

Brasseler USA STERILIZATION CASE Instructions for Use

BRASSELER USA Sterilization Cases

BRASSELER USA Sterilization Cases (also known as sterilization trays) are available in one size and one configuration. The current configuration holds 11 different twist drill sizes and holds a capacity of 27 twist drills. The devices are non-sterile, reusable and can be sterilized using steam sterilization in a gravity or pre-vacuum cycle.

Description

BRASSELER USA Sterilization Cases are made of perforated stainless steel with drilled holes designed to fit select rotary twist drills.

The BRASSELER USA Sterilization Case is comprised of four stainless steel panels and four washers and rivets. The sterilization case has a tri fold opening that allows the drills to enter the case. The base panel is connected to the lid and the drill holder with four rivets that are used as hinges. Welded to the drill holder is the drill isolator that aids in keeping the drills in place and secure. The base, lid and drill holder panels are perforated allowing steam to access the contents inside the case during steam sterilization cycles. Sterilization Cases are non-sterile and reusable.

Intended Use

BRASSELER USA Sterilization Cases are intended to store single use twist drills when not in use and during autoclave cycles. The perforated case allows the contents inside to be sterilized during an autoclave cycle but does not maintain a sterile barrier.

Warnings and Precautions

- BRASSELER USA Sterilization Cases used to hold twist drills for storage and steam sterilization are not intended to maintain sterility of the contained devices
- Use neutral pH cleaning agents following manufacturer’s directions
- Sterilization Cases 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 Cases, 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

General Instructions

1. The device is to be used by authorized persons 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 Case when wet as this may cause corrosion of the stainless steel or interaction with stored twist drills.

Cleaning and Sterilization Instructions








Scope	These instructions are applicable to all BRASSELER USA Sterilization Cases. They are applicable before initial use and after each subsequent use. Sterilization Cases are provided clean but are not sterile. Therefore, Sterilization Cases 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 Cases should be inspected for defects (i.e. missing pins, chipped holes, faded etching, broken lid etc.) during the cleaning process.

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Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.															
Containment/ Transportation	Sterilization Cases 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	<p>Manual (Hand Cleaning) is the only validated cleaning process for the Sterilization Case.</p> <ol style="list-style-type: none"> 1. Rinse the soiled consumable accessory thoroughly with a large amount of lukewarm (target lower end of the 72-110°F/22-43°C temperature range) running tap water for a minimum of one (1) minute. 2. Make an enzymatic cleaning solution such as STERIS® Prolystica™ 2x Concentrate Enzymatic Presoak and Cleaner [1/8 ounce per one (1) gallon of warm tap water] (target lower end of the 91-109°F/33-43°C temperature range). 3. Soak the consumable accessory in the enzymatic cleaning solution for two (2) minutes, making sure the consumable accessory is completely immersed to prevent aerosolization of contaminants. 4. Manually clean the consumable accessory using a soft-bristled brush for one (1) minute to remove soil and debris. 5. Rinse soiled consumable accessory by immersing the consumable accessory in a sufficient volume (enough to cover the device) of lukewarm, tap water (target lower end of the 72-110°F/22-43°C temperature range) for one (1) minute. 6. Repeat Step 5 two (2) more times for a total of three (3) rinses. Visually inspect consumable accessories for the presence or absence of residual soil and /or cleaner. 															
Inspection Testing	<ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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 twist drill 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 Case with the twist drills. Wrap Sterilization Cases in sterilization wraps per AAMI recognized guidelines.															
Sterilization	<p>Use the following cycle for steam sterilization on loaded and unloaded Sterilization Cases</p> <table border="1"> <thead> <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> </thead> <tbody> <tr> <td>Gravity</td> <td>270°F (132°C)</td> <td>4 minutes</td> <td>30 minutes</td> <td>30 minutes</td> </tr> <tr> <td>Pre-vacuum</td> <td>270°F (132°C)</td> <td>15 minutes</td> <td>30 minutes</td> <td>30 minutes</td> </tr> </tbody> </table> <p>The cool down time should take place outside the autoclave to allow the Sterilization Case to dry completely.</p> <p>Ensure that the sterilizer manufacturer's maximum load is not exceeded.</p>	Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Exposure Time	Minimum Dry Time	Minimum Cool Down Time	Gravity	270°F (132°C)	4 minutes	30 minutes	30 minutes	Pre-vacuum	270°F (132°C)	15 minutes	30 minutes	30 minutes
Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Exposure Time	Minimum Dry Time	Minimum Cool Down Time												
Gravity	270°F (132°C)	4 minutes	30 minutes	30 minutes												
Pre-vacuum	270°F (132°C)	15 minutes	30 minutes	30 minutes												
Storage	The Sterilization Case should be stored in the sterilization wrap until required. The Sterilization Case is not intended to maintain the sterility of the contained devices.															
Additional Information	These processes have been validated as being capable of preparing Sterilization Cases for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.															

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Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a "physician/surgeon" licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
Made in	Made in	N/A
	Manufacturer/Legal Manufacturer	ISO 15223-1



Brasseler USA Medical, L.L.C.
 One Brasseler Blvd.
 Savannah, GA 31419 USA
 Telephone 912-925-8525