Technical Information

Straumann® surgical and prosthetic instruments

Care and maintenance

straumann

Contents

1. General principles

A successful implantation depends on instruments that are precise and cared for properly. Therefore, keeping surgical and prosthetic instruments clean and fit for use is essential for success. In addition, avoiding contamination from patient to patient is essential and important for treatment practices.

All instruments must be cleaned, disinfected and sterilized before every use. This also applies to new instruments removed from protective transport packaging and single-use devices that are delivered non-sterile. The exception is instruments delivered sterile that are intended for one-time use (e.g. sterile single-patient drills). Each instrument must only be used for its intended purpose.

There are 5 steps in the complete reprocessing process
- Pretreatment
- Cleaning
- Disinfection
- Inspection, functional test and packaging
- Sterilization

Cleaning and disinfection cannot replace effective sterilization. Maintain and clean your instruments according to recommended instructions. Sterilization must follow the sterilization instructions stated in Chapter 6.

Surgical and prosthetic parts (e.g. closing screws and healing caps) that remain in the oral cavity directly after the surgery must be sterilized following the sterilization instructions.

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 is regularly maintained, checked and calibrated.
- Washer-disinfector complies with EN ISO 15883-1
- Sterilizer complies with EN 13060 or EN 285

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 hospital.

1.1 Material groups and their resistance

The groups below identify the materials used for Straumann® instruments and certain ingredients not to be used in disinfectants and cleaning agents.

Instruments must be separated according to these groups. Instruments from different materials should not be placed together in a liquid bath, as this increases the risk of contact corrosion. You will find information about the material of a device in the Straumann® Product Catalog.

Stainless steel
The corrosion resistance of stainless steel is created by the formation of a passive layer (chromium oxide layer) on its surface. This passive layer is extremely resistant to many chemical materials and physical parameters. However, it is wrong to think that "stainless" steel cannot rust. This material can also be affected by certain external conditions or lack of proper care.

Since the use of disinfectants and cleaning agents containing one or more of the following ingredients can cause pitting and contact corrosion, they are not recommended for stainless steel: chlorine, oxalic acid, hydrogen peroxide (H_2O_2).

Titanium
Titanium is a material that is very resistant to corrosion and external conditions due to the self-oxidation of its surface.

The use of disinfectants and cleaning agents containing one or several of the following ingredients can cause discoloration, hence it is not recommended for titanium: chlorine, oxidizing acids (e.g. nitric acid, sulfuric acid, oxalic acid), hydrogen peroxide (H_2O_2).

Aluminum
The aluminum used for our devices is anodized. The surface is coated with an oxide layer applied anodically, resulting in an increased resistance to corrosion of the material.

The use of acid or alkaline disinfectants and cleaning agents that have a pH value outside the acceptable range of 5 – 9 is not recommended for aluminum as they can destroy the oxide layer, thereby increasing the susceptibility of the material to corrosion.

Plastic

The plastics used for Straumann® devices can be sterilized at temperatures up to 134 °C (273 °F).

Since the use of disinfectants and cleaning agents that contain one or more of the following ingredients can cause deformation, they are not recommended for plastics: organic solvents (alcohols, ethers, ketones and benzines), hydrogen peroxide (H_2O_2), aldehyde, halogens (chlorine, iodine, bromine).

In summary
When selecting the cleaning agents and disinfectants, please make sure that they do **not** contain the following ingredients: • organic, mineral and oxidizing acids (minimum permissible pH value 5) • strong alkalis (maximum permissible pH value 9, mildly alkaline cleaners recommended) • organic solvents (e.g. alcohols, ethers, ketones, benzines) • oxidizing agents (e.g. hydrogen peroxide) • halogens (chlorine, iodine, bromine) • aromatic/halogenated hydrocarbons • salts of heavy metals • fixatives (e.g. aldehydes)

2. Troubleshooting

Below is a list of common issues observed during instrument reprocessing.

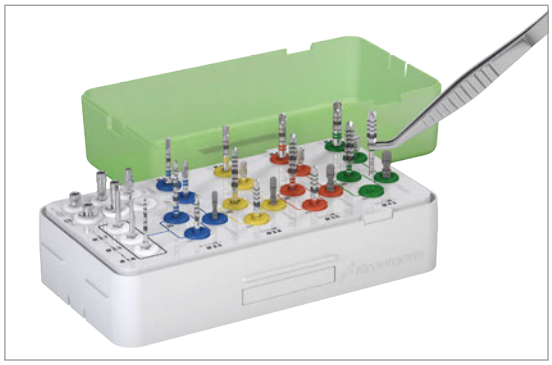
Possible types of damage and their potential causes:

Damage	Potential Cause
Corrosion, rust	Blood, pus, secretion, tissue residues, bone residues that stick and dry on instruments lead to corrosion Extended exposure of instruments to moisture for long periods Insufficient drying of the instruments
Pitting, discoloration	Saline solution, iodine tinctures, unsuitable water, unsuitable and/or incorrectly used cleaning agents and disinfectants
Contact corrosion, destruction of the material surface	Use of steel wool or steel brushes, which removes the oxide layer and increases susceptibility to corrosion
Contact corrosion	Contact between instruments of different metallic materials
Cutting surfaces become blunt or are damaged	Instruments are used beyond the defined lifetime Collision of instruments during cleaning
New instruments start to rust after sterilization	Impurities in the sterilizer, e.g. due to already corroded instruments or improper maintenance of the sterilizer Intact instruments contaminated by other instruments with rust

How to avoid problems

- Use each instrument only for its intended purpose.
- Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.
- Thoroughly clean off incrustations with soft brushes only.
- Disassemble instruments, clean cavities especially well.
- Never disinfect, clean, sonicate or sterilize instruments made of different materials together.
- Use only cleaning agents and disinfectants intended for the material and follow the manufacturers' instructions for use.
- Rinse off disinfectant agent and cleaning agents thoroughly with water.
- Use filtered compressed air to blow dry and allow enough time for drying.
- Never leave or store instruments moist or wet.

3. Before and during the surgery

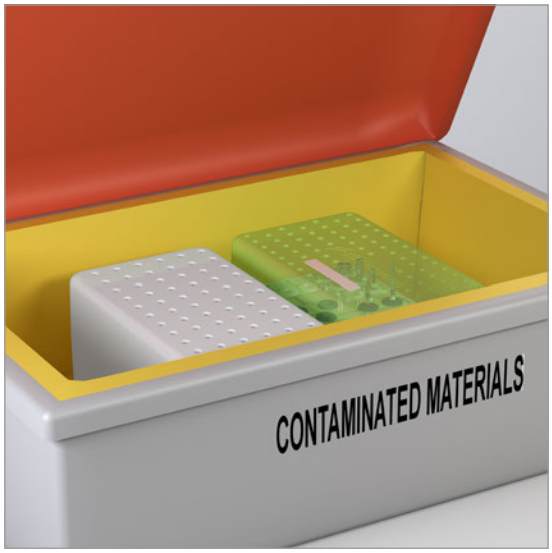


Use each instrument only for its intended purpose.

Make sure that all contaminated instruments are collected separately. Instruments can be damaged by incorrect handling, such as throwing them on a hard surface. Do not place them back in the instrument cassette to avoid contamination of the filled instrument cassette unless otherwise indicated by the specific cassette instructions. (e.g. Straumann® ProClean cassette).

Warning
Damaged and/or blunt instruments must be sorted out and disinfected, cleaned and disposed of separately.

After use, immerse instruments in a disinfection solution that does not contain any fixatives. Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean the instruments immediately after surgery. Process contaminated instruments as quickly as possible for cleaning (within one (1) hour at the most).



After surgery, safely store and transport the cassette with instruments in a closed container to the reprocessing area to avoid damaging or contaminating the environment.

4. Cleaning and disinfection

4.1 Principles

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).

Pretreatment is required prior to both the automated and manual methods.

It is important to use protective clothing while cleaning contaminated instruments. Always wear protective glasses, face mask, gloves, waterproof gown, etc. for your own safety during all activities.

4.2 Pretreatment

Coarse impurities must be removed from the instruments directly after use (within one (1) hour at the most).

Sort the instruments according to material groups (see “1.1 Material groups and their resistance”) and clean, disinfect and sterilize these groups separately. Never place instruments made of different materials together.

For cleaning, the device must be dismantled into its component parts (e.g. ratchet, distance indicator, 48h explantation device). Special nylon brushes (Art. No. 045.111) are available for cleaning the ratchet lumen. Cassettes are disassembled into lid, trays and base.

Before every use, the device must be carefully checked for proper function and damage.

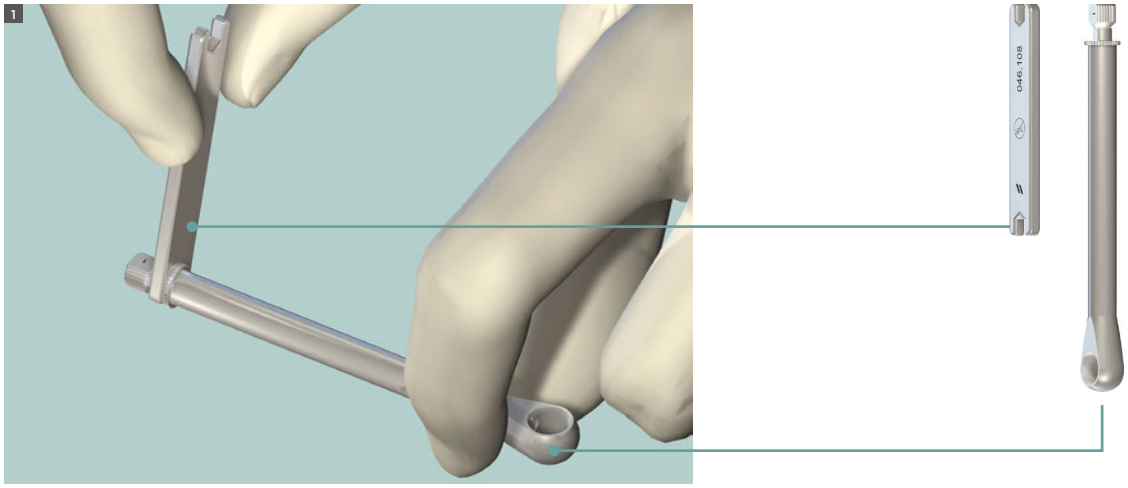
Place the instruments in a water bath for at least 10 minutes.

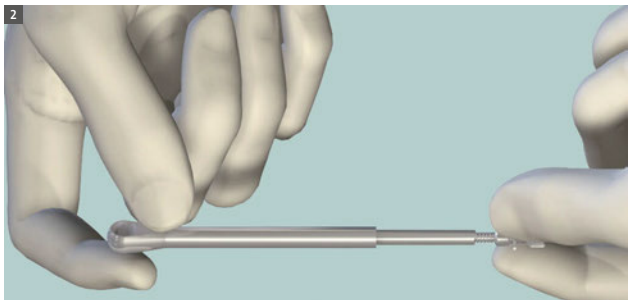
All visible dirt should be removed by brushing with a suitable soft bristled brush under running tap water. Never use metal brushes or steel wool.

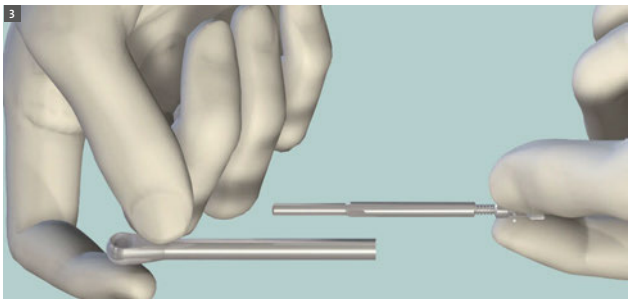
All movable components should be actuated 3 times under running water. Rinse out all cavities of the instruments five times (5×) with water using a disposable syringe (minimum syringe volume 20 ml).

Disassembly of the Ratchet (Art. No. 046.119)

For proper function, the ratchet must be disassembled immediately after every use and, if possible, should be cleaned immediately. To disassemble the ratchet, loosen the retaining screw with the Service Instrument for Ratchet (Art. No. 046.108) and unscrew the ratchet bolt.







Disassembly of instruments with screws

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

4.3 Cleaning and disinfection

For all instruments, cleaning and disinfection can be performed using the automated or manual method.

Ensure the following during cleaning and disinfection:

Water quality

- Pollutants/minerals from water can reduce the lifetime of instruments and impair the performance of cleaning solutions.
- Always use the highest water quality accessible for cleaning (e.g. distilled or deionized). At least potable water quality should be used.
- For the final rinse, Straumann® strongly recommends the use of fully demineralized, endotoxin-free water.

Cleaning agent and disinfectant agent

- Suitable for cleaning metal and plastic instruments.
- The chemicals used are compatible with the instruments (see "1.1 Material groups and their resistance").
- The cleaning agent is suitable for ultrasonic cleaning (no development of foam).
- The disinfectant has been tested for its effectiveness and does not contain fixatives (e.g. DGHM[1]/VAH[2])
- Do not combine cleaning agents with disinfectants.
- Use only freshly made solutions.
- Always follow the instructions for use of the manufacturers of cleaning agent and disinfectant. The concentrations and action times stated by the manufacturer of the cleaning agent and disinfectant must be strictly adhered to.

[1] DGHM – "Deutsche Gesellschaft für Hygiene und Mikrobiologie" www.dghm.org "German Association for Hygiene and Microbiology"
[2] VAH – "Verbund für Angewandte Hygiene E.V" www.vah-online.de "Association for Applied Hygiene"

4.3.1 Automated cleaning and disinfection (EN ISO 15883-1)

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 instruments 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 instruments in the disinfector so that joints are opened and water can flow out of cannulas and blind holes. Make sure that the instruments do not touch each other. Connect all cavities of the instruments that can be rinsed to the rinsing connections of the washer-disinfector using a suitable rinsing adapter.
2. Do not load the instruments in a cassette unless otherwise indicated by the specific cassette instructions. (e.g. Straumann® ProClean cassette). Refer to “8. Further Information” for information on specific cassette instructions.
3. Start the appropriate program suitable for instruments. Use appropriate cleaning agents according to the manufacturer’s instructions (e.g. 0.5% (v/v) neodisher® MediZym, Dr. Weigert).
4. Perform thermal disinfection at 90 °C for 5 min.
5. Remove the instruments from the washer-disinfector after the end of the program.
6. Inspect and pack the instruments as quickly as possible after removal (see “5. Inspection, functional test and packaging”). Make sure the instruments are dry before packaging them for sterilization. If additional drying is necessary, dry in a clean location.

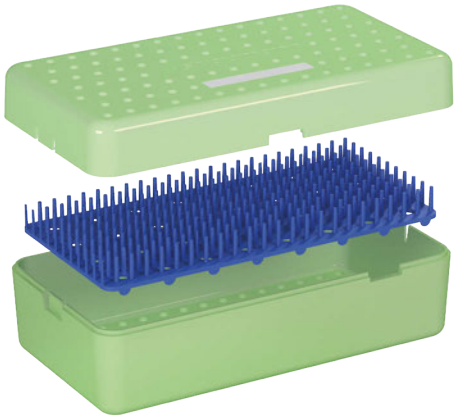
Note
Always follow the instructions stated by the manufacturer of the washer-disinfector.

The following devices, materials and machines have been used in the Straumann® Surgical Cassette automated cleaning and disinfection validation study:
- **Cleaning agent:** neodisher® MediZym, Dr. Weigert
- **Washer/Disinfector:** Miele G 7836 CD
- **Instrument Rack:** Miele E 439/3

4.3.2 Manual cleaning and disinfection

Cleaning in the ultrasonic bath

1. Place the disassembled cassette parts (lid, trays, base) in an ultrasonic bath.
2. Place the disassembled instruments in the Ultrasonic Cleaning Cassette (Art. No. 040.175) or on the Ultrasonic Mat (Art. No. 041.774) that is secured in a Straumann® Modular Cassette, B Module Lid (Art. No. 041.776). The C Module lid (Art. No. 041.772, 041.773 or 041.784) can be used to enclose the B Module lid to protect the contaminated instruments during transportation.
3. Make sure that the instruments do not touch each other. Instruments made of different materials may not be placed in the same bath. To improve the cleaning effect in the ultrasonic bath, cleaning without closing the cassette is recommended.
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 the instruments from the ultrasonic bath.
6. Rinse out all cavities of the instruments and cassette parts three times (3x) under running deionized water at room temperature (20 ± 2 °C) for at least 10 seconds or until no dirt residues are visible.



Disinfection

Manual Processing

1. Place the disassembled and cleaned instruments in the disinfection bath for the specified action time (e.g. 12 min in CIDEX® OPA, Advanced Sterilization Products) at room temperature (20 ± 2 °C). Ensure that the instruments are covered by the disinfection solution, filling all lumens and eliminating air pockets. Ensure that the instruments do not touch each other.
2. Rinse out all cavities of the instruments 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 instruments from the disinfection bath

Rinsing

4. Immerse instruments completely in a large volume (e.g. 8 liters) of water for a minimum of 1 minute.
5. Rinse instruments thoroughly with water at least five times (5×). Rinse out all cavities and lumens of the instruments with water five times (5×) using a disposable syringe (minimum syringe volume 20 ml).
6. Remove the instruments and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
7. Repeat steps 4 to 6, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX® OPA solution residues. Residues may cause serious side effects.

Drying

8. Dry the instruments inside/out with filtered compressed air.
9. Pack the instruments as quickly as possible after removal (see “Chapter 5 Inspection, functional test and packaging”). Make sure instruments are dry before packaging them for sterilization. If additional drying is necessary, dry in a clean location.

5. Inspection, functional test and packaging

5.1 Inspection

Always check all cassette parts and instruments after cleaning and disinfection for corrosion, damaged surfaces, chipping and contamination and sort out damaged parts. For the restriction of instrument reusability, see “7. Lifetime and replacement”. Critical areas such as handle structures, joints or blind holes must be inspected carefully. You can use a magnifying glass and direct lighting for better visibility. Instruments with illegible markings/labeling must also be replaced.

Instruments that are still contaminated must be cleaned and disinfected anew. Damaged, corroded or worn instruments should not come into contact with intact instruments to avoid contact corrosion. Replace missing devices with new parts that are cleaned and disinfected.

5.2 Functional test

The instruments must be subjected to a functional test. Multi-piece instruments are assembled for this purpose. Ensure that further contamination is avoided during assembly. Do not use instrument oil.

Functional test of the Ratchet (Art. No. 046.119)
Assemble the ratchet by introducing the ratchet bolt into the ratchet body and screw in the retaining screw by hand, the bolt automatically finds its correct position. Pull out the direction indicator and push back in again. Then tighten with the hexagonal end of the service instrument.

The functional test of the ratchet is performed with a SCS Screwdriver for Ratchet (Art. No. 046.400, 046.401 or 046.402). For example, the SCS screwdriver is inserted in the ratchet. The ratchet can be turned by holding the screwdriver. It can only be turned in the opposite direction of the arrow on the knob. Clearly audible clicking noises can be heard in this case. This inspection is performed for both arrow positions of the knob.

Functional test of SCS screwdriver and AS screwdriver
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.

Functional test of implant adapters and implant drivers
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.

5.3 Packaging

Make sure that the cassette and instruments are completely dry before packaging for sterilization.
Assemble the distance Indicators, 48 hr explantation device and screw-retained implant drivers, with the screw not tightened. Disassemble the ratchet.

Place all instruments in the designated slots in the cassette. Refer to “8. Further Information” for information on how to load the different cassettes. Assemble the cassette by putting together the tray, base and lid.

When sterilizing instruments 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 alone.

Sterilizing instruments on the Ultrasonic Cleaning Cassette (Art. No. 040.175) or Ultrasonic Mat (Art. No. 041.774) is not allowed. Both items should be packaged and sterilized individually.

For instruments to be sterilized individually, place the instruments in a double-pouch packaging satisfying the requirements below. For instruments loaded into cassettes, note that the cassette is not intended to maintain sterility on its own. Place the cassette in a metal sterilization container or in a double-pouch packaging satisfying the following requirements:

- Suitable for steam sterilization (temperature resistance up to at least 137 °C (278.6 °F), sufficient steam permeability).
- Sufficient protection of the instruments or sterilization packaging against mechanical damage.
- EN ISO/ANSI AAMI ISO 11607 – Packaging for terminally sterilized medical devices

An indicator strip with the date of the sterilization and the expiration date should be affixed to every sterilization packaging. This will help to indicate whether and when the material was sterilized.

6. 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.

Steam sterilization

- Fractionated vacuum method with sufficient device drying time and compliant with EN 13060[1] or EN 285[2]
- 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).

Recommended sterilization time (exposure time at the sterilization temperature) and drying time:

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

If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time.

Make sure that the cassette and instruments are completely dry before packing for sterilization. Sterilized devices should be used immediately after sterilization. In case of storage, strictly follow the manufacturer's instructions of the sterilization accessories and storage containers.

Caution

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

[1] EN 13060: Test method to demonstrate the suitability of a medical device simulator during steam sterilization – Medical device simulator testing
[2] 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

7. Lifetime and replacement

Frequent reprocessing has minor effects on the instruments. The end of the product life is determined by wear and damage during use. Therefore, general instruments can be reused with appropriate care, provided they are undamaged and not contaminated. For specific instruments, such as single-use instruments and cutting instruments, the defined lifetime is marked on the label. Do not use instruments beyond the effective product lifetime or damaged and/or contaminated instruments.

Disposal of instruments should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste for contaminated devices or sharps should be disposed of in appropriate containers that meet the specific technical requirements.

7.1 Single-use instruments

Single-use instruments are marked on the label by the “Do not reuse” symbol and should be disposed of after surgical usage.

Single-use instruments must not be reprocessed after surgical use. Re-use of single-use instruments creates a potential risk of contamination or device failure, which may lead to injury, illness or death of the patient.

7.2 Cutting instruments

Provided they are undamaged and not contaminated, cutting instruments can, with proper care, be reused up to a maximum of 10 times (1-time use = placement of 1 implant); any further use extending beyond this number or the use of damaged and/or contaminated instruments is not allowed.

These cutting instruments are marked on the label with the following symbol:

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

7.3 Limited lifetime instruments

Certain instruments have limited lifetime to remain effective. Provided they are undamaged and not contaminated, these instruments can be reused up to a maximum of 20 time use (1 time use = 1 surgery); any further use extending beyond this number or the use of damaged and/or contaminated instruments is not allowed.

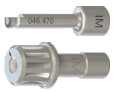
These instruments are marked on the label with the following symbol:

Maintain a checklist for these instruments recording the number of uses.

7.4 General Instruments

The table below lists the common visible signs of damage for different instruments to assist the user in determining whether a reusable instrument needs to be discarded.

All parts of the instruments must be carefully assessed for visible damage and/or proper functioning. The table below highlights common signs of instrument deterioration that indicate the end of the product life. Do not use instruments beyond the effective product life cycle or damaged and/or contaminated instruments.

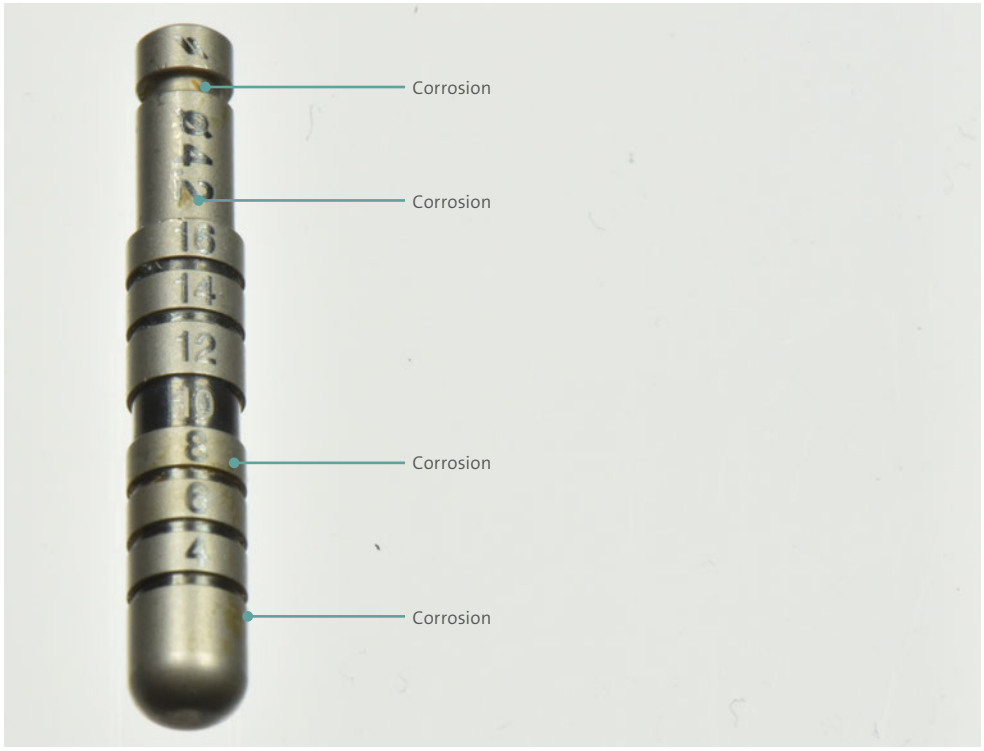
Product	Sample picture	Corrosion	Discoloration	Worn-out/Dented	Fracture
48 hour explantation device		●			●
Alignment pins & depth gauges		●	●		
Distance indicator		●	●	●	
Drill extender		●		●	
Guided drill handles		●	●	●	●
Adapter & inserting device		●	●		●
Position indicator				●	●
Ratchet and torque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

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

7.5 Visual examples

In order to help you to determine whether an instrument has reached the end of its product life, this section provides visual examples of the common signs of damage.

Corrosion of a **Depth Gauge**



Discoloration of a **Template Fixation Pin**

Worn-out/dented **Screwdriver**

Fracture of a **Torque Control Device**

8. Further information

For further information (e.g. warnings, cautions, precautions, compatibility), and information on how to load the cassette, please consult:

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)
- *Instrument List for Straumann® BLX Cassette* (703049/en)
- *Straumann® Basic Surgical Cassette* (490.070/en)
- *Straumann® Basic Guided Surgery Cassette* (490.121/en)
- *Straumann® Modular Cassette Selection Guide* (702824/en)
- *Basic Information on the Straumann® ProClean Cassette* (490.128/en)

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

8.1 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.

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