g., square, hexagonal) and/or generally arcuate shape (e.g., circular, elliptical).

[0142] Fulcrum 356 in FIGS. 39A and 39B includes handle 382. Handle 382 can project angularly away from body 380 to define a tissue retraction space 392. Tissue retraction space 392 may be a region bounded on one side by body 380 and one or more other sides by handle 382. In use, fulcrum 356 may be inserted into an intermetatarsal space with handle 382

extending out of the surgical incision and over an epidermal layer with tissue captured in tissue retraction space 392. For example, fulcrum 356 may be inserted into an intermetatarsal space with handle 382 projecting toward the lateral side of the foot being operated upon. Tissue retraction space 392 may help retract tissue and push the tissue laterally away from a first metatarsal and/or medial cuneiform being operated upon. FIG. 40 illustrates fulcrum 356 in such an application with the fulcrum inserted between a first metatarsal and a second metatarsal and handle 382 extending toward the lateral side of the foot being operated upon. As shown, handle 382 pushes the skin of the foot away from the surgical incision line, helping to provide access to the surgical site in addition to providing fulcrum functionality.

[0143] With further reference to FIGS. 39A and 39B, handle 382 is illustrated as projecting laterally at a non-zero degree angle away from body 380. The specific angular orientation of the handle 382 relative to the body 380 may vary. However, in some examples, handle 382 is oriented relative to the body 380 so a handle axis 393 intersects an axis 394 extending along the length of the body at an acute angle 396 ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees. Moreover, handle 382 may be composed of a single linear portion that intersects body 380 at a specific angular orientation or may be composed of multiple linear portions oriented at different angles relative to each other.

[0144] In the illustrated example, handle 382 includes a grip portion 398 and a handle body 402. The grip portion 398 can provide a surface that a clinician physically grips to insert fulcrum 356 into an intermetatarsal space. For example, grip portion 398 may contain knurling or other anti-friction surfacing texturing to allow the clinician to help grip the fulcrum. Handle body 402 may be positioned between the body 380 of fulcrum 356 and grip portion 398. Handle body 402 may or may not have a reduced cross-sectional width compared to body 380 and/or grip portion 398, as illustrated.

[0145] When configured with grip portion 398, the grip portion can be co-linear with handle body 402 or may be offset relative to the handle body. When grip portion 398 is offset from handle body 402, a grip axis 404 extending along the length of the grip portion may intersect the handle axis 393 at an acute ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees, although other angular arrangements can also be used. In the illustrated configuration, grip axis 404 is perpendicular to the axis 394 defined by body 380. Accordingly, when inserted into an intermetatarsal space, retracted tissue may be bounded by a laterally-facing side of body

380, by the lower surface of grip portion 393, and in the dorsal-lateral direction by handle portion 392.

[0146] In some examples, the bone-contacting faces of body 380 are configured to inhibit and/or facilitate relative motion between a bone and the respective bone-contacting face. With reference to FIG. 39A, body 380 of fulcrum 356 has a first face 410, which may be positioned in contact with a first metatarsal. First face 410 may have surface features which allow the contacting metatarsal (e.g., first metatarsal) to rotate in the frontal plane while contacting the face but inhibit movement of the metatarsal in the proximal to distal direction. The surface features may be implemented as directionally-oriented ribs and/or grooves, which are illustrated in FIG. 39A as being multiple grooves extending lengthwise across body 380. By orienting the grooves lengthwise, the edges of the grooves may have a tendency to engage or bite into the metatarsal if the metatarsal is moved proximally or distally, thereby inhibiting such movement. However, the grooves can allow the metatarsal to rotate in the frontal plane against first face 410 without inhibiting such rotation.

[0147] Additionally or alternatively, the body 380 may have different surface features on the opposite face from first face 410. With reference to FIG. 39B, for example, body 380 of fulcrum 356 has a second face 412 that is opposite first face 410. Second face 412 may have surface features that inhibit movement between fulcrum 356 and the contacting metatarsal (e.g., second metatarsal) in the dorsal-to-plantar direction. The surface features may be implemented as directionally-oriented ribs and/or grooves. For example, in FIG. 39B, second face 412 is illustrated as having knurling, or a series of intersecting and overlapping ridges. FIG. 41 is perspective view of the second face 412 of fulcrum 356 showing an alternative arrangement of surface features that may be used. In this alternative configuration, the surface features on second face 412 are illustrated as being multiple grooves extending widthwise across body 380. By orienting the grooves widthwise, the edges of the grooves may have a tendency to engage or bite into the metatarsal if the metatarsal is moved plantarly or dorsally, thereby inhibiting such movement. The knurling illustrated on FIG. 39B can also achieve this functionality.

[0148] In the configuration of FIGS. 39A and 39B, handle 382 includes grip portion 398 that can provide a surface a clinician physically grips to insert fulcrum 356. In other configurations, handle 382 may be implemented using a second fulcrum body that is a different size and/or shape than body 380. This arrangement can provide a clinician with a single instrument having

two functional ends, either one of which can be selected and used by the clinician, e.g., depending on the characteristics of the patient undergoing a surgical procedure.

[0149] FIGS. 42A and 42B are perspective and side views, respectively, of such an example fulcrum 356 having two fulcrum bodies. As shown in this example, fulcrum 356 includes the body 380 and the handle 382 projecting at a non-zero degree angle away from the body. The body 380 provides a first fulcrum body configured (e.g., sized and/or shaped) to be inserted into an intermetatarsal space. In addition, handle 382 in this example is defined at least in part by a second fulcrum body 420. The second fulcrum body 420 may also be configured (e.g., sized and/or shaped) to be inserted into an intermetatarsal space. The first fulcrum body 380 can differ from the second fulcrum 420 body by having a different size and/or shape.

[0150] In FIGS. 42A and 42B, the first fulcrum body 380 and the second fulcrum body 420 are shown as having the same shape but different sizes. In particular, first fulcrum body 380 has a length 383, a thickness 386, and a width orthogonal to the length and thickness. Further, the second fulcrum body 420 has a length 422, a thickness 424, and a width orthogonal to the length and thickness. The thickness 422 of the second fulcrum body 420 is illustrated as being greater than the thickness 386 of the first fulcrum body 380. The length and width of the first and second fulcrum bodies 380, 420 are illustrated as being the same but may be different in other examples (e.g., different width with same length, different length but same width, or different length and width).

[0151] In general, configuring the first fulcrum body 380 and second fulcrum body 420 with different thicknesses can be useful to facilitate use in different sized intermetatarsal spaces. For example, the clinician may select one sized fulcrum body over the other sized fulcrum body based on the anatomy (e.g., intermetatarsal space sizing) of the patient undergoing a surgical procedure. If the clinician determines upon beginning to insert the selected fulcrum that the selected fulcrum is inappropriately sized, the clinician may retract the fulcrum, flip the instrument, and insert the fulcrum on the opposite side of the instrument.

[0152] While the first fulcrum body 380 and second fulcrum body 420 can be configured with a variety of different sizes, in some examples, each fulcrum body has a thickness ranging from 0.5 millimeters to 12 millimeters, such as from 1 millimeter to 10 millimeters, or from 1 millimeter to 5 millimeters. The thickness 424 of the second fulcrum body 420 may be at least 0.2 millimeters thicker than the thickness 386 of the first fulcrum body, such as at least 0.5

millimeters thicker, at least 1 millimeter thicker, or at least 2 millimeters thicker. In some examples, first fulcrum body 380 and second fulcrum body 420 each have a width within a range from 5 millimeters to 15 millimeters (e.g., about 6 millimeters to about 10 millimeters) and a length ranging from 10 millimeters to 30 millimeters, although other dimensions can be used.

[0153] In the illustrated example of FIGS. 42A and 42B, the first fulcrum body 380 has a leading end 388 and a trailing end 390 and the second fulcrum body 420 has a leading end 426 and a trailing end 428. In some examples as shown, the leading end 388 of the first fulcrum body 380 and/or the leading end 426 of the second fulcrum body 420 has a thickness that tapers adjacent the leading end. This configuration can be useful to facilitate insertion of a fulcrum body into an intermetatarsal space. When configured with a tapered leading end, the exemplary thickness ranges discussed above may be measured as the maximum thickness of the fulcrum body at any location along the length of the body.

[0154] When fulcrum 356 is implemented with first fulcrum body 380 and second fulcrum body 420, the bone-contacting faces of one or both of the fulcrum bodies may be configured to inhibit and/or facilitate relative motion between a bone and the respective bone-contacting face, as discussed with respect to FIGS. 39A, 39B, and 41. For example, a first face 410 of first fulcrum body 380 and/or a first face 430 of second fulcrum body 420 may have surface features which allow a contacting metatarsal (e.g., first metatarsal) to rotate in the frontal plane while contacting the face but inhibit movement of the metatarsal in the proximal to distal direction, as discussed above. Similarly, a second face 412 of first fulcrum body 380 and/or a second face 432 of second fulcrum body 420 may have surface features that inhibit movement between fulcrum 356 and a contacting metatarsal (e.g., second metatarsal) in the dorsal-to-plantar direction, as also discussed above.

[0155] In the illustrated example, first fulcrum body 380 and second fulcrum body 420 are oriented at a non-zero degree relative to each other and separated by a handle body 402, e.g., of lesser cross-sectional width. For example, as discussed with respect to FIGS. 39A and 39B, handle 382 may be oriented relative to first fulcrum body 380 such that handle axis 393 intersects an axis 394 extending along the length of the body at an acute angle 396. When handle 382 includes the handle body 402 and the second fulcrum body 420, the second fulcrum body can be co-linear with handle body 402 or may be offset relative to the handle body. For example, an axis 404 extending along the length of the second fulcrum body may intersect the

handle axis 393 at an acute angle 406 ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees, as discussed above.

[0156] In yet other configurations where fulcrum 356 is configured with multiple ends of different dimensions, the ends may or may not be separated by a separate handle body 402. For example, first fulcrum body 380 and second fulcrum body 420 may be formed as a unitary structure (e.g., as opposed ends of a linear or curved unitary body).

[0157] FIGS. 43A and 43B are perspective and side views, respectively, of an example multidimensional fulcrum having ends of different dimensions. As shown, fulcrum 356 is composed of first fulcrum body 380 and second fulcrum body 420 as discussed above with respect to FIGS. 42A and 42B. In the configuration illustrated in FIGS. 43A and 43B, however, the first fulcrum body 380 and the second fulcrum body 420 are integrated together to form a unitary fulcrum body having two opposed ends of different dimensions. As illustrated, the unitary fulcrum body has a generally rectangular shape such that opposed ends of the fulcrum are separated by a linear length of the body. However, the body may be curved or non-linear in alternative configurations. As discussed above, the first fulcrum body 380 and the second fulcrum body 420 forming the respective portions of the unitary body can have a variety of different dimensions, and may or may not have surface features, to provide a clinician with a variety of fulcrum options in a single instrument.

[0158] Embodiments of the invention also include a disposable, sterile kit that includes an embodiment of a bone positioning guide and/or bone preparation guide and/or fulcrum described herein. Other components that may be included within the sterile kit include bone fixation devices.

[0159] Thus, embodiments of the invention are disclosed. Although the present invention has been described with reference to certain disclosed embodiments, the disclosed embodiments are presented for purposes of illustration, and not limitation, and other embodiments of the invention are possible. One skilled in the art will appreciate that various changes, adaptations, and modifications may be made without departing from the spirit of the invention.

CLAIMS:

1. A fulcrum for use in a bone realignment procedure comprising:

a body configured to be inserted in an intermetatarsal space between adjacent metatarsals, and

a handle operatively connected to the body,

wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

2. The fulcrum of claim 1, wherein the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion.

3. The fulcrum of claim 1, wherein the body defines an axis extending along the length of the body, the handle defines a handle axis projecting at the non-zero degree angle from the body, and an angle between the axis of the body and the handle axis ranges from 20 degrees to 75 degrees.

4. The fulcrum of claim 3, wherein the angle ranges from 35 degrees to 55 degrees.

5. The fulcrum of claim 1, wherein

the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion;

the handle axis is defined by the handle body;

the grip portion defines a grip axis, and

an angle between the grip axis and the handle axis ranges from 20 degrees to 75 degrees.

6. The fulcrum of claim 5, wherein the grip axis is perpendicular to the axis defined by the body of the fulcrum.

7. The fulcrum of claim 1, wherein the body and the handle are formed as a unitary structure.

8. The fulcrum of claim 1, wherein the body is configured to be inserted between a first metatarsal and a second metatarsal.

9. The fulcrum of claim 1, wherein the body configured to be inserted in the intermetatarsal space is a first body, and the handle defines a second body also configured to be inserted in the intermetatarsal space, the first body and the second body varying in size.

10. The fulcrum of claim 9, wherein the first body has a maximum thickness, the second body has a maximum thickness, and the maximum thickness of the first body is less than the maximum thickness of the second body.

11. The fulcrum of claim 10, wherein

the first body extends from a leading end to a trailing end and the leading end of the first body is tapered, and

the second body extends from a leading end to a trailing end and the leading end of the second body is tapered.

12. The fulcrum of claim 1, wherein

the body has a first face on a side that the handle projects away from and a second face on an opposite side that the handle projects towards,

the first face has surface features configured to inhibit proximal to distal movement of the first face along a metatarsal against which the first face is positioned, and

the second face has surface features configured to inhibit dorsal to plantar movement of the second face along a metatarsal against which the second face is positioned.

13. The fulcrum of claim 12, wherein

the first face has multiple grooves extending lengthwise across the body, and

the second face has at least one of knurling and multiple grooves extending widthwise across the body.

14. The fulcrum of claim 1, wherein the body is rectangular shaped.

15. The fulcrum of claim 14, wherein the body extends from a leading end to a trailing end, the handle projects off the trailing end, and the leading end is tapered.

16. A multidimensional fulcrum comprising:

a fulcrum body having a length extending from a first end to a second end, a width, and a thickness,

wherein the first end of the fulcrum has a first thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a first size,

the second end of the fulcrum has a second thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a second size, and

the second thickness is greater than the first thickness.

17. The fulcrum of claim 16, wherein the first thickness and the second thickness each fall within a range from 1 millimeter to 10 millimeters, and the second thickness is at least 1 millimeter greater than the first thickness.

18. The fulcrum of claim 16, wherein the first end if tapered and the second end is tapered.

19. The fulcrum of claim 16, wherein the fulcrum body has a rectangular shape.

ABSTRACT

A technique for correcting a bone deformity, such as a bunion, may be performed using a fulcrum. In some examples, the technique involves inserting a fulcrum between a first metatarsal that is anatomically misaligned with respect to a second metatarsal. The technique further includes preparing an end of the first metatarsal and preparing an end of a medial cuneiform opposing the end of the first metatarsal. In addition, a distal portion of the first metatarsal is moved toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.

66845045.1

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**785**

Electronic Acknowledgement Receipt

EFS ID:	36348876
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
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Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	71212.4.8.6
Receipt Date:	21-JUN-2019
Filing Date:	
Time Stamp:	13:18:25
Application Type:	Utility under 35 USC 111(a)

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Payment was successfully received in RAM	$785
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	71212-4-8-6_ADS.pdf	1257067 3c47339c0b03672ca2427546ed906d0deb6d605d	no	11
Warnings:					
Information:					
2	Oath or Declaration filed	71212-4-8-6_Executed_Declarations.PDF	12230019 5c0e81fa6cffe558aa1f3fdbbbfdf89bc486e6c9	no	10
Warnings:					
Information:					
3	Drawings-other than black and white line drawings	71212-4-8-6_FIGS.PDF	670617 49cf85f37d58e742b37fb1ec2032265d023e0a9d	no	49
Warnings:					
Information:					
4	Transmittal Letter	71212-4-8-6_IDS_COMM.pdf	101572 41b18bcb509a1b09928d355179a87afd5bac02a5	no	1
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_IDS1.PDF	1042254 0e88037006e1ac61265c67904c05143b05248024	no	31
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_IDS2.PDF	1039455 4f1359e05b217ce0fbc462a9ecfb4d7ebc4f35fa	no	11
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8		TMCDIV.pdf	246988 be5748545d2715b306c64efb02b468de6c89bf1c	yes	39

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	35
Claims	36	38
Abstract	39	39

Warnings:					
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9	Fee Worksheet (SB06)	fee-info.pdf	35008 39a27c234238ba39080ca544ed7df880d1aa241a	no	2
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	22859		
Email Address	IP@fredlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM		
Attorney Docket Number	71212.4.8.6	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	49	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	22859		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Division of	15236464	2016-08-14
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15236464	Claims benefit of provisional	62293189	2016-02-09
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15236464	Continuation in part of	14981335	2015-12-28	9622805	2017-04-18

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14981335	Claims benefit of provisional	62205338	2015-08-14

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
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Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Treace Medical Concepts, Inc.		
Mailing Address Information For Applicant:			
Address 1	203 Fort Wade Road		
Address 2	Suite 150		
City	Ponte Vedra	**State/Province**	FL
Country	US	Postal Code	32081
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Paul J. LaVanway, Jr./			Date (YYYY-MM-DD)	2019-06-19
First Name	Paul J.	Last Name	LaVanway, Jr.	Registration Number	64610

Additional Signature may be generated within this form by selecting the Add button. Add

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	71212.4.8.6
	Application Number	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/236,464

filed on August 14, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: F. Barry Bays Date (Optional): _____

Signature: F. Barry Bays

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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LEGAL NAME OF INVENTOR

Inventor: Robert D. Santrock Date (Optional): 11/3/16

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

As the below named inventor, I hereby declare that:

This declaration is directed to: ☐ The attached application, or

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filed on August 14, 2016

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LEGAL NAME OF INVENTOR

Inventor: Paul Dayton Date (Optional): 10/31/16

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Daniel J. Hatch Date (Optional): 9/17/16

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: W. Bret Smith Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Carlos Eduardo Gil Date (Optional): 10/19/16

Signature: [signature]

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/236,464 filed on August 14, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

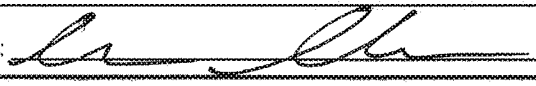
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Sean F. Scanlan Date (Optional): 10/18/2016

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/236,464 filed on August 14, 2016.

The above-identified application was made or authorized to be made by me.

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LEGAL NAME OF INVENTOR

Inventor: Joe William Ferguson Date (Optional): 10/18/16

Signature: Joe

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: John T. Treace Date (Optional): 10/19/16

Signature: John T. Treace

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

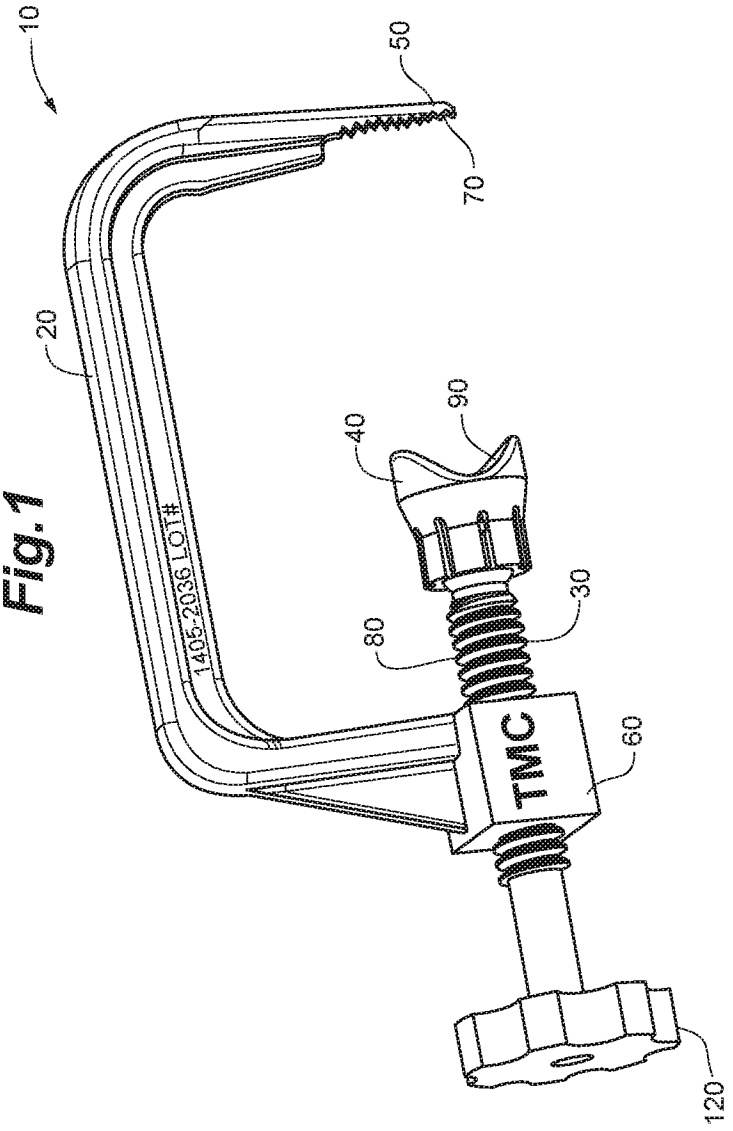


Fig.1

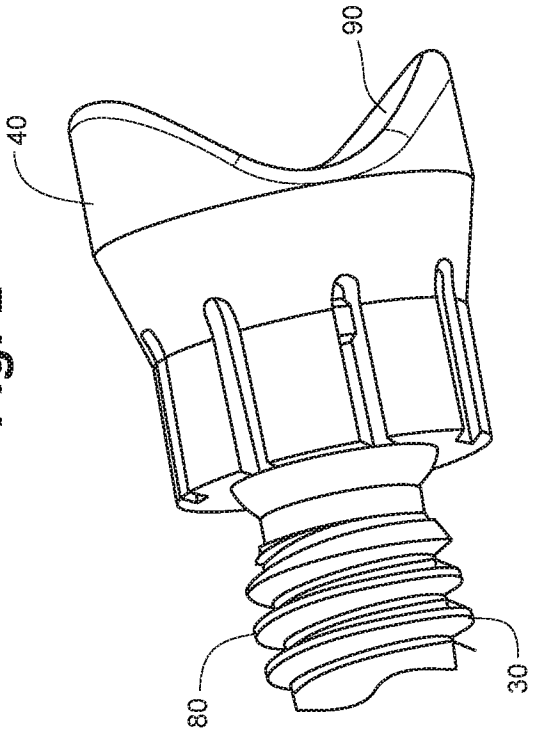


Fig. 2

Fig. 3A

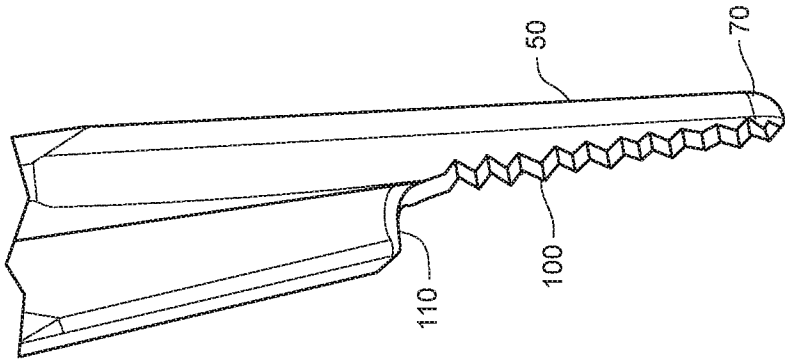


Fig. 3B

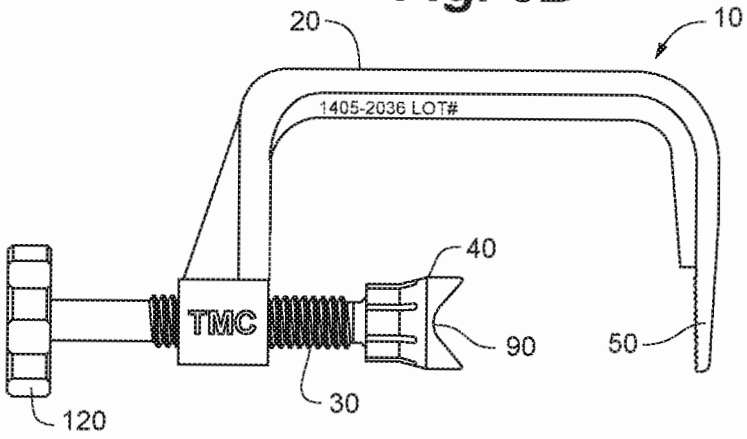

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1405-2036 LOT#
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TMC
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120
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Fig. 3C

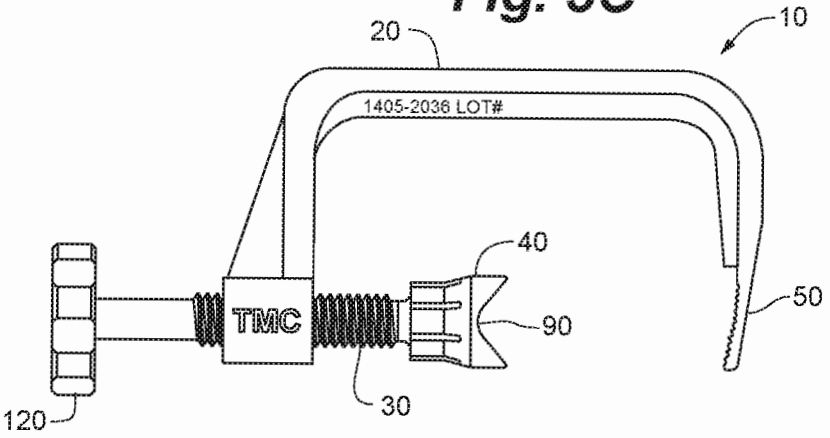

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1405-2036 LOT#
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TMC
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Fig. 4

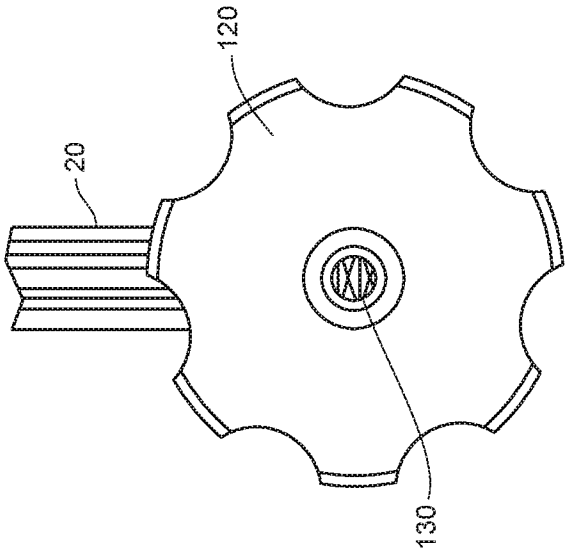


Fig. 5

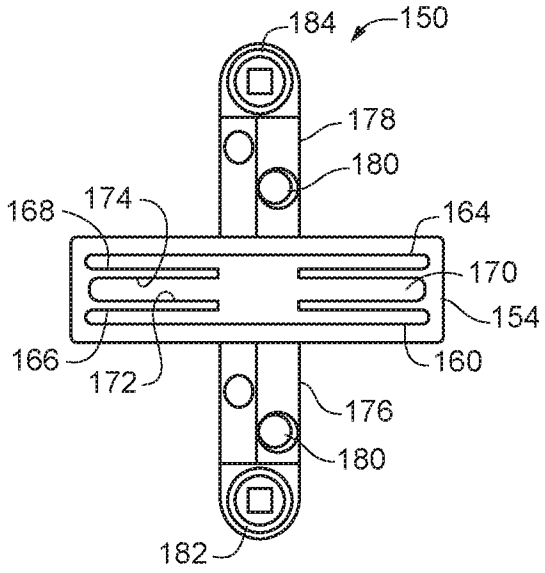
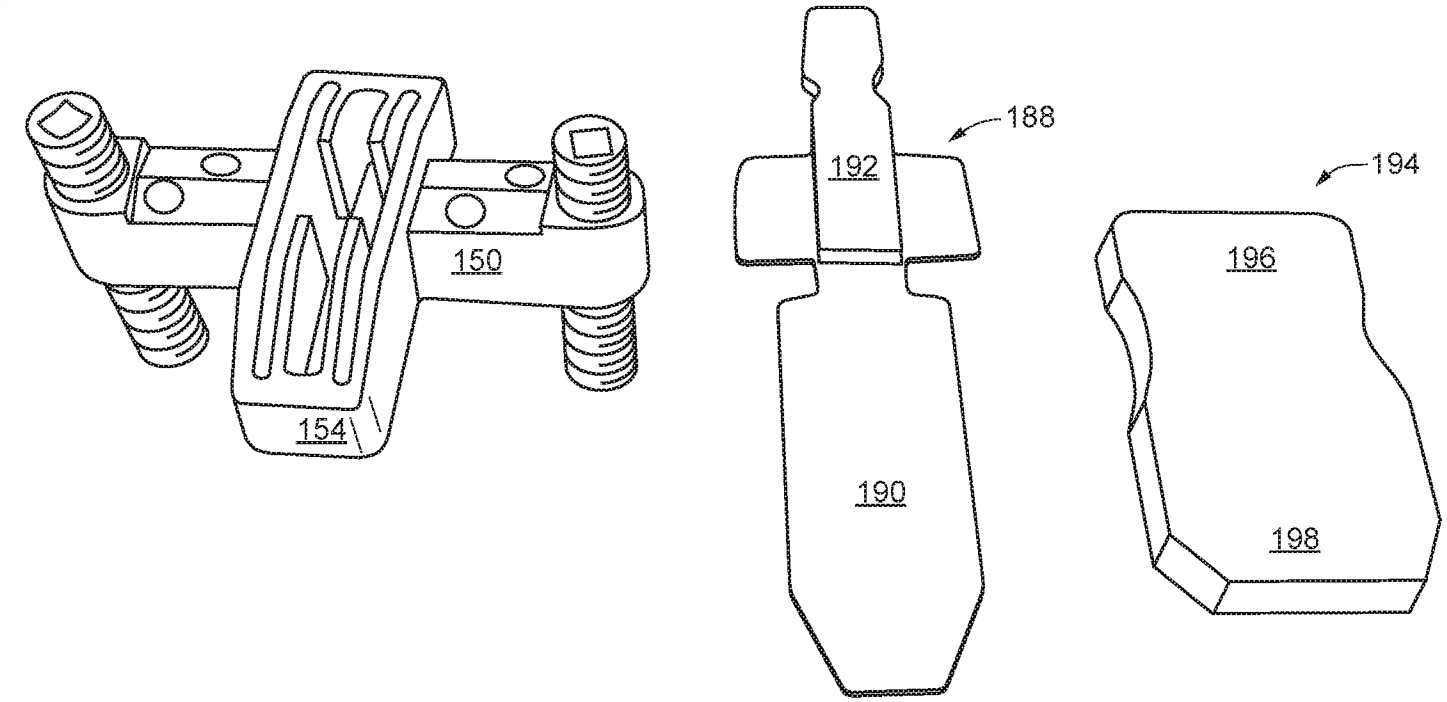


Fig. 6A



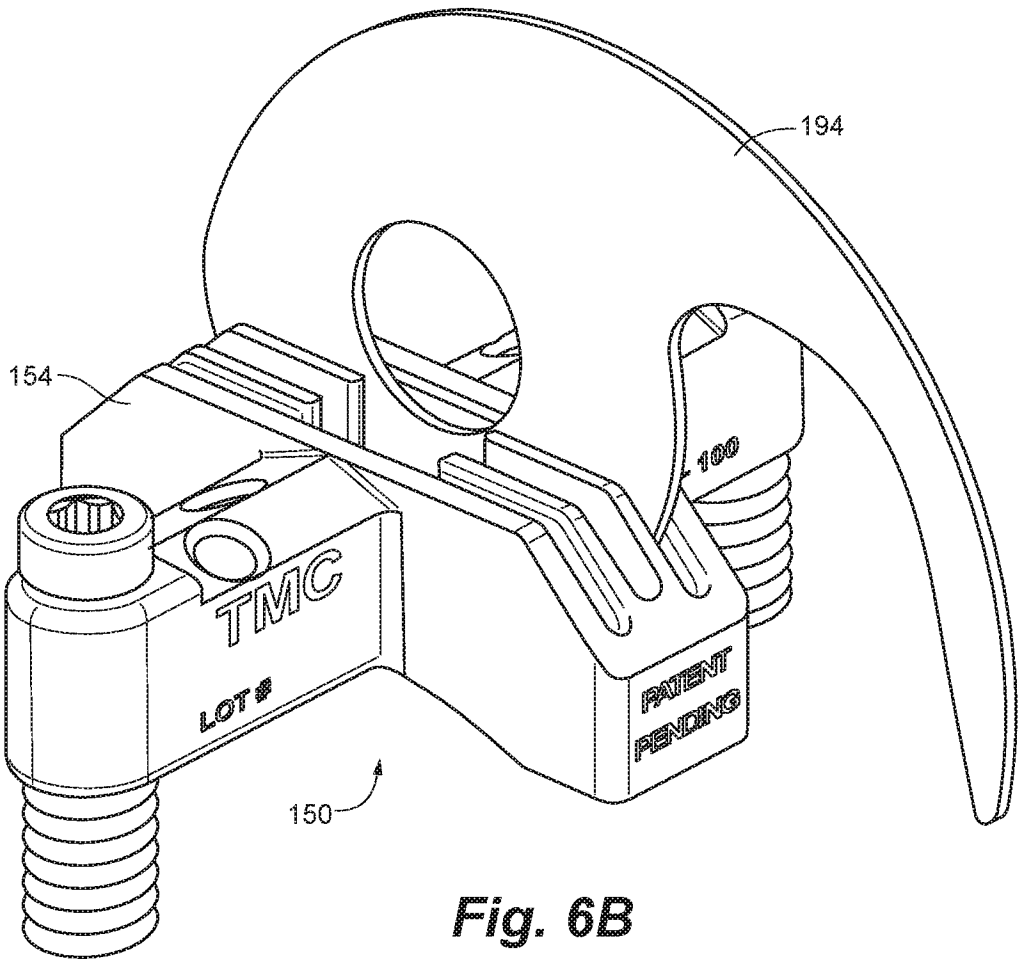


Fig. 6B

Fig. 7

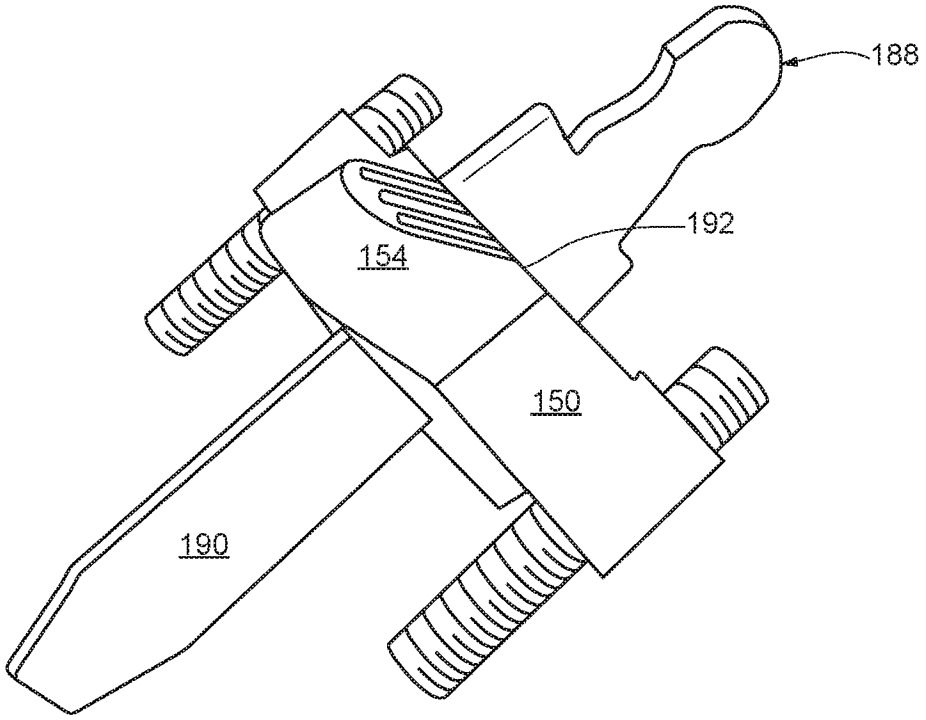


Fig. 8

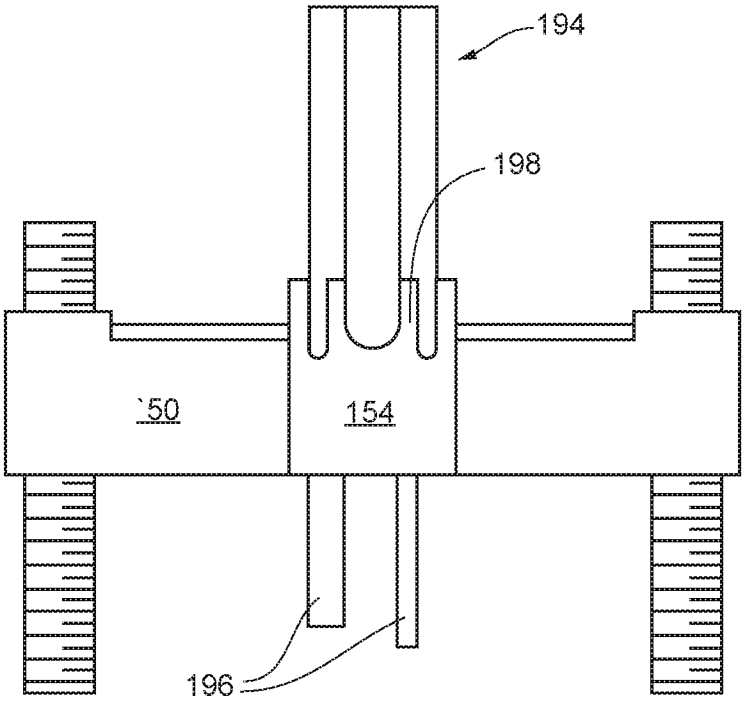


Fig. 9A

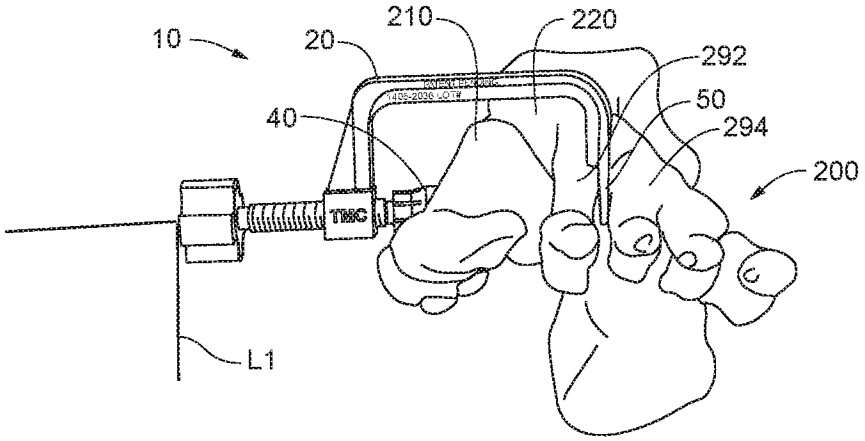

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Fig. 9B

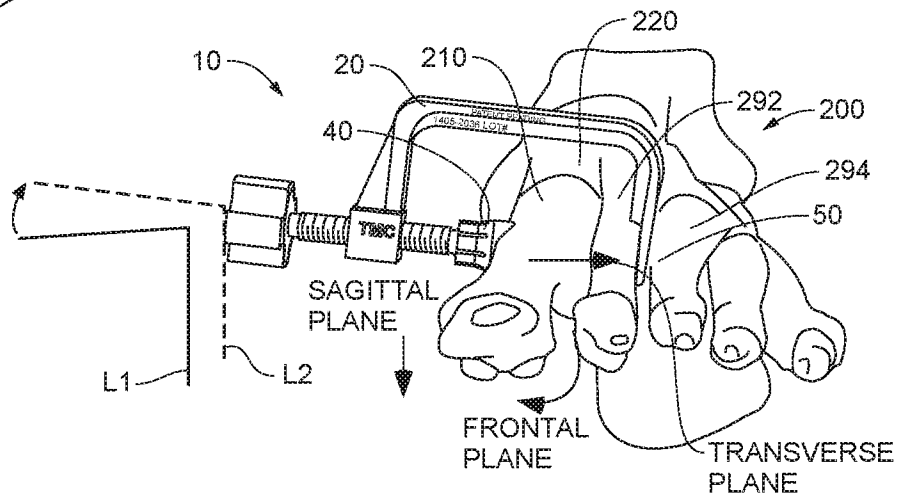

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SAGITTAL PLANE
L1
L2
FRONTAL PLANE
TRANSVERSE PLANE

Fig. 10A

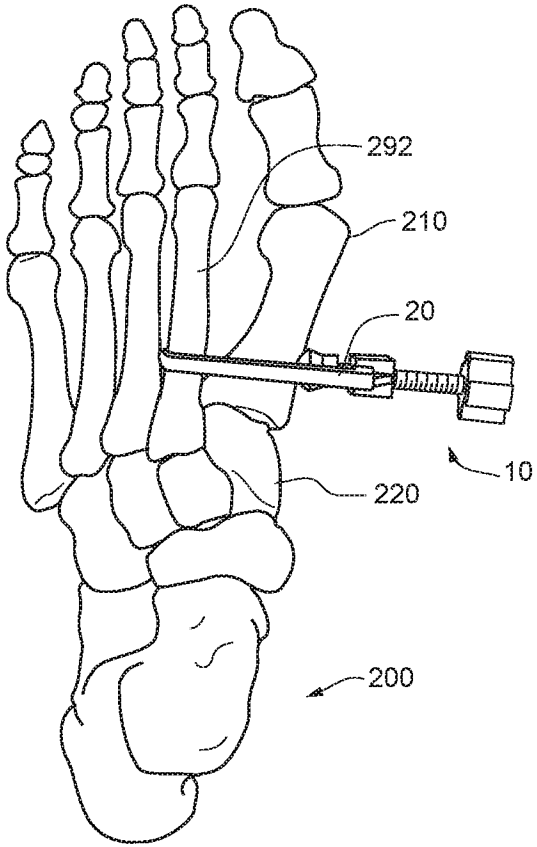


Fig. 10B

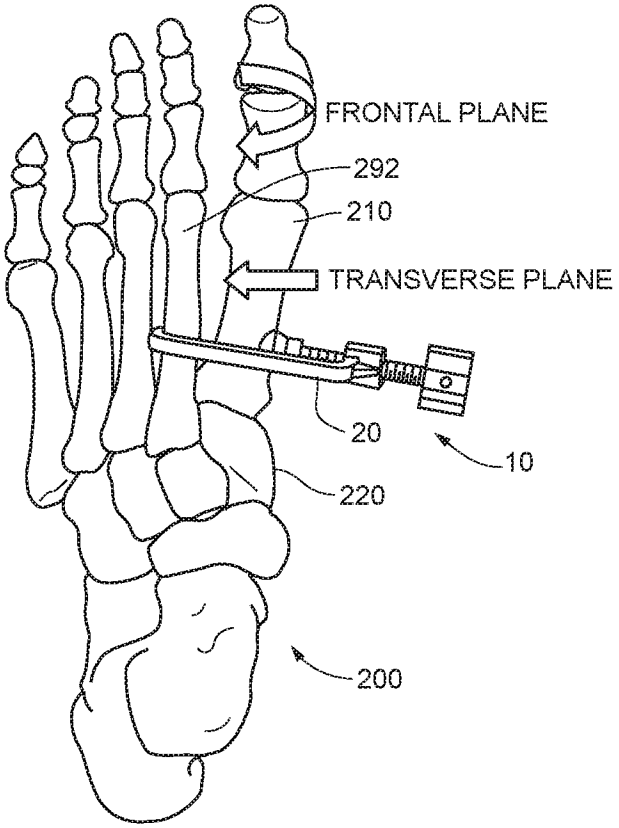


Fig. 11a

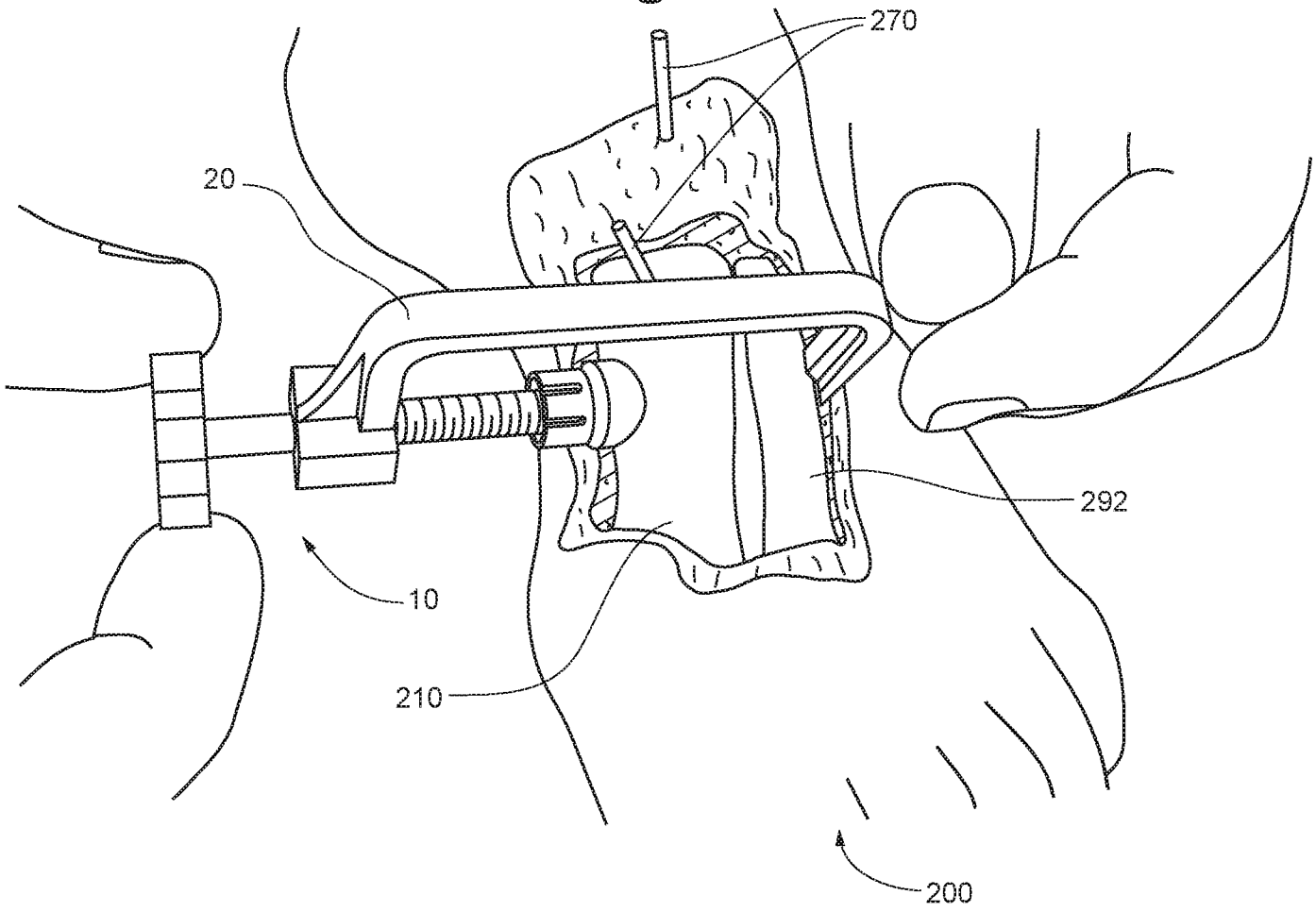


Fig. 11b

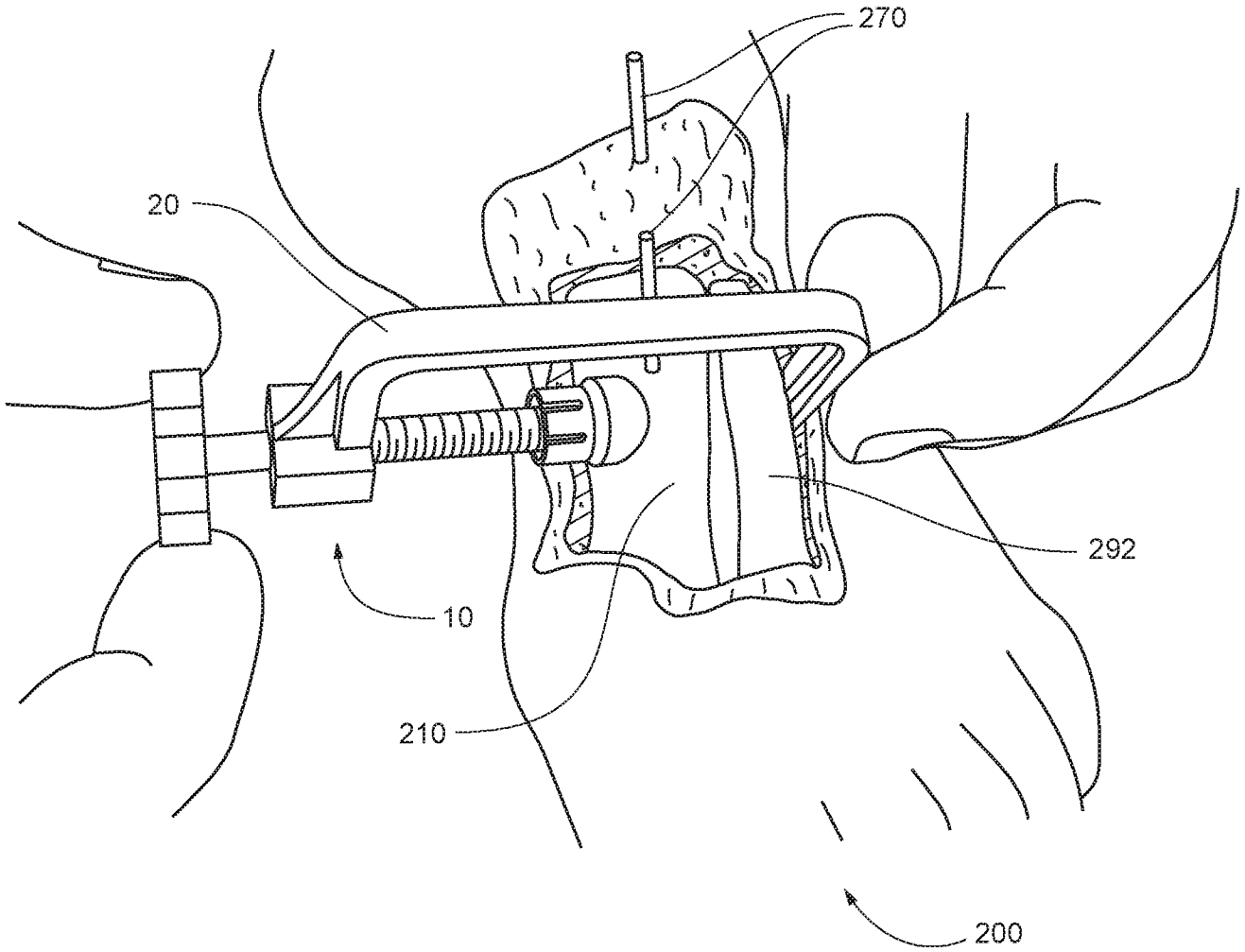


Fig. 11c

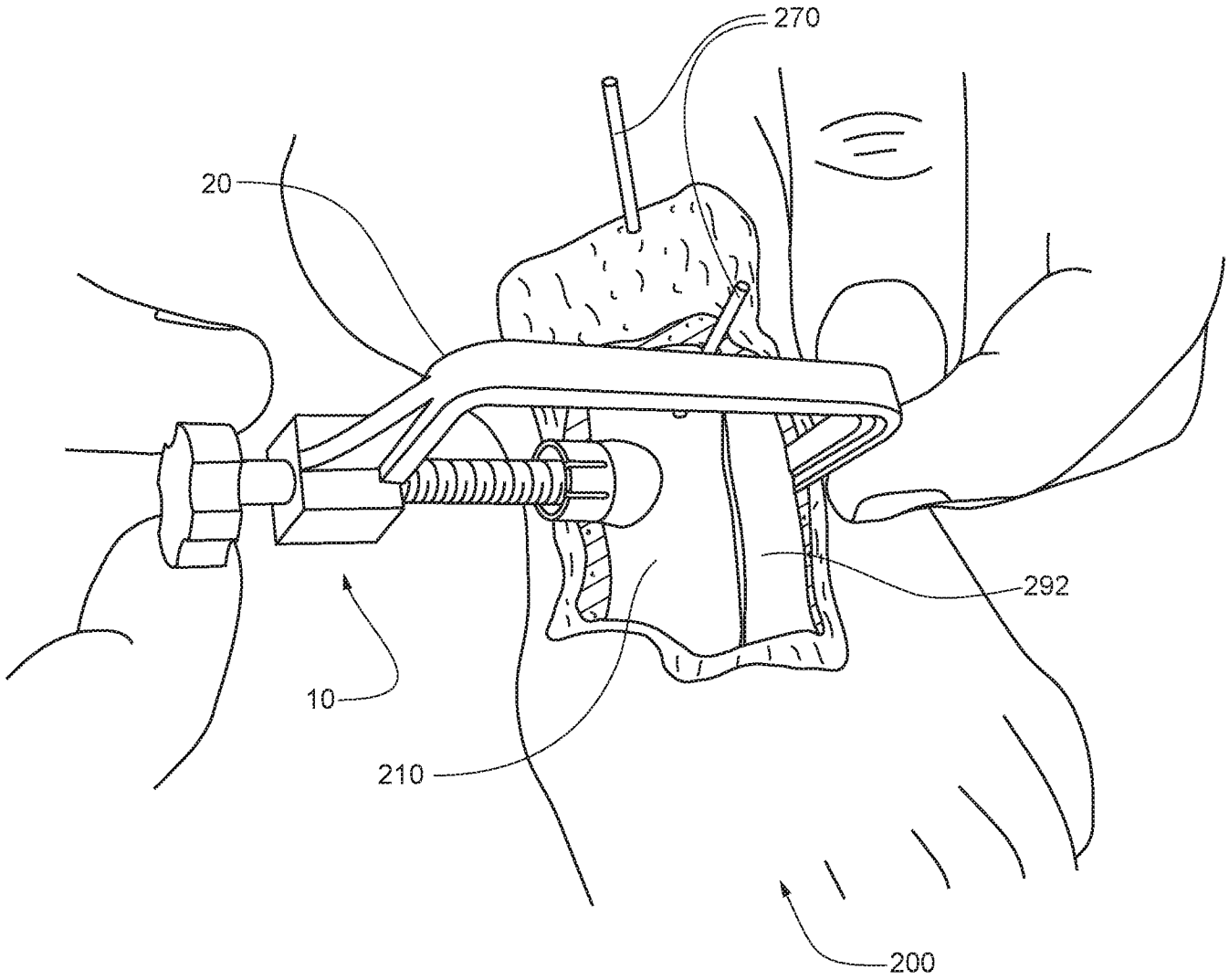


Fig. 12A

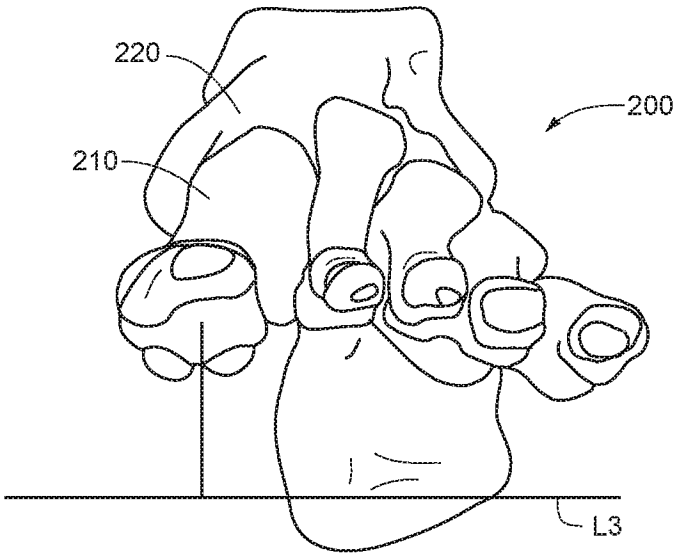


Fig. 12B

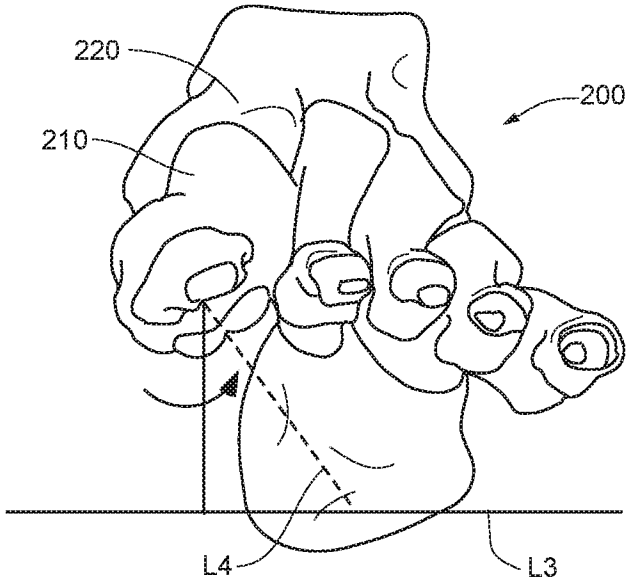


Fig. 13A

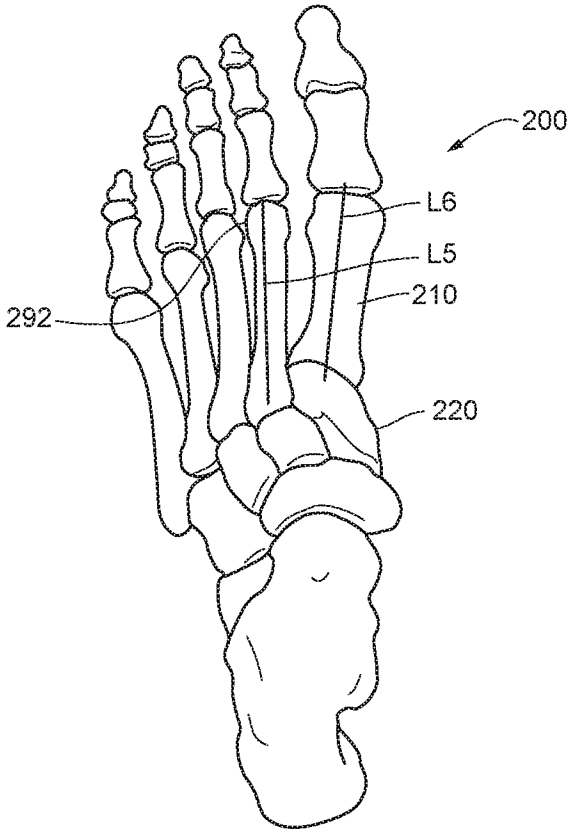


Fig. 13B

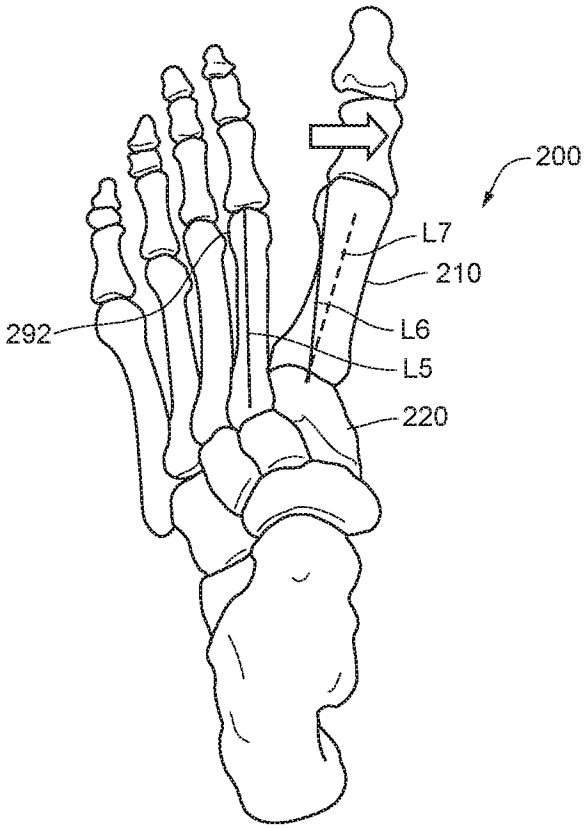


Fig. 14A

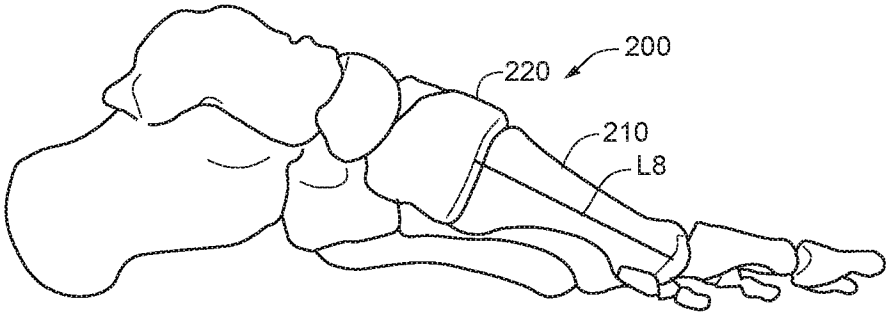


Fig. 14B

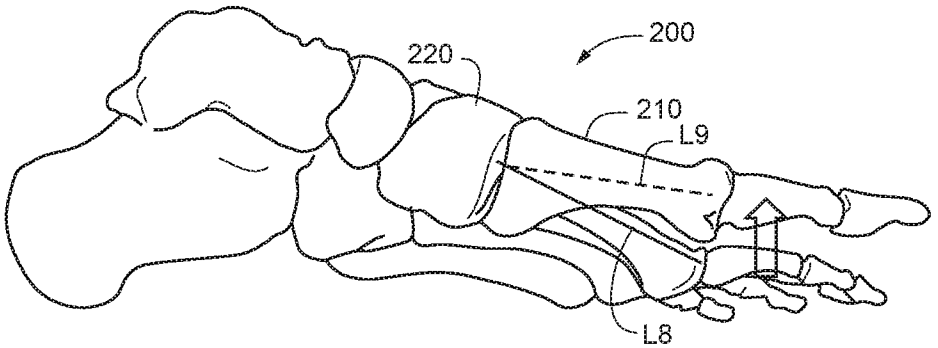


Fig. 15A

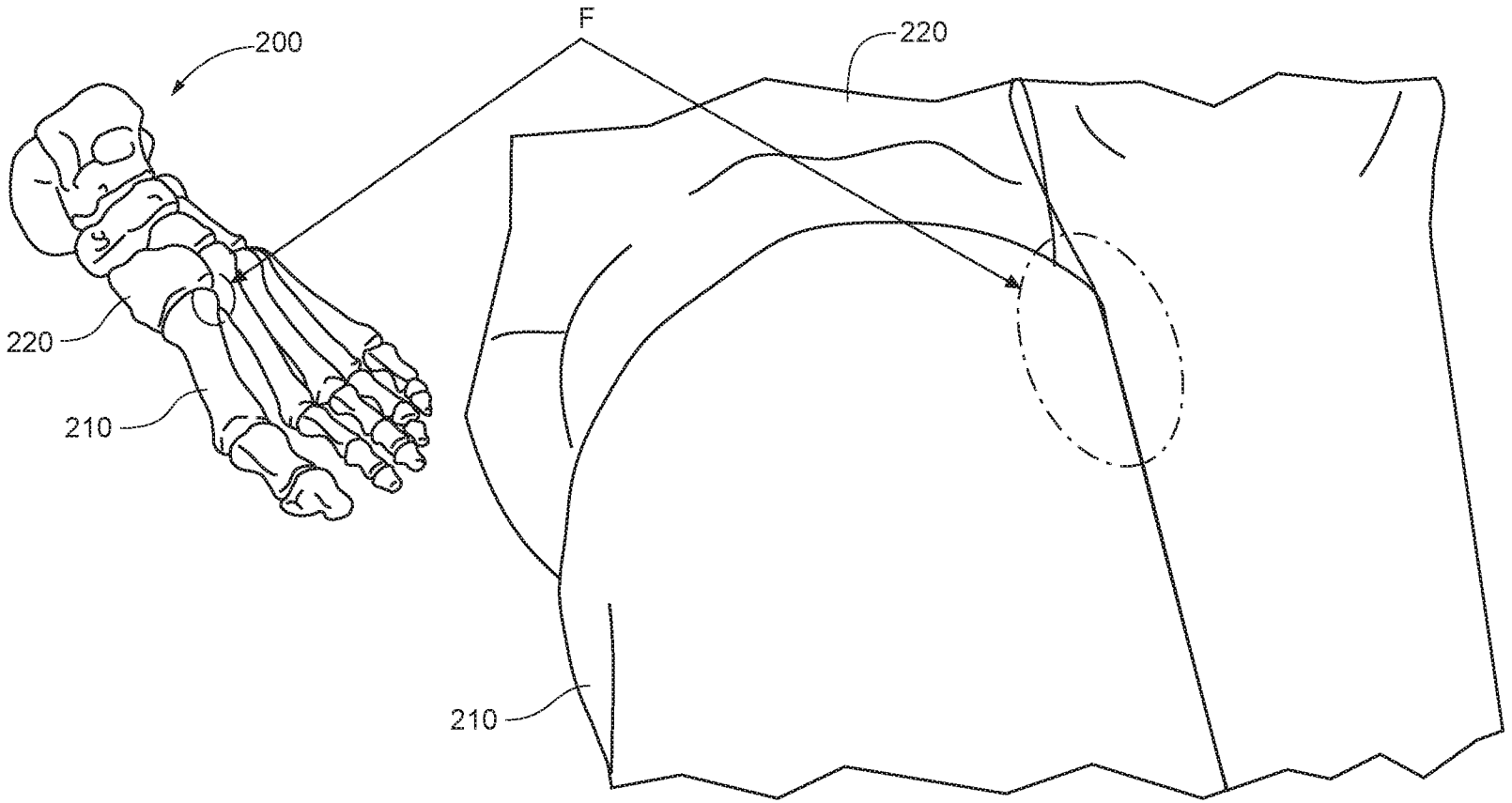


Fig. 15B

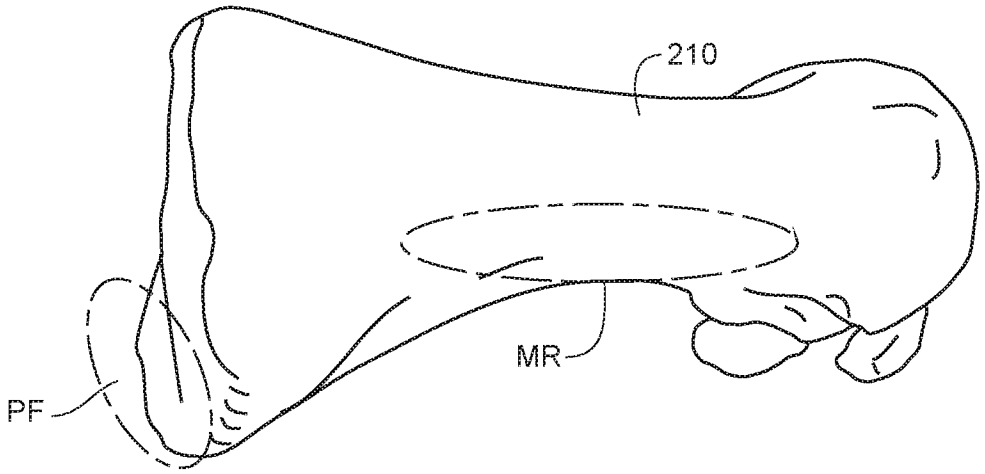


Fig. 16

Fig. 17

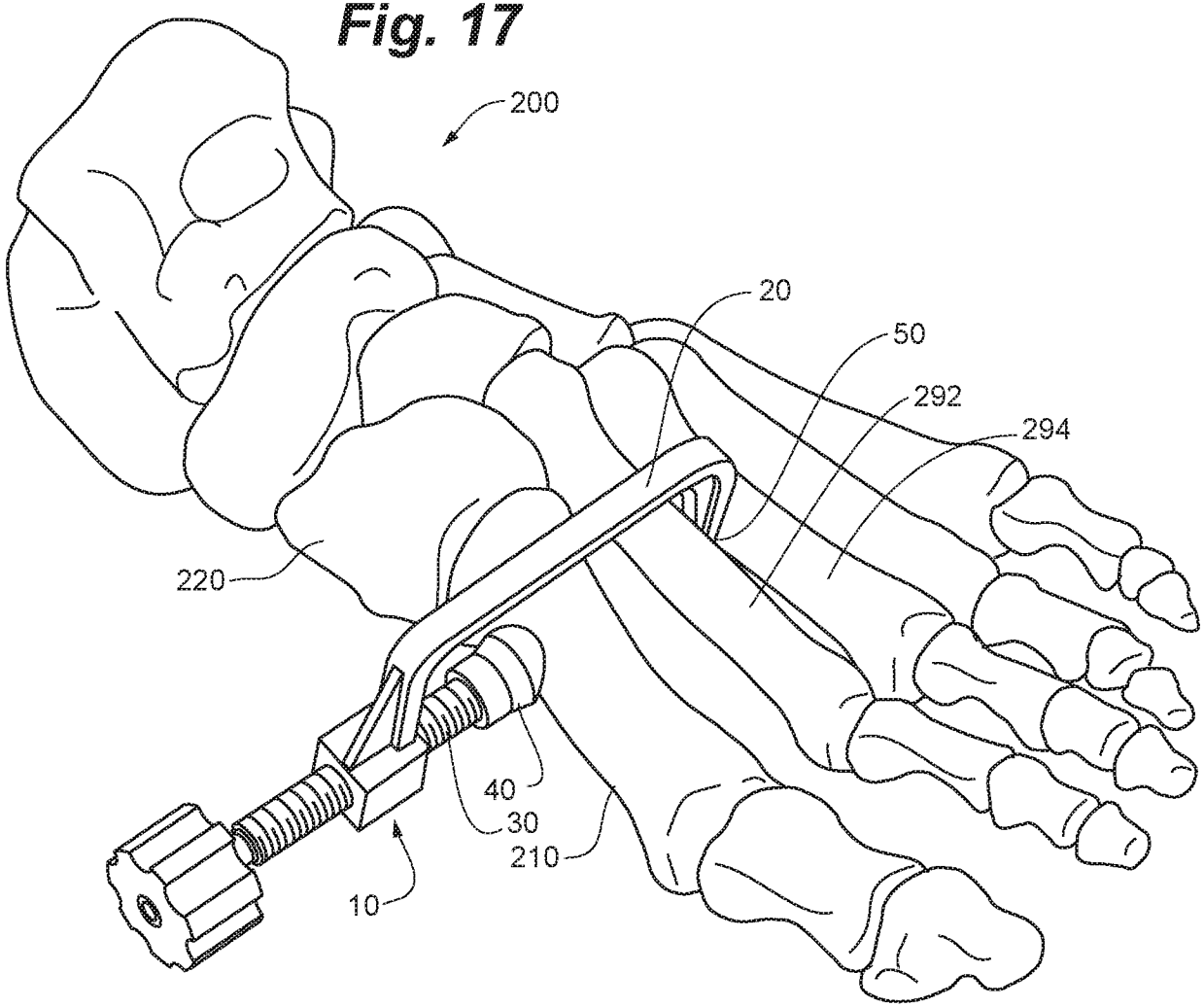


Fig. 18

Fig. 19

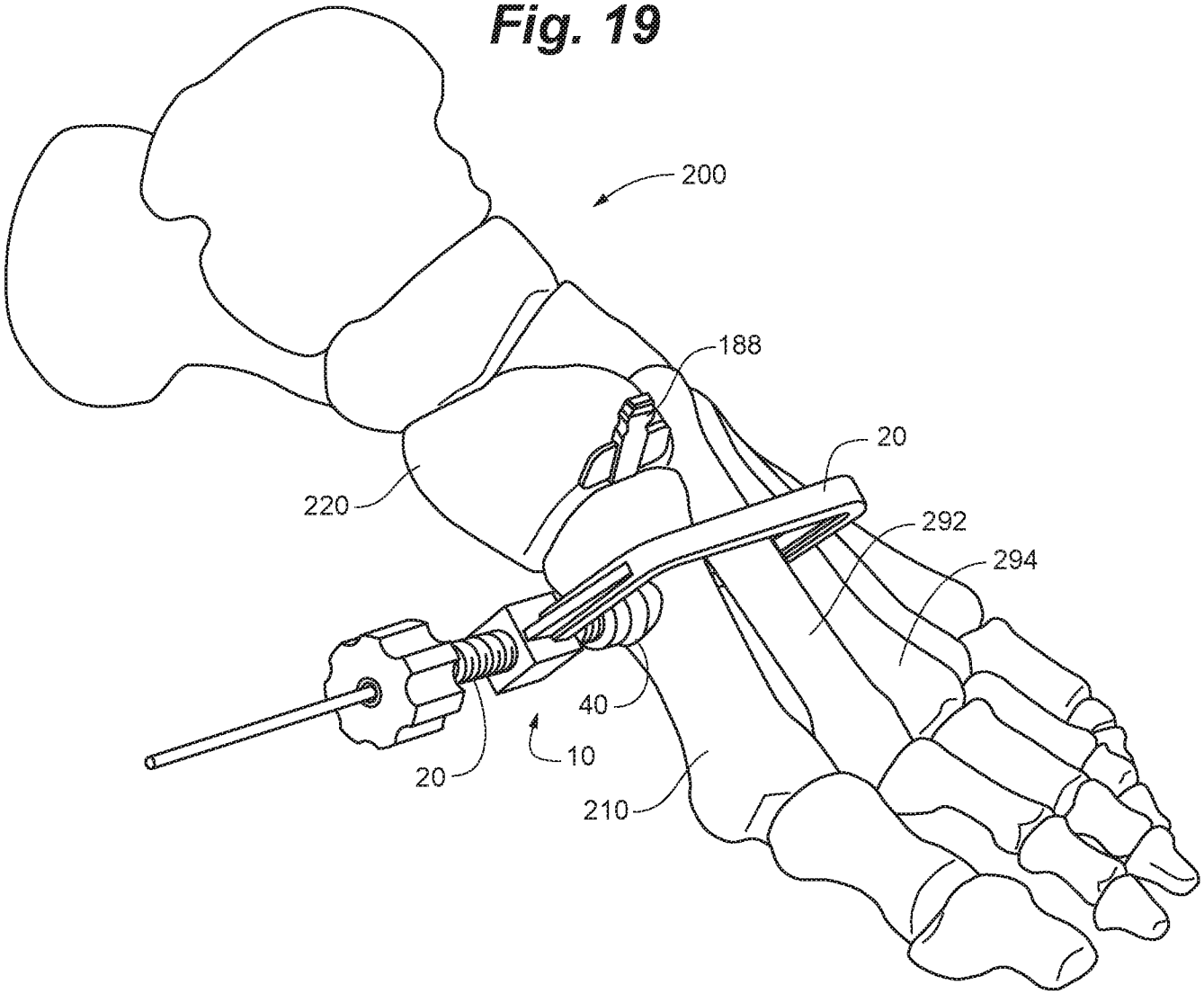


Fig. 20

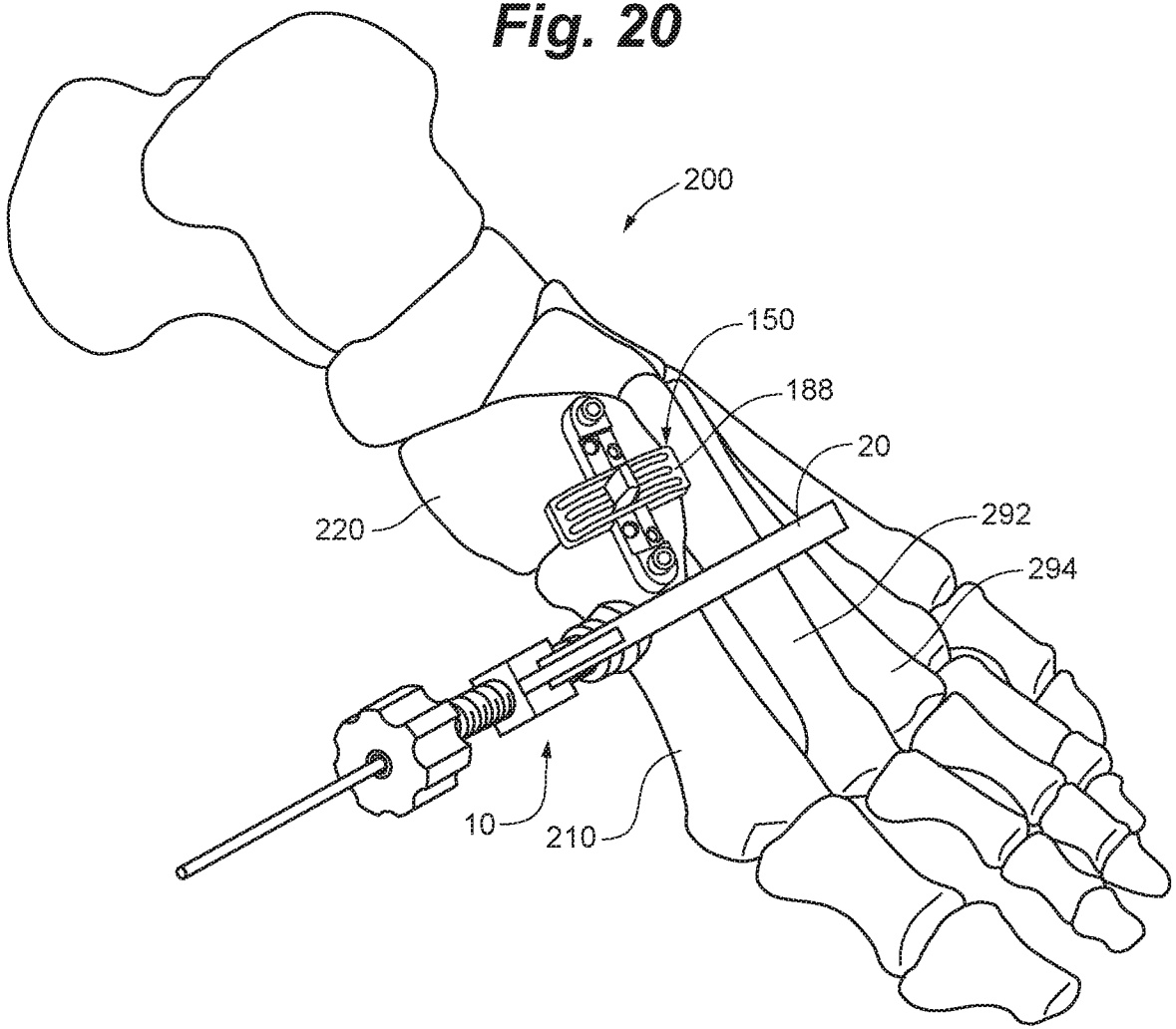


Fig. 21A

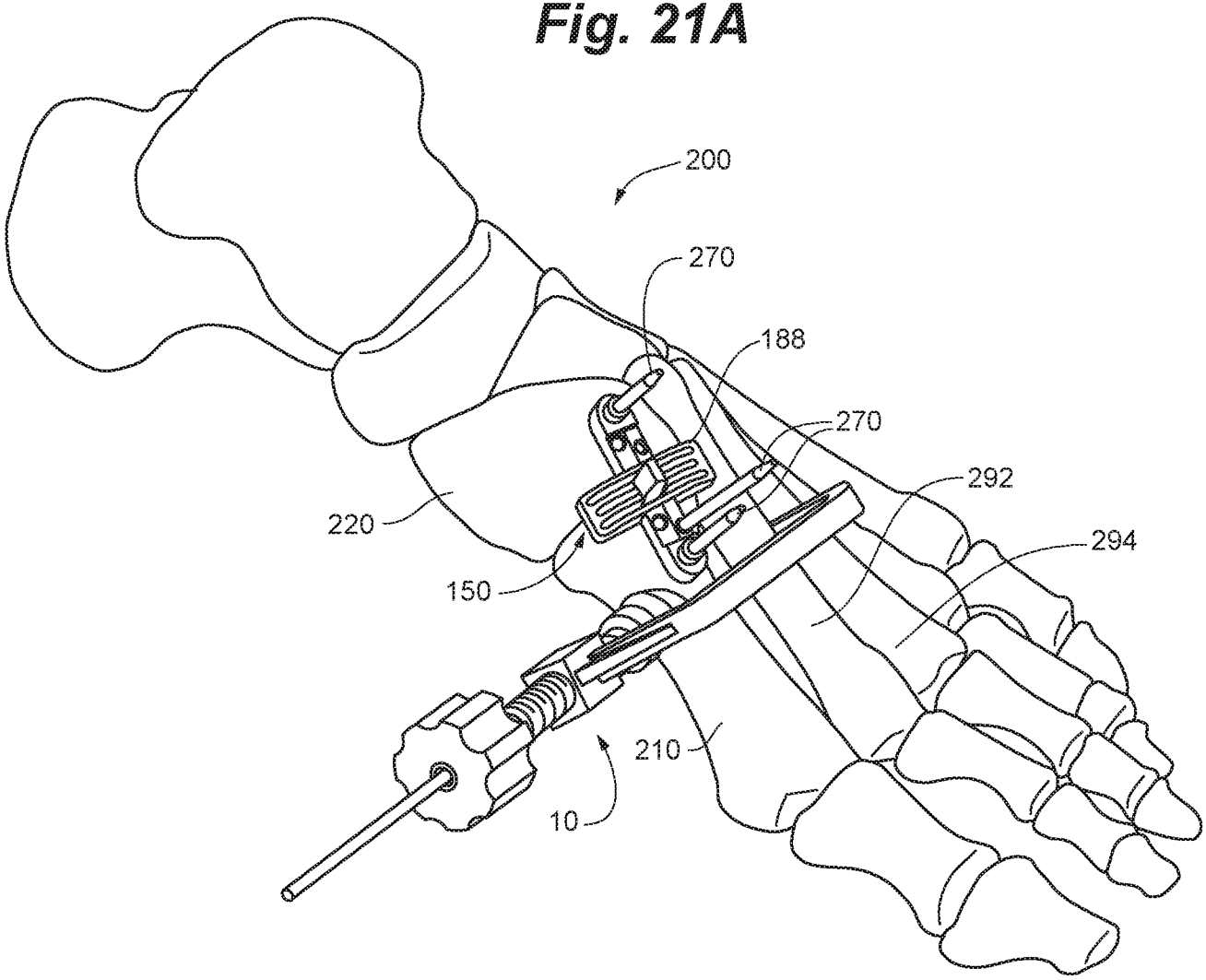


Fig. 21B

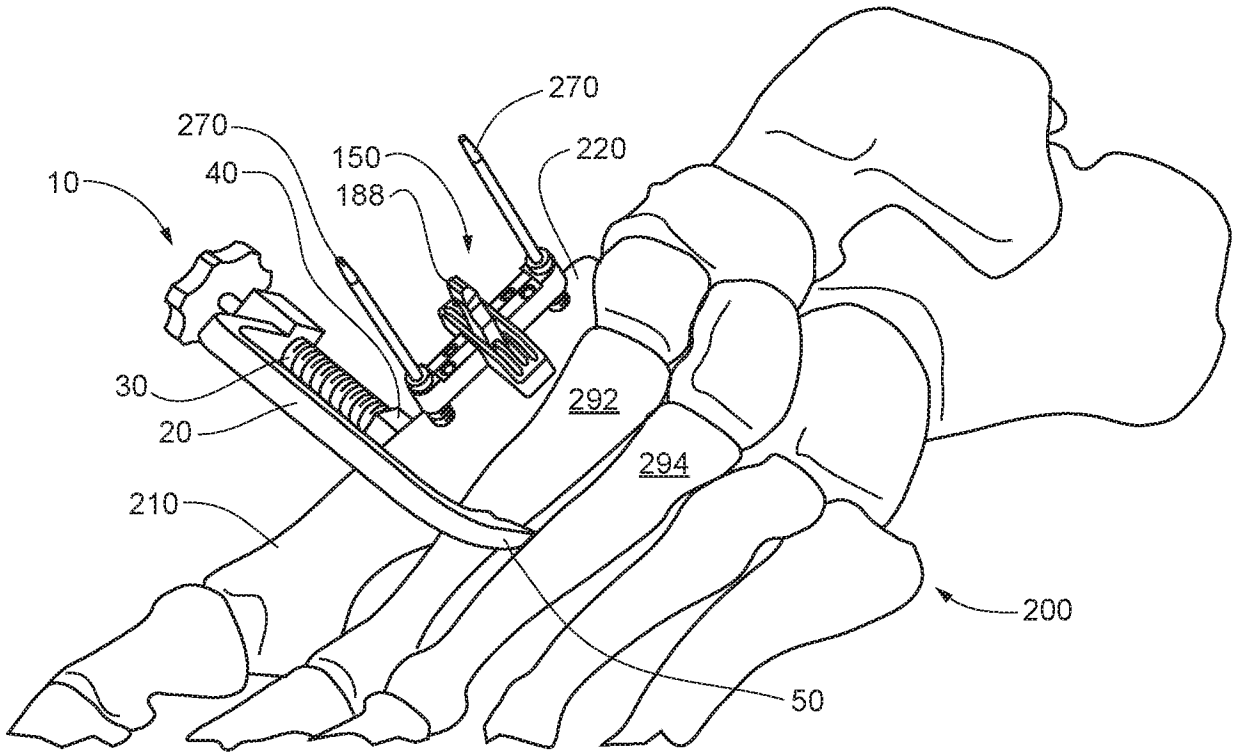


Fig. 22

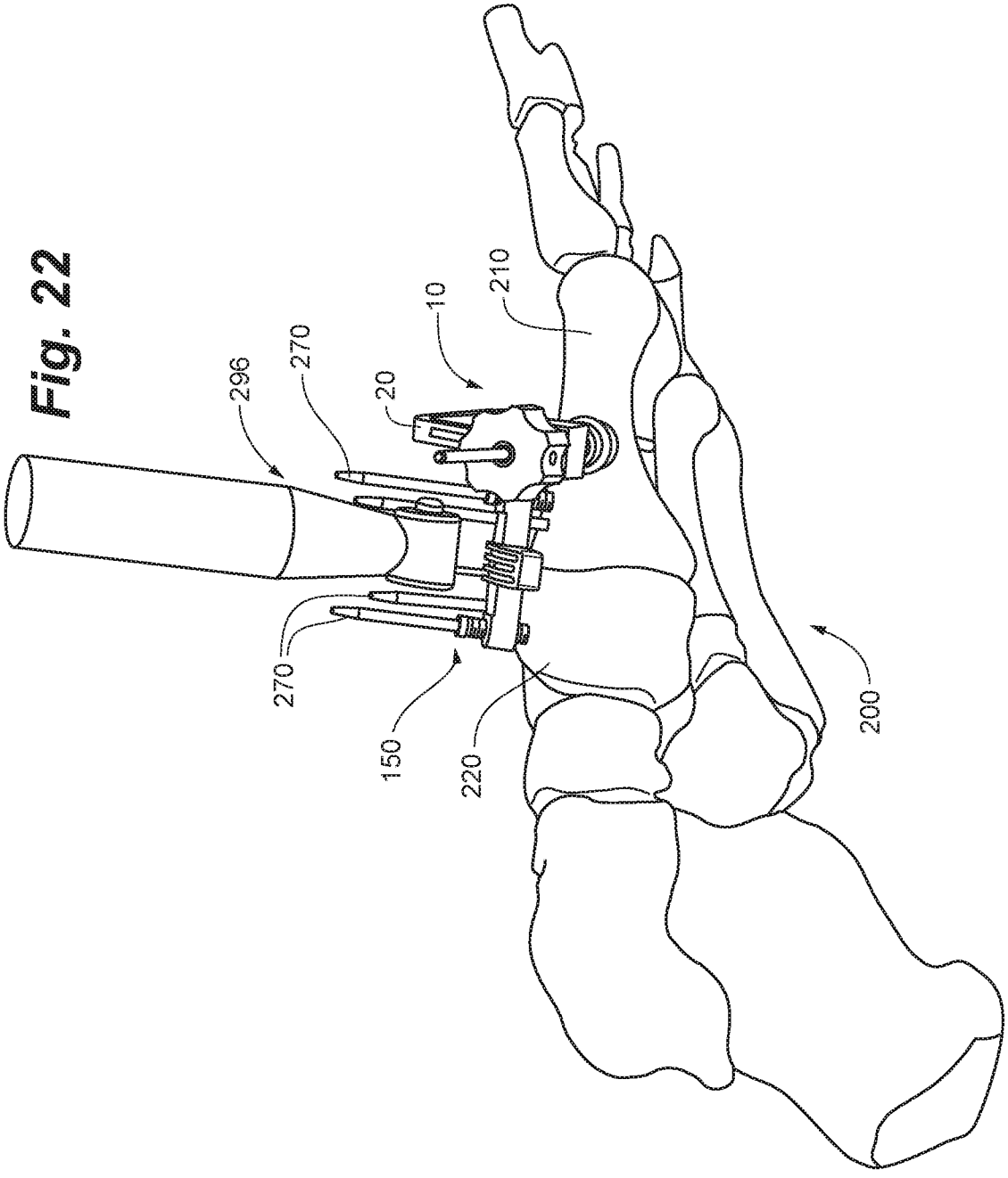


Fig. 23

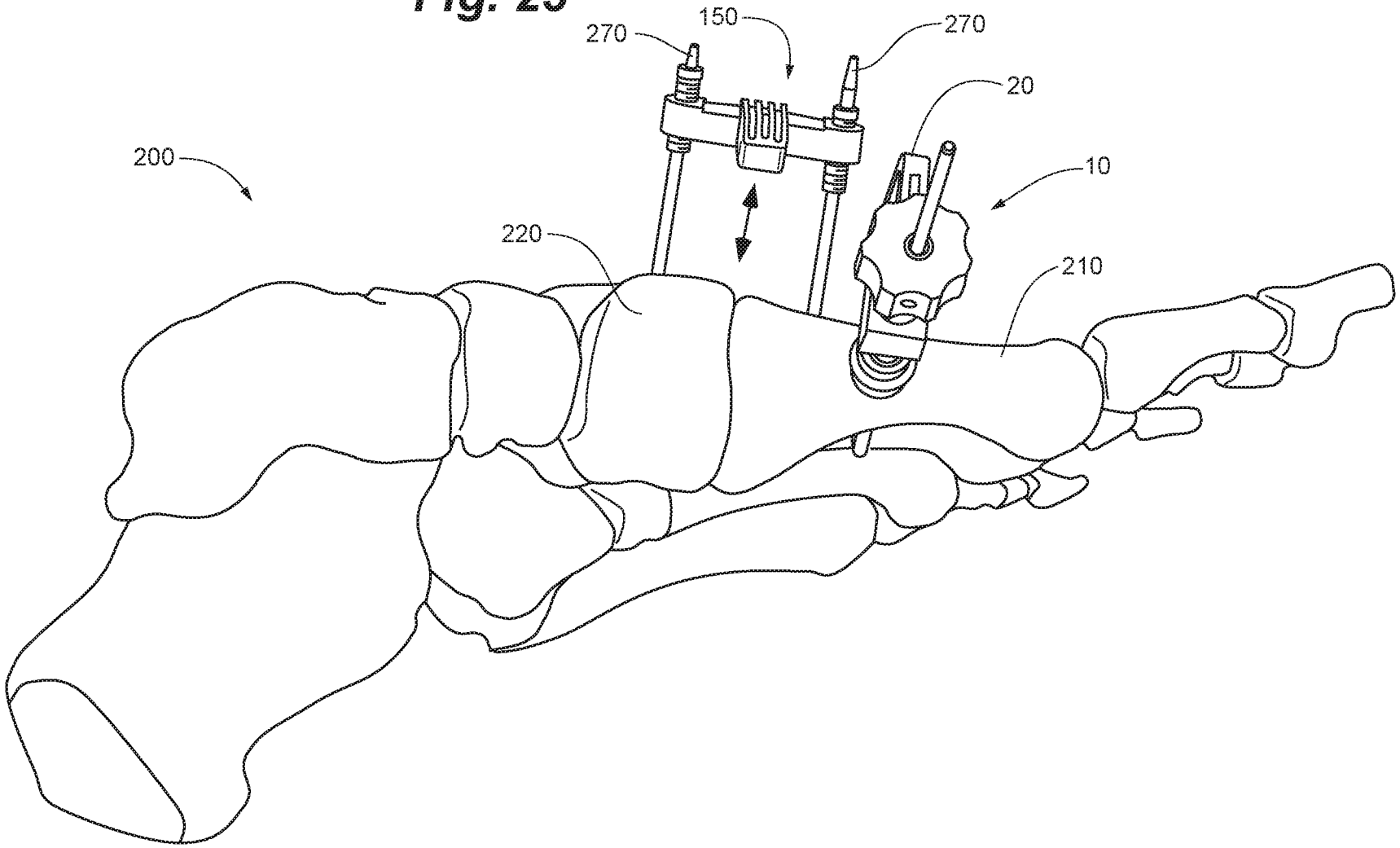


Fig. 24

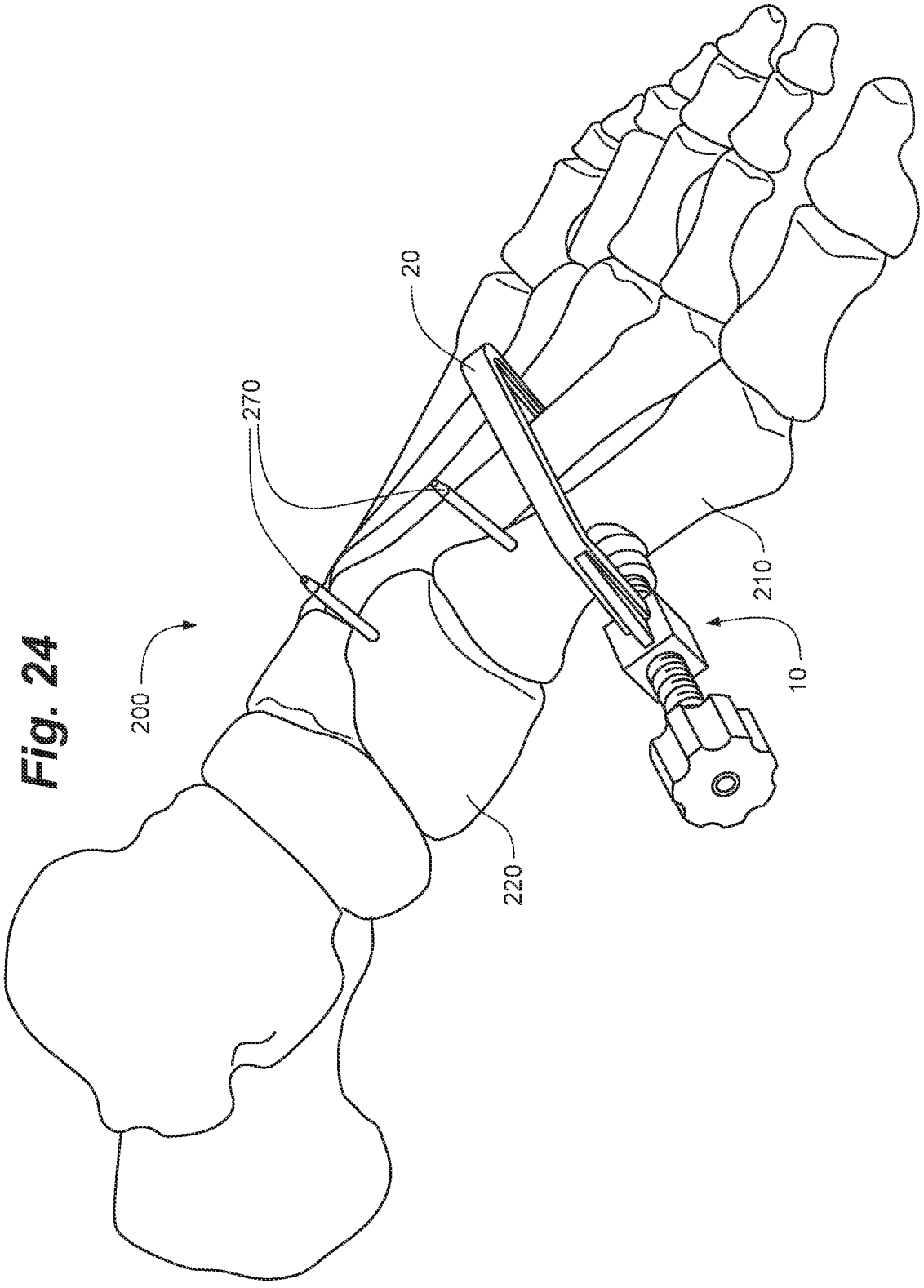


Fig. 25

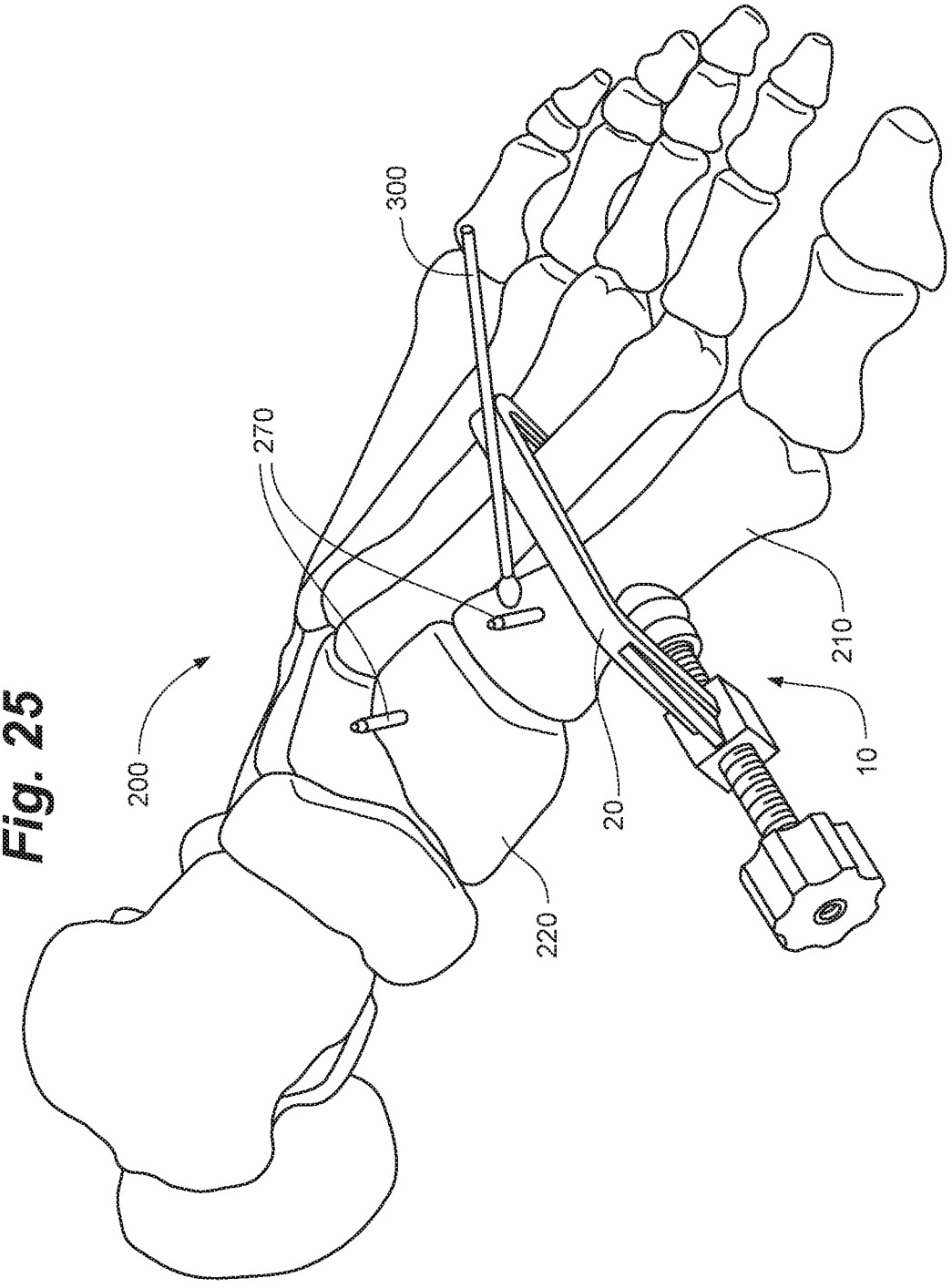


Fig. 26A

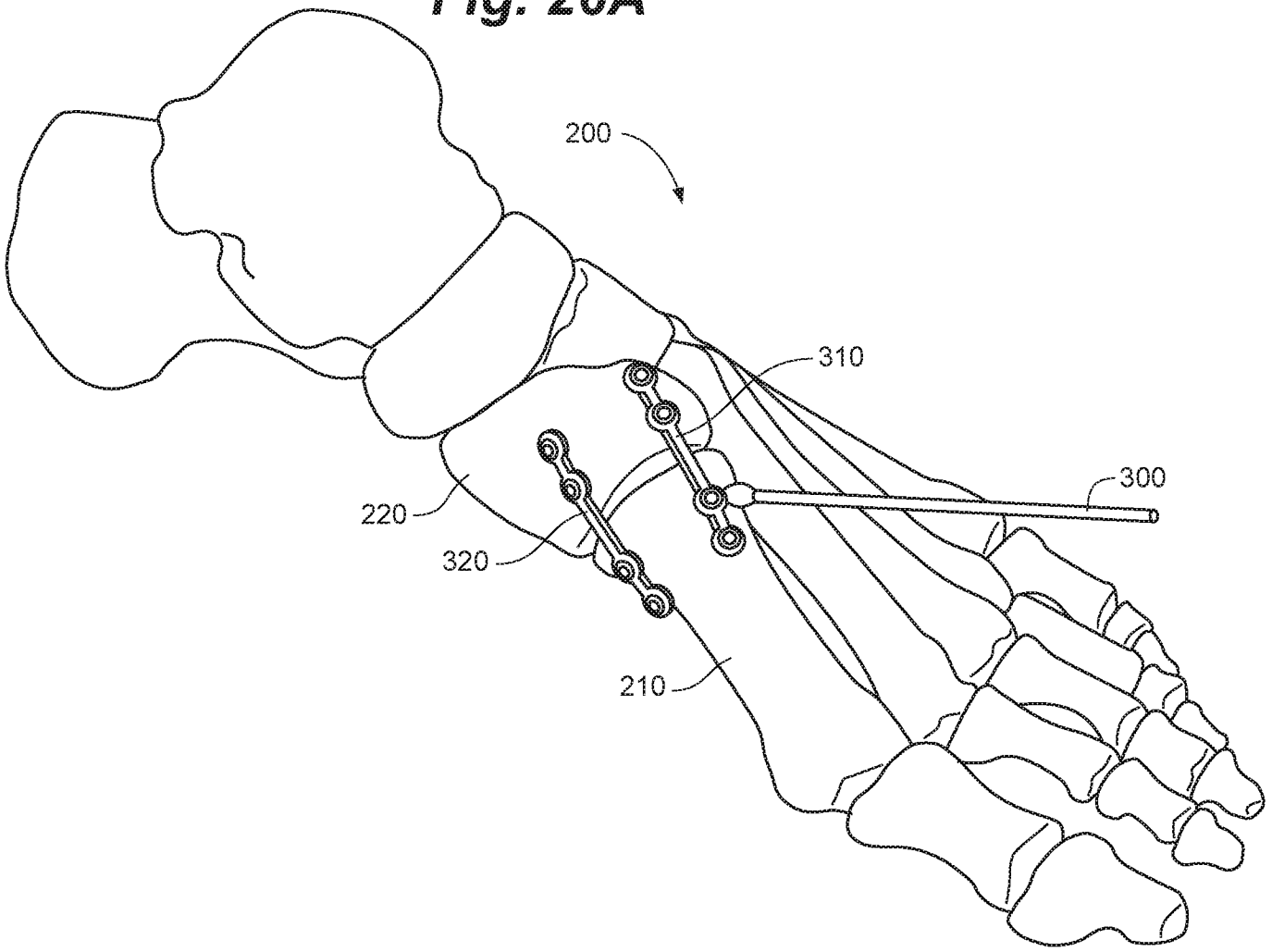


Fig. 26B

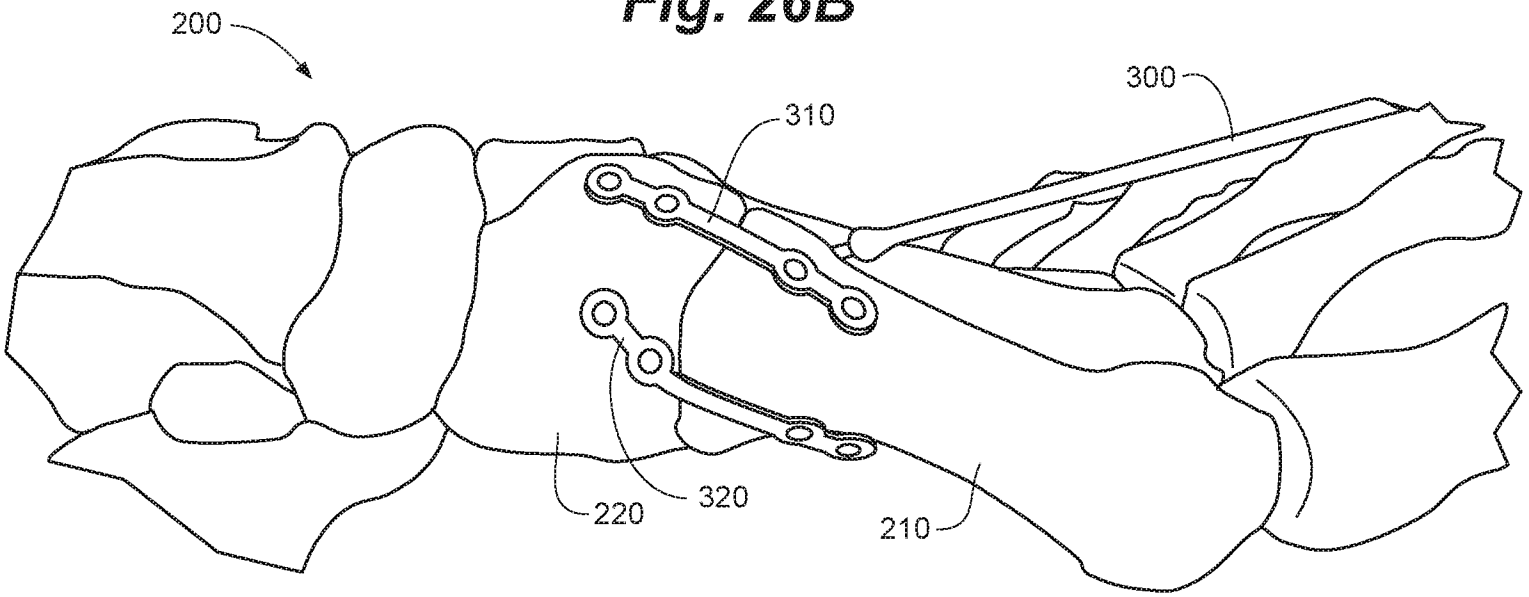


Fig. 27

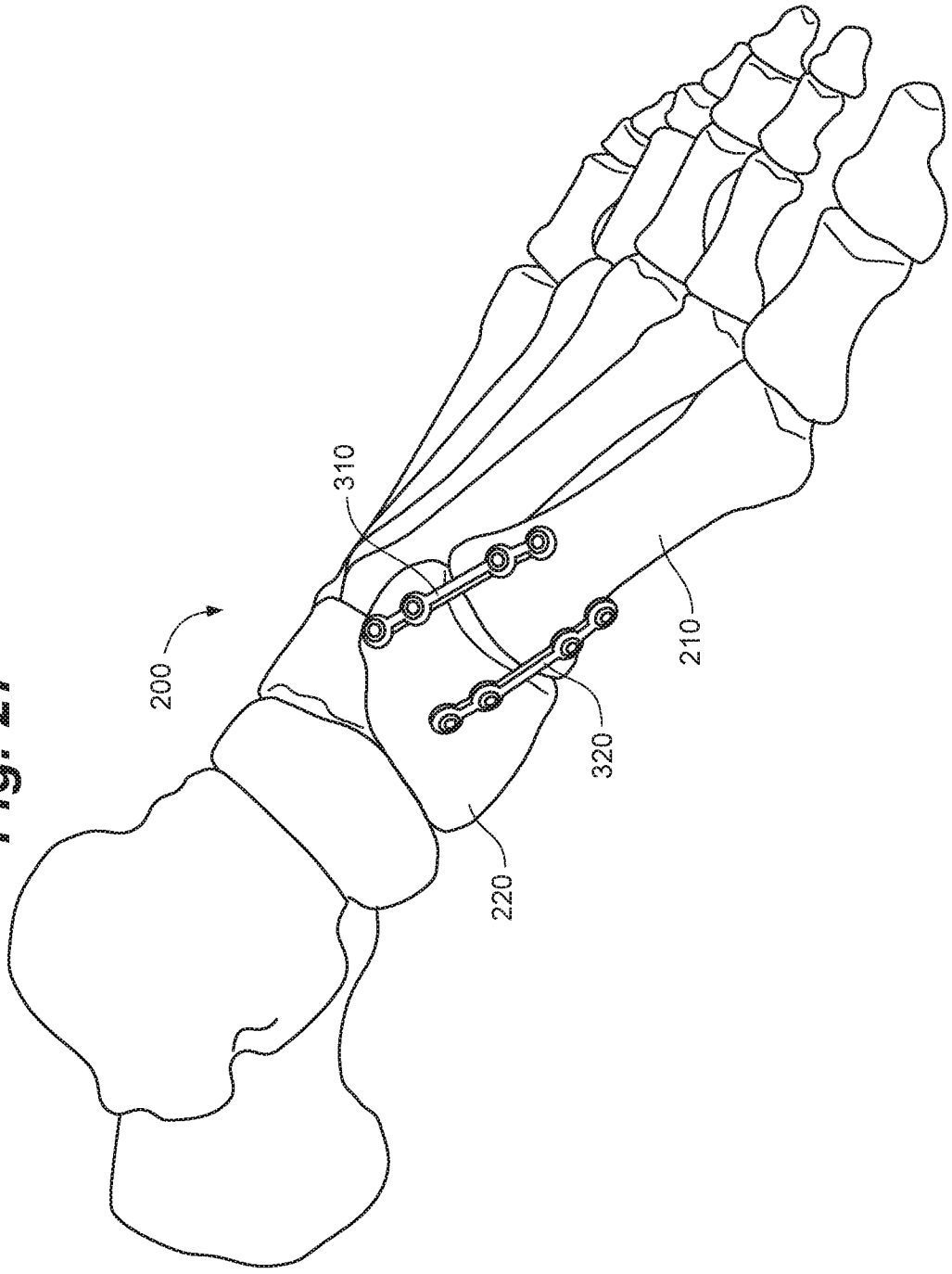


Fig. 28A

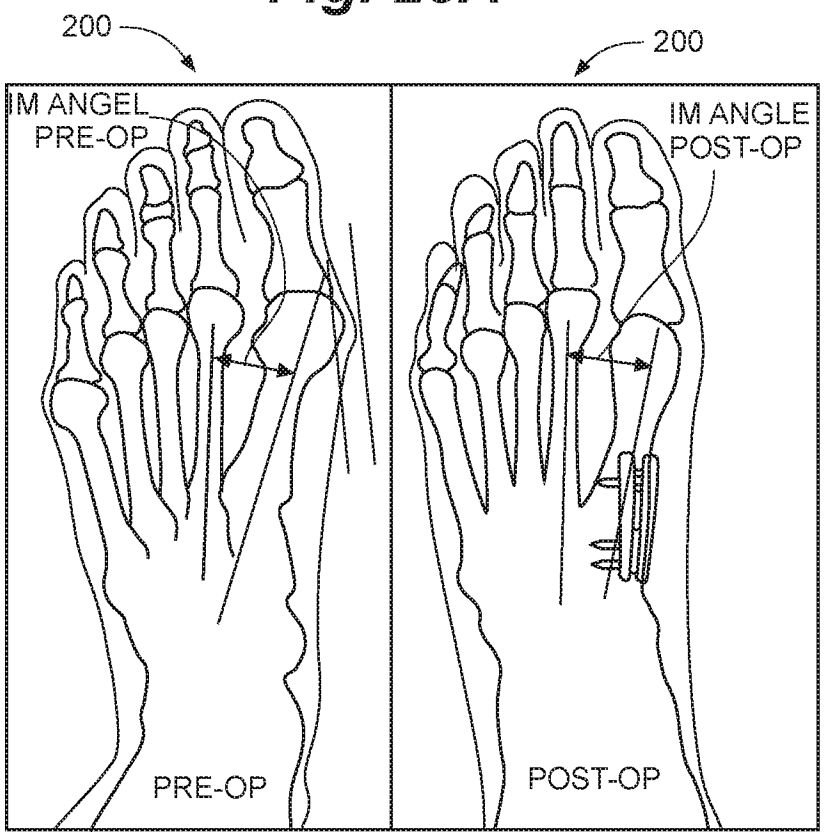


Fig. 28B

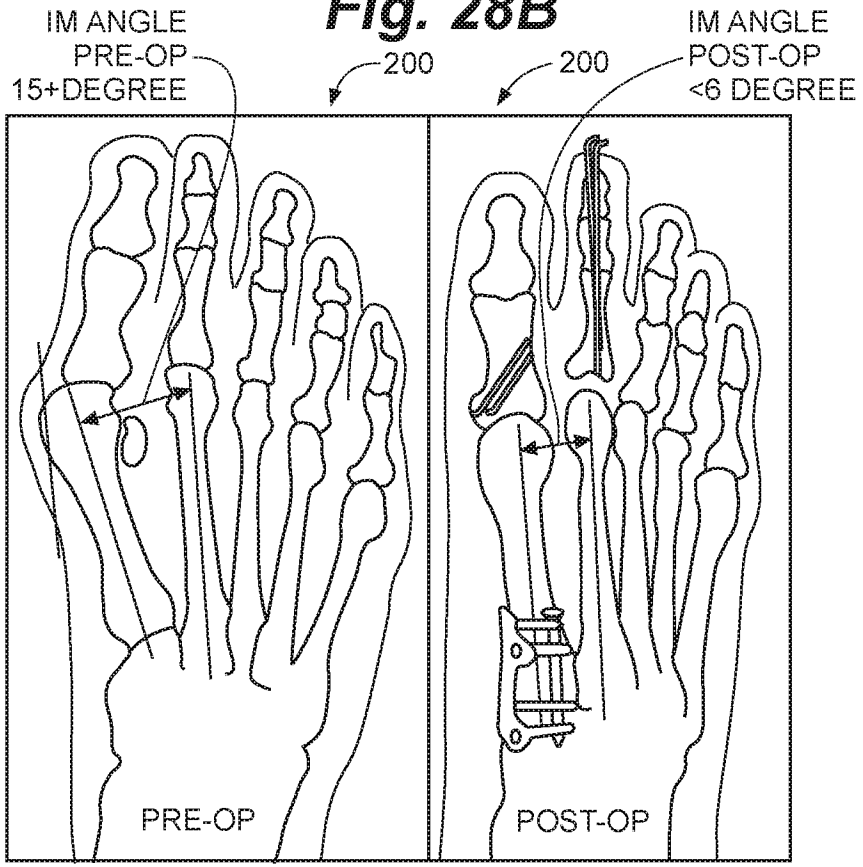


Fig. 29A

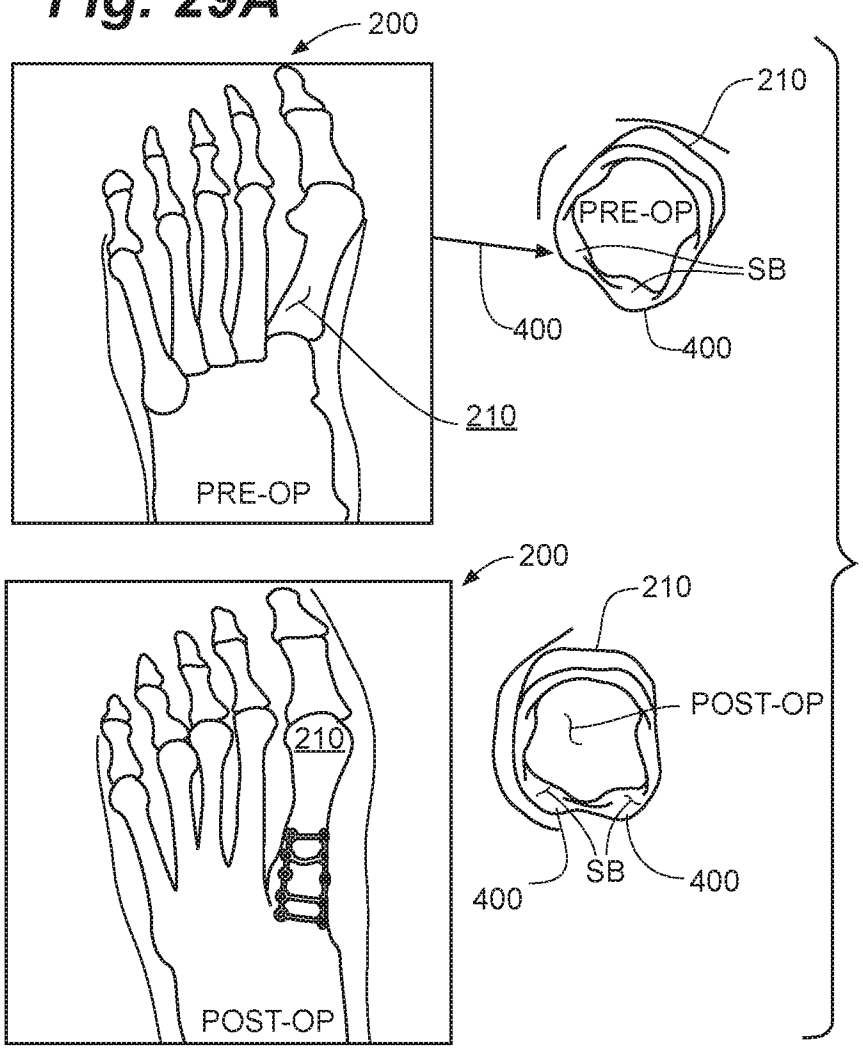


Fig. 29B

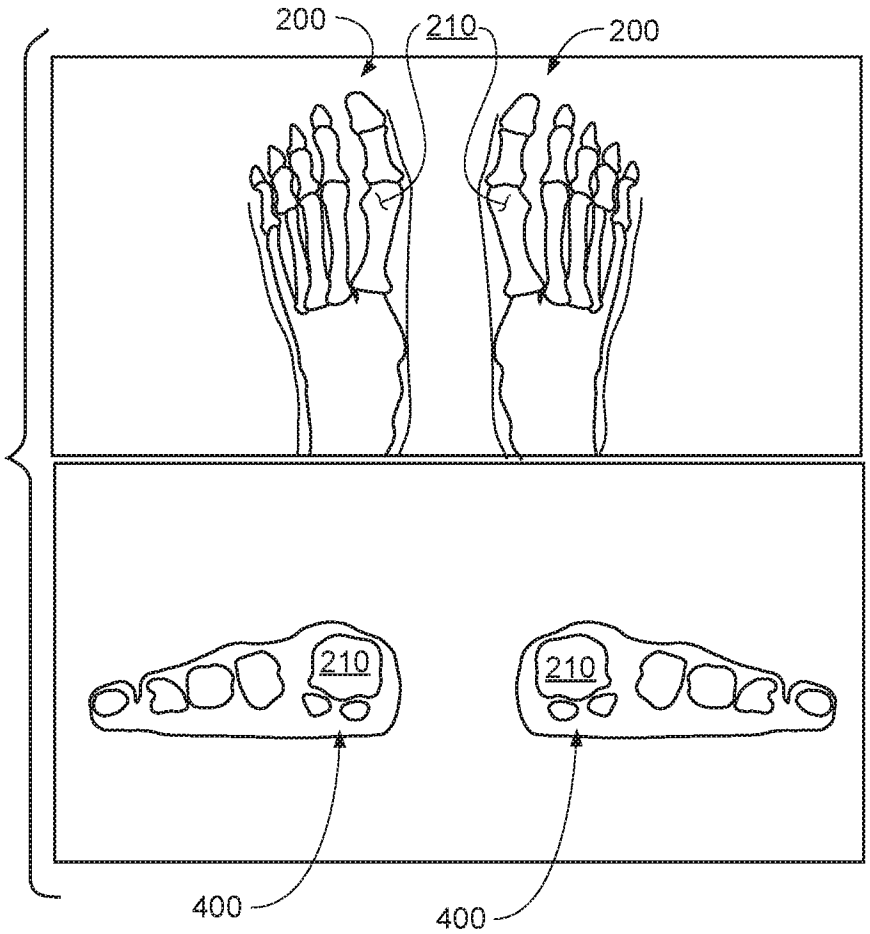


Fig. 30A

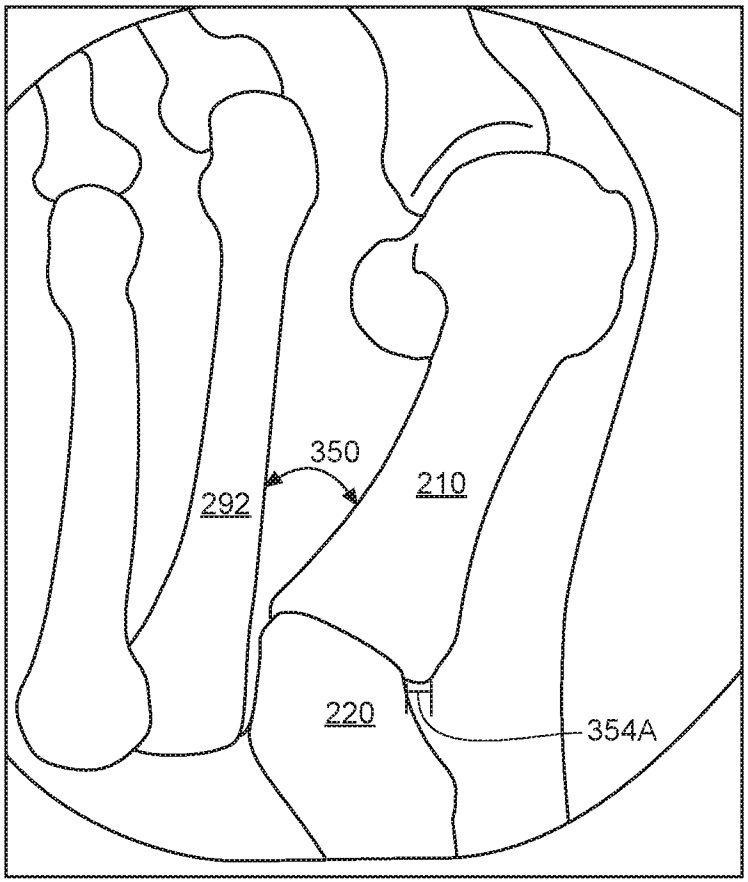


Fig. 30B

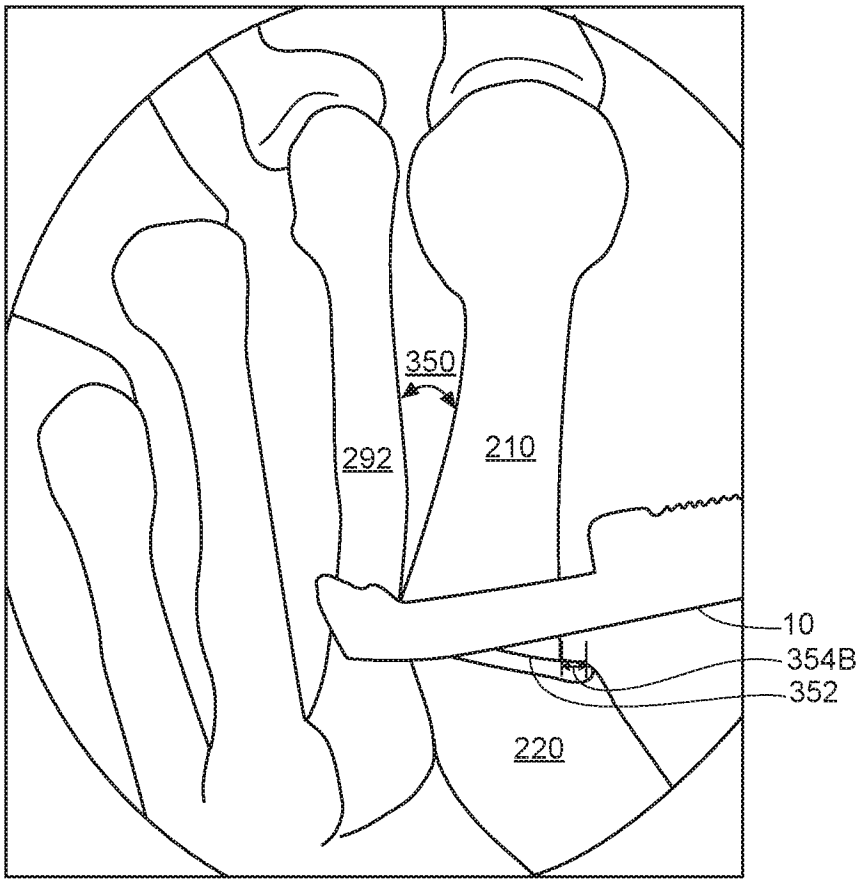
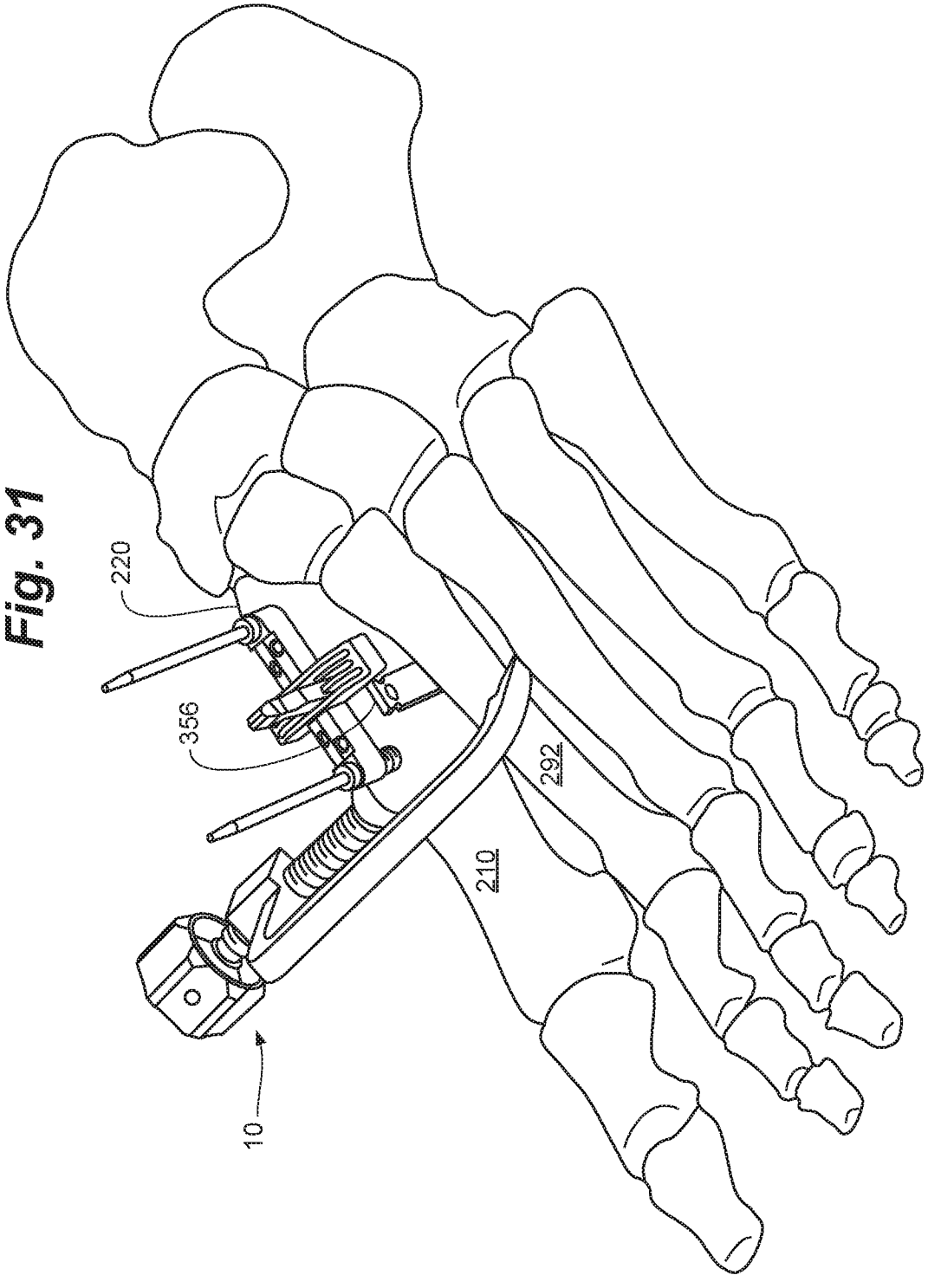


Fig. 31



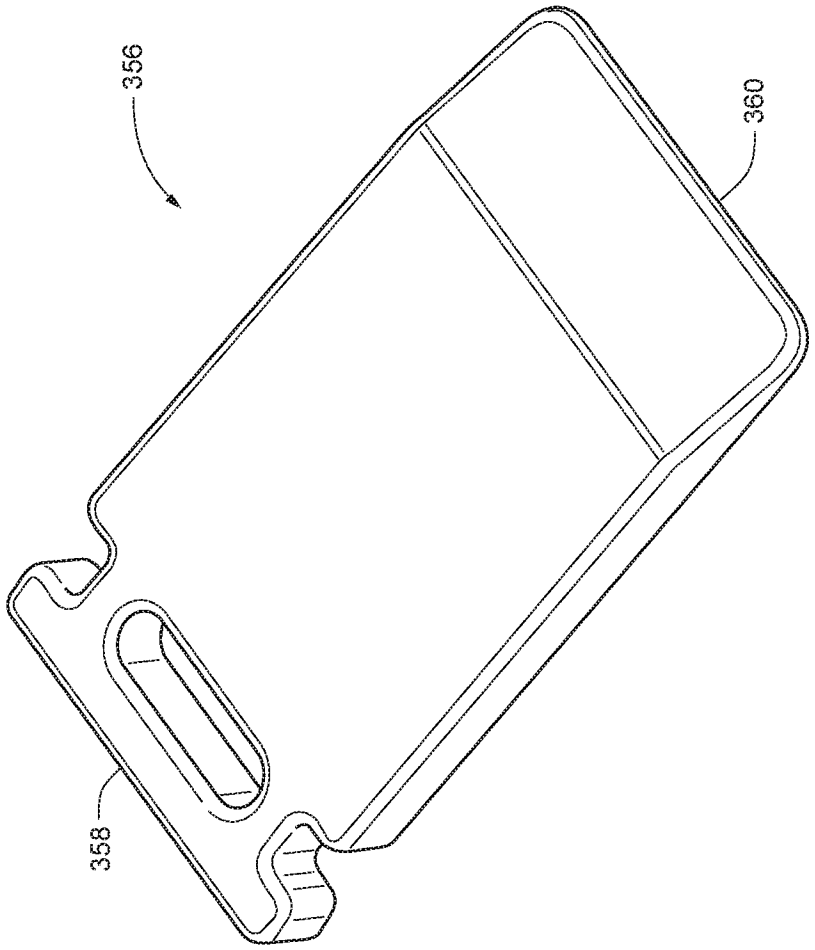


Fig. 32

Fig. 33

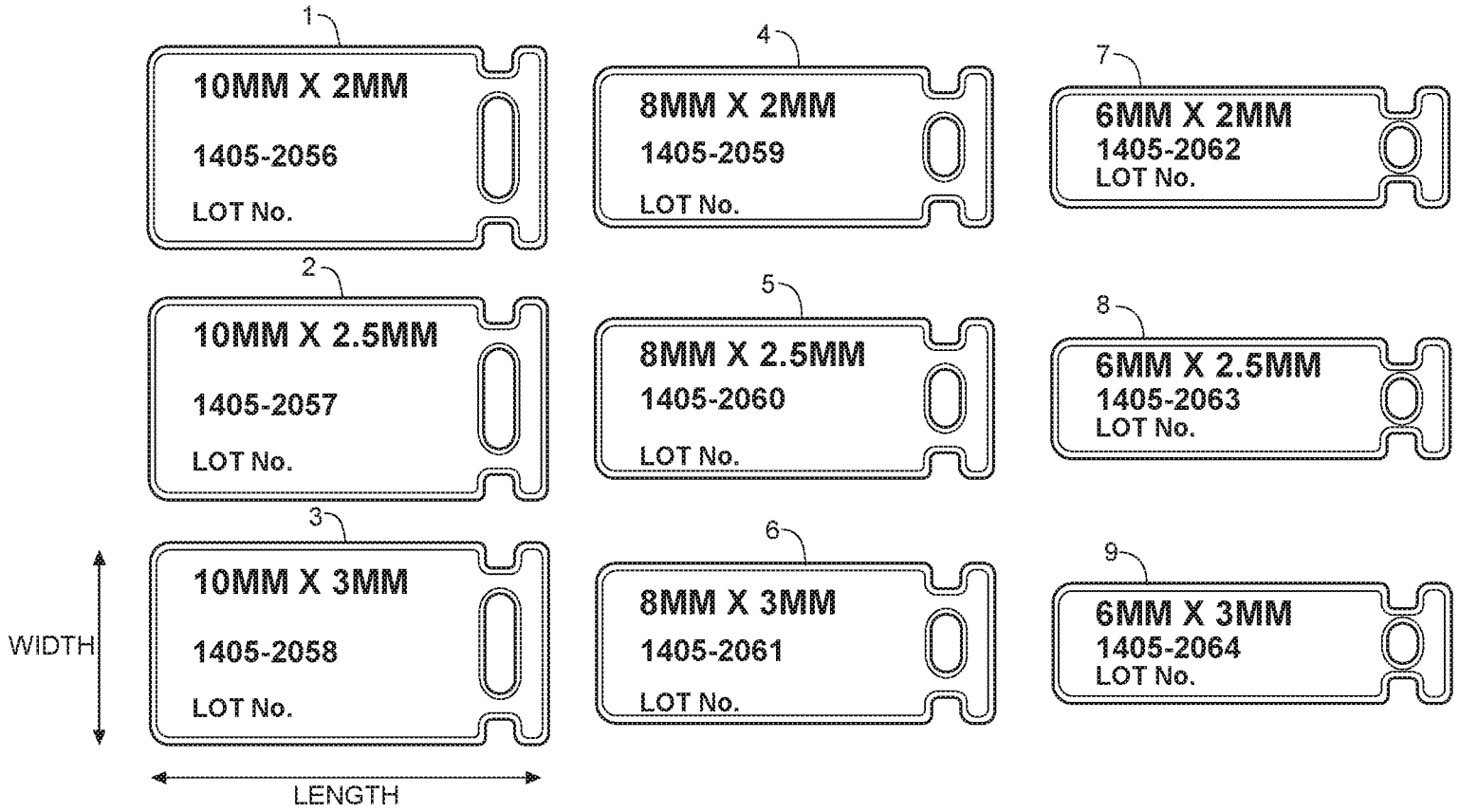

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10MM X 2MM
1405-2056
LOT No.
2
10MM X 2.5MM
1405-2057
LOT No.
3
10MM X 3MM
1405-2058
LOT No.
WIDTH
LENGTH
4
8MM X 2MM
1405-2059
LOT No.
5
8MM X 2.5MM
1405-2060
LOT No.
6
8MM X 3MM
1405-2061
LOT No.
7
6MM X 2MM
1405-2062
LOT No.
8
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1405-2063
LOT No.
9
6MM X 3MM
1405-2064
LOT No.

Fig. 34

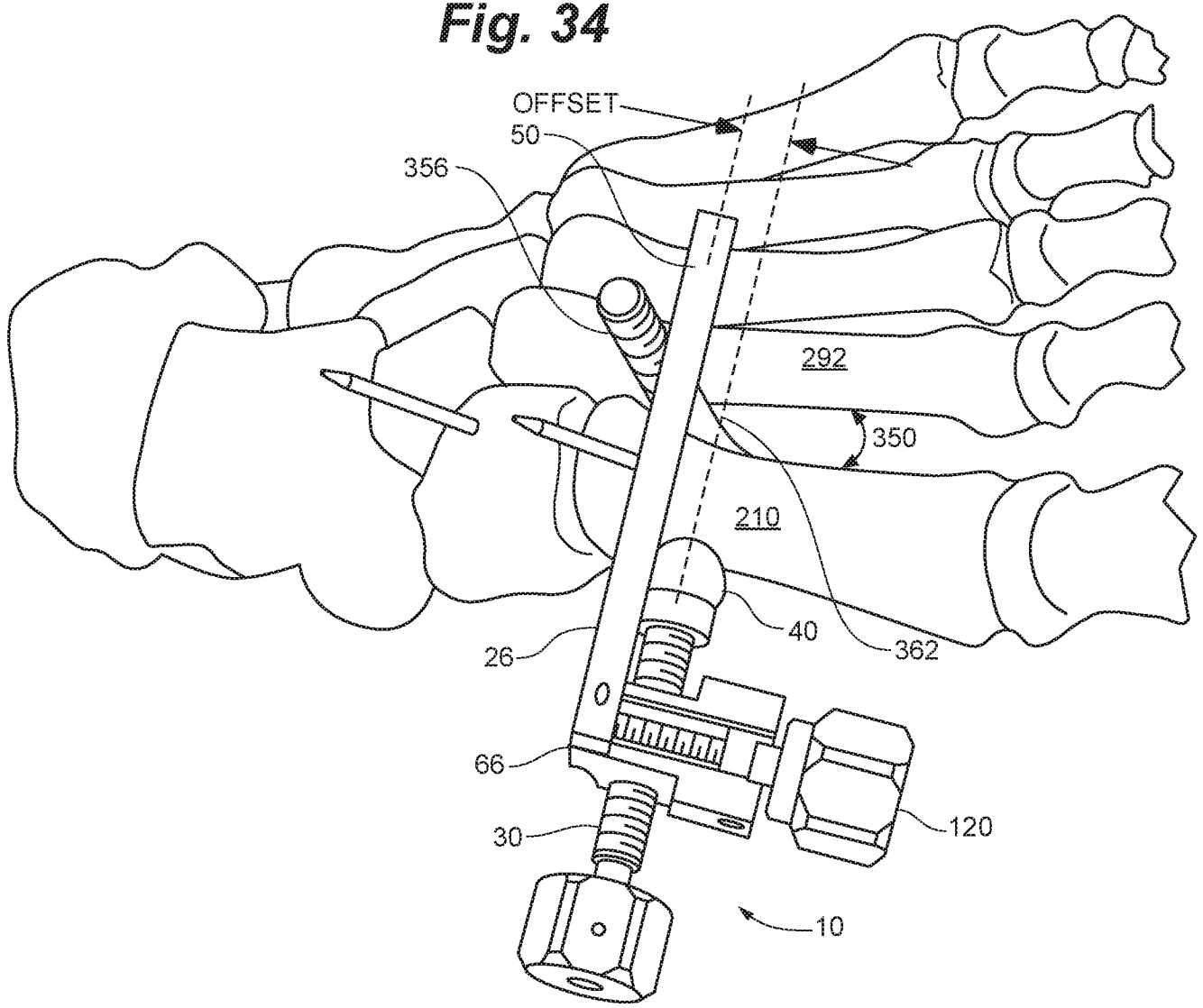


Fig. 35

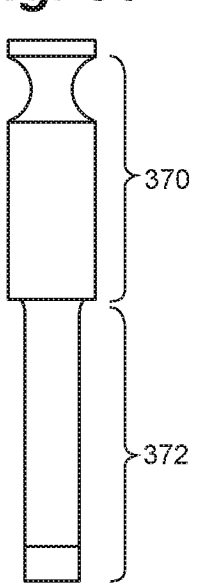


Fig. 36A

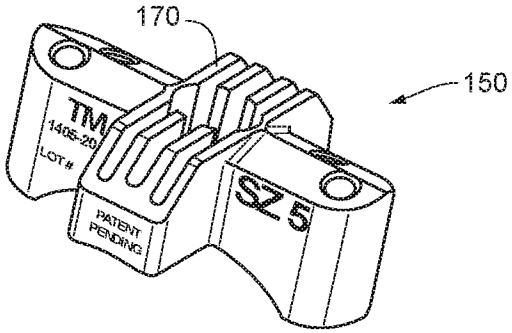
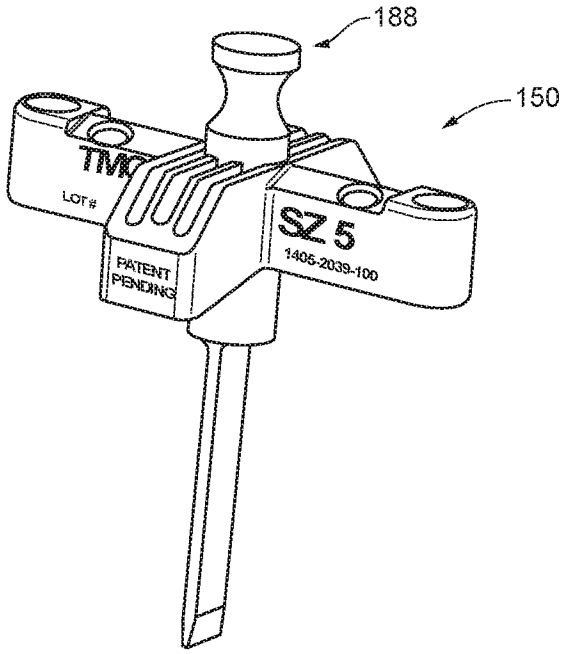


Fig. 36B



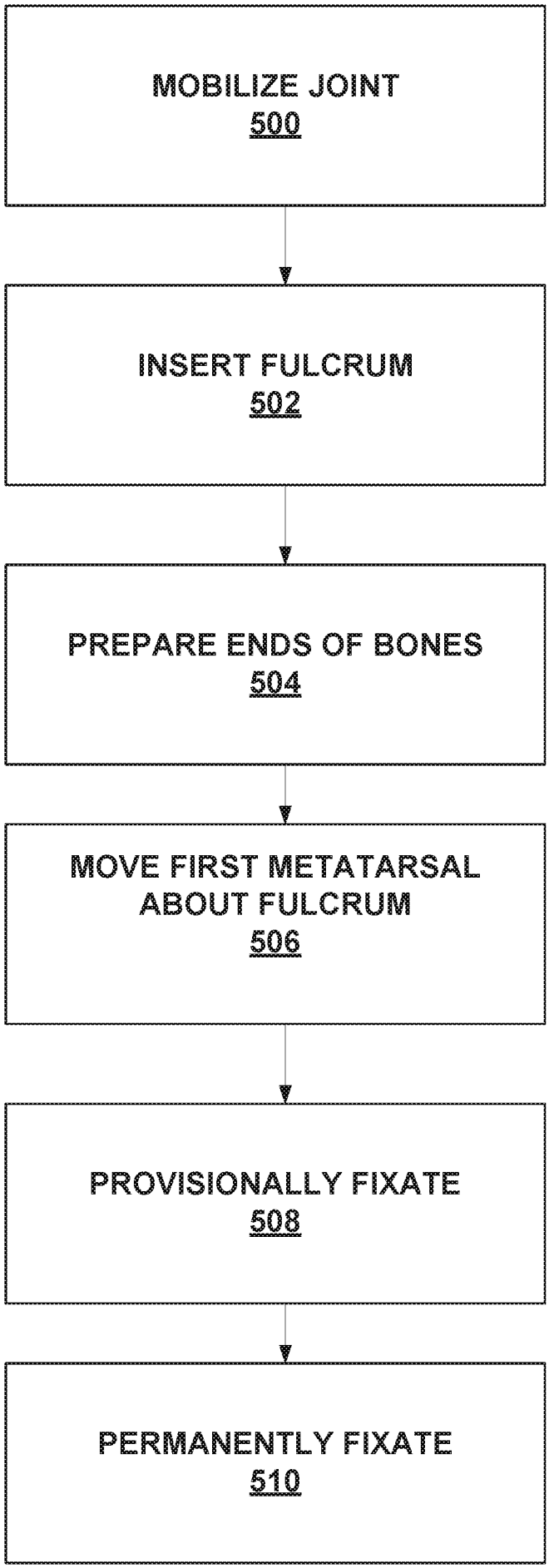

MOBILIZE JOINT
500
INSERT FULCRUM
502
PREPARE ENDS OF BONES
504
MOVE FIRST METATARSAL ABOUT FULCRUM
506
PROVISIONALLY FIXATE
508
PERMANENTLY FIXATE
510

FIG. 37

Fig. 38

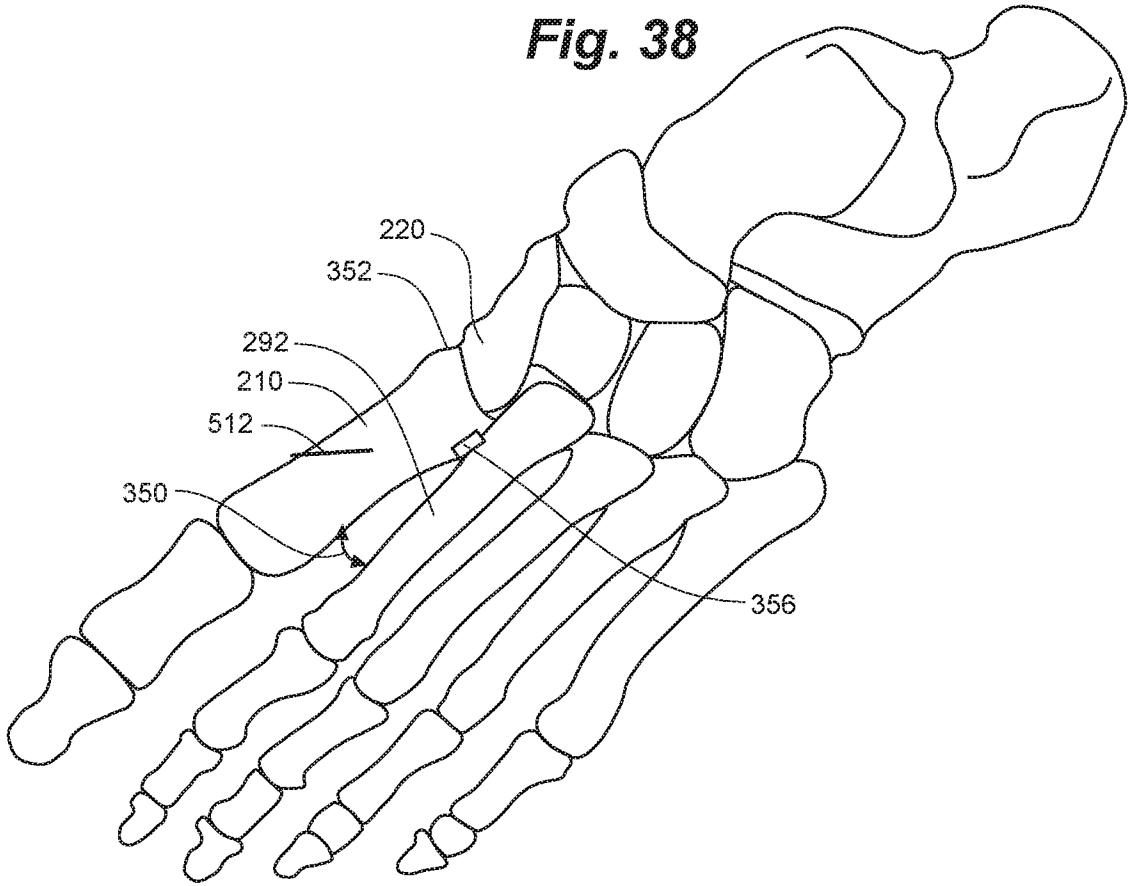


Fig. 39A

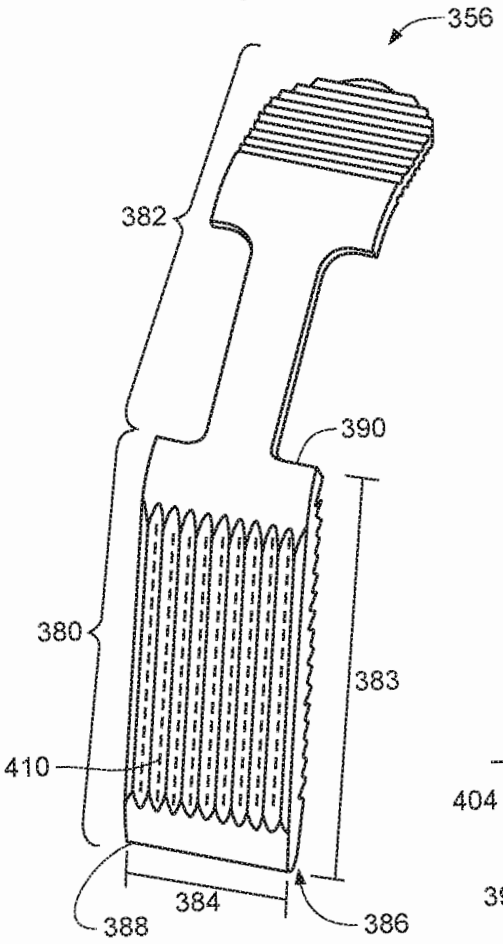


Fig. 39B

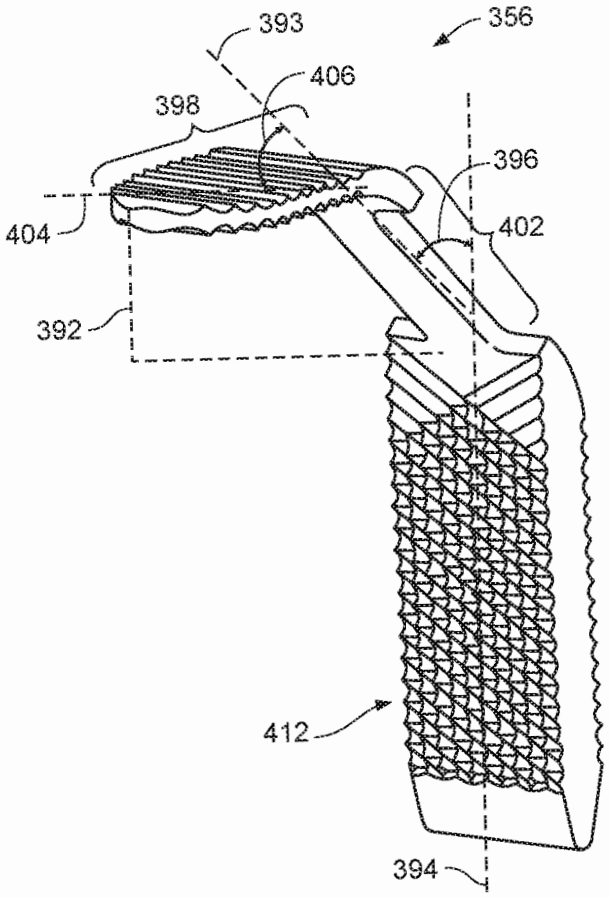
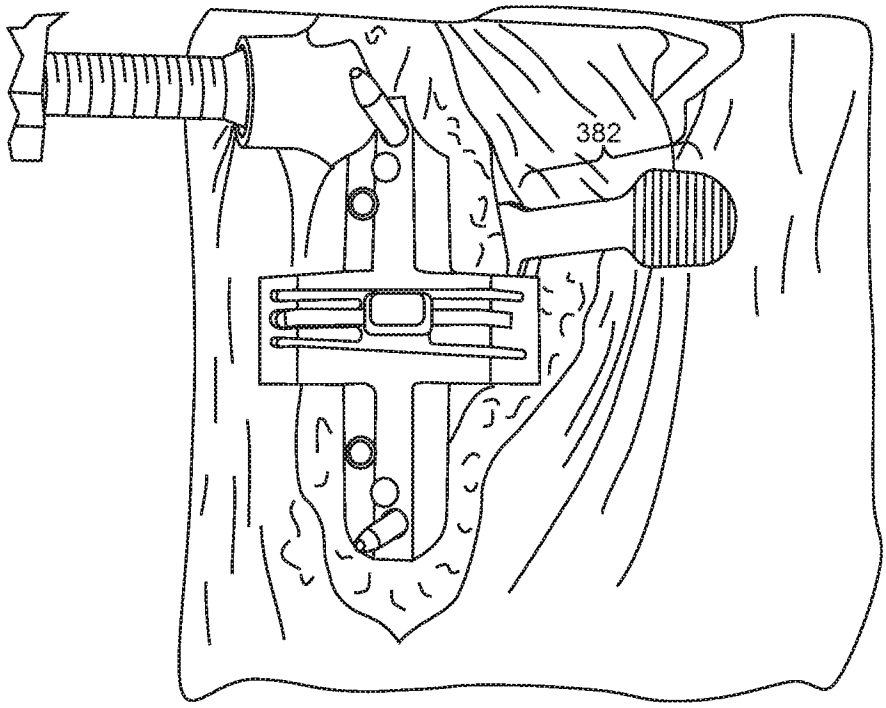


Fig. 40



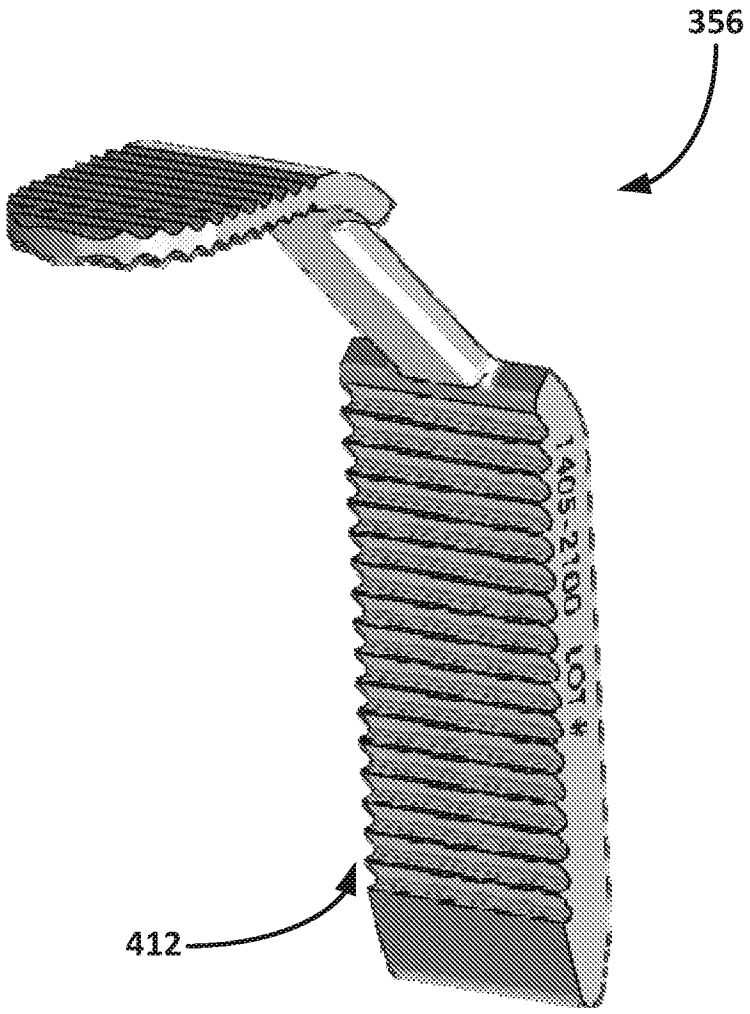


FIG. 41

Fig. 42A

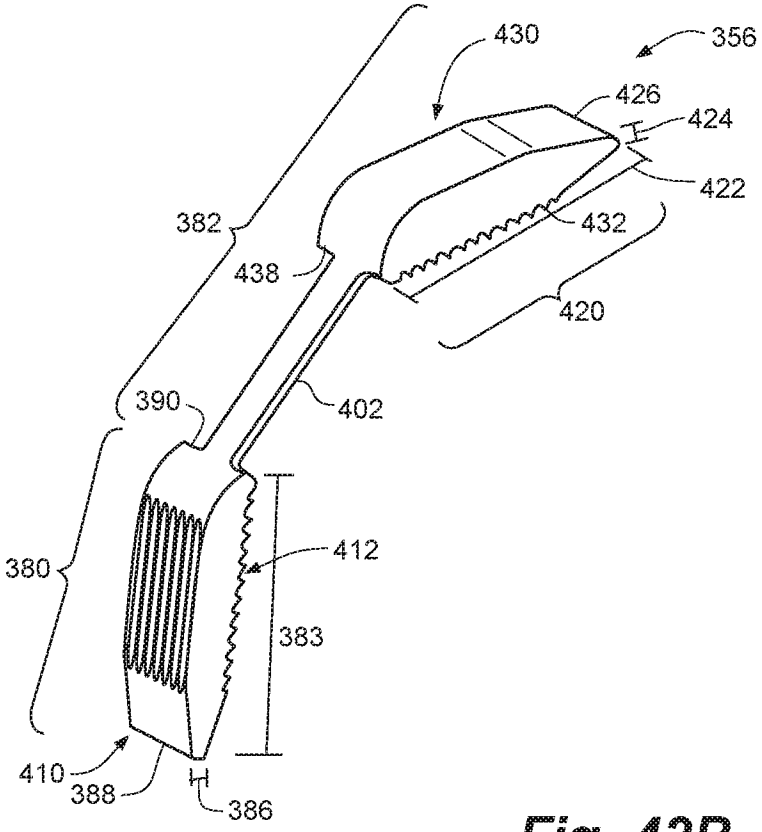
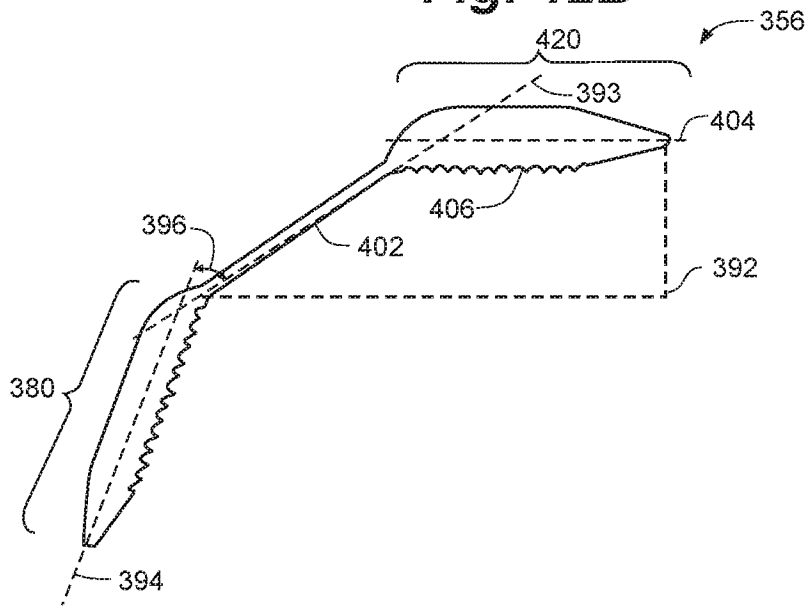


Fig. 42B



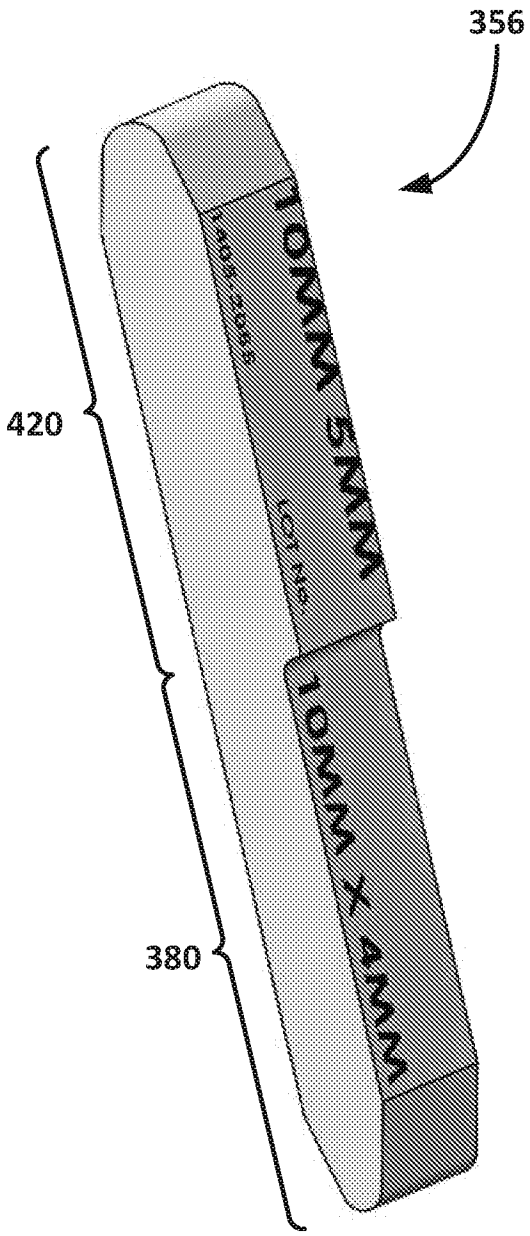


FIG. 43A

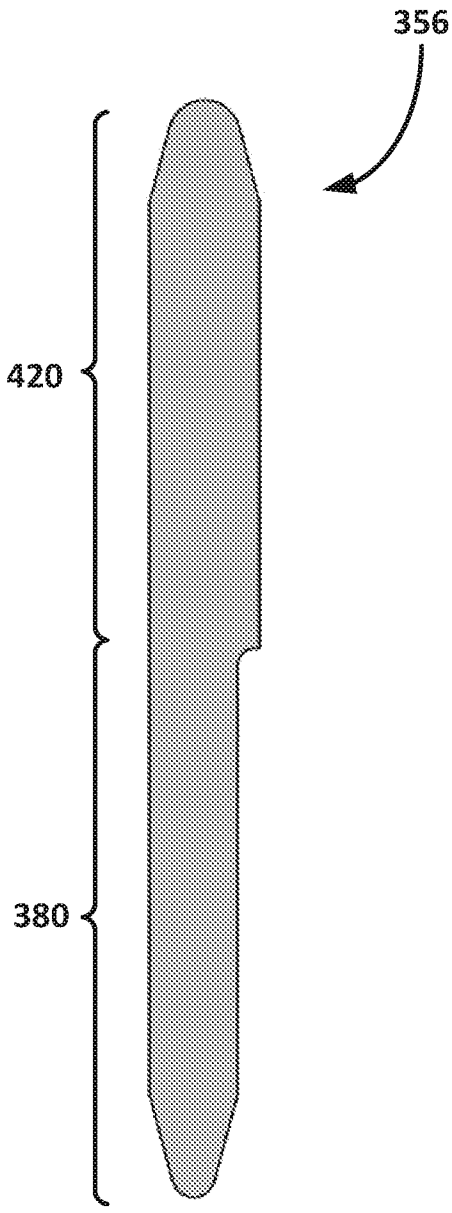


FIG. 43B

22859
Customer Number

PATENT
Attorney Docket No.: 71212.4.8.6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	F. Barry Bays		
Application No.:	Not Yet Assigned	Group Art Unit:	Not Yet Assigned
Filed:	Filed Herewith	Examiner:	Not Yet Assigned
Title:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Commissioner:

Pursuant to 37 C.F.R. § 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08a. Copies of references not enclosed with the application can be found in Application No. 15/236,464, filed August 14, 2016, from which the present application derives priority. In accordance with 37 C.F.R. § 1.98(d), Applicant is not enclosing additional copies of these references. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

By submitting these references, Applicant does not admit that the references are prior art to or material to this application, and reserves the right to establish that any reference is not prior art. Applicant does not represent that the references have been reviewed in detail; there may be details in the references of which Applicant is unaware.

Dated: June 19, 2019

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7000
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

66845698.1

SCORE Placeholder Sheet for IFW Content

Application Number: 16448357 Document Date: 06/21/2019

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Form Revision Date: March 1, 2019

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/448,357

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	19 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	785		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/448,357	06/21/2019		785	71212.4.8.6	19	2

CONFIRMATION NO. 6223

FILING RECEIPT

22859
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402
UNITED STATES OF AMERICA



Date Mailed: 07/24/2019

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

F. Barry Bays, Collierville, TN;
Robert D. Santrock, Morgantown, WV;
Paul Dayton, Fort Dodge, IA;
Daniel J. Hatch, Greeley, CO;
W. Bret Smith, Lexington, SC;
Carlos Eduardo Gil, Jacksonville Beach, FL;
Sean F. Scanlan, Jacksonville, FL;
Joe William Ferguson, Ponte Vedra Beach, FL;
John T. Treace, Ponte Vedra Beach, FL;

Applicant(s)

Treace Medical Concepts, Inc., Ponte Vedra, FL;

Power of Attorney: The patent practitioners associated with Customer Number 22859

Domestic Priority data as claimed by applicant

This application is a DIV of 15/236,464 08/14/2016 PAT 10342590
which claims benefit of 62/293,189 02/09/2016
and is a CIP of 14/981,335 12/28/2015 PAT 9622805
which claims benefit of 62/205,338 08/14/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 07/23/2019

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/448,357**

Projected Publication Date: 10/31/2019

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	Not Yet Assigned
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4069824	A	1978-01-24	WEINSTOCK	
	2	4335715	A	1982-06-22	Kirkley	
	3	4349018	A	1982-09-14	Chambers	
	4	4409973	A	1983-10-18	Neufeld	
	5	4440168	A	1984-04-03	Warren	
	6	4501268	A	1985-02-26	Comparetto	
	7	4502474	A	1985-03-05	COMPARETTO	
	8	4509511	A	1985-04-09	Neufeld	

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	Examiner Name	Not Yet Assigned
	Attorney Docket Number	71212.4.8.6

	9	4565191	A	1986-01-21	Slocum	
	10	4632102	A	1986-12-30	COMPARETTO	
	11	4664102	A	1987-05-12	Comparetto	
	12	4708133	A	1987-11-24	Comparetto	
	13	4750481	A	1988-06-14	Reese	
	14	5035698	A	1991-07-30	Comparetto	
	15	5042983	A	1991-08-27	Rayhack	
	16	5049149	A	1991-09-17	Schmidt	
	17	5053039	A	1991-10-01	Hofmann et al.	
	18	5078719	A	1992-01-07	Schreiber	
	19	5147364	A	1992-09-15	Comparetto	

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	20	5176685	A	1993-01-05	Rayhack	
	21	5246444	A	1993-09-21	Schreiber	
	22	5470335	A	1995-11-28	DU TOIT	
	23	5540695	A	1996-07-30	LEVY	
	24	5578038	A	1996-11-26	Slocum	
	25	5613969	A	1997-03-25	JENKINS JR	
	26	5620448	A	1997-04-15	PUDDU	
	27	5643270	A	1997-07-01	Combs	
	28	5667510	A	1997-09-16	COMBS	
	29	5722978	A	1998-03-03	Jenkins	
	30	5749875	A	1998-05-12	PUDDU	

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	31	5779709	A	1998-07-14	Harris et al.	
	32	5843085	A	1998-12-01	Graser	
	33	5911724	A	1999-06-15	Wehrli	
	34	5980526	A	1999-11-09	Johnson et al.	
	35	5984931	A	1999-11-16	GREENFIELD	
	36	6007535	A	1999-12-28	RAYHACK et al.	
	37	6027504	A	2000-02-22	MCGUIRE	
	38	6203545	B1	2001-03-20	Stoffella	
	39	6248109	B1	2001-06-19	Stoffella	
	40	6391031	B1	2002-05-21	Toomey	
	41	6547793	B1	2003-04-15	McGuire	

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	42	6676662	B1	2004-01-13	Bagga et al.	
	43	6755838	B2	2004-06-29	Trnka	
	44	6796986	B2	2004-09-28	Duffner	
	45	7018383	B2	2006-03-28	McGuire	
	46	7112204	B2	2006-09-26	Justin et al.	
	47	7540874	B2	2009-06-02	Trumble et al.	
	48	7572258	B2	2009-08-11	Stiernborg	
	49	7691108	B2	2010-04-06	Lavallee	
	50	7763026	B2	2010-07-27	Egger et al.	
	51	7967823	B2	2011-06-28	Ammann et al.	
	52	8062301	B2	2011-11-22	Ammann et al.	

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	53	8083746	B2	2011-12-27	Novak	
	54	8236000	B2	2012-08-07	Ammann et al.	
	55	8277459	B2	2012-10-02	Sand et al.	
	56	8409209	B2	2013-04-02	Ammann et al.	
	57	8496662	B2	2013-07-30	Novak et al.	
	58	8529571	B2	2013-09-10	Horan et al.	
	59	8540777	B2	2013-09-24	Ammann et al.	
	60	8657820	B2	2014-02-25	Kubiak et al.	
	61	8702715	B2	2014-04-22	Ammann et al.	
	62	8777948	B2	2014-07-15	Bernsteiner	
	63	8888785	B2	2014-11-18	Ammann et al.	

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	64	8900247	B2	2014-12-02	Tseng et al.	
	65	8906026	B2	2014-12-09	Ammann et al.	
	66	9113920	B2	2015-08-25	Ammann et al.	
	67	10292713	B2	2019-05-21	Fallin et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020165552	A1	2002-11-07	Duffner	
	2	20040138669	A1	2004-07-15	Horn	
	3	20170042598	A1	2017-02-16	Santrock et al.	
	4	20050070909	A1	2005-03-31	Egger et al.	
	5	20050251147	A1	2005-11-10	Novak	

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	Attorney Docket Number	71212.4.8.6

	6	20060129163	A1	2006-06-15	McGuire	
	7	20070010818	A1	2007-01-11	Stone et al.	
	8	20080039850	A1	2008-02-14	Rowley et al.	
	9	20080147073	A1	2008-06-19	Ammann et al.	
	10	20080195215	A1	2008-08-14	Morton	
	11	20090036931	A1	2009-02-05	Pech et al.	
	12	20090054899	A1	2009-02-26	Ammann et al.	
	13	20120185056	A1	2012-07-19	Warburton	
	14	20120191199	A1	2012-07-26	Raemisch	
	15	20130226252	A1	2013-08-29	Mayer	
	16	20130226248	A1	2013-08-29	Hatch et al.	

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	Attorney Docket Number	71212.4.8.6

	17	20140188139	A1	2014-07-03	Fallin et al.			
	18	20140194999	A1	2014-07-10	ORBAY et al.			
	19	20140343555	A1	2014-11-20	Russi et al.			
	20	20150057667	A1	2015-02-26	Ammann et al.			
	21	20160324532	A1	2016-11-10	MONTOYA et al.			

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	1	03075775	WO	A1	2003-09-18	KUPA PRAEZ SMASCHINEN GES M B		
	2	2004089227	WO	A2	2004-10-21	KUHN		
	3	2016134160	WO	A1	2016-08-25	TREACE MEDICAL CONCEPTS INC		

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	Art Unit	3775
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	71212.4.8.6

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	1	GREGG et al., "Plantar plate repair and Weil osteotomy for metatarsophalangeal joint instability," Foot and Ankle Surgery, Vol. 13, 2007, pp. 116–121.	
	2	WEIL et al., "Anatomic Plantar Plate Repair Using the Weil Metatarsal Osteotomy Approach," Foot & Ankle Specialist, Vol. 4, No. 3, 2011, pp. 145-150.	

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EXAMINER SIGNATURE

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	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	71212.4.8.6

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

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Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
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(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
A 382/2002 12. März 2002 (12.03.2002) AT

(71) Anmelder *(für alle Bestimmungsstaaten mit Ausnahme von US)*: **KUPA PRÄZISIONSMASCHINEN GESELLSCHAFT M.B.H.** [AT/AT]; Teslastrasse 6, A-8074 Grambach (AT).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: **FRANK, Erick** [AT/AT]; Johann Teufelgasse 17, A-1230 Wien (AT).

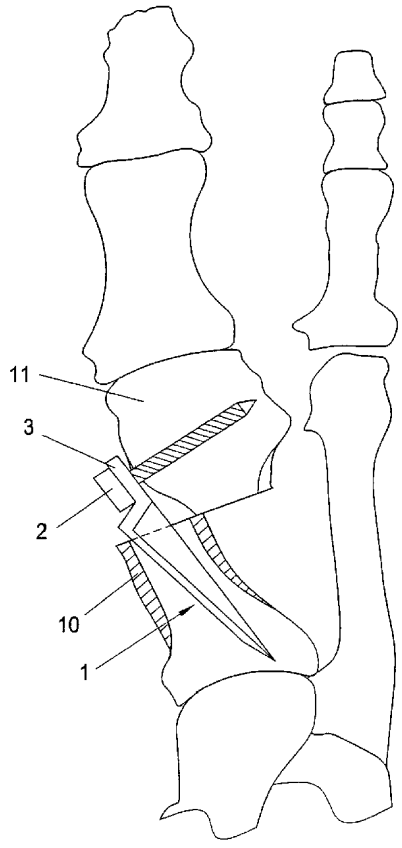
(74) Anwalt: **MIKSOVSKY, Alexander**; Miksovsky & Pollhammer OEG, Währinger Strasse 3, A-1096 Wien (AT).

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[Fortsetzung auf der nächsten Seite]

(54) Title: IMPLANT FOR THE DYNAMIC FIXATION OF A CORRECTIVE OSTEOTOMY

(54) Bezeichnung: IMPLANTAT ZUR DYNAMISCHEN FIXATION EINER KORREKTUROSTEOTOMIE



(57) Abstract: The invention relates to an implant for the dynamic fixation of a corrective osteotomy, whereby a fixing section (3) with a hole (9) for housing a spongiosa screw is connected by means of a swan bend (4) to a particularly laterally-offset extended anchoring section (1), embodied in the longitudinal direction as a rigid anchoring shaft (1) and with preferably at least three external anchoring edges (12) which may be engaged with the inside of a long bone. An implant with improved fixing and larger corrective range can thus be provided.

(57) Zusammenfassung: Bei einem Implantat zur dynamischen Fixation einer Korrekturosteotomie ist vorgesehen, dass ein Befestigungsabschnitt (3) mit einem Loch (9) zur Aufnahme einer Spongiosaschraube über eine Kröpfung (4) mit einem insbesondere seitlich versetzten, langgestreckten Verankerungsabschnitt (1) verbunden ist, der in Längsrichtung als steifer Verankerungsschaft (1) ausgebildet ist, welcher vorzugsweise mit zumindest drei aussen liegenden, mit der Innenseite eines Röhrenknochens in Eingriff bringbaren Verankerungskanten (12) ausgebildet ist, wodurch ein Implantat mit verbesserter Festlegung und grösserem Korrekturbereich zur Verfügung gestellt werden kann.

WO 03/075775 A1

SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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— *vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

IMPLANTAT ZUR DYNAMISCHEN FIXATION EINER KORREKTUROSTEOTOMIE

Die vorliegende Erfindung betrifft ein Implantat zur dynamischen Fixation einer Korrekturosteotomie.

Ein beispielhaftes, spezielles Anwendungsgebiet solcher Implantate ist die Korrekturosteotomie zur Behandlung von Achsenfehlstellungen an Mittelfußknochen des Menschen, wie beispielsweise Hallux valgus.

Aus der WO 97/35528 ist ein als V-förmige Spange ausgebildetes Implantat zur Behandlung einer Achsenfehlstellung eines Mittelfußknochens bekannt. Diese Spange erlaubt keine völlig rotationsstabile Fixierung der zu verbindenden Knochenfragmente. Dadurch ergeben sich unter anderem Nachteile bei der Belastung des Fußes. Weiters ist das Einsetzen der Spange schwierig, da das zu verschiebende Knochenfragment meist unter Sehnenspannung steht. Außerdem kann die Spange beim Explantieren brechen.

Aufgabe der vorliegenden Erfindung ist es, ein verbessertes Implantat zur dynamischen Fixation einer Korrekturosteotomie anzugeben.

Zur Lösung dieser Aufgabe ist ein Implantat zur dynamischen Fixation einer Korrekturosteotomie im wesentlichen dadurch gekennzeichnet, daß ein Befestigungsabschnitt mit einem Loch zur Aufnahme einer Spongiosaschraube über eine Kröpfung mit einem insbesondere seitlich versetzten, langgestreckten Verankerungsabschnitt verbunden ist, der in Längsrichtung als steifer Verankerungsschaft ausgebildet ist, welcher vorzugsweise mit zumindest drei außen liegen-

den, mit der Innenseite eines Röhrenknochens in Eingriff bringbaren Verankerungskanten ausgebildet ist.

Bei dieser Ausbildung kann das Implantat mit seinem Schaft besonders leicht in den Markraum des Knochens eingeführt werden, wobei die Verankerungskanten an der Knocheninnenseite anliegen und eine drehfeste Fixierung des Implantats ermöglichen. Diese Ausbildung gewährleistet auch, daß die Knochenfragmente ausreichend verschoben und präzise positioniert werden können.

Bei Verwendung des erfindungsgemäßen Implantats zur dynamischen Fixation einer Korrekturosteotomie wird insbesondere durch Vorsehen der Kröpfung zwischen dem Befestigungsabschnitt und dem Verankerungsabschnitt eine größere Versetzung zwischen durchtrennten Knochenteilen bzw. -fragmenten möglich, so daß mit einem einzigen Schnitt größere Korrekturen möglich werden, für welche bisher beispielsweise mehrfache Schnitte erforderlich waren. Weiters wird es durch Verwendung des erfindungsgemäßen Implantats möglich, durch Vorsehen des Schnitts entfernt von der Basis neben einer entsprechend der Größe der Kröpfung erzielbaren, größeren Versetzung und somit besseren Korrektur auch unmittelbar eine entsprechend verbesserte Rotationsmöglichkeit der Gelenksfläche zur Verfügung zu stellen, so daß wiederum durch Vorsehen eines einzigen Schnitts gleichzeitig sowohl eine Versetzung in gegenüber dem bisher bekannten Stand der Technik erhöhtem Ausmaß als auch eine Rotation der Gelenkfläche erzielbar ist, wofür gemäß dem bisher bekannten Stand der Technik üblicherweise zwei Schnitte mit entsprechend erhöhtem, operativem Aufwand erforderlich waren.

Durch Einsatz des erfindungsgemäßen Implantats mit einem in Längsrichtung steifen Verankerungsschaft, welcher vorzugsweise mit Verankerungskanten zur Festlegung an der Innenseite eines Röhrenknochens versehen ist, kann mit Hilfe einer minimal-invasiven Technik auch der Operationsvorgang verkürzt und vereinfacht werden, da nach Vorsehen einer verkürzten Schnittlänge im Bereich des zu durchtrennenden Knochens und nach einem Durchtrennen bzw. Schneiden desselben ein Aufweiten des Schnitts beispielsweise durch ein Einsetzen bzw. Einbringen des Verankerungsschafts zwischen die Knochenfragmente erfolgt, wonach nach einem Aufweiten des Schnitts der Verankerungsschaft unmittelbar in den Röhrenknochen eingesetzt bzw. eingetrieben wird, welcher über die vorzugsweise vorgesehenen Verankerungskanten unmittelbar fest im Röhrenknochens verankert wird, so daß zusätzliche, aufwendige Schritte zur Festlegung des Implantats neben der einfachen Festlegung über die Spongiosaschraube im Bereich des Befestigungsabschnitts nicht erforderlich sind.

Für eine besonders einfache Herstellung und zur Erzielung eines entsprechend stabilen Implantats ist gemäß einer weiters bevorzugten Ausführungsform vorgesehen, daß der Befestigungsabschnitt, die Kröpfung und der Verankerungsabschnitt einstückig ausgebildet sind.

Gemäß einem weiteren, bevorzugten Merkmal der Erfindung kann ein im Querschnitt T-förmiger Verankerungsschaft mit spitz zulaufendem Einschlagende vorgesehen sein, der aus einer ebenen, klingenförmigen Ankerplatte und einem von dieser abstehenden, zum Einschlagende hin spitz zulaufenden Steg besteht, wobei die Seitenränder der Ankerplatte und

der obere Rand des Steges als Verankerungskanten ausgebildet sind.

Erfindungsgemäß kann bevorzugt mindestens eine der Verankerungskanten zumindest im Bereich des Einschlagendes geschärft sein bzw. messerförmig ausgebildet sein.

Weiters kann der Versatz zwischen der Ankerplatte und dem Befestigungsabschnitt, d.h. die Höhe der Kröpfung, so gewählt werden, daß sie dem gewünschten Ausmaß der Lateralisierung des Knochenfragmentes angepaßt ist.

Gemäß einem weiteren, bevorzugten Merkmal der Erfindung kann das Loch in dem Befestigungsabschnitt als zylindrische Bohrung ausgebildet sein, die zusammen mit dem kopfnahen, zylindrischen Ende der Spongiosaschraube eine winkelstabile Verbindung zwischen Spongiosaschraube und Implantat bildet. Dadurch ist auch die Winkelstabilität zwischen den Knochenfragmenten gewährleistet.

Für eine besonders einfache Festlegung des Befestigungsabschnitts ist das erfindungsgemäße Implantat bevorzugt so ausgebildet, daß das Loch des Befestigungsabschnittes als zylindrische Bohrung ausgebildet ist, die zusammen mit dem kopfnahen, zylindrischen Ende der Spongiosaschraube eine winkelstabile Verbindung zwischen Spongiosaschraube und Implantat bildet.

Zur Verbesserung des Knochenbildungswachstums nach Einsetzen des Implantats und somit zur Verbesserung des Heilungsfortschritts als auch eine vereinfachte Handhabung beim Einbringen in das Innere des Röhrenknochens wird gemäß einer weiters bevorzugten Ausführungsform vorgeschlagen,

daß die Kröpfung in ihren seitlichen Bereichen mit einer Verjüngung bzw. Taillierung ausgebildet ist. Durch Vorsehen einer derartigen Verjüngung bzw. Taillierung läßt sich auch das Implantat einfach nach einem Zeitraum von beispielsweise 3 bis 4 Monaten wiederum entnehmen, wobei insbesondere im Bereich der Taillierung eine ausreichende Knochenbildung zur Festigung zwischen den einzelnen Knochenteilen bzw. -fragmenten sichergestellt werden kann.

Für eine besonders einfache Herstellung wird gemäß einer weiters bevorzugten Ausführungsform vorgeschlagen, daß es einstückig aus Metall gefertigt ist. Derartige Metalle bzw. metallische Legierungen, welche für einen Einsatz als Implantate bereits seit längerem erprobt sind, sind bekannt. Insbesondere für den Fall, daß zur Erhöhung der Stabilität der Verbindung zwischen den durchtrennten Knochenteilen eine Entfernung des Implantats nicht vorgenommen werden soll, wird gemäß einer weiters bevorzugten Ausführungsform der Erfindung vorgeschlagen, daß es aus resorbierbarem Kunststoff gefertigt ist.

Nachstehend wird die Erfindung an Ausführungsbeispielen anhand der Zeichnungen näher erläutert. In den Zeichnungen zeigt Fig. 1 die Osteosynthese mit einem erfindungsgemäßen Implantat zur Korrektur eines Hallux valgus. Fig. 2 zeigt ein erfindungsgemäßes Implantat von der Seite. Fig. 3 ist eine Draufsicht auf das Implantat der Fig. 2. Fig. 4 stellt einen Querschnitt durch das Implantat der Fig. 2 entlang der Linie IV-IV dar. Fig. 5 stellt eine Draufsicht ähnlich zu Fig. 3 auf eine abgewandelte Ausführungsform eines erfindungsgemäßen Implantats dar.

Eine Möglichkeit der operativen Korrektur des Hallux valgus besteht darin, daß das fehlgestellte Metatarsale I durchtrennt und in korrigierter Stellung fixiert wird. Fig. 1 zeigt eine solche Fixation mit Hilfe des Implantats gemäß Fig. 2. Nach durchgeführter Durchtrennung des Knochens wird der Verankerungsschaft 1 mit dem geschärften Einschlagende so weit in den Markraum des einen Knochenfragmentes 10 eingeschlagen, bis die Kröpfung in Höhe der Osteotomie zu liegen kommt. Dann wird das zweite Knochenfragment 11 mittels einer Spongiosaschraube 2 am Befestigungsabschnitt 3 fixiert. Das Implantat ermöglicht eine in der frontalen und transversalen Ebene sowie in der Rotation stabile Korrekturosteotomie, die in axialer Richtung eine dynamische Kompression der Knochenfragmente erlaubt. Das Implantat zeichnet sich durch hohe statische Stabilität aus. Ein Brechen beim Explantieren ist nicht zu befürchten.

Fig. 2 zeigt eine Ausführungsform des Implantats von der Seite. Das Implantat besteht aus einem Verankerungsschaft 1, der über eine Kröpfung 4 mit einem plattenförmigen Befestigungsabschnitt 3 verbunden ist. Der Verankerungsschaft 1 besteht aus einer ebenen, klingenförmigen Ankerplatte 5 und einem von dieser nach oben abstehenden, zum Einschlagende 6 hin nach vorne spitz zulaufenden Steg 7, wodurch sich die in Fig. 4 gezeigte T-Form des Querschnittes ergibt. Die Seitenränder der Ankerplatte und der obere Rand des Steges sind als Verankerungskanten 12 vorgesehen, die mit der Innenseite des Röhrenknochens in Eingriff zu bringen sind. Die Ankerplatte 5 und der Befestigungsabschnitt 3 liegen auf im wesentlichen parallelen Ebenen. Die Höhe 8 der Kröpfung 4 kann so gewählt sein, daß sie der gewünschten Verschiebung des Knochenfragmentes angepaßt ist.

Der Befestigungsabschnitt 3 weist ein Loch 9 zur Aufnahme einer Schraube 2 auf. Dieses Loch kann als zylindrische Bohrung ausgebildet sein, die mit dem kopfnahen, zylindrischen Ende einer Spongiosaschraube in Eingriff kommt und dabei die gewünschte winkelstabile Verbindung zwischen Schraube und Implantat ermöglicht.

In einer weiteren Ausführungsform des Implantats kann am hinteren Ende des Verankerungsschaftes 1 ein gegenüber der Ankerplatte 5 weiter nach oben versetzter Befestigungsabschnitt vorgesehen sein, wobei die Kröpfung 4 über den Keil nach oben vorsteht.

In Fig. 5 ist eine abgewandelte Ausführungsform dargestellt, wobei die Kröpfung 4 im Bereich ihrer Seitenkanten bzw. Seitenränder jeweils mit einer Taillierung bzw. Verjüngung oder Verengung 13 ausgebildet ist. Im Bereich dieser Verjüngung bzw. Taillierung 13 kann somit zwischen den zueinander versetzten Knochenteilen bzw. -fragmenten 10 und 11 eine verbesserte Knochenbildung und somit eine verbesserte Stabilisierung zwischen den Fragmenten 10 und 11 erzielt werden, wobei durch die Taillierung 13 auch die Handhabung und die nachträgliche Entfernung des Implantats verbessert bzw. vereinfacht wird.

Das Implantat kann aus Metall oder aus einem resorbierbaren Kunststoff gefertigt sein.

Patentansprüche:

1. Implantat zur dynamischen Fixation einer Korrekturosteotomie, dadurch gekennzeichnet, daß ein Befestigungsabschnitt (3) mit einem Loch (9) zur Aufnahme einer Spongiosaschraube über eine Kröpfung (4) mit einem insbesondere seitlich versetzten, langgestreckten Verankerungsabschnitt (1) verbunden ist, der in Längsrichtung als steifer Verankerungsschaft (1) ausgebildet ist, welcher vorzugsweise mit zumindest drei außen liegenden, mit der Innenseite eines Röhrenknochens in Eingriff bringbaren Verankerungskanten (12) ausgebildet ist.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß der Befestigungsabschnitt (3), die Kröpfung (4) und der Verankerungsabschnitt (1) einstückig ausgebildet sind.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß ein im Querschnitt T-förmiger Verankerungsschaft mit spitz zulaufendem Einschlagende (6) vorgesehen ist, der aus einer ebenen, klingenförmigen Ankerplatte (5) und einem von dieser abstehenden, zum Einschlagende hin spitz zulaufenden Steg (7) besteht, wobei die Seitenränder der Ankerplatte (5) und der obere Rand des Steges (7) als Verankerungskanten (12) ausgebildet sind.

4. Implantat nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, daß das Loch (9) des Befestigungsabschnittes (3) als zylindrische Bohrung ausgebildet ist, die zusammen mit dem kopfnahen, zylindrischen Ende der Spongiosaschraube (2) eine winkelstabile Verbindung zwischen Spongiosaschraube und Implantat bildet.

5. Implantat nach einem oder mehreren der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mindestens eine Verankerungskante (12) zumindest im Bereich des Einschlagendes messerförmig ausgebildet sind.

6. Implantat nach einem oder mehreren der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Kröpfung (4) in ihren seitlichen Bereichen mit einer Verjüngung bzw. Taillierung (13) ausgebildet ist.

7. Implantat nach einem oder mehreren der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß es einstückig aus Metall gefertigt ist.

8. Implantat nach einem oder mehreren der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß es aus resorbierbarem Kunststoff gefertigt ist.

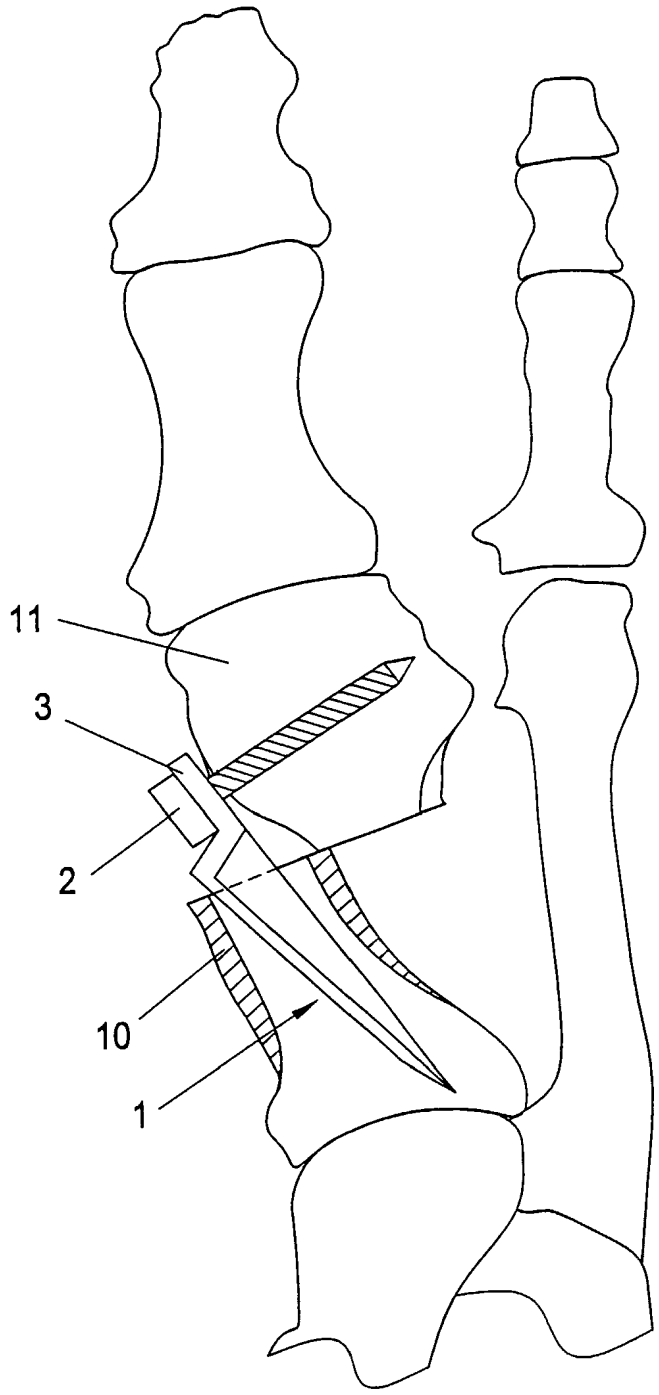


FIG. 1

FIG. 4

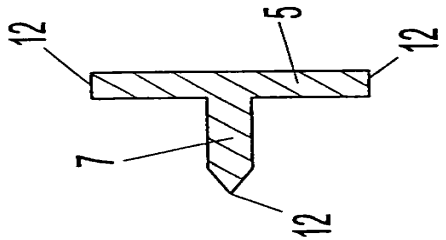


FIG. 3

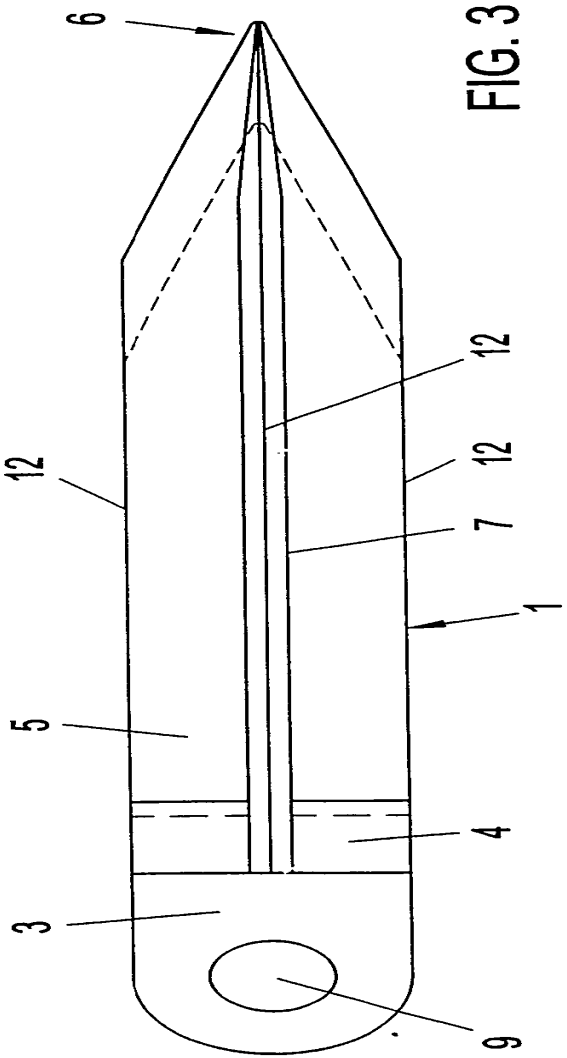
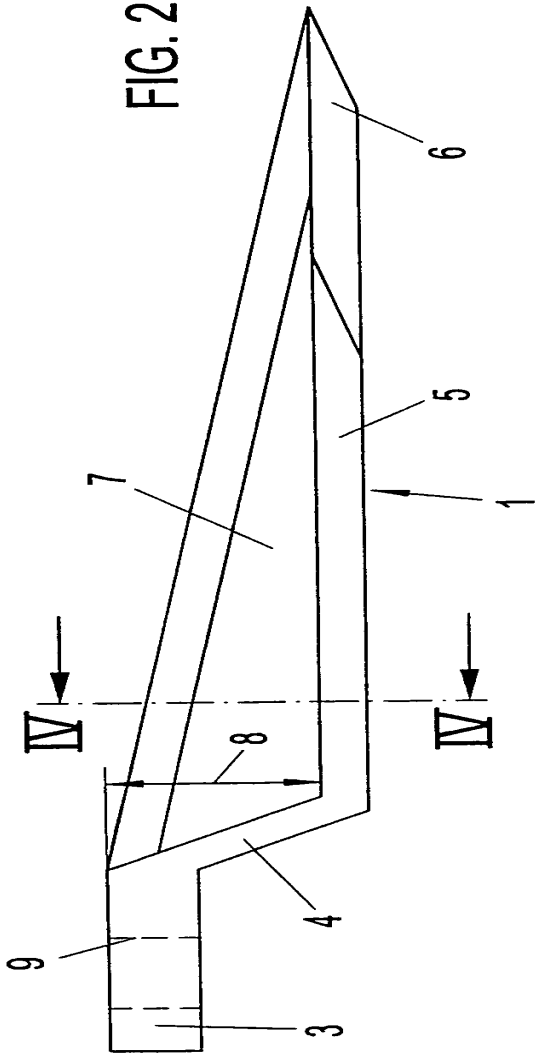


FIG. 2



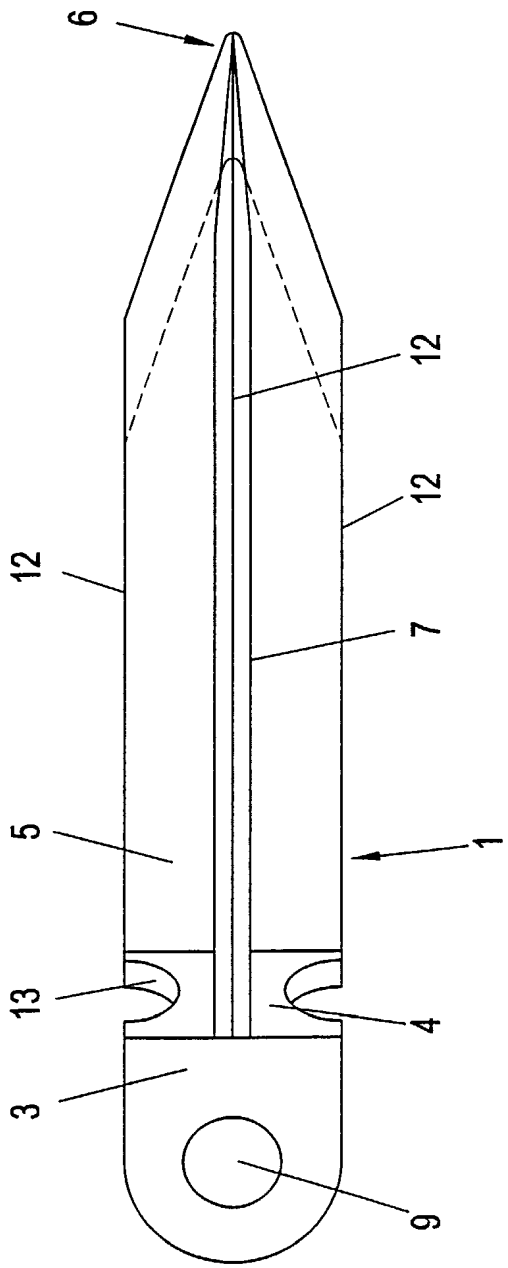


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/AT 03/00067

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 603 715 A (KESSLER SIGURD) 18 February 1997 (1997-02-18) column 4, line 66 -column 5, line 9; figure 1 ---	1,2,4,7 8
Y	FR 2 572 274 A (UNIV RENNES) 2 May 1986 (1986-05-02) page 3, line 30 -page 4, line 2; figures 3,4 page 6, line 1 - line 7 ---	8
A	GB 1 274 470 A (HALLORAN W X) 17 May 1972 (1972-05-17) page 4, line 81 - line 84; figure 20 --- -/--	1,3

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 August 2003	21/08/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Angeli, M

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 1 287 787 A (STOFFELLA RUDOLF DR ;LINK WALDEMAR GMBH CO (DE)) 5 March 2003 (2003-03-05) column 4, line 27 -column 5, line 5; figures 5,7	1

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5603715	A	18-02-1997	DE	4209122 A1	23-09-1993
			AT	137948 T	15-06-1996
			DE	59302554 D1	20-06-1996
			EP	0561295 A1	22-09-1993
FR 2572274	A	02-05-1986	FR	2572274 A1	02-05-1986
GB 1274470	A	17-05-1972	CH	492447 A	30-06-1970
			DE	1930354 A1	18-12-1969
EP 1287787	A	05-03-2003	EP	1287787 A1	05-03-2003
			JP	2003093400 A	02-04-2003
			US	2003040750 A1	27-02-2003

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/AT 03/00067

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61B17/68

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61B

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X Y	US 5 603 715 A (KESSLER SIGURD) 18. Februar 1997 (1997-02-18) Spalte 4, Zeile 66 -Spalte 5, Zeile 9; Abbildung 1 ---	1,2,4,7 8
Y	FR 2 572 274 A (UNIV RENNES) 2. Mai 1986 (1986-05-02) Seite 3, Zeile 30 -Seite 4, Zeile 2; Abbildungen 3,4 Seite 6, Zeile 1 - Zeile 7 ---	8
A	GB 1 274 470 A (HALLORAN W X) 17. Mai 1972 (1972-05-17) Seite 4, Zeile 81 - Zeile 84; Abbildung 20 --- -/--	1,3

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

° Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der internationalen Recherche	*Absendedatum des internationalen Recherchenberichts*
8. August 2003	21/08/2003

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Angeli, M

Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
P,X	EP 1 287 787 A (STOFFELLA RUDOLF DR ;LINK WALDEMAR GMBH CO (DE)) 5. März 2003 (2003-03-05) Spalte 4, Zeile 27 -Spalte 5, Zeile 5; Abbildungen 5,7 -----	1

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
US 5603715	A	18-02-1997	DE	4209122 A1	23-09-1993
			AT	137948 T	15-06-1996
			DE	59302554 D1	20-06-1996
			EP	0561295 A1	22-09-1993
FR 2572274	A	02-05-1986	FR	2572274 A1	02-05-1986
GB 1274470	A	17-05-1972	CH	492447 A	30-06-1970
			DE	1930354 A1	18-12-1969
EP 1287787	A	05-03-2003	EP	1287787 A1	05-03-2003
			JP	2003093400 A	02-04-2003
			US	2003040750 A1	27-02-2003

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
21. Oktober 2004 (21.10.2004)

PCT

(10) Internationale Veröffentlichungsnummer
WO 2004/089227 A2

(51) Internationale Patentklassifikation[7]: A61B 17/16

(21) Internationales Aktenzeichen: PCT/EP2004/003793

(22) Internationales Anmeldedatum:
8. April 2004 (08.04.2004)

(25) Einreichungssprache: Deutsch

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[Fortsetzung auf der nächsten Seite]

(54) Title: OSTEOTOME AND SURGICAL INSTRUMENT USED IN OSTEOTOMY

(54) Bezeichnung: OSTEOTOM SOWIE CHIRURGISCHES INSTRUMENT ZUR OSTEOTOMIE

(57) Abstract: The invention relates to an osteotome comprising a chisel that is attached to a handle (1) by means of a chisel base and is provided with a cutting edge or a hollow punch. The aim of the invention is to further develop said osteotome, especially when the chisel (3) can be made to perform a linear movement with the aid of a drive unit, in such a way that the separating joint allows the bone parts to be joined in a mutually fixed position while the contact area is increased and the instrument can be held with one hand during surgery. Said aim is achieved by providing the cutting edge with at least one longitudinally running groove that extends from the cutting edge in the longitudinal direction of the chisel (3) in order to prepare positive osteosyntheses. Alternatively, a hollow punch having a rectangular, single-trapezoidal, twin-trapezoidal, or ovally or circularly rounded cross section is provided as a cutting edge in order to punch out corresponding ends of the bone parts or a small bone column which is provided with a corresponding cross section and can be inserted into such a shaped bone part so as to perform osteotomies or arthrodeses. In a preferred further embodiment, a linear drive unit, the output of which causes the chisel (3) to perform the longitudinal movement in cooperation with the chisel seat (2), is arranged inside the handle (1).

(57) Zusammenfassung: Um ein Osteotom mit einem mit Meißelfuß an einem Handgriff (1) angesetzten Meißel mit Meißelschneide oder mit Hohlstanze, insbesondere, wenn der Meißel (3) mit einem Antrieb in Linearbewegung versetzbar ist, so weiter zu bilden, dass die Trennfuge ein Zusammenfügen der Knochenteile in gegeneinander fixierter Lage bei vergrößerter Anlagefläche ermöglicht und einhändiges Halten des Instrumentes während der Operation erlaubt, weist die Meißelklinge ausgehend von der Meißelschneide sich in Längsrichtung des Meißels (3) erstreckend zumindest eine längsverlaufende Nut auf, zum Vorbereiten formschlüssiger Osteosynthesen oder ist als Meißelklinge eine Hohlstanze mit rechteckförmigem, einfach- oder doppel-trapezförmigem oder oval- oder kreisförmig abgerundetem Querschnitt vorgesehen ist, zum Ausstanzen entsprechender Enden der Knochenpartien bzw. eines in eine solche Knochenpartie-Ausformung einsetzbaren Knochensäulchens mit korrespondierendem Querschnitt für Osteotomien oder für Arthrodesen; in bevorzugter Weiterbildung ist im Handgriff (1) Linear-Antrieb angeordnet ist, dessen Abtrieb mit der Meißelaufnahme (2) zusammenwirkend die Längsbewegung des Meißels (3) bewirkt.

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Osteotom sowie chirurgisches Instrument zur Osteotomie

Die Erfindung betrifft einen Osteotom mit einem an einen Handgriff (1) angesetzten oder ansetzbaren Meißel (3) mit Meißelfuß und Meißelklinge, die als Meißelschneide eine gerade, V-förmig oder gerundet ausgebildete Formschneide oder eine Hohlstanze aufweist; sie betrifft ferner ein chirurgisches Instrument zur Osteotomie, insbesondere in der Hand- und Fußchirurgie mit einem solchen Meißel.

Die Osteotomien an Hand und Fuß werden heutzutage in der orthopädischen Chirurgie mittels Hammer und Meißel oder mit oszillierenden Sägen durchgeführt. Die Meißel, sogenannte Osteotome, gibt es mit flacher und gebogener Meißelschneide (DE 23 05 699, US 4,150,675), mit V-förmiger Meißelschneide (US 6,391,031) und es gibt hinterschliffene Meißel. Der Hals kann gerade ausgebildet sein oder nach Bedarf Kröpfungen aufweisen, wie beim Schwanenhalsmeißel. Die Osteotome können in einem Stück geformt oder aus mehreren Teilen zusammengesetzt sein, wie zum Beispiel der Klingenmeißel. Sie können aus einem Material oder einer Materialkombination mit Härtung der beanspruchten Teile bestehen. Für oszillierende Sägen sind auch gerade und bogenförmige Sägeblätter bekannt, die mit der Säge verschraubt werden. Die Vorteile der oszillierenden Säge ist die weniger ausgeprägte Verdichtung des durchtrennten Knochens, nachteilig ist die erhöhte Hitzeentwicklung;

BESTÄTIGUNGSKOPIE

demgegenüber liegt der Vorteil der Meißelosteotomie in der geringeren Hitzeentwicklung mit geringgradiger Knochenrandzerstörung.

Nach Durchtrennung des Knochens wird die geplante neue Einstellung der Knochenteile im Normalfall durch eine Osteosynthese gehalten. Dazu finden Verklemmung, Naht, Draht, Schrauben, Platten oder Klammern und ähnliche metallische Materialien Anwendung; bioresorbable Implantate sind ebenfalls im Gebrauch. Eine Materialentfernung und somit eine erneute Operation ist bei Verklemmung und bei bioresorbablen Implantaten in der Regel nicht notwendig. Jedoch sind Versetzungen und Verschiebungen des abgetrennten Knochenteils nicht auszuschließen, darüber hinaus ist die Berührungsfläche der Knochenteile klein und somit auch die zum Verwachsen verfügbare Fläche. Weiter eignen sich diese bekannten Osteotome für die manuelle Anwendung mit Hammer und Meißel, wobei zweihändig gearbeitet wird.

Daraus folgt als technisches Problem, einen solchen Meißel so weiter zu bilden, dass die damit gebildete Trennfuge ein Zusammenfügen der Knochenteile in im Wesentlichen gegeneinander fixierter Lage bei vergrößerter Anlagefläche ermöglicht; ferner soll der Meißel in ein Osteotom eingesetzt, ein einhändiges Halten des Instrumentes während der Operation erlauben.

Die Lösung dieser Aufgabenstellung wird durch die kennzeichnenden Merkmale der unabhängigen Ansprüche gegeben; vorteilhafte Weiterbildungen und bevorzugte Ausführungsformen beschreiben die abhängigen Ansprüche.

Die axiale Krafteinleitung durch den Meißel mit ruhiger Meißelführung erlaubt die aufgeführten Formen der Knochendurchtrennung mit Nuten und Wülsten und weitere an diese angelehnte Varianten mit Hinterschneidungen, Kröpfungen, Krümmungen und Stufenbildungen anzuwenden, die mit der oszillierenden Säge nicht möglich sind. Solche Osteotomien vergrößern die Knochenkontaktflächen der Fragmente zueinander und/oder erhöhen deren Primärstabilität. Sie sind Voraussetzung, Varianten zur Optimierung gebräuchlicher Osteotomien durchzuführen und weiter zu entwickeln.

Das Wesen der Erfindung wird in den Figuren 1 bis 29 beispielhaft dargestellt, wobei sich die Beschreibungen auf die Meißelklinge mit Meißelschneide und Ausnehmungen, Verstärkungen, und den Meißelfuß, bezieht, sowie auf die Ausbildung für manuelle Anwendungen, sowie für axiale Antriebe wie

Druckluft- bzw. Hydraulikantrieb, elektromagnetischer, magneto- oder elektrostriktiver bzw. piezoelektrischer Antrieb; im Einzelnen zeigen:

Fig. 1: Meißelklinge gerade (Stand der Technik);
Fig. 2: Meißelklinge mit Nut mit rechteckigem Querschnitt;
Fig. 3: Meißelklinge mit Nut mit U-förmigen Querschnitt;
Fig. 4: Meißelklinge mit schwalbenschwanzförmiger Nut;
Fig. 5: Meißelklinge mit Omega-förmiger Nut;
Fig. 6: Meißelklinge V-förmig (Stand der Technik);
Fig. 7: Meißelklinge mit mehreren teilkreisförmigen Nuten;
Fig. 8: Meißelklinge mit rechteckiger, einseitig angeordneter Nut;
Fig. 9: Meißelklinge mit U-förmiger, einseitig angeordneter Nut;
Fig. 10: Meißelklinge mit U-förmiger Nut und Rinne, beide einseitig angeordnet;
Fig. 11: Meißelklinge abgerundet und hohl (Stand der Technik);
Fig. 12: Meißelklinge abgerundet, mit Omega-förmiger Nut;
Fig. 13: Meißelklinge löffelartig ausgebildet, ohne Nut;
Fig. 14: Meißelklinge löffelartig ausgebildet, mit Nut;
Fig. 15: Meißelklinge als rechteckförmige Hohlstanze;
Fig. 16: Meißelklinge als mehreckförmige Hohlstanze;
Fig. 17: Meißelklinge als doppel-trapezförmige Hohlstanze;
Fig. 18: Meißelklinge als kreisförmige Hohlstanze;
Fig. 19: Meißelklinge mit Rastnase an die Meißelhalterung angesetzt (Aufsicht);
Fig. 20: Meißelklinge nach Fig. 15 (Seitansicht);
Fig. 21: Meißelklinge mit Knebelverschluss an die Meißelhalterung angesetzt (Aufsicht);
Fig. 22: Meißelklinge nach Fig. 17 (Seitansicht);
Fig. 23: Osteotom mit Axial-Antrieb.
Fig. 24: Einzelheit druckluftbetriebener Axialantrieb;
Fig. 25: Einzelheit elektromagnetischer Axialantrieb;
Fig. 26: Einzelheit ektrostriktiver Axialantrieb;
Fig. 27: Einzelheit magnetostriktiver Axialantrieb;
Fig. 28: Fußskelett mit Hallux valgus Darstellung;
Fig. 29: Darstellung von Osteotomieen zur Hallux Valgus Korrektur,
Fig. 29 A: Arthodese mit Verzapfung,
Fig. 29 B: Interphaleare Resektions-Arthrodese,
Fig. 29 C: Sägezahn-Osteotomie mit Winkelkontrolle.

Die dargestellten Meißel 3 (Fig. 1 - 18) weisen jeweils eine Meißelschneide auf, die V- oder U-förmig, Omega-förmig oder hohlrund ausgebildet sein kann; die Meißelklinge mit durch Rasterung angedeuteter Ausformung ist zur

Ausformung der beim Durchtrennen des Knochens entstehenden Trennfuge mit mindestens einer längsverlaufenden Nut versehen. Mit dieser Meißel-Nut kann einseitig sowohl eine federartige Wulst am dem einen Knochenteil, wie auch eine korrespondierende Nut am anderen Knochenteil erzeugt werden, die in Art einer Nut-/Federverbindung zusammengefügt werden. Das abgetrennte Knochenteil kann auch nach Verschiebung und/oder Verdrehung im Wesentlichen mit Formschluss an das verbliebene Knochenteil angefügt werden.

Spezielle Anwendungen der in den Figuren 2 bis 18 dargestellten Meißelformen werden im Folgenden am Beispiel der operativen Behandlung u. a. eines Hallux Valgus näher erläutert. Die Figur 28 zeigt einen Fuß 30 mit ausgeprägtem Hallux Valgus. Der auf dem inneren Keilbein 37 (Os Cuneiformia I) aufsitzende Mittelfußknochen 32 des ersten Strahls (Os Metatarsale I) bildet mir dem Mittelfußknochen 36 des zweiten Strahls (Os Metatarsale II) einen Intermetatarsalwinkel von ca. 25°. Diese Fehlstellung ist von einer deutlich sichtbaren knöchernen Auswachsung 32.1 am inneren Rand des Mittelfußknochens 32 begleitet, sowie häufig von einer arthrotisch Gelenkveränderung. Durch den Zug der die Zehenglieder 33 des Großzehs 31 bewegenden Sehnen kommt es zu einer Drehung der Großzehe 31 nach innen (Innenrotaion). Statt von den anderen Zehen 35 weg nach innen wird die Großzehe 31 dadurch mit der Zeit immer mehr fußsohlenwärts gezogen (Flexion) und einwärts gewendet (Pronation) und zur permanenten Abweichung der Großzehe 31 aus der Normalstellung. Zusätzlich zieht die lange Strecksehne die Großzehe 31 noch weiter nach außen und verschlechtert den Zustand weiter. Bei manifestem Zustand kann oft nur eine Operation mit Osteotomie Hilfe bringen. Aus der Vielzahl der verschiedenen Operationstechniken werden im Folgenden einige dargestellt, bei denen auf die Verwendung der speziellen Meißelformen nach der Erfindung eingegangen wird.

A) Verschiebe-Osteotomie des Mittelfußköpfchens bei Mittelfußschmerz: Vornehmlich angewandt werden die Verfahren nach Weil, Gauthier, Helal und Uhthoff. Um ein korrektes Alignement der Mittelfußköpfchen in horizontaler und vertikaler Ebene zu erreichen oder einzelne Strahlen in der Belastungsverteilung in geänderter Form zu beteiligen, werden die Mittelfußköpfchen nach Weil etwa parallel zur Auftrittsfläche mit einem glatten Knochenschnitt von den Mittelfußknochen getrennt, proximal versetzt und mit einer Kleinfragmentschraube quer zur Osteotomieebene fixiert. Nach Gauthier wird ein zusätzlicher Keil mit distaler Basis entnommen, was eine zusätzliche Anhebung bewirkt. In beiden Fällen sind Rotationen des Köpfchens trotz

Verschraubung nicht ausgeschlossen. Nach Helal ist eine Verschraubung der rechtwinklig zur Auftrittsebene abgetrennten Mittelfußköpfchen nicht vorgesehen, das bei Belastung von selbst die korrekte Lage finden soll. Fehlstellungen und Falschgelenkbildungen sind nicht selten. Nach Uhthoff wird proximal vom Metatarsalköpfchen ein dorsaler Keil aus dem Mittelfußknochen entnommen, ohne diesen komplett zu durchtrennen. Der Spalt schließt sich bei Belastung. Eine kontrollierte Verschiebung und Grundgelenkentlastung erlaubt die Osteotomie nach Weil. Die nahezu auftrittsflächenparallele Osteotomie kann mit der Meißelklinge der Figur 3 mit längsverlaufender mittiger Nut vollzogen werden.

Als hier neu wird die rotationsstabile Verschiebung beschrieben, wie sie nach axialer Osteotomie mit den Meißelklingen der Figuren 2, 3, 4, 5 mit längsverlaufenden Nuten und der Figur 6 mit V-förmiger Schneide oder der Fig. 7 mit hohlrunder Schneide durchgeführt werden kann. Meißelklingen mit vorzugsweise schwalbenschwanzförmig hinterschnittener Nut nach Figur 4 (s. Fig. 29A) oder omegaförmig hinterschnittener Nut nach Figur 5 (Fig. 29 B), erzeugen im Vorteil gegenüber der Meißelklinge mit längsverlaufender Rechteck-Nut nach Figur 3 keine bruchgefährdeten Ecken in der vom Meißel erzeugten Rinne. Die Osteotomien mit Meißeln der Figuren 4 und 5 lassen durch die hinterschnittene Ausformung ein Abheben der Knochenfragmente voneinander nicht zu. Durch Eindrücken des Knochenüberstandes in den Osteotomiespalt können die durchtrennten Knochenpartner ohne oder mit minimaler weiterer Fixierung (Naht-Osteosynthese) in Position gehalten werden.

B) Verschiebe-Osteotomie des ersten Mittelfußköpfchens bei Hallux Valgus (Großzehenballen): Zur Verschmälerung eines Hallux Valgus Fußes und zur Reposition des Mittelfußköpfchens, auf die meist luxierten Sesambeine, wird das Mittelfußköpfchen des ersten Mittelfußknochen abgetrennt und fußaußenwärts verlagert. Hierfür stehen viele Verfahren zur Verfügung, als günstig hat sich die Verschiebung als Chevron-Osteotomie (Operation nach Austin) erwiesen. Der Sehnenzug drückt die Knochenflächen aufeinander, daher ist eine Osteosynthese mit Draht oder bioresorbablem Stift ausreichend, wobei der Knochen mit Flachmeißel (Fig. 2) oder oszillierender Säge durchtrennt wird. Diese Operation kann vorteilhaft mit einem V-förmigen oder teilcirculär gewölbten Meißel mit einer Vielzahl längsverlaufender Nuten nach der Erfindung (Fig. 7) durchgeführt werden. Die semicirculäre Variante erlaubt ein winkelkontrolliertes Herabsetzen oder Anheben des Köpfchens über die

Zahnung ein V-förmiger Meißel mit sägezahnähnlichen Nuten kann einen Schnitt ergeben, der Verschiebungen mit stabilen Fragmenten erlaubt.

Lässt sich das V-förmig abgetrennte Köpfchen vom Mittelfußknochen abheben, so bieten die Varianten der Meißel mit V-förmiger Schneide mit Nut (Fig. 8, 9, und 10) die bisher nicht beschriebene Möglichkeit, das Mittelfußköpfchen trotz Durchtrennung am Mittelfußknochen in axialer Zugrichtung zu halten; dabei können die Tiefkerbungen in den Flanken der Meißelschneiden (Fig. 8, 9 und 10) auch beidseitig vorgesehen sein.

C) Basisnahe Verschiebe-/Rotations-Osteotomie bei Metatarsus primus varus:
Diese Osteotomien werden zur Verkleinerung des Winkels zwischen dem ersten und zweiten Mittelfußknochen (Fig. 28) durchgeführt, sie eignen sich in Einzelfällen auch zur Verkleinerung eines übergroßen Winkels zwischen dem vierten und dem fünften Strahl. Üblicherweise wird der erste Mittelfußknochen basisnah durchtrennt. Bei gerader Osteotomie, wie mit dem Meißel der Figur 2 durchführbar, bieten sich die offene Keil-Osteotomie mit Einfügung eines vom Fußinnenrand eingebrachten Keiles und die geschlossene Keilosteotomie mit Entnahme eines Keiles an, der seine Spitze am Fußinnenrand hat. Eine weitere Variante ist die von der Seite V-förmig angelegte Osteotomie, wie sie mit Meißeln nach Fig. 6 und 7 durchgeführt werden kann.

Hierbei wird auch ein Keil entweder entnommen, oder hinzugefügt. Als neu beschriebene Varianten können die Meißel, bei denen Einkerbungen vorliegen, durch Verzahnung oder Verzapfung zu einer größeren Stabilität zwischen den Knochenpartnern führen, und somit eine weniger aufwendige Osteosynthese verlangen. Gebräuchlich ist die Crescentic Basis-Osteotomie nach Mann, von ihm mit der bogenförmigen oszillierenden Säge durchgeführt, so dass sich die Knochen, von oben durchtrennt, um die notwendigen Korrekturwinkelgrade schenken lassen. Nach Küster wird zur Vermeindung des Sägeschnitts der Knochen mit einem bogenförmigen Meißel oder einem Klingenmeißel und dem Hammer durchtrennt, was beidhändiges Arbeiten voraussetzt. Der Chirurg benötigt Hilfe, mit der das Operationsobjekt (der Fuß oder die Hand) in der für das Trennen geeigneten Position gehalten wird. Das Osteotom nach der Erfindung ermöglicht einhändiges Arbeiten, so kann der Chirurg selbst das Operationsobjekt (den Fuß oder die Hand) in der für sein Arbeiten gewünschten Position halten und die Trennung durchführen.

Die Knochendurchtrennung mit einem Meißel oder einer Klinge, wie in Figur 13 dargestellt, löffelförmig hohlrund, ohne Kröpfung oder Verzahnung, ermöglicht das Schwenken der Knochenpartner in allen Ebenen, mit späterer Osteosynthese in korrekter Stellung. Mit Verzahnung (Fig. 14) oder erweitert als schwalbenschwanz- oder Omega-förmige Verzahnung, wie weiter oben beschrieben, wird eine hohe primäre Verbindungsstabilität geschaffen. In Weiterbildung ist auch eine Meißelklinge mit einer Anzahl von Nuten (Fig. 7) möglich und lässt eine bogenförmige Osteotomie zu, deren definierte Verzahnungswinkel die Schwenkbreite vorgibt und eine Kombination aus lateraler und bogenförmiger Osteotomie darstellt (Fig. 29 C).

D) Basisnahe Anhebe-/Verkürzungs-Osteotomie bei Hohlfuß und metatarsaler Überlänge: Diverse Möglichkeiten der Osteotomie mit und ohne Verzahnung ergeben sich aus den oben aufgeführten Schnitttechniken in entsprechend anderen Ebenen.

E) Krallen-, Hammer- und Klauenzehbehandlung und andere Zehenfehlstellungen: Zur Korrektur erfolgt ein gelenknahes Formgeben mit Meißeln nach den Fig. 4, 5, 11, 13 und 14; dies erlaubt die Herstellung einer kongruenten Passung zur Gelenkeinsteifung (Fig. 29 A).

F) Fuß- und handchirurgische Korrekturosteotomien bei Überlängen, axialen Fehlstellungen, Arthrodesen (Gelenkeinsteifungen): In Fuß- bzw. Handchirurgie werden Knochendurchtrennungen und Verbindungen in üblicher, entsprechend dem Stand der Technik mit geradem oder schräg geführtem Schnitt durchgeführt und mit Osteosynthesematerialien (Drähte, Schrauben, Platten und bioresorbable Materialien) verbunden. Die oben aufgeführten V-förmigen, U-förmigen, Omega-förmigen und hohlrunden Knochendurchtrennungen mit eigens hierzu vorgerichteten Meißeln und Antrieben zur zwei- und einhändigen Anwendung sind nicht beschrieben. Den Ansprüchen für die Fußchirurgie entsprechend erlauben derartige Instrumente Verschiebungs- und Achskorrekturdurchtrennungen des Knochens, Verzapfungen bei Verkürzungs- oder Verlängerungsosteotomien und bei Gelenkeinsteifungen. Fig. 29 B zeigt eine Verzapfung zwischen Mittelfußknochen 32 und Keilbein 37, Fig. 29 C eine Einsteifung des Zehengrundgelenks 34 in Verbindung mit Sägezahn-Osteosynthese.

G) Weitere Osteotomien und Arthrodesen (Gelenkversteifugen am Skelett): Mit in der Größe entsprechend modifizierten Meißeln und der Möglichkeit einer Osteosynthese mit Verzapfung oder Verzahnung der entsprechend ausgeformten

Enden der Knochenpartner sind auch weitere Osteotomien und Arthrodesen, planbar, wobei besonders die geringere Wärmeentwicklung bei der Meißeltechnik vorteilhaft ist. Insbesondere bei Gelenkversteifungen können durch die hier aufgeführten Meißel in bisher nicht beschriebener Einhand-Technik die kommunizierenden Gelenkflächen für eine Versteifung vorbereitet werden. ,

Mit speziellen Meißeln, deren Schneide als rechteckförmige, einfach- oder doppel-trapezförmige sowie gerundet oval- oder kreisförmige Hohlstanze (Fig. 15, 16, 17 und 18) ausgebildet ist, kann der Knochen gelenküberbrückend ausgemeißelt werden. Nach Entnahme des ausgemeißelten Knochensäulchens, gegebenenfalls mit einem passgerechten Durchschlagstift, wird dieses um einen beliebigen Winkel gedreht und mit einem Einsetzstift zur Gelenküberbrückung wieder eingebracht (Fig. 29 A). Statt des entnommenen Säulchens kann auch ein gleichartiges Säulchen, das aus dem Beckenkamm, dem Schienbein und anderen Eigen- oder auch Fremdknochen entnommen oder aus einem bioresorbablen Material bestehend, wieder eingefügt werden.

Die Osteotome können als frei zu handhabende Meißel mit Schneide, Meißelfuß und -kopf oder als Klingen mit Adapter für die oben beschriebenen Antriebsformen ausgelegt werden. Eine Form der Adaptation ist in den Figuren 19 bis 22 gezeichnet, sie sieht eine Aussparung im Meißelfuß 4 vor, die formschlüssig in die Meißelaufnahme 2 eingeführt und mit einer Rastnase verklemmt oder durch Verdrehung eines Knebels gehalten wird. Andere Möglichkeiten der Befestigung sind Bajonettverschlüsse, die als Dreh- oder Schiebebajonett ausgebildet sein können; weiterhin sind auch Schraubenverschlüsse anwendbar.

Die in den Anwendungsbeispielen A) bis G) beschriebenen Meißelformen sind in manueller Anwendung einsetzbar, wozu die Meißelklinge 3 an ein Handgerät angesetzt wird. Die Meißelklinge 3 wird in die Meißelaufnahme 2 so eingesetzt, dass der Meißelfuß 4 in Arbeitsrichtung an einem Anschlag 7 anliegt, der die Kraftübertragung in Arbeitsrichtung sicherstellt. Vorteilhaft wird ein Formschluss mit Aufnahmen 6 auch seitlich hergestellt oder die Aufnahme 6 wird taschenförmig ausgebildet, so dass der Meißelfuß 4 starr mit der Meißelaufnahme 2 verbunden ist. Als Halterung für den Meißel 3 in der Meißelaufnahme werden vorteilhaft Rastmittel oder Knebelverschlüsse vorgesehen. Dazu weist der Meißel 3 im Bereich des Meißelfusses 4 eine Ausnehmung 3.1 auf, die der Verschluss-Form des Knebels 5.1 angepasst ist. Bei Verwendung einer Rastnase 5.2 wird die Ausnehmung 3.1 eine etwa rechteckige Form

haben, bei Verwendung eines umlegbaren Knebels 5.1 dagegen die Form einer "Acht". In beiden Fällen ist der Meißel 3 austauschbar: Bei der Rastnase 5.1 wird diese zurückgedrückt, bei Verwendung eines Knebels 5.1 wird dieser verdreht, wobei die Sperrlage des Knebels 5.1 vorteilhaft mit Rastmitteln gesichert wird. Es erscheint dabei selbstverständlich, dass hier zum Festlegen des Meißelfusses 4 in der Meißelaufnahme 2 auch andere Mittel wie etwa Bajonett- oder Schnellverschlüsse vorgesehen sein können.

Insbesondere für größere Hübe können zusammen mit Rotationsantrieben auch Getriebe oder rotierende Steuerscheiben, die im Zusammenwirken mit einem Stössel, einem Gestänge o.dgl. die lineare Bewegung formen, als Meißel-Antrieb vorgesehen sein. Dabei können als Rotationsantriebe neben elektromagnetischen Motoren auch Druckluft-Hubkolbenmotor, die über ein Gestänge mit der Steuerscheibe verbunden sind, vorgesehen und eingesetzt sein. Der mit der Steuerscheibe zusammenwirkende Abtrieb wirkt dann entweder direkt oder über ein zweites Gestänge auf den Meißel. Diese im Handgriff angeordneten Mitteln bewirken das Umsetzen der Rotationsbewegung in eine hin- und hergehende Liniearbewegung des Meißels. Die motorischen Antriebsteile können dabei sowohl im Handgriff wie auch außerhalb diesen angeordnet werden; bei der Anordnung außerhalb überträgt eine biegsame Welle die Rotation.

Vorteilhaft sind jedoch axiale Linearantriebe, etwa ein aktiver Linearantrieb, wie beispielsweise Pressluft- und Hydraulikantrieb (Fig. 23, 24), sowie elektromagnetische Antriebe (Fig. 25) oder elektro- bzw. magnetostriktive Antriebe (Fig. 26, 27), die gegen die Antriebs-Abstützung 5 abgestützt sind. Solche axialen Antriebe ermöglichen einen einhändigen Betrieb, so dass dem Operateur vorteilhaft die zweite Hand als Haltehand zur Verfügung steht. Der Linearantrieb arbeitet mit Schlagfrequenzen von über 1.000/min, vorzugsweise von über 10.000/min bei einem Hub von maximal 5 mm, vorzugsweise unter 1,5 mm. Für Feinarbeiten (Hand- oder Fußchirurgie) erscheinen Meißelhübe im Bereich unter 1 mm, für gröbere Arbeiten am Skelett sind Meißelhübe bis zu 5 mm sinnvoll. Um die kleinen Hübe zu erreichen, wird es im Allgemeinen ausreichen, wenn direkte Antriebe eingesetzt werden, etwa lineare Pneumatik- oder Hydraulikantriebe 10 bzw. 15, aber auch Elektro- bzw. Magnetostriktionsantriebe 20 bzw. 26.

Als Linearantrieb ist ein Druckluft- oder ein Hydraulikantrieb vorgesehen. Dabei können die Antriebe auch als direkt arbeitende Linearantriebe ausgebildet sein, deren Kolben mit dem Stössel zusammenwirkt, an dessen freiem

Ende die Aufnahme für den Meißelfuß vorgesehen ist. Alternativ können diese Antriebe als rotierende Antriebe ausgebildet sein, deren Rotor exzentrisch angeordnet auf einen Stössel wirkt, der in Längsrichtung geführt ist, und an dessen freiem Ende die Aufnahme für den Meißelschaft angeordnet ist. Dabei kann auch an Stelle des pressluftgetriebenen Rotors ein elektromagnetisch getriebener Rotor vorgesehen sein.

Ein anderer Linearantrieb weist ein elektrostriktives oder piezoelektrisches oder aber ein magnetostriktives Antriebsglied auf. Bei diesem Antrieb werden die Wirkungen elektrischer Spannungsimpulse oder die magnetische Wirkung elektrischer Stromimpulse ausgenutzt, um mechanische Längenänderungen zu erzielen. Zwar ergeben Effekte der Elektrostriktion, des piezoelektrischen Effekts oder der Magnetostriktion lediglich (relativ) kleine Längenänderung, jedoch mit hohen Schlagfrequenzen. Für größerer Hübe werden Kaskadenanordnungen eingesetzt, um die gewünschten Hubhöhe als Hub auf den Meißel zu bringen, wobei die auftretenden Kräfte durchaus für Knochen-Durchtrennung ausreichend sind.

Die Figur 23 zeigt ein Osteotom in Ansicht; in den Figuren 24 bis 27 sind Osteotome im schematischen Schnitt beispielhaft für solche Linearantriebe dargestellt: In dem Handgriff 1, der gleichzeitig das Gehäuse bildet, an dessen einem Ende die Energieversorgung als Strom-/Pressluftzuführung 9 ansetzt, ist das Antriebsorgan angeordnet. Der Abtrieb des Antrieborgans wirkt auf die Meißelaufnahme 2, die den Meißel 3 aufnimmt, der mit einem Knebel 5 in der Aufnahme gehalten ist. Zur einwandfreien Führung ist diese Meißelaufnahme 2 so ausgebildet, dass der Meißelfuß 4 mit Formschluss in diese eingeführt werden kann.

Der Antrieb nach Figur 20 ist mit einem pneumatischen Schlag-Antrieb 10 versehen. Die Pressluftzufuhr erfolgt über eine düsenartige Zuführdüse 9.1 durch eine erste Platte 11, der eine zweite Platte 12 gegenüberliegt. Diese zweite Platte 12, die von einer Feder 14 niedergehalten wird, wirkt mit einem Stössel 13 zusammen, der seinerseits mit der Meißelaufnahme 2 direkt verbunden ist. Die durch die Zuführdüse 9.1 einströmende Pressluft baut vor der zweiten Platte 12 Druck auf, der diese Platte gegen die Kraft der Feder 14 anhebt, wodurch sich zwischen erster Platte 11 und zweiter Platte 12 ein Spalt öffnet, durch den die Pressluft radial abströmt und ein Zusammenbrechen des Druckes bewirkt, wobei sich im Spalt noch ein Unterdruck ausbildet. Beide Effekte wirken zusammen und ermöglichen mit der Kraft der Feder

14 der zweiten Platte 12 in Ausgangsstellung zurückzukehren, so dass sich das Spiel wiederholen kann. Die dadurch in den Stössel 13 übertragene Linearbewegung wird auf die Meißelaufnahme 2 und somit auf den Meißel 3 übertragen. Frequenz und Hub werden durch das Zusammenspiel von Pressluftdurchfluss, -vordruck und Kraft der Rückstellfeder bestimmt. Pressluftvordruck und Pressluftdurchfluss lassen sich einstellen, so dass die für die Arbeit notwendigen Werte einstellbar sind, wobei das Einstellen zumindest des Pressluftdurchflusses am Handgriff 1 vorgenommen werden kann. Dazu ist hier ein Einstellrad 8 vorgesehen, das selbstverständlich auch seitlich herausragend angeordnet oder als ein Schieberegler ausgebildet sein kann.

Der Antrieb nach Figur 21 ist mit einem Rotations-Antrieb 15 versehen, der üblichen Rotationsantrieben entspricht, entweder - wie mit Turbinenantrieb dargestellt - mit pneumatisch/hydraulisch oder elektromagnetisch angetriebenem Rotor 16. Dieser wirkt auf den Stössel 17, der seinerseits die Linearbewegung der Meißelaufnahme 2 mit dem Meißel 3 bewirkt. Dabei ist eine mit dem Rotor 16 verbundene Steuerscheibe 18 exzentrisch gelagert, so dass der auf ihr aufstehende und von der Feder 19 gegen sie angedrückte Stössel 17 der Exzentrizität der Steuerscheibe 18 folgend eine Linearbewegung vollführt. Die exzentrische Steuerscheibe 18 hebt den Stössel 17 an, wobei die Feder 19 gespannt wird, die für die Rückstellung sorgt. Die mit dem Stössel 17 verbundene Meißelaufnahme 2 führt dabei eine lineare Hin- und Herbewegung aus, die sich auf den Meißel 3 überträgt. Die Drehzahl des Rotors 16 gibt dabei die Schlagfrequenz an, die vorteilhaft an dem Handgriff 1 einstellbar ist. Die Schlagamplitude hängt von der Exzentrizität ab und muss jeweils voreingestellt werden. Die Energieversorgung erfolgt über die Anschlussleitung 9, die als Stromkabel oder als Pressluftleitung ausgebildet ist. Dabei versteht es sich von selbst, dass zur elektrischen Versorgung des Antriebs auch eine im Handriff angeordnete Batterie vorgesehen werden kann, die austauschbar oder wieder aufladbar ist (wobei vorteilhaft die Ablage des Osteotoms als Ladestation ausgebildet ist).

Der Antrieb nach Figur 26 ist mit einem elektrostriktiven Antrieb 20 versehen. Dieser ist aus einer Vielzahl elektrostriktiver Elemente 21 aufgebaut, die gegeneinander durch Isolierlagen 22 jeweils über die Anschlussleitungen 23.1 und 23.2 für die positive bzw. negative Spannung gleichpolig von einer Spannungsquelle stammenden Impulsspannung so angeregt werden, dass sich die dadurch erzwungenen Längenänderungen addieren. Dabei gibt die Wiederholfrequenz der Impulse die Schlagzahl an, während die Spannungshöhe

ein Maß für die Schlagamplitude ist. Beide Größen lassen sich über die Impuls-Parameter regeln, wobei die Impuls-Parameter an der Spannungsquelle einstellbar sind. Gleiches gilt sinngemäß auch für piezoelektrische Antriebe. Die Längenänderung wird über den Stössel 24 auf die Meißelhalter 2 und somit auf den Meißel 3 übertragen. Hier können die elektrostriktiven Elemente 21, der Stössel 24 und die Meißelhalterung 2 starr gekoppelt sein, so dass die Rückstellfeder entfällt. In gleicher Weise ist der Antrieb nach Figur 27 als magnetostriktiver Antrieb 25 ausgebildet. In der von einem von einer Stromquelle kommenden Impulsstrom durchflossenen Spule 26 befindet sich ein Kern 27 aus einem magnetostriktiven Material, der auf den Stössel 24 wirkt, der seinerseits mit der Meißelaufnahme 2 zusammenwirkt. Bei Durchfluss der (relativ) hohen Impulsströme verkürzt/verändert sich die Länge des Kerns 27, was sich auf die Meißelaufnahme 2 überträgt und diese dadurch zu linearen Längsbewegungen zwingt, die sich auf den Meißel übertragen. Die Schlagfrequenz wird hier - wie auch bei der Elektrostriktion - durch die Wiederholfrequenz der Stromimpulse bewirkt, während der Schlaghub von der Größe des Impulsstromes bestimmt ist. Beide Werte lassen sich an der Stromquelle so einstellen, dass Frequenz und Hub im für die Operation gewünschten Bereich liegen. Die so erzielte Längenänderung wird vom Kern 27 unmittelbar auf die Meißelhalterung 2 übertragen, so dass auch hier eine starre Kupplung vorgesehen werden kann was eine Rückstell-Feder entbehrlich macht (was jedoch den Einsatz einer Rückstellfeder bei bloßer Anlage des Stössels am Antrieb nicht ausschließt).

Patentansprüche

1. Osteotom mit einem an einen Handgriff (1) angesetzten oder ansetzbaren Meißel (3) mit Meißelfuß und Meißelklinge mit einer gerade, V-förmig oder gerundet ausgebildeten Meißelschneide als Formschneide oder mit einer Hohlstanze, **dadurch gekennzeichnet,** dass die Meißelklinge ausgehend von der Meißelschneide sich in Längsrichtung des Meißels (3) erstreckend zumindest eine längsverlaufende Nut aufweist, zum Ausformen einer Nut bzw. einer korrespondierenden Wulst an dem durchtrennten Knochenende für formschlüssige Osteosynthesen.

2. Osteotom nach Anspruch 1, **dadurch gekennzeichnet,** dass der Nutquerschnitt, der "V"- oder trapezförmig ausgebildet ist, für eine Osteosythese mit vergrößerter Anlagefläche der Knochenenden.

3. Osteotom nach Anspruch 1, **dadurch gekennzeichnet,** dass der Nutquerschnitt zumindest halbkreisförmig ausgebildet ist,. wobei vorzugsweise die Halbkreisform zur Bildung eines Hinterschnitts über den Halbmesser hinaus geführt ist, für eine lagestabilisierte Osteosynthese.

4. Osteotom nach Anspruch 1,2 oder 3 **dadurch gekennzeichnet,** dass eine Anzahl der längsverlaufenden Nuten vorgesehen ist, zum Einstellen des Winkels, unter dem die Knochenenden zusammengefügt werden, für eine winkelkontrollierte Osteosythese.

5. Osteotom mit einem an einen Handgriff (1) angesetzten oder ansetzbaren Meißel (3) mit Meißelfuß und Meißelklinge mit einer gerade, V-förmig oder gerundet ausgebildeten Meißelschneide als Formschneide oder mit einer Hohlstanze, **dadurch gekennzeichnet,** dass die als Meißelklinge vorgesehene Hohlstanze mit einem rechteckförmigen, einen einfach- oder doppel-trapezförmigen oder einen oval- oder kreisförmig abgerundet ausgebildeten Querschnitt versehen ist, zum Ausstanzen entsprechend ausgeformter Enden der Knochenpartien bzw. eines in eine solche Knochenpartie-Ausformung einsetzbaren Knochensäulchens

mit korrespondierendem Querschnitt für Osteotomien oder für Arthrodesen.

6. Osteotom nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet,** dass zum Ansetzen des Meißels Meißelfuß (4) und Meißelaufnahme (2) mit Formschluss zusammenfügbar sind, und dazu eine Ausnehmung (311; 5.2) als Aufnahmeführung bzw. einen Vorsprung aufweisen, wobei vorzugsweise die Aufnahmeführung (6) mit einem Anschlag (7) zur Anlage des Meißelfußes (4) versehen ist, und Meißelfuß (4) und Meißelaufnahme (2) Mittel zum Festlegen des angesetzten Meißels aufweisen.

7. Osteotom nach Anspruch 6, **dadurch gekennzeichnet,** dass als Mittel zum Festlegen des angesetzten Meißels Meißelaufnahme (2) und Meißelfuß (4) mit den korrespondierenden Teilen eines vorzugsweise mit einem Rastknopf (5.2) entriegelbaren Bajonett-Verschlusses oder einem vorzugsweise mit einem verdrehbarer Knebel (5.1) entriegelbaren Übertotpunkt-Kippverschluss versehen sind.

8. Osteotom mit einem Übertotpunkt-Kippverschlusses nach Anspruch 7, **dadurch gekennzeichnet,** dass der verdrehbarer Knebel (5.1) in einer Ausnehmung angeordnet ist, die der Knebelform angepasst ausgeformt ist und wobei vorzugsweise Knebel (5.1) und Ausnehmung (3.1) im Wesentlichen die Form einer "Acht" derart aufweisen, dass der durch die Ausnehmung geführte Knebel (5.1) nach Verdrehung um etwa 90° quer zur Längsachse der "Acht" in Sperrstellung sitzt.

9. Chirurgisches Instrument zur Osteotomie, insbesondere in der Hand- und Fußchirurgie mit einem von einem Antrieb in Linearbewegung versetzbaren Meißel mit Formschneide oder Hohlstanze nach einem der vorstehenden Ansprüche 1 bis 8, **dadurch gekennzeichnet,** dass im Handgriff (1) ein pneumatischer oder hydraulischer Antrieb angeordnet ist, der als Linear-Antrieb ausgebildet, dessen Abtrieb mit der Meißelaufnahme (2) zusammenwirkend die Längenbewegung des Meißels (3) bewirkt.

10. Chirurgisches Instrument nach Anspruch 9, **dadurch gekennzeichnet,** dass der pneumatische oder hydraulische Linear-Antrieb als Schlagan-

trieb mit hin- und hergehenden Abtrieb ausgebildet ist, der einer Rückstellfeder (14; 19) aufweist, wobei die Rückstellfeder (14; 19) die Meißelaufnahme (2) aus ausgelenkter Stellung zurückholt.

11. Chirurgisches Instrument zur Osteotomie, insbesondere in der Hand- und Fußchirurgie mit einem von einem Antrieb in Linearbewegung versetzbaren Meißel mit Formschneide oder Hohlstanze nach einem der vorstehenden Ansprüche 1 bis 8, **dadurch gekennzeichnet,** dass der innerhalb oder außerhalb des Handgriffs angeordnete pneumatische, hydraulische oder elektromagnetische Antrieb einen rotierendem Abtrieb aufweist, der mit im Handgriff angeordneten Mitteln zum Umsetzen der rotierenden Bewegung in eine hin- und hergehende Linearbewegung zusammenwirkt, wobei der außerhalb des Handgriffs angeordneten Antrieb über eine biegsame Welle mit dem Handgriff verbunden ist.

12. Chirurgisches Instrument nach Anspruch 11, **dadurch gekennzeichnet,** dass als Mittel zum Umsetzen der rotierenden Bewegung des Abtriebs in Linearbewegung des Meißels eine mit dem Abtrieb zusammenwirkende Steuerscheibe oder ein mit dem Abtrieb zusammenwirkendes Getriebe vorgesehen ist, deren jeweiliger Ausgang auf die Meißelaufnahme einwirkend die Lineabewegung bewirkt.

13. Chirurgisches Instrument nach Anspruch 12, **dadurch gekennzeichnet,** dass als Steuerscheibe eine Exzenterscheibe vorgesehen ist, die über einen Stössel (17; 24) auf die Meißelaufnahme (2) einwirkt, wobei der Stössel (17; 24) oder die Meißelaufnahme (2) mit einer Rückstellfeder (14; 19) versehen ist, die die Meißelaufnahme (2) aus ausgelenkter Stellung zurückholt.

14. Chirurgisches Instrument zur Osteotomie, insbesondere in der Hand- und Fußchirurgie mit einem von einem Antrieb in Linearbewegung versetzbaren Meißel mit Formschneide oder Hohlstanze nach einem der vorstehenden Ansprüche 1 bis 8, **dadurch gekennzeichnet,** dass der Linear-Antrieb als im Handgriff angeordneter elektro- oder magnetostriktiver Antrieb (20) ausgebildet ist, gebildet von einer Anzahl von elektrostritiven bzw. magenetostriktiven Elementen (21) angeordnet in Art einer Kaskade, deren eines Ende im Handgriff abgestützt

ist, und deren freies Ende direkt oder indirekt auf die Meißelaufnahme (2) einwirkt.

15. Chirurgisches Instrument zur Osteotomie, insbesondere in der Hand- und Fußchirurgie mit einem von einem Antrieb in Linearbewegung versetzbaren Meißel mit Formschneide oder Hohlstanze nach einem der vorstehenden Ansprüche 1 bis 8, **dadurch gekennzeichnet**, dass der Linear-Antrieb als im Handgriff angeordneter Ultraschall-Antrieb (20) ausgebildet ist, dessen freies Ende direkt oder indirekt auf die Meißelaufnahme (2) einwirkt.

16. Chirurgisches Instrument nach einem der Ansprüche 11 bis 15, **dadurch gekennzeichnet**, dass für die Energieversorgung des Antriebs das Handstück mit einer Batterie versehen ist, die austauch- oder aufladbar ist.

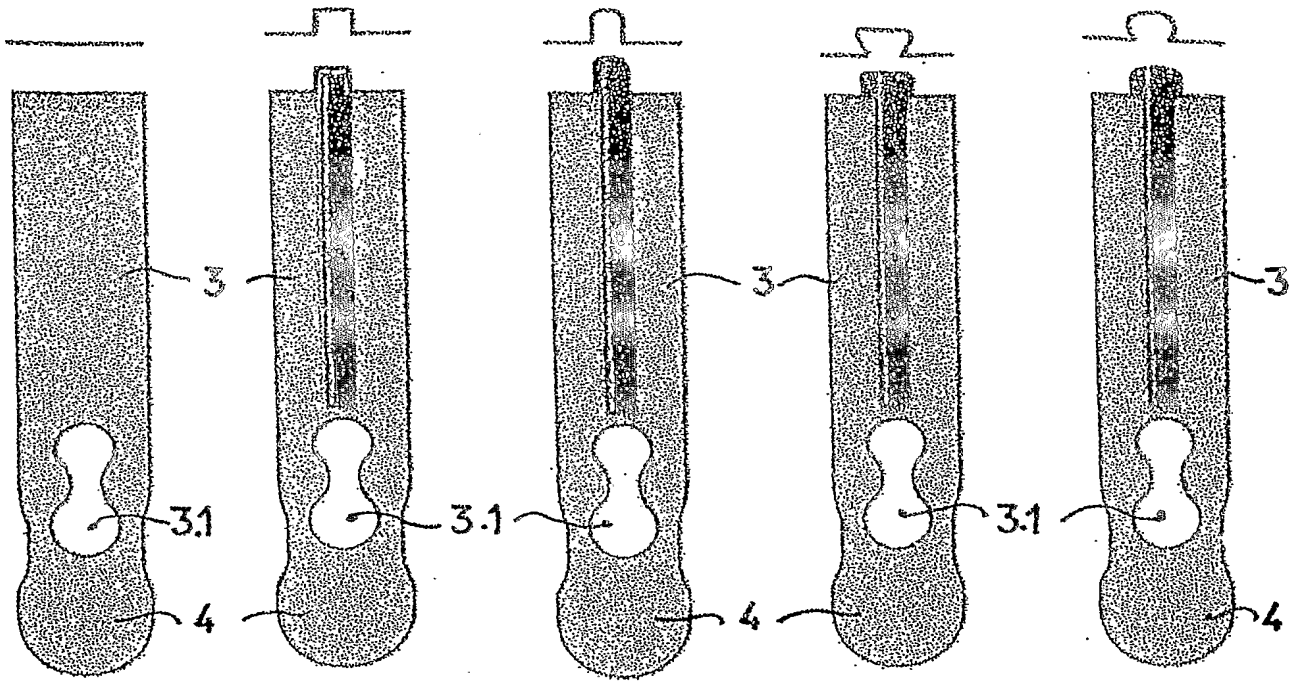


Fig. 1 Fig. 2 Fig. 3 Fig. 4 Fig. 5

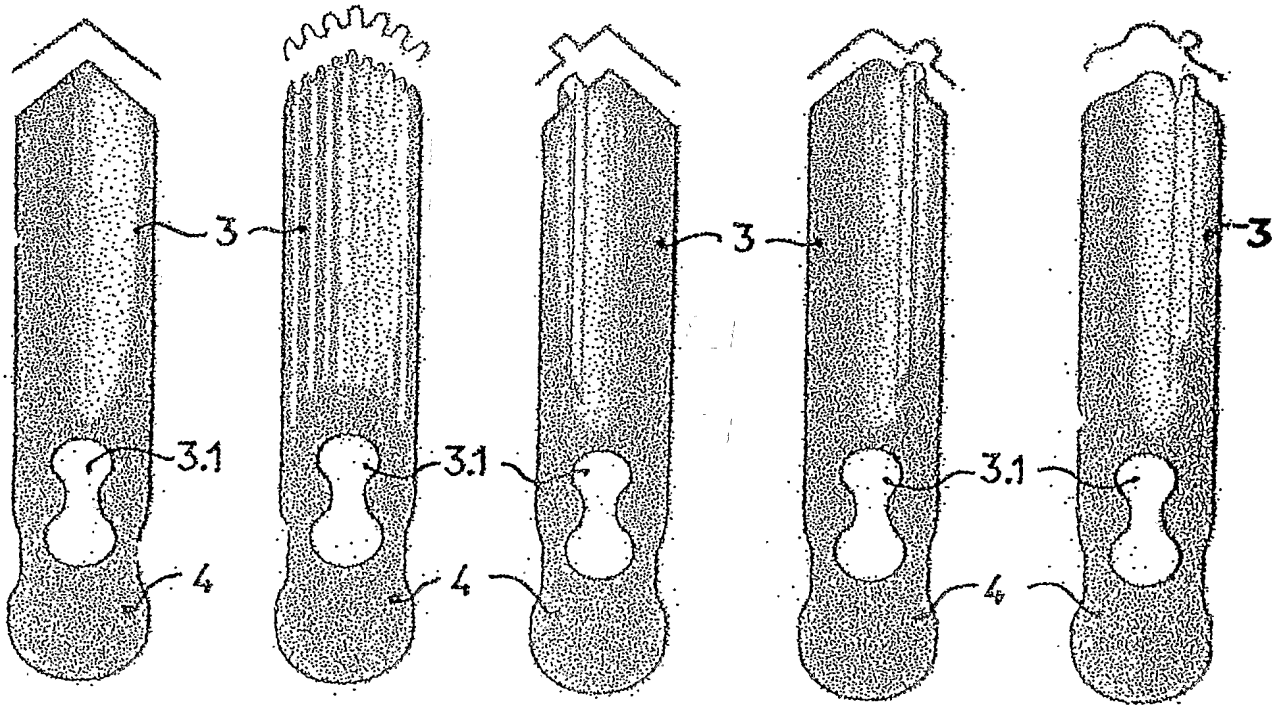


Fig. 6 Fig. 7 Fig. 8 Fig. 9 Fig. 10

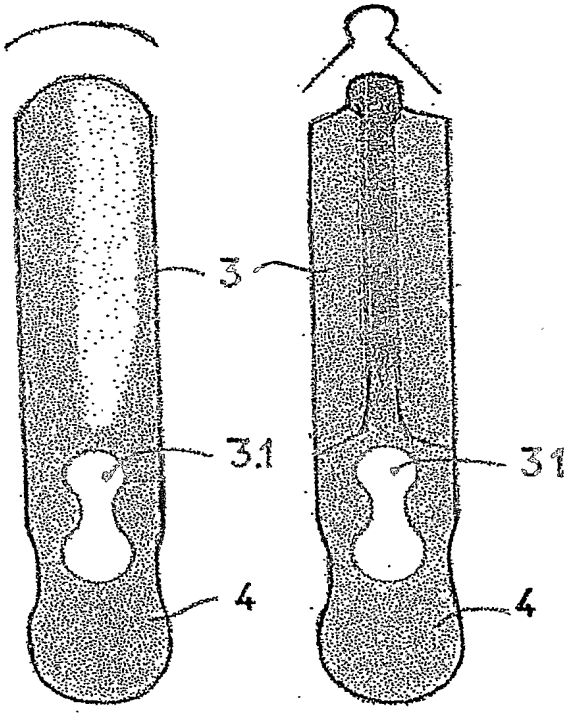


Fig. 11

Fig. 12

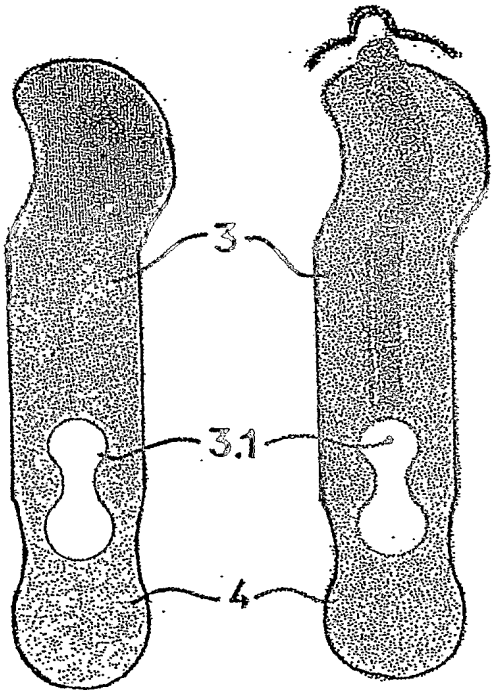


Fig. 13

Fig. 14

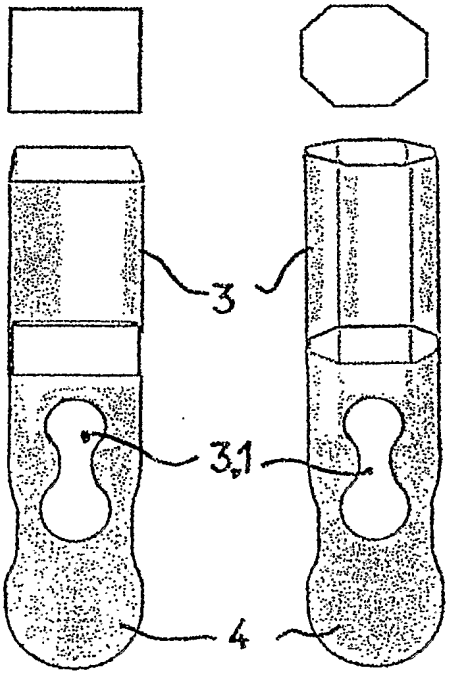


Fig. 15

Fig. 16

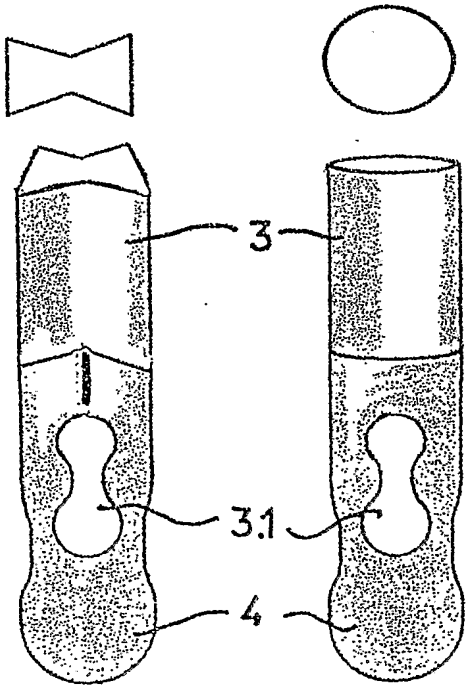


Fig. 17

Fig. 18

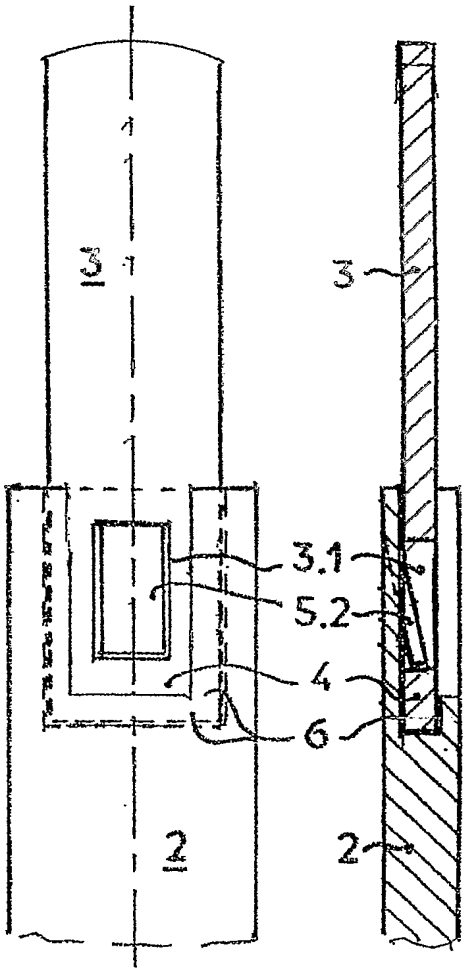


Fig. 19

Fig. 20

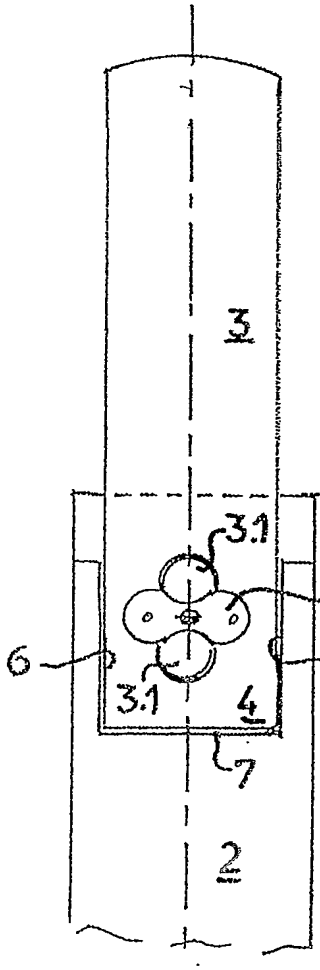


Fig. 21

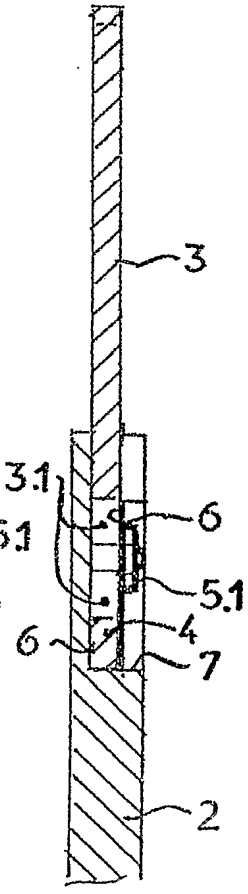


Fig. 22

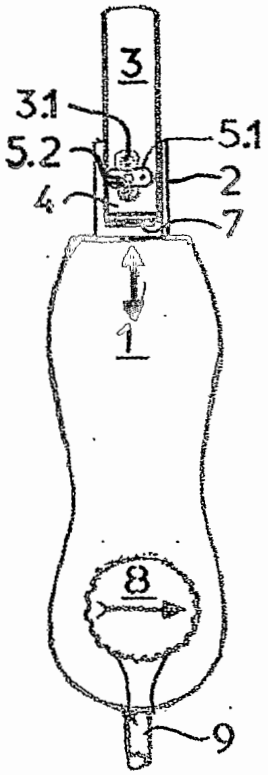


Fig. 23

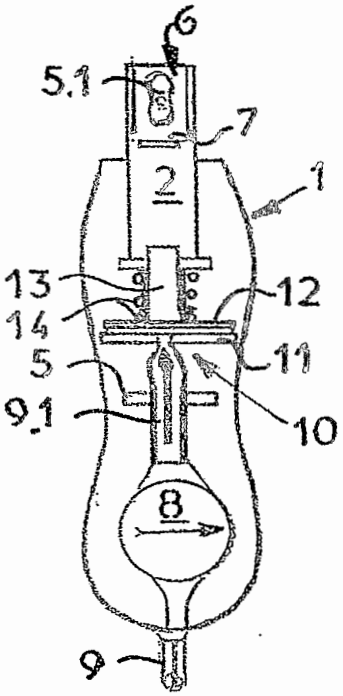


Fig. 24

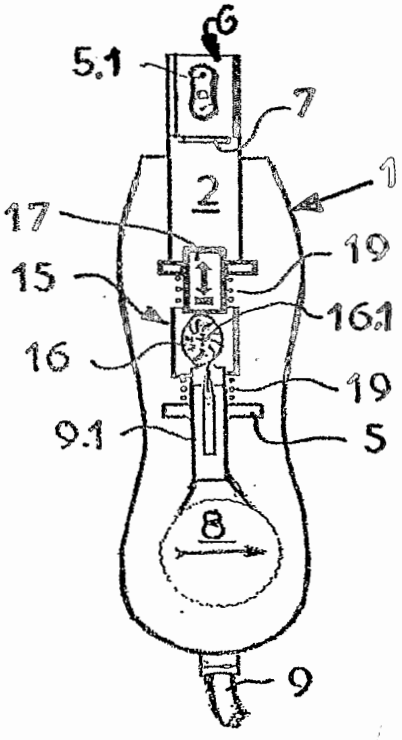


Fig. 25

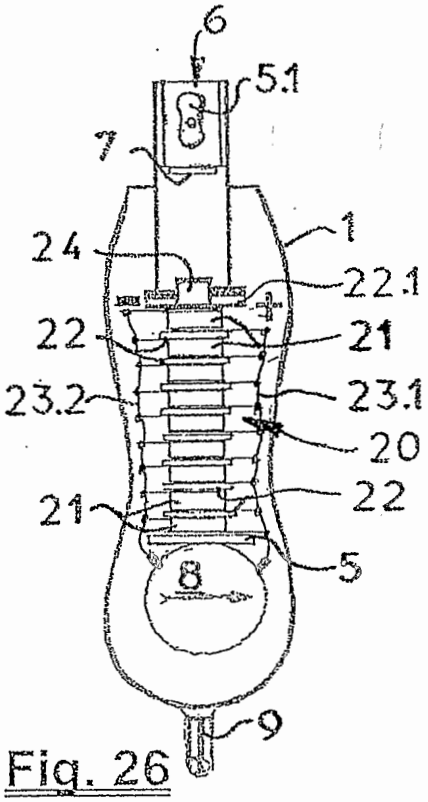


Fig. 26

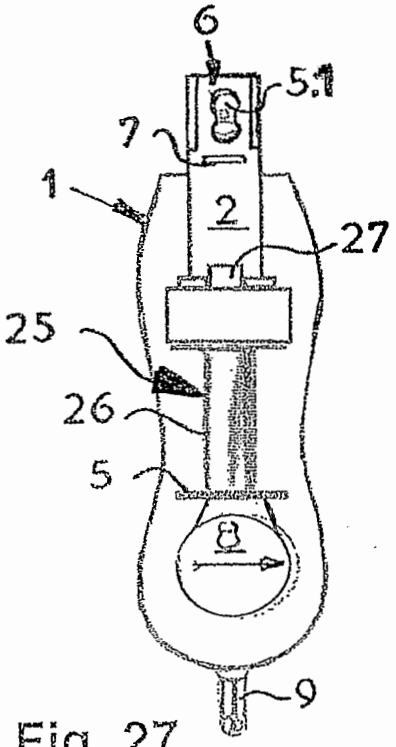


Fig. 27

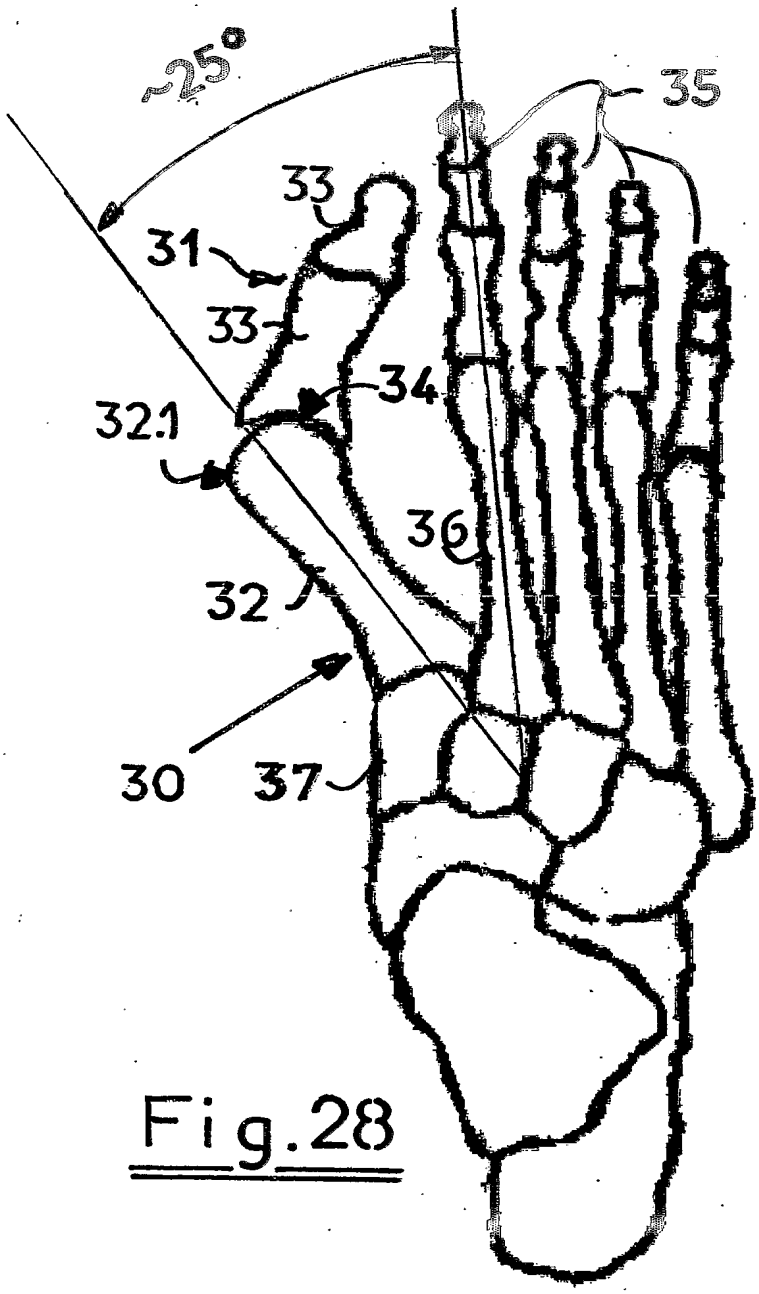


Fig.28

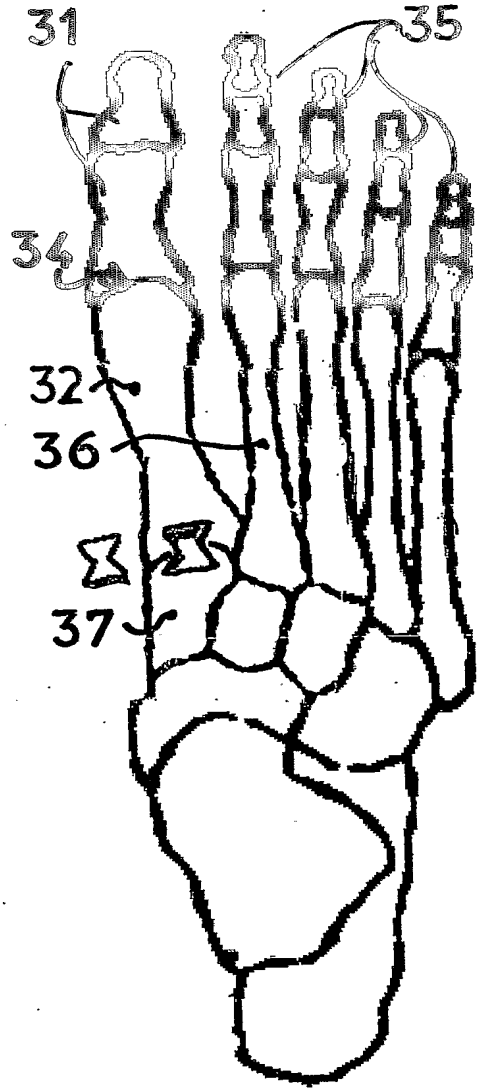


Fig.29A

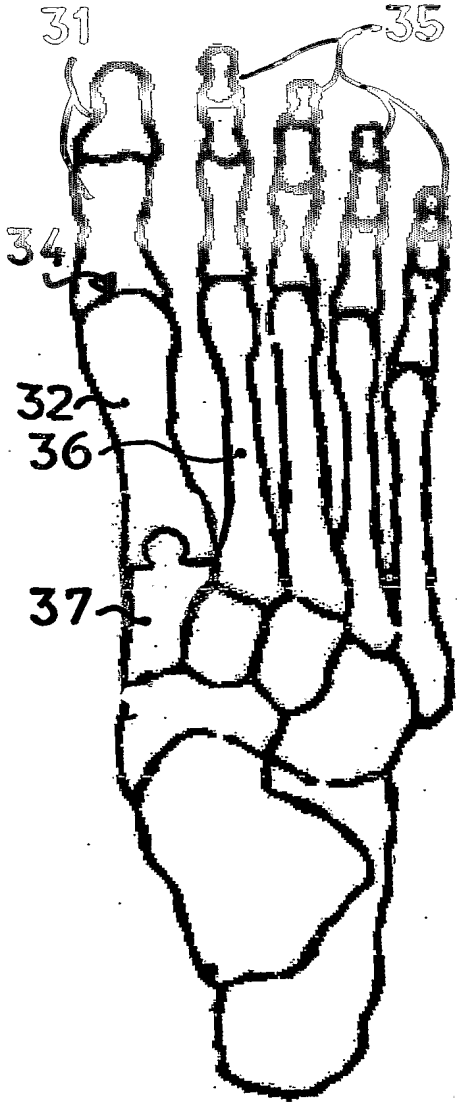


Fig.29B

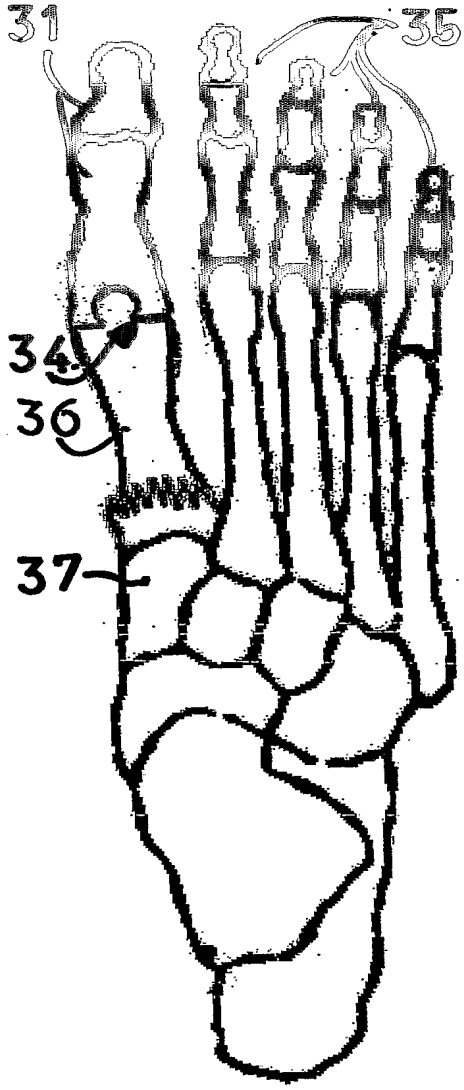


Fig.29C

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(54) **Title**: BONE PLATING KIT FOR FOOT AND ANKLE APPLICATIONS

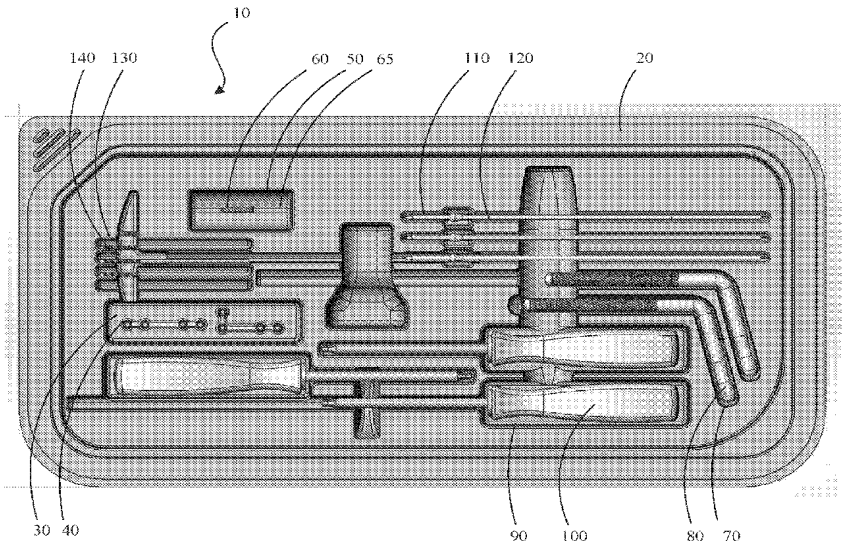


FIG. 1

(57) **Abstract**: A bone plate kit may be provided for a foot or ankle orthopedic procedure, such as a lapidus procedure. In some examples, the bone plate kit includes a sterile container that holds multiple unicortical bone plate fasteners and one or more bone plates. For example, the kit may contain two bone plates configured to be used together during a tarsal-metatarsal fusion procedure. Each of the two bone plates may be configured to span different regions of a tarsal-metatarsal joint. The unicortical bone plate fasteners can be used to secure the two bone plates to the first metatarsal and medical cuneiform of a patient undergoing a procedure. In some configurations, one of the bone plates is a helical bone plate while the other bone plate may or may not be a helical bone plate.

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BONE PLATING KIT FOR FOOT AND ANKLE APPLICATIONS

RELATED APPLICATION

[0001] This application claims the benefit of US Provisional Application Serial No. 62/117,788, filed February 18, 2015, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] This disclosure relates to a disposable single-use surgical kit for an orthopedic procedure on a foot or ankle and methods related to the disposable single-use surgical kit.

BACKGROUND

[0003] Bones, such as the bones of a foot, may be anatomically misaligned. In certain circumstances, surgical intervention is required to correctly align the bones to reduce patient discomfort and improve patient quality of life. Surgical intervention may involve cutting one or more of the misaligned bones and then physically realigning the bones into an anatomically corrected position. A bone plate or multiple bone plates may be used to hold the bones in the anatomically corrected position, helping to prevent the bones from shifting back to their misaligned position.

SUMMARY

[0004] In general, this disclosure is directed to a bone plating kit for use in an orthopedic procedure performed on the foot and/or ankle of a patient. In some examples, the bone plating kit includes one or more bone plates and a corresponding number of bone plate fasteners that are specifically selected and configured for a particular orthopedic procedure. For example, the bone plating kit may contain two bone plates configured to be used together during a tarsal-metatarsal fusion procedure. Each bone plate may be configured (e.g., sized and/or shaped) to span different regions of the tarsal-metatarsal joint. For example, one bone plate may be configured to span from a dorsal region of a medial cuneiform to a medial region of a first metatarsal and a second bone plate may be being configured to span from a plantar region of a first metatarsal to a medial region of a medial cuneiform. To attach the two bone plates to different bones being fused, the kit may include a number of unicortical fasteners at least equal to the number of fastener openings on the bone plates within the kit. The kit may be used on a wide variety of different patients having variations in anatomy size

and shape. The kit may be used in lieu of stocking a large number of different sized bone plates and fasteners.

[0005] In one example, a disposable single-use surgical kit for a foot or ankle orthopedic procedure is described that includes a sterile container, a plurality of unicortical fasteners, and at least one but no more than four bone plates, each contained within the sterile container. Each bone plate may have body having a top surface and a bone facing surface opposite the top surface as well as at least one fixation hole extending through the body from the top surface to the bone facing surface. The at least one fixation hole can be configured for receiving one of the plurality of unicortical bone plate fasteners included in the sterile container.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a top plan view of an embodiment of disposable single-use surgical kit including a sterile container with various surgical items in the sterile container.

[0007] FIG. 2A is a perspective view showing embodiments of bone plates, bone plate fasteners, and an external fastener with a washer.

[0008] FIG. 2B is a top plan view of a top surface of the bone plate of FIG. 2A.

[0009] FIGS. 2C and 2D show a top plan view and perspective view, respectively, of a bone facing surface of the bone plate of FIG. 2A.

[0010] FIGS. 2E shows an elevational view of the bone plate of FIG. 2A.

[0011] FIG. 2F shows a close-up elevational end view of the bone plate of FIG. 2A.

[0012] FIGS. 2G and 2H show an elevational view and perspective view, respectively, of the embodiment of the bone plate of FIG. 2A including attachment members.

[0013] FIGS. 2I and 2J illustrate different perspective views of an example bone plate having a helical curvature.

[0014] FIG. 3 is a perspective view of one embodiment of plate manipulation instruments.

[0015] FIG. 4 is a perspective view of an embodiment of a driver member that can also serve as a plate manipulation instrument.

[0016] FIG. 5 is a perspective view of another embodiment of a driver member that can also serve as a plate manipulation instrument.

[0017] FIG. 6 is a perspective view of one embodiment of bone cut pins.

[0018] FIG. 7 is a perspective view of one embodiment of bone fixation pins.

[0019] FIG. 8 is a perspective view of an embodiment of a single external fastener bone cut pin.

[0020] FIG. 9A is a perspective view of a first embodiment of a bone preparation instrument with some components shown in an exploded view.

[0021] FIG. 9B is a perspective view of the bone preparation instrument of FIG. 9A assembled.

[0022] FIG. 10A a perspective view of a second embodiment of a bone preparation instrument.

[0023] FIG. 10B is a side elevational view of the bone preparation instrument of FIG. 10A.

[0024] FIG. 10C is a perspective view of the bone preparation instrument of FIG. 10A showing guide members of the bone preparation instrument aligned at a skewed angle relative to a block of the bone preparation instrument.

[0025] FIGS. 11A and 11B show perspective and cross-sectional views, respectively, of a third embodiment of a bone preparation instrument.

[0026] FIG. 12 is a perspective view of one embodiment of bone preparation fixation pins.

DETAILED DESCRIPTION

[0027] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides some practical illustrations for implementing exemplary embodiments of the present invention. Examples of constructions, materials, and dimensions are provided for selected elements, and all other elements employ that which is known to those of ordinary skill in the field of the invention. Those skilled in the art will recognize that many of the noted examples have a variety of suitable alternatives.

[0028] Embodiments of the present invention include a disposable single-use surgical kit. The terms "disposable" and "single-use" are meant to convey that the surgical kit, in addition to all components included in the surgical kit, is intended for use on only one surgical patient. After the surgical procedure on the one surgical patient is completed, any components that are not implanted into the one surgical patient can be discarded using conventional methods.

[0029] Examples of the disposable single-use surgical kit can be configured such that the contents of the disposable single-use surgical kit are suited for a particular surgical procedure on the one surgical patient. For instance, an exemplary disposable single-use surgical kit can include only components suited for a Lapidus/tarsal-metatarsal (TMT) fusion procedure on one surgical patient. Similarly, other exemplary disposable single-use surgical kits can include components only suited for a Metatarsal Base Wedge procedure, metatarsal-

phalangeal (MTP) fusion procedure, Evans Lengthening procedure, or other procedure that addresses bone anatomy of the foot or hand of the one surgical patient.

[0030] Using a disposable single-use surgical kit configured for a specific surgical procedure on a single surgical patient may diminish the need for a surgical facility to maintain a large inventory of individual components that otherwise must be combined at the surgical facility and sterilized prior to the surgical procedure. By combining components specifically suited for the particular surgical procedure for which the kit is intended, a commonality of components can be realized which may reduce the size and complexity of the kit. Additionally, the disposable single-use surgical kit can reduce the need for assistance from agents of the component manufacturers while ensuring that the appropriate components needed for the particular procedure are available and in sterile condition. Furthermore, the disposable single-use surgical kit can be designated with a unique code in order to facilitate expensing the cost of the kit to the one surgical patient.

[0031] FIG. 1 is a top plan view of an embodiment of a disposable single-use surgical kit 10. The kit 10 includes a sterile container 20 in which various surgical items can be contained. The container 20 can be sterilized using any appropriate sterilizing means (e.g., exposure to ethylene oxide, steam autoclave, gamma radiation). In one embodiment, the various surgical items can be placed into the container 20, and the container 20 and the various surgical items included in the container 20 can be sterilized in a single step. The sterile container 20 may be partially or wholly enclosed in a packaging that can serve to protect the container 20 as well as seal and maintain a sterility of the container 20. The packaging and/or the sterile container 20 can be made of a transparent material, such as an appropriate polymer, to allow viewing of the surgical items included in the container 20.

[0032] As noted, the disposable single-use surgical kit 10 can include various surgical items which may be retained in the sterile container 20. Embodiments of the kit 10 can include different surgical items and/or different quantities of similar surgical items depending on the specific surgical procedure for which the particular embodiment of the kit 10 is to be used on the single surgical patient.

[0033] For example, the embodiment of the kit 10 illustrated in FIG. 1 has a partition 30 for retaining one or more bone plates 40. The partition 30 may, for instance, be integrally formed in the container 20 and used to compartmentalize the one or more bone plates 40 from the remainder of the container 20. The partition 30 can be configured (e.g. sized, shaped) to retain the one or more bone plates 40 within the container 20 until the one or more bone plates 40 are removed from the container 20 at an appropriate time, such as during a surgical

procedure and immediately prior to installation. In some embodiments, the container 20 can include at least one bone plate 40 but no more than four bone plates 40 (e.g. only one, two, three, or four bone plates). Including at least one and no more than four bone plates 40 in the container 20 of the kit 10 allows the kit 10 to be a disposable single-use surgical kit used for a specific surgical procedure on a single surgical patient. The at least one and no more than four bone plates 40 included in the container 20 can have similar or different configurations. Details on example configurations of the at least one and no more than four bone plates 40 will be discussed with reference to later figures.

[0034] The kit 10 can also have a partition 50 for retaining a plurality of bone plate fasteners 60 in the container 20. In some embodiments, the partition 50 can include a slot 65 configured to hold the bone plate fasteners 60 in a manner that allows the bone plate fasteners 60 to slide along a longitudinal axis of the slot 65. In some embodiments, a number of bone plate fasteners 60 included in the container 20 is equal to a total number of fixation holes (shown, e.g., in FIG. 2B) of the bone plates 40 included in the container 20. In other embodiments, the number of bone plate fasteners 60 included in the container 20 is equal to a total number of fixation holes of the bone plates 40 included in the container 20 plus one additional bone plate fastener 60. For example, where two bone plates 40 are included in the container 20 and each of the two bone plates 40 has four fixation holes (for a total of eight fixation holes), the number of bone plate fasteners 60 included in the container 20 can be nine. In yet other embodiments, the number of bone plate fasteners 60 included in the container 20 is equal to a total number of fixation holes of the bone plates 40 included in the container 20 plus two additional bone plate fasteners 60. In certain embodiments, the number of bone plate fasteners 60 included in the container 20 is equal to a total number of fixation holes of the bone plates 40 included in the container 20 plus three additional bone plate fasteners 60. In a specific embodiment, the number of bone plate fasteners 60 included in the container 20 is equal to a total number of fixation holes of the bone plates 40 included in the container 20 plus four additional bone plate fasteners 60.

[0035] Including one, two, three, or four bone plate fasteners 60 more than the number of fixation holes of the bone plates 40 included in the container 20 can be beneficial in instances where bone plate fasteners 60 may be dropped or lost during a surgical procedure. Overall, including a number of bone plate fasteners 60 in the container 20 equal to a total number of fixation holes of the bone plates 40 included in the container 20 and optionally plus one, two, three, or four additional bone plate fasteners 60 allows the kit 10 to be a disposable single-use surgical kit used for a specific surgical procedure on a single surgical patient. In certain

embodiments, no bone plate fasteners 60 more than a total number of fixation holes of the bone plates 40 included in the container 20 or more than a total number of fixation holes of the bone plates 40 included in the container 20 plus one, two, three, or four are included in the kit 10.

[0036] In addition to the bone plates 40 and the bone plate fasteners 60, the kit 10 may additionally have partitions 70 for retaining plate manipulation instruments 80. In some embodiments, the container 20 can include at least one and no more than three plate manipulation instruments 80. The kit 10 can also have partitions 90 for retaining driver members 100. In some embodiments, the container 20 can include at least one and no more than three driver members 100. Furthermore, the kit 10 may have partitions 110 for retaining bone cut pins 120. In certain embodiments, the container 20 can include at least one and no more than four bone cut pins 120. Additionally, the kit 10 can have partitions 130 for retaining bone preparation fixation pins 140. The container 20 may have at least one and no more than ten bone preparation fixation pins 140. Although not shown in FIG. 1, the container 20 may also have a partition adapted to receive a bone preparation instrument and the kit 10 can include at least one bone preparation instrument. Including the specified number of surgical items in the container 20 allows the kit 10 to be a disposable single-use surgical kit used for a specific surgical procedure on a single surgical patient.

[0037] The kit 10 shown in FIG. 1 is only exemplary. Other embodiments of a disposable single-use surgical kit may not include one or more of the surgical items shown in FIG. 1 and/or may include surgical items in addition to those shown in FIG. 1. However, in some embodiments, if a particular surgical item is included in an embodiment of a disposable single-use surgical kit, the quantity of that surgical item in the kit is within the quantity ranges noted herein.

[0038] FIGS. 2A–2H show the bone plates 40. FIG. 2A shows a perspective view of the bone plates 40, as well as the bone plate fasteners 60 and an external fastener 150. Each of the bone plate fasteners 60 can have a head 160 attached to a shaft 170. The head 160 of each bone plate fastener 60 may be the same size (e.g. same diameter). At least a portion of the shaft 170 of each bone plate fastener 60 can include a threading, and such threading may mate with threading in fixation holes of bone plates. The shaft 170 of each of the bone plate fasteners 60 can have a length that is one of a first length, a second length, a third length, or a fourth length. The shaft 170 of each one of the bone plate fasteners can have a diameter that is one of a first diameter, a second diameter, a third diameter, or a fourth diameter. Consequently, in some embodiments, the bone plate fasteners 60 included in the kit 10 of

FIG. 1 have shafts 170 with no lengths other than the first, second, third and/or fourth lengths and/or no diameters other than the first, second, third and/or fourth diameters. In other words, in some embodiments the kit 10 can include bone plate fasteners 60 with at most four different lengths and/or at most four different diameters. The bone plate fasteners 60 included in the kit 10 can have lengths that are the same or any combination of the first, second, third, and/or fourth lengths. The bone plate fasteners 60 included in the kit 10 can also have diameters that are the same or any combination of the first, second, third, and/or fourth diameters. And the bone plate fasteners 60 included in the kit 10 can have lengths and diameters that are the same or any combination of the first, second, third, and/or fourth lengths and the first, second, third, and/or fourth diameters. The bone plate fasteners 60 can be used to secure the bone plates 40 to one or more bones.

[0039] In some applications, one or more (e.g., all) of the bone plate fasteners 60 in the kit are unicortical bone plate fasteners. Cortical bone is one of the two types of osseous tissue that form bones. As its name implies, cortical bone forms the cortex, or outer shell, of a bone. Accordingly, a unicortical bone plate fastener may be configured (e.g., sized) to be inserted through one cortical surface of the bone but not an opposed cortical surface. For example, the tip of the unicortical bone plate fastener may reside within the cancellous or spongy bone of a bone structure (e.g., with the shaft extending through the first cortex and into the medullary structure of the bone structure) rather than passing through two cortical walls of the bone. The unicortical fastener may pass through a bone plate (e.g., with a head of the fastener bearing against the plate) and a tip of the fastener within the intramedullary cannel surrounded by cancellous bone, once installed and securing the bone plate to a desired bone. The use of unicortical bone plate fasteners instead of bicortical bone plate fasteners may help reduce the number of different sized and/or shaped fasteners required to be included in kit 10.

[0040] Other accessory screws not to intended or configured to be inserted through the fixation holes of the bone plates (e.g., bone plate 40) may be included in kit 10. For example, FIG. 2A illustrates external fastener 150 that may be included in the kit. Embodiments of the kit 10 can include in the container 20 at least one and no more than two external fasteners 150. The at least one and no more than two external fasteners 150 can have a head 180 attached to a shaft 190. At least a portion of the shaft 190 can include a threading. A washer 200 may be disposed around the shaft 190, and as such the washer 200 can be sized appropriately to receive the external fastener 150 via the shaft 190. Additionally, the at least one and no more than two external fasteners 150 may be sized different than the bone plate

fasteners 60 included in the container 20, such that, for example, the external fasteners 150 have a diameter different (e.g., greater) than a diameter of the bone plate fasteners 60 and/or a length different (e.g., greater) than a length of the bone plate fasteners. The at least one and no more than two external fasteners 150 can be used, with or without washers 200, as a separate bone fixation means independent of the bone plates 40. For example, the external fastener 150 can have an end (e.g., an end of the external fastener 150 opposite an end near which the washer 200 is disposed) inserted into a bone such to provide additional fixation of that bone.

[0041] FIGS. 2B–2F illustrate an embodiment of a bone plate 40 that defines a body 210. FIG. 2B illustrates a top plan view of a top surface 220 of the body 210, while FIGS. 2C and 2D illustrate a top plan view and perspective view, respectively, of a bone facing surface 230 of the body 210. For convenience, "bone facing surface" will refer to all surfaces generally facing bone when the plate is positioned on a bone, regardless of whether those surfaces are in the same plane. FIG. 2E is a side elevational view of the bone plate 40, and FIG. 2F is a close-up end elevational view of a portion of the bone plate 40.

[0042] The body 210, as noted, can include the top surface 220 and the bone facing surface 230, which is on a side of the body 210 opposite the top surface 220. In an exemplary application, the bone plate 40 can be positioned so that the bone facing surface 230 is made to interface with a bone. Additionally, the body 210 has a length defining a central longitudinal axis L and one or more widths W_1, W_2, and W_3 defining an extent of the body 210 (and thus the bone plate 40) transverse to the central longitudinal axis L. Although the bone plate 40 is illustrated as lying in a single plane along the axis L, in other embodiments the bone plate 40 can include curvature or bending of the body 210 along or around the axis L such that the body 210 of the bone plate 40 does not lie in a single plane.

[0043] The body 210 may include regions 240A, 240B, 240C, and 240D extending from the top surface 220 to the bone facing surface 230, and which can be spaced from one another along the axis L. Regions 240A, 240B, 240C, and 240D can each extend a distance along the axis L from a region leading edge $240A_L$, $240B_L$, $240C_L$, and $240D_L$ to a region trailing edge $240A_T$, $240B_T$, $240C_T$, and $240D_T$, respectively. The width W_1 can correspond to a width of the body 210 at each region 240A, 240B, 240C, and 240D, and in the illustrated embodiment the width W_1 is the greatest extent of the body 210 transverse to the axis L.

[0044] As shown for example in FIG. 2F, region 240B has an outer shape 250 that links the top surface 220 and the bone facing surface 230. The outer shape 250 may be any type of contour at region 240B that reduces stress or increases strength of the bone plate 40. The

outer shape 250 can also be used to minimize soft tissue irritation and increase bone healing during application of the bone plate 40. In the illustrated embodiment, the outer shape 250 includes a rounded edge contour that can increase strength for bending of the bone plate 40, reduce stresses in the bone plate 40 for improving the useful life of the bone plate 40, and reduce soft tissue irritation and increase bone healing when the bone plate 40 is utilized. Regions 240A, 240C, and 240D can also include outer shapes 250.

[0045] Included at the regions 240A, 240B, 240C, and 240D can be fixation holes 260A, 260B, 260C, and 260D, respectively. Fixation holes 260A, 260B, 260C, and 260D extend through the body 210 at regions 240A, 240B, 240C, and 240D, respectively, from the top surface 220 to the bottom surface 230. Fixation holes 260A, 260B, 260C, and/or 260D may be configured to receive fasteners, such as bone plate fasteners 60. For example, holes 260A, 260B, 260C, and/or 260D can be threaded to threadingly engage bone plate fasteners 60. As a result, the fixation holes 260A, 260B, 260C, and 260D may serve as a location for fixing the bone plate 40 to a bone.

[0046] In the illustrated embodiment the bone plate 40 has four regions 240A, 240B, 240C, and 240D and four fixation holes 260A, 260B, 260C, and 260D, but in other embodiments any number of regions and fixation holes can be included regardless of whether a particular region also includes a fixation hole. Additionally, the regions 240A, 240B, 240C, and 240D on the body 210 are shown as rounded, but in other embodiments the regions 240A, 240B, 240C, and 240D can have various other geometries. Where the regions 240A, 240B, 240C, and 240D are rounded, in one embodiment one or more of the regions 240A, 240B, 240C, and/or 240D may have a radius of curvature between about 2.7 mm and about 3.0 mm (e.g., 2.9 mm). Moreover, although the regions 240A, 240B, 240C, and 240D are illustrated to be of similar sizes, the regions 240A, 240B, 240C, and 240D can also be of varying sizes. For example, one region can include the width W_1 while another region may have its greatest width less than the width W_1, or greater than the width W_1.

[0047] Located on the bone facing surface 230 at a region 240A, 240B, 240C, or 240D can be a pad 270 that extends outward a distance from a first surface 274 (labeled in FIGS. 2C-D). In the embodiment shown, the first surface 274 is included on a region 276A that includes the thinnest cross-section of the bone plate 40. One or more additional regions 276B-E may be provided, each having the first surface 274 at generally the same elevation. In one application, the pad 270 can extend outward from the first surface 274 in a direction that is generally perpendicular to the first surface 274, but in other applications the pad 270 can extend out from the first surface 274 at various angles. In one example, the pad 270

extends outward about 0.3 millimeters to about 0.5 millimeters (e.g., about 0.42 millimeters) relative to the first surface 274. For instance, where the pad 270 extends out perpendicular to the surface 274 a ratio of a thickness of the bone plate 40 including the pad 270 to a thickness of the bone plate 40 at the first surface 274 can be between approximately 1.01 and 1.5 (e.g., about 1.3).

[0048] Thus, the pad 270 can be a point of contact with a bone on the bone facing surface 230 when the bone plate 40 is configured to interface with the bone. As shown, the bone facing surface 230 of the bone plate 40 includes a pad 270 at each of the regions 240A, 240B, 240C, and 240D such that the pads 270 are adjacent the fixation holes 260A, 260B, 260C, and 260D at the respective regions. In the illustrated embodiment, the pads 270 extend a length along the axis L from each region leading edge $240A_L$, $240B_L$, $240C_L$, and $240D_L$ to each region trailing edge $240A_T$, $240B_T$, $240C_T$, and $240D_T$, respectively. The pads 270 as shown also extend from a first end of the width W_1 of the body 210 to a first point on a perimeter of the fixation holes 260A, 260B, 260C, and 260D nearest the first end of the width W_1, and from a second end of the width W_1, located opposite the first end of the width W_1, of the body 210 to a second point on the perimeter of the fixation holes 260A, 260B, 260C, and 260D nearest the second end of the width W_1. Thus, in the embodiment shown the pads 270 do not span an entire width, including width W_1, of the regions 240A, 240B, 240C, and 240D on the bone facing surface 230. In some embodiments, the sum total of the surface area of the pads on a bone plate is less than 50% of the total surface area of the bone plate. Although the embodiment of bone plate 40 shown includes the pads 270 adjacent the fixation holes 260A, 260B, 260C, and 260D, any number of the pads 270 can be included at various locations on the bone facing surface 230 and the geometries of the pads 270 can vary according to the particular application of the bone plate 40.

[0049] The span of the pads 270 along the width of the regions 240A, 240B, 240C, and 240D is interrupted in the embodiment of bone plate 40 by channels 280 in the pads 270 at each of the regions 240A, 240B, 240C, and 240D. In the embodiment shown, the channels 280 extend outward a distance from the first surface 274, but in other embodiments the channels 280 can be flush with the first surface 274. In embodiments where one or more channels 280 do extend out a distance from the first surface 274, the distance these one or more channels 280 extend out is less than the distance the pads 270 extend out from the first surface 274. In such embodiments, the pads 270 are raised relative to the channels 280, and the channels 280 are elevated relative to the first surface 274, as shown in FIG. 3B. The channels 280 may extend a length along the axis L on the bone plate 40 from each region leading edge $240A_L$,

$240B_L$, $240C_L$, and $240D_L$ to each fixation hole 260A, 260B, 260C, and 260D of the respective region and from each fixation hole 260A, 260B, 260C, and 260D to each respective region trailing edge $240A_T$, $240B_T$, $240C_T$, and $240D_T$. The channels 280 may also extend a width along the width of each region 240A, 240B, 240C, and 240D between the pads 270. As such, in the illustrated embodiment fixation holes 260A, 260B, 260C, and 260D interface with the pads 270 or the channels 280 at all locations along the perimeters of the fixation holes 260A, 260B, 260C, and 260D. As shown, each channel 280 included at each region 240A, 240B, 240C, and 240D is aligned along the axis L with the channels 280 at each other region.

[0050] At locations where the channel 280 interfaces with the pad 270, a radiused surface 290 can be included to transition from the channel 280 to the pad 270. For example, the radiused surface 290 can have a continual slope from the raised pad 270 to the relatively lower channel 280. The radiused surface 290 may act, for example, to reduce stresses in the bone plate 40, and therefore can be useful for applications of the bone plate 40 where a greater strength is desired.

[0051] Including one or more pads 270 and/or one or more channels 280 can provide benefits during application of the bone plate 40. For instance, including a pad 270 and/or a channel 280 on the bone facing surface 230 may decrease trauma to a periosteal membrane of a bone when the bone plate 40 is attached to a bone in a surgical procedure. Decreasing trauma to the periosteal membrane of the bone can result in less disruption of blood flow, which can help with healing the area of the bone interfacing with the bone plate 40.

[0052] Additionally, the pad 270 and/or channel 280 can act to increase a bending strength of the bone plate 40 without impeding bending of the bone plate 40 in a desired location of bone plate 40. In certain embodiments, a desired location of bone plate bending includes at least one of the regions 276A-E. In such embodiments, one or more of the regions 276A-E can be configured to concentrate bending forces applied to the bone plate 40. In a particular embodiment, such regions are configured to concentrate bending stresses by having a smaller minimum bending force required to bend the plate at the region compared to other regions of the plate. In the embodiment shown, the smaller minimum bending stress is provided by the regions 276A-E having the thinnest cross-sections of the plate. Thus, this can allow the bone plate 40 to be bent as desired for a particular application and anatomy without deforming any threads included in any of the fixation holes 260A-D.

[0053] Extending along the axis L between regions 240B and 240C, and forming part of the body 210, can be a bridge 300. The bridge 300 may define a portion of the body 210 having

a width W_2. In the exemplary embodiment of the bone plate 40 shown, the width W_2 along the bridge 300 can be less than the width W_1 included at regions 240A, 240B, 240C, and 240D, but in other embodiments the bridge 300 can have widths W_2 equal to or greater than the width W_1. The bridge 300 as illustrated has sides running parallel to the axis L that are generally linear, but for other embodiments of the bone plate 40 the bridge 300 can have rounded sides similar to the regions 240A, 240B, 240C, and 240D or any other geometry suited for the specific application of the bone plate 40. In some embodiments, the bridge 300 is devoid of any apertures and extends between regions having fixation holes, such as regions 240B and 240C having fixation holes 260B, 260C, respectively.

[0054] On the bone facing surface 230, the bridge 300 may include one or more pads 310. The one or more pads 310 can be similar to the pad 270, such that the one or more pads 310 extend outward from the first surface 274. Also on the bone facing surface 230, the bridge 300 can have one or more channels 320 included along the width W_2 between the pad 310. The one or more channels 320 can be similar to the channel 280. In the embodiment shown, the channels 320 extend outward a distance from the first surface 274, but in other embodiments the channels 320 can be flush with the first surface 274. In embodiments where one or more channels 320 do extend out a distance from the first surface 274, the distance these one or more channels 320 extend out is less than the distance the pads 310 extend out from the first surface 274. In such embodiments, the pads 310 are raised relative to the channels 320, and the channels 320 are elevated relative to the first surface 274, as shown in FIG. 2D. In one exemplary application, the one or more channels 320 can be aligned with the channels 280 along the axis L. Further, the one or more channels 320 can extend outward the same distance as the channels 280 from the first surface 274. In addition, the one or more channels 320 can have the same width as the channels 280. Any of these embodiments can result in a continuous channel that is formed at all locations on the bone facing surface 230 along the axis L having a pad 270 or 310.

[0055] The bridge 300 as shown has two pads 310, the first pad 310 bordered by regions 276B and 276C, and the second pad 310 bordered by regions 276C and 276D, each pad 310 having a channel 320 located along the width W_2 between the pad 310, spaced along the axis L. In other embodiments of the bone plate 40 the bridge 300 can include any number and configuration of pads 310 and channels 320. The pads 310 and channels 320 may serve similar functions to those described with respect to the pads 270 and channels 280. Further, regions 276B-D can be configured as desired bending regions as described above for regions 276A and E.

[0056] Extending along the axis L between regions 240A and 240B as well as between regions 240C and 240D are branches 330. The branches 330 form a portion of the body 210 that connects the region 240A to the region 240B as well as the region 240C to the region 240D. The branches 330 have a width W_3. The width W_3 of the branches 330 as illustrated in less than the width W_1 and W_2, but in other embodiments the width W_3 can be equal to or greater than the width W_1 and/or the width W_2. Thus, for the bone plate 40 illustrated in FIGS. 2B–2F the width of the body 210 is greatest at the regions 240A, 240B, 240C, and 240D and least at branches 330. The branches 330 as shown have sides running parallel to the axis L that are generally linear, but for other embodiments of the bone plate 40 the branches 330 can have rounded sides similar to the regions 240A, 240B, 240C, and 240D or any other geometry suited for the specific application of the bone plate 40. In the embodiment shown, the branches include the first surface 274 and coincide with regions 276A and 276E.

[0057] FIGS. 2G and 2H show a side elevational view and a perspective view, respectively, of the bone plate 40. Although the bone plate 40 is referenced for illustrative purposes here, this discussion can apply to all bone plate embodiments of various shapes. In FIG. 2G, the bone plate 40 has been positioned such that the bone facing surface 230 is facing a bone 340. As the bone plate 40 is moved closer to the bone 340, the pads 270 and 310 can come into contact with the bone 340. Contacting the bone 340 with the pads 270 and 310, as opposed to contacting the bone 340 with the bone facing surface 230 in general, can help to decrease trauma to the periosteal membrane of the bone 340 to allow for increased blood flow for healing. The bone plate 40 may also be positioned such that the bridge 300 extends across a target area 345. In the illustration of FIG. 2G, the target area 345 is depicted as a fracture of the bone 340. However, in other applications positioning the bridge 300 across the target area 345 may include positioning the bridge 300 across a joint between two bones, such as a metatarsal-cuneiform joint, or across other areas needing bone fixation at adjacent locations. Positioning the bridge 300 of the bone plate 40 across the target area 345 can help increase the strength and healing of the bone 340.

[0058] The bone plate 40 as shown has attachment members 350 configured at least partially within the fixation holes 260A, 260B, 260C, and 260D. For example, where the fixation holes 260A, 260B, 260C, and 260D are threaded, the attachment members 350 can also be threaded so as to be attached within the fixation holes 260A, 260B, 260C, and 260D. The attachment members 350 can be utilized, for example, to assist in locating and aligning various surgical tools and reamers and/or bending the bone plate 40 to better align with a

contour of the bone 340 or other anatomy. For instance, it may be necessary to bend the bone plate 40 so that each of the pads 270 and 310 is in contact with the bone 340. The attachment members 350 can be, for example, cylindrical along an axial length of the members 350 and include apertures that are aligned with the respective fixation holes 260A, 260B, 260C, and 260D. As shown, the attachment members 350 have an elongated aperture, relative to the fixation holes 260A, 260B, 260C, and 260D, that can help align tools and/or drill bits used during various applications of the bone plate 40 in surgical procedures. Also, the extension of the attachment members 350 out from the top surface 220 can allow for greater leverage for bending the bone plate 40.

[0059] Although bone plate 40 can have a variety of different configurations, in some applications, the bone plate has a helical curvature extending between opposed fixation holes. The helical curvature can cause fixation hole(s) positioned in a distal section of the bone plate to be positioned in a different plane than fixation holes(s) positioned in a proximal section of the bone plate. For example, the helical curvature may follow a path traced along an imaginary cylinder or cone at an oblique angle so as to define a spiral or curved fold. In some examples, the angle and/or extent of curvature may be formed or adjusted *in-situ* by fabricating the bone plate out of a malleable material. The helical curvature of the bone plate may be configured to extend from the plantar region of a first metatarsal to the medial region of a medial cuneiform, thereby positioning the curvature across a metatarsal-cuneiform joint.

[0060] FIGS. 2I and 2J illustrate different perspective views of an embodiment of bone plate 40 that can be included in kit 10, where the bone plate has a helical curvature. As shown, the bone plate 40 defines a body 42 having a top surface 44 and a bone facing surface 46, where the bone facing surface 46 is on a side of the body 42 opposite the top surface 44. In an exemplary application, the bone plate 40 can be positioned so that the bone facing surface 46 interfaces with and/or is in contact with a bone. In the example shown in FIGS. 2I and 2J, the bone facing surface 46 includes multiple surfaces projecting different distances away from top surface 44. Thus, for convenience, "bone facing surface" will refer to the side of the bone plate generally facing bone when the plate is positioned on a bone, regardless of whether there is more than one surface and regardless of whether each surface is in contact with the bone when bone plate 40 is applied.

[0061] The body 42 of the bone plate 40 has a major length which defines the central longitudinal axis L. The body 42 can include a proximal region 48 at or near a first longitudinal end and a distal region 52 at or near a second longitudinal end that is opposite the first longitudinal end of the bone plate 40. The proximal region 48 may be separated

from the distal region 52 by an intermediate region. For example, the body 42 may include one or more fixation holes. In these examples, body 42 may include one or more fixation holes in proximal region 48, one or more additional fixation holes in distal region 52, and an intermediate region devoid of fixation holes positioned between proximal region 48 and distal region 52.

[0062] In the illustrated embodiment, the distal region 52 has at least one fixation hole, which is illustrated as two fixation holes 60A and 60B, and the proximal region 48 has at least one additional fixation hole, which is illustrated as two fixation holes 60C and 60D. In other examples, body 42 may include fewer fixation holes (e.g., one, none) or more fixation holes (e.g., three, four) in proximal region 48 and/or distal region 52. Moreover, the dimensions (e.g., length) of the proximal and distal regions 48, 52 can be adjusted to accommodate the particular number of fixation holes included.

[0063] In the example shown, the proximal region 48 extends longitudinally from the first longitudinal end of the bone plate 40 to an end of the fixation hole 60C on the axis L furthest from the first longitudinal end. In addition, in this example, the distal region 52 extends longitudinally from the second longitudinal end of the bone plate 40 to an end of the fixation hole 60B on the axis L furthest from the second longitudinal end. Thus, in the illustrated example, the bone plate 40 includes a region between proximal region 48 and distal region 52, specifically between the terminal edge of fixation hole 60B and the terminal edge of fixation hole 60C, which is devoid of fixation holes and is sometimes referred to herein as a "bridge."

[0064] As shown in FIGS. 2I and 2J, the body 42 of the bone plate 40 can include a helical curvature 62. Such a helical curvature can include a curve that resides in three-dimensional space. In some embodiments, the distal region 52 lies in a first plane and the proximal region 48 lies in a second plane different from, and offset from, the first plane both along and about the longitudinal axis L. Depending on the extent of the bend and/or twist of the helical curvature 62 desired for a particular application, the first plane including the distal region 52 and the second plane including the proximal region 48 can be substantially perpendicular about the longitudinal axis. In some embodiments, the radius of the helical curvature can vary as a function of longitudinal position on the body 42. In other embodiments, the radius of the helical curvature can be constant as a function of longitudinal position on the body 42.

[0065] In the embodiment of the bone plate 40 shown in FIGS. 2I and 2J, the helical curvature 62 includes both a bend along the central longitudinal axis L (e.g., around an axis perpendicular to axis L) and a twist about the axis L. The bend may curve the proximal

region 48 of the body 42 back toward the distal region 52 of the body about an intermediate bridge section between regions 55B and 55C. For example, the bend can reduce the distance between opposite end of body 42 as compared to when body 42 is flat or planar. The radius of the bend can vary or be constant as a function of longitudinal position on the body 42, and/or be concentrated in one or more portions of the body 42, such as the portion of the body between the proximal and distal portions. In some examples, the bend ranges from approximately 10° to approximately 45°, such as from approximately 15° to approximately 35°. In other examples, the bend ranges from 45° to 135°, such as from approximately 75° to approximately 105°. Other angles of bend are also possible.

[0066] The twist of helical curvature 62 about longitudinal axis L can rotate the proximal region of body 42 relative to the distal region 52 about axis L. For example, the twist may rotate regions 55C and 55D relative to regions 55A and 55B such that regions 55C and 55D, and the corresponding fixation holes defined therein, are radially offset from regions 55A and 55B, and the corresponding fixation holes defined therein. In some embodiments, the twist is concentrated in one or more portions of the body 42, such as the portion of the body between the proximal and distal portions. Further, in some examples, the twist of the body 42 ranges from approximately 45° to less than 180° about the axis L, such as from approximately 60° to approximately 100° about the axis L, or from approximately 70° to approximately 90° about the axis L. In other examples, the twist of the body 42 ranges from 25° to 100°, such as from 35° to 65°. Other angles of twist are also possible depending on the application.

[0067] While the bone plate 40 is described as having helical curvature 62, it should be appreciated that the curvature provided by the bone plate need not be a mathematically perfect helix. Rather, the helical curvature 62 may be a generally helical shape, such as a shape that follows the general contours of a helix even if the angles of contortion do not form a perfect helix. Therefore, it should be appreciated that a bone plate described as having a helical curvature according to the disclosure may, in practice, have a generally helical shape without forming a mathematically perfect helix. Additional bone plate details can be found in US Patent Application No. 14/990,368, filed January 7, 2016, the entire contents of which are incorporated herein by reference.

[0068] In some embodiments, the helical curvature 62 can be concentrated or entirely within a region of the body 42 between the proximal region 48 and distal region 52. Thus, any bend of the body 42 along the axis L and any twist of the body 42 about the axis L of the helical curvature 62 can begin at or near an end of the distal region 52 (e.g., begin at or adjacent fixation hole 60B) and proceed in a proximal direction toward the proximal region 48 (e.g.,

terminating at or adjacent fixation hole 60C). For instance, the helical curvature 62 (e.g., the bend along the axis L and the twist about the axis L) of the illustrated embodiment begins at the end of the distal region 52 and ends at the beginning of the proximal region 48. Thus, the helical curvature 62 as shown is located on a bridge portion of the body 42 between the fixation holes 60B and 60C. In such embodiments, the helical curvature 62 provides the transition of the body 42 from the first plane to the second plane. Moreover, in this embodiment, fixation holes 60A and 60B are positioned in the same plane, fixation holes 60C and 60D are also positioned in the same plane, and the plane fixation holes 60A and 60B are positioned in is offset from the plane fixation holes 60C and 60D are positioned in by helical curvature 62.

[0069] The helical curvature 62 can be included on the bone plate 40 so as to provide a twist and/or bend suitable for a particular application, e.g., such as facilitating positioning of the bone plate across a tarsal-metatarsal joint. In some examples, helical curvature 62 includes a twist of approximately 90° about the longitudinal axis of a bone (and the axis L of the bone plate 40). The helical curvature 62 also includes a bend along the axis L of the bone plate 40.

[0070] In some embodiments, the helical curvature 62 of the bone plate 40 is pre-formed, such that the bone plate includes the helical curvature when it is removed from kit 10. For example, helical curvature 62 may be formed in bone plate 40 before placing in kit 10, and the bone plate may be sufficiently rigid to hold the helical curvature until use. In some additional embodiments of the bone plate 40, body 42 can include malleable materials that allow for in-*situ* bending of the helical curvature 62. In still other embodiments, the bone plate may contain a pre-formed helical curvature 62 yet be formed of malleable materials such that the bone plate can be further bent during a surgical procedure. This can allow a clinician to adjust the radius of curvature and/or amount of bend of helical curvature 62 during a procedure to best fit the particular anatomy and/or patient undergoing the procedure (e.g., depending on the dimensions of the bones to which the bone plate 40 is to be fixed). For example, a clinician may remove the bone plate 40 from kit 10 and then bend the bone plate between proximal region 48 and distal region 52 until the shape of the helical curvature 62 best matches the anatomy across which the bone plate 40 is being positioned. In applications where bone plate 40 includes a pre-formed helical curvature 62, the amount of bending provided by the clinician may range from plus 20° (making the body 42 flatter) to minus 20°, such as from plus 10° to minus 10°, or from plus 5° to minus 5°, although other degrees of bending may also be used depending on the application.

[0071] In some embodiments, the kit 10 includes at least one and no more than four bone plates 40, with the exact number of bone plates 40 included in the kit 10 varying depending on the specific surgical procedure for which the kit 10 is configured to be used. For example, in some surgical procedures the bone plates are aligned with respect to the bone such that they reside in different planes. For example, two bone plates can be attached to a bone with the two bone plates positioned about 90 degrees, with respect to each other, along the outer circumference of the bone (e.g., left side and top, or top and right side). In certain surgical procedures, the longitudinal axes of the bone plates can be substantially parallel. This can, for instance, be beneficial for providing a strong fixation with respect to more than one plane.

[0072] FIG. 3 shows a perspective view of the embodiments of the plate manipulation instruments 80 shown and described as included in the kit 10 with respect to FIG. 1. The plate manipulation instruments 80 can have a first end 360 and a second end 370. In the illustrated embodiment, the first end 360 is at an angle relative to the second end 370. At least a portion of the first end 360 can include a friction surface so as to facilitate, for example, gripping at or near the first end 360 by, for example, a surgeon. The second end 370 may be configured so as to be insertable within the attachment member 350 (shown, e.g., in FIG. 2G). Where attachment members 350 are not present, the second end 370 may be configured so as to be insertable within the fixation holes 260A-D (shown, e.g., in FIG. 2B) of the bone plate 40. Inserting the second end 370 into the attachment member 350 (or fixation holes 260A-D) can allow the bone plate 40 to be bent or otherwise altered in geometry so as to substantially match a contour of a bone to which the bone plate 40 is to be fixed. The angle at which the second end 370 is disposed with respect to the first end 360 can facilitate bending the bone plate 40 by providing leverage complimentary to the force applied at the gripped first end 360.

[0073] In addition to the second end 370 being configured so as to alter the geometry of the bone plate 40, the second end 370 can also be configured so as to drive one or more of the bone plate fasteners 60. This can allow the kit 10 to be more compact where desired. For example, the second end 370 may include a tip 375 that is configured to mate with the head 160 of the bone plate fastener 60. As such, the tip 375 can be used to drive the bone plate fastener 60 received within one of the fixation holes 260A-D into a bone. In addition, in some embodiments, the tip 375 can be configured so as to drive one or more of the external fasteners 150 into a bone at a location spaced from the bone plate 40. Further, the tip 375 may be configured to mate with the attachment members to rotationally connect or remove the attachment members from the bone plate.

[0074] FIG. 4 shows a perspective view of the embodiments of the driver members 100 shown and described as included in the kit 10 with respect to FIG. 1. The driver members 100 can have a first end 380 and a second end 390. The driver member 100 can be gripped at or near the first end 380, while the second end 390 can be configured so as to mate with the head 160 of the bone plate fastener 60 and/or the head 180 of the external fastener 150, for instance, via a tip 395. As a result, the driver member 100 can be used to drive the bone plate fastener 60 received within one of the fixation holes 260A-D into a bone to fixate the bone plate 40 and/or drive the external fastener 150 into a bone (at a location spaced from the bone plate 40) to fixate the bone. In embodiments where the plate manipulation instrument 80 is not included in the kit 10, the driver member 100 can also be used to bend the bone plate 40 similar to that described for the plate manipulation instrument 80. Further, the tip 395 may be configured to mate with the attachment members to rotationally connect or remove the attachment members from the bone plate. This may allow the kit 10 to be more compact.

[0075] FIG. 5 shows a perspective view of an alternative embodiment of driver members 400. Instead of the driver member 100, the kit 10 may instead include at least one and no more than three driver members 400. Similar to the driver members 100, the driver members 400 can have a first end 410, at or near which the driver member 400 can be gripped, and a second end 420 configured so as to mate with the head 160 of the bone plate fastener 60 and/or the head 180 of the external fastener 150, for instance, via a tip 425. Additionally, where the plate manipulation instrument 80 is not included in the kit 10, the driver member 400 can also be used to bend the bone plate 40 similar to that described for the plate manipulation instrument 80. Further, the tip 425 may be configured to mate with the attachment members to rotationally connect or remove the attachment members from the bone plate.

[0076] FIG. 6 illustrates a perspective view of the bone cut pins 120 shown and described as included in the kit 10 with respect to FIG. 1. The bone cut pins 120 may have a first end 430 and a second end 440 having an end portion that can include a point 445, which may be fluted for cutting bone. In one application, the bone cut pin 120 can have the point 445 inserted through one fixation hole 260A-D of the bone plate 40 so as to contact the bone. The point 445 may be used to create an initial pilot hole in the bone at a location aligned with the fixation hole 260A-D. This initial pilot hole can then be used as a location where the bone plate fastener 60 is to be fixed to the bone after being received in the fixation hole 260A-D. Furthermore, the bone cut pins 120 can be of varying lengths. As illustrated, one of the bone cut pins 120 is longer than the others. The difference in length of the bone cut pins

120 can serve to prevent interference caused by the ends 430 to other surgical instruments used in a similar or proximate location.

[0077] A collar, sometimes referred to as an olive 450, can be included on the bone cut pin 120 at a location spaced from the point 445 as well as the second end 440. The collar 450 can have a diameter greater than a diameter of the point 445, and it can act as a depth gauge structure. As a result of the larger diameter of the collar 450 relative to the point 445, the tip 445 and end 440 cannot be inserted into the bone any further than the surface of the collar 450 nearest the end 440. Thus, the collar 450 can serve as a stopping point along a longitudinal axis of the bone cut pin 120. As such, the exact location of the collar 450 on the bone cut pin 120 can vary depending on the desired depth of penetration of the end 440 into the bone. Additionally, the collar 450 can serve as means to measure a depth of penetration of the tip 445 into the bone while creating the initial pilot hole.

[0078] FIG. 7 shows a perspective view of bone fixation pins 460. Although not shown in the embodiment of the kit 10 described with respect to FIG.1, at least one and no more than four bone fixation pins 460 can be included in various embodiments of the kit 10. Each bone fixation pin 460 can have a first end 470 and a second end 480 which may include a threaded portion as illustrated. A collar 490 can be included at a location on one or more of the bone fixation pins 460 spaced from the end 480 and serve a function similar to that described with respect to collar 450 of FIG. 6.

[0079] Bone fixation pins 460 can be used to fix one or more bones in a particular position as desired for a surgical procedure. The bone fixation pins 460 can be used to fix one or more bones independent of and at a location spaced from the bone plate 40. For instance, the threaded portion of the end 480 of one bone fixation pin 460 can be inserted into a bone in a manner that fixes the bone in the desired position. In some procedures, one or more additional bone fixation pins 460 can also be inserted into the same bone or one or more adjacent bones such that the one or more bones are appropriately fixed as desired. This can facilitate greater accuracy during a surgical procedure. For example, at least one bone fixation pin may be inserted into adjacent bones, crossing the joint space between the bones, and used to compress the bones together prior to the installation of a bone plate.

[0080] FIG. 8 illustrates a perspective view of an embodiment of a single external fastener bone cut pin 500. Although not shown in the embodiment of the kit 10 described with respect to FIG.1, where an embodiment of the kit 10 includes the external fastener 150 (shown and described with respect to FIG. 2A) the kit 10 can further include the single external fastener bone cut pin 500 and no other external fastener bone cut pins. In

embodiments where the external fastener has a diameter different than a diameter of a bone plate fastener, the single external fastener bone cut pin can be sized to accommodate the diameter of the external fastener. The external fastener bone cut pin 500 may have a first end 505 and a second end 510. At the second end 510 can be a point 515. The external fastener bone cut pin 500 can be used to create an initial pilot hole for the external fastener 150 via the point 515 at a location on a bone where the external fastener 150 is to be inserted.

[0081] In addition to the surgical items described previously, embodiments of the kit 10 may further include a bone preparation instrument that can be disposed after use on a single surgical patient. The bone preparation instrument can be useful during a surgical procedure to position and/or cut one or more bones. In some embodiments, the kits include only two or fewer (e.g., one) bone preparation instruments. Several embodiments of such instruments will be described in turn below.

[0082] FIGS. 9A and 9B show a first embodiment of a bone preparation instrument 520. FIG. 9A shows a perspective view of the bone preparation instrument 520 with some components shown in an exploded view, while FIG. 9B shows a perspective view of the bone preparation instrument 520 assembled. Additional discussion of exemplary instruments and techniques that can be included in, or used with, kit 10 are provided in US Patent Application Nos. 14/981,335, filed December 28, 2015, and 62/293,189, filed February 9, 2015, the entire contents of which are incorporated herein by reference.

[0083] With reference to FIGS. 9A and 9B, the bone preparation instrument 520 can include a support 530 which defines an inner cavity 540. In one embodiment, the support 530 can include a first fixation aperture 550A and a second fixation aperture 550B, each of which can extend through the support 530 and receive bone preparation fixation pins 140A and 140B, respectively, such that the fixation pins 140A and 140B extend through the support 530 via the fixation apertures 550A and 550B. In the embodiment shown, the fixation pins 140A and 140B have a threaded first end adapted to threadingly engage with a bone, and allow the support 530 to be translated along a longitudinal axis of both pins 140A and 140B. In the illustrated embodiments, the fixation apertures 550A and 550B are located on opposite longitudinal ends of the support 530, but in other embodiments the fixation apertures 550A and 550B can be located at various positions on the support 530. The support 530 can further include one or more extensions 570A and/or 570B protruding generally radially out from the support 530, which may define a concave surface configured to receive a generally cylindrical bone portion. In the embodiment shown, fixation aperture 550B is provided with an extension member 572 which can be threadingly coupled to the support 530. Such an

extension member 572 can be adjusted relative to the support 530 to allow the support to become parallel with a longitudinal axis of a bone, if desired. In such embodiments, the support 530 can rest on a bone via the extensions 570 A/B and extension member 572 in a position generally parallel to the bone. Fixation pin 140B may be received within an internal aperture of the extension member 572. Aperture 574A (and aperture 574B, not shown, on an opposite side of the support 530 from aperture 574A), such as tapered apertures, may be provided proximal to extension 570A (and 570B). Such apertures may extend through the support at a skewed angle relative to the longitudinal axis of the support, and may be used to engage a clamping instrument or receive fixation pins.

[0084] The support 530 can also include a slot 580 formed on at least a portion of a surface of the support 530. As illustrated in the embodiment of the bone preparation instrument 520 shown in FIG. 9B, the slot 580 can extend in a surface of the support 530 between fixation apertures 550A and 550B. A securing component 590 can be configured to translate along the slot 580 relative to the support 530. For example, the securing component 590 can have a first end with a diameter greater than a diameter of a second opposite end, such that the first end of the securing component 590 is supported by the slot 580 (i.e. the first end has a diameter greater than a radial width of the slot 580) while the second end of the securing component 590 is positioned within the slot 580 (i.e. the second end has a diameter less than a radial width of the slot 580).

[0085] The inner cavity 540 of the support 530 can have a shaft 600 positioned at least partially within the inner cavity 540. The shaft 600 can be configured so as to translate within the inner cavity 540 relative to the support 530, such that an end of the shaft 600 can be made to project out from the inner cavity 540. The shaft 600 may define a slot 605 which may be aligned with the slot 580 defined by the support 530. This slot 605 may receive the pin 140A to reduce interference when the shaft 600 translates. Furthermore, the shaft 600 can include a securing aperture 610 which can be configured to receive at least a portion of the securing component 590. In one embodiment, both the second end of the securing component 590, within the slot 580, and the securing aperture 610 can be threaded to allow the securing component 590 to mate with the securing aperture 610. Such a configuration can allow the shaft 600 to be fixed, such as by compressing a surface of the support 530 that defines the slot 580, and thus prevented from translating within the inner cavity 540, relative to the support 530. In another embodiment, the securing component 590 can be threadingly engaged with the support 530 to act against the shaft 600 to prevent the shaft 600 from traveling with the cavity 540 when desired.

[0086] On an end of the shaft 600, a main guide member 620 can be disposed. In some embodiments the main guide member 620 can be integral with the shaft 600, or in other embodiments the main guide member 620 and the shaft 600 can be separate components coupled together. The main guide member 620 can have a first guide surface 630A and a second guide surface 630B, and in some embodiments the main guide member 620 can include blocks 640A and/or 640B. The first and second guide surfaces 630A and 630B can be adjacent surfaces facing one another with a space defined between the first and second guide surfaces 630A and 630B. For example, the first guide surface 630A can be a surface of the main guide member 620 immediately opposite a surface of the main guide member 620 that interfaces with the shaft 600, and the second guide surface 630B can be a surface of the main guide member 620 immediately opposite a surface of the main guide member 620 that includes blocks 640A and 640B. In the illustrated embodiment, the second guide surface 630B contains a gap, such that the second guide surface 630B is not a single, continuous surface. In other embodiments, the second guide surface 630B can be a single, continuous surface lacking any such gap. The first guide surface 630A defines a first plane, while the second guide surface 630B defines a second plane. As shown, the first guide surface 630A and the second guide surface 630B can be configured such that the first plane is parallel to the second plane, with the space between. In further embodiments (not illustrated), the guide surfaces 630A and 630B can be configured such that the first and/or second planes are skewed.

[0087] As previously noted, a surface of the main guide member 620 can include one or more blocks 640A and 640B, either integral with the main guide member 620 or as separate components attached to the main guide member 620. As shown, the blocks 640A and 640B can be on a surface on a side of the main guide member 620 furthest from the interface with the shaft 600. In other applications, the blocks 640A and 640B can be located at various other positions on the main guide member 620. The blocks 640A and 640B can include fixation apertures 650A and 650B respectively. The fixation apertures 650A and 650B extend through the blocks 640A and 640B and provide a location for configuring additional fixation pins (e.g. bone fixation pins 460 shown in, e.g., FIG. 7) to, for example, position a bone or bones.

[0088] In addition to the support 530, the bone preparation instrument 520 can include a bridge component 660. As shown in FIG. 9B, the bridge component 660 can attach to the main guide member 620. In particular, in some applications of the bone preparation instrument 520 the bridge component 660 can have a geometry that allows the bridge

component 660 to attach to the main guide member 620 between the first and second guide surfaces 630A and 630B through an interference fit. Optionally, a locking mechanism can be provided to lock the bridge component to the main guide member, such as a locking tab, screw, pin, cam, etc. For example, the bridge component 660 may have a planar member 665 (shown in FIG. 9A) that is received within the gap between the surfaces 630A and 630B and an extending block 666 (shown in FIG. 9A) adapted to extend into the surface gap of 630B. In other applications, the bridge component 660 can be coupled to the main guide member 620 by any attachment mechanism, such as screws or clamps. The bridge component 660 can include rails 670A and 670B, each extending out from the bridge component 660 in a same general direction. In other embodiments, the rails 670A and 670B can extend out from the bridge component 660 at different angles.

[0089] The bone preparation instrument 520 can also include in some embodiments a fixating structure 680. The fixating structure 680 can be supported on the rails 670A and 670B. For example, the fixating structure 680 can include apertures 685A and 685B to receive the rails 670A and 670B, respectively. The fixating structure 680 can be secured to the rails 670A and 670B, such that the fixating structure 680 is obstructed from translating along the rails 670A and 670B, by turning or otherwise actuating an actuator 686 of the fixating structure 680, which moves a lock (not shown) to act against the rails. Furthermore, the fixating structure 680 can also include one or more fixation apertures 690A and/or 690B. Fixation apertures 690A and 690B extend through fixating structure 680 and can be located on opposite ends of the fixating structure 680, at a skewed angle, and serve to receive fixation pins or other means for stabilizing the bone preparation instrument 520 across a targeted anatomy and/or positioning a bone or bones.

[0090] Additionally, the bone preparation instrument 520 can have a secondary guide member 700. The secondary guide member 700 can be supported on the rails 670A and 670B. For example, the secondary guide member 700 may include slots 705A and 705B to receive the rails 670A and 670B such that the secondary guide member 700 is supported thereon. The secondary guide member 700 can also have a third guide surface 710A and a fourth guide surface 710B. The third and fourth guide surfaces 710A and 710B can be adjacent surfaces facing one another with a space defined between the third and fourth guide surfaces 710A and 710B. In the illustrated embodiments, third and fourth guide surfaces 710A and 710B are single, continuous surfaces that do not include a gap, but in other embodiments third and/or fourth guide surfaces 710A and 710B can include a gap. The third guide surface 710A defines a third plane, while the fourth guide surface 710B defines a

fourth plane. As shown, the third guide surface 710A and fourth guide surface 710B can be configured such that the third plane is parallel to the fourth plane, with the space between. In further embodiments (not illustrated), the guide surfaces 710A and 710B can be configured such that the third and/or fourth planes are skewed. Further, the third and/or fourth guide surfaces may be parallel to or skewed with respect to the first and/or second guide surfaces, such that the cutting guide can be adapted to make parallel cuts or angular cuts or cut shapes (e.g. a chevron shape). In some embodiments, the secondary guide member 700 can be locked to the rails 670A and/or 670B with a locking screw, cam, pin, etc.

[0091] In one application, the secondary guide member 700 can be supported on the rails 670A and 670B at a location along the rails 670A and 670B between the fixating structure 680 and the main guide member 620. Additionally shown in FIG. 9B are bone preparation fixation pins 140C and 140D received within fixation apertures 690A and 690B such that the fixation pins 140C and 140D extend through the fixating structure 680. In some applications of the bone preparation instrument 520, it may be desirable to provide the fixation pins 140C and 140D at an angle other than 90 degrees relative to a top surface of the fixating structure 680 by configuring the fixation apertures 690A and 690B to extend through the fixating structure 680 at a skewed angle to guide the fixating pins 140C and 140D. Fixation pins 140C and 140D can be used, for example, for stabilizing the bone preparation instrument 520 across a targeted anatomy and/or positioning a bone or bones.

[0092] Embodiments of the bone preparation instrument 520 can be useful in a surgical procedure for temporarily positioning a bone or bones and guiding a cutting of a bone or bones at a targeted anatomy. Bone cutting can be useful, for instance, to facilitate contact between leading edges of adjacent bones, separated by a joint, or different portions of a single bone, separated by a fracture, such as in a bone alignment and/or fusion procedure. Cuts can be made to bone with respect to the bone positioning instrument, and the bones can be positioned for an additional surgical step, such as bone plating, after the cuts have been made. As such, the bone preparation instrument 520 can be used in methods for temporarily fixing an orientation of a bone or bones, such as during a surgical procedure, and guiding cutting at desired bone locations.

[0093] The support 530 is placed on the bone. For embodiments of the bone preparation instrument 520 that include the extensions 570A and 570B, the extensions 570A and 570B can be used to at least partially straddle the bone and consequently provide both greater stability to the support 530 on the bone and anatomical alignment of the support 530 on a longitudinal axis of the bone (e.g., the slot 580 is generally parallel to the longitudinal axis of

the bone). Extension member 572 can be adjusted to a desired distance from support 530. Further, in some embodiments it can be desirable to align and fix the support 530 along the longitudinal axis of the bone using the fixation pins 140A and 140B. The pin 140A can be inserted through the fixation aperture 550A such that an end of the pin 140A protrudes out from the fixation aperture 550A adjacent the bone. The pin 140A can then be fixed to the bone. Similarly, the pin 140B can be inserted through fixation aperture 550B and fixed on an end to the bone. In this manner, the support 530 can be fixed in place to and aligned along the longitudinal axis of the bone.

[0094] In addition to fixing the support 530 to the bone, the main guide member 620 can be aligned such that the main guide member 620 is positioned at a location where a bone is to be cut. In one embodiment, the main guide member 620 can be positioned at the location where a bone is to be cut by appropriately positioning and fixing the support 530—the support 530 is fixed to the bone at a location along the bone that results in the main guide member 620 being positioned at the location where a bone is to be cut. In some embodiments, a joint alignment blade (not shown) is inserted though the main guide member and into a joint space to help align the main guide member in a desired position. Further, in certain embodiments, the bone fixation pin 460 can be inserted through a bone of interest and into an adjacent bone (e.g., though a first metatarsal and into a second metatarsal) to provide additional stability during the procedure.

[0095] However, in some applications a location of the main guide member 620 relative to the longitudinal axis of the bone can be adjusted without necessitating movement of the support 530. To accomplish this, the shaft 600 at least partially within the inner cavity 540 can be translated relative to the support 530 to cause the main guide member 620 to translate along the longitudinal axis of the bone a distance as a result of the shaft 600 being moved the same distance. Once the main guide member 620 is positioned at the location to be cut, the securing component 590 can be translated along the slot 580 such that the securing component 590 is aligned with securing aperture 610. The securing component 590 can then be fixed within the securing aperture 610 such that the shaft 600 is fixed relative to the support 530.

[0096] Once the main guide member 620 has been positioned at the location to be cut, a cutting member (e.g. a saw blade) can be inserted through the space defined between the first guide surface 630A and the second guide surface 630B to cut the bone. The guide surfaces 630A and 630B can serve to direct the cutting member to the location of the bone to be cut,

which in many applications can be a precise location. The break or window defined in the second guide surface 630B can assist in visualizing the portion of the bone being cut.

[0097] In some embodiments, the main guide member 620 can be used to make additional cuts. In such embodiments, the securing component 590 can be loosened and the shaft 600 can be translated within the cavity to a desired position. The securing component 590 can be then be fixed within the securing aperture so the shaft is again fixed relative to the support 530. In some embodiments, fixation pins may be inserted through fixation aperture 650A and/or 650B and into the bone to further stabilize the main guide member 620. After the main guide member 620 has been repositioned at the location to be cut, a cutting member (e.g. a saw blade) can be inserted through the space defined between the first guide surface 630A and the second guide surface 630B to cut the bone.

[0098] As shown in FIG. 9B, once the bone has been cut the additional components of the bone preparation instrument 520 can be added. In certain surgical procedures, it may be desirable to use bone preparation instrument 520 to make a second cut the same or different bone as the first cut. The secondary guide member 700 can be used to facilitate this second cut by positioning the secondary guide member at the location where the second cut is to be made. A cutting member (e.g. a saw blade) can be inserted through the space defined between the third and fourth guide surfaces 710A and 710B to cut the bone. The guide surfaces 710A and 710B can serve to direct the cutting member to the location on the bone to be cut. As illustrated, the cut made using the secondary guide member 700 will be a cut that is generally parallel to the cut made using the main guide member 620. However, in other embodiments components of the bone preparation instrument 520 (e.g. rails 670A and 670B) can be configured such that the cut made using the secondary guide member 700 is an angular cut (i.e. not parallel) relative to the first cut made using the main guide member 620.

[0099] When the bone or bones have been cut and positioned as desired on the single surgical patient, the bone preparation instrument 520 can be removed and discarded using convention means.

[00100] FIGS. 10A-C illustrate a second embodiment of a bone preparation instrument 720. The bone preparation instrument 720 can serve as a single bone preparation instrument included in embodiments the kit 10 and be disposed after use on a single surgical patient. FIG. 10A shows a perspective view of the bone preparation instrument 720, FIG. 10B shows a side elevational view of the bone preparation instrument 520, and FIG. 10C shows another perspective view of the bone preparation instrument 520.

[00101] The bone preparation instrument 720 can include a block 725 having first and second side ends 725A and 725B as well as a top end 725C and a bottom end 725D. The block 725 can be made, for example, from a polymeric material. In the illustrated embodiment, the block 725 is shaped and dimensioned such that the block 725 is capable of being gripped by hand during a surgical procedure. For example, the block 725 may include a recess 730 on one or more ends, such as the end 725B as shown, to assist in gripping the block 725. However, in other embodiments the block 725 can have various shapes and dimensions.

[00102] As shown in FIG. 10B, the block 725 can have one or more guide attachment members 740. For the bone preparation instrument 720 as shown, the one or more guide attachment members 740 are included on the end 725A of the block 725. In one embodiment, the one or more guide attachment members 740 can be fixed to the block 725 on an end of the members 740 nearest the top end 725C and free on an end of the attachment members 740 nearest the bottom end 725D. In such a configuration, the one or more members 740 can extend out from the end fixed to the block 725 in a direction that is generally parallel to an axis of the block 725 extending from the top end 725C to the bottom end 725D. But in other configurations of the block 725 that include the guide attachment members 740, the members 740 can be fixed at various positions on the block 725 and extend out from the block 725 at any angle. In the embodiment shown, the members 740 assume a cylindrical shape.

[00103] The block 725 can additionally include a projection 750 that extends out from an end, such as the bottom end 725D as illustrated, of the block 725. In an exemplary application, the bottom end 725D of the block 725 can be positioned so as to interface with, for instance, two bones while the projection 750 is configured to extend into a space defined between the bones (e.g. a joint between two bones, or a space between two bone portions of a fractured bone). As such, depending on the application of the bone preparation instrument 720, the projection 750 may have a width 755 that is dimensioned so as to be able to fit into the space defined between bones as desired. As shown, the projection may assume the shape of a planar member having two surfaces separated by a distance. In the embodiment shown, the distance, 755, is generally constant, and a leading edge of the projection 750 is provided with a wedge to facilitate insertion into a space. In other embodiments, the distance may vary from a narrower dimension near the leading region to a wider dimension near a proximal region.

[00104] The bone preparation instrument 720 can also include one or more guide members 760 and/or 770 positionable with respect to the block 725. The guide members 760 and 770

may be made of an appropriate metal or any other suitable material. The guide members 760 and 770 can each have a flange 780 and a support 790. The flange 780 is connected to the support 790, and in some embodiments the flange 780 and the support 790 can be one integral component.

[00105] Each flange 780 may include a first guide surface 800A and a second guide surface 800B. The first and second guide surfaces 800A and 800B can be adjacent surfaces facing one another with a space defined in the flange 780 between the first and second guide surfaces 800A and 800B. The space is useful for receiving a cutting instrument, such as a saw blade, and the surfaces 800A and 800B are useful for holding the cutting instrument in a desired plane during a cutting operation. As shown, the first guide surface 800A can be a surface of the flange 780 immediately opposite a surface of the flange 780 that connects to the support 790, and the second guide surface 800B can be a surface of the flange 780 immediately opposite a surface of the flange 780 that can interface with the block 725. In the illustrated embodiment, the guide surfaces 800A and 800B are both single, continuous surfaces lacking any gap. In some embodiments (not illustrated), a guide surface, for instance the second guide surface 800B, can contain a gap such that the guide surface is not a single, continuous surface. The first guide surface 800A defines a first plane, while the second guide surface 800B defines a second plane. As shown, the first guide surface 800A and the second guide surface 800B can be configured such that the first plane is parallel to the second plane, with the space (defined in the flange 780) between. In further embodiments (not illustrated), the guide surfaces 800A and 800B can be configured such that the first and/or second planes are skewed. Although the guide surfaces 800A and 800B are shown to be on the flange 780, in other embodiments the guide members 760 and/or 770 may have the guide surfaces 800A and 800B (and thus the space defined between the guide surfaces 800A and 800B) at various locations. For example, the guide surfaces 800A and 800B could be included as part of the support 790, such that the space defined in the flange 780 between the guide surfaces 800A and 800B would instead be defined in the support 790.

[00106] The support 790 of each guide member 760 and 770 can include one or more fixation apertures 810A and/or 810B. The fixation apertures 810A and 810B extend through the support 790. Each of the fixation apertures 810A and 810B can receive, for example, a bone preparation fixation pin that extends through the support 790 at the fixation apertures 810A and 810B such that an end of the bone preparation fixation pin can be fixed to a bone. In the illustrated embodiment, the fixation apertures 810A and 810B are located on opposite ends of the support 790. Specifically, the fixation apertures 810A and 810B as shown are located on

opposite ends of a longitudinal axis of the support 790 that extends perpendicular to the flange 780, and thus the first and second guide surfaces 810A and 810B. However, in other embodiments the support 790 can extend at various angles from the flange 780 and the one or more fixation apertures 810A and 810B can be positioned at various locations on the guide members 760 and 770 (e.g. the flange 780).

[00107] In some embodiments, the guide member 760 and/or 770 may be pivotally attached to the block 725 such that the guide member 760 and/or 770 can pivot with respect to the block 725. For example, in one embodiment, to pivotally attach the guide member 760 and/or 770 to the block 725 the guide member 760 and/or 770 may include an aperture 820 to receive the guide attachment member 740 of the block 725. The aperture may assume a cylindrical shape sized to mate with the attachment member 740. In the illustrated embodiment, the aperture 820 is included on an end of the flange 780 adjacent the first and second guide surfaces 800A and 800B, but in other variations the aperture 820 can be included at other locations on the guide member 760 and/or 770. Further, in some embodiments (not shown), the block 725 can include the aperture 820 and the guide member 760 and/or 770 can include the attachment member 740.

[00108] In either configuration, the aperture 820 can be aligned with the guide attachment member 740, and the guide member 760 and/or 770 can be attached to the block 725 by mating the attachment member 740 and the aperture 820. In some embodiments, the pivotable connection allows for the guide member 760 and/or 770 to slide along the attachment member 740 until the guide member 760 and/or 770 contacts a surface of the block 725. The guide member 760 and/or 770 can be free at an end opposite an end that contacts the block 725, which can allow the guide member 760 and/or 770 to translate along the guide attachment member 740 such that the guide members 760 and 770 may be at different elevations with respect to the block 725.

[00109] In the manner described, the guide member 760 and/or 770 is attached to the block 725 in a way that allows the guide member 760 and/or 770 to independently pivot with respect to the block 725 and to independently translate with respect to the block 725. The guide member 760 and/or 770 can be pivotally attached to the block 725 in numerous ways and at various locations on the block 725. For instance, as illustrated the guide members 760 and 770 are pivotally attached to the block 725 on the same end 725A of the block 725 and radially spaced from each other on that end 725A. In this configuration, the guide members 760 and 770 pivot about the block 725 at an end 725A opposite an end 725B of the block 725. Additionally, the embodiment shown has the guide members 760 and 770 configured to

pivot with respect to the block 725 about parallel axes of rotation. However, in other variations the guide members 760 and 770 can be attached to the block 725 at numerous locations, such as on opposite ends 725A and 725B, and in various configurations.

[00110] Depending on the location of the connections, separate bone preparation instruments 720 may be provided for left-side and right-side anatomies (e.g., a preparation instrument for a left foot and a preparation instrument for a right foot). In the embodiment shown, the bone preparation instrument 720 is configured for a left foot. In some embodiments, a bone preparation instrument configured for a right foot would be a mirror image of the instrument 720 configured for a left foot.

[00111] FIG. 10C illustrates a perspective view of the bone preparation instrument 720. In the illustrated embodiment, the guide members 760 and 770 are pivotally attached to the block 725. A location where a bone is to be cut can vary depending on the particular surgical procedure being performed on the single surgical patient. In some applications, the guide member 760 and/or 770 can be aligned at the location to be cut by appropriately positioning the block 725 such that the space defined between the guide surfaces 800A and 800B of the guide member 760 and/or 770 is located at the location to be cut.

[00112] In some embodiments, it may be desirable to adjust the location of the guide member 760 and/or 770 relative to the block 725 so that the guide member 760 and/or 770 is aligned at the location desired to be cut. In the example shown in FIG. 10C, the guide member 760 has been pivoted about the block 725 so that the guide member 760 is appropriately aligned at the location to be cut. Specifically, the guide member 760 has been pivoted about the block 725 so that the space defined between the guide surfaces 800A and 800B is positioned at the location desired to be cut. Similarly, the guide member 770 has been aligned at a second location to be cut by pivoting the guide member 770 about the block 725 so that the space defined between the guide surfaces 800A and 800B is positioned at the second location desired to be cut. Depending on the particular application, the guide members 760 and 770 can be pivoted about the block 725 to differing degrees. Therefore, by pivotally attaching the guide member 760 and/or 770 to the block 725, bone cuts can be made at a wide range of locations. Further, because the projection 750 can be positioned within a joint, a longitudinal axis of the cut can be generally parallel with the projection while the plane of the cut can be angularly adjusted relative to the projection as desired.

[00113] As previously noted, the guide members 760 and 770 can be attached to the block 725 in a manner that allows the guide members 760 and 770 to translate with respect to the block 725, such as up and down along the respective guide attachment members 740.

Configuring the guide members 760 and 770 to translate with respect to the block 725 allows the guide members 760 and 770 to be positioned at differing elevations, such as differing elevations along the guide members 740. This can be beneficial, for example, where the block 725 is positioned between two bones having differing elevations (i.e. differing heights). In such an application, the guide members 760 and 770 can translate with respect to the block 725 (e.g. along the respective guide attachment members 740) so that each guide member 760 and 770 rests on the respective bone on each side of the block 725, even though the bone on each side of the block 720 has a different elevation.

[00114] Additionally, configuring the guide members 760 and 770 to translate with respect to the block 725 can allow the block 725 to be removed, for instance from a space defined between bones, while the guide members 760 and 770 remain in place. In the embodiment of the bone preparation instrument 720 shown, the guide members 760 and 770 are free at an end opposite an end that can contact the block 725. This may allow the block 725 to be pulled away from the guide members 760 and 770 without disturbing the guide members 760 and 770, which may provide more working room during a surgical procedure.

[00115] During a surgical procedure the bone preparation instrument 720 can be positioned at a space defined between two bones. In particular, this can, for instance, include positioning the block 725 at the space defined between the bones. For embodiments where the block 725 includes the projection 750, the block 725 can be positioned at the space defined between the bones such that the projection 750 extends into the space defined between the bones. The projection 750 can, for example, assist in positioning and spacing the bones.

[00116] After positioning the bone preparation instrument 720, the guide members 760 and/or 770 can be aligned at the location(s) to be cut. Aligning the guide members 760 and 770 at the respective locations to be cut can include pivoting one or both guide members 760 and 770, for example at the apertures 820, about the block 725 as necessary. In addition, in some embodiments aligning the guide member 760 and/or 770 can include translating the guide member 760 and/or 770 relative to and along the block 725 such that an elevation of the guide member 760 and/or 770 can be adjusted, for instance, to match an elevation of the respective bones. The guide members 760 and 770 can be aligned such that cuts made to the bones using the respective guide members 760 and 770 are parallel cuts, but in other embodiments the guide members 760 and 770 can be aligned such that the cuts made to the bones are at various angles relative to each other.

[00117] Once the guide members 760 and/or 770 have been aligned at the respective locations to be cut, the guide members 760 and/or 770 can be fixed to the respective bones.

In the illustrated embodiment, the bone preparation fixation pins (not shown) may be inserted through the fixation apertures 810A and/or 810B of the guide members 760 and/or 770 to fix the guide members 760 and/or 770 to the respective bones. An end of a bone preparation fixation pin can be inserted through, for example, the fixation aperture 810B in the support 790 such that the end of the bone preparation fixation pin is fixed to the respective bone.

[00118] After aligning and fixing the guide members 760 and/or 770, the block 725 may be removed from the space defined between the bones. The block 725 can be removed by pulling the block 725 away from the bones in a direction opposite the bones. As such, in embodiments where the block 725 includes the projection 750, the projection 750 can also be removed from the space defined between the bones by removing the block 725. In this manner, the block 725 can slide out from the guide members 760 and 770 while the guide members 760 and 770 remain fixed to the respective bones.

[00119] The bones can be cut at the desired locations where the guide members 760 and/or 770 have been aligned. For example, the cutting member (e.g. a saw blade) can be inserted through the space defined between the first and second guide surfaces 800A and 800B to cut the respective bone. The guide surfaces 800A and 800B can serve to direct the cutting member to the location of the bone to be cut, which in many applications of the bone preparation instrument 720 can be a precise location.

[00120] When the bones have been cut on the one surgical patient, the guide members 760 and/or 770 can be removed and the bone preparation instrument 720 can be discarded using conventional means. Removing the guide members 760 and/or 770 may include removing any bone preparation fixation pins from the bones as well as from the guide members 760 and/or 770. In some embodiments, the bones may then be compressed together and one or more bone plates may be applied.

[00121] FIGS. 11A and 11B illustrate a third embodiment of a bone preparation instrument 830. The bone preparation instrument 830 can serve as a single bone preparation instrument included in embodiments the kit 10 and be disposed after use on a single surgical patient. FIG. 11A shows a perspective view of the bone preparation instrument 830, while FIG. 11B shows a perspective cross-sectional view of the bone preparation instrument 830. The bone preparation instrument 830 can be useful for temporarily fixing bones in a desired position during a surgical procedure, such as a bone alignment, osteotomy, and/or fusion procedure.

[00122] The bone preparation instrument 830 can include a first bone preparation fixation pin 140A for attachment to a first bone 840. A second bone preparation fixation pin 140B can be provided for attachment to a second bone 850, such as an adjacent bone separated by a joint

or different portions of a single bone. As shown best in Figure 11B, a first block 855 having a first aperture 856 can slidably receive the first bone preparation fixation pin 140A, and a second block 860 having a second aperture 861 can slidably receive the second fixation pin 140B. The first and second apertures 856, 861 can allow the first and second blocks 855, 860 to slide along a longitudinal axis of the first and second fixation pins 140A, 140B, respectively. The first and second apertures 856, 861 can also allow the first and second blocks 855, 860 to rotate about the longitudinal axis of the first and second fixation pins 140A, 140B, respectively. In some embodiments, the first and second fixation pins 140A, 140B are generally cylindrical and have a distal portion and a proximal portion, and the distal portion is threaded for retention within first and second bone, while the proximal portion is unthreaded for sliding within the first and second apertures and free rotational movement within the first and second apertures. In some embodiments, the proximal portion has a uniform diameter, such that it does not contain a flared or "head" portion. In such embodiments, the first and second blocks can be positioned on the first and second fixation pins before or after the pins are engaged with bone.

[00123] Again as best shown in FIG. 11B, a multi-axis joint 880 can be provided to connect the first block 855 and the second block 860 and located adjacent to a joint 885 between the first and second bones. In some embodiments, the multi-axis joint 880 allows the first block 855 and the second block 860 to move with respect to each other about more than one axis. In certain embodiments, the multi-axis joint 880 allows the first block 855 and the second block 860 to move with respect to each other about the three cardinal planes (i.e., X, Y, and Z axes). In the embodiment shown, the multi-axis joint 880 allows for angulation in all directions and rotation between the first and second blocks. In other examples, the bone positioning instrument 830 can be attached to first and second bones 840, 850, where the first and second bones are skewed relative to each other. In this case, a longitudinal axis of second bone 850 is skewed, for example, about 15 degrees relative to a longitudinal axis of first bone 840.

[00124] The multi-axis joint can include any suitable structure for allowing desired adjustments about more than one axis. In some embodiments, with reference to FIG. 11B, the multi-axis joint 880 includes a link 890 having a first end 894 rotatably connected to the first block 855 and a second end 898 rotatably connected to the second block 860. Such a multi-axis joint allows for the movement about the various axes discussed above at both the first end and the second end. In the embodiment shown, the first end 894 includes a first ball

received within a first socket of the first block 855, and the second end 898 includes a second ball received within a second socket of the second block 860.

[00125] Some embodiments of the instrument 830 allow the relative positions of the first and second bones to be fixed after a desired orientation has been achieved. For example, a first set screw 900 can extend through the first block 855 into the first aperture 856 and be positioned against the first fixation pin 140A, for fixation of the first block on a longitudinal axis of the first fixation pin and/or about the longitudinal axis of the first fixation pin. Further, a second set screw 910 can extend through the second block 860 into the second aperture 861 and be positioned against the second fixation pin 140B, for fixation of the second block on a longitudinal axis of the second fixation pin and/or about the longitudinal axis of the second fixation pin. In certain embodiments, the first and second set screws are positioned perpendicular to the first and second fixation pins. As shown in FIG. 11A, additional set screws 920, 930 extending through the first and second blocks can be positioned opposite of the first and second set screws, respectively. Such oppositely positioned set screws facilitate the use of the bone positioning device to be utilized, for example, on a left foot or a right foot.

[00126] Set screws can also be provided to fix positions across the multi-axis joint. In the embodiment shown in FIG. 11B, a first end set screw 940 extends through the first block 855 and is positioned against the first end 894 of the link 890. Further, a second end set screw 950 is shown extending through the second block 860 and positioned against the second end 898 of the link 890.

[00127] In some surgical procedures on a single surgical patient, the instrument 830 can be used to apply a compression force between two adjacent bones, or different portions of a single bone, while the bones are held in desired alignment and/or to facilitate a desired alignment between the bones. Such a compression force is useful for a surgical procedure such as bone fusion, for example. As shown in Figure11B, in some embodiments the instrument 830 includes a compression screw 960 operable to exert a compression force between first and second bones 840, 850 connected to first and second fixation pins 140A, 140B, respectively. In the embodiment shown, the compression screw 960 is generally perpendicular to the fixation pins and is threadingly received within a block and positioned to act against one of the fixation pins.

[00128] One of the blocks can be adapted to allow for relative movement to exert the compression force. In the embodiment shown in FIG. 11B, one of the blocks (e.g., the first block 855) has a first portion 970 slidingly connected to second portion 980. An aperture

(e.g., the first aperture 856) extends through the first portion and the second portion. In this embodiment, the first aperture has a first cross-sectional area in the first portion and a second cross-sectional area in the second portion, and the first cross-sectional area is smaller than the second cross-sectional area. The set screw 900 can extend through the first portion 970. The compression screw 960 can extend through the second portion 980. Upon actuation, the compression screw 960 will act against the fixation pin 140A and will pull the second portion 980 of the block 855 away from the fixation pin 140A. The force will be transmitted through the multi-axis joint 880 through the other block 860 and fixation pin 140B, thereby applying a compression force that tends to press together leading surfaces of the first and second bones 840, 850.

[00129] As will be appreciated, the bone preparation instrument 830 can find particular use in positioning one or more bones on the single surgical patient. Once the one or more bones no longer need to be positioned using the instrument 830, the instrument 830 can be discarded using conventional means.

[00130] Depending on the particular surgical procedure for which a specific embodiment of the kit 10 is intended, one of the three bone preparation instruments 520, 720, or 830 can be included in the kit 10, and no other bone preparation instrument need be included.

[00131] FIG. 12 illustrates a perspective view of bone preparation fixation pins 140, shown and described as included in the kit 10 with respect to FIG. 1. The bone preparation fixation pins 140 can be used in conjunction with any one of the bone preparation instruments 520, 720, or 830 to fixate the bone preparation instrument to one or more bones and provisionally position bones with respect to each other (e.g., rotationally, translationally, and/or elevationally) after removal of the bone preparation instrument and prior to installation of a bone plate. The bone preparation fixation pins 140 can include a first end 990 and a second end 995. The second end 995 can be pointed and optionally threaded or fluted and inserted through an aperture of a bone preparation instrument and into a bone. Because the bone preparation fixation pins 140 can be used across the various embodiments of the bone preparation instruments, efficiency is achieved when packing multiple kits 10 that each include a different single bone preparation instrument. Once the surgical procedure on the one surgical patient is finished, the at least one and no more than ten (e.g., 2, 4, 6, or 8) bone preparation fixation pins 140 included in a kit 10 can be discarded using conventional means.

[00132] Although not shown, some embodiments of the kit 10 can include at least one and no more than two cutting instruments. For example, an embodiment of the kit 10 can include at least one and no more than two saw blades. The saw blades can be used to cut one or more

bones, such as in conjunction with a bone preparation instrument. Once the bone or bones are cut as desired for the specific surgical procedure on the single surgical patient, the at least one and no more than two saw blades can be discarded.

[00133] Some embodiments of the kit 10 may also include at least one and no more than four reamer sets (e.g., each having 1, 2, 3, or 4 reamers). The reamer can be used to prepare a surface of one or more bones and/or drill a hole in one or more bones. After appropriate surface preparation and/or hole creation has been completed as needed for the particular surgical procedure on the single surgical patient, the at least one and no more than four reamer sets can be discarded. Further examples of the kit 10 that include at least one and no more than four reamer sets may also include a single reamer sizing template. In one instance, the single reamer sizing template can be integral to the container 20 such that when a reamer is to be removed from the kit 10 during a surgical procedure the reamer can be placed on the reamer sizing template to determine a dimension (e.g. length, diameter) of the chosen reamer. In other instances, the reamer sizing template can be a separate component included in the kit 10 that is removable from the container 20 so as to allow a dimension of the reamer to be determined external to the container 20. Once the specific surgical procedure has been completed on the single surgical patient, the reamer sizing template can be discarded.

[00134] Although not shown, some embodiments of the kit can include one or more implants. For example, one or more implants useful for filling a bone void created during a surgical procedure, such as, for example, a metatarsal base wedge procedure or an Evens lengthening procedure, may be provided. Examples of such a one or more implant include an allograft bone wedge, a titanium bone wedge, a titanium wedge, a synthetic bone wedge, or any other bone substitute.

[00135] In sum, various embodiments of the disposable single-use kit 10 can include all or any combination of one or more of the described surgical items. The items to be included in the kit 10 will vary depending on the specific surgical procedure for which the kit 10 is intended to be used. Items included in the kit 10 can be within the quantity ranges described herein, and the kit, including all of the surgical items included in the kit 10, may be discarded after use on a single surgical patient. Some embodiments of the kit can include all components in a single sterile package. Other embodiments of the kit can include two or more sterile packages with different components in each sterile package. For example, a first sterile package containing the bone plates, fasteners, and pins may be provided along with a second sterile package containing instruments such as plate manipulation and/or bone preparation instruments. Such a kit can also be provided in modular form with components

grouped together in separate sterile packages to be selected to provide a complete kit for the desired surgical procedure.

[00136] Thus, embodiments of the invention are disclosed. Although the present invention has been described with reference to certain disclosed embodiments, the disclosed embodiments are presented for purposes of illustration, and not limitation, and other embodiments of the invention are possible. One skilled in the art will appreciate that various changes, adaptations, and modifications may be made without departing from the spirit of the invention.

CLAIMS:

1. A disposable single-use surgical kit for a foot or ankle orthopedic procedure comprising:

a sterile container;

a plurality of unicortical bone plate fasteners included in the sterile container; and

at least one bone plate but no more than four bone plates included in the sterile container, each bone plate comprising:

a body having a top surface and a bone facing surface opposite the top surface; and

a first fixation hole extending through the body from the top surface to the bone facing surface and configured for receiving one of the plurality of unicortical bone plate fasteners included in the sterile container.

2. The kit of claim 1, wherein each bone plate is configured to be positioned across a tarsal-metatarsal joint for tarsal-metatarsal joint fusion.

3. The kit of either claims 1 or 2, wherein the at least one bone plate but no more than four bone plates is two bone plates, a first one of the two bone plates being configured to span from a dorsal region of a medial cuneiform to a medial region of a first metatarsal and a second one of the two bone plates being configured to span from a plantar region of the first metatarsal to a medial region of the medial cuneiform.

4. The kit of claim 3, wherein each of the two bone plates has four fixation holes with two of the four fixation holes positioned on a distal region of the bone plate and two of the four fixation holes positioned on a proximal region of the bone plate.

5. The kit of claim 4, wherein the plurality of unicortical bone plate fasteners is at least eight.

6. The kit of any one of the preceding claims, wherein at least one bone plate comprises a helical curvature.

7. The kit of any one of the preceding claims, wherein the helical curvature is formed between proximal and distal regions of the body and comprises both a bend of the body along a central longitudinal axis and a twist of the body about the central longitudinal axis, and wherein the distal region lies in a first plane and the proximal region lies in a second plane offset from the first plane both along and about the longitudinal axis such that the helical curvature provides a transition from the first plane to the second plane.

8. The kit of any one of the preceding claims, wherein each of the plurality of unicortical bone plate fasteners is configured to be inserted through a fixation hole of a bone plate and through only one cortical wall of at least one of a first metatarsal and a medial cuneiform.

9. The kit of any one of the preceding claims, wherein a number of the plurality of unicortical bone plate fasteners included in the sterile container is greater than or equal to a total number of fixation holes of the bone plates included in the sterile container.

10. The kit of any one of the preceding claims, wherein a number of the plurality of unicortical bone plate fasteners included in the sterile container is equal to a total number of fixation holes of the bone plates included in the sterile container plus at least one and no more than four, and no other bone plate fasteners are included in the sterile container.

11. The kit of any one of the preceding claims, wherein the bone facing surface of each bone plate includes a pad extending out a distance from a first surface.

12. The kit of claim 11, wherein the pad extends out the distance from the first surface at a location on the bone facing surface adjacent the first fixation hole.

13. The kit of any one of the preceding claims, wherein the body has a length defining a central longitudinal axis and a width defining an extent of the bone plate transverse to the central longitudinal axis, and wherein the width of the body is greater at a location along the central longitudinal axis having the first fixation hole compared to the width of the body at a location remote from the first fixation hole.

14. The kit of any one of the preceding claims, wherein at least one bone plate further comprises an attachment member at least partially within the first fixation hole.

15. The kit of any one of the preceding claims, wherein each one of the plurality of unicortical bone plate fasteners included in the sterile container comprises a head and a shaft, wherein the shaft of each one of the plurality of unicortical bone plate fasteners consists of one of one of two lengths, and there are no other lengths of bone plate fasteners within the sterile container.

16. The kit of any one of the preceding claims, wherein each one of the plurality of unicortical bone plate fasteners included in the sterile container comprises a head and a shaft, wherein the shaft of each one of the plurality of unicortical bone plate fasteners consists of one of a first diameter, a second diameter, a third diameter, and a fourth diameter, and there are no other diameters of bone plate fasteners within the sterile container.

17. The kit of any one of the preceding claims, further comprising at least one and no more than three plate manipulation instruments included in the sterile container.

18. The kit of claim 17, wherein at least one of the plate manipulation instruments includes an end configured to drive one of the plurality of unicortical bone plate fasteners received within the first fixation hole into a bone.

19. The kit of any one of the preceding claims, further comprising a bone preparation instrument included in the sterile container.

20. The kit of claim 19, further comprising at least one and no more than ten bone preparation fixation pins included in the sterile container.

21. The kit of any one of the preceding claims, further comprising at least one and no more than six bone cut pins included in the sterile container.

22. The kit of claim 21, wherein at least one of the bone cut pins includes a collar at a location on the bone cut pin spaced from an end of the bone cut pin.

23. The kit of any one of the preceding claims, further comprising at least one and no more than four bone fixation pins included in the sterile container.

24. The kit of claim 23, wherein each of the bone fixation pins includes a collar at a location on the bone fixation pin spaced from an end of the bone fixation pin.

25. The kit of any one of the preceding claims, further comprising at least one and no more than three external fasteners included in the sterile container and at least one and no more than three washers sized to receive the at least one and no more than three external fasteners.

26. The kit of any one of the preceding claims, further comprising at least one and no more than two external fasteners included in the sterile container, wherein the at least one and no more than two external fasteners have a length different than a length of each one of the plurality of unicortical bone plate fasteners included in the sterile container, and further including at least one and no more than two washers sized to receive the at least one and no more than two external fasteners.

27. The kit of any one of the preceding claims, further comprising at least one and no more than two saw blades included in the sterile container.

28. The kit of any one of the preceding claims, further comprising at least one and no more than four reamer sizes.

29. A method for performing a surgical operation, the method comprising the steps of:

removing a plurality of bone plate fasteners from a sterile container, wherein each one of the plurality of bone plate fasteners comprises a head and a shaft, and wherein the shaft of each one of the plurality of bone plate fasteners consists of one of a first length, a second length, a third length, and a fourth length, and further wherein the diameter of each one of the plurality of bone plate fasteners consists of one of a first diameter, a second diameter, a third diameter, or a fourth diameter, and there are no other lengths or diameters of bone plate fasteners within the sterile container;

removing at least one and no more than four bone plates from the sterile container, the at least one and no more than four bone plates each comprising:

a body having a top surface and a bone facing surface opposite the top surface; and

a first fixation hole extending through the body from the top surface to the bone facing surface and configured for receiving one of the plurality of bone plate fasteners;

contacting a bone with the at least one and no more than four bone plates removed from the sterile container; and

inserting one of the plurality of bone plate fasteners removed from the sterile container through the first fixation hole and into the bone.

30. The method of claim 29, wherein contacting the bone with the at least one and no more than four bone plates removed from the sterile container comprises contacting the bone with a pad extending out a distance from the first surface of each of the at least one and no more than four bone plates.

31. The method of either of claims 29 or 30,

wherein removing at least one and no more than four bone plates from the sterile container is removing two bone plates from the sterile container, and

contacting the bone comprises positioning each of the two bone plates across a tarsal-metatarsal joint.

32. The method of claim 31, wherein the plurality of bone plate fasteners comprise unicortical bone plate fasteners, and inserting one of the plurality of bone plate fasteners comprises inserting one of the plurality of unicortical bone plate fasteners.

33. The method of any one of claims 29–32, wherein removing at least one and no more than four bone plates comprises removing a bone plate having a helical curvature.

34. The method of any one of claims 29–33, further comprising:

removing at least one and no more than ten bone preparation fixation pins from the sterile container; and

fixing the single bone preparation instrument to the bone at a position near the bone location to be cut using the at least one and no more than ten bone preparation fixation pins.

35. The method of any one of claims 29–34, further comprising:

removing at least one and no more than three plate manipulation instruments from the sterile kit;

inserting an end of one of the plate manipulation instruments into an attachment member configured at least partially within the first fixation hole of one of the bone plates removed from the sterile container; and

bending one of the bone plates while the end of the plate manipulation instrument is inserted in the attachment member.

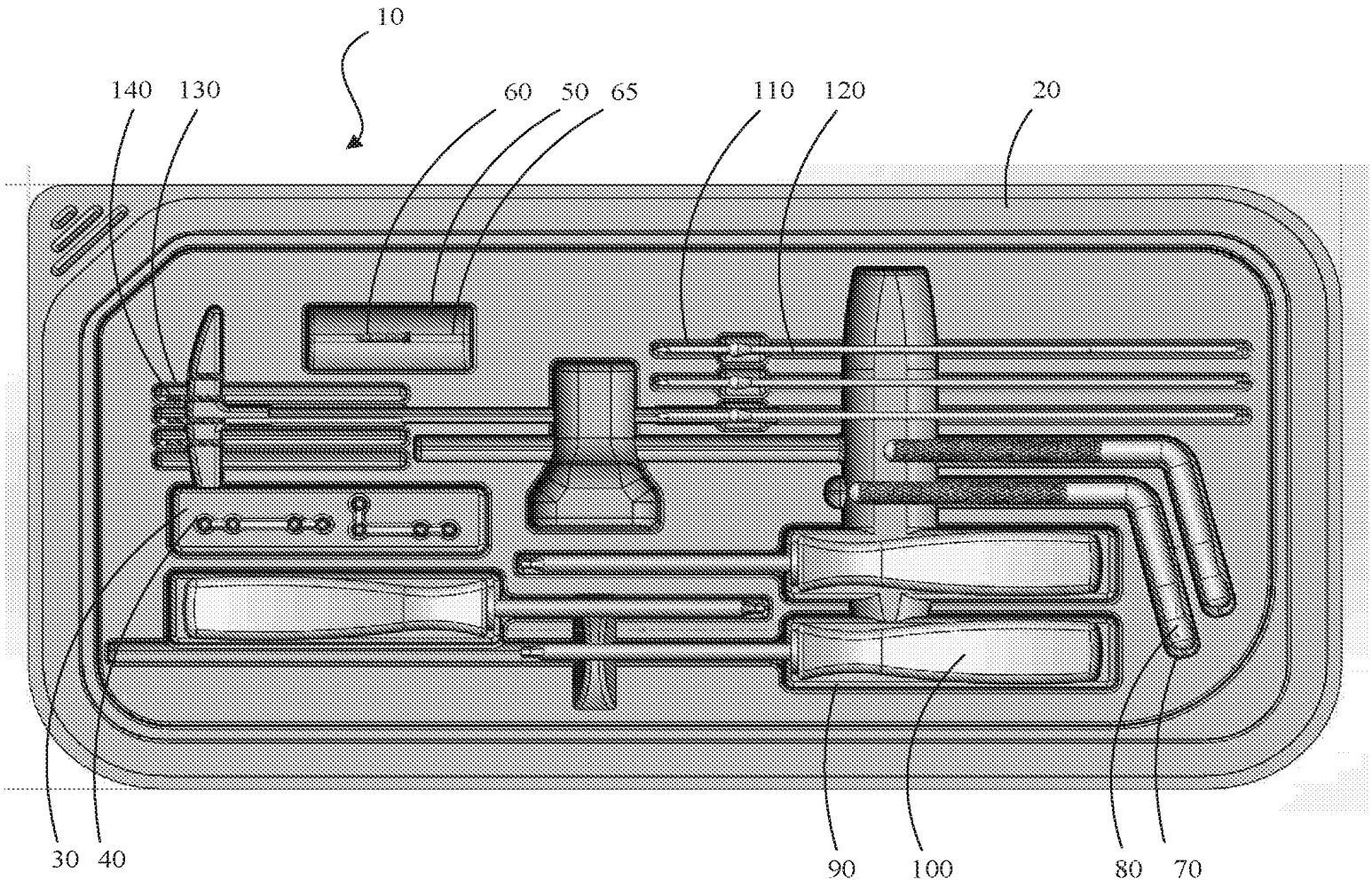


FIG. 1

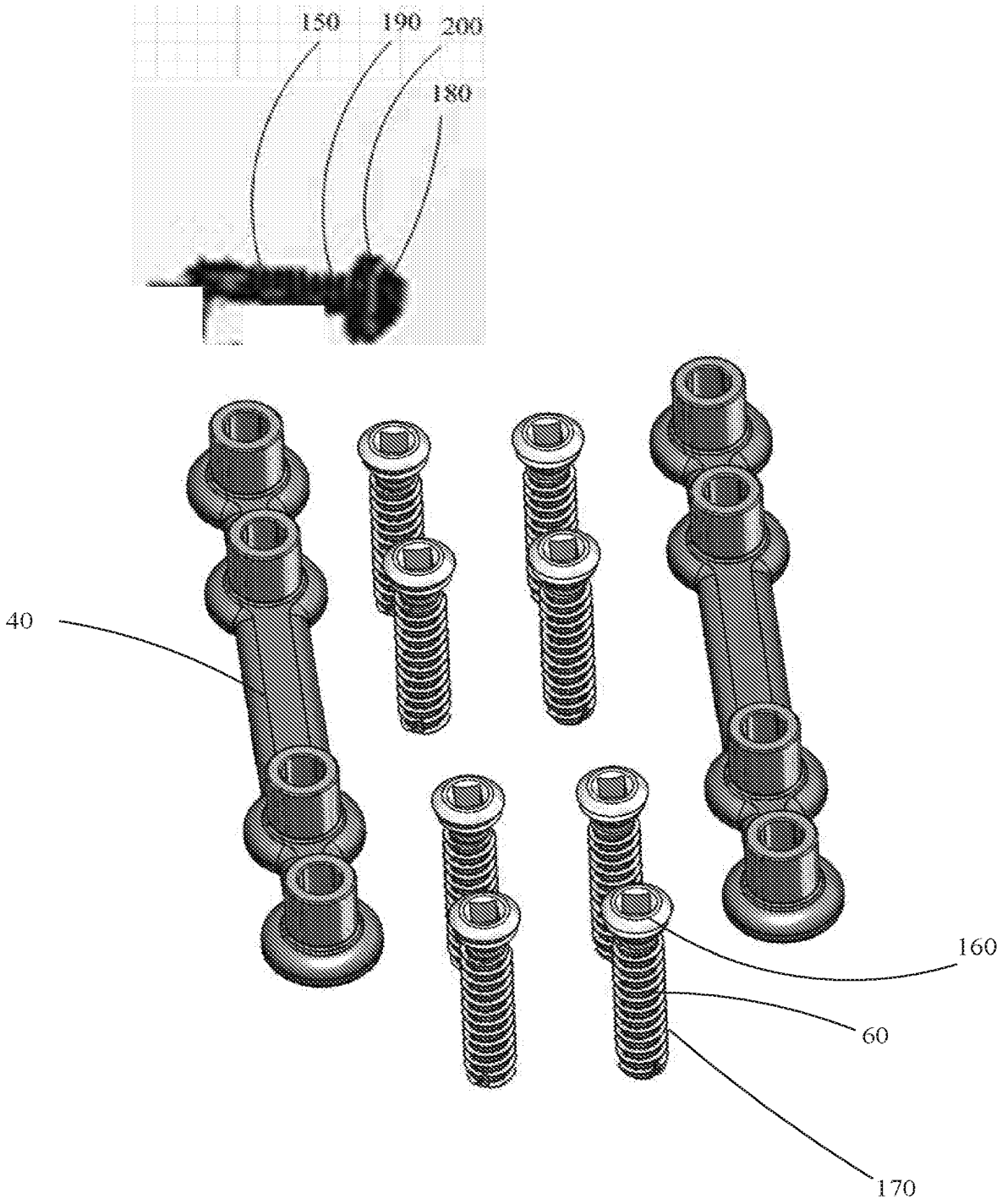


FIG. 2A

FIG. 2B

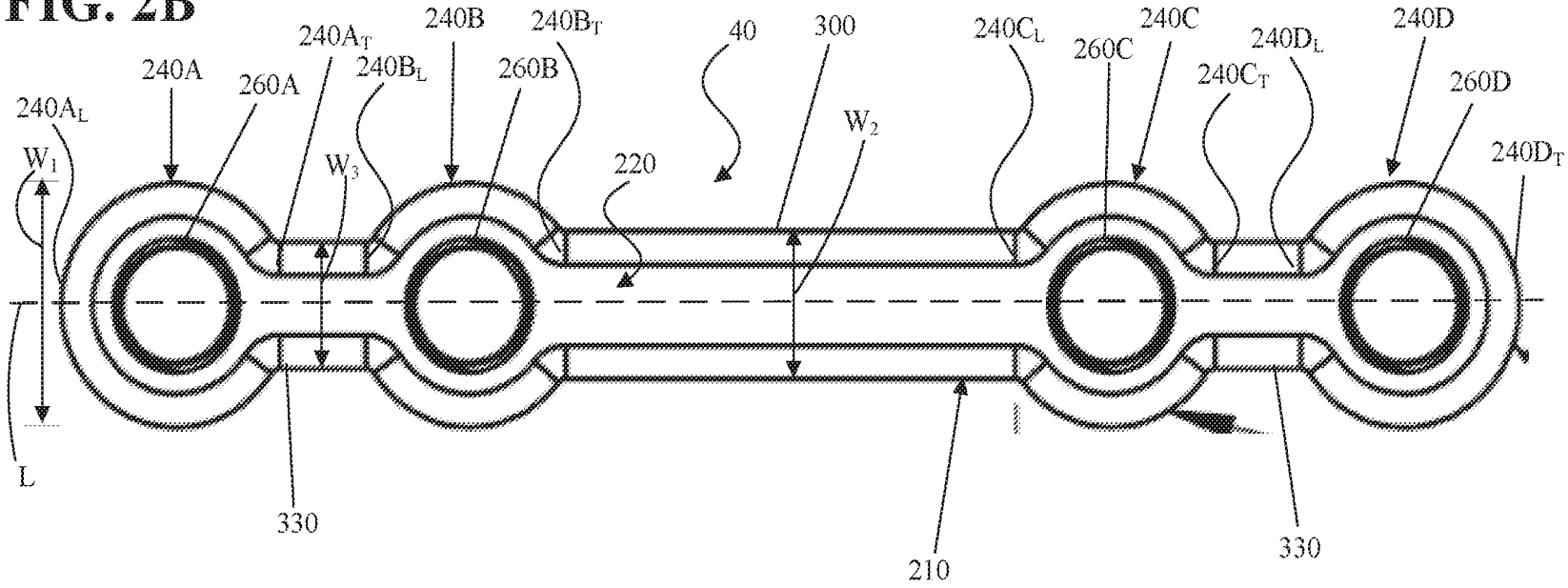
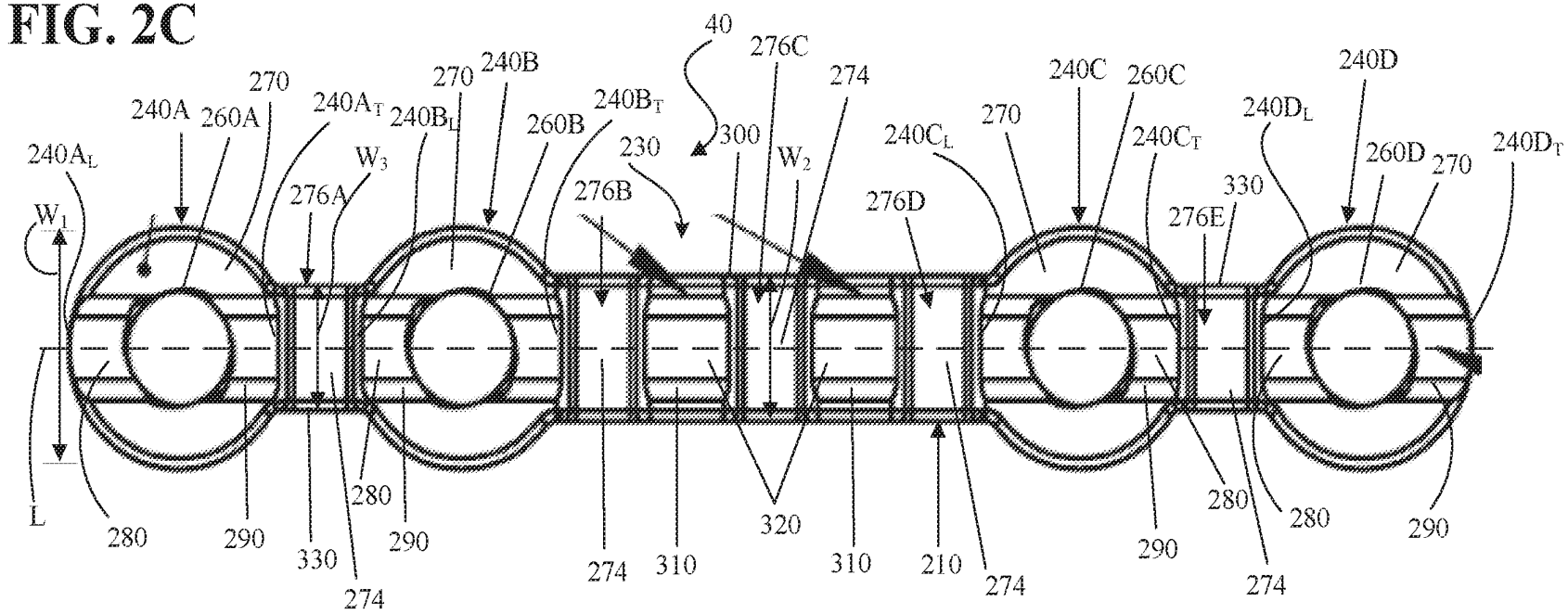

240A
240A_T
240A_L
260A
240B
240B_T
240B_L
260B
40
300
240C_L
260C
240C
240C_T
240D_L
240D
260D
240D_T
W_1
W_2
W_3
220
L
330
210
330

FIG. 2C


40
276C
274
270
240A
260A
240A_T
240B
240B_T
260B
240A_L
W_1
W_3
276A
276B
230
300
W_2
240C_L
240C
260C
240C_T
240D_L
240D
260D
240D_T
276D
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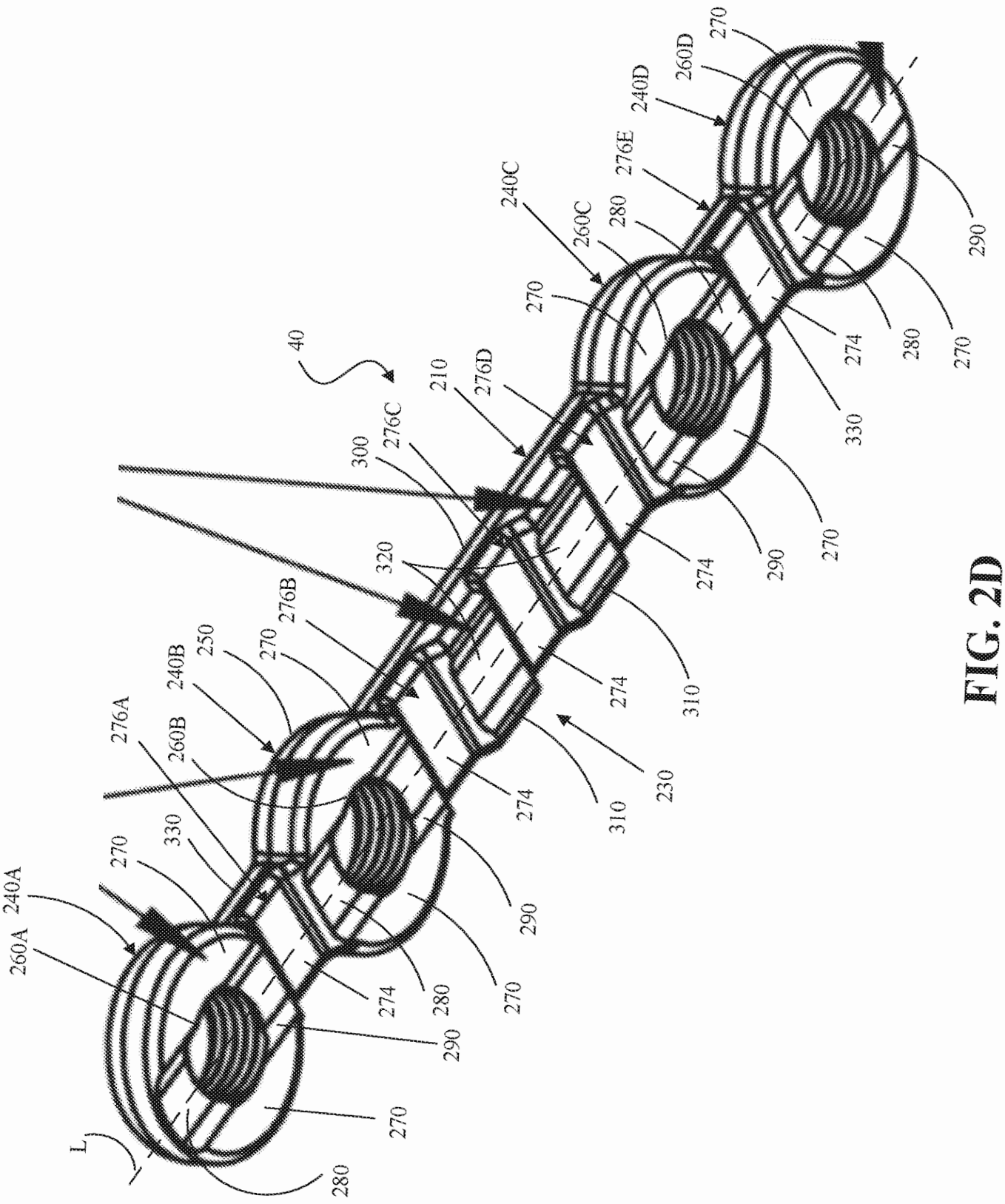

40
210
276A
276B
276C
276D
276E
240A
240B
240C
240D
250
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260B
260C
260D
270
274
280
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300
310
320
330
230
L

FIG. 2D

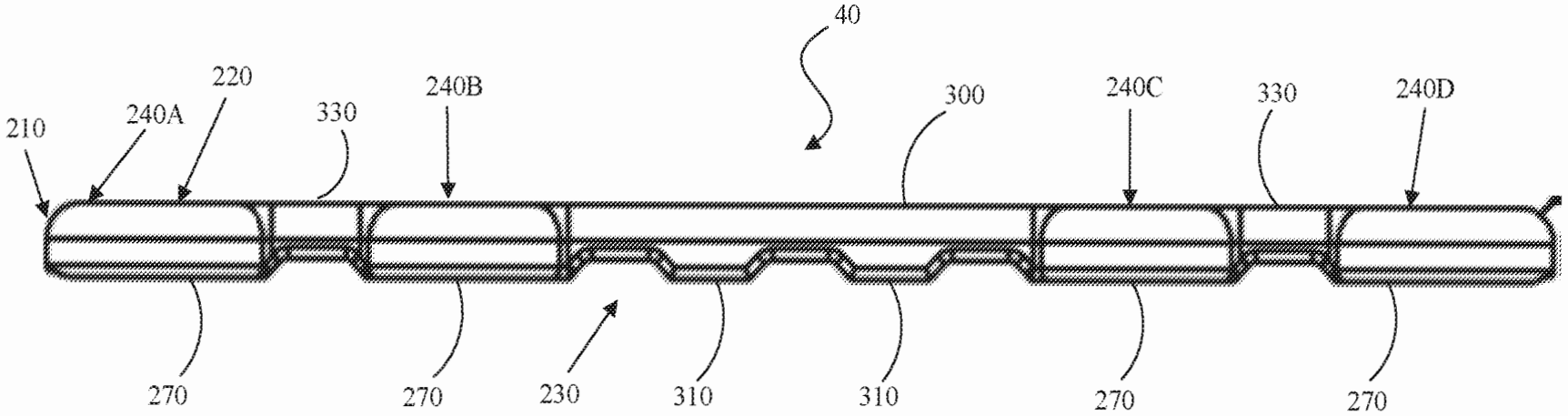

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240B
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240C
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240D
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310
270
270

FIG. 2E

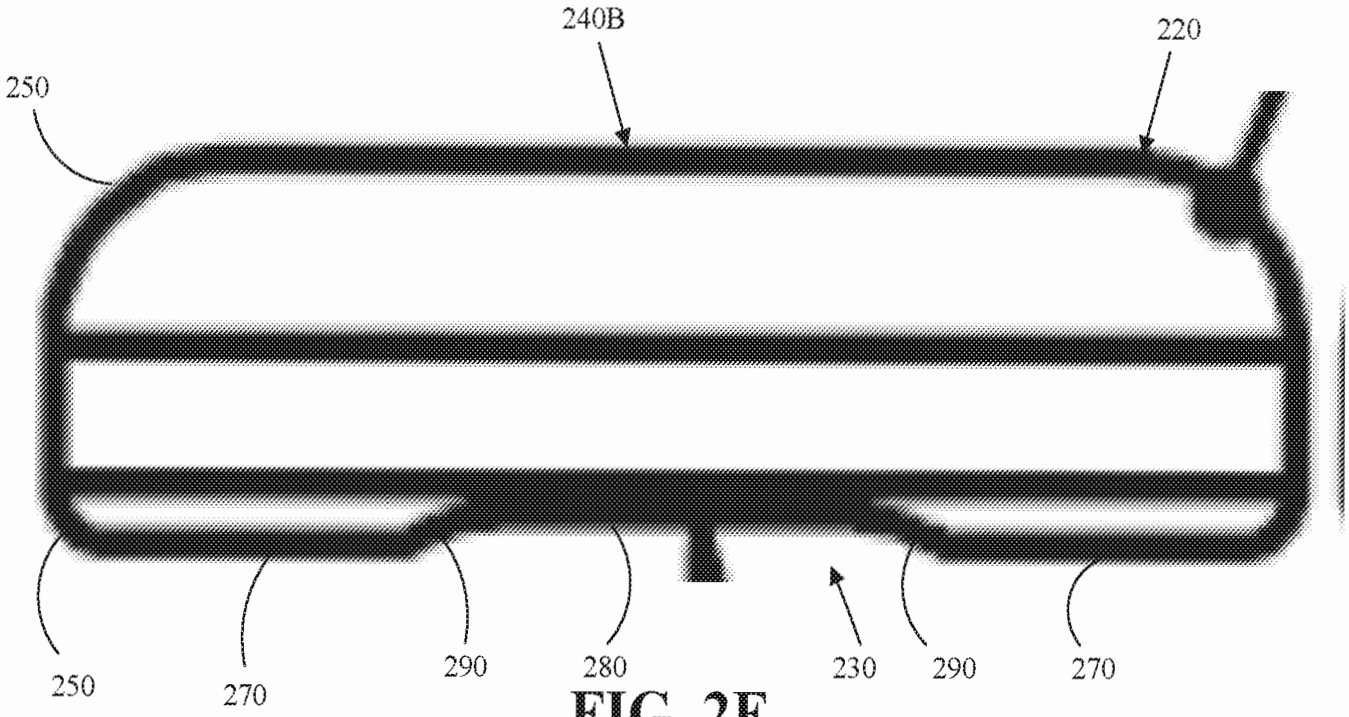

240B
220
250
250
270
290
280
230
290
270

FIG. 2F

FIG. 2G

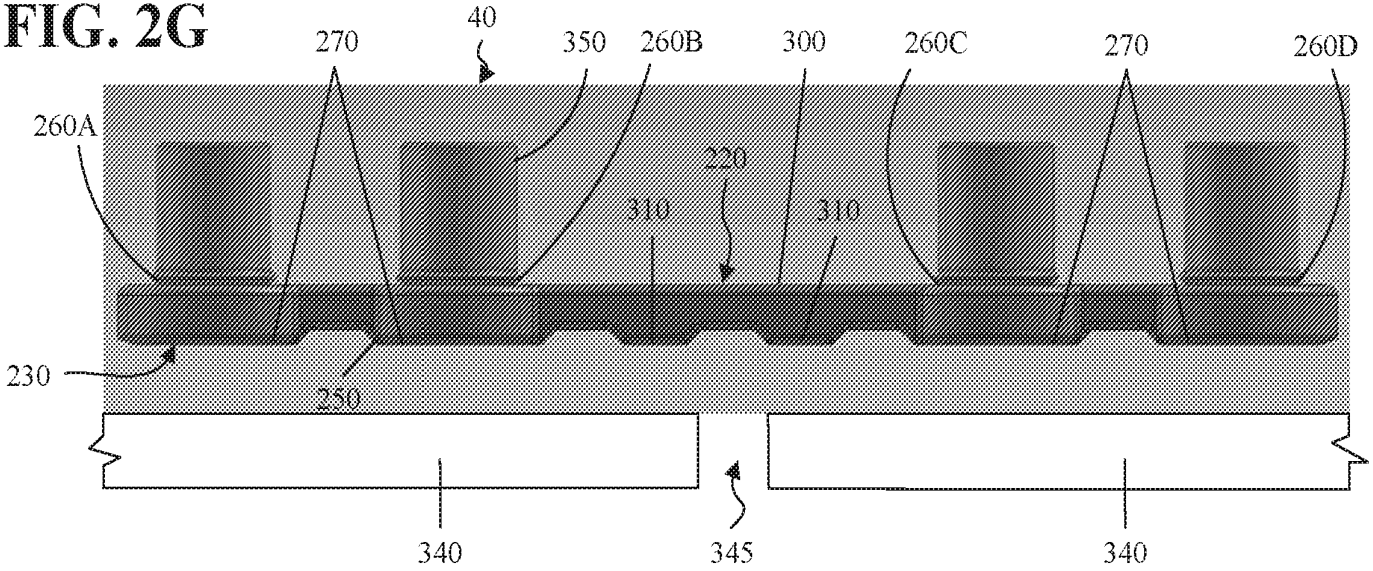
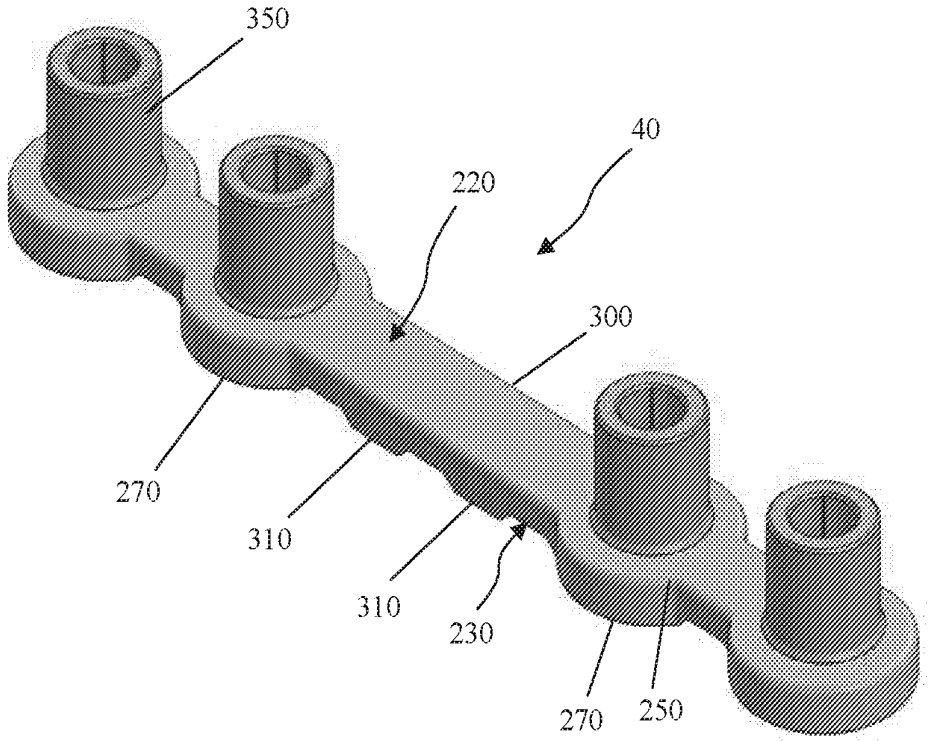

270
40
350
260B
300
260C
270
260D
260A
220
310
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230
250
340
345
340

FIG. 2H


350
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270
310
310
230
270
250

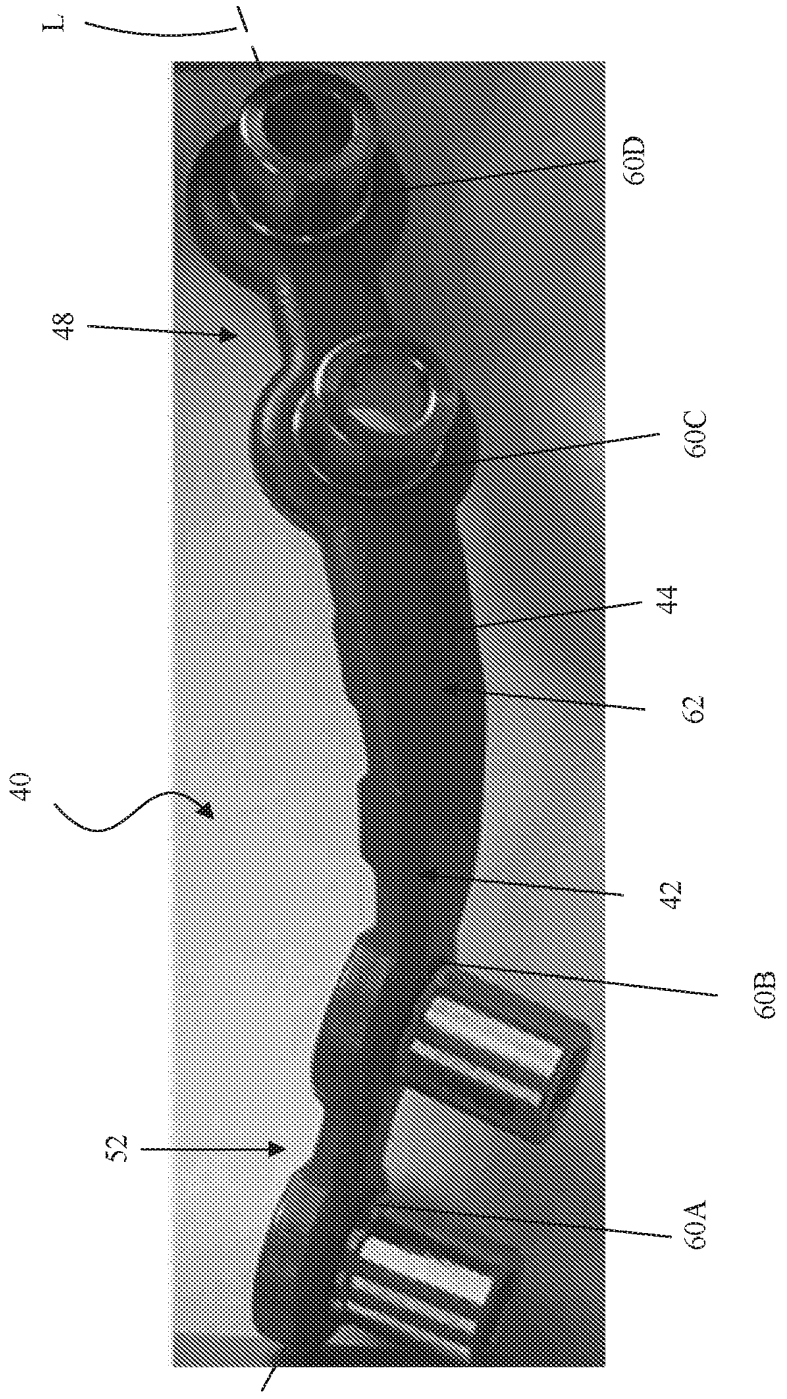


FIG. 2I

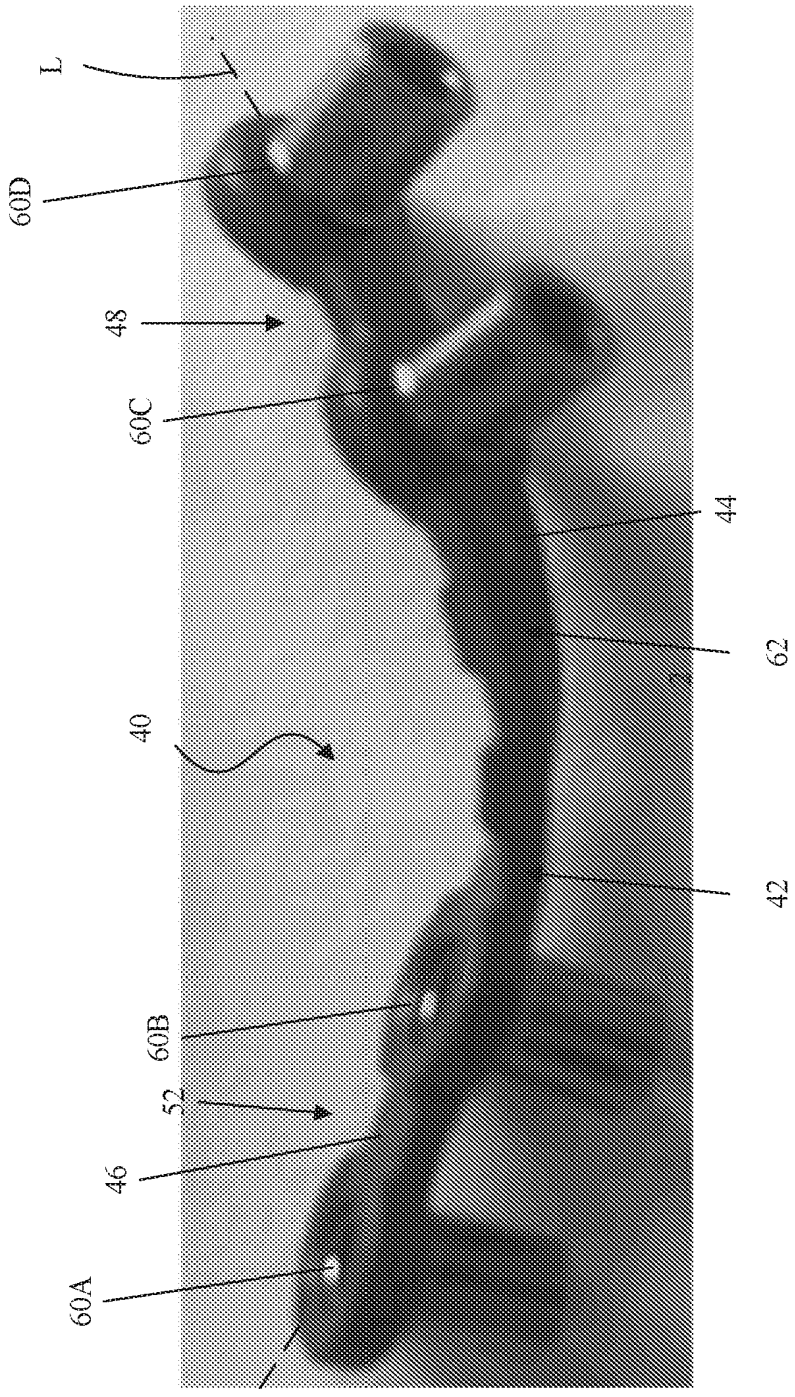


FIG. 2J

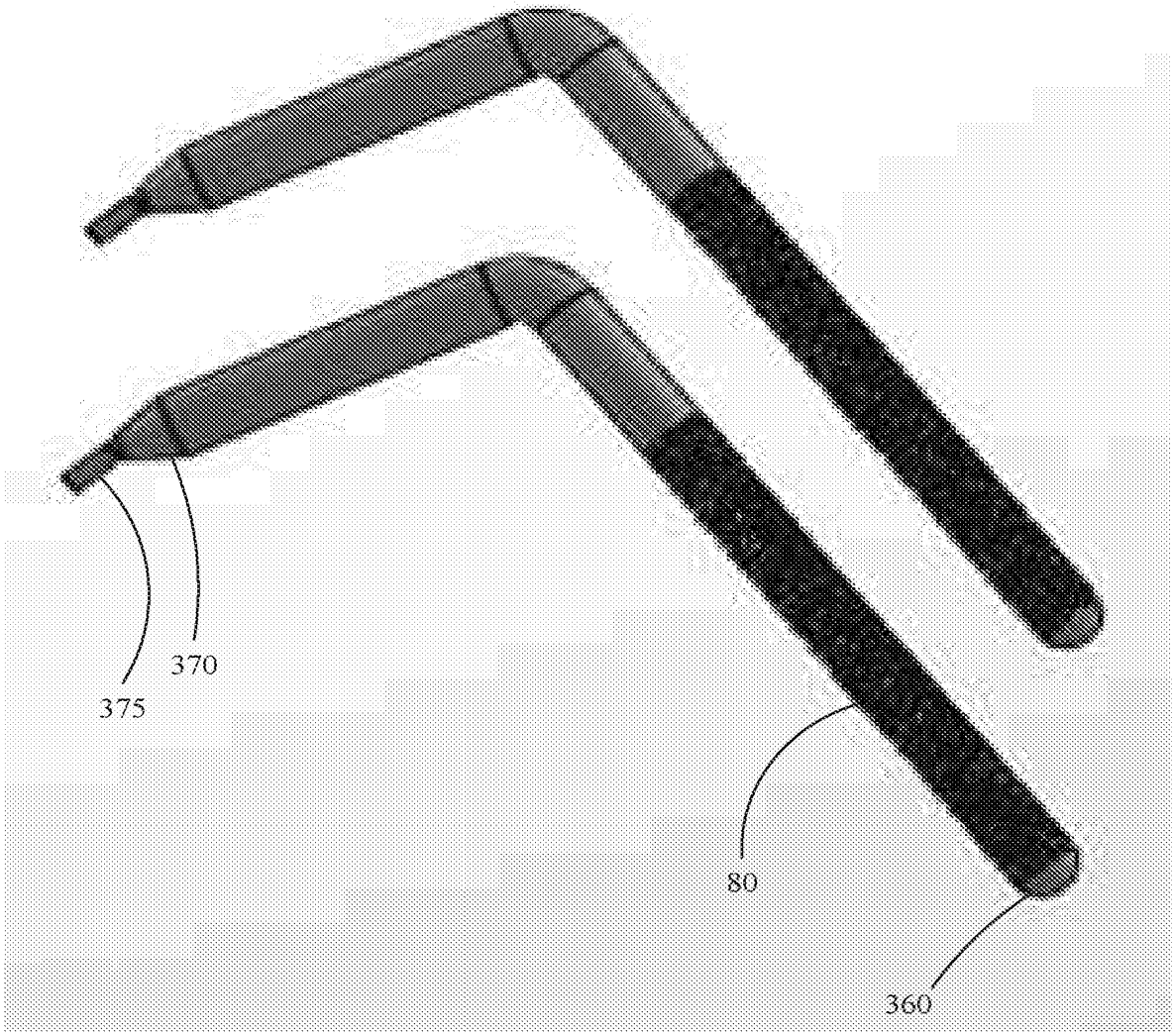


FIG. 3

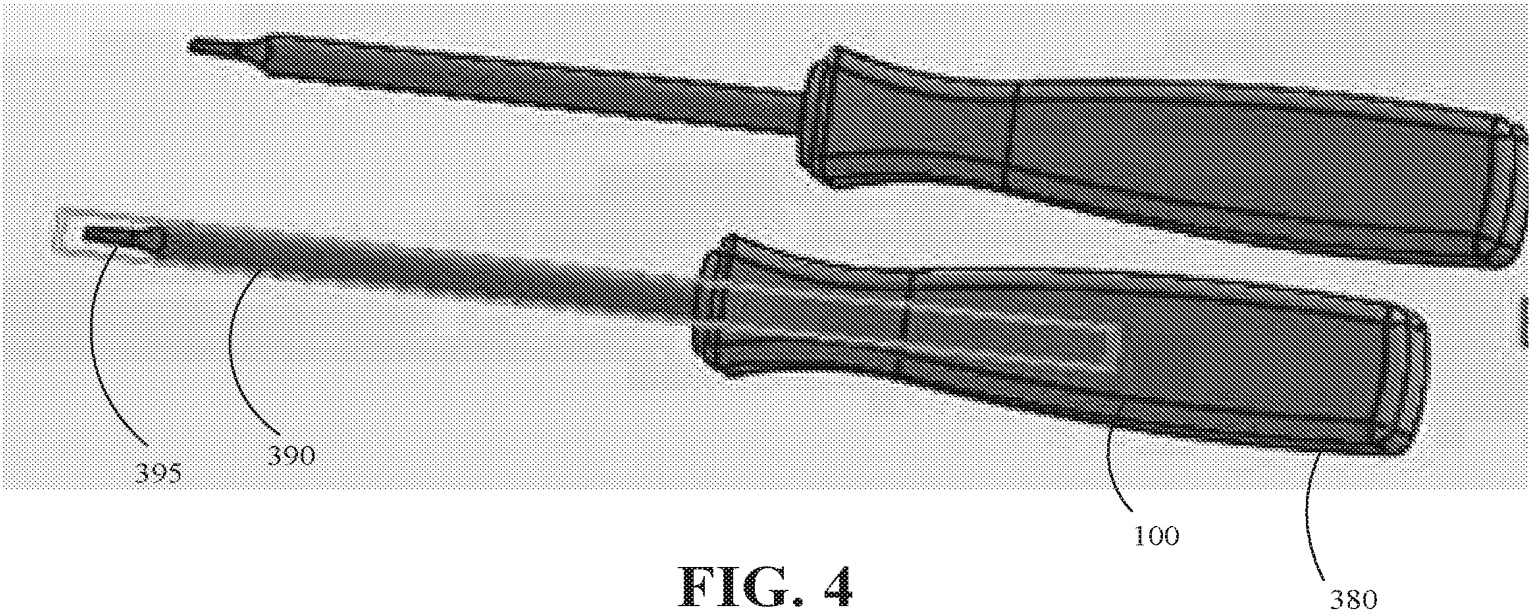


FIG. 4

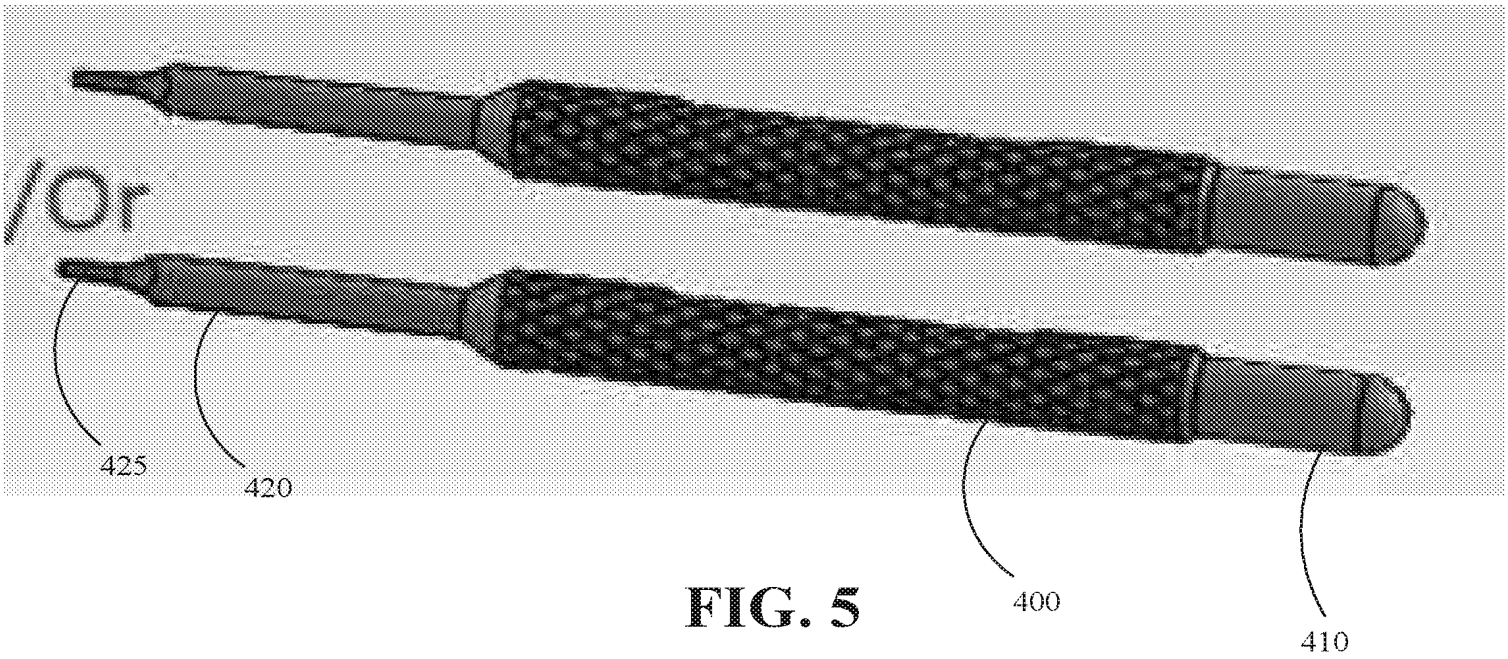


FIG. 5

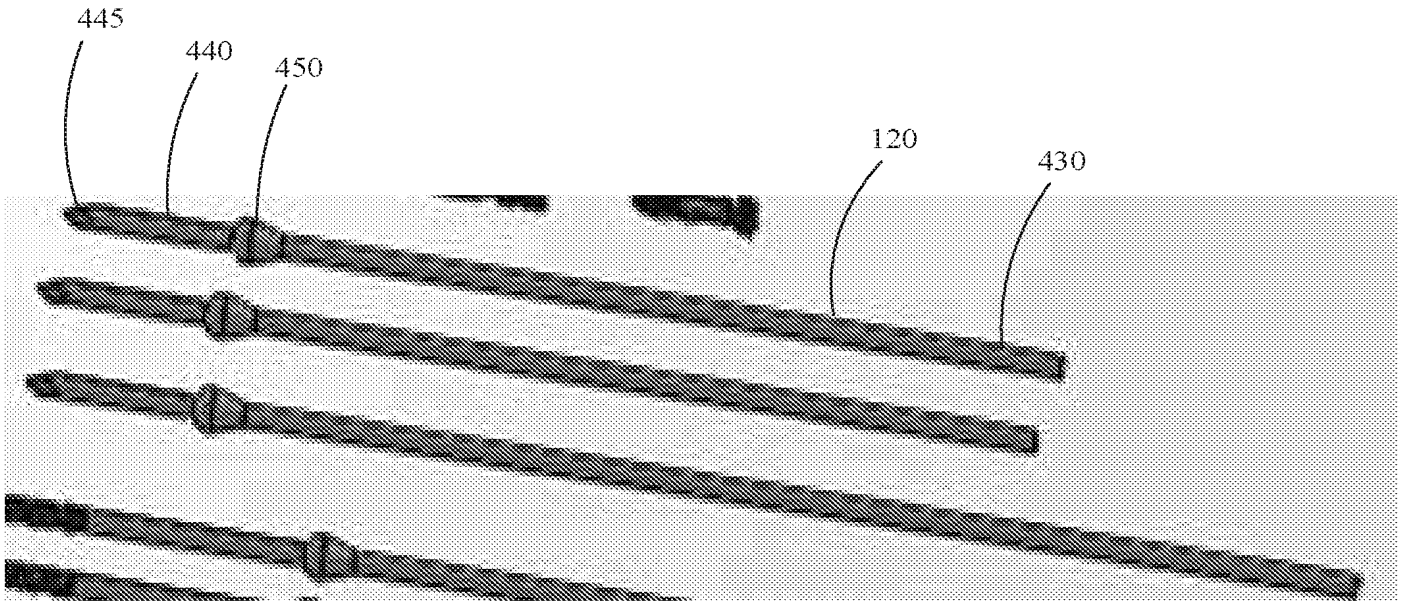


FIG. 6

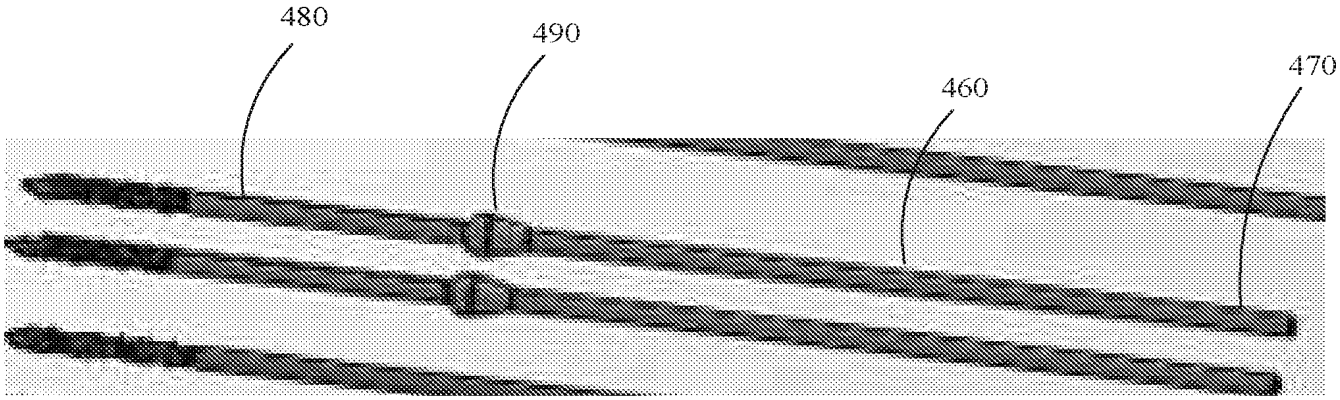


FIG. 7

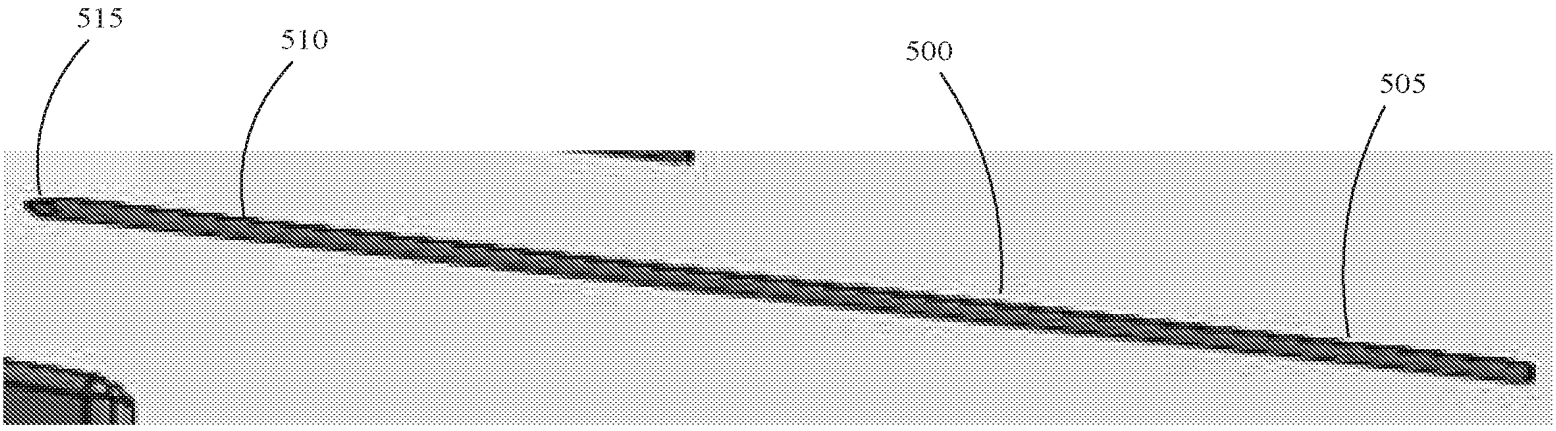


FIG. 8

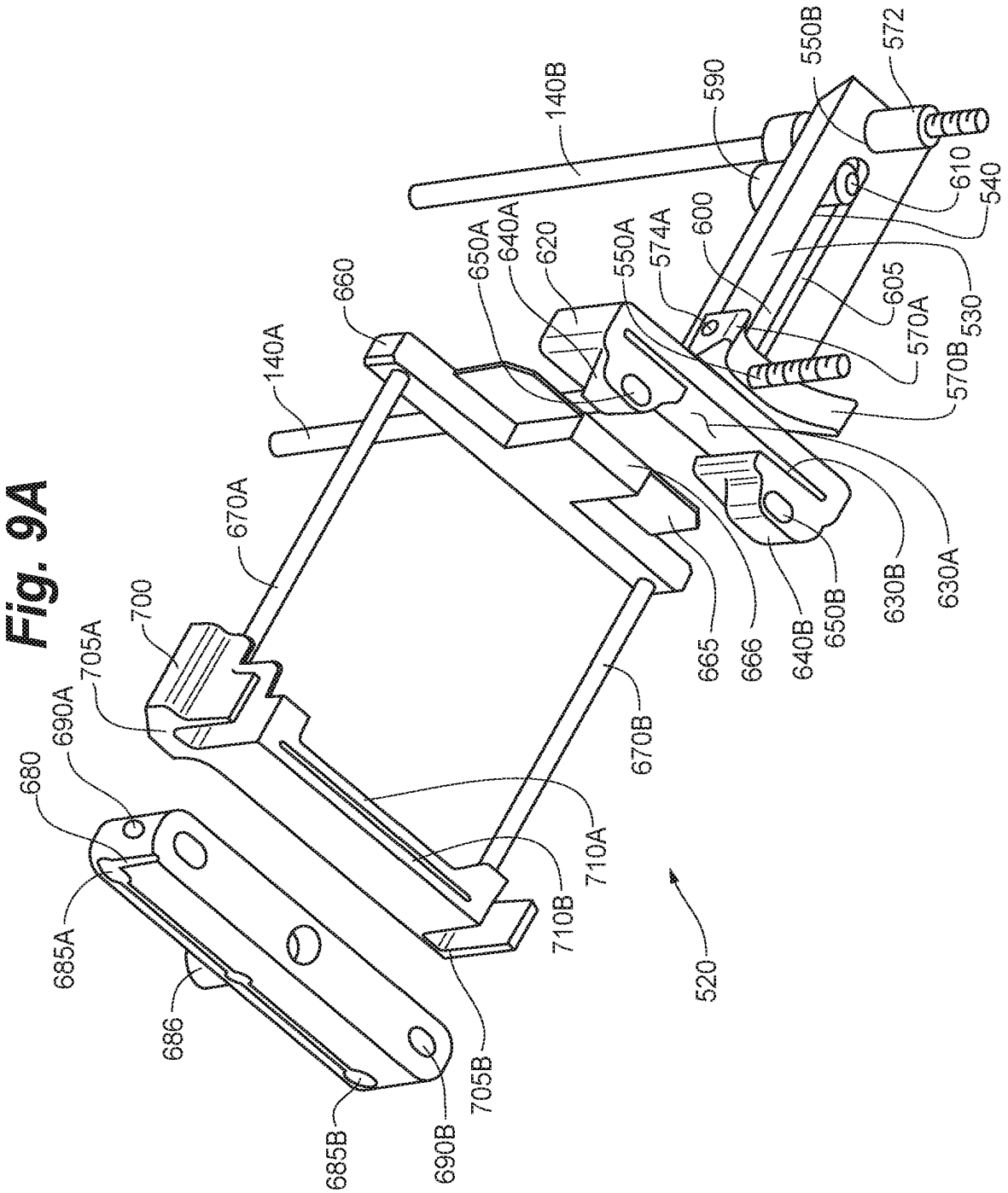
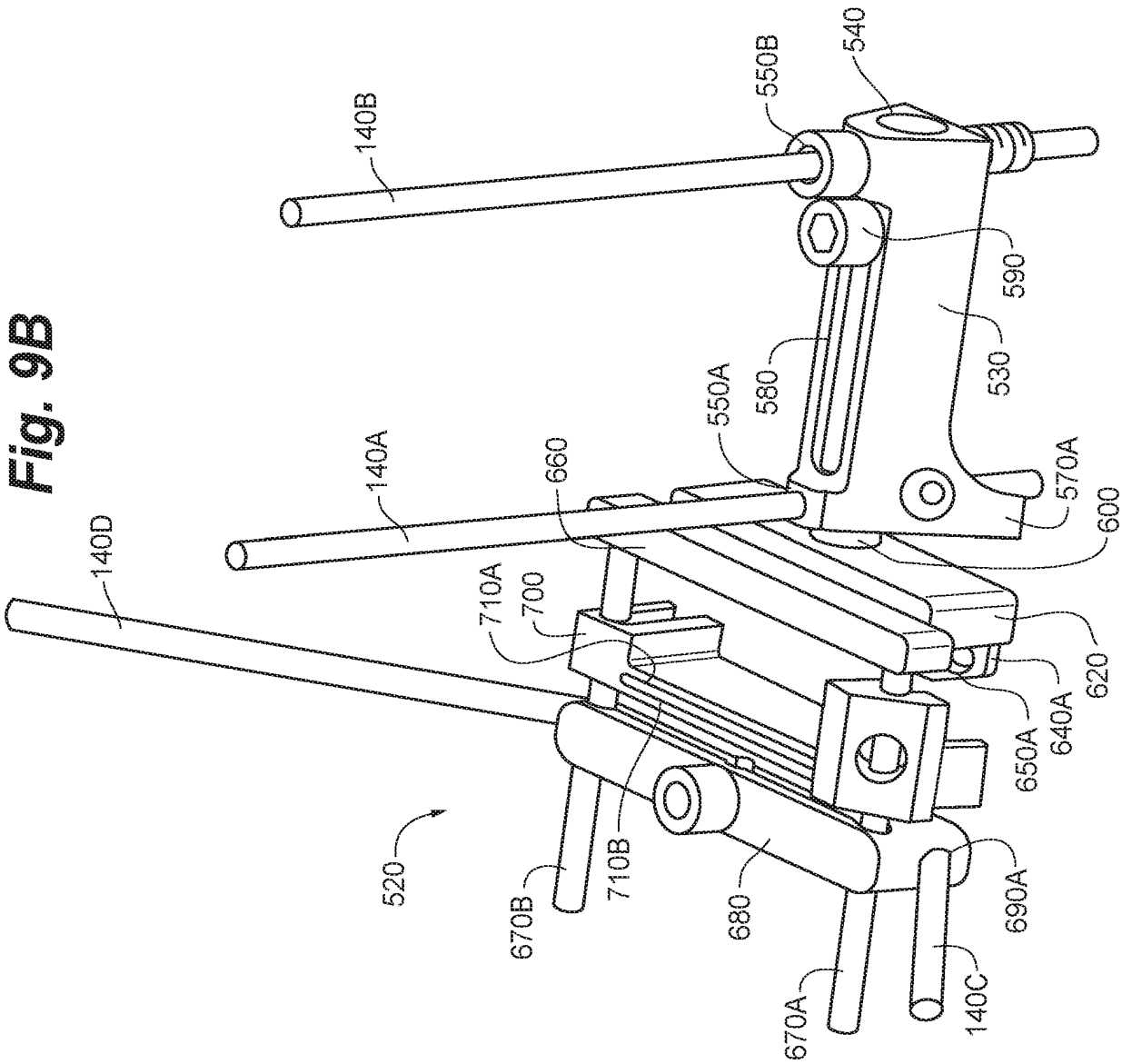

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670A
630B
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690A
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685A
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Fig. 9A

Fig. 9B


140B
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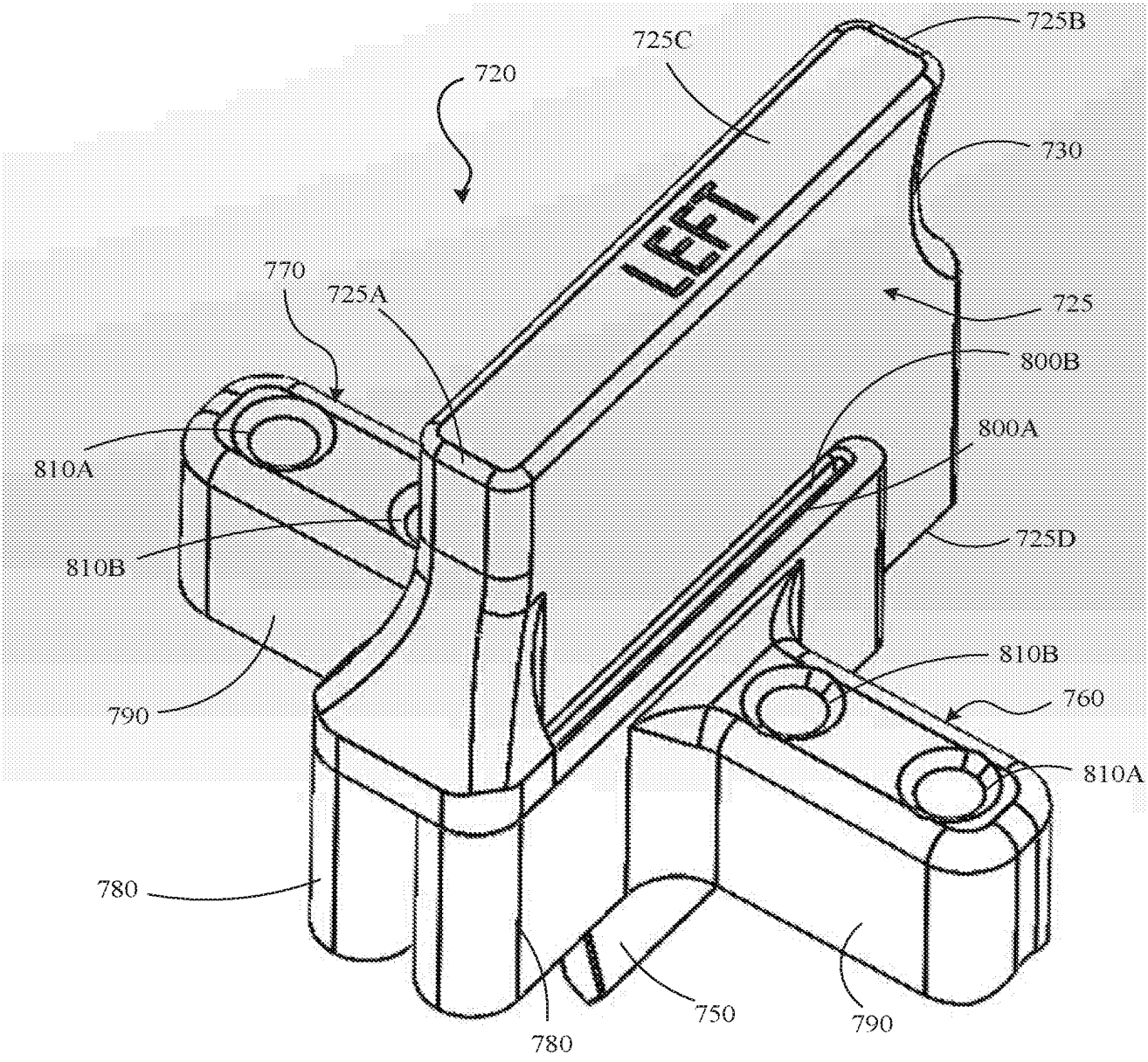

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FIG. 10A

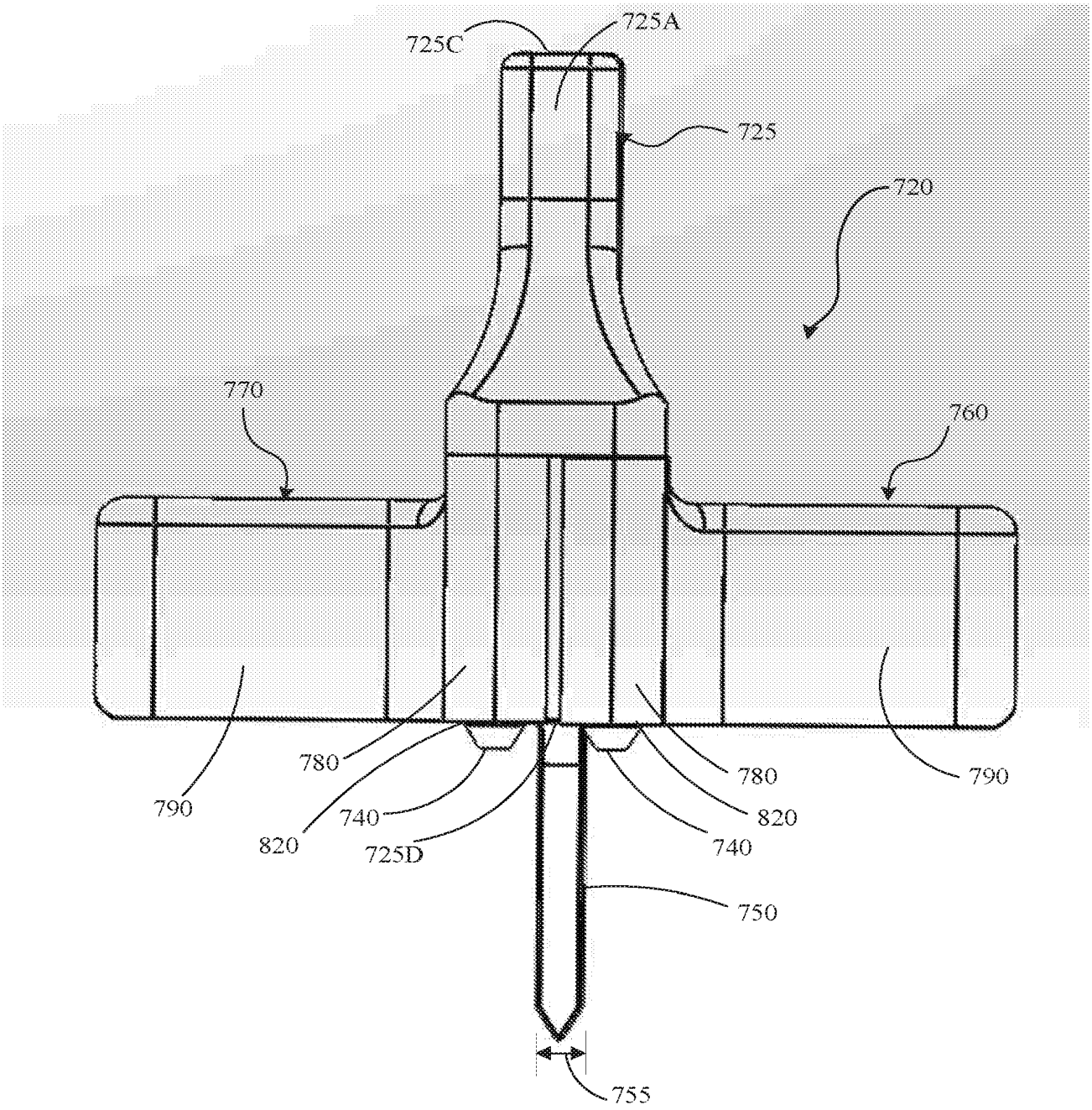

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FIG. 10B

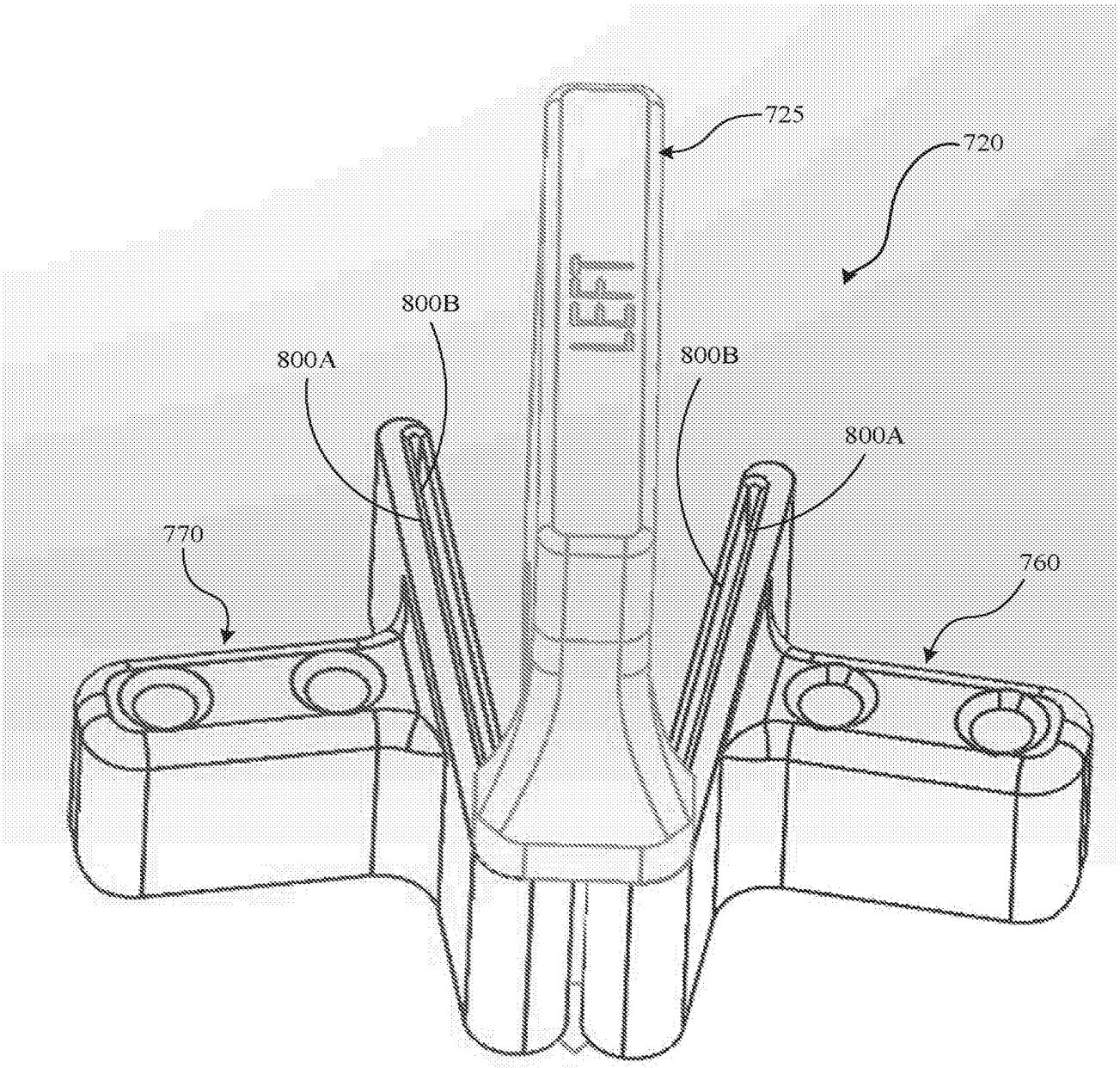


FIG. 10C

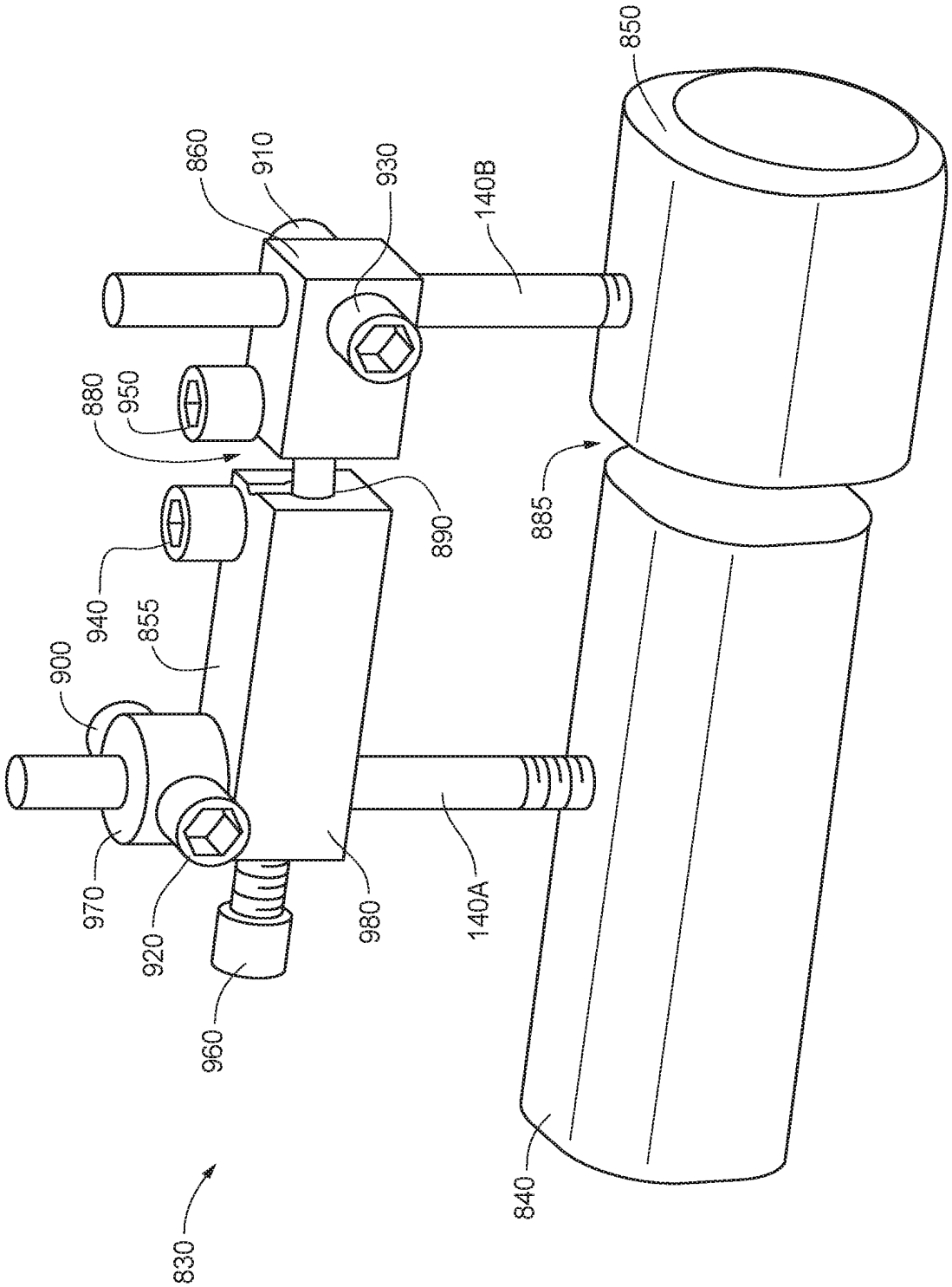

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Fig. 11A

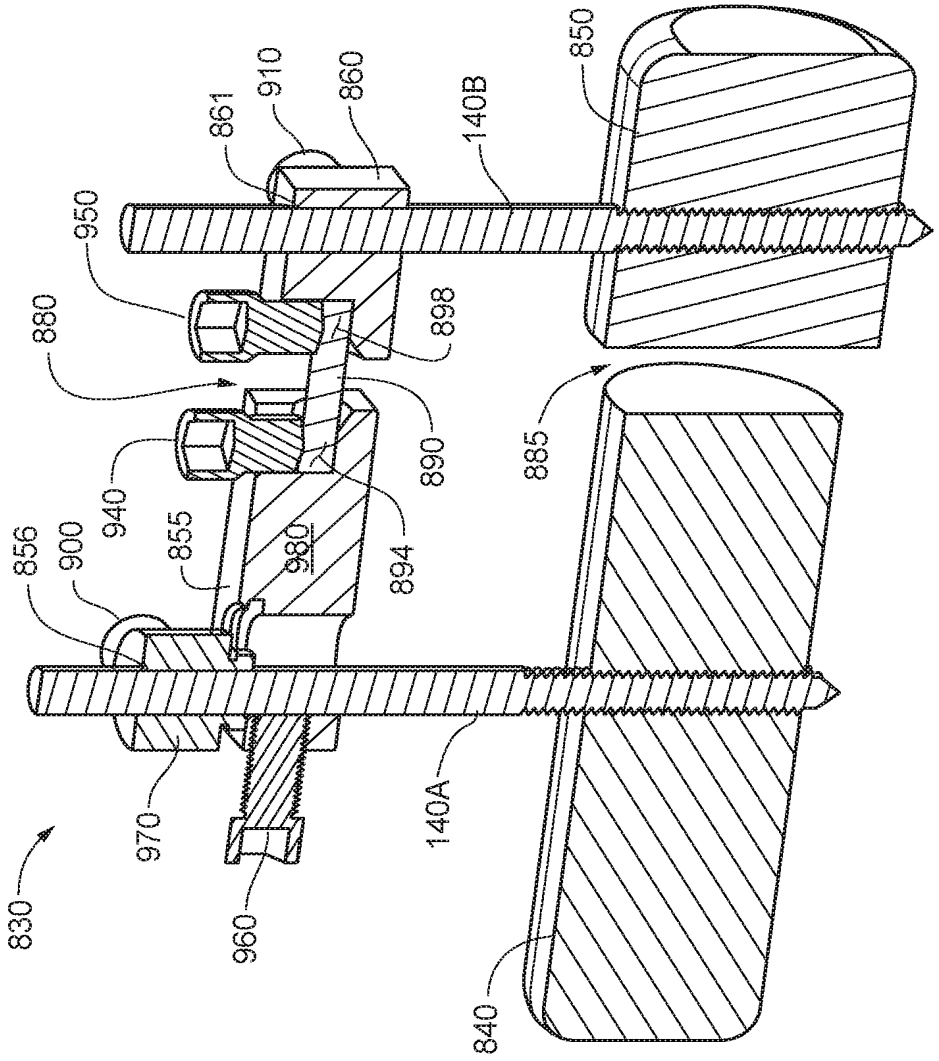

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Fig. 11B

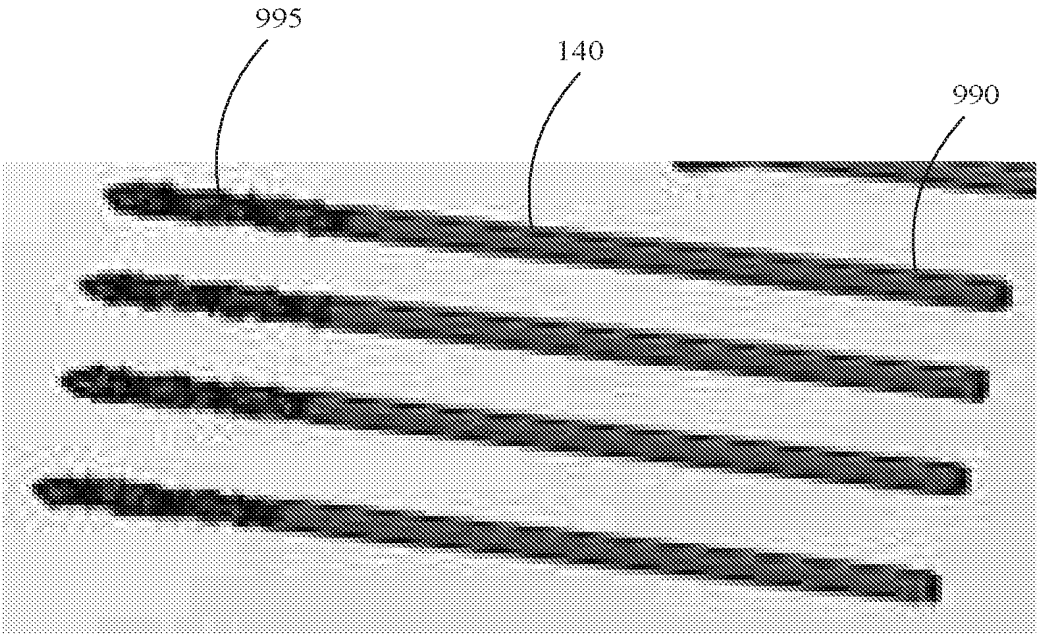


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/18495

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/58, 17/80, 17/88 (2016.01)
CPC - A61B 17/58, 17/80, 17/88
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) Classifications: A61B 17/58, 17/68, 17/80, 17/88 (2016.01)
CPC Classifications: A61B 17/58, 17/68, 17/7291, 17/80, 17/8061, 17/88; Y10S 606/906; USPC Classifications: 606/280, 906

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google; Google Scholar; EBSCO; IP.com; keywords: kit, container, box, receptacle, sterilized, screw, kit, container, remove, retrieve, pull, plate, device, unicortal, metatarsal, cuneiform, fastener, support, heal, fix, bone

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2011/0137351 A1 (HUEBNER RJ et al.) June 9, 2011; figures 4, 13, 14; paragraphs [0077], [0093], [0094], [0105]	1, 2 --- 3/1, 3/2, 4/3/1, 4/3/2, 5/4/3/1, 5/4/3/2, 32/31/29, 32/31/30
X --- Y	US 2005/0033430 A1 (POWERS R et al.) February 10, 2005; figures 1, 5, 6; paragraphs [0015], [0020], [0026], [0045], [0048], [0050]	29, 30 --- 31/29, 31/30, 32/31/29, 32/31/30
Y	US 2010/0125300 A1 (BLITZ N et al.) May 20, 2010; figures 2, 5B, 6; paragraphs [0025], [0033]	3/1, 3/2, 4/3/1, 4/3/2, 5/4/3/1, 5/4/3/2, 31/29, 31/30, 32/31/29, 32/31/30
Y	US 2014/0277176 A1 (MERETE MEDICAL GMBH) September 18, 2014; figure 1; paragraphs [0034], [0035]	3/1, 3/2, 4/3/1, 4/3/2, 5/4/3/1, 5/4/3/2, 31/29, 31/30, 32/31/29, 32/31/30
A	US 8,784,498 B2 (SCHELAND J) July 22, 2014; entire document	1, 2, 3/1, 3/2, 4/3/1, 4/3/2, 5/4/3/1, 5/4/3/2, 29, 30, 31/29, 31/30, 32/31/29, 32/31/30
A	US 2011/0093017 A1 (PRASAD P et al.) April 21, 2011; entire document	1, 2, 3/1, 3/2, 4/3/1, 4/3/2, 5/4/3/1, 5/4/3/2, 29, 30, 31/29, 31/30, 32/31/29, 32/31/30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
06 April 2016 (06.04.2016)	21 APR 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/18495

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 6-28, 33-35
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Electronic Acknowledgement Receipt

EFS ID:	36736406
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	31-JUL-2019
Filing Date:	21-JUN-2019
Time Stamp:	17:07:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_SIDS.pdf	1037062 1b93e773616a9072774c76dad6d3e01c51294c62	no	12

Warnings:

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2	Non Patent Literature	NPL_Gregg_2007.pdf	1355180 965fe0459c298ef2b45d7e8ae9d3fd93029e25c0	no	6
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3	Non Patent Literature	NPL_Weil_2011.pdf	289818 1ca174e414d0a8a61c6ef7003357ba8c496c30e9	no	6
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4	Foreign Reference	FR_WO03075775A1.PDF	636977 f56ef3d6e8c944ff15b8f894e14fc8d127245906	no	20
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6	Foreign Reference	FR_WO2016134160A1.PDF	6883422 991def5b94ea7232738c61334e12bce54ad4820e	no	69
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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

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	1	5490854	A	1996-02-13	Fisher et al.	
	2	6478799	B1	2002-11-12	Williamson	
	3	6859661	B2	2005-02-22	Tuke	
	4	7282054	B2	2007-10-16	Steffensmeier et al.	
	5	8303596	B2	2012-11-06	Plassky et al.	
	6	8764760	B2	2014-07-01	Metzger et al.	
	7	8882816	B2	2014-11-11	Kartalian et al.	
	8	D 720456	S	2014-12-30	Dacosta et al.	

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	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	9	8945132	B2	2015-02-03	Plassy et al.	
	10	D 740424	S	2015-10-06	Dacosta et al.	
	11	9785747	B2	2017-10-10	Geebelen	
	12	10028750	B2	2018-07-24	Rose	
	13	10064631	B2	2018-09-04	Dacosta et al.	
	14	10159499	B2	2018-12-25	Dacosta et al.	
	15	10327829	B2	2019-06-25	Dacosta et al.	

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	1	20100318088	A1	2010-12-16	Warne et al.	
	2	20130131821	A1	2013-05-23	Cachia	

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	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	3	20140135775	A1	2014-05-15	MAXSON et al.	
	4	20140288562	A1	2014-09-25	Von Zabern et al.	
	5	20170143511	A1	2017-05-25	Cachia	
	6	20170164989	A1	2017-06-15	WEINER et al.	

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	1	101237835	CN	B	2012-11-07	ARTHREX INC.	English Abstract Submitted	
	2	202006010241	DE	U1	2007-03-29	RHEE	English Abstract Submitted	
	3	102007053058	DE	B3	2009-04-09	NORMED MEDIZIN TECHNIK VERTRIE	English Abstract Submitted	
	4	1508316	EP	B1	2007-05-16	DEPUY FRANCE	English Abstract Submitted	
	5	2624764	EP	B1	2015-12-30	CERAMTEC GMBH	English Abstract Submitted	

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	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	6	2953120	FR	B1	2012-01-20	HECHARD	Partial English Translation Submitted	
	7	2334214	GB	B	2003-01-22	STANLEY		
	8	2015094409	WO	A1	2015-06-25	PARAGON 28, INC.		

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	1	"Accu-Cut Osteotomy Guide System," BioPro, Brochure, October 2018, 2 pages.	
	2	"Acumed Osteotomiesystem Operationstechnik," Acumed, 2014, 19 pages (including 3 pages English translation).	
	3	BLOMER, "Knieendoprothetik – Herstellerische Probleme und technologische Entwicklungen," Orthopade, Vol. 29, 2000, pp. 688–696, including English Abstract on page 689.	
	4	BOUAICHA et al., "Fixation of Maximal Shift Scarf Osteotomy with Inside-Out Plating: Technique Tip," Foot & Ankle International Journal, Vol. 32, No. 5, May 2011, pp. 567–569.	
	5	"Futura Forefoot Implant Arthroplasty Products," Tornier, Inc., 2008, 14 pages.	
	6	GOTTE, "Entwicklung eines Assistenzrobotersystems für die Knieendoprothetik," Forschungsberichte, Technische Universitat Munchen, 165, 2002, 11 pages, including partial English Translation.	

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	First Named Inventor	F. Barry Bays
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	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	7	'HAT-TRICK Lesser Toe Repair System, Foot and Ankle Technique Guide, Metatarsal Shortening Osteotomy Surgical Technique," Smith & Nephew, 2014, 16 pages.	
	8	HETHERINGTON et al., "Evaluation of surgical experience and the use of an osteotomy guide on the apical angle of an Austin osteotomy," The Foot, Vol. 18, 2008, pp. 159–164.	
	9	HIRAO et al., "Computer assisted planning and custom-made surgical guide for malunited pronation deformity after first metatarsophalangeal joint arthrodesis in rheumatoid arthritis: A case report," Computer Aided Surgery, Vol. 19, Nos. 1–3, 2014, pp. 13–19.	
	10	LIESKE et al., "Implantation einer Sprunggelenktotalendo-prothese vom Typ Salto 2," Operative Orthopädie und Traumatologie, Vol. 26, No. 4, 2014, pp. 401–413, including English Abstract on page 403.	
	11	MAGIN, "Computernavigierter Gelenkersatz am Knie mit dem Orthopilot," Operative Orthopädie und Traumatologie, Vol. 22, No. 1, 2010, pp. 63-80, including English Abstract on page 64.	
	12	MAGIN, "Die belastungsstabile Lapidus-Arthrodese bei Hallux-valgus-Deformität mittels IVP-Plattenfixateur (V-TEK-System)," Operative Orthopädie und Traumatologie, Vol. 26, No. 2, 2014, pp. 184–195, including English Abstract on page 186.	
	13	MIYAKE et al., "Three-Dimensional Corrective Osteotomy for Malunited Diaphyseal Forearm Fractures Using Custom-Made Surgical Guides Based on Computer Simulation," JBJS Essential Surgical Techniques, Vol. 2, No. 4, 2012, 11 pages.	
	14	NAGY et al., "The AO Ulnar Shortening Osteotomy System Indications and Surgical Technique," Journal of Wrist Surgery, Vol. 3, No. 2, 2014, pp. 91–97.	
	15	NexFix from Nexa Orthopedics, MetaFix I from Merete Medical, Inc. and The BioPro Lower Extremities from BioPro, found in Foot & Ankle International Journal, Vol. 28, No. 1, January 2007, 4 pages.	
	16	ODENBRING et al., "A guide instrument for high tibial osteotomy," Acta Orthopaedica Scandinavica, Vol. 60, No. 4, 1989, pp. 449–451.	
	17	OTSUKI et al., "Developing a novel custom cutting guide for curved per-acetabular osteotomy," International Orthopaedics (SICOT), Vol. 37, 2013, pp. 1033–1038.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	18	"Patient to Patient Precision, Accu-Cut, Osteotomy Guide System," BioPro, Foot & Ankle International, Vol. 23, No. 8, August 2002, 2 pages.	
	19	PETERS et al., "Flexor Hallucis Longus Tendon Laceration as a Complication of Total Ankle Arthroplasty," Foot & Ankle International, Vol. 34, No. 1, 2013, pp. 148–149.	
	20	"Prophecy Inbone Preoperative Navigation Guides," Wright Medical Technology, Inc., November 2013, 6 pages.	
	21	"RAYHACK Ulnar Shortening Generation II Low-Profile Locking System Surgical Technique," Wright Medical Technology, Inc., December 2013, 20 pages.	
	22	SALTZMAN et al., "Prospective Controlled Trial of STAR Total Ankle Replacement Versus Ankle Fusion: Initial Results," Foot & Ankle International, Vol. 30, No. 7, July 2009, pp. 579–596.	
	23	"Smith & Nephew scores a HAT-TRICK with its entry into the high-growth hammer toe repair market," Smith & Nephew, July 31, 2014, 2 pages.	
	24	TRICOT et al., "3D-corrective osteotomy using surgical guides for posttraumatic distal humeral deformity," Acta Orthopaedica Belgica, Vol. 78, No. 4, 2012, pp. 538–542.	
	25	VITEK et al., "Die Behandlung des Hallux rigidus mit Cheilektomie und Akin-Moberg-Osteotomie unter Verwendung einer neuen Schnittlehre und eines neuen Schraubensystems," Orthopadische Praxis, Vol. 44, November 2008, pp. 563–566, including English Abstract on page 564.	
	26	VITEK, "Neue Techniken in der Fußchirurgie Das V-tek-System," ABW Wissenschaftsverlag GmbH, 2009, 11 pages, including English Abstract.	
	27	WENDL et al., "Navigation in der Knieendoprothetik," OP-Journal, Vol. 17, 2002, pp. 22–27, including English Abstract.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16448357
	Filing Date	2019-06-21
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	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2019-09-25
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Apparatus for performing an open wedge, high tibial osteotomy

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Applicant(s): ARTHREX INC ± (IBALANCE MEDICAL INC, ; ARTHREX,INC)

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Abstract of CN101237835 (B)

Apparatus for performing an open wedge, high tibial osteotomy, the apparatus comprising: cutting apparatus for forming an osteotomy cut in the tibia, the cutting apparatus comprising: targeting apparatus for identifying a cutting plane through the tibia and a boundary line for terminating a cut made along the cutting plane, wherein the boundary line is located within the tibia, parallel to the anterior-posterior slope of the tibia and parallel to the sagittal plane of the patient. A method for performing an open wedge, high tibial osteotomy, the method comprising: positioning targeting apparatus for identifying a cutting plane through the tibia and a boundary line for terminating a cut made along the cutting plane, wherein the boundary line is located within the tibia, parallel to the anterior-posterior slope of the tibia and parallel to the sagittal plane of the patient; cutting the bone along the cutting plane, with the cut terminating at the boundary line; moving the bone on eitherside of the cut apart so as to form the wedge-like opening in the bone; and stabilizing the bone.

(19)中华人民共和国国家知识产权局

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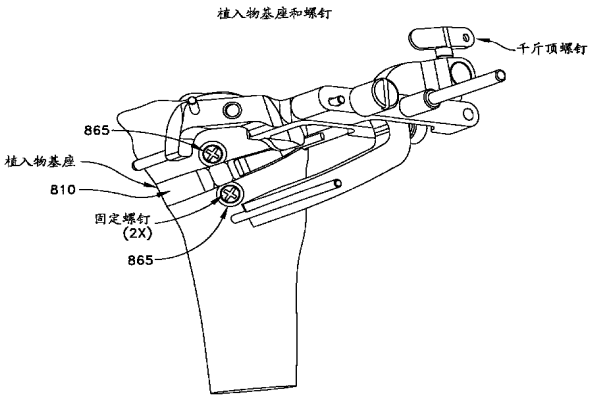
权利要求书 2 页 说明书 13 页 附图 41 页

(54)发明名称

用于执行打开楔高位胫骨切开术的设备

(57)摘要

用于执行打开楔高位胫骨切开术的设备，该设备包括：用于在胫骨内形成骨切开术切割口的切割设备，该切割设备包括：用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面－后面斜面并且平行于病人的矢平面。用于执行打开楔高位胫骨切开术的方法，该方法包括：定位用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面－后面斜面并且平行于病人的矢平面；沿切割平面切割骨，切割终止于边界线；运动切割口的每侧上的骨分开以便在骨内形成楔状的开口；及稳定骨。



CN 101237835 B

1. 一种用于执行打开楔高位胫骨切开术的设备，该设备包括：

用于在胫骨内形成骨切开术切割口的切割设备，该切割设备包括：

靶向设备，用于识别通过胫骨的切割平面；

沿边界线布置的顶点销，其提供用于限制沿切割平面的切割的确定的停止器；和

千斤顶，用于打开沿切割平面形成的切割口，以便在骨内形成楔状的开口；

其中，所述切割设备限定出用于终止沿切割平面进行的切割的边界线，其中，所述边界线定位在胫骨内部，平行于胫骨的前面－后面斜面并且平行于病人的矢平面。

2. 根据权利要求 1 所述的设备，其中，靶向设备构造为形成沿边界线的孔，其中所述孔的直径大于在形成所述楔状的开口之前在骨中形成的所述切割口的厚度。

3. 根据权利要求 1 所述的设备，其中，顶点销确定尺寸为形成沿边界线的孔，其中所述孔的直径大于在形成所述楔状的开口之前在骨中形成的所述切割口的厚度。

4. 根据权利要求 1 所述的设备，其中，顶点销包括在确定的停止器处的平部。

5. 根据权利要求 1 所述的设备，其中，顶点销在确定的停止器处颈缩。

6. 根据权利要求 1 所述的设备，其中，靶向设备构造为使得切割途径处于前面－内侧的方向。

7. 根据权利要求 1 所述的设备，其中，靶向设备包括斜面导向器，用于确定胫骨的前面－后面斜面，由此确定边界线的位置。

8. 根据权利要求 7 所述的设备，其中，斜面导向器包括具有非圆形的截面的伸长的主体。

9. 根据权利要求 1 所述的设备，其中，靶向设备包括对准机构，用于确定冠平面并且从而确定矢平面，由此确定边界线的位置。

10. 根据权利要求 1 所述的设备，其中，切割设备包括位置导向器和切割导向器；

其中，位置导向器构造为用于接附到胫骨，以便相对于胫骨建立切割平面和边界线；并且

其中，切割导向器构造为用于接附到位置导向器，以便对准切割槽与切割平面。

11. 根据权利要求 10 所述的设备，其中，切割导向器构造为使得切割途径处于前面－内侧的方向。

12. 根据权利要求 10 所述的设备，其中，切割设备包括钻导向器，用于在胫骨内邻近切割平面形成至少一个键孔。

13. 根据权利要求 12 所述的设备，其中，切割设备构造为使得该至少一个键孔交迭切割平面。

14. 根据权利要求 1 所述的设备，其中，千斤顶构造为用于安装在顶点销上。

15. 根据权利要求 1 所述的设备，其中，设备还包括楔形的植入物，用于布置在当打开沿切割平面形成的切割口时在胫骨内形成的楔形的开口内。

16. 根据权利要求 15 所述的设备，其中，楔形的植入物包括多个部件。

17. 根据权利要求 15 所述的设备，其中，楔形的植入物包括当从顶部观察时的 U 形的构造。

18. 根据权利要求 15 所述的设备，其中，楔形的植入物包括用于布置在设置在胫骨内的键孔内的至少一个键。

19. 一种用于执行打开楔高位胫骨切开术的设备，该设备包括：

用于在骨内形成骨切开术切割口的切割设备，该切割设备包括：

靶向设备，用于识别通过胫骨的切割平面；

和

千斤顶，用于打开沿切割平面形成的切割口，以便在骨内形成楔状的开口；

其中靶向设备还限定出用于终止沿切割平面进行的切割的深度的边界线，其中边界线定位在胫骨内部并且与病人的矢平面成选择的角；并且靶向设备包括沿边界线布置的顶点销，其在边界处提供确定的停止器。

20. 根据权利要求 19 所述的设备，其中，通过以逆时针的方式平移边界线选择的角度建立该选择的角，以便产生前面 - 后面斜面的改变和外侧 - 内侧斜面的改变。

21. 根据权利要求 19 所述的设备，其中，通过以顺时针的方式平移边界线选择的角度建立该选择的角，以便产生前面 - 后面斜面的改变和外侧 - 内侧斜面的改变。

用于执行打开楔高位胫骨切开术的设备

[0001] 对未决的在先专利申请的参考

[0002] 本专利申请：

[0003] (i) 为 Vincent P.Novak 在 01/31/05 提出的题目为“OPEN WEDGEOSTEOTOMY SYSTEM AND SURGICAL METHOD”(律师案卷号 No.NOVAK-010203I) 的未决的在先美国专利申请序号 No.11/047,159 的部分继续；

[0004] (ii) 为 Vincent P.Novak 在 01/31/05 提出的题目为“OPEN WEDGEOSTEOTOMY SYSTEM AND SURGICAL METHOD”(律师案卷号 No.NOVAK-010203SM) 的未决的在先美国专利申请序号 No.11/047,551 的部分继续；

[0005] (iii) 为 Vincent P.Novak 等人在 02/09/06 提出的题目为“MULTI-PART IMPLANT FOR OPEN WEDGE KNEEOSTEOTOMIES”(律师案卷号 No.NOVAK-4) 的未决的在先美国专利申请序号 No.11/352,103 的部分继续；

[0006] (iv) 为 Vincent P.Novak 等人在 02/08/06 提出的题目为“METHODAND APPARATUS FOR FORMING A WEDGE-LIKE OPENING IN ABONE FOR AN OPEN WEDGE OSTEOTOMY”(律师案卷号 No.NOVAK-5) 的未决的在先美国专利申请序号 No.11/350,333 的部分继续；

[0007] (v) 要求 Kelly Ammann 等人在 04/01/05 提出的题目为“OPENWEDGE OSTEOTOMY SYSTEM AND SURGICAL METHOD”(律师案卷号 No.NOVAK-6 PROV) 的未决的在先美国临时专利申请序号 No.60/667,401 的优先权；

[0008] (vi) 要求 Kelly Ammann 等人在 11/10/05 提出的题目为“DESCRIPTION OF A METHOD FOR OBTAINING AN ANTERIOR TOPOSTERIOR(AP)SLOPE CORRECTION IN CONJUNCTION WITH ALATERAL TO MEDIAL(LM)CORRECTION USING HIGH TIBIALOSTEOTOMY”(律师案卷号 No.NOVAK-7 PROV) 的未决的在先美国临时专利申请序号 No.60/736,135 的优先权；

[0009] (vii) 要求 Vincent P.Novak 等人在 11/21/05 提出的题目为“METHOD AND SYSTEM OF INSTRUMENTATION FORPERFORMING AN OPENING WEDGE OSTEOTOMY”(律师案卷号 No.NOVAK-8 PROV) 的未决的在先美国临时专利申请序号 No.60/738,429 的优先权；并且

[0010] (viii) 要求 Kelly Ammann 等人在 12/01/05 提出的题目为“METHODAND SYSTEM OF FIXATION FOR PERFORMING AN OPENINGWEDGE OSTEOTOMY”(律师案卷号 No.NOVAK-9 PROV) 的未决的在先美国临时专利申请序号 No.60/741,313 的优先权。

[0011] 八个以上确定的专利申请作为参考加入这里。

技术领域

[0012] 本发明一般地涉及外科手术方法和设备，并且更特别地涉及用于执行膝部的打开楔骨切开术的外科手术方法和设备。

背景技术

[0013] 膝部骨切开术为用于治疗膝部骨关节炎的重要的技术。本质上，膝部的骨切开术调节膝部关节的几何形状，以便将重量负载从关节的关节炎的部分传递到关节的相对未受

影响的部分。

[0014] 膝部骨切开术也是用于解决例如由于出生缺陷、伤害等的不正常的膝部几何形状的重要的技术。

[0015] 大多数膝部骨切开术设计为修改胫骨的几何形状，以便调节穿过膝部关节传递负载的方式。

[0016] 基本上存在两种调节胫骨的定向的方法：(i) 关闭楔技术；及 (ii) 打开楔技术。

[0017] 通过关闭楔技术，从胫骨的上部的部分移除楔状的骨，并且随后操纵胫骨以便关闭引起的间隙，由此相对于胫骨坪重新定向胫骨的下部的部分并且从而调节将负载从股骨传递到胫骨的方式。

[0018] 通过打开楔技术，在胫骨的上部的部分内形成切割口，操纵胫骨以便在骨内打开楔状的开口，并且随后将骨固定在此位置（例如，通过将金属板螺钉连接到骨或通过将楔形的植入物插入骨内的开口），由此相对于胫骨坪重新定向胫骨的下部的部分并且从而调节将负载从股骨传 递到胫骨的方式。

[0019] 虽然关闭楔骨切开术和打开楔骨切开术都为病人提供实质的好处，对于外科医生来说，它们在过程上是具有挑战性的。除了别的以外，关于打开楔骨切开术，具有必要的精确度并且对周围组织的损伤最小地在骨内形成楔状的开口可能是困难的。

[0020] 本发明针对膝部的打开楔骨切开术。

发明内容

[0021] 本发明包括用于执行打开楔高位胫骨切开术的新型的方法和设备。更特别地，本发明包括新型的方法和设备的提供和使用，新型的方法和设备用于在胫骨的上部的部分内形成适当的骨切开术切割口，操纵胫骨以便在胫骨内打开适当的楔状的开口，并且随后将适当的楔形的植入物插入胫骨内的楔状的开口，以便以希望的定向稳定胫骨，由此相对于胫骨坪重新定向胫骨的下部的部分并且从而调节将负载从股骨传递到胫骨的方式。

[0022] 在本发明的一个形式中，提供了用于执行打开楔高位胫骨切开术的设备，该设备包括：

[0023] 用于在胫骨内形成骨切开术切割口的切割设备，该切割设备包括：

[0024] 用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面 - 后面斜面并且平行于病人的矢平面。

[0025] 在本发明的另一个形式中，提供了用于执行打开楔高位胫骨切开术的方法，该方法包括：

[0026] 定位用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面 - 后面斜面并且平行于病人的矢平面；

[0027] 沿切割平面切割骨，切割终止于边界线；

[0028] 运动切割口的每侧上的骨分开以便在骨内形成楔状的开口；及

[0029] 稳定骨。

[0030] 在本发明的另一个形式中，提供了用于执行打开楔高位胫骨切开术的设备，该设

备包括：

[0031] 用于布置在形成在胫骨内的楔形的开口内的楔形的植入物，其中， 楔形的植入物包括用于布置在邻近形成在胫骨内的楔形的开口的形成在胫骨内的键孔内的至少一个键。

[0032] 在本发明的另一个形式中，提供了用于执行打开楔高位胫骨切开术的方法，该方法包括：

[0033] 沿切割平面切割骨，切割终止于边界线，并且邻近切割口在胫骨内形成至少一个键孔；

[0034] 运动切割口的每侧上的骨分开以便在骨内形成楔状的开口；及

[0035] 将楔形的植入物定位在形成在胫骨内的楔形的开口内，其中，楔形的植入物包括至少一个键，并且其中，该至少一个键布置在形成在胫骨内的至少一个键孔内。

[0036] 在本发明的另一个形式中，提供了用于执行打开楔高位胫骨切开术的设备，该设备包括：

[0037] 用于在胫骨内形成骨切开术切割口的切割设备，该切割设备包括：

[0038] 用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面－后面斜面并且与病人的矢平面成选择的角度。

[0039] 在本发明的另一个形式中，提供了用于执行打开楔高位胫骨切开术的方法，该方法包括：

[0040] 定位用于识别通过胫骨的切割平面和用于终止沿切割平面进行的切割的边界线的靶向设备，其中，边界线定位在胫骨内部，平行于胫骨的前面－后面斜面并且与病人的矢平面成选择的角度；

[0041] 沿切割平面切割骨，切割终止于边界线；

[0042] 运动切割口的每侧上的骨分开以便在骨内形成楔状的开口；及

[0043] 稳定骨。

附图说明

[0044] 通过接下来结合附图考虑的对本发明的优选的实施例的详细描述更加全面地披露本发明的这些和其它目的和特征或使其显而易见，其中，相似的数字用于指示相似的零件，并且其中：

[0045] 图 1-3 为示出了在胫骨内形成用于打开楔高位胫骨切开术的楔状的开口并且将楔形的植入物定位在胫骨内的楔状的开口内的示意图；

[0046] 图 3A 为示出了选择的解剖学的平面的示意图；

[0047] 图 4-9 示出了打开楔高位胫骨切开术中的有关的平的表面；

[0048] 图 10-30 为示出了用于在胫骨的上部的部分内形成适当的骨切开术切割口，操纵胫骨以便在胫骨内打开适当的楔状的开口，并且随后将适当的楔形的植入物插入胫骨内的楔状的开口的优选的方法和设备的示意图；

[0049] 图 31-37 为示出了可以结合打开楔高位胫骨切开术使用的不同的顶点销布置的示意图；及

[0050] 图 38 为示出了如何根据本发明调节顶点销的布置的示意图。

具体实施方式

[0051] 打开楔高位胫骨切开术概述

[0052] 首先看图1-3，示出了膝部关节5，将在膝部关节5上执行打开楔骨切开术。膝部关节5通常包括胫骨10和股骨15。根据本发明，通过首先在上部的胫骨内形成切割口20（图1），并且随后操纵胫骨的下部的部分以便在骨内打开楔状的开口25（图2），使得楔状的开口25构造为调节将负载从股骨传递到胫骨的方式，实现打开楔骨切开术。切割口20和楔状的开口25可以以本领域中已熟知的多种方式形成。

[0053] 除了别的以外，本发明提供用于形成切割口20和楔状的开口25的新的和改进的方法和设备，如将在下面更加详细地讨论的。

[0054] 一旦已经在胫骨10内形成希望的楔状的开口25以便将胫骨10重新构造为希望的几何形状，可以以本领域中众所周知的多种方式（例如，通过将金属板螺钉连接到骨或通过将楔形的植入物插入骨内的开口）将骨固定到位，由此调节将负载从股骨传递到胫骨的方式。作为示例，图3示出了插入形成在胫骨内的楔状的开口25内由此将胫骨稳定在其重新构造的几何形状的楔形的植入物27。

[0055] 除了别的以外，本发明还提供新的和改进的楔形的植入物，和用于将该植入物部署到胫骨内的楔形的开口内的相关的方法和设备。

[0056] 对本发明的高位胫骨切开术中的有关的平的表面的讨论

[0057] 为了理解本发明的某些方面，对在执行本发明的高位胫骨切开术中有关的胫骨的平的表面的彻底的理解是有帮助的。从而，接下来的讨论提出了对本发明的打开楔高位胫骨切开术有关的平的表面的几何的描述。为了当前的讨论，参考选择的解剖学的平面，例如，冠平面、矢平 面和横平面（图3A）可能有时是有帮助的。

[0058] 现在看图1-4，为了本发明，胫骨坪30可以描述为沿胫骨10的在上面的表面延伸的水平（或横）平面。作为参考，图4中还示出了矢平面32。如图5所示，胫骨坪30还垂直于额（或冠）平面40。通过沿胫骨的倾斜的顶部表面从前面向后面延伸的前面－后面(A-P)倾斜平面45限定前面－后面(AP)斜面。公布的研究已经证明前面－后面(A-P)斜面通常以对胫骨坪30大约7度到11度的角度延伸；然而，特定的角度可以从个体到个体变化。

[0059] 接下来看图6，对于本发明的高位胫骨切开术，通常希望保持在A-P倾斜平面45下方大约2cm。此偏移可以称作A-P偏移平面50。

[0060] 如图7所示，外侧的方位(aspect)和切割深度可以通过外侧的方位平面55和切割深度平面60限定，使得切割深度为胫骨的外侧的方位的内侧大约1cm。

[0061] 接下来看图8，骨切开术切割平面65（如图8的直接的额视图所示）通过经由通过切割深度平面60和A-P偏移平面50相交形成的轴线离开A-P偏移平面50旋转的平面形成。旋转的角度选择为使得足够将骨切开术切割平面65的入口放置在胫骨的内侧的颈66（图8）处。应该注意，因为A-P偏移平面50和骨切开术切割平面65跟随A-P倾斜平面45（图6）的倾斜，A-P偏移平面50和骨切开术切割平面65从前面向后面稍微“倾斜”（但是在图8的直接的额视图中不可见）。A-P偏移平面50和切割深度平面60的相交形成轴线70，根据本发明，轴线70限定骨切开术切割口的外侧的限制。换句话说，轴线70限定通

过胫骨的线，该线（i）平行于 A-P 倾斜平面 45，并且（ii）包含在骨切开术切割平面 65 内。此外，根据本发明，轴线 70 用于限定将要在胫骨内形成的骨切开术切割口的外侧的限制。

[0062] 如图 9 所示，骨切开术平面的直接的视图为和骨切开术一致的直接的视图。此视图从直接的额视图向下倾斜（例如，以大约 7 度）。同样，向下倾斜的角度等于 A-P 斜面。换句话说，对于本发明，骨切开术切割平面 65 平行于 A-P 倾斜平面 45（在前面到后面方向，而不是在内侧到外侧方向）延伸，并且当在前面到后面方向观察时通常向下倾斜（例如，以大约 7-11 度的角度）。此外，对于本发明，轴线 70（限定对骨切开术切割口的外侧的限制）包含在骨切开术切割平面 65 内。

[0063] 用于执行本发明的打开楔高位胫骨切开术的新型的方法和设备

[0064] 在本发明的一个优选的实施例中，提供了新型的骨切开术系统，该系统包括用于优选地使用前面 - 内侧的途径形成用于打开楔高位胫骨切开术的精确的和可重复的骨切开术切割口的仪器。新型的骨切开术系统通常包括位置导向器 100（图 16）、斜面导向器 200（图 11）、顶点销 300（图 16）、键孔钻导向器 400（图 18）、后面的保护器 500（图 20）、和切割导向器 600（图 20），如将在下文中更加详细地讨论的。

[0065] 优选地，新型的骨切开术系统还包括用于打开胫骨内的切割口以便在胫骨内形成楔状的开口的新型的打开千斤顶 700（图 22），如将在下文中更加详细地讨论的。

[0066] 并且，优选地，新型的骨切开术系统还包括用于定位在胫骨内的楔状的开口内以便将胫骨稳定在其修正的构造的新型的植入物 800（图 24），如将在下文中更加详细地讨论的。

[0067] 在本发明的优选的形式中，新型的骨切开术系统构造为使得：

[0068] （i）形成在骨切开术切割口的外侧的限制处的轴线 70（当打开骨切开术切割口时形成外侧的骨铰链）平行于 A-P 胫骨斜面；

[0069] （ii）通过骨切开术形成的外侧的骨铰链的轴线位于垂直于额（即，冠）平面的平面内；并且

[0070] （iii）当骨切开术完成并且楔打开时，围绕骨铰链旋转远侧（即，下部）的胫骨以便大致维持 A-P 斜面和额平面的解剖学的对准。

[0071] 在本发明的优选的形式中，新型的骨切开术系统还构造为使得：

[0072] （iv）骨切开术能够更小侵害地执行；及

[0073] （v）骨切开术能够对诸如内侧的副韧带、外侧的副韧带、和腘腱的软组织的切口最小地执行。

[0074] 在本发明的一个优选的形式中，新型的骨切开术系统如下构造和使用。

[0075] 1. 首先在膝部的前面 - 内侧部分上形成垂直的切口，大约距离髌腱的内侧的边缘 1cm，使得切口在关节线下方大约 2.5-3cm 开始，并且延伸大约 6-10cm 的长度。

[0076] 2. 随后切开髌腱和近侧的胫骨表面之间的软组织以便在髌腱下面，正好在髌腱插入近侧的胫骨的上方形成小的隧道状的开口。

[0077] 3. 现在看图 10，包括位置导向器 100（图 10 和 16）、斜面导向器 200（图 10 和 11）和导引器 105（图 10 和 11）的组件前进到外科手术部位。优选地，位置导向器 100、斜面导向器 200 和导引器 105 的组件在打开皮肤之间预先装配。通过使用通过斜面导向器 200 并且被接收在形成在位置导向器 100 内的有螺纹的孔眼 120 内的螺钉 115（图 10）将斜面导

向器 200 安装到位置导向器 100 并且随后将导引器 105 安装到斜面导向器 200 和位置导向器 100 来装配组件。

[0078] 在本发明的一个优选的形式中，斜面导向器 200 可以包括固定在一起的两个分开的元件，通过销 205 连接的基座 210 和导向器元件 215，基座 210 由射线半透明的材料（例如，塑料）形成并且导向器元件 215 由射线不透明的材料（例如，不锈钢）形成，由此，导向器元件 215 将在荧光透视法下可见并且基座 210 将在荧光透视法下有效地不可见，如将在下文中讨论的。在本发明的一个优选的形式中，导引器 105 可以包括臂 125 和柄 130。臂 125 和柄 130 可以形成为固定在一起的两个分开的元件，或臂 125 和柄 130 可以形成为单一的构造。

[0079] 4. 接下来，操纵前述的组件，使得将位置导向器 100 的胫骨结节定位突出部 135（图 10 和 16）插入髌腱（没有示出）和胫骨之间，并且使得胫骨结节定位突出部 135 靠在胫骨结节上放置。这样，胫骨结节提供用于对准位置导向器 100 与胫骨的粗略的对准导向器。

[0080] 5. 使用在胫骨坪的水平的从内侧的侧取的外侧的荧光镜视图，组件对准为使得斜面导向器 200（图 11）的导向器元件 215 的下侧的表面 220 与胫骨的内侧的髁 75 的顶部对准。看图 11。替代地，如果外科医生更喜欢在胫骨上稍微远侧地偏移骨切开术，斜面导向器 200 的导向器元件 215 的顶部的边缘 225 能够与内侧的踝 75 对准，远侧地偏移骨切开术固定的距离（例如，3mm）。

[0081] 通过用射线不透明的材料形成斜面导向器 200 的导向元件 215 并且通过用射线半透明的材料形成斜面导向器 200 的基座 210，基座 210 将在荧光透视法下有效地不可见并且导向器元件 215 将对照骨清晰明显地突出。

[0082] 应该注意，斜面导向器 200 的导向器元件 215 优选地形成为“Z 形”（图 10 和 11A）以便提供附加的功能。更特别地，通过将导向元件 215 形成为“Z 形”获得数个显著的优点。首先，此构造允许导向元件 215 围绕胫骨的周缘包绕。其次，导向元件 215 的“Z 形”还操作以指示斜 面导向器是否没有垂直地与荧光镜的水平对准。更特别地，如果斜面导向器 200 没有垂直地与荧光镜的水平对准，导向器元件 215 的“Z 形”将在荧光镜上表现为锯齿状的或 Z 字形曲折的形状（图 11B）。然而，如果导向器元件 215 垂直地与荧光镜的水平对准，那么导向器元件将在荧光镜上表现为直的线（图 11 和 11C）。此垂直的对准是重要的，因为这使得能够对准斜面导向器 200（并且从而对准位置导向器 100）与内侧的踝，即，A-P 倾斜平面。

[0083] 7. 随后操纵组件使得内侧的定位销 140（图 10、11 和 16）靠在胫骨的内侧的方位 80 上定位（图 16），内侧的定位销优选地形成为销，然而，其也能够形成为突出部、翅片等。当进行更进一步的位置调节时，保持内侧的定位销 140 与胫骨的内侧的方位接触，从而确保仪器的适当的对准。内侧的定位销 140 参考胫骨的内侧的方位，从而设置从胫骨的内侧的方位到顶点销 300（图 10）的距离，如将在下文中讨论的。此参考距离结合骨切开术植入物 27（图 3）的确定尺寸使用，以确保适当的胫骨重新构造，即，从胫骨的内侧的方位到顶点销 300 的中心的距离设计为对应从植入物的内侧的方位到植入物的楔角的角顶的距离。

[0084] 在本发明的另一个形式中，参考距离可以为从胫骨的内侧的方位到骨铰链内的中立的旋转轴线的距离，该距离可以通过计算估计。在该情况下，从胫骨的内侧的方位到骨铰

链的中立的轴线的距离对应从植入物的内侧的方位到植入物的楔角的角顶的距离。

[0085] 8. 随后通过以侧到侧的运动滑动导引器柄 130 来围绕主要的胫骨解剖学的轴线旋转组件，使得仪器垂直于额（冠）平面对准，即，使得导引器 105 和顶点销 300（看下面）将平行于病人的矢平面延伸。为此，斜面导向器 200 提供有球 230 和凹槽 235。在荧光镜设置为使得荧光镜被设置在外侧的模式，并且在胫骨坪的水平从内侧的侧取图像的情况下（看图 11），操纵组件直到球 230 在凹槽 235 内居中（图 11）。当这发生时，系统与矢平面对准（即，位置导向器 100 布置为使得顶点销 300 将垂直于额平面延伸，如将在下文中讨论的）。

[0086] 9. 从而，当斜面导向器 200 与内侧的踝 75 对准时，并且当球 230 与凹槽 235 对准时，系统与 (i)A-P 斜面，和 (ii) 矢平面对准。换句话说，当斜面导向器 200 与内侧的踝 75 对准时，并且当球 230 与凹槽 235 对准时，仪器定位为使得顶点销 300（看下面）将与 A-P 斜面和矢 平面对准，如将在下文中讨论的。

[0087] 10. 在全部上述调节到位的情况下，检验 (i) 胫骨结节定位突出部 135，(ii) 斜面导向器 200，(iii) 内侧的定位销 140，和 (iv) 球和凹槽观测器 230、235 的位置。在确认全部位置的情况下，额销 145（图 16）和前面 - 内侧 (AM) 销 150（图 16）插入通过位置导向器 100 并且插入胫骨。这将位置导向器 100 以希望的对准固定到胫骨。

[0088] 11. 接下来，顶点销 300 插入通过位置导向器 100 并且插入胫骨。顶点瞄准具 155（图 14 和 16）用来将顶点销 300 以适当的定向引导到胫骨内，即，使得顶点销 300 沿形成在骨切开术切割口的外侧的限制处的轴线 70 定位，使得顶点销 300 平行于 A-P 斜面、垂直于冠平面、并且在切割平面 65 内延伸。从而，顶点销 300 能够用作用于骨切开术锯的外侧的停止器，由此清晰地限定骨铰链的周缘，如将在下文中讨论的。顶点销 300 可以攻螺纹或钻入原始骨，或者其可以被接收在预先钻的孔（例如，使用顶点瞄准具 155 形成的）内。翼形螺钉 160（图 16）可以用于将顶点销 300 固定到位置导向器 100。

[0089] 顶点销 300 可以为圆柱形的。

[0090] 替代地，顶点销 300 可以具有形成在其上的平部 305（图 12 和 13）以促进骨切开术的完全的切割通过。在顶点销 300 提供有明显的平部 305 的位置，其优选地提供有对应的平部 310（图 12 和 13），使得当顶点销 300 到位并且翼形螺钉 160 靠在平部 310 上上紧时，前面提到的平部 305 将与骨切开术切割口对准，由此确保骨切开术刀完全地切割通过骨以到达顶点销。看图 13。

[0091] 在此构造的另一个版本中（没有示出），平部 305、310 可以直径地彼此相反，使得翼形螺钉 160 也与骨切开术切割口对准，以使得插入顶点销 300 较不倾向于错误。

[0092] 并且在本发明的另一个实施例中，顶点销 300 可以在骨切开术的区域内颈缩到更小的直径。作为此构造的结果，存在稍微缓冲的区域以适应锯条，以便帮助促进完全的切割通过，但是和顶点销形成为具有明显的平部的情况相同，不需要顶点销相对于骨切开术平面的任何特定的定向。

[0093] 并且在本发明的另一个版本中，顶点瞄准具 155 可以与导向器套筒 160 和小直径的导向器销 165 一起使用，以便首先检查小直径的导向器 销 165 相对于顶点销的希望的轴线的位置，其后部署更大直径的顶点销 300。看图 14。在这点上，应该理解，与重新定位错误定向的更大直径的顶点销 300 相比，重新定位错误定向的小直径的导向器销 165 更加容

易并且对于接受体骨的创伤更小。

[0094] 如图 15 所示，胫骨结节定位突出部 135 优选地确定尺寸为使得其通过在振动的锯条（稍后在过程中用于形成骨切开术切割口 20）和前面的软组织结构例如髌腱之间提供保护性的防护物还用作前面的保护器。

[0095] 12. 根据前述内容，可以看出顶点销 300 部署到病人的胫骨内，使得顶点销（i）平行于胫骨的 A-P 斜面，并且（ii）平行于病人的矢平面延伸。从而，当随后通过沿骨切开术切割平面切割直到顶点销接合，使得骨铰链的周缘通过顶点销的位置限定，在骨（看下面）内形成骨切开术切割口时，骨铰链将（i）平行于胫骨的 A-P 斜面，并且（ii）平行于病人的矢平面延伸。通过确保顶点销 300 以此方式设置，并且从而确保骨铰链这样形成，当其后打开骨切割口以便形成打开楔骨切开术时，能够适当地调节胫骨的最终的构造。

[0096] 13. 一旦顶点销 300 已经被适当地定位在骨内，移除斜面导向器 200 和导引器 105，留下位置导向器 100 适当地对准在并且固定到胫骨上，并且顶点销 300 适当地部署到胫骨内（即，顶点销 300 平行于 A-P 斜面并且平行于病人的矢平面延伸）。看图 16。位置导向器 100 和相关的仪器的尺寸用于准备骨切开术以配合小、中或大的特别的植入物的尺寸确定。更特别地，内侧的定位销 140、位置导向器 100 的尺寸、和顶点销 300 全部结合以实现植入物尺寸确定方案。如图 17 所示，内侧的定位销 140、位置导向器 100 和顶点销 300 结合以提供从胫骨的内侧的方位到顶点销的已知的、固定的距离。随后设置计划的骨切开术的尺寸，允许特定的尺寸的植入物（例如，小、中或大）标称地配合在内侧的方位和顶点销之间。

[0097] 在图 17 所示的实施例中，内侧的定位销 140 和骨切开术的入口点之间有已知的外侧的偏移。稍微减小植入物的尺寸以此偏移距离的因子，以便提供适当的配合。

[0098] 在替代的构造中，内侧的定位销 140 可以与计划的骨切开术的入口点完全地对准（没有示出）。

[0099] 14. 接下来看图 18，随后通过使得键孔钻导向器 400 越过额销 145 和顶点瞄准具 155 将键孔钻导向器 400 接附到位置导向器 100。随后用翼形螺钉 405 将键孔钻导向器 400 固定在此位置。在这点上，远侧的销 410 插入通过键孔钻导向器 400 并且插入胫骨。远侧的销 410 还将仪器固定到胫骨。接下来，表面定位器销 415 插入通过键孔钻导向器 400。表面定位器销 415 滑动通过键孔钻导向器 400，直到表面定位器销 415 的远侧的尖端接触胫骨的表面。对本发明来说，此表面可以称作“前面 - 内侧表面”或“A-M 表面”，该表面为对应骨切开术的前面 - 内侧的途径的胫骨的解剖学的表面。当表面定位器销 415 接触 A-M 表面时，表面定位器销能够作为对 A-M 表面的位置的指示器。此信息能够随后用于设置为了改进的植入物配合将在胫骨（看下面）内形成的键孔的深度。

[0100] 接下来，将立铣刀 420 插入键孔钻导向器 400 的远侧的孔 425（即，底部的孔 425）并且钻，直到立铣刀 420 上的停止法兰 430 接触表面定位器销 415 的近侧的端部，由此在胫骨内形成远侧的键孔 85（图 21）。随后对于近侧的孔 435（即，顶部的孔 435）重复钻过程，由此在胫骨内形成近侧的键孔 90（图 21）。虽然可能在远侧的键孔之前钻近侧的键孔，通常优选首先钻远侧的键孔。这是因为在近侧的键孔之前钻远侧的键孔减小骨的倾斜的性质将导致稍后钻的键孔滑入较早钻的键孔的可能性。应该理解，键孔钻导向器 400 构造为使得远侧的孔 425 和近侧的孔 435 将某种程度上交迭骨切开术切割平面 65（图 21），使得当其后

形成骨切开术切割口 20 并且随后打开胫骨以便形成楔状的开口 25 时，远侧的键孔 85 和近侧的键孔 90 将交迭，并且与楔状的开口 25 连通（图 29）。

[0101] 15. 一旦已经在胫骨内钻了两个植入物键孔，移除立铣刀 420，放松翼形螺钉 405，并且随后移除键孔钻导向器 400。

[0102] 16. 接下来，并且现在看图 19，用翼形螺钉 510 将后面的保护器 500 接附到导引器 505。后面的保护器 500 的远的尖端 515（图 19 和 21）插入切口。后面的保护器 500 优选地有些柔性的材料形成，以便允许后面的保护器稍微弯曲以允许更加容易插入切口并且符合后面的皮质的形状。看图 19。通过围绕胫骨的后面的皮质逐渐地滑动后面的保护器 500 直到后面的保护器 500 的远的尖端 515 大致穿过顶点销 300 的轴线 并且在一些情况下实际地接合顶点销 300（图 21）来插入后面的保护器 500。后面的保护器 500 优选地包括靠近柔性的尖端 515 的硬的弯曲的部分 520。一旦已经适当地部署后面的保护器 500，旋松翼形螺钉 510，并且移除导引器柄 505。

[0103] 17. 接下来看图 20，随后使用切割导向器翼形螺钉 605 将切割导向器 600 接附到位置导向器 100 并且固定到位。切割导向器 600 包括从切割导向器延伸进入预先钻的键孔 85、90（图 21）以帮助切割对准的对准杆 610。更特别地，对准杆 610 确保切割导向器 600、其切割槽 615（图 20 和 21）和之前用立铣刀 420 形成在胫骨内的预先钻的键孔 85、90 之间的适当的对准，并且最终确保植入物和胫骨之间的希望的配合。

[0104] 随后，使用翼形螺钉 620（图 20）将后面的保护器 500 接附到切割导向器 600。

[0105] 在这点上，仪器准备好形成骨切开术切割口，使得切割导向器 600 的切割槽 615 与骨切开术切割平面适当地对准，顶点销 300 适当地定位在骨切开术切割口的远的（外侧的）限制处，胫骨结节定位突出部 135 形成用于髌腱的保护性的防护物，并且后面的保护器 500 形成用于在膝部的后部的血管和神经结构的保护性的防护物。在这点上，应该理解，切割导向器 600 确定尺寸并且确定形状为并且切割槽 615 定位为使得除了与顶点销 300 对准外，切割平面到胫骨内的入口点定位在胫骨的内侧的颈 66 上的适当的位置处。

[0106] 18. 接下来，将锯条 625（接附到振动的锯，没有示出）插入切割导向器 600 的切割槽 615。随后通过将振动的锯条插入通过切割槽 615 并且插入骨（图 20）形成骨切开术切割口。锯条将完全地切割通过内侧的和后面的皮质。操作锯直到锯条 625 接触后面的保护器 500 和顶点销 300。当锯条切割通过胫骨时，锯条受到切割槽 615、顶点销 300 和后面的保护器 500 的约束，使得锯条可以仅沿骨切开术平面切割骨，达到但是不超过骨铰链的希望的位置，并且不切割软组织。在切割期间，胫骨结节定位突出部 135 还确保锯条不会不注意地切割髌腱。

[0107] 在锯条 625 形成沿切割平面的希望的骨切开术切割口 20 之后，移除锯条，并且将本领域中众所周知的类型的手持式骨凿（没有示出）插入通过切割槽 615 并且插入骨切开术切割口 20，并且随后完成通过靠近顶点销 300 和后面的保护器 500 的后面的皮质骨的切割口。随后移除手 持式骨凿。

[0108] 在这点上，已经完成骨切开术切割口 20，使得骨切开术切割口终止于顶点销 300 处的外侧的侧上，使得将骨铰链适当地定位在希望的位置处，即，平行于 A-P 斜面并且垂直于冠平面。

[0109] 接下来，放松翼形螺钉 620 并且移除后面的保护器 500。随后放松翼形螺钉 605 并

且移除切割导向器 600。

[0110] 在这点上，已经在胫骨内形成希望的骨切开术切割口 20，使得键孔 85 和 90 分别形成在骨切开术切割口的下方和上方。

[0111] 为了完成过程，必须现在打开骨以便将胫骨重新构造为希望的几何形状，并且随后用希望的构造稳定胫骨，例如，通过将楔形的植入物 27 插入楔状的开口 25。

[0112] 19. 接下来看图 22，通过将额销 145 接收在形成在千斤顶臂 710 内的孔 705 内，通过将顶点瞄准具 155 接收在形成在千斤顶臂 710 和千斤顶臂 725 内的另一个孔 715 内，并且通过将远侧的销 410 接收在形成在千斤顶臂 725 内的槽 720 内，将打开千斤顶 700 装配到仪器上。用翼形螺钉 730 将打开千斤顶 700 固定到位置导向器 100。

[0113] 一旦打开千斤顶 700 到位，通过旋转千斤顶螺钉 735 打开千斤顶。这导致千斤顶臂 725 围绕顶点瞄准具 155 枢转，以便打开千斤顶并且由此打开胫骨内的希望的楔状的开口 25。看图 23。优选地，当转动千斤顶螺钉 735 时，操纵病人的下部的腿，以便帮助打开骨。当在骨内形成楔状的开口 25 时，由于将通过使用顶点销 300 在轴线 70 处精确地定位骨铰链，即，骨铰链将平行于 A-P 斜面并且平行于矢平面延伸的事实，将以高度受控的方式重新定向胫骨。此外，当在骨内形成楔状的开口 25 时，由于顶点销 300 在骨切割口的外侧的端部处形成过大尺寸的孔 95（图 23A 和 27），即，相对于骨切开术切割口的厚度“过大尺寸”，由此减小应力上升等的发生的事实，将最小化骨折的危险。

[0114] 20. 随后，在打开千斤顶 700 仍然就位的情况下，将植入物定位在楔状的开口 25 内。根据需要，植入物可以为“一般的”植入物，诸如图 3 所示的植入物 27。然而，更优选地，并且现在看图 24，示出了根据本发明形成的楔形的植入物 800。楔形的植入物 800 的特征为构造为匹配楔状的开口 25 的几何形状的楔状的侧型面。优选地，楔形的植入物 800 还形成为使得具有 U 形的顶部型面，使得其能够形成围绕楔状的 开口 25 的障碍物，由此约束可以定位在楔状的开口 25 的内部的移植物材料（例如，骨胶，骨接合剂等）。在本发明的一个优选的形式中，楔形的植入物 800 形成为当在顶视图中观察时具有不对称的构造，以便当使用前面 - 内侧的途径定位植入物时与胫骨的几何形状匹配。根据需要，楔形的植入物 800 可以由可吸收的材料或不可吸收的材料形成。

[0115] 在本发明的一个优选的形式中，并且现在看图 25 和 26，植入物 800 优选地包括三零件组件，包括后面的移植物容纳臂 (GCA)805、基座 810 和前面的移植物容纳臂 (GCA)815。根据需要，植入物 800 的单独的部件可以每个由可吸收的材料和 / 或不可吸收的材料形成。此外，在植入物部件中的一个或多个由可吸收的材料形成的情况下，材料的吸收特性可以根据需要变化。作为示例而不是限制，基座 810 可以由相对慢地吸收的材料形成，而后面的移植物容纳臂 (GCA)805 和前面的移植物容纳臂 (GCA)815 可以由相对更快地吸收的材料形成。基座 810 优选地包括一对键 820、825。

[0116] 在本发明的一个优选的形式中，植入物 800 形成为使得后面的移植物容纳臂 (GCA)805 具有通常楔形的型面，其包括接合座 826，包含对准柱 827 和在部件的前面 - 内侧的侧上开口的用于与导引器 845（看下面）接合的导引器孔 828。优选地如图所示提供加强肋 829。另外，可以提供凸起的点或坑 831 以帮助将 GCA805 固定到骨。对准突出部 832 提供为用于当 GCA805 定位在楔形的开口 25 内时延伸进入上部的键孔 90（图 29）。

[0117] 并且，在本发明的一个优选的形式中，基座 805 形成为使得其键 820、825 每个分别

包括渐缩的轴向的孔眼 833、834，使得键纵向地开槽，以便当其后将螺钉 865 部署到渐缩的轴向的孔眼内时允许键扩张。可以在键 820、825 的外部表面上提供外部的肋 836，以便帮助将键 820、825 分别固定在键孔 85、90 内，如将在下文中更加详细地讨论的。对准机构（没有示出）提供为用于与 GCA805 的对准柱 827 匹配。

[0118] 前面的移植物容纳臂 (GCA)815 也包括通常楔形的型面，并且对准突出部 834 提供为用于当 GCA815 定位在楔形的开口 25 内时延伸进入下部的键孔 85。

[0119] 马蹄形的植入物 800 优选地现场装配。

[0120] 更特别地，首先使用导引器 845 将包括后面的移植物容纳臂 (GCA) 805、植入物试验基座 830 和两个导向器套筒 835、840 的预先装配的组件插入骨内的楔状的开口 25。看图 27 和 28。

[0121] 接下来，将钻套筒 850 和钻 855 插入导向器套筒 840（图 27）。用钻在胫骨内钻上部的孔。随后对于导向器套筒 835 重复钻过程以便形成下部的孔。随后从外科手术部位移除钻套筒 850 和钻 855。接下来，将丝锥 860 插入导向器套筒 840 并且为上部的孔攻螺纹。看图 28。随后将丝锥插入导向器套筒 835 并且为下部的孔攻螺纹。随后从外科手术部位移除丝锥 860。

[0122] 21. 接下来，从导引器 845 释放后面的移植物容纳臂 (GCA)805，并且随后移除导引器 845 和植入物试验基座 830。

[0123] 22. 随后，根据需要，将移植物材料装填到骨切开术开口内。

[0124] 23. 接下来，将前面的移植物容纳臂 (GCA)815 放置到骨切开术开口内并且与准备好的植入物孔对准。看图 29。如有必要，根据需要旋转千斤顶螺钉 735 以便促进插入前面的 GCA815。

[0125] 24. 随后，将植入物基座 810 插入准备好的骨切开术，使得键 820 和 825 分别安置在胫骨孔 85 和 90 内。看图 29。安置在胫骨孔 85 和 90 内的键 820 和 825 帮助确保将植入物精确地配合到骨。在这样进行时，根据需要调节千斤顶螺钉 735 以促进将基座插入骨切开术。随后，稍微上紧千斤顶螺钉 735 以确保植入物部件完全地安置在骨切开术楔内。接下来，将固定螺钉 865 插入通过基座 810 内的键 820 和 825 并且插入胫骨内的攻螺纹的孔，并且上紧到位。看图 30。最终，从外科手术部位移除打开千斤顶 700、位置导向器 100、顶点销 300、远侧的销 410、额销 145 和 A-M 销 150，并且关闭切口。

[0126] 前面 - 外侧的骨切开术

[0127] 在前面的描述中，在使用前面 - 内侧的途径执行打开楔骨切开术的情况中讨论本发明。当然，应该理解，本发明也可以用于前面 - 外侧的途径，或者对于本领域中的普通技术人员众所周知的其它途径。

[0128] 用于在高位胫骨切开术中实现结合外侧 - 内侧 (L-M) 修正的前面 - 后面 (A-P) 斜面修正的方法

[0129] 在前面的描述中，披露了用于实现高位胫骨切开术的途径，其中，外科医生确定胫骨的前面 - 后面 (A-P) 斜面并且确定骨切开术相对于胫骨的额（即，冠）平面的适当的定向。在这完成之后，外科医生将顶 点销放置到胫骨内，以便精确地限定骨切开术切割口的外侧的限制并且从而限定骨切开术的骨铰链。前面的讨论说明了设置顶点销平行于 A-P 胫骨斜面并且垂直于额（即，冠）平面的重要性。见图 31，其示出了垂直于冠平面的顶点销，

并且见图 32，其示出了平行于 A-P 斜面的顶点销的轴线。这样的途径对于防止当执行对准修正时（和骨切开术打开时）对 A-P 胫骨斜面的不注意的或非故意的改变是重要的。

[0130] 然而，可以存在这样的情形，其中，外科医生可以故意地希望将 A-P 斜面改变引入胫骨，例如，诸如当解决膝部不稳定或膝部韧带松弛时。

[0131] 接下来的披露物描述了允许外科医生对 A-P 胫骨斜面进行可以定量的改变的途径。此途径主要包括围绕胫骨的纵轴线旋转顶点销的轴线到相对于矢平面的指定的角度。这与上面披露的优选的途径形成对比，在上面披露的优选的途径中，顶点销的轴线平行于矢平面。

[0132] 更特别地，图 33 示出了披露的平行于矢平面设置的顶点销的轴线。如前面提到的，因为插入的顶点销平行于 A-P 斜面，此定向在不影响 A-P 斜面的情况下产生外侧 - 内侧 (L-M) 修正。

[0133] 现在看图 34，顶点销的轴线示出为在后面的方向（即，当从图 34 的顶视图看时的逆时针方向）旋转。顶点销的此替代的定向产生与对应的 L-M 斜面的调节一起的增加的 A-P 斜面。引起的 L-M 和 A-P 斜面修正为总的修正角度，即顶点销的轴线相对于矢平面旋转的总的量的函数。

[0134] 现在看图 35，顶点销的轴线示出为在前面的方向（即，当从图 35 的顶视图看时的顺时针方向）旋转。顶点销的此替代的定向产生与对应的 L-M 斜面的调节一起的减小的 A-P 斜面。同样，引起的 L-M 和 A-P 斜面修正为总的修正角度，即顶点销的轴线相对于矢平面旋转的总的量的函数。

[0135] 为了讨论的目的，可以假定在顶点销的定向上没有外科手术上的限制。这允许为了说明操作的构思对极端的定向的检查。然而，从外科手术的观点，存在顶点销能够相对于“标准”位置（即，平行于矢平面）旋转多远的实际的限制。然而，接下来的示例适用于说明性的目的。

[0136] 现在看图 36，明白如果顶点销后面地并且平行于额（冠）平面定向，打开楔骨切开术仅产生 A-P 斜面增加，对 L-M 斜面没有影响。

[0137] 相似地，并且现在看图 37，前面地并且平行于额（冠）平面定向的顶点销仅产生 A-P 斜面减小，对 L-M 斜面没有影响。

[0138] 从图 36 和 37 明白，使用此方法并且内插在极端的定向之间，通过相对于矢平面重新定向顶点销，可能实现 L-M 斜面和 A-P 斜面增加和 / 或 A-P 斜面减小的任何组合。

[0139] 对于给定的总的修正角度，定向为从矢平面 45 度的顶点销将必然地产生相等的 L-M 和 A-P 修正。45 度的后面的定向产生相等角度的 L-M 增加和 A-P 增加。45 度的前面的定向产生相等角度的 L-M 增加和 A-P 减小。

[0140] 此外，能够示出，靠近内侧的皮质而不是外侧的皮质定位的顶点销将产生在相反的方向的 L-M 斜面改变。这可以用于修正外翻足不对准。

[0141] 不同的构造可以用于用相对于矢平面的希望的角度定向顶点销 300。作为示例而不是限制性的，图 38 示出了顶点瞄准具 155 可以如何滑动地安装到弯曲的吊臂 B，使得可以调节顶点销相对于矢平面的角度。考虑到本披露物，其它构造对于本领域中的普通技术人员是明显的。

[0142] 修改

[0143] 应该理解，本领域中的普通技术人员可以在不偏离本发明的原理和范围的情况下作出对于已经在这里描述并且说明以便解释本发明的性质的细节、材料、步骤和零件的设置的许多改变。

左腿前视图

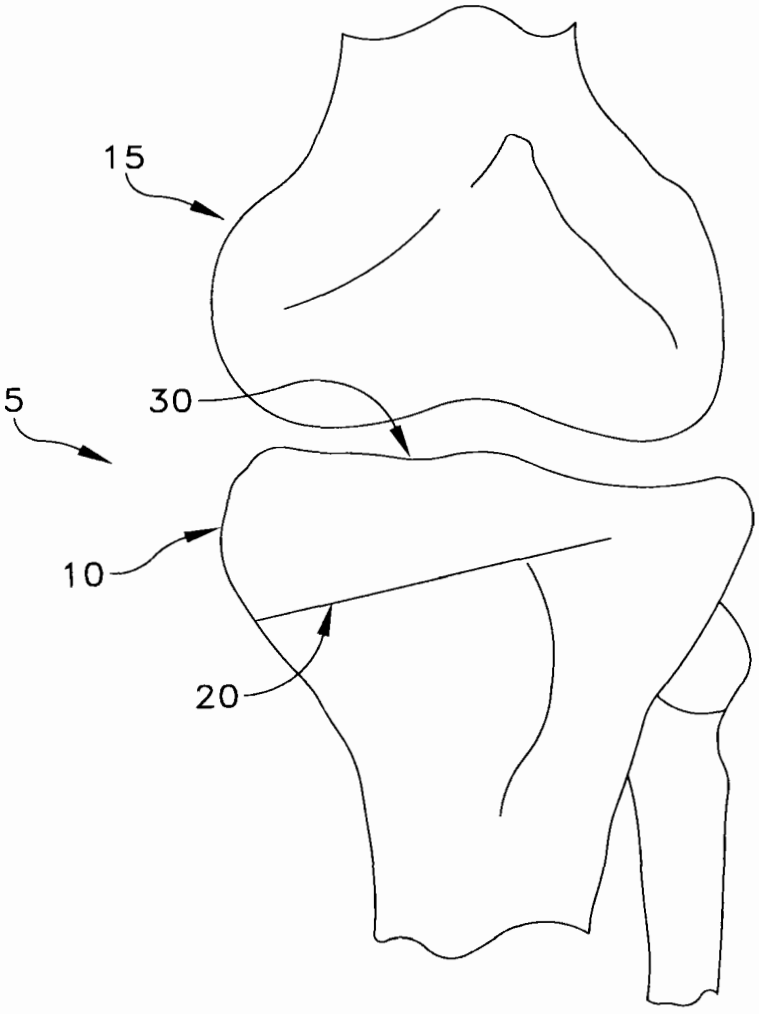


图 1

左腿前视图

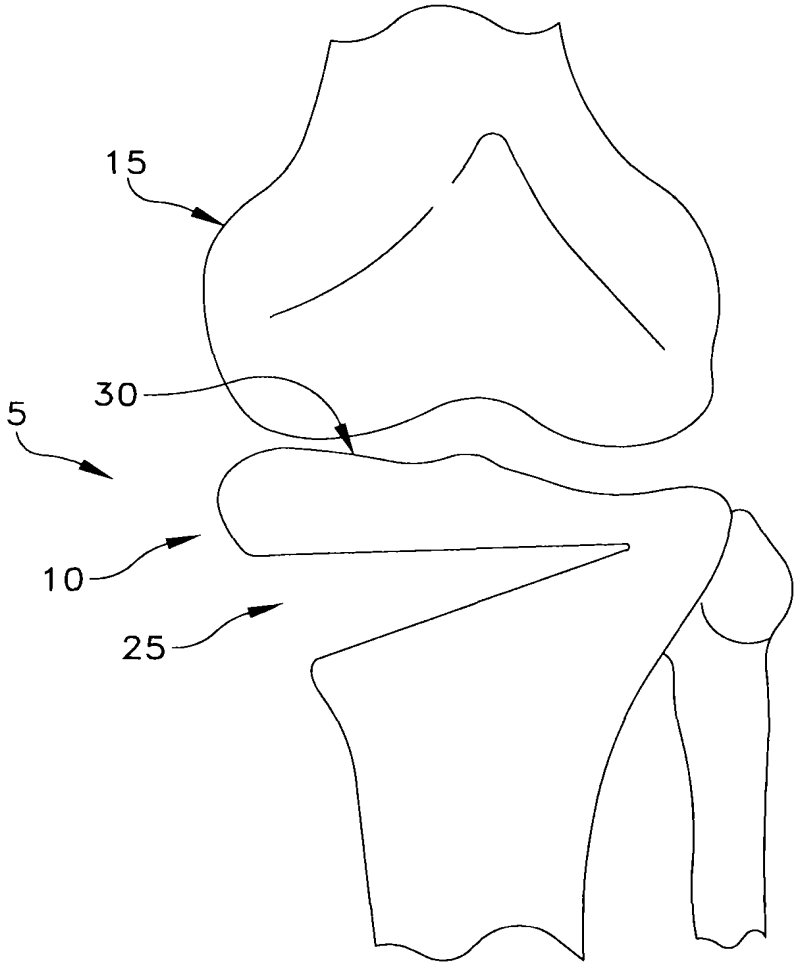


图 2

左腿前视图

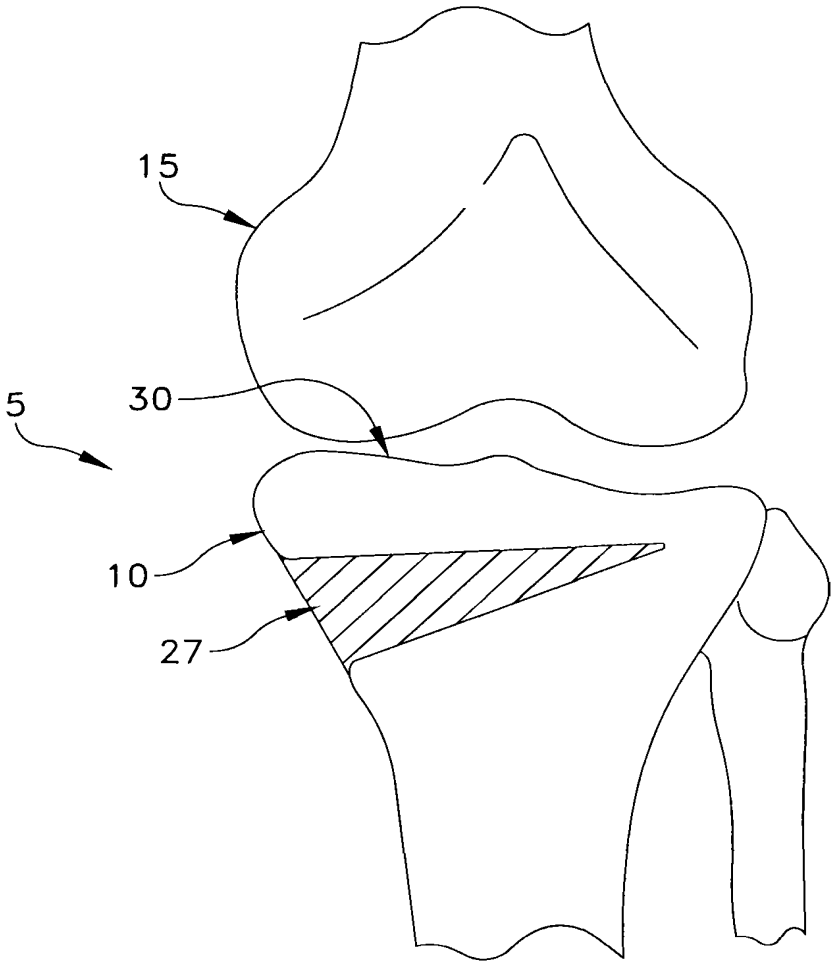


图 3

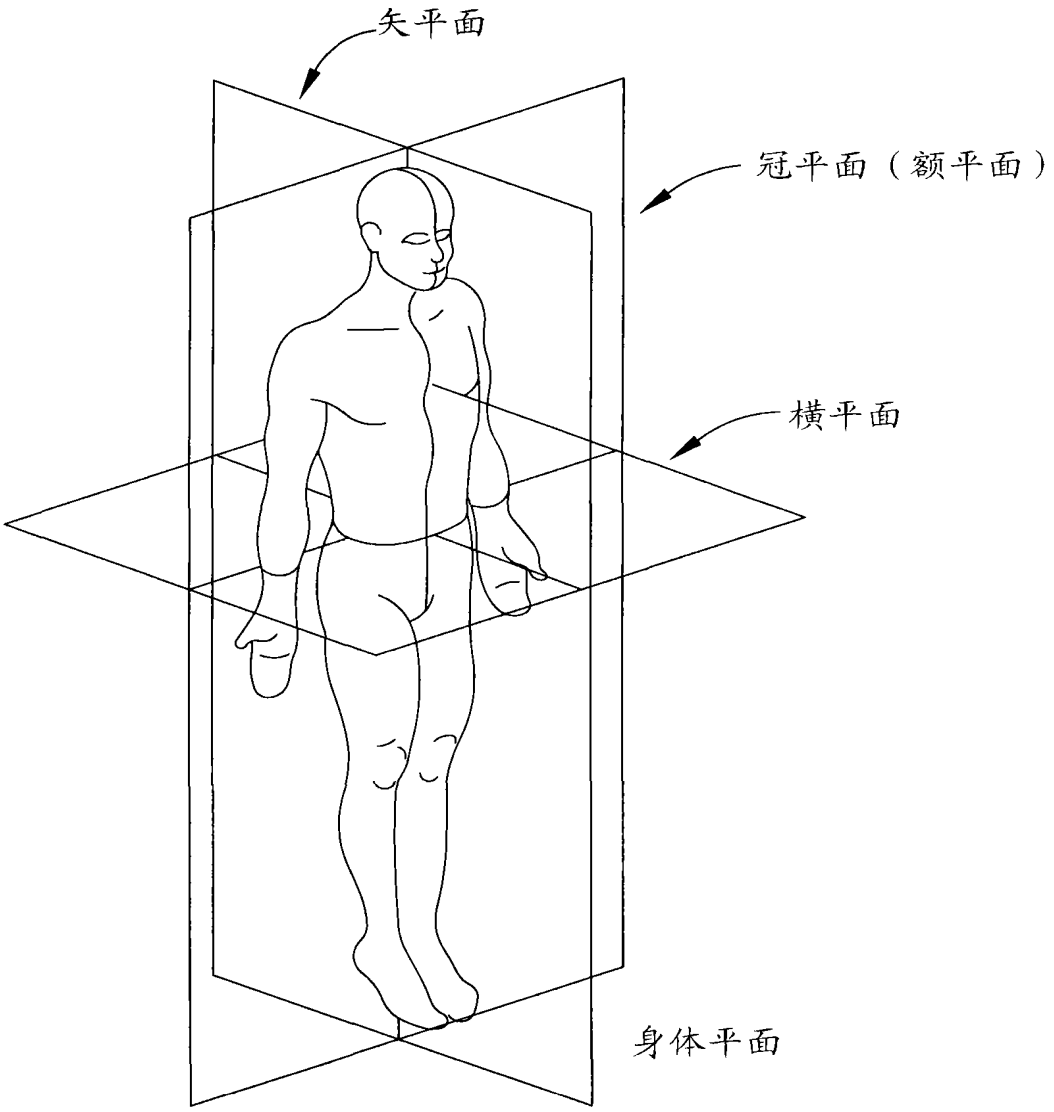


图 3A

左腿前视图

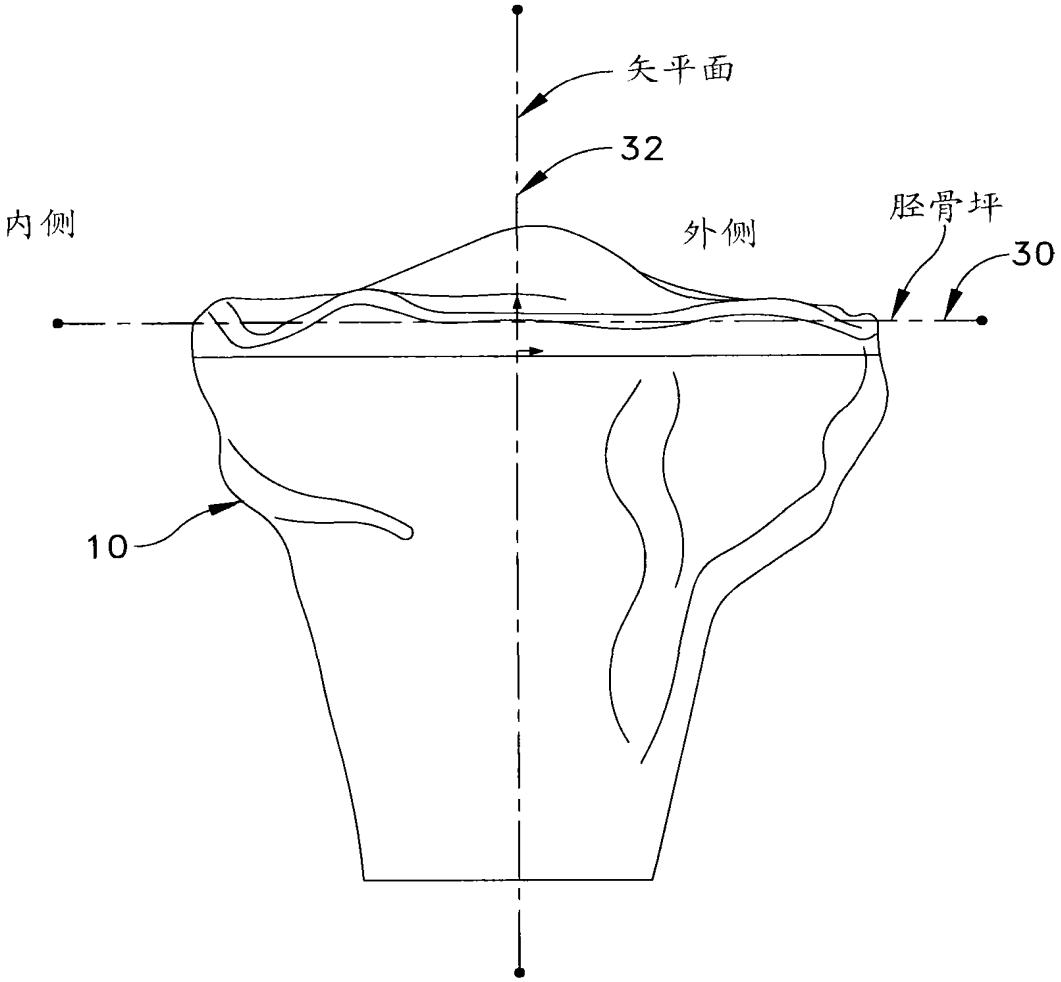


图 4

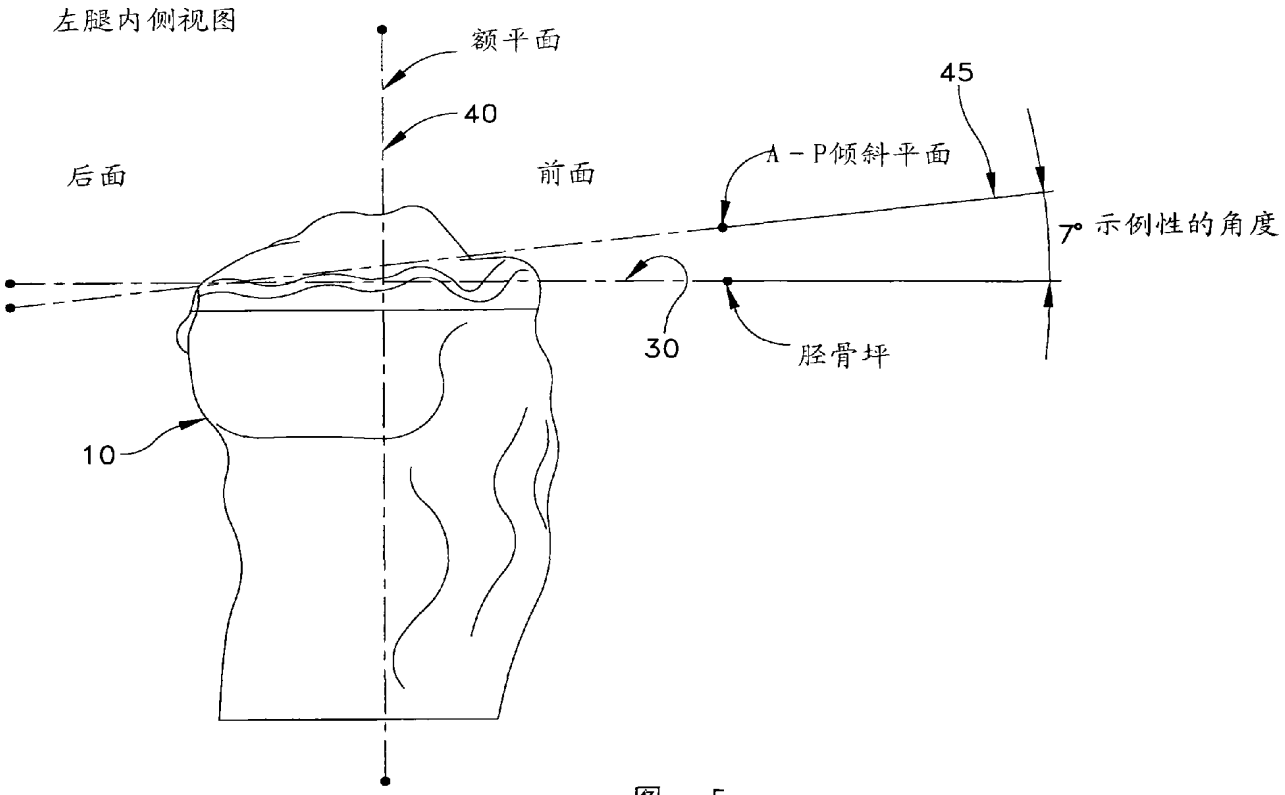


图 5

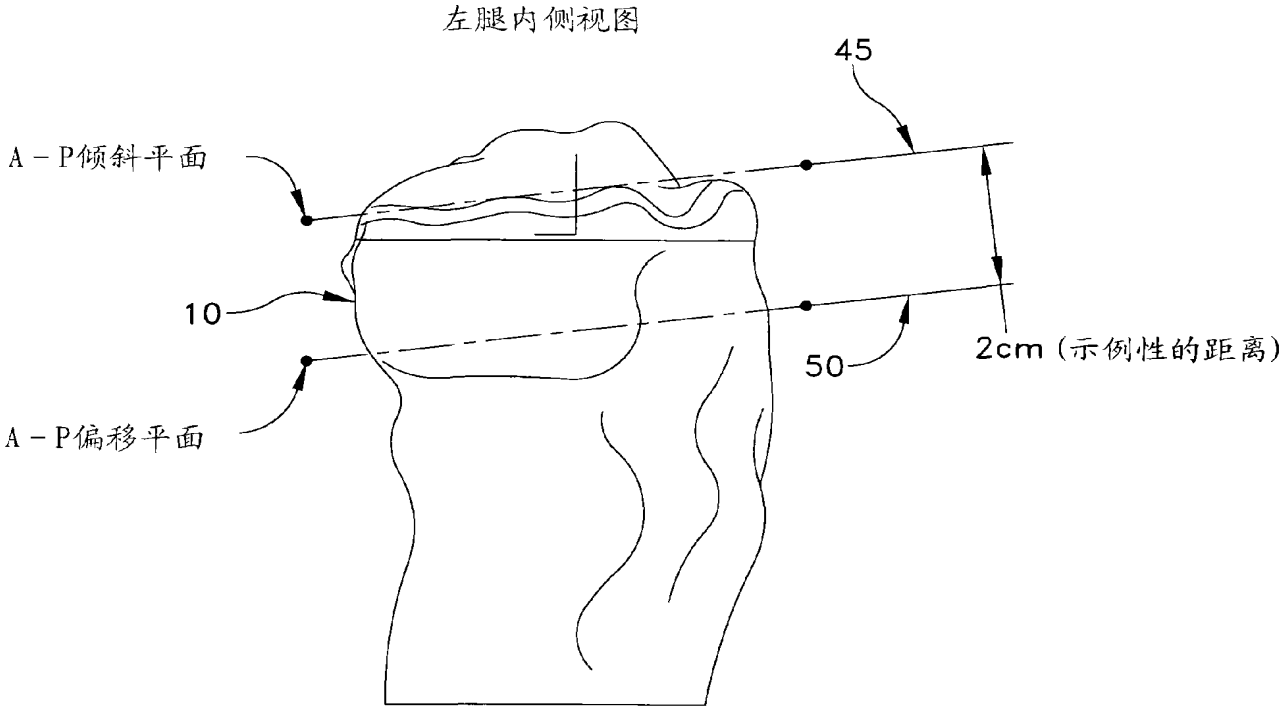


图 6

左腿前视图

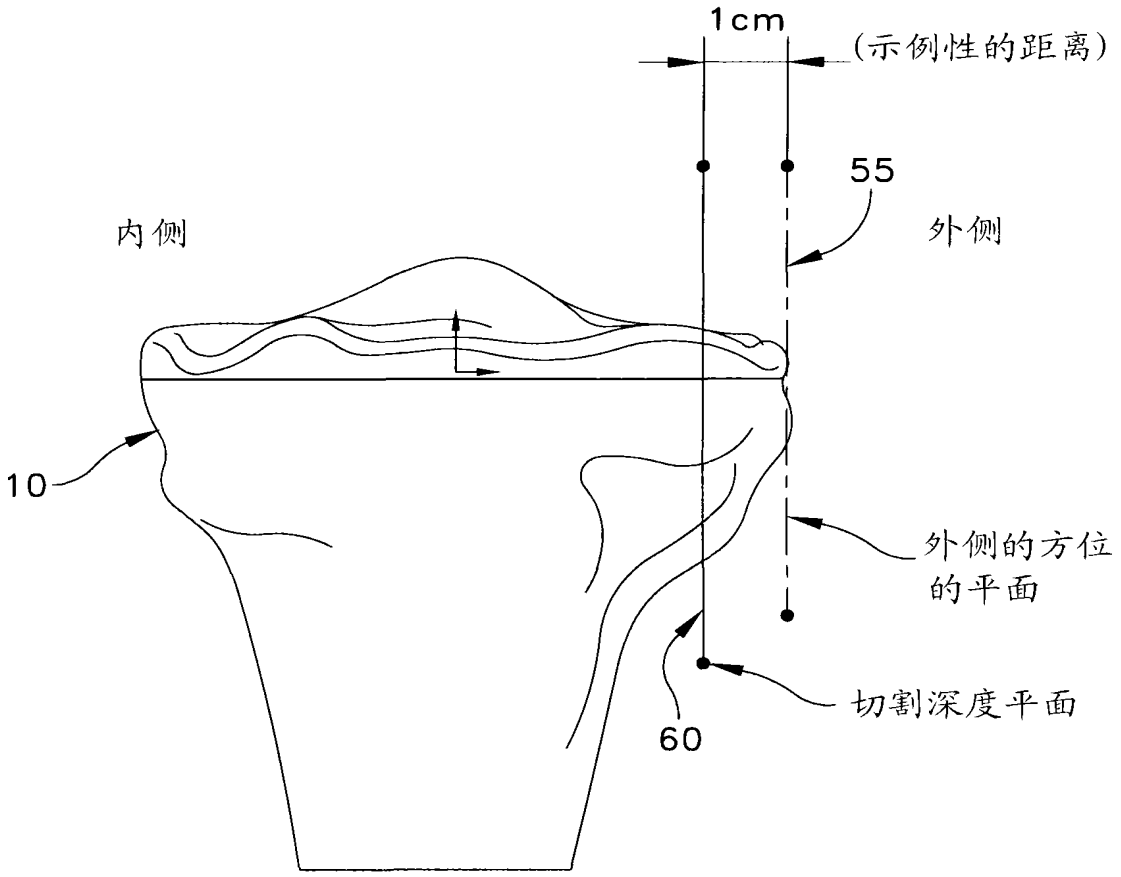


图 7

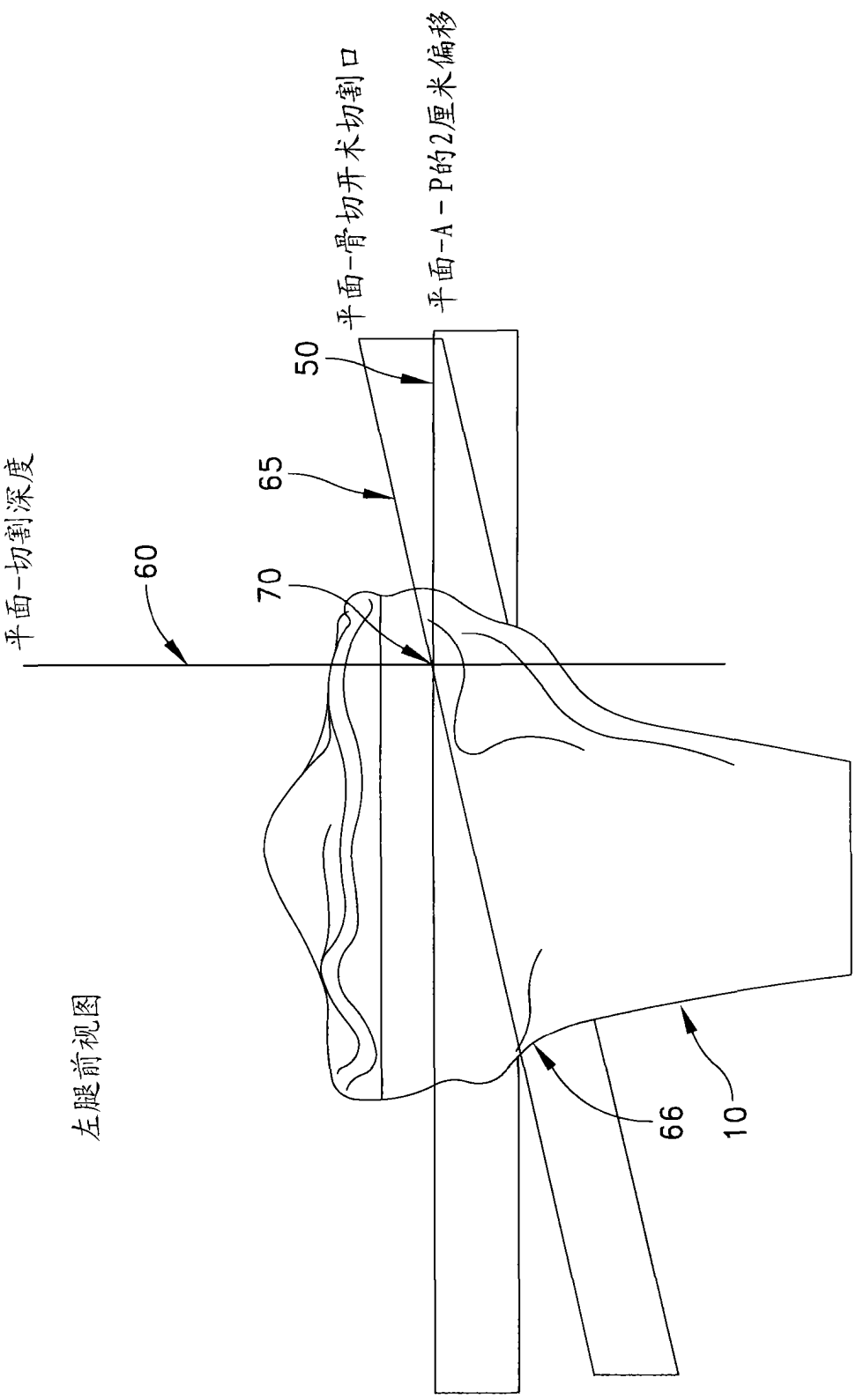


图 8

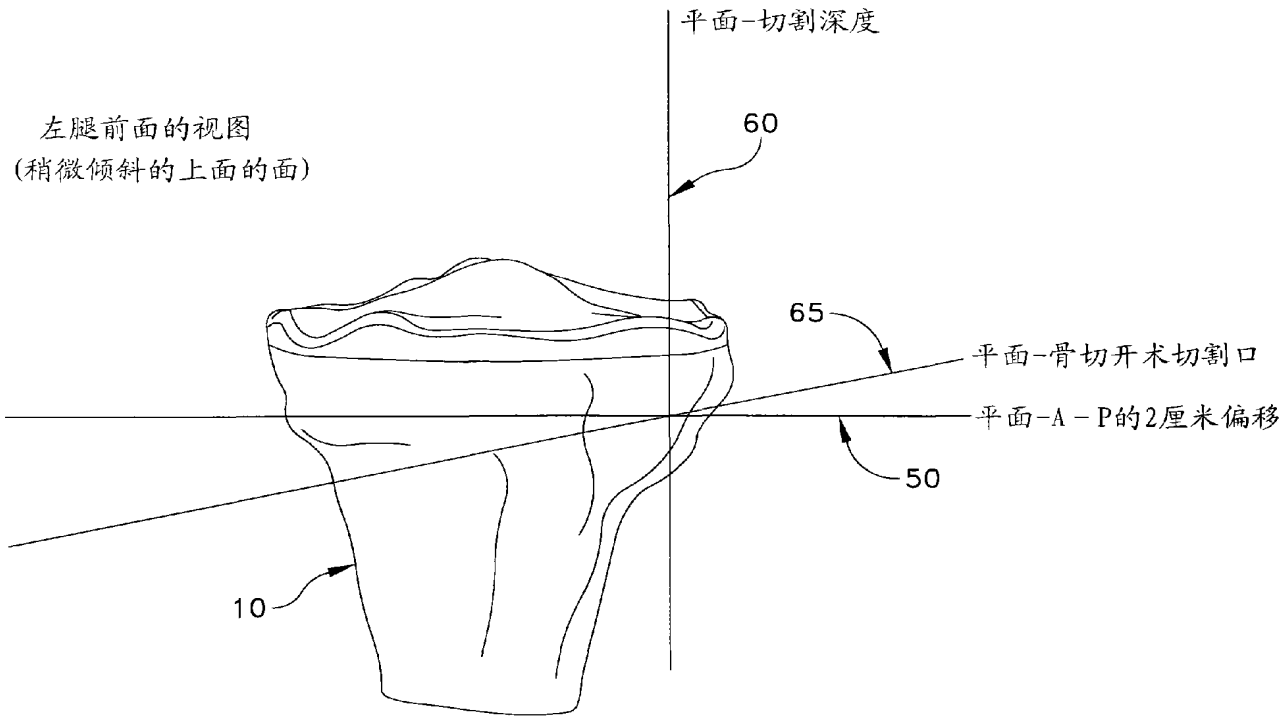


图 9

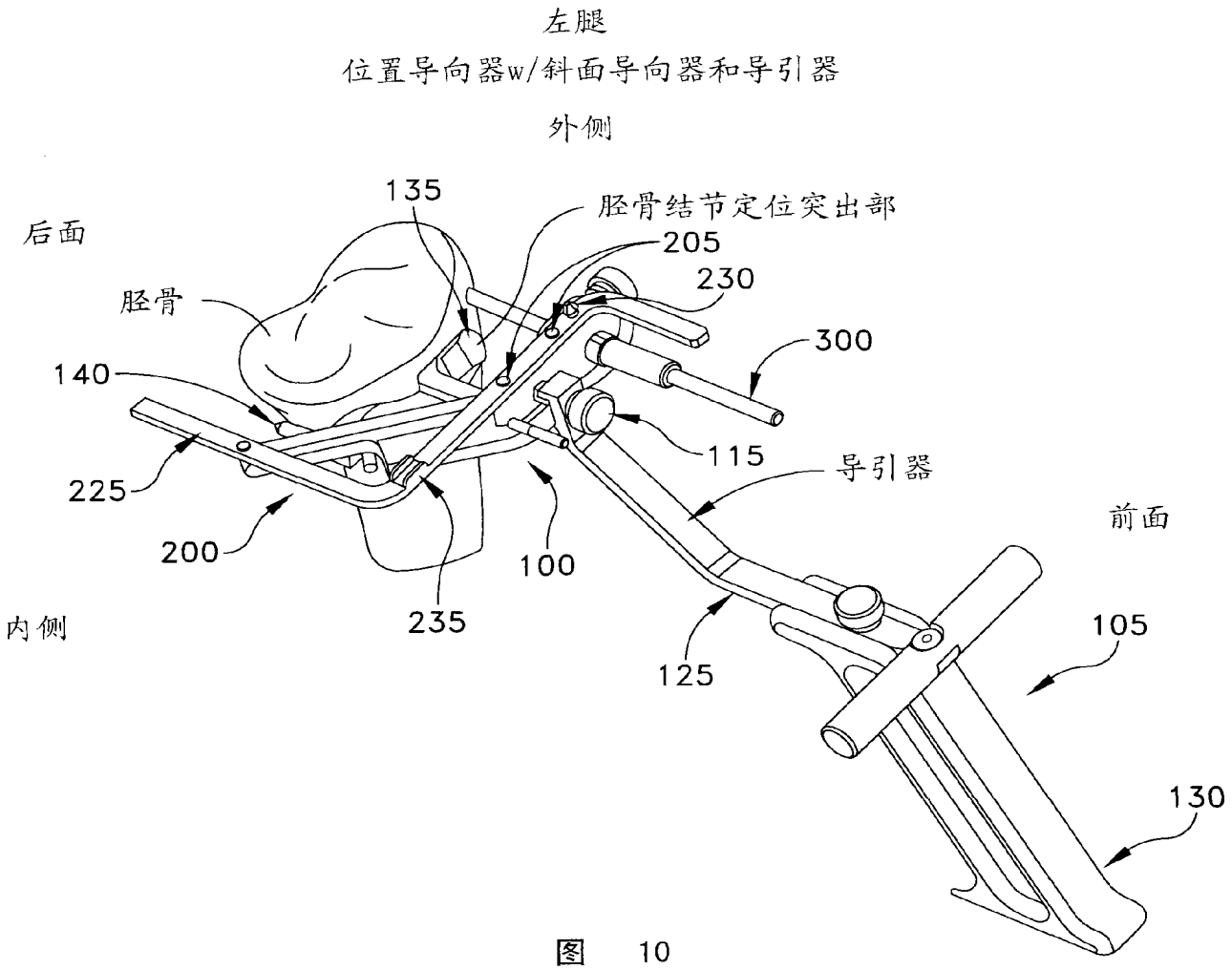

左腿
位置导向器w/斜面导向器和导引器
外侧
135
胫骨结节定位突出部
后面
205
230
胫骨
300
140
115
导引器
225
前面
200
100
内侧
235
105
125
130

图 10

斜面导向器

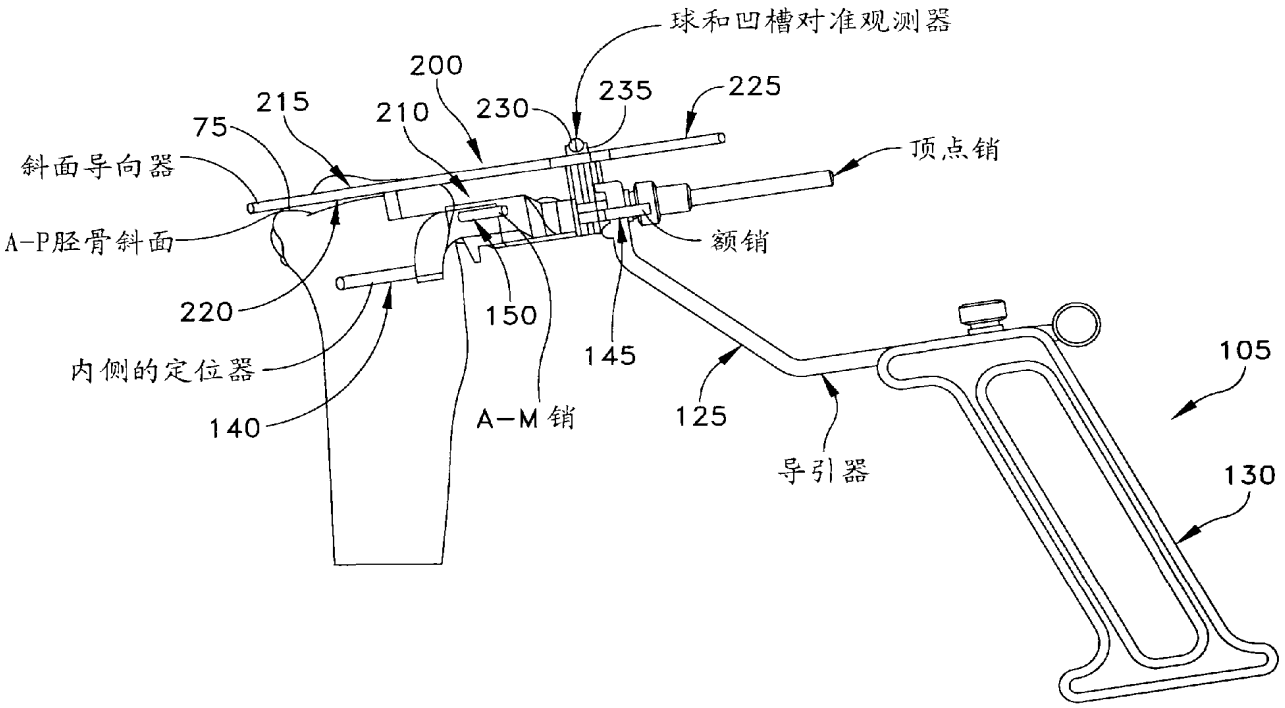

球和凹槽对准观测器
200
215
210
230
235
225
75
斜面导向器
顶点销
A-P胫骨斜面
额销
220
150
145
105
内侧的定位器
140
A-M 销
125
导引器
130

图 11

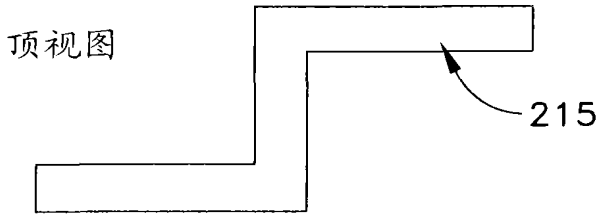


图 11A

在荧光透视法下的外侧的视图，其中，导向器元件没有垂直地与荧光镜对准

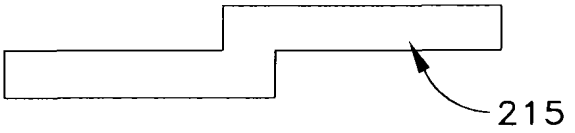


图 11B

在荧光透视法下的外侧的视图，其中，导向器元件垂直地与荧光镜对准

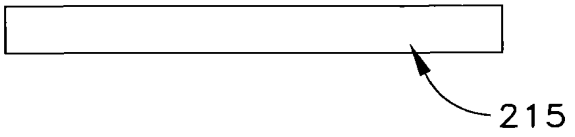


图 11C

具有平部的顶点销

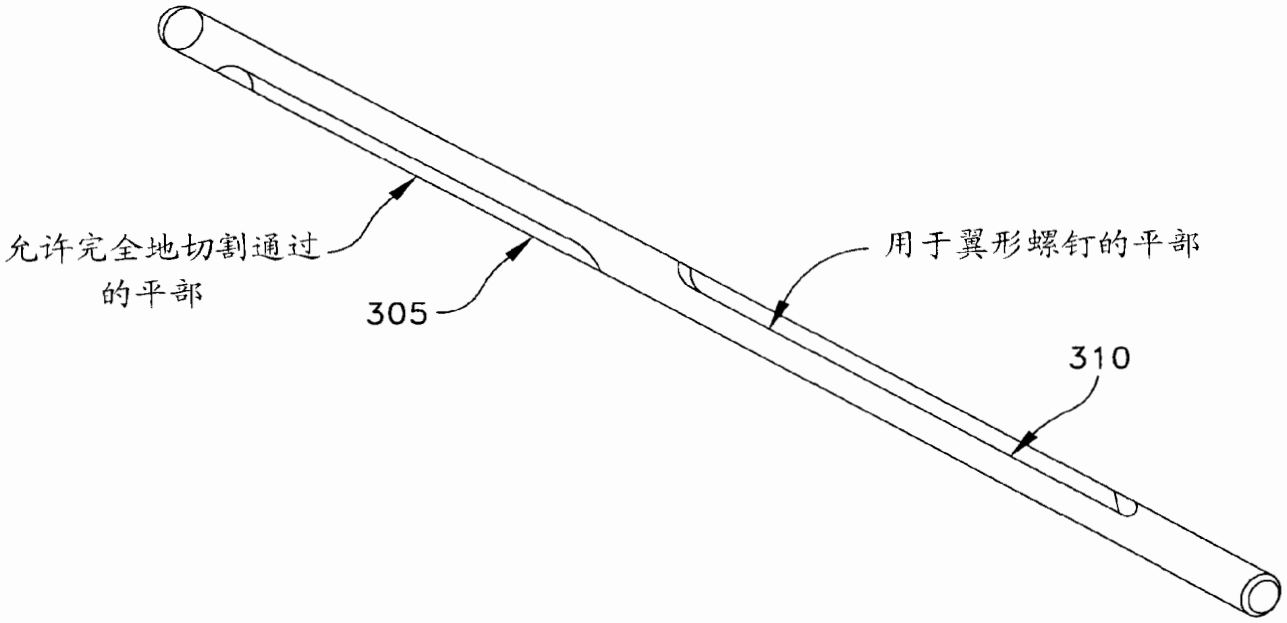


图 12

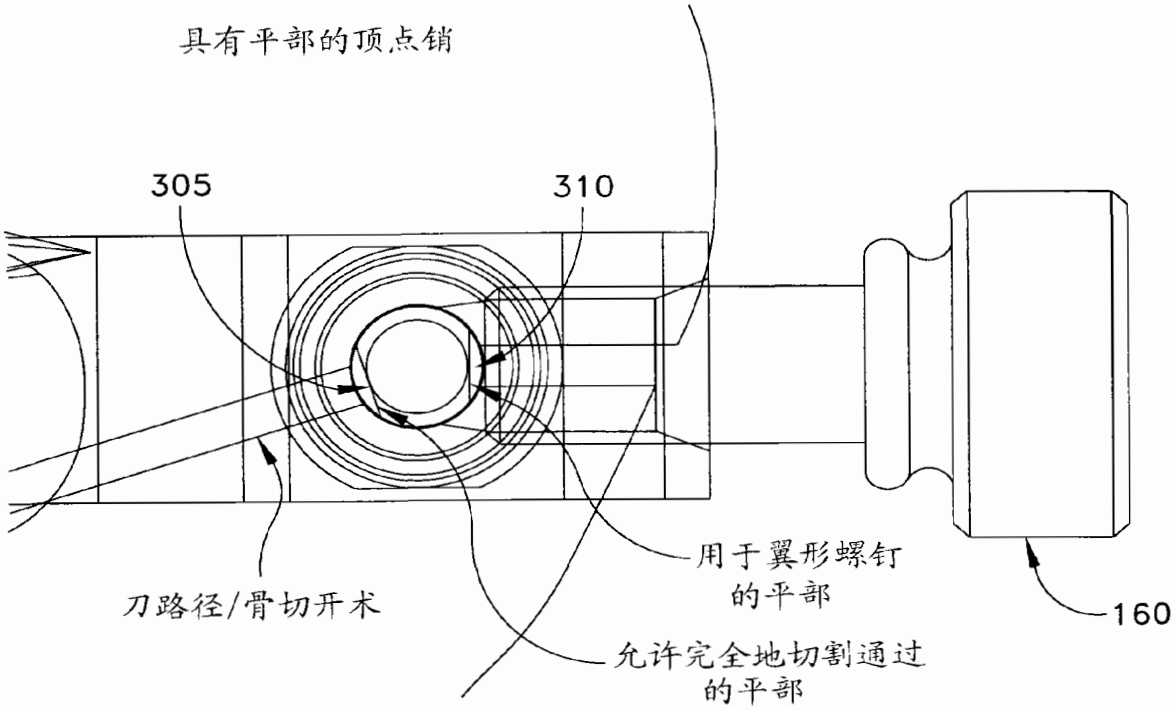


图 13

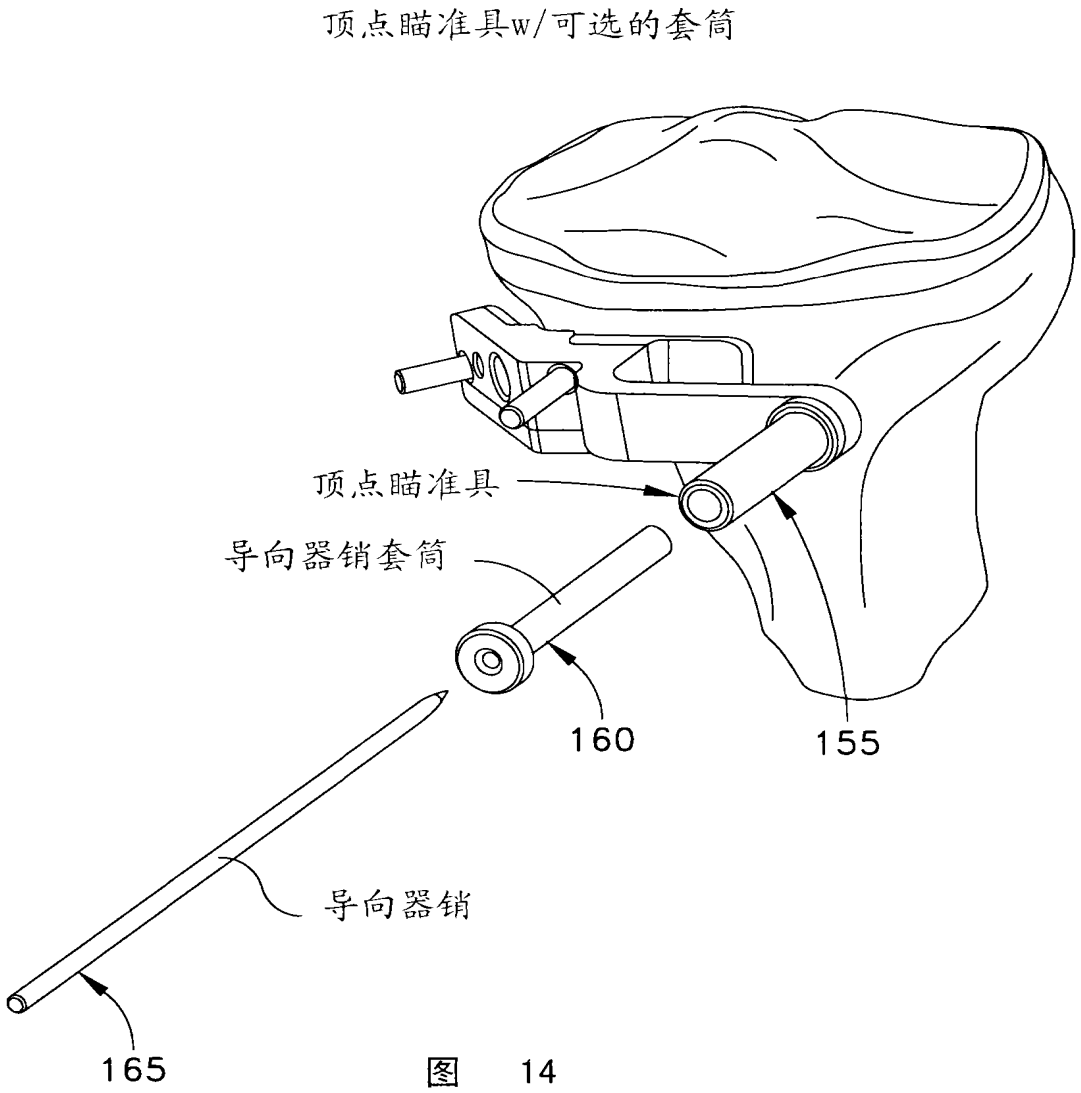


图 14

前面的保护器

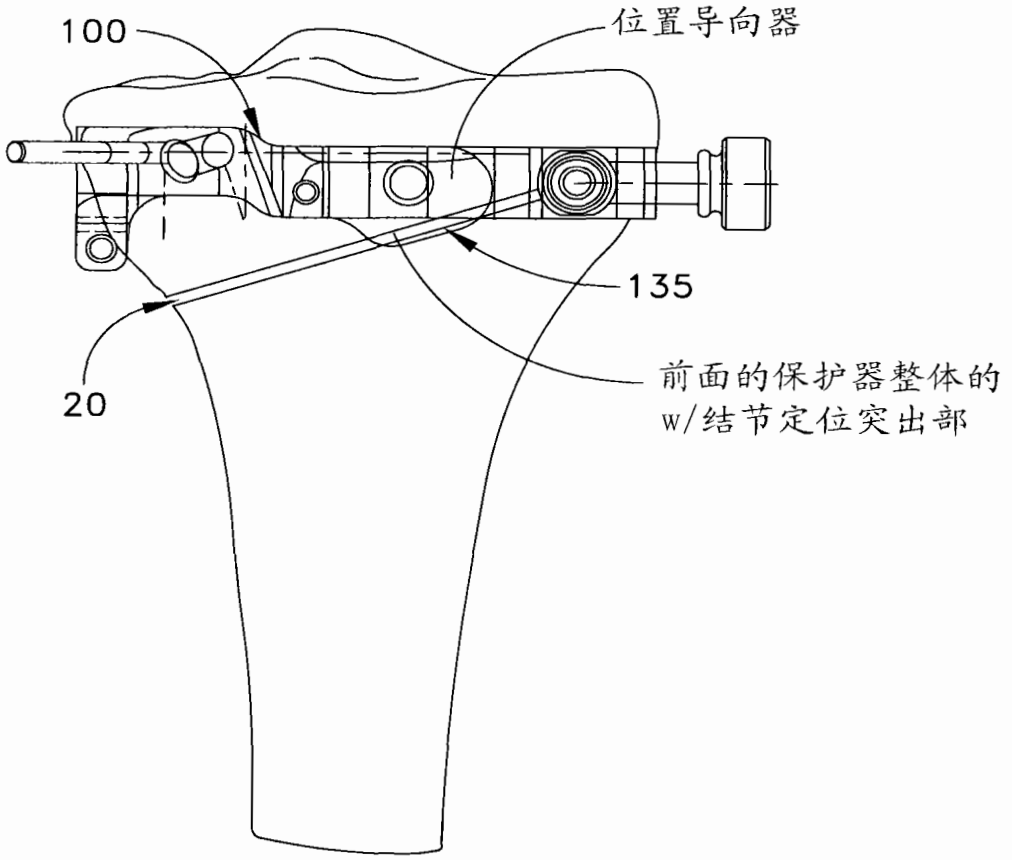


图 15

位置导向器

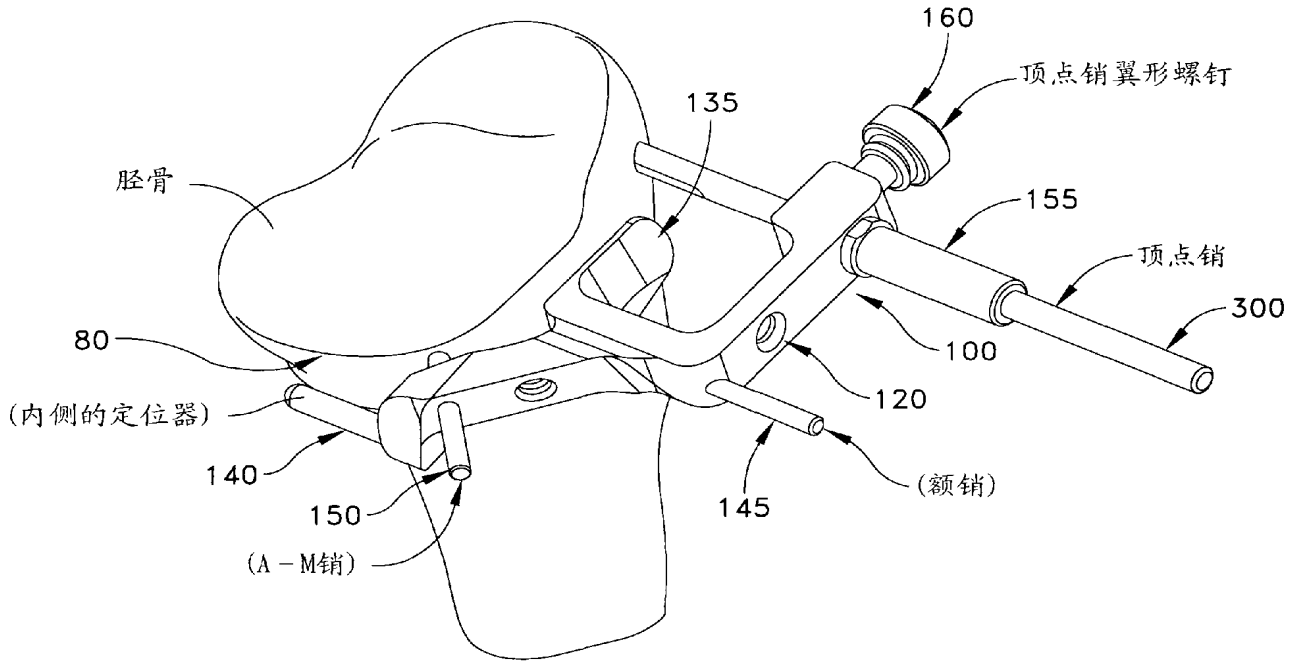

160
顶点销翼形螺钉
135
胫骨
155
顶点销
300
80
100
120
(内侧的定位器)
140
(额销)
145
150
(A－M销)

图 16

用于确定尺寸的固定的距离

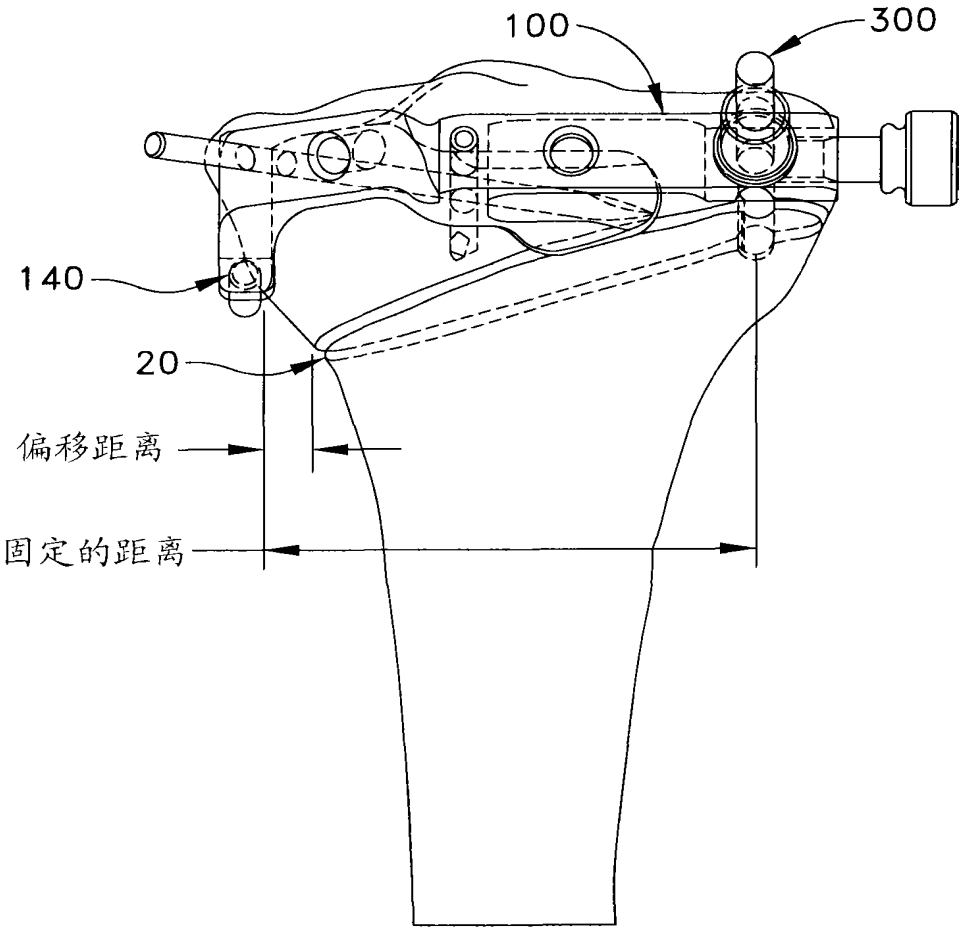


图 17

钻导向器

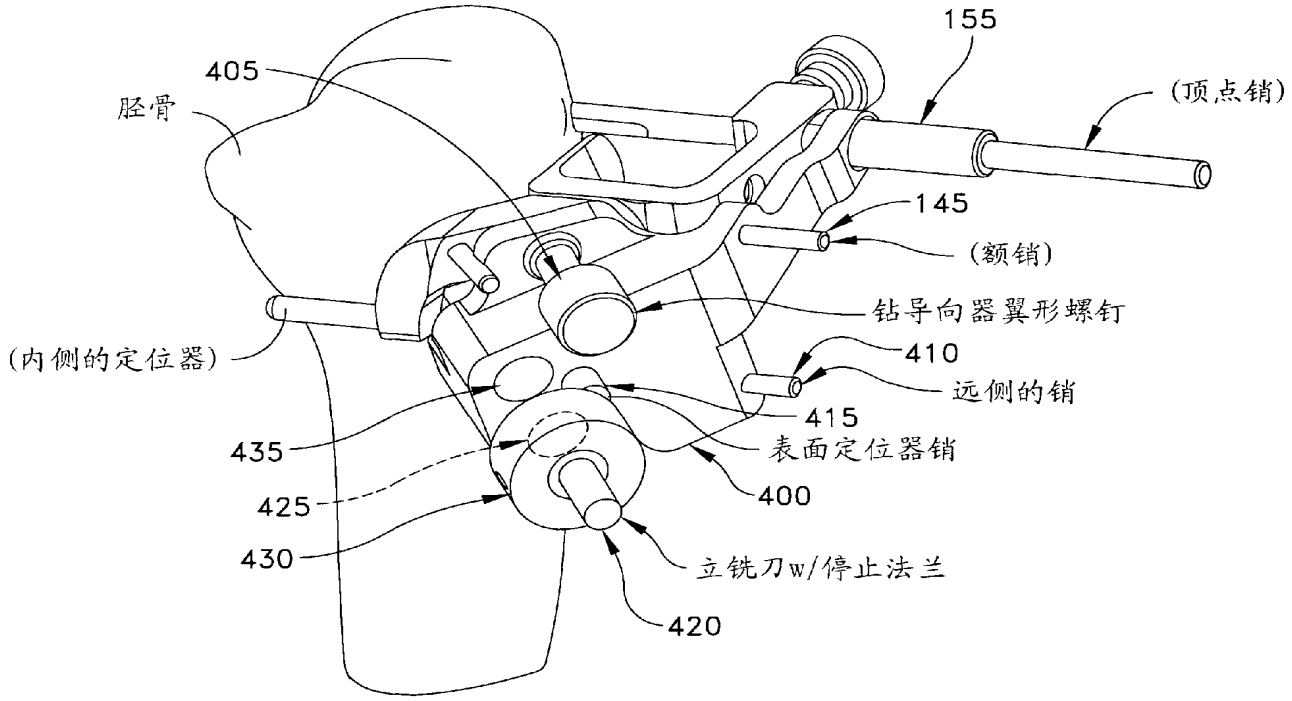

155
405
(顶点销)
胫骨
145
(额销)
钻导向器翼形螺钉
(内侧的定位器)
410
远侧的销
415
435
表面定位器销
400
425
430
立铣刀w/停止法兰
420

图 18

后面的保护器和导引器

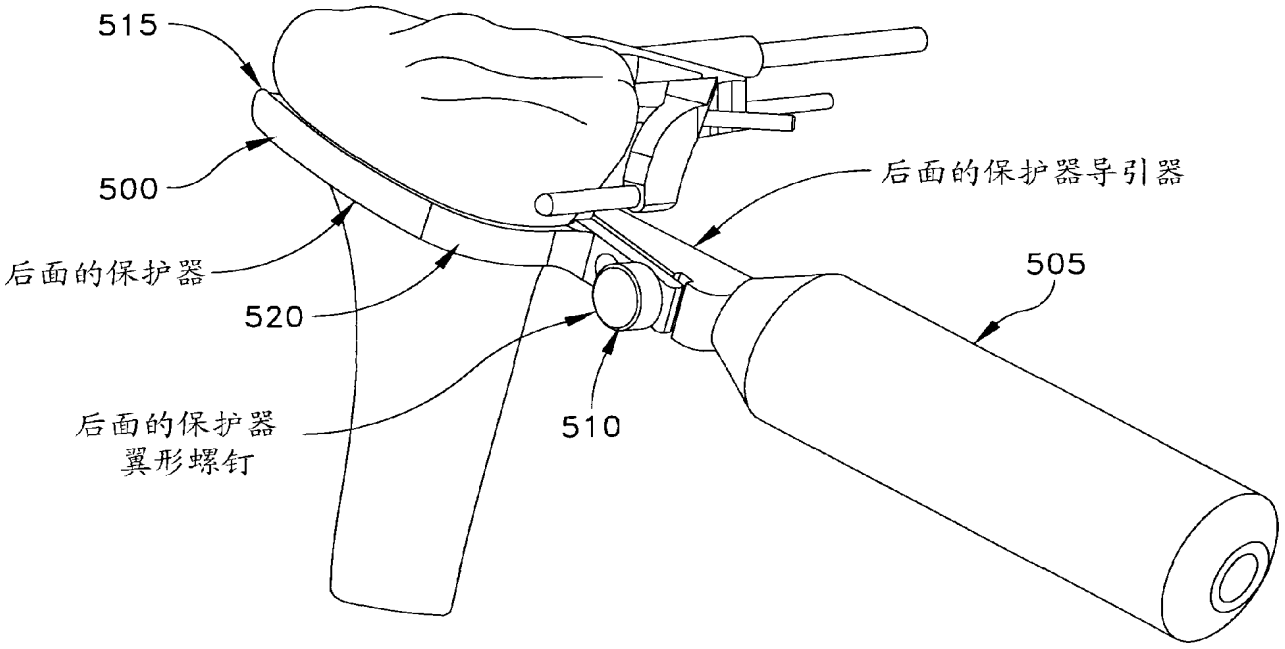


图 19

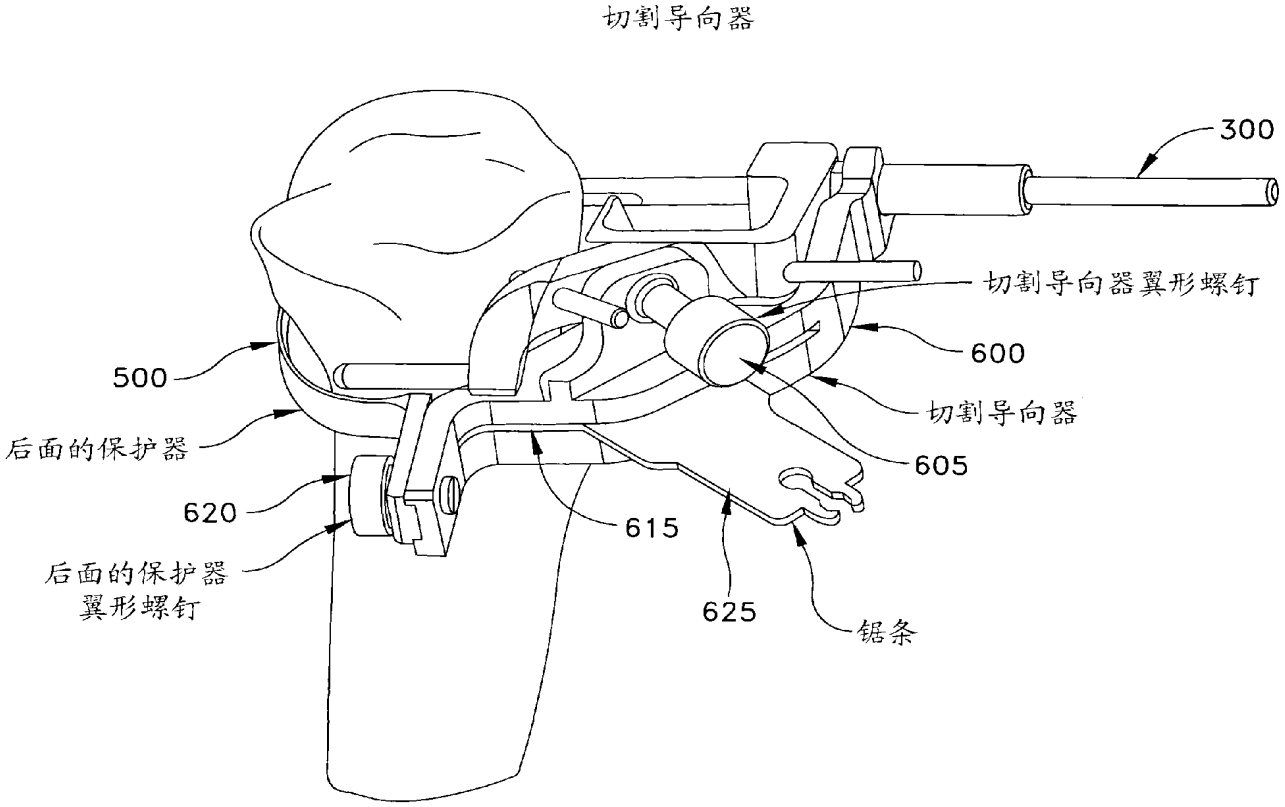

切割导向器
300
切割导向器翼形螺钉
600
500
切割导向器
后面的保护器
605
620
615
后面的保护器
翼形螺钉
625
锯条

图 20

切割导向器对准特征

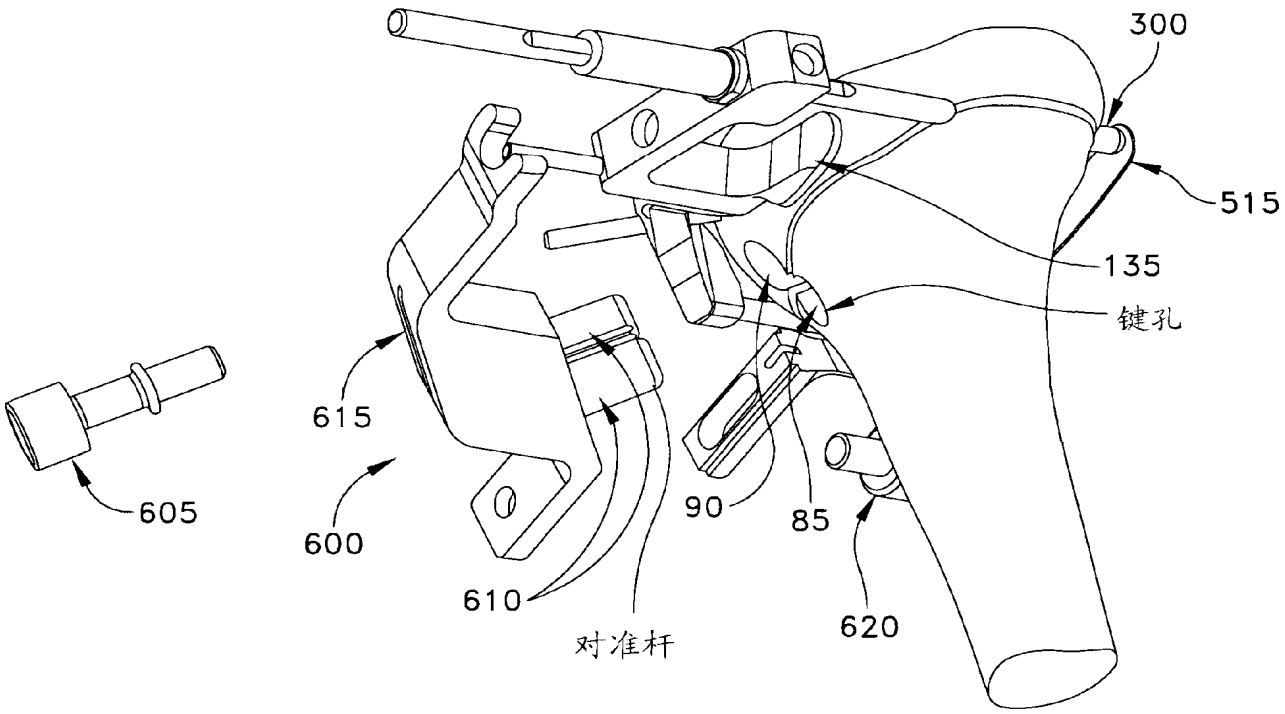


图 21

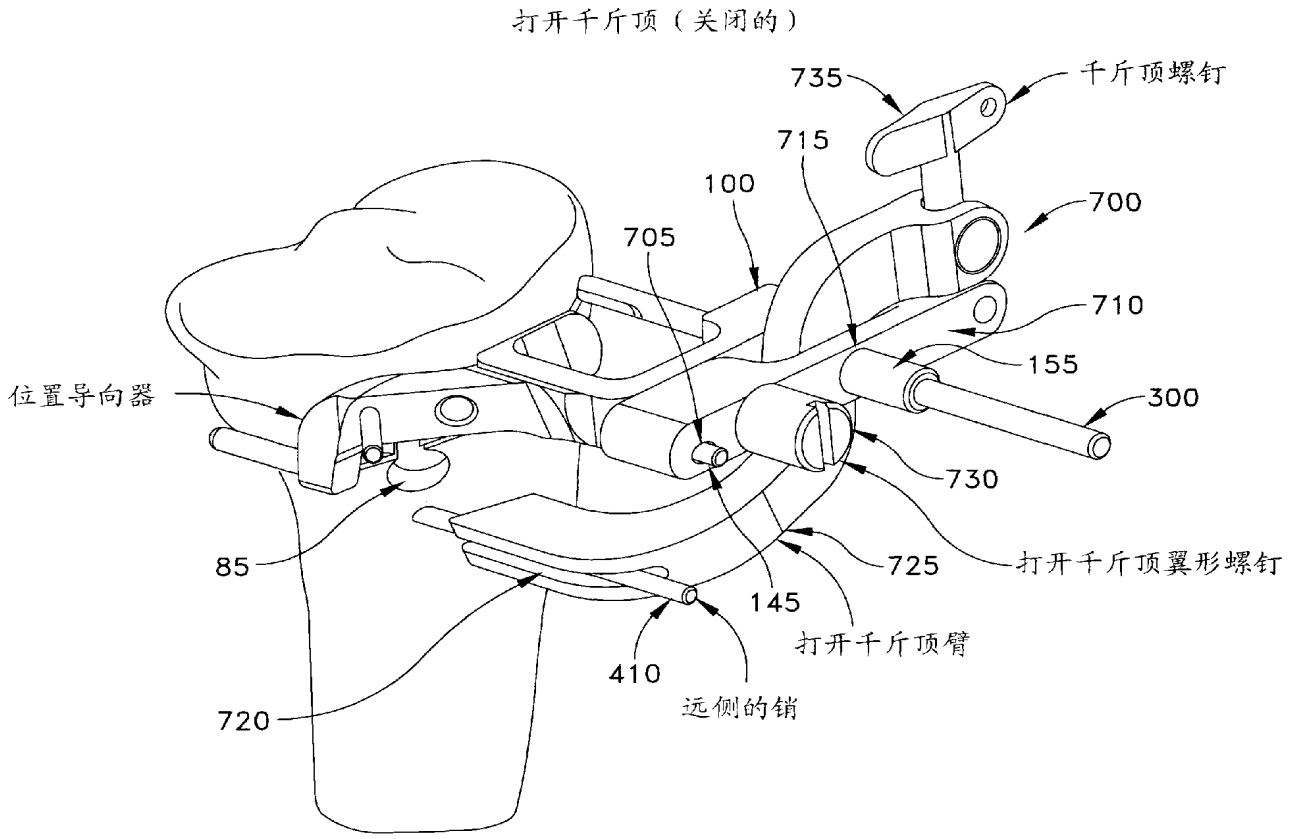

打开千斤顶（关闭的）
735
千斤顶螺钉
715
100
700
705
710
155
位置导向器
300
730
85
725
打开千斤顶翼形螺钉
145
打开千斤顶臂
410
远侧的销
720

图 22

打开千斤顶（打开的）

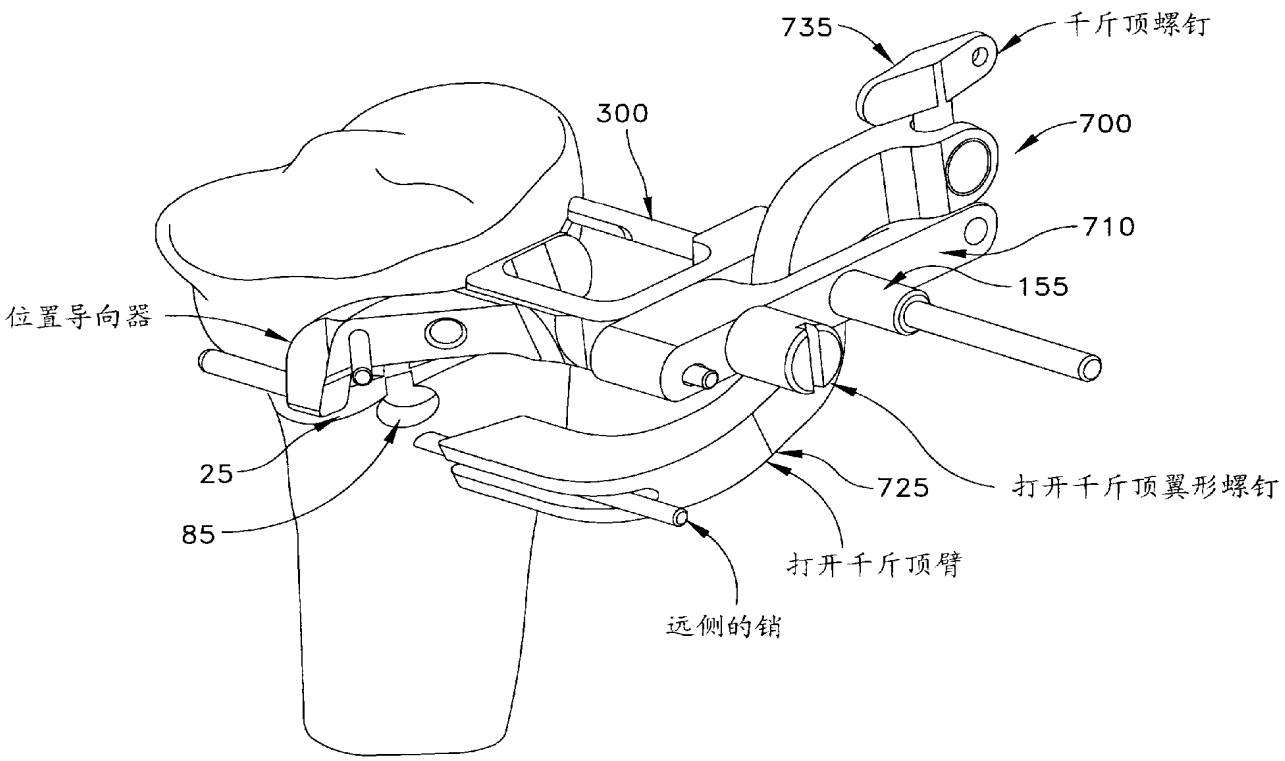


图 23

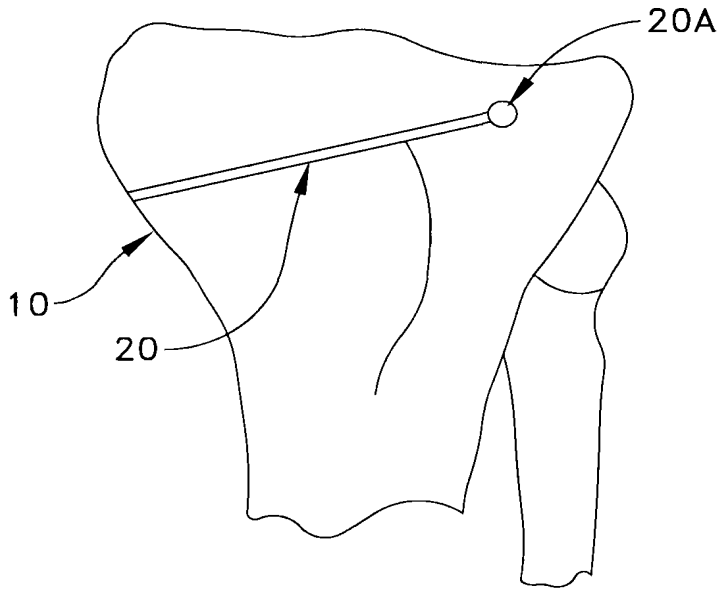


图 23A

植入物部件（装配的）（优选的实施例）

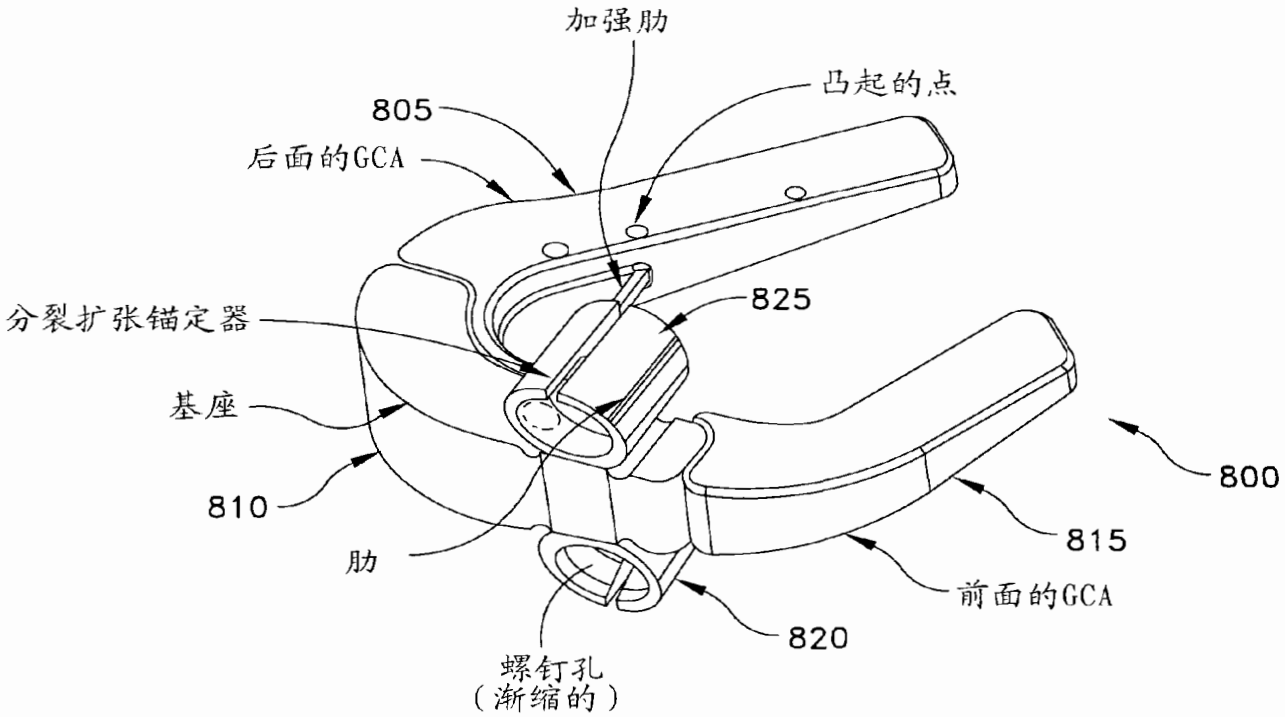


图 24

植入物部件（优选的实施例）

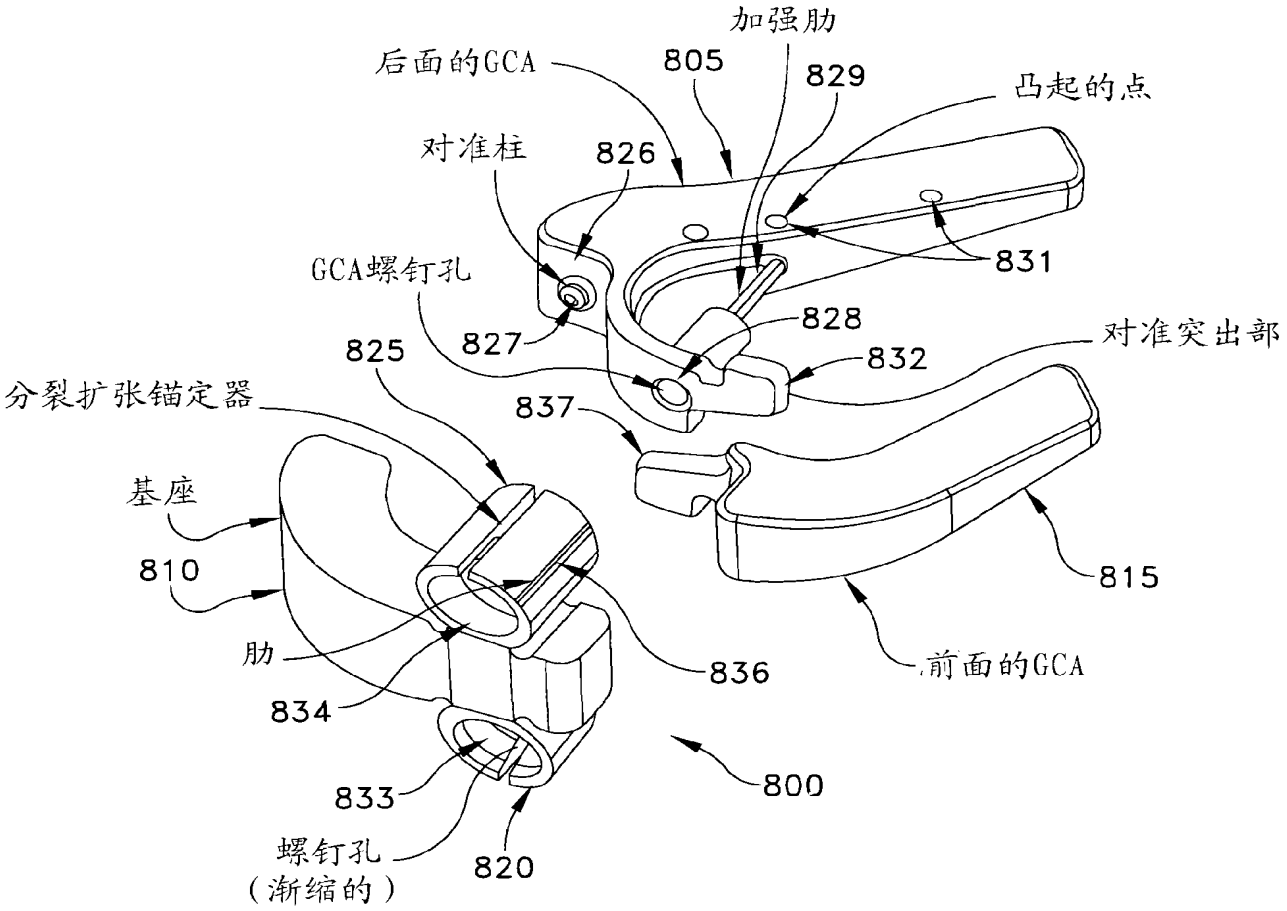


图 25

植入物和固定（优选的实施例）

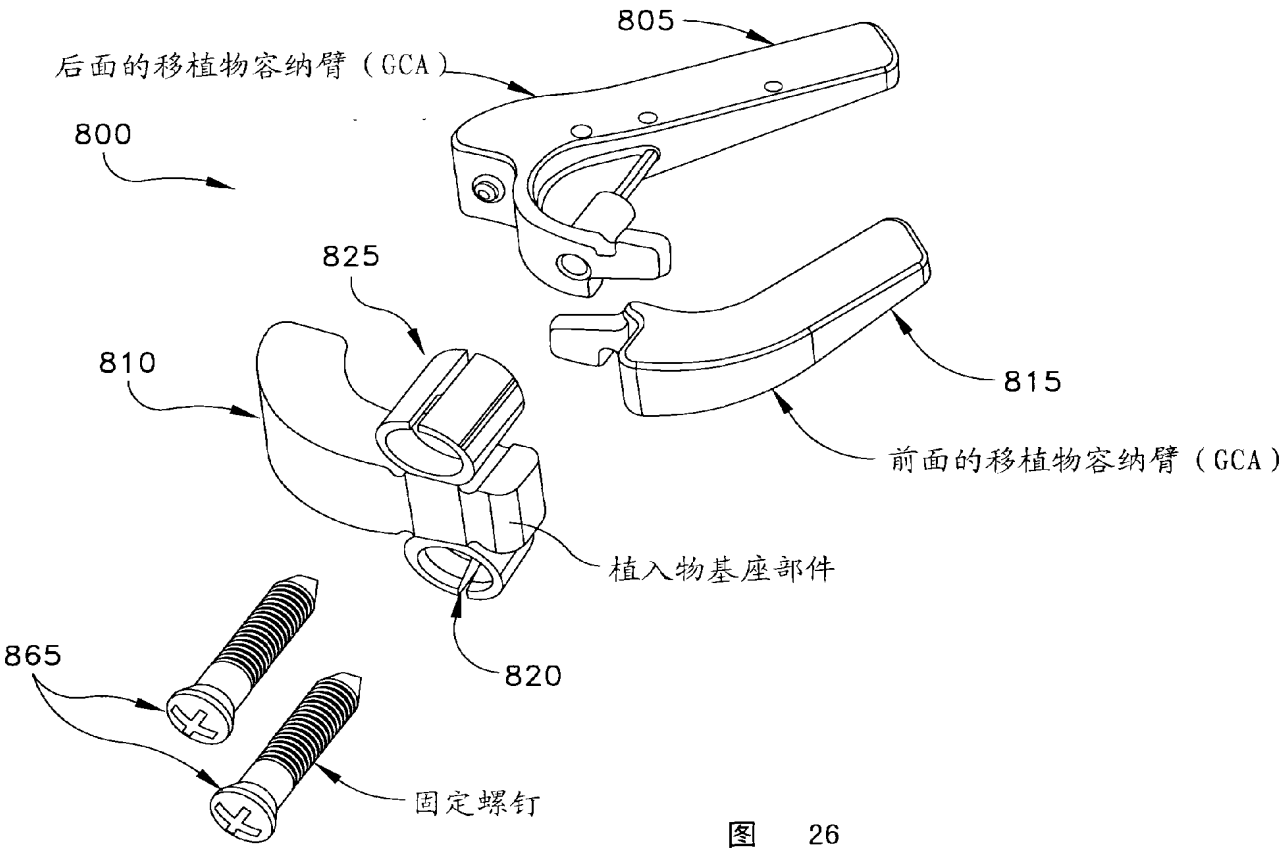


图 26

后面的移植物容纳臂和试验的植入物（后视图）

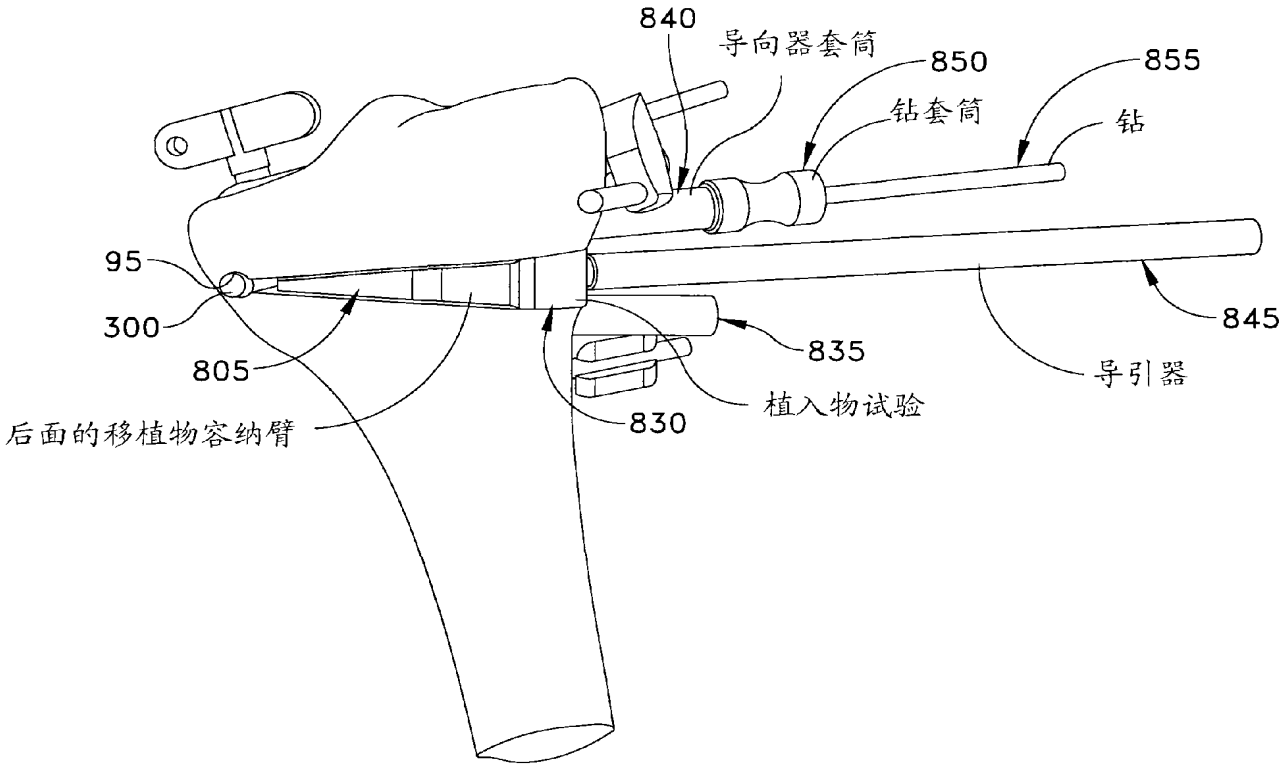


图 27

后面的移植物容纳臂和试验的植入物

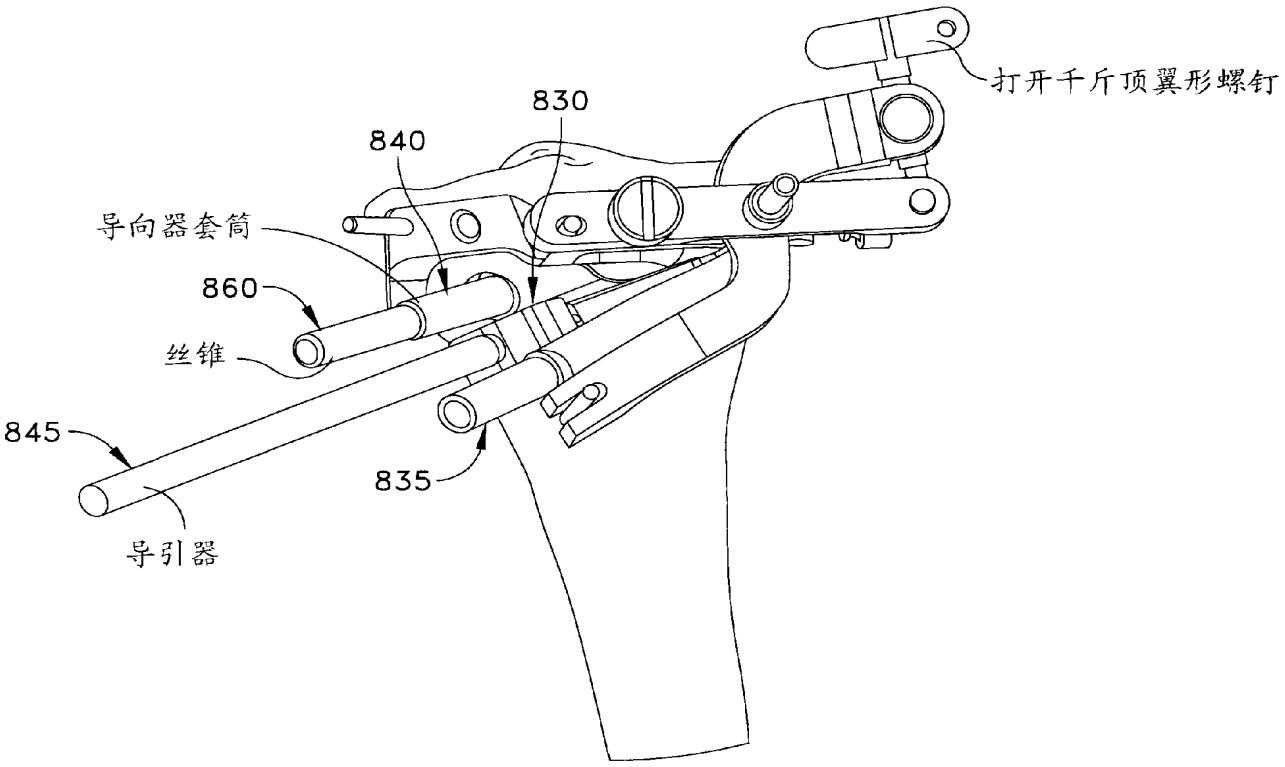


图 28

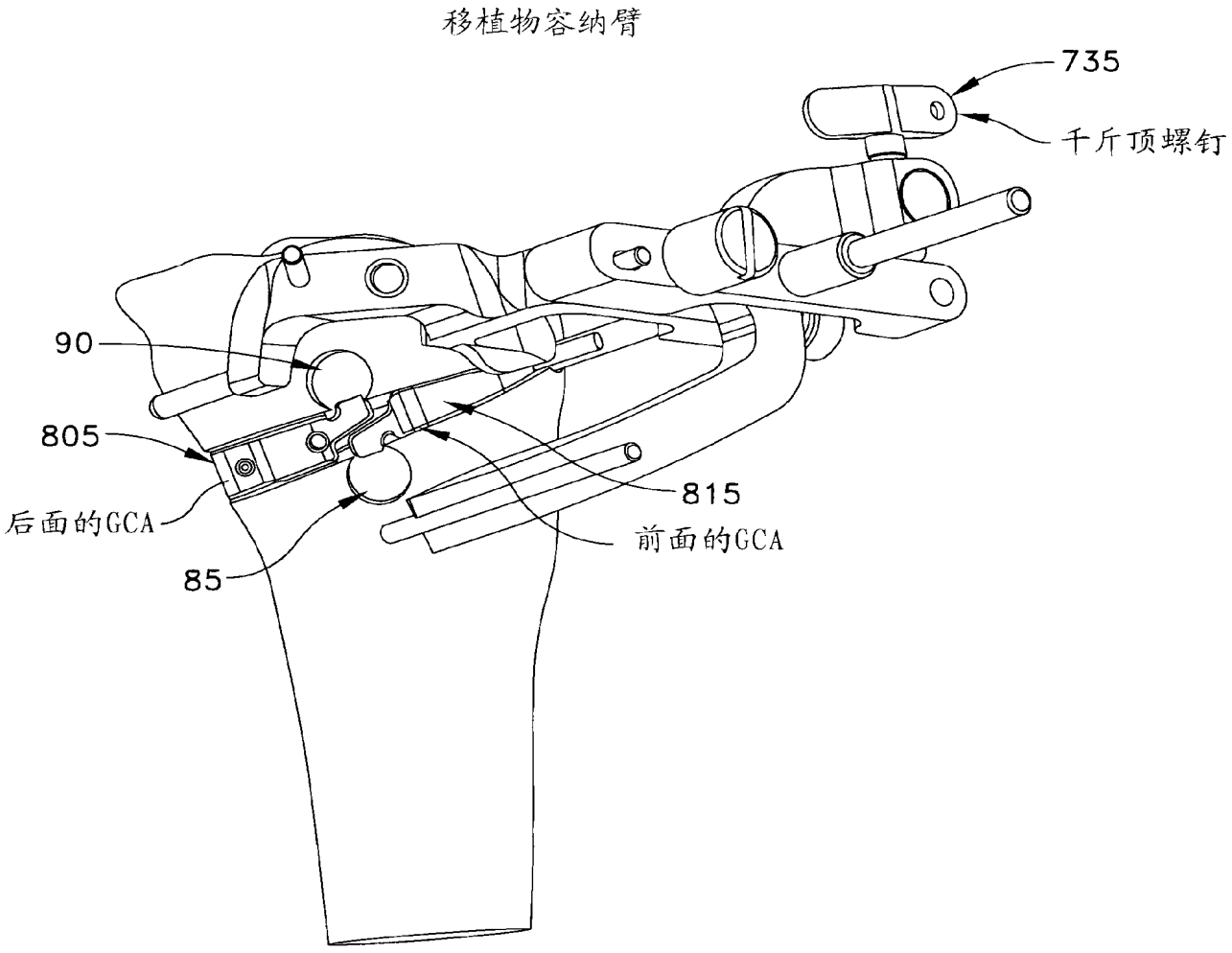


图 29

植入物基座和螺钉

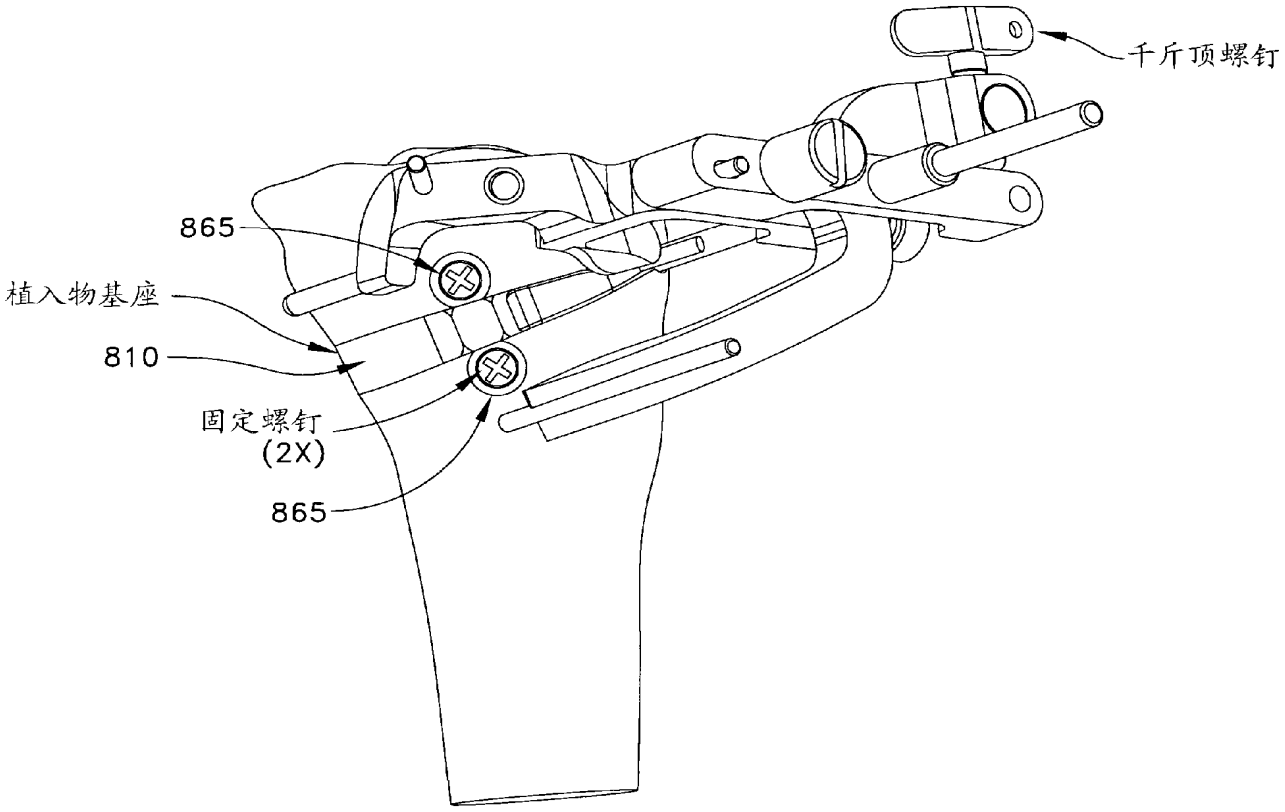


图 30

左腿，前视图

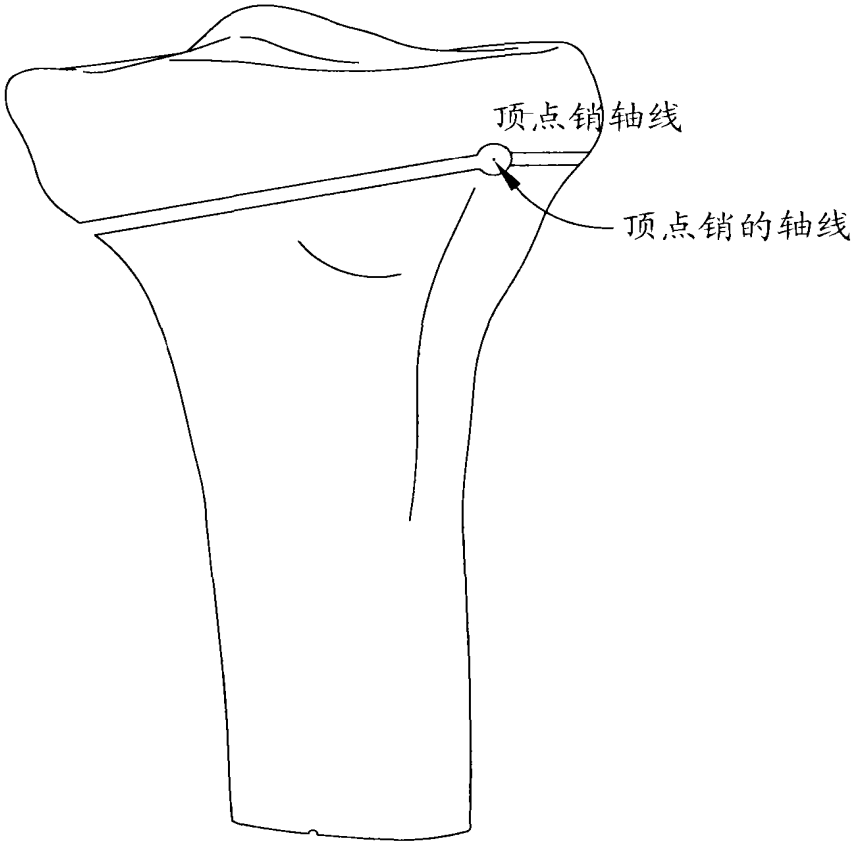


图 31

左腿，外侧的视图

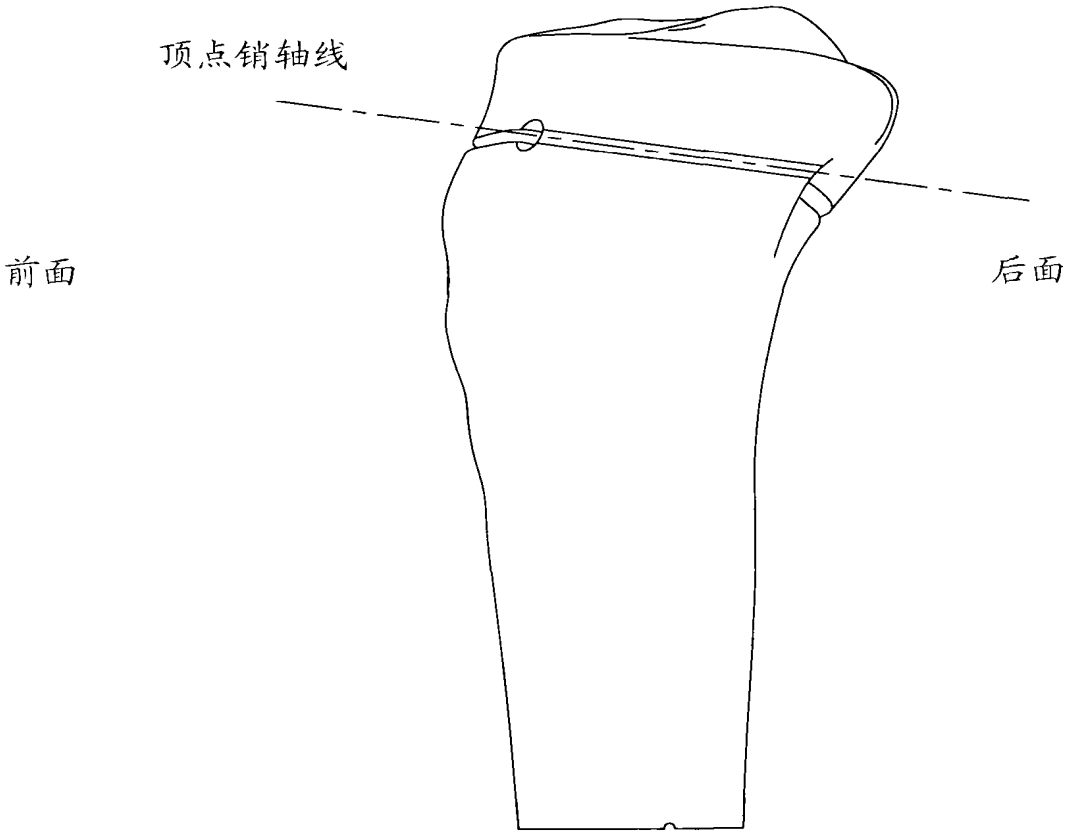


图 32

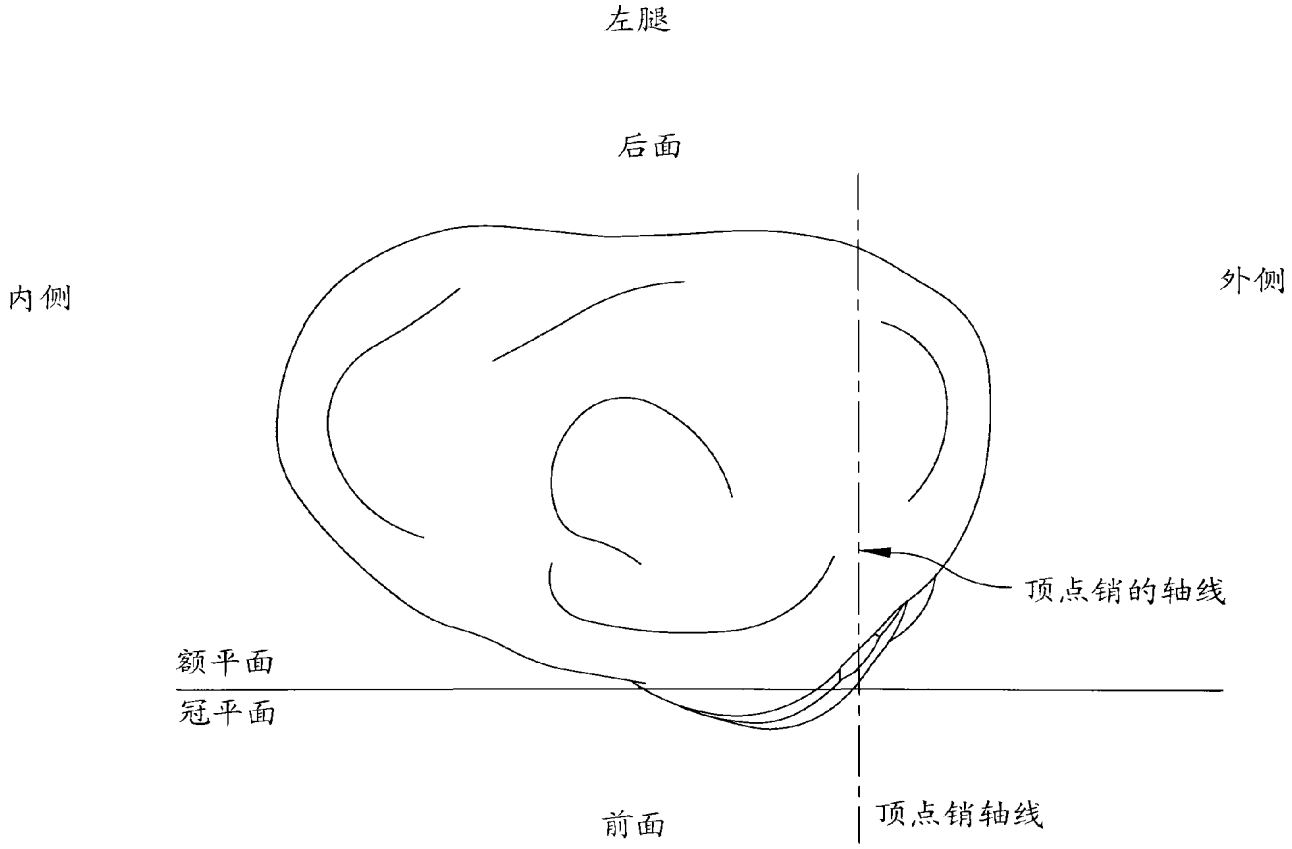


图 33

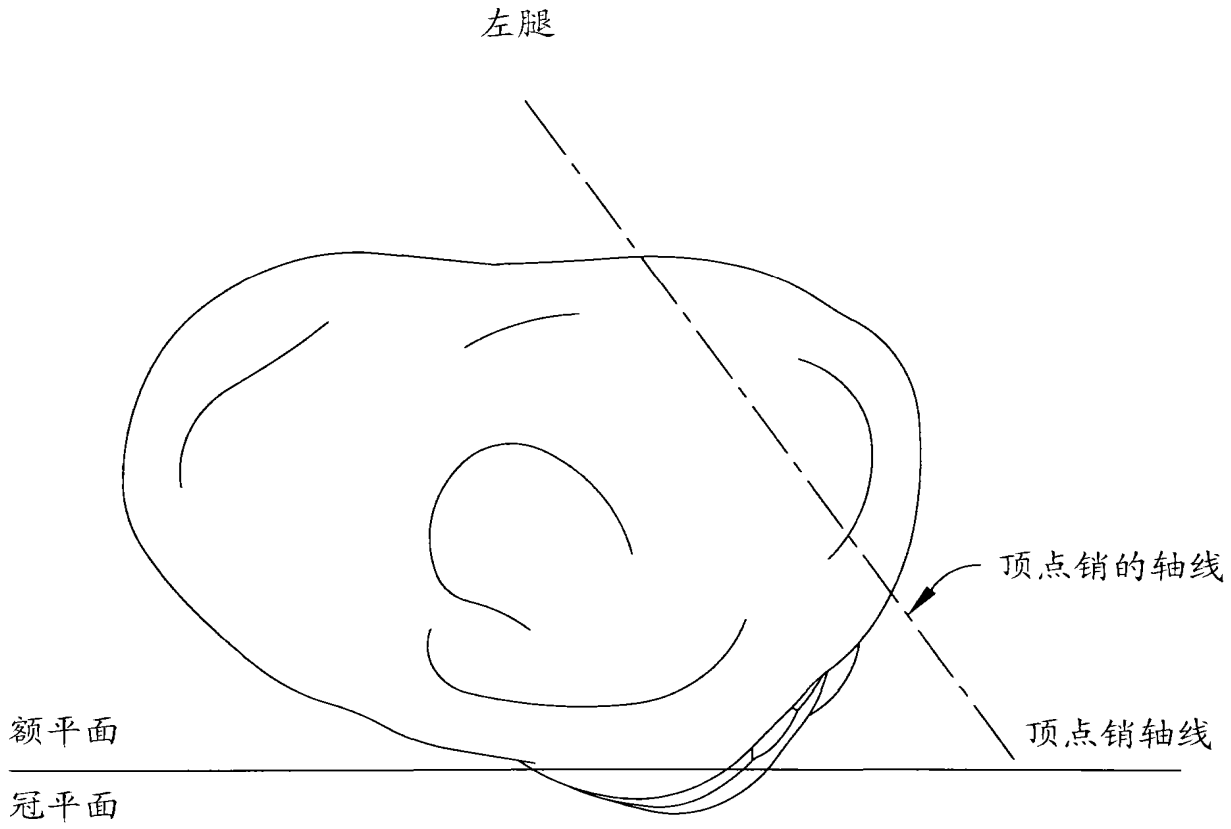


图 34

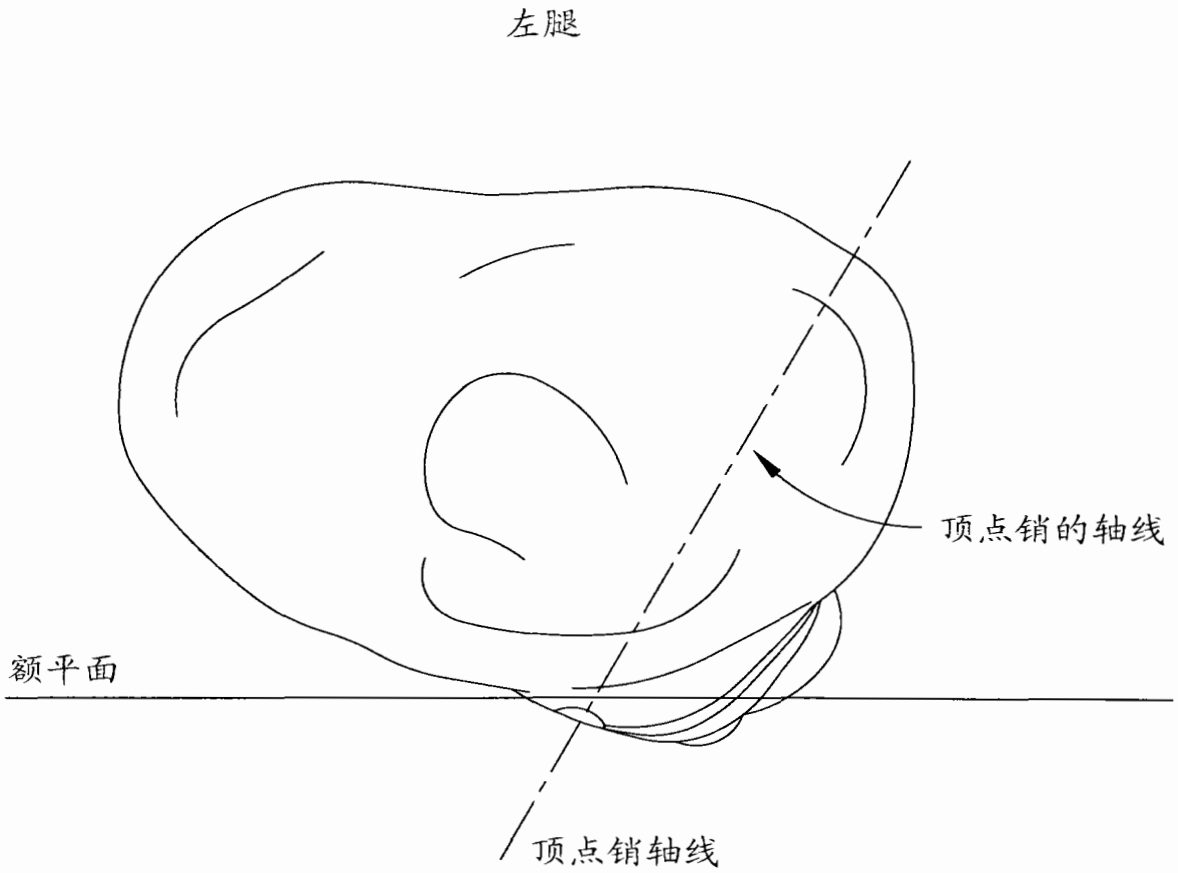


图 35

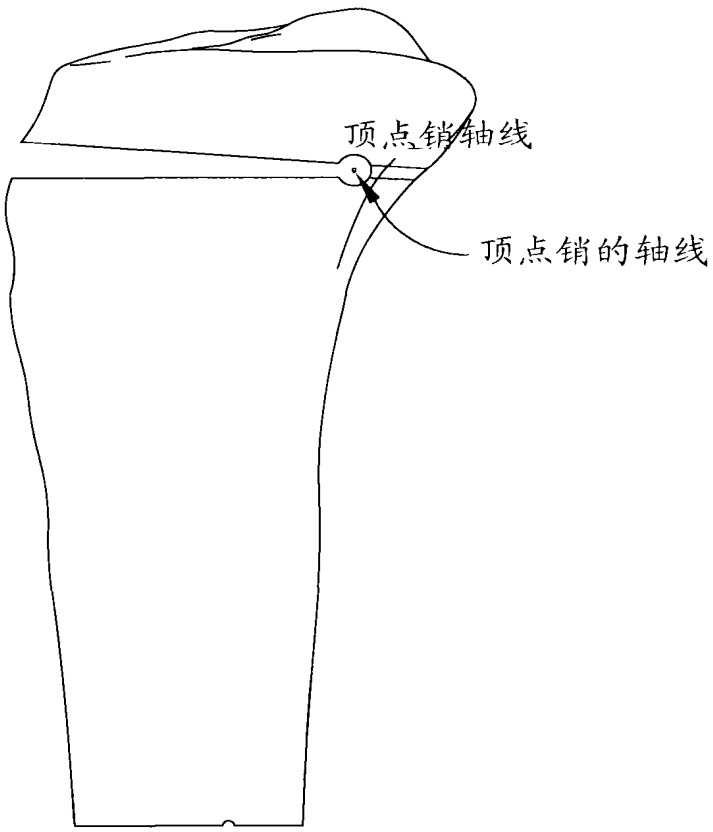


图 36

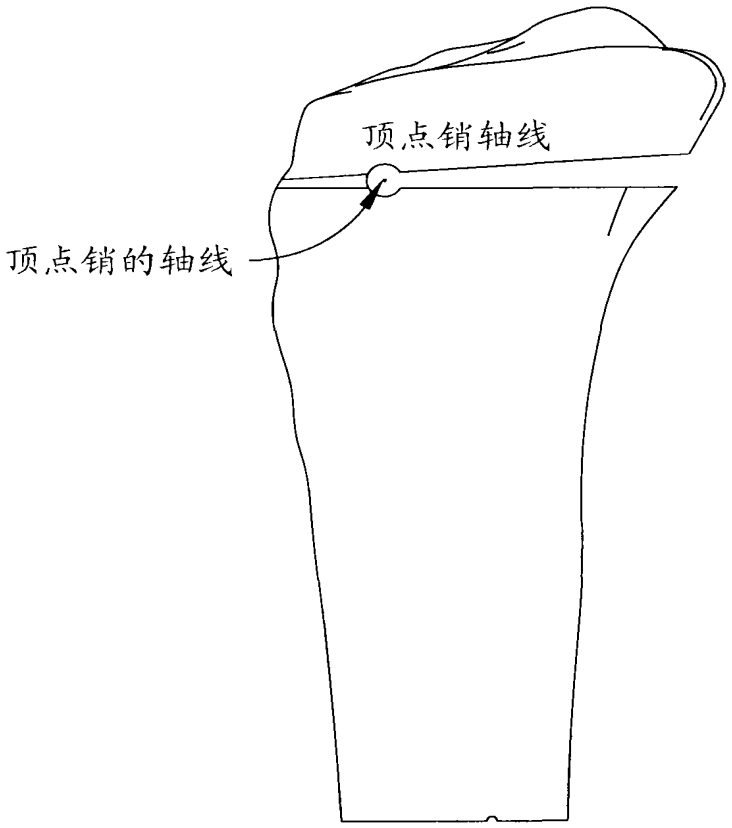


图 37

位置导向器

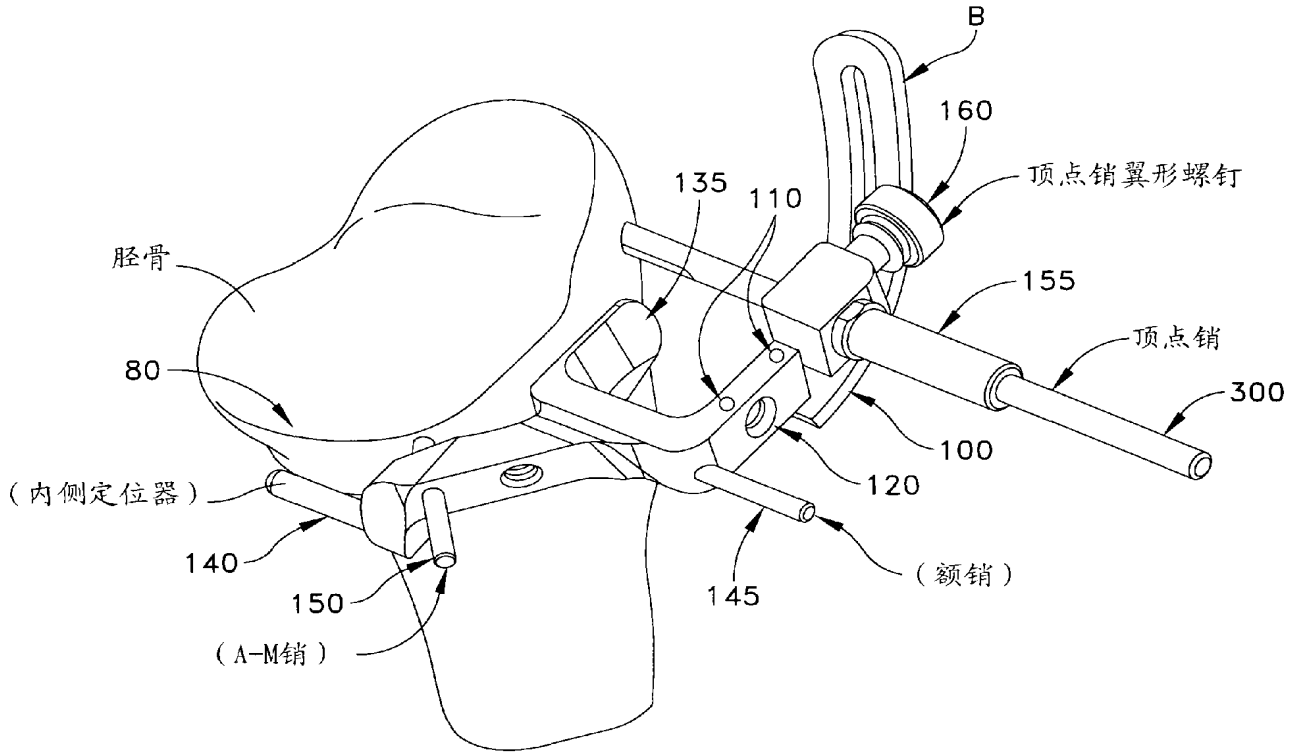

B
160
顶点销翼形螺钉
135
110
胫骨
155
顶点销
80
300
100
120
（内侧定位器）
140
150
（A-M销）
145
（额销）

图 38

Espacenet

Bibliographic data: DE202006010241 (U1) — 2007-02-22

Surgical instrument, especially for an osteotomy, acts as a gage for the saw to guide the blade at a precise and controlled angle

Inventor(s):

Applicant(s): RHEE RYSZARD VAN [DE] ± (RHEE, RYSZARD VAN)

Classification: **- international:** ***A61B17/00; A61B17/15***
- cooperative: **A61B17/15 (EP); A61B17/152 (EP)**

Application number: DE20062010241U 20060701

Priority number(s): DE20062010241U 20060701

Abstract of DE202006010241 (U1)

The surgical instrument for an osteotomy, especially in the treatment of a displaced great toe in relation to the others, acts as a gage for the saw with a saw blade guide and a hinged bone laying surface as an extension of the hand grip. An indicator shows the angle between them.

(19) Bundesrepublik Deutschland
Deutsches Patent- und Markenamt

(10) **DE 20 2006 010 241 U1** 2007.03.29

(12) # Gebrauchsmusterschrift

(21) Aktenzeichen: **20 2006 010 241.8**
(22) Anmeldetag: **01.07.2006**
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(43) Bekanntmachung im Patentblatt: **29.03.2007**

(51) Int Cl.[8]: ***A61B 17/15*** (2006.01)
A61B 17/00 (2006.01)

(73) Name und Wohnsitz des Inhabers:
Rhee, Ryszard van, Dr.med., 30559 Hannover, DE

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Bezeichnung: **Sägelehre zur winkelgenauen Anlage einer Osteotomie an kleinen Röhrenknochen**

(57) Hauptanspruch: Chirurgisches Instrument, dadurch gekennzeichnet, dass es aus einer Knochenauflage und einer Sägeblattführung besteht, in deren Verlängerung ein Handgriff angebracht ist.

Beschreibung

[0001] Die basisnahe Osteotomie (Knochendurchtrennung) ist eine chirurgische Operationstechnik zur Behandlung von Vorfußdeformitäten, meist Hallux valgus. Bei der aufklappenden Osteotomie wird der Knochen inkomplett quer zur Achse durchtrennt und unter Erhalt der fibularen Cortikalis aufgespreizt, um dadurch eine Achskorrektur vorzunehmen. Bei der zuklappenden Osteotomie wird ein Keil aus dem Knochen heraus genommen und die Osteotomie dann geschlossen. Bei der sog. Chevron-Osteotomie (körperferne Osteotomie des ersten Mittelfußknochens) erfolgt ebenfalls eine quere Osteotomie.

[0002] Die Osteotomien am ersten Mittelfußknochen erfolgen bislang ohne Kontrolle der genauen Winkelstellung der Osteotomie zur Längsachse des Knochens. Dabei führt eine schräge Anlage der Osteotomie zu einer Veränderung der Beinlänge des Mittelfußknochens mit Auswirkungen auf die Belastung des Mittelfußes.

[0003] Die Erfindung soll eine kontrollierte, winkelgenaue Durchführung der Osteotomie ermöglichen.

[0004] Die Sägelehre besteht aus einer Sägeblattführung und einer in einem verstellbaren Winkel mit Anzeige angebrachten Knochenauflage. Der eingestellte Winkel lässt sich mittels einer von Hand bedienbaren Schraube arretieren. Die Anzeige erlaubt den beidseitigen Einsatz der Sägelehre. Das Gerät wird an einem Handgriff gehalten, der abgewinkelt in Verlängerung der Sägeblattführung angebracht ist. Nach Einstellung des gewünschten Winkels erfolgt Anlage der Sägelehre mit der Knochenauflage an den Knochen und Durchführung des Knochenschnittes.

Schutzansprüche

1. Chirurgisches Instrument, **dadurch gekennzeichnet**, dass es aus einer Knochenauflage und einer Sägeblattführung besteht, in deren Verlängerung ein Handgriff angebracht ist.

2. Chirurgisches Instrument nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Knochenauflage und die Sägeblattführung mittels eines Scharniers miteinander verbunden sind.

3. Chirurgisches Instrument nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass es mit einer Winkelanzeigevorrichtung ausgestattet ist, die den Winkel zwischen der Knochenauflage und der Sägeblattführung anzeigt.

Es folgt kein Blatt Zeichnungen

Espacenet

Bibliographic data: DE102007053058 (B3) — 2009-04-09

Surgical saw jig, has lower contact surface extending transverse to side surfaces for contacting bones, and wedge edge running at angle to longitudinal extension of contact surface, where angle deviates from specific degrees

Inventor(s): PECH UWE [DE]; VITEK MICHAEL [AT] ± (PECH, UWE, ; VITEK, MICHAEL)

Applicant(s): NORMED MEDIZIN TECHNIK VERTRIE [DE] ± (NORMED MEDIZIN-TECHNIK VERTRIEBS-GMBH)

Classification: **- international:** ***A61B17/15***
- cooperative: **A61B17/151 (EP)**

Application number: DE20071053058 20071105

Priority number (s): DE20071053058 20071105

Abstract of DE102007053058 (B3)

The jig (1) has a pair of side surfaces (3, 4) with a common wedge edge (5), where the surfaces are arranged with a wedge edge angle (beta) between each other. A lower contact surface (2) extends approximately transverse to the side surfaces for contacting bones. The wedge edge runs at an angle to a longitudinal extension of the contact surface, where the angle deviates from 90 degrees. The wedge edge extends in the longitudinal direction of the jig away from the contact surface. The wedge edge angle is constant over the longitudinal extension of the wedge edge.

(19) Bundesrepublik Deutschland
Deutsches Patent- und Markenamt

(10) **DE 10 2007 053 058 B3** 2009.04.09

(12) # Patentschrift

(21) Aktenzeichen: **10 2007 053 058.9**
(22) Anmeldetag: **05.11.2007**
(43) Offenlegungstag: –
(45) Veröffentlichungstag der Patenterteilung: **09.04.2009**

(51) Int Cl.[8]: ***A61B 17/15*** (2006.01)

Innerhalb von drei Monaten nach Veröffentlichung der Patenterteilung kann nach § 59 Patentgesetz gegen das Patent Einspruch erhoben werden. Der Einspruch ist schriftlich zu erklären und zu begründen. Innerhalb der Einspruchsfrist ist eine Einspruchsgebühr in Höhe von 200 Euro zu entrichten(§ 6 Patentkostengesetz in Verbindung mit der Anlage zu § 2 Abs. 1 Patentkostengesetz).

(73) Patentinhaber:
Normed Medizin-Technik Vertriebs-GmbH, 78532 Tuttlingen, DE

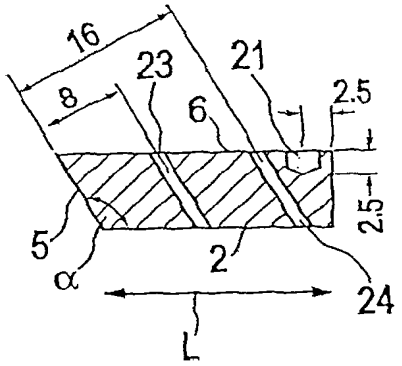
(74) Vertreter:
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(72) Erfinder:
Pech, Uwe, 78532 Tuttlingen, DE; Vitek, Michael, Dr., Wien, AT

(56) Für die Beurteilung der Patentfähigkeit in Betracht gezogene Druckschriften:
NICHTS ERMITTELT;

(54) Bezeichnung: **Chirurgische Sägelehre sowie Sägelehrensatz**

(57) Zusammenfassung: Die Erfindung betrifft eine chirurgische Sägelehre (1) mit zwei, eine gemeinsame Keilkante (5) aufweisenden und winklig unter mindestens einem Keilkantenwinkel (?) zueinander angeordneten Seitenflächen (3, 4), und mit einer unteren, sich zumindest näherungsweise quer zu den Seitenflächen (3, 4) erstreckenden Anlagefläche (2) zur Anlage an einem Knochen. Erfindungsgemäß ist vorgesehen, dass die Keilkante (5) unter einem von 90° abweichenden Winkel (?) zur Längserstreckung (L) der Anlagefläche (2) verläuft. Ferner betrifft die Erfindung einen Sägelehrensatz.



Beschreibung

[0001] Die Erfindung betrifft eine chirurgische Sägelehre gemäß Anspruch 1 sowie einen Sägelehrensatz gemäß Anspruch 12.

[0002] In der Fußchirurgie sind Sägelehren bekannt, entlang derer der Chirurg mittels einer Knochensäge einen Metatarsalknochen durchtrennen kann. Um den Metatarsalknochen um eine erforderliche Länge zu kürzen, wird nach einem ersten Durchtrennen des Metatarsalknochens die Sägelehre in Längsrichtung des Metatarsalknochens verschoben und durch Sägen entlang der Sägelehre ein Zwischenstück des Metatarsalknochens abgetrennt. Daraufhin werden die verbleibenden Metatarsalknochensegmente mit Hilfe von Knochenschrauben aneinander fixiert. In der Praxis kommen dabei Sägelehren zum Einsatz mit denen entweder ein gerader Schnitt, ein schräger Schnitt, ein Z-förmig konturierter Schnitt oder ein V-förmig konturierter Schnitt ausgeführt werden können. Bei bekannten Sägelehren, mit denen der Metatarsalknochen mit einem V-förmigen Schnitt durchtrennt werden kann, erstreckt sich eine vordere Keilkante der spitz zulaufenden Sägelehre im rechten Winkel zur Längserstreckung einer Anlagefläche der Sägelehre, mit der die Sägelehre am Metatarsalknochen anlegbar ist.

[0003] Bei geraden oder schrägen Schnitten ist von Nachteil, dass die gebildeten Knochensegmente nur mit Hilfe mehrerer Knochenschrauben rotationsstabil aneinander fixierbar sind. Bei sämtlichen bekannten Schnitt-Formen ist darüber hinaus nachteilig, dass, wenn die erhaltenen Knochensegmente in Längsrichtung des Knochens relativ mit Abstand zueinander verschoben angeordnet werden sollen, ein zwangsläufig zwischen diesen entstehender Spalt mit Knochenmaterial aufgefüllt werden muss, um eine stabile dauerhafte Fixation der Knochensegmente aneinander mit Hilfe von Knochenschrauben zu ermöglichen.

[0004] Der Erfindung liegt die Aufgabe zugrunde, eine alternative Sägelehre vorzuschlagen, mit der ein Knochen derart durchtrennbar ist, dass eine rotationsstabile Fixation der entstehenden Knochensegmente mit nur einer Knochenschraube möglich ist. Bevorzugt soll die Sägelehre derart beschaffen sein, dass zwei mit dieser geschaffene Knochensegmente in Längsrichtung des Knochens relativ zueinander verstellt werden können, ohne dass dabei ein Spalt zwischen den Knochensegmenten entsteht. Ferner besteht die Aufgabe darin, einen Sägelehrensatz, umfassend mehrere entsprechend verbesserte Sägelehren vorzuschlagen. Insbesondere soll der Sägelehrensatz derart beschaffen sein, dass mit diesem ein Knochen präzise um eine erforderliche Länge gekürzt werden kann.

[0005] Diese Aufgabe wird hinsichtlich der Sägelehre mit den Merkmalen des Anspruchs 1 und hinsichtlich des Sägelehrensatzes mit den Merkmalen des Anspruchs 12 gelöst. Vorteilhafte Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben. In den Rahmen der Erfindung fallen auch sämtliche Kombinationen aus zumindest zwei von in der Beschreibung, den Ansprüchen und/oder den Figuren angegebenen Merkmalen.

[0006] Der Erfindung liegt der Gedanke zugrunde, die chirurgische Sägelehre gemäß einer ersten Alternative im Wesentlichen schiffsbugförmig auszubilden, also die Keilkante einer zumindest in einem vorderen Bereich im Wesentlichen keilförmigen Sägelehre nicht rechtwinklig zur Längserstreckung der Anlagefläche sondern unter einem von 90° abweichenden Winkel zur Längserstreckung der Anlagefläche anzuordnen. Hierdurch wird eine im Wesentlichen V-förmige Schnittkontur erhalten, bei der die zur Keilkante der Sägelehre korrespondierende Scheitellinie des Schnittes nicht senkrecht zur Knochenoberfläche, sondern unter einem vom 90° abweichenden Winkel zu dieser verläuft. Werden zwei auf diese Weise voneinander getrennte Knochensegmente relativ zueinander in Hochrichtung verschoben, derart, dass die beiden Knochenelemente weiterhin aneinander anliegen, resultiert aufgrund der schrägen Schnittanordnung automatisch eine Verstellung der Knochensegmente relativ zueinander entlang ihrer Längserstreckung, wobei sich zwischen den Knochensegmenten eine Stufe ausbildet, die umso größer wird, je weiter die Knochensegmente relativ zueinander entlang der Schnitterstreckung verschoben werden. Die beiden Knochensegmente liegen also, obwohl sie in Längsrichtung zueinander verstellt wurden, zumindest in einem Teilbereich in axialer Richtung aneinander an, sodass kein mit Knochenmaterial aufzufüllender Spalt entsteht. Ein weiterer Vorteil einer nach dem Konzept der Erfindung ausgebildeten Sägelehre besteht darin, dass zwei Knochensegmente mit nur einer Schraube rotationsstabil fixiert werden können. Die Knochenschraube wird hierzu bevorzugt von dem proximalen Knochensegment schräg in Richtung des distalen Knochensegments geführt. Es liegt im Rahmen der Erfindung, dass die Anlagefläche, beispielsweise durch das Vorsehen einer konkaven Wölbung, an die Außenkontur des zu durchtrennenden Knochens angepasst ist. Es ist jedoch auch eine Ausführungsform der Sägelehre realisierbar, bei der die Anlagefläche eben ausgebildet ist. Eine nach dem Konzept der Erfindung ausgebildete chirurgische Sägelehre eignet sich insbesondere als Fußchirurgiesägelehre, vorzugsweise zum präzisen Durchtrennen eines Metatarsalknochens, bzw. einen Metatarsalknochen um eine erforderliche Länge zu kürzen. Die Erfindung ist jedoch nicht auf fußchirurgische Sägelehren beschränkt. So können mit einer nach dem Konzept der Erfindung ausgebildeten Sägelehre bei entsprechender Dimensionierung

auch andere tierische, oder bevorzugt menschliche Knochen, wie Arm- oder Beinknochen präzise durchtrennt und ggf. um eine erforderliche Länge gekürzt werden.

[0007] Neben der zuvor beschriebenen ersten Alternative bei der die Sägelehre schiffsbugartig ausgeformt ist, also neben einer Sägelehre, bei der die Keilkante der Sägelehre sich in Längserstreckung der Sägelehre gesehen von der Anlagefläche weg erstreckt und somit eine vordere Keilkante bildet, ist eine zweite Alternative realisierbar, bei der die Keilkante nicht nach vorne, sondern rückwärtig geneigt ist, also mit der Anlagefläche einen Winkel von weniger als 90° einschließt und somit als innere Keilkante ausgebildet ist. Auch bei dieser zweiten Alternative ist es möglich, die beiden mit Hilfe der Sägelehre geschaffenen Knochensegmente durch relatives Verstellen zueinander in Hochrichtung, gleichzeitig in Längsrichtung, relativ zueinander zu verstellen, und gleichzeitig eine zumindest abschnittsweise Anlage der Schnittflächen der Knochensegmente aneinander zu gewährleisten. Bei einer nach hinten geneigten Keilkante liegen die Seitenflächen einander schräg gegenüber, wohingegen bei einer nach vorne geneigten Keilkante die Seitenflächen nach außen weisende Seiten der Sägelehre bilden. Die Sägelehre weist also einen inneren Keil auf. Sämtliche vorgenannten, in Zusammenhang mit der ersten Alternative erläuterten Vorteile gelten als entsprechend.

[0008] Von besonderem Vorteil in Hinblick auf die Realisierung möglichst großer Anlageflächen ist eine Ausführungsform, bei der sich der Keilkantenwinkel über seine Längserstreckung nicht ändert. Anders ausgedrückt sind die Seitenflächen der Sägelehre, entlang derer vom Chirurgen die Säge geführt wird, lediglich unter einem einzigen Winkel, nämlich dem Keilkantenwinkel, zueinander geneigt. Bei dieser Ausführungsform verlaufen die Seitenflächen senkrecht zur Längserstreckung der Anlagefläche, bzw. bei einer ebenen Anlagefläche senkrecht zu dieser.

[0009] Besonders bevorzugt ist eine Ausführungsform, bei der auf der von der Anlagefläche abgewandten Seite der Sägelehre eine Oberfläche vorgesehen ist, die sich zumindest näherungsweise parallel zur Anlagefläche erstreckt. Sowohl die Oberfläche als auch die Anlagefläche weisen einen vorderen, keilförmigen Flächenabschnitt auf, wobei die Flächenabschnitte entlang der Längserstreckung der Sägelehre zueinander versetzt angeordnet sind, also in Hochrichtung der Sägelehre nicht miteinander fluchten. Bei einer schiffsbugartigen Ausgestaltungsform der Sägelehre ist der keilförmige Oberflächenabschnitt relativ zu dem keilförmigen Anlageflächenabschnitt nach vorne versetzt. Ebenso ist eine nach hinten versetzte Anordnung bei rückwärtig weisender Keilkante realisierbar.

[0010] Besonders bevorzugt ist eine Ausführungsform, bei der die Keilwinkel des Anlageflächenabschnitts und des Oberflächenabschnitts zumindest näherungsweise identisch sind. Anders ausgedrückt entspricht die Umfangskontur des vorderen Anlageflächenabschnitts bevorzugt der Umfangskontur des vorderen Oberflächenabschnitts, wodurch erreicht wird, dass der Keilkantenwinkel entlang der Keilkante, also der Winkel zwischen den beiden Seitenflächen konstant bleibt.

[0011] In Weiterbildung der Erfindung ist mit Vorteil vorgesehen, dass beide Seitenflächen eben ausgebildet sind. Diese Ausführungsform ermöglicht ein großflächiges und damit exaktes Führen einer Säge entlang der Seitenflächen zum Herstellen eines V-förmigen Schnittes mit schräger Keilkante.

[0012] Von besonderem Vorteil ist eine Ausführungsform, bei der der Keilkantenwinkel, also der Winkel, unter dem die beiden Seitenflächen angewinkelt sind, aus einem Winkelbereich zwischen etwa 90° und etwa 30° gewählt ist. Zu bevorzugen ist ein Keilkantenwinkel aus einem Winkelbereich zwischen etwa 80° und etwa 40°, wobei ein Winkel aus einem Winkelbereich zwischen etwa 70° und etwa 50° besonders zu bevorzugen ist.

[0013] Bei einer besonders bevorzugten Ausführungsform der Sägelehre beträgt der Winkel zwischen der Längserstreckung der Anlagefläche und der Keilkante zwischen etwa 100° und 170°. Bei dieser Ausführungsform ist die Keilkante nach vorne geneigt. Besonders bevorzugt ist es, wenn dieser Winkel zwischen der Keilkante und der Längserstreckung der Anlagefläche zwischen etwa 100° und etwa 150°, besonders bevorzugt zwischen etwa 110° und etwa 130° beträgt. Besonders bevorzugt ist es, wenn der Winkel zumindest näherungsweise 120° beträgt.

[0014] Bei einer Ausführungsform, bei der die Keilkante nicht nach vorne, sondern nach hinten geneigt ist, die Sägelehre also eine nach innen weisende Keilform aufweist, beträgt der Winkel zwischen der Längserstreckung der Anlagefläche und der Keilkante zwischen etwa 10° und etwa 80°. Bevorzugt ist eine Ausführungsform mit einem Winkel aus einem Winkelbereich zwischen etwa 10° und etwa 70°, bevorzugt zwischen etwa 20° und etwa 50°. Besonders bevorzugt ist eine Ausführungsform, bei der der Winkel zumindest näherungsweise 30° beträgt.

[0015] Um die Sägelehre exakt am zu durchtrennenden Knochen positionieren zu können, ist eine Ausführungsform bevorzugt, bei der die Sägelehre einen Griff aufweist, der ein erleichtertes Greifen durch den Chirurgen ermöglicht. Besonders bevorzugt ist der Griff nicht dauerhaft fest mit der Sägelehre verbunden, sondern lösbar mit dieser verbindbar.

Hierzu ist in Weiterbildung der Erfindung ein, insbesondere als Sackloch ausgebildetes, vorzugsweise ein Innengewinde aufweisendes Loch vorgesehen. Dieses befindet sich bevorzugt auf einer Oberseite der Sägelehre.

[0016] Um ein Relativverschieben der Sägelehre zu dem zu durchtrennenden Knochen beim eigentlichen Sägevorgang entlang der Seitenflächen der Sägelehre zu vermeiden, ist in Weiterbildung der Erfindung mit Vorteil vorgesehen, dass die Sägelehre mindestens ein Durchgangsloch aufweist. Dieses Durchgangsloch reicht bevorzugt von der Oberseite der Sägelehre bis zur Anlagefläche. Das Durchgangsloch ist derart beschaffen und/oder dimensioniert, dass es zur Aufnahme eines Kirchnerdrahtes oder einer Knochenschraube dient. Eine besonders exakte Positionierung der Sägelehre am Knochen ist für den Fall möglich, dass die Längsachse des Durchgangsloches parallel zur Keilkante der Sägelehre verläuft.

[0017] Eine besonders exakte und definierte Positionierung der Sägelehre am Knochen ist insbesondere dann möglich, wenn mehr als ein Durchgangsloch vorgesehen ist, sodass die Sägelehre beispielsweise mit mindestens zwei Kirchnerdrähten am Knochen für die Zeit des Sägevorgangs fixierbar ist. Dabei ist eine Ausführungsform bevorzugt, bei der die mindestens zwei, vorzugsweise die ausschließlich zwei, Durchgangslöcher in Längsrichtung der Sägelehre beabstandet angeordnet sind. Bevorzugt befinden sich die Sägelöcher auf der Längsmittelachse der Sägelehre.

[0018] Die Erfindung führt auch auf einen Sägelehrensatz mit mindestens zwei nach dem Konzept der Erfindung ausgebildeten Sägelehren. Besonders bevorzugt ist ein Sägelehrensatz mit acht Sägelehren.

[0019] Um ein präzises Heraustrennen eines V-querschnittlichen Knochenzwischenstücks mit einer definierten Länge zu ermöglichen, ist eine Ausführungsform des Sägelehrensatzes bevorzugt, bei der bei mindestens zwei Sägelehren ein unterschiedlicher Abstand zwischen zumindest einem Durchgangsloch zur lösbaren Fixierung der Sägelehre am Knochen und der Keilkante vorgesehen ist. Soll also beispielsweise ein Knochenzwischenstück mit einer Längserstreckung bzw. Dickenerstreckung von 3 mm herausgetrennt werden, so wird zunächst eine Sägelehre an einer definierten Position des Knochens fixiert und der Knochen wird entlang der Seitenflächen der Sägelehre mit Hilfe einer Säge durchtrennt. Daraufhin wird an derselben Position eine Sägelehre positioniert, bei der der Abstand zwischen einem Durchgangsloch und der Keilkante um 3 mm geringer ist, als bei der zuvor eingesetzten Sägelehre. Wird nun entlang der Seitenflächen dieser (zweiten) Sägelehre der Knochen durchtrennt, so erhält man ein Knochenzwischenstück mit einer Axialerstreckung bzw. Dickenerstreckung von exakt 3 mm. Der Knochen wurde also um exakt 3 mm verkürzt. Nun können die verbleibenden beiden Knochensegmente aneinandergeführt und entlang der schrägen Keilkante relativ zueinander verschoben werden, bis die gewünschte Position eingestellt ist. Daraufhin erfolgt die rotationsstabile Fixation der Knochensegmente mit Hilfe einer Knochenschraube, die bevorzugt vom proximalen Knochensegment zum distalen Knochensegment reicht. Besonders bevorzugt ist eine Ausführungsform des Sägelehrensatzes, bei der die Abstandsabstufung (Stufung der Abstände zwischen dem Durchgangsloch und der Keilkante) zwischen den einzelnen Sägelehren konstant ist. Vorzugsweise beträgt sie 1 mm.

[0020] Weitere Vorteile, Merkmale und Einzelheiten der Erfindung ergeben sich aus der nachfolgenden Beschreibung bevorzugter Ausführungsbeispiele sowie anhand der Zeichnungen. Diese zeigen in:

[0021] Fig. 1: eine Ansicht einer chirurgischen Sägelehre von unten,

[0022] Fig. 2: eine Seitenansicht der Sägelehre gemäß Fig. 1,

[0023] Fig. 3: eine Ansicht der Sägelehre gemäß den Fig. 1 und Fig. 2 von oben,

[0024] Fig. 4: eine Längsschnittansicht der Sägelehre gemäß den Fig. 1 bis Fig. 3,

[0025] Fig. 5: eine Ansicht der Sägelehre gemäß den Fig. 1 bis Fig. 3 von hinten,

[0026] Fig. 6: eine Ansicht der Sägelehre von vorne

[0027] Fig. 7: zwei unterschiedliche perspektivische Ansichten einer Sägelehre von einem Typ A,

[0028] Fig. 8: zwei perspektivische Ansichten einer Sägelehre vom Typ B,

[0029] Fig. 9: eine mögliche Anordnung der beiden Sägelehretypen,

[0030] Fig. 10: zwei Draufsichten auf unterschiedliche Typen von Sägelehren,

[0031] Fig. 11: einen ersten Operationsschritt bei der Verkürzung eines Fuß-Metatarsalknochens, wobei bei diesem Schritt der Metatarsalknochen freigelegt wird,

[0032] Fig. 12: ein zweiter Operationsschritt, bei dem Fixierlöcher zur lösbaren Fixierung der Sägelehre in den Metatarsalknochen eingebracht werden,

[0033] Fig. 13: einen dritten Operationsschritt, bei

dem eine Sägelehre von einem Typ A aus einem Sägelehrensatz mit Hilfe von Kirchnerdrähten am Metatarsalknochen festgelegt wird,

[0034] Fig. 14: einen vierten Operationsschritt bei dem der Metatarsalknochen entlang einer ersten Seitenfläche der Sägelehre durchtrennt wird,

[0035] Fig. 15: einen fünften Operationsschritt, bei dem der Metatarsalknochen entlang der zweiten Seitenfläche der Sägelehre durchtrennt wird,

[0036] Fig. 16: zwei um 90° gedrehte Ansichten der Sägelehre am Metatarsalknochen, wobei aus den Ansichten die Schnittführung zu ersehen ist,

[0037] Fig. 17: einen sechsten Operationsschritt, bei dem die Sägelehre vom Typ A von den Kirchnerdrähten entfernt wird,

[0038] Fig. 18: einen siebten Operationsschritt, bei dem auf die im Metatarsalknochen verbliebenen Kirchnerdrähte eine Sägelehre vom Typ B aufgeschoben und dadurch lösbar am Knochen fixiert wird,

[0039] Fig. 19: zwei schematisierte, um 90° gedrehte Ansichten der Vorgänge bei den in den Fig. 17 und Fig. 18 gezeigten Operationsschritten,

[0040] Fig. 20: einen achten Operationsschritt, bei dem der Metatarsalknochen entlang der ersten Seitenfläche der Sägelehre vom Typ B durchtrennt wird,

[0041] Fig. 21: einen neunten Operationsschritt bei dem der Metatarsalknochen entlang der zweiten Seitenfläche der Sägelehre vom Typ B durchtrennt wird,

[0042] Fig. 22: zwei schematisierte um 90° gedrehte Ansichten der Vorgehensweise bei den in den Fig. 20 und Fig. 21 gezeigten Operationsschritten,

[0043] Fig. 23: einen zehnten Operationsschritt, bei dem die Sägelehre vom Typ B sowie die Kirchnerdrähte vom Metatarsalknochen entfernt werden und ein heraus gesägtes Knochenzwischenstück entfernt wird,

[0044] Fig. 24: einen elften Operationsschritt, bei dem die verbleibenden beiden Knochensegmente des Metatarsalknochens aneinandergefügt werden,

[0045] Fig. 25: in zwei um 90° gedrehten Ansichten die Relativpositionen der verbleibenden Knochensegmente des Metatarsalknochens vor dem Zusammenfügen,

[0046] Fig. 26: einen zwölften Operationsschritt, bei dem ein das proximale Knochensegment durchsetzendes, sich schräg im distalen Knochensegment fortsetzendes Aufnahmeloch gebohrt wird,

[0047] Fig. 27: einen dreizehnten Operationsschritt, bei dem die Knochensegmente temporär mit Hilfe von Kirchnerdraht aneinander fixiert werden,

[0048] Fig. 28: einen vierzehnten Operationsschritt, bei dem der Kirchnerdraht mit einem Kopfraumfräser überbohrt wird, um die Aufnahmebohrung in einem oberen Bereich zu vergrößern, damit ein Kopf einer Knochenschraube vollständig im Knochen versenkbar ist,

[0049] Fig. 29: in zwei um 90° ineinander verdrehten Ansichten die Operationsschritte gemäß den Fig. 27 und Fig. 28,

[0050] Fig. 30: einen fünfzehnten Operationsschritt, bei dem die Knochenschraube in das Aufnahmeloch zur rotationsstabilen Fixation der Knochensegmente eingeschraubt wird, wobei die Knochenschraube entlang des Kirchnerdrahtes geführt wird,

[0051] Fig. 31: die Knochenschraube in einer vergrößerten Ansicht, wobei ein zentrischer Kanülenkanal zu erkennen ist,

[0052] Fig. 32: einen sechzehnten Operationsschritt, bei dem der Kirchnerdraht aus dem Kanülenkanal der Knochenschraube entfernt wird,

[0053] Fig. 33: die im Knochen aufgenommene Knochenschraube in zwei um 90° zueinander gedrehten Ansichten.

[0054] In den Figuren sind gleiche Bauteile und Bauteile mit der gleichen Funktion mit den gleichen Bezugszeichen gekennzeichnet.

[0055] In den Figuren sind bevorzugte Abmessungen der Sägeplatte angegeben. Die Abmessungen und die sich daraus ergebenden Abmessungsverhältnisse sollen als offenbart gelten und beanspruchbar sein. Die Erfindung ist jedoch nicht auf eine Sägelehre mit den gezeigten Abmessungen beschränkt.

[0056] Im Folgenden werden als Ausführungsbeispiele eine fußchirurgische Sägelehre sowie ein Fußchirurgieoperationsverfahren beschrieben. Die Erfindung ist hierauf jedoch nicht beschränkt. Insbesondere bei einer entsprechenden Dimensionierung der Sägelehre kann diese zum Durchtrennen und/oder Kürzen anderer Knochen, wie beispielsweise von Unterarmknochen, etc. eingesetzt werden.

[0057] In den Fig. 1 bis Fig. 6 ist die chirurgische Sägelehre **1** gezeigt. Die Sägelehre **1** weist eine untere Anlagefläche **2** auf, sowie zwei im Wesentlichen senkrecht zu der Anlagefläche **2** angeordnete Seitenflächen **3**, **4**, die eine gemeinsame Keilkante **5** aufweisen bzw. bilden. Die ebenen Seitenflächen **3**,**4**

dienen zur Führung einer Säge zum Durchtrennen eines Knochens. Die Keilkante **5** erstreckt sich, wie aus Fig. 4 ersichtlich ist, unter einem Winkel α von 120° zur Längserstreckung L der Anlagefläche **2**. In dem gezeigten Ausführungsbeispiel ist die Anlagefläche **2** eben ausgebildet. Alternativ sind an die Oberflächenkontur angepasste Formgebungen der Anlagefläche **2** realisierbar. Wesentlich ist, dass die Keilkante **5** nicht senkrecht, sondern unter einem von 90° abweichenden Winkel α zur Längserstreckung L der Anlagefläche **2**, also in diesem Ausführungsbeispiel unter einem Winkel α von 120° verläuft. Anders ausgedrückt ist die Keilkante **5** in dem gezeigten Ausführungsbeispiel um 30° zur Normalen auf der Längserstreckung L der Anlagefläche **2** abgewinkelt. Die gezeigte Sägelehre weist im vorderen Bereich eine Schiffsbugform auf.

[0058] Wie sich aus den Fig. 1 bis Fig. 6 ergibt, ist eine parallel zur Anlagefläche **2** verlaufende Oberfläche **6** vorgesehen. Wie sich weiter aus Fig. 1 ergibt, weist die Anlagefläche **2** einen vorderen, keilförmig konturierten Anlageflächenabschnitt **7** auf. Dieser wird seitlich begrenzt von zwei Seitenkanten **8**, **9** die gleichzeitig die Unterkanten der Seitenflächen **3**, **4** bilden.

[0059] Wie sich aus Fig. 3 ergibt weist die Oberfläche **6** einen keilförmigen, vorderen Oberflächenabschnitt **10** auf, der begrenzt wird von zwei winklig zueinander angeordneten Seitenkanten **11**, **12**. Die Seitenkanten **11**, **12** bilden zugleich Oberkanten der Seitenflächen **3**, **4**. Wie sich insbesondere aus den Fig. 1, Fig. 2 und Fig. 3 ergibt, ist der vordere Oberflächenabschnitt **10** in Richtung der Längserstreckung der Sägelehre **1** betrachtet zu dem Anlageflächenabschnitt **7** versetzt angeordnet, derart, dass sich die Spitze **13** des Oberflächenabschnittes **10** vor der Spitze **14** des Anlageflächenabschnittes **7** befindet. Die beiden Spitzen **13**, **14** werden von der Keilkante **5** linear miteinander verbunden. Dabei ist die Keilkante **5** in dem gezeigten Ausführungsbeispiel in einer nicht eingezeichneten, gedachten eine Längsmittelachse aufnehmende Symmetrieebene der Sägelehre **1** angeordnet.

[0060] Wie sich aus den Fig. 1 und Fig. 3 ergibt, beträgt der Keilwinkel β in dem gezeigten Ausführungsbeispiel 60°. Der Keilwinkel β ist in dem gezeigten Ausführungsbeispiel entlang der Längserstreckung der Keilkante **5** konstant, sodass sowohl der Winkel zwischen den Seitenkanten **8**, **9** als auch der Winkel zwischen den Seitenkanten **11**, **12** sowie sämtliche in Schnittebenen dazwischen befindlichen Keilwinkel 60° betragen.

[0061] Wie sich aus Fig. 2 ergibt, beträgt ein Winkel γ zwischen der Keilkante **5** und der Seitenkante **11** des Oberflächenabschnittes **10** 60°. Analog beträgt auch der nicht eingezeichnete Winkel γ zwischen der Keilkante **5** und der Seitenkante **12** des Oberflächenabschnittes **10** 60°.

[0062] Jede Seitenfläche **3**, **4** geht an einer schrägen Hochkante **15**, **16** in axialer Richtung über in eine hintere Seitenfläche **17**, **18**. Die hinteren Seitenflächen **17**, **18** sind, wie sich aus Fig. 5 ergibt parallel zueinander angeordnet und 10 mm voneinander beabstandet. Ebenfalls aus Fig. 5 ergibt sich der Abstand zwischen der Anlagefläche **2** und der Oberfläche **6** von 8 mm. Die Gesamtlänge der Sägelehre **1** beträgt 25 mm. Die Anlagefläche **2** weist eine entsprechend kürzere Längserstreckung auf.

[0063] Entgegen dem gezeigten Ausführungsbeispiel ist eine Ausführungsform realisierbar, bei der die Keilkante **5** nicht nach vorne, sondern nach hinten geneigt ist. Hierdurch wird eine Sägelehre mit einer inneren V-Form bzw. einen nach hinten bzw. innen weisenden Keil erhalten. Die Keilkante **5** ist dann keine vordere Kante, sondern eine zurückversetzte Kante. Die Vorderkanten der Sägelehre werden dann von den Hochkanten **15**,**16** entsprechenden Kanten gebildet.

[0064] Wie sich aus Fig. 2 ergibt, beträgt der Winkel **6** zwischen der Hochkante **15** und einer oberen Seitenkante **19** der Oberfläche **6** 50°. Aufgrund der symmetrischen Ausbildung beträgt auch der nicht eingezeichnete Winkel **6** zwischen der Hochkante **16** und einer parallel zur oberen Seitenkante **19** verlaufenden oberen Seitenkante **20** ebenfalls 50°.

[0065] Insbesondere aus den Fig. 3 und Fig. 4 ist ersichtlich, dass ausgehend von der Oberfläche **6** in die Sägelehre **1** ein Loch **21** mit einem Durchmesser von 3,0 mm und einer Tiefe von 2,5 mm eingebracht ist. Die Längsmittelachse des Loches **21** ist 2,5 mm von einer rechteckig konturierten Rückseite **25** der Sägelehre **1** beabstandet. Dieses Sackloch kann bei Bedarf mit einem Innengewinde ausgebildet werden und dient zum Festlegen eines beispielsweise in Fig. 7 gezeigten Griffes **22**.

[0066] Ferner sind in der Sägelehre **1** zwei Durchgangslöcher **23**, **24** vorgesehen, wobei die beiden Durchgangslöcher **24** in der nicht mit einem Bezugszeichen versehenen Symmetrieebene der Sägelehre **1** liegen. Die Durchgangslöcher **23**, **24** sind parallel zur Keilkante **5** ausgebildet. Die Längsmittelachse des vorderen Durchgangslochs **23** weist einen Abstand zur Keilkante **5** von 8 mm und die Längsmittelachse des hinteren Durchgangsloches **24** zur Keilkante **5** einen Abstand von 16 mm auf. Wie später noch erläutert werden wird, dienen die Durchgangslöcher **23**, **24** zur lösbaren Fixierung der Sägelehre **1** an einem Knochen.

[0067] In Fig. 7 ist in zwei perspektivischen Ansichten eine Sägelehre **1** gezeigt, bei der die Längsmittel-

achse des vorderen Durchgangslochs **23** einen Abstand von 5 mm und die Längsmittelachse des hinteren Durchgangslochs **24** einen Abstand von 13 mm von der Keilkante **5** aufweisen. Die in den Fig. 7 gezeigte Sägelehre **1** wird im Folgenden als Typ A bezeichnet.

[0068] In Fig. 8 ist eine als Typ B bezeichnete Sägelehre **1** in zwei unterschiedlichen perspektivischen Ansichten gezeigt. Die Sägelehre **1** gemäß Fig. 8 unterscheidet sich von der Sägelehre gemäß Fig. 7 (Typ A) lediglich dadurch, dass der Abstand der Längsmittelachsen der Durchgangslöcher **23**, **24** zur Keilkante **5** um jeweils 3 mm geringer ist als bei dem Ausführungsbeispiel gemäß Fig. 7. Anders ausgedrückt beträgt der Abstand der Längsmittelachse des vorderen Durchgangslochs **23** zur Keilkante **5** lediglich 2 mm und der Abstand der Längsmittelachse des hinteren Durchgangslochs **24** 10 mm zur Keilkante **5**. Die hinteren Seitenkanten **17**, **18** sind also entsprechend kürzer ausgebildet.

[0069] In Fig. 9 sind die Sägelehren **1** von Typ A und Typ B in einer Darstellung gezeigt, bei der die Längsmittelachsen der vorderen Durchgangslöcher **23** sowie die Längsmittelachsen der hinteren Durchgangslöcher **24** miteinander fluchten.

[0070] In Fig. 10 sind die Sägelehren **1** von Typ A und B in einer Draufsicht von oben gezeigt.

[0071] In Fig. 11 ist ein erster Operationsschritt zur Verkürzung eines Metatarsalknochens **26** gezeigt. Zunächst wird hierzu der Metatarsalknochen **26** mittels eines Skalpells **27** freigelegt.

[0072] In Fig. 12 ist ein Operationsschritt gezeigt, bei dem die Sägelehre **1** vom Typ A nach einer Kapsulatomie und ggf. einer erfolgten Stecksehnenverlängerung knapp hinter der Knorpel-Knochengrenze auf der Oberseite des Metatarsalknochens **26** angelegt wird. Hierzu wird die Sägelehre **1** am Griff **22** gegriffen. Daraufhin wird mittels eines Bohrers **28** durch die Durchgangslöcher **23**, **24** hindurch in den Metatarsalknochen gebohrt, sodass zwei Aufnahmebohrungen für Kirchnerdrähte **29** im Metatarsalknochen **26** resultieren.

[0073] Wie aus Fig. 13 ersichtlich ist wird nach dem Einbringen der Aufnahmebohrungen in diese jeweils ein Kirchnerdraht **29** eingebracht, sodass die Sägelehre **1** positionsfest auf dem Metatarsalknochen **26** angeordnet ist.

[0074] Daraufhin wird, wie aus den Fig. 14 bis Fig. 16 ersichtlich ist, eine distale Osteotemie präzise durchgeführt, wobei hierzu mittels einer Knochensäge **30** entlang der Seitenflächen **3**, **4** der Sägelehre **1** gesägt wird. Es entsteht ein aus Fig. 16 ersichtlicher V-förmiger Schnitt **31** mit einer vorderen zur Keilkante **5** korrespondierenden schrägen Scheitellinie **32**.

[0075] Daraufhin, wird, wie aus den Fig. 17 bis Fig. 18 ersichtlich ist, die Sägelehre **1** vom Typ A durch Abziehen von den Kirchnerdrähten **29** vom Metatarsalknochen **26** entfernt und durch eine Sägelehre **1** vom Typ B ersetzt. Diese wird auf die Kirchnerdrähte **29** aufgeschoben und erhält somit eine zur Positionierung der Sägelehre **1** vom Typ A korrespondierende Position auf dem Metatarsalknochen **26**. Da der Abstand der Durchgangslöcher **23**, **24** von der Keilkante **5** bei der Sägelehre **1** vom Typ B um jeweils 3 mm geringer ist als beim Typ A, kann in den Fig. 20 bis Fig. 22 ein Knochenzwischenstück **33** bei der proximalen Osteotemie (vgl. Fig. 32) herausgeschnitten werden. In den gezeigten Ausführungsbeispielen beträgt die Abstandsdifferenz von der Keillinie zu den Durchgangsöffnungen wie erläutert 3 mm. Welche der Sägelehren eines Sägelehrensatzes zum Einsatz kommen muss, also um welchen Betrag der Metatarsalknochen gekürzt werden muss, kann beispielsweise vor der Operation anhand eines Röntgenbildes ermittelt werden.

[0076] Wie erwähnt, wird in den Fig. 20 bis Fig. 22 die proximale Osteotemie durchgeführt. Hierzu wird mittels der Knochensäge **30** entlang der Seitenkanten **3**, **4** der Sägelehre **1** vom Typ B gesägt, sodass ein zu dem Schnitt **31** paralleler Schnitt **34** erhalten wird (vgl. Fig. 22).

[0077] Wie sich aus den Fig. 23 bis Fig. 25 ergibt, verbleiben nach der proximalen Osteotemie zwei Knochensegmente **35**, **36** des Metatarsalknochens **26**. Das Knochenzwischenstück **33** weist eine Dickenerstreckung von 3 mm im Bereich der zueinander parallelen Scheitellinien auf. Bevorzugt nach Entfernen der Kirchnerdrähte **29** und der Sägelehre **1**, werden die Knochensegmente **35**, **36** relativ zueinander positioniert, bevorzugt derart, dass das distale Knochensegment **35** in Hochrichtung zu dem proximalen Knochensegment **36** verschoben und somit gleichzeitig in Längsrichtung zu diesem verstellt wird und trotzdem noch eine Anlage der Knochensegmente **35**, **36** aneinander gewährleistet ist.

[0078] Daraufhin, wird, wie aus Fig. 26 ersichtlich ist eine Aufnahmebohrung **37** gebohrt, die von den proximalen Knochensegment **36** schräg nach vorne in das distale Knochensegment **35** führt. Daraufhin erfolgt, wie aus Fig. 27 ersichtlich ist, eine temporäre Bohrdrahtfixation mit einem Kirchnerdraht **38**, der in die Aufnahmebohrung **37** eingebracht wird. Daraufhin wird, wie aus Fig. 28 ersichtlich ist, der Kirchnerdraht **38** mit einem Kopfraumfräser **39** überbohrt, sodass der Kopf einer noch einzubringenden Knochenschraube **40** im Metatarsalknochen **26** vollständig versenkt werden kann. Bevorzugt erfolgt vor dem Einbringen der Knochenschraube **40** noch eine Län-

genbestimmung mit einem Tiefenmessgerät.

[0079] In Fig. 30 ist das Einbringen einer Knochenschraube **40** zur Fixation der Knochensegmente **35**, **36** relativ zueinander gezeigt. Die in Fig. 31 vergrößert dargestellte Knochenschraube **40** weist einen inneren Durchgangskanal **41** (Kanülenkanal) auf, sodass die Knochenschraube **40** auf den noch in der Aufnahmebohrung **37** befindlichen Kirchnerdraht **38** aufgeschoben und relativ zu diesem verdreht werden kann. Nach Einbringen der Knochenschraube **40** in die Knochensegmente **35**, **36** wird der Kirchnerdraht **38** entfernt.

Patentansprüche

1. Chirurgische Sägelehre mit zwei, eine gemeinsame Keilkante (**5**) aufweisenden und winklig unter mindestens einem Keilkantenwinkel (β) zueinander angeordneten Seitenflächen (**3**, **4**) und mit einer unteren, sich zumindest näherungsweise quer zu den Seitenflächen (**3**, **4**) erstreckenden Anlagefläche (**2**) zur Anlage an einem Knochen, wobei die Keilkante (**5**) unter einem von 90° abweichenden Winkel (α) zur Längserstreckung (L) der Anlagefläche (**2**) verläuft.

2. Sägelehre nach Anspruch 1, dadurch gekennzeichnet, dass sich die Keilkante (**5**) in Längsrichtung (L) der Sägelehre (**1**) von der Anlagefläche (**2**) weg erstreckt.

3. Sägelehre nach einem der Ansprüche 1 oder 2, dadurch gekennzeichnet, dass der Keilkantenwinkel (β) über die Längserstreckung der Keilkante (**5**) konstant ist.

4. Sägelehre nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass eine sich zumindest näherungsweise parallel zur Anlagefläche (**2**) erstreckende Oberfläche (**6**) mit einem vorderen keilförmigen Oberflächenabschnitt (**10**) vorgesehen ist, der zu einem vorderen, keilförmigen Anlageflächenabschnitt (**7**) entlang der Längserstreckung (L) der Sägelehre (**1**) versetzt ist.

5. Sägelehre nach Anspruch 4, dadurch gekennzeichnet, dass die Umfangskontur des vorderen Anlageflächenabschnitts (**7**) zumindest näherungsweise der Umfangskontur des vorderen Oberflächenabschnitts (**10**) entspricht.

6. Sägelehre nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die beiden Seitenflächen (**3**, **4**) eben sind.

7. Sägelehre nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Keilkantenwinkel (β) aus einem Winkelbereich zwischen etwa 90° und 30°, vorzugsweise aus einem Winkelbereich zwischen etwa 80° und 40°, besonderes bevorzugt aus einem Winkelbereich zwischen 70° und 50° gewählt ist, und/oder dass der Keilkantenwinkel (β) zumindest näherungsweise 60° beträgt.

8. Sägelehre nach einem der vorhergehenden Ansprüchen, dadurch gekennzeichnet, dass der Winkel (α) zwischen der Längersteckung (L) der Anlagefläche (**2**) und der Keilkante (**5**) aus einem Winkelbereich zwischen 100° und 170°, vorzugsweise zwischen 100° und 150°, insbesondere zwischen 110° und 130° gewählt ist und/oder zumindest näherungsweise 120° beträgt, oder dass der Winkel (α) zwischen der Längersteckung (L) der Anlagefläche (**2**) und der Keilkante (**5**) aus einem Winkelbereich zwischen 10° und 80°, vorzugsweise zwischen 10° und 70°, insbesondere zwischen 20° und 50° gewählt ist und/oder zumindest näherungsweise 30° beträgt

9. Sägelehre nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass ein, insbesondere als Sackloch (**21**) ausgebildetes, vorzugsweise eine Innengewinde aufweisendes, Loch (**21**) zum, insbesondere lösbaren, Festlegen eines Griffs (**22**) vorgesehen ist.

10. Sägelehre nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass mindestens ein die Anlagefläche (**2**) durchsetzendes, vorzugsweise parallel zur Keilkante (**5**) verlaufendes, Durchgangsloch (**23**, **24**) zur Aufnahme einer Knochenschraube (**40**) oder eines Kirchnerdrahtes (**29**) zum, insbesondere lösbaren, Festlegen der Sägelehre (**1**) an einem Knochen vorgesehen ist.

11. Sägelehre nach Anspruch 10, dadurch gekennzeichnet, dass zwei, vorzugsweise parallel zur Keilkante (**5**) verlaufende, entlang der Längserstreckung (L) der Sägelehre voneinander beabstandete Durchgangslöcher (**23**, **24**) vorgesehen sind.

12. Sägelehrensatz umfassend mehrere Sägelehren (**1**) nach einem der vorhergehenden Ansprüche.

13. Sägelehrensatz nach Anspruch 11, dadurch gekennzeichnet, dass der Abstand entlang der Längserstreckung (L) der Sägelehre (**1**) zwischen der Keilkante (**5**) und mindestens eines Durchgangsloches (**23**, **24**) zur Aufnahme einer Knochenschraube (**40**) oder eines Kirchnerdrahtes (**29**, **38**) zum, insbesondere lösbaren, Festlegen der Sägelehre (**1**) an einem Knochen bei mindestens zwei Sägelehren (**1**), vorzugsweise bei sämtlichen Sägelehren (**1**), unterschiedlich groß ist.

14. Sägelehrensatz nach Anspruch 13, dadurch gekennzeichnet, dass der Abstandsunterschied zwischen einzelnen Sägelehren (**1**) des Sägelehrensatzes 1 mm beträgt.

Es folgen 9 Blatt Zeichnungen

Anhängende Zeichnungen

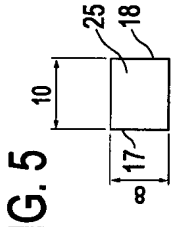


FIG. 5

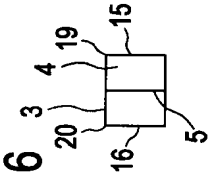


FIG. 6

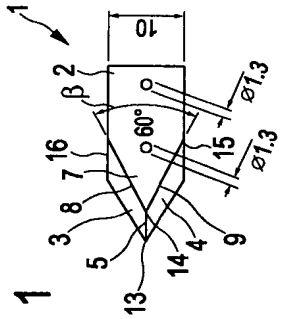


FIG. 1

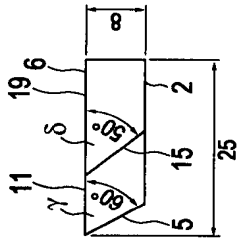


FIG. 2

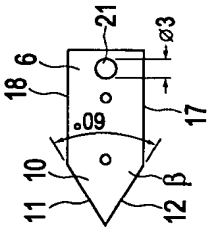


FIG. 3

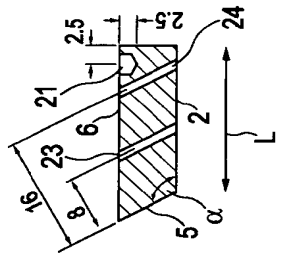


FIG. 4

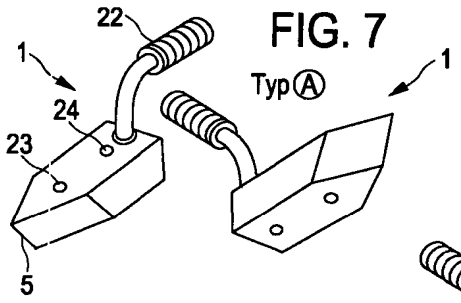


FIG. 7

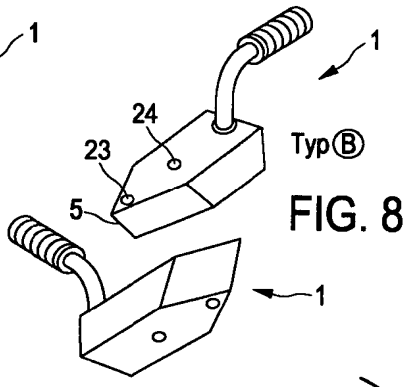


FIG. 8

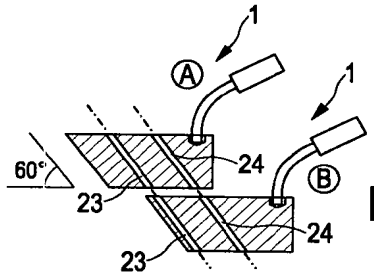


FIG. 9

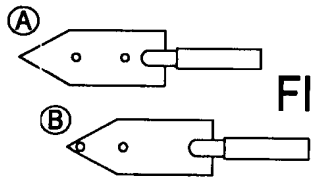


FIG. 10

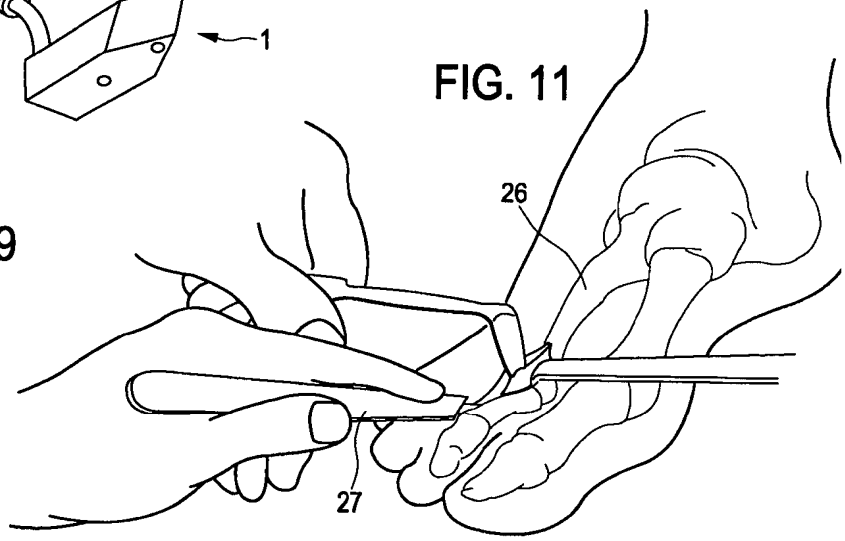


FIG. 11

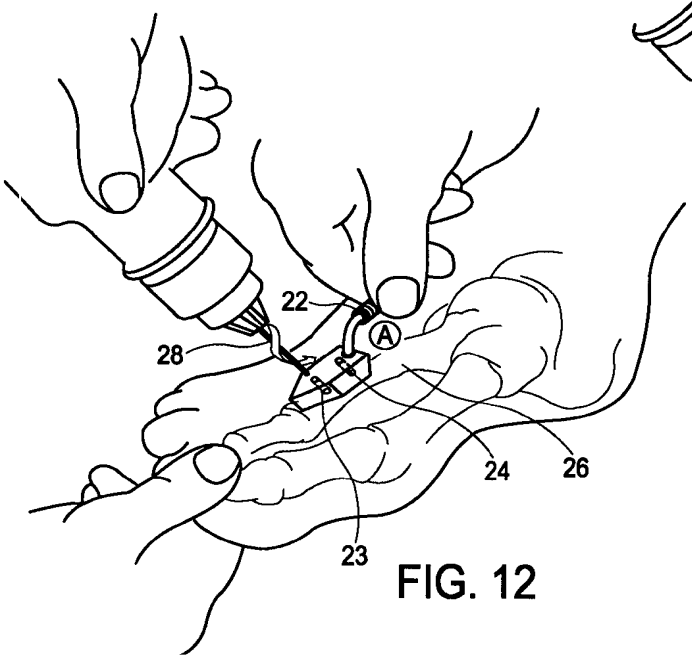


FIG. 12

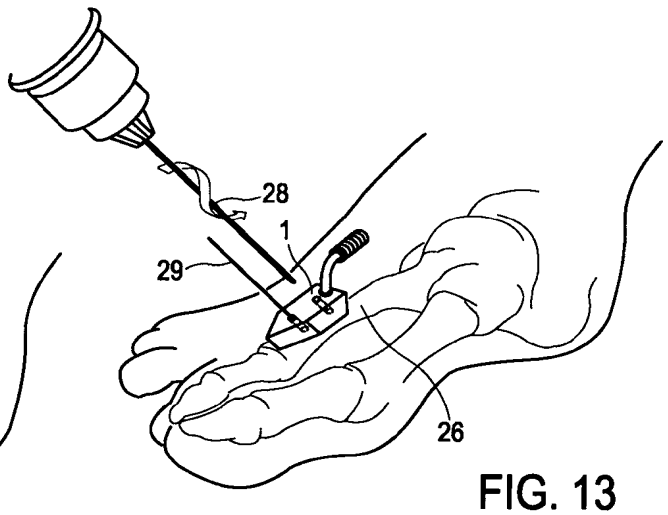


FIG. 13

FIG. 14

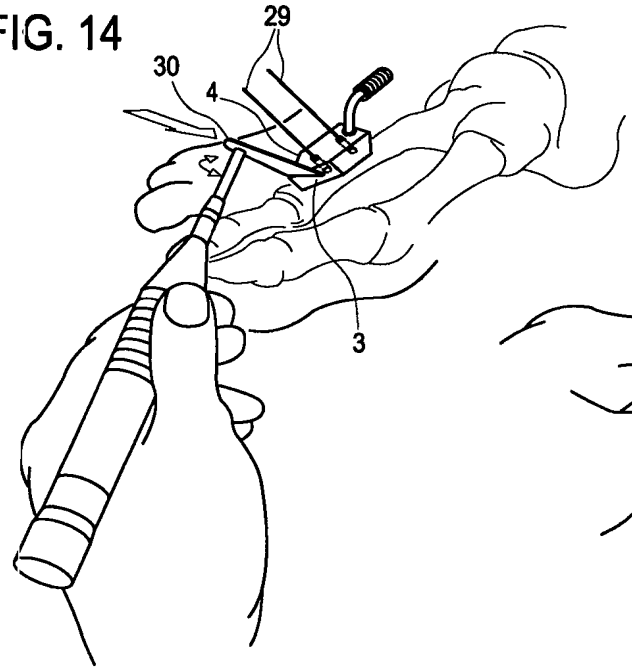


FIG. 15

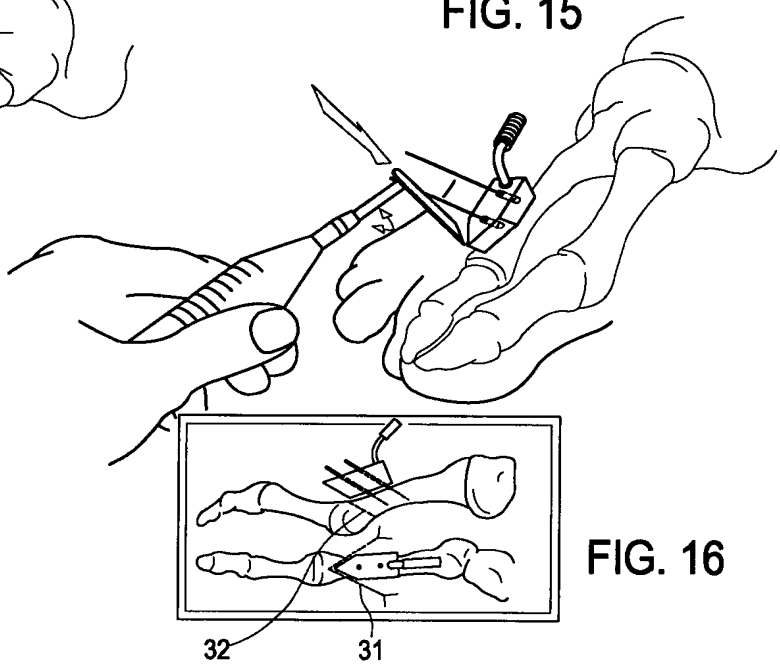


FIG. 16

FIG. 17

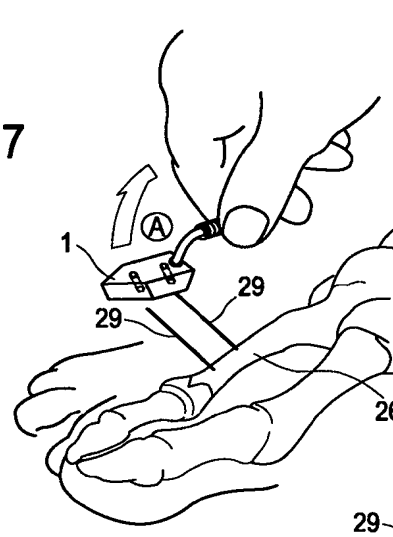


FIG. 19

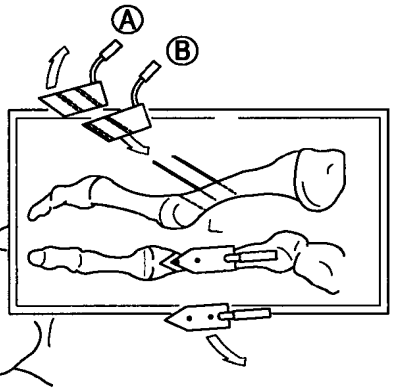


FIG. 18

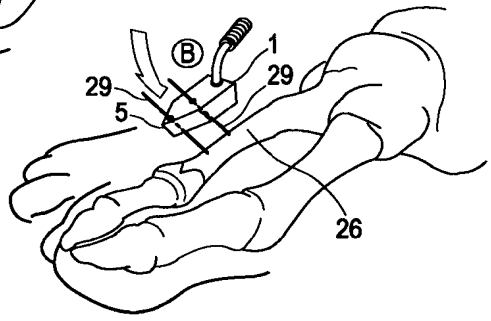
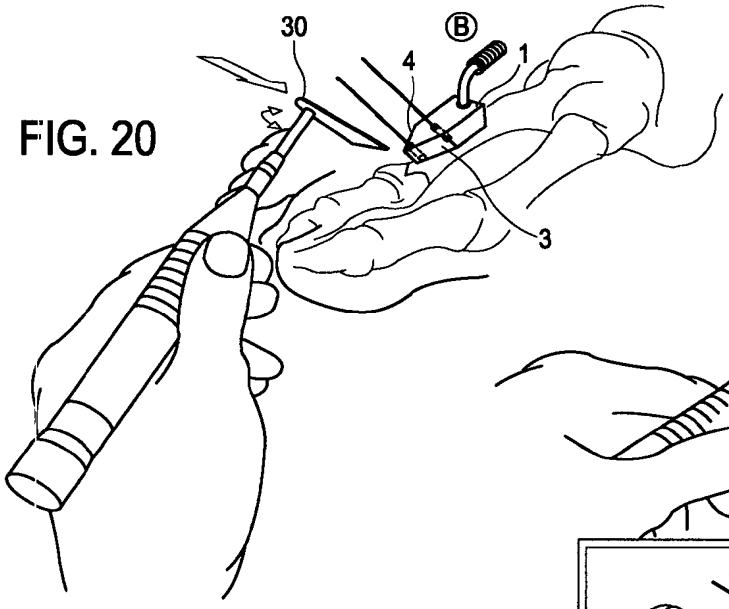


FIG. 20



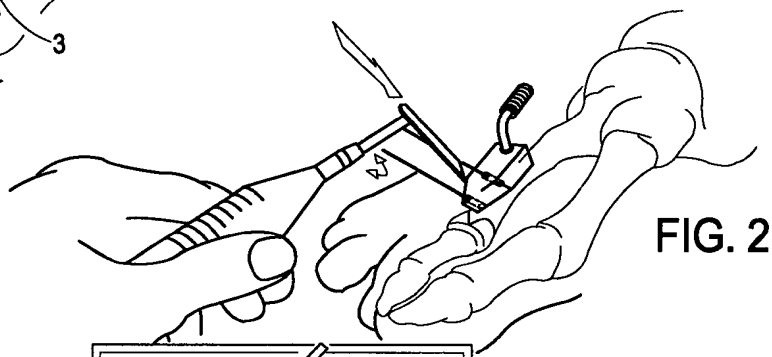


FIG. 21

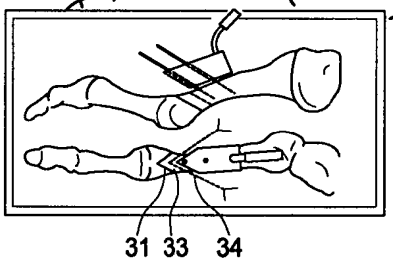


FIG. 22

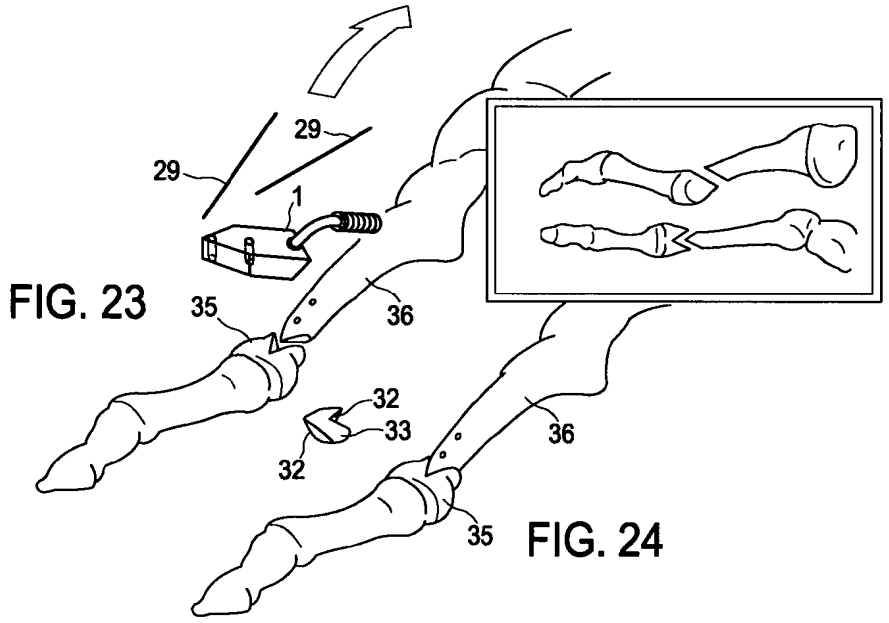


FIG. 23

FIG. 24

FIG. 25

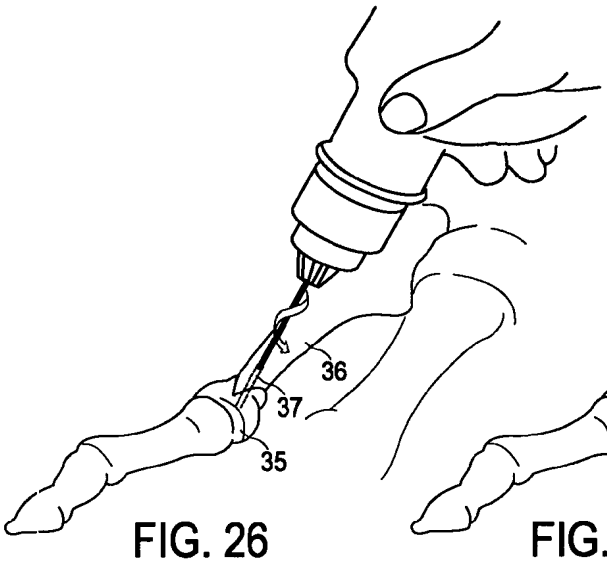


FIG. 26

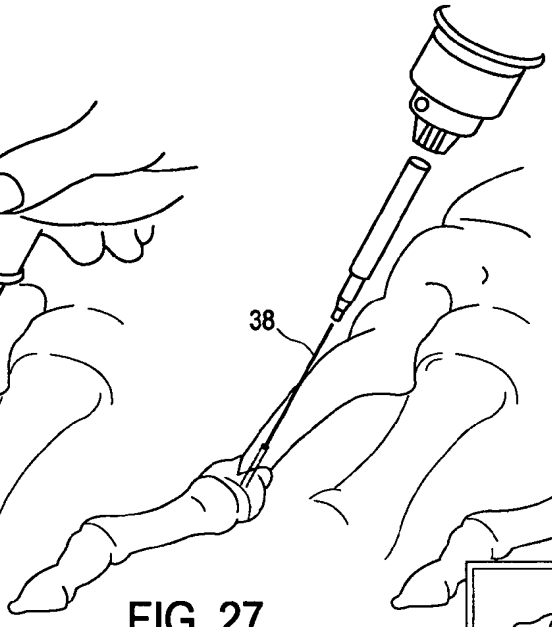


FIG. 27

FIG. 28

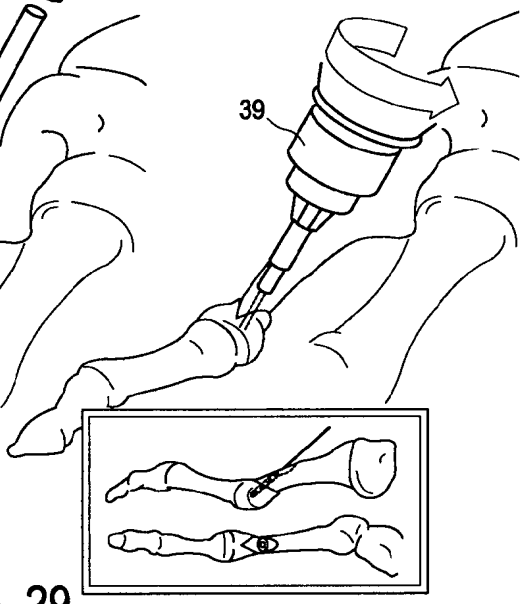


FIG. 29

FIG. 31

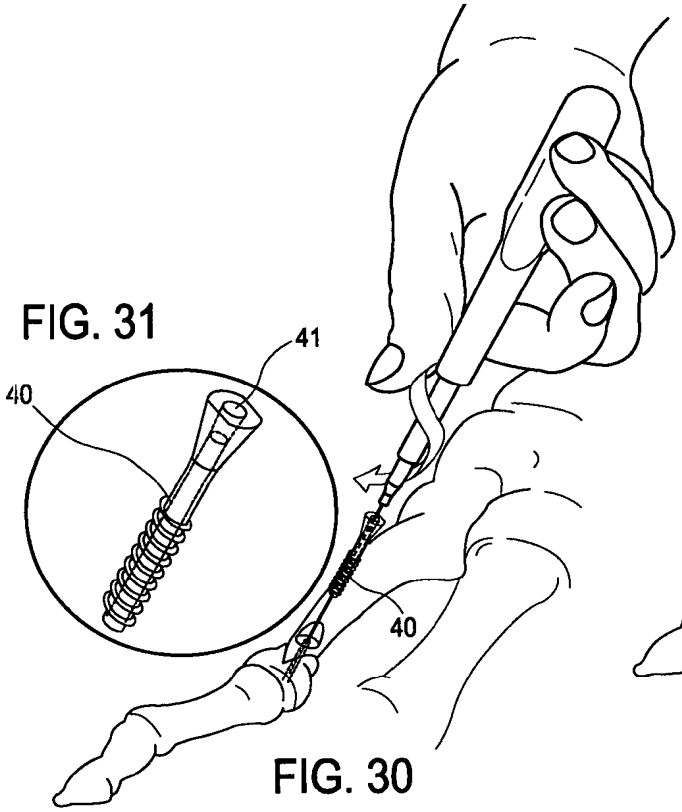


FIG. 30

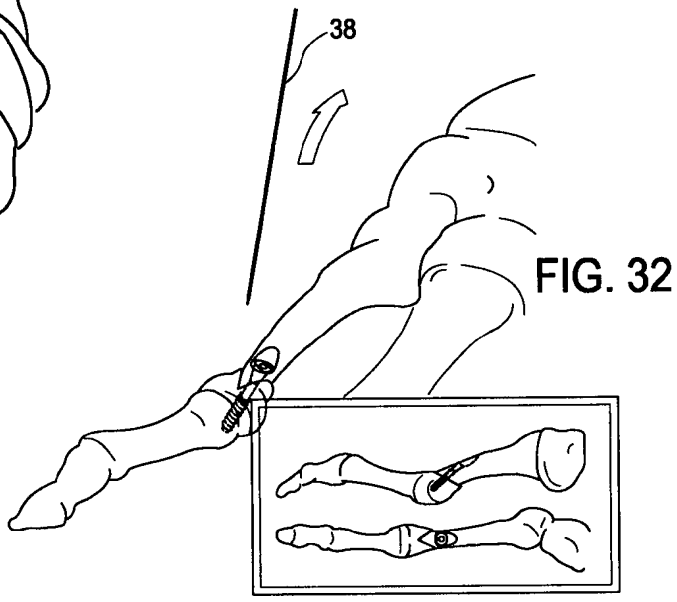


FIG. 32

FIG. 33

Espacenet

Bibliographic data: EP1508316 (A1) — 2005-02-23

Total metatarsalphalangeal prothesis and ancillary for setting same.

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Applicant(s): DEPUY FRANCE [FR]; PIED INNOVATION 2 P 1 2 [FR] ± (DEPUY FRANCE, ; PIED INNOVATION 2 "P.1.2", ; DEPUY (IRELAND) LIMITED)

Classification: - international: ***A61B17/15; A61F2/42;*** *A61B19/00; A61F2/00; A61F2/30; A61F2/46;* (IPC1-7): A61F2/42

- cooperative: **A61B17/15 (EP); A61F2/4225 (EP);** A61B2090/067 (EP); A61F2002/3021 (EP); A61F2002/30214 (EP); A61F2002/30217 (EP); A61F2002/30224 (EP); A61F2002/30345 (EP); A61F2002/30604 (EP); A61F2002/30616 (EP); A61F2002/30878 (EP); A61F2002/30884 (EP); A61F2002/4233 (EP); A61F2002/4235 (EP); A61F2002/4668 (EP); A61F2220/0033 (EP); A61F2230/0067 (EP); A61F2230/0069 (EP)

Application number: EP20040290319 20040206 Global Dossier

Priority number(s): FR20030009707 20030806

Also published as: EP1508316 (B1) AT362352 (T) AU2004201647 (A1) AU2004201647 (B2) DE602004006471 (T2) ES2285370 (T3) FR2858545 (A1) FR2858545 (B1) JP2005052629 (A) NZ531099 (A) less

Abstract of EP1508316 (A1)

The prosthesis has a metatarsal implant (1) including head (6) whose inclined rear plane side (7) forms preset angle with a plane normal to an axis of an anchoring rod. An articular surface of the head and the rear side meet at a lower point of the implant. A distance between the axis of the rod and the lower point is determined, such that the head does not extend in the sesamoid grooves arranged on a lower base of a metatarsal. - Independent claims are also included for the following: (a) an identification supplementary for implementing metatarsal phalange prosthesis (b) a guiding supplementary of a metatarsal phalange (c) a phalange cut supplementary for implementing a metatarsal phalange prosthesis.

(19) Europäisches Patentamt
European Patent Office
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(11) EP 1 508 316 B1

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16.05.2007 Bulletin 2007/20

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A61F 2/42 *(2006.01)*

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(22) Date de dépôt: **06.02.2004**

(54) Prothèse totale métatarso-phalangienne, et ancillaires pour la mise en place de cette prothèse

Metatarsalphalangeale Vollprothese und Hilfsgerät zum Einsetzen einer solchen Prothese.

Total metatarsalphalangeal prothesis and ancillary for setting same.

(84) Etats contractants désignés:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR
Etats d'extension désignés:
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(30) Priorité: **06.08.2003 FR 0309707**

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(56) Documents cités:
WO-A-01/03613
WO-A-02/43627
DE-A- 10 130 796
FR-A- 2 787 013
FR-A- 2 803 509
US-A- 5 458 648
US-A- 5 601 565
US-A- 5 843 085
US-A- 6 030 391

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EP 1 508 316 B1

Description

[0001] La présente invention a trait à une nouvelle prothèse totale métatarso-phalangienne, dite à coupe, notamment pour l'articulation entre le premier métatarsien et la première phalange du gros orteil, ainsi qu'à des ancillaires pour la mise en place de cette prothèse.

[0002] Elle a également pour objets un jeu d'implants métatarsiens et un jeu de telles prothèses de dimensions différentes permettant au chirurgien un choix per-opératoire des dimensions des différents constituants de la prothèse.

[0003] On connaît déjà des prothèses totales métatarso-phalangiennes comprenant un implant métatarsien présentant une tige d'ancrage osseuse et un corps articulaire disposé à l'extrémité de cette tige, un implant phalangien et un plot ou plateau intermédiaire destiné à être disposé sur l'implant phalangien et présentant une surface articulaire complémentaire de la surface articulaire de l'implant métatarsien.

[0004] Une telle prothèse est, par exemple, décrite dans le brevet FR-B-2 787 013.

[0005] La présente invention se propose, d'une façon générale, d'améliorer les prothèses totales métatarso-phalangiennes. Elle se propose en particulier de simplifier ces prothèses et de leur conférer de meilleures propriétés anatomiques améliorant la fonctionnalité de l'articulation métatarso-phalangienne établie par une prothèse ainsi que l'adaptation de cette prothèse dans le milieu anatomique de cette articulation.

[0006] L'invention se propose également de fournir des ancillaires permettant la mise en place précise des implants, dans tous les cas de figure rencontrés.

[0007] L'invention a pour objet une prothèse totale métatarso-phalangienne comprenant

[0008] un implant métatarsien comprenant une tige d'ancrage destinée à être disposée longitudinalement dans le métatarsien, et une tête située à l'extrémité de la tige, destiné à être appliquée contre la surface de la coupe de l'extrémité du métatarsien, et présentant une surface articulaire,

et un implant phalangien présentant un corps destiné à être introduit axialement dans la phalange et une margelle située à l'extrémité proximale de ladite partie et susceptible de présenter une surface articulaire complémentaire de la surface articulaire présentée par le corps de l'implant métatarsien,

ladite surface articulaire de l'implant phalangien pouvant, de préférence, être portée par un plot distinct susceptible d'être introduit et maintenu dans l'implant phalangien,

caractérisé en ce que la tête de l'implant métatarsien présente, à l'opposé de la surface articulaire, une face plane arrière inclinée, destinée à venir s'appliquer contre une surface de coupe du métatarsien, ladite face arrière formant, avec le plan perpendiculaire à l'axe de la tige d'ancrage, un angle de 20° ± 5° pour s'étendre en arrière vers le haut, depuis la base inférieure du métatarsien,

et en ce que la surface articulaire de ladite tête de ladite face arrière inclinée se rencontrent en un point inférieur, formant le point le plus bas de l'implant métatarsien, la distance entre l'axe de la tige d'ancrage et ledit point le plus bas étant déterminée pour que la tête d'implant ne s'étende pas dans les gorges sésamoïdes disposées sur la base inférieure du métatarsien.

[0009] Il en résulte que lorsque le pied est posé à plat sur le sol, la face arrière de la tête de l'implant métatarsien se trouve dans une position sensiblement perpendiculaire au sol. Par ailleurs, la liberté laissée au niveau des gorges sésamoïdes permet de conserver la fonctionnalité des ligaments et de l'articulation.

[0010] Dans une forme de réalisation préférée, la surface articulaire du corps de l'implant ne présente qu'un seul rayon dans le plan sagittal. En d'autres termes, une section sagittale de cette surface forme un arc de cercle. Egalement de façon très avantageuse, ladite surface peut aussi ne présenter, dans le plan horizontal, qu'un seul rayon.

[0011] Bien entendu la surface articulaire en regard de l'implant phalangien est complémentaire.

[0012] De façon particulièrement préférée, la surface articulaire complémentaire est formée par un plot intermédiaire, porté par l'implant phalangien, et libre en rotation autour de l'axe de la phalange.

[0013] On obtient ainsi une parfaite congruence dans toutes les positions, le plot rotatif s'adaptant en permanence dans toutes les positions angulaires.

[0014] La surface articulaire du plot peut avantageusement présenter, sur sa périphérie, et plus précisément sur une partie sensible de la périphérie de la moitié inférieure et/ou de la périphérie de la moitié supérieure, une échancrure déterminant un rebord convexe pour le dégagement de l'articulation en position de flexion et/ou d'extension.

[0015] Dans une forme de réalisation préférée de l'invention, et notamment dans le cas où la surface articulaire phalangienne est formée par un plot tournant librement dans l'implant phalangien, ce dernier présente un corps d'ancrage tronconique creux se poursuivant, à son extrémité proximale, par une tête en forme de margelle tronconique périphérique, le plot présentant une forme correspondante, à savoir une partie distale tronconique dont la conicité correspond à celle du corps, se poursuivant par un plateau ayant une surface distale périphérique dont la conicité correspond à celle de la margelle de l'implant, ce qui permet également de donner au plot une forme particulièrement résistante.

[0016] A la périphérie, la margelle peut venir au contact de la corticale de la phalange, et y prendre appui.

[0017] De préférence, la face proximale inclinée à 20° ± 5° de la tête de l'implant métatarsien se prolonge, vers le haut, par une face supérieure formant, avec la précédente, un dièdre, de préférence d'un angle obtus de 145° ± 20°, destiné à être appliqué contre un plan de coupe supérieur incliné du même angle par rapport à la coupe recevant la face proximale.

[0018] L'invention a aussi pour objet un jeu d'implants

métatarsiens, comprenant plusieurs implants métatarsiens de tailles différentes, adaptés pour former une partie de la prothèse définie ci-dessus, la distance entre l'axe de la tige d'ancrage et le point le plus bas étant sensiblement constante pour tous les implants du jeu.

[0019] Les gorges sésanoïdiennes restent ainsi dégagées, quelque soit l'implant métatarsien utilisé.

[0020] Dans ce jeu, les faces articulaires des têtes des implants métatarsiens sont de préférence dimensionnées pour rencontrer la face supérieure correspondante en un point supérieur à des distances respectives prédéterminées différentes de l'axe de la tige d'ancrage.

[0021] Lors de pose de la prothèse, il est aussi possible de choisir un implant métatarsien dont la partie supérieure est adaptée au mieux à l'état ligamentaire du niveau supérieur de l'articulation. Ces ligaments sont en effet souvent déformés, figés ou durcis par la pathologie qui a nécessité la pose de la prothèse. L'implant métatarsien sera notamment choisi pour ne pas gêner les ligaments latéraux lors de la flexion dorsale de l'articulation.

[0022] Avantageusement, le diamètre de la tige de l'implant métatarsien peut être sensiblement constant, quel que soit l'implant du jeu et l'on peut, éventuellement, faire simplement varier la longueur de cette tige d'un implant à l'autre dans le jeu.

[0023] L'invention a également pour objet un jeu de prothèses métatarso-phalangiennes présentant tout ou partie des caractéristiques de la prothèse définie ci-dessus.

[0024] Un jeu de prothèses selon l'invention, et qui comprend plusieurs implants métatarsiens d'un jeu tel que défini ci-dessus, plusieurs implants phalangiens de tailles différentes et plusieurs plots, de tailles également différentes, se caractérise par le fait que le plot dont la surface articulaire est congruente avec la surface articulaire d'un implant métatarsien donné, peut être reçu dans, au moins, deux implants phalangiens de tailles consécutives.

[0025] Ceci permet en outre de procéder à la même découpe en dièdre en utilisant les mêmes ancillaires, quelle que soit la taille du métatarsien.

[0026] L'implant phalangien peut présenter un corps tronconique ayant la même dimension pour tous les implants dans le jeu, ce cône étant suivi de la margelle tronconique, seul le diamètre de la périphérie de cette margelle étant variable d'un implant à l'autre dans le jeu de façon, de préférence, à venir s'appliquer contre la corticale phalangienne en étant cependant en retrait par rapport à l'encombrement extérieur de la phalange au niveau de la coupe.

[0027] On peut définir plusieurs plots dans le jeu, ayant tous la même partie tronconique de plot adaptée au corps tronconique de l'implant phalangien et ayant des diamètres périphériques et/ou des épaisseurs de plateau différents dans le jeu.

[0028] Le jeu d'implants est de préférence présenté en kits stériles.

[0029] Dans une forme de réalisation particulière, du jeu selon l'invention, on prévoit trois ou quatre tailles d'implants métatarsiens ayant des tiges de 5mm de diamètre. Par exemple pour un jeu comprenant trois implants métatarsiens, les rayons de courbure de la surface articulaire 10 sont respectivement de 7 $\pm$ 0,5, 8 $\pm$ 0,5 et 9 $\pm$ 0,5 mm dans le plan sagittal et 14 $\pm$ 1, 16 $\pm$ 1 et 18 $\pm$ 1 mm dans le plan horizontal, et les points les plus bas dans le plan sagittal (l'axe d'implant étant horizontal) sont situés à une distance commune comprise entre environ 2 et 6 mm de l'axe.

[0030] Dans un tel jeu, on préfère avoir quatre tailles d'implants phalangiens, chaque implant ayant un corps d'implant avec un diamètre d'extrémité distale de 4,7 $\pm$ 2 mm et un diamètre de périphérie de margelle de 12 $\pm$ 1, 13,3 $\pm$ 1, 14,6 $\pm$ 1 et 16 $\pm$ 1 mm.

[0031] On peut prévoir alors trois ou quatre plots de tailles différentes, à savoir des plots de diamètre de 12 $\pm$ 0,5, 13 $\pm$ 0,5 et 14 $\pm$ 0,5 mm pour un jeu de trois plots.

[0032] L'invention a également pour objet un ensemble d'ancillaires permettant la pose de la prothèse selon l'invention.

[0033] Cet ensemble d'ancillaire comporte avantageusement les pièces suivantes :

- un ancillaire de repérage présentant un corps muni d'un passage interne cylindrique lui permettant de coulisser et de tourner autour d'une broche implantée axialement dans le métatarsien, et, à partir dudit corps, deux bras coudés dont les extrémités sont agencées dans l'espace pour pouvoir venir sensiblement s'immobiliser dans les gorges sésamoïdiennes, vers leur extrémité distale à la partie inférieure du métatarsien, de façon à maintenir le corps dans une position angulaire convenable par rapport auxdites deux gorges sésamoïdiennes, ledit corps présentant, en outre, un moyen de réception et de positionnement d'un ancillaire de coupe métatarsienne, ce moyen pouvant être avantageusement une tige de préférence non circulaire, s'étendant parallèlement à l'axe de l'implant et donc à la broche, et à distance du métatarsien dans la direction latérale vers le plan sagittal du patient.
- un ancillaire de guidage de coupe métatarsienne présentant un corps avec un passage lui permettant de coulisser sur le moyen de réception de l'ancillaire de repérage, ledit corps présentant des moyens de fixation par rapport à l'os, de préférence des passages transversaux susceptibles d'être traversés par de petites broches de fixation latérales que l'on vient visser dans la corticale latérale du métatarsien, ledit corps présentant, en outre, au moins une et de préférence deux fentes de coupe pour le passage d'une scie oscillante, ladite au moins une fente étant inclinée d'un angle à 70° $\pm$ 20°, par rapport à l'axe de la broche lorsque l'ensemble est monté sur le métatarsien, la deuxième fente étant plus inclinée de façon que, lesdites deux fentes permettant ainsi de réaliser d'une part la coupe recevant la face arrière

de la tête d'implant et la deuxième coupe qui forme un angle obtus, de préférence de 145° ± 20° avec la coupe précitée ;

- un ancillaire de coupe phalangienne présentant un corps lui permettant d'être fixé également par de petites broches, latéralement sur la corticale de la phalange, au moins une fente et de préférence deux fentes parallèles de coupe phalangienne, et un prolongement destiné à venir s'appliquer, de préférence par emboîtement, sur une extrémité correspondante de l'ancillaire de coupe métatarsien, de façon à définir exactement les positions relatives des deux ensembles de coupe, les fentes de coupe métatarsienne et phalangienne étant, lorsque les deux ancillaires de coupe sont réunis, sensiblement parallèles.

[0034] D'autres avantages et caractéristiques de l'invention apparaîtront avec la description suivante faite à titre d'exemple non limitatif et se référant au dessin annexé dans lequel :

la figure 1 représente, schématiquement une vue en perspective d'un implant selon l'invention posé,
la figure 2 représente, de façon schématique, en coupe sagittale de la position de trois implants métatarsiens d'un jeu par rapport à un métatarsien,
la figure 3 représente, en coupe schématique, un implant métatarsien avec son plot,
les figures 4 à 9 représentent des vues respectives de dessus et de côté de trois implants métatarsiens de tailles différentes,
les figures 10 à 12 représentent, en élévation, trois plots de tailles différentes,
les figures 13 à 16 représentent, en élévation, quatre implants phalangiens de tailles différentes,
la figure 17 représente une vue schématique en élévation de l'ancillaire de repérage,
la figure 18 représente une vue de dessous de cet ancillaire,
la figure 19 représente une vue schématique d'une extrémité de métatarsien avec des positions angulaires différentes de l'ancillaire de repérage par rapport aux gorges sésamoïdes,
la figure 20 représente une vue en élévation de l'ancillaire de coupe métatarsienne lors de sa mise en place,
la figure 21 représente une vue de dessous lors de la fixation de cet ancillaire,
la figure 22 représente une vue latérale de l'ancillaire de coupe phalangienne positionné sur l'ancillaire de coupe métatarsien,
la figure 23 représente une vue de dessous de l'assemblage de la figure 22.

[0035] En se référant à la figure 1, on voit un métatarsien M et une phalange P ayant reçu, après mise en place des coupes correspondantes, un implant métatarsien 1, et un implant phalangien 2 avec un plot formant surface d'articulation 3.

[0036] En se référant à la figure 2, on voit en trait plein, une section schématique de l'implant métatarsien 1. Les traits pointillés et mixtes représentent respectivement deux autres tailles d'implants métatarsiens disposés dans la même position sur le métatarsien M, les trois implants métatarsiens formant un exemple d'un jeu d'implants métatarsiens selon l'invention.

[0037] Comme on le voit également en se référant aux figures 4 à 9, chaque implant métatarsien 1 présente une tige cylindrique 4 se terminant par une extrémité chanfreinée puis arrondie 5. Le diamètre de cette tige est destiné à permettre la fixation de l'implant dans un perçage préalablement pratiqué axialement dans le métatarsien.

[0038] L'implant métatarsien présente également une tête 6 présentant deux faces formant un angle diédrique. L'une est la face arrière 7 qui forme avec l'axe de la tige 4 un angle de 20° environ, de façon à ce que la face arrière soit inclinée vers le haut et vers l'arrière. A peu près au niveau de l'encombrement supérieure de la tige 4, la face plane 7 se poursuit par une face 8 inclinée d'un angle d'environ 145° par rapport à la face 7. Dans l'exemple représenté la tige 4 vient se raccorder intégralement à la face 7 mais on comprend que l'axe 9 du dièdre pourrait également être plus bas ou plus haut.

[0039] Du côté distal, la tête 6 présente une surface articulaire 10 qui, dans le plan sagittal représenté, possède un rayon de courbure unique pour former un arc de cercle. Dans le plan perpendiculaire, c'est à dire dans le plan horizontal, la surface 10 présente également un rayon de courbure unique. La surface articulaire 10 vient se raccorder à la face arrière 7, dans le plan sagittal, en un point inférieur 11 situé à une distance h de l'axe de la tige 4.

[0040] De préférence, dans le cadre de l'invention, cette distance h est choisie entre 2 et 6 mm. Cette distance h est identique ou sensiblement identique pour tous les implants métatarsiens d'un même jeu. La distance h est telle que lorsque l'implant est mis en position comme représenté sur la figure 2, sur les métatarsiens, la position du point 11 soit telle que la surface articulaire, dans sa partie inférieure, ne vienne pas empiéter sur le débouché des gorges sésamoïdes S représentées sur la figure 19.

[0041] De plus, on voit que selon les dimensions des faces articulaires 10 des implants métatarsiens du jeu représenté sur les figures 4 à 9, le point haut 12 de l'implant formé par la rencontre des surfaces 8 et 10 peut, grâce au choix de la dimension de l'implant, déborder ou non au-delà de l'encombrement supérieur du métatarsien M et s'adapter au mieux à l'état ligamentaire local.

[0042] Afin d'éviter des risques de rotation de l'implant métatarsien dans le métatarsien, la tige de l'implant peut encore comprendre des moyens d'immobilisation en rotation, telles que des ailettes radiales 13 situées au niveau de la face 8.

[0043] On voit encore sur la figure 2, que lorsque l'implant est mis en place à l'extrémité du métatarsien, la face arrière 7 vient s'appliquer contre la face de coupe correspondante, de même inclinaison, à l'extrémité du métatarsien, alors que la face inclinée 8 vient s'appliquer contre une autre face, inclinée de façon correspondante, d'une coupe de l'extrémité du métatarsien.

[0044] En se référant à la figure 3, on voit l'implant phalangien 2 qui présente un corps tronconique 14 ayant une petite base distale 15 et se poursuivant, à son extrémité proximale, par une margelle conique 16. Dans le corps 14, et dans le prolongement de la face proximale de la margelle 16, est disposé un évidement tronconique 17.

[0045] De façon avantageuse, le diamètre de la partie 15 est faible, par exemple de l'ordre de 4,7 mm. A ce niveau, dans le débouché de l'évidement 17, le diamètre interne est avantageusement de 6 cm, l'évidemment tronconique dans le corps 14 permettant de recevoir des plots de 6 mm par exemple.

[0046] Le diamètre maximum de la margelle 16 peut également varier en fonction de la taille de l'implant phalangien.

[0047] Cet implant phalangien peut recevoir le plot 3 comprenant un plateau 18 et une queue 19. La face distale du plateau 18 est congruente à la face conique interne de la margelle 16, alors que la surface externe de la queue 19 est congruente et de même conicité que l'évidemment 17 dans le corps d'implant 14. On comprend, que de cette façon, le plot 3 est reçu dans l'implant et présente une forme lui conférant une résistance particulière. On peut, par exemple, obtenir avec des plots en polyéthylène, des résistances au cisaillement d'environ 42 daN.

[0048] La queue du plot présente toujours la même dimension alors que le diamètre et/ou l'épaisseur du plateau 18 peuvent varier.

[0049] La face articulaire proximale du plot, comme on le voit sur la figure 1, est concave et congruente à la surface articulaire de l'implant métatarsien, c'est-à-dire que cette face présente, dans des plans perpendiculaires, des rayons de courbure respectivement constants et identiques à ceux de la surface de l'implant métatarsien.

[0050] On voit, enfin, que l'on a pratiqué en périphérie de la face articulaire du plot deux entailles ou chanfrein, à savoir un chanfrein inférieur 20 et un chanfrein supérieur 21 qui s'étendent sur presque toute la moitié de l'arc de cercle périphérique concerné, ces chanfreins permettant un dégagement supplémentaire en flexion, respectivement en extension.

[0051] En se référant plus précisément aux figures 4 à 16, on a représenté un jeu complet comprenant trois implants métatarsiens 1, quatre implants phalangiens 2, et trois plots 3.

[0052] Le diamètre des tiges 4 est, pour chaque implant métatarsien, de 5 mm environ, par exemple à plus ou moins 2 mm. Les rayons de courbure, comme cela est indiqué sur les dessins, dans le plan sagittal sont, par taille croissante, de 7 $\pm$ 0,5, de 8 $\pm$ 0,5 et de 9 $\pm$ 0,5 mm et, dans le plan frontal, de 14, de 16 et de 18 mm. Les encombrements dans le plan horizontal sont de 16, 18 et 20 mm.

[0053] Les quatre implants phalangiens 2 du jeu ont respectivement des diamètres extérieurs de margelle de 12 $\pm$ 1, 13,3 $\pm$ 1 , 14,6 $\pm$ 1 et 16 $\pm$ 1 mm. Les logements et surfaces recevant les plots sont identiques.

[0054] Le jeu comporte enfin trois plots 3 dont les diamètres maximum de plateau sont respectivement de 12 $\pm$ 0,5, 13 $\pm$ 0,5 et 14 $\pm$ 0,5 mm.

[0055] Toutes les combinaisons implant métatarsien/ plot/ implant phalangien sont envisageables grâce à l'adaptabilité des composants. On a représenté sur la planche comprenant les figures 4 à 16, par des flèches en traits mixtes, les correspondances médicalement préférées entre les trois constituants, à savoir les implants métatarsiens, les plots et les implants phalangiens.

[0056] On se réfère, maintenant aux figures 17 à 19.

[0057] Pour poser une prothèse selon l'invention, après avoir luxé la phalange, on aborde l'extrémité distale du métatarsien M et on réalise un perçage axial dans le centre de la surface articulaire pathologique à l'aide d'une broche filetée 30 que l'on laisse en place.

[0058] On enfile ensuite sur la broche un ancillaire de repérage 31 capable de glisser et de tourner sur la broche et présentant, à cet effet, un corps 32 muni d'un passage correspondant. A son extrémité proximale, le corps 32 présente deux bras 33 et 34 coudés, d'abord latéralement puis vers le bas, puis vers l'avant, dont les extrémités sont émoussées et s'étendent de façon oblique vers le bas. L'écartement entre les deux extrémités des bras 33 et 34 correspond sensiblement à la distance entre les deux gorges sésamoïdes S lorsqu'elles débouchent à la face antérieure articulaire du métatarsien. Du corps 31 s'étend également un autre bras coudé allongé 35, dont la plus grande partie s'étend parallèlement à la broche 30 et à une certaine distance de la surface latérale du métatarsien.

[0059] On enfile la pièce 31 sur la broche 30 et on la fait coulisser et tourner convenablement pour l'amener dans la position dans laquelle les deux extrémités des bras 33 et 34 pénètrent dans le début des gorges sésamoïdes S jusqu'à ce que toute rotation soit empêchée, ce qui fixe à la fois la position axiale et la position en rotation de l'ancillaire 31.

[0060] On se réfère maintenant aux figures 20 et 21.

[0061] On enfile, alors dans l'autre sens, sur le bras 35, un ancillaire de coupe métatarsienne 40 qui présente un corps rectangulaire 41 muni d'un passage allongé recevant le bras 35 sur lequel l'ancillaire 40 peut coulisser mais sans pivoter.

[0062] Le corps 41 présente une pluralité de trous transversaux 42 par lesquels pourront passer des petites broches 43 qui permettront de fixer l'ancillaire 40 sur le métatarsien M. Vers sa partie antérieure le corps 41 présente des élargissements dans lesquels est pratiquée

une première fente transversale 44, inclinée de 70° par rapport au corps 40 et au bras 35 et donc à la broche 30. Un peu au-dessous du dernier tiers supérieur de la fente 44, débute une deuxième fente 45 oblique vers le haut et formant avec la fente 44 un angle obtus.

[0063] Enfin le corps 41 présente, à son extrémité distale, une surface 46 présentant un petit logement interne.

[0064] On fait coulisser l'ancillaire 40 sur le bras 35 jusqu'à ce que la fente 44 vienne, dans son plan transversal, en alignement avec la partie supérieure de l'extrémité du bras 33, comme on le voit sur la figure 20, ce qui détermine le point 11 d'encombrement inférieur de l'implant métatarsien qui va être posé. Dans cette position on visse les broches 43 et l'on fixe rigidement le corps 41 par rapport au métatarsien. Ensuite, on retire l'ancillaire 31, puis la broche 30, dont le diamètre correspond au diamètre de la tige 4 de l'implant métatarsien, qui pourra ultérieurement être impacté dans le trou laissé par une broche.

[0065] Enfin, on assure la coupe de l'extrémité du métatarsien à l'aide d'une scie vibrante, d'abord par la fente 44, puis par la fente 45, ce qui crée à l'extrémité antérieure les deux plans de coupe correspondants, et inclinés selon les inclinaisons des fentes.

[0066] On peut ensuite introduire une prothèse métatarsienne d'essai similaire à la prothèse métatarsienne définitive, ce qui permet, dans le jeu de prothèses, de choisir la taille la plus adéquate.

[0067] L'implant 1 métatarsien d'essai étant en place, on réduit la luxation et on ramène la phalange P dans la position naturelle avec sa surface articulaire contre la surface articulaire de l'implant métatarsien d'essai, comme on le voit bien notamment sur la figure 23.

[0068] Comme représenté sur les figures 22 et 23, on vient alors mettre en place l'ancillaire de coupe phalangienne 50. Cet ancillaire présente un corps 51, également muni d'une pluralité de trous qui permettront le passage de petites broches de fixation sur la phalange. Vers son extrémité proximale, ce corps 51 présente un élargissement 52 dans lequel sont disposées deux fentes parallèles 53 et 54. L'extrémité proximale de cet élargissement se poursuit par une terminaison 55 qui présente un court embout lui permettant de pénétrer dans le petit logement de l'extrémité 46 de l'ancillaire métatarsien 40, ce qui détermine exactement les positions respectives des deux ancillaires 40 et 50. Comme on le voit sur la figure 23, dans cette position le corps 50 est légèrement incliné pour reproduire la légère position naturelle en varus de la première phalange P. On peut alors, en utilisant des broches similaires aux broches 43, fixer le corps 50 sur la face latérale de la phalange P. Dans cette position on voit que les fentes 53 et 54 sont parallèles à la fente 44 de l'implant métatarsien.

[0069] Le chirurgien utilise alors l'une des deux fentes 53 et 54 pour pratiquer une coupe droite de l'extrémité de la phalange à l'aide d'une lame oscillante ou vibrante.

[0070] Ensuite, on dépose, par retrait des broches correspondantes, les deux implants de coupe 40 et 50.

[0071] On effectue ensuite à une nouvelle luxation de la phalange et on procède au choix de la dimension d'implant phalangien.

[0072] De façon optionnelle, on peut utiliser pour cela un gabarit formé d'un disque situé, à l'extrémité d'un manche dans le plan du disque, présentant éventuellement en son intérieur un trou central, ce disque permettant de déterminer le diamètre de la coupe phalangienne.

[0073] Eventuellement, ce gabarit peut être mis en place à l'aide d'une broche que l'on fait passer à travers son trou central, de façon à être disposé dans la bonne position dans la phalange.

[0074] Après retrait du gabarit, on procède ensuite au fraisage de la phalange pour pratiquer le trou qui recevra l'implant phalangien. Pour cela on utilise une fraise ayant une forme extérieure et conique à deux étages correspondant aux deux étages coniques de l'implant. Le cas échéant, cette fraise peut être guidée par une broche laissée préalablement en place et ayant servi lors du positionnement du gabarit.

[0075] Après fraisage, on peut mettre en place un implant phalangien d'essai, puis, après retrait de celui-ci, on impacte définitivement l'implant phalangien 2 choisi.

[0076] On extrait ensuite l'implant d'essai métatarsien, que l'on remplace par l'implant métatarsien définitif correspondant, que l'on impacte dans le métatarsien M.

[0077] Il reste ensuite à choisir la dimension du plot et, notamment, l'épaisseur du plateau du plot pour obtenir le bon écartement entre la phalange et le métatarsien. Une fois le plot mis en place dans l'implant phalangien, on réduit la luxation et on procède à la fermeture des plans anatomiques.

[0078] Divers aménagements et variantes aux ancillaires décrits ci-dessus sont en outre envisageables, notamment en ce qui concernent le nombre et la disposition des fentes de coupe.

Revendications

1. Prothèse totale métatarso-phalangienne comprenant
   un implant métatarsien (1) comprenant une tige d'ancrage (4) destinée à être disposée longitudinalement dans le métatarsien (M), et une tête (6) située à l'extrémité de la tige, destiné à être appliquée contre la surface de la coupe de l'extrémité du métatarsien, et présentant une surface articulaire (10),
   et un implant phalangien (2) présentant un corps (14) destiné à être introduit axialement dans la phalange et une margelle (16) située à l'extrémité proximale de ladite partie et susceptible de présenter une surface articulaire (18) complémentaire de la surface articulaire (10) présentée par le corps de l'implant métatarsien,
   caractérisé en ce que la tête (6) de l'implant métatarsien présente, à l'opposé de la surface articulaire (10), une face plane arrière inclinée (7), destinée à

venir s'appliquer contre une surface de coupe du métatarsien (M), ladite face arrière (7) formant, avec le plan perpendiculaire à l'axe de la tige d'ancrage (4), un angle de 20° ± 5° pour s'étendre en arrière vers le haut, depuis la base inférieure du métatarsien,
et **en ce que** la surface articulaire (10) de ladite tête et ladite face arrière inclinée (7) se rencontrent en un point inférieur (11), formant le point le plus bas de l'implant métatarsien, la distance entre l'axe de la tige d'ancrage (4) et ledit point le plus bas (11) étant déterminée pour que la tête d'implant (6) ne s'étende pas dans les gorges sésamoides disposées sur la base inférieure du métatarsien.

2. Prothèse selon la revendication 1, **caractérisée en ce que** ladite surface articulaire (18) de l'implant phalangien (2) est portée par un plot (3) distinct susceptible d'être introduit et maintenu dans l'implant phalangien (2).

3. Prothèse selon l'une des revendications précédentes, **caractérisée en ce que** la surface articulaire (10) du corps de l'implant ne présente qu'un seul rayon dans le plan sagittal et un seul rayon dans le plan horizontal, la face articulaire (18) de l'implant phalangien étant congruente et portée par un plot (3) susceptible de tourner autour de l'axe de l'implant phalangien.

4. Prothèse selon l'une des revendications 2 ou 3, **caractérisée en ce que** la surface articulaire (18) du plot (3) présente sur sa périphérie, notamment sur une partie sensible de la périphérie de la moitié inférieure et/ou de la périphérie de la moitié supérieure, une échancrure (20, 21) déterminant un rebord convexe pour le dégagement de l'articulation en position de flexion et/ou d'extension.

5. Prothèse selon l'une des revendications 2 à 4, **caractérisée en ce que** l'implant phalangien (2) présente un corps d'ancrage tronconique creux (14) se poursuivant, à son extrémité proximale, par une tête en forme de margelle tronconique périphérique (16), le plot (3) présentant une forme correspondante, à savoir une partie distale tronconique (19) dont la conicité correspond à celle du corps, se poursuivant par un plateau (18) ayant une surface distale périphérique dont la conicité correspond à celle de la margelle (16) de l'implant, ce qui permet également de donner au plot une forme particulièrement résistante.

6. Prothèse selon l'une des revendications précédentes, **caractérisée en ce que** la face proximale (7) inclinée à 20° ± 5° de la tête (6) de l'implant métatarsien se prolonge, vers le haut, par une face supérieure (8) formant, avec la précédente, un dièdre, de préférence d'un angle obtus de 145° ± 20°, destiné à être appliqué contre un plan de coupe supérieur incliné du même angle par rapport à la coupe recevant la face proximale (7).

7. Jeu d'implants métatarsiens comprenant plusieurs implants métatarsiens (1) de tailles différentes, adaptés pour former une partie d'une prothèse conforme à l'une quelconque des revendications 1 à 6, la distance (h) entre l'axe de la tige d'ancrage (4) et le point le plus bas (11) étant sensiblement constante pour tous les implants du jeu.

8. Jeu d'implants suivant la revendication 7, **caractérisé en ce que** les implants métatarsiens (1) présentent les caractéristiques de la revendication 6, les faces articulaires (10) des têtes (6) de ces implants étant dimensionnées pour rencontrer la face supérieure correspondante (8) en un point supérieur (12) à des distances respectives prédéterminées différentes de l'axe de la tige d'ancrage (4).

9. Jeu d'implants selon l'une des revendications 7 ou 8, **caractérisé en ce que** le diamètre de la tige (4) des implants métatarsiens (1) est sensiblement constant.

10. Jeu de prothèses qui comprend un jeu d'implants métatarsiens (1) conforme à l'une quelconque des revendication 7 à 9, plusieurs implants phalangiens (2) de tailles différentes et plusieurs plots (3), de tailles également différentes, **caractérisé par le fait que** le plot (3) dont la surface articulaire (18) est congruente avec la surface articulaire (18) d'un implant métatarsien donné, peut être reçu dans, au moins, deux implants phalangiens de tailles consécutives pour former une prothèse conforme à l'une quelconque des revendications 1 à 7.

11. Jeu selon la revendication 9, **caractérisé en ce que** l'implant phalangien (2) présente un corps tronconique (14) ayant la même dimension pour tous les implants dans le jeu, ce cône étant suivi de la margelle tronconique (16), seul le diamètre de la périphérie de cette margelle (16) étant variable d'un implant à l'autre dans le jeu de façon.

12. Jeu selon l'une des revendications 10 ou 11, comprenant trois implants métatarsiens (1), **caractérisé en ce que** les rayons de courbure de la surface articulaire (10) sont respectivement de 7 ± 0,5, 8 ± 0,5 et 9 ± 0,5 mm dans le plan sagittal et 14 ± 1, 16 ± 1 et 18 ± 1 mm dans le plan horizontal, et les points les plus bas (11) dans le plan sagittal sont situés à une distance commune (h) comprise entre environ 2 et 6 mm de l'axe.

13. Jeu selon la revendication 12, **caractérisé par** qua-

tre tailles d'implants phalangiens (2), chaque implant ayant un corps d'implant (14) avec un diamètre d'extrémité distale de 4,7 ± 2 mm et un diamètre de périphérie de margelle (16) de 12 ± 1, 13,3 ± 1, 14,6 ± 1 et 16 ± 1 mm.

14. Jeu selon la revendication 13, **caractérisé en ce qu'**il comporte trois plots (3) de tailles différentes, à savoir des plots de diamètre de 12 ± 0,5, 13 ± 0,5 et 14 ± 0,5 mm pour un jeu de trois plots.

15. Ancillaire de repérage (31) pour la pose d'une prothèse selon l'une des revendications 1 à 6 présentant un corps (32) muni d'un passage interne cylindrique lui permettant de coulisser et de tourner autour d'une broche implantée axialement dans le métatarsien, et, à partir dudit corps (32), deux bras coudés (33, 34) dont les extrémités sont agencées dans l'espace pour pouvoir venir sensiblement s'immobiliser dans les gorges sésamoïdiennes, vers leur extrémité distale à la partie inférieure du métatarsien, de façon à maintenir le corps (32) dans une position axiale et angulaire convenable par rapport auxdites deux gorges sésamoïdiennes, ledit corps (32) présentant, en outre, un moyen (35) de réception et de positionnement d'un ancillaire de coupe métatarsienne, s'étendant parallèlement à l'axe de l'implant et donc à la broche, et à distance du métatarsien dans la direction latérale vers le plan sagittal du patient.

16. Ancillaire selon la revendication 15, **caractérisé en ce que** ledit moyen de réception (35) est une tige de section non circulaire.

17. Ancillaire (40) de guidage de coupe métatarsienne pour la pose d'une prothèse selon l'une des revendications 1 à 6 présentant un corps (41) avec un passage lui permettant de coulisser sur le moyen de réception un ancillaire de repérage (31) selon l'une des revendications 15 et 16, ledit corps présentant des moyens (42) de fixation par rapport à l'os, ledit corps (41) présentant, en outre, au moins une fente de coupe pour le passage d'une scie oscillante, ladite fente (44) étant inclinée d'un angle à 70° ± 20°, par rapport à l'axe de la broche lorsque l'ensemble est monté sur le métatarsien.

18. Ancillaire selon la revendication 17, **caractérisé en ce qu'**il comporte une deuxième fente (45) plus inclinée de façon que, lesdites deux fentes (44, 45) permettent ainsi de réaliser d'une part la coupe recevant la face arrière (7) de la tête (6) d'implant et la deuxième coupe qui forme un angle obtus, de préférence de 145° ± 20° avec la coupe précitée.

19. Ancillaire (50) de coupe phalangienne pour la pose d'une prothèse selon l'une des revendications 1 à 6 présentant un corps (51) lui permettant d'être fixé, latéralement sur la corticale de la phalange, au moins une fente (53) de coupe phalangienne, et un prolongement (55) destiné à venir s'appliquer, contre une extrémité correspondante de l'ancillaire de coupe métatarsien (40) selon l'une des revendications 17 et 18, de façon à définir exactement les positions relatives des deux ensembles de coupe, les fentes de coupe métatarsienne et phalangienne étant, lorsque les deux ancillaires de coupe sont réunis, sensiblement parallèles.

20. Ancillaire selon la revendication 19, **caractérisé en ce qu'**il comporte deux fentes de coupe parallèles (53, 54).

Claims

1. Total metatarsophalangeal prosthesis comprising a metatarsal implant (1) comprising an anchoring bar (4) intended to be located longitudinally in the metatarsal (M), and a head (6) located at the end of the bar intended to be applied against the cut surface of the end of the metatarsal and having an articular surface (10),
and a phalangeal implant (2) having a body (14) intended to be inserted axially into the phalange, and a collar (16) located at the proximal end of said part and suitably configured to have an articular surface (18) complementary to the articular surface (10) presented by the body of the metatarsal implant, **characterised in that** opposite the articular surface (10) the head (6) of the metatarsal implant has an inclined plane rear face (7) intended to come to rest against a cut surface of the metatarsal (M), said rear face (7) forming an angle of 20° ± 5° with the plane perpendicular to the axis of the anchoring bar (4) to extend to the rear and upwards from the lower base of the metatarsal,
and **in that** the articular surface (10) of said head and said inclined rear face (7) meet at a lower point (11) to form the lowest point of the metatarsal implant, the distance between the axis of the anchoring bar (4) and said lowest point (11) being determined such that the implant head (6) does not extend into the sesamoid grooves located on the lower base of the metatarsal.

2. Prosthesis according to Claim 1, **characterised in that** said articular surface (18) of the phalangeal implant (2) is supported by a separate stud (3) capable of being inserted and held in the phalangeal implant (2).

3. Prosthesis according to one of the preceding claims, **characterised in that** the articular surface (10) of the body of the implant only has a single radius in the sagittal plane and a single radius in the horizontal

plane, the articular surface (18) of the phalangeal implant being congruent and supported by a stud (3) capable of rotating around the axis of the phalangeal implant.

4. Prosthesis according to one of Claims 2 or 3, **characterised in that** on its periphery, in particular on a sensitive section of the periphery of the lower half and/or the periphery of the upper half, the articular surface (18) of the stud (3) has a bevel (20, 21) defining a convex edge for clearance for articulation in the flexion and/or extension position.

5. Prosthesis according to one of Claims 2 to 4, **characterised in that** the phalangeal implant (2) has a hollow tapered anchoring body (14) extended at its proximal end by a head in the shape of a tapered peripheral collar (16), the stud (3) having a corresponding shape, i.e. a tapered distal section (19), the conicity of which corresponds to that of the body, extended by a plate (18) having a distal peripheral surface, the conicity of which corresponds to that of the collar (16) of the implant, and this also allows the stud to be configured particularly solidly.

6. Prosthesis according to one of the preceding claims, **characterised in that** the proximal face (7) inclined at 20° ± 5° of the head (6) of the metatarsal implant is extended upwards by way of an upper face (8) and with this forms a dihedron preferably with an obtuse angle of 145° ± 20° intended to be applied against an upper cutting plane inclined at the same angle relative to the cut receiving the proximal face (7).

7. Set of metatarsal implants comprising several metatarsal implants (1) of different sizes adapted to form a section of a prosthesis in accordance with any one of Claims I to 6, wherein the distance (h) between the axis of the anchoring bar (4) and the lowest point (11) is essentially constant for all the implants of the set.

8. Set of implants according to Claim 7, **characterised in that** the metatarsal implants (1) have the features of Claim 6, wherein the articular faces (10) of the heads (6) of these implants are dimensioned to meet the corresponding upper face (8) at an upper point (12) at respectively different predetermined distances from the axis of the anchoring bar (4).

9. Set of implants according to one of Claims 7 or 8, **characterised in that** the diameter of the bar (4) of the metatarsal implants (1) is substantially constant.

10. Set of prostheses comprising a set of metatarsal implants (1) in accordance with any one of Claims 7 to 9, several phalangeal implants (2) of different sizes and several studs (3) also of different sizes, **characterised in that** the stud (3), of which the articular surface (18) is congruent to the articular surface (18) of a given metatarsal implant, can be received at least in two phalangeal implants of consecutive sizes to form a prosthesis in accordance with any one of Claims 1 to 7.

11. Set according to Claim 9, **characterised in that** the phalangeal implant (2) has a tapered body (14) having the same dimension for all the implants in the set, the tapered collar (16) adjoining this cone, wherein only the diameter of the periphery of this collar (16) is variable from one implant to another in the respective set.

12. Set according to one of Claims 10 or 11, comprising three metatarsal implants (1), **characterised in that** the radii of curvature of the articular surface (10) are respectively 7 ± 0.5, 8 ± 0.5 and 9 ± 0.5 mm in the sagittal plane and 14 ± 1, 16 ± 1 and 18 ± 1 mm in the horizontal plane, and the lowest points (11) in the sagittal plane are located at a common distance (h) in the range of between about 2 and 6 mm from the axis.

13. Set according to Claim 12, **characterised by** four sizes of phalangeal implants (2), wherein each implant has an implant body (14) with a diameter of the distal end of 4.7 ± 2 mm and a diameter of the periphery of the collar (16) of 12 ± 1, 13.3 ± 1, 14.6 ± 1 and 16 ± 1 mm.

14. Set according to Claim 13, **characterised in that** it comprises three studs (3) of different sizes, i.e. studs with a diameter of 12 ± 0.5, 13 ± 0.5 and 14 ± 0.5 mm for a set of three studs.

15. Positioning aid (31) for fitting a prosthesis according to one of Claims 1 to 6, having a body (32) provided with a cylindrical inside passage to allow it to slide and rotate around a pin implanted axially into the metatarsal, and from said body (32) two arms (33, 34), the ends of which are spatially arranged to enable them to lock into the sesamoid grooves, are elbowed towards their distal end at the lower section of the metatarsal in order to hold the body (32) in an appropriate axial and angular position in relation to said two sesamoid grooves, said body (32) additionally having a means (35) for receiving and positioning a metatarsal cutting aid extending parallel to the axis of the implant, and therefore to the pin, and at a distance from the metatarsal in the lateral direction towards the sagittal plane of the patient.

16. Aid according to Claim 15, **characterised in that** said receiving means (35) is a bar with a non-circular cross-section.

17. Aid (40) for guiding a metatarsal cut for fitting a prosthesis according to one of Claims 1 to 6, having a body (41) with a passage to allow it to slide onto the receiving means, a positioning aid (31) according to one of Claims 15 and 16, said body having means (42) for fastening in relation to the bone, said body (41) additionally having at least one cutting slot for passage of an oscillating saw, said slot (44) being inclined at an angle of 70° ± 20° in relation to the axis of the pin when the assembly in mounted on the metatarsal.

18. Aid according to Claim 17, **characterised in that** it comprises a second slot (45) with a greater inclination such that said two slots (44, 45) thus allow the cut to be performed to receive the rear face (7) of the head (6) of the implant as well as the second cut that forms an obtuse angle, preferably 145° ± 20, with the previous cut.

19. Phalangeal cutting aid (50) for fitting a prosthesis according to one of Claims 1 to 6, having a body (51) to allow it to be secured laterally on the cortical area of the phalange, at least one phalangeal cutting slot (53), and an extension (55) intended to be applied against a corresponding end of the metatarsal cutting aid (40) according to one of Claims 17 and 18, in order to precisely define the relative positions of the two cutting assemblies, the metatarsal and phalangeal cutting slots being substantially parallel when the two cutting aids are joined.

20. Aid according to Claim 19, **characterised in that** it comprises two parallel cutting slots (53, 54).

Patentansprüche

1. Metatarsalphalangeale Vollprothese, mit
einem Metatarsalimplantat (1) mit einer Verankerungsstange (4) für eine Längsanordnung im Mittelfußknochen (M) und einem am Ende der Stange gelegenen Kopf (6), der zur Anbringung an der Oberfläche des Schnittes am Ende des Mittelfußknochens bestimmt ist und eine Gelenkfläche (10) darbietet,
und mit einem phalangealen Implantat (2), das einen Körper (14) zum axialen Einführen in das Zehenglied und eine Einfassung (16) darbietet, die am proximalen Ende des genannten Teils gelegen und geeignet ist, eine Gelenkfläche (18) komplementär zu der vom Körper des metatarsalen Implantats dargebotenen Gelenkfläche (10) darzubieten,
dadurch gekennzeichnet, daß der Kopf (6) des Metatarsalimplantats, in Gegenüberlage zur Gelenkoberfläche (10), eine plane hintere Schrägfläche (7) zur Anlage an einer Schnittoberfläche des Mittelfußknochens (M) darbietet, wobei die hintere Fläche (7) mit der zur Achse der Verankerungsstange (4) senkrechten Ebene einen Winkel von 20° ± 5° für eine rückwärtige Erstreckung nach oben von der unteren Basis des Mittelfußknochens aus bildet, und daß sich die Gelenkoberfläche (10) des Kopfes und die hintere Schrägfläche (7) an einem unteren Punkt (11) treffen, der den tiefsten Punkt des Metatarsalimplantats bildet, wobei der Abstand zwischen der Achse der Verankerungsstange (4) und dem tiefsten Punkt (11) so bestimmt ist, daß sich der Implantatkopf (6) nicht in die auf der unteren Basis des Mittelfußknochens angeordneten Sesamhälse erstreckt.

2. Prothese nach Anspruch 1, **dadurch gekennzeichnet, daß** die Gelenkoberfläche (18) des phalangealen Implantats (2) von einem gesonderten Klotz (3) abgestützt ist, der in das phalangeale Implantat (2) einsetzbar und festsetzbar ist.

3. Prothese nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** die Gelenkoberfläche (10) des Implantatkörpers nur einen einzigen Radius in der Sagittalebene und einen einzigen Radius in der Horizontalebene aufweist und daß die Gelenkfläche (18) des phalangealen Implantats kongruent und von einem um die Achse des phalangealen Implantats drehbaren Klotz (3) abgestützt ist.

4. Prothese nach einem der Ansprüche 2 oder 3, **dadurch gekennzeichnet, daß** die Gelenkoberfläche (18) des Klotzes (3) auf ihrem Umfang, insbesondere auf einem wesentlichen Teil des Umfangs der unteren Hälfte und/oder des Umfangs der oberen Hälfte, einen Ausschnitt (20,21) aufweist, der einen konvexen Rand für das Freimachen des Gelenks in Flexions- und/oder Extensionsposition definiert.

5. Prothese nach einem der Ansprüche 2 bis 4, **dadurch gekennzeichnet, daß** das phalangeale Implantat (2) einen kegelstumpfförmigen hohlen Verankerungskörper (14) aufweist, der sich an seinem proximalen Ende in einen Kopf in Form einer kegelstumpfförmigen Umfangseinfassung (16) fortsetzt, und der Klotz (3) eine entsprechende Form aufweist, nämlich einen distalen kegelstumpfförmigen Teil (19), dessen Konizität derjenigen des Körpers entspricht und der sich in einer Scheibe (18) mit einer distalen Umfangsfläche fortsetzt, deren Konizität derjenigen der Einfassung (16) des Implantats entspricht, was es gleichermaßen ermöglicht, dem Klotz eine besonders haltbare Form zu geben.

6. Prothese nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** sich die mit 20° ± 5° schrägverlaufende proximale Fläche (7) des Kopfes (6) des Metatarsalimplantats nach oben in einer oberen Fläche (8) fortsetzt, die mit der vorher-

gehenden einen Flächenwinkel, vorzugsweise mit einem stumpfen Winkel von 145° ± 20°, für eine Anlage an einer oberen Schnittebene bildet, die im gleichen Winkel in bezug auf den die proximale Fläche (7) aufnehmenden Schnitt schräg verläuft.

7. Metatarsalimplantatsatz von mehreren Metatarsalimplantaten (1) von unterschiedlicher Größe, geeignet zur Bildung eines Teils einer Prothese nach einem der Ansprüche 1 bis 6, wobei der Abstand (h) zwischen der Achse der Verankerungsstange (4) und dem tiefsten Punkt (11) für sämtliche Implantate des Satzes im wesentlichen konstant ist.

8. Implantatsatz nach Anspruch 7, **dadurch gekennzeichnet, daß** die Metatarsalimplantate (1) die Merkmale des Anspruchs 6 aufweisen, wobei die Gelenkflächen (10) der Köpfe dieser Implantate so bemessen sind, daß sie auf die entsprechende obere Fläche (8) an einem oberen Punkt (12) mit einem jeweils vorherbestimmten unterschiedlichen Abstand von der Achse der Verankerungsstange (4) treffen.

9. Implantatsatz nach einem der Ansprüche 7 oder 8, **dadurch gekennzeichnet, daß** der Durchmesser der Stange (4) der Metatarsalimplantate (1) im wesentlichen konstant ist.

10. Prothesensatz, der einen Metatarsalimplantatsatz (1) nach einem der Ansprüche 7 bis 9, mehrere phalangeale Implantate (2) von unterschiedlicher Größe und mehrere Klötze (3) von ihrerseits unterschiedlicher Größe umfaßt, **gekennzeichnet durch** die Tatsache, daß der Klotz (3), dessen Gelenkoberfläche (18) mit der Gelenkoberfläche (10) eines gegebenen Metatarsalimplantats kongruent ist, in, zumindest, zwei Phalangealimplantaten mit aufeinanderfolgender Größe zur Bildung einer Prothese nach einem der Ansprüche 1 bis 7 aufnehmbar ist.

11. Satz nach Anspruch 9, **dadurch gekennzeichnet, daß** das Phalangealimplantat (2) einen kegelstumpfförmigen Körper (14) mit der gleichen Abmessung für sämtliche Implantate des Satzes aufweist, wobei die kegelstumpfförmige Einfassung (16) auf diesen Kegel folgt und nur der Durchmesser des Umfangs dieser Einfassung (16) von einem Implantat zum anderen in dem Bausatz veränderbar ist.

12. Satz nach einem der Ansprüche 10 oder 11, mit drei Metatarsalimplantaten (1), **dadurch gekennzeichnet, daß** die Krümmungsradien der Gelenkoberfläche (10) jeweils 7 ± 0,5, 8 ± 0,5 und 9 ± 0,5 mm in der Sagittalebene und 14 ± 1, 16 ± 1 und 18 ± 1 mm in der Horizontalebene betragen und die tiefsten Punkte (11) in der Sagittalebene mit einem gemeinsamen Abstand (h) zwischen etwa 2 und 6 mm von der Achse gelegen sind.

13. Satz nach Anspruch 12, **gekennzeichnet durch** vier Größen von Phalangealimplantaten (2), wobei jedes Implantat einen Implantatkörper (14) mit einem Durchmesser am distalen Ende von 4,7 ± 2 mm und einem Umfangsdurchmesser der Einfassung (16) von 12 ± 1, 13,3 ± 1, 14.6 ± 1 und 16 ± 1 mm besitzt.

14. Satz nach Anspruch 13, **dadurch gekennzeichnet, daß** er drei Klötze (3) von unterschiedlicher Größe umfaßt, nämlich Klötze mit einem Durchmesser von 12 ± 0,5, 13 ± 0,5 und 14 ± 0,5 mm für einen Satz von drei Klötzen.

15. Einpassungshilfsgerät (31) zum Einsetzen einer Prothese nach einem der Ansprüche 1 bis 6, mit einem Körper (32), der mit einem zylindrischen Innenkanal versehen ist, der es ihm ermöglicht, um eine in axialer Richtung in den Mittelfußknochen eingesetzte Spindel zu gleiten und umzulaufen, und, ausgehend vom Körper (32), zwei Winkelhebeln (33,34), deren Enden so im Raum angeordnet sind, daß sie sich in den Sesamhälsen zu ihrem distalen Ende hin am unteren Teil des Mittelfußknochens festlegen können, um den Körper (32) in einer passenden axialen und Winkelposition in bezug auf die beiden Sesamhälse zu halten, wobei der Körper (32) außerdem ein Mittel (35) zur Aufnahme und Positionierung eines Hilfsgerätes für einen Metatarsalschnitt aufweist, das sich parallel zur Achse des Implantats und damit der Spindel und mit einem Abstand vom Mittelfußknochen in seitlicher Richtung zur Sagittalebene des Patienten erstreckt.

16. Hilfsgerät nach Anspruch 15, **dadurch gekennzeichnet, daß** das Aufnahmemittel (35) eine Stange mit nicht-kreisförmigem Querschnitt ist.

17. Hilfsgerät (40) zur metatarsalen Schnittführung für die Anbringung einer Prothese nach einem der Ansprüche 1 bis 6, das einen Körper (41) mit einem Kanal aufweist, der es ihm ermöglicht, auf dem Aufnahmemittel eines Einpassungshilfsgeräts (31) nach einem der Ansprüche 15 und 16 zu gleiten, wobei der Körper (41) Fixiermittel (42) in bezug auf den Knochen aufweist und der Körper (41) außerdem zumindest einen Schneidschlitz für den Durchgang einer Pendelsäge aufweist, wobei der Schlitz (44) in einem Winkel von 70° ± 20° in bezug auf die Achse der Spindel geneigt ist, wenn die Einheit auf dem Mittelfußknochen montiert ist.

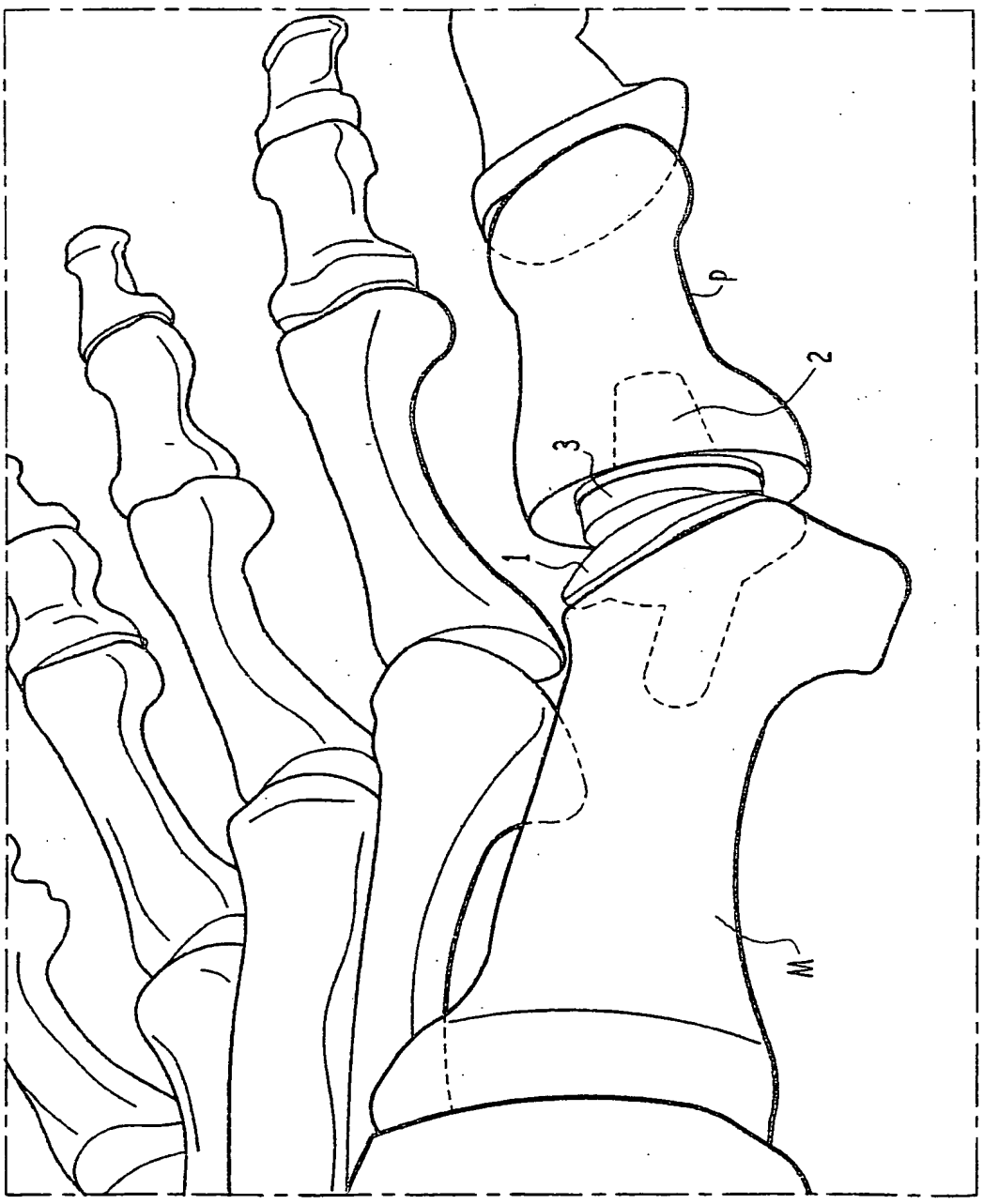
18. Hilfsgerät nach Anspruch 17, **dadurch gekennzeichnet, daß** es einen schrägeren zweiten Schlitz (45) aufweist, derart, daß es die beiden Schlitze (44,45) somit ermöglichen, einerseits den die hintere

Fläche (7) des Implantatkopfes (6) erhaltenden Schnitt und den zweiten Schnitt auszuführen, der einen stumpfen Winkel vorzugsweise von 145° ± 20° mit dem vorgenannten Schnitt bildet.

19. Hilfsgerät (50) für einen Phalangealschnitt zum Einsetzen einer Prothese nach einem der Ansprüche 1 bis 6, mit einem Körper (51), der seitlich auf der Kortikalen des Zehengliedes festlegbar ist, zumindest einem Schlitz (53) für den Phalangealschnitt und einer Verlängerung (55) für eine Anlage an einem entsprechenden Ende des Hilfsgerätes (40) für den Metatarsalschnitt nach einem der Ansprüche 17 und 18, derart, daß die relativen Positionen der beiden Schneideinheiten exakt definiert werden, wobei die Schlitze für den Metatarsal- und den Phalangealschnitt, bei Vereinigung der beiden Schneidhilfsgeräte, im wesentlichen parallel verlaufen.

20. Hilfsgerät nach Anspruch 19, **dadurch gekennzeichnet, daß** es zwei parallele Schneidschlitze (53,54) umfaßt.

FIG.1



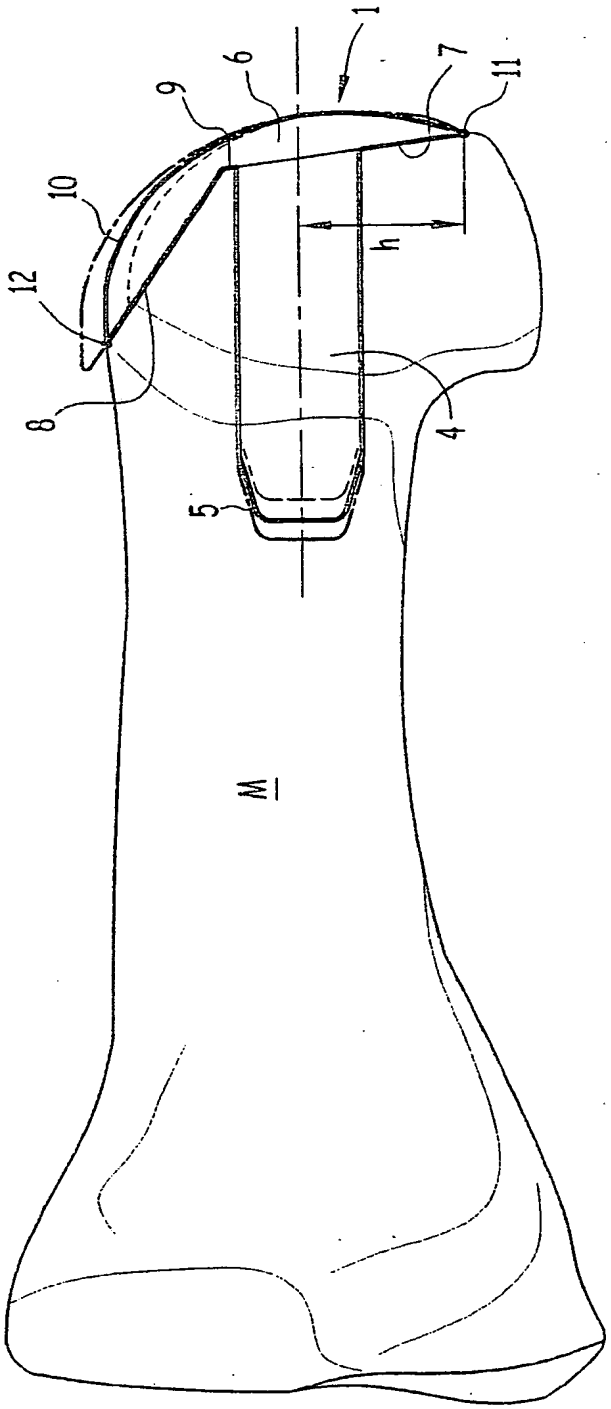


FIG.2

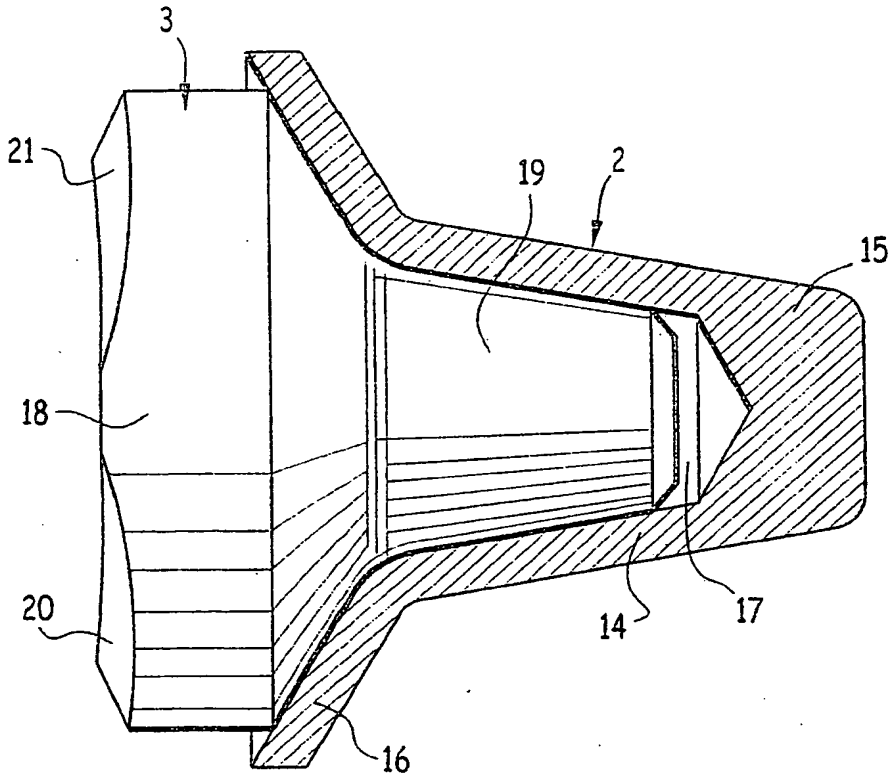


FIG.3

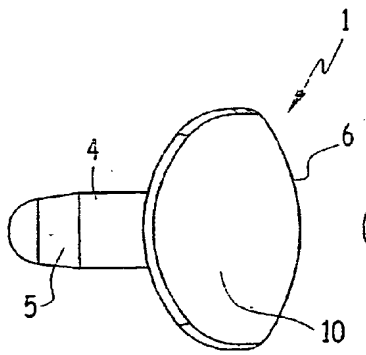


FIG.4

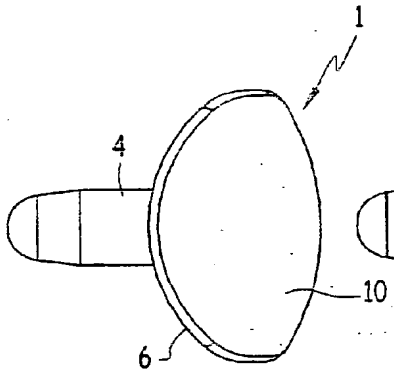


FIG.6

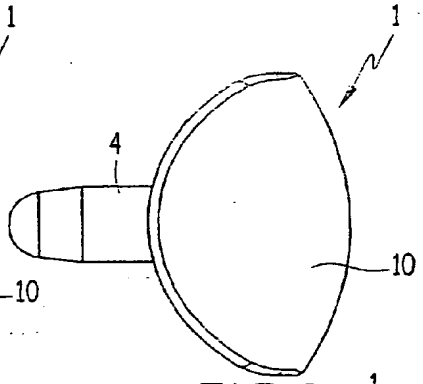


FIG.8

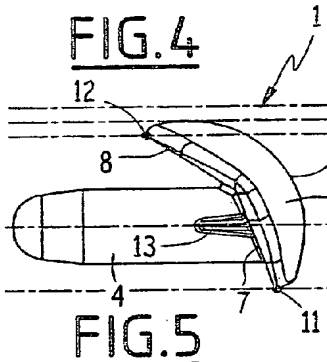


FIG.5

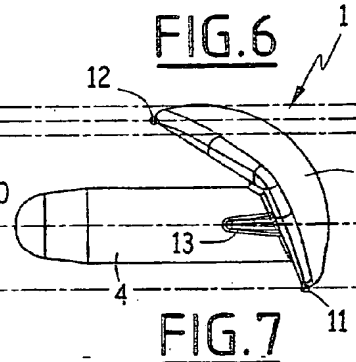


FIG.7

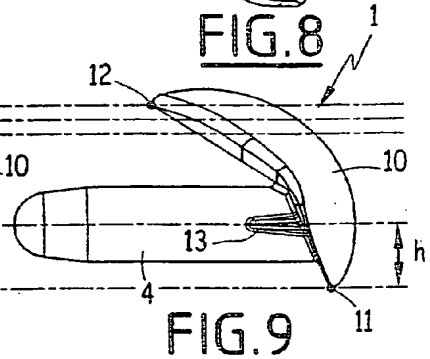


FIG.9

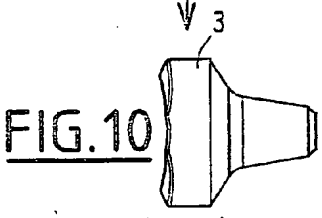


FIG.10

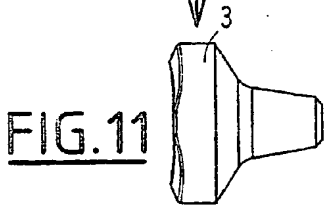


FIG.11

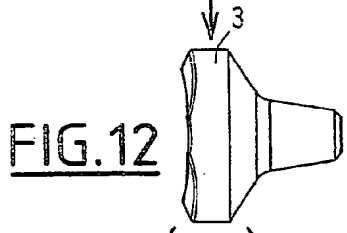


FIG.12

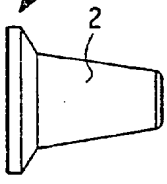


FIG.13

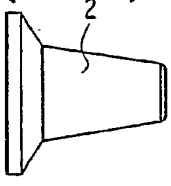


FIG.14

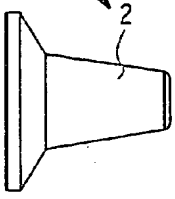


FIG.15

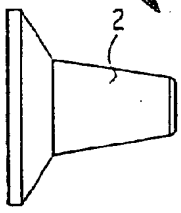


FIG.16

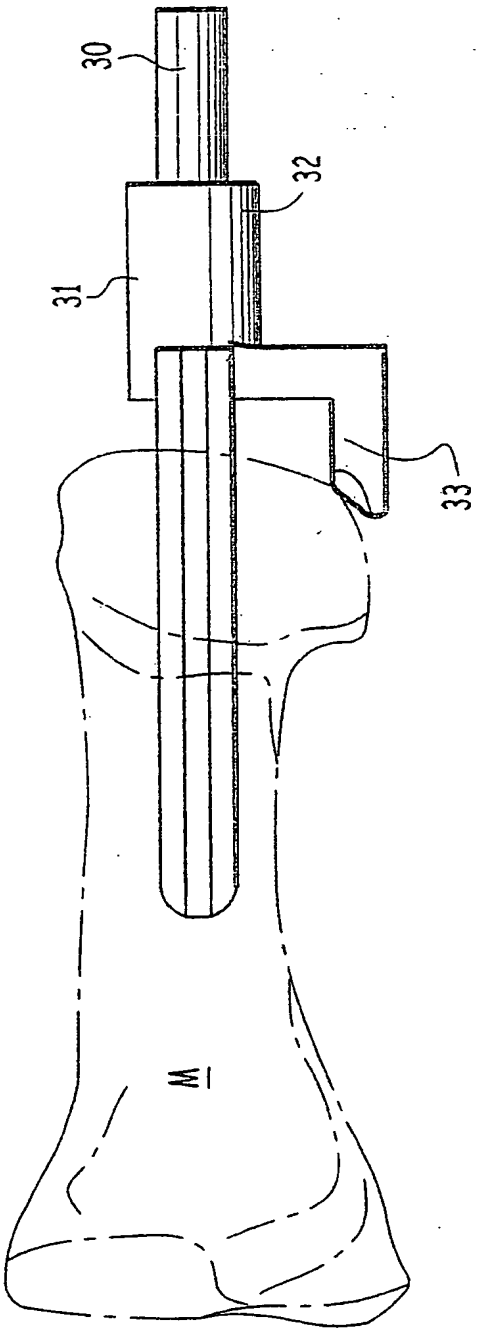


FIG.17

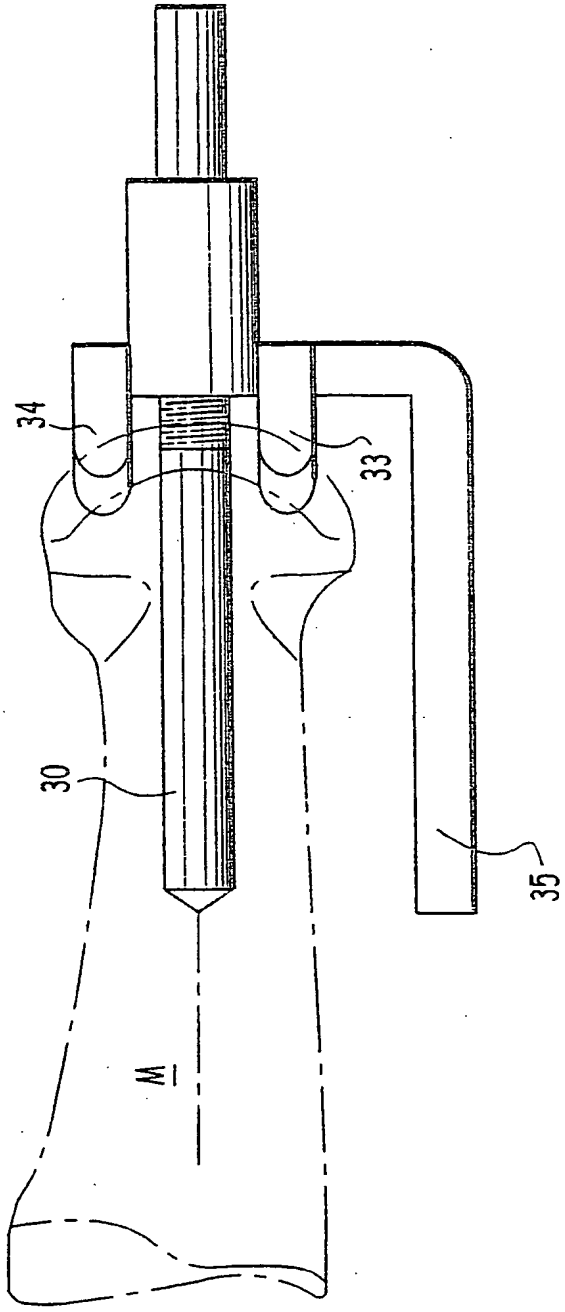


FIG.18

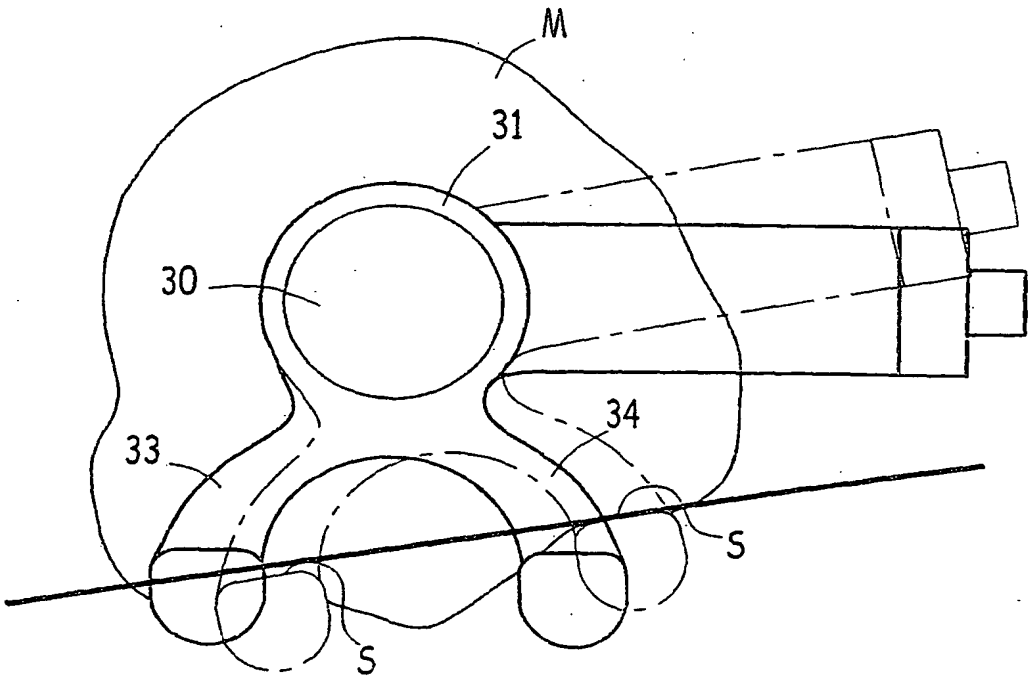


FIG.19

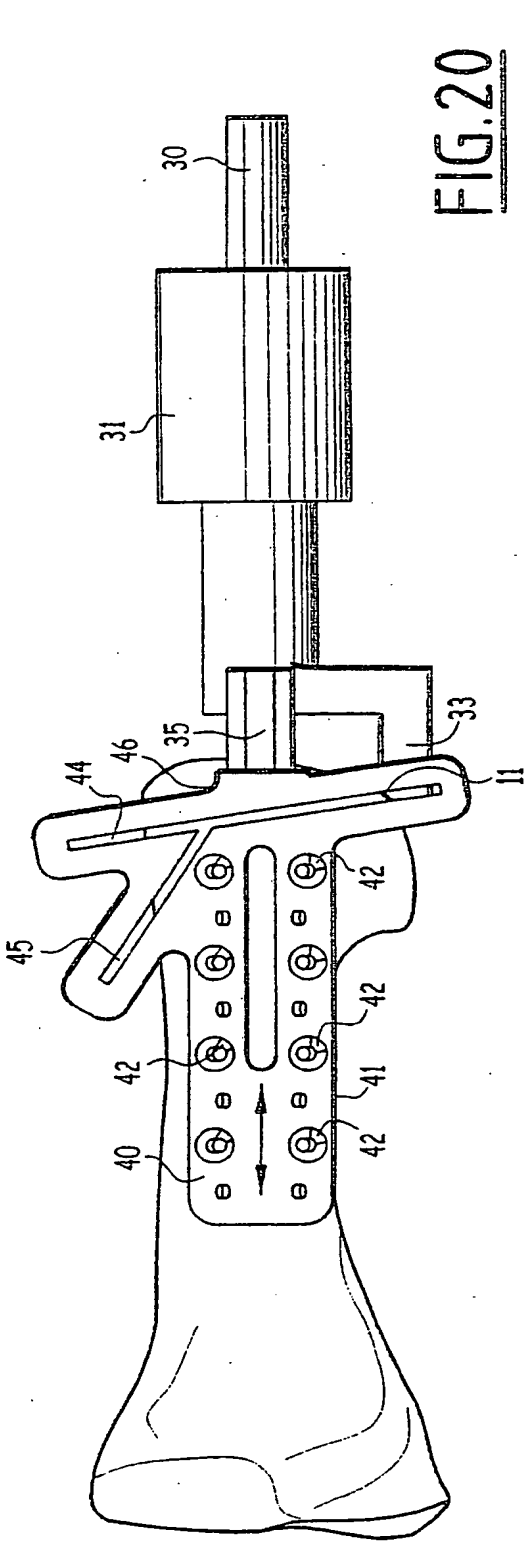


FIG.20

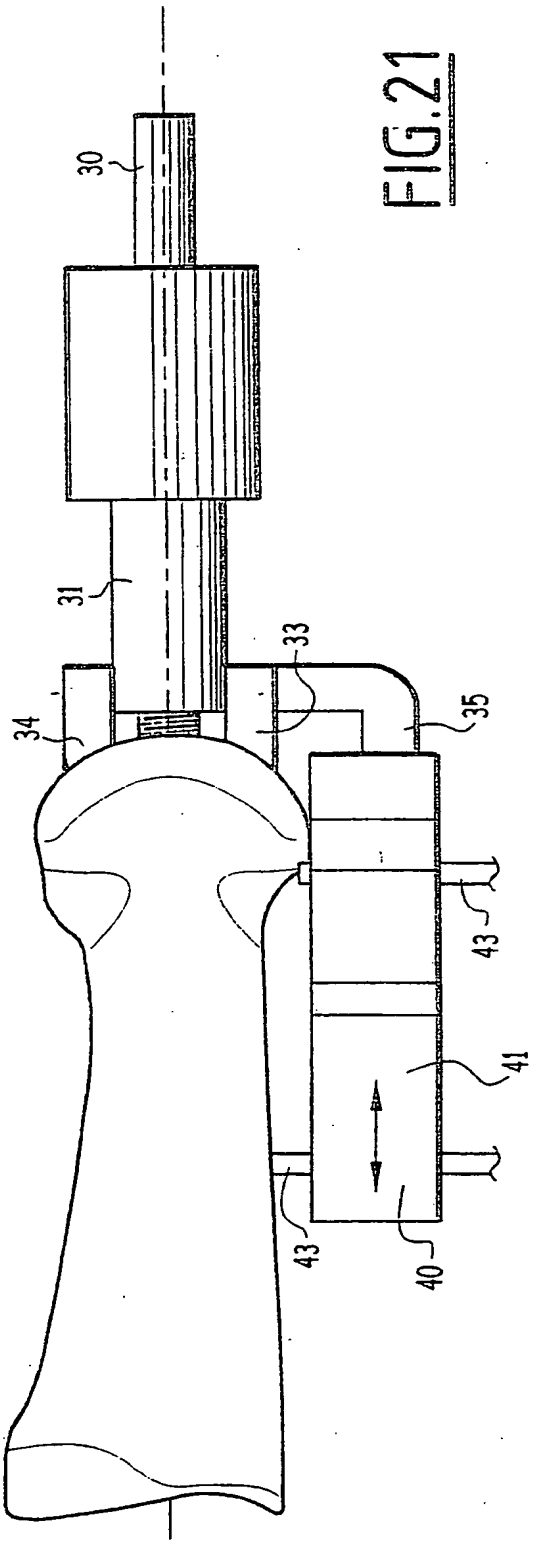


FIG.21

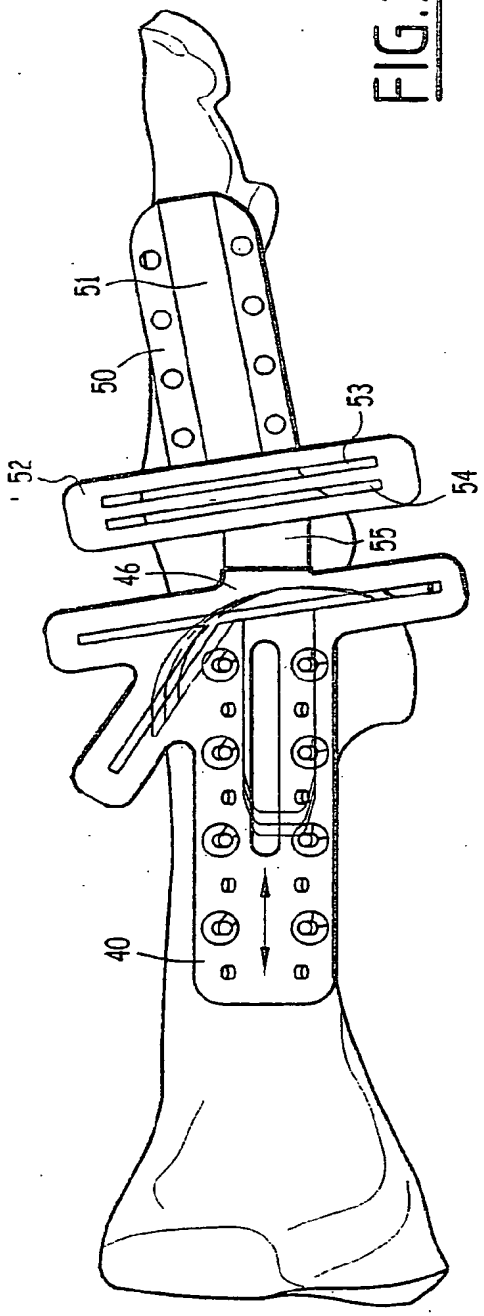


FIG.22

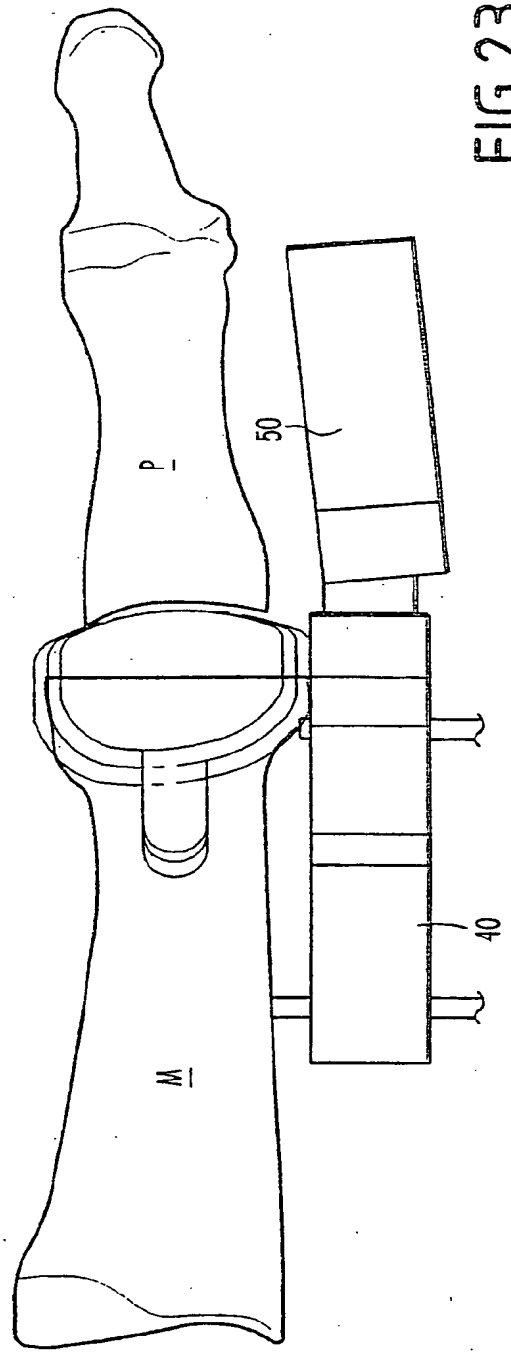


FIG.23

Espacenet

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CERAMIC CUTTING TEMPLATE

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Applicant(s): CERAMTEC GMBH [DE] ± (CERAMTEC GMBH)

Classification: - international: ***A61B17/00; C04B35/48***
- cooperative: **A61B17/155 (EP)**; **A61B17/1764 (US)**; **C04B35/486 (EP)**; **C04B35/4885 (EP)**; **C04B35/6261 (EP)**; **C04B35/62655 (EP)**; **C04B35/62695 (EP)**; **C04B35/6455 (EP)**; C04B2235/3217 (EP); C04B2235/3225 (EP); C04B2235/604 (EP); C04B2235/612 (EP); C04B2235/661 (EP); C04B2235/662 (EP); C04B2235/765 (EP); C04B2235/77 (EP); C04B2235/785 (EP); C04B2235/81 (EP); C04B2235/945 (EP); C04B2235/9661 (EP)

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Abstract not available for EP2624764 (B1)
Abstract of corresponding document: WO2012045826 (A1)

The invention relates to a cutting template, to a cutting block, preferably a cutting template, and to a cutting block for use in medical technology.

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CERAMIC CUTTING TEMPLATE

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EP-A1- 1 514 578
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WO-A2-2010/112589
JP-A- 2006 104 023
JP-A- 2009 269 812

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EP 2 624 764 B1

Beschreibung

[0001] Gegenstand der vorliegenden Erfindung ist eine Schnittschablone bzw. ein Sägeblock, vorzugsweise eine Schnittschablone bzw. ein Sägeblock zum Einsatz in der Medizintechnik.

[0002] Schnittschablonen bzw. Sägeblocks werden in der Chirurgie vielfach eingesetzt, um das Operationsfeld vorzubereiten bzw. anzupassen, beispielsweise wenn es darum geht, Implantationen vorzunehmen.

[0003] So wird beispielsweise bei jeder Knie-TEP-Implantation eine Schnittschablone bzw. ein Sägeblock auf dem Femur fixiert. Mit dieser Schnittschablone werden im Normalfall drei Schnitte zur Anpassung der Femuroberfläche an die Geometrie der Femurkomponente durchgeführt. Für jeden Schnitt befindet sich in der Schnittschablone eine Führung (3 bzw. 4 Schnittführungen in 1 Schablone). In dieser Führung wird der Schnitt mit einem Schneideinstrument, im Normalfall mit einem oszillierenden Sägeblatt durchgeführt. Die Sägeblätter sowie die Schnittschablonen sind heute grundsätzlich aus biokompatiblen Metalllegierungen gefertigt.

[0004] Die Führungsschienen im Sägeblock haben je nach Hersteller eine Breite von 1,2 - 1,5 mm. Bedingt durch das Oszillieren des Sägeblatts und die auftretende Reibung zwischen Sägeblatt und Führungsschiene tritt ein hoher Metallabrieb auf Seiten der Führungsschiene auf. Dieser Abrieb wird nicht bzw. kann nur unzureichend intraoperativ aus der Wunde entfernt werden. Somit kann dieser Abrieb wiederum zur Ursache von Infektionen werden und vor allem zu allergischen Reaktionen des Patienten führen. Aus diesem Grund gilt es, diesen Abrieb grundsätzlich zu reduzieren, insbesondere jedoch, wenn durch den Einsatz einer keramischen Femurkomponente beim potentiellen Allergiker eine Implantatreaktion vermieden werden soll.

[0005] Nach heutigem Kenntnisstand entsteht der überwiegende Teil des Metallabriebs durch den Verschleiß der Führungsschienen in der Schnittschablone. Nach ca. 20 - 40-maliger Verwendung einer Schnittschablone im Rahmen von Knie-TEP-Implantationen weisen die Führungsschienen um ca. 0,5 - 1,5 mm vergrößerte Führungsspalte auf. Infolgedessen nimmt die Führungsgenauigkeit der Schnittschablone erheblich ab. Die Folgen für den Chirurgen sind entsprechend, eine präzise Schnittführung des Sägeblattes ist nicht mehr möglich, Ausrichtung und Ebenheit der Schnittflächen des Femurs weisen zunehmend Abweichungen auf. Dies führt zu größeren Spalten zwischen Schnittflächen und Femurkomponente. Diese Spalte müssen intraoperativ durch ein größeres als sonst übliches Volumen an Knochenzement aufgefüllt werden, was einen negativen Einfluss auf die Standzeit des Systems haben kann.

[0006] Die der vorliegenden Erfindung zugrunde liegende Aufgabe bestand darin, die Nachteile der Schnittschablonen / der Sägeblöcke des Standes der Technik zu beseitigen und insbesondere:

- den Metallabrieb zu reduzieren, wobei eine Reduzierung des Metallabriebs um bis zu 90% gegenüber den bisherigen Metalllösungen angestrebt werden soll;
- die Standzeit einer Schnittschablone zu verlängern und damit Kosten einzusparen;
- das Allergierisiko sowie das Risiko von Infektionen zu reduzieren.

[0007] Die erfindungsgemäße Aufgabe wurde überraschenderweise durch eine Schnittschablone / einen Sägeblock aus Keramik (im Folgenden werden für die erfindungsgemäße Schnittschablone / den erfindungsgemäßen Sägeblock auch die Begriffe Sinterformkörper oder Sinterkörper verwendet) mit den Merkmalen der unabhängigen Ansprüche gelöst. Vorzugsweise Ausgestaltungen finden sich in den Unteransprüchen. Es wurde überraschenderweise festgestellt, dass die Lösung der anstehenden Aufgaben Sinterformkörper mit ganz speziellen Zusammensetzungen erfordert.

[0008] Sinterformkörper, die die Lösung der anstehenden Aufgaben ermöglichen, sind sogenannte "yttria-stabilized tetragonal zirconia-Keramiken" auch Y-TZP-Keramiken genannt. Erfindungsgemäß geeignet sind solche Y-TZP-Keramiken, die der Norm für medizinische Anwendungen entsprechen.

Geeignete Y-TZP-Keramiken enthalten

[0009]

3 bis 8 Gew.-% Y_2O_3, vorzugsweise 4 bis 6 Gew.-% Y_2O_3, besonders bevorzugt 4,5 bis 5,5 Gew.-% Y_2O_3, 0 bis 0,5 Gew.-% Al_2O_3, vorzugsweise 0,05 bis 0,4 Gew.-% Al_2O_3, besonders bevorzugt 0,1 bis 0,3 Gew.-% Al_2O_3 und Rest auf 100 Gew.-% ZrO_2, wobei bis zu 3 Gew.-% HfO_2, vorzugsweise bis zu 2 Gew.-% HfO_2 im Zirkonoxid enthalten sein können.

[0010] Der Monoklinanteil im ZrO_2 liegt dabei bei weniger als 2 Vol-%, vorzugsweise bei weniger als 1 Vol-%

[0011] Die Eigenschaften der geeigneten Y-TZP-Keramiken weisen eine Festigkeit von 900 bis 1600 MPa, vorzugsweise von 1000 bis 1500 MPa auf. Die Korngröße der Keramik bewegt sich dabei in einem Bereich von < 0,5 µm, vorzugsweise in einem Bereich von 0,1 bis 0,3 µm.

[0012] Vorzugsweise Ausgestaltungen sind in der folgenden Tabelle aufgeführt:

	Beispiel 1	Beispiel 2	
	Wert	Wert	Einheit
Yttriumoxid (Y_2O_3)	4,9	5,2	Gew.-%
Hafniumoxid (HfO_2)	2,0	2,0	Gew.-%
Aluminiumoxid (Al_2O_3)	0,1	0,1	Gew.-%
Verunreinigungen	< 0,1	< 0,1	Gew.-%
Zirkonoxid (ZrO_2)	Rest auf 100	Rest auf 100	Gew.-%

[0013] Die Eigenschaften der vorzugsweise eingesetzten Keramiken sind in den folgenden Tabellen aufgeführt.

Beispiel 1:

[0014]

Korngröße	0,15 - 0,2	µm	
Farbe	Elfenbein		
Dichte	6,08	g/cm^3	DIN EN 623-2
Wasseraufnahmevermögen	0	%	ASTM C 373
Festigkeit (4-Punkt-Biegung)	1400	MPa	DIN ENV 843-1
Weibull-Modul	10		DIN ENV 843-5
Bruchzähigkeit	7,5	MPa√m	ISO 23 146
Vickers-Härte (HV 0,5)	13	GPa	DIN ENV 843-4
E-Modul	210	GPa	DIN ENV 843-2
Poisson-Zahl	0,3		DIN ENV 843-2
Wärmeausdehnungskoeffizient			DIN EN 821-1
20 - 200 °C	10,4	10^{-6} K^{-1}	
20 - 1000 °C	11,4	10^{-6} K^{-1}	
Spezifische Wärmekapazität (20 °C)	0,4	kJ / kg K	DIN EN 821-3
Wärmeleitfähigkeit (20 °C)	2,5	W/mK	DIN EN 821-2

Beispiel 2:

[0015]

Korngröße	< 0,5	µm	
Farbe	weiß		
Dichte	6,05	g/cm^3	DIN EN 623-2
Wasseraufnahmevermögen	0	%	ASTM C 373
Gasdurchlässigkeit	0	%	
Festigkeit (4-Punkt-Biegung)	1050	MPa	DIN ENV 843-1

(fortgesetzt)

Druckfestigkeit	2200	MPa	DIN 51067 T1
Weibull-Modul	>10		DIN ENV 843-5
Vickers-Härte (HV 1)	1250		DIN ENV 843-4
E-Modul (dynamisch)	210	GPa	DIN ENV 843-2
Poisson-Zahl	0,3		DIN ENV 843-2
Wärmeausdehnungskoeffizient			DIN EN 821-1
20 - 200 °C	11,1	10^{-6} K^{-1}	
20 - 1000 °C	11,7	10^{-6} K^{-1}	
Spezifische Wärmekapazität (20 °C)	0,4	kJ / kg K	DIN EN 821-3
Wärmeleitfähigkeit (20 °C)	2,5	W/mK	DIN EN 821-2
Wärmespannungsparameter R1	321	K	
Dielektrizitätskonstante	29 (1 MHz)		IEC 672-1
Dielektrischer Verlustfaktor	0,002 (1 GHz)		IEC 672-1

[0016] Bei den erfindungsgemäß aus Y-TZP-Keramiken hergestellten Schnittschablonen bzw. Sägeblöcken ist der Metallabrieb um bis zu 90% gegenüber den bisherigen Schnittschablonen bzw. Sägeblöcken aus Metall reduziert. Die Standzeit der erfindungsgemäßen Schnittschablonen bzw. der erfindungsgemäßen Sägeblöcke im Einsatz ist deutlich verlängert, da nur geringer Verschleiß der Schnittschablonen auftritt. Dies reduziert die Kosten. Außerdem sind das Allergierisiko bzw. die allergischen Reaktionen von Patienten sowie das Risiko von Infektionen reduziert.

[0017] Bevorzugt werden die erfindungsgemäßen Schnittschablonen in der Medizintechnik, insbesondere bei Operationen zur Bearbeitung eines Knochens, in bevorzugter Weise bei Knie-TEP-Implantationen verwendet.

[0018] Die Vorteile der erfindungsgemäßen keramischen Schnittschablone bzw. die der Keramik, aus der sie hergestellt ist, sind:

- ➢ Die Schnittschablone weist einen extrem geringen Abrieb auf.
- ➢ Das Material ist biokompatibel.
- ➢ Wenn die erfindungsgemäße Schnittschablone mit einem Laser beschriftet wird, ist diese sehr gut sichtbar und lesbar und kann somit Fehlhandhabungen beim Einsatz der Schnittschablone reduzieren.
- ➢ Die Schnittschablone besitzt gute tribologische Eigenschaften.

[0019] Die Herstellung der Schnittschablone erfolgt mittels konventioneller Keramiktechnologie.

[0020] Die wesentlichen Prozessschritte sind:

a) Pulvermischung gemäß vorgegebener Zusammensetzung in Wasser ansetzen, Verwendung von Verflüssigern zur Vermeidung der Sedimentation.
b) Homogenisieren im Dissolver (schnelllaufender Rührer).
c) Mahlen in Rührwerkskugelmühle, dabei Erhöhung der spezifischen Oberfläche der Pulvermischung (= Zerkleinerung).
d) Zugabe von organischen Bindern.
e) Sprühtrocknen, dabei entsteht ein rieselfähiges Granulat mit definierten Eigenschaften.
f) Befeuchten des Granulats mit Wasser.
g) Axial oder isostatisch pressen.
h) Spanabhebende Grünbearbeitung, dabei wird unter Berücksichtigung der Sinterschwindung weitgehend die Endkontur abgebildet.
i) Vorbrand, dabei Schwindung auf ca. 98% der theoretischen Dichte. Die noch verbleibenden Restporen sind nach außen geschlossen.
j) Heißisostatisches Pressen unter hoher Temperatur und hohem Gasdruck, dadurch praktisch vollständige End-

verdichtung.
k) So genannter Weißbrand, dadurch wird das beim heißisostatischen Pressen erzeugte Ungleichgewicht der Sauerstoffionen in der Keramik ausgeglichen.
l) Hartbearbeitung durch Schleifen und Polieren.
m) Tempern.

[0021] Die Figuren 1 bis 4 zeigen beispielhaft eine erfindungsgemäße Schnittschablone 1 aus Keramik für den Einsatz bei der Implantation eines künstlichen Kniegelenks in verschiedenen Ansichten. Eine derartige Schnittschablone 1 dient zur Führung eines chirurgischen Schneideinstruments, beispielsweise eines Sägeblatts oder eines Bohrers. Figur 5 soll die intraoperative Verwendung einer erfindungsgemäßen Schnittschablone bei der Implantation eines künstlichen Kniegelenks illustrieren.

[0022] Die gezeigte Schnittschablone besteht aus einem Grundkörper 2, welcher mit schlitzartigen Ausnehmungen 3 zur Durchführung und passgenauen Führung eines plattenförmigen Schneideinstruments, beispielsweise eines Sägeblatts, versehen ist, wobei die schlitzartigen Ausnehmungen 3 einander gegenüberliegende Führungsflächen 4 aufweist. An diesen Führungsflächen 4 liegt das Schneideinstrument (siehe Figur 5) beim Schnittvorgang an. In den Grundkörper 2 sind Durchgangsbohrungen 5 eingebracht, die zur Verschraubung der Schnittschablone 1 auf dem Femur dienen.

[0023] Für den Fachmann ist es selbstverständlich, dass die erfindungsgemäße Schnittschablone je nach Einsatzzweck angepasst werden kann. So kann sie beispielsweise auch in der Form einer Bohrlehre ausgestaltet sein, bei der beispielsweise eine oder mehrere der Ausnehmungen 3 als Durchgangsbohrung zur Durchführung und passgenauen Führung eines Bohrers als Schneideinstrument ausgeführt sind.

[0024] Im Rahmen der vorliegenden Erfindung bezeichnen die Begriffe Sinterformkörper / Sinterkörper eine Keramik in Form von bzw. zur Verwendung als Schnittschablone bzw. Sägeblock. Als Schnittschablone bzw. Sägeblock im Sinne der vorliegenden Erfindung soll auch eine erfindungsgemäß ausgestaltete Bohrlehre verstanden werden.

[0025] Aus dem Vorstehenden ergibt sich, dass die erfindungsgemäße Lehre eine keramische Schnittschablone betrifft:

- die aus einem Grundkörper 2, mit ein oder mehreren Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments besteht, wobei die Keramik 3 bis 8 Gew.-% Y_2O_3, vorzugsweise 4 bis 6 Gew.-% Y_2O_3, besonders bevorzugt 4,5 bis 5,5 Gew.-% Y_2O_3, 0 bis 0,5 Gew:-% Al_2O_3, vorzugsweise 0,05 bis 0,4 Gew.-% Al_2O_3, besonders bevorzugt 0,1 bis 0,3 Gew.-% Al_2O_3 und den Rest auf 100 Gew.-% ZrO_2 enthält und wobei bis zu 3 Gew.-% HfO_2, vorzugsweise bis zu 2 Gew.-% HfO_2 im ZrO_2 enthalten sein können und der Monoklinanteil im ZrO_2 vorzugsweise bei weniger als 2 Vol.-%, vorzugsweise bei weniger als 1 Vol.-%. liegt.

[0026] Bevorzugt ist eine keramische Schnittschablone, bei der:

- die Keramik eine Festigkeit von 900 bis 1600 MPa, vorzugsweise eine Festigkeit von 1000 bis 1500 MPa aufweist;
- sich die Korngröße der Keramik in einem Bereich von < 0,5 µm, vorzugsweise in einem Bereich von 0,1 bis 0,3 µm bewegt;
- die Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments schlitzartig sind;
- die Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments Durchgangsbohrungen sind;
- die schlitzartigen Ausnehmungen 3 einander gegenüberliegende Führungsflächen 4 aufweisen;
- in den Grundkörper 2 zusätzlich ein oder mehrere Durchgangsbohrungen 5 eingebracht sind.

Patentansprüche

1. Keramische Schnittschablone, **dadurch gekennzeichnet, dass** sie aus einem Grundkörper 2, mit ein oder mehreren Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments besteht, wobei die Keramik 3 bis 8 Gew.-% Y_2O_3, vorzugsweise 4 bis 6 Gew.-% Y_2O_3, besonders bevorzugt 4,5 bis 5,5 Gew.-% Y_2O_3, 0 bis 0,5 Gew.-% Al_2O_3, vorzugsweise 0,05 bis 0,4 Gew.-% Al_2O_3, besonders bevorzugt 0,1 bis 0,3 Gew.-% Al_2O_3 und den Rest auf 100 Gew.-% ZrO_2 enthält und wobei bis zu 3 Gew.-% HfO_2, vorzugsweise bis zu 2 Gew.-% HfO_2

im ZrO_2 enthalten sein können und der Monoklinanteil im ZrO_2 vorzugsweise bei weniger als 2 Vol.-%, vorzugsweise bei weniger als 1 Vol.-%. liegt.

2. Keramische Schnittschablone gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die Keramik eine Festigkeit von 900 bis 1600 MPa, vorzugsweise eine Festigkeit von 1000 bis 1500 MPa aufweist.

3. Keramische Schnittschablone gemäß Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** sich die Korngröße der Keramik in einem Bereich von < 0,5 µm, vorzugsweise in einem Bereich von 0,1 bis 0,3 µm bewegt.

4. Keramische Schnittschablone gemäß einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments schlitzartig sind.

5. Keramische Schnittschablone gemäß einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die Ausnehmungen 3 zur Durchführung und passgenauen Führung eines Schneideinstruments Durchgangsbohrungen sind.

6. Keramische Schnittschablone gemäß Anspruch 4, **dadurch gekennzeichnet, dass** die schlitzartigen Ausnehmungen 3 einander gegenüberliegende Führungsflächen 4 aufweisen.

7. Keramische Schnittschablone gemäß einem oder mehreren der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** in den Grundkörper 2 zusätzlich ein oder mehrere Durchgangsbohrungen 5 eingebracht sind.

8. Verwendung der keramischen Schnittschablone nach einem oder mehreren der Ansprüche 1 bis 6 in der Medizintechnik, insbesondere bei Operationen zur Bearbeitung eines Knochens.

9. Verwendung der keramischen Schnittschablone nach einem oder mehreren der Ansprüche 1 bis 6 bei einer Knie-TEP-Implantation.

Claims

1. A ceramic cutting template, **characterised in that** it consists of a base body 2 having one or more recesses 3 for passing through and guiding, with a precise fit, a cutting instrument, wherein the ceramic material contains 3 to 8 % by weight Y_2O_3, preferably 4 to 6 % by weight Y_2O_3, particularly preferably 4.5 to 5.5 % by weight Y_2O_3, 0 to 0.5 % by weight Al_2O_3, preferably 0.05 to 0.4 % by weight Al_2O_3, particularly preferably 0.1 to 0.3 % by weight Al_2O_3, and the remainder to 100 % by weight ZrO_2, and wherein up to 3 % by weight HfO_2, preferably up to 2 % by weight HfO_2, can be contained in the ZrO_2, and the monoclinic proportion in the ZrO_2 lies preferably at less than 2 % by volume, preferably at less than 1 % by volume.

2. A ceramic cutting template according to claim 1, **characterised in that** the ceramic material has a strength of 900 to 1600 MPa, preferably a strength of 1000 to 1500 MPa.

3. A ceramic cutting template according to claim 1 or 2, **characterised in that** the grain size of the ceramic material lies in a range of < 0.5 µm, preferably in a range of 0.1 to 0.3 µm.

4. A ceramic cutting template according to one of claims 1 to 3, **characterised in that** the recesses 3 for passing through and guiding, with a precise fit, a cutting instrument are slot-like.

5. A ceramic cutting template according to one of claims 1 to 3, **characterised in that** the recesses 3 for passing through and guiding, with a precise fit, a cutting instrument are through-bores.

6. A ceramic cutting template according to claim 4, **characterised in that** the slot-like recesses 3 have opposing guide surfaces 4.

7. A ceramic cutting template according to one or more of claims 1 to 5, **characterised in that** in addition one or more through-bores 5 are introduced into the base body 2.

8. Use of the ceramic cutting template according to one or more of claims 1 to 6 in medical technology, in particular in operations for working on a bone.

9. Use of the ceramic cutting template according to one or more of claims 1 to 6 in a knee-TEP-implantation.

Revendications

1. Gabarit de coupe en céramique, **caractérisé en ce qu'**il est constitué d'un corps de base 2 doté d'un ou plusieurs évidements 3 pour le passage et le guidage avec ajustage précis d'un instrument de coupe, la céramique contenant de 3 à 8 % en poids de Y_2O_3, de préférence de 4 à 6 % en poids de Y_2O_3, de façon préconisée de 4,5 à 5,5 % en poids de Y_2O_3, de 0 à 0,5 % en poids de Al_2O_3, de préférence de 0,05 à 0,4 % en poids de Al_2O_3, de façon préconisée de 0,1 à 0,3 % en poids de Al_2O_3, et le reste jusqu'à 100 % en poids de ZrO_2, et jusqu'à 3 % en poids de HfO_2, de préférence jusqu'à 2 % en poids de HfO_2. pouvant être contenus dans le ZrO_2, et la proportion monoclinique dans le ZrO_2 étant de préférence inférieure à 2 % en volume, de façon préconisée inférieure à 1 % en volume.

2. Gabarit de coupe en céramique selon la revendication 1, **caractérisé en ce que** la céramique présente une résistance allant de 900 à 1 600 MPa, de préférence une résistance allant de 1 000 à 1 500 MPa.

3. Gabarit de coupe en céramique selon la revendication 1 ou 2, **caractérisé en ce que** la grosseur de grains de la céramique se situe dans une plage < 0,5 µm, de préférence dans une plage allant de 0,1 à 0,3 µm.

4. Gabarit de coupe en céramique selon l'une des revendications 1 à 3, **caractérisé en ce que** les évidements 3 pour le passage et le guidage avec ajustage précis d'un instrument de coupe ont une forme de type fente.

5. Gabarit de coupe en céramique selon l'une des revendications 1 à 3, **caractérisé en ce que** les évidements 3 pour le passage et le guidage avec ajustage précis d'un instrument de coupe sont des trous débouchants.

6. Gabarit de coupe en céramique selon la revendication 4, **caractérisé en ce que** les évidements 3 en forme de fente présentent des surfaces de guidage 4 situées mutuellement en vis-à-vis.

7. Gabarit de coupe en céramique selon une ou plusieurs des revendications 1 à 5, **caractérisé en ce qu'**en plus, un ou plusieurs trous débouchants 5 sont réalisés dans le corps de base 2.

8. Utilisation du gabarit de coupe en céramique selon une ou plusieurs des revendications 1 à 6, dans la technologie médicale, en particulier pour des opérations en vue du traitement d'un os.

9. Utilisation du gabarit de coupe en céramique selon une ou plusieurs des revendications 1 à 6, pour une implantation TEP du genou.

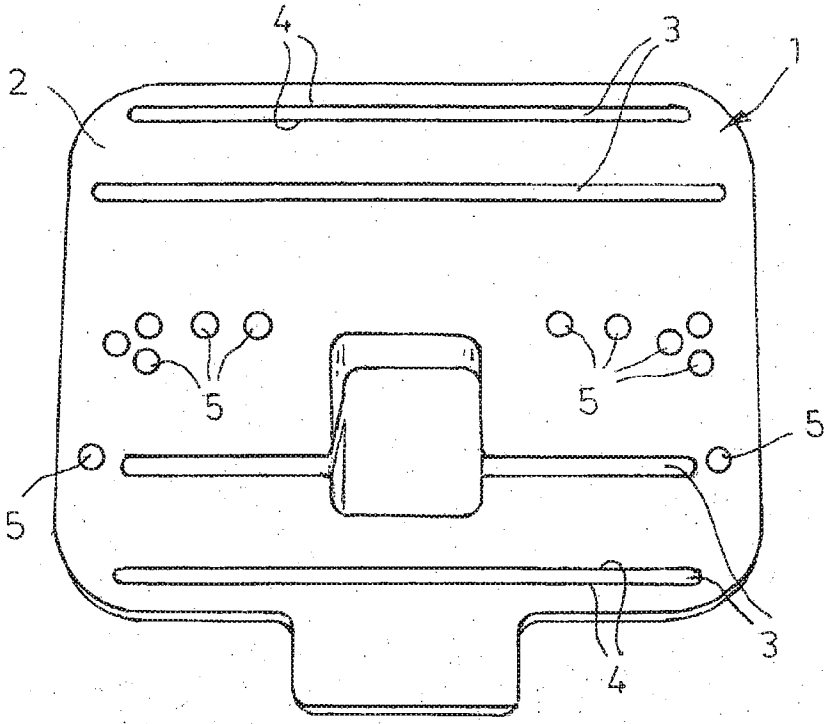


Fig.1

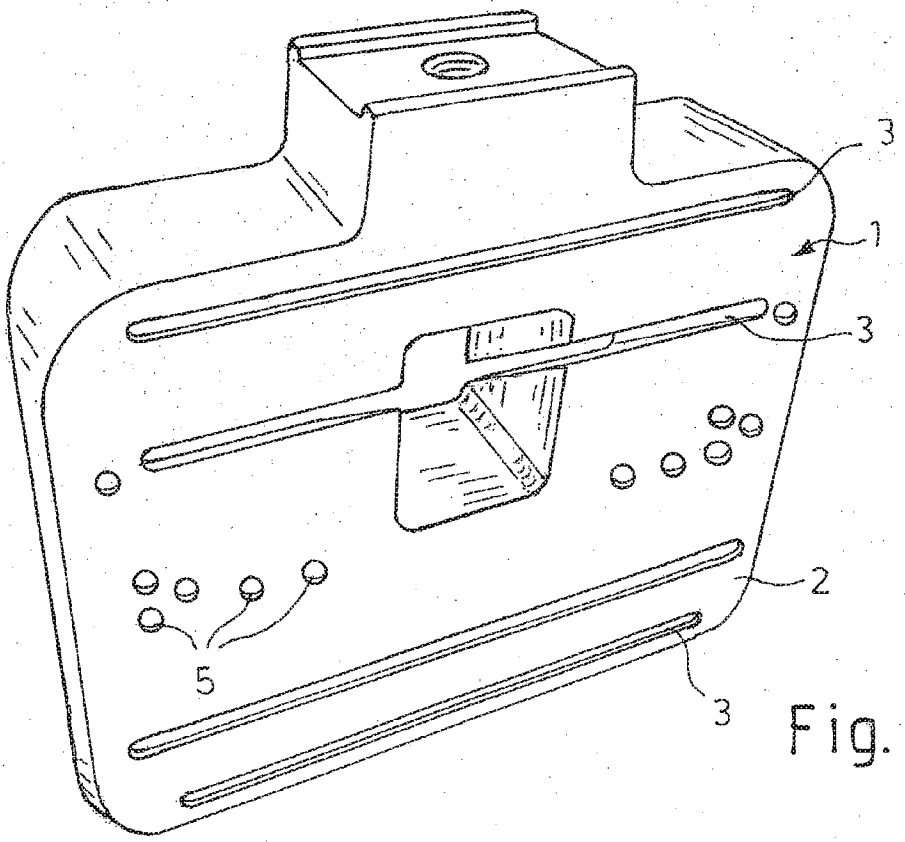


Fig.2

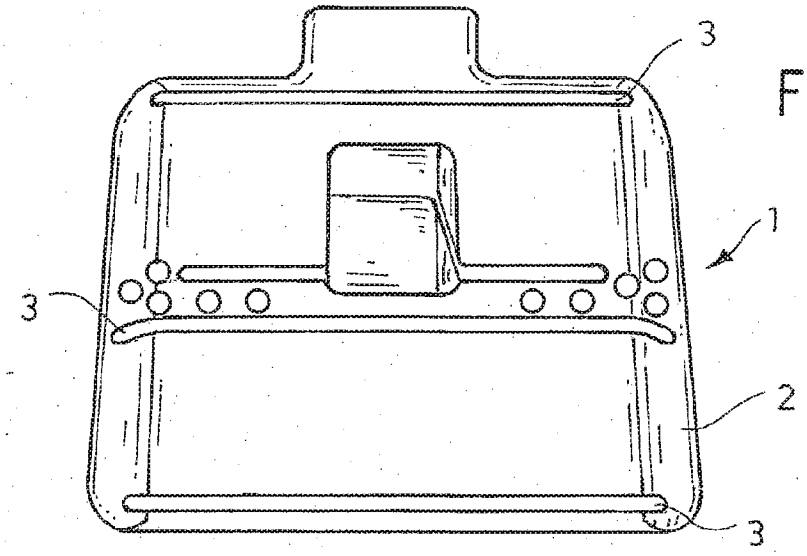


Fig. 3

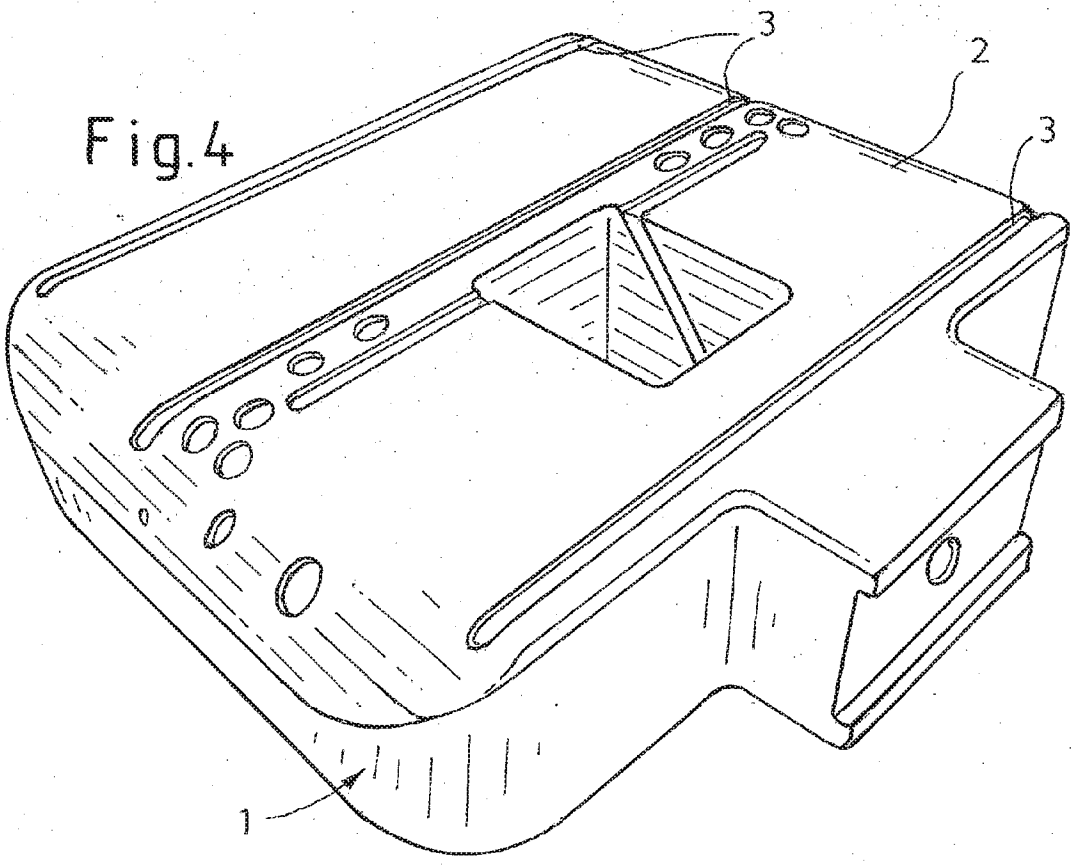


Fig.4

Fig.5



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ABSTRACT FR2953120

The present invention relates to systems for assisting the realization of femoral sections 11 and tibial 12 for the fitting of a joint prosthesis of a knee 13 when this prosthesis comprises a femoral component and a tibial component and when the knee is in position not folded. The system according to the invention is essentially characterized by the fact that it comprises two interline cards 21, 22 positioned between the femur Fe and the tibia Ti, a block 30 in one piece comprising a bearing face 32, two holes 33, 34, 35 through to receive the two pins 21, 22, the axes of these orifices being located in a plane 36, a slot 40 passing through the block 30 to guide a saw blade Isc and of a substantially parallel length at the plane 36, and a plurality of slots 51, 52, 53 passing through the block 30 to guide a saw blade Isc, all parallel to each other and having their lengths substantially parallel to the plane 36, and located in the portion 55 of the block 30 which is delimited by the plane 36 and which does not contain the slot 40.

SYSTEM FOR ASSISTING FEMORAL AND TIBIAL CUTS

The invention relates to a surgical system for assisting the realization of 5 femoral and tibial cuts for the placement of a knee prosthesis when the latter is in its so-called "extended" position. The positioning of the two parts of a total knee prosthesis depends on the quality of realization of the bone cuts allowing the adjustment of the implants. In order to optimize this positioning, pledge of the biomechanical success of the intervention and its perpetuation, it is necessary to fulfill certain conditions: height of joint space, orientation of prosthetic parts in the three planes of space in particular. For this purpose, viewers guided by an electronic browser have been proposed. The use of currently known viewers makes it possible to secure the poses, but lengthens the operating time and especially involves a high cost of the intervention as a whole. Usually, the surgeon has a material of assistance to the pose dedicated to a particular type of prosthesis. The positioning of the cutting guides allowing it to embed each prosthesis depends on the orientation given to the respective sections. He must therefore know perfectly the characteristics of each material. To secure the orientation of the cuts, it can for this purpose make use of a computer assistance whose effectiveness is not proven and which remains a very high cost. In all cases, the cuts made on the femur and the tibia are separately, the knee being maintained in flexion, which implies two complicated systems, and hence two possible sources of error. The object of the present invention is thus to provide a system which overcomes the aforementioned drawbacks of the systems of the prior art, in particular to secure the femoral and tibial cuts, to obtain a saving in operating time and to substantially reduce the manufacturing cost. ancillary equipment necessary for the installation of total knee prostheses.

the axes of said orifices being situated in the same plane substantially perpendicular to said bearing face, at least a first slot passing through it and able to guide a saw blade, said first slot being made in said block so that its length is substantially parallel to said plane and so that it is at a determined distance from said plane, and * a plurality of second slots therethrough, each second slot being adapted to guide a saw blade (Ise), said seconds slots being made in said block so that they are all parallel to each other and that their lengths are substantially parallel to said plane, and so that they are located in the part of the block which is delimited by said plane and which contains not the first slot. 25 D '

It is first of all specified that, in the figures, the same references designate the same elements, whatever the figure on which they appear and whatever the form of representation of these elements. Similarly, if elements are not specifically referenced in one of the figures, their references can be easily found by referring to the other figure. It is also stated that the figures essentially represent an embodiment of the object according to the invention, but that there may be other embodiments that meet the definition of this invention. It is further specified that, when, according to the definition of the invention, the object of the invention comprises "at least one" element having a given function, the embodiment described may comprise several of these elements. Conversely, if the embodiment of the object according to the invention as illustrated comprises several elements of identical function and if, in the description, it is not specified that the object according to this invention must obligatorily comprise a particular number of these elements, the object of the invention may be defined as include "at least one" of these elements. Finally, it is

pointed out that when, in the present description, an expression alone defines, without specific particular mention concerning it, a set of structural characteristics, these characteristics can be taken for the definition of the object of the protection sought. when technically possible, either separately, either in total and / or partial combination. With reference to the two appended figures, the present invention relates to a system for assisting the production of femoral and tibial cuts 12 for the fitting of a joint prosthesis of a knee 13 of a human being when this prosthesis comprises a femoral piece and a tibial piece and when the knee is in the unfolded position, that is to say "in extension" according to the terminology of the 30 persons of the profession. According to the invention, the system comprises at least two spacing sheets 21, 22 adapted to be positioned between the femur Fe and the tibia Ti before the an articular prosthesis of a knee 13 of a human being when this prosthesis comprises a femoral component and a tibial component and when the knee is in the unfolded position, that is to say "in extension" according to the terminology of the 30 persons of the profession. According to the invention, the system comprises at least two spacing sheets 21, 22 adapted to be positioned between the femur Fe and the tibia Ti before the an articular prosthesis of a knee 13 of a human being when this prosthesis comprises a femoral component and a tibial component and when the knee is in the unfolded position, that is to say "in extension" according to the terminology of the 30 persons of the profession. According to the invention, the system comprises at least two spacing sheets 21, 22 adapted to be positioned between the femur Fe and the tibia Ti before the

making the cuts, and a block 30 of one piece, this block comprising. a bearing surface 32, advantageously flat, adapted to be positioned against the Fe femur and tibia Ti at the knee joint. This block 30 comprises at least two orifices 33, 34, 35 passing therethrough, these orifices having a cross-section respectively complementary to the cross-section of the two spacing cards 21, 22. Moreover, the axes of these orifices are located in the same plane 36 substantially perpendicular to the bearing face 32. The block 30 further comprises at least a first slot 40 adapted to guide a saw blade Isc. This first slot 40 is made in the block so as to pass through it and to be located at a determined distance from the plane 36 containing the axes of the orifices 33-35, and so that its length is substantially parallel to this plane 36. The block 30 also comprises a plurality of second slots 51, 52, 53 each adapted to guide a saw blade Isc. These second slots are made so as to cross the block 30 while being all parallel to each other and located in the portion 55 of the block 30 delimited by the plane 36 defined above and which does not contain the first slot 40, and so that their lengths are substantially parallel to this plane 36.

According to an advantageous embodiment, it is possible for the interlacing cards 21, 22 to have different cross-sections and for the block to have more than two through-holes 33, 34, 35 of sections respectively adapted to those of the cards which are intended to be used. to cooperate with them, which allows to better adjust the position of the block 30 relative to the joint. According to another advantageous embodiment, the system according to the invention further comprises a plurality of positioning pins 60 and the block 30 further comprises a plurality of through-holes 61, 62, 63, each of these through-holes being adapted to receive a positioning pin to fix the block 30 at least on the Fe femur or tibia Ti, and advantageously on both. According to another advantageous embodiment,

rectilinear direction substantially perpendicular to the plane 36 defined above, to locate the femoral-tibial axis. According to one possible embodiment, these reference means 70 are constituted by at least one of the following elements: a line 71 materialized on the face 37 of the block opposite to the bearing face 32, a rod 72 plugged into the block 30 and at least one end emerges from the block 30, advantageously both emerging on either side of the block, a slide mounted in cooperation with the block, a telescopic rod plugged into the block, etc. In a very preferential manner, the block 30 is made of radiolucent material, for example polyethylene or any other resistant resin, in particular to verify the correct implantation of the plugs and / or the pins, as well as the making of the cuts. According to a preferred embodiment, the slots 40, 51, 52, 53 are all the same width, which allows to use the same saw blades lsc, and therefore have the same thickness of cut on both bones. In addition, for ease of implementation and therefore a lower production cost, the block 30 has the shape of substantially a parallelepiped, preferably rectangle. The present invention therefore relates to a system for the introduction of total knee prostheses. More particularly, the system makes it possible to perform the femoral-diotal and tibial-proximal sections in a very short time thanks to an integrated system for automatically locating the axes of the femur Fe and the tibia Ti. In addition, it offers the possibility of ensuring its attachment to the skeleton so as to allow sawing the bones, safely and with the utmost precision. The present system makes it possible to perform the two sections, perpendicular to the femoro-tibial axis previously determined on radiographic or tomodensitometric documents, or even magnetic resonance, with the block 30 of parallelepipedal shape having a first upper slot 40 in which a lsc saw blade may be inserted for the lower end of the femur and several lower seconds 51-53 for performing the tibial cut at the proper level.

The block 30 comprises a horizontal row of several orifices 33-35, for example 3mm in diameter, materializing, by the introduction of pins 21, 22, as rods, the femoral-tibial spacing and automatically adjusting the slope of the cuts. in the sagittal plane. Some orifices, so also interligne cards that are intended to cooperate with them, may be of greater diameter to compensate for greater wear of the knee condyles. In view of these elements, it has been developed the system according to the invention described above which further provides a simplified cutting guide for practicing in one step the main femoral distal and proximal tibial bone sections, and this in a coordinated way to ensure the ligament balance of the knee when the knee is in the extended position. The block 30 is perforated, for example at its corners, with pins 60 to allow the stabilization of the bones and the system during the cutting of the bones which generally generates vibrations. The block 30 may be made of a metallic material, but advantageously in a transparent radio-resistant material in order to allow intraoperative radioscopic checks to check the level and orientation of the cuts before they are made.

The validation of the orientation can be carried out on the block itself which comprises, according to one possible embodiment, a vertical gutter in which can be placed a rod 72 of suitable dimensions and of sufficient length to project on the tibial crest and achieve the level of the ankle. Therefore, the cuts in question can be made safely by automatically adjusting their thickness, orientation and level.

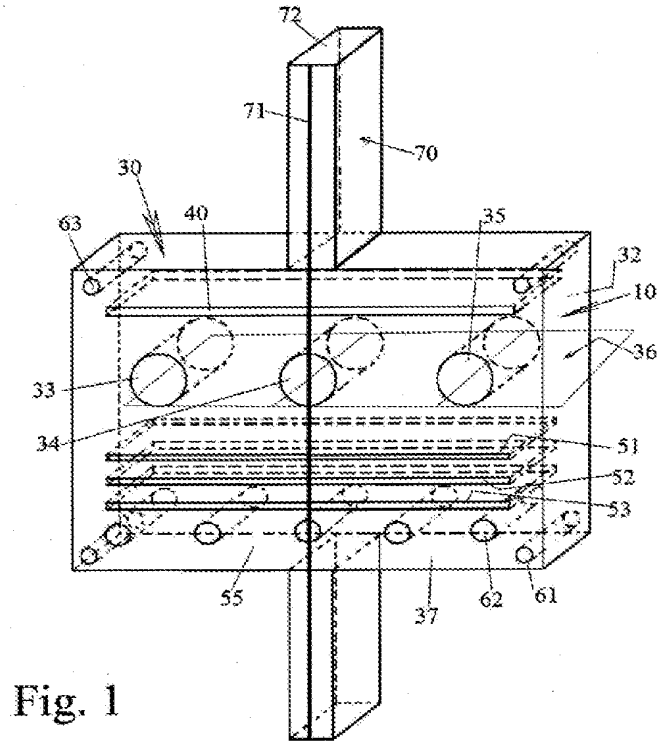

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Fig. 1

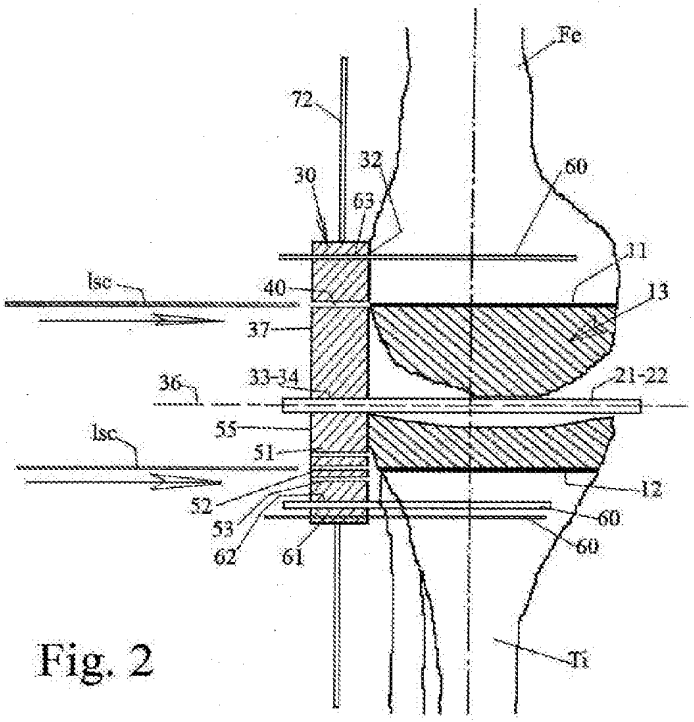

Fe
72
30
32
63
60
11
Isc
40
13
37
36
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21-22
55
Isc
51
12
52
53
60
62
61
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Ti

Fig. 2

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(12) **BREVET D'INVENTION** **B1**

(54) SYSTEME D'AIDE A LA REALISATION DE COUPES FEMORALE ET TIBIALE.

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(56) **Liste des documents cités dans le rapport de recherche :**

Se reporter à la fin du présent fascicule

(60) **Références à d'autres documents nationaux apparentés :**

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FR 2 953 120 - B1

SYSTEME D'AIDE A LA REALISATION DE COUPES FEMORALE ET TIBIALE

L'invention concerne un système chirurgical d'aide à la réalisation de coupes fémorale et tibiale pour la mise en place d'une prothèse de genou lorsque ce dernier est dans sa position dite "en extension".

Le positionnement des deux pièces d'une prothèse totale de genou dépend de la qualité de réalisation des coupes osseuses permettant l'ajustement des implants.

Pour optimiser ce positionnement, gage de la réussite biomécanique de l'intervention et de sa pérennisation, il est nécessaire de remplir certaines conditions: hauteur de l'interligne articulaire, orientation des pièces prothétiques dans les trois plans de l'espace notamment. A cet effet, des viseurs guidés par un navigateur électronique ont été proposés.

L'utilisation des viseurs connus actuellement permet de sécuriser les poses, mais rallonge le temps opératoire et surtout entraîne un coût élevé de l'intervention dans son ensemble.

Habituellement, le chirurgien dispose d'un matériel d'aide à la pose dédié à un type de prothèse particulier. Le positionnement des guides de coupe lui permettant d'encastrer chaque prothèse dépend de l'orientation donnée aux coupes respectives. Il doit donc connaître parfaitement les caractéristiques de chaque matériel. Pour sécuriser l'orientation des coupes, il peut à cet effet faire usage d'une assistance par ordinateur dont l'efficacité n'est pas prouvée et qui reste d'un prix de revient très élevé.

Dans tous les cas, les coupes effectuées sur le fémur et le tibia le sont séparément, le genou étant maintenu en flexion, ce qui implique deux systèmes compliqués, et par là même deux sources possibles d'erreur.

La présente invention a ainsi pour but de réaliser un système qui pallie les inconvénients mentionnés ci-dessus des systèmes de l'art antérieur, notamment pour sécuriser les coupes fémorale et tibiale, obtenir un gain de temps opératoire et diminuer substantiellement le coût de fabrication du matériel ancillaire nécessaire à la pose des prothèses totales de genou.

La présente invention a pour objet un système d'aide à la réalisation de coupes fémorale et tibiale pour la pose d'une prothèse articulaire d'un genou d'un être humain lorsque cette prothèse comporte une pièce fémorale et une pièce tibiale et lorsque le genou est en position dite "en extension", caractérisé par le fait qu'il comporte :

• au moins deux fiches d'interligne aptes à être positionnées entre le fémur et le tibia avant la réalisation des coupes,

• un bloc d'une seule pièce, ledit bloc comprenant une face d'appui apte à être positionnée contre le fémur et le tibia au niveau de l'articulation du genou, ledit bloc comportant :

* au moins deux orifices le traversant et d'une section respectivement complémentaire de la section transversale des deux fiches d'interligne, les axes des dits orifices étant situés dans un même plan sensiblement perpendiculaire à ladite face d'appui,

* au moins une première fente le traversant et apte à guider une lame de scie, ladite première fente étant réalisée dans ledit bloc de façon que sa longueur soit sensiblement parallèle au dit plan et de façon qu'elle soit à une distance déterminée du dit plan, et

* une pluralité de secondes fentes le traversant, chaque seconde fente étant apte à guider une lame de scie (lsc), lesdites secondes fentes étant réalisées dans ledit bloc de façon qu'elles soient toutes parallèles entre elles et que leurs longueurs soient sensiblement parallèles au dit plan, et de façon qu'elles soient situées dans la partie du bloc qui est délimitée par ledit plan et qui ne contient pas la première fente.

D'autres caractéristiques et avantages de la présente invention apparaîtront au cours de la description suivante donnée en regard des dessins annexés à titre illustratif mais nullement limitatif, dans lesquels :

La figure 1 est une vue en perspective d'une partie du système selon l'invention pour une aide à la réalisation de coupes fémorale et tibiale pour la pose d'une prothèse articulaire d'un genou, et

La figure 2 est une vue en coupe et de côté du système selon l'invention représenté en coopération avec l'articulation d'un genou.

Il est tout d'abord précisé que, sur les figures, les mêmes références désignent les mêmes éléments, quelle que soit la figure sur laquelle elles apparaissent et quelle que soit la forme de représentation de ces éléments. De même, si des éléments ne sont pas spécifiquement référencés sur l'une des figures, leurs références peuvent être aisément retrouvées en se reportant à l'autre figure.

Il est aussi précisé que les figures représentent essentiellement un mode de réalisation de l'objet selon l'invention, mais qu'il peut exister d'autres modes de réalisation qui répondent à la définition de cette invention.

Il est en outre précisé que, lorsque, selon la définition de l'invention, l'objet de l'invention comporte "au moins un" élément ayant une fonction donnée, le mode de réalisation décrit peut comporter plusieurs de ces éléments. Réciproquement, si le mode de réalisation de l'objet selon l'invention tel qu'illustré comporte plusieurs éléments de fonction identique et si, dans la description, il n'est pas spécifié que l'objet selon cette invention doit obligatoirement comporter un nombre particulier de ces éléments, l'objet de l'invention pourra être défini comme comportant "au moins un" de ces éléments.

Il est enfin précisé que lorsque, dans la présente description, une expression définit à elle seule, sans mention particulière spécifique la concernant, un ensemble de caractéristiques structurelles, ces caractéristiques peuvent être prises, pour la définition de l'objet de la protection demandée, quand cela est techniquement possible, soit séparément, soit en combinaison totale et/ou partielle.

En référence aux deux figures annexées, la présente invention concerne un système d'aide à la réalisation de coupes fémorale 11 et tibiale 12 pour la pose d'une prothèse articulaire d'un genou 13 d'un être humain lorsque cette prothèse comporte une pièce fémorale et une pièce tibiale et lorsque le genou est en position non pliée, c'est-à-dire "en extension" selon la terminologie des personnes du métier.

Selon l'invention, le système comporte au moins deux fiches d'interligne 21, 22 aptes à être positionnées entre le fémur Fe et le tibia Ti avant la

réalisation des coupes, et un bloc 30 d'une seule pièce, ce bloc comprenant une face d'appui 32, avantageusement plane, apte à être positionnée contre le fémur Fe et le tibia Ti au niveau de l'articulation du genou.

Ce bloc 30 comporte au moins deux orifices 33, 34, 35 le traversant, ces orifices ayant une section respectivement complémentaire de la section transversale des deux fiches d'interligne 21, 22. De plus, les axes de ces orifices sont situés dans un même plan 36 sensiblement perpendiculaire à la face d'appui 32.

Le bloc 30 comporte en outre au moins une première fente 40 apte à guider une lame de scie Isc. Cette première fente 40 est réalisée dans le bloc de façon à le traverser et à être située à une distance déterminée du plan 36 contenant les axes des orifices 33-35, et de façon que sa longueur soit sensiblement parallèle à ce plan 36.

Le bloc 30 comporte aussi une pluralité de secondes fentes 51, 52, 53 aptes chacune à guider une lame de scie Isc. Ces secondes fentes sont réalisées de façon à traverser le bloc 30 en étant toutes parallèles entre elles et situées dans la partie 55 du bloc 30 délimitée par le plan 36 défini ci-dessus et qui ne contient pas la première fente 40, et de façon que leurs longueurs soient sensiblement parallèles à ce plan 36.

Selon un mode de réalisation avantageux, il est possible que les fiches d'interligne 21, 22 aient des sections transversales différentes et que le bloc comporte plus de deux orifices traversants 33, 34, 35 de sections respectivement adaptées à celles des fiches qui sont destinées à coopérer avec eux, ce qui permet de mieux ajuster la position du bloc 30 par rapport à l'articulation.

Selon un autre mode de réalisation avantageux, le système selon l'invention comprend en outre une pluralité de broches de positionnement 60 et le bloc 30 comporte en outre une pluralité des percées traversantes 61, 62, 63, chacune de ces percées traversantes étant apte à recevoir une broche de positionnement pour fixer le bloc 30 au moins sur le fémur Fe ou sur le tibia Ti, et avantageusement sur les deux.

Selon un autre mode de réalisation avantageux, le système comprend en outre des moyens de repère 70 réalisés sur le bloc 30 et définissant une

direction rectiligne sensiblement perpendiculaire au plan 36 défini ci-avant, pour repérer l'axe fémoral-tibial.

Selon une réalisation possible, ces moyens de repère 70 sont constitués par au moins l'un des éléments suivants : un trait 71 matérialisé sur la face 37 du bloc opposée à la face d'appui 32, une tige 72 enfichée dans le bloc 30 et dont au moins une extrémité émerge du bloc 30, avantageusement les deux émergeant de part et d'autre du bloc, une glissière montée en coopération avec le bloc, une tige télescopique enfichée dans le bloc, etc.

De façon très préférentielle, le bloc 30 est en matériau radio-transparent, par exemple du polyéthylène ou toute autre résine résistante, pour pouvoir notamment vérifier la bonne implantation des fiches et/ou des broches, ainsi que la réalisation des coupes.

Selon une réalisation préférentielle, les fentes 40, 51, 52, 53 ont toutes la même largeur, ce qui permet d'utiliser les mêmes lames de scie lsc, et d'avoir donc une même épaisseur de coupe sur les deux os. De plus, pour une facilité de réalisation et donc un moindre coût de production, le bloc 30 présente la forme sensiblement d'un parallélépipède, avantageusement rectangle.

La présente invention concerne donc un système permettant la mise en place de prothèses totales de genou. Plus particulièrement, le système permet de réaliser les coupes fémorale-distale et tibiale-proximale en un temps très court grâce à un système intégré de repérage automatique 70 des axes du fémur Fe et du tibia Ti. De plus, il offre la possibilité d'assurer sa fixation au squelette de façon à permettre de scier les os, en toute sécurité et avec le maximum de précision.

Le présent système permet de pratiquer les deux coupes liées, perpendiculairement à l'axe fémoro-tibial préalablement déterminé sur des documents radiographiques ou tomodensitométriques, voire de résonance magnétique, avec le bloc 30 de forme parallélépipédique disposant d'une première fente supérieure 40 dans laquelle peut s'immiscer une lame de scie lsc pour l'extrémité inférieure du fémur et de plusieurs secondes fentes inférieures 51-53 pour effectuer la coupe tibiale selon le niveau adéquat.

Le bloc 30 comprend une rangée horizontale de plusieurs orifices 33-35, par exemple de 3mm de diamètre, matérialisant, par l'introduction de fiches 21, 22, comme des tiges, l'interligne fémoro-tibial et réglant automatiquement la pente des coupes dans le plan sagittal. Certains orifices, donc aussi les fiches d'interligne qui sont destinées à coopérer avec eux, peuvent être de diamètre supérieur pour permettre de compenser une usure plus importante des condyles du genou.

Compte tenu de ces éléments, il a été mis au point le système selon l'invention décrit ci-dessus qui constitue en outre un guide de coupe simplifié permettant de pratiquer en un seul temps les sections osseuses principales fémorale distale et tibiale proximale, et cela de façon coordonnée afin d'assurer l'équilibre ligamentaire du genou quand le genou est en position d'extension.

Le bloc 30 est perforé, par exemple à ses angles, avec des broches 60 pour permettre la stabilisation des os et du système lors de la coupe des os qui généralement engendre des vibrations.

Le bloc 30 peut être réalisé dans un matériau métallique, mais avantageusement dans une matière résistante radio transparente afin de permettre des contrôles radioscopiques per opératoires pour vérifier le niveau et l'orientation des coupes avant leur réalisation.

La validation de l'orientation peut être effectuée sur le bloc lui-même qui comporte, selon une réalisation possible, une gouttière verticale dans laquelle peut être placée une tige 72 de dimensions adaptées et de longueur suffisante pour se projeter sur la crête tibiale et atteindre le niveau de la cheville.

Dès lors, les coupes en question peuvent être réalisées en toute sécurité en réglant automatiquement leur épaisseur, leur orientation et leur niveau.

REVENDICATIONS

1. Système d'aide à la réalisation de coupes fémorale (11) et tibiale (12) pour la pose d'une prothèse articulaire d'un genou (13) d'un être humain lorsque cette prothèse comporte une pièce fémorale et une pièce tibiale et lorsque le genou est en position dite "en extension", caractérisé par le fait qu'il comporte :

• au moins deux fiches d'interligne (21, 22) aptes à être positionnées entre le fémur (Fe) et le tibia (Ti) avant la réalisation des coupes,

• un bloc (30) d'une seule pièce, ledit bloc comprenant une face d'appui (32) apte à être positionnée contre le fémur (Fe) et le tibia (Ti) au niveau de l'articulation du genou, ledit bloc (30) comportant :

* au moins deux orifices (33, 34, 35) le traversant et d'une section respectivement complémentaire de la section transversale des deux fiches d'interligne (21, 22), les axes des dits orifices étant situés dans un même plan (36) sensiblement perpendiculaire à ladite face d'appui (32),

* au moins une première fente (40) le traversant et apte à guider une lame de scie (lsc), ladite première fente (40) étant réalisée dans ledit bloc (30) de façon que sa longueur soit sensiblement parallèle au dit plan (36) et de façon qu'elle soit à une distance déterminée du dit plan, et

* une pluralité de secondes fentes (51, 52, 53) le traversant, chaque seconde fente étant apte à guider une lame de scie (lsc), lesdites secondes fentes étant réalisées dans ledit bloc (30) de façon qu'elles soient toutes parallèles entre elles et que leurs longueurs soient sensiblement parallèles au dit plan (36), et de façon qu'elles soient situées dans la partie (55) du bloc (30) délimitée par ledit plan (36) qui ne contient pas la première fente (40).

2. Système selon la revendication 1, caractérisé par le fait que, lesdites fiches d'interligne (21, 22) ont des sections transversales différentes et que le bloc comporte plus de deux orifices traversants (33, 34, 35).

3. Système selon l'une des revendications 1 et 2, caractérisé par le fait qu'il comprend en outre une pluralité de broches de positionnement (60) et que le bloc (30) comporte en outre une pluralité des percées traversantes (61, 62, 63), chacune de ces percées traversantes étant apte à recevoir une broche de positionnement pour fixer le bloc (30) au moins sur le fémur (Fe) ou sur le tibia (Ti).

4. Système selon l'une des revendications précédentes, caractérisé par le fait qu'il comprend en outre des moyens de repère (70) réalisés sur le bloc (30) et définissant une direction rectiligne sensiblement perpendiculaire au dit plan (36).

5. Système selon la revendication 4, caractérisé par le fait que les moyens de repère (70) sont constitués par au moins l'un des éléments suivants : un trait (71) matérialisé sur la face (37) du bloc opposée à la face d'appui (32), une tige (72) enfichée dans le bloc (30) et dont au moins une extrémité émerge du dit bloc, une glissière montée en coopération avec le bloc (30), une tige télescopique enfichée dans ledit bloc.

6. Système selon l'une des revendications précédentes, caractérisé par le fait que le bloc (30) est en matériau radio-transparent.

7. Système selon la revendication 6, caractérisé par le fait que ledit matériau radio-transparent est choisi parmi les produits suivants : polyéthylène, résine.

8. Système selon l'une des revendications précédentes, caractérisé par le fait que lesdites fentes (40, 51, 52, 53) ont toutes la même largeur.

9. Système selon l'une des revendications précédentes, caractérisé par le fait que ledit bloc (10) présente la forme sensiblement d'un parallélépipède rectangle.

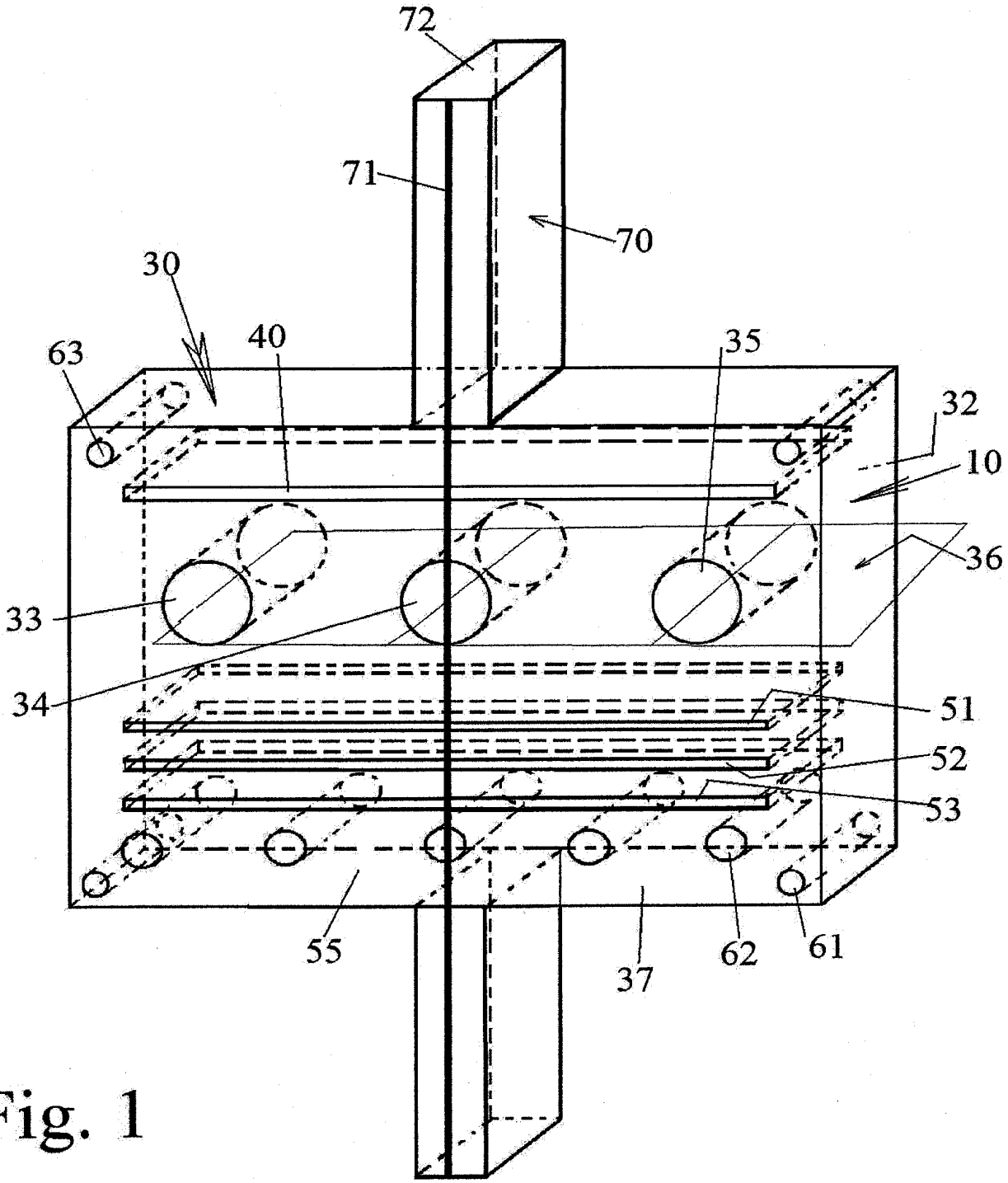


Fig. 1

2/2

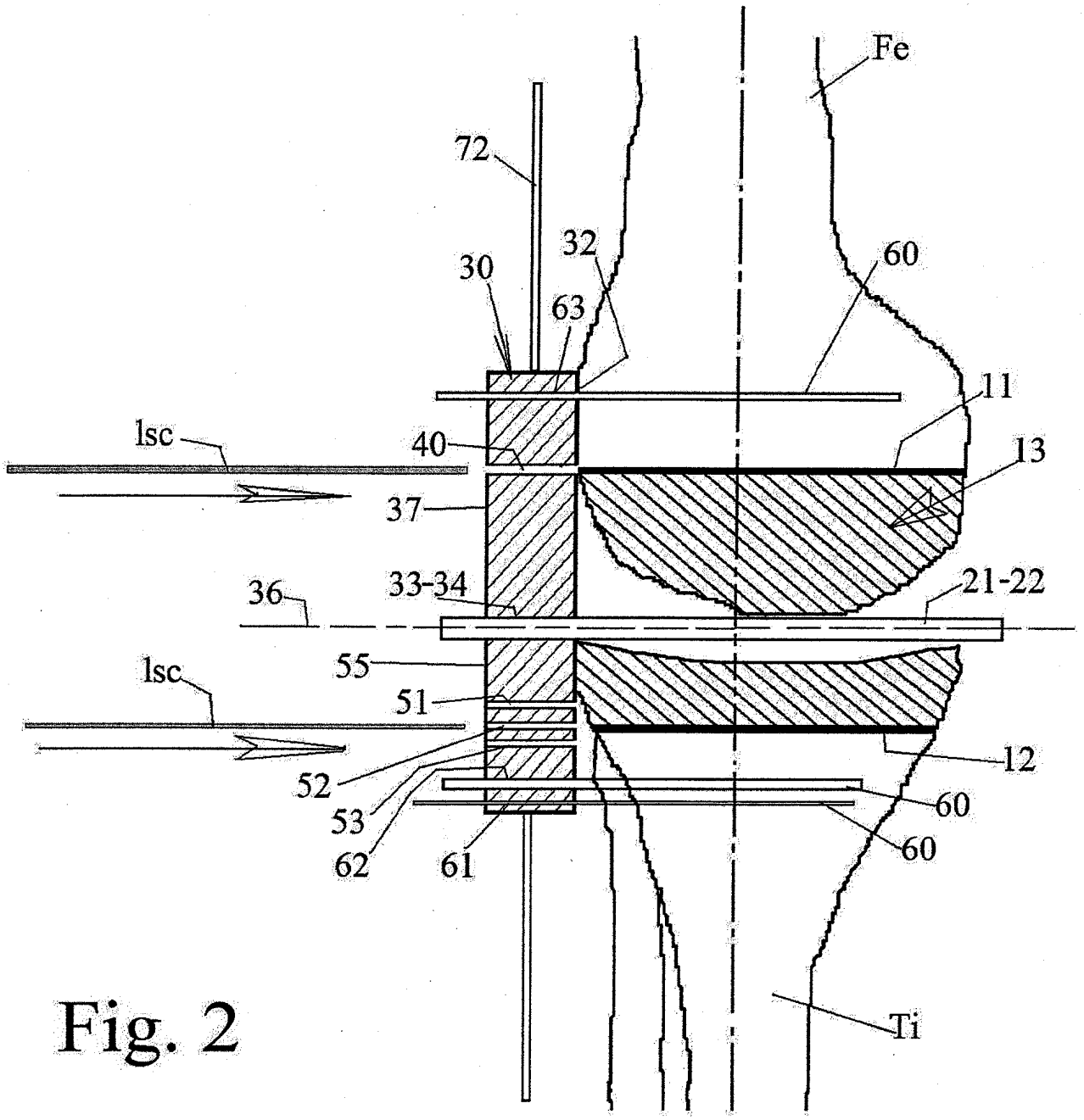

Fe
72
32
30
63
60
11
lsc
40
13
37
36
33-34
21-22
lsc
55
51
12
52
60
53
60
62
61
Ti

Fig. 2

N° d'enregistrement national : 0905699 N° de publication : 2953120

RAPPORT DE RECHERCHE

articles L.612-14, L.612-17 et R.612-53 à 69 du code de la propriété intellectuelle

OBJET DU RAPPORT DE RECHERCHE

L'I.N.P.I. annexe à chaque brevet un "RAPPORT DE RECHERCHE" citant les éléments de l'état de la technique qui peuvent être pris en considération pour apprécier la brevetabilité de l'invention, au sens des articles L. 611-11 (nouveauté) et L. 611-14 (activité inventive) du code de la propriété intellectuelle. Ce rapport porte sur les revendications du brevet qui définissent l'objet de l'invention et délimitent l'étendue de la protection.

Après délivrance, l'I.N.P.I. peut, à la requête de toute personne intéressée, formuler un "AVIS DOCUMENTAIRE" sur la base des documents cités dans ce rapport de recherche et de tout autre document que le requérant souhaite voir prendre en considération.

CONDITIONS D'ÉTABLISSEMENT DU PRÉSENT RAPPORT DE RECHERCHE

- ☐ Le demandeur a présenté des observations en réponse au rapport de recherche préliminaire.
- ☒ Le demandeur a maintenu les revendications.
- ☐ Le demandeur a modifié les revendications.
- ☐ Le demandeur a modifié la description pour en éliminer les éléments qui n'étaient plus en concordance avec les nouvelles revendications.
- ☐ Les tiers ont présenté des observations après publication du rapport de recherche préliminaire.
- ☐ Un rapport de recherche préliminaire complémentaire a été établi.

DOCUMENTS CITÉS DANS LE PRÉSENT RAPPORT DE RECHERCHE

La répartition des documents entre les rubriques 1, 2 et 3 tient compte, le cas échéant, des revendications déposées en dernier lieu et/ou des observations présentées.

- ☐ Les documents énumérés à la rubrique 1 ci-après sont susceptibles d'être pris en considération pour apprécier la brevetabilité de l'invention.
- ☒ Les documents énumérés à la rubrique 2 ci-après illustrent l'arrière-plan technologique général.
- ☐ Les documents énumérés à la rubrique 3 ci-après ont été cités en cours de procédure, mais leur pertinence dépend de la validité des priorités revendiquées.
- ☐ Aucun document n'a été cité en cours de procédure.

N° d'enregistrement national : 0905699 N° de publication : 2953120

1. ELEMENTS DE L'ETAT DE LA TECHNIQUE SUSCEPTIBLES D'ETRE PRIS EN CONSIDERATION POUR APPRECIER LA BREVETABILITE DE L'INVENTION

NEANT

2. ELEMENTS DE L'ETAT DE LA TECHNIQUE ILLUSTRANT L'ARRIERE-PLAN TECHNOLOGIQUE GENERAL

US 2005/149037 A1 (STEFFENSMEIER SCOTT J [US] ET AL)
7 juillet 2005 (2005-07-07)

US 2005/085920 A1 (WILLIAMSON RICHARD V [US])
21 avril 2005 (2005-04-21)

3. ELEMENTS DE L'ETAT DE LA TECHNIQUE DONT LA PERTINENCE DEPEND DE LA VALIDITE DES PRIORITES

NEANT

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(52) UK CL (Edition V):
A5R RECX REP
B5L LGX L104

(56) Documents Cited:
EP 0570187 A1 **WO 1996/024295 A1**
US 5540695 A **US 5042983 A**

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As for published application 2334214 A *viz:*
UK CL (Edition P) **A5R** RAT RECX REP
INT CL[6] **A61B** 17/15 17/17, **A61D** 1/00
Other:
updated as appropriate

Additional Fields
UK CL (Edition T) **A5R** RAT RECX REP, **B5L** LGA LGB LGX
INT CL[7] **A61B** 17/15 17/17, **A61D** 1/00, **B23D** 51/02
Other: **ONLINE:- EPODOC, WPI, JAPIO**

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FIG. 1

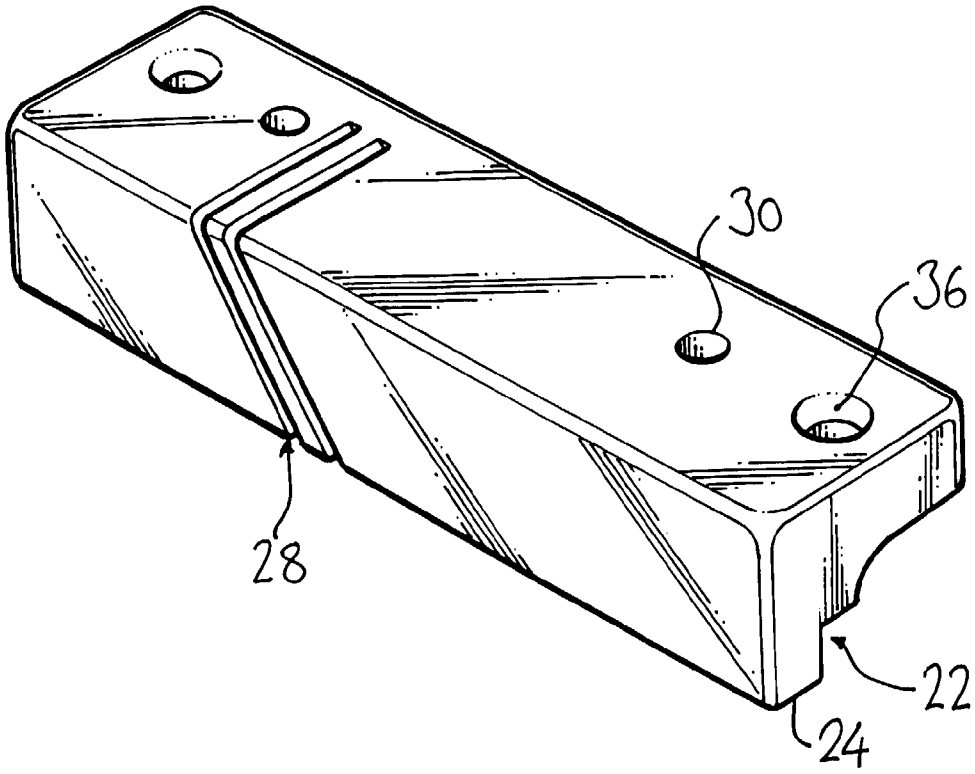


FIG. 2

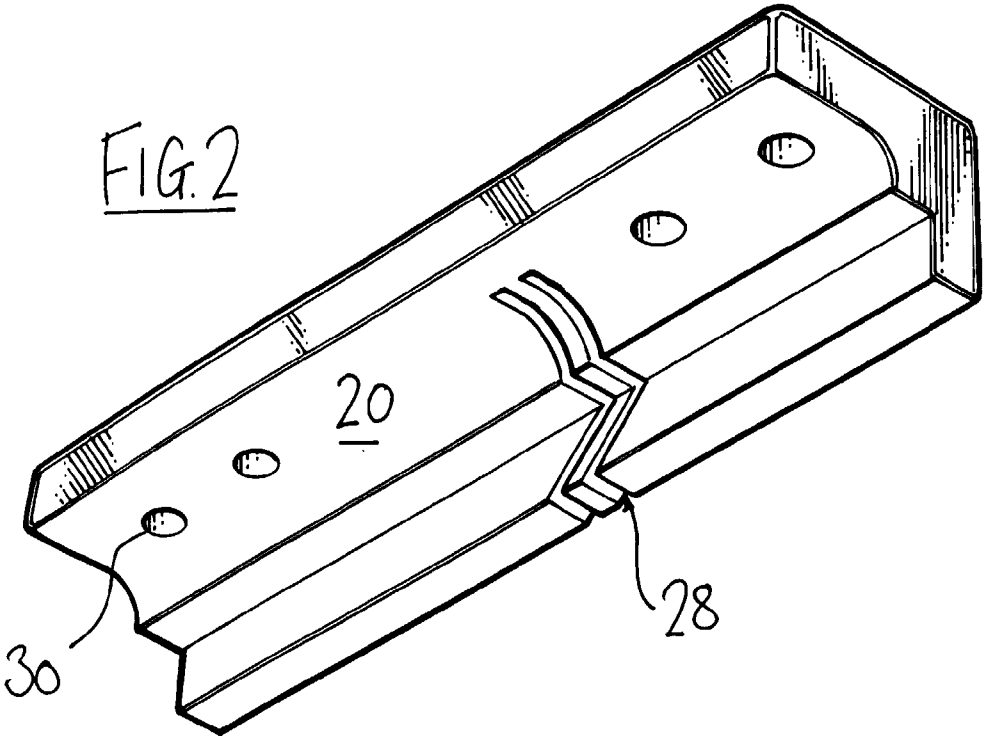
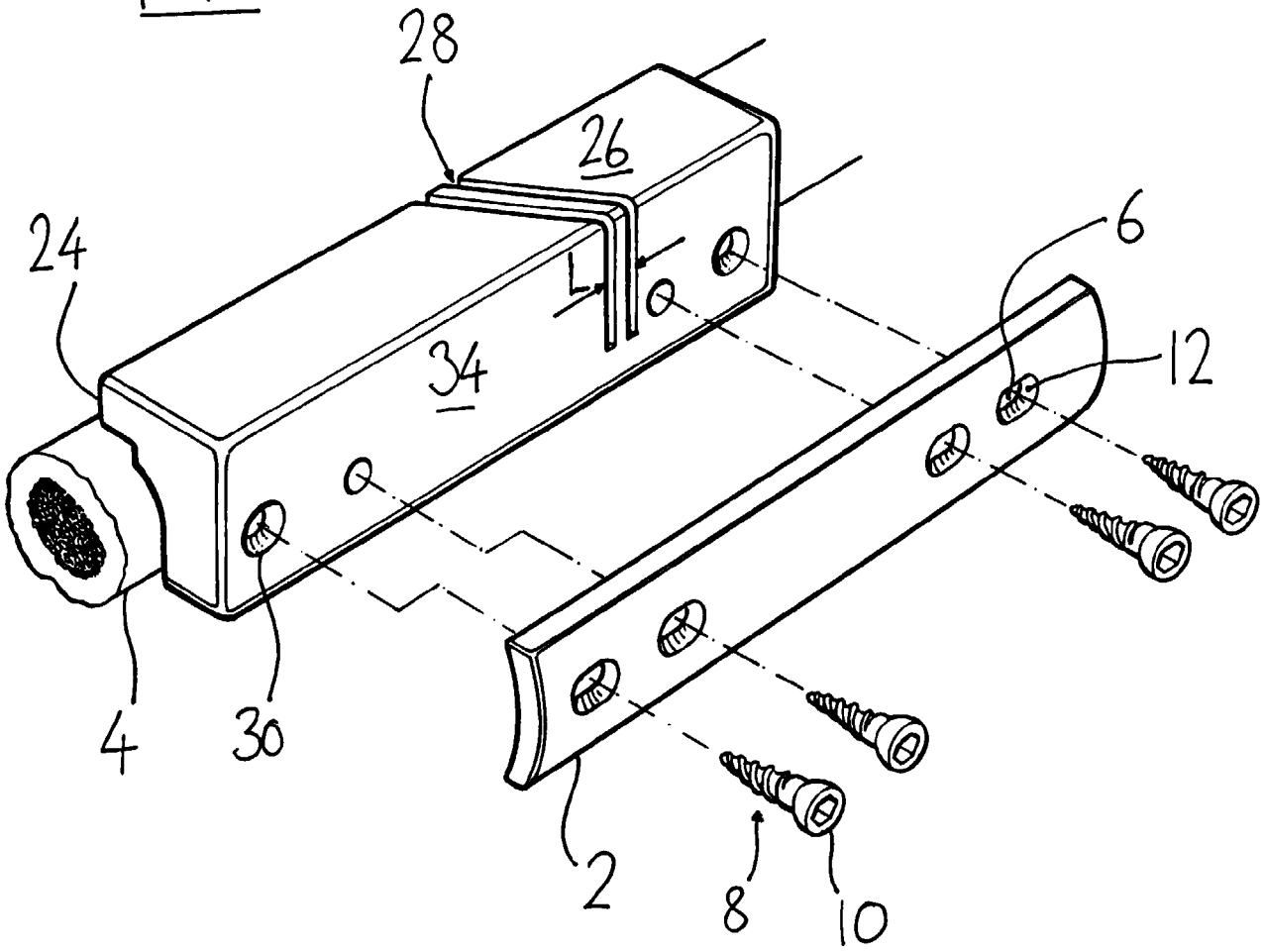


FIG. 3



DESCRIPTION

CUTTING GUIDE

The present invention relates to a cutting guide for use in shortening a bone of a human or animal.

Surgical techniques for shortening long bones are well known.

According to the conventional method, the surgeon makes a pair of approximately parallel saw cuts through the bone freehand, the plane of the cuts being approximately perpendicular to the longitudinal axis of the bone. The portion of the bone lying between the two saw cuts is removed, and the cut ends of the remaining two parts of the bone are brought together to produce the required shortening.

A plate such as the one illustrated at 2 in Fig. 3 is used to set the bone. According to the known technique, the surgeon drills and taps (ie forms screw-threads in) holes in the bone 4 corresponding to the locations of slots 6 in the plate. The plate is then screwed to the bone using screws 8 having heads 10 which are conical (ie countersunk). The slots 6 are correspondingly formed with inclined faces.

The surgeon positions the screw holes such that as each screw is screwed into the bone its conical head contacts and moves down the part 12 of the inclined face of a slot which is remote from the cut,

and in so doing draws one part of the bone toward the other, ensuring that where the two parts of the bone meet they are under compression.

Such a procedure is used, for example, in shortening the ulna of a human patient.

One shortcoming of the known procedure is that the accuracy with which the bone is cut and set is dependent on the manual skill of the surgeon. If the cut ends of the bone are not flat, then undesirable gaps will initially be present in the joint. If the bones are misaligned when set using the plate, because of inaccuracies in the positioning of the screw holes and/or because the two saw cuts are not precisely parallel, then the shape of the bone may be distorted.

The procedure described above produces a joint whose plane is roughly perpendicular to the longitudinal axis of the bone, which will be referred to as a "butt joint". An improvement in the joint would be achieved by inclining the plane of the joint - ie by making the two parallel cuts at an angle of, say, 45° to the bone axis. The resulting inclined joint would have an increased area of abutment between the two parts of the bone, and provide improvements in strength, circulation, and in rapidity of healing.

Unfortunately, the inaccuracies arising from freehand cutting and setting of the bone have hitherto made it very difficult to successfully form an inclined

joint. The abutting surfaces of the two parts of the bone, having increased length and surface area, need to be cut to a greater degree of accuracy in the inclined joint than in the case of the butt joint. Moreover, a minor inaccuracy in the longitudinal position of one part of the bone relative to the other can cause one bone-part to project laterally relative to the other, adjacent the joint, in a manner which is unacceptable. Rotation of one bone-part relative to the other when the bone is set can cause the bone to be undesirably bowed along its length.

It is an object of the present invention to enable accurate formation of the two cuts through the bone needed in order to shorten it.

It is also desired to enable subsequent accurate setting of the bone.

In accordance with a first aspect of the present invention, there is a cutting guide for use in shortening a bone of a human or animal, comprising a guide body defining a pair of guide slots which are spaced apart, and means for securing the guide body to the bone, such that while the guide body is secured to the bone a cutter can be received in the guide slots and guided thereby while cutting into the bone to form two spaced apart cuts defining a section of the bone which is to be removed, the rear of the guide body having a support surface whose cross section is a concave curve substantially conforming to

the cross sectional curvature of the bone and, adjacent the curved surface, a cutaway portion effective to raise the guide body from the bone surface in the region of the cutaway portion.

The cutting guide thus makes it possible to

accurately control the position and orientation of the two cuts into the bone and hence of the section removed. It has been found that the cutting, preferably by means of a saw, can be achieved a great deal more quickly using the guide; operating times have in some instances been halved, with resulting benefits for patients.

The two guide slots are preferably parallel.

The guide body is provided with a support surface shaped to substantially conform to the shape of the bone. Such a surface can assist in orienting the guide relative to the bone and in preventing rocking or other movement relative to the bone. The surface may be elongate and has a concave cross section. Such a surface can conveniently rest on the exterior of a long bone, its longitudinal axis being substantially parallel to that of the bone.

The guide slots are preferably parallel sided and of appropriate width to guide a surgical saw. They may be oriented such as to be perpendicular to the bone-axis in use, or (more preferably) inclined to the bone axis.

The means for securing the guide body to the bone most preferably comprise holes disposed on either side of the guide slots receiving screws to be secured in the bone.

According to a particularly advantageous

embodiment of the present invention, the spacing of the holes is such that following securing of the guide body to the bone using the screws, cutting of the bone, and removal of a section, the bone can be set by means of a plate secured to the bone using screws received in the same holes in the bone used to secure the guide body, the spacing of the holes being such that the cut ends of the bone are brought into contact. Also within the scope of the present invention is a surgical bone shortening apparatus comprising a cutting guide in accordance with the invention and joining plate having holes for receiving bone setting screws, the spacing of the holes being such that following securing of the guide body to the bone using screws, cutting of the bone, and removal of a section, the bone can be set by securing the joining plate to the bone using screws received in the same holes in the bone used to secure the guide body, the spacing of the holes being such that the cut ends of the bone are brought into contact.

This has great advantages. Using the known technique it has been necessary to drill the screw holes used for setting the bone after cutting, the positioning of the holes being determined by the surgeon, working freehand. Using the present invention, the screw holes needed to set the bone can be drilled before cutting using the cutting guide to ensure that the holes are accurately positioned. After cutting, the two parts of

the bone are automatically aligned and abutted, simply by inserting screws in the existing holes, greatly improving the accuracy with which the bone is set and thereby making possible inclined jointing as described above.

A specific embodiment of the present invention will now be described, by way of example only, with reference to the accompanying figures in

which:-

FIG. 1 is a perspective illustration of a cutting guide constructed in accordance with the present invention, viewed from above;

FIG. 2 is a perspective illustration of the same cutting guide from below; and

FIG. 3 is a perspective illustration of a bone to which the cutting guide is being secured, and of a conventional plate to be used for subsequently setting the bone.

The principal constructional features of the illustrated cutting guide, and its mode of operation, will be apparent from a study of Fig. 3. The guide is machined from surgical steel.

The rear of the cutting guide has a surface 20 whose cross section is a concave curve intended to substantially conform to the cross sectional curvature of the bone 4 to be shortened, so that the guide can be seated against the bone as shown in Fig. 3. The rear of the guide also has, adjacent the curved surface 20, a cutaway 22 (see Fig. 1), formed as a right-angled cutaway, leading to an upper portion 24. When the cutting guide is secured to the bone, the upper portion 24 stands above the bone to receive and guide the saw upon commencement of a cut - see Fig. 3.

The cutting guide has a parallel pair of guide slots 28, which are open at an upper face 26 of

the cutting guide, the width of the slots being appropriate to receive and guide a surgical saw. The guide slots 28 are inclined relative to the longitudinal axis of the cutting guide (in the illustrated embodiment the angle of inclination is 45°) so that the cuts formed in use are at approximately this angle to the longitudinal axis of the bone.

The two guide slots 28 are separated by a distance related to the length of bone to be removed. More specifically, the length of bone removed corresponds to the length marked L in Fig. 3, between respective remote edges of the two slots.

To enable securing of the cutting guide to the bone, the guide is provided with holes 30 which are a clearance fit for screws 32. In the illustrated embodiment, four holes are provided each extending from a front face 34 of the cutting guide to the rear face 20. Two of the holes 30 are positioned to one side of the guide slots 28, the remaining two holes being positioned to the other side of the slots. The positioning of the screw holes 30 is selected to correspond to the positioning of the slots 6 in the plate 2, as will be further explained below.

The sequence of operations when using the cutting guide in shortening a bone is as follows.

Having first exposed the bone, the surgeon drills and taps a first approximately radial hole in

the bone, then attaches the cutting guide to the bone using a first screw 8 extending through one of the holes 30 and into the bone.

Using the cutting guide to locate and guide the drill, the surgeon then drills and taps a second hole in the bone, and inserts a second screw. the first and second screws/holes serve to securely locate the guide, and in order to do so effectively should typically be widely separated. Hence the outermost holes of the guide (ie the holes nearest to the end of the guide) receive the first and second screws. To further assist in securely locating the cutting guide, these outermost holes (and the screws received in them) are countersunk, as Fig. 1 shows at 36.

Holes are then drilled and tapped through the remaining holes 30 in the guide, further screws then being inserted.

A saw, guided in the slots 28, is used to form the two cuts part way through the bone. When using the illustrated guide, the saw reaches the bottom of the slots 28 before passing all of the way through the bone.

The screws, and then the cutting guide, are removed from the bone, and the saw cuts are then completed.

The bone is then set using the plate 2 and screws driven into the same holes used to secure the

cutting guide. It is for this reason that the positioning of holes in the guide is relates to the positioning of holes in the plate. The holes in the guide are positioned such that when the "waste" part of the bone has been removed and the bone is set using the plate, the cut ends of the bone are appropriately abutted. In this way accurate setting of the bone is facilitated.

CLAIMS

1. A surgical cutting guide for use in shortening a bone of a human or animal, comprising a guide body defining a pair of guide slots which are spaced apart, and means for securing the guide body to the bone, such that while the guide body is secured to the bone a cutter can be received in the guide slots and guided thereby while cutting into the bone to form a spaced pair of cuts defining a section of the bone which is to be removed, the rear of the guide body having a support surface whose cross section is a concave curve substantially conforming to the cross sectional curvature of the bone and, adjacent the curved surface, a cutaway portion effective to raise the guide body from the bone surface in the region of the cutaway portion.

2. A surgical cutting guide as claimed in claim 1, wherein the guide slots are parallel.

3. A surgical cutting guide as claimed in any preceding claim, wherein the guide slots are parallel sided and of appropriate width to guide a surgical saw.

4. A surgical cutting guide as claimed in any preceding claim, wherein the guide slots are oriented such as to be inclined to the longitudinal bone axis in use.

5 A surgical cutting guide as claimed in any preceding claim, wherein the means for securing the guide body to the bone comprise holes disposed on either side of the guide slots receiving screws to be secured in the bone.

6. A surgical cutting guide as claimed in claim 5, wherein the spacing of the holes is such that following securing of the guide body to the bone using screws, cutting of the bone, and removal of a section, the bone can be set by means of a plate secured to the bone using screws received in the same holes in the bone used to secure the guide body, the spacing of the holes being such that the cut ends of the bone are brought into contact.

7. A surgical bone shortening apparatus comprising a cutting guide as claimed in claim 5 or claim 6 and a joining plate having holes for receiving bone setting screws, the spacing of the holes being such that following securing of the guide body to the bone using screws, cutting of the bone, and removal of a section, the bone can be set by securing the joining plate to the bone using screws received in the same holes in the bone used to secure the guide body, the spacing of the holes being such that the cut ends of the bone are brought into contact.

8. A surgical cutting guide substantially as herein described with reference to, and as

illustrated in, the accompanying drawings.

9. A surgical bone shortening apparatus comprising a cutting guide and a joining plate both substantially as herein described with reference to, and as illustrated in, the accompanying drawings.

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(54) **Title**: ALIGNMENT GUIDE APPARATUS, METHODS AND SYSTEMS

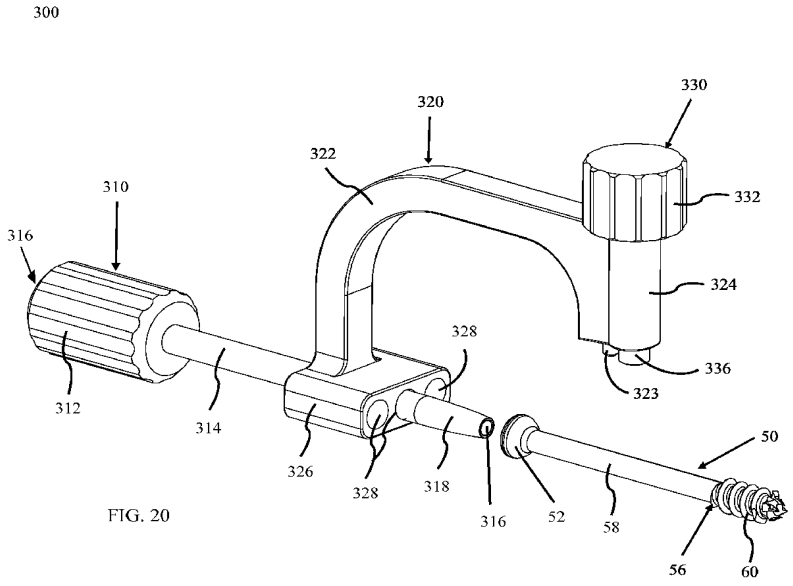


FIG. 20

(57) **Abstract**: The present invention discloses an alignment guide apparatus, system, and method. The alignment guide apparatus includes a body, a fixation insert, a guide pin, and a screw. The body may include an arm with a first end and a second end, an attachment portion at the first end, and an alignment portion at the second end. The fixation insert may be configured to pass through the attachment portion and the guide pin may be configured to pass through the alignment portion. The screw may be configured to engage the guide pin. The alignment system may include a bone plate, an alignment guide, a screw, at least one first fastener, and at least one second fastener. A method for moving a joint is also disclosed.

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ALIGNMENT GUIDE APPARATUS, METHODS AND SYSTEMS

CROSS REFERENCE

This application claims priority benefit to International application No. PCT/US2013/77211 filed December 20, 2013, which claims priority benefit under 35 U.S.C. §119(e) of U.S. provisional application No. 61/746,928 filed December 28, 2012, which are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates generally to the field of orthopedics related to a bone plate alignment guide apparatus', systems, and methods for using the bone plate alignment guide apparatus.

SUMMARY OF THE INVENTION

The present invention is directed toward devices, methods and systems for aligning and securing an orthopedic bone plate for compression of a joint.

In one aspect, provided herein is a bone plate alignment guide apparatus. The bone plate alignment guide apparatus may include a body. The body may include an arm with a first end and a second end, an attachment portion at the first end, and an alignment portion at the second end. The bone plate alignment guide apparatus may also include a fixation insert configured to pass through the attachment portion and a guide pin configured to pass through the alignment portion. The bone plate alignment guide apparatus may also include a screw configured to engage the guide pin.

In another aspect, provided herein is a bone plate alignment system. The bone plate alignment system includes a bone plate, a bone plate alignment guide, a screw, at least one first fastener, and at least one second fastener. The bone plate of the system includes a first end, a second end, and an intermediate portion connecting the first end and the second end. The bone plate may include at least one through hole in the first end, at least one through hole in the second end, and at least one opening between the first end and the second end. The bone plate alignment guide of the system includes a body including an arm with a first end and a second end, an attachment portion at the first end, and an alignment portion at the second end. The bone plate alignment guide also includes a fixation insert configured to pass through the attachment portion and a guide wire configured to pass through the alignment portion. The fixation insert couples to the at least one opening of the bone plate. The system may also include a screw configured to engage the guide wire during insertion into at least

one portion of bone. The system also includes at least one first fastener for insertion through the at least one through hole on the first end of the bone plate and into a first portion of bone. The system may also include at least one second fastener for insertion through the at least one through hole on the second end of the bone plate and into a second portion of bone.

In yet another aspect, provided herein is a method for moving a joint. The method including preparing the joint and obtaining a bone plate alignment guide apparatus. The bone plate alignment guide apparatus may include a body, a fixation insert, a guide pin, and a screw. The body includes an arm with a first end and a second end, an attachment portion at the first end, and an alignment portion at the second end. The fixation insert is configured to engage the attachment portion. The guide pin is configured to pass through the alignment portion. The screw is configured to engage the guide pin. The method may also include aligning a bone plate on the joint and inserting at least one first temporary fixation pin to secure the bone plate to a first bone of the joint. The method may further include inserting at least one second temporary fixation pin to secure the bone plate to a second bone of the joint. The method may also include attaching the bone plate alignment guide apparatus to the bone plate in a desired position relative to the joint. In addition, the method may also include inserting the guide pin across the joint through the alignment portion of the body of the bone plate alignment guide apparatus and inserting the screw over the guide pin to move the joint. The method may further include securing the bone plate to the first bone and the second bone of the joint and removing the bone plate alignment guide apparatus. Further, the method may include closing the incision in the patient.

These, and other objects, features and advantages of this invention will become apparent from the following detailed description of the various aspects of the invention taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate embodiments of the invention and together with the detailed description herein, serve to explain the principles of the invention. It is emphasized that, in accordance with the standard practice in the industry, various features are not drawn to scale. In fact, the dimensions of the various features may be arbitrarily increased or reduced for clarity of discussion. The drawings are only for purposes of illustrating preferred embodiments and are not to be construed as limiting the invention.

FIG. 1 is a side view of a bone plate alignment guide apparatus, in accordance with an aspect of the present invention;

FIG. 2 is an exploded side view of the bone plate alignment guide apparatus of FIG. 1, in accordance with an aspect of the present invention;

FIG. 3 is an end perspective view of the alignment guide of the bone plate alignment guide apparatus of FIG. 1, in accordance with an aspect of the present invention;

FIG. 4 is a bottom perspective view of the alignment guide of FIG. 3, in accordance with an aspect of the present invention;

FIG. 5 is a top view of a bone plate for use with the bone plate alignment guide apparatus of FIG. 1, in accordance with an aspect of the present invention;

FIG. 6 is a top view of the bone plate alignment guide of FIG. 1 being used to insert a fastener into a patient's bones, in accordance with an aspect of the present invention;

FIG. 7 is a side view of the bone plate alignment guide of FIG. 1 being used to align the bone plate of FIG. 5 onto a patient's bones, in accordance with an aspect of the present invention;

FIG. 8 is the side view of FIG. 7 with transparent bones showing the guide pin, compression screw and fasteners inserted into the patient's bones, in accordance with an aspect of the present invention;

FIG. 9 is a side view of a bone plate alignment guide apparatus, in accordance with an aspect of the present invention;

FIG. 10 is an exploded side view of the bone plate alignment guide apparatus of FIG. 9, in accordance with an aspect of the present invention;

FIG. 11 is an end perspective view of the body of the bone plate alignment guide apparatus of FIG. 9, in accordance with an aspect of the present invention;

FIG. 12 is a bottom perspective view of the body of FIG. 11, in accordance with an aspect of the present invention;

FIG. 13 is a side view of the bone plate alignment guide apparatus and the guide pin tissue protector of FIG. 9 for use in inserting a fastener into the patient's bones, in accordance with an aspect of the present invention;

FIG. 14 is a side view of the bone plate alignment guide, guide pin tissue protector, and guide pin of FIG. 9 being used to insert a fastener into a patient's bones, in accordance with an aspect of the present invention;

FIG. 15 is a side view of the bone plate alignment guide and guide pin of FIG. 9 being used to insert a fastener into a patient's bones, in accordance with an aspect of the present invention;

FIG. 16 is a side view of the patient's bones after removal of the bone plate alignment guide of FIG. 9 with the guide pin of FIG. 9 inserted across the patient's joint, in accordance with an aspect of the present invention;

FIG. 17 is a side view of the patient's bones with a fastener partially inserted into the bones over the guide pin of FIG. 9, in accordance with an aspect of the present invention;

FIG. 18 is a side view of the patient's bones with a fastener inserted across the patient's joint after removal of the guide pin of FIG. 9, in accordance with an aspect of the present invention;

FIG. 19 depicts one embodiment of a method for compressing a joint, in accordance with an aspect of the present invention;

FIG. 20 is a perspective view of a bone plate alignment guide apparatus, in accordance with an aspect of the present invention;

FIG. 21 is a side view of the bone plate alignment guide apparatus of FIG. 20, in accordance with an aspect of the present invention;

FIG. 22 is an exploded side view of the bone plate alignment guide apparatus of FIG. 20, in accordance with an aspect of the present invention;

FIG. 23 is a bottom perspective view of the body of the bone plate alignment guide apparatus of FIG. 20, in accordance with an aspect of the present invention; and

FIG. 24 is an end perspective view of the body of the bone plate alignment guide apparatus of FIG. 20, in accordance with an aspect of the present invention.

DETAILED DESCRIPTION FOR CARRYING OUT THE INVENTION

Generally stated, disclosed herein is an embodiment of a bone plate alignment guide apparatus. Further, a surgical method for using the bone plate alignment guide apparatus is discussed.

In this detailed description and the following claims, the words proximal, distal, anterior, posterior, medial, lateral, superior and inferior are defined by their standard usage for indicating a particular part of a bone or implant according to the relative disposition of the natural bone or directional terms of reference. For example, "proximal" means the portion of an implant nearest the torso, while "distal" indicates the portion of the implant farthest from the torso. As for directional terms, "anterior" is a direction towards the front side of the

body, "posterior" means a direction towards the back side of the body, "medial" means towards the midline of the body, "lateral" is a direction towards the sides or away from the midline of the body, "superior" means a direction above and "inferior" means a direction below another object or structure.

Referring to the drawings, wherein like reference numerals are used to indicate like or analogous components throughout the several views, and with particular reference to FIGS. 1-5, there is illustrated an exemplary embodiment bone plate alignment guide apparatus 10. The bone plate alignment guide apparatus 10 includes a body 20, a fixation insert 30, a guide wire or pin 40, and a compression or lag screw 50. The body 20 may include an arm 22 with an attachment portion 24 at a first end and an alignment portion 26 at a second end. The arm 22 may be configured to position the through hole of the attachment portion generally perpendicular to the at least one through hole of the alignment portion, as shown in FIGS. 1-4. The arm 22 may be arcuate, curved, angled, and the like. The fixation insert 30 may include a knob portion 32 and a shaft portion 34 with an alignment portion or alignment member 36 and a threaded section 38 for engaging the bone plate 80. The guide pin 40 may be, for example, a pin, k-wire or the like. The compression screw 50 may include a head portion 52 with a through hole 54 extending from the proximal end to the distal end of the screw 50 and a shank portion 56 extending away from the head portion 52 with a smooth upper portion 58 and a threaded portion 60 on the distal end of the screw 50.

As seen in FIGS. 3 and 4, the body 20 may also include a through hole 18 in the attachment portion 24 of the body 20 and a through hole 28 in the alignment portion 26 of the body 20. The body 20 may also include an opening 16 in the attachment portion 24 for inserting an alignment post or pin which may also engage the plate 80 for positioning the bone plate alignment guide apparatus 10 on the bone plate 80, as shown in FIG. 4.

Referring now to FIGS. 5 and 6, the bone plate 80 may include a first end 82 for attachment to a first bone 84 and a second end 86 for attachment to a second bone 88. The first end 82 may be connected to the second end 86 of the bone plate 80 by an intermediate member or portion 85. The bone plate 80 may also include at least one through hole 90 on the first end 82 of the plate 80 and at least one through hole 92 and a compression slot 94 on the second end 86 of the plate 80. The at least one through hole 90 may be used to insert fasteners, for example, fixation screws or bone screws 100 into the first bone 84, for example, the distal bone. The at least one through hole 92 may be used to insert fasteners, for example, fixation screws or bone screws 102 into the second bone 88, for example, the proximal bone. The compression slot 94 may allow for insertion of a fastener which may translate within the

slot 94 while the distal and proximal bones 84, 88 are moved or compressed. The plate 80 may also include a first opening 96 for receiving the alignment post or pin (Not Shown). The alignment post or pin may also engage the opening 16 in the attachment portion 24 of the body 20 to align the alignment guide apparatus 10 with the plate 80. The plate 80 may also include a second opening 98 which the through hole 18 may align with to allow for insertion of the alignment portion 36 and the threaded section 38 of the fixation insert 30. The first opening 96 may be offset from the second opening 98 along the longitudinal axis of the plate 80 by, for example, approximately 30 to 40 degrees and more preferably by approximately 35 degrees. The intermediate member 85 may include at least one alignment marking 87 for use in alignment of the plate 80 with respect to the joint space.

Referring now to FIGS. 6-8, the method of using the bone plate alignment guide apparatus 10 includes opening the patient where joint compression and fixation is needed, for example a patient's foot, and preparing the joint for fixation. The joint may be, for example, a metatarsal-phalangeal joint or any other joint or bones where compression and fixation is necessary. The method may also include aligning the bone plate 80 on the distal and proximal bones 84, 88 by referring to the intermediate portion 85 of the plate 80 and aligning the at least one alignment marking 87 over the joint space. The method may further include inserting, for example, temporary fixation pins, olive wires, k-wires or the like may be inserted to hold the bone plate 80 in position on the distal and proximal bones 84, 88. In the preferred embodiment, olive wires or other temporary fixation mechanisms which hold the plate 80 to the bones 84, 88 during compression and fixation are used. The physician may then use fluoroscopy to confirm that the plate 80 is positioned on the distal and proximal bones 84, 88 in the desired position. The bone plate alignment guide apparatus 10 may then be attached to the bone plate 80.

As shown in FIGS. 4-5, the alignment guide apparatus 10 may be attached to the bone plate 80 by first inserting an alignment pin or post (Not Shown) into the first opening 96 on the plate 80 and then aligning the opening 16 in the body 20 with the alignment post or pin inserted into the plate 80. Once the alignment post or pin is inserted into the first opening 96 in the plate 80 and the opening 16 in the body 20, then the shaft portion 34 of the fixation insert 30 may be inserted into through hole 18 in the body 20 of the alignment guide apparatus 10 to engage the second opening 98 in the plate 80.

Alternatively, the fixation insert 30 may be inserted into the through hole 18 and used to align the body 20 with the second opening 98 on the plate 80, without using an alignment pin or post. The plate 80 may, for example, include at least two positive stops (Not Shown)

on the plate 80, providing the surgeon minimal amount of pivot of the body 20 of the alignment guide apparatus 10 about the second opening 98 of the plate 80.

Another alternative embodiment of the plate 80, may, for example, include having a plurality of first openings 96 for aligning the guide body 20 for insertion of the compression screw 50 without interfering with another fastener 100, 102. In still another alternative plate embodiment, the plate 80 may, for example, include at least two alignment markings 87 on the plate 80, which the surgeon may use to align the guide body 20 in a position to avoid the compression screw 50 and the fasteners 100, 102 from coming into contact with each other. Additional alignment mechanisms for aligning the guide body 20 to ensure the fasteners 100, 102 and the compression screw 50 do not come in contact are also contemplated.

The guide body 20 may then be aligned in the desired position relative to distal and proximal bones 84, 88 and the fixation insert 30 tightened to secure the body 20 of the alignment guide apparatus 10 to the plate 80 in the desired position. After securing the guide body 20 of the alignment guide apparatus 10 to the plate 80 using any of the above described methods, the guide pin 40, for example, a k-wire, may be inserted in through hole 28 and into the distal and proximal bones 84, 88. Next, a drill may be inserted into the through hole 28 of the body 20 over the guide wire 40 to drill an opening in the distal and proximal bones 84, 88 for inserting the compression screw 50. The drill may then be removed from the through hole 28 and a compression screw 50 may be inserted into the through hole 28 over the guide wire 40. As the compression screw 50 is inserted over the guide wire 40 and into the distal and proximal bones 84, 88, the bones 84, 88 are pulled and compressed together.

Once the physician reaches a desired amount of movement or compression between the distal and proximal bones 84, 88, the temporary fixation means, for example, pins, olive wires, k-wires or the like, may be removed from the distal end 82 of the plate 80. Then the fasteners 100 may be inserted into the at least one through hole 90, for example, in the depicted embodiments, there are three through holes 90, in the plate 80 and into the distal bone 84, for example, the proximal phalange. The method may also include removing the temporary fixation means, for example, pins, olive wires, k-wires or the like from the proximal end 86 of the plate 80 and the fasteners 102 may be inserted into the at least one through hole 92, for example, in the depicted embodiments there are two through holes 92, in the plate 80 and into the proximal bone 88, for example, the metatarsal. Next, the position of the distal and proximal bones 84, 88 may be checked using, for example, fluoroscopy. If the bones 84, 88 are in the desired position, then the physician may remove the alignment guide apparatus 10, by first removing the guide wire 40, then loosening the fixation insert 30 to

disengage the second opening 98 in the plate 80 and remove the fixation insert 30 and the body 20 of the alignment guide apparatus 10 from the patient's bones 84, 88. Finally, the patient's incision may be closed.

Referring to FIGS. 1-8, a bone plate alignment system may include, for example, a bone plate 80, an alignment guide apparatus 10, at least one first fastener 100, and at least one second fastener 102. The bone plate 80 may, for example, be of the type described above with reference to FIG. 5. The alignment guide apparatus 10 may, for example, be of the type described above with reference to FIGS. 1-4 and may include a body 20, a fixation insert 30, a guide pin 40, and a compression screw 50. The fasteners 100, 102 may be, for example, the type described above with reference to FIGS. 6-8. The bone plate alignment system may enable a physician or surgeon to use the bone plate 80 to pivot the alignment guide apparatus 10 into a position to allow for accurate insertion of the compression screw 50 relative to the bone plate 80. By enabling the surgeon to align and insert the compression screw 50 based on the orientation of the bone plate 80, the compression screw 50 may be inserted to, for example, avoid the positions where the fasteners 100, 102 will be inserted or where the fasteners 100, 102 are already positioned. The bone plate alignment system may be used, for example, to secure a bone plate 80 over a joint or at least two portions of a fractured bone.

Another embodiment bone plate alignment guide apparatus 200 is shown in FIGS. 9-12. The bone plate alignment guide apparatus 200 may include a body or alignment guide 220, a fixation member 230, a guide pin tissue protector 210, a guide wire or pin 240, and a fastener 50. The fixation member 230 may include a knob portion 232 and a shaft portion 234 with an engagement portion 236 for engaging the bone plate 80. The guide wire 240 may be, for example, a pin, k-wire, olive wire, or the like. The fastener 50 may be of the type described above with reference to FIGS. 1-5 and may be, for example, a compression screw, lag screw, headless screw, or a solid screw. The fastener 50 may include a head portion 52 with a through hole 54 extending from a first end to a second end of the fastener 50 and a shaft portion 56 extending away from the head portion 52. The shaft portion 56 may include a smooth upper portion 58 and a threaded portion 60 on the second end of the fastener 50.

The guide pin tissue protector 210, as shown in FIG. 10, may include a handle portion 212 at a first end and a shaft 214 extending away from the handle portion 212 to a tip 218 at a second end. The guide pin tissue protector 210 may also include a through hole 216 extending from the first end to the second end to enable a guide wire 240 to pass through the tissue protector 210.

As shown in FIGS. 9-12, the body 220 may include an arm 222 with an attachment portion 224 at a first end and an alignment portion 226 at a second end. The alignment portion 226 of the body 220 may be, for example, a variable hole alignment portion, and may include a plurality of holes 228. The plurality of holes 228 may include a center hole, a top hole above the center hole, a bottom hole below the center hole, a right hole to the right of the center hole, and a left hole to the left of the center hole. The plurality of holes 228 may be angled to a desired insertion angle relative to the arm 222 of the body 220. By way of specific example, the top hole, bottom hole, left hole, and right hole may each be slightly angled toward the center hole such that each of the outer holes slightly converge toward the center hole. The body 220 may also include a through hole 227 in the attachment portion 224 of the body 220. The body 220 may also include an alignment protrusion 223 extending away from the attachment portion 224 for engaging an opening in the bone plate 80. The alignment protrusion 223 may be used to position the bone plate alignment guide apparatus 200 on the bone plate 80, as shown in FIGS. 13-15.

As shown in FIGS. 13-18, a method for using the bone plate alignment guide apparatus 200 is shown. The body 220 of the alignment guide apparatus 200 may be secured to the bone plate 80 prior to aligning the plate 80 on the patient's bones. The body 220 of the alignment guide apparatus 200 may be secured to the plate 80 by inserting the alignment protrusion 223 into the first opening 96 in the plate 80 and also by inserting the fixation member 230 through the attachment portion 224 of the body 220 to engage the second opening 98 in the plate 80. Specifically, the engagement portion 236 may be coupled to the second opening 98 in the bone plate 80.

The bone plate 80 with the attached alignment guide apparatus 200 may then be aligned over the patient's bones 84, 88, as shown in FIG. 13. The alignment markings 87 on the plate 80 may be used to assist the surgeon in aligning the plate 80 on the patient's bones 84, 88. Next, at least one temporary fixation device may be inserted to secure the bone plate 80 to the patient's bones 84, 88. The temporary fixation devices (Not Shown) may be inserted, for example, into at least one through hole 90 in the first end 82 of the plate 80 and into the compression slot 94 in the second end 86 of the plate 80. Alternatively, as shown in FIG. 13, fasteners 100 may be inserted into the first end 82 of the plate 80 and at least one temporary fixation device, now shown, may be inserted into the compression slot 94 in the second end 86 of the plate 80. The first end 82 of the plate 80 may be the distal end of the plate 80 while the second end 86 of the plate 80 may be the proximal end of the plate 80. Once the plate 80 is positioned and secured, at least temporarily, to the bones 84, 88, then the

guide pin tissue protector 210 may be inserted into one of the plurality of holes 228 in the alignment portion 226, as shown in FIG. 13.

As shown in FIG. 14, the guide wire 240 may then be inserted through the tissue protector 210 and into the bones 84, 88 across the joint. After the guide wire 240 is inserted into the bones 84, 88 in a desired position, the tissue protector 210 may be removed from the alignment portion 226 of the body 220, as shown in FIG. 15. Next, a drill may be inserted through the alignment portion 226 and over the guide wire 240 to drill an opening (Not Shown) into the bones 84, 88 across the joint. After the opening is drilled, the drill may be removed and then the body 220 of the alignment guide apparatus 200 may be removed, as shown in FIG. 16. The body 220 of the alignment guide apparatus 200 may be removed by loosening the fixation member 230 to disengage the engagement portion 236 from the second opening 98 in the plate 80.

Next, as shown in FIG. 17, a fastener 50 may be inserted over the guide wire 240 and into the opening (Not Shown) in the bones 84, 88 across the joint. As the fastener 50 is inserted into the opening in the bones 84, 88, the bones 84, 88 will move or compress to decrease the joint space between the first bone 84 and the second bone 88. Then the guide wire 240 may be removed as shown in FIG. 18. The temporary fixation device (Not Shown) in the compression slot 94 may then be removed and at least one fastener 102 may be inserted into at least one through hole 92 to secure the second end 86 of the plate 80 to the second bone 88. After the plate is secured to the bones 84, 88 at the first end 82 and second end 86 of the plate 80 and the fastener 50 has been inserted across the joint space, the patient's incision may be closed.

Referring now to FIG. 19, another method for using a bone plate alignment guide apparatus 10, 200 is illustrated. As shown in FIG. 19, the method may include, for example, preparing a joint for compression 110. The method may further include obtaining a bone plate and an alignment guide apparatus 112 and aligning the bone plate on the joint 114. The method may also include inserting at least one fixation pin to secure the bone plate to at least one bone of the joint 116 and aligning the alignment guide apparatus with respect to the joint 118. Further, the method may include securing the alignment guide apparatus to the bone plate in the desired position 120 and inserting a guide wire through the alignment portion of the alignment guide apparatus 122. The method may also include drilling over the guide wire to form an opening in the at least one bone 124 and inserting a fastener over the guide wire across the joint 126. In addition, the method may include securing the bone plate to at least

one bone of the joint 128 and removing the alignment guide apparatus from the bone plate 130. Finally, the method may include closing the patient's incision 132.

Another bone plate alignment guide apparatus 300 is shown in FIGS. 20-24. The bone plate alignment guide apparatus 300 may include a body or alignment guide 320, a fixation member 330, a guide pin tissue protector 310, a guide wire or pin (not shown), and a fastener 50. The fixation member 330 may include a knob portion 332 and a shaft portion 334 with an engagement portion 336 for engaging a bone plate, for example, bone plate 80 of FIG. 5. The engagement portion 336 may be, for example, threaded to engage corresponding threads in an opening in a bone plate, deformable to be removeably press fit into the opening in the bone plate, or similar configurations that achieve a coupling of the guide apparatus 300 to a bone plate. The guide wire (not shown) may be of the type described above with reference to guide wire 240, which will not be described again here for brevity sake. The fastener 50 may be of the type described above with reference to FIGS. 1-5 and includes, for example, a compression screw, lag screw, headless screw, or a solid screw, which will also not be described again here for brevity sake.

The guide pin tissue protector 310, as shown in FIG. 22, may include a handle portion 312 at a first end and a shaft 314 extending away from the handle portion 312 to a tip 318 at a second end. The shaft 314 may taper at the second end to form the tip 318. The guide pin tissue protector 310 may also include a through hole 316 extending from the first end to the second end to enable a guide wire (not shown) to pass through the tissue protector 310 and engage the patient's bone.

As shown in FIGS. 20-24, the body 320 may include an arm 322 with an attachment portion 324 at a first end and an alignment portion 326 at a second end. The alignment portion 326 of the body 320 may be, for example, a variable hole alignment portion, and may include a plurality of holes 328. The plurality of holes 328 may be positioned in a linear arrangement with a center hole, a right hole to the right of the center hole, and a left hole to the left of the center hole. The plurality of holes 328 may be straight or angled to a desired insertion position relative to the arm 322 of the body 320. By way of specific example, the left hole and right hole may each be slightly angled toward the center hole such that each of the side holes converge toward the center hole. The body 320 may also include a through hole 327 in the attachment portion 324 of the body 320, as seen in FIGS. 23-24. Further, the body 320 may include an alignment protrusion 323 extending away from the attachment portion 324, as shown in FIGS. 20-23, for engaging an opening in a bone plate, such as bone

plate 80 of FIG. 5. The alignment protrusion 323 may be used to position the bone plate alignment guide apparatus 300 on a bone plate.

The method for using a bone plate alignment guide apparatus, as described above with reference to FIG. 19, may also be performed using the bone plate alignment guide apparatus 300.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has", and "having"), "include" (and any form of include, such as "includes" and "including"), and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method or device that "comprises," "has," "includes," or "contains" one or more steps or elements possesses those one or more steps or elements, but is not limited to possessing only those one or more steps or elements. Likewise, a step of a method or an element of a device that "comprises," "has," "includes," or "contains" one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

The invention has been described with reference to the preferred embodiments. It will be understood that the architectural and operational embodiments described herein are exemplary of a plurality of possible arrangements to provide the same general features, characteristics, and general system operation. Modifications and alterations will occur to others upon a reading and understanding of the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations.

CLAIMS

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A bone plate alignment guide apparatus, comprising:

a body, the body comprising:

an arm with a first end and a second end;

an attachment portion at the first end; and

an alignment portion at the second end;

a fixation insert configured to pass through the attachment portion;

a guide pin configured to pass through the alignment portion; and

a screw configured to engage the guide pin.

2. The alignment guide apparatus of claim 1, wherein the attachment portion comprises a through hole configured to receive the fixation insert.

3. The alignment guide apparatus of claim 2, wherein the alignment portion comprises at least one through hole configured to receive the guide pin.

4. The alignment guide apparatus of claim 1, wherein the fixation insert comprises:

a knob portion; and

a shaft portion extending away from the knob portion.

5. The alignment guide apparatus of claim 4, wherein the shaft portion comprises an alignment portion and a threaded section.

6. The alignment guide apparatus of claim 1, wherein the screw has a first end and a second end, the screw comprising:

a head portion at the first end;

a shaft portion extending away from the head portion to the second end, wherein the shaft portion comprises a smooth portion and a threaded portion; and

a through hole extending from the first end to the second end.

7. The alignment guide apparatus of claim 3, wherein the arm is configured to position the through hole of the attachment portion generally perpendicular to the at least one through hole of the alignment portion.

8. A bone plate alignment system, comprising:

a bone plate with a first end, a second end, and an intermediate portion connecting the first end and second end, the bone plate comprising:

at least one through hole in the first end;

at least one through hole in the second end; and

at least one opening between the first end and the second end;

a bone plate alignment guide, comprising:

a body, comprising:

an arm with a first end and a second end;

an attachment portion at the first end; and

an alignment portion at the second end;

a fixation insert configured to pass through the attachment portion;

a guide wire configured to pass through the alignment portion;

wherein the fixation insert couples to the at least one opening of the bone plate;

a screw configured to engage the guide wire during insertion into at least one portion of bone;

at least one first fastener for insertion through the at least one through hole on the first end of the bone plate and into a first portion of bone; and

at least one second fastener for insertion through the at least one through hole on the second end of the bone plate and into a second portion of bone.

9. The alignment system of claim 7, wherein the bone plate further comprises a compression slot on the second end.

10. The alignment system of claim 8, further comprising:

a temporary fixation mechanism configured to engage the compression slot.

11. The alignment system of claim 7, wherein the intermediate portion of the bone plate comprises at least one alignment marking.

12. The alignment system of claim 7, wherein the at least one opening between the first end and the second end comprises a first opening and a second opening.

13. The alignment system of claim 12, wherein the fixation insert comprises:
a knob portion; and
a shaft portion extending away from the knob portion.

14. The alignment system of claim 13, wherein the shaft portion comprises an alignment member and a threaded section and the alignment member is configured to engage the second opening in the bone plate.

15. The alignment system of claim 14, wherein the second opening is threaded and configured to engage the threaded section of the fixation insert.

16. The alignment system of claim 12, further comprising:
an alignment post configured to engage an opening in the attachment portion adjacent to a through hole in the attachment portion on a first end and the first opening in the bone plate on a second end.

17. The alignment system of claim 7, wherein the screw has a first end and a second end and comprises a through hole extending from the first end to the second end, the through hole is configured to receive the guide wire.

18. A method for moving a joint, comprising:
preparing the joint;
obtaining a bone plate alignment guide apparatus, comprising:
a body, the body comprising:
an arm with a first end and a second end;
an attachment portion at the first end; and
an alignment portion at the second end;
a fixation insert configured to engage the attachment portion;
a guide pin configured to pass through the alignment portion; and
a screw configured to engage the guide pin;

aligning a bone plate on the joint;

inserting at least one first temporary fixation pin to secure the bone plate to a first bone of the joint;

inserting at least one second temporary fixation pin to secure the bone plate to a second bone of the joint;

attaching the bone plate alignment guide apparatus to the bone plate in a desired position relative to the joint;

inserting the guide pin across the joint through the alignment portion of the body of the bone plate alignment guide apparatus;

inserting the screw over the guide pin to move the joint;

securing the bone plate to the first bone and second bone of the joint;

removing the bone plate alignment guide apparatus; and

closing the incision of the patient.

19. The method of claim 18, wherein securing the bone plate to the bones of the joint comprises:

removing the at least one first temporary fixation pin from the first bone;

inserting at least one fastener through the bone plate and into the first bone;

removing the at least one second temporary fixation pin from the second bone; and

inserting at least one fastener through the bone plate and into the second bone.

20. The method of claim 18, further comprising:

inserting a drill over the guide pin to drill an opening into the first bone and second bone; and

removing the drill from the guide pin before inserting the screw across the joint.

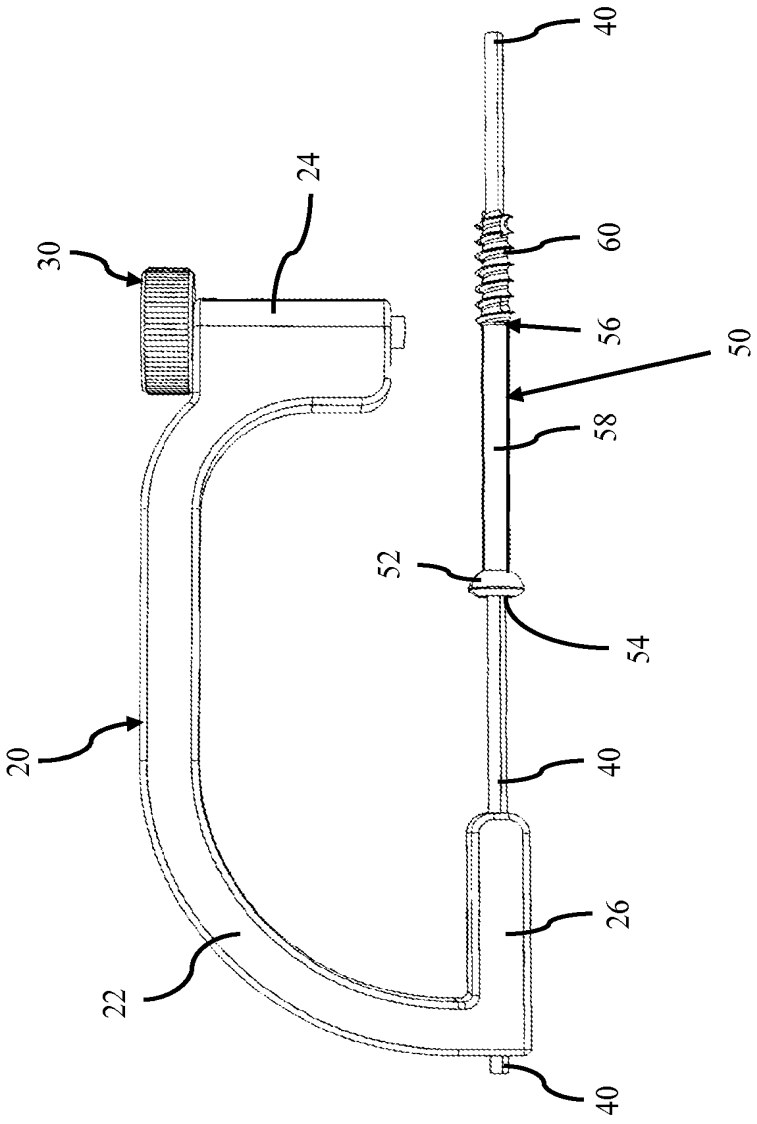


FIG. 1

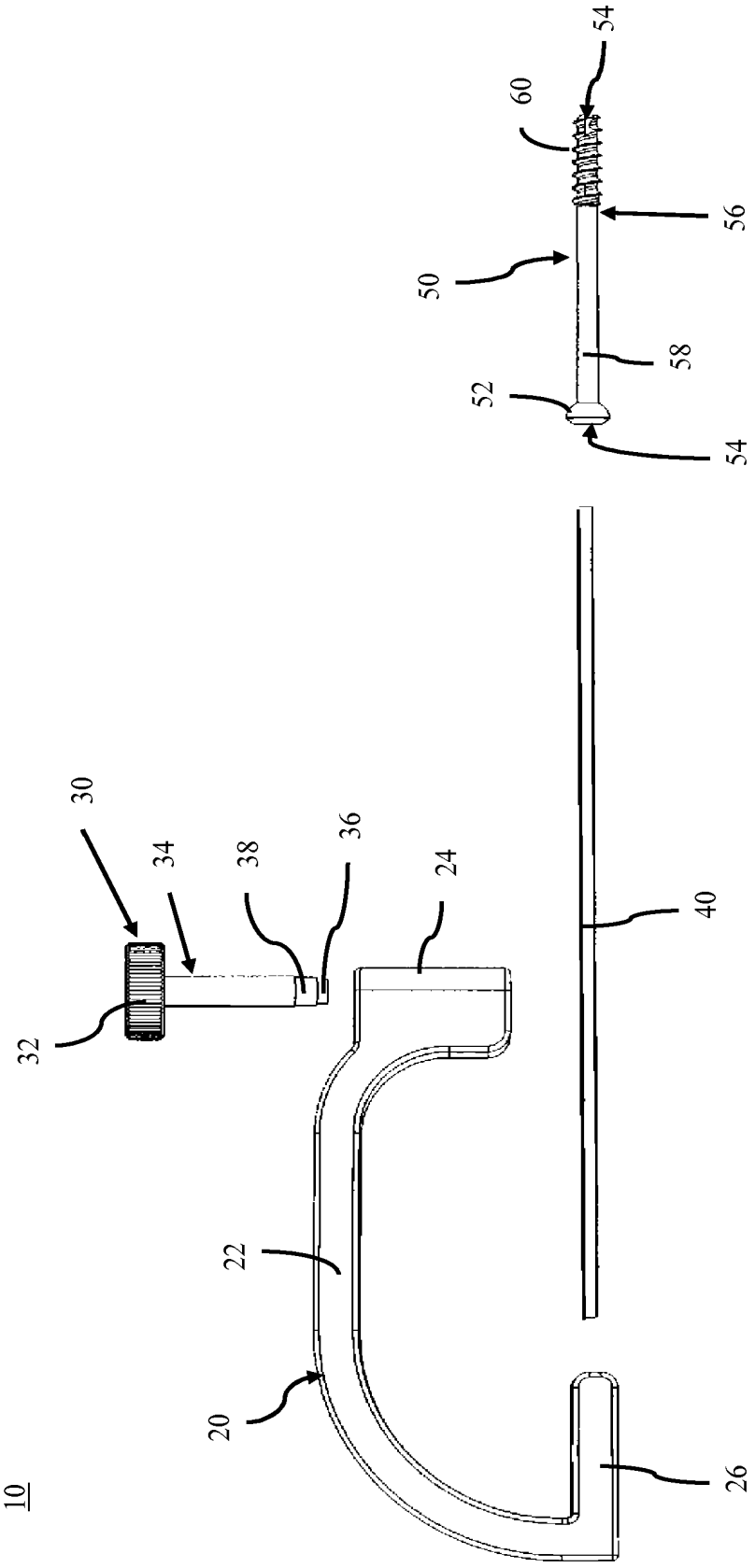


FIG. 2

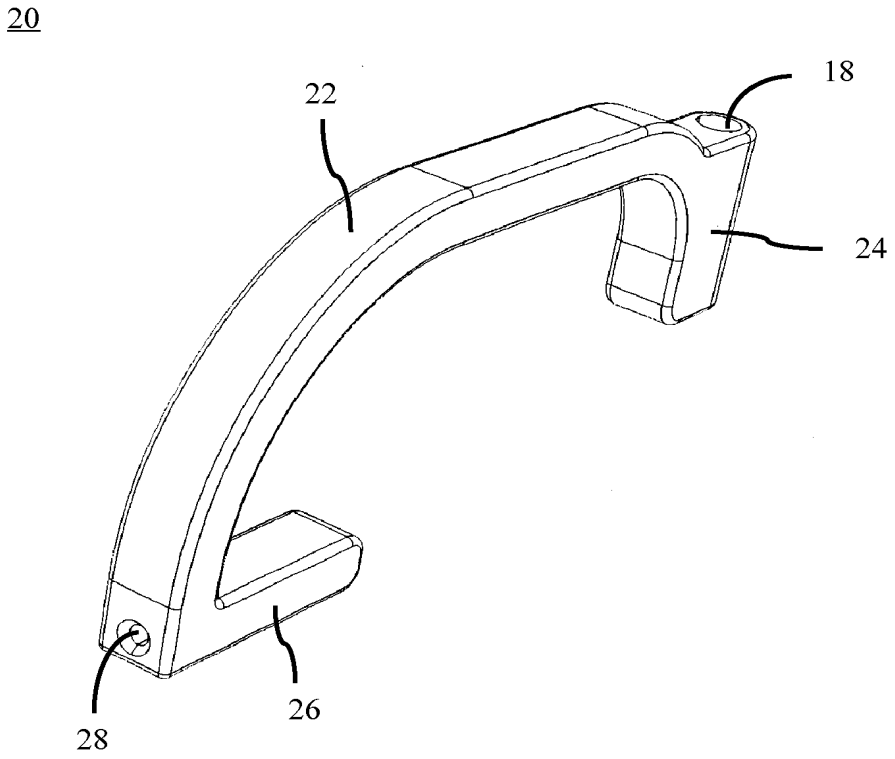


FIG. 3

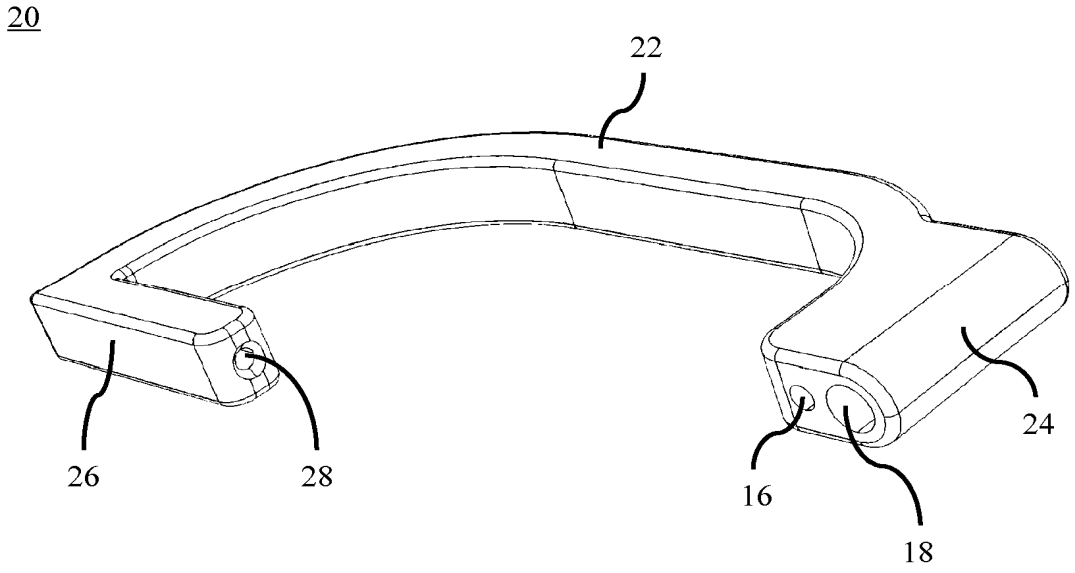


FIG. 4

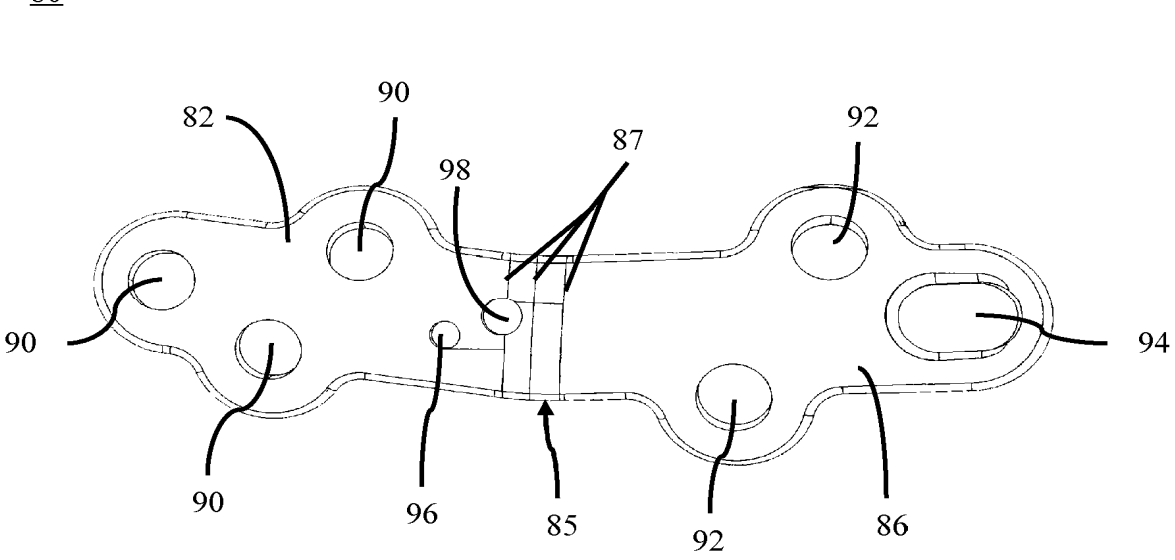

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FIG. 5

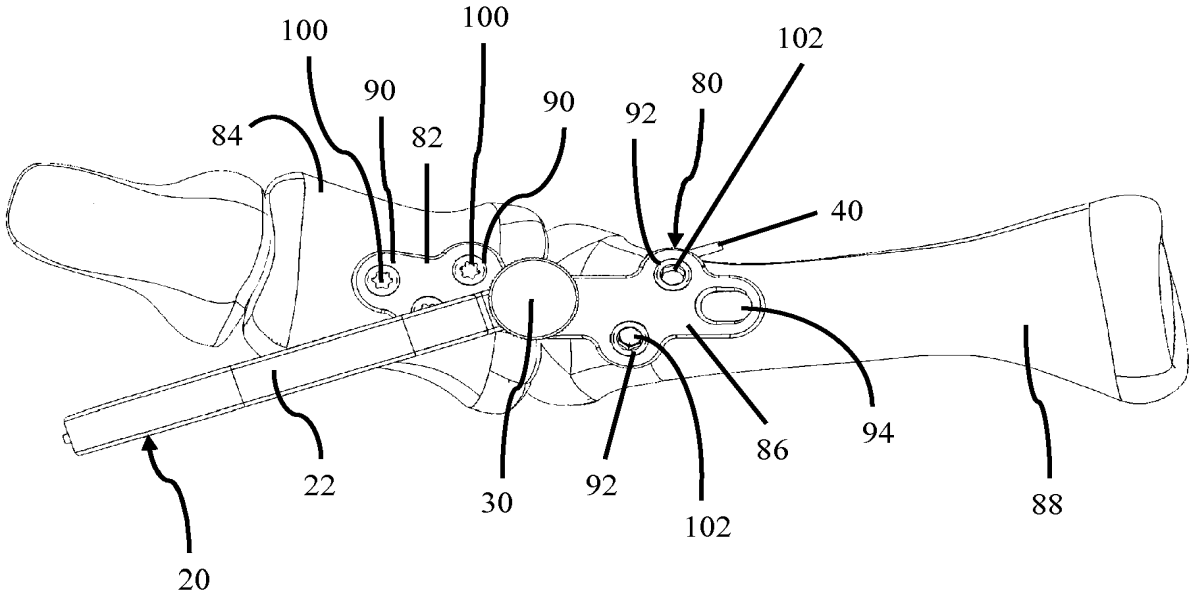

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FIG. 6

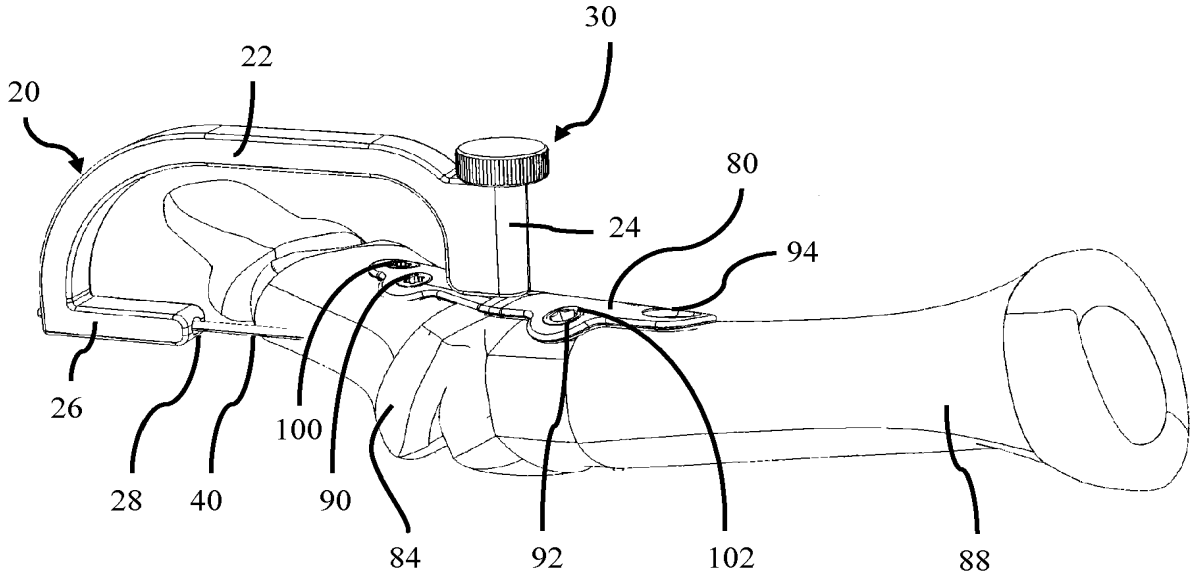

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FIG. 7

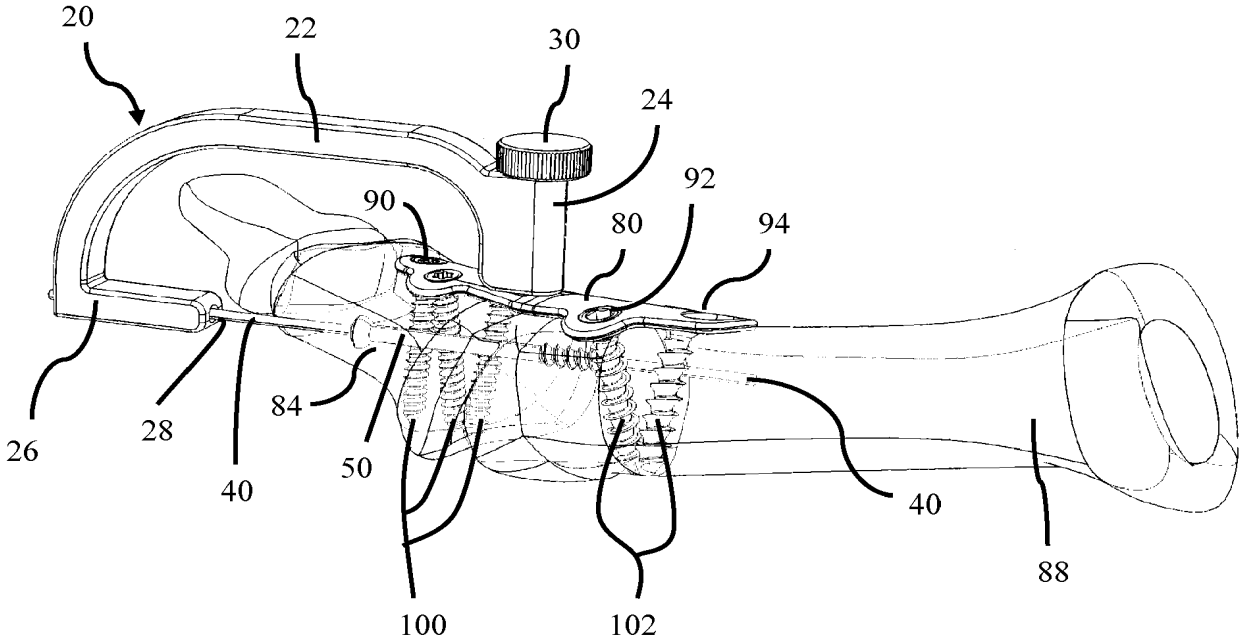

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FIG. 8

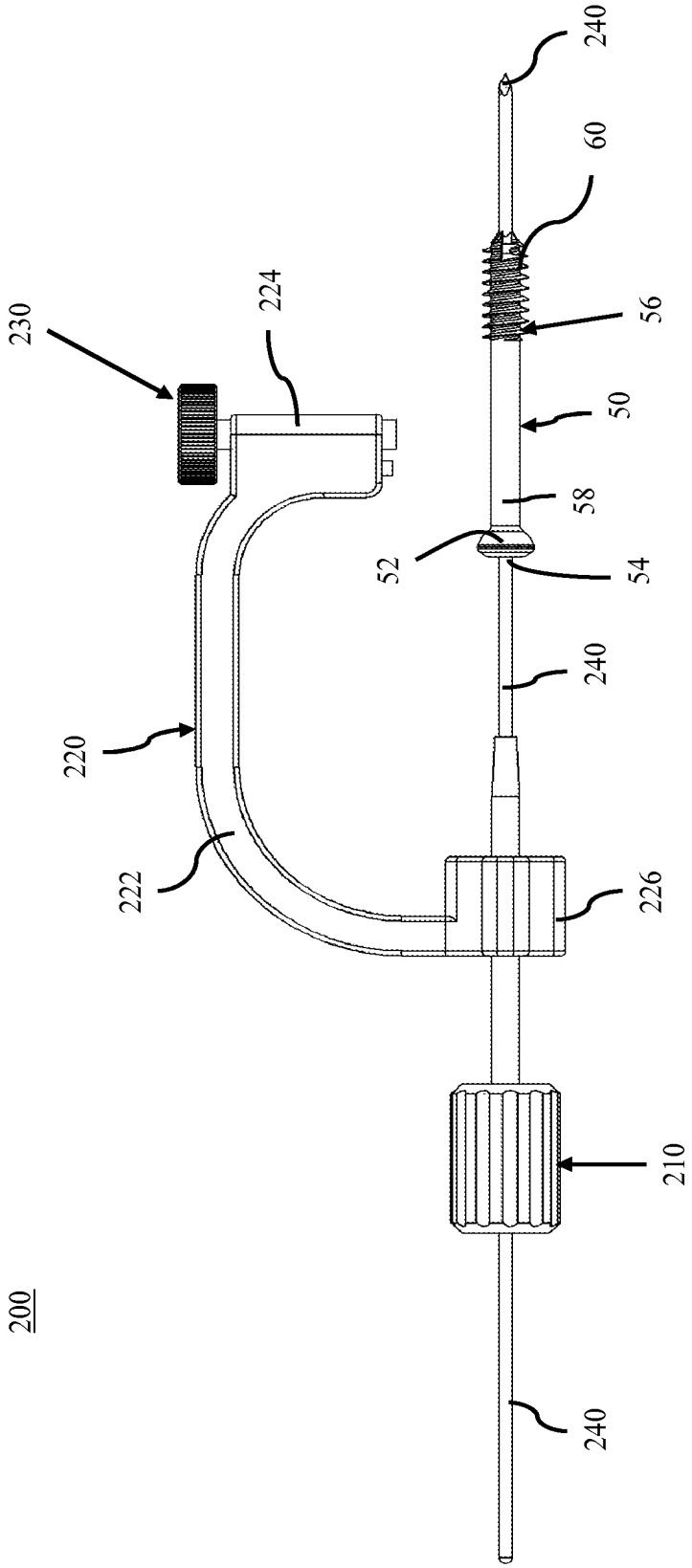


FIG. 9

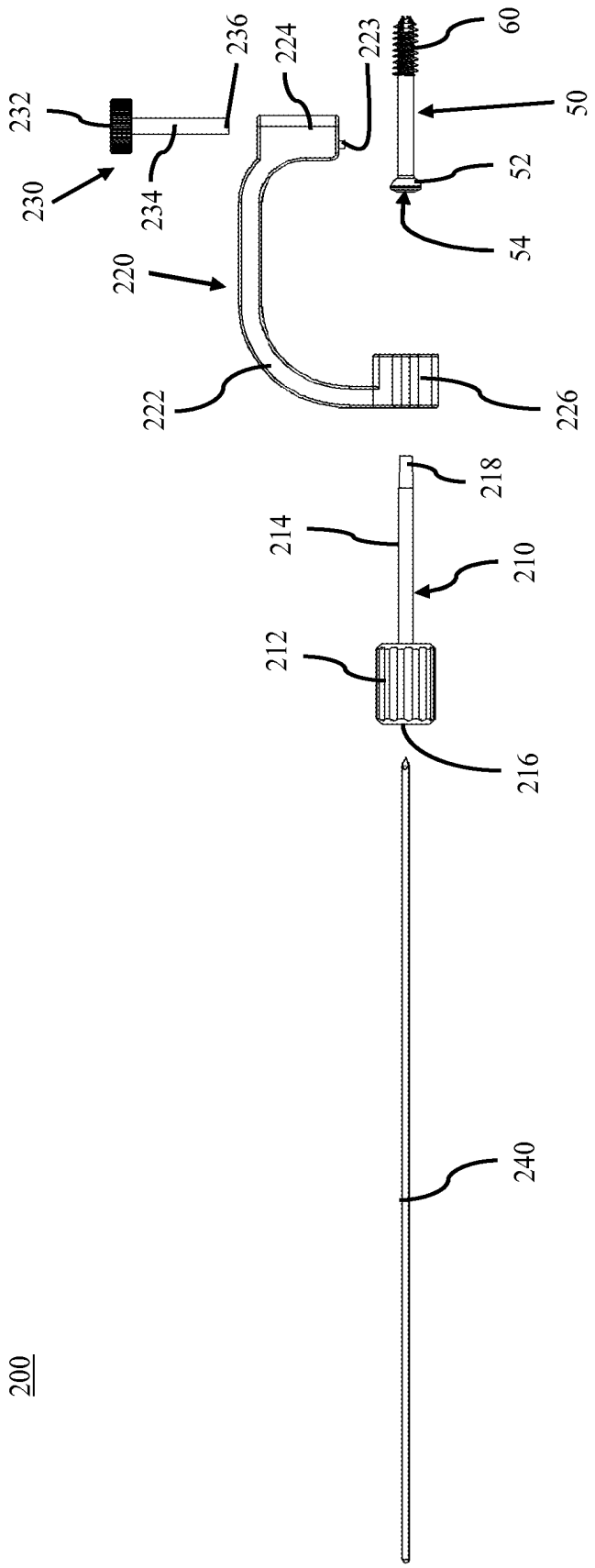

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FIG. 10

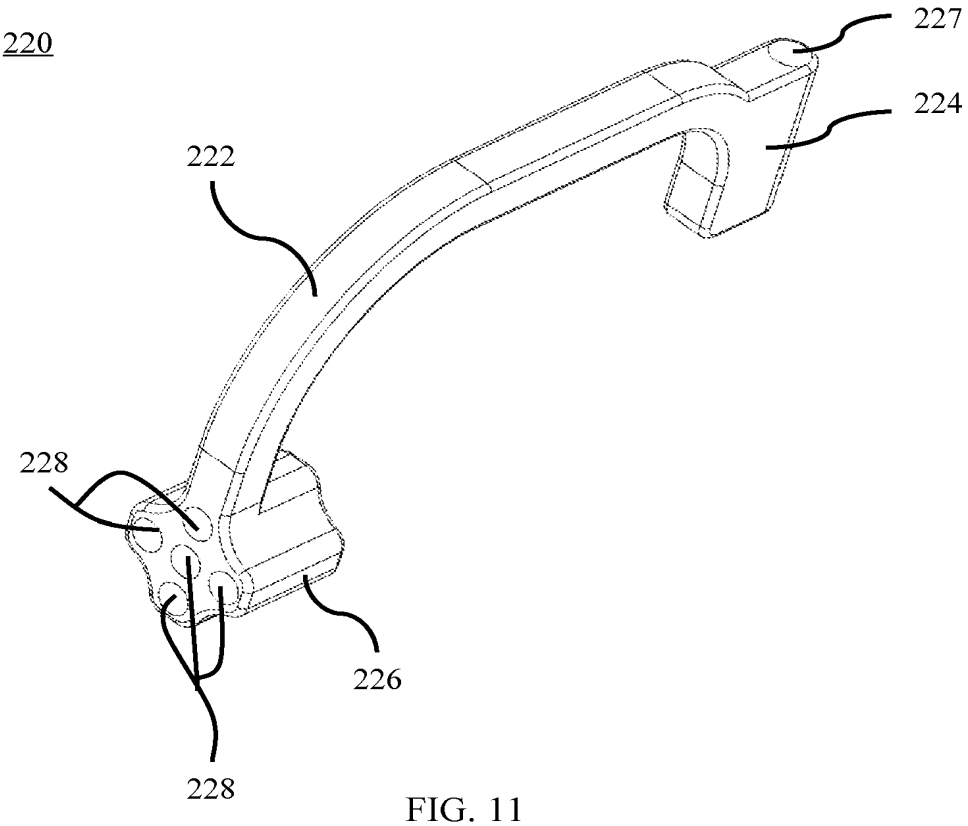


FIG. 11

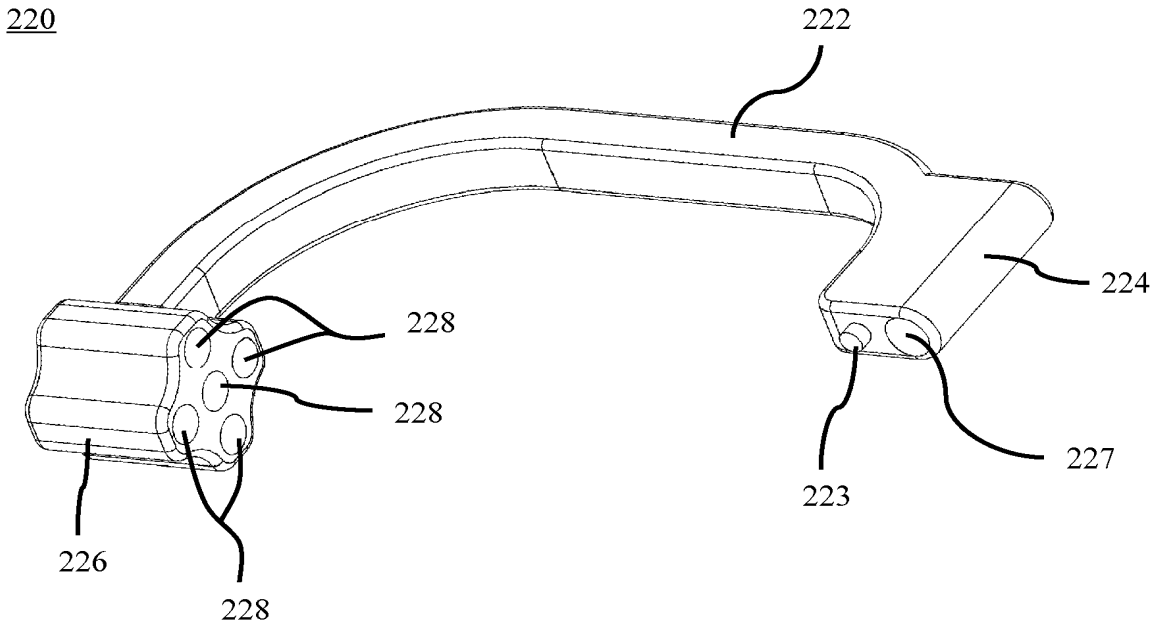


FIG. 12

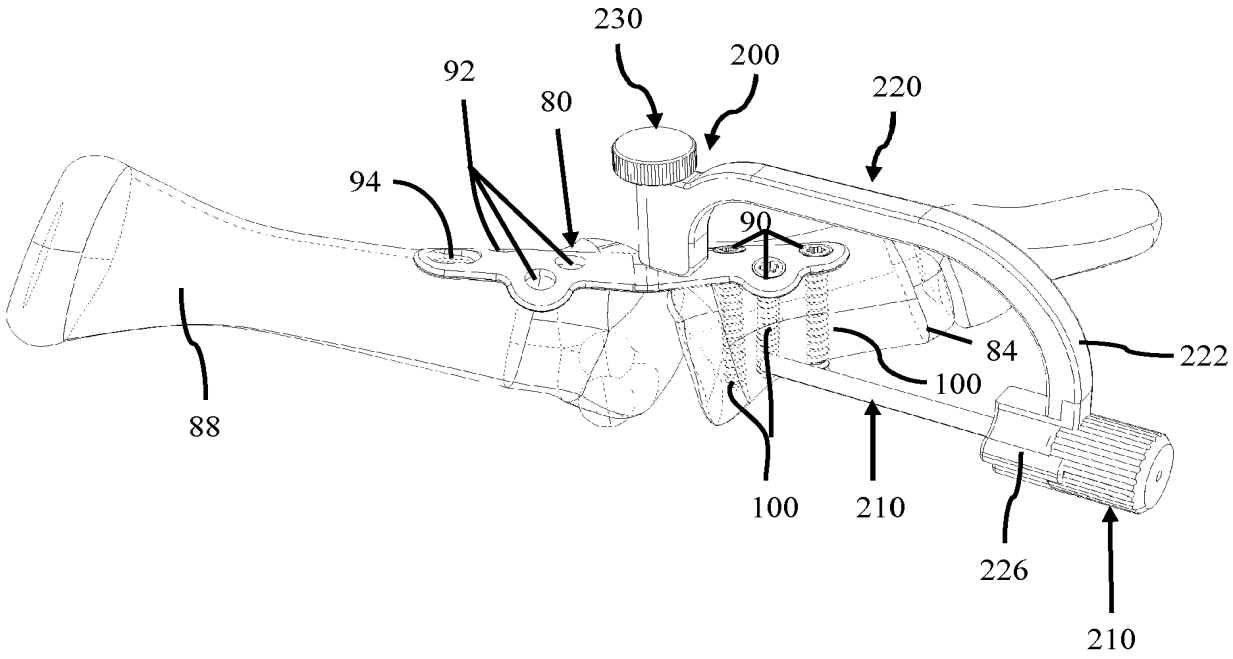

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FIG. 13

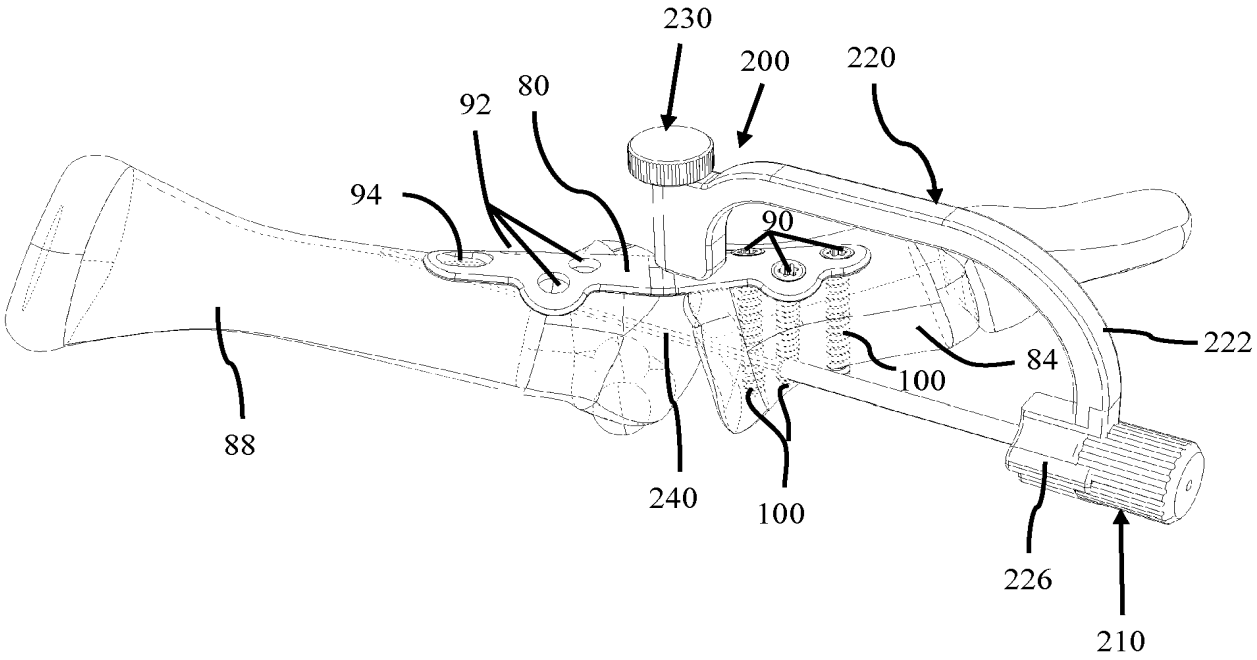

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FIG. 14

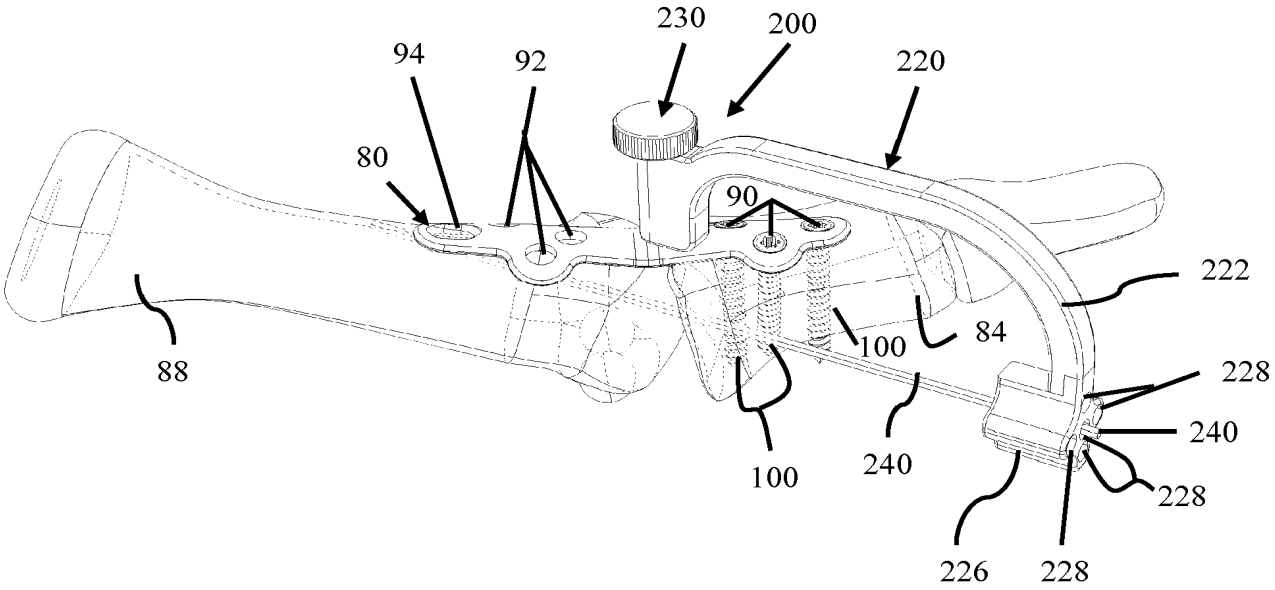

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FIG. 15

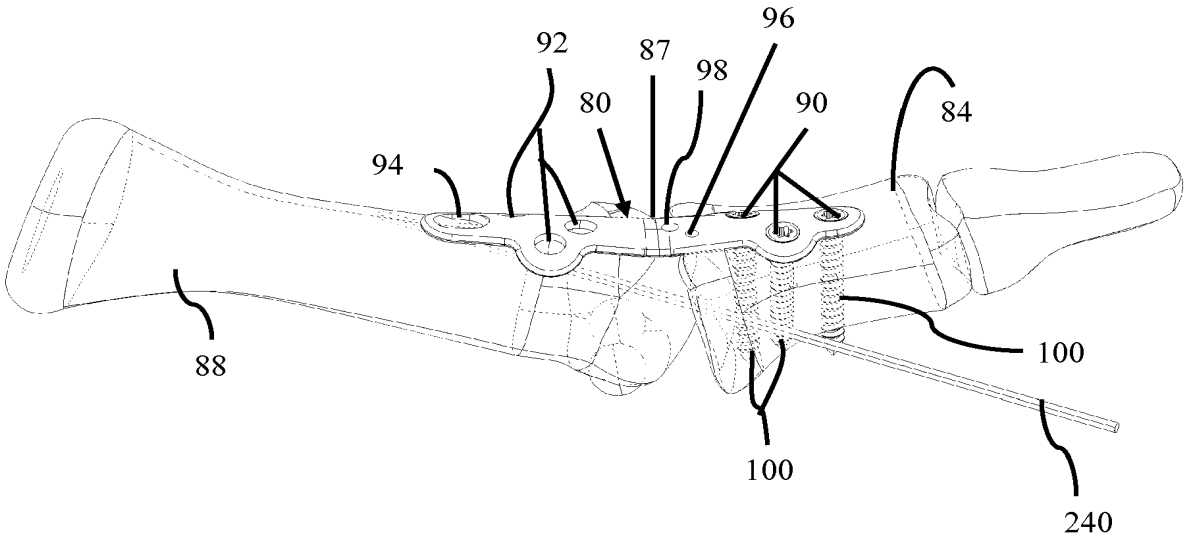

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FIG. 16

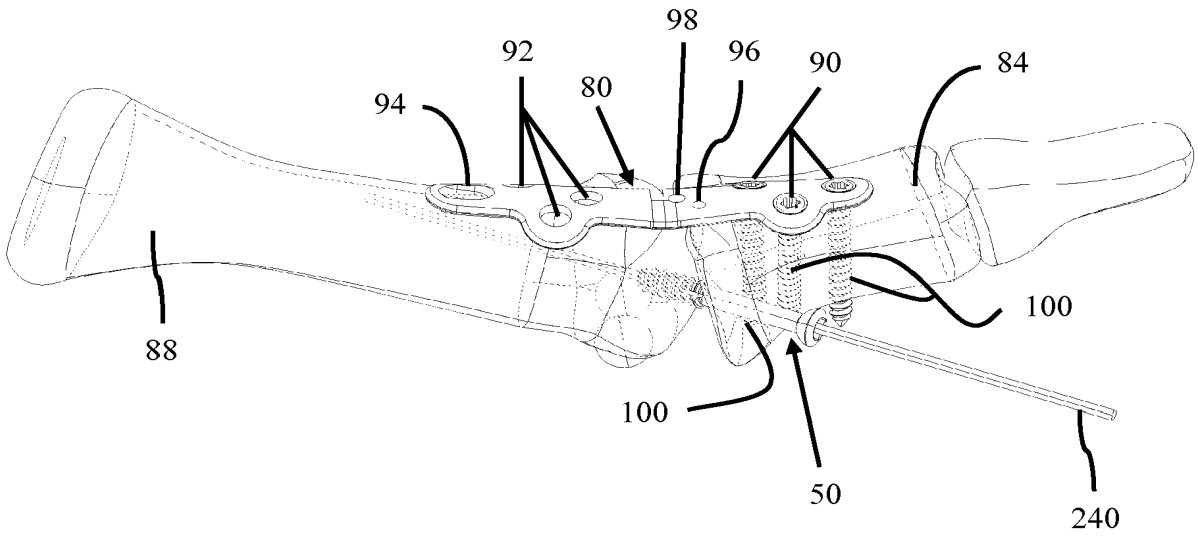

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FIG. 17

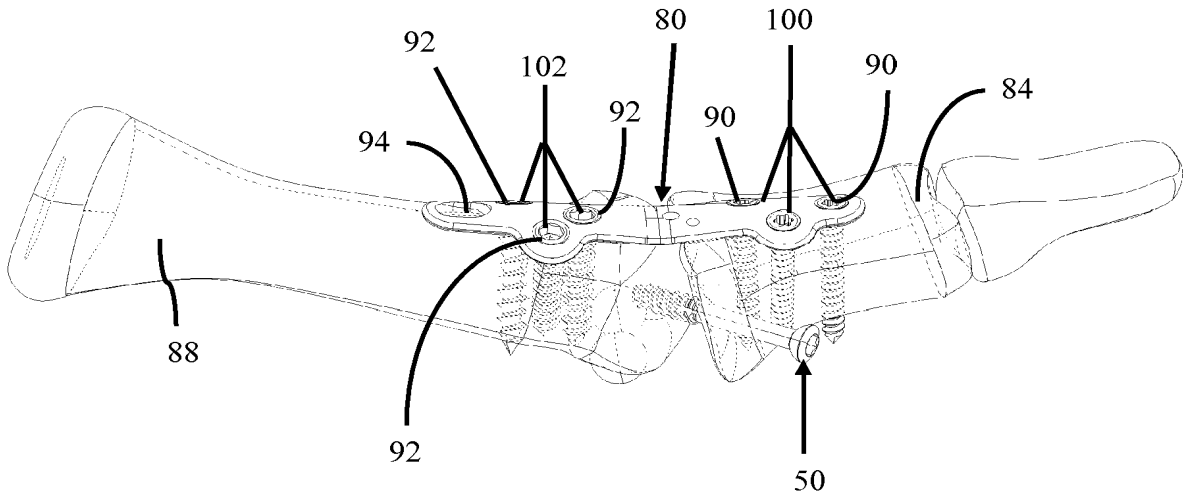

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FIG. 18

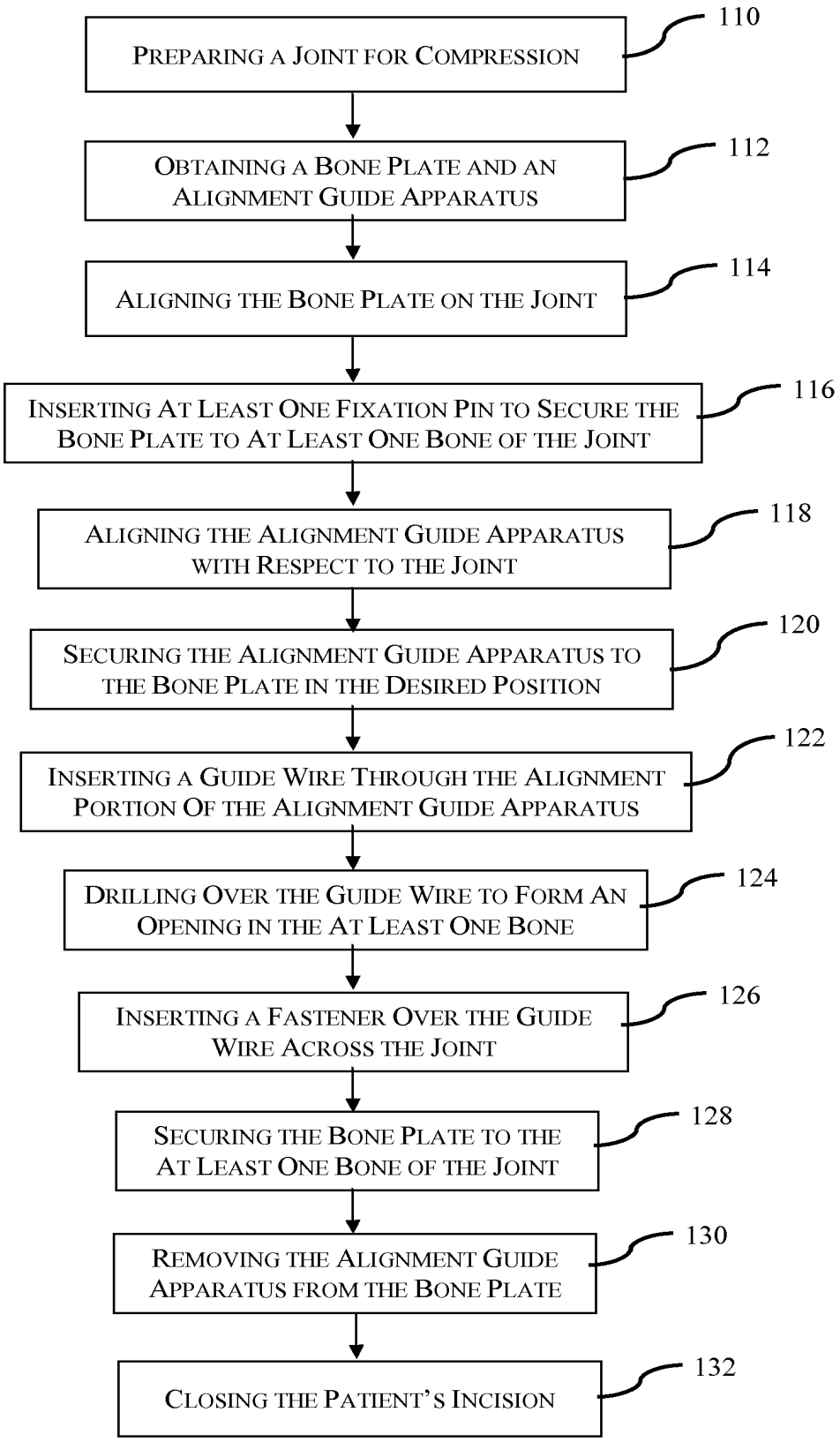

PREPARING A JOINT FOR COMPRESSION
110
OBTAINING A BONE PLATE AND AN ALIGNMENT GUIDE APPARATUS
112
ALIGNING THE BONE PLATE ON THE JOINT
114
INSERTING AT LEAST ONE FIXATION PIN TO SECURE THE BONE PLATE TO AT LEAST ONE BONE OF THE JOINT
116
ALIGNING THE ALIGNMENT GUIDE APPARATUS WITH RESPECT TO THE JOINT
118
SECURING THE ALIGNMENT GUIDE APPARATUS TO THE BONE PLATE IN THE DESIRED POSITION
120
INSERTING A GUIDE WIRE THROUGH THE ALIGNMENT PORTION OF THE ALIGNMENT GUIDE APPARATUS
122
DRILLING OVER THE GUIDE WIRE TO FORM AN OPENING IN THE AT LEAST ONE BONE
124
INSERTING A FASTENER OVER THE GUIDE WIRE ACROSS THE JOINT
126
SECURING THE BONE PLATE TO THE AT LEAST ONE BONE OF THE JOINT
128
REMOVING THE ALIGNMENT GUIDE APPARATUS FROM THE BONE PLATE
130
CLOSING THE PATIENT'S INCISION
132

FIG. 19

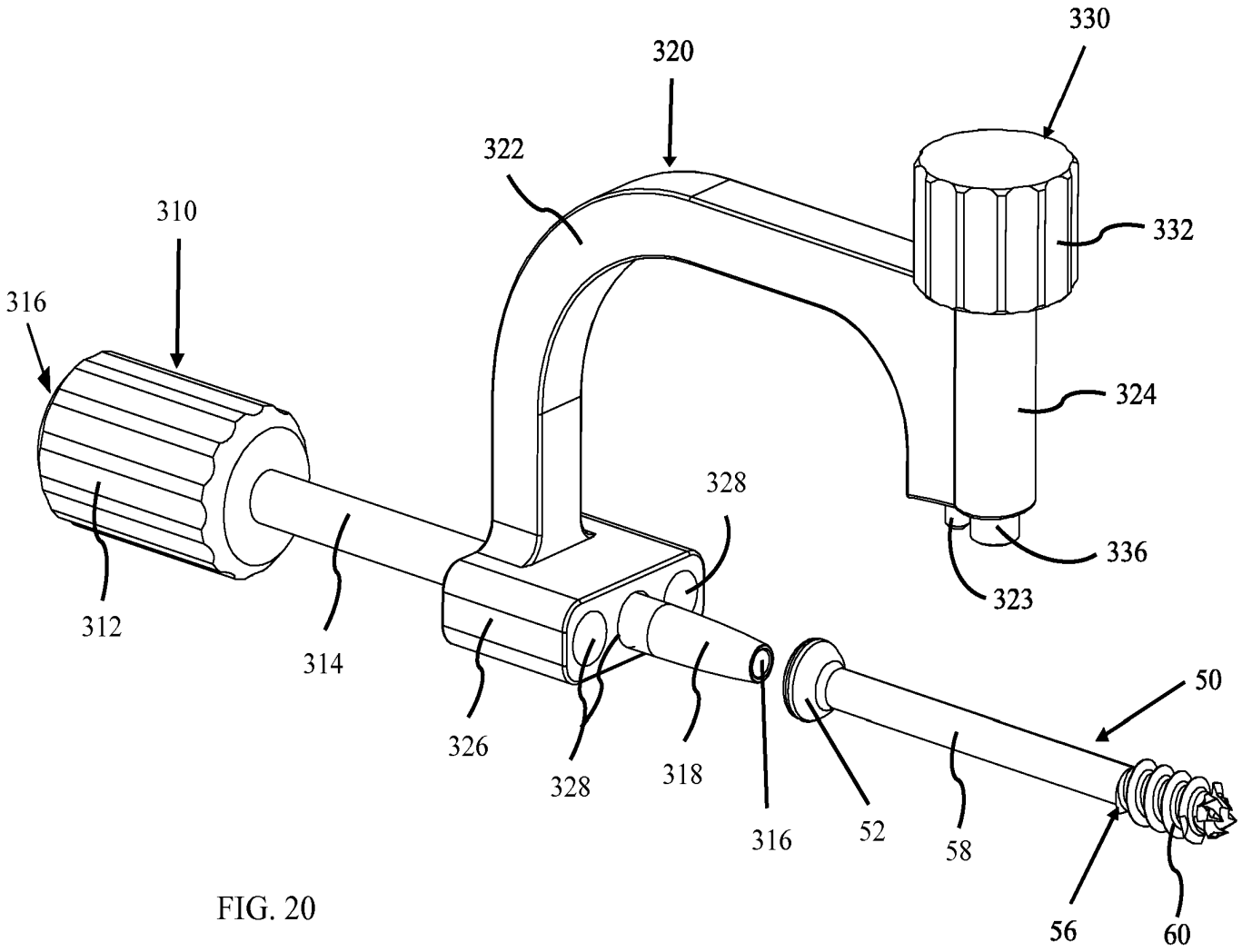

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FIG. 20

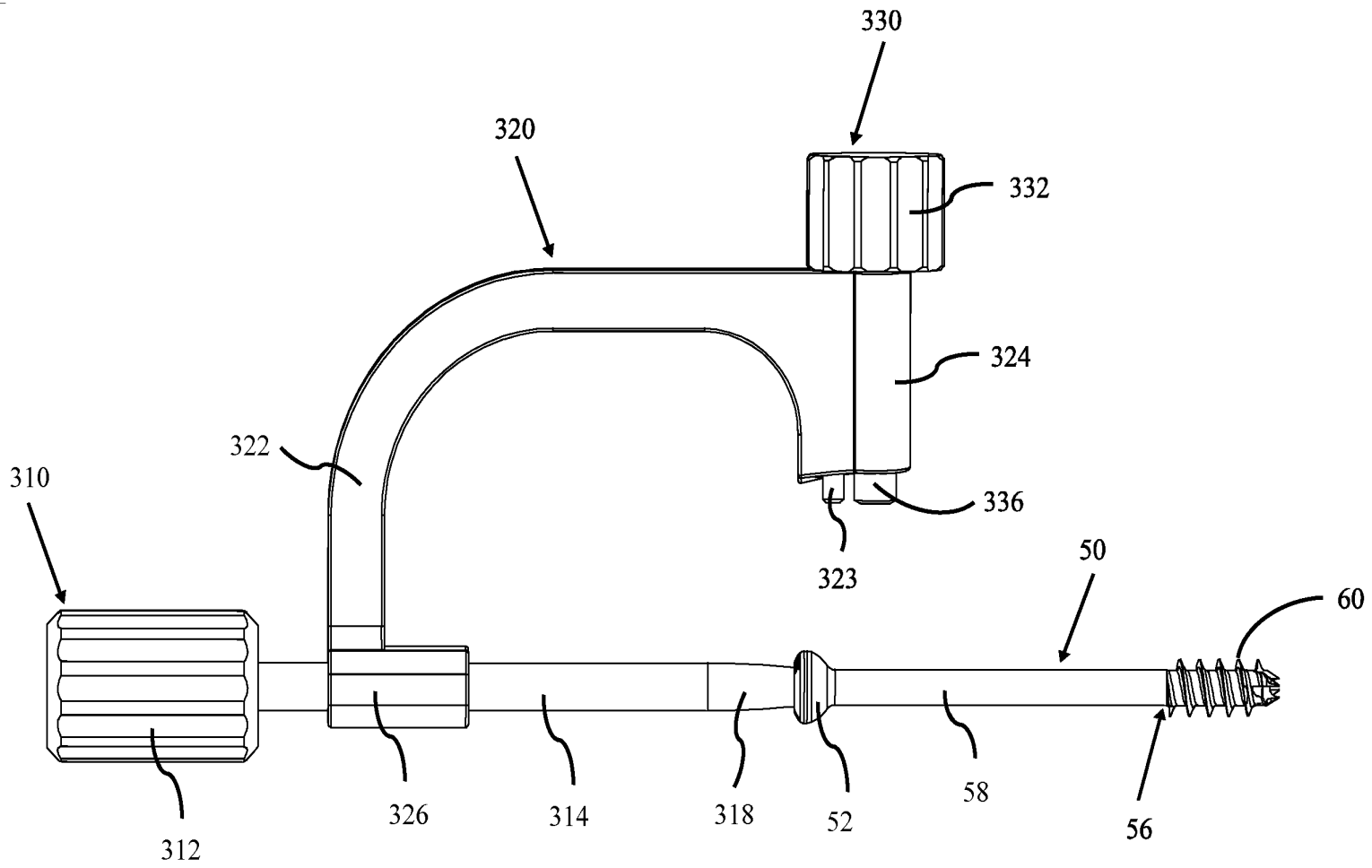


FIG. 21

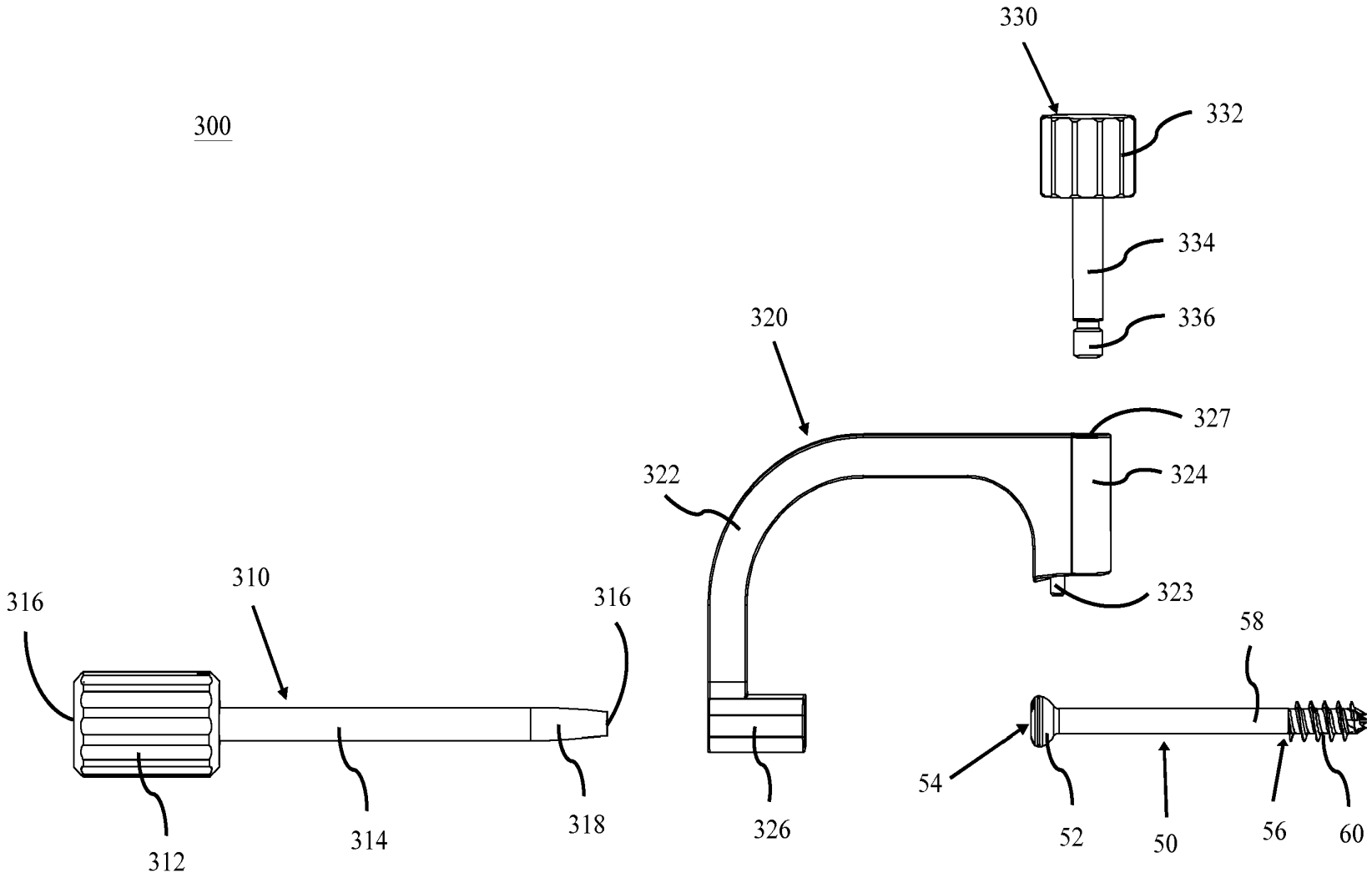

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FIG. 22

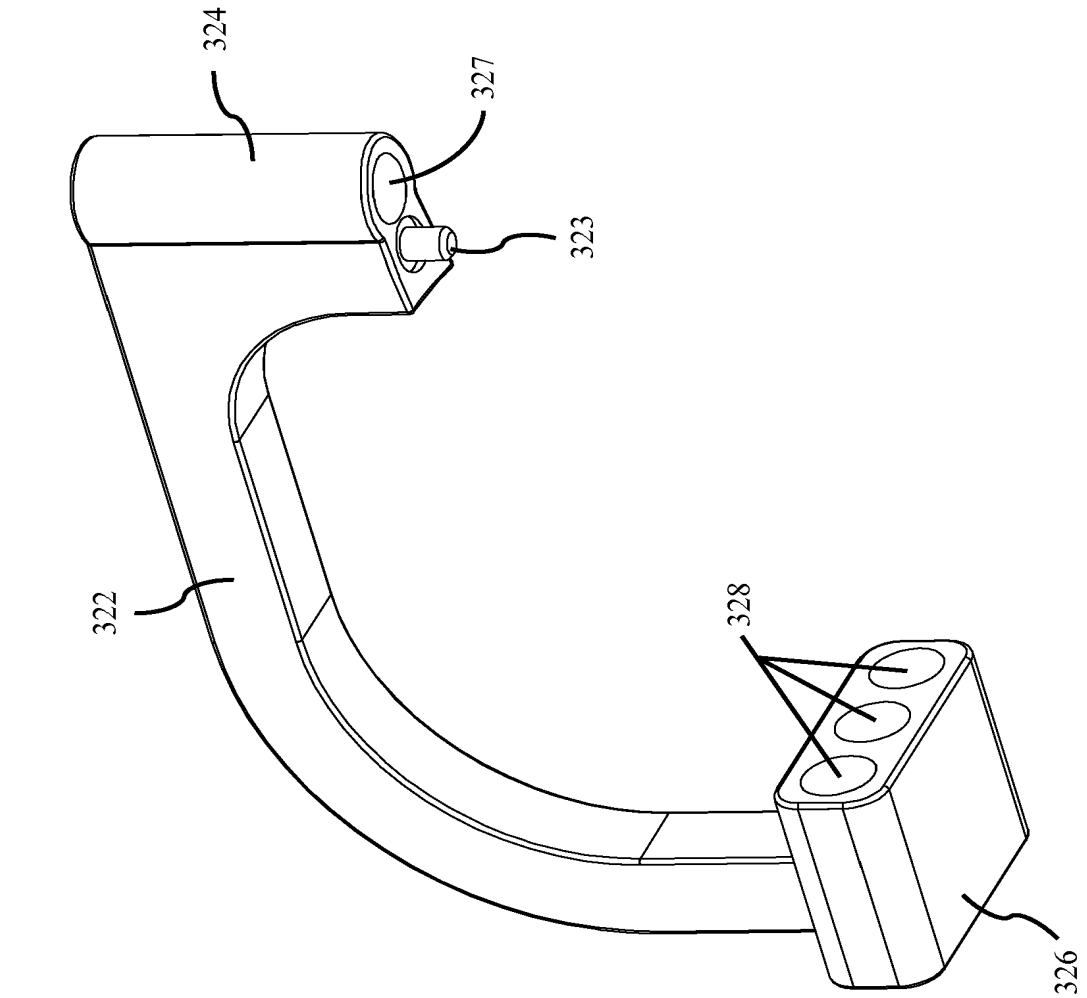


FIG. 23

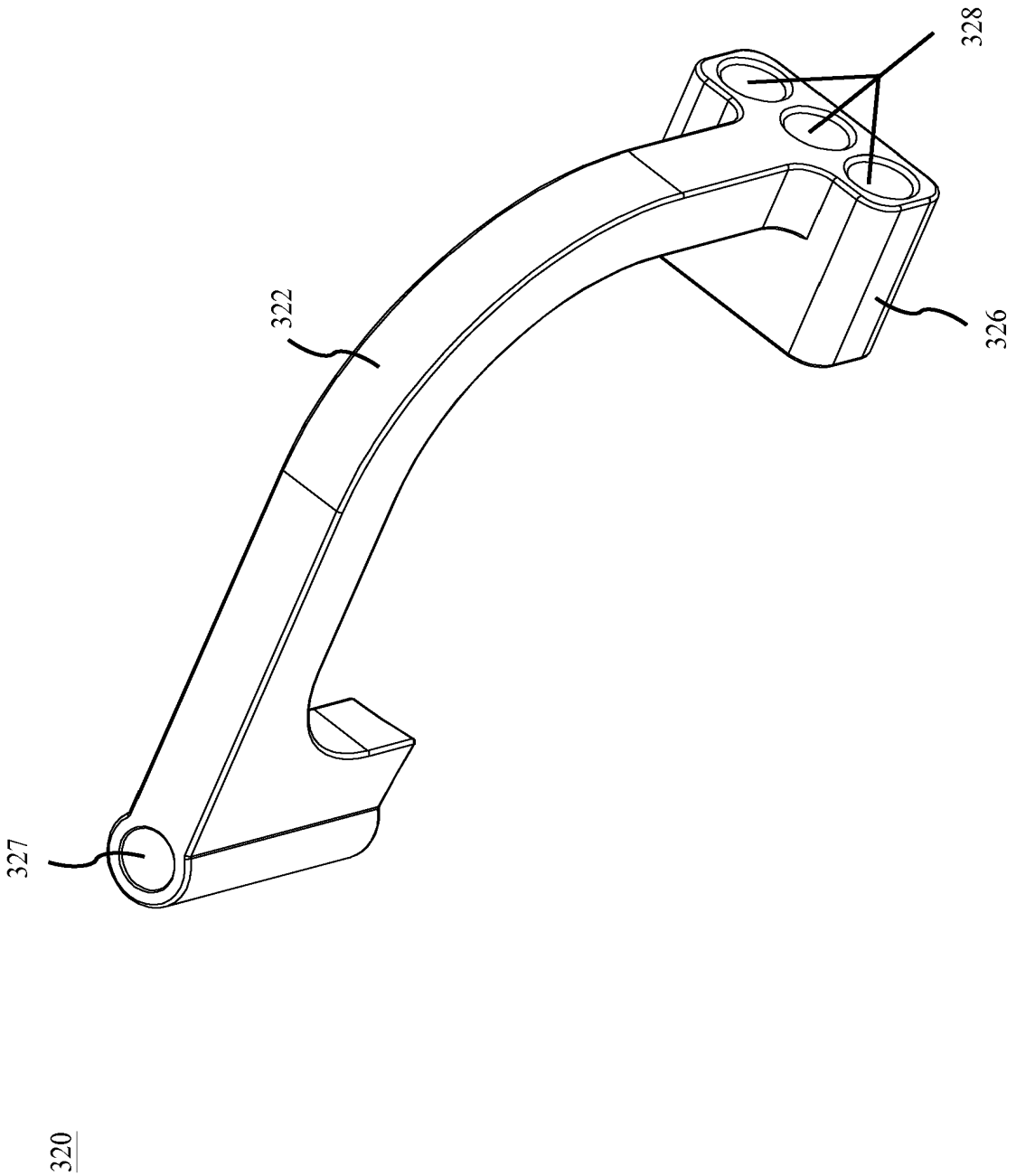


FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/045441

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/17, 17/56 (2014.01)
CPC - A61B 17/1728, 2017/564 (2014.10)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/17, 17/56, 17/58, 17/80, 17/86, 17/90 (2014.01)
CPC - A61B 17/17, 17/171, 17/1728, 17/1739, 17/1742, 17/175, 17/1757, 17/1764, 17/1767, 17/56, 2017/564, 17/58, 17/80 (2014.10)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC (con't) - A61B 17/8019, 17/86, 17/90 (2014.10) (keyword delimited)
USPC - 24/569; 144/269, 278.1, 307; 269/182, 249, 261; 439/803; 606/86, 87, 96, 98, 280, 286, 300, 902-906

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google Scholar.
Search terms used: bone, plate, alignment, tool, guide, pin, compression, lag, screw, arc, curved, align, joint

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0033301 A1 (LOMBARDO et al) 10 February 2005 (10.02.2005) entire document	1-7,17
Y		8-16
Y	US 2007/0225714 A1 (GRADL) 27 September 2007 (27.09.2007) entire document	8-16
A	US 2006/0189996 A1 (ORBAY et al) 24 August 2006 (24.08.2006) entire document	1-20
A	US 2012/0253347 A1 (MURASHKO JR) 04 October 2012 (04.10.2012) entire document	1-20
A	US 7,011,665 B2 (NULL et al) 14 March 2006 (14.03.2006) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2014	25 NOV 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Electronic Acknowledgement Receipt

EFS ID:	37274169
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	26-SEP-2019
Filing Date:	21-JUN-2019
Time Stamp:	12:57:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_FandR-SIDS.PDF	1037656 b48f3e34ba79ff10b9e86bdf1eaa8058d3e2fe37	no	9

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2	Foreign Reference	FR_CN101237835B_with-Abstract.pdf	1699382 6e5d632fe2a7cf0c302fa73f9e47d788bebf4579	no	58
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6	Foreign Reference	FR_EP2624764B1_with-Abstract.pdf	313236 ae67a52ccc45014c9bc8ec17873314987324808c	no	11
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8	Foreign Reference	FR_GB2334214B.pdf	207411 0cc4657d5301c21423c146fb59c272d4f786f605	no	17
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10	Non Patent Literature	NPL_AccuCut-Brochure_10-2018.pdf	494379 cb5222b3c606ef739e1b0ffe832dc84c4a3af6df	no	2
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11	Non Patent Literature	NPL_Acumed-Osteotomisystem_2014-with-Partial-English-Translation.pdf	1454887 9940eb6a1a8b3c497e134cec0220d72512c9ec92	no	19
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12	Non Patent Literature	NPL_Blomer_2000.pdf	436576 3fc8e051586cee58d7622964629d6d002cb4ba11	no	9
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13	Non Patent Literature	NPL_Bouaicha_2011.pdf	860215 2fbb07b610a6e816312529a3cee16d19b4b2f7ab	no	3
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14	Non Patent Literature	NPL_Futura-Forefoot-Implant_2008.pdf	2488386 c28f698fce2e079a9a05a65c797d74269665169f	no	12
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15	Non Patent Literature	NPL_Gotte_2002_with-Partial-English-Translation.pdf	11981444 33bf7faa49909059de24eac64eaccc9f1937a6da	no	11
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16	Non Patent Literature	NPL_Hat-Trick_Metatarsal-Shortening_2014.pdf	2346625 0d65dddfb2a13e058462c59b3ceec86a284aee06	no	16
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27	Non Patent Literature	NPL_Patient-to-Patient-BioPro_08-2002.pdf	1338703 c88568a4f157312566a423c82432a8ca16d2bbc0	no	2
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Information:					
36	Non Patent Literature	NPL_Wendl_2002_with-Abstract.pdf	578426 8f70daefd8dedf1e15550cfc924ed7fe63771c57	no	7
Warnings:					
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6

CONFIRMATION NO. 6223

22859
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

PUBLICATION NOTICE

OC000000112303662

Title:TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

Publication No.US-2019-0328435-A1
Publication Date:10/31/2019

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5374271	A	1994-12-20	Hwang	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20110009865	A1	2011-01-13	Orfaly	
	2	20120130382	A1	2012-05-24	Iannotti et al.	
	3	20110118739	A1	2011-05-19	TYBER et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2020-04-13
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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EFS ID:	39148208
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	16-APR-2020
Filing Date:	21-JUN-2019
Time Stamp:	16:59:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_SIDS.pdf	1034437 ff7fd2e2d7bdd1ef277587dcde234f19ea84c586	no	4

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Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3664022	A	1972-05-23	SMALL	
	2	9522023	B2	2016-12-20	HADDAD et al.	

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	1	20080288004	A1	2008-11-20	SCHENDEL	

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	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	ALVINE et al., "Peg and Dowel Fusion of the Proximal Interphalangeal Joint," Foot & Ankle, Vol. 1, No. 2, 1980, pp. 90–94.	
	2	BEDNARZ et al., "Modified Lapidus Procedure for the Treatment of Hypermobile Hallux Valgus," Foot & Ankle International, Vol. 21, No. 10, October 2000, pp. 816–821.	
	3	CARR et al., "Correctional Osteotomy for Metatarsus Primus Varus and Hallux Valgus," The Journal of Bone and Joint Surgery, Vol. 50-A, No. 7, October 1968, pp. 1353–1367.	
	4	COETZEE et al., "The Lapidus Procedure: A Prospective Cohort Outcome Study," Foot & Ankle International, Vol. 25, No. 8, August 2004, pp. 526–531.	
	5	DOTY et al., "Hallux valgus and hypermobility of the first ray: facts and fiction," International Orthopaedics, Vol. 37, 2013, pp. 1655-1660.	
	6	GALLI et al., "Enhanced Lapidus Arthrodesis: Crossed Screw Technique With Middle Cuneiform Fixation Further Reduces Sagittal Mobility," The Journal of Foot & Ankle Surgery, Vol. 54, Vol. 3, May/June 2015, published online: November 21, 2014, pp. 437-440.	
	7	LAPIDUS, "The Author's Bunion Operation From 1931 to 1959," Clinical Orthopaedics, Vol. 16, 1960, pp. 119-135.	
	8	OSHER et al., "Accurate Determination of Relative Metatarsal Protrusion with a Small Intermetatarsal Angle: A Novel Simplified Method," The Journal of Foot & Ankle Surgery, Vol. 53, No. 5, September/October 2014, published online: June 3, 2014, pp. 548-556.	
	9	PATEL et al., "Modified Lapidus Arthrodesis: Rate of Nonunion in 227 Cases," The Journal of Foot & Ankle Surgery, Vol. 43, No. 1, January/February 2004, pp. 37-42.	
	10	TOTH et al., "The Effect of First Ray Shortening in the Development of Metatarsalgia in the Second Through Fourth Rays After Metatarsal Osteotomy," Foot & Ankle International, Vol. 28, No. 1, January 2007, pp. 61-63.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

	11	DAYTON et al., "Comparison of the Mechanical Characteristics of a Universal Small Biplane Plating Technique Without Compression Screw and Single Anatomic Plate With Compression Screw," The Journal of Foot & Ankle Surgery, Vol. 55, No. 3, May/June 2016, published online: February 9, 2016, pp. 567-571.

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2020-06-15
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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