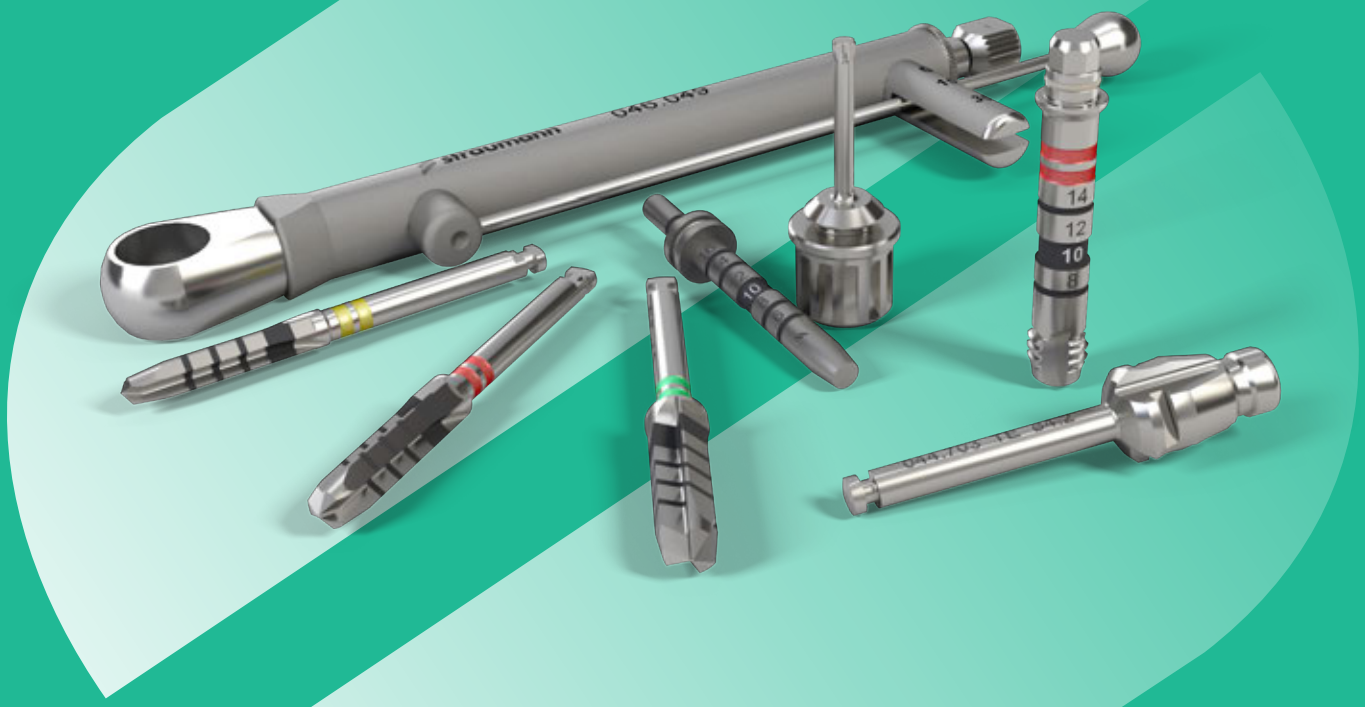
straumann

CARE AND MAINTENANCE

Straumann® surgical and prosthetic instruments



Technical Information

CONTENTS

1. GENERAL PRINCIPLES

1.1 INTRODUCTION

Proper care and maintenance of surgical and prosthetic dental instruments are important to ensuring successful implantation procedures. Precise instruments that are meticulously maintained are essential for achieving optimal clinical outcomes. This brochure provides comprehensive guidelines to help you maintain your instruments effectively, ensuring they remain clean, functional, and safe for use.

Each instrument must be used solely for its intended purpose to maintain its integrity and effectiveness. Straumann devices are intended to be used as a part of dental implant treatments with Straumann implants and restorative components. For specific details of intended use, please refer to the respective *Instructions for Use (IFU)* for the implant or restorative component.

The complete reprocessing process includes the following critical steps:
- pretreatment
- cleaning
- disinfection
- inspection
- assembly
- functional testing
- packaging
- sterilization.

Cleaning and disinfection are vital to ensure effective sterilization. It is important to follow recommended instructions for each step to ensure comprehensive reprocessing. Adherence to sterilization instructions detailed in Section 2.8 is essential.

Users must ensure:
- Only validated procedures for cleaning, disinfection, and sterilization are employed (ISO 17664).
- Regular maintenance, checks, and calibration of equipment are necessary to ensure processing efficacy.
- Washer-disinfectors should comply EN ISO 15883-1 standards.
- Sterilizers should comply with EN 13060 or EN 285 standards.

Note: Additionally, it is crucial to observe and adhere to the legal regulations in your country, as well as the hygiene regulations specific to your dental practice or hospital.

By adhering to these guidelines, you ensure that your surgical and prosthetic instruments are maintained to the highest standards of cleanliness and functionality, supporting successful and safe dental procedures.

1.2 MATERIAL GROUPS AND THEIR RESISTANCE

To prevent contact corrosion, it is crucial to segregate instruments based on their material composition during the disinfection and cleaning processes. Detailed material information for each device is available in the *Straumann® Product Catalog*.

While the materials used in Straumann products exhibit notable resistance to corrosion and damage, it is essential to recognize that they are not impervious to harm. Therefore, opting for suitable cleaning agents and disinfectants, and avoiding ingredients that negatively affect the instruments, are essential measures in preserving the longevity of these products.

Summary of Non-Recommendable Ingredients
• Organic - mineral, and oxidizing acids (pH < 5) • Strong alkalis (pH > 9; mildly alkaline cleaners are recommended) • Organic solvents (e.g., alcohols, ethers, ketones, benzines) • Oxidizing agents (e.g., hydrogen peroxide) • Halogens (e.g., chlorine, iodine, bromine) • Aromatic/halogenated hydrocarbons • Salts of heavy metals • Fixatives (e.g., aldehydes)

Materials used in Straumann devices:

Material	Resistance properties	Ingredients to avoid in disinfectants and cleaning agents	Issues caused by incompatible cleaning agents and disinfectants
Stainless steel	Forms a passive chromium oxide layer for corrosion resistance	• Chlorine • Oxalic acid • Hydrogen peroxide (H_2O_2)	Pitting and contact corrosion
Titanium	Resists corrosion and external factors by self-oxidization	• Chlorine • Oxidizing acids (e.g., nitric acid, sulfuric acid, oxalic acid) • Hydrogen peroxide (H_2O_2)	Discoloration
Aluminum	Anodized to enhance corrosion resistance	• Alkaline agents with a pH between 5-9	Increases susceptibility to corrosion.
Plastics	Plastics (without PMMA) can be sterilized. PMMA: Different PMMA types used for Straumann devices. Consult IFU for processing instructions	• Organic solvents (e.g., alcohols, ethers, ketones, benzines) • Hydrogen peroxide (H_2O_2) • Aldehydes • Halogens (e.g., chlorine, iodine, bromine)	Deformation

1.3 ESSENTIAL GUIDELINES TO FOLLOW PRIOR TO THE DECONTAMINATION PROCESS

It is recommended to adhere to the following guidelines before starting the decontamination process for our devices:

Protective clothing and equipment

It is important to use protective clothing such as gloves, lab coats, masks, and protective eye wear while handling and cleaning the instruments. It helps protect the staff against contaminated splatter during cleaning.

Water quality

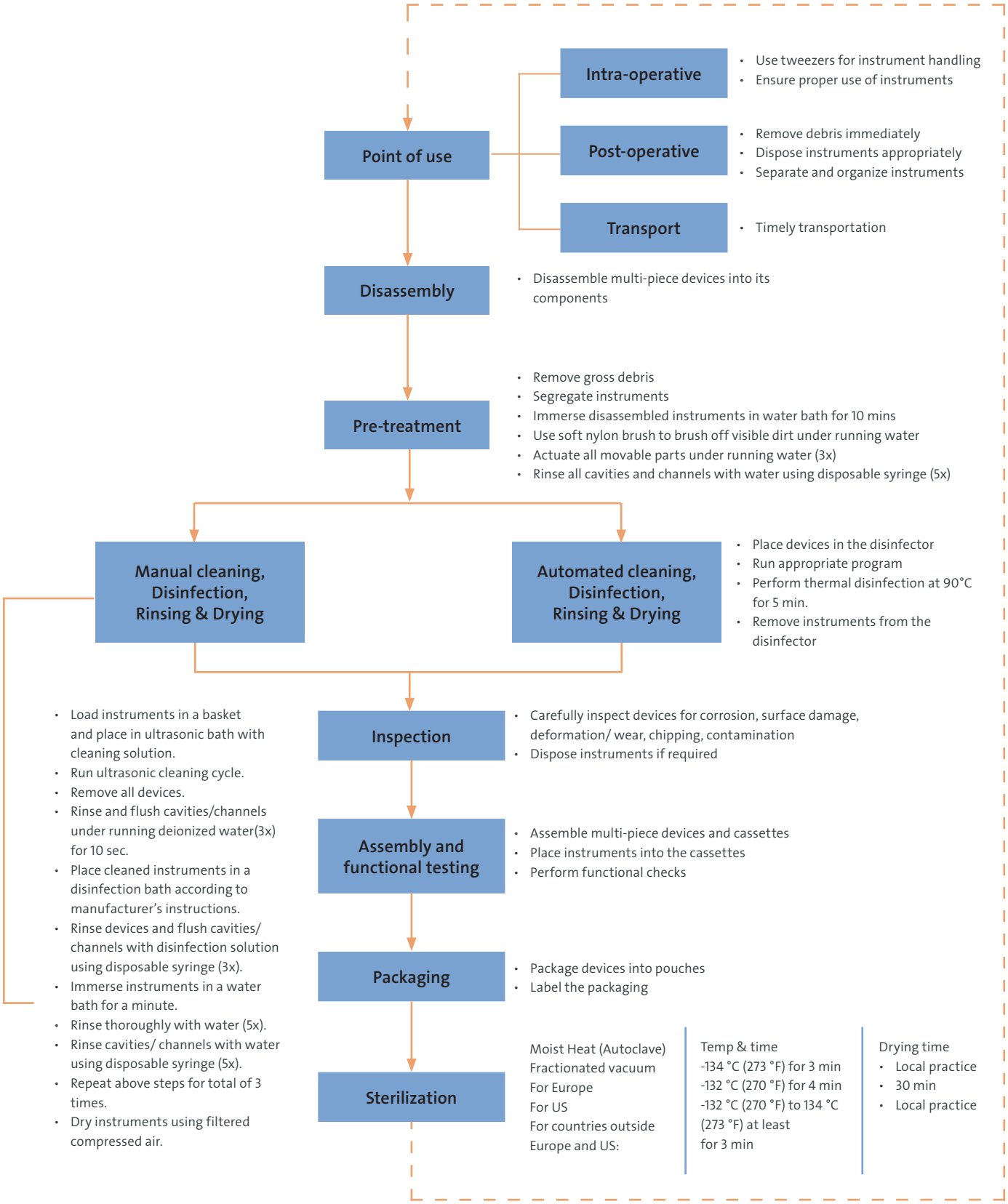
- Pollutants/minerals from water can reduce the lifetime of instruments and impair the performance of cleaning solutions.
- Always use the highest quality water to help in removing impurities and preventing contamination with impurities from the water.
- Contamination of the water with microorganisms and endotoxins can prevent effective cleaning, disinfection, and sterilization.
- Recommended water quality for cleaning is distilled or deionized water. If this is not available, at least use tap water that meets the quality specifications of utility water[1].
- For the final rinse, Straumann strongly recommends the usage of freshly prepared critical water[1] or fully demineralized sterile and endotoxin-free water.

Cleaning agent and disinfectant

- Selecting appropriate cleaning agents and disinfectants is essential for the thorough decontamination of surgical and prosthetic devices. The cleaning agents should be effective to combat a wide range of pathogens, while still being compatible with the instrument materials.
- Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants. The concentrations and action times provided by the manufacturers of the cleaning agents and disinfectants must be strictly followed.
- Ensure that the devices remain in contact with these agents for the recommended duration to achieve maximum efficacy.
- Always check compatibility of the cleaning and disinfectant solution with the material of the instrument.
- Use only freshly made solutions.
- Cleaning agents used for ultrasonic cleaning should be suitable, i.e. they do not develop any foam.
- Disinfectants must have been tested for their effectiveness and should not contain any fixatives (e.g. DGHM[2]/VAH[3]).
- Do not combine cleaning agents with disinfectants.
- After cleaning and disinfection, thoroughly rinse the devices to remove any residual chemicals that could cause irritation and damage.

1. AAMI TIR34:2014 (R2017) - Water for The Reprocessing Of Medical Devices
2. DGHM – "Deutsche Gesellschaft für Hygiene und Mikrobiologie" www.dghm.org "German Association for Hygiene and Microbiology"
3. VAH – "Verbund für Angewandte Hygiene E.V" www.vah-online.de "Association for Applied Hygiene"

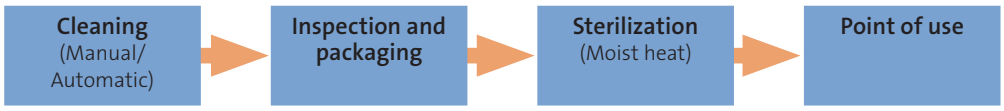
1.4 WORKFLOW OVERVIEW



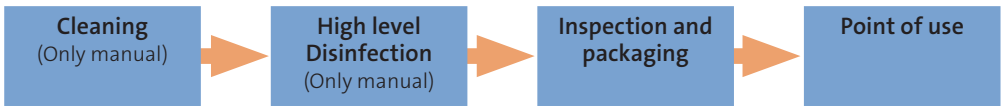
1.5 WORKFLOW STEPS FOR SINGLE-USE VS. MULTIPLE-USE DEVICES

Different workflows are to be followed for single-use vs. multiple use devices and based on their sensitivity.

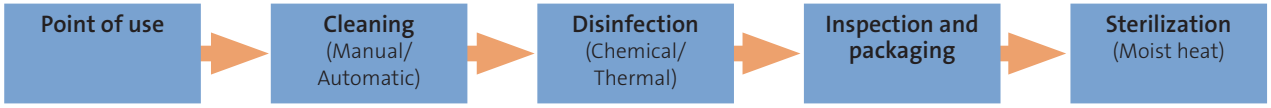
Single-Use Devices



Single-Use Sensitive Devices



Multiple-Use Devices



***Sensitive Materials:** materials unable to withstand the temperatures during thermal disinfection or moist heat sterilization, e.g. certain plastics.

Note: Between sterilization and patient use- devices could be stored. After inspection, discard non reusable or single-use.

2. PROCESS STEPS

2.1 POINT OF USE

Dental devices require proper care and maintenance from the very beginning of the process, including in the dental office. It is extremely important that these devices are handled in accordance with the protocol found below to limit infections and support device longevity and patient safety.

Intraoperative:

a. Use Tweezers for Instrument Handling

- Always use tweezers to handle dental tools, to maintain sterility, and to avoid injury during surgery.
- Damaged and/or blunt instruments must be sorted out and disinfected, cleaned and disposed of separately.

b. Ensure Proper Use of Instruments

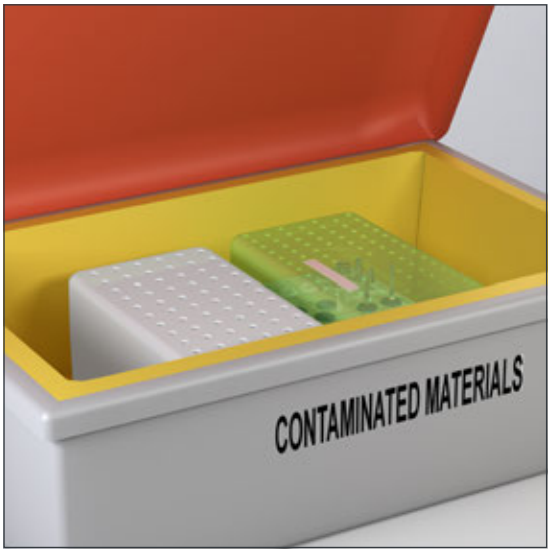
- Use each device strictly for its intended purpose. Unintended use of devices can damage and compromise its performance. Avoid inappropriate and careless handling of instruments such as throwing or dropping them onto hard surfaces. This can lead to physical damage.

Postoperative:

- Coarse impurities must be removed from the instruments directly after use (within one (1) hour at the most).
- Next, rinse the instruments thoroughly under running water to prevent the fixation of biological debris on the device surface.
- Never allow surgical residues such as blood, secretions, or tissue to dry on instruments. Debris left on instruments can significantly impair the cleaning, disinfection, and sterilization process. Furthermore, debris could cause corrosion, restricting performance and reducing the longevity of instruments.
- Dispose of instruments appropriately. Utilize appropriate containers within the operating room to safely discard these items, minimizing the risk of injury and contamination.
- Place instruments in a designated tray or container to keep them secure and organized before they undergo further cleaning and sterilization.
- Do not place instruments back into the cassette unless otherwise indicated by the specific cassette instructions to avoid cross-contamination.

Transport:

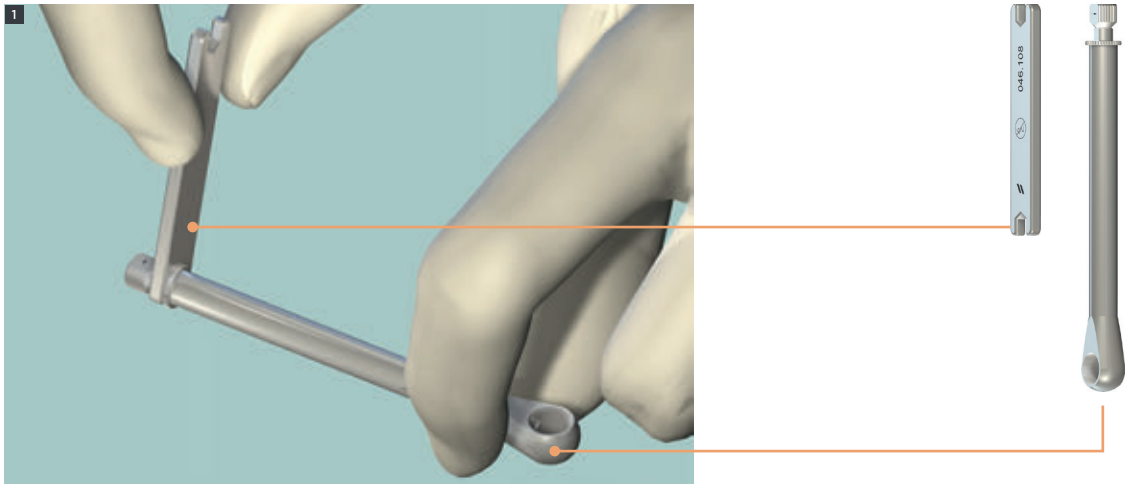
a. Safely store and ensure timely transportation to re-processing area
   - Safely store and promptly transport the cassette with instruments in a closed container to the reprocessing area to prevent infection of healthcare personal.
   - Ensure that the transport containers are clearly labeled/color-coded and used exclusively for contaminated instruments.
   - If transport to the reprocessing area is delayed, protect the devices by either covering them with a wet cloth or soaking them in lukewarm cleaning solution.

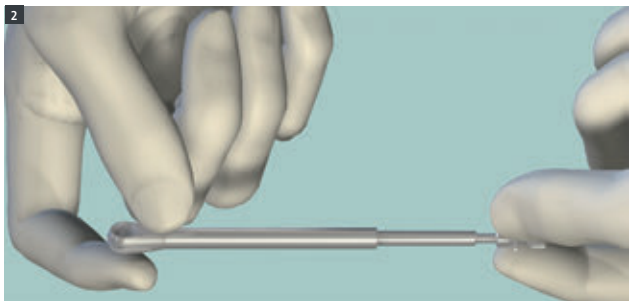


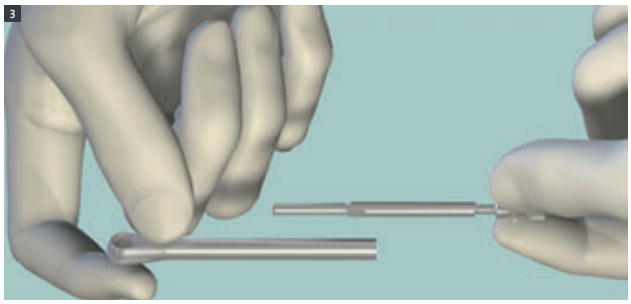
2.2 DISASSEMBLY OF DEVICES

Disassembly of the Ratchet (Art. No. 046.119)

1. Loosen the ratchet nut with the service instrument or the holding key.
2. Unscrew and remove the internal bolt by sliding it out of the ratchet body.





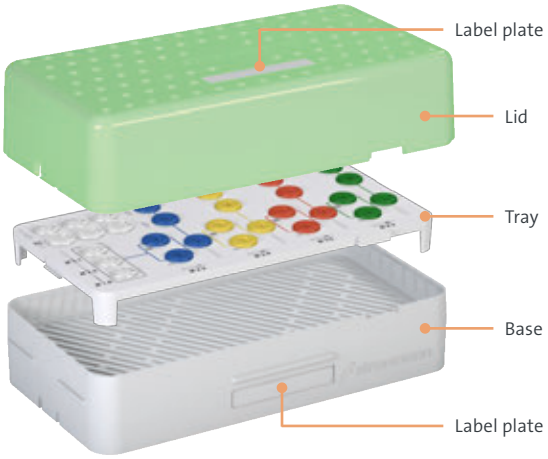


Disassembly of instruments with screws

Loosen the screw to separate the distance indicator, screw-retained implant drivers and the 48-hour explantation device

Disassembly of cassettes

1. Remove all instruments from the tray.
2. Disassemble cassette into each individual component – lid, base and tray.
3. It is recommended that the grommets are disassembled.



Base separation:

Gently apply even force on both sides by hand to break the connection.

Note: The modules separate easiest when force is evenly distributed over the long side of the modules, as shown in the picture.

Tray removal:

A Module – Use a blunt instrument to push the trays out from the back. (e.g.: ratchet bolt from the disassembled ratchet).

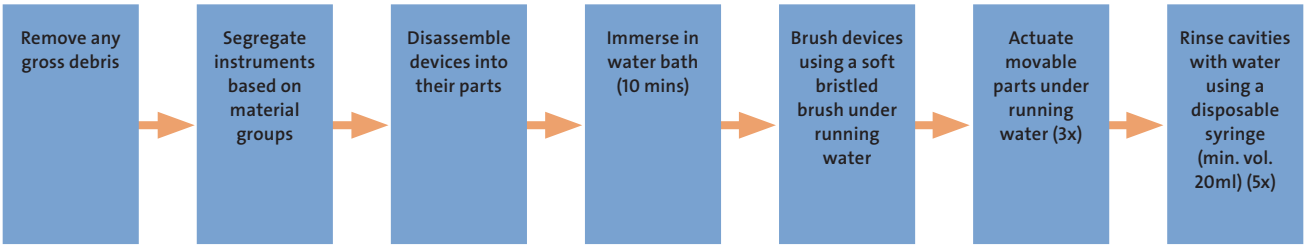
B Module – Gently pull the tray out by hand.

2.3 PRETREATMENT

Pretreatment is a crucial step that needs to be carried out before initiating the cleaning process. This step ensures that the devices are effectively prepared for further cleaning and disinfection, facilitating the removal of debris and contaminants. New non-sterile devices and reusable devices after every use must undergo the pretreatment process.

Procedure:

1. Always **remove coarse impurities** from the instruments directly after use (within one (1) hour at the most).
2. **Segregate instruments** according to material groups. Clean, disinfect and sterilize these groups separately to prevent potential interactions during the cleaning process. *(Refer to "Material groups and their resistance")*
3. **Disassemble devices** into their constituent parts such as the ratchet, distance indicator and explantation device. Cassettes must be dismantled into their respective parts such as the lid, trays, and base.
4. **Immerse the devices in a water bath** for at least 10 minutes. This aids in softening the debris and facilitating subsequent cleaning.
   Note: Water quality should be at least potable water.
5. **Remove all visible dirt** from the outer and if applicable inner cavities using a soft bristled nylon brush under running tap water.
   Note: Do not use abrasive tools like metal brushes or steel wool as they can damage the devices.
6. **If applicable, actuate all movable parts** of the instruments three times (3x) under running water. This helps remove debris stuck within joints and hinges.
7. **Rinse all the internal cavities and channels** thoroughly with tap water using a disposable syringe, performing a total of five rinses (5x). Maintain a minimum syringe volume of 20 ml.



2.4 CLEANING AND DISINFECTION

Cleaning and disinfection are mandatory steps of processing as they ensure that soil and micro-organism do not interfere with the sterilization process.

The objectives are:

- Ensure patient and staff safety
- Maintain instrument integrity by prevention of corrosion and damage
- Compliance with standards for infection control practices
- Ensure effective sterilization.

Straumann recommends the following methods for cleaning and disinfection:

I. Manual cleaning using an ultrasonic bath followed by manual disinfection
II. Automated cleaning and thermal disinfection using a washer-disinfector

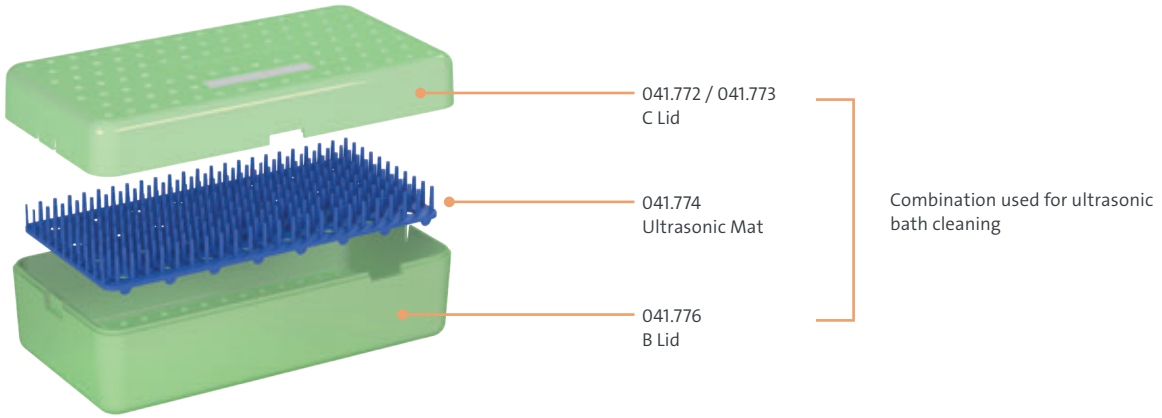
If possible, an automated method (washer-disinfector) should be used for cleaning and disinfection. A manual method should be used only if an automated method is not available (ISO 17664).

2.4.1 Manual cleaning and disinfection

Manual cleaning using an ultrasonic bath must be followed by disinfection, rinsing and drying. Ultrasonic baths must be operated precisely, choosing an appropriate detergent and following the manufacturer's instructions.
Routine replacement of the cleaning solution is important, and it should be changed after every session or when visibly contaminated.

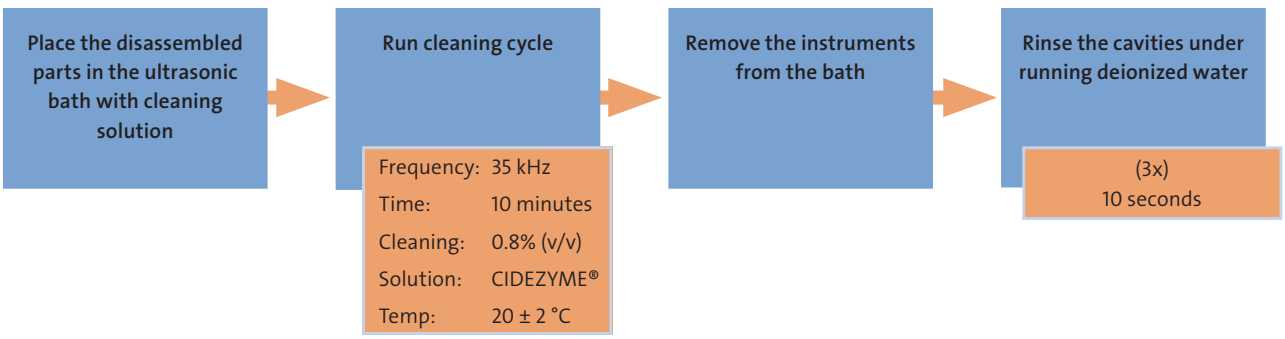
2.4.1.1 Manual cleaning with ultrasonic support

1. **Fill the ultrasonic bath** with a suitable cleaning solution, e.g. 0.8% (v/v) CIDEZYME®.
2. Immerse the devices in the ultrasonic unit with detergent solution. Ensure the devices are fully covered with the cleaning solution.
3. The disassembled instruments can be placed in the Ultrasonic Cleaning Cassette or on the Ultrasonic Mat (Straumann® Modular Cassette, B Module Lid).



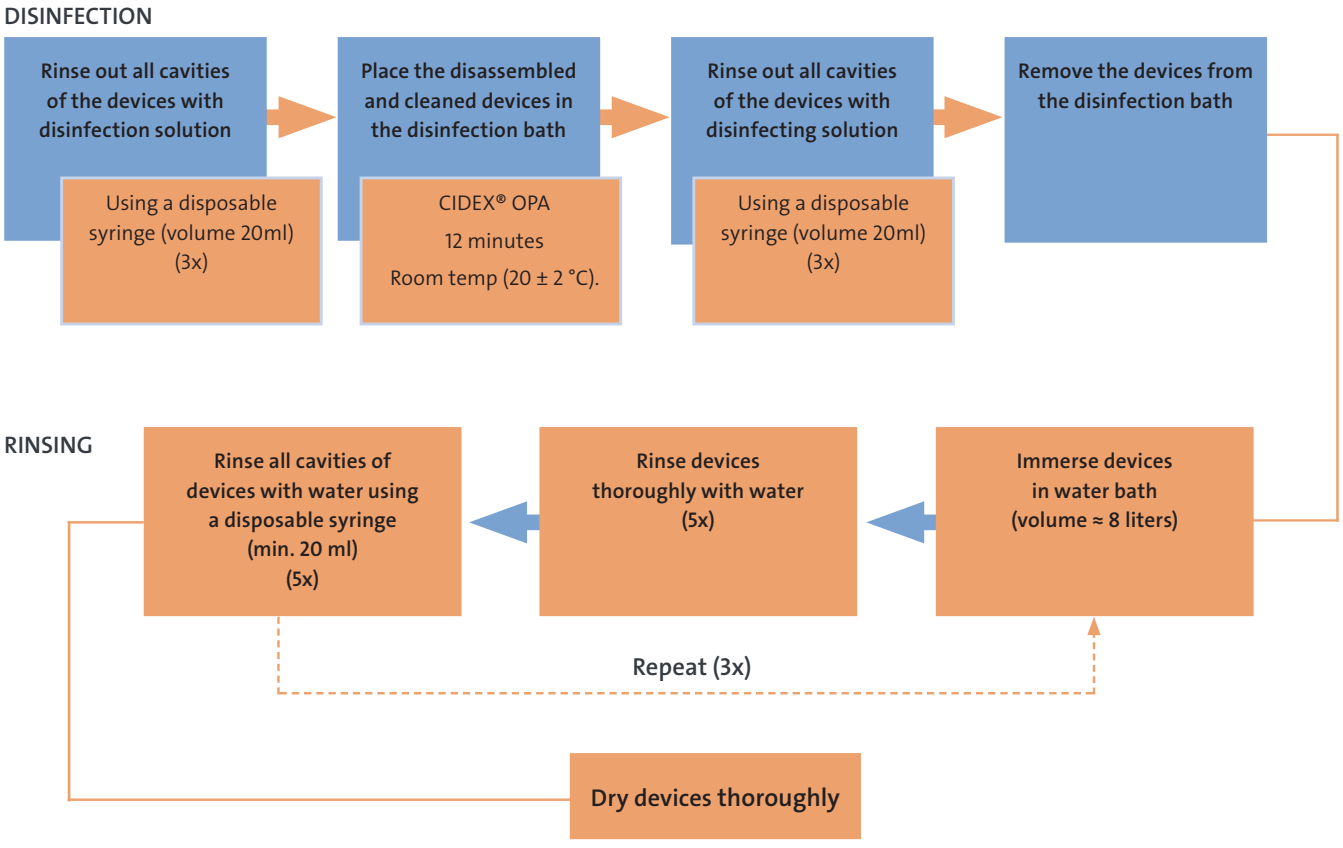
Note: Do not close the cassette for improved cleaning in the ultrasonic bath.
Do not overload as this can result in improper cleaning.
Ensure that the instruments do not touch or overlap each other.
Avoid placing different materials in the same bath.

4. **Run an ultrasonic cleaning cycle** (frequency 35 kHz) for 10 minutes in a bath of deionized water supplemented with cleaning solution (e.g. 0.8% (v/v) CIDEZYME® (Advanced Sterilization Products)) at room temperature (20 ± 2 °C).
5. **Remove all the devices from** the ultrasonic bath, after completion of the running cycle.
6. **Rinse the devices and flush out** all internal cavities and channels three times (3x) under running deionized water at room temperature (20 ± 2 °C) for at least 10 seconds or until no visible dirt remains.



2.4.1.2 Manual Disinfection

1. Place the disassembled and cleaned devices in the disinfection bath for the specified action time (e.g. 12 minutes in CIDEX® OPA, Advanced Sterilization Products) at room temperature (20 ± 2 °C). Ensure that the devices are covered by the disinfection solution, all lumens are filled and air pockets eliminated. Ensure that the devices do not touch each other.
2. Rinse the devices and flush the cavities and channels three times (3×) with disinfection solution at the beginning and at the end of the action time using a disposable syringe (minimum syringe volume 20 ml).
3. Remove the devices from the disinfection bath.
4. Immerse devices in a water bath (e.g. volume ≈ 8 liters) for at least a minute.
5. Rinse the devices thoroughly with water for a minimum of five times (5x).
6. If applicable, rinse all the devices cavities thoroughly with water using a disposable syringe, performing a total of five rinses (5x).
   Maintain a minimum syringe volume of 20 ml.
   Note: Straumann strongly recommends the use of freshly prepared critical water[1] or fully demineralized, sterile, and endotoxin-free water.
7. Repeat steps 6,7 and 8 for a total of three times (3x). Make sure to discard the water at the end of each rinse and use fresh volumes of water at the beginning of each rinse. Do not reuse the water for rinsing or any other purpose.
8. After the final rinse, ensure that the devices do not have any residue of the disinfection solution as this may cause serious side effects.
9. Dry the devices inside and outside using filtered compressed air. Pack the instruments as quickly as possible after removal (see Chapter 2.5-2.7). Make sure instruments are dry before packaging them for sterilization. If additional drying is necessary, dry in a clean location.



2.4.2 Automated cleaning and disinfection

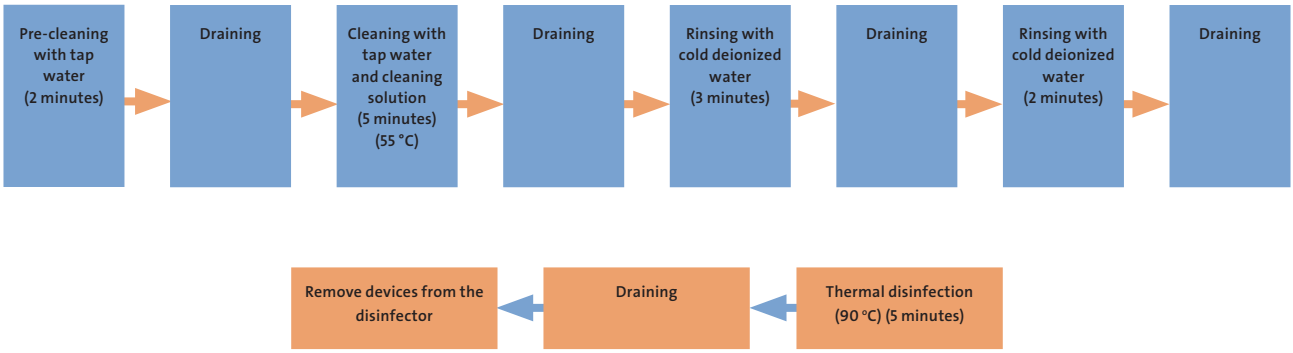
When using a washer-disinfector for automated cleaning and thermal disinfection, ensure the following:

- The washer-disinfector has been tested for its effectiveness (e.g. DGHM/VAH).
- A validated program for thermal disinfection (A_0 value > 3000) is used.
- The program used for the devices is suitable and includes sufficient rinsing cycles.
- The air used for drying is filtered.
- The washer-disinfector is regularly maintained and checked.

Procedure:

1. **Place the devices in the washer-disinfector** with the joints open to allow the water to flow easily through the cannulas and blind holes. Avoid instruments touching or overlapping each other.
   Note: Do not load the instruments in a cassette unless otherwise mentioned in the cassette manual.
2. If applicable, **connect all rinseable cavities** of the instruments to the rinsing connections of the washer-disinfector using a compatible rinsing adaptor.
3. **Start the appropriate program** as specified by the washer-disinfector manufacturer. Use suitable cleaning agents, according to the manufacturer's instructions (e.g. 0.5% (v/v) neodisher® MediZym, Dr. Weigert).
   Program parameters used in the Straumann® automated cleaning validation study:
   - Pre-cleaning with tap water – 2 minutes
   - Draining
   - Cleaning with tap water at 55 °C – 5 minutes
   - Draining
   - Rinsing with deionized water – 3 minutes
   - Draining
   - Rinsing with deionized water – 2 minutes
   - Draining

   Washer/Disinfector:
   Miele G7836 CD
   Cleaning agent:
   0.5% (v/v) neodisher®
   MediZym, Dr. Weigert
   Instrument Rack:
   Miele E 439/3
4. **Perform thermal disinfection** at 90 °C for 5 minutes.
5. **Remove the devices** from the disinfector after the end of the program.
6. Inspect and pack the devices as quickly as possible after removal (see sections 2.5, 2.6, 2.7). Make sure the devices are dry before packaging them for sterilization. If additional drying is necessary, dry them with filtered compressed air in a clean location.



2.5 INSPECTION

To ensure safety and maintain the functionality of the devices, it is recommended to visually check for the following using a magnifying glass and direct sunlight for better visibility:

- Corrosion: Look for rust or any signs of corrosion especially at joints and hinges
- Surface damage: Inspect for scratches, dents or other surface imperfections.
- Deformation/Wear: Ensure there are no bends, warps or excessive wear.
- Chipping: Check for chipping, particularly on cutting edges and tips.
- Contamination: Verify that all organic debris has been completely removed.

Critical areas to inspect include:

- Handles
- Joints
- Hinges
- Blind holes
- Cutting edges

Follow-up actions:

- If any contamination is found, repeat the cleaning and disinfection process.
- Replace any instruments with illegible markings or labels.
- Keep damaged, corroded or worn-out devices separate from intact ones to avoid contact corrosion. Discard these items properly.
- Replace any missing devices or components with new, cleaned and disinfected parts.

For detailed guidelines or device reusability: Refer to section on ‘Lifetime and Replacement.

2.6 ASSEMBLY AND FUNCTIONAL TESTING

Reassemble the disassembled instruments and functionally test instruments with moving parts to ensure proper function.

Assembly	Functional test
(1) Ratchet	
• Introduce the ratchet bolt into the ratchet body. • Screw in the retaining screw by hand, the bolt automatically finds its correct position. • Pull out the direction indicator and push back in again. • Tighten with the hexagonal end of the service instrument.	• The functional test of the ratchet is performed with an SCS Screwdriver for Ratchet (Art. No. 046.400, 046.401 or 046.402). • The SCS screwdriver is inserted in the ratchet. • The ratchet can be turned by holding the screwdriver. It can be turned only in the opposite direction of the arrow on the knob. • Clearly audible clicking noises can be heard when this is done correctly. • This inspection is performed for both arrow positions of the knob.
(2) Instruments with screws	
• The distance Indicators, 48 hr. explantation device and screw-retained implant drivers are assembled with the screws not tightened.	• SCS screwdriver and AS screwdriver should be tested for retention force. • Mount the SCS screwdriver on a Basal Screw (Art. No. 048.356 or 025.4900) and the AS screwdriver on a Basal Screw AS (Art. No. 048.906 or 025.0055). • Gently shake the screwdriver to see if the basal screw is secured.
(3) Implant drivers and Implant adapters	
n/a	• Implant drivers and implant adapters should be tested for retention force. • Straumann® provides different models at the 1:1 scale, which can be found in the Straumann® product catalog. • Mount the implant driver onto implants in the model with TorcFit™ connection. • Insert a Loxim® transfer piece into implants in the model with synOcta® or CrossFit® connection and mount the implant adapter. • Check whether the retention force is adequate for the implant driver. • Check whether you can pull off the Loxim® from the implant with the implant adapter.
(4) Cassettes	
• Assemble the tray, module and lid. • Place all devices in the designated slots in the cassette. • Refer to the Straumann® Modular Cassette Selection Guide (702824/en) for guidance on loading the cassette.	

2.7 PACKAGING

Make sure that the cassette and instruments are completely dry before packaging for sterilization. For individual devices, place each device in double-pouch packaging.
For devices loaded into cassettes, place the instruments in the designated slots of the cassette and then secure the cassette by placing it in double-pouch packaging. Disassemble the ratchet. Assemble the cassette by combining the tray, base and lid.

Note: When sterilizing devices with the Straumann® Modular Cassette, the maximum permissible stacking limit is one B Module on top of two C Modules.
The A Module should be sterilized on its own. The Ultrasonic Mat should be packaged and sterilized individually in a double pouch. Sterilization instruments on the Ultrasonic Mat is not allowed.

To ensure highest standards of hygiene and safety, it is essential to use double-pouch packaging that meets stringent specifications for steam sterilization and mechanical protection.

The double-pouch packaging must meet the following requirements:
- Steam sterilization compatibility:
  - Temperature resistance at least up to **137 °C(278 °F)**
  - Sufficient steam permeability to ensure proper sterilization.
- Provides adequate protection against mechanical damage during handling and storage.
- **EN ISO/ANSI AAMI ISO 11607:** Packaging of terminally sterilized medical devices.
- **For USA:** Always use FDA (510k) cleared sterilization accessories.

Important packaging considerations:
- Prior to packaging, make sure that the cassette and instruments are completely dry-assembled (see section 2.6) before packaging for sterilization.
- Ensure packaging is intact and seals are not broken.
- Verify that the dates of sterilization and batch numbers are clearly marked.
- Do not overfill pouches or containers. Instruments should fit comfortably without stretching or bulging the packaging material.
- An indicator strip with the date of sterilization and the expiration date should be affixed to every sterilization packaging. This will help to indicate whether, and if so when, the material was sterilized.

2.8 STERILIZATION

When loading the sterilizer, always place the cassette on the shelf in such a way that under no circumstances does it come in contact with the walls of the sterilizer. Do not put the cassette on its side or upside down with the lid facing down.
Do not place corroded or rusty instruments in the cassette for sterilization. These contaminate the water circulation system of the sterilizer with rust particles. During every subsequent sterilization cycle, these rust particles can cause rust to form on instruments that were originally intact.
The sterilizer manufacturer's instructions for use must be strictly followed. Always observe the operating instructions of the manufacturer for the sterilizer, especially with regard to the loading weight, operating time and functional testing.
Only steam sterilization methods listed below may be used for sterilization. Other sterilization methods (hot air, radiation, plasma, formaldehyde or ethylene oxide sterilization) are not allowed.
For steam sterilization Straumann strongly recommends the use of freshly prepared critical water[1] or fully demineralized, sterile, and endotoxin free water.

Steam sterilization:

- Fractionated vacuum method with sufficient device drying time and compliant with EN 13060[2] or EN 285[3].
- Validated according to EN ISO 17665[3] (valid IQ/OQ and product-specific performance assessment (PQ)).
- Maximum sterilization temperature of 134 °C (273 °F); plus, tolerance corresponding to EN ISO 17665[3], i.e. 137 °C (278 °F).

For steam sterilization, Straumann strongly recommends the use of freshly prepared critical water[1] or fully demineralized, sterile, and endotoxin-free water.

Note: Other sterilization methods (hot air, radiation, plasma, formaldehyde, or ethylene oxide sterilization) are not allowed.

Recommended sterilization parameters:	Method	Conditions	Drying time
For Europe:			
	Moist Heat (Autoclave) Fractionated vacuum	134 °C (273 °F) for 3 min	Local practice
For United States:			
	Moist Heat (Autoclave) Fractionated vacuum	132 °C (270 °F) for 4 min	30 min
For countries outside Europe and the United States:			
	Moist Heat (Autoclave) Fractionated vacuum	132 °C (270 °F) to 134 °C (273 °F) at least for 3 min	Local practice

Important device sterilization considerations:

- Always observe the operating instructions of the manufacturer for the sterilizer, especially with regard to the loading weight, operating time, and functional testing.
- When loading the sterilizer, always place the cassette on the shelf in such a way that under no circumstances does it come in contact with the walls of the sterilizer.
- Do not put the cassette on its side or upside down with the lid facing down.
- Do not place corroded or rusty devices in the cassette for sterilization. These contaminate the water circulation system of the sterilizer with rust particles. During every subsequent sterilization cycle, these rust particles can cause rust to form on devices that were originally intact.

Caution

All instruments and cassettes must not be exposed to temperatures higher than 134 °C (273 °F).

[1] AAMI TIR34:2014 (R2017) - Water for The Reprocessing Of Medical Devices
[2] EN 13060: Test method to demonstrate the suitability of a medical device simulator during steam sterilization – Medical device simulator testing
[3] EN 285 Sterilization – Steam sterilizers – Large sterilizers.
[3] 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

2.9 STORAGE

Dry and clean environment – store packaged instruments in a clean, dry environment to maintain package integrity before sterilization. Strictly follow the manufacturer's instructions for the sterilization accessories and storage containers.

Ensure that the storage area is free from contamination sources and that packaged instruments are not compromised before the sterilization cycle.

3. APPENDICES

3.1 LIFETIME AND REPLACEMENT

Frequent reprocessing has minor effects on the devices. The lifespan of each instrument is primarily determined by wear and damage incurred during use. Therefore, general instruments can be reused with appropriate care, as long as they remain undamaged and uncontaminated.

For specific instruments, such as single-use devices and cutting instruments, the defined lifetime is indicated on the label. Do not use devices beyond their effective product lifetime or if they are damaged and/or contaminated.

Disposal guidelines:
Ensure that the disposal of devices is done in an environmentally sustainable manner, adhering to local regulations
Hazardous waste should be disposed of in appropriate containers that meet specific technical requirements to handle hazardous waste safely.

Single-use devices

Limited

	• Devices are marked on the label with the "Do not reuse" symbol. • Should be disposed of after surgical usage. • These devices must not be reprocessed after surgical use. • Re-use of single-use devices creates a potential risk of contamination or device failure, which may lead to injury, illness or death of the patient.

Multiple-use devices

	*E.g.: Cutting devices* • Provided they are undamaged and not contaminated, • these devices can be reused up to a maximum of 10 processings. *(1 use = 1 processing). • Any further use extending beyond this number, or the use of damaged and/or contaminated devices, is not allowed.
	*E.g.: Other devices (Plan abutment)* • Provided they are undamaged and not contaminated, these devices can be reused up to a maximum of 20 processings. *(1 use = 1 processing). • Any further use extending beyond this number, or the use of damaged and/or contaminated devices, are not allowed.

Note: Maintain a checklist for cutting devices recording the number of uses. The Straumann® Surgery Tracking Sheet (152.755/en) is available for this purpose.

Unlimited
Devices designed for repeated use with no limit on processing.

Devices must be discarded if there are visible signs of damage and/or improper functioning.

The table below highlights common signs of device deterioration that indicate the end of the product life. Do not use devices beyond the effective product life cycle or damaged and/or contaminated devices.

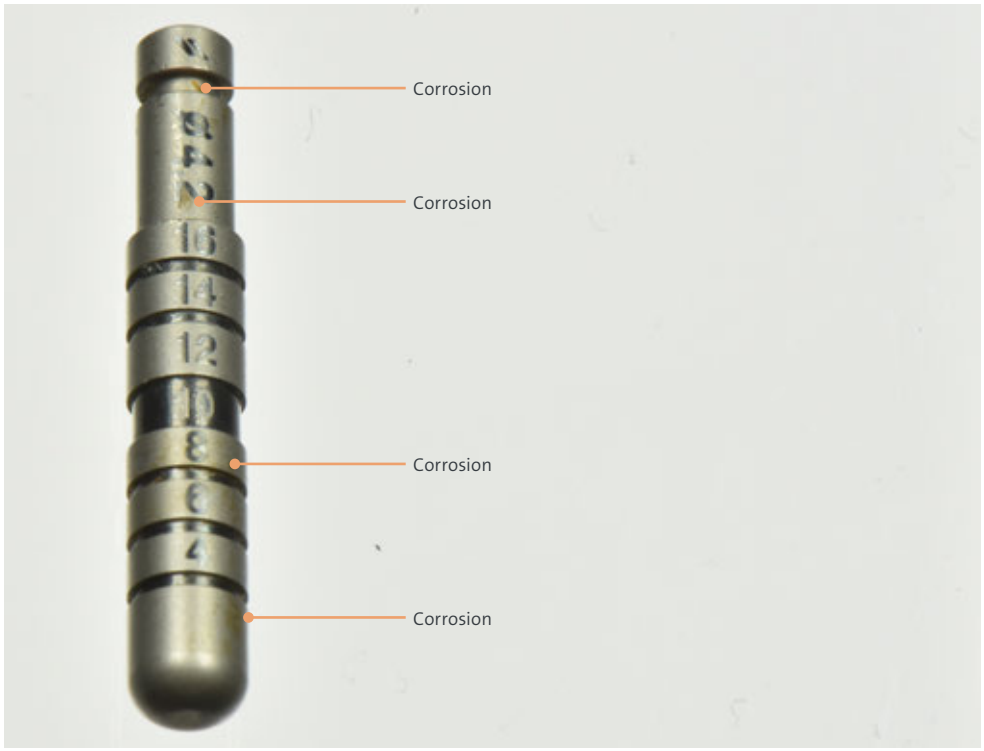
Product	Sample picture	Corrosion	Discoloration	Worn-out/Dented	Fracture
48 hour explantation device		●			●
Alignment pins & depth gauges		●	●		
Distance indicator		●	●	●	
Drill extender		●		●	
Guided drill handles		●	●	●	●
Adapter & inserting device		●	●		●
Position indicator				●	●
Ratchet and torque control device		●		●	●
Screwdrivers		●		●	●
Implant drivers		●		●	
Template fixation pins		●	●		●

● Common signs of damage that indicate the end of product life.

Visual examples:

To help determine whether a device has reached the end of its product life, this section provides visual examples of the common signs of damage.

Corrosion of a depth gauge



Worn-out/dented screwdriver

Discoloration of a template fixation pin

Fracture of a torque control device

3.2 FURTHER INFORMATION

For further information regarding warnings, cautions, precautions, material compatibility, loading the cassette, please refer to the following documents:

Instructions for use

- *Straumann® Modular Cassette (702407)*
- *Straumann® Cassette (702908)*
- *Straumann® ProClean Cassette (701624)*

Technical information

- *Straumann® ProClean Cassette, Basic Information (702070/en)*
- *Straumann® Modular Cassette, Basic Information (702527/en)*

How to load the cassette

- *Instrument List for Straumann® Surgical Cassette (152.746/en)*
- *Straumann® Basic Surgical Cassette (490.070/en)*
- *Straumann® Modular Cassette Selection Guide (702824/en)*
- *Basic Information on the Straumann® ProClean Cassette (702070/en)*

Tracking sheet

- *Straumann® Surgery Tracking Sheet (152.755/en)*

3.3 VALIDITY

Upon publication of these documents, all previous versions are superseded. Some items of the Straumann® Dental Implant System are not available in all countries.

3.4 TROUBLESHOOTING

Glossary

Types of damage	Potential causes	Preventive measures
Corrosion and rust	• Residual blood, pus, secretions, tissue residues, bone residues • Prolonged exposure to moisture • Insufficient drying of the devices	• Use instruments only for their intended purpose • Clean instruments immediately after use • Ensure thorough drying
Pitting and discoloration	• Exposure to saline solutions, iodine tinctures, unsuitable water, improper cleaning agents and disinfectants	• Use only appropriate cleaning agents and disinfectants • Follow manufacturer's instructions • Rinse agents thoroughly with water
Material surface destruction	• Use of abrasive materials like steel wool or steel brushes	• Clean with soft brushes only • Disassemble and clean all cavities • Do not reprocess different materials together
Cutting surface damage	• Device used beyond the defined lifetime • Collision of instruments during cleaning	• Ensure to follow lifetime and reusability instructions for instruments • Handle instruments with care
Rust on new instruments	• Contaminants in the sterilizer (e.g., from corroded instruments or improper maintenance) • Cross-contamination from rusting instruments	• Ensure proper maintenance of the sterilizer • Prevent cross-contamination by separating rusted instrument
General preventive measures		• Rinse off disinfectants and cleaning agents thoroughly with water • Use filtered compressed air to blow dry • Never leave or store instruments moist or wet

Decontamination: process of rendering an article or area free of danger from contaminants, including microbial, chemical, radioactive, or other hazards. It includes cleaning, disinfection, inspection, and sterilization.

Cleaning: removal of visible or adhered dirt and invisible organic matter to prevent microorganisms from maintaining, multiplying, and spreading.

Disinfection: destruction or removal of all pathogenic organisms, or organisms capable of giving rise to infection.

Sterilization: process by which an article, surface or medium is freed of all living microorganisms either in the vegetative or spore state.

Disinfectant: antimicrobial agents that are applied to the surfaces of non-living objects to destroy microorganisms that are living on the objects.

Thermal disinfection: disinfection achieved by the action of moist heat.

Sensitive materials: materials unable to withstand the temperatures during thermal disinfection or moist heat sterilization

3.5 MECHANISM OF ACTION

Washer-disinfector

The washer-disinfector uses the mechanical action of high-pressure water jets and detergent to thoroughly clean the instruments. This is followed by thermal disinfection, where water is heated to high temperatures to kill microorganisms. The cycle concludes with hot air drying to ensure the instruments are moisture-free and ready for sterilization.

Ultrasonic bath

Ultrasonic cleaning generates high-frequency ultrasound waves. As these waves propagate through the cleaning solution, they form bubbles, a process called cavitation. The bubbles collapse or implode, producing a tremendous amount of energy and pressure. This, in combination with a specialized cleaning solution, allows the cleaning action to penetrate intricate areas that are difficult to clean manually.

152.008/en/E/03 01/25
702000/en/E/04 01/25

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
www.straumann.com

straumann