CarboMedics®
A company of SULZER medica
1300 EAST ANDERSON LANE, AUSTIN, TEXAS 78752-1793

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510(k) SUMMARY
VASCUTEK VASCUSOFT™ PLUS VASCULAR GRAFT

The Vascusoft™ Plus Vascular Graft is a warp knitted polyester prosthesis with a porosity of 2591 ml/min/cm^2 which is available in a straight tube and bifurcated configurations. The Vascusoft™ Plus Vascular Graft is indicated for systemic vascular repair, i.e. replacement or bypass in aneurysmal and occlusive disease of arteries. Coronary vascular repair and blood access fistula (e.g. hemodialysis) are contraindicated with this device.

The Vascusoft™ Plus vascular graft is manufactured from material that has an extensive history of use in cardiovascular and other medical applications. This polyester material has been thoroughly tested and characterized with regard to biocompatibility and suitability for its intended use. The Vascusoft™ Plus vascular graft is supplied sterile and must be preclotted prior to use. The method of sterilization used is Ethylene Oxide. A shelf-life of 5 years has been established for the Vascutek Vascusoft™ Plus vascular graft.

Comprehensive performance testing has been performed on the Vascutek Vascusoft™ Plus Vascular Graft, which includes in-vitro and animal evaluations. In-vitro performance testing performed on both the Vascusoft™ Plus and the Vascusoft™ vascular graft, which includes burst strength, suture retention, tensile strength and water permeability provides evidence that the Vascusoft™ "Plus" vascular graft is substantially equivalent to the Vascusoft™ vascular graft and has shown enhanced resistance to dilatation in in-vitro studies. Animal testing has demonstrated acceptable in-vivo performance for the Vascusoft™ Plus graft's intended purpose.

CarboMedics considers the Vascutek Vascusoft™ Plus Vascular Graft safe, effective and substantially equivalent in intended use, material (polyester), and function to the Vascutek Vascusoft™ Vascular Graft, which received 510(k) marketing clearance under K830016/F, later reassigned 510(k) number K910866 on April 1, 1991.