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(54) **SYSTEM AND METHOD FOR VISUALIZING CATHETER PLACEMENT IN A VASCULATURE**

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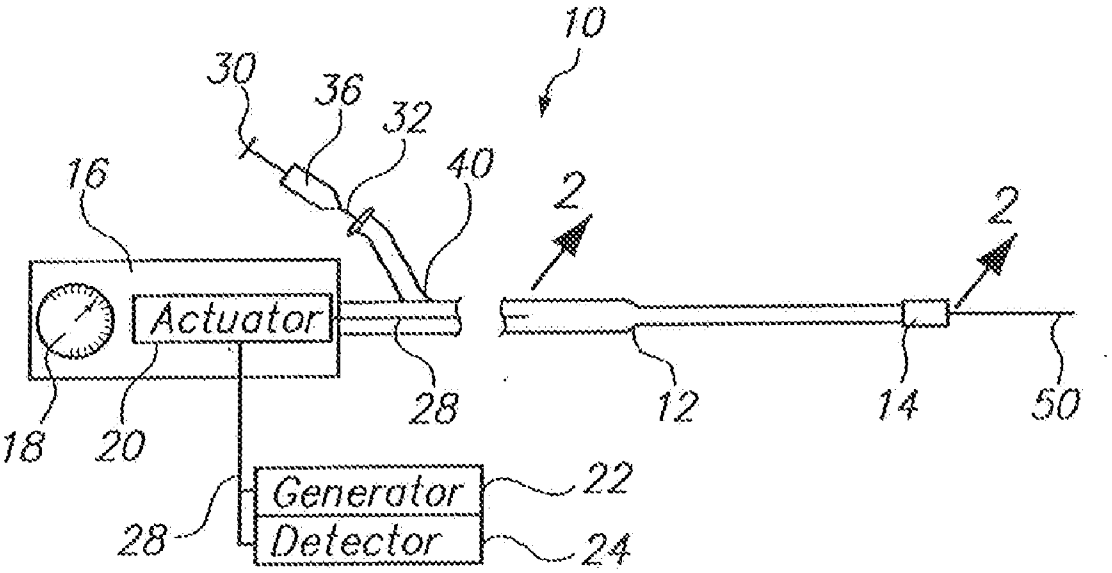
USPC **600/424**

(57) **ABSTRACT**

A system for advancing a needle through a vasculature to an injection site at the heart of a patient includes a guide catheter with a reflective distal tip. Also included is an imaging unit that is mounted on the catheter to radiate an energy field. Structurally, a distal portion of the catheter is biased to bend into a predetermined configuration that will position the distal end of the catheter for interception by the energy field. If necessary, coincidence of the reflective tip with the energy field is established by moving the energy field along the length of the guide catheter. With coincidence, the reflective tip reflects a signal that is useful for advancement of the needle **34***b* from the guide catheter and into the injection site.



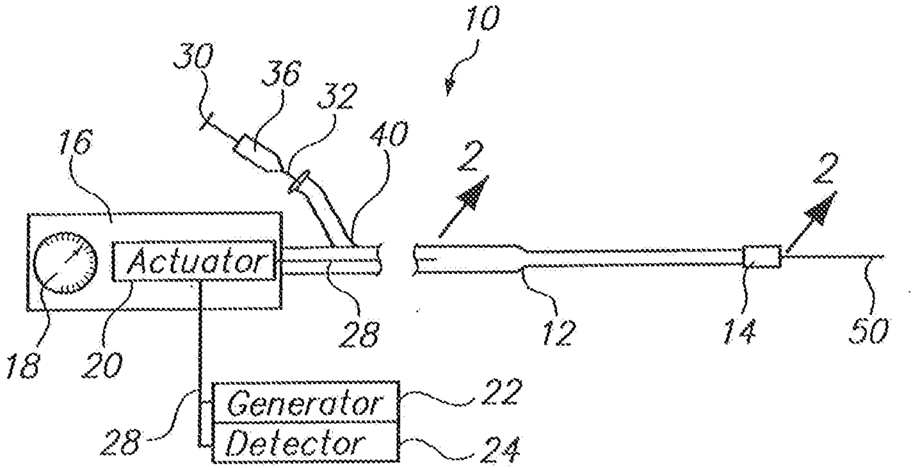

10
30
36
32
40
2
2
16
Actuator
18
20
28
12
14
50
Generator
Detector
22
24
28

FIG. 1

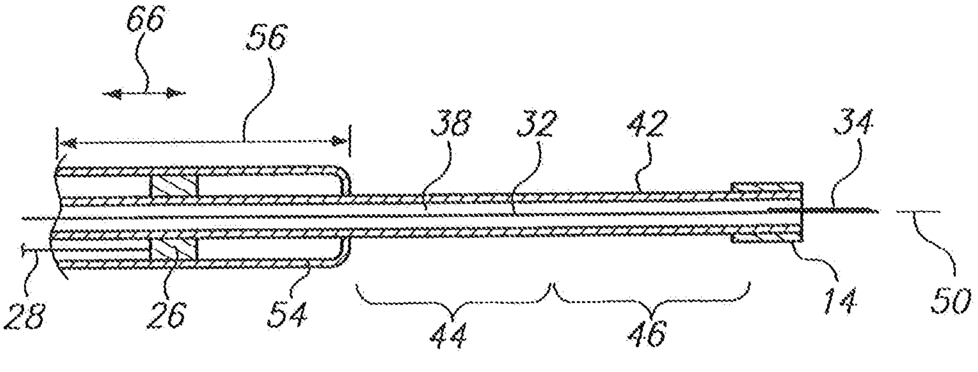

66
56
38
32
42
34
28
26
54
44
46
14
50

FIG. 2

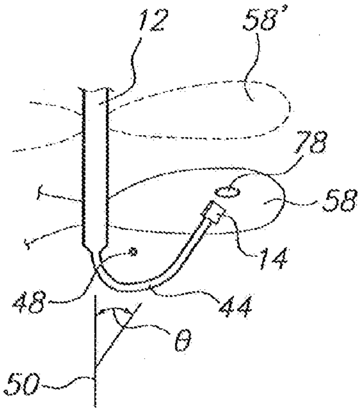


FIG. 3A

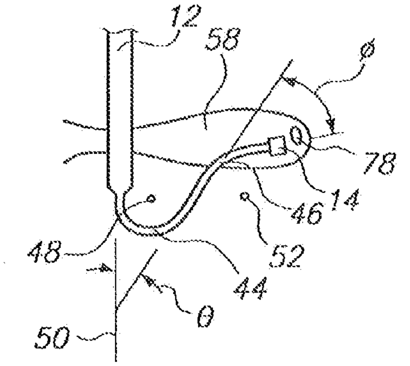


FIG. 3B

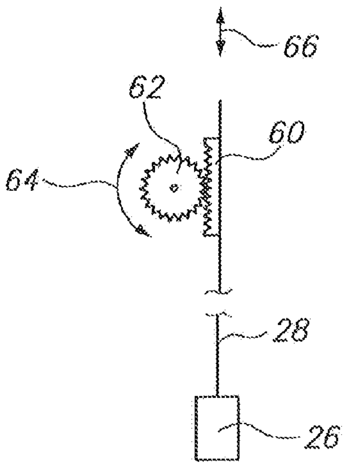


FIG. 4A

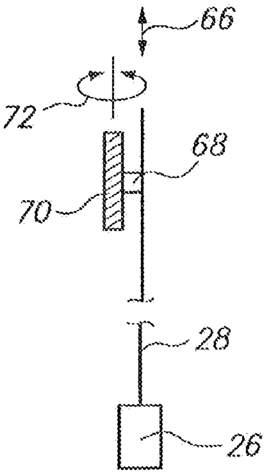


FIG. 4B

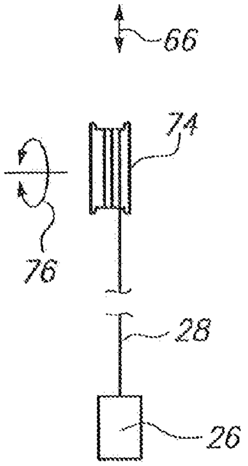


FIG. 4C

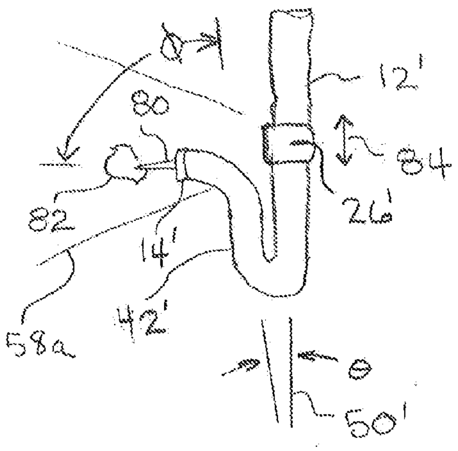


Fig. 5

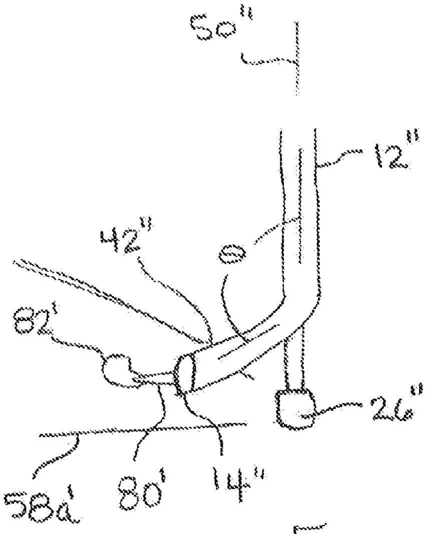


Fig. 6

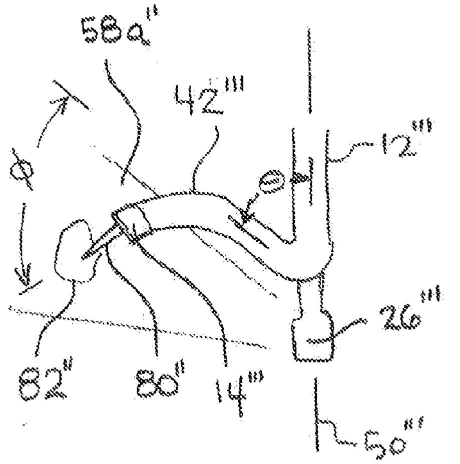


Fig 7

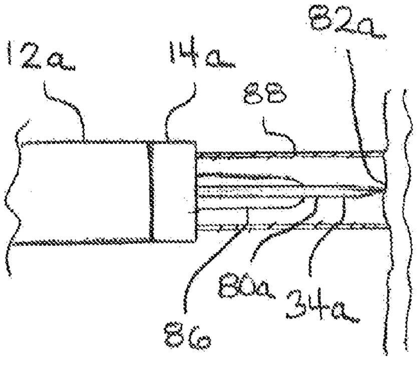


Fig. 8

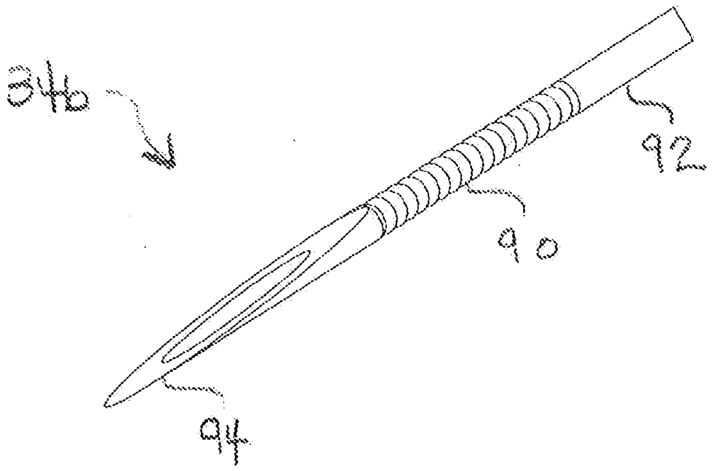


Fig. 9

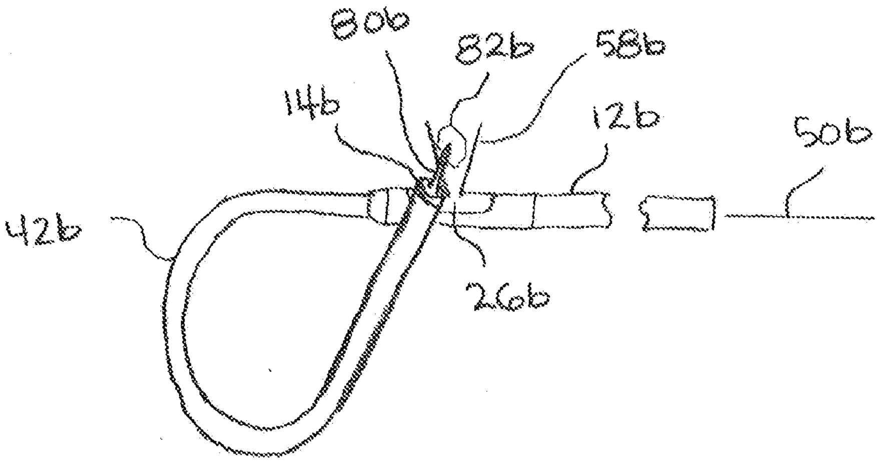

80b
82b
58b
14b
12b
50b
42b
26b

Fig. 10

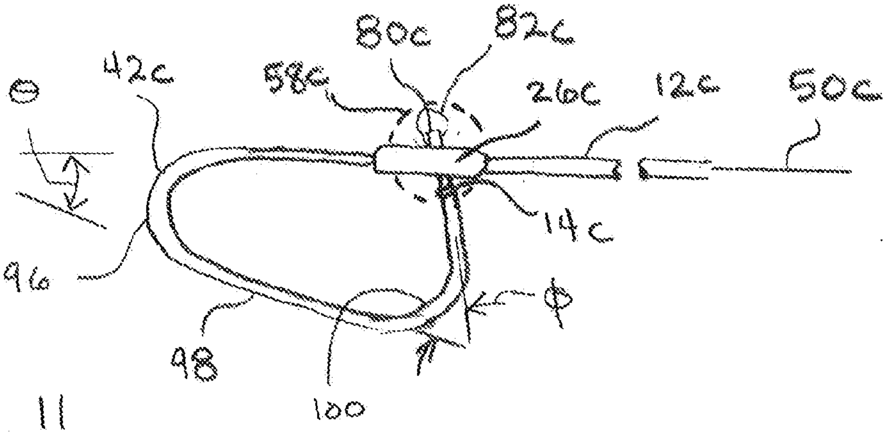

θ
42c
58c
80c
82c
26c
12c
50c
14c
96
98
100
φ

Fig. 11

SYSTEM AND METHOD FOR VISUALIZING CATHETER PLACEMENT IN A VASCULATURE

[0001] This application is a continuation-in-part application of application Ser. No. 12/788,194, titled "SYSTEM AND METHOD FOR VISUALIZING CATHETER PLACEMENT IN A VASCULATURE" filed May 26, 2010 to Nabil Dib, the entire contents of which are hereby incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention pertains generally to systems for advancing a needle or other secondary instrument through the vasculature of a patient to a treatment site at the heart. More particularly, the present invention pertains to systems that incorporate an imaging modality, such as ultrasound or Optical Coherence Tomography (OCT), to image a needle or other secondary instrument in the vasculature. The present invention is particularly, but not exclusively, useful as a system and method for bringing the energy field of an imaging modality into coincidence with the distal end of a catheter, to monitor the advancement of a needle, wire or other secondary instrument from the distal end of the catheter.

BACKGROUND OF THE INVENTION

[0003] Intravascular operations are always complicated by the simple fact that there is typically no direct visual contact with the instruments that are being used to perform the operation. To help overcome this inconvenience, several effective imaging modalities have been developed for use in the vasculature. For example, ultrasound technology is a well established imaging modality that has proven useful for many applications inside a body. Optical Coherence Tomography (OCT) is another accepted imaging modality. These imaging modalities, however, have their respective unique, operational limitations that must be accounted for. In particular, the energy fields that are used by the imaging modalities must somehow be made incident on the target area that is to be imaged, and instruments to be used in the target area must be observable.

[0004] It happens that many intravascular operations can be relatively easily accomplished. Moreover, they can often be done with minimal structural manipulations. As an example, the delivery of biologics (e.g. cells, genes, protein and drugs) to a selected injection site can be easily accomplished by using a needle injector. For such an operation, however, it is essential to properly position the instrument that is being used (e.g. a needle injector). In particular, for instances wherein an imaging modality is being used to position an instrument, the energy field of the imaging modality must be positioned to both cover the injection site, and intercept (i.e. become coincident with) the instrument.

[0005] With the above in mind, it is an object of the present invention to provide a navigation system for use in advancing a needle or a wire (i.e. a guide wire) to an injection site at the heart of a patient which reconfigures a guide catheter to position its distal tip for visualization by an imaging unit. Another object of the present invention is to provide a navigation system, for use when advancing a needle or wire through the vasculature of a patient, that provides for the movement of an imaging unit so its energy field will intercept the distal tip of a guide catheter for visualization of the catheter tip at an injection site. Still another object of the present invention is to provide systems and methods for performing atrial septum procedures having the ability to image the catheter positioned in a forward looking position relative to the target tissue to reduce procedure time and increase success rate over traditional systems and methods. Yet another object of the present invention is to provide a navigation system for use in advancing a needle or wire to an injection site in the vasculature or at the heart of a patient which is simple to manufacture, is easy to use, and is cost effective.

SUMMARY OF THE INVENTION

[0006] A system in accordance with the present invention is provided for advancing a needle to an injection site in the vasculature or at the heart of a patient. The system essentially includes a guide catheter and an imaging unit that is associated with the guide catheter. In more detail, the guide catheter has a reflective distal tip, and the imaging unit radiates an energy field in a substantially radial direction from the axis of the guide catheter for the purpose of locating the tip.

[0007] Insofar as structure of the guide catheter is concerned, a distal portion of the guide catheter is biased to bend into a predetermined configuration (i.e. the guide catheter may have a pre-bent portion). As envisioned for the present invention, this configuration will position the distal end of the catheter in the vasculature for interception by the energy field. If necessary, a coincidence of the reflective tip with the energy field can be established by manipulation of an actuator. Specifically, such a manipulation will move the energy field axially along the length of the guide catheter to intercept the reflective distal tip of the catheter. Once there is coincidence (i.e. when the reflective tip of the guide catheter is located and visualized in the energy field), the reflective tip will reflect a signal. Importantly, this reflective signal is useful for further positioning of the distal tip and for advancing the needle from the guide catheter and into the injection site. For an alternate embodiment of the present invention, the distal portion of the catheter can be steerable, rather than being pre-bent.

[0008] Structurally, the guide catheter defines an axis and it has a proximal end and a distal end. It also has a lumen that extends between the proximal and distal ends of the guide catheter. Further, the lumen is dimensioned to receive either a needle injector that includes a needle for injection into the myocardium, or a wire that passes through the lumen of the catheter to navigate the vasculature, such as by crossing heart valves or septal defects. An extracorporeal source of a fluid (e.g. biologics: cells, genes, protein and drugs) is attached to the proximal end of the injector for delivery through the needle.

[0009] An important structural aspect of the present invention is that the distal portion of the guide catheter is formed with a bendable section. Specifically, at least one part in the bendable section is biased to be bent through an angle θ. In an alternate embodiment, there can also be a second part in the bendable section that is further biased to bend through an angle ϕ. For the alternate embodiment, the center of rotation for the angle θ is axially opposite the center of rotation for the angle ϕ. Stated differently, the bendable section can be simultaneously bent in two different directions. Further, a reflective tip is attached to the bendable section at the distal end of the guide catheter, and a handle is affixed to the proximal end of the guide catheter.

[0010] Mounted on the guide catheter is an imaging unit that interacts with the reflective tip of the guide catheter to visualize the tip's location in the vasculature. In detail, the imaging unit includes a generator, a detector, and a transceiver that is mounted for axial movement on the guide catheter. Further, the imaging unit includes an actuator that is positioned in the handle of the guide catheter to move the transceiver axially along the guide catheter. The actuator will typically have a dial that is mounted on the handle, and it will include an activation wire wherein a first end of the activation wire is attached to the transceiver and a second end is engaged with the dial. Manipulation of the dial will then produce an axial movement of the transceiver along the guide catheter. Structurally, the operative components of the actuator can be selected as any one of several well-known types, such as a rack and pinion, a lead screw or a reel.

[0011] Operationally, the system of the present invention will use the generator, in combination with the transceiver, to radiate an energy field into the vasculature. This radiation will typically be in a substantially radial direction from the axis of the guide catheter. Preferably, the generator will generate ultrasound energy, but, it is well known that OCT systems can also be effective for purposes of the present invention. In either case, when the reflective tip is in the energy field, energy (e.g. ultrasound energy) will be reflected from the tip. Also, the energy will be reflected by target tissue, such as the heart. A detector that is electronically connected to the transceiver will then receive and evaluate the signal of reflected energy to determine where exactly the reflective tip is located, relative to target tissue (e.g. heart), in the energy field. The needle injector can then be advanced through the lumen of the guide catheter for extension of the needle beyond the reflective tip and from the distal end of the guide catheter for use at an injection site. As indicated above, a guide wire, rather than the needle injector, may be advanced through the catheter.

[0012] In another aspect, a system for performing a procedure on targeted heart tissue of a patient with a secondary instrument is described that includes a catheter formed with a lumen that has a pre-bent or actively bendable section that is located along a distal portion of the catheter. The secondary instrument can be inserted into the lumen of the catheter for advancement therein to extend at least a portion of the secondary instrument beyond a distal end of the catheter. For example, the secondary instrument can be a needle injector, electrophysiology ablation catheter or a delivery catheter for delivering an embolic protection device or some other device. Also, an imaging unit transceiver is coupled with the catheter to radiate an energy field in a substantially radial direction from the axis. With this arrangement, the imaging unit is able to simultaneously image a reflective tip on the distal end of the catheter, the secondary instrument and the targeted heart tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

[0014] FIG. **1** is a schematic drawing of a system in accordance with the present invention;

[0015] FIG. **2** is a cross sectional view of the distal portion of the guide catheter of the present invention as seen along the line **2-2** in FIG. **1**;

[0016] FIG. **3**A is a view of the distal portion of the guide catheter shown in its operational environment and configured with a single bend used for positioning the catheter's distal end at an injection site;

[0017] FIG. **3**B is a view of the distal portion of the guide catheter shown in its operational environment and configured with a double bend used for positioning the catheter's distal end at an injection site;

[0018] FIG. **4**A shows a rack and pinion arrangement for the actuator of the present invention;

[0019] FIG. **4**B shows a lead screw arrangement for the actuator of the present invention;

[0020] FIG. **4**C shows a reel arrangement for the actuator of the present invention;

[0021] FIG. **5** is a view of the distal portion of another embodiment of a catheter, shown in its operational environment and configured with a double bend for positioning the catheter's distal end at a treatment site;

[0022] FIG. **6** is a view of the distal portion of another embodiment of a catheter, shown in its operational environment and configured with a single bend and an extended ultrasound transceiver for positioning the catheter's distal end at a treatment site;

[0023] FIG. **7** is a view of the distal portion of another embodiment of a catheter, shown in its operational environment and configured with a double bend and an extended ultrasound transceiver for positioning the catheter's distal end at a treatment site;

[0024] FIG. **8** is a sectional view as in FIG. **2** showing an injector having a needle, dilator and needle sheath;

[0025] FIG. **9** is a perspective view of an injection needle having a spiral pattern laser cut on its exterior surface to increase flexibility and/or ultrasound reflectivity;

[0026] FIG. **10** is a view of the distal portion of another embodiment of a catheter, shown in its operational environment and configured with a pigtail bend for positioning the catheter's distal end at a treatment site and within the observable energy field of an ultrasound transceiver; and

[0027] FIG. **11** is a view of the distal portion of another embodiment of a catheter, shown in its operational environment and configured with a bend having a substantially straight portion between two curved portions for positioning the catheter's distal end at a treatment site and within the observable energy field of an ultrasound transceiver.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] Referring initially to FIG. **1**, a system in accordance with the present invention is shown and is generally designated **10**. As shown, the system **10** includes a guide catheter **12** that has a reflective tip **14** at its distal end. The system **10** also has a handle **16** that is mounted at the proximal end of the guide catheter **12**, with a dial **18** and an actuator **20** being included as part of the handle **16**. Structurally, the dial **18** is connected directly to the actuator **20** for manipulating the actuator **20** during an operation of the system **10**. FIG. **1** further indicates that the system **10** includes an energy generator **22** and a detector **24**. More specifically, with cross reference to FIG. **2**, it is to be appreciated that both the energy generator **22** and the detector **24** are electronically connected to a transceiver **26** via an activation wire **28**. It is also to be appreciated that the activation wire **28** can be manipulated by the actuator **20** to move the transceiver **26**. Collectively, the energy generator **22**, detector **24** and the transceiver **26** are hereinafter sometimes referred to as an imaging unit.

[0029] Still referring to FIG. **1**, it will be seen that the guide catheter **12** is to be used with a needle injector **30**. More specifically, the needle injector **30** includes a needle wire **32** that has a needle **34** formed at its distal end (see FIG. **2**). A fluid source **36** is also provided for the injector **30**, and this source **36** will typically hold a fluid that includes biologics (e.g. cells, genes, protein and drugs) for delivery through the injector **30**. As shown, access into the lumen **38** (see FIG. **2**) of the guide catheter **12** for both the needle **34** and the needle wire **32** of the injector **30** is provided via a y-site **40**.

[0030] An important structural aspect of the guide catheter **12** is its ability to be reconfigured. This will be best appreciated with reference to FIG. **2**, along with reference to FIGS. **3**A and **3**B. In FIG. **2** it is shown that a bendable section **42**, at the distal portion of the guide catheter **12**, can be considered as having at least one reconfigurable part **44**. Alternatively, there can be an additional reconfigurable part **46**. Consider first, a structure for the guide catheter **12** wherein there is no part **46** and, instead, only a part **44**. With reference to FIG. **3**A, it will be seen that for this embodiment of the guide catheter **12**, the bendable section **42** can be biased to bend around a center of curvature **48** to establish an angle θ. As shown, the angle θ is measured relative to an axis **50** that is generally defined by the length of the guide catheter **12**. On the other hand, as shown in FIG. **3**B, when parts **44** and **46** are both incorporated into the bendable section **42** of the guide catheter **12**, the bendable section **42** can be respectively biased to rotate through the angle θ and, additionally, through an angle ϕ around a center of curvature **52**. As shown, the angles θ and ϕ are measured in opposite directions with their respective centers of curvature **48** and **52** on opposite sides of the axis **50**. In addition to providing for structural biasing in the bendable section **42**, it is well known that various devices have been proposed for bending or steering a catheter through the vasculature of a patient (not shown). For purposes of the present invention, any such device would be suitable for reconfiguring the guide catheter **12**.

[0031] Another structural aspect of the guide catheter **12** that is of more general importance for the entirety of the system **10** concerns the actuator **20**. More specifically, the manipulation of the imaging unit and the consequent movement of the transceiver **26** is essential for the operation of the system **10**. This aspect will be best appreciated by sequentially cross referencing FIG. **2** with FIGS. **4**A, **4**B and **4**C. Specifically, this aspect regards movements of the transceiver **26** along the axis **50** of the guide catheter **12**.

[0032] With reference to FIG. **2** it will be noted that, proximal to its bendable section **42**, the guide catheter **12** is formed with a sleeve **54**. Further, it is to be understood that the transceiver **26** is moveable inside the sleeve **54** by a manipulation of the actuator **20**. More specifically, movements of the transceiver **26** by the actuator **20** are made on the guide catheter **12**, through a range **56**, in directions back and forth along the axis **50** indicated by arrows **66**. The real purpose here is to move an energy field **58** (i.e. transceiver **26**) that is radiated from the transceiver **26**. In detail, the energy field **58** will be primarily oriented in a direction perpendicular to the axis **50**, and will be radiated whenever the transceiver **26** is activated by the generator **22**. As envisioned for the present invention, although the generator **22** will preferably generate ultrasound energy, any other type of energy field that is known for use as an imaging modality is suitable (e.g. OCT). Further, although a two-dimensional field of ultrasound energy is typical, a three-dimensional ultrasound field may also be used.

[0033] In accordance with the system **10**, several different types of mechanisms can be incorporated into the actuator **20** for the purpose of moving the energy field **58**. The mechanisms shown in FIGS. **4**A, **4**B and **4**C are only exemplary. In FIG. **4**A, the components for the actuator **20** are shown to include a straight toothed rack **60** that is affixed to the activation wire **28**. A pinion **62** is shown engaged with the rack **60** and, with this engagement, the pinion **62** can be rotated by the dial **18** on handle **16** in the directions indicated by arrows **64**. This rotation of the pinion **62** will then move the transceiver **26** axially along the guide catheter **12** in the directions of arrows **66**. In another arrangement of components for the actuator **20** shown in FIG. **4**B, a projection **68** is affixed to the activation wire **28**. A lead screw **70** is then engaged with the projection **68**. Consequently, a rotation of the lead screw **70** by the dial **18** in directions indicated by arrows **72** will move the transceiver **26** axially along the guide catheter **12** in the directions of arrows **66**. Further, in another embodiment of components for the actuator **20** shown in FIG. **4**C, a reel **74**, is incorporated to take-up the activation wire **28**. More specifically, with a rotation of the reel **74** in the directions indicated by arrows **76**, the transceiver **26** will move axially along the guide catheter **12** in the directions of arrows **66**.

[0034] For an operation of the system **10**, the guide catheter **12** is positioned in the vasculature of a patient (not shown), and there it is reconfigured as shown in either FIG. **3**A or FIG. **3**B. The transceiver **26** can then be moved by the actuator **20**, as disclosed above, so that the energy field **58** radiated by the transceiver **26** will intercept the reflective tip **14** of the guide catheter **12**. For example, such a movement of the energy field **58** is shown in FIG. **3**A where it can be seen that the energy field **58'** has been moved axially along the guide catheter **12** to a new position for the energy field **58**. Once there is coincidence (i.e. the reflective tip **14** of the guide catheter **12** is located in the energy field **58**, and can be visualized with the detector **24** of the particular imaging modality being used), the reflective tip **14** can be further manipulated. Also, in this configuration the reflective tip **14** is positioned so that an advancement of needle **34** (or a guide wire) from reflective tip **14** will be seen as an axial movement of the needle **34**. Further, because the energy field **58** will also see an injection site **78** on target tissue (e.g. the heart), advancement of the needle **34** can be made relative to the injection site **78** (target tissue). In particular, this additional manipulation may be necessary in order to properly position the reflective tip **14** at a predetermined injection site **78**. The needle injector **30** can then be advanced through the guide catheter **12** to perform an injection with the needle **34** at the injection site **78**.

[0035] FIG. **5** shows the distal end of another embodiment of a catheter **12'** having a reflective tip **14'** and bendable section **42'**. As shown, for this embodiment, the bendable section **42'** can be configured as a compound curve at the distal portion of the catheter **12'**. FIG. **5** further shows that a secondary instrument **80**, such as the needle injector described above or some other type of secondary instrument (see below), can be extended from the lumen of the catheter **12'** and beyond the distal end of the catheter **12'** for interaction with target tissue **82**. Depending on the type of procedure, the secondary instrument **80** can be an injection catheter as described above, a needle and or needle/dilator assembly (see FIG. **8**) for example to puncture and or cross the atrial septum, a stylet, an electrophysiology ablation catheter or some other type of ablation catheter known in the pertinent art to ablate target tissue, a delivery catheter for delivering an embolic protection device, a snare or some other device or implant, a guidewire, for example, for crossing a heart valve, atrial septum or ventricular septum or any other secondary instrument known in the pertinent art.

[0036] Continuing with FIG. **5**, it can be seen that the catheter **12'** includes a transceiver **26'**, as described above, that is positioned on the catheter **12'** proximal to the bendable section **42'**, for producing an energy field **58***a*. For example, the transceiver **26'** can be a phased array transceiver having a plurality of individually controllable ultrasound transducers. With this arrangement, the shape, and in some cases the direction of the ultrasound energy field **58***a* emitted by the transceiver **26'** can be controlled by activating the phased array transceiver **26'** with the appropriate drive signal(s). As shown, the transceiver **26'** can be configured to produce a substantially cone shaped energy field **58***a*. It is to be appreciated that within the cone, suitable imaging may be performed. Typically, the ultrasound energy is able to look through and image behind standard catheter materials including braided materials. Also shown in FIG. **5**, the cone shaped energy field **58***a* can extend in a substantially radial direction relative to the catheter axis **50'**. In some implementations of the catheter **12'**, the transceiver **26'** can be moveable, as described above, back and forth along the axis **50'** (see arrow **84**) to selectively move the energy field **58***a* and intercept the reflective tip **14'**, secondary instrument **80** and target tissue **82** in a single image. In addition, in some implementations, the transceiver **26'** can be rotated about the axis **50'** to selectively move the energy field **58***a* to a desired location. Alternatively, a transceiver **26'** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0037] For the catheter **12'** shown in FIG. **5**, the bendable section **42'** can be biased to establish an angle, θ, measured relative to an axis **50'** (i.e. the axis **50'** is generally defined by the straight portion of the catheter **12'** proximal to the bendable section **42'**), and, additionally, biased to establish an angle ϕ (as described above with reference to FIG. 3B). For the embodiment shown in FIG. **5**, the angle, θ is typically in the range of 0 degrees $<\theta\leqq 90$ degrees, and the angle, ϕ is typically in the range of 0 degrees $<\phi\leqq 90$ degrees to place the reflective tip **14'**, secondary instrument **80** and target tissue **82** in the observable portion of the energy field **58***a*, as shown. More typically, as shown, an angle, θ greater than about 160 degrees and an angle, ϕ greater than about 70 degrees is used for the embodiment shown in FIG. **5**. The compound bend can be a single plane curve, as shown, or, a bi-plane curve may be used. With the arrangement shown, an image can be produced using the transceiver **26'** in which the secondary instrument **80** is positioned in a forward looking position relative to the target tissue **82**.

[0038] For the embodiment shown in FIG. **5**, the compound curve can be established using a pre-bent section **42'**. In this case, the pre-bent section **42'** can be delivered over a guidewire which straightens the section for navigation through the vasculature. At the location of the procedure, the section **42'** will assume its pre-bent shape as the guidewire is retracted. Alternatively, the section **42'** can be actively deflected at the treatment site. For example, to create the compound curve the catheter **12'** can include a pair of wires (not shown) extending along the length of the catheter **12'** and connected to respective anchor rings (not shown) located at the distal end of each curve making up the compound curve.

[0039] FIG. **6** shows the distal end of another embodiment of a catheter **12"** having a reflective tip **14"** and bendable section **42"** that can be placed in a so-called "hockey stick" shape. As shown, for this embodiment, the bendable section **42"** can be configured as a single curve at the distal portion of the catheter **12"**. FIG. **6** further shows that a secondary instrument **80'**, such as the needle injector described above or some other type of secondary instrument (described above), can be extended from the lumen of the catheter **12"** and beyond the distal end of the catheter **12"** for interaction with target tissue **82'**.

[0040] Continuing with FIG. **6**, it can be seen that the catheter **12"** includes a transceiver **26"**, as described above, for producing an energy field **58***a*' which, as shown, can be a substantially fan or coned shaped energy field **58***a*'. It is to be appreciated that within the cone, suitable imaging may be performed allowing for dynamic monitoring of the catheter **12"**, reflective tip **14"** and target tissue **82'**. Also shown in FIG. **6**, the cone shaped energy field **58***a*' can extend in a substantially radial direction relative to the catheter axis **50"**. FIG. **6** shows that the transceiver **26"** is integral with the catheter **12"**. For example, the transceiver **26"** can extend from a lumen of the catheter **12"**, or both the catheter **12"** and transceiver **26"** can be delivered to the treatment site in a common guide catheter (not shown). For both cases, as shown, the transceiver **26"** can be extended from a location proximal to the bendable section **42"** and along axis **50"** to a location spaced from the catheter **12"**. In some implementations the transceiver **26"** can be moveable, as described above, back and forth along the axis **50"** to selectively move the energy field **58***a*' and intercept the reflective tip **14"**, secondary instrument **80'** and target tissue **82'** in a single image. In addition, in some implementations, the transceiver **26"** can be rotated about the axis **50"** to selectively move the energy field **58***a*' to a desired location. Alternatively, a transceiver **26"** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0041] For the catheter **12"** shown in FIG. **6**, the bendable section **42"** can be biased to establish an angle, θ, (as described above with reference to FIG. 3A) measured relative to an axis **50"** (i.e. the axis **50"** is generally defined by the straight portion of the catheter **12"** proximal to the bendable section **42"**). For the embodiment shown in FIG. **6**, the angle, θ is typically in the range of 90 degrees $<\theta<180$ degrees to distance the reflective tip **14"** from the transceiver **26"** and place the reflective tip **14"**, secondary instrument **80'** and target tissue **82'** in the observable portion of the energy field **58***a*', as shown.

[0042] More typically, as shown, an angle in the range of 125 degrees $<\theta<145$ degrees is used for the embodiment shown in FIG. **6**. With the arrangement shown, an image can be produced using the transceiver **26"** in which the secondary instrument **80'** is positioned in a forward looking position relative to the target tissue **82'**. For the embodiment shown in FIG. **6**, the curve can be established using a pre-bent bendable section **42"** or can be actively deflected at the treatment site.

[0043] FIG. **7** shows the distal end of another embodiment of a catheter **12'"** having a reflective tip **14'"** and bendable section **42'"**. As shown, for this embodiment, the bendable section **42'"** can be configured as a compound curve at the distal portion of the catheter **12'"**. FIG. **7** further shows that a secondary instrument **80"**, such as the needle injector (described above) or some other type of secondary instrument (described above), can be extended from the lumen of the catheter **12'''** and beyond the distal end of the catheter **12'''** for interaction with target tissue **82''**.

[0044] Continuing with FIG. **7**, it can be seen that the catheter **12'''** includes a transceiver **26'''**, as described above, for producing an energy field **58***a*'' which, as shown, can be a substantially coned shaped energy field **58***a*''. It is to be appreciated that within the cone, suitable imaging may be performed. Also shown in FIG. **7**, the cone shaped energy field **58***a*'' can extend in a substantially radial direction relative to the catheter axis **50'''**. FIG. **7** shows that the transceiver **26'''** is integral with the catheter **12'''**. For example, the transceiver **26'''** can extend from a lumen of the catheter **12'''** or both the catheter **12'''** can both be delivered to the treatment site in a common guide catheter (not shown). For both cases, as shown, the transceiver **26'''** can be extended from a location proximal to the bendable section **42'''** and along axis **50'''** to a location spaced from the catheter **12'''**. In some implementations the transceiver **26'''** can be moveable, as described above, back and forth along the axis **50'''** to selectively move the energy field **58***a*'' and intercept the reflective tip **14'''**, secondary instrument **80''** and target tissue **82''** in a single image. In addition, in some implementations, the transceiver **26'** can be rotated about the axis **50'''** to selectively move the energy field **58***a*'' to a desired location. Alternatively, a transceiver **26'''** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0045] For the catheter **12'''** shown in FIG. **7**, the bendable section **42'''** can be biased to establish an angle, θ, measured relative to an axis **50'''** (i.e. the axis **50'''** is generally defined by the straight portion of the catheter **12'''** proximal to the bendable section **42'''**), and, additionally, biased to establish an angle ϕ (as described above with reference to FIG. **31**). For the embodiment shown in FIG. **7**, the angle, θ is typically in the range of 0 degrees $<\theta\leqq 90$ degrees, and the angle, ϕ is typically in the range of 0 degrees $<\phi\leqq 90$ degrees to place the reflective tip **14'''**, secondary instrument **80''** and target tissue **82''** in the observable portion of the energy field **58***a*'', as shown. More typically, as shown, an angle, θ in the range of 35 degrees $<\theta\leqq 55$ degrees and an angle, ϕ in the range of 30 degrees $<\phi\leqq 60$ degrees is used for the embodiment shown in FIG. **7**. The compound bend can be a single plane curve, as shown, or, a bi-plane curve may be used. With the arrangement shown, an image can be produced using the transceiver **26'''** in which the secondary instrument **80''** is positioned in a forward looking position relative to the target tissue **82''**. For the embodiment shown in FIG. **7**, the compound curve can be established using a pre-bent bendable section **42''** or can be actively deflected at the treatment site.

[0046] FIG. **8** shows an embodiment of a secondary instrument **80***a* for use in any of the embodiments described above (i.e. FIGS. **3**A, **3**B and **5**-**7**) to pierce and dilate target tissue **82***a* such as an atrial or ventricular septum. As shown in FIG. **8**, the secondary instrument **80***a* includes a needle **34***a* that extends distally from the reflective tip **14***a* of catheter **12***a*. Secondary instrument **80***a* also includes a dilator **86** and sheath **88**. For the embodiments described herein, the needle, including injection needles and puncturing needles, can include a needle tip that is straight, curved (not shown) or can include a one or more pre-defined bends (not shown). These curves and/or bends are typically on the section of the needle that will extend distally from the distal end of the catheter. Continuing with FIG. **8**, the sheath **88**, for example, may be shaped as a tube and made of a polymer, a reinforced polymer or metal. In use, the distal end of the catheter **12***a* is positioned relative to the target tissue. With the catheter **12***a* positioned, the sheath **88** can be advanced distally, telescoping out from the distal end of catheter **12***a* until the sheath contacts the target tissue **82***a*. Next, the needle **34***a* can be advanced distally to puncture the target tissue **82***a*, (e.g. atrial suptum) while the sheath **88** protects the needle **34***a* against damage to the needle **34***a* or collateral (i.e. non-target) tissue. Once the target tissue **82***a* is punctured, the dilator **86** can be distally advanced through the hole made by the needle **34***a* to dilate the hole to a desired size. It is to be appreciated that the sheath **88** described herein can also be used with the injector systems (described above) to deliver a medicament or cell therapy to target tissue. The integration of the transceiver **26''** with the needle **34***a* allows the user to see the depth of the needle **34***a* in the tissue **82***a* in relation to anatomical landmarks and boundaries, and allows the user to see the interaction of the needle sheath **88** and needle **34***a* with the anatomic wall of the heart or other anatomical structure. This helps the user watch the impact of the pressure against the wall (i.e. condensing/displacing tissue) and helps reduce the risk of puncturing through a wall. It also helps the user see penetration and depth of needle **34***a* to insure injection of stem cells/biologic material to the right target area. In some cases, the needle may not be hollow all the way through, but may have a solid core until the tip, allowing for more pushability and control. In addition, for some embodiments the needle and/or needle sheath may have some steering mechanism and also may be preshaped and deflectable to help align the needle in the field of view of the imaging window. In an alternative embodiment, the injector can include a plurality of needles coming out as a bundle for infusion.

[0047] FIG. **9** shows an injection needle **34***b* that has been treated to increase the needle **34***b*'s reflection of ultrasonic energy, and thus, increase the observability of the needle **34***b* when used with the imaging units described herein. Untreated, the relatively thin needles used for treating heart tissues, having a thickness of about AWG **27**-**28** and made of stainless steel or nitanol, are often difficult to observe using ultrasound. Preferably, the needle **34***b* is observable when advancing, penetrating and injecting inside the tissue/organ/muscle. As shown in FIG. **9**, a pattern **90** can be scribed on the exterior surface **92** of needle **34***b* to increase the surface area and increase the amount of needle surface area that reflects energy back, along a particular angle, to a transceiver (not shown). For example, the pattern **90** may be scribed onto the surface using a laser, a suitable machining process or cut with another similar process. As shown, the pattern **90** may consist of a spiral that extends along a portion of the needle **34***b*, near the sharp distal tip **94**. Other suitable patterns can include one or more spaced apart rings formed on the surface **92** (not shown). In addition, surface features may be established on the surface **92** of the needle **34***b* to increase the flexibility of the needle **34***b*, allowing the needle **34***b* to navigate through the vasculature. Alternatively, or in addition to the scribed pattern **90**, a coating can be applied to a portion or all of the surface **92** of the needle **34***b* (not shown) to increase ultrasound reflectivity and observability. For example, an echogenic polymer coating manufactured by (STS Biopolymers, Henrietta, N.Y.) which produces a polymer film having a porous microstructure that entraps microbubbles of air may be used to increase needle observability.

[0048] FIG. **10** shows the distal end of another embodiment of a catheter **12*b*** having a reflective tip **14*b*** and bendable section **42*b***. As shown, for this embodiment, the bendable section **42*b*** can be configured as a so-called "pigtail curve" creating a full loop at the distal portion of the catheter **12*b***. FIG. **10** further shows that a secondary instrument **80*b***, such as the needle injector (described above) or some other type of secondary instrument (described above), can be extended from the lumen of the catheter **12*b*** and beyond the distal end of the catheter **12*b*** for interaction with target tissue **82*b***.

[0049] Continuing with FIG. **10**, it can be seen that the catheter **12*b*** includes a transceiver **26*b***, as described above, for producing an energy field **58*b*** which, as shown, can be a substantially coned shaped energy field **58*b***. It is to be appreciated that within the cone, suitable imaging may be performed. Also shown in FIG. **10**, the cone shaped energy field **58*b*** can extend in a substantially radial direction relative to the catheter axis **50*b***. FIG. **10** shows that the transceiver **26*b*** is mounted on the catheter **12*b*** proximal to the bendable section **42*b*** and is thus integral with the catheter **12*b***. In some implementations the transceiver **26*b*** can be moveable, as described above, back and forth along the axis **50*b*** to selectively move the energy field **58*b*** and intercept the reflective tip **14*b***, secondary instrument **80*b*** and target tissue **82*b*** in a single image. In addition, in some implementations, the transceiver **26*b*** can be rotated about the axis **50*b*** to selectively move the energy field **58*b*** to a desired location. Alternatively, a transceiver **26*b*** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0050] For the catheter **12*b*** shown in FIG. **10**, the bendable section **42*b*** is biased to bend greater than 180 degrees such that the distal end of the catheter **12*b*** approaches or crosses a portion of the catheter **12*b*** proximal to the bendable section **42*b*** to position the reflective tip **14*b***, secondary instrument **80*b*** and target tissue **82*b*** in the observable portion of the energy field **58*b***, as shown. For the embodiment shown in FIG. **10**, the pigtail curve can be established using a pre-bent bendable section **42*b*** or can be actively deflected at the treatment site.

[0051] FIG. **10** shows the distal end of another embodiment of a catheter **12*b*** having a reflective tip **14*b*** and bendable section **42*b***. As shown, for this embodiment, the bendable section **42*b*** can be configured as a so-called "pigtail curve" creating a full loop at the distal portion of the catheter **12**. FIG. **10** further shows that a secondary instrument **80*b***, such as the needle injector (described above) or some other type of secondary instrument (described above), can be extended from the lumen of the catheter **12*b*** and beyond the distal end of the catheter **12*b*** for interaction with target tissue **82*b***.

[0052] Continuing with FIG. **10**, it can be seen that the catheter **12*b*** includes a transceiver **26*b***, as described above, for producing an energy field **58*b*** which, as shown, can be a substantially coned shaped energy field **58*b***. It is to be appreciated that within the cone, suitable imaging may be performed. Also shown in FIG. **10**, the cone shaped energy field **58*b*** can extend in a substantially radial direction relative to the catheter axis **50*b***. FIG. **10** shows that the transceiver **26*b*** is mounted on the catheter **12*b*** proximal to the bendable section **42*b*** and is thus integral with the catheter **12*b***. In some implementations the transceiver **26*b*** can be moveable, as described above, back and forth along the axis **50*b*** to selectively move the energy field **58*b*** and intercept the reflective tip **14*b***, secondary instrument **80*b*** and target tissue **82*b*** in a single image. In addition, in some implementations, the transceiver **26*b*** can be rotated about the axis **50*b*** to selectively move the energy field **58*b*** to a desired location. Alternatively, a transceiver **26*b*** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0053] For the catheter **12*b*** shown in FIG. **10**, the bendable section **42*b*** is biased to bend greater than 180 degrees such that the distal end of the catheter **12*b*** approaches or crosses a portion of the catheter **12*b*** proximal to the bendable section **42*b*** to position the reflective tip **14*b***, secondary instrument **80*b*** and target tissue **82*b*** in the observable portion of the energy field **58*b***, as shown. For the embodiment shown in FIG. **10**, the pigtail curve can be established using a pre-bent bendable section **42*b*** or can be actively deflected at the treatment site.

[0054] FIG. **11** shows the distal end of another embodiment of a catheter **12*c*** having a reflective tip **14*c*** and bendable section **42*c***. As shown, for this embodiment, the bendable section **42*c*** can create a full loop at the distal portion of the catheter **12*c***. FIG. **11** further shows that a secondary instrument **80*c***, such as the needle injector (described above) or some other type of secondary instrument (described above), can be extended from the lumen of the catheter **12*c*** and beyond the distal end of the catheter **12*c*** for interaction with target tissue **82*c***.

[0055] Continuing with FIG. **11**, it can be seen that the catheter **12*c*** includes a transceiver **26*c***, as described above, for producing an energy field **58*c*** which, as shown, can be a substantially coned shaped energy field **58*c*** (field is oriented into the plane of the page). It is to be appreciated that within the cone, suitable imaging may be performed. Also shown in FIG. **11**, the cone shaped energy field **58*c*** can extend in a substantially radial direction relative to the catheter axis **50*c***. FIG. **11** shows that the transceiver **26*c*** is mounted on the catheter **12*c*** proximal to the bendable section **42*c*** and is thus integral with the catheter **12*c***. In some implementations the transceiver **26*c*** can be moveable, as described above, back and forth along the axis **50*c*** to selectively move the energy field **58*c*** and intercept the reflective tip **14*c***, secondary instrument **80*c*** and target tissue **82*c*** in a single image. In addition, in some implementations, the transceiver **26*c*** can be rotated about the axis **50*c*** to selectively move the energy field **58*c*** to a desired location. Alternatively, a transceiver **26*c*** producing another type of energy field known in the pertinent art for use as an imaging modality, such as OCT, may be used.

[0056] For the catheter **12*c*** shown in FIG. **11**, the bendable section **42*c*** includes portions **96**, **98** and **100**. As shown, portions **96** and **100** are curved portions and portion **98** is substantially straight. As further shown, portion **96** can be biased to establish an angle, θ, measured relative to an axis **50*c*** (i.e. the axis **50*c*** is generally defined by the straight portion of the catheter **12*c*** proximal to the bendable section **42*c***), and, additionally, portion **100** can be biased to establish an angle ϕ (as described above with reference to FIG. 3B). For the embodiment shown in FIG. **11**, the angle, θ is typically in the range of 0 degrees $<\theta\leqq 90$ degrees, and the angle, ϕ is typically in the range of 0 degrees $<\phi\leqq 180$ degrees to place the reflective tip **14*c***, secondary instrument **80*c*** and target tissue **82*c*** in the observable portion of the energy field **58*c***, as shown. More typically, as shown, an angle, θ in the range of 35 degrees $<\theta\leqq 55$ degrees and an angle, ϕ in the range of 45 degrees $<\theta\leqq 90$ degrees is used for the embodiment shown in FIG. **10**, The compound bend can be a single plane curve with a small out of plane curve to allow the secondary instrument **80***c* to cross the catheter **12***c*, as shown, or, a more pronounced bi-plane curve may be used. For the embodiment shown in FIG. **11**, the curve can be established using a pre-bent bendable section **42***c* or can be actively deflected at the treatment site.

[0057] Applications of the systems described above include procedures/treatments of the atrial septum. These treatments include puncturing the atrial septum, crossing the atrial septum with a wire (for example, to perform mitral valve repair or atrial ablation), atrial septal defect (ASD) closure and patent foramen ovale (PFO) closure. In the past, these atrial septum procedures have had extremely low success rates, a lengthy procedure time (e.g. 10-30 minutes) and have often resulted in undesirable perforations of the septum. These shortcomings have been attributed to poor imaging of the catheter and secondary instruments using a nonintegrated imaging system (i.e. a system in which the ultrasound transceiver is not integrated with the catheter/secondary instrument). Using the imaging system as described herein, and in particular, the ability to image the catheter tip, secondary instrument and target tissue in a single image, with the catheter positioned in a forward looking position relative to the target tissue can reduce procedure time and increase success rate.

[0058] Additional applications of the systems described above include crossing the aortic valve, delivering cells, such as stem cells, or other medicaments to the endocardium (see description above), crossing the ventricular septum and repairing or replacing a heart valve.

[0059] The systems described herein are compatible with other imaging systems found in a modern cathlab and can be used together with one or more of these other imaging systems to accurately deliver and view the needle or other secondary instrument as it is introduced into the heart or other tissue. These other imaging systems include, but are not limited to, 2D ultrasound, 3D ultrasound, MRI, MRI integrated picture, the NOGA mapping system (Cordis), angiography, CT, PET/nuclear imaging, a 3D mapping system, 3D left ventricle angiogram and 3D echocardiogram.

[0060] While the particular System and Method for Visualizing Catheter Placement in a Vasculature as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of construction or design herein shown other than as described in the appended claims.

What is claimed is:

1. A system for performing a procedure on targeted heart tissue of a patient with a secondary instrument, the system comprising:

a catheter defining an axis and having a proximal end and a distal end, wherein the catheter is formed with a lumen extending between the ends thereof for extending at least a portion of the secondary instrument beyond the distal end of the catheter, and wherein the catheter has a bendable section located along a distal portion of the catheter;

a reflective tip attached to the bendable section at the distal end of the catheter; and

an imaging unit transceiver coupled with the catheter to radiate an energy field in a substantially radial direction from the axis of the catheter, the imaging unit transceiver for simultaneously imaging the reflective tip, the secondary instrument and the targeted heart tissue.

2. A system as recited in claim **1** wherein the secondary instrument is a needle injector having a reflective needle.

3. A system as recited in claim **1** wherein the reflective needle has an exterior surface and includes surface features on the exterior surface to increase the reflectivity of the needle.

4. A system as recited in claim **1** wherein the needle injector further comprises a needle sheath advanceable beyond the distal end of the catheter.

5. A system as recited in claim **1** wherein the secondary instrument is an electrophysiology ablation catheter.

6. A system as recited in claim **1** wherein the secondary instrument is a delivery catheter for delivering an embolic protection device.

7. A system as recited in claim **1** wherein the secondary instrument comprises a needle and a dilator.

8. A system as recited in claim **1** further wherein the bendable section of the guide catheter is pre-bent.

9. A system as recited in claim **1** further comprising an actuator for moving the imaging unit transceiver to intercept the reflective tip with the energy field to create a signal from the reflective tip for receipt by the imaging unit transceiver to determine where the reflective tip is located in the energy field.

10. A system as recited in claim **1** wherein the imaging unit transceiver comprises a phased array transceiver having a plurality of transducers.

11. A system as recited in claim **1** further comprising:

an imaging unit generator electronically connected to the transceiver for generating energy for the energy field; and

an imaging unit detector electronically connected to the imaging unit transceiver for receiving and evaluating reflected energy signal.

12. A system as recited in claim **11** wherein the imaging unit generator generates ultrasound energy for the energy field.

13. A system as recited in claim **11** wherein the imaging unit generator generates Optical Coherence Tomography (OCT) energy for the energy field.

14. A system as recited in claim **1** wherein the bendable section of the catheter is biased to be bent around a center of rotation through an angle θ to position the reflective tip in the energy field.

15. A system as recited in claim **14** wherein the center of rotation for the angle θ is a first center of rotation, and a first part of the bendable section is bent through the angle θ, and wherein a second part of the bendable section is further biased to bend around a second center of rotation through an angle ϕ, and further wherein the first center of rotation is axially opposite the second center of rotation.

16. A system for performing a procedure on targeted heart tissue of a patient which comprises:

a catheter means defining an axis and having a proximal end and a distal end, wherein the catheter means is formed with a lumen extending between the ends thereof, and wherein the catheter means has a bendable section located along a distal portion of the catheter means;

an instrument means insertable into the lumen of the catheter means for advancement therein to extend a reflective portion of the instrument means beyond the distal end of the catheter means;

a means for reflecting energy attached to the bendable section at the distal end of the catheter means; and

a transceiver means for use as part of an imaging unit, the transceiver means mounted on the catheter means to radiate an energy field in a substantially radial direction from the axis of the catheter means, the transceiver means for simultaneously imaging the means for reflecting energy, the reflective portion of the instrument means and the target tissue.

17. A method for performing a procedure on targeted heart tissue of a patient which comprises the steps of:

positioning a distal end of a catheter in a patient,

activating and imaging unit transceiver integrally coupled with the catheter to radiate an energy field in a substantially radial direction from the axis of the catheter;

bending a distal portion of the catheter to place a reflective tip attached to the bendable section of the guide catheter at a position to reflect the energy field;

advancing a secondary instrument through a lumen of the catheter to extend a reflective portion of the secondary instrument beyond the distal end of the catheter; and

simultaneously imaging the reflective tip, the reflective portion of the secondary instrument and the target tissue.

18. A method as recited in claim **17** wherein the procedure is a cell therapy injection procedure.

19. A method as recited in claim **17** wherein the procedure is a tissue ablation procedure.

20. A method as recited in claim **17** wherein the procedure is an atrial septal crossing procedure.

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