ANNULOPLASTY
RINGS

CARBOMEDICS ANNULOFLEX™ & ANNULOFLO™

Making implantation easy[1]

CORCYM
WE TAKE LIFE TO HEART

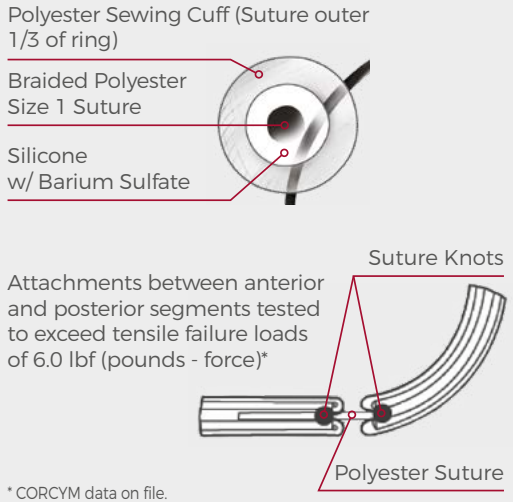
CARBOMEDICS ANNULOFLEX™

Complete or partial annuloplasty of the mitral and tricuspid valves.

FLEXIBLE

THE FLEXIBLE DESIGN OF THE CARBOMEDICS ANNULOFLEX ANNULOPLASTY SYSTEM PROVIDES IMPLANT VERSATILITY TO ACCOMMODATE SURGEON PREFERENCE AND VARIOUS CLINICAL INDICATIONS.[1-3]

- Three-in-one prosthesis easily converts from mitral ring to mitral band or tricuspid band, thanks to two suture cut points.
- Reduces hospital inventory.
- Full flexibility delivers three-dimensional compliance that mirrors natural valve dynamics.[1,2]
- Ring constructed with internal size 1 suture along with four knots, designed to reduce post-implantation dilatation.[2]
- Barium-impregnated silicone facilitates radiographic visualization.



* CORCYM data on file.

Technical claims are supported by CORCYM data on file.

Versatility has a certain ring to it

Enhanced visibility through[1]

- Translucent low profile holder
- Spacing guides on the holder ensure correct suture placement

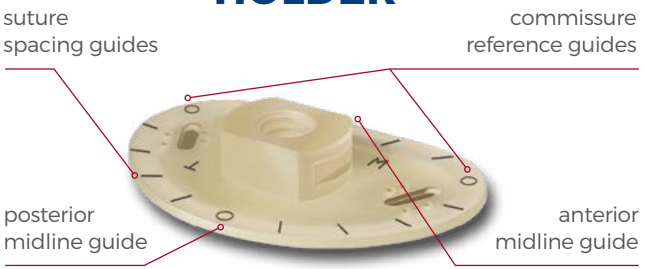
Improved ring stability by adding two more suture attachment points to make surgical suture placement and parachuting of ring easier

Two additional suture attachment points to simplify suturing and parachuting.

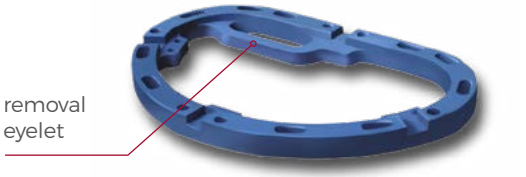
Easy template removal

Safe suture release cut points in the template.[1,2]

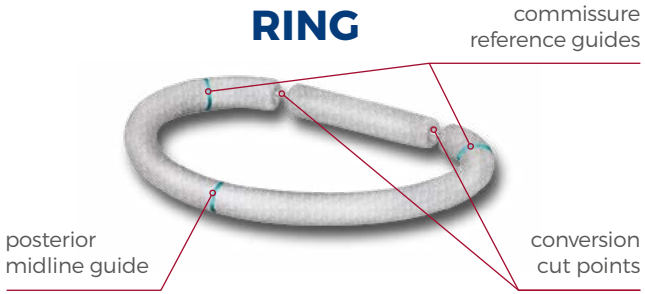
HOLDER



TEMPLATE



RING



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CARBOMEDICS ANNULOFLO™

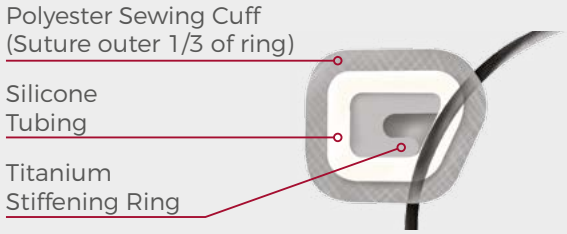
The design of Carbomedics AnnuloFlo allows for reproducible results when a rigid remodelling is desired.[3]

RIGID

A RIGID RING WITH EASY TO USE INSTRUMENTATION.

- Implant holder and handle facilitate suture placement and implantation.
- Ring shape and rigidity are designed to restore annular 3 to 4 dimensional ratio.
- Titanium rigid core provides annulus remodeling and is radiopaque.
- Knitted polyester (PET) fabric, coated with Carbofilm™ for increased hemocompatibility and biocompatibility.[4]

Carbofilm coating enhances biocompatibility and hemocompatibility and minimizes the fibrous overgrowth.[4]



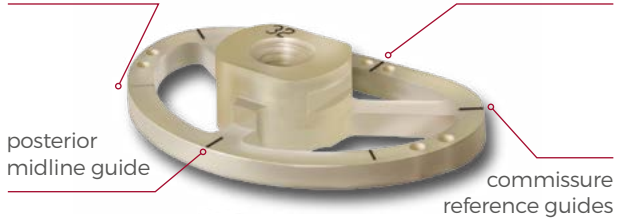
Technical claims are supported by CORCYM data on file.

Provides a rigid remodeling

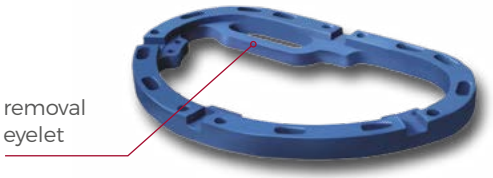
Enhanced visibility through[1]

- Translucent and windowed low profile holder
- Spacing guides on the holder ensure correct suture placement

HOLDER



RING



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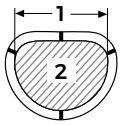
PRODUCT ORDERING INFORMATION

RING SPECIFICATIONS [A]

SIZE (mm)	1 Nominal Ring Inner Dimension (mm) [B]	2 Ring Area (cm^2)
26	26.0	2.81
28	28.0	3.30
30	30.0	3.85
32	32.0	4.43
34	34.0	5.03
36	36.0	5.70



Carbomedics AnnuloFlex and Carbomedics AnnuloFlo Ring are MRI Compatible

CARBOMEDICS ANNULOFLEX

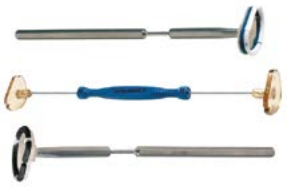
Catalog Number [C]
AF-826
AF-828
AF-830
AF-832
AF-834
AF-836

CARBOMEDICS ANNULOFLO

Catalog Number [D]
AR-726
AR-728
AR-730
AR-732
AR-734
AR-736

ACCESSORIES ORDERING INFORMATION (not provided sterile)

One set of instruments accomodate both Carbomedics AnnuloFlex and Carbomedics AnnuloFlo System



System includes complete sizers set to facilitate surgical procedures and achieve optimal clinical results.[1-3]

Malleable, notched sizers for mitral and tricuspid use

Malleable, detachable implant handle

INSTRUMENTS [A]

Catalog Number	Name	Description
ARMI-700	Sizer set	Sizer Set (which includes): - One sizer, size 26/28 - One sizer, size 30/32 - One sizer, size 34/36

VH-100	Holder handle	Carbomedics Universal Handle

A Ring/Sizer Specifications and Instruments are identical for both Carbomedics AnnuloFlo and Carbomedics AnnuloFlex systems.

B Represents transverse diameter at points 1 mm inside inner diameter (inside one third) on both sides of ring.

C Mitral and tricuspid indications.

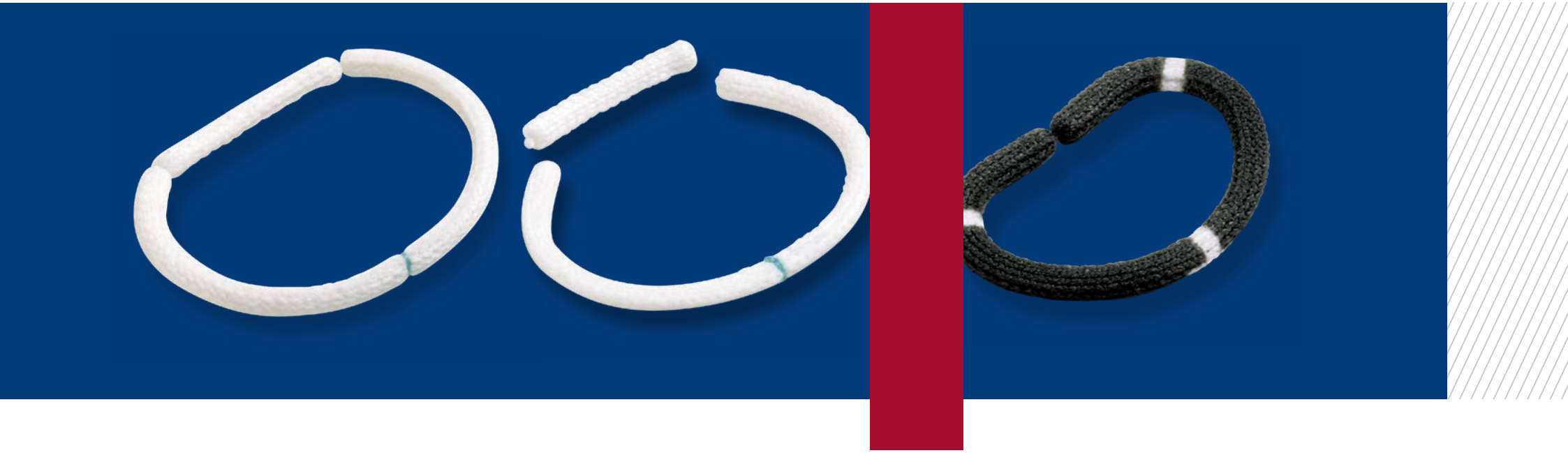
D Mitral indication only.

EMPTY TRAY

Catalog Number
ICV1230

CARBOMEDICS ANNULOFLEX™ & ANNULOFLO™

ANNULOPLASTY RINGS



REFERENCES

1. Khsettry et al., "**Prospective Study of Mitral Valve Repair with the CarboMedics AnnuloFlex™ Annuloplasty System: Effectiveness and Safety after One Year".** T*he Journal of Heart Valve Disease 2005;14:105-113*
2. Pragliola et al., **"Long-term results of an open flexible prosthetic band for mitral insufficiency".** *Asian Cardiovascular & Thoracic Annals 2014, Vol. 22(7) 811–815*
3. Khsettry et al., **"Current Trends in Mitral Valve Repair Techniques in North America".** *The Journal of Heart Valve Disease 2012;21:690-695*
4. Della Barbera et al., **"Sovering annuloplasty rings: Experimental pathology in the sheep model."** *Cardiovascular Pathology 14 (2005) 96–103*

INTENDED USE/INDICATIONS

Europe, US, Canada: The Carbomedics Annuloflo Device is intended to support the mitral annulus after the surgical repair. The Carbomedics Annuloflex Device is intended to support the mitral or the tricuspid annulus after the surgical repair. The Carbomedics Annuloflo is indicated for acquired or congenital mitral valve insufficiency characterized by the dilatation or deformation of the native annulus, or as a replacement for a previously implanted annuloplasty ring. The Carbomedics Annuloflex is indicated for acquired or congenital mitral and tricuspid valves insufficiency, characterized by the dilatation or deformation of the native annulus both organic and functional, or as a replacement for a previously implanted annuloplasty ring.

Australia: The Carbomedics Annuloplasty Rings are indicated as reinforcement for repair of the human cardiac mitral valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The Carbomedics Annuloflex Annuloplasty Ring, is also indicated as reinforcement for repair of the human cardiac tricuspid valve damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring.

KEY CONTRAINDICATIONS

The annuloplasty devices are contraindicated for the following: severe organic lesions with retracted chordæ; congenital malformations with lack of valvular tissue; evolving bacterial endocarditis; extensive calcification, which upon removal, does not result in pliable leaflets.

KEY WARNINGS

For single patient use only. Do not attempt to clean, resterilize, or reuse the prosthesis. Do not sterilize the annuloplasty ring or accessory instrumentation by Ethylene Oxide (EtO) or radiation methods. Use only appropriate accessories supplied by Corcym sales organization. For Annuloflo, do not deform or alter the configuration of the annuloplasty ring: this can damage the ring; if the ring is not properly sized for the annulus, select the appropriate ring size.

TOP POTENTIAL SIDE EFFECTS

Adverse events potentially associated with the use of mechanical prosthetic annuloplasty rings include: death; reoperation and explant; residual or recurrent regurgitation; stenosis; thromboembolism; haemolysis; A-V block; low cardiac output; right heart failure; failure or degeneration of the patient's natural valvular apparatus due to progression of disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures; suture obliteration of the circumflex coronary artery; complications related to prolonged bypass, aortic cross-clamping, and inadequate myocardial protection; partial dislodgment of the ring from its site of attachment; malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components; tearing of the cloth covering with the use of cutting needles or serrated forceps; bleeding diatheses related to the use of anticoagulant therapy; systolic anterior motion and left ventricular outflow tract obstruction whenever a large anterior and/or posterior leaflet is present; prosthesis thrombosis; infection.

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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WE TAKE LIFE TO HEART

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