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(54) **STEERABLE ENDOLUMINAL PUNCH**

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(63) Continuation of application No. 13/944,448, filed on Jul. 17, 2013, now Pat. No. 9,445,836, which is a continuation of application No. 12/785,309, filed on May 21, 2010, now Pat. No. 8,491,619, which is a continuation of application No. 11/492,328, filed on Jul. 24, 2006, now abandoned.

(60) Provisional application No. 60/702,239, filed on Jul. 25, 2005.

(51) **Int. Cl.**

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A61B 17/00	(2006.01)
A61B 17/34	(2006.01)
A61B 18/00	(2006.01)

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

CPC .. ***A61B 17/32053*** (2013.01); ***A61B 17/00234*** (2013.01); ***A61B 17/34*** (2013.01); ***A61B 17/3478*** (2013.01); *A61B 17/3415* (2013.01); *A61B 17/3468* (2013.01); *A61B 2017/003* (2013.01); *A61B 2017/00247* (2013.01); *A61B 2017/00331* (2013.01); *A61B 2017/320044* (2013.01); *A61B 2018/0038* (2013.01); *A61B 2018/00357* (2013.01); *A61B 2018/00392* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/34; A61B 17/00234; A61B 17/3468; A61B 17/3415; A61B 2017/003; A61B 2017/00247; A61B 2018/00392

See application file for complete search history.

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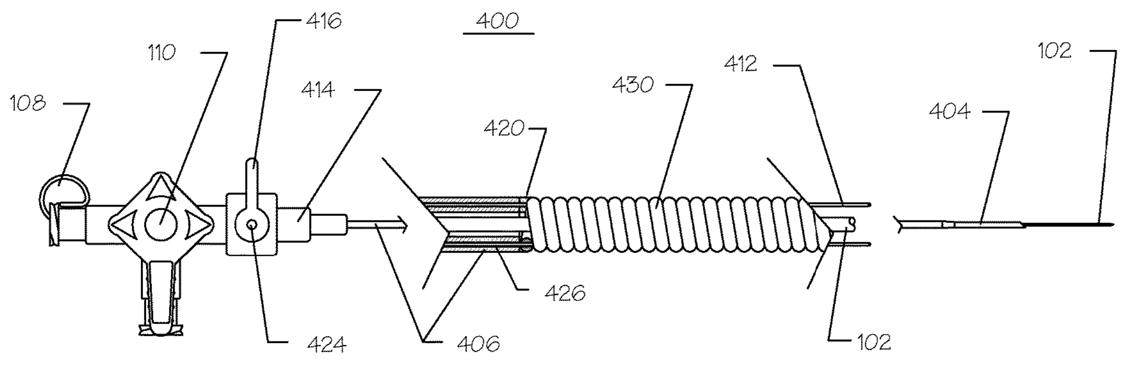
(57) **ABSTRACT**

A transseptal punch with a steering mechanism within the punch, such that punch can be steered and deflected within a guide catheter during delivery, to avoid skiving of the guide catheter inner wall by passage of the punch tip through the guide catheter. The punch can be advanced through a body lumen in its straight configuration and then be selectively articulated or curved to permit negotiation of tortuous curvature or to permit optimal approach or access to a puncture site. The punch is able to create holes in the atrial septum of the heart or other structures and is easier to use than punches that are pre-curved near their distal tip since it is easier to advance through accessory catheters.

1 Claim, 6 Drawing Sheets



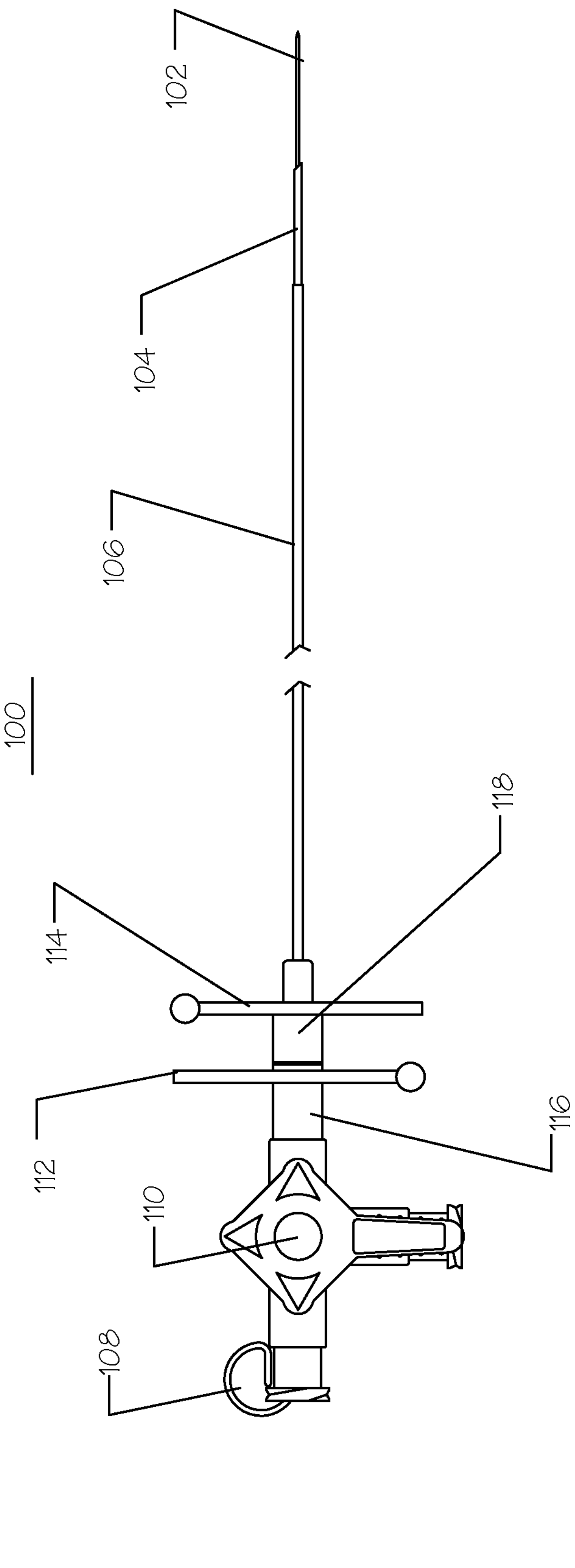
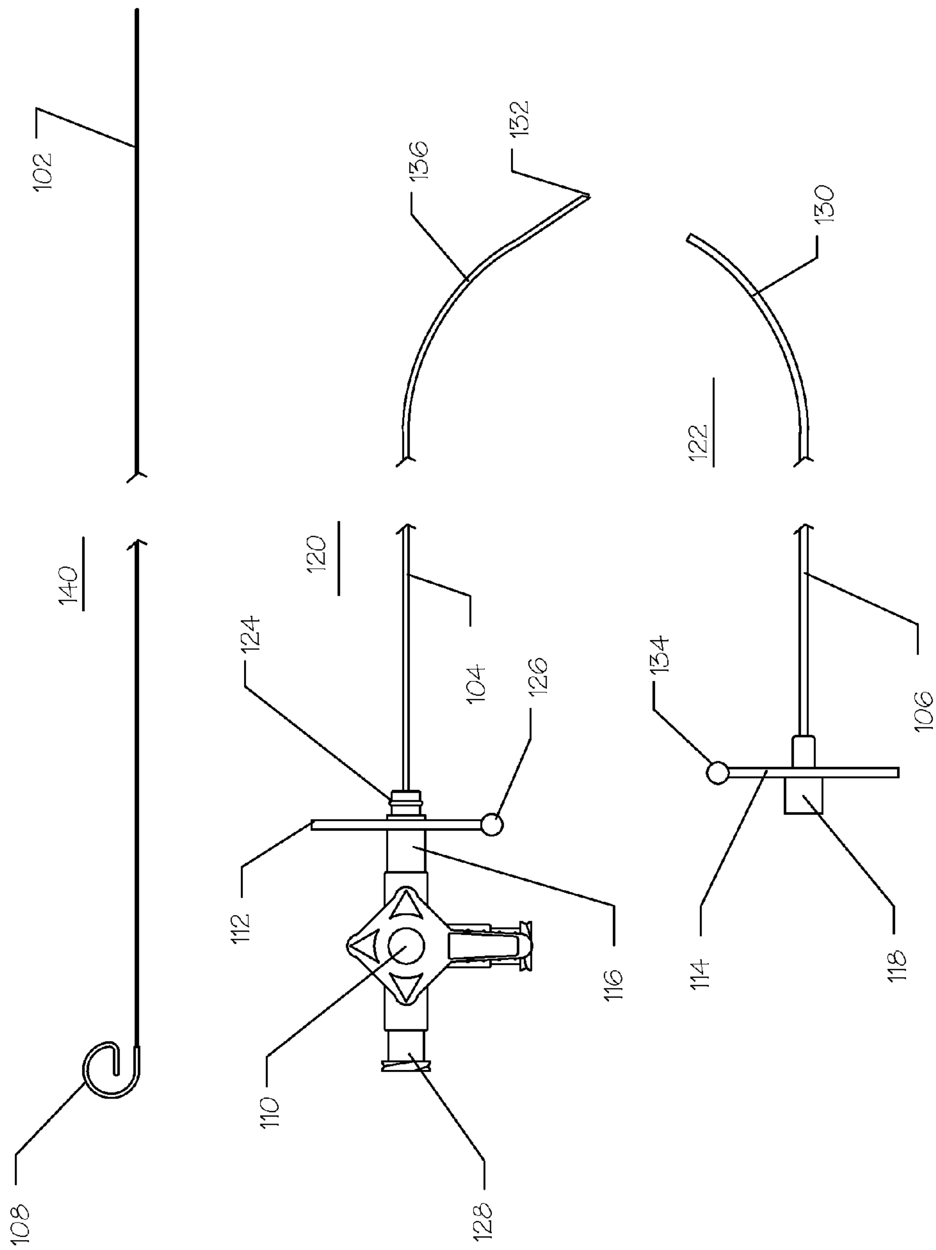


Fig. 1


102
140
108
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132
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118

Fig. 2

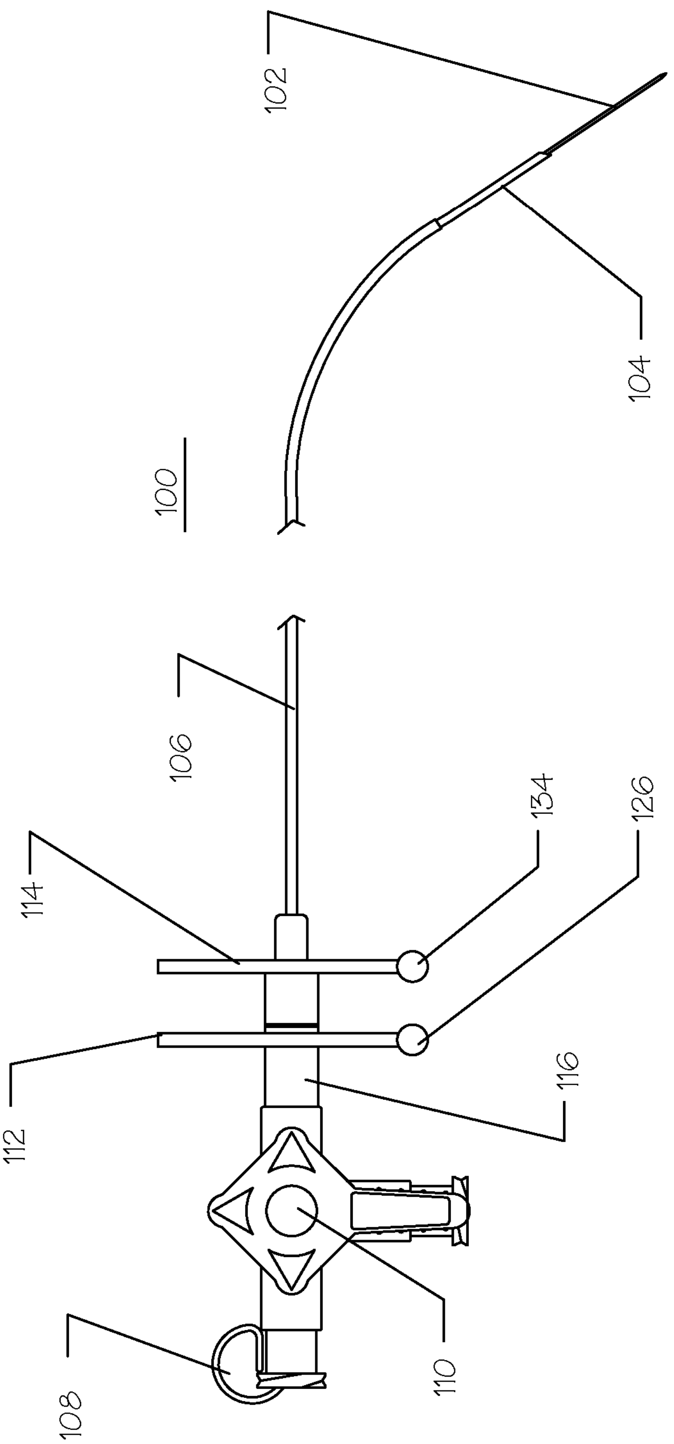

Fig. 3

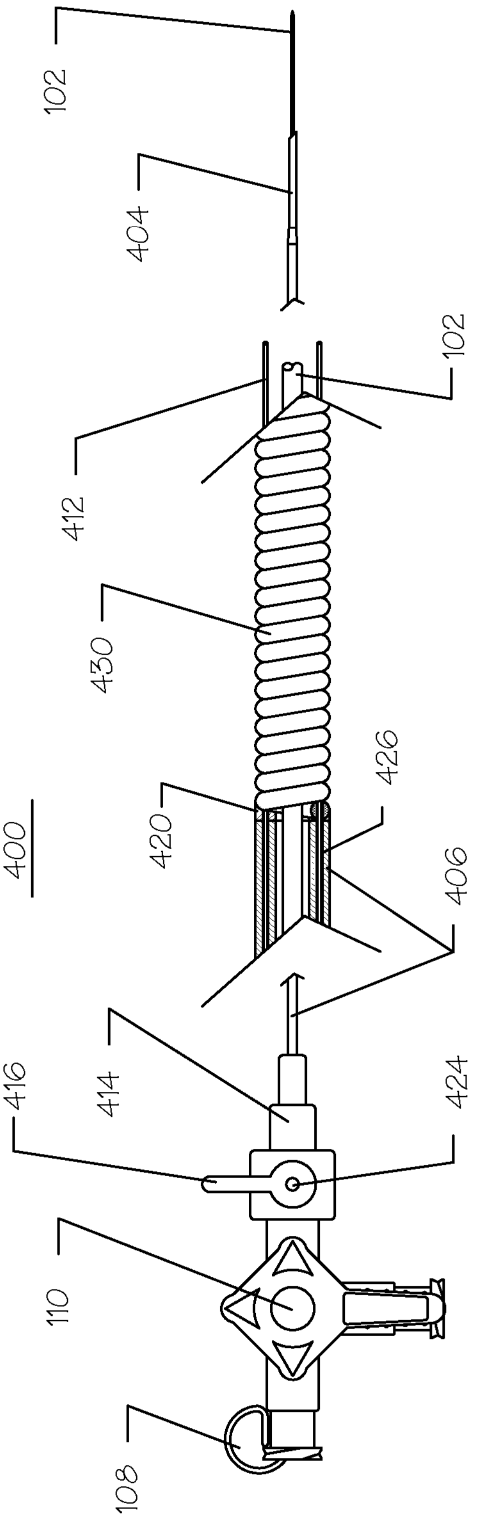

Fig. 4

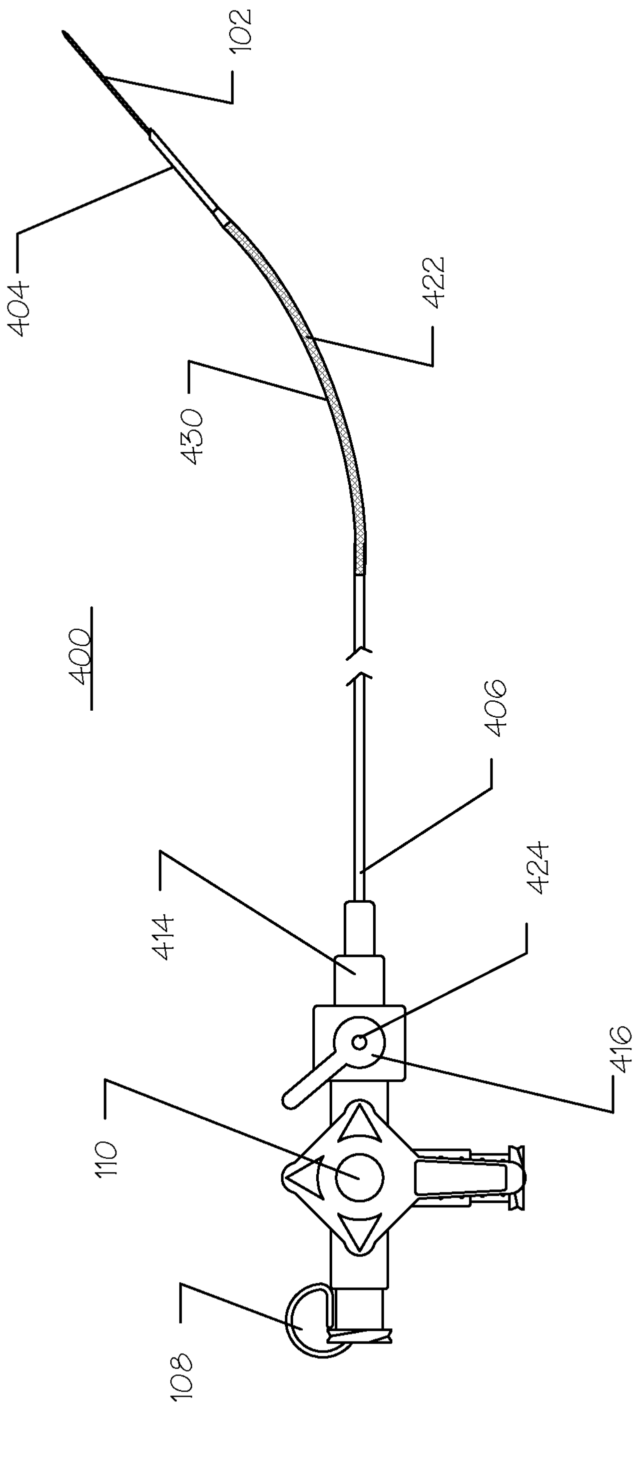

Fig. 5

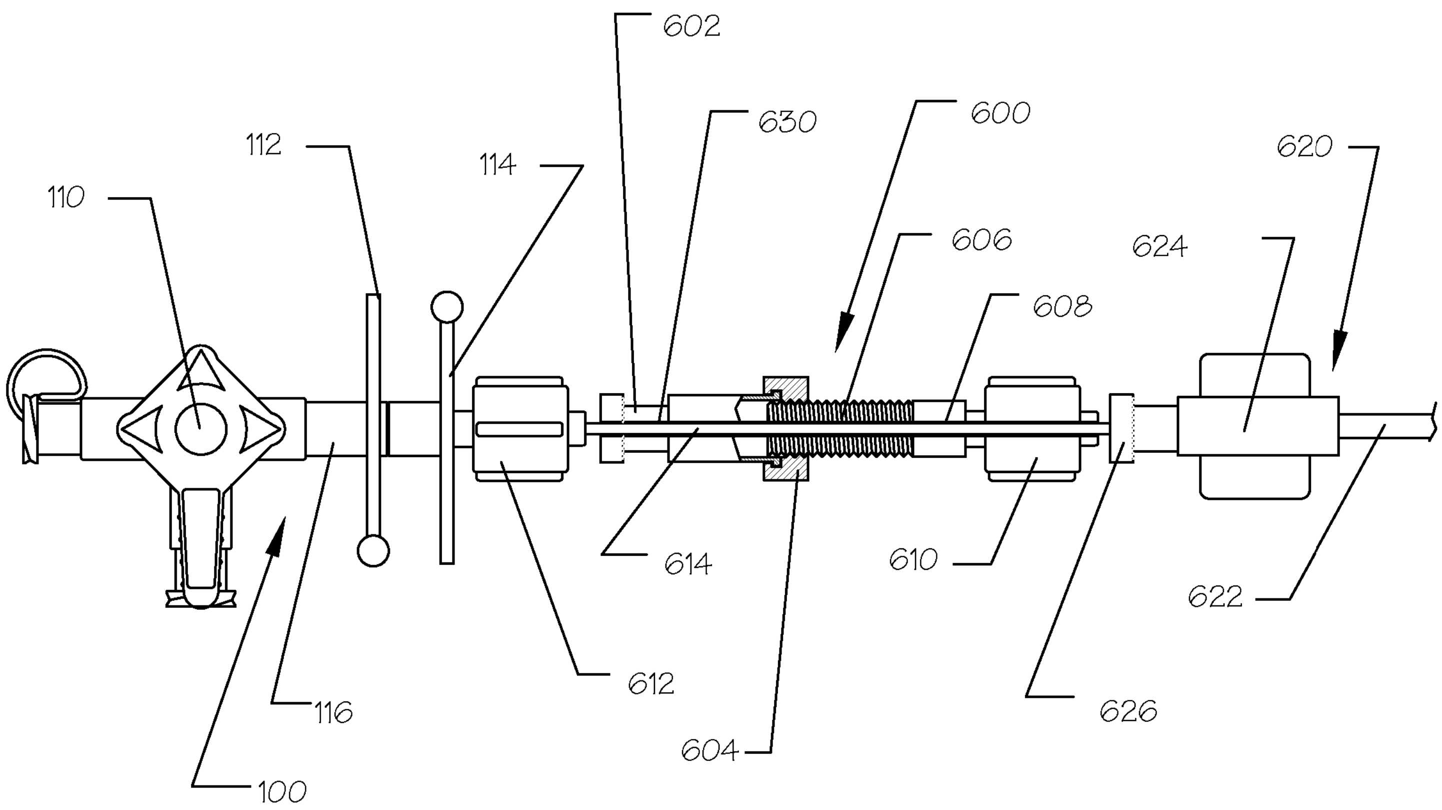
602
630
600
112
114
620
110
606
624
608
614
610
622
612
116
626
604
100

Fig. 6

STEERABLE ENDOLUMINAL PUNCH

This application is a continuation of U.S. application Ser. No. 13/944,448, filed Jul. 17, 2013, now U.S. Pat. No. 9,445,836, which is a continuation of U.S. application Ser. No. 12/785,309, filed May 21, 2010, now U.S. Pat. No. 8,491,619, which is a continuation of U.S. application Ser. No. 11/492,328, filed Jul. 24, 2006, which in turn claims priority benefit under 35 USC § 119(e) to U.S. Provisional Application No. 60/702,239, filed Jul. 25, 2005, the entire contents of which are hereby incorporated herein by reference.

FIELD OF THE INVENTION

The invention relates to devices and methods for performing endovascular access to the cardiovascular system or other body vessels or body lumens, especially procedures performed in the fields of cardiology, radiology, electrophysiology, and surgery.

BACKGROUND OF THE INVENTION

During certain interventional procedures that are directed at cardiac access, the patient is catheterized through an access point in a vein or artery. A catheter is routed to the heart or other region of the cardiovascular system through the access point, which may be created by a cutdown or a percutaneous access procedure. The catheter may be routed to a target location within the heart, cerebrovasculature, or other region of the cardiovascular system. In certain cases, it becomes necessary to create a hole in a cardiovascular structure so that catheters or devices can be routed through a wall so as to provide for placement on the other side of the wall. One such case is the need to punch a hole in the septum that divides the right atrium of the heart from the left atrium. Such atrial septal punctures are increasingly used to gain access to the left atrium by way of the central venous system and the right atrium. Access to the left atrium of the heart is often useful in therapeutic and diagnostic procedures such as, but not limited to, valve replacement, valve repair, electrophysiology mapping, cardiac ablation, atrial appendage plug placement, and the like.

The currently accepted procedure for left atrial access involves routing a needle called a Brockenbrough™ needle into the right atrium with the Brockenbrough needle preplaced within a guiding catheter. The guiding catheter specifically preferred for use with a Brockenbrough needle is called a Mullins™ catheter. The Brockenbrough needle is a long punch formed from a stainless steel wire stylet that is surrounded by a stainless steel tube. The distal end of the stainless steel tube forms a relatively sharp circular punch capable of penetrating certain vascular structures such as the inter-atrial septum. Brockenbrough needle stylets are typically 0.013 to 0.014 inches in diameter while the stainless steel tube is generally between 0.045 and 0.050 inches in outside diameter. The Brockenbrough needle outside diameter is configured to slidingly fit within the central lumen of the Mullins catheter. The stainless steel tube is substantially straight along most of its length but is pre-bent into a curved or "J" shape at its distal end. A loop at the proximal end of the Brockenbrough stylet facilitates grasping of the stylet and performing manual advance or retraction. The current art considers the access to the right atrium from the femoral vein to be relatively straight so the current devices are straight except for the distal curve, which is shaped for the approach to the atrial septal wall.

The Brockenbrough needle, a relatively rigid structure, is operated by advancing the device, with its stylet wire advanced to blunt the sharp tip, within its guiding catheter through the inferior vena cava and into the superior vena cava. Under fluoroscopic guidance, the Brockenbrough needle, retracted inside the distal tip of the Mullins catheter, is withdrawn caudally into the right atrium until it falls or translates medially into the Fossa Ovalis. The force of the Brockenbrough needle/Mullins catheter assembly pushing against the relatively weak atrial septal wall causes the Fossa Ovalis to become tented toward the left atrium. The Brockenbrough needle, protected by the blunt distal tip of the Mullins catheter, is firmly held against the Fossa Ovalis of the atrial septum. Pressure monitoring and dye injection are carried out through the central lumen of the punch following removal of the stylet wire. The circular or hollow punch is next advanced distally to puncture a hole through the atrial septum. Erroneous placement of the punch can lead to penetration of adjacent structures such as the aorta, damage to which would cause potentially severe hemorrhage and potentially compromise the health of the patient. Thus, extreme care is exercised to verify location prior to the actual punching step. The Brockenbrough needle is next advanced through the atrial septum. The guide catheter, which includes a removable, tapered, distal dilator, having a central lumen for the Brockenbrough needle, is advanced over the Brockenbrough needle system and into the left atrium. The Brockenbrough needle is next removed from the Mullins guide catheter along with the central dilator or obturator.

A main disadvantage of this system is that the Brockenbrough needle system is pre-curved at its distal end and is relatively rigid. This pre-curving, rigidity, and necessary distal sharpness causes the Brockenbrough needle system to carve material from the interior wall of the otherwise straight guiding catheter when the Brockenbrough needle assembly is inserted therethrough. The material carved from the guide catheter could potentially be released into the cardiovascular system and generate emboli with any number of serious clinical sequelae. Should this embolic catheter material enter the left atrium it could flow into and block important arterial vasculature such as the coronary arteries or cerebrovasculature. Furthermore, advancing a precurved, rigid punch through the cardiovascular system is difficult and could potentially damage the vessel wall or any number of significant cardiovascular structures, during the advancement.

It would be desirable to have a Brockenbrough needle system that was initially straight and then became curved after being inserted into the guiding catheter. Such a straight Brockenbrough configuration would be advantageous during ex-vivo insertion as well as insertion after the guide catheter has already been placed into the cardiovascular system. During ex-vivo insertion, the debris can be flushed from the lumen of the guide catheter but complete removal is not assured and emboli can still be generated by the device. However, if the guide catheter was already inserted into the cardiovascular system, the debris could not be flushed out ahead of time and could easily flow toward or be released into the cardiovascular system with potentially catastrophic or fatal results. Furthermore, the needle or punch could be more easily advanced into the body lumen if it were not pre-curved.

SUMMARY OF THE INVENTIONS

In an embodiment, the invention is a transvascularly or endovascularly placed tissue punch, with internal deflect-ability or the ability to articulate, at its distal end, in a direction away from its longitudinal axis. The punch can also be termed a catheter, needle, or cannula. The punch is generally fabricated from stainless steel and comprises an outer tube, an inner tube, a central stylet wire, and a distal articulating region. The deflecting or articulating mechanism is integral to the punch. The punch, needle, or catheter is sufficiently rigid, in an embodiment, that it can be used as an internal guidewire or internal guide catheter. The punch is useful for animals, including mammals and human patients and is routed through body lumens or other body structures to reach its target destination.

In an embodiment, the punch comprises an inner core wire or stylet, an inner tube and an outer tube. In an embodiment, the stylet can be removable or non-removable. The punch further comprises a hub at its proximal end which permits grasping of the punch and also includes a stopcock or valve to serve as a lock for the stylet, or inner core wire, as well as a valve for control of fluid passage into and out from the innermost lumen within which the stylet or inner core wire resides. The proximal end further comprises one or more control handles to manipulate the amount of articulation at the distal end of the catheter. The proximal end further is terminated with a female Luer or Luer lock port, which is suitable for attachment of pressure monitoring lines, dye injection lines, vacuum lines, a combination thereof, or the like.

The punch is fabricated so that it is substantially straight from its proximal end to its distal end. Manipulation of a control mechanism at the proximal end of the punch causes a distal region of the punch to bend or curve away from its longitudinal axis. The bending, steering, or articulating region is located near the distal end of the punch and can be a flexible region or structure placed under tension or compression by pull wires or control rods routed from the control handle at the proximal end of the punch to a point distal to the flexible region. In another embodiment, the bending or articulating mechanism can also be created by pre-bending the outer tube in one direction and bending the inner tube in another direction. The two tubes can be rotated relative to each other, about their longitudinal axis, by turning knobs or grips at the proximal end of the punch. When the curvatures of both tubes are aligned, the tubes will generally cooperate and not oppose each other, thus, maximum curvature or deflection is generated. When the tubes are rotated so their natural curvatures are aligned 180 degrees from each other, the curves will oppose each other or cancel out. Thus, the nested tubes will be substantially straight when the curvatures of the two concentric tubes oppose each other. Alignment marks or graduations at the proximal end can be used to assist with proper rotational alignment of the two tubes. The central core wire or stylet is generally straight and flexible and does not contribute to the curvature. In another embodiment, however, the stylet can be imparted with a curvature to assist with steering or articulation. Rotation of the two concentric tubes at relative angles between 180 degrees and 0 degrees will result in intermediate amounts of deflection so the amount of deflection can be increased or decreased in an analog, continuously variable, digital, or stepwise fashion. The stepwise or digital response can be generated using detents or interlocks that weakly engage at specific pre-determined locations. A locking mechanism can be further utilized to hold the two tubes in rotational alignment once the desired amount of curvature has been achieved.

In another embodiment, steerability can be obtained using actuators on the surface or within the interior of the cannula to force bending of the cannula. These actuators can be typically electrically powered. In an embodiment, an actuator can comprise electrical leads, a power source, a compressible substrate, and shape memory materials such as nitinol. Such actuators may be distributed along the length of the cannula. The actuators may be placed so as to oppose each other. Opposing actuators are activated one at a time and not simultaneously and can generate a steering effect or back and forth motion.

Other embodiments of the inventions comprise methods of use. One method of use involves inserting the central core wire so that it protrude out the distal end of the punch. A percutaneous or cutdown procedure is performed to gain access to the vasculature, either a vein or an artery. An introducer and guidewire are placed within the vasculature and the guidewire is routed proximate to the target treatment site. The introducer can be removed at this time. A guiding catheter, preferably with a central obturator or dilator is routed over the guidewire to the target site. In an embodiment, the target site can be the atrial septum. The guidewire can be removed at this time. The punch is adjusted so that it assumes a substantially straight configuration. The punch can be advanced through the central lumen of the already placed catheter. By making the punch as straight as possible, there is no curvature to force the sharpened distal edges of the punch to scrape the inside of the catheter lumen as the punch is advanced distally inside the guide catheter and potentially dislodge or scythe away debris or material which could cause embolic effects to the patient. Carefully ensuring that the punch does not protrude beyond the distal end of the catheter or its obturator, the punch is next deflected so that it forms a curve. The curve is oriented so that it is medially directed toward the atrial septum. Alignment with any curvature of the catheter can be completed at this time. The punch and guide catheter/obturator are withdrawn caudally, as a unit, into the right atrium. The punch and guide catheter are positioned using fluoroscopy or other imaging system against the Fossa Ovalis. The Fossa Ovalis is a relatively thin structure and the force of the punch will tent the Fossa Ovalis toward the left atrium. In one embodiment, the central core wire or stylet, initially advanced, can next be withdrawn to expose the sharp distal edge of the punch. When correctly positioned under fluoroscopy, ultrasound, or other imaging system, dye can be injected into the central lumen of the punch at its proximal end and be expelled out of the distal end of the punch and obturator to paint or mark the Fossa Ovalis. A generally "V-shaped" mark can be observed under fluoroscopy, which denotes the location of the Fossa Ovalis. The curvature of the punch can be increased or decreased by articulation to gain optimal alignment with the Fossa Ovalis. This steering function can be very beneficial in device placement.

Maintaining the position of the guiding catheter against the Fossa Ovalis, the punch is advanced distally against and through the atrial septum, in the region of the Fossa Ovalis, so that it penetrates and protrudes into the left atrium. In order to stabilize the atrial septal tissue prior to coring, a distally protruding corkscrew tipped wire or a vacuum head operably connected to the proximal end of the punch, can be used to grasp and retract the septal tissue. Once the initial penetration is completed, the guide catheter is next advanced, with its tapered obturator leading the way, across the atrial septum until it resides within the left atrium. The tapered obturator or dilator along with the punch can be removed at this time to allow for catheter placement through the guiding catheter. In another embodiment, a calibrated spacer can be used between the guide catheter hub and the punch hub to ensure that the punch does not protrude beyond the distal end of the guide catheter tip until the desired time for punching the hole. At this point, the spacer is unlocked and removed from the punch or catheter.

In another embodiment, the core wire or stylet is sharpened and serves as a tissue punch. In this embodiment, the distal end of the hollow tubes of the punch are blunted and made relatively atraumatic. Once the core wire punch has completed tissue penetration, the outer tubes are advanced over the central punch wire through the penetration and into the left atrium. In another embodiment, a pressure monitoring device such as a catheter tip pressure transducer, or a pressure line terminated by a pressure transducer, can be affixed to a quick connect, generally a Luer fitting, at the proximal end of the punch hub. By monitoring pressure, it is possible to determine when the distal end of the punch has passed from, for example, the right atrium into the left atrium, because the pressure versus time curves in these two chambers are measurably, or visually, different. The proximal end of the hub further has provision for attachment to a dye injection line for use in injecting radiographic contrast media through the central lumen of the punch. Typically a manifold can be attached to the Luer fitting on the proximal end of the hub, the manifold allowing for pressure monitoring, for example on a straight through port, and for radiopaque dye injection, for example through a side port. A stopcock, or other valve, can be used to control which port is operably connected to the central lumen of the punch.

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

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.

FIG. **1** illustrates a side view of a trans-septal punch assembled so that the inner tube is bent in a direction 180 degrees opposite that of the outer tube, resulting in a substantially straight punch configuration;

FIG. **2** illustrates a side view of the disassembled trans-septal punch showing the central core wire or stylet, the inner tube bent in one direction and the outer tube bent in another direction;

FIG. **3** illustrates a side view of the trans-septal punch assembled so that the inner tube bend is aligned in the same direction as the outer tube bend, resulting in a curved distal end on the punch assembly;

FIG. **4** illustrates a side view of a trans-septal punch comprising a flexible region proximal to the distal end and pull-wires disposed between the distal end and the proximal end of the punch;

FIG. **5** illustrates a side view of the trans-septal punch of FIG. **4** wherein one of the pull-wires is placed in tension causing the distal flexible region of the punch to deflect into an arc away from the longitudinal axis of the punch;

FIG. **6** illustrates an adjustable, spacer, which sets and maintains the distance between the distal end of the punch hub and the proximal end of a guide catheter hub.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with current terminology pertaining to medical devices, the proximal direction will be that direction on the device that is furthest from the patient and closest to the user, while the distal direction is that direction closest to the patient and furthest from the user. These directions are applied along the longitudinal axis of the device, which is generally an axially elongate structure having one or more lumens or channels extending through the proximal end to the distal end and running substantially the entire length of the device.

FIG. **1** illustrates a side view of a punch, needle, or catheter assembly **100**, with an integral articulating or bending mechanism. The punch assembly **100** comprises a stylet or obturator wire **102**, an inner tube **104**, an outer tube **106**, an obturator grasping tab **108**, a stopcock **110**, an inner tube pointer **112**, an outer tube pointer **114**, an inner tube hub **116**, and an outer tube hub **118**.

Referring to FIG. **1**, the obturator wire **102** is affixed to the obturator grasping tab **108**. The stylet or obturator wire **102** is inserted through the central lumen of the inner tube **104** and is slidably disposed therein. The stopcock **110** is affixed to the inner tube hub **116** and the through lumen of the stopcock **110** is operably connected to the central lumen of the inner tube **104**. The inner tube pointer **112** is affixed to the inner tube hub so that it is visible to the user. The outer tube pointer **114** is affixed to the outer tube hub **118** so that it is visible to the user. The inner tube hub **116** and the inner tube **104** are able to rotate about the longitudinal axis within the outer tube hub **118** and the outer tube **106**. In an embodiment, the inner tube **104** is restrained from longitudinal motion relative to the outer tube **106**. In another embodiment, the inner tube **104** can be advanced distally relative to the outer tube **106**. In this latter embodiment, advancement of the inner tube **104** can be used to facilitate punching. The distal end of the inner tube **104** can be sharpened and serve as a punch. The distal end of the inner tube **104** is sheathed inside the outer tube **106** to protect the tissue from the sharp distal edge of the inner tube **104** until the inner tube **104** is advanced distally outside the distal end of the outer tube **106**. A releaseable lock can be used to maintain the axial or longitudinal position of the inner tube **104** relative to the outer tube **106** until punching is required. A releaseable lock can further be used to maintain the rotational position of the inner tube hub **116** and thus the inner tube **104** relative to the outer tube hub **118** and the outer tube **106**.

All components of the punch assembly **100** can be fabricated from metals such as, but not limited to, stainless steel, Elgiloy™, cobalt nickel alloy, titanium, nitinol, or the like. The nitinol can be shape-memory or it can be superelastic. The metals used in the obturator wire **102**, the inner tube **104** and the outer tube **106** are advantageously cold rolled, heat treated, or otherwise processed to provide a full spring hardness. The inner tube **104**, the outer tube **106**, or both, are relatively rigid, resilient structures. Polymeric materials, such as, but not limited to, polycarbonate, ABS, PVC, polysulfone, PET, polyamide, polyimide, and the like, can also be used to fabricate the stopcock **110**, the inner tube hub **116**, the outer tube hub **118**, the inner tube pointer **112**, and the outer tube pointer **114**. The materials are beneficially radiopaque to maximize visibility under fluoroscopy during the procedure. Additional radiopaque markers fabricated from tantalum, platinum, iridium, barium sulfate, and the like can be added to improve visibility if needed. The inner tube **104** is curved or bent near its distal end into a gentle curve, preferably with a radius of between 1 to 5 inches and so that the distal tip is deflected through an angle of approximately 10 to 90 degrees from the longitudinal axis of the inner tube **104**. The outer tube **106** is curved or bent near its distal end into a gentle curve, preferably with a radius of between 1 to 5 inches and so that the distal tip is deflected through an angle of approximately 10 to 90 degrees from the longitudinal axis of the outer tube **106**. The inner tube hub **116** is welded, silver soldered, bonded, crimped, or otherwise fastened to the proximal end of the inner tube **104** so that the inner tube pointer **112** points in the direction of the bend in the inner tube **104**. The outer tube hub **118** is welded, silver soldered, bonded, crimped, or otherwise fastened to the proximal end of the outer tube **106** so that the outer tube pointer **114** points in the direction of the bend in the outer tube **106**. When the inner tube pointer **112** is oriented 180 degrees away from the direction of the outer tube pointer **114**, the bend in the inner tube **104** substantially counteracts or opposes the bend of the outer tube **106** and the coaxial assembly **100** is substantially straight, as shown in FIG. **1**. The stopcock **110** can also be a ring seal, Tuohy-Borst valve, membrane valve, hemostasis valve, gate valve, or other valve, generally, but not necessarily manually operated. The stiffness of the inner tube **104** and the outer tube **106** are sufficient that the punch can be used as a guide for other catheters through which the punch **100** is passed.

FIG. **2** illustrates a side view of a stylet or obturator **140** further comprising the obturator wire **102** and the obturator-grasping tab **108**. The obturator wire **102** is blunted at its distal end to render it as atraumatic as possible. In another embodiment, the obturator wire **102** can be tapered in diameter to render it very flexible and therefore atraumatic at its distal end. The obturator wire **102**, in another embodiment, can be sharpened and serve as a needle or primary punching mechanism. FIG. **2** also illustrates an intermediate punch assembly **120** further comprising the inner tube **104**, the stopcock **110**, the inner tube pointer **112**, the inner tube hub **116**, an inner tube seal **124**, an inner tube pointer ball **126**, a through lumen port **128**, a beveled distal tip **132**, and a pre-set curve **136**. FIG. **2** further illustrates an outer tube assembly **122** further comprising the outer tube **106**, the outer tube hub **118**, the outer tube pointer **114**, an outer tube distal curve **130**, and an outer tube pointer ball **134**.

Referring to FIG. **2**, the obturator-grasping tab **108** is affixed, either integral to, silver soldered, welded, crimped, adhered, pinned, or otherwise attached, to the proximal end of the obturator wire **102**. The inner tube **104** is affixed to the inner tube hub **116** by silver soldering, welding, potting, crimping, setscrew, pin, or other fixation method, such that the hub **116** rotates 1 to 1 with the inner tube **104**. An optional inner tube pointer ball **126** is affixed to the inner tube pointer **112** and provides additional visual and tactile rotational positioning sense for the intermediate punch or needle assembly **120**. A curve or bend **136** is heat set, or cold worked into the inner tube **104** at or near its distal end. The distal end of the inner tube **104** comprises a bevel **132** which helps serve as a punch or cutting edge for the inner tube **104**. The angle of the bevel **132** can range between 20 and 70 degrees from the direction perpendicular to the longitudinal axis of the inner tube **104**. In another embodiment, the bevel is removed and the distal tip of the inner tube **104** is a gentle inward taper or fairing moving distally that serves as a dilator should the obturator wire **102** be used as the punching device rather than the blunt distal tip obturator of the inner tube **104**. The inner tube hub **116** further comprises a circumferential groove with an “O” ring **124** affixed thereto. The “O” ring **124** serves to form a fluid (e.g. air, blood, water) tight seal with the inner diameter of the outer sheath hub **118** central lumen and allows for circumferential rotation of the inner tube hub **116** within the outer tube hub **118**. The “O” ring **124** is fabricated from rubber, silicone elastomer, thermoplastic elastomer, polyurethane, or the like and may be lubricated with silicone oil or similar materials. The stopcock **110** can be a single way or a three-way stopcock without or with a sideport, respectively.

The outer punch assembly **122** comprises the bend **130**, which is heat set or cold worked into the outer tube **106** in the same longitudinal location as the bend **136** of the inner tube. The wall thicknesses of the inner tube **104** and the outer tube **106** are chosen to provide bending forces that cancel out when the curves **136** and **130** are oriented in opposite directions and the inner tube **104** is inserted fully into the outer tube **106**. The wall thickness of the outer tube **106** and the inner tube **104** can range between 0.003 inches and 0.20 inches, preferably ranging between 0.004 and 0.010 inches. The outer diameter of the outer tube **106** can range between 0.014 and 0.060 inches and preferably between 0.025 and 0.050 inches. The outer diameter of the obturator wire **102** can range between 0.005 and 0.030 inches and preferably range between 0.010 and 0.020 inches.

FIG. **3** illustrates a side view of the punch assembly **100** fully assembled and aligned so that both the inner tube distal curve **136** (Refer to FIG. **2**) and the outer tube distal curve **130** are aligned in the same direction resulting in a natural bend out of the axis of the punch **100**. The punch assembly **100** comprises the obturator wire **102**, the inner tube **104**, the outer tube **106**, the obturator grasping tab **108**, the stopcock **110**, the inner tube pointer **112**, the outer tube pointer **114**, the inner tube hub **116**, the inner tube pointer ball **126**, and the outer tube pointer ball **134**.

Referring to FIG. **3**, the outer tube pointer **114** and inner tube pointer **112** are aligned together and in this configuration, the tubing assembly possesses its maximum curvature, which is oriented in the same directions as the pointers **112** and **114**. The pointer balls **126** and **134** are aligned together to provide additional tactile and visual indices of curvature direction. In an embodiment, the curvature of the tube assembly **104** and **106** is unbiased with no net force exerted therebetween and an angle of approximately 45 degrees is subtended by the device in the illustrated configuration. Further curvature can also occur out of the plane of the page so that the curvature takes on a 3-dimensional shape, somewhat similar to a corkscrew. In another embodiment, the curvature of the aligned inner tube **104** and the outer tube **106** subtends an angle of 90-degrees or greater. Again, the inner tube **104** and the outer tube **106** have stiffness sufficient that the assembly is capable of guiding any catheter through which the punch **100** is passed. In another embodiment, the inner tube **104** and the outer tube **106** have different degrees of curvature so that when they are aligned, a net force still is generated between the two tubes, although a maximum curvature configuration is still generated. This embodiment can be advantageous in permitting articulation in a direction away from the direction of primary curvature.

The radius of curvature of the punch **100** can range from substantially infinity, when straight, to as little as 0.5-cm, with a preferred range of infinity to as little as 2-cm radius when fully curved or articulated. One embodiment permits a substantially infinite to a 3-cm radius of curvature. The overall working length of the punch, that length from the proximal end of the outer tube hub to the distal most end of the punch, can range from 10 to 150-cm and preferably between 60 and 100-cm, with a most preferred range of between 70 and 90-cm. A preferred curve has a radius of about 3-cm and is bent into an arc of about 45 to 90 degrees.

FIG. **4** illustrates a side view of another embodiment of a needle or punch assembly **400** comprising an obturator wire **102**, an obturator wire grasping tab **108**, a stopcock **110**, an inner tube **404**, an outer tube **406**, a plurality of deflecting wires **412**, an outer tube hub **414**, a deflecting lever **416**, a weld **420**, an axis cylinder **424**, a plurality of deflecting wire channels **426**, and a flexible region **430**. The distal end of the region just proximal to the flexible region **430** is shown in breakaway view. Furthermore, the distal end of the region just proximal to the flexible region **430** as well as the flexible region **430** has been expanded in scale so that certain details are more clearly visible.

Referring to FIG. **4**, the flexible region **430** is affixed to the outer tube **406** by a weld **420**. The flexible region **430** can also be fixed to the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. The attachment between the flexible region **430** and the outer tube **406** is made at the proximal end of the flexible region **430** and a second attachment or weld **420** can be made at the distal end of the flexible region **430** so as to attach to a length of distal outer tube **406**. The flexible region **430** can comprise a length of coiled wire such as that used in guidewires, it can be a tube that comprises cutouts to provide a backbone configuration to impart flexibility, it can be a length of polymeric tube with elastomeric characteristics, or it can be another type of structure that is known in the art as providing flexibility. These preferred structures also advantageously provide column strength and kink resistance to the flexible region **430**. The center of the flexible region **430** is hollow and comprises a lumen, which is operably connected to the central lumen of the outer tube **406** at both the proximal and distal end of the flexible region **430**. The stopcock **110** is affixed, at its distal end, to the outer tube hub **414**. The outer tube hub **414** further comprises a deflecting lever **416** that is affixed to the axis cylinder **424**, which serves as an axle or rotational pin, and can be moved proximally or distally by manual action on the part of the operator or by a motor or other electromechanical actuator (not shown). The deflecting lever **416** is operably connected to the proximal ends of the deflecting wires **412**. In an exemplary embodiment, one of the deflecting wires **412** is affixed to the top of the axis cylinder **424** and the other deflecting wire is affixed to the bottom of the axis cylinder **424**. When the deflecting lever is pulled proximally, for example, the top wire **412** is placed under tension and the tension on the bottom wire is relieved causing tension to be exerted on the distal end of the punch **400**. The deflecting wires **412** are slidably routed through the deflecting wire channels **420** within the outer tube **406**. The deflecting wires **412** also run through the deflecting wire channels **420** within the flexible region **430**. The deflecting wires **412** can also be routed through the internal lumen of the outer tube **406** and the flexible region **430**.

Referring to FIG. **4**, the outer tube hub **414** is affixed to the proximal end of the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. The inner tube **404** is affixed to the distal end of the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. In another embodiment, the inner tube **404** is routed throughout the length of the outer tube **406**. In this embodiment, the inner tube can comprise grooves (not shown) that serve as deflecting wire channels **420** when the inner tube **404** is inserted inside the outer tube **406**. Such grooves can also be disposed on the interior surface of the outer tube **406**, rather than on the exterior surface of the inner tube **404**. The obturator wire **102** and the attached grasping loop **108** are slidably disposed within the inner lumen of the outer tube **406**, or the inner tube **404**. The inner tube **404** is gently tapered up to the outer tube **406** at the distal end of the outer tube **406** in a transition region so that a dilator effect can be created during distal advancement of the punch **400**. The distal end of the inner tube **404** can comprise a bevel **132** (FIG. **2**) or other sharp point for punching through biological tissue. The distal end of the inner tube **404** preferably forms a non-coring needle or punch that does not excise a tissue sample. The non-coring punch feature is achieved by keeping the central lumen closed or very small. The non-coring punch **400** embodiment can comprise filling the lumen of the inner tube **404** with the obturator or stylet wire **102** to prevent the sharp edge of the inner tube from functioning as a trephine.

FIG. **5** illustrates a side view of the punch assembly **400** wherein the deflecting lever **416** has been withdrawn proximally causing increased tension in one of the deflecting wires **412**, causing the flexible region **430** to bend **422** out of the longitudinal axis. The punch assembly **400** further comprises the obturator wire **102**, the obturator wire grasping tab **108**, the stopcock **110**, the deflecting lever **416**, an axis cylinder **424**, the hub **414**, the outer tube **406**, the inner tube **404**, and the bend **422**.

Referring to FIG. **5**, the deflecting lever **416** has been moved proximally and the axis cylinder **424** causing the top deflecting wire **412** to be placed in tension while the bottom deflecting wire **412** is relaxed. The deflecting wires **412** are affixed at their distal end to the outer tube **406** or the inner tube **404** at a point substantially at or beyond the distal end of the flexible region **420**. The distal fixation point (not shown) of the deflecting wires **412** is off-center from the axis of the outer tube **406** or inner tube **404**. When uneven tension is created in the opposing deflecting wires **412**, the uneven tension on the distal end of the punch **400** causes the bendable region **430** to undergo deflection into a curve or bend **422**. Similarly, forward movement of the deflecting lever **416** will place the bottom deflecting wire **412** in tension while the upper deflecting wire **412** will be relaxed, causing the punch **400** to undergo a bend in the opposite direction (downward). The deflecting lever **416** can further comprise a ratchet and lock, a friction lock, a spring-loaded return, or other features to hold position or cause the lever and the bendable region **430** to return to a neutral deflection configuration (substantially straight). The spring nature of the outer tube **406** and the bendable region **430** can advantageously be used to cause a return to neutral once the deflection force is removed from the deflecting lever **416**. The stylet or obturator wire **102** can be withdrawn or extended to expose or protect (respectively) the distal end of the inner tube **404** which can be sharpened or blunted. The obturator wire **102** can further be used as the primary punch, especially if the distal tip of the obturator wire **102** is sharpened. If the obturator wire **102** is used as the primary punch, the proximal end of the inner tube hub is fitted with a Tuohy-Borst or other hemostatic valve to permit the obturator wire **102** to remain in place. In this embodiment, sidearms affixed proximal to the proximal end of the punch, and operably connected to the central lumen, serve to permit pressure monitoring and dye contrast injection without compromising hemostasis or air entry into the punch assembly **400**.

FIG. **6** illustrates a side view of an adjustable spacer **600** interconnecting a guide catheter **620** and a punch assembly **100**. The spacer **600** further comprises a proximal connector **602**, a rotating nut **604**, an inner telescoping tube **608**, a threaded region **606**, a distal locking connector **610**, and an outer telescoping tube **614**. The guide catheter further comprises a tube **622**, a hub **624**, and a proximal connector **626**. The punch assembly **100** further comprises the stopcock **110**, the distal rotating locking connector **612**, the inner tube pointer **112**, the outer tube pointer **114**, and the inner tube hub **116**. The spacer **600** can comprise an optional slot **630**.

Referring to FIG. **6**, the punch assembly **100** is inserted through the central lumen of the adjustable spacer **600**. The distal end of the punch assembly **100** is then inserted through the central lumen of the guide catheter **620**. The hub **624** of the guide catheter **620** is affixed to the proximal end of the guide catheter tube **622**. The distal end of the hub **624** comprises a female Luer lock connection, which is bonded to, or integrally affixed to the hub **624**. The hub **624** can further comprise a seal or hemostasis valve such as a Tuohy-Borst fitting. The punch **100** hub **116** is terminated at its distal end by a swivel male Luer lock connector **612**. The adjustable spacer **600** comprises an outer telescoping tube **614**, shown in partial cutaway view that is terminated at its proximal end with a female Luer lock **602**. The proximal end of the outer telescoping tube **614** has a flange that permits rotational attachment of the rotating nut **604**, shown in partial cutaway view, so that the rotating nut is constrained in position, longitudinally, relative to the outer telescoping tube **614** but is free to rotate. The inner telescoping tube **608** is affixed at its distal end with a swivel male Luer connector **610**, or equivalent. The proximal end of the inner telescoping tube **608** is affixed to, or comprises, the integral threaded region **606**. The threaded region **606** mates with the internal threads on the rotating nut **604**. As the rotating nut **604** is rotated, either manually or by an electromechanical device, it moves forward or backward on the inner telescoping tube **608** and threaded region **606** thus changing the space between the hub **116** of the punch **100** and the proximal end of the hub **624** of the guide catheter **620**. The system is preferably set for spacing that pre-sets the amount of needle or stylet travel. In an embodiment, the rotating nut **604** comprises a quick release that allows disengagement of the inner telescoping tube **608** from the outer telescoping tube **614** so that collapse is permitted facilitating the tissue punching procedure of advancing the punch **100** distally relative to the hub **624**. The system further comprises hemostatic valves at some, or all, external connections to prevent air leaks into the punch **100**. The telescoping tube **608** can be set to disengage from the outer telescoping tube **614** to allow for longitudinal collapse so that the punch **100** can be advanced distally to provide its tissue punching function. In another embodiment, the spacer **600** comprises the slot **630** that permits the spacer to be removed sideways off the punch **100**. The slot **630** is wide enough to allow the outer tube **106** to fit through the slot **630** so the spacer **600** can be pulled off, or removed from, the punch **100** prior to the punching operation. Thus, the slot **630** can be about 0.048 to 0.060 inches wide and extend the full length of the spacer **600**. With the slot **630**, the spacer **600** comprises a generally "C-shaped" lateral cross-section. The spacer **600** can further comprise a slot closure device (not shown) to prevent inadvertent removal of the punch **100**.

In another embodiment, the threaded region **606** and the rotating nut **604** are replaced by a friction lock on telescoping tubes, a ratchet lock, or other suitable distance locking mechanism. In yet another embodiment, a scale or series of markings (not shown) is incorporated into the adjustable spacer **600** to display the exact distance between the proximal end and the distal end of the spacer **600**. In another embodiment, the proximal end and the distal end of the spacer **600** do not comprise one or both of the female Luer lock **602** or the rotating male Luer lock **610**. In this embodiment, the spacer **600** provides positional spacing but does not affix the punch **100** to the guide catheter **620** so that the two devices move longitudinally as a unit. In another embodiment, the pull wires **412** of FIG. **4**, which are strong in tension but cannot support compression are replaced by one or more control rods, which are flexible but which have column strength. Thus, deflection can be generated by imparting either tension on the control rod or compression and such tension and compression is capable of deflecting the distal tip of the punch **400** without the need of a separate control rod to impart tension in the other direction. The inner tube hub **116** is terminated at its proximal end by a female Luer, Luer lock, threaded adapter, bayonet mount, or other quick release connector. The quick connect or female Luer can be releasably affixed to a hemostasis valve, other stopcock, pressure transducer system, "Y" or "T" connector for pressure and radiopaque contrast media infusion, or the like.

In another embodiment, a vacuum line can be connected to a port affixed to the proximal end of the punch. The port can be operably connected to a bell, cone, or other structure at [he] the distal end of the punch by way of a lumen, such as the central lumen of the inner tube or an annulus between the intermediate and outer tube, within the punch. By application of a vacuum at the proximal end of the punch, the distal structure can be releasably secured to the atrial septum prior to punching through. In another embodiment, a corkscrew structure projects out the distal end of the punch and is operably connected to a knob or control at the proximal end of the punch by way of a control rod slidably or rotationally free to move within a lumen of the punch. The corkscrew structure can be screwed into tissue to releasably secure the distal end of the punch to the tissue, for example, to enhance stability of the punch prior to, during, or after the punching operation.

Referring to FIG. **1**, in another embodiment, the inner tube **104**, the outer tube **106**, or both, are fabricated from shape memory nitinol. In this embodiment, electrical energy can be applied to the pre-bent regions of the inner tube **104**, the outer tube **106**, or both. Upon application of electrical energy, Ohmic or resistive heating occurs causing temperature of the tubes to increase. The nitinol changes its state from martensitic to austenitic, with the increase in temperature, and can assume a pre-determined configuration or stress state, which is in this case curved. The austenite finish temperature for such a configuration is approximately 40 degrees centigrade or just above body temperature. In yet another embodiment, the austenitic finish temperature can be adjusted to be approximately 28 to 32 degrees centigrade. The punch **100** can be maintained at room temperature where it is substantially martensitic and non-rigid. Upon exposure to body temperatures when it is inserted into the core lumen of the guide catheter, it will assume its austenitic shape since body temperature is around 37 degrees centigrade. This can cause the punch **100** to curve from substantially straight to substantially curved. In this configuration, only a single tube, either the inner tube **104** or the outer tube **106** is necessary, but both tubes, while potentially beneficial, are not required.

The punch can be used to create holes in various structures in the body. It is primarily configured to serve as an articulating or variable deflection Brockenbrough needle. However, the steerable punch can be used for applications such as transluminal vessel anastomosis, biopsy retrieval, or creation of holes in hollow organs or lumen walls. The punch can be used in the cardiovascular system, the pulmonary system, the gastrointestinal system, or any other system comprising tubular lumens, where minimally invasive access is beneficial. The punch can be configured to be coring or non-coring in operation, depending on the shape of the distal end and whether an obturator or the circular hollow end of the punch is used to perform the punching operation. In the coring configuration, a plug of tissue is removed, while in the non-coring configuration, substantially no tissue is removed from the patient. The punch facilitates completion of transseptal procedures, simplifies routing of the catheters, minimizes the chance of embolic debris being dislodged into the patient, and improves the ability of the cardiologist to orient the punch for completion of the procedure. The punch of the present invention is integral and steerable. It is configured to be used with other catheters that may or may not be steerable, but the punch disclosed herein does not require external steerable catheters or catheters with steerability to be steerable as it is steerable or articulating on its own. The punch is capable of bending and unbending a practically unlimited number of times. The punch is especially useful with catheters that are not steerable since the punch comprises its own steering system.

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. For example, the deflecting wires **412** can be replaced by an electromechanical actuator and external control unit. 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.

I claim:

1. A transseptal punch system for penetrating the atrial septum of a patient, said system comprising:

a guide catheter adapted for insertion into the right atrium of a patient's heart, said guide catheter characterized by a distal end, a proximal end, and a guide catheter lumen extending from the distal end to the proximal end;

a transseptal punch, said transseptal punch having a distal end and a proximal end, said transseptal punch fitting within the guide catheter lumen and being longitudinally advanceable within the guide catheter, said punch comprising:

an outer tube, said outer tube characterized by a distal end and a proximal end, and an outer tube lumen extending from the distal end to the proximal end thereof, said outer tube having a flexible region near the distal end of the outer tube;

a control rod disposed within the outer tube, said control rod characterized by a distal end and a proximal end;

wherein the control rod is fixed to the distal end of the outer tube; and

an inner tube fixed to the distal end of the outer tube, said inner tube having a sharp point for penetrating the atrial septum of the patient; wherein

the control rod is fixed to the distal end of the outer tube at a point distal to the flexible region and off-center relative to a longitudinal axis of the outer tube.

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