GUIDELINE FOR CLEANING, DISINFECTION AND STERILIZATION

Straumann® implant-borne prosthetic components

COMMITTED TO
SIMPLY DOING MORE
FOR DENTAL PROFESSIONALS

CONTENTS

1. GENERAL PRINCIPLES

The guidelines for reprocessing stated in the instructions for use must be followed. All prosthetic components must be cleaned, disinfected and, if required, sterilized before every use. This applies for first-time use of multiple-use components after delivery, as well as for single-use devices that are delivered non-sterile and might have to be sterilized prior to use. Cleaning and disinfection are performed after removal of the protective transport packaging. Effective cleaning and disinfection are mandatory requirements for efficient sterilization.

It is the responsibility of the user to ensure the following:

- Only procedures that are sufficiently validated specifically for the equipment or devices are used for cleaning, disinfection and sterilization.
- The equipment used (disinfector, sterilizer) is regularly maintained, checked and calibrated.
- The instructions regarding Straumann® components, the equipment, disinfectants and cleaning fluids must be observed at all time.

In addition to these instructions, please observe the legal regulations valid in your country as well as the hygiene regulations of the dental practice or the hospital.

Note

Each prosthetic component must only be used for its intended purpose.

2. CLEANING AGENTS AND DISINFECTANTS

For cleaning and sterilization, the prosthetic components must be separated in accordance to their material composition. In particular, components from different materials should never be placed together in one bath, especially components made from different metals (as this will result in an increased risk of contact corrosion). Information regarding the material of the devices can be found on the label, in the respective instructions for use or in the Straumann® product catalog.

2.1 Cleaning agents

For **automated cleaning** purposes use an **alkaline cleaning agent**, e.g. neodisher® MediClean.

For **manual cleaning** purposes use a mild **enzyme-based detergent solution**, e.g. Cidezyme® GI.

2.2 Disinfectants

For **manual disinfecting** use an **ortho-phthalaldehyde based high-level disinfectant**, e.g. Cidex® OPA.

Note
For the mixing ratio, consult the instructions for use of the cleaning/disinfecting agent. For aluminum components, neutral/enzymatic detergents are recommended.

2.3 Cleaning agents and disinfectants used during validation

Method	Supplier	Designation	Solution
Automated cleaning	Dr. Weigert	neodisher® MediClean	0.2 %
Manual cleaning	Johnson & Johnson	Cidezyme®	1.6 %
Manual disinfection	Johnson & Johnson	Cidex® OPA	undiluted

Note

In all cases

- Follow the indications, instructions and warnings provided by the supplier of the cleaning agent and/or disinfectant.
- Select only detergents intended for cleaning and/or disinfection of medical devices made of metals, plastics and zirconium dioxide.
- Select only disinfectants with approved efficiency, EN ISO 15883, VAH[1]/ DGHM[2] or FDA[3] approval or CE[4] mark).

3. CLEANING AND DISINFECTING

3.1 Principles

An automatic method (disinfector) should be used for the cleaning and the disinfection. Manual methods alone are not recommended because of their clearly lower effectiveness and reproducibility, also when using an ultrasonic bath.

It is important that the user is properly trained and that protective clothing is worn while cleaning contaminated prosthetic components. The user always has to wear protective glasses, face mask, gloves etc. for his or her own safety during all activities.

It is the responsibility of the user to ensure the following:

- Only procedures sufficiently validated specifically for the equipment or device are used for cleaning, disinfection and sterilization.
- The equipment used (disinfector, sterilizer) is regularly maintained, checked and calibrated.
- The instructions regarding the equipment, disinfectant and cleaning agents must be respected at all time.
- The user has to be trained adequately.
- The guidelines for reprocessing stated in the instruction for use of the Straumann® device must be followed.

⚠ Caution
Never clean products and sterilization cassettes with metal brushes or steel wool. This can cause corrosion, deposition of metal particles, oxidation etc.

3.2 Pre-treatment

Coarse impurities must be removed from the products (multiple use components within two hours [2 h] at the most after use).

Sort the products in material groups and clean, disinfect and sterilize these groups separately. Never place products made of different materials together.

- Disassemble multi-piece components into their single parts (e.g. healing cap and screw).
- Place the products in a water bath or in a disinfectant solution. If the components are contaminated with blood, the disinfectant should be aldehyde-free (otherwise fixation of blood contamination may occur), should have tested effectiveness (e.g. VAH[1]/DGHM[2] or FDA[3] approval or CE[4] mark), be suitable for disinfection of the products and be compatible with the products (see "2. Cleaning agents and disinfectants").
- Only use a soft brush or a clean soft cloth that is only used for this purpose.
- Never use metal brushes or metal wool for the manual removal of impurities.
- Rinse out all cavities of the products with disinfection solution at least five times (5 x) using a disposable syringe (minimum volume 20 ml).

Please keep in mind that the disinfectant used in the pre-treatment is meant for your protection only and cannot replace the disinfection step after cleaning!

3.3 Automatic cleaning and disinfection

Cleaning and disinfecting using a disinfector/cleaning and disinfection unit (CDU).

Make sure when selecting the disinfector that

- The disinfector has been tested for its effectiveness (for example CE marking according to EN ISO 15883 or DGHM[2] or FDA[3] approval).
- If possible, a tested program for thermal disinfection (A0 value > 3000 or – for older units – at least 5 min at 90°C) is used (risk of disinfectant residues on the products in chemical disinfection).
- The program used for the components is suitable and contains sufficient rinsing cycles.
- The water used has at least drinking quality.
- The air used for drying is filtered.
- The disinfector is regularly maintained and checked.

When selecting the cleaning agent system, make sure that it is basically suitable for cleaning metal, polymer and ceramic products. Unless the disinfection is thermal, a disinfectant with tested effectiveness (e.g. VAH[1]/DGHM[2] or FDA[3] approval or CE[4] mark) is used. The disinfectant must be compatible with the cleaning agents. The cleaning agents used have to be compatible with the instruments.

Note

- Use compatible cleaning agents for medical use described in "2. Cleaning agents and disinfectants" that are suitable for automated cleaning.
- Always follow the instructions stated by the manufacturer of the cleaning agent, disinfectant and disinfector.

Procedure

1. Place the disassembled prosthetic components in the disinfector so that water can flow out of canulas and blind holes. Make sure that the parts do not touch one another. Connect all cavities of the products that can be rinsed to the rinsing connections of the disinfector using a suitable rinsing adapter.
2. Start the program.
3. Remove the parts from the disinfector after the end of the program.
4. Inspect and if necessary, pack the products as quickly as possible after removal in a sterilization bag.

3.4 Manual cleaning and disinfection

When selecting the cleaning agents and disinfectants, ensure the following:
- They are suitable for cleaning metal, zirconium dioxide and polymer components.
- The cleaning agent is suitable for ultrasonic cleaning (no formation of foam).
- A disinfectant with tested effectiveness is used and is compatible with the cleaning agents.
- The chemicals used are compatible with the prosthetic components (see "2. Cleaning agents and disinfectants").

Note
- Use compatible cleaning agents and disinfectants for medical use described in section "2. Cleaning agents and disinfectants" that are suitable for manual cleaning.
- Combined cleaning agents/disinfectants should not be used.
- Always follow the instructions stated by the manufacturer of the cleaning agent and disinfectant.

It must be strictly adhered to the concentrations and action times stated by the manufacturer of the cleaning agent and disinfectant. Use only solutions prepared shortly prior to use, only sterile or low-germ content (max. 10 germs/ml) as well as low endotoxin content (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only filtered air for drying.

Cleaning with the Ultrasonic Cleaning Cassette and disinfection

1. Place the disassembled components in the Ultrasonic Cleaning Cassette. Make sure that the parts do not touch one another. Separate the components according to the material. To improve the cleaning effect in the ultrasonic bath, cleaning without the lid is recommended.
2. Remove the parts from the Ultrasonic Cleaning Cassette after cleaning and rinse thoroughly at least three times (3 x) with tap water. Rinse out all cavities of the instruments three times (3 x) using a disposable syringe (minimum volume 20 ml).
3. Inspect the components.
4. Place the disassembled, cleaned and inspected components for the specified action time in the disinfection bath. Ensure that the prosthetic components are sufficiently covered by the disinfection solution and that the instruments do not touch one another. Rinse out all cavities of the parts three times (3 x) with disinfectant at the beginning or at the end of the action time using a disposable syringe (min. volume 20 ml).
5. Remove the components from the disinfection bath and rinse them thoroughly with water at least five times (5 x). Rinse out all cavities of the parts five times (5 x) with sterile water using a disposable syringe (min. volume 20 ml).
6. Dry the components inside/outside with filtered compressed air.
7. Inspect and if necessary, pack the products in a sterilization bag as quickly as possible after removal.

Use of the Ultrasonic Cleaning Cassette

The prosthetic components can be placed in the ultrasonic bath in the Ultrasonic Cleaning Cassette (see below).

- Before first-time use, manually clean the Ultrasonic Cleaning Cassette with water.
- The components must be pretreated according to section "3.2 Pretreatment", especially if blood residues have already dried in. Proper cleaning can be performed only in this way.
- It is not allowed to sterilize any components in the Ultrasonic Cleaning Cassette.

Cleaning without ultrasonic support

1. Place the disassembled components in the cleaning bath for the specified action time so that the parts are sufficiently covered (if necessary, brush carefully with a soft brush). Make sure that the parts do not touch one another. Rinse out all cavities of the instruments three times (3 x) with the cleaning agent at the beginning or at the end of the action time using a disposable syringe (min. volume 20 ml).
2. Remove the parts from the cleaning bath and rinse them thoroughly with water at least three times (3 x). Rinse out all cavities of the parts three times (3 x) using a disposable syringe (min. volume 20 ml).
3. Inspect the parts.
4. Place the disassembled, cleaned and inspected parts for the specified action time in the disinfection bath. Ensure that the components are sufficiently covered by the disinfection solution and that the instruments do not touch one another. Rinse out all cavities of the instruments three times (3 x) with disinfectant at the beginning or at the end of the action time using a disposable syringe (min. volume 20 ml).
5. Remove the parts from the disinfection bath and rinse them thoroughly with water at least five times (5 x). Rinse out all cavities of the parts with water five times (5 x) using a disposable syringe (min. volume 20 ml).
6. Dry the instruments inside/outside with filtered compressed air.
7. Inspect and if necessary, pack the products as quickly as possible after removal in a sterilization bag.

4. STERILIZATION

Only the sterilization methods listed below may be used for sterilization. Other sterilization methods are not permissible.

Steam sterilization (fractionated vacuum method)

- Fractionated vacuum method (with sufficient device drying)
- Steam sterilizer corresponding to DIN EN 13060[5] or DIN EN 285[6]
- Validated corresponding to DIN EN ISO 17665[7] (valid IQ/OQ[8] (commissioning) and product-specific performance assessment [PQ])
- Maximum sterilization temperature 134 °C (273 °F; plus tolerance corresponding to DIN EN ISO 17665)
- Sterilization time (exposure time at the sterilization temperature)

Basic sterilization information

<table>
<tr><th>Material</th><th>Sterilizing Method</th><th>Sterilizing Parameters</th><th>Specific Requirements</th></tr>
<tr><td>Metal (Gold) alloy Ceramicor®</td><td rowspan="5">Autoclave, moist heat</td><td rowspan="5">134 °C (273 °F), 5 min.,
18 min. for prion inactivation</td><td rowspan="5">–</td></tr>
<tr><td>Ti/Ti alloy</td></tr>
<tr><td>coron®</td></tr>
<tr><td>POM</td></tr>
<tr><td>PEEK/PEEK with Ti/Ti alloy inlay</td></tr>
<tr><td>ZrO_2</td><td>Dry heat</td><td>160 °C (320 °F) for 4 h
In general, do not autoclave or chemiclave!</td><td rowspan="2">Please read instructions for use for specific product-related exceptions.</td></tr>
<tr><td>PMMA</td><td>In general,
do not sterilize!</td><td>–</td></tr>
</table>

Note

Only the following Straumann® prosthetic components are for multiple use:

- Straumann® PLAN abutments

Always observe the operating instructions of the manufacturer for your sterilizer especially with regard to the loading weight, the operating time and testing for functioning.

Corroded and rusty products can contaminate the water circuit of the sterilizer with rust particles. These rust particles will cause initial rust on intact products in all future sterilization cycles. It is important to regularly inspect and clean the unit!

The products must be stored dry after sterilization.

Caution

Flash sterilization method is not permissible. Also, do not use hot air sterilization, irradiation sterilization, plasma sterilization, formaldehyde or ethylene oxide sterilization.

5. REFERENCES

[1] *VAH – Verbund für Angewandte Hygiene E.V http://www.vah-online.de/ "Association for Applied Hygiene"*
[2] *DGHM – Deutsche Gesellschaft für Hygiene und Mikrobiologie http://www.dghm.org/ "German Association for Hygiene and Microbiology"*
[3] *FDA – U.S. Food and Drug Administration http://www.fda.gov/*
[4] *CE – Conformité Européenne http://ec.europa.eu/ "European Conformity"*
[5] *DIN EN 13060: Test method to demonstrate the suitability of a medical device simulator during steam sterilisation – Medical device simulator testing*
[6] *DIN EN 285 Sterilization – Steam sterilizers – Large sterilizers; German version*
[7] *DIN EN ISO 17665, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*
[8] *IQ/OQ Installation qualification/Operational qualification*

6. IMPORTANT GUIDELINES

Please note
Practitioners must have appropriate knowledge and instruction in the handling of the Straumann CADCAM products or other Straumann products ("Straumann Products") for using the Straumann Products safely and properly in accordance with the instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in this document or in the instructions for use for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann in this document or in the respective instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

Availability
Some of the Straumann Products listed in this document may not be available in all countries.

Caution
In addition to the caution notes in this document, our products must be secured against aspiration when used intraorally.

Validity
Upon publication of this document, all previous versions are superseded.

Documentation
For detailed instructions on the Straumann Products contact your Straumann representative.

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Explanation of the symbols on labels and instruction leaflets

LOT	Batch code
REF	Catalogue number
STERILE R	Sterilized using irradiation
	Lower limit of temperature
	Upper limit of temperature
	Temperature limitation
Rx only	Caution: Federal law restricts this device to sale by or on the order of a dental professional.
	Do not re-use
	Non-sterile
	Caution, consult accompanying documents
	Use by
	Keep away from sunlight
CE	Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42 EEC
CE 0123	
	Consult instructions for use

NOTES

www.straumann.com

International Headquarters
Institut Straumann AG
Peter Merian-Weg 12
CH-4002 Basel, Switzerland
Phone +41 (0)61 965 11 11
Fax +41 (0)61 965 11 01

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