

connected to the valve stent 125. Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

5 [00127] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

10 [00128] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

15 [00129] Figure 14 illustrates a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated
20 using a double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

[00130] Figures 15a and 15b depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. In this embodiment the sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

[00131] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to the embodiment shown in Figure 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET (polyethylene terephthalate) mesh 167 or other impermeable material.

[00132] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention, wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b),

ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[00133] Figures 17c and 17d show front and side views of the geometrical
5 restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall. Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is
10 crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is
15 expanded, as shown in the right side of Figure 17e, point 175 moves up, pulling the stent to the shape shown in 17d .

[00134] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being
20 advanced toward the stenotic aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[00135] Inflating balloon 183, as shown in Figure 18c, anchors valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of pericardium (or other suitable patch material) inserted on sutures 181 and
5 pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

[00136] Figures 19a to 19d depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. First elastic sealing stent 195 is inserted in the desired location. Then, valve
10 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[00137] Figure 19b shows the two stents placed in the native aortic valve. Sealing
15 stent 195 compensates for irregular shapes, while the stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable material. Sealing stent
20 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[00138] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

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