AV-cusp gauges

	REF	**Description** (measurements: h x w)
bicuspid	MVB-1	AV-cusp gauge size 1B, 20 x 25 mm
	MVB-2	AV-cusp gauge size 2B, 22 x 28 mm
	MVB-3	AV-cusp gauge size 3B, 24 x 31 mm
	MVB-4	AV cusp gauge size 4B, 26 x 34 mm
	MVB-5	AV-cusp gauge size 5B, 28 x 37 mm
	MVB-6	AV-cusp gauge size 6B, 30 x 41 mm
	MVB-7	AV-cusp gauge size 7B, 32 x 45 mm
	MVB-8	AV-cusp gauge size 8B, 34 x 48 mm
	MVB-9	AV-cusp gauge size 9B, 36 x 52 mm
tricuspid	MVC-0	AV-cusp gauge size 0T, 18 x 18 mm
	MVC-1	AV-cusp gauge size 1T, 18 x 19 mm
	MVC-2	AV-cusp gauge size 2T, 20 x 22 mm
	MVC-3	AV-cusp gauge size 3T, 22 x 25 mm
	MVC-4	AV-cusp gauge size 4T, 24 x 28 mm
	MVC-5	AV-cusp gauge size 5T, 26 x 31 mm
	MVC-6	AV-cusp gauge size 6T, 28 x 34 mm
	MVC-7	AV cusp gauge size 7T, 30 x 37 mm
	MVC-8	AV-cusp gauge size 8T, 32 x 40 mm
	MVC-9	AV-cusp gauge size 9T, 34 x 43 mm

Only trained medical personnel may use, reprocess or dispose of FEHLING AV-cusp gauges!

Intended use:

FEHLING INSTRUMENTS AV cusp gauges are intended as aids for the determination of the size of AV cusp implants to be prepared from suitable material.

Indications and contraindications for use

Indications:

- As an aid during aortic valve reconstruction, specifically for the manufacture of aortic valve implants (referred to as AV cusps below)

Contraindications:

- Known nickel and/or titanium sensitivities

Known adverse effects:

No adverse effects are known at present.

Prior to use:

FEHLING INSTRUMENTS AV cusps are delivered non-sterile and must be inspected, cleaned and sterilised before initial use and before each further use (see Reprocessing).
FEHLING AV-cusp gauges implants offer the user an indication of the size and shape into which aortic valve implants should be formed for the purpose of reconstruction. The absolute sizes of the gauges are not significant as they serve as a comparator during manufacture of the implant.

Warning:
The AV-cusp gauges consist of an austenite NiTi shape memory alloy.
Do not use Orthovario or Oxivario procedures for cleaning! Using these procedures will destroy instruments containing titanium over time due to their oxidative processes (corrosion of titanium due to H_2O_2)! The instrument must undergo risk assessment prior to reprocessing.

Risk of injury! Use only AV-cusp gauges in perfect condition!
Handle AV-cusp gauges carefully during storage, transport and cleaning! Avoid impacts and point loading! A safety check must be carried out before each use with particular attention to the physical integrity, especially to cracks or breaks (see Maintenance, Inspection and Functional Testing p5).

During use:

During AV cusp reconstruction, the user can utilize the gauges to estimate the size and shape of the cusp to be replaced. Because of the NiTi material the gauges can be shaped at room temperature and as a result adapted to the physical form of the valve cusp which is to be replaced. After selecting the correct gauge, a suitable piece implant material can be matched to its contours and trimmed to the physical requirements of the cusp to be replaced. Before the manufactured implant is used, it should be rinsed several times with, for example, physiological saline solution. The implants thus produced can be used for the reconstruction.

Markings are located on the edges of the gauges (Fig. 1) for estimating the commissure and the center of the AV cusp. The gauges do not constitute an absolute size but rather are intended to serve the user as a point of reference for manufacturing the AV cusps. When using the gauges and the reconstruction, proper hygiene and sterility must be maintained.

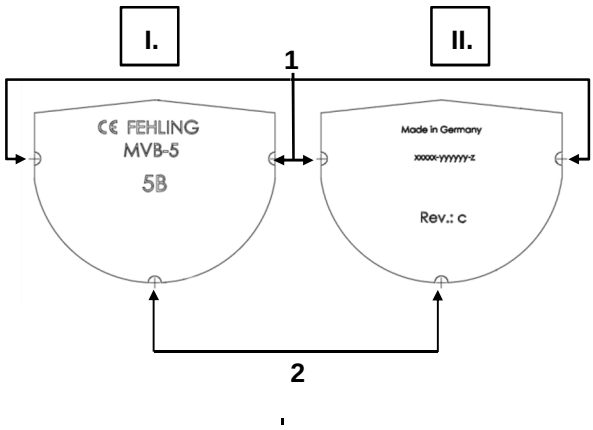

Figure 1: Schematic of the AV cusps (the size and description are variable). The gauges have a shape for bicuspid cusps **(I.)** indicated by "B" on the gauge and a shape for tricuspid cusps **(II.)** indicated by a "T" on the gauge. The commissure is marked by the two notches on the side **(1).** The lower notch marks the vertical midline **(2)** of the gauge**.** The number printed on the gauge indicates the size. The individual sizes and measurements are listed in the overview of the models presented on page 1 of these Instructions for Use.

Warning: The gauges are manufactured from austenite NiTi material and have a shape memory. They can be flexibly deformed at room temperature and regain their initial flat shape during sterilization.
When deforming the gauge during use, do not bend and do not go below the minimum bending radius of 3.8 mm. Bending the gauge too sharply can result in permanent deformation or irreparable kinks in the material that compromise the gauge's function!

Reprocessing:	
Reprocessing restrictions: Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use.	
Point of use::	Use a disposable cloth/paper towel to remove surface contamination – pre-cleaning.
Storage:	Store the instruments in a dry place in order to avoid condensation. It is recommended to reprocess the instruments immediately after use, because it is very difficult to remove dried residues from instrument parts that are difficult to access.
Cleaning preparation: mechanical cleaning in accordance with Robert Koch Institute (RKI) guidelines. Mechanical cleaning is preferable to manual cleaning.**:**	Ensure that blood, tissue and drug residues are removed from the instruments immediately after completion of the procedure and that they undergo mechanical cleaning immediately. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemical manufacturer's recommendation for the mixture). Avoid overfilling instrument trays and washing trays. Use only suitable instrument holders. When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck anywhere.
Cleaning/Disinfection in accordance with **EN ISO 15883-1:2009**	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with.
Cleaning/Disinfection: Mechanical in accordance with DIN EN 15883-1:2009	<u>Validated procedure:</u> Equipment: Washer-disinfector G7836 CD (Miele) Process: 2-component process alkaline/enzymatic Detergents: deconex® TWIN PH10 and TWINZYME (Borer Chemie, Schwitzerland) <u>Preparation:</u> • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no unwashed areas are left. <u>Parameters:</u> • Pre-wash for 3 minutes with cold water. • Empty • Wash for 10 minutes with tap water with 0.3% TWIN PH10 at 35 °C and 0.2 % TWINZYME at 40 °C. • Empty • Rinse for 2 minutes with fully deionized water at at least 30 °C. • Empty • Rinse for 1 minute with fully deionized cold water. • Empty • Perform thermodisinfection for at least 5 minutes at 93 °C. • After mechanical cleaning, inspect the instruments for visible contamination. Repeat the cycle or manually clean as necessary. • Other locally validated methods, including those specified in HTM2030, may be used.

	Alternatively, the following validated procedure can be used: Manual precleaning Equipment:.....Basin, soft brushes Detergent: .....Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner (Steris®) Mixing ratio: .....0,5 – 2 % Prolystica® in tap water Temperature: .....40 °C Exposure time:.....10 – 30 min. Soak the devices in the detergent solution. Remove gross soil using soft -bristled brush. Actuate mobile parts of device minimum 5 times. Rinse each device with cold deionized water for 1 min. Remove gross soil using a soft-bristled brush. Actuate mobile parts of the device minimum 5 times.
	Automated Cleaning Equipment:.....Miele PG 8536 Detergent: .....neodisher® MediClean forte (Dr. Weigert) Parameters 1. 3 min pre-cleaning with tap water (< 45 °C) 2. 10 min cleaning with a solution of 0,5 - 2 % neodisher® in tap water at 55 °C 3. 2 min rinsing with cold tap water (< 45 °C) 4. 5 min rinsing with deionized water (90 °C) **5.** 25 min drying (> 50 °C)
Cleaning: Manual	Validated procedure Equipment: Bandelin Sonorex RK 1028 H Detergents: Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz. After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Disinfection: Manual	Disinfection: Consult the instructions on the label when selecting a disinfectant (see information on chemical manufacturers). Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Drying	If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Maintenance, checking and functional testing:	Use a magnifying lamp to visually inspect the components for damage and wear and tear. It is especially important to check the integrity of the delicate crosspieces of the mesh. Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.

Packaging:	Single: in accordance with the standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately.
Sterilization:	Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! 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. Validated procedure: Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: at least 10 minutes Other locally validated methods, including those described in HTM2010, may be used.
Storage:	In accordance with §4 of the Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

⚠ Any modification to the device or deviation from these instructions for use will result in exclusion of liability. Subject to change without notice.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.

Symbols

Store in a dry place.!	Article number	Lot number	Follow the instructions for use.
Manufacturer	CE marking	Warning	Protect from excessive heat!

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