CARBOMEDICS CARBOSEAL™
CARBOMEDICS CARBOSEAL VALSALVA™
Ascending aortic prostheses

Flexibility, handling and natural shape to coexist in a better way with nature
CARBOMEDICS CARBOSEAL™
Ascending aortic prostheses

<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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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 CARBOSEAL VALSALVA™

## Ascending aortic prostheses

### 30 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.

![Image of Carbo-Seal Valsalva AAP]

## 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>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.
A better way to coexist with nature

**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.

Natural blood flow
CARBOMEDICS CARBOSEAL VALSALVA™

First to feature

- 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**.

**Data on file at LivaNova
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.

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
RESULTS OF A NEW MECHANICAL VALVED CONDUIT WITH SINUSES OF VALSALVA

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.

METHODS Review of prospectively collected data on patients undergoing composite mechanical valve replacement from December 2002 to September 2004.

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

P. Urbanski, M. Wagner, M. Zacher, R.W. Hacker
AORTIC ROOT REPLACEMENT VERSUS AORTIC VALVE REPLACEMENT: A CASE-MATCH STUDY

G.B. Luciani, G. Casali, L. Barozzi, A. Mazzucco
AORTIC ROOT REPLACEMENT WITH THE CARBOMEDICS CARBO-SEAL COMPOSITE GRAFT: 7-YEAR EXPERIENCE WITH THE FIRST 100 IMPLANTS

REPLACEMENT OF THE PROXIMAL AORTA AND AORTIC VALVE USING A COMPOSITE BILEAFLET PROSTHESIS AND GELATIN-IMPREGNATED POLYESTER GRAFT (CARBO-SEAL): EARLY RESULTS IN 143 PATIENTS
J Thorac Cardiovasc Surg 1999;118:1014-20

Carbomedics Carbo-Seal Valsalva


R. De Paulis, G.M. De Matteis, P. Nardi, R. Scaffa, C. Bassano, L. Chiariello

R. De Paulis, G.M. De Matteis, P. Nardi, R. Scaffa, M.M. Buratta, L. Chiariello

R. De Paulis, G.M. De Matteis, P. Nardi, R. Scaffa, D.F. Colella, L. Chiariello
RESEARCH METHOD AND NEW THERAPIES A NEW AORTIC DACRON CONDUIT FOR SURGICAL TREATMENT OF AORTIC ROOT PATHOLOGY – Ital Heart J 2000;1(7):457-463