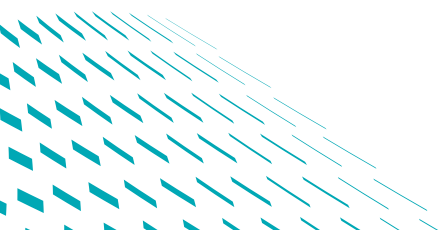


LivaNova

Health innovation that matters

CROWN PRT™

Inservice implantation guide



CROWN PRT™

DEVICE DESCRIPTION

- The Crown PRT aortic pericardial heart valve consists of a single piece of bovine pericardium that is preserved with glutaraldehyde and sewn onto a polyester covered polymer stent
- A radiopaque, silicone sewing ring is attached to the outer perimeter of the inflow side of the valve
- The valves are sterilized using glutaraldehyde/formaldehyde liquid chemical sterilant and are packaged in a sealed plastic jar containing 4% formaldehyde storage solution
- Crown PRT is available in aortic sizes 19, 21, 23, 25, 27, 29mm

INDICATIONS

- The Crown PRT valve is intended for the replacement of malfunctioning native or prosthetic aortic valves
- The Crown PRT valve is suggested for use in those patients where long-term anticoagulation therapy may be undesirable for a variety of reasons, such as patients living in remote areas, patients with gastrointestinal or other bleeding problems, patients who may be expected to undergo other surgery, elderly patients and others where difficulty may be expected with anticoagulants, for social, or other medical reasons

CROWN PRT™

CONTRAINDICATIONS

- There are no absolute contraindications for the use of the Crown PRT valve
- Clinical experience described in the medical literature suggests that patients in particular conditions (for example who are undergoing chronic haemodialysis, or with parathyroid disease, impaired calcium metabolism, or who are 55 years of age or less) may have an increased tendency toward calcification of valvular bioprosthesis

WARNING AND PRECAUTIONS

- Do not pass any transvalvular diagnostic catheters or transarterial pacing leads through the in situ bioprosthesis
- Extreme care should be exercised when placing sutures. If a valve is damaged, the valve must be explanted and replaced

ANTICOAGULANT AND/OR ANTIPLATELET THERAPY

- Some form of anticoagulant therapy may be beneficial after cardiac valve replacement with a bioprosthesis
- For bioprostheses, consideration should be given to anticoagulation therapy for 30 to 60 days after aortic valve replacement



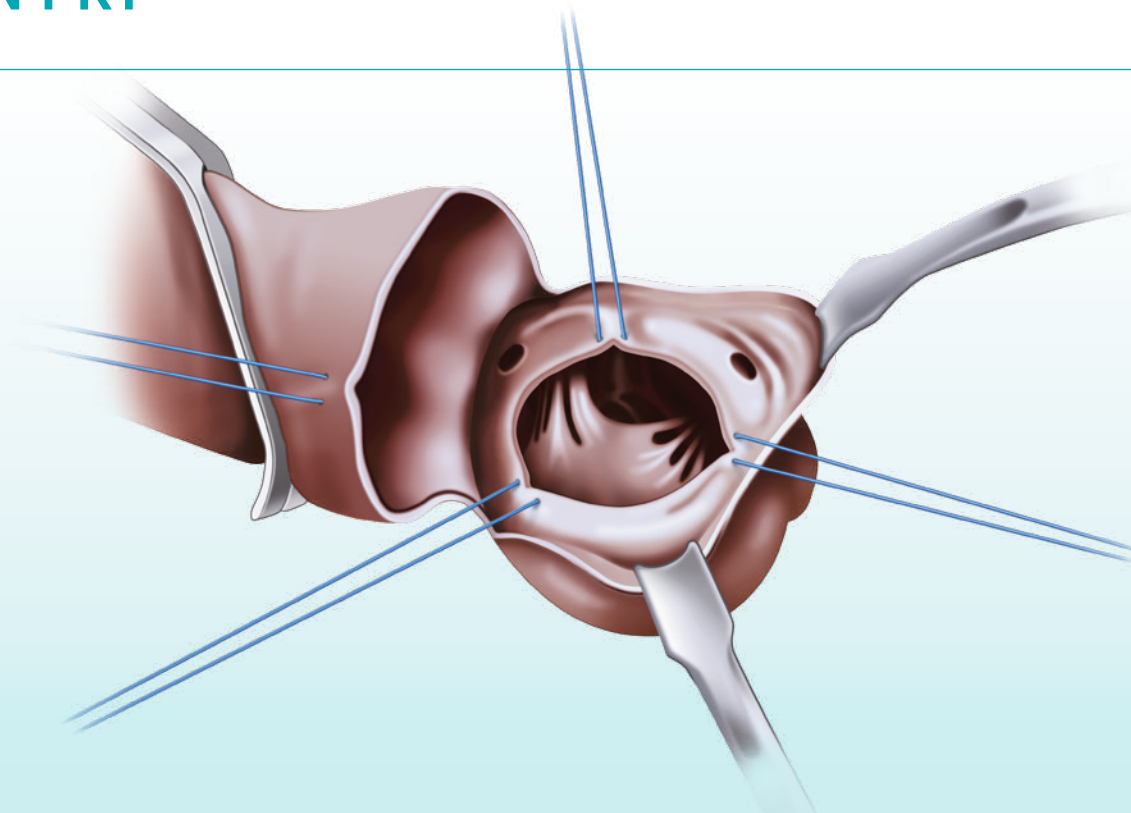
One minute rinse in the first 500ml basin



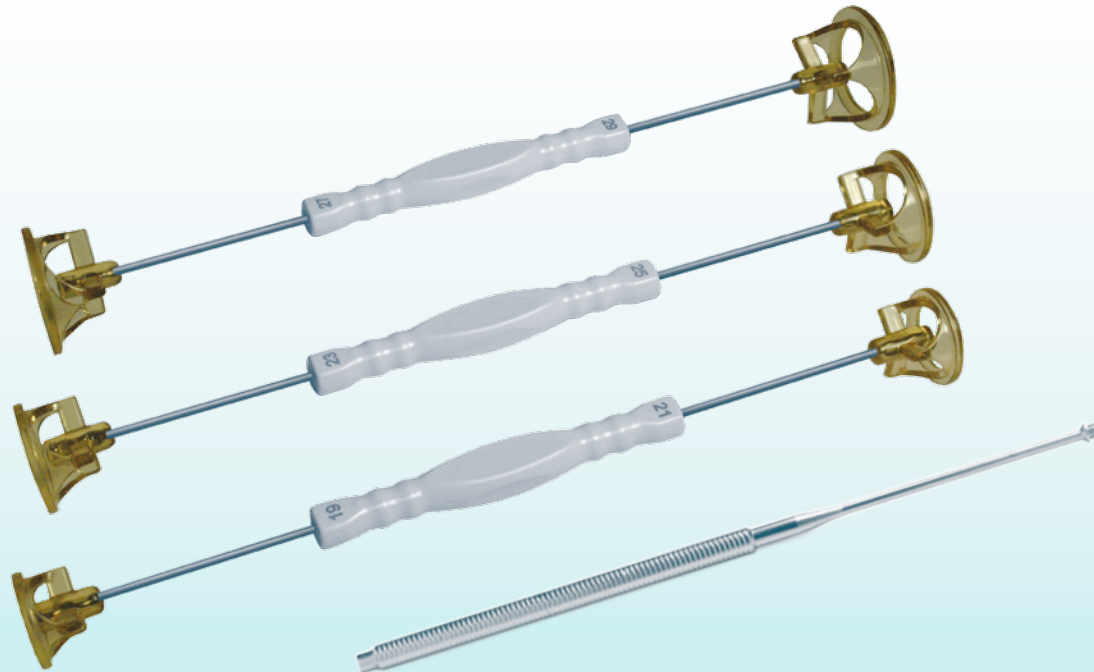
One minute rinse in the second 500ml basin

- Two tall rinse basins are prepared with approx 500ml of saline solution
- The valve is gently agitated for one minute in the first rinse basin

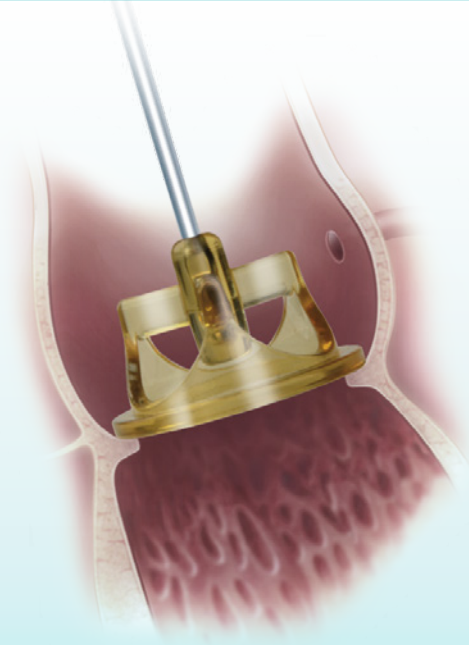
- The one-minute rinse is repeated in the second basin
- Total rinse time of at least 2 minutes



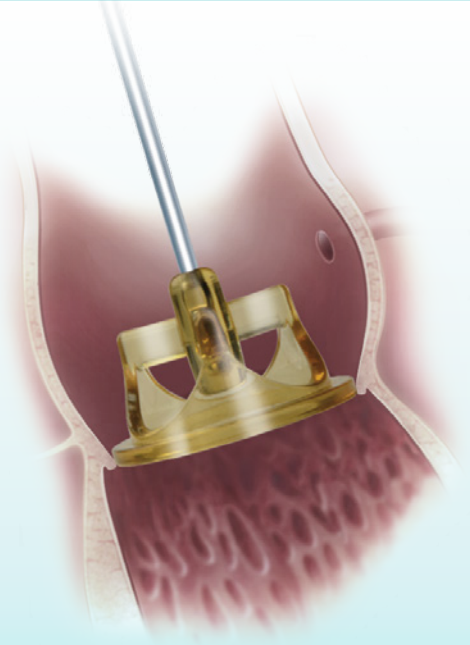
- Place 3 stay sutures through the annulus commissures
- Excise the native valve's leaflets
- Remove all calcium deposits



- Use only the Crown PRT sizers (ICV1353) and handle (AH-11)



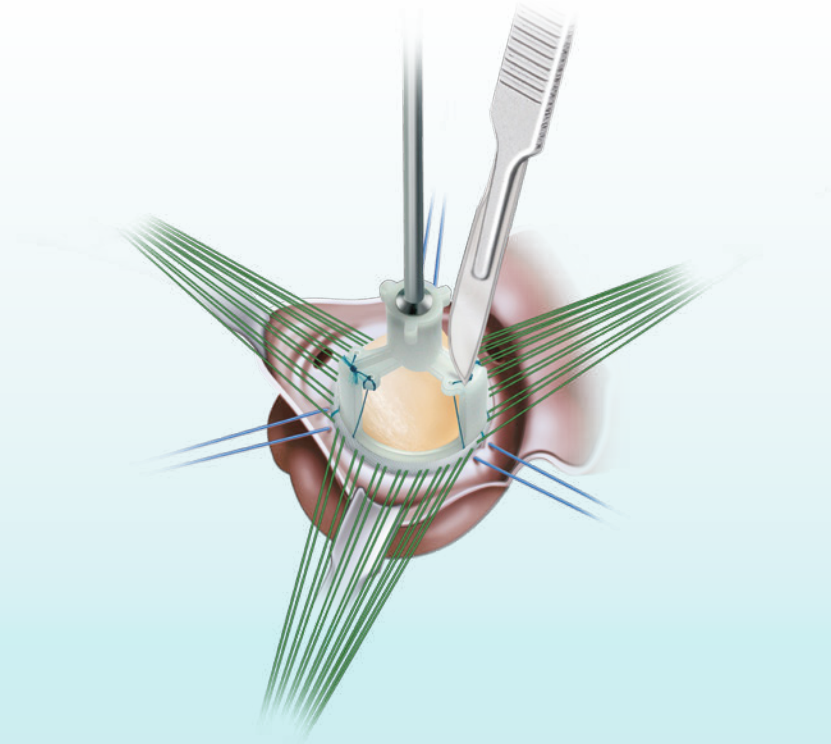
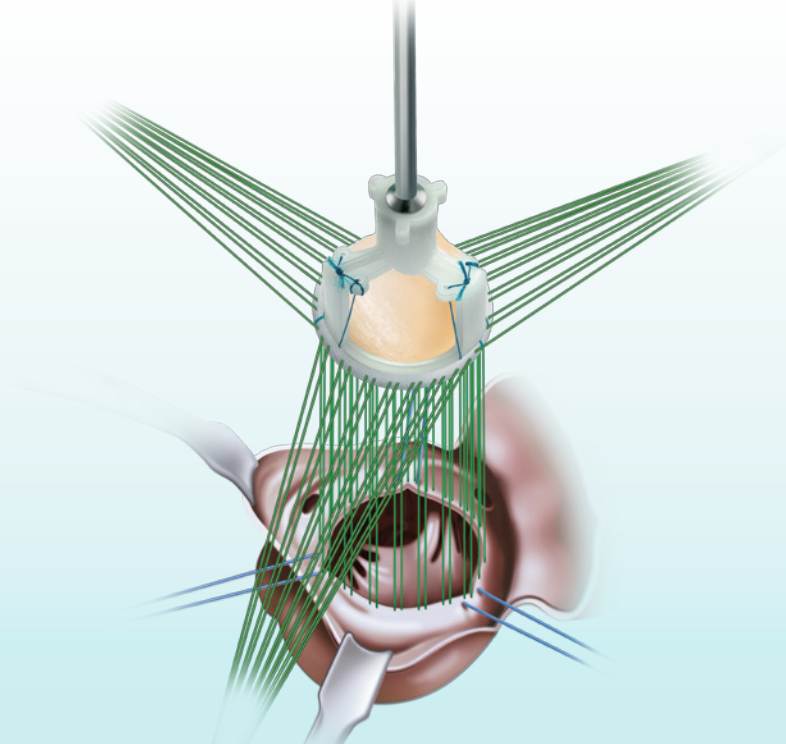
Supra-annular positioning



Intra-annular positioning

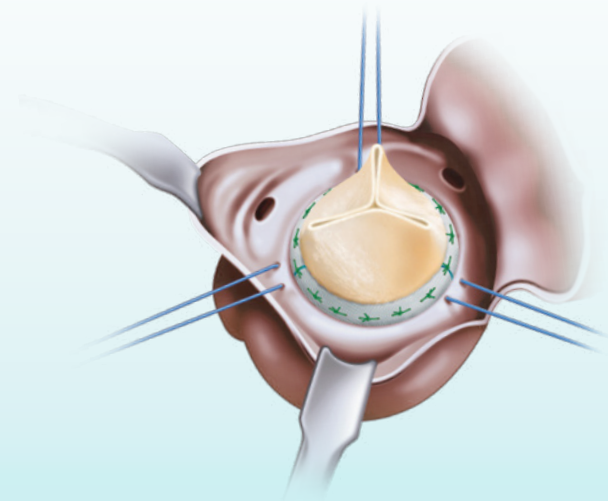
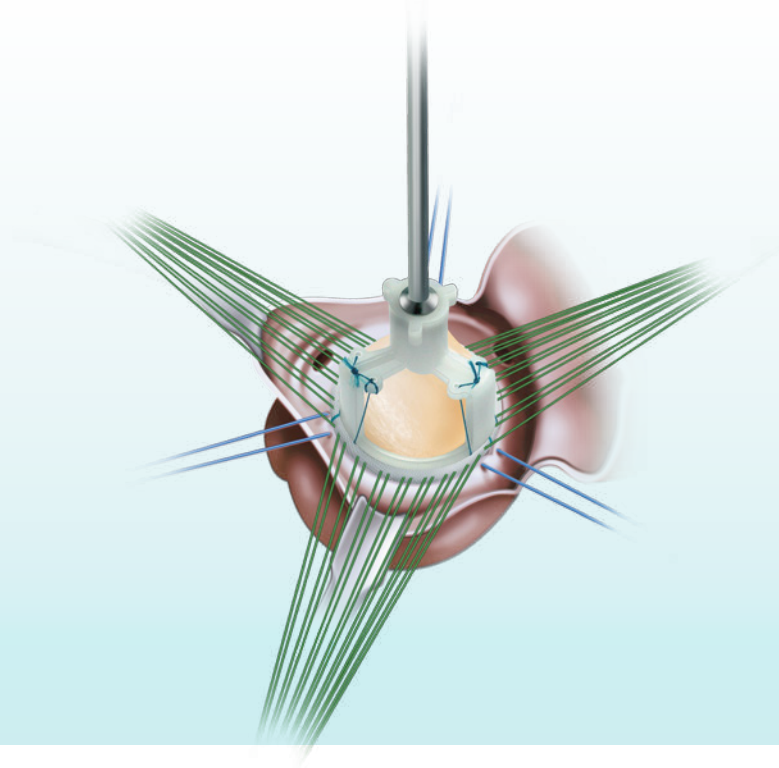
- Position the whole sizer above the annulus
- The valve's replica of the sizer gives an indication of the valve seating
- Choose the valve size which corresponds to the selected sizer. The valve will seat supra-annular

- Insert the whole sizer into the annulus
- The sizer's rim should slip through the annulus without causing distortion
- Choose the valve size which corresponds to the selected sizer. The valve will seat intra-annular



- Place all annular sutures in the sewing cuff
- Lower gently the valve into position

- Remove the valve holder

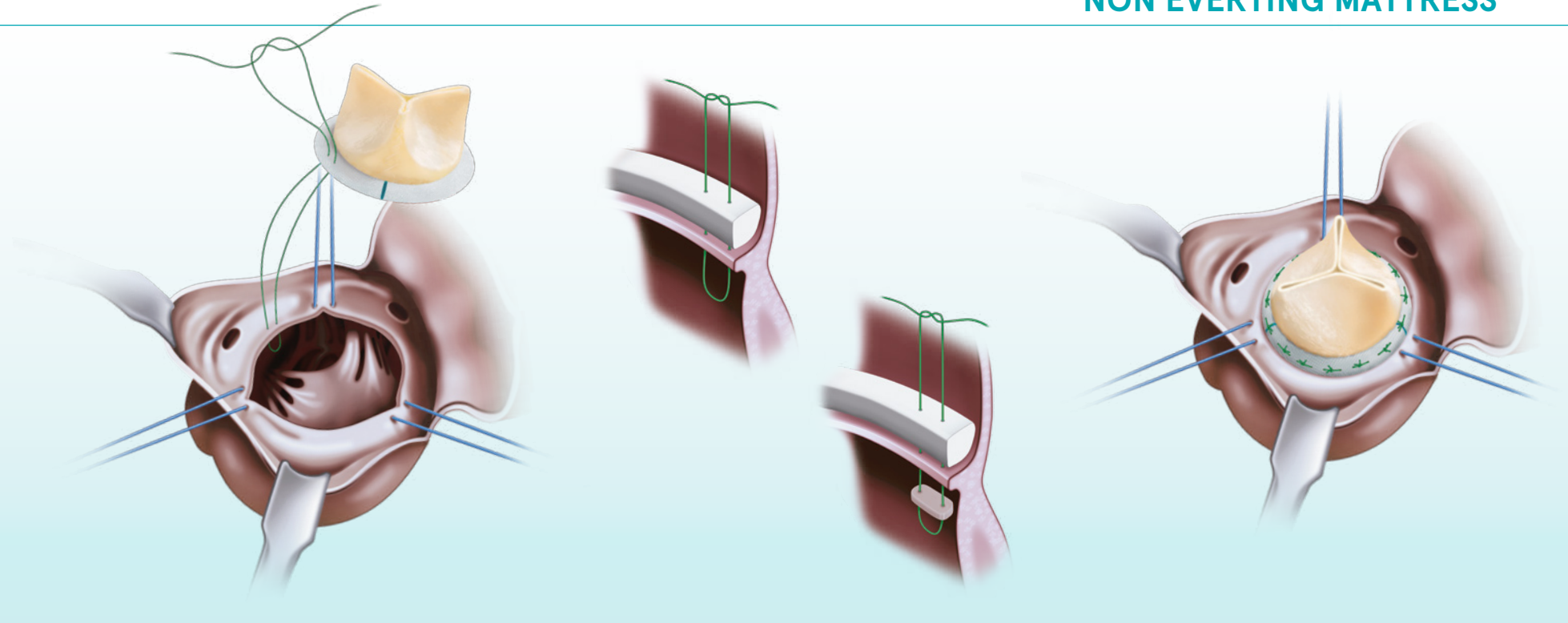


- Check the coaptation of annulus and sewing ring

- Tie the sutures and cut them short

CROWN PRT™

SUTURE TECHNIQUES NON EVERTING MATTRESS

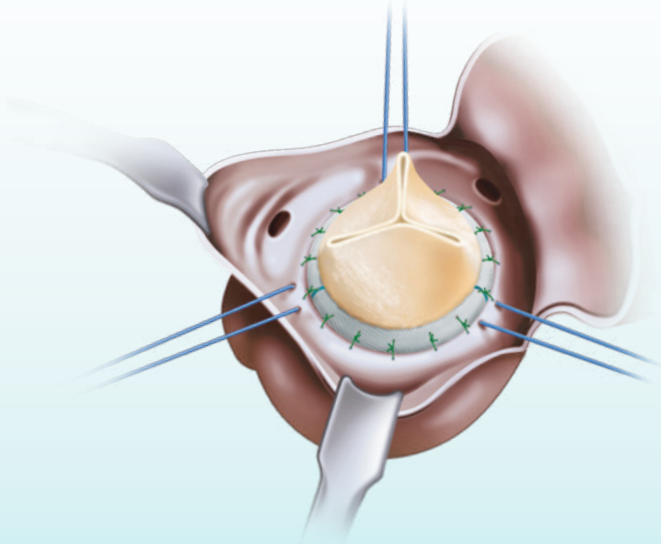
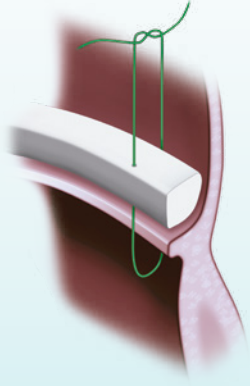
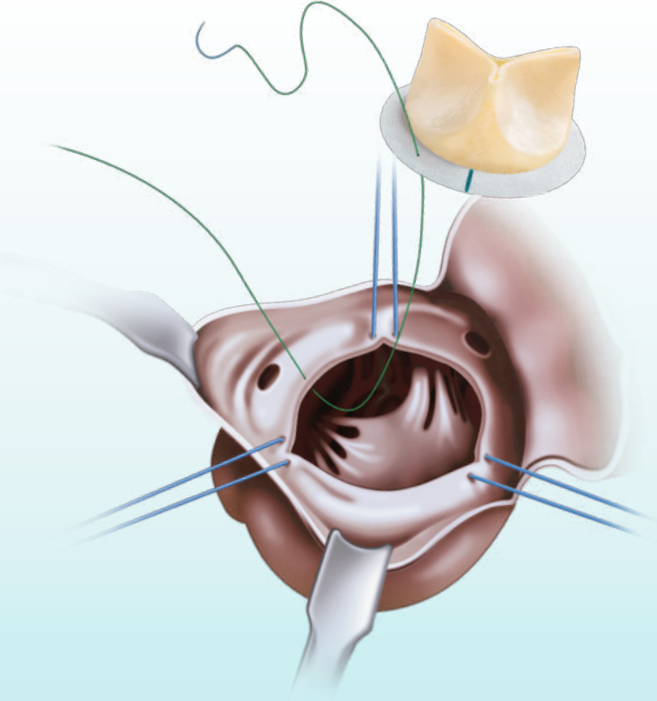


This technique allows the valve to seat completely above the annulus

- With intra-annular pledgets if the annulus is fragile

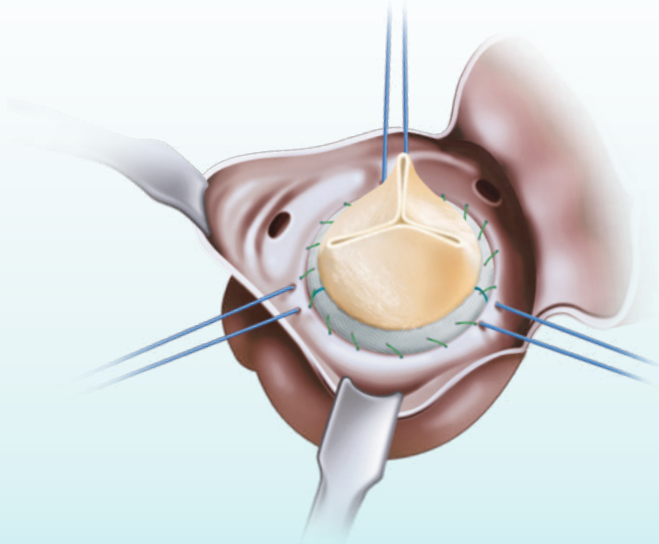
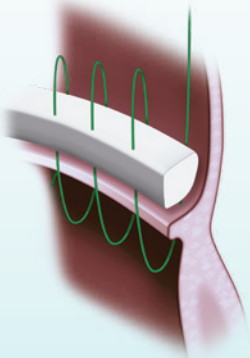
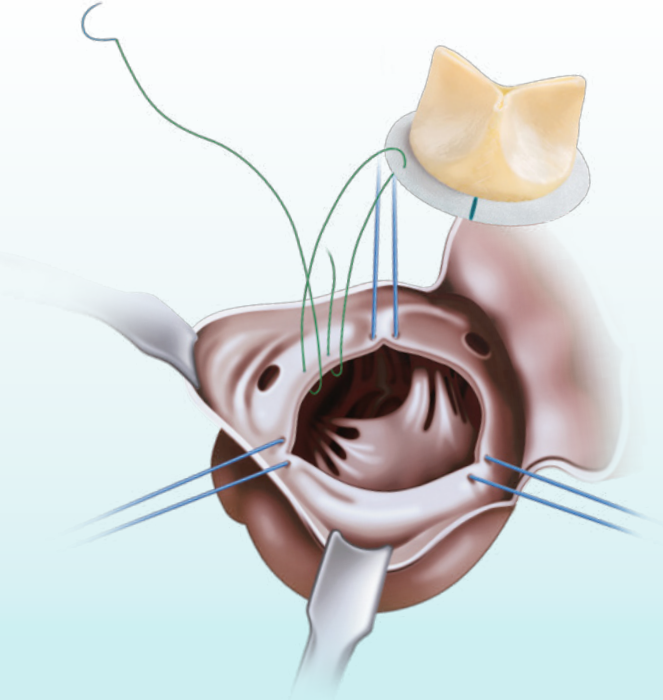
CROWN PRT™

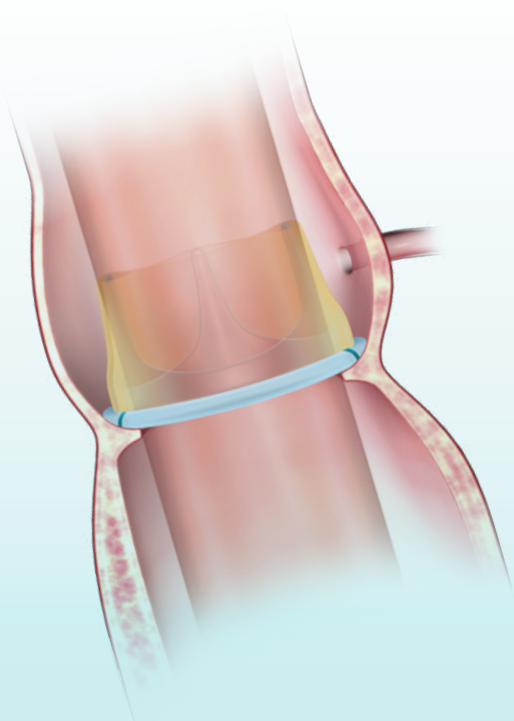
SUTURE TECHNIQUES SIMPLE INTERRUPTED



CROWN PRT™

SUTURE TECHNIQUES CONTINUOUS OR RUNNING



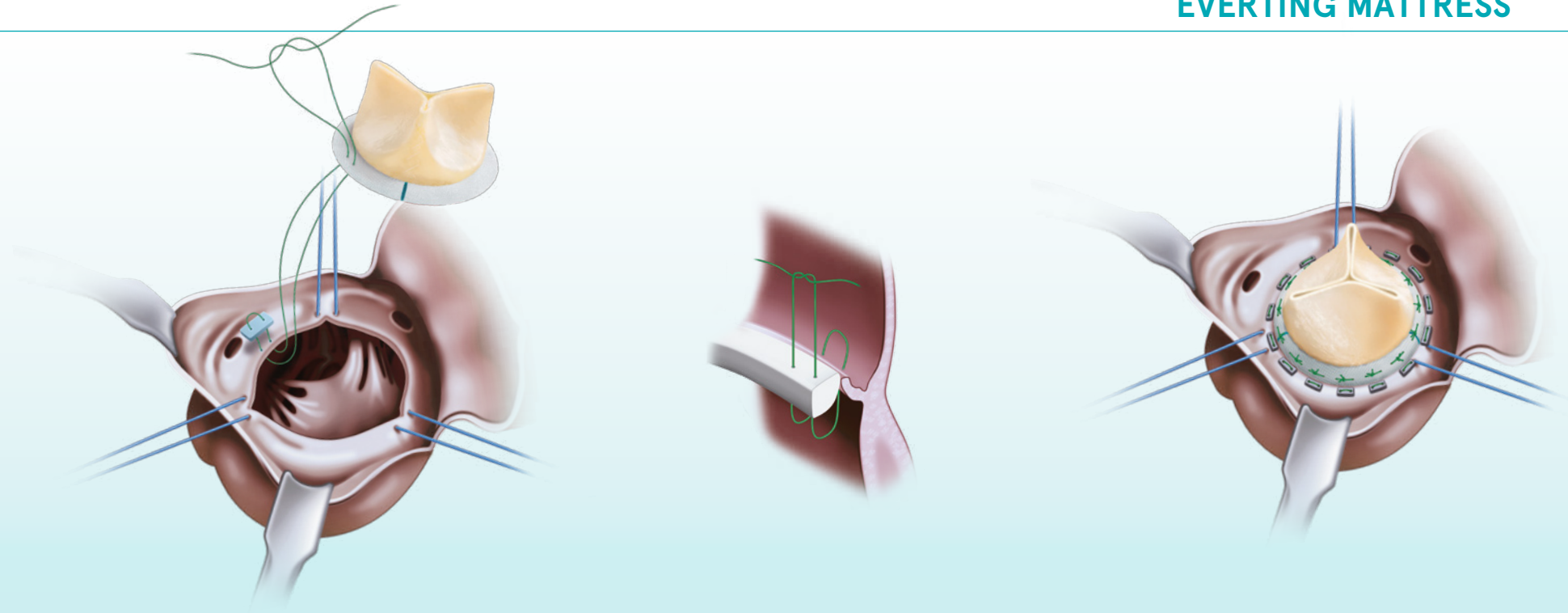


- The Crown PRT valve is a valid solution in the case of low coronary ostia

- When the valve is properly seated the blood flow through the coronary ostia is not compromised thanks to the low stent profile

CROWN PRT™

SUTURE TECHNIQUES EVERTING MATTRESS



This technique can pull the sewing cuff into the annulus

- With supra-annular pledgets if the annulus is fragile

CROWN PRT™

DEVICE IMPLANTATION

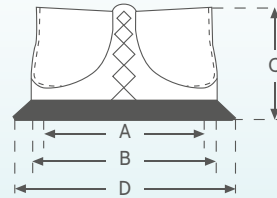
- Prior to suturing the valve into the annulus, identify the direction of flow through the valve to ensure proper orientation and subsequent function
- Orient the valve so that the coronary ostia are not compromised
- Do not handle the tissue portion of the valve with instruments
- During implantation, frequently irrigate the valve tissue with sterile, physiologic saline to prevent drying
- OR personnel should hold the valve handle during the entire suturing of the sewing cuff
- Do not use cutting edge suture needles as these will damage the valve sewing ring
- If interrupted sutures are used, care must be exercised to cut the sutures close to the knots and ensure that the suture tails do not come into contact with the leaflet tissue
- Extreme care should be exercised when placing sutures through the sewing ring to avoid possible laceration of the leaflet tissue
- Looping or catching suture around the commissural posts will interfere with the valve's clinical performance
- We recommend the non-everting or figure of eight suture techniques to maximize a supra-annular placement

CROWN PRT™

PRODUCT SPECIFICATIONS




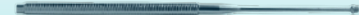
Product ordering information

Size	A Inside Diameter (mm)	B Outside Diameter (mm)	C Overall Height (mm)	D Sewing Ring Width (mm)
CNA19	15.4	18.6	11	21
CNA21	17.3	20.7	13	23
CNA23	20.0	22.7	14	26
CNA25	21.0	25.1	15	29
CNA27	22.9	27.3	16	31
CNA29	24.7	29.5	16	33



A = Inside Diameter
 B = Outside Diameter
 C = Overall Height
 D = Sewing Ring Width

Accessories ordering information

Cat. #	Description
ICV1353	Bendable dual-ended sizers
	19-21mm 
	23-25mm 
	27-29mm 
AH-11	Handle 

LivaNova

Health innovation that matters

Manufactured by:
LivaNova Canada Corp.
 5005 North Fraser Way
 Burnaby BC V5J5M1 - Canada
 Tel: 1-604-412-5650

Sorin Group Italia Srl
 A wholly-owned subsidiary of LivaNova PLC
 Via Crescentino - 13040 Saluggia (VC) Italy
 Tel: +39 0161 487472 - Fax: +39 0161 487316
 info.cardiacsurgery@livanova.com

www.livanova.com



WARNING: Please always consult the Instructions for Use (IFU) manual which is included in the valve and accessories' packaging.

© 2016 LivaNova all rights reserved.