AMPLATZER® PFO OCCLUDER - H000007

FDA approved this device under the Humanitarian Device Exemption (HDE) program http://www.fda.gov/cdrh/ode/hdeinfo.html. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	AMPLATZER® PFO Occluder
Manufacturer:	AGA Medical Corporation
Address:	682 Mendelssohn Avenue, Golden Valley, MN 55427
Approval Date:	April 5, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/h000007a.pdf

What is it? The AMPLATZER® PFO Occluder is a device that functions as a plug (called an "occluder") to close an abnormal opening in the wall between the two upper chambers of the heart. This abnormality is called a "PFO," or "patent foramen ovale." The Occluder is made of self-expanding wire-mesh with double discs. It contains inner polyester fabric patches that, along with the wire mesh, causes the formation and accumulation of a blood clot which actually blocks the opening. After the device is in place, tissue will grow over it, and the device then becomes part of the wall of the heart.

How does it work? A delivery tube (a catheter) containing the folded Occluder is threaded into a vein in the groin and guided into the heart. Once in the heart, it is advanced through the defect in the heart's wall. When it is in the correct position, the Occluder is opened so that each side of the defect is blocked (or sandwiched) by a mesh disc of the Occluder.

When is it used? The AMPLATZER® PFO Occluder is intended for the non-surgical closure of a PFO in patients with recurring strokes presumed to be caused by this defect who have failed conventional drug therapy.

What will it accomplish? This device can prevent blood from passing through the PFO, which may cause a stroke. It does so without the use of open-heart surgery or blood-thinning drugs.

When should it not be used? It should not be used in patients with:

- blood clots present at the intended site of implant or blood clots in the vessels through which access to the defect is gained.
- active inflammation of the heart (endocarditis)
- infections that cause bacteria to be released into the bloodstream
- certain blood clotting disorders
- tumors or other growths within the heart

Additional information: The Summary of Safety and Probable Benefit and Labeling will be available at: http://www.fda.gov/cdrh/ode/H000007sum.html

Other:

- Information "on hole in heart": http://216.185.112.5/presenter.jhtml?identifier=3000101
- Eating for a healthy heart: http://www.fda.gov/opacom/lowlit/hlyheart.pdf
- Varied information (some Spanish): http://www.nlm.nih.gov/medlineplus/heartdiseasesgeneral.html

(Updated June 4, 2002)