The OZAKI VRec Sizer™ (13, 15, 17 mm)

REF JD-001-P

FOR

The OZAKI VRec Sizer™ System

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

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 is supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed Sizers.

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™ 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 valve. The OZAKI VRec Sizer™ consists of three individual, single-end sizers with stainless steel
handle and is available in a size range from 13 to 17 mm. A set of size 19 to 35 mm Sizers, Template and other components as the System are available separately, Ref JD-001.

Figure 1: The OZAKI VRec Sizer™ (Smaller Sizers: 13, 15 and 17 mm)

2. INDICATION
The OZAKI VRec Sizer™ 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 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. Place 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 (provided within code VRec Sizer System, Ref. JD-001) 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. Sizers must be properly cleaned and sterilized prior to each use. Please follow the proper cleaning and sterilization instructions in Section 7 of this manual. For reprocessing instructions of the Template, please refer to the Instructions For Use of Ref. JD-001. Always check that there is no damage or deterioration after the sterilization. Do not use the Sizer and template if there are signs of deterioration.

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

7.1.1. Cleaning and Disinfection Instructions for OZAKI VRec™ Sizer

WARNING: OZAKI VREC SIZER INSTRUMENTS 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 OZAKI VRec™ Sizers:

7.1.2. Manual Cleaning and Disinfection

a. Wipe Sizers 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>Sizers</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 VR rec Sizer is supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed Sizers set components.

The Sizer is composed of the following components:

- Sizers (3-size variation: 13/15/17mm)

The size of the corresponding valve is shown on the head of each Sizer and on the template (the template is a component of product code JD-001). 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 times 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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