

veniences.

CAUTION



The signal word CAUTION identifies hazards which, if disregarded, can lead to mild to moderate injuries or to a negative impact on transport and security.

WARNING



The signal word WARNING identifies hazards which, if disregarded, can lead to serious injuries or severe negative impacts via transport and security.

Opening the Wash-Tray

After sterile removal of the wash-tray from the sterile packaging, the tray can be opened on a sterile support surface. To do so, push in on the locking plates on the left and right side. Then the lid can be removed.

Division of the Wash-Tray

The Wash-Tray is subdivided into three main areas. Drills and insertion tools for the torque ratchet and handpiece can be stored in the upper area. The Counter- and Measure Tool and the torque ratchet, for example, can be inserted in the lower right-hand area. In the lower left-hand area, in the screen basket, there is space for additional accessories, such as the instruments for guided surgery, of the BoneTrust® guide system.

The screen basket has a separate lid which can be unlocked by pushing the plastic closure in the direction of the screen basket and then removed.

INSTRUCTIONS FOR CLEANING AND STERILIZING

NOTE



It is recommended to perform reprocessing of the wash-tray no later than one hour after use.



CAUTION

The incorrect processing or the use of nonsterile

products can cause allergic reactions through which inflammation can occur. Therefore ensure that the Wash-Tray is processed according to these instructions.

After use on the patient, the manual instruments and drills should be placed in a container with physiological saline solution or water and coarse contamination should be removed. In doing so, the torque ratchet should be disassembled beforehand in accordance with the associated instructions for use from the manufacturer.

For preparation for the thermal disinfection, the manual instruments and drill bits should be removed from the container and wiped with a lint-free disposable cloth. After wiping, place them in a second container with unused physiological saline solution or water. Then arrange the components in the wash-tray.

Thermal disinfection

NOTE



For the thermal disinfection, the Tray Guide should be removed from the wash-tray and placed separately in the thermal disinfecter.

CAUTION



No blood and tissue residue should be allowed to dry on the trays. Coarse contamination on the tray must be removed immediately.



The thermal disinfection must be started within 2 hours after the surgery.



The Tray Guide may be cleaned only with mildly alkaline cleaning chemicals in order to preserve the protective surface layer.

Automated cleaning and disinfection is recommended strictly according to the information in Table 2 and 3 and is subject to a validated method:

Table 2: Validated automated alkaline cleaning and thermal disinfection of the Wash-Tray without Tray Guide

Step	T [°C/°F]	t [min]	Water quality	Chemical/info
Pre-rinsing	<25/77	3	Drinking water	-
Cleaning	55/131	10	Demineralized water	Concentrate, alkaline: - pH ~ 13 - <5 % anionic surfactants
Intermediate rinsing	>10/50	1	Demineralized water	-
Thermal disinfection	90/194	5	Demineralized water	-
Drying	-	-	-	According to the program for the cleaning and disinfecting device

Table 3: Validated automatic mildly alkaline cleaning and thermal disinfection of the Tray Guide

Step	T [°C/°F]	t [min]	Water quality	Chemical/info
2x pre-rinsing	<25/77	3	Drinking water	-
Cleaning	55/131	10	Demineralized water	Concentrate, mildly alkaline: - pH ~ 10 (e.g. Mediclean Fort Dr. Weigert)
Intermediate rinsing	>10/50	1	Demineralized water	-
Thermal disinfection	91/196	5	Demineralized water	-
Drying, pulsating	100/212	30	-	Rinse aid (e.g. Mediclair Dr. Weigert)



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NOTE



After automated cleaning and disinfection, all visible sites on the product should be checked for residues, deficiencies and intactness. It is recommended to perform an 8x magnification of a visual inspection.

CAUTION



If residual contamination can still be detected on the instrument after automated processing, repeat cleaning and disinfection until no more contamination is visible.

The following deficiencies necessitate rejection of the product:

Deficiencies
Distorted shapes (bent, twisted or fractured parts)
Corroded surfaces

Sterilization

NOTE



Sterilization is to be performed in a disposable paper/film pouch. Closures should 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 adhered to each cycle.

Permissible sterilization methods are fractionated vacuum methods (type B) with sufficient product drying. Other sterilization methods are not permissible. The sterilization hold time is at least

4 minutes at 132°C (270°F) or at least 3 minutes at 135°C (275°F). The maximum sterilization temperature should not exceed 137°C (279°F).

The steam sterilizers used must have a CE mark and meet the requirements of EN 13060 or EN 285. As a general rule, only sufficiently device- and product-specific validated methods according to ISO 17664 may be used for the sterilization.

HANDLING AND STORAGE

The products must be stored after processing in a sterile paper/film pouch. The packaged sterile materials are transported and stored protected from dust, moisture and recontamination. It must always be ensured that the materials are stored such that they are protected from dust, moisture and recontamination. Improper storage can affect product characteristics and lead to failure of the treatment.

DISPOSAL

Disposal of the product must be done according to the locally applicable regulations and environmental standards and the respective degree of contamination must be taken into account.



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SYMBOL LEGEND



Batch code



Catalogue number



Consult operating instructions