FEHLING SUPERPLAST gauges for AV cusps

	Description	REF	Size (mm) W x H
bicuspid	AV cusp gauge size 1B	MVD-1	25 x 20
	AV cusp gauge size 2B	MVD-2	28 x 22
	AV cusp gauge size 3B	MVD-3	31 x 24
	AV cusp gauge size 4B	MVD-4	34 x 26
	AV cusp gauge size 5B	MVD-5	37 x 28
	AV cusp gauge size 6B	MVD-6	40 x 30
	AV cusp gauge size 7B	MVD-7	43 x 32
	AV cusp gauge size 8B	MVD-8	46 x 34
	AV cusp gauge size 9B	MVD-9	49 x 36
tricuspid	AV cusp gauge size 0T	MVE-0	18 x 18
	AV cusp gauge size 1T	MVE-1	19 x 20
	AV cusp gauge size 2T	MVE-2	22 x 22
	AV cusp gauge size 3T	MVE-3	25 x 24
	AV cusp gauge size 4T	MVE-4	28 x 26
	AV cusp gauge size 5T	MVE-5	31 x 28
	AV cusp gauge size 6T	MVE-6	34 x 30
	AV cusp gauge size 7T	MVE-7	37 x 32
	AV cusp gauge size 8T	MVE-8	40 x 34
	AV cusp gauge size 9T	MVE-9	43 x 36

This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
Only trained medical personnel may use, reprocess or dispose of AV cusp gauges!
AV cusp gauges are intended for re-use.

1) Intended purpose

Gauges are intended for the approximate comparison or adjustment of diameters, distances, shapes, and volumes or for checking or simulating the presence of such characteristics. These include, e.g.

- compatibility tests of hollow bodies (e.g. blood vessels, intestines) for anastomoses
- as an auxiliary body for reconstruction of the aortic valve for probing height differences of the free margins of valve cusps
- as distance gauges for the intervertebral disc space after discectomy

Note: Although the names of some instruments may imply this, they are not instruments with a measuring function according to 80/181/EEC, but are instruments for the approximate comparison/adjustment of dimensions.

Additional information regarding the intended purpose

Duration of application: gauges are intended for temporary use.

Field of application: gauges are used in all patients where diameters, distances, shapes and volumes have to be compared or adjusted and the presence of such characteristics has to be checked or simulated.

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

Application environment: gauges are only to be used in controlled environments (e.g. OR).

2) Indications

Treatment methods in which the dimensions of hollow organs, hollow bodies, natural or diseased or injured cavities must be determined to evaluate further treatment.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual test instrument model are contraindicated. There are no generally applicable contraindications for the use of test instruments.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

Known nickel and/or titanium intolerances.

4) Possible adverse effects

None known

5) Prior to use

FEHLING INSTRUMENTS gauges for AV cusps are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see 6) Reprocessing).

FEHLING AV-cusp gauges offer the user a point of reference for the size and shape in which the AV cusps should be cut out for use in reconstruction. The gauges do not constitute an absolute size but rather serve as a point of reference for manufacturing the AV cusps.

⚠	Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and Testing).
⚠	AV cusp gauges must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to AV cusp gauges, so as not to cause any consequential damage! Do not overstrain functional parts!

⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	The AV cusp gauges consist of an austenite NiTi shape memory alloy. Do not clean titanium instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments.
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization should be used to activate the shape memory. The following should be observed here: • The SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e.g., other instruments or restricted space). • After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of 40 °C.
Limitations on reprocessing	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 (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").
Initial 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 prior to cleaning	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. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.

Disassembly	See 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 tap water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn dirt with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold town water of drinking 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 tap 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 are moved back and forth in the cleaning bath. • During the exposure time, use appropriate brushes to remove coarse contamination. • Rinse the instruments for one minute in cold deionized water (see "Additional Information") and, if applicable, move movable parts back and forth.
Cleaning/Disinfection	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. Compliance with the recommended concentrations, application times and temperatures is also assumed. 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 sterilization 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)

	Preparation: • The joint instruments are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. Procedure/Parameters: • Pre-wash for 3 minutes with cold tap water (potable water quality, < 40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® MediClean forte in tap water (potable water quality) at 55°C • Emptying • Rinse for 2 minutes with tap 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: Manual	Validated procedure Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) Procedure/Parameters • Place instruments, if possible in disassembled condition, in cold tap 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 no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun (or similar). Ultrasonic cleaning • Clean for 10 minutes at < 40 °C with 0.5 – 2 % cleaning solution at 35 kHz

	• After ultrasonic cleaning, rinse the instruments with a water spray gun (or similar) for at least 20 seconds. • Rinse the instruments for at least 10 seconds with tap water (potable water quality, <40°C). • Deionized water (<40 °C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF <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 9) Assembly
Maintenance, checking 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 sterilizable and steam-permeable is to be applied. 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 question the effect of steam sterilization. Perform a safety check of the instruments prior to 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 play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. 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 authorized by the manufacturer. A verification 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	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. 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 <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134°C Holding time: 4 – 5 min. Drying time: 20 min.
Storage	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, 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 largely consist of Nitinol. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any sharp or pointed edges are protected.
Additional information	Both potable quality tap water as well as deionized tap water (deionized water) are used for cleaning. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
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 results. This normally requires validation and routine monitoring of the	

process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness 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

During AV cusp reconstruction, the user can utilize the gauges to estimate the size and shape of the cusp to be replaced. Thanks to the NiTi material, the gauges can be deformed at room temperature. This enables the spatial structure to be adapted to the cusp to be replaced. After the user selects the proper gauge, the outline can be transferred to a suitable implant material, which can be cut to fit the cusp to be replaced in line with the physical requirements.

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the gauges for AV cusps, ensure that the surgical field has been prepared accordingly beforehand.

During use

Before the AV cusp is inserted, it should be rinsed several times, for example, with normal saline solution. The AV cusps manufactured in this manner can be used for reconstruction. Markings are located on the margins of the gauges (see Figures) 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.

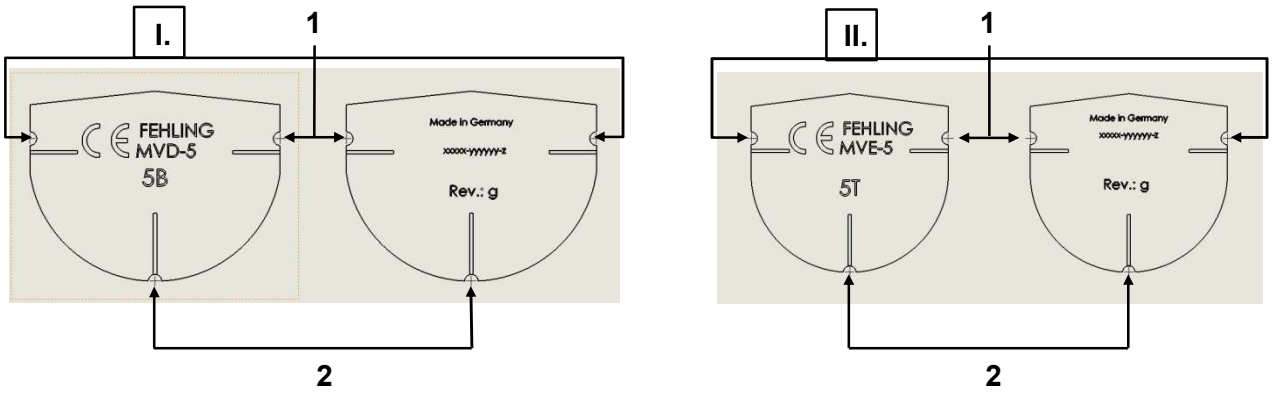

Figure: Schematic of the AV cusps (the size and description are variable). The gauges have a shape for bicuspid cusps (**I.**) indicated by "B" on the gauge and a shape for tricuspid cusps (**II.**) indicated by a "T" on the gauge. The intended commissure is marked by the two notches on the side **(1).** The lower notch marks the intended vertical midline (**2**) of the gauge. To provide better orientation, additional horizontal and vertical lines are applied to the AV cusp. The number printed on the gauge indicates the size. The individual sizes and measurements are listed 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 shape 45°C ± 5°C.

	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!

8) Required accessories

No accessories are required for using the gauges for AV cusps.
Gauges are stand-alone instruments and therefore a combination with other products is not intended.

9) Assembly

No assembly is necessary for gauges for AV cusps´.

10) Disassembly

No disassembly is necessary for gauges for AV cusps.

11) Obligation to report serious incidents

The user is obliged to report serious incidents relating to the medical device to the manufacturer and the competent authority of the Member State where the user is registered.

Symbols

In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:

 Manufacturer	 Follow the Instructions for Use	 Warning
 Article number	 Batch code	 Serial number
 CE labeling	 CE labeling	 Oil can for points to be lubricated

To contact the manufacturer		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Tel.: 06188-957440 Fax: 06188-957445 E-Mail: info@fehling-instruments.de www.fehling-instruments.de	CE