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(54) **MICRO SEWING DEVICE**

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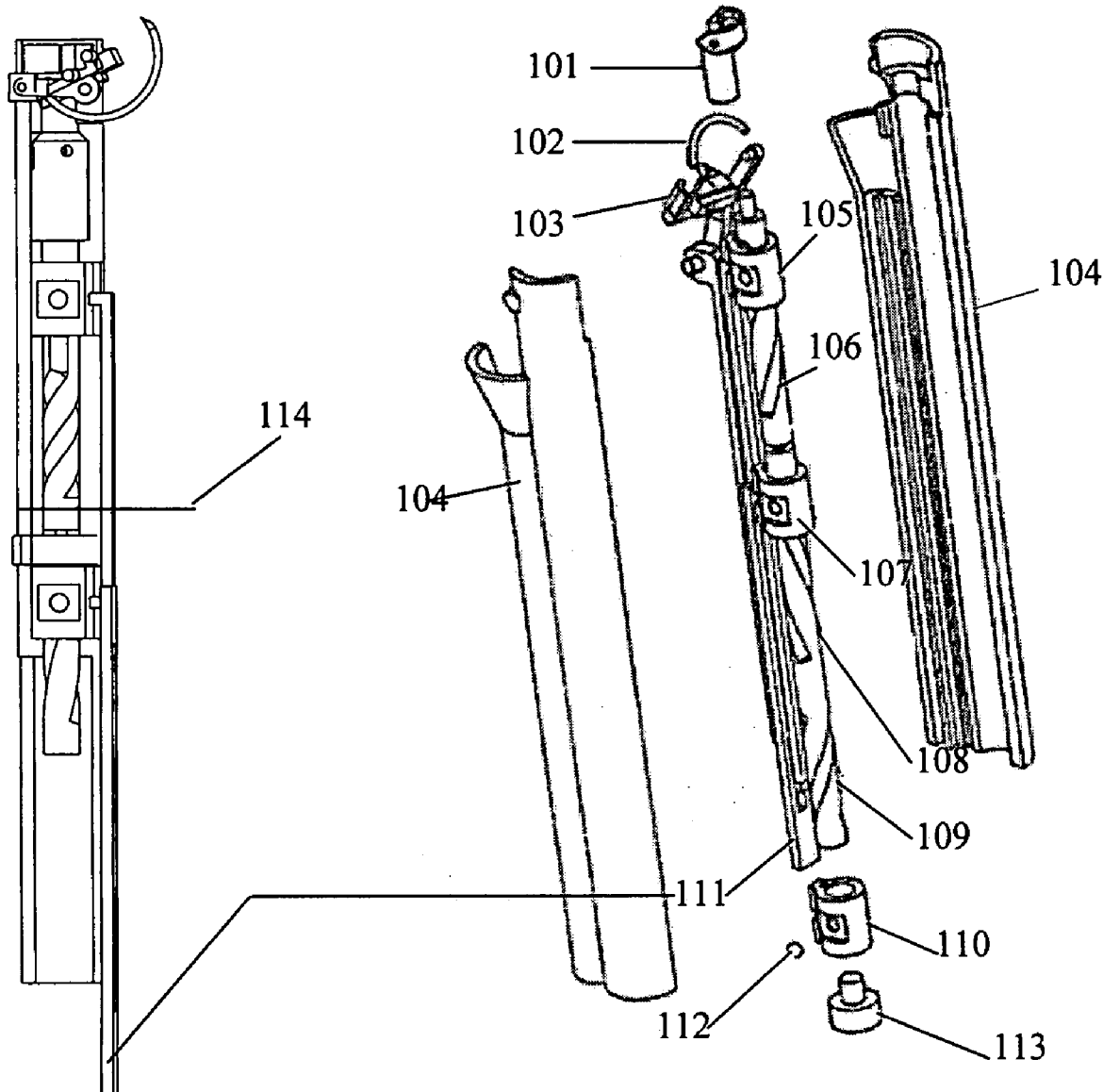
(52) **U.S. Cl.** **112/169**

(57) **ABSTRACT**

The present invention discloses a micro sewing device for percutaneous, endoscopic, laposcopic and minimally invasive surgical procedures for suturing in very small internal body spaces. The device is of cylindrically specific design to provide suturing in the small spaces available.

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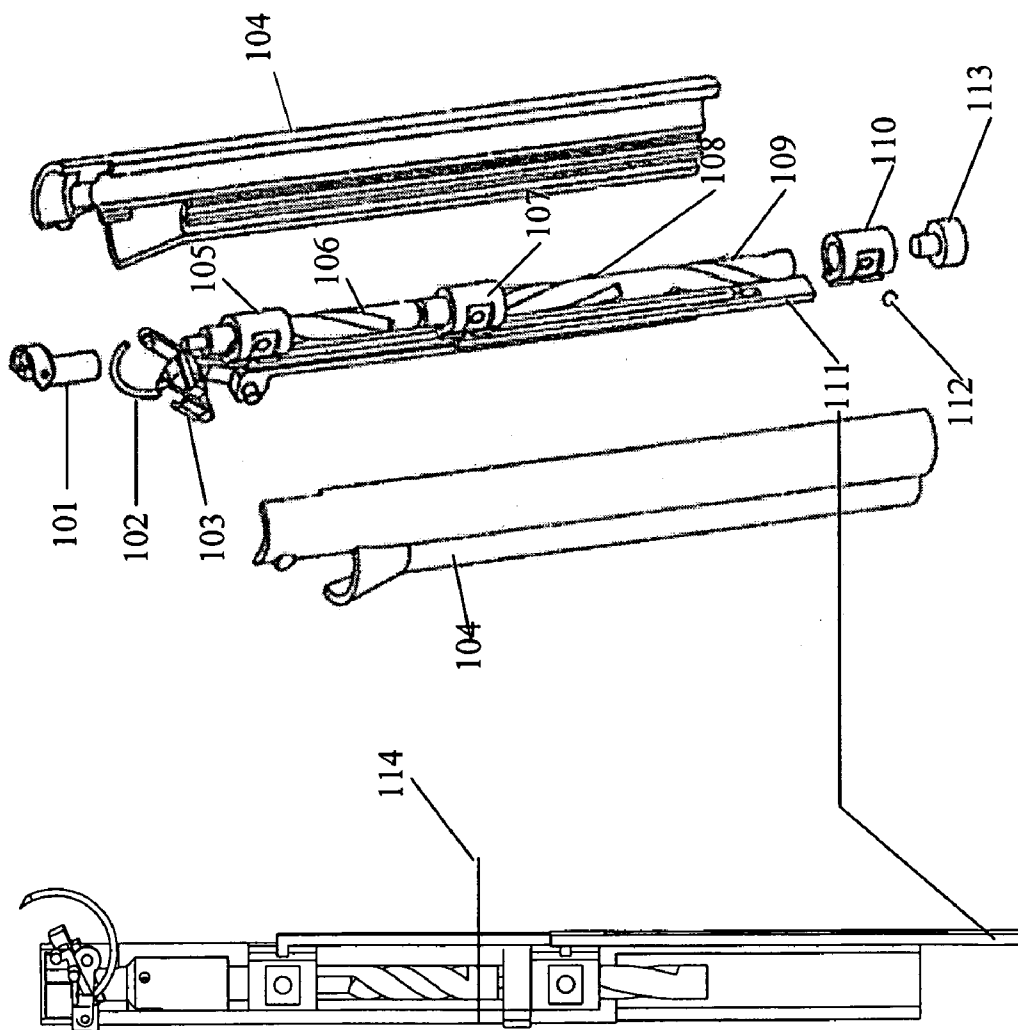


FIG. 1

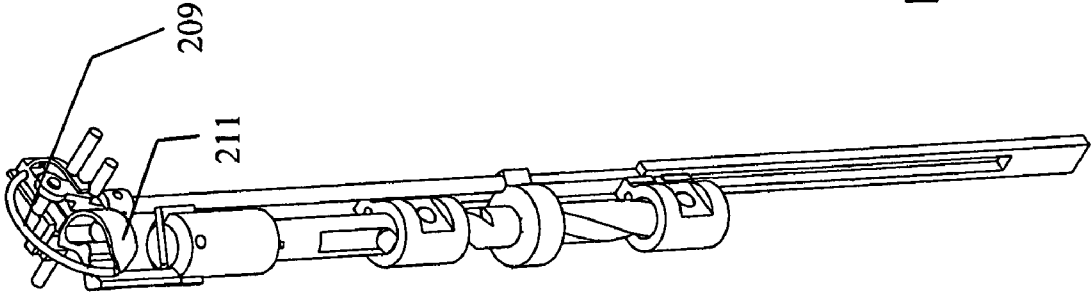
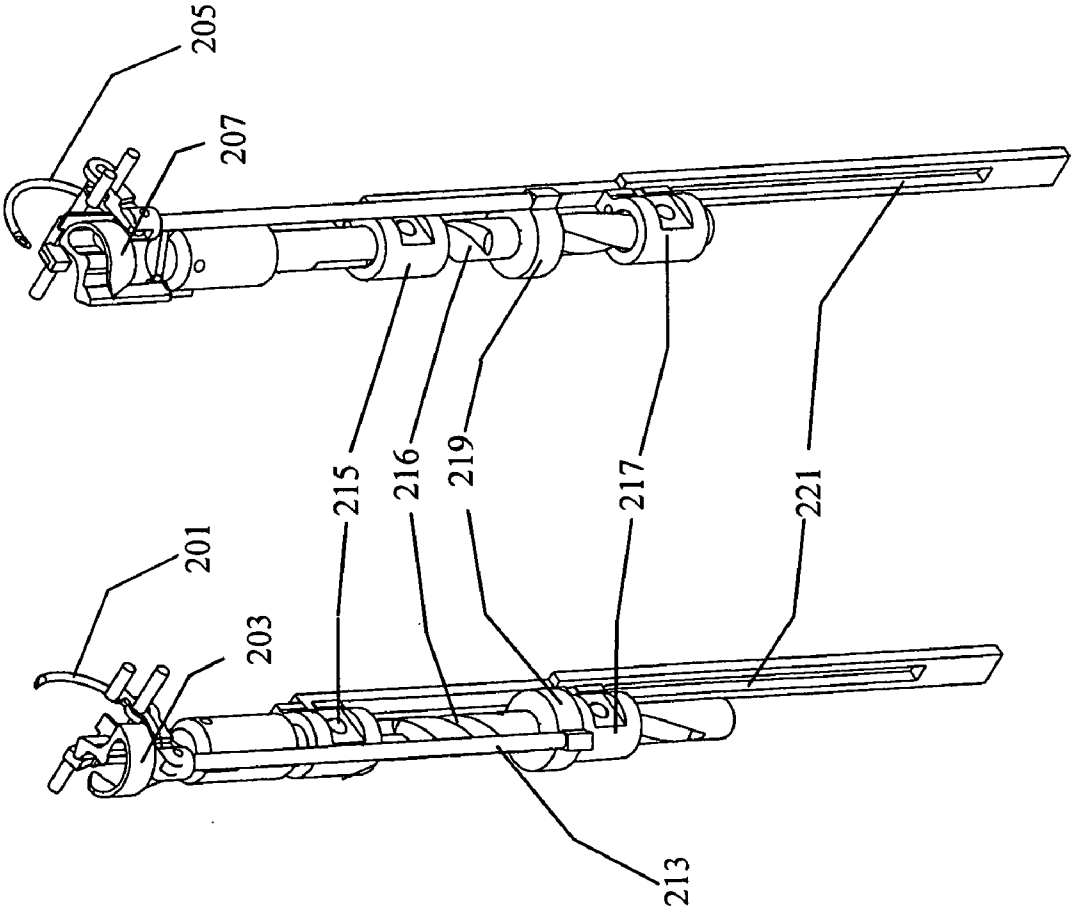


FIG. 2



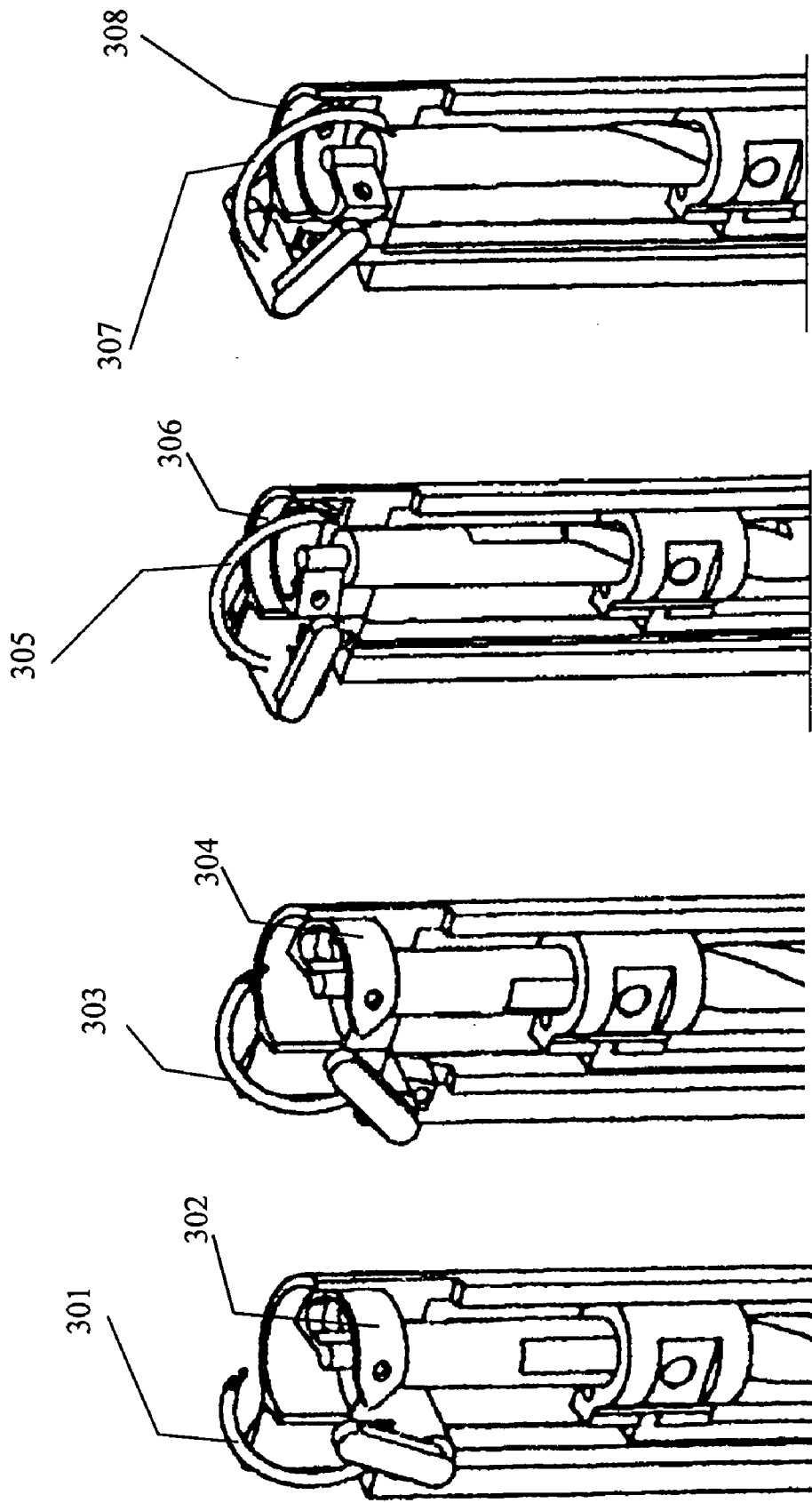


FIG.3

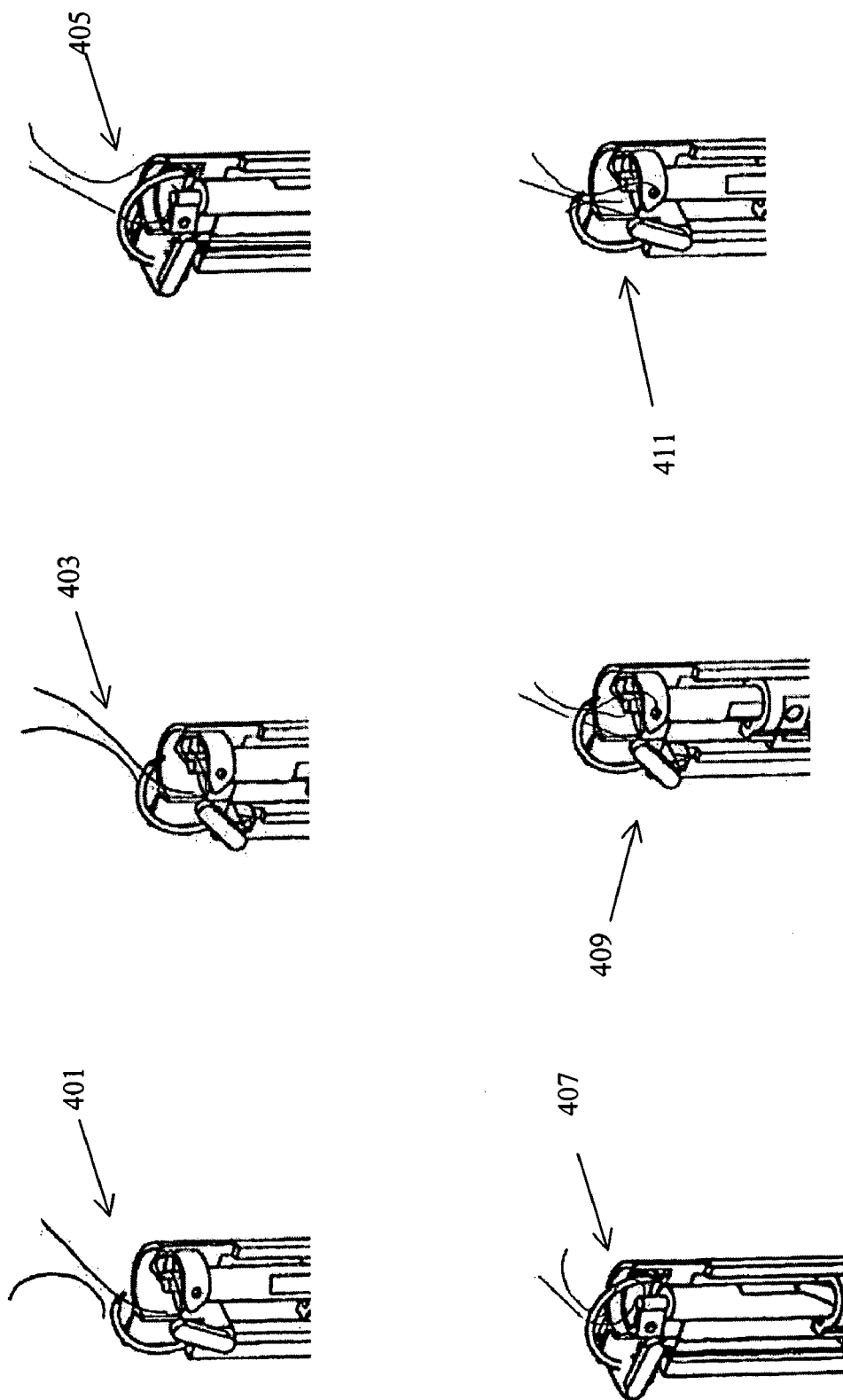


FIG. 4

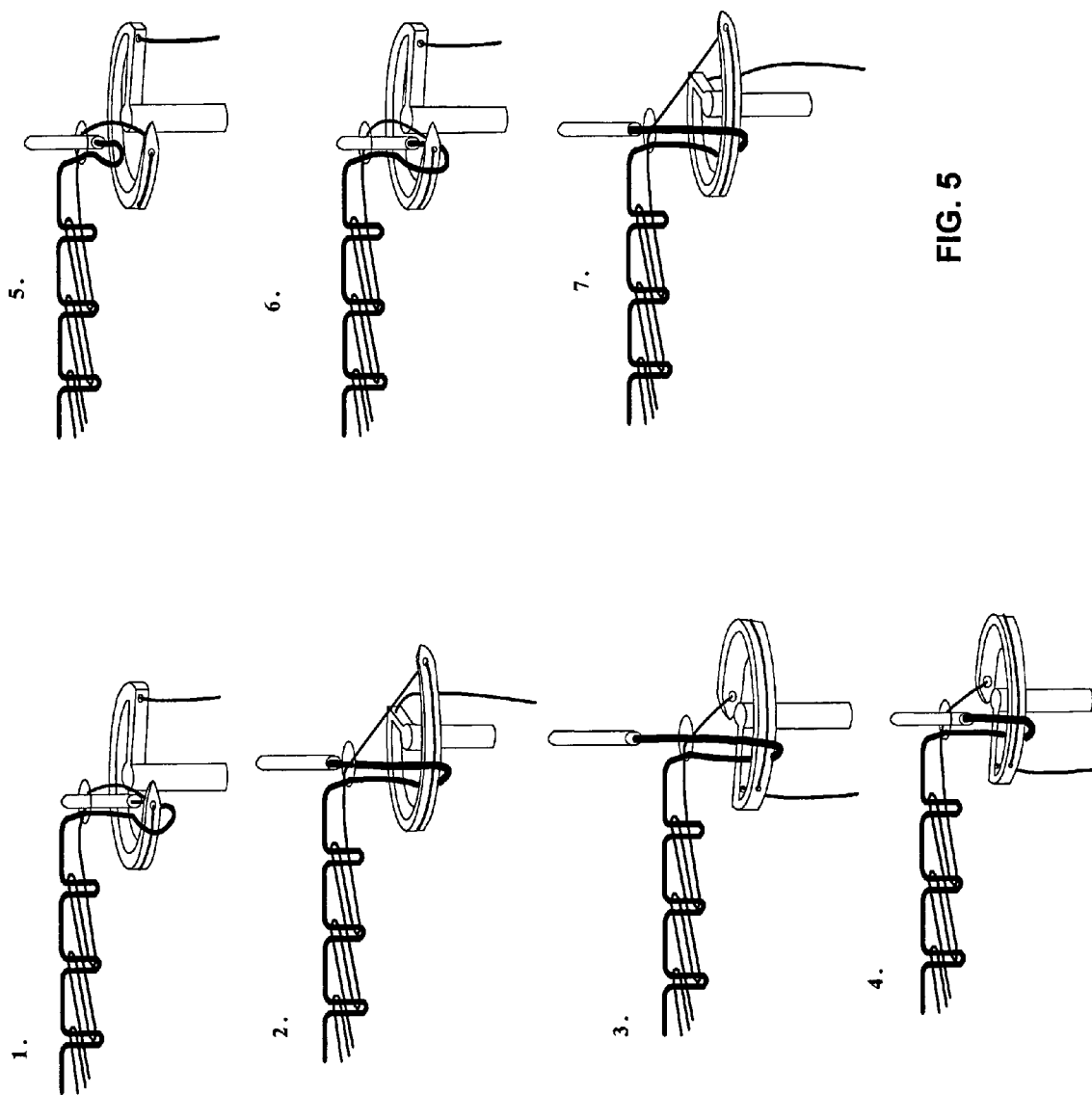
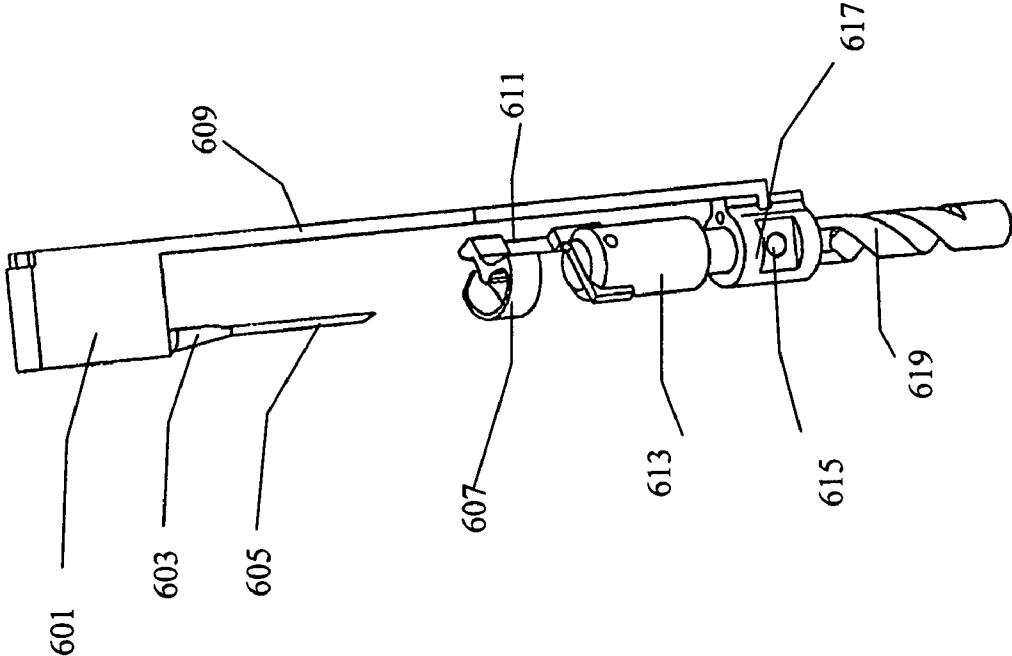


FIG. 5



Straight Needle Configuration

FIG. 6

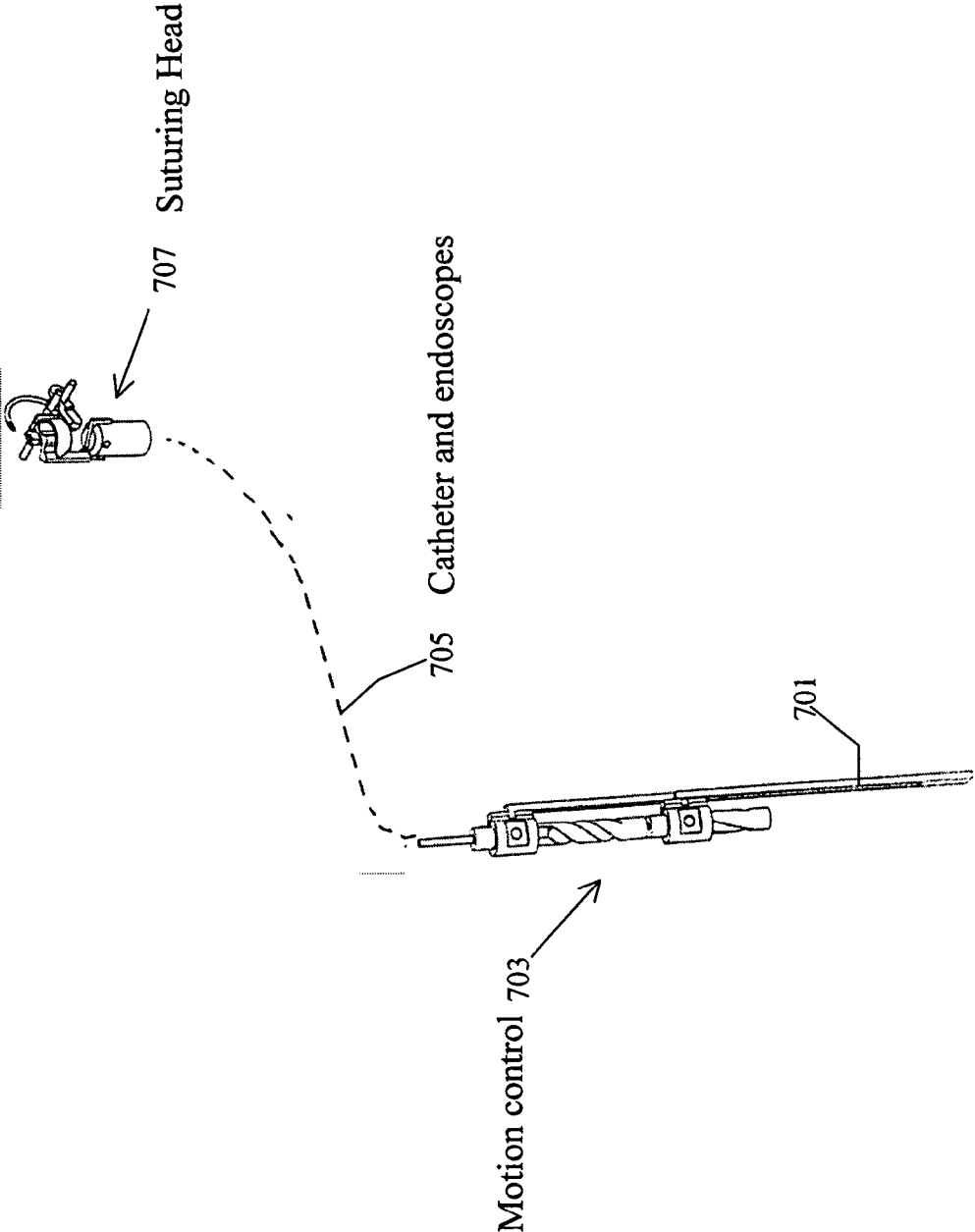


FIG. 7

MICRO SEWING DEVICE

BACKGROUND

Field of the Invention

[0001] The present invention generally relates to sewing devices and more specifically, to very small sewing devices for micro dimension precision needed in surgical environments.

[0002] Precision stitching in the last several decades has grown more widely in the medical industry because simply, surgeons sew where they can to remove abnormalities or install continuing smaller medical devices. It is a skill honed and mastered early, used virtually in every procedure they are called upon to perform. Originating from basic fabric sewing, it is not that difficult and with practice relatively safe. However, the trend in surgery of implanting medical devices organ removal and bypass type surgical procedures has grown while device size has shrunk.

[0003] Some medical device manufacturing companies are now offering suturing systems and devices aimed at delivering the tactile control and precision associated with open procedures to minimally invasive surgery.

[0004] Present surgical procedures are challenged for device placement in difficult if not thought to be impossible locations previously and much smaller suturing work spaces. As medical devices grow smaller, components must become stronger to handle the resulting stresses, and surgical techniques and tools must change to meet the challenge of working with yet smaller devices with smaller working spaces. This applies to endoscopic, laparoscopic and minimally invasive surgical procedures as well as more traditional medical procedures.

[0005] Some procedures for device implantation have proven inadequate because of weakened attachment and dislodged devices pose ongoing danger. The securing of many medical devices such as stints requires suturing into tissue and onto new and tougher artificial materials, weaves and fabrics. The securing of these potentially dislodged devices is problematic, requiring smaller sewing devices and stronger needles. Smaller devices so that generally means weaker needles, and any breakages from weakened sutures or overstressed needles adds to the operation risk. But smaller devices also means less intrusive means of suturing, simplifying the healing, and speeding recovery.

[0006] Where the risk is too high, a particular otherwise helpful medical procedure cannot be used. What is needed are smaller stitching devices, devices which can suture a running stitch or continuous chain of stitching without tearing the tissue or the compromising the thread. What are needed are stitching devices which give the surgeon more precise thread control.

[0007] Very Small Tubular Devices

[0008] Catheters and other medical devices require very small tubular shapes to enable deployment in the arteries. Many products like Endovascular stent grafts for abdominal and thoracic aortic aneurysms are made of tubular shaped graft material that is either hand sewn together or precision sewn by machine like the small arm lock stitch machine as taught by Sew Fine™, in 2002 or on sewing devices like the Endovascular deployment machines used to sew deployment sheaths as taught by Sew Fine™, in 1997 and additional equipment provided in 2006. Medical devices used in procedures to support blood vessels, such as Endovascular stent

graft, and devices to keep a vessel open, as in coronary stints, it is often the case that the devices are smaller then can be sewn mechanically because the precision cannot meet the dimensional requirements of the work.

[0009] The evolving requirements of medical devices and other non-medical devices press the envelope for sewing on smaller parts and yet smaller parts. In attaching Endovascular devices, it is often the case that a sewn device requires a smaller more protective stitching needle then what is currently available. Heart tissue weaknesses can be strengthened with suture repairs. Also, with new technologies evolving in the coronary and other endovascular devices, it is necessary to sew closer to a stent or device than is currently possible. What are needed as smaller stitching devices, small enough to work around stent devices, yet strong enough not to break during the procedure with thread strong enough to last after the procedure.

[0010] What is needed are percutaneous surgeries that can be performed without requiring little if any recovery time, and leaves no visible scars.

[0011] One such surgery is called Transgastric surgery, or natural orifice transluminal endosurgery, and involves passing flexible surgical tools and a camera in through the patient's mouth to reach the abdominal cavity via an incision made in the stomach lining. Once the operation is over, the surgeon draws any removed tissue out through the patient's mouth and stitches up the hole in the stomach. Surgeons have performed appendectomies through the mouth.

[0012] In many ways, transgastric surgery is a natural extension of keyhole surgery, in which slim surgical tools are inserted into the abdomen via small incisions in the skin, avoiding a large cut in the belly. It has now become routine for procedures such as gall bladder removal.

[0013] Transgastric surgery promises to go one better. Much of the discomfort and recovery time after conventional surgery, even keyhole surgery, is due to the incisions made in the abdominal wall. However, because transgastric surgeons reach the abdominal cavity through the mouth, there is no need for an incision, so patients should be back up on their feet much faster. Although an incision is still made in the stomach lining, this is relatively painless, because the stomach has fewer nerve fibers that register pain than our skin. The reduced pain also makes it possible for the procedure to be carried without. Consequently, elderly or infirm patients who would not be fit enough to receive a general anesthetic, could still be treated.

[0014] Going in via the esophagus to the stomach may also reduce the risk of post-operative infections with, say, the drug-resistant superbug MRSA, which often lives on the skin. If you don't have skin incisions then you don't get MRSA. And while there is a risk of infecting the abdominal cavity with bacteria from the gastrointestinal tract, animal studies suggest that risk is small because stomach acid is cleansing.

[0015] What is needed is surgery that can be made pain-free, convalescence-free and scar-free, whilst reducing the risk of complications and infections.

[0016] Stapling is used to close opened tissue in some procedures. However, staples instead of suture provide a large form body for the body to attack. Also stapling is not a flexible connector often altering the original, natural attachment and the scar tissue is generally more prevalent as a result of stapling. Also, with suture you have the options of using different types sizes and strength of suture. What is needed are more suture options. Thus what is needed are micro sized

suturing devices and procedures which can be used in endoscopic, laparoscopic and minimally invasive surgical procedures.

[0017] Common Catheterization Procedures

[0018] The most common types of interventional catheterization procedures are those performed to: create septal defects, open stenotic valves, open stenotic vessels, close abnormal vessels, or close certain septal defects. Devices and procedures to do these kinds operations are needed, more efficiently and effectively, with less recovery time, smaller chances of infection, and all around cleaner.

[0019] Atrial septal defect (ASD) is a hole in the wall, septum, between the heart's two uppermost chambers, the right and left atrium. This hole allows blood to flow in either direction between the left and right atrium. ASDs may cause several problems. First, this creates a condition in which the right side of the heart now contains extra blood, and extra blood also now flows to the lungs. This diversion of blood puts strain on the heart because it has to pump this extra blood to the lungs. In addition, the strain put on the right-sided pumping chamber can lead to a weakening or enlargement of the right side of the heart and eventually heart failure, if left untreated. This enlargement may also cause arrhythmias (irregular heart rhythms) to develop. This extra blood flow to the lungs may damage the arteries to the lungs over time, leading to high blood pressure in these vessels. Also, ASDs in some circumstances can allow blood clots from the body to enter the brain and cause a stroke. Open heart surgery is currently the only option and is done only after all other solutions have failed. What is needed is a small device or procedure to close the hole invasively, so that more drastic, possibly catastrophic an expensive solutions are not the only option.

SUMMARY

[0020] The present invention discloses a micro sewing device having a needle rigidly coupled to a shank or needle bar; the shank or support bar rotably coupled to an actuator arm; the actuator arm parallel and adjacent to a cylindrical looper cam; a cylindrical looper rigidly coupled to the cylindrical looper cam; the looper cam with flutes pitched in a helical configuration about the cam cylinder axis, with ball drivers in the flutes; the flute pitch tuned to the rotation necessary looper motion in concert with needle tip travel; the looper cam with a cylindrical sleeve like cam drivers on both cam ends, slidable coupled along the cam axis and concentric to the cam; each cam driver containing at least one ball driver trapped between the sleeve cam driver and the cam, riding each cam flute; the actuator bar rigidly coupled to the looper cam driver, and a housing enclosing the cam, cam drivers, and the actuator arm, whereby actuator arm movement will cause the needle tip locus to thread a stitch in concert with the looper, coupled to the moving cam driver turning the cam coupled to the looper, cam driver rotating the looper through pitched flutes in concert with the needle point locus for a designed stitch.

[0021] The micro sewing device can sport another cam axially adjacent to the looper cam and supported by another cam driver sleeve for more and enhanced synchronicity between the looper and needle, such that other stitches can be made.

BRIEF DESCRIPTION OF DRAWINGS

[0022] Specific embodiments of the invention will be described in detail with reference to the following figures.

[0023] FIG. 1 is a perspective view illustration of a micro sewing device according to an embodiment of the present invention.

[0024] FIG. 2 is a perspective view illustration of a curved needle for inside wall to inside suturing with a micro sewing device according to an embodiment of the present invention.

[0025] FIG. 3 is a perspective view illustration of a curved needle and looper in in synchronous motion sequence for a stitch according to an embodiment of the present invention.

[0026] FIG. 4 is an illustration of a micro sewing device needle and looper step wise stitching process according to an embodiment of the present invention.

[0027] FIG. 5 is an illustration of micro sewing device 401 stitch sequence according to an embodiment of the present invention.

[0028] FIG. 6 is a perspective view of a straight needle micro sewing device according to an embodiment of the present invention.

[0029] FIG. 7 is a perspective view of catheter piloted micro sewing device according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0030] Specific embodiments of the invention will now be described in detail with reference to the accompanying figures.

[0031] In the following detailed description of embodiments of the invention, specific details are set forth in order to provide a more thorough understanding of the invention. However, it will be apparent to one of ordinary skill in the art that the invention may be practiced without these specific details in lieu of substitutes. In other instances, features have not been described in detail to avoid unnecessarily duplication and complication.

[0032] Objects and Advantages

[0033] The present invention discloses a micro sewing device for very small dimension surgical applications. The sewing device, is size adapted for endovascular operations, and for endovascular and/or endoscopic micro-suturing applications. Insertion of medical devices into vessels to effect a repair and/or remove blockage is common practice. However, stints have come loose or dislodged during normal use, and remotely suturing medical components to vessel walls carries the inherent advantage of not having to surgically open a body, yet still be able to repair and reuse.

[0034] In another objective of the invention, with sufficiently small and remotely manipulable devices, internal organs with damaged or otherwise weakened tissue can be accessed and repaired through vessels. It is an object of the present invention to provide a sewing device of dimensions small enough to insert through a vessel, to position adjacent to tissue requiring repair, and subsequently repairs the tissue through suturing and reinforcing, adding strength to tissue so that deterioration is arrested and healing promoted.

[0035] Another object of the invention is to have the capability to sew off, that is the ability to sew the stitch without material. This also lends itself to pre sewing, or having the device sew several stitches before it contacts the material to be sewn.

[0036] Another object of the invention is the use of straight or curved needle as to accommodate the sewing device requirements. All references to a curved needle will be a hypo curved needle, that is a hollow needle through which the

thread or suture extends from a base orifice to the tip, to which the thread control passes.

[0037] It is an object of the invention to provide a percutaneous sewing device using a (401) 2 thread chain lock. This involves a continuous 2 thread chain of stitches that can be used to close, connect, or pull. It is commonly used for sewing products that require strength and stretch. One pull of the trigger produces one stitch in a continuous chain of stitches. Also this stitch can sew the 2 thread chain on or off the material being sewn. This enables the before and after ends to have a mechanical tie off.

[0038] It is another object of the invention to provide a device to be used for laparoscopic surgeries. In this application, the mechanical drive components are external to the body and surgical site. The head of the machine will be designed to deliver the stitch from 45 to 180 degrees to the tissue. The sewing head can be mounted to a catheter by moving the motion producing parts to the distal end of the device for endovascular surgery. Other shapes and configurations of this technology can be utilized for specific procedures. It is another object of the invention applications related to laparoscopic surgeries. The stitch is a 401 chain lock that is secured with 2 threads/sutures. One pull of the trigger gives one stitch in a continuous chain of stitches. The suture and the mechanical drive components will be external to the body. This stitch is used where considerable elasticity and give are required. Also this stitch can sew the 2 thread chain on or off the material being sewn. This enables the before and after ends to have a mechanical tie off.

Embodiments of the Invention

[0039] FIG. 1 is a perspective view illustration of a micro sewing device according to an embodiment of the present invention.

[0040] An embodiment of the invention is a small two thread or suture sewing device that sews a 401 chain lock stitch. This stitch has give but is strong and is used for sewing article such as leather gloves and tennis nets. An embodiment of the invention also has the ability to sew the stitch without material, commonly referred to as sewing off. It also lends itself to pre-sewing, or having the device sew several stitches before it contacts the material to be sewn. This is a very necessary characteristic to have inside the body, as stable stitch ends must be made to prevent unraveling and dislodging of repairs. In the Health care profession as medical devices become smaller and more complex as seen with endovascular stent grafts and tissue based products, the attachment of the devices, anchoring, to prevent migration of the device becomes more difficult. Many of the suturing technique are preformed with the aide of suturing devices that either require multiple instruments or have a very limited stitching ability. An embodiment of the invention is intended to sew the 401 stitch type inside or outside of a body, solving the anchoring problem.

[0041] In another embodiment of the invention, the device is designed to be mounted to an endoscope or catheter type device. The head will be able to rotate 360° and sew one stitch per pull of a triggering device. Take for instance the procedure of gastric bypass surgery. This type of surgery requires a large number of stitches and a good degree of flexibility in the stitch.

[0042] There are several instances where stitching inside the body provides large advantages. The reader will appreciate that closing the aortic appendage or Patent Foramen

Ovale, surgery to close part of the Heart with out open heart surgery is very difficult. Another application for the invention is to repair an Anastomosis of parallel arteries and veins in cases of compromised blood supply.

[0043] Another embodiment of the invention can be built such that the device cams or motors are external to the body. Using the technology for miniaturization of small parts, an embodiment of the invention can be used for heart surgeries and be mounted on catheters or endoscopes devices. With sufficiently strong needle technology, the needle can be made very small and yet offer protection the suture as well. An embodiment of the invention is designed to work with either a straight needle or a curved needle.

[0044] FIG. 1 is a perspective and a side view illustration of a micro sewing device according to an embodiment of the present invention.

[0045] FIG. 1 shows the components of the device which includes a looper 101, curved needle 102, Needle bar 103, housing 104, looper cam driver 105 sleeve, looper cam 106, needle cam driver 107 containing ball drivers which ride the cam flutes, needle cam 108 with flutes at design pitches determining the relative motion between the needle 102 and looper 1001, auxiliary cam driver 110 sleeve, and an actuator 111 linkage bar.

[0046] An aspect of the invention sewing device has a cylindrical design and thus a long axial dimension relative to its diameter which serves several functions, the internal percutaneous nature of its purpose of entry through orifices and vessels which are tubular in geometry.

[0047] In an embodiment of the invention, the looper 101 is slidably coupled to the looper cam 106, such that any axial helical forces are transferred from the looper cam 105 to the looper 101 via the looper cam driver 105. The actuator 111 is a linkage bar running parallel to the device cylindrical axis inside the housing 104. Forces pushing and pulling on the actuator 111, move the needle bar 103 which controls the needle 102 point locus of travel, and also axially move the looper cam driver 105. The looper cam driver translates axial motion to the looper cam driver axial helical forces, twist turning the looper cam 106 which rotate the looper 101 around the cylindrical axis in concert with the needle 102. The looper cam driver 105 sleeve traps ball bearings in the driver sleeve which travel in the looper cam 106 flutes. The flutes 109 are of dimensions compatible with the ball drivers 102, which ride in the cam drivers to rotate the helical flute cams. The flute pitch determines the amount of axial motion imparted to the needle bar 103 in relation to the rotation imparted to the looper 101 via the looper cam 106.

[0048] In another embodiment, a two cam arrangement is used. Any motion on the actuator 111 linkage conformably moves the needle cam driver 107 in accordance with the needle cam 108 flute pitch, whose movement axially determines the needle 102 point locus via the needle bar 103 coupling to an axial one bar linkage 114 to the needle cam driver 107. Synchronously, the needle cam 108 rotates and translates the needle 102, in concert with the looper cam 106 which rotates the looper 101. The needle cam 108 conforms concentrically to a sleeve 110 which is cap 113 anchored to the housing 104.

[0049] FIG. 2 is a perspective view illustration of a curved needle for inside wall to inside suturing with a micro sewing device according to an embodiment of the invention.

[0050] What is shown sequentially is that the embodiment sewing device needle point 201 205 209 locus extends from

inside a vessel wall, wall not shown, penetrating that wall and entering back into the vessel. The needle point **201 205 209** must have sufficient travel to make the necessary stitch. Thus the synchronicity of the needle **201 205 209** and the looper **203 207 211** respectfully, are accomplished by the design parameters of the helical cam **216** flute pitch which turns the looper, and the cam **216** traveler **219** one bar linkage **213** from the traveler **219** to the needle **201** bar, which rotates the needle **201 205 209** through an arc. The needle head extends the curved needle **201 205 209** on an arcuent path out through a tissue wall, not shown, and back into the tissue originating side, to stitch with the looper inside the tissue wall.

[0051] FIG. 3 is a perspective view illustration of a curved needle and looper in in synchronous motion sequence for a stitch according to an embodiment of the present invention.

[0052] A dwell in the looper cam holds the looper **302** at 9:30 as the needle **301** begins to descend. As the needle **303** continues to descend the looper **304** holds at 9:30. As the needle **305** enters the material the looper **306** moves counter clockwise to 5:00.

[0053] As the needle begins to group the needle **307** thread gets caught on the looper **308**. After the chain is started as the needle starts descending the looper holds the looper suture at 9:30 to form a triangle for the suture to enter as it goes through the material and into the needle plate. As the needle starts going up the needle suture forms a loop and the looper catches the needle thread, not shown. As the needle goes up the looper advances to 9:30. Holding the needle thread, not shown, on the looper. As the looper goes back to 5:30 the needle suture, not shown, is cast off the looper forming a 2 suture chain stitch.

[0054] FIG. 4 is an illustration of a micro sewing device needle and looper step wise stitching process according to an embodiment of the present invention.

[0055] Looking down on the device with the needle at 12:00 and priming the sewing device (starting the chain), with the looper and needle threaded **401**. The Needle descends **403** to bottom of its stroke bottom dead center BDC **405**. As the needle starts the up stroke **407** a loop is formed **409** in the needle suture. The looper enters the needle suture loop **411**. The needle continues to go up to Top dead center TDC as the looper moves to 9:30 position. The needle goes down as the looper remains at the 9:30 position entering in fount of the looper thread that is held behind the needle entering position. As The needle enters the looper rotates from the 9:30 position to the 5:30 position. As the looper moves from the 6:00 to the 5:30 position. The needle thread pulls off the looper, cast off. At this point the stitch has been formed. It is recommended this be repeated several times to start the chain.

[0056] FIG. 5 is an illustration of micro sewing device **401** stitch sequence according to an embodiment of the present invention.

[0057] Stitch Formation by Steps

[0058] 1. The needle is on the up stroke and forms a loop in the needle thread. The looper advances through the needle loop; 2. The needle is on the up stroke and looper advances through the needle thread.; 3. The needle is at TDP (top dead center) and is ready to be advanced to the next stitch location; 4. The needle is on the down stroke. The needle enters the thread triangle formed by the looper thread being held in the correct spot; 5. The needle is on the down stroke. The needle thread is cast off the looper; 6. The needle in on the up stroke. The needle thread forms a loop and the looper goes through it;

7. The needle in on the up stroke. When the needle gets to top dead center the machine can be moved to the next stitch location.

[0059] FIG. 6 is a perspective view of a straight needle micro sewing device according to an embodiment of the present invention. In some applications, a straight needle is adaptable, where a curved needle will not do. The straight needle rectangular support structure **601** rigidly couples the needle shank **603** on one corner and the support bar actuator **609** on the other looper **607** facing side corner. The straight needle **605** is rigidly coupled to the needle shank **603**. The needle **605** motion is toward the looper **607**, whose motion is radially around the needle **605** approach axis and perpendicular. The looper is rigidly coupled to the cam **619** head **613** via a stem **611** which rotates the looper **607** by virtue of the cam driver **615** axial motion. The cam driver rotates the cam **619** via a ball driver fitted inside the cam driver sleeve. The cam driver is rigidly coupled to the needle support structure **601** via a bar linkage **609**. The turning cam **619** translates the cam driver **615** axially and thus the needle **605** via the bar linkage **617**. This is done in concert with the cam top **613** which rotates the looper **607** through rotation of the looper stem **611** rotating with the cam top **613**. Thus as the cam turn, the cam driver moves the needle in and out of the looper inside plane perpendicular to the device central cylindrical axis.

[0060] FIG. 7 is a perspective view of catheter piloted micro sewing device according to an embodiment of the present invention. The sewing head **707**, and motion controller **703** are coupled by flexible catheter **705**. The motion controller **703** and the sewing head **707** function substantial as the embodiments described, with the cam driver motion originating from the actuator bar **701**. The manipulator or device position controller **703** can be externalized. By remotely operating the actual stitching function, an embodiment of the invention can provide even further device size reduction, providing a smaller internal foot print device. Thus by placing the motion producing parts **705** at the distal end of the catheter **705** and the looper and needle end **707** at the proximal end of the catheter, this embodiment undergoes another effective size reduction. The catheter **705** as shown by a dotted line, contains two flexible but torsion transferring wirelike components, coupled together but independent force and torsion carrying wirelike components. This additional internal footprint reduction allows this embodiment of the invention to be used for telescopic and minimally invasive surgeries as well as Vascular and endovascular procedures.

[0061] Therefore, while the invention has been described with respect to a limited number of embodiments, those skilled in the art, having benefit of this invention, will appreciate that other embodiments can be devised which do not depart from the scope of the invention as disclosed herein. Other aspects of the invention will be apparent from the following description and the appended claims.

What is claimed is:

1. A micro sewing device comprising:
 - a curved hypo or straight needle rigidly coupled to a shank or needle bar;
 - the shank or needle bar rotably coupled to an actuator arm; the actuator arm parallel and adjacent to a cylindrical looper cam;
 - a cylindrically curved looper rigidly coupled to the cylindrical looper cam;

the looper cam with flutes pitched in a helical configuration about the cam cylinder axis, with ball drivers riding in the flutes;

the flute pitch tuned to the rotation defining looper motion in concert with needle tip travel;

the looper cam with a cylindrical sleeve like cam drivers on both cam ends, slidably coupled along the cam axis and concentric to the cam, housing the ball drivers;

each cam driver containing at least one ball driver trapped between the cam driver sleeve and the cam, riding each cam flute;

the actuator bar rigidly coupled to the looper cam driver, and

a housing enclosing the cam, cam drivers, and the actuator arm,

whereby actuator arm movement determines the needle tip locus to thread a stitch in concert with the looper, coupled to the moving cam driver turning the cam coupled to the looper, cam driver rotating the looper through pitched flutes in concert with the needle point locus for a designed stitch.

2. The micro sewing device as in claim **1** further comprising another cam axially adjacent to the looper cam and supported by another cam driver sleeve.

3. The micro sewing device as in claim **2** further comprising another actuator bar rigidly coupled to the cam driver on the looper cam end opposite the looper end.

4. The micro sewing device as in claim **1** further comprising an annular traveler riding the looper cam flutes between two cam drivers, with traveler axially coupled to an actuating needle bar for movement in concert with the looper cam flute pitch determined looper rotation.

5. The micro sewing device as in claim **1** further comprising tuning the cam flute pitches for loop rotations and needle movement to various stitches.

6. The micro sewing device as in claim **1** further comprising a curved hypodermic needle as described in U.S. patent application Ser. No. 11/975,868.

7. The micro sewing device as in claim **1** further comprising a straight hypodermic needle.

8. The micro sewing device as in claim **1** further comprising a flexible catheter enclosure with force and torsion transmitting cables transmitting forces and torsion from the cam-cam drivers-actuator-housing component motion control integration to the suturing head integration containing the needle-needle bar-looper components, whereby the suturing head can be manipulated remotely and through the catheter from the integrated component end comprising the motion control function.

9. The micro sewing device as in claim **1** further comprising a sew off a stitch without material, whereby a stitch maybe started or ended without loose end threads.

* * * * *