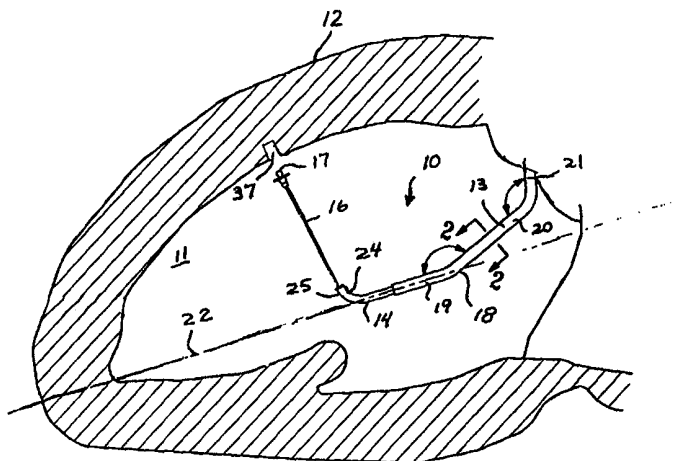




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(54) Title: GUIDING CATHETER SYSTEM FOR ABLATING HEART TISSUE



(57) Abstract

A guiding catheter system (10) for delivering an elongated therapeutic or diagnostic device into a patient's left ventricle (11) which includes a first guiding catheter (13) with a shaped distal extremity (18) configured to be aligned with or parallel to a longitudinal axis (22) or long dimension of the patient's left ventricle and a second guiding catheter (14) slidably and rotatably disposed within an inner lumen (15) of the first guiding catheter which has a shaped distal shaft section (24) and an inner lumen (18) configured to slidably receive an elongated therapeutic or diagnostic device (16 and 17) such as a tissue ablation device, e.g. an optical fiber connected to a laser source, an ultrasonic energy emitting device or a radio frequency energy emitting device. The shaped distal section (18) of the first guiding catheter is shaped or is shapable within the patient's heart chamber. The second guiding catheter is advanced out of the inner lumen of the first guiding catheter until the distal end extends out of the port in the distal end of the first guiding catheter and provides a passageway for the therapeutic or diagnostic device to engage the endocardium surface at a perpendicular or near perpendicular orientation.

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GUIDING CATHETER SYSTEM FOR ABLATING HEART TISSUE

RELATED APPLICATIONS

This application is a continuation-in-part of copending application Serial No. 646,856, filed on May 8, 1996, entitled SYSTEM AND METHOD FOR TREATING
5 OR DIAGNOSING HEART TISSUE, which is a continuation-in-part of copending application Serial No. 08/438,743, filed on May 10, 1995, entitled DELIVERY SYSTEM AND METHOD FOR MYOCARDIAL REVASCULARIZATION, both of which are incorporated herein in their entirety by reference.

BACKGROUND OF THE INVENTION

10 This invention relates to elongated devices for therapeutic or diagnostic procedures in a wall of a patient's heart, particularly to the treatment of myocardial tissue experiencing ischemic conditions, by revascularization of such myocardial tissue.

Myocardial revascularization typically involves formation of one or more
15 channels in a patient's heart wall which defines the heart chamber, particularly the left ventricle. The first trials of the revascularization process were apparently made by Mirhoseini et al. See for example the discussions in Lasers in General Surgery (Williams & Wilkins; 1989), pp 216-223. Other early disclosures of this procedure are found in an article by Okada et al. in Kobe J. Med. Sci 32, 151-161, October
20 1986 and in U.S. Patent No. 4,658,817 (Hardy). Both of these references describe intraoperative revascularization procedures which require the chest wall to be

opened and which include formation of the revascularization channels completely through the heart wall, i.e. the epicardium, the myocardium and the endocardium.

Copending application Serial No. 08/078,443, filed on June 15, 1993 (Aita et al.), which is incorporated herein in its entirety, describes an intravascular system for myocardial revascularization which is introduced percutaneously into a peripheral artery and advanced through the patient's arterial system into the left ventricle of the patient's heart. The revascularization channels are not usually formed through the entire heart wall but only the endocardium and into the myocardium from within the left ventricle. This procedure eliminates the need of the prior intraoperative procedures to open the chest cavity and to penetrate through the entire heart wall in order to form the channel through the endocardium into the myocardium. While the percutaneous method and system for introducing the revascularization device developed by Aita *et al.* represents a substantial advance, one of the difficulties in forming revascularization channels from within a patient's left ventricle by means of a percutaneously introduced revascularization system has been accurately directing the distal tip of the channel forming device to a desired region of the patient's endocardium and maintaining the placement of the distal end of the channel forming device against a desired region of the ventricular wall at a proper angle, i.e. perpendicular or near perpendicular to the endocardium, while the heart is beating. Maintaining placement of the operative distal tip of the device is important because lateral displacement can affect the channel formation within the heart wall. The anatomy of human hearts and particularly the relationship of the ascending aorta and the left ventricle can vary considerably from patient to patient.

The entry angle from the ascending aorta through the aortic valve into the left ventricle of a human heart does not facilitate the easy access to the free wall of the patient's heart which in substantial part defines the left ventricle. Direct entry from the ascending aorta through the aortic valve usually leads into the cordae tendonae
5 of the mitral valve and to the posterior sulcus adjacent to the inferolateral papillary muscle to which the cordae are attached. As a result, the distal extremity of a guiding catheter advanced into the left ventricle through the aortic valve from the ascending aorta can inadvertently become entrapped or entangled with the cordae tendonae or be positioned in the posterior sulcus adjacent to the base of the
10 inferolateral papillary muscle.

What has been needed is an improved delivery system and method for delivering a channel forming or other ablation device within the patient's heart chamber, particularly via percutaneous introduction into the patient's vasculature, which provides for an easy and accurate placement of the device against a desired
15 region of the endocardium at the desired orientation and the maintenance of the position of the device within the patient's heart chamber while tissue is being ablated and the heart is beating. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

20 The present invention is directed to a system for delivering an elongated therapeutic or diagnostic device into the interior of a patient's heart chamber that provides access to a wide region of the patient's endocardium defining at least in part the heart chamber. Additionally, the system disclosed accurately places and

effectively holds the operative distal end of the device at a desired location within the patient's heart chamber. One embodiment of the present invention may be used to form a channel into the wall defining the heart chamber or to perform other treatments or diagnosis. The system also allows the position of the operative distal
5 end of the device to be readily changed to facilitate performing therapeutic or diagnostic procedures at a plurality of locations within the heart chamber at a desired perpendicular or near perpendicular orientation with respect to the patient's endocardium.

The guiding catheter system of the invention generally includes a first
10 guiding or delivery catheter which has a relatively straight main shaft section and a shaped distal shaft section having a discharge axis selected so that is generally aligned with or parallel to the longitudinal axis of the patient's left ventricle, and a second guiding or delivery catheter slidably and rotatably disposed within an inner lumen of the first guiding catheter and provided with a shaped distal section
15 configured to have a discharge axis which is normal or near normal to the patient's endocardial layer which defines in part the left ventricle.

In accordance with the present invention the first guiding catheter has proximal and distal ends, a port in the distal end and an inner lumen extending within the catheter to the port in the distal end. The first guiding catheter has a
20 relatively straight main shaft section and a preshaped distal section configured to point in a direction so that the discharge axis of this catheter is aligned with or parallel or near parallel to the longitudinal axis of the left ventricle. For many

applications the first guiding catheter is about 90 to about 130 cm, preferably about 100 to about 120 cm in length.

In one presently preferred embodiment of the invention, the first guiding catheter has a main shaft section and a shaped distal section with a proximal and
5 distal angled segments which provide a discharge axis approximating the longitudinal axis or long dimension of the heart chamber.

In this embodiment the first segment of the distal shaft section is at an angle of about 95° to about 160° , preferably about 100° to about 140° with respect to a proximally adjacent second segment of the distal shaft section and the proximally
10 adjacent second segment is at an angle of about 95° to about 160° , preferably about 100° to about 135° with respect to either the proximally adjacent main shaft section or a third segment of the distal shaft section proximally adjacent to the second segment. If there is a third segment of the distal section, it is at an angle of about angle of about 110° to about 170° , preferably about 120° to about 150° with respect to proximally
15 adjacent main shaft section. The first and second segments should each be about 0.5 to about 5, preferably about 0.5 to about 4 cm in length, with the total length of the shaped distal section with two segments being about 2 to about 6 cm. If the distal section has a third segment, it should have a length of about 1 to about 5 cm, preferably about 2 to about 4 cm. The length of the shaped distal section with three
20 segments should be about 3 to about 8 cm, preferably about 4 to about 7 cm.

In another presently preferred embodiment, the shaped distal section of the first guiding catheter has a single angled segment which provides a discharge axis approximating the longitudinal axis or long dimension of the heart chamber. In this

embodiment the single angled segment of the distal shaft section has a length of about 2 to about 8 cm, preferably about 4 to about 6 cm and is at an angle of about 95° to about 160°, preferably about 100° to about 140° with respect to a proximally adjacent portion of the main shaft section.

- 5 The second guiding catheter of the invention is longer than the first guiding catheter, and is slidably and preferably rotatably disposed within inner lumen of the first guiding catheter. The second guiding catheter likewise has proximal and distal ends, a port in the distal end and an inner lumen extending within the second guiding catheter to the port in the distal end. The second guiding catheter has a
- 10 relatively straight main shaft section and a distal section which is at an angle of about 80° to about 140°, preferably about 90° to about 120° with respect to the main shaft section thereof. The second guiding catheter should be at least 10 cm longer, preferably about 15 to about 50 cm longer, than the first guiding catheter and is about 100 to about 150 cm, preferably about 110 to about 140 cm in length.
- 15 The shaped distal section of the second guiding catheter should have a radius of curvature of about 2 to 30 mm, preferably about 4 to about 20 mm between the main shaft section and the exit or discharge axis through the port in the distal end of the shaped distal section. The length of the shaped distal section is about 0.5 to about 4 cm, preferably about 1 to about 3 cm.

- 20 The angles of the various segments of the distal section of the first catheter and the angle of the second guiding catheter facilitate directing the operative distal end of an elongated therapeutic or diagnostic device which is slidably disposed within the inner lumen of the second guiding catheter toward the region of the

endocardium where the procedure is to be performed at an orientation that is preferably perpendicular or near perpendicular with the endocardial surface of the patient's heart wall.

A presently preferred elongated therapeutic or diagnostic device is a system
5 for ablating tissue within the wall of the patient's heart, particularly for the
revascularization of an ischemic region thereof. The ablation system is adapted to
emit ablation energy from its distal end which may be based on laser, radio
frequency, ultrasonic or other high energy emissions. The ablation system is
slidably disposed within the inner lumen of the second guiding catheter and is long
10 enough so that the distal operative end extends out the port in the distal end of the
second guiding catheter and contacts the endocardium and proximal end which
extends out the proximal end of the second guiding catheter and be operatively
connected to a source of ablation energy such as laser, RF, ultrasound and the like.
Preferably, the distal extremity of the ablation system which extends out the distal
15 end of the guide catheter has sufficient rigidity to be self-supporting within the
environment of the heart chamber.

In a presently preferred embodiment of practicing the method of the
invention, the first guiding catheter of the delivery system is introduced into a
peripheral artery, such as the femoral artery, and advanced through the patient's
20 arterial system until the distal end of the first catheter is disposed within the
patient's left ventricle. The position of the first guiding catheter is adjusted by the
physician under fluoroscopic observation or other techniques until the distal tip is
oriented generally along or parallel to the longitudinal axis of the left ventricle. The

second guiding catheter is advanced through the previously introduced first guiding catheter which has a distal end appropriately positioned within the left ventricle. The second guiding catheter is rotatably and slidably disposed within the inner lumen of the first delivery catheter to facilitate the desired placement and orientation

5 of the shaped distal section of the second guiding catheter within the left ventricle normal to the endocardium. In this manner the elongated therapeutic or diagnostic device slidably disposed within the inner lumen of the second guiding catheter is properly oriented with respect to the endocardial surface of the heart chamber in order to effectively couple emitted ablation energy to the tissue of the heart wall.

10 Additionally, such perpendicularity helps to maintain the position of the distal end of the device, particularly a channel forming device, against the heart wall during multiple heart cycles. Without such perpendicular orientation, the operative tip of the therapeutic or diagnostic device tends to move laterally while the heart is beating resulting in mislocation of the channel, or ablated tissue or medical

15 procedure.

The longitudinal and rotational movements of the first and second guiding catheters, particularly when the distal extremity of both are shaped, provide access to a wide region of the patient's endocardial surface and allow for the accurate placement of the operative end of the therapeutic or diagnostic device within the

20 patient's left ventricle in a number of positions. The location of the distal end of the therapeutic or diagnostic device within the heart chamber, and particularly with respect to the endocardial surface, can be detected fluoroscopically by providing a radiopaque marker on the distal extremities of the ablation device and each of the

guiding catheters. The use of dye injections through a port in the distal end of first and/or the second guiding catheter may be employed to further facilitate the location of the distal end of these catheters. Other means such as a variety of proximity detectors may be employed to detect contact between the distal end of
5 the therapeutic or diagnostic device or the delivery catheters and the endocardium.

The distal sections of the first and second delivery catheters are preferably preformed into a desired shape so that they will provide a desired orientation for the delivery system when they extend into the patient's heart chamber. However, the catheters may alternatively be provided with control lines or other suitable means
10 (e.g. a shape memory or a superelastic or pseudoelastic NiTi element) to deflect or otherwise shape the distal sections of the catheters once the distal extremity of the delivery system extends into the heart chamber.

With the system of the invention, essentially the entire semi-conical inner surface of the free wall defining part the patient's heart chamber and the
15 intraventricular septum are accessible at a desired normal or near normal orientation by rotating one or both of the guiding catheters.

The first and second guiding catheters are preferably relatively stiff catheters so that the position of the therapeutic or diagnostic device disposed within the inner lumen of the second guiding catheter and extending out the port in the distal end
20 thereof will be maintained during the procedure even though the heart is beating and blood is flowing within the chamber. A supporting sheath may be disposed within the inner lumen of the second guiding catheter which is extended to the

surface of the heart wall, to further support the therapeutic or diagnostic device if the ablation device is insufficiently self supporting.

The anatomy of the left ventricle can vary considerably from patient to patient as to dimensions and shape. As a result, in some instances the ablation
5 device may not be able to be directed to the entire region to be treated, particularly in the apex region of the heart chamber where the shape of the second guiding catheter may not be suitable to maintain a perpendicular orientation. In this case, the shape of the distal section of the second guiding catheter can be adjusted to another, more suitable angle to ensure a normal orientation between the operative
10 distal end of the ablation device and the endocardial surface by pulling the second guiding catheter back into the inner lumen of the first guiding catheter a short distance so that part of the shaped distal section is pulled back into the inner lumen of the first guiding catheter. This changes the angle of the particular distal segment with respect to an adjacent segment or an adjacent portion of the main
15 shaft section. Thus, normal or near normal orientation can be maintained in these difficult to reach regions.

While the present invention is described in terms of guiding catheters having permanently shaped distal sections, those skilled in the art will recognize that the distal section which can be deformed or shaped once positioned within the patient's
20 heart chamber by means such as control wires or strands or by controlling the temperature of a shape memory element within the distal section, in order to facilitate directing the distal portion of the channel forming device or other type of ablation device, toward the region of the endocardium where the procedure is to be

performed. A variety of other means may be employed to provide shape to the distal extremities of the guiding catheters.

In one presently preferred embodiment, the ablation or channel forming device is an elongated optical fiber system slidably disposed within the inner lumen of the second guiding catheter. The orientation of the distal extremity of the optical fiber system, controlled by the exit or discharge axis of the distal section of the second guiding catheter, is directed to the area of the endocardium to be ablated or into which a channel is to be formed, is perpendicular or nearly perpendicular to the endocardial surface of the patient's heart wall. The optical fiber system is preferably a laser based optical fiber system for forming channels within the wall of the patient's heart. The distal extremity of the optical fiber system which extends out the distal end of the second guiding catheter is sufficiently stiff to be self-supporting, i.e. it does not sag significantly when unsupported, and can be pressed against the endocardial or myocardial surface with sufficient pressure while forming the channel or performing ablation or other procedure without collapsing. Generally, the distal section of the optical fiber is considered as being "self supporting" if a force of at least 4 grams, preferably at least 8 grams, is required to deflect the free end of a cantilevered specimen 0.5 inch (12.7 mm) in length (span length) of the optical fiber a distance of one millimeter.

In a presently preferred embodiment of practicing one aspect of the invention, the system is introduced into a peripheral artery, such as the femoral or brachial artery, and advanced through the patient's arterial system until the shaped distal portion of the first guiding catheter is disposed within the patient's left

ventricle. The second guiding catheter may be advanced through and out the port in the distal end of the first guiding catheter where it is oriented toward the heart wall. The perpendicular or near perpendicular orientation of the distal extremity of the elongated optical fiber system with respect to the endocardial surface of the heart chamber is required in order to effectively couple the ablation energy emitted from the distal end of the optical fiber system to the tissue. Additionally, such perpendicularity helps to maintain the position of the distal end of the optical fiber system against the tissue to be ablated or removed to form the channel. If not pressed against the endocardial tissue in a relatively normal orientation, the operative distal tip tends to move laterally while the heart is beating resulting in mislocation of the channel, or ablation of tissue outside the desired region. As used herein the terms "normal" and "perpendicular" shall include variations of up to 30° from a normal or perpendicular orientation.

The longitudinal and rotational movements of the guiding catheters provide access to a wide region of the patient's endocardial surface from within the heart chamber and allows for the accurate placement of the operative distal end of the ablation device within the patient's left ventricle in a number of positions. With the system of the invention, essentially the entire inner surface of the wall defining the patient's heart chamber is accessible to deliver an elongated ablation device to the desired location with the desired orientation while the heart is beating.

The guiding catheters, and particularly the first guiding catheter, are preferably provided with relatively stiff proximal and shaped distal sections with a more flexible intermediate section which is configured to be disposed within the

patient's aortic arch during the procedure as described in copending application Serial No. 08/813,503 entitled CATHETER WITH FLEXIBLE INTERMEDIATE SECTION and filed on March 7, 1997, which is incorporated herein by reference. In this manner, the position of the distal end of the optical fiber system will be
5 maintained during the procedure even though the heart is beating.

While forming a passageway through the endocardium into the myocardium of the patient's heart for the purpose of revascularization is of significant interest, the passageway formed into the myocardium may be used for other purposes. For example, therapeutic or diagnostic agents may be introduced into the channel for
10 delivery to the patient's endocardium or myocardium. The therapeutic or diagnostic agent may be incorporated into a biocompatible matrix deposited within the channel for delivery or release over an extended period. When delivering a therapeutic or diagnostic agent to the interior of the channel, the channel forming device may be removed and a catheter with an inner lumen extending the length thereof may be
15 advanced through the inner lumen of the delivery catheter until the distal end of the catheter extends into the channel formed in the wall of the patient's heart. A therapeutic or diagnostic agent may then be delivered through the inner lumen of the catheter and out a port in the distal end into the channel such as described in copending application Serial No. 08/483,512, filed on June 7, 1995, entitled
20 THERAPEUTIC AND DIAGNOSTIC AGENT DELIVERY which is incorporated herein by reference. The drug delivery catheter may be generally a simple elongated flexible tube with an inner lumen extending therein to a port or opening in the distal end of the catheter. The outer dimensions and surface characteristics are

suitable to provide longitudinal movement of the drug delivery catheter within the delivery catheter. The distal extremity of the drug delivery catheter is preferably configured to readily fit into the channel formed in the endocardium and myocardium so that delivery of the therapeutic or diagnostic agent well into the
5 channel is ensured. Systemic delivery of drugs and various therapeutic and diagnostic agents to the ablated tissue can also be employed.

There is evidence which tends to support the position that ablation or insult of heart tissue may, by itself, over the long term enhance or even be a significant factor in the revascularization thereof causing angiogenesis. Thus, other means,
10 including mechanical ablation means and a variety of energy sources such as radio frequency ablation means and ultrasonic ablation means which damage or insult myocardial tissue can be the causal factor in revascularization. For example, an RF energy or an ultrasonic energy system which damages myocardial tissue with or without forming a channel may be used. There is also some evidence that ablation
15 of heart tissue within an ischemic region which is causing the patient discomfort by angina or chest pain, can cause the denervation of the ischemic tissue which results in the termination of the angina. Such pain relief may by itself be a substantial clinical advantage because, without the pain, the patient can resume normal or near normal activity. Denervation minimizes or eliminates the need for
20 debilitating pain medication and allows the patient to exercise which can strengthen the heart tissue resulting in further recovery. These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of a guiding catheter system embodying features of the invention with the distal extremity of the system disposed within the patient's left ventricle, which is seen in a left lateral cutaway view.

5 Fig. 2 is a transverse cross-sectional view of the guiding catheter system shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is an elevational view of the first guiding catheter shown in Fig. 1.

Fig. 4 is an elevational view of the second guiding catheter shown in Fig. 1.

10 Fig. 5 is an elevational view similar to Fig. 3 of an alternative first guiding catheter having a shaped distal section with a single distal segment.

Fig. 6 is an elevational view similar to Fig. 3 of an alternative first guiding catheter having a shaped distal section with three distal segments.

DETAILED DESCRIPTION OF THE INVENTION

15 Figs. 1-4 schematically illustrates one presently preferred delivery system 10 of the invention with a distal portion thereof disposed within the left ventricle 11 of a patient's heart 12. The delivery system 10 includes a first guiding catheter 13 and a second catheter 14 slidably and rotatably disposed within the inner lumen 15 (shown in Fig. 2) of the first guiding catheter. An optical fiber 16 with a lens 17 at the distal tip is slidably disposed within the inner lumen 18 (shown in Fig. 2) of the
20 second guiding catheter 14.

The first guiding catheter 13, as shown in more detail in Fig. 3, has a shaped distal shaft section 18 with two distal segments 19 and 20. The most distal segment 19 is shaped to be at an angle with respect to the proximally adjacent

second segment 20 and the second segment 20 is shaped to be at an angle with respect to the proximally adjacent main shaft section 21. The segments of the distal shaft section 18 of the first guiding catheter 13 are angled to discharge the second guiding catheter generally along or parallel with the longitudinal axis 22 of the left ventricle. The second guiding catheter 14, shown in more detail in Fig. 4, has a shaped distal shaft section 24 with a distal segment 25 which is at an angle with respect to the main shaft section 26 of the second guiding catheter to ensure that the discharge axis thereof is perpendicular or near perpendicular with the region of the heart wall in which the procedure is to be performed.

As shown in greater detail in Fig. 2, the guiding catheter 13 may be of conventional guiding catheter construction which includes wall structure having a inner lubricous lining 27, a fiber reinforcement 28 in a polymer matrix which may be braided or wound and an outer jacket 29 which may be formed of suitable polymeric material in a conventional manner, e.g. extruding onto the fiber reinforcement. Suitable polymers include polyethylene, polyurethane and the like. The strands of the fiber reinforcement 28 may be stainless steel, or other suitable high strength materials including suitable polymeric materials such as Kevlar® or nylon. The lubricous inner liner 27 may be formed of a suitable fluoropolymer such as poly(tetrafluoro)ethylene which is sold under the trademark Teflon®. An adaptor 29 is provided on the proximal end of the catheter 13 for the introduction of fluids and the second guiding catheter and the like. The overall length of the guiding catheter 13 is about 70 to about 110 cm, the outer diameter is about 0.1 to about 0.15 inch

(2.5-3.75 mm) and the diameter of the inner lumen 15 about 0.07 to about 0.1 inch (1.8-2.5 mm).

The second guiding catheter 14, as also shown in Fig. 4, has a structure similar to or the same as the guiding catheter 13 and has a lubricious lining 30, a
5 fiber reinforcement 31 which may be braided or wound and an outer polymer jacket 32. The outer diameter of the second guiding catheter 14 is configured so that it can be readily moved longitudinally and readily rotated within the inner lumen 15 of the first guiding catheter 13 by manipulating the proximal end of the second guiding catheter which extends out of the patient. An adapter 33 is provided on the
10 proximal end of the catheter 14 for the introduction of fluids and therapeutic and diagnostic devices. The overall length of the first guiding catheter 14 is about 10 to about 40 cm longer than the guiding catheter 13 to ensure that both the distal end and the proximal end of the second guiding catheter can simultaneously extend out the distal end and the proximal end respectively of the first guiding catheter so that
15 movement of the distal end of the first delivery catheter can be effected by manipulation of the proximal end. The outer diameter of the second guiding catheter 14 is about 0.04 to less than about 0.1 inch (1-2.5 mm) and the diameter of the inner lumen 15 about 0.02 to about 0.07 inch (0.5-1.8 mm). The first guiding catheter 13 may be provided with soft, nontraumatic distal tip 32 to facilitate
20 advancement of the catheter through a patient's vasculature without significant damage to the vessel lining. The second guiding catheter 14 need not have a non-traumatic tip.

The junction between the distal segment 25 and the main shaft section 26 of the second guiding catheter 14 should have a radius of curvature from about 2 to about 30 mm, preferably about 4 to about 20 mm to allow for the passage of a therapeutic or diagnostic device such as optical fiber 16. The radius of curvature need not be constant along the length of the curved section. For example, the curvature can increase progressively in the distal direction along the length of the curved or bent section of the catheter.

In a presently preferred method of the invention, the first guiding catheter 13 is first introduced into the patient's arterial system, preferably by means of the Seldinger technique through the femoral artery and advanced through the patient's arterial system including the aorta until the distal end of the first guiding catheter is disposed at a desired location within the left ventricle 11 generally aligned with or parallel to the longitudinal axis 22 of the left ventricle. The guiding catheter 14 and the optical fiber 18, or other channel forming, therapeutic or diagnostic device, may then be advanced together or sequentially through the inner lumen 15 of the first guiding catheter 14 into the left ventricle. The guiding catheter 14 is advanced out of, rotated within or withdrawn into the inner lumen 15 of the first guiding catheter 13 to orient the distal segment 25 of the second guiding catheter toward a desired region within the left ventricle 11 where the channel is to be formed or the procedure is to be performed. The distal segment 24 of the guiding catheter 14 is preshaped so that it forms the desired shape when exiting the port 35 in the distal end of guiding catheter 13. The elongated channel forming or tissue ablation device such as optical fiber 16 may then be advanced through the inner lumen 18 of the

second guiding catheter 14 and out the port 36 in the distal end thereof onto the endocardium tissue to form a channel 37 or otherwise ablate tissue therein. Preferably pressure is applied to the channel forming means 16 or other tissue ablation device from its proximal end extending out of the patient so as to maintain
5 contact with the tissue of the heart wall when forming the channel 37 or otherwise ablating tissue. The axial force applied to the proximal end of the optical fiber 16 or other device is preferably sufficient to ensure contact with tissue of the heart wall, but the force should not exceed the level which will cause the operative distal tip of the device to mechanically penetrate heart tissue. Once the channel is formed or
10 tissue is otherwise ablated, the channel forming or ablation device may be withdrawn and repositioned within the left ventricle 11 to form a channel or otherwise ablate tissue at another location within the patient's heart wall.

Generally, the overall length of the optical fiber 16 (or other therapeutic or diagnostic device used) is longer than the second guiding catheter 14 and it is
15 preferably configured to extend out of the second guiding catheter a distance of up to about 15 cm, preferably about 4 to about 10 cm to form the channel 37 or to otherwise perform the desired therapeutic or diagnostic procedure. The optical fiber 16 should have the flexibility required to pass through the inner lumen 18 of the second guiding catheter 14. Further details of optical fibers and laser sources may
20 also be found in U.S. Patent 5,093,877 (Aita et al.), which is incorporated herein in its entirety by reference. The optical fiber 16 may be a single fiber as describe above or a bundle of optical fibers.

Fig. 5 illustrates an alternative embodiment of the first guiding catheter 40 which has a main shaft section 41 and a shaped distal shaft section 42 comprising a single angled distal segment 43. An adapter 44 is provided on the proximal end of the main shaft section 41. The structural components and compositions of the first
5 guiding catheter may be the same as found in the first and second guiding catheters 13 and 14 of the first embodiment.

Another alternative embodiment of the invention is shown in Fig. 6 where a first guiding catheter 50 is provided with a main shaft section 51 and a shaped distal shaft section 52 comprising three distal segments, a distal segment 53, an
10 intermediate segment 54 and a proximal segment 55. The distal segment 53 is angled with respect to the intermediate segment 54 and the intermediate segment 54 is angled with respect to the proximal segment 55. An adaptor 56 is provided on the proximal end of the main shaft section 51. The structural components and compositions of the first guiding catheter 50 may be the same as found in the first
15 guiding catheter 13 of the first embodiment.

While the present invention is described herein in terms of certain preferred embodiments, those skilled in the art will recognize that various modifications and improvements may be made to the invention without departing from the scope thereof. For example, a limited number of presently preferred embodiments are
20 given to illustrate various ablation means for forming the channel, whereas the invention may be used to deliver any suitable ablation means even those which may not form a channel but which ablate tissue sufficiently to cause angiogenesis or denervation to minimize angina. Moreover, although individual features of one embodiment of the invention may be discussed herein or shown in the drawings of

the one embodiment and not in other embodiments, it should be apparent that individual features of one embodiment may be combined with one or more features of another embodiment or features from a plurality of embodiments.

WHAT IS CLAIMED IS:

1 1. A guiding catheter system for the delivery of an elongated device to
2 perform a therapeutic or diagnostic procedure in a region of a patient's heart wall
3 which defines at least in part a left ventricle of the patient's heart, comprising:

4 a) a first guiding catheter which has proximal and distal ends, a
5 port in the distal end, an inner lumen extending therein to and in fluid
6 communication with the port in the distal end, a relatively straight main shaft
7 section and a shaped distal shaft section having at least one segment
8 forming an angle with respect to a proximally adjacent portion of the main
9 shaft section so that the shaped distal shaft section has a discharge axis
10 which can generally be aligned with or parallel to a longitudinal axis of the
11 patient's left ventricle; and

12 b) a second elongated guiding catheter which is slidably and
13 rotatably disposed within the inner lumen of the first guiding catheter, which
14 is longer than the first guiding catheter and which has proximal and distal
15 ends, a port in the distal end, an inner lumen extending to and in fluid
16 communication with the port in the distal end configured to slidably receive
17 and elongated ablation device, an elongated main shaft section at least a
18 portion of which is aligned with the discharge axis of the first guiding catheter
19 and a distal section configured to have a discharge axis at an angle of about
20 80° to about 135° with respect to a portion of the main shaft section thereof
21 aligned with the discharge axis of the first guiding catheter so as to be
22 normal to the region of the heart wall to be subjected to the procedure.

1 2. The guiding catheter system of claim 1 wherein the shaped distal
2 shaft section of the second guiding catheter is configured to have a discharge axis
3 at an angle of about 90° to about 120° with respect to the portion of the main shaft
4 section thereof aligned with the discharge axis of the first guiding catheter.

1 3. The guiding catheter of claim 1 wherein the shaped distal section of
2 the first guiding catheter has at least a first segment and a proximally adjacent
3 second segment.

1 4. The guiding catheter system of claim 1 wherein the first segment is at
2 an angle of about 95° to about 160° with respect to the proximally adjacent second
3 segment and the second segment is at an angle of about 95° to about 150° with
4 respect to a proximally adjacent third segment or the main shaft section proximally
5 adjacent thereto.

1 5. The guiding catheter system of claim 1 wherein the first segment of
2 the shaped distal shaft section of the first guiding catheter is at an angle of about
3 100° to about 140° with respect to the second segment.

1 6. The guiding catheter of claim 1 wherein the shaped distal shaft
2 section of the first guiding catheter includes a third segment proximally adjacent to
3 the second segment which is at an angle with respect to the main shaft section
4 proximal thereto of about 110° to about 170°.

1 7. The guiding catheter system of claim 1 wherein the shaped distal
2 shaft section of the first guiding catheter includes a third segment proximally

adjacent to the second section which is at an angle with respect to the main shaft section proximal thereto of about 120° to about 150°.

8. The guiding catheter system of claim 3 wherein the first segment of the shaped distal shaft section of the first guiding catheter has a length of about 0.5 to about 5 cm.

9. The guiding catheter system of claim 3 wherein the first segment of the shaped distal shaft section of the first guiding catheter has a length of about 1 to about 4 cm.

10. The guiding catheter system of claim 3 wherein the second segment of the shaped distal shaft section of the first guiding catheter has a length of about 0.5 to about 5 cm.

11. The guiding catheter system of claim 3 wherein the second segment of the shaped distal shaft section of the first guiding catheter has a length of about 1 to about 4 cm.

12. The guiding catheter system of claim 7 wherein the third segment of the shaped distal shaft section of the first guiding catheter has a length of about 1 to about 5 cm.

13. The guiding catheter system of claim 7 wherein the third segment of the shaped distal shaft section of the first guiding catheter has a length of about 2 to about 4 cm.

1 14. The guiding catheter of claim 3 wherein the length of the shaped distal
2 shaft section of the first guiding catheter is about 2 to about 8 cm.

1 15. The guiding catheter of claim 3 wherein the length of the shaped distal
2 shaft section of the first guiding catheter is about 4 to about 7 cm.

1 16. The guiding catheter of claim 1 wherein the shaped distal section of
2 the first guiding catheter has a single segment.

1 17. The guiding catheter system of claim 16 wherein the single segment is
2 at an angle of about 95° to about 160° with respect to the proximally adjacent main
3 shaft section.

1 18. The guiding catheter system of claim 16 wherein the single segment is
2 at an angle of about 100° to about 140° with respect to the proximally adjacent main
3 shaft section.

1 19. The guiding catheter system of claim 16 wherein the single segment
2 has a length of about 3 to about 8 cm.

1 20. The guiding catheter system of claim 16 wherein the single segment
2 has a length of about 4 to about 6 cm.

1 21. An elongated guiding catheter comprising:

2 a) an elongated shaft which has proximal and distal ends, a port
3 in the distal end and an inner lumen extending therein to and in fluid
4 communication with the port in the distal end;

5 b) a relatively straight main shaft section; and

6 c) a shaped distal shaft section having at least a first segment and
7 a second segment proximally adjacent to the first segment with the first
8 segment being at an angle of about 95° to about 160° with respect to the
9 proximally adjacent second segment and the second segment being at an
10 angle of about 95° to about 160° with respect to a proximally adjacent third
11 segment or the main shaft section proximally adjacent thereto.

1 22. The guiding catheter of claim 21 wherein the first segment is at an
2 angle of about 100° to about 140° with respect to the second segment.

1 23. The guiding catheter of claim 21 wherein the second segment is at an
2 angle of about 100° to about 140° with respect to an adjacent third segment or the
3 main shaft section adjacent thereto.

1 24. The guiding catheter of claim 21 wherein the distal shaft section
2 includes a third segment proximally adjacent to the second section which is at an
3 angle with respect to the main shaft section proximal thereto of about 110° to about
4 170°.

1 25. The guiding catheter of claim 21 wherein the distal shaft section
2 includes a third segment proximally adjacent to the second section which is at an
3 angle with respect to the main shaft section proximal thereto of about 120° to about
4 150°.

1 26. The guiding catheter of claim 21 wherein the first segment has a
2 length of about 0.5 to about 5 cm.

1 27. The guiding catheter of claim 21 wherein the first segment has a
2 length of about 1 to about 4 cm.

1 28. The guiding catheter of claim 21 wherein the second segment has a
2 length of about 0.5 to about 5 cm.

1 29. The guiding catheter of claim 21 wherein the second segment has a
2 length of about 1 to about 4 cm.

1 30. The guiding catheter of claim 21 wherein distal section has a third
2 segment the third segment proximally adjacent to the second segment.

1 31. The guiding catheter of claim 30 wherein the third segment has a
2 length of about 1 to about 5 cm.

1 32. The guiding catheter of claim 30 wherein the third segment has a
2 length of about 2 to about 4 cm.

1 33. The guiding catheter of claim 21 wherein the length of the shaped
2 distal section is about 2 to about 8 cm.

1 34. The guiding catheter of claim 21 wherein the length of the shaped
2 distal section is about 4 to about 7 cm.

1 35. A method for performing a therapeutic or diagnostic procedure in a
2 region of a wall of a patient's heart defining a left ventricle, comprising:

3 a) introducing into a peripheral artery of the patient a guiding
4 catheter system which includes;

5 a first guiding catheter having an elongated shaft which has proximal
6 and distal ends, a port in the distal end and an inner lumen extending therein
7 to and in fluid communication with the port in the distal end, a relatively
8 straight main shaft section and a shaped distal shaft section forming an
9 angle with respect to a proximally adjacent portion of the main shaft section
10 so that the distal section has a discharge axis which is generally aligned with
11 or parallel to longitudinal axis of the patient's left ventricle; and

12 a second elongated guiding catheter which is slidably and rotatably
13 disposed within the inner lumen of the first guiding catheter, which is longer
14 than the first guiding catheter and which has proximal and distal ends, a port
15 in the distal end, an inner lumen extending to and in fluid communication with
16 the port in the distal end, an elongated main shaft section and a shaped
17 distal shaft section configured to have a discharge axis at an angle of about
18 80° to about 135° with respect to a portion of the main shaft section thereof
19 aligned with the discharge axis of the first guiding catheter so as to be
20 normal to said region of the heart wall, and

21 an elongated therapeutic or diagnostic device having an operative
22 distal extremity slidably disposed within the inner lumen of the second
23 guiding catheter;

24 b) advancing at least the first guiding catheter through the
25 patient's arterial system until the shaped distal section of the first guiding
26 catheter extends into the patient's left ventricle aligned with or parallel to the
27 longitudinal axis of the left ventricle;

28 c) advancing the second guiding catheter within the first guiding
29 catheter until at least a portion of the shaped distal shaft section of the
30 second guiding catheter extends out the port in the distal end of the first
31 guiding catheter; and

32 d) positioning the second guiding catheter within the left ventricle
33 so that the shaped distal shaft section thereof is normal to the region of the
34 heart wall where the procedure is to be performed.

1 36. The method of claim 35 wherein the elongated therapeutic or
2 diagnostic device is extended out the port in the distal end of the second guiding
3 catheter until the operative distal extremity thereof is in an operative position with
4 respect to the desired region of the patient's heart wall.

1 37. The method of claim 36 including the step of activating the elongated
2 therapeutic or diagnostic device so as to perform the procedure at said region.

1 38. A system for percutaneously delivering an elongated ablation
2 device to a left ventricle, comprising:

3 a) a first guiding catheter having an elongated shaft which has
4 proximal and distal ends, a port in the distal end and an inner lumen
5 extending therein to and in fluid communication with the port in the distal
6 end, a relatively straight main shaft section and a shaped distal shaft section
7 with a plurality of segments including at least a first segment, a second
8 segment proximally adjacent to the first segment at an angle of about 95° to
9 about 160° with respect to the first segment and at an angle of about 95° to

about 160° with respect to a proximally adjacent third segment or the main shaft section proximally adjacent thereto so that the shaped distal shaft section has a discharge axis which is generally aligned with or parallel to the longitudinal axis of the patient's left ventricle; and

b) a second elongated guiding catheter which is slidably and rotatably disposed within the inner lumen of the first guiding catheter, which is longer than the first guiding catheter and which has proximal and distal ends, a port in the distal end, an inner lumen extending to and in fluid communication with the port in the distal end configured to slidably receive an elongated ablation device, an elongated main shaft section at least a portion of which is aligned with the discharge axis of the first guiding catheter and a distal section configured to have a discharge axis at an angle of about 80° to about 135° with respect to a portion of the main shaft section thereof aligned with the discharge axis of the first guiding catheter so as to be normal to the region of the heart wall.

39. The system of claim 38 wherein the first segment of the shaped distal shaft section of the first guiding catheter is at an angle of about 100° to about 135° with respect to the second segment.

40. The system of claim 38 wherein the second segment of the shaped distal shaft section of the first guiding catheter is at an angle of about 100° to about 135° with respect to an adjacent third segment or the main shaft section adjacent thereto.

1 41. The system of claim 38 wherein the shaped distal shaft section of the
2 first guiding catheter includes a third segment proximally adjacent to the second
3 section which is at an angle with respect to the main shaft section proximal thereto
4 of about 110° to about 170°.

1 42. The system of claim 38 wherein the shaped distal shaft section of the
2 first guiding catheter includes a third segment proximally adjacent to the second
3 section which is at an angle with respect to the main shaft section proximal thereto
4 of about 120° to about 150°.

1 43. The system of claim 38 wherein the first segment of the shaped distal
2 shaft section of the first guiding catheter has a length of about 0.5 to about 5 cm.

1 44. The system of claim 38 wherein the first segment of the first guiding
2 catheter has a length of about 0.5 to about 5 cm.

1 45. The system of claim 38 wherein the first segment of the first guiding
2 catheter has a length of about 0.5 to about 4 cm.

1 46. The system of claim 38 wherein the second segment of the first
2 guiding catheter has a length of about 0.5 to about 5 cm.

1 47. The system of claim 38 wherein the second segment of the first
2 guiding catheter has a length of about 0.5 to about 4 cm.

1 48. The system of claim 38 wherein the length of the first and second
2 segments of the first guiding catheter is about 2 to about 6 cm.

1 49. The system of claim 38 wherein the distal shaft section has a third
2 segment between the main shaft section and the second segment of the distal shaft
3 section.

1 50. The system of claim 49 wherein the third segment has a length of
2 about 1 to about 5 cm.

1 51. The system of claim 49 wherein the third segment has a length of
2 about 2 to about 4 cm.

1 52. The system of claim 50 where in the total length of the first, second
2 and third segments is about 3 to about 8 cm.

1 53. The system of claim 50 where in the total length of the first, second
2 and third segments is about 4 to about 7 cm.

1 54. The system of claim 38 wherein the shaped distal shaft section of the
2 second guiding catheter is configured to have a discharge axis at an angle of about
3 90° to about 120° with respect to the portion of the main shaft section thereof
4 aligned with the discharge axis of the first guiding catheter.

1 55. The system of claim 38 including an elongated ablation device
2 disposed within the inner lumen of the second guiding catheter.

1 56. A method for performing transmyocardial revascularization of a region
2 of a patient's heart wall defining a left ventricle, comprising:

3 a) advancing a first guiding catheter through the patient's
4 vasculature until a distal section of the first guiding catheter extends into the
5 patient's left ventricle and is aligned with or parallel to a longitudinal axis of
6 the left ventricle ;

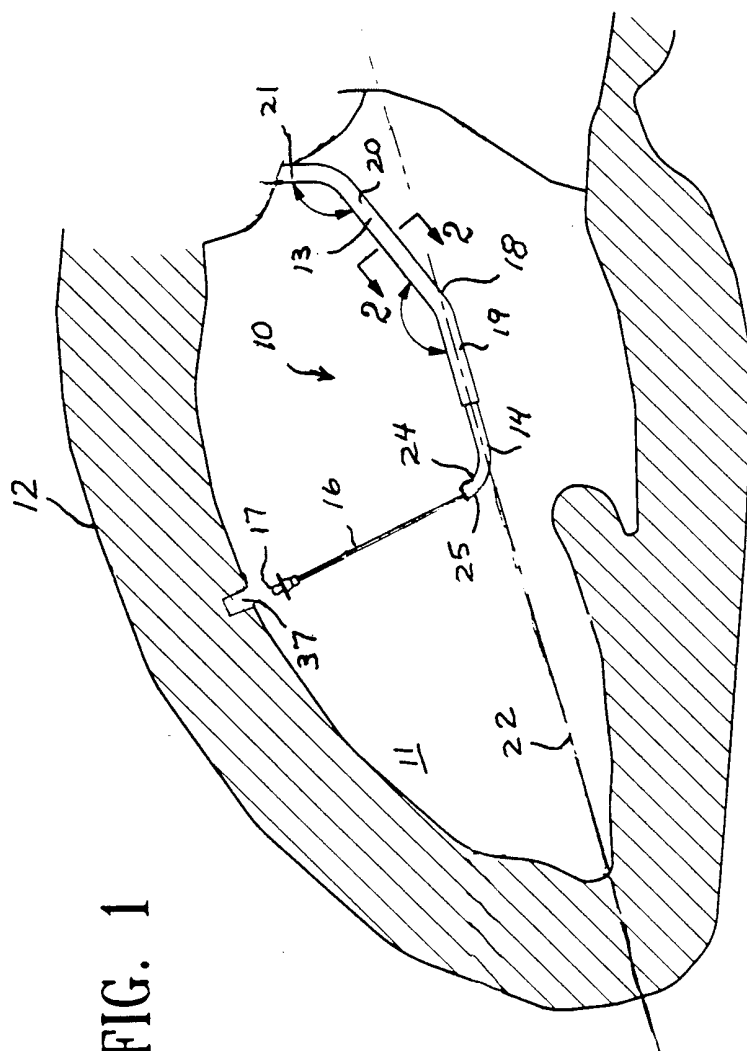
7 b) advancing a second guiding catheter through an inner lumen of
8 the first guiding catheter until a shaped distal section of the second guiding
9 catheter extends out of the distal end of the first guiding catheter and
10 adjusting the position of the second guiding catheter until a discharge axis of
11 the second guiding catheter is oriented normal to the region of the heart wall
12 in which the transmyocardial revascularization is to be performed;

13 c) advancing an elongated ablation device through the second
14 guiding catheter and out a port in a distal end of the second guiding catheter
15 so that an operative distal end thereof contacts the desired region of the
16 patient's heart wall; and

17 d) activating the elongated ablation device so that the operative
18 distal end thereof ablates tissue within the heart wall.

1 57. The method of claim 56 wherein the elongated ablation device is an
2 optical fiber and the ablation of tissue by laser energy emitted from a distal
3 extremity thereof forms a channel within the heart wall.

1 58. The method of claim 57 wherein the ablation device emits RF energy.



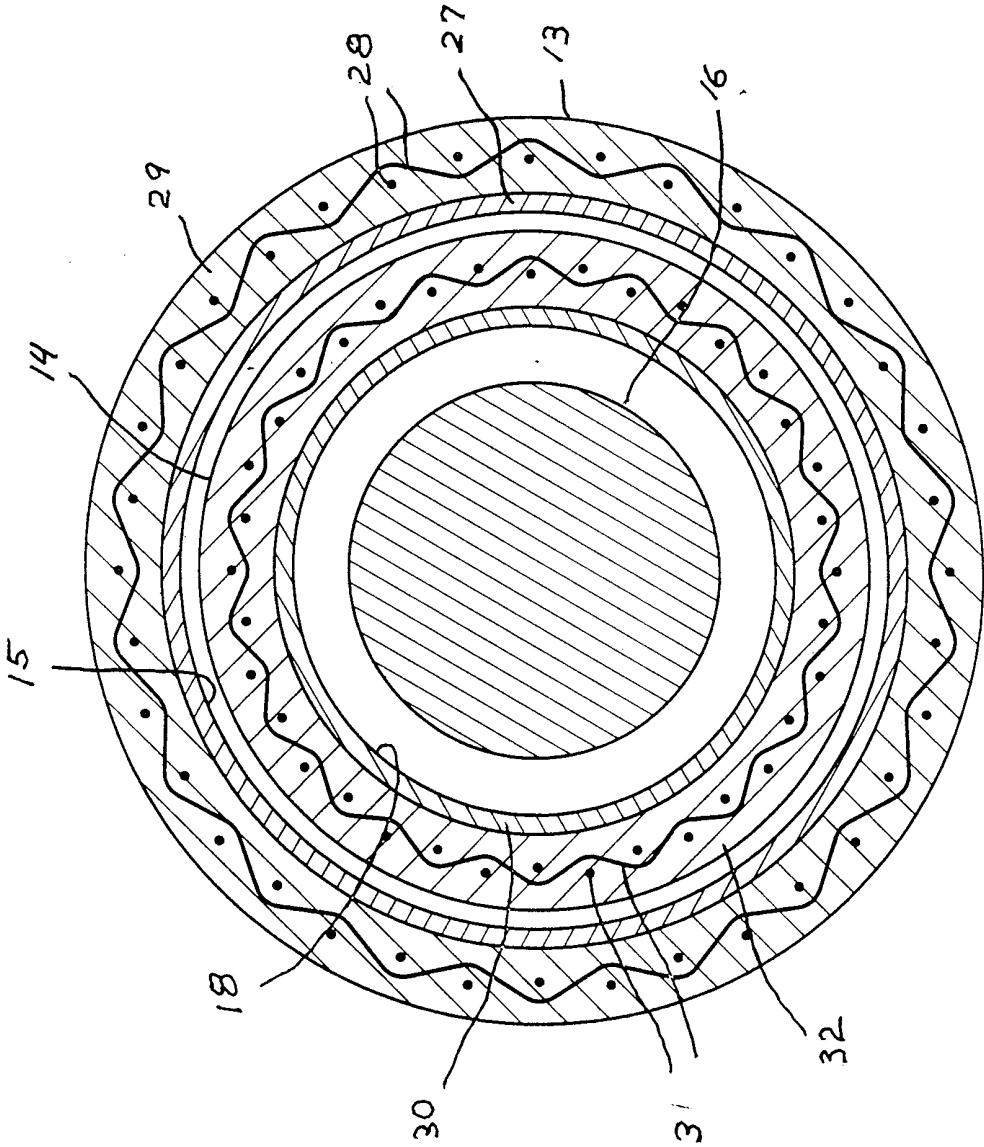
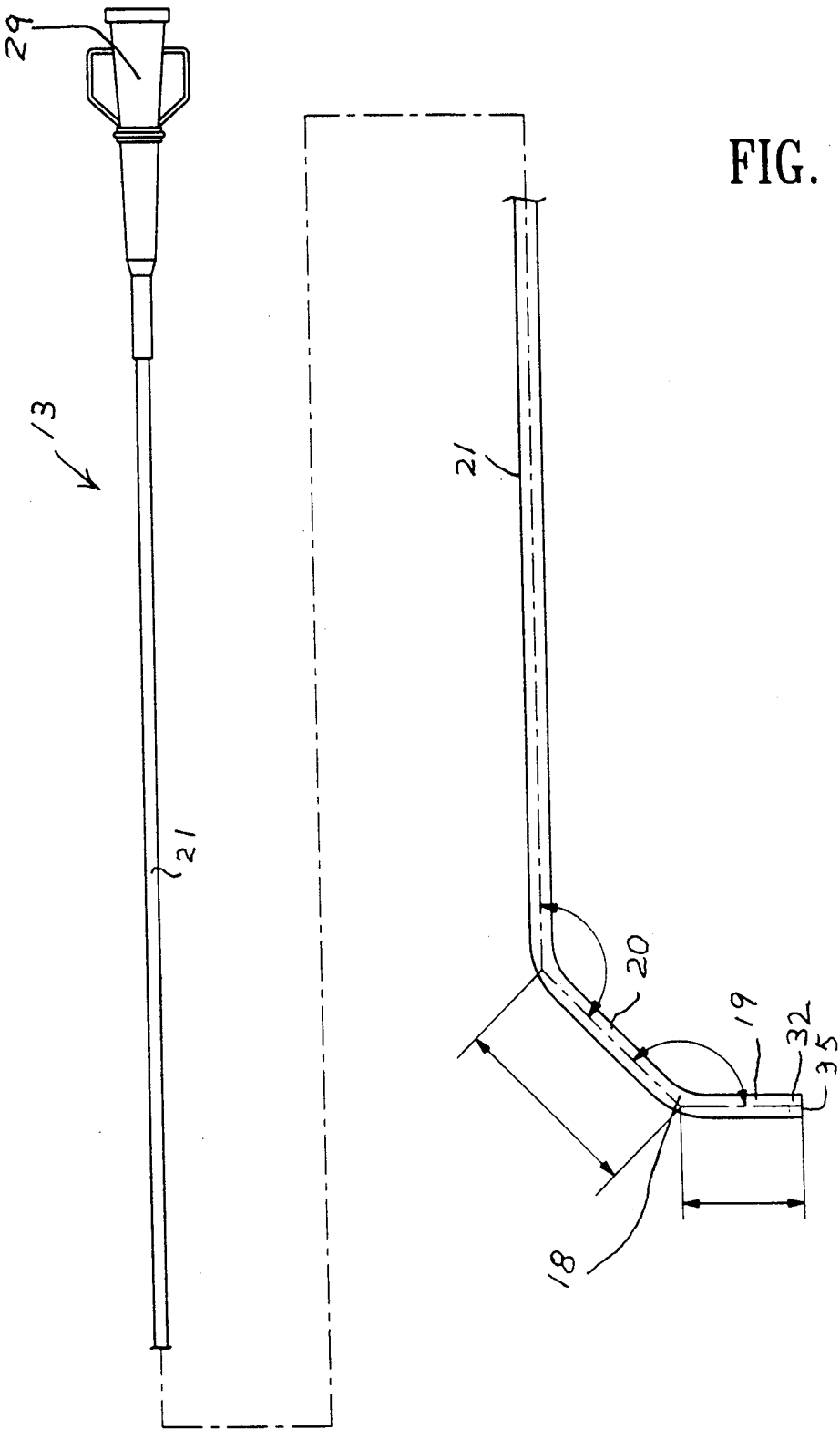


FIG. 2



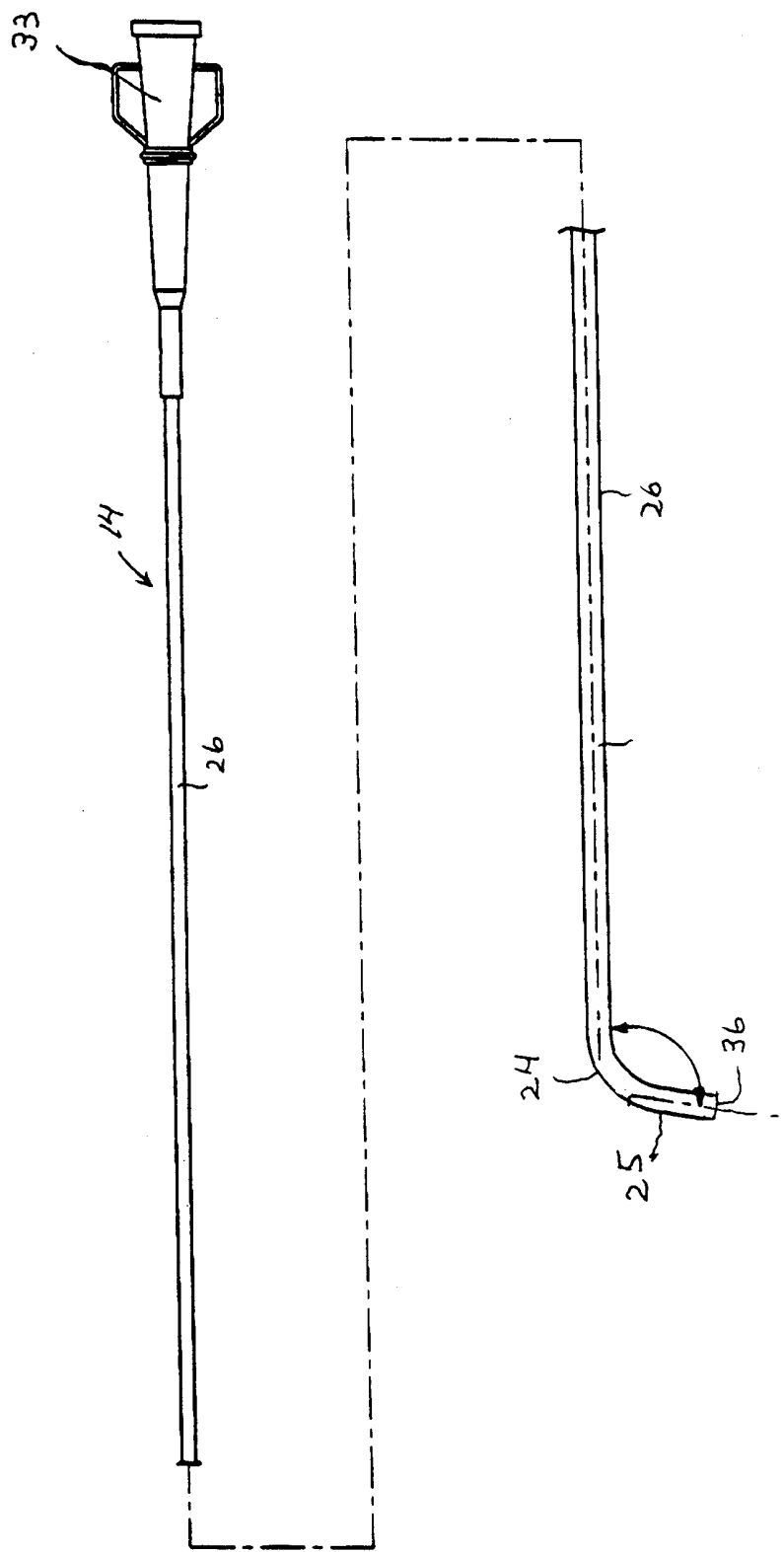


FIG. 4

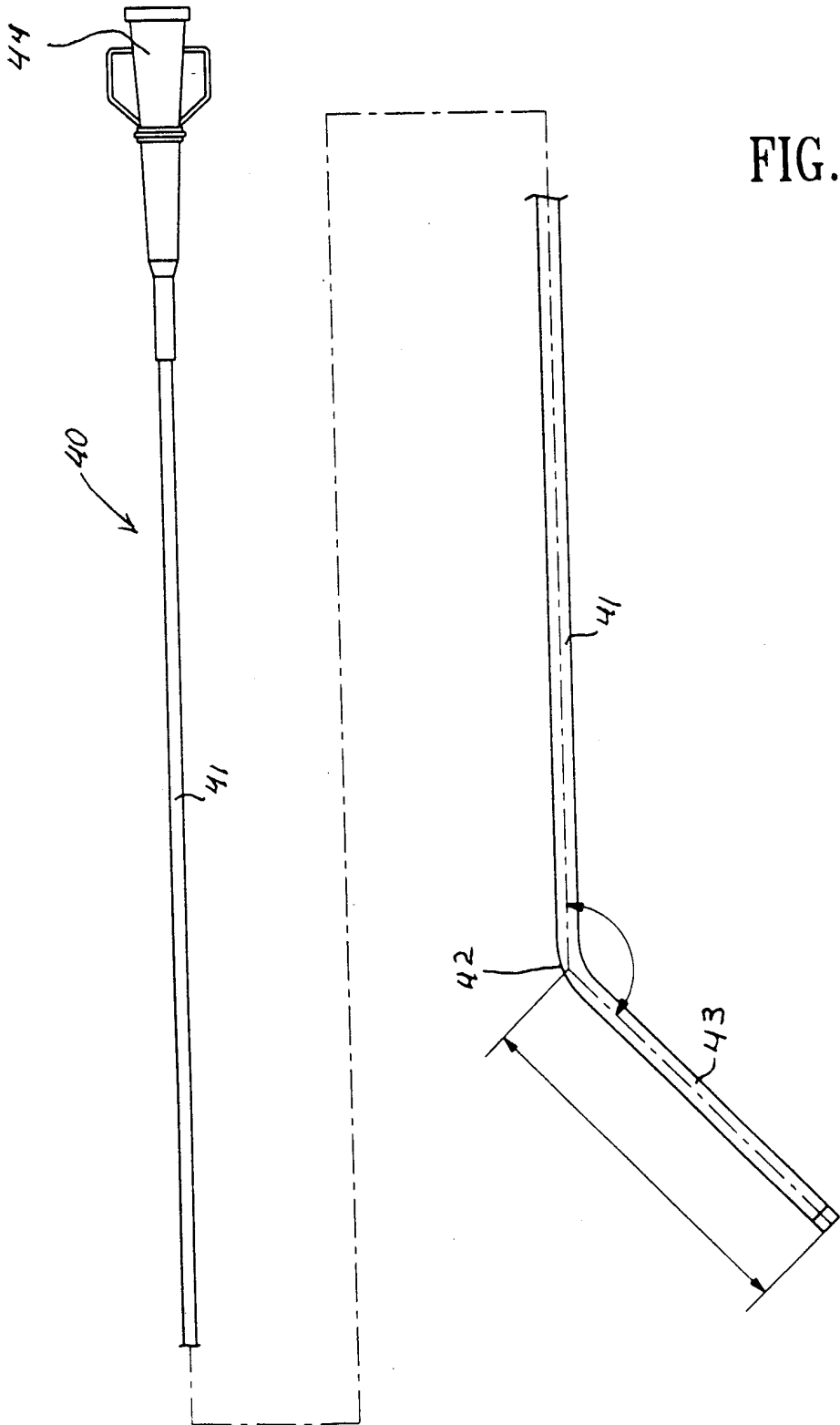
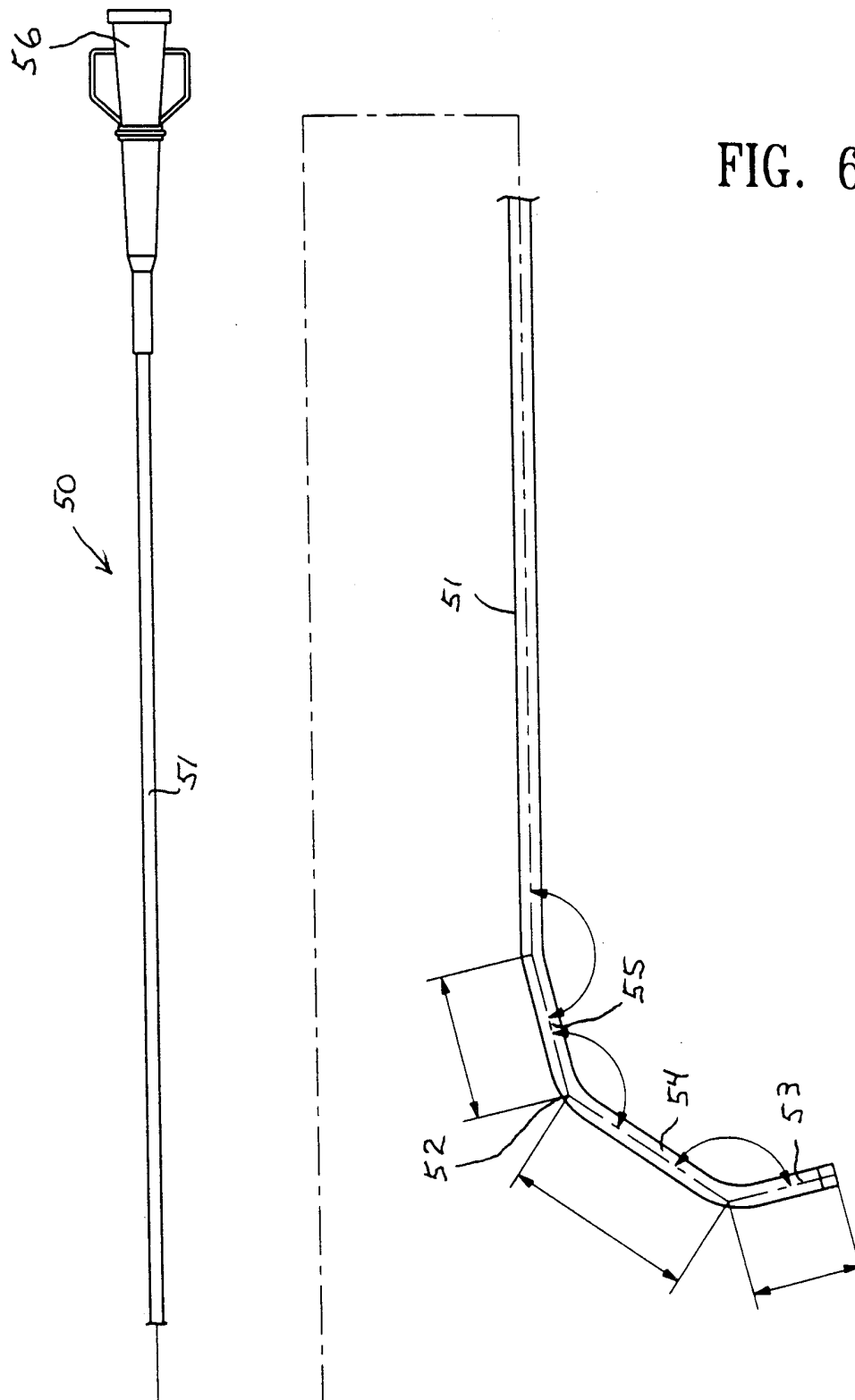


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/23276

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M25/01

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 6 A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 92 15 779 U (DAMMENHAYN LUTZ) 4 February 1993	21-23, 26-29, 33, 34
A	see the whole document	1-5, 8-11, 14, 15, 38
X	EP 0 727 236 A (DAIG CORP) 21 August 1996	1, 2, 16-18
A	see the whole document	3, 21, 38
X	WO 96 35469 A (CARDIOGENESIS CORP) 14 November 1996	1, 2, 16-18
A	see the whole document	21, 38
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

9 February 1999

Date of mailing of the international search report

16/02/1999

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/23276

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category ²	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 30072 A (HEARTPORT INC) 3 October 1996 see page 40, line 5 - page 42, line 23; figures 14A-B ----	1,21,38
A	EP 0 728 494 A (SCHNEIDER EUROP AG) 28 August 1996 see abstract; figure 1 -----	1,21,38

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/ 23276

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: claims 35-37, 56-58
because they relate to subject matter not required to be searched by this Authority, namely:
claims: 35-37, 56-58: Rule 39.1 (iv) PCT - Method for treatment of the
human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 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 an additional fee, this Authority did not invite payment
of any additional fee.
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 claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/23276

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 9215779	U	04-02-1993	NONE	
EP 0727236	A	21-08-1996	US 5722400 A US 5833673 A CA 2151019 A CA 2153303 A EP 0727237 A JP 8266551 A JP 8252262 A US 5814029 A	03-03-1998 10-11-1998 17-08-1996 17-08-1996 21-08-1996 15-10-1996 01-10-1998 29-09-1998
WO 9635469	A	14-11-1996	CA 2220689 A EP 0892651 A	14-11-1996 27-01-1999
WO 9630072	A	03-10-1996	AU 5188596 A CA 2215970 A EP 0819013 A	16-10-1996 03-10-1996 21-01-1998
EP 0728494	A	28-08-1996	AU 691999 B AU 4034595 A CA 2165255 A JP 8215313 A	28-05-1998 20-06-1996 16-06-1996 27-08-1996