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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4887605	A	1989-12-19	Angelsen et al.	
	2	5348008	A	1994-09-20	Bornn Robert et al.	
	3	5533499	A	1996-07-09	Johnson Bruce C	
	4	5542916	A	1996-08-06	Hirsch Chaya et al.	
	5	5611798	A	1997-03-18	Eggers	
	6	5624439	A	1997-04-29	Edwards Stuart D et al.	
	7	5674191	A	1997-10-07	Edwards Stuart D et al.	
	8	5707349	A	1998-01-13	Edwards Stuart D	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	9	5718702	A	1998-02-17	Edwards Stuart D	
	10	5728094	A	1998-03-17	Edwards Stuart D	
	11	5730719	A	1998-03-24	Edwards Stuart D	
	12	5733280	A	1998-03-31	Avitall	
	13	5738114	A	1998-04-14	Edwards Stuart D	
	14	5743904	A	1998-04-28	Edwards Stuart D	
	15	5743870	A	1998-04-28	Edwards Stuart D	
	16	5746224	A	1998-05-05	Edwards Stuart D	
	17	5800429	A	1998-09-01	Edwards Stuart D	
	18	5807306	A	1998-09-15	Shapland J Edward et al.	
	19	5817049	A	1998-10-06	Edwards Stuart D	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	20	5816095	A	1998-10-06	Nordell Ii Benjamin T et al.	
	21	5820580	A	1998-10-13	Edwards Stuart D et al.	
	22	5823197	A	1998-10-20	Edwards Stuart D	
	23	5827277	A	1998-10-27	Edwards Stuart D	
	24	5843077	A	1998-12-01	Edwards Stuart D	
	25	5843021	A	1998-12-01	Edwards Stuart D et al.	
	26	5846235	A	1998-12-08	Pasricha et al.	
	27	5879349	A	1999-03-09	Edwards Stuart D	
	28	5938659	A	1999-08-17	Tu Hosheng et al.	
	29	6045549	A	2000-04-04	Smethers et al.	
	30	6096033	A	2000-08-01	Tu et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	31	6102907	A	2000-08-15	Smethers et al.	
	32	6109268	A	2000-08-29	Thapliyal et al.	
	33	6126657	A	2000-10-03	Edwards Stuart D et al.	
	34	6131579	A	2000-10-17	Thorson et al.	
	35	6139546	A	2000-10-31	Koenig Franklin R et al.	
	36	6152143	A	2000-11-28	Edwards Stuart D	
	37	6165173	A	2000-12-26	Kamdar Kirti P et al.	
	38	6179803	B1	2001-01-30	Edwards et al.	
	39	6210355	B1	2001-04-03	Edwards et al.	
	40	6228079	B1	2001-05-08	Koenig	
	41	6231569	B1	2001-05-15	Bek et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	42	6293941	B1	2001-09-25	Strul et al.	
	43	6309386	B1	2001-10-30	Bek	
	44	6371926	B1	2002-04-16	Thorson et al.	
	45	6383181	B1	2002-05-07	Johnston et al.	
	46	6391028	B1	2002-05-21	Fanton et al.	
	47	6416491	B1	2002-07-09	Edwards et al.	
	48	6425151	B2	2002-07-30	Barnett	
	49	6431174	B1	2002-08-13	Knudson et al.	
	50	6451013	B1	2002-09-17	Bays et al.	
	51	6502574	B2	2003-01-07	Stevens et al.	
	52	6551310	B1	2003-04-22	Ganz et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
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	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	53	6562036	B1	2003-05-13	Ellman et al.	
	54	6575969	B1	2003-06-10	Rittman et al.	
	55	6589235	B2	2003-07-08	Wong et al.	
	56	6659106	B1	2003-12-09	Hovda et al.	
	57	6911027	B1	2005-06-28	Edwards et al.	
	58	6978781	B1	2005-12-27	Jordan	
	59	7055523	B1	2006-06-06	Brown	
	60	7097641	B1	2006-08-29	Arless et al.	
	61	7114495	B2	2006-10-03	Lockwood, Jr.	
	62	7322993	B2	2008-01-29	Metzger et al.	
	63	7361168	B2	2008-04-22	Makower et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	64	7416550	B2	2008-08-26	Protsenko et al.	
	65	7442191	B2	2008-10-28	Hovda et al.	
	66	7655243	B2	2010-02-02	Deem et al.	
	67	7678069	B1	2010-03-16	Baker et al.	
	68	7780730	B2	2010-08-24	Saidi	
	69	7824394	B2	2010-11-02	Manstein	
	70	7850683	B2	2010-12-14	Elkins et al.	
	71	7997278	B2	2011-08-16	Utley et al.	
	72	8114062	B2	2012-02-14	Muni et al.	
	73	8128617	B2	2012-03-06	Bencini et al.	
	74	8137345	B2	2012-03-20	Mcnall, Iii et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	75	8317782	B1	2012-11-27	Ellman et al.	
	76	8317781	B2	2012-11-27	Owens et al.	
	77	8936594	B2	2015-01-20	Wolf et al.	
	78	8986301	B2	2015-03-24	Wolf et al.	
	79	9027597	B2	2015-05-12	Kubo	
	80	9072597	B2	2015-07-07	Wolf et al.	
	81	9125677	B2	2015-09-08	Sobol et al.	
	82	9179967	B2	2015-11-10	Wolf et al.	
	83	9179964	B2	2015-11-10	Wolf et al.	
	84	9237924	B2	2016-01-19	Wolf et al.	
	85	9247989	B2	2016-02-02	Truckai	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	86	9415194	B2	2016-08-16	Wolf et al.	
	87	9433463	B2	2016-09-06	Wolf et al.	
	88	9452087	B2	2016-09-27	Holm et al.	
	89	9452010	B2	2016-09-27	Wolf et al.	
	90	9486278	B2	2016-11-08	Wolf et al.	
	91	9526571	B2	2016-12-27	Wolf et al.	
	92	9687296	B2	2017-06-27	Wolf et al.	
	93	9687288	B2	2017-06-27	Saadat	
	94	9763743	B2	2017-09-19	Lin et al.	
	95	9763723	B2	2017-09-19	Saadat	
	96	9770293	B2	2017-09-26	Dresher	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	97	9788886	B2	2017-10-17	Wolf et al.	
	98	9801752	B2	2017-10-31	Wolf et al.	
	99	9888957	B2	2018-02-13	Wolf et al.	
	100	9913682	B2	2018-03-13	Wolf et al.	
	101	9943361	B2	2018-04-17	Wolf et al.	
	102	10028781	B2	2018-07-24	Saadat	
	103	10028780	B2	2018-07-24	Wolf et al.	
	104	10265115	B2	2019-04-23	Wolf et al.	
	105	10335221	B2	2019-07-02	Wolf et al.	
	106	10376300	B2	2019-08-13	Wolf et al.	
	107	10398489	B2	2019-09-03	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	108	10456186	B1	2019-10-29	Wolf et al.	
	109	10456185	B2	2019-10-29	Wolf et al.	
	110	10470814	B2	2019-11-12	Wolf et al.	
	111	10485603	B2	2019-11-26	Wolf et al.	
	112	10603059	B2	2020-03-31	Dinger et al.	
	113	D 880694	S	2020-04-07	Ng et al.	
	114	D 881904	S	2020-04-21	Angeles et al.	
	115	10631925	B2	2020-04-28	Wolf et al.	
	116	10722282	B2	2020-07-28	Wolf et al.	
	117	10779873	B2	2020-09-22	Wolf et al.	
	118	10932853	B2	2021-03-02	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	WOLF
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020010460	A1	2002-01-24	Joye et al.	
	2	20020016588	A1	2002-02-07	Wong et al.	
	3	20020049464	A1	2002-04-25	Donofrio et al.	
	4	20020087155	A1	2002-07-04	Underwood et al.	
	5	20020128641	A1	2002-09-12	Underwood et al.	
	6	20030144659	A1	2003-07-31	Edwards	
	7	20030208194	A1	2003-11-06	Hovda et al.	
	8	20030225403	A1	2003-12-04	Woloszko et al.	
	9	20040193238	A1	2004-09-30	Mosher et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-05-21
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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	10	20040210214	A1	2004-10-21	Knowlton	
	11	20040215235	A1	2004-10-28	Jackson et al.	
	12	20040220644	A1	2004-11-04	Shalev et al.	
	13	20050020901	A1	2005-01-27	Belson et al.	
	14	20050119643	A1	2005-06-02	Sobol et al.	
	15	20050222565	A1	2005-10-06	Manstein	
	16	20050234443	A1	2005-10-20	Rioux et al.	
	17	20050234439	A1	2005-10-20	Underwood	
	18	20050240147	A1	2005-10-27	Makower et al.	
	19	20050288665	A1	2005-12-29	Woloszko	
	20	20060190022	A1	2006-08-24	Beyar et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	21	20060195169	A1	2006-08-31	Gross et al.	
	22	20060235377	A1	2006-10-19	Earley et al.	
	23	20060253117	A1	2006-11-09	Hovda et al.	
	24	20060276817	A1	2006-12-07	Vassallo et al.	
	25	20070043350	A1	2007-02-22	Soltesz et al.	
	26	20070049999	A1	2007-03-01	Esch et al.	
	27	20070066944	A1	2007-03-22	Nyte	
	28	20070073282	A1	2007-03-29	Mcgaffigan et al.	
	29	20070093710	A1	2007-04-26	Maschke	
	30	20070219600	A1	2007-09-20	Gertner et al.	
	31	20070244529	A1	2007-10-18	Choi et al.	

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	Filing Date	2021-05-21
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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	32	20080004613	A1	2008-01-03	Barbut et al.	
	33	20080027480	A1	2008-01-31	Van Der Burg et al.	
	34	20080027423	A1	2008-01-31	Choi et al.	
	35	20080082090	A1	2008-04-03	Manstein	
	36	20080125626	A1	2008-05-29	Chang et al.	
	37	20080154237	A1	2008-06-26	Chang et al.	
	38	20080183251	A1	2008-07-31	Azar et al.	
	39	20080255642	A1	2008-10-16	Zarins et al.	
	40	20080312644	A1	2008-12-18	Fourkas et al.	
	41	20090018485	A1	2009-01-15	Krespi et al.	
	42	20090124958	A1	2009-05-14	Li et al.	

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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	43	20090143821	A1	2009-06-04	Stupak	
	44	20090192505	A1	2009-07-30	Askew et al.	
	45	20090292358	A1	2009-11-26	Saidi	
	46	20090299355	A1	2009-12-03	Bencini et al.	
	47	20100144996	A1	2010-06-10	Kennedy et al.	
	48	20100152730	A1	2010-06-17	Makower et al.	
	49	20100160906	A1	2010-06-24	Jarrard	
	50	20100174283	A1	2010-07-08	Mcnall, Iii et al.	
	51	20100204560	A1	2010-08-12	Salahieh et al.	
	52	20100241112	A1	2010-09-23	Watson	
	53	20100260703	A1	2010-10-14	Yankelson et al.	

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	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	54	20110009737	A1	2011-01-13	Manstein	
	55	20110118726	A1	2011-05-19	De La Rama et al.	
	56	20110180064	A1	2011-07-28	Tanaka et al.	
	57	20110282268	A1	2011-11-17	Baker et al.	
	58	20110288477	A1	2011-11-24	Ressemann et al.	
	59	20110301587	A1	2011-12-08	Deem et al.	
	60	20120029512	A1	2012-02-02	Willard et al.	
	61	20120039954	A1	2012-02-16	Cupit et al.	
	62	20120078377	A1	2012-03-29	Gonzales et al.	
	63	20120179154	A1	2012-07-12	Goldberg et al.	
	64	20120265188	A1	2012-10-18	Buchbinder et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	65	20120298105	A1	2012-11-29	Osorio	
	66	20120310233	A1	2012-12-06	Dimmer et al.	
	67	20120316557	A1	2012-12-13	Sartor et al.	
	68	20120316473	A1	2012-12-13	Bonutti et al.	
	69	20130116679	A1	2013-05-09	Van Der Weide et al.	
	70	20130158536	A1	2013-06-20	Bloom	
	71	20130218158	A1	2013-08-22	Danek et al.	
	72	20140114233	A1	2014-04-24	Deem et al.	
	73	20150164571	A1	2015-06-18	Saadat	
	74	20160045277	A1	2016-02-18	Lin et al.	
	75	20160121112	A1	2016-05-05	Azar	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	76	20180177546	A1	2018-06-28	Dinger et al.	
	77	20180177542	A1	2018-06-28	Wolf et al.	
	78	20180263678	A1	2018-09-20	Saadat	
	79	20180317997	A1	2018-11-08	Dinger et al.	
	80	20180333195	A1	2018-11-22	Greep et al.	
	81	20190076185	A1	2019-03-14	Dinger et al.	
	82	20190201069	A1	2019-07-04	Wolf et al.	
	83	20190231409	A1	2019-08-01	Wolf et al.	
	84	20190282289	A1	2019-09-19	Wolf et al.	
	85	20190336196	A1	2019-11-07	Wolf et al.	
	86	20200100829	A1	2020-04-02	Wolf et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	87	20200129223	A1	2020-04-30	Angeles et al.	
	88	20200205884	A1	2020-07-02	Wolf et al.	

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	1	WO2003024349	WO	A1	2003-03-27	Mcclurken et al.		
	2	WO2007037895	WO	A2	2007-04-05	Nyte		
	3	WO2007134005	WO	A1	2007-11-22	Friedman		
	4	CN101325919	CN	A	2008-12-17		corresponding English US2007073282	X
	5	WO2010077980	WO	A1	2010-07-08	Baker et al.		☐
	6	WO2012174161	WO	A1	2012-12-20	Wolf et al.		☐
	7	WO2013028998	WO	A2	2013-02-28	Huszar et al.		☐

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	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	8	WO2014022436	WO	A1	2014-02-06	Caplan et al.		☐
	9	WO2015047863	WO	A1	2015-04-02	Kesten et al.		☐
	10	WO2015048806	WO	A2	2015-04-02	Saadat		☐
	11	WO2015153696	WO	A1	2015-10-08	Wolf et al.		☐
	12	WO1999007299	WO		1999-02-18			☐
	13	WO2001043653	WO		2001-06-21			☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Buckley et al., "High-resolution spatial mapping of shear properties in cartilage," J Biomech., 2010 Mar 3;43 (4):796-800, Epub Nov. 5, 2009.	
	2	Buckley et al., "Mapping the depth dependence of shear properties in articular cartilage," J Biomech., 41 (11):2430-2437, Epub Jul. 10, 2008.	
	3	Chen et al., China Journal of Endoscopy, Vol. 11, No. 3. pp. 239-243, March 2005, [English Translation of Title] 'Radiofrequency treatment of nasal posterior-under nerve ethmoidal nerve and infraturbinal for perennial allergic rhinitis under nasal endoscope," [also translated as] "Preliminary exploration of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior nasal concha under nasal endoscopy in the treatment of perennial allergic rhinitis." 9 pages.	

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	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	4	Cole, "Biophysics of nasal airflow: a review," Am J Rhinol., 14(4):245-249, Jul-Aug. 2000.	
	5	Cole, "The four components of the nasal valve," Am J Rhinol., 17(2):107-110, Mar-Apr. 2003.	
	6	Fang et al., J First Mil Med Univ, Vol. 25 No. 7, pp. 876-877, 2005, [English translation of title] "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis" [also translated as] "Nasal Endoscopic Surgery Combined with Multisite Radiofrequency Technology for Treating Perennial Allergic Rhinitis," 4 pages.	
	7	Griffin et al., "Effects of enzymatic treatments on the depth-dependent viscoelastic shear properties of articular cartilage," J Orthop Res., 32(12):1652-1657, Epub Sep. 5, 2014.	
	8	Kjaergaard et al., "Relation of nasal air flow to nasal cavity dimensions," Arch Otolaryngol Head Neck Surg., 135 (6):565-570, Jun 2009.	
	9	Kong et al., Journal of Clinical Otorhinolaryngology, 2005. "Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis," Retrieved from the Internet: <URL:http://en.cnki.com.cn/Article_en/CJFDTOTAL-LCEH200505015.htm>, 1 page.	
	10	Liu et al., China Journal of Endoscopy, Vol. 14, No. 11, pp. 1127-1130, November 2008, [English Translation of Title] "Impact of treatment of perennial rhinitis by radiofrequency thermo-coagulations to vidian and antirior ethomoidal nerves on mucociliary clearance," [also translated as] "Impact of radiofrequency thermocoagulation of bilateral vidian and anterior ethmoidal nerve cluster regions on nasal mucociliary transport function in perennial allergic rhinitis and vasomotor rhinitis." 12 pages.	
	11	Silverberg et al., "Structure-function relations and rigidity percolation in the shear properties of articular cartilage," Biophys J., 107(7):1721-1730, Oct. 7, 2014.	
	12	Stewart et al., "Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale," Otolaryngol Head Neck Surg., 130(2):157-163, Feb. 2004.	
	13	Stupak, "A Perspective on the Nasal Valve," Dept. of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009.	
	14	Stupak, "Endonasal repositioning of the upper lateral cartilage and the internal nasal valve," Ann Otol Rhinol Laryngol., 120(2):88-94, Feb. 2011.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	15	International Search Report and Written Opinion for PCT/US2012/042316, mailed Aug. 24, 2012, 15 pages.
	16	International Search Report and Written Opinion for PCT/US2014/054726, mailed December 23, 2014, 5 pages.
	17	International Search Report and Written Opinion for PCT/US2015/023742, mailed June 29, 2015, 5 pages.
	18	Singapore Search Report for Application Serial No. 201309238-2, mailed April 17, 2014, 27 pages.
	19	Supplementary European Search Report for Application No. 15772528, mailed September 26, 2017, 7 pages.
	20	Search Report in European Application No. 18204723.3 dated February 18, 2019, 8 pages.
	21	Extended European Search Report for Application No. 19199126.4, mailed December 9, 2019, 6 pages.

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-05-21
Name/Print	Robert A. Kalinsky	Registration Number	50471

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

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Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	
Filing Date	2021-05-21
First Named Inventor	WOLF
Title	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US18

SIGNATURE of Applicant or Patent Practitioner

Signature	/Robert A. Kalinsky/	Date (Optional)	
Name	Robert A. Kalinsky	Registration Number	50471
Title (if Applicant is a juristic entity)	Attorney		
Applicant Name (if Applicant is a juristic entity)	AERIN MEDICAL, INC.		

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

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: PA..
Document Description: Power of Attorney

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 23552

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note. Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

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

AERIN MEDICAL, INC.

☐ Inventor or Joint Inventor (title not required below)

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

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

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

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

Signature		Date (Optional)	
Name	Fred Dinger		
Title	CEO		

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

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF	Examiner:	*to be determined*
Appl. No.:	*to be determined*	Group Art Unit:	*to be determined*
Filed:	May 21, 2021	Docket No.:	17713.0001US18
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

AUTHORIZATION FOR EXTENSION OF TIME ALL REPLIES

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

Attention: Commissioner for Patents

Please consider this a petition for extension of time for a sufficient number of months to enter these papers or any future papers, if appropriate.

Please further charge any additional fees required to enter these papers or any future papers, or credit any overpayment of fees, to Deposit Account No. 13-2725.

Respectfully submitted,
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 336-4771

Date: May 21, 2021

/Robert A. Kalinsky/
Robert A. Kalinsky
Reg. No.: 50,471

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF	Examiner:	*to be determined*
Appl. No.:	*to be determined*	Group Art Unit:	*to be determined*
Filed:	May 21, 2021	Docket No.:	17713.0001US18
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

REQUEST FOR DEFERMENT OF FILING, EXAMINATION, and SEARCH FEES

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

Dear Commissioner:

Payment of the filing, examination, and search fees is deferred under 37 C.F.R. § 1.53(f). The grant of a filing date and the issuance of a Notice to File Missing Parts to allow for the fees to be paid are requested under 37 C.F.R. § 1.53(f)(1).

Respectfully submitted,
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(6612) 332-5300

Date: May 21, 2021

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

Electronic Acknowledgement Receipt

EFS ID:	42791516
Application Number:	17327254
International Application Number:	
Confirmation Number:	1056
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Robert A. Kalinsky/Juliana Hoffman
Filer Authorized By:	Robert A. Kalinsky
Attorney Docket Number:	17713.0001US18
Receipt Date:	21-MAY-2021
Filing Date:	
Time Stamp:	17:01:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2021-05-21_ADS_17713-0001US18.PDF	1256602 d0ad1bfaf7a4c56549a829ceeb22ea1575711e00	no	9

Warnings:

Information:					
2		2021-05-21_Specification_17713-0001US18.PDF	1182312 e828a744a7fe8025efcff04c3fed6c615bc10f30	yes	77
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Abstract		77	77	
	Claims		76	76	
	Specification		1	75	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	2021-05-21_Drawings_17713-0001US18.pdf	4726487 0e0ea0f44825f6a86cf20662af428d853cfc916f	no	61
Warnings:					
Information:					
4	Oath or Declaration filed	2021-05-21_Declarations_17713-0001US18.PDF	2533324 36c3d38ddc1ec98bea210dce9210ec6f6d41804a	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	2021-05-21_IDS_17713-0001US18.PDF	1040902 927e644bc7fdcbfccc7dc3412ccfe9b8f2d60a76	no	25
Warnings:					
Information:					
6	Power of Attorney	2021-05-21_General-POA_17713-0001US18.PDF	1006004 7f1aa7f37e6ef6d9d9d3b57ed36e97fd5c4b5c19	no	2
Warnings:					
Information:					
7	Extension of Time	2021-05-21_EOT_17713-0001US18.PDF	68276 616a90027a55e9edd9f4155f441ac27875fd7c64	no	1

Warnings:					
Information:					
8	Transmittal Letter	2021-05-21_Defer-Fees_17713-0001US18.PDF	69651 c6949a927a09e32ef33cdc4178fa7d37b508cf6b	no	1
Warnings:					
Information:					
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Scott	J.	WOLF	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Menlo Park	CA	US

Mailing Address of Inventor:

Address 1	319 Trenton Way
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State/Province	CA
Postal Code	94025
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		FRAZIER	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Sunnyvale	CA	US

Mailing Address of Inventor:

Address 1	517 Fern Ridge Court
Address 2	
City	Sunnyvale
State/Province	CA
Postal Code	94087
Country	US

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

Correspondence Information:

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

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

Customer Number	23552		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		
Attorney Docket Number	17713.0001US18	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	61	**Suggested Figure for Publication (if any)**	

Filing By Reference:

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

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

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

Publication Information:

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

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

Representative Information:

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

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	23552		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Domestic Benefit/National Stage Information:

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

Prior Application Status	Pending			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of	16/412982	2019-05-19	

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/412982	Continuation of	15/686265	2017-08-25	10335221	2019-07-02

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/686265	Continuation of	15/272007	2016-09-21	9788886	2017-10-17

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15/272007	Continuation of	14/754087	2015-06-29	9452010	2016-09-27

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/754087	Continuation of	14/319087	2014-06-30	9072597	2015-07-07

Prior Application Status	Patented			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14/319087	Continuation in part of	13/495844	2012-06-13	8936597	2015-01-20

Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13/495844	Claims benefit of provisional	61/603864	2012-02-27	

Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13/495844	Claims benefit of provisional	61/496930	2011-06-14	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Foreign Priority Information:

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
	Application Number	
Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Applicant Information:

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

Applicant 1 — Remove

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

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Aerin Medical, Inc.		
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Address 1	232 East Caribbean Drive		
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City	Sunnyvale	**State/Province**	CA
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Email Address			

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Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	17713.0001US18
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Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS	

Assignee 1

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

Remove

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

Organization Name	Aerin Medical, Inc.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	232 East Caribbean Drive		
Address 2			
City	Sunnyvale	**State/Province**	CA
Country i	US	Postal Code	94089
Phone Number		Fax Number	
Email Address			

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Signature:

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

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

Signature	/Robert A. Kalinsky/			Date (YYYY-MM-DD)	2021-05-21
First Name	Robert	Last Name	Kalinsky	Registration Number	50471

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

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

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

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

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

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

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

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

ABSTRACT

Methods and devices for treating nasal airways are provided. Such devices and methods may improve airflow through an internal and/or external nasal valve, and comprise the use of mechanical re-shaping, energy application and other treatments to modify the shape, structure, and/or air flow characteristics of an internal nasal valve, an external nasal valve or other nasal airways.

CLAIMS

What is claimed is:

1. A method of treating a patient's airway, the method comprising:

advancing a non-expandable, elongate treatment element of a treatment device through a nostril and into the patient's airway, wherein the elongate treatment element includes a tissue-contact surface having a shape;

contacting a pair of bipolar, radiofrequency electrodes protruding from the tissue-contact surface with tissue in the airway;

applying force against the tissue with the shape of the tissue-contact surface to at least temporarily deform the tissue to a desired shape;

delivering radiofrequency energy between the electrodes, to at least one of reshape, remodel, strengthen or change a property of the tissue; and

removing the treatment element from the airway.

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Inventors: Scott J. WOLF
Andrew FRAZIER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 16/412,982, filed May 15, 2019, which is a continuation of U.S. Patent Application No. 15/686,265 now U.S. Patent No. 10,335,221, filed August 25, 2017, which is a continuation of U.S. Patent Application No. 15/272,007, now U.S. Patent No. 9,788,886, filed September 21, 2016, entitled "METHODS AND DEVICES TO TREAT AIRWAYS," which is a continuation of U.S. Patent Application No. 14/754,087, now U.S. Patent No. 9,452,010 filed June 29, 2015, which is a continuation of U.S. Patent Application No. 14/319,087, now U.S. Patent No. 9,072,597, filed June 30, 2014, which is a continuation-in-part of U.S. Patent Application No. 13/495,844, now U.S. Patent No. 8,936,594, filed June 13, 2012, which claims priority to U.S. Provisional Patent Application Serial Nos. 61/603,864, filed on February 27, 2012, and 61/496,930, filed June 14, 2011. The disclosures of all the above-referenced patent applications are hereby incorporated by reference in their entireties herein.

[0002] This application is related to Applicant's U.S. Patent Nos. 8,986,301, issued March 24, 2015 and 9,237,924, issued January 19, 2016, the entireties of both of which are hereby incorporated by reference in their entireties herein.

BACKGROUND

[0003] This application relates generally to the field of medical devices and treatments, and in particular to systems, devices and methods for treating structures within the nose and upper airway to reduce resistance to airflow and/or change the pressure level in the nose, nasal cavities, and/or and nasal passages and improve airflow and/or the feeling and effects of nasal obstruction during breathing.

DESCRIPTION OF THE RELATED ART

[0004] During respiration, the anatomy, shape, tissue composition and properties of the human airway produce airflow resistance. The nose is responsible for almost two thirds of this resistance. Most of this resistance occurs in the anterior part of the nose, known as the internal nasal valve, which acts as a flow limiter. The external nasal valve structure also causes resistance to nasal airflow. Effective physiological normal respiration occurs within a range of airflow resistance. However, excessive resistance to airflow can result in abnormalities of respiration, which can significantly affect a patient's quality of life.

[0005] Inadequate nasal airflow can result from a number of conditions causing an inadequate cross sectional area of the nasal airway in the absence of any collapse or movement of the cartilages and soft tissues of the nasal airway. These include deviation of the nasal septum, turbinate enlargement, mucosal swelling, excessive mucous production, and nasal valve insufficiency, narrowing or collapse. No matter what the cause of inadequate nasal airflow, the nasal valve area is still a site of significant nasal airflow resistance. Increased nasal valve resistance can be due to static narrowing or movement or collapse of the nasal valve area often due to weakness or malformation of cartilage structures of the nose. In more extreme cases, nasal valve dysfunction is a serious medical condition.

[0006] Cartilage is an avascular tissue composed of a specialized matrix of collagens, proteoglycans, and non-collagen proteins, in which chondrocytes constitute the unique cellular component. Cartilage is specialized connective tissue found in various locations throughout the body. Cartilage basically consists of two components: water and a framework of structural macromolecules (matrix) that give the tissue its form and function. The matrix is highly organized and composed of collagens, proteoglycans and noncollagenous proteins.

[0007] The interaction of water and the macromolecular framework give the tissue its mechanical properties and thus its function. Up to 65%-80% of the wet weight of cartilage consists of water, while the rest is matrix, mainly collagens and proteoglycans. Chondrocytes are specialized cells that produce and maintain the extracellular matrix (ECM) of cartilage. The ECM makes up most of the tissue, where dense, covalently-linked heterotypic collagen fibrils interact with a number of other specialized matrix components.

[0008] The nasal valve was originally described by Mink in 1903. It is divided into external and internal portions. The external nasal valve is the external nasal opening formed by the columella at the base of the septum, the nasal floor, and the nasal rim (the lower region of the nasal wall, also known as the caudal border of the lower lateral cartilage). The nasalis muscle dilates the external nasal valve portion during inspiration.

[0009] The internal nasal valve, which accounts for the larger part of the nasal resistance, is located in the area of transition between the skin and respiratory epithelium. The internal nasal valve area is formed by the nasal septum, the caudal border of the upper lateral cartilage (ULC), the head of the inferior turbinate, and the pyriform aperture and the tissues that surround it.

[0010] The angle formed between the caudal border of the ULC and the nasal septum is normally between about 10 degrees-15 degrees as illustrated in FIG. 1. The internal nasal valve is usually the narrowest part of the nasal airway and is responsible for more than two thirds of the resistance produced by the nose.

[0011] In 1894, Franke performed nasal-flow experiments in models and cadavers and found that whirl formation occurred near the head of the turbinate during calm breathing. Mink in 1903 developed this concept further in 1920, suggesting that the greatest area of resistance was in the limen nasi or the union of the lobular cartilage and ULCs. In 1940, Uddstromer found that 70% of the resistance of the nose was produced in the internal nasal valve area and the remaining 30% was due to the nasal fossa. Van Dishoeck further investigated the mechanisms of the nasal valve in 1942, and in 1970, Bridger and Proctor wrote about a "flow-limiting segment" that included the limen nasi and the pyriform aperture. In 1972, Bachman and Legler found the pyriform aperture to have the smallest cross-sectional area of the nasal airway. In 1983, Haight and Cole continued the study of Bridger and Proctor and demonstrated that the maximal nasal resistance was localized near the pyriform aperture and depended on engorgement of the head of the inferior turbinate. A description of the nasal valve and its functions are more fully described in Cole, "The Four Components of the Nasal Valve", American Journal of Rhinology, Vol. 17, No. 2, pp. 107-110 (2003). See also, Cole, "Biophysics of Nasal Air Flow: A Review", American Journal of Rhinology, Vol. 14, No. 4, pp. 245-249 (2000).

[0012] Because ventilation involves pressure changes, the nasal airways must be stable both at rest and under the negative pressures created during quiet and forced inspiration. Proper

airflow through the nasal airway depends on satisfactory structural stability (and/or resistance to conformational change resulting from pressure changes) of the upper and lower lateral cartilages and soft tissues respectively. Satisfactory skeletal stability is present when the upper and lower lateral cartilages have sufficient structural stability to resist conformational changes resulting from air pressure changes. When either the skeletal or the soft tissue component is congenitally deficient or has been compromised by surgery or trauma, the patient experiences a conformation change of the valves during inspiration, with resultant change in the airflow and/or pressure in the nasal airway. Normally, the upper lateral cartilages move, change shape, partially collapse and/or change nasal airway pressure with all ventilatory flow rates. Thus, even normal nasal valves are affected by respiration. However, a patient with dynamic nasal valve dysfunction may have a nasal airway walls that inadequately resist the pressure changes and restrict airflow even during normal nasal breathing.

[0013] Inadequate nasal valve structural strength, stiffness or conformation can be a consequence of previous surgery, trauma, aging, or primary weakness of the upper lateral cartilage and is often symptomatic and debilitating. As many as 13% of the patients with chronic nasal obstruction have some degree of nasal valve collapse. Of these patients, 88% have unilateral collapse.

[0014] Poor nasal breathing and/or nasal congestion has profound effects on a person's health and quality of life, which can be measured by validated questionnaires such as the NOSE score, as described in Stewart M G, Witsell D L, Smith T L, Weaver E M, Yueh B, Hannley M T. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg 2004; 130:157-63.

[0015] Causes of inadequate nasal airflow and the structure of the nasal valve inadequacy can be clinically detected by direct visualization (preferably with minimal disturbance so as not to alter the structure by visualizing) or endoscopic examination. Alternatively, CT, MRI, ultrasound or other non-invasive imaging technologies may be employed. One method of evaluating the potential improvement in nasal airflow from widening the nasal valve area nasal valve obstruction is the cottle test, which involves gently pulling the skin of a patient's cheek laterally away from the nose with two fingers, thereby opening the internal nasal valve.

[0016] Existing methods of correcting nasal valve inadequacy include surgically repositioning the upper lateral cartilage or adding structural grafts to support the lateral wall of the nose. Surgical structural enhancement of the valve can include the use of cartilage grafts and grafts made from a number of materials. The most frequent methods surgically correct internal nasal valve collapse and involve the use of spreader grafts placed between the upper lateral cartilage and septum. Alternately, stents, spreaders or other devices may be implanted to reposition the ULC. Invasive surgical and implant solutions carry substantial risk and discomfort.

[0017] External (non-implanted) nasal dilators which are placed temporarily and removed by the patient are also available. Such external devices are possibly placed on the outside surface of the nose such as the "Breathe Right" strips as shown for example in U.S. Pat. No. 5,533,499 to Johnson or similar devices taught by U.S. Pat. No. 7,114,495 to Lockwood. Other devices may be temporarily placed in the nasal cavity (but not implanted in the nose), such as those taught in U.S. Pat. No. 7,055,523 to Brown, and U.S. Pat. No. 6,978,781 to Jordan. However, such devices can be uncomfortable, unsightly, and require the patient to remove and replace the device on a periodic basis. These devices can cause skin irritation.

[0018] Poor nasal airflow can also occur in people with a structurally normal nasal and/or nasal valve anatomy, as well as a normal nasal passage cross-sectional area. The strength, structure and resistance to collapse of the nasal passage can also be normal in people with poor nasal airflow. People can have poor nasal airflow from other causes, including deviated septum, allergic rhinitis, non-allergic rhinitis, turbinate hyperplasia, nasal tip ptosis, and nasal polyposis. Whatever the cause, the tissues of the nasal valves are intimately involved in nasal airflow and nasal airflow inadequacy. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to improve nasal airflow.

SUMMARY

[0019] Embodiments of the present application are directed to devices, systems and methods for treating nasal airways. Such embodiments may be utilized to improve breathing by decreasing airflow resistance and/or improving nasal airflow or perceived airflow resistance in the nasal airways. For example, the devices, systems and methods described herein may be utilized to reshape, remodel, strengthen, or change the properties of the tissues of the nose,

including, but not limited to the skin, muscle, mucosa, submucosa and cartilage in the area of the nasal valves.

[0020] According to one aspect, a device for treating a patient's nasal airway is provided. In one embodiment, the device comprises an energy delivery element sized to be inserted into a nose or to be delivered external to a nose. The energy delivery element is configured to deliver energy to tissues within the nose and to reshape a region of the nose to a new conformation.

[0021] According to one embodiment, a device for treating a patient's nasal airway comprises an elongate shaft having a proximal end and a distal end. The device further comprises a handle at the proximal end of the elongate shaft. The device also comprises a treatment element at the distal end of the elongate shaft. The treatment element is sized to be inserted into the nasal airway or to be delivered external to a nose. The treatment element is configured to reshape a region of the nose to a new conformation and comprises an electrode configured to deliver radiofrequency (RF) energy to the nasal tissue.

[0022] Other embodiments of devices for treating a patient's nasal airway include devices that apply other types of treatment. For example, a treatment device may apply energy in the form selected from the group consisting of ultrasound, quantic molecular resonance, microwave, heat, cold, radiofrequency, electrical, light and laser. The treatment device may also be configured to inject a polymerizing liquid or to deliver a cauterizing agent to nasal tissue. Other embodiments are described below.

[0023] The devices described herein may be configured to be positioned internally within the nose, external to the nose, or both. Certain embodiments are configured to be delivered into one nostril, and other embodiments are configured to be delivered into both nostrils. In some embodiments the device may comprise a reshaping element having a shape configured to alter a conformation of a region of the nose to a new conformation. For embodiments utilizing an energy delivery element, the reshaping element may be a separate element from the energy delivery element, or the energy delivery element and the reshaping element may be part of the same element. The energy delivery element and/or reshaping element in one embodiment may have a convex shape to create a concavity in nasal tissue.

[0024] In embodiments utilizing energy delivery, a handle may be provided comprising a button or other input control to active one or more electrodes. Electrodes may comprise one or

more monopolar needles, one or more monopolar plates, or one or more bipolar electrode pairs (which may also comprise one or more needles or plates). These electrodes may be located in various locations, for example, inside the nasal passageway, external to the nose or both. For example, when using bipolar electrode pairs, a first electrode surface may be positioned internal to the nose and a second electrode surface may be positioned external to the nose, so that the two electrode surfaces are positioned on opposite sides of nasal tissue.

[0025] Furthermore, in embodiments utilizing energy delivery, the reshaping element may incorporate features designed to assist location of the device in the nose as well as protection of tissue around the treatment area.

[0026] The device of one energy delivery embodiment may comprise an adaptor configured to be connected to an energy source, such as an RF energy source. The device may also comprise a control system configured to control the characteristics of energy applied to tissue. A thermocouple or other sensor may be provided to measure a temperature near tissue or other tissue or device parameter.

[0027] In another aspect, a system is provided comprising a device as described above and further below in combination with one or more other components. One such component may be an energy source, such as an RF energy source. Another component may be a control system for controlling the energy source and/or treatment device. In another embodiment, the device or system may comprise a cooling mechanism to cool desired tissue locations while treatment is being applied. In monopolar electrode embodiments, a grounding pad may also be provided as part of the system. Another system includes a positioning device that may be used pre-treatment to determine the optimal device and positioning and/or other parameters for using the device to be treat to the nasal airway.

[0028] According to another aspect, a method of treating a patient's nasal airway is provided. In one embodiment, the method comprises alerting a structure, shape or conformation of one or more nasal structures in an area of a nasal valve by applying a treatment sufficient to modify, by reshaping, tissue at or adjacent to the nasal valve.

[0029] According to one embodiment, a method of treating a patient's nasal airway comprises positioning a treatment element within the nasal airway adjacent to nasal tissue to be treated. The treatment element comprises one or more electrodes, such as described above and in further

detail below. The method further comprises deforming the nasal tissue into a desired shape by pressing a surface of the treatment element against the nasal tissue to be treated. The method further comprises delivering radiofrequency (RF) energy to the one or more electrodes to locally heat the nasal tissue, wherein delivering RF energy while deforming the nasal tissue causes the nasal tissue to change shape. The method also comprises removing the treatment element from the nasal airway.

[0030] The methods, devices and systems described herein may be used to reshape tissue without a surgical incision or implant. In certain embodiments, the reshaping of tissue may be accomplished by ablating tissue. In other embodiments, the reshaping of tissue is accomplished without ablation of tissue. In one embodiment, a treatment element is positioned within a nasal passageway. The treatment element may be used to simultaneously mechanically alter the shape of the internal or external nasal valve and apply treatment to tissue of the nose. The treatment applied may comprise modifying a nasal structure in a manner that increases a volumetric airflow rate of air flowing from an exterior of the patient's body into the patient's nasopharynx without changing a shape of an internal nasal valve, said modifying comprising modifying a mechanical property of at least one nasal valve. A positioning element may be used to determine a desired position of a treatment element before the treatment element is delivered to the nasal tissue.

[0031] The treatment may involve delivering energy in the form selected from the group selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser. The nasal tissue to be treated may be cooled prior to, during or after delivering energy. Delivering energy may comprise measuring a temperature near nasal tissue to be treated, and adjusting a level of energy delivered to the tissue. When RF or other types of energy are used, the energy may be delivered to at least one of the nasal valve, tissue near the nasal valve, or the upper lateral cartilage of tissue. For example, RF energy or other energy may be delivered to the one or more electrodes for about 15 seconds to about 1 minute. RF energy or other energy may be delivered to heat an area of tissue to a temperature of about 50 degrees C. to about 70 degrees C.

[0032] Other methods not utilizing energy delivery include injecting a polymerizing liquid, delivering a cauterizing agent, or other embodiments described below.

[0033] Energy or treatment may be delivered for a sufficient period of time or in a sufficient quantity to cause a desired effect. For example, the treatment may cause stress relaxation in the nasal tissue without weakening the tissue. The treatment may also be applied to injure a tissue to be re-shaped.

[0034] In another aspect, a method of treating a patient's nasal airway may involve: advancing a treatment element of a treatment device into an incision in mucosal tissue of the nasal airway to contact submucosal tissue of the nasal airway, delivering an energy based therapy to the submucosal tissue through the treatment element to reshape, remodel, strengthen and/or change a property of the submucosal tissue; and removing the treatment element from the nasal airway. Optionally, the method may also involve forming the incision in the mucosal tissue, using the treatment device. For example, forming the incision may involve cutting the mucosal tissue with a cutting edge of the treatment device. Alternatively, the incision may be formed during another procedure or may be formed by a separate cutting device as part of the same procedure.

[0035] In various embodiments, the energy delivered may be ultrasound, microwave, heat, radiofrequency, electrical, light, laser or quantic molecular resonance energy. In one alternative embodiment, energy may be removed from tissues using cryotherapy. Various submucosal tissues that may be treated include upper lateral cartilage, lower lateral cartilage, nasal septum within the nasal valve, nasal septum outside of the nasal valve, swell bodies located on a nasal septum, a septal turbinate, a high deviated nasal septum, a nasal scroll, a floor of the nasal cavity, a piriform area, and/or swell bodies on a floor of the nasal cavity.

[0036] Optionally, the method may further include applying force to the submucosal tissue with the treatment element before, during and/or after delivering the energy based therapy to deform the submucosal tissue. In some embodiments, a tissue contacting surface of the treatment element has a shape convex, concave or flat shape.

[0037] In another aspect, a method of treating a patient's nasal airway may involve: adjusting a shape of a nasal airway treatment device; contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway; delivering an energy based therapy to the mucosal tissue and/or an underlying tissue beneath the mucosal tissue, using the treatment element; and removing the treatment element from the nasal airway. Adjusting the shape may involve shaping the treatment element to have a convex treatment surface, a concave treatment

surface or a flat surface, or adjusting a height of at least one electrode on a treatment surface of the treatment element. In some embodiments, adjusting the height involves adjusting multiple heights of multiple electrodes to form a treatment surface profile.

[0038] In other embodiments, adjusting the shape may involve manipulating a secondary component of the treatment element to increase a surface area of the treatment element. In yet another embodiment, adjusting the shape may involve inflating the treatment element to increase a surface area of the treatment element. In yet another embodiment, adjusting the shape may involve forming at least one bend in a shaft of the treatment device. In some embodiments, adjusting the shape involves rotating the treatment element relative to a shaft of the treatment device.

[0039] In various embodiments, the treated mucosal tissue may be located in the nasal valve and/or a part of the nasal airway other than an internal nasal valve of the airway, such as the tissues listed above. The method may further involve applying force to the mucosal tissue with the treatment element before, during and/or after delivering the energy based therapy to deform the mucosal tissue. In some embodiments, delivering the energy based therapy may modify at least one property of the mucosal tissue or the underlying tissue without reshaping the tissue. The treated underlying tissue may include, for example, cartilage, submucosa, muscle, ligament and/or tendon. Optionally, the method may also include cooling the mucosal tissue and/or another tissue in the nasal airway.

[0040] In another aspect, a method of treating a nasal valve of a nose, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in a nasal airway, may involve: contacting a treatment element of the treatment device with mucosal tissue in the patient's nasal airway; delivering an energy based therapy to at least one of the mucosal tissue or an underlying tissue beneath the mucosal tissue, using the treatment element; sensing at least one temperature of at least one of the mucosal tissue or the underlying tissue, using a sensing element on the treatment device; adjusting the delivery of the energy based therapy, based on the temperature; and removing the treatment element from the nasal airway.

[0041] In some embodiments, sensing the temperature involves sensing multiple temperatures with multiple thermocouples located at or near multiple electrode pairs on the treatment element, where each of the multiple thermocouples is located at or near one of the multiple electrode

pairs. The method may also include determining an average temperature of at least two of the multiple temperatures, wherein the delivery of the energy based therapy is adjusted based on the average temperature. In some embodiments, adjusting the delivery may involve adjusting delivery to at least one of the electrode pairs separately from at least one other of the electrode pairs.

[0042] In another aspect, a device for modifying at least one property of at least one tissue in a nasal airway may include: a head portion configured for passing through an incision in mucosal tissue to a location between the mucosal tissue and submucosal tissue; a shaft extending from the head portion; and a handle attached to the shaft at an opposite end from the head portion. The head portion may include an energy based therapy delivery member and an incision forming member. The handle may include a housing to hold a power source for providing energy to the energy delivery member.

[0043] In some embodiments, the energy delivery member may include a contact surface with a convex shape configured to at least temporarily create a concavity in the at least one tissue. In some embodiments, the energy delivery member may have a contact surface with flat shape. In some embodiments, the energy delivery member may include multiple flexible sections configured to be manipulated. For example, the flexible sections may include multiple protruding electrodes configured to at least temporarily deform nasal tissue. Such protruding electrodes may include two rows of electrodes, where the energy delivery member comprises a bipolar radio frequency delivery member, and where radio frequency energy travels from one row of electrodes to the other row of electrodes.

[0044] In some embodiments, the housing is configured to hold at least one battery. Some embodiments may include at least one sensor configured to sense at least one of temperature or impedance in nasal tissue. In some embodiments, the sensor(s) may be attached to the device on or near the energy delivery member. The device may also further include a tissue cooling member attached to the device at or near the energy delivery member.

[0045] In one embodiment, the energy delivery member may include at least one electrode pair configured to apply energy to the at least one tissue. The device may also further include at least one thermocouple configured to sense temperature at each electrode pair. Some embodiments may further include a processor to determine an average temperature from multiple

temperatures sensed by more the thermocouples. In some embodiments, each of the electrode pairs is adjustable separately from adjustment of any other of the electrode pairs.

[0046] In some embodiments, the energy delivery member is designed to be inserted into the nasal valve angle to apply energy to a swell body. The energy is intended to shrink the size of the swell body. The energy delivery member can be designed to hold a position in the nasal valve angle to position the electrodes to only treat the area of the swell body located on the medial wall of the nasal valve. The energy delivery member can be designed with the electrodes positioned in such a way as to direct the energy into the submucosa, while minimizing damage to the mucosal tissue and underlying cartilage. The energy delivery member can also be designed to direct the energy into the underlying cartilage to induce a shape change.

BRIEF DESCRIPTION OF DRAWINGS

[0047] Certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description below having reference to the figures that follow.

[0048] FIG. 1 depicts an illustration of bone and cartilage structures of a human nose.

[0049] FIG. 2A illustrates a cross-sectional view illustrating tissues and structures of a human nose.

[0050] FIG. 2B shows a detailed cross-sectional view illustrating a detailed section of the structures of FIG. 2A.

[0051] FIG. 2C illustrates a view of the nostrils illustrating tissues and structures of a human nose.

[0052] FIG. 3 depicts a schematic illustration of a nasal valve re-shaping treatment device.

[0053] FIG. 4A is a perspective illustration of an embodiment of a treatment element shape.

[0054] FIG. 4B depicts a perspective illustration of another embodiment of a treatment element shape.

[0055] FIG. 4C shows a perspective illustration of another embodiment of a treatment element shape.

[0056] FIG. 4D depicts a cross-sectional view of a treatment device comprising a plurality of microneedles puncturing tissue in order to apply treatment at a desired tissue depth.

[0057] FIG. 5A illustrates one embodiment of a clamp-type nasal valve treatment device.

[0058] FIG. 5B illustrates another embodiment of a clamp-type nasal valve treatment device.

[0059] FIG. 6 depicts a partially-transparent perspective view showing a stent implanted in a nose.

[0060] FIG. 7 depicts a perspective view illustrating an energy delivery balloon being inserted into a nose.

[0061] FIGS. 8A-8J depict embodiments of various electrode arrangements for applying energy to the nasal valve area.

[0062] FIGS. 9A and 9B illustrate embodiments of devices for applying energy to the nasal valve area using a monopolar electrode.

[0063] FIGS. 10A and 10B illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode and an external mold.

[0064] FIGS. 11A and 11B illustrate embodiments of devices for applying energy to the nasal valve area using electrode(s) and a counter-traction element.

[0065] FIGS. 12A and 12B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously.

[0066] FIGS. 13A-13E illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having a mold or counter-traction element for engaging the nose externally.

[0067] FIGS. 14A and 14B illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate external molds.

[0068] FIGS. 15A-15C illustrate embodiments of devices for applying energy to the nasal valve area configured to be inserted into both nostrils simultaneously, having separate counter-traction elements.

[0069] FIG. 16 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with an external electrode and a separate internal mold.

[0070] FIGS. 17A and 17B illustrate an embodiment of a device for applying energy to the nasal valve area comprising an external electrode and an internal mold.

[0071] FIG. 18 shows an embodiment of a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.

[0072] FIGS. 19A and 19B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in only one nostril.

[0073] FIGS. 20A and 20B illustrate an embodiment of a device for applying energy to the nasal valve area configured for use in either nostril.

[0074] FIGS. 21A and 21B illustrate an embodiment of a device for applying energy to the nasal valve area having a symmetrical shape.

[0075] FIGS. 22A-22G illustrate an embodiment of a device for applying energy to the nasal valve area using a monopolar electrode.

[0076] FIGS. 23A-23G illustrate an embodiment of a device for applying energy to the nasal valve area using an array of needle electrodes.

[0077] FIG. 24A depicts a cross-section of tissue at the nasal valve.

[0078] FIG. 24B depicts heat effects of RF treatment of tissue at the nasal valve.

[0079] FIGS. 25A and 25B illustrate embodiments of devices for applying energy to the nasal valve area incorporating cooling systems.

[0080] FIG. 26 shows an embodiment of a device for applying energy to the nasal valve area incorporating a heat pipe.

[0081] FIG. 27 depicts an embodiment of a device for applying energy to the nasal valve area incorporating heat pipes.

[0082] FIGS. 28A-28E depict embodiments of differential cooling mechanisms.

[0083] FIG. 29 shows an embodiment of a system comprising a device for applying energy to the nasal valve area with electrode needles and a separate cooling mechanism.

[0084] FIG. 30A-30D shows an embodiment of a method for applying energy to the nasal valve area using.

[0085] FIG. 31 illustrates an embodiment of a nasal valve treatment device.

[0086] FIG. 32A illustrates an embodiment of a nasal valve treatment device comprising an electrode array.

[0087] FIG. 32B illustrates an embodiment of a nasal valve treatment device comprising an electrode array arranged in a number of surface profiles.

[0088] FIG. 33 illustrates an embodiment of a nasal valve treatment device comprising a first treatment element and a second treatment element.

[0089] FIG. 34 illustrates an embodiment of a nasal valve treatment device comprising a head section that is offset relative to a shaft section of the device.

[0090] FIG. 35 illustrates an embodiment of a nasal valve treatment device comprising a head section adapted to be at an angle relative to a shaft section of the device.

[0091] FIG. 36 depicts a cross-section of tissue at the nasal valve.

[0092] FIG. 37 is a diagram illustrating a cross-section of tissue at the nasal valve showing a number of target anatomies.

[0093] FIGS. 38A and 38B are frontal see-through and sagittal cross-section illustrations, respectively, of a human head, illustrating nasal and upper airway anatomy, includingthe superior turbinate, the middle turbinate, and the inferior turbinate.

[0094] FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration.

[0095] FIG. 40 is a block diagram depicting an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit.

[0096] FIG. 41 is a block diagram depicting an electrode array arranged such that each electrode pair of the array of electrodes may have its own individual subsystem.

[0097] FIG. 42A is a block diagram depicting an electrode array in which temperature readings may be the average of three adjacent thermocouples.

[0098] FIG. 42B is a block diagram depicting an electrode array in which temperature reading may be the average of four adjacent thermocouples.

[0099] FIG. 43 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 39, in which the positive electrodes may share a common negative electrode.

[0100] FIG. 44 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 40, in which the positive electrodes may share a common negative electrode.

[0101] FIG. 45 illustrates an embodiment of a device for applying energy into an incision in the nasal valve area using an array of electrodes.

[0102] FIG. 46A illustrates an embodiment of a device for applying energy into an incision in the nasal valve area directly over a target tissue using an array of electrodes.

[0103] FIG. 46B illustrates an embodiment of a device for applying energy into an incision in the nasal valve area offset from a target tissue using an array of electrodes.

[0104] FIG. 47 illustrates an embodiment of a device for creating an incision in the nasal valve area and applying energy into the incision using an array of electrodes.

DETAILED DESCRIPTION

[0105] The following disclosure provides embodiments of systems and methods for improving breathing by decreasing airflow resistance or perceived airflow resistance at or near a site of an internal or external nasal valve. Such embodiments may include methods and devices for reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose, including, but not limited to the skin, muscle, mucosa, submucosa, and cartilage in the area of the nasal valves.

[0106] While, in some instances, nasal dysfunction can lead to poor airflow, nasal breathing can also be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance in the nasal valve and associated nasal anatomy. Remodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as deviated septum,

enlarged turbinates, mucosal swelling, and/or mucous production. The methods and devices described above are generally invasive methods or unsightly devices that a person with normal breathing and/or anatomy may not necessarily be inclined to use or undergo. Thus, there remains an unmet need in the art for non-invasive and minimally invasive methods and devices to decrease nasal airflow resistance or perceived nasal airflow resistance and/or to improve nasal airflow or perceived nasal airflow and the resulting symptoms or sequella of poor nasal airflow including but not limited to snoring, sleep disordered breathing, perceived nasal congestion and poor quality of life through the change of structures within the nose that form the passageways for airflow. Methods and devices described herein may be used to treat nasal airways without the need for more invasive procedures (e.g., ablation, surgery).

[0107] Nasal breathing can be improved in people with normal breathing and/or normal nasal anatomy by decreasing nasal airflow resistance or perceived nasal airflow resistance in the nasal valve and associated nasal anatomy. Restructuring the shape, conformation, angle, strength, and cross sectional area of the nasal valve may improve nasal airflow. Changing the nasal valve can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices can lead to improved nasal airflow, increased volume of nasal airflow in patients with normal or reduced nasal airflow.

[0108] The internal nasal valve area is the narrowest portion of the nasal passage and thus functions as the primary regulator of airflow and resistance. The cross-sectional area of the internal nasal valve area is normally about 55-83 mm.sup.2. As described by the Poiseuille law, airflow through the nose is proportional to the fourth power of the radius of the narrowest portion of the nasal passageway. Thus, changes as small as 1 mm in the size of the nasal valve have an exponential effect on airflow and resistance through the nasal cavity and the entire respiratory system.

[0109] FIGS. 1 and 2A-C illustrate anatomical elements of a human nose. The lower lateral cartilage (LLC) includes an external component referred to as the lateral crus and an internal component referred to as the medial crus. The medial crus and septal nasal cartilage create a nasal septum that separates the left and right nostrils. Upper lateral cartilage lies between the lower lateral cartilages and the nasal bone. The left ULC is separated from the right ULC by the septal cartilage extending down the bridge of the nose. The opposing edges of the LLC and ULC

may move relative to one another. Disposed between the opposing edges is an accessory nasal cartilage. The septal nasal cartilage and the ULC form an angle (.THETA.) called the nasal valve angle.

[0110] FIG. 2B illustrates a detailed cross-section of a segment of nose tissue in the area of the intersection of the ULC and the LLC. As shown in the detailed view of FIG. 2A, both inner and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin.

[0111] FIG. 2C illustrates a view of the nose as seen from the nostrils. FIG. 2 depicts the nasal valve 1 shown between the septum 2 and the Upper Lateral Cartilage 3. FIG. 2A also depicts the position of the turbinate 4.

[0112] The internal nasal valve area of the nasal airway passage can be visualized prior to and/or during any treatment by any suitable method, including but not limited to direct visualization, endoscopic visualization, visualization by the use of a speculum, transillumination, ultrasound, MRI, x-ray or any other method. In some embodiments, treatments of the nasal valve area as described herein may be performed in conjunction with or following another procedure (e.g., a surgical procedure such as surgically repairing a deviated septum). In such embodiments, the nasal valve area may be visualized and accessed during surgery. In some embodiments, it may be desirable to visualize the internal nasal valve with minimum disturbance, so as to avoid incorrect assessments due to altering the shape of the nasal valve during visualization. In some embodiments, visualization elements may be incorporated into or combined with treatment devices configured for treating internal and/or external nasal valves.

[0113] Airflow through the nasal passage can be measured prior to and/or during any treatment by any suitable method, including, but not limited to, a nasal cannula connected to a pressure measurement system, rhinomanometry, and rhino-hygrometer. Nasal airflow and resistance can also be evaluated by subjective evaluation before and after a manipulation to increase the cross-sectional area of the nasal passage, such as the Cottle maneuver. In some embodiments, it may be desirable to measure nasal airflow and/or resistance prior to, during and/or after a procedure.

[0114] The internal nasal valve area of the nasal airway passage can be accessed through the nares. In some embodiments, one or more devices may be used to pull the tip of the nose

caudally and increase the diameter of the nares in order to further facilitate access to the internal nasal valve for treatment. Such devices may include speculum type devices and retractors. In other embodiments, access to the internal nasal valve may also be achieved endoscopically via the nares, or via the mouth and throat. In some embodiments, visualization devices may be incorporated or combined with treatment devices for treating internal and/or external nasal valves. These and any other access and/or visualization devices may be used with any of the methods and devices below.

[0115] During inhalation, airflow through the nostrils creates an inward pressure at the junction between the upper and lower cartilages. This pressure may be expressed as a function of nasal resistance which may be estimated as 10 centimeters of water per one liter per second in congested patients (see "The Four Components of the Nasal Valve" by Cole, published in the American Journal of Rhinology, pages 107-110, 2003). In response to these low pressures relative to the environment outside the nose, a normal, weakened and/or structurally inadequate nasal valve may move inwardly with the junction between the upper and lower cartilages acting as a hinge point for the inward deflection. Furthermore, a small increase in area through which air flows can greatly decrease the pressure differential in these structures resulting in less inward movement of the internal nasal valve structures. Increasing the cross sectional area of the nasal valve area thus has the beneficial effects of decreasing nasal airflow resistance and decreasing the amount and likelihood of inward movement of the nasal valve structures during inspiration.

[0116] Some embodiments below provide apparatus and methods for increasing the area of the opening at the nasal valve and/or treating nasal valve insufficiency by modifying the structure and/or structural properties of tissues at or adjacent to the internal and/or external nasal valve. Other embodiments below provide apparatus and methods for treating nasal valve insufficiency and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. Still other embodiments combine the two approaches of re-shaping and modifying tissue and structures of and adjacent to the internal and/or external nasal valves. Still other embodiments provide apparatus and methods for increasing the area of the opening at the nasal valve and treating nasal obstruction resulting from causes other than nasal valve restriction or insufficiency by improving the structure or function

of the nasal valve tissue to increase airflow. Still other embodiments below provide apparatus and methods for decreasing airflow resistance in a structurally normal nasal valve and/or increasing the area of the opening at nasal valve by re-shaping structures within and/or adjacent to an internal and/or external nasal valve to achieve a more optimum shape and minimize or remove airflow obstructions. For example, patients having a normal nasal valve anatomy may still benefit from the devices and treatments described herein, as improvement in the nasal valve structure and/or increasing the area of the opening at the nasal valve may improve breathing problems caused by other conditions. Still other embodiments provide for structural changes in the nasal cavity and airway that improve the relative positions of the structures of the nasal cavity to improve nasal breathing.

[0117] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal internal nasal valve angle, shown as .theta. in FIG. 2. An internal nasal valve angle (i.e. the angle formed between the caudal border of the ULC and the nasal septum) of less than the normally optimal range of between about 10 degrees-15 degrees can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the nasal valve angle falls within the optimal range of 10-15 degrees. In some embodiments, the internal valve angle may also be increased to be greater than 15 degrees.

[0118] In some embodiments, airflow restrictions to the internal nasal valve may be the result of a smaller-than-optimal area of the internal nasal valve. An internal nasal valve with a less than optimal area can result in airflow restrictions. Thus, in some embodiments, treatments may be designed to re-shape structures at or adjacent to the internal nasal valve in order to increase the internal nasal valve angle sufficiently that after such treatments, the area of the nasal valve falls within an optimal range. In some embodiments, increasing the area of the opening at the nasal valve without increasing the angle of the nasal valve may improve airflow. In some embodiments, increasing the angle of the nasal valve without increasing the area of the opening at the nasal valve may improve airflow. In some embodiments, both the opening at the area of the nasal valve and the angle of the nasal valve may be increased to improve airflow.

[0119] In some embodiments, nasal airflow can be increased in the presence of normal nasal valve anatomy and/or normal or enlarged nasal valve angle or area.

[0120] With reference to FIG. 2A, in some embodiments, the internal valve angle .theta. or area may be increased by mechanically pressing laterally outwards against the internal lateral nasal wall. In some embodiments, this outward pressing may be performed by an inflatable balloon (such as those discussed below with reference to FIGS. 4A-4B) which may be positioned between the upper portion of the nasal septum 20 and the outer lateral wall 22 and then inflated, pressing against the lateral nasal wall until the nasal valve angle reaches a desired size. Similarly, other mechanical devices such as spreaders or retractors (such as those discussed below with reference to FIGS. 5A & 5B) or molds may be used. In alternative embodiments, short-term removable implants may be used to re-shape the nasal valve. Some examples of short-term implants may include stents, molds or plugs. In further alternative embodiments, external re-shaping elements, such as adhesive strips or face masks may be used to modify the shape of a nasal valve. In some embodiments, energy application or other treatments as described below may be applied to substantially fix the re-shaped tissue in a desired conformational shape before, during or after applying a mechanical re-shaping force (e.g., with the balloon, mechanical devices, molds, short-term implants, or external re-shaping elements described above or any of the mechanical devices described below).

[0121]] In another embodiment, a re-shaping device may be used to expand the diameter of the nasal passage at the site of the internal or external nasal valve. The expansion device can be a balloon, user controlled mechanical device, self expanding mechanical device, fixed shape device or any combination thereof. The expansion can increase the diameter over the normal range in order for the diameter to remain expanded after removal of the device and healing of the tissue.

[0122] In some embodiments, a re-shaping device may be used to conformationally change the structure of the internal or external nasal valve anatomy to allow greater airflow without necessarily expanding the diameter of the nasal passage.

[0123] In some embodiments, a re-shaping or remodeling device can be used to conformationally change the structure of areas of the internal nasal valve other than the nasal

valve that causes the cross sectional or three dimensional structure of the nasal airway to assume a shape less restrictive to airflow without widening the nasal valve angle.

[0124] In some embodiments, the tissue of the internal and/or external nasal valve and/or surrounding tissues may be strengthened or otherwise modified to resist a conformational change in response to the negative pressure of inspiration. In some embodiments, this strengthening may be performed by applying treatments selected to change mechanical or structural properties of the treated tissue. In some embodiments, such treatments may include the application of energy to selected regions of nasal valve and/or surrounding tissues.

[0125] In some embodiments, energy may be applied in the form of heat, radiofrequency (RF), laser, light, ultrasound (e.g. high intensity focused ultrasound), microwave energy, electromechanical, mechanical force, cooling, alternating or direct electrical current (DC current), chemical, electrochemical, or others. In alternative embodiments, the nasal valve and/or surrounding tissues may be strengthened through the application of cryogenic therapy, or through the injection or application of bulking agents, glues, polymers, collagen and/or other allogenic or autogenic tissues, or growth agents.

[0126] Any one or more of the above energy-application mechanisms may also be used to re-shape, remodel, or change mechanical or physiologic properties of structures of a nasal valve or surrounding tissues. For example, in some embodiments, energy may be applied to a targeted region of tissue adjacent a nasal valve such that the tissue modification results in a tightening, shrinking or enlarging of such targeted tissues resulting in a change of shape. In some such embodiments, re-shaping of a nasal valve section may be achieved by applying energy without necessarily applying a mechanical re-shaping force. For example energy can be used to selectively shrink tissue in specific locations of the nasal airway that will lead to a controlled conformational change.

[0127] In alternative embodiments, strengthening and/or conformation change (i.e., re-shaping) of nasal valve tissue to reduce negative pressure during inspiration may include modification of tissue growth and/or the healing and fibrogenic process. For example, in some embodiments energy may be applied to a targeted tissue in the region of the internal nasal valve in such a way that the healing process causes a change to the shape of the nasal valve and/or a change in the structural properties of the tissue. In some embodiments, such targeted energy

application and subsequent healing may be further controlled through the use of temporary implants or re-shaping devices (e.g. internal stents or molds, or external adhesive strips).

[0128] In some embodiments, energy may be delivered into the cartilage tissue to cause a conformational change and/or a change in the physical properties of the cartilage. Energy delivery may be accomplished by transferring the energy through the tissue covering the cartilage such as the epithelium, mucosa, sub-mucosa, muscle, ligaments, tendon and/or skin. In some embodiments, energy may also be delivered to the cartilage using needles, probes or microneedles that pass through the epithelium, mucosa, submucosa, muscle, ligaments, tendon and/or skin (as illustrated for example in FIG. 4D).

[0129] In some embodiments, energy may be delivered into the submucosal tissue to cause a conformational change and/or a change in the physical properties of the submucosal tissue. Energy delivery may be accomplished by transferring the energy through the tissue covering the submucosa such as the epithelium, mucosa, muscle, ligaments, cartilage, tendon and/or skin. In some embodiments, energy may also be delivered to the submucosa using needles, probes, microneedles, micro blades, or other non-round needles that pass through the epithelium, mucosa, muscle, ligaments, tendon and/or skin.

[0130] FIG. 3 illustrates an embodiment of a nasal valve treatment device 30. The device 30 comprises a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway to deliver the desired treatment. In some embodiments, the device 30 may further comprise a handle section 34 which may be sized and configured for easy handheld operation by a clinician. In some embodiments, a display 36 may be provided for displaying information to a clinician during treatment.

[0131] In some embodiments, the information provided on the display 36 may include treatment delivery information (e.g. quantitative information describing the energy being delivered to the treatment element) and/or feedback information from sensors within the device and/or within the treatment element. In some embodiments, the display may provide information on physician selected parameters of treatment, including time, power level, temperature, electric impedance, electric current, depth of treatment and/or other selectable parameters.

[0132] In some embodiments, the handle section 34 may also comprise input controls 38, such as buttons, knobs, dials, touchpad, joystick, etc. In some embodiments, controls may be

incorporated into the display, such as by the use of a touch screen. In further embodiments, controls may be located on an auxiliary device which may be configured to communicate with the treatment device 30 via analog or digital signals sent over a cable 40 or wirelessly, such as via bluetooth, WiFi (or other 802.11 standard wireless protocol), infrared or any other wired or wireless communication method.

[0133] In some embodiments the treatment system may comprise an electronic control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway. In some embodiments, a control system 42 may be integrally incorporated into the handle section 34. Alternatively, the control system 42 may be located in an external device which may be configured to communicate with electronics within the handle section 34. A control system may include a closed-loop control system having any number of sensors, such as thermocouples, electric resistance or impedance sensors, ultrasound transducers, or any other sensors configured to detect treatment variables or other control parameters.

[0134] The treatment system may also comprise a power supply 44. In some embodiments, a power supply may be integrally incorporated within the handle section 34. In alternative embodiments, a power supply 44 may be external to the handle section 34. An external power supply 44 may be configured to deliver power to the handle section 34 and/or the treatment element 32 by a cable or other suitable connection. In some embodiments, a power supply 44 may include a battery or other electrical energy storage or energy generation device. In other embodiments, a power supply may be configured to draw electrical power from a standard wall outlet. In some embodiments, a power supply 44 may also include a system configured for driving a specific energy delivery technology in the treatment element 32. For example, the power supply 44 may be configured to deliver a radio frequency alternating current signal to an RF energy delivery element. Alternatively, the power supply may be configured to deliver a signal suitable for delivering ultrasound or microwave energy via suitable transducers. In further alternative embodiments, the power supply 44 may be configured to deliver a high-temperature or low-temperature fluid (e.g. air, water, steam, saline, or other gas or liquid) to the treatment element 32 by way of a fluid conduit.

[0135] In some embodiments, the treatment element 32 may have a substantially rigid or minimally elastic shape sized and shaped such that it substantially conforms to an ideal shape and size of a patient's nasal passageway, including the internal and external nasal valves. In some embodiments, the treatment element 32 may have a curved shape, either concave or convex with respect to the interior of the lateral wall of the nasal passage. In some embodiments, the shape of a fixed-shape treatment element may be substantially in a shape to be imparted to the cartilage or other structures of the internal or external nasal valve area.

[0136] In some embodiments, as shown for example in FIG. 3, the treatment element 32 may comprise a substantially cylindrical central portion with a semi-spherical or semi-ellipsoid or another shaped end-cap section at proximal and/or distal ends of the treatment element 32. In alternative embodiments, the treatment element may comprise a substantially ellipsoid shape as shown, for example in FIGS. 4A-4D. In some embodiments, an ellipsoid balloon as shown in FIG. 4A may have an asymmetrical shape. In alternative embodiments, the treatment element 32 may have an asymmetrical "egg-shape" with a large-diameter proximal end and a smaller-diameter distal end. In some embodiments, the element 32 can be shaped so as to impart a shape to the tissue treated that is conducive to optimal nasal airflow. Any suitable solid or expandable medical balloon material and construction available to the skilled artisan may be used.

[0137] FIG. 4B illustrates an embodiment of a treatment element configured to deliver energy to an interior of a nasal valve. In some embodiments, the treatment element of FIG. 4B also includes an expandable balloon.

[0138] FIG. 4C illustrates an embodiment of a bifurcated treatment element 70 having a pair of semi-ellipsoid elements 72, 74 sized and configured to be inserted into the nose with one element 72, 74 on either side of the septum. The elements may each have a medial surface 75a & 75b which may be substantially flat, curved or otherwise shaped and configured to lie adjacent to (and possibly in contact with) the nasal septum. In some embodiments, the elements 72, 74 may include expandable balloons with independent inflation lumens 76, 78. In alternative embodiments, the elements 72, 74 have substantially fixed non-expandable shapes. In still further embodiments, the elements 72, 74 may include substantially self-expandable sections. In some embodiments, the bifurcated treatment element halves 72, 74 may also carry energy delivery structures as described elsewhere herein. In some embodiments, the shape of the

elements 72, 74 may be modified by the operator to impart an optimal configuration to the treated tissue. The shape modification of elements 72, 74 can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0139] In some embodiments, a nasal valve treatment system may also comprise a re-shaping device configured to mechanically alter a shape of soft tissue and/or cartilage in a region of a nasal valve in order to impart a desired shape and mechanical properties to the tissue of the walls of the nasal airway. In some embodiments the re-shaping device may be configured to re-shape the internal and/or external nasal valve into a shape that improves the patency of one or both nasal valve sections at rest and during inspiration and/or expiration. In some embodiments, the reshaping device may comprise balloons, stents, mechanical devices, molds, external nasal strips, spreader forceps or any other suitable structure. In some embodiments, a re-shaping device may be integrally formed with the treatment element 32. In alternative embodiments, a re-shaping device may be provided as a separate device which may be used independently of the treatment element 32. As described in more detail below, such re-shaping may be performed before, during or after treatment of the nose tissue with energy, injectable compositions or cryo-therapy.

[0140] With reference to FIGS. 4A-4C, some embodiments of treatment elements 32 may comprise one or more inflatable or expandable sections configured to expand from a collapsed configuration for insertion into the nasal passageway, to an expanded configuration in which some portion of the treatment element 32 contacts and engages an internal surface of a nasal passageway. In some embodiments, an expandable treatment element may comprise an inflation lumen configured to facilitate injection of an inflation medium into an expandable portion of the treatment element. In alternative embodiments, an expandable treatment element may comprise one or more segments comprising a shape-memory alloy material which may be configured to expand to a desired size and shape in response to a change of temperature past a transition temperature. In some embodiments, such a temperature change may be brought about by activating an energy-delivery (or removal) element in the treatment element 32.

[0141] In some embodiments, the treatment element 32 may expand with various locations on the element expanding to different configurations or not expanding at all to achieve a desired shape of the treatment element. In some embodiments, such expandable treatment elements or

sections may be elastic, inelastic, or pre-shaped. In some embodiments, expandable treatment elements or sections there of may be made from shape-memory metals such as nickel-cobalt or nickel-titanium, shape memory polymers, biodegradable polymers or other metals or polymers. Expandable balloon elements may be made of any elastic or inelastic expandable balloon material.

[0142] In alternative embodiments, the treatment element 32 can act to change the properties of the internal soft tissue of the nasal airway in conjunction with an external treatment device of fixed or variable shape to provide additional force to change the shape of the internal and/or external nasal valve. In some embodiments, an external mold element can be combined with an internal element.

[0143] FIGS. 5A and 5B illustrate re-shaping treatment devices 80 and 90, respectively. The treatment devices 80 and 90 are structured as clamp devices configured to engage a targeted section of the nasal valve with either a clamping force or a spreading force. In some embodiments, the treatment devices of FIGS. 5A and 5B may include energy delivery elements (of any type described herein) which may be powered by a fluid lumen or cable 86.

[0144] The treatment device of FIG. 5A includes an outer clamp member 82 and an inner clamp member 84 joined at a hinge point 85. In some embodiments, the outer clamp member 82 may include an outwardly-bent section 86 sized and configured to extend around the bulk of a patient's nose when the inner clamp member may be positioned inside the patient's nose. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0145] The treatment device of FIG. 5B includes an outer clamp member 92 and an inner clamp member 94 joined at a hinge point 95. The inner and outer tissue-engaging tips at the distal ends of the inner and outer clamp members may be configured to impart a desired shape to the internal and/or external nasal valve. In the illustrated embodiment, the outer clamp member 92 includes a concave inner surface, and the inner clamp member includes a mating convex inner surface. The shape and dimensions of the mating surfaces may be designed to impart a desired shape to the structures of a patient's nose. In some embodiments, the shape of the mating

surfaces may be modified by the operator to impart an optimal configuration to the treated tissue. The shape modification of the mating surfaces can be accomplished pre-procedure or during the procedure and can be either fixed after modification or capable of continuous modification.

[0146] In some embodiments, the tissue-engaging tips may be removable to allow for sterilization and/or to allow for tips of a wide range of shapes and sizes to be used with a single clamp handle.

[0147] In alternative embodiments, the devices of FIGS. 5A and 5B may be used as spreader devices by placing both clamp tips in one nasal valve and separating the handles, thereby separating the distal tips. In alternative embodiments, the handles may be configured to expand in response to a squeezing force. The shapes of the distal tips may be designed to impart a desired shape when used as a spreading device.

[0148] The re-shaping elements of FIGS. 3-5B are generally configured to be used once and removed from a patient's nose once a treatment is delivered. In some embodiments, treatments may further involve placing longer term treatment elements, such as stents, molds, external strips, etc. for a period of time after treatment. An example of such a stent placed within a patient's nose after treatment is shown in FIG. 6. In some embodiments, the stent may be configured to be removed after a therapeutically effective period of time following the treatment. In some embodiments, such a therapeutically effective period of time may be on the order of days, weeks or more.

[0149] In some embodiments, the treatment element 32 may be configured to deliver heat energy to the nasal valve. In such embodiments, the treatment element may comprise any suitable heating element available to the skilled artisan. For example, the treatment element 32 may comprise electrical resistance heating elements. In alternative embodiments, the heating element may comprise conduits for delivering high-temperature fluids (e.g. hot water or steam) onto the nasal tissue. In some embodiments, a high-temperature fluid heating element may comprise flow channels which place high-temperature fluids into conductive contact with nasal tissues (e.g. through a membrane wall) without injecting such fluids into the patient’s nose. In further embodiments, any other suitable heating element may be provided. In further embodiments, the treatment element 32 may comprise elements for delivering energy in other

forms such as light, laser, RF, microwave, cryogenic cooling, DC current and/or ultrasound in addition to or in place of heating elements.

[0150] U.S. Pat. No. 6,551,310 describes embodiments of endoscopic treatment devices configured to ablate tissue at a controlled depth from within a body lumen by applying radio frequency spectrum energy, non-ionizing ultraviolet radiation, warm fluid or microwave radiation. U.S. Pat. No. 6,451,013 and related applications referenced therein describe devices for ablating tissue at a targeted depth from within a body lumen. Embodiments of laser-treatment elements are described for example in U.S. Pat. No. 4,887,605 among others. U.S. Pat. No. 6,589,235 teaches methods and device for cartilage reshaping by radiofrequency heating. U.S. Pat. No. 7,416,550 also teaches methods and devices for controlling and monitoring shape change in tissues, such as cartilage. The devices described in these and other patents and publications available to the skilled artisan may be adapted for use in treating portions of a nasal valve or adjacent tissue as described herein. U.S. Pat. Nos. 7,416,550, 6,589,235, 6,551,310, 6,451,013 and 4,887,605 are hereby incorporated by reference in their entireties.

[0151] In alternative embodiments, similar effects can be achieved through the use of energy removal devices, such as cryogenic therapies configured to transfer heat energy out of selected tissues, thereby lowering the temperature of targeted tissues until a desired level of tissue modification is achieved. Examples of suitable cryogenic therapy delivery elements are shown and described for example in U.S. Pat. Nos. 6,383,181 and 5,846,235, the entirety of each of which is hereby incorporated by reference.

[0152] In some embodiments, the treatment element 32 may be configured to deliver energy (e.g. heat, RF, ultrasound, microwave) or cryo-therapy uniformly over an entire outer surface of the treatment element 32, thereby treating all nasal tissues in contact with the treatment element 32. Alternatively, the treatment element 32 may be configured to deliver energy at only selective locations on the outer surface of the treatment element 32 in order to treat selected regions of nasal tissues. In such embodiments, the treatment element 32 may be configured so that energy being delivered to selected regions of the treatment element can be individually controlled. In some embodiments, portions of the treatment element 32 are inert and do not deliver energy to the tissue. In further alternative embodiments, the treatment element 32 may be configured with energy-delivery (or removal) elements distributed over an entire outer surface of the treatment

element 32. The control system 42 may be configured to engage such distributed elements individually or in selected groups so as to treat only targeted areas of the nasal passageway.

[0153] In some embodiments, the treatment element 32 may be a balloon with energy delivery elements positioned at locations where energy transfer is sufficient or optimal to effect change in breathing. Such a balloon may be configured to deliver energy while the balloon is in an inflated state, thereby providing a dual effect of repositioning tissue and delivering energy to effect a change the nasal valve. In other embodiments, a balloon may also deliver heat by circulating a fluid of elevated temperature though the balloon during treatment. The balloon can also deliver cryotherapy (e.g. by circulating a low-temperature liquid such as liquid nitrogen) while it is enlarged to increase the nasal valve diameter or otherwise alter the shape of a nasal valve. FIG. 7 illustrates an example of an energy-delivery balloon being inserted into a patient's nose for treatment. Several embodiments may be employed for delivering energy treatment over a desired target area. For example, in some embodiments, a laser treatment system may treat a large surface area by scanning a desired treatment pattern over an area to be treated. In the case of microwave or ultrasound, suitably configured transducers may be positioned adjacent to a target area and desired transducer elements may be activated under suitable depth focus and power controls to treat a desired tissue depth and region. In some embodiments, ultrasound and/or microwave treatment devices may also make use of lenses or other beam shaping of focusing devices or controls. In some embodiments, one or more electrical resistance heating elements may be positioned adjacent to a target region, and activated at a desired power level for a therapeutically effective duration. In some embodiments, such heating elements may be operated in a cyclical fashion to repeatedly heat and cool a target tissue. In other embodiments, RF electrodes may be positioned adjacent to and in contact with a targeted tissue region. The RF electrodes may then be activated at some frequency and power level therapeutically effective duration. In some embodiments, the depth of treatment may be controlled by controlling a spacing between electrodes. In alternative embodiments, RF electrodes may include needles which may puncture a nasal valve tissue to a desired depth (as shown for example in FIG. 4D and in other embodiments below).

[0154] In some embodiments, the treatment element 32 and control system 42 may be configured to deliver treatment energy or cryotherapy to a selected tissue depth in order to target

treatment at specific tissues. For example, in some embodiments, treatments may be targeted at tightening sections of the epithelium of the inner surface of the nasal valve. In other embodiments, treatments may be targeted at strengthening soft tissues underlying the epithelium. In further embodiments, treatments may be targeted at strengthening cartilage in the area of the upper lateral cartilage. In still further embodiments, treatments may be targeted at stimulating or modifying the tissue of muscles of the nose or face in order to dilate the nasal valve.

[0155] In some embodiments, the treatment element 32 and control system 42 may be configured to deliver treatment energy to create specific localized tissue damage or ablation, stimulating the body's healing response to create desired conformational or structural changes in the nasal valve tissue.

[0156] In some embodiments, the treatment element 32 and control system 42 may be configured to create specific localized tissue damage or ablation without the application of energy. For example the treatment element 32 may be configured to chemically cauterize tissue around a nasal valve by delivering a cauterizing agent (e.g., silver nitrate, trichloroacetic acid, cantharidin, etc.) to the tissue. The treatment element 32 may comprise apertures configured to permit the cauterizing agent pass through to the nose. In some embodiment, the treatment element 32 may aerosolize the cauterizing agent. Other delivery methods are also contemplated. The treatment element 32 may comprise a lumen through which the cauterizing agent passes. The lumen may be fluidly connected to a reservoir or container holding the cauterizing agent. The device may comprise an input control (e.g., a button or switch) configured to control the delivery of the cauterizing agent. In some embodiments, the treatment element 32 comprises an applicator that can be coated in a cauterizing agent (e.g., dipped in a reservoir of cauterizing agent, swabbed with cauterizing agent, etc.) and the coated treatment element applicator may be applied to tissue to be treated. In some embodiments, the treatment element may be configured to apply cauterizing agent to the patient over a prolonged period of time (e.g., 30 seconds, 1 minute, 2 minutes, etc.). In some embodiment, the treatment element 32 comprises shields configured to protect tissue surrounding the tissue to be treated from coming into contact with the cauterizing agent. In some embodiments, a separate element is used to shield tissue surrounding the tissue to be treated from coming into contact with the cauterizing agent. While such treatments may be

performed without the application of energy, in some embodiments, they are performed in conjunction with energy treatments.

[0157] In some embodiments, a treatment element may be configured to treat a patient's nasal valve by applying treatment (energy, cryotherapy, or other treatments) from a position outside the patient's nose. For example, in some embodiments, the devices of FIGS. 5A and 5B may be configured to apply energy from an element positioned outside a patient's nose, such as on the skin. In another embodiment, a device may be placed on the external surface of the nose that would pull skin to effect a change in the nasal airway. Treatment may then be applied to the internal or external nasal tissue to achieve a desired nasal valve function.

[0158] In some embodiments, the device is configured to position tissue to be re-shaped. In some embodiments, the device comprises features and mechanisms to pull, push or position the nasal tissue into a mold for re-shaping. For example, suction, counter traction, or compression between two parts of the device may be used.

[0159] In some embodiments, the treatment device comprises one, two, three, four, or more molds configured to re-shape tissue. The mold or re-shaping element may be fixed in size or may vary in size. The mold may also be fixed in shape or may vary in shape. For example, the size or shape of the element may be varied or adjusted to better conform to a nasal valve of a patient. Adjustability may be accomplished using a variety of means, including, for example, mechanically moving the mold by way of joints, arms, guidewires, balloons, screws, stents, and scissoring arms, among other means. The mold may be adjusted manually or automatically. The mold is configured to impart a shape to the tissues of the nasal valve area to improve airflow or perceived airflow. The mold is configured to act near the apex of the nasal valve angle, the point at which the upper lateral cartilage meets the cartilage of the nasal septum. It may be desirable to treat in an area near, but not at, the nasal valve so as to avoid post procedure scarring and/or adhesions. This may be accomplished by focusing treatment on the lateral part of the nasal valve angle.

[0160] In some embodiments, the mold or re-shaping element comprises a separate or integrated energy delivery or treatment element (e.g., an electrode such as those described below with respect to FIGS. 8A-8J). The treatment element may be fixed or adjustable in size. For example, the treatment element may be adjusted to better conform to the nasal valve of a patient.

In the case of a separate re-shaping element and treatment element, a distance between the two elements may either be fixed or adjustable. Adjustability may be accomplished using a variety of means, including, for example, mechanically moving the mold by way of joints, arms, guidewires, balloons, screws, stents, and scissoring arms, among other means.

In some embodiments, the mold or another part of the device is configured to deliver cooling (discussed in more detail below). In some embodiments, the mold or re-shaping element comprises a balloon configured to reshape and/or deform tissue. A balloon may also be configured to deliver energy such as heat using hot liquid or gas.

Examples of Various Electrode Arrangements

[0161] Described below are embodiments of various treatment devices and, more particularly, electrode arrangements that may be used for applying energy to the nasal valve area. These electrodes may, for example, deliver RF energy to preferentially shape the tissue to provide improved nasal breathing. In some embodiments, one or more electrodes may be used alone or in combination with a tissue shaping device or mold. In other embodiments, one or more electrodes may be integrally formed with a tissue shaping device or mold, so that the electrodes themselves create the shape for the tissue. In some embodiments, the energy delivery devices may utilize alternating current. In some embodiments, the energy delivery devices may utilize direct current. In certain such embodiments, the energy delivery device may comprise a configuration utilizing a grounding pad.

[0162] In some embodiments, the term "electrode" refers to any conductive or semi-conductive element that may be used to treat the tissue. This includes, but is not limited to metallic plates, needles, and various intermediate shapes such as dimpled plates, rods, domed plates, etc. Electrodes may also be configured to provide tissue deformation in addition to energy delivery. Unless specified otherwise, electrodes described can be monopolar (e.g., used in conjunction with a grounding pad) or bipolar (e.g., alternate polarities within the electrode body, used in conjunction with other tissue-applied electrodes).

[0163] In some embodiments, "mold", "tissue shaper", "re-shaping element" and the like refer to any electrode or non-electrode surface or structure used to shape, configure or deflect tissue during treatment.

[0164] In some embodiments, "counter-traction" refers to applying a force opposite the electrode's primary force on the tissue to increase stability, adjustability, or for creating a specific shape.

[0165] As shown in FIG. 8A, in some embodiments, bipolar electrodes may be used to deliver energy, with one electrode 202 placed internally in the nasal valve, for example against the upper lateral cartilage, and one electrode 204 placed externally on the outside of the nose. This embodiment may advantageously provide direct current flow through the tissue with no physical trauma from needles (as shown in some embodiments below). As shown in FIG. 8B, in some embodiments, bipolar electrodes may be used to deliver energy, with both electrodes 210, 212 placed internally. An insulating spacer 214 may be placed between them. This embodiment may be simple and may advantageously minimize current flow through the skin layer. In some embodiments, bipolar electrodes 220, 222 may be both placed externally and may be connected to a passive molding element 224 placed inside the nasal valve adjacent to tissue to be treated, as shown in FIG. 8C. This embodiment may advantageously minimize the potential for mucosal damage. In some embodiments, electrodes placed internally may be shaped to function as a mold or may comprise an additional structure that may function as a mold.

[0166] In some embodiments, a monopolar electrode may be used to deliver energy. As shown in FIG. 8D, the electrode 230 may be placed internally and may be connected to an external, remote grounding pad 232. The grounding pad 232 may, for example, be placed on the abdomen of a patient or in other desired locations. This embodiment may advantageously be simple to manufacture and may minimize current flow through the skin. In some embodiments, a monopolar electrode may be placed externally and may be connected to a molding element placed inside the nasal valve as well as a remote grounding pad. This embodiment may also advantageously be simple to manufacture, may minimize mucosal current flow, and may also be simple to position. In some embodiments, electrodes placed internally may be shaped to function as a mold or may comprise an additional structure that may function as a mold.

[0167] In some embodiments, monopolar transmucosal needles may be used to deliver energy. The needle electrodes 240 may be placed internally, as shown in FIG. 8E penetrating through the mucosa to the cartilage, and a remote grounding pad 242 or element may be placed externally. In some embodiments, monopolar transmucosal needles may be used in conjunction

with one or more molding elements which may be disposed on or around the needles. In some embodiments, monopolar transdermal needles may be used to deliver energy. In other embodiments (not shown), the needles may be placed external to the nose, and penetrate through to tissue to be treated. Needle configurations may advantageously target the cartilage tissue to be treated specifically. The monopolar transdermal needles may be used in conjunction with an internal molding device (not shown).

[0168] In some embodiments, bipolar transmucosal needles may be used to deliver energy to tissue to be treated. The needles may be placed internally, with an insulating spacer between them and may penetrate through the mucosa to the cartilage to be treated. In some embodiments, the bipolar transmucosal needles may be used in combination with one or more internal molding elements. The one or more molding elements may be placed on or near the needles. In some embodiments, bipolar transdermal needles may be used to deliver energy. In other embodiments, the transdermal needles may be placed externally and penetrate through to tissue to be treated. Needle configurations may advantageously target the cartilage tissue to be treated specifically. The transdermal bipolar needles may be utilized in conjunction with an internal molding element.

[0169] As shown in FIG. 8F, in some embodiments, an array of electrodes comprising one, two, or many pairs of bipolar needles 252 are located on a treatment element configured to be placed into contact with the cartilage. An insulator 254 may be disposed between the bipolar needles 252. An insulator may also be utilized on part of the needle's length to allow energy to be delivered only to certain tissue structures, such as cartilage. The electrodes may be placed either internally or transmucosally or they may be placed externally or transdermally. In the embodiment illustrated in FIG. 8F, the insulator 254 may also function as a mold or molding element. In other embodiments (not shown), the array of electrodes is used in conjunction with a separate tissue re-shaping element.

[0170] FIG. 8G illustrates another embodiment of a treatment element comprises one, two or many pairs of bipolar electrodes 260. As opposed to FIG. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 8G arranges the pairs of electrodes along the length of the treatment element. The electrodes of FIG. 8G are also non-penetrating, in contrast

to the needles of FIG. 8F. The electrodes 260 may be placed against either the skin, externally, or the mucosa, internally as a means of delivering energy to target tissue such as cartilage.

[0171] In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For example, the needles or needle pairs of FIG. 8F may be individually controlled to produce an optimal treatment effect. For another example, the separate electrodes of FIGS. 8B and 8C may be individually controlled to produce an optimal treatment effect. Other examples are also contemplated. The channels may also comprise separate or integrated feedback. This may advantageously allow for more accurate temperature control and more precise targeting of tissue. Separate control may also allow energy to be focused and/or intensified on a desired region of the treatment element in cases where the anatomy of the nasal tissue/structures does not allow the entire electrode region of the treatment element to engage the tissue. In such embodiments, the nasal tissue that is in contact with the treatment element may receive sufficient energy to treat the tissue.

[0172] Combinations of the described electrode configurations may also be utilized to deliver energy to tissue to be treated (e.g., by being reshaped). For example, transmucosal needles 264 may be placed internally, penetrating through to the tissue to be treated, and an electrode 266 may be placed externally, as shown in FIG. 8H. This embodiment may advantageously target the cartilage tissue specifically and be biased for mucosal preservation. For another example, transdermal needles 268 may be placed externally and an electrode 270 may be placed internally, as shown in FIG. 8I. This embodiment may advantageously target the cartilage tissue specifically and be biased towards skin preservation. For another example bipolar needle electrodes 272, 274 can be placed both transdermally or externally and transmucosally or internally, as shown in FIG. 8J. This embodiment may advantageously target the cartilage tissue specifically. Some embodiments of treatment elements may include inert areas which do not delivery energy to the tissue. Other combinations of electrode configuration are also possible.

Examples of Treatment Devices Including Electrodes

[0173] Embodiments of treatment devices incorporating treatment elements such as the electrodes described above are illustrated in FIGS. 9A-21B. The instrument designs described in

these embodiments may be used in a device such as the device 30, described above, and in the system of FIG. 3. In some embodiments, the devices provide tissue re-shaping or molding in addition to energy delivery. Applying energy to the nasal valve may require properly positioning the electrode(s) at the nasal valve, deflecting or deforming the tissue into a more functional shape, and delivering or applying energy consistently prior to device removal. Embodiments described herein may advantageously provide adjustability, visualization of effect, ease of use, ease of manufacturability and component cost. Molding and reshaping of the tissues of the nasal valve may allow for non-surgical nasal breathing improvement without the use of implants.

[0174] FIG. 9A depicts a device 300 comprising a single inter-nasal monopolar electrode 301 located at the end of a shaft 302. The shaft is attached to a handle 303. The electrode configuration may be similar to that described with respect to FIG. 8D. FIG. 9B depicts another device 304 comprising a single inter-nasal, monopolar electrode 305. The electrode 305 is located at the distal end of a shaft 306, which is attached to a handle 307. The handle comprises a power button 308 that may be used to activate and deactivate the electrode. As stated above, the device 304 may either comprise a generator or be connected to a remote generator. The electrode 305 may be provided on an enlarged, distal end of the shaft 306, and in the embodiment illustrated has a convex shape configured to press against and create a concavity in the nasal valve cartilage.

[0175] FIG. 10A depicts a side view of a device 310 comprising a single inter-nasal electrode 312 located at the end of a shaft 314. The shaft is attached to a handle 316. An external mold 318 is attached to the handle 316 and can be moved relative to the electrode shaft 314. The external mold 318 has a curved shape with an inner concave surface that may be moved in order to press against an external surface of a patient's nose to compress tissue between the external mold 318 and the electrode 312. FIG. 10B provides a front view of the device 310.

[0176] FIG. 11A depicts a device 320 comprising a single inter-nasal electrode 322 attached to the end of a shaft 324. The shaft 324 is attached to a handle 326. An internal shaft 328 comprising a tissue-contacting surface is attached to the handle 326. The internal shaft 328 can be moved relative to the electrode shaft 324 and may provide counter-traction and/or positioning. For example, when the electrode 322 is placed against a patient's upper lateral cartilage, the counter-traction element 328 may be pressed against the patient's nasal septum.

[0177] FIG. 11B depicts a device 450 similar to device 320 of FIG. 11A comprising an inter-nasal electrode 451 located at a distal end of a shaft 452 connected to a handle 454. The device 450 further comprises a counter-traction element 456 connected to a handle 458. Like the device 320 depicted in FIG. 11A, the connection 460 between the two handles 454, 458 is such that squeezing the two handles 454, 458 together causes the electrode 451 and the counter-traction element 456 to move away from each other, spreading the tissue they are contacting.

[0178] FIG. 12A depicts a device 330 comprising a single inter-nasal electrode 332 located at the end of a shaft 334. The shaft 334 is attached to a handle 336. The device 330 comprises another single inter-nasal electrode 338 attached to the end of a shaft 340. The shaft 340 is attached to a handle 342. The device comprises a connection 344 between the two handles 340, 342 that allows simultaneous deformation and treatment of both nostrils.

[0179] FIG. 12B depicts a device 470 similar to device 330 of FIG. 12A comprising a first inter-nasal electrode 472 located at a distal end of a shaft 474 connected to a handle 476. The device 470 comprises a second inter-nasal electrode 478 located at a distal end of a second shaft 480 connected to a second handle 482. The connection 484 between the two handles 476, 482 is such that squeezing the handles 476, 482 together causes the electrodes 472, 478 to move away from one another, spreading any tissue they may be in contact with. The device 470 comprises a ratcheting mechanism 475 between the two handles 476, 482 that allows the relative positions of the electrodes 472, 478 to be locked during treatment.

[0180] FIG. 13A depicts a side view of a device 350 also used for treating two nostrils comprising an inter-nasal electrode 352 attached to the end of a shaft 354. The shaft 354 is attached to a handle 356. As seen in the front view provided in FIG. 13B, the device 350 comprises a second inter-nasal electrode 358. The second inter-nasal electrode 358 is attached to the end of a shaft which is attached to a handle. A connection between the two handles allows simultaneous deformation and treatment of the nostrils. An external mold 366 is attached to the handles. The mold 366 may be moved relative to the electrode shafts 354, 360 and may provide counter-traction (e.g., against the bridge of the nose) and positioning.

[0181] FIGS. 13C-E depicts a device 490 similar to the device 350 shown in FIG. 13A and FIG. 13B. FIGS. 13C and 13D depict side and top views of a device 490 comprising a handle 492. The handle 492 bifurcates into a first shaft 494 with a first inter-nasal electrode 496 located

at a distal end of the shaft 494 and a second shaft 498 with a second inter-nasal electrode 500 located at a distal end of the shaft 498. The device 490 comprises a mold 502 configured to provide counter-traction or compression of the bridge of the nose. The mold 502 comprises a handle 504. The connection 506 between the handles 492, 504 is such that squeezing the two handles 492, 504 causes the electrodes 496, 600 and the mold 502 to be compressed together. FIG. 13E depicts the device 490 being used on a patient. The arrows indicate the directions in which the handles 492, 504 are configured to be squeezed.

[0182] FIG. 14A depicts a front view of a device 370 comprising an inter-nasal electrode 372 attached to the end of a shaft 374 (shown in top view of FIG. 14B). The shaft 374 is attached to a handle 376. The device 370 comprises a second inter-nasal electrode 378 attached to the end of a second shaft 380. The second shaft 380 is attached to a second handle 382. A connection 384 between the two handles 376, 382 may allow simultaneous deformation and treatment of the nostrils. External molds 386, 388 are attached to the handles and can be moved relative to each electrode shaft 374, 380. The molds 386, 388 may provide counter-traction, compression of tissue, positioning, and external tissue deformation.

[0183] FIG. 15A depicts a front view of device 390 comprising a first inter-nasal electrode 392 and a second inter-nasal electrode 398. As shown in the side view of FIG. 15B, the device 390 comprises a first inter-nasal electrode 392 attached to the end of a shaft 394. The shaft is attached to a handle 396. A second inter-nasal electrode 398 is attached to the end of a second shaft 400, as shown in the top view of FIG. 15C. The second shaft 400 is attached to a second handle 402. A connection 404 between the two handles 396, 402 may allow simultaneous deformation and treatment of the nostrils. Additional internal shafts 406, 408 comprise tissue-contacting surfaces and are attached to the handles 396,402. The internal shafts 406, 408 may be moved relative to each electrode shaft 394, 400 (shown in FIG. 15B) and may provide counter-traction and positioning.

[0184] FIG. 16 depicts a system 410 comprising a first device having an extra-nasal electrode 412 along a concave surface configured to positioned against an external surface of a patient's nose, the electrode 412 being attached to the end of a shaft 414. The shaft 414 is attached to a handle 416. A separate device 417 comprising an internal tissue mold 418 is attached to a shaft 420. The internal tissue mold is configured to be positioned inside the patient's nasal valve. The

shaft 420 is attached to a handle 422. Each handle 422, 416 may be manipulated individually and may apply energy and deformation to create a desired tissue effect.

[0185] FIG. 17A depicts a side view of a device 430 comprising an extra-nasal electrode 431 attached to the end of a shaft 432. The shaft 432 is attached to a handle 434. The device 430 also comprises an internal tissue mold 436 attached to a shaft 438 which is attached to a handle 440. The handles 434, 440 are attached together and may be moved relative to each other to simultaneously deliver energy and deform tissue. FIG. 17B depicts a front view of the device 430.

[0186] FIG. 18 depicts a device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394. The electrodes may be similar to the electrodes described with respect to the electrode configuration of FIG. 8G in that they are non-penetrating. The shaft 394 is connected to a handle 398 which comprises a button configured to activate and deactivate the electrodes. As stated above, the device 380 may either comprise a generator or be connected to a remote generator.

[0187] FIG. 19A depicts the treatment element 502 of a treatment device (e.g., device 30). The treatment element 502 of the device comprises a monopolar electrode 504. A cross-section of the treatment element 502 is shown in FIG. 19B. It comprises an asymmetrical shape and has a convex surface where the electrode is positioned configured to conform to only one of a patient's nostrils (for example, a patient's right nostril). More specifically, the convex surface is configured such that when inserted into the particular nostril, the convex surface would be located adjacent the upper lateral cartilage of the nasal valve of that nostril. The treatment element 502 further comprises a light 506 configured to illuminate the treatment area. For example an LED or a visible laser may be used. The visible laser may experience less diffusion in the tissue. Furthermore, the light 506 can be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location. Because the electrode 504 is not centered on the treatment element 502 of the device, a separate device having a mirror-image configuration may be required to treat the other nostril.

[0188] FIG. 20A depicts the treatment element 512 of a treatment device (e.g., device 30). The treatment element 512 of the device comprises two monopolar electrodes 514, 516 provided

side-by-side on a convex surface of the treatment element. The cross section of the treatment element 512, shown in FIG. 20B, is configured to conform to the shape either nostril, depending on which side of the device (and accordingly, which of electrode 514 or 516) is placed in contact with the patient's nasal valve. Comprising two monopolar electrodes 514, 516 may allow the same treatment element 512 to be used for treatment in both nostrils, and each electrode may be activated separately depending on which side needs to be utilized. The treatment element 512 also comprises two lights 518, 520 (e.g., LEDs, lasers) configured to illuminate the treatment area for both nostrils. One or both of the lights 518, 520 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location.

[0189] FIG. 21A depicts a treatment element 522 of a treatment device (e.g., device 30). The tip 522 of the device comprises a monopolar electrode 524. The tip 522 comprises a symmetrical cross-section as shown in FIG. 21B. The tip 522 comprises a light 526 (e.g., LED) configured to illuminate the treatment area. The light 526 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The symmetrical tip allows the user to treat either left or right nostril. The user can then use the light to properly position the device in the desired location.

[0190] FIGS. 22A-G depict a treatment device 530 similar to the embodiments of FIGS. 8D, 9A, and 9B. FIGS. 22A and 22F provide perspective views of the device 530. The device 530 comprises a treatment element 532 at its distal tip 534. The treatment element 532 comprises an electrode 535. The body of the treatment element 532, itself, may comprise an insulating material. The treatment element 532 may be provided on an enlarged distal tip 534 of an elongate shaft 536, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in the upper lateral cartilage near the nasal valve). The distal tip 534 is located at the distal end of shaft 536. The shaft is attached at its proximal end to a handle 538. The handle 538 comprises an input control such as a power button 540 on its front side that may be used to activate and deactivate the electrode. The power button 540 may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above.

[0191] The device 530 comprises a flexible wire or cable 542 electrically connected to an adaptor 544. The adaptor 544 can be used to connect the device 530 to a remote generator (not shown). The adaptor 544 may allow transmission of treatment energy between a remote generator and the device 530. The adaptor may also allow transmission of any sensor signals between the device 530 and a generator or control unit. The device 530 may either comprise an integrated generator or be connected to a remote generator. The treatment device 530 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as described above and further below. In some embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0192] FIGS. 22B and 22C depict front and back views of the device. As shown in FIGS. 22B and 22C, the handle 538 of the device generally as a rounded elongate shape. Other shapes are also possible. For example the device 530 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 538 may increase distally along the length of the handle 538.

[0193] FIGS. 22D and 22E depict side views of the device. As shown in FIGS. 22D and 22E, the handle 538 of the device 530 may comprise an indentation or recess around the middle of the handle 538. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 540 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0194] In some embodiments, the shaft has a width or diameter of about 0.125 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0195] FIG. 22G depicts a larger view of the distal tip 534 of the device 530. As shown best in FIG. 22G, the treatment element 532 comprises a generally elongate shape. The front of the treatment element 532 comprises a shallow, curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back of the treatment element 532 also comprises a shallow curved surface. As best seen in FIGS. 22D and 22E, the back surface varies in width along the length of the back surface of the treatment element 532. The back surface widens, moving distally along the tip until it is nearly in line with the proximal end of the electrode plate 532. The back surface then narrows towards the distal tip of the treatment element 532. This shape may maximize visualization of the area to be treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 532 comprises a monopolar electrode plate 532. The monopolar electrode plate 532 can be in the shape of a rectangle having a curved or convex tissue-facing surface. Other shapes are also possible (e.g., square, circular, ovular, etc.). The electrode 532 may protrude slightly from the treatment element 535. This may allow the electrode to itself provide a convex shape configured to create a concavity in tissue to be treated.

[0196] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused

polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0197] In some embodiments, the electrode has a width of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0198] As shown in the embodiment of FIG. 22G, the treatment element 532 further comprises a pin-shaped structure comprising a thermocouple 533 within an insulating bushing extending through a middle portion of the plate 532. In some embodiments, different heat sensors (e.g., thermistors) may be used. In some embodiments, the thermocouple 533 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 532 itself. The temperature measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to FIG. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment

element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0199] As shown in FIG. 22G, in some embodiments the thermocouple is within a pin shaped protrusion on the surface of the electrode 532. In other embodiments, the thermocouple can simply be on the surface of the electrode. In other embodiments, the thermocouple can protrude from the surface of the electrode in a rounded fashion. Rounded structures may be pressed into the tissue to obtain subsurface temperature readings. Other configurations and locations for the thermocouple are also possible. The use of thermocouples or temperature sensors may be applied not only to the embodiment of FIG. 22G, but also to any of the other embodiments described herein.

[0200] FIGS. 23A-G depict a treatment device 550 similar to the embodiments of FIGS. 8F and 18. FIGS. 23A and 23F are perspective views of the device 550 and show the device 550 comprising a treatment element 552 at the distal tip 556 of the device 550. The treatment element 552 may be provided on an enlarged distal tip 556 of an elongate shaft 558, and as in the embodiment illustrated, may have a convex shape configured to press against and create a concavity in the nasal valve cartilage (e.g., in upper lateral cartilage of the nasal valve). The distal tip 556 is located at a distal end of shaft 558. The shaft is attached at its proximal end to a handle 560. The handle 560 comprises an input control, such as a power button 562, on its front side that may be used to activate and deactivate the electrode. The power button may be positioned in a recess of the handle to allow for finger stability when activating and deactivating the electrode. In other embodiments, the input control is in the form of a switch or dial. Other configurations are also possible as described above. The device 550 may either comprise a generator or be connected to a remote generator. The device 550 may comprise a flexible wire or cable 564 that connects to an adaptor 566 that is configured to be plugged into a remote

generator (not shown). The adaptor 566 may allow transmission of treatment energy between a remote generator and the device 550. The adaptor 566 may also allow transmission of any sensor signals between the device 550 and a generator or control unit. The treatment device 550 may be provided in a system or kit also including the remote generator. The system or kit (with or without the remote generator) may also include a grounding device and/or a cooling device as described above and further below. In some embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0201] In some embodiments, the shaft has a width or diameter or about 0.235 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft and/or handle comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0202] FIGS. 23B and 23C depict side views of the device. As shown in FIGS. 23B and 23C, the handle 560 of the device 550 may comprise an indentation or recess around the middle of the handle 560. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 562 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0203] FIGS. 23D and 23E depict front and back views of the device. As shown in FIGS. 23D and 23E, the handle 560 of the device generally comprises a rounded elongate shape. Other shapes are also possible. For example the device 550 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 560 may increase distally along the length of the handle 560.

[0204] FIG. 23G depicts a larger view of the distal tip 556 of the device 550. As shown best in FIG. 23G, the treatment element 552 comprises a generally elongate shape. The front of the treatment element 552 comprises a shallow curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the

treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back surface of the treatment element 552 comprises a shallow curved surface along most of its length. As best seen in FIGS. 23B and 23C, the back surface narrows distally along the length of the element 552 from approximately the distal end of the needle electrodes to the distal tip of the treatment element 552. This shape may maximize visualization of the area to be treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 552 comprises a monopolar or bipolar needle array comprising multiple needles 554. In some embodiments, the needles 554 are energized in between select needles to deliver bipolar energy. In other embodiments, the energy is delivered between the needles (554) and a remote grounding pad (not shown). In some embodiments, the electrode needle pairs are arranged horizontally across the treatment element 552. In some embodiments, the electrode needle pairs are arranged vertically across the treatment element 552, or along the direction of the shaft 558 and handle 560. Other configurations are also possible. For example, the needle pairs may be arranged diagonally across the treatment element 552. The treatment element 552 may be placed either internally, with the needle pairs 554 positioned transmucosally or the treatment element 552 may be placed externally with the needle pairs 554 positioned transdermally. The distal tip 556 of the device 550 may also function as a mold or molding element. In a monopolar embodiment, the energy may be selectively delivered between certain sets of needles, all needles, or even individual needles to optimize the treatment effect.

[0205] The treatment element 552 of the device 550 further comprises a pin-shaped structure comprising a thermocouple 555 within an insulating bushing extending through a middle portion of the front surface of the treatment element 552. In some embodiments, different heat sensors (e.g., thermistors) may be used. As described above, in some embodiments, the thermocouple 555 is configured to measure a temperature of the surface or subsurface of tissue to be treated or tissue near the tissue to be treated. A pin-shape having a sharp point may allow the structure to penetrate the tissue to obtain temperature readings from below the surface. The thermocouple can also be configured to measure a temperature of the treatment element 552 itself. The

temperature measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to FIG. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0206] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0207] In some embodiments, the electrodes have a width or diameter of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy).

Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0208] Energy applied to the tissue to be treated using any combination of the embodiments described in this application may be controlled by a variety of methods. In some embodiments, temperature or a combination of temperature and time may be used to control the amount of energy applied to the tissue. Tissue is particularly sensitive to temperature; so providing just enough energy to reach the target tissue may provide a specific tissue effect while minimizing damage resulting from energy causing excessive temperature readings. For example, a maximum temperature may be used to control the energy. In some embodiments, time at a specified maximum temperature may be used to control the energy. In some embodiments, thermocouples, such as those described above, are provided to monitor the temperature at the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to FIG. 3). In some embodiments, tissue impedance may be used to control the energy. Impedance of tissue changes as it is affected by energy delivery. By determining the impedance reached when a tissue effect has been achieved, a maximum tissue impedance can be used to control energy applied.

[0209] In the embodiments described herein, energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or as part of a separate assembly that delivers energy or control signals to the handpiece via a cable or other connection. In some embodiments, the generator is an RF energy source configured to communicate RF energy to the treatment element. For example, the generator may comprise a 460 KHz sinusoid wave

generator. In some embodiments, the generator is configured to run between about 1 and 100 watts. In some embodiments, the generator is configured to run between about 5 and about 75 watts. In some embodiments, the generator is configured to run between about 10 and 50 watts.

[0210] In some embodiments, the energy delivery element comprises a monopolar electrode (e.g., electrode 535 of FIG. 22G). Monopolar electrodes are used in conjunction with a grounding pad. The grounding pad may be a rectangular, flat, metal pad. Other shapes are also possible. The grounding pad may comprise wires configured to electrically connect the grounding pad to an energy source (e.g., an RF energy source).

[0211] In some embodiments, the energy delivery element such as the electrodes described above can be flat. Other shapes are also possible. For example, the energy delivery element can be curved or comprise a complex shape. For example, a curved shape may be used to place pressure or deform the tissue to be treated. The energy delivery element may comprise needles or microneedles. The needles or microneedles may be partially or fully insulated. Such needles or microneedles may be configured to deliver energy or heat to specific tissues while avoiding tissues that should not receive energy delivery.

[0212] In some embodiments, the electrodes or energy delivery elements described herein comprise steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0213] In some embodiments, the treatment elements (e.g., non-electrode portion of treatment element) of the devices described herein, including but not limited to FIGS. 8A-J, 9A-B, 10A-b, 11A-B, 12A-B, 13A-E, 14A-B, 15A-C, 16, 17A-B, 18, 22A-G, 19A-B, 20A-B, 21A-B, 22A-G,

23A-G, 25A-B, 26, 27, 28A-E, and 29, comprise an insulating material such as a ceramic material (e.g., zirconium, alumina, silicon glass). In some embodiments, the treatment elements comprise an insulating material interposed between multiple electrodes or electrode section. These insulating sections may provide an inert portion of the treatment element that does not delivery energy to the tissue. Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the insulators described herein comprise polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the insulators described herein comprise thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the insulators described herein comprise thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the insulators described herein comprise glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0214] In some embodiments, the handle and/or shaft of the devices comprise the same materials as those described with respect to the insulators. In some embodiments, the handle and/or shaft of the device comprises a metal, such as stainless steel. In other embodiments, the handle and/or shaft of the device comprises a polymer, such as polycarbonate. Other metals and polymers are also contemplated.

[0215] In some embodiments, the device may be used in conjunction with a positioning element that can be used to aid in positioning of the device. The positioning element may be integrated into the device itself or can be separate. The positioning element may be used to determine the optimal placement of the device to achieve maximal increase in efficacy. In some embodiments, a positioning element is configured to be inserted and manipulated within the nose until the patient reports a desired improvement in breathing. The treatment device may then be used to treat while the positioning element is holding the nose in the desired configuration. In some embodiments, molds described herein may be used for the same purpose.

[0216] In some embodiments, a positioning element comprises a shaft comprising measurement marks indicating depth. For example, a physician may insert this element into the nose to manipulate the tissue to find the depth of treatment at which the patient reports the best

breathing experience. The positioning element may comprise marks around the base of the shaft indicating which point of rotation of the device within the nostril provides the best breathing experience. The positioning element may also comprise marks indicating angle of insertion. The physician may then use the measurement marks to guide insertion of the treatment element to the same spot.

[0217] It will be appreciated that any combination of electrode configurations, molds, handles, connection between handles, and the like may be used to treat the nasal valve.

Cooling Systems

[0218] Embodiments of devices configured to heat specific tissue while maintaining lower temperatures in other adjacent tissue are provided. These devices may be incorporated into any of the treatment apparatuses and methods described herein. The nasal valve is an example of a tissue complex that includes adjacent tissues that may benefit from being maintained at different temperatures. Other examples include the skin, which comprises the epidermis, dermis, and subcutaneous fat, the tonsils, which comprise mucosa, glandular tissue, and vessels. Treatment of other tissue complexes is also possible. For example, in some embodiments, the internal structures of the nasal valve may be heated while maintaining a lower temperature in the mucosal lining of the nose and/or skin. In other embodiments, the mucosa may be heated, while maintaining lower temperatures in the skin. Limiting unwanted heating of non-target tissues may allow trauma and pain to be reduced, may reduce scarring, may preserve tissue function, and may also decrease healing time. Combinations of heat transfer and/or heat isolation may allow directed treatment of specific tissue such as cartilage, while excluding another tissue, such as mucosa, without surgical dissection.

[0219] Generally, when using a device 570 with an electrode 572 (e.g., monopolar RF electrode) to heat nasal cartilage, the electrode 572 must be in contact with the mucosa. FIG. 24A shows a cross-section of tissue at the nasal valve. The cross-section shows that the nasal cartilage 704 sits in between a layer of mucosa (internal) 702 and a layer of skin (external) 706. When the electrode 572 is activated, both the mucosa and the cartilage are heated by the current flowing from the electrode to the return (e.g., ground pad), as shown in FIG. 24B. The tissue closest to the electrode 572 receives the highest current density, and thus, the highest heat. A surface cooling mechanism may allow the temperature of the electrode surface to be reduced.

Such a cooling mechanism may maintain a lower temperature at the mucosa even though current flow will continue to heat the cartilage.

[0220] FIG. 25A depicts a device 580 configured to treat the nasal valve using an electrode while maintaining a reduced temperature at the mucosa. The device comprises a treatment element 582 comprising an electrode 584 at the distal tip of the device 580. The treatment element 582 is attached to a distal end of a shaft 586, which is attached to the distal end of a handle 588. Input and output coolant lines 590, 592 are attached to a pump and reservoir 594 and extend into the handle 588, through the distal end of the treatment element 582 to the electrode 582 and return back through the shaft 586 and handle 588 to the pump and reservoir 594. The coolant may be remotely cooled in the reservoir and may comprise a fluid or gas. The coolant flowing through the electrode 582 may allow the treatment element 582 to be maintained at a reduced temperature while still allowing current flow to heat the cartilage. Examples of coolant include air, saline, water, refrigerants, and the like. Water may advantageously provide moderate heat capacity and be non reactive. Refrigerants may advantageously be able to transfer significant amounts of heat through phase change. The coolant may flow through internal or external cavities of the electrode or wand tip. For example, FIG. 25B depicts an embodiment of a device 600 comprising a treatment element 602 with an electrode 604 at the distal tip of the device 600. The treatment element 602 is attached to the distal end of a shaft 606 which is attached to the distal end of a handle 608. The handle may be attached to a cable comprises a lumen or channel 611 through which gas or fluid may flow. The lumen 611 may diverge, near the treatment element 602, into separate external channels flowing over the electrode 604. The lumen 611 and channels 610 or cavities may be attached to a fan or fluid pump 612. In some embodiments, the fan or fluid pump may remotely cool the gas or fluid.

[0221] FIG. 26 depicts another embodiment of a device 620 configured to treat the nasal valve using an electrode 624 while maintaining a reduced temperature at the mucosa and/or skin. The device comprises a treatment element 622 comprising an electrode 624 at its distal end. The treatment element 622 is connected to the distal end of a shaft 626 which is connected to the distal end of a handle 628. The device 620 comprises a heat pipe 630 attached to the electrode 624 or treatment element 622. The heat pipe 630 is configured to transfer heat to a remote heat sink 632. As shown in FIG. 26, the heat sink 632 may be placed in the handle of the device. In

some embodiments, the heat sink may be placed remotely. The heat pipe 630 may comprise a sealed tube (e.g., a copper tube) filled with a material that evaporates at a given temperature. When one end of the heat pipe 630 is heated, the fluid may evaporate and flow to the opposite end where it may condense and subsequently transfer heat to the heat sink 632. Using a material such as copper for the heat pipe 630 and/or heat sink 632 may advantageously provide high heat and electrical conductivity.

[0222] FIG. 27 depicts another embodiment of a device 640 configured to treat the nasal valve using a bipolar electrode pair while maintaining a reduced temperature at the skin. The device 640 comprises a first treatment element 642 comprising a first electrode 644 of a bipolar electrode pair at the distal end of a shaft 646. The treatment element 642 comprises a thermocouple pin 650 like that described with respect to FIG. 22G. The shaft 646 is connected to the distal end of a handle 648. The handle 648 is connected to another handle 652 comprising a shaft 654 with a treatment element 656 at its distal tip. The treatment element 656 comprises a second electrode 657 of the bipolar electrode pair. The first and second treatment elements 642, 656 can be placed on either side of nasal tissue. For example, the first treatment element 642 may be in contact with the mucosa and the second treatment element 656 may be in contact with the skin. Similar to the device depicted in FIG. 26, the device of FIG. 27 comprises a heat pipe within both shafts 654, 646. Thus heat from the tissue is transferred from the treatment elements 642, 656 and is transported down the shafts 654, 646 into an integrated or a remote heat sink (not shown). This heat transfer may keep the skin and the mucosa relatively cool while still delivering sufficient treatment energy to the cartilage. The connection 658 and spring 647 between the two handles 648, 652 is configured to bias the two shafts 646, 654 and treatment elements 642, 656 towards a collapsed state. Squeezing the handles 648, 652 may separate the two shafts 646, 654 and treatment elements 642, 656. Thus, the handles 648, 652 can be squeezed to properly position the device 640 at the nasal tissue to be treated. Releasing the handles 648, 652 can cause the treatment element 642 and the cooling element 656 to contact the tissue. In some embodiments, the device 640 may only comprise one heat pipe. In some embodiments, the device 640 may comprise a treatment element with a monopolar electrode on one shaft and a molding element on the other shaft. Multiple configurations are contemplated. For example, the device may comprise one heat pipe and a bipolar electrode pair. For another example, the device may comprise one heat pipe and a monopolar electrode. For another example, the device may

comprise two heat pipes and a monopolar electrode. Other device configurations are also possible.

[0223] The embodiments described with respect to FIGS. 25A-27 employ specific differential cooling mechanisms to maintain different and particular temperatures in adjacent tissues. FIGS. 28A-28E depicts various examples of more general mechanisms configured to maintain different temperatures in adjacent tissues. FIGS. 28A-28E depict examples of differential cooling mechanisms as applied to a cross-section of tissue at the nasal valve, like that shown in FIG. 24A.

[0224] As shown in FIG. 28A, in some embodiments, the differential cooling mechanism comprises two elements: a first element 708 and a second element 710. The two elements are on either side of the thickness of the nasal tissue. In one embodiment, the mechanism is configured to maintain normal temperatures in the cartilage 704 while cooling the mucosa 702 and the skin 706. In such an embodiment, the first and second elements 708, 710 comprise a cooling apparatus such as those described above (e.g., heatsink, coolant lines, etc.). In some embodiments, the mucosa 702 and the skin 706 are heated while normal temperatures are maintained in the cartilaginous middle layer 704. The cartilage 704 may be somewhat warmed, in such embodiments, but may be cooler than the mucosa 702 and the skin 706. In such embodiments, the first and second elements 708, 710 comprise a heating apparatus, such as radio frequency electrodes or resistive heating elements. In some embodiments, the mucosa 702 is heated, the skin 706 is cooled, and normal temperatures are maintained in the cartilage 704. In such embodiments, the first element 708 comprises a heating apparatus and the second element 710 comprises a cooling apparatus. For example, the device 580, described with respect to FIG. 27, may use such a mechanism. In some embodiments, the skin 706 is heated, the mucosa 702 is cooled, and normal temperatures are maintained in the cartilage 704. In such embodiments, the first element 708 comprises a cooling apparatus and the second element 710 comprises a heating apparatus. Again, the device 580, described with respect to FIG. 27, is an example of a device that may use such a mechanism.

[0225] FIG. 28B shows an example of one of the embodiments described with respect to FIG. 28A. The first element 730 is on the mucosal surface 702. The second element 732 is an energy delivery element and is positioned on the skin side 706 of the tissue thickness. The first element

730 comprises a cooling apparatus and the second element 732 comprises an energy delivery element (e.g., an RF electrode). The mucosal layer 702 is cooled while the skin 706 and cartilaginous areas 704 are heated. In other embodiments, the first element 730 can be positioned on the skin 706 and the second element 732 can be positioned on the mucosa 702. In such embodiments, the skin 706 is cooled while the mucosa 702 and the cartilage 704 are heated.

[0226] As shown in FIG. 28C, in some embodiments, the differential cooling mechanism comprises a first element 720 and a second element 722. Both elements 720, 722 are on the mucosa 702 side of the tissue thickness. In some embodiments, the mucosal layer 702 is cooled while higher temperatures are maintained in the middle cartilaginous layer 704. In such embodiments, the first element 720 comprises a cooling apparatus, and the second element 722 comprises an energy delivery apparatus (e.g., a monopolar radiofrequency electrode). In some embodiments, the first element 720 is sufficiently efficient to maintain cool temperatures at the mucosa 702 despite the energy provided by the second element 722. In other embodiments, the first and second elements 720, 722 are both positioned on the skin side 706 of the tissue thickness. In such embodiments, the skin 706 is cooled while higher temperatures are maintained in the middle cartilaginous layer.

[0227] As shown in FIG. 28D, in some embodiments, the differential cooling mechanism comprises a first surface element 740 and a second surface element 742 on either side of the tissue thickness. A third subsurface element 744 is engaged through the mucosa 702 and into the cartilage area 704. In some embodiments, the mucosa 702 and the skin 706 are cooled while the middle cartilaginous layer 704 is heated. In such embodiments, the first and second elements 740, 742 comprise cooling apparatus while the third element 744 comprises a heating element (e.g., RF monopolar electrode, RF bipolar needles, etc.). In other embodiments, the third subsurface element 744 may be engaged through the skin 706 and into the cartilage area 704.

[0228] As shown in FIG. 28E, in some embodiments, the differential cooling mechanism comprises a first surface element 750 and a second surface element 752 on either side of the tissue thickness. The differential cooling mechanism further comprises a third surface element 754 and a fourth surface element 756 on either side of the tissue thickness. In some embodiments, the cartilage layer 704 is heated while the mucosa 702 and the skin 706 are cooled. In such embodiments, the first and second elements 750, 752 comprise cooling apparatus

and the third and fourth elements 754, 756 comprise energy delivery apparatuses (e.g., bipolar plate electrodes). In some embodiments, the cartilage 704 and mucosal 702 layers are heated while the skin 706 is cooled. In such embodiments, the first element 750 comprises a heating apparatus; the second element 752 comprises a cooling apparatus; and the third and fourth elements 754, 756 comprise energy delivery apparatuses. It will be appreciated that different differential temperature effects can be achieved by reconfiguring and adding or subtracting to the described configuration of elements.

[0229] Cooling occurring before, during, or after treatment may effect reduced temperature of the skin and/or mucosa. In some embodiments, attaching passive fins or other structures to the electrode or wand tip may allow for heat dissipation to the surrounding air. In some embodiments, the device may be configured to spray a cool material such as liquid nitrogen before, during, or after treatment. Using a material such as copper for the passive fins or other structure may advantageously provide high heat and electrical conductivity. In some embodiments, using metals with a high heat capacity in the device (e.g., in the energy delivery element, the re-shaping element, or both) may advantageously provide the ability to resist temperature change during energy delivery. In some embodiments, pre-cooling the electrode (e.g., by refrigeration, submersion, spraying with a cool substance like liquid nitrogen, etc.) may maintain a reduced temperature at the mucosa. Any combination of the cooling methods described herein may be used in conjunction with any of the energy delivery methods described herein (e.g., bipolar RF electrodes, arrays needles, plates, etc.). For example, FIG. 29 depicts an embodiment of a device 800 comprising a treatment element 802 comprising electrode needles 804 at its distal tip. The device 800 may be used in conjunction with a separate cooling device 810 which may comprise channels 812 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0230] In embodiments using laser energy to heat cartilage, it is possible to use a combination of two or more lasers whose beams converge at a location within the target tissue. This convergence may cause more heat at that junction as compared to locations where only a single beam is acting. The junction may be controlled manually or via computer control. Specific treatment may be provided.

[0231] In some embodiments, insulating material may be used to protect non-target tissue during energy delivery. For example, an electrode needle may be preferentially insulated on a portion of the needle that is in contact with non-target tissue. For another example, flat electrode blades may be insulated on a portion of the blade that is in contact with non-target tissue. Other configurations for heat isolation are also possible.

[0232] Any of the cooling mechanisms or combinations of the cooling mechanisms described herein may be used in conjunction with any of the devices or combinations of devices described herein, or the like.

Examples of Methods of Treatment

[0233] Embodiments of methods for treating nasal airways are now described. Such methods may treat nasal airways by decreasing the airflow resistance or the perceived airflow resistance at the site of an internal or external nasal valve. Such treatments may also address related conditions, such as snoring.

[0234] In one embodiment, a method of decreasing airflow resistance in a nasal valve comprises the steps of inserting an energy-delivery or cryo-therapy device into a nasal passageway, and applying energy or cryo-therapy to a targeted region or tissue of the nasal passageway. For example, in some embodiments, the method may include delivering energy or cryo-therapy to a section of internal nasal valve cartilage in the area of the upper lateral cartilage, or in the area of intersection of the upper and lower lateral cartilage. In alternative embodiments, the method may deliver energy to the epithelium, or underlying soft tissue adjacent to the upper lateral cartilage and/or the intersection of the ULC and the LLC.

[0235] In another embodiment, a method comprises heating a section of nasal valve cartilage to be re-shaped, applying a mechanical re-shaping force, and then removing the heat. In some embodiments, the step of applying a mechanical re-shaping force may occur before, during or after the step of applying heat.

[0236] In some embodiments, the method may further include the step of inserting a re-shaping device into the nasal passageway after applying an energy or cryo-therapy treatment. In such embodiments, a re-shaping device such as an external adhesive nasal strip (such as those described for example in U.S. Pat. No. 5,533,499 to Johnson or U.S. Pat. No. 7,114,495 to

Lockwood, the entirety of each of which is hereby incorporated by reference) may be applied to the exterior of the nose after the treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In alternative embodiments, a temporary internal re-shaping device (such as those taught in U.S. Pat. No. 7,055,523 to Brown or U.S. Pat. No. 6,978,781 to Jordan, the entirety of each of which is hereby incorporated by reference) may be placed in the nasal passageway after treatment in order to allow for long-term re-shaping of nasal valve structures as the treated tissues heal over time. In some embodiments, the dilating nasal strips can be worn externally until healing occurs.

[0237] In alternative embodiments, internal and/or external re-shaping devices may be used to re-shape a nasal valve section prior to the step of applying energy or cryo-therapy treatments to targeted sections of the epithelial, soft tissue, mucosa, submucosa and/or cartilage of the nose. In some embodiments, the energy or cryo-therapy treatment may be configured to change the properties of treated tissues such that the tissues will retain the modified shape within a very short time of the treatment. In alternative embodiments, the treatment may be configured to re-shape nasal valve structures over time as the tissue heals.

[0238] In some embodiments, a portion of the nose, the nasal valve and/or the soft tissue and cartilage of the nasal valve may be reshaped using a re-shaping device and then fixed into place. In some embodiments, such fixation may be achieved by injecting a substance such as a glue, adhesive, bulking agent or a curable polymer into a region of the nasal tissue adjacent the target area. Alternatively, such a fixation substance may be applied to an external or internal surface of the nose.

[0239] In some embodiments, an injectable polymer may be injected into a region of the nose, either below the skin on the exterior of the nose, or under the epithelium of the interior of the nose. In some embodiments, an injectable polymer may include a two-part mixture configured to polymerize and solidify through a purely chemical process. One example of a suitable injectable two-part polymer material is described in US Patent Application Publication 2010/0144996, the entirety of which is hereby incorporated by reference. In other embodiments, an injectable polymer may require application of energy in order to cure, polymerize or solidify. A re-shaping device may be used to modify the shape of the nasal valve before or after or during injection of a polymer. In embodiments employing an energy-curable polymer, a re-shaping device may

include energy-delivery elements configured to deliver energy suitable for curing the polymer to a desired degree of rigidity.

[0240] In another embodiment, the soft tissue of the upper lip under the nares may be debulked or reshaped to reduce airflow resistance. In some embodiments, such re-shaping of the upper lip soft tissue may be achieved by applying energy and/or cryotherapy from an external and/or internal treatment element. In some embodiments, the tissue of the upper lip under the nares may be compressed by an internal or external device prior to or during application of the energy or cryo-therapy. For example, devices such as those shown in FIGS. 5A and 5B may be adapted for this purpose by providing tissue-engaging clamp tips shaped for the purpose.

[0241] In another embodiment, the muscles of the nose and/or face are stimulated to dilate the nasal valve area prior to or during application of other treatments such as energy/cryo application or fixation treatments. In such embodiments, the muscles to be treated may include the nasal dilator muscles (nasalis) the levetator labii, or other facial muscles affecting the internal and/or external nasal valves. In some embodiments, the targeted muscles may be stimulated by applying an electric current to contract the muscles, mentally by the patient, or manually by the clinician.

[0242] In some embodiments, the muscles of the nose and/or face may also be selectively deactivated through chemical, ablative, stimulatory, or mechanical means. For example, muscles may be deactivated by temporarily or permanently paralyzing or otherwise preventing the normal contraction of the muscle tissue. Chemical compounds for deactivating muscle tissues may include botulinum toxin (aka "botox"), or others. Ablative mechanisms for deactivating muscle tissue may include RF ablation, laser ablation or others. Mechanical means of deactivating muscle tissues may include one or more surgical incisions to sever targeted muscle tissue.

[0243] In another embodiment, the tissue of the nasal valve may be reshaped by applying energy to the internal and external walls of the nasal valve using a clamp like device as illustrated for example in FIGS. 5A and 5B. One arm of the clamp may provide inward pressure to the external, skin side tissue covering the nasal valve and the other side of the clamp may provide outward pressure to the mucosal tissue on the lateral wall of the nasal airway above the ULC and LLC or both.

[0244] In some embodiments, energy may be applied to the skin of the nose to effect a shrinkage of the skin, epidermis, dermis, subdermal, subcutaneous, tendon, ligament, muscle,

cartilage and/or cartilage tissue. The tissue shrinkage is intended to result in a change of forces acting on the tissues of the nasal valve to improve airflow through the nasal airway.

[0245] In another embodiment, the nasal valve tissue may be damaged or stimulated by energy application, incisions, injections, compression, or other mechanical or chemical actions. Following such damage, a device may be used on the tissue to mold or shape the tissue of the valve during healing. In some embodiments, such a re-shaping device may be temporarily placed or implanted inside or outside the patient's nose to hold a desired shape while the patient's healing process progresses.

[0246] In another embodiment, the aesthetic appearance of the nose may be adjusted by varying the device design and/or treatment procedure. The predicted post-procedure appearance of the nose may be shown to the patient through manipulating the nasal tissue to give a post procedure appearance approximation. The patient may then decide if the predicted post procedure appearance of the face and nose is acceptable or if the physician needs to change parameters of the device or procedure to produce an appearance more acceptable to the patient.

[0247] In another embodiment, reduction of the negative pressure in the nasal airway can be effected to reduce collapse of the structures of the nasal airway on inspiration without changing a shape of the nasal valve. For example, this may be accomplished by creating an air passage that allows flow of air directly into the site of negative pressure. One example of this is creating a hole through the lateral wall of the nose allowing airflow from the exterior of the nose through the nasal wall and into the nasal airway.

[0248] In another embodiment, energy, mechanical or chemical therapy may be applied to the tissue of the nasal airway with the express purpose of changing the properties of the extracellular matrix components to achieve a desired effect without damaging the chondrocytes or other cells of the nasal airway tissue.

[0249] In some embodiments, devices (e.g., devices like those described with respect to FIGS. 9A-21B) may be used to provide tissue re-shaping/molding and to impart energy to the nasal valve. The electrode may be placed in contact with the target nasal valve tissue. The electrodes and molds may be moved to shape the tissue as necessary to achieve improvement in nasal airway. The electrodes may be activated while the tissue is deformed in the new shape to

treat the tissue. The electrode may then be deactivated and the device may be removed from the nasal valve area.

[0250] FIGS. 30A-30D depict a method for using a device 900 similar to those devices described above, including but not limited to FIGS. 8A, 9B, 18, 22A-G, and 23A-G, to provide tissue re-shaping/molding and to impart energy to tissue near the nasal valve.

[0251] The method may include identifying a patient who desires to improve the airflow through their nasal passageways and/or who may benefit from an increase in a cross-sectional area of the opening of the nasal valve. The patient may be positioned either in an upright position (e.g., seated or standing) or be lying down. Local anesthesia may be applied to an area near or surrounding the tissue to be treated. General anesthesia may also be used.

[0252] Optionally, a positioning element, like that described herein, may be used to measure a desired depth or angle of treatment. As described above, the positioning element may be inserted to the desired depth of treatment and rotated to a desired angle of treatment. Marks along the positioning element can indicate the desired depth. Marks along the base of the shaft of the positioning element can indicate the desired angle. The physician or other medical professional administering the treatment can then insert the treatment device to the desired location. The physician may also assess any other characteristics relevant to the treatment of the patient's nose that may influence the manner of treatment. In some embodiments, a re-shaping element may be used to manipulate the nasal tissue into a configuration allowing improved airflow; and treatment may be performed while such a re-shaping element is maintaining the desired configuration of the nasal tissue.

[0253] If the treatment device comprises a monopolar electrode or electrode needles, a ground pad may be attached to the patient. The ground pad may be attached at the patient's torso, for example the shoulder or abdomen. Other locations are also possible, such as the patient's buttocks. Preferably, the point of attachment is a large, fleshy area. After being attached, the ground pad may be plugged into a power source. If the device is powered by a remote generator (e.g., RF generator), the device may then be plugged into the generator.

[0254] FIG. 30A depicts the nose of a patient prior to insertion of the device. As shown in FIG. 30B, the device is then inserted into a nostril of the patient. The treatment element 802 of the device 800 may be positioned within the nasal airway, adjacent to nasal tissue (e.g., upper

lateral cartilage) to be treated. The treatment element 802 may be positioned so that the electrode is in contact with the tissue to be treated. The device 800 (as shown in FIG. 30C) comprises multiple needle electrodes 804. The needle electrodes 804 may be inserted so that they are penetrating or engaging tissue to be treated.

[0255] The treatment element 802 may be used to deform the nasal tissue into a desired shape by pressing a convex surface of the treatment element 802 against the nasal tissue to be treated. FIG. 30C shows an internal view, from the nares, of the treatment element 802 pushing against the upper lateral cartilage 806 of the nose, deforming the upper lateral cartilage 806 and increasing the area of the opening of the nasal valve 808. FIG. 30D depicts an external view of the treatment element 802 deforming the upper lateral cartilage 806. Even from the outside, the nose appears to be bulging near the area to be treated. In some embodiments, the deformation required to treat the nose is not visually detectable. A control input such as button 814 may be used to activate the electrode and deliver energy (e.g., RF energy) to the tissue to be treated.

[0256] In some embodiments, temperature of the area around the electrode during treating is from about 30 degrees C. to about 90 degrees C. In some embodiments, temperature of the area around the electrode during treating is from about 40 degrees C. to about 80 degrees C. In some embodiments, temperature of the area around the electrode during treating is from about 50 degrees C. to about 70 degrees C. In some embodiments, temperature of the area around the electrode during treating is about 60 degrees C. In some embodiments, for example during cryo-therapy, temperature of the area around the electrode may be lower.

[0257] In some embodiments, treating the target tissue comprises treatment for about 1 s to about 3 minutes. In some embodiments, treating the target tissue comprises treatment for about 10 s to about 2 minutes. In some embodiments, treating the target tissue comprises treatment for about 15 s to about 1 minute. In some embodiments, treating the target tissue comprises treatment for about 20 s to about 45 s. In some embodiments, treating the target tissue comprises treatment for about 30 s.

[0258] In some embodiments, treating the target tissue comprises delivering between about 1 and about 100 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 5 and about 75 watts to the tissue. In some embodiments, treating the target tissue comprises delivering between about 10 and about 50 watts to the tissue.

[0259] As shown in FIGS. 30B and 30D, a thermocouple 812 may be provided on the electrode (e.g., as described with reference to FIGS. 22G and 27). In some embodiments, more than one thermocouple may be provided. For example, in embodiments comprising more than one electrode or electrode pair, each electrode or electrode pair may comprise a thermocouple. The thermocouple 812 may monitor temperature of the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to FIG. 3). The control unit may use the data from the thermocouple 812 to regulate temperature and auto-shutoff once treatment has been achieved or in the case of an overly high temperature.

[0260] After treating the tissue, the device 800 may be removed from the nostril. If a grounding pad is used, the grounding pad may be detached from the patient.

[0261] In some embodiments, differential cooling mechanisms may be used to treat the nasal valve using electrodes or other energy delivery elements while maintaining a reduced temperature at the skin and/or mucosa. For example, devices like those described with respect to FIGS. 25A-27 or devices employing the differential cooling mechanisms described with respect to FIGS. 28A-28E may be used. The cooling system may be activated. The device may then be inserted into the nose and placed in contact with the nasal vale. The device may then be activated. Activation of the device may cause an increase in the cartilage temperature while minimizing the temperature increase in the skin and/or mucosa. The device may then be deactivated and removed from the nose.

[0262] In some embodiments, devices may be used in which insulating material is used to protect non-target tissue during energy delivery. In an embodiment, a device comprises an electrode needle preferentially insulated on a portion of the needle. The needle may be inserted into the cartilage so that the insulated portion is in contact with the mucosa and/or the skin and the non-insulated portion is in contact with the cartilage. The device may be activated, causing an increase in the cartilage temperature while minimizing temperature increase in the skin and/or mucosa. The device may be deactivated and removed from the nose.

[0263] FIG. 31 illustrates an embodiment of a nasal valve treatment device 900. The device 900 may include a treatment element 901 positioned on a head section 902 of the device 900, which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway to deliver the desired treatment. The treatment element 901 may be positioned on an interior

portion 904 and/or an exterior portion 905 of the head section 902. In some embodiments, the device 900 may further comprise a shaft section 903, which may be sized and configured for easy handheld operation by a clinician. In some embodiments, the head section 902 may be adjustable. It may be advantageous to use an adjustable head section 902 to treat anatomy that may vary in shape and size. The shape of the head section 902 or parts of the head section 902 may be actively or passively adjusted to affect the engagement to the tissue or the effect on the tissue. In some embodiments, the adjustment of the head section 902 may result in a change in shape and/or size of the interior portion 904 and/or the exterior portion 905.

[0264] The head section 902 may be implemented using flexible sections configured to be adjusted depending on the anatomy to be treated. Electrodes (not shown) may be positioned on the interior or the exterior of the flexible sections. In some embodiments, electrodes may be positioned on both the interior 904 and the exterior 905 of the flexible sections. For example, in the case of a convex anatomy, the flexible sections may be adjusted to wrap around the anatomy utilizing electrodes on the interior 904 of the flexible sections. In the case of a concave anatomy, the flexible sections may be adjusted to fit into the anatomy utilizing electrodes on the exterior 905 of the flexible sections. In some embodiments, the head section 902 may include functionality to inflate and deflate the flexible sections to adjust the size of a treatment surface of the device 900 in a radial direction. In some embodiments, the head section 902 may include functionality to rotate the head section 902 in any direction to allow the head section 902 to be angled in a desired position.

[0265] FIG. 32A and FIG. 32B illustrate an embodiment of a nasal valve treatment device 900 comprising an electrode array 910. The electrode array 910 may include numerous electrodes positioned on a surface of a treatment element 901 of the device 900. In some embodiments, the electrodes may be arranged in a grid pattern. The electrodes may be arranged in any pattern. One or more of the electrodes may be extended or retracted to a preset height. It may be advantageous to manipulate the heights of the electrodes of the electrode array 910 to achieve a combination that forms a required treatment surface profile 911. The treatment surface profile 911 may include any combination of electrode numbers and heights. For example, the electrodes may be arranged and manipulated to achieve a generally concave treatment surface

profile, a generally convex treatment surface profile, and/or a generally flat treatment surface profile (See FIG. 32B).

[0266] FIG. 33 illustrates an embodiment of a nasal valve treatment device 900, comprising a first treatment element 901 and a second treatment element 921. The first treatment element 901 may be positioned on a first side of a head section 902. The first treatment element 901 may include a first electrode array 910. In some embodiments, the head section 902 may be implemented with an extendable component 922. It may be advantageous to provide an extendable component 922 to allow the size of the treatment surface 923 to be adjustable. The extendable component 922 may include a second treatment element 921, including a second electrode array 920. In some embodiments, the extendable component 922 may be positioned on a second side of the head section 902 such that it is behind the first treatment element 901. The extendable component 922 may include functionality to move such that it may be shifted from behind the first treatment element 901 of the head section 902 to adjacent to the first treatment element 901 of the head section 902. This shift may expose the second electrode array 920, thereby extending the treatment surface 923. The extendable component 922 may be moved in any direction, and the direction depicted in FIG. 33 is merely an example of one direction in which it may be moved.

[0267] FIG. 34 illustrates an embodiment of a nasal valve treatment device 900 comprising a head section 902 that is offset relative to a shaft section 903 of the device 900. In some embodiments, the shaft section 903 may be coupled to an offsetting element 930 configured to offset the head section 902 of the device 900 from the shaft section 903. It may be advantageous to offset the shaft section 903 and the head section 902 to provide better access to a target anatomy, for example when the target anatomy is out of a field of view. The offsetting element 930 may include functionality allowing it to be extended or contracted depending on the position of the target anatomy. By adjusting the offsetting element 930, the target anatomy may be contacted by a treatment element 901 incorporated within the head section 902 to apply treatment to the target anatomy.

[0268] FIG. 35 illustrates an embodiment of a nasal valve treatment device 900 comprising a head section 902 adapted to be at an angle 935 relative to a shaft section 903 of the device. In some embodiments, the shaft section 903 may be coupled to an angularly deflecting element,

such as a hinge, flexible portion, or the like, including functionality to adjust the angle 935 of the head section 902 relative to the shaft section 903. In some embodiments, the head section 902 may be coupled directly to the shaft section 903 at a predefined angle 935. It may be advantageous to angle the head section 902 relative to the shaft section 903 to provide better access to a target anatomy, for example when the target anatomy is at an angle relative to the insertion point of the device. By angling the head section 902 relative to the shaft section 903, the target anatomy may be contacted by a treatment element 901 incorporated within the head section 902 to apply treatment to the target anatomy.

[0269] Most of the description above focuses on treatment of tissues in and around the nasal valve. More specifically, much of the discussion above focuses on treating the lateral portion of the nasal valve. In some cases, however, it may possible and even desirable to treat (1) the medial portion of the nasal valve (e.g., nasal septum) and/or (2) one or more airway tissues that are separate from and distanced away from the nasal valve. Such a treatment of tissue(s) may be in addition to, or as an alternative to, treating the lateral portion of the nasal valve, according to various different embodiments. In short, the devices and methods described herein may be applied to any tissue or combination of tissues, according to various embodiments, in an effort to improve breathing, decrease airflow resistance, increase patient comfort and/or the like. Such tissues may be internal, within the airway, and/or external, such as on or through the skin of the nose, sinuses or the like.

[0270] Various anatomical areas may be particularly amenable to treatment for nasal valve disorders or other breathing or nasal issues. For example, in some embodiments, the devices and methods described herein may be used to treat a nasal septum, either as part of a surgical septoplasty procedure or as a stand-alone procedure. At least a portion of the nasal septum—the upper portion—lies within what is usually considered to make up the nasal valve. Thus, treating this part of the septum may be advantageous. Various other areas of the nasal septum for possible treatment using the devices and methods described herein include, but are not limited to, swell bodies located on the septum, the septal turbinate, a high deviated septum and the nasal scroll. A high deviated septum is typically defined by the junction of the inferior and superior lateral cartilage plates. Additionally, the floor of the nasal cavity, part of which may help make up the nasal valve, and which is sometimes referred to as the piriform area, may be treated in

some embodiments. Swell bodies may also occur on the floor of the nasal cavity and may be amenable to treatment. In general, the devices and method described herein may be used in a variety of treatments in a variety of anatomical locations in the upper airway and/or external to the airway.

[0271] The nasal swell body (NSB) is a widened region of the septum located superior to the inferior turbinates and anterior to the middle turbinates, and of importance to the airflow-regulating nasal valve. The NSB is composed of septal cartilage. Septal cartilage is thicker here than the other parts of nasal septum. The mucosal covering of septal body is thicker than the other portions of nasal septum. This body is in intimate relationship to the internal nasal valve. It is suspected to play a role in the maintenance of nasal resistance.

[0272] The NSB is a highly glandular structure of the anterior-superior septum, with a moderate proportion of venous sinusoids. Located at the distal valve segment, the NSB appears structured for secretory function and vasoactive airflow regulation. In some embodiments, the energy delivery member is designed to be inserted into the nasal valve angle to apply energy to a swell body. The energy is intended to shrink the size of the swell body. The energy delivery member can be designed to hold a position in the nasal valve angle to position the electrodes to only treat the area of the swell body located on the medial wall of the nasal valve. The energy delivery member can be designed with the electrodes positioned in such a way as to direct the energy into the submucosa while minimizing damage to the mucosal tissue and underlying cartilage. The energy delivery member can also be designed to direct the energy into the underlying cartilage to induce a shape change.

[0273] Impairment of nasal airflow can be caused by the strength, shape or size of any of the components of the nasal valve. The positions of the components relative to each other also determine the volume, speed and pressure of nasal airflow. The three angles of the nasal valve area are between the nasal septum and the ULC, the ULC and the pyriform aperture and the pyriform aperture and the nasal septum. All of these tissues and angles can be treated to increase the size of the nasal valve area to improve nasal airflow.

[0274] The upper portion of the nasal septum near the angle between the ULC and nasal septum is sometimes curved inward or bulging towards the ULC, reducing the angle between them and impairing nasal airflow. This can be caused by a deviated septum, swell body or septal

turbinate. All of these causes can be treated to enlarge the nasal valve area and/or improve nasal airflow.

[0275] High septal deviations are another cause of narrowing of the nasal valve. These deviations are difficult to treat surgically because removal of cartilage in this area can cause destabilization of the nose and cerebrospinal fluid leakage.

[0276] Any of the devices and systems described herein may be used to treat any of the anatomical locations or structures described herein, either alone or in combination. Certain embodiments of the devices and systems may be particularly advantageous for certain anatomical structures. For example, an energy delivery device with a flat-shaped head may be advantageous for use in treating a high nasal septum deviation. However, none of the embodiments are limited to treatment of any particular tissue or anatomy.

[0277] FIG. 36 depicts a cross-section of a nose in the area of the nasal valve, and FIG. 37 is a diagram illustrating a nasal valve area in cross-section. These cross-sectional illustrations show that the nasal valve is bordered by the caudal end of the upper lateral cartilages (ULC) 940 and the septum 941. The angle formed between the ULC 940 and the septum 941 may be referred to as the nasal valve angle. Treatment may be performed on a number of surfaces within the nasal valve, including a first lateral surface 942, a second lateral surface 943, the apex 944 of the nasal valve angle, or combinations thereof. As shown in FIG. 36, the surfaces within the nasal valve may be shaped in a non-uniform manner that may pose challenges when a uniform treatment across the surfaces is desired. Adjustable treatment surface features, such as those described above, may help facilitate treatment in these anatomical areas. FIGS. 38A and 38B are frontal/partial see-through and sagittal cross-sectional views, respectively, of a human head, illustrating the upper airway. These figures illustrate the superior turbinate, the middle turbinate, and the inferior turbinate. The turbinates may vary in size and position. The inferior turbinate is often the largest turbinate, and it may extend horizontally along the lateral wall of the nasal cavity. The medial surface of the inferior turbinate may be convex, and the lateral surface may be concave. The middle turbinate may be smaller than the inferior turbinate, and may project downwards over the opening of the maxillary and anterior and middle ethmoid sinuses. The superior turbinate may be a smaller structure connected to the middle turbinate by nerve-endings.

Treatment of the turbinates may require a device capable of adjustable treatment surface areas in order to treat the different shapes and sizes of different parts of the turbinates.

[0278] FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration. As described above, different target anatomies may have treatment surface areas of varying size and shape. Additionally, users operating a nasal treatment device may vary in skill, dexterity, and habits. Due to these variabilities, each electrode pair of the device may have varying degrees of contact with tissue of the target anatomy. For a configuration in which all pairs of electrodes are controlled by one main electrical channel, this may lead to varying magnitudes of treatment energy passing through each electrode pair. The pair(s) of electrodes that have a higher degree of contract with the tissue may experience higher magnitudes of impedance in their individual circuit. Since treatment energy takes the path of least resistance, this may lead to treatment energy being diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact. Thus, it may be advantageous to control the treatment energy through each electrode to ensure repeatable treatments.

[0279] In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. In some embodiments, each electrode pair may be paired with its own thermocouple. By controlling the treatment energy flowing through each pair of electrodes using parameters including, but not limited to, temperature, a greater degree of control and accuracy over the treatment energy may be obtained, such that treatments may be repeatable.

[0280] As shown in FIG. 39, the nasal treatment device may include one or more thermocouples 962 and an RF output channel 961 assigned to each electrode pair for feedback. An electrode pair may include a positive electrode 963 and a negative electrode 964. In some embodiments, the positive electrode 963 and the negative electrode 964 may be positioned opposite to one another. Each electrode pair may have its own individual subsystem 960. The individual subsystem 960 may include a controlled RF output channel 961 and a thermocouple 962 to allow for independent adjustments. The thermocouple 962 may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

[0281] FIG. 40 is a block diagram depicting an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes 963 to any of the negative electrodes 964 to form a complete circuit. A positive electrode 963 may be paired with the opposite negative electrode 964 or to any of the other negative electrodes 964 regardless of its location in the device. The device may include a plurality of thermocouples 962 and an RF output channel 961 assigned to each pair of electrodes for feedback. Temperature readings from two adjacent thermocouples 962 may be averaged to obtain a temperature reading for the region in which the circuit is located. In some embodiments, the two thermocouples 962 may be the thermocouples in the closest proximity to the positive electrode 963 and the negative electrode 964.

[0282] FIG. 41 is a block diagram depicting an electrode array arranged such that each electrode pair of the array of electrodes may have its own individual subsystem 970. An electrode pair may include a positive electrode 973 and a negative electrode 974. Each individual subsystem 970 may include controlled RF channels 971, a first thermocouple 972a, and a second thermocouple 972b to allow for independent temperature readings. In some embodiments, a temperature reading for an individual subsystem 970 may be obtained from the average temperature input signals of the neighboring thermocouples 972a and 972b. The temperature reading may act as a feedback control to ensure that proper temperature is maintained at the site of treatment.

[0283] FIG. 42A and 42B are block diagrams depicting an array of electrodes of a nasal treatment device. In some embodiments, the device may include a multiplexed configuration by providing functionality to allow pairing of any of the positive electrodes 973 to any of the negative electrodes 974 to form a complete circuit. A positive electrode 973 may be paired with the opposite negative electrode 974, or to any of the other negative electrodes 974 regardless of its location in the device. FIG. 42A shows one example where temperature readings may be the average of three adjacent thermocouples 972a, 972b, and 972c. FIG. 42B shows one example where temperature reading may be the average of four adjacent thermocouples 972a, 972b, 972c, and 972d. It will be appreciated that the average of any number of thermocouples may be used to obtain a temperature reading.

[0284] FIG. 43 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 39. In some embodiments, positive electrodes 983 of the array of electrodes may share a common negative electrode 984. Each RF output channel may include a positive electrode 983 and the negative electrode 984. While the negative electrode 984 is common, each positive electrode 983 may be independently controlled to achieve the desired treatment. In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouples 982.

[0285] FIG. 44 is a block diagram depicting an array of electrodes of a nasal treatment device as depicted in FIG. 40. In some embodiments, positive electrodes 993 of the array of electrodes may share a common negative electrode 994. Each RF output channel may include a positive electrode 993 and the negative electrode 994. While the negative electrode 994 is common, each positive electrode 993 may be independently controlled to achieve the desired treatment. In some embodiments, a temperature reading may be obtained from temperature input signals sensed from one or more thermocouples 992.

[0286] Most, if not all, of the devices and methods have been described above for use without making an incision in tissue. These incision-free devices and methods may be highly advantageous for a number of reasons, one being that no incision is required. On the other hand, there may be cases in which one of the embodiments described above may be used in a procedure involving an incision. For example, if another surgical procedure is being performed in the airway, and that procedure involves making an incision in mucosa, in some embodiments, one of the devices described above may be inserted into the incision to access and treat submucosa, cartilage and/or other tissues below the mucosa. In other embodiments, such as those described immediately below, an incision may be formed exclusively for the treatment using one of the devices described herein. In alternative embodiments, the incision may be formed by the treatment device or by a separate device. Therefore, in general, any of the methods and devices described herein may be used for either incision-less procedures or for procedures that include an incision.

[0287] FIG. 45 illustrates an embodiment of a device 1000 and method for applying energy to submucosal tissues where the treatment device 1000 is advanced through an incision in the mucosa. Such a device 1000 and method may be used in the nasal valve area or any other

suitable anatomy in the upper airway. In some embodiments, an incision 1004 may be created to apply treatment energy to a submucosal target tissue, for example the submucosa 1001, which is generally located between the mucosa 1002 and the cartilage 1007 in the nasal valve. The incision 1004 may be created by the treatment device 1000 or, alternatively, by a separate device, such as a scalpel or any other cutting device. In some embodiments, the incision may extend to a portion of the submucosa 1001 to provide access to a target portion of the submucosa 1001. In some embodiments, a head portion 1009 of the device 1000 may be inserted through the incision 1004, such that electrodes 1003 of the head portion 1009 are in contact with the submucosa 1001. In some embodiments, the head portion 1009 may be in contact with the cartilage 1007 and/or the dermis 1008. A shaft portion 1005 of the device 1000 may be coupled to the head portion 1009 and extend to a handle portion 1006 of the device 1000, so that a user may hold the handle portion 1006 while energy is being applied to the target tissue. In some embodiments, the device 1000 may be coupled to an RF generator 1010 for providing a treatment energy. The treatment energy may include a continuous, intermittent, and/or any other pattern of treatment energy. In alternative embodiments, any other type of energy may be used. In fact, any of the embodiments or features of various embodiments described above may alternatively or additionally be used in performing an incision-based method, such as the one illustrated in FIG. 45.

[0288] FIG. 46A illustrates another embodiment of a method for applying energy to tissue through an incision 1011, for example in the nasal valve area of the upper airway. In this embodiment, the incision 1011 is made directly over a target tissue. The incision may be sized to accommodate the head portion 1009 of the device 1000. In some embodiments, the incision 1011 may be expanded by the head portion 1009 upon insertion of the head portion into the incision 1011. The head portion 1009 may include a relatively narrow portion at its tip that allows it to enter into the incision 1011. The incision 1011 may temporarily or permanently expand as a relatively wider part of the head portion 1009 passes through the incision 1011 during insertion of the device. Electrodes of the head portion 1009 may be positioned to come in contact with the target tissue upon insertion of the device 1000 into the incision 1011. For example, an array of electrodes may be positioned at the tip of the head portion 1009 to come into contact with a target tissue when the device 1000 is inserted through an incision opening 1011 that is directly

over the target tissue. Upon coming into contact with the target tissue, the device 1000 may be used to apply energy to the target tissue using the array of electrodes.

[0289] FIG. 46B illustrates another alternative embodiment of a method for applying energy to tissues through an incision 1011 in the nasal valve area. In this embodiment, the incision 1011 is offset from a target tissue. The target tissue may be accessed by dissection or tunneling from the incision 1011 to the target tissue. It may be advantageous to create an offset incision 1011 to be closer to the opening of the nose or to reduce the chance of the incision 1011 reopening post-procedure. The use of an offset incision 1011 may mitigate a risk of creating an ulcer. The head portion 1009 of the device 1000 may be inserted through the offset incision 1011, which allows the device 1000 to pass through the mucosa 1002 to contact the submucosa 1001. The device 1000 may be tunneled through the submucosa 1001 to a target tissue. The target tissue may be adjacent to cartilage 1007 or the mucosa 1002, or it may be a region of tissue within the submucosa 1001. Electrodes of the head portion 1009 may be positioned to be in contact with the target tissue upon insertion of the device through the incision 1011 and dissection through the submucosa 1001. For example, an array of electrodes may be positioned around the circumference of the head portion 1009 to come into contact with the target tissue when the device 1000 is inserted through an incision. Upon coming into contact with the target tissue, the device 1000 may apply energy to the target tissue using the array of electrodes.

[0290] FIG. 47 illustrates an embodiment of a device 1020 for creating an incision in upper airway mucosa and treating one or more submucosal tissues. The device 1020 may include a blade 1013 for creating an incision in the nasal valve area or other portion of the upper airway. In some embodiments, the blade 1013 may be removable and/or retractable. The blade 1013 may create an incision directly over a target tissue or may create an incision offset from the target tissue. When the incision is offset from the target tissue, the blade 1013 may be used to dissect a path from the incision to the target tissue to contact the target tissue with an electrode array 1012 of the head portion 1009 of the device 1020. When the electrode array 1012 is contacted with the target tissue, the device 1020 may be used to apply energy through the electrode array 1012 to the target tissue.

[0291] In alternative embodiments, the blade 1013 may be replaced by any other suitable cutting member(s), such as but not limited to an electrode for cutting and optionally cauterizing

tissue. As mentioned above, other incision-based treatment devices may include no cutting member, and whatever incision is used for a procedure may be formed with a separate cutting device.

[0292] Although various embodiments are described herein, the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and modifications and equivalents thereof. Thus, the scope of the present invention should not be limited by the disclosed embodiments, but should be determined only by a fair reading of the claims that follow.

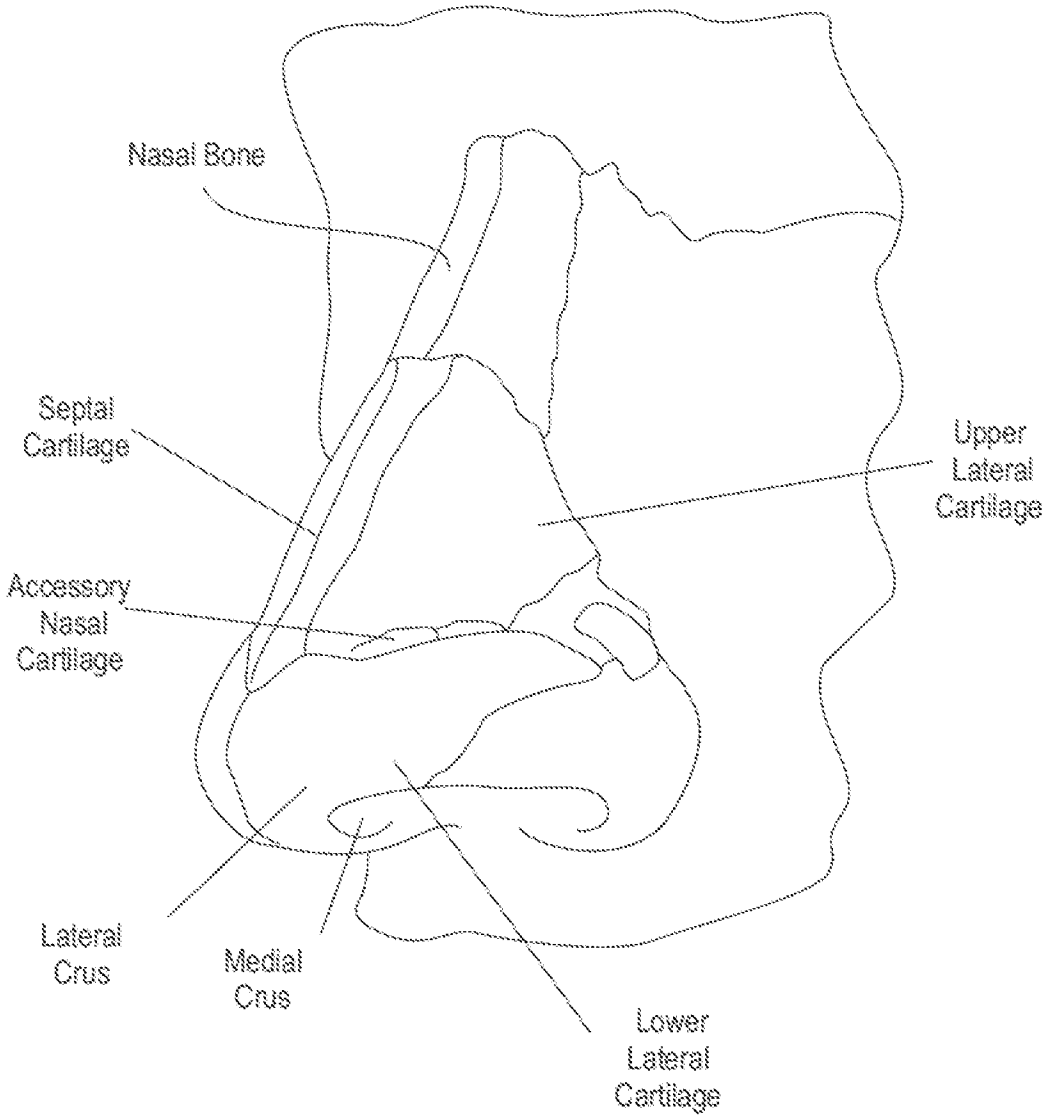

Nasal Bone
Septal Cartilage
Upper Lateral Cartilage
Accessory Nasal Cartilage
Lateral Crus
Medial Crus
Lower Lateral Cartilage

FIG. 1

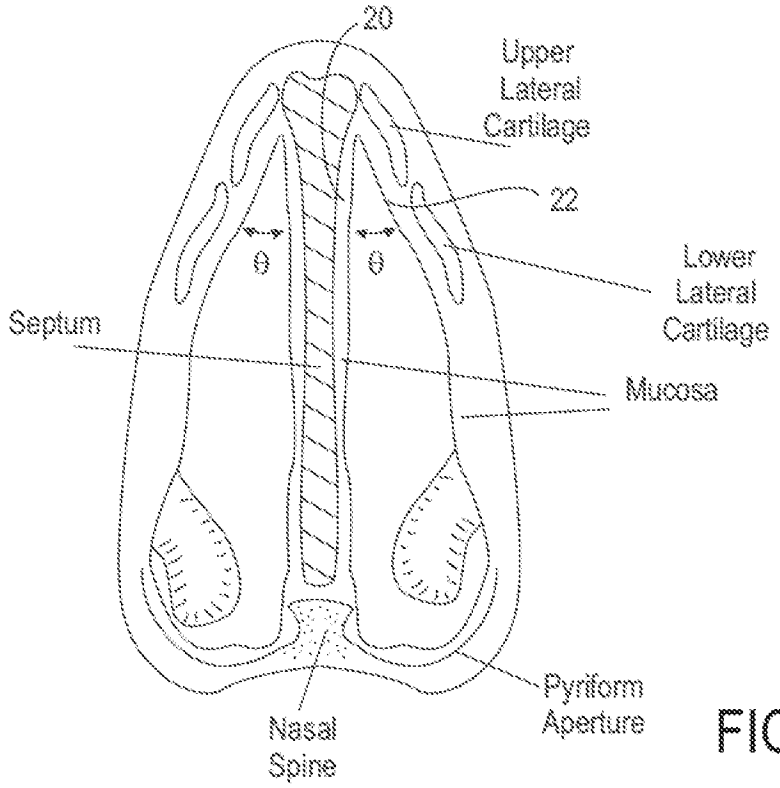

20
Upper
Lateral
Cartilage
22
θ
θ
Lower
Lateral
Cartilage
Septum
Mucosa
Pyriform
Aperture
Nasal
Spine

FIG. 2A

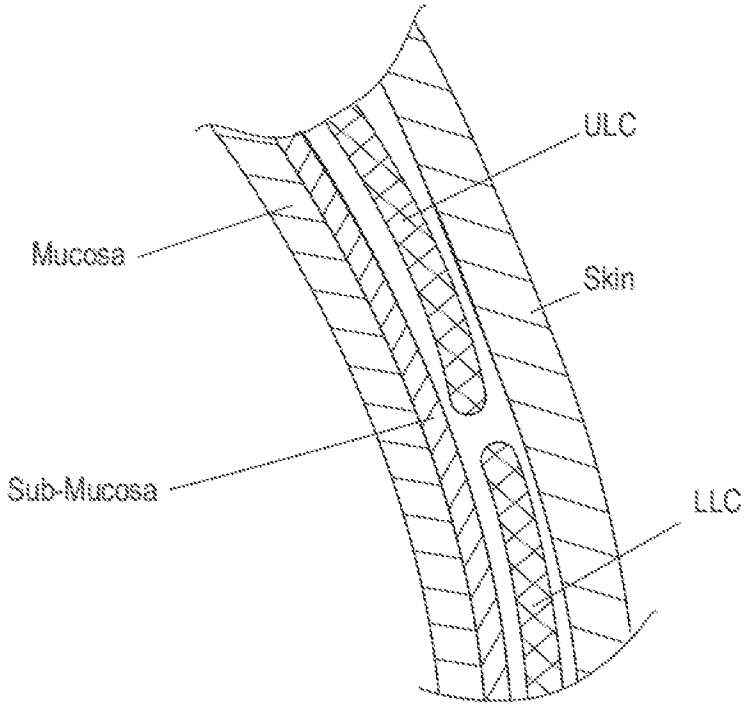

ULC
Mucosa
Skin
Sub-Mucosa
LLC

FIG. 2B

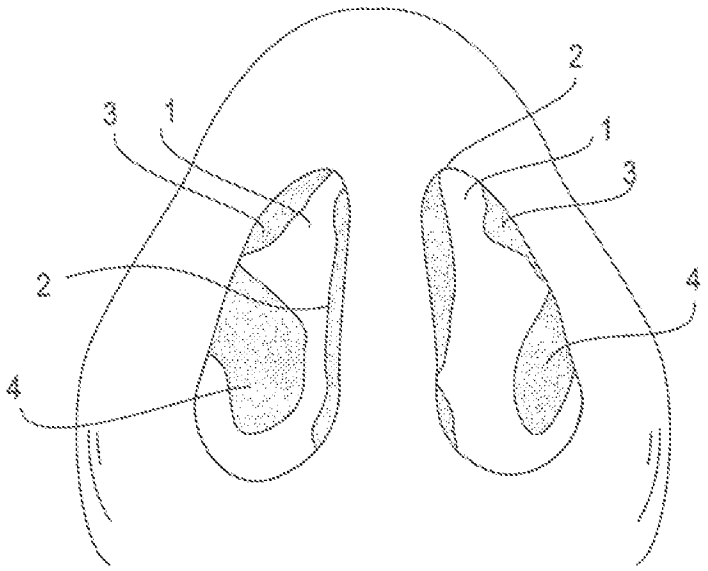


FIG. 2C

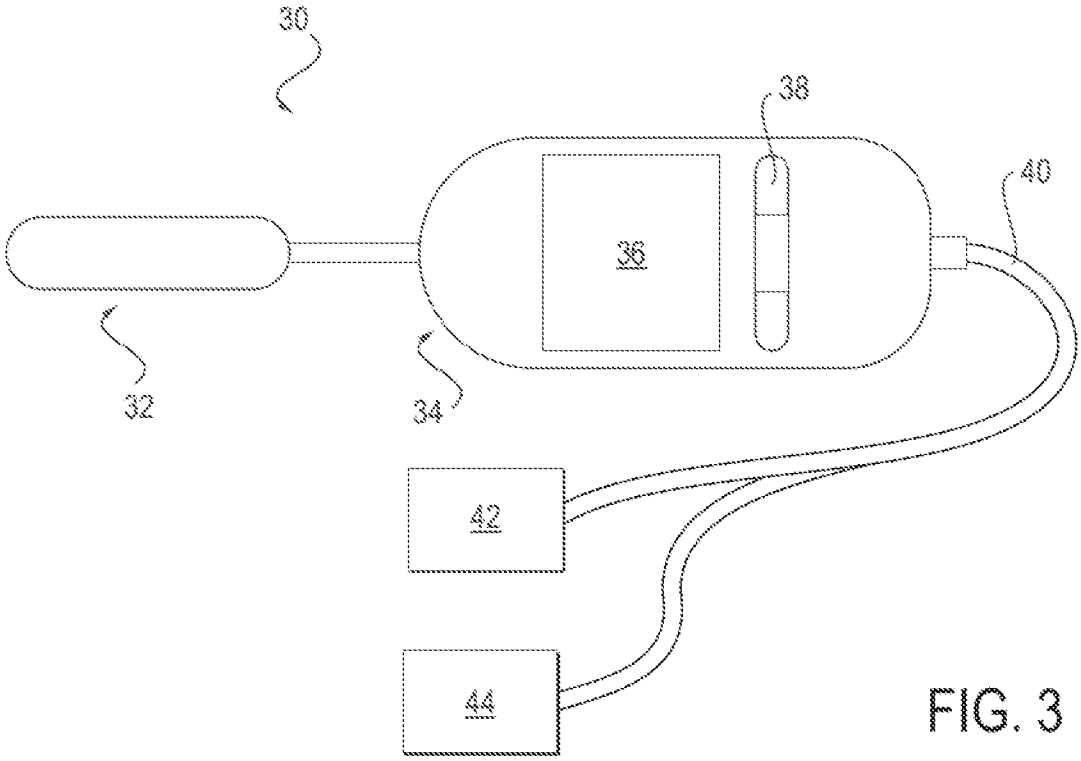


FIG. 3

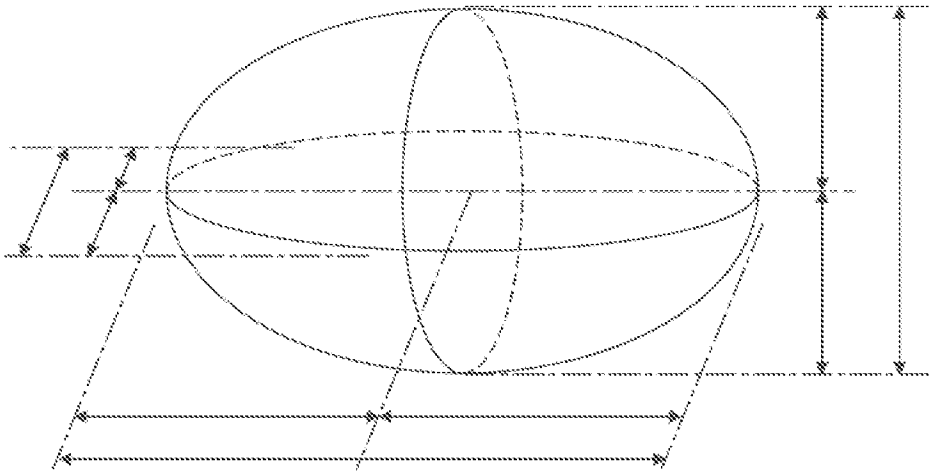


FIG. 4A

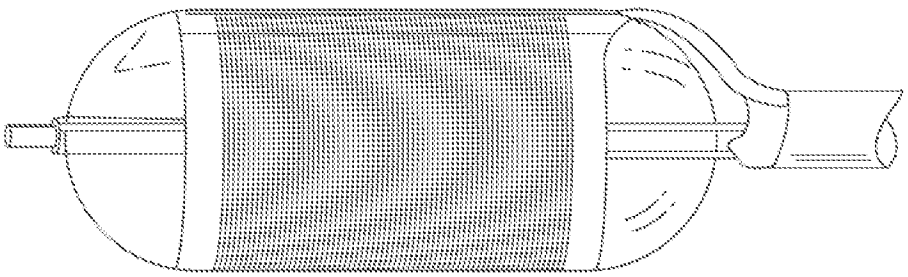


FIG. 4B

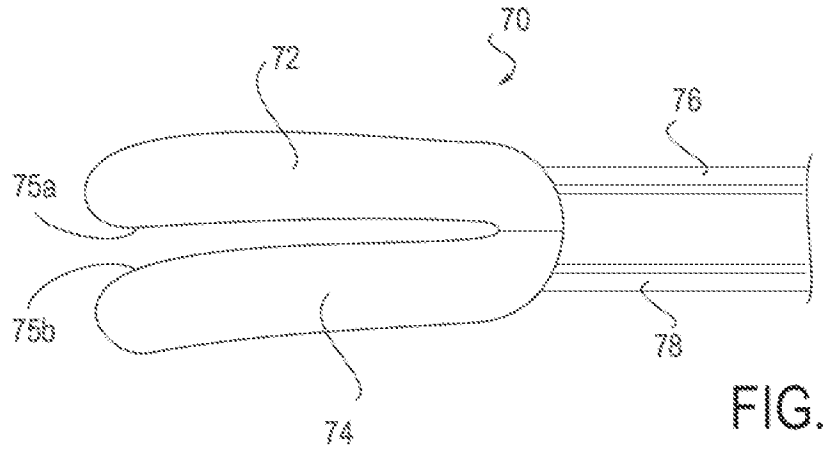


FIG. 4C

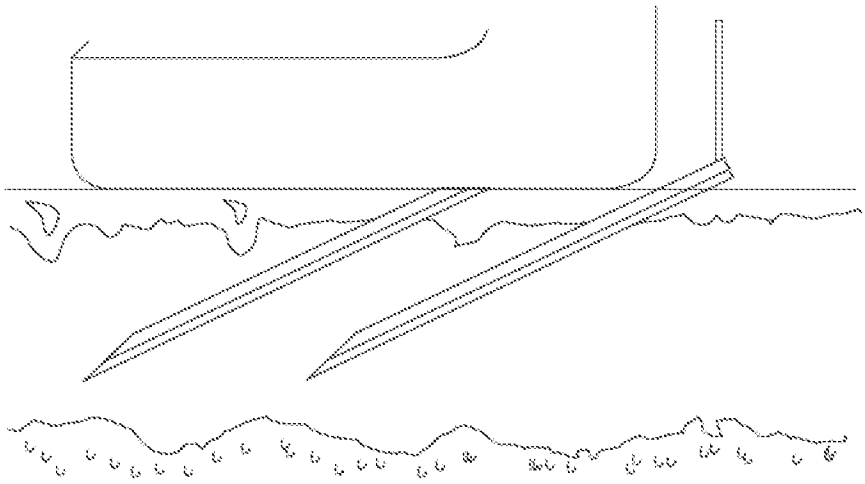


FIG. 4D

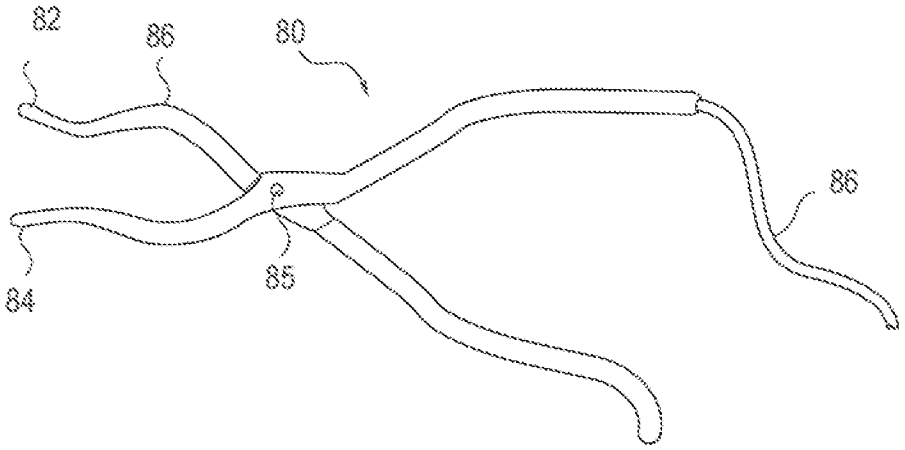


FIG. 5A

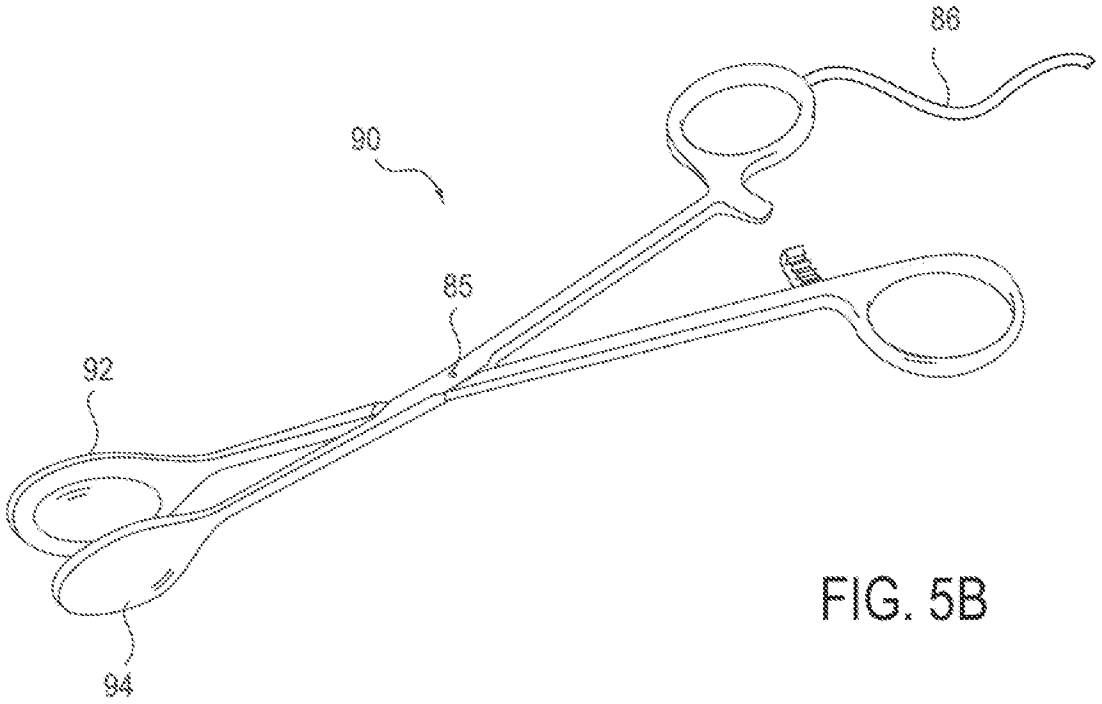


FIG. 5B

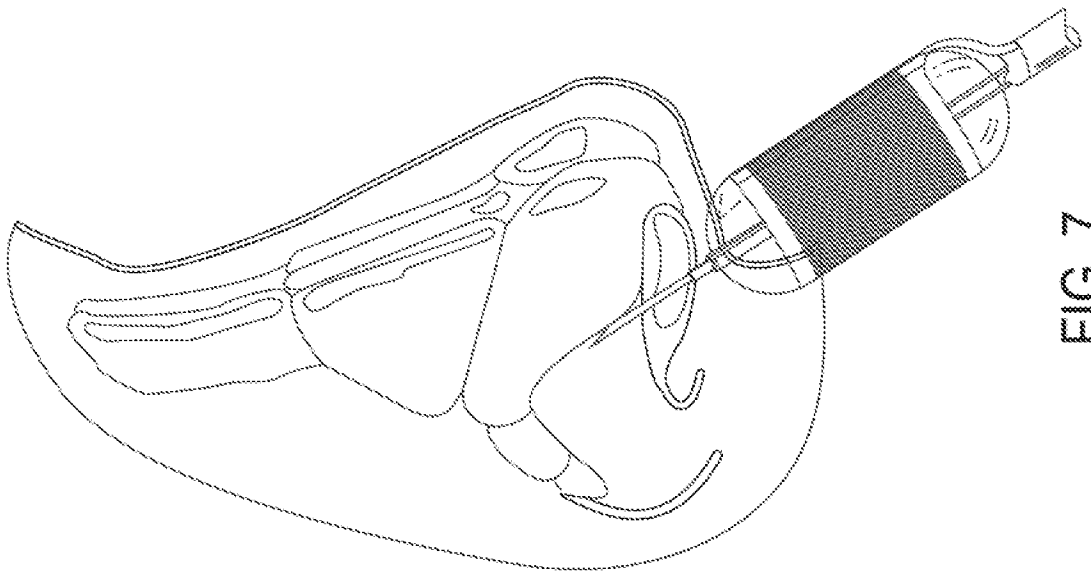


FIG. 7

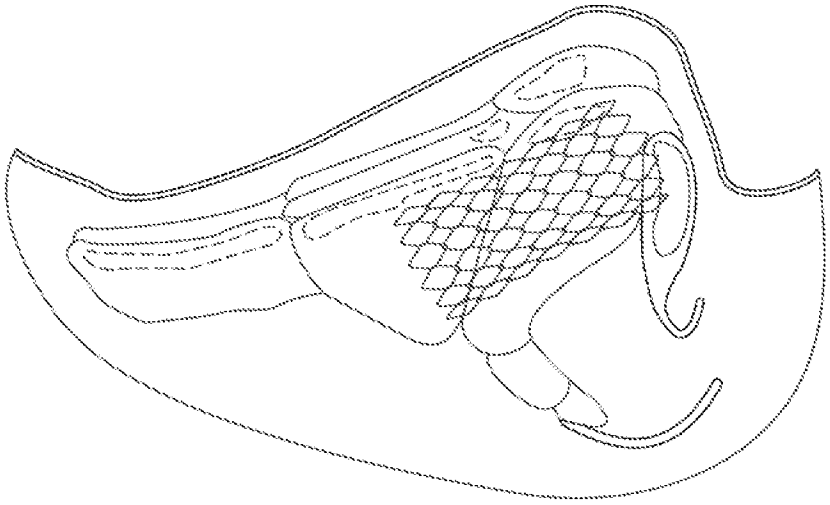


FIG. 6

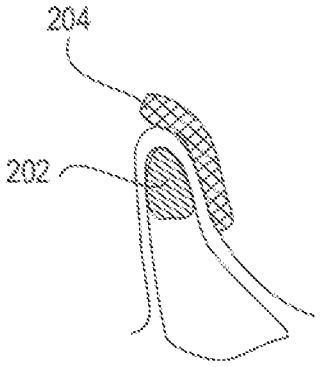


FIG. 8A

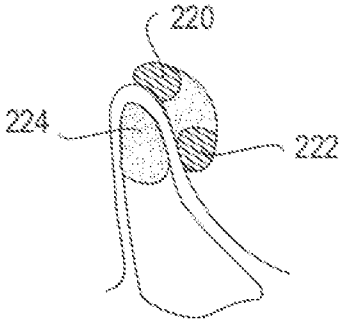


FIG. 8C

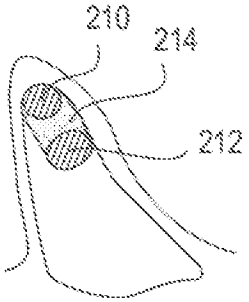


FIG. 8B

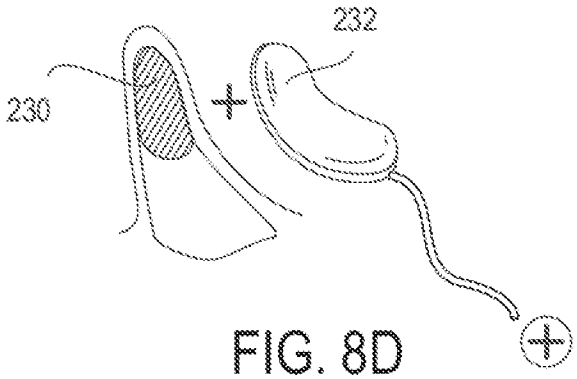


FIG. 8D

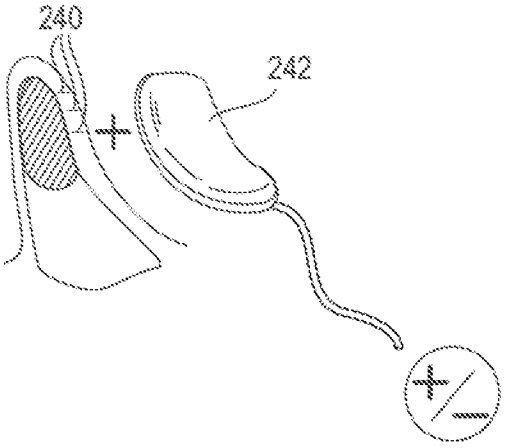


FIG. 8E

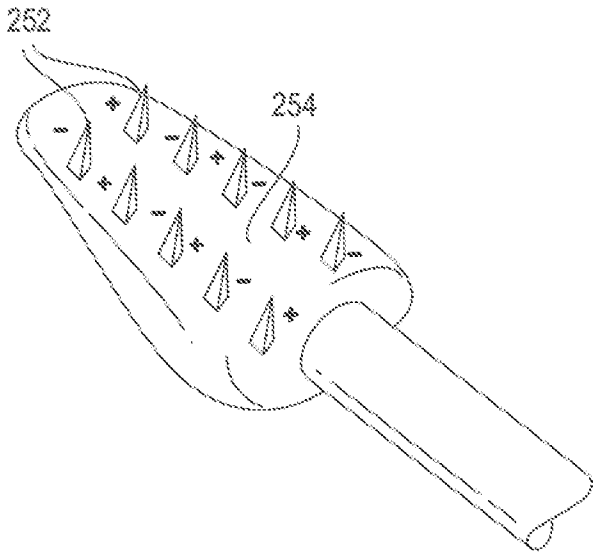


FIG. 8F

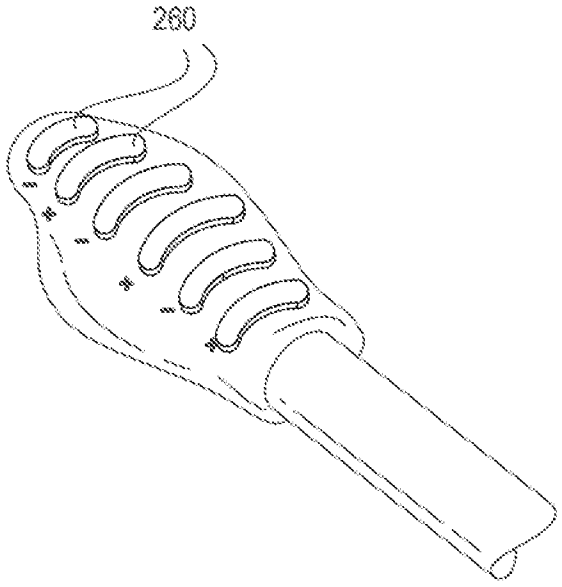


FIG. 8G

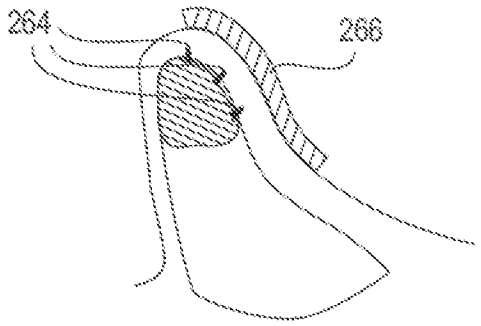


FIG. 8H

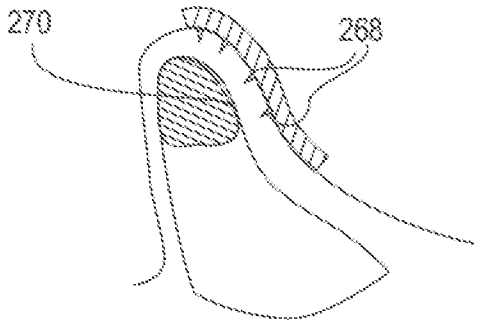


FIG. 8I

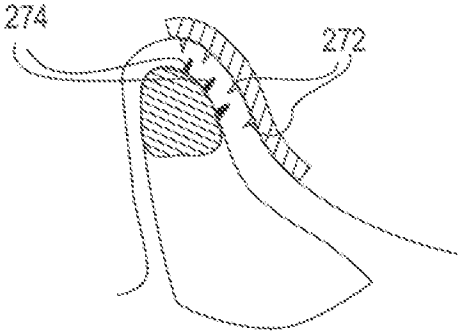


FIG. 8J

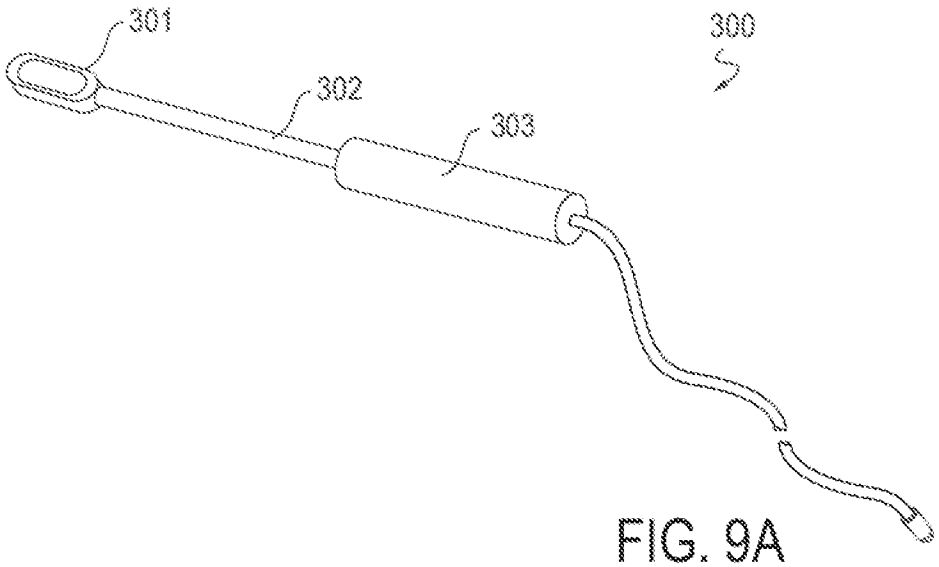


FIG. 9A

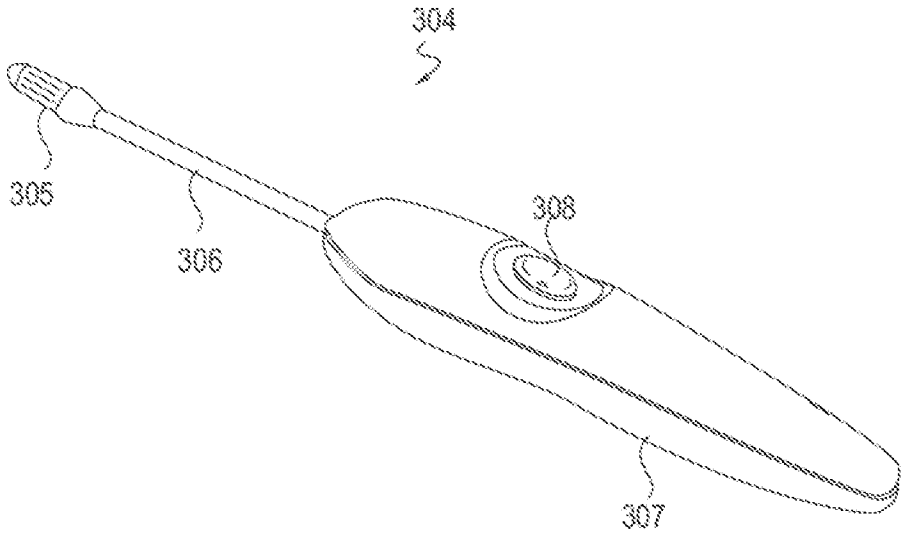


FIG. 9B

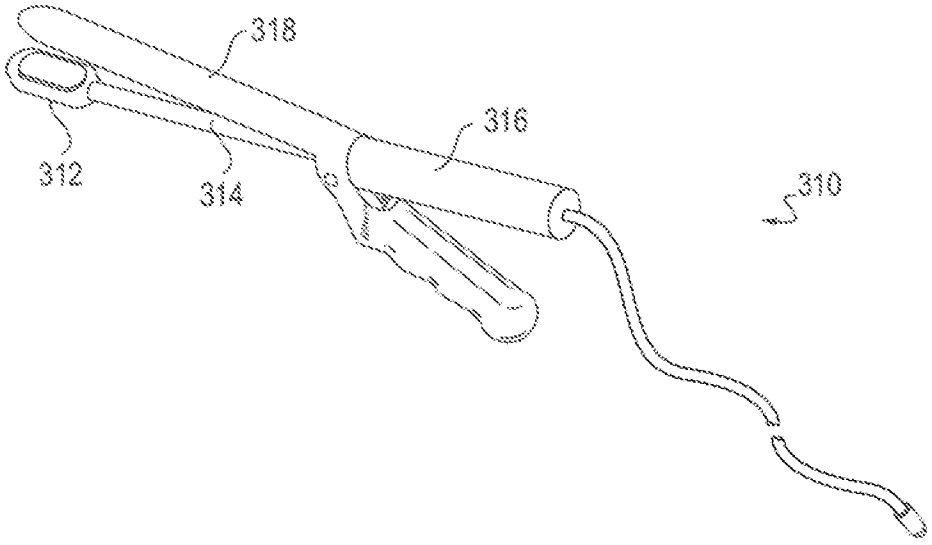


FIG. 10A

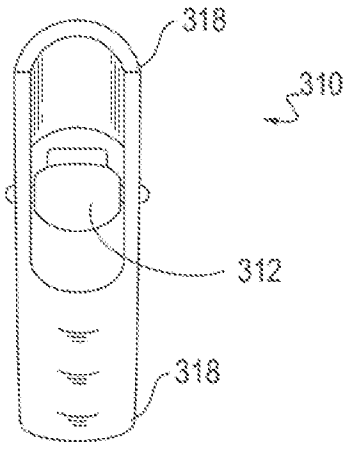


FIG. 10B

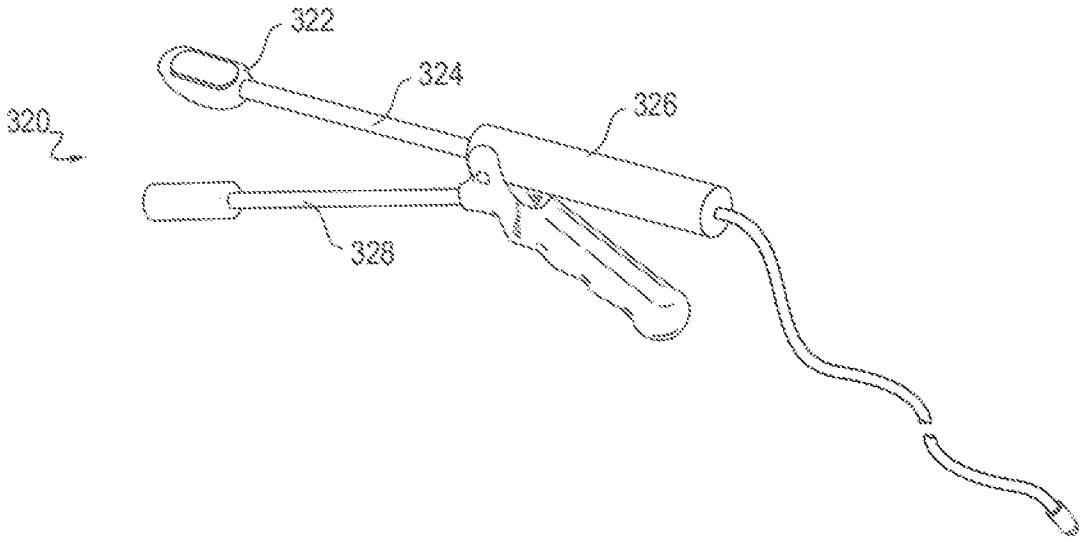


FIG. 11A

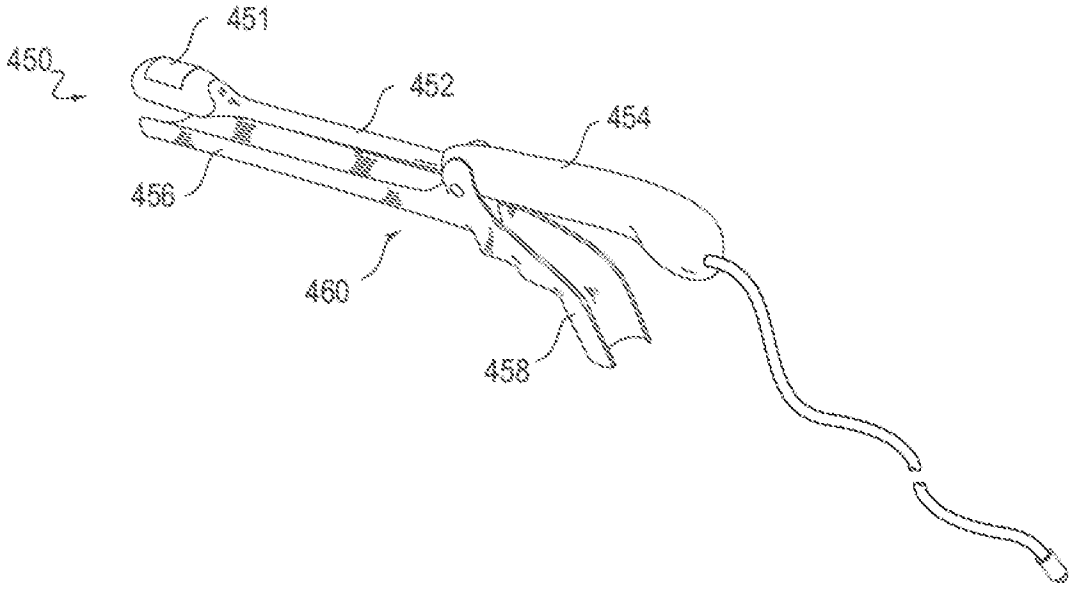


FIG. 11B

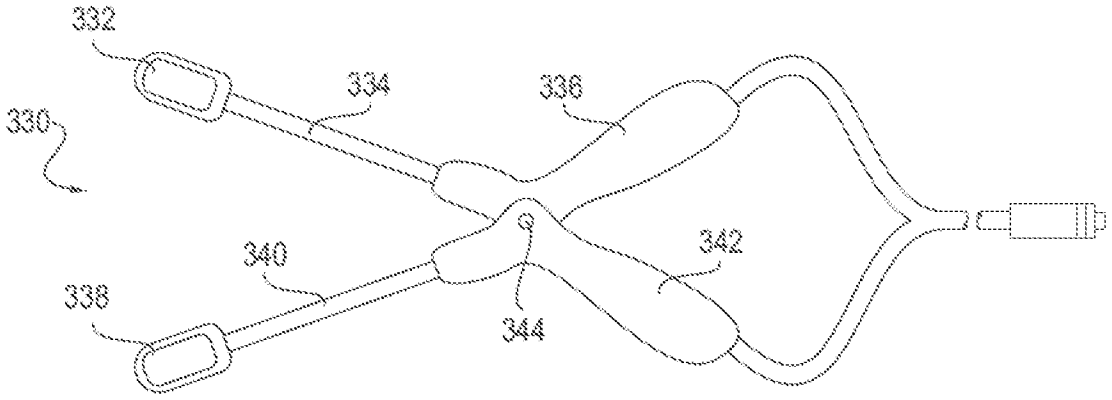


FIG. 12A

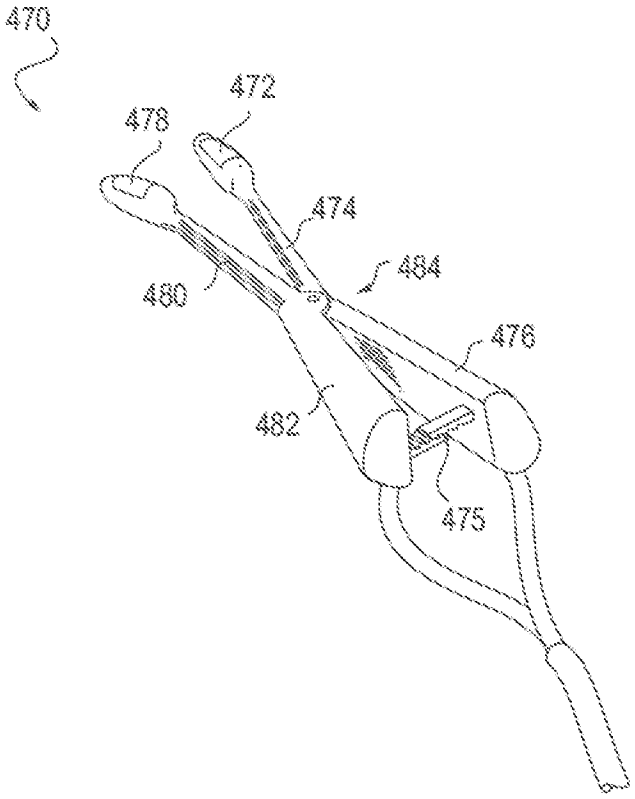


FIG. 12B

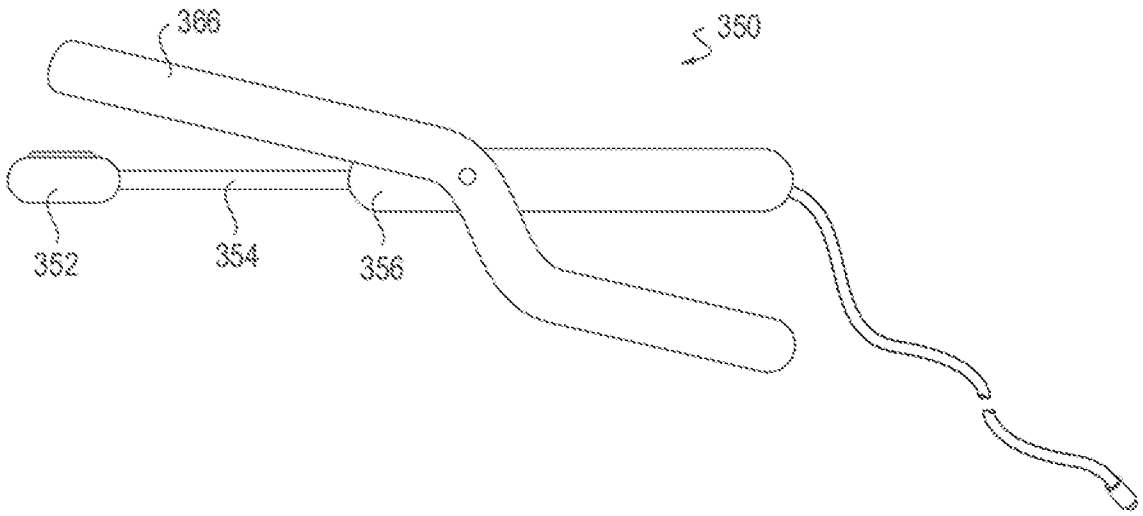


FIG. 13A

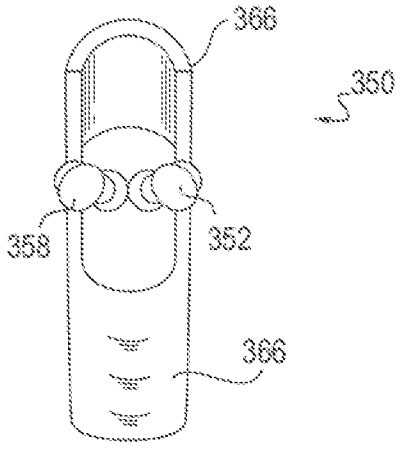


FIG. 13B

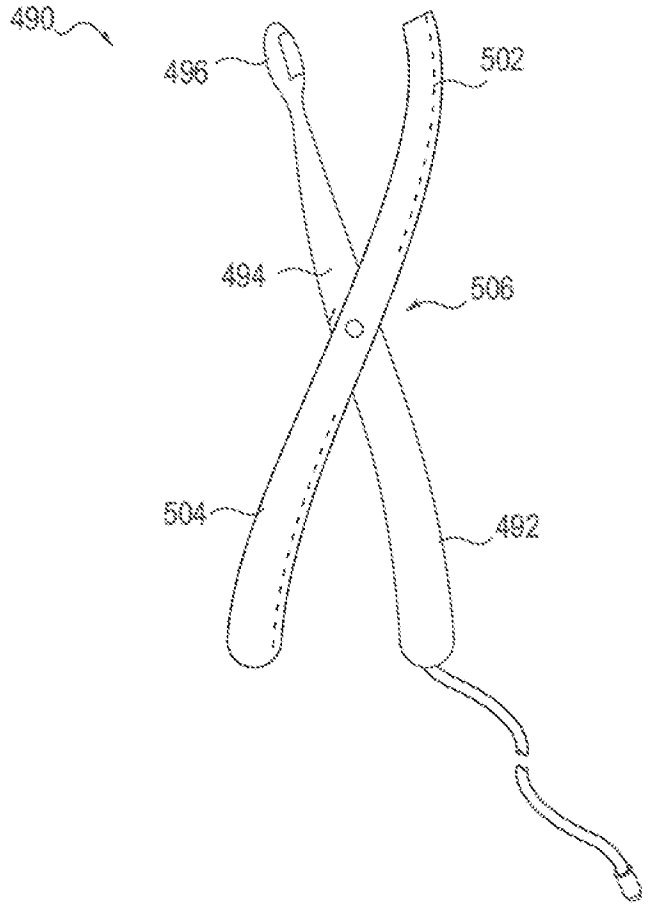


FIG. 13C

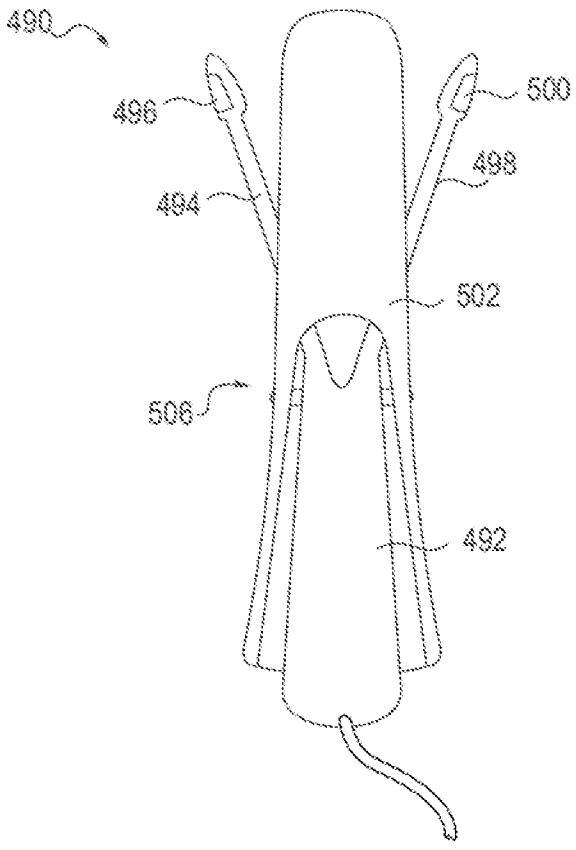


FIG. 13D

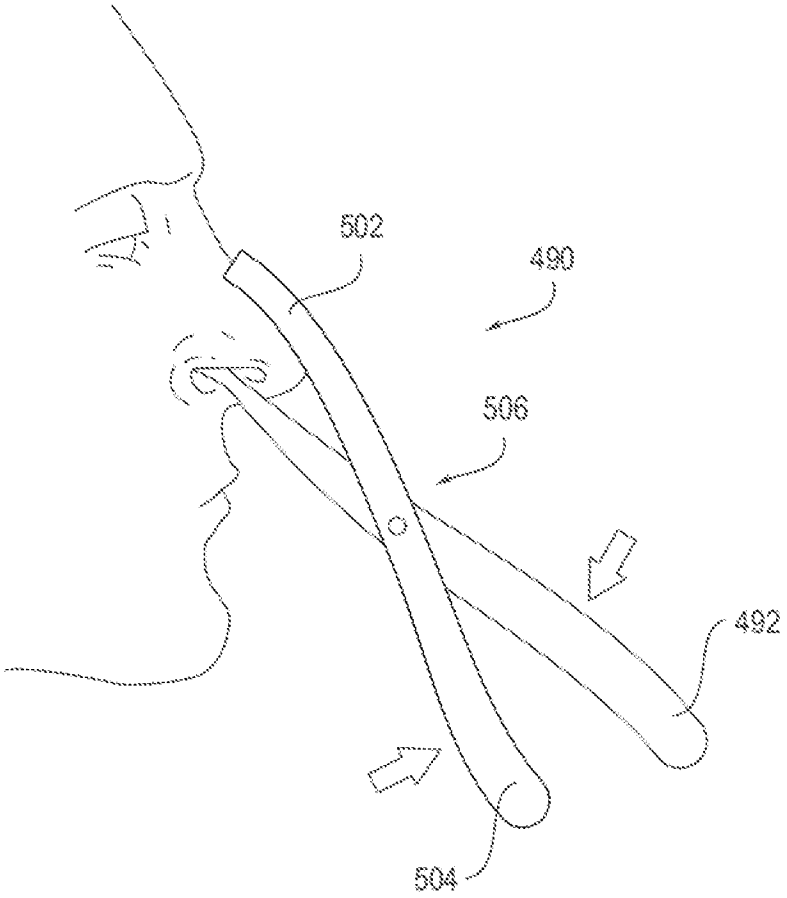


FIG. 13E

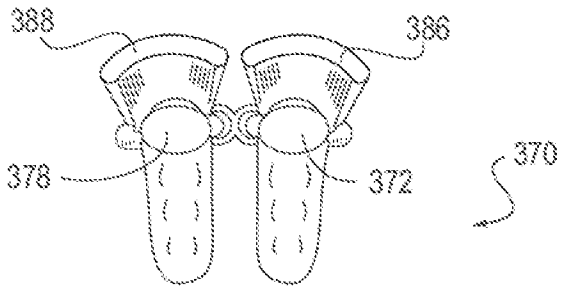


FIG. 14B

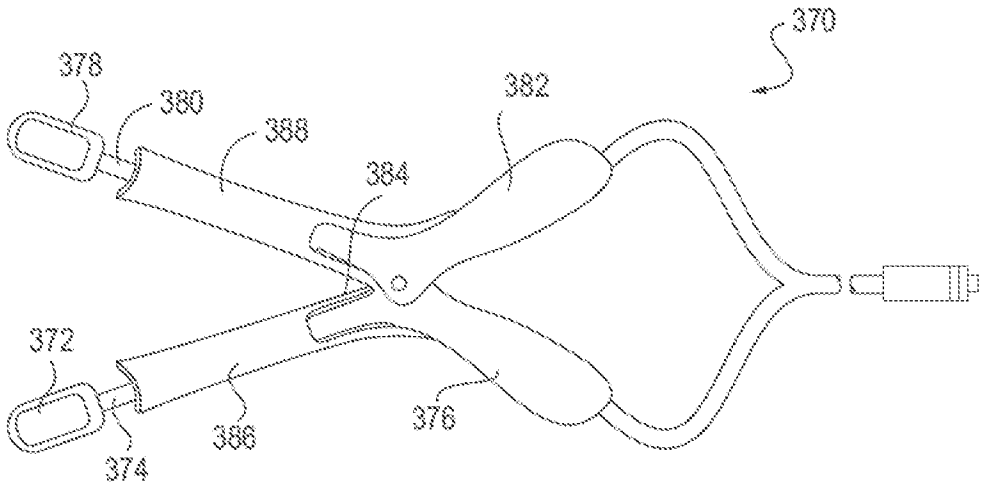


FIG. 14A

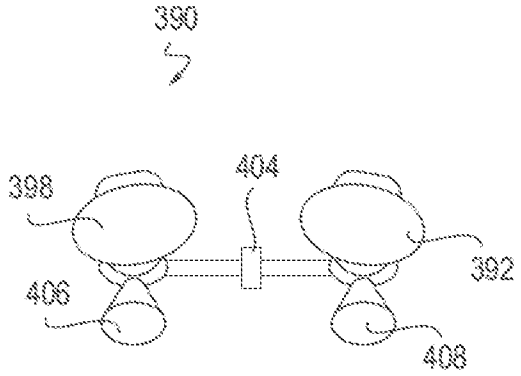


FIG. 15A

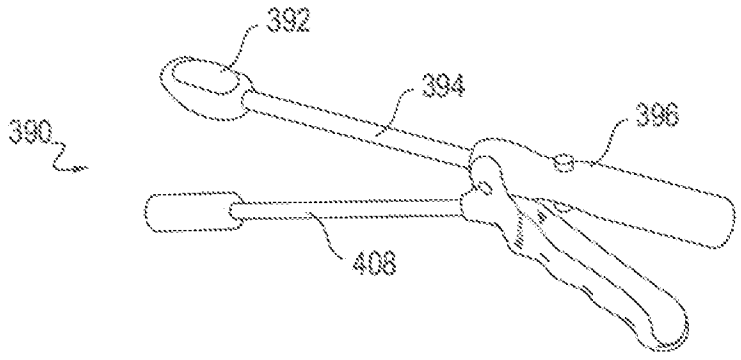


FIG. 15B

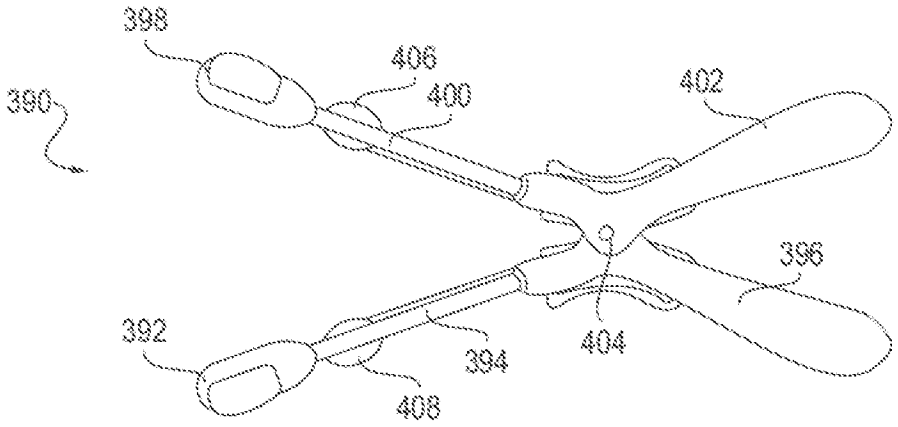


FIG. 15C

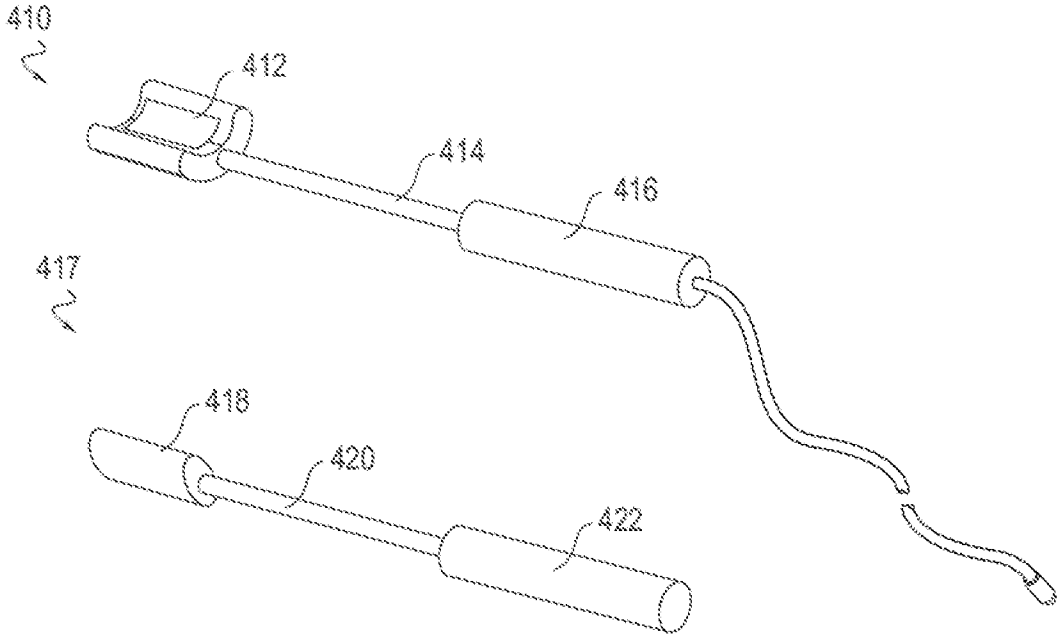


FIG. 16

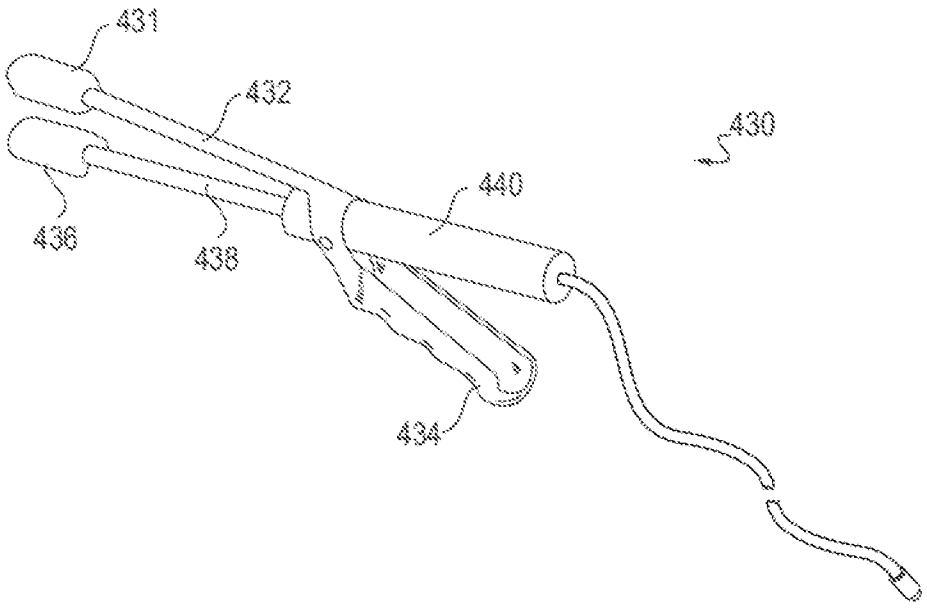


FIG. 17A

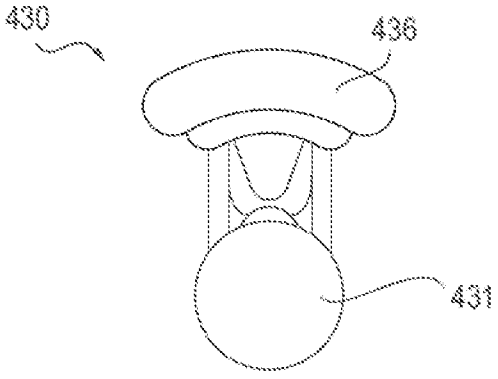


FIG. 17B

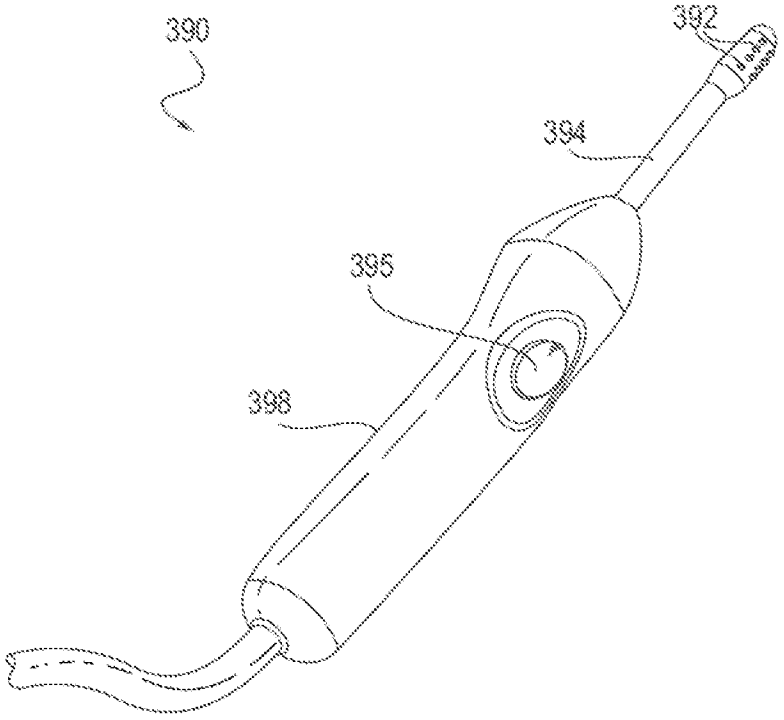


FIG. 18

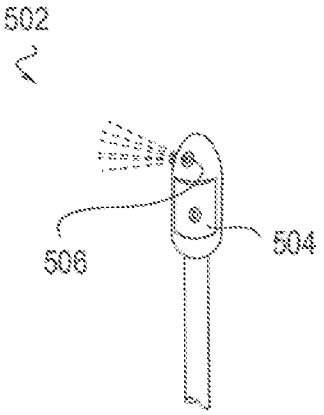


FIG. 19A

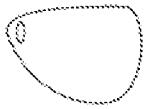


FIG. 19B

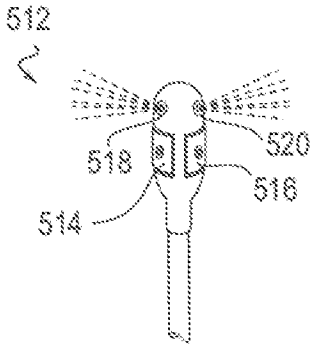


FIG. 20A



FIG. 20B

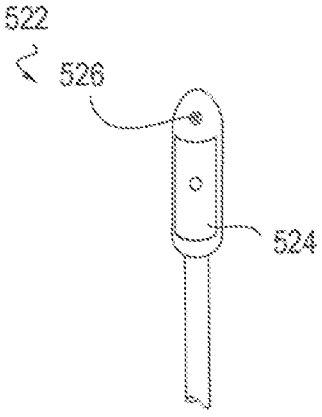


FIG. 21A

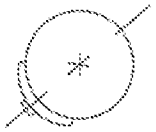


FIG. 21B

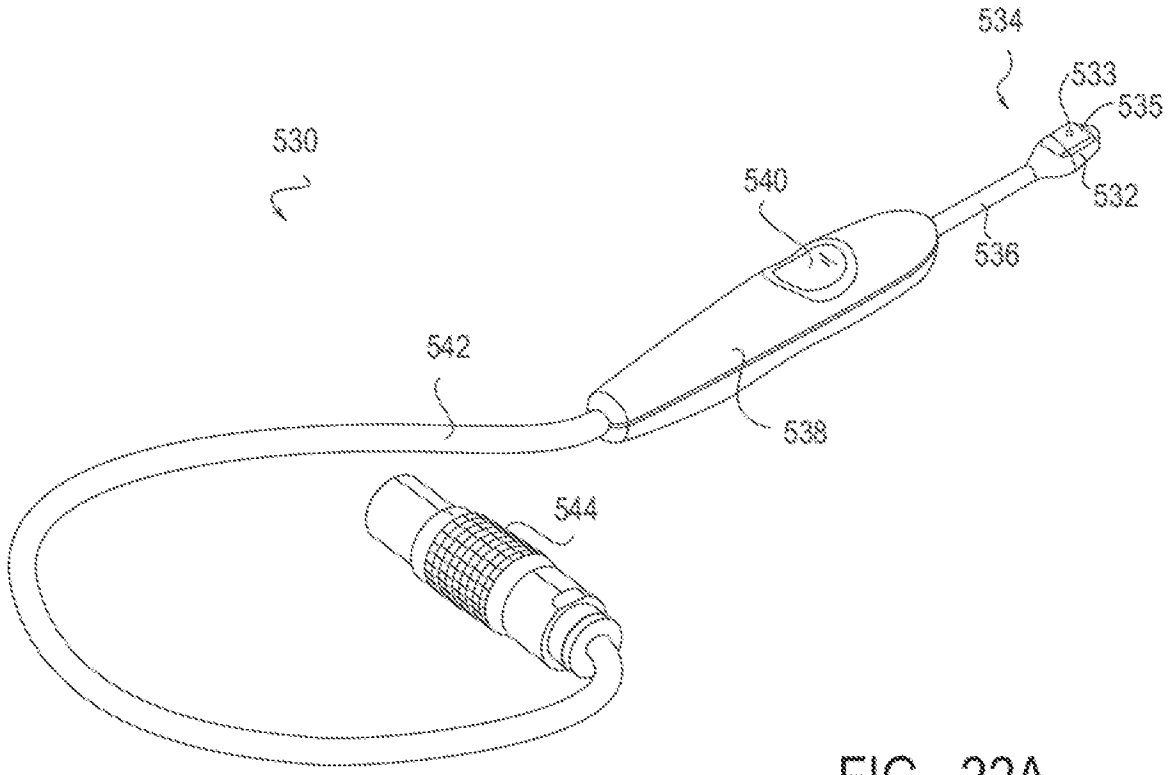


FIG. 22A

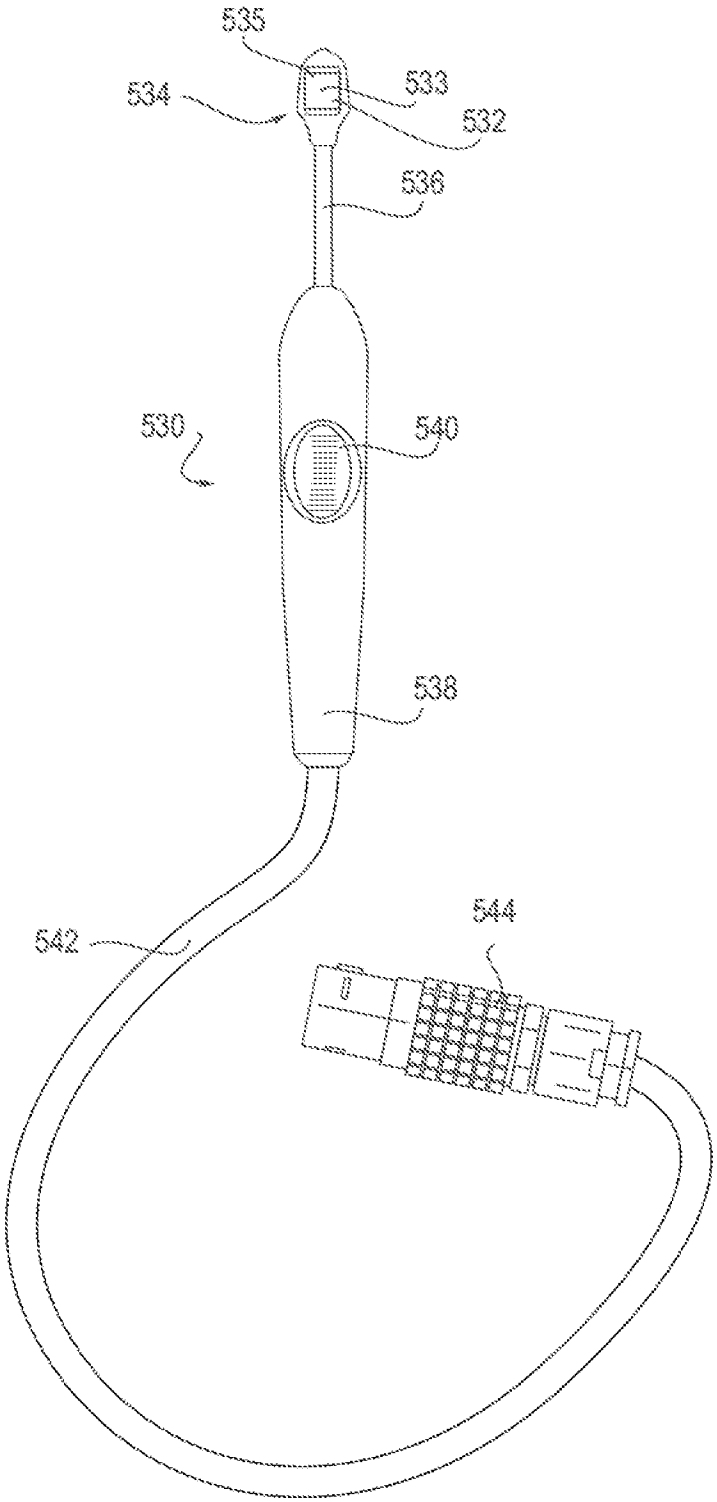


FIG. 22B

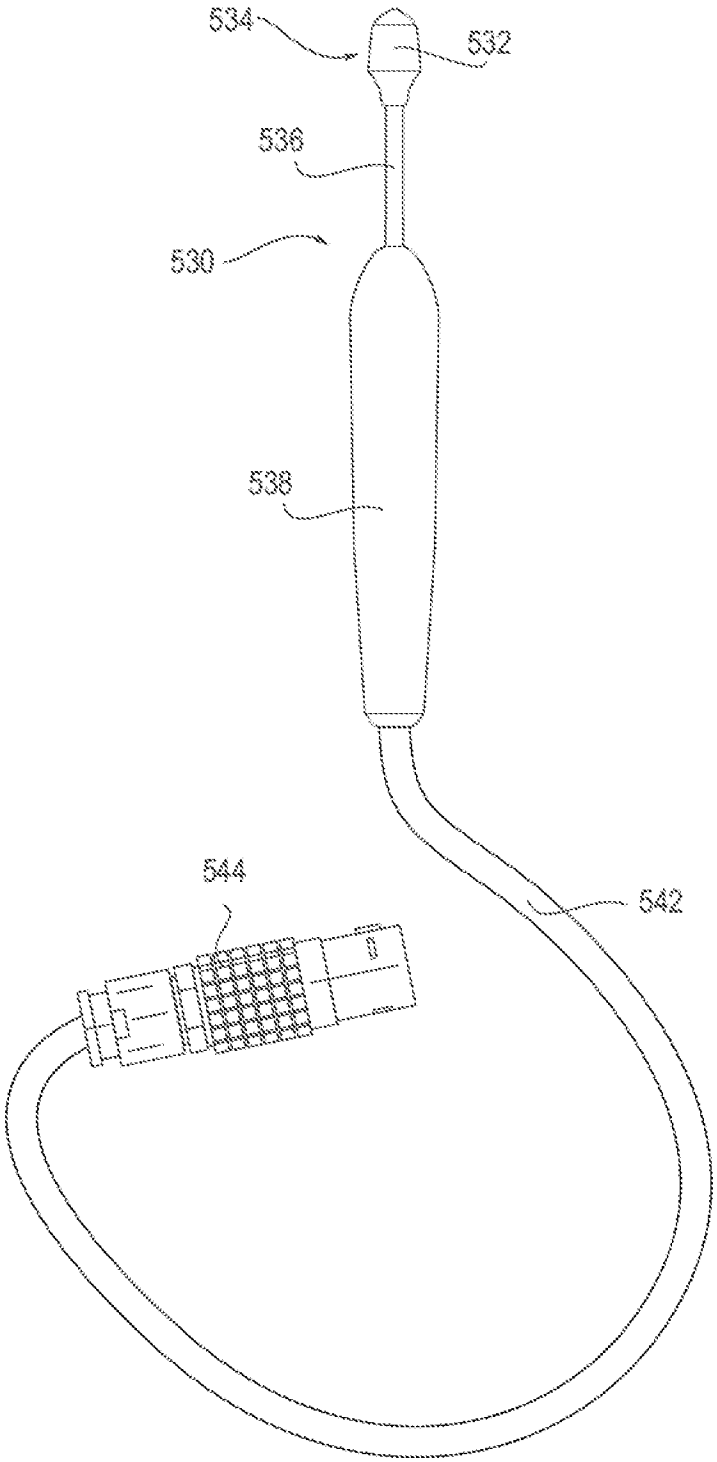


FIG. 22C

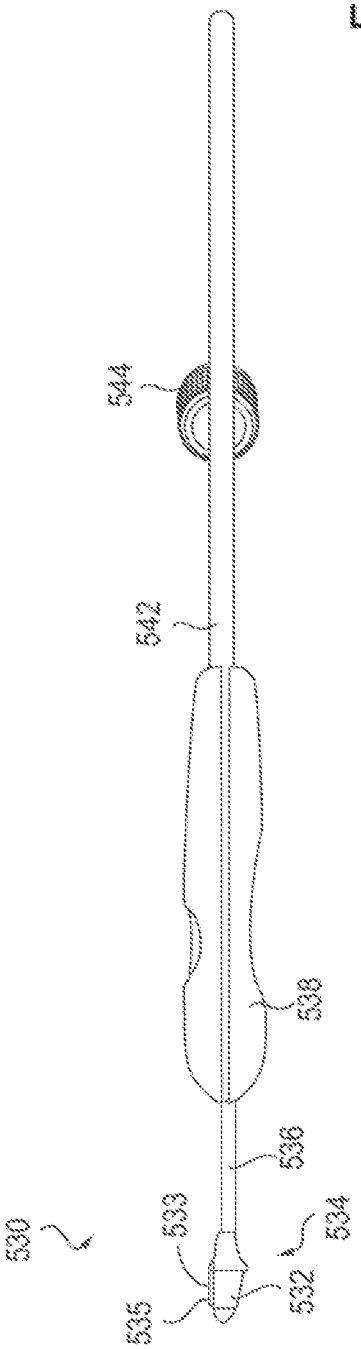


FIG. 22D

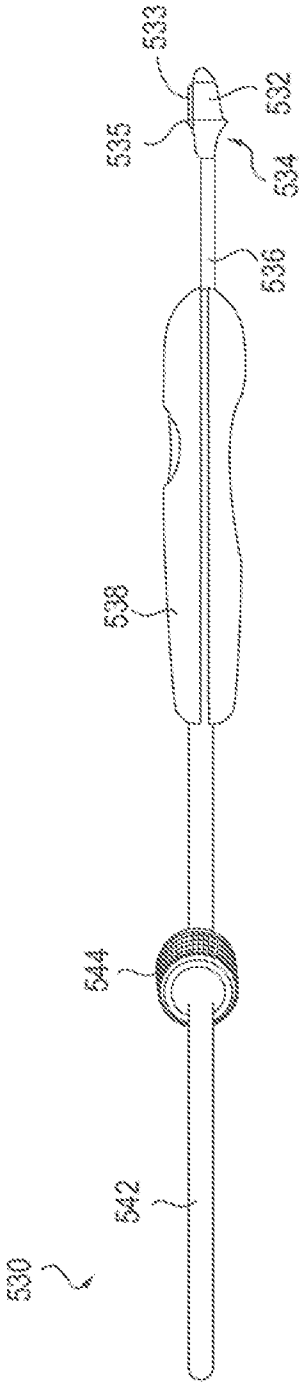


FIG. 22E

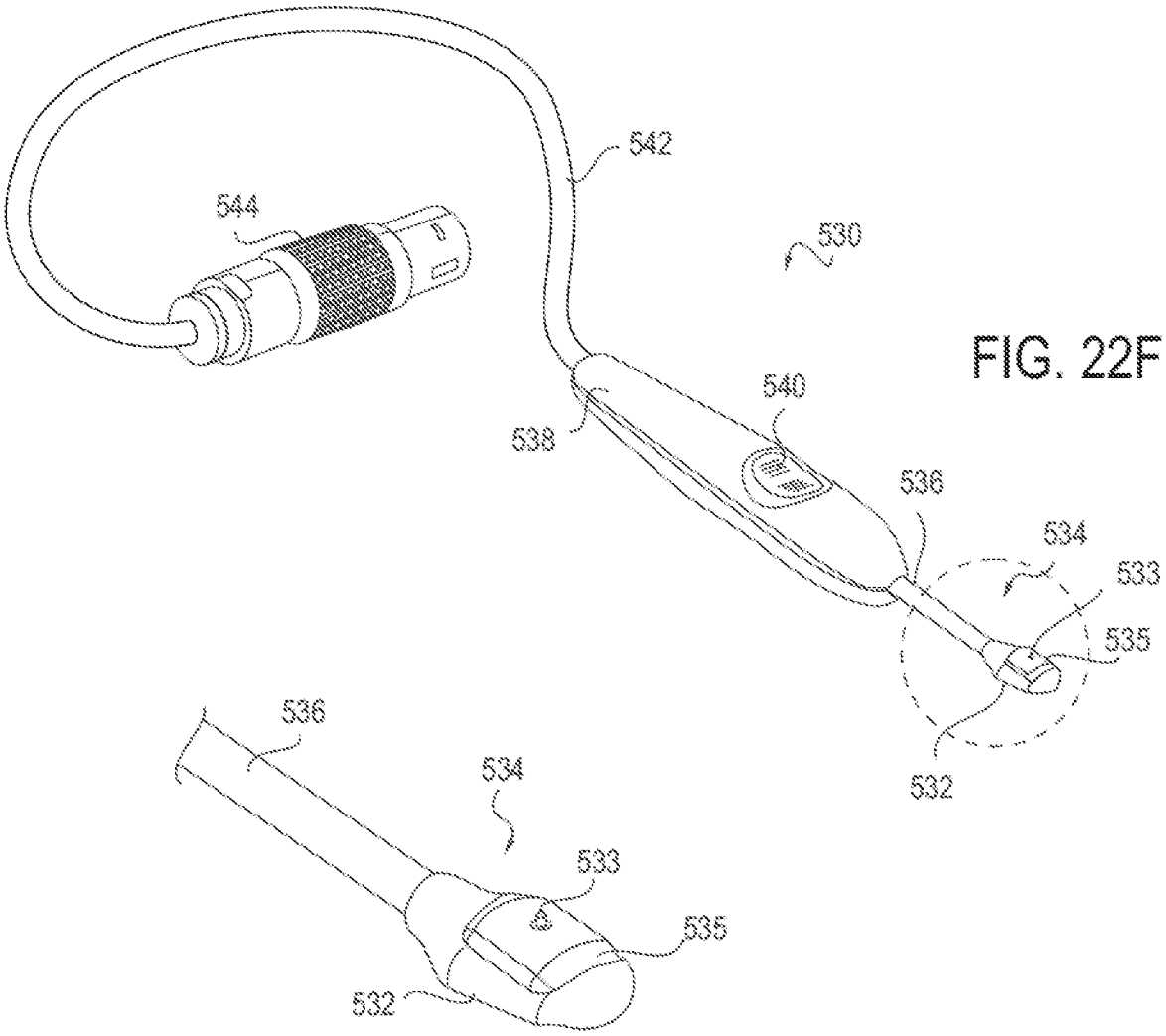


FIG. 22F

FIG. 22G

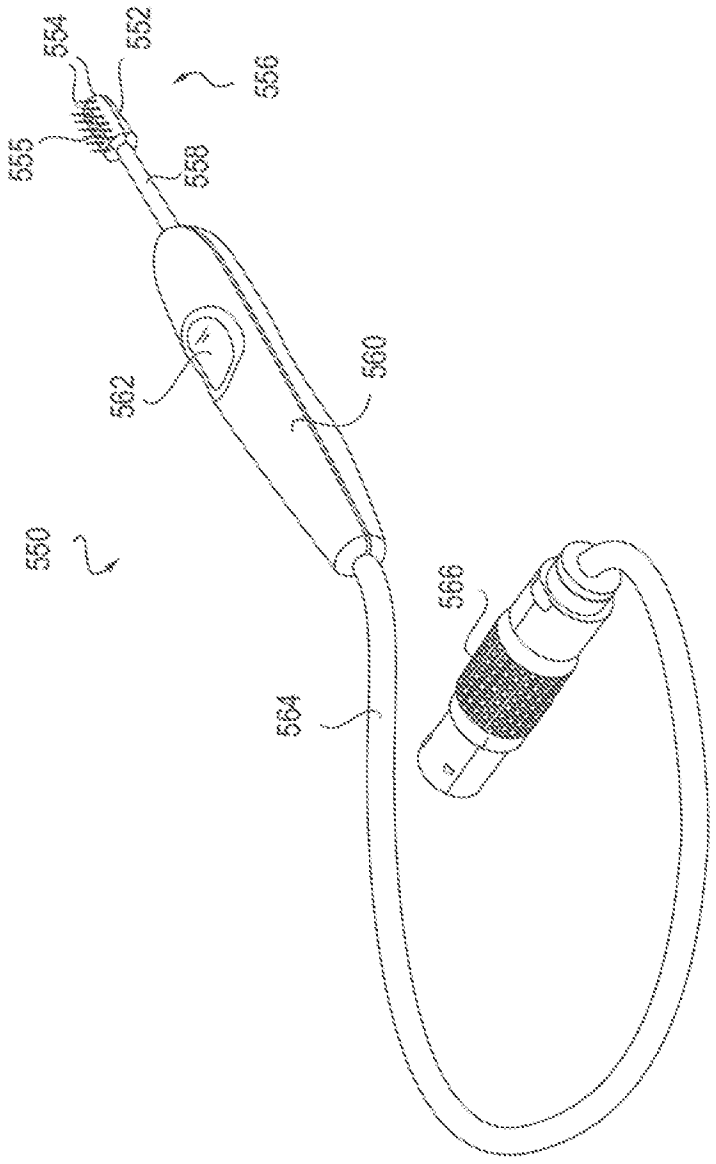


FIG. 23A

FIG. 23B

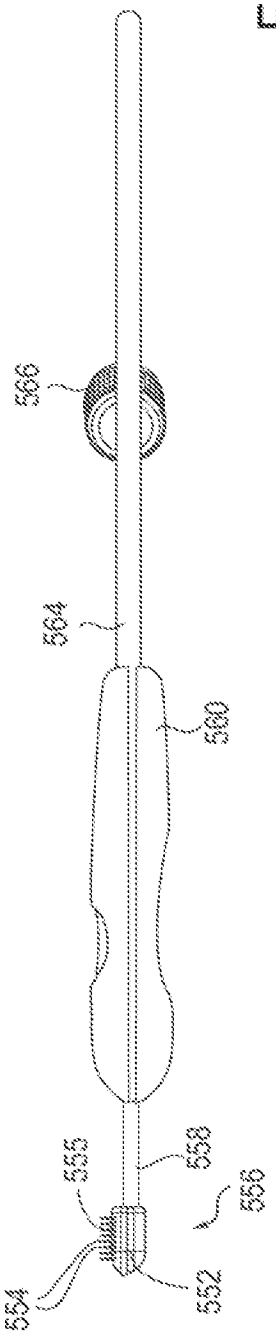
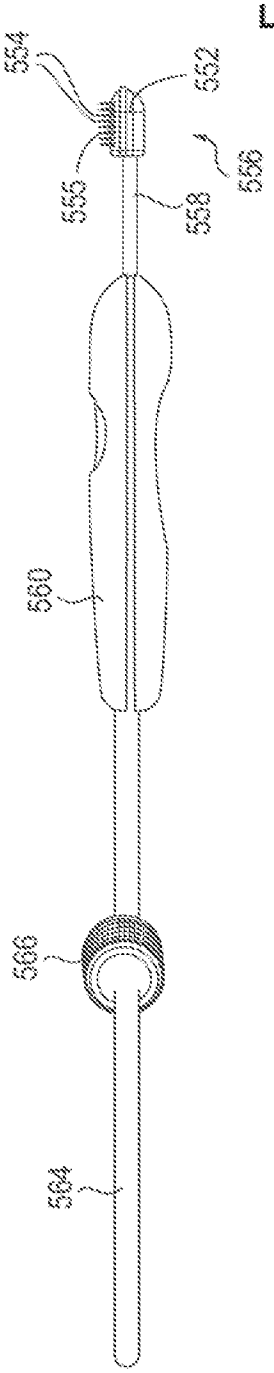


FIG. 23C



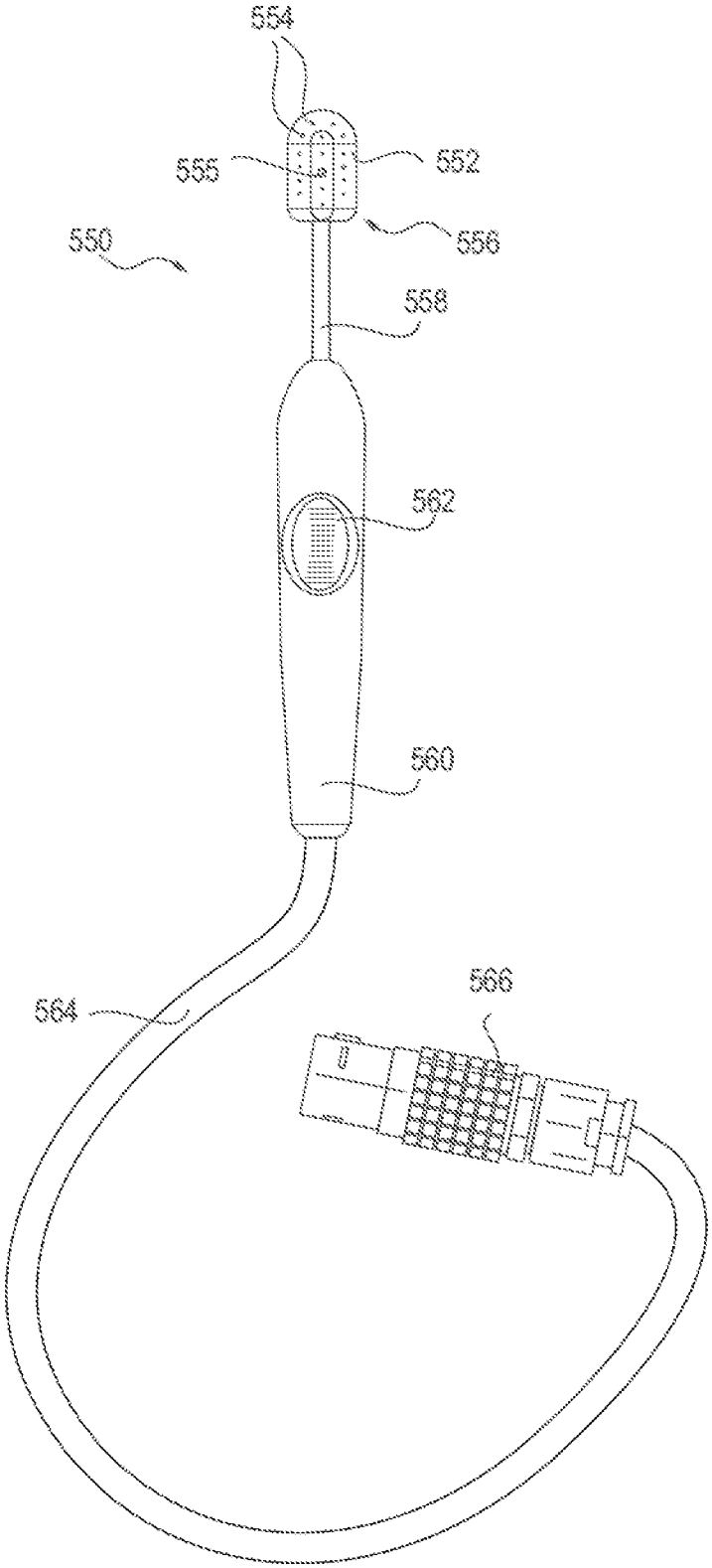


FIG. 23D

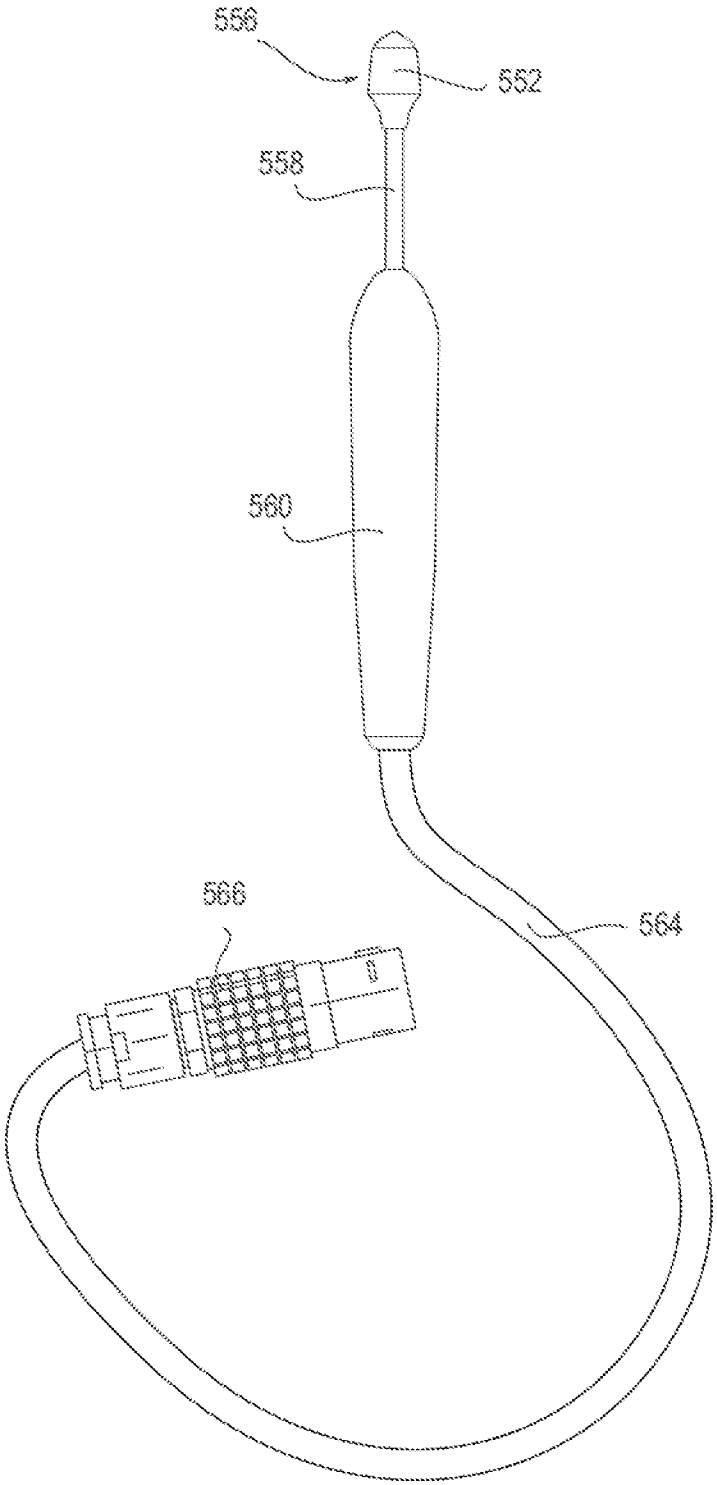


FIG. 23E

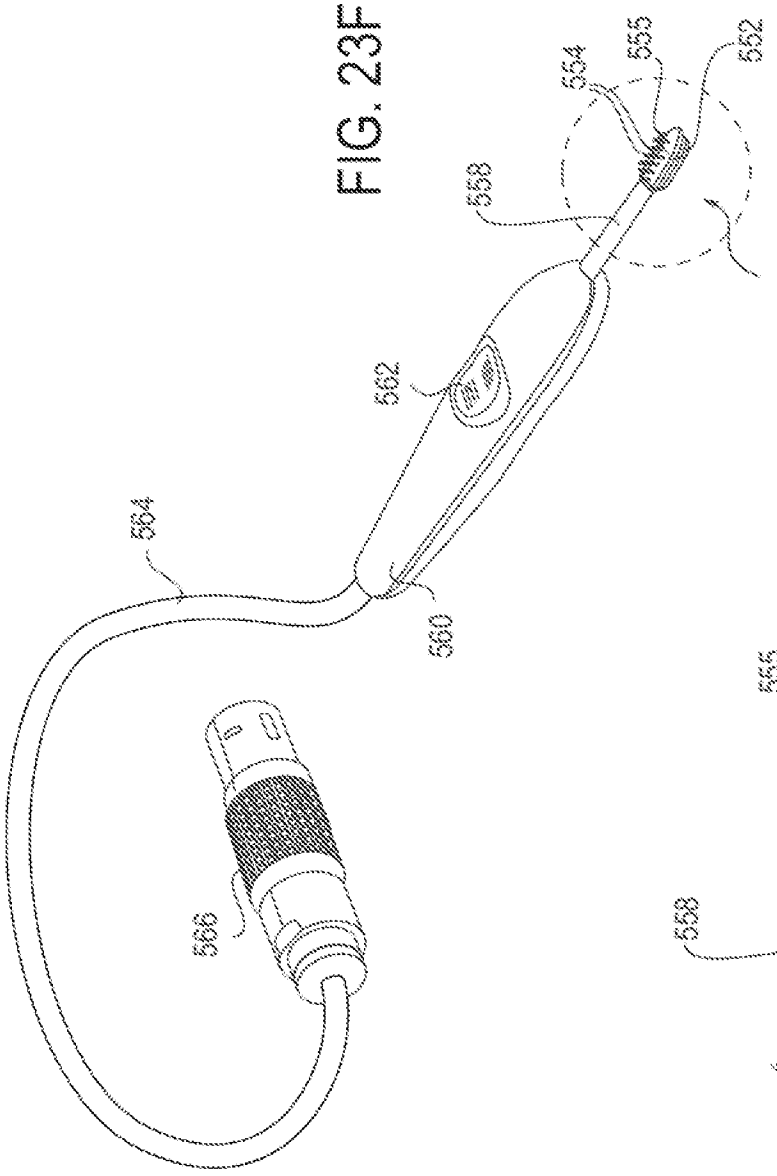


FIG. 23F

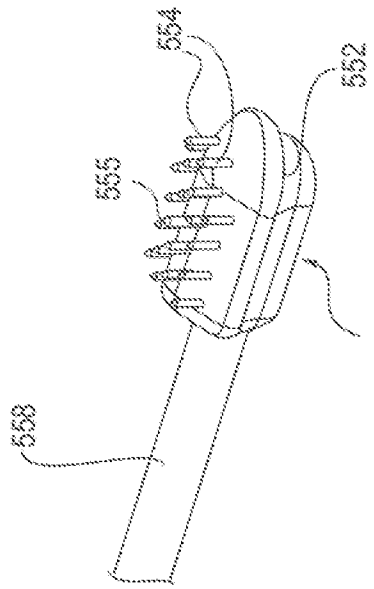


FIG. 23G

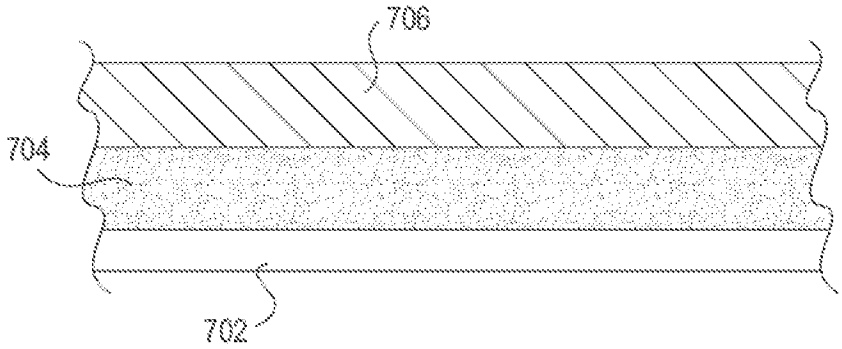


FIG. 24A

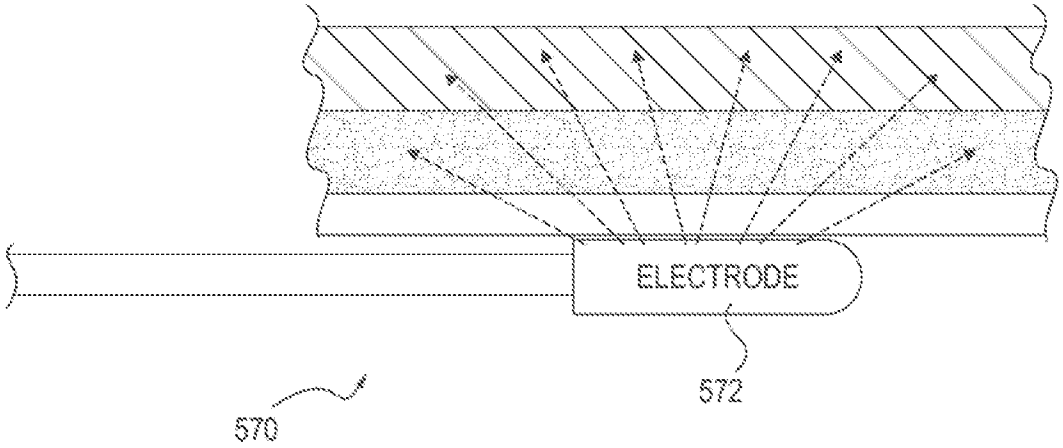


FIG. 24B

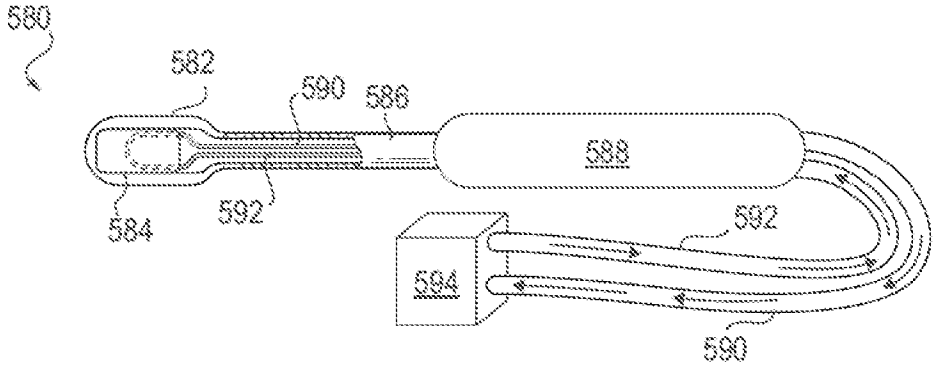


FIG. 25A

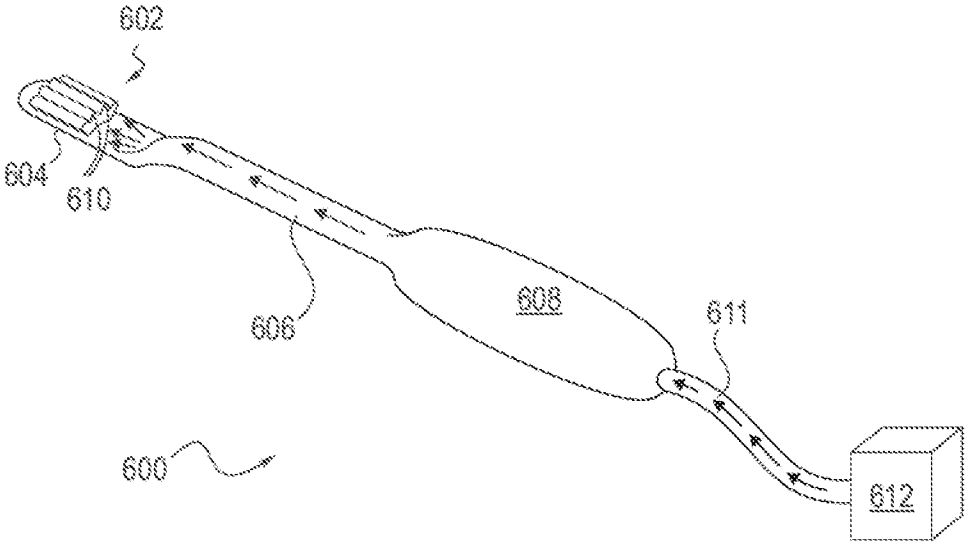


FIG. 25B

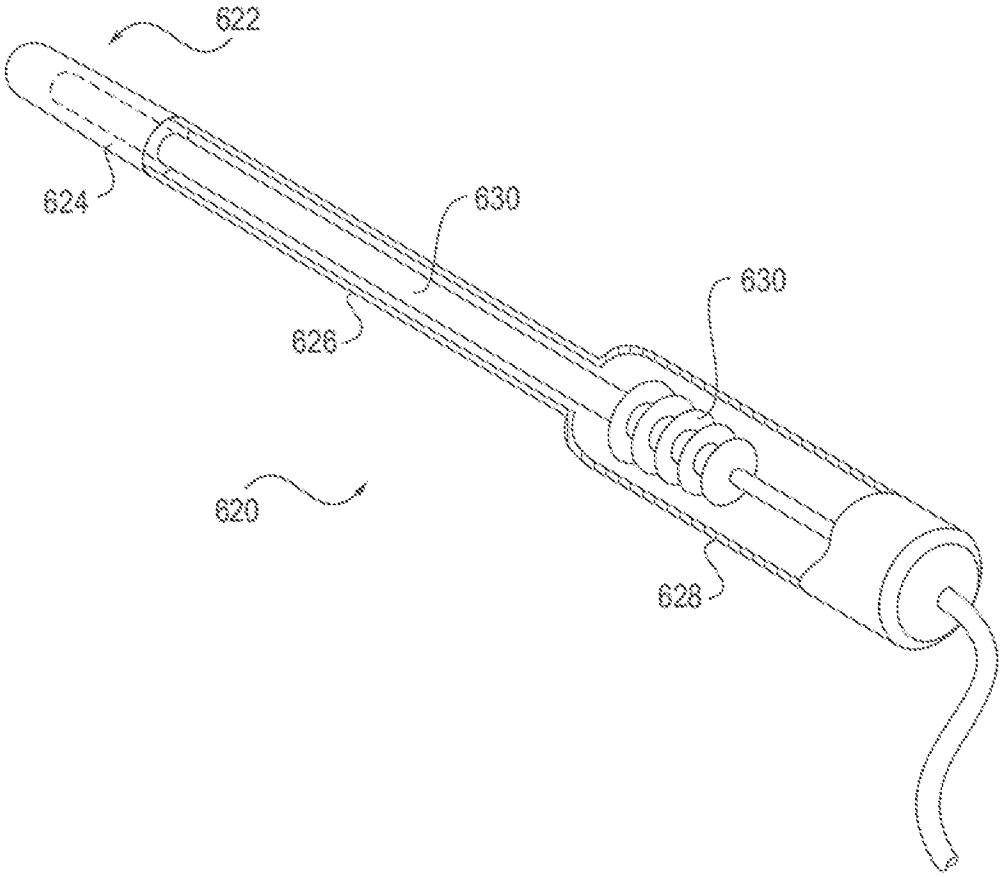


FIG. 26

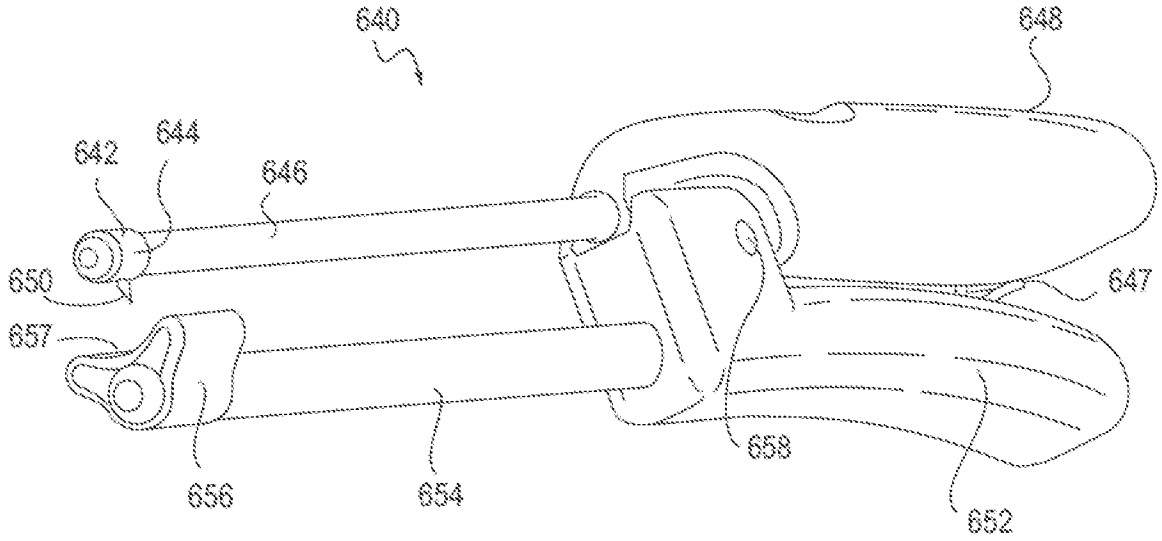


FIG. 27

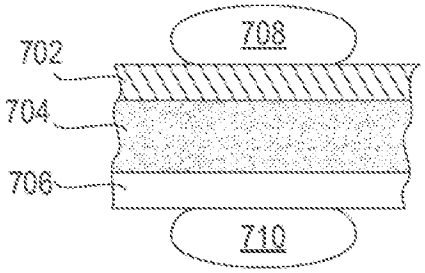


FIG. 28A

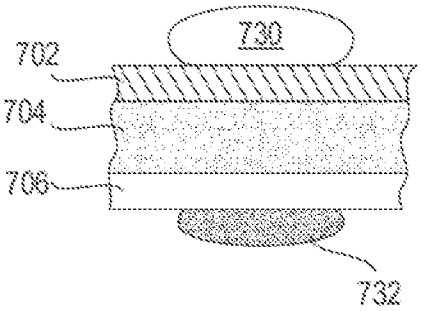


FIG. 28B

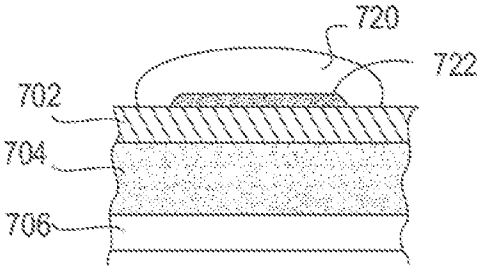


FIG. 28C

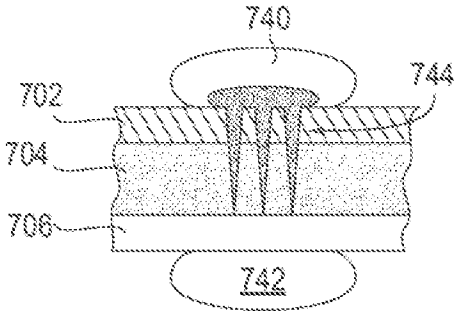


FIG. 28D

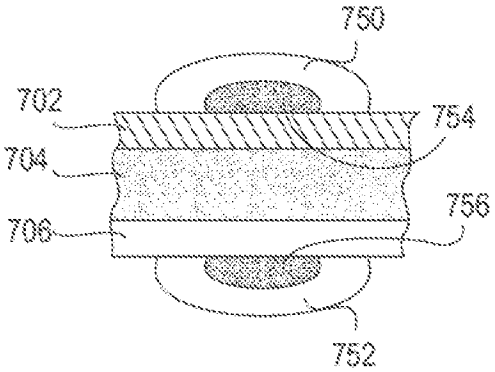


FIG. 28E

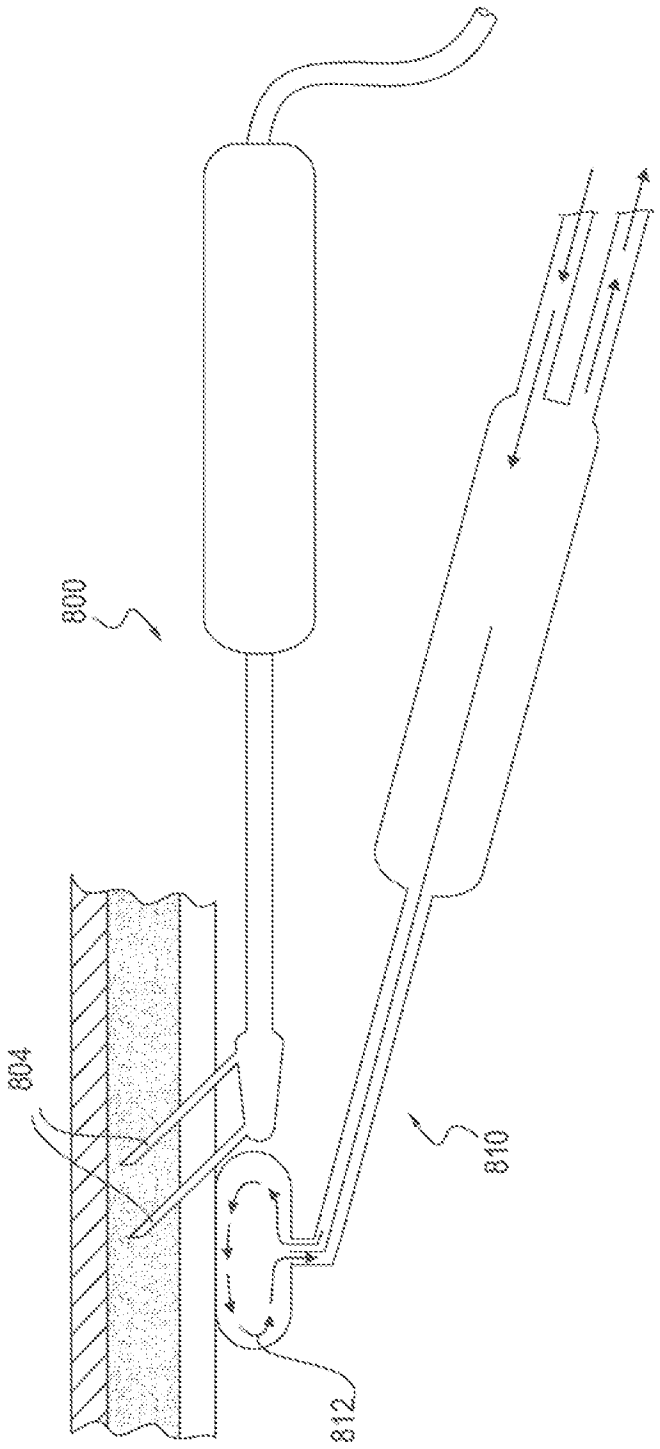


FIG. 29

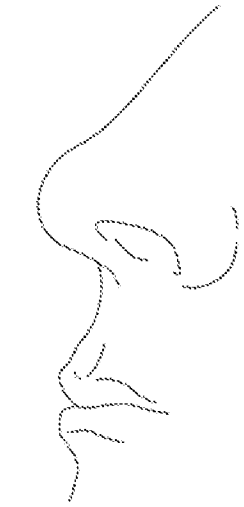


FIG. 30A

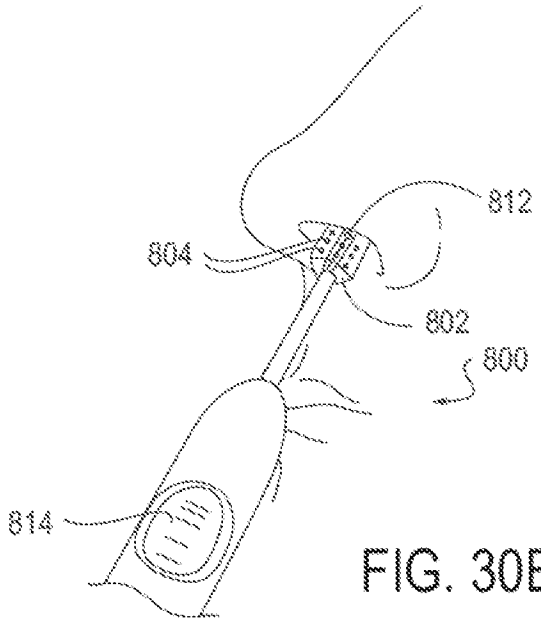


FIG. 30B

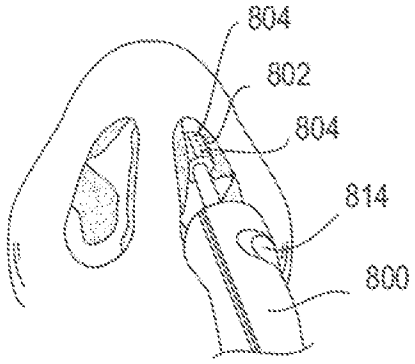


FIG. 30C

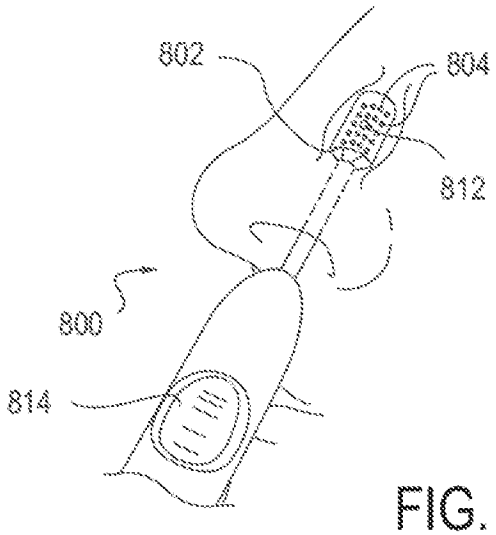


FIG. 30D

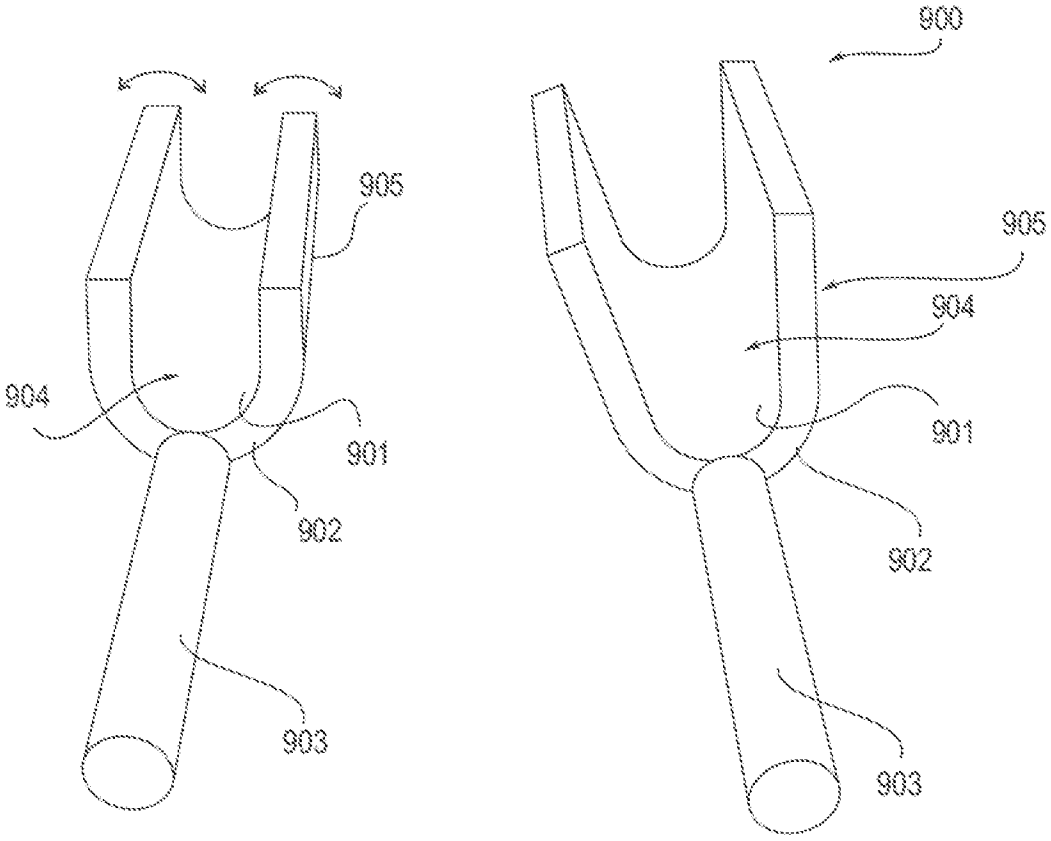


FIG. 31

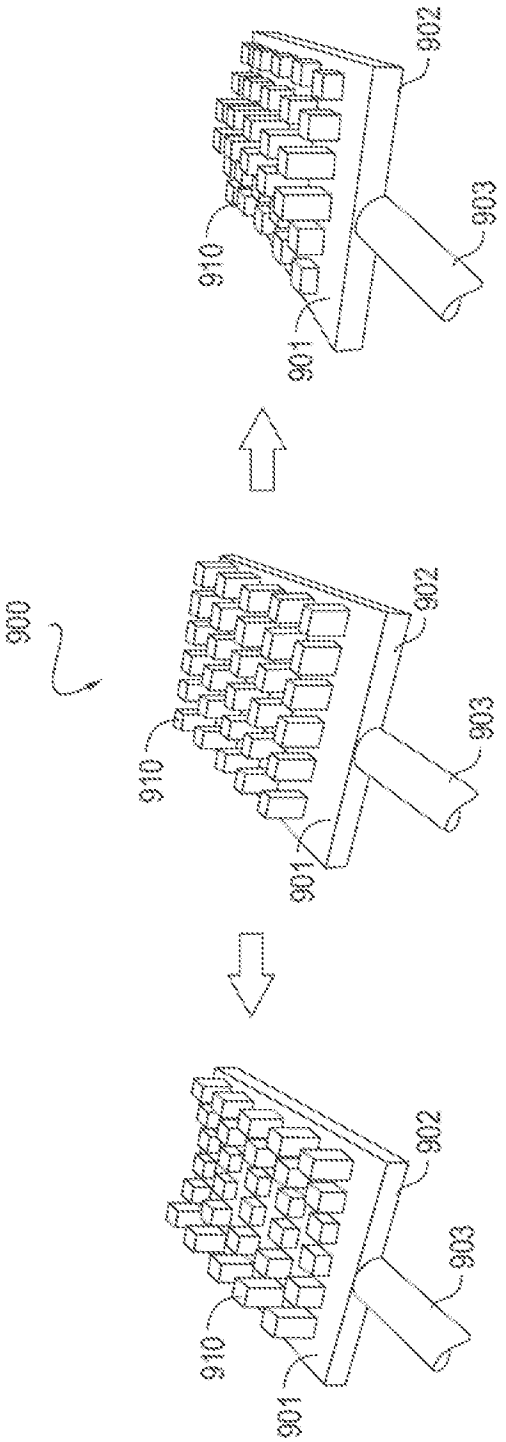


FIG. 32A

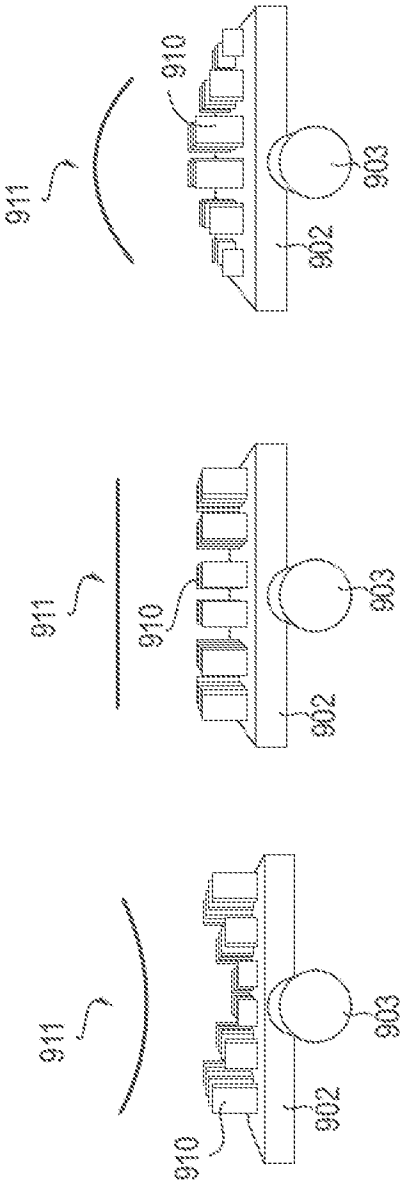


FIG. 32B

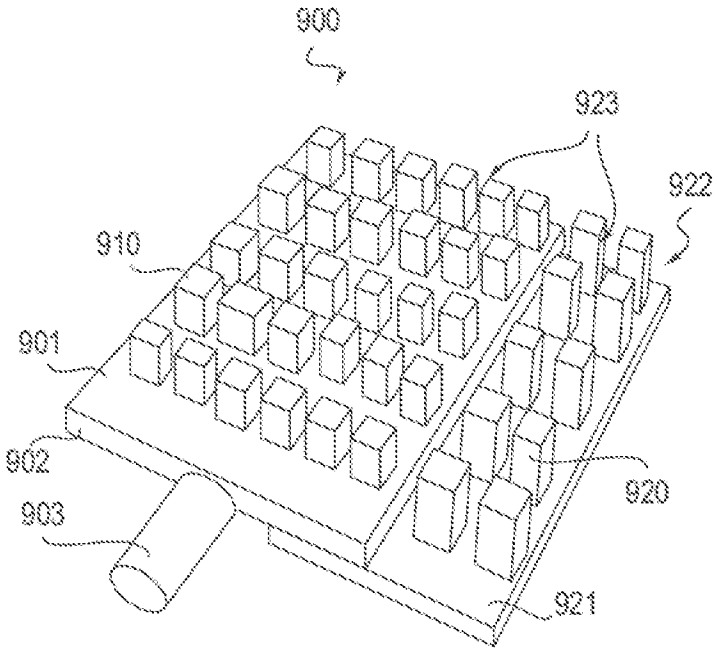


FIG. 33

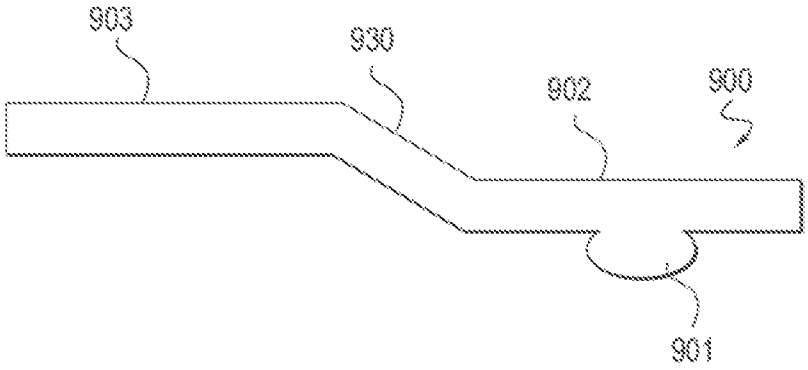


FIG. 34

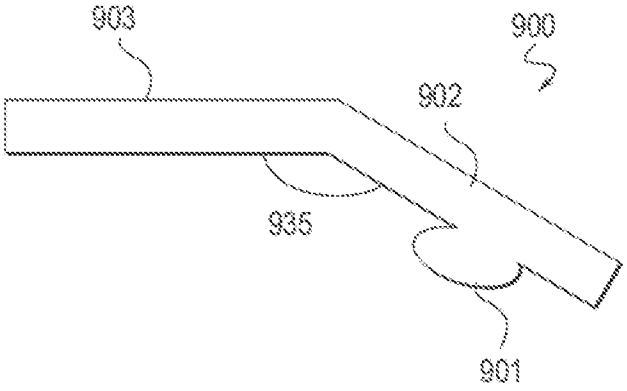


FIG. 35

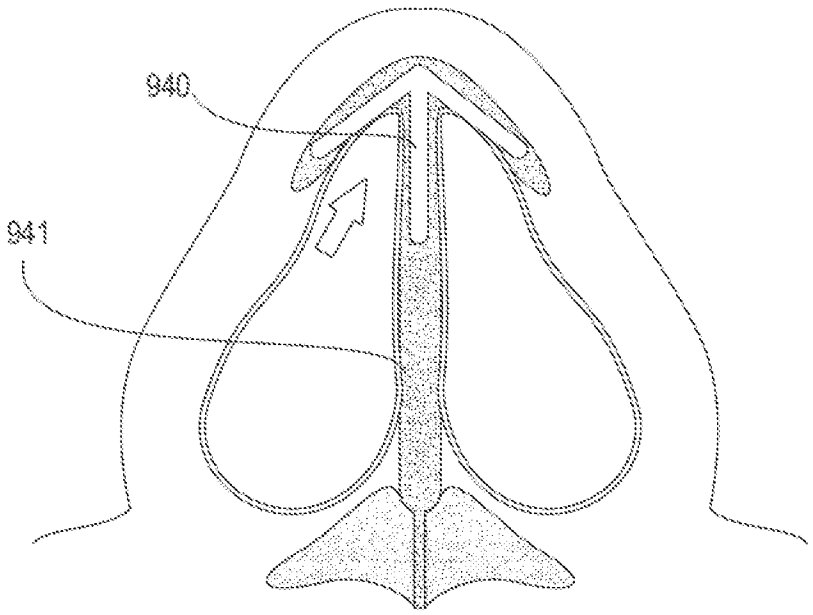


FIG. 36

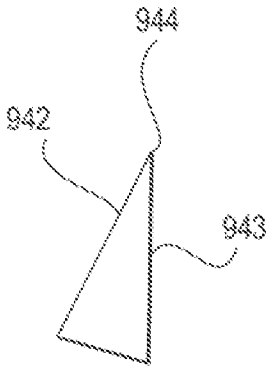


FIG. 37

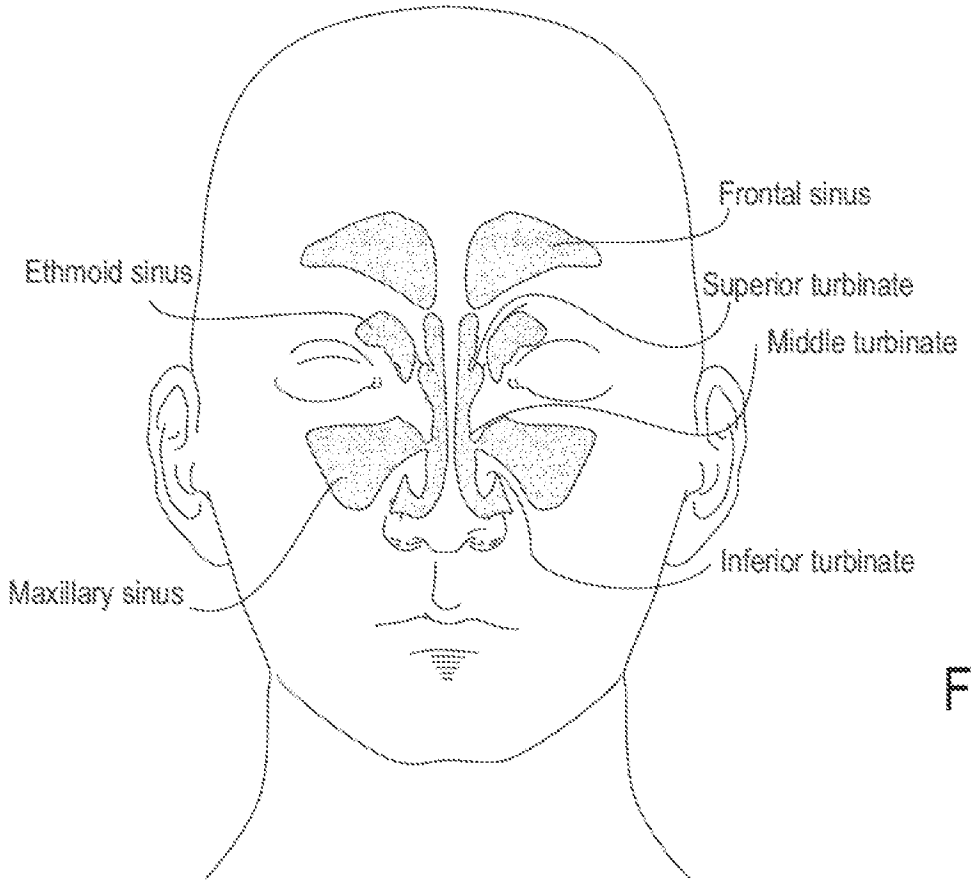


FIG. 38A

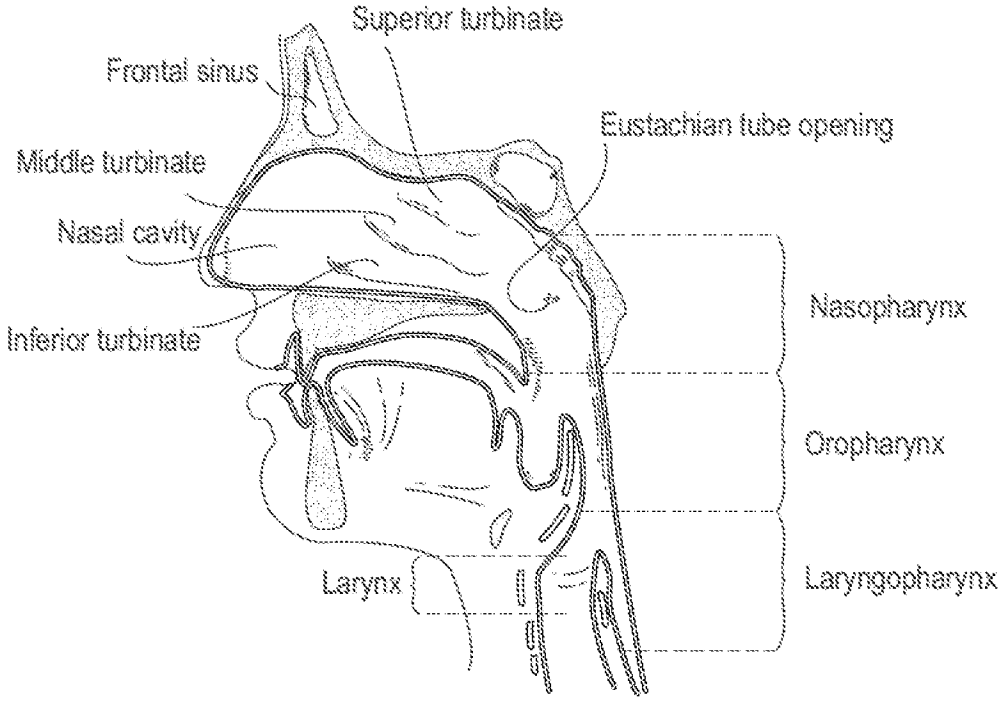


FIG. 38B

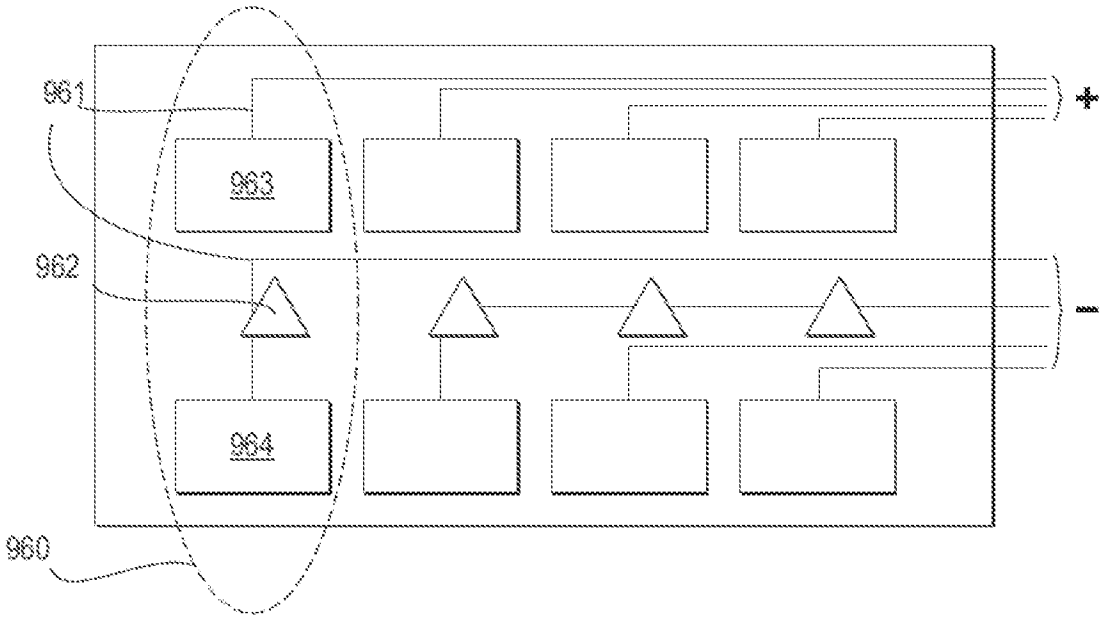


FIG. 39

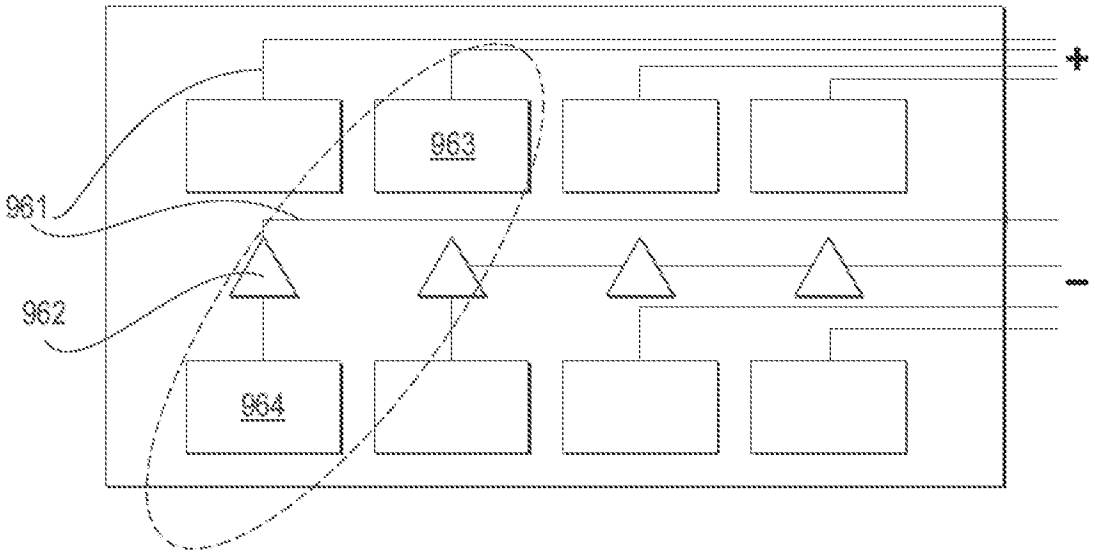


FIG. 40

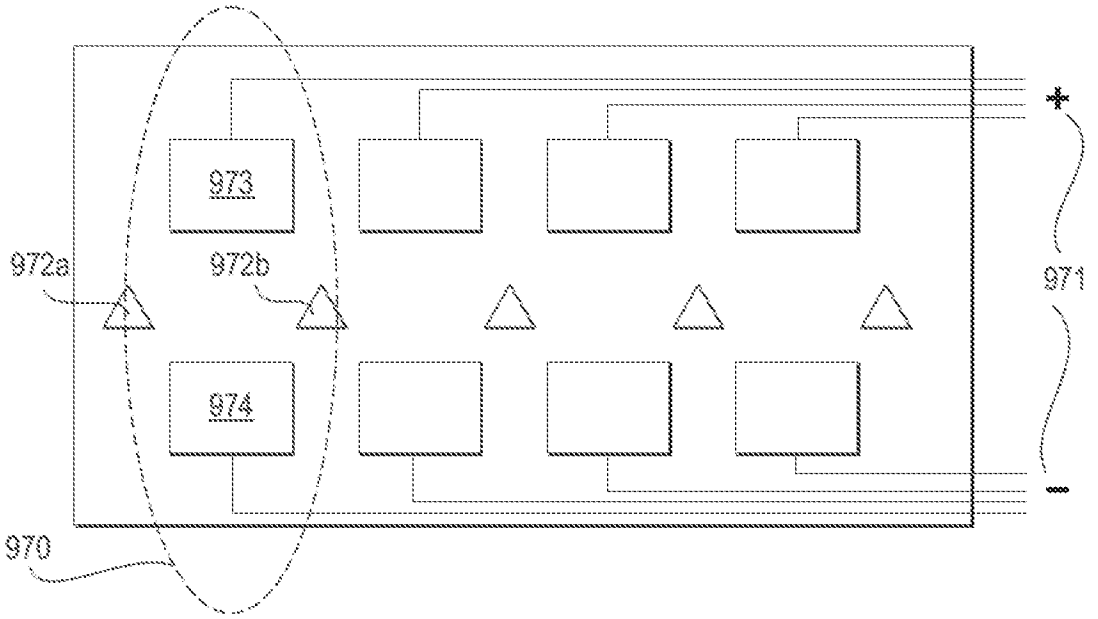


FIG. 41

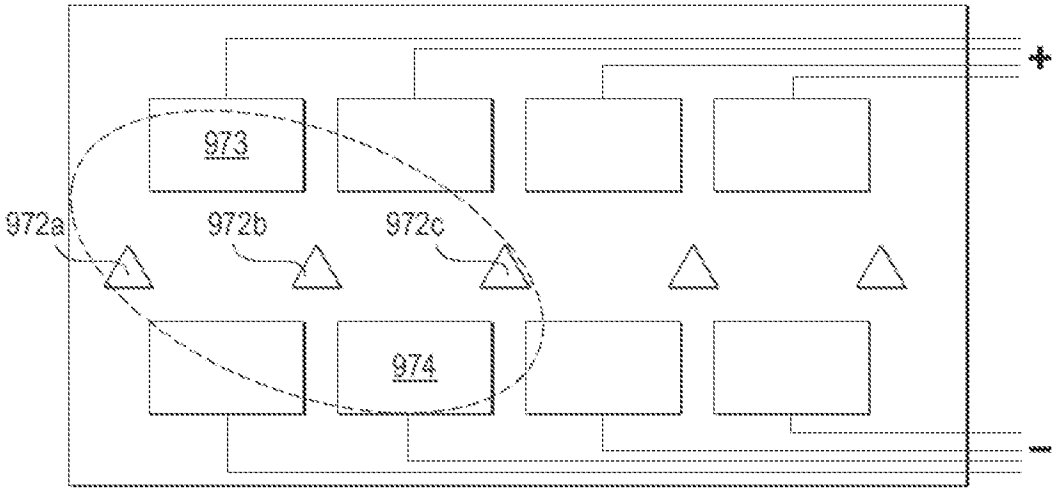


FIG. 42A

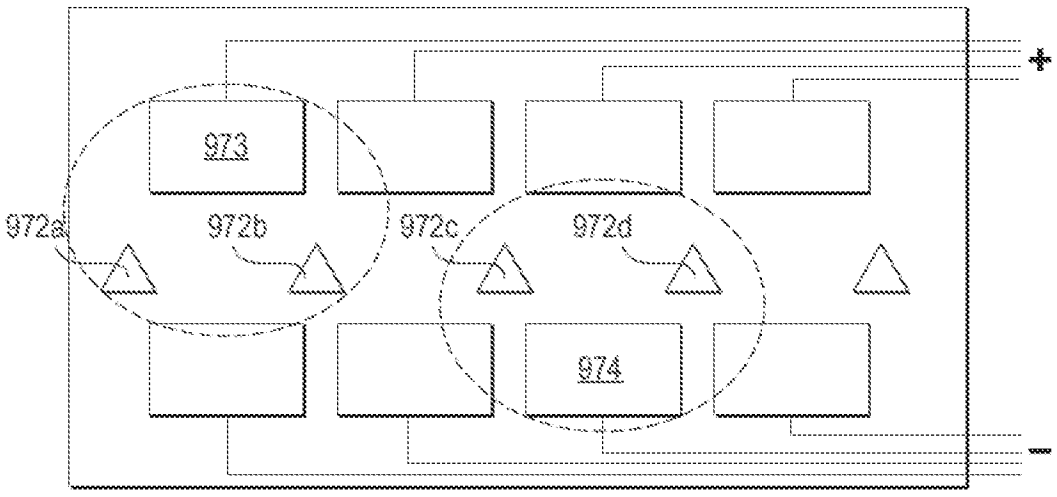


FIG. 42B

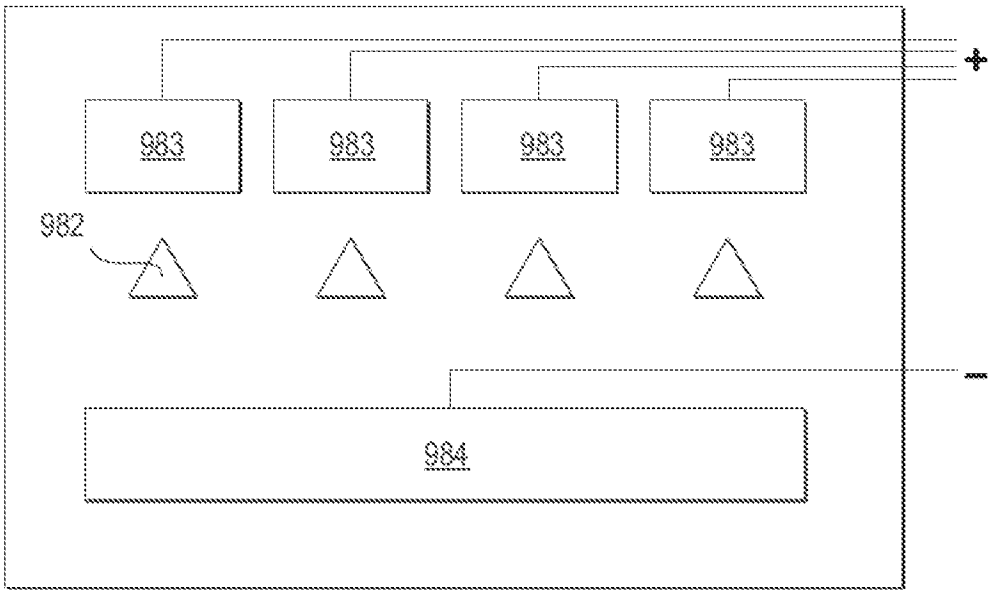


FIG. 43

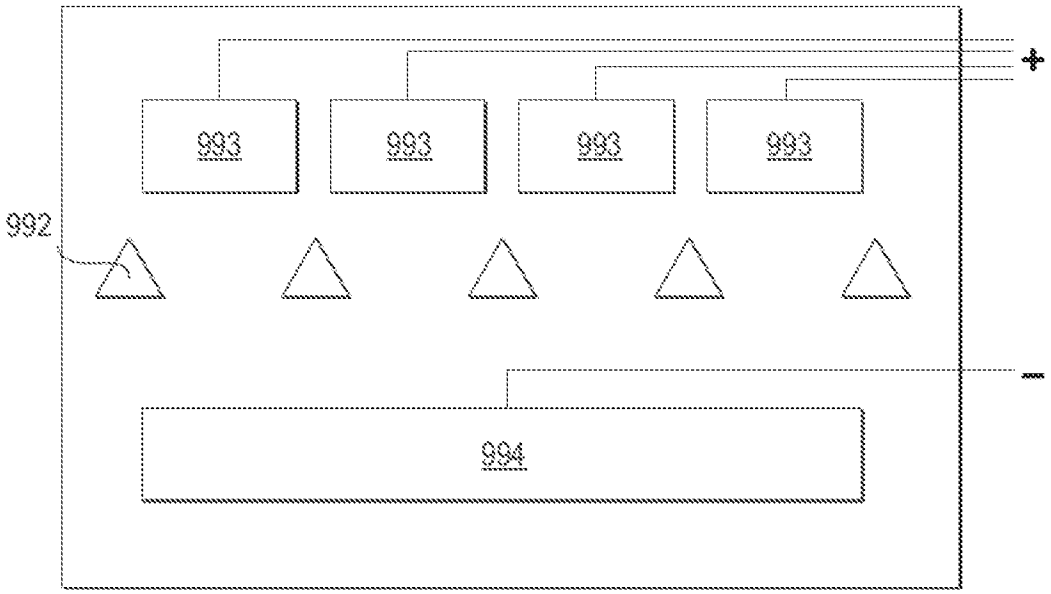


FIG. 44

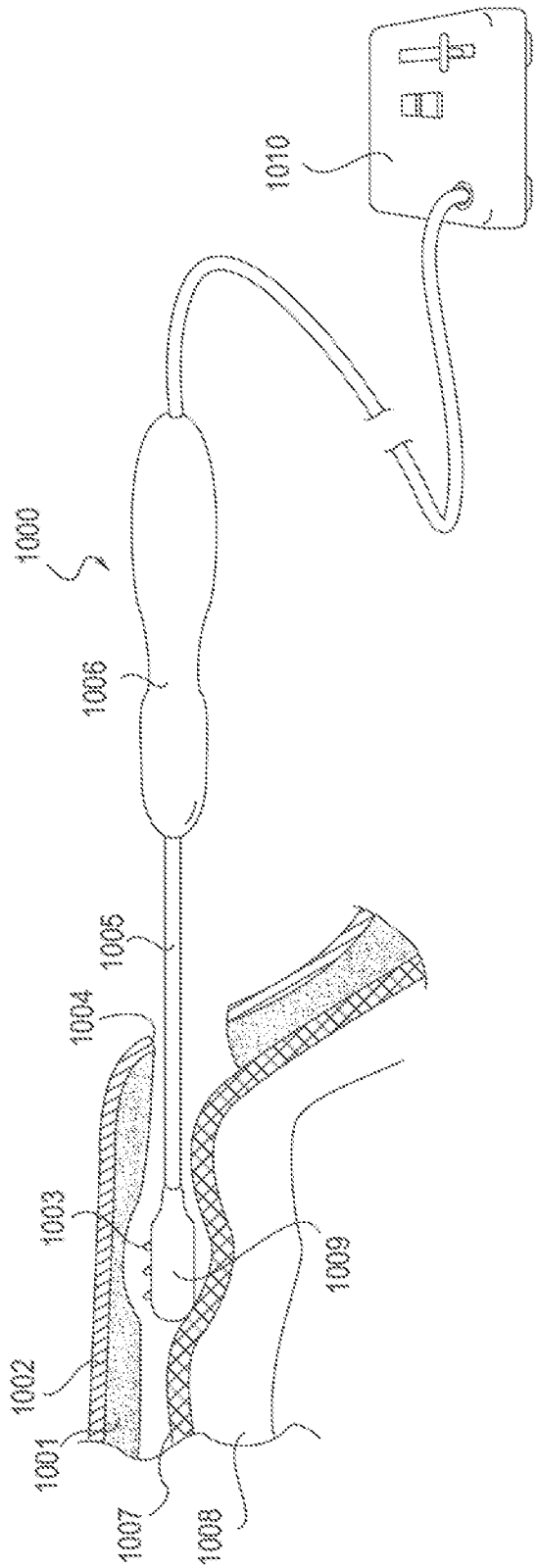


FIG. 45

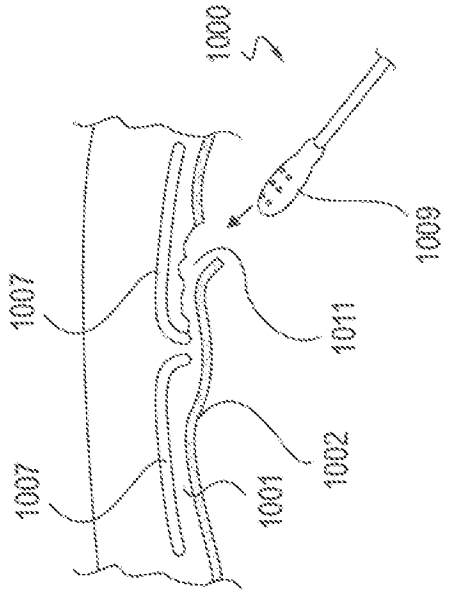


FIG. 46B

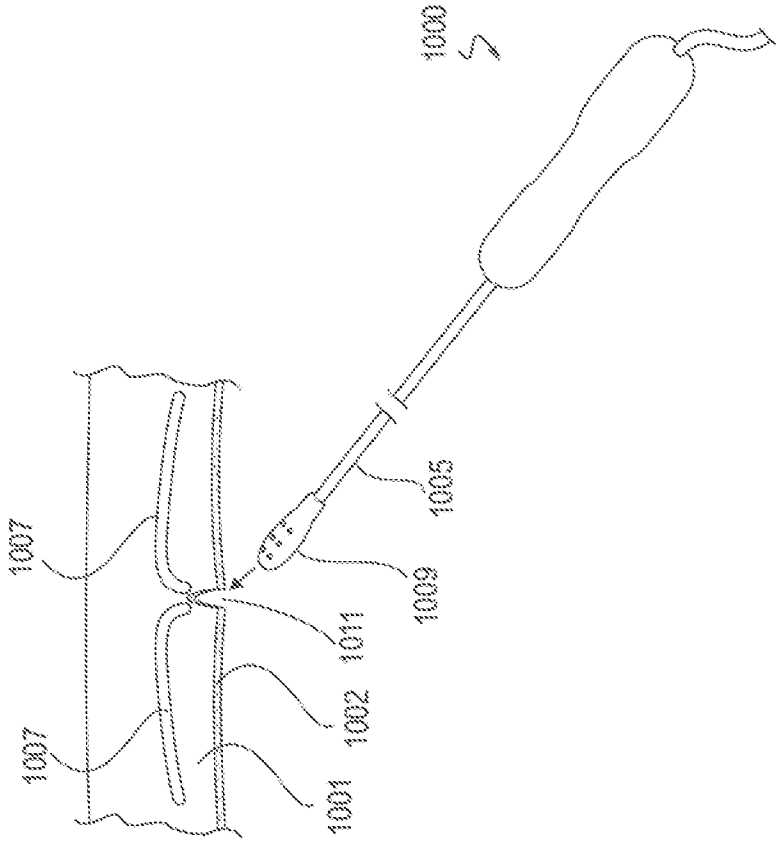


FIG. 46A

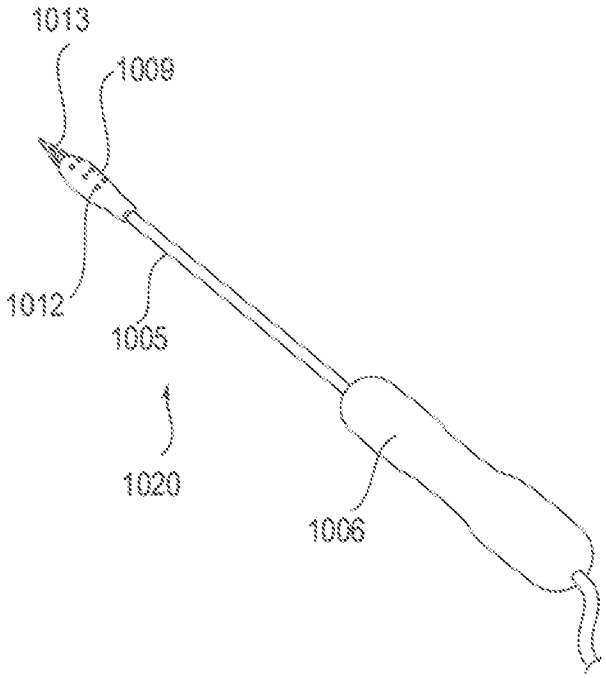


FIG. 47

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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

Title of Invention	METHODS AND DEVICES TO TREAT NASAL AIRWAYS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [ ] The attached application, or
- [X] United States application or PCT international application number 14/319,087 filed on June 30, 2014.

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

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

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

WARNING:

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

LEGAL NAME OF INVENTOR

Inventor: Scott J. WOLF Date (Optional): _____

Signature: _____

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

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

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

PTO/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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

Title of Invention	Methods and Devices to Treat Nasal Airways

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 14/319,087 filed on June 30, 2014.

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

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

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LEGAL NAME OF INVENTOR

Inventor: Andrew FRAZIER Date (Optional): _____

Signature: _____

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

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

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

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18

CONFIRMATION NO. 1056

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

FORMALITIES LETTER

OC000000125958029

Date Mailed: 06/01/2021

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **80** basic filing fee.
- $ **210** for **2** electronically equivalent pages in excess of **100** application size fee.
- $ **80** surcharge.
- $ **350** search fee.
- $ **400** examination fee.
- $(**0**) previous unapplied payment amount.
- $ **1120** TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/slee/

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number
17/327,254

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	1 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			210			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1040		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/327,254	05/21/2021		0.00	17713.0001US18	1	1

CONFIRMATION NO. 1056

FILING RECEIPT

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

OC000000125958028

Date Mailed: 06/01/2021

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

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

Inventor(s)

Scott J. WOLF, Menlo Park, CA;
Andrew FRAZIER, Sunnyvale, CA;

Applicant(s)

Aerin Medical, Inc., Sunnyvale, CA;

Assignment For Published Patent Application

Aerin Medical, Inc., Sunnyvale, CA

Power of Attorney: The patent practitioners associated with Customer Number 23552

Domestic Priority data as claimed by applicant

This application is a CON of 16/412,982 05/15/2019 PAT 11033318
which is a CON of 15/686,265 08/25/2017 PAT 10335221
which is a CON of 15/272,007 09/21/2016 PAT 9788886
which is a CON of 14/754,087 06/29/2015 PAT 9452010
which is a CON of 14/319,087 06/30/2014 PAT 9072597
which is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 05/27/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/327,254**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Preliminary Class

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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Electronic Patent Application Fee Transmittal

Application Number:	17327254
Filing Date:	21-May-2021
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Filer:	Robert A. Kalinsky/Theresa Powless
Attorney Docket Number:	17713.0001US18

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	2081	1	210	210
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1120**

Electronic Acknowledgement Receipt

EFS ID:	43225280
Application Number:	17327254
International Application Number:	
Confirmation Number:	1056
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Robert A. Kalinsky/Theresa Powless
Filer Authorized By:	Robert A. Kalinsky
Attorney Docket Number:	17713.0001US18
Receipt Date:	12-JUL-2021
Filing Date:	21-MAY-2021
Time Stamp:	16:06:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1120
RAM confirmation Number	E20217BG07094769
Deposit Account	132725
Authorized User	Theresa Powless

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Preliminary Amendment	2021-07-12--Preliminary-Amendment--17713-0002US18.PDF	88458 4b220e533f0c91986280707cbdce9c8e36423997	no	6
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38565 f710b2a7de5db176c59007d32f0199b20b0baef3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	127023		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	WOLF		
Appl. No.:	17/327,254		
Filed:	May 21, 2021	Docket No.:	17713.0001US18
Customer No.:	23552	Confirmation No.:	1056
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

PRELIMINARY AMENDMENT

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

Attention: Commissioner for Patents

Please consider this Preliminary Amendment before examining the referenced application.

Amendments to the Specification are included with this paper.

Amendments to the Claims are included with this paper.

Remarks are included with this paper.

If a petition for an extension of time under 37 C.F.R. § 1.136(a) is necessary to maintain the pendency of this patent application in connection with this response, and is not otherwise requested in this patent application, it is requested that the Commissioner consider this paper to be a petition for an appropriate extension of time and an authorization for the Commissioner to charge the fee as set forth in 37 C.F.R. § 1.17(a) corresponding to the needed extension of time to Deposit Account No. 13-2725.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification beginning at page 1, paragraph 1, as follows:

[0001] This application is a continuation of U.S. Patent Application No. 16/412,982, now U.S. Patent No. 11,033,318, filed May 15, 2019, which is a continuation of U.S. Patent Application No. 15/686,265 now U.S. Patent No. 10,335,221, filed August 25, 2017, which is a continuation of U.S. Patent Application No. 15/272,007, now U.S. Patent No. 9,788,886, filed September 21, 2016, entitled "METHODS AND DEVICES TO TREAT AIRWAYS," which is a continuation of U.S. Patent Application No. 14/754,087, now U.S. Patent No. 9,452,010 filed June 29, 2015, which is a continuation of U.S. Patent Application No. 14/319,087, now U.S. Patent No. 9,072,597, filed June 30, 2014, which is a continuation-in-part of U.S. Patent Application No. 13/495,844, now U.S. Patent No. 8,936,594, filed June 13, 2012, which claims priority to U.S. Provisional Patent Application Serial Nos. 61/603,864, filed on February 27, 2012, and 61/496,930, filed June 14, 2011. The disclosures of all the above-referenced patent applications are hereby incorporated by reference in their entireties herein.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method of treating a patient's airway, the method comprising:

advancing ~~a non-expandable,~~ an elongate treatment element of a treatment device through a nostril and into the patient's airway, wherein the elongate treatment element includes a tissue-contact surface ~~having a shape~~;

contacting ~~a pair of bipolar, radiofrequency electrodes protruding from~~ the tissue-contact surface with mucosal tissue in the airway, wherein the tissue-contact surface includes at least one energy delivery member;

~~applying force against the tissue with the shape of the tissue-contact surface to at least temporarily deform the tissue to a desired shape;~~

delivering ~~radiofrequency~~ energy from the at least one energy delivery member to submucosal tissue ~~between the electrodes~~, to ~~at least one of reshape,~~ remodel~~, strengthen or change a property of~~ the submucosal tissue; and

removing the elongated treatment element from the airway.

2. (New) The method of claim 1, wherein the method is performed without creating a surgical incision or implanting a surgical implant.

3. (New) The method of claim 1, wherein delivering the energy comprises applying energy in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser.

4. (New) The method of claim 1, further comprising applying force against the mucosal tissue with the tissue-contact surface, to at least temporarily deform the mucosal tissue and the submucosal tissue to a desired shape.

5. (New) The method of claim 4, further comprising maintaining application of the force while the energy is being delivered.

6. (New) The method of claim 5, wherein the tissue-contact surface has a convex shape, and wherein the desired shape of the mucosal tissue and the submucosal tissue is a concave shape corresponding to the convex shape of the tissue-contact surface.

7. (New) The method of claim 1, wherein the mucosal tissue and the submucosal tissue form at least part of a nasal valve of the airway.

8. (New) The method of claim 1, wherein remodeling the submucosal tissue increases a volumetric airflow rate of air flowing from an exterior of the patient's body into the patient's nasopharynx without changing a shape of an internal nasal valve.

9. (New) The method of claim 1, further comprising delivering a cauterizing agent to the patient's nasal tissue.

10. (New) The method of claim 1, wherein the at least one energy delivery member comprises multiple pairs of bipolar radiofrequency electrodes.

11. (New) The method of claim 10, wherein delivering the energy comprises delivering radiofrequency energy for about 15 seconds to about 1 minute.

12. (New) The method of claim 11, further comprising, before removing the elongated treatment element:

moving the elongated treatment element to a new location in the airway;

contacting the tissue-treatment surface with the mucosal tissue at the new location; and

delivering energy from the at least one energy delivery member to the submucosal tissue at the new location to remodel the submucosal tissue at the new location.

13. (New) The method of claim 10, wherein delivering the energy comprises heating an area of tissue surrounding the multiple pairs of bipolar radiofrequency electrodes to a temperature of 50 degrees Celsius to 70 degrees Celsius.

REMARKS

Claim 1 is amended and claims 2-13 are added. No new matter is added. Favorable consideration is requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(6612) 332-5300

Date: July 12, 2021

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/327,254	05/21/2021		1120	17713.0001US18	13	1

CONFIRMATION NO. 1056

UPDATED FILING RECEIPT

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

OC000000128942533

Date Mailed: 07/14/2021

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

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

Inventor(s)

Scott J. WOLF, Menlo Park, CA;
Andrew FRAZIER, Sunnyvale, CA;

Applicant(s)

Aerin Medical, Inc., Sunnyvale, CA;

Assignment For Published Patent Application

Aerin Medical, Inc., Sunnyvale, CA

Power of Attorney: The patent practitioners associated with Customer Number 23552

Domestic Priority data as claimed by applicant

This application is a CON of 16/412,982 05/15/2019 PAT 11033318
which is a CON of 15/686,265 08/25/2017 PAT 10335221
which is a CON of 15/272,007 09/21/2016 PAT 9788886
which is a CON of 14/754,087 06/29/2015 PAT 9452010
which is a CON of 14/319,087 06/30/2014 PAT 9072597
which is a CIP of 13/495,844 06/13/2012 PAT 8936594
which claims benefit of 61/603,864 02/27/2012
and claims benefit of 61/496,930 06/14/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 05/27/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/327,254**

Projected Publication Date: 10/21/2021

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Preliminary Class

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

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

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community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number
17/327,254

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	13 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			210			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1040		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17327254
Filing Date	2021-05-21
First Named Inventor	Scott J. WOLF
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US18

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	20140088463	A1	2014-03-27	Wolf et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327254
	Filing Date	2021-05-21
	First Named Inventor	Scott J. WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	1	Extended European Search Report for Application No. 21172995.9 mailed July 9, 2021.

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327254
	Filing Date	2021-05-21
	First Named Inventor	Scott J. WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US18

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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

A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-08-07
Name/Print	Robert A. Kalinsky	Registration Number	50,471

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	43455074
Application Number:	17327254
International Application Number:	
Confirmation Number:	1056
Title of Invention:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS
First Named Inventor/Applicant Name:	Scott J. WOLF
Customer Number:	23552
Filer:	Robert A. Kalinsky/Kristine Wacek
Filer Authorized By:	Robert A. Kalinsky
Attorney Docket Number:	17713.0001US18
Receipt Date:	09-AUG-2021
Filing Date:	21-MAY-2021
Time Stamp:	10:23:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS-2-17713-0001US18.PDF	1034325 077c53648b1c852248b2926f528f170c1e451228	no	4

Warnings:

Information:					
2	Non Patent Literature	Extended-European-Search-Report-for-21172995-9-mailed-07-09-2021.PDF	1559311 193330962b631372ed0029548b7da379d9c0efd6	no	8
Warnings:					
Information:					
		Total Files Size (in bytes):	2593636		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18

CONFIRMATION NO. 1056

23552
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

PUBLICATION NOTICE



Title:METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Publication No.US-2021-0322083-A1
Publication Date:10/21/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,254	Filing Date 05/21/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	05/08/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

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

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/327,254	**05/08/2023 10:46:00 AM ET**	**17713.0001US18**

Title of Invention

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1056	FILED BY	Theresa Powless
PATENT CENTER #	62050643	FILING DATE	05/21/2021
CUSTOMER #	23552	FIRST NAMED INVENTOR	Scott J. WOLF
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Kalinsky

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-05-08--2nd Preliminary Amendment--17713.0001US18.PDF	4	Preliminary Amendment	83 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-05-08--2nd Preliminary Amendment--17713.0001US18.PDF	8C04AC854D3BF29E35DDC75246BC87321C702BF2CB53E7D7FA991C6987BB07C5D2D7983664B4A91BEED2E46EA96CC104659AA1CF5C4E51F3D9348D593A0C88CC

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Scott J. WOLF		
Appl. No.:	17/327,254		
Filed:	May 21, 2021	Docket No.:	17713.0001US18
Customer No.:	23552	Confirmation No.:	1056
Title:	METHODS AND DEVICES TO TREAT NASAL AIRWAYS		

SECOND PRELIMINARY AMENDMENT

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

Attention: Commissioner for Patents

Please consider this Preliminary Amendment before examining the referenced application.

Amendments to the Claims are included with this paper.

Remarks are included with this paper.

If a petition for an extension of time under 37 C.F.R. § 1.136(a) is necessary to maintain the pendency of this patent application in connection with this response, and is not otherwise requested in this patent application, it is requested that the Commissioner consider this paper to be a petition for an appropriate extension of time and an authorization for the Commissioner to charge the fee as set forth in 37 C.F.R. § 1.17(a) corresponding to the needed extension of time to Deposit Account No. 13-2725.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1.-13. (Canceled)

14. (New) A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:

a handle;

a shaft extending from one end of the handle;

a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;

multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;

multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

15. (New) The device of claim 14, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.

16. (New) The device of claim 15, wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.

17. (New) The device of claim 15, wherein the multiple segments are pre-shaped and comprise a shape-memory alloy material configured to expand to a desired size and shape.

18. (New) The device of claim 14, wherein at least some electrodes of the multiple pairs of bipolar radiofrequency electrodes have a height that is adjustable relative to a tissue treatment surface of the treatment element, and wherein changing the treatment element from the first configuration to the second configuration comprises adjusting the height of at least some of the electrodes of the multiple pairs of bipolar radiofrequency electrodes.

19. (New) The device of claim 18, wherein the height of the electrodes is adjustable to create a desired treatment surface profile.

20. (New) The device of claim 14, further comprising:

a radiofrequency generator configured to receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and

a cable coupled to the handle for plugging the handle into the radiofrequency generator.

21. (New) The device of claim 20, wherein the radiofrequency generator is configured to deliver the radiofrequency energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts.

22. (New) The device of claim 14, wherein the multiple pairs of bipolar radiofrequency electrodes and the multiple radiofrequency output channels are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes and one of the multiple radiofrequency output channels.

23. (New) The device of claim 14, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.

REMARKS

Claims 1-13 are canceled, and claims 14-23 are added. No new matter is added. Favorable consideration is requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(6612) 332-5300

Date: May 5, 2023

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

23552 7590 06/23/2023

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
06/23/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO23552@merchantgould.com

Office Action Summary	Application No. 17/327,254	Applicant(s) WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08 May 2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 14-23 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 14-23 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 21 May 2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

Claims 14-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 11,033,318. Although the claims at issue are not identical, they are not patentably distinct from each other because the present claims are directed to an obvious variation of a device comprising a reconfigurable treatment element for

delivering energy to a nasal airway comprising multiple pairs of bipolar radiofrequency electrodes and an impedance sensor as claimed in claims 1-17 of U.S. Patent No. 11,033,318.

Allowable Subject Matter

Claims 14-23 are rejected, but would be allowable subject to filing an acceptable Terminal Disclaimer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lettice et al (US 2002/0120259) disclose a related radiofrequency energy device for ablating tissue and teach a surgeon needs to be careful during a nasal tissue ablation procedure to avoid damage to the bone or nerves within and around the nasal cavity. In addition, the disclosure of Lettice et al provides for removing tissue in extremely small depths of to avoid collateral tissue damage, allowing the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3792

6/16/2023

Notice of References Cited	Application/Control No. 17/327,254	Applicant(s)/Patent Under Reexamination WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20020120259-A1	08-2002	Lettice, John J.	A61B18/149	606/41
	B					
	C					
	D					
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	H					
	I					
	J					
	K					
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	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B17/24, A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/1815, A61B18/20, A61B2017/248, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00648, A61B2018/00702, A61B2018/00708, A61B2018/00714, A61B2018/00791, A61B2018/00797, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1465, A61B2018/1467, A61B2018/1807, A61B2018/1861, A61B2090/062, A61B5/01, A61B5/0531, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	06/16/2023	GM

CPC Combination Sets - Searched*		
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US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PE2E-SEARCH Conducted. Inventor Name Search Conducted.	06/16/2023	GM

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/15/2023								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	✓								
	22	✓								
	23	✓								

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2021-05-21
First Named Inventor	
Art Unit	WOLF
Examiner Name	
Attorney Docket Number	17713.0001US18

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4887605	A	1989-12-19	Angelsen et al.	
	2	5348008	A	1994-09-20	Bomn Robert et al.	
	3	5533499	A	1996-07-09	Johnson Bruce C	
	4	5542916	A	1996-08-06	Hirsch Chaya et al.	
	5	5611798	A	1997-03-18	Eggers	
	6	5624439	A	1997-04-29	Edwards Stuart D et al.	
	7	5674191	A	1997-10-07	Edwards Stuart D et al.	
	8	5707349	A	1998-01-13	Edwards Stuart D	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	9	5718702	A	1998-02-17	Edwards Stuart D	
	10	5728094	A	1998-03-17	Edwards Stuart D	
	11	5730719	A	1998-03-24	Edwards Stuart D	
	12	5733280	A	1998-03-31	Avitall	
	13	5738114	A	1998-04-14	Edwards Stuart D	
	14	5743904	A	1998-04-28	Edwards Stuart D	
	15	5743870	A	1998-04-28	Edwards Stuart D	
	16	5746224	A	1998-05-05	Edwards Stuart D	
	17	5800429	A	1998-09-01	Edwards Stuart D	
	18	5807306	A	1998-09-15	Shapland J Edward et al.	
	19	5817049	A	1998-10-06	Edwards Stuart D	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	20	5816095	A	1998-10-06	Nordell Ii Benjamin T et al.	
	21	5820580	A	1998-10-13	Edwards Stuart D et al.	
	22	5823197	A	1998-10-20	Edwards Stuart D	
	23	5827277	A	1998-10-27	Edwards Stuart D	
	24	5843077	A	1998-12-01	Edwards Stuart D	
	25	5843021	A	1998-12-01	Edwards Stuart D et al.	
	26	5846235	A	1998-12-08	Pasricha et al.	
	27	5879349	A	1999-03-09	Edwards Stuart D	
	28	5938659	A	1999-08-17	Tu Hosheng et al.	
	29	6045549	A	2000-04-04	Smethers et al.	
	30	6096033	A	2000-08-01	Tu et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	31	6102907	A	2000-08-15	Smethers et al.	
	32	6109268	A	2000-08-29	Thapliyal et al.	
	33	6126657	A	2000-10-03	Edwards Stuart D et al.	
	34	6131579	A	2000-10-17	Thorson et al.	
	35	6139546	A	2000-10-31	Koenig Franklin R et al.	
	36	6152143	A	2000-11-28	Edwards Stuart D	
	37	6165173	A	2000-12-26	Kamdar Kirti P et al.	
	38	6179803	B1	2001-01-30	Edwards et al.	
	39	6210355	B1	2001-04-03	Edwards et al.	
	40	6228079	B1	2001-05-08	Koenig	
	41	6231569	B1	2001-05-15	Bek et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	42	6293941	B1	2001-09-25	Strul et al.	
	43	6309386	B1	2001-10-30	Bek	
	44	6371926	B1	2002-04-16	Thorson et al.	
	45	6383181	B1	2002-05-07	Johnston et al.	
	46	6391028	B1	2002-05-21	Fanton et al.	
	47	6416491	B1	2002-07-09	Edwards et al.	
	48	6425151	B2	2002-07-30	Barnett	
	49	6431174	B1	2002-08-13	Knudson et al.	
	50	6451013	B1	2002-09-17	Bays et al.	
	51	6502574	B2	2003-01-07	Stevens et al.	
	52	6551310	B1	2003-04-22	Ganz et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	53	6562036	B1	2003-05-13	Ellman et al.	
	54	6575969	B1	2003-06-10	Rittman et al.	
	55	6589235	B2	2003-07-08	Wong et al.	
	56	6659106	B1	2003-12-09	Hovda et al.	
	57	6911027	B1	2005-06-28	Edwards et al.	
	58	6978781	B1	2005-12-27	Jordan	
	59	7055523	B1	2006-06-06	Brown	
	60	7097641	B1	2006-08-29	Arless et al.	
	61	7114495	B2	2006-10-03	Lockwood, Jr.	
	62	7322993	B2	2008-01-29	Metzger et al.	
	63	7361168	B2	2008-04-22	Makower et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	64	7416550	B2	2008-08-26	Protsenko et al.	
	65	7442191	B2	2008-10-28	Hovda et al.	
	66	7655243	B2	2010-02-02	Deem et al.	
	67	7678069	B1	2010-03-16	Baker et al.	
	68	7780730	B2	2010-08-24	Saidi	
	69	7824394	B2	2010-11-02	Manstein	
	70	7850683	B2	2010-12-14	Elkins et al.	
	71	7997278	B2	2011-08-16	Utley et al.	
	72	8114062	B2	2012-02-14	Muni et al.	
	73	8128617	B2	2012-03-06	Bencini et al.	
	74	8137345	B2	2012-03-20	Mcnall, Iii et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	75	8317782	B1	2012-11-27	Ellman et al.	
	76	8317781	B2	2012-11-27	Owens et al.	
	77	8936594	B2	2015-01-20	Wolf et al.	
	78	8986301	B2	2015-03-24	Wolf et al.	
	79	9027597	B2	2015-05-12	Kubo	
	80	9072597	B2	2015-07-07	Wolf et al.	
	81	9125677	B2	2015-09-08	Sobol et al.	
	82	9179967	B2	2015-11-10	Wolf et al.	
	83	9179964	B2	2015-11-10	Wolf et al.	
	84	9237924	B2	2016-01-19	Wolf et al.	
	85	9247989	B2	2016-02-02	Truckai	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	86	9415194	B2	2016-08-16	Wolf et al.	
	87	9433463	B2	2016-09-06	Wolf et al.	
	88	9452087	B2	2016-09-27	Holm et al.	
	89	9452010	B2	2016-09-27	Wolf et al.	
	90	9486278	B2	2016-11-08	Wolf et al.	
	91	9526571	B2	2016-12-27	Wolf et al.	
	92	9687296	B2	2017-06-27	Wolf et al.	
	93	9687288	B2	2017-06-27	Saadat	
	94	9763743	B2	2017-09-19	Lin et al.	
	95	9763723	B2	2017-09-19	Saadat	
	96	9770293	B2	2017-09-26	Dresher	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	97	9788886	B2	2017-10-17	Wolf et al.	
	98	9801752	B2	2017-10-31	Wolf et al.	
	99	9888957	B2	2018-02-13	Wolf et al.	
	100	9913682	B2	2018-03-13	Wolf et al.	
	101	9943361	B2	2018-04-17	Wolf et al.	
	102	10028781	B2	2018-07-24	Saadat	
	103	10028780	B2	2018-07-24	Wolf et al.	
	104	10265115	B2	2019-04-23	Wolf et al.	
	105	10335221	B2	2019-07-02	Wolf et al.	
	106	10376300	B2	2019-08-13	Wolf et al.	
	107	10398489	B2	2019-09-03	Wolf et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	108	10456186	B1	2019-10-29	Wolf et al.	
	109	10456185	B2	2019-10-29	Wolf et al.	
	110	10470814	B2	2019-11-12	Wolf et al.	
	111	10485603	B2	2019-11-26	Wolf et al.	
	112	10603059	B2	2020-03-31	Dinger et al.	
	113	D 880694	S	2020-04-07	Ng et al.	
	114	D 881904	S	2020-04-21	Angeles et al.	
	115	10631925	B2	2020-04-28	Wolf et al.	
	116	10722282	B2	2020-07-28	Wolf et al.	
	117	10779873	B2	2020-09-22	Wolf et al.	
	118	10932853	B2	2021-03-02	Wolf et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

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	1	20020010460	A1	2002-01-24	Joye et al.	
	2	20020016588	A1	2002-02-07	Wong et al.	
	3	20020049464	A1	2002-04-25	Donofrio et al.	
	4	20020087155	A1	2002-07-04	Underwood et al.	
	5	20020128641	A1	2002-09-12	Underwood et al.	
	6	20030144659	A1	2003-07-31	Edwards	
	7	20030208194	A1	2003-11-06	Hovda et al.	
	8	20030225403	A1	2003-12-04	Woloszko et al.	
	9	20040193238	A1	2004-09-30	Mosher et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	10	20040210214	A1	2004-10-21	Knowlton	
	11	20040215235	A1	2004-10-28	Jackson et al.	
	12	20040220644	A1	2004-11-04	Shalev et al.	
	13	20050020901	A1	2005-01-27	Belson et al.	
	14	20050119643	A1	2005-06-02	Sobol et al.	
	15	20050222565	A1	2005-10-06	Manstein	
	16	20050234443	A1	2005-10-20	Rioux et al.	
	17	20050234439	A1	2005-10-20	Underwood	
	18	20050240147	A1	2005-10-27	Makower et al.	
	19	20050288665	A1	2005-12-29	Woloszko	
	20	20060190022	A1	2006-08-24	Beyar et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	21	20060195169	A1	2006-08-31	Gross et al.	
	22	20060235377	A1	2006-10-19	Earley et al.	
	23	20060253117	A1	2006-11-09	Hovda et al.	
	24	20060276817	A1	2006-12-07	Vassallo et al.	
	25	20070043350	A1	2007-02-22	Soltesz et al.	
	26	20070049999	A1	2007-03-01	Esch et al.	
	27	20070066944	A1	2007-03-22	Nyte	
	28	20070073282	A1	2007-03-29	Mcgaffigan et al.	
	29	20070093710	A1	2007-04-26	Maschke	
	30	20070219600	A1	2007-09-20	Gertner et al.	
	31	20070244529	A1	2007-10-18	Choi et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	32	20080004613	A1	2008-01-03	Barbut et al.	
	33	20080027480	A1	2008-01-31	Van Der Burg et al.	
	34	20080027423	A1	2008-01-31	Choi et al.	
	35	20080082090	A1	2008-04-03	Manstein	
	36	20080125626	A1	2008-05-29	Chang et al.	
	37	20080154237	A1	2008-06-26	Chang et al.	
	38	20080183251	A1	2008-07-31	Azar et al.	
	39	20080255642	A1	2008-10-16	Zarins et al.	
	40	20080312644	A1	2008-12-18	Fourkas et al.	
	41	20090018485	A1	2009-01-15	Krespi et al.	
	42	20090124958	A1	2009-05-14	Li et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-05-21
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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	43	20090143821	A1	2009-06-04	Stupak	
	44	20090192505	A1	2009-07-30	Askew et al.	
	45	20090292358	A1	2009-11-26	Saidi	
	46	20090299355	A1	2009-12-03	Bencini et al.	
	47	20100144996	A1	2010-06-10	Kennedy et al.	
	48	20100152730	A1	2010-06-17	Makower et al.	
	49	20100160906	A1	2010-06-24	Jarrard	
	50	20100174283	A1	2010-07-08	Mcnall, Iii et al.	
	51	20100204560	A1	2010-08-12	Salahieh et al.	
	52	20100241112	A1	2010-09-23	Watson	
	53	20100260703	A1	2010-10-14	Yankelson et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	54	20110009737	A1	2011-01-13	Manstein	
	55	20110118726	A1	2011-05-19	De La Rama et al.	
	56	20110180064	A1	2011-07-28	Tanaka et al.	
	57	20110282268	A1	2011-11-17	Baker et al.	
	58	20110288477	A1	2011-11-24	Ressemann et al.	
	59	20110301587	A1	2011-12-08	Deem et al.	
	60	20120029512	A1	2012-02-02	Willard et al.	
	61	20120039954	A1	2012-02-16	Cupit et al.	
	62	20120078377	A1	2012-03-29	Gonzales et al.	
	63	20120179154	A1	2012-07-12	Goldberg et al.	
	64	20120265188	A1	2012-10-18	Buchbinder et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2021-05-21
	First Named Inventor	
	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	65	20120298105	A1	2012-11-29	Osorio	
	66	20120310233	A1	2012-12-06	Dimmer et al.	
	67	20120316557	A1	2012-12-13	Sartor et al.	
	68	20120316473	A1	2012-12-13	Bonutti et al.	
	69	20130116679	A1	2013-05-09	Van Der Weide et al.	
	70	20130158536	A1	2013-06-20	Bloom	
	71	20130218158	A1	2013-08-22	Danek et al.	
	72	20140114233	A1	2014-04-24	Deem et al.	
	73	20150164571	A1	2015-06-18	Saadat	
	74	20160045277	A1	2016-02-18	Lin et al.	
	75	20160121112	A1	2016-05-05	Azar	

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	Attorney Docket Number	17713.0001US18

	76	20180177546	A1	2018-06-28	Dinger et al.	
	77	20180177542	A1	2018-06-28	Wolf et al.	
	78	20180263678	A1	2018-09-20	Saadat	
	79	20180317997	A1	2018-11-08	Dinger et al.	
	80	20180333195	A1	2018-11-22	Greep et al.	
	81	20190076185	A1	2019-03-14	Dinger et al.	
	82	20190201069	A1	2019-07-04	Wolf et al.	
	83	20190231409	A1	2019-08-01	Wolf et al.	
	84	20190282289	A1	2019-09-19	Wolf et al.	
	85	20190336196	A1	2019-11-07	Wolf et al.	
	86	20200100829	A1	2020-04-02	Wolf et al.	

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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	87	20200129223	A1	2020-04-30	Angeles et al.	
	88	20200205884	A1	2020-07-02	Wolf et al.	

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	1	WO2003024349	WO	A1	2003-03-27	Mcclurken et al.		
	2	WO2007037895	WO	A2	2007-04-05	Nyte		
	3	WO2007134005	WO	A1	2007-11-22	Friedman		
	4	CN101325919	CN	A	2008-12-17		corresponding English US2007073282	X
	5	WO2010077980	WO	A1	2010-07-08	Baker et al.		☐
	6	WO2012174161	WO	A1	2012-12-20	Wolf et al.		☐
	7	WO2013028998	WO	A2	2013-02-28	Huszar et al.		☐

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	Filing Date	2021-05-21
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	Examiner Name	
	Attorney Docket Number	17713.0001US18

	8	WO2014022436	WO	A1	2014-02-06	Caplan et al.		☐
	9	WO2015047863	WO	A1	2015-04-02	Kesten et al.		☐
	10	WO2015048806	WO	A2	2015-04-02	Saadat		☐
	11	WO2015153696	WO	A1	2015-10-08	Wolf et al.		☐
	12	WO1999007299	WO		1999-02-18			☐
	13	WO2001043653	WO		2001-06-21			☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Buckley et al., "High-resolution spatial mapping of shear properties in cartilage," J Biomech., 2010 Mar 3;43 (4):796-800, Epub Nov. 5, 2009.	
	2	Buckley et al., "Mapping the depth dependence of shear properties in articular cartilage," J Biomech., 41 (11):2430-2437, Epub Jul. 10, 2008.	
	3	Chen et al., China Journal of Endoscopy, Vol. 11, No. 3. pp. 239-243, March 2005, [English Translation of Title] "Radiofrequency treatment of nasal posterior-under nerve ethmoidal nerve and infraturbinal for perennial allergic rhinitis under nasal endoscope," [also translated as] "Preliminary exploration of radiofrequency thermocoagulation of the posterior inferior nasal nerve, anterior ethmoidal nerve, and inferior nasal concha under nasal endoscopy in the treatment of perennial allergic rhinitis." 9 pages.	

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	Filing Date	2021-05-21
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	Examiner Name	
	Attorney Docket Number	17713.0001US18

	4	Cole, "Biophysics of nasal airflow: a review," Am J Rhinol., 14(4):245-249, Jul-Aug. 2000.
	5	Cole, "The four components of the nasal valve," Am J Rhinol., 17(2):107-110, Mar-Apr. 2003.
	6	Fang et al., J First Mil Med Univ, Vol. 25 No. 7, pp. 876-877, 2005, [English translation of title] "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis" [also translated as] "Nasal Endoscopic Surgery Combined with Multisite Radiofrequency Technology for Treating Perennial Allergic Rhinitis," 4 pages.
	7	Griffin et al., "Effects of enzymatic treatments on the depth-dependent viscoelastic shear properties of articular cartilage," J Orthop Res., 32(12):1652-1657, Epub Sep. 5, 2014.
	8	Kjaergaard et al., "Relation of nasal air flow to nasal cavity dimensions," Arch Otolaryngol Head Neck Surg., 135 (6):565-570, Jun 2009.
	9	Kong et al., Journal of Clinical Otorhinolaryngology, 2005. "Clinical observation on radiofrequency ablation treatment in perennial allergic rhinitis," Retrieved from the Internet: <URL:http://en.cnki.com.cn/Article_en/CJFDTOTAL-LCEH200505015.htm>, 1 page.
	10	Liu et al., China Journal of Endoscopy, Vol. 14, No. 11, pp. 1127-1130, November 2008, [English Translation of Title] "Impact of treatment of perennial rhinitis by radiofrequency thermo-coagulations to vidian and antirior ethomoidal nerves on mucociliary clearance," [also translated as] "Impact of radiofrequency thermocoagulation of bilateral vidian and anterior ethmoidal nerve cluster regions on nasal mucociliary transport function in perennial allergic rhinitis and vasomotor rhinitis." 12 pages.
	11	Silverberg et al., "Structure-function relations and rigidity percolation in the shear properties of articular cartilage," Biophys J., 107(7):1721-1730, Oct. 7, 2014.
	12	Stewart et al., "Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale," Otolaryngol Head Neck Surg., 130(2):157-163, Feb. 2004.
	13	Stupak, "A Perspective on the Nasal Valve," Dept. of Otorhinolaryngology, Albert Einstein College of Medicine, Nov. 6, 2009.
	14	Stupak, "Endonasal repositioning of the upper lateral cartilage and the internal nasal valve," Ann Otol Rhinol Laryngol., 120(2):88-94, Feb. 2011.

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	Attorney Docket Number	17713.0001US18

	15	International Search Report and Written Opinion for PCT/US2012/042316, mailed Aug. 24, 2012, 15 pages.
	16	International Search Report and Written Opinion for PCT/US2014/054726, mailed December 23, 2014, 5 pages.
	17	International Search Report and Written Opinion for PCT/US2015/023742, mailed June 29, 2015, 5 pages.
	18	Singapore Search Report for Application Serial No. 201309238-2, mailed April 17, 2014, 27 pages.
	19	Supplementary European Search Report for Application No. 15772528, mailed September 26, 2017, 7 pages.
	20	Search Report in European Application No. 18204723.3 dated February 18, 2019, 8 pages.
	21	Extended European Search Report for Application No. 19199126.4, mailed December 9, 2019, 6 pages.

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EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	06/15/2023

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	Art Unit	WOLF
	Examiner Name	
	Attorney Docket Number	17713.0001US18

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-05-21
Name/Print	Robert A. Kalinsky	Registration Number	50471

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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L7	1	"20200268439" AND 406a	(US-PGPUB)	OR	ON	ON	2023/06/16 12:58 PM
L8	62	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$4) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR	(US-PGPUB)	OR	ON	ON	2023/06/16 01:09 PM

		A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L9	1	"20200179683" AND channel	(US-PGPUB)	OR	ON	ON	2023/06/16 01:44 PM
L10	1	"20200179683" AND channel AND impedance	(US-PGPUB)	OR	ON	ON	2023/06/16 02:05 PM
L11	44	((("Aerin") near3 ("Medical") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2023/06/16 03:31 PM
L12	135	((("WOLF") near3 ("Scott") near3 ("J"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 03:34 PM
L13	261	((("FRAZIER") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 03:38 PM
L14	62	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$4)	(US-PGPUB)	OR	ON	ON	2023/06/16 03:49 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	95	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR	(USPAT)	OR	ON	ON	2023/06/16 11:40 AM

		A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
N2	75	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR	(USPAT)	OR	ON	ON	2023/06/16 12:16 PM

		A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17327254
Filing Date	2021-05-21
First Named Inventor	Scott J. WOLF
Art Unit	
Examiner Name	
Attorney Docket Number	17713.0001US18

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140088463	A1	2014-03-27	Wolf et al.	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327254
	Filing Date	2021-05-21
	First Named Inventor	Scott J. WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US18

	1	Extended European Search Report for Application No. 21172995.9 mailed July 9, 2021.	

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EXAMINER SIGNATURE

Examiner Signature	/GEORGE MANUEL/	Date Considered	06/15/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327254
	Filing Date	2021-05-21
	First Named Inventor	Scott J. WOLF
	Art Unit	
	Examiner Name	
	Attorney Docket Number	17713.0001US18

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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

A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Robert A. Kalinsky/	Date (YYYY-MM-DD)	2021-08-07
Name/Print	Robert A. Kalinsky	Registration Number	50,471

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

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

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

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

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

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

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

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.M./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	17/327254
Filed:	May 21, 2021
Docket No.:	17713.0001US18

AMENDMENT AND RESPONSE

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

Attention Commissioner:

Please consider the amendments and remarks contained herein in response to the recent action for this patent application.

If a petition for an extension of time under 37 C.F.R. § 1.136(a) is necessary to maintain the pendency of this patent application in connection with this response, and is not otherwise requested in this patent application, it is requested that the Commissioner consider this paper to be a petition for an appropriate extension of time and an authorization for the Commissioner to charge the fee as set forth in 37 C.F.R. § 1.17(a) corresponding to the needed extension of time to Deposit Account No. 13-2725.

REMARKS

This is in response to the non-final Office Action dated June 23, 2023. Favorable reconsideration is requested for at least the following reasons.

Double Patenting

Claims 14-23 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 11,033,318. This rejection is respectfully traversed.

While the correctness of the rejection is not conceded, a terminal disclaimer is filed herewith. Reconsideration is requested.

Allowable Subject Matter

Claims 14-23 are noted as being allowable subject to the filing an acceptable terminal disclaimer. The identification of allowable subject matter is appreciated. All claims are in condition for allowance.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future.

Please contact the undersigned with any questions regarding this patent application.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: July 13, 2023

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/327,254	**07/13/2023 10:44:43 AM ET**	**17713.0001US18**

Title of Invention

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1056	FILED BY	Theresa Powless
PATENT CENTER #	62433962	FILING DATE	05/21/2021
CUSTOMER #	23552	FIRST NAMED INVENTOR	Scott J. WOLF
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Kalinsky

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-07-13--Response--17713.0001US18.PDF	2	Amendment/Request for Reconsideration-After Non-Final Rejection	101 KB
2023-07-13--Terminal Disclaimer 11033318 --17713.0001US18.PDF	2	Terminal Disclaimer Filed	236 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

2023-07-13--Response--17713.0001US18.PDF	764168C83D304D7B068054CB4BF2D92DD32400E2114E76B3E7DC6235EB7D43968E6CAC39C5C2042F428920BD6059F19D827D20FF391E162D23FDF3B9CF2EE04A
2023-07-13--Terminal Disclaimer 11033318 --17713.0001US18.PDF	D412AAE26E40B9B44DA32C5A9926FB534B4CEBFAC815D85601736227222C0616FE68C8A7778367D52CFB60A51258F8AC1D86A2AE0E4C11E0EE84E23E894F568B

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New Applications Under 35 U.S.C. 111

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

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

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

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/327,254	07/13/2023 10:44:43 AM ET	17713.0001US18

Title of Invention

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1056	FILED BY	Theresa Powless
PATENT CENTER #	62433962	AUTHORIZED BY	Robert Kalinsky
CUSTOMER #	23552	FILING DATE	05/21/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Scott J. WOLF

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 4938	E20237CA46236702	Theresa Powless

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
132725	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	$170.00

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New International Application Filed with the USPTO as a Receiving Office

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

PTO/AIA/26 (04-14)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 17713.0001US18

In re Application of: Aerin Medical Inc.

Application No.: 17/327,254

Filed: May 21, 2021

For: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

The applicant, Aerin Medical Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 11,033,318 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 50,471

/Robert A. Kalinsky/ — Signature
July 13, 2023 — Date

Robert A. Kalinsky — Typed or printed name

Attorney of Record — Title
612.332.5300 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013). https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to: 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law; 2) a Federal, state, local, or international agency, in response to its request; 3) a contractor of the USPTO having need for the information in order to perform a contract; 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record; 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record; 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations; 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals; 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)); 9) the Office of Personnel Management (OPM) for personnel research purposes; and 9) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Additional Uses

Additional USPTO uses of the information in this record may include disclosure to: 1) the International Bureau of the World Intellectual Property Organization, if the record is related to an international application filed under the Patent Cooperation Treaty; 2) the public i) after publication of the application pursuant to 35 U.S.C. 122(b), ii) after issuance of a patent pursuant to 35 U.S.C. 151, iii) if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections, or an issued patent, or iv) without publication of the application or patent under the specific circumstances provided for by 37 CFR 1.14(a)(1)(v)-(vii); and/or 3) the National Archives and Records Administration, for inspection of records.

Application Number * 17/327,254 *	Application/Control No. 17/327,254	Applicant(s)/Patent under Reexamination WOLF et al.	
	Examiner MANUEL, GEORGE C	Art Unit 3792	

Document Code - DISQ	Internal Document - DO NOT MAIL

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: 13 July 2023	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/JEAN PROCTOR/

Technology Center: OPLC

Telephone: (571)272-1040

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

23552 7590 08/10/2023

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/10/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	11/13/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23552 7590 08/10/2023

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	11/13/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

23552 7590 08/10/2023

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 08/10/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 17/327,254	Applicant(s) WOLF et al.	
	Examiner GEORGE MANUEL	Art Unit 3792	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the Terminal Disclaimer, filed 7/13/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 14-23 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/GEORGE MANUEL/
Primary Examiner, Art Unit 3792

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Allowable Subject Matter

Claims 14-23 are allowed.

The following is an examiner's statement of reasons for allowance:

A device for delivering radiofrequency energy to a nasal airway comprising multiple bipolar radiofrequency electrodes and output channels and an impedance sensor configured to measure impedance as claimed is not taught nor suggested by the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

The examiner can normally be reached on regular business days.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit: 3792

8/2/2023

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B17/24, A61B17/2816, A61B17/320068, A61B18/02, A61B18/06, A61B18/085, A61B18/1206, A61B18/14, A61B18/1442, A61B18/1445, A61B18/1477, A61B18/1485, A61B18/16, A61B18/1815, A61B18/20, A61B2017/248, A61B2018/00005, A61B2018/00023, A61B2018/0016, A61B2018/00178, A61B2018/0022, A61B2018/00327, A61B2018/00577, A61B2018/00595, A61B2018/00642, A61B2018/00648, A61B2018/00702, A61B2018/00708, A61B2018/00714, A61B2018/00791, A61B2018/00797, A61B2018/00821, A61B2018/00875, A61B2018/00886, A61B2018/0091, A61B2018/00922, A61B2018/00982, A61B2018/00994, A61B2018/0212, A61B2018/0225, A61B2018/0262, A61B2018/1253, A61B2018/126, A61B2018/1425, A61B2018/143, A61B2018/1465, A61B2018/1467, A61B2018/1807, A61B2018/1861, A61B2090/062, A61B5/01, A61B5/0531, A61F5/08, A61F5/56, A61F7/10, A61N1/403, A61N5/025, A61N5/0603, A61N5/0625, A61N7/022, F04C2270/041	06/16/2023	GM
SEARCH Updated.	08/02/2023	GM

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	Art Unit
	GEORGE MANUEL	3792

Search Notes		
Search Notes	**Date**	**Examiner**
PE2E-SEARCH Conducted. Inventor Name Search Conducted.	06/16/2023	GM
PE2E-SEARCH Updated. Interference Search History Printout.	08/02/2023	GM

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61B	17/24, 17/2816, 17/320068, 18/02, 18/06, 18/085, 18/1206, 18/14, 18/1442, 18/1445, 18/1477, 18/1485, 18/16, 18/1815, 18/20, 2017/248, 2018/00005, 2018/00023, 2018/0016, 2018/00178, 2018/0022, 2018/00327, 2018/00577, 2018/00595, 2018/00642, 2018/00648, 2018/00702, 2018/00708, 2018/00714, 2018/00791, 2018/00797, 2018/00821, 2018/00875, 2018/00886, 2018/0091, 2018/00922, 2018/00982, 2018/00994, 2018/0212, 2018/0225, 2018/0262, 2018/1253, 2018/126, 2018/1425, 2018/143, 2018/1465, 2018/1467, 2018/1807, 2018/1861, 2090/062, 5/01, 5/0531	08/02/2023	GM
A61F	5/08, 5/56, 7/10	08/02/2023	GM
A61N	1/403, 5/025, 5/0603, 5/0625, 7/022	08/02/2023	GM
F04C	2270/041	08/02/2023	GM

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

CPC								
Symbol							**Type**	**Version**
A61B	/	18	/	02			F	2013-01-01
A61B	/	18	/	1477			I	2013-01-01
A61B	/	18	/	1445			I	2013-01-01
A61B	/	18	/	1442			I	2013-01-01
A61B	/	18	/	06			I	2013-01-01
A61B	/	18	/	20			I	2013-01-01
A61F	/	5	/	56			I	2013-01-01
A61F	/	5	/	08			I	2013-01-01
A61N	/	5	/	025			I	2013-01-01
A61B	/	5	/	01			I	2013-01-01
A61N	/	7	/	022			I	2013-01-01
A61F	/	7	/	10			I	2013-01-01
A61N	/	1	/	403			I	2013-01-01
A61B	/	17	/	2816			I	2013-01-01
A61N	/	5	/	0603			I	2013-01-01
A61N	/	5	/	0625			I	2013-01-01
A61B	/	18	/	14			I	2013-01-01
A61B	/	18	/	1485			I	2013-01-01
A61B	/	18	/	16			I	2013-01-01
A61B	/	18	/	1206			I	2013-01-01
A61B	/	18	/	085			I	2013-01-01
A61B	/	18	/	1815			I	2013-01-01
A61B	/	2018	/	0262			A	2013-01-01
A61B	/	17	/	320068			A	2013-01-01
A61B	/	2018	/	0091			A	2013-01-01
F04C	/	2270	/	041			A	2013-01-01
A61B	/	2018	/	143			A	2013-01-01
A61B	/	2018	/	00023			A	2013-01-01
A61B	/	2018	/	00005			A	2013-01-01
A61B	/	2018	/	00922			A	2013-01-01
A61B	/	2018	/	00821			A	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	10	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	02 August 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

U.S. Patent and Trademark Office — Part of Paper No.: 20230802

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

CPC						
Symbol					**Type**	**Version**
A61B	/	2018	/	00702	A	2013-01-01
A61B	/	2018	/	00994	A	2013-01-01
A61B	/	2018	/	0016	A	2013-01-01
A61B	/	2018	/	00178	A	2013-01-01
A61B	/	2018	/	00791	A	2013-01-01
A61B	/	2018	/	00886	A	2013-01-01
A61B	/	2018	/	1425	A	2013-01-01
A61B	/	2017	/	248	A	2013-01-01
A61B	/	2018	/	00708	A	2013-01-01
A61B	/	2018	/	1807	A	2013-01-01
A61B	/	2018	/	00577	A	2013-01-01
A61B	/	2018	/	1861	A	2013-01-01
A61B	/	2018	/	0212	A	2013-01-01
A61B	/	2018	/	00982	A	2013-01-01
A61B	/	2018	/	00875	A	2013-01-01
A61B	/	2018	/	00642	A	2013-01-01
A61B	/	2018	/	0225	A	2013-01-01
A61B	/	2018	/	0022	A	2013-01-01
A61B	/	2018	/	00595	A	2013-01-01
A61B	/	2018	/	1253	A	2013-01-01
A61B	/	2018	/	00327	A	2013-01-01
A61B	/	2018	/	126	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	10	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	02 August 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

U.S. Patent and Trademark Office — Part of Paper No.: 20230802

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B18/02	/	18	/	02	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	10	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792	02 August 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5B

U.S. Patent and Trademark Office — Part of Paper No.: 20230802

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,254	WOLF et al.
	Examiner	**Art Unit**
	GEORGE MANUEL	3792

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	14	10	23												
2	15														
3	16														
4	17														
5	18														
6	19														
7	20														
8	21														
9	22														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 10	
/GEORGE MANUEL/ Primary Examiner, Art Unit 3792 (Primary Examiner)	02 August 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 5B

U.S. Patent and Trademark Office

Part of Paper No.: 20230802

Bibliographic Data

Application No: 17/327,254

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /GEORGE MANUEL/ Examiner's Signature | Initials

Title: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/21/2021	606	3792	17713.0001US18
RULE			

APPLICANTS

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INVENTORS

Scott J. WOLF, Menlo Park, CA, UNITED STATES

Andrew FRAZIER, Sunnyvale, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 16412982 05/15/2019 PAT 11033318

16412982 is a CON of 15686265 08/25/2017 PAT 10335221

15686265 is a CON of 15272007 09/21/2016 PAT 9788886

15272007 is a CON of 14754087 06/29/2015 PAT 9452010

14754087 is a CON of 14319087 06/30/2014 PAT 9072597

14319087 is a CIP of 13495844 06/13/2012 PAT 8936594

13495844 has PRO of 61603864 02/27/2012

13495844 has PRO of 61496930 06/14/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

05/27/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

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MINNEAPOLIS, MN 55402-0903

UNITED STATES

FILING FEE RECEIVED

$1,120

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	"11033318".pn.	(USPAT)	OR	ON	ON	2023/06/15 07:58 PM
L2	206	("10028780" OR "10028781" OR "10265115" OR "10335221" OR "10376300" OR "10398489" OR "10456185" OR "10456186" OR "10470814" OR "10485603" OR "10603059" OR "10631925" OR "10722282" OR "10779873" OR "10932853" OR "20020010460" OR "20020016588" OR "20020049464" OR "20020087155" OR "20020128641" OR "20030144659" OR "20030208194" OR "20030225403" OR "20040193238" OR "20040210214" OR "20040215235" OR "20040220644" OR "20050020901" OR "20050119643" OR "20050222565" OR "20050234439" OR "20050234443" OR "20050240147" OR "20050288665" OR "20060190022" OR "20060195169" OR "20060235377" OR "20060253117" OR "20060276817" OR "20070043350" OR "20070049999" OR "20070066944" OR "20070073282" OR "20070093710" OR "20070219600" OR "20070244529" OR "20080004613" OR "20080027423" OR "20080027480" OR "20080082090" OR "20080125626" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/06/15 10:12 PM

		"20080154237" OR "20080183251" OR "20080255642" OR "20080312644" OR "20090018485" OR "20090124958" OR "20090143821" OR "20090192505" OR "20090292358" OR "20090299355" OR "20100144996" OR "20100152730" OR "20100160906" OR "20100174283" OR "20100204560" OR "20100241112" OR "20100260703" OR "20110009737" OR "20110118726" OR "20110180064" OR "20110282268" OR "20110288477" OR "20110301587" OR "20120029512" OR "20120039954" OR "20120078377" OR "20120179154" OR "20120265188" OR "20120298105" OR "20120310233" OR "20120316473" OR "20120316557" OR "20130116679" OR "20130158536" OR "20130218158" OR "20140114233" OR "20150164571" OR "20160045277" OR "20160121112" OR "20180177542" OR "20180177546" OR "20180263678" OR "20180317997" OR "20180333195" OR "20190076185" OR "20190201069" OR "20190231409" OR "20190282289" OR "20190336196" OR "20200100829" OR "20200129223" OR "20200205884" OR "4887605" OR "5348008" OR "5533499" OR "5542916" OR "5611798" OR "5624439" OR					

		"5674191" OR "5707349" OR "5718702" OR "5728094" OR "5730719" OR "5733280" OR "5738114" OR "5743870" OR "5743904" OR "5746224" OR "5800429" OR "5807306" OR "5816095" OR "5817049" OR "5820580" OR "5823197" OR "5827277" OR "5843021" OR "5843077" OR "5846235" OR "5879349" OR "5938659" OR "6045549" OR "6096033" OR "6102907" OR "6109268" OR "6126657" OR "6131579" OR "6139546" OR "6152143" OR "6165173" OR "6179803" OR "6210355" OR "6228079" OR "6231569" OR "6293941" OR "6309386" OR "6371926" OR "6383181" OR "6391028" OR "6416491" OR "6425151" OR "6431174" OR "6451013" OR "6502574" OR "6551310" OR "6562036" OR "6575969" OR "6589235" OR "6659106" OR "6911027" OR "6978781" OR "7055523" OR "7097641" OR "7114495" OR "7322993" OR "7361168" OR "7416550" OR					

		"7442191" OR "7655243" OR "7678069" OR "7780730" OR "7824394" OR "7850683" OR "7997278" OR "8114062" OR "8128617" OR "8137345" OR "8317781" OR "8317782" OR "8936594" OR "8986301" OR "9027597" OR "9072597" OR "9125677" OR "9179964" OR "9179967" OR "9237924" OR "9247989" OR "9415194" OR "9433463" OR "9452010" OR "9452087" OR "9486278" OR "9526571" OR "9687288" OR "9687296" OR "9763723" OR "9763743" OR "9770293" OR "9788886" OR "9801752" OR "9888957" OR "9913682" OR "9943361" OR "D880694" OR "D881904").pn.					
L3	1	"17327254"	(US-PGPUB)	OR	ON	ON	2023/06/16 11:30 AM
L4	176	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR	(US-PGPUB)	OR	ON	ON	2023/06/16 11:37 AM

		A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L5	139	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR	(US-PGPUB)	OR	ON	ON	2023/06/16 12:35 PM

		A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L6	121	(energy AND nasal AND bipolar SAME radiofrequency SAME	(US-PGPUB)	OR	ON	ON	2023/06/16 12:47 PM

		electrode AND impedance SAME sens$4) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR					

		A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L7	1	"20200268439" AND 406a	(US-PGPUB)	OR	ON	ON	2023/06/16 12:58 PM
L8	62	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$4) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR	(US-PGPUB)	OR	ON	ON	2023/06/16 01:09 PM

		A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L9	1	"20200179683" AND channel	(US-PGPUB)	OR	ON	ON	2023/06/16 01:44 PM
L10	1	"20200179683" AND channel AND impedance	(US-PGPUB)	OR	ON	ON	2023/06/16 02:05 PM
L11	44	((("Aerin") near3 ("Medical") near3 ("Inc"))).AS,AANM.	(USPAT)	OR	ON	ON	2023/06/16 03:31 PM
L12	135	((("WOLF") near3 ("Scott") near3 ("J"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 03:34 PM
L13	261	((("FRAZIER") near3 ("Andrew"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/06/16 03:38 PM
L14	62	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$4)	(US-PGPUB)	OR	ON	ON	2023/06/16 03:49 PM
L15	42	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$3)	(US-PGPUB)	OR	ON	ON	2023/08/02 06:12 PM
L16	140	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode$ AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR	(US-PGPUB)	OR	ON	ON	2023/08/02 06:52 PM

		A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
L17	1	"17327254"	(USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV,	OR	ON	ON	2023/08/02 07:30 PM

			MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L18	100	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode$ AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR	(USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/02 07:30 PM

		A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	95	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR	(USPAT)	OR	ON	ON	2023/06/16 11:40 AM

		A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
N2	75	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR	(USPAT)	OR	ON	ON	2023/06/16 12:16 PM

		A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					
N3	24	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode AND impedance SAME sens$4 AND deform$3)	(USPAT)	OR	ON	ON	2023/08/02 06:28 PM
N4	80	(energy AND nasal AND bipolar SAME radiofrequency SAME electrode$ AND impedance) AND ((A61B17/24 OR A61B17/2816 OR A61B17/320068 OR A61B18/02 OR A61B18/06 OR A61B18/085 OR A61B18/1206 OR A61B18/14 OR A61B18/1442 OR A61B18/1445 OR A61B18/1477 OR	(USPAT)	OR	ON	ON	2023/08/02 06:46 PM

		A61B18/1485 OR A61B18/16 OR A61B18/1815 OR A61B18/20 OR A61B2017/248 OR A61B2018/00005 OR A61B2018/00023 OR A61B2018/0016 OR A61B2018/00178 OR A61B2018/0022 OR A61B2018/00327 OR A61B2018/00577 OR A61B2018/00595 OR A61B2018/00642 OR A61B2018/00648 OR A61B2018/00702 OR A61B2018/00708 OR A61B2018/00714 OR A61B2018/00791 OR A61B2018/00797 OR A61B2018/00821 OR A61B2018/00875 OR A61B2018/00886 OR A61B2018/0091 OR A61B2018/00922 OR A61B2018/00982 OR A61B2018/00994 OR A61B2018/0212 OR A61B2018/0225 OR A61B2018/0262 OR A61B2018/1253 OR A61B2018/126 OR A61B2018/1425 OR A61B2018/143 OR A61B2018/1465 OR A61B2018/1467 OR A61B2018/1807 OR A61B2018/1861 OR A61B2090/062 OR A61B5/01 OR A61B5/0531 OR A61F5/08 OR A61F5/56 OR A61F7/10 OR A61N1/403 OR A61N5/025 OR A61N5/0603 OR A61N5/0625 OR A61N7/022 OR F04C2270/041).cpc.)					

UNITED STATES
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/327,254	**08/15/2023 05:22:14 PM ET**	**17713.0001US18**

Title of Invention

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1056	FILED BY	Theresa Powless
PATENT CENTER #	62621392	FILING DATE	05/21/2021
CUSTOMER #	23552	FIRST NAMED INVENTOR	Scott J. WOLF
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Kalinsky

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-08-15--Part B-Fees Xmtl--17713.0001US18.PDF	1	Issue Fee Payment (PTO-85B)	209 KB
2023-08-15--Comments re RFA--17713.0001US18.PDF	2	Miscellaneous Incoming Letter	51 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-08-15--Part B-Fees Xmtl--17713.0001US18.PDF	B6263EBD3FAEE20790782D8295D6AF7AEADE0BF3C53EED263D46AE11A981CECC1198726368FCF207B884EF443EA798B5C

B6F1CA3E5F872157A349355663EBD52

2023-08-15--Comments re RFA--17713.0001US18.PDF	6D79B77E5BB76B26903B1D265D7A448EF0F9FCF43098E9B53 3FC540BB9763CD8FA3D60F6A5F06E1F8A11288BCF2DC31E7 AF9F3FA98F849BA7CCD54C9B8DC037A

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/327,254	08/15/2023 05:22:14 PM ET	17713.0001US18

Title of Invention

METHODS AND DEVICES TO TREAT NASAL AIRWAYS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1056	FILED BY	Theresa Powless
PATENT CENTER #	62621392	AUTHORIZED BY	Robert Kalinsky
CUSTOMER #	23552	FILING DATE	05/21/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Scott J. WOLF

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 4938	E20238EH24016933	Theresa Powless

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
132725	37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2501	UTILITY ISSUE FEE	480.00	1	480.00
			TOTAL AMOUNT:	$480.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

Receipt will establish the filing date of the application

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

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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23552 7590 08/10/2023
MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

TITLE OF INVENTION: METHODS AND DEVICES TO TREAT NASAL AIRWAYS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	11/13/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MANUEL, GEORGE C	3792	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Merchant & Gould P.C.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Aerin Medical Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Sunnyvale, California

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ☒ Corporation or other private group entity ❑ Government

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 13-2725

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Robert A. Kalinsky/ Date August 15, 2023

Typed or printed name Robert A. Kalinsky Registration No. 50471

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	17/327254
Filed:	May 21, 2021
Docket No.:	17713.0001US18

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

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

Attention Commissioner:

This is in response to the recent Notice of Allowance for this patent application. Applicants point out that the reasons set forth by the Examiner are not the only reasons that these claims are allowable.

Applicants agree with the Examiner's Reasons for Allowance in the Notice of Allowance to the extent that the claims of the present application are patentable over the references in the record. However, Applicants do not necessarily acquiesce or agree in any manner as to the comments made by the Examiner regarding what the prior art does or does not teach. In addition, Applicants respectfully traverse the Examiner's Reasons for Allowance to the extent that any comment is intended or has the effect of limiting a claim scope, explicitly or implicitly, by not reciting verbatim the respective claim language, or is intended or has the effect of limiting a claim scope by stating or implying that all the reasons for patentability are in any way fully enumerated.

Further reasons for allowance beyond those enumerated by the Examiner are described and set forth in the Applicant's specification. As the Examiner's reasons for allowance are not exhaustive, such reasons for allowance do not establish an estoppel against Applicants seeking and obtaining allowance of additional, broader claims in a continuation application.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: August 15, 2023

/Robert A. Kalinsky/
Name: Robert A. Kalinsky
Reg. No.: 50,471

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	09/26/2023	11766286	17713.0001US18	1056

23552 7590 09/06/2023

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 337 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (https://patentcenter.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Scott J. WOLF, Menlo Park, CA;
Andrew FRAZIER, Sunnyvale, CA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Aerin Medical, Inc., Sunnyvale, CA;

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,254	05/21/2021	Scott J. WOLF	17713.0001US18	1056

23552 7590 09/26/2023

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MINNEAPOLIS, MN 55402-0903

EXAMINER	
MANUEL, GEORGE C	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
09/26/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO23552@merchantgould.com

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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/327,254	26-Sep-2023	11766286

MERCHANT & GOULD P.C.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants