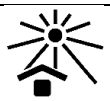
Contents

1 Symbol descriptions

Symbol	Definition
	CE-labelling
	Attention
	Validated Parameters
	Manufacturer
	Lot-description
	Reference code
	Medical device / FDA Prescription device
	Medical device
	Non sterile
	Keep away from sunlight
	Dry storage required
	(Electronic) instrucion for use

2 Introduction

Our products are exclusively intended for professional use by appropriately trained and qualified personnel and may only be acquired by them.
By purchasing this instrument, you are now the owner of a high-quality product whose use and correct handling are described in the following. In order to minimize possible risks to patients and users, please observe these instructions carefully. Use, disinfection, cleaning and sterilization may only be performed by suitably trained specialist personnel.

3 Scope

The use of meassuring Instruments is mainly in the following areas:

Dynamometer; Neurological Pinwheel; Marking instruments; Percussion Hammers; Tuning forks: The instrument is used in various examinations. The examination may only be carried out by suitably trained and qualified specialist personnel.

Finger-Goniometer; Goniometer(Flexometer); Testing and measuring instrument; Laser-Instruments; Width ruler; Depth ruler: The instrument is used in various surgical procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Pelvimeters: The instrument is used for surgical procedures in gynecology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Uterine Sounds: The instrument is used in various procedures for histopathological examinations. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Marker graduated: The instrument is used for surgical procedures in ophthalmology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Measuring probe: The instrument is used during ENT procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

3.1 Intended Use

Finger-Goniometer; Goniometer(Flexometer); Testing and measuring instrument: An instrument for comparative measurements of the degree of rotation, e.g. from the eyeball or shaft of a long bone. The instrument is not calibrated and can be reused. The instrument is intended for transient use.

Dynamometer: A product to investigate and determine the level of vibration needed to determine the vibratory threshold of perception on the skin anywhere on the body. It is used for neuropathological diagnoses, early detection of dysfunction, e.g. in the case of suspected diabetes, patients with neurotoxic mixtures, unfavorable working conditions or car accidents. It is a reusable product.

Neurological Pinwheel: A manual sensiometer for determining the tactile sensation of a patient by distinguishing the distance of rods mounted on a disc. It typically consists of a disc with protruding rods that differ in diameter. The disc is mounted on a rotating pin. The disc is manually moved on the skin of the patient via an integrated handle. The rods can be pointed to test the pain sensation. It is a reusable product.

Pelvimeters: A medical device for comparison measurement of the pool size. These are usually the inner / outer dimensions of the pelvis, its diameter and its capacity. It is commonly used in gynaecological procedures / procedures. The instrument is not calibrated and can be reused. The instrument is intended for transient use.

Laser-Instruments; Width ruler; Depth ruler: A surgical instrument used to determine the depth of a cavity (usually a drilled hole). It usually consists of a movable (sliding) central piece (a pin) whose point is inserted into the cavity; if the tip touches the bottom of the cavity, the value can be read

visually on a marked scale on the side of the instrument. It is a comparative measuring instrument and is often used to determine the depth of drill holes in bones so that the surgeon can determine the length of bone screws to use thereafter. It is made of corrosion-resistant materials (eg: stainless steel, titanium). It is a reusable instrument intended for transient use.

Marker graduated: An ophthalmic instrument consisting of two legs pivotally anchored at a point used to measure the diameter, length, angle and thickness of the eye. The instrument is not calibrated and is used for comparative measurements. It is a reusable instrument intended for transient use.

Marking Instruments: An instrument, usually in the form of a suitable pen containing non-toxic ink, used to demarcate areas on a patient's skin (e.g., incisions and for dermatological applications). This is a reusable instrument.

Percussion Hammers: A surgical hand instrument for gently tapping the reflex points (e.g., near the knee, ankle). It is composed of a handle and a shaft, usually made of stainless steel. Its head may be annular, wedge-shaped or dome-shaped and made of a soft material (e.g., rubber or plastic). Some designs may be provided with a spike, brush or other interchangeable components for neurological examinations. It is a reusable instrument.

Tuning forks: A U-shaped instrument, usually made of stainless steel, with a handle at the base of the "U". The vertical forks of the "U" are cut to a specific length to produce a sound at a particular wavelength when the "U" is struck against a hard object, usually rubber. It is typically used during an ENT examination to test the auditory sharpness. It is a reusable instrument.

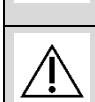
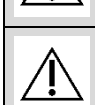
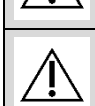
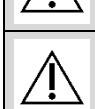
Uterine Sounds: A instrument for probing and measuring the internal length or depth of the uterus, cervix and vagina. It is a narrow, hollow or solid instrument made of steel or plastic in a cylindrical shape and is usually provided with length gradations on its working end. It is produced in different designs and elasticities. It is a reusable comparative measurement instrument.

Measuring probe: A product / instrument used for comparative measurement in clinical use, e.g. inner and outer diameters, lengths, depths or thicknesses to measure. It is a non-calibrated product that is reusable and intended for transient use.

3.2 Contraindications

No contraindications are known.

4 Warning

	Medical products are delivered in a non-sterile condition and must be cleaned, disinfected and sterilized prior to their initial use.
	The use of faulty instruments is in principle forbidden and they have to go through the whole cleaning process before return.
	Please take into consideration that through higher power a bigger damage of the tissue can result: f.e. on forceps: the power at the end of the jaw is higher than at the tip of the jaw
	Please observe the additional information enclosed with the products.
	Remove all protective sleeves and films prior to first using or preparation for use.
	The safe combination of different products or of products with implants must be reviewed prior to clinical application by the user.
	Avoid improper throwing or dropping of instruments
	Avoid mechanical overstressing of the instrument beyond the structural design, this can lead to breakage and deformation!
	A visual inspection of the instrument for damage and contamination must be carried out before each use!
	To prevent all contact corrosion, instruments with damaged surfaces must be separated immediately.
	If the products are used on patients with transmissible spongiform encephalopathy or HIV infection, we decline any responsibility for their reuse.
	After ophthalmical use, please pay attention to water quality during treatment (according to the specifications of AAMI TIR34 and the recommendations of the Rober-Koch-Institute on preparation of medical devices)!
	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5 Handling

The type of treatment must be determined in each individual case by the surgeon in cooperation with the internist and the anaesthetist.
For operational use in various surgical disciplines must be done by appropriately trained and qualified personnel.

6 Preparation

The person in charge of preparatory treatment is responsible for ensuring that the treatment is duly carried out using the relevant equipment, materials and personnel in the treatment facility and so achieves the desired result. This necessitates validation and routine monitoring of the process used. We urge you to take note of the national regulations dealing with instrument preparation.

The validated parameters refer to reusable surgical instruments. The validated parameters should also be observed for the other products described, unless a different procedure is explicitly described.

Marking instruments cannot be prepared.

6.1 Reutilization restrictions

Frequent repeat preparatory treatment has minimal effects on the product. The end of the product life is normally determined by wear and damage due to use.

6.2 Information on instrument preparation

- Use cleaning and/or disinfection agents with a pH-value within 9-10. Please observe manufacturer instructions regarding dosage, exposure time and renewal of solutions.
- Do **not** use hard brushes (e.g. metal brushes or metal sponges) or coarse abrasive cleaners.
- Never leave instruments in cleaning or disinfection agents for longer than the specified time.
- Only used demineralized water for rinsing.
- Rinse and dry carefully through channels and pipes.
- Sensitive instruments must be cleaned in a storage or clamping fixture.
- Observe manufacturer instructions of cleaning – and sterilizing equipment.

6.3 Preparation at the place of use

Directly after using remove coarse dirt of the instruments and rinse out the working cannulas. Do not use fixing agents or hot water (> 40°C), as this results in residues becoming fixed and can affect the success of the subsequent cleaning operation
Dismantle and/or open instruments as far as possible. Within short time after use the instruments clean the instruments for reducing a drying of the residues.
This enables an easier cleaning. If instruments come into contact with corroding medicines or cleaning agents, wash these up with water immediately after use.

Longer drying times, e.g. for dry disposal are not validated and therefore not recommended.

The drying time during validation was 1 hour.

6.4 Ultrasound bath (optional)

All instruments must be opened, dismantled and any cavities rinsed through.
Place instruments in the screen basket in such a way that overlaps and contact between instruments are avoided. Add cleaning agent to the water and adjust the temperature of the solution in line with the cleaning agent manufacturer's instructions.
The cleaning in the ultrasound bath should be at 35-40 kHz, 5 minutes at least.

To validate cleaning in an ultrasonic bath, the test items were ultrasonically treated in Neodisher Mediclean forte 0,5 % for 5 minutes.

Subsequently rinse instruments including all cavities before cleaning and disinfection.
Medicine products which are possessing a bad ultrasound transmission, e.g. soft materials are not usable for the ultrasound bath.

6.5 Manual cleaning

Since mechanical processes can be standardizied, reproduced and therefore validated, mechanical cleaning/disinfection should be preferred to manual processes.
Manual cleaning and disinfection process ist not validated and therefore needs to be validated additionally by the end user.

6.6 Mechanical cleaning

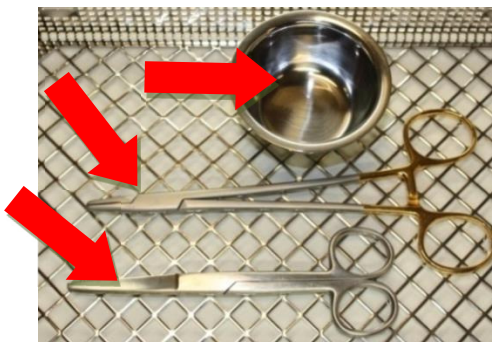
On the basis of international standards (EN ISO 15883) and national directives, only validated machine cleaning and disinfection methods may be used. For the mechanical cleaning we recommend a standard programme for surgical instruments, f.e. instruments from Miele.

Only completely deminieralized water should be used for cleaning, neutralisation and rinsing, in accordance with the „Guidance Complied by the DGKH (Germany Society for Hospital Hygiene), DGSV (German Society for Sterile Supply) and AKI (Working Group on Instrument Reprocessing) for the Validation and Routine Monitoring of Automated Cleaning and Thermal Disinfection Processes for Medical Devices as well as Advice on Selecting Washer-Disinfectors“ (which refers to DIN EN ISO 15883-1 Point 6.4.2)

Flexible (complex) instruments with invisible surfaces must be pre-cleaned manually before mechanical cleaning.
We recommend for all push shafts, -and pipe shafts instruments and instruments whose surfaces are on top of each others during the cleaning (f.e. bone forceps and gouge forceps) a manually pre-cleaning for an optimal cleaning result without residues.

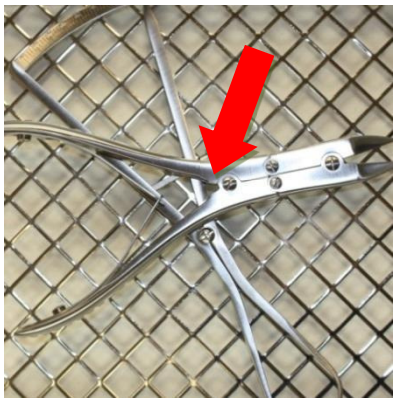
Observe the following by loading:

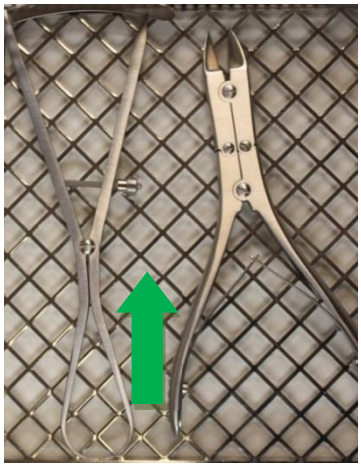
- Place the dismantled/opened instruments securely in the tray.
- Instruments with openings and gaps have to be faced down with the opened side so that they can be cleaned and no water of the cleaning process is collecting inside them. If available use balanced devices for rinsing



- Place the instruments with joints in an opened position into the cleaning,-and disinfection machine.

- If needed use an adapter for the cleaning
- Do not overload trays, avoid creating any overlaps.





Preliminary rinsing (cold, if applicable fully demineralized water without additives) is followed by chemical. The chemical cleaning should take place at **40°C -60°C** for at **least 5 minutes**.

We recommend products with a **pH-value within 9-10,** e.g. Neodisher MediClean forte from Dr. Weigert. The cleaning agents used should be selected depending on the material and properties of the instruments and in accordance to national regulations: If there is a high chloride concentration in the water, pitting and tension crack corrosion can occur on the instruments. The occurrence of this type of
corrosion is minimized by using alkaline cleaning agents and demineralized water. By adding an acid-based neutralization medium, the rinsing off of alkaline cleaning agent residues is facilitated during the first intermediate rinsing process (warm or cold water).

In order to prevent the formation of deposits, it is advisable to use neutral cleaners where the water quality is unfavourable. After the second intermediate rinsing process, thermal disinfection takes place.
The thermal disinfection should take place at temperatures of between **80 and 95°C**, with an **exposure time as outlined in EN ISO 15883**.

After the finishing of the programme take the good out of the machine because corrosion can arise if the instrument remains in the machine.

Parameters used for the validation of preparation	
Pre-rinsing	1 minute with cold tap water
Cleaning	Temperature: 55 °C
	Soaking Time: 5 minutes (worst case)
	Neodischer Mediclean forte 0,4% (worst case)
Neutralization	Temperature: cold DI water
	Soaking Time: 2 minutes
	Neodisher Z 0,1%
Post-rinsing	2 minutes with cold DI water
Disinfection	Temperature: 90 °C (A_0 3000)
	Soaking Time: 5 minutes

6.7 Drying

Ensure adequate drying by the cleaning and disinfection device or using other suitable measures.

Drying was omitted in the validation (worst case condition)

7 Maintenance, inspection

After cooling to room temperature, the instruments must be visually inspected for protein residues and other contamination, paying particular attention to cavities, blocks, inclusions, pipes, and other inaccessible areas. Instruments which are not free of residues must be returned for a complete retreatment process.

Carry out the functional check mentioned above. Instruments with stains, which are blunt, bent, no longer function or which are otherwise damaged must be segregated!
To help identify faulty instruments that need to be sorted out, we recommend the brochure "Instrument Reprocessing" from the Working Group “Instrumenten Aufbereitung”. This includes Chapter 8 " Checks and Care" and Chapter 12 " Surface Changes: Deposits, Discoloration, Corrosion, Aging, Swelling and Stress Cracks".

7.1 Functional check

A newly purchased product must be subjected to a thorough visual and function check after its delivery and before each use.
Products must be checked for irregularities. Paying attention to cracks, fractures and the occurrence of corrosion.

If there are joints, the instruments should be oiled with a care product before the functional test. We recommend a medical white oil based on paraffin oil.
Check instruments with joints for ease of movement. Carry out a function check in accordance with the intended application of the instrument.
Defective products must not be used and must have undergone the complete preparatory treatment process again before being returned.

8 Sterilization

Prior to sterilization, products must undergo cleaning and disinfection, be rinsed off without residue using demineralized water and subsequently dried. HEBUmedical recommends using a validated steam sterilization process (e.g. sterilizer in compliance with EN 285 and validated in accordance with DIN EN ISO 17665-1).
On using the fractionated vacuum method, **sterilization** must be performed with at least **134°C (USA 132° C)** with a **minimum dwell period of 3 minutes.** Vacuum drying must then be carried out for at least 20 minutes.

Parameters used for the validation of steam sterilization	
Prevacuum	3 times
Sterilization temperature	132 °C
Sterilization time	1,5 minutes (half cycle method)
Drying time	20 minutes

The vapour must be free of ingredients, recommended limiting values of feed water and vapour condensate are determined through EN 285.

Other sterilization processes are compatible but not validatet from HEBUmedical.

When loading, observe the recommended total weight. After the sterilization, check the sterile product packaging for damage, and inspect the sterilization indicators

8.1 Packaging

Compliant packaging of products for sterilization in line with ISO 11607. Packaging used must be suitable for the instruments and protect them from microbiological contamination during storage. The seal must not be under tension. HEBUmedical recommends container or hospital common sterilization paper/film packagings for sterilized packaging.

During validation the instruments were packaged in hospital common sterilization packagings (paper/film packagings) and steam sterilized.

9 Lifetime

The steam sterilization procedure was validated by laboratory tests. The products were sterile validated at a pre-vacuum of at least 5min duration and a temperature of 134°C for a lifetime of 50 cycles.

You can continue to use the instruments at your own responsibility over this cycle value if the tests described in chapter 7 have been successfully completed.

10 Storage

Store products in a dry, clean and dust-free environment at moderate temperatures from 5°C to 40°C. Protect from the effects of the sun’s rays and artificial light.

11 Warranty / Repair

Our products are manufactured from high-grade materials and carefully checked prior to dispatch. However, even if used properly in accordance with their intended purpose they are subject to a greater or lesser degree of wear depending on their intensity of use.

This wear is technically induced and unavoidable.

Should faults occur independently of wear, please contact our customer services. Defective products should no longer be used.

They must undergo the complete preparatory treatment process before being returned.

12 Manufacturer and servicing address

Should you require the instructions for use in paper form, please use the contact details below. The instructions for use in paper form will be made available to you within seven calendar days of receipt of the request.
Alternatively, you can print out the electronic instructions for use yourself.

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