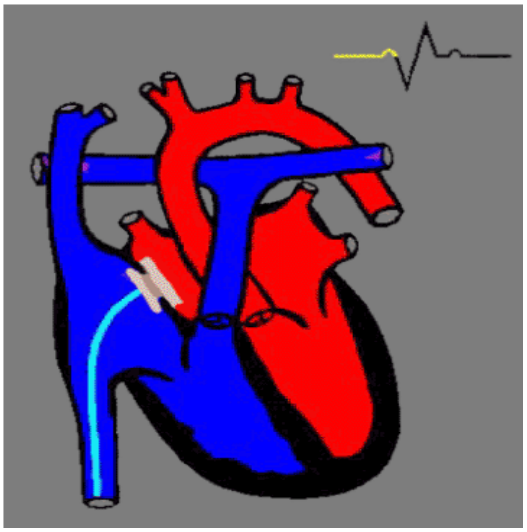
AMPLATZER® Septal Occluder - P000039

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:	AMPLATZER® Septal Occluder
Manufacturer:	AGA Medical Corporation
Address:	682 Mendelssohn Avenue, Golden Valley, MN 55427
Approval Date:	December 5, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/P000039a.pdf

What is it? The AMPLATZER® Septal Occluder is a device used to close an abnormal opening in the wall between the two upper chambers of the heart (the atria), without using open-heart surgery. The opening in the heart may occur naturally, in which case it is called an atrial septal defect (ASD). It may also result from a certain type of heart surgery (see below).



The device consists of two parts: (1) a delivery system and (2) a permanent implant. The delivery system helps transport the implant to the site of the defect in the heart. The implant is the part of the device that remains in the heart to block the hole. The implant is a self-expandable double disk made from wire mesh and polyester fabric.

How does it work? A doctor makes a small incision in the groin and threads the delivery system and implant through blood vessels to the heart. Inside the heart, the device is advanced to the site of the defect. When the doctor is certain the device is placed properly, the implant is released from the delivery system and opened so that the defect is blocked (or sandwiched) by the mesh discs. The implant remains in the heart and the delivery system is removed.

Once the device is in place, tissue will grow over it closing the defect. The device then becomes part of the wall of the heart.

When is it used? The AMPLATZER® Septal Occluder is intended to close openings between the atria (the two upper chambers of the heart). It can be used to treat patients with certain types of atrial septal defects. The device can also be used to close a passageway intentionally made during a surgical operation called a fenestrated Fontan procedure if the surgeon determines the passageway is no longer necessary. (The fenestrated Fontan procedure is an open-heart surgery in which a surgeon makes a new passageway for blood to travel through the heart. It is used to treat a variety of congenital heart defects.)

What will it accomplish? The implant will permanently close the defect in the heart without open-heart surgery. This may result in a shorter hospital stay and a faster recovery time.

When should it not be used? The Amplatzer® Septal Occluder should not be used in patients who:

- have extensive cardiac anomalies and require open-heart surgery;
- have certain types of infections that do not respond to treatment;
- cannot take aspirin or other blood-thinning drugs;
- have blood clots in or near the heart;
- are allergic to nickel.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/P000039.html

Other:

- MEDLINE Plus Information on Atrial Septal Defect
  http://www.nlm.nih.gov/medlineplus/ency/article/000157.htm
- MEDLINE Plus Information on Congenital Heart Defect Corrective Surgery
  http://www.nlm.nih.gov/medlineplus/ency/article/002948.htm
- MEDLINE Plus Information on Congenital Heart Disease: News, Diagnosis, Symptoms, Management, Nutrition, Treatment, Dictionaries, and Organizations
  http://www.nlm.nih.gov/medlineplus/congenitalheartdisease.html

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