CARBOMEDICS CARBO-SEAL®
AND CARBOMEDICS CARBO-SEAL® VALSALVA
ASCENDING AORTIC PROSTHESIS

FLEXIBILITY, HANDLING AND NATURAL SHAPE TO
COEXIST IN A BETTER WAY WITH NATURE
CARBOMEDICS CARBO-SEAL® ASCENDING AORTIC PROSTHESIS

Specifications and Ordering Information

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Valve Size</th>
<th>Valve Orifice Area (cm²)</th>
<th>Graft Inner Diameter (mm)</th>
<th>Minimum Graft Length (cm)</th>
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<td>AP-021</td>
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Unparalleled Flexibility and Handling

Carbomedics Carbo-Seal® AAP uses Gelweave™ Graft

- Carbomedics Carbo-Seal® AAP includes the Carbomedics Standard Aortic Valve, a fully rotatable valve with unsurpassed thromboembolic performance, excellent hemodynamics, and NO post-operative structural failures.

- Thinner, more pliable, woven polyester from Vascutek requires no pre-clotting.

- Easier handling and suturing in comparison to bulkier velour materials.

- Gelweave’s tissue-like flexibility allows for easy contouring.

- Ultra-low porosity fabric results in less leakage, weeping and blushing.

- Resists fraying and minimizes suture hole bleeding.

- Orientation reference lines help in suture placement and graft-graft anastomosis.

*Floating yarns provide a solid anchor for the fibrous tissue, preventing intimal peel*
CARBOMEDICS CARBO-SEAL® VALSALVA
ASCENDING AORTIC PROSTHESIS...

20 years of experience in Mechanical Heart Valves

Carbomedics Carbo-Seal® Valsalva AAP includes the Carbomedics Standard Aortic Valve, a fully rotatable valve with unsurpassed thromboembolic performance and excellent hemodynamics. Implanted over 20 years without a single post-operative structural failure.

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<th>Valve Orifice Area (cm²)</th>
<th>Graft Inner Diameter (mm)</th>
<th>Maximum Sinus Inner Diameter (mm)</th>
<th>Sinus Region Length* (mm)</th>
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* Based on cadaveric anatomic studies, it was determined that the length of the sinus region should equal the bore diameter of the straight portion of the graft.
Sinus of Valsalva

- Vertical orientation of pleats facilitates coronary anastomosis.
- Replicates the native sinus, reducing stress on the coronary anastomoses.
- Sinus design encourages natural formation of systolic vortex.

A better way to coexist with nature
Replicated Sinus of Valsalva.

- Low profile taper to reduce stress on the coronary ostia buttons.
- Sealed graft with no pre-clotting requirements.
- Full-sized rotatable valve that maximizes the valve orifice to annulus ratio.
- Pre-sterilized, disposable cautery unit supplied with every conduit.

Gelatin Promotes Natural Healing

Carbomedics Carbo-Seal® AAP’s Gelweave™ graft is infused with minimally cross-linked gelatin instead of collagen for faster healing, encouraging a secure neo-intimal attachment with reduced inflammatory response**.

At one month, this light micrograph shows the formation of a smooth interluminal surface (top) with newly formed collagen and endothelial cells.

**Data on file at Carbomedics
Unlike collagen-coated grafts which are enzymatically metabolized, the Carbomedics Carbo-Seal’s gelatin sealant is biodegraded by hydrolysis and rapidly absorbed within 14 days.

User Friendly Instrumentation

- Carbomedics Carbo-Seal® and Carbomedics Carbo-Seal® Valsalva AAP come on a holder assembly to facilitate initial proximal placement

- Disposable cautery included inside every implant packaging

- Dual-ended, flexible annular sizers

- Valve rotator

- Disposable leaflet tester
Results of a New Mechanical Valved Conduit with Sinuses of Valsalva
Jehangir J Appoo; Alberto Pochettino; Katherine F Cornelius; Joseph E Bavaria
Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, United States.
Presented at the Biennial Meeting of the Society of Heart Valve Disease, June 2005

Objectives We describe our experience with a new mechanical valved conduit, the Carbomedics Sinus of Valsalva composite graft. It is the only composite graft on the market manufactured with sinuses of Valsalva. The presence of the sinuses of Valsalva allow for less extensive coronary mobilization especially in redo situations.


Results 64 patients were identified. Indications for operation included: ascending aortic aneurysm (87.5%), infective endocarditis (18.8%), and acute Type A dissection (10.9%). Twenty patients (31.2%) required a 2nd or 3rd time sternotomy. Concomitant procedures included arch replacement in 60.9%, mitral valve procedure in 9.4%, and CABG in 14.1%. Mean CPB, aortic cross clamp and DHCA times were: 242±77 mins, 193±66 mins and 26±11 mins respectively. Periop mortality was 3.1% (n=2). The incidence of bleeding requiring mediastinal re-exploration was 1.6% (n=1). The incidence of stroke was 4.7% (n=3). All patients with CVA underwent an arch reconstruction and 2 of the 3 stroke patients presented with acute Type A dissection. None of the patients required reoperation for valve dysfunction.

Conclusions Despite the degree of complexity of operations in this study, this valved conduit is a very acceptable prosthesis for a modified Bentall procedure. It can be used for a variety of aortic pathology, both electively and in emergent settings. Due to the technical advantages the sinuses confer, it has become our valved conduit of choice when a mechanical prosthesis is chosen for aortic root replacement.

Carbomedics Carbo-Seal and Carbomedics Carbo-Seal Valsalva clinical studies

Carbomedics Carbo-Seal Clinical Studies
Paul Urbanski, Matthias Wagner, Michael Zacher, Robert W Hacker
Giovanni Battista Luciani, Gianluca Casali, Luca Barozzi, Alessandro Mazzucco

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ONE YEAR APPRAISAL OF A NEW AORTIC ROOT CONDUIT WITH SINUSES OF VALSALVA - J Thoracic and Cardiovascular Surgery 2002;123 (1):33-39
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