

IMPLANTATION TECHNIQUE QUICK REFERENCE GUIDE

The **HAART 300 Aortic Annuloplasty Device** is a three dimensional annuloplasty device designed to be implanted intra-annularly in the aortic valve in patients with tri-leaflet valve morphology.

This document is a quick reference for the implantation procedure for the **HAART 300 Aortic Annuloplasty Device**.

It will guide you through the implantation technique steps:

IMPLANTATION

- Post Sutures
- Device Insertion and Holder Removal
- Looping Sutures
- Suture Management

PREPARATION

- Sizing

RECONSTRUCTION

- Assessment and Repair

CATALOG NUMBERS

HAART 300 Aortic Annuloplasty Device

Description	US Catalog No.
HAART 300 Aortic Annuloplasty Device, Size 19mm	300-19US
HAART 300 Aortic Annuloplasty Device, Size 21mm	300-21US
HAART 300 Aortic Annuloplasty Device, Size 23mm	300-23US
HAART 300 Aortic Annuloplasty Device, Size 25mm	300-25US

12 Pledgets are included with each Device

HAART 300 Pledgets (if extra are needed)

Description	US Catalog No.
Pledgets (6 packets of 6 pledgets)	100-06US

HAART 300 Instruments

Description	US Catalog No.
HAART 301 Instrument Set	301-00US
Each 301 Instrument Set contains	
HAART Handle	
HAART Gage Sphere	
HAART 301 Instrument Case	
HAART 301 Sizer, Size 19mm	
HAART 301 Sizer, Size 21mm	
HAART 301 Sizer, Size 23mm	
HAART 301 Sizer, Size 25mm	



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HAART 300™ AORTIC ANNULOPLASTY DEVICE

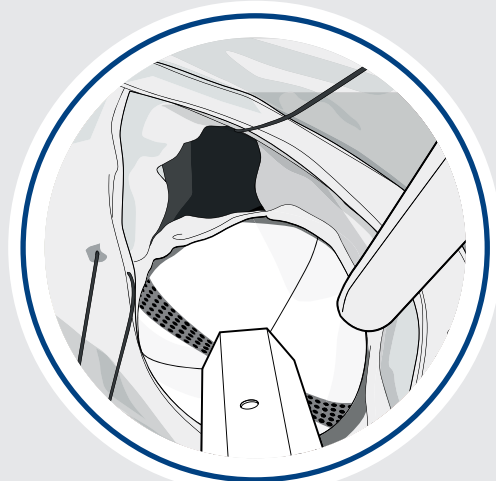


Implantation Technique
Quick Reference Guide

Aortic Valve Repair
Technologies

PREPARATION

1 Sizing



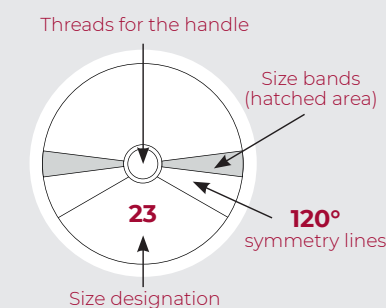
Sizing of Nonfused Leaflet Free-edge Length

- Place sizer in the sinus behind the leaflet
- Ensure leaflet free-edge lays smoothly across the sizer
- With the correct sizer, both commissures should fall within size bands

Size all 3 leaflets

- Use the smaller size when there is a one size difference among the 3 leaflets
- Use a middle size or consider leaflet replacement with 3 different sizes

ILLUSTRATION OF SIZER ATTRIBUTES



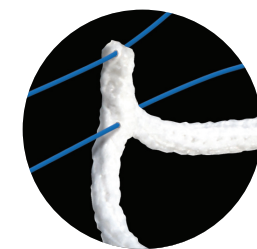
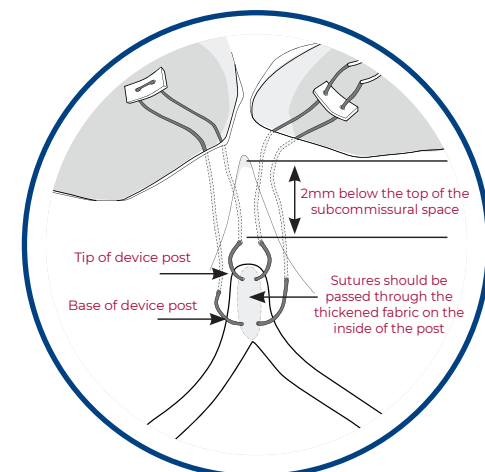
IMPLANTATION

2 Post Sutures



Suturing Technique

- Post sutures establish the subvalvular device positioning
- Attach the HAART device to the handle and position it above the valve
- Orient the device so that each post is aligned with its corresponding commissure
- Suture the Left / Noncoronary post first
- Using 4.0 polypropylene, create a horizontal mattress suture in a cabrol-like configuration, passing through the inside of the post at the tip and at the base
- Pass sutures deeply through the annulus
- Place pledgets on both sides of the commissure



Sutures should be passed through the thickened fabric on the inside of the post.

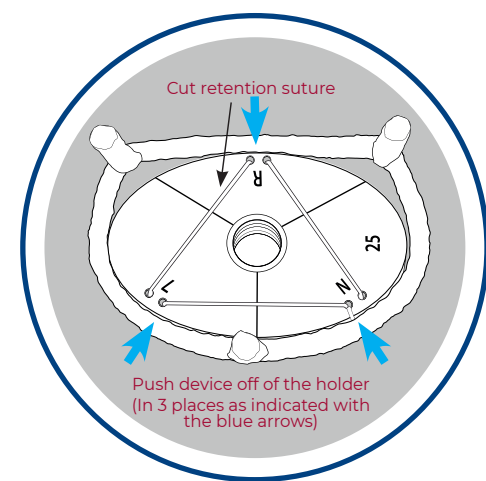
Suture Placement

- Subvalvular suture position should locate the post tip 2mm below the top of the subcommissural space
- Supravulvular suture position should position the pledgets within the aorta and away from the leaflets

Tips for suture placement

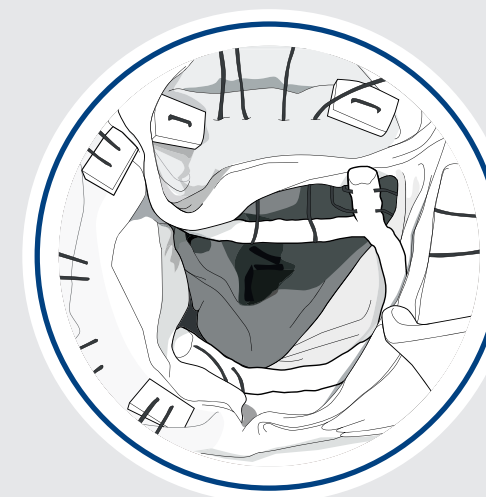
- Make shallow passes of the needle through the inside of the post. The needle should pass just under the surface of the fabric to avoid touching the titanium frame of the device
- Ensure the top suture pass is close to the post tip and the bottom suture pass is close to the base
- Pass needles through the pledgets near the edges

3 Device Insertion and Holder Removal



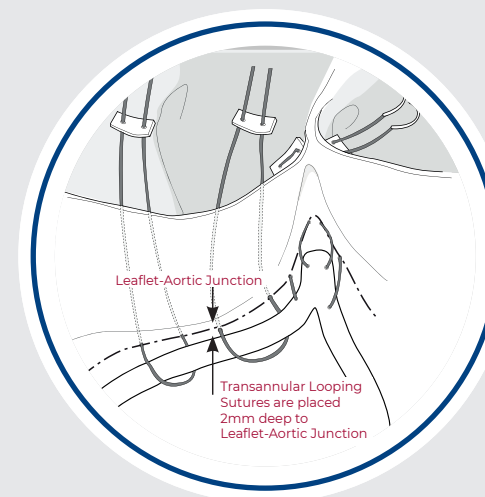
- Carefully insert the device below the valve
- DO NOT remove the handle
- Cut the retention suture
- While holding the handle steady, push the Device off the Holder at the 3 contact points
- Carefully extract the detached holder from the valve

4 Looping Sutures



Suturing Technique

- Using 4.0 polypropylene sutures, place 2 looping sutures around each belly section
- DO NOT pass sutures through the fabric
- Pass the needles deeply through the annulus
- Place a pledget on each suture above the valve



Suture Placement

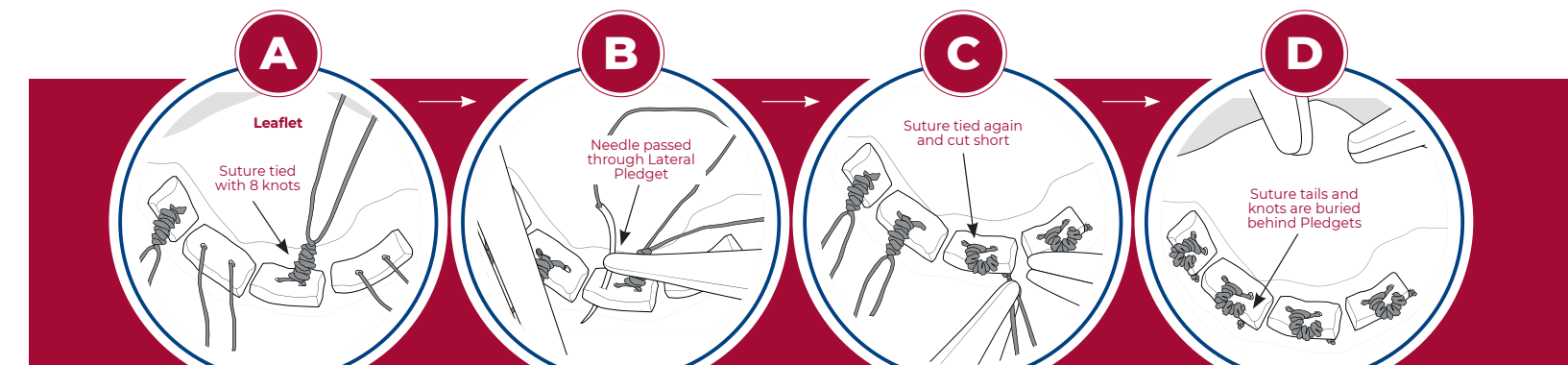
- Space sutures equally between the commissures
- Subvalvular sutures should exit the annulus 2mm deep to the leaflet-aortic junction
- Supravulvular sutures should position the pledgets within the aorta and away from the leaflets

Tips for looping sutures

- Pull the device away from the location being sutured to create more exposure
- Pass needles through the pledgets near the edges

5 Suture Lateralization

The figures below illustrate the Lateral Suture Fixation Technique:



Tie all sutures with 8 tight knots

Pass both needles through lateral edge of the pledget

Tie suture with 6 additional tight knots and cut short

The resulting suture tails and knots are buried behind the pledget and away from the leaflet

Tips for suture management

- Annular reduction results in significant suture tension. **TIE KNOTS TIGHTLY.**
- Ensure knot towers are pointed away from the leaflets. A 6.0 polypropylene suture can be used to stitch the knot tower to the annulus if required

RECONSTRUCTION

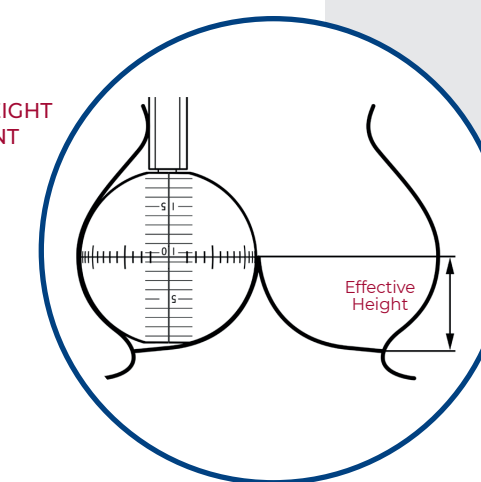
Assessment and Repair

- Assess leaflet coaptation and effective height to assure valve competence
- Effective height of 8-10 mm should be restored
- Leaflet repair and reconstruction should be performed as required
- Symmetric, perinodular plication with 7.0 polypropylene suture is recommended for increasing leaflet effective height

Effective Height Assessment Using the HAART Gage Sphere

- Attach the Gage Sphere to the handle and insert into the sinus behind the leaflet
- Gently push the Gage Sphere to the bottom of the sinus
- Ensure the leaflet free-edge is at the level of the Gage Sphere equator

DIAGRAM OF EFFECTIVE HEIGHT MEASUREMENT



Note:
Reference the HAART 300 Aortic Annuloplasty Device IFU for complete device information and procedure instructions.