



**MANUFACTURER'S INFORMATION** regarding the preparation of **resterilisable medical devices** complies with **EN ISO 17664**

#### Please read carefully!

#### Medical devices which may be re-processed are

- tools for abutments and screws
- torques control instruments and ratchets
- Instruments for preparing endosseous bone cavities (drills, cutters)
- Bone expansion screws and distractors
- Drill guide sleeves
- Abutments and screws, provided they do not remain in/with the patient between individual treatment appointments and are not used on other patients. They should be stored by the operator between the treatment appointments, e.g. together with the patient's file.
- Manual instruments for the placement of implants and bone preparation.

#### Re-usability

Frequent re-processing has influence on the product especially if high temperatures are applied for sterilisation. Drills for bone cavities should be used only 10 times. Tools and ratchets may be used as long as they fit to the 2<sup>nd</sup> part. In general the operator is responsible for the decision of re-using and re-processing of instruments. Damaged instruments and instruments showing signs of wear must be discarded. Liability of the manufacturer is void, if these restrictions are not regarded.

#### Legal bases

The following legal bases, regulations and recommendations are applied with regard to the products mentioned above; (Germany)

- Directive 93/42 EEC
- Medical device regulations (which is valid in the country where the medical device is used for treatment or where the functionality of the medical device is being evaluated)
- Bundesgesundheitsblatt (Federal Health Gazette) 2001 : 44 : 1115-1126

Hygiene requirements for the processing of medical devices (Recommendation of the Commission for Hospital Hygiene [Kommission für Krankenhaushygiene] at the Robert-Koch Institute and the Federal Ministry for Drugs and Medical Devices [Bundesministerium für Arzneimittel und Medizinprodukte]).

#### Legal information:

Implants and other components of the implant system Diskos, BOI, BCS, BECES, GBC as well as KOS PLUS (basal implants according to the Consensus on basal/strategic implants as issued by the International Implant Foundation/Munich, see [www.implantfoundation.org/en/consensus-papers](http://www.implantfoundation.org/en/consensus-papers)) are sold only to licensed practitioners with valid authorisation of the manufacturer (or issued by the IF) for the use of the system. This demand for further and continuous education is also valid for advising patients before and after the placement of the implants.

#### General principles

All reusable products must be cleaned, disinfected and sterilised before each use; this also applies to the initial use of products that are supplied nonsterile. Efficient cleaning and disinfection is essential for effective sterilisation. Special cleaning/sterilisation instructions should be obtained from the instructions for use. The operating instructions of the practice units must also be observed. As the operator is responsible for the sterility of instruments during use, please ensure that only adequate, validated parameters specific to the unit and product are constantly maintained during each cycle. Please also observe all valid legal and hygiene regulations of the dental practice and dental hospital. This applies in particular to the different guidelines regarding effective prion inactivation. Important: Always wear protective gloves for your own safety when handling contaminated instruments!

- Instruments made from different materials should never be disinfected, cleaned or sterilised together. This also applies when using an ultrasonic cleaner.
- During mechanical cleaning, instruments should be arranged so that they cannot come into contact, as otherwise there is the risk of damage.
- Multi-part instruments such as ratchets, trephine drills, screw-drivers etc. should be disassembled into their component parts and these should be individually disinfected, cleaned or sterilised.
- These instruments should also be stored disassembled until the next use.

#### Care instructions of surgical steel instruments

Surgical steel instruments can quickly become damaged with inadequate or incorrect care. Only commercially available solvents should be used for surgical steel; if in doubt contact **Simpladent GmbH**. The following are not recommended:

- Disinfection/cleaning agent with a high chlorine content
- Disinfection/cleaning agent with a high oxalic acid content

The following are not recommended for instruments with colour coding

- Too high solvent concentrations, disinfection/cleaning agent with the ingredients mentioned above
- Too high temperatures with mechanical cleaning and sterilisation; never higher than 137° C

#### Conditioning

Coarse impurities must be removed from the products immediately after use (within 1-2 hrs maximum). Surgical residue (blood, secretions, tissue residue) should not be allowed to dry on the products. Instruments should be placed in a disinfectant solution immediately after surgery. For temporary storage and pre-disinfection/cleaning immediately after use on patients the instruments can be placed in an interim stand filled with a suitable cleaning/disinfection agent. Contamination should then be cleaned from the instruments under running water or in a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood and contamination), have proven efficacy (e.g. DGHM [German Society for Hygiene and Microbiology]/ FDA approved and CE Mark), be suitable for instrument disinfection and compatible with the instruments (see Section "Material compatibility"). Follow the disinfectant instructions for use. For manual removal of contamination use only a clean, soft brush

or a clean soft cloth which is used specifically for this purpose. Never use metal brushes or steel wool.

- Please note that the disinfectant used for conditioning is only for personal protection and cannot replace the subsequent disinfection step to be performed after cleaning.
- Never allow instruments to remain wet or moist for a longer period of time.
- Corroded, rusty instruments must be cleaned in an ultrasonic cleaner. If the corrosion cannot be removed, the instrument should be discarded and may no longer be used.

- Encrustations must be thoroughly removed using nylon brushes.
- Encrusted blood can also be dissolved using hydrogen peroxide 3%
- Instrument disinfectant residues can be removed by rinsing several times with water.

#### Cleaning/disinfection

For cleaning and disinfection **Simpladent** recommends the use of:

Instrument disinfectant (reaction time with high bacterial loading 15 minutes in a 3% concentration) or drill disinfectant (reaction time with high bacterial loading 15 min.).

- Ensure when using other products for cleaning and disinfection,
- that the products are basically suitable for the cleaning and disinfection of instruments
- that the cleaning and disinfection agent – if applicable – is suitable for ultrasonic cleaning (no foaming)
- that a cleaning and disinfection agent with proven efficacy (e.g. DGHM or FDA approved and CE Mark) is used
- that the chemicals used are compatible with the instruments; alkaline cleaning solutions should be preferred. A prerequisite for the use of a combined cleaning/disinfection agent is very low bacterial preloading (no visible contamination) due to effective pre-cleaning of the instruments. The concentrations and reaction times given by the manufacturer of the cleaning/disinfection agent must be strictly adhered to.

Use only freshly mixed solutions, sterile or low-bacteria (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units /ml) water (e.g. aqua valde purificata) and only filtered air for drying. Instruments that cannot be autoclaved must be disinfected before each use.

#### Process: Cleaning and disinfection

#### Automatic cleaning in a cleaning and disinfection unit in combination with the cleaning agent recommended by the unit manufacturer.

##### Procedure:

Insert the instruments so that the liquid can flow out of the drain tubes and blind holes. Set the cycle and adhere to the unit manufacturer's wash and rinse times. The cleaned components should be examined for visible dirt when removing the instruments. If necessary, repeat the cycle or clean manually.

#### Manual cleaning

1. Thoroughly clean disinfection/cleaning agent from the instruments by rinsing them with water and, if required, with the aid of a soft nylon brush. **Ultrasonic cleaner:** Place the components in a basket, avoid acoustic shadows. Add an enzymatic cleaning agent to the water and clean the components at a temperature of 40 - 50° C in the ultrasonic cleaner (35-40 kHz) for 3 minutes. Ensure that the components are immersed completely in the water without bubbles.
2. Then remove the instruments from the cleaning solution and rinse them thoroughly (minimum 1 min.) under running water. Use fully desalinated water for this stage, if possible.
3. Then dry the instruments with compressed air
4. Check the instruments visually and repeat the cleaning stage, if necessary.
5. Pack the instrument as soon as possible after removal (see Section "Packaging"), if necessary after drying again at a clean location).
6. Document the approval.

#### Mechanical cleaning and disinfection

Cleaning, disinfection and drying according to DIN EN ISO 15883-1:2014 and DIN EN 15883:2006

**Pre-cleaning:** The disassembled instruments are placed in cold water for 5 minutes in the ultrasound. The handle is placed in cold water for 10 minutes in the ultrasound. The disassembled instruments are then brushed under water with a soft nylon brush to remove coarse dirt.

**Mechanical cleaning and disinfection:** e.g. with the Miele PG 8582 device with 1 minute of cold pre-cleaning, 5 minutes of cleaning at 55 degrees C, 1 minute of intermediate rinsing and 5 minutes of disinfection at 90° - 95° C with an enzymatic cleaner.

#### Important points

- All instruments must be sterilised after cleaning.
- When sterilising multi-part instruments in an autoclave without a drying programme, it is essential that the instruments are always sterilised in a disassembled state!
- The instruments should always be checked for corrosion after sterilisation.
- The scaling of the instruments must still be visible after sterilisation; otherwise the instruments should be replaced.
- New instruments must be cleaned and sterilised without packaging before using for the first time.
- Preparation of all instruments with cavities is particularly critical. This applies especially to internally cooled drills, placement aids and instruments with blind holes. As the water supply cavity cannot be checked with internally cooled drills and bone chips and debris could be carried from patient to patient, we recommend using these instruments as single-use products only or using them exclusively on one patient. With all other instruments it must be ensured that the cavities are completely clean. Multi-part placement aids should be disassembled for cleaning, if possible.

#### Control

Check all instruments after cleaning and cleaning/disinfection for corrosion, damaged surfaces, chipping, damage to the shape (e.g. bent and non-concentric

running instruments, damaged or blunt blades) as well as contamination and discard any damaged instruments. Instruments that are still contaminated must be cleaned and disinfected again. Then check the function and integrity of the instruments. It is not necessary to apply care products (e.g. oil) to instruments and abutments or screws.

#### Special aspects to observe with drills and cutters

Use cutting instruments for a maximum of 10 times. Thoroughly check these instruments after each use for cleanliness (including the internal cooling sections in particular) and the sharpness of the blades. The wear of bone drills depends on the hardness of the bone at the site. If in doubt, drills should only be used once. There is a considerable loss of cutting performance if the tip is damaged. To ensure care of the drills it is therefore essential to observe the following points:

- During the operation drills should be placed gently in the storage tray, which can be filled with physiological saline solution. Drills should not be kept in the physiological saline solution for longer than 1 hour to avoid corrosion.
- Never drop the drills directly on the tip
- The drills should not come into contact during ultrasonic cleaning

#### Packaging

Sort out the instruments in the sterilisation tray and then pack them in single-use sterilisation packaging (single or double packaging) and/or sterilisation container, which

- complies with DIN EN 868-2ff/DIN EN ISO/ANSI AAMI ISO 11607
- is suitable for steam sterilisation (temperature resistant up to min. 137° C (279° F), adequate steam permeability)
- provides adequate protection of the instruments and sterilisation packaging against mechanical damage
- is regularly serviced according to the manufacturer's instructions (sterilisation container)

#### Sterilisation

**Method:** Fractional pre-vacuum procedure (according to ISO 17665 or ISO 13060) in a unit that complies with EN 285  
**Temperature:** Heat to **134° C**; max. 137° C  
**Pressure:** 3 pre-vacuum stages with min. 60 millibar pressure  
**Hold time:** minimum **4 min. at 134-137° C**  
**Drying time:** minimum **15 min.**

Check the sterile instrument packaging for damage after sterilisation, check the sterilisation indicators.

To avoid staining and corrosion the steam must not contain any ingredients. The disinfectant therefore has to have been thoroughly removed. The recommended threshold limits of the ingredients for drinking water and steam condensate are specified in EN 285. Sterilisation using hot-air sterilizers and/or glass bead sterilizers is not advised, as the high temperatures blunt the cutting surfaces of the drills. Instruments should be sterilised in the trays recommended by the autoclave manufacturers if there is not a system-specific instrument tray available.

#### Storage

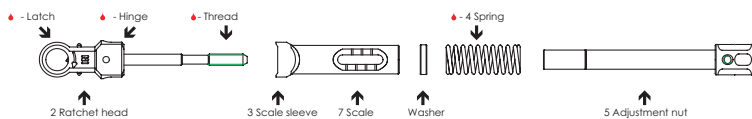
After sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging. The instruments should also be protected against sunlight and heat. The maximum storage period (expiry date) depends on several factors and must be determined and validated by the user.

#### Information on handling multi-part instruments

Multi-part instruments must be disassembled before sterilisation. Please note the schematic diagram below. **RA12:** Unscrew the coverscrew and remove the push-rod. The push-rod and ratchet housing (inner and outer) must be thoroughly cleaned and then dried. The individual components of the ratchet are shrink-wrapped

#### Schematic diagram of the TW/TW2 torque wrench

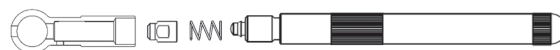
- After use the instrument should be disassembled into its individual parts – no tool is required for disassembly



- Pre-clean the individual parts under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the components.

#### Schematic diagram of the RA12 ratchet

- After use the instrument should be disassembled into its individual parts – no tool is required for disassembly



- Pre-clean the individual parts under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the components. The ratchet should be autoclaved in the disassembled state and reassembled immediately before use.

#### Schematic diagram of the handle REF 311431 (cannot be disassembled)



- Pre-clean the instrument under running cold water using a soft brush. Do not allow blood residue and other adhering deposits to dry on the handle. The handle should be thoroughly cleaned manually using an ultrasonic cleaner before mechanical cleaning.
- Manual cleaning including ultrasonic cleaner (see above) and mechanical cleaning should be performed in sequence.

#### Legend



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together in a sterilisation bag and sterilised. Ensure that the paper side of the sterilisation bag is placed so that the water vapour can escape and that the ratchet or its parts are not lying in water. After sterilisation, generally just before the beginning of implant placement, the ratchet should be thinly lubricated using a silicone oil and reassembled. The function of the ratchet should then be checked before beginning surgery.

#### Warnings

We do not know of any warnings, provided the instructions for use are followed for the products to be used as well as the corresponding disinfection and cleaning agent.

**Simpladent GmbH** reserves the right to change the design of the products and components or their packaging, adapt instructions for use as well as renegotiate prices and delivery conditions. Liability is limited to the use of defective products. Any further claims are excluded.

Further information about the preparation of medical products is available in the internet at [www.rki.de](http://www.rki.de) or [www.a-k-i.org](http://www.a-k-i.org).

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