Class 1 Recall VASCUGUARD Pheripheral Vascular Patch

See Related Information[23]

Date Posted	May 29, 2015
Recall Status[1]	Open
Recall Number	Z-1637-2015
Recall Event ID	71191[24]
Premarket Notification 510(K) Number	K142461[25]
Product Classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene[26] - **Product Code** DXZ[27]
Product	Synovis VASCU-GUARD Peripheral Vascular Patch of the following sizes and product codes: 1x6cm, product code 1504026, 0.8x8cm, product code 1504028, 1x10cm, product code 1504030, and 2x9cm, product code 1504032. VASCU-GUARD is prepared from bovine pericardium which is cross-linked with glutaraldehyde. VASCU-GUARD has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25®C. VASCU-GUARD is terminally sterilized using gamma irradiation. VASCU-GUARD is packaged between two pieces of foam within a double sterile barrier pouch system. The contents of the unopened, undamaged package are sterile. VASCU-GUARD is intended for use in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda, and tibial blood vessels and arteriovenous access revisions
Code Information	all lot numbers
Recalling Firm/ Manufacturer	Synovis Surgical Innovations, Inc. 2575 University Ave W Saint Paul, Minnesota 55114-1073
For Additional Information Contact	Center for Service 888-229-0001
Manufacturer Reason for Recall	Baxter healthcare is recalling specific product codes of Vascu-Guard Peripheral Vascular Patch due to complaints received for difficulty in distinguishing the smooth from rough surface.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	The firm, Baxter, sent an "Urgent Product Recall" letter dated 5/2/2015 via USPS overnight delivery to its customers. The letter identified the affected product, problem and actions to be taken. The customers were instructed to immediately discontinue use and segregate the affected product, locate and remove all affected product from your facility and to return it to Baxter. Customers are to contact Baxter Healthcare Center, 888-229-0001, for Service to arrange for return and credit. In addition, the customers were to complete and return the Customer Reply Form by faxing to 224-270-5457 or emailing to fca@baxter.com. If you have any questions, contact Director, Quality at 651-796-7543 or email: heidi_drafall@baxter.com.
Quantity in Commerce	3,974
Distribution	Nationwide Distribution.