# Ancure® Aortoiliac System - P990017/S030

*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.*

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| Product Name: | Ancure® Aortoiliac System (A prosthetic endograft)) |
| Manufacturer: | Guidant Corporation |
| Address: | 1525 O'Brien Drive, Menlo Park, CA 94025 |
| Approval Date: | April 24, 2002 |
| Approval Letter: | http://www.fda.gov/cdrh/pdf/p990017S030a.pdf |

What is it and how does it work? The Guidant Ancure® Aortoiliac System is blood vessel graft, called an endovascular graft, that is used to repair an abdominal aneurysm. An aneurysm is a diseased or weakened section of an artery wall that tends to balloon or bulge due to arterial blood pressure. The device consists of a woven polyester graft that is housed within a long flexible delivery tube (catheter). The delivery tube containing the graft is inserted through a small incision in the groin where it is advanced through a blood vessel and positioned in the body's largest artery (the aorta) at the location of the aneurysm. The graft is attached to the wall of the aorta with tiny metal hooks. Once it is in place, blood flow can continue through the aorta without filling the aneurysm. This can prevent further growth and possible rupture of the aneurysm.

The Ancure® System comes in two other configurations, a single tube and a bifurcated (or "Y" shaped tube), which was approved by the FDA in 1999.

For a drawing of an abdominal aortic aneurysm:
http://www.nlm.nih.gov/medlineplus/ency/imagepage/18072.htm

When is it used? The Ancure® Aortoiliac System is used instead of the more invasive open surgery in patients who have an abdominal aortic aneurysm and whose anatomy is not suited for the use of the single tube or bifurcated ("Y" shaped) endograft device.

What will it accomplish? The Ancure® Aortoiliac System should benefit patients with an abdominal aortic aneurysm by preventing further growth and rupture of the aneurysm.

When should it not be used? Although there are no known contraindications for use, the device should not to be used in patients who are unable to undergo the necessary preoperative and postoperative imaging and implantation studies, or patients who are sensitive to, or allergic to the device materials.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p990017S030.html

Other:

National Institutes of Health

- Information on abdominal aortic aneurysm: http://www.nlm.nih.gov/medlineplus/ency/article/000162.htm
- Information on aortic aneurysm: http://www.nlm.nih.gov/medlineplus/ency/article/001122.htm#treatment
- Information on aneurysms: news, overviews, research, treatment, etc.: http://www.nlm.nih.gov/medlineplus/aneurysms.html

*(Updated June 18, 2002)*