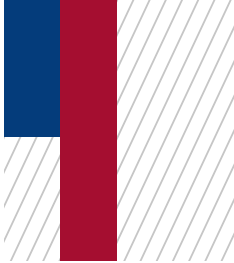


ASCENDING AORTIC
PROSTHESES

CARBOMEDICS CARBO-SEAL™ & CARBO-SEAL VALSALVA™



 **CORCYM**
WE TAKE LIFE TO HEART



CARBOMEDICS CARBO-SEAL™ & CARBO-SEAL VALSALVA™

Over 30 years of experience in mechanical heart valves

Carbomedics Carbo-Seal AAP includes the Carbomedics Standard Aortic Valve, a fully rotatable valve with a very low rate of thromboembolic events, favorable hemodynamics, and negligible post-operative structural failures.¹⁻⁶



**FLEXIBILITY, HANDLING
AND NATURAL SHAPE
TO COEXIST IN A BETTER
WAY WITH NATURE**

AAP: Aortic Ascending Prostheses

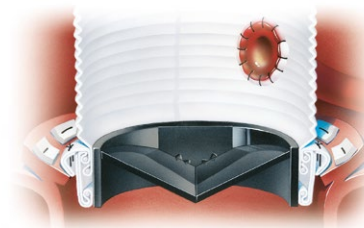
Technical claims are supported by CORCYM data on file.



CARBOMEDICS CARBO-SEAL™

Flexibility and Handling

- Thin, pliable, woven polyester from Vascutek® requires no pre-clotting.
- Easier handling and suturing in comparison to bulkier velour materials.¹²
- Gelatin coated and crimped structure for optimal flexibility.
- Ultra-low porosity fabric and gelatin sealing result in less leakage, weeping and blushing.
- Resists fraying and minimizes suture hole bleeding.¹⁰
- Orientation markers provide easy visual suture positioning.



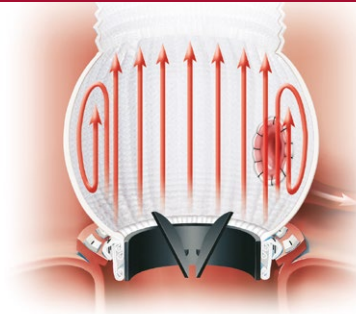
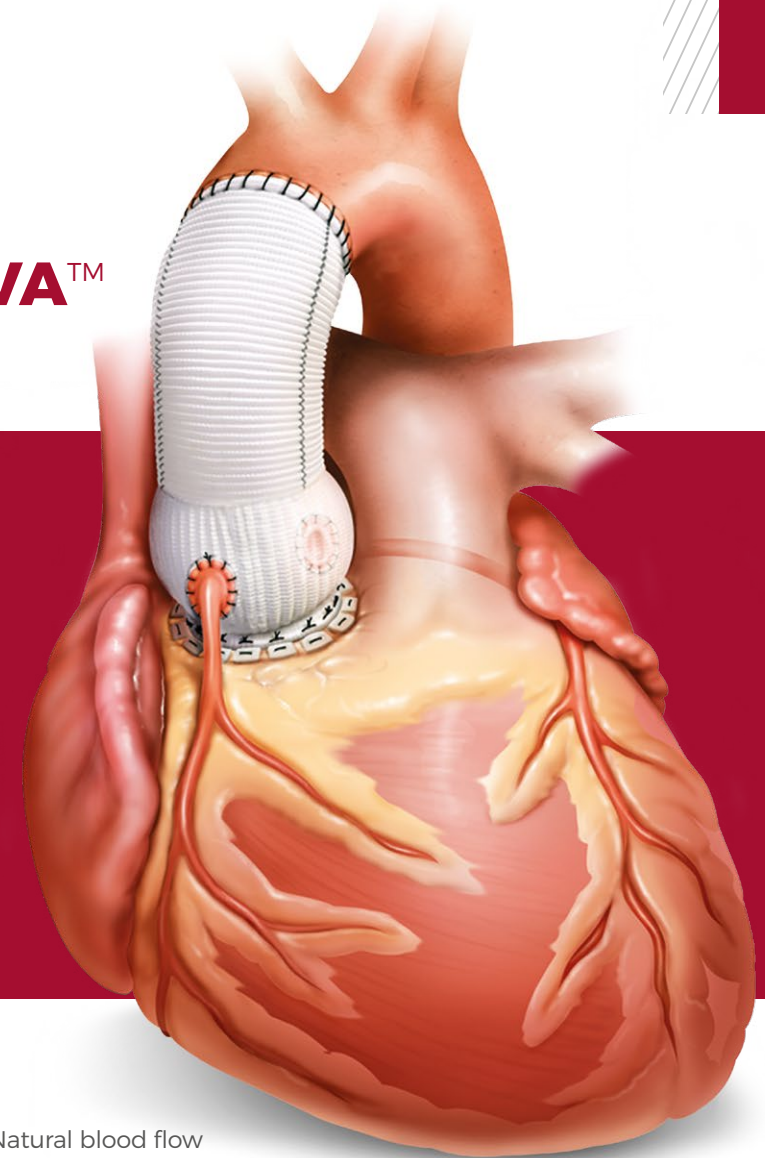


CARBOMEDICS CARBO-SEAL VALSALVA™

A better way to coexist with nature

SINUS OF VALSALVA

- Vertical orientation of pleats facilitates coronary anastomosis.⁷
- Reproduces the native sinus, reducing stress on the coronary anastomosis.⁷
- Sinus design encourages natural formation of systolic vortex.^{8,9}
- Low profile taper to reduce stress on the coronary ostia buttons.⁷
- Sealed graft with no pre-clotting requirements.
- Full-sized standard aortic valve provides favorable hemodynamics.^{1,2}

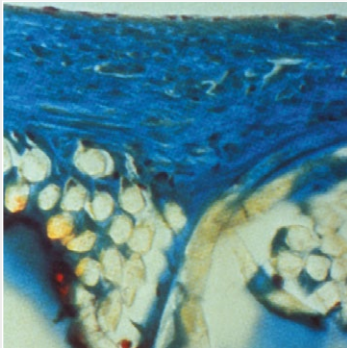


Natural blood flow

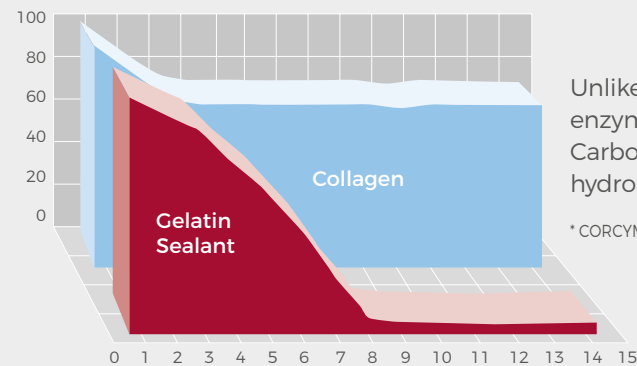
Technical claims are supported by CORCYM data on file.

Gelatin promotes natural healing¹⁰

Carbomedics Carbo-Seal AAP's Gelweave™ graft is infused with minimally crosslinked gelatin that does not alter the healing process, encouraging a secure neo-intimal attachment with reduced inflammatory response.¹⁰



The histology at three months shows a typical, well-incorporated Dacron graft. The pseudointima is thin and is not proliferating.



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.*

* CORCYM data on file

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.



Technical claims are supported by CORCYM data on file.



CARBOMEDICS CARBO-SEAL

ASCENDING AORTIC PROSTHESIS (AAP)
Sizes 21-33 mm

PRODUCT ORDERING INFORMATION

Valve Size	OD-H* (mm)	Graft Inner Diameter (mm)	Minimum Graft Length (cm)	Catalog Number
21	21.8	24	10	AP-021
23	23.8	26	10	AP-023
25	25.8	28	10	AP-025
27	27.8	30	10	AP-027
29	29.8	32	10	AP-029
31	31.8	34	10	AP-031
33	33.8	34	10	AP-033



CARBOMEDICS CARBO-SEAL VALSALVA

ASCENDING AORTIC PROSTHESIS (AAP)
Sizes 21-29 mm

PRODUCT ORDERING INFORMATION

Valve Size	OD-H* (mm)	Graft Inner Diameter (mm)	Maximum Sinus Inner Diameter (mm)	Sinus Region Length** (mm)	Minimum Graft Length (cm)	Catalog Number
21	21.8	24	32	24	10	CP-021
23	23.8	26	34	26	10	CP-023
25	25.8	28	36	28	10	CP-025
27	27.8	30	38	30	10	CP-027
29	29.8	32	40	32	10	CP-029

* OD-H = Outer Diameter of Housing – implant diameter.

** 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.

ACCESSORIES ORDERING INFORMATION

CODE	ARTICLE	DESCRIPTION
TR-101	Empty tray	1 empty tray
VS-200	Sizer set	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
AR-150	Rotators set	Rotators set
VT-100	Occluder tester	10 disposable occluder tester (provided sterile)



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INTENDED USE/INDICATIONS

The Carbomedics Ascending Aortic Prostheses are intended for use in open heart surgery for simultaneous replacement of the ascending aorta and the aortic valve in cases of aneurysm, dissection, or other disease conditions of the aorta combined with disease or degeneration of the aortic valve.

KEY CONTRAINDICATIONS

The Carbomedics Ascending Aortic Prostheses are contraindicated in patients unable to tolerate long term anticoagulation therapy or for whom this type of therapy is difficult to maintain.

KEY WARNINGS

For single use only. Do not attempt to clean, resterilize, or reuse any prosthesis that has been in contact with organic blood or tissue. This product should not be implanted in patients who exhibit sensitivity to polyester or material of bovine origin. Do not preclot.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with the use of prosthetic aortic heart valves include, but Adverse events potentially associated with the use of prosthetic aortic heart valves include: angina; cardiac

arrhythmia; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage; myocardial infarction; prosthesis nonstructural dysfunction; prosthesis perivalvular leak; prosthesis regurgitation; prosthesis structural dysfunction; prosthesis thrombus; stroke; thromboembolism. Adverse events potentially associated with the use of vascular grafts include: aneurysm; clinical reactions to collagen implantation have been described as infrequent, mild, localized, and self limiting; embolism; hemorrhage; infection; occlusion; pseudoaneurysm; seroma. It is possible that these complications could lead to: reoperation, explant, permanent disability, death.

MRI conditional

For professional use. Instructions for Use are available upon request through the manufacturer's website. Not approved in all geographies. Consult your labeling



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