



CAUTIONS:

It is recommended that the Surgical Tray is used only with Loocid surgical instruments and components. The storage and organization of non-Loocid instruments and components can lead to mechanical and / or instrumental failure.

SURGICAL TRAY INSTRUCTIONS FOR USE:

It is strongly recommended that clinicians, new as well as experienced implant surgeons, always go through special training before undertaking a new treatment method. Loocid offers a courses for various levels of knowledge and experience. For more information, please contact Loocid LLC. Loocid has a network of mentors available who are experienced with the new device/treatment method to support new users to avoid possible complications.

All components, instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Do not rotate the drill or apply force while evaluating the length of the depth marking using the scale on the plate.

REPROCESSING INSTRUCTIONS:

The Surgical Tray is delivered non-sterile and intended for re-use. Prior to first use and re-use clean, disinfect and sterilize the product using the recommended parameters.

⚠ Warning: Use of non-sterile devices may lead to infection of tissues or infectious diseases. The Surgical Tray has been designed for both manual and automated cleaning and disinfection (by means of thermodisinfectors) as well as sterilization. The following section describes the reprocessing of the Surgical Tray step by step. Do not deviate from the described reprocessing instructions.

POINT OF USE:

1. Dispose single-use instruments, dull reusable drills and any other worn-out reusable instruments directly after use.
2. Remove excess soil from reusable instruments and surgical tray directly after use (within a maximum of 1 hour postoperatively), using absorbent paper wipes. Additionally, rinse the medical devices with running water.

3. During surgery, always put used reusable instruments back into the Surgical Tray using their designated holders (see pictograms and color-coded workflow on the plate). The sharp instruments should be handled with a pair of tweezers to avoid injury.

CONTAINMENT AND TRANSPORTATION:

1. Transport the Surgical Tray to the area where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the Surgical Tray with a damp cloth or store it in a closed container to avoid drying of soil and / or debris.
2. Store the Surgical Tray with the instruments in a container to avoid any contamination of the environment.

AUTOMATED CLEANING, DISINFECTION AND DRYING (INCL. PRE-CLEANING):

1. Remove all multi-piece instruments (e.g. Manual Torque Wrench) from the Surgical Tray and disassemble the instruments according to their respective Instructions for Use.

2. Remove all instruments with lumens and difficult-to-reach areas (e.g. blind holes, cavities) from the Surgical Tray.
3. Remove the plate from the Surgical Tray.
4. Flush thoroughly all lumens and difficult-to-reach areas of the removed instruments with a water pistol.
5. Place all drill bit instruments back into the designated holders in the Surgical Tray.
6. Place the assembled Surgical Tray in a bath of 0.5 % solution of alkaline cleaning agent A for 5–10 minutes at 40 °C temperature with ultrasonic actions. The manufacturer's instructions for use for the ultrasonic bath and the detergent must be strictly followed. Caution: Do not place the plate into the ultrasonic bath.
7. Put the Surgical Tray and the plate into the washer-disinfector separately. Place the plate beside the Surgical Tray in a vertical position. Caution: Please ensure that the plate is removed from the Surgical Tray before the automatic cleaning and disinfection is carried out.
8. Carry out automatic cleaning and disinfection under consideration of national requirements in regards to A0-Value (EN ISO 15883). The manufacturer's Instructions for Use for the washer-disinfector must be strictly followed. The following parameters were used in the Loocid validation:
 - 2 minutes pre-washing with cold demineralized water.
 - 5 minutes washing with tap water at 55 °C with a 0.5 % solution of alkaline cleaning agent B. Caution: The use of a cleaning solution with acidic pH (pH below 7) could potentially damage the plate.
 - 3 minutes rinsing with cold demineralized water.
 - 5 minutes thermal disinfection with demineralized water at 93 °C.
9. Dry the Surgical Tray and the plate by following the instructions provided by the manufacturers of the washer-disinfector.

INSTRUCTIONS FOR USE

Date: August 2023

LOOCID BCP™ SURGICAL TRAY

⚠ Important: Please read.

DESCRIPTION:

The Surgical Tray is a reusable surgical tray to be used in combination with Loocid surgical instruments and components. The Surgical Tray is used to store and organize the instruments and components during both the surgical and reprocessing procedures. The Surgical Tray consists of three parts:

1. A base with holders to accommodate the different surgical instruments, ratchets and components,
2. a removable plate to indicate the surgical workflow and the position of the instruments within the tray, and
3. a lid to securely contain the instruments during reprocessing.

There are different versions of the Surgical Tray available for the different Loocid drill bit products.

INDICATIONS & INTENDED USE:

The Surgical Tray is used to store and organize Loocid surgical instruments and components during cleaning / sterilization and implant treatment.

CONTRAINDICATIONS:

There are no specific contraindications relevant for the Surgical Tray.



MANUAL CLEANING, DISINFECTION AND DRYING:

1. Remove all the instruments from the Surgical Tray.
2. Disassemble the multi-piece instruments (e.g. Manual Torque Wrench) according to their respective Instructions for Use.
3. Remove the plate from Surgical Tray.
4. Manually clean all the instruments according to the information provided in the respective Instructions for Use for the instrument.
5. Scrub the Surgical Tray under running water (water quality: drinking water) with a soft bristled nylon brush until all visible soil are removed.
6. Take the soft bristled nylon brush and immerse it into a 0.5 % solution of alkaline cleaning agent A at 40 °C. Scrub the plate with the soft bristled nylon brush until all visible soil are removed. Caution: The use of a cleaning solution with acidic pH (pH below 7) could potentially damage the plate. Make sure the complete surface area is scrubbed. If needed, repeat several times.
7. Rinse the plate to remove all cleaning solution (follow the instructions provided by the manufacturer of the cleaning solution) under running water (water quality: drinking water).
8. Flush the grommets (instrument holders) with a water pistol until all visible soil is removed.
9. Place the Surgical Tray (without the plate) into an ultrasonic bath for 5 - 10 minutes with a 0.5 % solution of alkaline cleaning agent A at 40 °C. The manufacturer's Instructions for Use for the ultrasonic bath and detergent must be strictly followed.
10. Rinse the Surgical Tray to remove all cleaning solution (follow the instructions provided by the manufacturer of the cleaning solution) under running water (water quality: drinking water).
11. Dry the Surgical Tray and the plate with suitable equipment such as compressed air or a soft cloth. Do not use abrasive sponges or metal that might damage any surfaces.
12. Immerse the Surgical Tray into a 100 % disinfection solution C at ambient temperature (20 °C ± 10 °C) for 12 minutes. Caution: Do not place the plate into the disinfection solution.

13. Disinfect the plate using wipe disinfection D for 1 minute ± 10 seconds or follow the instructions provided by the manufacturer.
14. Rinse the Surgical Tray and the plate with demineralized water 3 times for 1 minute ± 10 seconds to remove all disinfection solution (follow the instructions provided by the manufacturer of the disinfection solution).
15. Dry the Surgical Tray and the plate with suitable equipment (such as compressed air).
16. Assemble the Surgical Tray with plate and reusable instruments (incl. multi-piece instruments). Caution: Please ensure that the plate is carefully placed on the Surgical Tray.
17. Inspect products with naked eye for impairment. If any product is impaired or visibility and readability are reduced, new product should be ordered.

MAINTENANCE AND PACKAGING:

1. After cleaning, disinfection and drying, visually inspect the Surgical Tray (including plate and reusable instruments) for cleanliness, function and readability of text. Check all parts for visual soil, corrosion and damage. All devices with signs of corrosion and / or damage must be disposed and replaced. The plate should be replaced as soon as discoloration is compromising visibility of the pictograms or readability of the text.
2. Pack the assembled Surgical Tray in a metal sterilization container, sterilization pouch or single wrap. The metal sterilization container, sterilization pouch or sterilization single wrap should fulfill the following requirements:

USA: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters.

Note: The Surgical Tray is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization container, sterilization pouch or sterilization wrap in order to maintain sterility of the enclosed medical instruments until used.
3. Label metal sterilization container, sterilization pouch or sterilization wrap with necessary information such as expiration date, lot (if applicable), sterility information, product name with article number.

STERILIZATION:

1. Place the sealed Surgical Tray into the autoclave / sterilizer. The Surgical Tray must be sterilized in its "ready for use" state.
2. Run the autoclave / sterilizer with the following recommended parameters:

USA: Temperature 270 °F (132 °C) for 4 minutes when using pre-vacuum method (sterilization container, sterilization pouch and sterilization wrap) and 15 minutes when using the gravity method (sterilization pouch and sterilization wrap). Dry for 30 minutes. FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters. Caution: Do not use gravity sterilization if the Surgical Tray is sealed in a sterilization container. Note: Autoclave design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves / sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with, SN EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard. The manufacturer's Instructions for Use for the autoclave / sterilizer must be strictly followed.
3. After sterilization, place the sealed Surgical Tray in a dry and dark place such as a closed cupboard or drawer. Follow the instructions provided by the manufacturer of the sterilization containers, sterilization pouches and sterilization wraps regarding storage conditions and expiration date of sterilized goods. Loocid reprocessing information:

A Alkaline cleaning agent – ultrasonic bath: Neodisher® MediClean
B Alkaline cleaning agent – automated cleaning: Neodisher® MediClean
C Manual disinfection solution: CIDEX® OPA
D Wipe disinfection: Meliseptol® HBV tissues

Washer / disinfectant: Steelco DS 500.

With these cleaning and sterilization instructions, Loocid provides a validated procedure to ensure clean and sterile products. According to EN ISO 17664, it remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieves

the desired result. Likewise, any deviation by the processor from the provided instructions should be properly evaluated for effectiveness and potential adverse consequences.

⚠ Warning: The use of non-sterile components may lead to infection of tissues or infectious diseases.

⚠ Warning: Do not use device if the packaging has been damaged or previously opened.

MATERIALS:

Surgical Tray: Stainless steel / Polyphenylsulfone (PPSU)/ Silicone.

Plate: Plastic with print.

Disposal: Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.


Storage, handling, and transportation:

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

DISCLAIMER OF LIABILITY:








This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Loocid LLC. Non-recommended use of products made by third parties in conjunction with Loocid LLC products will void any warranty or other obligation, express or implied, of Loocid LLC. The user of Loocid LLC products must determine whether any product is suitable for the particular patient and circumstances. Loocid LLC disclaims any liability, expressed or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Loocid LLC products. The user is also obligated to study the latest developments in regard to Loocid LLC products and their applications regularly. In cases of doubt, the user must contact Loocid LLC. Since the utilization of this product is under the control of the user, it is his / her responsibility. Loocid LLC does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

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EXPLANATION OF SYMBOLS:

	
Manufacturer	Consult instructions for use
	
Batch code	Catalogue number
	
Caution	Non-sterile
	
Do not use if package is damaged	