# HAART 200/HAART 300 – Important Safety Information

## INTENDED USE/INDICATIONS

### HAART 200

EUROPE:
The HAART 200 Aortic Annuloplasty Device is indicated in adult patients undergoing bicuspid aortic valve repair for aortic insufficiency or concomitant to repair of an aortic aneurysm.
US:
The HAART 200 Aortic Annuloplasty Device is indicated in patients undergoing bicuspid aortic valve repair for aortic insufficiency (from moderate to severe) or concomitant to repair of an aortic aneurysm.

### HAART 300

EUROPE:
The HAART 300 Aortic Annuloplasty Device is indicated in adult patients undergoing trileaflet aortic valve repair for aortic insufficiency or concomitant to repair of an aortic aneurysm.
US:
The HAART 300 Aortic Annuloplasty Device is indicated in patients undergoing trileaflet aortic valve repair for aortic insufficiency (from moderate to severe) or concomitant to repair of an aortic aneurysm.

## KEY CONTRAINDICATIONS

Porcelain aorta; evolving bacterial endocarditis; heavily calcified valves.

## KEY WARNINGS

Do not undersized: this could result in valve stenosis or device dehiscence. Do not oversized: this could result in valve regurgitation. Do not use the Holder as a sizing tool, use only the Sizers included in the Instrument Set. Do not attempt to deform or reshape the annuloplasty Device. Direct the sutures tails down and away from the leaflets to prevent any damage.

## TOP POTENTIAL SIDE EFFECTS

Potential adverse events associated with heart valve repair with a device and the related surgical procedure include: abrasion of the natural valve, aortic insufficiency, bleeding, endocarditis, leaflet damage, left ventricular outflow tract obstruction, device dehiscence, stenosis, thromboembolism.

## 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.