



A company of **SULZERmedica**

1300 EAST ANDERSON LANE, AUSTIN, TEXAS 78752-1793

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The Vascutek Cardiovascular Fabric product line consists of a non-crimped Gelseal™ patch, Gelsoft™ patch, and a Thin Wall Carotid patch. Each patch product line is gelatin-sealed, knitted polyester, with a base fabric porosity of 1460 ml/min/cm², 2118 ml/min/cm² and 3515 ml/min/cm² respectively, and are available in various square or rectangular sizes. The polyester fabrics have been impregnated with an absorbable mammalian gelatin which seals the prostheses in the same manner as the fibrin deposited in traditional preclotting procedures. The gelatin sealant obviates the need for preclotting prior to implantation. The gelatin is of United States Pharmacopeia (USP) standard and is derived from bovine bone. The result is a family of cardiovascular patches that do not require preclotting even when patients have been anticoagulated or when bleeding is a prime concern. The gelatin has been shown to be safe and effective through the approval of the Vascutek Gelseal™ Vascular Graft, PMA# P890045 on January 11, 1993.

Vascutek Cardiovascular Fabric is indicated for vascular patch grafting and for intracardiac patching. The Thin Wall Carotid Patch is, in addition, indicated for patch closure after endarterectomy, particularly of the carotid arteries. Vascutek Cardiovascular Fabric is manufactured from materials that have an extensive history of use in cardiovascular and other medical applications. This polyester material and gelatin sealant have been thoroughly tested and characterized with regard to biocompatibility and suitability for their intended use. Vascutek Cardiovascular Fabric is supplied sterile. The method of sterilization used is Ethylene Oxide. A shelf-life of 4 years has been established.

Comprehensive in-vitro performance testing has been performed on Vascutek Cardiovascular Fabric. In-vitro performance testing performed on the Vascutek Gelseal™, Gelsoft™, and Thin Wall Carotid patches and the Meadox Hemashield Microvel Double Velour Fabric, which included burst strength, suture retention, tensile strength and water porosity, provides evidence that Vascutek Cardiovascular Fabric is substantially equivalent to the predicate fabric. Previously accepted animal testing has demonstrated acceptable in-vivo performance for the Vascutek Cardiovascular Fabric gelatin-sealed polyester material.

CarboMedics considers Vascutek Cardiovascular Fabric safe, effective and substantially equivalent in intended use, material (polyester and sealant), and function to the Meadox Hemashield® Microvel® Double Velour Fabric which received marketing clearance on May 27, 1993 under 510(k) K931386.

Common name of the device:	Cardiovascular Patch
Trade name of Proprietary name:	Vascutek Cardiovascular Fabric: Vascutek Gelseal™ Patch Vascutek Gelsoft™ Patch Vascutek Thin Wall Carotid Patch
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