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(54) METHOD AND APPARATUS FOR TREPHINATING BODY VESSELS AND HOLLOW ORGAN WALLS

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Publication Classification

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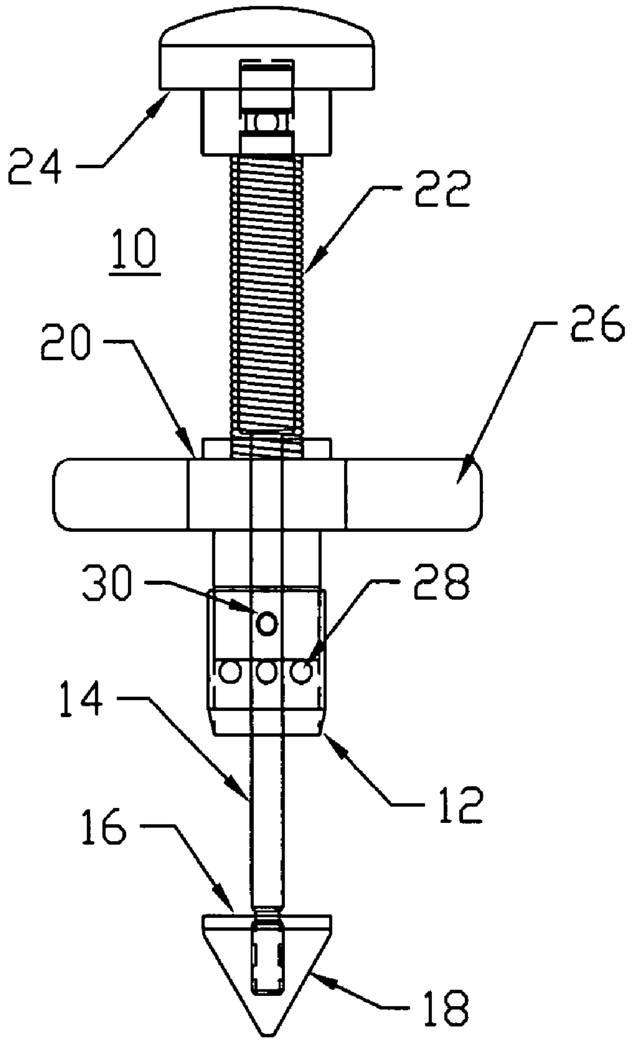
(52) **U.S. Cl.** **606/184**

(57) **ABSTRACT**

A system is disclosed for creating a hole in a body vessel or hollow organ. Such holes are useful in surgically preparing the hollow organ or body vessel for connection with another hollow organ, body vessel or prosthetic conduit. For example, an assist device is generally connected to the left ventricle through a ventriculotomy created at the apex of the left ventricle. This ventriculotomy is most easily created with a punch or trephine. Control over such a procedure must be precise so as not to damage the ventricular wall or intracardiac structures such as papillary muscles, chordae tendinae, etc. The punch of the current invention allows for precise location and alignment of the cutting segment. The punch of the current invention also allows for precise advance of the cutting blade and a very clean cut of the tissue. Such clean cuts improve the healing when the hole in the body vessel or hollow organ is closed or attached to a connection, either prosthetic or natural.



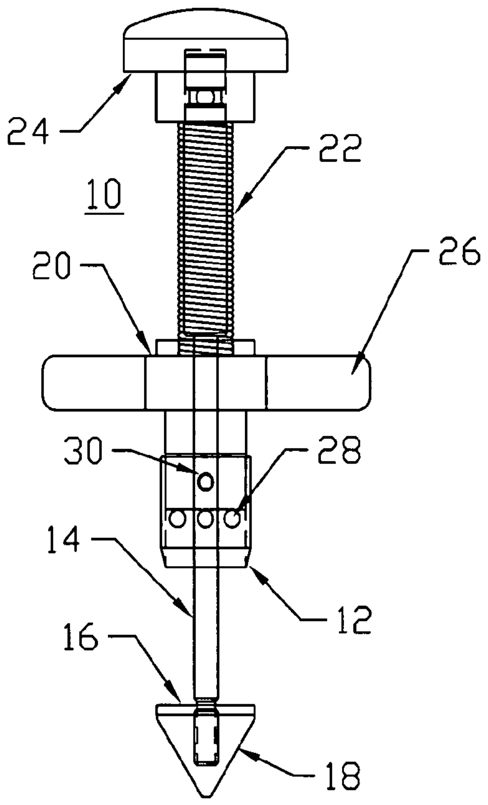


FIG. 1A

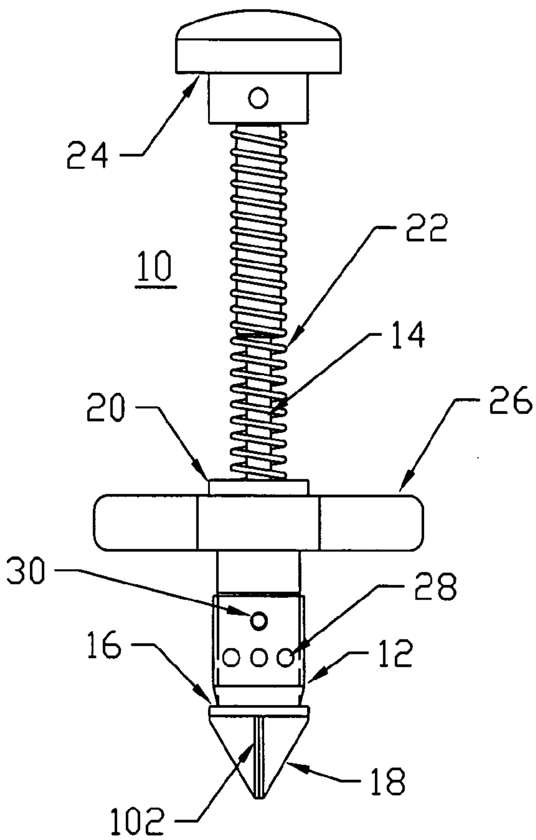


FIG. 1B

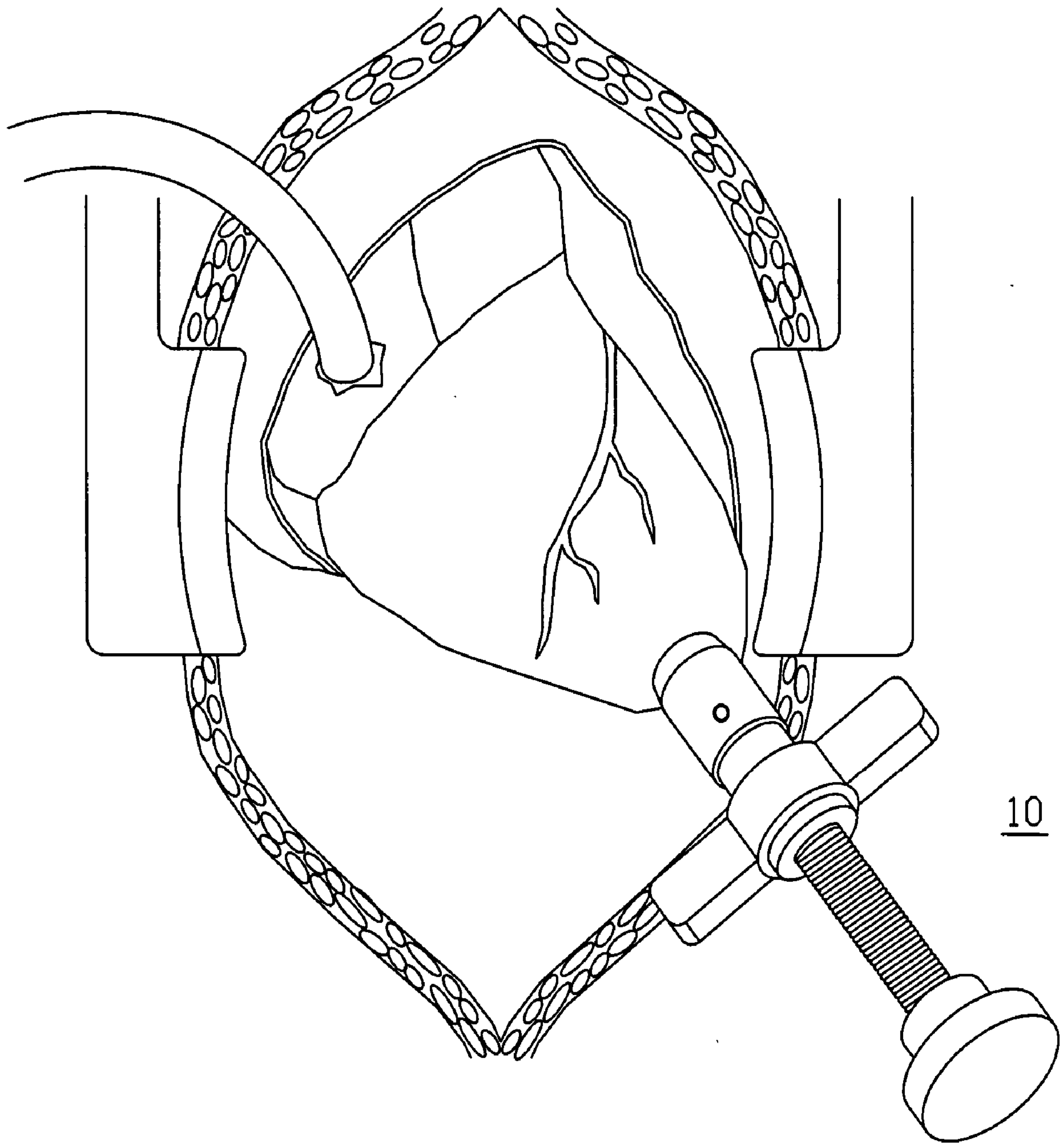


FIG. 2

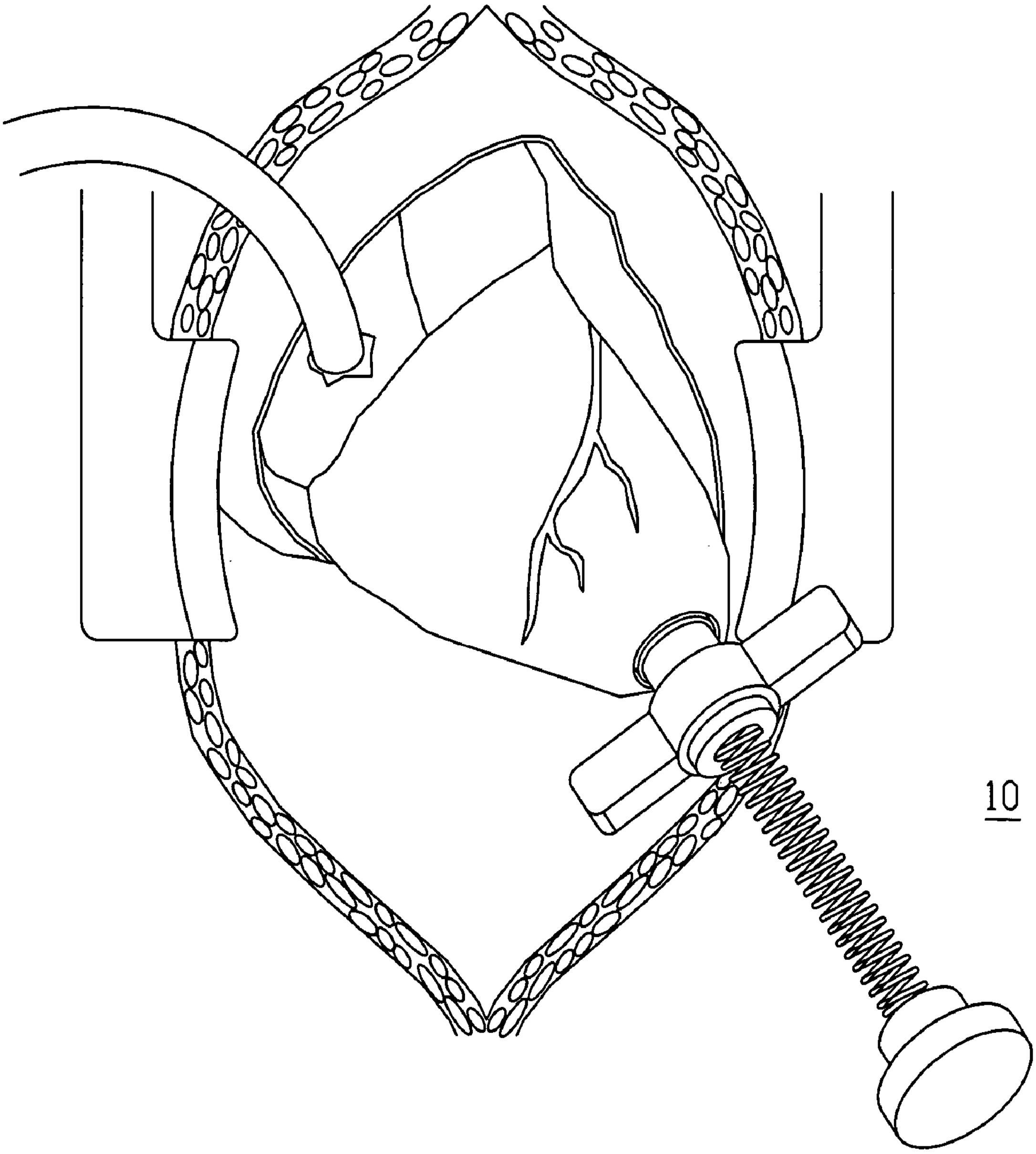


FIG. 3

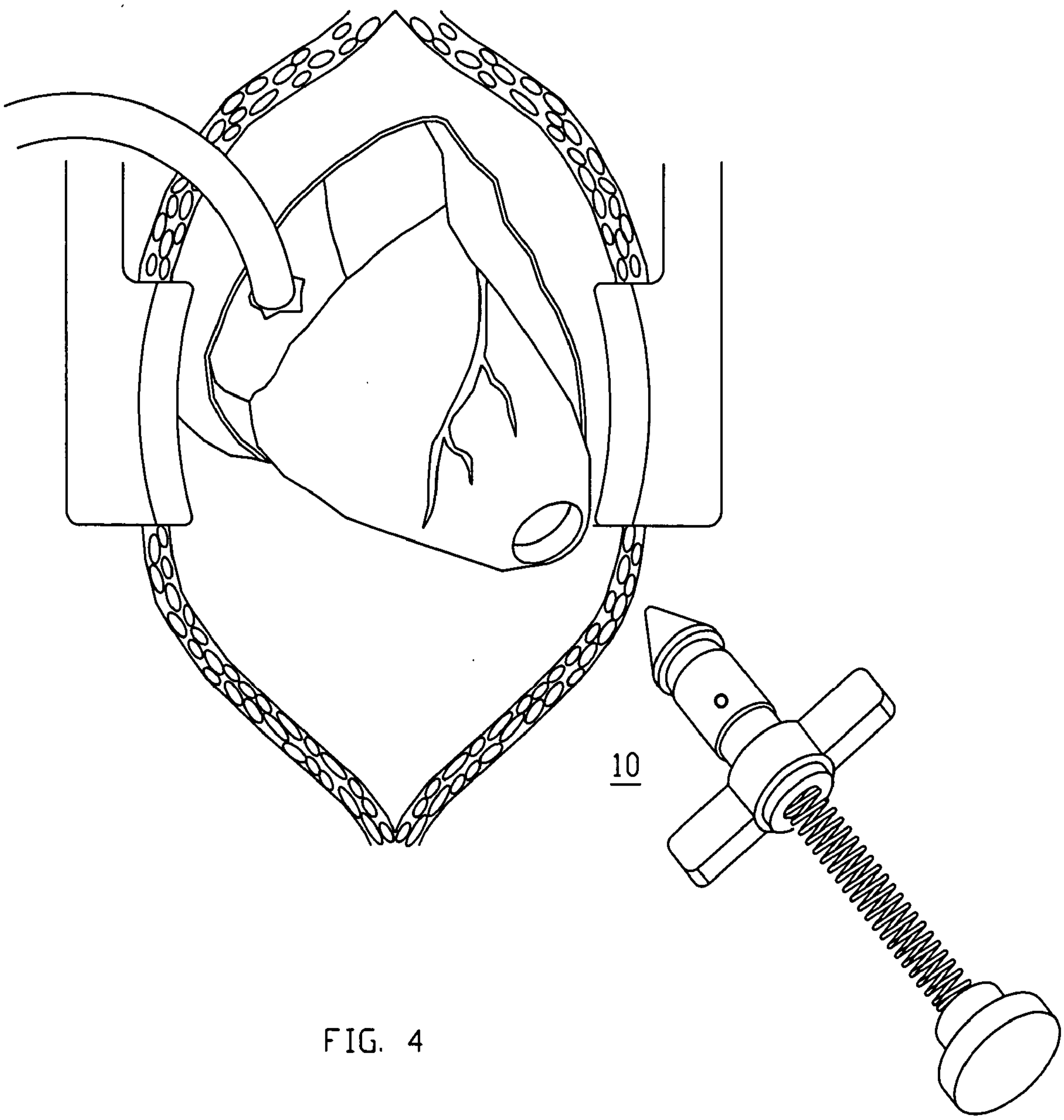


FIG. 4

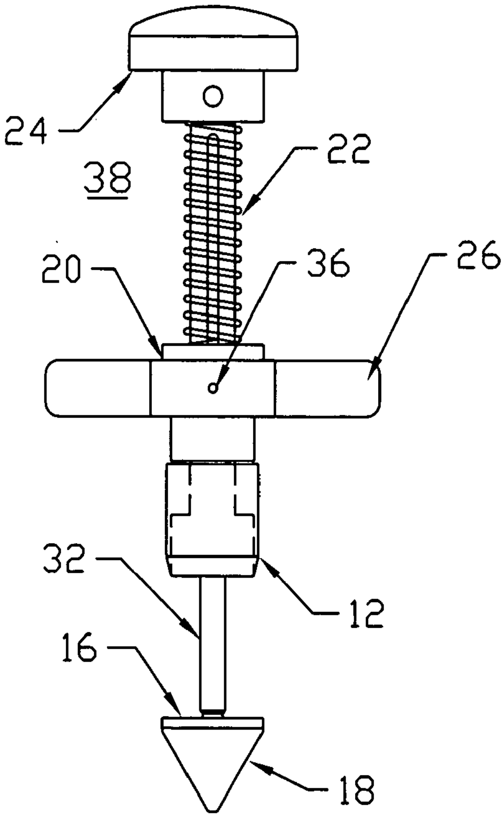


FIG. 5A

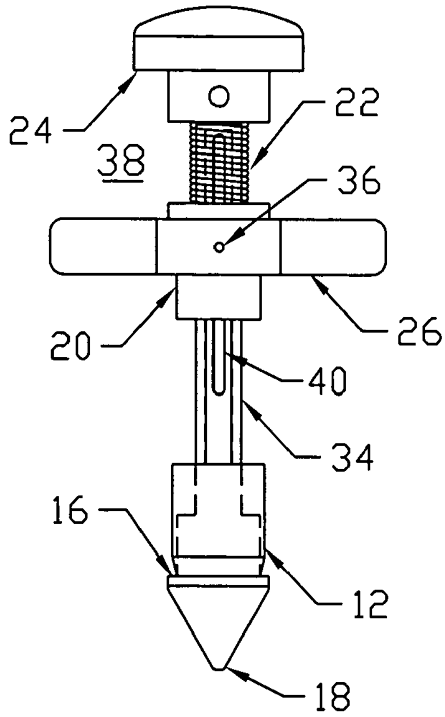


FIG. 5B

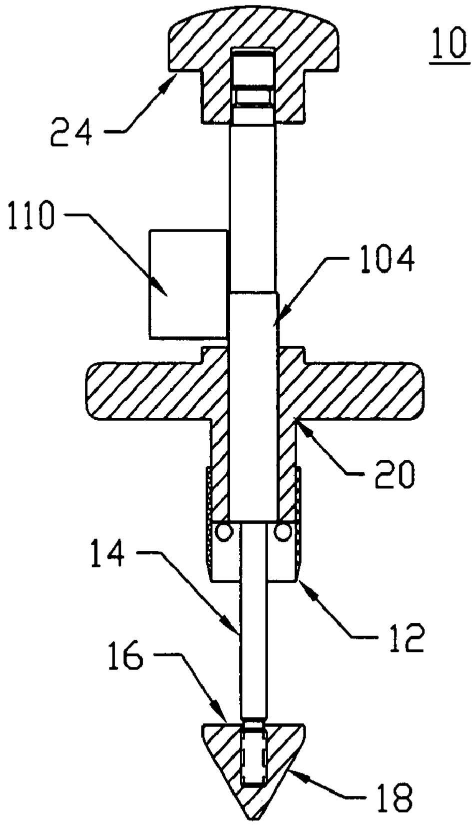


FIG. 6A

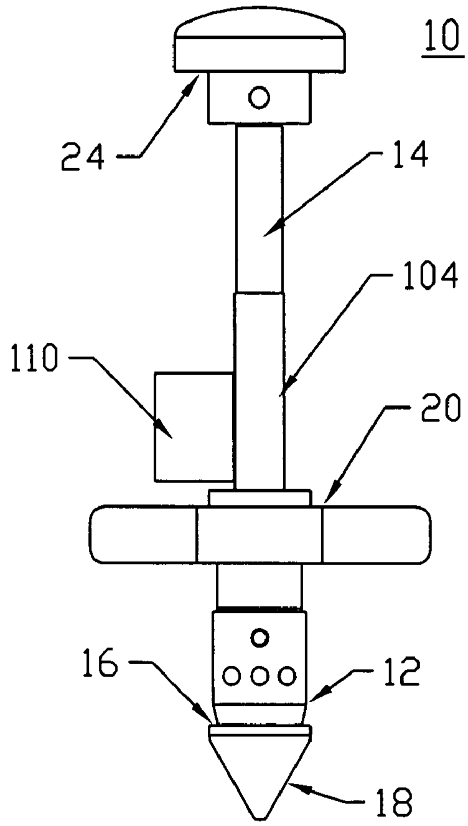


FIG. 6B

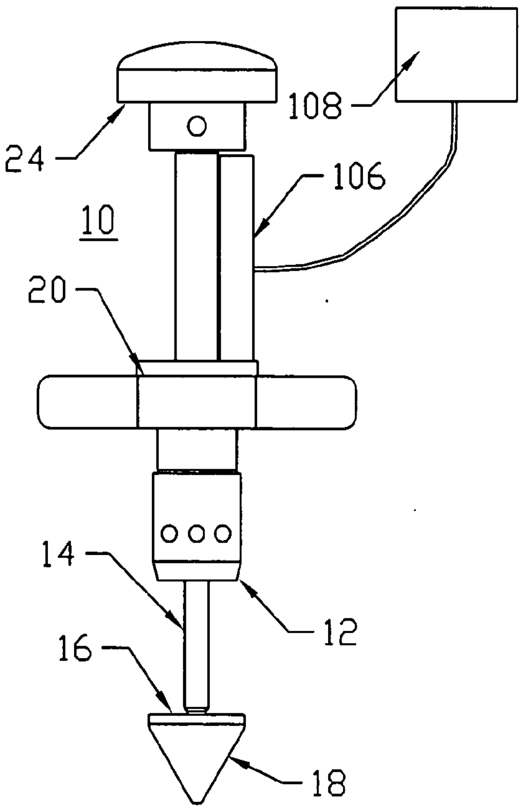


FIG. 7A

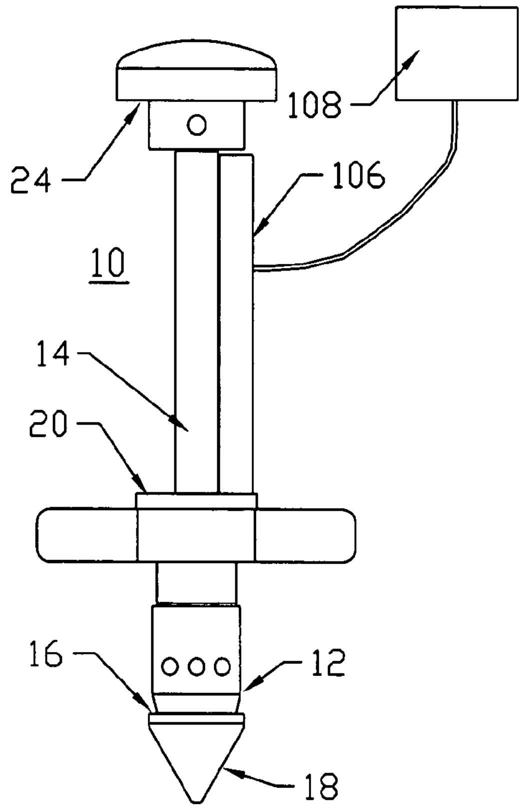


FIG. 7B

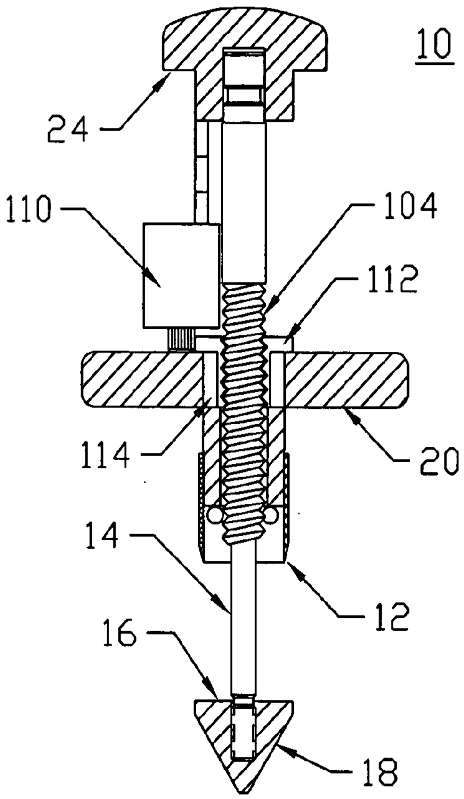


FIG. 8A

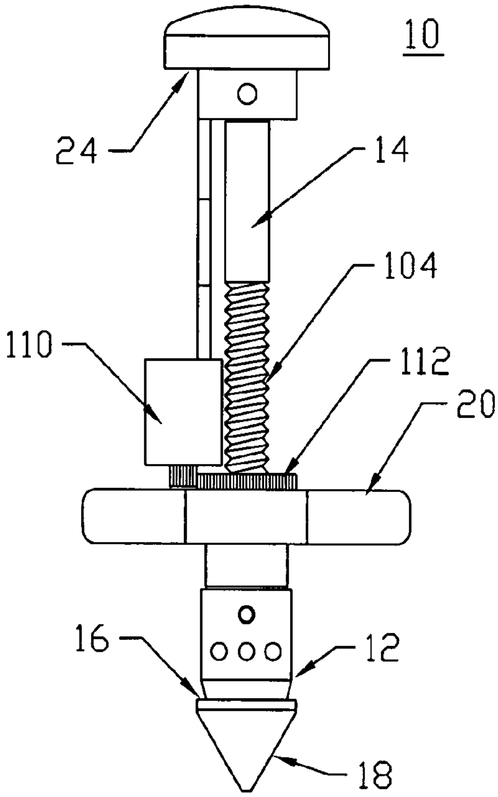


FIG. 8B

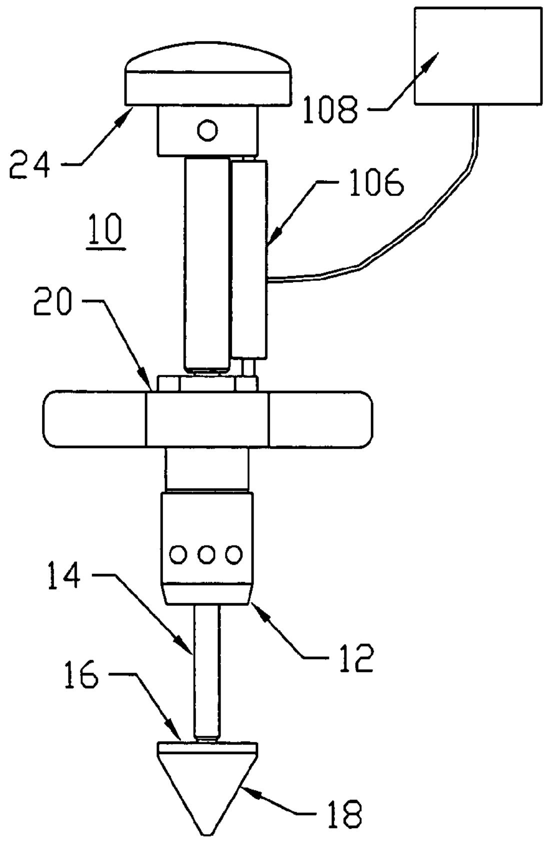


Figure 9A

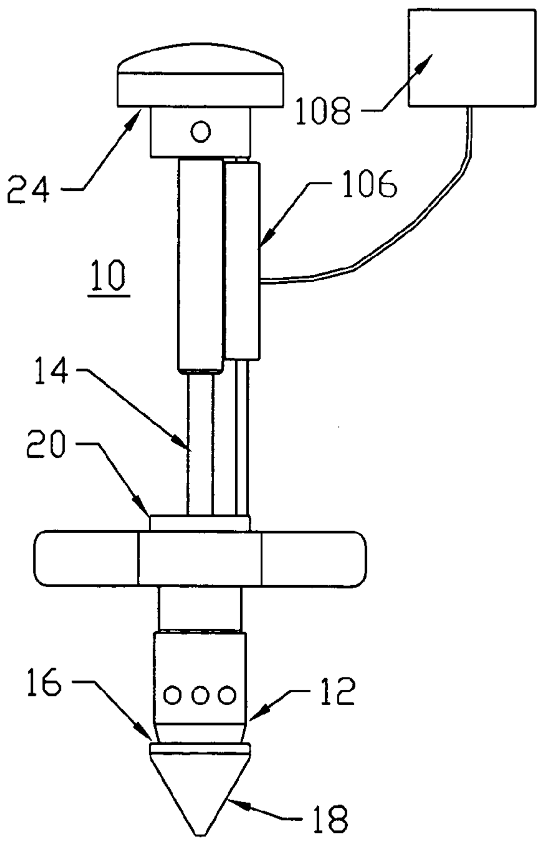


Figure 9B

METHOD AND APPARATUS FOR TREPHINATING BODY VESSELS AND HOLLOW ORGAN WALLS

PRIORITY INFORMATION

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 09/938,428, filed Aug. 23, 2001, now U.S. Pat. No. 6,863,677.

FIELD OF THE INVENTION

[0002] The field of this invention is related to instrumentation and devices for surgery and especially, interventional, cardiovascular, general or peripheral vascular surgery.

BACKGROUND OF THE INVENTION

[0003] During surgical procedures such as placement of a ventricular assist device, blood vessel anastomosis, aortotomy, gastrotomy, enterotomy, or access to other hollow organs and vessels, it is useful to have a specialized tool to create a circular opening or fenestration in the wall of the vessel or organ. Punches have been developed for use in surgery that create such fenestrations. Examples of the prior art include U.S. Pat. No. 3,776,237 to Hill, U.S. Pat. No. 3,949,747 to Hevesy, U.S. Pat. No. 4,018,228 to Goosen, U.S. Pat. No. 4,122,855 to Tezel, U.S. Pat. No. 4,216,776 to Downie et al., U.S. Pat. No. 5,129,913 to Ruppert, U.S. Pat. No. 5,403,338 to Milo, U.S. Pat. No. 5,868,711 to Kramer et al., U.S. Pat. No. 5,827,316 to Young et al., U.S. Pat. No. 5,910,153 to Mayenberger, and U.S. Pat. No. 5,972,014 to Nevins. More recent patents include U.S. Pat. No. 6,033,419 to Hamblin, Jr. et al., U.S. Pat. No. 6,080,173 to Williamson IV et al., U.S. Pat. No. 6,080,176 to Young, U.S. Pat. No. 6,176,867 to Wright, and U.S. Pat. No. 6,187,022 to Alexander Jr. et al.

[0004] Problems with the current punches or coring devices occur both when the punch is positioned and actuated. With current systems, the cutting occurs by application of manual force by the surgeon. By requiring manual force to punch the hole in the organ or vessel wall without an adequate point of reference, the surgeon is not able to ascertain that the hole will be created along the correct path and at the selected location, prior to actually punching the hole. In addition, the current punches operate by means of a die without opposing back-up-plate cutting members. Examples of current punch mechanisms are similar to scissors where the cutting blade passes by an opposing brace or other cutting blade. These systems all create sub-optimal openings and leave ragged tissue edges.

[0005] New devices and methods are needed which facilitate creation of a hole in the hollow organ or vessel and allow confirmation of proper location, orientation, and coring path prior to actual creation of the hole in the hollow organ or vessel wall. In addition, devices are needed to make more precise, cleaner holes in the tissue. Such cleaner holes allow for more precise surgery, more controlled placement of anastomoses, more control over surgically created geometry, reduced blood loss and resultant improved patient outcome.

SUMMARY OF THE INVENTION

[0006] This invention relates to a trephine, coring tool, or punch for creating a hole or stoma at a precise, desired location in a hollow organ or body vessel. The present invention is a cutting surface or edge that is opposed by an anvil to create a clean cut. The anvil comprises a tapered nose to facilitate penetration into the organ or vessel once a preliminary incision has been performed. The cutting surface or edge is spring loaded to perform the actual cutting under pre-assigned force. The system allows for location reference by allowing the punch to rest, under spring, or otherwise generated, force, against the tissue to be cut while final alignment is completed, thus allowing a more accurate cut. The system further provides for rotation of the cutting surface or edge as it approaches the anvil. Preferably, the cutting edge rotation is substantial, and greater than ¼ revolution (90 degrees) as it approaches, or is approached by, the anvil. The anvil in this type of system may be described as a Hammer Anvil since the face of the anvil that faces the cutting surface serves as a stop for the cutting surface as the distance between the anvil and the cutting surface or edge is reduced to zero.

[0007] In the prior art previously cited, including U.S. Pat. No. 4,018,228 to Goosen, U.S. Pat. No. 4,216,776 to Downie et al., U.S. Pat. No. 5,129,913 to Ruppert, U.S. Pat. No. 5,827,316 to Young et al., U.S. Pat. No. 5,910,153 to Mayenberger, U.S. Pat. No. 5,972,014 to Nevins, U.S. Pat. No. 6,080,173 to Williamson IV et al., and U.S. Pat. No. 6,080,176 to Young use a shearing or scissoring action between two blades to cut tissue. U.S. Pat. No. 3,949,855 to Hevesy, U.S. Pat. No. 4,122,855 to Tezel, and U.S. Pat. No. 6,187,022 to Alexander et al. use a knife or single sharpened edge with no opposing blade or surface to cut tissue. Both of these methods produce a ragged cut. The invention distinguishes over the cited prior art because the tissue is cut between a sharp edge and an opposing, flat, anvil-like surface to produce a clean cut. The embodiments of the punch disclosed herein provide further advantages over the prior art in that they create a hole that is closer to the diameter of the cutting edge than the holes made by the prior art punches.

[0008] The invention is most useful in cardiac surgery to create an opening or channel for cannula access to the ventricles of the heart or blood vessels near the heart. It is also useful for vascular surgery where side-to-side or end-to-side anastomoses need to be made. Alternatively, the system allows for general tissue biopsies and other general surgical applications on hollow organs or vessels such as a tracheostomy. Another aspect of the invention includes a method for creating a hole in a body vessel via an endovascular or interventional approach. Access to the vessel is created using a percutaneous approach such as the Seldinger technique. The method consists of creating an incision in the body vessel with a sharp object, inserting a sheath having a fluid-tight seal into the body vessel, and advancing a punch, further comprising a cutting blade and an anvil located at the distal end of a catheter, through the lumen of the sheath and extending out the distal end of the sheath into the body vessel until the distal end of the punch has reached a target location within the body vessel. The method further comprises advancing a sharp tip, affixed to the distal end of the punch, through the body vessel at the target site to create a puncture in the vessel wall. Next, an anvil with a tapered tip is advanced through the puncture in the body vessel at the target site and a circular cutting blade is located so that the cutting blade is positioned with the wall of the body vessel between the anvil and cutting blade. Next, the cutting blade is advanced through said body vessel wall under controlled force until the cutting blade fully rests against a distal surface of the anvil whose outside diameter is no less than the outer diameter of said cutting blade so that a hole is cut in the body vessel from the inside. The method further includes removing the cutting blade and excised tissue from the body vessel. It is advantageous that the cutting blade is rotated at least one revolution while said cutting blade is being advanced toward said anvil. It is further advantageous that a hemostatic plug or closure be provided to seal the vessel, generally on a temporary basis, immediately following creation of the punch hole and prior to further procedures on the vessel that require the presence of the punch hole.

[0009] For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein. These and other objects and advantages of the present invention will be more apparent from the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] A general architecture that implements the various features of the invention will now be described with reference to the drawings. The drawings and the associated descriptions are provided to illustrate embodiments of the invention and not to limit the scope of the invention. Throughout the drawings, reference numbers are re-used to indicate correspondence between referenced elements.

[0011] **FIG. 1A** illustrates a side view of the trephine, punch or coring tool with the cutter fully retracted, according to an embodiment of the invention;

[0012] **FIG. 1B** illustrates a side view of the trephine, punch or coring tool with the cutter fully advanced against the anvil, according to an embodiment of the invention;

[0013] **FIG. 2** illustrates the trephine, punch or coring tool applied to the apex of the ventricle of the heart prior to advancing the cutting blade, according to an embodiment of the invention;

[0014] **FIG. 3** illustrates the trephine, punch or coring tool after the blade has been advanced through the apex of the ventricular wall of the heart, according to an embodiment of the invention;

[0015] **FIG. 4** illustrates the ventricular wall after removal of the trephine, punch or coring tool and the excised tissue, according to an embodiment of the invention;

[0016] **FIG. 5A** illustrates a side view of the trephine, punch or coring tool with the anvil fully advanced, according to an embodiment of the invention;

[0017] **FIG. 5B** illustrates a side view of the trephine, punch or coring tool with the anvil fully retracted against the cutter, according to an embodiment of the invention;

[0018] **FIG. 6A** illustrates a longitudinal cross-sectional view of the trephine, punch or coring tool comprising a jackscrew to replace the function of the spring, according to an embodiment of the invention;

[0019] **FIG. 6B** illustrates a side view of the trephine, punch or coring tool comprising the jackscrew, wherein the cutter has been advanced against the anvil, according to an embodiment of the invention;

[0020] **FIG. 7A** illustrates a side view of the trephine, punch or coring tool comprising a hydraulic cylinder to replace the function of the spring, according to an embodiment of the invention;

[0021] **FIG. 7B** illustrates a side view of the trephine, punch or coring tool comprising the hydraulic cylinder, wherein the cutter has been advanced against the anvil, according to an embodiment of the invention;

[0022] **FIG. 8A** illustrates a longitudinal cross-sectional view of the trephine, punch or coring tool comprising a jackscrew to replace the function of the spring, wherein the jackscrew is shown in detail, according to an embodiment of the invention;

[0023] **FIG. 8B** illustrates a side detailed view of the trephine, punch or coring tool comprising the jackscrew, wherein the cutter has been advanced against the anvil, according to an embodiment of the invention;

[0024] **FIG. 9A** illustrates a side detailed view of the trephine, punch or coring tool comprising a hydraulic cylinder to replace the function of the spring, according to an embodiment of the invention; and

[0025] **FIG. 9B** illustrates a side detailed view of the trephine, punch or coring tool comprising the hydraulic cylinder, wherein the cutter has been advanced against the anvil, according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

[0027] The invention, which is generally termed a surgical instrument, can be described as being an axially elongate structure having a proximal end and a distal end. The axially elongate structure further has a longitudinal axis. As is commonly used in the art of medical devices, the proximal end of the device is that end that is closest to the user, typically a surgeon. The distal end of the device is that end closest to the patient or that is first inserted into the patient. A direction being described as being proximal to a certain landmark will be closer to the surgeon, along the longitudinal axis, and further from the patient than the specified landmark.

[0028] **FIG. 1A** illustrates a hollow organ coring tool, trephine, or punch **10** of the present invention. The coring tool **10** comprises a cutter **12**, a central axially elongated shaft **14**, an anvil **16**, a trocar or tapered tip **18**, a handle **20**, a spring **22**, and a knob **24**. The cutter **12** comprises a plurality of holes **28**. The handle **20** further comprises a plurality of wide flange-like members or wings **26**. The handle **20** optionally comprises a setscrew **30**. The cutter **12**, the anvil **16**, the trocar or tapered tip **18**, the handle **20**, the spring **22**, and the knob **24** are disposed concentrically on the axially elongate shaft **14**. The knob **24** is affixed to the proximal end of the shaft **14**. The handle **20** is affixed to the cutter **12** with the optional setscrew **30**. The handle **20** and attached cutter **12** slide rotationally and longitudinally in a one to one motion along and around the shaft **14**. The spring **22** is slidably disposed between the knob **24** and the handle **20** and imparts a pre-determined force on the handle **20**-cutter **12** assembly. The anvil **16** is affixed to the proximal end of the trocar or tip **18** and the tip **18** is affixed to the distal end of the shaft **14**.

[**0029**] **FIG. 1A** shows the coring tool **10** with the cutter **12** in the fully retracted position. The cutter **12** is a cylindrical blade made from materials capable of being sharpened and with a high degree of hardness. Such materials include but are not limited to stainless steel, cobalt-nickel-chrome alloys, titanium alloys and the like. The cutter **12** has a sharpened configuration on its distal most edge to permit surgical cutting of body tissue. The distal cutting edge of the cutter **12** is, preferably, smooth but sharpened. Alternatively, the distal cutting edge may be serrated like a bread knife. The hollow interior of the cutter **12** is sufficiently long to allow the cored-out tissue to reside therein without being compressed. Holes **28** are optionally provided in the proximal end or sides of the cutter **12** to allow for fluid escape during cutting, thus preventing pressure buildup within the cutter **12**. The cutter **12** may be any diameter necessary for the surgical procedure. The diameter of the cutter **12** ranges from 0.5 mm to 100 mm or even larger with the diameter range preferably being from 1 mm to 50 mm.

[**0030**] In another embodiment, the cutter **12** may be an electrocautery or electrocutting device consisting of an electrode. The electrode is electrically connected to a cable leading to one pole of an external electrocautery power supply. Another electrical pole of the power supply is an electrically conducting grounding pad electrically affixed to the patient's skin or other body organ, often with the aid of electrically conducting gel.

[**0031**] In a further embodiment, the cutter **12** may be rotationally vibrated using an electrical motor or one or more electrical actuators. Examples of electrical actuators include those fabricated from shape-memory nitinol with or without an elastic substrate. Ohmic heating of the nitinol actuators by application of electrical current causes reversible length change in said actuators. Opposably mounted actuators, energized one at a time, provide torque to rotationally vibrate the cutter **12** about the shaft **14**. The actuators and cutter **12** operate at frequencies up to about 200 Hz. Electrical current is provided through an electrical cable leading to an external set of batteries and a controller. Alternatively, said controller and batteries could be mounted integral to the coring tool **10**, such as in the knob **24**, for example. Such rotational vibration makes the cutter **12** function like an electric bread knife with enhanced cutting capability over a stationary knife-edge. In another embodiment, however, a circumferential vibrational, reciprocating, or reciprocal motion using microactuators affixed at or near the distal end of the punch **10** can be performed. An electrical switch on the handle **20** or knob **24** (not shown) cause the microactuators to alternately pull the cutter **12** in one direction and then the other direction. The microactuators can be located at the distal end of the punch **10** and serve to vibrate or oscillate the cutter **12** circumferentially relative to the shaft **14**. A description of the microactuators can be found in U.S. Pat. No. 5,405,337 to R. S. Maynard, the entirety of which is incorporated herein by reference. The vibrational motion generated by these microactuators is small and generally less than ¼ of a rotation. Further application of such actuators to cause rotational vibration of a device is disclosed in U.S. Pat. No. 6,110,121 to Lenker, the entirety of which is included herein by reference.

[**0032**] In a preferred embodiment, the handle **20** is affixed to the cutter **12**. The handle **20** provides rotational force to the cutter **12** to assist in tissue penetration. The optional setscrew **30** may be used to attach the handle **20** to the cutter **12**. Other ways to attach the handle **20** to the cutter **12** are the use of a rolled-pin, adhesives or over-molding. Mechanical advantage for manual rotation is derived from the wide flange like members or wings **26** on the handle **20** that allow increased moment arm to be applied to the handle **20** by the fingers of the surgeon. The handle **20** is preferably made from polymers such as but not limited to polycarbonate, acetal copolymers, acrylonitrile butadiene styrene, polyvinyl chloride and the like. The handle **20** optionally is provided with holes or openings that communicate with the optional holes **28** in the cutter **12** to allow for air and fluid escape from the interior of the cutter **12** through the handle **20** to the external environment during the coring process.

[**0033**] Optionally, the handle **20** comprises a latch or lock to maintain its position on shaft **14** in the retracted position under force of the spring **22**. To move the handle **20** distally, the optional lock is released allowing the handle **20** to be advanced along the shaft **14** toward the anvil **16**. The handle **20** further optionally comprises a damper or shock absorber to prevent the high velocity accidental release of the handle **20** and cutter **12** into the tissue.

[**0034**] Alternatively, as illustrated in **FIGS. 6A and 6B**, the handle **20** may be rotated by a motor or gear motor **110**, which is electrically powered by a battery disposed either external to or internal to the punch **10**. External battery power is delivered to the motor **110** through a cable with a plurality of conductors. On and off operation of the motor **110** is controlled through a switch on the punch knob **24** or the handle **20**, by a foot switch, or by a sound activated switch.

[**0035**] **FIG. 1B** shows the handle **20**-cutter **12** assembly fully advanced against the anvil **16**. The spring **22** is disposed between the knob **24** and the handle **20** and applies the desired force to the handle **20**-cutter **12** assembly distally toward the anvil **16** with a pre-determined force. The pre-determined force is between 0.10 and 25 pounds and, preferably, between 1 and 10 pounds. This force is advantageous in performing a controlled tissue excision. The spring **22** also allows the cutter **12** to be disposed against the tissue prior to actual excision, without cutting, so that correct alignment may be determined by the surgeon. The spring **22** is, preferably, made from spring hardened metals such as stainless steel 304, stainless steel 316, nitinol, titanium alloys and the like. The spring **22** ensures that a seal is maintained between the cutter **12** and the tissue so that hemostasis is maximized or leakage of body fluids is minimized.

[0036] In another embodiment, as illustrated in **FIGS. 6A and 6B**, the function of the spring **22** is replaced by a threaded jackscrew assembly **104**. The shaft **14** is threaded and engages mating threads on the handle **20**. By rotating the handle **20**, the cutter **12** is rotated and simultaneously advanced proximally or distally in a positive displacement fashion. **FIG. 6A** shows the coring tool **10** with the cutter **12** retracted away from the anvil **16**. **FIG. 6B** shows the coring tool **10** with the cutter **12** advanced against the anvil **16**. The anvil **16**, serves as a stop for the cutter **12**. This type of anvil **16** is also known as a hammer anvil.

[0037] In yet another embodiment, as illustrated in **FIGS. 7A and 7B**, the function of the spring **22** is replaced by a hydraulic cylinder **106** and hydraulic pressure source **108** with a valve or switch to control pressure into said cylinder **106**. **FIG. 7A** shows the coring tool **10** with the cutter **12** retracted away from the anvil **16**. **FIG. 7B** shows the coring tool **10** with the cutter **12** advanced against the anvil **16**.

[0038] The central shaft **14** maintains axial and longitudinal orientation of the punch **10** components. The shaft **14** is preferably fabricated from metals such as stainless steel, cobalt-nickel-chrome alloys, titanium alloys and the like. The shaft **14** may also be fabricated from hardened polymers such as glass-filled polycarbonate and the like. Holes or circumferential depressions in the shaft **14** permit attachment of components using setscrews or over-molding techniques. The shaft **14** geometry allows for expeditious replacement of optionally disposable components such as the cutter **12**, anvil **16** and tip **18**. The central shaft **14**, optionally, comprises one or more circumferential alignment marks to confirm the position of the cutter **12** from the proximal end of the punch **10**.

[0039] The tapered tip **18** is affixed to the distal end of the shaft **14** in a stationary manner. Fixation of the tip **18** to the shaft **14** is accomplished by over-molding, a setscrew or by internal threads on the trocar or tapered tip **18** engaging male threads on the shaft **14**. The trocar or tapered tip **18** has a conical configuration and allows penetration of the hollow organ or vessel by the entire tip **18** anvil **16** assembly following an initial incision with a sharp surgical instrument. The distal end of the trocar **18** may be either sharp or rounded. Use of the sharp end on the trocar **18** permits use of the coring tool **10** without first making a separate surgical incision in the tissue. Longitudinal edges or ridges **102** are optionally disposed on the conical surface of trocar or tip **18** to enhance tissue penetration. Alternatively, the tip **18** may be oscillated or vibrated with an electrical actuator or motor to facilitate penetration into the tissue. The oscillation is useful for either blunt dissection or sharp dissection of the tissue.

[0040] The anvil **16** is a flat surface disposed distally to the cutter **12** and aligned in a plane generally perpendicular to the axis of the shaft **14**. The anvil **16** is at least as wide as the largest exterior cutting dimension of the cutter **12**. In this way, the anvil **16** serves to positively stop the cutter **12**. The cutter **12** is advanced against the anvil **16** during the cutting procedure. The cutter **12** does not pass beyond the proximal surface of the anvil **16**. In its lowest energy or inactive state, the cutter **12** rests against the anvil **16** with a net compressive force and the spring **22** expanded to its maximum allowable amount. The compressive force between the closed cutter **12** and the anvil **16** serves to maintain contact between the surfaces and promote cutting at the end of the stroke.

[0041] The anvil **16** and the tapered tip **18** are, preferably fabricated from the same piece of material for economy and ease of fabrication. Alternatively, the anvil **16** and the tapered tip **18** may be separate components and may be longitudinally disconnected or they may be longitudinally connected. Both the anvil **16** and the trocar or tapered tip **18** are radially constrained by the shaft **14**. The anvil **16** is attached to shaft **14** by a setscrew, internal threads for engagement with male threads on the shaft **14**, adhesive bonding or over-molding. The anvil **16** and the trocar or tapered tip **18** are, preferably, fabricated from polymeric materials such as but not limited to polyvinyl chloride, acetal copolymers, polycarbonate, acrylonitrile butadiene styrene and the like. They may alternatively be fabricated from metals such as stainless steel, cobalt-chrome-nickel alloys, titanium alloys and the like.

[0042] The anvil **16** optionally comprises pre-placed attachment devices, such as staples, sutures or posts that remain in the tissue around the coring site to facilitate subsequent placement of anastomotic devices.

[0043] The knob **24** terminates the proximal end of the shaft **14** and allows for positioning of the punch **10** by the surgeon. The knob **24** is blunt and preferably is fabricated from the same materials as the trocar or tip **18** or the anvil **16**. The knob **24** is affixed to the shaft **14** with setscrews, adhesives, or over-molding or the knob **24** is affixed by female threads that engage male threads on the shaft **14**.

[0044] Referring to **FIGS. 2, 3**, and **4**, the procedure for hollow organ coring or trephination is accomplished by first creating a small incision at the desired penetration location using a sharp surgical instrument such as a scalpel. The cutter **12** is retracted by manually withdrawing the handle **20** wings **26** proximally toward the knob **24**. The spring **22** is compressed when retracting the handle **20** and cutter **12**. The tapered tip **18** and anvil **16** assembly is advanced into the incision until the anvil **16** has passed beyond the interior surface of the hollow organ or vessel. The handle **20** is next released and the cutter **12** is positioned against the exterior of the hollow organ as shown in **FIG. 2**. Once position has been confirmed or adjusted, the handle **20** is manually rotated to initiate cutting of the tissue by the cylindrical cutter **12**. As shown in **FIG. 3**, the handle **20** and cutter **12** are rotated until full penetration of the hollow organ has occurred, under force of the spring **22**, and the distal edge of the cutter **12** rests against the anvil **16**.

[0045] Complete penetration and cutter **12** to anvil **16** contact may be confirmed by placement of a plurality of alignment marks on the shaft **14**. The alignment marks become visible once the cutter **12** and handle **20** have been advanced sufficiently. The punch **10** is next withdrawn proximally, removing the cored-out piece of tissue from the organ as shown in **FIG. 4**. Prevention of hemorrhage or fluid leakage from the hollow organ or vessel is accomplished by manual compression or placement of a temporary plug. This device and procedure are especially useful when performing coring on the beating heart.

[0046] Typically, the surgeon manually cores the patient's hollow organ or vessel using the punch or coring tool **10**.

The coring tool **10** can alternatively, be held and manipulated by a robotic arm, endovascularly routed device such as a catheter, or a laparoscopic instrument. The laparoscopic instrument is generally placed through a sheath or trocar that has been inserted into the body through a percutaneous puncture site. In a laparoscopic embodiment, the shaft **14** is extended in length, relative to the device shown in **FIG. 1A** or **FIG. 8A**. The anvil **16** and tapered tip **18** reside at the distal end of the shaft **14** and are within the body distal to the distal end of the sheath. Furthermore, the region between the cutter **12** and the handle **20** is correspondingly extended in length so that the rotational force can be transmitted to the cutter **12**, which resides within the body while the handle **20** and knob **24** are outside the body. Thus, all operational controls are outside the body and proximal to the proximal end of the laparoscopic sheath and a pressure seal. Visual control of the cutter is accomplished using a laparoscope routed through another trocar or sheath, or it is accomplished using ultrasound, fluoroscopy, or magnetic resonance imaging. The laparoscopic device is generally rigid and flexibility is not required, although it could be advantageous to make the shaft **14** flexible to allow some curvature. The laparoscopic device cutter and anvil **16** are generally between 1 and 15 mm in diameter. The length of the shaft **14** between the handle **20** and the proximal end of the cutter **12** can range between 5 and 50-cm.

[0047] An endovascular, interventional, or endoluminal device embodiment comprises a flexible shaft **14** that is capable of being routed through a sheath into a body vessel or lumen. The punch in this embodiment is affixed to a catheter. A hemostasis valve, fluid-tight seal or other gasket is provided at the proximal end of the sheath to prevent loss of blood, or body fluids, or the retrograde flow of air into the body. Typical cardiovascular access sheaths known in the art of endovascular access are appropriate for this application. The cutter **12** and anvil **16** reside at the distal end of the shaft **14**. The shaft **14** is a torqueable axially elongate structure that also has column strength. The region between the handle **20** and the cutter **12** is generally very long in this embodiment. This length and the corresponding length of the shaft **14** may range from 10-cm to over 200-cm depending on the distance between the access site and the treatment site. The diameter of the cutter **12** is small enough to fit through the sheath, generally less than 24 French, or 8 mm in diameter. The cutter **12** and the anvil **16** can also be fabricated from structures that are radially expandable to allow them to fit through small diameter sheaths and then be enlarged to perform their coring function. The endovascular embodiment can also comprise a guidewire lumen (not shown) which is a central lumen extending from the proximal end of the knob **24** to the distal end of the tapered tip **18** so that the device can be routed over a guidewire, a slideable fit with a lumen diameter of 0.010 inches to 0.042 inches. All rotational operations and cutter **12** to anvil **16** closure operations are performed from the proximal end of the punch **10**.

[0048] **FIGS. 5A and 5B** illustrate another embodiment of a hollow organ coring tool, trephine, or punch **38**. The coring tool **38** comprises the cutter **12**, the anvil **16**, the trocar or tapered tip **18**, the handle **20**, the spring **22**, and the knob **24**. The coring tool **38** also comprises an inner shaft **32**, an outer shaft **34**, a pin **36**, and an axial slot **40**. The handle **20** further comprises the plurality of wide flange-like members or wings **26**.

[0049] The cutter **12**, the handle **20**, the spring **22**, and the knob **24** are disposed concentrically on the axially elongate outer shaft **34**. The anvil **16** and the trocar or tip **18** are both disposed concentrically on the axially elongate inner shaft **32**. The inner shaft **32** is slideably disposed inside the outer shaft **34** and the inner shaft **32** extends beyond the outer shaft **34** at least the thickness of the vessel or organ to be cored.

[0050] The handle **20** is not affixed to the cutter **12**. Instead, the handle **20** is affixed to the inner shaft **32** by the pin **36** through the axial slot **40** in the outer shaft **34**. The cutter **12** is affixed to the distal end of the outer shaft **34**. The handle **20**, which is affixed to the inner shaft **32**, sets above the cutter **12**, which is affixed to the outer shaft **34**.

[0051] The knob **24** is affixed to the proximal end of the outer shaft **34**. The anvil **16** is affixed to the proximal end of the trocar or tip **18** and the tip **18** is affixed to the distal end of the inner shaft **32**.

[0052] The spring **22** sets around the outer shaft **34**, between the knob **24** and the handle **20**. The spring **22** forces the tip **18** and anvil **16** distally away from the cutter **12**. Manual retraction of the handle **20** proximally causes proximal retraction of the anvil **16** toward the cutter **12**. The spring **22** becomes increasingly compressed as the handle **20** is moved proximally toward the knob **24**.

[0053] Referring to **FIG. 5A**, the handle **20**, the tip **18**, the anvil **16**, and inner shaft **32** of the trephine **38** are fully advanced. The spring **22** is not compressed and is in its lowest energy position. The pin **36** rests in the distal end of the slot **40** and prevents the handle **20**, the tip **18** and the anvil **16** from advancing further.

[0054] The handle **20** or the knob **24** optionally comprise a lock that is manually operated and selectively prevents movement of the inner shaft **32** relative to the outer shaft **34**.

[0055] Referring to **FIG. 5B**, the handle **20**, the tip **18**, the anvil **16**, and the inner shaft **32** are fully retracted. The spring **22** is fully compressed and in its highest energy position. Retraction of the handle **20** is accomplished with one hand over the knob **24** and fingers wrapped around the wings **26** in the handle **20**. Pulling the fingers toward the knob **24** causes the anvil **16** to move proximally toward the cutter **12**. The movement stops when the anvil **16** meets the cutter **12**.

[0056] In an embodiment, as illustrated in **FIGS. 8A and 8B**, the function of the spring **22** of **FIG. 1A** is replaced by a threaded jackscrew assembly **104**. The shaft **14** is threaded and engages mating threads on the handle **20**. By application of an electrical energy source, such as a battery, which causes rotation of the motor **110**, the cutter **12** is rotated. Optionally the cutter **12** may be simultaneously advanced proximally or distally in a positive displacement fashion by the threads **104** between the handle **20** and the shaft **14**. This axial travel of the cutter **12** can be generated by the motor **110**, rotation of the handle **20**, or by a spring **22**. The motor **110** can be a linear motor or it can be a rotational motor and actuate rotation of the cutter **12** through a gear assembly **112**. A ratchet or rotational disconnect **114** can controllably and reversibly separate rotational motion of the handle **20** from the cutter **12**. Actuation of the ratchet or rotational disconnect **114** can be accomplished through use of a lever or button (not shown) on the handle **20** or the knob **24**. **FIG. 8A** shows the coring tool **10** with the cutter **12** retracted away from the anvil **16**. **FIG. 8B** shows the coring tool **10** with the cutter **12** advanced against the anvil **16**. The anvil **16**, serves as a stop for the cutter **12**. This type of anvil **16** is also known as a hammer anvil. **FIGS. 8A and 8B** illustrate a more detailed layout of the construction of one of the embodiments of the punch of **FIGS. 6A and 6B**.

[0057] In an embodiment, as illustrated in **FIGS. 9A and 9B**, the function of the spring **22** is replaced by a hydraulic cylinder **106** and hydraulic pressure source **108** with a valve or switch to control pressure into said cylinder **106**. **FIG. 9A** shows the coring tool **10** with the cutter **12** retracted away from the anvil **16**. **FIG. 9B** shows the coring tool **10** with the cutter **12** advanced against the anvil **16**. **FIGS. 9A and 9B** illustrate a more detailed layout of the construction of one of the embodiments of the punch of **FIGS. 7A and 7B**. In this embodiment, rotation of the cutter **12** is generated by rotating the handle **20**. This cutter **12** rotation can also be generated by an electric motor or gear-motor **110** (see **FIGS. 8A and 8B**) or by a turbine (not shown) driven by the hydraulic pressure source **108**.

[0058] In an embodiment, the cutter **12** is rotated by the motor **110**. The cutter **12** is advanced toward the anvil **16**, or the anvil retracted toward the cutter **12** by being biased by a spring **22**. The cutter **12** can be retracted away from the anvil **16**, or the anvil **16** advanced away from the cutter **12** by applying manual force to the handle **20** relative to the knob **24**. It is beneficial that the cutter **12** be rotated substantially, in excess of ¼ revolution while approaching the anvil **16**. Preferably, the cutter **12** is rotated in excess of 1 revolution as it approaches the anvil **16**. Most preferably, the cutter **12** rotates two (2) or more times while approaching the anvil **16**. This substantial rotation is beneficial in making the cleanest cuts in soft tissue. The substantial rotation is easily accomplished with a motor **110** or gear-motor. The substantial rotation can also be accomplished by manually turning the handle **20** or by a lever-ratchet assembly (not shown) with gearing to provide large rotational motion for a small amount of linear motion in the lever-ratchet assembly.

[0059] The procedure for hollow organ coring or trephination is accomplished by first creating a small incision at the desired penetration location using a sharp surgical instrument such as a scalpel. The tapered tip **18** and anvil **16** assembly is advanced into the incision until the anvil **16** has passed beyond the interior surface of the hollow organ or vessel and the cutter **12** rests on the exterior of the hollow organ or vessel. Once position has been confirmed or adjusted, the handle **20** is pulled toward the knob **24** to initiate cutting of the tissue by the circular cutter **12**. The handle **20** is pulled until the distal edge of the cutter **12** rests against the anvil **16** and the organ has been cored. Complete penetration and cutter **12** to anvil **16** contact may be confirmed by placement of a plurality of alignment marks on the outer shaft **34**. The alignment marks become visible once the anvil **16** and the handle **20** have been retracted sufficiently. The punch **38** is next withdrawn proximally, removing the cored-out piece of tissue from the organ.

[0060] The hollow organ coring tool, trephine, or punch **38** is fabricated from the same materials as the hollow organ coring tool, trephine, or punch **10** and comprises the same or similar options as the hollow organ coring tool, trephine, or punch **10**. In an embodiment, the cutter **12** of the punch **38** can be rotated by a motor or actuator to facilitate tissue penetration.

[0061] The punch, in another embodiment, can comprise elements that plug or close the hole left behind following the coring procedure. The plug (not shown) can be a cylindrical or other axially elongate structure, affixed distal to the anvil such that it can be detached from the anvil **16**. The plug is detached by actuation of a lever or other control element a the proximal end of the punch with the energy being mechanically, electrically, hydraulically, or pneumatically transmitted down the shaft **14** of the punch to the distal end, where a coupler is released to detach the plug. The plug can optionally comprise a line, tether, or string, routed out the proximal end of the punch, so that it can be removed from the tissue after a period of temporary placement. The punch, in another embodiment, can comprise suture elements that are routed through the tissue surrounding the punch hole. These suture elements, optionally tipped with needles or other sharp tissue penetration devices, can be captured and withdrawn from the proximal end of the punch to temporarily or permanently close the punch hole on itself or around a cannula or other axially elongate tube or vessel, placed therethrough. The needles or tissue penetration devices can be "J" shaped to permit easy recapture of the sharp distal end by mechanical motions generated within the punch. In yet another embodiment, the punch can comprise injection ports at its distal end for delivering adhesives to the punch hole site for the purposes of closure or enhanced anastomosis at the punch hole site. Adhesives, such as cyanoacrylate or other biological adhesives known in the art, can be stored in the shaft and injected by actuation at the proximal end, or they can be injected from the proximal end and delivered down the shaft **14** and exit at the injection ports at the distal end of the punch. Such adhesives can include single and multi-part adhesives that require mixing.

[0062] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An apparatus adapted for cutting holes in a body vessel or hollow organ comprising:

a cutting blade,

a controlled force to advance the cutting blade, and

an anvil having a proximal surface against which the cutting blade is advanced,

wherein the cutting blade rotates at least ¼ turn relative to the anvil while the cutting blade is being advanced toward the anvil.

2. The apparatus of claim 1 wherein said controlled force on the cutting blade is generated by a spring with a predetermined or selected spring constant.

3. The apparatus of claim 1 wherein the rotation of said cutting blade is generated by a lever assembly.

4. The apparatus of claim 1 wherein the rotation of the cutting blade is generated by a motor.

5. The apparatus of claim 1 wherein said rotation of the cutting blade is generated by manually turning a handle.

6. The apparatus of claim 1 wherein said cutting blade rotates at least two times while being closed against the anvil.

7. The apparatus of claim 1 wherein said cutting blade rotates at least one time while being advanced toward the anvil.

8. The apparatus of claim 1 wherein the cutting blade and anvil are located at the distal end of a long, flexible catheter while the handle and knob are located at the proximal end of the catheter.

9. The apparatus of claim 1 wherein said cutting blade and are advanced through a laparoscopic sheath.

10. The apparatus of claim 9 wherein said rotation of said cutting blade is generated by force applied proximally to the proximal end of said laparoscopic sheath.

11. The apparatus of claim 9 wherein said controlled force is generated proximally to the proximal end of said laparoscopic sheath.

12. The apparatus of claim 1 wherein said rotational force is generated by actuators that provide a reciprocating motion to the cutting blade.

13. A method for creating a hole in a body vessel comprising the steps of:

creating an incision in said body vessel with a sharp object,

inserting a sheath having a fluid-tight seal into said body vessel,

advancing a punch, further comprising a cutting blade and an anvil located at the distal end of a catheter, through said sheath into said body vessel until the distal end of the punch has reached a target location within the body vessel,

advancing a sharp tip, affixed to the punch, through the body vessel at the target site to create a puncture,

advancing an anvil with a tapered tip through the puncture in the body vessel at the target site,

locating a circular cutting blade so that said cutting blade is positioned with the wall of the body vessel between the anvil and cutting blade,

advancing said cutting blade into said body vessel wall under controlled force until said cutting blade fully rests against a distal surface of the anvil whose outside diameter is no less than the outer diameter of said cutting blade so that a hole is cut in the body vessel from the inside, and

removing said cutting blade and excised tissue from the body vessel,

wherein the cutting blade is rotated at least one revolution while said cutting blade is being advanced toward said anvil.

14. The method of claim 13 wherein the punch is introduced through a laparoscopic sheath rather than a vascular access sheath and wherein the hole is created in a hollow organ or body vessel from the outside, rather than the inside.

15. An apparatus adapted for cutting holes in a body vessel or hollow organ comprising:

an anvil,

a cutting blade against which the anvil is advanced wherein the anvil positively stops against the cutting blade, and

a controlled force to advance the anvil,

wherein the cutting blade rotates relative to the anvil at least ¼ turn while the anvil is being advanced toward the cutting blade.

16. The apparatus of claim 15 wherein said controlled force is generated by a spring to move the anvil against the cutting blade.

17. The apparatus of claim 15 wherein said rotation of the cutter is generated by a motor.

18. The apparatus of claim 15 wherein said rotation of the cutter is generated by an electrically powered microactuator that causes a reciprocal motion.

19. The apparatus of claim 15 wherein said rotation of the cutter is generated by a lever.

20. The apparatus of claim 15 wherein said rotation of the cutter is generated by manually turning a handle.

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专利名称(译)	用于使身体血管和中空器官壁褶皱的方法和设备		
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摘要(译)

公开了一种用于在身体血管或中空器官中形成孔的系统。这些孔可用于手术制备中空器官或身体血管以与另一个中空器官，身体血管或假体导管连接。例如，辅助装置通常通过在左心室的顶点处产生的脑室切开术连接到左心室。这种脑室切开术最容易用冲头或环钻创建。对这种手术的控制必须精确，以免损伤心室壁或心内结构，例如乳头肌，腱索等。本发明的冲头允许切割段的精确定位和对准。本发明的冲头还允许切割刀片的精确前进和非常干净的组织切割。当身体血管或中空器官中的孔被关闭或附接到假肢或自然的连接时，这种清洁切口改善了愈合。