[0011] The present invention addresses these needs and others.

Summary of the Invention

[0012] Various embodiments of the present application ~~provide~~ seek to provide prosthetic valves and methods of use for replacing a defective native valve in a human heart. Certain embodiments ~~are~~ may be particularly well adapted for use in a surgical procedure for quickly and easily replacing a heart valve while minimizing time using extracorporeal circulation (i.e., bypass pump).

[0013] In one embodiment, a method for treating a native aortic valve in a human heart to replace the function of the aortic valve, comprises: 1) accessing a native valve through an opening in a chest; 2) placing guiding sutures in the annulus 3) advancing a heart valve within a lumen of the annulus; and 4) plastically expanding a metallic anchoring skirt on the heart valve to mechanically couple to the annulus in a quick and efficient manner.

[0014] The native valve leaflets may be removed before delivering the prosthetic valve. Alternatively, the native leaflets may be left in place to reduce surgery time and to provide a stable base for fixing the anchoring skirt within the native valve. In one advantage of this method, the native leaflets may recoil inward to enhance the fixation of the metallic anchoring skirt in the body channel. When the native leaflets are left in place, a balloon or other expansion member may be used to push the valve leaflets out of the way and thereby dilate the native valve before implantation of the anchoring skirt. The native annulus may be dilated between 1.0-5 mm from their initial orifice size to accommodate a larger sized prosthetic valve.

[0015] In accordance with ~~a preferred aspect~~the disclosure, a heart valve includes a prosthetic valve defining therein a non-expandable, non-collapsible orifice, and an expandable anchoring skirt extending from an inflow end thereof. The anchoring skirt has a contracted state for delivery to an implant position and an expanded state configured for outward connection to the surrounding annulus. Desirably, the anchoring skirt is plastically expandable.

[0016] In ~~one preferred form~~an embodiment, a prosthetic heart valve for implant at a heart valve annulus comprises a non-expandable, non-collapsible annular support structure defining a flow orifice and having an inflow end. Valve leaflets attach to the support structure and are mount to alternately open and close across the flow orifice. A plastically-expandable stent frame has a first end extending around the flow orifice and connected to the valve at the inflow end of the support structure. The stent frame has a second end projecting in the inflow direction away from the support structure and is capable of assuming a contracted state for delivery to an implant position and a wider expanded state for outward contact with an annulus. The stent frame has an undulating first end with peaks and valleys that conform to a similar shape of the inflow end of the support structure, and the stent frame in the contracted state extends away from the inflow end of the support structure in a tubular portion between the peaks and valleys and then angles inward in a conical portion to the second end. In one embodiment, the stent frame angles inward in a conical portion in the contracted state and the second end defines an orifice that is non-circular, such as by non-uniform crimping.

[0017] ~~In another aspect~~An aspect of the present invention provides, a prosthetic heart valve for implant at a heart valve annulus, ~~comprises~~comprising:

a. a non-expandable, non-collapsible annular support structure defining a flow orifice and having an inflow end;

b. valve leaflets attached to the support structure and mounted to alternately open and close across the flow orifice;

c. a plastically-expandable stent frame having a first end extending around the flow orifice and connected to the valve at the inflow end of the support structure, the stent frame having a second end projecting in the inflow direction away from the support structure and being capable of assuming a contracted state for delivery to an implant position and a wider expanded state for outward contact with an annulus; and

d. a fabric covering around the stent frame including an enlarged sealing flange ~~surrounding the second end.~~arranged to contact the annulus and prevent paravalvular leaking, the fabric sealing flange comprising a strip of textured PET fabric that has a smooth side and a plush textured side, and the strip is connected at free ends to form a ring and folded in half

about its mid-section to form a double layer with the smooth sides facing each other inward and the plush textured sides facing outward.