FEHLING gauges

Chordae gauge and knot assistant

MNV-1	1.5 x 9 x 240 mm
MNV-4	15-40 x 230 mm
MNV-7	15-40 x 350 mm
MNV-9	3-35 x 200 mm, pediatric

Gage for aortic valve cusps

MSS-1V	200 mm
MSS-2V	200 mm, smaller version
MSS-3	200 mm, medium version

Ruler

MNV-0	0-50 mm/160 mm

HOLUBEC anterior leaflet gauge

MSS-5	8x40/360 mm

Component for caliper for aortic valve cusp (optional)

ZDS-6	Lock nut for MSS-1V/MSS-2V/MSS-3

This instrument or medical device is supplied non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).

The gauges may only be used, prepared, and disposed of by qualified medical personnel!

The gauges are intended for reuse.

1) Intended purpose

Test instruments are intended for the approximate comparison or comparison of diameters, distances, shapes and volumes or for checking/simulating the presence of such features. These include, for example,

- compatibility tests of hollow bodies (e.g. blood vessels, intestines) for anastomoses
- as an auxiliary body for reconstructing the aortic valve to map differences in height of the free edge of valve cusps
- as spacing 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 in accordance with 80/181/EEC, but instruments for the approximate comparison/adjustment of dimensions.

Supplementary information on the intended purpose

Duration of application: Test instruments are intended for temporary use.

Field of application: Test instruments are used for all patients where diameters, distances, shapes and volumes need to be compared and the presence of such characteristics checked or simulated.

User profile: Test instruments may only be used by medically trained specialists (e.g. medical specialists).

Application environment: Test instruments are only used under controlled environmental conditions (e.g. operating theater).

Anticipated patient population: No restrictions

2) Indications
Treatment methods in which the dimensions of hollow organs, hollow bodies, natural cavities or cavities caused by disease or injury must be determined in order to assess further treatment.

3) Contraindication
All applications that run counter to the physical and/or mechanical properties of the individual test instrument model are considered contraindicated. There are no generally valid contraindications for the use of test instruments. Nevertheless, attention must be paid to increased risks that could arise from the anatomical and physiological conditions as well as the clinical picture of the patient. Known nickel and/or titanium intolerances.

4) Possible side effects	
The following side effects are described in the medical literature, which may also occur during the intended purpose of the instruments: - Infections - Wound healing disorders	
⚠	Medical devices may contain chromium and/or nickel, for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use	
The gauges are supplied non-sterile and must be cleaned and sterilized by the user before initial use and before each subsequent use. (see chap. *6) Reprocessing*).	
⚠	A safety inspection must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see chap. *6) Reprocessing* under *"Maintenance, inspection and testing"*).
⚠	Handle the gauges with care during storage, transport, and cleaning! Avoid blows and localized stress on the gauges to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!

6) Reprocessing	
⚠	The medical device must be prepared before use. Before reprocessing, it must be risk-assessed according to the RKI guidelines (non-critical/semicritical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for preparation must be complied with.
⚠	The respective national regulations for the treatment of instruments used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants must be observed.

⚠	The instruments may only be used, prepared and disposed of by qualified medical personnel.
⚠	Handle the instruments with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the instruments in order not to cause any possible consequential damage! Do not overload functional parts!
⚠	Do not clean CERAMO instruments (recognizable by their black-brown surface) using oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these procedures leads to the destruction of the titanium-containing CERAMO coating after some time due to the dissolution of titanium.

Limitations during reprocessing	Frequent reprocessing has little effect on the label of the instruments and does not impair the function of the instruments. The end of the product's life is normally determined by wear and damage caused by use (e.g. damage, illegible labeling, functional failure - see also *"Maintenance, inspection and testing"*). When used and reprocessed properly, the instruments have been shown to withstand at least 500 processing cycles.
General information on reprocessing	Reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". For validation, the recommended reprocessing agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Automated preparation is preferable to manual cleaning because it provides a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical material changes or material damage, such as corrosion, fractures or premature aging.
Pre-treatment at the point of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and medication residues are removed from the instruments with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for machine cleaning. Once the instruments have been pre-treated, visual inspections must be carried out to ensure that they are complete. The instruments must be transported from the place of use to the place of preparation in such a way that neither users, 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	It is recommended that the instruments be cleaned immediately after use, as dried residues are difficult to remove from hard-to-reach places. Do not place in NaCl solutions (otherwise risk of pitting or stress corrosion cracking).

	Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See chap. *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse the instrument in disassembled condition under cold running water (drinking water quality, < 40 °C) until all visible soiling has been removed. Use a soft brush (not a wire brush!) to remove stubborn dirt. • Cavities, gaps, slits and lumen must be rinsed intensively (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Soak the products for 10 – 30 minutes in a solution containing 0.5 – 2 % Neodisher® MediClean forte with water (drinking water quality, < 40 °C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be observed. • Make sure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). • Rinse the instrument for 1 minute under cold demineralized water (see *"General information on reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ disinfection	If possible, a washer-disinfector that uses thermal disinfection and complies with DIN EN ISO 15883 is preferable.
Cleaning: Machine	Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert)

	Preparation: • Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. • If applicable, relax springs • Make sure that all cavities are completely flushed out, including the inside. • Make sure that no areas are left unwashed. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector. Procedure/parameters: • 3 minutes pre-rinse with cold water (drinking water quality, < 40 °C) • Emptying • 10 minutes cleaning with a solution of 0.5 – 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C • Emptying • 2 minutes rinsing with water (drinking water quality, < 40 °C) • Emptying • 1 minute rinse with cold demineralized water (< 30 °C) • Emptying • 5 minutes thermal disinfection with demineralized water (> 90 °C) • 30 minutes drying (90 °C) After machine cleaning, cavities, blind holes, etc. in particular have to be inspected for visible dirt. If necessary, repeat the cycle or clean manually.
Cleaning: Manual	Validated procedure: Equipment: Basin Soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) Procedure/parameters: • If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. • Operate moving parts, if any, through their full range of movement. • Clean the instruments with a soft brush (not a wire brush!) until no visible contamination remains. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). Ultrasonic cleaning: • 10 minutes sonication at < 40 °C with 0.5 – 2 % detergent solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar).

	• Rinse the instruments with water (drinking water quality, < 40 °C) for at least 10 seconds. • Deionized water (< 40 °C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • After cleaning, immerse the products for 5 minutes in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med AF). Ensure that all surfaces are wetted with the disinfectant. If necessary, move mobile 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 necessary, move mobile parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Then dry with suitable compressed air in accordance with RKI recommendations. Pay particular attention to drying areas that are difficult to access.
Assembly	See chap. *9) Assembly*
Maintenance, inspection and testing	For instruments with moving components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such points may also be indicated by an oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to stiffness and impair the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). If applicable, check the locking mechanisms. All instruments: Visually inspect for damage and wear using a magnifying lamp. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments whose labeling is no longer legible must be sorted out and cleaned and disinfected before being returned to the man-

	ufacturer. Repairs may only be carried out by the manufacturer or workshops authorized 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 in the standard hospital scrap metal disposal system. In this case, especially for surgical instruments with pointed or sharp edges, it is important to ensure safe storage in a closed, puncture- and break-proof disposable container. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into trays provided for this purpose or place them on all-purpose sterilization trays. A suitable method must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance according to DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended limit values for the ingredients of feed water and steam condensate are defined in 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 minutes Drying time: 20 minutes When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see appliance manufacturer's instructions).
Storage	In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 1607 and DIN 58953 series. Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage). If applicable, always store instruments in a tension-free state. This helps to prevent premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are mainly made of steel. These must be cleaned before disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care should be taken to ensure that any pointed or sharp edges are protected.
The instructions listed above have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The person carrying out the preparation is responsible for ensuring that the preparation actually carried out with the equipment, materials and personnel used in the preparation facility achieves the desired result. This requires verification and/or	

validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for effectiveness and possible adverse consequences.

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

7) Configuration and application

The gage for aortic valve cusps is a three-part instrument with a sliding element. It consists of a screw handle, gauge body and slider. An optional lock nut (ZDS-6) can be fitted to the gage for aortic valve cusps.

The Chordae gauges are instruments with a movable inner axis with a locking knob and two distance or depth sensors that can be moved against each other.

The measuring rod and the CERAMO HOLUBEC anterior leaflet gauge have a simple design with a proximal handle section and scaling at the distal end.

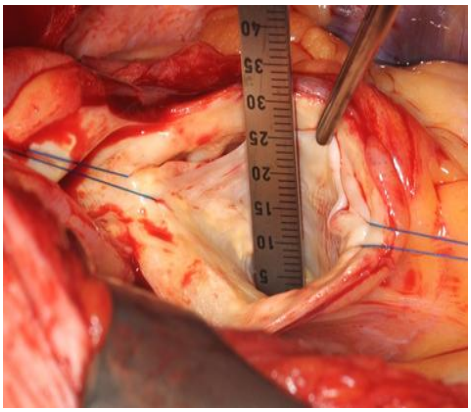
⚠	Only use flawless and sterilized products!
⚠	Before inserting the test instruments, ensure that the surgical field has been prepared accordingly.
⚠	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of test instruments depends on the anatomical and physiological conditions as well as the area of application. It is important to ensure that the test instruments used are the right size and geometry as well as sufficiently stable.

During the application

<u>Ruler</u>

The measuring rod is used to determine the geometric height of the AV cusp.

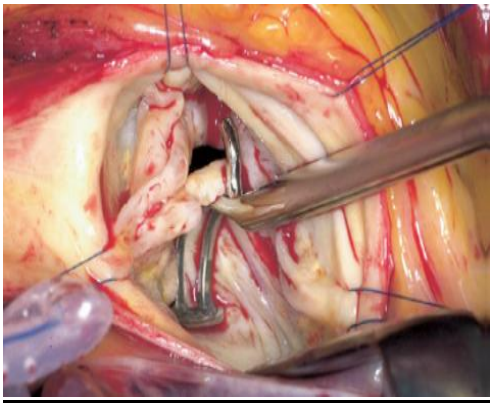
The adjacent in-situ illustration shows how the cusp is raised in the center between the commissures and the height is assessed with the measuring rod.



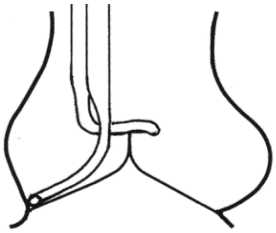
Chordae gauges

When using, insert the gage into the OP field in the area of the parameter to be checked. Then push the movable inner axle until the two distance or depth sensors touch the end points of the test section without pressure. With the length gage, the inner lever is released by pressing the locking button and can then be moved.
The dimension of the tested parameter is shown on a scale at the proximal end of the instrument; additional information that is not required for the intended use.

Gage for aortic valve cusps



To measure the effective height of the free AV edge, the inner part of the gage is moved towards the handle by turning the handle counterclockwise until the mark in the center of the instrument is at 9 - 10. The instrument is then gently placed on the bottom of the pocket with its semicircular distal double bracket and positioned on the free edge of the pocket to be measured by turning the handle of the distal horizontal bracket of the inner piece. The value displayed in the marking field is a reference to the effective height of the free edge. This process is repeated for all pockets of the flap.



HOLUBEC anterior leaflet gauge

The HOLUBEC anterior leaflet gauge is used to determine the depth of the large cusp of the mitral valve. The medical device is inserted through an incision between the ribs on the opposite side of the chest and moved towards the mitral valve.

8) Required accessories

No accessories are required to use the gauges.
The gauges are stand-alone instruments. Therefore, no combination with other products is intended.

9) Assembly

Please follow the relevant assembly instructions for fitting the gauges.
List of the assembly instructions:

Gage for aortic valve cusps (MSS-1V, MSS-2V and MSS-3) ..... M 03V
Chordae gauge and knot assistant (MNV-1, MNV-4, MNV-7, MNV-9) ..... M 28

No assembly of the ruler (MNV-0) and the CERAMO HOLUBEC anterior leaflet gauge (MSS-5) necessary.

10) Disassembly	
To dismantle the gauges, please follow the corresponding assembly instructions (see chap. *9) Assembly*).	
⚠	Place small parts in suitable containers (e.g. needle box) for storage and reprocessing!

11) Obligation to report serious incidents
The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.

Symbols		
If displayed on the medical device, the label of the medical device or the instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meaning:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalog number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points that require lubrication	CE CE marking	

Contact the manufacturer	
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