CryoLife BioGlue Surgical Adhesive - P010003

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:	CryoLife BioGlue Surgical Adhesive
Manufacturer:	CryoLife, Inc.
Address:	1655 Roberts Boulevard, NW, Kennesaw, GA 30144
Approval Date:	December 3, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010003a.pdf

What is it? BioGlue is an animal-based sealant that is made of a bovine serum albumin (a cow protein) and a chemical called glutaraldehyde.

How does it work? The cow protein and the chemical join in the patient's tissue to seal the area, like a glue. This product can also seal non-tissue materials such as plastic artificial arteries, by filling in gaps and plugging the holes in the material.

When is it used? BioGlue is used to help seal leaks around sutures (surgical stitches) or staples in large blood vessels such as the aorta or the femoral and carotid arteries.

What will it accomplish? In a research study, BioGlue successfully sealed leaking suture areas in 61% of patients compared to only 39% of patients who did not receive the BioGlue.

When should it not be used? BioGlue should not be used:

- in patients who are allergic to bovine (cow) materials,
- inside the blood vessels,
- to correct problems with blood vessels in the brain,
- instead of sutures or staples,
- when infection is present,
- where there will be contact with nerve tissue or heart valve tissue,
- inside the heart,

- in children because the chemical glutaraldehyde has been connected with calcification (calcium buildup).

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p010003.html

Other: National Institutes of Health Information on heart and blood vessels: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/004006.htm

(Updated 01/17/2002