US009017326B2

(12) **United States Patent**
DiNardo et al.

(10) **Patent No.: US 9,017,326 B2**
(45) **Date of Patent: Apr. 28, 2015**

(54) **IMPEDANCE MONITORING APPARATUS, SYSTEM, AND METHOD FOR ULTRASONIC SURGICAL INSTRUMENTS**

(75) Inventors: **Brian DiNardo**, Cincinnati, OH (US); **David C. Yates**, West Chester, OH (US); **Jeffrey D. Messerly**, Cincinnati, OH (US); **Eitan T. Wiener**, Cincinnati, OH (US); **David A. Witt**, Maineville, OH (US); **James R. Giordano**, Milford, OH (US); **Jeffrey L. Aldridge**, Lebanon, OH (US)

(73) Assignee: **Ethicon Endo-Surgery, Inc.**, Cincinnati, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1090 days.

(21) Appl. No.: **12/503,766**

(22) Filed: **Jul. 15, 2009**

(65) **Prior Publication Data**

US 2011/0015627 A1 Jan. 20, 2011

(51) **Int. Cl.**

A61B 17/285	(2006.01)
A61B 17/3209	(2006.01)
A61B 17/295	(2006.01)
A61B 18/08	(2006.01)
A61B 18/14	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 18/1445*** (2013.01); ***A61B 17/320092*** (2013.01); *A61B 18/1206* (2013.01); *A61B 2017/00026* (2013.01); *A61B 2017/0003* (2013.01); *A61B 2017/00973* (2013.01); *A61B 2017/320088* (2013.01); *A61B 2018/00589* (2013.01); *A61B 2018/00601* (2013.01); *A61B 2018/00875* (2013.01)

(58) **Field of Classification Search**

USPC 606/32–34, 37–42, 45–52, 205–207; 310/314, 316.01

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

969,528 A 9/1910 Disbrow
1,570,025 A 1/1926 Young

(Continued)

FOREIGN PATENT DOCUMENTS

CN 1634601 A 7/2005
CN 1640365 A 7/2005

(Continued)

OTHER PUBLICATIONS

Partial International Search Report for PCT/US2010/041663, Oct. 28, 2010 (2 pages).

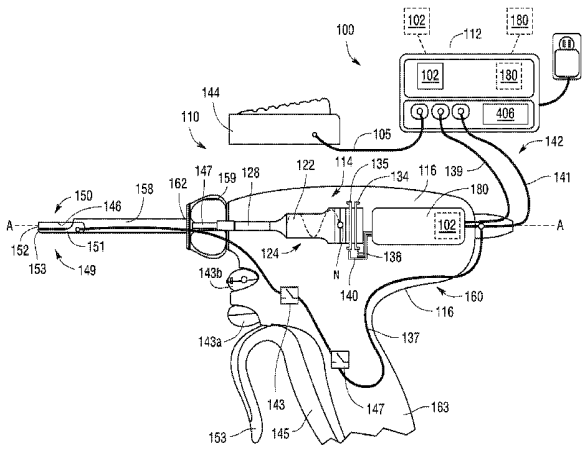
(Continued)

Primary Examiner — Ronald Hupczey, Jr.

(57) **ABSTRACT**

In one general aspect, various embodiments are directed to a surgical instrument that can supply mechanical energy and electrical energy to an end effector of the surgical instrument. The surgical instrument comprises an ultrasonic generator module coupled to an ultrasonic drive system, which comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide. The ultrasonic drive system is configured to resonate mechanically at a resonant frequency to generate a first ultrasonic drive signal. An electronic circuit is coupled to the ultrasonic generator module to monitor an electrical characteristic of the ultrasonic drive system. A processor is coupled to the electronic circuit to control the ultrasonic drive signal in response to the monitored electrical characteristic of the ultrasonic drive system.

24 Claims, 15 Drawing Sheets



(51) **Int. Cl.**

A61B 17/32	(2006.01)
A61B 18/12	(2006.01)
A61B 17/00	(2006.01)
A61B 18/00	(2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,704,333	A		3/1955	Calosi et al.
2,736,960	A		3/1956	Armstrong
2,849,788	A		9/1958	Creek
RE25,033	E		8/1961	Balamuth et al.
3,015,961	A		1/1962	Roney
3,513,848	A		5/1970	Winston et al.
3,526,219	A		9/1970	Balamuth
3,614,484	A		10/1971	Shoh
3,636,943	A		1/1972	Balamuth
3,776,238	A		12/1973	Peyman et al.
3,805,787	A		4/1974	Banko
3,830,098	A		8/1974	Antonevich
3,854,737	A		12/1974	Gilliam, Sr.
3,862,630	A		1/1975	Balamuth
3,900,823	A		8/1975	Sokal et al.
3,918,442	A		11/1975	Nikolaev et al.
3,946,738	A		3/1976	Newton et al.
3,955,859	A		5/1976	Stella et al.
3,956,826	A		5/1976	Perdreaux, Jr.
4,156,187	A		5/1979	Murry et al.
4,188,927	A		2/1980	Harris
4,200,106	A		4/1980	Douvas et al.
4,306,570	A		12/1981	Matthews
4,445,063	A		4/1984	Smith
4,491,132	A		1/1985	Aikins
4,504,264	A		3/1985	Kelman
4,574,615	A		3/1986	Bower et al.
4,617,927	A		10/1986	Manes
4,633,119	A		12/1986	Thompson
4,634,420	A		1/1987	Spinosa et al.
4,640,279	A		2/1987	Beard
4,649,919	A		3/1987	Thimsen et al.
4,708,127	A		11/1987	Abdelghani
4,712,722	A		12/1987	Hood et al.
4,827,911	A		5/1989	Broadwin et al.
4,832,683	A		5/1989	Idemoto et al.
4,838,853	A		6/1989	Parisi
4,850,354	A		7/1989	McGurk-Burleson et al.
4,865,159	A		9/1989	Jamison
4,896,009	A		1/1990	Pawlowski
4,903,696	A		2/1990	Stasz et al.
4,922,902	A		5/1990	Wuchinich et al.
4,965,532	A		10/1990	Sakurai
4,979,952	A	*	12/1990	Kubota et al. 606/169
4,981,756	A		1/1991	Rhandhawa
5,026,387	A		6/1991	Thomas
5,109,819	A		5/1992	Custer et al.
5,112,300	A		5/1992	Ureche
5,123,903	A		6/1992	Quaid et al.
5,126,618	A		6/1992	Takahashi et al.
5,162,044	A		11/1992	Gahn et al.
5,163,537	A		11/1992	Radev
5,167,725	A		12/1992	Clark et al.
D332,660	S		1/1993	Rawson et al.
5,176,677	A		1/1993	Wuchinich
5,176,695	A		1/1993	Dulebohn
5,184,605	A		2/1993	Grzeszykowski
5,188,102	A		2/1993	Idemoto et al.
5,213,569	A		5/1993	Davis
5,221,282	A		6/1993	Wuchinich
5,226,909	A		7/1993	Evans et al.
5,226,910	A		7/1993	Kajiyama et al.
5,241,236	A		8/1993	Sasaki et al.
5,257,988	A		11/1993	L'Esperance, Jr.
5,261,922	A		11/1993	Hood
5,263,957	A		11/1993	Davison
5,275,609	A		1/1994	Pingleton et al.
5,282,800	A		2/1994	Foshee et al.
5,304,115	A		4/1994	Pflueger et al.
D347,474	S		5/1994	Olson
5,322,055	A		6/1994	Davison et al.
5,324,299	A		6/1994	Davison et al.
5,326,342	A		7/1994	Pflueger et al.
5,344,420	A		9/1994	Hilal et al.
5,346,502	A		9/1994	Estabrook et al.
5,353,474	A		10/1994	Good et al.
5,357,164	A		10/1994	Imabayashi et al.
5,357,423	A	*	10/1994	Weaver et al. 700/28
5,366,466	A		11/1994	Christian et al.
5,371,429	A		12/1994	Manna
D354,564	S		1/1995	Medema
5,381,067	A		1/1995	Greenstein et al.
5,403,312	A		4/1995	Yates et al.
D358,887	S		5/1995	Feinberg
5,411,481	A		5/1995	Allen et al.
5,419,761	A		5/1995	Narayanan et al.
5,421,829	A		6/1995	Olichney et al.
5,438,997	A		8/1995	Sieben et al.
5,449,370	A	*	9/1995	Vaitekunas 606/169
5,471,988	A		12/1995	Fujio et al.
5,483,501	A		1/1996	Park et al.
5,486,162	A		1/1996	Brumbach
5,500,216	A		3/1996	Julian et al.
5,501,654	A		3/1996	Failla et al.
5,505,693	A		4/1996	Mackool
5,507,738	A		4/1996	Ciervo
5,527,331	A		6/1996	Kresch et al.
5,562,609	A		10/1996	Brumbach
5,562,610	A		10/1996	Brumbach
5,577,654	A		11/1996	Bishop
5,601,601	A		2/1997	Tal et al.
5,603,773	A		2/1997	Campbell
5,607,436	A		3/1997	Pratt et al.
5,618,492	A		4/1997	Auten et al.
5,628,760	A		5/1997	Knoepfler
5,630,420	A	*	5/1997	Vaitekunas 600/459
D381,077	S		7/1997	Hunt
5,651,780	A		7/1997	Jackson et al.
5,653,713	A		8/1997	Michelson
5,669,922	A		9/1997	Hood
5,674,235	A		10/1997	Parisi
5,690,269	A		11/1997	Bolanos et al.
5,694,936	A		12/1997	Fujimoto et al.
5,713,896	A		2/1998	Nardella
5,730,752	A		3/1998	Alden et al.
5,733,074	A		3/1998	Stöck et al.
5,741,226	A		4/1998	Strukel et al.
5,792,135	A		8/1998	Madhani et al.
5,792,165	A		8/1998	Klieman et al.
5,808,396	A		9/1998	Boukhny
5,810,859	A		9/1998	DiMatteo et al.
5,817,084	A		10/1998	Jensen
5,817,119	A		10/1998	Klieman et al.
5,827,323	A		10/1998	Klieman et al.
5,828,160	A		10/1998	Sugishita
5,833,696	A		11/1998	Whitfield et al.
5,836,897	A	*	11/1998	Sakurai et al. 601/2
5,843,109	A		12/1998	Mehta et al.
5,878,193	A		3/1999	Wang et al.
5,879,364	A		3/1999	Bromfield et al.
5,883,615	A		3/1999	Fago et al.
5,893,835	A		4/1999	Witt et al.
5,897,523	A		4/1999	Wright et al.
5,897,569	A		4/1999	Kellogg et al.
5,906,628	A		5/1999	Miyawaki et al.
5,911,699	A		6/1999	Anis et al.
5,935,143	A		8/1999	Hood
5,935,144	A		8/1999	Estabrook
5,938,633	A		8/1999	Beaupre
5,944,718	A		8/1999	Austin et al.
5,944,737	A		8/1999	Tsonton et al.
5,954,736	A		9/1999	Bishop et al.
5,954,746	A		9/1999	Holthaus et al.
5,957,882	A		9/1999	Nita et al.
5,957,943	A		9/1999	Vaitekunas
5,968,007	A		10/1999	Simon et al.
5,968,060	A		10/1999	Kellogg

(56) **References Cited**

U.S. PATENT DOCUMENTS

D416,089 S 11/1999 Barton et al.
5,980,510 A 11/1999 Tsonton et al.
5,989,274 A 11/1999 Davison et al.
5,989,275 A 11/1999 Estabrook et al.
5,993,972 A 11/1999 Reich et al.
6,024,741 A 2/2000 Williamson, IV et al.
6,027,515 A 2/2000 Cimino
6,033,375 A 3/2000 Brumbach
6,050,943 A 4/2000 Slayton et al.
6,051,010 A 4/2000 DiMatteo et al.
6,056,735 A 5/2000 Okada et al.
6,063,098 A 5/2000 Houser et al.
6,066,132 A 5/2000 Chen et al.
6,066,151 A 5/2000 Miyawaki et al.
6,068,647 A 5/2000 Witt et al.
6,077,285 A 6/2000 Boukhny
6,083,191 A 7/2000 Rose
6,086,584 A 7/2000 Miller
6,090,120 A 7/2000 Wright et al.
6,109,500 A 8/2000 Alli et al.
6,110,127 A 8/2000 Suzuki
6,113,594 A 9/2000 Savage
6,117,152 A 9/2000 Huitema
6,126,629 A 10/2000 Perkins
6,129,735 A 10/2000 Okada et al.
6,132,368 A 10/2000 Cooper
6,139,320 A 10/2000 Hahn
6,139,561 A 10/2000 Shibata et al.
6,142,615 A 11/2000 Qiu et al.
6,147,560 A 11/2000 Erhage et al.
6,152,902 A 11/2000 Christian et al.
6,159,160 A 12/2000 Hsei et al.
6,159,175 A 12/2000 Strukel et al.
6,165,150 A 12/2000 Banko
6,204,592 B1 3/2001 Hur
6,206,844 B1 3/2001 Reichel et al.
6,210,403 B1 4/2001 Klicek
6,214,023 B1 4/2001 Whipple et al.
6,231,565 B1 5/2001 Tovey et al.
6,233,476 B1 5/2001 Strommer et al.
6,238,366 B1 5/2001 Savage et al.
6,252,110 B1 6/2001 Uemura et al.
D444,365 S 7/2001 Bass et al.
6,254,623 B1 7/2001 Haibel, Jr. et al.
6,258,034 B1 7/2001 Hanafy
6,267,761 B1 7/2001 Ryan
6,270,831 B2 8/2001 Kumar et al.
6,273,852 B1 8/2001 Lehe et al.
6,274,963 B1 8/2001 Estabrook et al.
6,277,115 B1 8/2001 Saadat
6,278,218 B1 8/2001 Madan et al.
6,283,981 B1 9/2001 Beaupre
6,309,400 B2 10/2001 Beaupre
6,319,221 B1 11/2001 Savage et al.
6,325,811 B1 12/2001 Messerly
6,328,751 B1 12/2001 Beaupre
6,340,352 B1 * 1/2002 Okada et al. 601/2
6,352,532 B1 3/2002 Kramer et al.
6,364,888 B1 4/2002 Niemeyer et al.
6,379,320 B1 4/2002 Lafon et al.
D457,958 S 5/2002 Dycus et al.
6,383,194 B1 5/2002 Pothula
6,387,109 B1 5/2002 Davison et al.
6,388,657 B1 5/2002 Natoli
6,391,042 B1 5/2002 Cimino
6,405,733 B1 6/2002 Fogarty et al.
6,416,486 B1 7/2002 Wampler
6,423,073 B2 7/2002 Bowman
6,423,082 B1 7/2002 Houser et al.
6,428,539 B1 8/2002 Baxter et al.
6,432,118 B1 8/2002 Messerly
6,436,114 B1 8/2002 Novak et al.
6,436,115 B1 8/2002 Beaupre
6,443,969 B1 9/2002 Novak et al.
6,454,781 B1 * 9/2002 Witt et al. 606/169
6,454,782 B1 9/2002 Schwemberger
6,458,142 B1 10/2002 Faller et al.
6,480,796 B2 11/2002 Wiener
6,485,490 B2 11/2002 Wampler et al.
6,491,708 B2 12/2002 Madan et al.
6,497,715 B2 12/2002 Satou
6,500,176 B1 12/2002 Truckai et al.
6,500,188 B2 12/2002 Harper et al.
6,524,251 B2 2/2003 Rabiner et al.
6,524,316 B1 2/2003 Nicholson et al.
6,527,736 B1 3/2003 Attinger et al.
6,533,784 B2 3/2003 Truckai et al.
6,537,291 B2 3/2003 Friedman et al.
6,543,452 B1 4/2003 Lavigne
6,543,456 B1 4/2003 Freeman
6,544,260 B1 4/2003 Markel et al.
6,561,983 B2 5/2003 Cronin et al.
6,572,632 B2 6/2003 Zisterer et al.
6,575,969 B1 6/2003 Rittman, III et al.
6,582,451 B1 6/2003 Marucci et al.
6,589,200 B1 7/2003 Schwemberger et al.
6,589,239 B2 7/2003 Khandkar et al.
6,610,059 B1 8/2003 West, Jr.
6,616,450 B2 9/2003 Mossle et al.
6,623,501 B2 9/2003 Heller et al.
6,626,926 B2 9/2003 Friedman et al.
6,633,234 B2 10/2003 Wiener et al.
6,656,177 B2 12/2003 Truckai et al.
6,662,127 B2 12/2003 Wiener et al.
6,663,941 B2 12/2003 Brown et al.
6,669,690 B1 * 12/2003 Okada et al. 606/40
6,676,660 B2 1/2004 Wampler et al.
6,678,621 B2 1/2004 Wiener et al.
6,679,875 B2 1/2004 Honda et al.
6,679,899 B2 1/2004 Wiener et al.
6,682,544 B2 1/2004 Mastri et al.
6,689,146 B1 2/2004 Himes
6,716,215 B1 4/2004 David et al.
6,731,047 B2 5/2004 Kauf et al.
6,733,506 B1 5/2004 McDevitt et al.
6,762,535 B2 7/2004 Take et al.
6,770,072 B1 8/2004 Truckai et al.
6,773,443 B2 8/2004 Truwit et al.
6,773,444 B2 8/2004 Messerly
6,783,524 B2 8/2004 Anderson et al.
6,786,382 B1 9/2004 Hoffman
6,786,383 B2 9/2004 Stegelmann
6,790,216 B1 9/2004 Ishikawa
D496,997 S 10/2004 Dycus et al.
6,802,843 B2 10/2004 Truckai et al.
6,827,712 B2 12/2004 Tovey et al.
6,828,712 B2 12/2004 Battaglin et al.
6,869,439 B2 3/2005 White et al.
6,875,220 B2 4/2005 Du et al.
6,905,497 B2 6/2005 Truckai et al.
6,908,472 B2 6/2005 Wiener et al.
6,913,579 B2 7/2005 Truckai et al.
6,923,804 B2 8/2005 Eggers et al.
6,926,716 B2 8/2005 Baker et al.
6,929,632 B2 8/2005 Nita et al.
6,929,644 B2 8/2005 Truckai et al.
6,933,656 B2 8/2005 Matsushita et al.
D509,589 S 9/2005 Wells
6,942,677 B2 9/2005 Nita et al.
6,945,981 B2 9/2005 Donofrio et al.
D511,145 S 11/2005 Donofrio et al.
6,974,450 B2 12/2005 Weber et al.
6,976,844 B2 12/2005 Hickok et al.
6,976,969 B2 12/2005 Messerly
6,977,495 B2 12/2005 Donofrio
6,984,220 B2 1/2006 Wuchinich
7,001,335 B2 2/2006 Adachi et al.
7,011,657 B2 3/2006 Truckai et al.
7,033,357 B2 4/2006 Baxter et al.
7,041,083 B2 5/2006 Chu et al.
7,041,088 B2 5/2006 Nawrocki et al.
7,041,102 B2 5/2006 Truckai et al.
7,070,597 B2 7/2006 Truckai et al.
7,074,219 B2 7/2006 Levine et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,077,039 B2 7/2006 Gass et al.
7,077,853 B2 7/2006 Kramer et al.
7,083,619 B2 8/2006 Truckai et al.
7,087,054 B2 8/2006 Truckai et al.
7,090,672 B2 8/2006 Underwood et al.
7,101,371 B2 9/2006 Dycus et al.
7,101,378 B2 9/2006 Salameh et al.
7,108,695 B2 9/2006 Witt et al.
7,112,201 B2 9/2006 Truckai et al.
D531,311 S 10/2006 Guerra et al.
7,118,564 B2 10/2006 Ritchie et al.
7,124,932 B2 10/2006 Isaacson et al.
7,125,409 B2 10/2006 Truckai et al.
7,135,018 B2 11/2006 Ryan et al.
7,135,030 B2 11/2006 Schwemberger et al.
7,144,403 B2 12/2006 Booth
7,153,315 B2 12/2006 Miller
D536,093 S 1/2007 Nakajima et al.
7,156,189 B1 1/2007 Bar-Cohen et al.
7,156,853 B2 1/2007 Muratsu
7,157,058 B2 1/2007 Marhasin et al.
7,159,750 B2 1/2007 Racenet et al.
7,160,299 B2 1/2007 Baily
7,163,548 B2 1/2007 Stulen et al.
7,169,146 B2 1/2007 Truckai et al.
7,179,271 B2 2/2007 Friedman et al.
7,186,253 B2 3/2007 Truckai et al.
7,189,233 B2 3/2007 Truckai et al.
D541,418 S 4/2007 Schechter et al.
7,204,820 B2 4/2007 Akahoshi
7,217,269 B2 5/2007 El-Galley et al.
7,220,951 B2 5/2007 Truckai et al.
7,223,229 B2 5/2007 Inman et al.
7,229,455 B2 6/2007 Sakurai et al.
7,273,483 B2 * 9/2007 Wiener et al. 606/169
7,285,895 B2 10/2007 Beaupré
7,309,849 B2 12/2007 Truckai et al.
7,311,709 B2 12/2007 Truckai et al.
7,317,955 B2 1/2008 McGreevy
7,326,236 B2 2/2008 Andreas et al.
7,331,410 B2 2/2008 Yong et al.
7,353,068 B2 4/2008 Tanaka et al.
7,354,440 B2 4/2008 Truckal et al.
7,380,695 B2 6/2008 Doll et al.
7,380,696 B2 6/2008 Shelton, IV et al.
7,381,209 B2 6/2008 Truckai et al.
7,390,317 B2 6/2008 Taylor et al.
7,404,508 B2 7/2008 Smith et al.
7,408,288 B2 8/2008 Hara
D576,725 S 9/2008 Shumer et al.
D578,643 S 10/2008 Shumer et al.
D578,644 S 10/2008 Shumer et al.
D578,645 S 10/2008 Shumer et al.
7,431,704 B2 10/2008 Babaev
7,441,684 B2 10/2008 Shelton, IV et al.
7,455,208 B2 11/2008 Wales et al.
7,472,815 B2 1/2009 Shelton, IV et al.
7,473,263 B2 1/2009 Johnston et al.
7,479,148 B2 1/2009 Beaupre
7,479,160 B2 1/2009 Branch et al.
7,488,285 B2 2/2009 Honda et al.
7,494,468 B2 2/2009 Rabiner et al.
7,503,893 B2 3/2009 Kucklick
7,503,895 B2 3/2009 Rabiner et al.
7,506,790 B2 3/2009 Shelton, IV
7,506,791 B2 3/2009 Omaits et al.
7,524,320 B2 4/2009 Tierney et al.
7,530,986 B2 5/2009 Beaupre et al.
7,534,243 B1 5/2009 Chin et al.
D594,983 S 6/2009 Price et al.
7,549,564 B2 6/2009 Boudreaux
7,559,450 B2 7/2009 Wales et al.
7,567,012 B2 7/2009 Namikawa
7,578,820 B2 8/2009 Moore et al.
7,654,431 B2 2/2010 Hueil et al.
7,665,647 B2 2/2010 Shelton, IV et al.
7,670,334 B2 3/2010 Hueil et al.
7,674,263 B2 3/2010 Ryan
7,691,098 B2 4/2010 Wallace et al.
7,713,202 B2 * 5/2010 Boukhny et al. 600/439
7,714,481 B2 5/2010 Sakai
D618,797 S 6/2010 Price et al.
7,751,115 B2 7/2010 Song
D621,503 S 8/2010 Otten et al.
7,770,774 B2 8/2010 Mastri et al.
7,770,775 B2 8/2010 Shelton, IV et al.
7,780,054 B2 8/2010 Wales
7,780,659 B2 8/2010 Okada et al.
7,784,662 B2 8/2010 Wales et al.
7,798,386 B2 9/2010 Schall et al.
7,803,152 B2 9/2010 Honda et al.
7,806,891 B2 10/2010 Nowlin et al.
7,810,693 B2 10/2010 Broehl et al.
D627,066 S 11/2010 Romero
7,824,401 B2 11/2010 Manzo et al.
7,837,699 B2 11/2010 Yamada et al.
7,846,155 B2 12/2010 Houser et al.
7,854,735 B2 12/2010 Houser et al.
D631,155 S 1/2011 Peine et al.
7,861,906 B2 1/2011 Doll et al.
7,876,030 B2 1/2011 Taki et al.
D631,965 S 2/2011 Price et al.
7,892,606 B2 2/2011 Thies et al.
7,905,881 B2 3/2011 Masuda et al.
7,922,651 B2 4/2011 Yamada et al.
D637,288 S 5/2011 Houghton
D638,540 S 5/2011 Ijiri et al.
7,959,050 B2 6/2011 Smith et al.
7,959,626 B2 6/2011 Hong et al.
7,976,544 B2 7/2011 McClurken et al.
7,998,157 B2 8/2011 Culp et al.
8,038,693 B2 10/2011 Allen
8,061,014 B2 11/2011 Smith et al.
8,089,197 B2 1/2012 Rinner et al.
8,152,825 B2 4/2012 Madan et al.
8,157,145 B2 4/2012 Shelton, IV et al.
8,177,800 B2 5/2012 Spitz et al.
D661,801 S 6/2012 Price et al.
D661,802 S 6/2012 Price et al.
D661,803 S 6/2012 Price et al.
D661,804 S 6/2012 Price et al.
8,253,303 B2 8/2012 Giordano et al.
8,287,485 B2 10/2012 Kimura et al.
2001/0025183 A1 9/2001 Shahidi et al.
2001/0025184 A1 9/2001 Messerly
2001/0031950 A1 10/2001 Ryan
2001/0039419 A1 11/2001 Francischelli et al.
2002/0002377 A1 1/2002 Cimino
2002/0019649 A1 2/2002 Sikora et al.
2002/0022836 A1 2/2002 Goble et al.
2002/0049551 A1 4/2002 Friedman et al.
2002/0052617 A1 5/2002 Anis et al.
2002/0077550 A1 6/2002 Rabiner et al.
2002/0156466 A1 10/2002 Sakurai et al.
2002/0156493 A1 10/2002 Houser et al.
2003/0036705 A1 2/2003 Hare et al.
2003/0055443 A1 3/2003 Spotnitz
2003/0204199 A1 10/2003 Novak et al.
2003/0212332 A1 11/2003 Fenton et al.
2003/0212422 A1 11/2003 Fenton et al.
2003/0229344 A1 12/2003 Dycus et al.
2004/0030254 A1 2/2004 Babaev
2004/0047485 A1 3/2004 Sherrit et al.
2004/0054364 A1 3/2004 Aranyi et al.
2004/0092921 A1 5/2004 Kadziauskas et al.
2004/0097919 A1 5/2004 Wellman et al.
2004/0097996 A1 5/2004 Rabiner et al.
2004/0176686 A1 9/2004 Hare et al.
2004/0199193 A1 10/2004 Hayashi et al.
2004/0204728 A1 10/2004 Haefner
2004/0243157 A1 12/2004 Connor et al.
2004/0260300 A1 12/2004 Gorensek et al.
2005/0004589 A1 * 1/2005 Okada et al. 606/169
2005/0021065 A1 1/2005 Yamada et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0033337 A1 2/2005 Muir et al.
2005/0049546 A1 3/2005 Messerly et al.
2005/0070800 A1 3/2005 Takahashi
2005/0096683 A1 5/2005 Ellins et al.
2005/0143769 A1 6/2005 White et al.
2005/0149108 A1 7/2005 Cox
2005/0165345 A1 7/2005 Laufer et al.
2005/0177184 A1 8/2005 Easley
2005/0192610 A1 9/2005 Houser et al.
2005/0209620 A1 9/2005 Du et al.
2005/0261581 A1 11/2005 Hughes et al.
2005/0261588 A1 11/2005 Makin et al.
2005/0273090 A1 12/2005 Nieman et al.
2005/0288659 A1 12/2005 Kimura et al.
2006/0030797 A1 2/2006 Zhou et al.
2006/0063130 A1 3/2006 Hayman et al.
2006/0066181 A1 3/2006 Bromfield et al.
2006/0079876 A1 4/2006 Houser et al.
2006/0079878 A1 4/2006 Houser
2006/0084963 A1 4/2006 Messerly
2006/0095046 A1 5/2006 Trieu et al.
2006/0190034 A1 8/2006 Nishizawa et al.
2006/0206115 A1 9/2006 Schomer et al.
2006/0211943 A1 9/2006 Beaupre
2006/0235306 A1 10/2006 Cotter et al.
2006/0253050 A1 11/2006 Yoshimine et al.
2006/0264809 A1 11/2006 Hansmann et al.
2007/0016235 A1 1/2007 Tanaka et al.
2007/0016236 A1 1/2007 Beaupre
2007/0055228 A1 3/2007 Berg et al.
2007/0056596 A1 3/2007 Fanney et al.
2007/0060915 A1 3/2007 Kucklick
2007/0060935 A1 3/2007 Schwardt et al.
2007/0063618 A1 3/2007 Bromfield
2007/0106317 A1 5/2007 Shelton, IV et al.
2007/0129716 A1 6/2007 Daw et al.
2007/0130771 A1 6/2007 Ehlert et al.
2007/0131034 A1 6/2007 Ehlert et al.
2007/0149881 A1 6/2007 Rabin
2007/0162050 A1 7/2007 Sartor
2007/0173872 A1 7/2007 Neuenfeldt
2007/0185380 A1 8/2007 Kucklick
2007/0219481 A1 9/2007 Babaev
2007/0239028 A1 10/2007 Houser et al.
2007/0249941 A1 10/2007 Salehi et al.
2007/0260234 A1 11/2007 McCullagh et al.
2007/0265560 A1 11/2007 Soltani et al.
2007/0275348 A1 11/2007 Lemon
2007/0282335 A1 12/2007 Young et al.
2007/0287933 A1 12/2007 Phan et al.
2008/0009848 A1 1/2008 Paraschiv et al.
2008/0051812 A1 2/2008 Schmitz et al.
2008/0058585 A1 3/2008 Novak et al.
2008/0058775 A1 3/2008 Darian et al.
2008/0058845 A1 3/2008 Shimizu et al.
2008/0082039 A1 4/2008 Babaev
2008/0082098 A1 4/2008 Tanaka et al.
2008/0125768 A1 5/2008 Tahara et al.
2008/0171938 A1 7/2008 Masuda et al.
2008/0172051 A1* 7/2008 Masuda et al. 606/37
2008/0177268 A1 7/2008 Daum et al.
2008/0188878 A1 8/2008 Young
2008/0200940 A1 8/2008 Eichmann et al.
2008/0208231 A1 8/2008 Ota et al.
2008/0234708 A1 9/2008 Houser et al.
2008/0234709 A1 9/2008 Houser
2008/0234710 A1 9/2008 Neurohr et al.
2008/0234711 A1 9/2008 Houser et al.
2008/0243106 A1 10/2008 Coe et al.
2008/0245371 A1 10/2008 Gruber
2008/0249553 A1 10/2008 Gruber et al.
2008/0262490 A1 10/2008 Williams
2008/0281200 A1 11/2008 Voic et al.
2008/0287948 A1 11/2008 Newton et al.
2009/0030311 A1 1/2009 Stulen et al.
2009/0030351 A1 1/2009 Wiener et al.
2009/0030437 A1 1/2009 Houser et al.
2009/0030438 A1 1/2009 Stulen
2009/0030439 A1 1/2009 Stulen
2009/0036911 A1 2/2009 Stulen
2009/0036912 A1 2/2009 Wiener et al.
2009/0036913 A1 2/2009 Wiener et al.
2009/0036914 A1 2/2009 Houser
2009/0048537 A1 2/2009 Lydon et al.
2009/0054886 A1 2/2009 Yachi et al.
2009/0054894 A1 2/2009 Yachi
2009/0076506 A1 3/2009 Baker
2009/0082716 A1 3/2009 Akahoshi
2009/0105750 A1 4/2009 Price et al.
2009/0118802 A1 5/2009 Mioduski et al.
2009/0138006 A1 5/2009 Bales et al.
2009/0143795 A1 6/2009 Robertson
2009/0143796 A1 6/2009 Stulen et al.
2009/0143797 A1 6/2009 Smith et al.
2009/0143798 A1 6/2009 Smith et al.
2009/0143799 A1 6/2009 Smith et al.
2009/0143800 A1 6/2009 Deville et al.
2009/0143801 A1 6/2009 Deville et al.
2009/0143802 A1 6/2009 Deville et al.
2009/0143803 A1 6/2009 Palmer et al.
2009/0143804 A1 6/2009 Palmer et al.
2009/0143805 A1 6/2009 Palmer et al.
2009/0143806 A1 6/2009 Witt et al.
2009/0149801 A1 6/2009 Crandall et al.
2009/0270853 A1 10/2009 Yachi et al.
2009/0270899 A1 10/2009 Carusillo et al.
2009/0318945 A1 12/2009 Yoshimine et al.
2009/0327715 A1 12/2009 Smith et al.
2010/0004668 A1 1/2010 Smith et al.
2010/0004669 A1 1/2010 Smith et al.
2010/0016785 A1 1/2010 Takuma
2010/0030248 A1 2/2010 Palmer et al.
2010/0036370 A1 2/2010 Mirel et al.
2010/0036405 A1 2/2010 Giordano et al.
2010/0069940 A1 3/2010 Miller et al.
2010/0158307 A1 6/2010 Kubota et al.
2010/0179577 A1 7/2010 Houser
2010/0187283 A1 7/2010 Crainich et al.
2010/0193567 A1 8/2010 Scheib et al.
2010/0228264 A1 9/2010 Robinson et al.
2010/0234906 A1 9/2010 Koh
2010/0268211 A1 10/2010 Manwaring et al.
2010/0298743 A1 11/2010 Nield et al.
2010/0298851 A1 11/2010 Nield
2010/0331869 A1 12/2010 Voegele et al.
2010/0331870 A1 12/2010 Wan et al.
2010/0331871 A1 12/2010 Nield et al.
2010/0331872 A1 12/2010 Houser et al.
2011/0009850 A1 1/2011 Main et al.
2011/0015631 A1 1/2011 Wiener et al.
2011/0015660 A1 1/2011 Wiener et al.
2011/0082486 A1 4/2011 Messerly et al.
2011/0087212 A1 4/2011 Aldridge et al.
2011/0087213 A1 4/2011 Messerly et al.
2011/0087214 A1 4/2011 Giordano et al.
2011/0087215 A1 4/2011 Aldridge et al.
2011/0087216 A1 4/2011 Aldridge et al.
2011/0087217 A1 4/2011 Yates et al.
2011/0087218 A1 4/2011 Boudreaux et al.
2011/0087256 A1 4/2011 Wiener et al.
2011/0125175 A1 5/2011 Stulen et al.
2011/0196286 A1 8/2011 Robertson et al.
2011/0196287 A1 8/2011 Robertson et al.
2011/0196398 A1 8/2011 Robertson et al.
2011/0196399 A1 8/2011 Robertson et al.
2011/0196400 A1 8/2011 Robertson et al.
2011/0196401 A1 8/2011 Robertson et al.
2011/0196402 A1 8/2011 Robertson et al.
2011/0196403 A1 8/2011 Robertson et al.
2011/0196404 A1 8/2011 Dietz et al.
2011/0196405 A1 8/2011 Dietz
2011/0288452 A1 11/2011 Houser et al.
2012/0029546 A1 2/2012 Robertson
2012/0059289 A1 3/2012 Nield et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2012/0078139	A1	3/2012	Aldridge et al.
2012/0078243	A1	3/2012	Worrell et al.
2012/0078244	A1	3/2012	Worrell et al.
2012/0078247	A1	3/2012	Worrell et al.
2012/0083783	A1	4/2012	Davison et al.
2012/0083784	A1	4/2012	Davison et al.
2012/0132450	A1	5/2012	Timm et al.
2012/0138660	A1	6/2012	Shelton, IV
2012/0177005	A1	7/2012	Liang et al.
2012/0184946	A1	7/2012	Price et al.
2012/0199630	A1	8/2012	Shelton, IV
2012/0199631	A1	8/2012	Shelton, IV et al.
2012/0199632	A1	8/2012	Spivey et al.
2012/0199633	A1	8/2012	Shelton, IV et al.
2012/0203247	A1	8/2012	Shelton, IV et al.
2012/0203257	A1	8/2012	Stulen et al.
2012/0205421	A1	8/2012	Shelton, IV
2012/0210223	A1	8/2012	Eppolito
2012/0211546	A1	8/2012	Shelton, IV
2012/0259353	A1	10/2012	Houser et al.
2012/0265196	A1	10/2012	Turner et al.
2012/0269676	A1	10/2012	Houser et al.
2012/0289984	A1	11/2012	Houser et al.
2012/0310262	A1	12/2012	Messerly et al.
2012/0310263	A1	12/2012	Messerly et al.
2012/0310264	A1	12/2012	Messerly et al.
2012/0323265	A1	12/2012	Stulen
2013/0012970	A1	1/2013	Houser
2013/0103023	A1	4/2013	Monson et al.
2013/0103024	A1	4/2013	Monson et al.
2013/0123776	A1	5/2013	Monson et al.
2013/0123777	A1	5/2013	Monson et al.
2013/0123782	A1	5/2013	Trees et al.

FOREIGN PATENT DOCUMENTS

CN	1694649	A	11/2005
CN	1922563	A	2/2007
CN	1951333	A	4/2007
CN	101040799	A	9/2007
CN	101467917	A	1/2009
EP	0171967	A2	2/1986
EP	0443256	A1	8/1991
EP	0456470	A1	11/1991
EP	0482195	B1	4/1992
EP	0482195	B1	1/1996
EP	0612570	B1	6/1997
EP	0908148	B1	1/2002
EP	0908155	B1	6/2003
EP	1199044	B1	12/2005
EP	1199043	B1	3/2006
EP	1433425	B1	6/2006
EP	1844720	A1	10/2007
EP	1862133	A1	12/2007
EP	1199045	B1	6/2008
EP	1974771	A1	10/2008
EP	1498082	B1	12/2008
EP	1832259	B1	6/2009
EP	2074959	A1	7/2009
EP	2298154	A2	3/2011
GB	2032221	A	4/1980
GB	2379878	B	11/2004
GB	2447767	B	8/2011
JP	62-292153	A	12/1987
JP	63-315049	A	12/1988
JP	02-71510	U	5/1990
JP	04-25707	U	2/1992
JP	4-30508	U	3/1992
JP	6-104503	A	4/1994
JP	6-705081	A	8/1994
JP	H 7-508910	A	10/1995
JP	7-308323	A	11/1995
JP	8-24266	A	1/1996
JP	8-275951	A	10/1996
JP	H 09-503146	A	3/1997
JP	10-295700	A	11/1998
JP	11-253451	A	9/1999
JP	2000-041991	A	2/2000
JP	2000-070279	A	3/2000
JP	2001-309925	A	11/2001
JP	2002-186901	A	7/2002
JP	2002-263579	A	9/2002
JP	2003-510158	A	3/2003
JP	2003-126110	A	5/2003
JP	2003-310627	A	5/2003
JP	2003-339730	A	12/2003
JP	2005027026	A	1/2005
JP	2005-066316	A	3/2005
JP	2005-074088	A	3/2005
JP	2005-534451	A	11/2005
JP	2006-158525	A	6/2006
JP	2006217716	A	8/2006
JP	2007-050181	A	3/2007
JP	2007-229454	A	9/2007
JP	2008-508065	A	3/2008
JP	2008-119250	A	5/2008
JP	2009-511206	A	3/2009
JP	2009-523567	A	6/2009
WO	WO 92/22259	A2	12/1992
WO	WO 93/14708	A1	8/1993
WO	WO 94/21183	A1	9/1994
WO	WO 95/09572	A1	4/1995
WO	WO 98/26739	A1	6/1998
WO	WO 98/37815	A1	9/1998
WO	WO 01/54590	A1	8/2001
WO	WO 01/95810	A2	12/2001
WO	WO 2004/037095	A2	5/2004
WO	WO 2005/122917	A1	12/2005
WO	WO 2006/012797	A1	2/2006
WO	WO 2006/042210	A2	4/2006
WO	WO 2006/058223	A2	6/2006
WO	WO 2006/063199	A2	6/2006
WO	WO 2006/083988	A1	8/2006
WO	WO 2006/129465	A1	12/2006
WO	WO 2007/008710	A2	1/2007
WO	WO 2007/047531	A2	4/2007
WO	WO 2007/087272	A2	8/2007
WO	WO 2007/143665	A2	12/2007
WO	WO 2008/016886	A2	2/2008
WO	WO 2008/042021	A1	4/2008
WO	WO 2008/130793	A1	10/2008
WO	WO 2009/018406	A2	2/2009
WO	WO 2009/027065	A1	3/2009
WO	WO 2011/144911	A1	11/2011

OTHER PUBLICATIONS

U.S. Appl. No. 12/703,860, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,864, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,866, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,870, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,875, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,877, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,879, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,885, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,893, filed Feb. 11, 2010.
U.S. Appl. No. 12/703,899, filed Feb. 11, 2010.
U.S. Appl. No. 29/361,917, filed May 17, 2010.
U.S. Appl. No. 12/896,351, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,479, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,360, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,345, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,384, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,467, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,451, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,470, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,411, filed Oct. 1, 2010.
U.S. Appl. No. 12/896,420, filed Oct. 1, 2010.
Huston et al., "Magnetic and Magnetostrictive Properties of Cube Textured Nickel for Magnetostrictive Transducer Applications," IEEE Transactions on Magnetics, vol. 9(4), pp. 636-640 (Dec. 1973).

(56) **References Cited**

OTHER PUBLICATIONS

Incropera et al., Fundamentals of Heat and Mass Transfer, Wiley, New York (1990). (Book—not attached).
F. A. Duck, "Optical Properties of Tissue Including Ultraviolet and Infrared Radiation," pp. 43-71 in *Physical Properties of Tissue* (1990).
Orr et al., "Overview of Bioheat Transfer," pp. 367-384 in Optical-Thermal Response of Laser-Irradiated Tissue, A. J. Welch and M. J. C. van GeMert, eds., Plenum, New York (1995).
Campbell et al, "Thermal Imaging in Surgery," p. 19-3, in *Medical Infrared Imaging*, N. A. Diakides and J. D. Bronzino, Eds. (2008).
U.S. Appl. No. 29/402,697, filed Sep. 26, 2011.
U.S. Appl. No. 29/402,699, filed Sep. 26, 2011.
U.S. Appl. No. 29/402,700, filed Sep. 26, 2011.
U.S. Appl. No. 29/402,701, filed Sep. 26, 2011.
U.S. Appl. No. 13/251,766, filed Oct. 3, 2011.
U.S. Appl. No. 29/404,676, filed Oct. 24, 2011.
Technology Overview, printed from www.harmonicscalpel.com, Internet site, website accessed on Jun. 13, 2007, (3 pages).
Sherrit et al., "Novel Horn Designs for Ultrasonic/Sonic Cleaning Welding, Soldering, Cutting and Drilling," Proc. SPIE Smart Structures Conference, vol. 4701, Paper No. 34, San Diego, CA, pp. 353-360, Mar. 2002.
AST Products, Inc., "Principles of Video Contact Angle Analysis," 20 pages, (2006).
Lim et al., "A Review of Mechanism Used in Laparoscopic Surgical Instruments," Mechanism and Machine Theory, vol. 38, pp. 1133-1147, (2003).
Gooch et al., "Recommended Infection-Control Practices for Dentistry, 1993," Published: May 28, 1993; [retrieved on Aug. 23, 2008]. Retrieved from the internet: URL: http//wonder.cdc.gov/wonder/prevguid/p0000191/p0000191.asp (15 pages).
U.S. Appl. No. 29/327,737, filed Nov. 12, 2008.
U.S. Appl. No. 12/469,293, filed May 20, 2009.
U.S. Appl. No. 12/469,308, filed May 20, 2009.
U.S. Appl. No. 12/490,906, filed Jun. 24, 2009.
U.S. Appl. No. 12/490,922, filed Jun. 24, 2009.
U.S. Appl. No. 12/490,933, filed Jun. 24, 2009.
U.S. Appl. No. 12/490,948, filed Jun. 24, 2009.
U.S. Appl. No. 12/503,775, filed Jul. 15, 2009.
U.S. Appl. No. 12/503,769, filed Jul. 15, 2009.
U.S. Appl. No. 12/503,770, filed Jul. 15, 2009.
International Preliminary Report on Patentability for PCT/US2010/041663, Jan. 17, 2012 (8 pages).
U.S. Appl. No. 13/294,576, filed Nov. 11, 2011.
International Search Report for PCT/US2010/041663, Feb. 17, 2011 (8 pages).
U.S. Appl. No. 13/448,175, filed Apr. 16, 2012.
U.S. Appl. No. 13/151,181, filed Jun. 2, 2011.
U.S. Appl. No. 13/369,561, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,569, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,578, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,584, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,588, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,594, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,601, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,609, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,629, filed Feb. 9, 2012.
U.S. Appl. No. 13/369,666, filed Feb. 9, 2012.
U.S. Appl. No. 13/545,292, filed Jul. 10, 2012.
U.S. Appl. No. 13/584,020, filed Aug. 13, 2012.
U.S. Appl. No. 13/584,445, filed Aug. 13, 2012.
U.S. Appl. No. 13/584,878, filed Aug. 14, 2012.
U.S. Appl. No. 13/585,124, filed Aug. 14, 2012.
U.S. Appl. No. 13/585,292, filed Aug. 14, 2012.
U.S. Appl. No. 13/849,627, filed Mar. 25, 2013.

* cited by examiner

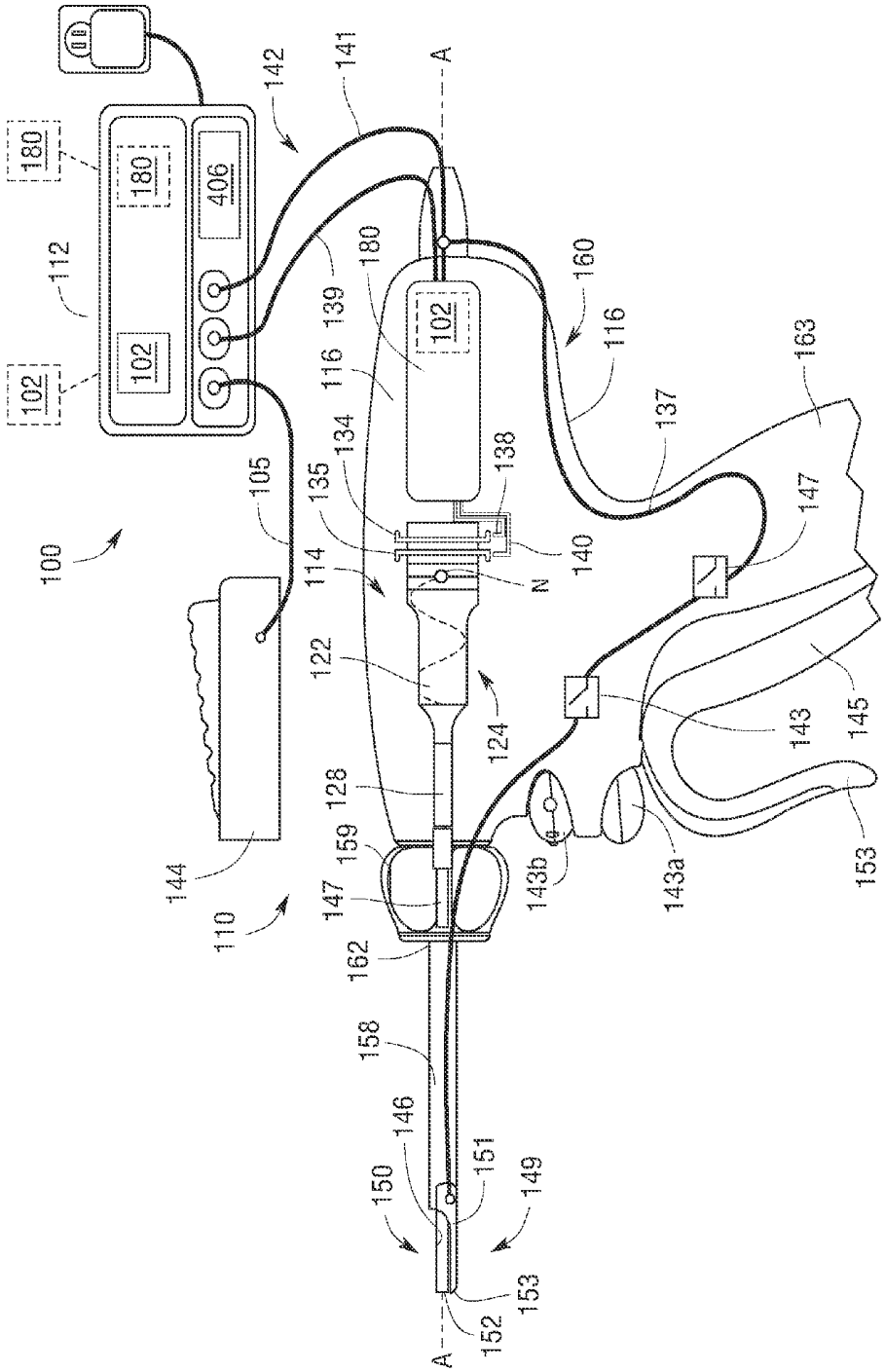

100
102
180
112
406
142
141
A
139
160
116
137
163
105
135
134
138
140
147
114
N
122
124
143
145
128
159
144
110
147
143b
143a
153
162
158
146
151
150
149
153
152
A

Fig. 1

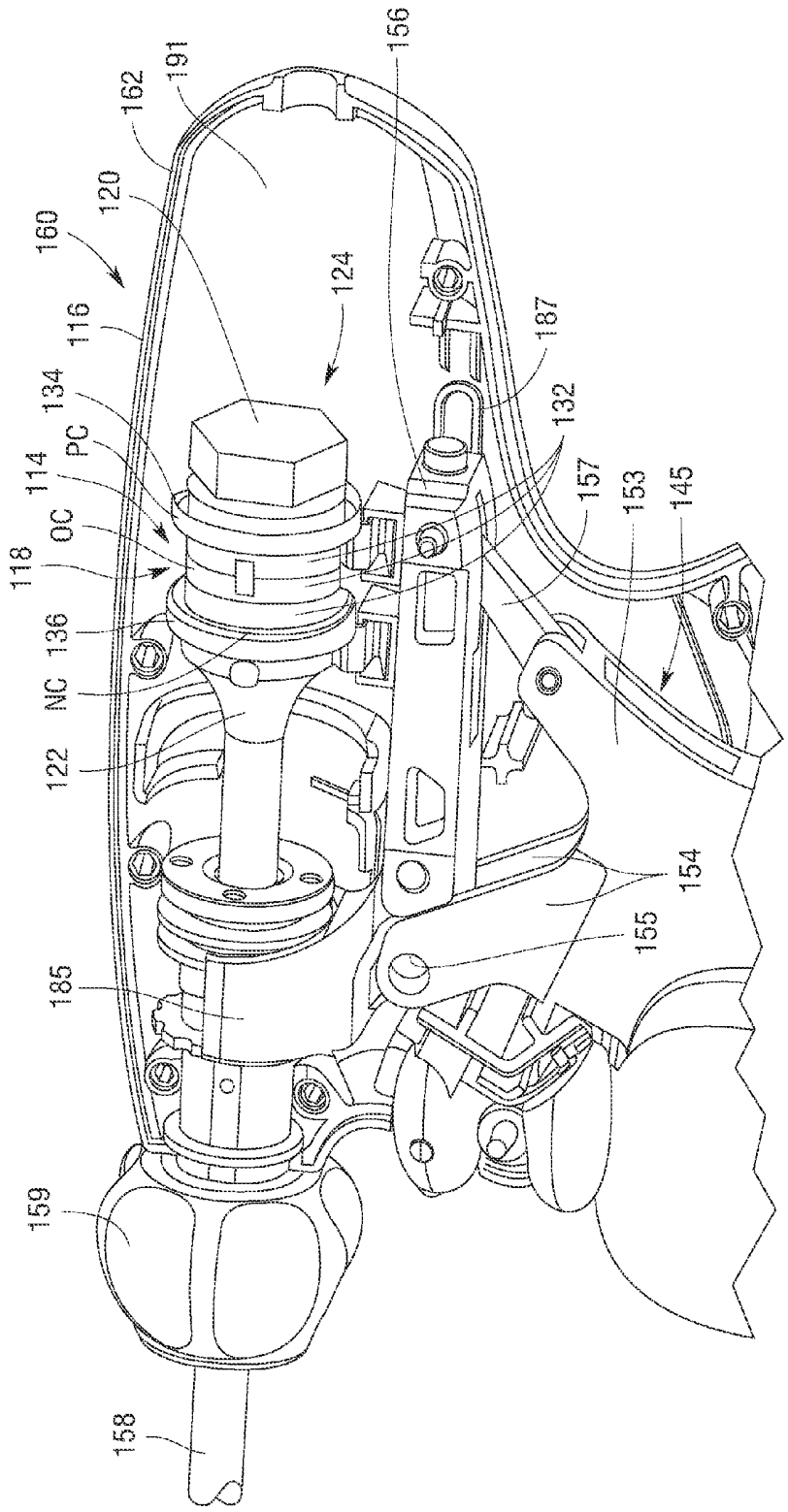

156
191
162
120
160
124
116
187
134
132
PC
114
157
153
145
OC
118
136
NC
122
154
155
185
159
158

Fig. 2

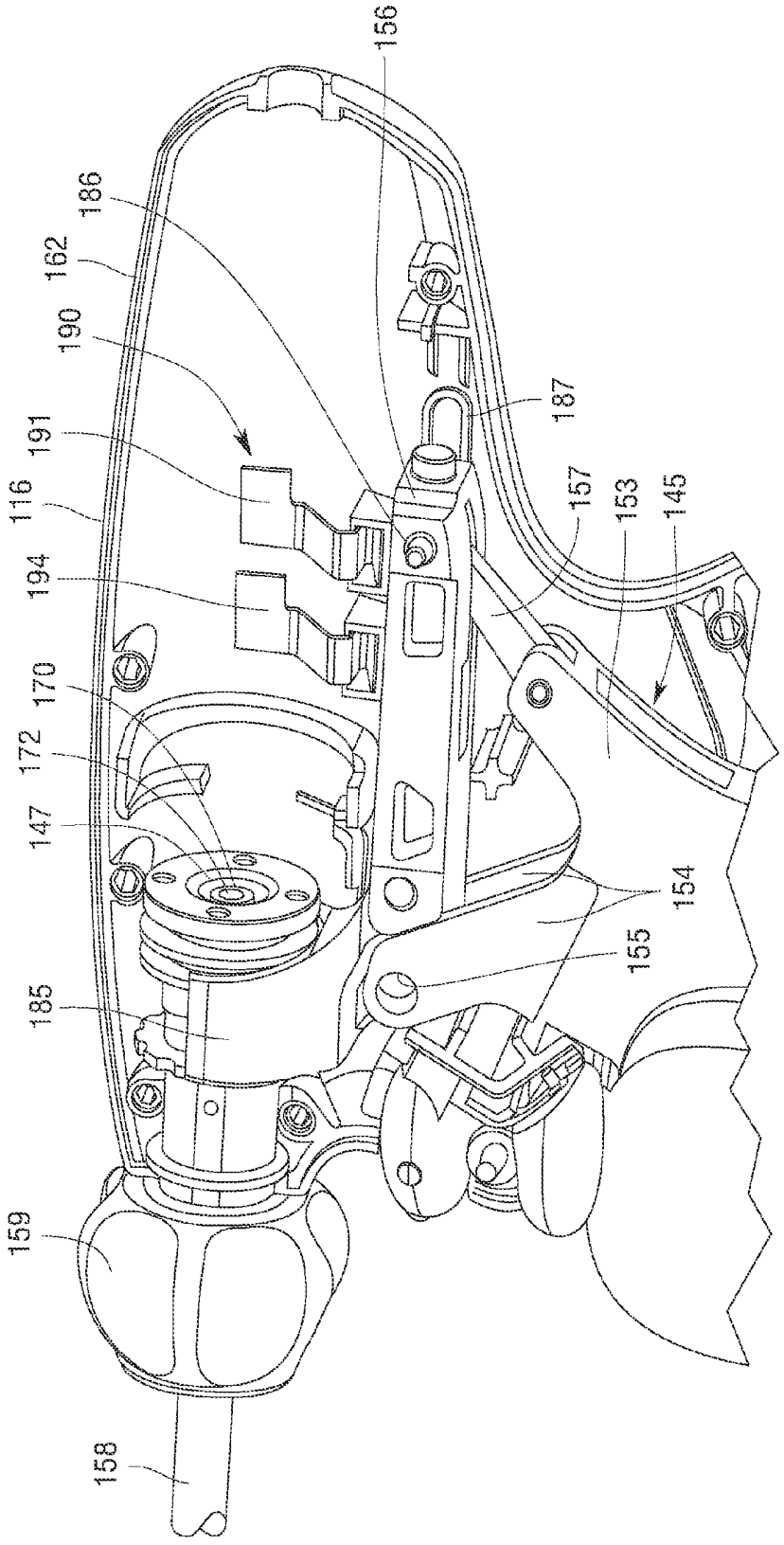

156
186
162
190
187
191
157
153
145
116
194
170
172
147
154
155
185
159
158

Fig. 3

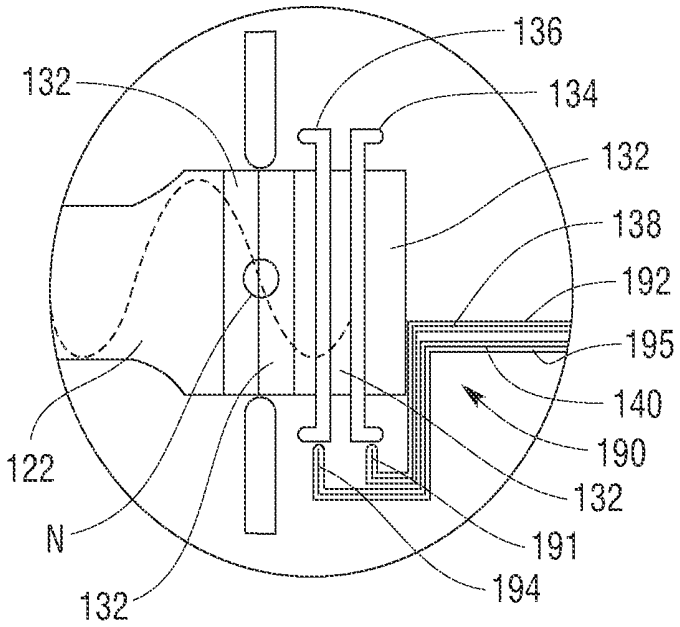


Fig.4

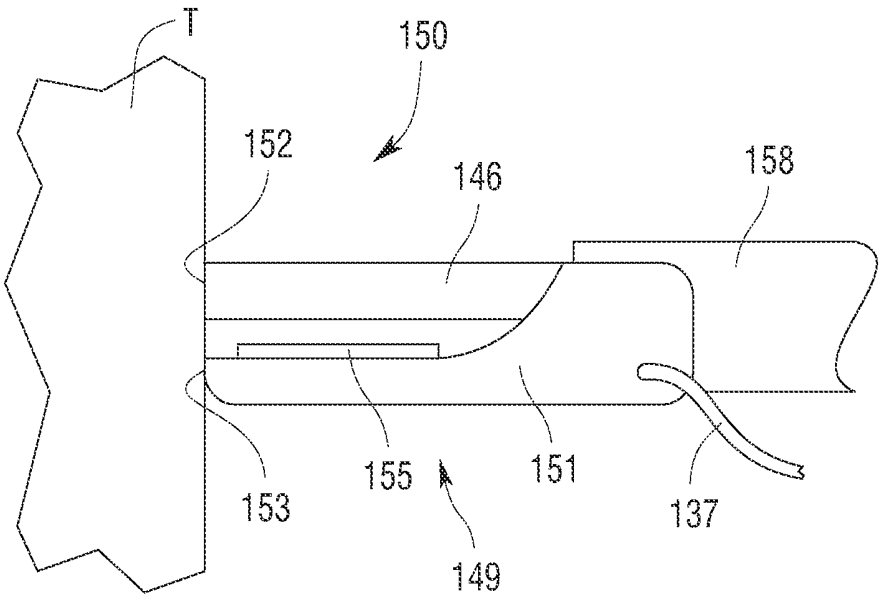


Fig.5

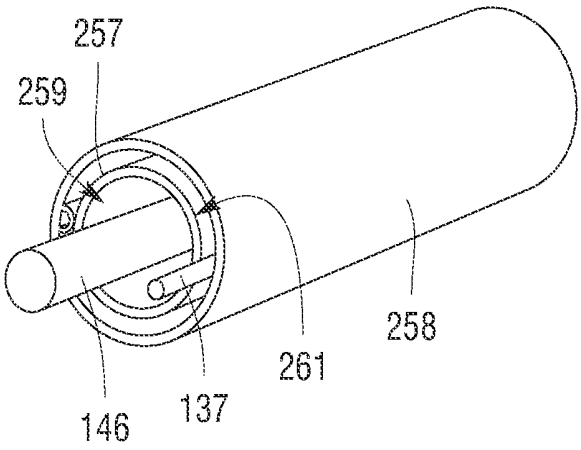


Fig.6

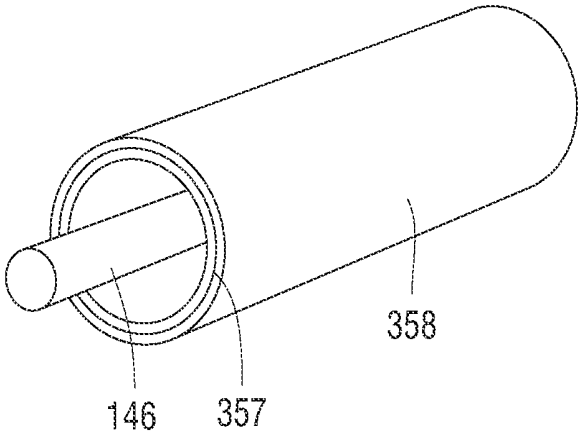


Fig.7

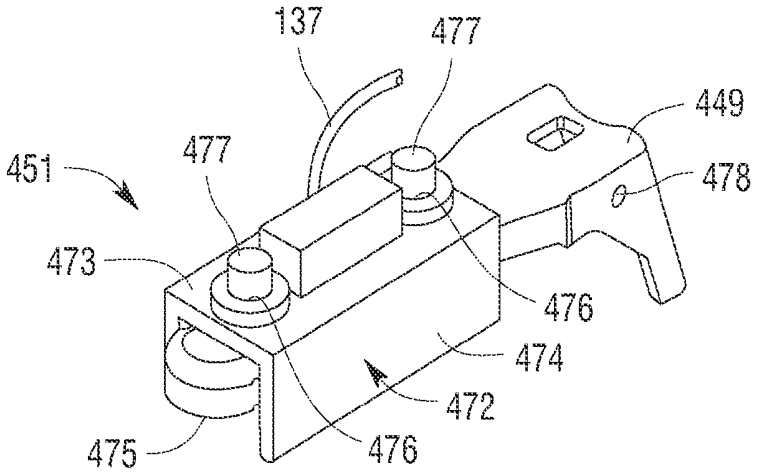

137
477
449
451
477
478
473
476
474
472
475
476

Fig.8

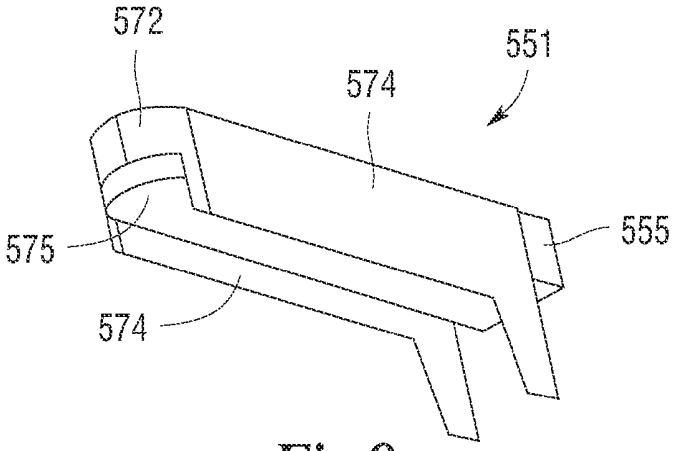

572
551
574
555
575
574

Fig.9

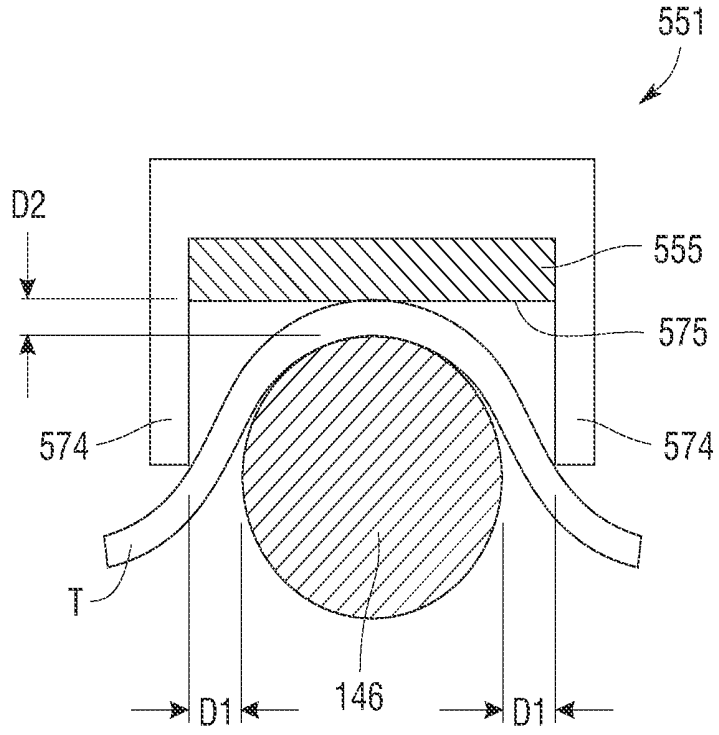


Fig.10

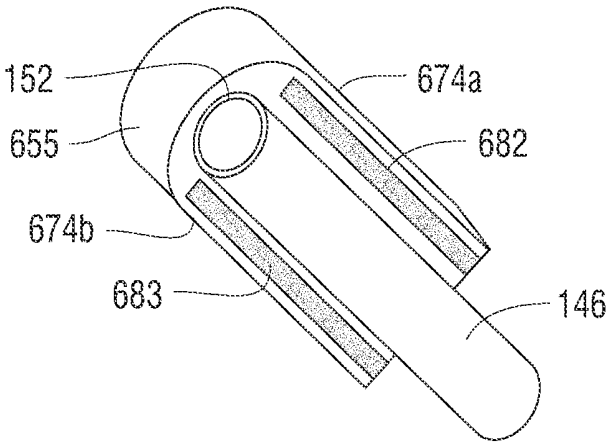


Fig.11

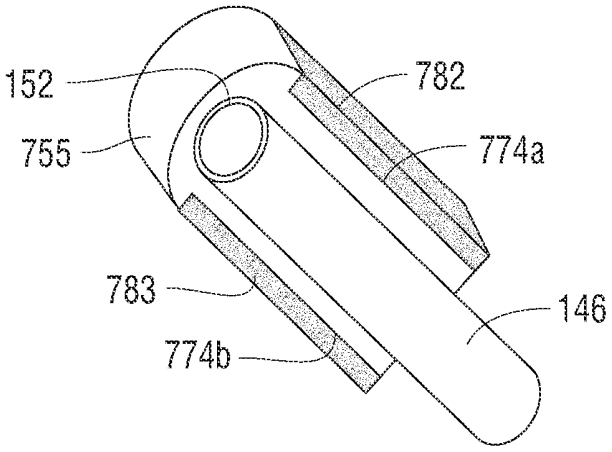


Fig.12

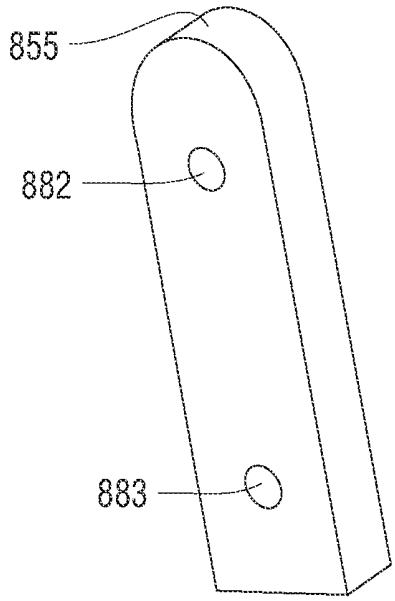


Fig.13

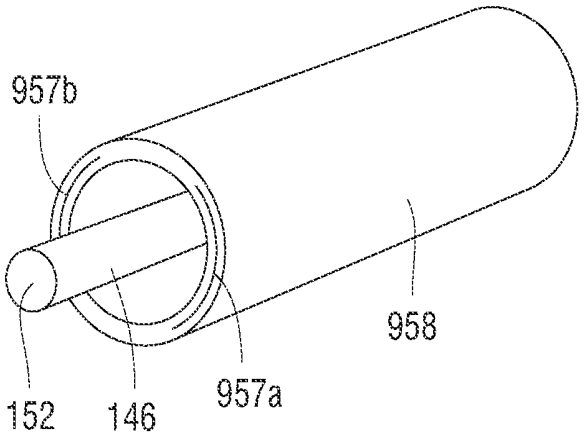


Fig.14

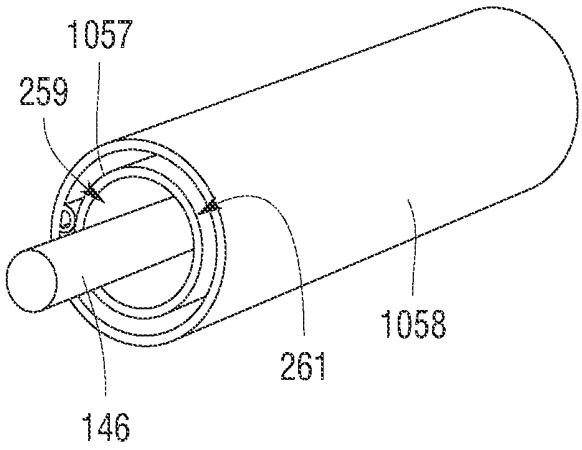


Fig.15

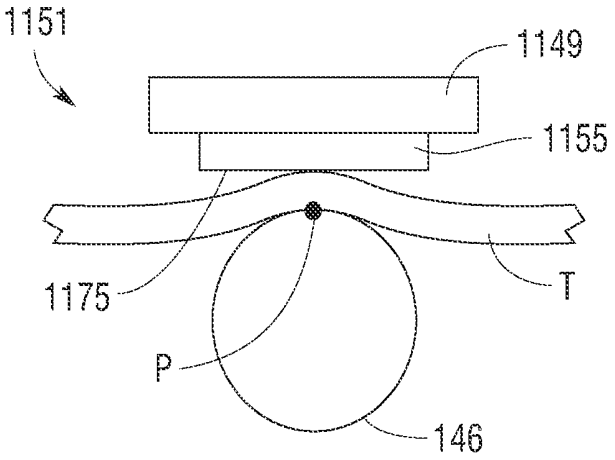

1151
1149
1155
1175
T
P
146

Fig.16

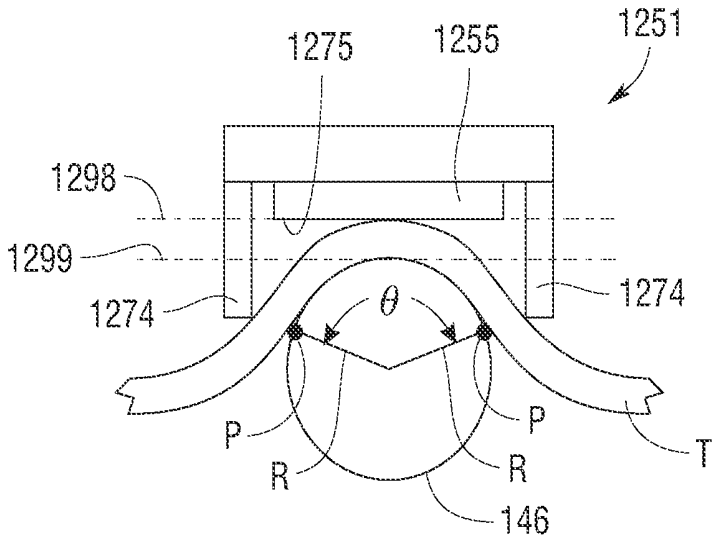

1275
1255
1251
1298
1299
1274
θ
1274
P
P
R
R
T
146

Fig.17

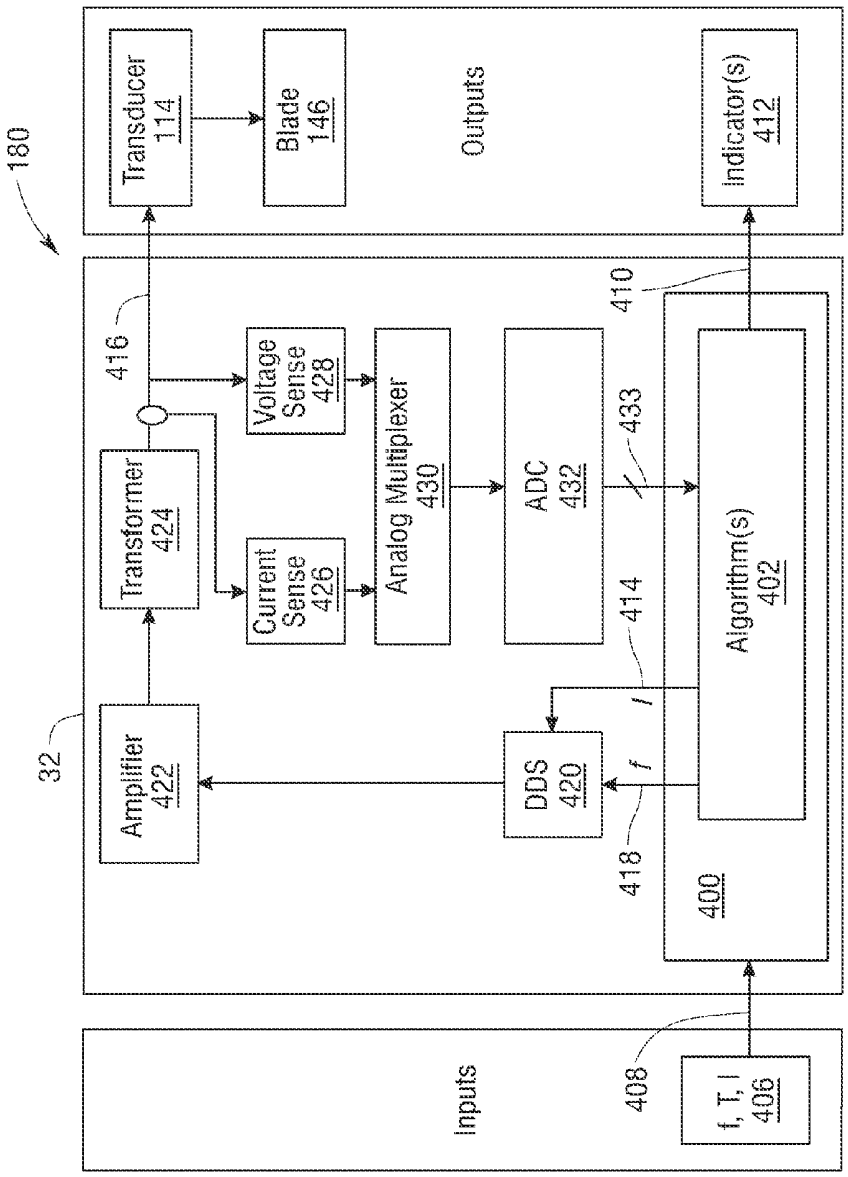

180
Transducer 114
Blade 146
Outputs
Indicator(s) 412
410
416
Voltage Sense 428
Analog Multiplexer 430
ADC 432
433
Transformer 424
Current Sense 426
414
Algorithm(s) 402
32
Amplifier 422
DDS 420
I
f
418
400
Inputs
408
f, T, I 406

Fig.18

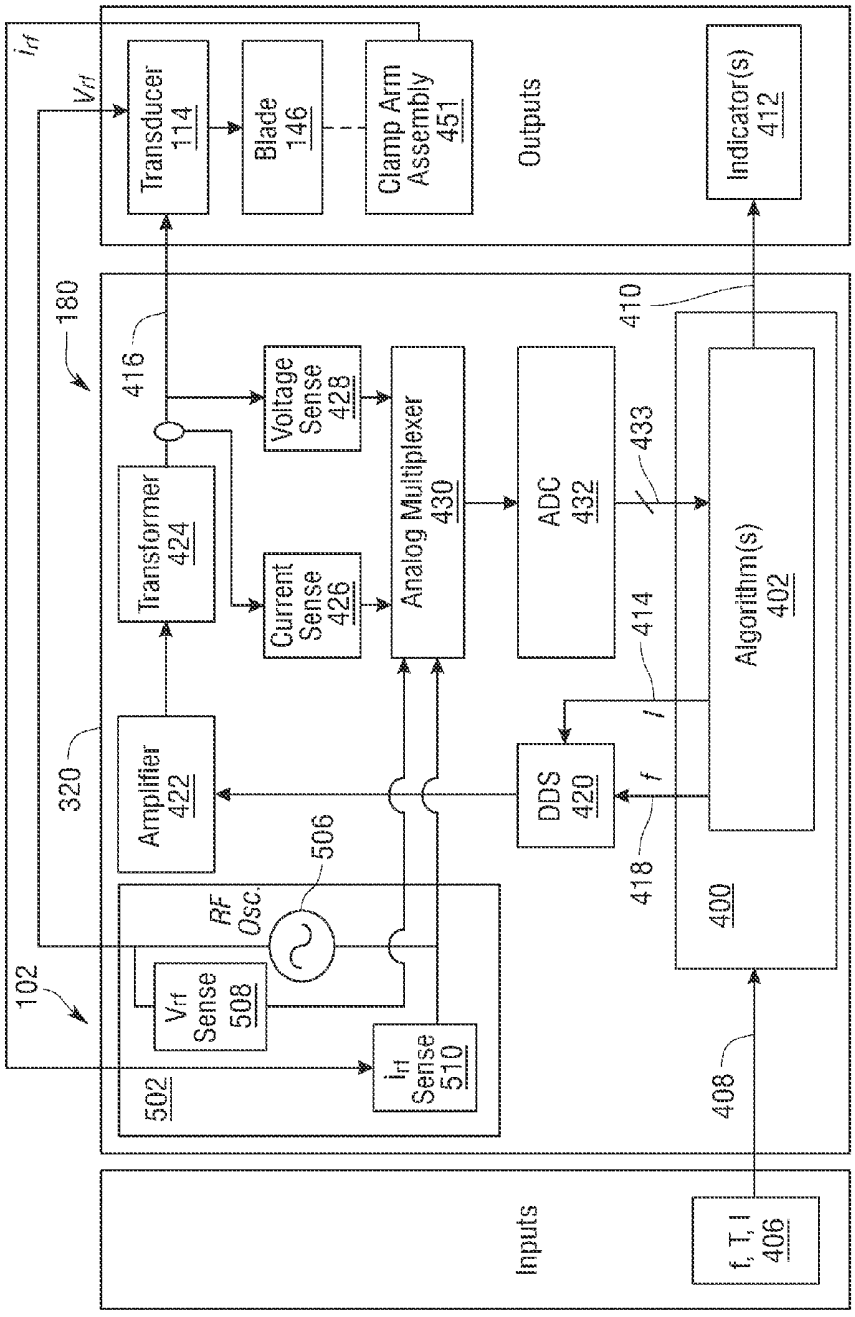

i_{rf}
V_{rf}
Transducer 114
Blade 146
Clamp Arm Assembly 451
Outputs
Indicator(s) 412
180
416
Voltage Sense 428
Transformer 424
Current Sense 426
Analog Multiplexer 430
ADC 432
433
410
Algorithm(s) 402
414
I
f
DDS 420
Amplifier 422
320
506
RF Osc.
418
400
102
V_{rf} Sense 508
i_{rf} Sense 510
502
408
Inputs
f, T, I 406

Fig. 19

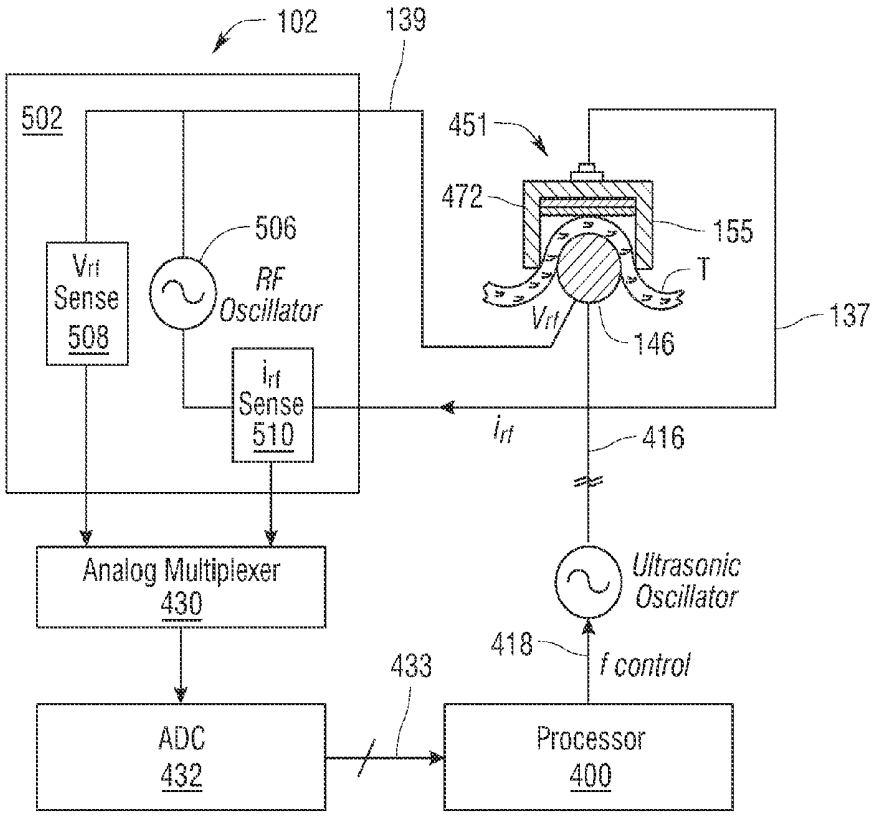

102
139
502
451
472
155
T
506
RF
Oscillator
Vrf
Sense
508
irf
Sense
510
Vrf
146
137
irf
416
Analog Multiplexer
430
Ultrasonic
Oscillator
418
f control
433
ADC
432
Processor
400

Fig.20

IMPEDANCE MONITORING APPARATUS, SYSTEM, AND METHOD FOR ULTRASONIC SURGICAL INSTRUMENTS

BACKGROUND

The present disclosure generally relates to ultrasonic surgical systems and, more particularly, to ultrasonic systems that allow surgeons to perform cutting and coagulation.

Ultrasonic surgical instruments are finding increasingly widespread applications in surgical procedures by virtue of the unique performance characteristics of such instruments. Depending upon specific instrument configurations and operational parameters, ultrasonic surgical instruments can provide substantially simultaneous cutting of tissue and homeostasis by coagulation, desirably minimizing patient trauma. The cutting action is typically realized by an-end effector, or blade tip, at the distal end of the instrument, which transmits ultrasonic energy to tissue brought into contact with the end effector. Ultrasonic instruments of this nature can be configured for open surgical use, laparoscopic, or endoscopic surgical procedures including robotic-assisted procedures.

Some surgical instruments utilize ultrasonic energy for both precise cutting and controlled coagulation. Ultrasonic energy cuts and coagulates by using lower temperatures than those used by electrosurgery. Vibrating at high frequencies (e.g., 55,500 times per second), the ultrasonic blade denatures protein in the tissue to form a sticky coagulum. Pressure exerted on tissue with the blade surface collapses blood vessels and allows the coagulum to form a hemostatic seal. The precision of cutting and coagulation is controlled by the surgeon's technique and adjusting the power level, blade edge, tissue traction, and blade pressure.

A primary challenge of ultrasonic technology for medical devices, however, continues to be sealing of blood vessels. Work done by the applicant and others has shown that optimum vessel sealing occurs when the inner muscle layer of a vessel is separated and moved away from the adventitia layer prior to the application of standard ultrasonic energy. Current efforts to achieve this separation have involved increasing the clamp force applied to the vessel.

Furthermore, the user does not always have visual feedback of the tissue being cut. Accordingly, it would be desirable to provide some form of feedback to indicate to the user that the cut is complete when visual feedback is unavailable. Moreover, without some form of feedback indicator to indicate that the cut is complete, the user may continue to activate the harmonic instrument even though the cut is complete, which cause possible damage to the harmonic instrument and surrounding tissue by the heat that is generated exponentially when activating a harmonic instrument with nothing between the jaws.

It would be desirable to provide an ultrasonic surgical instrument that overcomes some of the deficiencies of current instruments. The ultrasonic surgical instrument described herein overcomes those deficiencies.

SUMMARY

In one general aspect, various embodiments are directed to an ultrasonic surgical instrument that comprises a transducer configured to produce vibrations along a longitudinal axis at a predetermined frequency. In various embodiments, an ultrasonic blade extends along the longitudinal axis and is coupled to the transducer. In various embodiments, the ultrasonic blade includes a body having a proximal end and a distal end, wherein the distal end is movable relative to the longitudinal axis by the vibrations produced by the transducer.

In one general aspect, various embodiments are directed to a surgical instrument that can supply mechanical energy and electrical energy to an end effector of the surgical instrument. The surgical instrument comprises an ultrasonic generator module coupled to an ultrasonic drive system. The ultrasonic drive system comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide. The ultrasonic drive system is configured to resonate mechanically at a resonant frequency. The ultrasonic generator module is to generate a first ultrasonic drive signal. An electronic circuit is coupled to the ultrasonic generator module to monitor an electrical characteristic of the ultrasonic drive system. A processor is coupled to the electronic circuit to control the ultrasonic drive signal in response to the monitored electrical characteristic of the ultrasonic drive system.

FIGURES

The features of various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with further objects and advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings as follows.

FIG. **1** illustrates a surgical instrument comprising an ultrasonic surgical instrument system and an electrosurgery surgical instrument system.

FIG. **2** illustrates a portion of a handpiece assembly of the surgical instrument of FIG. **1** with a portion of the handpiece housing removed and an acoustic assembly operably engaged with a waveguide of the surgical instrument.

FIG. **3** illustrates the handpiece assembly of FIG. **2** with the acoustic assembly removed to illustrate positive and negative electrode contacts configured to supply the acoustic assembly with power.

FIG. **4** is a detail view of a portion of the acoustic assembly of FIG. **2**.

FIG. **5** is a detail view of the end effector of the ultrasonic surgical instrument of FIG. **1**.

FIG. **6** is a perspective view of an embodiment of a sheath assembly comprising an inner sheath and an outer sheath which can define a first passageway for a waveguide of an ultrasonic instrument and a second passageway for a return conductor.

FIG. **7** is a perspective view of an embodiment of a sheath configured to surround at least a portion of a waveguide of an ultrasonic surgical instrument, wherein a conductor can be embedded in at least a portion of a sheath.

FIG. **8** is a perspective view of an embodiment of a clamp arm assembly configured to hold tissue against a waveguide of an ultrasonic surgical instrument.

FIG. **9** is a perspective view of another embodiment of a clamp arm assembly having downwardly-extending walls which extend below a tissue-contacting surface.

FIG. **10** is a cross-sectional end view of the clamp arm assembly of FIG. **9** positioned in a closed position relative to a waveguide of an ultrasonic surgical instrument.

FIG. **11** is a perspective view of a tissue-contacting pad of a clamp arm assembly, wherein the pad includes first and second electrodes embedded therein and positioned relative to a waveguide of an ultrasonic surgical instrument.

FIG. **12** is a perspective view of another embodiment of a tissue-contacting pad of a clamp arm assembly, wherein the

pad includes first and second electrodes mounted thereto and positioned relative to a waveguide of an ultrasonic surgical instrument.

FIG. **13** is a perspective view of another embodiment of a tissue-contacting pad of a clamp arm assembly, wherein the pad includes first and second point electrodes embedded therein.

FIG. **14** is a perspective view of an embodiment of a sheath configured to surround at least a portion of a waveguide of an ultrasonic surgical instrument, wherein first and second conductors can be embedded in at least a portion of a sheath.

FIG. **15** is a perspective view of an embodiment of a sheath assembly comprising an inner sheath and an outer sheath, wherein the inner sheath and the outer sheath may comprise first and second conductors.

FIG. **16** is an end view of a clamp arm assembly holding tissue against a waveguide.

FIG. **17** is an end view of an alternative embodiment of a clamp arm assembly holding tissue against a waveguide.

FIG. **18** illustrates one embodiment of a drive system of an ultrasonic generator module, which creates the ultrasonic electrical signal for driving an ultrasonic transducer.

FIG. **19** illustrates one embodiment of a drive system of a generator comprising a tissue impedance module.

FIG. **20** is a schematic diagram of a tissue impedance module coupled to a blade and a clamp arm assembly with tissue located therebetween.

DESCRIPTION

Before explaining various embodiments of ultrasonic surgical instruments in detail, it should be noted that the illustrative embodiments are not limited in application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description. The illustrative embodiments may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Further, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments for the convenience of the reader and are not for the purpose of limitation thereof.

Further, it is understood that any one or more of the following-described embodiments, expressions of embodiments, examples, can be combined with any one or more of the other following-described embodiments, expressions of embodiments, and examples.

Various embodiments are directed to improved ultrasonic surgical instruments configured for effecting tissue dissecting, cutting, and/or coagulation during surgical procedures. In one embodiment, an ultrasonic surgical instrument apparatus is configured for use in open surgical procedures, but has applications in other types of surgery, such as laparoscopic, endoscopic, and robotic-assisted procedures. Versatile use is facilitated by selective use of ultrasonic energy.

It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician gripping a handpiece assembly. Thus, an end effector is distal with respect to the more proximal handpiece assembly. It will be further appreciated that, for convenience and clarity, spatial terms such as "top" and "bottom" also are used herein with respect to the clinician gripping the handpiece assembly. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

The various embodiments will be described in combination with an ultrasonic instrument as described herein. Such description is provided by way of example, and not limitation, and is not intended to limit the scope and applications thereof. For example, any one of the described embodiments is useful in combination with a multitude of ultrasonic instruments including those described in, for example, U.S. Pat. Nos. 5,322,055; 5,449,370; 5,630,420; 5,935,144; 5,938,633; 5,944,737; 5,954,736; 6,278,218; 6,283,981; 6,309,400; 6,325,811; and 6,436,115, wherein the disclosure of each of the patents is herein incorporated by reference. Also incorporated by reference in its entirety is commonly-owned, co-pending U.S. patent application Ser. No. 11/726,625, entitled ULTRASONIC SURGICAL INSTRUMENTS, filed on Mar. 22, 2007. The disclosure of each of the following commonly-owned and contemporaneously-filed U.S. Patent Applications is incorporated herein by reference in its entirety:

(1) U.S. patent application Ser. No. 12/503,769, entitled "ULTRASONIC SURGICAL INSTRUMENTS," now U.S. Pat. App. Pub. No. 2011/0015631;

(2) U.S. patent application Ser. No. 12/503,770, entitled "ULTRASONIC SURGICAL INSTRUMENTS," now U.S. Pat. App. Pub. No. 2011/0015660; and

(3) U.S. patent application Ser. No. 12/503,775, entitled "ULTRASONIC DEVICE FOR CUTTING AND COAGULATING WITH STEPPED OUTPUT," now U.S. Pat. No. 8,058,771.

As will become apparent from the following description, it is contemplated that embodiments of the surgical instrument described herein may be used in association with an oscillator module of a surgical system, whereby ultrasonic energy from the oscillator module provides the desired ultrasonic actuation for the present surgical instrument. It is also contemplated that embodiments of the surgical instrument described herein may be used in association with a signal generator module of a surgical system, whereby electrical energy in the form of radio frequencies (RF), for example, is used to provide feedback to the user regarding the surgical instrument. The ultrasonic oscillator and/or the signal generator modules may be non-detachably integrated with the surgical instrument or may be provided as separate components, which can be electrically attachable to the surgical instrument.

One embodiment of the present surgical apparatus is particularly configured for disposable use by virtue of its straightforward construction. However, it is also contemplated that other embodiments of the present surgical instrument can be configured for non-disposable or multiple uses. Detachable connection of the present surgical instrument with an associated oscillator and signal generator unit is presently disclosed for single-patient use for illustrative purposes only. However, non-detachable integrated connection of the present surgical instrument with an associated oscillator and/or signal generator unit is also contemplated. Accordingly, various embodiments of the presently described surgical instruments may be configured for single use and/or multiple uses and with either detachable and/or non-detachable integral oscillator and/or signal generator modules, without limitation. All combinations of such configurations are contemplated to be within the scope of the present disclosure.

FIG. **1** illustrates one embodiment of a surgical system **100**. The surgical system **100** includes a generator **112** and an ultrasonic surgical instrument **110**. The generator **112** is connected to an ultrasonic transducer **114** portion of the ultrasonic surgical instrument **110** via a suitable transmission medium such as a cable **142**. In one embodiment, the generator **112** is coupled to an ultrasonic generator module **180** and a signal generator module **102**. In various embodiments, the ultrasonic generator module **180** and/or the signal generator module **102** each may be formed integrally with the generator

112 or may be provided as a separate circuit modules electrically coupled to the generator 112 (shown in phantom to illustrate this option). In one embodiment, the signal generator module 102 may be formed integrally with the ultrasonic generator module 180. Although in the presently disclosed embodiment, the generator 112 is shown separate from the surgical instrument 110, in one embodiment, the generator 112 may be formed integrally with the surgical instrument 110 to form a unitary surgical system 100. The generator 112 comprises an input device 406 located on a front panel of the generator 112 console. The input device 406 may comprise any suitable device that generates signals suitable for programming the operation of the generator 112 as subsequently described with reference to FIG. 18. Still with reference to FIG. 1, the cable 142 may comprise multiple electrical conductors 139, 141 for the application of electrical energy to positive (+) and negative (-) electrodes of the ultrasonic transducer 114. It will be noted that, in some applications, the ultrasonic transducer 114 may be referred to as a "handle assembly" because the surgical instrument 110 of the surgical system 100 may be configured such that a surgeon may grasp and manipulate the ultrasonic transducer 114 during various procedures and operations.

In one embodiment, the generator 112 may be implemented as an electro surgery unit (ESU) capable of supplying power sufficient to perform bipolar electrosurgery using radio frequency (RF) energy. In one embodiment, the ESU can be a bipolar ERBE ICC 350 sold by ERBE USA, Inc. of Marietta, Ga. In bipolar electrosurgery applications, as previously discussed, a surgical instrument having an active electrode and a return electrode can be utilized, wherein the active electrode and the return electrode can be positioned against, or adjacent to, the tissue to be treated such that current can flow from the active electrode to the return electrode through the tissue. Accordingly, the generator 112 may be configured for therapeutic purposes by applying electrical energy to the tissue T sufficient for treating the tissue (e.g., cauterization).

In one embodiment, the signal generator module 102 may be configured to deliver a subtherapeutic RF signal to implement a tissue impedance measurement module. In one embodiment, the signal generator module 102 comprises a bipolar radio frequency generator as described in more detail below. In one embodiment, signal generator module 102 may be configured to monitor the electrical impedance Z_t of tissue T (FIG. 5) and to control the characteristics of time and power level based on the tissue impedance Z_t. The tissue impedance Z_t may be determined by applying the subtherapeutic RF signal to the tissue T and measuring the current through the tissue T (FIGS. 5, 10, 16, 17) by way of a return electrode provided on a clamp member 151, as discussed in more detail below. Accordingly, the signal generator module 102 may be configured for subtherapeutic purposes for measuring the impedance or other electrical characteristics of the tissue T. Techniques and circuit configurations for measuring the impedance or other electrical characteristics of the tissue T are discussed in more detail below with reference to FIGS. 18-20 below.

A suitable ultrasonic generator module 180 may be configured to functionally operate in a manner similar to the GEN 300 sold by Ethicon Endo-Surgery, Inc. of Cincinnati, Ohio as is disclosed in one or more of the following U.S. patents, all of which are incorporated by reference herein: U.S. Pat. No. 6,480,796 (Method for Improving the Start Up of an Ultrasonic System Under Zero Load Conditions); U.S. Pat. No. 6,537,291 (Method for Detecting a Loose Blade in a Handle Connected to an Ultrasonic Surgical System); U.S. Pat. No. 6,626,926 (Method for Driving an Ultrasonic System to Improve Acquisition of Blade Resonance Frequency at Startup); U.S. Pat. No. 6,633,234 (Method for Detecting Blade Breakage Using Rate and/or Impedance Information); U.S. Pat. No. 6,662,127 (Method for Detecting Presence of a Blade in an Ultrasonic System); U.S. Pat. No. 6,678,621 (Output Displacement Control Using Phase Margin in an Ultrasonic Surgical Handle); U.S. Pat. No. 6,679,899 (Method for Detecting Transverse Vibrations in an Ultrasonic Handle); U.S. Pat. No. 6,908,472 (Apparatus and Method for Altering Generator Functions in an Ultrasonic Surgical System); U.S. Pat. No. 6,977,495 (Detection Circuitry for Surgical Handpiece System); U.S. Pat. No. 7,077,853 (Method for Calculating Transducer Capacitance to Determine Transducer Temperature); U.S. Pat. No. 7,179,271 (Method for Driving an Ultrasonic System to Improve Acquisition of Blade Resonance Frequency at Startup); and U.S. Pat. No. 7,273,483 (Apparatus and Method for Alerting Generator Function in an Ultrasonic Surgical System).

In accordance with the described embodiments, the ultrasonic generator module 180 produces electrical signals of a particular voltage, current, and frequency, e.g. 55,500 cycles per second (Hz). The generator is 112 connected by the cable 142 to the ultrasonic generator module 180 in the handpiece assembly 160, which contains piezoceramic elements forming the ultrasonic transducer 114. In response to a switch 143 on the handpiece assembly 160 or a foot switch 144 connected to the generator 112 by another cable 105 the generator signal is applied to the transducer 114, which causes a longitudinal vibration of its elements. A structure connects the transducer 114 to a surgical blade 146, which is thus vibrated at ultrasonic frequencies when the generator signal is applied to the transducer 114. The structure is designed to resonate at the selected frequency, thus amplifying the motion initiated by the transducer 114. In one embodiment, the generator 112 is configured to produce a particular voltage, current, and/or frequency output signal that can be stepped with high resolution, accuracy, and repeatability.

Referring now to FIGS. 1-4, the handpiece assembly 160 of the surgical instrument system 110 may include a handpiece housing 116 that operably supports the end effector 150. The handpiece housing 116 rotatably supports an acoustic assembly 124 therein. The acoustic assembly 124 includes the ultrasonic transducer 114 that generally includes a transduction portion 118, a first resonator or end-bell 120, a second resonator or fore-bell 122, and ancillary components as shown in FIG. 2. In various embodiments, the ultrasonic energy produced by the transducer 114 can be transmitted through the acoustic assembly 124 to the end effector 150 via the ultrasonic transmission waveguide 147 as shown in FIGS. 1 and 3. In order for the acoustic assembly 124 to deliver energy to the waveguide 147, and ultimately to the end effector 150, the components of the acoustic assembly 124 are acoustically coupled to the blade 146. For example, the distal end of the ultrasonic transducer 114 may be acoustically coupled to the proximal end 170 of the waveguide 146 by a coupling assembly that enables the acoustic assembly 124 to freely rotate relative to the waveguide 147 while transmitting ultrasonic energy thereto.

As shown in FIG. 3, the proximal end 170 of the waveguide 146 may be provided with an aperture 172 therein that is sized to receive a stem (not shown) that protrudes distally from the fore-bell 122. In various embodiments, piezoelectric elements 132, for example, can be compressed between the end-bell 120 and the fore-bell 122 to form a stack of piezoelectric elements when the end-bell 120 and the fore-bell 122 are assembled together as illustrated in FIGS. 2-4. The piezoelectric elements 132 may be fabricated from any suitable

material, such as, for example, lead zirconate-titanate, lead meta-niobate, lead titanate, and/or any suitable piezoelectric crystal material, for example. As shown in FIGS. **2** and **4**, the transducer **114** may comprise electrodes, such as at least one positive electrode **134** and at least one negative electrode **136**, for example, which can be configured to create a voltage potential across the one or more piezoelectric elements **132**. As shown in FIG. **2**, the positive electrode **134** and the negative electrode **136**, and the piezoelectric elements **132** can each be configured with a bore (not shown) that cooperates to form a passageway that can receive a threaded portion of the end-bell **120**. In one embodiment, the positive electrode **134** is provided in the form of an annular ring that has a first circumference "PC" and the negative electrode **136** is also provided in the form of an annular ring that has a second circumference "NC." As shown in FIG. **2**, in various embodiments, the stack of piezoelectric elements **132** may have an outer circumference "OC" that is less than the first and second circumferences "PC" and "NC."

In various embodiments, the handpiece housing **116** may support the ultrasonic generator module **180** and/or the signal generator module **102**. In one embodiment, the ultrasonic generator module **180** may be electrically coupled to an electrical contact assembly **190** that may comprise a positive slip ring contact **191** that is mounted within handpiece housing **116** for rotatable contact with the positive electrode **134**. The positive slip ring contact **191** is electrically coupled to the ultrasonic generator module **180** by a positive ultrasonic supply cable/conductor **192**. The electrical contact assembly **190** may further comprise a negative slip ring contact **194** that is mounted within handpiece housing **116** for rotatable contact with the negative electrode **136**. The negative slip ring contact **194** is electrically coupled to the ultrasonic generator module **180** by a negative ultrasonic supply cable **195**. It will be appreciated that such arrangement enables the acoustic assembly **124** to freely rotate relative to the ultrasonic generator module **180** while remaining in full electrical contact therewith.

In various embodiments, the ultrasonic transmission waveguide **147** may comprise a plurality of stabilizing silicone rings or compliant supports (not shown) positioned at, or at least near, a plurality of nodes. As was discussed above, the silicone rings can dampen undesirable vibration and isolate the ultrasonic energy from the sheath **158** that at least partially surrounds the waveguide **147**, thereby assuring the flow of ultrasonic energy in a longitudinal direction to the distal end **152** of the end effector **150** with maximum efficiency.

As shown in FIGS. **2** and **3**, the sheath **158** can be coupled to a rotation wheel **159** that is rotatably attached to the distal end of the handpiece assembly **160**. The rotation wheel **159** facilitates selective rotation of the sheath **158** and the waveguide **147** relative to the handpiece assembly **160**. The sheath **158** may have an adapter portion **162** that may be threaded or snapped onto the rotation wheel **159**. The rotation wheel **159** may include a flanged portion (not shown) that is snapped into an annular groove in the handpiece assembly **160** to facilitate rotation of the sheath **158** and waveguide **146** relative to the handpiece assembly **160** about axis A-A. In one embodiment, the sheath **158** also includes a hollow tubular portion **164** through which the waveguide **146** extends in the manner described in further detail above. In various embodiments, the adapter **162** of the sheath **158** may be constructed from ULTEM®, for example, and the tubular portion **164** may be fabricated from stainless steel, for example. In at least one embodiment, the ultrasonic transmission waveguide **147** may have polymeric material, for example, surrounding it in order to isolate it from outside contact.

In the embodiment, as shown in FIG. **1**, the ultrasonic generator module **180** is electrically coupled to the electronic signal/radio frequency generator **112** by the cables **139**, **141** which may be housed in a sheath to form the cable **142**. Because the acoustic assembly **124** can freely rotate relative to the ultrasonic generator module **180**, the waveguide **147** and the end effector **150** may be freely rotated about axis A-A relative to the handpiece assembly **160** without causing the cable **142** to undesirably twist and tangle.

As illustrated in FIGS. **2** and **3**, the handpiece assembly **160** may have a pistol grip configuration and operably support a movable trigger assembly **145** that is pivotally supported within the handpiece assembly **160**. To facilitate easy assembly, the handpiece assembly **160** may comprise two housing segments **162** that are coupled together by threaded fasteners, snap features, adhesive. The movable trigger assembly **145** includes a trigger portion **153** that has a pair of spaced attachment arms **154** that each has a hole **155** therethrough. Holes **155** are each sized to receive a corresponding pivot pin (not shown) that protrudes from each of the housing segments **162**. Such arrangement permits the trigger portion **153** to pivot relative to the handpiece assembly **160** about an axis that is substantially transverse to axis A-A.

As shown in FIGS. **2** and **3**, the trigger assembly **145** may comprise an actuation arm **156** that is attached to the trigger portion **153** via an intermediate link **157**. The actuation arm **156** is pivotally coupled (pinned) to the trigger yoke **185**. The arm **156** has a mounting pin **186** extending transversely therethrough that is sized to be slidably received in corresponding elongated cavities **187** formed in the housing segments **162**. See FIGS. **2** and **3**. Such arrangement facilitates the axial movement of the actuation arm **156** within the handpiece assembly **160** in response to pivoting the trigger portion **153**.

In the embodiment illustrated in FIG. **1**, the end effector **150** portion of the surgical system **100** comprises a clamp arm assembly **149** connected at a distal end of the surgical instrument **110**. The blade **146** forms a first (e.g., energizing) electrode and the clamp arm assembly **149** comprises an electrically conductive portion that forms a second (e.g., return) electrode. The signal generator module **102** is coupled to the blade **146** and the clamp arm assembly **149** through a suitable transmission medium such as a cable **137**. The cable **137** comprises multiple electrical conductors for applying a voltage to the tissue and providing a return path for current flowing through the tissue back to the signal generator module **102**. In various embodiments, the signal generator module **102** may be formed integrally with the generator **112** or may be provided as a separate circuit coupled to the generator **112** and, in one embodiment, may be formed integrally with the ultrasonic generator module **180** (shown in phantom to illustrate these options).

In one embodiment, the surgical system **100** illustrated in FIG. **1** may comprise components for selectively energizing an end effector **150** and transmitting mechanical energy thereto and, in addition, selectively energizing the end effector **150** with therapeutic and/or subtherapeutic electrical energy. The surgical instrument **110** may be switchable between a first operating mode in which mechanical energy, or vibrations at ultrasonic frequencies (e.g., 55.5 kHz), are transmitted to the end effector **150** and a second operating mode in which electrical energy (e.g., therapeutic and/or subtherapeutic), or current, is permitted to flow through the end effector **150**. In certain embodiments, referring to FIG. **1**, in a first operating mode of the surgical instrument **110**, for example, the transducer **114** converts electrical energy supplied thereto by the ultrasonic generator module **180** (e.g., an ultrasonic oscillator) of the generator **112** into mechanical

vibrations and transmit the vibrations into a waveguide **147** to the blade **146** portion of the end effector **150**, for example. Such mechanical vibrations can be generated at ultrasonic frequencies, although any suitable frequency, or frequencies, can be used. In the second operating mode of the surgical instrument **110**, an electrical current may be supplied by the generator **112** that can flow through the transducer **114**, the waveguide **147**, and the end effector **150**. The current flowing through the waveguide **147** and end effector **150** can be an alternating current (AC current), wherein, in various embodiments, the wave form of the AC current can be sinusoidal and/or may comprise a series of step intervals, for example.

In one embodiment, the current supplied by the signal generator module **102** is an RF current. In any event, the surgical instrument **110** may comprise a supply path and a return path, wherein the tissue T (FIG. **5**) being treated completes, or closes, an electrical circuit, or loop, comprising a supply path through the transducer **114**, the waveguide **147**, and the blade **146** and a return path through conductor cable **137**. In one embodiment, the patient can be positioned on a conductive pad wherein the current can flow from a supply path of the surgical instrument, through the patient, and into the conductive pad in order to complete the electrical circuit.

Still referring to FIG. **1**, as previously discussed, in one embodiment the surgical instrument **110** may be energized by the generator **112** by way of the foot switch **144** in order to energize the end effector **150**. When actuated, the foot switch **144** triggers the generator **112** to deliver electrical energy to the handpiece assembly **160**, for example. Although the foot switch **144** may be suitable in many circumstances, other suitable switches can be used. In various embodiments, the surgical instrument system **110** may comprise at least one supply conductor **139** and at least one return conductor **141**, wherein current can be supplied to handpiece assembly **160** via the supply conductor **139** and wherein the current can flow back to the generator **112** via return conductor **141**. In various embodiments, the supply conductor **139** and the return conductor **141** may comprise insulated wires and/or any other suitable type of conductor. In certain embodiments, as described below, the supply conductor **139** and the return conductor **141** may be contained within and/or may comprise a cable extending between, or at least partially between, the generator **112** and the transducer **114** portion of the handpiece assembly **160**. In any event, the generator **112** can be configured to apply a sufficient voltage differential between the supply conductor **139** and the return conductor **141** such that sufficient current can be supplied to the transducer **114**.

In various embodiments, still referring to FIG. **1**, the supply conductor **139** and the return conductor **141** may be operably connected to a transducer drive unit **135**, wherein the drive unit **135** can be configured to receive current from the generator **112** via the supply conductor **139**. In certain embodiments, the handpiece assembly **160** may comprise a switch, such as a toggle switch **143**, for example, which can be manipulated to place the surgical instrument **110** in one of a first operating mode and a second operating mode. In one embodiment, as described below, the toggle switch **143** may comprise a first toggle button **143***a* which can be depressed to place the surgical instrument **110** in the first operating mode and, in addition, a second toggle button **143***b* which can be depressed to place the surgical instrument in the second operating mode. Although a toggle switch is illustrated and described herein, any suitable switch, or switches, can be used. When the first toggle button **143***a* is depressed, the transducer drive unit **135** can operate a transducer, such as the transducer **114**, for example, such that the transducer **114** produces vibrations. The transducer **114** may comprise one or more piezoelectric elements **132**, wherein the drive unit **135** can be configured to apply a voltage differential, and/or a series of voltage differentials, across the piezoelectric elements **132** such that they mechanically vibrate in a desired manner. Also, the transducer **114** may comprise one or more electrodes, such as a positive electrode **134** and a negative electrode **136**, for example, positioned intermediate and/or adjacent to the piezoelectric elements **132**. In one embodiment, the surgical instrument **110** may comprise a positive polarizing conductor **192** operably connected to the drive unit **135** and a positive electrode **134** and, in addition, a negative polarizing conductor **195** operably connected to the drive unit **135** and the negative electrode **136**, wherein the drive unit **135** can be configured to polarize the electrodes **134**, **136** via the polarizing conductors **192**, **195**, respectively.

In various embodiments, the transducer **114** may comprise a fore-bell **122** and a velocity transformer **128** which can be configured to conduct the vibrations produced by the piezoelectric elements **132** into the transmission waveguide **147**. In certain embodiments, referring still to FIG. **1**, the transmission waveguide **147** may comprise an elongate shaft portion surrounded, or at least partially surrounded, by a sheath **158**, for example, wherein the waveguide **147** may comprise a distal end **152**. The distal end **152** of the waveguide **147** may comprise part of the end effector **150**, wherein the end effector **150** may comprise the clamp member **151** having a rotatable clamp arm, or jaw, which can be pivoted between an open position in which tissue can be positioned intermediate the blade **146** and the clamp member **151** and a closed position in which clamp member **151** can position and/or compress the tissue T (FIG. **5**) against the blade **146**. In various embodiments, a surgical instrument may comprise a lever or actuator, such as a jaw closure trigger **145**, for example, which can be actuated by a surgeon in order to pivot the clamp member **151** between its open and closed positions. In at least one embodiment, the jaw closure trigger **145** can be operably engaged with a push/pull rod operably engaged with the clamp member **151** wherein, when the jaw closure trigger **145** is closed or moved toward the handpiece assembly **160**, the closure trigger **145** can push the push/pull rod distally and pivot the clamp member **151** toward the blade **146** into its closed position. Correspondingly, the jaw closure trigger **145** can be pivoted into its open position in order to pull the rod proximally and pivot the clamp member **151** away from the blade **146** into its open position.

In any event, once the tissue T (FIG. **5**) has been suitably positioned within the jaws of the end effector **150**, the transducer **114** can be operated by the drive unit **135** in order to transmit mechanical energy, or vibrations, into the targeted tissue T. In some embodiments, the actuation of the foot switch **144** may be sufficient to actuate the transducer **114**. In certain other embodiments, the actuation of a different switch may be required in addition to or in lieu of the actuation of the foot switch **144**. In one embodiment, the actuation of the foot switch **144** can supply power to the drive unit **135**, although the actuation of the jaw closure trigger **145**, and the trigger closure switch **147**, may be required before the drive unit **135** can drive the transducer **114**. In various embodiments, the jaw closure trigger **145** can be moved between a first, or open, position in which the trigger closure switch **147** is in an open state, or condition, and a second, or closed, position in which the trigger closure switch **147** is in a closed state, or condition. When the trigger closure switch **147** is in its closed condition, in various embodiments, a circuit within the drive unit **135**, for example, can be closed such that the drive unit **135** can drive the transducer **114**.

Referring still to FIG. **1**, In various applications, a surgeon may desire to treat tissue using mechanical energy, or vibrations, transmitted through the blade **146**, for example. In various other applications, the surgeon may desire to treat the tissue using therapeutic electrical energy transmitted through the blade **146**. In various other applications, the surgeon may desire to obtain feedback in regards to a state of the tissue T (FIG. **5**) by measuring the electrical properties of the tissue T (e.g., impedance) using subtherapeutic electrical energy transmitted through the blade **146**. In various embodiments, the toggle switch **143** can be manipulated to place the surgical instrument **110** in the second operating mode. In at least one such embodiment, the second toggle button **143***b* of the toggle switch **143** can be depressed in order to switch the surgical instrument **110** from the first operating mode into the second operating mode. As described below, the depression of the second toggle button **143***b* can configure the handpiece assembly **160** such that the drive unit **135** does not drive the transducer **114** but rather, the power supplied to the handpiece assembly **160** from generator **112** can flow into the blade **146** without being converted into mechanical energy, or vibrations. In one embodiment, referring now to FIG. **5**, the distal end **152** of the blade **146** can be positioned against the targeted tissue "T" and, in addition, the distal end **153** of the clamp member **151** can also be positioned against the tissue T such that current can flow from the supply conductor **139** into the blade **136**, through the tissue T, and return back to the generator **112** via the clamp member **151**, the return conductors **137**, **141**. As shown in FIG. **5**, the clamp member **151** can be configured such that it is not in contact with the blade **146** when the clamp member **151** is in the closed position.

With reference now back to FIG. **1**, in various embodiments, the return conductor **137** may comprise an insulated wire having a first end operably coupled with the clamp member **151** and a second end operably coupled with the return conductor **141**, wherein current can flow through the return conductor **137** when the toggle switch **143** is in the second configuration and the trigger closure switch **147** has been closed by the trigger **145**. In one embodiment, current will not flow through the return conductor **137** when the trigger closure switch **147** is in an open condition and/or when the toggle switch **143** is in the first configuration, i.e., when the first toggle button **143***a* is depressed, as described above. In any event, in various circumstances, the current flowing through the tissue T (FIG. **5**) from the distal end **152** of the blade **146** to the distal end **153** of the clamp member **151** can treat the tissue positioned intermediate, and/or surrounding, the distal ends **152**, **153**. In another embodiment, the current may be subtherapeutic for measuring the electrical state of the tissue T (FIG. **5**).

The distal end **152** of the blade **146** may comprise a supply electrode while the distal end **153** of the clamp member **151** may comprise a return electrode. In various other embodiments, current can be supplied to the conductor **137** such that the distal end **153** of the clamp member **151** may comprise the supply electrode and the distal end **152** of the blade **146** may comprise the return electrode. In one embodiment, the current can return to the generator **112** via the blade **146**, the waveguide **147**, and the conductor **139**. In either event, referring again to FIG. **1**, at least a portion of the return conductor **137** can extend along the outside of the sheath **158**, wherein at least another portion of the return conductor **137** can extend through the handpiece assembly **160**. In certain embodiments, although not illustrated, at least a portion of the return conductor **137** can be positioned within the sheath **158** and can extend alongside the blade **146**.

As shown in FIG. **6**, in some embodiments, the surgical instrument **110** may comprise an inner sheath **257** and an outer sheath **258**, wherein the inner sheath **257** can define a first, or inner, passageway **259**, and wherein the inner sheath **257** and the outer sheath **258** can define a second, or outer, passageway **261** therebetween. In one embodiment, the blade **146** can extend through the inner passageway **259** and the return conductor **137**, and/or any other suitable conductor, can extend through the outer passageway **261**. In various other embodiments, a conductor can be embedded in at least a portion of the inner sheath **257** or the outer sheath **258**.

As shown in FIG. **7**, in one embodiment, a sheath may comprise a non-electrically conductive or insulative material **358**, such as plastic and/or rubber, for example, overmolded onto a conductive insert **357**, which can be comprised of copper, for example, wherein the conductive insert **357** can allow current flowing through the blade **146** to return to the generator **112** after it has passed through the targeted tissue T (FIG. **5**) as described above. In various embodiments, the insulative material **358** can entirely, or at least substantially, surround the conductive insert **357** such that current flowing through the conductive insert **357** does not unintentionally short to non-targeted tissue, for example. In at least one embodiment, the insulative material **358** can cover the inside surface and the outside surface of the conductive insert **357**. In certain embodiments, although not illustrated, an insulative material of a sheath may cover only the outer surface of a conductive insert, for example.

In various embodiments, as described above, a first end of the return conductor **137** can be operably coupled to the clamp member **151** such that current can flow therethrough. In certain embodiments, the first end of the return conductor **137** can be soldered and/or welded to the clamp member **151**. In one embodiment, although not illustrated, the clamp member **151** may comprise an aperture configured to receive the first end of the return conductor **137** wherein a fastener can be inserted into the aperture in order to secure the first end therein. In at least one such embodiment, the sidewalls of the aperture can be at least partially threaded and the fastener can be threadably received in the threaded aperture.

As shown in FIG. **8**, in one embodiment, a clamp arm assembly **451** may comprise a conductive jacket **472** mounted to a base **449**. In one embodiment, the first end of the return conductor **137** may be mounted to the conductive jacket **472** such that current can flow from the blade **146**, through tissue positioned intermediate the jacket **472** and the blade **146**, and then into the jacket **472** and to the return conductor **137**. In various embodiments, the conductive jacket **472** may comprise a center portion **473** and at least one downwardly-extending sidewall **474** which can extend below bottom the surface **475** of the base **449**. In the illustrated embodiment, the conductive jacket **472** has two sidewalls **474** extending downwardly on opposite sides of the base **449**. In certain embodiments, the center portion **473** may comprise at least one aperture **476** which can be configured to receive a projection **477** extending from the base **449**. In one embodiment, the projections **477** can be press-fit within the apertures **476** in order to secure the conductive jacket **472** to the base **449** although, in some embodiments, the projections **477** can be deformed after they have been inserted into the apertures **476**. In various embodiments, fasteners can be used to secure the conductive jacket **472** to the base **449**.

In various embodiments, the clamp arm assembly **451** may comprise a non-electrically conductive or insulative material, such as plastic and/or rubber, for example, positioned intermediate the conductive jacket **472** and the base **449**. The insulative material can prevent current from flowing, or short-

ing, between the conductive jacket **472** and the base **449**. In various embodiments, referring again to FIG. **8**, the base **449** may comprise at least one aperture **478**, for example, which can be configured to receive a pivot pin (not illustrated), wherein the pivot pin can be configured to pivotably mount the base **449** to the sheath **158**, for example, such that the clamp arm assembly **451** can be rotated between open and closed positions relative to the sheath **158**. In the embodiment illustrated in FIG. **8**, the base **449** includes two apertures **478** positioned on opposite sides of the base **449**. In one embodiment, the pivot pin can be comprised of a non-electrically conductive or insulative material, such as plastic and/or rubber, for example, which can be configured to prevent current from flowing into the sheath **158** even if the base **449** is in electrical contact with the conductive jacket **472**, for example.

In various embodiments, as described above, the surgical instrument system **110** can be configured such that current can flow from the distal tip of the blade **146**, through the tissue T (FIG. **5**), and then to the distal tip of the clamp member **151**. In one embodiment, as shown in to FIG. **5**, the clamp member **151** may comprise a tissue engaging pad or clamp pad **155**, for example, mounted thereto, wherein the pad **155** can be configured to contact tissue positioned intermediate the clamp member **151** and the waveguide **146**. In one expression of the embodiment, the pad **155** may be formed of a non-electrically conductive or insulative material, such as polytetrafluoroethylene (PTFE), such as for example TEFLON® a trademark name of E. I. Du Pont de Nemours and Company, a low coefficient of friction polymer material, or any other suitable low-friction material. The non-electrically conductive or insulative material can also server to prevent current from flowing between the clamp member **151** and the blade **146** without first passing through the distal end **152** of the blade **146**, the targeted tissue T, and the distal end **153** of the clamp member **151**. In various embodiments, the pad **155** can be attached to the clamp member **151** utilizing an adhesive, for example. The clamp pad **155** mounts on the clamp member **151** for cooperation with the blade **146**, with pivotal movement of the clamp member **151** positioning the clamp pad **155** in substantially parallel relationship to, and in contact with, the blade **146**, thereby defining a tissue treatment region. By this construction, tissue is grasped between the clamp pad **155** and the blade **146**. The clamp pad **155** may be provided with a non-smooth surface, such as a saw tooth-like configuration to enhance the gripping of tissue in cooperation with the blade **146**. The saw tooth-like configuration, or teeth, provide traction against the movement of the blade **146**. The teeth also provide counter traction to the blade **146** and clamping movement. It will be appreciated that the saw tooth-like configuration is just one example of many tissue engaging surfaces to prevent movement of the tissue relative to the movement of the blade **146**. Other illustrative examples include bumps, criss-cross patterns, tread patterns, a bead, or sand blasted surface.

In various other embodiments, the surgical instrument **110** can be configured such that current can flow through tissue clamped between the blade **146**, for example, and the clamp member **151** without having to first pass through the distal ends thereof. In at least one embodiment, referring now to FIG. **9**, a clamp arm assembly **551** may comprise an electrically-conductive member **572** and a pad **555** attached thereto, wherein the electrically-conductive member **572** may comprise at least one sidewall **574** extending downwardly therefrom. In one embodiment, current can flow between the blade **146**, for example, through tissue positioned between the blade **146** and the sidewalls **574** of the clamp arm assembly **551**, and into the sidewalls **574**. In various embodiments, gaps can be defined between each sidewall **574** and the blade **146** and, in addition, a gap can be defined between the tissue-contacting surface **575** of the pad **555** and the blade **146**.

In one embodiment, referring now to FIG. **10**, the gaps between each sidewall **574** and the waveguide **146** can be defined by a distance "D**1**," wherein the distance D**1** can be selected such that, when the clamp arm assembly **551** is positioned in a closed position, the tissue positioned intermediate each of the sidewalls **574** and the blade **146** can be compressed. Although these gaps are illustrated as having the same distance D**1**, other embodiments are envisioned in which the gaps have different distances. A gap between the tissue-contacting surface **575** and the blade **146** can be defined by a distance "D**2**," wherein the distance D**2** also may be selected such that, when the clamp arm assembly **551** is positioned in a closed position, the tissue-contacting surface **575** can be contact and/or compress the tissue against blade **146**.

In various embodiments, a clamp arm assembly may comprise an electrically-conductive pad mounted thereto. In at least one such embodiment, such a pad can be configured to contact and/or compress tissue positioned intermediate the clamp arm assembly and a waveguide, such as the blade **146**, for example, such that current can flow from the blade **146** into the pad. In certain embodiments, the electrically conductive pad can be comprised of a typically conductive material, such as copper, for example. In at least one embodiment, the pad can be comprised of a typically non-conductive material, such as PTFE, for example, which can be impregnated with electrically conductive particles, such as medical grade stainless steel, for example, such that the pad is sufficiently conductive to permit current to flow between the blade **146** and the clamp arm.

In one embodiment, as previously discussed, the surgical instrument **110** comprises the blade **146**, for example, which may comprise a first electrode and, in addition, a clamp arm, such as the clamp member **151**, for example, which may comprise a second electrode. In various embodiments, as also discussed above, the blade **146** may comprise a supply electrode whereas the clamp member **151** may comprise a return electrode. Alternatively, the clamp member **151** may comprise the supply electrode while the blade **146** may comprise the return electrode. In various other embodiments, a clamp arm may comprise both the supply electrode and the return electrode. In certain embodiments, referring now to FIG. **11**, a clamp arm may comprise a pad **655** and two or more electrodes, such as a first electrode **682** and a second electrode **683**, for example. In one embodiment, the pad **655** can be comprised of a non-electrically conductive or insulative material, such as PTFE, for example, as previously discussed with reference to the clamp pad **155** (FIG. **5**), whereas the electrodes **682**, **683** can be comprised of an electrically conductive material, such as copper and/or a PTFE material having electrically conductive particles mixed therein, for example. In various embodiments, the first electrode **682** and/or the second electrode **683** can be embedded within the pad **655**. In at least one such embodiment, the pad **655** can be molded onto the electrodes **682**, **683** whereas, in certain embodiments, the electrodes **682**, **683** can be inserted and/or press-fit into openings formed in the pad **655**.

In various embodiments, the first electrode **682** can be positioned adjacent to a first side **674***a* of the pad **655** while the second electrode **683** can be positioned adjacent to a second side **674***b* of the pad **655**. In use, the first electrode **682** may comprise a supply electrode and the second electrode **683** may comprise a return electrode, wherein current can

flow from the supply electrode **682**, through tissue clamped or positioned between the pad **655** and the blade **146**, for example, and into the return electrode **683**. In one embodiment, a supply wire can be operably coupled with the first electrode **682** and a return wire can be operably coupled with the second electrode **683** such that current can be supplied thereto from a power source, such as the generator **112**, for example. In various embodiments, referring still to FIG. **11**, the electrodes **682**, **683** can be positioned within the pad **655** such that the electrodes **682**, **683** do not contact the blade **146** when the clamp member **151** (FIG. **5**) is in a closed position and short to the blade **146**. Although the illustrated embodiment comprises one supply electrode and one return electrode positioned within a pad, embodiments are envisioned in which a pad includes more than one supply electrode and/or more than one return electrode.

As discussed above, electrodes can be embedded within the pad of a clamp arm assembly. In various embodiments, first and second electrodes can be mounted to the sides of a clamp arm pad. Referring now to FIG. **12**, a clamp arm may comprise a pad **755**, for example, which can be configured to hold tissue against the blade **146**, for example, wherein a first electrode **782** can be mounted to a first side **774***a* of the pad **755** and wherein a second electrode **783** can be mounted to a second side **774***b* of the pad **755**. In various embodiments, the electrodes **782**, **783** can be positioned within cut-outs in the sides of the pad **755** wherein, in certain embodiments, the electrodes **782**, **783** can be adhered and/or fastened, for example, to the pad **755**. The first electrode **782** may comprise a supply electrode and the second electrode **783** may comprise a return electrode, wherein current can flow from the supply electrode **782**, through tissue clamped or positioned between the pad **755** and the blade **146**, for example, and into the return electrode **783**. In one embodiment, a supply wire can be operably coupled with the first electrode **782** and a return wire can be operably coupled with the second electrode **783** such that current can be supplied thereto from a power source, such as the generator **112**, for example. Furthermore, the electrodes **782**, **783** can be mounted to the pad **755** such that the electrodes **782**, **783** do not contact the blade **146** and create an electrical short thereto. Although the illustrated embodiment comprises one supply electrode and one return electrode mounted to a pad, embodiments are envisioned in which a pad includes more than one supply electrode and/or more than one return electrode.

Still referring to FIG. **12**, various electrodes can be configured such that they extend in a longitudinal direction which is parallel, or at least substantially parallel, to the longitudinal axis of the blade **146**, for example. In various embodiments, the electrodes can extend along an end effector such that the entire length of the tissue positioned within the end effector can be treated. In various embodiments, referring now to FIG. **13**, a clamp arm may comprise a pad **885** having two point electrodes. More particularly, in one embodiment, the pad **855** may comprise a first point electrode **882** and a second point electrode **883** positioned therein, wherein current can flow through tissue positioned intermediate the first point electrode **882** and the second point electrode **883**. In at least one such embodiment, the pad **855** can be comprised of a non-electrically conductive material, the first point electrode **882** may comprise a supply electrode, and the second point electrode **883** may comprise a return electrode. In various embodiments, the electrodes **882**, **883** can be embedded within the pad **885** and, in one embodiment the pad **885** can be molded around the electrodes **882**, **883**. In certain embodiments, the electrodes **882**, **883** can be inserted into apertures within the pad **855**. A supply wire can be operably coupled with the first electrode **882** and a return wire can be operably coupled with the second electrode **883** such that current can be supplied thereto from a power source, such as the generator **112**, for example. Furthermore, the electrodes **882**, **883** can be positioned within the pad **855** such that the electrodes **882**, **883** do not contact the blade **146** and create an electrical short thereto. In one embodiment, the clamp arm supporting pad **885**, and/or a sheath rotatably supporting the clamp arm, may further comprise a stop which can be configured to prevent the pad **855** from rotating into a position in which the electrodes **882**, **883** contact the blade **146**. Although the illustrated embodiment comprises one supply point electrode and one return point electrode positioned within a pad, other embodiments are envisioned in which a pad includes more than one supply point electrode and/or more than one return point electrode. Various embodiments are envisioned in which a pad includes an array of supply point electrodes and/or an array of return point electrodes.

In various embodiments, as described above, a surgical instrument may comprise a clamp arm including both a supply electrode and a return electrode. In one embodiment, the surgical instrument may comprise a waveguide which does not comprise an electrode. In certain embodiments, a supply electrode and a return electrode can be configured such that current can flow therebetween along a predetermined path. In various embodiments, such a path can be one-dimensional. Embodiments having two point electrodes, for example, can permit such a path. In other embodiments, such a path can be two-dimensional. Embodiments having an array of point electrodes, for example, can permit such a path. A two-dimensional path can be referred to as a field. In certain embodiments, a path can be three-dimensional. In at least one such embodiment, a clamp arm assembly can have a supply electrode and a return electrode while the waveguide may comprise one of a supply electrode or a return electrode. In embodiments where the waveguide comprises a return electrode, current can flow from the supply electrode of the clamp arm assembly to the return electrode of the clamp arm assembly and the return electrode of the waveguide. In one such embodiment, the return electrodes may comprise a common ground. In embodiments where the waveguide comprises a supply electrode, current can flow from the waveguide and the supply electrode of the clamp arm assembly to the return electrode of the clamp arm assembly. Such arrangements can permit the current to flow in a three-dimensional path, or field.

In various embodiments, referring now to FIG. **14**, the surgical instrument **110** may comprise a sheath encompassing, or at least partially encompassing, a portion of the blade **146** wherein a sheath may comprise both at least one supply conductor and at least one return conductor. In one embodiment, a sheath may comprise a plurality of conductive inserts, such as a first conductive insert **957***a* and a second conductive inserts **957***b*, for example, wherein the first conductive insert **957***a* may comprise a supply conductor and wherein the second conductive insert **957***b* may comprise a return conductor. In various embodiments, a non-electrically conductive or insulative material **958**, such as plastic and/or rubber, for example, can be overmolded onto the first and second conductive inserts **957***a*, **957***b* in order to comprise the sheath. In various other embodiments, the surgical instrument **110** may comprise, referring now to FIG. **15**, a sheath assembly encompassing, or at least partially encompassing, a portion of a waveguide wherein the sheath assembly may comprise an inner sheath, such as an inner sheath **1057**, for example, and an outer sheath, such as an outer sheath **1058**, for example. In one embodiment, the inner sheath **1057** may comprise a supply conductor operably coupled with a supply electrode in a

clamp arm assembly, wherein the outer sheath **1058** may comprise a return conductor operably coupled with a return electrode in the clamp arm assembly. In certain embodiments, the inner sheath **1057** and/or the outer sheath **1058** may be comprised of an electrically conductive material, such as medical grade stainless steel, for example, wherein, in one embodiment, one or more surfaces of the inner sheath **1057** and/or the outer sheath **1058** can be coated, or at least partially coated, in a non-conductive material, such as a material comprising poly(p-xylylene) polymers, for example. Materials comprised of poly(p-xylylene) polymers are often sold under the tradename of Parylene™.

In various embodiments, a clamp arm can be moved between open and closed positions in order position and/or compress tissue T against a blade. In one embodiment, referring to FIG. **16**, a clamp arm **1151** may comprise a base **1149** and a pad **1155** mounted to the base **1149**, wherein the pad **1155** can be configured to contact and compress tissue T against the blade **146**, for example. As illustrated in FIG. **16**, the pad **1155** may comprise a tissue-contacting surface **1175** which, although it may include various serrations, ridges, and/or surface texturing, is planar, or at least substantially planar. In such embodiments, especially when the blade **146** has a round or arcuate cross-section, only a small portion of the tissue T positioned intermediate the blade **146** and the pad **1155** may contact the surface area, or perimeter, of the blade **146**. As illustrated in FIG. **16**, the tissue T may contact the blade **146** at a contact point P. Various alternative embodiments are envisioned in which the clamp arm **1251**, for example, may comprise downwardly-extending sidewalls **1274** which extend below a tissue-contacting surface **1275** of the pad **1255**, for example, although a clamp arm may comprise a tissue-contacting surface with or without a pad. In one embodiment, referring to FIG. **17**, the sidewalls **1274** can be configured to contact the tissue T positioned laterally with respect to the blade **146** and push the tissue T downwardly. As illustrated in FIG. **17**, the sidewalls **1274** can push the tissue T downwardly such that the tissue T positioned intermediate the sidewalls **1274** contacts a larger surface area, or perimeter, on the blade **146** as compared to the embodiment illustrated in FIG. **16**. Owing to the larger contact area, the blade **146** may be more efficient in cutting, coagulating, and/or otherwise treating the tissue. In embodiments where the blade **146** may comprise a circular or arcuate cross-section, the perimeter contact distance, i.e., the distance in which the tissue is in contact with the perimeter of the blade **146**, may comprise an arclength (s) which can equal the product of the radius of curvature of the arc R and the sweep angle θ defined between the two contact points P. As illustrated in FIG. **17**, the contact points P can represent the endpoints of the perimeter in which the tissue T contacts the blade **146**. Although the illustrated blade **146** is depicted as having a curved or arcuate cross-section, any other suitable cross-section may be used.

In various embodiments, the tissue-contacting surface **1275** of the clamp arm **1251** can define a plane **1298** which can represent the portions of the pad **1255** which contact the tissue T positioned within the end effector when the clamp arm **1251** is rotated between its open and closed positions. As illustrated in FIG. **17**, the sidewalls **1274** of the clamp arm **1251** can extend through the plane **1298**, wherein, when the clamp arm **1251** is rotated from an open position into a closed position, the sidewalls **1274** can be positioned laterally along the opposite sides of the blade **146** and, in addition, the tissue-contacting surface **1275** can be positioned against, or adjacent to, the top surface of the blade **146** such that the plane **1298** is aligned with, or respect to, a plane **1299** extending through the top surface of the blade **146**. In one embodiment, the plane **1299** can be defined as a tangential plane which is tangential to the perimeter of the blade **146**. In one embodiment, the plane **1299** can be tangential to the top tissue-contacting surface of the blade **146**, for example, wherein the top tissue-contacting surface of the **146** may comprise the surface closest to the clamp tissue-contacting surface **1275** when the clamp arm **1271** is in its closed position. In the illustrated embodiment, still referring to FIG. **17**, the planes **1298**, **1299** can be parallel, or at least substantially parallel, to one another when the tissue-contacting surface **1275** is positioned adjacent to the blade **146**, while the planes **1298**, **1299** can be co-planar, or at least substantially co-planar, with one another when the tissue-contacting surface **1275** is in contact with the blade **146**. The sidewalls **1274** can be sized and configured such that they extend through the blade plane **1299** when the clamp arm **1271** is in the closed position. In various embodiments, the sidewalls **1274** may not extend through the plane **1299** when the clamp arm **1251** is in the open position. In one embodiment, the sidewalls **1274** may "break" the plane **1299** as the clamp arm **1251** is being closed, but before it is completely closed. In one embodiment, the sidewalls **1274** may break the plane **1299** just before the clamp arm **1251** reaches its completely closed position.

FIG. **18** illustrates one embodiment of a drive system **32** of the ultrasonic generator module **180** shown in FIG. **1**, which creates an ultrasonic electrical signal for driving an ultrasonic transducer. With reference now to FIGS. **1** and **18**, the drive system **32** is flexible and can create an ultrasonic electrical drive signal **416** at a desired frequency and power level setting for driving the ultrasonic transducer **114**. In various embodiments, the generator **112** may comprise several separate functional elements, such as modules and/or blocks. Although certain modules and/or blocks may be described by way of example, it can be appreciated that a greater or lesser number of modules and/or blocks may be used and still fall within the scope of the embodiments. Further, although various embodiments may be described in terms of modules and/or blocks to facilitate description, such modules and/or blocks may be implemented by one or more hardware components, e.g., processors, Digital Signal Processors (DSPs), Programmable Logic Devices (PLDs), Application Specific Integrated Circuits (ASICs), circuits, registers and/or software components, e.g., programs, subroutines, logic and/or combinations of hardware and software components.

In one embodiment, the ultrasonic generator module **180** drive system **32** may comprise one or more embedded applications implemented as firmware, software, hardware, or any combination thereof. The ultrasonic generator module **180** drive system **32** may comprise various executable modules such as software, programs, data, drivers, application program interfaces (APIs), and so forth. The firmware may be stored in nonvolatile memory (NVM), such as in bit-masked read-only memory (ROM) or flash memory. In various implementations, storing the firmware in ROM may preserve flash memory. The NVM may comprise other types of memory including, for example, programmable ROM (PROM), erasable programmable ROM (EPROM), electrically erasable programmable ROM (EEPROM), or battery backed random-access memory (RAM) such as dynamic RAM (DRAM), Double-Data-Rate DRAM (DDRAM), and/or synchronous DRAM (SDRAM).

In one embodiment, the ultrasonic generator module **180** drive system **32** comprises a hardware component implemented as a processor **400** for executing program instructions for monitoring various measurable characteristics of the ultrasonic surgical instrument **110** and generating a corresponding output control signal for operating the surgical

instrument **110**. In various embodiments, the output control signal is for driving the ultrasonic transducer **114** in cutting and/or coagulation operating modes, measuring electrical characteristics of the surgical instrument **110** and/or the tissue T, and providing feedback to use. It will be appreciated by those skilled in the art that the ultrasonic generator module **180** and the drive system **32** may comprise additional or fewer components and only a simplified version of the ultrasonic generator module **180** and the drive system **32** are described herein for conciseness and clarity. In various embodiments, as previously discussed, the hardware component may be implemented as a DSP, PLD, ASIC, circuits, and/or registers. In one embodiment, the processor **400** may be configured to store and execute computer software program instructions to generate the step function output signals for driving various components of the ultrasonic surgical instrument **110**, such as the transducer **114**, the end effector **150**, and/or the blade **146**.

In one embodiment, under control of one or more software program routines, the processor **400** executes the methods in accordance with the described embodiments to perform a variety of functions, such as, for example, generating a step function formed by a stepwise waveform of drive signals comprising current (I), voltage (V), and/or frequency (f) for various time intervals or periods (T), driving the ultrasonic transducer **114**, driving the end effector **150** using therapeutic and/or subtherapeutic electrical signals (e.g., RF signal), measuring the impedance (Z) of the transducer **114**, measuring the impedance (Z_t) of the tissue T, and/or providing feedback to the user. In one embodiment, stepwise waveforms of the drive signals may be generated by forming a piecewise linear combination of constant functions over a plurality of time intervals created by stepping the ultrasonic generator module **180** drive signals, e.g., output drive current (I), voltage (V), and/or frequency (f). The time intervals or periods (T) may be predetermined (e.g., fixed and/or programmed by the user) or may be variable. Variable time intervals may be defined by setting the drive signal to a first value and maintaining the drive signal at that value until a change is detected in a monitored characteristic. Examples of monitored characteristics may comprise, for example, transducer impedance, tissue impedance, tissue heating, tissue transection, tissue coagulation, and the like. The ultrasonic drive signals generated by the ultrasonic generator module **180** include, without limitation, ultrasonic drive signals that excite various vibratory modes of the ultrasonic transducer **114** such as the primary longitudinal mode and harmonics thereof as well flexural and torsional vibratory modes.

In one embodiment, the executable modules comprise one or more algorithm(s) **402** stored in memory that when executed causes the processor **400** to perform a variety of functions, such as, for example, generating a step function formed by a stepwise waveform of drive signals comprising current (I), voltage (V), and/or frequency (f) for various time intervals or periods (T), driving the ultrasonic transducer **114**, driving the end effector **150** using a therapeutic and/or subtherapeutic electrical signal (e.g., RF signal), measuring the impedance (Z) of the transducer **114**, measuring the impedance (Z_t) of the tissue T, and/or providing feedback in accordance with a state of the tissue T. In one embodiment, an algorithm **402** is executed by the processor **400** to generate a step function formed by a stepwise waveform of drive signals comprising current (I), voltage (V), and/or frequency (f) for various time intervals or periods (T). The stepwise waveforms of the drive signals may be generated by forming a piecewise linear combination of constant functions over two or more time intervals created by stepping the generator's **30** output drive current (I), voltage (V), and/or frequency (f). The drive signals may be generated either for predetermined fixed time intervals or periods (T) of time or variable time intervals or periods of time in accordance with the one or more stepped output algorithm(s) **402**. Under control of the processor **400**, the ultrasonic generator module **180** steps (e.g., increment or decrement) the current (I), voltage (V), and/or frequency (f) up or down at a particular resolution for a predetermined period (T) or until a predetermined condition is detected, such as a change in a monitored characteristic (e.g., transducer impedance, tissue impedance). The steps can change in programmed increments or decrements. If other steps are desired, the ultrasonic generator module **180** can increase or decrease the step adaptively based on measured system characteristics. In other embodiments, algorithms **402** may be executed by the processor **400** to drive the ultrasonic transducer **114**, drive the end effector **150** using a therapeutic and/or subtherapeutic electrical signal (e.g., RF signal), measure the impedance (Z) of the transducer **114**, measure the impedance (Z_t) of the tissue T, and/or to provide feedback in accordance with a state of the tissue T.

In operation, the user can program the operation of the ultrasonic generator module **180** using the input device **406** located on the front panel of the ultrasonic generator module **180** console. The input device **406** may comprise any suitable device that generates signals **408** that can be applied to the processor **400** to control the operation of the ultrasonic generator module **180**. In various embodiments, the input device **406** includes buttons, switches, thumbwheels, keyboard, keypad, touch screen monitor, pointing device, remote connection to a general purpose or dedicated computer. In other embodiments, the input device **406** may comprise a suitable user interface. Accordingly, by way of the input device **406**, the user can set or program the current (I), voltage (V), frequency (f), and/or period (T) for programming the step function output of the ultrasonic generator module **180**. The processor **400** then displays the selected power level by sending a signal on line **410** to an output indicator **412**.

In various embodiments, the output indicator **412** may provide visual, audible, and/or tactile feedback to the surgeon to indicate the status of a surgical procedure, such as, for example, when tissue cutting and coagulating is complete based on a measured characteristic of the ultrasonic surgical instrument **110**, e.g., transducer impedance, tissue impedance, or other measurements as subsequently described. By way of example, and not limitation, visual feedback comprises any type of visual indication device including incandescent lamps or light emitting diodes (LEDs), graphical user interface, display, analog indicator, digital indicator, bar graph display, digital alphanumeric display. By way of example, and not limitation, audible feedback comprises any type of buzzer, computer generated tone, computerized speech, voice user interface (VUI) to interact with computers through a voice/speech platform. By way of example, and not limitation, tactile feedback comprises any type of vibratory feedback provided through the instrument handpiece assembly **160** or simply housing handle assembly.

In one embodiment, the processor **400** may be configured or programmed to generate a digital current signal **414** and a digital frequency signal **418**. These signals **414**, **418** are applied to a direct digital synthesizer (DDS) circuit **420** to adjust the amplitude and the frequency (f) of the current output signal **416** to the transducer **114**. The output of the DDS circuit **420** is applied to an amplifier **422** whose output is applied to a transformer **424**. The output of the transformer **424** is the signal **416** applied to the ultrasonic transducer **114**, which is coupled to the blade **146** by way of the waveguide **147**.

In one embodiment, the ultrasonic generator module **180** comprises one or more measurement modules or components that may be configured to monitor measurable characteristics of the ultrasonic instrument **110**. In embodiment illustrated in FIG. **18**, the processor **400** may be employed to monitor and calculate system characteristics. As shown, the processor **400** measures the impedance Z of the transducer **114** by monitoring the current supplied to the transducer **114** and the voltage applied to the transducer **114**. In one embodiment, a current sense circuit **426** is employed to sense the current flowing through the transducer **114** and a voltage sense circuit **428** is employed to sense the output voltage applied to the transducer **114**. These signals may be applied to the analog-to-digital converter **432** (ADC) via an analog multiplexer **430** circuit or switching circuit arrangement. The analog multiplexer **430** routes the appropriate analog signal to the ADC **432** for conversion. In other embodiments, multiple ADCs **432** may be employed for each measured characteristic instead of the multiplexer **430** circuit. The processor **400** receives the digital output **433** of the ADC **432** and calculates the transducer impedance Z based on the measured values of current and voltage. In response to the transducer impedance (Z), the processor **400** controls the operation of the surgical instrument **110**. For example, the processor **400** can adjust the power delivered to the transducer **114**, can shut off the power to the transducer **114**, and/or provide feedback to the user. In one embodiment, the processor **400** adjusts the output drive signal **416** such that it can generate a desired power versus load curve. In one embodiment, in accordance with a programmed step function algorithms **402**, the processor **400** can step the drive signal **416**, e.g., the current or frequency, in any suitable increment or decrement in response to the transducer impedance Z.

With reference back now to FIGS. **1** and **18**, to actually cause the surgical blade **146** to vibrate, e.g., actuate the blade **146**, the user activates the foot switch **144** or the switch **143** on the handpiece assembly **160**, as discussed above. This activation outputs the drive signal **416** to the transducer **114** based on programmed values of current (I), frequency (f), and corresponding time periods (T). After a predetermined fixed time period (T), or variable time period based on a measurable system characteristic such as changes in the impedance Z of the transducer **114**, the processor **400** changes the output current step or frequency step in accordance with the programmed values. The output indicator **412** communicates the particular state of the process to the user.

The operation of the ultrasonic generator module **180** may be programmed to provide a variety of output drive signals to measure electrical properties of current, voltage, power, impedance, and frequency associated with the transducer **114** in an unloaded state, a lightly loaded state, and a heavily loaded state, for example. When the ultrasonic transducer **114** is in an unloaded state, the ultrasonic generator module **180** output may be stepped in a first sequence, for example. In one embodiment, the ultrasonic generator module **180** is initially activated at about time **0** resulting in a drive current rising to a first set point I_1 of about 100 mA. The current is maintained at the first set point I1, for a first period T_1. At the end of the first period T_1, e.g., about 1 second, the current set point is changed, e.g., stepped, by the ultrasonic generator module **180** in accordance with the software, e.g., the step function algorithm(s) **402**, to a second set point I_2 of about 175 mA for a second period T_2, e.g., about 2 seconds. At the end of the second period T_2, e.g., at about 3 seconds, the ultrasonic generator module **180** software changes the current to a third set point I_3 of about 350 mA. The voltage, current, power, and frequency respond only slightly because there is no load on the system.

When the ultrasonic transducer **114** is in a heavily loaded state, the ultrasonic generator module **180** is activated at about time **0** resulting in the current rising to the first set point I_1, of about 100 mA. At about 1 second the current set point is changed within the ultrasonic generator module **180** by the software to I_2 of about 175 mA, and then again at about 3 seconds the ultrasonic generator module **180** changes the current **300** set point to I_3 of about 350 mA. The voltage, current, power, and frequency respond to the heavy load.

When the ultrasonic transducer **114** is in a heavily loaded state, the ultrasonic generator module **180** is activated at about time **0** resulting in the current rising to the first set point I_1 of about 100 mA. At about 1 second the current set point is changed within the ultrasonic generator module **180** by the software to I_2 of about 175 mA, and then again at about 3 seconds the ultrasonic generator module **180** changes the current 300 set point to I_3 of about 350 mA. The voltage, current, power, and frequency respond to the heavy load.

It will be appreciated by those skilled in the art that the current step function set points (e.g., I_1, I_2, I_3) and the time intervals or periods (e.g., T_1, T_2) of duration for each of the step function set points described above are not limited to the values described herein and may be adjusted to any suitable value as may be desired for a given set of surgical procedures. Additional or fewer current set points and periods of duration may be selected as may be desired for a given set of design characteristics or performance constraints. As previously discussed, the periods may be predetermined by programming or may be variable based on measurable system characteristics. The embodiments are not limited in this context.

Having described operational details of various embodiments of the surgical system **100**, operations for the above surgical system **100** may be further described in terms of a process for cutting and coagulating a blood vessel employing a surgical instrument comprising the input device **406** and the transducer impedance measurement capabilities described with reference to FIG. **18**. Although a particular process is described in connection with the operational details, it can be appreciated that the process merely provides an example of how the general functionality described herein can be implemented by the surgical system **100**. Further, the given process does not necessarily have to be executed in the order presented herein unless otherwise indicated. As previously discussed, the input device **406** may be employed to program the stepped output (e.g., current, voltage, frequency) to the ultrasonic transducer **114**/blade **146** assembly.

Accordingly, one technique for sealing a vessel includes separating and moving the inner muscle layer of the vessel away from the adventitia layer prior to the application of standard ultrasonic energy to transect and seal the vessel. Although conventional methods have achieved this separation by increasing the force applied to the clamp member **151**, disclosed is an alternative apparatus and method for cutting and coagulating tissue without relying on clamp force alone. In order to more effectively separate the tissue layers of a vessel, for example, the ultrasonic generator module **180** may be programmed to apply a frequency step function to the ultrasonic transducer **114** to mechanically displace the blade **146** in multiple modes in accordance with the step function. In one embodiment, the frequency step function may be programmed by way of the user interface **406**, wherein the user can select a stepped-frequency program, the frequency (f) for each step, and the corresponding time period (T) of duration for each step for which the ultrasonic transducer **114** will be

excited. The user may program a complete operational cycle by setting multiple frequencies for multiple periods to perform various surgical procedures.

In one embodiment, a first ultrasonic frequency may be set initially to mechanically separate the muscle tissue layer of a vessel prior to applying a second ultrasonic frequency to cut and seal the vessel. By way of example, and not limitation, in accordance with one implementation of the program, initially, the ultrasonic generator module **180** is programmed to output a first drive frequency f_1 for a first period T_1 of time (for example less than approximately 1 second), wherein the first frequency f_1 is significantly off resonance, for example, $f_o/2$, $2f_o$ or other structural resonant frequencies, where f_o is the resonant frequency (e.g., 55.5 kHz). The first frequency f_1 provides a low level of mechanical vibration action to the blade **146** that, in conjunction with the clamp force, mechanically separates the muscle tissue layer (subtherapeutic) of the vessel without causing significant heating that generally occurs at resonance. After the first period T_1, the ultrasonic generator module **180** is programmed to automatically switch the drive frequency to the resonant frequency f_o for a second period T_2 to transect and seal the vessel. The duration of the second period T_2 may be programmed or may be determined by the length of time it actually takes to cut and seal the vessel as determined by the user or may be based on measured system characteristics such as the transducer impedance Z as described in more detail below.

In one embodiment, the tissue/vessel transection process (e.g., separating the muscle layer of the vessel from the adventitia layer and transecting/sealing the vessel) may be automated by sensing the impedance Z characteristics of the transducer **114** to detect when the transection of the tissue/vessel occurs. The impedance Z can be correlated to the transection of the muscle layer and to the transection/sealing of the vessel to provide a trigger for the processor **400** to generate the frequency and/or current step function output. As previously discussed with reference to FIG. **18**, the impedance Z of the transducer **114** may be calculated by the processor **400** based on the current flowing through transducer **114** and the voltage applied to the transducer **114** while the blade **146** is under various loads. Because the impedance Z of the transducer **114** is proportional to the load applied to the blade **146**, as the load on the blade **146** increases the impedance Z of the transducer **114** increases and as the load on the blade **146** decreases the impedance Z of the transducer **114** decreases. Accordingly, the impedance Z of the transducer **114** can be monitored to detect the transection of the inner muscle tissue layer of the vessel from the adventitia layer and can also be monitored to detect when the vessel has been transected and sealed.

In one embodiment, the ultrasonic surgical instrument **110** may be operated in accordance with a programmed step function algorithm responsive to the transducer impedance Z. In one embodiment, a frequency step function output may be initiated based on a comparison of the transducer impedance Z and one or more predetermined thresholds that have been correlated with tissue loads against the blade **146**. When the transducer impedance Z transitions above or below (e.g., crosses) a threshold, the processor **400** applies a digital frequency signal **418** to the DDS circuit **420** to change the frequency of the drive signal **416** by a predetermined step in accordance with the step function algorithm(s) **402** responsive to the transducer impedance Z. In operation, the blade **146** is first located at the tissue treatment site. The processor **400** applies a first digital frequency signal **418** to set a first drive frequency f_1 that is off resonance (e.g., $f_o/2$, $2f_o$ or other structural resonant frequencies, where f_o is the resonant frequency). The drive signal **416** is applied to the transducer **114** in response to activation of the switch **312***a* on the handpiece assembly **160** or the foot switch **434**. During this period the ultrasonic transducer **114** mechanically activates the blade **146** at the first drive frequency f_1. A force or load may be applied to the clamp member **151** and the blade **146** to facilitate this process. During this period, the processor **400** monitors the transducer impedance Z until the load on the blade **146** changes and the transducer impedance Z crosses a predetermined threshold to indicate that the tissue layer has been transected. The processor **400** then applies a second digital frequency signal **418** to set a second drive frequency f_2, e.g., the resonant frequency f_o or other suitable frequency for transecting, coagulating, and sealing tissue. Another portion of the tissue (e.g., the vessel) is then grasped between the clamp member **151** and the blade **146**. The transducer **114** is now energized by the drive signal **416** at the second drive frequency f_2 by actuating either the foot switch **434** or the switch **312***a* on the handpiece assembly **160**. It will be appreciated by those skilled in the art that the drive current (I) output also may be stepped as described with reference to FIGS. **6-8** based on the transducer impedance Z.

According to one embodiment of a step function algorithm **402**, the processor **400** initially sets a first drive frequency f_1 that is significantly off resonance to separate the inner muscle layer of the vessel from the adventitia layer. During this period of operation the processor **400** monitors the transducer impedance Z to determine when the inner muscle layer is transected or separated from the adventitia layer. Because the transducer impedance Z is correlated to the load applied to the blade **146**, for example, cutting more tissue decrease the load on the blade **146** and the transducer impedance Z. The transection of the inner muscle layer is detected when the transducer impedance Z drops below a predetermined threshold. When the change in transducer impedance Z indicates that the vessel has been separated from the inner muscle layer, the processor **400** sets the drive frequency to the resonant frequency f_o. The vessel is then grasped between the blade **146** and the clamp member **151** and the transducer **114** is activated by actuating either the foot switch or the switch on the handpiece assembly **160** to transect and seal the vessel. In one embodiment, the impedance Z change may range between about 1.5 to about 4 times a base impedance measurements from an initial point of contact with the tissue to a point just before the muscle layer is transected and sealed.

With reference now to FIGS. **1**, **8**, and **19**, as previously discussed, in one embodiment, the surgical system **100**, and the ultrasonic surgical instrument **110**, comprises the signal generator module **102**. In one embodiment, the signal generator module **102** may be implemented as a tissue impedance module **502**. Although in the presently disclosed embodiment, the signal generator module **102** is shown separate from the surgical instrument **110**, in one embodiment, the signal generator module **102** may be formed integrally with the surgical instrument **110**, as shown in phantom in FIG. **1**, such that the surgical instrument **110** forms a unitary surgical system. In one embodiment, surgical instrument the signal generator module **102** may be configured to monitor the electrical impedance Z_t of the tissue T (FIGS. **5**, **10**, **16**, **17**) to control the characteristics of time and power level based on the impedance Z_t of the tissue T. In one embodiment, the tissue impedance Z_t may be determined by applying a subtherapeutic radio frequency (RF) signal to the tissue T and measuring the current through the tissue T by way of a return electrode on the clamp member **151**, as previously discussed. In another embodiment, the tissue impedance Z_t may be determined by measuring a therapeutic radio frequency (RF) signal applied

to the tissue T by measuring the current through the tissue T by way of a return electrode on the clamp member **151**. In the schematic diagram shown in FIG. **19**, an end effector portion of the surgical system **100** comprises the clamp arm assembly **451** (FIG. **8**) connected to the distal end of the outer sheath **158**. The blade **146** forms a first (e.g., energizing) electrode and the clamp arm assembly **451** comprises an electrically conductive portion that forms a second (e.g., return) electrode. The tissue impedance module **502** is coupled to the blade **146** and the clamp arm assembly **451** through a suitable transmission medium such as a cable **137**. The cable **137** comprises multiple electrical conductors for applying a voltage to the tissue T and providing a return path for current flowing through the tissue T back to the impedance module **502**. In various embodiments, the tissue impedance module **502** may be formed integrally with the generator **112** or may be provided as a separate circuit coupled to the generator **112** (shown in phantom to illustrate this option). In one embodiment, the signal generator module **102** may generate a therapeutic RF signal in response to a change in the tissue impedance Z_t.

Still with reference to FIGS. **1**, **8**, and **19** illustrates one embodiment of an integrated generator module **320** comprising the ultrasonic generator module **180** and the signal generator module **102**. As shown, the signal generator module **102** is configured as a tissue impedance module **502**. The integrated generator module **320** generates the ultrasonic electrical drive signal **416** to drive the ultrasonic transducer **114**. In one embodiment, the tissue impedance module **502** may be configured to measure the impedance Z_t of the tissue T (FIGS. **5**, **10**, **16**, **17**) grasped between the blade **146** and the clamp arm assembly **451**. The tissue impedance module **502** comprises an RF oscillator **506**, a voltage sensing circuit **508**, and a current sensing circuit **510**. The voltage and current sensing circuits **508**, **510** respond to the RF voltage v_{rf} applied to the blade **146** electrode and the RF current i_{rf} flowing through the blade **146** electrode, the tissue, and the conductive portion of the clamp arm assembly **451**. The sensed voltage v_{rf} and current i_{rf} are converted to digital form by the ADC **432** via the analog multiplexer **430**. The processor **400** receives the digitized output **433** of the ADC **432** and determines the tissue impedance Z_t by calculating the ratio of the RF voltage v_{rf} to current i_{rf} measured by the voltage sense circuit **508** and the current sense circuit **510**. In one embodiment, the transection of the inner muscle layer and the tissue may be detected by sensing the tissue impedance Z_t. Accordingly, detection of the tissue impedance Z_t may be integrated with an automated process for separating the inner muscle layer from the outer adventitia layer prior to transecting the tissue without causing a significant amount of heating, which normally occurs at resonance. Additional clamp arm and sheath assemblies comprising an electrode as shown in FIGS. **9-17** may be employed without limitation.

FIG. **20** is a schematic diagram of the signal generator module **102** configured as the tissue impedance module **502** coupled to the blade **146** and the clamp arm assembly **415** with tissue T located therebetween. With reference now to FIGS. **1**, **8**, and **18-20**, the generator **112** comprises the signal generator module **102** configured as the tissue impedance module **502** configured for monitoring the impedance Z_t of the tissue T located between the blade **146** and the clamp arm assembly **451** during the tissue transection process. The tissue impedance module **502** may is coupled to the ultrasonic surgical instrument **110** by way of the cables **137**, **139**. The cable includes a first "energizing" conductor **139** connected to the blade **146** (e.g., positive [+] electrode) and a second "return" conductor **137** connected to the conductive jacket **472** (e.g., negative [−] electrode) of the clamp arm assembly **451**. In one embodiment, RF voltage v_{rf} is applied to the blade **146** to cause RF current i_{rf} to flow through the tissue T. The second conductor **137** provides the return path for the current i_{rf} back to the tissue impedance module **502**. The distal end of the return conductor **137** is connected to the conductive jacket **472** such that the current i_{rf} can flow from the blade **146**, through the tissue T positioned intermediate the conductive jacket **472** and the blade **146**, and the conductive jacket **472** to the return conductor **137**. The impedance module **502** connects in circuit, by way of the first and second conductors **137**, **139**. In one embodiment, the RF energy may be applied to the blade **146** through the ultrasonic transducer **114** and the waveguide **147**. It is worthwhile noting that the RF energy applied to the tissue T for purposes of measuring the tissue impedance Z_t is a low level subtherapeutic signal that does not contribute in a significant manner, or at all, to the treatment of the tissue T.

Having described operational details of various embodiments of the surgical system **100**, operations for the above surgical system **100** may be further described with reference to FIGS. **1**, **8**, and **18-20** in terms of a process for cutting and coagulating a blood vessel employing a surgical instrument comprising the input device **406** and the tissue impedance module **502**. Although a particular process is described in connection with the operational details, it can be appreciated that the process merely provides an example of how the general functionality described herein can be implemented by the surgical system **100**. Further, the given process does not necessarily have to be executed in the order presented herein unless otherwise indicated. As previously discussed, the input device **406** may be employed to program the step function output (e.g., current, voltage, frequency) to the ultrasonic transducer **114**/blade **146** assembly.

In one embodiment, the ultrasonic surgical instrument **110** may be operated in accordance with a programmed step function algorithm **402** responsive to the tissue impedance Z_t. In one embodiment, a frequency step function output may be initiated based on a comparison of the tissue impedance Z_t and predetermined thresholds that have been correlated with various tissue states (e.g., desiccation, transection, sealing). When the tissue impedance Z_t transitions above or below (e.g., crosses) a threshold, the processor **400** applies a digital frequency signal **418** to the DDS circuit **420** to change the frequency of an ultrasonic oscillator by a predetermined step in accordance with the step function algorithm **402** responsive to the tissue impedance Z_t.

In operation, the blade **146** is located at the tissue treatment site. The tissue T is grasped between the blade **146** and the clamp arm assembly **451** such that the blade **146** and the conductive jacket **472** make electrical contact with the tissue T. The processor **400** applies a first digital frequency signal **418** to set a first drive frequency f_1 that is off resonance (e.g., $f_o/2$, $2f_o$ or other structural resonant frequencies, where f_o is the resonant frequency). The blade **146** is electrically energized by the low level subtherapeutic RF voltage v_{rf} supplied by the tissue impedance module **502**. The drive signal **416** is applied to the transducer **114**/blade **146** in response to actuation of the switch **143** on the handpiece assembly **160** or the foot switch **144434** until the tissue impedance Z_t of the tissue T changes by a predetermined amount. A force or load is then applied to the clamp arm assembly **451** and the blade **146**. During this period the ultrasonic transducer **114** mechanically activates the blade **146** at the first drive frequency f_1 and as a result, the tissue T begins to desiccate from the ultrasonic action applied between the blade **146** and the one or more clamp pads **155** of the clamp arm assembly **451** causing the

impedance Z_t of the tissue T to increase. Eventually, as the tissue T is transected by the ultrasonic action and applied clamp force, the impedance Z_t of the tissue T becomes very high or infinite. It will be appreciated by those skilled in the art that the drive current (I) output also may be stepped as described above based on measured impedance Z_t of the tissue T.

In one embodiment, the impedance Z_t of tissue T may be monitored by the impedance module **502** in accordance with the following process. A measurable RF current i_1 is conveyed through the first energizing conductor **139** to the blade **146**, through the tissue T, and back to the impedance module **502** through the conductive jacket **472** and the second conductor **137**. As the tissue T is desiccated and cut by the ultrasonic action of the blade **146** acting against the one or more clamp pads **155**, the impedance of the tissue **514** increases and thus the current i_1 in the return path, i.e., the second conductor **137**, decreases. The impedance module **502** measures the tissue impedance Z_t and conveys a representative signal to the ADC **432** whose digital output **433** is provided to the processor **400**. The processor **400** calculates the tissue impedance Z_t based on these measured values of v_{rf} and i_{rf}. In response to the transducer impedance (Z_t), the processor **400** controls the operation of the surgical instrument **110**. For example, the processor **400** can adjust the power delivered to the transducer **114**, can shut off the power to the transducer **114**, and/or provide feedback to the user. In one embodiment, the processor **400** steps the frequency by any suitable increment or decrement in response to changes in the impedance Z_t of the tissue T. In other embodiments, the processor **400** controls the drive signals **416** and can make any necessary adjustments in amplitude and frequency in response to the tissue impedance Z_t In one embodiment, the processor **400** can cut off the drive signal **416** when the tissue impedance Z_t reaches a predetermined threshold value.

Accordingly, by way of example, and not limitation, in one embodiment, the ultrasonic surgical instrument **110** may be operated in accordance with a programmed stepped output algorithm to separate the inner muscle layer of a vessel from the adventitia layer prior to transecting and sealing the vessel. As previously discussed, according to one step function algorithm, the processor **400** initially sets a first drive frequency f_t that is significantly off resonance. The transducer **114** is activated to separate the inner muscle layer of the vessel from the adventitia layer and the tissue impedance module **502** applies a subtherapeutic RF voltage v_{rf} signal to the blade **146**. During this period T_1 of operation the processor **400** monitors the tissue impedance Z_t to determine when the inner muscle layer is transected or separated from the adventitia layer. The tissue impedance Z_t is correlated to the load applied to the blade **146**, for example, when the tissue becomes desiccated or when the tissue is transected the tissue impedance Z_t becomes extremely high or infinite. The change in tissue impedance Z_t indicates that the vessel has been separated or transected from the inner muscle layer and the generator **112** is deactivated for a second period of time T_2. The processor **400** then sets the drive frequency to the resonant frequency f_o. The vessel is then grasped between the blade **146** and the clamp arm assembly **451** and the transducer **114** is reactivated to transect and seal the vessel. Continuous monitoring of the tissue impedance Z_t provides an indication of when the vessel is transected and sealed. Also, the tissue impedance Z_t may be monitored to provide an indication of the completeness of the tissue cutting and/or coagulating process or to stop the activation of the generator **112** and/or the ultrasonic generator module **180** when the impedance Z_t of the tissue T reaches a predetermined threshold value. The threshold for the tissue impedance Z_t may be selected, for example, to indicate that the vessel has been transected. In one embodiment, the tissue impedance Z_t may range between about 10 Ohms to about 1000 Ohms from an initial point to a point just before the muscle layer is transected and sealed.

The applicants have discovered that experiments that run varying current set points (both increasing and decreasing) and dwell times indicate that the described embodiments can be used to separate the inner muscle layer from the outer adventitia layer prior to completing the transection resulting in improved hemostasis and potentially lower total energy (heat) at the transection site. Furthermore, although the surgical instrument **110** has been described in regards to impedance threshold detection schemes to determine when the muscle layer is separated from the adventitia, other embodiments that do not employ any detection scheme are within the scope of the present disclosure. For example, embodiments of the surgical instrument **110** may be employed in simplified surgical systems wherein non-resonant power is applied to separate the layers for a predetermined time of approximately 1 second or less, prior to applying a resonant power to cut the tissue. The embodiments are not limited in this context.

In one embodiment, the surgical instrument may be operated to produce a therapeutic RF signal in response to the monitored impedance Z_t of tissue T. In this embodiment, the processor **400** may initially set a first drive frequency f_t for operating the transducer. The tissue impedance module **502** may be operated to apply a subtherapeutic RF voltage v_{rf} signal to the blade **146**. During this period T_1 f operation the processor **400** monitors the tissue impedance Z_t to determine when a successful ultrasonic operation has been completed. The ultrasonic operations may include, for example separation of the inner muscle layer from the adventitia layer or coagulation of a vessel. The change in tissue impedance Z_t indicates the completion of the ultrasonic operation and the generator **112** may be deactivated for a second time period T_2. The processor **400** may then set the signal generator module **102** to produce a therapeutic RF signal. The processor **400** may operate the signal generator module **102** to deliver the therapeutic RF signal through cables **137**, **139**. The cables may include a first "energizing" conductor **139** connected to the blade **146** (e.g., positive [+] electrode) and a second "return" conductor **137** connected to the conductive jacket **472** (e.g., negative [−] electrode) of the clamp arm assembly **451**. The processor **400** may continuously monitor the tissue impedance Z_t to provide an indication of a completed electrosurgical treatment, such as, for example, tissue desiccation. When the tissue impedance Z_t reaches a predetermined threshold value, the generator **112** may be deactivated. The threshold for the tissue impedance Z_t may be selected, for example, to indicate that the tissue T has been desiccated.

In various embodiments, the surgical instrument **110** may be programmed for detecting a change of state of tissue being manipulated by an ultrasonic surgical instrument and providing feedback to the user to indicate that the tissue has undergone such change of state or that there is a high likelihood that the tissue has undergone such change of state. As used herein, the tissue may undergo a change of state when the tissue is separated from other layers of tissue or bone, when the tissue is cut or transected, when the tissue is coagulated, and so forth while being manipulated with an end effector of an ultrasonic surgical instrument, such as, for example, the end effector **150** of the ultrasonic surgical instrument **110**. A change in tissue state may be determined based on the likelihood of an occurrence of a tissue separation event.

With reference to FIGS. **1**, **5**, and **18-20**, in various embodiments, the impedance Z and the tissue Z_t, as well as any other suitable electrical measurements, that can be made with the surgical system **100**, may be used to provide feedback by the output indicator **412** shown in FIGS. **18** and **19**. The output indicator **412** is particularly useful in applications where the tissue being manipulated by the end effector **151** is out of the user's field of view and the user cannot see when a change of state occurs in the tissue T. The output indicator **412** communicates to the user that a change in tissue state has occurred as determined in accordance with the operations described with respect to various logic flows. As previously discussed, the output indicator **412** may be configured to provide various types of feedback to the user including, without limitation, visual, audible, and/or tactile feedback to indicate to the user (e.g., surgeon, clinician) that the tissue has undergone a change of state of the tissue. By way of example, and not limitation, as previously discussed, visual feedback comprises any type of visual indication device including incandescent lamps or LEDs, graphical user interface, display, analog indicator, digital indicator, bar graph display, digital alphanumeric display. By way of example, and not limitation, audible feedback comprises any type of buzzer, computer generated tone, computerized speech, VUI to interact with computers through a voice/speech platform. By way of example, and not limitation, tactile feedback comprises any type of vibratory feedback provided through the instrument housing handpiece assembly **160**.

The processor **400** to determines a change in tissue state in accordance with the operations described above and provides feedback to the user by way of the output indicator **412**. The processor **400** monitors and evaluates the voltage, current, and/or frequency signal samples available from the generator **32**, **320** and according to the evaluation of such signal samples determines whether a change in tissue state has occurred. A change in tissue state may be determined based on the type of ultrasonic instrument and the power level that the instrument is energized at. In response to the feedback, the operational mode of the ultrasonic surgical instrument **110** may be controlled by the user or may be automatically or semi-automatically controlled.

In one embodiment, the processor **400** portion of the drive system **32**, **320** samples the voltage (v), current (i), and frequency (f) signals of the ultrasonic generator module **180** and/or the signal generator module **102**. As previously discussed, the output indicator **412** may provide visual, audible, and/or tactile feedback to alert the user of the ultrasonic surgical instrument **110** that a change in tissue state has occurred. In various embodiments, in response to the feedback from the output indicator **412**, the operational modes of the generator **112**, the ultrasonic generator module **180**, the signal generator module **102**, and/or the ultrasonic instrument **110** may be controlled manually, automatically, or semi-automatically. The operational modes include, without limitation, disconnecting or shutting down the output power, reducing the output power, cycling the output power, pulsing the output power, and/or outputting momentary surge of high-power. In one embodiment, the operational modes include, operating the surgical instrument **110** in a first operating mode in which the transducer **14** produces mechanical energy, or vibrations, that are transmitted to the end effector **151** and a second operating mode in which electrical energy, or current, can flow through the end effector **151** to perform electrosurgery. The operational modes of the ultrasonic instrument **110** in response to the change in tissue state can be selected, for example, to minimize heating effects of the end effector **151**, e.g., of the clamp pad **155**, to prevent or minimize possible damage to the surgical instrument **110**, and/or surrounding tissue. This is advantageous because heat is generated exponentially when the transducer **114** is activated with nothing between the jaws of the end effector **151** as is the case when a change in tissue state occurs.

In various embodiments, the change of state of the tissue may be determined based on transducer and tissue impedance measurements as previously described, or based on voltage, current, and frequency measurements in accordance with the operations described in the disclosure of the following commonly-owned, contemporaneously-filed U.S. patent application, which is incorporated herein by reference in its entirety: U.S. patent application Ser. No. 12/503,775, entitled "ULTRASONIC DEVICE FOR CUTTING AND COAGULATING WITH STEPPED OUTPUT," now U.S. Pat. No. 8,058,771.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the various embodiments described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility. Sterilization can also be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, and/or steam.

In various embodiments, an ultrasonic surgical instrument can be supplied to a surgeon with a waveguide and/or end effector already operably coupled with a transducer of the surgical instrument. In at least one such embodiment, the surgeon, or other clinician, can remove the ultrasonic surgical instrument from a sterilized package, plug the ultrasonic instrument into a generator, as outlined above, and use the ultrasonic instrument during a surgical procedure. Such a system can obviate the need for a surgeon, or other clinician, to assemble a waveguide and/or end effector to the ultrasonic surgical instrument. After the ultrasonic surgical instrument has been used, the surgeon, or other clinician, can place the ultrasonic instrument into a sealable package, wherein the package can be transported to a sterilization facility. At the sterilization facility, the ultrasonic instrument can be disinfected, wherein any expended parts can be discarded and replaced while any reusable parts can be sterilized and used once again. Thereafter, the ultrasonic instrument can be reas-

sembled, tested, placed into a sterile package, and/or sterilized after being placed into a package. Once sterilized, the reprocessed ultrasonic surgical instrument can be used once again.

Although various embodiments have been described herein, many modifications and variations to those embodiments may be implemented. For example, different types of end effectors may be employed. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

What is claimed is:

1. A method of controlling a surgical instrument, the method comprising:

generating a first ultrasonic drive signal by an ultrasonic generator coupled to an ultrasonic drive system, wherein the first ultrasonic drive signal has a first frequency f_1, wherein the ultrasonic drive system comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide, and wherein the ultrasonic drive system is configured to resonate mechanically at a resonant frequency;

operating the ultrasonic transducer at the first ultrasonic drive signal for a first period;

monitoring an electrical characteristic;

controlling the ultrasonic generator in response to the monitored electrical characteristic, wherein the ultrasonic generator is controlled based on a predetermined function responsive to the monitored electrical characteristic, wherein the predetermined function comprises a step function, wherein the first ultrasonic drive signal operates the end effector to separate a muscle layer from a tissue section;

generating a second ultrasonic drive signal by the ultrasonic generator, wherein the second ultrasonic drive signal has a second frequency f_0, wherein the first frequency f_1 and the second frequency f_0 are different, and wherein the second ultrasonic drive signal operates the end effector to cut and seal the tissue section; and

operating the ultrasonic transducer at the second drive signal for a second period, wherein the first period and the second period are continuous, and wherein the first period and the second period are determined by the predetermined function.

2. The method of claim **1**, wherein the monitored electrical characteristic is impedance of the ultrasonic transducer.

3. The method of claim **1**, wherein the monitored electrical characteristic is impedance of a tissue portion contacting the end effector.

4. The method of claim **1**, comprising:

generating a therapeutic electrical signal by an electrosurgical generator coupled to the end effector in response to the monitored electrical characteristic.

5. The method of claim **1**, comprising:

providing feedback in response to the monitored electrical characteristic.

6. The method of claim **1**, comprising:

generating a subtherapeutic electrical signal by a signal generator coupled to the end effector;

applying the subtherapeutic electrical signal to a tissue portion contacting the end effector; and

monitoring an electrical characteristic of the tissue portion.

7. The method of claim **6**, comprising:

controlling one of the first and second ultrasonic drive signals in response to the monitored electrical characteristic of the tissue portion.

8. The method of claim **7**, comprising:

generating a therapeutic electrical signal by an electrosurgical generator coupled to the end effector in response to the monitored electrical characteristic of the tissue portion.

9. The method of claim **6**, comprising:

providing feedback in response to the monitored electrical characteristic of the tissue portion.

10. The method of claim **1**, wherein the first frequency is an off resonance frequency f_1, and wherein the second frequency is a resonance frequency f_0.

11. The method of claim **10**, wherein the off resonance frequency f_1 is defined as a frequency of $2*f_0$.

12. The method of claim **1**, wherein the off resonance signal f_1 is defined as a frequency of $f_0/2$.

13. The method of claim **1**, wherein the monitored electrical characteristic comprises an electrical characteristic of the ultrasonic generator.

14. A surgical instrument, comprising:

an ultrasonic generator coupled to an ultrasonic drive system, wherein the ultrasonic drive system comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide, and wherein the ultrasonic drive system is configured to resonate mechanically at a resonant frequency, wherein the ultrasonic generator is to generate a first ultrasonic drive signal having a first frequency and a second ultrasonic drive signal having a second frequency, wherein the first and second frequencies are different;

an electronic circuit coupled to the ultrasonic generator module, wherein the electronic circuit is to monitor an electrical characteristic; and

a processor coupled to the electronic circuit, wherein the processor is to control one of the first and second ultrasonic drive signals in response to the monitored electrical characteristic, wherein the processor operates the ultrasonic transducer at the first ultrasonic drive signal for a first period, wherein the first period ends at a predetermined electrical characteristic, wherein the processor operates the ultrasonic transducer at the second ultrasonic drive signal for a second period, wherein the first period and the second period are continuous, wherein the first period and the second period are determined by a predetermined function responsive to the predetermined electrical characteristic, wherein the predetermined function comprises a step function, wherein the first ultrasonic drive signal operates the end effector to separate a muscle layer from a tissue section, and wherein the second ultrasonic drive signal operates the end effector to cut and seal the tissue section.

15. The surgical instrument apparatus of claim **14**, wherein the electronic circuit comprises:

a current sense circuit to sense electrical current flowing through the transducer; and

a voltage sense circuit to sense output voltage applied to the transducer.

16. The surgical instrument of claim **14**, comprising:

an electrosurgical generator coupled to the end effector, wherein the electrosurgical generator is to generate a therapeutic electrical signal in response to the monitored electrical characteristic.

17. The surgical instrument of claim **14**, comprising:

an output indicator coupled to the processor to provide feedback in response to the monitored electrical characteristic.

18. The surgical instrument of claim **14**, comprising:

a signal generator coupled to the end effector to generate a subtherapeutic electrical signal;

an electrode coupled to the end effector and to the signal generator, wherein the electrode is to apply the subtherapeutic electrical signal to a tissue portion contacting the end effector;

a current sense circuit coupled to the signal generator to sense electrical signal flowing through the tissue portion; and

a voltage sense circuit coupled to the signal generator to sense the voltage applied to the tissue portion.

19. A surgical system, the system comprising:

an ultrasonic generator coupled to an ultrasonic drive system, wherein the ultrasonic drive system comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide, wherein the ultrasonic drive system is configured to resonate mechanically at a resonant frequency, wherein the ultrasonic generator is to generate a first ultrasonic drive signal having a first frequency and a second ultrasonic drive signal having a second frequency, wherein the first and second frequencies are different;

an electrosurgical generator coupled to the end effector to generate a therapeutic electrical signal;

a signal generator coupled to the end effector to generate a subtherapeutic electrical signal; and

a processor coupled to the ultrasonic generator and the signal generator, wherein the processor monitors an electrical characteristic of the ultrasonic drive system, wherein the processor operates the ultrasonic transducer at the first ultrasonic drive signal for a first period, wherein the first period ends at a predetermined electrical characteristic, wherein the processor operates the ultrasonic transducer at the second ultrasonic drive signal for a second period, wherein the first period and the second period are continuous, and wherein the first period and the second period are determined by a predetermined function responsive to the predetermined electrical characteristic, wherein the predetermined function comprises a step function, wherein the first drive signal operates the end effector to separate a muscle layer from a tissue section, and wherein the second drive signal operates the end effector to cut and seal the tissue section.

20. The system of claim **19**, comprising:

an electronic circuit coupled to the ultrasonic generator module, wherein the electronic circuit is to monitor the electrical characteristic of the ultrasonic drive system, wherein the electronic circuit comprises:

a current sense circuit to sense electrical current flowing through the ultrasonic transducer; and

a voltage sense circuit to sense output voltage applied to the ultrasonic transducer.

21. The system of claim **19**, wherein the electrosurgical generator is to generate a therapeutic electrical signal in response to the monitored electrical characteristic of the ultrasonic drive system.

22. The system of claim **19**, comprising:

an output indicator coupled to the processor to provide feedback in response to the monitored electrical characteristic of the ultrasonic drive system.

23. The system of claim **19**, comprising:

an electrode coupled to the end effector and to the signal generator, wherein the electrode is to apply the subtherapeutic electrical signal to a tissue portion contacting the end effector;

a current sense circuit coupled to the signal generator to sense electrical signal flowing through the tissue portion; and

a voltage sense circuit coupled to the signal generator to sense voltage applied to the tissue portion.

24. A method of controlling a surgical instrument, the method comprising:

generating a first ultrasonic drive signal by an ultrasonic generator coupled to an ultrasonic drive system, wherein the first ultrasonic drive signal has a first frequency, wherein the ultrasonic drive system comprises an ultrasonic transducer coupled to a waveguide and an end effector coupled to the waveguide, wherein the ultrasonic drive system is configured to resonate mechanically at a resonant frequency, and wherein the first frequency is an off resonance frequency f_1;

operating the ultrasonic transducer at the first ultrasonic drive signal for a first period;

monitoring an electrical characteristic;

controlling the ultrasonic generator in response to the monitored electrical characteristic, wherein the ultrasonic generator is controlled based on a predetermined function responsive to the monitored electrical characteristic;

generating a second ultrasonic drive signal by the ultrasonic generator, wherein the second ultrasonic drive signal has a second frequency, and wherein the second frequency is a resonance frequency f_0;

operating the ultrasonic transducer at the second ultrasonic drive signal for a second period, wherein the first period and the second period are continuous, and wherein the first period and the second period are determined by the predetermined function, and

wherein the off resonance frequency f_1 is defined as a half-integer multiple of the resonant frequency f_0.

* * * * *

专利名称(译)	用于超声外科手术器械的阻抗监测装置，系统和方法		
公开(公告)号	US9017326	公开(公告)日	2015-04-28
申请号	US12/503766	申请日	2009-07-15
[标]申请(专利权)人(译)	伊西康内外科公司		
申请(专利权)人(译)	爱惜康内镜手术，INC.		
当前申请(专利权)人(译)	爱惜康内镜手术，INC.		
[标]发明人	DINARDO BRIAN YATES DAVID C MESSERLY JEFFREY D WIENER EITAN T WITT DAVID A GIORDANO JAMES R ALDRIDGE JEFFREY L		
发明人	DINARDO, BRIAN YATES, DAVID C. MESSERLY, JEFFREY D. WIENER, EITAN T. WITT, DAVID A. GIORDANO, JAMES R. ALDRIDGE, JEFFREY L.		
IPC分类号	A61B17/285 A61B17/3209 A61B17/295 A61B18/08 A61B17/00 A61B17/32 A61B18/00 A61B18/12 A61B18/14		
CPC分类号	A61B18/1445 A61B17/320092 A61B18/1206 A61B2017/00026 A61B2017/0003 A61B2017/00973 A61B2017/320088 A61B2018/00589 A61B2018/00601 A61B2018/00875 A61B2017/320093 A61B2017/320094 A61B2017/320095		
其他公开文献	US20110015627A1		
外部链接	Espacenet USPTO		

摘要(译)

在一个总体方面，各种实施例涉及一种外科器械，其可以向外科器械的末端执行器提供机械能和电能。手术器械包括耦合到超声驱动系统的超声发生器模块，超声驱动器模块包括耦合到波导的超声换能器和耦合到波导的末端执行器。超声驱动系统被配置为以共振频率机械地共振以产生第一超声驱动信号。电子电路耦合到超声发生器模块以监测超声驱动系统的电特性。处理器耦合到电子电路，以响应于所监测的超声驱动系统的电特性来控制超声驱动信号。