The OZAKI VRec Sizer™ System

REF JD-001

INSTRUCTIONS FOR USE
The OZAKI VRec Sizer™ System (Ref: JD-001)

Rx Only

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

NON-STERILE: The OZAKI VRec Sizer System is supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed Sizer set components.

SYMBOL LEGEND

Consult Instructions for Use

Non sterile

Date of Manufacture

Batch code

Serial number

Catalogue number

Authorized Representative in the European Community.

Quantity

Manufacturer

CE Mark - Compliance with Medical Device Directive 93/42/EEC

1. DEVICE DESCRIPTION

The OZAKI VRec Sizer™ System is designed to aid the surgeon to accurately measure the size of the natural valve opening to determine the size of the appropriate replacement heart
2. INDICATION
The OZAKI VRec Sizer™ System is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve for cardiac valve reconstruction or plasty utilizing self-pericardium or similar.

3. WARNINGS
• Before using this product (including the first use), you must clean and perform the high-pressure steam sterilization under the conditions shown in Section 7 “CLEANING AND STERILIZATION”.
• Check that there are no cracks and rust on the Sizer before using. If signs of deterioration are found, do not use the Sizer.

4. PRECAUTIONS
• Do not use this product with an annuloplasty ring or a similar device, because this
product uses the patient’s own pericardium or similar material for the aortic valve reconstruction or plasty procedure.

- Do not sterilize with gamma radiation or with hydrogen peroxide low temperature plasma, as it will cause the deterioration of material.
- Prohibit the washing by organic solvent-based cleaning solution (Because it will cause the deterioration of material.).
- Do not expose this product to strong alkaline detergent/solution, strong acid detergent/solution, chemical substances containing ketone body, and chlorinated solvent.
- At end-of-life, please discard used product as medical waste in accordance with local laws and rules of your facility, to avoid risk of microbial infection.
- Do not use product in case of separation of the sizer head from the stainless steel handle.

5. POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with the use of the OZAKI VRec™ Sizer System include:

- Possible trauma or injury to aortic wall or left ventricle from contact with the Sizer.
- Allergic reaction to polyphenylsulfone and medical grade stainless steel.

6. DIRECTIONS FOR USE

a. Put the protruding portion of the Sizer to the commissure of the exposed aortic valve annulus and measure the distance between commissures.

b. In case of a bicuspid valve, this product is used to measure the distance between virtual commissures if necessary.

c. Determine the size of the replacement valve by using the template that corresponds to the Sizer number, and cut a valve leaflet from the previously excised and treated pericardium.

d. Clean and re-sterilize properly after using, according to the instructions given in Section 7 "Cleaning and Sterilization".

e. Sizer and template must be properly cleaned and sterilized prior to each use. Please follow the proper cleaning and sterilization instructions in Section 7 of this manual. Always check that there is no damage or deteriorations after the sterilization. Do not use the Sizer and template if there are signs of deterioration.
7. CLEANING AND STERILIZATION

The OZAKI VRRec™ Sizer System is supplied NON-STERILE and must be cleaned and sterilized prior to each use. Do not use the Sizer System if there are signs of damage or aging such as cracking or crazing. Do not use the Sizer System if printed text is not legible or the Sizer System appears to be damaged. Contact your sales representative for instrument replacement.

7.1.1. Cleaning and Disinfection Instructions for OZAKI VRRec™ Sizer System

WARNING: OZAKI VRREC SIZER INSTRUMENTS (COMPONENTS) MAY BE DAMAGED BY STRONG ALKALINE OR STRONG ACIDIC DETERGENTS AND SOLUTIONS, ORGANIC SOLVENT-BASED CLEANING SOLUTION, AND BY CHEMICALS CONTAINING KETONES OR CHLORINATED SOLVENTS.

The following cleaning and disinfection methods are recommended for the instruments of OZAKI VRRec™ Sizer System:

7.1.2. Manual Cleaning and Disinfection

a. Wipe instrument with wet, disposable sponge to remove gross soil.

b. Rinse instrument in hot, running tap water for a minimum of 1 minute to remove visible soil.

c. Prepare an enzymatic detergent per manufacturer’s recommendation.

d. Soak all reusable components in the detergent for a minimum of 1 minute. Follow the detergent manufacturer’s guidelines for the correct dilution, temperature, water quality (i.e. pH, hardness), exposure time and rinsing. Using Enzol® Enzymatic Detergent, or a suitable equivalent is recommended.

e. Scrub instrument thoroughly with a soft bristle brush for a minimum of 1 minute.

f. Rinse instrument with de-ionized water for a minimum of 1 minute to remove remaining soil and cleaning agent.

g. Prepare a neutral detergent in a sonication unit. Immerse all reusable components and allow them to sonicate for 10 minutes.

h. Remove the components from the detergent solution and thoroughly rinse them under the de-ionized water for a minimum of 1 minute.
i. Dry them completely with disposable lint free cloths

j. Visually inspect each component for visible soil.

WARNING: OZAKI VREC SIZER INSTRUMENTS CANNOT WITHSTAND AUTOMATIC CLEANING.

Note: It is recommended that the device is reprocessed as soon as is reasonably practical following use.

7.1.3. Sterilization

Recommended high-pressure steam sterilization conditions for this product are as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Sterilization Method</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Template</td>
<td>Gravity</td>
<td>121°C (250°F)</td>
<td>30 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Instruments except Template</td>
<td>Prevacuum</td>
<td>135°C (275°F)</td>
<td>3 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

8. HOW SUPPLIED

The OZAKI VRec Sizer System is supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed Sizer set components.

The System is composed of the following components:

- Sizer (9-size variation: 19/21/23/25/27/29/31/33/35mm)
- Template with corresponding sizer value
- Stainless Steel Plate
- Valve Leaflet Tray
- Sterilization Box
- Tray

The size of the corresponding valve is shown on the head of each Sizer and on the template. Sizer head is made of polyphenylsulfone material and sizer handle is medical grade stainless steel.
9. STORAGE

- Store in a cool, dry and dark place.
- Store in a stable state and avoid tilting, vibration, shock (including during transport).
- Store away from the storage location of chemical agent (especially, organic solvent) and gas.

10. MAINTENANCE, INSPECTION & DEVICE DISPOSAL

The maintenance and inspection items by user

- This product can be sterilized up to 50 cycles. Discontinue use after 50 sterilization cycles or before one year from the start of use, whichever comes first.
- Check that there are no cracks and rust on the Sizer before using. If you found the signs of deterioration, please do not use the Sizer.
- At end-of-life, please discard used product as medical waste in accordance with local laws and rules of your facility, to avoid risk of microbial infection.

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