Consumer Information on: EXOSEAL Vascular Closure Device - P100013

U.S. Food & Drug Administration

Product Name: EXOSEAL Vascular Closure Device
PMA Applicant: Cordis Corporation
Address: 430 Route 22 East, Bridgewater NJ 08807
Approval Date: May 19, 2011
Approval Letter: A link to web for the approval letter TBA

What is it? The EXOSEAL Vascular Closure Device (VCD) is composed of a bioabsorbable plug and a Plug Delivery System. The bioabsorbable plug is made entirely of a synthetic, absorbable polymer (polyglycolic acid (PGA)). PGA material has been used extensively by the medical community since 1970, primarily with bioabsorbable sutures. The PGA plug material is constructed to stop bleeding from the puncture site. The Plug Delivery System is designed to position and release the bioabsorbable plug to seal the puncture site in the main artery of the thigh (femoral artery).

The Plug uses a standard introducer sheath. To help with the positioning and deployment, the delivery system incorporates two unique markers that provide the surgeon with visual targets to determine the location of the plug relative to the outside of the vascular wall prior to initiating and deploying the plug.

How does it work? Following a procedure involving intravascular access through the femoral artery, the EXOSEAL VCD is used to close the femoral artery wound. The EXOSEAL VCD delivers a resorbable polyglycolic acid plug to the opening in the artery to stop the bleeding.

When is it used? The EXOSEAL VCD is intended to close the femoral artery following arterial access. The EXOSEAL VCD is designed for use in small vascular punctures.

What will it accomplish? The EXOSEAL VCD uses a polyglycolic acid plug and is an alternative to applying manual pressure (compression) to stop the bleeding. The EXOSEAL VCD enables patients to stop bleeding faster and allows them to become mobile sooner than it is possible with standard compression methods.

When should it not be used? There are no known contraindications for this device.

Additional information : Summary of Safety and Effectiveness and labeling [1] will be available online.

SOURCE [2]

Source URL (retrieved on *05/19/2013 - 12:04pm*):
http://www.mdtmag.com/news/2011/06/consumer-information-exoseal-vascular-closure-device-p100013

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p100017
[2] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm257674.htm