















Contents

1	Symbol descriptions	16
2	Introduction	16
3	Scope	17
3.1	Intended Use	17
3.2	Contraindications.....	19
4	Warning	20
5	Handling	20
6	Preparation.....	21
6.1	Reutilization restrictions	21
6.2	Information on instrument preparation	21
6.3	Preparation at the place of use	21
6.4	Ultrasound bath (optional).....	21
6.5	Manual cleaning	22
6.6	Mechanical cleaning.....	22
6.7	Drying	24
7	Maintenance, inspection	24
7.1	Functional check	24
8	Sterilization.....	25
8.1	Packaging.....	25
9	Lifetime.....	25
10	Storage.....	26
11	Warranty / Repair	26
12	Manufacturer and servicing address.....	26

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) instruction 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 Scissors is mainly in the following areas:

Nail Scissors; Nail Nippers; Nail Splitting Scissors: The instrument is used for nail and foot care.

Enterotomy Scissors: The instrument is used during rectal procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Tissue Scissors, Anatomy Scissors; Operating Scissors; Fine Operating Scissors; Fine Scissors; Fine Tenotomy Scissors; Incision Scissors; Cartilage Scissors; Dissecting Scissors; Scissors with TC; Abdominal scissors; Vascular Scissors; Lobectomy Scissors; Micro Scissors; Tenotomy Scissors: The instrument is used in various surgical procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Ligature Scissors: The instrument is used for surgical procedures on the spine. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Secondary Cataract Scissors; Fine eye Scissors; Iris Scissors; Corneal Scissors; Iridectomy Scissors: The instrument is used for surgical procedures in ophthalmology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Umbilical Scissors: The instrument is used during childbirth. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Operating and gynaecological Scissors; Perineum Scissors; Cephalotomy Scissors; Uterine Scissors: The instrument is used for surgical procedures in gynecology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bone and Rip Shears: The instrument is used in various surgical procedures in orthopedics. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Scissors for plastic surgery: The instrument is used in plastic surgery. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Plaster-of-paris shears; Bandage Scissors: The instrument is used in various procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Tonsil Scissors; Septum Scissors; Nasal Scissors; Wire cutting scissors: 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

Nail Scissors; Nail Nippers: An instrument for cutting fingernails and toenails. It can be bent to match the natural curvature of human nails. The toenail models are usually made more robust to cut thick toenails. The instrument consists of two movable branches, with holes for fingers and thumbs in the handle, and cuts by closing the leaves over the nail. It is a reusable instrument.

Enterotomy Scissors: A surgical instrument for cutting tissue during a rectal procedure. It consists of two moving leaves, usually with holes for the fingers. The distal end of the leaves can be designed differently. It is a reusable instrument.

Tissue Scissors, Anatomy Scissors: A surgical instrument for cutting tissue during a surgical procedure. It consists of two movable blades, usually with ring handles for the finger and thumb. The distal end of the blades may have different designs. It is a reusable instrument and intended for transient use.

Nail Splitting Scissors: A instrument for cutting and dividing a finger or toe nail, usually for removal. It consists of two swiveling branches with ring handles for thumb and fingers. The lower leaf is forced

under the nail to be cut and the leaves are closed. These cutting leaves are usually very short, pointed and robust. It is a reusable instrument.

Operating Scissors; Fine Operating Scissors; Fine Scissors; Fine Tenotomy Scissors: An instrument for cutting e.g. tissue, clothing or seams. It consists of two movable branches, with holes for fingers and thumbs in the handle, and cuts by closing the leaves over the material to be separated. The working end can have different designs. It is a reusable instrument intended for transient use.

Operating and gynaecological Scissors; Perineum Scissors; Cephalotomy Scissors; Uterine Scissors: A surgical instrument for performing tissue sections in the area of the female reproductive system during gynaecological procedures. It consists of two movable blades, which are usually provided with finger and thumb ring handles. The distal end of the leaves can be designed differently. It is a reusable instrument intended for transient use.

Vascular Scissors; Lobectomy Scissors: A surgical instrument for cutting tissue in the thoracic cavity. It consists of two movable blades, which are usually provided with finger and thumb ring handles. The distal end of the leaves can be designed differently. It is a reusable instrument intended for transient use.

Incision Scissors; Cartilage Scissors; Dissecting Scissors; Scissors with TC; Abdominal scissors: A surgical instrument for cutting tissue by dissection and/or cutting. The scissors consist of two movable blades and handles with rings for fingers and thumbs and cut by shearing movements (the blades cut when the sharp blades meet when closed). The instrument is usually made of stainless steel and is available in a variety of sizes and styles. In some designs, the cutting edges may be reinforced with carbide. It is a reusable instrument and intended for transient use.

Ligature Scissors: A surgical instrument for cutting or removing sutures. It consists of two leaves, usually with finger and thumb ring grips. The distal end of the leaves can be designed differently. It is a pair of scissors for general use, with some surgical scissors having a particular use. It is a reusable instrument intended for transient use.

Umbilical Scissors: An obstetric surgical instrument for cutting the umbilical cord after birth. It consists of two connected branches with a thumb and finger ring grip which cut by a shearing motion (i.e., the leaves intersect when the sharp edges meet on closing). It is usually made of stainless steel and is available in different designs and sizes. It is a reusable instrument intended for transient use.

Tonsil Scissors: A surgical instrument for cutting tonsillar tissue. It consists of two movable scissor blades, usually with holes for fingers and thumbs in the handles. The distal end of the scissor blades can have different designs. It is a reusable instrument intended for transient use.

Scissors for plastic surgery: A surgical instrument used to cut tissue during cosmetic surgery. It consists of two moving leaves that are usually provided with finger and thumb grips. The distal end of the blades can have different shapes. This is a reusable instrument.

Plaster-of-paris sheares: A large, scissor-type, hand-held instrument whose leaves, distal to the end, merge into various mouth shapes suitable for cutting thick layers of plaster or synthetic material used for a plaster cast on various body parts. The tip of one of the distal blades of the scissor-type cutting mechanism is typically rounded at its lower edge to prevent injury to the patient when cutting the cast. The product is usually made of stainless steel and usually has a spring mechanism that helps to open the mouth. It is a reusable instrument intended for transient use.

Bandage Scissors: An instrument for cutting dressings. It consists of two movable branches, with finger and thumb holes in the handle. The distal end can have different designs and is usually rounded for safety. The scissors are typically made of stainless steel and the blades can be reinforced with carbide. It is a reusable instrument.

Wire cutting scissors: A surgical instrument shaped like a pair of scissors, for ENT surgery, designed to cut the wire designed to replace the ossicle replacement. The blades are stronger than ordinary scissors to allow for the forces required to cut surgical wire. It is a reusable instrument intended for transient use.

Bone and Rip Shears: A surgical tool to cut bone or cartilage tissue during orthopedic surgery. It consists of two movable blades, which are usually provided with finger and thumb ring handles. The distal end of the leaves can be designed differently. It is a reusable instrument intended for transient use.

Septum Scissors; Nasal Scissors: A surgical instrument for cutting tissue during an ENT procedure or during plastic surgery on the nose and its adjacent areas. The scissors consists of two movable blades, which are usually provided with finger and thumb ring handles. The distal end of the leaves can be designed differently. It is a reusable instrument intended for transient use.

Micro Scissors; Tenotomy Scissors: A narrow knife with a tapering blade on a narrow handle, usually for cutting tendons. This general product group is sometimes used for fine scissors for cutting tendons, which are often provided with a spring to keep the scissors open. It is a reusable instrument intended for transient use.

Corneal Scissors; Iridectomy Scissors: A surgical eye instrument used to cut tissue during cataract surgery. It consists of two moving leaves, normally provided with a finger-thumb-ring handle, which cuts with a shearing function (i.e., cutting the sharpened leaves as they are closed). Typically, it is made in different designs and sizes, made of high quality stainless steel. It is a reusable instrument intended for transient use.














Secondary Cataract Scissors; Fine eye Scissors: A surgical eye instrument used to cut either front or back segment tissue during eye surgery. Typically it has: 1) two movable blades, normally provided with a finger thumb-ring handle, that cut with a shearing function (i.e., cut the sharpened blades while they are being closed); or 2) an instrument tip, with blades at the distal end, which is inserted into a suitable handle by which the blades are operated. It is typically made of high quality stainless steel and plastic, and is available in various sizes. It is a reusable instrument intended for transient use.

Iris Scissors: A surgical eye instrument used to cut tissue during eye surgery, involving the iris. It consists of two moving leaves, normally provided with a finger thumb-ring handle, which cut with a shearing function (i.e., cut the sharpened leaves while they are being closed). Typically, it is made in different designs and sizes, made of high quality stainless steel. It is a reusable instrument 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.

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 standardized, reproduced and therefore validated, mechanical cleaning/disinfection should be preferred to manual processes.

Manual cleaning and disinfection process is not validated and therefore needs to be validated additionally by the end user.

6.6 Mechanical cleaning

Based on 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.

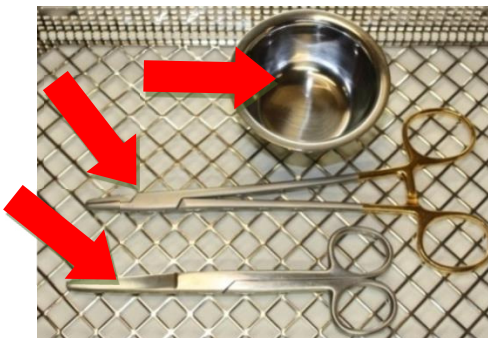
Only completely demineralized water should be used for cleaning, neutralisation and rinsing, in accordance with the „Guidance Compiled by the DGKH (Germany Society for Hospital Hygiene), DGSV (German Society for Sterile Supply) and AKI (Working Group on Instrument Reprocessing) for the Validation and 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.

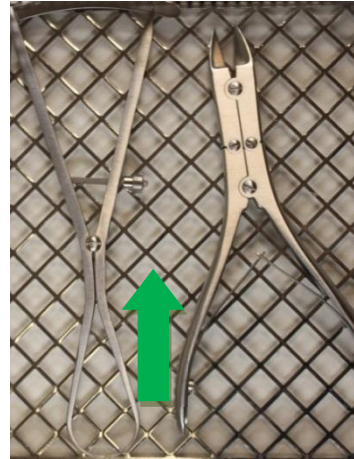
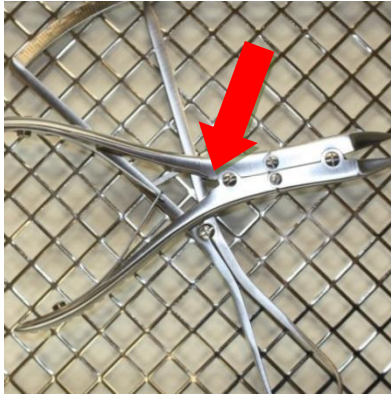
We recommend for all push shafts, -and pipe shafts instruments and instruments whose surfaces are on top of each others during the cleaning (f.e. bone forceps and gouge forceps) a manually pre-cleaning for an optimal cleaning result without residues.

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.
- 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.

V 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.

Essential tests for Scissors are among others:

- Correct opening and closing (smooth movement)
- Smooth cutting edges
- Intact tips
- No "scraping" or grinding noise when closing

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).

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.

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.

V 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 validated 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.

V 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.



HEBUmedical GmbH
Badstraße 8
78532 Tuttlingen / Germany
Tel. +49 7461 94 71 - 0
Fax +49 7461 94 71 - 22
eMail: service@HEBUmedical.de
Web: www.HEBUmedical.de





**Unser umfangreiches Sortiment umfasst
über 10 000 verschiedene Instrumente.
Besuchen Sie uns im Internet oder fordern Sie unseren Katalog an.**

**Our vast range of products covers over 10 000 various instruments.
They can be found in Internet or request our catalog.**

**Notre assortiment complet comprend plus de 10 000 instruments
différents. Vous le trouverez sur Internet. Ou bien demandez notre
catalogue.**

**Nuestro amplio instrumental consta de más de 10 000 artículos
diferentes. Usted puede visitarnos en Internet
o solicitar nuestro catálogo.**

**Il nostro assortimento comprende più di 10000 strumenti differente.
Lei ci può vistare in Internet
o chiedo il nostro catalogo**



HEBUmedical GmbH

**Badstraße 8 • 78532 Tuttlingen / Germany
Tel. +49 (0) 7461 94 71 - 0 • Fax +49 (0) 7461 94 71 - 22
info@HEBUmedical.de • www.HEBUmedical.de**