Summary of the Invention

[0010] Preferred embodiments of the present invention provide a heart valve delivery system for delivery of a prosthetic (i.e., replacement) heart valve to a native valve site without an open chest procedure. The delivery system includes a valve delivery catheter having a steerable section to facilitate positioning of the valve.

[0011]In accordance with an aspect~~one embodiment~~ of the present invention~~application~~, there is provided a medical catheter introducer and heart valve delivery catheter combination, comprising; a delivery catheter having a distal balloon of sufficient diameter to expand a crimped heart valve thereon; and an introducer that receives the delivery catheter therethrough and has an elongated tubular sheath extending distally from a proximal housing containing at least one introducer valve for fluidly sealing around a proximal length of the delivery catheter, characterized by the sheath including a proximal segment extending a length of at least one half a total length **L** of the sheath and having a first stiffness, and a distal section having a length **l** of one half or less of the total length **L** of the sheath that has a second stiffness different than the first stiffness~~includes an elongated tubular sheath extending distally from a proximal housing and containing at least one introducer valve for fluidly sealing around a catheter. The sheath has a proximal segment with a first stiffness extending a length **L** of at least one half the length of the sheath, and a distal section with a second stiffness less than the first stiffness and having a length *l*~~.

[0011a] Desirably, the length *l* of the distal section ranges between about 4-12 cm. In one embodiment, the length **L** of the proximal segment is at least 24 cm, and the length *l* of the distal section ranges between about 6-9 cm. Also, the tubular sheath may have an inner liner and a reinforcing coil that both extend the entire length, and at least two sections of outer tubes in series having different durometers that create the differing stiffnesses of the sheath.

[0012] There is ~~Another aspect~~ disclosed herein ~~is~~ a medical introducer and heart valve delivery catheter combination comprising a delivery catheter having a distal balloon of sufficient diameter to expand a crimped heart valve thereon. An introducer that receives the delivery catheter therethrough has an elongated tubular sheath extending distally from a proximal housing. The proximal housing contains at least one introducer valve for fluidly sealing around a proximal length of the delivery catheter. The sheath further includes a proximal segment with a first stiffness extending a length **L** of at least one half the length of the sheath, and a distal section with a second stiffness different than the first stiffness and a length *l*. A tubular loader defines a throughbore that receives a distal portion of the delivery catheter, the tubular loader having structure for engaging mating structure on a proximal end of the introducer housing and a

distal nose that extends through and opens the introducer valve and facilitates passage therethrough of the balloon of the delivery catheter.

[0013] There is also disclosed ~~A still further feature of the present application is~~ a medical introducer and heart valve delivery catheter combination, comprising a delivery catheter having a distal balloon of sufficient diameter to expand a crimped heart valve thereon. The catheter includes a marker band at a proximal end of the balloon, and a tubular valve pusher that moves longitudinally with respect to the balloon and has a distal marker band. An introducer having an elongated tubular sheath extending distally from a proximal housing contains at least one introducer valve for fluidly sealing around a proximal length of the delivery catheter. The introducer sheath has a throughbore for passage of the delivery catheter and a marker dot array around its distal tip to distinguish the distal tip from the marker bands of the balloon and the pusher.

[0014] There is also disclosed ~~In accordance with a still further aspect,~~ a medical introducer and heart valve delivery catheter combination comprise~~s~~ing a delivery catheter, an introducer, and a tubular loader therebetween. The delivery catheter has a distal balloon of sufficient diameter to expand a crimped heart valve thereon. The introducer has an elongated tubular sheath extending distally from a proximal housing which contains at least one introducer valve for fluidly sealing around a proximal length of the delivery catheter. Finally, the tubular loader includes a throughbore that receives a distal portion of the delivery catheter, structure for engaging mating structure on a proximal end of the introducer housing, and a distal nose that extends through and opens the introducer valve, facilitating passage therethrough of the balloon of the delivery catheter. The loader also has a proximal housing with a seal for fluidly sealing around the introducer sheath, and a single-handed vent for aspirating air from within the loader.

[0015] A heart valve delivery catheter as disclosed herein ~~of the present application~~ includes a catheter tube having a distal balloon thereon of sufficient diameter to fully expand a crimped heart valve from within. The balloon is disposed on the end

of a deflectable portion of the catheter tube actuated by a deflection pull wire. The delivery catheter further includes a tubular valve pusher that slides over the catheter tube and moves longitudinally with respect to the balloon. The delivery catheter also has a proximal control handle on which are mounted both a deflection actuator for deflecting the deflectable portion of the catheter tube and a pusher actuator for displacing the valve pusher. Preferably, the delivery catheter includes a plurality of concentric tubes extending from within the control handle, and at least one passive seal within the handle for sealing around one of the tubes without preventing its movement.

[0016] Another benefit as disclosed herein~~of the present application~~ is a medical introducer and heart valve delivery catheter combination that comprises a delivery catheter having a catheter tube with a distal balloon thereon of sufficient diameter to fully expand a crimped heart valve from within. An introducer has an elongated tubular sheath extending distally from a proximal housing which contains at least one introducer valve for fluidly sealing around a proximal length of the delivery catheter. A tubular loader defines a throughbore that receives a distal portion of the delivery catheter, and includes structure for engaging mating structure on a proximal end of the introducer housing and a distal nose that extends through and opens the introducer valve and facilitates passage therethrough of the balloon of the delivery catheter. The loader has a proximal housing with a loader seal for fluidly sealing around the introducer sheath, and a single-handed vent for aspirating air from within the loader.

[0017] A heart valve delivery catheter and heart valve combination disclosed herein features an expandable prosthetic heart valve having a crimped configuration and proximal and distal ends. A delivery catheter includes a catheter tube with a distal balloon thereon of sufficient diameter to fully expand the crimped heart valve from within. The balloon has a length greater than the length of the heart valve so as to have proximal and distal exposed portions, and the balloon is folded in a manner that leaves only longitudinal fold lines to contrast with the ends of the heart valve under echocardiography.

[0018]A heart valve delivery catheter as disclosed herein includes~~of the present application~~ a delivery catheter having a catheter tube with a distal balloon thereon of sufficient diameter to fully expand the crimped heart valve from within, the balloon being disposed on the end of a deflection tube actuated by a deflection pull wire, the deflectable portion comprising a braided structure and the deflection wire extending along its length up to a distal coil to which the deflection wire attaches, the deflectable portion having a dimension no greater than 8 French.

[0019]A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

Brief Description of the Drawings

[0020]Features and advantages of the present invention will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[0021]Fig. 1 is a schematic frontal view of a patient showing the location of an intercostal incision providing access to the apex of the left ventricle of the heart;

[0022]Figs. 2A-2B are cross-sectional views through the left side of a patient's heart showing a procedure for dilating a calcified aortic annulus prior to implantation of a prosthetic heart valve in accordance with the present invention;

[0023]Figs. 3A-3E are cross-sectional views through the left side of a patient's heart showing several steps in a procedure for implanting a prosthetic heart valve in accordance with the present invention;

[0024]Fig. 4 is an exploded perspective view of an introducer/dilator combination used in the port access heart valve implantation procedure of the present invention;