FEHLING OZAKI leaflet templates

Description	REF	Dimensions (mm) W x H
OZAKI leaflet template, size 11	OZA-2A	33.9 x 48.5
OZAKI leaflet template, size 13	OZA-2B	35.8 x 49.5
OZAKI leaflet template, size 15	OZA-2C	37.8 x 50.5
OZAKI leaflet template, size 17	OZA-2D	39.6 x 53.5
OZAKI leaflet template, size 19	OZA-2E	46.6 x 54.5
OZAKI leaflet template, size 21	OZA-2F	48.6 x 55.5
OZAKI leaflet template, size 23	OZA-2G	50.6 x 56.5
OZAKI leaflet template, size 25	OZA-2H	52.5 x 57.5
OZAKI leaflet template, size 27	OZA-2I	54.5 x 58.5
OZAKI leaflet template, size 29	OZA-2J	56.5 x 59.5
OZAKI leaflet template, size 31	OZA-2K	58.5 x 60.5
OZAKI leaflet template, size 33	OZA-2L	60.4 x 61.5
OZAKI leaflet template, size 35	OZA-2M	62.4 x 62.5
OZAKI leaflet template, size 37	OZA-2N	64.4 x 63.5

This instrument or medical device is non-sterile when delivered. It is to be reprocessed before use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing.

The OZAKI leaflet templates may only be used, reprocessed and disposed of by qualified medical personnel!

The OZAKI leaflet templates are intended for re-use.

1) Intended purpose

Sizing instruments are intended for the approximate comparison or matching of diameters, lengths, shapes and volumes, and for checking or simulating the presence of such features. These include, for example,

- compatibility checks of hollow bodies (e.g. blood vessels, intestines) in anastomoses
- as auxiliary bodies for the reconstruction of the aortic valve for palpating height differences of the free edge of valve leaflets
- as gauges for the intervertebral disc space after discectomy

Note: Even if the name of some instruments suggests this, these are not instruments with a measuring function according to 80/181/EEC, but rather instruments for the approximate comparison/matching of dimensions.

Additional information regarding the intended purpose

Duration of application: Templates are intended for temporary use.

Field of application: Templates are used in all patients where diameters, lengths, shapes and volumes are to be compared or matched and the presence of such features is to be checked or simulated.

User profile: Templates may only be used by medically trained personnel (e.g. specialist physician).

Application environment: Templates are only to be used in controlled environments (e.g., in the operating room).

Target patient population: No restrictions.

2) Indications

Treatment methods in which dimensional determination of hollow organs, hollow bodies, natural or disease- or injury-related cavities is to be performed to assess further treatment.

3) Contraindication

Any use that is incompatible with the physical and/or mechanical properties of the specific sizing instrument is contraindicated. There are no generally applicable contraindications for the use of sizing instruments.

Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.

Known nickel and/or titanium incompatibilities.

4) Possible side effects

The following side effects are described in the medical literature and may also occur during the intended use of the instruments:

- Infections
- Wound healing disorders

⚠	Medical devices may contain, e.g., chromium and/or nickel. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Before use

The OZAKI leaflet templates are non-sterile when delivered, so they must be cleaned and sterilised by the user before initial use and every time before they are used thereafter (see section 6) Reprocessing).

The OZAKI leaflet templates provide the user with an indication of the size and shape in which aortic valve leaflet implants are to be cut for reconstruction. The templates do not represent an absolute size, but serve as a guide in the manufacture of the implants.

⚠	Perform a safety check before each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section *6) Reprocessing* under *"Maintenance, Inspection and Testing"*).

⚠	OZAKI leaflet templates must be handled with care during storage, transportation and cleaning! Avoid mechanical shock and point loading on OZAKI leaflet templates to minimise causing any secondary damage! Do not overload functional parts.
⚠	Use only intact and sterilised products!

6) Reprocessing	
⚠	The medical device is to be reprocessed before use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid mechanical shock and point loading on instruments to minimise causing any secondary damage! Do not overload functional parts.
Limitations on reprocessing	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure – also see "Maintenance, Inspection and Testing"). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.

General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilisation) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionised water (deionised water, demineralised, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-treatment at the place of use	Pre-cleaning: Ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation before cleaning	Instruments should be reprocessed immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section *10) Disassembly*
Manual pre-cleaning:	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush). • Cavities, crevices, slits and lumens must be rinsed intensively (> 10 seconds) with cold water (potable water quality, < 40 °C) using a water spray gun (or similar).

	• Place the products for 10 – 30 minutes in a solution with 0.5 – 2% Neodisher® MediClean forte with water (potable water quality, < 40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument may be moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush) during the exposure time. • Rinse the instruments for one minute in cold deionised water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilisation baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the washer/disinfector. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, < 40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 – 2% Neodisher® MediClean forte in water (potable water quality) at 55 °C • Emptying • Rinse for 2 minutes with water (potable water quality, < 40 °C) • Emptying • Rinse for 1 minute with cold deionized water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (> 90 °C)

	• Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Place instruments, if possible in disassembled condition, in cold water (potable water quality, < 40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until contamination is no longer visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at < 40 °C with 0.5 – 2% cleaning solution at 35 kHz. • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, < 40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant solution (e.g., 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (< 40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth.

	• Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilisable and steam-permeable is to be applied before sterilisation. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and compromise the effect of steam sterilisation. Perform a safety check of the instruments before each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorised by the manufacturer. A confirmation form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments.
Packaging	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665 (Parts 1 and 2). In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer autoclave Type B 3870 EHS / Lautenschläger ZentraCert

	Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products are made of stainless steel. They are to be cleaned before disposal. They can be disposed of at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy and potential adverse consequences.	
⚠	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability. Subject to change without notice.

7) Configuration and application	
In aortic valve leaflet reconstruction according to Ozaki, the size and shape of the leaflets to be replaced must be assessed by the user. After selecting the correct OZAKI leaf template to match the size of the aortic valve to be replaced, the outline can be transferred to a suitable implant material and cut to size according to the physical requirements of the valve leaflet to be replaced.	
⚠	Use only intact and sterilised products!
⚠	Before using the OZAKI leaf templates, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.

⚠	The choice of OZAKI leaf templates depends on the anatomical and physiological conditions as well as the field of application. Care must be taken to ensure that the OZAKI leaf templates used have the correct size and geometry, as well as sufficient stability.
⚠	The OZAKI leaf templates are only for the approximate estimation of the geometry of the valve leaflets to be created. The patient-specific anatomy must be observed.

An example OZAKI leaf template is shown below. The OZAKI templates do not represent an absolute size, but serve as a guide for the user when creating the implants. When using the templates and during reconstruction, care must be taken to ensure appropriate hygiene and sterility.

Fig. 1: Example illustration of the product OZA-2G as a variant of the OZAKI leaflet templates (size and name vary).

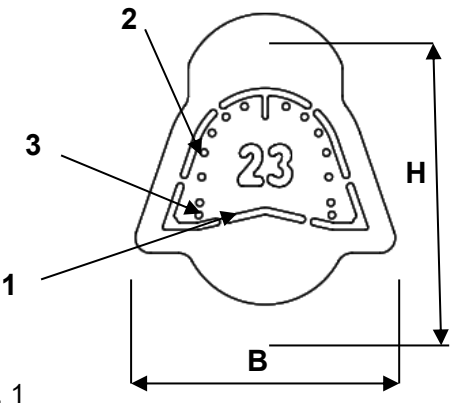

Fig. 1

There is a size indication (1) on the OZAKI leaflet templates to allow the different variations to be distinguished from each other easily and quickly. These are not dimensional measurements.
After selecting the correct template, the outline can be transferred to a suitable implant material through the laser-cut slots (2). The holes (3) can be used to mark suture points.

⚠	The OZAKI leaflet templates must not be bent during use. Risk of breakage!

8) Required accessories

No accessories are required for using the OZAKI leaflet templates.
The OZAKI leaflet templates are stand-alone instruments. Combination with other products is therefore not intended.

9) Assembly

No assembly of the OZAKI leaflet templates is necessary.

10) Disassembly

No disassembly of the OZAKI leaflet templates is necessary.

11) Obligation to report serious incidents
The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer's contact information		
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