



Braseler USA STERILIZATION TRAY Instructions for Use

BRASSELER USA Sterilization Tray

BRASSELER USA Sterilization Trays are available in two different configurations, depending on the consumable that is being held in the tray.

The devices are non-sterile, reusable, and can be sterilized using steam sterilization in a gravity or pre-vacuum cycle.

Description

BRASSELER USA Sterilization Trays are made of perforated stainless steel with drilled holes designed to fit select rotary twist drills, k-wires, and Steinmann Pins.

The BRASSELER USA Sterilization Trays are made by using rivets to hold bent sections of perforated stainless steel together to create the tray.

The base, lid and drill holder panels are perforated allowing steam to access the contents inside the tray during steam sterilization cycles. Sterilization Trays are non-sterile and reusable.

Intended Use

BRASSELER USA Sterilization Trays are intended to store single use twist drills, K-Wires, and Steinmann pins when not in use and during autoclave cycles. The perforated trays allows the contents inside to be sterilized during an autoclave cycle but do not maintain a sterile barrier. BRASSELER USA Sterilization Trays are intended to be used in conjunction with a legally marketed sterilization wrap in to maintain sterility of the contents inside.

Indications

BRASSELER USA Sterilization Tray are used during the storage and sterilization process to house the consumables.

Contraindications

Do not use products in the trays that are not indicated for use.

Warnings and Precautions

- BRASSELER USA Sterilization Trays are used to hold consumables for storage and steam sterilization are not intended to maintain sterility of the contained devices.
- Use neutral pH cleaning agents following the manufacturer's directions.
- Sterilization Trays must be thoroughly cleaned prior to the first use and prior to each subsequent reuse. Do not use chemical or dry heat to sterilize BRASSELER USA Sterilization Trays, as these processes have not been validated for use.
- Do not use if etched markings are illegible.
- Do not use if drilled holes are obstructed, chipped, or otherwise damaged in any manner.
- Do not use if the device exhibits signs of corrosion or damage.
- Do not use if the device has a loose lid or if the lid does not open or close properly.
- Do not use if the device is missing parts or is broken in any manner.
- Do not leave device in wet condition as this may lead to corrosion or interaction with stored devices.
- Carefully read package labels to ensure use of the appropriate device.

Residual Risks

- Improper cleaning, drying, or sterilization can compromise sterility of the tray and its contents potentially leading to user or patient infection.
- Improper cleaning may result in residues being left that potentially could lead to patient sensitivity, irritation, or toxicity.



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General Instructions

1. The device is to be used by authorized personnel who are fully trained in their safe and effective use.
2. Clean and sterilize the device in accordance with the validated procedures provided below prior to first use and each subsequent reuse.
3. Do not store the Sterilization Tray when wet as this may cause corrosion of the stainless steel or interaction with stored consumables.

Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all BRASSELER USA Sterilization Trays. They are applicable before initial use and after each subsequent use. Sterilization Trays are provided clean but are not sterile. Therefore, Sterilization Trays should be cleaned and sterilized before first use and subsequent reuses.
Reprocessing Limitations	The end of life is determined by wear and damage during cleaning and sterilization. Sterilization Trays should be inspected for defects (i.e., missing rivets, chipped holes, faded etching, broken lid etc.) during the cleaning process.
Point of Use	Delays in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult. Excess soil should be removed after point of use.
Containment/ Transportation	Sterilization Trays can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion of the stainless steel. Prolonged storage in cleaning solutions may result in degradation of the product and must be avoided.
Manual Cleaning Procedure	Manual (Hand Cleaning) is the only validated cleaning process for the Sterilization Trays. 1. Completely disassemble the device, if applicable. 2. Pre-Treat all contaminated devices by soaking in an enzymatic cleaning solution for at least 5 minutes. Contaminated device should be pre-treated within one hour of use, and it is necessary that all device surfaces are completely submerged. 3. Remove the device from the cleaning solution and remove any remaining debris or deposits using a soft brush. Do not use any brush with metal bristles or steel wool. 4. Rinse device completely with low contaminated and deionized water for at least 30 seconds, making certain that there is no remaining residue, debris or residual cleaner left on the device. 5. Prepare a detergent bath in an ultrasonic unit using an enzymatic cleaning solution such as Enzol Enzymatic Cleaner. Follow the detergent manufacturer's instructions. 6. Soak the disassembled device for the recommended soaking time in the cleaning solution and make sure that the device is sufficiently immersed. Sonicate the device for at least 6 minutes. 7. Do not overload the Ultrasonic Cleaning unit. Use "Sweep mode" if available. 8. Remove the device from the cleaning solution and post rinse them intensively with low contaminated and deionized water for at least 30 seconds. 9. Before reassembly and before packaging for sterilization, thoroughly dry the device using lint-free cloths and/or filtered compressed air. 10. Inspect the device to make certain that all residue, debris, and residual cleaning solution are removed from the device and that the device is free of defects and are safe to use. Inspect the device to confirm they are still functional.
Inspection Testing	1. Carefully inspect each device to ensure that all debris has been removed. 2. Visually inspect the device for damage/ wear that would prevent proper operation.



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	a. Do not use if drilled holes are obstructed. b. Do not use if the lid is broken or loose. c. Do not use if the laser etching has faded or disappeared as the interior etchings identifying the consumable location may be obscured or lost. d. Do not use if there is evidence of corrosion, rotary instrument interaction or other signs of damage.															
Packaging	Load the Sterilization Tray with the consumables. Wrap Sterilization Tray in a legally marketed sterilization wrap per AAMI recognized guidelines.															
Sterilization	Use the following cycle for steam sterilization on the loaded and unloaded Trays: <table><tr><th>Cycle Type</th><th>Minimum Sterilization Exposure Temperature</th><th>Minimum Exposure Time</th><th>Minimum Dry Time</th><th>Minimum Cool Down Time</th></tr><tr><td>Pre-vacuum</td><td>270°F (132°C)</td><td>4 minutes</td><td>45 minutes</td><td>30 minutes</td></tr><tr><td>Gravity</td><td>270°F (132°C)</td><td>15 minutes</td><td>45 minutes</td><td>30 minutes</td></tr></table> The cool down time should take place outside the autoclave to allow the Sterilization Tray to dry completely. Ensure that the sterilizer manufacturer’s maximum load is not exceeded.	Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Exposure Time	Minimum Dry Time	Minimum Cool Down Time	Pre-vacuum	270°F (132°C)	4 minutes	45 minutes	30 minutes	Gravity	270°F (132°C)	15 minutes	45 minutes	30 minutes
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Pre-vacuum	270°F (132°C)	4 minutes	45 minutes	30 minutes												
Gravity	270°F (132°C)	15 minutes	45 minutes	30 minutes												
Storage	The Sterilization Tray should be stored in the sterilization wrap until required. The Sterilization Tray is not intended to maintain the sterility of the contained devices.															
Additional Information	These processes have been validated as being capable of preparing Sterilization Trays for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.															

Glossary of Symbols:

[Brasselerusamedical.com/resources/](https://brasselerusamedical.com/resources/)

Return Goods Policy:

Contact your distributor regarding return goods policy.

Product Disposal

Dispose of product or recycle in accordance with local laws and regulations.



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