



New Device Approvals

Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P- P000007

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P
Manufacturer: Edwards Lifesciences LLC
Address: One Edwards Way, Irvine, CA 92614
Approval Date: February 27, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000007a.pdf>

What is it? The Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P is a segment of pig (porcine) aortic artery that contains the pig's aortic valve. It is treated with preservatives to keep it durable and flexible, and sterilized for human implantation. At the time of implantation, the surgeon removes the patient's diseased aortic valve and sews in the porcine valve in its place. This procedure is called subcoronary aortic valve implantation. (See Illustration)

How does it work? The valve functions like the patient's natural aortic valve. Three leaflets flap open to permit blood flow from the heart into the aorta and then to the body. Once the flow of blood ceases, the leaflets close, preventing backflow of blood into the heart.

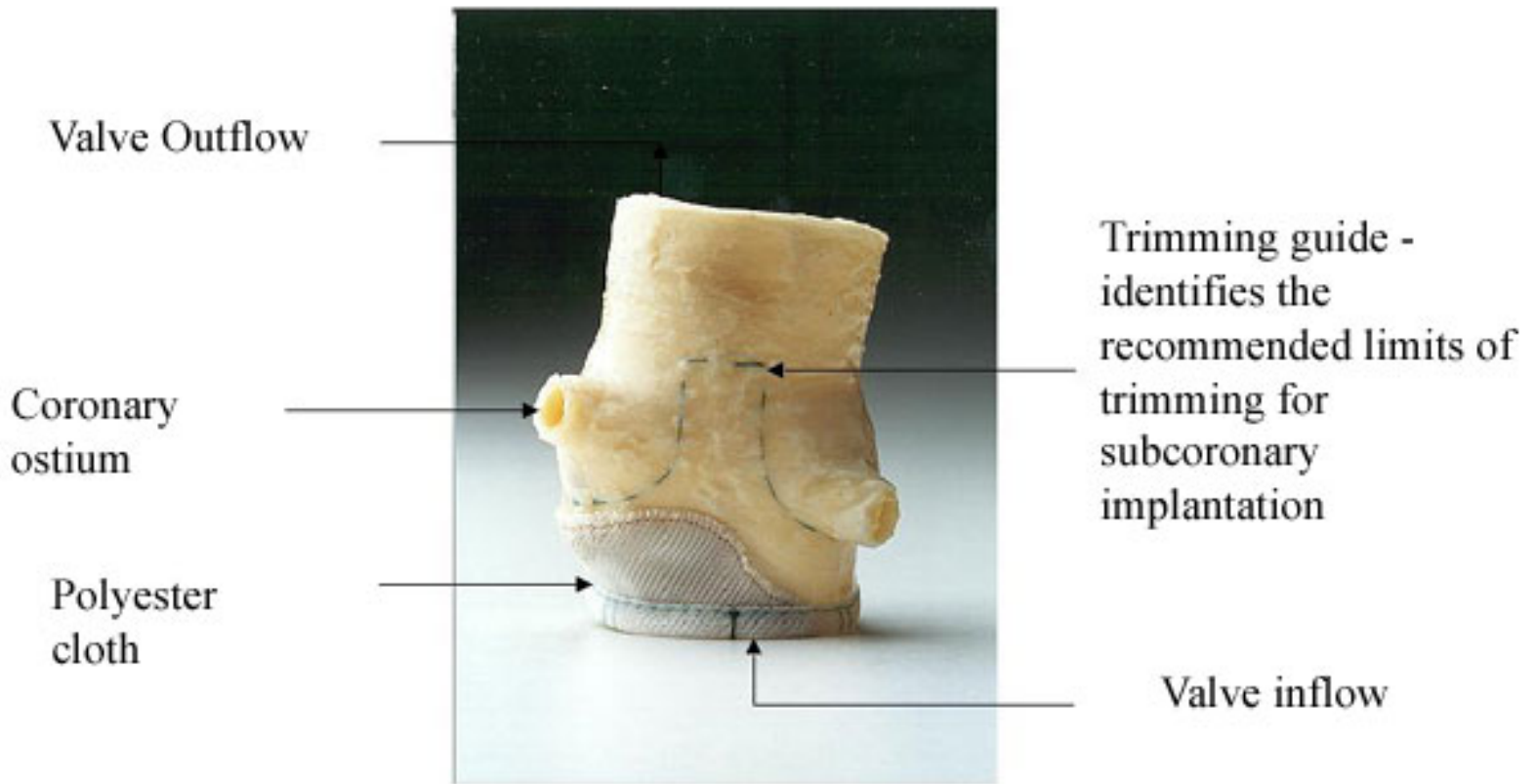
When is it used? The Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P is used to replace a patient's diseased aortic valve. A diseased valve either fails to allow ejection of blood from the heart, or fails to close adequately, allowing blood to flow back into the heart. In either case, strain is placed on the heart, which can lead to heart failure and death.

What will it accomplish? Replacement of the patient's malfunctioning valve with an effective substitute valve will correct stress on the heart caused by improper blood flow and permit recovery of heart function. This can reverse heart failure symptoms, such as chronic weakness or tiredness.

When should it not be used? The Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P should not be used in patients with heightened calcium metabolism because porcine valves tend to deteriorate rapidly in such cases. Heightened calcium metabolism occurs normally in children, adolescents and young adults, and abnormally in some older adults.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p000007.html>

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[Back to Consumer Information on P000007](#)