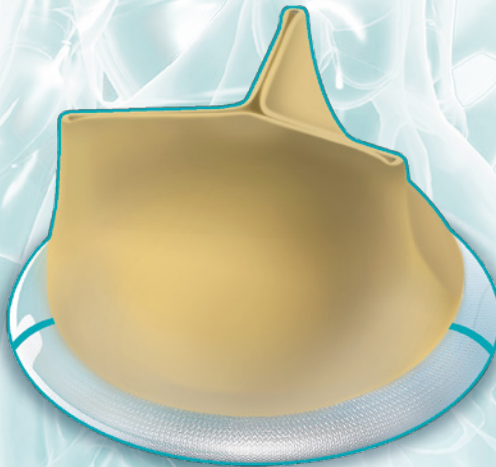


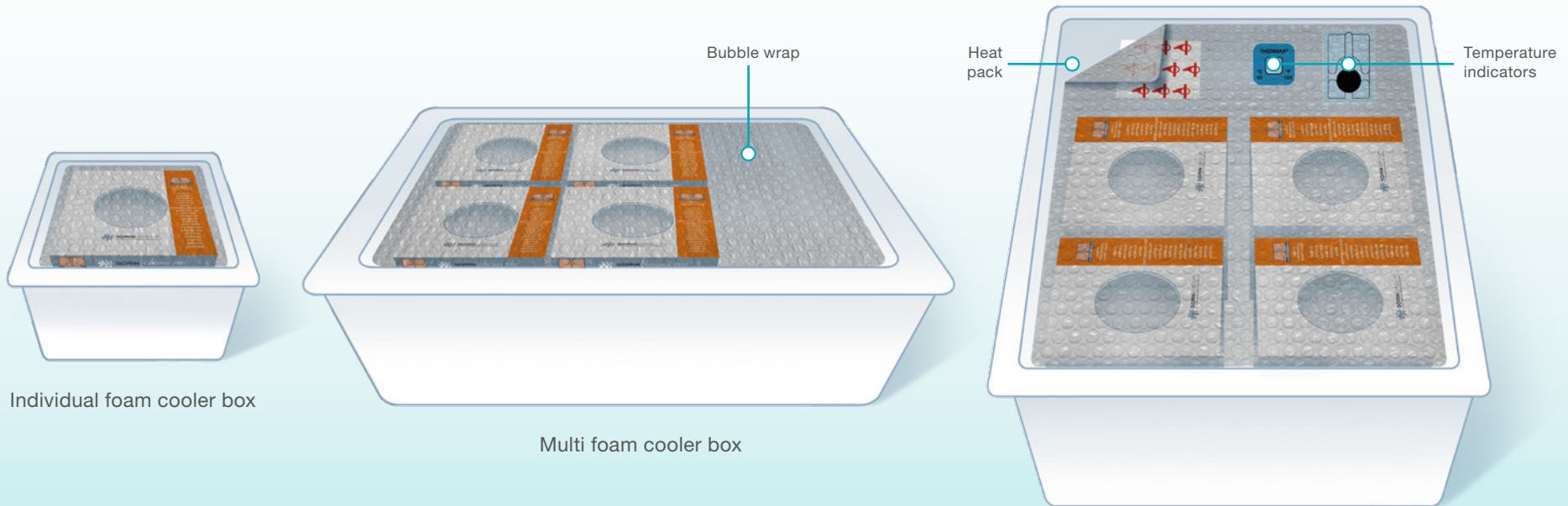
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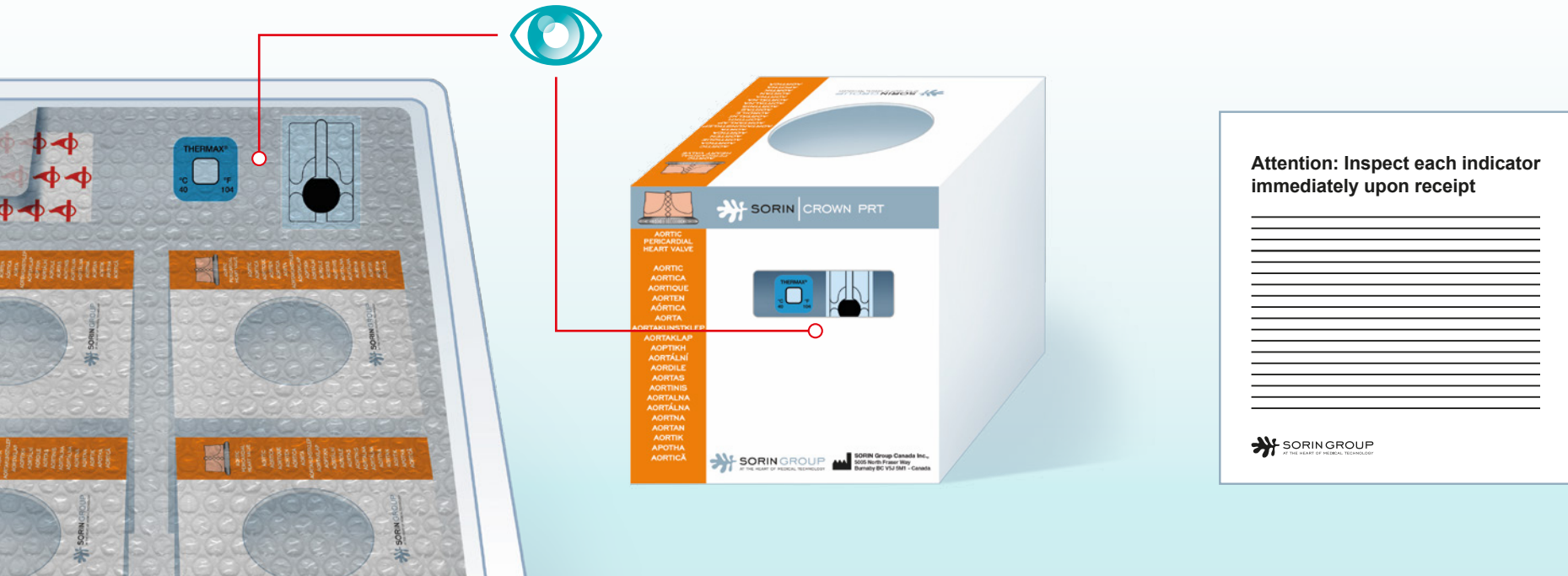
# CROWN PRT™

Inservice nurse guide





- Crown PRT valves will be shipped in foam cooler boxes
- Valves will be shipped in either an individual foam cooler box or a multi foam cooler box
- Each cooler box will contain bubble wrap and/or chips, temperature indicators and valve cartons
- During winter periods, a heat pack will be inserted in the cooler box to help maintain the correct temperature range

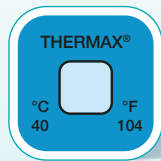


- Upon receipt of a shipment, check the temperature indicators in the cooler box and in each Crown PRT valve carton
- Follow the instructions sheet on how the temperature indicator should be read
- These instructions can be found within the insulated container

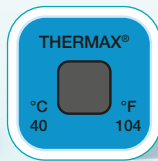


- Each Crown PRT valve is shipped with two temperature indicators:
  - one that monitors cool temperatures
  - one that monitors warm temperatures
- It is imperative that each individual valve's indicators be inspected prior to placing product into your storage location

### High temperature indicators

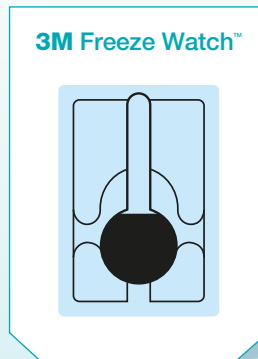


Normal

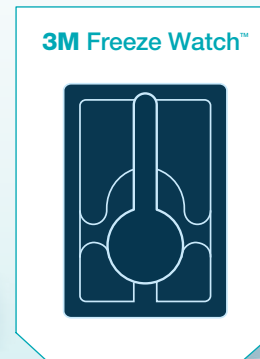


Exposed  
(Activated)

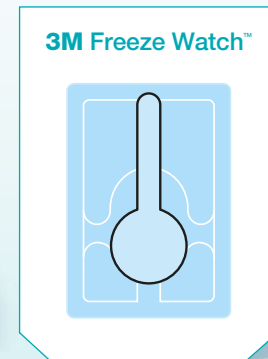
### Low temperature indicators



Normal



Exposed (Activated)

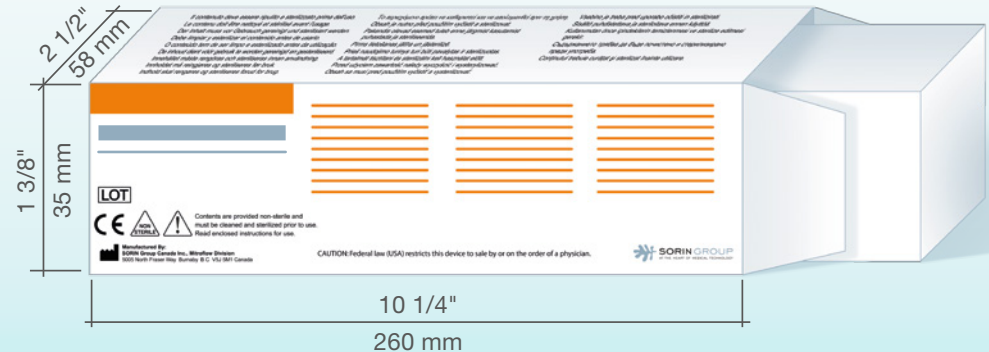


- If either, or both, of these indicators are activated, please contact your local representative to have the valve replaced



- Inspect each valve jar to ensure accuracy of shipment:
  - Does the serial number on your valve jar and outer carton match?
  - Are valve cartons in good conditions?

If not please contact your local sales representative



- The Crown PRT carton dimensions are:

- L 4 1/8" x W 4 1/8" x H 3 13/16"
- L 104,6 mm W 104,6 mm H 96,2 mm

- The handle and obturator (sizer) carton dimensions are:

- L 10 1/4" x W 2 1/2" x H 1 3/8"
- L 260 mm W 58 mm H 35 mm

# CROWN PRT™

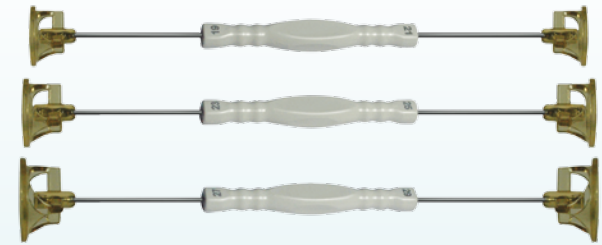
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## PACKAGING STORAGE

- Crown PRT valves must be stored between 5°C (41°F) and 25°C (77°F)
- Avoid locations where extreme temperature fluctuations may occur
  - (i.e., near steam, hot water pipes, air conditioning ducts, direct sunlight, etc.)
- Refrigeration is not required
- Regular inspection of temperature indicators is recommended
- Handles and sizers do not require special storage

# CROWN PRT™

## INSTRUMENTATION UNPACKING

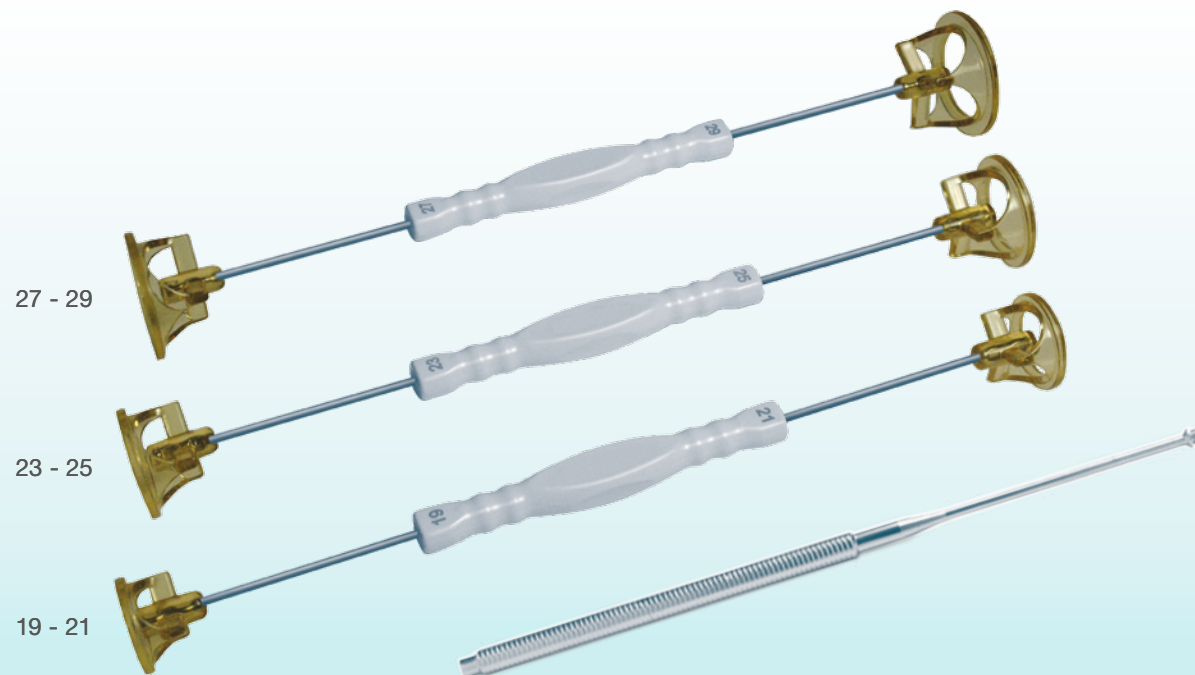


Aortic sizer set

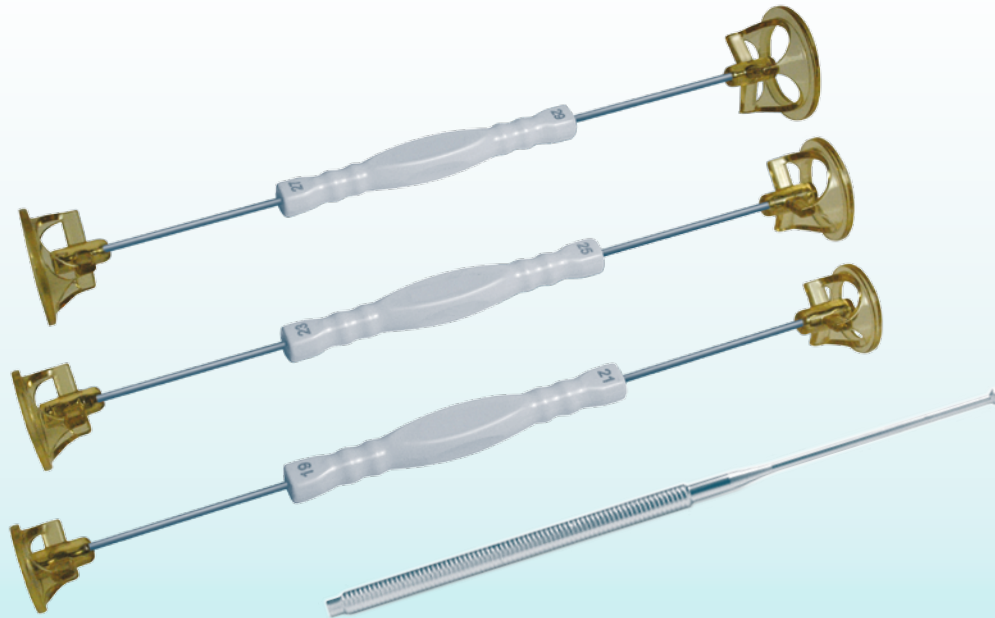


Aortic handle

- The Crown PRT carton dimensions are:
  - L 4 1/8" x W 4 1/8" x H 3 13/16"
  - L 104,6 mm W 104,6 mm H 96,2 mm
- After removing instruments, dispose carton
- Instructions For Use are found in each instrument carton

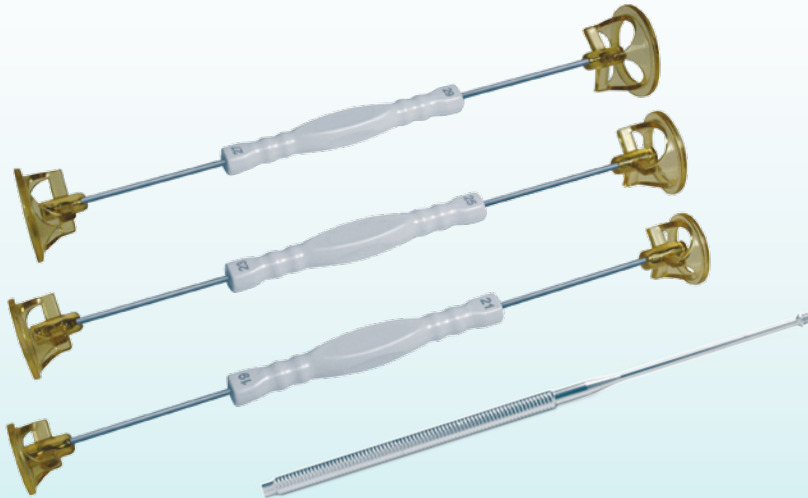


- The sizer set includes bendable dual-ended sizers:
  - 19 – 21 mm
  - 23 – 25 mm
  - 27 – 29 mm



- Instruments should be inspected for visible signs of cracking, crazing or evidence of aging that may affect function before each use
- If damage exists, the instruments should be replaced: contact your local sales representative and the instruments will be replaced

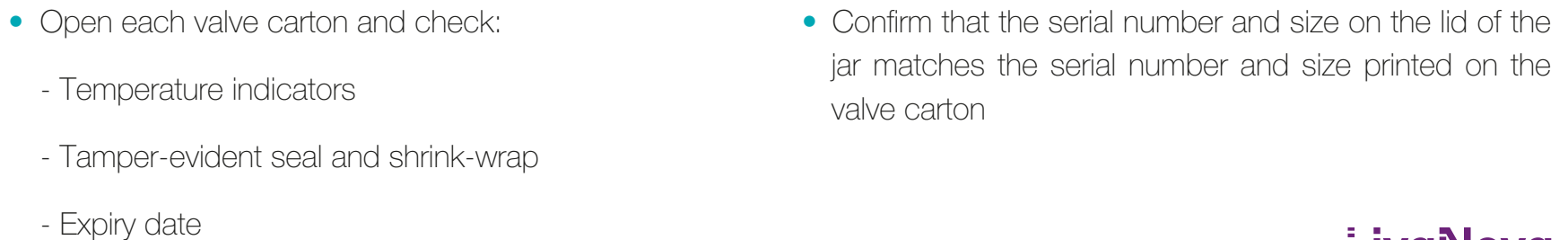
Note: Handles and sizers supplied by other manufacturers are not suitable for use with Crown PRT valves

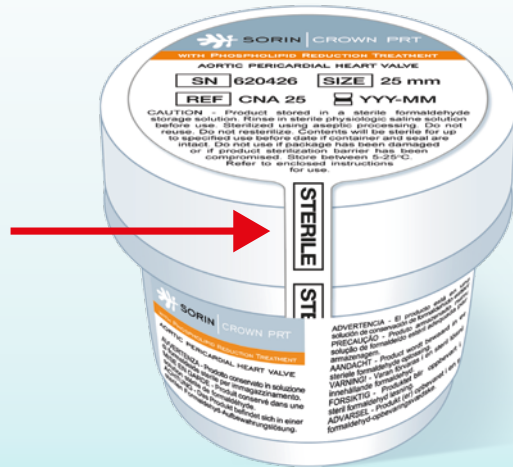


<b>Container</b>	Double-wrapped* instruments
<b>Temperature</b>	$134 \pm 1^{\circ} \text{C}$ ( $273 \pm 1^{\circ} \text{F}$ )
<b>Time</b>	3 minutes
<b>Cycle</b>	Pre-Vacuum

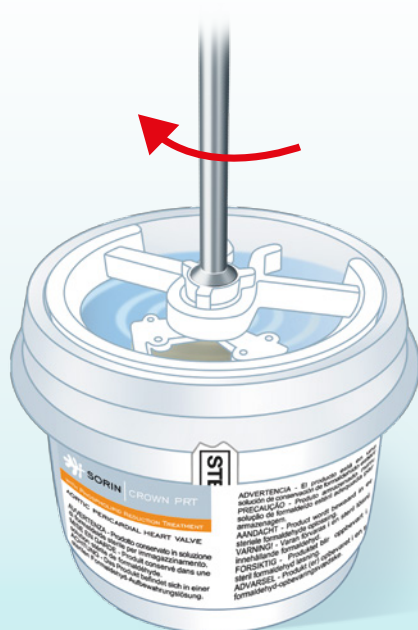
- Handles and Sizers must be cleaned and sterilized prior to use
- It is recommended they are sterilized in autoclave

- Please note that Crown PRT instruments may be damaged by:
  - Strongly alkaline or strongly acidic detergents and solutions
  - Chemicals containing ketones or chlorinated solvents

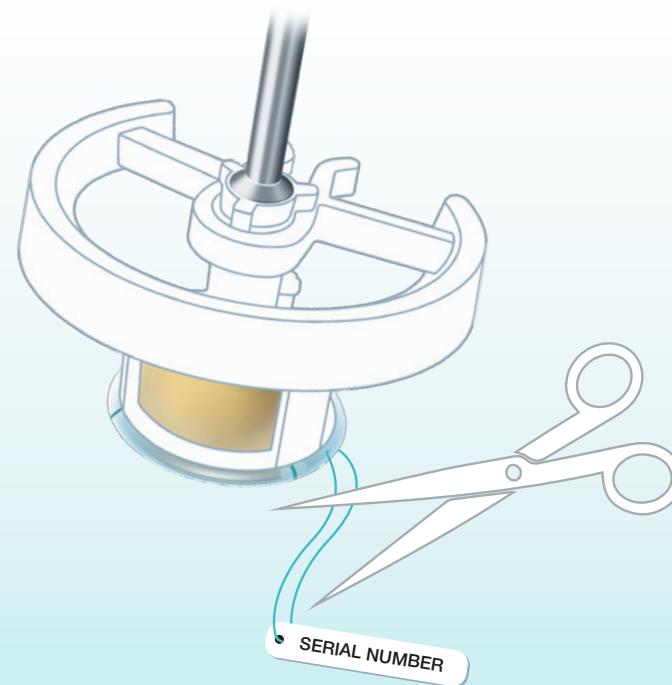
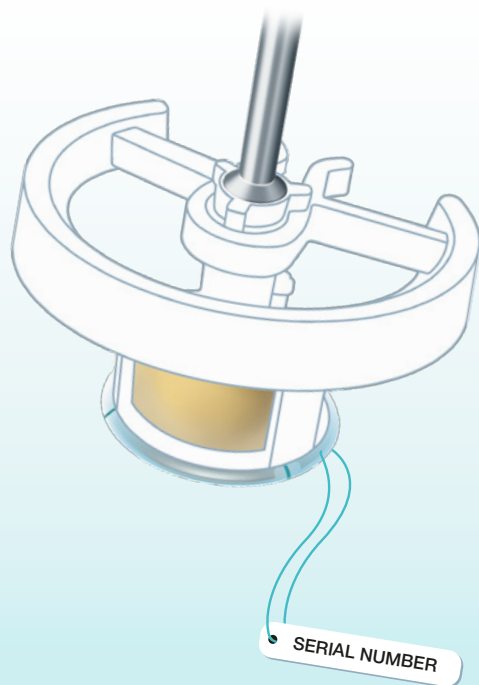




- Prior to opening the jar, check that the “Sterile” sticker has not been compromised
- Remove the shrink wrap and open the jar to expose the valve

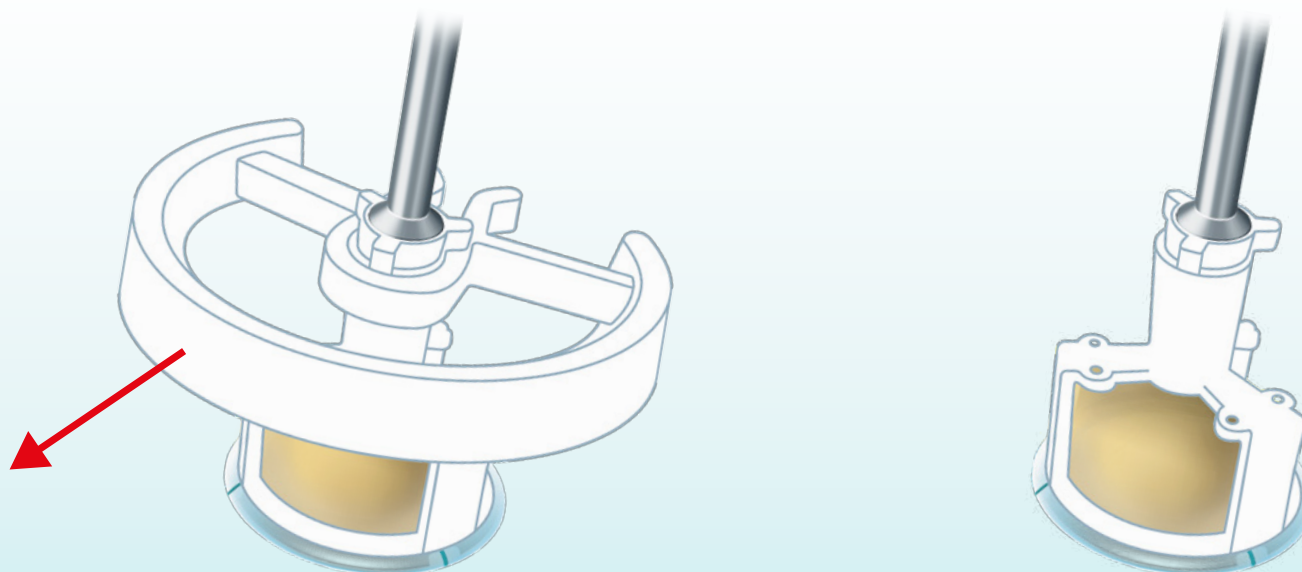


- To remove the valve from the jar, use the valve handle
- To attach the handle, thread the handle into the valve holder with a clockwise rotation
- Gently pull the valve out of the jar together with its holder and anchoring ring



- Before rinsing the valve, confirm that the serial number on the serial tag matches the serial number on the cap label

- Remove the serial tag and attached suture



- Remove the anchoring ring from the valve holder and valve handle



One minute rinse in the first 500ml basin



One minute rinse in the second 500ml basin

- Prepare 2 tall rinse basins with approx 500ml of saline solution
- Gently agitate the valve for one minute in the first rinse basin

- Repeat the one-minute rinse in the second basin
- Total rinse time of at least 2 minutes

Notes:

- A tall rinse basin is recommended so the valve handle will not tip over
- Do not touch the leaflets or squeeze the valve during rinsing
- Allow the valve to remain in the second basin until required by the surgeon

# CROWN PRT™

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## WARNING PRIOR TO USE

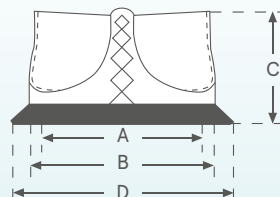
- **For Single Use Only:**
  - The Crown PRT valve cannot be resterilized
  - The valve jar should never be subjected to sterilization procedures
- **Do not use the Crown PRT valve if:**
  - The expiration date is elapsed
  - Either of the temperature indicators is activated
  - The valve carton and/or jar shows damage or leakage
  - The tamper evident seal is broken
  - The bioprosthesis shows evidence of damage
  - The storage solution does not completely cover the valve
  - The valve and its holder are separated from the anchoring ring and the valve is floating free in the jar

## WARNING PRIOR TO USE

- The exterior of the valve jar is non-sterile and should not be introduced into the sterile field
- Once the tamper evident seal on the valve jar is broken, the Crown PRT valve should be used immediately or returned to your local sales representative
- Adequate rinsing with sterile physiological saline is mandatory before implantation: use of other solutions, drugs, antibiotics etc may cause irreparable damage to the valve and should not be used




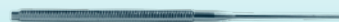
### Product ordering information

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 

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

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