Processing Instructions Document
0001770_06 — 2025-09
EN

KURZ Instruments

Instructions for processing

KURZ Meter / Soft-CliP Hook/SteadyCrimP Forceps/KURZ Precise Cartilage Knife/KURZ Precise Cartilage Punch/ Cartilage Forceps Schimanski Design/Titanium Tweezers/Titanium Micro Closing Forceps/Cutting Forceps/Micro Scissors/Sizer OMEGA CONNECTOR/Trocar Handle/Sizer Breathe Implant àWengen/Test Weight Set / Tray TTP-VARIAC / Tray KURZ Meter / Tray KURZ Precise / Instrument Tray Cartilage Punch
Full product list inside.

CE 0124 CE

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1 About this Document

1.1 Abbreviations

- WD: Washer Disinfector

1.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

⚠ CAUTION

Non-compliance may result in light or moderate injuries or a light or moderate deterioration of the general condition of the patient, user, or a third party.

1.3 Additional Information

This document describes the processing (cleaning, disinfection, sterilization) of the products listed here [Product Codes / REF, page 3] .

This document does not replace the respective instructions for use for the products and does not apply to products other than those listed herein.

This document is available in electronic form on the manufacturer's website. If required, a printed copy of this document can be requested from the manufacturer.

Download link for the processing instructions: [1]	https://www.kurzmed.com/en/ifu/reprocessing.html
International addresses:	https://www.kurzmed.com/en/contact.html

[1] Updated on an ongoing basis.

2 Product Codes / REF

The table indicates whether the products typically come into contact with tissue during use. For products that do not come into contact with tissue, pre-treatment at the point of use and preparation for cleaning are not required.

For devices contaminated with bodily fluids, follow all processing steps.

REF	Name	Tissue contact	Product groups	CE 0124	CE
8000 100	KURZ Meter	Yes	Stapes prosthesis	+	
8000 106	Set KURZ Meter	Yes	Stapes prosthesis	+	
8000 174	Tray KURZ Meter	No	Stapes prosthesis		+
8000 127	Soft-CliP Hook	Yes	Stapes prosthesis		+
8000 188	SteadyCrimP Forceps	Yes	Stapes prosthesis		+
8000 155	KURZ Precise Cartilage Knife Set, including Tray KURZ Precise Tray Stainless Steel	Yes	Tympanoplasty Prosthesis		+
8000 105	Distance plate 1.0 mm	Yes	Tympanoplasty Prosthesis		+
8000 177	Tray KURZ Precise including Tray Stainless Steel and POM insert plate	No	Tympanoplasty Prosthesis		+
8000 124	Tray Stainless Steel	No	Tympanoplasty Prosthesis		+
8000193	Cartilage Forceps Schimanski Design	Yes	Tympanoplasty Prosthesis		+
8000 200	KURZ Precise Cartilage Punch , including Instrument Tray Cartilage Punch	Yes	Tympanoplasty Prosthesis		+
8000 176	Instrument Tray Cartilage Punch	No	Tympanoplasty Prosthesis		+
8000 136	Titanium Tweezers	No	Tympanoplasty Prosthesis		+
8000 137	Titanium Micro Closing Forceps	No	Tympanoplasty Prosthesis		+
8000 171	Cutting Forceps	No	Tympanoplasty Prosthesis		+
8000172	Micro Scissors	No	Tympanoplasty Prosthesis		+
8000 173	Instrument Tray (Tray TTP-VARIAC)	No	Tympanoplasty Prosthesis		+

REF	Name	Tissue contact	Product groups	CE 0124	CE
8000 555	Sizer OMEGA CONNECTOR	Yes	Tympanoplasty Prosthesis		+
8000 143	Trocar Handle	No	Tympanic ventilation tube		+
8000 249 - 8000254	Sizer Breathe Implant àWengen	Yes	Implant for rhinoplasty		+
800 111	Test Weight Set	Yes *	Upper Eyelid Implant		+
*Intact skin only; mechanical cleaning and disinfection is sufficient for processing.					

Table 1: Scope of this document

3 Processing

The instructions listed below have been validated by the medical device manufacturer as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process.

The fundamental suitability of the product for effective processing has been demonstrated by an independent, governmentally accredited and recognized test laboratory. To do so, the detergents and equipment listed in this manual were used and the procedure described in this manual was carried out.

It is possible to use detergents and equipment other than those listed in these instructions. In this case, the processor must ensure that the equipment used meets the respective criteria listed and that the processing achieves the desired result.

Observe the local regulations and hygienic rules of the medical office or hospital.

3.1 Warnings

3.1.1 General Information

⚠ WARNING

- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions.

3.1.2 Cleaning and Disinfection Agents

Do not use cleaning and disinfection agents that contain the following substances:

- Organic, mineral or oxidizing acids (minimum permissible pH value 5.5)
- Strong lyes (maximum permissible pH value 11; neutral / enzymatic cleaning agent is recommended)
- Organic solvents (e.g., alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic / halogenated hydrocarbons

Corrosion inhibitors, neutralising agents and rinse aids can cause potentially critical residues on the instruments.

Do not use any rinse agents.

Only use agents suitable for cleaning / disinfection of plastic and metals.

Only use agents with proven efficacy (e.g. CE/FDA approval).

Only use agents that are compatible with each other and with the devices in use.

Only use agents suitable for the cleaning / disinfection of instruments.

Observe all information provided by the manufacturer of the cleaning or disinfection agent (e.g. concentration, soaking time, temperature, post-rinsing).

Only use freshly prepared solutions.

3.1.3 Sterilization Trays

To avoid unnecessary contamination of the sterilization trays: Collect contaminated instruments separately. Pre-clean, clean, disinfect and inspect contaminated instruments and sterilization trays separately. Only then place the instruments in the sterilization trays for sterilization.

Always clean and disinfect the sterilization trays when empty. Separate the lid from the sterilization tray and position both components with the respective openings facing downwards.

3.2 Limitations on Processing

Frequent processing has little impact on these instruments. The end of the product lifetime is usually based on wear and tear as well as damage from use.
Maximum number of processing cycles (adequately treated, undamaged and clean products): 100
Any further use of the product / use of damaged or contaminated products is the sole responsibility of the user.

3.3 Cleaning Preparation

[Cleaning and Disinfection Agents, page 4]

3.3.1 Pre-treatment at the Point of Use

Clean the product immediately after use from rough impurities, corrosive solutions and drugs. To do this, rinse the product in flowing cold water and wipe it clean.

3.3.2 Preparation for Cleaning

	The validation was carried out using the following equipment and method:
Cleaning solution:	Neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg) Concentration according to the instructions for use of the cleaning agent
Ultrasonic bath:	SONOREX, 35 kHz (BANDELIN electronic, Berlin)
Start:	As soon as possible, but at the latest 2 h after product use
	The validation was carried out under worst-case conditions, taking into account the program parameters and the specifications of the manufacturer of the cleaning and disinfecting agent.

1. Open/dismantle the instruments as far as possible. For complex products: [Dismantling Instructions, page 7]
2. Rinse instruments/components under running water (temperature < 35°C/95°F) for a minimum of 1 minute. While doing so, agitate any moving parts at least 3 times.
3. Use a disposable syringe to flush all lumina at least 3 times (minimum 10 ml).
   KURZ meter, punch parts with oval and circular end (cartilage punch set): Flush the inner lumen of the device using a suitable syringe of 1 ml capacity. The tip of the syringe must fit into the lumen for effective flushing.
4. Completely immerse the instruments/components in the cleaning solution.
   Ensure that the instruments/components do not come in contact with each other.
   To aid cleaning, brush all surfaces (inside and outside) with a soft bristle brush at the beginning of the soak time.
   During pre-cleaning: Agitate all moving parts at least 3 times.
5. Rinse all lumina at least three times using a single-use syringe.
6. Activate the ultrasonic bath for an additional soak time of at least 5 minutes.
7. At the end of the soaking time: Remove the instruments/components from the cleaning solution and rinse thoroughly under running water at least 3 times for at least 1 minute each. While doing so, agitate all moving parts at least 3 times.
8. Rinse all lumina at least three times using a single-use syringe.

3.4 Cleaning and Disinfection

3.4.1 Automated Cleaning and Disinfection

When selecting the washer disinfector (WD) and the program, please observe the following:

- Ensure that the WD complies with EN ISO/ANSI AAMI ST15883 and that its effectiveness has been proven in principle (e.g. CE marking according to EN ISO 15883).
- Use an approved program for thermal disinfection (A_0-Wert ≥ 3000 / at least 5 min at 90 °C / 194 °F or according to country-specific specifications)
- Confirm the suitability of the program for instruments.
- In order to prevent any remnants of the detergent: Either select a program with at least 3 rinsing cycles after cleaning (including neutralization, if applied) or with a conductance based rinsing control.
- Use only low-endotoxin (maximum 0.25 endotoxin units) and sterile/low-germ water (maximum 10 microbes/ml) for post-rinsing (e.g. purified water).

	The validation was carried out using the following equipment and method:
Cleaning agent:	Neodisher MediClean (Dr. Weigert GmbH & Co. KG, Hamburg)

	The validation was carried out using the following equipment and method:
WD:	G 7836 CD (Miele & Cie. GmbH & Co., Gütersloh) Attach all lumina of the instrument by means of a suitable cleaning adaptor to the rinsing connection of the WD.
Programme:	DES-VAR-TD
	The validation was carried out under worst-case conditions, taking into account the program parameters and the specifications of the manufacturer of the cleaning and disinfecting agent.

1. Place the instruments/components in the washer-disinfector. Ensure that the instruments/components do not come in contact with each other.
2. Start the program.
3. Remove the instruments/components from the washer-disinfector at the end of the program and check them immediately.

3.5 Control, Functional Test and Maintenance

1. Inspect the product for any remaining contaminants. Clean and disinfect contaminated products again.
2. Inspect the products for damage (e.g., corrosion, damaged surfaces, deformations, inscriptions that have become illegible, other mechanical damage). Separate damaged products.
3. Check movable components for ease of movement. Separate the components that do not move with ease.
4. If desired, carefully lubricate moving parts and joints with maintenance oil approved for steam sterilization (e.g. STERILIT oil spray JG 600 or maintenance oil JG 598). Wipe off any excess oil.

ATTENTION: Do not reuse discarded products.

3.6 Packaging

When selecting the sterilization packaging, ensure that the following requirements are met:

- Single-use sterilization packaging, single-layer or double-layer
- Adequate protection of the product and the sterilization packaging from mechanical damage
- Suitable for steam sterilization (temperature resistant up to at least 138 °C (280 °F), adequate steam permeability)

Only use standardized and certified packaging systems (EN ISO/ANSI AAMI ISO 11607). For USA: With FDA approval.

1. Place the instruments/components in the provided recesses of the tray.
2. Place the lid onto the tray and secure the latches.
3. Wrap the tray and instruments in sterilization wrap and seal the sterilization wrap. Wrap the individual instruments in sterilization pouches and seal the sterilization pouches.

3.7 Sterilisation

Do not use sterilization methods other than those described.

Only use standardized and certified steam sterilizers (EN 13060 / EN 285 / ANSI AAMI ST79).

	The validation was carried out using the following equipment and method:
Steam sterilizer:	HST 6x6x6 (Zirbus technology GmbH, Bad Grund)
Sterilization procedure:	Fractionated prevacuum method
Prevacuum phases:	3
Maximum temperature:	138 °C (280 °F)
Minimum drying time:	20 min The actual drying time depends on parameters such as loading or sterilization parameters.
Sterilization Parameters	Germany: 5 min at 134°C (273°F) Switzerland: 18 min at 134°C (273°F) USA: 4 min at 132 °C (270 °F) Other countries: At least 3 min at 132°C (270°F)/134°C (273°F); with prion inactivation at least 18 min

3.8 Storage

After sterilization, store the product dry and dust-free in the sterilization packaging.

4 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

⚠ CAUTION

- The product has points / sharp edges. For disposal, pack the product in a suitable stable container.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

5 Dismantling Instructions

5.1 KURZ Meter

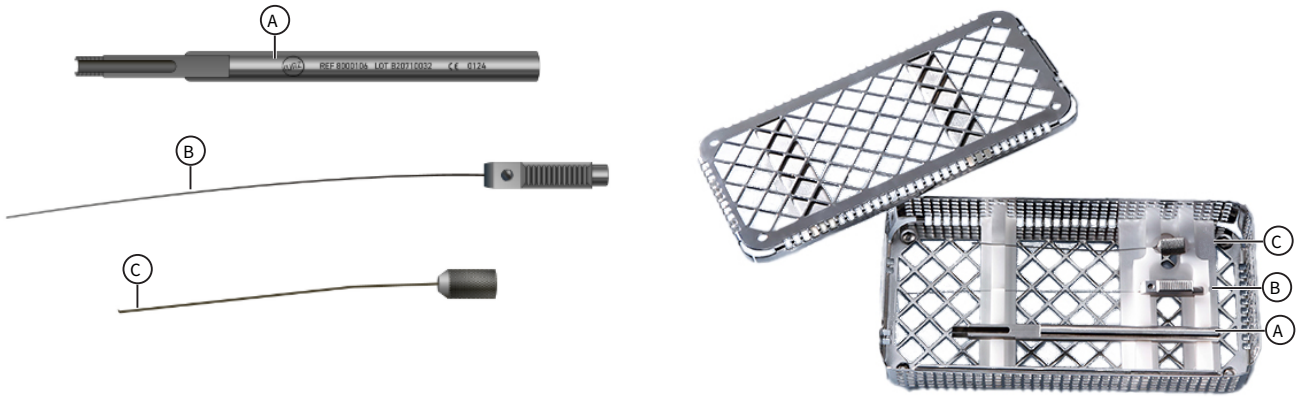


Illustration 1: Left: KURZ Meter (REF 8000 100), right: KURZ Meter in Tray KURZ Meter (REF 8000 174)

A Handle

B Probe (straight), with grip and slider

C Tube (angled), with union nut

ATTENTION: Rinse the probe during preparation before cleaning: Flush the inner lumen of the device using a suitable syringe of 1 ml capacity. The tip of the syringe must fit into the lumen for effective flushing.

5.2 KURZ Precise Cartilage Knife

Illustration 2: Left: Cartilage knife (REF 8000 155) and blade (REF 8000 140), right: Cartilage knife in Tray KURZ Precise (REF 8000 177) with Tray Stainless Steel (REF 8000 124)

A Blade holder - part with pins
B Blade (no processing)
C Blade holder - holed part
D Nut for cutting block
E Cutting block, lower part
F Cutting block, upper part
G Distance plates
H Tray Stainless Steel (container for distance plates)
I Screw for blade holder

ATTENTION: The blades are disposable products. The blades are not intended for processing.

5.3 KURZ Precise Cartilage Knife

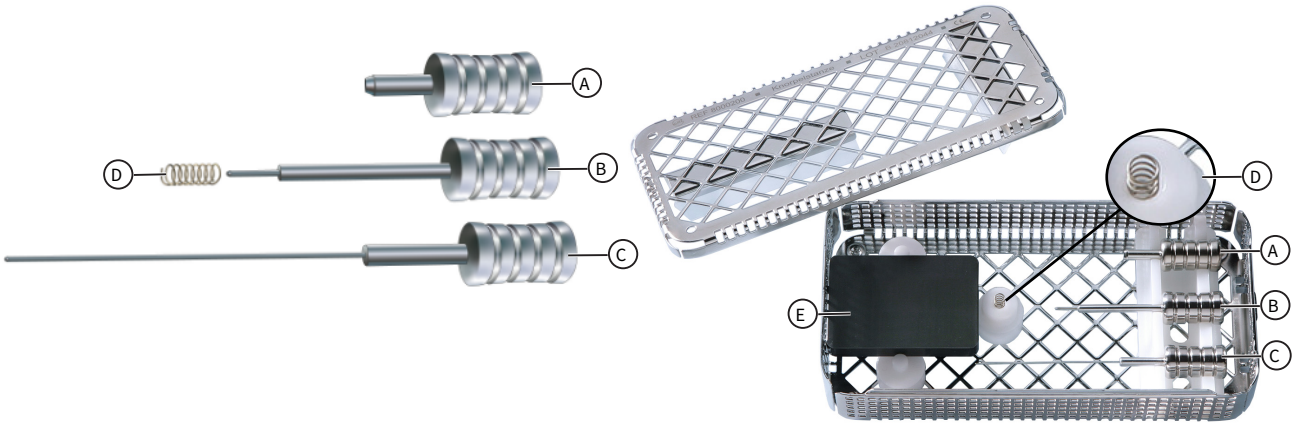


Illustration 3: Left: Cartilage Punch (REF 8000 200), right: Cartilage Punch in Instrument Tray Cartilage Punch (REF 8000 176)

A Punch part with oval end
B Punch part with circular end
C Ejector
D Spring
E POM cutting board

ATTENTION: Rinse punch part with the circular end and the punch part with the oval end during preparation before cleaning. Flush the inner lumen of the device using a suitable syringe of 1 ml capacity. The tip of the syringe must fit into the lumen for effective flushing.

5.4 Steady CrimP Forceps

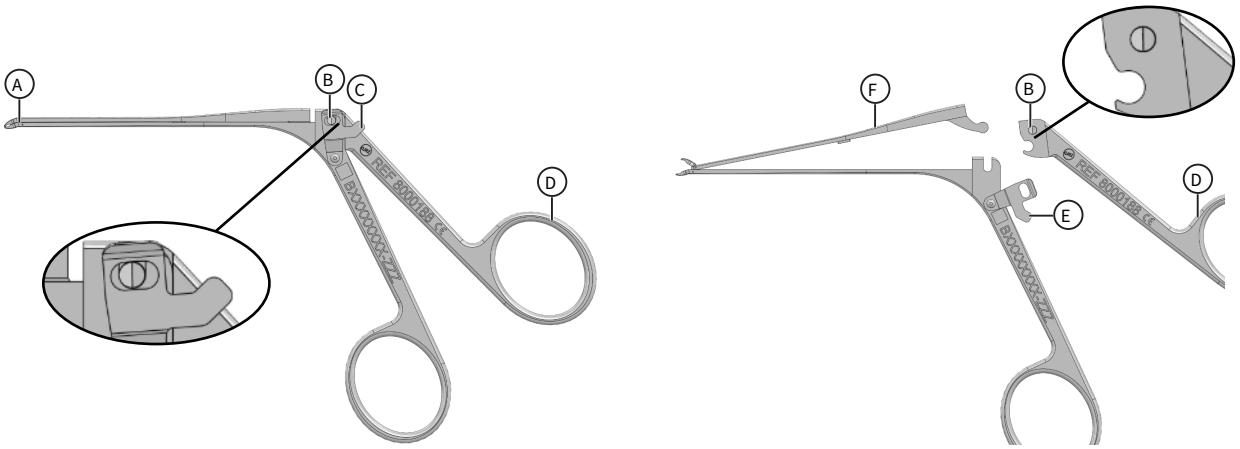


Illustration 4: Steady CrimP Forceps (REF 8000,188), left: assembled, right: disassembled

A Jaw piece

B Pin

C Latch, upper position

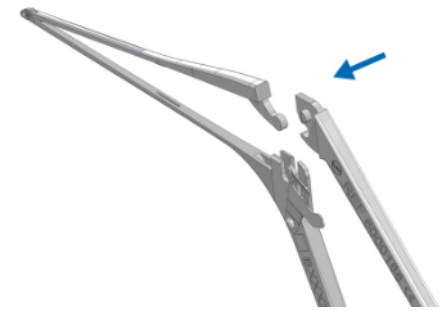
D Thumb grip (refers to the entire component)

E Latch, lower position

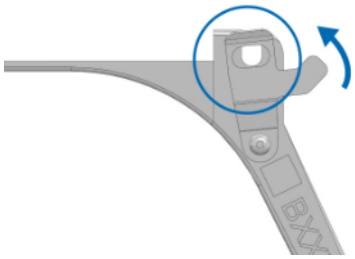
F Upper arm

ATTENTION: Disassemble the Steady CrimP forceps for cleaning and disinfection and assemble for sterilization.

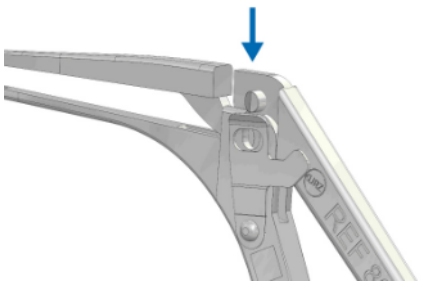
5.4.1 Assemble the Steady CrimP



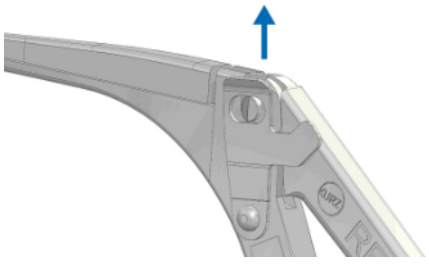
1. Assemble the upper part. To do this, slide the semicircular extension of the upper arm from the side into the recess on the thumb grip.



2. Adjust the latch so that the recesses on the latch and the lower part are aligned.

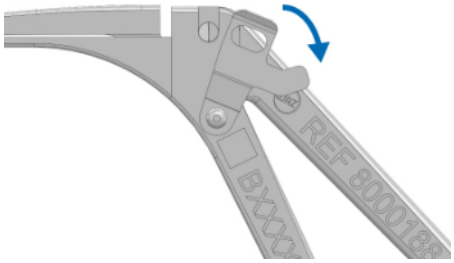


3. Slide the upper part (upper arm and thumb grip) onto the lower part in the direction of the arrow so that the pin engages in the recesses.

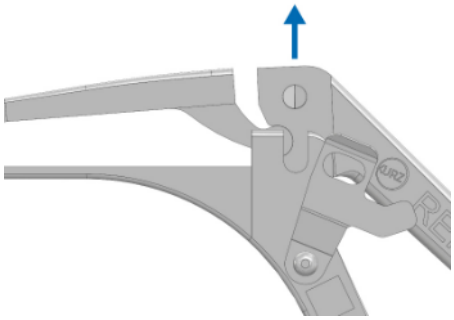


4. Carry out a function check: Move the thumb grip in the direction of the arrow. Make sure that the latch is securely seated and that the lock does not open. Make sure that the jaws open and close.

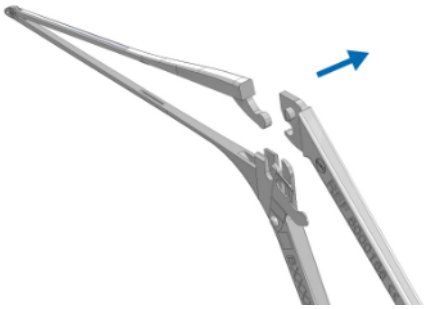
5.4.2 Dismantle the Steady CrimP



1. Open the locking mechanism. To do this, turn the latch in the direction of the arrow.
   Info: The bolt slides over a chamfered surface of the pin and is lifted so that the lock is released.



2. Separate the upper part (thumb grip and upper arm) from the lower part.
   Info: Both parts remain connected to each other on the jaw part.



3. Release the thumb grip from the upper arm in the direction of the arrow.
   Info: The instrument is now disassembled