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(71) Applicant *(for all designated States except US)*: **PRESSURE PRODUCTS MEDICAL SUPPLIES, INC.** [US/US]; 1861 North Gaffey Street, Suite B, San Pedro, CA 90731 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **KURTH, Paul** [US/US]; 49 Via Alicia, Santa Barbara, CA 93108 (US). **ARMOUR, Andrew, W.** [US/US]; 20 Woodbrook Lane, Swarthmore, PA 19081 (US).

(74) Agent: **COHEN, Joshua, L.**; RatnerPrestia, P.O. Box 980, Valley Forge, PA 19482 (US).

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(54) **Title:** APPARATUS, SYSTEM, AND METHOD FOR SHIELDING THE SHARP TIP OF A TRANSSEPTAL GUIDEWIRE

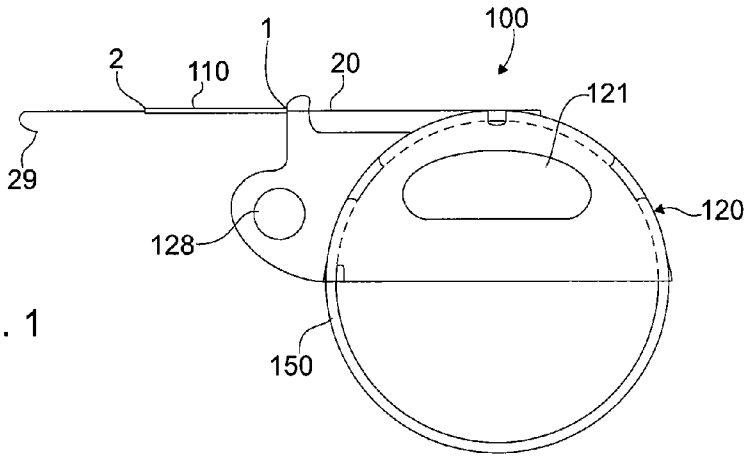

FIG. 1

(57) **Abstract:** Apparatus, system, and methods for introducing a sharp tip (29) of a transseptal guidewire (20) through a hub (60) of a transseptal needle (80) and into a lumen (81) of a transseptal needle (80) are provided. The apparatus (100) includes a holder (150) that contains the transseptal guidewire and a shield (110) coupled to the holder. The shield has a wall (111) defining a lumen (115) that accommodates the sharp tip (29) of the transseptal guidewire (20). The cross-sectional shape of the wall is substantially constant along at least a portion of its length and sized to fit within the lumen (81) of the transseptal needle (80), thereby inhibiting contact between the sharp tip (29) of the transseptal guidewire and the hub of the transseptal needle (80) when the wall of the shield is positioned to extend into the lumen of the transseptal needle. The lumen (115) of the shield (110) has a substantially constant cross-sectional area along at least a portion of its length and an outer surface of the wall (111) of the shield is cylindrical along the same length.

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APPARATUS, SYSTEM, AND METHOD FOR SHIELDING THE SHARP TIP OF A TRANSSEPTAL GUIDEWIRE

CROSS REFERENCE TO RELATED APPLICATIONS

This PCT application claims priority of U.S. non-provisional application Serial No. 12/015,097, filed January 16, 2008, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to surgical equipment. More particularly, the present invention relates to apparatus, systems, and methods for introducing the sharp tip of a transseptal guidewire into a lumen of a transseptal needle while inhibiting contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle.

BACKGROUND OF THE INVENTION

Guidewires are typically used to navigate catheters. For example, U.S. Patent Application Publication No. 2004/0073141 describes a guidewire that assists with endovascular deployment. The guidewire has a J curve and atruamatic tip to prevent damage to tissue. Introducers can be used to straighten the tips of such guidewires. For example, U.S. Patent Nos. 5,125,905 and 5,282,479 relate to a guidewire straightener and protective tube to introduce a catheter into a patient's blood vessel.

Transseptal introducer systems are typically used to introduce Brockenbrough needles or other puncture devices into the heart of a patient to perforate the intra-atrial septum. For example, a transseptal guidewire is described in U.S. Patent Application Serial No. 11/875,365, which is incorporated herein in its entirety by reference. The transseptal guidewire differs from conventional guidewires at least in that it has a tip that is sharp enough to puncture the septum, thereby providing a puncture device. Although the transseptal guidewire represents an improvement over prior puncture devices, damage to the sharp tip of the transseptal guidewire could render it unsuitable for use or require the surgeon to apply extra force to puncture the intra-atrial septum. For example, the sharp tip of the transseptal guidewire may be inadvertently damaged as it is introduced into the lumen of a transseptal needle through a hub of the needle or may be difficult to introduce into the lumen of the transseptal needle.

Accordingly, there remains a need for an apparatus, system and method for introducing the sharp tip of a transseptal guidewire into a lumen of a transseptal needle while inhibiting damage to the sharp tip of the transseptal guidewire.

SUMMARY OF THE INVENTION

In one aspect, the invention provides an apparatus for introducing a sharp tip of a transseptal guidewire through a hub of a transseptal needle and into a lumen of a transseptal needle while inhibiting damage to the sharp tip of the transseptal guidewire. The apparatus includes a holder configured to contain the transseptal guidewire and a shield coupled to the holder. The shield has a wall defining a lumen sized to accommodate the sharp tip of the transseptal guidewire. The cross-sectional shape of the wall is substantially constant along at least a portion of its length and is sized to fit within the lumen of the transseptal needle, thereby inhibiting contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle when the wall of the shield is positioned to extend into the lumen of the transseptal needle. The lumen of the shield has a substantially constant cross-sectional area along at least a portion of its length between proximal and distal ends of the shield, thereby facilitating insertion of the sharp tip of the transseptal guidewire through the lumen of the shield. An outer surface of the wall of the shield is cylindrical along at least a portion of its length between the proximal and distal ends of the shield, thereby facilitating insertion of the shield through the lumen of the transseptal needle to a point distal of the needle's hub and/or eliminating resistance between an outer surface of the shield and the inner surface of the lumen of the transseptal needle.

In another aspect, a system for perforating an intra-atrial septum is provided. The system includes a transseptal needle having proximal and distal ends, a hub positioned at the proximal end, and a lumen extending from the hub to the distal end. The system also includes a transseptal guidewire having a sharp tip sized to extend through the lumen of the transseptal needle. A holder at least partially contains the transseptal guidewire, and a shield is coupled to the holder. The shield has a wall defining a lumen sized to accommodate the sharp tip of the transseptal guidewire. The transseptal guidewire has a retracted position in which the sharp tip of the transseptal guidewire is contained within the lumen of the shield and an extended position in which the sharp tip of the transseptal guidewire extends distally from the shield and into the lumen of the transseptal needle. The shield has a first position in which the distal end of the shield does not extend into the lumen of the transseptal needle and a second position in which the distal end of the shield extends into the lumen of the transseptal

needle to a position that is distal of the hub of the transseptal needle. The transseptal guidewire is in the retracted position when the shield is in the first position, and the transseptal guidewire is moved to the extended position when the shield is in the second position, thereby inhibiting contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle or the proximal end of the transseptal needle when the shield is in the second position.

According to yet another aspect, a method of shielding a sharp tip of a transseptal guidewire as it is introduced into a transseptal needle from a dispenser is provided. The method includes inserting a tip of a shield of the dispenser through a hub of the transseptal needle and into a lumen of the transseptal needle. The tip of the shield is then advanced to a point in the lumen distal of the hub without restriction. The sharp tip of the transseptal guidewire is introduced from a lumen of the shield of the dispenser and into the lumen of the transseptal needle at the point in the lumen distal of the hub, thereby avoiding contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle or a proximal end of the transseptal needle and associated damage to the sharp tip of the transseptal guidewire.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawings, with like elements having the same reference numerals. This emphasizes that according to common practice, the various features of the drawings are not drawn to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

FIG. 1 is a plan view of a transseptal guidewire dispenser assembly according to an exemplary embodiment of the present invention;

FIG. 2 is a perspective view of an embodiment of a transseptal guidewire of the transseptal guidewire dispenser assembly shown in FIG. 1;

FIG. 3 is a plan view of an embodiment of a handle component of the transseptal guidewire dispenser assembly shown in FIG. 1, illustrated in an unfolded condition;

FIG. 4 is a plan view of a portion of the transseptal guidewire dispenser assembly shown in FIG. 1, illustrating an end portion of the transseptal guidewire in a stored position;

FIG. 5 is a plan view of a portion of the transseptal guidewire dispenser assembly shown in FIG. 1, illustrating an end portion of the transseptal guidewire being retracted into a holder component of the transseptal guidewire dispenser;

FIG. 6 is a plan view of an exemplary embodiment of a transseptal guidewire system including the transseptal guidewire dispenser assembly illustrated in FIG. 1 and a transseptal needle;

FIG. 7 is an enlarged plan view of the transseptal guidewire system shown in FIG. 6;

FIG. 8A is a cross-sectional side view of a shield component of the transseptal guidewire dispenser, the cross-section being taken along lines 8A-8A shown in FIG. 8B; and

FIG. 8B is a cross-sectional end view of the shield component shown in FIG. 8A, the cross-section being taken along lines 8B-8B shown in FIG. 8A.

DETAILED DESCRIPTION OF THE INVENTION

Although the invention is illustrated and described herein with reference to specific embodiments, the invention is not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the invention.

Referring generally to the drawings (FIGs. 1-8B), in accordance with one exemplary embodiment, the invention provides a transseptal guidewire dispenser 100, shown assembled with a transseptal guidewire 20 in FIG. 1, for introducing a sharp tip 29 of the transseptal guidewire 20 through a hub 60 of a transseptal needle 80 and into a lumen 81 of the transseptal needle 80. The dispenser 100 includes a holder 150 that contains the transseptal guidewire 20 and a shield 110 coupled to the holder 150. Shield 110 has a wall 111 defining a lumen 115 that is sized to accommodate the sharp tip 29 of the transseptal guidewire 20. The cross-sectional shape of the wall 111 is substantially constant along at least a portion of its length and is sized to fit within the lumen 81 of the transseptal needle 80, thereby inhibiting contact between the sharp tip 29 of the transseptal guidewire 20 and the hub 60 of the transseptal needle 80 when the wall 111 of the shield 110 is positioned to extend into the lumen 81 of the transseptal needle 80. The lumen 115 of the shield 110 has a substantially constant cross-sectional area along at least a portion of its length between proximal 1 and distal 2 ends of shield 110, thereby facilitating insertion of the sharp tip 29 of the transseptal guidewire 20 through the lumen 115 of the shield 110. An outer surface of the wall of the shield 110 is substantially cylindrical along at least a portion of its length between

the proximal 1 and distal ends 2 of the shield 110, thereby facilitating insertion of the shield 110 through the lumen 81 of the transseptal needle 80.

According to another aspect of the invention, an exemplary embodiment of a method for shielding a sharp tip 29 of a transseptal guidewire 20 as it is introduced into a transseptal needle 80 is provided. The tip 2 of the shield 110 is inserted through the hub 60 and into the lumen 81 of the transseptal needle 80. The tip 2 of the shield 110 is then advanced to a point in the lumen 81 distal of the hub 60 without restriction. The sharp tip 29 of the transseptal guidewire 20 is introduced from the lumen 115 of the shield 110 of the dispenser 100 and into the lumen 81 of the transseptal needle 80 at the point in the lumen 81 distal of the hub 60, thereby avoiding contact between the sharp tip 29 of the transseptal guidewire 20 and the hub 60 of the transseptal needle 80 or a proximal end of the transseptal needle 80 and associated damage to the sharp tip 29 of the transseptal guidewire 20.

Referring now to the drawings in detail, FIG. 1 illustrates the transseptal guidewire dispenser 100 assembled with the transseptal guidewire 20. Dispenser 100 is used to dispense the transseptal guidewire 20 so it may be advanced into the lumen (81, FIG. 6) of the transseptal needle (80, FIG. 6) for performing a surgical procedure. The guidewire 20 and transseptal needle 80 may be inserted into a sheath and then introduced through a patient's vein into the heart so the sharp tip 29 of the guidewire 20 may be used to puncture the intra-atrial septum.

As shown in FIG. 2, the transseptal guidewire 20 includes an elongated body 22, an end section 26, and a tapered distal section 28. The tapered distal section 28 terminates at the pointed tip 29 at the distal end of transseptal guidewire 20. In an exemplary embodiment, when transseptal guidewire 20 is positioned fully within a transseptal needle, transseptal guidewire 20 retains a substantially straight configuration. When end section 26 is not otherwise supported, it flexes to a curved conformation such as that shown for illustration purposes in FIG. 2. Thus, in use, when the distal end of the transseptal needle contacts the intra-atrial septum of a patient, transseptal guidewire 20 may extend so that pointed tip 29 perforates the intra-atrial septum and is positioned in the left atrium of the heart. As transseptal guidewire 20 continues along its path along axis A-A into the left atrium, end section 26 curves into a non-traumatic conformation so that the lateral wall of the left atrium is not exposed to pointed tip 29. Preferably, the tip 29 is sufficiently flexible so that it does not need the optional curve to be atraumatic.

A portion of end section 26 is ovalized such that end section 26 has a substantially non-circular cross section. Portion 24, however, has a substantially circular cross section relative to end section 26. In one embodiment, portion 24 is an

imagable section having at least one radiopaque marker 25. Further details of transseptal guidewire 20 and methods for using transseptal guidewire 20 are described in U.S. Patent Application Serial No. 11/875,365, which is incorporated herein in its entirety by reference.

Referring again to FIG. 1, dispenser 100 includes a holder 150 that has a lumen to contain the transseptal guidewire 20. Holder 150 is optionally provided in the form of a tube but may be any structure capable of holding or supporting at least a portion of the transseptal guidewire 20. According to an exemplary embodiment, holder 150 may have various diameters or sizes to accommodate guidewires 20 of different lengths and sizes. Guidewire 20 may be coiled within holder 150 to provide a compact dispenser 100. Holder 150 has a cross-sectional diameter that can accommodate guidewires 20 of different thicknesses so guidewire 20 may be slid in or out of the holder 150 as needed to advance or retract the guidewire 20 from holder 150.

According to an exemplary embodiment, holder 150 may be made out of a polymer or co-polymer such as high-density polyethene, low-density polyethylene, polyetherblockamide, nylon, polystyrene, or other suitable plastic material. The preferred material is high-density polyethylene. In other embodiments, holder 150 may be made out of any material that can be easily sterilized such as by the application of heat, chemicals, or irradiation prior to packaging or use before surgery. After surgery, it is contemplated that the entire dispenser 100 and guidewire 20 may be disposed, but the dispenser 100 and/or guidewire 20 can also be configured for sterilization and reuse.

Referring now to FIG. 1, 8A, and 8B, dispenser 100 also includes the shield 110 that is coupled to holder 150 by means of a handle component 120. In another embodiment, shield 110 may be directly coupled to holder 150. Shield 110 has a wall 111 defining a lumen 115 that is sized to accommodate transseptal guidewire 20. The cross-sectional shape of the wall 111 is constant or substantially constant along its length and sized to fit within the lumen 81 (FIG. 6) of the transseptal needle 80 (FIG. 6). An outer surface of the wall 111 of the shield 110 is cylindrical along its length between the proximal 1 and distal 2 ends of the shield 110 such that the outer diameter OD of wall 111 may be constant or substantially constant and sized to fit within the lumen 81 of the transseptal needle 80.

According to an exemplary embodiment, shield 110 may be flexible so it may be manipulated for insertion into the lumen 81 of the transseptal needle 80 or so that it may be bent in a packaged or stored configuration (FIG. 4) or partially bent (FIG. 5) to facilitate insertion into the hub and lumen of the needle. For example, the shield 110 may be made from a flexible rubber or polymer. Materials such as

polyetherblockamide, polyurethane, polystyrene, high-density or low-density polyethylene, polyetherether ketone, polycarbonate, or nylon may be used though the preferred material is polycarbonate. It is contemplated that other polymeric or metallic or alternative materials for shield 110 may also be used.

As further illustrated in FIG. 1, a portion of transseptal guidewire 20 is inserted through the shield 110 such that a gap 135 (FIG. 4) exists between holder 150 and shield 110 to provide access to transseptal guidewire 20 for finger manipulation. Transseptal guidewire 20 has a J-shaped end portion near tip 29 that extends beyond shield 110. According to an exemplary embodiment, tip 29 is flexible so that when guidewire 20 is retracted into holder 150, the tip 29 may straighten in shield 110. This prevents the sharp tip 29 from contacting the hub 60 of the transseptal needle 80, shown in FIG. 6, as the sharp tip 29 is advanced into the lumen 115 of the shield 110, thereby minimizing or preventing damage to the tip 29. In another embodiment, sharp tip 29 is substantially straight such that when transseptal guidewire 20 is advanced or retracted from holder 150, the tip 29 does not contact the wall 111 of shield 110.

As shown in FIG. 1, dispenser 100 also includes a handle component 120. Handle component 120 is coupled to holder 150, but can be optionally excluded from dispenser 100 as well or formed integrally with holder 150. Handle component 120 includes a handle opening 121 and finger opening 128 so that dispenser 100 may be easily transported and held in placed during surgery. According to an exemplary embodiment, handle component 120 may be molded plastic or cut from a sheet of material and separately attached to dispenser 100. According to an exemplary embodiment, handle component 120 may be made out of a polymer or co-polymer such as high-density polyethene, low-density polyethylene, polyetherblockamide, nylon, polystyrene, polycarbonate, glycol-modified polyethylene terephthalate (PETG), or other suitable plastic material. The preferred material is PETG. Handle component 120 made also be made from other materials such as medical grade high density paper. It is contemplated that handle component 120 may be made from other materials as well. Additional aspects of the handle component 120 will be described in detail below.

Referring again to FIG. 2, aspects of the transseptal guidewire 20 are described in further detail. Transseptal guidewire 20 is configured to perforate the intra-atrial septum of the heart and is disposed within holder 150 so that transseptal guidewire 20 is reciprocally and axially moveable within holder 150. If necessary, the transseptal guidewire 20 can be rotated as well. Transseptal guidewire 20 has a length longer than transseptal needle (80, FIG. 6) and a diameter sized to fit through the lumen of commercially available transseptal needles.

As mentioned above, transseptal guidewire 20 includes an elongated body 22, an end section 26, and a tapered distal section 28. The tapered distal section 28 terminates at the pointed tip 29 at the distal end of transseptal guidewire 20. In an exemplary embodiment, when transseptal guidewire 20 is positioned fully within shield 110, transseptal guidewire 20 retains a substantially straight configuration. When transseptal guidewire 20 extends through the distal end of shield 150 along longitudinal axis A-A (FIG. 2), end section 26 is no longer supported within shield 150 and flexes to a curved conformation shown in FIG. 2.

As also illustrated in FIG. 2, elongated body 22 of transseptal guidewire 20 has a portion 24 proximal of end section 26. Portion 24 has a substantially circular cross section relative to end section 26. In an embodiment, portion 24 is an imagable section 24 having radiopaque markers 25 coupled to the imagable section 24. Radiopaque markers 25 may be made of a platinum/iridium alloy that emit low level radiation to the area surrounding imagable section 24 to assist with imaging of the operative area. In an exemplary embodiment, when a portion of imagable section 24 extends into the left atrium from the perforation hole (not shown), radioactive imaging of radiopaque markers 25 may confirm successful perforation of the intra-atrial septum. Radiopacity of markers 25 is generally equal or greater than transseptal needle 20, thus eliminating the need for radioscopy fluid solution.

Referring now to FIG. 3, the handle component 120 of dispenser 100 is illustrated in an unfolded condition. Handle component 120 includes a wall 126 that may be folded over to provide a handle opening 121 for dispenser 100. Handle component 120 includes tabs 123a-c that also fold over and engage slots 124a-c to attach handle component 120 to holder 150. Handle component 120 also includes an extension 122 configured to support a portion of transseptal guidewire 20. A flap 122a adjacent extension 122 may be folded about the vertical fold line with respect to extension 122 to provide an aperture through which the shield 110 can be inserted and mounted. As shown in FIGs. 4-6, flap 122a may be bonded at 129 to extension 122 in at least one location to provide the aperture through which the shield 110 may be mounted. According to an exemplary embodiment, bonds 129 may be formed using conventional techniques such as heat bonding, ultrasonic bonding, gluing, or pressure bonding. Other bonding methods may also be used. Shield 110 is coupled to extension 122 to facilitate insertion of guidewire 20 into a lumen of transseptal needle (80, FIG. 6) while inhibiting damage to the sharp tip 29 of transseptal guidewire 20, as will be described in greater detail below.

Shield 110 is attached to extension 122 by adhesive, heat bond, ultrasonic bond, or other attachment means, depending on the materials of the shield 110 and

the handle component 120. As described above, handle component 120 is optionally die cut from a sheet of material such as a polymeric material, vacuum formed, molded, or produced in other known manners. It is then folded in half about the holder 150 along the broken horizontal lines shown in FIG. 3. The tabs 123a-c are then folded over along the broken lines and inserted into the corresponding slots 124a-c to form the handle. The resulting handle component 120 has finger openings 128 so that the dispenser 100 can be grasped by the user during a surgical procedure.

Referring now to FIGs. 4-6, use of the dispenser 100 is illustrated. Specifically, FIGs. 4-6 illustrate a dispensing system in various positions, including a stored position in which the dispenser 100 with transseptal guidewire 20 can be packaged for sale, shipment, and storage (FIG. 4); a preparatory position in which the transseptal guidewire 20 is moved from the stored position toward a position in which the tip 29 will be shielded within the shield 110 (FIG. 5); and an extended position in which the tip 29 of transseptal guidewire 20 is extended from the distal end 2 of the shield 110 and advanced into the lumen 81 of the transseptal needle 80. Together, the dispenser 100, the transseptal guidewire 20, and the transseptal needle 80 form a dispenser system.

Referring specifically to FIG. 4, to inhibit damage, protect the sterile package, and retain the curvature of the J-shaped tip 29 of transseptal guidewire 20 during shelf-life, a distal portion of guidewire 20 is engaged onto a tab 125 of handle component 120 outside of the shield 110. When transseptal guidewire dispenser 100 is in use, guidewire 20 is first disengaged from tab 125 of handle component 120 and retracted into shield 110 in a direction indicated by the arrow shown in FIGs. 4 and 5.

Referring now to FIG. 6, when the pointed tip 29 of transseptal guidewire 20 is positioned within the lumen of shield 110, a portion of shield 110 is then inserted into a transseptal needle 80 such that the distal end surface 2 of shield 110 lies in a plane that is transverse to the lumen of transseptal needle 80 and distal of the hub 60 of the needle. In the illustrated cross-section of transseptal needle 80, hub 60 includes a tapered chamber through which the shield 110 may be inserted. The cross-sectional shape of the shield 110 is substantially constant and sized to fit within the lumen of transseptal needle 80. For example, the outer diameter of shield 110 may be smaller than the inner diameter of the transseptal needle lumen so it may fit inside transseptal needle 80. Thus, when guidewire 110 is positioned to extend into the lumen of transseptal needle 80 in a direction shown by the illustrated arrow in FIG. 6, contact is inhibited or prevented between the sharp tip 29 of transseptal guidewire 20 and hub 60.

Referring now to FIG. 7, an enlarged view of the transseptal needle 80 and hub 60 is illustrated. Hub 60 optionally includes a flange 65 that may be positioned against a portion of handle component 120 to align shield 110 with a distal position within the lumen 81 of the transseptal needle 80. In other words, the handle component 120 may be provided with a surface, such as portion 122 of the handle component 120, to restrict the depth that shield 110 can be inserted into the needle hub 60. The handle may or may not come into contact with the flange 65 or have any surface positioned to contact the flange 65 of the hub 60. In this way, the depth to which the shield 110 can be advanced within the needle 80 can be limited. Because there is no or little resistance between the shield and the needle's lumen, and because there is no surface of shield 110 to limit its insertion into the needle's lumen, the optional contact between the handle component and the flange 65 of the hub 60 can provide such a limit.

According to an embodiment, when shield 110 is inserted within hub 60, an annular recess 63 exists between the outer surface of shield and the inner surface of the hub 60. Hub 60 has shoulder 61a, 61b that facilitates the insertion of shield 110 into a portion of the transseptal needle lumen 81. While shoulders 61a, 61b provide transitions between interior regions of the hub 60 and the proximal end of the constant cross-sectional lumen 81 of the needle, such shoulders 61a, 61b may bind the sharp tip 29 of the transseptal guidewire 20 (especially if the tip 29 is at the terminal end of a J tip).

According to an exemplary embodiment, when the distal tip 2 of shield 110 contacts shoulders 61a, 61b, the distal tip of shield 110 is guided past shoulder 61a, 61b and into the lumen 81 of transseptal needle 80. As the sharp tip 29 of transseptal guidewire 20 is advanced beyond the distal tip 2 of shield 110 and into the lumen 81 of the transseptal needle 80, damage to the sharp tip 29 of transseptal guidewire 20 is inhibited or prevented.

As further illustrated in FIG. 7, the end surface of shield 110, such as the distal tip 2, may be oriented at an acute angle with respect to a longitudinal axis of the shield 110. The angled distal tip 2 of shield 110 may facilitate advancement of the end surface of shield 110 into and through hub 60 when the tip 2 contacts shoulders 61a, 61b. Alternatively, the distal tip 2 of the shield 110 may lie in a plane that is perpendicular to the longitudinal axis. Accordingly, the distal tip 2 of shield 110 may be blunt, yet still able to be inserted into the transseptal needle lumen 81 when it contacts shoulder 61a, 61b.

Without shield 110, it is contemplated that proper insertion of a J-shaped transseptal guidewire 20 into the lumen of transseptal needle 80 would damage the sharp tip 29. Similarly, in an embodiment with a substantially straight guidewire 20,

when the sharp tip 29 of guidewire 20 contacts shoulders 61a and/or 61b, it is contemplated that the sharp tip 29 may be damaged and thus, render the guidewire 20 unusable. It is also contemplated that the dispenser assembly 100 can be used with a needle that does not have a shoulder in a transition between a hub and a lumen. Even without such a shoulder, the shield of the dispenser facilitates introduction of the transseptal guidewire into the lumen of the needle.

Referring now to FIGs. 7, 8A, and 8B, additional aspects of shield 110 are illustrated. As described above, shield 110 has a wall 111 that is substantially cylindrical along its length so the shield 110 may be inserted through the hub 60 and into the lumen 81 of transseptal needle 80. Thus, the outer diameter of shield 110 is sized such that it fits within the lumen 81 of transseptal needle 80. For example, the outer diameter of shield 110 is smaller than the diameter of the transseptal needle lumen 81 for unrestricted advancement of the shield 110 into the transseptal needle lumen 81. The wall 111 of shield 110 defines a lumen 115 having a circular cross-sectional area along the length of shield 110 so it is sized to accommodate transseptal guidewire 20 and prevent damage to the sharp tip 29.

Although an exemplary embodiment of shield 110 in the form of a cylindrical tube is illustrated in FIGs. 8A and 8B, other embodiments are contemplated as well. For example, the outer surface of the wall 111 of the shield 110 may have a non-cylindrical shape, and the cross-sectional shape of the outer surface of the wall 111 may be non-circular. Also, the inner surface of the wall 111 of the shield 110 may have a non-cylindrical shape, and the cross-sectional shape of the inner surface of the wall 111 may be non-circular.

Although the present invention has been particularly described in conjunction with specific embodiments, it is evident that many alternatives, modifications, and variations will be apparent to those skilled in the art. It is therefore contemplated that the appended claims will embrace any such alternatives, modifications, and variations as falling within the true scope and spirit of the present invention.

What is Claimed:

1. An apparatus for introducing a sharp tip of a transseptal guidewire through a hub of a transseptal needle and into a lumen of the transseptal needle, the apparatus comprising:

a holder configured to contain the transseptal guidewire; and

a shield coupled to the holder, the shield having a wall defining a lumen sized to accommodate the sharp tip of the transseptal guidewire, the cross-sectional shape of the wall being substantially constant along at least a portion of its length and sized to fit within the lumen of the transseptal needle, thereby inhibiting contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle when the wall of the shield is positioned to extend into the lumen of the transseptal needle;

wherein the lumen of the shield has a substantially constant cross-sectional area along at least a portion of its length between proximal and distal ends of the shield, thereby facilitating insertion of the sharp tip of the transseptal guidewire through the lumen of the shield; and

wherein an outer surface of the wall of the shield is substantially cylindrical along at least a portion of its length between the proximal and distal ends of the shield, thereby facilitating insertion of the shield through the lumen of the transseptal needle.

2. The apparatus of claim 1, further comprising a handle component coupled to the holder.

3. The apparatus of claim 2, wherein the shield is coupled to the handle.

4. The apparatus of claim 1, wherein the shield is indirectly coupled to the holder.

5. The apparatus of claim 1, the apparatus defining a gap between the holder and the shield, thereby providing access to the transseptal guidewire at said gap.

6. The apparatus of claim 1, wherein the shield is made of a polymer.

7. The apparatus of claim 6, the wall of the shield being flexible.

8. The apparatus of claim 1, wherein the wall of the shield has an outer diameter smaller than an inner diameter of the lumen of the transseptal needle.

9. The apparatus of claim 1, wherein an end surface at the distal end of the shield is oriented at an angle acute with respect to a longitudinal axis of the shield, thus facilitating advancement of the distal end of the shield past a shoulder between the hub and the lumen of the transseptal needle.

10. The apparatus of claim 9, the end surface of the shield lying in a plane.

11. A system for perforating an intra-atrial septum comprising:

a transseptal needle having proximal and distal ends, a hub positioned at the proximal end, and a lumen extending from the hub to the distal end;

a transseptal guidewire having a sharp tip sized to extend through the lumen of the transseptal needle;

a holder at least partially containing the transseptal guidewire; and

a shield coupled to the holder, the shield having a wall defining a lumen sized to accommodate the sharp tip of the transseptal guidewire;

the transseptal guidewire having a retracted position in which the sharp tip of the transseptal guidewire is contained within the lumen of the shield and an extended position in which the sharp tip of the transseptal guidewire extends distally from the shield and into the lumen of the transseptal needle;

the shield having a first position in which the distal end of the shield does not extend into the lumen of the transseptal needle and a second position in which the distal end of the shield extends into the lumen of the transseptal needle to a position that is distal of the hub of the transseptal needle;

wherein the transseptal guidewire is in the retracted position when the shield is in the first position and the transseptal guidewire is moved to the extended position when the shield is in the second position, thereby inhibiting contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle or the proximal end of the transseptal needle when the shield is in the second position.

12. The system of claim 11, further comprising a handle component coupled to the holder.

13. The system of claim 12, wherein the shield is coupled to the handle.

14. The system of claim 11, wherein the shield is indirectly coupled to the holder.

15. The system of claim 11, the assembly defining a gap between the holder and the shield, thereby providing access to the transseptal guidewire.

16. The system of claim 11, wherein the shield is made of a polymer.

17. The system of claim 11, wherein the shield is tubular.

18. The system of claim 17, wherein an outer surface of the wall of the shield is cylindrical along its length between the proximal and distal ends of the shield.

19. The system of claim 11, wherein an end surface of the shield is oriented at an angle acute with respect to a longitudinal axis of the shield, thus facilitating advancement of the end surface of the shield past a shoulder between the hub and the lumen of the transseptal needle.

20. The system of claim 19, the end surface of the shield lying in a plane.

21. The system of claim 11, the transseptal guidewire having a curved tip.

22. A method of shielding a sharp tip of a transseptal guidewire as it is introduced into a transseptal needle from a dispenser, the method comprising:

inserting a tip of a shield of the dispenser through a hub of the transseptal needle and into a lumen of the transseptal needle;

advancing the tip of the shield to a point in the lumen distal of the hub without restriction; and

introducing the sharp tip of the transseptal guidewire from a lumen of the shield of the dispenser and into the lumen of the transseptal needle at the point in the lumen distal of the hub, thereby avoiding contact between the sharp tip of the transseptal guidewire and the hub of the transseptal needle or a proximal end of the transseptal needle and associated damage to the sharp tip of the transseptal guidewire.

23. The method of claim 22, further comprising the step of positioning the sharp tip of the transseptal guidewire into the lumen of the shield prior to inserting the shield through the hub of the transseptal needle.

24. The method of claim 22, further comprising the step of advancing the transseptal guidewire from a holder of the dispenser.

25. The method of claim 22, wherein the step of inserting the shield through the hub comprises advancing an angled tip of the shield past a shoulder of the hub, thereby facilitating insertion of the shield into the lumen of the transseptal needle.

26. The apparatus of claim 1, said holder comprising a tube.

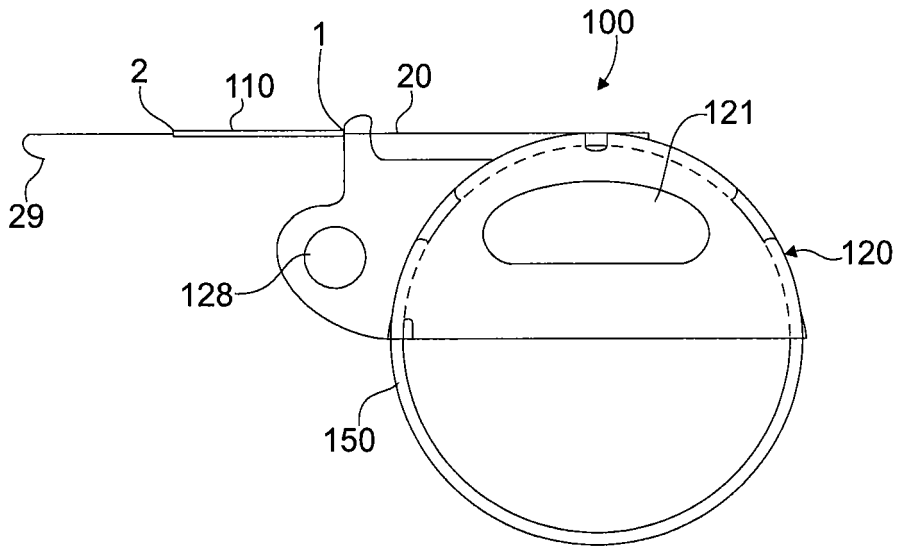

FIG. 1

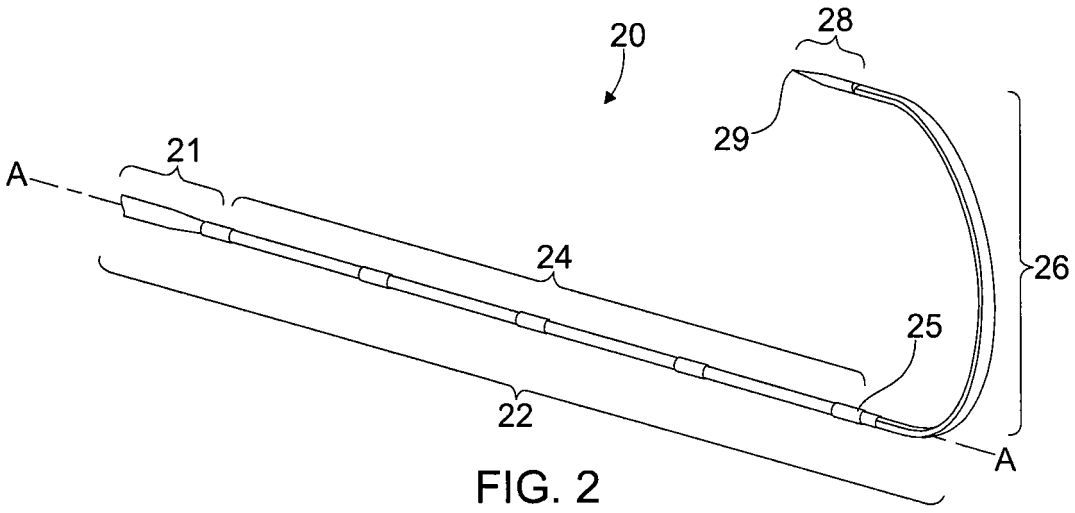

FIG. 2

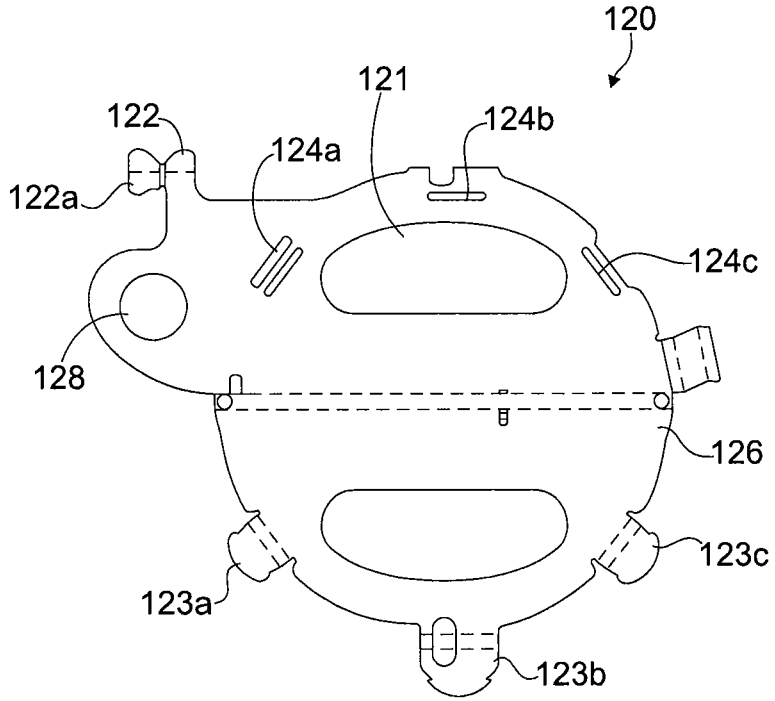

FIG. 3

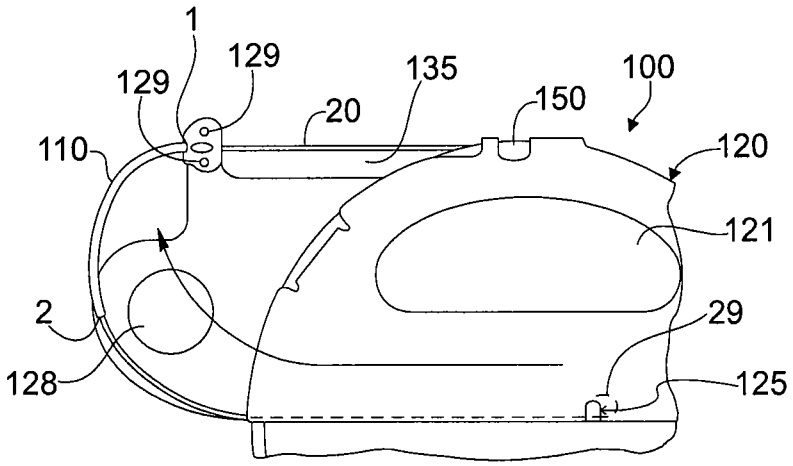

FIG. 4

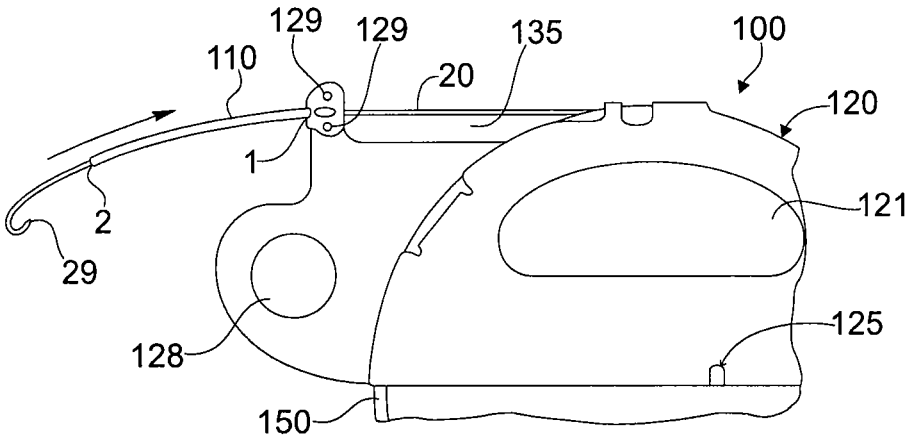

FIG. 5

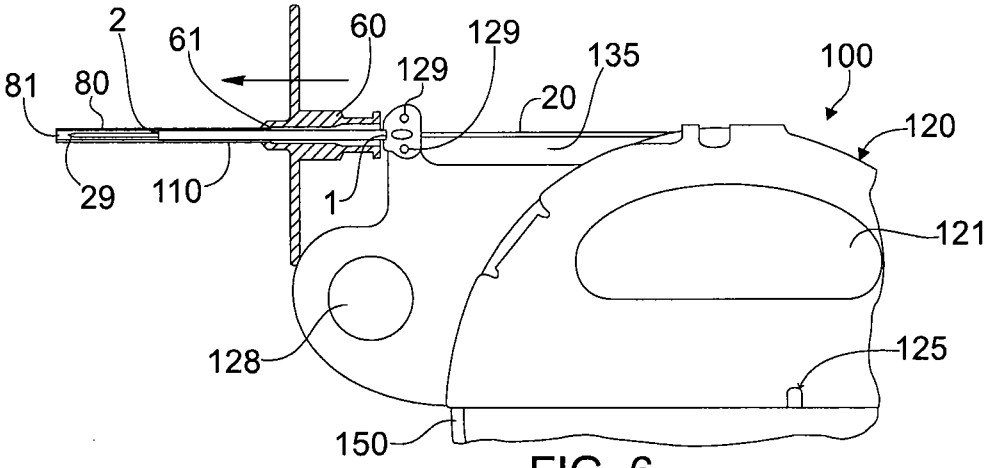

FIG. 6

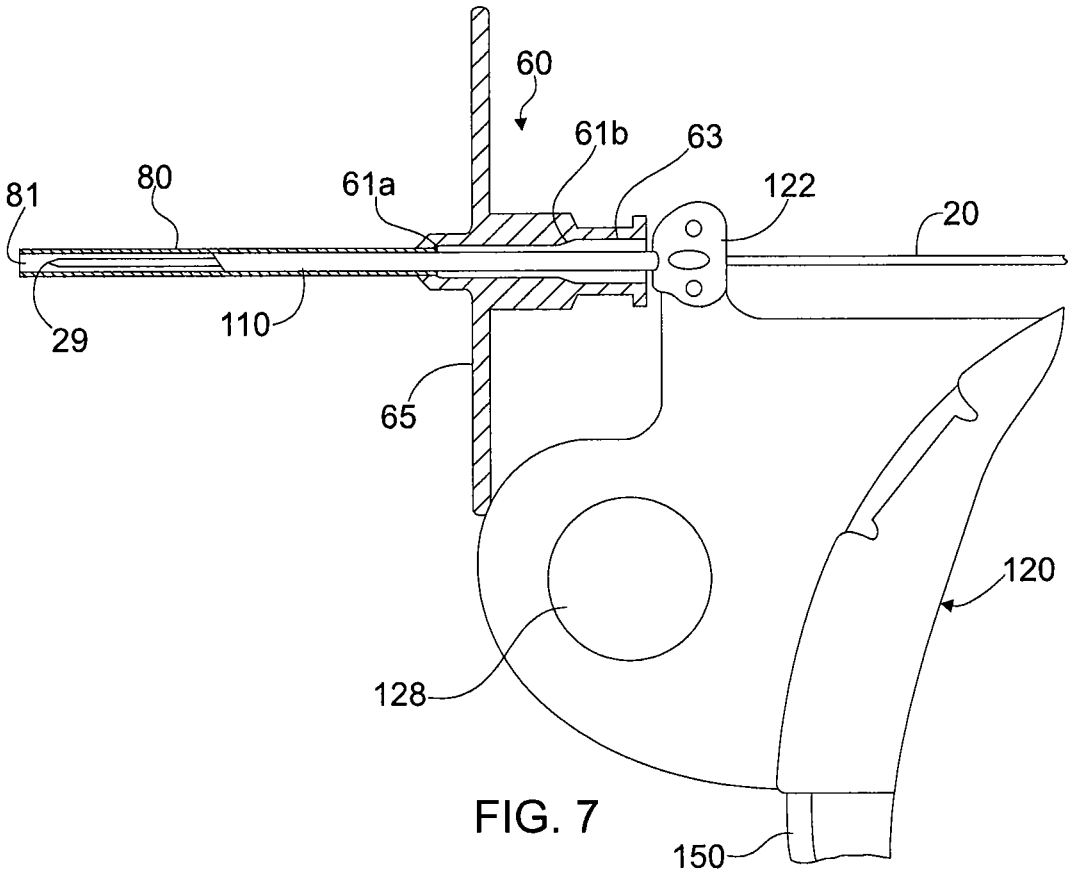

FIG. 7

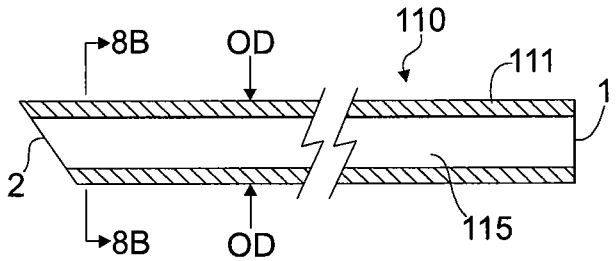

FIG. 8A

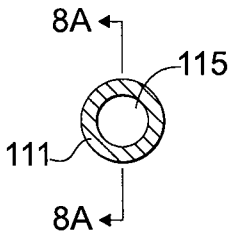

FIG. 8B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/030703

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/01 A61M25/09

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/185413 A1 (ASAI TOSHIYA [JP] ET AL) 9 August 2007 (2007-08-09) figures 1-5,8 paragraphs [0035] - [0116]	1-21
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X	WO 97/47350 A (BAXTER INT [US]) 18 December 1997 (1997-12-18) figures 1-6 pages 7-13	1-21
X	US 2003/036712 A1 (HEH KOK BOON [SG] ET AL) 20 February 2003 (2003-02-20) figures 1-4	1-21

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 2009	03/04/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Rodrigues, Elodie

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 484 419 A (FLECK PHILIP B [US]) 16 January 1996 (1996-01-16) figures 1-3,6,6a,6b columns 4,5	1-21
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X	US 5 125 905 A (WRIGHT LARRY A [US] ET AL) 30 June 1992 (1992-06-30) figures 1-3 columns 2-4	1,5-11, 15-21
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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/245847 A1 (SCHAEFFER DARIN G [US]) 3 November 2005 (2005-11-03) figures 1,2	1,5-11, 15-21
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A	EP 1 570 878 A (TERUMO CORP [JP]) 7 September 2005 (2005-09-07) abstract figures 1-3,6,7	1-21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/030703

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

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

1. [X] Claims Nos.: 22-26
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 22-26

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

It is not specified whether the methods of shielding a sharp tip described in claims 22-26 are to be carried out while the transseptal needle is inserted into a patient's body. Actually and according to normal insertion techniques known from the prior art, the steps of these methods are to be carried out while the transseptal needle is inserted into the patient's body. Since claims 22-26 do not explicitly exclude the possibility of performing these steps while the transseptal needle is inserted into the patient's body, these claims at least comprise surgical methods in the sense of Rule 39.1(iv) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/030703

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International application No
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