Dental Instruments by

stoma®

With passion for perfection

Preparation of Instruments

MADE IN GERMANY

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2 Intended purpose/Indication

The stoma® medical devices are reusable medical devices. The stoma® medical devices for the dental field are used in the fields of diagnostics, conserving treatment, endodontics, periodontics, surgery, implantology, osteosynthesis, organization and prosthetics. Generally these are stoma® medical devices with the functions of cutting, grasping, removing, holding, touching, as well as auxiliary products. The stoma® medical devices are partly surgically invasive and for temporary use.

Due to the design features of the medical devices described here, the intended purpose or indication must exclude their use in the central nervous system and central cardiovascular system, as the reusable medical devices do not meet the requirements of risk class III.

3 Patient population

There is no limit to the patient population. Storz am Mark GmbH offers a wide range of stoma® medical devices and sizes for different patient populations and indications for the field of dentistry. The choice is made by the professional user.

4 Contraindication

The stoma® medical devices are contraindicated for all applications except for the intended purpose and indication described. The general contraindications known in surgery must be observed. Any risk to anatomical structures in the area of the planned measure must also be avoided. Improper use can lead to tissue damage, premature wear, destruction of the instrument and endanger the patient, user or third parties. Precise anatomical knowledge on the part of the user is required to rule out any danger to neighboring structures such as blood vessels and nerve fibers. A good view of the operation site must be ensured at all times.

Blaue Inhalte werden zur Veröffentlichung ausgeblendet

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5 Intended use

The stoma® medical products may only be used for their intended use in the field of dentistry by appropriately trained and qualified personnel. The attending doctor, buyer or user is responsible for selecting the instruments for specific applications or operations. Storz am Mark GmbH assumes no liability for direct or consequential damage caused by misuse, improper use, handling, processing or maintenance and by failure to observe the instructions for use.

Please note:

Our stoma® medical devices are non-sterile on delivery and therefore have to be put through the entire preparation process described below before they are used for the first time and after each use. We recommend carrying out three complete preparation cycles for new stoma® medical devices before using them for the first time.
stoma® medical devices returned from repairs have to be cleaned/disinfected and sterilised like used instruments before they are used again.

6 Preparation of stoma® medical devices

When stoma® medical devices are delivered with special, product-specific instructions for use, the information these contain must be observed in addition.

6.1 General principles

All stoma® medical devices and laboratory products must be cleaned, disinfected and sterilised prior to each use; this also applies in particular to first-time use after delivery, since all stoma® medical devices are non-sterile on delivery (cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

Within the scope of your responsibility for the sterility of the stoma® medical devices during use, please note:
- Only adequate, device and product-specific, validated procedures for cleaning/disinfection and sterilisation may be used
- The equipment (cleaning and disinfection device, steriliser) that is used must be maintained and inspected regularly
- Compliance with the validated parameters is mandatory for every cycle

In the course of application, ensure that contaminated stoma® medical devices are collected separately and not put back into the instrument tray in order to avoid increased contamination of the loaded instrument tray. Clean/disinfect contaminated stoma® medical devices, then put them back into the instrument tray and subsequently sterilise the fully loaded instrument tray.

Also observe the applicable legal regulations in your country and the hygiene regulations of the medical practice or hospital. This applies in particular to various specifications for the effective deactivation of prions (not applicable for the USA).

Additional and/or deviating specifications have to be observed for some instruments (see the section “Special instructions”)!

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7 Cleaning and disinfection

7.1 Basic principles

A mechanical process (cleaning and disinfection device) should be used for cleaning and disinfection if possible. Due to the significantly lower effectiveness and reproducibility, a manual process – including the use of an ultrasound bath – should only be used if a mechanical process is not available.

Pre-treatment is required in either case.

7.2 Pre-treatment

Coarse contaminants must be removed from the stoma® medical devices directly after use (within 2 hours max.):

7.2.1 Procedure | Pre-treatment

1. Disassemble the stoma® medical devices as far as possible (see the section “Special instructions”).
2. Rinse the stoma® medical devices for at least 1 minute under running water (temperature < 35 °C/95 °F). If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices three times (for the minimum volume and implements, see the section “Special instructions”). Moveable parts must be moved back and forth at least three times while rinsing.
3. Place the disassembled stoma® medical devices into the pre-treatment bath[1] for the specified exposure time, ensuring the stoma® medical devices are adequately covered. Make sure the stoma® medical devices do not touch each other. Support the pre-treatment by fully brushing off all interior and exterior surfaces (at the beginning of the exposure time; for implements, see the section “Special instructions”) and with ultrasonic treatment (for the minimum exposure time but no less than 5 minutes). Movable components must be moved back and forth several times during pre-treatment if applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least three times at the beginning and end of the exposure time (for the minimum volume and implements, see the section “Special instructions”).
4. Then remove the stoma® medical devices from the pre-treatment bath and rinse them thoroughly with water at least three times (for at least 1 minute).
5. If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least three times (for the minimum volume and implements, see the section “Special instructions”).

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In selecting the cleaning agents[1] that are used, ensure that
- they are fundamentally suitable for cleaning metal and plastic instruments,
- they are suitable for ultrasound cleaning (no foaming), and
- they are compatible with the stoma® medical devices (see the section “Material resistance”).

Complying with the concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent/disinfectant as well as the instructions for rinsing is mandatory. Only use freshly prepared solutions, sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (purified/highly purified water according to the pharmacopoeia).

Use a soft, clean, lint free cloth and/or filtered (oil-free, low-germ, low-particle) air for drying.

7.3 Mechanical cleaning/disinfection (cleaning and disinfection device)

In choosing cleaning and disinfection devices, ensure that
- the effectiveness of the cleaning and disinfection device has been tested fundamentally (e.g. DGHM or FDA approval/clearance/registration and/or CE marking according to DIN EN ISO 15883),
- a verified programme for disinfection (A_0-value> 3000 or – for older equipment – min. 5 minutes at 90 °C/194 °F) is used if possible (with chemical disinfection, there is a risk of disinfectant residues on the stoma® medical devices),
- that the chosen programme is suitable for the stoma® medical devices and has a sufficient number of rinsing cycles,
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (purified/highly purified water according to the pharmacopoeia) is used for rinsing,
- that the air used for drying is filtered (oil-free, low-germ and low-particle), and
- that the cleaning and disinfection device is maintained and inspected regularly.

In selecting the cleaning agent system that is used, ensure that
- it is fundamentally suitable for cleaning metal and plastic instruments,
- if thermal disinfection is not used, a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration and/or CE marking) is used in addition and that it is compatible with the cleaning agent being used, and
- the chemicals being used are compatible with the stoma® medical devices (see the section “Material resistance”).

Complying with the concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and if applicable the disinfectant as well as the instructions for rinsing is mandatory.

7.3.1 Procedure | Mechanical cleaning/disinfection

1. Disassemble the stoma® medical devices as far as possible (see the section “Special instructions”).
2. Load the disassembled stoma® medical devices into the cleaning and disinfection device. Make sure the stoma® medical devices do not touch each other. If applicable (see the section “Special instructions”): Connect all lumina of stoma® medical devices to the flushing connection of the cleaning and disinfection device.
3. Start the programme.
4. Remove the stoma® medical devices from the cleaning and disinfection device after the programme ends.
5. Carefully inspect the stoma® medical devices for cleanliness under an illuminated magnifier (20x magnification) and repeat the entire cleaning and disinfection process until residual contamination is no longer detectable.
6. Maintain the stoma® medical devices (see the section “Maintenance”) and carry out a functional test (see the section “inspection”). Then pack the stoma® medical products as soon as possible after removal (see the section "Packaging”, if applicable after subsequent drying in a clean location).

Proof of fundamental suitability of the stoma® medical products for effective mechanical cleaning and disinfection was provided by an independent, officially accredited and approved test laboratory using the cleaning and disinfection device G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaner and cleaning agent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account here. The supplement for cleaning medical devices with hy-light handle design and the negative proof of accumulation was provided by a DAkkS accredited test laboratory using the cleaning and disinfection device Miele PG 8535 and the cleaning agent Neodisher MediClean forte 0.5 % (v/v). The report / proof can be viewed under report numbers 28197, 28198 / 206951 at Storz am Mark GmbH.

7.4 Manual cleaning and disinfection

In selecting the cleaning agents and disinfectants that are used, ensure that
- they are fundamentally suitable for cleaning/disinfecting metal and plastic instruments,
- the cleaning agent – if applicable – is suitable for ultrasound cleaning (no foaming),
- a suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration and/or CE marking) is used and that it is compatible with the cleaning agent being used, and
- the chemicals being used are compatible with the stoma® medical devices (see the section “Material resistance”).

Using combined cleaning agents/disinfectants should be avoided if possible. Only in cases of very minor contamination (no visible contaminants) can combined cleaning agents/disinfectants be used.

Complying with the concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent/disinfectant as well as the instructions for rinsing is mandatory. Only use freshly prepared solutions, sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (purified/highly purified water according to the pharmacopoeia).

Use a soft, clean, lint free cloth and/or filtered (oil-free, low-germ, low-particle) air for drying.

[1] If cleaning agents and disinfectants are used – for example due to occupational health and safety reasons – please note that they should be aldehyde-free (to avoid fixation of contamination with blood), that their effectiveness should have been tested (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration and/or CE marking), and verify that they are suitable for disinfecting the stoma® medical devices and compatible with them (see the section “Material resistance”). Please note that disinfectants used during pre-treatment are for personal safety only and cannot replace the disinfection step that has to be carried out subsequently after cleaning.

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7.4.1 Procedure | Manual cleaning

1. Disassemble the stoma® medical devices as far as possible (see the section “Special instructions”).
2. Place the disassembled stoma® medical devices into the cleaning bath for the specified exposure time, ensuring that the stoma® medical devices are adequately covered. Make sure the stoma® medical devices do not touch each other. Support cleaning by fully brushing off all interior and exterior surfaces (at the beginning of the exposure time; for implements, see the section “Special instructions”) and with ultrasonic treatment (for the minimum exposure time but no less than 5 minutes). Moveable parts must be moved back and forth several times during cleaning.
   If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least three times at the beginning and end of the exposure time (for the minimum volume and implements, see the section “Special instructions”).
3. Then remove the stoma® medical devices from the cleaning bath and rinse them thoroughly with water at least three times (for at least 1 minute).
   If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least three times (for the minimum volume and implements, see the section “Special instructions”).
4. Carefully inspect the stoma® medical devices for cleanliness under an illuminated magnifier (20x magnification) and repeat the entire cleaning and disinfection process until residual contamination is no longer detectable.

7.4.2 Procedure | Manual disinfection

1. Place the disassembled, cleaned and inspected stoma® medical devices into the disinfection bath for the specified exposure time, ensuring that the stoma® medical devices are adequately covered. Make sure the stoma® medical devices do not touch each other. Moveable parts must be moved back and forth at least three times during disinfection. If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least three times at the beginning and end of the exposure time (for the minimum volume and implements, see the section “Special instructions”).
2. Then remove the stoma® medical devices from the disinfection bath and rinse them thoroughly with water at least five times (for at least 1 minute).
   If applicable (see the section “Special instructions”): Rinse all lumina of stoma® medical devices at least five times (for the minimum volume and implements, see the section “Special instructions”).
3. Dry the stoma® medical devices by blowing them off/out with filtered (oil-free, low-germ and low-particle) compressed air.
4. Maintain and check the stoma® medical devices before sterilisation (see the section „Maintenane“ and „Inspection“).
5. Package the stoma® medical devices as promptly as possible after removal (see the section “Packaging”), if applicable after subsequent drying in a clean location.

Proof of fundamental suitability of the stoma® medical devices for effective manual cleaning and disinfection was provided by an independent, officially accredited and approved test laboratory using the pre-cleaner and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account here.

7.5 Maintenance

Reassemble instruments that have been disassembled (see the section “Special instructions”).
Check all stoma® medical devices for damage during maintenance. The stoma® medical devices with damaged surfaces, tips, blades, cracks, splinters, as well as discoloration and corrosion, etc. must be sorted out and labeled. They must be excluded before further use. Replace the discarded stoma® medical devices with new stoma® medical devices. Stoma® medical devices that are still soiled must be completely cleaned and disinfected again. Hinges and functional surfaces such as locks, cutting edges or threads must be oiled with as little oil as possible. Remove excess oil. Care should be taken to ensure that only instrument oils (paraffinic white oil without corrosion inhibitors or other additives) are used which - taking into account the maximum sterilization temperature used - are approved for steam sterilization and have a tested biocompatibility.

7.6 Inspection

Careful inspections and functional tests before sterilisation are the best way to identify and reject stoma® medical devices that are no longer usable. Special care must be taken when inspecting blades and tips as well as the work areas such as closures, locks, ratchets and all moving components. In the case of moving parts, such as closures, locks, ratchets and functional surfaces, care must be taken to ensure that the stoma® medical devices run smoothly and evenly. stoma® medical devices that no longer meet these properties must be professionally repaired or replaced with new stoma® medical devices.

For the maximum number of reuse cycles, see the sections “Reusability” and “Special instructions” (column “Maximum allowable number of cycles”).

7.7 Packaging

Sort the cleaned and disinfected stoma® medical devices into the corresponding instrument tray (if applicable, see the section “Special instructions”).

Package the tray using disposable sterilisation packaging (single or double packaging) or sterilisation containers that meet the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance),
- suitable for steam sterilisation (temperature-resistant up to min. 138 °C (280 °F), adequate vapour permeability),
- adequate protection of the stoma® medical devices and/or sterilisation packaging against mechanical damage, and
- regular maintenance according to the instructions of the manufacturer (sterilisation containers).

The maximum allowable weight of a filled sterilisation tray is 2 kg (without sterilisation container).

8 Sterilisation

Only the sterilisation methods listed below may be used for sterilisation; other sterilisation methods are not permissible.

8.1 Steam sterilisation

- Fractionated vacuum method [2, 3] (with adequate product drying [4])
- Steam steriliser according to DIN EN 13060/DIN EN 285 and/or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)
- Sterilisation time (exposure time at the sterilisation temperature):

Country	Fractionated vacuum method	Gravitation method
USA/Canada	Min. 4 minutes at 132 °C (270 °F), drying time min. 20 minutes[4]	Not recommended
Other countries	Min. 5 minutes[5] at 132 °C (270 °F) /134 °C (273 °F)	Not recommended

Proof of fundamental suitability of the stoma® medical devices for effective steam sterilisation was provided by an independent, officially accredited and approved test laboratory using the steam steriliser HST 6x6x6 (ZIRBUS technology GmbH, Bad Grund) and the fractionated vacuum method. The typical conditions in clinics and medical practices as well as the procedure described above were taken into account. The supplement for cleaning medical devices with hy-light handle design and the negative proof of accumulation was provided by a DAkkS accredited test laboratory using the Lautenschläger ZentraCert steam autoclave. The report / proof can be viewed under report numbers 28197, 28198 / 206951 at Storz am Mark GmbH.

The flash sterilisation method is prohibited on principle.

Also do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

8.2 Storage

After sterilisation, the stoma® medical devices have to be stored in the sterilisation packaging in a dry place free of dust. With regard to the maximum possible storage times, the specifications of the manufacturers of the sterile barrier systems used must be observed.

9 Material resistance

In choosing the cleaning agents and disinfectants, please ensure they do not contain the following substances:

- Organic, mineral and oxidising acids (minimum allowable pH value 5.5)
- Concentrated bases, the maximum pH value of 12 must not be exceeded in the preparation.
- Organic solvents (such as alcohols, ether, ketones, benzine)
- Oxidants (such as hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Never clean the stoma® medical devices with metal brushes or steel wool!
Acidic rinsing agents or neutralising agents must not be used!
All stoma® medical devices may only be exposed to temperatures up to a maximum of 138 °C (280 °F)!

10 Reusability

The stoma® medical devices are intended for multiple use, whereby the end of the product life cycle is usually determined by wear and damage after use. An absolute time specification or specification of the number of possible processing cycles is not expedient, as these do not have any effect on the useful life.
The number of usage cycles may be limited for certain stoma® medical devices. Therefore, please note the information in the section “Special instructions” (column “Maximum allowable number of cycles”).

The service life of stoma® medical devices is only marginally influenced by the number of preparation cycles carried out if these are carried out according to the validated processes described here. Rather, it depends on the careful handling of the stoma® medical devices in all phases of use, preparation, transport and storage. The end of the service life is reached when signs of wear or defects that limit the functionality of the stoma® medical devices are detected during the prescribed visual and functional check. In this case, the stoma® medical devices must be labeled and excluded from further use and replaced with functional stoma® medical devices. Furthermore, the end of the life cycle has been reached when the unambiguous identification of the stoma® medical devices is no longer given due to the lack of labeling.

All liability is excluded in case of failure to comply. This applies correspondingly for damage caused by improper reconditioning or handling, such as unreasonable mechanical effects, falling, excessive strain and so on.

11 Repairs

Storz am Mark GmbH offers a repair service for its stoma® medical devices. Any and all warranties are voided for stoma® medical devices that have been repaired by companies and persons who were not expressly authorised to do so by Storz am Mark GmbH.

[2] Minimum three vacuum steps
[3] The use of the less effective gravitation method is only permitted if the fractionated vacuum method is not available. It requires considerably longer sterilisation times that must be determined and validated for the specific instruments, device and parameters under the personal responsibility of the user.
[4] The drying time that is actually required depends directly on the parameters that are under the sole responsibility of the user (loading configuration and density, condition of the steriliser...) and therefore has to be determined by the user. Nevertheless, a minimum drying time must not be less than 20 minutes.
[5] or 18 minutes (deactivation of prions, not relevant for the USA)

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12 Manufacturer information

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Graphic symbols
The graphic symbols used for identifi cation correspond to the following significations:

	Consult instructions for use		Attention, important safety-related information
	Manufacturer informa-tion		Date of manufacture
REF	Article number	LOT	Production lot number (batch number)
MD	Medical device	SRN	Registration number of the manufacturer in the EU-DAMED database
CE	CE marking	UDI HIBC	Health Industry Bar Code / Unique Device Identification
	Keep dry	NON STERILE	Non sterile
Rx Only	Prescription only (USA)		

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13 Special instructions (divided by product categories)

	Product category and examples of corresponding article numbers	Flushing volume	Brush	Special/additional procedures for: Pre-treatment (Dissassembly and cleaning of possibly existing knurled screws and detachable set screws is mandatory for all product groups mentioned – see line 18)	Special/additional procedures for: Manual cleaning/disinfection	Special/additional procedures for: Mechanical cleaning/disinfection recommended in the cleaning and disinfection device	Special/additional procedures for: Maintenance/ assembly/ inspection	Packaging	Sterilisation	Maximum allowable number of cycles	Classification recommendation according to KRINKO/RKI/BfArM (Germany only, when used as intended)
1	blade holder (14510.00/14512.00), micro-probe handle (11555.00), bone applicator Testori (14631.00), amalgam pistol (2280.25), bone ring holding forceps (14640.00)  sample illustration	20 ml (disposable syringe)	standard brushes, conical inter-dental brush	disassemble/take apart (fully unscrew threaded rod/nut or piston, remove swivel head/tongs), rinse blade gap(s) under running water, then rinse exterior under running water/flush interior with disposable syringe, brush off/out	disassembled: brush off/out, rinse exterior/flush interior with disposable syringe	disassembled: slide onto thinnest possible flushing pin (< 3 mm) with lateral flushing openings, small parts into small parts sieve	assemble: (in reverse sequence), then loosen screw connections again by 2-3 turns (threads) (check the function of the thread in the swivel head, tongs and piston)	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
2	bone applicator with pusher (14634.00/14635.00)  sample illustration	not applicable	standard brushes, conical inter-dental brush	disassemble/take apart (to do so, lift the button of the pusher and slide it back), then rinse/flush under running water, brush off/out (gap with standard brush and conical inter-dental brush)	disassembled: brush off/out (gap with standard brush and conical inter-dental brush), rinse/flush	disassembled: load applicator with gap facing down, small parts in small parts sieve	assemble: (in reverse sequence, then push button back), check the function of the pusher	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
3	screwdriver with claw, square drive micro-screw (23049.00)  sample illustration	50 ml (disposable syringe)	standard brushes	disassemble/take apart, flush under running water, brush off/out, flush handle with disposable syringe (50 ml), brush gap off/out with standard brush	disassembled: flush under running water, brush off/out, flush handle with disposable syringe (50 ml), brush gap off/out with standard brush	disassembled: slide onto thinnest possible flushing pin (< 3 mm) with lateral flushing openings, small parts in small parts sieve, handle upright with opening facing down	assemble: (in reverse sequence) check the function of the claw	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B
4	matrix retrainer (3408.05 - 3421.22)  sample illustration	not applicable	standard brushes, conical inter-dental brush	disassemble/take apart, loosen all screws, rinse/flush under running water, brush off/out	disassembled: rinse/flush, brush off/out	disassembled: small parts in small parts sieve	assemble: screw connections loosened, check the function	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
5	crown remover with weight, without inserts (5305.00), adapter for crown remover (5315.10)  sample illustration	5 ml (disposable syringe)	standard brushes, conical inter-dental brush	disassemble/take apart, rinse/flush under running water, brush off/out, rinse exterior under running water/flush interior with disposable syringe, brush off/out	disassembled: rinse/flush under running water, rinse exterior/flush interior with disposable syringe	disassembled: small parts in small parts sieve	standard procedure, check the function on the thread	package in the disassembled state	standard procedure, sterilisation in the disassembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B
6	mouth mirrors (4814.00 - 4964.00), resection mirror (4970.08)  sample illustration	not applicable	soft, non-scratching brush	rinse under running water, brush off, disassemble and immerse in disinfection solution immediately after use. Then rinse, dry	disassembled: rinse, dry	inserts in small parts sieve without contact between the mirror glass and other instruments	assemble: handle and mirror, check the surface of the mirror	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B

	Product category and examples of corresponding article numbers	Flushing volume	Brush	Special/additional procedures for: Pre-treatment (Dissassembly and cleaning of possibly existing knurled screws and detachable set screws is mandatory for all product groups mentioned – see line 18)	Special/additional procedures for: Manual cleaning/disinfection	Special/additional procedures for: Mechanical cleaning/disinfection recommended in the cleaning and disinfection device	Special/additional procedures for: Maintenance/ assembly/ inspection	Packaging	Sterilisation	Maximum allowable number of cycles	Classification recommendation according to KRINKO/RKI/BfArM (Germany only, when used as intended)
7	measuring calliper Zielinsky (6116.00)  sample illustration	not applicable	standard brushes	disassemble/take apart, rinse/flush under running water, brush off/out	disassembled: rinse/flush under running water, brush off/out	disassembled: small parts in small parts sieve	assemble, oil the functional surfaces, check the function	standard procedure	standard procedure sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B
8	hinged instruments (except for extracting forceps with teflon disc in the forceps hinge): extracting forceps with pin hinge (86.00),  sample illustration needle holder (4701.14),  sample illustration scissors (3562.13), clamps (3840.13), forceps for crown remover (5316.00) ——	not applicable	standard brushes	rinse/flush under running water, brush off/out, open and close hinge 3x in the process	brush off/out, rinse/flush, open and close hinge 3x in the process	load with opened hinge	oil the hinge, locks, ratchets and functional surfaces, check the function	standard procedure	standard procedure,	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
9	crown removing forceps with exchangeable plastic jaws (5451.01), telescope crown forceps, curved, with inserts (6088.24)  sample illustration	not applicable	standard brushes	disassemble removable parts, rinse/flush under running water, brush off/out, open and close hinge 3x in the process	disassembled: rinse/flush under running water, brush off/out, open and close hinge 3x in the process	disassembled: load pliers with opened hinge, small parts in small parts sieve	assemble, oil the functional surfaces, check the function	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B
10	extracting forceps with integrated teflon disc in the forceps hinge (811.10)  sample illustration	not applicable	standard brushes	rinse/flush under running water, brush off/out, open and close hinge 3x in the process	brush off/out, rinse/flush, open and close hinge 3x in the process	load with opened hinge	oiling not permitted, check the function	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
11	bone rongeur forceps, Boehler (3230.14, 3250.18)  sample illustration	not applicable	standard brushes	rinse/flush under running water, brush off/out, open and close hinge 3x in the process	brush off/out, rinse/flush, open and close hinge 3x in the process	load with opened hinge (hold hinge open with stainless steel wire loop)	oil the hinge and the functional surfaces, check the function, check the cutting edges	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B

	Product category and examples of corresponding article numbers	Flushing volume	Brush	Special/additional procedures for: Pre-treatment (Dissassembly and cleaning of possibly existing knurled screws and detachable set screws is mandatory for all product groups mentioned – see line 18)	Special/additional procedures for: Manual cleaning/disinfection	Special/additional procedures for: Mechanical cleaning/disinfection recommended in the cleaning and disinfection device	Special/additional procedures for: Maintenance/ assembly/ inspection	Packaging	Sterilisation	Maximum allowable number of cycles	Classification recommendation according to KRINKO/RKI/BfArM (Germany only, when used as intended)
12	Products with hy-light handle design  sample illustration	10 ml (disposable syringe) products with internal rotary catch	standard brushes	rinse/fl ush under running water, brush off /out, open and close hinge 3x in the process, fl ush with disposable syringe (10 ml) under lock	validation and verification of the process is subject to the user	load with opened hinge or in open state	oil the hinge and the functional surfaces, check the function	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B
13	handle for sinutome/condenser inserts (13325.00) 	not applicable	standard brushes	rinse/flush exterior and interior under running water, brush off/out	rinse/flush exterior and interior under running water, brush off/out	load handle upright with the opening down into a suitable basket	oil the functional surfaces, check the function with insert	standard procedure	standard procedure, sterilisation in the disassembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B
14	cannula (5383.06), surgical suction cannula (3333.18), Coupland mount (3320.01 – 3320.14)  sample illustration	50 ml (disposable syringe)	standard brushes, cleaning brushes for Frazier suction tubes	remove wire (stylet, if any) and prepare separately, rinse interior with disposable syringe (50 ml), brush interior with suitable cleaning brush for Frazier suction tubes, rinse/flush, brush off/out	remove wire (if any) and prepare separately, rinse interior with disposable syringe (50 ml), brush interior with suitable cleaning brush for Frazier suction tubes, rinse/flush, brush off/out	recommended procedure: slide onto thinnest possible flushing pin (< 3 mm) with lateral flushing openings, connect cannulas with Luer Lock connection to corresponding Luer Lock hose adapter or to corresponding flushing hose	Visual inspection for residual dirt, check for continuity, separate out strongly bent suction instruments and those with cracks	package in the disassembled state	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
15	trephine drills (22349.02 – 22349.09)  sample illustration product marking: CE 0297	5 ml (disposable syringe)	standard brushes	brush off exterior/brush out, flush with disposable syringe (5 ml) and attached disposable needle, rinse exterior/flush with running water, visual inspection for cleanliness (magnifying glass), repeat in case of residual contamination	brush off exterior/brush out, flush with disposable syringe (5 ml) and attached disposable needle, rinse exterior/flush with running water, visual inspection for cleanliness (magnifying glass), repeat in case of residual contamination	small parts sieve	check the cutting edges	standard procedure	standard procedure	The trephine drills can be used approximately four times depending on the application conditions (bone quality etc.). If increased pressure has to be exerted during application due to dulling, the product may have to be discarded sooner.	critical B
16	handle for tissue punches (13389.00), added piece for wire loop (5318.05)  sample illustration	not applicable	standard brushes, conical inter-dental brush	disassemble/take apart (loosen screws on the side), rinse/flush under running water brush off/out	disassembled: (screws on the side loosened), rinse/flush under running water brush off/out	disassembled: small parts sieve	assemble oiling not permitted, check the function with insert	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontam-inated	semi-critical B/ critical B
17	tissue punch (13388.01 – 13388.06)  sample illustration product marking: CE 0297	5 ml (disposable syringe)	standard brushes	rinse/flush under running water, brush off/out, flush with disposable syringe (5 ml)	rinse/flush under running water, brush off/out, flush with disposable syringe (5 ml)	small parts sieve	assemble, check the cutting edges	standard procedure	standard procedure	approximately four times; if the cutting performance decreases, the product may have to be discarded sooner	semi-critical B/ critical B

	Product category and examples of corresponding article numbers	Flushing volume	Brush	Special/additional procedures for: Pre-treatment (Dissassembly and cleaning of possibly existing knurled screws and detachable set screws is mandatory for all product groups mentioned – see line 18)	Special/additional procedures for: Manual cleaning/disinfection	Special/additional procedures for: Mechanical cleaning/disinfection recommended in the cleaning and disinfection device	Special/additional procedures for: Maintenance/ assembly/ inspection	Packaging	Sterilisation	Maximum allowable number of cycles	Classification recommendation according to KRINKO/RKI/BfArM (Germany only, when used as intended)
18	single or disassembled small parts: explorer inserts, perio probe inserts, crown remover inserts (5315.02), adapter for crown remover, tip for handpiece and contra-angle piece for bone screws (23040.00, 23041.00, 23049.30), needles (4212.13 – 4218.08), insets for forceps (6088.54), matrix band sections (3429.01 – 3435.07), adjusting screws, set screws, locating pin for spacer, strip clip (3451.00), rubber dam clamps (3460.26 – 3460.51), added piece for wire loop for crown remover (also see row no. 29)  sample illustration	not applicable	standard brushes	rinse/flush under running water brush off/out	rinse/flush under running water brush off/out, for wire loops for crown remover manual cleaning not permitted.	small parts sieve	oil the functional surfaces, check the function	standard procedure	standard procedure, sterilisation in the assembled state if applicable (handles/inserts)	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B
19	forceps (3827.14)  sample illustration	not applicable	standard brushes	brush off/out, rinse/flush, open and close hinge 3x in the process, visual inspection of gripping surfaces for cleanliness, repeat in case of residual contamination	brush off/out, rinse/flush, open and close hinge 3x in the process, visual inspection of gripping surfaces for cleanliness, repeat in case of residual contamination	load with opened hinge	oil the hinge and the functional surfaces, check function for clean closure of the jaws and firm fit of the lock	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B
20	bone crusher (14662.00)  sample illustration	not applicable	standard brushes	rinse under running water, brush off, brush serrated pestle surface, visual inspection for cleanliness (magnifying glass), repeat in case of residual contamination	rinse under running water, brush off, brush serrated pestle surface, visual inspection for cleanliness (magnifying glass), repeat in case of residual contamination	disassembled	check the function	disassembled	standard procedure, sterilisation in the disassembled state, separately	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B
21	bone files (3352.01), inter-dental files (12855.00)  sample illustration	not applicable	standard brushes	brush off/out under running water, rinse/flush, visual inspection of file surface for cleanliness (magnifying glass), repeat in case of residual contamination	brush off/out under running water, rinse/flush, visual inspection of file surface for cleanliness (magnifying glass), repeat in case of residual contamination	standard procedure	check the function	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B
22	forceps with replaceable plastic inlays (5430.00, 5435.00)  sample illustration	not applicable	standard brushes	disassemble/take apart, rinse/flush under running water, brush off/out	disassembled: rinse/flush under running water, brush off/out	disassembled: plastic inserts in small parts sieve Instrument: standard procedure	assemble, check the function	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B

	Product category and examples of corresponding article numbers	Flushing volume	Brush	Special/additional procedures for: Pre-treatment (Dissassembly and cleaning of possibly existing knurled screws and detachable set screws is mandatory for all product groups mentioned – see line 18)	Special/additional procedures for: Manual cleaning/disinfection	Special/additional procedures for: Mechanical cleaning/disinfection recommended in the cleaning and disinfection device	Special/additional procedures for: Maintenance/ assembly/ inspection	Packaging	Sterilisation	Maximum allowable number of cycles	Classification recommendation according to KRINKO/RKI/BfArM (Germany only, when used as intended)
23	mallets with replaceable plastic inserts (3318.17)  sample illustration	not applicable	standard brushes	disassemble/take apart, rinse/flush under running water, brush off/out	disassembled: rinse/flush under running water, brush off/out max. pH 8,5	disassembled max. pH 8,5	assemble, check the plastic inserts	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B
24	needle holder with lock (latch) (14749.18, 14745.15)  sample illustration	10 ml (disposable syringe)	standard brushes	rinse/flush under running water, brush off/out, open and close hinge 3x in the process, flush with disposable syringe (10 ml) under lock	rinse/flush under running water, brush off/out, open and close hinge 3x in the process, flush with disposable syringe (10 ml) under lock	load with opened hinge	oil the hinge and the functional surfaces, check the function	standard procedure	standard procedure	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B
25	micro-screw and titanium screws  sample illustration product marking: CE 0297	See information in the instructions for use accompanying the product, GA_0026 for stoma titanium screws or GA_0038 for stoma micro-screw									
26	pilot drill (23072.08)  sample illustration product marking: CE 0297	not applicable	standard brushes	rinse/flush under running water, brush off/out, immerse in drill bit bath (burr steriliser)	rinse/flush under running water, brush off/out, immerse in drill bit bath (burr steriliser)	small parts sieve	check the cutting edges and the tip	standard procedure	sterilisation individually packaged or in drill bit stand	Instruments made of stainless steel can be used approximately 4 times. This guiding value may deviate from the actual service life depending on the application and/or the material being processed. In some cases the instruments can be used longer if there is no apparent wear.	semi-critical B/ critical B
27	sterilisation trays  sample illustration	not applicable	standard brushes	rinse/flush under running water, brush off/out, movable parts must be moved back and forth 3x in the process	brush off/out, rinse/flush, movable parts must be moved back and forth 3x in the process	with the “opening” down, supported laterally (= all surfaces angles)	assemble, check the function	standard procedure, maximum weight (without sterilisation container) 2 kg	standard procedure, maximum weight (without sterilisation container) 2 kg	a number cannot be specified, the instrument must be undamaged and uncontaminated	not applicable
28	adapter for crown remover, here: added piece for wire loop, replacement wires (5318.06/5317.00/5319.00/5318.05) sample illustration	not applicable	standard brushes	disassemble/take apart, rinse/flush under running water, brush off/out	not permissible	small parts sieve	assemble, check the function	standard procedure	standard procedure, sterilisation in the assembled state	a number cannot be specified, the instrument must be undamaged and uncontaminated	semi-critical B/ critical B

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