General principles

All instruments must be cleaned, disinfected and sterilised prior to each use; this applies in particular in the first use following delivery because all instruments are delivered unsterile (Cleaning and disinfection following removal of the protective transport packaging: Sterilisation after packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation. As part of your responsibility for the sterility of the instruments during use, please note that:

- in principle only adequate device and product-specific validated methods are used for the cleaning/disinfection and sterilisation,
- the used devices (washer-disinfector, steriliser) are regularly maintained and checked, and
- the validated parameters must be complied with during each cycle.

Please also comply with the current legislation in your country as well as the hygiene regulations of the doctor’s practice or hospital. This applies in particular to the different specifications regarding effective inactivation of prions (not applicable for the USA).

Cleaning and disinfection

Basic principles

If possible, an automated method (washer-disinfector) should be used for the cleaning and disinfection. A manual method - also when using an ultrasound bath - should only be used if an automated method is not available, due to the markedly reduced effectiveness and reproducibility of a manual method.

The pre-treatment should be carried out in both cases.

Pre-treatment

Procedure:

1. Disassemble the instruments as far as is possible.
2. Rinse the disassembled instruments under running water for at least 1 min (temperature ≈ 35°C/95°F). Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments five times using a disposable syringe (minimum volume 1 ml).
3. Place the instruments in the pre-cleaning bath for the specified exposure time in such a way that the implants are sufficiently covered. Make sure that the instruments are not touching. Adp the pre-cleaning by carefully brushing all internal (conical interdental brush) and external surfaces (at the start of the exposure time). Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least five times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.
4. Then remove the instruments from the pre-cleaning bath and rinse them thoroughly at least five times (for at least 1 min) with water. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the instruments at least three times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.

When selecting the cleaning agent to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- the cleaning agent is compatible with the instruments (see section "Material durability”).

The concentrations, temperatures, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent or the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions and water that is sterile or of low microbiological contamination (max. 0.25 endotoxin units/ml) (e.g. purified water, highly purified water), and only use a soft, clean, lint free cloth and/or filtered air for drying.

If for example, for health and safety reasons a combined cleaning agent and disinfectant is used, please take into account that it should be aldehyde-free (as aldehyde flex blood claires), and should be proven to be effective (e.g. VAH/DGHM or FDA approval/clearance/registration).

Please note that the disinfectant that may be used for pre-treatment serves only to protect the personnel and cannot replace the disinfection step to be carried out later, after cleaning.

Automated cleaning/disinfection (washer-disinfector)

When selecting the washer-disinfector, it should be ensured that:

- the washer-disinfector corresponds in principle to DIN EN ISO/ANSI AMI ST15883 and that it has proven effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking pursuant to DIN EN ISO 15883),
- if possible, a verified programme for thermal disinfection (At value ≥ 3000, alternatively for older devices at least 5 mins at 90 °C) is used (alternatively, if chemical disinfecion is performed, the risk of disinfectant residue on the instruments should be taken into consideration),
- the used programme is suitable for the instruments and includes sufficient rinse cycles,
- only water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) is used for the rinsing (e.g. purified water/ highly purified water),
- the air used for drying is filtered and
- the washer-disinfector is regularly maintained and checked.

When selecting the cleaning agent system to be used, it should be ensured that:

- it is generally suitable for the cleaning of metal and plastic instruments,
- a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) is additionally used (provided that there is no thermal disinfection) and that this is compatible with the used cleaning agent and
- the chemicals used are compatible with the instruments (see section "Material durability”).

The concentrations specified by the manufacturer of the cleaning agent, and if applicable the disinfectant, must be strictly observed.

Procedure:

1. Disassemble the torque wrench inserts as much as possible.
2. Place the disassembled torque wrench inserts into the washer-disinfector, if possible using a closed-tray (small parts basket). Ensure that the torque wrench inserts are not touching and that a position is selected in which the spray jets of the washer-disinfector are not obscured.
3. Start the programme.
4. Remove the torque wrench inserts from the washer-disinfector after the programme sequence.
5. Check and package the torque wrench inserts as soon as possible after they are removed (see section “Checks”, "Maintenance" and "Packaging", if applicable after additional drying in a clean location).

Verification of the general suitability of the torque wrench inserts for effective automated cleaning and disinfection was provided by an independent, accredited testing laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Mike & Cie. GmbH & Co., Gütersloh) and the pre-cleaning agent and cleaning agent neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). For this purpose, the above-described method was followed.

Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant to be used, it should be ensured that:

- they are generally suitable for the cleaning and disinfection of instruments made out of metals and plastics,
- the cleaning agent - if applicable - is suitable for ultrasonic cleaning (no foam formation),
- a suitable disinfectant with proven effectiveness is used (e.g. VAH/DGHM or FDA approval/clearance/registration or CE marking) and that this is compatible with the used cleaning agent and
- the chemicals used are compatible with the instruments (see section "Material durability”).

If possible, combined cleaning agents/disinfectants should not be used. Only in cases of very low levels of contamination (no visible soiling) can combined cleaning agents/disinfectants be used (not in the USA).

The concentrations, exposure times and rinsing guidelines specified by the manufacturer of the cleaning agent and disinfectant must be strictly observed. Only use freshly prepared solutions, water that is sterile or of low microbiological contamination (max. 10 microbes/ml) as well as low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/ highly purified water), and only use filtered air for drying.
Manual cleaning
1. Disassemble the torque wrench inserts as much as possible.
2. Place the disassembled torque wrench inserts into the cleaning bath for the specified exposure time in such a way that the torque wrench inserts are completely covered by the liquid (if necessary, with ultrasound support or by carefully brushing with a soft brush).
3. Ensure that the torque wrench inserts are not touching and that there are no air bubbles in the cavities.
4. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the torque wrench inserts at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula at the start and at the end of the exposure time.
5. Remove the torque wrench inserts from the cleaning bath and rinse them thoroughly with water for 1 min at least three times.
6. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the torque wrench inserts with filtered compressed air.
7. Check the torque wrench inserts (see section “Checks” and “Maintenance”).

Manual disinfection
1. Place the disassembled, cleaned and checked torque wrench inserts into the disinfection bath for the specified exposure time in such a way that the torque wrench inserts are completely covered by the liquid.
2. Ensure that the torque wrench inserts are not touching and there are no air bubbles in the cavities.
3. Rinse all the lumens and blind lumens (with the fitted disposable cannula) of the torque wrench inserts at least five times using a disposable syringe (minimum volume 1 ml) at the start and at the end of the exposure time.
4. Remove the torque wrench inserts from the disinfection bath and rinse them thoroughly with water for 1 min at least three times.
5. Rinse of the lumens and blind lumens (with the fitted disposable cannula) of the torque wrench inserts at least five times using a disposable syringe (minimum volume 1 ml) and a disposable cannula.
6. Dry the torque wrench inserts by blowing off/blowing out with filtered compressed air.
7. Package the torque wrench inserts as soon as possible after they are removed (see section “Packaging”, after additional drying in a clean location if necessary).

Documentation
You can digitally monitor the number of times processing is carried out or document this using the K.00.75.DE01 form.