INSTRUCTIONS FOR USE / REPROCESSING RECOMMENDATION WASH-TRAY

Exclusion of liability

This product is an accessory to a comprehensive treatment plan and is to be used only in combination with the associated original products in accordance with the instructions and recommendations of Medical Instinct® Deutschland GmbH (Medical Instinct). Non-recommended use of third-party products in combination with Medical Instinct products will void the warranty and any other express or implied obligations of Medical Instinct. Medical Instinct assumes no liability, express or implied, for any direct or indirect damages, punitive damages including compensatory damages, or any other damages arising out of or in connection with errors in professional judgment or practice in the use of Medical Instinct products. The user is also required to keep himself/herself regularly informed of the latest developments concerning this Medical Instinct product and its application. In case of doubt, Medical Instinct should be contacted. Since the use of the product is under the control of the user, the user assumes all responsibility. Medical Instinct assumes no liability for damages resulting from the use of the product.

1. Scope of application of the instructions for use

These instructions for use are valid for the product described in Table 1.

Article no.	Product name
190-300420	Wash-Tray, unbestückt

Table 1 Wash Tray; Tray e

2. Design and safety instructions

Symbols of safety instructions

NOTE — Notes are general precautions that, if ignored, may result in impairment or short-term inconvenience.

Coution — The signal word CAUTION indicates hazards which, if ignored, may result in minor or moderate injury or impairment of transport and safety.

Warning — The signal word WARNING indicates hazards which, if ignored, may result in serious injury or severe impairment due to the transport and securing.

3. Areas of application and limitation of use

3.1. Intended use

3.1.1. Wash tray

The Medical Instinct Wash-Tray is used for machine cleaning and sterilization of burs and other dental implantology instruments and accessories of the Medical Instinct BoneTrust® implant system according to the instructions for use for reprocessing.

Figure 1Medical Instinct Wash-Tray

3.1.2. Tray tamplate

The template for the wash tray is used to show the arrangement of the instruments in the storage and provides a possible positioning of the hand instruments and burs.

Note

Please refer to the Tray Template instructions for use/reprocessing recommendationVers.01 March 2021

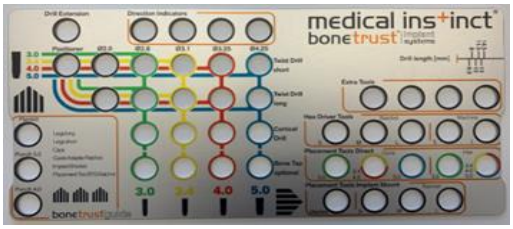

Figure 2 Medical Instinct template for the wash tray (optional)

3.2. Compatible products

The tray template shows the products which, inter alia, are compatible with the Wash-Tray in combination and are reprocessed with the tray. In the Wash-Tray, all Medical Instinct system parts that can be used several times and are necessary for an implant insertion can be combined specifically. After individual cleaning, the parts can be treated in the tray in the thermal disinfector and then sterilized.
The positions of the system parts can be identified by the inserted tray template (see Figure 2).
The positions marked with "Extra Tool" can be equipped individually by the user.
The cleaning, reprocessing and sterilization or the admissibility of multiple use of these parts are the sole responsibility of the dentist.

3.3. Indication/contraindication

3.3.1. Indication: see intended use

3.2.2. Contraindication: N/A

3.4. Safety instructions

3.4.1 General safety instructions

Note

To avoid damage due to improper supply and use and to avoid jeopardizing warranty and liability:

- Use product only in accordance with the instructions for use
- Observe safety information and maintenance instructions
- Product and accessories may only be used by trained professionals.
- brand new or unused products should be stored in a dry, clean and protected place.
- Before using the product, check that in functionality and in proper condition.

Note

The user is obliged to report all serious incidents occurring in connection with the product to the manufacturer and the competent authorities of the state in which the user is established.

3.4.2 Opening the wash tray

After sterile removal of the wash tray from the sterile packaging, the tray can be opened on a sterile base. To do this, the lock plates on the left and right sides must be pressed in. The lid can then be removed.

3.4.3 Division of the wash tray

The wash tray is divided into three main areas.
Burs and insertion tools for the torque ratchet and contra-angle handpieces can be stored in the upper area. In the lower right area, for example, the counter key with depth probe and the torque ratchet can be used.

In the lower left area, in the screen basket, there is space for further accessories such as the instruments for guided surgery, of the BoneTrust® guide system. The screen basket has an independent lid, which can be unlocked by sliding the plastic lock towards the screen basket and then removed.

4. Validated reprocessing procedure

4.1 Cleaning and sterilization instructions

4.1.1 General safety instructions

- National legal regulations national and international standards and guidelines and own hygiene regulations for reprocessing must be observed

- machine reprocessing is preferable to manual cleaning due to a better and safer cleaning result.

- It is important to note that successful reprocessing of this medical device can only be ensured after prior validation of the reprocessing process.

- If no final sterilization is performed, a virucidal disinfectant must be used

4.1.2 General notes

Caution

- Dried-on or fixed surgical residues can make cleaning difficult or ineffective and lead to corrosion. The time interval between application and reprocessing should not exceed 6 h.
- no fixing pre-cleaning temperatures >45 °C
- and no fixing disinfectants (active substance basis: aldehyde, alcohol) should be used.
- Overdosed neutralizing agents or basic cleaners can lead to chemical attack and/or fading and visual or machine illegibility of the laser marking on stainless steel.
- In the case of stainless steel, residues containing chlorine or chloride (e.g. surgical residues, pharmaceuticals, saline solutions, in the water used for cleaning, disinfection and sterilization) lead to corrosion damage (pitting corrosion, stress corrosion) and thus to the destruction of the products.
- For removal, adequate rinsing with fully demineralized water followed by drying must be carried out. Re-drying, if necessary.
- Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE marking) and recommended by the chemical manufacturer with regard to material compatibility may be used. All application specifications of the chemical manufacturer must be strictly adhered to. Otherwise, this may lead to the following problems:

Note

- Optical material changes such as fading or color changes in titanium or aluminum.
- In the case of aluminum, visible surface changes can already occur at a pH value of >8 in the application/use solution.
- Material damage, such as corrosion, cracks, fractures, premature aging or swelling.

- For cleaning, do not use metal brushes or other abrasive agents which damage the surface, otherwise there is a risk of corrosion.

4.2. Cleaning/disinfection

4.2.1. Product-specific safety instructions for the reprocessing procedure

Caution

Risk of infection or damage to the medical devices due to inadequate or unsuitable reprocessing!
The reprocessing procedure described below applies only to unloaded screen baskets.

- For loaded screen baskets, read and follow the instructions for reprocessing of the products in the respective instructions for use.

Note

After treatment on the patient, place hand instruments and burs in a container with suitable aldehyde-free disinfectant.
Remove tray template before cleaning, if applicable.

Damage to or destruction of the product due to unsuitable cleaning/disinfection agents and/or excessively high temperatures!

- Do not use a metal brush.
- Use cleaning and disinfecting products according to the manufacturer's instructions.
- Observe information on concentration, temperature and exposure time.
- In the case of wet disposal, use suitable cleaning/disinfection agents. To avoid foaming and deterioration of the effectiveness of the process chemistry: Before mechanical cleaning and disinfection, rinse product thoroughly with running water.

´4.2.2 Validated cleaning and disinfection process

Validated procedure	Features
Manual cleaning with immersion disinfection 1. the instruments should be rinsed under flowing water, coarse contamination removed with a nylon brush. 2. cleaning and chemical disinfection is carried out with suitable, material-compatible agents (follow manufacturer's instructions).	use a suitable cleaning brush. Drying: with medical compressed air or lint-free tissue. For disinfection, only use agents with proven effectiveness (VAH list) and which have been tested and approved (e.g. VAH or FDA approval or CE marking).
Mechanical alkaline cleaning and thermal disinfection	Lay the product in a manner suitable for cleaning (avoid rinsing shadows).

Table 2 validated cleaning-disinfection procedures (manual/machine)

4.3 Manual cleaning/disinfection

- Before manual disinfection, let the rinsing water drip off the product sufficiently to prevent dilution of the disinfectant solution.
- After manual cleaning/disinfection, visually inspect visible surfaces for residues.
- If necessary, repeat the cleaning/disinfection process.

Phase	Step	T [°C/°F]	t [min]	ConC. [%]	Water quality	Chemical
I	Disinfection, Cleaning	RT (cold)	> 15 min MD immerse in the bath	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	Intermediate rinse	RT (cold)	1 min	-	D-W	
III	Disinfection	RT (cold)	5 Min	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
IV	Final rinsing	RT(cold)	1Min	-	FD-W	-
V	Drying	RT	compressed air/ lint free tissue	-	-	-

Table 3 manual cleaning procedure

T-W: Drinking water
FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water qualityat least)
RT: Room temperature
MD: Medical Device

4.3. Mechanical cleaning/disinfection

Note
The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approval or CE mark according to DIN EN ISO 15883).

The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

For thermal disinfection, the template must be removed from the wash tray and placed separately in the thermal disinfector.

4.4.1 Mechanical alkaline cleaning and thermal disinfection

Stept	t [°C/°F]	t [min]	Water quality	Chemical/Note
Pre-rinsing	<25/77	3	D-W	-
Cleaning	55/131	10	FD-W	Concentrate, alkaline: –pH=13 – <5 % anionic surfactant 0.5 % working solution – pH = 11*
Intermediate rinse	>10/50	1	FD-W	-
Thermo-disinfaction	90/194	5	FD-W	-
Draying	-	-	-	According to the program for cleaning and disinfection device

Table 4 Machine cleaning and disinfection process

Note
After machine cleaning and disinfection, all visible areas of the product must be checked for residues, defects and integrity.
An 8x magnification of an optical visual inspection is recommended.

Caution
If residual contamination is still visible on the instrument after machine reprocessing, repeat cleaning and disinfection until no more contamination is visible.

Products must be sorted out in the event of the following defects.

Defects
Shape damage (bent, twisted or fractured parts)
Corroded surfaces

Table 5 Defects leading to the exclusion

4.5 Sterilization

Note
Sterilization must be performed in a single-use paper/film bag. Closures must not be under tension.

Caution
A drying time of at least 20 minutes is recommended.

The sterilizers used must be regularly maintained and checked. The validated parameters must be maintained for each cycle.

Ensure that the sterilant has access to all external and internal surfaces (e.g. by opening valves and taps).).

4.5.1. Validated sterilization process

- Steam sterilization in fractionated vacuum process.
- Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665.
- Sterilization in fractionated vacuum process at 134 °C, holding time 5 min.

In case of simultaneous sterilization of several products in one steam sterilizer: Ensure that the maximum permissible load of the steam sterilizer is not exceeded according to the manufacturer's specifications.

Handling and storage

The products must be stored in a sterile paper/film bag after reprocessing. The transport and storage of the packaged sterile goods must be protected against dust, moisture and recontamination. Storage must always be protected against dust, moisture and recontamination. Improper storage may affect the product properties and lead to supply failure.

Disposal

The product must be disposed of in accordance with local regulations and environmental requirements, taking into account the level of *contamination.*

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Symbols

Batch description

Item number


Observe instructions for use

Medical Device

Unique Device Identification