



New Device Approvals

ATS Open Pivot® Bileaflet Heart Valve

This is a brief overview of information related to FDA's approval to market this product. See 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: ATS Open Pivot® Bileaflet Heart Valve
Manufacturer: ATS Medical, Inc.
Address: 3905 Annapolis Lane, Suite 105, Minneapolis, Minnesota 55447
Approval Date: October 13, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990046a.pdf>

What is it? The ATS Open Pivot® Bileaflet Heart Valve is a mechanical heart valve with two leaflets (flap like structures) in the shape of a circle, each leaflet a half the circle, surrounded by a ring made of polyester fabric. The leaflets are made of carbon. The valve is used to replace a patient's own aortic or mitral valve, or another prosthetic aortic or mitral valve.

How does it work? The ATS Open Pivot® Bileaflet Heart Valve uses two half discs (bileaflets) that open and close as blood flows through the valve to operate like the patient's natural heart valve. (Heart valves control the blood flow through the chambers of the heart.)

When is it used? The ATS Open Pivot® Bileaflet Heart Valve is intended to replace diseased, damaged, or malfunctioning natural or prosthetic aortic or mitral valves. Heart valves may not always work as well as they should. Disease or other heart valve malfunction may cause the heart valve tissue to thicken, harden, weaken, or stretch. If the valve fails to open and close properly, it can block or interfere with blood flow 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 heart 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 therapy or the use of blood-thinning drugs.

Additional information: The Summary of Safety and Effectiveness and product labeling can be obtained at:

<http://www.fda.gov/cdrh/pdf/p990046.html>