Vascular Solutions Duett™ Sealing Device

This is a brief overview of information related to FDA's approval to market this product. See 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: Vascular Solutions Duett™ Sealing Device
Manufacturer: Vascular Solutions, Inc.
Address: 2495 Xenium Lane North, Minneapolis, MN 55441
Approval Date: June 22, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p990037a.pdf

What is it? The Vascular Solutions Duett™ sealing device is a single-use, disposable, medical device used during surgery that stops bleeding from the femoral artery puncture site, following the passage of the catheter (a thin hollow tube) through the blood vessel. The Duett™ is made up of two main parts: a thick liquid called a *procoagulant* that rapidly clots blood upon contact, and a *flexible balloon catheter* used to access and temporarily seal the puncture site. The procoagulant contains thrombin and collagen, which are substances naturally found in the human body that stimulate the clotting of blood. The balloon catheter is a small plastic tube that is inserted into a tubular sheath, called an introducer, used during the catheterization procedure.

How does it work? At the end of the catheterization procedure, the doctor inserts the Duett™ catheter through the sheath that was placed into the femoral artery of the leg. A small balloon at the end of the catheter is inflated and positioned inside of the artery at the puncture site to temporarily stop bleeding. The liquid procoagulant is then delivered to the outside of the puncture site and stimulates the body's natural clotting process to stop any bleeding. The catheter and sheath are then removed, and, after a few minutes with applied light pressure, the puncture site is completely sealed.

When is it used? The Duett™ is used at the end of a catheterization procedure, to stop bleeding from the femoral artery puncture site. Such procedures include a heart catheterization (when a long narrow tube is threaded through blood vessels and into a chamber of the heart to do various tests), and other procedures, such as balloon angioplasty and inserting blood vessel stents to treat blocked blood vessels.

What will it accomplish? Once delivered to the puncture site, the Duett™ procoagulant stimulates the body's natural clotting process, allowing for rapid sealing of the puncture site and elimination of much of the discomfort caused by the more common manual compression method. Use of the Duett™ also allows the patient to get out of bed and walk sooner than with the manual compression method.

When should it not be used? The Duett™ should not be used in patients with known sensitivity to materials made from cattle. Patients should talk to their doctors before the Duett™ is used if they have any of the following conditions: blood clotting disorders, blockages in, or previous surgeries on a leg; leg pain when walking; high blood pressure; or pregnancy.

Additional information: Summary of Safety and Effectiveness and product labeling can be found at:

http://www.fda.gov/cdrh/pdf/p990037.html

Other: http://jama.ama-assn.org/issues/v284n6/ffull/jfd00006-1.html