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

Ruler

MNV-0	0-50 mm/160 mm

Caliper for aortic valve cusp

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

Components for caliper for aortic valve cusp (optional)

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

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 gauges!
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.

4) Possible adverse effects

In medical literature, the following adverse effects are described that can possibly occur during the intended use of the instruments.

- Infections
- Impaired wound healing

5) Prior to use

FEHLING INSTRUMENTS gauges 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).

⚠	Perform a safety check prior to each use. Check for cracks, fractures or mechanical malfunctions and missing components (see also Maintenance, Checking and Testing).
⚠	Gauges must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to 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!

⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and 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 or the titanium-containing CERAMO® coating after some time. Similarly, instruments with Propylux plastic handles should not be cleaned with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.
Limitations on re-processing	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 town water of drinking 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) <u>Preparation:</u> • 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. <u>Procedure/Parameters:</u> • 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	<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 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). <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 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 steel or titanium. 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

The gauge for aortic valve cusps is a three-part instrument with a sliding element. It consists of a screw handle, gauge body and slider. A counter nut (ZDS-6) can be installed as an option in the gauge for aortic valve cusps.
Chordae gauges are instruments with a movable inner axis with a locking button and two distance or depth probes that can be moved relative to each other.
The ruler is of a simple design with a proximal handle part and scale at the distal end.

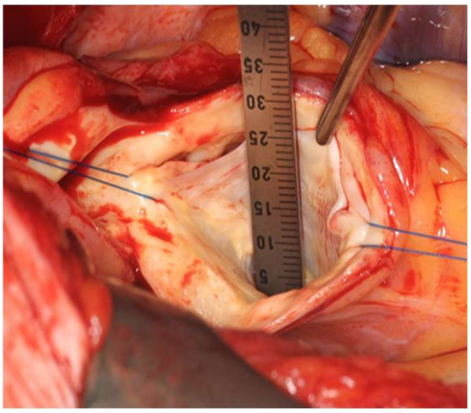
⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the gauge, ensure that the surgical field has been prepared accordingly beforehand.

During use

Ruler

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

The in-situ illustration opposite depicts how the cusp is erected in the middle between the commissures and the height is assessed with the ruler.

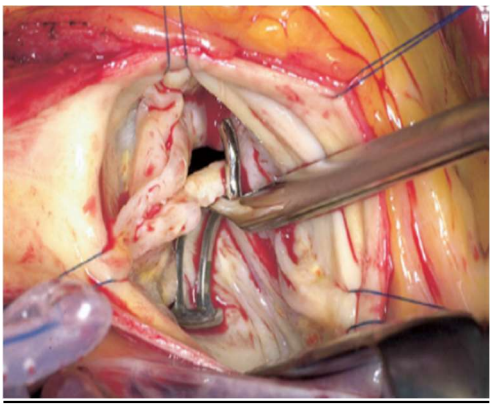


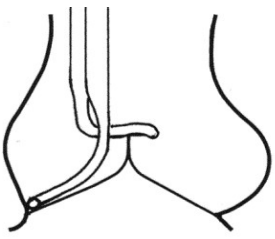
Chordae gauges

When using, insert the gauge into the surgical field in the area of the parameter to be examined. Then push the movable inner axis until the two distance or depth probes touch the end points of the distance to be tested without applying pressure. With the length gauge, the inner lever is released by pressing the locking button and can then be shifted.
The dimension of the tested parameter is indicated on a scale at the proximal end of the instrument; this is additional information that is not necessary for the intended use.

Caliper for aortic valve cusp

To measure the effective height of the free AV margin, the inner part of the gauge is moved in direction of the handle by rotating the handle counterclockwise until the mark in the middle of the instrument is at 9 - 10. Then the instrument is gently placed on the bottom of the pocket with its semicircular distal double bracket and positioned on the free margin of the pocket to be measured by rotating the handle of the distal horizontal bracket of the inner part. The value displayed in the check field relates to the effective height of the free margin. This procedure is repeated for all pockets of the valve.





8) Required accessories

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

9) Assembly

To assemble the gauges please follow the corresponding assembly instructions.
List of assembly instructions:

Caliper for aortic valve cusp (MSS-1V, MSS-2V und MSS-3) M03V
Chordae gauge and knot assistant (MNV-1, MNV-4, MNV-7, MNV-9) M28

Assembly of the ruler (MNV-0) is not necessary.

10) Disassembly

To disassemble the gauges please follow the corresponding assembly instructions (see 9) Assembly).

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
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

To contact the manufacturer:

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CE