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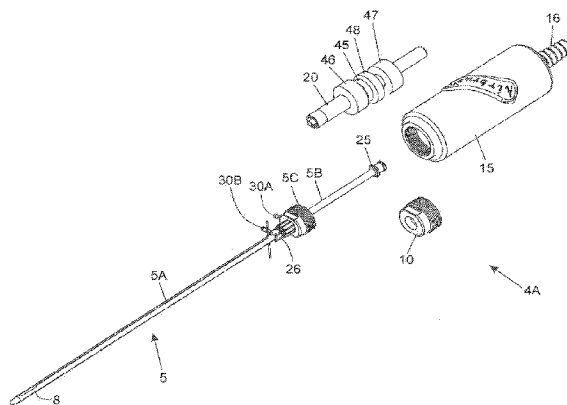


FIG. 2A2

(57) Abstract: A method of and apparatus for safely removing visceral fatty tissue from the patient's mesentery and omentum is disclosed. The method involves using a novel minimally invasive or laparoscopic surgical procedure involving the inflation of the abdominal region with gas that creates a space between the wall of the abdomen and the organs inside. Using short incisions in the skin, narrow tubes are inserted through the abdominal wall so that a laparoscopically-guided electro-cauterizing and irrigating visceral fat aspiration instrument can be passed through the incision to perform the maneuvers necessary for the operation. Removal of visceral fat from the mesentery is observed directly on a video monitor, which receives its picture from a video camera attached to the laparoscope. Using this technique, it is now possible to safely remove visceral fat from the patient's mesentery to treat abdominal obesity, type II diabetes mellitus and/or metabolic syndrome in human patients.

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METHOD OF AND APPARATUS FOR TREATING ABDOMINAL OBESITY, METABOLIC SYNDROME AND TYPE II DIABETES MELLITUS IN HUMAN PATIENTS

Applicant: Rocin Laboratories, Inc.

BACKGROUND OF THE INVENTION

Field of The Invention:

The present invention relates to a novel way of and means for treating abdominal obesity, metabolic syndrome and Type II diabetes mellitus in human patients.

Brief Description of the State of Knowledge in the Art

In general, there are three kinds of fat in the human body: subcutaneous fat, intramuscular fat, and visceral fat.

Subcutaneous fat is found underneath the skin, and intramuscular fat is found interspersed in skeletal muscle. Fat in the lower body, e.g. in thighs and buttocks, is subcutaneous. Visceral fat, also known as organ fat or intra-abdominal fat, is located inside the peritoneal cavity, packed in between the internal organs and torso of the abdomen. There are several adipose tissue deposits of visceral fat in the human body, namely: mesenteric, epididymal white adipose tissue, and perirenal deposits. [Adipose tissue as an endocrine organ Kershaw EE, Flier JS. J. Clin. Endocrinol. Metab. 89 (6): 2548–56 (2004).] An excess of visceral fat is known as central obesity, "belly fat," the "pot belly" or "beer belly," where the abdomen protrudes excessively.

Over 250 years ago, Johannes Baptista Morgagni described android obesity as increased intra-abdominal and mediastinal fat accumulation. Back then, he recognized the association between visceral obesity, hypertension, hyperuricemia, atherosclerosis, and obstructive sleep apnea syndrome. [Historical perspective: visceral obesity and its relation to morbidity in Johannes Baptista Morgagni's 'De sedibus et causis morborum per anatomen indagata' Enzi G, Busetto L, Inelmen EM, Coin A, Sergi G Int. J. Obes Relat Metab Disord 27: 534-535 (2003)]

Today, Morgagni's android obesity condition is now described as *metabolic syndrome*, and is associated with insulin resistance and increased risk of Coronary Heart Disease. The Metabolic syndrome is a condition defined by any three of five risk factors, one of which is waist circumference (female waist >88 cm (>35"), male waist >102 cm.>40"). The others are triglycerides: (men < 40mg/dl; women < 50 mg/dl), HDL cholesterol (≥ 110 mg/dl), blood pressure ($\geq 130/ \geq 85$ mm Hg), and FBS (>150 ml/dl). [Dyslipidemia of central obesity and insulin resistance. Brunzell, JD, Hokanson, JE Diabetes Care: 22(3); Mediastinal fat, insulin resistance and hypertension. Sharma AM Hypertension: 44:117 (2004)].

Over the past 40 years, the prevalence of obesity in the US increased from 13% to 32%. In 2003-2004, 66% of U.S. adults were overweight or obese.

Abdominal obesity as measured by waist circumference and waist hip ratio (WHR) is an independent predictor of mortality. Marginally increased waist circumference is strongly associated with prevalent hypertension in normal-weight and overweight adults. Also, there is a strong correlation between central (i.e. abdominal) obesity and cardiovascular disease. [Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries. Yusuf S, Hawken S, Ounpu S, Dans T, Avezum A, Lanas F, McQueen M, Budaj A, Pais P, Varigos J, Lisheng L, Lancet 364: 937-52 (2004).] Because of this, the WHR ratio has been used as a measure of obesity and is an indicator or measure of the health of a person, and the risk of developing serious health conditions. Research shows that people with "apple-shaped" bodies (with more weight around the waist) face more health risks than those with "pear-shaped" bodies who carry more weight around the hips. [Waist-hip ratio should replace Body Mass Index as an indicator of mortality risk in older people. Am. J. Clin. Nutrition (Aug. 12, 2006).]

A WHR of 0.7 for women and 0.9 for men have been shown to correlate strongly with general health and fertility. Women within the 0.7 range have optimal levels of estrogen and are less susceptible to major diseases such as diabetes, cardiovascular disorders and ovarian cancers. Men with WHR's around 0.9, similarly, have been shown to be more healthy and fertile with less prostate cancer and testicular cancer. Studies show that 80 percent of women over the age of 18 have a WHR of at least 0.9. This is a 40 percent increase since 2002, and it keeps increasing.

Although maintaining a healthy weight is a cornerstone in the prevention of chronic diseases and premature death, maintaining a healthy waist size should also be an important goal.

Markedly obese patients are typically directed towards diet and exercise programs, and failing that, presented with the option of bariatric surgery or living with and dying from the increased morbidity of obesity. After bariatric surgery, plastic surgeons perform skin excisions of the redundant folds of tissue remaining on patients who had lost 50 – 200 lbs. These post-bariatric surgery patients are frequently nutritional cripples with hypoalbuminemia, cirrhosis, and renal stones and suffer increased complications reflecting their impaired nutritional status.

Traditional plastic surgical approaches have been cosmetic, targeted only at removing (i) localized subcutaneous fat deposits in non-obese or modestly obese patients, and (ii) the redundant folds of abdominal wall or pannus that remain after massive weight loss from gastric banding or intestinal bypass procedures.

Before subcutaneous visceral fat aspiration, combined hemostasis and analgesia is achieved in the patient by infusing tumescent solutions of lactated Ringer's solution, containing dilute amounts of xylocaine and epinephrine. Performing *tumescent visceral fat aspiration* in this manner allows increased volumes of fat to be removed and obviates the need for general anaesthesia which, in turn, facilitates outpatient surgery in office-based facilities. [Tumescent Technique Klein, J. Mosby (2000).]

Studies have now shown large volume subcutaneous fat aspiration and abdominoplasty as feasible alternatives for improving body shape. [Large-volume visceral fat aspiration and extensive

abdominoplasty: a feasible alternative for improving body shape. Cardenas-Camarena L, Gonzalez LE *Plast Reconstr Surg.* 102: 1698-707 (1998).]

Clinical studies have shown large volumes of fat can be safely removed in serial visceral fat aspiration procedures performed at safe intervals. Pilot studies have also shown improvement in the cardiovascular risk profile with large volume subcutaneous visceral fat aspiration. [Improvements in cardiovascular risk profile with large-volume visceral fat aspiration: a pilot study. Giese SY, Bulan EJ, Commons GW, Spear SL, Yanovski JA. *Plastic Reconstr Surg.* 108 510-21(2001).]

However, it should be noted that such large volume subcutaneous fat aspiration approaches are still mainly cosmetic, as only the less metabolically active, subcutaneous fat is addressed and removed during such procedures.

Recently, animal research has discovered that only the removal of visceral fat in mice has been shown to stop insulin resistance. [Visceral fat removal stops insulin resistance. Barzilai N. *Diabetes* 51: 2951-2958 (2002).] Increased visceral fat shortens mammalian longevity and its removal lengthens it. [Visceral adipose tissue modulates mammalian longevity. Muzumdar R., Allison DB, Huffman, DM, Xiaohui M, Einstein, FH, Fishman S, Poduval AD, McVei T, Keith, SW, Barzilai, N. *Aging Cell* 7(3) 438-440 (2008).] [The effect of fat removal on glucose tolerance is depot specific in male and female mice. Haifei S, Strader AD, Woods, SC, Seeley, RJ *Am. J. Physiol Endocrinol Metab* 293: E1012-1020 (2007).]

Adipose tissue is a metabolically active tissue and serves as an important endocrine organ. The hypertrophic fat cells of adipose tissue in obese patients produce increased quantities of leptin and tumor necrosis factor- α (TNF- α) and are less sensitive to insulin. Studies have revealed effect of visceral fat aspiration on insulin resistance and vascular inflammatory markers in obese women. Giugliano G, Nicoletti G, Grella E, Giugliano F, Esposito K, Scuderi N, D'Andrea F. *Br J Plast Surg.* 2004 Apr; 57(3): 190-4.) The most important secreted products of fat cells are leptin, resistin, tumornecrosisfactor- α (TNF- α), and adiponectin. The first three products are increased in obese patients as a result of increased production by enlarged fatcells. In contrast, adiponectin, which improves glucose handling by peripheral tissues, is present at lower levels in obese patients [Bastard JP, MaachiM, van Nhieu JT, Jardel C, Bruckert E, Grimaldi A, Robert JJ, Capeau J, Hainque B: Adipose tissue content correlates with resistance to insulin activation of glucose uptake both *invivo* and *invitro*. *J Clin Endocrinol Metab* 87:2084-2089, 2002; Borst SE: The role of TNF- α in insulinresistance. *Endocrine*23: 177, 2004; Fernandez-Real JM, Lopez-Bermejo A, Casamitjana R, et al.: Novel interactions of adiponectin with the endocrine system and inflammatory parameters. *J Clin Endocrinol Metab* 88:2714-2718, 2003; Rashid MN, Fuentes F, Touchon RC, Wehner PS: Obesity and the risk for cardiovascular disease. *Prev Cardiol*6: 42-47, 2003].

Hypertrophic fat cells present in the subcutaneous tissue of obese patients generally produce increased quantities of secreted products such as leptin [Friedman JM: Obesity in the new millennium. *Nature* 404: 632,2000] and TNF- α [Hotamisligil GS, Shargill NS, Spiegelman BM: Adi-pose expression of tumor necrosis factor- α : Direct role in obesity-linked insulin resistance. *Science* 259:87, 1993], but

are less sensitive to insulin in vivo and in vitro [Chlouverakis C, Hojnicky D: Effect of fat cell size on its sensitivity to insulin measured by a new method. *Steroids Lipids Res* 5:351,1974; Olefsky JM: Mechanism of decreased responsiveness of large adipocytes. *Endocrinology* 100:1169, 1977].

Many studies assert that excising a large amount of subcutaneous fat by large-volume visceral fat aspiration (LVL) is metabolically safe [Giese SY, Bulan EJ, Commons GW, et al.: Improvements in cardiovascular risk profile with large-volume visceral fat aspiration: A pilot study. *Plast Reconstr Surg* 108:510, discussion 520, 2001; Gonzalez-Ortiz M, Robles-Cervantes JA, Cardenas-Camarena L, et al.: The effects of surgically removing subcutaneous fat on the metabolic profile and insulin sensitivity in obese women after large-volume liposuction treatment. *Horm Metab Res* 34:446,2002; Robles-Cervantes JA, Yanez-Diaz S, Cardenas-Camarena L: Modification of insulin, glucose, and cholesterol levels in nonobese women undergoing visceral fat aspiration. *Ann Plast Surg* 52:64,2004] and associated with improvement in inflammatory markers and insulin sensitivity in obese women [Giugliano G, Nicoletti G, Grella E, et al.: Effect of visceral fat aspiration on insulin resistance and vascular inflammatory markers in obese women. *Br J Plast Surg* 57:190, 2004; Gonzalez-Ortiz M, Robles-Cervantes JA, Cardenas-Camarena L, et al.: The effects of surgically removing subcutaneous fat on the metabolic profile and insulin sensitivity in obese women after large-volume visceral fat aspiration treatment. *Horm Metab Res* 34:446,2002] and nonobese women [Robles-Cervantes JA, Yanez-Diaz S, Cardenas-Camarena L: Modification of insulin, glucose, and cholesterol levels in nonobese women undergoing visceral fat aspiration. *Ann Plast Surg* 52:64,2004]

Also, it is known that visceral fat cells within the abdomen have their secretions poured directly into the portal blood circulation with a much more profound effect on metabolism. Human mesenteric adipose tissue in obese diabetic subjects has high basal glycerol release and impaired isoproterenol stimulated glycerol release. The obesity-related gene expressions in the mesenteric adipose tissue are up regulated, suggesting that the alterations of these genes in mesenteric adipose depot may play a critical role in insulin resistance of type 2 diabetes and metabolic syndrome. [Cell Physiol Biochem. 2008; 22(5-6):531-8. Epub 2008 Dec 9. Human mesenteric adipose tissue plays unique role versus subcutaneous and omental fat in obesity related diabetes. Yang YK, Chen M, Clements RH, Abrams GA, Aprahamian CJ, Harmon CM.]

In Brazil, clinical trials are being carried out with partial omentectomy to determine the effect on insulin sensitivity. However, such studies have used direct surgical excision, posing high risk of vascular injury, with concomitant bleeding and vascular compromise of the intestine. [Surgical removal of visceral fat tissue (omentectomy) associated to bariatric surgery: effect on insulin sensitivity. Clinical Trials NCT00545805 University of Campinas, Brazil].

Thus, while there is great promise that the removal of visceral fat in the mesenteric region of human patients stands to ameliorate the metabolic syndrome and abdominal obesity, and reduce morbidity due to obesity, there is a great need in the art for a new and improved method of and apparatus for safely removing visceral fat in human patients, without employing conventional direct surgical excision

techniques, and posing high risk of vascular injury with concomitant bleeding and vascular compromise of the intestine, associated with conventional surgical procedures and apparatus.

OBJECTS OF THE PRESENT INVENTION

Accordingly, it is a primary object of the present invention to provide a new and improved method of and apparatus for safely removing mesenteric fat in human patients to ameliorate the metabolic syndrome, or abdominal obesity, while avoiding the shortcomings and drawbacks of conventional surgical procedures and apparatus.

Another object of the present invention is to provide such an apparatus in the form of a laparoscopically-guided intra-abdominal visceral fat aspiration system including a powered hand-supportable fat aspiration instrument held by a surgeon and having an electro-cauterizing, irrigating and fiber-illuminating twin-cannula assembly for the safe removal of visceral fat from the mesenteric region of a patient, through a small incision in the patient's body.

Another object of the present invention is to provide such a laparoscopically-guided intra-abdominal visceral fat aspiration system, designed for safely removing visceral fat from the mesenteric region of a patient.

Another object of the present invention is to provide such a laparoscopically-guided intra-abdominal visceral fat aspiration system, wherein twin-cannula assembly support bipolar electro-cauterization about the aspiration aperture of a moving inner cannula, supported in a stationary outer cannula connected to the hand-supportable housing of the instrument.

Another object of the present invention is to provide a novel method of and apparatus for performing laparoscopic mesenteric visceral fat aspiration for ameliorating the metabolic syndrome, or abdominal obesity of the patient.

Another object of the present invention is to provide such a method comprising the steps of inserting a laparoscopic instrument and an electro-cauterizing visceral fat aspiration instrument into the mesenteric region of a patient, for the purpose of safely removing visceral fat to ameliorate the metabolic syndrome, or abdominal obesity of the patient.

Another object of the present invention is to provide a novel method of laparoscopically-guided intra-abdominal visceral fat aspiration, involving the simultaneously infusion of a tumescent solution into the mesenteric region of treatment, while synchronizing that infusion with the forward or return ("action") stroke of the inner cannula of the twin (dual) cannula assembly of the instrument.

Another object of the present invention is to provide a novel system for removing both subcutaneous and visceral fat deposits in a minimally invasive manner.

A further object of the present invention is to provide a novel method of minimally invasive visceral fat aspiration which is equally applicable to both subcutaneous and visceral fat deposits.

Yet a further object of the present invention is to provide a novel method of a lowering of the waist-to-hips circumference ratio, a treatment for and amelioration of type II diabetes mellitus, effect a

favorable effect on metabolism as may be comprised of an increased insulin sensitivity, lowered fasting blood sugar, a lowering of blood pressure (particularly diastolic), an improvement in the lipid profile (lowered cholesterol, raising HDL, lowered triglycerides, lowered serum adipocytokine (Leptin) and inflammatory markers (TNF- α = tumor necrosis factor, resitin, IL-6 and IL-9), and by doing so effect a decrease in insulin resistance and reduce the risk of coronary artery disease associated with metabolic syndrome.

Another object of the present invention is to provide a method of treating type II diabetes by way of selected removal of visceral fat cells and components contained therein (e.g. fat, adipocytokine (Leptin) and inflammatory markers (TNF- α = tumor necrosis factor, resitin, IL-6 and IL-9), to improve the sensitivity of tissue cells to insulin.

Another object of the present invention is to provide a powered visceral fat aspiration instrument employing a twin (dual) cannula assembly, having a moving aspiration aperture that reciprocates over a range of about ¼" to about 1" which is appropriate to the thickness of mesenteries and omental fat deposits.

Another object of the present invention is to provide a powered visceral fat aspiration instrument employing a twin-cannula assembly supporting bipolar electro-cauterization of targeted visceral fat target being aspirated through the reciprocating inner aspiration aperture, in a safe and effective manner.

Another object of the present invention is to provide a powered visceral fat aspiration instrument employing a twin-cannula assembly which is driven in such a manner to substantially reduce vibration or disturbances which might be caused by the positioning of the instrument and thus its associated vacuum tubing, when repositioning of the aspirating cannula within visceral fat tissue.

Another object of the present invention is to provide a powered visceral fat aspiration instrument having a small size and footprint thereby facilitating its use in a laparoscopic procedure where multiple viewing and retracting instruments are inserted into key hole incisions in the patient abdomen and the added bulk would be detrimental and impede adoption.

Another object of the present invention is to provide a powered visceral fat aspiration instrument employing a twin-cannula assembly which supports simultaneous fluid irrigation and visceral fat aspiration about the moving aspiration aperture, in order to achieve a sump effect facilitating aspiration through the twin-cannula assembly.

Another object of the present invention is to provide a powered visceral fat aspiration instrument employing a twin-cannula assembly during a laparoscopic visceral fat aspiration procedure, which prevents the escape of compressed carbon dioxide (used to distend the patient's abdomen during the procedure) through the instrument, or its cannula assembly, or through the incision through which it is placed, other than through the inner cannula itself as a result of fat aspiration through the inner cannula aperture(s).

Another object of the present invention is to provide a coaxially-driven visceral fat aspiration instrument employing a twin-cannula assembly that performs visceral fat aspiration operations in a mechanically assisted manner.

Another object of the present invention to provide a visceral fat aspiration instrument system which comprises a hand-supportable fat aspiration instrument having a hand-supportable housing with a stationary tubing connector provided at the rear of the housing and receiving a length of flexible tubing connected to a vacuum source, and including a twin-cannula assembly coupled to a cannula drive mechanism disposed within the hand-supportable housing and powered by an external power source (e.g. electrical power signals, pressurized air-streams, etc) so as to periodically exert forces on the cannula base portion along the longitudinal axis of the the cannula assembly (i.e. coaxially exerted on the cannula base portion) and cause the hollow inner cannula base portion to reciprocate within the cylindrical (inner cannula base portion) guide tube, while tissue is being aspirated along the cannula lumen, through the lumen formed in the cannula base portion, through the cylindrical guide tube and through the stationary tubing connector, along the flexible tubing towards the vacuum source.

Another object of the present invention is to provide a visceral fat aspiration instrument system which comprises a hand-supportable fat aspiration instrument and a single-type cannula assembly, wherein the hand-supportable fat aspiration instrument includes (i) a hand-supportable housing having (i) a front portion and a rear portion aligned along a longitudinal axis, (ii) an interior volume and a cylindrical guide tube mounted within the interior volume, (iii) a cannula drive mechanism disposed adjacent the cylindrical guide tube, and (iv) a stationary tubing connector coaxially mounted to the rear portion of the hand-supportable housing along the longitudinal axis, connected to the cylindrical guide tube, and having an exterior connector portion permitting a section of flexible aspiration tubing to be connected at its first end to the exterior connector portion, and where the second end of the section of flexible tubing is connected to a vacuum source.

Another object of the present invention is to provide a visceral fat aspiration instrument system which comprises a hand-supportable fat aspiration instrument and a twin-type cannula assembly.

An even further object of the present invention is to provide such a fat aspiration instrument which can be driven by pressurized air or electricity.

A further object of the present invention is to provide such a visceral fat aspiration instrument, in which the cannula assembly is disposable.

An even further object of the present invention is to provide an improved method of performing visceral fat aspiration, in which one of the cannulas of the cannula assembly is automatically reciprocated back and forth relative to the hand-holdable housing, to permit increased control over the area of subcutaneous tissue where fatty and other soft tissue is to be aspirated.

Another object of the present invention is to provide a power-assisted visceral fat aspiration instrument, with a means along the cannula assembly to effect hemostasis during visceral fat aspiration procedures and the like, using RF-based electro cauterization.

Another object of the present invention is to provide an air-powered tissue-aspiration (e.g., visceral fat aspiration) instrument system, wherein the powered visceral fat aspiration instrument has an inner cannula that is automatically reciprocated within a stationary outer cannula by electronically

controlling the flow of pressurized air streams within a dual-port pressurized air cylinder supported within the hand-supportable housing of the instrument.

Another object of the present invention is to provide such an air-powered visceral fat aspiration instrument system, wherein digital electronic control signals are generated within an instrument controller unit and these control signals are used to generate a pair of pressurized air streams within the instrument controller which are then supplied to opposite ends of the dual-port pressurized air cylinder within the powered visceral fat aspiration instrument.

Another object of the present invention is to provide such an air-powered visceral fat aspiration instrument system, wherein the rear end of the powered visceral fat aspiration instrument has a pressurized air-power supply-line connector, and an electrical control signal connector.

Another object of the present invention is to provide such an air-powered visceral fat aspiration instrument system, wherein the hollow inner cannula base portion of cannula assembly inserts into a front accessible port in the hand-supportable housing, while the aspiration tubing is connected to the stationary tube connector provided at the rear portion of the hand-supportable housing.

Another object of the present invention is to provide such an air-powered tissue-aspiration instrument system, wherein an intelligent instrument controller is used to supply air-power to the inner cannula reciprocation mechanism within the hand-supportable instrument, while communicating control signals between the instrument and its intelligent controller.

Another object of the present invention is to provide such an tissue-aspiration instrument system with an alternative electro-cauterizing dual cannula assembly, wherein a stream of irrigation fluid is automatically pumped from the base portion of the outer cannula to the distal portion thereof, along a micro-sized fluid conduit formed along the surface walls of the outer cannula, and released into the interior distal portion of the outer cannula through a small opening formed therein, for infiltration and irrigation of tissue during aspiration in order to facilitate pump action.

These and other objects of the present invention will be described in greater detail hereinafter in the claims to invention appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS

The above Objects of the Present Invention will be more fully understood when taken in conjunction with the following Figure Drawings, wherein like elements are indicated by like reference numbers, wherein:

Fig. 1 is a system block diagram of the laparoscopically-guided bipolar power-assisted twin-cannula visceral fat aspiration system of the present invention, showing an obese patient in an operating room undergoing a mesenteric visceral fat aspiration procedure carried out using the same in accordance with the principles of the present invention;

Fig. 2 is a perspective view of a first illustrative embodiment of the bipolar electro-cauterizing twin-cannula visceral fat aspiration instrumentation system of the present invention, depicted in the

system of Fig. 1, and shown comprising (i) a hand-supportable fat aspiration instrument having (i) a hand-supportable housing with a stationary tubing connector provided at the rear of the housing and receiving a length of flexible tubing connected to a vacuum source and connecting to the cylindrical cannula base portion guide tube, and a twin tumescent-type cannula assembly having an inner cannula coupled to an pneumatically-powered cannula drive mechanism disposed within the hand-supportable housing and powered by a source of pressurized air or other gas, while its stationary outer cannula is releasably connected to the front portion of the hand-supportable housing, and (ii) a system controller for controlling the electro-cautery, irrigation and illumination functions supported by the fat aspiration instrument;

Fig. 2A1 is a perspective view of the air-powered fat aspiration instrument shown in Fig. 2, having an twin-cannula assembly supporting three-functions (i.e. tumescent infusion, electro-cautery and variable-spectrum illumination) about the aspiration aperture during visceral fat aspiration operations;

Fig. 2A2 is a partially exploded diagram of the fat aspiration instrument shown in Fig. 2A1, showing its hand-supporting housing, in which its cylindrical (cannula base portion) guide tube and air-powered driven mechanism are installed, while its cannula base portion, cannula and cannula lock nut are shown disassembled outside of the hand-supportable housing;

Fig. 2B is a cross-sectional view of the hand-supportable fat aspiration instrument shown in Fig. 2A1;

Fig. 2C is a perspective view of the multi-function twin-cannula assembly of the present invention employed on the instrument shown in Figs. 2A and 2A1;

Fig. 2D1 is a perspective view of the outer cannula component of the twin-cannula assembly of Fig. 2C, constructed of stainless steel tubing coated with a white-colored PFA (Dupont Teflon®) coating, and showing its integrated irrigation port and irrigation channel, and its integrated fiber-optic port and fiber-optic channel;

Fig. 2D2 is an elevated side view of the outer cannula component of the twin-cannula assembly of Fig. 2D1, showing electro-cautery contacts on the base portion of the outer cannula to which RF signal signal cables are connected;

Fig. 2D3 is a first partially cut-away perspective view of the distal (tip) portion of the outer cannula component of the twin-cannula assembly of Figs. 2D1 and 2D2, illustrating that the fiber carrying the illumination source terminates at the outer aspiration aperture to the field of aspiration about the aspiration aperture, and irrigation enters into the bullet tip area of the outer cannula;

Fig. 2D4 is a second partially cut-away perspective view of the distal (tip) portion of the outer cannula component of the twin-cannula assembly of Figs. 2D1 and 2D2, illustrating that the fiber carrying the illumination source terminates at the outer aspiration aperture to the field of aspiration about the aspiration aperture, and irrigation enters into the bullet tip area of the outer cannula;

Fig. 2E1 is a first perspective view of the base portion of the outer cannula component of the bipolar electro-cauterizing cannula assembly shown in Fig. 2C;

Fig. 2E2 is a second perspective view of the inner cannula base portion of the outer cannula component employed in the bipolar electro-cauterizing cannula assembly shown in Fig. 2C;

Fig. 2E3 is a plan view of the base portion of the electrically-conductive outer cannula component of the bipolar electro-cauterizing cannula assembly shown in Fig. 2C, revealing its set of radially arranged electrical contacts disposed about the central axis of the outer cannula base portion, while the inner cannula base portion is slidably received within the cylindrical guide structure within the housing, so as to enable electrical contact between the electrically-conductive inner cannula and radially-arranged electrical contacts;

Fig. 2E4 is a perspective view of the outer cannula base portion shown in Fig. 2E3;

Fig. 2E5 is an exploded view of the outer cannula base portion shown in Figs. 2E1 through 2E4;

Fig. 2F is a schematic diagram for the system controller employed by the first illustrative embodiment of the fat aspiration instrumentation system of Fig. 2A, supporting electro-cauterizing, irrigation and illuminating functions about the outer aspiration aperture of the fat aspiration instrument;

Fig. 2G is a flow chart describing the operation of the infusion pump of Fig. 2A in cooperation with irrigating electro-cauterizing visceral fat aspiration instrument illustrated in Figs. 2A through 2F;

Fig. 2H shows a cautery control program written in programming language, describing when to open and close the cautery relay switch employed within the electro-cautery RF power signal generation module of the system controller;

Fig. 3 is a perspective view of a second illustrative embodiment of the bipolar electro-cauterizing twin-cannula visceral fat aspiration instrumentation system of the present invention, depicted in the system of Fig. 1, and shown comprising (i) a hand-supportable fat aspiration instrument having (i) a hand-supportable housing with a stationary tubing connector provided at the rear of the housing and receiving a length of flexible tubing connected to a vacuum source and connecting to the cylindrical cannula base portion guide tube, and a twin tumescent-type cannula assembly having an inner cannula coupled to an electrically-powered cannula drive mechanism disposed within the hand-supportable housing and powered by a source of electrical power, while its stationary outer cannula is releasably connected to the front portion of the hand-supportable housing, and (ii) a system controller for controlling the electro-cautery, irrigation and illumination functions supported by the fat aspiration instrument;

Fig. 3A is a perspective view of the electromagnetically-powered fat aspiration instrument shown in Fig. 3, having an twin-cannula assembly supporting three-functions (i.e. tumescent infusion, electro-cautery and variable-spectrum illumination) about the aspiration aperture during visceral fat aspiration operations;

Fig. 3B is a perspective view of the multi-function twin-cannula assembly of the present invention employed on the instrument shown in Figs. 2A and 3A, showing electro-cautery contacts on the base portion of the outer cannula to which RF signal signal cables are connected;

Fig. 3C is a first partially cut-away perspective view of the distal (tip) portion of the outer cannula component of the twin-cannula assembly of the present invention, illustrating its fiber carrying the illumination source to the field about the outer aspiration aperture, and irrigation channel conducting irrigation fluid to the bullet tip area of the outer cannula;

Figs. 3D1 through 3D8 show a series of exploded views of the bipolar electro-cauterizing fat aspiration instrument of the present invention, showing its components disassembled;

Fig. 3E is a partially-cutaway cross-sectional view of the bipolar electro-cauterizing fat aspiration instrument taken along line 3F-3F in Fig. 3A;

Fig. 3F1 is a perspective view of the back housing plate employed in the hand-supportable instrument;

Fig. 3F2 is a perspective view of the cylindrical guide tube supporting its first and second electromagnetic coils;

Fig. 3F3 is an elevated side view of the cylindrical guide tube supporting its first and second electromagnetic coils;

Fig. 3F4 is a perspective partially-cutaway view showing the connection of the two electromagnetic coils to the contact plug employed in the hand-supportable fat aspiration instrument of the present invention illustrated in Fig. 3A;

Fig. 3F5 is schematic diagram of a two coil push-pull type of circuit for enabling the cannula drive mechanism employed in the hand-supportable fat aspiration instrument of the present invention illustrated in Fig. 3A;

Fig. 3G1 is a sectional-view of a second embodiment of the hand-supportable fat aspiration instrument of Fig. 3A, showing a cylindrical (cannula base portion) guide tube supporting three electromagnetic coils used to realize the cannula drive mechanism employed in the fat aspiration instrument;

Fig. 3G2 is schematic diagram of a three coil push-pull type of circuit for enabling the cannula drive mechanism employed in the second embodiment of the hand-supportable fat aspiration instrument of the present invention illustrated in Fig. 3A;

Fig. 3H is a schematic diagram for the system controller employed by the second illustrative embodiment of the fat aspiration instrumentation system of Fig. 3A, supporting electro-cauterizing, irrigation and illuminating functions about the outer aspiration aperture of the fat aspiration instrument;

Fig. 3I shows a cautery control program written in programming language, describing when to open and close the cautery relay switch employed within the electro-cautery RF power signal generation module;

Fig. 4 is a perspective view of the in-line fat sampling device of the present invention connected between the vacuum source and the twin-cannula visceral fat aspiration instrument of the present invention, shown in Figs. 2A and 3A;

Fig. 4A is a first perspective view of the in-line fat sampling device of the present invention;

Fig. 4B is a second perspective view of the in-line fat sampling device of the present invention;

Fig. 4C is a first exploded view of the in-line fat sampling device of the present invention, shown comprising a collection chamber, a lid with barbed connector for connection to the suction tubing, a

suction plate having six projections for supporting six sample syringes, a selector with a passage from center to periphery to control flow of aspirated fat sample into the selected syringe, and a barbed connector for connecting to tubing extending to the hand-supportable fat aspiration instrument, and a spring pushing up the turning knob and keeping the selector at the bottom of the collection chamber;

Fig. 4D is a second exploded view of the in-line fat sampling device of the present invention,

Fig. 4E is a third exploded view of the in-line fat sampling device of the present invention;

Fig. 4F1 is a cross-sectional view of the in-line fat sampling device of the present invention shown in Figs. 4A through 4E, illustrating the passage within the selector component, extending from the center of the device to the periphery thereof to control the flow of aspirated fat samples into the selected syringe;

Fig. 4F2 is a cross-sectional view of the in-line fat sampling device shown in 4F1, illustrating the flow of an aspirated fat sample from the patient, through the fat aspiration instrument of the present invention, to the selector component of the fat sampling device, through the passageway/flow director, into the selected syringe, whereupon fat cells are collected within the selected syringe while excess fluid is expressed through holes in the selected syringe, and passed out through the barded connector towards to vacuum source;

Fig. 4G is a graphical representation illustrating the process of removing collected visceral fat samples contained in syringes from the collection container of the in-line fat sampling device of the present invention;

Fig. 4H is a perspective view of a syringe removed from the collection container of the in-line fat sampling device of the present invention, and arranged in proximity with a hole excluder and syringe plunger, for use together when desiring to eject a visceral fat sample collected in a selected syringe within collection container of the in-line fat sampling device of the present invention;

Figs. 4I1 and 4I2 set forth a graphical representation illustrating the process of using the hole exclude and syringe plunger to eject a visceral fat sample that has been collected in a syringe removed from the collection container of the in-line fat sampling device of the present invention;

Fig. 5A is a schematic diagram of the process illustrating the increased negative feedback effect (i.e. decrease in fat burn) which an increase in hypertrophic visceral fat cells have upon the basal metabolic rate (BMR) within a human being's metabolism, by the increased secretion of Leptin, Resistin and TNF- α -- prior to treatment according to the principles of the present invention;

Fig. 5B is a schematic diagram of the process illustrating a decreased secretion of Cytokines (i.e. Adipopectin) in response to an increase in hypertrophic visceral fat cells, favoring a decrease in sensitivity of peripheral tissues to insulin and thus a decrease in glucose utilization thereby -- prior to treatment according to the principles of the present invention;

Fig. 5C is a schematic diagram of a process illustrating a reduction in the number of hypertrophic fat cells and their harmful secretions (i.e. Leptin, Resistin and TNF- α) by the method of treatment according to the present invention, and the favorable impact on the patient's metabolism by increasing fat burn and the basal metabolic rate (BMR);

Fig. 5D is a schematic diagram of the process illustrating an increased circulation of secretion of Cytokines (i.e. Adipopectin) in response to a decrease in hypertrophic visceral fat cells by practicing the method of treatment according to the present invention, and the favorable increase in sensitivity of peripheral tissues to insulin and thus an increase in glucose utilization thereby;

Figs. 6A and 6B a flow chart illustrating the primary steps carried out during the illustrative embodiment of the method of treating obesity by mesenteric visceral fat aspiration according to the present invention, comprising diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated;

Figs. 7A and 7B a flow chart illustrating the primary steps carried out during the illustrative embodiment of the method of treating WHR and metabolic syndrome by mesenteric visceral fat aspiration according to the present invention, comprising diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated;

Figs. 8A and 8B a flow chart illustrating the primary steps carried out during the illustrative embodiment of the method of treating type II diabetes by mesenteric visceral fat aspiration according to the present invention, comprising diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated;

Fig. 9A is a perspective view of the patient's abdominal region during the first phase of a mesenteric visceral fat aspiration procedure of the present invention, showing the inspection of the small bowel and placing a region of proximal jejunum under tension between two graspers for treatment, following creation of routine laparoscopy portals and customary CO₂ infusion for abdominal distension;

Fig. 9B is perspective view of the patient's abdominal region during a second phase of the mesenteric visceral fat aspiration procedure of the present invention, showing the insertion of a cannula into the mesentery for infusion of tumescent solution;

Fig. 9C is perspective view of the patient's abdominal region during a third phase of the mesenteric visceral fat aspiration procedure of the present invention, showing the insertion of the bipolar electro-cauterizing twin-cannula visceral fat aspiration instrument shown in Fig. 1, into the mesentery of the patient and fat removal by way of visceral fat aspiration under laparoscopy guidance with the laparoscope shown;

Fig. 10 is a graphical illustration of the cross-section partially cut away view of the patient's abdominal region during a later phase of the mesenteric visceral fat aspiration procedure of the present invention, showing the aspiration and electro-cauterization of visceral fatty tissue in the mesentery, using the laparoscopically-guided irrigating bipolar electro-cauterizing twin-cannula visceral fat aspiration instrumentation of the present invention; and

Fig. 11 is a graphical illustration of the abdominal region of a patient, showing areas where visceral fat is to be removed in the middle 1/3 of the mesentery, while avoiding the major vessels at the

root of the mesentery near the aorta and the smaller direct supply vessels (vasa recti) near the bowel itself (i.e. where a great amount of visceral fat is located - in the fan-folded condensation of mesentery thickened with visceral fat).

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS OF THE PRESENT INVENTION

Referring to the figures in the accompanying Drawings, the various illustrative embodiments of the present invention will be described in great detail, wherein like elements will be indicated using like reference numerals.

Overview On Methods Of Treatment According To Principles Of The Present Invention

In general, the method of treatment according to the present invention involves performing vacuum-assisted aspiration of mesenteric fat from a patient in the intra-abdominal region, using either an “open direct-viewing” based laparotomy procedure, or preferably, a minimally-invasive, “laparoscopic” based procedure using the new and improved fat aspiration instruments of the present invention.

The open direct-viewing based procedure involves a surgical team making a direct laparotomy incision into the abdomen of the patient using their own direct human vision to guide their surgical instruments, while performing a visceral fat aspiration procedure/method in accordance with the principles of the present invention.

The laparoscopic-based procedure involves a surgical team making one or more limited access portals into the patient’s abdomen and using laparoscopic and/or camera monitor assistance for their human vision, while performing the visceral fat aspiration procedure/method in a minimally invasive fashion according to the principles of the present invention.

Using either method, visceral fat is safely removed from the mesenteric region of a patient to help to ameliorate the metabolic syndrome, abdominal obesity and/or type II diabetes.

Specification Of The Laparoscopically-Guided Intra-Abdominal Visceral Fat Aspiration Instrument System Of The Present Invention, Designed For Safely Removing Visceral Fat From The Mesenteric Region Of A Patient

In Fig. 1A, there is shown a preferred laparoscopically-guided intra-abdominal visceral fat aspiration instrument system 1 for performing the mesenteric visceral fat aspiration methods of the present invention, typically in an operating room environment. The system 1 comprises: an endoscopy (e.g. laparoscopy) subsystem, or laparoscope 2 having (i) a video probe 2A provided with an embedded 2D high-resolution digital color image sensor with a field of view (FOV) for insertion into the abdomen of the patient 3, (ii) one or more video monitors (e.g. LCD displays and controller) 2B for displaying to surgeons and assistants, real-time digital color video images of the patient’s abdominal region captured along the field of view (FOV) of the video probe 2A, and (iii) digital recording equipment 2C for recording captured digital video during the operation and marking the same by the surgeons, as required;

a bipolar electro-cauterizing twin-cannula powered visceral fat aspiration system 4 having (i) a powered hand-supportable fat aspiration instrument 4A provided with a self-irrigating, bipolar electro-cauterizing and fiber-illuminating twin-cannula assembly 5, (ii) a system controller 4B connected to the hand-supportable instrument 4A by way of a flexible multi-lumen cable assembly 4C, for supplying (i) pressurized air streams 6 from pressurized gas source 6A to drive the inner cannula of the hand-supportable instrument 4A (shown in Figs. 2A through 2H), or (ii) electrical power signals 6' from electrical power source 6B to drive hand-supportable instrument 4A' (shown in Figs. 3 through 3I), and optionally (iii) RF-power signals 7 generated by an RF signal generating module 4D for powering the self-irrigating bipolar electro-cauterizing and illuminating twin cannula assembly 5, as taught in US Patent No. 7,384,417 B2; a vacuum pump 4E operably connected to the inner cannula via a flexible tubing and other components, for aspirating visceral fat through the aspiration aperture 9 of the twin cannula assembly 5 during system operation; an infusion pump 4F controlled by the system controller 4B, for periodically or continuously pumping irrigation fluid through irrigation tube 12 and into an irrigation port on the cannula assembly for infusing solution near the distal portion of the cannula assembly 5 during system operation; an operating table 11 for supporting a patient; a multi-spectral illumination source 4G providing the surgeon with selectable spectrum control, to deliver a desired spectrum of illumination along an optical fiber 12 to the outer cannula and produce a field of illumination spatially-overlapping the field of aspiration about the reciprocating inner aspiration aperture 9 at the distal portion of the twin-cannula assembly 9; in-line fat sampling device 14 installed in-line along the flexible tubing 9A, 9B, for collecting and indexing samples of visceral fat while the surgeon samples the abdominal region of the patient, for subsequent analysis and testing/measurement for compounds indicative of obesity, metabolic syndrome and/or type II diabetes; and other operating room equipment including high intensity lighting apparatus, retraction clips, stitches etc.

In addition, the laparoscopically-guided visceral fat aspiration system 1 of the present invention further includes instruments such as trochars for penetrating the abdomen, laparoscopic graspers, laparoscopic scissors, and a CO2 infusion tube (supplied from CO2 gas source 6A), as described in detail in US Patent No. 7,384,417 B2, incorporated herein by reference.

Typically, infusion pump 4F will include a roller pump which compresses the tubing to create forward flow, as disclosed in US Patent No. 7,384,417 B2 incorporated herein by reference. The infusion pump 4F supplies a pulsatile flow of irrigation fluid through the distal tip portion of the twin-cannula assembly of the present invention, as shown in Figs. 2D 3 and 2D4, so that controlled amounts of fluid are delivered under short periods of time to facilitate synchronization with either the forward or return stroke of the inner cannula 5B. This feature will be described in great detail hereinafter.

In the illustrative embodiment of the present invention, the multi-spectral illumination source 4G can be constructed from a white light source producing a white light beam that is filtered by a selectable color filter wheel, with associated optics, interfaced with a fiber-optic delivery cable, to provide the surgeon with selectable spectrum control, to deliver a desired spectrum of illumination (e.g. red, blue and/or yellow) at and about the aspiration aperture of the fat aspiration instrument 4A. Alternatively, the

illumination source 4G can be realized using a multi-spectral LED array with associated optics, interfaced with a fiber-optic delivery cable, to provide the surgeon with selectable spectrum control, to deliver a desired spectrum of illumination (e.g. red, blue and/or yellow) at and about the aspiration aperture of the fat aspiration instrument 4A. The multi-spectral illumination source 4G can also be adapted to generate and deliver a bright red light beam at the time of, and at the location of visceral fat aspiration about the distal portion of the twin-cannula assembly 5. Also, in addition to white-type light being supplied by the laparoscopic light source during operations, the multi-spectral illumination source 4G can supply red/blue/yellow light (i.e. illumination) through the fiber-optic channel along the twin-cannula assembly, to illuminate tissue about the aspiration aperture, to help visually distinguish and accentuate arterial vessels, veins and fat itself, and facilitate visculature of arterial blood vessels, portal and systemic veins, and fat. In yet alternative embodiments, the color wheel may be rotated continuously, offering a 3-D emphasis of the treatment area.

In Figs. 2A through 2G, a hand-supportable multi-function visceral fat aspiration instrument 4A is shown for use with system 1 depicted in Fig. 1A. This embodiment of the instrument of the present invention is powered by a source of pressured air or gas (e.g. a pressurized-air cylinder driven by source of pressurized gas (e.g. CO₂)). In Figs. 3A through 3J, an alternative embodiment of the hand-supportable multi-function visceral fat aspiration instrument 4A' is shown for use with system 1 depicted in Fig. 1A. This alternative embodiment of the instrument is powered by an electromagnetic motor driven by electrical current delivered through coil windings at a given voltage. Both instruments 4A and 4A' employ the multi-function twin-cannula assembly 5 of the present invention shown in Figs. 2C through 2D4, and supporting its multiple functions, namely: bipolar electro-cauterization, fluid irrigation, and spectrum-controlled illumination at and about the reciprocating aspiration aperture 9 of the twin-cannula assembly.

In Figs. 4 through 4I2, an in-line visceral fat sampling device 14 for use with the fat aspiration instruments of the present invention, is described in technical detail. This in-line fat sampling device allows the surgeon to easily collect and index samples of visceral fat aspirated in particular regions of the patient's abdominal cavity, for subsequent analysis that may be informative during subsequent serial fat aspiration procedures during a particular course of treatment.

It is appropriate at this junction, to now describe in greater detail the coaxially-driven multi-function visceral fat aspiration instruments 4A and 4B of the present invention.

Specification Of The First Illustrative Embodiment Of The Twin-Cannula Multi-Function Co-Axially Driven Visceral Fat Aspiration Instrument Of The Present Invention

In Fig. 2A, the first illustrative embodiment of the twin-cannula visceral fat aspiration instrumentation system 1 is shown comprising: a hand-supportable fat aspiration instrument 4A having (i) a hand-supportable housing 15 with a stationary tubing connector 16 provided at the rear of the housing and receiving a length of flexible tubing 9A connected to a vacuum source 4E and connecting to

the cylindrical cannula base portion guide tube 20 , and (ii) a multi-function twin-cannula assembly 5 having an inner cannula 5B with a inner cannula base portion 20 disposed within the cylindrical cannula base portion guide tube 21, and coupled to an pneumatically-powered cannula drive mechanism (as illustrated in Fig. 2A2) housed within the hand-supportable housing and powered by a source of pressurized air or other gas, while its stationary outer cannula 5A is releasably connected to the front portion of the hand-supportable housing 14; system controller 4B for controlling the electro-cautery, irrigation and illumination functions supported by the fat aspiration instrument; an aspiration source 4E; a pneumatic power source 6A; and a flexible multi-core cable assembly 20 connecting the system controller 4B and the hand-supportable instrument 4A; and an infusion pump 4F for supplying irrigation fluid to an infusion port 35 on the outer cannula via flexible tubing, and connected to the system controller 4B for synchronized pulse control, and operational to synchronize the release of irrigation fluid (i.e. infusion) with inner cannula motion.

As shown in Fig. 2A, the air-powered fat aspiration instrument 4A comprises a single-button quick connect plug 22 provided on the rear portion of the hand-supportable housing, for connecting the multi-core cable assembly 23 and supporting two gas lines and three electric wires between the instrument and the system controller in a single bundle, as taught in US Patent No. 7,381,206 to Cucin, incorporated herein by reference, with appropriate modifications for the application at hand. While RF power signals can also be supplied through the multi-core cable assembly, and routed as necessary to the cautery leads 30A and 30B provided on the outer cannula base portion, as shown in Figs. 2A and 2A1, RF power signals can be supplied through power cables 31 that are separate from the multi-core cable assembly 23.

As shown in Figs. 2B and 2C, the twin-cannula assembly 5 comprises an inner cannula component 5B that is slidably received within an outer cannula component 5A. The inner cannula component 5B has a distal end and a proximal end and an inner aspiration aperture 8, and is provided with a Leur-lock fitting 25 at its proximal end so as to be able to connect to a matched fitting provided on the inner cannula base portion 20 which reciprocates within the cylindrical cannula base portion guide tube 21, mounted within the hand-supportable housing 15. The outer cannula component 5A also has a distal end and a proximal end and an elongated outer aspiration aperture 9, and is provided with a Leur-lock fitting 26 at its proximal end so as to be able to connect to a matched fitting provided on the outer cannula base portion 5C which connects to the front portion of the housing 15 by way of a threaded hole formed therein as shown in Fig. 2A2. The inner and outer cannulas are keyed to ensure that the inner aspiration aperture 8 is always in registration (i.e. cannot rotate within the outer cannula, and remains in constant alignment) with the elongated aspiration aperture (i.e. slot) during instrument operation.

The outer cannula component 5A is shown detailed in Figs. 2D1 through 2D4, the outer cannula base portion 5C is detailed in Figs. 2E1 through 2E5, and the inner cannula component 5B is detailed in Figs. 2A2 and 2B. When fully assembled, and configured with its hand-supportable instrument housing, and the other components of the system 1, the twin-cannula assembly 5 of the present invention simultaneously performs a number of important functions during visceral fat aspiration operations,

namely: tumescent infusion of an irrigation fluid, electro-cauterization of aspirated fat passing through the inner aspiration aperture 9, and variable-spectrum fiber-illumination delivered across the field of irrigation, about the outer aspiration aperture 9. These functions will be described in greater detail hereinafter.

As shown in Figs. 2D1 and 2D2, the outer cannula component 5A is realized as a thin tube made from stainless steel tubing (No. 304) and then coated with a white-colored PFA (Dupont Teflon®) coating. Also, the inner cannula component 5B is realized as a thin tube (of slightly smaller outer diameter dimensions than the outer cannula) made from stainless steel tubing (No. 304) and then coated with a black-colored PFA (Dupont Teflon®) coating. These high contrast coatings will serve to render the moving “white” (reflective and bright) inner cannula aspiration aperture 9 highly visible against the “black” (absorptive and dark) outer cannula, in digital video images captured, buffered and displayed (in real-time) during video-guided fat aspiration operations carried out in accordance with the principles of the present invention. While PFA coatings are applied over the outer surfaces of the inner and outer cannulas, PFA coating material should be removed from the peripheral edges of the outer cannula aspiration aperture 8 and the inner cannula aspiration aperture 9 where electrical field potentials are to be generated during bipolar electro-cauterization operations about the relatively moving outer aspiration apertures. Also, PFA coating material should be removed from the outer surface of the proximal portion of the inner cannula so that electrical contact can be established between the radially extending contacts (brushes) 30 supported within the non-conducting outer cannula base portion 5C, shown in Figs. 2E2 and 2E3, and electrically connected to the bipolar RF signal supply port 30A provided on the exterior of the outer cannula base portion 5C.

As shown in Figs. 2D1 through 2D4, an irrigation supply port 31 is provided on the proximal end of the outer cannula before its Leur-lock fitting, and an irrigation channel 32 is formed along the wall of the outer cannula component (via longitudinal brazing) and terminates at an irrigation release port 33 located at the distal tip portion of the cannula, for supplying irrigation fluid on the inside of the bullet-shaped distal portion of the outer cannula, adjacent its outer aspiration aperture/slot 8, as clearly shown in Figs. 2D3 and 2D4, to provide continuity with the interior of the outer cannula at the tip to maximize sump effects and directed irrigation.

By delivering the irrigation fluid into the very tip of the inside region of outer cannula the following benefits are achieved: (1) maximal sump effect to help aspiration of fat; and (2) hydrostatic dissection every time the inner cannula advances and push the irrigation solution that has collected inside the outer cannula between the back-stroked inner cannula and the dome of the outer cannula into the tissues (mesentery) to facilitate dissection. Tumescent solution may be employed, e.g. lactated Ringers and a very dilute solution of epinephrine may be employed to minimize bleeding.

On the opposite side of the outer cannula component, a fiber optic supply port 35 is integrated fiber-optic port is provided on the proximal end of the outer cannula before its Leur-lock fitting 30B, and an fiber optic channel 36 is formed along the wall of the outer cannula component (via longitudinal brazing) and terminates at an illumination port 37 located at the distal tip portion of the cannula. An

optical fiber 38 is installed through the fiber optic supply port 35 and along the fiber channel 36, and provided with a conventional fiber optic cable connector at the fiber optic supply port 35, so as to supply an illumination signal that is delivered to the illumination port 37 to illuminate tissue in the region outer aspiration aperture 8 of the outer cannula 5A during fat imaging and aspiration operations. Notably, the end of the optical fiber will be shaped appropriately at the illumination port 37 to provide a field of illumination that spatially overlaps the field of aspiration about the outer aspiration aperture, to ensure that tissue within and about the field of aspiration is optimally illuminated while digital video images of the distal portion of the twin-cannula assembly 5 are being captured, buffered and display on video display units mounted in the operating room, for the surgeon to view and use while manually guiding the distal portion of the cannula within the patient's abdominal region during surgery, to remove visceral fat in the patient's mesentery region.

In order to supply bipolar RF signals to the electrically conductive inner and outer cannula component of the twin-cannula assembly of Fig. 2D1, the non-conductive outer cannula base portion 5C is provided with first RF power signal port 30A to which a first RF signal cable is connected in a conventional manner, whereas the electrically conductive outer cannula is provided with second RF power signal port 30B to which a second RF signal cable is connected in a conventional manner. A first electrical connection is established between the RF power signal port 30B and the electrically-conductive outer cannula tubing 5B, which may be realized using electrical wiring and soldering in a manner known in the art, or other techniques known in the art. Also, a second electrical connection is established between the RF power signal port 30A and the array of radially-projecting electrical contacts (i.e. brushes) 30 mounted within the inside bore of the outer cannula base portion 5C, as shown in Fig. 2E4 and 2E5. The second electrical connection may also be realized using electrical wiring and soldering in a manner known in the art, but other techniques may be used as well.

During twin-cannula operation, the set of radially arranged electrical contacts 30 establish low-friction electrical contact with the exposed non-coated portion of the outer surface of the electrically conductive inner cannula 5B. With this arrangement, a first polarity of the supplied RF power signal is conducted to the electrode region 32B formed about the peripheral edge of the inner cannula aspiration aperture 8, while the second polarity of the RF power signal is conducted to the electrode region 32A formed about the peripheral edge of the outer cannula aspiration aperture 5A, to thereby provide bipolar electro-cauterization about the moving inner aspiration aperture, within the fields of aspiration, irrigation and illumination.

As shown in Fig. 2A2, the reciprocating inner cannula 5B has luer lock fitting 25 to mate to luer lock fitting 25' on the inner cannula base portion 20; magnet 48 is affixed to inner cannula base portion 20 using a screw-on nut 45; front and rear gas tubes 57 and 58 run to from the front of the housing to the rear multi-core quick connect plug 22; the quick connect multi-core plug 22 connects to multi-core cable containing two fluidic (gas) channels and at least three low voltage electrical circuits; the cable 23 runs to controller 4B within which the gas channels directly attached to the compressed gas source (not shown); the front and rear Hall sensors 22 and 23 are provided within the hand-supportable housing, for detecting

the excursion of the cannula base portion 20 within the cylindrical guide tube 1; front and rear flat sealing washers 46 and 47 are provided for slidably supporting the inner cannula base portion 20 along the cylindrical guide tube 21; threaded chamber cover 10 is provided with a hole, through which the inner cannula 5B protrudes; sufficiently large through-and-through vents are formed in the threaded chamber cover 10 to allow any gas that leaks past the front washer 46, to exit the chamber. Such air venting to the ambient is less critical because the concentric tube-with-a-tube structure, and the sliding of the cannula base portion 20 inside the rear tubing connector assembly, provides effective seals in and of themselves. Also, in this embodiment, the walls of at least the front (pneumatic) chamber portion of housing should be made from a non-magnetizable metal (e.g. SS 304) or other material that will support the necessary gas pressure of actuation (e.g. ~100 PSI).

During instrument operation, the Hall effect sensors 52 and 53 sense the position of the inner cannula base portion 20 within cylindrical guide tube 21 by sensing the magnetic field of its magnetic ring 8. As the inner cannula base portion 20 reciprocates within the cylindrical guide tube 21, the aspiration/vacuum tubing 9A connected to the barb connector 16 on the stationary tubing connector, remains stationary and thereby preventing any jerking action on the surgeon's hands and reducing image jitter during video image capture and display operations. Also, the inner and outer cannulas 5A, 5B are provided with luer-lock fittings 25, 26 respectively, while the inner cannula base portion 20 is typically realized or provided as a sterile single-use disposable item, made from plastic or metal, and having a low cost magnet and silicone washers to provide fluid seals between the inner cannula base portion 20 and the cylindrical guide tube 21 within the hand-supportable housing 15.

In Fig. 2F, the system controller 4B is shown comprising a number of components, namely: an analog-to-digital converter (ADC) receiving signals generated by the front and rear Hall-effect cannula base position sensors installed within the hand-supportable housing of the instrument; a LCD panel; communication ports; LED indicators; and panel membrane switches supported on the controller console housing; digital signal processor (DSP); and a digital-to-analog converter (DAC) and proportional valve contained within the controller console housing, and supplying gas tubes (via the multi-core cable assembly); and ports for receiving a supply of pressurized gas, for controlled supply to the inner cannula drive mechanism of this embodiment of the present invention. For further details on constructing a system controller, such as system controller 4B, reference should be made to US Patent No. 7,381,206 to Cucin, incorporated herein by reference.

The flow chart of Fig. 2G describes the operation of the infusion pump 4F in cooperation with irrigating electro-cauterizing visceral fat aspiration instrument illustrated in Figs. 2A through 2E. The cautery control program written set forth in Fig. 2H describes when to open and close the cautery relay switch employed within the electro-cautery RF power signal generation module of the system controller. Such control operations are carried out by the DSP in the system controller. A control program is also

provided within the DSP for activating the illumination source when the twin-cannula assembly is being driven by its integrated pneumatic motor.

During system operation, the inner cannula base portion 20 reciprocates within the cylindrical guide tube 21, while the aspiration/vacuum tubing 9A connected to the barb connector 16 on the stationary tubing connector, remains stationary and thereby preventing jerking action on the surgeon's hands and reducing image jitter and blurring during video capture and display operations during surgery. Also, the infusion pump 4F delivers controlled amounts of fluid through the irrigation channel 32 and out the irrigation port 33, over short periods of time, in synchronization with either the forward or return stroke of the inner cannula 5B within the outer cannula 5A. Such irrigation facilitates fluid flows out of the irrigation aperture 33 and proximate to the elongated aperture 8, while visceral fat is being electro-cauterized by electrodes 32A, 32B and aspirated through the reciprocating aspiration aperture 9 of the hand-supportable visceral fat aspiration instrument. At the same time, the fiber optic supply port 35 and fiber delivery channel 36 illuminates tissue within the field of aspiration, while a high resolution digital imager 2A with a field of view (FOV) on the distal portion of the twin-cannula assembly captures high contrast images of the white (reflective) and black (absorptive) colored PFA-coatings on the outer and inner cannulas 5A and 5B respectively, to assist the surgeon in practicing the method of the present invention.

Fig. 2C describes the primary control operations performed by system controller 4B during fluid irrigation delivery operations using the surgical system of Fig. 1. Specifically, as indicated at Step A in Fig. 2C, the inner cannula 5B is driven to reciprocate within the outer cannula 5A while the hand-supportable visceral fat aspiration instrument is being used during a laparoscopically-guided mesenteric visceral fat aspiration operation on an obese patient, wherein visceral fatty tissue is aspirated through its moving aspiration aperture. As indicated at Step B, when the inner cannula is displaced at its maximal stroke position within the outer cannula, irrigation fluid is automatically pulsed through the irrigation channel/lumen integrated within the outer cannula, so that irrigation fluid is expressed out of the irrigation aperture, proximate to the outer aspiration aperture, and into the region where visceral tissue is being aspirated within the mesentery of the patient. As indicated at Step C, the automatic pulsing of irrigation fluid through the irrigation aperture is ceased when the inner aperture moves away from its maximal stroke position and towards its minimal stroke position. As indicated at Step D, the operations of Steps B and C are repeated while driving the inner cannula to reciprocate within the outer cannula. The control routine of Fig. 2F will be realized using computer programming techniques well known in the art.

Specification Of The Second Illustrative Embodiment Of The Twin-Cannula Multi-Function Co-Axially Driven Visceral Fat Aspiration Instrument Of The Present Invention

In Fig. 3, the second illustrative embodiment of the multi-function twin-cannula visceral fat aspiration instrument 4A' is shown for use in the system 1 of Fig. 1. As shown, this visceral fat aspiration instrument 4A' comprises: a hand-supportable housing 15 with a stationary tubing connector provided at

the rear of the housing and receiving a length of flexible tubing 9 connected to vacuum source 4E and connecting to the cylindrical cannula base portion guide tube 50, and (ii) the twin tumescent-type cannula assembly 5 employed in the first illustrative embodiment 4A (Figs. 2D1 through 2E5) having an inner cannula 5B coupled to an electrically-powered cannula drive mechanism disposed within the hand-supportable housing and powered by a source of electrical power, while its stationary outer cannula 5B is releasably connected to the front portion of the hand supportable housing; (ii) a system controller 4B' for controlling the electro-cautery, irrigation and illumination functions supported by the fat aspiration instrument 4A' of the present invention.

Figs. 3D1 through 3D8 show how the components of the visceral fat aspiration instrument of the present invention are assembled, in a step wise manner.

As shown in Fig. 3E, the hand-supportable visceral fat aspiration instrument 4A' comprises: a cylindrical guide tube 1 mounted within the hand-supportable housing 2, and the (disposable) inner cannula base portion 50 carries a permanent magnetic ring 58 between a set of fluid seals 56 and 7 that slidably support the cannula base portion 60 within the cylindrical guide tube 50. The inner cannula 5B is coupled to the cannula base portion 60 by way of a mated leur-lock coupling 25, 25' and the lumen extending within the cannula and its inner cannula base portion 60 is in fluid communication with the stationary tubing connector 16, by way of the interior volume of the cylindrical guide tube 50 between the cannula base portion 60 and the stationary tubing connector 16. The stationary tubing connector 16 (having a barbed tubing connector portion) is adapted to unscrew from the rear portion of the hand-supportable housing so that housing back plate 59 can be removed so that the cylindrical guide tube 50 (i.e. the wound bobbin) can be slid into the hand-supportable housing 15. The top and bottom of the hollow cylindrical ring magnet 58 produce opposing magnetic poles, and magnet 58 is secured onto the inner cannula base portion 60 and against flange 54 by way of nut 55 which screws onto a set of threads form on other surface of the cannula base portion 60. In the illustrative embodiment, the fluid seals 56, 57 are realized as a pair of thin-walled, collapsable (i.e. invertible) bell-shaped silicone sealing washers which act as front and rear diaphragms allowing motion of the cannula base portion within the cylindrical guide tube. By setting mid-point geometry, one washer can effect a return stroke without need of coil polarity reversal, simply pulsing sufficing. Mounted about outer surface of the cylindrical guide tube, front and rear coil windings 61 and 62 are formed, respectively, and electrically connected to the connector plug 64 formed on the rear end of the hand-supportable housing.

Fig. 3D2 clearly reveals the components of the instrument 4A' as comprising: cylindrical guide tube 50 with flanges for containing electromagnetic coil windings (61, 62); hand-supportable housing 15; housing back plate 59; stationary tubing connector 16 with a vacuum tubing barb; flange 54 on inner cannula base portion 60; magnet fastening nut 55; front washer 56; back washer 57; ring magnet 58; inner cannula 5B provided with a luer lock fastener 25; front chamber screw cap 10; back electromagnetic coil 61; front electromagnetic coil 62; disposable inner cannula base portion 60 provided with as luer lock fastener 25'; and contact/connector plug 59 (e.g. Binder 719).

Figs. 3D1 through 3D8 show how these components are assembled in step order fashion, in a front-loading manner, and the twin-cannula assembly 5 is simply connected to the (disposable) inner cannula base portion 60, using luer lock coupling mechanisms 25, 25' well known in the art, to completely assemble the instrument and prepare it for use in surgery.

Taken together, Figs. 3F1 through 3F4 shows how the first and second electromagnetic coils 61, 62 are wound about the cylindrical guide tube 50, and then how wiring of these coils are electrically connected to the electrical connector mounted on the housing back plate 59, employed in the first illustrative embodiment shown in Figs. 2A through 5E. Fig. 3F5 shows a schematic diagram depicting how the two coil 61 and 62 are driven by a push-pull type of circuit, for the purpose of enabling the inner cannula drive mechanism employed in the hand-supportable fat aspiration instrument 4A' illustrated in Fig. 3A.

Third Illustrative Embodiment Of The Visceral Fat Aspiration Instrument System Of The Present Invention

In Fig. 3G1, an alternative embodiment of the hand-supportable fat aspiration instrument of Fig. 3A, depicted as 4A'' is shown, comprising: a cylindrical (inner cannula base portion) guide tube 50'' adapted to support three electromagnetic coils, rather than two coils used in the first illustrative embodiment 4A', for the purpose of implementing the inner cannula drive mechanism employed in the fat aspiration instrument. Fig. 3G2 shows a schematic diagram for this three coil push-pull type of circuit, driven by a 1-30HS AC electrical signal, for enabling the inner cannula drive mechanism employed in the alternative embodiment of the hand-supportable fat aspiration instrument 4A'' in Fig. 6A. In all other respects, the fat aspiration instrument of the third illustrative embodiment 4A'' is like the fat aspiration instrument 4A'.

Specification Of The In-Line Visceral Fat Sampling Device Of The Present Invention

Referring to Figs. 4 through 4I2, the in-line fat sampling device 14 of the present invention will now be described.

As shown in Figs. 4C through 4E, the in-line fat sampling device 14 comprises: a optically-transparent collection chamber 70 having closed end 71 with a central aperture 72, and an open end 72 with hollow inner chamber/space disposed between the closed end 71 and the open end 73; a removable lid 74 for threaded connection to the open end of the collection chamber, and having a central flow channel 75 terminated in a first barbed connector 76 for connecting the device to vacuum source 4E by way of a section of flexible vacuum tubing 9B; a stationary suction plate 77 having six hollow projections 78A through 78H for supporting the open ends of six sample syringes 80A through 80H, each having perforations 81 in the walls thereof (to allow fluid to flow therethrough while in the collection chamber) and being keyed for registration with the collection chamber (to prevent rotation); a rotatable selector 82 (shown in Fig. 4F1) for rotational engagement with the suction plate 77 and having a hollow

central post section 82A that passes through central aperture 72 and establishes fluid communication with a passage/conduit 82B that extends from center of the to periphery to control the flow of aspirated fat sample from the instrument 4A, 4A', 4A'' through the first section of tubing 9A, through the selector 82 and into the selected syringe/projection 80 combination; a turning knob 84 mounted on and engaging with the hollow selector post 82A and enabling the turning of the rotatable selector 82 relative to the stationary suction plate 77 to select the syringe/projection combination into which an aspirated fat sample should flow for collection and indexing purposes during surgery; a spring 85 mounted between the turning knob 84 and hollow selector post 82A to push up the turning knob and keeping the selector 82 at the bottom of the collection chamber; and a second barbed connector 86 connected by threads to the hollow selector post 82A allowing the fat sampling device 14 to be connected to the fat aspiration instrument 4A, 4A' by way of a second section of flexible vacuum tubing 9B.

Surgeon installs the fat sampling device 14 inline between the fat aspiration instrument 4A, 4A' and the vacuum source 4E as shown in Fig. 4A. The collection chamber 70 is labeled for orientation, indicating the side to patient and the side to vacuum source. The turning knob 84 has an arrow on it. The suction plate 77 has numbers 1 - 6 for each of the stoppered perforated syringe barrels 80A-80H connected to it. The surgeon then pushes down on turning knob 84 against the biasing force of spring 85 and that pushes the selector slightly forward so the knob can be turned to select which syringe to collect to, until it is full, counting from 1 to six. The selector 82 has a detente dome extrusion which fits into the corresponding dimple below the selected syringe. The spring 85 maintains the selector 82 in its selected position. As shown in Fig. 4E and 4F1, suction plate 77 has two flanges 87A and 87B which snap over the selector 82, and grip a groove that runs around it to secure it in place relative to the selector 82.

When practicing the method of treatment according to the present invention, the surgeon initially performs sampling of visceral fat in the SB mesentery of the small bowel, starting at the duodenum, the beginning, middle and distal jejunum and the ileum before returning to the proximal jejunum to begin the first defatting treatment, with the circulating nurse noting into which syringe the aspirated fat from each area is being collected. When all syringes are full with fat, unit is disconnected and vacuum source is connected directly to the hand piece. The fat sampling device may be replaced with another one for sampling at shorter distances if desired.

As shown in Fig. 4F2, during fat aspiration operation using the system of the present invention, an aspirated fat sample flows from the abdominal region of the patient, through the fat aspiration instrument of the present invention, through tubing 9A and the hollow selector post 82A, through passageway/flow director 82B, into the selected collection syringe 80A-80H supported on the stationary suction plate 77 and capped with cap portion 80A-80H, respectively. Fat cells are collected within the selected syringe while excess fluid is expressed through holes in the selected syringe, and passed out through the barded connector 76 towards to vacuum source 4E.

Fig. 4G shows a process of removing collected visceral fat samples contained in syringes in the in-line fat sampling device of the present invention. This involves removing the lid portion 74, and withdrawing the syringes supported on the suction plate assembly 77. Then as shown in Figs. 4H and 4I, a

capped fat containing syringe 80A is removed from the suction plate 77 and snapped into an syringe hole occluder 90 and rotated to as to occlude the holes/perforations 81 formed in the walls of the syringe, as shown in Fig. 4A1. Then a plunger 91 is inserted into the syringe, and the indexed fat samples is expressed out for testing and analysis purposes, typically in one or more of the laboratory methods described below.

In general, the kind of tests/measurements to be performed on a visceral fat sample will depend on the condition being treated. However, it would be helpful to measure concentrations of particular ____ per gm of aspirated fat per region, using the following laboratory methods: measure resistin levels using the Resistin human ELISA kit (VinciBiochem, Vinci-FI, Italy); determine adiponectin levels using a radioimmunoassay method [Linco Research, St. Charles, MO, USA; and quantify TNF- α , interleukin-6 (IL-6), and IL-10 using an enzyme-linked immunoassay (ELISA) method [BioSource Cytoscreen, ELISA UltraSensitive Kits, Camarillo, USA].

Subsequent serial defattings will target the region showing the highest (measured) levels of leptin, and resistin, TNF- α , and Interleukin 6 (IL-6) and lowest levels of adiponectin. IL-6 is aninflammatory markers associated with increased risk of coronary artery disease and insulin resistance.

The Science Underlying The Methods Of Treatment According To The Present Invention

The science underlying the visceral fat aspiration based methods of the present invention is represented in the schematic illustrations set forth in Figs. 5A through 5D.

Fig. 5A illustrates the increased negative feedback effect (i.e. decrease in fat burn) which an increase in hypertropic visceral fat cells have upon the basal metabolic rate (BMR) within a human being's metabolism, by the increased secretion of Leptin, Resistin and TNF- α -- i.e. prior to treatment according to the principles of the present invention.

Fig. 5B illustrates a decreased secretion of Cytokines (i.e. Adipopectin) in response to an increase in hypertropic visceral fat cells, favoring a decrease in sensitivity of peripheral tissues to insulin and thus a decrease in glucose utilization thereby – i.e. prior to treatment according to the principles of the present invention.

Fig. 5C illustrates a process caused by reducing the number of hypertropic fat cells and their harmful secretions (i.e. Leptin, Resistin and TNF- α) by the method of treatment according to the present invention, and the favorable impact on the patient's metabolism by increasing fat burn and the basal metabolic rate (BMR).

Fig. 5D illustrates a process of increased circulation of secretion of Cytokines (i.e. Adipopectin) in response to a decrease in hypertropic visceral fat cells by practicing the method of treatment according to the present invention, and the favorable increase in sensitivity of peripheral tissues to insulin and thus an increase in glucose utilization thereby.

In Fig. 10, a cross-sectional view of the patient's abdominal region is provided during a later phase of the mesenteric visceral fat aspiration procedure of the present invention, showing the aspiration

and electro-cauterization of visceral fatty tissue in the mesentery, using the laparoscopically-guided irrigating bipolar electro-cauterizing twin-cannula visceral fat aspiration instrumentation of the present invention.

Fig. 11 shows areas where visceral fat is to be removed in the middle 1/3 of the mesentery - i.e. avoiding the major vessels at the root of the mesentery near the aorta and avoiding the smaller direct supply vessels (vasa recti) near the bowel itself i.e. where most the fat is anyway - in the fan-folded condensation of mesentery thickened with visceral fat.

Method of Treating Obesity According To The Principles of the Present Invention

Figs. 6A and 6B illustrate the primary steps carried out when practicing the method of treating morbid obesity by mesenteric visceral fat aspiration according to the illustrative embodiment of the present invention, comprising the steps: diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated. Preferably, the fat aspiration operations indicated above are carried out using the apparatus described in Figs. 1 through 4I2, although it is understood that other techniques and apparatus can be used.

As indicated in Step A in Fig. 6A, the surgeon diagnoses a patient with metabolic syndrome and/or obesity (morbid obesity) using the waist-to-hip ratio (WHR) and by physical measurements and lab tests. Morbid Obesity is defined as being 100lbs over the ideal body weight or having a Body Mass Index (BMI) greater than or equal to 40.

As indicated in Step B in Fig. 6A, the surgeon performs a brief abdominal exploration or inspection to eliminate the presence of inflammatory bowel disease and other contraindications to surgery, such as, diverticulitis and a Meckel's diverticulum, or any other pathology. At her option, the surgeon may infuse a tumescent solution (Ringer's lactate with or without dilute epinephrine, and with or without xylocaine) as described above to prepare the area for treatment.

As indicated in Step C in Fig. 6A, the surgeon performs a partial omentectomy by removing the redundant omental apron.

As indicated in Step D in Fig. 6A, when performed as an open direct-viewing procedure, the omentum is retracted and the jejunum is exposed. Either by the hands of an assistant in an open procedure or with aid of atraumatic laparoscopic graspers [Endo Babcock or Dolphin Nose Grasper], the proximal jejunum is isolated and placed under gentle tension. One atraumatic grasper is inserted in the right upper quadrant for retraction of the jejunum towards the liver, and a second atraumatic grasper is inserted in the left lower quadrant, placed on a section of jejunum approximately 6 to 8 inches distal to the previously placed grasper, and retracted caudally towards the left lower quadrant. The jejunum is placed under tension and the mesentery exposed and straightened.

As indicated at Step D in Fig. 6A, when performed as a laparoscopic procedure, a pneumoperitoneum is created in the usual fashion and the trochars are inserted so the procedure may be

performed under laparoscopic guidance with multiple monitors. A partial omentectomy may be carried out by removing the caudal portions of the omentum. When performed laparoscopically, omentum is removed in strips to facilitate removal through laparoscopic portals. Care is taken to obtain strict hemostasis and to preserve an apron of protective omentum while it is substantially shortened and defatted.

Fig. 9A depicts the bowel grasped between two clamps to tent up the mesentery.

Fig. 9B depicts a cannula inserted into the tented mesentery to infuse tumescent solution.

As indicated in Step E in Fig. 6A, a retractor is inserted through the right lower quadrant and placed posteriorly beneath the tented mesentery. An incision is made anteriorly in the mesentery, approximately 2/3 of the distance between its base and the bowel. The surgeon then inserts the power-assisted twin cannula assembly 5 into the region, and applies 30-40 cm Hg of vacuum to the inner cannula, and conservatively aspirates mesenteric fat. Fig. 9C depicts insertion of the twin cannula device 5 into the previously tumesced and tented mesentery.

When using the laparoscopically-guided twin-cannula visceral fat aspiration instrument system shown in Figs. 1 and 2, there is much less risk of vascular disruption or visceral injury than when using single cannula instrument, because the twin-cannula instrument of the present invention protects the adventitia of the arboreal blood vessels from injury, and allows treatment of larger areas more rapidly and effectively.

As indicated in Step F in Fig. 6A, the surgeon optionally, applies bipolar electro-cautery, with or without synchronized tumescence. By including a separate fluidic channel in the outer cannula, extending from its base to its tip, it is possible to synchronize a pulsed infusion of tumescent solutions or irrigation (e.g. lactated Ringer's solution with or without small amounts of epinephrine (e.g. 1:100,000 - 1:400,000) through this additional channel in the tip of the twin cannula assembly with the advancement of the inner cannula, to facilitate fat aspiration with a sump effect. Alternatively, a totally separate cannula may be placed with the mesentery and used for pulsatile or non-pulsatile, synchronized or unsynchronized infusion near the tip of the twin cannula assembly 5.

By eliminating the battering ram effect of a reciprocating cannula and the need for tumescent solution for hemostasis, twin cannula visceral fat aspiration allows the minimally invasive removal of soft tissue in any location, including the intestinal mesentery by either open or laparoscopic approaches. Unlike single cannula visceral fat aspiration cannulas, the tube-within-a-tube construction of the twin cannula assembly 5 is particularly suited to a laparoscopic approach as all viscera are spared disruption from the moving member except the limited area of fat being aspirated in the mesentery adjacent to the outer cannula slot. The relatively stationary outer cannula reduces friction caused by the continually reciprocating inner cannula and the laparoscopy portal. Placement of the outer cannula 5A is positional, rather than actively reciprocating, to avulse particles of fat.

Twin cannula mesenteric visceral fat aspiration according to the principles of the present invention described above, thus allows direct correction of abdominal obesity, and in a less invasive and

dramatically immediate fashion without the untoward nutritional consequences, hepatic, or renal complications of gastric bypass or banding procedures.

The use of twin cannula visceral fat aspiration, with or without bipolar cautery hemostasis and with or without a synchronized pulsed infusion of tumescent or irrigation solution through the cannula, offers a controlled, rapid, and safer way of treating a length of intestine with much less risk of bleeding or vascular injury.

Although bipolar hemostasis obviates the need for tumescence with epinephrine containing solutions, small amounts of epinephrine could be added to small pulses of lactated Ringer's solution, with or without small quantities of local anaesthetic, which are synchronized with the advancement of the inner cannula within the outer cannula.

Since the irrigation solution is immediately aspirated through the aspiration aperture 55 of the twin (twin) cannula assembly 5 of Fig. 2A and 3A, the systemic effects of vasopressor and local anesthetics during twin cannula synchronized tumescence (TCST) would be more limited than an alternative means, such as infusion of a similarly dilute epinephrine and xylocaine in lactated Ringer's solution with a Tenckoff catheter via *peritoneal lavage*.

Epidural or general anaesthesia could replace or augment synchronized infusion or peritoneal lavage. Although TCST is the preferred embodiment of the described method, the present invention contemplates choosing modalities that are optimized for each individual patient's physiologic and cardiovascular status, and concentrations of xylocaine and epinephrine in the employed solutions from zero to therapeutic, as the situation dictates.

As indicated in Step G in Fig. 6B, the surgeon cautiously defats the mesentery, leaving skip areas of untreated mesentery every 6-8" of bowel length to minimize chances of vascular compromise. This step can be achieved by applying a vacuum of 30-40 cm Hg, and defatting the mesentery by initiating mechanical reciprocation of the inner cannula 5B within the outer cannula 5A of the transiently stationary twin cannula assembly 5. Care is taken to retain some fat and avoid creating defects that might allow intestine to herniate through, and any perforations in the mesentery are closed to eliminate this hazard. The area of treatment is inspected for hemostasis and any defects in the mesentery repaired. The jejunum between clamps is inspected for good vascular supply.

As indicated in Step H in Fig. 6B, during a single session or during smaller, serial sessions, the surgeon defats the mesentery from jejunum to distal ileum, avoiding terminal ileum. Then, as with the open approach, a small area is skipped much like a radiating spokes on a wheel to assure continuity of blood supply, and the next 8" area of jejunum is tented and the procedure repeated until the terminal ileum is reached and left untreated. Any difficulties with hemostasis or questionable vascular viability of the bowel indicate the necessity of a resection and possible conversion to an open procedure.

As indicated in Step I in Fig. 6B, the surgeon repeats the procedure on the large bowel and/or the small bowel for greatest effect. The mesentery of the large bowel would be approached from the ascending colon to the sigmoid colon, avoiding the area surrounding the ileocecal valve, and the distal

sigmoid colon as it descends into the pelvis, and the mesentery to any areas of large bowel which appear grossly involved with diverticulitis.

As indicated in Step J in Fig. 6B, the surgeon performs subsequent subcutaneous serial, visceral fat aspiration, abdominal lipectomy, dermatolipectomies, and ventral herniorrhaphies, as indicated for both functional and cosmetic indications. Large volume subcutaneous visceral fat aspiration, panniculectomy, abdominoplasty, repair of any ventral hernias or diastasis recti could be carried out in serial sessions to obtain a much tightened abdominal corset for both functional and cosmetic improvement. The majority of these procedures can be performed under conscious sedation and on an ambulatory basis on these patients with minimal complications because of their improved metabolic profiles.

As indicated in Step K in Fig. 6B, the surgeon prescribes a diet and exercise program to optimize therapeutic results, and monitors laboratory parameters and adjust any pharmacologic regimen that had been previously prescribed.

Method of Treating WHR and Metabolic Syndrome According To The Principles of the Present Invention

Figs. 7A and 7B illustrates the primary steps carried out during the illustrative embodiment of the method of treating WHR and metabolic syndrome by mesenteric visceral fat aspiration according to the present invention, comprising diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated.

As indicated in Step A in Fig. 7B, the surgeon diagnoses a patient with metabolic syndrome and/or obesity, using the waist-to-hip ratio (WHR), by physical measurements and lab tests. Metabolic Syndrome will be diagnosed upon the presence of any Three Risk Factors: Abdominal obesity; Triglycerides; HDL cholesterol; Blood Pressure; and FBS.

Defining levels for males and females are as follows:

Female >88 cm (>35")

Men: >102 cm.(>40")

≥ 150 ml/dl

Men < 40mg/dl

Women < 50 mg/dl

≥130/ ≥85 mm Hg

≥110 mg/dl

As indicated in Step B in Fig. 7A, the surgeon performs a brief abdominal exploration or inspection to eliminate the presence of inflammatory bowel disease and other contraindications to surgery, such as, diverticulitis and a Meckel's diverticulum, or any other pathology. At her option, the surgeon may infuse a tumescent solution (Ringer's lactate with or without dilute epinephrine, and with or without xylocaine) as described above to prepare the area for treatment.

As indicated in Step C in Fig. 7A, the surgeon performs a partial omentectomy by removing the redundant omental apron.

As indicated in Step D in Fig. 7A, when performed as an open direct-viewing procedure, the omentum is retracted and the jejunum is exposed. Either by the hands of an assistant in an open procedure or with aid of atraumatic laparoscopic graspers [Endo Babcock or Dolphin Nose Grasper], the proximal jejunum is isolated and placed under gentle tension. One atraumatic grasper is inserted in the right upper quadrant for retraction of the jejunum towards the liver, and a second atraumatic grasper is inserted in the left lower quadrant, placed on a section of jejunum approximately 6 to 8 inches distal to the previously placed grasper, and retracted caudally towards the left lower quadrant. The jejunum is placed under tension and the mesentery exposed and straightened.

As indicated at Step D in Fig. 7A, when performed as a laparoscopic procedure, a pneumoperitoneum is created in the usual fashion and the trochars are inserted so the procedure may be performed under laparoscopic guidance with multiple monitors. A partial omentectomy may be carried out by removing the caudal portions of the omentum. When performed laparoscopically, omentum is removed in strips to facilitate removal through laparoscopic portals. Care is taken to obtain strict hemostasis and to preserve an apron of protective omentum while it is substantially shortened and defatted.

Fig. 9A depicts the bowel grasped between two clamps to tent up the mesentery.

Fig. 9B depicts a cannula inserted into the tented mesentery to infuse tumescent solution.

As indicated in Step E in Fig. 7A, a retractor is inserted through the right lower quadrant and placed posteriorly beneath the tented mesentery. An incision is made anteriorly in the mesentery, approximately 2/3 of the distance between its base and the bowel. The surgeon then inserts either a single cannula through the right lower quadrant and into an anterior incision in the jejunal mesentery, and reciprocates it manually, or preferably inserts the power-assisted twin cannula assembly 5 into the region, and applies 30-40 cm Hg of vacuum to the inner cannula, and conservatively aspirates mesenteric fat. Fig. 9C depicts insertion of the twin cannula device 5 into the previously tumesced and tented mesentery.

When using a laparoscopically-guided electro-cauterizing twin-cannula visceral fat aspiration instrument system shown in Fig. 1, there is much less risk of vascular disruption or visceral injury than when using single cannula instrument, because the twin cannula instrument protects the adventitia of the arboreal blood vessels from injury, and allows treatment of larger areas more rapidly and effectively.

As indicated in Step F in Fig. 7A, the surgeon optionally, applies monopolar or bipolar cautery, with or without synchronized tumescence. By including a separate fluidic channel in the outer cannula, extending from its base to its tip, it is possible to synchronize a pulsed infusion of tumescent solutions or irrigation (e.g. lactated Ringer's solution with or without small amounts of epinephrine (e.g. 1:100,000 - 1:400,000) through this additional channel in the tip of the twin cannula assembly with the advancement of the inner cannula, to facilitate fat aspiration with a sump effect. Alternatively, a totally separate cannula may be placed with the mesentery and used for pulsatile or non-pulsatile, synchronized or unsynchronized infusion near the tip of the twin cannula assembly 5.

By eliminating the battering ram effect of a reciprocating cannula and the need for tumescent solution for hemostasis, twin cannula visceral fat aspiration allows the minimally invasive removal of soft tissue in any location, including the intestinal mesentery by either open or laparoscopic approaches. Unlike single cannula visceral fat aspiration cannulas, the tube-within-a-tube construction of the twin cannula assembly 5 is particularly suited to a laparoscopic approach as all viscera are spared disruption from the moving member except the limited area of fat being aspirated in the mesentery adjacent to the outer cannula slot. The relatively stationary outer cannula reduces friction caused by the continually reciprocating inner cannula and the laparoscopy portal. Placement of the outer cannula 5A is positional, rather than actively reciprocating, to avulse particles of fat.

Twin cannula mesenteric visceral fat aspiration (TCML) according to the principles of the present invention described above, thus allows direct correction of abdominal obesity, and in a less invasive and dramatically immediate fashion without the untoward nutritional consequences, hepatic, or renal complications of gastric bypass or banding procedures.

The use of twin cannula visceral fat aspiration, with or without bipolar cautery hemostasis and with or without a synchronized pulsed infusion of tumescent or irrigation solution through the cannula, offers a controlled, rapid, and safer way of treating a length of intestine with much less risk of bleeding or vascular injury.

Although bipolar hemostasis obviates the need for tumescence with epinephrine containing solutions, small amounts of epinephrine could be added to small pulses of lactated Ringer's solution, with or without small quantities of local anaesthetic, which are synchronized with the advancement of the inner cannula within the outer cannula.

Since the irrigation solution is immediately aspirated through the aspiration aperture 55 of the twin (twin) cannula assembly 5 of Fig. 2A or 3A, the systemic effects of vasopressor and local anesthetics during twin cannula synchronized tumescence (TCST) would be more limited than an alternative means, such as infusion of a similarly dilute epinephrine and xylocaine in lactated Ringer's solution with a Tenckhoff catheter via *peritoneal lavage*.

Epidural or general anaesthesia could replace or augment synchronized infusion or peritoneal lavage. Although TCST is the preferred embodiment of the described method, the present invention contemplates choosing modalities that are optimized for each individual patient's physiologic and cardiovascular status, and concentrations of xylocaine and epinephrine in the employed solutions from zero to therapeutic, as the situation dictates.

As indicated in Step G in Fig. 7B, the surgeon cautiously defats the mesentery, leaving skip areas of untreated mesentery every 6-8" of bowel length to minimize chances of vascular compromise. This step can be achieved by applying a vacuum of 30-40 cm Hg, and defatting the mesentery by initiating mechanical reciprocation of the inner cannula 5B within the outer cannula 5A of the transiently stationary twin cannula assembly 5. Care is taken to retain some fat and avoid creating defects that might allow intestine to herniate through, and any perforations in the mesentery are closed to eliminate this hazard.

The area of treatment is inspected for hemostasis and any defects in the mesentery repaired. The jejunum between clamps is inspected for good vascular supply.

As indicated in Step H IN Fig. 7B, during a single session or during smaller, serial sessions, the surgeon defats the mesentery from jejunum to distal ileum, avoiding terminal ileum. Then, as with the open approach, a small area is skipped much like a radiating spokes on a wheel to assure continuity of blood supply, and the next 8" area of jejunum is tented and the procedure repeated until the terminal ileum is reached and left untreated. Any difficulties with hemostasis or questionable vascular viability of the bowel indicate the necessity of a resection and possible conversion to an open procedure.

As indicated in Step I in Fig. 7B, the surgeon repeats the procedure on the large bowel and/or the small bowel for greatest effect. The mesentery of the large bowel would be approached from the ascending colon to the sigmoid colon, avoiding the area surrounding the ileocecal valve, and the distal sigmoid colon as it descends into the pelvis, and the mesentery to any areas of large bowel which appear grossly involved with diverticulitis.

As indicated in Step J in Fig. 7B, the surgeon performs subsequent subcutaneous serial, visceral fat aspiration, abdominal lipectomy, dermatolipectomies, and ventral herniorrhaphies, as indicated for both functional and cosmetic indications. Large volume subcutaneous visceral fat aspiration, panniculectomy, abdominoplasty, repair of any ventral hernias or diastasis recti could be carried out in serial sessions to obtain a much tightened abdominal corset for both functional and cosmetic improvement. The majority of these procedures can be performed under conscious sedation and on an ambulatory basis on these patients with minimal complications because of their improved metabolic profiles.

As indicated in Step K in Fig. 7B, the surgeon prescribes a diet and exercise program to optimize therapeutic results, and monitors laboratory parameters and adjust any pharmacologic regimen that had been previously prescribed.

Method of Treating Type II Diabetes According To The Principles of the Present Invention

Figs. 8A and 8B illustrate the primary steps carried out during the method of treating type II diabetes by mesenteric visceral fat aspiration according to the illustrative embodiment of the present invention, comprising the steps of: diagnosis, exploration, partial omentectomy, small bowel mesenteric visceral fat aspiration, large bowel mesenteric visceral fat aspiration, followed by subcutaneous visceral fat aspiration, abdominal and dermatolipectomies as indicated.

As indicated in Step A in Fig. 8A, the surgeon diagnoses a patient with type II diabetes by physical measurements and lab tests. Typically, this diagnosis is made using Fasting Blood Sugar, Glucose Tolerance or Insulin resistance (hyperinsulinemic glucose clamp test, considered to be the gold standard technique for quantification of insulin sensitivity. [Halaas JL, Gajiwala KS, Ma ei M, Cohen SL,et al.:Weight-reducing e ects of the plasma protein encoded by the obese gene. Science 269:543,1995]. This test is based on infusing a known dose of insulin (1mU/kg/min) and glucose (20% solution) at a constant speed to achieve a stable plasma concentration of insulin. The plasma glucose level

is continually determined using a bedside glucose analyzer, and the exogenous glucose infusion rate is adjusted continually to prevent hypoglycemia. Once the steady state is reached, the amount of infused glucose is the same as that used by the peripheral tissue. Therefore, insulin sensitivity can be calculated as the glucose infusion rate (mg/kg/min) over the last 60 min. A diagnosis of diabetes will be made if you have a fasting blood sugar level of 126 milligrams per deciliter or higher on two separate days.

Diabetes also may be diagnosed based on a random high glucose level of ³ 200mg/dl and symptoms of the disease. The most common glucose tolerance test is the oral glucose tolerance test (OGTT). The patient cannot eat or drink anything after midnight before the test. For the test, the patient will be asked to drink a liquid containing a certain amount of glucose. The patient's blood will be taken before s/he does this, and again every 30 to 60 minutes after s/he drinks the solution. The test takes up to 3 hours.

Normal blood values for a 75-gram oral glucose tolerance test used to check for type 2 diabetes:
Fasting: 60 to 100 mg/dL
1 hour: less than 200 mg/dL
2 hours: less than 140 mg/dL. Between 140-200 mg/dL is considered impaired glucose tolerance or pre-diabetes. This group is at increased risk for developing diabetes. Greater than 200 mg/dL is diagnostic of diabetes mellitus

As indicated in Step B in Fig. 8A, the surgeon performs a brief abdominal exploration or inspection to eliminate the presence of inflammatory bowel disease and other contraindications to surgery, such as, diverticulitis and a Meckel's diverticulum, or any other pathology. At her option, the surgeon may infuse a tumescent solution (Ringer's lactate with or without dilute epinephrine, and with or without xylocaine) as described above to prepare the area for treatment.

As indicated in Step C in Fig. 8A, the surgeon performs a partial omentectomy by removing the redundant omental apron.

As indicated in Step D in Fig. 8A, when performed as an open direct-viewing procedure, the omentum is retracted and the jejunum is exposed. Either by the hands of an assistant in an open procedure or with aid of atraumatic laparoscopic graspers [Endo Babcock or Dolphin Nose Grasper], the proximal jejunum is isolated and placed under gentle tension. One atraumatic grasper is inserted in the right upper quadrant for retraction of the jejunum towards the liver, and a second atraumatic grasper is inserted in the left lower quadrant, placed on a section of jejunum approximately 6 to 8 inches distal to the previously placed grasper, and retracted caudally towards the left lower quadrant. The jejunum is placed under tension and the mesentery exposed and straightened.

As indicated at Step D in Fig. 8A, when performed as a laparoscopic procedure, a pneumoperitoneum is created in the usual fashion and the trochars are inserted so the procedure may be performed under laparoscopic guidance with multiple monitors. A partial omentectomy may be carried out by removing the caudal portions of the omentum. When performed laparoscopically, omentum is removed in strips to facilitate removal through laparoscopic portals. Care is taken to obtain strict

hemostasis and to preserve an apron of protective omentum while it is substantially shortened and defatted.

Fig. 9A depicts the bowel grasped between two clamps to tent up the mesentery.

Fig. 9B depicts a cannula inserted into the tented mesentery to infuse tumescent solution.

As indicated in Step E in Fig. 8A, a retractor is inserted through the right lower quadrant and placed posteriorly beneath the tented mesentery. An incision is made anteriorly in the mesentery, approximately 2/3 of the distance between its base and the bowel. The surgeon then inserts either a single cannula through the right lower quadrant and into an anterior incision in the jejunal mesentery, and reciprocates it manually, or preferably inserts the power-assisted twin cannula assembly 5 into the region, and applies 30-40 cm Hg of vacuum to the inner cannula, and conservatively aspirates mesenteric fat. Fig. 9C depicts insertion of the twin cannula device 5 into the previously tumesced and tented mesentery.

When using a laparoscopically-guided electro-cauterizing twin-cannula visceral fat aspiration instrument system shown in Figs. 1A, there is much less risk of vascular disruption or visceral injury than when using single cannula instrument, because the twin cannula instrument protects the adventitia of the arboreal blood vessels from injury, and allows treatment of larger areas more rapidly and effectively.

As indicated in Step F in Fig. 8A, the surgeon optionally, applies monopolar or bipolar cautery, with or without synchronized tumescence. By including a separate fluidic channel in the outer cannula, extending from its base to its tip, it is possible to synchronize a pulsed infusion of tumescent solutions or irrigation (e.g. lactated Ringer's solution with or without small amounts of epinephrine (e.g. 1:100,000 - 1:400,000) through this additional channel in the tip of the twin cannula assembly with the advancement of the inner cannula, to facilitate fat aspiration with a sump effect. Alternatively, a totally separate cannula may be placed with the mesentery and used for pulsatile or non-pulsatile, synchronized or unsynchronized infusion near the tip of the twin cannula assembly 5.

By eliminating the battering ram effect of a reciprocating cannula and the need for tumescent solution for hemostasis, twin cannula visceral fat aspiration allows the minimally invasive removal of soft tissue in any location, including the intestinal mesentery by either open or laparoscopic approaches. Unlike single cannula visceral fat aspiration cannulas, the tube-within-a-tube construction of the twin cannula assembly 5 is particularly suited to a laparoscopic approach as all viscera are spared disruption from the moving member except the limited area of fat being aspirated in the mesentery adjacent to the outer cannula slot. The relatively stationary outer cannula reduces friction caused by the continually reciprocating inner cannula and the laparoscopy portal. Placement of the outer cannula 5A is positional, rather than actively reciprocating, to avulse particles of fat.

Twin cannula mesenteric visceral fat aspiration according to the principles of the present invention described above, thus allows direct correction of abdominal obesity, and in a less invasive and dramatically immediate fashion without the untoward nutritional consequences, hepatic, or renal complications of gastric bypass or banding procedures.

The use of twin cannula visceral fat aspiration, with or without bipolar cautery hemostasis and with or without a synchronized pulsed infusion of tumescent or irrigation solution through the cannula,

offers a controlled, rapid, and safer way of treating a length of intestine with much less risk of bleeding or vascular injury.

Although bipolar hemostasis obviates the need for tumescence with epinephrine containing solutions, small amounts of epinephrine could be added to small pulses of lactated Ringer's solution, with or without small quantities of local anaesthetic, which are synchronized with the advancement of the inner cannula within the outer cannula.

Since the irrigation solution is immediately aspirated through the aspiration aperture 55 of the twin (twin) cannula assembly 5 of Fig. 2A or 3A, the systemic effects of vasopressor and local anesthetics during twin cannula synchronized tumescence (TCST) would be more limited than an alternative means, such as infusion of a similarly dilute epinephrine and xylocaine in lactated Ringer's solution with a Tenckhoff catheter via *peritoneal lavage*.

Epidural or general anaesthesia could replace or augment synchronized infusion or peritoneal lavage. Although TCST is the preferred embodiment of the described method, the present invention contemplates choosing modalities that are optimized for each individual patient's physiologic and cardiovascular status, and concentrations of xylocaine and epinephrine in the employed solutions from zero to therapeutic, as the situation dictates.

As indicated in Step G in Fig. 8B, the surgeon cautiously defats the mesentery, leaving skip areas of untreated mesentery every 6-8" of bowel length to minimize chances of vascular compromise. This step can be achieved by applying a vacuum of 30-40 cm Hg, and defatting the mesentery by initiating mechanical reciprocation of the inner cannula 5B within the outer cannula 5A of the transiently stationary twin cannula assembly 5. Care is taken to retain some fat and avoid creating defects that might allow intestine to herniate through, and any perforations in the mesentery are closed to eliminate this hazard. The area of treatment is inspected for hemostasis and any defects in the mesentery repaired. The jejunum between clamps is inspected for good vascular supply.

As indicated in Step H in Fig. 8B, during a single session or during smaller, serial sessions, the surgeon defats the mesentery from jejunum to distal ileum, avoiding terminal ileum. Then, as with the open approach, a small area is skipped much like a radiating spokes on a wheel to assure continuity of blood supply, and the next 8" area of jejunum is tented and the procedure repeated until the terminal ileum is reached and left untreated. Any difficulties with hemostasis or questionable vascular viability of the bowel indicate the necessity of a resection and possible conversion to an open procedure.

As indicated in Step I in Fig. 8B, the surgeon repeats the procedure on the large bowel and/or the small bowel for greatest effect. The mesentery of the large bowel would be approached from the ascending colon to the sigmoid colon, avoiding the area surrounding the ileocecal valve, and the distal sigmoid colon as it descends into the pelvis, and the mesentery to any areas of large bowel which appear grossly involved with diverticulitis.

As indicated in Step J in Fig. 8B, the surgeon performs subsequent subcutaneous serial, visceral fat aspiration, abdominal lipectomy, dermatolipectomies, and ventral herniorraphies, as indicated for both functional and cosmetic indications. Large volume subcutaneous visceral fat aspiration, panniculectomy,

abdominoplasty, repair of any ventral hernias or diastasis recti could be carried out in serial sessions to obtain a much tightened abdominal corset for both functional and cosmetic improvement. The majority of these procedures can be performed under conscious sedation and on an ambulatory basis on these patients with minimal complications because of their improved metabolic profiles.

As indicated in Step K in Fig. 8B, the surgeon ascertains the degree of metabolic improvement that has been attained by measuring blood pressure, lipid profile, adipocytokine and inflammatory markers, fasting blood sugar, or insulin resistance via the hyperinsulimic glucose clamp test previously described, repeating testing at 2 mos/6mos/9mos/1yr/1.5yrs/2yrs.

Alternative Embodiments Which Readily Come To Mind

While the multi-function twin-cannula assembly described above has been shown used with a twin cannula assembly, it is understood that in alternate embodiments, the inner cannula can be adapted to provide a similar fluid infusion channel that terminates proximal to the luer fitting and allows for fluid infusion.

While a barb Christmas-tree type connector is shown on the stationary tubing connector, of each hand-supportable housing, it is understood that the stationary tubing connector may also be realized as a snap-lock type connector for establishing and maintaining a connection with the end portion of flexible aspiration tubing.

Further, the powered fat aspiration instrument of the present invention can be designed so that its cylindrical guide tube is made very simple, inexpensively and is disposable so as to eliminate the need for a magnet which can lose its strength with autoclaving. The cannula base portion can be made so as to use washers that are wafer thin, for only one day of surgery. Such washers can function as diaphragms, staying in place and deforming to allow to-and-fro motion of the cylindrical guide tube within the cylindrical guide tube. Also, these washers can have an umbrella-shape, or be have a thin cylindrical geometry.

Several modifications to the illustrative embodiments have been described above. It is understood, however, that various other modifications to the illustrative embodiment of the present invention will readily occur to persons with ordinary skill in the art. All such modifications and variations are deemed to be within the scope and spirit of the present invention as defined by the accompanying Claims to Invention.

WHAT IS CLAIMED IS:

1. A laparoscopically-guided intra-abdominal visceral fat aspiration system comprising a powered hand-supportable instrument held by a surgeon and having an electro-cauterizing cannula assembly for the safe removal of visceral fat from the mesenteric region of a patient, through a small incision in the patient's body.
2. An irrigating bipolar electro-cauterizing twin-cannula visceral fat aspiration system comprising: a hand-supportable visceral fat aspiration instrument, having a twin cannula assembly wherein an inner cannula having an aspiration aperture is mechanically reciprocated within a stationary outer cannula having an elongated aperture along which said aspiration aperture moves, while said inner cannula is operably affixed to a vacuum source, and a controller controls bipolar electro-cautery, and synchronized pulsed tumescent infusion about said aspiration aperture during system operation.
3. A laparoscopically-guided electro-cauterizing power-assisted visceral fat aspiration system, for safely removing visceral fat from the mesenteric region of a patient, comprising:
 - a laparoscopy system having
 - a video probe for insertion into the patient by one or more surgeons,
 - one or more video monitors for displaying, to surgeons and assistants, digital video images of the patient's abdominal region, captured along the field of view (FOV) of the video probe, and
 - digital recording equipment for recording captured digital video during the operation, and marking the same by the surgeons;
 - an electro-cauterizing visceral fat aspiration system having
 - (i) a powered hand-supportable instrument provided with an electro-cauterizing cannula assembly, and
 - (ii) a system controller operably connected to said powered hand-supportable instrument, for supplying power to drive the inner cannula of the hand-supportable instrument, and (b) RF-power signals generated by an RF signal generating module for powering said electro-cauterizing cannula assembly;
 - an vacuum pump operably connected to the inner cannula, for aspirating visceral fat through the aspiration aperture of said cannula assembly, during system operation; and
 - an infusion pump controlled by the system controller, for periodically or continuously infusing solution near the distal portion of the cannula assembly during system.
4. The laparoscopically-guided electro-cauterizing power-assisted visceral fat aspiration system of claim 3, wherein said electro-cauterizing cannula assembly has a distal portion and an proximate portion, and includes an outer cannula insertable within said hand-supportable housing and having an elongated aperture formed at the distal portion of said outer cannula, and an inner cannula having an aspiration

aperture and supported within said outer cannula and being operably connected to said vacuum pump for aspiration of visceral fat tissue from the mesentery of said patient.

5. An electro-cauterizing visceral fat aspiration instrument system for removing visceral fat from said mesenteric region of a patient comprising:

a hand-supportable housing containing a motor source, and having a removably supporting a bipolar electro-cauterizing cannula assembly;

wherein said bipolar electro-cauterizing cannula assembly having a distal portion and an proximate portion, and including

an outer cannula insertable within said hand-supportable housing and having an elongated aperture formed at the distal portion of said outer cannula, and

an inner cannula having an aspiration aperture and supported within said outer cannula and being operably connected to a vacuum pump for aspiration of visceral fat tissue from the mesentery of said patient;

electrodes formed along said elongated aperture and said aspiration aperture for electro-cauterizing fat tissue as said fat tissue is being aspiration through said aspiration aperture;

wherein said motor source drives said inner cannula to reciprocate within said outer cannula, so that said aspiration aperture formed in said inner cannula reciprocates along the elongated aperture of said outer cannula, during instrument operation, while the surgeon removes visceral fat from the mesentery of the patient;

an irrigation channel formed along said cannula cannula, and in fluid communication with an irrigation aperture formed at the distal portion of said outer cannula and proximate to said elongated aperture; and

an infusion pump, operably connected to said outer cannula, for delivering controlled amounts of fluid to said irrigation channel, over short periods of time, in synchronization with either the forward or return stroke of said inner cannula within said outer cannula, so that said fluid flows out of said irrigation aperture and proximate to said elongated aperture during the aspiration of visceral fat through, and electro-cauterization of visceral fat about said reciprocating aspiration aperture.

6. A method of performing mesenteric visceral fat aspiration for ameliorating the metabolic syndrome, or abdominal obesity of the patient, comprising the steps of :

(a) diagnosing a metabolic syndrome or abdominal obesity in a patient;

(b) inserting a powered visceral fat aspiration instrument into the mesenteric region of said patient; and

(c) while viewing said mesenteric region of said patient, using said electro-cauterizing visceral fat aspiration instrument to remove visceral fat from said mesenteric region, so as to ameliorate said metabolic syndrome or abdominal obesity in the patient.

7. A method of performing mesenteric visceral fat aspiration for ameliorating the metabolic syndrome, or abdominal obesity of the patient, comprising the steps of :

- (a) diagnosing a metabolic syndrome or abdominal obesity in a patient;
- (b) inserting an electro-cauterizing powered visceral fat aspiration instrument into the mesenteric region of said patient; and
- (c) while viewing said mesenteric region of said patient, using said electro-cauterizing powered visceral fat aspiration instrument to remove visceral fat from said mesenteric region, so as to ameliorate said metabolic syndrome or abdominal obesity in the patient.

8. A method of performing mesenteric visceral fat aspiration for ameliorating the metabolic syndrome, or abdominal obesity of the patient, comprising the steps of :

- (a) diagnosing a metabolic syndrome or abdominal obesity in a patient;
- (b) inserting a laparoscopic instrument into the abdominal region of said patient;
- (c) inserting an electro-cauterizing powered visceral fat aspiration instrument into the mesenteric region of said patient; and
- (d) while viewing said mesenteric region of said patient using said laparoscopic instrument, using said electro-cauterizing powered visceral fat aspiration instrument to remove visceral fat from said mesenteric region

9. A method of performing intra-abdominal visceral fat aspiration comprising the steps of:

- (a) inserting a laparoscopic instrument into the abdominal region of a patient;
- (b) inserting an electro-cauterizing powered visceral fat aspiration instrument into the mesenteric region of said patient; and
- (c) while viewing said mesenteric region of said patient using said laparoscopic instrument, using said electro-cauterizing powered visceral fat aspiration instrument to remove visceral fat from said mesenteric region, to ameliorate the metabolic syndrome, or abdominal obesity of the patient.

10. The method of claim 9, which further comprises:

- (d) simultaneously infusing a tumescent solution into the mesenteric region of said patient while removing visceral fat from said mesenteric region using said electro-cauterizing powered visceral fat aspiration instrument.

11. The method claim 9, wherein said electro-cauterizing powered visceral fat aspiration instrument comprises a hand-supportable housing, a powered inner cannula within aspiration aperture and supported within an outer cannula mounted to said hand-supportable housing and having an elongated aperture, wherein said inner cannula is driven to reciprocate within said outer cannula so that said aspiration aperture reciprocates during instrument operation.

12. Apparatus in the form of a laparoscopically-guided intra-abdominal visceral fat aspiration system including a powered hand-supportable fat aspiration instrument held by a surgeon and having an electro-cauterizing, irrigating and fiber-illuminating twin-cannula assembly for the safe removal of visceral fat from the mesenteric region of a patient, through a small incision in the patient's body.

13. A laparoscopically-guided intra-abdominal visceral fat aspiration system, designed for safely removing visceral fat from the mesenteric region of a patient, comprising: a hand-supportable instrument provided with a twin-cannula assembly support ingbipolar electro-cauterization about the aspiration aperture of a moving inner cannula, supported in a stationary outer cannula connected to the hand-supportable housing of the instrument.

14. A method of performing laparoscopic mesenteric visceral fat aspiration for ameliorating the metabolic syndrome, or abdominal obesity of the patient, comprising the steps of: inserting a laparoscopic instrument and an electro-cauterizing visceral fat aspiration instrument into the mesenteric region of a patient, for the purpose of safely removing visceral fat to ameliorate the metabolic syndrome, or abdominal obesity of the patient.

15. A method of laparoscopically-guided intra-abdominal visceral fat aspiration, comprising the steps of: simultaneously infusing a tumescent solution into the mesenteric region of treatment, while synchronizing that infusion with the forward or return stroke of the inner cannula of a twin cannula assembly of a power visceral fat aspiration instrument.

16. A method of a lowering of the waist-to-hips circumference ratio, a treatment for and amelioration of type II diabetes mellitus, effect a favorable effect on metabolism as may be comprised of an increased insulin sensitivity, lowered fasting blood sugar, a lowering of blood pressure (particularly diastolic), an improvement in the lipid profile (lowered cholesterol, raising HDL, lowered triglycerides, lowered serum adipocytokine (Leptin) and inflammatory markers (TNF- α = tumor necrosis factor, resitin, IL-6and IL-9), and by doing so effect a decrease in insulin resistance and reduce the risk of coronary artery disease associated with metabolic syndrome.

17. A method of treating type II diabetes by way of selected removal of visceral fat cells and components contained therein (e.g. fat, adipocytokine (Leptin) and inflammatory markers (TNF- α = tumor necrosis factor, resitin, IL-6and IL-9), to improve the sensitivity of tissue cells to insulin.

18. A powered visceral fat aspiration instrument employing a twin cannula assembly having a moving aspiration aperture that reciprocates over a range of about ¼" to about 1" which is appropriate to the thickness of mesenteries and omental fat deposits.

19. A powered visceral fat aspiration instrument comprising a twin-cannula assembly supporting bipolar electro-cauterization of a visceral fat target being aspirated through a reciprocating inner aspiration aperture, in a safe and effective manner.

20. A powered visceral fat aspiration instrument employing a twin-cannula assembly which is driven in such a manner to substantially reduce vibration or disturbances which might be caused by the positioning of the instrument and thus its associated vacuum tubing, when repositioning of the aspirating cannula within visceral fat tissue.

21. A powered visceral fat aspiration instrument employing a twin-cannula assembly which supports simultaneous fluid irrigation and visceral fat aspiration about the moving aspiration aperture, in order to achieve a sump effect facilitating aspiration through the twin-cannula assembly.

22. A powered visceral fat aspiration instrument employing a twin-cannula assembly during a laparoscopic visceral fat aspiration procedure, which prevents the escape of compressed carbon dioxide used to distend the patient's abdomen during the procedure, through the instrument, or its cannula assembly, or through the incision through which it is placed, other than through the inner cannula itself as a result of fat aspiration through the inner cannula aperture(s).

23. A method of ameliorating metabolic syndrome and abdominal obesity in a human patient, comprising the steps of:

(a) removing visceral fat in said human patient, using a twin-cannula fat aspiration instrument and avoiding the use of direct surgical excision techniques.

24. A twin-cannula visceral fat aspiration instrument system comprising:

a hand-supportable fat aspiration instrument having

(i) a hand-supportable housing with a stationary tubing connector provided at the rear of the housing and receiving a length of flexible tubing connected to a vacuum source and connecting to the cylindrical cannula base portion guide tube, and

(ii) a twin tumescent-type cannula assembly having an inner cannula coupled to a cannula drive mechanism disposed within the hand-supportable housing and having an inner aspiration aperture that is reciprocated within the outer aspiration aperture of an outer cannula releasably connected to the front portion of said hand-supportable housing; and

a controller for controlling the electro-cautery and irrigation functions supported about said inner and outer aspiration apertures.

25. The twin-cannula visceral fat aspiration instrument system of claim 24, wherein said twin tumescent-type cannula assembly further supports fiber-based illumination across the field of aspiration about said aspiration aperture.

26. The twin-cannula visceral fat aspiration instrument system of claim 24, wherein the distal portion of said outer cannula has a low light reflectivity, and the distal portion of said inner cannula has a high reflectivity so as to provide said inner and outer aspiration apertures with high contrast light reflective characteristics when being digitally imaged by a digital imager during a laproscopically-guided visceral fat aspiration procedure carried out on a human patient.

27. The twin-cannula visceral fat aspiration instrument system of claim 24, wherein said outer cannula further comprises an optical fiber carrying an illumination source and terminating at said outer aspiration aperture, while irrigation enters into distal tip portion of said outer cannula.

28. A method treating type II diabetes in a human patient comprising the steps of:

- (a) diagnosing said human patient with said type II diabetes; and
- (b) reducing the number of hypertrophic fat cells and their harmful secretions (i.e. Leptin, Resistin and TNF- α) in the mesentery of said human patient using a twin-cannula type fat aspiration instrument, and thereby favorably impacting said human patient's metabolism by increasing fat burn and the basal metabolic rate (BMR).

29. A method treating type II diabetes in a human patient comprising the steps of:

- (a) diagnosing said human patient with said type II diabetes; and
- (b) reducing the number of hypertrophic fat cells and their harmful secretions (i.e. Leptin, Resistin and TNF- α) in the mesentery of said human patient using a twin-cannula type fat aspiration instrument, thereby increasing the secretion of Cytokines (i.e. Adipopectin) in said human patient, and the favorably increasing the sensitivity of peripheral tissues to insulin and thus increasing glucose utilization thereby.

30. A laproscopically-guided intra-abdominal visceral fat aspiration system for performing mesenteric visceral fat aspiration operations typically in an operating room environment, said system comprising:

an endoscopy (e.g. laparoscopy) subsystem, or laparoscope having (i) a video probe provided with an embedded 2D high-resolution digital color image sensor with a field of view (FOV) for insertion into the abdomen of the patient, (ii) one or more video monitors for displaying to surgeons and assistants, real-time digital color video images of the patient's abdominal region captured along the field of view (FOV) of the video probe, and (iii) digital recording equipment for recording captured digital video during the operation and marking the same by the surgeons, as required;

a twin-cannula powered visceral fat aspiration subsystem having (i) a powered hand-supportable fat aspiration instrument provided with a bipolar electro-cauterizing twin-cannula assembly, (ii) a system

controller connected to the hand-supportable instrument by way of a flexible cable, for supplying pressurized air streams from a pressurized gas source to drive the inner cannula of the hand-supportable instrument, or electrical power signals from an electrical power source to drive hand-supportable instrument.

31. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 30, wherein RF-power signals are generated by an RF signal generating module and supplied to said bipolar electro-cauterizing and illuminating twin-cannula assembly.

32. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 30, which further comprises an infusion pump controlled by said system controller, for periodically or continuously pumping irrigation fluid through irrigation tube and into an irrigation port provided on said outer cannula for infusing solution near and within the distal tip portion of said outer cannula during system operation.

33. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 32, wherein said infusion pump supplies a pulsatile flow of irrigation fluid through the distal tip portion of said outer cannula so that controlled amounts of fluid are delivered to the inner cannula under short periods of time to facilitate synchronization.

34. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 30, which further comprises a multi-spectral illumination source with selectable spectrum control, for delivering a spectrum of illumination along an optical fiber, mounted to said outer cannula, to the distal tip portion of said outer cannula and produce a field of illumination about the inner and outer aspiration apertures of the twin-cannula assembly, that spatially overlaps the field of aspiration about said inner and outer aspiration apertures.

35. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 34, wherein said multi-spectral illumination source generates a red, blue and/or yellow illumination for delivery to the field of aspiration about said inner and outer aspiration apertures, to illuminate tissue thereabout and help the surgeon visually distinguish arterial vessels, veins and fat, and facilitate viscultation of arterial blood vessels, portal and systemic veins and fat, when viewing color digital video images thereof captured by said video probe and displayed by said video monitors during said mesenteric visceral fat aspiration operations.

36. The laparoscopically-guided intra-abdominal visceral fat aspiration system of claim 30, which further comprises: an in-line fat sampling device installed in-line between a vacuum source and said powered hand-supportable fat aspiration instrument, for collecting and indexing samples of visceral fat while the

surgeon samples the abdominal region of the patient, for subsequent analysis and testing/measurement for compounds indicative of obesity, metabolic syndrome and/or type II diabetes.

37. A method of aspirating visceral fat from within the abdomen of a human patient, comprising the steps:

(a) providing a surgeon with a powered twin-cannula visceral fat aspiration instrument in an operating room, and also with a fat sampling device installed between said instrument and a vacuum source, wherein said fat sampling device includes a plurality fat collection syringes each of which can be selected individually and filled with aspirated visceral fat and indexed for subsequent analysis and testing in a laboratory;

(b) providing said surgeon with laproscopic imaging probe in said operating room;

(c) said surgeon selecting a first fat collection syringe in said fat sampling device to be fill with aspirated visceral fat from a first specified location in said abdomen;

(d) using said powered twin-cannula visceral fat aspiration instrument and said laproscopic imaging probe to aspirate visceral fat from said human patient and collecting said visceral fat in said selected syringe;

(e) said surgeon selecting a second fat collection syringe in said fat sampling device to be fill with aspirated visceral fat from a second specified location in said abdomen;

(f) removing said first and second fat collection syringes from said fat collection device, and testing the visceral fat samples contained therein for the concentration level of particular types of biochemical secretions which can indicate the patient's risk of coronary artery disease and/or insulin resistance.

38. The method of claim 35, wherein said biochemical secretions are selected from the group consisting of resistin level, adiponectin level, TNF-a marker level, interleukin-6 (IL-6) aninflammatory marker level, and IL-10 aninflammatory marker level.

39. An in-line fat sampling device comprising:

a optically-transparent collection chamber having closed end with a central aperture, and an open end with hollow inner chamber/space disposed between the closed end and the open end;

a removable lid for threaded connection to the open end of the collection chamber, and having a central flow channel terminated in a first barbed connector for connecting the device to vacuum source by way of a section of flexible vacuum tubing;

a stationary suction plate having plurality of hollow projections for supporting the open ends of a plurality of sample fat collection syringes, each having perforations in the walls thereof (to allow fluid to flow therethrough while in the collection chamber) and being keyed for registration with the collection chamber (to prevent rotation);

a rotatable selector for rotational engagement with the suction plate and having a hollow central post section that passes through central aperture and establishes fluid communication with a

passage/conduit that extends from center of the to periphery to control the flow of aspirated fat sample from the instrument through a first section of tubing, through said rotatable selector and into the selected syringe/projection combination;

a turning knob mounted on and engaging with the hollow selector post and enabling the turning of the rotatable selector relative to the stationary suction plate to select the syringe/projection combination into which an aspirated fat sample should flow for collection and indexing purposes during surgery;

a spring mounted between the turning knob and hollow selector post to push up the turning knob and keeping the selector at the bottom of the collection chamber; and

a second barbed connector connected by threads to the hollow selector post allowing the fat sampling device to be connected to the fat aspiration instrument by way of a second section of flexible vacuum tubing.

40. A method of treating morbid obesity in a human patient by mesenteric visceral fat aspiration, said method comprising the steps of:

- (a) diagnose morbid obesity in said human patient;
- (b) explore abdominal region of said human patient;
- (c) perform a partial omentectomy if indicated;
- (d) perform mesenteric visceral fat aspiration in the bowel using a twin-cannula visceral fat aspiration instrument;
- (e) perform subcutaneous visceral fat aspiration as and where indicated using said twin-cannula visceral fat aspiration instrument; and
- (f) perform abdominal and dermatolipectomies if and as indicated.

41. The method of claim 40, wherein step (d) further comprises using laparoscopic imaging techniques to guide the use of said twin-cannula visceral fat aspiration instrument while aspirating said mesenteric aspiration fat.

42. A method of treating metabolic syndrome in a human patient by mesenteric visceral fat aspiration, said method comprising the steps of:

- (a) diagnose metabolic syndrome in said human patient;
- (b) explore abdominal region of said human patient;
- (c) perform a partial omentectomy if indicated;
- (d) perform mesenteric visceral fat aspiration in the bowel using a twin-cannula visceral fat aspiration instrument;
- (e) perform subcutaneous visceral fat aspiration as and where indicated using said twin-cannula visceral fat aspiration instrument; and
- (f) perform abdominal and dermatolipectomies if and as indicated.

43. The method of claim 42, wherein step (d) further comprises using laparoscopic imaging techniques to guide the use of said twin-cannula visceral fat aspiration instrument while aspirating said mesenteric aspiration fat.

44. A method of treating type II diabetes in a human patient by mesenteric visceral fat aspiration, said method comprising the steps of:

- (a) diagnose type II diabetes in said human patient;
- (b) explore abdominal region of said human patient;
- (c) perform a partial omentectomy if indicated;
- (d) perform mesenteric visceral fat aspiration in the bowel using a twin-cannula visceral fat aspiration instrument;
- (e) perform subcutaneous visceral fat aspiration as and where indicated using said twin-cannula visceral fat aspiration instrument; and
- (f) perform abdominal and dermatolipectomies if and as indicated.

45. The method of claim 44, wherein step (d) further comprises using laparoscopic imaging techniques to guide the use of said twin-cannula visceral fat aspiration instrument while aspirating said mesenteric aspiration fat.

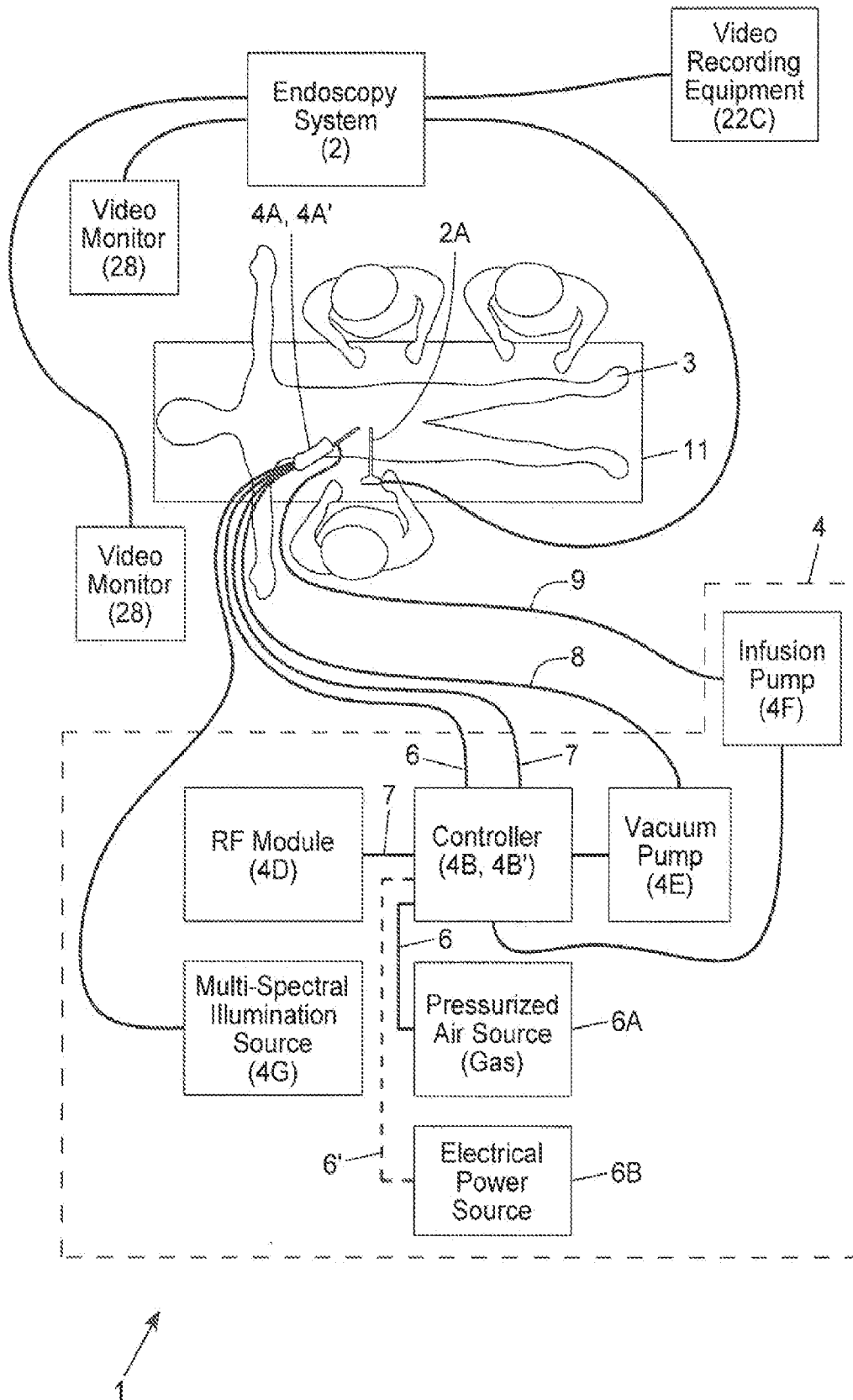


FIG. 1

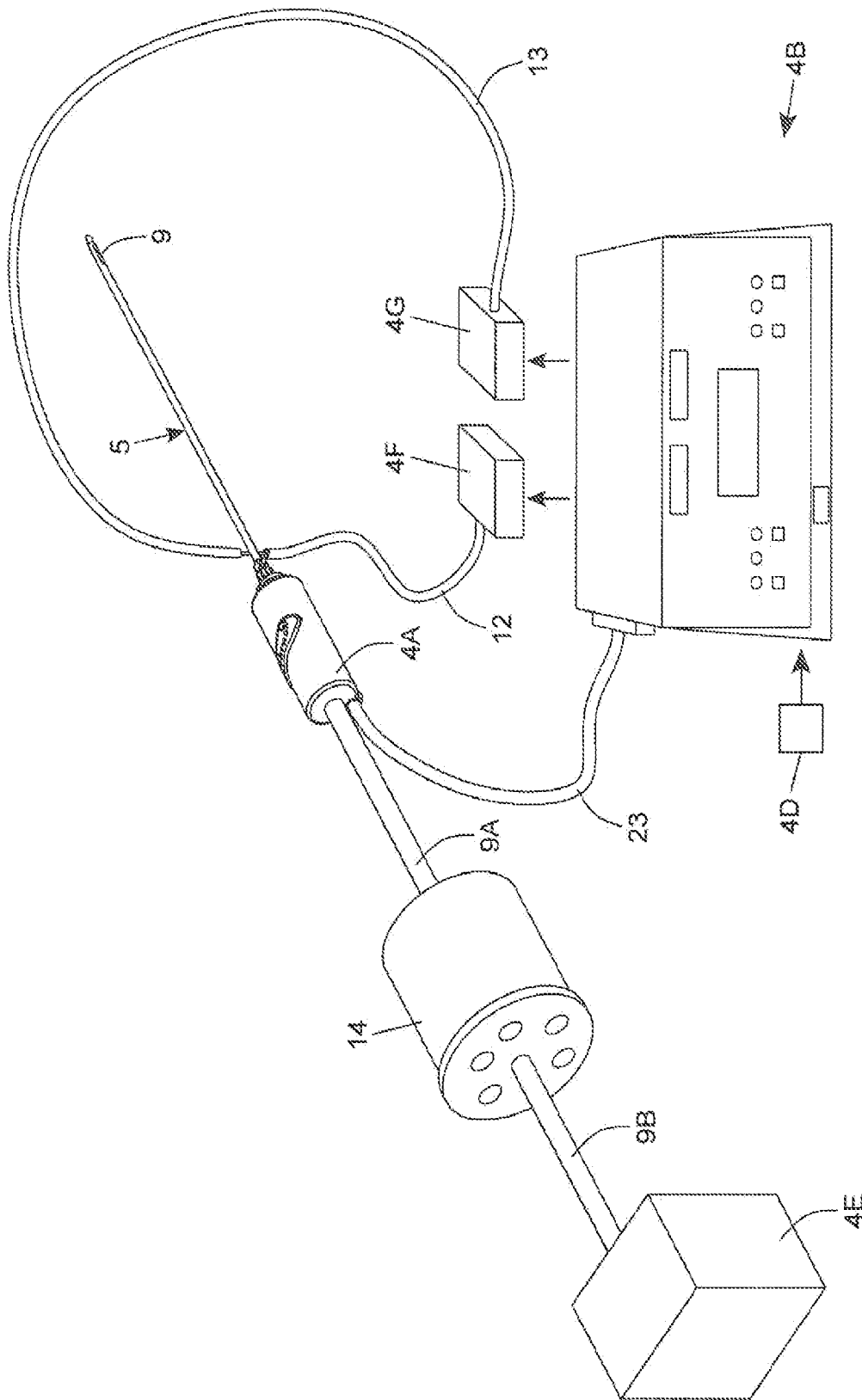


FIG. 2

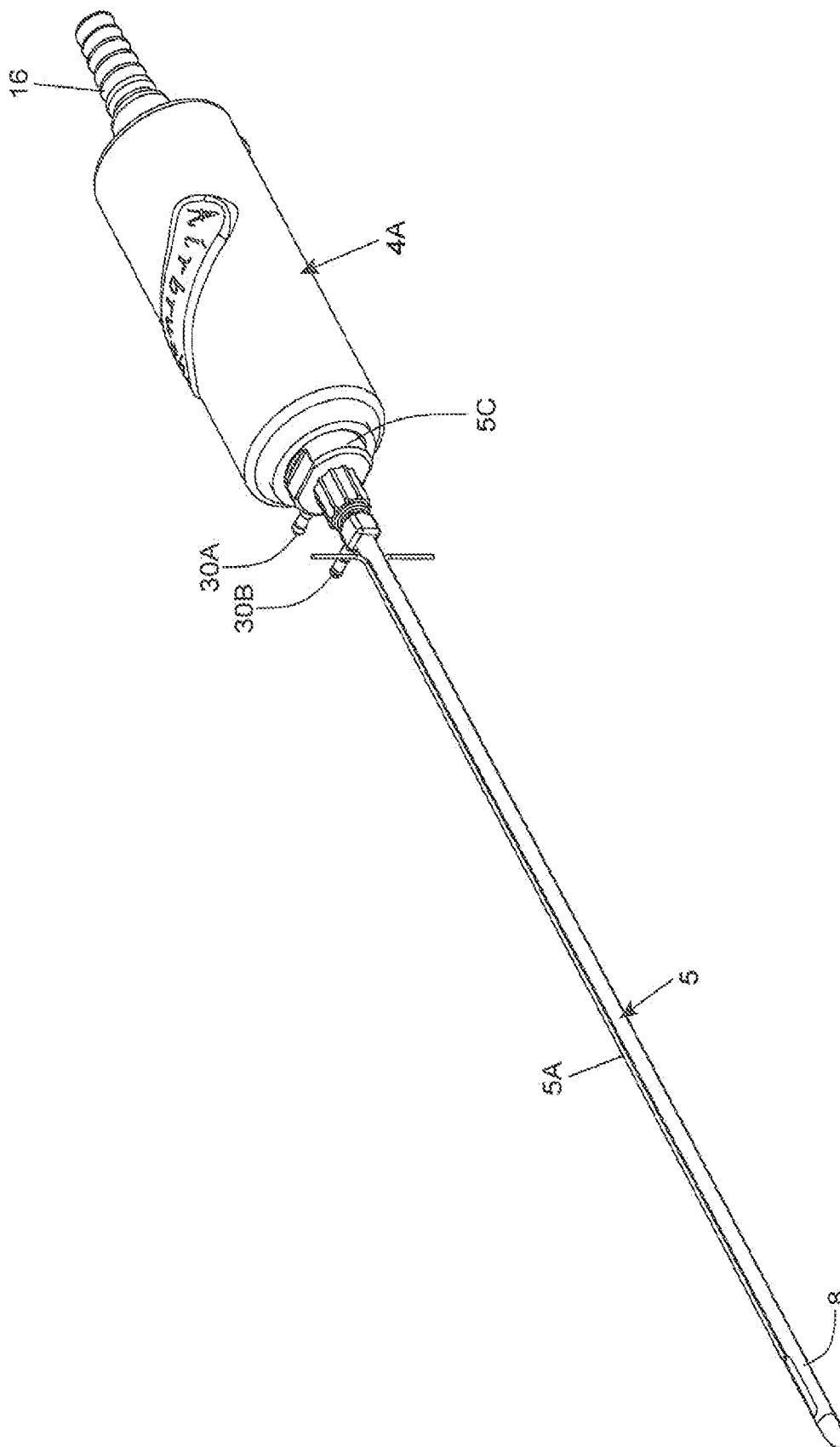


FIG. 2A1

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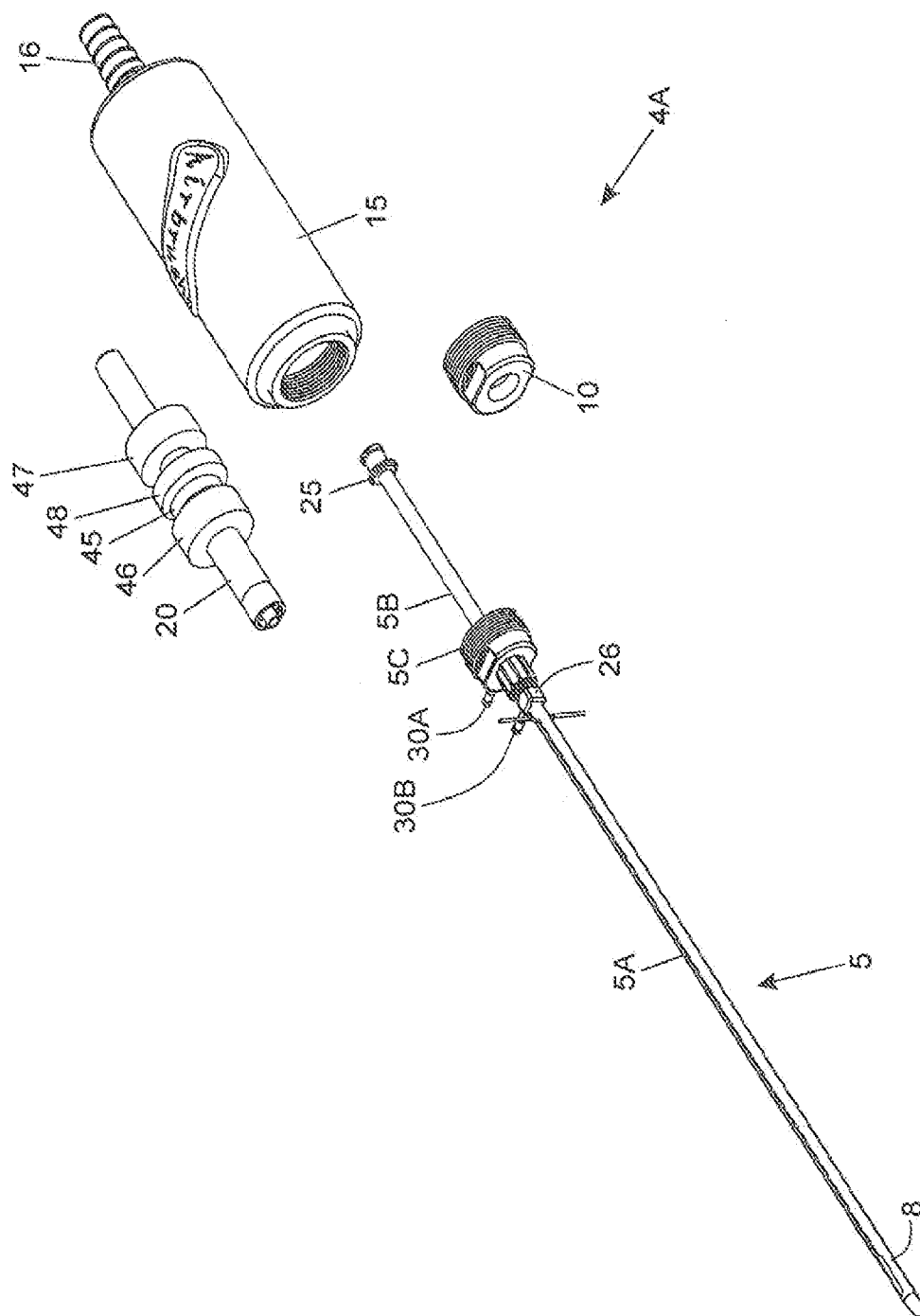


FIG. 2A2

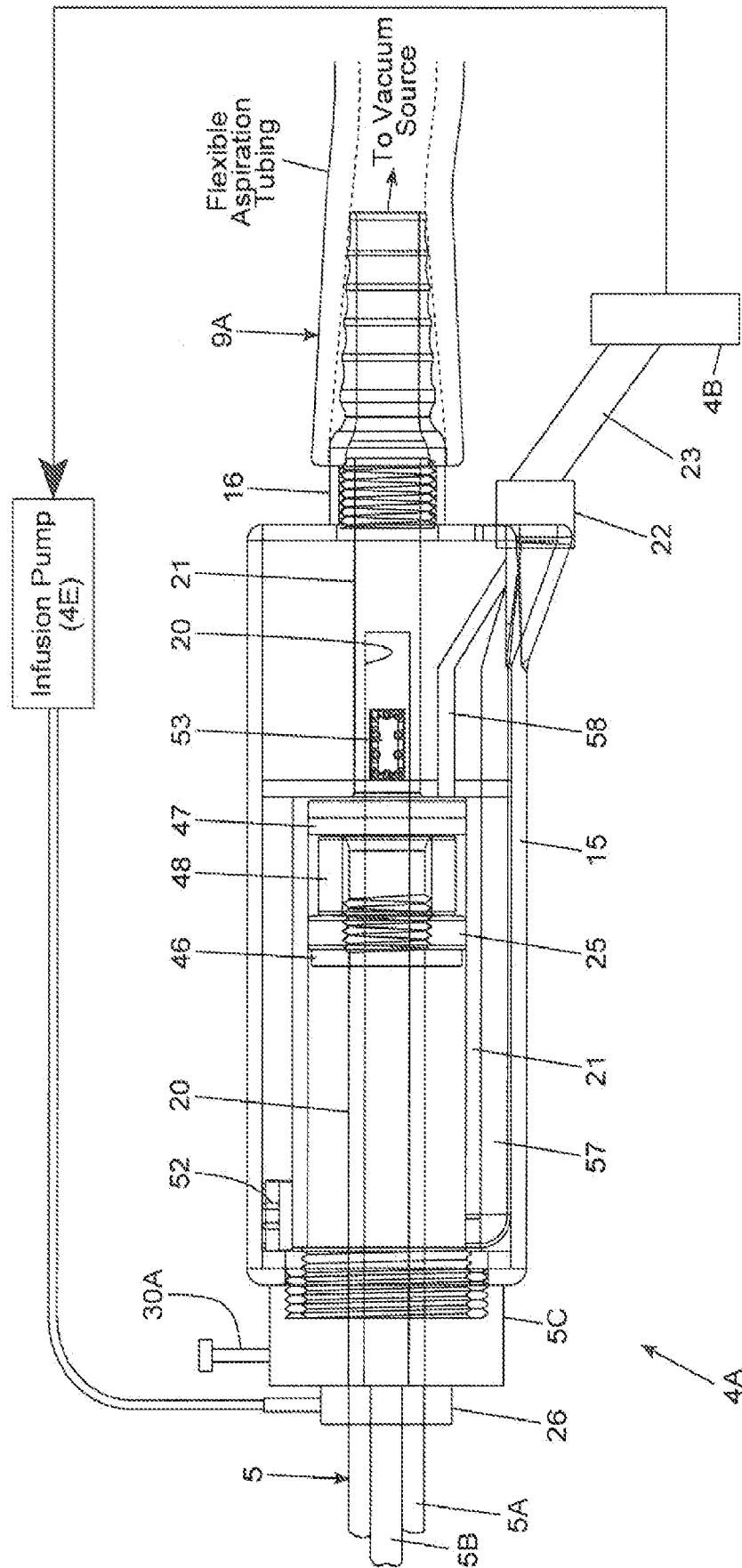


FIG. 2B

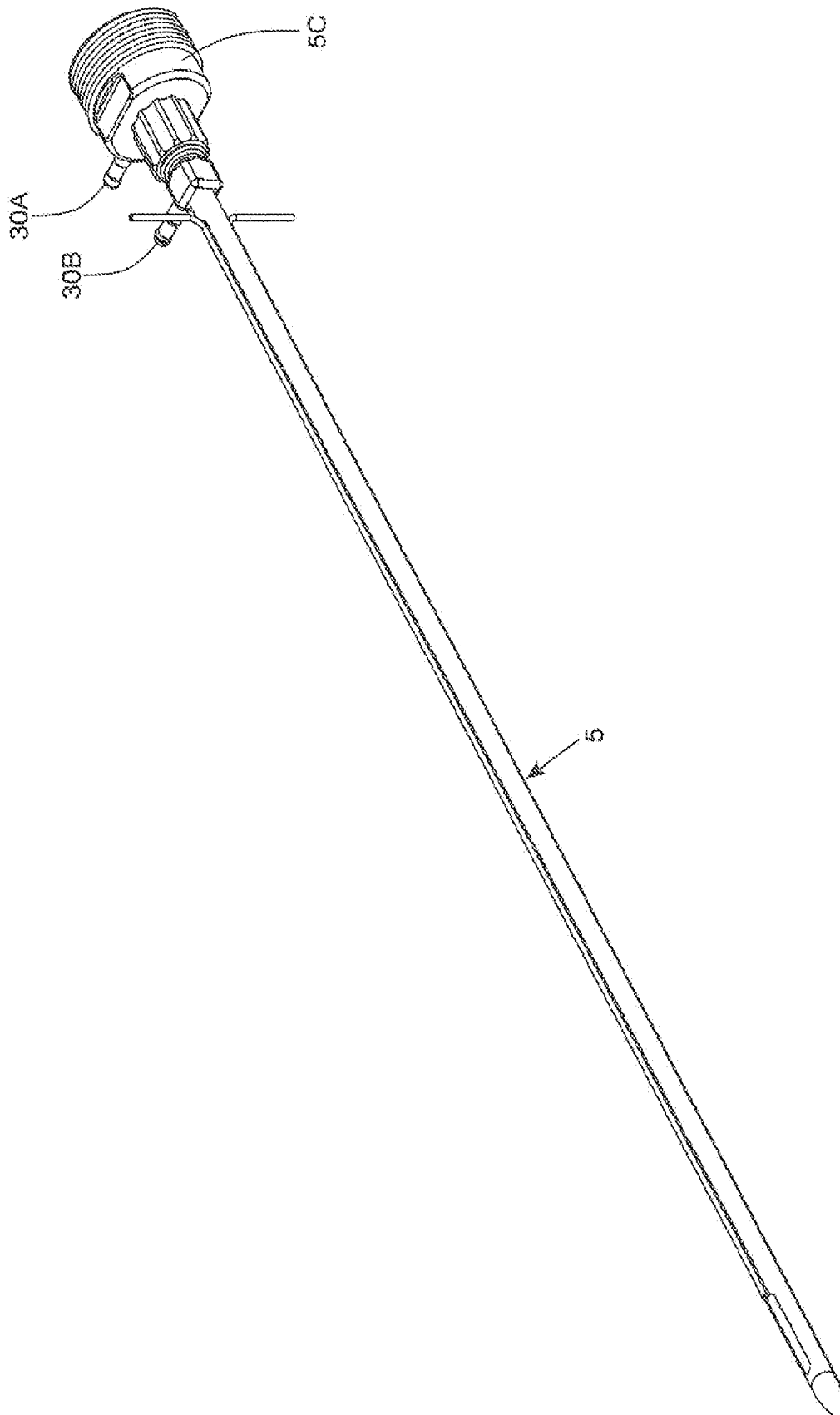


FIG. 2C

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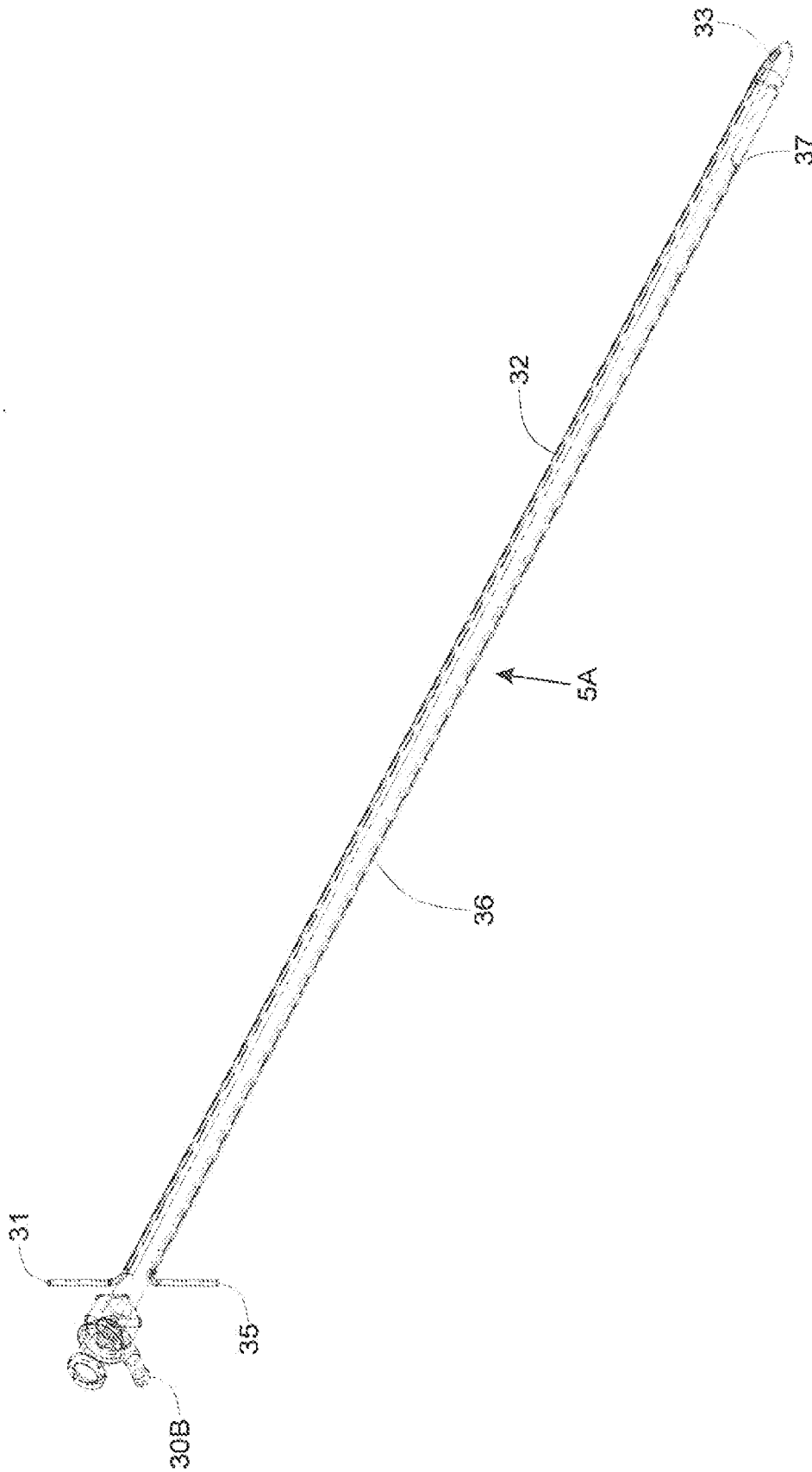


FIG. 2D1

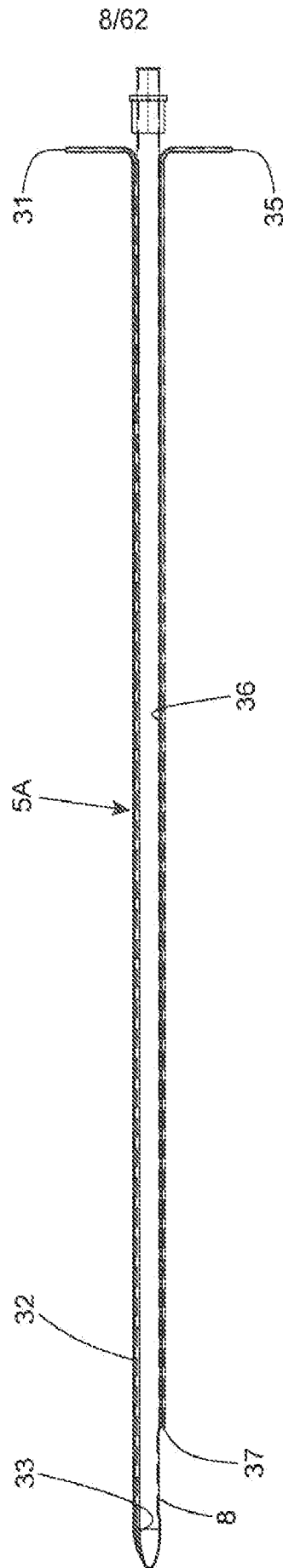


FIG. 2D2

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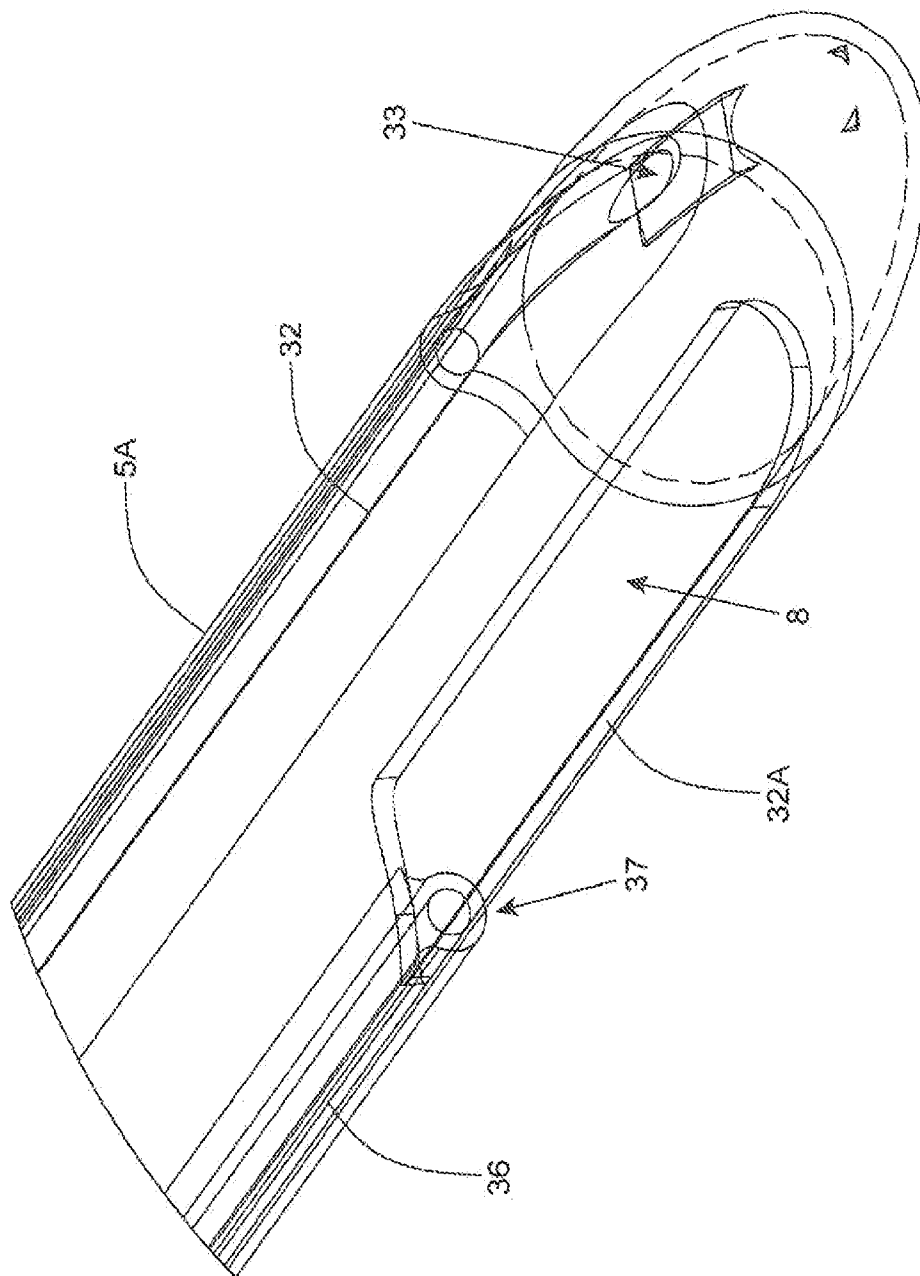


FIG. 2D3

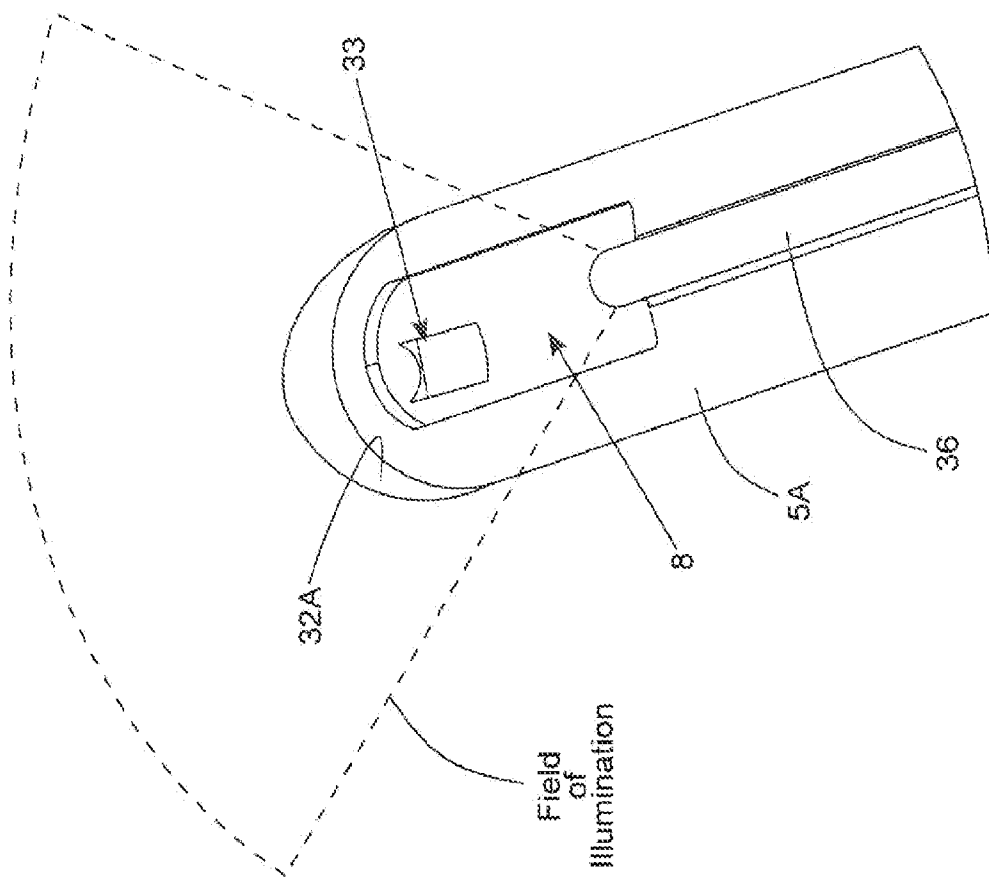
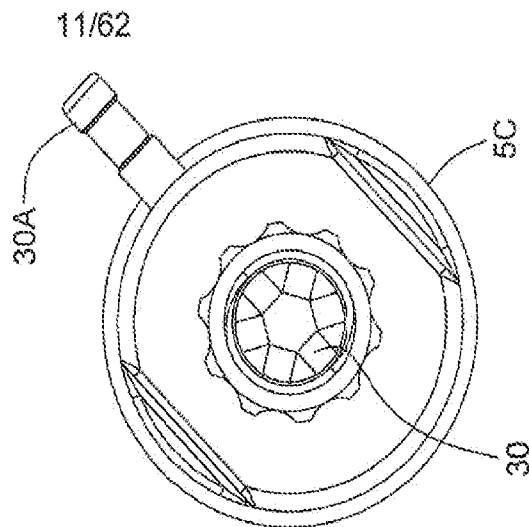
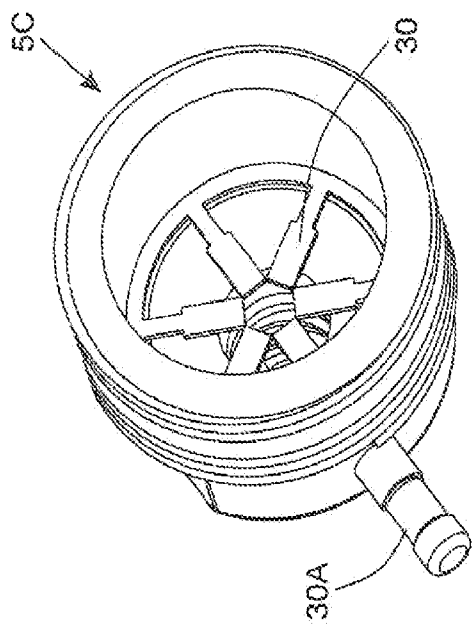
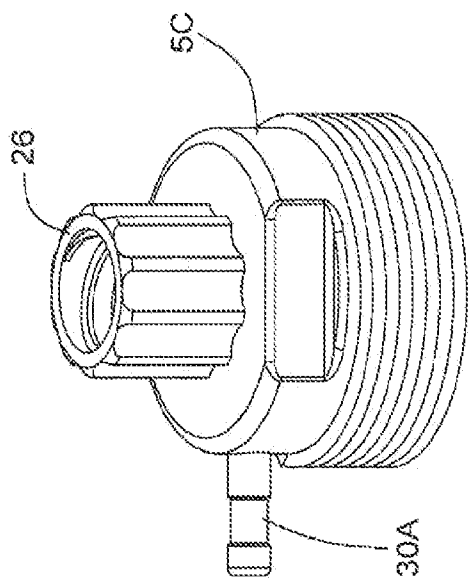


FIG. 2D4



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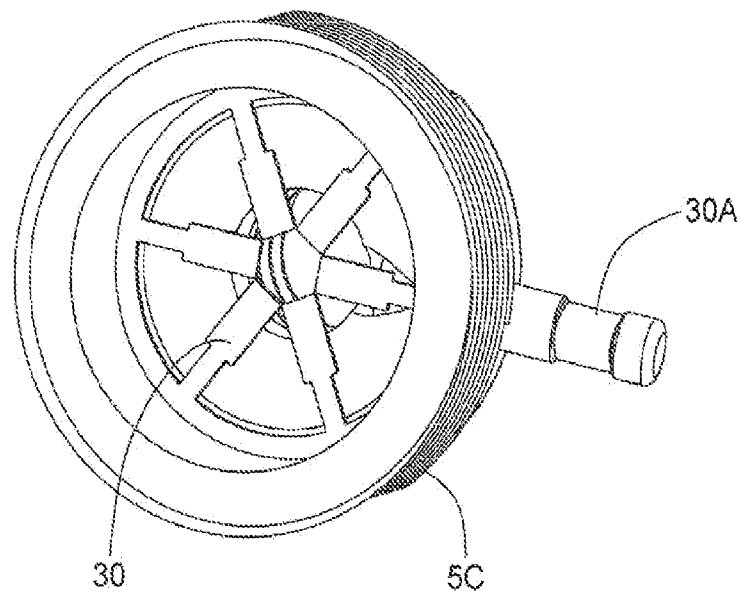


FIG. 2E4

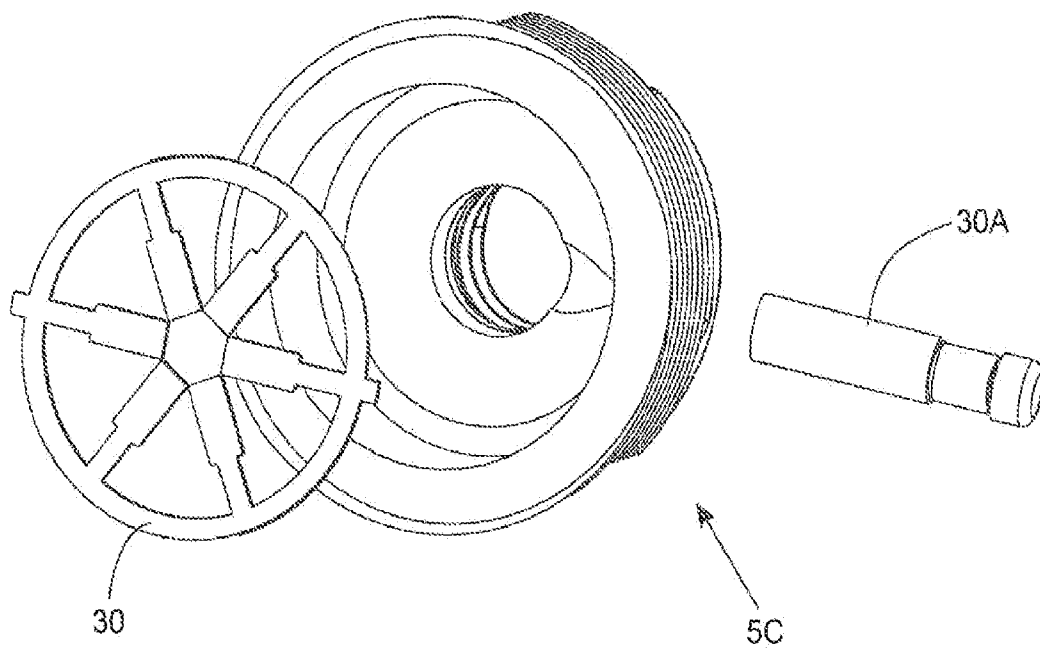


FIG. 2E5

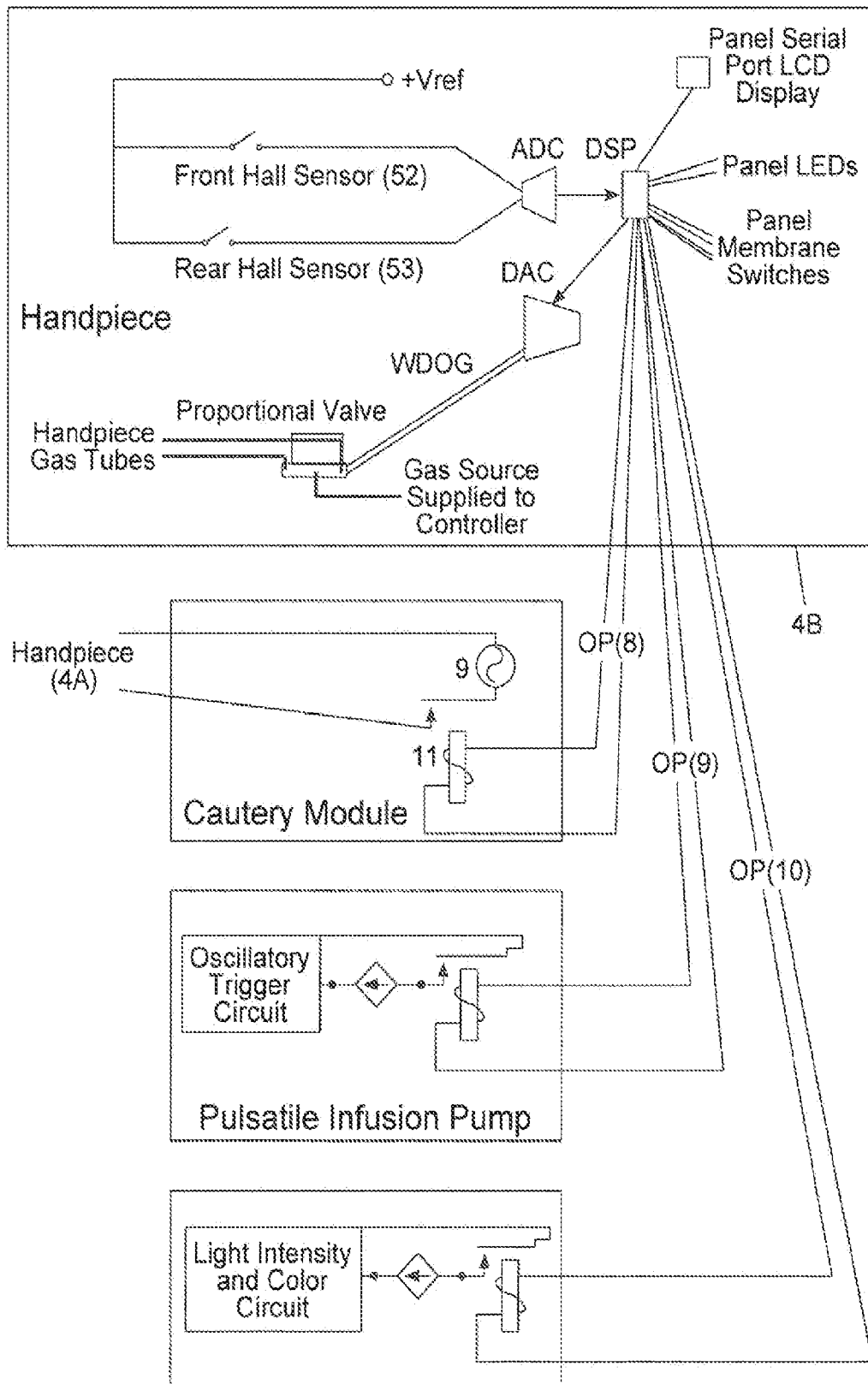


FIG. 2F

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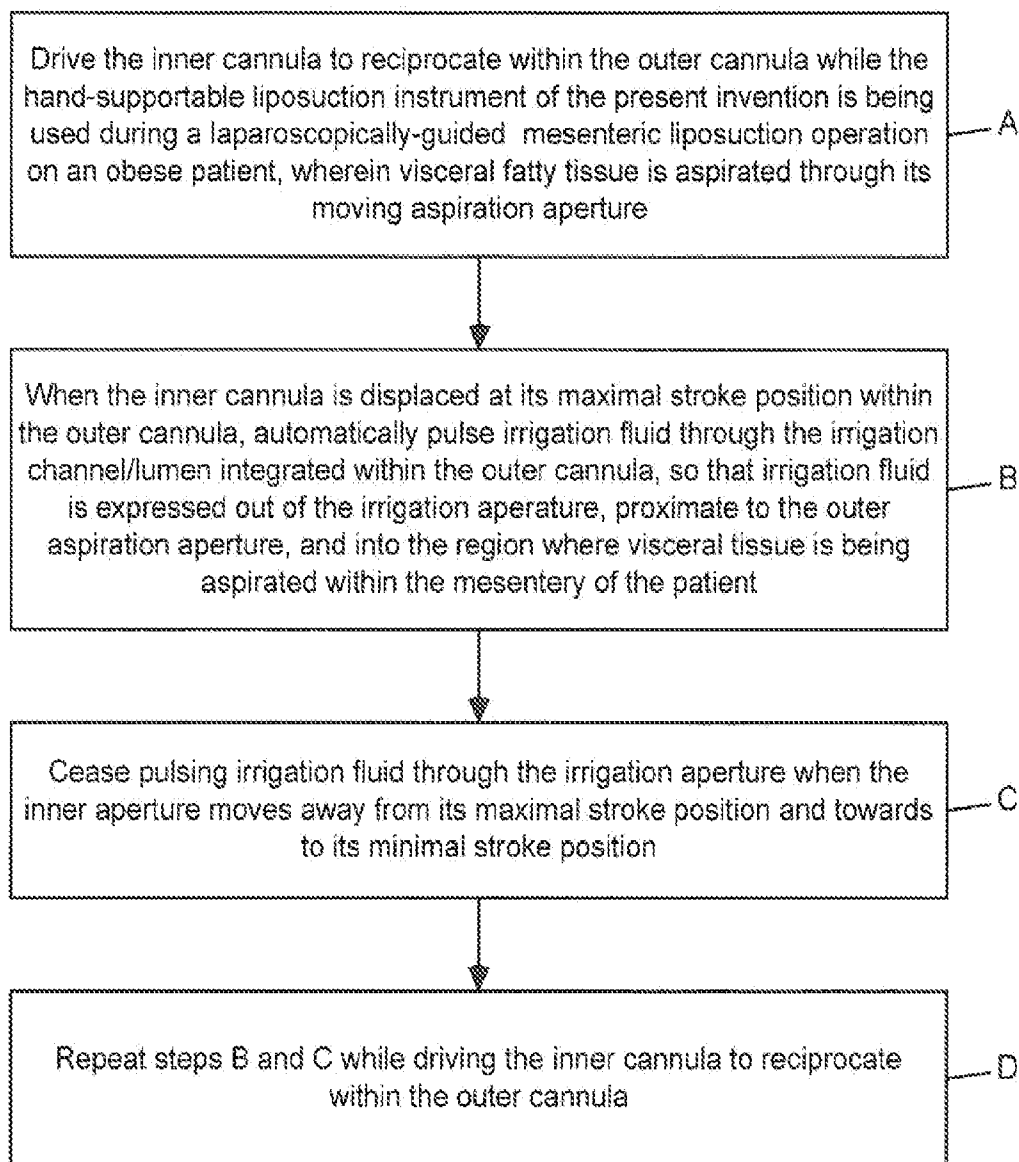


FIG. 2G

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```
'enable cautery if appropriate on forward stroke
IF VR(14)=1 THEN
  IF VR(11)=1 THEN
    WDOG=ON 'close cautery relay
  ELSE
    WDOG=OFF 'open cautery relay
  ENDIF
ENDIF
ENDIF
```

VR(14) Doc enabled cautery by
pushing console button

VR(11) Cannula is not in the same
position on this loop (2ms later) as
last time

FIG. 2H

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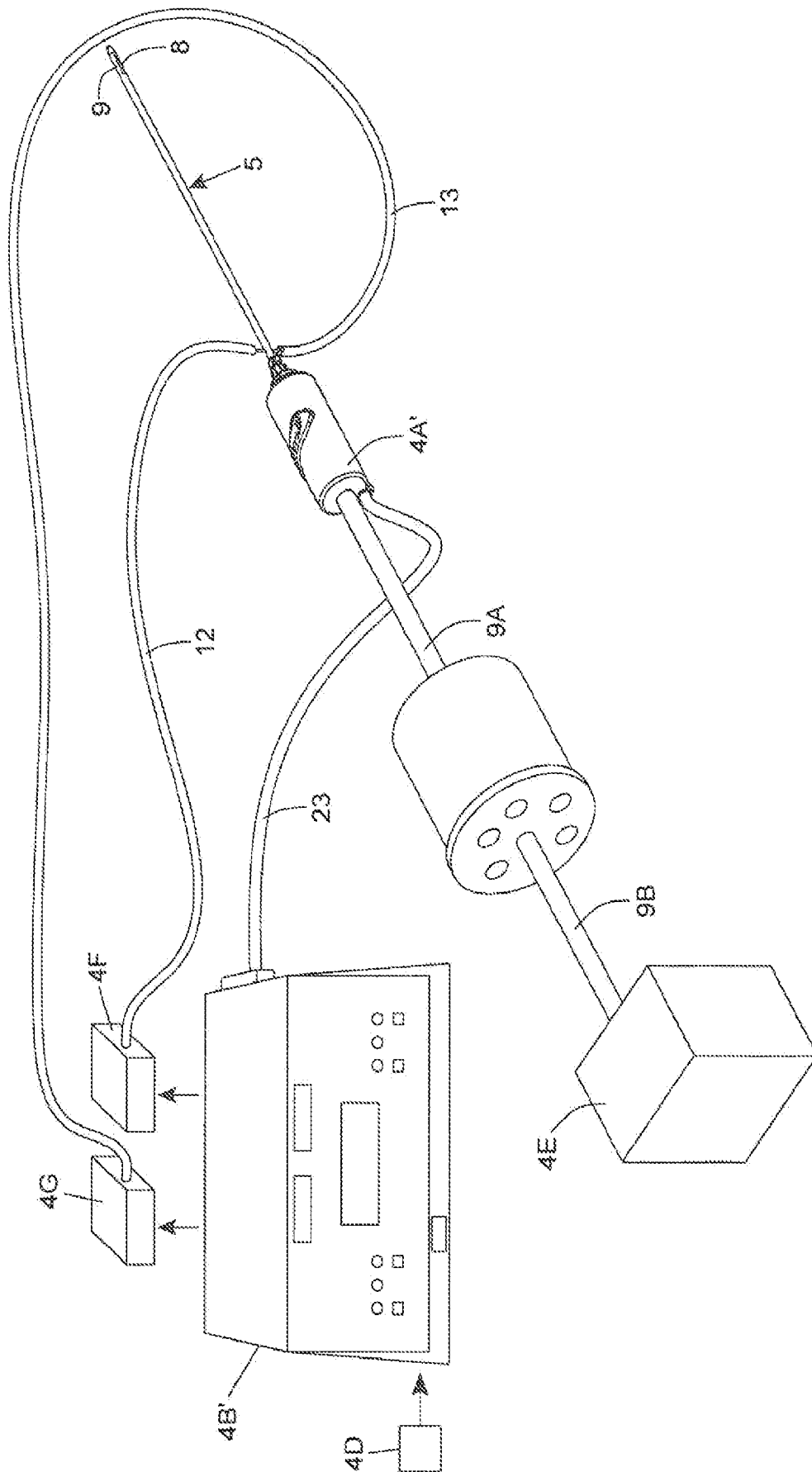


FIG. 3

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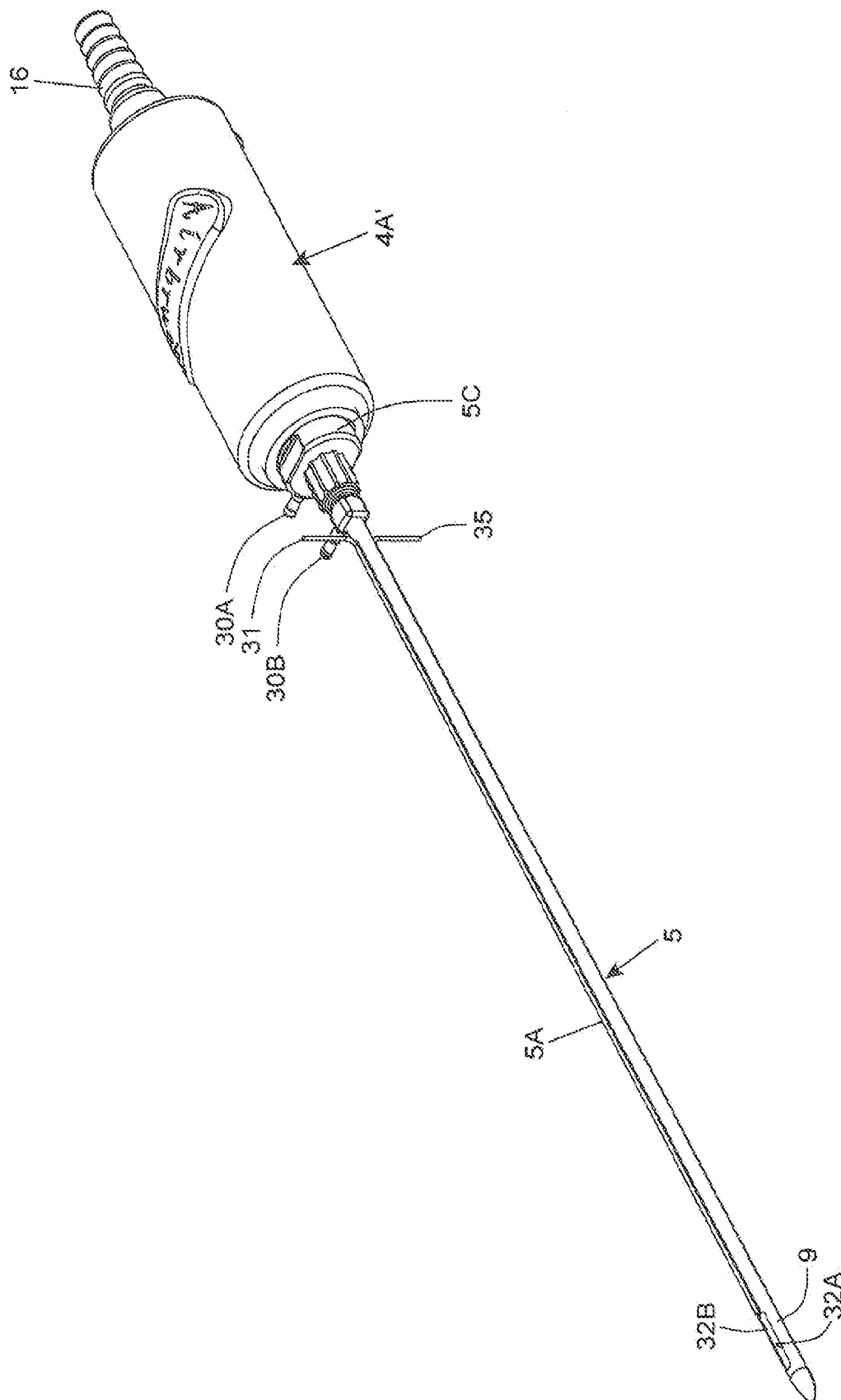


FIG. 3A

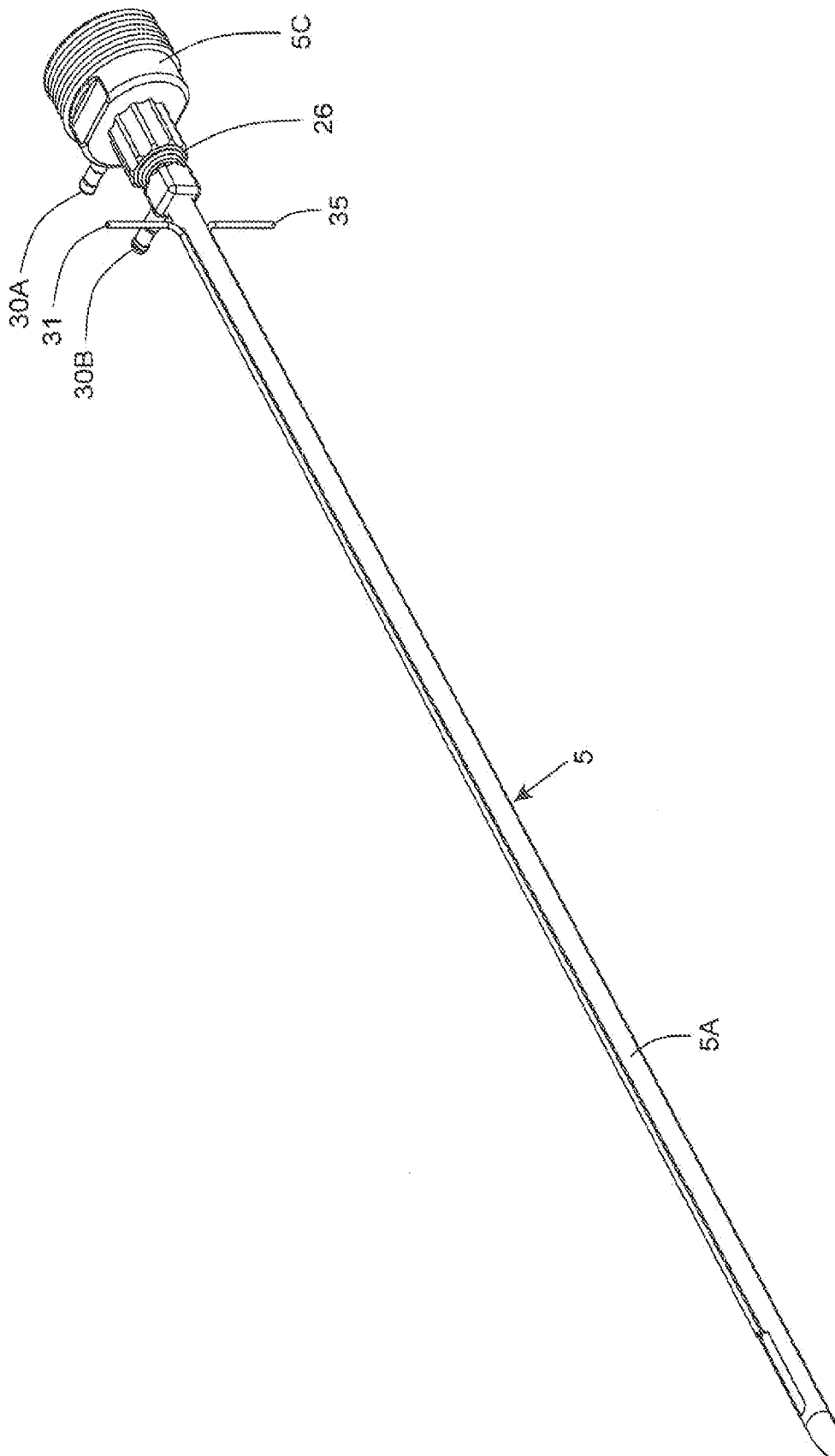


FIG. 3B

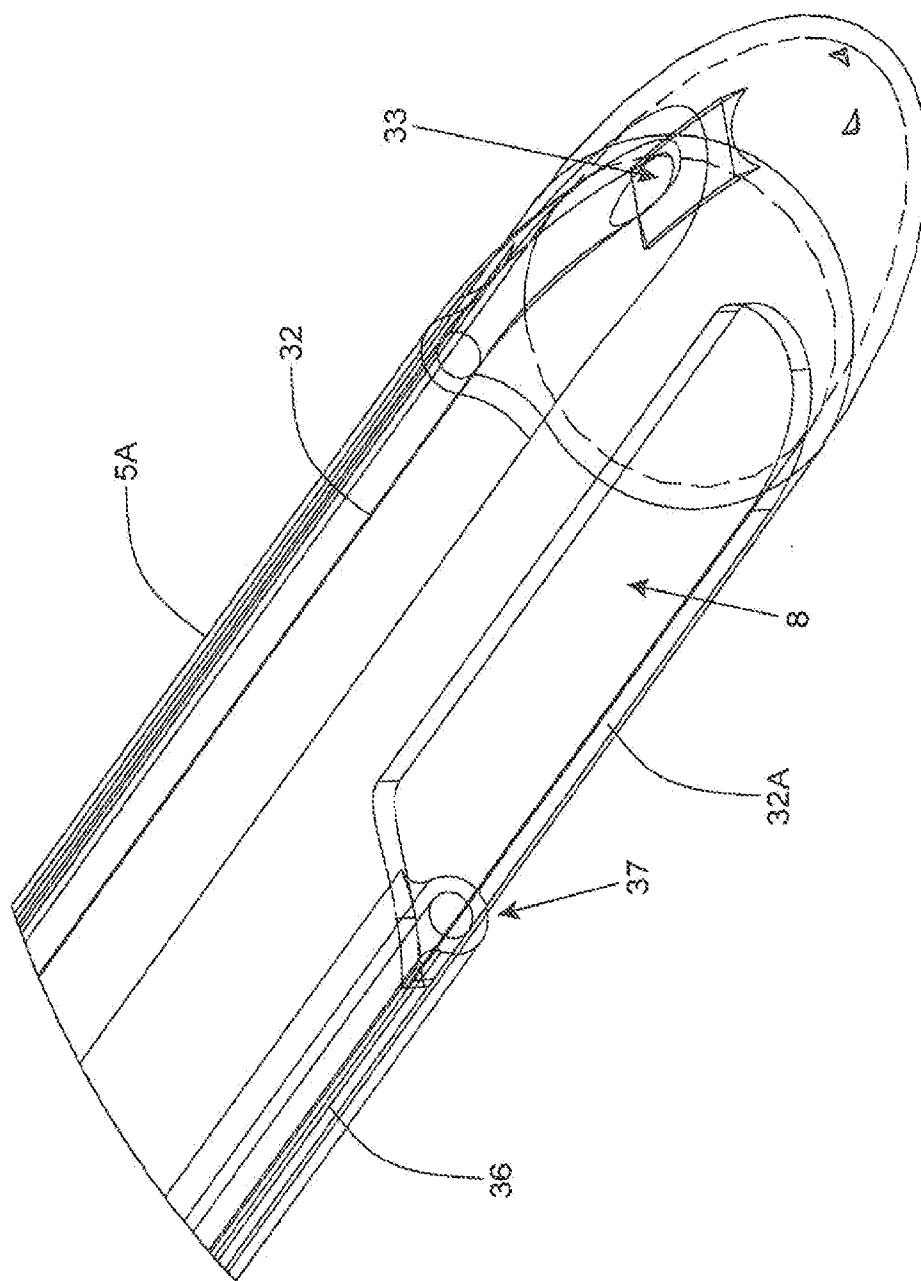
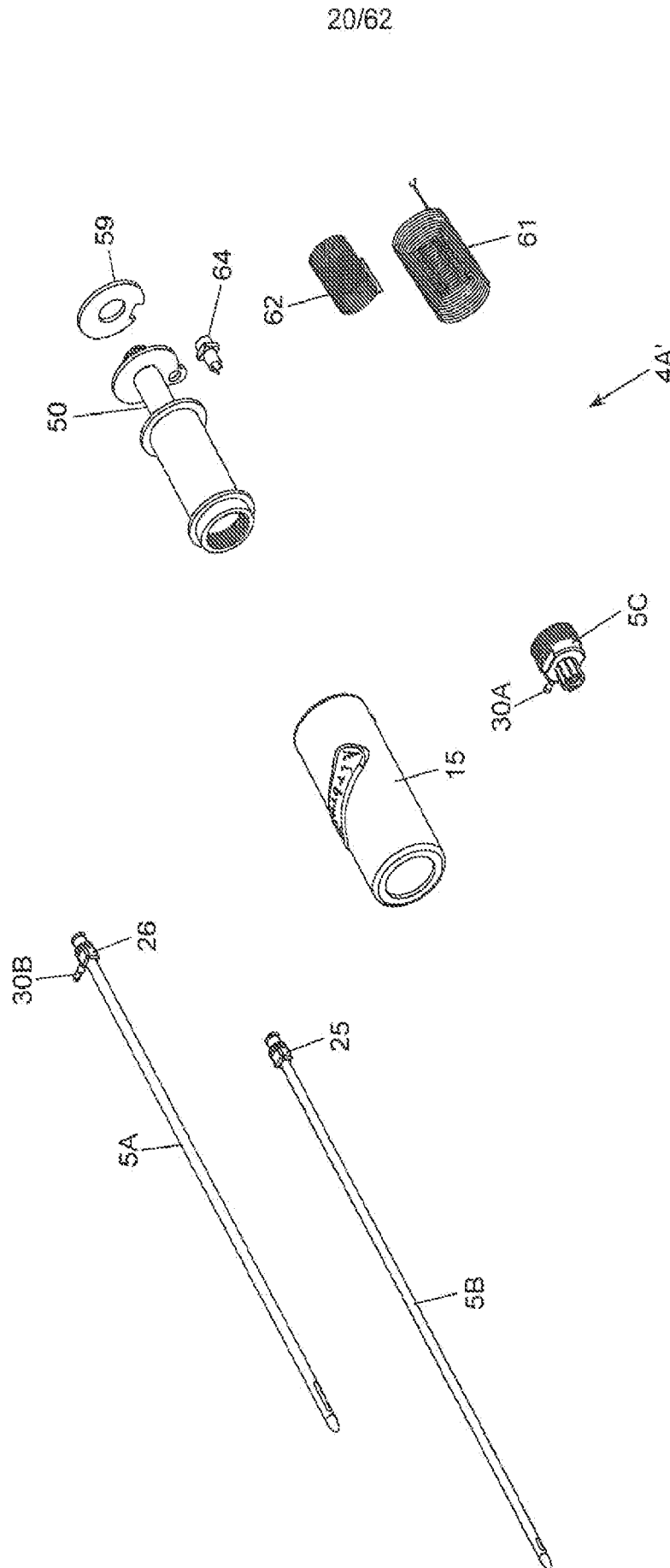


FIG. 3C



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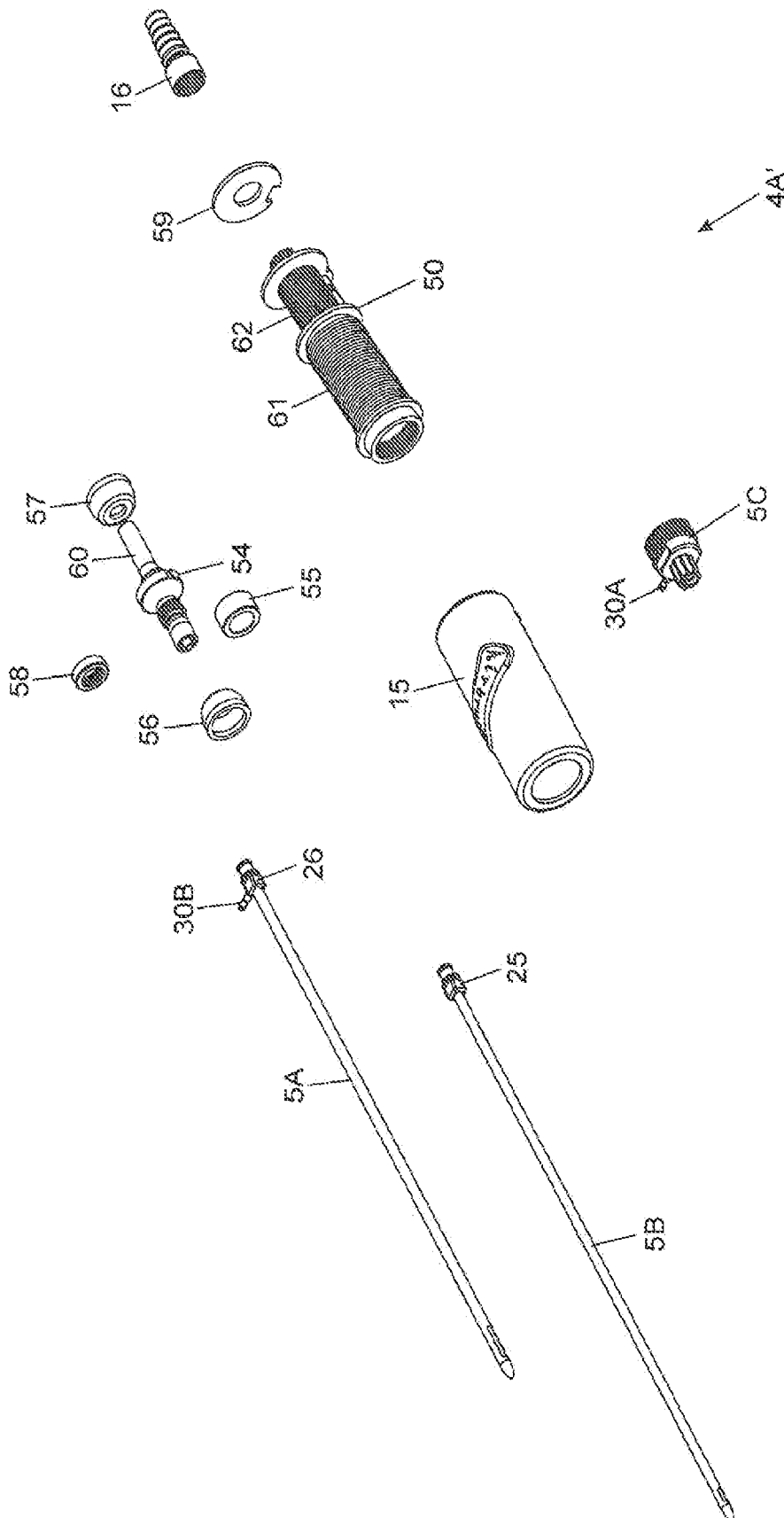


FIG. 3D2

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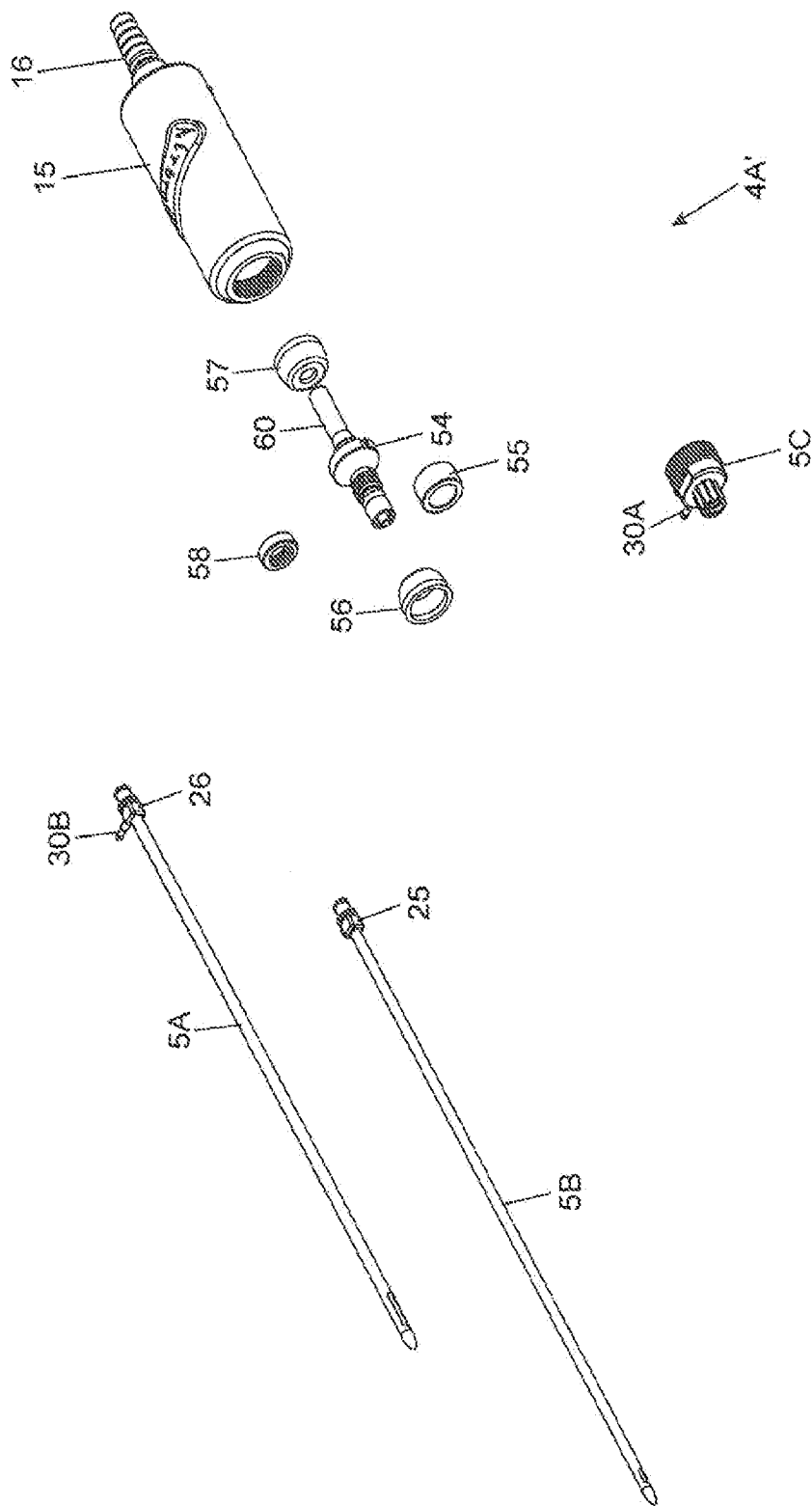


FIG. 3D3

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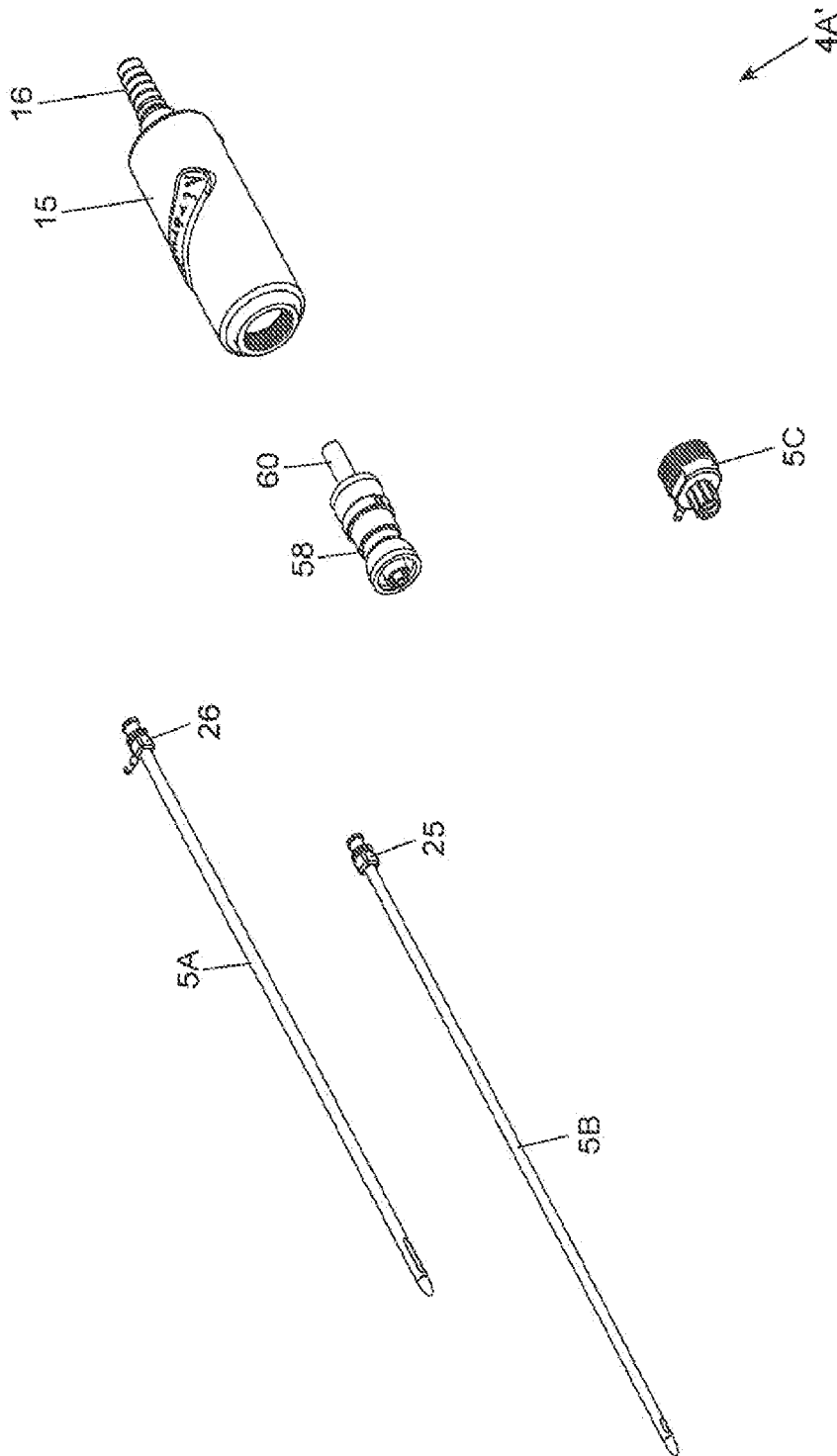


FIG. 3D4

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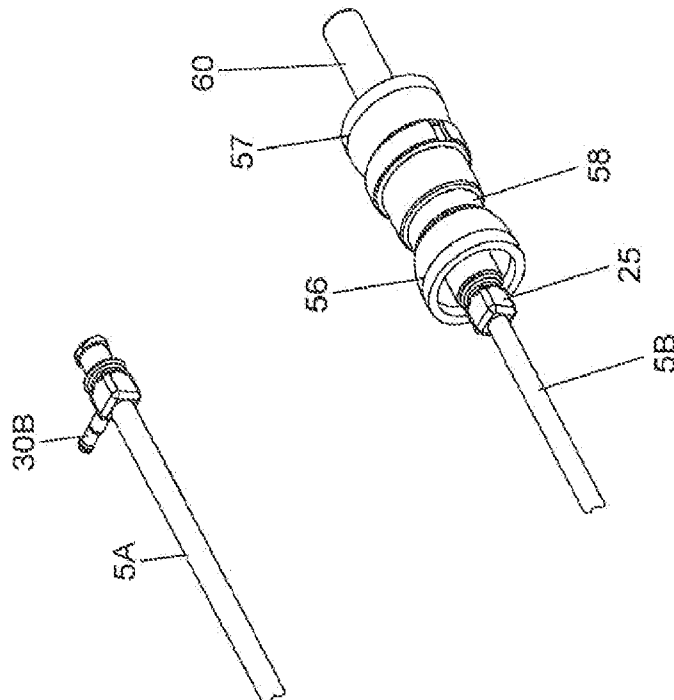
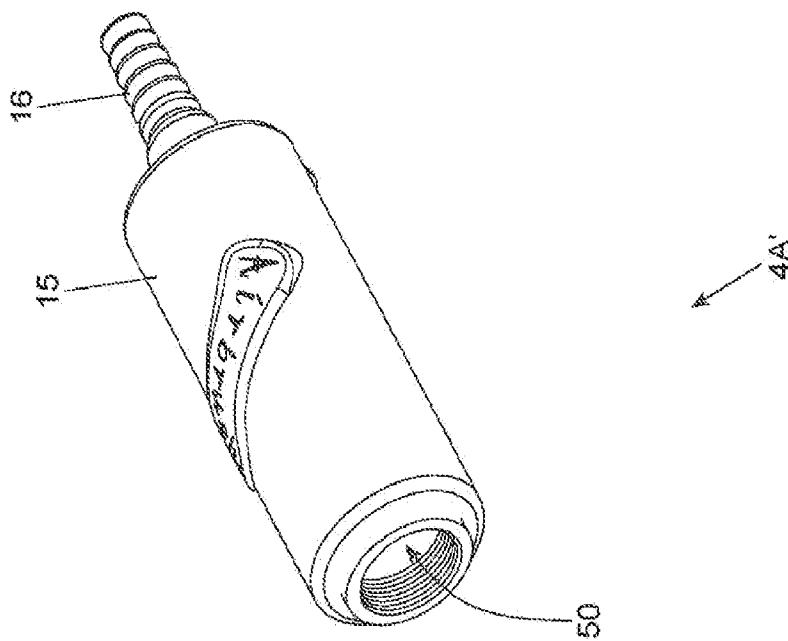


FIG. 3D5

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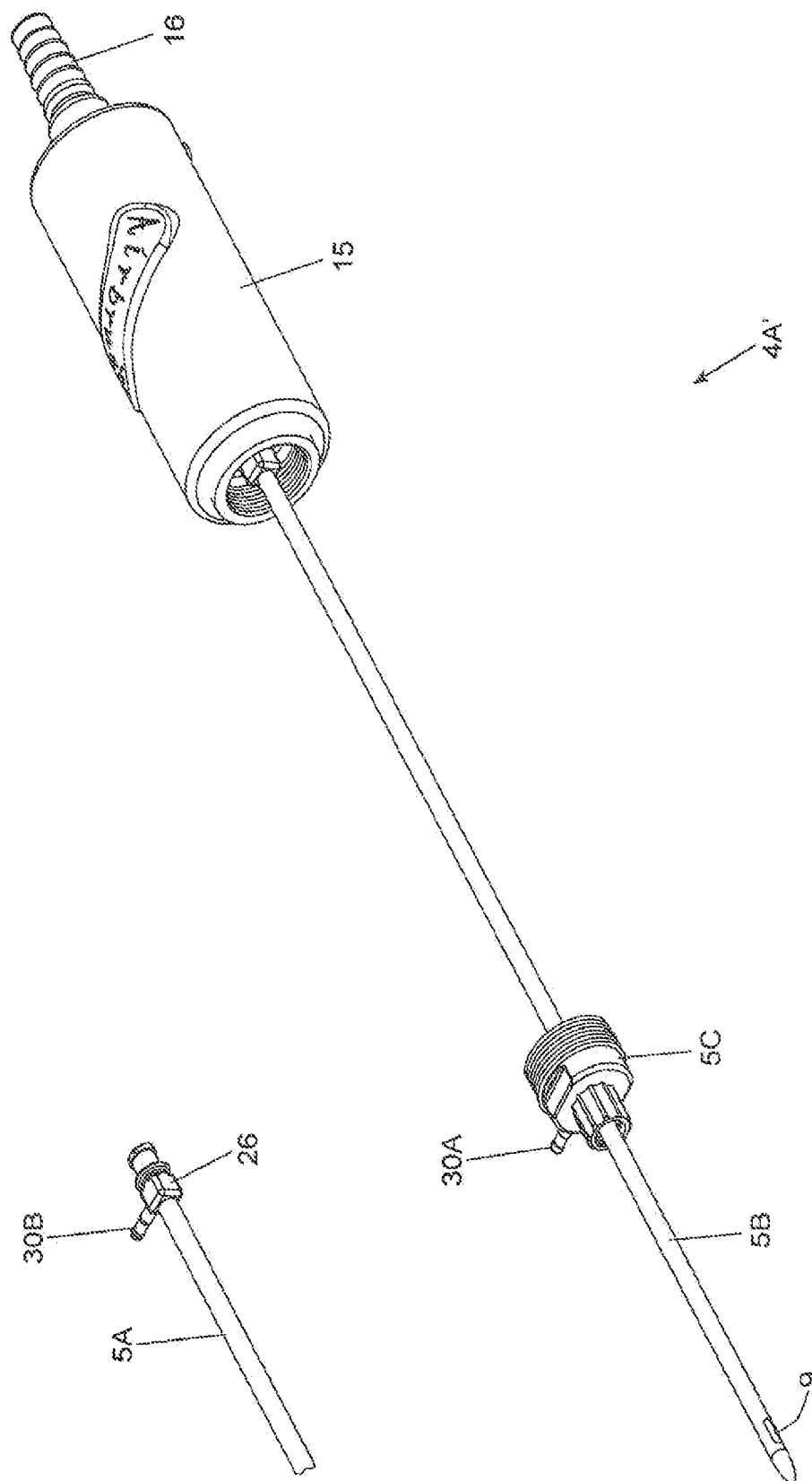


FIG. 3D6

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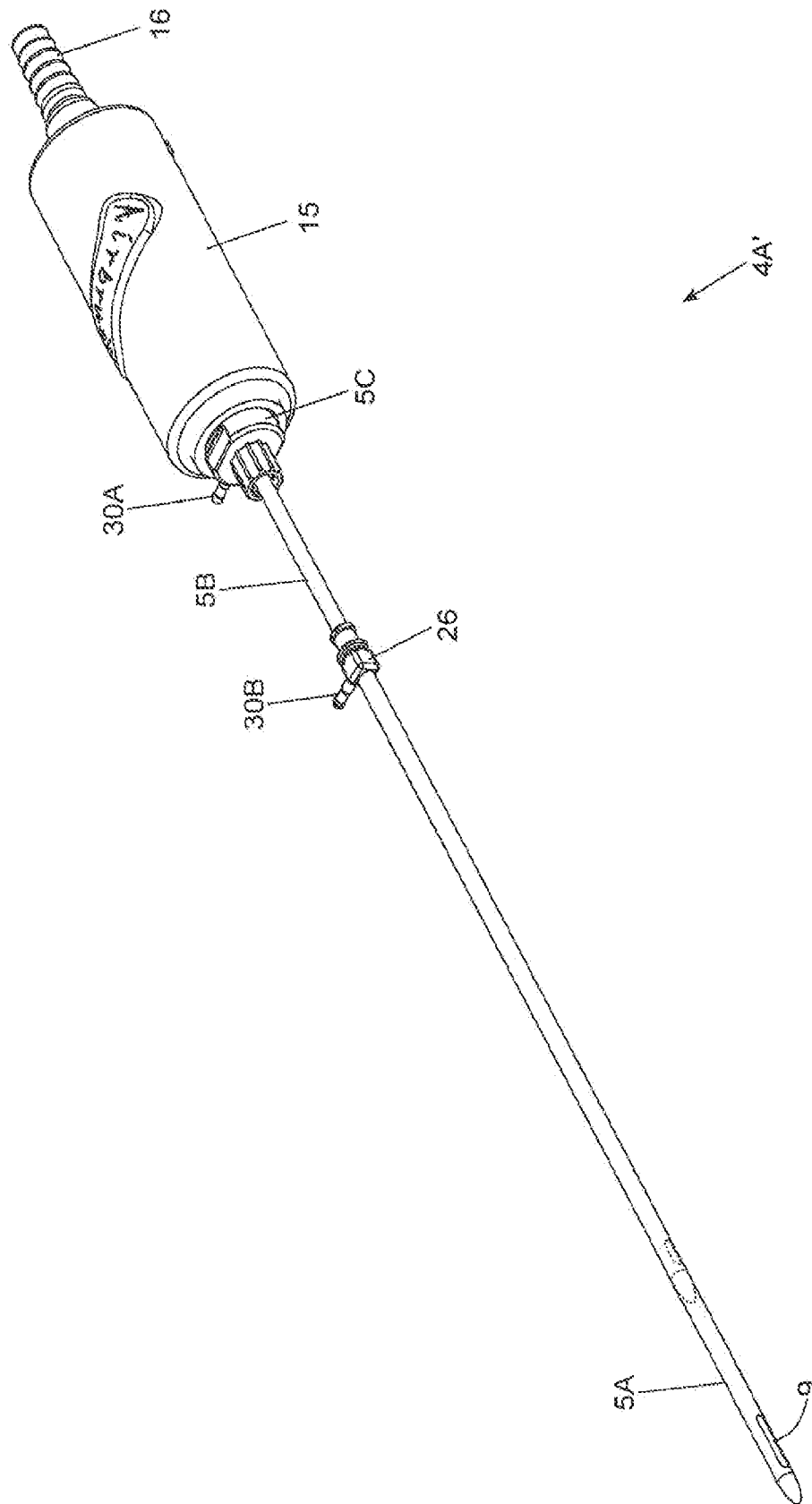


FIG. 3D7

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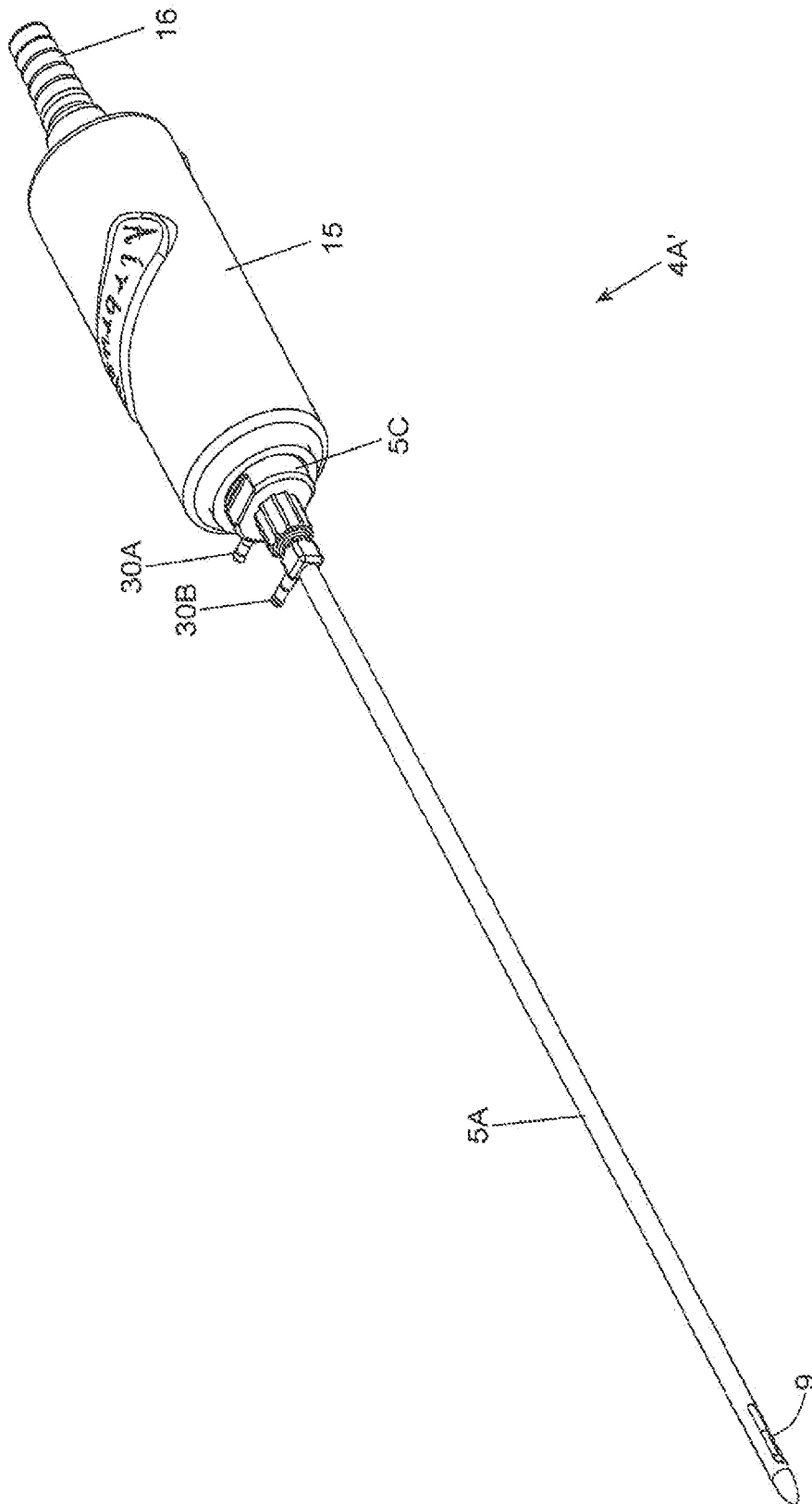


FIG. 3D8

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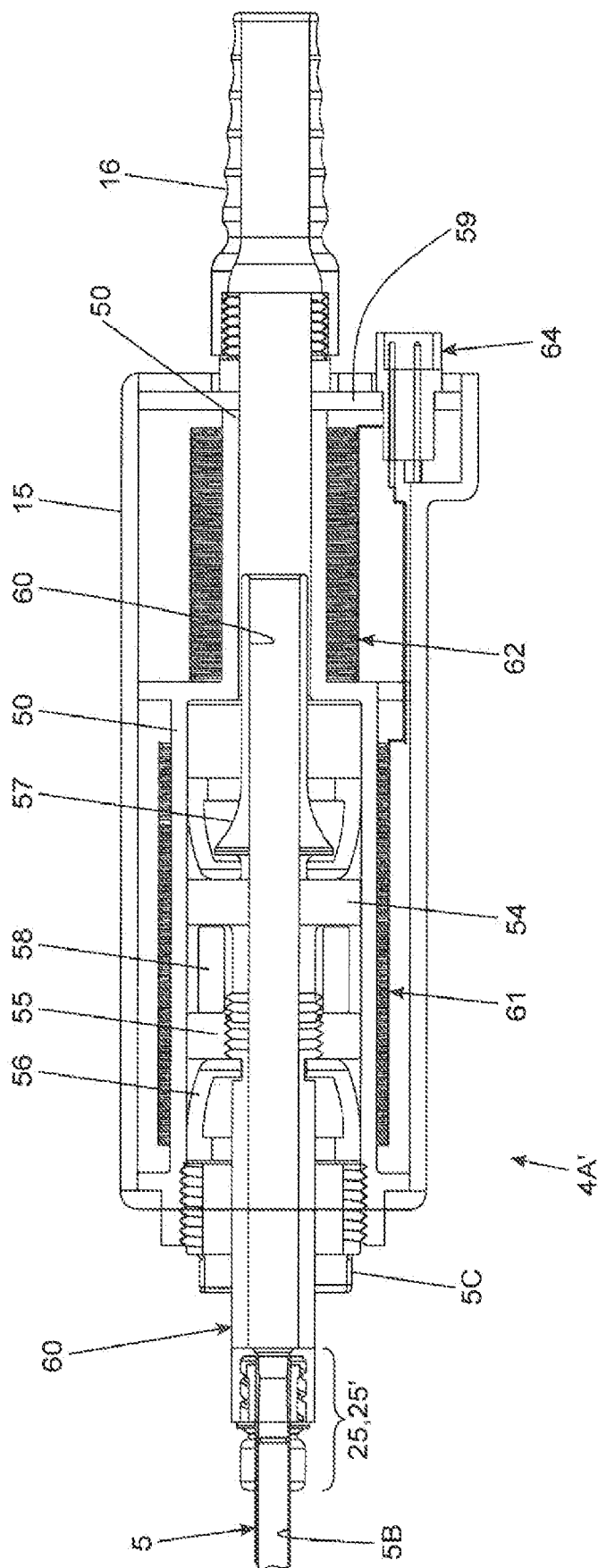


FIG. 3E

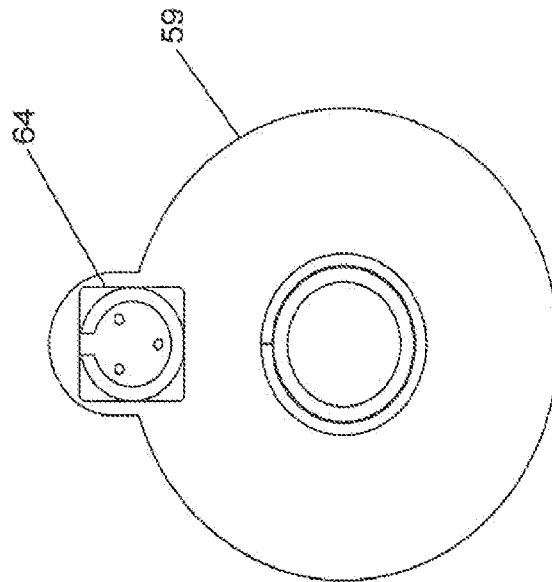


FIG. 3F1

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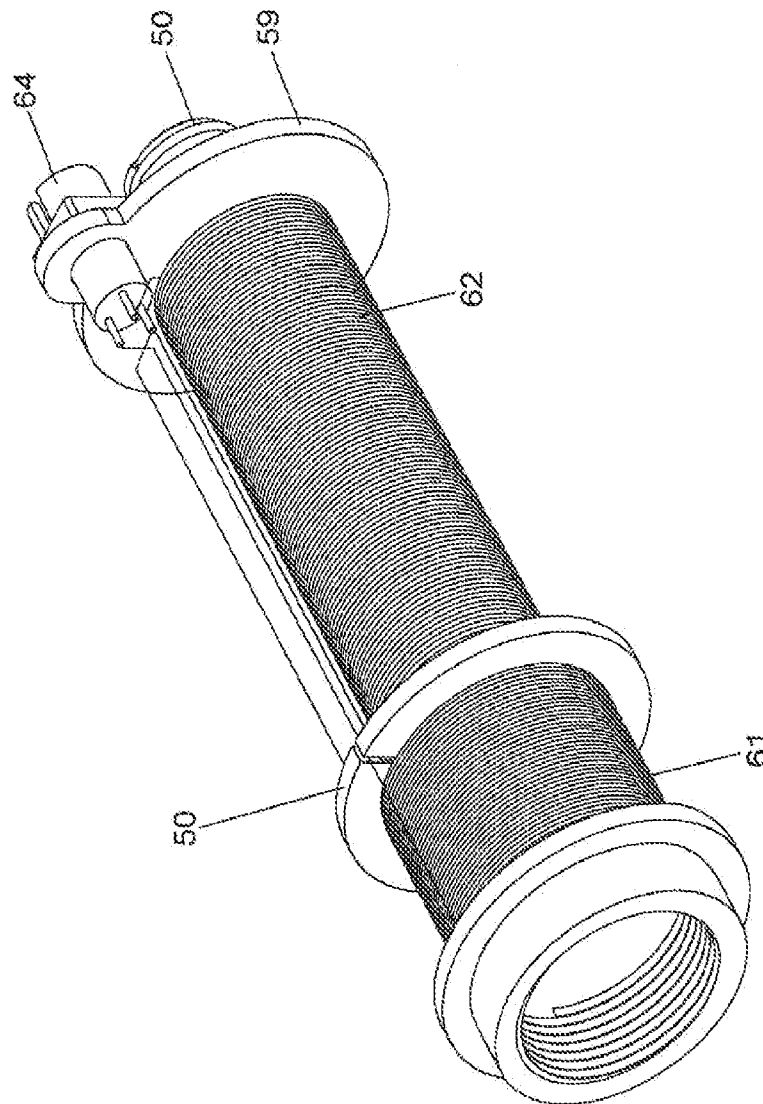


FIG. 3F2

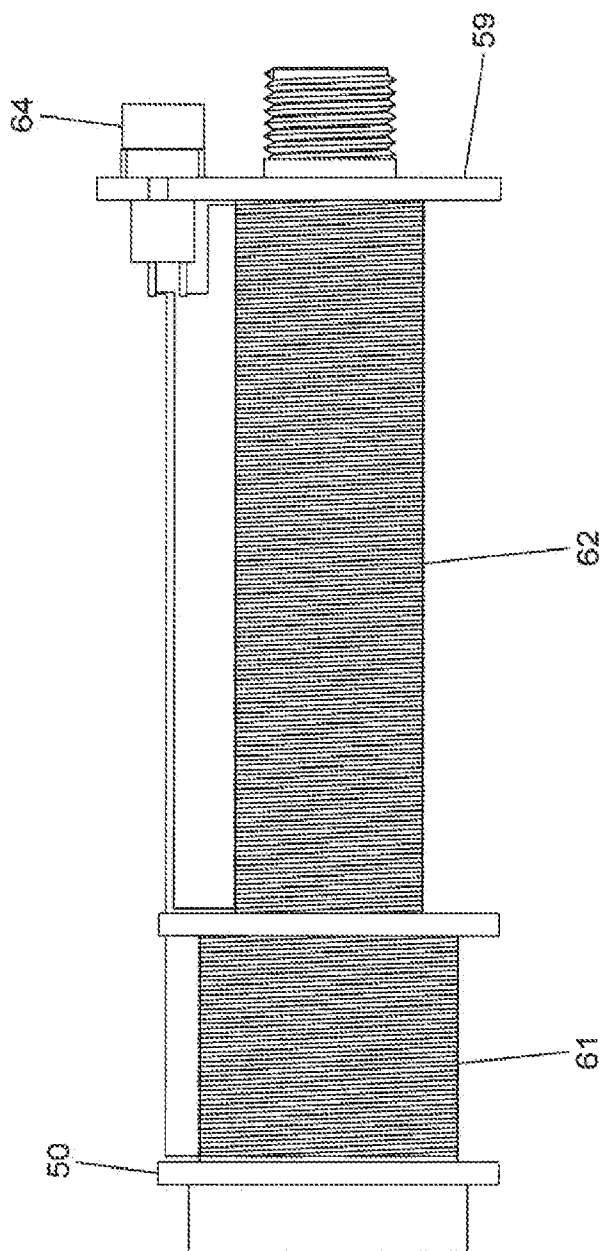


FIG. 3F3

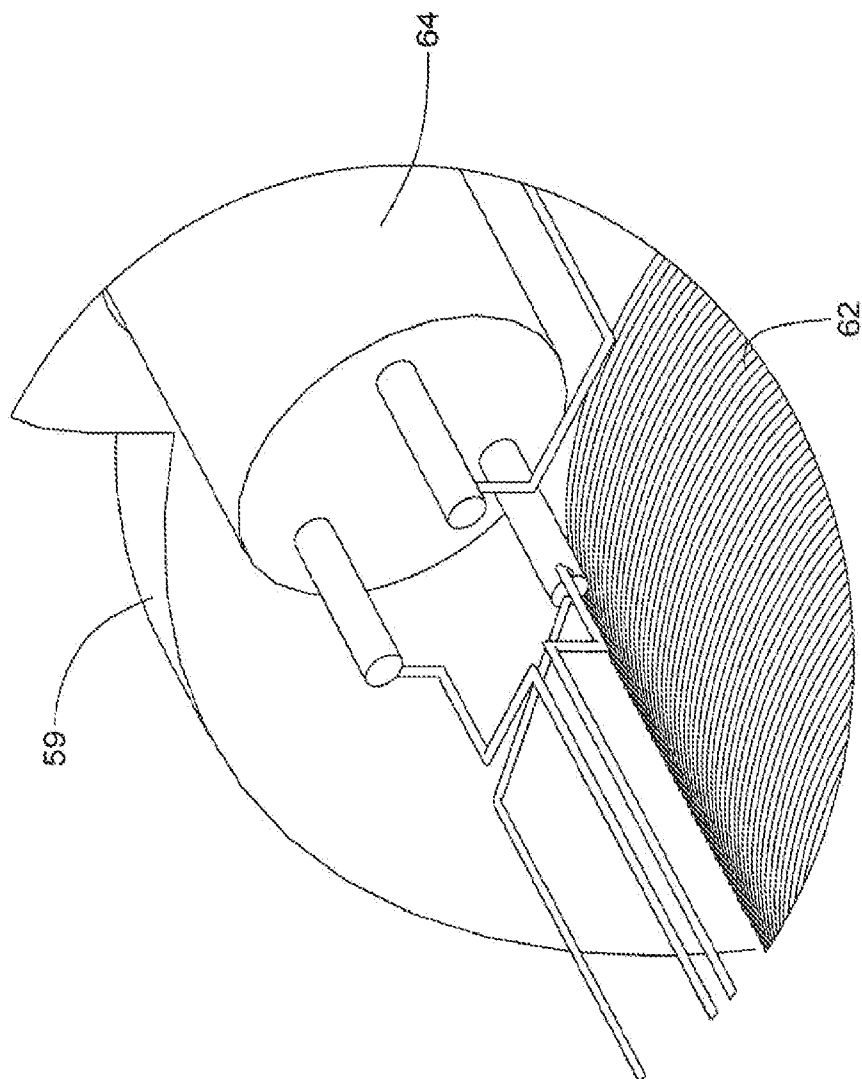
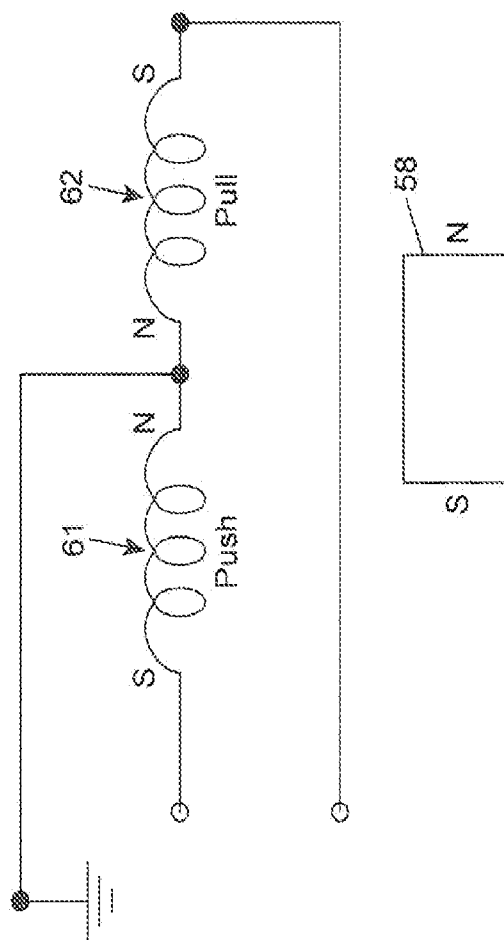


FIG. 3F4

Two Coil Push Pull Type Drive Circuit Diagram



Two Coils with Opposing Polarity, Alternately Energized

FIG. 3F5

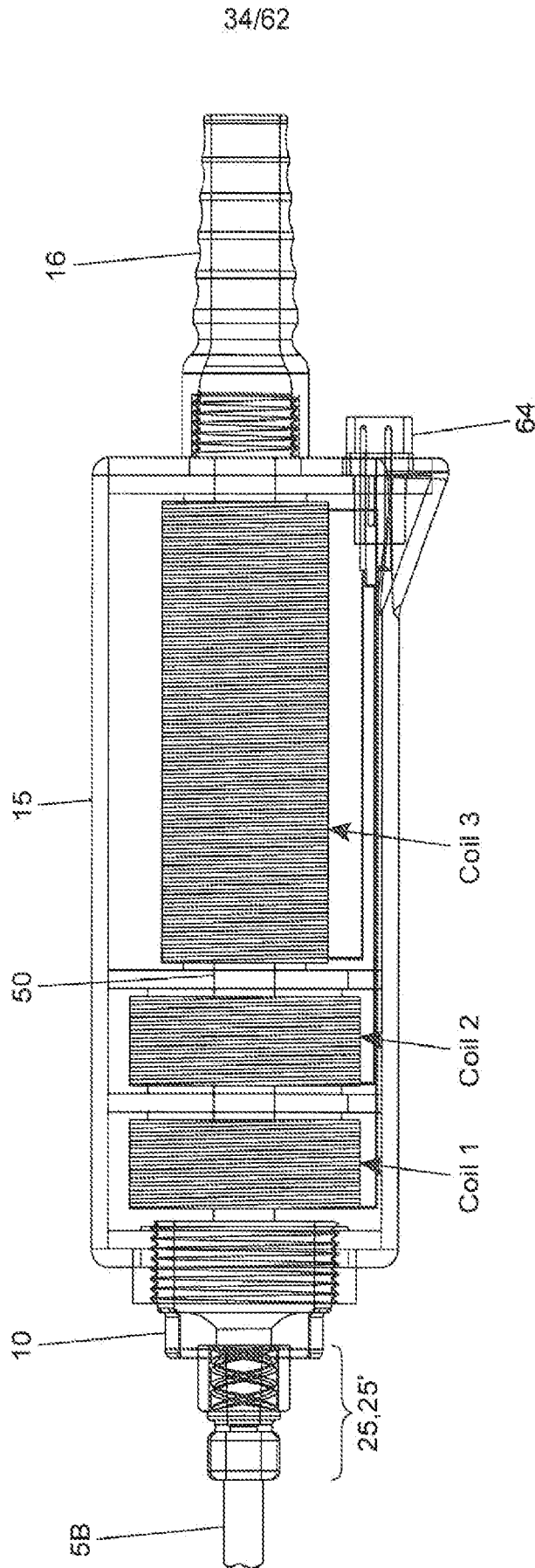


FIG. 3G1

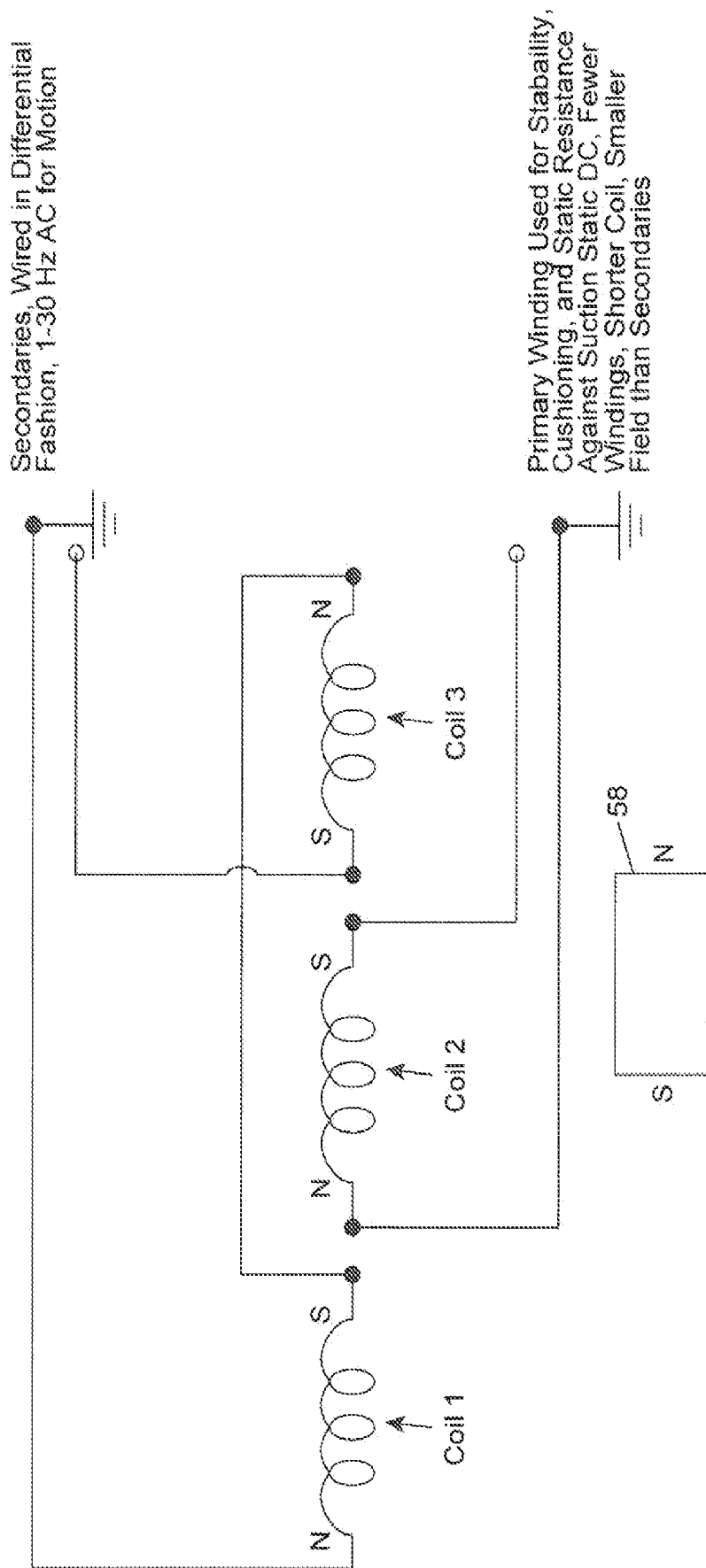


FIG. 3G2

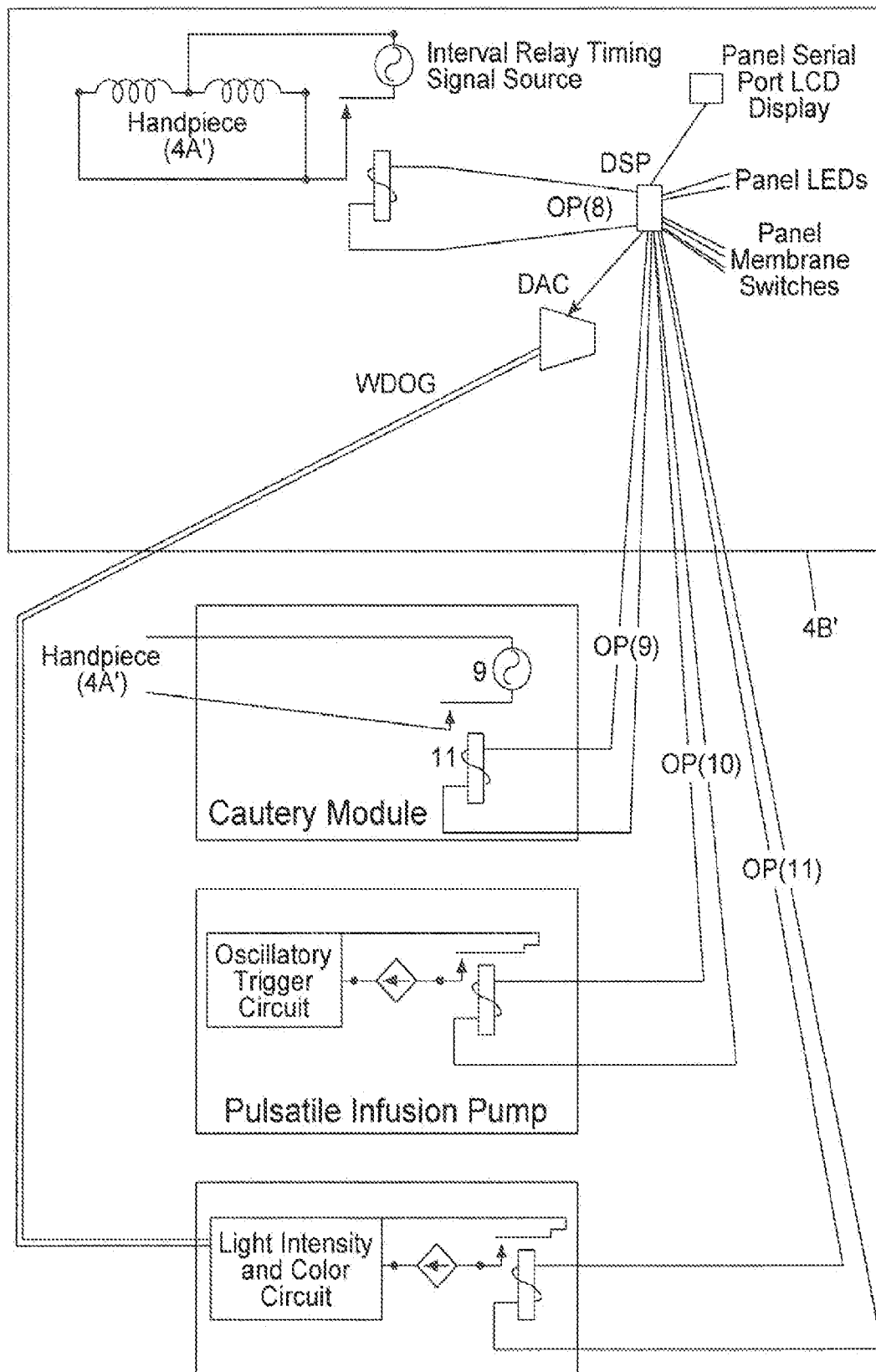


FIG. 3H

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```
'enable cautery if appropriate on forward stroke
IF VR(14)=1 THEN
  IF VR(11)=1 THEN
    WDOG=ON 'close cautery relay
  ELSE
    WDOG=OFF 'open cautery relay
  ENDIF
ENDIF
ENDIF
```

VR(14) Doc enabled cautery by
pushing console button

VR(11) Cannula is not in the same
position on this loop (2ms later) as
last time

FIG. 3I

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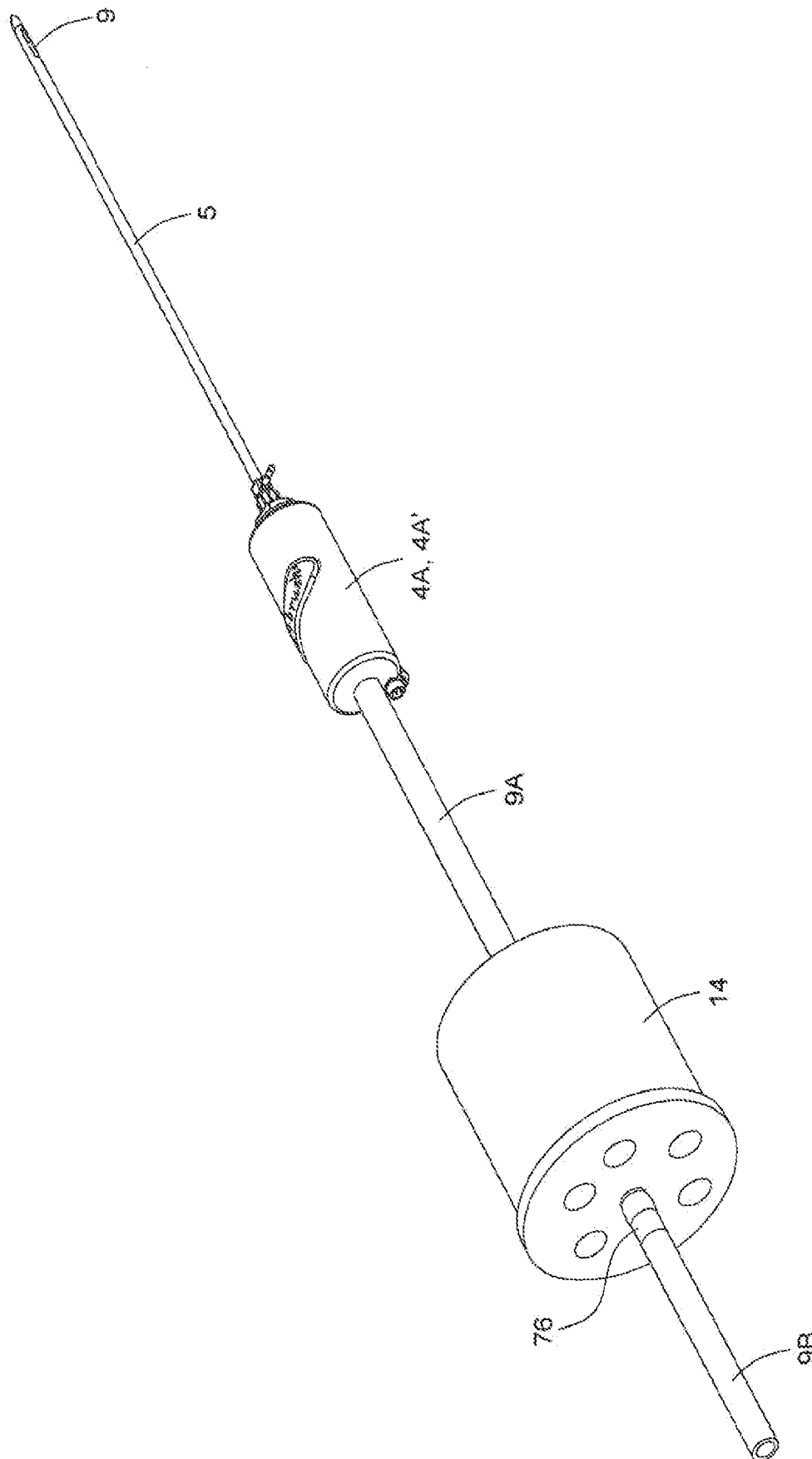


FIG. 4

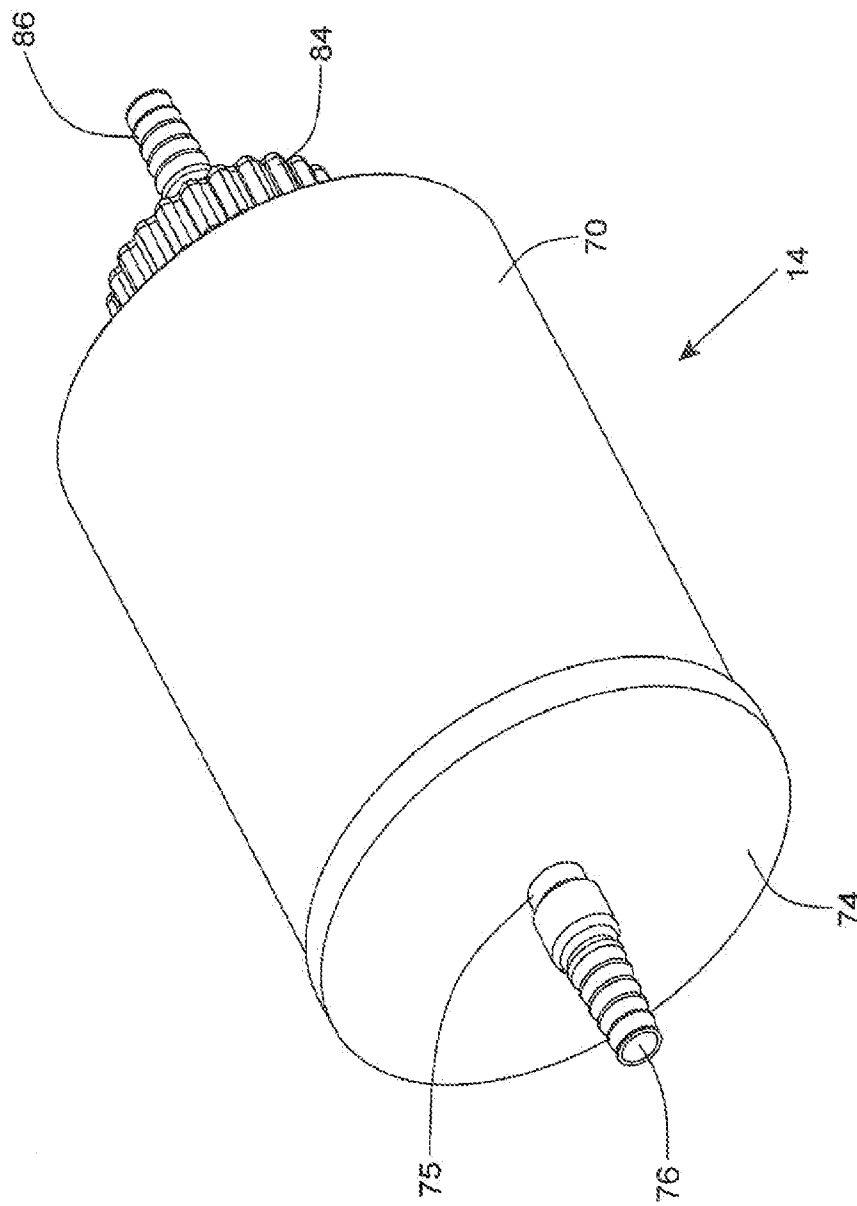


FIG. 4A

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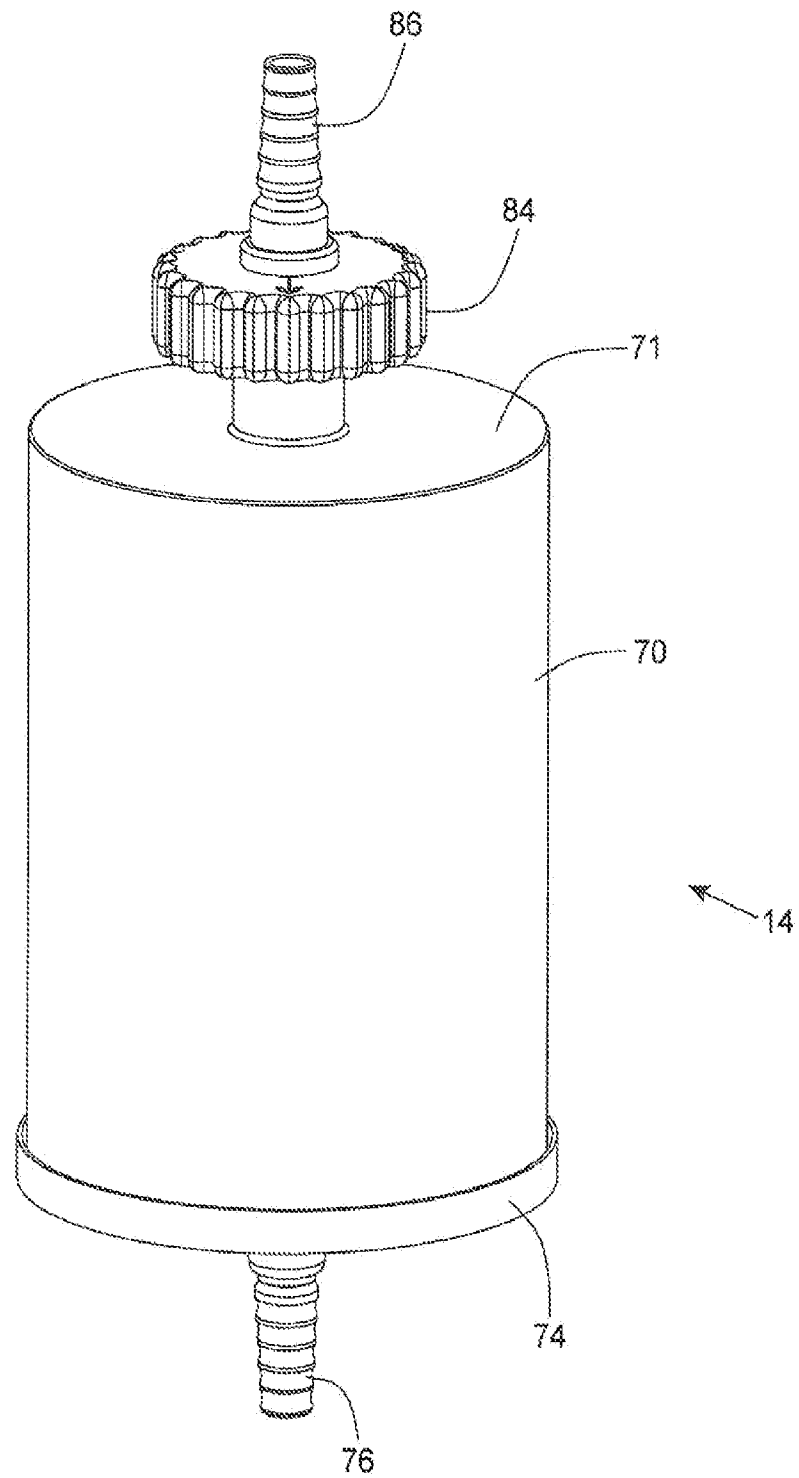


FIG. 4B

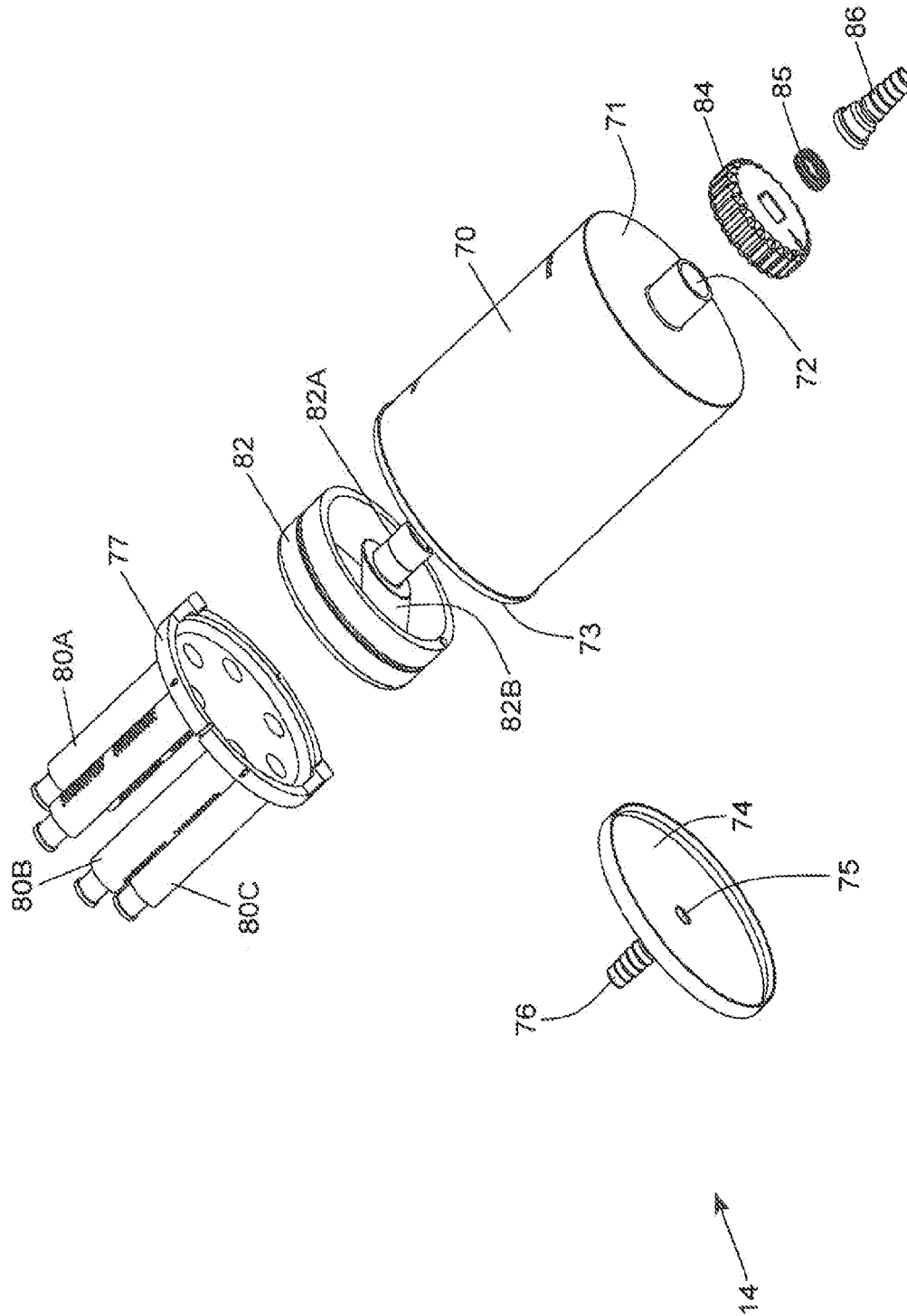


FIG. 4C

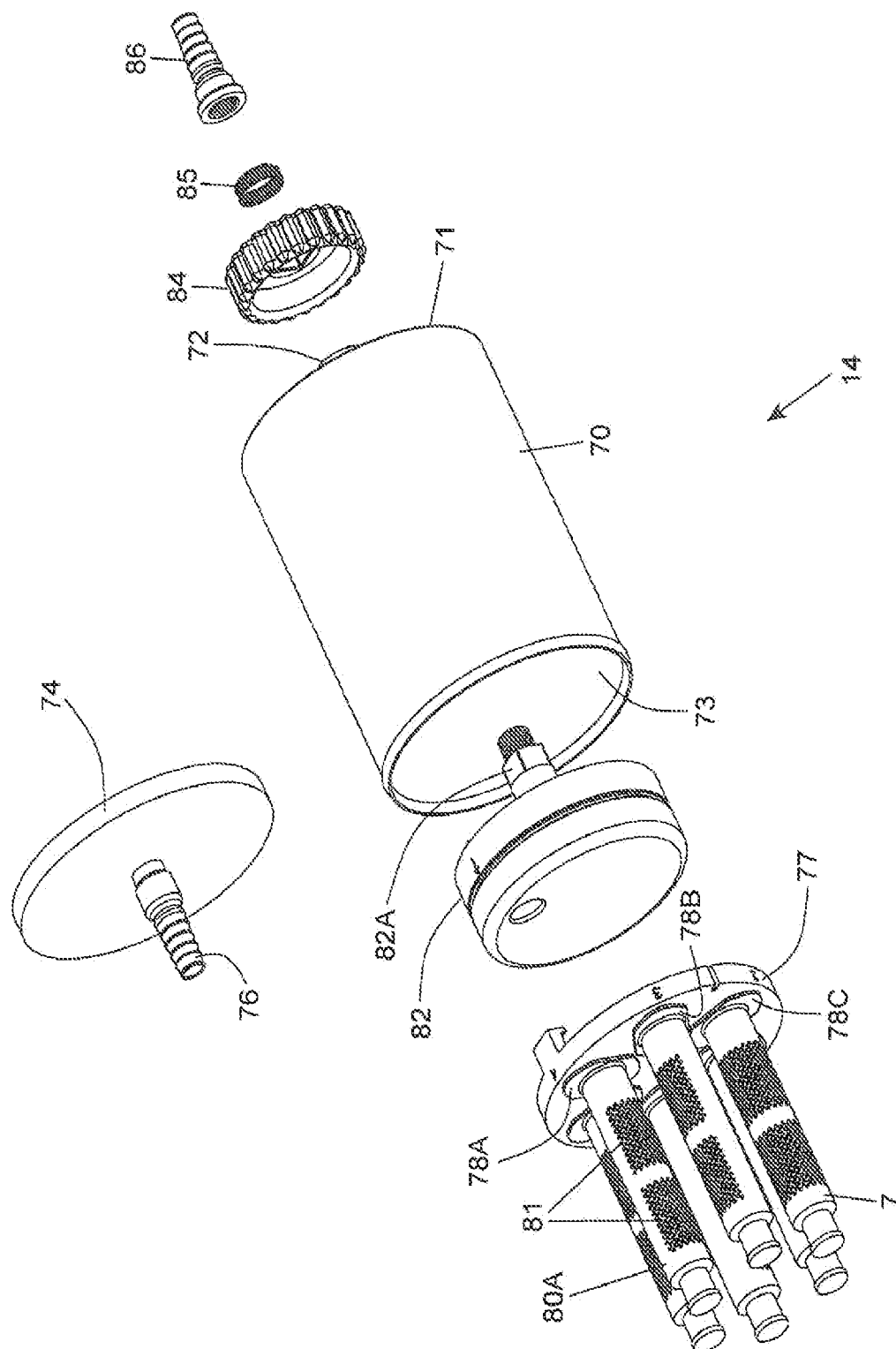


FIG. 4E

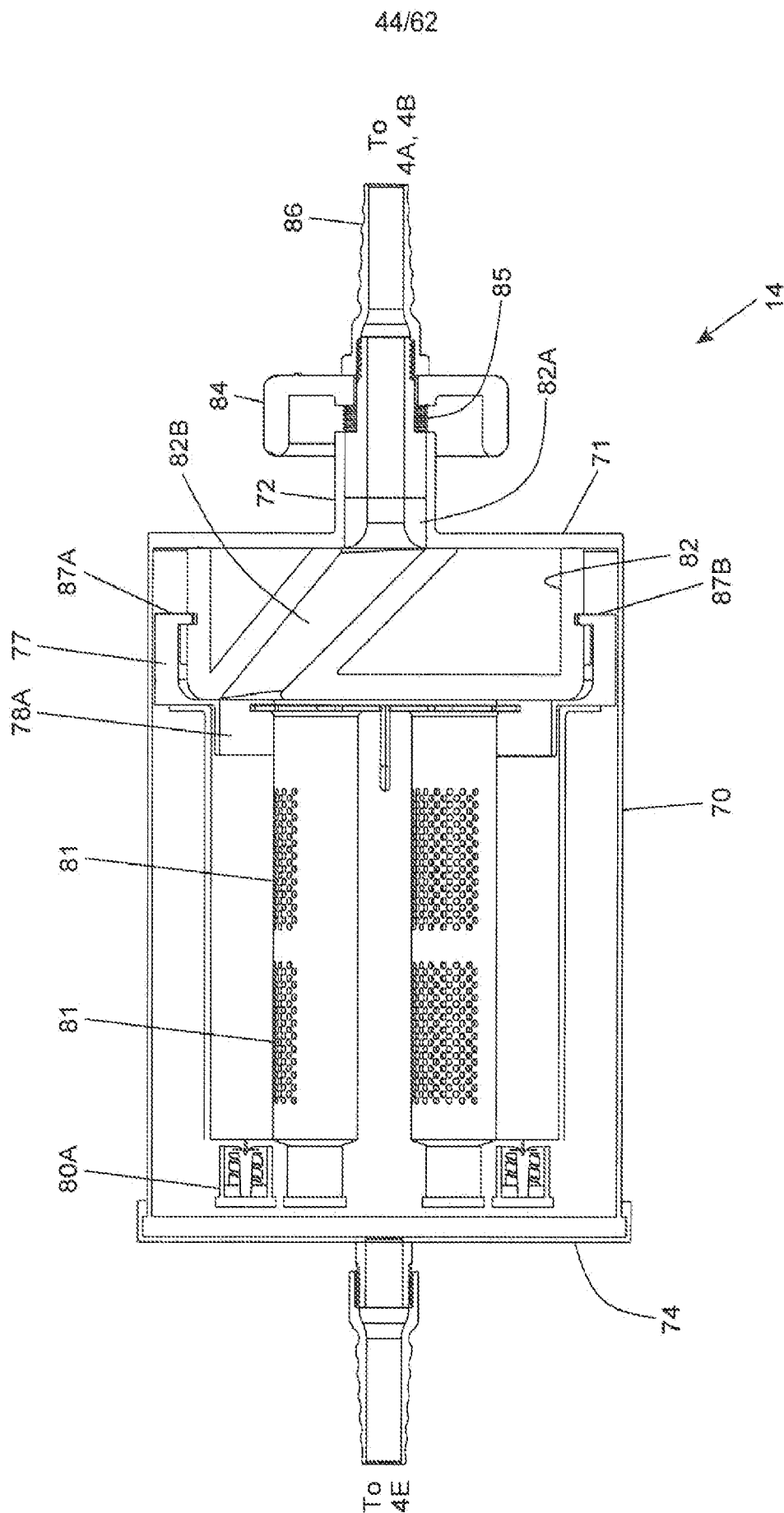


FIG. 4F1

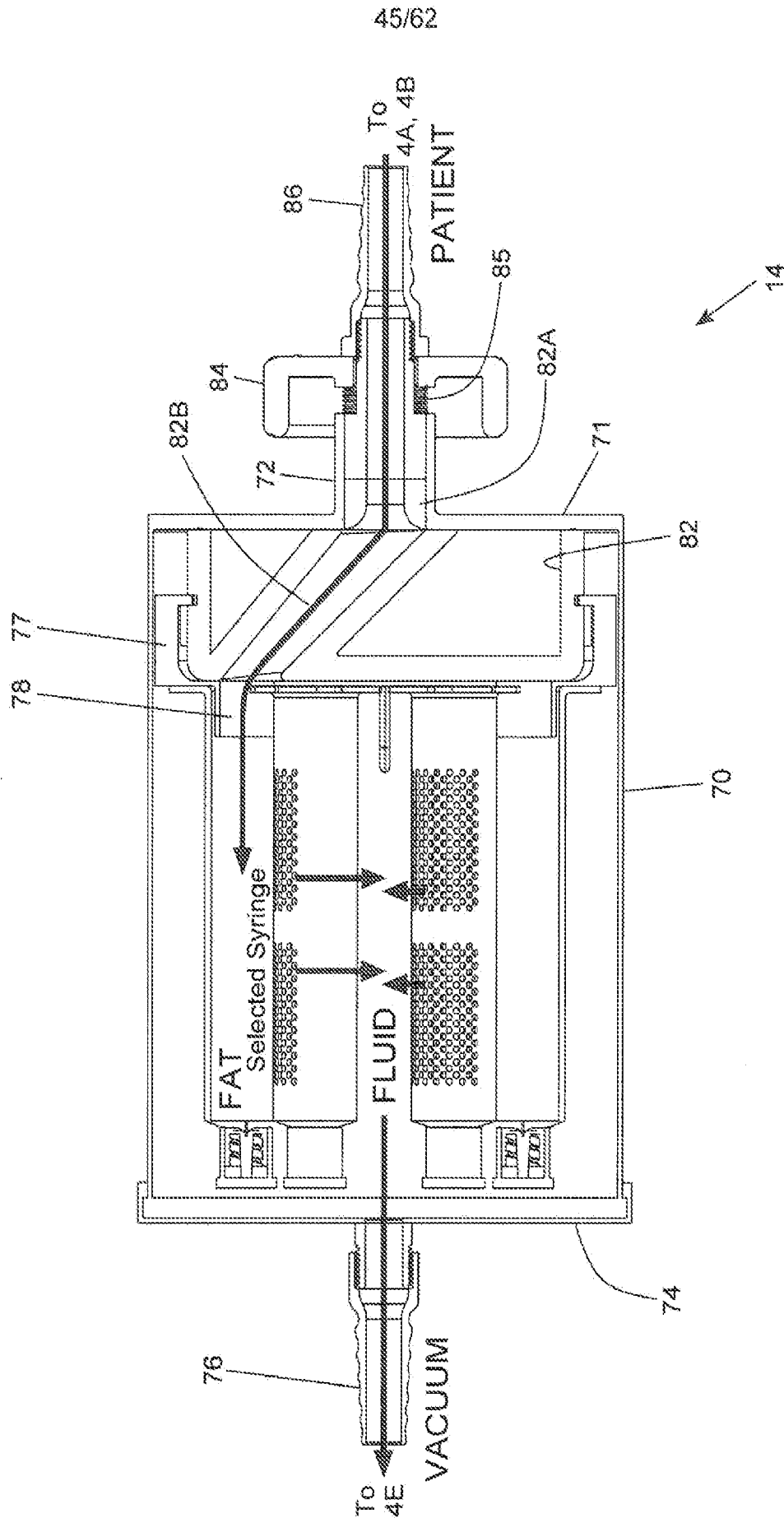


FIG. 4F2

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Removing Collected Fat Samples

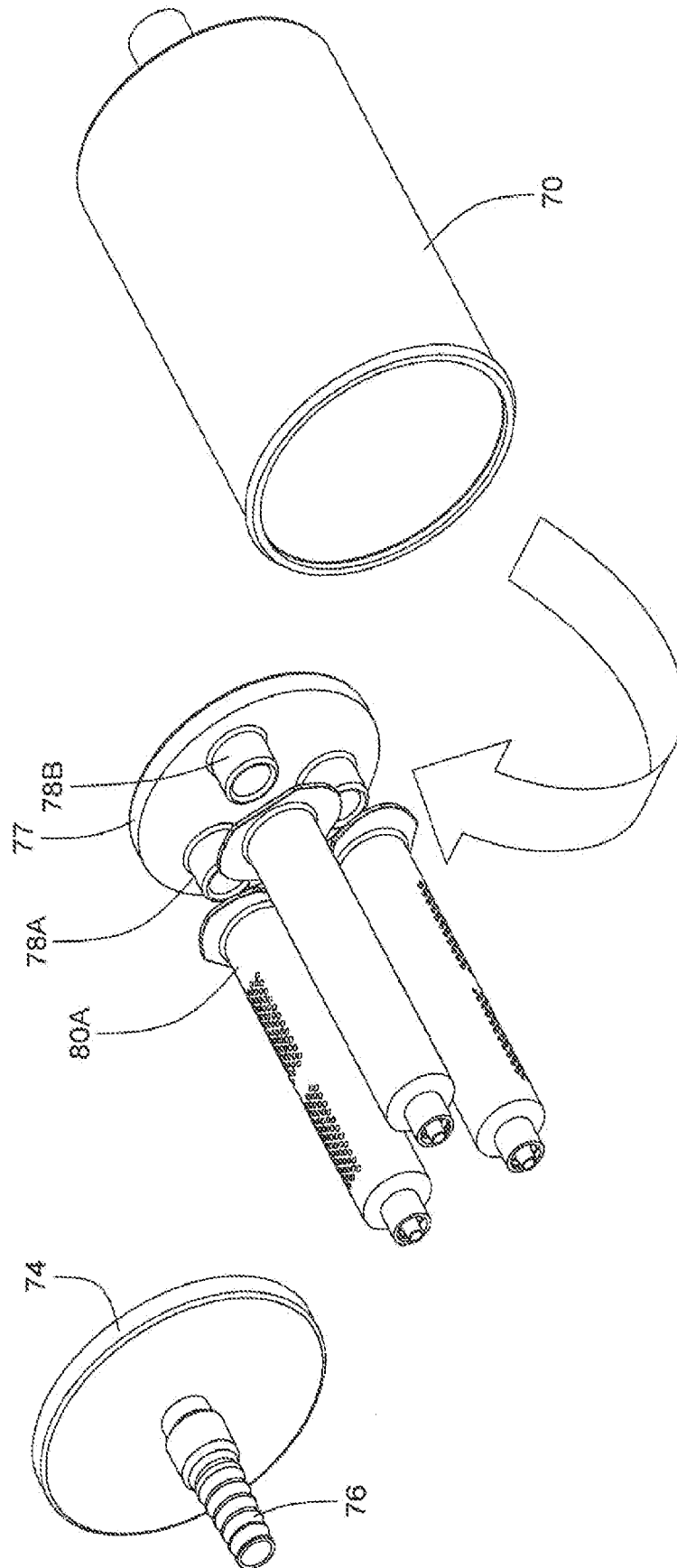


FIG. 4G

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Exjecting Fat Samples From Collection Cartridges

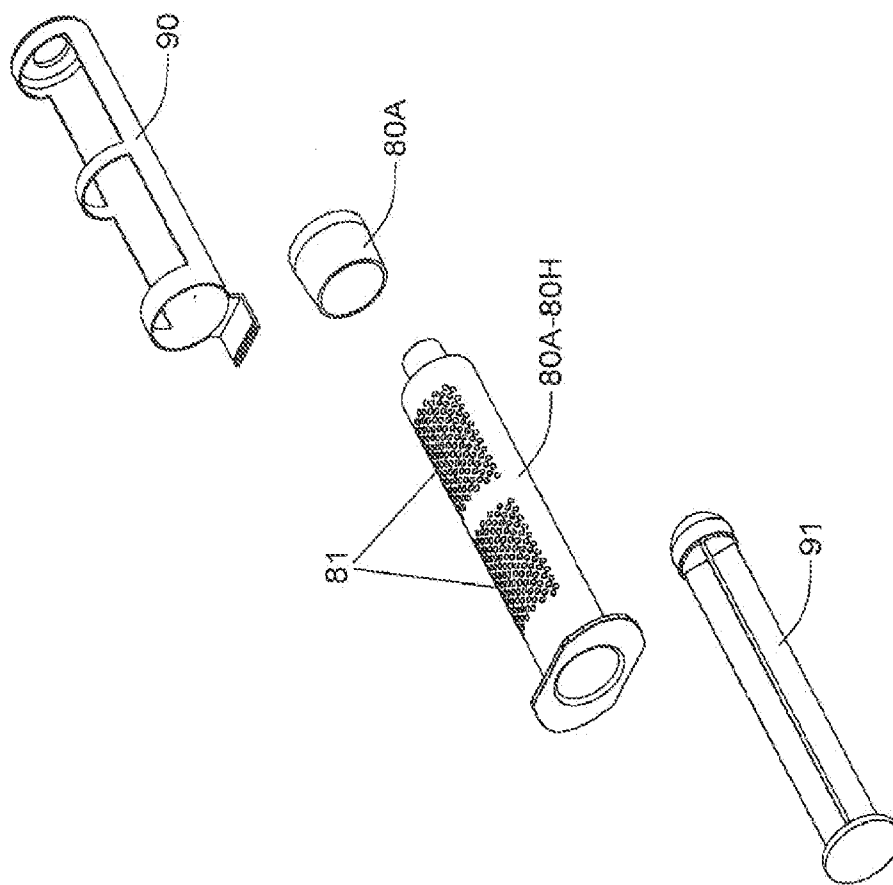


FIG. 4H

Sliding Occluder Down Barrel to Rotate to Cover Holes

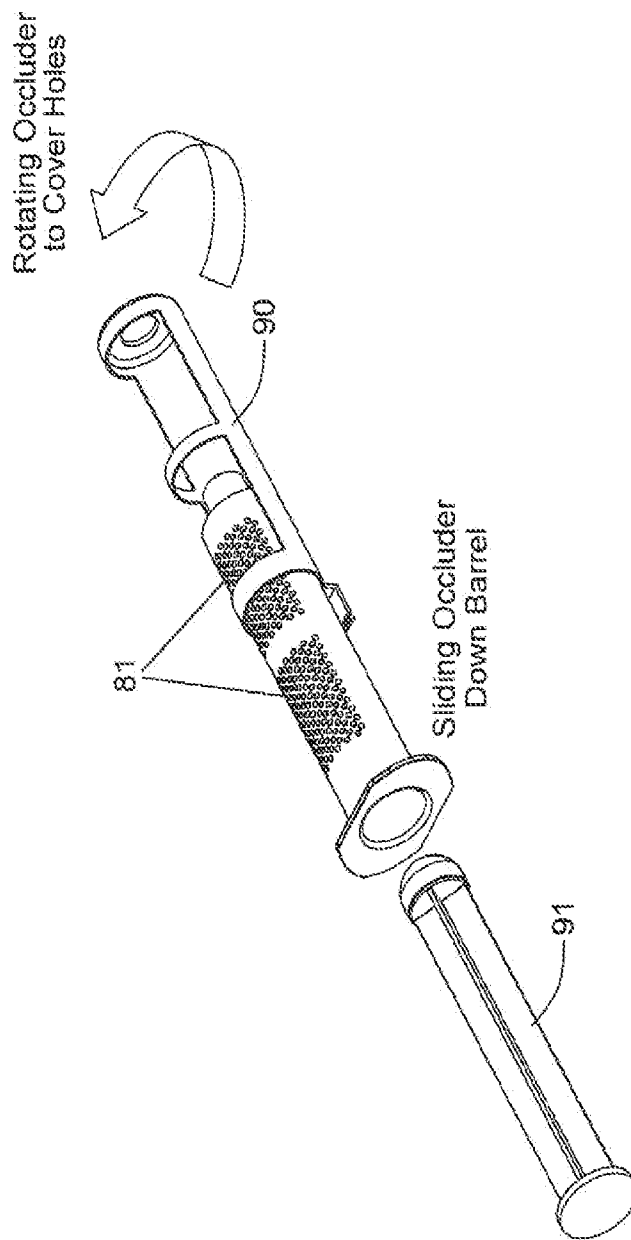


FIG. 411

Holes Occluded (For Ejecting Sample)

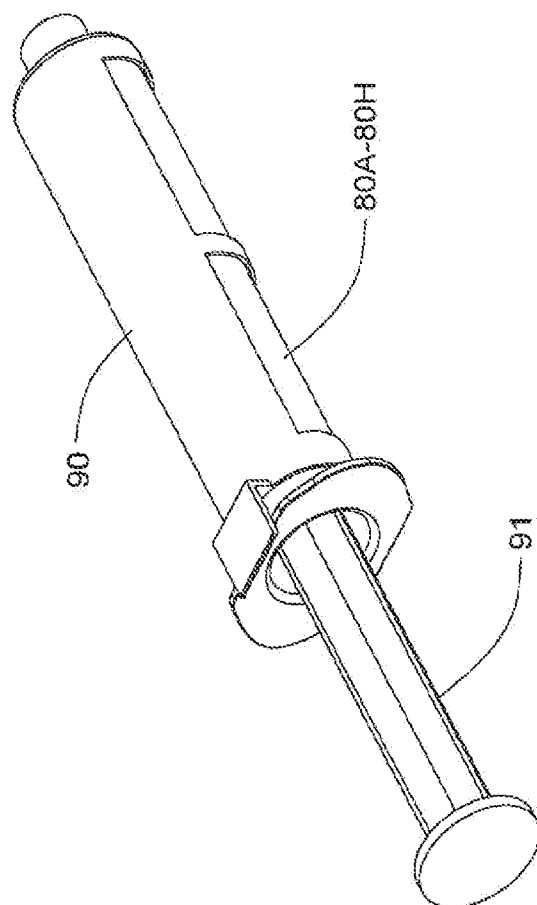


FIG. 412

Increased Negative Feedback Effect of Hypertrophic Visceral Fat Cells
-- Prior To Treatment Using The Method of The Present Invention

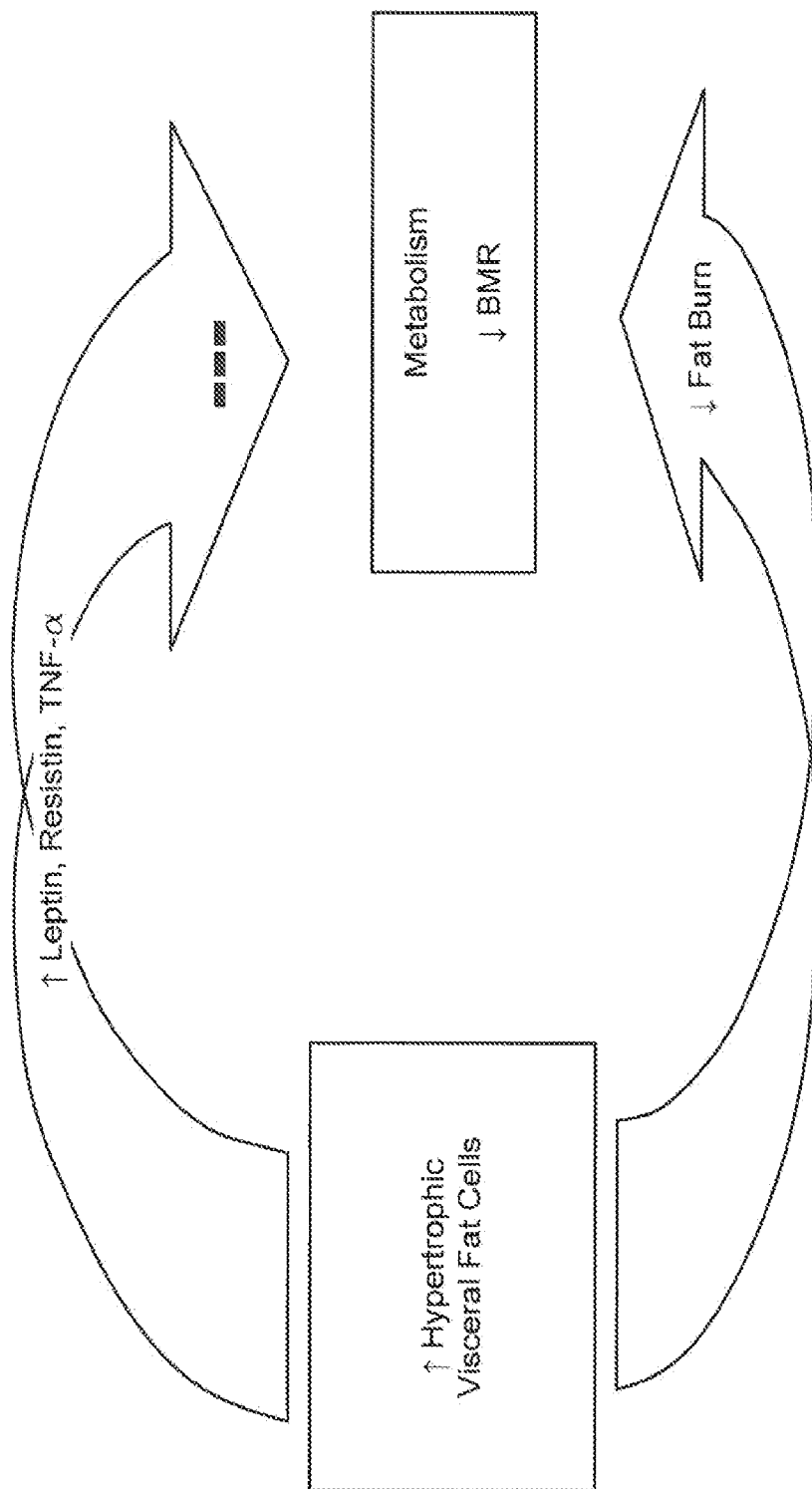


FIG. 5A

Pre-treatment Decreased Secretion of Cytokines favoring Insulin Sensitivity by Hypertrophic Fat Cells
-- Prior To Treatment Using The Method of The Present Invention

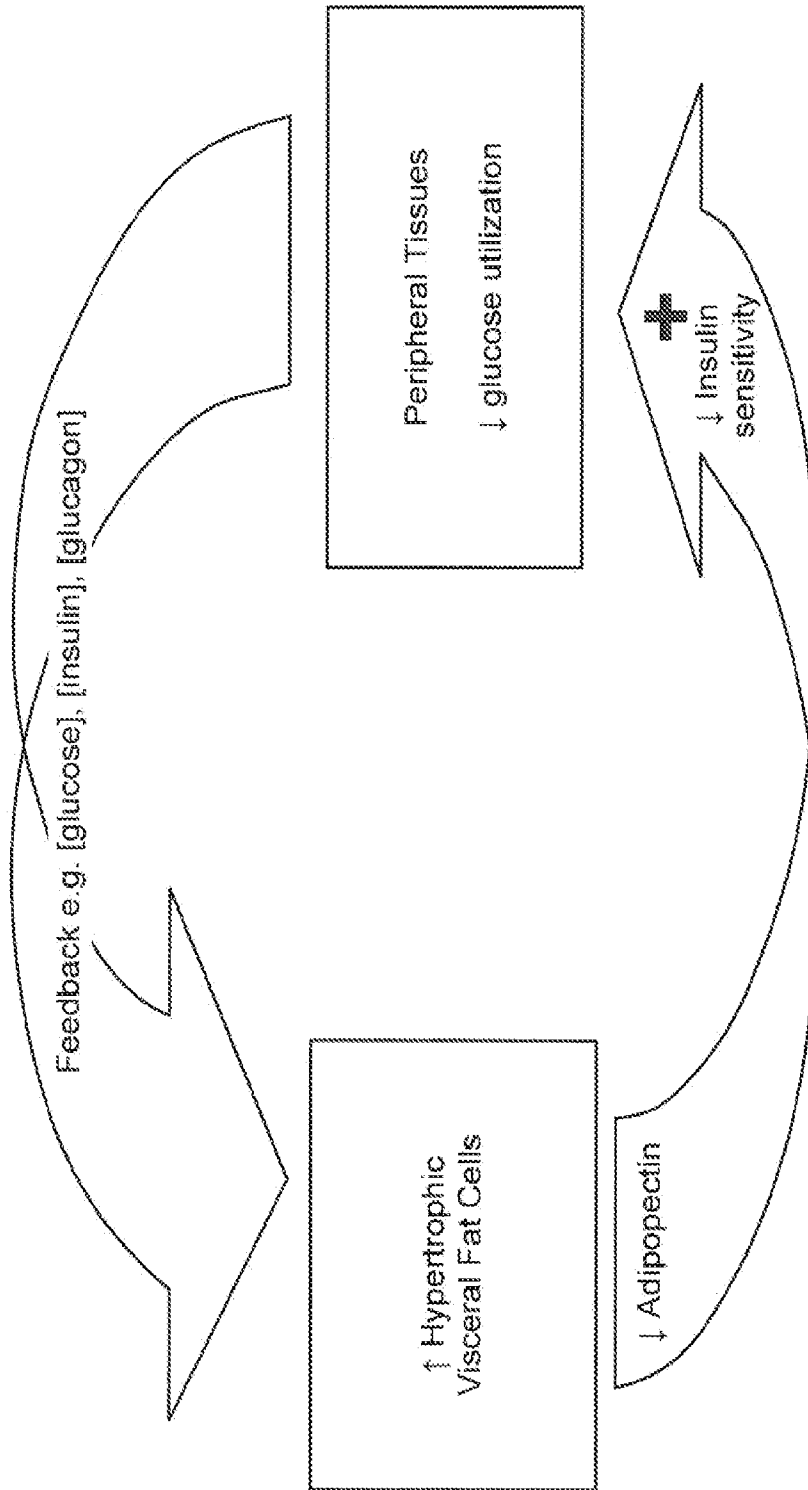


FIG. 5B

Reduction of the Number of Hypertrophic Fat Cells and their Harmful Secretions with Favorable Impact on Energy Homeostasis -- After Treatment Using The Method of The Present Invention

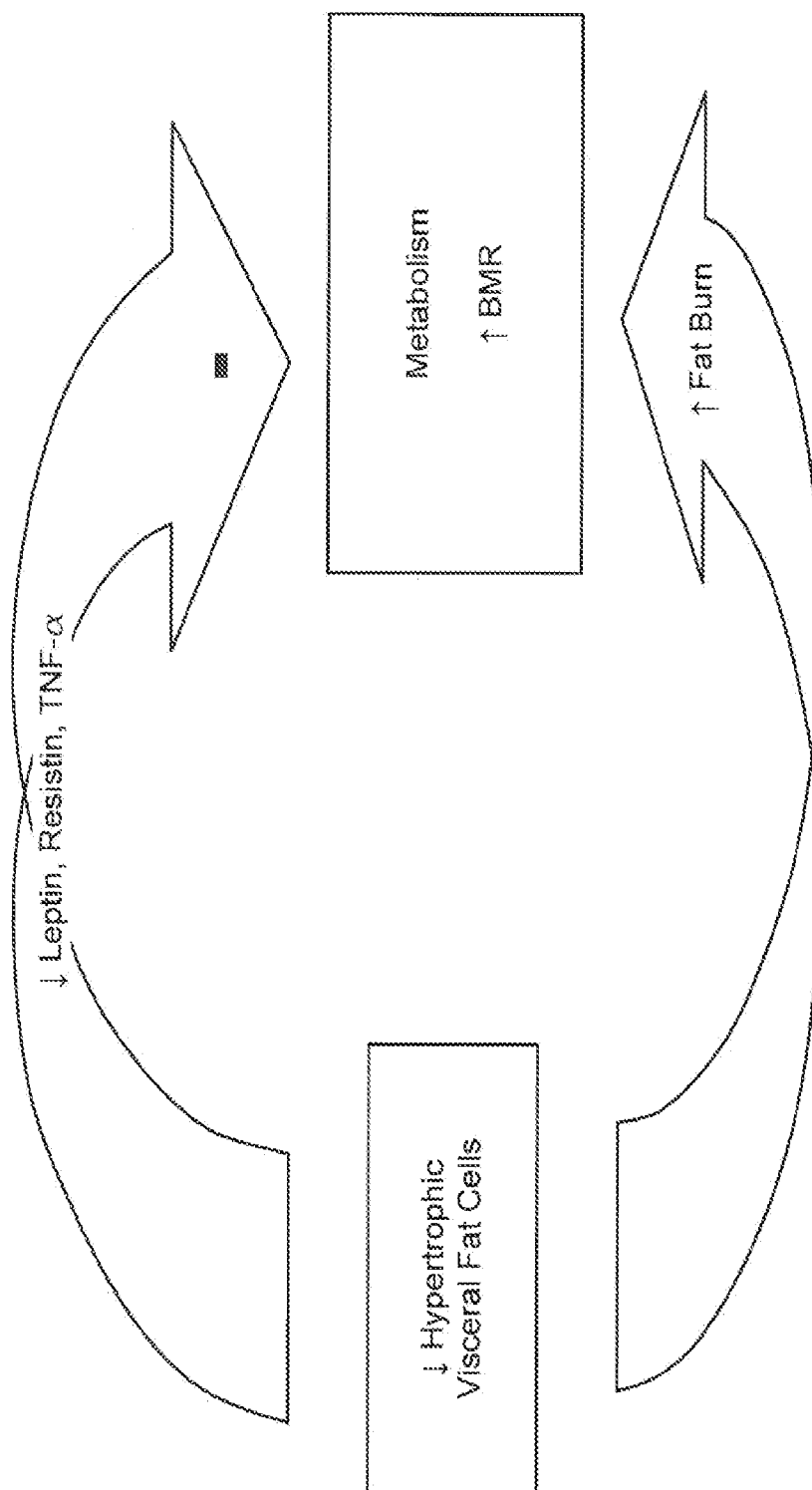


FIG. 5C

Increased Circulating Adipopectin from Remaining Non-Hypertrophic Fat Cells
-- After Treatment Using The Method of The Present Invention

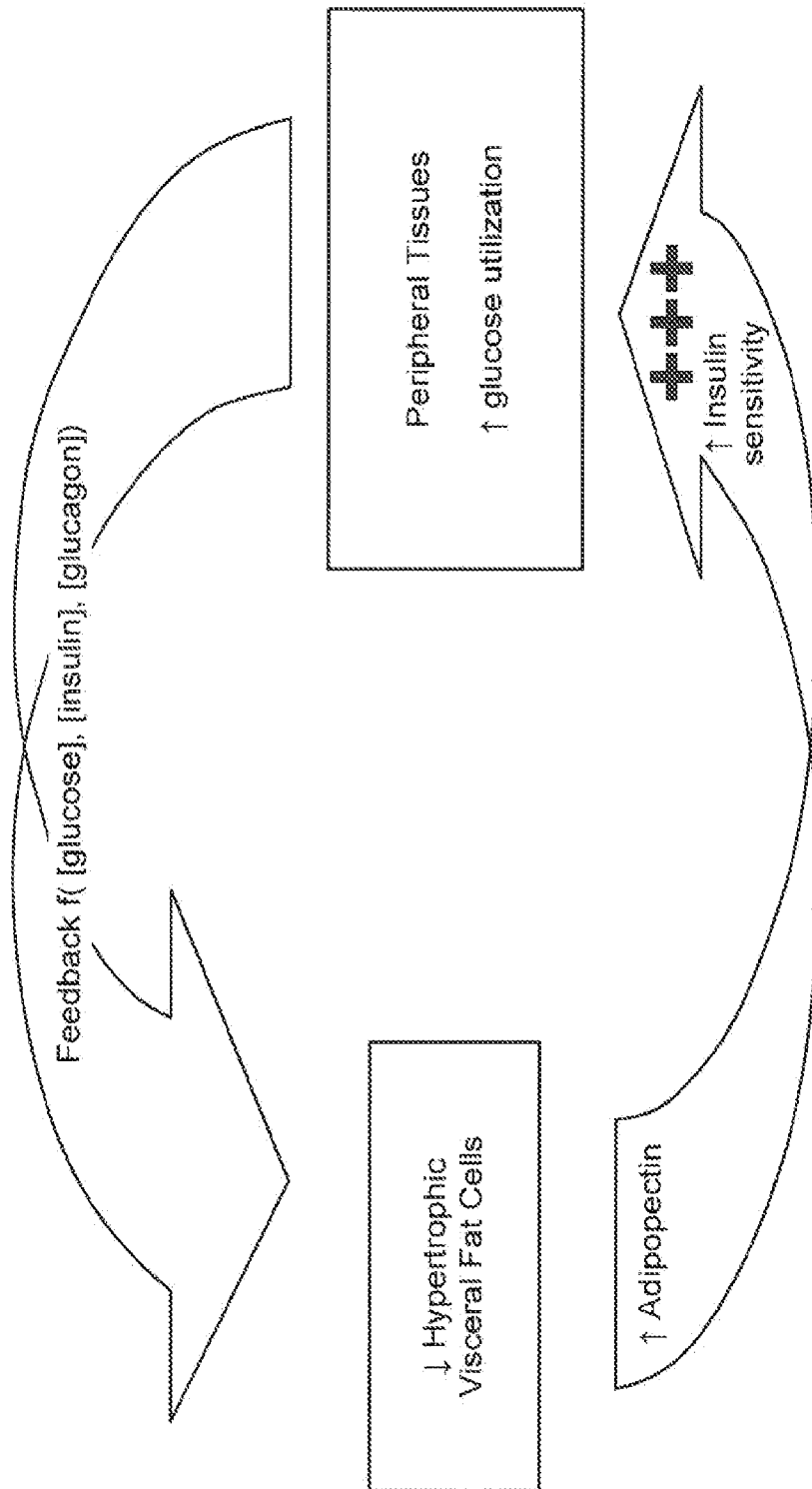


FIG. 5D

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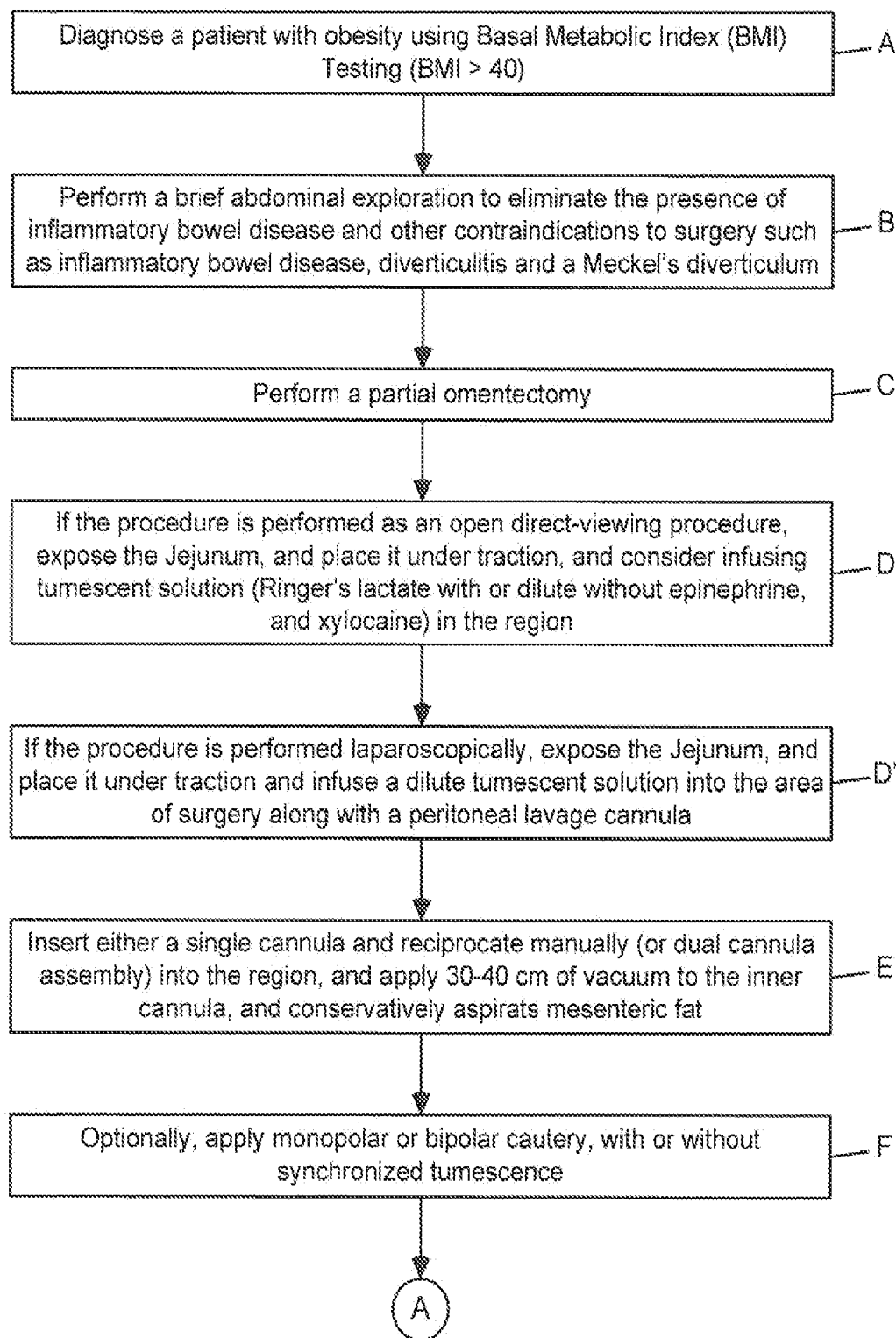


FIG. 6A

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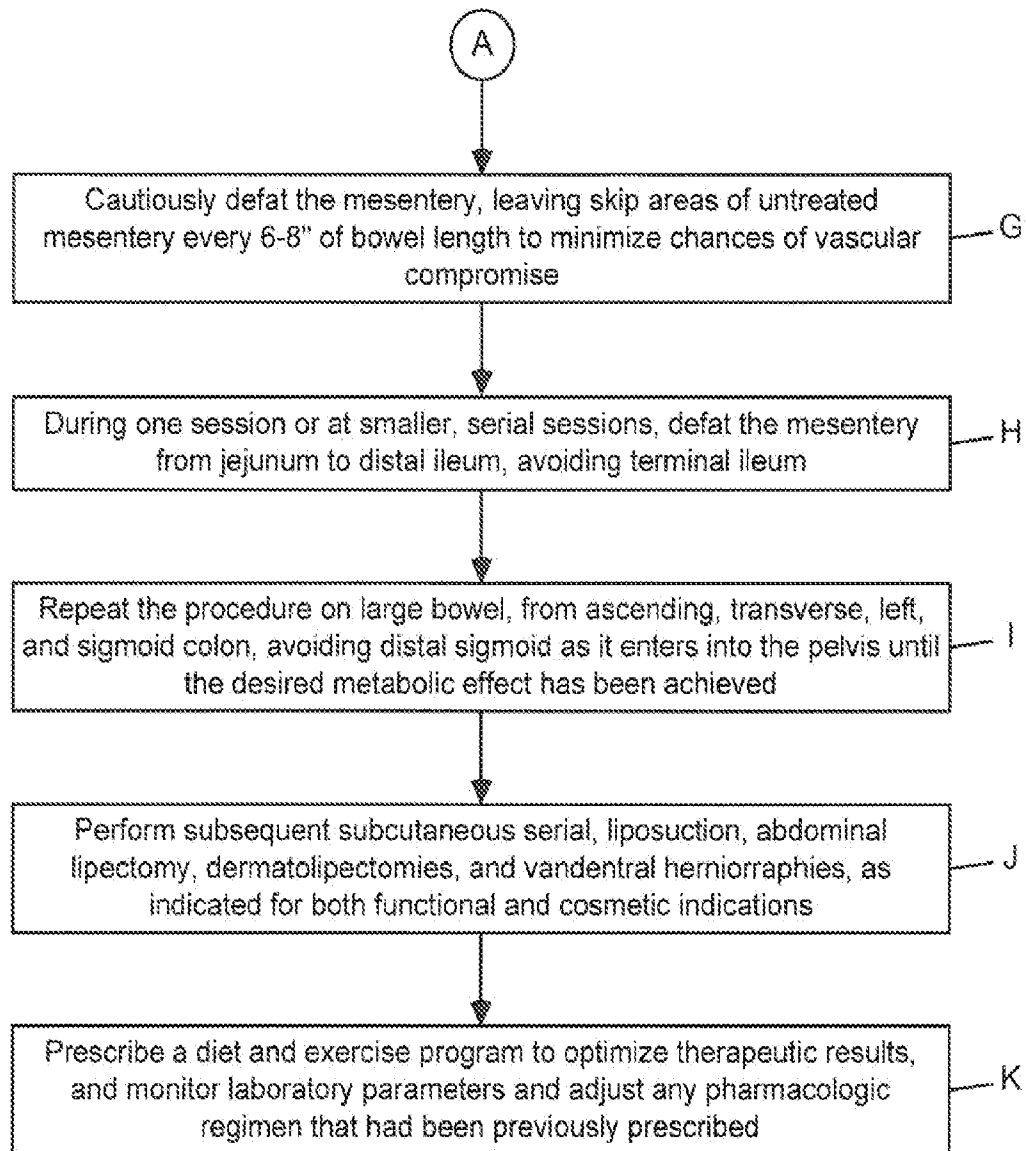


FIG. 6B

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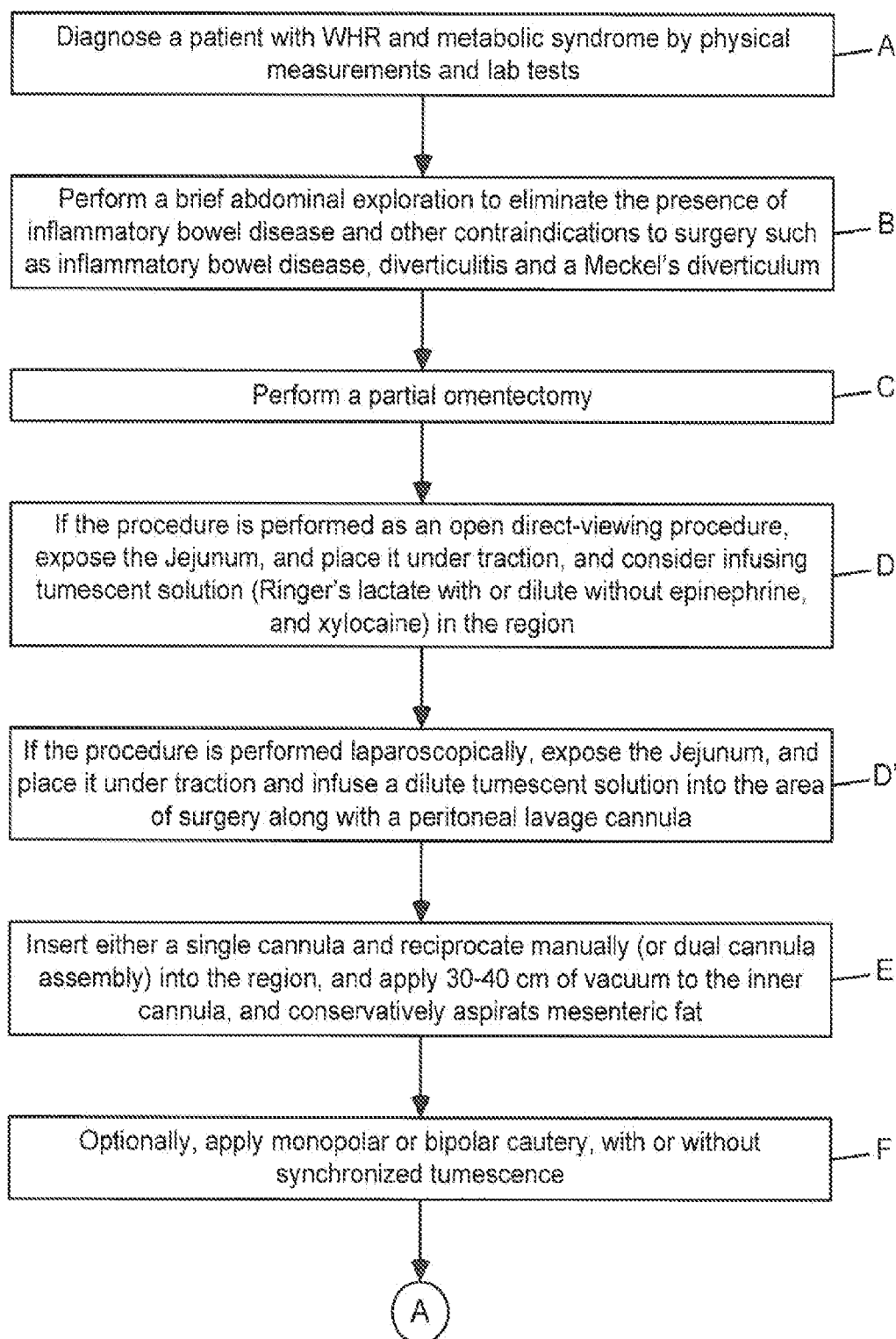


FIG. 7A

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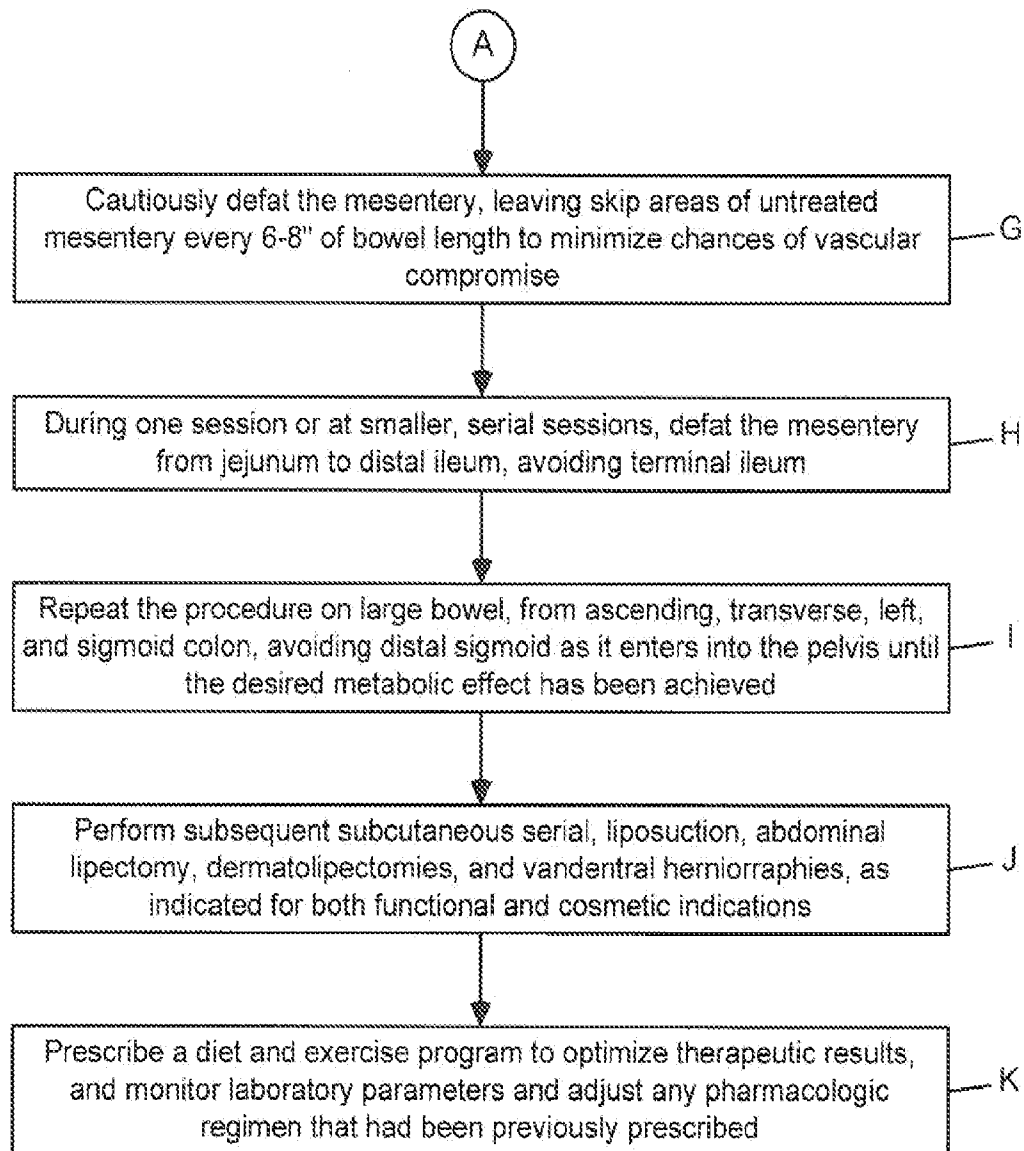


FIG. 7B

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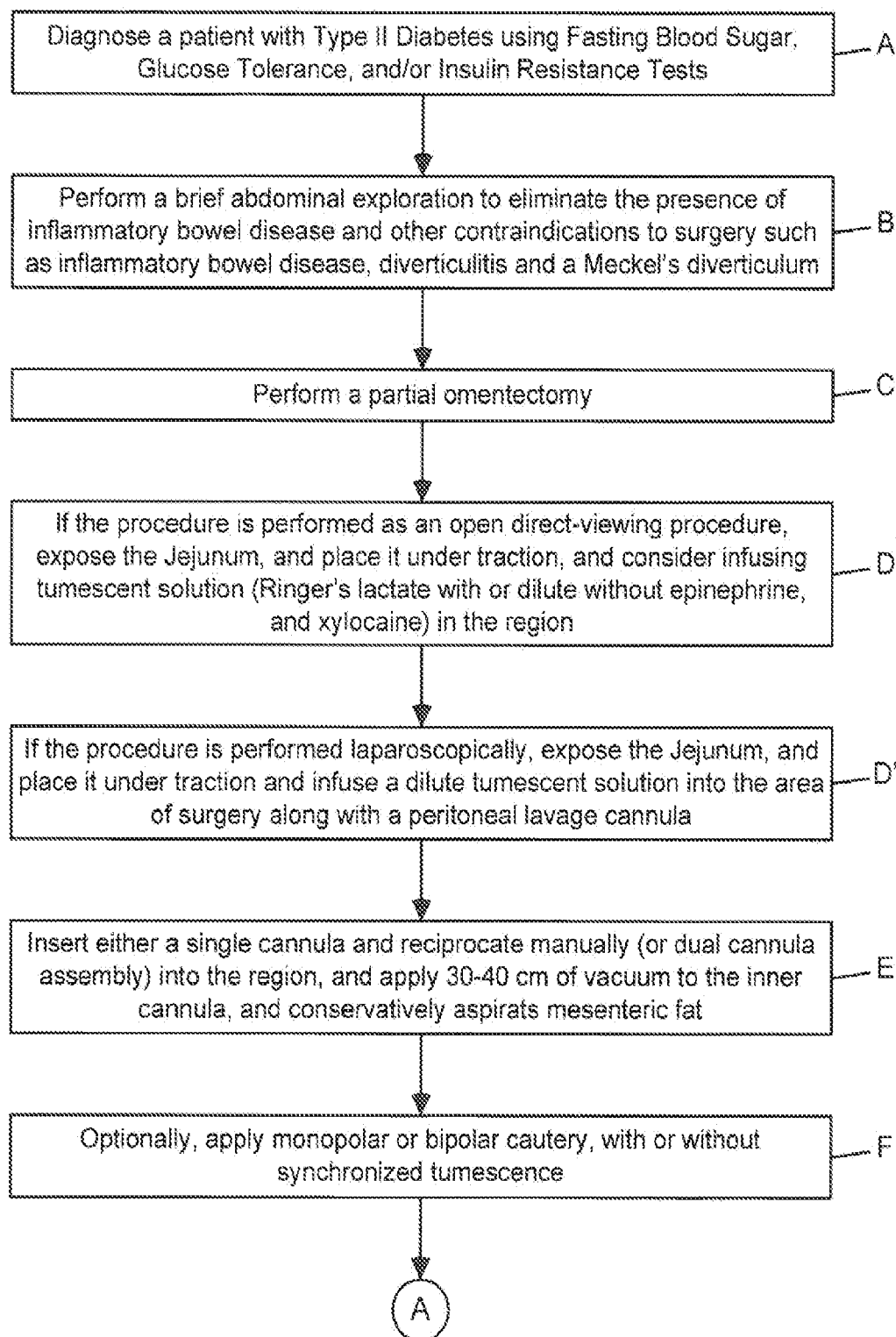


FIG. 8A

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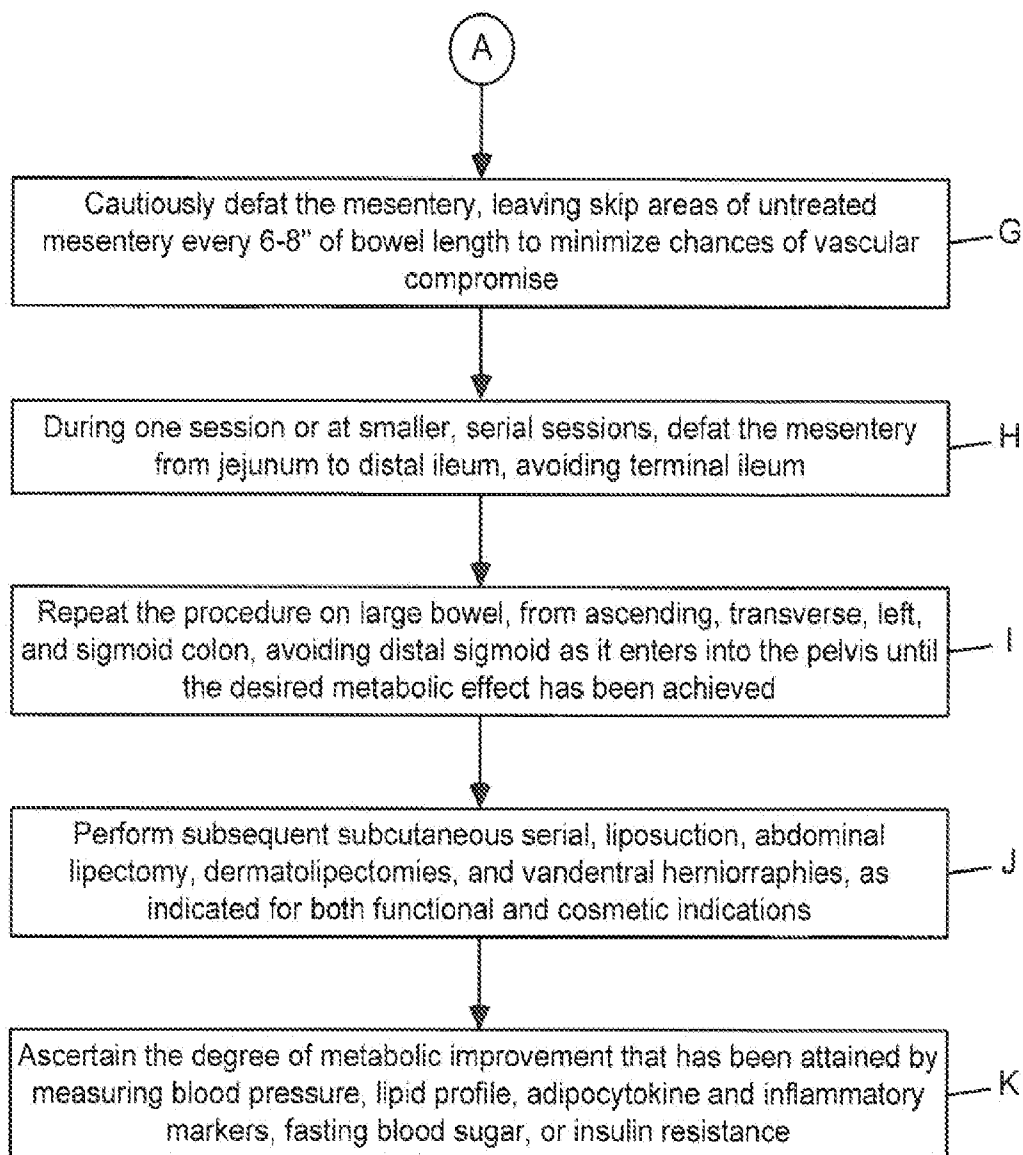


FIG. 8B

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FIG. 9A

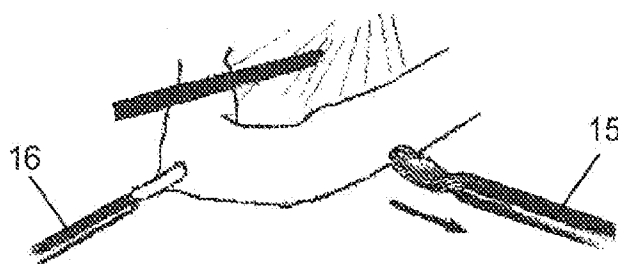


FIG. 9B

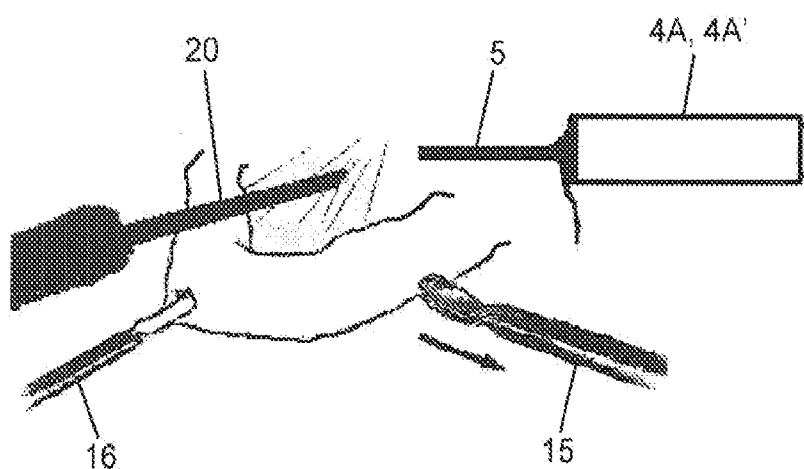


FIG. 9C

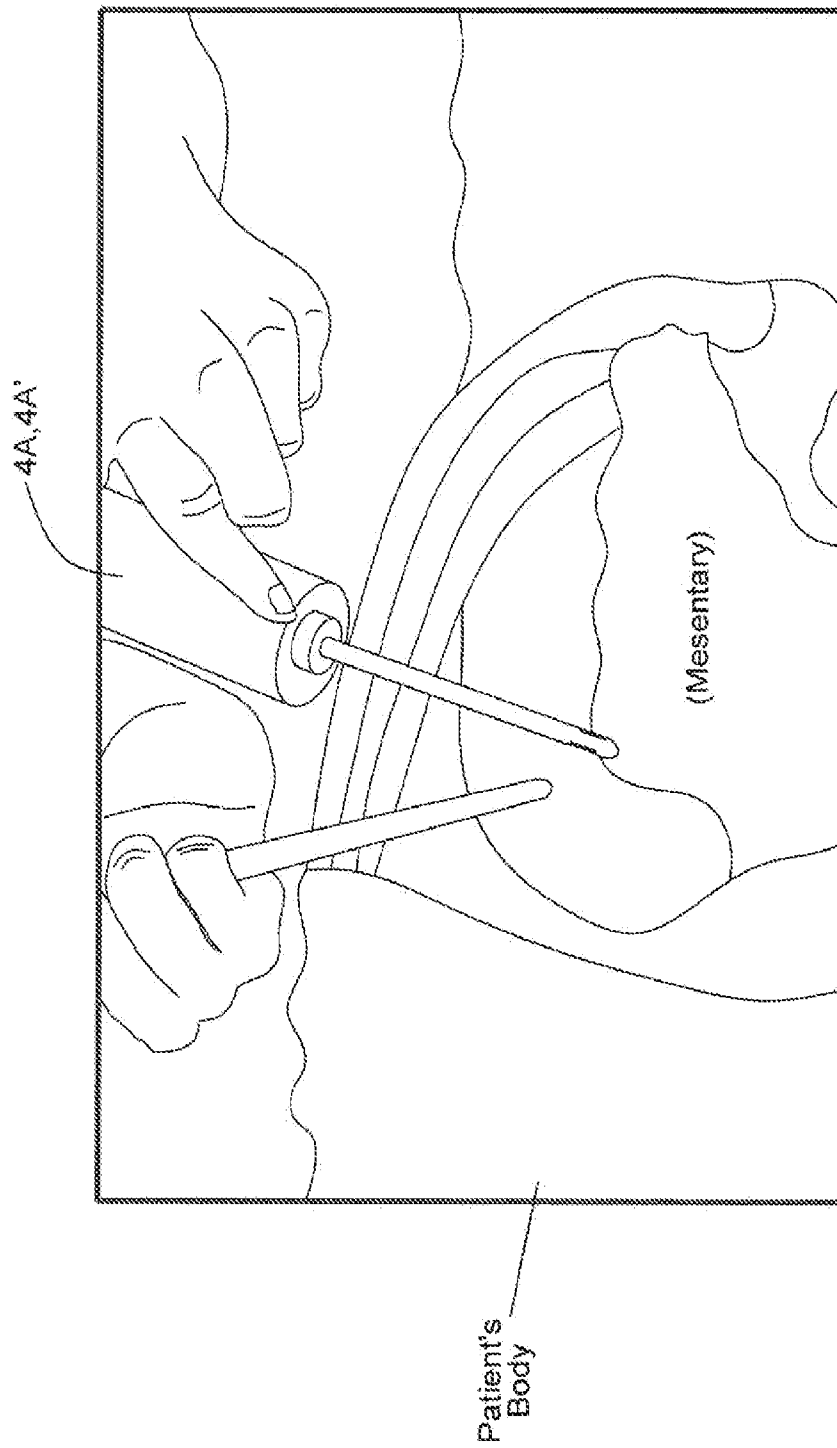


FIG. 10

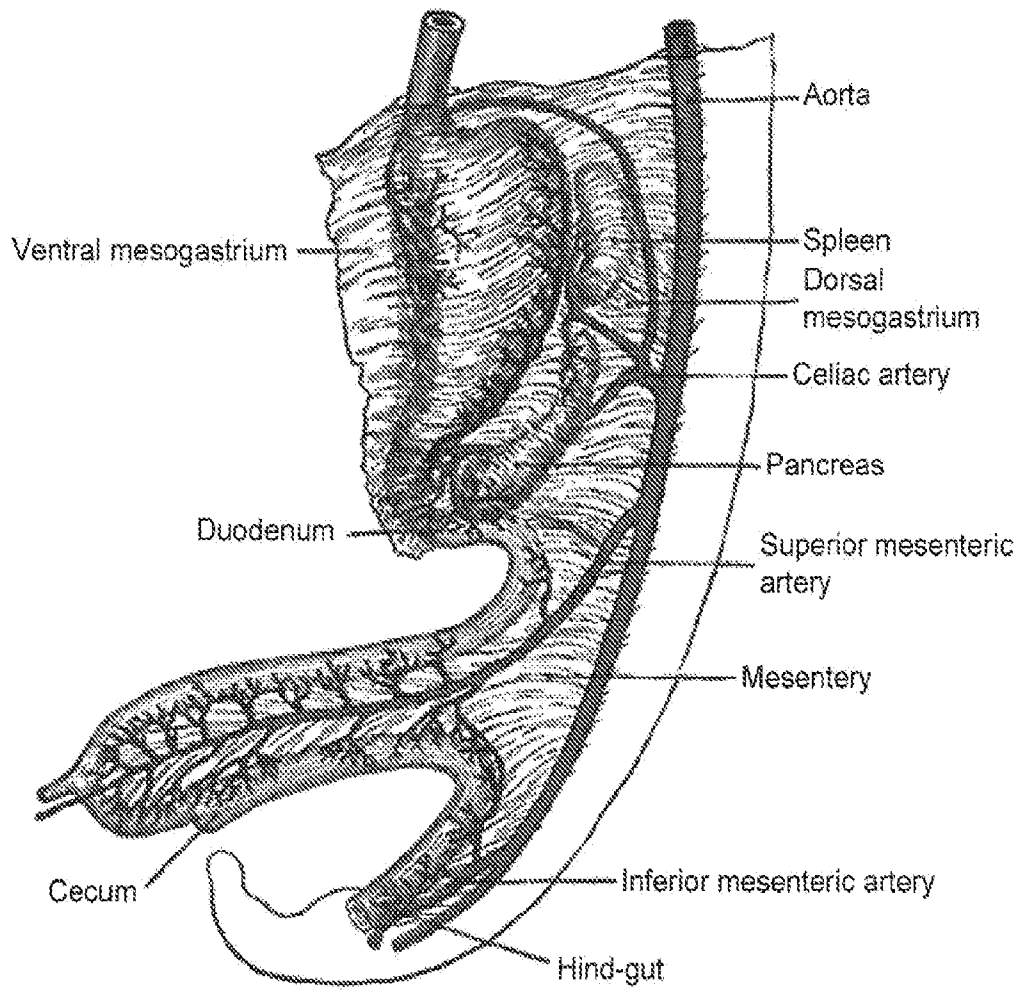


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/44543

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 18/14 (2010.01) USPC - 604/542 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(8): A61B 18/14 (2010.01) USPC: 604/542 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched additional IPC(8): A61B 18/00, A61B 18/4, A61B 18/12, A61M 1/00 additional USPC: 604/19, 604/48, 604/93.01, 604/113, 604/114, 604/540, 606/32, 606/34, 606/41 Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST(PGPB,USPT,USOC,EPAB,JPAB); Google Patents, Google, Google Scholar Search terms used: laparoscopic cannula, fat, tissue, removal, liposuction, mesenteric, cauterize, visceral fat, aspiration, vacuum, suction, negative pressure, cauterizing, cauterization, aspirate, electrocautery, cautery, tumescent infusion, inner outer cannula, etc.		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,626,890 B2 (Nguyen et al.) 30 September 2003 (30.09.2003) Figs 5, 8, 13, 16; col 5, ln 49-51; col 6, ln 12-16; col 7, ln 39-53; col 8, ln 23-33; col 9, ln 9-34; col 10, ln 1-10, ln 27-32, ln 51-54; col 11, ln 24-31; col 12, ln 8-11, 28-32; col 14, ln 1-5, 26-41; col 16 ln 48-59; col 17, ln 12-18; col 18, ln 22-26	1-5, 7-15, 18-27, 30-38, 40-45
X	US 2009/0192498 A1 (Andrew et al.) 30 July 2009 (30.07.2009) para [0002-0003]; para [0029]; para [0032-0033]; para [0038-0040]; para [0045]; para [0059-0060]; para [0071]; para [0073]; para [0076]	6
Y	US 4,617,013 A (Betz) 14 October 1986 (14.10.1986) Abstract; col 2, ln 21-39	1-5, 7-15, 18-27, 30-38, 40-45
Y	US 2006/0247514 A1 (Panasyuk et al.) 2 November 2006 (02.11.2006) para [0012-0013]; para [0057]; para [0086-0087]	12, 25-27, 31
Y	Pitombo, et al. "Amelioration of diet-induced diabetes mellitus by removal of visceral fat" in Journal of Endocrinology (2006) 191: p. 699-706.	34-35
Y		36-38
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 20 December 2010 (20.12.2010)		Date of mailing of the international search report 06 JAN 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/44543

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

- Group I: claims 1-15, 18-27, 30-38, 40-45 directed to a fat aspiration system
- Group II: claims 16, 17, 28, 29 directed to a method of treating diabetes
- Group III: claim 39 directed to a fat sampling device

The groups of inventions above do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The special technical feature of the Group I claims is an aspirating and electro-cauterizing cannula, which is not present in the claims of Groups II or III.
- The special technical feature of the Group II claims is selective removal of fat cells to improve lipid profile, which is not present in the claims of Groups I or III.
- The special technical feature of the Group III claims is a collection chamber, which is not present in the claims of Groups I or II.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 18-27, 30-38, 40-45

- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
 - The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
 - No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 10/44543

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0151874 A1 (Kolster et al.) 17 October 2002 (17.10.2002) entire document	1-15
Y	US 2005/0165345 A1 (Laufer et al.) 28 July 2005 (28.07.2005) entire document	1-15
Y	US 6,872,199 B2 (Cucin) 29 March 2005 (29.03.2005) entire document	1-15
A	Doublet et al. European Association of Urology. Guidelines to Laparoscopy. 2002. entire document	1-15

专利名称(译)	用于治疗人类患者的腹部肥胖症，代谢综合征和II型糖尿病的方法和设备		
公开(公告)号	EP2461757A4	公开(公告)日	2014-12-24
申请号	EP2010807155	申请日	2010-08-05
[标]申请(专利权)人(译)	ROCIN LAB		
申请(专利权)人(译)	ROCIN LABORATORIES , INC.		
当前申请(专利权)人(译)	ROCIN LABORATORIES , INC.		
[标]发明人	CUCIN ROBERT L		
发明人	CUCIN, ROBERT L.		
IPC分类号	A61B18/14		
CPC分类号	A61M1/0058 A61B18/1402 A61B18/1477 A61B18/148 A61B2018/00464 A61B2018/00595 A61B2018/1425 A61B2218/002 A61B2218/007		
优先权	12/462596 2009-08-05 US		
其他公开文献	EP2461757A1		
外部链接	Espacenet		

摘要(译)

一种内窥镜引导的动力辅助组织抽吸方法和系统，用于从患者的肠系膜区域安全地去除脂肪组织。内窥镜引导的动力辅助组织抽吸系统包括：具有视频探头的内窥镜系统，一个或多个视频监视器，以及数字记录设备；以及一种动力辅助组织抽吸系统，包括动力的可手持的器械，该器械包括可手动支撑的壳体，并且设置有双套管组件，该双套管组件包括安装成用于在外套管内往复运动的内套管；可操作地连接到动力的可手动支撑的器械的动力源，用于在组织抽吸操作期间供应动力以驱动内套管使所述内套管在外套管内往复运动；和可操作地连接到内套管的真空泵，用于从患者的肠系膜区域吸出内脏脂肪组织，通过双套管组件的外部 and 内部抽吸孔，同时视频探针捕获内部脂肪组织的数字图像。FOV，视频监视器显示从患者的肠系膜区域移除的脂肪组织的捕获数字图像，并且数字记录设备正在记录该数字图像。