Processing instruction Titanmagnetics®

This processing instruction applies to all Titanmagnetics® torque wrench adapters (H….) as well as the positioning aids (P.62….) of the Titanmagnetics® Y-Line extrusion system and to the one-off processing of Titanmagnetics® inserts (I....) and positioning cuffs (P.00….) as well as Titanmagnetics® extrusion magnets (V.62...).

General principles

All instruments must be cleaned, disinfected and sterilised prior to each use; this applies in particular to 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).

Attention: For the respective instruments, additional or deviating specifications must be observed (see chapter "Special instructions").

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. If applicable (see chapter "Special instructions"):
   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).
   If applicable (see chapter "Special instructions"):
   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[1] for the specified exposure time in such a way that the implants are sufficiently covered. Make sure that the instruments are not touching. Aid the pre-cleaning by carefully brushing all internal (conical interdental brush) and external surfaces (at the start of the exposure time), at least 1 min each, for aids see chapter "Special instructions").
   If applicable (see chapter "Special instructions"):
   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.
   If applicable (see chapter "Special instructions"):
   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[1] 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. 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 a soft, clean, lint free cloth and/or filtered air for drying.

[1] If for example, for health and safety reasons a combined cleaning agent and disinfectant is used, please consider that it should be aldehyde-free (as aldehyde fixes blood stains), and should be proven to be effective (e.g. VAH/DGHM or FDA/EPA 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 AAMI ST15883 and that it has proven effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking pursuant to DIN EN ISO/ANSI AAMI 15883),
- if possible, a verified programme for thermal disinfection (A_0 value ≥ 3000, alternatively for older devices at least 5 mins at 90 °C) is used (alternatively, if chemical disinfection 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, (at least three depleting steps after cleaning (or neutralisation, if applied) or conductivity control recommended to effectively prevent detergent residues)
- 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, that the programme used contains a sufficient number of rinsing cycles (at least two depleting steps after disinfection or conductivity control are recommended to effectively prevent residues of the disinfectant) 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.

MADE IN GERMANY

steco-system-technik GmbH & Co. KG Kollaustr. 6 22529 Hamburg Germany
Telephone: +49 (0)40 – 55 77 81-0 Telefax +49 (0)40 – 55 77 81-99 E-Mail info@steco.de Internet www.steco.de

Procedure:
1. If applicable (see chapter "Special instructions"): Disassemble the torque wrench adapters as much as possible
2. Place the instruments - using a close-meshed tray (small parts basket) - in the washer-disinfector. Ensure that the instruments 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 instruments from the washer-disinfector after the programme sequence.
5. Check and package the instruments 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 instruments for effective automated cleaning and disinfection was provided by an independent, accredited testing laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning agent and cleaning agent neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). Worst case settings have been considered in relation to the procedure described above as well as to the concentration specified in the detergent instructions for use (taking into account the detergent manufacturer's specifications according to Note 1 in Chapter 6.6.2.2 of ISO 17664-1: 2021 as given above).

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. If applicable (see chapter "Special instructions"): Disassemble the instruments as much as possible
2. Place the instruments in the cleaning bath for the specified exposure time so that the instruments are completely covered by the liquid, careful brushing of the bores and the outer surface (at the beginning of the exposure time, at least 1 min each time, for aids see chapter "Special instructions").
3. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
4. If applicable (see chapter "Special instructions"):
   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) and a disposable cannula at the start and at the end of the exposure time.
5. Remove the instruments from the cleaning bath and rinse them thoroughly with water for 1 min at least three times.
6. If applicable (see chapter "Special instructions"):
   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).
7. Check the instruments (see section “Checks” and “Maintenance”).

Manual disinfection

1. Place the disassembled, cleaned and checked instruments into the disinfection bath for the specified exposure time in such a way that the instruments are completely covered by the liquid.
2. Ensure that the instruments are not touching and that there are no air bubbles in the cavities.
3. If applicable (see chapter "Special instructions"):
   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. Remove the instruments from the disinfection bath and rinse them thoroughly with water for 1 min at least three times.
5. If applicable (see chapter "Special instructions"):
   Rinse of 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) and a disposable cannula.
6. Dry the instruments by blowing off/ blowing out with filtered compressed air.
7. Package the torque wrench adapters as soon as possible after they are removed (see section “Packaging”, after additional drying in a clean location if necessary).

Verification of the general suitability of the instruments for effective manual cleaning and disinfection was provided by an independent, accredited testing laboratory using the pre-cleaning agent and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). Worst case settings were considered in relation to the procedure described above as well as to the instructions for use of the detergent and disinfectant.

Checks

Following the cleaning or cleaning/disinfection, check all of the instruments for corrosion, damaged surfaces, splintering and soiling (in particular on the wrench flats) and discard damaged instruments (for the limit on the number of reuses see section “Reusability”). Any instruments that are still dirty must be cleaned and disinfected again.
If applicable (see chapter "Special instructions"):
Pay particular attention to the O-rings on an intact surface. None of the components (e.g. a burr) that could find their way into the implant or the surgical site should be detached from the surface. Damaged O-rings must be replaced so as to guarantee a reliable hold of the torque wrench insert in the torque wrench. In addition, pay attention to the intactness of the wrench flats.

Maintenance/assembly

Instrument oils and/or instrument lubricants must not be used.

Packaging

Please package the instruments in disposable sterilisation packaging (single-use packaging) that meets the following requirements:
- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistance up to at least 142°C (288°F) and sufficient vapour permeability)
- adequate protection for the torque wrench adapters and sterilisation packaging against mechanical damage

MADE IN GERMANY

steco-system-technik GmbH & Co. KG Kollaustr. 6 22529 Hamburg Germany
Telephone: +49 (0)40 – 55 77 81-0 Telefax +49 (0)40 – 55 77 81-99 E-Mail info@steco.de Internet www.steco.de

Sterilisation

Only the below listed sterilisation methods should be used for the sterilisation; other sterilisation methods are not permitted.
Steam sterilisation

- fractionated vacuum method or gravity displacement method[2] (with adequate product drying[3])
- steam steriliser in accordance with DIN EN 13060 or DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance evaluation (PQ))
- maximum sterilisation temperature 138°C (280°F; plus tolerance in accordance with DIN EN ISO 17665)
- sterilisation time (duration of exposure at the sterilisation temperature):

Country	Fractionated vacuum method	Gravity displacement method
Germany	at least 5 mins at 134°C	Not recommended
Germany	at least 20 mins at 121°C	Not recommended
USA	at least 4 mins at 132°C (270°F), drying time at least 20 mins	Not recommended
Other countries	at least 3 mins at 132°C (270°F) / 134°C (273°F) [3]	at least 40 mins at 121°C (250°F)
Other countries	at least 20 mins at 121°C (250°F)	Not recommended

[2] It is only permitted to use the less effective gravity displacement method if the fractionated vacuum method is not available

[3] The drying time predominantly depends on factors that are the sole responsibility of the user (e.g. type of steam steriliser actually used, how it is equipped (in particular passive or active drying) as well as its maintenance and calibration status, the actually used sterilisation cycle, the actually used packaging configuration, the actually used loading configuration and in particular the loading density etc.); instrument-specific aspects play a secondary role in this regard. The user is thus obligated to check whether the conditions actually used guarantee adequate drying.

[4] or 18 mins (inactivation of prions)

Moreover, do not use dry heat sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.
If applicable (see chapter "Special instructions"): It is not permitted to sterilise the torque wrench adapters when assembled (only H.06.01.X1/Z1/K1).
Verification of the general suitability of the torque wrench insert for effective steam sterilisation was provided by an independent, accredited testing laboratory using the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using both the fractionated vacuum method and the gravity displacement method. For this purpose, typical conditions of a hospital or doctor's practice were taken into consideration together with the above-described methods.

Storage

Following sterilisation, the torque wrench adapters must be kept dry and dust-free in the sterilisation packaging.

Material durability

When selecting the cleaning agents and disinfectants please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- strong alkaline solutions (maximum permitted pH value 8.5, neutral/enzymatic cleaners recommended)
- organic solvents (e.g. alcohols, ethers, ketones, petroleum ether)
- oxidizing agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- oils

Never clean any of the instruments with metal brushes or steel wool.
All instruments may only be exposed to temperatures not exceeding 142°C (288°F).

Reusability

The instruments can - with appropriate care and if they are undamaged and uncontaminated (see also chapter "Checks") - be reused up to the number specified in chapter "Special instructions". Any further re-use beyond this limit or the use of damaged and/or soiled instruments is the responsibility of the user.
We assume no liability if these instructions are not followed.

Documentation

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

MADE IN GERMANY

steco-system-technik GmbH & Co. KG Kollaustr. 6 22529 Hamburg Germany
Telephone: +49 (0)40 – 55 77 81-0 Telefax +49 (0)40 – 55 77 81-99 E-Mail info@steco.de Internet www.steco.de

Special notes

		Torque wrench adapters	Extrusion magnets	Positioning aids for extrusion magnets	Positioning cuff	Inserts
Rinsing volume (disposable syringe with attached disposable needle)		1 ml	-	-	-	-
Brush		Blind cavities: conical interdental brush Outside: Soft standard brush (toothbrush)	Soft standard brush (toothbrush)	Soft standard brush (toothbrush)	Soft standard brush (toothbrush)	Soft standard brush (toothbrush)
Special procedure for	Dismantling	only for variant with small screw: Unscrew screw for variants with O-ring: Do not dismantle O-ring	If composite residues are still present or ground: Dispose (no reuse)	-	-	-
	Pre-treatment	Blind cavities: rinse and brush Exterior: brush	Brushes	Brushes	not required	Brushes
	Manual cleaning/ disinfection	Blind cavities: rinse and brush Exterior: brush	Brushes	Brushes	Brushes	Brushes
	Mechanical cleaning/ Disinfection	in small parts basket	in small parts basket	in small parts basket	in small parts basket	in small parts basket
	Maintenance/ assembly	Pack variant with screw disassembled for variants with O-ring: Check, replace O-ring if necessary, oiling or greasing prohibited	Standard Oiling or greasing prohibited	Standard Oiling or greasing prohibited	Standard Oiling or greasing prohibited	Standard Oiling or greasing prohibited
Packaging		Standard	Standard	Standard	Standard	Standard
Sterilisation		Standard	Standard	Standard	Standard	Standard
Maximum permissible number of cycles		50	1 (!)	50 (only if no composite residues are present or positioning aids are not ground!)	1 (!)	1 (!)

MADE IN GERMANY

steco-system-technik GmbH & Co. KG Kollaustr. 6 22529 Hamburg Germany
Telephone: +49 (0)40 – 55 77 81-0 Telefax +49 (0)40 – 55 77 81-99 E-Mail info@steco.de Internet www.steco.de