CarboMedics
A company of SULZERmedica
1300 EAST ANDERSON LANE, AUSTIN, TEXAS 78752-1793

K964665

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510(k) SUMMARY
VASCUTEK GELWEAVE™ VASCULAR GRAFT (BIFURCATED CONFIGURATION)

The Gelweave™ vascular graft (bifurcated configuration) is a gelatin-sealed, woven polyester graft, with a base graft porosity of 350 ml/min/cm^2. The woven polyester material has been impregnated with an absorbable mammalian gelatin which seals the prosthesis 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 vascular prosthesis that does not require preclotting even when patients have been anticoagulated or when bleeding is a prime concern. This gelatin has been shown to be safe and effective through the approval of PMA# P890045 on January 11, 1993.

The Gelweave™ vascular graft (bifurcated configuration) is indicated for repair or replacement of damaged and diseased vessels of the abdomen in cases of aneurysmal or occlusive disease.

The Gelweave™ vascular graft (bifurcated configuration) 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. The Gelweave™ vascular graft is supplied sterile. The method of sterilization used is Ethylene Oxide. A shelf-life of 4 years has been established for the Vascutek Gelweave™ vascular graft.

CarboMedics considers the Vascutek Gelweave™ vascular graft (bifurcated configuration) to be substantially equivalent to the Vascutek Gelweave™ vascular graft (straight configuration) in intended use, composition, and function. Side-by-side in-vitro performance testing has been performed on the Vascutek Gelweave™ straight and bifurcated vascular grafts. In-vitro performance testing performed on the Gelweave™ including burst strength, suture retention, tensile strength and base graft (water) porosity provides evidence that the Gelweave™ vascular graft (bifurcated configuration) is substantially equivalent to the straight configuration. Animal testing has demonstrated acceptable in-vivo performance for the Gelweave™ graft's intended purpose.

CarboMedics considers the Vascutek Gelweave™ vascular graft (bifurcated configuration) safe, effective, and substantially equivalent in intended use, composition, and function to the straight configuration which received marketing clearance on December 19, 1995 510(k) via K952293.

Common name of the device:	Prosthesis, Vascular Graft
Trade or Proprietary name:	Vascutek Gelweave™ vascular graft (bifurcated configuration)
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