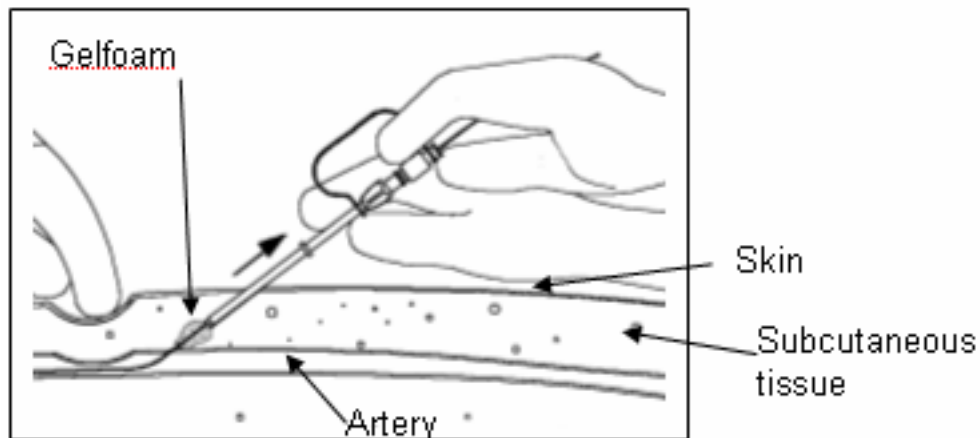




# New Device Approvals

## QuickSeal Arterial Closure System - P010049



*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: QuickSeal Arterial Closure System  
Manufacturer: SUB-Q, Inc.  
Address: 1062-D Calle Negocio, San Clemente, CA 92673  
Approval Date: March 25, 2002  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010049a.pdf>

**What is it?** The QuickSeal Arterial Closure System stops bleeding in the femoral artery after cardiac catheterization. During catheterization, a needle is used to make a small tunnel through the skin and tissue and into a blood vessel in the leg (the femoral artery). Then a thin, flexible, hollow tube (catheter) is threaded through the blood vessel until it reaches the heart. The catheter is used to carry specialized tools and medicines for the diagnosis and treatment of heart disease.

At the end of the procedure, when the catheter is removed, it is necessary to stop the bleeding in the femoral artery. QuickSeal helps the body make a clot at the place the catheter entered the blood vessel.

**How does it work?** QuickSeal is made of two parts: a sponge-like material called Gelfoam and a rigid plastic tube used to place the Gelfoam at the puncture site. After the catheter is removed from the artery,

the plastic tube portion of the device is slipped into the same hole, stopping just short of the artery. The Gelfoam passes through the tube so that it covers the hole in the artery. The tube is then removed and the Gelfoam stays in place, where it helps a clot to form.

**When is it used?** QuickSeal is used after a cardiac catheterization procedure. For a picture of a cardiac catheterization, use the following link:

<http://www.nlm.nih.gov/medlineplus/ency/imagepages/1080.htm>

**What will it accomplish?** QuickSeal helps the body produce a blood clot to seal the hole in the femoral artery. Without this device, the doctor applies manual pressure to the puncture site to stop the bleeding. Pressure is still necessary with this device, but it can be applied for a shorter time. QuickSeal also lets patients get out of bed and walk sooner than they would be able to if they did not receive the device. If the cardiac catheterization was only for diagnosis, using QuickSeal may reduce the time that the patient is hospitalized.

**When should it not be used?** QuickSeal should not be used in patients who:

- have sensitivity or allergy to materials made from pigs;
- have blood clotting problems; or
- have uncontrollable high blood pressure.

**Additional information:** Summary of Safety and Effectiveness and labeling will be available at: <http://www.fda.gov/cdrh/pdf/p010049.html>

Other:

National Institutes of Health

- Heart (cardiac) catheterization information  
<http://www.nlm.nih.gov/medlineplus/ency/article/003419.htm>
- Left side of heart catheterization information  
<http://www.nlm.nih.gov/medlineplus/ency/article/003871.htm>

Center for Food Safety and Nutrition

- Diet information and links to other government sites with heart information:  
<http://www.cfsan.fda.gov/~dms/wh-heart.html>

*(Updated 4/18/2002)*