Consumer Information on: ArterX Surgical Sealant - P100030

U.S. Food & Drug Administration

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 Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: ArterX Surgical Sealant
PMA Applicant: Tenaxis Medical, Inc.
Address: 835 Maude Ave,
Mountain View, CA 94043
Approval Date: March 1, 2013
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100030a.pdf [1]

What is it? The Tenaxis Medical ArterX Surgical Sealant (ArterX) is a medical sealant that is used to help stop leaks in blood vessels. It is made of two components, bovine serum albumin (BSA) and polyaldehyde. The BSA component is derived from cow (bovine) tissue. The two components are contained in separate barrels of a syringe.

How does it work? During surgery, the two components are mixed together and applied to locations where blood vessels or grafts have been sutured together to form a glue that seals gaps and holes.

When is it used? It is used during surgical procedures to help seal leaks around sutures in natural or artificial blood vessels.

What will it accomplish? In a clinical research study, immediately after treatment, leaking suture areas were successfully sealed in 101 out of 167 patients (61%) treated with ArterX, as compared to only 65 out of 164 patients (40%) who received another kind of treatment to stop bleeding. After 10 minutes, leaking

suture areas were successfully sealed in 137 out of 167 patients (82%) treated with ArterX, as compared to 118 out of 164 patients (72%) who received another kind of treatment to stop bleeding.

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

- In patients with known allergies to materials of cow or shellfish origin;
- Within blood vessels;
- In procedures involving blood vessels in the brain or near the spinal cord.

Additional information: The Summary of Safety and Effectiveness Data and labeling [2] are available online.

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