TW Surgical ® surgical instruments

Care and maintenance

TW SURGICAL

Contents

1. General principles

An implantation can only be carried out successfully if the instruments are precise and have been cared for properly. TW Surgical manufactures its instruments from high-quality materials and with high precision. Keeping surgical and prosthetic instruments clean and fit for use lies with you. 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 for first-time use after delivery, as well as for single-use devices that are delivered non-sterile and have to be sterilized prior to use (exception: instruments delivered sterile that are intended for one-time use .
Cleaning and disinfection are performed after removal of the protective transport packaging. Sterilize according to sterilization instructions in the package insert.
Effective cleaning and disinfection are indispensable requirements for efficient sterilization.

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 in the package insert.

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 (disinfector, sterilizer) is regularly maintained, checked and calibrated.

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 of the hospital.

Note
Maintain and clean your instruments according to recommended instructions.
Each instrument must only be used for its intended purpose.

1.1 Material groups and their resistance

The groups below identify the materials used for TW Surgical instruments and certain ingredients not to be used in disinfectants and cleaning agents. For cleaning and sterilization, the instruments must be separated in accordance to these groups. In particular, instruments from different materials should never be placed together in a liquid bath (as this will result in an increased risk of contact corrosion). You will find information about the material of a device in the respective instructions for use or in the TW Surgical 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, e.g. no or incorrect care.

The use of disinfectants and cleaning agents containing one or several of the following ingredients is not recommended for stainless steel: chlorine, oxalic acid, hydrogen peroxide. Pitting and contact corrosion can occur if this is not followed.

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 is not recommended for titanium: chlorine, oxidizing acids (e.g. nitric acid, sulfuric acid, oxalic acid), hydrogen peroxide. The material can be discolored if this is not followed.

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 TW Surgical devices are very resistant and can be sterilized at temperatures up to 134 °C (273 °F).

The use of disinfectants and cleaning agents that contain one or several of the following ingredients is not recommended for plastics: organic solvents (alcohols, ethers, ketones and benzines), hydrogen peroxide, aldehyde, halogens (chlorine, iodine, bromine). The plastic can be deformed and destroyed if this is not followed.

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)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenized hydrocarbons
- salts of heavy metals
- aldehydes

Caution

Never clean instruments and sterilization cassettes with metal brushes or steel wool. All instruments and sterilization cassettes may not be exposed to temperatures higher than 134 °C (273 °F).

1.2 Reusability

Frequent processing has minor effects on the instruments. The end of the product life is normally determined by wear and damage during use (cutting instruments are an exception; see below). Therefore, instruments can be reused with appropriate care, provided they are undamaged and not contaminated. Do not use instruments beyond the effective product life cycle nor use damaged and/or contaminated instruments.

Cutting instruments
If appropriately cared for, and provided they are undamaged and not contaminated, the cutting instruments can 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.

2. How not to do it!

All surgical residues that stick to and dry on the instruments (incrustations) lead to corrosion. Exposing instruments to moisture for long periods of time also leads to damage!

Possible initial and further damages and their causes

Cause	Damage occurring
Blood, pus, secretion, tissue residues, bone residues	Corrosion, rusting
Saline solution, iodine tinctures, unsuitable water, unsuitable and/or incorrectly used cleaning agents and disinfectants	Pitting, discoloration
Steel wool, steel brushes	Contact corrosion, destruction of the material surface, removal of oxide layer → increased susceptibility to corrosion
Contact between instruments of different metallic materials	Contact corrosion
Overloading the instruments	Cutting surfaces become blunt, are damaged → increased susceptibility to corrosion
Mutual contact of the instruments	Damage of the instruments, especially of cutting surfaces → increased susceptibility to corrosion
Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer	Initial rust: contaminating intact instruments with rust
Insufficient drying of the instruments	Corrosion, rust

How to avoid greater 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 (also ultrasound) or sterilize instruments made of different materials together.
- Use only cleaning agents and disinfectants intended for the material and follow the instructions for use of the manufacturers.
- Rinse disinfectants and cleaning agents very thoroughly with water.
- Never leave or store instruments moist or wet.

3. Before and during the surgery

Basic principle: Use each instrument only for its intended purpose.

Make sure that all contaminated instruments are collected separately. Do not place them back in the instrument cassette to avoid contamination of the filled instrument cassette.

Contaminated instruments can be placed carefully on the lid of the Ultrasonic Cleaning Cassette or a similar container. The instruments can be damaged by incorrect handling, such as throwing them into the container.

However, the lid of the Ultrasonic Cleaning Cassette is not suitable as a holder for instruments required during the operation, since the lid cannot be sterilized and therefore could lead to contamination of sterilized instruments.

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

Process contaminated instruments as quickly as possible for cleaning (within two (2) hours at the most).

4. Cleaning and disinfection

4.1 Principles

If possible, a mechanical method (disinfector) should be used for cleaning and disinfection. A manual method should be used only if a mechanical method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath.

Perform pretreatment both in manual and in mechanical cleaning!

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

4.2 Pretreatment

Coarse impurities must be removed from the instruments directly after use (within two (2) hours at the most).

Sort the instruments according to material groups
and clean, disinfect and sterilize these groups separately.
Disassemble multi-piece instruments into their single parts

Place the instruments in a water bath or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood contamination may occur), should have tested effectiveness , should be suitable
for disinfection of the instruments and be compatible with the instruments

Never place instruments from different materials together.
Use only a soft brush or a clean soft cloth that is used only for this purpose.
Never use metal brushes or steel wool for the manual removal of impurities.
Rinse out all cavities of the instruments five times (5×) using a disposable syringe (minimum volume 20 ml).
Shift movable parts forwards and backwards several times during pre-cleaning.

Please observe that the disinfectant used in pretreatment serves only for your own protection and cannot replace the disinfection step to be performed later after cleaning!

4.3 Cleaning

4.3.1 Mechanical cleaning and disinfection

Cleaning and disinfection using a disinfector/CDU (cleaning and disinfection unit).

When selecting the disinfector, ensure the following:

- The disinfector has been tested for its effectiveness .
- If possible, a tested program for thermal disinfection (A0 value > 3000 or – for older units – at least 5 min at 90 °C) is used (risk of disinfectant residues on the instruments in chemical disinfection).
- The program used for the instruments is suitable and contains sufficient rinsing cycles.
- Only sterile or low-germ content (max. 10 germs/ml) as well as low-endo toxin content (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used.
- The air used for drying is filtered.
- The disinfector is regularly maintained and checked.

When selecting the cleaning agent system, ensure the following:

- It is basically suitable for cleaning metal and plastic instruments.
- Unless the disinfection is thermal, a disinfectant with tested effectiveness is used. The disinfectant must be compatible with the cleaning agents.
- The chemicals used are compatible with the instruments

Note

Always follow the instructions stated by the manufacturer of the cleaning agent, disinfectant and disinfector.

Procedure

1. Place the disassembled instruments in the disinfector so that joints are opened and water can flow out of canulas and blind holes. Make sure that the instruments do not touch one another. Connect all cavities of the instruments that can be rinsed to the rinsing connections of the disinfector using a suitable rinsing adapter.
2. Start the program.
3. Remove the instruments from the disinfector after the end of the program.
4. Inspect and pack the instruments as quickly as possible after removal
   If additional drying is necessary, dry in a clean location.

4.3.2 Manual cleaning and disinfection

When selecting the cleaning agents and disinfectants, ensure the following:

They are suitable for cleaning metal and plastic instruments.

The cleaning agent (if used) is suitable for ultrasonic cleaning (no development of foam).

A disinfectant with tested effectiveness is used. The disinfectant is compatible-with the cleaning agents.

The chemicals used are compatible with the instruments

Note

Combined cleaning agents/disinfectants should not be used.

The concentrations and action times stated by the manufacturer of the cleaning agent and disinfectant must be strictly adhered to. Use only freshly made solutions, only sterile or low-germ content (max. 10 germs/ml) as well as low-endotoxin content (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only filtered air for drying.

Note

Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants.

Procedure A

Cleaning in the ultrasonic bath with the Ultrasonic Cleaning Cassette

1. Place the disassembled instruments in the Ultrasonic Cleaning Cassette
   Make sure that the instruments do not touch one another. The instruments may not consist of different materials in this case. To improve the cleaning effect in the ultrasonic bath, cleaning without the lid is recommended.
2. Remove the instruments from the Ultrasonic Cleaning Cassette after cleaning and rinse thoroughly at least three times (3×) with water. Rinse out all cavities of the instruments three times (3×) using a disposable syringe (minimum volume 20 ml).
3. Inspect the instruments (see “5. Inspection, maintenance, functional test and packaging”).

Disinfection

4. Place the disassembled, cleaned and inspected instruments for the specified action time in the disinfection bath. Ensure that the instruments are sufficiently covered by the disinfection solution and that the instruments do not touch each other.
5. Rinse out all cavities of the instruments three times (3×) at the beginning or at the end of the action time using a disposable syringe (minimum volume 20 ml).
6. Then remove the instruments from the disinfection bath and rinse them thoroughly with water at least five times (5×).
7. Rinse out all cavities of the instruments five times (5×) using a disposable syringe (minimum volume 20 ml).
8. Dry the instruments inside/out with filtered compressed air.
9. Pack the instruments as quickly as possible after removal (see “5 Inspection, maintenance, functional test and packaging”). If additional drying is necessary, dry in a clean location.

Use of the Ultrasonic Cleaning Cassette

The used surgical instruments can be placed in the ultrasonic bath in the Ultrasonic Cleaning Cassette (Art. No. 040.175, see below).

Clean the Ultrasonic Cleaning Cassette manually with water before first-time use.

The used surgical instruments must be pretreated by removing coarse impurities before cleaning in the ultrasonic bath (see “4.2 Pretreatment”), especially if blood residues have already dried in. Proper cleaning can be performed only in this way.

To improve the cleaning effect, cleaning without the lid is recommended.

Sterilizing instruments in the ultrasonic cassette is not allowed.

Procedure B

Cleaning without ultrasonic support

1. Place the disassembled instruments in the cleaning bath for the specified action time so that the instruments are sufficiently covered (if necessary, brush carefully with a soft brush). Make sure that the instruments do not touch each other.
2. Rinse out all cavities of the instruments three times (3×) at the beginning or at the end of the action time using a disposable syringe (minimum volume 20 ml).
3. Then remove the instruments from the cleaning bath and rinse them thoroughly with water at least three times (3×).
4. Rinse out all cavities of the instruments three times (3×) using a disposable syringe (minimum volume 20 ml).
5. Inspect the instruments (see “5 Inspection, maintenance, functional test and packaging”).

Disinfection

6. Place the disassembled, cleaned and inspected instruments for the specified action time in the disinfection bath. Ensure that the instruments are sufficiently covered by the disinfection solution and that the instruments do not touch each other.
7. Rinse out all cavities of the instruments three times (3×) at the beginning or at the end of the action time using a disposable syringe (minimum volume 20 ml).
8. Then remove the instruments from the disinfection bath and rinse them thoroughly with water at least five times (5×).
9. Rinse out all cavities of the instruments five times (5×) using a disposable syringe (minimum volume 20 ml).
10. Dry the instruments inside/out with filtered compressed air.
11. Pack the instruments as quickly as possible after removal (see “5 Inspection, maintenance, functional test and packaging”). If additional drying is necessary, dry in a clean location.

5. Inspection, maintenance, functional test and packaging

5.1 Inspection

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping and contamination and sort out damaged instruments.
Critical areas such as handle structures, joints or blind holes, in particular, 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 which 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.

5.2 Maintenance

Reassemble the disassembled instruments (see specific instructions).

Assembly of the Ratchet
Insert ratchet bolt and tighten it by hand. Tighten the cover screw with the guide key. Optional: assembling of distance indicator.

Instrument oils should not be used. In the event that oil is needed, only instrument oils (white oil) which are approved for steam sterilization and have tested biocompatibility should be used (taking into account the maximum applied sterilization temperature).

5.3 Functional test

The instruments must be subjected to a functional test. Multi-piece instruments are assembled for this purpose. Further contamination must be absolutely avoided in assembly.

Functional test of the Ratchet
The functional test of the Ratchet is performed with a screwdriver with ratchet head, for example. The screwdriver is inserted in the Ratchet. The Ratchet can be turned by holding the screwdriver. It can only be turned opposite to the direction of the arrow on the knob. Clearly audible clicking noises can be heard in this case. The screwdriver must also move in the direction of the arrow. This inspection is performed for both arrow positions of the knob.

5.4 Packaging

If applicable: Sort the cleaned and disinfected instruments into the associated sterilization cassette.

Pack the instruments or the sterilization cassettes singly or doubly in disposable sterilization packaging corresponding to 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.
- DIN EN ISO/ANSI AAMI ISO 11607[1].

Note

The pictures on the right show the complete cassette with all instruments. Normally, the cassette is provided only with the instruments required by each customer.

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 if and when the material was sterilized.

6. Sterilization

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

Steam sterilization

Fractionated vacuum method or gravitation method[1] (with sufficient device drying)
Steam sterilizer corresponding to DIN EN 13060[2] or DIN EN 285[3]
Validated corresponding to DIN EN ISO 176654 (previously: DIN EN 554/ANSI AAMI ISO 11134)
(valid IQ/OQ5 (commissioning) and product-specific performance assessment (PQ))
Maximum sterilization temperature 134 °C (273 °F; plus tolerance corresponding to DIN EN ISO 17665[5] (previously: DIN EN 554/ANSI AAMI ISO 11134))
Sterilization time (exposure time at the sterilization temperature):
Fractionated vacuum method
at least 20 min. at 121 °C (250 °F)
or
at least 3 min.[6] at 132 °C (270 °F) up to 134 °C (273°F)
Gravitation method
at least 5 min. at 132 °C (270 °F) up to 134 °C (273 °F)

Note
Always observe the operating instructions of the manufacturer for your sterilizer, especially with regard to the loading weight, the operating time and functional testing.

Corroded and rusty instruments can contaminate the water circuit of the sterilizer with rust particles. These rust particles will cause initial rust on intact instruments in all future sterilization cycles. It is important to regularly inspect and clean the unit!

The instruments must be stored dry after sterilization.

Caution
Flash sterilization method is not permissible. Also, do not use hot air sterilization, radiation sterilization, plasma sterilization, formaldehyde or ethylene oxide sterilization.

7. Storage

The instruments must be stored dry and free of dust in the sterilization packaging after sterilization.

Treasure Wright Ltd.
152-160 City Road, London EC1V 2NX, United Kingdom
Email: info@twrightmedical.com

www.twrightmedical.com

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