

IMPLANT SYSTEMS

MICRODENT

MAINTENANCE
OF SURGICAL INSTRUMENTS
AND PROSTHETICS

www.microdentsystem.com



MICRODENT
IMPLANT SYSTEM

GENERAL CONSIDERATIONS

Implant placement can only be carried out successfully if the instruments are accurate and have been properly looked after. Microdent manufactures its instruments with top quality materials and with high precision. It is the user's responsibility to keep the surgical and prosthetic instruments clean and in usable condition. Avoiding contamination from one patient to another is essential to therapeutic practice. All instruments should be cleaned, disinfected and sterilized before each use. This also applies for the first use after delivery, for products that are delivered non-sterile and which must be sterilized before initial use. Cleaning and disinfection is performed after removal of the protective packaging for transport. Effective cleaning and disinfection are prerequisites for proper sterilization. Sterilize according to the sterilization instructions indicated in our user instructions corresponding to the type of products to be used.

The user is responsible for ensuring the following:

- That only cleaning, disinfection and sterilization procedures sufficiently validated for the equipment or product are used.
- That the equipment used (disinfection apparatus, sterilizer) be regularly subjected to maintenance, testing and calibration.

In addition to these instructions, please observe the applicable legal regulations as well as the hygiene of the dental office or respective centre.

TYPES OF MATERIAL

The materials used in Microdent instruments are identified below, as well as certain ingredients that should not be present in disinfectants and detergents. For cleaning and sterilization it is necessary to separate the instruments according to the type of material. In particular, instruments made of different materials should never be placed together in a liquid bath (as this increases the risk of contact corrosion). Information on the material of each product can be found in the respective user instructions or in the Microdent product catalogue.

Stainless steel

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

Disinfectants or detergents containing one or more of the following ingredients are not recommended for stainless steel: chlorine, oxalic acid or hydrogen peroxide (H₂O₂). If this is not observed, it may cause pitting and contact corrosion.

Titanium

Titanium, due to its surface self-oxidation, is a material that is highly resistant to corrosion and external conditions.

Disinfectants or detergents containing one or more of the following are not recommended for use on titanium: chlorine, oxidizing acids (e.g., nitric acid, sulphuric acid and oxalic acid), or hydrogen peroxide (H₂O₂). If this is not observed, it may fade in colour.

Aluminium

The aluminium used for our products is treated so that it has a higher resistance to corrosion. The use of acidic or basic disinfectants and detergents whose pH value is outside the acceptable range of 5-9 is not recommended for aluminium, as they may destroy the protective layer, increasing the susceptibility of the material to corrosion.

Plastic

The plastics used in Microdent products are very resistant and can be sterilized at temperatures of up to 134 °C. Disinfectants or detergents containing one or more of the following ingredients are not recommended for plastics: organic solvents (alcohols, ethers, ketones and benzines), hydrogen peroxide (H₂O₂), aldehydes or halogens (chlorine, iodine or bromine). If this is not observed, plastics may be deformed and/or destroyed.

In summary

When selecting detergents and disinfectants, make sure they do not contain the following ingredients:

- Organic, mineral or oxidizing acids (minimum permissible pH value: 5).
- Strong bases (maximum permissible pH value: 9, slightly alkaline cleaners are recommended).
- Organic solvents (such as alcohols, ethers, ketones and benzines).
- Oxidizing agents (e.g. hydrogen peroxide).
- Halogens (chlorine, iodine or bromine).
- Aromatic or halogenated hydrocarbons.
- Heavy metal salts.
- Aldehydes.

Other precautions to be taken into account are the following:

- Never clean the instruments or surgical boxes with metallic brushes or steel wool.
- Instruments and surgical cases should not be exposed to temperatures above 134°C.

MATERIAL REUSES

Frequent use has a minimal effect on the instruments. The end of the useful life of the instruments is normally due to wear and tear and deterioration during use (cutting tools are an exceptions). Therefore, the instruments can be reused with due care, provided that they are not damaged or contaminated. Do not use instruments beyond their effective life cycle, nor damaged and/or contaminated instruments.

Dispose of single-use instruments and worn reusable instruments immediately after use.

Drilling instruments, if properly cared for, and provided they are not damaged or contaminated, can be reused 20 to 30 times (one use = implant placement). Use beyond this number of times and use of damaged and/or contaminated instruments is not permitted.

It is recommended that you make a checklist for these instruments where you record the number of uses.

All surgical debris that adheres and dries on the instruments (encrustations) produces corrosion.

Exposure of instruments to moisture over long periods of time also leads to deterioration.

Summary of types of damage and their probable causes

Damage	Likely cause
Corrosion and oxidation	<ol style="list-style-type: none"> 1. Blood, secretions, bone residues, etc. 2. Contact between materials of a different nature. 3. Insufficient drying. 4. Impurities in the cleaning/sterilization machines.
Pitting and discolouration	<ol style="list-style-type: none"> 1. Saline solution. 2. Inadequate water. 3. Iodine. 4. Inadequate detergents/disinfectants or incorrectly used.
Destruction of the material surface	<ol style="list-style-type: none"> 1. Brushes or steel wool. 2. Excessive temperature.
Blunt or damaged cutting surfaces	<ol style="list-style-type: none"> 1. Overload of instruments in the cleaning machine. 2. Brushes or steel wool.
Bending or deformation without apparent cause (with no knocks)	<ol style="list-style-type: none"> 1. Forced and accelerated cooling of parts subjected to a heating process, such as sterilization.

The following measures can help to avoid major problems

- Use each instrument only for its intended use.
- Never let surgical waste (blood, secretions and tissue debris) dry on an instrument; clean the instrument immediately after surgery.
- Thoroughly clean encrustations with soft brushes only. Disassemble the instruments and clean the cavities especially thoroughly.
- Never disinfect, clean (even with ultrasound) or sterilize instruments of different materials together.
- Use only detergents and disinfectants suitable for the material and follow the instructions for use of the manufacturer.
- Rinse disinfectants and detergents thoroughly with water.
- Never leave or store wet or damp instruments.

USE OF MATERIALS BEFORE AND DURING SURGERY

Use each instrument only for its intended use.

Ensure that all contaminated instruments are collected separately. Do not put them back in the instrument case to avoid contamination of the case with the other instruments.

Instruments can be damaged by improper handling, such as dropping them on surfaces, etc.

Damaged and/or broken instruments should be set aside and disinfected, cleaned and disposed of separately.

Send contaminated instruments for washing as soon as possible, within a maximum of 1 hour.

CLEANING AND DISINFECTION

A pre-treatment should be carried out whether manual or mechanical cleaning is used. It is important to wear protective clothes when cleaning contaminated instruments.
For your own safety, always wear protective goggles, mask, gloves, etc. during all activities.

Pre-treatment

Coarse impurities should be removed from the instruments directly after use, within a maximum of time of 1 hour.

Classify the instruments according to material groups (see section 1 of this document) and clean, disinfect and sterilize the different types of materials separately.

Disassemble multi-part instruments into their individual parts (e.g. ratchet wrench).

Place the instruments in a water bath or in a disinfectant solution, the disinfectant must be free of aldehydes (otherwise, a fixation of blood contamination may occur), have a proven efficacy, be suitable for disinfection of the instruments and be compatible with them (see section 1 of this document).

Never place instruments of different types of materials together.

Use only soft brushes or soft, dry cloths which are only used for this purpose.

Never use metal brushes or steel wool to manually remove impurities.

Rinse all instrument cavities 5 times using a disposable syringe (minimum volume: 20 ml).

Move the moving parts back and forth several times during pre-cleaning.

Please note that the disinfectant used in the pre-treatment is only for your own protection and cannot replace the disinfection step that is performed later after cleaning.

Cleaning and disinfection

When selecting detergents and disinfectants, make sure of the following:

- They always follow the detergent and disinfectant manufacturers' instructions for use.
- They are suitable for cleaning metal and plastic instruments.
- That the detergent (if used) is suitable for ultrasonic cleaning (non-foaming).
- That a disinfectant of proven efficacy be used.
- That the disinfectant is compatible with detergents.
- That the chemical compounds used are compatible with the instruments (see section 1 of this document).
- The concentrations and action times indicated by the manufacturer of the detergent and disinfectant must be strictly observed.
- Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water, e.g. purified water or highly purified water, and only filtered air for drying.

A. Mechanical cleaning and disinfection

For cleaning and disinfection using a disinfection device or a cleaning unit, the instructions of the device manufacturer must be followed.

B. Mechanical cleaning and disinfection

B1. In the case of using an ultrasonic device, the manufacturer's instructions should be followed.

B2. The procedure for cleaning **without ultrasonic support** is:

1. Place the disassembled instruments in the cleaning bath during the specified actuation time so that the instruments are sufficiently covered (if necessary brush carefully with a soft brush).
2. Then remove the instruments from the cleaning bath and rinse them thoroughly with water at least 3 times and especially all the instrument cavities, using a disposable syringe (minimum volume: 20 ml).
3. Visually inspect the instruments.
4. Disinfection:
 - a) Place the disassembled, cleaned and inspected instruments in the disinfection bath for the specified time of actuation. Make sure that the instruments are sufficiently covered by the disinfectant solution and that the instruments do not touch each other.
 - b) Then remove the instruments from the disinfectant bath and rinse them thoroughly with water at least 5 times, especially all the cavities, using a disposable syringe (minimum volume: 20 ml).
 - c) Dry the instruments from the inside out with filtered compressed air.
 - d) Pack the instruments as soon as possible after removal. If additional drying is necessary, dry in a clean place.

INSPECTION, TESTING AND PACKAGING

After cleaning, or cleaning and disinfection, check all instruments for corrosion, damaged surfaces, nicks or contamination and separate damaged instruments. In particular, critical areas such as handle structures, joints or blind holes should be carefully inspected. For better visibility you can use a magnifying lens and direct illumination. Any instruments with illegible markings or labels should also be replaced.

Dispose of single-use instruments and worn reusable instruments immediately.

Instruments that are still contaminated should be cleaned and disinfected again. Damaged, corroded or worn instruments should not come into contact with intact instruments in order to avoid contact corrosion.

Maintenance

Reassemble the disassembled instruments (see the relative instrument-specific instructions).

Functional test

The instruments must be subjected to a functional test. For this purpose, multi-piece instruments must be assembled and tested for correct operation. Contamination must be completely avoided during assembly.

Packaging

Pack instruments or cases one at a time, or two at a time, in disposable sterilization containers that meet the following requirements:

- Suitable for steam sterilization (temperature resistance of at least 137 °C and sufficiently vapour permeable).
- That there is sufficient protection of the instruments or sterilization containers against mechanical damage.
- Conformity to DIN EN ISO/ANSI AA MI ISO 116071.

STERILIZATION

Prior considerations

Always observe the operating instructions of the manufacturer of your sterilizer, especially with regard to the load weight, operating time and functional tests.

Corroded and rusted instruments can contaminate the sterilizer water circuit with rust particles. These oxide particles would cause initial oxidation on intact instruments in all future sterilization cycles. It is important to inspect and clean the unit regularly.

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

Steam sterilization

- Maximum sterilization temperature of 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665).
- Sterilization time (exposure time at sterilization temperature): at least 20 min at 121 °C or at least 3 min at 132-134 °C
- The "flash" sterilization method is not admissible. Do not use hot air sterilization either, for example, by irradiation, plasma, formaldehyde or ethylene oxide.

STORAGE

After sterilization, the instruments should be stored dry and free of dust and should remain at rest until all components have returned to room temperature before being used again.

Under no circumstances should its cooling be forced by means of liquids or cold air.

WARNING

It is the responsibility of the user of surgical instruments to safely dispose of any product that may be contaminated or no longer usable as medical waste in accordance with local health guidelines, national and governmental legislation or policy. Separation, recycling or disposal of packaging material should be carried out in accordance with national and governmental packaging legislation, as applicable.