INSTRUCTIONS FOR USE / REPROCESSING RECOMMENDATION TRAY GUIDE

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
190-300421	Tray Guide, single

Table 1; Tray Guide

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.

CAUTION — 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. Tray Guide

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.

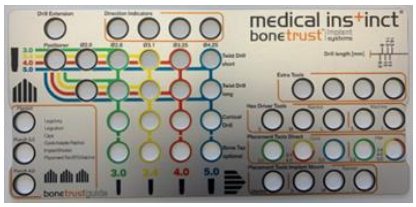

Figure 1 Medical Instinct guide for the Wash-Tray

3.1.2 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.

Figure 2 Wash- Tray Medical-Instinct

3.2. Indication/contraindication

3.2.1. Indication: see intended use

3.2.2. Contraindication: N/A

3.3. Safety instructions

3.3.1 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.

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.

4.1.3 Preparation before cleaning

Caution

Contaminated instruments due to incorrect cleaning!
Remove the graphic template from the wash tray before cleaning.

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.

Validated cleaning and disinfection process

Validated procedure	Features
Manual cleaning with wipe disinfection	Drying phase: Use lint-free tissue
Machine cleaning with neutral or mild alkaline products cleaning and disinfection	Insert product in a suitable manner 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	Cleaning	RT (cold)	-	2	D-W	-
II	Drying	RT	-	-	-	-
III	Wipe disinfection	-	>1	-	-	Melisptol HBV wipes 50% Propan-1-ol
IV	Final rinsing	RT (cokd)	0,5	-	FD-W	-
V	Drying	RT	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

Phase I

- Clean the product under running faucet water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.

Phase II

- Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

Phase III

- Wipe all surfaces of the product with a single-use disinfectant wipe.

Phase IV

- After the specified exposure time (at least 1 min), rinse the disinfected surfaces under running FD water.
- Drain any remaining water fully.

Phase V

- Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

4.4. 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 neutral or mild alkaline cleaning and thermal disinfecting

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	Prerinse	<25/77	3	T-W	-
II	Cleaning	55/131	10	VE-W	**Neutral:** ■ Concentrate: – pH neutral – <5 % anionic surfactant ■ 0.5 %* working solution Mildly alkaline: ■ Concentrate: – pH = 9.5 – <5 % anionic surfactant ■ 0.5 % solution
III	Inter mediate rinse	>10/50	1	VE-W	-
IV	Thermal disinfecting	90/194	5	VE-W	-
V	Drying	-	-	-	According to the program for cleaning and disinfection device

Table 4 Machine cleaning and disinfection process

Note

After mechanical cleaning and disinfection, all visible areas of the product must be visible areas of the product must be checked for residues, defects and intactness. 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.

Inspection, maintenance and checks

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, functioning properly, are not damaged and have no parts that are bent, broken, cracked, or fractured.
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that still show impurities or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical Service.
- Check for compatibility with associated products.

Packaging

- Place the product in its holder or on a suitable wash tray. Ensure that sharp edges are covered.
- Pack trays appropriately for the intended sterilization process (e.g. In Aesculap sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

4.5 Sterilization

	Note Sterilization must be performed in a single-use paper/film bag. Closures Ensure that the sterilant has access to all external and internal surfaces (e.g. by opening valves and taps). Closures must not be under tension.
	Caution A drying time of at least 20 minutes is recommended.
	Sterilization devices must be regularly maintained and checked. The validated parameters must be adhered to for each cycle.

Validated sterilization process

- Steam sterilization using fractionated vacuum process.
- Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665.
- Sterilization using 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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Medical Instinct® Deutschland GmbH
Graseweg 24
D– 37120 Bovenden
Tel.: +49 5593 95196
E-Mail: info@medical-instinct.de
www.medical-instinct.de

Symbols

Batch description

Item number


Observe instructions for use

Medical Device

Unique Device Identification

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