Examine the valve container for integrity. Check that the transparent seal is preserved. Tear off the transparent film and open the container by unscrewing the jar lid.

Prepare a bowl containing sterile saline solution to submerge the valve (at room temperature).

Remove the valve from the container.

Cut the green thread and remove the collar (fig.1).

Release the prosthetic valve from the valve support by cutting the blue threads at the three points marked and cut the green ID tag’s thread (fig.2).

Remove the identification tag attached to the prosthetic valve. Confirm that the serial number on the tag matches the serial number on the jar lid label.

Note: valve does not require rinsing.

WARNING: The external surface of the container is not sterile and therefore must not come into contact with sterile instruments.

**ITEMS REQUIRED**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Size</th>
<th>Picture</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICV1208</td>
<td>PERCEVAL</td>
<td>S</td>
<td><img src="ICV1208.jpg" alt="Image" /></td>
<td>Single use</td>
</tr>
<tr>
<td>ICV1209</td>
<td>PERCEVAL</td>
<td>M</td>
<td><img src="ICV1209.jpg" alt="Image" /></td>
<td>Single use</td>
</tr>
<tr>
<td>ICV1210</td>
<td>PERCEVAL</td>
<td>L</td>
<td><img src="ICV1210.jpg" alt="Image" /></td>
<td>Single use</td>
</tr>
<tr>
<td>ICV1211</td>
<td>PERCEVAL</td>
<td>XL</td>
<td><img src="ICV1211.jpg" alt="Image" /></td>
<td>Single use</td>
</tr>
<tr>
<td>ICV1232</td>
<td>Dual Collapser base</td>
<td>S/M L/XL</td>
<td><img src="ICV1232.jpg" alt="Image" /></td>
<td>Re-usable</td>
</tr>
<tr>
<td>0218TS</td>
<td>Inflation device</td>
<td>S/M L/XL</td>
<td><img src="0218TS.jpg" alt="Image" /></td>
<td>Single use</td>
</tr>
</tbody>
</table>

**DUAL COLLAPSER & BASE PREPARATION**

Choose the Dual Collapser consistent with the size of the selected prosthesis.

1. Place the Dual Collapser base on the sterile field so that it is accessible from both sides. Mount the Dual Collapser on its base and fix in place (fig.1) by closing the locking mechanism (fig.2).

2. Place the lever in the open position to free the collapsing area (A) (fig.3).

**DUAL HOLDER PREPARATION**

Select the Dual Holder indicated for the selected surgical approach and consistent with the size of the prosthesis.

1. Pull the sheath back towards the handle.

2. Turn the knob clockwise (opened - lock - arrow) until it stops (fig.1).

3. Place the Dual Holder onto the base by aligning the groove on the handle with the notch on the support (fig.2).

The Dual Holder must be positioned so that its logo points upwards and fits in a stable position.
INDICATIONS:

EUROPE: The Perceval® prosthesis is indicated for the replacement of diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated for use in adult patients who are diagnosed to have aortic valve stenosis or steno-insufficiency.

USA: The Perceval bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

CANADA: The Perceval S bioprosthesis is intended for use in patients aged ≥ 65 years when the aortic valve pathology is in an advanced stage to require the replacement of the native or malfunctioning previously implanted prosthesis.

AUSTRALIA: Perceval S prosthesis is indicated for the replacement of a diseased native or a malfunctioning prosthetic aortic valve via open heart surgery. The prosthesis is indicated in patients who meet the following criteria: 1) subjects of age ≥ 65 years 2) subjects with aortic valve stenosis or steno-insufficiency.

MRI conditional.

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

N.B. This is a summary of the main steps to prepare the Perceval. Please consult the Inservice Guide and the Instructions for Use (IFU) manual which is included in the valve and accessories’ packaging.

POSITIONING THE VALVE

IMPORTANT: The valve must be positioned so that the black suture on the inflow ring points upwards

1 While holding the valve by the inflow portion (pericardium), align and insert it into the Dual Collapser (fig.1).

- Check the valve leaflets while pushing to make sure they allow the holder tip to pass through.
- Check valve positioning by gently pushing back on the outflow ring.

VALVE COLLAPSING

1 Turn the lever of the Dual Collapser until the inflow and outflow rings of the valve are collapsed (fig.1).

- Check that the struts are evenly collapsed and that they do not overlap.

2 Keeping the lever in closed position and securing the Dual Holder in place, slide the sheath until it covers the collapsed outflow ring (fig.2).

NOTICE: Slide the sheath by following the arrow direction.

3 Position the Smart Clip between the sheath and the handle of the Dual Holder, as shown in (fig.3). by gently pressing the Smart Clip until it is completely inserted in the slot.

4 Turn the knob (fig.4) counterclockwise (closed lock arrow) until it stops. Do not dislodge the Dual Holder, to ensure the inflow cap grips the inflow ring.

5 Turning the lever to the open position, release the Dual Collapser; the Smart Clip will automatically push the sheath forward to completely cover the outflow ring of the prosthesis (fig.5).

6 Open the Dual Collapser completely before pulling the Dual Holder out.