



New Device Approvals

On-X® Prosthetic Heart Valve - P000037

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: On-X® Prosthetic Heart Valve, Model ONXA
Manufacturer: Medical Carbon Research Institute (MCRI™), LLC
Address: 8200 Cameron Road, A-196, Austin, TX 78754
Approval Date: May 30, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000037a.pdf>

What is it? The On-X® Prosthetic Heart Valve is a mechanical heart valve with two movable half-discs (“bileaflets”), contained within a housing surrounded by a man-made fabric-covered ring. (The fabric is poly-tetra-fluor-ethylene). The leaflets are made of graphite and tungsten, with a carbon coating. The valve is used to replace a patient’s own aortic valve or another implanted prosthetic aortic valve.

How does it work? The two half-discs open and close as blood flows through the valve. As with all heart valves, this controls the direction of blood flow through the chambers of the heart.

When is it used? Like other prosthetic heart valves, the On-X® Prosthetic Heart Valve is intended to replace diseased, damaged, or malfunctioning natural or prosthetic aortic valves. Disease or damage to the patient’s natural valve may thicken, harden, weaken, or stretch it. This can make the valve fail to open and close properly, causing a decrease in the efficient flow of blood through the heart. This can reduce a patient’s quality of life.

What will it accomplish? A patient who has a diseased, damaged, or malfunctioning heart valve may feel weak, tired, or otherwise handicapped. Surgical replacement of the affected valve may be an effective option to improve the patient’s quality of life.

When should it not be used? The valve should not be used in patients who are unable to tolerate anticoagulant (blood-thinning) drugs.

Additional information: The SSED and Labeling will be available at:
<http://www.fda.gov/cdrh/pdf/p000037.html>

Other: <http://www.americanheart.org>

(Updated 5/31/2001)