

US00RE43328E

# (19) United States

# (12) Reissued Patent

Foley et al.

## (10) Patent Number:

US RE43,328 E

## (45) Date of Reissued Patent:

Apr. 24, 2012

#### IMAGE GUIDED AWL/TAP/SCREWDRIVER

Inventors: **Kevin T. Foley**, Memphis, TN (US);

Anthony J. Melkent, Lafayette, CO (US); Catalina J. Carroll, Memphis, TN

(US)

Medtronic Navigation, Inc, Louisville,

CO (US)

Appl. No.: 10/062,265

Jan. 31, 2002 (22)Filed:

### Related U.S. Patent Documents

Reissue of:

6,021,343 (64)Patent No.: Issued: Feb. 1, 2000 Appl. No.: 08/971,126 Filed: Nov. 20, 1997

(51)Int. Cl.

A61B 5/05 (2006.01)

**U.S. Cl.** ...... **600/429**; 600/417; 600/407; 600/473; (52)600/476; 606/130; 606/79; 606/80; 606/96; 606/60; 606/61; 606/62; 606/104

Field of Classification Search .............................. 600/429, (58)600/417, 407, 473, 476; 606/130, 79, 80, 606/96, 60–62, 104

See application file for complete search history.

#### (56)**References Cited**

#### U.S. PATENT DOCUMENTS

1,576,781 A	3/1926	Phillips
1,735,726 A	11/1929	Bornhardt
2,407,845 A	9/1946	Nemeyer
2,650,588 A	9/1953	Drew
2,697,433 A	12/1954	Sehnder
3,016,899 A	1/1962	Stenvall
3.017.887 A	1/1962	Hever

3,061,936 A	11/1962	Dobbeleer
3,073,310 A	1/1963	Mocarski
3,109,588 A	11/1963	Polhemus et al.
3,294,083 A	12/1966	Alderson
3,367,326 A	2/1968	Frazier
3,439,256 A	4/1969	Kähne et al.
3,577,160 A	5/1971	White
3,614,950 A	10/1971	Rabey
3,644,825 A	2/1972	Davis, Jr. et al.
	(Con	tinued)

#### FOREIGN PATENT DOCUMENTS

CA964149 3/1975 (Continued)

#### OTHER PUBLICATIONS

Barrick, "Distal Locking Screw Insertion Using a Cannulated Drill Bit: Technical Note," Journal of Orthopaedic Trauma, vol. 7, No. 3, 1993, pp. 248-251.

(Continued)

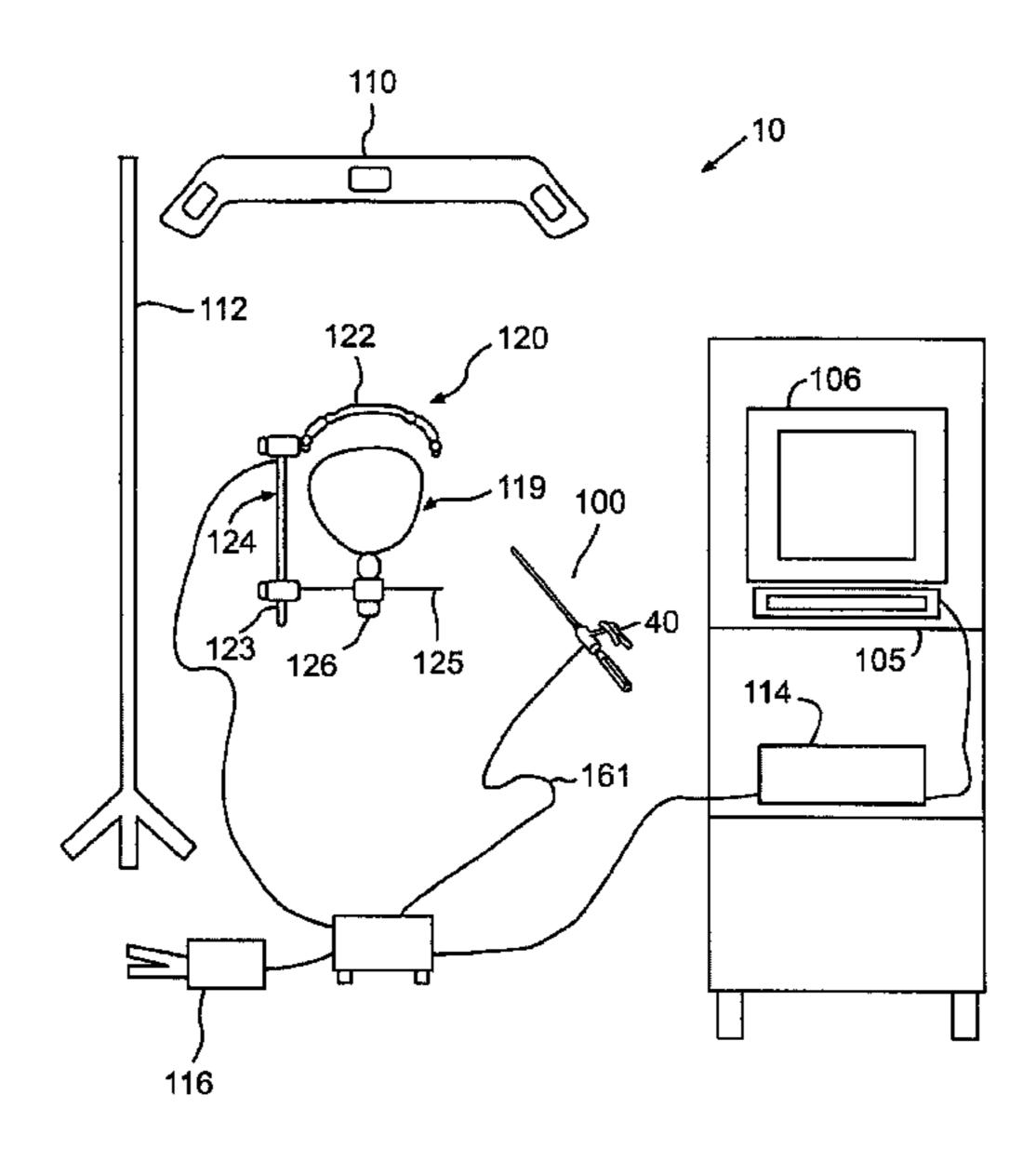
Primary Examiner — Tse Chen Assistant Examiner — Mark Remaly

(74) Attorney, Agent, or Firm — Harness, Dickey

#### **ABSTRACT** (57)

A trackable medical instrument for use in a computer assisted image guided medical and surgical navigation systems that generate images during medical and surgical procedures, includes a guide member having an emitter array for being tracked by the system and a drive shaft contained within the guide member having a proximal and a distal end, the drive shaft being rotatable within the guide member while being fixable axially inside the guide member, the proximal end of the drive shaft having a first connector for interchangeably receiving at least one drive source, and the distal end having a second connector for interchangeably receiving at least one instrument tip.

## 88 Claims, 5 Drawing Sheets



# US RE43,328 E Page 2

U.S. PATENT	DOCUMENTS	4,737,921 A	4/1988	Goldwasser et al.
3,674,014 A 7/1972	Tillander	4,742,356 A		Kuipers
, ,	Carey et al.	4,742,815 A 4,743,770 A	5/1988	Ninan et al. Lee
	Halloran	4,743,771 A		Sacks et al.
	Whetstone et al. Kuipers	4,745,290 A		Frankel et al.
	Froning	4,750,487 A 4,753,528 A		Zanetti Hines et al.
	Cooley et al.	4,753,328 A 4,761,072 A	8/1988	
	Kuipers	4,764,016 A		Johansson
	Kuipers Kronner	4,771,787 A		Wurster et al.
	Brunnett	4,779,212 A 4,782,239 A	10/1988	Levy Hirose et al.
4,054,881 A 10/1977		4,788,481 A	11/1988	
	Staats Van Steenwyk et al.	4,791,934 A	12/1988	_
	Mushabac	4,793,355 A 4,794,262 A		Crum et al. Sato et al.
	Jones	4,797,907 A		Anderton
· · · · · · · · · · · · · · · · · · ·	Anichkov et al. Kopf et al.	4,803,976 A	2/1989	Frigg et al.
	Renner	4,804,261 A		Kirschen
4,287,809 A 9/1981	Egli et al.	4,805,615 A 4,809,694 A	2/1989 3/1989	Caroi Ferrara
	Kuipers	4,821,200 A	4/1989	••
4,314,251 A 2/1982 4,317,078 A 2/1982	Weed et al.	4,821,206 A	4/1989	
	Jinkins	4,821,731 A 4,822,163 A		Martinelli et al. Schmidt
	Crow et al.	4,825,091 A		Breyer et al.
4,328,813 A 5/1982 4,339,953 A 7/1982	Ray Iwasaki	4,829,373 A		Leberl et al.
4,341,220 A 7/1982		4,836,778 A		Baumrind et al.
4,346,384 A 8/1982		4,838,265 A 4,841,967 A		Cosman et al. Chang et al.
	Stivender et al.	4,845,771 A		Wislocki et al.
, , ,	Pfeiler Constant	4,849,692 A	7/1989	
	DiMatteo et al.	4,860,331 A		Williams et al.
	DiMarco	4,862,893 A 4,869,247 A		Martinelli Howard, III et al.
	Richter et al.	4,875,165 A		Fencil et al.
	Stephenson et al. Lienau	4,875,478 A	10/1989	
	McCormick	4,884,566 A 4,889,526 A		Mountz et al. Rauscher et al.
	Amplatz	4,896,673 A		Rose et al.
	Duska Sepponen	4,905,698 A		Strohl, Jr. et al.
	Niemi	4,923,459 A		Nambu Chair et al
	Fraser et al.	4,931,056 A 4,945,305 A	7/1990	Ghajar et al. Blood
	Codrington Onik et al.	4,945,914 A	8/1990	
	Temple	4,951,653 A		Fry et al.
	Brown	4,955,891 A 4,961,422 A	9/1990 10/1990	Carol Marchosky et al.
	Blood	4,977,655 A		Martinelli
	Laitinen Cosman	4,989,608 A	2/1991	
	Bludermann	4,991,579 A 5,002,058 A	2/1991	Allen Martinelli
, ,	Olerud et al.	5,002,038 A 5,005,592 A		Cartmell
	Shelden et al. Hansen	5,013,317 A		Cole et al.
	Stockdale et al.	5,016,639 A	5/1991	
4,649,504 A 3/1987	Krouglicof et al.	5,017,139 A 5,027,818 A		Mushabac Bova et al.
	Frederick	5,030,196 A	7/1991	
	Oloff et al. Suzuki et al.	5,030,222 A		Calandruccio et al.
	Ferrano	5,031,203 A 5,042,486 A	7/1991 8/1001	Trecha Pfeiler et al.
	Thong	5,042,480 A 5,047,036 A		Koutrouvelis
	Hansen Krieg	5,050,608 A	9/1991	Watanabe et al.
	Beckmann et al.	5,054,492 A		Scribner et al.
4,705,395 A 11/1987	Hageniers	5,057,095 A 5,059,789 A	10/1991 10/1991	Fabian Salcudean
	Addleman et al.	, ,	1/1992	
4,706,665 A 11/1987 4,709,156 A 11/1987	Murphy et al.	5,079,699 A		Tuy et al.
	Rorden et al.	5,086,401 A		Glassman et al.
4,719,419 A 1/1988		5,094,241 A 5,097,839 A	3/1992 3/1992	
	Roberts et al. Kim et al.	5,097,835 A 5,098,426 A		Sklar et al.
	Moore et al.	5,099,845 A	3/1992	Besz et al.
4,727,565 A 2/1988	Ericson	5,099,846 A	3/1992	
	Damadian Casa et al	5,105,829 A 5,107,839 A		Fabian et al. Houdek et al.
, ,	Case et al. Addleman et al.	5,107,839 A 5,107,843 A		Aarnio et al.
4,737,794 A 4/1988		5,107,862 A		Fabian et al.

# US RE43,328 E Page 3

5,109,194	A 4/1992	Cantaloube	5,383,454 A	1/1995	Bucholz
5,119,817	A 6/1992	Allen	5,385,146 A	1/1995	Goldreyer
5,142,930	A 9/1992	Allen et al.	5,385,148 A		Lesh et al.
5,143,076		Hardy et al.	5,386,828 A		Owens et al.
, ,		•	, ,		
5,152,288		Hoenig et al.	5,389,101 A		Heilbrun et al.
5,160,337		Cosman	5,391,199 A		Ben-Haim
5,161,536	A 11/1992	Vikomerson et al.	5,394,457 A	2/1995	Leibinger et al.
5,178,164	A 1/1993	Allen	5,394,875 A	3/1995	Lewis et al.
5,178,621	A 1/1993	Cook et al.	5,397,329 A	3/1995	Allen
5,186,174		Schlondorff et al.	5,398,684 A	3/1995	
, ,			5,399,146 A		Nowacki et al.
5,187,475		Wagener et al.	*		
5,188,126		Fabian et al.	5,400,384 A		Fernandes et al.
5,190,059		Fabian et al.	5,402,801 A	4/1995	Taylor
5,193,106	A 3/1993	DeSena	5,408,409 A	4/1995	Glassman et al.
5,197,476	A 3/1993	Nowacki et al.	5,413,573 A	5/1995	Koivukangas
5,197,965		Cherry et al.	5,417,210 A		Funda et al.
5,198,768		Keren	5,419,325 A		Dumoulin et al.
, ,			, , ,		
5,198,877		Schulz	5,423,334 A	6/1995	
5,207,681		Ghadjar et al.	5,425,367 A		Shapiro et al.
5,207,688	A 5/1993	Carol	5,425,382 A	6/1995	Golden et al.
5,211,164	A 5/1993	Allen	5,426,683 A	6/1995	O'Farrell, Jr. et al.
5,211,165	A 5/1993	Dumoulin et al.	5,426,687 A	6/1995	Goodall et al.
5,211,176		Ishiguro et al.	5,427,097 A	6/1995	
5,212,720		Landi et al.	5,429,132 A		Guy et al.
, ,					
5,214,615		Bauer	5,433,198 A		
5,219,351		Teubner et al.	RE35,025 E	8/1995	Anderton
5,222,499	A 6/1993	Allen et al.	5,437,212 A	8/1995	Thompson
5,224,049	A 6/1993	Mushabac	5,437,277 A	8/1995	Dumoulin et al.
5,228,442		Imran	5,443,066 A		Dumoulin et al.
5,230,338		Allen et al.	5,443,489 A		Ben-Haim
, ,			, ,		
5,230,623		Guthrie et al.	5,444,756 A		Pai et al.
5,233,990	A 8/1993	Barnea	5,445,144 A	8/1995	Wodicka et al.
5,237,996	A 8/1993	Waldman et al.	5,445,150 A	8/1995	Dumoulin et al.
5,249,581	A 10/1993	Horbal et al.	5,445,166 A	8/1995	Tavlor
5,251,127		_	5,446,548 A		Gerig et al.
5,251,635		Dumoulin et al.	5,447,154 A		Cinquin et al.
, ,			, ,		-
5,253,647		Takahashi et al.	5,448,610 A		Yamamoto et al.
5,255,680		Darrow et al.	5,453,686 A		Anderson
5,257,636	A 11/1993	White	5,456,718 A	10/1995	Szymaitis
5,257,998	A 11/1993	Ota et al.	5,457,641 A		Zimmer et al.
5,261,404		Mick et al.	*		Dreessen et al.
5,265,610		Darrow et al.	5,469,847 A		Zinreich et al.
/ /			, , ,		
5,265,611		Hoenig et al.	5,474,558 A		Neubardt
5,269,759		Hernandez et al.	5,478,341 A		Cook et al.
5,271,400	A 12/1993	Dumoulin et al.	5,478,343 A	12/1995	Ritter
5,273,025	A 12/1993	Sakiyama et al.	5,480,422 A	1/1996	Ben-Haim
5,274,551	A 12/1993	Corby, Jr.	5,480,439 A	1/1996	Bisek et al.
5,279,309		Taylor et al.	5,483,961 A		Kelly et al.
5,285,787		Machida	5,485,849 A		Panescu et al.
5,291,199		Overman et al.	5,487,391 A		Panescu
, ,			/ /		
5,291,889		Kenet et al.	5,487,729 A		Avellanet et al.
5,295,483		Nowacki et al.	5,487,757 A		Truckai et al.
5,297,549	A 3/1994	Beatty et al.	5,490,196 A	2/1996	Rudich et al.
5,299,253	A 3/1994	Wessels	5,494,034 A	2/1996	Schlondorff et al.
5,299,254	A 3/1994	Dancer et al.	5,503,416 A	4/1996	Aoki et al.
5,299,288		Glassman et al.	5,513,637 A		Twiss et al.
5,300,080		Clayman et al.	5,513,037 A 5,514,146 A		Lam et al.
, ,			, ,		
5,305,091		Gelbart et al.	5,515,160 A		Schulz et al.
5,305,203			5,517,990 A		Kalfas et al.
5,306,271	A 4/1994	Zinreich et al.	5,531,227 A	7/1996	Schneider
5,307,072	A 4/1994	Jones, Jr.	5,531,520 A	7/1996	Grimson et al.
5,309,913		Kormos et al.	5,542,938 A		Avellanet et al.
5,315,630		Sturm et al.	5,543,951 A		Moehrmann
, , , , , , , , , , , , , , , , , , , ,			, , ,		
5,316,024		Hirschi et al.	5,546,940 A		Panescu et al.
5,318,025		Dumoulin et al.	5,546,949 A		Frazin et al.
5,320,111		Livingston	5,546,951 A		Ben-Haim
5,325,728	A 7/1994	Zimmerman et al.	5,551,429 A	9/1996	Fitzpatrick et al.
5,325,873	A 7/1994	Hirschi et al.	5,558,091 A	9/1996	Acker et al.
5,329,944		Fabian et al.	5,564,437 A		Bainville et al.
, ,			, ,		
5,330,485		Clayman et al.	5,566,681 A		Manwaring et al.
5,333,168		Fernandes et al.	5,568,384 A		Robb et al.
5,353,795	A 10/1994	Souza et al.	5,568,809 A	10/1996	Ben-haim
5,353,800	A 10/1994	Pohndorf et al.	5,572,999 A	11/1996	Funda et al.
5,353,807		DeMarco	5,573,533 A	11/1996	
, ,			, ,		
5,359,417		Müller et al.	5,575,192 A	11/1996	
<b>へ りたい ハウハ</b>	4 4 1 4 ~ ~ ~	/inraich at al	5,575,794 A	11/1996	Walus et al.
5,368,030			, ,		
5,368,030 2		Yanof et al.	5,575,798 A		
5,371,778		Yanof et al.	, ,	11/1996	Koutrouvelis
5,371,778 <i>x</i> 5,375,596 <i>x</i>	A 12/1994 A 12/1994	Yanof et al.	5,575,798 A	11/1996 12/1996	Koutrouvelis Hanover

# US RE43,328 E Page 4

5,590,215 A	12/1996	Allen	5,800,352	A 9/1998	Ferre et al.
5,591,207 A	1/1997	Coleman	5,800,535	A 9/1998	Howard, III
5,592,939 A		Martinelli	5,802,719		O'Farrell, Jr. et al.
5,595,193 A		Walus et al.	5,803,089		Ferre et al.
, ,			, ,		
5,596,228 A		Anderton et al.	5,807,252		Hassfeld et al.
5,600,330 A		Blood	5,810,008		Dekel et al.
5,603,318 A	2/1997	Heilbrun et al.	5,810,728	A 9/1998	Kuhn
5,611,025 A	3/1997	Lorensen et al.	5,810,735	A 9/1998	Halperin et al.
5,617,462 A	4/1997		5,810,828		Lightman et al.
5,617,857 A *		Chader et al 600/424	5,820,553		Hughes
, ,			, ,		~
5,619,261 A		Anderton	5,823,192		Kalend et al.
5,622,169 A	4/1997	Golden et al.	5,823,958	A 10/1998	Truppe
5,622,170 A	4/1997	Schulz	5,828,725	A 10/1998	Levinson
5,627,873 A	5/1997	Hanover et al.	5,828,770	A 10/1998	Leis et al.
5,628,315 A		Vilsmeier et al.	5,829,444		Ferre et al.
/ /			/ /		
5,630,431 A		Taylor	5,831,260		
5,636,644 A	6/1997	Hart et al.	5,833,608	A 11/1998	Acker
5,638,819 A	6/1997	Manwaring et al.	5,834,759	A 11/1998	Glossop
5,640,170 A	6/1997	Anderson	5,836,954	A 11/1998	Heilbrun et al.
5,642,395 A		Anderton et al.	5,840,024		Taniguchi et al.
, ,		Vilsmeier et al.	, ,		
5,643,268 A			5,840,025		Ben-Haim
5,645,065 A		Shapiro et al.	5,843,076		Webster, Jr. et al.
5,645,545 A *	7/1997	Bryant 606/62	5,848,967	A 12/1998	Cosman
5,646,524 A	7/1997	Gilboa	5,851,183	A 12/1998	Bucholz
5,647,361 A	7/1997	Damadian	* *	A 2/1999	
5,662,111 A		Cosman	5,868,674		Glowinski et al.
, ,			, ,		
5,664,001 A		Tachibana et al.	5,868,675		Henrion et al.
5,674,296 A	10/1997	Bryan et al.	5,871,445	A 2/1999	Bucholz
5,676,673 A	10/1997	Ferre et al.	5,871,455	A 2/1999	Ueno
5,681,260 A		Ueda et al.	5,871,487		Warner et al.
5,682,886 A			5,873,822		Ferre et al.
•		<b>±</b>	, ,		
, ,		Kormos et al 600/417	5,882,304		Ehnholm et al.
5,690,108 A	11/1997	Chakeres	5,884,410	A 3/1999	Prınz
D387,427 S	12/1997	Bucholz et al.	5,889,834	A 3/1999	Vilsmeier et al.
5,694,945 A	12/1997	Ben-Haim	5,891,034	A 4/1999	Bucholz
5,695,500 A		Taylor et al.	5,891,157		Day et al.
/ /					_
5,695,501 A		Carol et al.	5,904,691		Barnett et al.
5,697,377 A		Wittkampf	5,907,395		Schultz et al.
5,702,406 A	12/1997	Vilsmeier et al.	5,913,820	A 6/1999	Bladen et al.
5,711,299 A	1/1998	Manwaring et al.	5,920,395	A 7/1999	Schulz
5,713,946 A		Ben-Haim	5,921,992		Costales et al.
5,715,822 A		Watkins	5,923,727		Navab
			, ,		
5,715,836 A		Kliegis et al.	5,928,248		_
5,718,241 A	2/1998	Ben-Haim et al.	5,938,603	A 8/1999	Ponzi
5,727,552 A	3/1998	Ryan	5,938,694	A 8/1999	Jaraczewski et al.
5,727,553 A	3/1998		5,947,980		Jensen et al.
5,729,129 A	3/1998	_	5,947,981		Cosman
, ,			, ,		
5,730,129 A		Darrow et al.	5,950,629		Taylor et al.
5,730,130 A	3/1998	Fitzpatrick et al.	5,951,475	A 9/1999	Gueziec et al.
5,732,703 A *	3/1998	Kalfas et al 600/407	5,951,571	A 9/1999	Audette
5,735,278 A	4/1998	Hoult et al.	5,954,647	A 9/1999	Bova et al.
5,738,096 A		Ben-Haim	5,957,844		Dekel et al.
5,740,802 A		Nafis et al.	5,964,796		
, ,			, ,		
5,741,214 A		Ouchi et al.	5,967,980		Ferre et al.
5,742,394 A	4/1998	Hansen	5,967,982	A 10/1999	Barnett
5,744,953 A	4/1998	Hansen	5,968,047	A 10/1999	Reed
5,748,767 A	5/1998	Raab	5,971,997	A 10/1999	Guthrie et al.
5,749,362 A		Funda et al.	, ,	A 11/1999	
5,749,835 A		Glantz	, ,	A 11/1999	•
, ,			, ,		
5,752,513 A		Acker et al.	· ·	A 11/1999	<b>-</b>
5,755,725 A		Druais	/ /	A 11/1999	
RE35,816 E	6/1998	Schulz	5,987,960	A 11/1999	Messner et al.
5,758,667 A	6/1998	Slettenmark	5,999,837	A 12/1999	Messner et al.
5,762,064 A		Polyani	5,999,840		Grimson et al.
5,767,669 A		Hansen et al.	6,001,130		Bryan et al.
, ,			, ,		-
5,767,960 A		Orman	6,006,126		Cosman
5,769,789 A		Wang et al.	6,006,127		Van Der Brug et al.
5,769,843 A	6/1998	Abela et al.	6,013,087	A 1/2000	Adams et al.
5,769,861 A	6/1998	Vilsmeier	6,014,580	A 1/2000	Blume et al.
5,772,594 A		Barrick	6,016,439		
, ,			, ,		
5,775,322 A		Silverstein et al.	6,019,725		Vesely et al.
5,776,064 A	7/1998	Kalfas et al.	6,024,408	A $2/2000$	Greenberg et al.
5,782,765 A	7/1998	Jonkman	6,050,724		Schmitz et al.
5,787,886 A		Kelly et al.	6,059,718		Taniguchi et al.
, ,			/ /		
5,792,055 A	-	McKinnon	6,063,022		Ben-Haim
5,795,294 A	8/1998	Luber et al.	6,071,288	A 6/2000	Carol et al.
5,797,849 A	8/1998	Vesely et al.	6,073,043		Schneider
5,799,055 A		J	- 7 9 - 10		
, , ,	ጸ/100ዩ	Peshkin et al	6 በ <b>7</b> 6 በበዩ	<b>A</b> 6/2000	Bucholz
·		Peshkin et al.	6,076,008		Bucholz
5,799,099 A		Peshkin et al. Wang et al.	6,076,008 6,096,050		Bucholz Audette

6,104,944	A		Martinelli	EP	0350996 A1	1/1990
6,118,845 A	A	9/2000	Simon et al.	EP	0 651 968 A1	8/1990
6,122,538	A	9/2000	Sliwa, Jr. et al.	EP	0 427 358	10/1990
6,122,541	A	9/2000	Cosman et al.	EP	0 501 993 B1	11/1990
6,131,396 A	A	10/2000	Duerr et al.	EP	0501993 B1	11/1990
6,139,183 A	A	10/2000	Graumann	EP	0 456 103	5/1991
6,147,480 A	A	11/2000	Osadchy et al.	EP	0 469 966 A1	7/1991
6,149,592	A		Yanof et al.	EP	0469966 A1	7/1991
6,156,067	A	12/2000	Bryan et al.	EP	0 581 704 B1	7/1993
6,161,032	A	12/2000	•	EP	0655138 B1	8/1993
6,165,181	A	12/2000	Heilbrun et al.	EP	0894473 A2	1/1995
6,167,296	A	12/2000	Shahidi	EP	0 908 146	10/1998
6,172,499 I	B1	1/2001	Ashe	EP	0 930 046	10/1998
6,175,756 I		1/2001	Ferre et al.	FR	2417970	2/1979
6,178,345 I		1/2001	Vilsmeier et al.	FR	2 618 211	7/1987
6,194,639 I			Botella et al.	GB	2 094 590	2/1982
6,201,387 I		3/2001	_	GB	2 164 856	10/1984
6,203,497 I			Dekel et al.	JP	61-94639	10/1984
6,211,666 I		4/2001	_	JP	62-327	6/1985
6,223,067 I			Vilsmeier	JP	63-240851	3/1987
6,233,476 I			Strommer et al.	JP	3-267054	3/1990
6,236,875 I			Bucholz et al 600/407	JP	2765738	4/1991
6,246,231 I		6/2001		WO	WO 88/09151	12/1988
6,259,942 I			Westermann et al.	WO	WO 89/05123	6/1989
6,273,896 I			Franck et al.	WO	WO 90/05494	11/1989
6,285,902 I			Kienzle, III et al.	WO	WO/90/05494	5/1990
6,298,262 I			Franck et al.	WO	WO 91/03982	4/1991
6,314,310 H			Ben-Haim et al.	WO	WO 91/04711	4/1991
6,332,089 I			Acker et al.	WO	WO 91/07726	5/1991
6,341,231 H			Ferre et al.	WO	WO 92/03090	3/1992
6,351,659 I			Vilsmeier	WO	WO 92/06645	4/1992
6,381,485 I			Hunter et al.	WO	WO 94/04938	3/1994
6,424,856 I			Vilsmeier et al.	WO	WO 95/07055	9/1994
6,427,314 I		8/2002		WO	WO 94/23647	10/1994
6,428,547 I			Vilsmeier et al.	WO	WO 94/24933	11/1994
6,434,415 I			Foley et al.	WO	WO 96/32059	11/1995
6,437,567 I			Schenck et al.	WO	WO96/11624	4/1996
6,445,943 I			Ferre et al.	WO	WO97/15234	5/1997
6,470,207 I			Simon et al.	WO	WO 97/49453	6/1997
6,474,341 I			Hunter et al.	WO	WO 97/36192	10/1997
6,478,802 I			Kienzle, III et al.	WO	WO 99/23956	11/1997
6,484,049 I			Seeley et al.	WO	WO 98/08554	3/1998
6,490,475 I			Seeley et al.	WO	WO 98/38908	9/1998
6,493,573 I			Martinelli et al.	WO	WO 99/15097	9/1998
6,498,944 I			Ben-Haim et al.	WO	WO 99/21498	10/1998
6,516,046 I			Fröhlich et al.	WO	WO 99/27839	12/1998
6,527,443 I			Vilsmeier et al.	WO	WO 99/33406	12/1998
6,551,325 H			Neubauer et al.	WO	WO 99/38449	1/1999
6,584,174 I			Schubert et al.	WO	WO 99/52094	4/1999
6,609,022 I			Vilsmeier et al.	WO	WO 99/32094 WO 99/26549	6/1999
6,611,700 I			Vilsmeier et al.	WO	WO 99/20349 WO 99/29253	6/1999
6,640,128 I			Vilsmeier et al.	WO	WO 99/29233 WO 99/37208	7/1999
6,694,162 I		2/2004		WO	WO 99/5/208 WO 99/60939	12/1999
, ,			±	WO	WO 99/00939 WO 01/30437 A1	5/2001
6,701,179 I			Martinelli et al.	***	TTO OI/JUTJ/ AI	5/2001
2001/0007918			Vilsmeier et al.		OTHER PU	BLICATIO
2002/0095081			Vilsmeier		OTTILIC O	
2004/0024200	A 1	$\alpha / \alpha \wedge \alpha \wedge A$	$\mathbf{r}$ $\mathbf{r}$ - $1$			

## FOREIGN PATENT DOCUMENTS

2/2004 Ferre et al.

CA	1336451	1/1988
DE	3042343 A1	6/1982
DE	35 08730	3/1985
DE	37 17 871	5/1987
DE	38 38011	11/1988
DE	3831278 A1	3/1989
DE	42 13 426	4/1992
DE	42 25 112	7/1992
DE	4233978 C1	4/1994
DE	197 15 202	4/1997
DE	197 47 427	10/1997
DE	197 51 761	11/1997
DE	198 32 296	7/1998
DE	10085137	11/2002
EP	0 062 941	3/1982
EP	0 119 660	9/1984
EP	0 155 857	1/1985
EP	0 319 844 A1	1/1988
EP	0 326 768	12/1988
EP	0419729 A1	9/1989
	V .15 . 25 111	3,2303

2004/0024309 A1

#### OTHER PUBLICATIONS

Batnitzky et al., "Three-Dimensinal Computer Reconstructions of Brain Lesions from Surface Contours Provided by Computed Tomography: A Prospectus," Neurosurgery, vol. 11, No. 1, Part 1, 1982, pp. 73-84.

Benzel et al., "Magnetic Source Imaging: a Review of the Magnes System of Biomagnetic Technologies Incorporated," Neurosurgery, vol. 33, No. 2 (Aug. 1993), pp. 252-259.

Bouazza-Marouf et al.; "Robotic-Assisted Internal Fixation of Femoral Fractures", IMECHE., pp. 51-58 (1995).

Brack et al., "Accurate X-ray Based Navigation in Computer-Assisted Orthopedic Surgery," CAR '98, pp. 716-722.

Bryan, "Bryan Cervical Disc System Single Level Surgical Technique", Spinal Dynamics, 2002, pp. 1-33.

Bucholz et al., "Variables affecting the accuracy of stereotactic localizationusing computerized tomography," Journal of Neurosurgery, vol. 79, Nov. 1993, pp. 667-673.

Champleboux et al., "Accurate Calibration of Cameras and Range Imaging Sensors: the NPBS Method," IEEE International Conference on Robotics and Automation, Nice, France, May 1992.

Champleboux, "Utilisation de Fonctions Splines pour la Mise au Point D'un Capteur Tridimensionnel sans Contact," Quelques Applications Medicales, Jul. 1991.

Cinquin et al., "Computer Assisted Medical Interventions," IEEE Engineering in Medicine and Biology, May/Jun. 1995, pp. 254-263. Cinquin et al., "Computer Assisted Medical Interventions," International Advanced Robotics Programme, Sep. 1989, pp. 63-65.

Clarysse et al., "A Computer-Assisted System for 3-D Frameless Localization in Stereotaxic MRI," IEEE Transactions on Medical Imaging, vol. 10, No. 4, Dec. 1991, pp. 523-529.

Feldmar et al., "3D-2D Projective Registration of Free-Form Curves and Surfaces," Rapport de recherche (Inria Sophia Antipolis), 1994, pp. 1-44.

Foley et al., "Fundamentals of Interactive Computer Graphics," The Systems Programming Series, Chapter 7, Jul. 1984, pp. 245-266.

Foley et al., "Image-guided Intraoperative Spinal Localization," Intraoperative Neuroprotection, Chapter 19, 1996, pp. 325-340.

Foley, "The StealthStation: Three-Dimensional Image-Interactive Guidance for the Spine Surgeon," Spinal Frontiers, Apr. 1996, pp. 7-9.

Gildenberg et al., "Calculation of Stereotactic Coordinates from the Computed Tomographic Scan," Neurosurgery, vol. 10, No. 5, May 1982, pp. 580-586.

Gonzalez, "Digital Image Fundamentals," Digital Image Processing, Second Edition, 1987, pp. 52-54.

Gottesfeld Brown et al., "Registration of Planar Film Radiographs with Computer Tomography," Proceedings of MMBIA, Jun. 1996, pp. 42-51.

Gueziec et al., "Registration of Computed Tomography Data to a Surgical Robot Using Fluoroscopy: A Feasibility Study," Computer Science/Mathematics, Sep. 27, 1996, 6 pages.

Hamadeh et al, "Kinematic Study of Lumbar Spine Using Functional Radiographies and 3D/2D Registration," TIMC UMR 5525—IMAG. Hamadeh et al., "Automated 3-Dimensional Computed Tomographic and Fluorscopic Image Registration," Computer Aided Surgery (1998), 3:11-19.

Hamadeh et al., "Towards Automatic Registration Between CT and X-ray Images: Cooperation Between 3D/2D Registration and 2D Edge Detection," MRCAS '95, pp. 39-46.

Hatch, "Reference-Display System for the Integration of CT Scanning and the Operating Microscope," Thesis, Thayer School of Engineering, Oct. 1984, pp. 1-189.

Heilbrun et al., "Preliminary experience with Brown-Roberts-Wells (BRW) computerized tomography stereotaxic guidance system," Journal of Neurosurgery, vol. 59, Aug. 1983, pp. 217-222.

Henderson et al., "An Accurate and Ergonomic Method of Registration for Image-guided Neurosurgery," Computerized Medical Imaging and Graphics, vol. 18, No. 4, Jul.-Aug. 1994, pp. 273-277.

Hoerenz, "The Operating Microscope I. Optical Principles, Illumination Systems, and Support Systems," Journal of Microsurgery, vol. 1, 1980, pp. 364-369.

Hofstetter et al., "Fluoroscopy Based Surgical Navigation—Concept and Clinical Applications," Computer Assisted Radiology and Surgery, 1997, pp. 956-960.

Horner et al., "A Comparison of CT-Stereotaxic Brain Biopsy Techniques," Investigative Radiology, Sep.-Oct. 1984, pp. 367-373.

Hounsfield, "Computerized transverse axial scanning (tomography): Part 1. Description of system," British Journal of Radiology, vol. 46, No. 552, Dec. 1973, pp. 1016-1022.

Jacques et al., "A Computerized Microstereotactic Method to Approach, 3-Dimensionally Reconstruct, Remove and Adjuvantly Treat Small CNS Lesions," Applied Neurophysiology, vol. 43, 1980, pp. 176-182.

Jacques et al., "Computerized three-dimensional stereotaxic removal of small central nervous system lesion in patients," J. Neurosurg., vol. 53, Dec. 1980, pp. 816-820.

Joskowicz et al., "Computer-Aided Image-Guided Bone Fracture Surgery: Concept and Implementation," CAR '98, pp. 710-715.

Kelly et al., "Computer-assisted stereotaxic laser resection of intraaxial brain neoplasms," Journal of Neurosurgery, vol. 64, Mar. 1986, pp. 427-439. Kelly et al., "Precision Resection of Intra-Axial CNS Lesions by CT-Based Stereotactic Craniotomy and Computer Monitored CO2 Laser," Acta Neurochirurgica, vol. 68, 1983, pp. 1-9.

Laitinen et al., "An Adapter for Computed Tomography-Guided, Stereotaxis," Surg. Neurol., 1985, pp. 559-566.

Laitinen, "Noninvasive multipurpose stereoadapter," Neurological Research, Jun. 1987, pp. 137-141.

Lavallee et al, "Matching 3-D Smooth Surfaces with their 2-D Projections using 3-D Distance Maps," SPIE, vol. 1570, Geometric Methods in Computer Vision, 1991, pp. 322-336.

Lavallee et al., "Computer Assisted Driving of a Needle into the Brain," Proceedings of the International Symposium CAR '89, Computer Assisted Radiology, 1989, pp. 416-420.

Lavallee et al., "Computer Assisted Interventionist Imaging: The Instance of Stereotactic Brain Surgery," North-Holland MEDINFO 89, Part 1, 1989, pp. 613-617.

Lavallee et al., "Computer Assisted Spine Surgery: A Technique For Accurate Transpedicular Screw Fixation Using CT Data and a 3-D Optical Localizer," TIMC, Faculte de Medecine de Grenoble.

Lavallee et al., "Image guided operating robot: a clinical application in stereotactic neurosurgery," Proceedings of the 1992 IEEE Internation Conference on Robotics and Automation, May 1992, pp. 618-624.

Lavallee et al., "Matching of Medical Images for Computed and Robot Assisted Surgery," IEEE EMBS, Orlando, 1991.

Lavallee, "A New System for Computer Assisted Neurosurgery," IEEE Engineering in Medicine & Biology Society 11th Annual International Conference, 1989, pp. 0926-0927.

Lavallee, "VI Adaption de la Methodologie a Quelques Applications Cliniques," Chapitre VI, pp. 133-148.

Leksell et al., "Stereotaxis and Tomography—A Technical Note," ACTA Neurochirurgica, vol. 52, 1980, pp. 1-7.

Lemieux et al., "A Patient-to-Computed-Tomography Image Registration Method Based on Digitally Reconstructed Radiographs," Med. Phys. 21 (11), Nov. 1994, pp. 1749-1760.

Levin et al., "The Brain: Integrated Three-dimensional Display of MR and PET Images," Radiology, vol. 172, No. 3, Sep. 1989, pp. 783-789.

Mazier et al., "Computer-Assisted Interventionist Imaging: Application to the Vertebral Column Surgery," Annual International Conference of the IEEE Engineering in Medicine and Biology Society, vol. 12, No. 1, 1990, pp. 0430-0431.

Mazier et al., Chirurgie de la Colonne Vertebrale Assistee par Ordinateur: Appication au Vissage Pediculaire, Innov. Tech. Biol. Med., vol. 11, No. 5, 1990, pp. 559-566.

Pelizzari et al., "Accurate Three-Dimensional Registration of CT, PET, and/or MR Images of the Brain," Journal of Computer Assisted Tomography, Jan./Feb. 1989, pp. 20-26.

Pelizzari et al., "Interactive 3D Patient-Image Registration," Information Processing in Medical Imaging, 12th International Conference, IPMI '91, Jul. 7-12, 136-141 (A.C.F. Colchester et al. eds. 1991).

Pelizzari et al., No. 528—"Three Dimensional Correlation of PET, CT and MRI Images," The Journal of Nuclear Medicine, vol. 28, No. 4, Apr. 1987, p. 682.

Phillips et al., "Image Guided Orthopaedic Surgery Design and Analysis," Trans Inst. MC, vol. 17, No. 5, 1995, pp. 251-264.

Potamianos et al., "Intra-Operative Imaging Guidance for Keyhole Surgery Methodology and Calibration," First International Symposium on Medical Robotics and Computer Assisted Surgery, Sep. 22-24, 1994, pp. 98-104.

Reinhardt et al., "CT-Guided 'Real Time' Stereotaxy," ACTA Neurochirurgica, 1989.

Roberts et al., "A frameless stereotaxic integration of computerized tomographic imaging and the operating microscope," J. Neurosurg., vol. 65, Oct. 1986, pp. 545-549.

Rosenbaum et al., "Computerized Tomography Guided Stereotaxis: A New Approach," Applied Neurophysiology, vol. 43, No. 3-5, 1980, pp. 172-173.

Sautot, "Vissage Pediculaire Assiste Par Ordinateur," Sep. 20, 1994. Schueler et al., "Correction of Image Intensifier Distortion for Three-Dimensional X-Ray Angiography," SPIE Medical Imaging 1995, vol. 2432, pp. 272-279.

Selvik et al., "A Roentgen Stereophotogrammetric System," Acta Radiologica Diagnosis, 1983, pp. 343-352.

Shelden et al., "Development of a computerized microsteroetaxic method for localization and removal of minute CNS lesions under direct 3-D vision," J. Neurosurg., vol. 52, 1980, pp. 21-27.

Smith et al., "Computer Methods for Improved Diagnostic Image Display Applied to Stereotactic Neurosurgery," Automedical, vol. 14, 1992, pp. 371-382 (4 unnumbered pages).

Smith et al., "The Neurostation<sup>TM</sup>—A Highly Accurate, Minimally Invasive Solution to Frameless Stereotactic Neurosurgery," Computerized Medical Imaging and Graphics, vol. 18, Jul.-Aug. 1994, pp. 247-256.

The Laitinen Stereotactic System, E2-E6.

Viant et al., "A Computer Assisted Orthopaedic System for Distal Locking of Intramedullary Nails," Proc. of MediMEC '95, Bristol, 1995, pp. 86-91.

Watanabe et al., "Three-Dimensional Digitizer (Neuronavigator): New Equipment for Computed Tomography-Guided Stereotaxic Surgery," Surgical Neurology, vol. 27, No. 6, Jun. 1987, pp. 543-547. Watanabe, "Neuronavigator," Igaku-no-Ayumi, vol. 137, No. 6, May 10, 1986, pp. 1-4.

Weese et al., "An Approach to 2D/3D Registration of a Vertebra in 2D X-ray Fluoroscopies with 3D CT Images," pp. 119-128.

Germano, "Instrumentation, Technique and Technology", Neurosurgery, vol. 37, No. 2, Aug. 1995, pp. 348-350.

Merloz, et al., "Computer Assisted Spine Surgery", Clinical Assisted Spine Surgery, No. 337, pp. 86-96.

Hatch, et al., "Reference-Display System for the Integration of CT Scanning and the Operating Microscope", Proceedings of the Eleventh Annual Northeast Bioengineering Conference, Mar. 14-15, 1985, pp. 252-254.

"Prestige Cervical Disc System Surgical Technique", 12 pgs.

Adams et al., "Orientation Aid for Head and Neck Surgeons," Innov. Tech. Biol. Med., vol. 13, No. 4, 1992, pp. 409-424.

Barrick et al., "Prophylactic Intramedullary Fixation of the Tibia for Stress Fracture in a Professional Athlete," Journal of Orthopaedic Trauma, vol. 6, No. 2, pp. 241-244 (1992).

Barrick et al., "Technical Difficulties with the Brooker-Wills Nail in Acute Fractures of the Femur," Journal of Orthopaedic Trauma, vol. 6, No. 2, pp. 144-150 (1990).

3-D Digitizing Accessories, Pixsys, Jul. 2, 1992, 6 pages.

Adams et al., Computer-Assisted Surgery, IEEE Computer Graphics & Applications, pp. 43-51, (May 1990).

Adams, L., et al., "Aide Au Reperage Tridimensionnel Pour La Chirurgie de la Base du Crane," Innov. Tech. Biol. Med., vol. 13, No. 4, pp. 409-424, 1992.

Alignment Procedure for the PixSys Two-Emitter Offset Probe for the SAC GP83d Sonic Digitizer, Pixsys, Jul. 2, 1992, 4 pages.

Bergstrom et al. Stereotaxic Computed Tomography, Am. J. Roentgenol, vol. 127 pp. 167-170 (1976).

Brown, R., M.D., A Stereotactic Head Frame for Use with CT Body Scanners, Investigative Radiology © J.B. Lippincott Company, pp. 300-304 (Jul.-Aug. 1979).

Bucholz, R.D., et al. Image-guided surgical techniques for infections and trauma of the central nervous system, Neurosurg. Clinics of N.A., vol. 7, No. 2, pp. 187-200 (1996).

Bucholz, R.D., et al., A Comparison of Sonic Digitizers Versus Light Emitting Diode-Based Localization, Interactive Image-Guided Neurosurgery, Chapter 16, pp. 179-200 (1993).

Bucholz, R.D., et al., Intraoperative localization using a three dimensional optical digitizer, SPIE—The Intl. Soc. for Opt. Eng., vol. 1894, pp. 312-322 (Jan. 17-19, 1993).

Bucholz, R.D., et al., Intraoperative Ultrasonic Brain Shift Monitor and Analysis, Stealth Station Marketing Brochure (2 pages) (undated).

Bucholz, R.D., et al., The Correction of Stereotactic Inaccuracy Caused by Brain Shift Using an Intraoperative Ultrasound Device, First Joint Conference, Computer Vision, Virtual Reality and Robotics in Medicine and Medical Robotics and Computer-Assisted Surgery, Grenoble, France, pp. 459-466 (Mar. 19-22, 1997).

Bucholz, Richard D., "Halo vest versus spinal fusion for cervical injury: evidence from an outcome study," J. Neurosurg 70:884-892, Jun. 1989.

Bucholz, Richard, D., M.D., "A Comparison of Sonic Digitizers Versus Light Emitting Diode-Based Localization," Interactive Image-Guided Neurosurgey, pp. 179-200, 1993.

Cutting M.D. et al., Optical Tracking of Bone Fragments During Craniofacial Surgery, Second Annual International Symposium on Medical Robotics and Computer Assisted Surgery, pp. 221-225, (Nov. 1995).

Friets, E.M., et al. A Frameless Stereotaxic Operating Microscope for Neurosurgery, IEEE Trans. on Biomed. Eng., vol. 36, No. 6, pp. 608-617 (Jul. 1989).

Gallen, C.C., et al., Intracranial Neurosurgery Guided by Functional Imaging, Surg. Neurol., vol. 42, pp. 523-530 (1994).

Galloway, R.L., et al., Interactive Image-Guided Neurosurgery, IEEE Trans. on Biomed. Eng., vol. 89, No. 12, pp. 1226-1231 (1992).

Galloway, R.L., Jr. et al, Optical localization for interactive, imageguided neurosurgery, SPIE, vol. 2164, pp. 137-145 (undated.

Germano, Isabelle M., "The NeuroStation System fir Unage-Guided, Frameless Stereotaxy," Neurosurgery, vol. 37, No. 2 Aug. 1995, pp. 348-350.

Gomez, C.R., et al., Transcranial Doppler Ultrasound Following Closed Head Injury: Vasospasm or Vasoparalysis?, Surg. Neurol., vol. 35, pp. 30-35 (1991).

Grimson, W.E.L., An Automatic Registration Method for Frameless Stereotaxy, Image Guided Surgery, and enhanced Reality Visualization, IEEE, pp. 430-436 (1994).

Grimson, W.E.L., et al., Virtual-reality technology is giving surgeons the equivalent of x-ray vision helping them to remove tumors more effectively, to minimize surgical wounds and to avoid damaging critical tissues, Sci. Amer., vol. 280, No. 6, pp. 62-69 (Jun. 1999).

Guthrie, B.L., Graphic-Interactive Cranial Surgery: The Operating Arm System, Handbook of Stereotaxy Using the CRW Apparatus, Chapter 13, pp. 193-211 (undated.

Hardy, T., M.D., et al., CASS: A Program for Computer Assisted Stereotaxic Surgery, The Fifth Annual Symposium on Comptuer Applications in Medical Care, Proceedings, Nov. 1-4, 1981, IEEE, pp. 1116-1126, (1981).

Heilbrun, M.D., Progressive Technology Applications, Neurosurgery for the Third Millenium, Chapter 15, J. Whitaker & Sons, Ltd., Amer. Assoc. of Neurol. Surgeons, pp. 191-198 (1992). Heilbrun, M.P., Computed Tomography—Guided Stereotactic Systems, Clinical Neurosurgery, Chapter 31, pp. 564-581 (1983).

Heilbrun, M.P., et al., Stereotactic Localization and Guidance Using a Machine Vision Technique, Sterotact & Funct. Neurosurg., Proceed. of the Mtg. of the Amer. Soc. for Sterot. and Funct. Neurosurg. (Pittsburgh, PA) vol. 58, pp. 94-98 (1992).

Kall, B., The Impact of Computer and Imgaging Technology on Stereotactic Surgery, Proceedings of the Meeting of the American Society for Stereotactic and Functional Neurosurgery, pp. 10-22 (1987).

Kato, A., et al., A frameless, armless navigational system for computer-assisted neurosurgery, J. Neurosurg., vol. 74, pp. 845-849 (May 1991).

Kelly, P.J., Computer Assisted Stereotactic Biopsy and Volumetric Resection of Pediatric Brain Tumors, Brain Tumors in Children, Neurologic Clinics, vol. 9, No. 2, pp. 317-336 (May 1991).

Kelly, P.J., Computer-Directed Stereotactic Resection of Brain Tumors, Neurologica Operative Atlas, vol. 1, No. 4, pp. 299-313 (1991).

Kelly, P.J., et al., Results of Computed Tomography-based Computer-assisted Stereotactic Resection of Metastatic Intracranial Tumors, Neurosurgery, vol. 22, No. 1, Part 1, 1988, pp. 7-17 (Jan. 1988).

Kelly, P.J., Stereotactic Imaging, Surgical Planning and Computer-Assisted Resection of Intracranial Lesions: Methods and Results, Advances and Technical Standards in Neurosurgery, vol. 17, pp. 78-118, (1990).

Kim, W.S. et al., A Helmet Mounted Display for Telerobotics, IEEE, pp. 543-547 (1988).

Klimek, L., et al., Long-Term Experience with Different Types of Localization Systems in Skull-Base Surgery, Ear, Nose & Throat Surgery, Chapter 51, pp. 635-638 (undated).

Kosugi, Y., et al., An Articulated Neurosurgical Navigation System Using MRI and CT Images, IEEE Trans. on Biomed, Eng. vol. 35, No. 2, pp. 147-152 (Feb. 1988).

Krybus, W., et al., Navigation Support for Surgery by Means of Optical Position Detection, Computer Assisted Radiology Proceed. of the Intl. Symp. CAR '91 Computed Assisted Radiology, pp. 362-366 (Jul. 3-6, 1991).

Kwoh, Y.S., Ph.D., et al., A New Computerized Tomographic-Aided Robotic Stereotaxis System, Robotics Age, vol. 7, No. 6, pp. 17-22 (Jun. 1985).

Lavallee, S., et al., Computer Assisted Knee Anterior Cruciate Ligament Reconstruction First Clinical Tests, Proceedings of the First International Symposium on Medical Robotics and Computer Assisted Surgery, pp. 11-16 (Sep. 1994).

Lavallee, S., et al., Computer Assisted Medical Interventions, NATO ASI Series, vol. F 60, 3d Imaging in Medic., pp. 301-312 (1990).

Leavitt, D.D., et al., Dynamic Field Shaping to Optimize Stereotactic Radiosurgery, I.J. Rad. Onc. Biol. Physc., vol. 21, pp. 1247-1255 (1991).

Maurer, Jr., et al., Registration of Head CT Images to Physical Space Using a Weighted Combination of Points and Surfaces, IEEE Trans. on Med. Imaging, vol. 17, No. 5, pp. 753-761 (Oct. 1998).

McGirr, S., M.D., et al., Stereotactic Resection of Juvenile Pilocytic Astrocytomas of the Thalamus and Basal Ganglia, Neurosurgery, vol. 20, No. 3, pp. 447-452, (1987).

Ng, W.S. et al., Robotic Surgery—A First-Hand Experience in Transurethral Resection of the Prostate Surgery, IEEE Eng. in Med. and Biology, pp. 120-125 (Mar. 1993).

Offset Probe for SAC GP8-3d Digitizer, 2 pages, not dated.

Penn, R.D., et al., Stereotactic Surgery with Image Processing of Computerized Tomographic Scans, Neurosurgery, vol. 3, No. 2, pp. 157-163 (Sep.-Oct. 1978).

Pixsys, 3-D Digitizing Accessories, by Pixsys (marketing brochure)(undated) (2 pages).

Reinhardt, H., et al., A Computer-Assisted Device for Intraoperative CT-Correlated Localization of Brain Tumors, pp. 51-58 (1988).

Reinhardt, H.F. et al., Sonic Stereometry in Microsurgical Procedures for Deep-Seated Brain Tumors and Vascular Malformations, Neurosurgery, vol. 32, No. 1, pp. 51-57 (Jan. 1993).

Reinhardt, H.F., et al., Mikrochirugische Entfernung tiefliegender Gefäβmiβbildungen mit Hilfe der Sonar-Stereometrie (Microsurgical Removal of Deep-Seated Vascular Malformations Using Sonar Stereometry). Ultraschall in Med. 12, pp. 80-83 (1991).

Reinhardt, Hans. F., Neuronavigation: A Ten-Year Review, Neurosurgery, pp. 329-341 (undated).

Simon, D.A., Accuracy Validation in Image-Guided Orthopaedic Surgery, Second Annual Intl. Symp. on Med. Rob. an Comp-Assisted surgery, MRCAS '95, pp. 185-192 (undated).

Smith, K.R., et al. Multimodality Image Analysis and Display Methods for Improved Tumor Localization in Stereotactic Neurosurgery, Annul Intl. Conf. of the IEEE Eng. in Med. and Biol. Soc., vol. 13, No. 1, p. 210 (1991).

Tan, K., Ph.D., et al., A frameless stereotactic approach to neurosurgical planning based on retrospective patient-image registration, J Neurosurgy, vol. 79, pp. 296-303 (Aug. 1993).

Thompson, et al., A System for Anatomical and Functional Mapping of the Human Thalamus, Computers and Biomedical Research, vol. 10, pp. 9-24 (1977).

Trobraugh, J.W., et al., Frameless Stereotactic Ultrasonography: Method and Applications, Computerized Medical Imaging and Graphics, vol. 18, No. 4, pp. 235-246 (1994).

Von Hanwhr et al., Foreword, Computerized Medical Imaging and Graphics, vol. 18, No. 4, pp. 225-228, (Jul.-Aug. 1994).

Wang, M.Y., et al., An Automatic Technique for Finding and Localizing Externally Attached Markers in CT and MR Volume Images of the Head, IEEE Trans. on Biomed. Eng., vol. 43, No. 6, pp. 627-637 (Jun. 1996).

Watanabe, E., M.D., et al., Open Surgery Assisted by the Neuronavigator, a Stereotactic, Articulated, Sensitive Arm, Neurosurgery, vol. 28, No. 6, pp. 792-800 (1991).

Bucholz et al., Richard D.; "Clinical Applications of Modern Imaging Technology," SPIE vol. 1894; pp. 312-322; Jan. 19, 1993.

Bucholz et al., Richard D.; "Poster #1120, Use of An Intraoperative Optical Digitizer in A System for Free-Hand Stereotactic Surgery," Scientific Program, Am. Assoc. of Neurological Surgeons 1992 Annual Meeting, pp. 284-285; Apr. 16, 1992.

C. Hunter Shelden, M.D, et al., "Development of a computerized microstereotaxic method for localization and removal of minute CNS lesions under direct 3-D vision," J. Neurosurg 52: 21-27, 1980.

M. Peter Heilbrun, M.D., "Computer Tomography—Guided Stereotactic Systems," Computed Tomographic Stereotaxy, Ch.31 pp. 564-581, 1983.

Richard D. Bucholz, M.D. and K. Charles Cheung, M.D., "Halo vest versus spinal fusion for cervical injury: evidence from an outcome study," J. Neurosurg 70:884-892, Jun. 1989.

W. Krybus, et al., "Navigation Support for Surgery by Means of Optical Position Detection," p. 362-366, 1990.

Kurt R. Smith and Richard D. Bucholz, "Computer Methods for Improved Diagnostic Image Display Applied to Stereotactic Neurosurgery," Stereotactic Neurosurgery Display, vol. 14, pp. 371-382, 1992.

L. Adams, et al., "Aide Au Reperage Tridimensionnel Pour La Chirurgie de la Base du Crane," Innov. Tech. Biol. Med., vol. 13, No. 4, pp. 409-424, 1992.

Hans F. Reinharts, M.D., et al., "Sonic Stereometry in Microsurgical Procedures for Deep-Seated Brain Tumors and Vascular Malformations," Neurosurgery, vol. 32, No. 1, Jan. 1993 pp. 51-57.

Skip Jacques, et al., "A Computerized Microstereotactic Method to Approach, 3-Dimensionally Reconstruct, Remove and Adjuvantly Treat Small CNS Lesions," Meeting of the Amer. Soc. Stereotactic & Functional Neurosurgery, Houston 1980, Appl. Neurophysiol. 43: 176-182 (1980).

Richard D. Bucholz, M.D., and Kurt R. Smith, "A Comparison of Sonic Digitizers Versus Light Emitting Diode-Based Localization," Interactive Image-Guided Neurosurgery, pp. 179-200, 1993.

Richard D. Bucholz, et al., "Clinical Applications of Modern Imaging Technology," SPIE vol. 1894 pp. 312-322, Jan. 19, 1993.

Richard D. Bucholz, et al., "Intraoperative localization using a three dimensional optical digitizer," Proceedings of Clinical Applicatins of Modern Imaging Technology, vol. 1894, pp. 312-322, 1993.

Kevin T. Foley, et al., "Image-guided Intraoperative Spinal Localization," Intraoperative Neuroprotection: Monitoring, Ch. 19, pp. 325-340, 1996.

Kurt R. Smith, et al., "The Neurostation™—A Highly Accurate, Minimally Invasive Solution To Frameless Stereotactic Neurosurgery," Computerized Medical Imaging and Graphics, Jul.-Aug. 1994, vol. 18, No. 4, pp. 247-256.

Isabelle M. Germano, "The NeuroStation System for Image-Guided, Frameless Stereotaxy," Neurosurgery, vol. 37, No. 2, Aug. 1995, pp. 348-350.

"Alignment Procedure for the PixSys Two-Emitter Offset Probe for the SAC GP-8-3d Sonic Digitizer," PixSys, Jul. 2, 1992, 4 pages. "3-D Digitizing Accessories," PixSys, Jul. 2, 1992, 6 pages.

Richard D. Bucholz, M.D., et al., "Poster #1120, Use of an Intraoperative Optical Digitizer in a System for Free-Hand Stereotactic Surgery," Scientific Program, Am. Assoc. of Neurological Surgeons 1992 Annual Meeting, pp. 284-285, Apr. 16, 1992.

<sup>\*</sup> cited by examiner

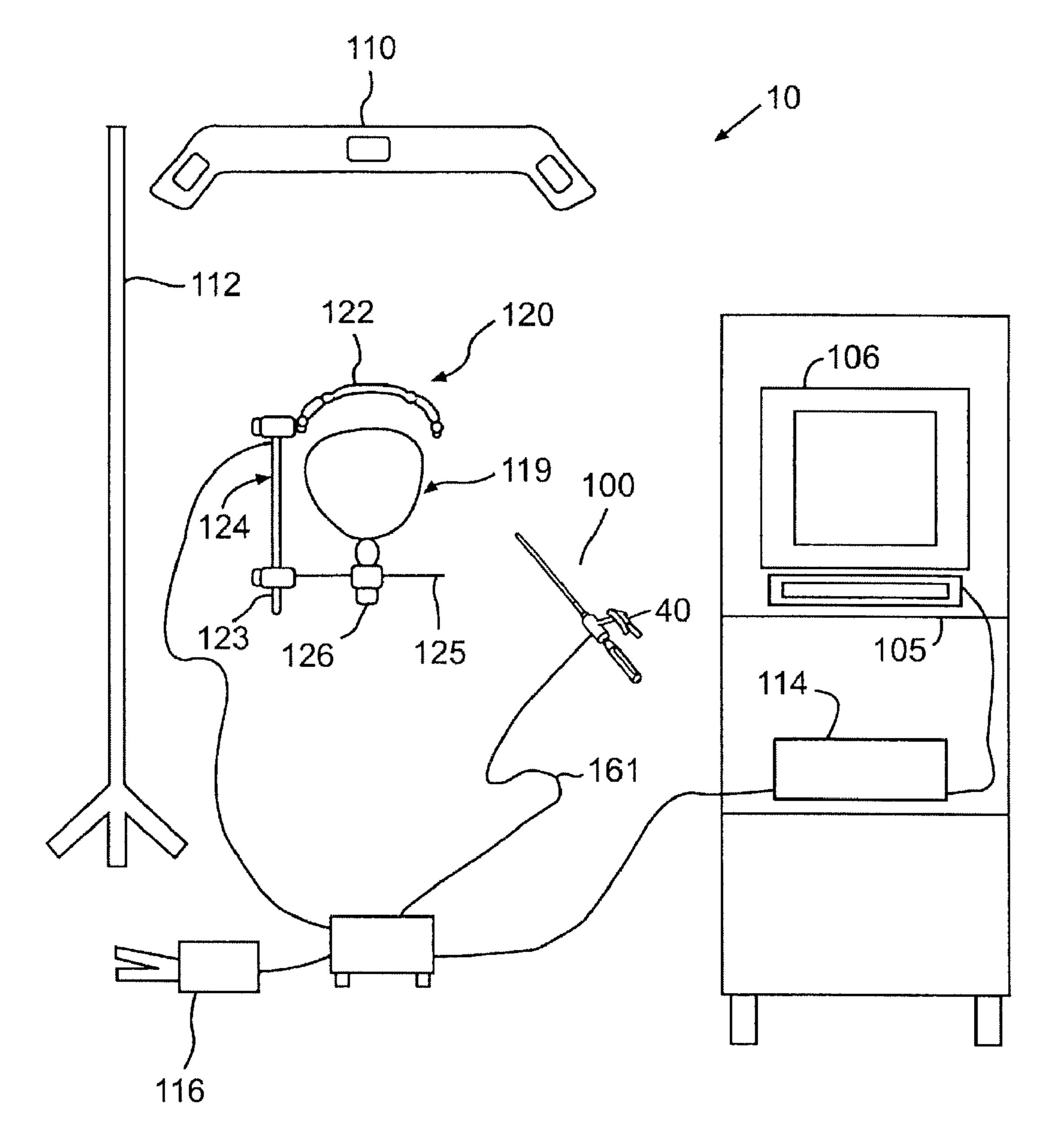
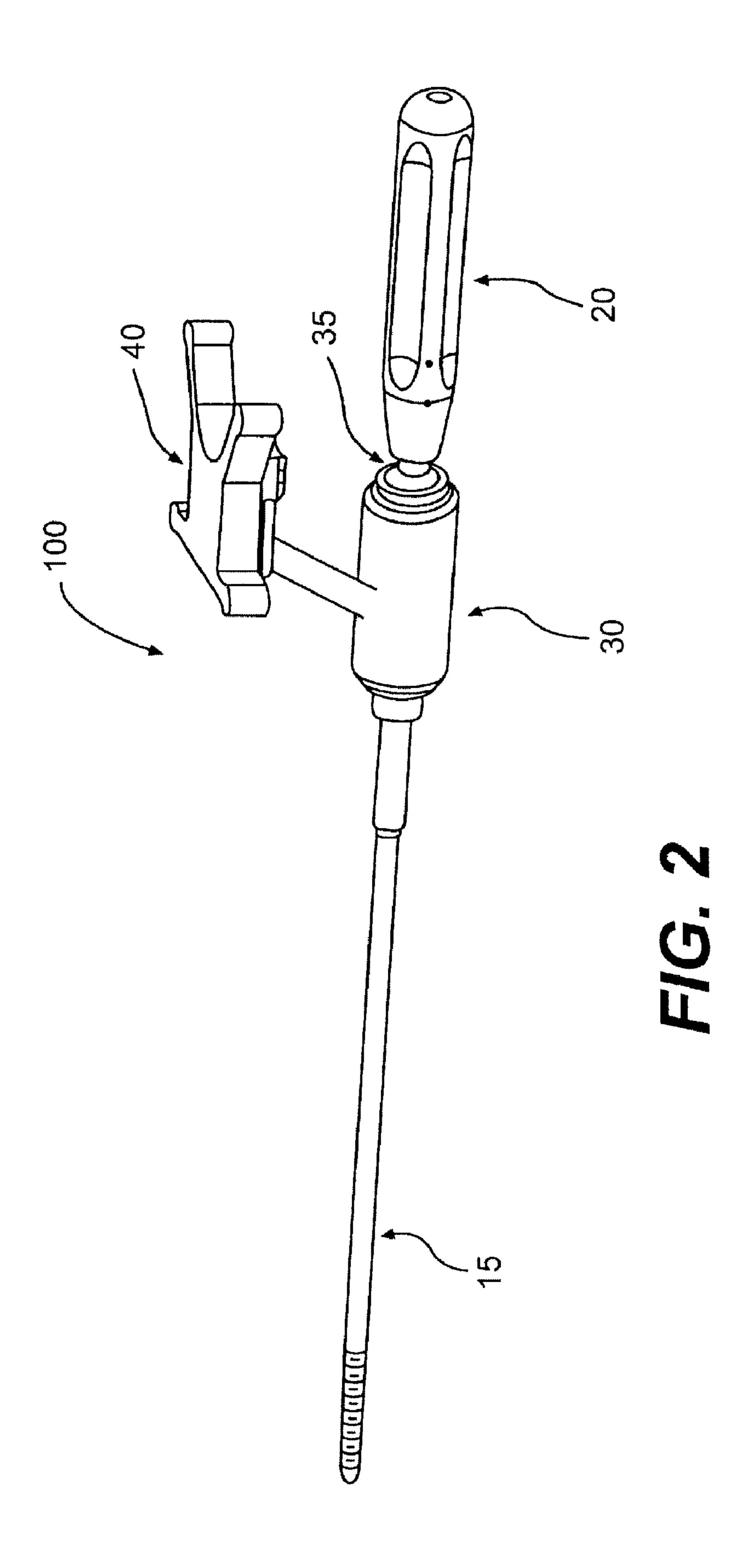
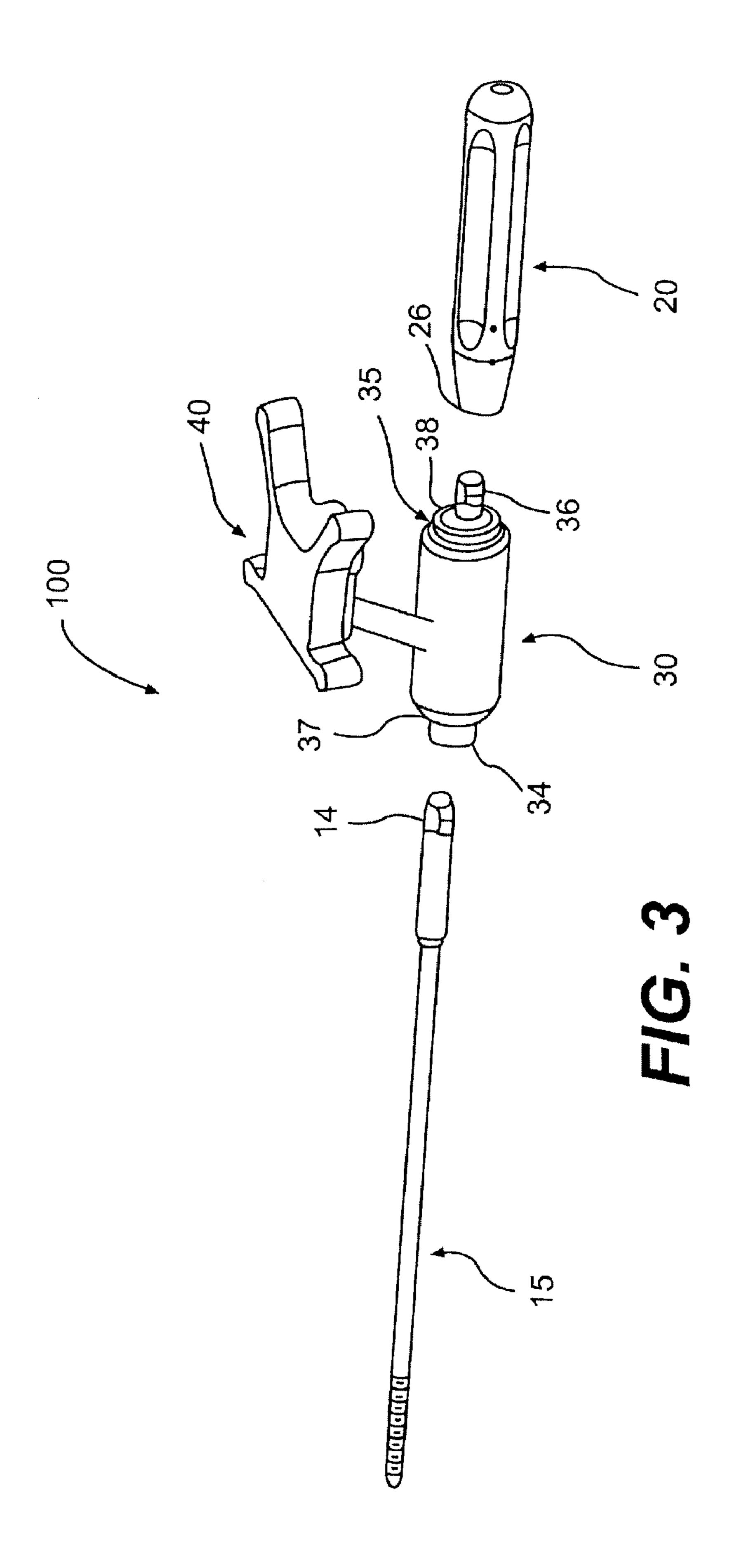
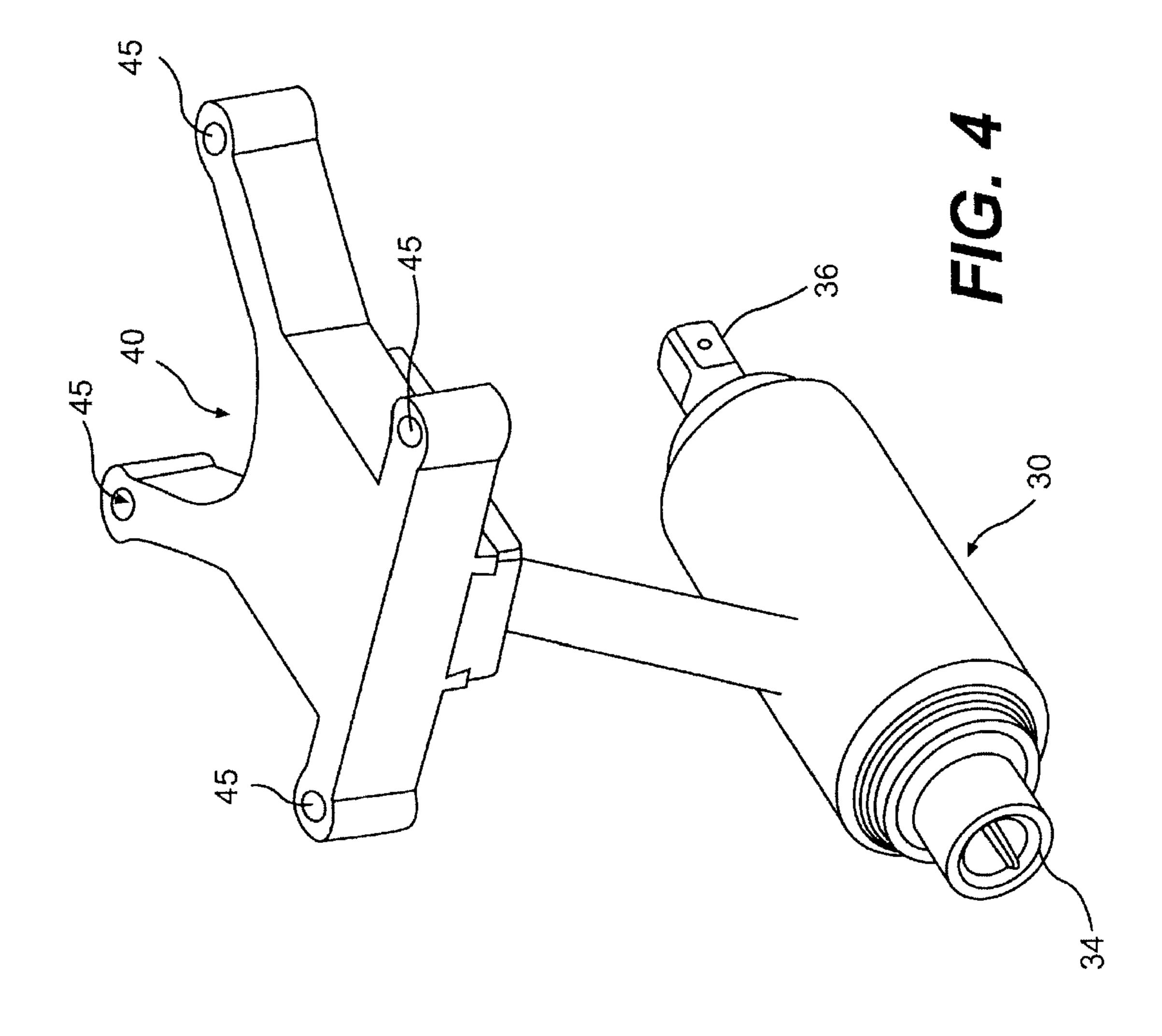


FIG. 1

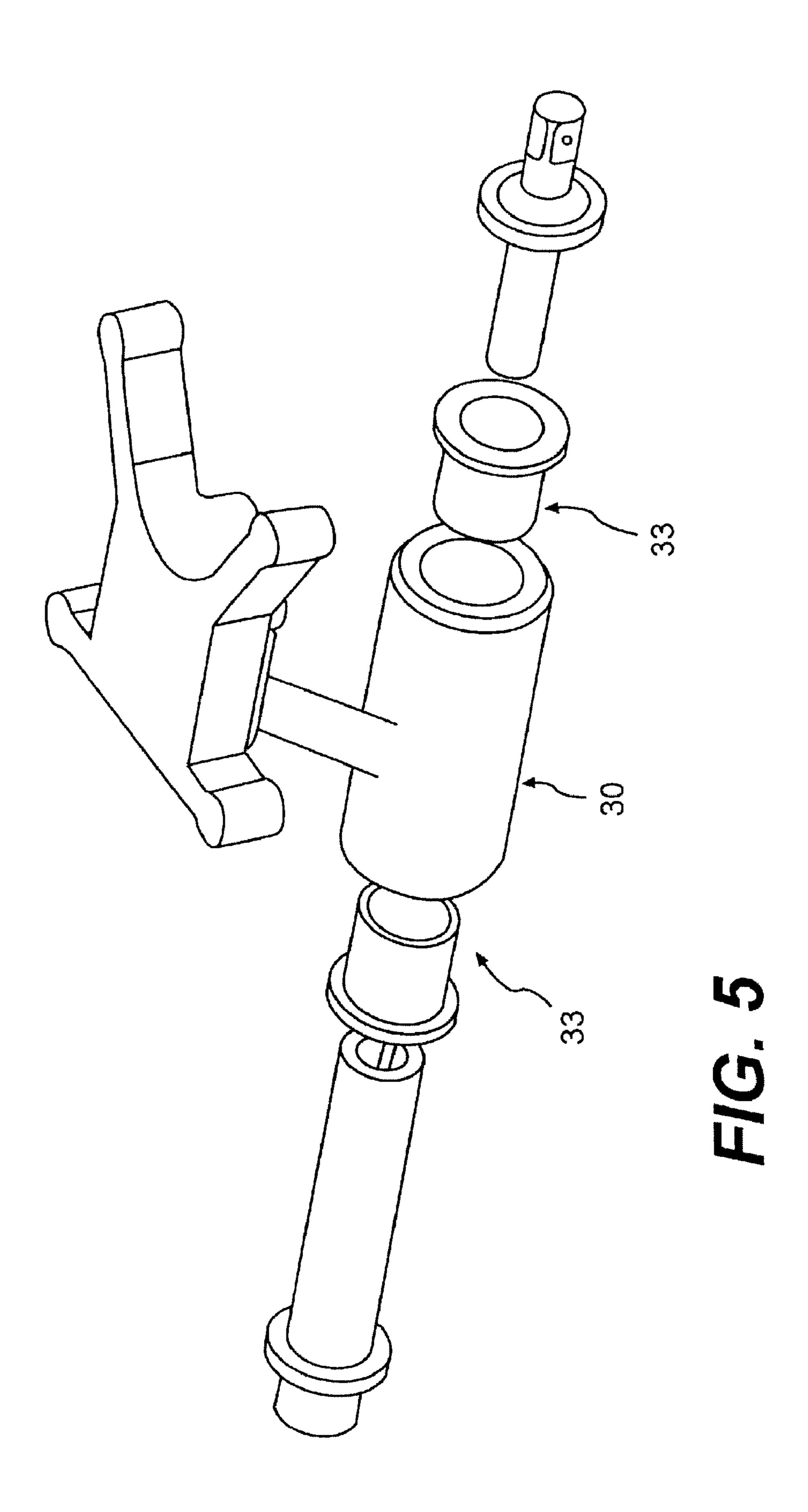


Apr. 24, 2012





Apr. 24, 2012



1

#### IMAGE GUIDED AWL/TAP/SCREWDRIVER

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

#### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates generally to computer assisted image guided medical and surgical navigation systems that generate images during medical and surgical procedures indicating the relative position of various body parts, surgical implants, and instruments. In particular, the present invention relates to an instrument for use in an image guided surgery navigation system that enables the system to track both the depth and the trajectory of the instrument during surgery.

#### 2. Background of Related Art

Computer assisted image guided medical and surgical navigation systems are known and used to generate images in order to guide a doctor during a surgical procedure. Such systems are disclosed, for example, in U.S. Pat. No. 5,383, 25 454 to Bucholz; PCT application Ser. No. PCT/US94/04530 (Publication No. WO 94/24933) to Bucholz; and PCT application Ser. No. PCT/US95/12984 (Publication No. WO 96/11624) to Bucholz et al., incorporated herein by reference.

In general, these image guided systems use images of a body part, such as CT scans, taken before surgery to generate images on a display, such as a CRT monitor screen, during surgery for representing the position of a surgical instrument with respect to the body part. The systems typically include tracking devices such as, for example, an LED array mounted on a surgical instrument as well as a body part, a digitizer to track in real time the position of the body part and the instrument used during surgery, and a monitor screen to display images representing the body and the position of the instrument relative to the body part as the surgical procedure is 40 performed.

There is a need in the art for a surgically navigable tool for use with these image guided systems that is simple to use and manipulate, that enables the computer tracking system to track both the trajectory of the instrument and the depth that 45 the instrument is inserted into the body, and that is easily interchangeable with alternative drive sources such as a ratcheting handle or other instruments such as awls, taps, and screwdrivers.

## SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an image guided medical instrument whose tip and trajectory can be simultaneously tracked.

It is a further object of the invention to provide an image guided medical instrument capable of generating a signal representing the trajectory and the depth of the tip of the instrument.

It is a still further object of the invention to provide an 60 image guided medical instrument that may easily be used with any number of different tips and handles.

It is another object of the invention to provide an image guided medical instrument that is of relatively simple construction and relatively easy to use.

Additional objects and advantages of the invention will be set forth in the description which follows and, in part, will be

2

obvious from the description or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

To achieve the objects and in accordance with the purpose of the invention, as embodied and broadly described herein, the invention comprises a trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for tracking the position of the instrument in three dimensional space and a display providing an indication of the position of the instrument with respect to images of a body part taken preoperatively. The instrument includes a guide member having an emitter array mounted thereon for being tracked by the digitizer, and a drive shaft contained within the guide member, the drive shaft having a proximal and a distal end, the drive shaft being rotatable within the guide member while being fixable axially within the guide member, the proximal end of the drive shaft having a first connector for interchangeably receiving at least one drive source, and the distal end having a second connector for interchangeably receiving at least one instrument tip. The instrument may further include at least one instrument tip for connection to the distal end of the drive shaft and a drive handle for connection to the proximal end of the drive shaft for transmitting torque to the instrument tip to cause rotation of the instrument tip.

In another aspect of this invention, the instrument may further include a sensor which senses the removal and the connection of an instrument tip to the instrument. The sensor may be an electromechanical switch on the guide member.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are not restrictive of the invention as claimed.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification. The drawings illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention.

FIG. 1 is a schematic front view of a computer assisted image guided surgery system used with an instrument according to the present invention.

FIG. 2 is a perspective view of an instrument according to the present invention.

FIG. 3 is an exploded view of the instrument shown in FIG. 2.

FIG. 4 is a view of a portion of the instrument shown in FIG. 2.

FIG. 5 is an exploded view of the portion of the instrument shown in FIG. 4.

# DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used in the drawings and the description to refer to the same or like parts.

The medical instrument of the present invention is shown generally at 10 in FIG. 1. Instrument 100 can be used in many known computer assisted image guided surgical navigation systems such the system shown in FIG. 1 and disclosed in

PCT application Ser. No. PCT/US95/12984 (Publication No. WO 96/11624) to Bucholz et al., incorporated herein by reference. A computer assisted image guided surgery system, shown at 10, generates an image for display on a monitor 106 representing the real time position of a body part and the position of instrument 100 relative to the body part.

An image may be generated on monitor **106** from an image data set stored in a controller, such as computer **108**, usually generated preoperatively by some scanning technique such as by a CAT scanner or by magnetic resonance imaging. The image data set and the image generated have reference points for at least one body part. The reference points for the particularly body part have a fixed spatial relation to the particular body part.

System 10 also generally includes a processor for process- 15 ing image data, shown as digitizer control unit 114. Digitizer control unit 114 is connected to monitor 106, under control of computer 108, and to instrument 100. Digitizer 114, in conjunction with a reference frame arc 120 and a sensor array 110 or other known position sensing unit, tracks the real time 20 position of a body part, such as a cranium shown at 119 clamped in reference frame 120, and an instrument 100. Reference frame 120 has emitters 122 or other tracking means that generate signals representing the position of the various body reference points. Reference frame 120 is fixed spatially 25 in relation to a body part by a clamp assembly indicated generally at 124,125, and 126. Instrument 100 also has a tracking device shown as an emitter array 40 which generates signals representing the position of the instrument during the procedure.

Sensor array 110, mounted on support 112, receives and triangulates the signals generated by emitters 122 and emitter array 40 in order to identify during the procedure the relative position of each of the reference points and the instrument. Digitizer 114 and computer 108 may then modify the image 35 date set according to the identified relative position of each of the reference points during the procedure. Computer 108 may then generate an image data set representing the position of the body elements and the instrument during the procedure. System 10 may also include a foot switch 116 connected to 40 instrument 100 and digitizer 114 for controlling operation of the system. The structure and operation of an image guided surgery system is well known in the art and need not be discussed further here.

Referring to FIGS. 2 and 3, an instrument according to the 45 present invention is shown at 100. Instrument 100 includes a guide member 30, an interchangeable instrument tip 15, and an interchangeable driving handle 20.

A drive shaft 35 is housed within guide member 30 and is removably connected to an end, here the proximal end 37, to surgical instrument tip 15 and at the other end, here the distal end 38, to driving handle 20 such that torque applied manually or by motorized means to drive handle 20 is transmitted to drive shaft 35 which in turn is transmitted to tip 15. Drive shaft 35, while it could be extractable such as for service, is 55 fixable axially in relation to guide member 30, but is rotatable within guide member 30. As shown in FIG. 5, bushings 33 may be provided at each end of guide member 30 to ensure smooth motion between drive shaft 35 and guide member 30. Guide member 30 is preferably made of stainless steel, but 60 can also be made of titanium, aluminum or plastic. Shaft 35 is preferably made from stainless steel, titanium, or aluminum.

Instrument 100 further includes a tracking device such as emitter array 40 attached to guide member 30 for tracking the location and trajectory of instrument 100. As shown in FIG. 4, 65 array 40 is equipped with a plurality of emitters or tracking means 45, preferably four emitters, for generating a signal

4

representing the trajectory of instrument 100 and the depth of instrument tip 15. Preferably emitters 45 are light emitting diodes; however, other tracking devices known in the art capable of being tracked by a corresponding sensor array are within the scope of the invention. For purposes of illustration, not limitation, the tracking device may generate signals actively such as with acoustic, magnetic, electromagnetic, radiologic, and micropulsed radar systems, or passively such as with reflective surfaces.

Drive handle 20 and instrument tip 15 are shown as modular units that can be attached to drive shaft 35 with corresponding and interlocking male and female socket joints. As shown in FIGS. 3 and 4, drive shaft 35 has a female socket joint 34 for connection with a male socket 14 on tip 15, and drive shaft 35 has a male socket joint 36 for connection with a female socket joint **26** on drive handle **20**. With the use of male and female socket joints, various instrument tips and various type and sized drive handles can be easily interchangeable. Instrument tip 15 could be any of a variety of instruments used in surgery such as taps, awls, and shaped tools for interacting with a work piece, such as a screwdriver for driving screws. Drive handle 20 could be any number of existing or specially designed handles and could be ratcheting, nonratcheting or motorized. Instrument tip 15 and drive handle 20 could also be permanently attached to drive shaft 35. Other suitable connection means are within the scope of the invention as well.

In operation, torque applied to drive handle 20 is transmitted through drive shaft 35 to instrument tip 15. Because drive shaft 35 is fixed axially in relation to guide member 30, guide member 30 can remain stationary while drive shaft 35 rotates without translating along the axis of drive shaft 35. The relationship between array 40 and the axis of drive shaft 35, therefore, remains constant. Instrument tip 15 is also fixed axially in relation guide member 30. As a result, the relationship between array 40 and instrument tip 15 also remains constant. Because the relationship between array 40 and tip 15 is constant, the signals emitted by emitters 45 can be used by the computer assisted image guided surgical navigation system to inform the surgeon of the position of instrument 100, indicating both the trajectory or orientation in three dimensional space of instrument 100 and the length of travel along the trajectory, i.e., the depth instrument tip 15 has been inserted into a body part.

It should be recognized that other variations or modifications may be made to provide an instrument that has an emitter array fixed axially relative to the instrument tip while allowing the instrument tip to rotate relative to the emitter array. For example, guide member 30 may also be integral with instrument tip 15 and/or drive handle 20. The array could then be fixed axially relative to the instrument and means could be provided to allow rotation of the instrument relative to the array.

As discussed above, a variety of different instrument tips may be easily interchanged on instrument 100. To use these different instrument tips, information concerning the dimensions of the different tips may be entered into computer 108. As a result, computer 108 can process the various image data for the specific instrument tip being used so that system 10 tracks the depth of the tip being used or, in the case of a screwdriver, so that system 10 tracks the depth of the screw being inserted.

System 10 may also be provided with a mechanism to prevent the system from operating after a new tip has been connected until computer 108 has been recalibrated. For example, an electromechanical switch, or other suitable sensors, could be provided on instrument 100 to provide a signal

to computer 108 indicating that instrument tip 15 has been removed from instrument 100 or that a new instrument tip 15 has been coupled to instrument 100. The switch is preferably a micro switch but can be embodied by any suitable electrical or electromechanical device or sensing device capable of providing a signal in response to attachment or detachment at a particular point on guide member 30 or tip 15.

The switch may be automatically actuated when tip 15 is removed or coupled to instrument 100. Computer 108 may be operably connected to the switch, such as through cable 161, and is responsive to the operation of the switch. Alternatively, if a wireless instrument is used such as one with passive reflective surfaces in place of LED emitters, any suitable form of communication known in the art can be used. An alarm or other indication of some type, such as a message or display on monitor 106, may be generated by computer 108 indicating to the user that tip 15 has been changed. The computer 108 may further prevent the system from operating until the system has been recalibrated for the new instrument tip. Recalibration may be accomplished by touching the instrument tip to a known reference point. Recalibration of the instrument tip can be positively confirmed by means of a light emission from the emitter array 40 detected by sensor array 110 and triangulated to determine the position of the instrument tip. Alternatively, the dimensions of the instrument or tool type may be entered into computer 108 or selected from a pre-programmed list of tool dimensions or tool types. Further, recalibration could be accomplished by a fiber optic device for reading a bar code on the instrument tip, or by any other 30 suitable recalibration technique.

It will also be apparent to those skilled in the art that various modifications and variations can be made to the structure and methodology of the present invention without departing from the scope or spirit of the invention. In view of the foregoing, it is intended that the present invention cover modifications and variations of this invention provided they fall within the scope of the following claims and their equivalents.

#### What is claimed is:

- 1. A trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for tracking the position of the instrument in three dimensional space and a display providing an indication of the position of the instrument with respect to images of a body part [take] 45 taken preoperatively, the instrument comprising:
  - a guide member having an emitter array mounted thereon for being tracked by a digitizer; and
  - a drive shaft contained within the guide member, the drive shaft having a longitudinal axis and a proximal and a 50 distal end, the drive shaft being rotatable within the guide member while being fixable within the guide member in a direction of the longitudinal axis, the proximal end of the drive shaft having a first connector for interchangeably receiving at least one drive source for 55 transmitting torque to the drive shaft causing rotation of the drive shaft relative to the guide member, and the distal end having a second connector for interchangeably receiving at least one instrument tip.
- 2. The instrument according to claim 1, further comprising 60 at least one instrument tip for removable connection to the distal end of the drive shaft.
- 3. The instrument according to claim 2, wherein the at least [on] *one* drive source comprises a drive handle for removable connection to the proximal end of the drive shaft for trans-65 mitting torque to the drive shaft and the instrument tip to cause rotation of the instrument tip.

6

- 4. The instrument according to claim 3, wherein the drive handle and the drive shaft include a male-female socket joint to removably connect the drive shaft to the drive handle.
- 5. The instrument according to claim 3, wherein the drive handle includes a ratchet.
- 6. The instrument according to claim 3, wherein the drive handle includes a motor for imparting torque to the drive shaft.
- 7. The instrument according to claim 2, wherein the instrument tip and the drive shaft include a male-female socket joint to removably connect the drive shaft to the instrument tip.
  - 8. The instrument according to claim 2, wherein the instrument tip is an awl.
- 9. The instrument according to claim 2, wherein the instru-15 ment tip is a tap.
  - 10. The instrument according to claim 2, wherein the instrument tip has a shaped end for mating with a workpiece to be rotated by said drive shaft.
- 11. The instrument according to claim 2, wherein the instrument tip is a drill bit.
  - 12. The instrument according to claim 1, wherein the emitter array includes at least one LED array for emitting light signals.
  - 13. The instrument according to claim 12, wherein the LED array includes a base and a plurality of LED emitters disposed on the base.
  - 14. The instrument according to claim 1, wherein at least one bushing is provided in the guide member to reduce friction between the guide member and drive shaft.
  - 15. The instrument according to claim 1, wherein the instrument includes a sensor which senses the removal and connection of an instrument tip to the instrument.
  - 16. The instrument according to 15, wherein the sensor includes an electromechanical switch on the guide member electrically connected to the system.
- 17. A trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for receiving signals representing a position of the instrument during surgery, a computer for processing the signals received, and a display for providing an image representing the position of the instrument in three dimensional space during surgery, the instrument comprising:
  - guiding means for guiding the instrument in three dimensional space, the guiding means including signaling means for providing a signal representing the trajectory of the instrument and the location of the instrument; and driving means for driving the instrument contained within the guiding means, the driving means having a longitudinal axis and being fixable in relation to the guiding means in a direction of the longitudinal axis while being rotatable in relation to the guiding means, the driving means having a first end adapted to interchangeably receive at least one medical instrument tip and an opposite end adapted to interchangeably receive at least one drive source.
  - 18. The instrument according to claim 17, wherein the instrument includes a sensing means for sensing the removal and the connection of an instrument tip to the instrument.
  - 19. The instrument according to 18, wherein the sensing means includes an electromechanical switch on the guiding means connected to [the] a means for processing.
  - 20. The instrument according to claim 17, wherein the guiding means comprises a housing for receiving the driving means, the driving means being rotatable within the housing while being retained axially within the housing.
  - 21. The instrument according to claim 20 wherein the signaling means comprises an LED array.

- 22. The instrument according to claim 21, further comprising an instrument tip for connection to the first end of the driving means.
- 23. The instrument according to claim 22, further comprising a drive handle for connection to the opposite end of the driving means for transmitting torque to the instrument tip to cause rotation of the instrument tip.
- 24. The instrument according to claim 20, wherein the driving means comprises a drive shaft having mating connectors on both ends for connection to corresponding connectors disposed on an instrument tip and a drive source.
- 25. The instrument according to claim 24, wherein at least one bushing is provided between the housing and the drive shaft to reduce friction between the guide handle and drive 15 tion between the guide member and drive shaft. shaft.
- 26. The instrument according to claim 22, wherein the instrument tip is an awl.
- 27. The instrument according to claim 22, wherein the instrument tip is a tap.
- 28. The instrument according to claim 22, wherein the instrument tip has a shaped end for mating with a workpiece.
- 29. A trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for tracking the position of the instrument in three dimensional 25 space and a display providing an indication of the position of the instrument with respect to images of a body part [take] taken preoperatively, the instrument comprising:
  - a guide member having an emitter array mounted thereon for being tracked by a digitizer;
  - a drive shaft contained within the guide member, the drive shaft having a longitudinal axis and a proximal and a distal end, the drive shaft being rotatable within the guide member while being fixable within the guide member in a direction of the longitudinal axis;
  - an instrument tip extending from the proximal end of the drive shaft; wherein the instrument tip rotates freely relative to the guide member while being fixable axially relative to the guide member; and
  - a drive handle extending from the distal end of the drive 40 shaft for guiding the instrument, including the guide member, and for imparting rotary motion to the drive shaft and the instrument tip independent of the guide member.
- 30. The instrument according to claim 29, further compris- 45 ing a proximal coupler for interchangeably coupling the drive source to the drive shaft.
- 31. The instrument according to claim 30, wherein the proximal coupler comprises a male-female socket joint disposed on the drive shaft and the drive source to removably 50 connect the drive source to the drive shaft.
- 32. The instrument according to claim 29, wherein the drive handle includes a ratchet.
- 33. The instrument according to claim 29, wherein the drive handle includes a motor for imparting rotary motion to 55 ment tip to the drive shaft. the drive shaft.
- 34. The instrument according to claim 29, further comprising a distal coupler for interchangeably coupling the instrument tip to the drive shaft.
- 35. The instrument according to claim 34, wherein the 60 distal coupler includes a male-female socket joint disposed on the drive shaft and the instrument tip to removably connect the instrument tip to the drive shaft.
- 36. The instrument according to claim 29, wherein the instrument tip is an awl.
- 37. The instrument according to claim 29, wherein the instrument tip is a tap.

- 38. The instrument according to claim 29, wherein the instrument tip has a shaped end for mating with a workpiece to be rotated by said drive shaft.
- 39. The instrument according to claim 29, wherein the instrument tip is a drill bit.
- 40. The instrument according to claim 29, wherein the emitter array includes at least one LED array for emitting light signals.
- **41**. The instrument according to claim **29**, wherein the at least one LED array includes a base and a plurality of LED emitters disposed on the base.
- **42**. The instrument according to claim **29**, wherein at least one bushing is provided in the guide member to reduce fric-
- 43. A trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for tracking the position of the instrument in three dimensional space and a display providing an indication of the position of 20 the instrument with respect to images of a body part taken preoperatively, the instrument comprising:
  - a guide member having a tracking device mounted thereon for being tracked by a digitizer;
  - a drive shaft contained within the guide member, the drive shaft having a longitudinal axis and a proximal and a distal end, the drive shaft being rotatable within the guide member while being fixable within the guide member in a direction of the longitudinal axis;
  - an instrument tip extending from the proximal end of the drive shaft; wherein the instrument tip rotates freely relative to the guide member while being fixable axially relative to the guide member; and
  - a drive handle extending from the distal end of the drive shaft for guiding the instrument, including the guide member, and for imparting rotary motion to the drive shaft and the instrument tip independent of the guide member.
  - 44. The instrument according to claim 43, wherein the tracking device includes a passive signal generator.
  - 45. The instrument according to claim 44, wherein the instrument comprises at least one reflective surface for reflecting signals to be tracked by the digitizer.
  - **46**. The instrument according to claim **44**, wherein the instrument comprises at least three reflective surfaces for reflecting signals to be tracked by the digitizer.
  - 47. The instrument according to claim 43, further comprising a proximal coupler for interchangeably coupling the drive source to the drive shaft.
  - 48. The instrument according to claim 47, wherein the proximal coupler comprises a male-female socket joint disposed on the drive shaft and the drive source to removably connect the drive source to the drive shaft.
  - **49**. The instrument according to claim **43**, further comprising a distal coupler for interchangeably coupling the instru-
  - **50**. The instrument according to claim **49**, wherein the distal coupler includes a male-female socket joint disposed on the drive shaft and the instrument tip to removably connect the instrument tip to the drive shaft.
- 51. A trackable medical instrument for use in a computer assisted image guided surgery system having a digitizer for tracking the position of the instrument in three dimensional space and a display providing an indication of the position of the instrument with respect to images of a body part taken 65 preoperatively, the instrument comprising:
  - a guide member having an emitter array mounted thereon for being tracked by a digitizer; and

- a drive shaft contained within the guide member, the drive shaft having a longitudinal axis and a proximal and a distal end, the drive shaft being rotatable within the guide member while being fixable within the guide member in a direction of the longitudinal axis, the proximal end of the drive shaft having a first connector for receiving at least one drive source for transmitting torque to the drive shaft causing rotation of the drive shaft relative to the guide member, and the distal end having a second connector for receiving at least one instrument tip.
- 52. A trackable medical instrument for use with a surgical navigation system, the trackable medical instrument comprising:

a surgical implement having a distal end;

- a guide member coupled to the surgical implement; and a tracking device mounted to the guide member, wherein the tracking device is rotatable relative to the surgical implement wherein the relationship between the tracking device and the distal end of the surgical implement 20 remains substantially constant upon rotating the tracking device relative to the surgical implement and the substantially constant relationship enables the distal end of the surgical implement to be tracked by the surgical navigation system.
- 53. The trackable medical instrument as defined in claim 52, wherein the substantially constant relationship between the tracking device and the distal end of the surgical implement is a distance between the tracking device and the distal end of the surgical implement.
- 54. The trackable medical instrument as defined in claim 52, wherein the surgical implement comprises a proximal end comprising a coupling member.
- 55. The trackable medical instrument as defined in claim 52, wherein the substantially constant relationship enables both orientation in three-dimensional space of the surgical implement and a depth the distal end of the surgical implement has been inserted into a body part to be tracked by the surgical navigation system.
- 56. The trackable medical instrument as defined in claim 52, wherein the tracking device is fixed axially with respect to the distal end of the surgical implement.
- 57. The trackable medical instrument as defined in claim 52, wherein the surgical implement is rotatably coupled to the 45 guide member.
- 58. The trackable medical instrument as defined in claim 57, wherein the tracking device is fixedly secured to the guide member.
- 59. The trackable medical instrument as defined in claim 50 52, wherein the surgical implement and the guide member are integral.
- 60. The trackable medical instrument as defined in claim 52, wherein the tracking device is selected from at least one of a LED, a reflector, an acoustic device, a magnetic device, an 55 electromagnetic device, a radiologic device, a micropulsed radar device or combinations thereof.
- 61. The trackable medical instrument as defined in claim 52, wherein the tracking device is one of either an active tracking device or a passive tracking device.
- 62. The trackable medical instrument as defined in claim 52, wherein the surgical implement is selected from at least one of a tap, an awl, a driving instrument, a drill, or combinations thereof.
- 63. The trackable medical instrument as defined in claim 65 52, further comprising a drive source coupled to the guide member to drive the surgical implement.

10

- 64. The trackable medical instrument as defined in claim 63, wherein the drive source, the surgical implement and the guide member are integral.
- 65. The trackable medical instrument as defined in claim 63, wherein the drive source is a drive handle.
- 66. The trackable medical instrument as defined in claim 65, wherein the drive handle includes a ratchet.
- 67. The trackable medical instrument as defined in claim 63, wherein the drive source is a motor.
- 68. The trackable medical instrument as defined in claim 63, further comprising a drive shaft housed within the guide member, wherein the drive source is operable to rotate the drive shaft to rotate the surgical implement.
- 69. The trackable medical instrument as defined in claim 68, wherein the surgical implement and the drive source are removable from the drive shaft.
- 70. The trackable medical instrument as defined in claim 52, wherein the tracking device includes a plurality of tracking devices.
- 71. The trackable medical instrument as defined in claim 52, further comprising a sensor operable to sense a removal and connection of the surgical implement to the medical instrument.
- 72. The trackable medical instrument as defined in claim 52, further comprising a bushing operable to allow the tracking device to be rotated relative to the surgical implement.
- 73. The trackable medical instrument as defined in claim 72, wherein the bushing is positioned within the guide member.
- 74. The trackable medical instrument as defined in claim 52, further comprising a plurality of surgical implements each operable to be interchangeably coupled to the guide member.
- 75. The trackable medical instrument as defined in claim 52, wherein the tracking device includes a tracking array mounted to the guide member.
- 76. The trackable medical instrument as defined in claim 52, wherein the guide member includes a mount for mounting the tracking device.
  - 77. The trackable medical instrument as defined in claim 76, wherein the guide member further includes an elongated tubular body with the guide member mount extending from the elongated tubular body.
  - 78. A trackable medical instrument for use with a surgical navigation system, the trackable medical instrument comprising:
    - a surgical implement having a distal end;
    - a guide member coupled to the surgical implement;
    - a tracking device mounted to the guide member; and
    - a means for rotating the tracking device relative to the surgical implement; wherein the relationship between the tracking device and the distal end of the surgical implement remains substantially constant upon rotating the tracking device relative to the surgical implement and the substantially constant relationship enables the distal end of the surgical implement to be tracked.
- 79. The trackable medical instrument as defined in claim 60 78, wherein the surgical implement is rotatably coupled to the guide member.
  - 80. The trackable medical instrument as defined in claim 78, wherein the surgical implement is integral with the guide member.
  - 81. The trackable medical instrument as defined in claim 78, wherein the tracking device is fixed axially with respect to the distal end of the surgical implement.

- 82. The trackable medical instrument as defined in claim 78, further comprising a drive source coupled to the guide member to drive the surgical implement.
- 83. The trackable medical instrument as defined in claim 78, wherein the tracking device is a passive reflective tracking 5 device and the medical instrument is a wireless instrument.
- 84. The trackable medical device as defined in claim 78, wherein the surgical implement and the guide member extend along a longitudinal axis.
- 85. The trackable medical instrument as defined in claim 78, further comprising a sensor operable to sense a removal and connection of the surgical implement to the medical instrument.
- 86. A trackable medical instrument for use with a surgical navigation system, the trackable medical instrument comprising:

a surgical implement having a distal end;

12

- a handle positioned near a proximal end of the medical instrument;
- a guide member coupled to the surgical implement and handle; and
- a tracking device mounted to the guide member, wherein the tracking device is rotatable relative to the surgical implement; and the relationship between the tracking device and the distal end of the surgical implement remains substantially constant upon rotating the tracking device relative to the surgical implement.

87. The trackable medical instrument as defined in claim 86, wherein the handle is a drive handle.

88. The trackable medical instrument as defined in claim 86, wherein the surgical implement is selected from at least one of a tap, an awl, a driving instrument, a drill, or combinations thereof.

\* \* \* \* \*

## UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

PATENT NO. : RE43,328 E Page 1 of 1

APPLICATION NO. : 10/062265

DATED : April 24, 2012

INVENTOR(S) : Kevin T. Foley et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 1, line 8, above the heading, "BACKGROUND OF THE INVENTION" insert:

-- Notice: More than one reissue application has been filed for the reissue of patent 6,021,343. The reissue applications are application number 10/062,265, filed January 31, 2002, now U.S. Reissued Patent No. 43,328, and application number 13/453,709, filed April 23, 2012, which is a continuation reissue application of the 10/062,265 application and claims the benefit of the prior reissue application. --

Signed and Sealed this Twelfth Day of November, 2013

Teresa Stanek Rea

Deputy Director of the United States Patent and Trademark Office

## UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

PATENT NO. : RE43,328 E

APPLICATION NO. : 10/062265

DATED : April 24, 2012

INVENTOR(S) : Foley et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

At Column 1, at Line 8 (approx.), above the heading "BACKGROUND OF THE INVENTION" at Line 9 (approx.), insert the following:

--CROSS-REFERENCE TO RELATED APPLICATIONS

NOTICE: More than one reissue application has been filed for the reissue of U.S. Patent No. 6,021,343 A. The reissue applications are U.S. Reissue Patent Application Serial No. 14/691,954, filed on April 21, 2015, now abandoned, U.S. Reissue Patent Application Serial No. 14/691,159, filed on April 20, 2015, now U.S. Reissue Patent No. RE46,409 E, issued May 23, 2017, and U.S. Reissue Patent Application Serial No. 14/545,311, filed on April 20, 2015, now U.S. Reissue Patent No. RE46,422 E, issued June 6, 2017, each of which are a continuation reissue application of U.S. Reissue Patent Application Serial No. 13/453,709, filed on April 23, 2012, now U.S. Reissue Patent No. RE45,484 E, issued April 21, 2015, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 10/062,265 (the present application), filed on January 31, 2002, now U.S. Reissue Patent No. RE43,328 E, issued April 24, 2012, which is a reissue application of 08/971,126, filed on November 20, 1997, now U.S. Patent No. 6,021,343 A, issued February 1, 2000. The disclosures of the--

This certificate supersedes the Certificates of Correction issued November 12, 2013 and June 5, 2018.

Signed and Sealed this Twelfth Day of January, 2021

Andrei Iancu

Director of the United States Patent and Trademark Office

## UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

PATENT NO. : RE43,328 E

APPLICATION NO : 10/062265

APPLICATION NO. : 10/062265

DATED : April 24, 2012

INVENTOR(S) : Foley et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

## In the Specification

Please amend the paragraph beginning at Column 1, Line 8, as follows: Notice: More than one reissue application has been filed for the reissue of U.S. Patent No. 6,021,343. The reissue applications are U.S. Reissue Patent Application Serial No. 14/691,159, filed on April 20, 2015, now U.S. Reissue Patent No. RE46,409 E, issued May 23, 2017, and U.S. Reissue Patent Application Serial No. 14/545,311, filed on April 20, 2015, now U.S. Reissue Patent No. RE46,422 E, issued June 6, 2017, each of which are a continuation reissue application of U.S. Reissue Patent Application Serial No. 13/453,709, filed on April 23, 2012, now U.S. Reissue Patent No. RE45,484 E, issued April 21, 2015, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 10/062,265 (the present application), filed on January 31, 2002, now U.S. Reissue Patent No. RE43,328 E, issued April 24, 2012.

Signed and Sealed this Fifth Day of June, 2018

Andrei Iancu

Director of the United States Patent and Trademark Office