Processing instructions for RatioPlant® products according to DIN EN ISO 17664 – revision 07.2020

1. General information

The following descriptions contain detailed instructions for cleaning, disinfection and sterilisation of unsteril delivered products from the following product groups of the RatioPlant® implant system:

- RatioPlant® Abutments
- RatioPlant® Screws
- RatioPlant® Healing Caps
- RatioPlant® Drills
- RatioPlant® Countersinks
- RatioPlant® Cutters
- RatioPlant® MU Prosthetic Cap Ti

and the unsteril products of the following product groups of the RatioPlant® SMART implant system:

- RatioPlant® SMART Screws
- RatioPlant® SMART Final Drills
- RatioPlant® SMART Bar Connector

The products must be cleaned, disinfected and sterilised before the first and any further use on the patient. Effective cleaning and disinfection is an indispensable requirement for effective sterilisation.

Please note within your responsibility for the sterility of the products during the application,

- that in principle only sufficiently device- and product-specific validated procedures for cleaning/disinfection and sterilisation are used.
- that the devices used (cleaning and disinfection device, steriliser) are regularly maintained and checked.
- that the validated parameters are adhered to for each cycle.
- compliance with the applicable national legislation as well as the hygiene rules of the dental, doctor's office or hospital.

2. Warnings

- Plastic parts of the implant system, except abutments and healing caps made of PEEK, must not be sterilised (only clean and disinfect). Abutments and healing caps made of PEEK are sterilizable.
- It is imperative to ensure that cross-contamination of RatioPlant® and RatioPlant® SMART products with blood, serum or other human tissue is avoided during the processing and disinfection cycle.

3. Limitations in processing

- Products delivered unsterile may, unless otherwise specified in the corresponding instruction for use, be reprocessed as often as desired, provided that the inspections prescribed in accordance with the instructions for use or this processing instruction is successfully passed.
- The following prosthetic components may only be used for care in a single patient:
    - RatioPlant® Abutment...
    - RatioPlant® Screws...
    - RatioPlant® MU Prosthetic Cap Ti
    - RatioPlant® SMART Screws...
    - RatioPlant® SMART Bar Connector...

  These must be cleaned and disinfected before and after utilisation at the patient (e.g. for transfer to the dental laboratory). We recommend an additional sterilisation.
- Zirconium oxide abutments (5011410022, 5011410032, 5011410042, 5011410023, 5011410033, 5011410043) are intended only for a one-off processing cycle.

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4. Instruction on necessary processing steps

4.1 Initial treatment at the place of use

4.1.1 Products that have not yet been used on the patient

- Unsteril delivered RatioPlant® and RatioPlant® SMART products are delivered in equipped Ratioplant containers with internal Ratioplant® Tray (subsequent Instrument Kits) or individually packaged. The individual packaging must be intact at the time of delivery.
- If products are still in the original packaging, these are to be taken from the packaging for the following processing steps.

4.1.2 Products that have already been used on the patient

- Impurities on the Instrument Kits must be removed immediately.
- When using the instruments and the Instrument Kit, care must be taken to ensure that polluted instruments and drills are collected separately and not put back into the Instrument Kit in order to avoid contamination of the equipped tray.
- No blood and tissue residues on the products are allowed to dry. Products have to be placed in containers with water after use on patients.

4.2 Preparation before cleaning

- Products consisting of several components must be disassembled for appropriate cleaning:
    - For the angled Multiunit Abutments (5011110423, 5011110424, 5011110426, 5011110427, 5011110445, 5011110446, 5011110447, 5011110448, 5011110451, 5011110452, 5011110453, 5011110454, 5011110430, 5011110431, 5011110432, 5011110433) the pre-assembled Prosthetic Screws must be disassembled using the Screwdriver hex hand long (5012301006), Screwdriver hex hand short (5012301004), Screwdriver hex ratchet short (5012301003) or Screwdriver hex ratchet long (5012301005).
    - For the MU Prosthetic Cap Ti (5011110012) the pre-assembled Prosthetic Screws must be disassembled using the Screwdriver hex hand long (5012301006), Screwdriver hex hand short (5012301004), Screwdriver hex ratchet short (5012301003) or Screwdriver hex ratchet long (5012301005).
- All products stored in the supplied Instrument Kits must be taken from these for the following procedures.
- Containers, trays and covers must be cleaned separately from the products.
- The cleaning procedures described below require that all coarse contamination (tissue, bone residue, etc.) be removed before cleaning by appropriate non-blood-fixing techniques (e.g. rinsing, wiping, etc.).
- Areas that are difficult to access or precisely interacting surfaces can be better rinsed out with a syringe or a water nozzle.

4.3 Manual cleaning (max. 2 hours after application)

- Completely immerse the products for 10 minutes in the cleaning medium (0.5 % (v/v) neodisher® MediClean forte dissolved in demineralised water at a temperature of 30 ± 2 °C). At the beginning of the immersion time, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- After the immersion time, the entire accessible surface of the products, in particular the hard-to-access areas (cavities, gaps and recesses), must be cleaned with a soft non-metallic brush (medium hard toothbrush) in the cleaning medium until residues are no longer visible (for at least 30 seconds per product).
- Rinse the products 1 minute with demineralised water at room temperature.
- Transfer the products to an ultrasonic bath and clean for 10 minutes at a frequency of 35 kHz at an initial temperature of 25 °C to 30 °C. A mixture of 0.5 % (v/v) neodisher® MediClean forte dissolved in demineralised water is used as a cleaning agent for the ultrasonic bath.
- Rinse the products under demineralised water at room temperature for 3 minutes after ultrasonic cleaning.

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4.4 Manual disinfection

- Completely immerse the products in a disinfectant solution (3.0 % (v/v) neodisher® Septo Fin dissolved in demineralised water) at a temperature of 20 ± 2 °C for 15 minutes. At the beginning of the immersion time, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- Dip the products after the disinfection bath for 1 minute in cold demineralised water and then an extensive rinsing must be ensured to remove remaining disinfectant residues from the products.
- Ensure complete drying.

Basic note:

Proof of the basic suitability for effective manual cleaning and disinfection was provided by an independent accredited test laboratory, taking into account the procedure described in the previous chapter.
Neodisher® MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg) was used as a detergent and as a disinfectant neodisher® Septo Fin (Dr. Weigert GmbH & Co. KG, Hamburg).
In addition, an ultrasonic tank RK 510H (manufacturer: Bandelin electronic GmbH & Co. KG, Berlin) and a medium hard Dr. Best toothbrush (manufacturer: GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Munich) used.

4.5 Combined manual/automatic cleaning and disinfection

4.5.1 Manual pre-cleaning (max. 2 hours after application)

- Completely immerse the products for 10 minutes in the cleaning medium (0.5 % (v/v) neodisher® MediClean forte dissolved in demineralised water at a temperature of 30 ± 2 °C). At the beginning of the immersion time, ensure that air bubbles are no longer present on the products by moving them briefly by hand in the cleaning solution.
- After the immersion time, the entire accessible surface of the products, in particular the hard-to-access areas (cavities, gaps and recesses), must be cleaned with a soft non-metallic brush (medium hard toothbrush) in the cleaning medium until residues are no longer visible (for at least 30 seconds per product).
- Rinse the products 1 minute with demineralised water at room temperature.

4.5.2 Automatic cleaning and thermal disinfection

4.5.2.1 Information on the selection of the cleaning and disinfectant device

When selecting the cleaning and disinfectant device, care must be taken to ensure that:

- the cleaning and disinfection device has a tested effectiveness.
- a tested program for thermal disinfection is used (A_0 value > 3000).
- the cleaning and disinfection device is regularly maintained and checked.

The instructions of the manufacturer of cleaning and disinfection equipment must be complied with.

4.5.2.2 Steps for automatic cleaning and thermal disinfection

- Place the products in a screen basket for automatic cleaning and disinfection.The products must not touch each other. Then place the equipped screen basket in a load carrier of the cleaning and disinfection device and insert it in the cleaning and disinfection device.
- Start the program – the program must be executed according to the process sequence described in Table 1.
- At the end of the program, remove the products from the device.
- Ensure complete drying.
- Allow products to cool to room temperature.

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Table 1 Process for automatic cleaning and thermal disinfection

Step	Description
1	Rinse 1 minute with water at a water temperature of 25 ± 2 °C
2	Clean for 5 minutes at 55 °C ± 2 °C with cleaning medium consisting of a mixture of 0.5 % (v/v) neodisher® MediClean forte dissolved in water
3	Neutralise 1 minute at 42 ± 2 °C with neutralisation medium consisting of a mixture of 0.1 % neodisher® Z dissolved in water
4	Rinse 1 minute with water at 42 ± 2 °C
5	5 minutes thermal disinfection at 90 °C (A_0 >3000) with demineralised water

Basic note:
Proof of the basic suitability for effective combined manual and automatic cleaning and disinfection was provided by an independent accredited testing laboratory, taking into account the procedure described above. A cleaning and disinfectant PG8535 (manufacturer: Miele & Cie.Kg, goods loh) equipped with standard upper and lower load carriers and a screen basket E373 (manufacturer: Miele & Cie.Kg, Gütersloh) was used. Neodisher® MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg) and as neutraliser neodisher® Z (Dr. Weigert GmbH & Co. KG, Hamburg) were used as cleaning agents.The procedure described above was taken into account.
Furthermore a medium hard Dr. Best toothbrush (manufacturer:GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Munich) was used.
The automatic disinfection has not been experimentally tested, since according to ISO 15883-1, Annex B, Chapter B.1, it can be assumed that a certain temperature over a given period leads to predictable killing in a standardised population of microorganisms.The thermal disinfection at a temperature of 90 °C for 5 minutes results in an A_0 value of 3000.

5. Maintenance/examination

- After cleaning and disinfection, check the products for cleanliness, corrosion, wear, function and damage, e.g. bent, broken, cracked, worn and broken parts.
- Sort and replace damaged and defective products.
- Products containing residues from the previously described cleaning and disinfection process shall be cleaned and disinfected again.
- The drills shall also be checked for blunt cutting or damage after each application and shall be, if necessary, replaced. The maximum permissible number of drill applications, as prescribed in the instructions for use, shall be observed.

6. Assembly

Assemble all products disassembled in advance of processing:

- For the angled Multiunit Abutments (5011110423, 5011110424, 5011110426, 5011110427, 5011110445, 5011110446, 5011110447, 5011110448, 5011110451, 5011110452, 5011110453, 5011110454, 5011110430, 5011110431, 5011110432, 5011110433) the Prosthetic Screws must be mounted using the Screwdriver hex hand long (5012301006), Screwdriver hex hand short (5012301004), Screwdriver hex ratchet short (5012301003) or Screwdriver hex ratchet long (5012301005).
- For the MU Prosthetic Cap Ti (5011110012) the Prosthetic Screws must be mounted using the Screwdriver hex hand long (5012301006), Screwdriver hex hand short (5012301004), Screwdriver hex ratchet short (5012301003) or Screwdriver hex ratchet long (5012301005).

7. Packaging

Products intended for storage in the Instrument Kit (cutters, drills, countersinks, etc.), place in the tray and immediately pack the tray with the products, or pack the products individually in a one-off sterilisation package.
Prosthetic components, such as e.g. abutments and healing caps are immediately to be packed individually in a one-off sterilisation packaging for sterilisation.
HumanTech Dental recommends the use of single-use sterilisation packaging that meets the requirements of DIN EN ISO 11607 and DIN 868-5. It must be ensured that the packaging is suitable for steam sterilisation and that the products are adequately protected against mechanical damage.

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8. Sterilisation

When selecting the autoclave, care must be taken to:

- that the autoclave has in principle a tested efficacy.
- that in principle only procedures according to ISO 17665 are used.
- that the autoclave is regularly maintained, checked and calibrated.

The instructions of the autoclave manufacturer and the recommended guidelines for maximum loading with sterilisation material must be observed.

Attention: All unsteril packaged products of the RatioPlant®and RatioPlant® SMART implant system must not be sterilised in the original packaging!

Only steam sterilisation methods are permitted for sterilisation.The recommended sterilisation parameters are as follows:

Sterilisation medium	Sterilisation procedure	Pressure for venting processes	Pressure for sterilisation phase (saturated vapour pressure)	Sterilisation temperature	Time to hold	Drying time
Saturated steam	3x fractionated prevacuum	15 kPa	287 kPa ± 9 kPa(1)	132 °C ± 1 °C	5 minutes	10 minutes
Note: Due to the different loading configurations (including the type and extent of additional loads) as well as the density/total weight, as well as the performance characteristics of the steam steriliser (including its equipment), drying times generally vary greatly.The specified drying time must not be exceeded. (1) Since the sterilisation is carried out with saturated steam, the pressure for the sterilisation phase (saturated steam pressure) is directly dependent on the sterilisation temperature.The given values were taken from Table C.1 of DIN ISO/TS 17665-2.						

Basic note:

Proof of the basic suitability for effective sterilisation has been provided by an independent accredited test laboratory, taking into account the procedure described above. It was used for the validation of the sterilisation of products in a single sterilisation packaging a steam autoclave Systec HX-320 (manufacturer: Systec GmbH, Linden) and as packaging the disposable sterilisation packaging STERICLIN® bag (paper/foil; Manufacturer: Vereinigte Papierwarenfabriken GmbH, Feuchtwangen).The procedure described above was taken into account.

For the validation of the sterilisation of products in the provided Instrument Kit a steam autoclave Lautenschläger ZentraCert (F. & M. Lautenschläger GmbH & Co. KG, Cologne) was used.The procedure described above was taken into account.

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