

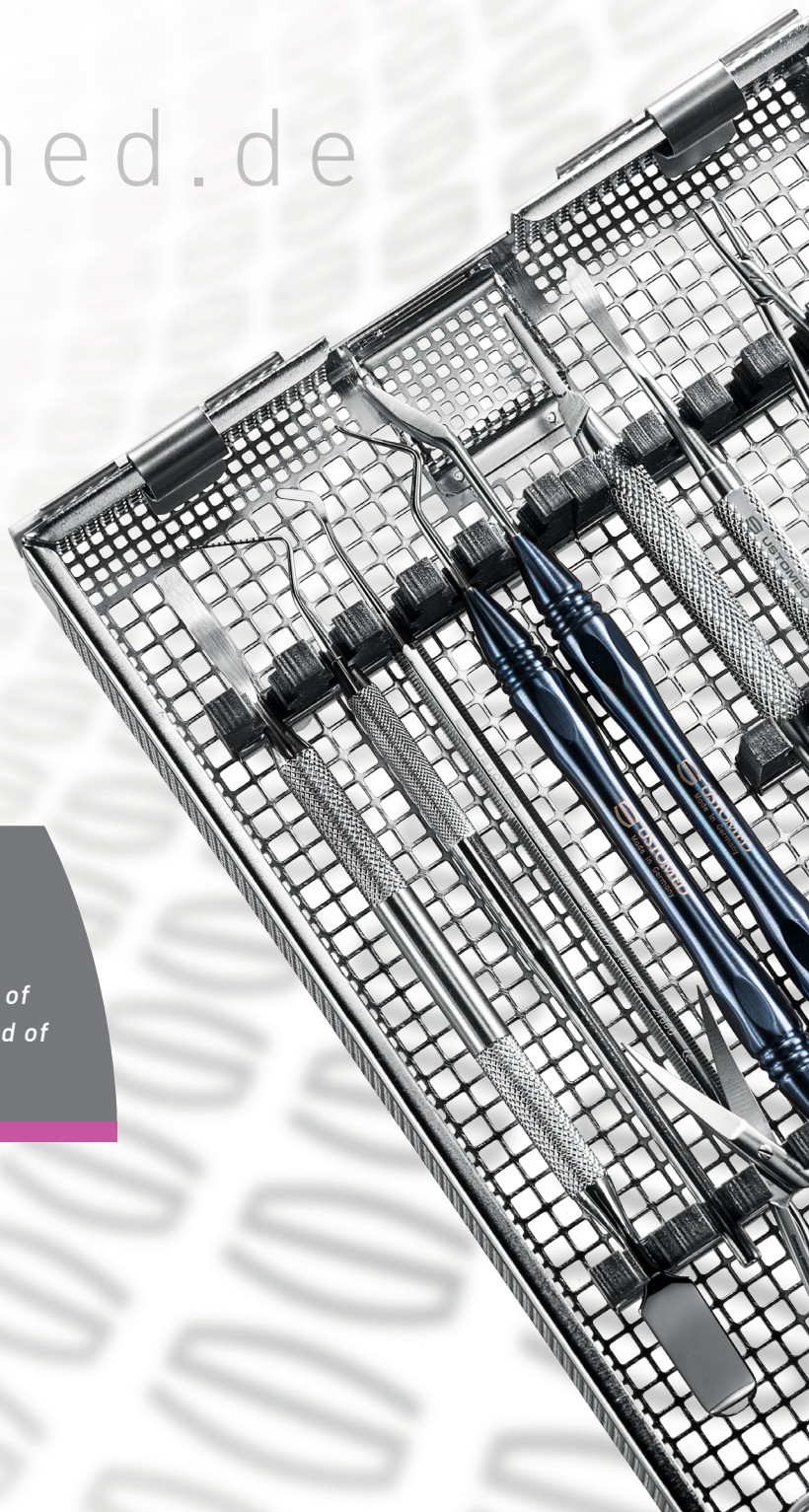
Instructions for use / Processing

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Medical devices can only be mounted, operated, used and maintained by persons with necessary education or knowledge and experience. The instructions of the users for an appropriate handling of medical devices is of elementary importance for the protection of his own and of the patient.



Competence in Instruments



Processing procedures for USTOMED INSTRUMENTE

(in accordance with DIN EN 17664)

Brand new instruments	Brand new instruments and instruments received back from repair must be removed from the transport packaging, and all protective materials (such as foils, protective caps etc.) must be removed from them, before they are introduced into the instrument cycle. Prior to initial processing, the instruments must first be thoroughly cleaned, and particularly any oil residues removed. This is achieved by using hot water to which a commercially available detergent (e.g. Priil) is admixed and a soft brush. Only after removing all residues, may the actual processing according to these processing instructions be started. The instruments are supplied non-sterile and must have undergone a complete processing cycle before being used for the first time according to these instructions for use.	
Notes	Limitation of processing: Frequent processing has only minor effects on our instruments. The end of the product service life is normally determined by wear and tear and damage through use. For the protection of our employees, all instruments returned to us for repair and/or as a result of a claim (return) must have undergone a complete processing cycle (cleaning and sterilisation). This is to be confirmed with a declaration of decontamination. Our declaration of decontamination can be downloaded from our homepage at any time under the following link. "https://ustomed.de/downloads" A fully completed declaration of decontamination is a prerequisite for accepting the return. Returns not accompanied by a declaration of decontamination will not be processed and will be returned to the sender.	
Preparation	- Care must be taken to ensure that residues of blood, tissue and drugs are completely removed from the instruments under running water (<40°C), e.g. with a soft brush, as soon as possible after the end of the intervention, but no later than 6 hours thereafter. Special attention has to be paid to rough surfaces, e.g. knurled handles or the working end of a needle holder (inside of the tip / working area). To prevent fixation of the residues, the instruments can be placed in cold water (<40°C) immediately after use. Never use warm water (>40°C) or cleaning agent, since this can promote fixing of the residues on the product (risk of protein coagulation (denaturation)), which can have an impact on the success of the subsequent processing steps. - Do not "throw off" instruments, but deposit them properly (to avoid risk of mechanical damage). - Do not deposit them in NaCl solutions (to avoid risk of pitting or stress corrosion). Only use an approved solution of a combined cleaning agent and disinfectant that has no protein-fixing effect (always be sure to observe the manufacturer's mixing recommendation). - Avoid overfilling of instrument sieve trays and wash trays. - Always process articulated instruments in opened condition. - Instruments designed for disassembly should always be processed in a disassembled state.	
Cleaning and disinfection:	Manual cleaning and disinfection: - Rinse products under cold mains water (<40°C) until all visible contaminations have been removed. Fixed dirt must be removed using a soft brush or the enclosed cleaning spike; - Place products in an enzymatic cleaner solution to soak (in connection with the use of ultrasound, ultrasound exposure times of at least 3 minutes and frequencies of at least 35 kHz have proven reliable). When doing this, the cleaning agent manufacturer's instructions must be followed. - Rinse the products under running mains water to remove the cleaning agent.	Automatic cleaning and disinfection: - Pre-clean for 1 minute with cold tap water - Shake off water - Pre-clean for 3 minutes with cold tap water - Shake off water - Clean for 5 minutes at 55°C with 0.5% alkaline cleaning agent solution - Shake off water - Neutralise for 3 minutes with cold tap water - Shake off water - Rinse for 2 minutes with cold tap water - The specific instructions of the manufacturer of the cleaning machine must be observed.

	Manual disinfection: 1. Immerse products in an enzymatic disinfectant. When doing this, the disinfectant manufacturer's instructions must be followed. 2. Rinse the products with purified water.	• Automatic thermal disinfection in the washer-disinfector, taking into account the national requirements with regard to the A0 value. Note: The washer-disinfector is loaded according to the manufacturer's instructions and the validator's specifications (loading pattern).
Drying:	Manual drying with lint-free cloth. In order to largely avoid residual water in cavities, it is recommended to blow these out using sterile compressed air.	Automatic drying according to the drying process of the washer-disinfector. If necessary, subsequent manual drying with lint-free cloth and blowing-out of lumens using sterile compressed air.
Maintenance / inspection:	• Instruments with joints and/or other moving parts must be treated with a steam-permeable maintenance product that is suitable for sterilising (heed and follow the instructions of the maintenance product manufacturer). • All instruments must be checked for proper functioning as soon as they have cooled off. • Damaged instruments (crack, corrosion etc.) must be rejected.	
Packaging:	• A packaging suitable for the instrument and the sterilising procedure must be chosen. The packaging must be large enough that the instrument slides in easily and does not touch the side seams. The German Society for Sterile Supply (DGSV) guideline also has to be observed. • In the set: Sort instruments into the tray provided for this, or place them on all-purpose sterilising trays. The instruments must be protected. A suitable procedure for packing the tray must be applied.	
Sterilisation:	• Steam sterilisation with fractionated vacuum procedure at 134°C in a device as specified in EN 285; validated sterilising processes! Sterilising temperature: 134°C, 3 bar Holding time: 5 minutes Drying time: 10 minutes • In order to avoid the formation of spots as well as corrosion on the instruments, the steam must be free of other substances. • The recommended limit values for the dissolved substances in feed water and steam condensate are specified by EN 285. • If other sterilising procedures are used, information on material stability of USTOMED INSTRUMENTE can be requested.	
Storage:	Store processed products at 5°C - 40°C, in a dry, dust-free and clean environment, protected from damage and direct sunlight.	

Exceptions

For the following list, please observe the processing instructions indicated:

- The instruments listed in the following are for technical reasons partly made of aluminium. Therefore, please only use disinfectants suitable for aluminium - e.g. "neodisher Septo MED" from Dr. Weigert (www.drweigert.de). Of course, these instruments are fully autoclavable / sterilisable. Please check the instruments for any surface damage. In this case, damage can sometimes lead to corrosion.

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Artikel-Nr.	Bezeichnung
67-670-720	OMBREDANNE, mallet, 26 cm, 720 g
67-682-000	BULL, bone mill without cutting cyl.
84-145-018	CITOJECT, Pressure syringe f.intraligament.anaesth
90-250-000	Stick-on labels, red
90-250-001	Stick-on labels, blue
90-250-002	Stick-on labels, green
90-250-003	Stick-on labels, yellow
90-604/616-040	Dental-sterile-container, 310x190x40 mm
90-604/616-065	Dental-sterile-container, 310x190x65 mm
90-604/616-130	Dental-sterile-container, 310x190x130 mm
90-626-040	Sterile-container, safety filter, 4 cm
90-626-065	Sterile-container, safety filter, 6,5 cm
90-628-040/-065	Demi-sterile container, safety filter,
90-650-000/1/2/3/4/5	Identification label, incl.inscript.
90-686/4-040	Sterile-container, without filters
90-692-000	Storing frame for instruments, for

- For the instruments listed below, chromium-plated components have been partially used for technical reasons. Therefore neither a thermal disinfectant nor ultrasonic bath may be used for processing them. Moreover only a suitable disinfectant – e.g. "neodisher Septo MED" from Dr. Weigert (www.drweigert.de) – is permitted. Of course these instruments are fully autoclavable/sterilisable.

38-670-015	HAJEK, irrigating cannula, 1, 5 mm diam.
38-670-020	HAJEK, irrigating cannula, 2, 0 mm diam.
48-085-001	Mouth wedge, silicone, with chain, child
48-085-002	Mouth wedge, silicone, with chain, adult
84-080-018	Cartridge syringe, ring handle, compact
84-100-018	Cartridge syringe, ring handle
84-102-018	Cartridge syringe, crutch handle
84-104-018	Zylinderampullen-Spritze, 3-Ringgriff
84-110-018	Ointment syringe, ring handle
84-112-018	Ointment syringe, crutch handle
84-116-003	Exchangeable cartridge holders, 3 ea.
84-116-018	Cartridge syringe w/exchang.cartr.hold.
84-118-018	Cartridge syringe w/exchang.cartr.hold.
84-126-050	Spare attachment only f. ointm. cannulas
84-135-000	Ointment cannulas, 10 ea.
84-137-000	<i>Ointment cannulas, olive tip, 12 ea.</i>

84-142-018	Pressure syringe f.intraligament.anaesth
84-142-100	Dispos.needles f.intraligament.anaesth.
84-144-018	Pressure syringe, w/limit.of power press.
84-167-015	Spec. irrigating cannula, olive tip, 9 cm
84-981-220	LANGENBECK, finger protector, Ø 22 mm
84-981-245	LANGENBECK, finger protector, Ø 24,5 mm
84-981-265	LANGENBECK, finger protector, Ø 26,5 mm
84-990-000	ADAMS, napkin holder
86-921-001	Amalgam gun, metal, metal tip, slight.cvd.
86-921-002	Amalgam gun, metal, metal tip, medium cvd.
86-921-003	Amalgam gun, metal, metal tip, strong cvd.
86-924-006	Spare tips, metal, 6 ea. pack.
86-927-001	Amalgam gun, metal, plastic tip, slight.cvd
86-927-002	Amalgam gun, metal, with plastic tip
86-927-003	Amalgam gun, metal, plastic tip, strong cvd
86-933-000	Amalgam gun, metal, with metal tip
86-936-006	Spare tips, metal f. 86-933-000, 6 ea.pack
86-939-000	Amalgam gun, metal, with plastic tip
88-440-000	SCHREINEMAKERS, impress.trays, edent., set
88-440-021	SCHREINEMAKERS, impress.tray, edent., sz.21
88-440-022	SCHREINEMAKERS, impress.tray, edent., sz.22
88-440-023	SCHREINEMAKERS, impress.tray, edent., sz.23
88-440-024	SCHREINEMAKERS, impress.tray, edent., sz.24
88-440-025	SCHREINEMAKERS, impress.tray, edent., sz.25
88-440-026	SCHREINEMAKERS, impress.tray, edent., sz.26
88-440-031	SCHREINEMAKERS, impress.tray, edent., sz.31
88-440-032	SCHREINEMAKERS, impress.tray, edent., sz.32
88-440-033	SCHREINEMAKERS, impress.tray, edent., sz.33
88-440-034	SCHREINEMAKERS, impress.tray, edent., sz.34
88-440-035	SCHREINEMAKERS, impress.tray, edent., sz.35
88-444-000	SCHREINEMAKERS, caliper for edent. trays
88-500-001	Impression tray, water-cooled, upper, sz.S
88-500-002	Impression tray, water-cooled, upper, sz.M
88-500-003	Impression tray, water-cooled, upper, sz.L
88-500-004	Hydrocolloid-Abdrucklöffel, OK, XL
88-510-001	Impression tray, water-cooled, lower, sz.S
88-510-002	Impression tray, water-cooled, lower, sz.M
88-510-003	Impression tray, water-cooled, lower, sz.L
88-510-004	Impression tray, water-cooled, lower, sz.XL
88-530-000	Impress. tray, water-cooled, partial, left
88-540-000	Impress.tray, water-cooled, partial, right

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- To maximize the long-life-cycle of the instruments, neither a thermal disinfectant nor ultrasonic bath should be used for processing them. The instruments listed below can be processed with a thermo desinfektor or ultrasonic bath. However this may lead to a faster wear and tear.

Artikel-Nr.	Bezeichnung:
84-226-000	Mouth mirror handle, hexagonal, chrom.
84-251-003	Mouth mirrors, magnif., size 3, 12 ea.
84-251-004	Mouth mirrors, magnif., size 4, 12 ea.
84-251-005	Mouth mirrors, magnif., size 5, 12 ea.
84-251-006	Mouth mirrors, magnif., size 6, 12 ea.
84-253-003	Mouth mirrors, plane, size 3, 12 ea.
84-253-004	Mouth mirrors, plane, size 4, 12 ea.
84-253-005	Mouth mirrors, plane, size 5, 12 ea.
84-253-006	Mouth mirrors, plane, size 6, 12 ea.
84-273-003	Mouth mirrors, plane, rhodium, sz.3, 12 ea.
84-273-004	Mouth mirrors, plane, rhodium, sz.4, 12 ea.
84-273-005	Mouth mirrors, plane, rhodium, sz.5, 12 ea.
84-279-004	Mouth mirror/cheek retractor, pl., size 4
84-279-005	Mouth mirror/cheek retractor, pl., size 5
84-281-006	Root resection mirror, plane, Ø 6 mm
84-281-008	Root resection mirror, plane, Ø 8 mm
84-285-003	Root res. mirror, plane, rhodium, Ø 3 mm
84-285-005	Root res. mirror, plane, rhodium, Ø 5 mm
84-285-062	Root res. mirror, plane, rhodium, 6x3 mm
84-290-225	Mirror for intraoral fotogr., occlusal
84-292-210	Mirror for intraoral fotogr., lingual
84-295-170	Mirror for intraoral fotogr., buccal

- *Disinfect only manually – not thermal disinfectors suitable and not autoclavable.*

Artikel-Nr.	Bezeichnung
36-272-000	Stethoscope, black
36-298-000	GUTOWSKI, stereo-stethoscope
36-460-000	Blood pressure manometer
36-970-100	Original AMBU respiration bag
36-970-112	Original AMBU clear vision mask, size 2
36-970-115	Original AMBU clear vision mask, size 5
36-970-120	Original AMBU oxygen reservoir
36-970-130	Original AMBU hyperventilation adapter
36-970-290	Diagnostic lamp, for pupillary diagnostic
36-970-300	Vein compressor, with quick release
36-970-708	Oxygen bottle, 0, 8 l, 200 bar, complete
36-970-850	Original AMBU twin suction pump
36-970-900	Ampoule case for 37 ampoules
38-520-006	Cleaning brushes for suct. tubes, 6 pcs.
88-590-000	Kühlschlauch für Hydrocolloid-Löffel
89-179-099	Inbus-Schlüssel, allein
89-580-125	Cooling tube for impression trays
89-586-140	End nippers of chrome vanadium steel
89-752-130	Mixing bowl of soft silicone, Ø 13 cm
89-790-075	Alcohol burner, 60 ml, metal
89-792-100	Alcohol burner, 100 ml, metal
89-798-190	Plaster cast cutting fcps., 19 cm, DBGM

- Do not use a thermal disinfectant or hot-air sterilizer for the following items.

Artikel-Nr.	Bezeichnung
90-126-100	Paper filters for Norm-Trays, 100 ea.pack
90-326-500	Paper filters for semi-size trays, 500 ea
90-630-010	Long-term-textile sterile filters, 10 ea.
90-662-100	Indicator labels, pack. 100 ea.
90-665-100	Sealing plombs, pack. 100 ea.



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