

CARE AND MAINTENANCE OF SURGICAL AND PROSTHETIC INSTRUMENTS



COMMITTED TO
SIMPLY DOING MORE
FOR DENTAL PROFESSIONALS



Strauman is industrial partner of the ITI (International Team for Implantology) in the areas of research, development and education.

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1. VALUABLE SURGICAL AND PROSTHETIC INSTRUMENTS!

Implantation can only be carried out successfully if the instruments are precise and have been cared for properly.

We support your efforts by manufacturing our instruments from high-grade materials and making them as precise as possible.

In the dental practice, you are responsible for these valuable instruments.

Well maintained instruments not only safeguard your patients and entire practice staff against infection but are also essential for successful treatment.

The following is a brief overview of the materials we use and their special features:

Stainless steel:

Thanks to its special composition, this material is very resistant.

Different grades (= compositions) are available for different applications:

1. all cutting, surgical instruments and
2. all non-cutting, surgical and prosthetic instruments can be grouped together according to their grade.

The instruments must be separated according to these groups for cleaning and sterilizing!

However, it is not true that "stainless" steel does not rust (regardless of the quality).

Even this material can be damaged by certain external effects such as lack of or incorrect maintenance.

Plastic – PEEK:

Some of our stainless steel instruments include plastic (PEEK) parts. The plastic we use is very resistant and can be sterilized at temperatures of up to 134 °C (273 °F).

Plastic–Radel:

The surgical cassette is made of the high-impact thermoplastic Radel (polyphenylsulphone). The cassette can be autoclaved at temperatures of up to a maximum of 134 °C (273 °F).

Refer to package insert.

Titanium:

Thanks to its self-oxidising surface, titanium is a metal which is very resistant to corrosion and external effects.

Aluminium:

Prosthetic instrument cassettes are made of anodised (= the surface is oxidised electrolytically) aluminium.

This increases the corrosion resistance of the material.

All instruments are only as good as the care they receive!

Each instrument must only be used for its intended purpose.

Once removed from the package, new instruments must be cleaned and sterilized before being used for the first time. And they must be cleaned and sterilized properly in between each subsequent use.

Components, which remain in the mouth immediately after surgery must also be sterilized prior to using (e.g. closure screws and healing caps).

Improper or insufficient care of these materials may result in damage to the instruments within a very short time (e.g. tips of drills).

Cleaning agents and disinfectants are available commercially, that are intended for use on the various materials.
Please ask your supplier for details.

When purchasing cleaning material, please ensure that it does **not contain** the following constituents:

Not recommended for stainless steel:

Disinfectant or cleaner containing a high percentage of **chlorine** (if used, nonetheless, never apply for longer than one hour).

Disinfectant or cleaner containing **oxalic acid**.

Possible adverse affects can occur in cases of non-compliance:

Pitting and contact corrosion.

Not recommended for titanium components:

All **oxidising acids** (nitric acid, sulfuric acid, axalic acid), **H₂O₂** (hydrogen peroxide).

Possible adverse affects can occur in cases of non-compliance:

Discolouration of the material.

Not recommended for anodised aluminium:

Alkaline cleaners (lyes) with a pH value exceeding 9! pH values of 5–9 are acceptable.

Possible adverse affects can occur in cases of non-compliance:

Destruction of the anodised layer.
Increased susceptibility to corrosion!

Not recommended for plastic (Radel):

Chemical sterilization is NOT recommended. No dry heat sterilization!

Possible adverse effects can occur in cases of non-compliance:








The plastic surface can be damaged by the aggressive chemicals, and hot air sterilization can make the plastic melt!

Please note:


If you adhere strictly to the cleaning agent/disinfectant manufacturer's instructions, many possible errors will be eliminated!

Those components which require special procedures in addition to the careful cleaning mentioned previously are listed on the following pages. The full assortment (all sizes) is included in our catalogue.


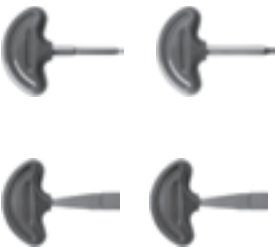
Surgical instruments

| Instrument | Special requirements | Material |
|--|---|--------------------------|
| Trephine drill  | Clean the cannulation in the drill very carefully! Check whether bone is stuck in the interior – remove it prior to disinfecting! | Stainless steel |
| Trephine drill, internal cooling  | The cooling ring must be removed and the handpiece hose disconnected prior to disinfecting, cleaning, and sterilizing! | Stainless steel |
| Cooling ring  | Remove from trephine drill immediately after use. Disconnect the hose from the cooling ring. Disinfect, clean, and sterilize separately! | PEEK/stainless steel |
| Cleaning instrument for trephine drills  | If necessary, bend to shape! | Stainless steel |
| Drill/bur  | It is extremely important to handle all drills and burs carefully. Even slight damage to their tips, as occurs if drills are “tossed” into a dish of water, can harm them. Damage to the tips impedes their cutting performance considerably! The following aspects must be observed if the drills are to be maintained properly: Place the drill “gently” in the storage dish (e.g. filled with physiological saline solution) and never drop it directly onto its tip. Never allow drills to touch one another while being cleaned in an ultrasonic unit. To avoid contact between the drills in the ultrasonic unit, the Ultrasonic Cleaning Cassette can be used. | Stainless steel |
| Ratchet  | Dismantle immediately after use. Disinfect, clean, and sterilize the individual parts! | Stainless steel |
| Tweezers  | Never use the tweezers in close proximity to the implant site – only use them for passing over sterile parts! | Stainless steel/titanium |

Surgical instruments

| Instrument | Special requirements | Material |
|--|--|----------------------|
| Bone Graft Inserting device  | Generally, Ti-N-coated instruments can be sterilized together with other surgical, stainless steel instruments. We recommend treating these instruments separately, however, to prevent them touching while being sterilized. This precludes possible reactions. | Stainless steel/Ti-N |
| Surgical Kit | Dismantle completely for disinfecting and cleaning! Dry well before reassembling! Instruments can be sterilized in their holders. Be certain to put filter paper in. Refer to package insert! | Aluminium, anodised |
| Surgical cassette | Refer to package insert! | Thermoplastic |
| Starter Sets | Must not be sterilized! | Plastic |

Prosthetic instruments

| Instrument | Special requirements | Material |
|--|--|------------------------------|
| Ratchet instruments  | Grooves in handles should be cleaned particularly carefully! | Stainless steel |
| Activator/Deactivator  | Red handle Never place in a sterilizer because this plastic is not heat-resistant! | Stainless steel/plastic |
| | Blue handle Never place in a sterilizer because this plastic is not heat-resistant! | Brass, chrome-plated/plastic |

2. HOW NOT TO DO IT!

Please note:

Any remains from the operation which are allowed to adhere and dry onto (incrustation) the instruments for too long will cause corrosion. Immersing the instruments in solution for too long or allowing them to remain moist will also damage them!

| Damage may be caused by: | Possible damage: |
|--|---|
| a) Blood, pus, secretion, remains of tissue or bone | a) Corrosion, rust |
| b) Saline solutions, iodine tinctures, water, cleaner, and disinfectant | b) Pitting, discolouration |
| c) Wire wool, wire brushes | c) Destruction of the material surface = susceptible to corrosion and contact corrosion |
| d) Contact between instruments made of different metals | d) Rust spots on the contact areas = contact corrosion |
| e) Instrument fatigue | e) Cutting surfaces become blunt and damaged = increased susceptibility to corrosion |
| f) Contamination of the sterilizer due to instruments which are already corroded | f) Rust film, intact instruments "catch" rust |
| g) Allowing the instruments to remain moist (improper drying) | g) Corrosion, rust |

Please note:

6 points which help prevent serious problems:

1. Never allow remains (blood, secretion, tissue remains) to dry on, always immerse the instruments in disinfectant immediately after the operation.
2. Incrustations must be cleaned off thoroughly with nylon brushes only!
Clean cannulations (trephine drills) especially well!
3. Rinse, disinfect and clean off thoroughly with water!
4. Never store instruments while they are still moist or wet.
5. Never disinfect, clean (even ultrasonically), or sterilize instruments made of different materials together.
6. Only use cleaning agent/disinfectant intended for the material in question and always adhere strictly to the manufacturer's directions for use!

► cf. pictures on page 7



Stainless steel ratchet:

Existing remains from operations (incrustation) cause pitting. Rust begins to form. The ratchet was not fully dismantled for disinfecting, cleaning, and sterilizing!



Stainless steel drill:

Existing remains from operations (incrustation) cause pitting. Rust begins to form. Severe remains were not cleaned off carefully. In addition, they were baked on during sterilization!



Instruments:

Very severely corroded instruments, some with pitting corrosion. The instruments were treated with cleaning agents and disinfectants containing a very high percentage of chlorine, which caused severe corrosion.



Stainless steel tap:

Discolouration of the tap, remains of the operation baked on. The remains of the operation (bone and blood) were not cleaned off carefully and were baked on during sterilization!



Titanium closure screw:

Discolouration of the closure screws. Immersing the screws in hydrogen peroxide (H₂O₂) causes an additional oxide layer to form.

3. YOU ARE RESPONSIBLE!

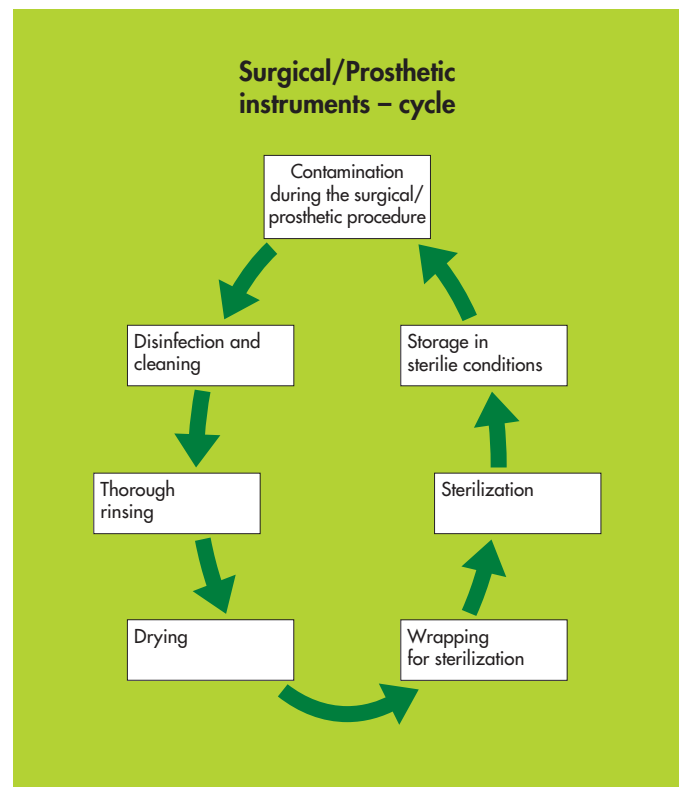
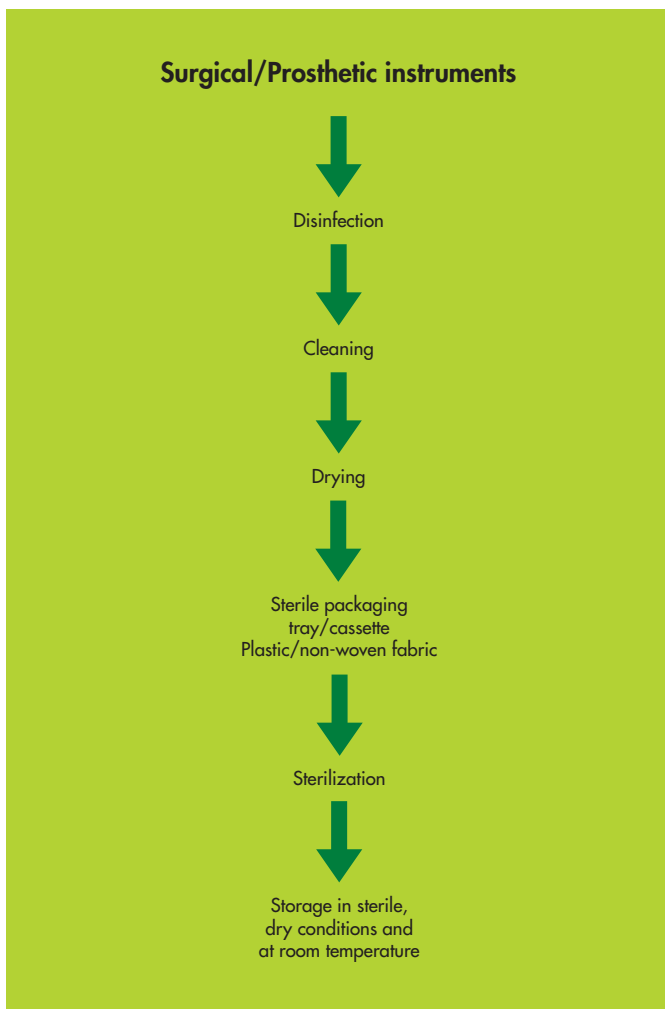
Always bear in mind that all care and maintenance procedures for instruments are part of the practice **hygiene plan**.

This plan protects the patient and the operating team against infection.

The chairside assistant, can play a very important role in carrying out all the necessary procedures.

Hint: Set aside a sterile area in which everything required for the operation is sterile!

Further supplies come from the outside, via the second assistant, who uses sterile tweezers.

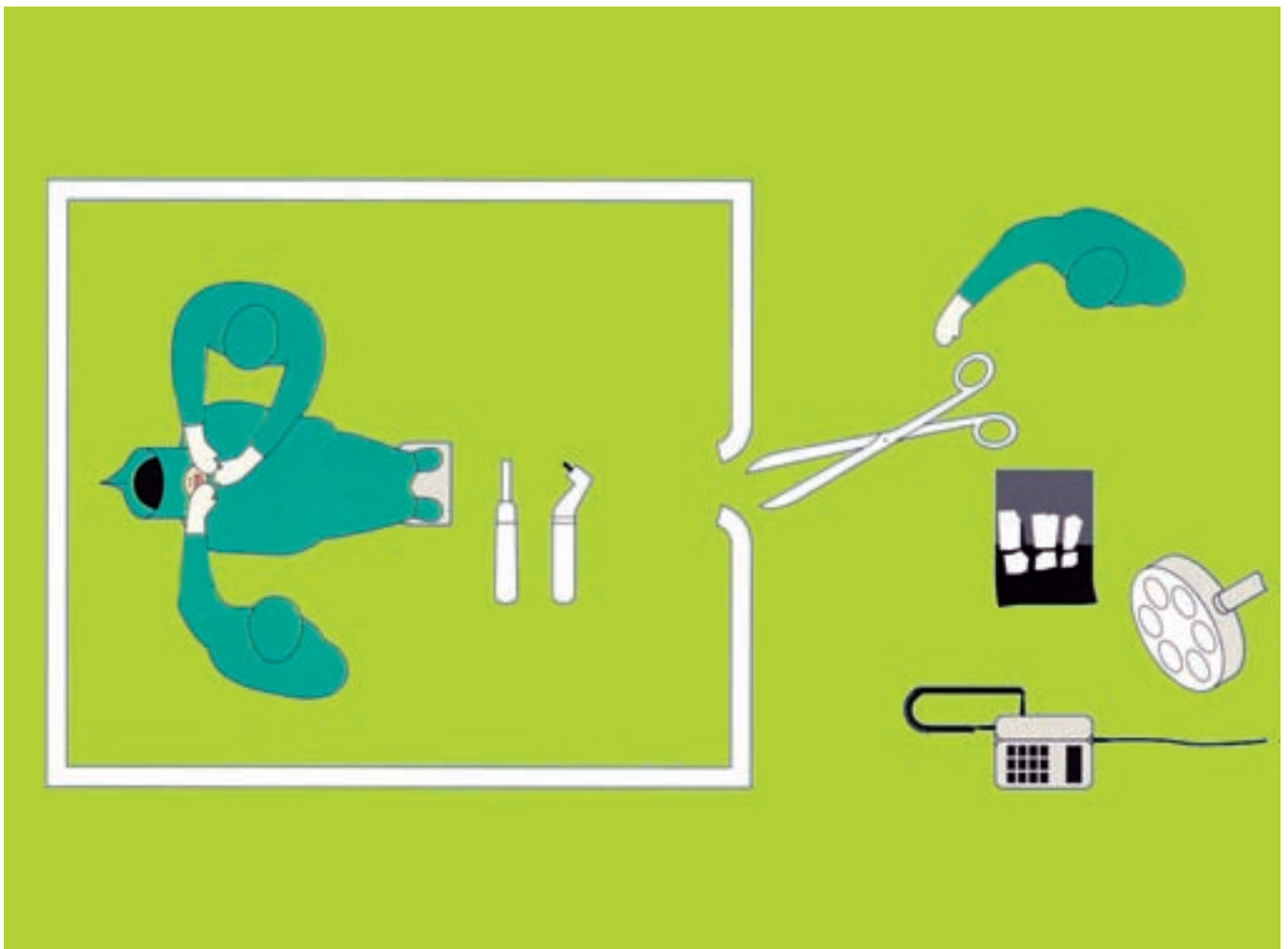


Please note:

The primary objective is to safeguard the patient and entire operating team against serious infections!

Once removed from their package, new instruments must be cleaned and sterilized before being used for the first time.

Always heed the **manufacturer's instructions** for all equipment, disinfectants, and cleaning agents.



4. PREOPERATIVE PROCEDURES

The operating team:

All persons participating in the operation should prepare themselves as follows:

Protective clothing:

Operating gown (knee-length), closed at the front or jacket, closed at the front and trousers. Elbow-length arms in either case. Sterile.

Gloves:

Disposable, sterile.

Facemask:

Covering nose and mouth, made of single or multi-layer non-woven fabric.

Surgical hand disinfection:

Disinfect the hands and lower arms with topical antiseptic.

Protective glasses:

We recommend that plastic protective spectacles be worn during surgery.

The patient:

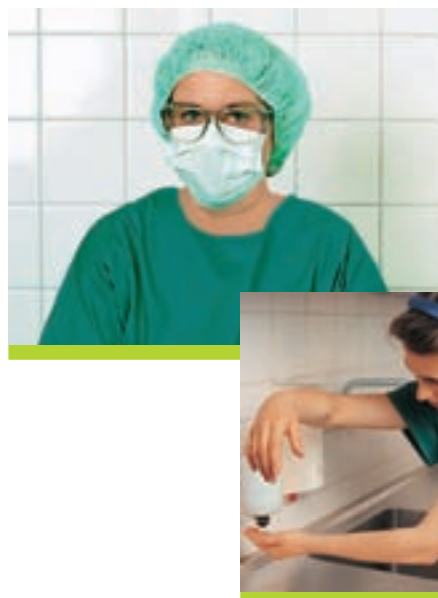
Cleaning and disinfecting the mouth:

1. With a pledget soaked in suitable liquid. Rinse the mouth with oral disinfectant.
2. **Covering:** Use a sterile operating sheet with an opening sufficiently large for the operating site (mouth, nose, eyes).



The instruments:

All the surgical instruments can be sterilized in the surgical cassette so that they are sorted and ready to hand.



Please note:

Always use sterile tweezers when placing the instruments in the holder or passing them over. The contaminated instruments can be placed on the lid of the box. Ensure that you always have additional sterilized instruments and Straumann implants in reserve.

INTRAOPERATIVE AND POSTOPERATIVE PROCEDURES

During the operation:

Basic principle: every instrument must only be used for its specific purpose.

Contaminated instruments can be placed in the Ultrasonic Cleaning Cassette or other appropriate container.



After the operation:

Remove the remains of blood, secretion, tissue, or bone immediately. Do not allow them to dry.

Instruments consisting of several parts should be dismantled (ratchet, trephines with interior cooling).

Contaminated instruments must be passed over for disinfecting immediately.



Please note:

Used instruments must always be **disinfected before cleaning!**

Contaminated instruments must only be placed where intended – either in the Ultrasonic Cleaning Cassette or other appropriate container.


Damaged instruments must be disinfected, cleaned, and disposed of separately.



5. THE DISINFECTION

Once implantation has been completed, the following must be carried out immediately:

Instruments consisting of several parts should be dismantled (ratchet, trephines with internal cooling). Refer to pages 17 and 18.


Check all instruments visually. Damaged or blunt instruments must be picked out (cutting instruments should be replaced after a maximum use of 10 times) and must be disinfected and cleaned separately. If the scaling is illegible, the instrument must be replaced. 


Immerse the instruments in a suitable disinfectant – **adhere strictly to the manufacturer's instructions regarding dispensing/concentration, reaction time, and temperature.**




Disinfection can be carried out manually or mechanically. Instruments must not touch each other. To avoid damage, the Ultrasonic Cleaning Cassette can be used.

Please note:

Only use disinfectant which is intended specifically for the material in use! Always adhere strictly to the manufacturer's instructions regarding dispensing/concentration, reaction time, and temperature! 

Never warm disinfectants for manual disinfection above room temperature! 

When disinfecting mechanically, the **initial temperature** must not exceed 45 °C (113 °F).

Gloves must always be worn when handling contaminated instruments (for your own safety). 



6. AFTER DISINFECTING: THE CLEANING

The instruments must be cleaned after disinfecting because remains from the operation adhere to them and must be removed to prevent incrustation!



Manual or mechanical cleaning:

Always use a suitable cleaner. Adhere strictly to the manufacturer's instructions regarding dispensing of the cleaning agent/disinfectant, temperature, and time.



Only use nylon brushes for **manual** cleaning! Hollow spaces (e.g. trephines) must be cleaned especially carefully!



When cleaning **mechanically**, make certain that the **instruments do not touch** as this may damage them! Adhere strictly to the manufacturer's instructions regarding dispensing of the cleaning agent/disinfectant, temperature, and time.



Only clean those instruments together which are made of the same material. 




Please note:

After cleaning, rinse the instruments very thoroughly with water.

All cleaning agent and disinfectant residue must be removed.

Dry the instruments immediately afterwards using disposable towels.


Adequate protection should be worn while cleaning contaminated instruments (safety glasses, face mask, gloves etc.).

Gloves must always be worn when handling contaminated instruments (for your own safety). 



ULTRASONIC CLEANING

Please note:


Never place instruments made of different materials together in an ultrasonic cleaner. 

The instruments must not touch.

Adhere strictly to the manufacturer's instructions: Temperature (**min. 40 °C/104 °F, max. 45 °C/113 °F**), amount of liquid (never exceed 50% of tank capacity), cleaning time, suitable cleaners.



After cleaning the instruments, **rinse them thoroughly in water and dry them immediately!**

Check the instruments visually, separate any damaged instruments, and dispose of them in a suitable manner! 

Severely contaminated instruments must be cleaned in an ultrasonic unit. The procedure leading up to and including disinfection is as described above.

Sort the instruments according to grade (refer to page 2), place them in the ultrasonic cleaning cassette (or other appropriate container), and clean them in an ultrasonic unit.



Use of Ultrasonic Cleaning Cassette

After each use, surgical instruments should be placed in the Ultrasonic Cleaning Cassette to help ensure proper cleaning and disinfection in the ultrasonic bath.

- The Ultrasonic Cleaning Cassette must be rinsed manually with water before being used for the first time.
- After each use, surgical instruments must be pre-cleaned using a brush under running water.
- Cleaning should be carried out using commercially available products with both a cleaning and disinfectant solution according to the manufacturer's instructions.

- The cleaning time depends on the selected cleaning agents and their concentration. Follow the instructions from the manufacturer of the cleaning agent.
- In order to improve the cleaning effect, we recommend leaving the lid off during cleaning.
- After cleaning in the ultrasonic bath, cutting instruments must be rinsed under running water and then dried.
- Do not use the Ultrasonic Cleaning Cassette for sterilization of instruments. Instead, they should be placed in the surgical cassette for autoclaving.



7. THE STERILIZATION

After cleaning, **all surgical instruments must** be sterilized.

The prosthetic instruments may be sterilized (except activators/deactivators – blue handle).

Sterilization should only be carried out in an autoclave (i.e., steam sterilization prevacuum cycle at a maximum of 134 °C/ 273 °F, exposure time 4–18 min.).

Important:

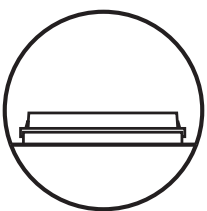
- Chemical sterilization is not recommended since this procedure can damage the plastic surface!
- No hot air sterilization since the high temperature (appr. 180 °C) would make the plastic cassette melt!
- No sterilization in spherical sterilizers (temperature up to 300 °C)!
- In order to avoid damages to the surgical cassette during steam sterilization, the surgical cassette has to be placed correctly in the autoclave!
- Ensure that the individual sterilization parameters meet national requirements.

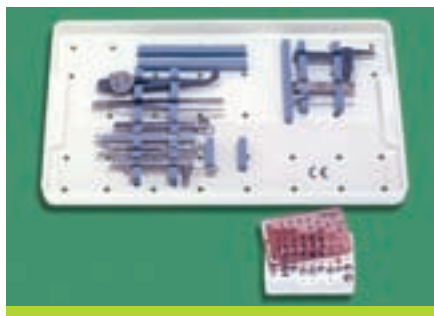
Preparing the instruments for autoclaving:

After cleaning, disinfecting and drying, the instruments are either sorted into the cleaned surgical cassette, placed on a paper filter on the perforated trays or packed in a sterile packet (plastic or paper).

Refer to package insert!

Completely enclose the cassette in commercially available sterilization wrap to maintain sterility.





Important:

A strip indicating the date of sterilization and expiration date should be stuck to the wrapping of every sterilized item to show that it has been autoclaved. A bacteriological check must be carried out regularly by appropriate means (e.g. with a spore sachet). After sterilization, the instruments must be stored in a dry place. Please refer to page 19 for further details regarding storage.

Please note:

The following must not be placed in an autoclave:

Non-perforated metal cassettes.
 Double packaging (sachet within a sachet, box wrapped in towel or in a sachet).
 Plastic foil tubes are not suitable for packaging instruments for sterilizing.

To avoid mishaps, please adhere strictly to the manufacturer's operating instructions!

These include: The weight of the load, suitable sterilization packaging, operating time, and checking for correct functioning.



Corroded, rusty instruments contaminate the water circulation system of the autoclave with rust particles.

During every subsequent sterilization cycle, these rust particles cause rust film to form on intact instruments! Do not forget to check and clean your equipment regularly! ✓



8. MULTI-COMPONENT INSTRUMENTS



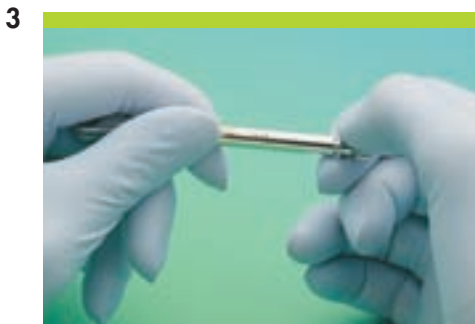
Cleaning and maintaining the ratchet:

To ensure that the ratchet functions properly, **it must always be dismantled and cleaned after use.**

Dismantling the ratchet:
Loosen the ratchet nut with the holding key or service instrument and unscrew the internal bolt.



Checking the ratchet for correct functioning:
After reassembling the ratchet, it must be checked for correct functioning. The ratchet adapter is used to check the ratchet for correct functioning. The ratchet adapter should be placed into the ratchet so that the **arrow** on the **direction setting knob indicates counter-clockwise.**



If the ratchet adapter is now held firmly, the ratchet can be turned counter-clockwise.
The **same check** must then be carried out for the **opposite direction.**



Please pay special attention to these care and maintenance instructions for the ratchet!

Ratchet

The ratchet must be dismantled immediately after the operation. Otherwise, any blood which may have penetrated into it will cause the ratchet bolt to stick in the ratchet body = corrosion!
Disinfect, clean, and sterilize as described on the relevant pages – please treat each component separately!

Please note:

Dismantle all multi-component instruments immediately after the operation.
Disinfect, clean, and sterilize every component separately, as described above.
Store the individual components in a sterile state until they are required again or the expiration date is reached.
As a precaution, keep a second sterilized ratchet ready during the operation.
Check for correct functioning in good time before the operation!



Please pay special attention to these care and maintenance instructions for the trephine drill with internal cooling!

Trephine drill, internal cooling

Remove the cooling ring immediately after using the drill and disconnect the hose from the contra-angle. All components must be disinfected, cleaned, and sterilized carefully.

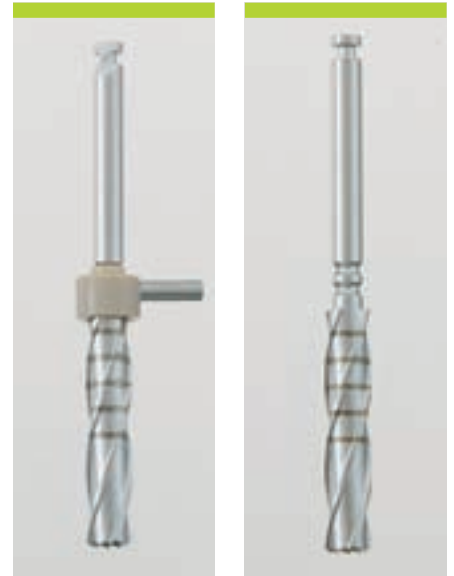
Trephine drill, internal cooling

The trephine drill with internal cooling consists of a hollow drill with cooling ring.

The irrigant is attached to the cooling ring. The cooling ring must be removed from the trephine drill immediately after the operation. The hose must also be disconnected from the cooling ring.

You must check whether remains of bone are trapped in the trephine drill. If so, they must be removed especially thoroughly (use the cleaning device and a nylon brush).

All components must be disinfected separately and cleaned thoroughly (the hollow spaces in particular). All components must be sterilized separately and not reassembled until just before commencing the next operation! Check for correct functioning!



Please note:

Dismantle all multi-component instruments immediately after the operation. Disinfect, clean, and sterilize every component separately, as described above. Store the individual components in a sterile state until they are required again or the expiration date is reached. As a precaution, keep a second sterilized ratchet ready during the operation. Check that the instruments are functioning correctly before beginning the operation.

9. FURTHER INFORMATION

Storage of sterile instruments

The sterilized packs must be stored at room temperature, in a dry place where they cannot become dusty. The units in which they are stored must also be disinfected regularly.

Trays can be stored two to nine (max.) **weeks**, sachets one to six **months**.



Please, use our catalogue and order forms for reordering.

Our staff will be pleased to receive your order by telephone or fax.

Please note:

Should the maximum storage time have been exceeded, the instruments must be resterilized!

Write the date of sterilization and expiration date on the sterilized pack (tray or sachet).

Important:

Operating instruments with cutting edges (i.e. burs and cutters) have a limited service life. After being used 10 times, they should be replaced with new instruments!
Keep count!

Recall appointments

Every patient who has received one or more implants should be in a regular recall schedule.

Refer to the dentist's recommendations, draw up a recall plan, and provide the patient with an easily understandable appointment schedule. Check that the patient attends the appointments and, if necessary, send reminders.



Documentation

Every implant case must be documented accurately. If case complications should set in, this will help the dentist to analyse the case properly and identify the problems.

The following should be noted in the patient's records:

Photographic records of the case – preoperative and postoperative. The label on the implant packaging (indicates the LOT No. and Art. No.) must be stuck to the record sheet. Technician's model (not included in the records, but kept in the laboratory).

Keeping a stock and reordering

Check the instruments for damage after each procedure.

Damaged instruments must be disinfected, cleaned, and disposed of separately and safely.

Replace the instrument from your own stock or order a new one. Thus, you can be certain that the set of operating instruments is always complete.

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IMPORTANT NOTES

Disclaimer of liability

The Straumann dental implant is part of an overall concept and may only be used in conjunction with the associated original components and instruments according to Institut Straumann AG's instructions and recommendations.

Use of products made by third parties in conjunction with the Straumann® Dental Implant System will void any warranty or other obligation, express or implied, of Institut Straumann AG. Instructions as to application of our products take place verbally, in writing, by electronic media or in hands-on trainings corresponding to state of the art at the time of introduction of the product.

The user of Straumann products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Straumann disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of Straumann products.

The user is also obliged to study the latest developments of the Straumann® Dental Implant System and their applications regularly.

Please note

The descriptions contained in this document are not sufficient for immediate use of the Straumann® Dental Implant System. Knowledge of dental implantology and instruction in the handling of the Straumann® Dental Implant System provided by an operator with the relevant experience are always necessary.

Availability

Not all products listed in this brochure are available in all countries.

Validity

Upon publication of this brochure, all previous versions are superseded.

Caution

Our products must be secured against aspiration when used intraorally. Do not use damaged or blunt instruments.

Units per package

Unless stated otherwise, there is one unit in each package.

Documentation

You can obtain detailed instructions on the Straumann® Dental Implant System from your Straumann representative.

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Definition SLActive

Sand-blasted, Large grit, Acid-etched, chemically active and hydrophilic

Definition SLA®

Sand-blasted, Large grit, Acid-etched

Explanation of the symbols on labels and instruction leaflets

| | |
|---|--|
|  | Lot/batch number |
|  | Article number |
|  | Sterile by gamma irradiation |
|  | Nonsterile |
|  | Lower temperature limit |
|  | Upper temperature limit |
|  | Temperature limit |
| Rx only | Caution: Federal (USA) law restricts this product to sale by or on the order of a dentist or physician |
|  | Do not use on patients |
|  | Do not reuse |
|  | Refer to instructions for use |
|  | Use before expiry date |
|  | Protect from exposure to strong light or heat |
|  | Straumann products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42 EEC |

Colored warning labels

| | |
|------------------|---|
| YELLOW = CAUTION | Indicates hazards or unsafe handling which might cause minor injury or damage to property |
| ORANGE = WARNING | Indicates hazards which might cause serious or fatal injury |
| RED = DANGER | Indicates hazards which might cause immediate serious or fatal injury |

www.straumann.com



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