# IMPLANTATION TECHNIQUE QUICK REFERENCE GUIDE

The **HAART 200 Aortic Annuloplasty Device** has been designed specifically for use during the repair of bicuspid aortic valves.

The **HAART 200 Aortic Annuloplasty Device** is designed to reduce annular dilatation while reorienting the two leaflets into a semicircular configuration.

This document is a quick reference for the implantation procedure for the **HAART 200 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 200** Aortic Annuloplasty Device

| Description | US Catalog No. |
|---|---|
| HAART 200 Aortic Annuloplasty Device, **Size 19mm** | 200-19US |
| HAART 200 Aortic Annuloplasty Device, **Size 21mm** | 200-21US |
| HAART 200 Aortic Annuloplasty Device, **Size 23mm** | 200-23US |
| HAART 200 Aortic Annuloplasty Device, **Size 25mm** | 200-25US |

12 Pledgets are included with each Device

### **HAART 200** Pledgets (if extra are needed)

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

### **HAART 200** 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 200™

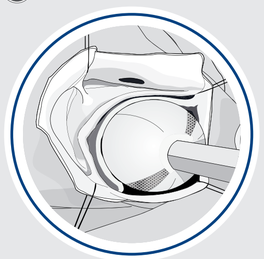
AORTIC ANNULOPLASTY DEVICE

## Implantation Technique Quick Reference Guide

Aortic Valve Repair Technologies

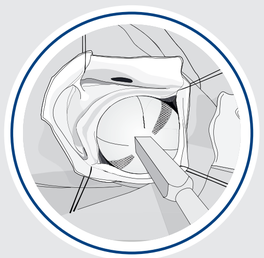
# PREPARATION

## 1 Sizing



### Sizing of Nonfused Leaflet Free-edge Length

- Place sizer in the sinus behind the non fused leaflet
- Ensure leaflet free-edge lays smoothly across the sizer
- With the correct sizer, both commissures should fall within the size bands
- Device size is indicated on the surface of the sizer



### Sizing Confirmation

- Measure the distance between the commissures with the selected Sizer
- Device choice should not cause excessive reduction of intercommisural distance
- There should be 1-2 mm gap on each side. If there is no gap, the next smaller Device size should be selected

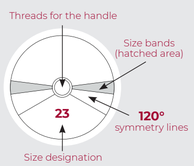
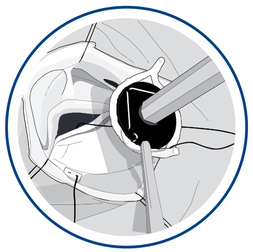



ILLUSTRATION OF SIZER ATTRIBUTES

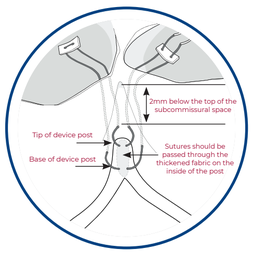
# IMPLANTATION

## 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
- Create a horizontal mattress suture in a cabrollike onfiguration, 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 postv.

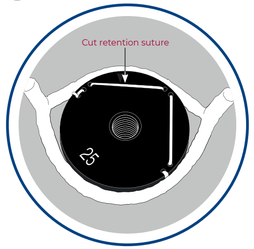
### Suture Placement

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

### Tips for suture placement

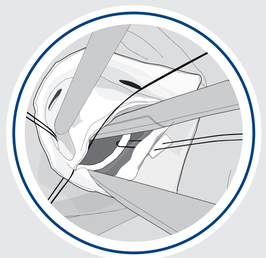
- Make shallow passes of the needle through the inside of the post. The needle should pass just under the surface of the fabric to avoid touching the titanium frame of the device
- Ensure the top suture pass is close to the post tip and the bottom suture pass is close to the base
- Pass needles through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

## 3 Device Insertion and Holder Removal



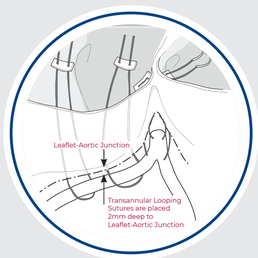

- Carefully insert the device below the valve
- DO NOT remove the handle
- Cut the retention suture at one location
- While holding the handle steady, push the device off the Holder
- Twisting the Holder within the device can help loosen the retention suture
- Carefully remove the detached Holder from the Device

## 4 Looping Sutures



### Suturing Technique

- Place 7 looping sutures around the belly sections of the device
- 3 looping sutures in the annulus of the nonfused leaflet
- 4 looping sutures in the annulus of the fused leaflet
- 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

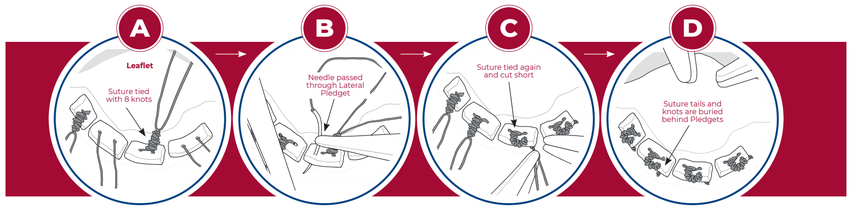
- Space sutures equally between the commissures
- Subvalvular sutures should exit the annulus 2mm deep to the leaflet-aortic junction
- Supravalvular sutures should position the pledgets within the aorta and away from the leaflets

### 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

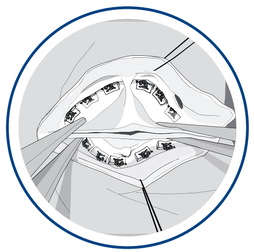
Tie suture with 6 additional tight knots and cut short

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

## 6 Final Suture Configuration



- Confirm that all sutures have been secured with the lateral suture fixation technique
- Proceed with assesment of coaptation and repair of the leaflets

# RECONSTRUCTION

### Assessment and Repair

- First establish 8-10mm effective height of the non-fused leaflet
- Use the non-fused leaflet as a reference for establishing leaflet free-edge length and effective height of the fused cusp

**Note**:
Reference the HAART 200 Aortic Annuloplasty Device IFU for complete device information and procedure instructions.