



(51) International Patent Classification:

A61M 25/01 (2006.01) A61M 25/098 (2006.01)
A61B 18/02 (2006.01) A61M 25/10 (2006.01)
A61B 18/08 (2006.01)

(21) International Application Number:

PCT/CA2011/000064

(22) International Filing Date:

21 January 2011 (21.01.2011)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

12/696,233 29 January 2010 (29.01.2010) US

(71) Applicant (for all designated States except US):
MEDTRONIC CRYOCATH LP [CA/CA]; 9000 Tran-
scanadienne, Pointe-Claire, Québec H9R 5Z8 (CA).

(72) Inventor: **PAGEARD, Jean-Luc**; 90 rue des Soeurs
Grises #612, Montreal, Québec H3C 6N1 (CA).

(74) Agent: **MOFFAT & CO.**; P.O. Box 2088, Station D, Ot-
tawa, Ontario K1P 5W3 (CA).

(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: MULTIFUNCTIONAL ABLATION DEVICE

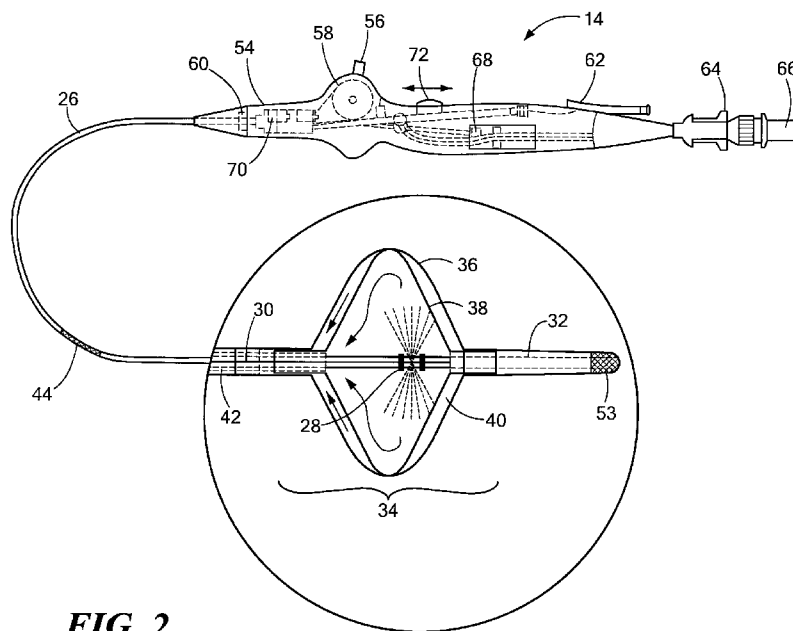


FIG. 2

(57) Abstract: An intravascular catheter is provided, including a flexible elongate body; an expandable element positioned on the elongate body; a substantially linear thermal segment located proximally of the expandable element, the thermal segment defining a first flexibility, where the thermal segment is positioned between two portions of the catheter body each including a flexibility less than that of the thermal segment; a first fluid flow path in fluid communication with the expandable element; and a second fluid flow path in fluid communication with the thermal segment.

MULTIFUNCTIONAL ABLATION DEVICE

FIELD OF THE INVENTION

The present invention relates to a method and system for thermal tissue treatment, and in particular, towards systems and methods of use thereof for treating
5 multiple tissue sites having varying geometries.

BACKGROUND OF THE INVENTION

Minimally invasive devices, such as catheters, are often employed for surgical procedure, including those involving ablation, dilation, and the like. In a particular situation, an ablation procedure may involve creating a series of inter-connecting
10 lesions in order to electrically isolate tissue believed to be the source of an arrhythmia. During the course of such a procedure, a physician may employ several different catheters having variations in the geometry and/or dimensions of the ablative element in order to produce the desired ablation pattern. Each catheter may have a unique geometry for creating a specific lesion pattern, with the multiple catheters
15 being sequentially removed and replaced to create the desired multiple lesions. Exchanging these various catheters during a procedure can cause inaccuracies or movement in the placement and location of the distal tip with respect to the tissue to be ablated, and may further add to the time required to perform the desired treatment. These potential inaccuracies and extended duration of the particular procedure
20 increase the risk to the patient undergoing treatment. Accordingly, it would be desirable to provide a single medical device having the ability to provide ablative patterns of various shapes, without the need for additional catheters or the like having a single geometric orientation, and thus, limited in the ability to provide multiple ablative patterns.

25 SUMMARY OF THE INVENTION

The present invention advantageously provides a medical system having the ability to provide ablative patterns of various shapes to treat different targeted tissue sites while maintaining a substantially static position of the medical device. In particular, a medical device is provided, having an elongate catheter body; a first
30 treatment region on the catheter body; a second treatment region proximal to the first treatment region, where the second treatment region defines a first deflection profile and is disposed between two adjacent catheter body segments defining deflection

profiles different from the first deflection profile, and a third treatment region located distally of the first treatment region. The first treatment region may include an expandable element and the second treatment region can include a substantially linear thermal segment. The first treatment region may be operable independently from the second treatment region. The device may further include a first fluid flow path in fluid communication with the first treatment region, a second fluid flow path in fluid communication with the second treatment region, and a cryogenic fluid source in fluid communication with at least one of the first and second fluid flow paths. Radiopaque markers may be positioned at a boundary between the second treatment region and one of the adjacent catheter body segments.

An intravascular catheter is also provided, including a flexible elongate body; an expandable element positioned on the elongate body; a substantially linear thermal segment located proximally of the expandable element, the thermal segment including a flexibility or deformational capacity, where the thermal segment is positioned between two adjacent portions of the catheter body each including a flexibility or deformational capacity different from the thermal segment (for example, the adjacent portions having a rigidity greater than a rigidity of the thermal segment); a first fluid flow path in fluid communication with the expandable element; and a second fluid flow path in fluid communication with the thermal segment. The first fluid flow path may be operable independently from the second fluid flow path. The first fluid flow path may include a first fluid injection lumen, the second fluid flow path may include a second fluid injection lumen; and the first fluid flow path and the second fluid flow path can include a common exhaust lumen.

A method of treating cardiac tissue is also provided, including positioning an expandable element of a medical device proximate a pulmonary vein; positioning a substantially linear thermal segment of the medical device proximate an atrial wall, the thermal segment being more flexible than medical device segments adjacent to the thermal segment; applying a deflective force from a proximal portion of the medical device to the thermal segment, the deflective force causing the thermal segment to deflect towards the atrial wall; and ablating at least one of the pulmonary vein and the atrial wall with the medical device. Positioning the expandable element can include expanding the expandable element in the pulmonary vein to substantially occlude the

pulmonary vein; applying a deflective force can include applying an axial force in a distal direction along a longitudinal axis of the medical device; and ablating at least one of the pulmonary vein and the atrial wall can include circulating a cryogenic fluid through at least one of the expandable element and the thermal segment.

5 BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

10 FIG. 1 is an illustration of an embodiment of a medical system constructed in accordance with the principles of the present invention;

FIG. 2 is an illustration of an embodiment of a medical device constructed in accordance with the principles of the present invention;

FIG. 3 is an additional illustration of the medical device shown in FIG.2; and

15 FIG. 4 is an illustration of an exemplary use of a medical device constructed in accordance with the principles of the present invention; and

FIG. 4 is an additional illustration of an exemplary use of a medical device constructed in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

20 The present invention advantageously provides a medical system having the ability to provide ablative patterns of various shapes to treat different targeted tissue sites while maintaining a substantially static position of the medical device. Referring now to the drawing figures in which like reference designations refer to like elements, an embodiment of a medical system constructed in accordance with principles of the present invention is shown in FIG. 1 and generally designated as "10." The system
25 generally includes a cooling unit or console 12 coupled to a medical device 14 through an umbilical system 16. The medical device 14 may be a medical probe, a catheter, a balloon-catheter, as well as other devices deliverable or otherwise positionable through the vasculature and/or proximate to a tissue region for treatment.
30 In particular, the medical device 14 may include a device operable to thermally treat a selected tissue site, including cardiac tissue. The medical system 10 may also include one or more sensors to monitor the operating parameters throughout the system,

including for example, pressure, temperature, flow rates, volume, or the like in the console 12, the umbilical system 16, and/or the medical device 14.

Umbilical system 16 may include three separate umbilicals: a coaxial cable umbilical 18, an electrical umbilical 20 and a vacuum umbilical 22. Although separate
5 umbilicals are shown, it is contemplated that one or more connections may be included in one or more umbilicals having one or more coaxial or otherwise integrally contained passages or conduits therethrough providing electrical and fluid communication between the medical device 14 and the console 12. An outer vacuum umbilical may be suitable for a medical device having multiple layers or balloons. If
10 the user wishes to perform a radiofrequency (“RF”) ablation procedure, radiofrequency energy can be provided to electrodes on the medical device 14 via electrical umbilical 20 to perform an RF ablation technique. Electrical umbilical 20 can include an electrocardiograph (“ECG”) box 24 to facilitate a connection from one or more electrodes on the medical device 14 to an ECG monitor (not shown). Coaxial
15 umbilical 18 may include both a cooling injection umbilical and a vacuum umbilical that provide respective inlet and return paths for a refrigerant or coolant used to cool a tissue-treating section of the device 14. The vacuum umbilical 22 may provide a safety conduit allowing excess coolant or gas to escape from the device 14 if the pressure within the medical device 14 exceeds a predefined limit. The vacuum
20 umbilical 22 can also be used to capture air through a leak of the outer vacuum system where it is outside the patient and as a lumen to ingress blood when inside the patient.

Now referring to FIG. 2, the medical device 14 is shown in more detail. The medical device 10 may include an elongate body 26 passable through a patient’s vasculature. The elongate body 26 may define a proximal portion and a distal portion,
25 and may further include one or more lumens may disposed within the elongate body 26 thereby providing mechanical, electrical, and/or fluid communication between the proximal portion of the elongate body 26 and the distal portion of the elongate body 26. For example, the elongate body 26 may include an injection lumen 28 and an exhaust lumen 30 defining a fluid flow path therethrough. In addition, the elongate
30 body 26 may include a guidewire lumen 32 movably disposed within and/or extending along at least a portion of the length of the elongate body 26 for over-the-wire applications. The guidewire lumen 32 may define a proximal end and a distal

end, and the guidewire lumen 32 may be movably disposed within the elongate body 26 such that the distal end of the guidewire lumen 32 extends beyond and out of the distal portion of the elongate body 26.

The medical device may include one or more treatment regions for energetic or other therapeutic interaction between the medical device 14 and a treatment site. The treatment regions may deliver, for example, radiofrequency energy, cryogenic therapy, or the like. For example, the device 14 may include a first treatment region 34 having a thermal treatment element, such as an expandable membrane or balloon and/or one or more electrodes or other thermally-transmissive components, at least partially disposed on the elongate catheter body. In a particular example, the first treatment region 34 may include a first expandable/inflatable element or balloon 36 defining a proximal end coupled to the distal portion of the elongate body 26 of the medical device 14, while further defining a distal end coupled to the distal end of the guidewire lumen 32. As such, due to the movable nature of the guidewire lumen 32 about the elongate body 26, any axial and/or longitudinal movement of the guidewire lumen 32 may act to tension or loosen the first expandable element 36, i.e., extend or retract the expandable element 36 from a lengthened state to a shortened state during an inflation or deflation thereof. In addition, the first expandable element 36 may have any of a myriad of shapes, and may further include one or more material layers providing for puncture resistance, radiopacity, or the like. The first expandable element 36 may be in communication with the fluid injection and exhaust lumens of the medical device 14 as described above.

The medical device 14 may further include a second expandable/inflatable element or balloon 38 contained within or otherwise encompassed by the first expandable element 36 such that an interstitial region, envelope or space 40 is defined therebetween. The second expandable element 38 may be in communication with the fluid injection and exhaust lumens of the medical device 14 as described above, i.e., a fluid flow path may provide an inflation fluid or coolant, such as a cryogenic fluid or the like, to the interior of the second expandable element 38. Further, the interstitial region 40 may be in fluid communication with an interstitial lumen 42 providing a fluid flow path or avenue separate and independent from a fluid flow path delivering fluid or otherwise in communication with an interior of the second expandable

element 38. The second pathway provides an alternate exhaust route for fluid that may leak from the interior of the second expandable element 38 into the interstitial region 40 or fluid entering the medical device 14 from the exterior. In particular, the isolation of the interstitial lumen 42 from the interior of the second expandable element 38 provides an alternate route for fluid to circulate in the case of a rupture or leak of either the first or second expandable elements, as well as allowing for the injection or circulation of fluids within the interstitial region 40 independently of fluids directed towards the second expandable element 38. Towards that end, the interstitial region may be in fluid communication with a fluid source, a vacuum source, or the like separate from a fluid source, vacuum source or otherwise in fluid communication with the interior of the second expandable element 38. Alternatively, the interstitial lumen 42 may be joined to or otherwise in fluid communication with the injection lumen 28 and the interior of the second expandable element 38 to provide a single exhaust or vacuum source for the medical device 14.

Now referring to 3, the medical device may further include a second treatment region 44 located proximally of the first treatment region 34, where the second treatment region 44 is operable independently and separately from the first treatment region 34. For example, the second treatment region 44 may be fluidically isolated or sealed from fluid flow with the first treatment region 34. The first and second treatment regions 34, 44 may generally provide the ability to deliver therapeutic treatment to a plurality of locations while maintaining the medical device 14 in a substantially fixed or static position.

The two treatment regions may also provide the ability to provide treatment or therapeutic energy to varying locations having different dimensions, shapes, or other geometric and anatomical characteristics. As described above, the first treatment region 34 may include one or more expandable elements or balloons. The first treatment region 34 may thus provide for arcuate, circular, and/or circumferential treatment patterns. In turn, the second treatment region 44 may include a substantially linear, elongate thermal segment 46 enabling energetic or thermal exchange with a contacted tissue area. Of note, the thermal segment 46 may be substantially linear when not experiencing any external loading or force, but may retain sufficient flexibility to curve into an arcuate, curvilinear shape to contact a desired tissue region.

The thermal segment may be constructed from one or more materials imparting thermally conductive properties, such as nylon, polyethylene terephthalate (“PET”), and/or polyethylene (“PE”) for example. In particular, the thermal segment 46 may provide sufficient thermal conductivity for ablation of contacted tissue through the use of a cryogenic refrigerant or a radiofrequency or other heat source coupled to or otherwise in thermal communication with the thermal segment 46.

Such thermal communication may be achieved, for example, by a fluid flow path in fluid communication with the thermal segment 46 that is independently operated or otherwise separated from a fluid flow path delivering a cooling or treatment medium to the first treatment region 34. For example, a secondary fluid injection lumen 48 may be in fluid communication with an interior of the thermal segment 46 of the second treatment region 44. The secondary fluid injection lumen 48 may include one or more apertures 50 therein for dispersing, expanding, or otherwise delivering a fluid to the thermal segment 46. The secondary fluid injection lumen 48 may be placed in fluid communication with a fluid supply common to the first treatment region 34, or may be coupled to a separate and independently operated fluid source. Where a common fluid source is elected, one or more valves, controllers, or the like may provide for the controlled, independent, and separate dispersion or circulation of fluid through the two injection lumens. Such valves, controllers, or the like may be located in a portion of the medical device 14 and/or in the console 12.

The thermal segment 46 may further include sealed transverse sections or walls 52, 52' spanning from the outer walls or layers of the elongate body 26 and around the one or more lumens extending towards the distal portion of the medical device that restrict or wholly prevent fluid dispersed within the thermal segment 46 from travelling distally towards the first treatment region 34. The thermal segment 46 may further include a secondary exhaust lumen (not shown), or the exhaust lumen 30 may be in fluid communication with the second treatment region 44, thereby allowing a single exhaust or vacuum source to remove expended coolant from both the first and second treatment regions jointly.

Continuing to refer to FIG. 3, the medical device may further include a third treatment region 53 located distally of the first treatment region 34, where the third treatment region 53 is operable independently and separately from the first and second

treatment regions 34, 44 through one or more independently operated and/or isolated fluid lumens (not shown). For example, the third treatment region 53 may be fluidically isolated or sealed from fluid flow with the first and second treatment region. The plurality of treatment regions 34, 44, 53 may generally provide the ability to deliver therapeutic treatment to a plurality of locations while maintaining the medical device 14 in a substantially fixed or static position. In particular, the third treatment region 53 may provide for a “spot” ablation of discrete tissue locations, while also providing for anchoring of the distal end of the medical device 14 through cryoadhesion with contacted tissue. The third treatment region 53 may be constructed from one or more metals, thermally conductive polymers, and/or composites thereof.

The medical device 14 may further include one or more temperature and/or pressure sensors (not shown) proximate the treatment region(s) for monitoring, recording or otherwise conveying measurements of conditions within the medical device 14 or the ambient environment at the distal portion of the medical device 14. The sensor(s) may be in communication with the console 12 for initiating or triggering one or more alerts or therapeutic delivery modifications during operation of the medical device 14.

Referring to FIGS. 2 and 3, the medical device 14 may include a handle 54 coupled to the proximal portion of the elongate body 26, where the handle 54 may include an element such as a lever or knob 56 for manipulating the catheter body and/or additional components of the medical device 14. For example, a pull wire 58 with a proximal end and a distal end may have its distal end anchored to the elongate body 26 at or near the distal end. The proximal end of the pull wire 58 may be anchored to an element such as a cam in communication with and responsive to the lever 56.

The handle 54 can further include circuitry for identification and/or use in controlling of the medical device 14 or another component of the system. For example, the handle may include one or more pressure sensors 60 to monitor the fluid pressure within the medical device 14. Additionally, the handle may be provided with a fitting 62 for receiving a guidewire that may be passed into the guidewire lumen 32.

The handle 54 may also include connectors that are matable directly to a fluid supply/exhaust and control unit or indirectly by way of one or more umbilicals. For

example, the handle may be provided with a first connector 64 that is matable with the co-axial fluid umbilical 18 and a second connector 66 that is matable with the electrical umbilical 20. The handle 54 may further include blood detection circuitry 68 in fluid and/or optical communication with the injection, exhaust and/or interstitial lumens. The handle 54 may also include a pressure relief valve 70 in fluid communication with the injection, exhaust and/or interstitial lumens to automatically open under a predetermined threshold value in the event that value is exceeded.

Continuing to refer to FIGS. 2-3, the medical device 14 may include an actuator element 72 that is movably coupled to the proximal portion of the elongate body 26 and/or the handle 54. The actuator element 72 may further be coupled to the proximal portion of the guidewire lumen 32 such that manipulating the actuator element 72 in a longitudinal direction causes the guidewire lumen 32 to slide towards either of the proximal or distal portions of the elongate body 26. As a portion of either and/or both the first and second expandable elements 36,38 may be coupled to the guidewire lumen 32, manipulation of the actuator element 72 may further cause the expandable element(s) to be tensioned or loosened, depending on the direction of movement of the actuator element 72, and thus, the guidewire lumen 32.

Accordingly, the actuator element 72 may be used to provide tension on the expandable element(s) 36,38 during a particular duration of use of the medical device 14, such as during a deflation sequence, for example. The actuator element 72 may include a thumb-slide, a push-button, a rotating lever, or other mechanical structure for providing a movable coupling to the elongate body 26, the handle 54, and/or the guidewire lumen 32. Moreover, the actuator element 72 may be movably coupled to the handle 54 such that the actuator element 72 is movable into individual, distinct positions, and is able to be releasably secured in any one of the distinct positions.

Referring again to FIG. 3, the second treatment region 44 may be deflectable, steerable, or otherwise manipulated into a desired position or configuration independently or differently from the first treatment region 34 and/or adjacent portions of the elongate body 26. In particular, the elongate body 26 of the medical device 14 may be constructed from one or more layers 74, 74' of material or differing components to provide a desired degree of flexibility while maintaining the capability to transmit torque along the length of the medical device 14. The layers 74, 74' may

include a multitude of polymers, plastics, and composites thereof, as well as braided or other structural reinforcing materials/components running therethrough. The elongate body 26 may further include one or more steering wires 76 or actuation mechanisms to deliver a force to a particular segment or portion of the medical device 14, such as a region proximate to the second treatment region 44, in addition to the pull wire 58 described above, which may provide deflection or steering of the first treatment region 34. The construction of the elongate body 26 substantially dictates its resulting deflection or bending behavior when a force is applied, i.e., its deflection profile.

10 The second treatment region 44 may define a deflection profile different from a deflection profile or behavior of adjacent sections 78, 78' of the catheter body 26. For example, the thermal segment 46 of the second treatment region 44 may have a construction different from the adjacent sections 78, 78' of the catheter body 26, resulting in a different flexibility, deflection or bending result when a force is applied.

15 The different construction may include different use or multitudes of select materials, as well as using selected materials in a different order or relationship to one another. In a particular example, the second treatment region 44 may have greater flexibility than the adjacent section 78, 78'. The thermal segment 46 may have a width or thickness of material less than a width of material constituting portions of the catheter

20 body 26. In addition and/or as an alternative, the thermal segment 46 may be devoid of or have reduced structural reinforcing components (such as braided constructs, longitudinal splines, deflection biasing members, or the like) compared to portions of the catheter body 26. The variations in deflection behavior between the second treatment region 44 and the surrounding portions of the catheter body 26 may allow

25 the second treatment region 44 to be deflected or bent towards a targeted tissue for treatment while the medical device 14 remains substantially static or in place. In addition, the variations in bending or deflection behavior between the second treatment region 44 and the surrounding catheter body segments may allow for the transmission of a deflective force from a catheter body section to the second treatment

30 region 44, as described in more detail below. In addition, one or more radiopaque markers 79, 79' may be positioned at a boundary between the second treatment region

44 and either of the adjacent catheter body sections or segments 78, 78' to facilitate positioning of the treatment region through known medical imaging methodologies.

In an exemplary system, a fluid supply 80 including a coolant, cryogenic refrigerant, or the like, an exhaust or scavenging system (not shown) for recovering or venting expended fluid for re-use or disposal, as well as various control mechanisms for the medical system may be housed in the console 12. In addition to providing an exhaust function for the catheter fluid supply, the console 12 may also include pumps, valves, controllers or the like to recover and/or re-circulate fluid delivered to the handle 54, the elongate body 26, and treatment region(s) 34,44 of the medical device 14. A vacuum pump in the console 12 may create a low-pressure environment in one or more conduits within the medical device 14 so that fluid is drawn into the conduit(s) of the elongate body 26, away from the treatment region(s) 34, 44, and towards the proximal end of the elongate body 26. The console 12 may include one or more controllers, processors, and/or software modules containing instructions or algorithms to provide for the automated operation and performance of the features, sequences, or procedures described herein.

Now referring to FIGS. 4-5, in an exemplary method of use, the medical system 10 may be used to deliver therapeutic treatment to a plurality of targeted tissue areas. For example, the medical device 14 may be positioned and operated to ablate targeted tissue region in the heart. The first treatment region 34 may be positioned in the proximity of a pulmonary vein opening or junction 82 with a portion of the atrial wall 84. Where the first treatment region 34 includes an expandable element, the expandable element may be inflated or otherwise expanded to substantially occlude the pulmonary vein. The occlusion reduces the blood flow around the treatment region 34, thereby allowing enhanced thermal exchange between the medical device 14 and the targeted tissue. The occlusion may further anchor a distal portion of the medical device 14, thereby facilitating additional maneuvering, deflection, or the like of proximal portions of the catheter body 26.

In particular, once the first treatment region 34 has been positioned where desired, the second treatment region 44 may subsequently be positioned proximate targeted tissue for treatment elsewhere in the heart, such as the right atrial isthmus. The general placement and positioning of the second treatment region 44 may be

facilitated by the imaging and tracking of the markers 79, 79' located at the boundaries of the second treatment region 44. Further to the general placement of the second treatment region 44, the second treatment region may then be steered or otherwise deflected towards the specific tissue to be treated. The deflection may be achieved by applying a deflection force at the proximal end of the catheter body 26, through the handle 54 for example. The force may be a compressive, linear force transmitted along a longitudinal axis of the catheter body 26. Given the anchoring of the first treatment region 34, and the increased rigidity of the catheter body segments 78, 78' adjacent the second treatment region 44, the second treatment region 44 may deflect outwards or "buckle" as a result of the linearly/longitudinally applied deflection force (as shown in FIG. 5). This deflection or "buckling" may thus cause increased contact and pressure between the second treatment region 44 and the targeted tissue, thereby providing enhanced or otherwise increased thermal exchange for tissue treatment.

Once the first and second treatment regions have been appropriately positioned as described above, the first and second treatment regions 34, 44 may be operated to affect a desired therapy, such as tissue ablation. The tissue ablation may be achieved by the circulation of a cryogenic fluid through either and/or both of the first and second treatment regions sequentially and/or simultaneously, for example.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.

What is claimed is:

1. A medical device, comprising:
 - an elongate catheter body;
 - a first treatment region on the catheter body;
 - 5 a second treatment region proximal to the first treatment region, wherein the second treatment region defines a first deflection profile and is disposed between two adjacent catheter body segments defining deflection profiles different from the first deflection profile.
- 10 2. The medical device of claim 1, wherein the first treatment region includes an expandable element.
3. The medical device of claim 2, wherein the second treatment region includes a substantially linear thermal segment.
4. The medical device of claim 1, wherein the second treatment region is more flexible than the adjacent catheter body segments.
- 15 5. The medical device of claim 1, further comprising a third treatment region located distally of the first treatment region.
6. The medical device of claim 1, wherein the first treatment region is operable independently from the second treatment region.
- 20 7. The medical device of claim 6, further comprising a first fluid flow path in fluid communication with the first treatment region, and a second fluid flow path in fluid communication with the second treatment region.
8. The medical device of claim 7, further comprising a cryogenic fluid source in fluid communication with at least one of the first and second fluid flow paths.
- 25 9. The medical device of claim 1, further comprising a radiopaque marker positioned at a boundary between the second treatment region and one of the adjacent catheter body segments.

10. An intravascular catheter, comprising:
- a flexible elongate body;
 - an expandable element positioned on the elongate body;
 - a substantially linear thermal segment located proximally of the expandable element, wherein the thermal segment is positioned between two adjacent portions of the catheter body, the adjacent portions having a rigidity greater than a rigidity of the thermal segment;
 - a first fluid flow path in fluid communication with the expandable element; and
 - a second fluid flow path in fluid communication with the thermal segment.
11. The intravascular catheter of claim 10, wherein the first fluid flow path is operable independently from the second fluid flow path.
12. The intravascular catheter of claim 10, wherein the first fluid flow path includes a first fluid injection lumen, and the second fluid flow path includes a second fluid injection lumen.
13. The intravascular catheter of claim 12, wherein the first fluid flow path and the second fluid flow path include a common exhaust lumen.
14. The intravascular catheter of claim 10, further comprising a cryogenic fluid source in fluid communication with at least one of the first and second fluid flow paths.
15. The intravascular catheter of claim 10, further comprising a radiopaque marker positioned at a boundary between the second treatment region and one of the adjacent catheter body segments.
16. A method of treating cardiac tissue, comprising:

positioning an expandable element of a medical device proximate a pulmonary vein;

5 positioning a substantially linear thermal segment of the medical device proximate an atrial wall, the thermal segment being more flexible than medical device segments adjacent to the thermal segment;

applying a compressive force from a proximal portion of the medical device to the thermal segment, the compressive force causing the thermal segment to deflect towards the atrial wall; and

10 ablating at least one of the pulmonary vein and the atrial wall with the medical device.

17. The method of Claim 16, wherein positioning the expandable element includes expanding the expandable element in the pulmonary vein to substantially occlude the pulmonary vein.
18. The method of Claim 16, wherein applying a compressive force includes
15 applying an axial force in a distal direction along a longitudinal axis of the medical device.
19. The method of Claim 16, wherein ablating at least one of the pulmonary vein and the atrial wall includes circulating a cryogenic fluid through at least one of the expandable element and the thermal segment.

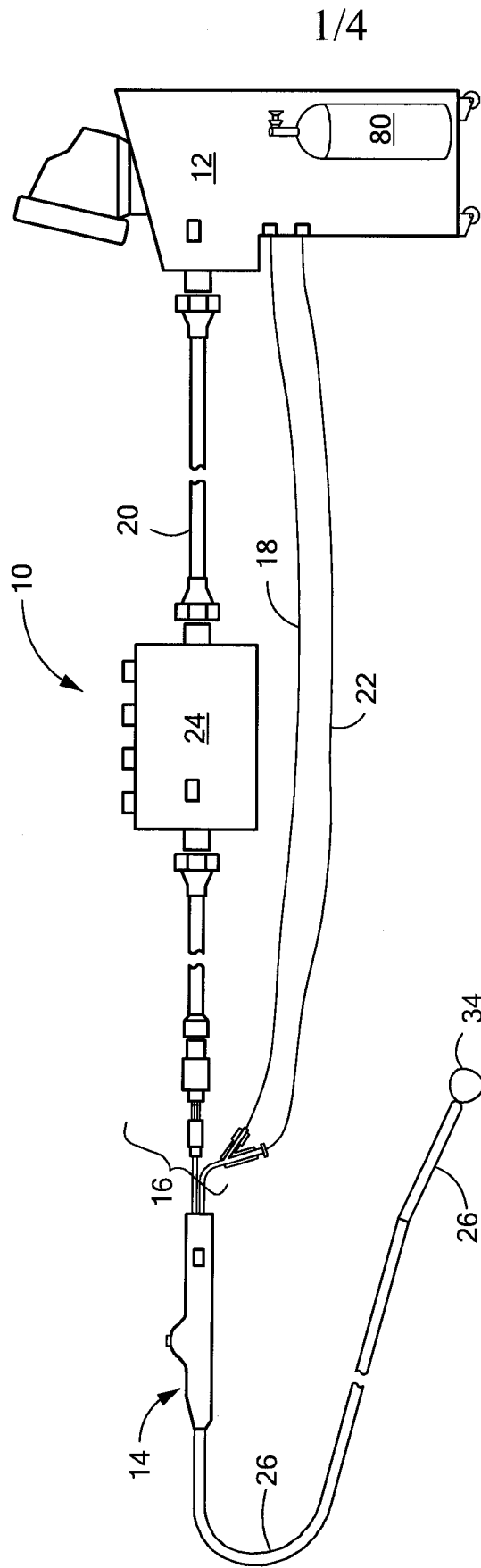


FIG. 1

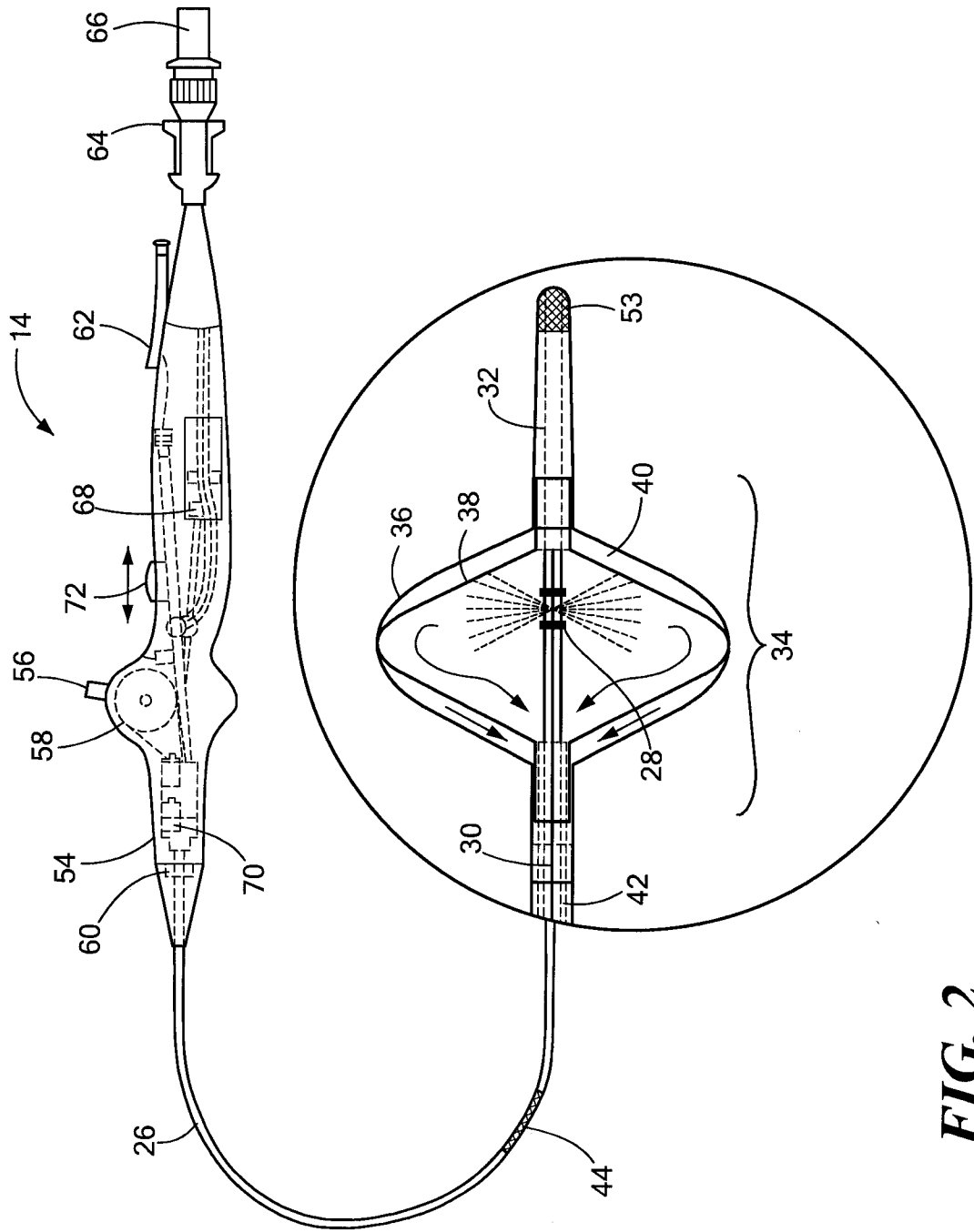


FIG. 2

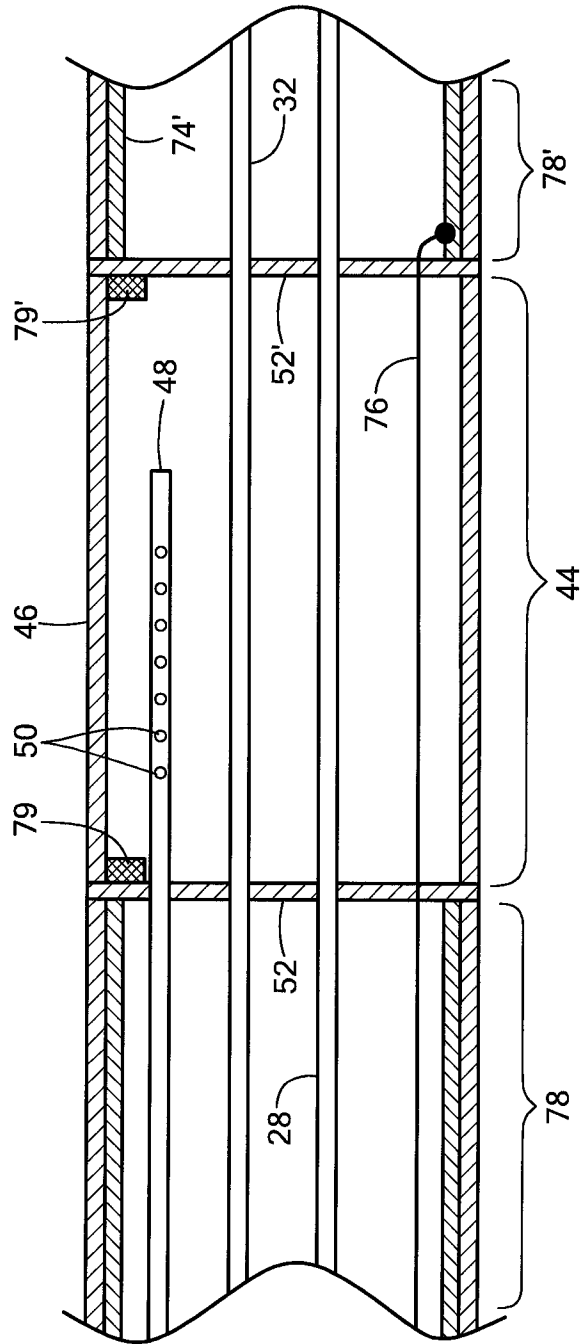


FIG. 3

4/4

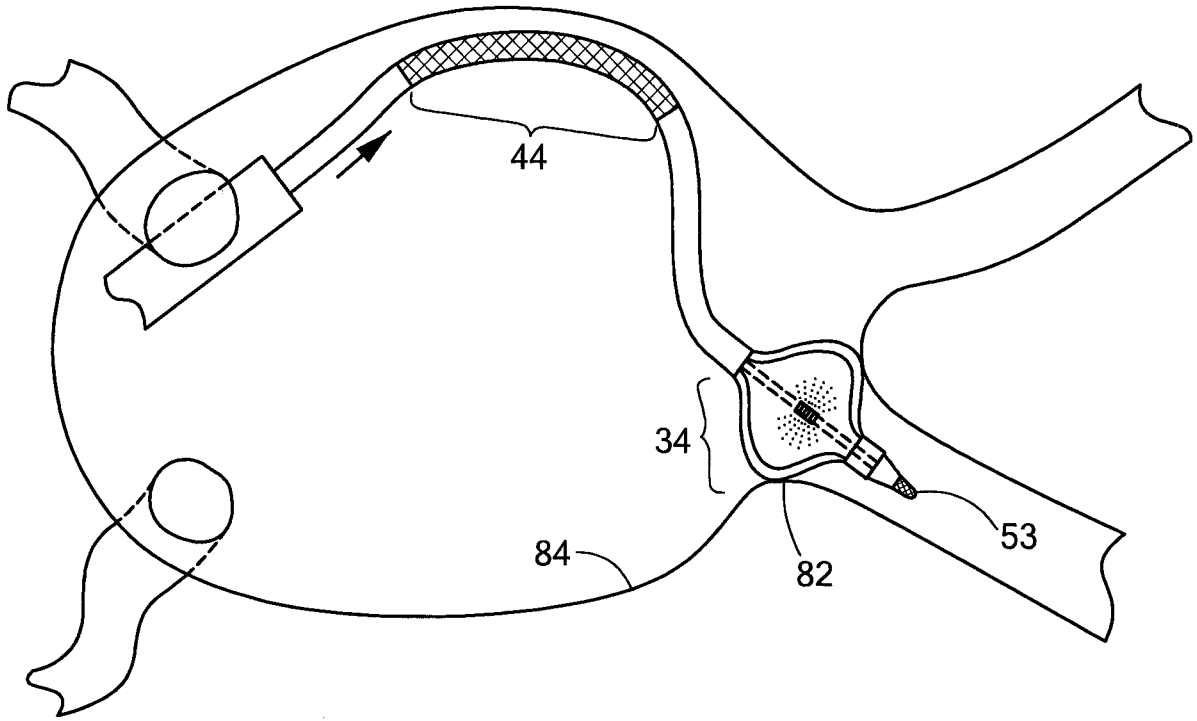


FIG. 4

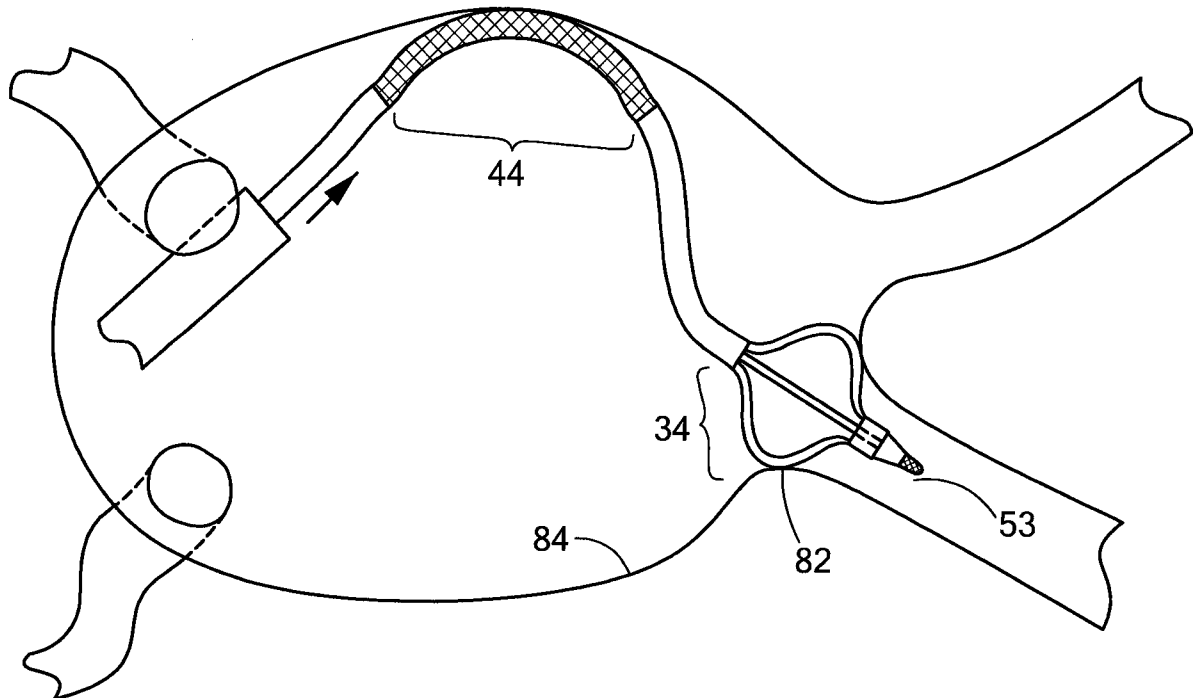


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2011/000064

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: **A61M 25/01** (2006.01) , **A61B 18/02** (2006.01) , **A61B 18/08** (2006.01) , **A61M 25/098** (2006.01) , **A61M 25/10** (2006.01)
 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)
 IPC (2011.01): A61M 25/01, A61B 18/02, A61B 18/08, A61M 25/098, A61M 25/10

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
 Canadian Patent Database, EPOQUE(EPODOC)
 keywords: thermal, heat, cool, cryogenic, multiple, second, plurality, separate, site, region, area, zone, section, treat, balloon

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5542928 (Evans, M. A. et al.) 06 August 1996 (06-09-2006) *figure 11, column 12, lines 25-36*	1, 5, 6 2, 3, 7, 8
Y	WO 2006/124176 A1 (Mihalik, T. A. et al.) 23 November 2006 (23-11-2006) *figure 1, page 4, lines 12-22*	2, 3, 7, 8
A	US 5788647 (Eggers, P. E.) 04 August 1998 (04-09-1998) *figure 1 and 6*	1-15
A	US 5261411 (Hughes, T. J.) 16 November 1993 (16-11-1993) *figure 1*	1-15

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 31 March 2011 (31-03-2011)	Date of mailing of the international search report 8 April 2011 (08-04-2011)
---	---

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Alison Canteenwalla 934-8534
---	---

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. Claim Nos. : 16-19
because they relate to subject matter not required to be searched by this Authority, namely :

Claims 16-19 relate to a method of treating cardiac tissue, which falls into the category of a method for treatment of the human or animal body by surgery or therapy which the International Search Authority is not required to search.
2. Claim 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. Claim 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 all searchable claims.
2. As all searchable claims could be searched without effort justifying 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 report covers only those claims for which fees were paid, specifically claim 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 claim 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.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2011/000064

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US5542928A	06-08-1996	AU655262B2	08-12-1994
		AU1634692A	19-11-1992
		EP0766533A4	04-01-1995
		EP0766533A1	09-04-1997
		US5433708A	18-07-1995
		WO9220290A1	26-11-1992
WO2006124176A1	23-11-2006	CA2607175A1	23-11-2006
		EP1881796A1	30-01-2008
		EP2269528A2	05-01-2011
		EP2269528A3	02-03-2011
		US2006270982A1	30-11-2006
		US7727191B2	01-06-2010
		US2010211056A1	19-08-2010
US5788647A	04-08-1998	AU757810B2	06-03-2003
		AU2033299A	30-09-1999
		AU6248598A	18-08-1998
		AU6376600A	13-02-2001
		CA2256915A1	17-09-1999
		CA2256915C	11-03-2003
		EP0943289A1	22-09-1999
		IL128840D0	31-01-2000
		JP11318834A	24-11-1999
		NO991259D0	15-03-1999
		NO991259A	20-09-1999
		US5928155A	27-07-1999
		US6299583B1	09-10-2001
		WO0106920A1	01-02-2001
		WO9832373A1	30-07-1998
US5261411A	16-11-1993	AU3329893A	28-07-1993
		WO9312716A1	08-07-1993