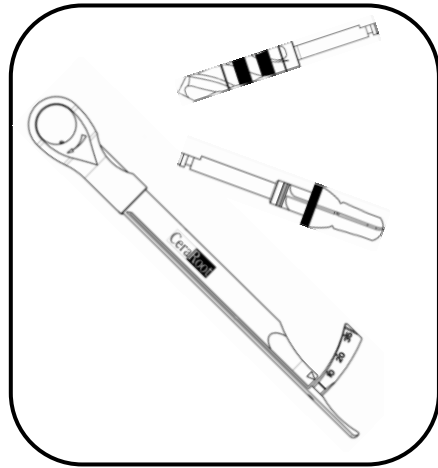


CARE AND MAINTENANCE OF SURGICAL AND PROSTHETIC INSTRUMENTS



CeraRoot
Zirconium Oxide Dental Implants

www.ceraroot.com

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Precise instruments



WARNING: To avoid injury, read all operating instructions in this guide and safety information in the *Important Product Information Guide* at www.ceraroot.com/support/manuals/ceraroot before using CeraRoot implants.

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 highgrade 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:

Zirconium Oxide: Several instruments are made of high performance ceramics composed of zircon-dioxide ceramic partly stabilized by yttrium and aluminium ceramic. Only use brushes with metal-free bristles for pre-cleaning, as these do not leave discolorations caused by abrasion on the instruments. Sterilization is carried out in the autoclave (134°C) following the usual methods.

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: The mallet is made of anodised (the surface is oxidised electrolytically) aluminium. This increases the corrosion resistance of the material.

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 (impacting tool ref. 005.214). The plastic we use is very resistant and can be sterilized at temperatures of up to 134 °C (273 °F).

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 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!

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, oxalic acid), H₂O₂ (hydrogen peroxide).

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

Discolouration of the material.

Surgical instruments

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.

Ratchet: Dismantle immediately after use. Disinfect, clean, and sterilize the individual parts, which are made of titanium. Grooves in handles and head should be cleaned particularly carefully!

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!

Be aware

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!

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!

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 might have been treated with cleaning agents and disinfectants containing a very high percentage of chlorine (which can cause severe corrosion).

Titanium ratchet:

Discolouration of some parts. Immersing the ratchet in hydrogen peroxide (H₂O₂) causes an additional oxide layer to form.

Your responsibility



PLEASE NOTE: The primary objective is to safeguard the patient and the 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.

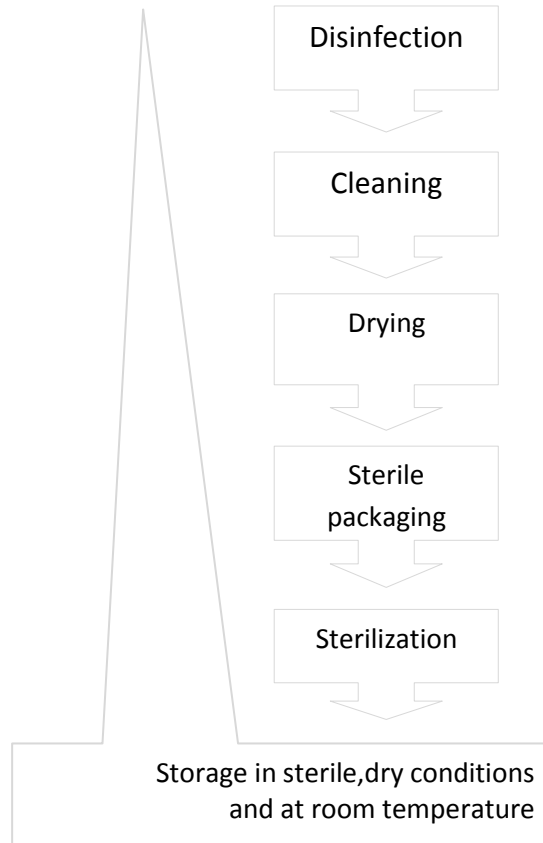
Always bear in mind that all care and maintenance procedures for instruments are part of the practice hygiene plan.

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.

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.

All the professional staff should have a similar protocol as shown below when Surgical/Prosthetic instruments are used, and should maintain the working cycle without skipping any step:



Preoperative procedures

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 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 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 CeraRoot 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.

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.

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.

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).

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.

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).

Disinfection can be carried out manually or mechanically.

Instruments must not touch each other. To avoid damage, the Ultrasonic Cleaning Cassette can be used.

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

The cleaning

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

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

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 immediately afterwards using disposable towels.

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

Ultrasonic cleaning

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.

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!

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 precleaned 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.

The sterilization

After cleaning, all surgical instruments must be sterilized.

The prosthetic instruments may be sterilized.

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 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!

Multi-component instruments

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 head to stick in the ratchet handle = corrosion!

Disinfect, clean, and sterilize as described on the relevant pages – please treat each component separately!

Cleaning and maintaining the ratchet:

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

Dismantling the ratchet:

Press in the recess of the head with a finger and gently pull the head out of the handle. There are ONLY 2 parts to be dismantled.

Checking the ratchet for correct functioning:

After reassembling the ratchet, it must be checked for correct functioning.

If the ratchet adapter is now held firmly, the ratchet can be turned counterclockwise.

The same check must then be carried out for the opposite direction.

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!

Additional 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 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).

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.

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).

Drills

Recommendations for maintenance

The drills are supplied in non-sterile condition. Prior to first use, the drills must therefore be cleaned, disinfected and sterilized.

- Do not allow residues from the operation (blood, secretions, tissue) to dry.
- Immerse the drills in disinfecting solution immediately after the operation.
- Disinfect the drills with disinfecting and cleaning agents for rotary.

For recommendations for use (immersion time, concentration, suitability) of the disinfecting and cleaning agents please refer to the manufacturers' instructions. Only use brushes with metal-free bristles for pre-cleaning, as these do not leave discolorations caused by abrasion on the instruments.

Disinfecting and cleaning agents must be rinsed off thoroughly with water and the instruments must be dried carefully (e.g. by airstream). Do not store instruments in wet or damp condition for a longer period of time. The drills should not be allowed to come in contact with each other during the cleaning in the ultrasonic bath.

Examine the cleaned instruments visually. Damaged or blunt instruments must be rejected and their use discontinued. The same applies to instruments that were subjected to sudden stress (for example by getting dropped off the table or similar). Do not continue using these instruments, as there is an increased risk of breakage!

Sterilization is carried out in the autoclave (134°C) following the usual methods. Make sure to observe the instructions provided by the manufacturer of the devices. After sterilization, the instruments have to be examined for surface damages (cracks).

Discontinue the use of damaged instruments (increased risk of breakage).

The operator of medical products is responsible for seeing that proper treatment is carried out by qualified personnel using the appropriate materials and suited equipment. Work instructions with regard to proper reprocessing of instruments according to DIN EN ISO 17664 can be downloaded from our web site www.ceraroot.com.

Safety and liability

Due to the cutting of hard bone material and tooth substance premature blunting of the blades may occur. Therefore, the drills have to be checked for blunt blades or other damages after each use. Exchange if necessary. Be sure to observe the indicated speed in order to avoid instrument breakage.



Attention: Risk of injury caused by the sharp blades of the drill!
Risk of injury due to jamming and slipping of the drill!

Prior to application, the user undertakes to check whether the product is suited for the intended use. The user is responsible for the application of the drill. In case of contributory negligence by the user, Oral Iceberg partially or totally declines liability for all resulting damages, particularly if these are due to nonobservance of our recommendations for use or warnings as well as inadvertent misuse by the user.