

## Valve Repair vs. Valve Replacement

Valve repair has become the recognized standard for the surgical treatment of mitral valve insufficiency due to its superior patient benefits in comparison to valve replacement.<sup>1</sup> With the development of advanced surgical techniques and the introduction of ring annuloplasty devices, use of mitral valve repair has increased to 65% of surgical procedures on the mitral valve in Germany.<sup>2</sup> Surgeon interest in aortic valve repair has grown considerably in the last few years. Multiple authors have demonstrated that aortic valve repair also has the potential to provide clinical outcomes superior to valve replacement for patients suffering from aortic insufficiency.<sup>3-6</sup> However, because of the complexity of current aortic valve repair techniques and the lack of enabling medical device technologies, valve repair currently represents less than 3% of open aortic valve procedures in Germany.<sup>2</sup>

## HAART™ 300 Aortic Annuloplasty Device

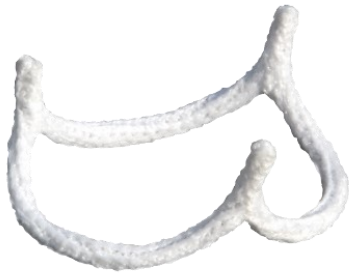
### *Simplifying and Standardizing Aortic Valve Repair*

The HAART 300 Aortic Annuloplasty Device was designed to simplify and standardize aortic valve repair by providing a method for stable, three-dimensional annuloplasty of the aortic valve annulus. The HAART 300 Aortic Annuloplasty Device is implanted through a simple, repeatable surgical technique to:

**Resize** the aortic valve annulus to reduce dilatation

**Reshape** the valve to restore normal elliptical coaptation geometry

**Stabilize** the annulus to prevent recurrent dilatation



*HAART 300 Aortic Annuloplasty Device*

Stable valve annuloplasty is widely recognized as the foundation of all successful valve repair procedures and the HAART 300 Aortic Annuloplasty Device is the first three-dimensional, internal annuloplasty device designed for the aortic valve.

## Why Adopt the HAART 300 Aortic Annuloplasty Device?

### A Better Surgical Option for Valve-Sparing Root Aneurysm Repair

BioStable's Root Restoration procedure is the combination of the Yacoub remodeling root procedure and stable valve annuloplasty using the HAART 300 Aortic Annuloplasty Device. Root Restoration avoids the deep root resection and complicated valve reimplantation required for the David operation.

#### Root Restoration vs. Re-implantation (David)

- Shorter aortic cross clamp times
- Fewer bleeding complications associated with root dissection
- Rigid, three dimensional annuloplasty



*Root Restoration for Aortic Root Aneurysm*

## A Better Surgical Option for Patients

The patient benefits of valve repair over valve replacement are well established from the mitral and tricuspid valve repair experience. By simplifying and standardizing aortic valve repair, the HAART Aortic Annuloplasty Device allows surgeons to offer the benefits of valve repair to patients suffering from aortic valve insufficiency.

### The benefits of valve repair include

- Low operative mortality
- Lower risk of valve related complications
- No need for long-term anticoagulation therapy
- Improved long-term survival<sup>7</sup>

### HAART 300 Aortic Annuloplasty Devices

Description	Catalog Number
HAART 300 Aortic Annuloplasty Device, Size 19mm	300-19
HAART 300 Aortic Annuloplasty Device, Size 21mm	300-21
HAART 300 Aortic Annuloplasty Device, Size 23mm	300-23
HAART 300 Aortic Annuloplasty Device, Size 25mm	300-25

## A Novel New Technology to Distinguish Aortic Valve Repair Centers of Excellence

Aortic valve repair is a topic of great interest to many heart surgery centers because of the clear clinical benefits for patients and the lack of good surgical repair options for patient with aortic insufficiency. The HAART 300 Aortic Annuloplasty Device was designed to enable heart centers to offer the benefits of valve repair to more patients in their community. To support the successful adoption of the HAART 300 Aortic Annuloplasty Device, BioStable Science & Engineering will provide in-depth product training and surgeon proctoring of initial clinical cases. The resource requirements to implement the training programs will limit the number of centers that can be trained.

### HAART 301 Instruments

Description	Catalog Number
HAART 301 Instrument Set	301-00
HAART Handle	301-01
HAART Gage Sphere	301-02
HAART 301 Instrument Case	301-03
HAART 301 Sizer, Size 19mm	301-19
HAART 301 Sizer, Size 21mm	301-21
HAART 301 Sizer, Size 23mm	301-23
HAART 301 Sizer, Size 25mm	301-25

### Indications for Use:

The HAART 300 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients undergoing valve repair for aortic valve disease. It is designed to return aortic annular geometry toward normal for a given leaflet size and to assist in producing adequate leaflet competence by recovering normal coaptation geometry and area. The Device is intended for use in patients with tri-leaflet valve morphology.

1. Nishimura, R.A., et al., 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg, 2014. 148(1): p. e1-e132.
2. Beckmann, A., et al., Cardiac Surgery in Germany during 2014: A Report on Behalf of the German Society for Thoracic and Cardiovascular Surgery. Thorac Cardiovasc Surg, 2015. 63(4): p. 258-69.
3. Badiu, C.C., et al., Aortic root replacement: comparison of clinical outcome between different surgical techniques. Eur J Cardiothorac Surg, 2014. 46(4): p. 685-92; discussion 692.
4. de Meester, C., et al., Valve repair improves the outcome of surgery for chronic severe aortic regurgitation: A propensity score analysis. J Thorac Cardiovasc Surg, 2014. 148(5): p. 1913-20.
5. Lamana Fde, A., et al., Surgery of the aortic root: should we go for the valve-sparing root reconstruction or the composite graft-valve replacement is still the first choice of treatment for these patients? Rev Bras Cir Cardiovasc, 2015. 30(3): p. 343-52.
6. Bassano, C., et al., Mid-term follow-up of aortic root remodelling compared to Bentall operation. Eur J Cardiothorac Surg, 2001. 19(5): p. 601-5.
7. Arabkhani, B., et al., Reported Outcome After Valve-Sparing Aortic Root Replacement for Aortic Root Aneurysm: A Systematic Review and Meta-Analysis. Ann Thorac Surg, 2015.



Not available for sale in the United States