



New Device Approvals

CoSeal® Surgical Sealant - P010022

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: CoSeal® Surgical Sealant
Manufacturer: Cohesion Technologies, Inc
Address: 2500 Faber Place, Palo Alto, California 94303, USA
Approval Date: December 14, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010022a.pdf>

What is it? CoSeal® is a medical sealant that is used to help stop leaks in blood vessels. It is made of two chemicals called polyethylene glycols (PEGs), and does not include any human or animal materials.

How does it work? The two PEGs are mixed together as they are applied during surgery to form a glue-like product which seals the area. CoSeal® fills gaps and plugs holes in the patient's blood vessels.

When is it used? CoSeal® is used to help seal leaks around sutures in natural or artificial blood vessels.

What will it accomplish? In a research study, immediately after treatment, leaking suture areas were successfully sealed in 47% of patients treated with CoSeal®, as compared to only 20% of patients who received another kind of treatment to stop bleeding. After 10 minutes, leaking suture areas were successfully sealed in 81% of patients treated with CoSeal®, as compared to 78% of patients who received another kind of treatment to stop bleeding.

When should it not be used? CoSeal® should not be used:

- Inside blood vessels,
- As a replacement for sutures or staples

The safety and performance of CoSeal® have not been determined in children and pregnant women or when used in quantities greater than 16 milliliters per patient.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p010022.html>

Other:

FDA:

- Center for Food Safety and Nutrition (CFSAN): Information on heart disease and nutrition from CFSAN and other government sources:
<http://www.cfsan.fda.gov/~dms/wh-heart.html>

National Institutes of Health (NIH):

- Information on arteries and aging: <http://www.nia.nih.gov/health/pubs/hearts-arteries/p4.htm>
- Information on blood vessels:
<http://medlineplus.nlm.nih.gov/medlineplus/ency/article/004006.htm>

(Updated 06/18/2002)