



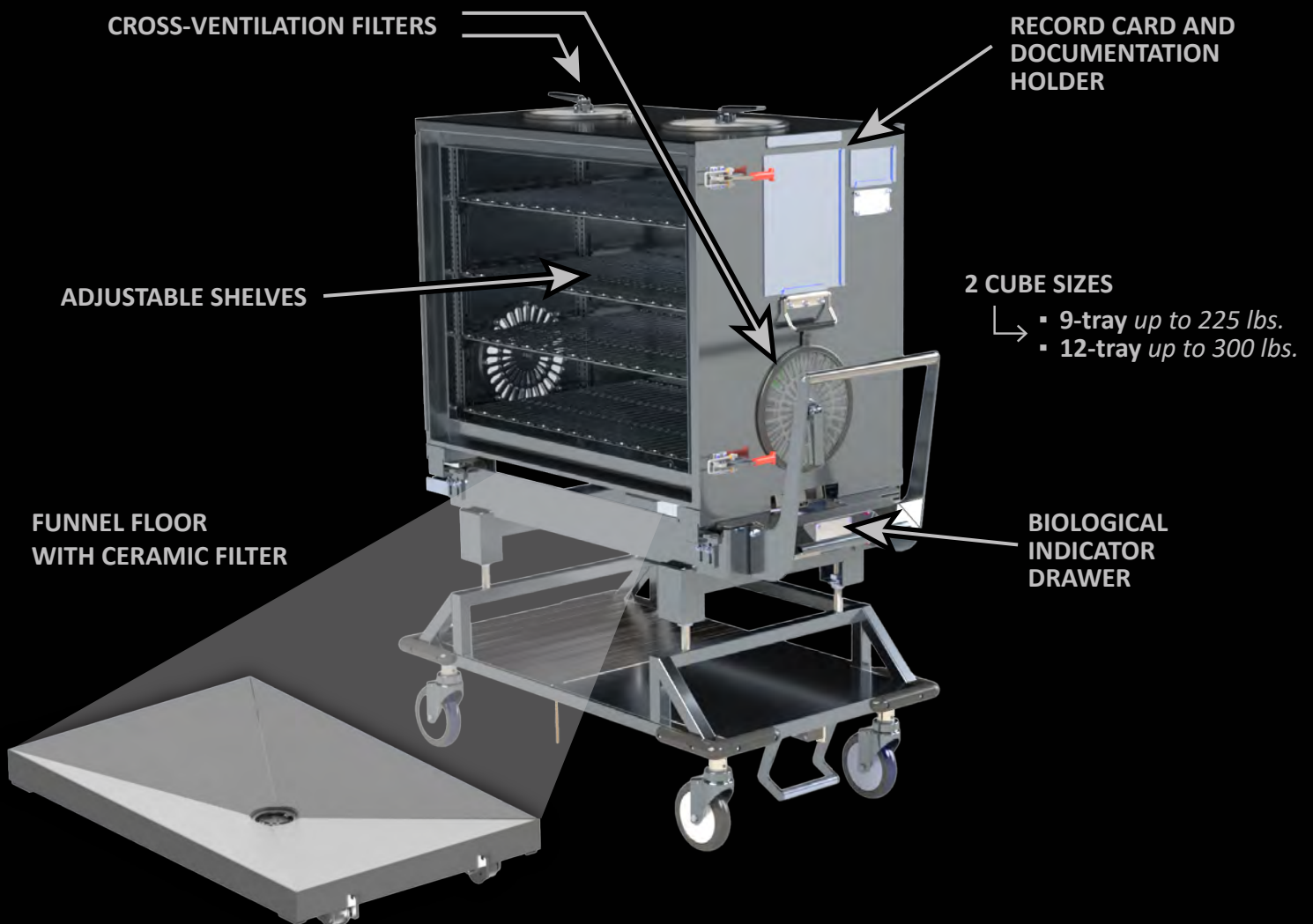
INSTRUCTIONS FOR USE

All newly set-up SteriCUBEs passed a sterilization test on _____ day _____ month _____ year

If the SteriCUBE system is not functioning properly, contact the SteriCUBE corporate office:

Phone: 833-411-CUBE

Preventative maintenance **MUST** be performed by a qualified bio-mechanical or mechanical equipment technician, or by a trained and qualified SteriCUBE representative.



SteriCUBE® Sterilization Cabinet Indications for Use

The SteriCUBE® Multiple Tray Sterilization System is indicated for enclosing medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SteriCUBE® System Transfer Cart, SteriCUBE® filters and integrity locks.

The SteriCUBE® System is intended to be used in pre-vacuum steam sterilizers with a pre- vacuum cycle of 270°F at a minimum exposure time of 4 minutes. Use no more than 3 trays per shelf at a maximum of 25 lbs. each tray or 75 lbs. per shelf.

The SteriCUBE® System was tested and validated with rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length longer than 500mm or lumens with an inner diameter smaller than 1.0mm and an overall length longer than 850mm.

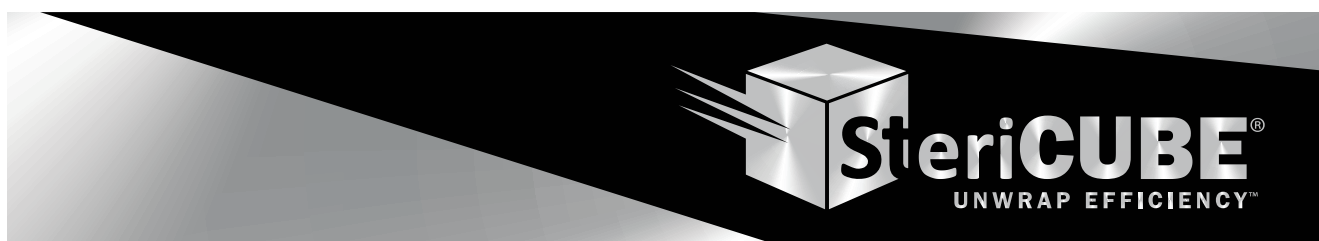
Use only uncovered, perforated or wire mesh general delivery trays within the SteriCUBE® System.

Device Description

The SteriCUBE® Multiple Tray Sterilization Systems are also referred to as the “SteriCUBE Systems” and include the SteriCUBE MTS225 System and the SteriCUBE MTS300 System. The SteriCUBE System is comprised of the stainless steel sterilization cabinet and adjustable transfer cart. A reusable ceramic drain filter and single use filters and integrity locks with sterilization indicator dots are used with the system for each sterilization cycle. The ceramic drain filter should be replaced every 6 months or after 160 uses, whichever comes first. An optional STEAMPlus™ tray record card with STEAMPlus sterilization integrator (SPS Medical) may be utilized by the healthcare provider.

Adjustable shelves within the cabinet can hold up to three trays (uncovered, perforated or wire mesh) of devices and/or surgical instruments intended for a single patient surgery. No more than 25 pounds can be loaded per tray for a maximum of 75 pounds per shelf. The MTS300 Cabinet (with four shelves) can hold up to 300 pounds per load and the MTS225 Cabinet (with three shelves) can hold up to 225 pounds per load.

The loaded cabinet is deployed from the adjustable transfer cart and processed in pre-vacuum steam sterilizers. Processing includes the standard conditioning phase of the autoclave followed by a sterilization cycle time of 4 minutes and a dry cycle of a minimum of 5 minutes. The IFU of the what is being sterilized in the SteriCUBE should be followed. Sterility is maintained for up to 30 days.



CONTENTS

Device overview and description	4-5
Frequently asked questions (FAQs)	6-7
How to clean the CUBE	8-9
How to clean the ceramic drain filter	10
Preparing the CUBE for loading with contents	11-12
CUBE contents tracking	13
Loading the CUBE with contents	14-15
How to autoclave the CUBE	16-17
Unloading the CUBE in the OR	18-19
SteriCUBE System weights and dimensions	20

FAQ



Call SteriCUBE Preventative Maintenance
833-411-CUBE (2823) to arrange a no-cost technician visit.

Do not make adjustments to a SteriCUBE yourself!

Q

How are the CUBEs cleaned?



CUBEs are compatible with cart washers. However, the washers can blur the small signs on the CUBEs.



Alternatively, CUBEs may be wiped down with non-chlorine cleaners (to avoid metal corrosion) such as CaviWipes™ in pink containers or Sani-Cloth® AF3 with grey lids.

Q

How long will the instruments remain sterile in the unopened CUBE?



CUBEs maintain sterility for up to 30-days.

Q

What if bioburden is found in a tray when the CUBE is opened?



Follow your facility process for when bioburden is found in a surgical tray.

Q

How many trays can the CUBEs hold?



The MTS-225 has a 225lbs. weight limit which usually equals 9 trays.
The MTS-300 has a 300lbs. weight limit which usually equals 12 trays.

Q

Does there have to be an indicator on every layer of a tray?



Follow your facility policy for multiple-layer trays.

Q

Can one blue filter be used on a filter port instead of two?



No. Two blue filters must be used.

Q

When do we change the filters or separators?



- Any blue filter is **SINGLE-USE** only.
- White, plastic filter separators and ceramic filters are reusable for up to 160 sterilizations or 6-months; whatever comes first.

NOTE: Separators and ceramic filters will be exchanged during preventative maintenance.

FAQ Continued

Q How long do CUBEs need to cool after sterilization?



CUBEs are generally cool enough for surgery after about 45 minutes (depending on environmental factors), but hospital procedures should be followed.

Q What trays and devices can be sterilized in the CUBE?



- Perforated trays without lids (like most vendor/loaner trays) or wire mesh.
- Implants such as screws with cannulas. CUBEs are FDA-cleared for lumens as small as .7mm diameter and 500mm long.
- Surgical power equipment (drills, saws, reamers, steam-sterilizable batteries, etc...).

NOTE: The CUBE shelves can be moved or removed to fit large or oddly shaped objects (disassembled positioners, etc...).



Q Can trays be stacked?



If instrument cases are designed with inner stackable trays (like many vendor/loaner joint replacement cases), they may be sterilized in their designed orientations. Other trays and cases **CANNOT** be stacked upon each other.



Q What is the CUBE sterile/drying cycle?

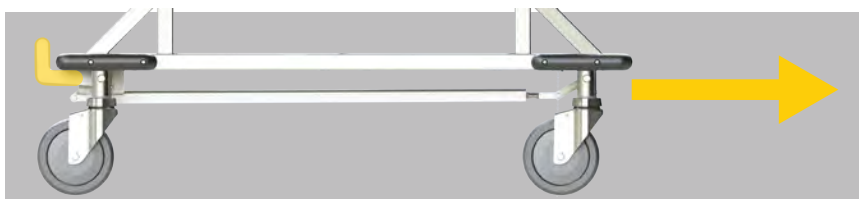


Cubes are validated for a 4-minute exposure with a 5-minute dry and may be used for sterilizing any company's trays as long as their Instructions for Use (IFU) are followed.

Q How is the foot pedal used?



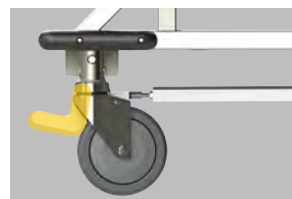
- **Up** – Locks rotation of front wheels for steering stability over long straights. Ensure all wheels are turned the same direction.
- **Middle** – Wheels can turn 360° for tight spaces.
- **Down** – Brake for all wheels.



UP



MIDDLE



DOWN

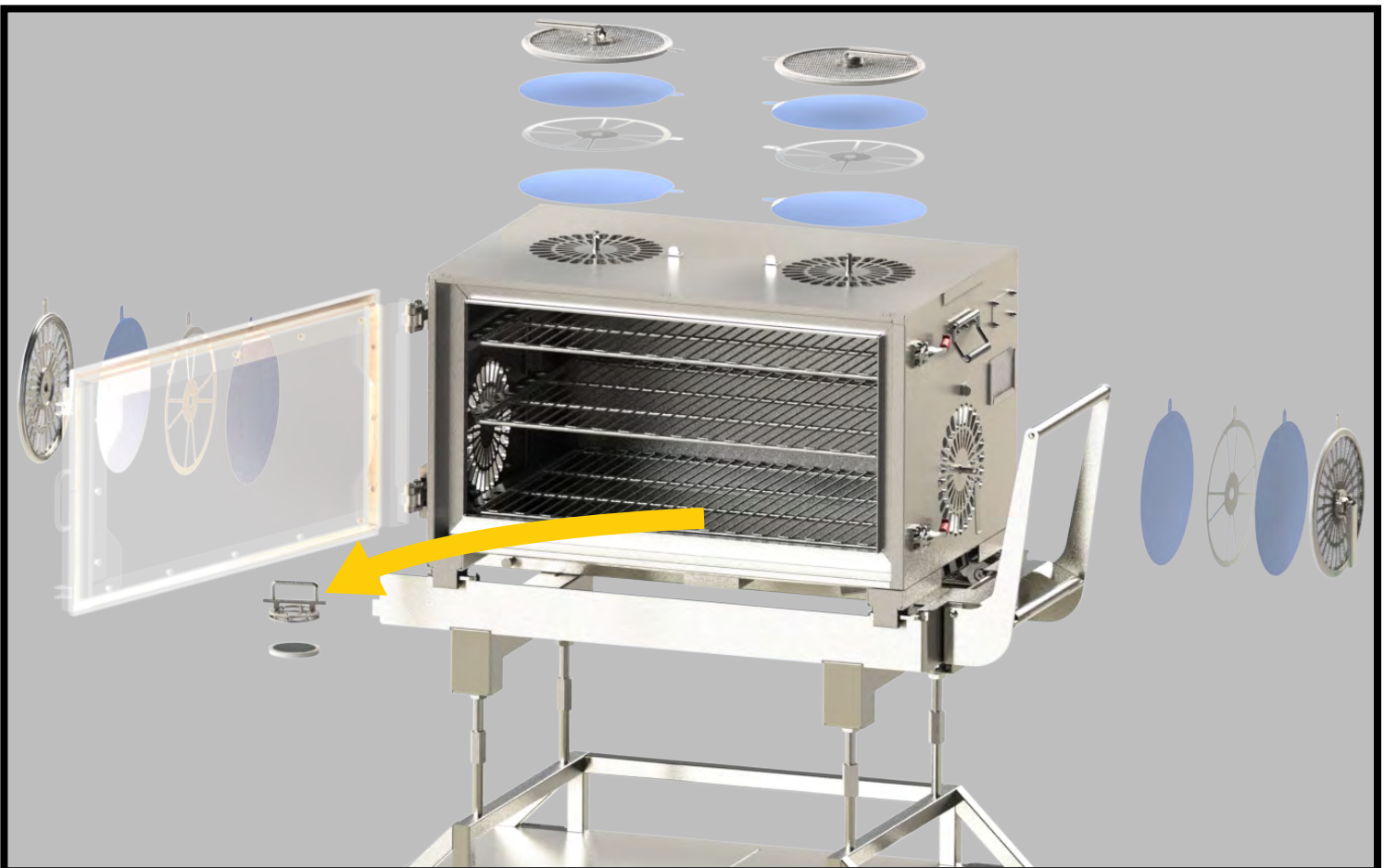
How To Clean The CUBE

MANUAL CLEANING

NOTE: The SteriCUBE cabinet and transfer cart should be cleaned after each use. Before cleaning, discard all used integrity locks, disposable blue filters, locator tags, integrators and old paperwork. Additionally, remove all contents (instruments and/or trays) from the shelves.

NOTE: To ensure product longevity, do not use abrasive brushes, powders or cleaners and never use solutions containing chloride detergents on either the SteriCUBE cabinet or the transfer cart. The SteriCUBE System is manufactured from 100% stainless steel (with the exception of the gaskets and cart wheels). Abrasive products can permanently damage the surface areas.

NOTE: The white filter separators and ceramic filter are **NOT disposable**.



1 Remove the filter plates, filter separators, filters, drain cover and the bottom ceramic filter.

2 Use a soft cloth or sponge saturated with a mild detergent and water to clean all surfaces free of soil.

3 Use a soft non-abrasive brush with mild detergent and water to clean all interior corners. Rinse the CUBE thoroughly with clean water to remove any residue.

How To Clean The CUBE

Continued

Visually inspect the CUBE for cleanliness.

If any contaminants are found, repeat the first three steps.

4

After all gross soil is removed, manually clean all surfaces and white filter separators with a hospital approved general-purpose germicidal solution that is indicated for stainless steel. Liberally apply the solution to all surfaces with a saturated soft cloth or with a spray application bottle, inside and out. Follow the general-purpose germicidal solution manufacturer recommendations.

Rinse the CUBE thoroughly with clean water to remove any residue and dry the CUBE with a clean, soft, lint-free cloth.

CART WASHER CLEANING

1



Remove the filter plates, filter separators, filters, drain cover and the bottom ceramic filter.

Place the filter plates and drain cover on the shelves within the CUBE.

2

Load the CUBE on its cart in the cart washer. Leave the door on the cabinet in the open position facing the cart washer water delivery jets.

3

Run the cart washer cycle according to manufacturer recommendations.

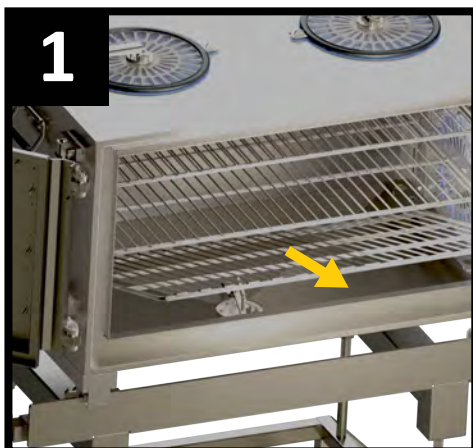
4

After the cart washer cycle, remove the CUBE and cart to allow cooling prior to hand drying with a clean, soft, lint-free cloth.

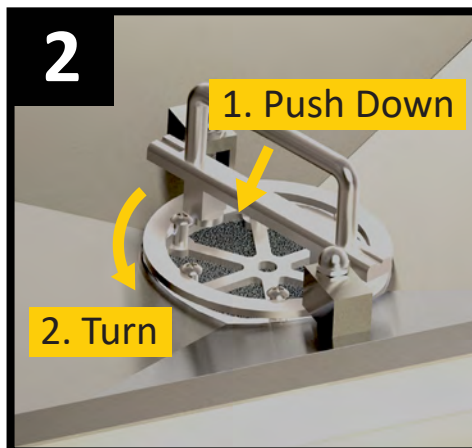
How To Clean The Ceramic Drain Filter

NOTE: The ceramic filter is reusable for up to 160 cycles.

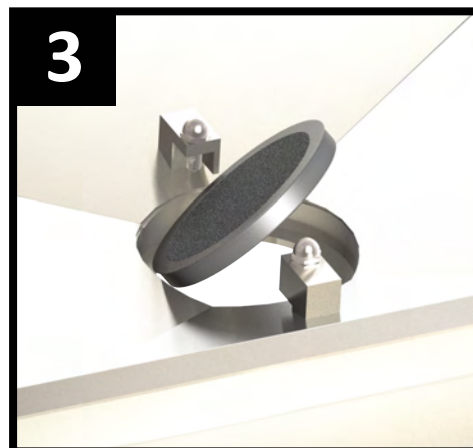
NOTE: Clean the ceramic filter after every use to prevent clogging.



Lift the bottom shelf to access the drain cover.



Remove the drain cover by pushing down on the handle and turning it **counter-clockwise**.



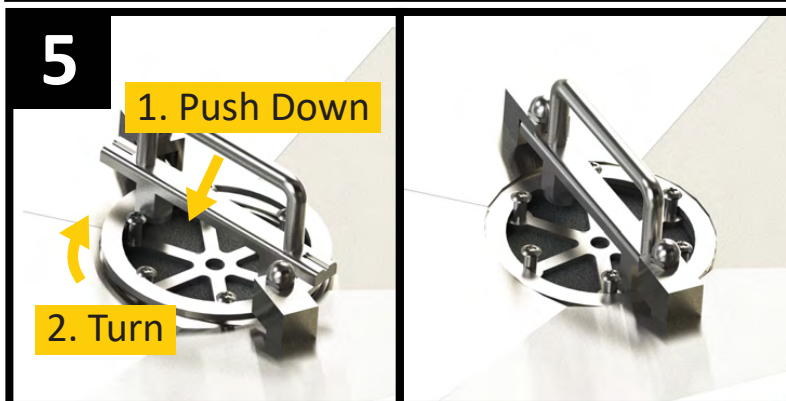
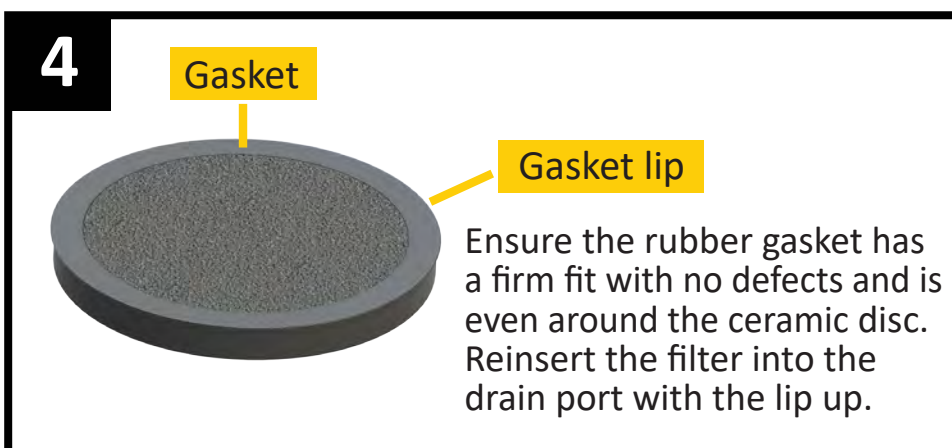
Remove the ceramic filter by reaching under the CUBE and pushing the filter up.

The ceramic filter can be washed by hand, in a washer or ultrasonic and then air dried.

Remove any excessive foreign material by soaking the filter in water until the foreign material is loose, then brush and rinse the filter.

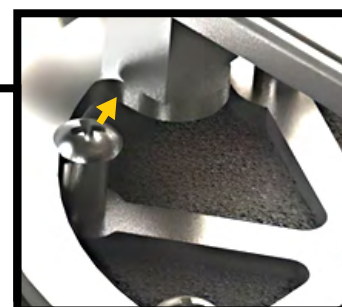
Flush the filter from the back-side with running water.

NOTE: DO NOT dry the filter with cloth or paper. It can clog the filter with lint.



Replace the drain cover.

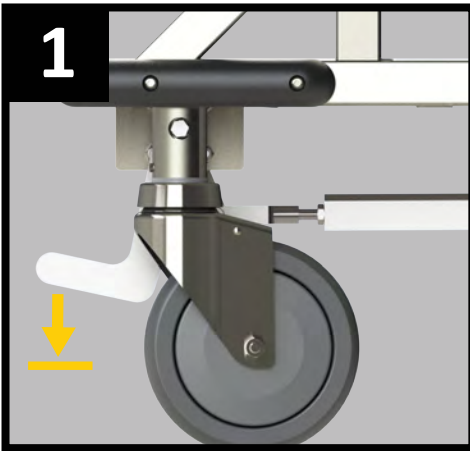
To help replace the drain cover, rotate the spokes of the base plate clockwise until the screw touches the handle before pressing the handle down and twisting it into place.



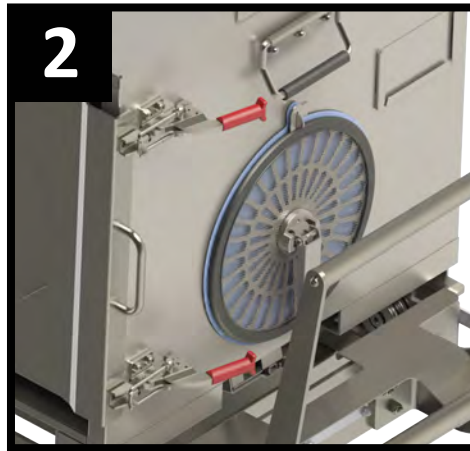
NOTE: Use heat resistant protection on the hands or allow the ceramic filter to cool prior to removal from washing equipment.

NOTE: Crack lines on the top surface of the filter are considered evidence of damage and the filter should not be used.

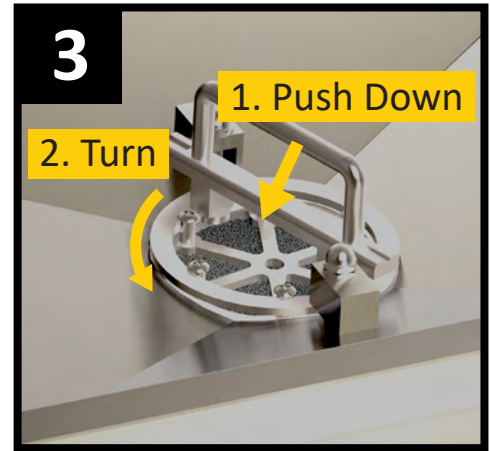
Preparing The CUBE For Loading With Contents



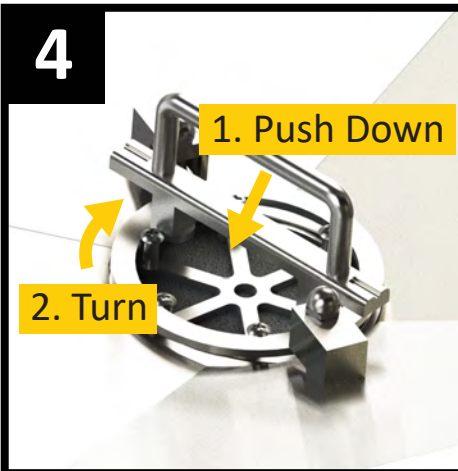
1
Push the cart pedal to the lowest setting to lock the wheels.



2
Open the main door by releasing both red-handled latches.



3
Remove the drain cover (by pushing down on the handle and rotating counterclockwise) Confirm the ceramic drain filter is seated securely in the drain port.

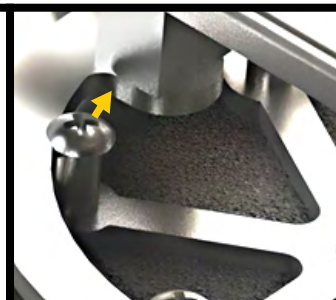


4
Replace the drain cover.



QUICK TIP

Rotate the spokes of the base plate clockwise until the screw touches the handle before pressing the handle down and twisting it into place.



Preparing The CUBE For Loading With Contents

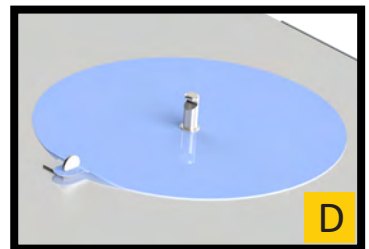
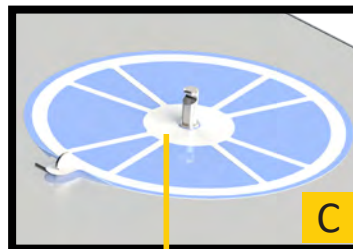
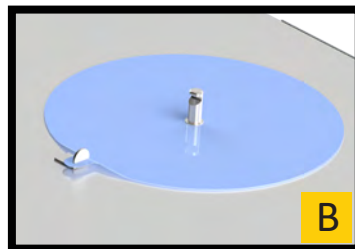
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NOTE: Two blue filters must be used on each filter port.

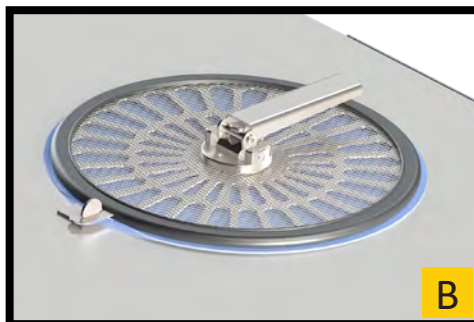
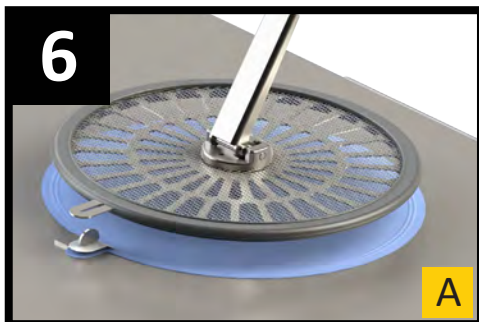
NOTE: Only SteriCUBE filters are validated for this device.

Load the Cross-Ventilation Filters.

On each filter port (A) place 1 blue filter (B), then 1 white plastic reusable filter separator - *optional* (C), then another blue filter (D). Ensure the filter tabs are loaded onto the half-moon cabinet tabs.



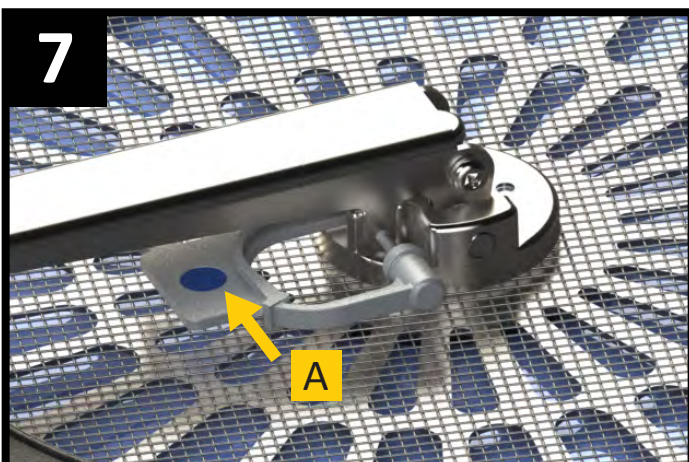
NOTE: If the center of a separator is tenting up, it should face out to avoid perforating the under filter.



NOTE: A small amount of blue filter should be visible around each filter plate.

NOTE: Visually inspect the filter plate gaskets for a firm fit without defects.

Load the filter plates by first holding the handle in the open position (A) and centering the plate over the filter post. Align the filter plate tabs over the half-moon cabinet tabs. Next, seat the plate and press the handle down (B) to lock it in place.

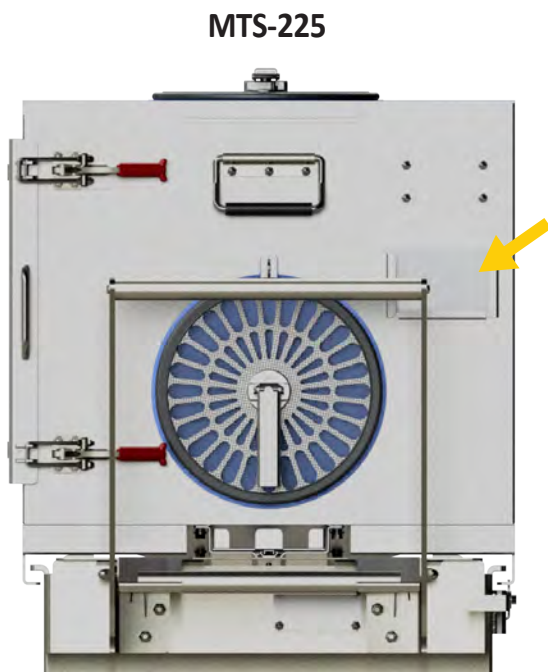


Load an integrity lock (A) through the holes in the filter plate handle and the base of the filter plate with the dot facing up. Confirm the lock is through both holes so the filter plate cannot be removed without breaking the lock.

CUBE Contents Tracking

CUBEs feature a holder for a destination card that can be completed with the surgeon name, surgery date, type of surgery, patient initials, and a list of contents.

STEAMPlus® tray record cards and sterilization integrators are provided and can be added to the patient chart or filed for infection control traceability.



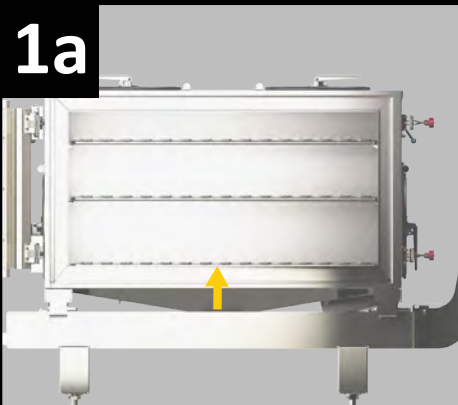
MTS-225 features a card holder



MTS-300 features a card holder and document holder

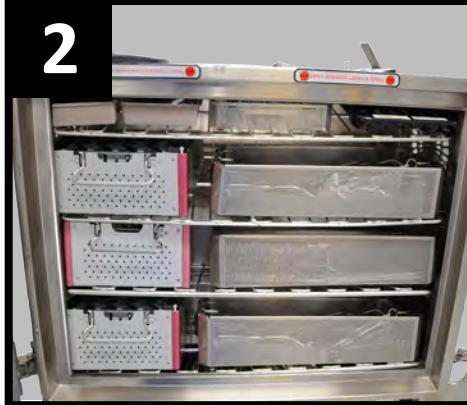
Loading The CUBE With Contents

1a



Ensure a shelf is in the lowest position for proper steam flow and filter function.

2



Place trays or devices in the CUBE. Trays **MUST** be placed in the CUBE **without lids**.

Plastic and lighter trays should be placed on the higher shelves to facilitate drying.

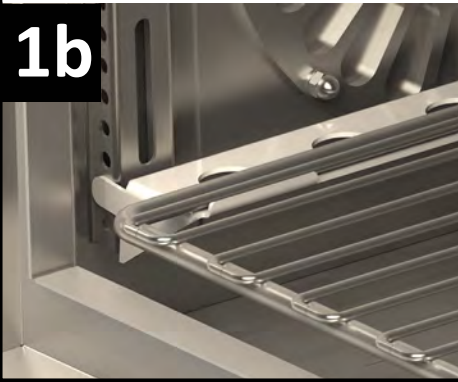


NOTE: DO NOT stack (or lean) trays if they are not designed to be sterilized stacked.

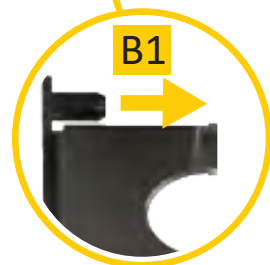
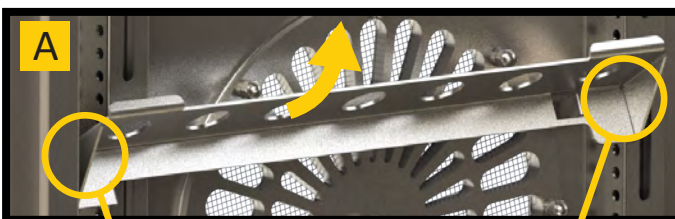
NOTE: Maintain recommended weight limitations of 25 lbs. per tray and 3 trays per shelf.

The MTS-300 has a maximum load weight of 300 lbs. and the MTS-225 has a limit of 225 lbs.

1b



Shelf brackets should be in the 2nd hole from the bottom of the shelf rails.



The CUBE shelves can be moved or removed to fit large or oddly shaped objects such as unassembled positioners.

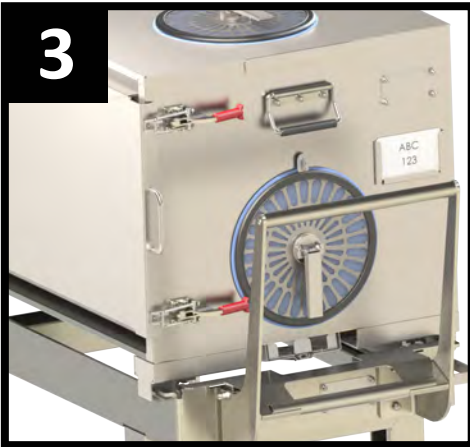
Adjust the shelves by repositioning the shelf supports.

To reinsert a support, angle the support (A) and partially insert its longer **rear** post (B2) in a hole in the rear shelf rail.

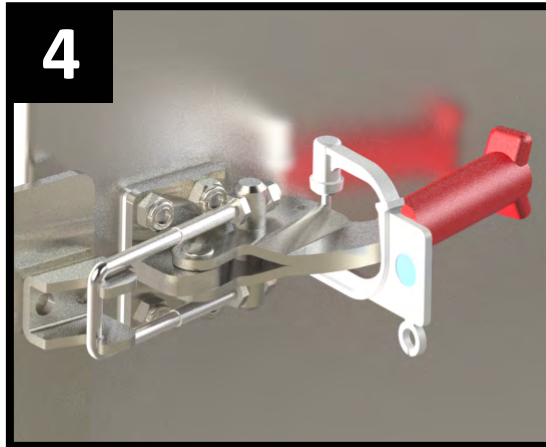
Next insert the **front** support post (B1) in the rail hole at the same level and fully seat the posts. Lower the support (C).

Loading The CUBE With Contents

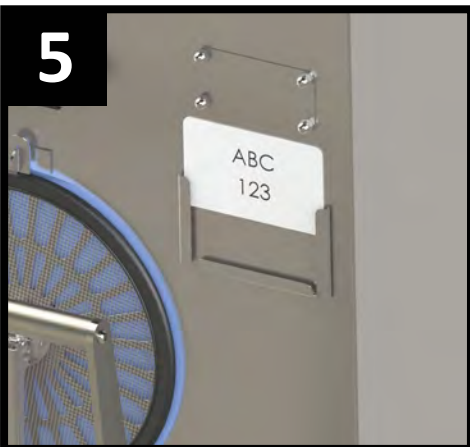
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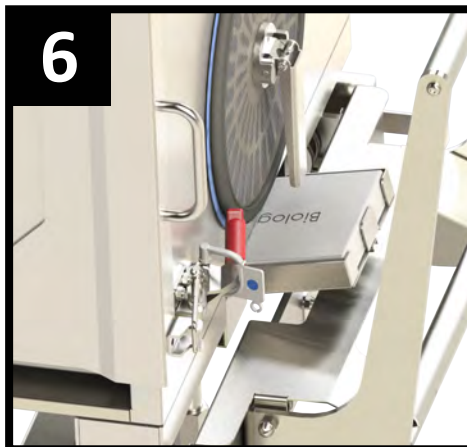
Lock the door closed with the two red-handled latches.



Connect the integrity locks **OVER** the latch handles so the locks will break if the handle is ever opened. Confirm the indicator dots are visible from the front of the cube.



Complete the Record Card and place it in the CUBE card holder.

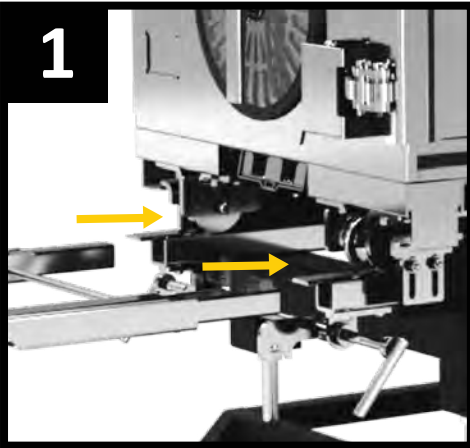


Insert the biological indicator pack (if necessary) in the biological indicator drawer.

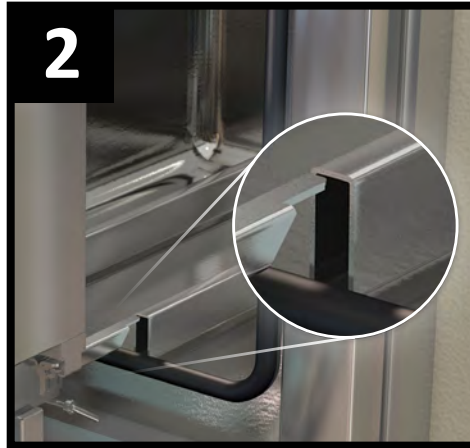
Place the pick-sheet on the cart handle in a document holder.

How To Autoclave The CUBE

Loading CUBEs into an autoclave



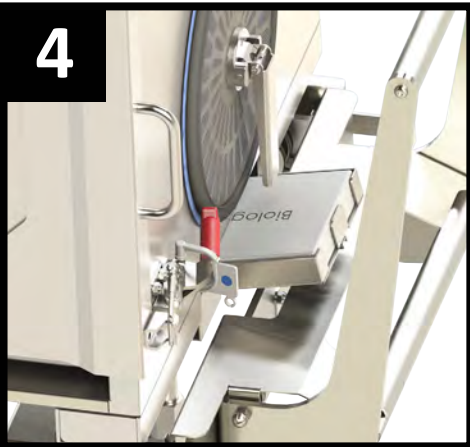
1
Insert and lock the extension rails into the SteriCUBE cart (or deploy drop down rails).



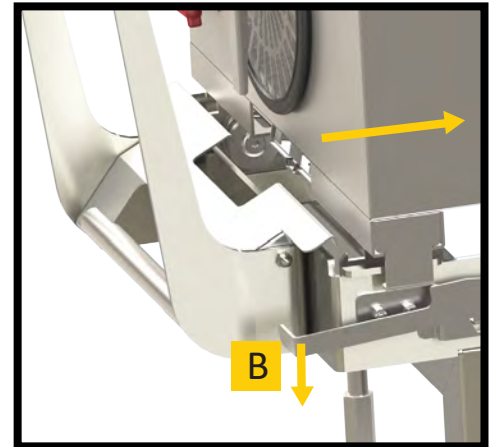
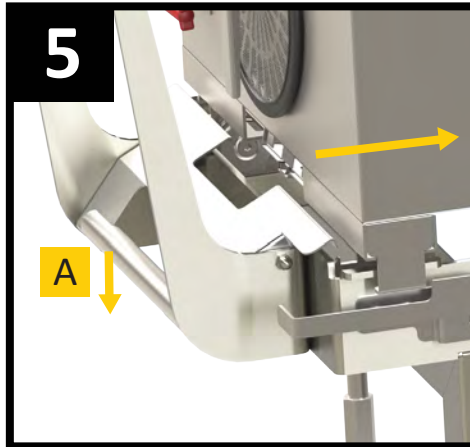
2
Dock with the autoclave; visually confirm secure docking.



3
Push the foot pedal down to its lowest position to lock the wheels and immobilize the cart. Reconfirm docking alignment.



4
If required, place the biological indicator pack in the biological indicator drawer on the end of the CUBE that will be positioned over the autoclave drain when in the chamber.



5
Push down the primary paddle lock (A) and inch the CUBE forward until it meets the secondary lock. Release the secondary lock lever (B) and push the CUBE into the sterilizer.

NOTE: Ensure the CUBE **DOES NOT** touch the back wall of the sterilizer.

6
Initiate the autoclave cycle specific to the contents inside the cabinet.

How To Autoclave The CUBE

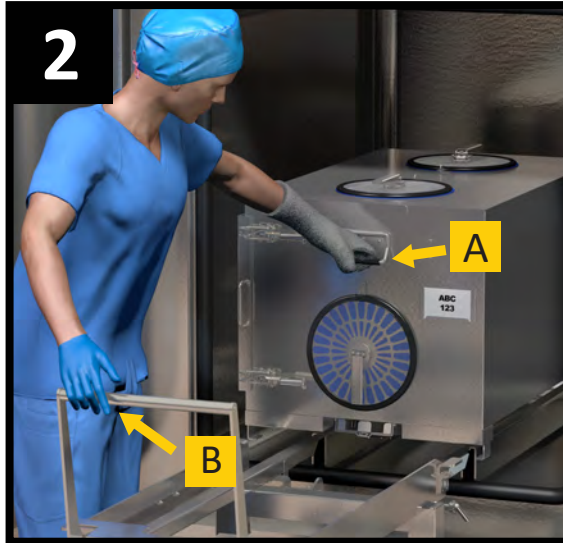
Continued

How to remove the CUBE from the autoclave

1

Ensure the CUBE cart extension rails are securely docked with the sterilizer and the wheels are locked.

2



Pull the CUBE out of the autoclave with a gloved hand by the **BLACK HANDLE IN THE MIDDLE OF THE CUBE (A)**.

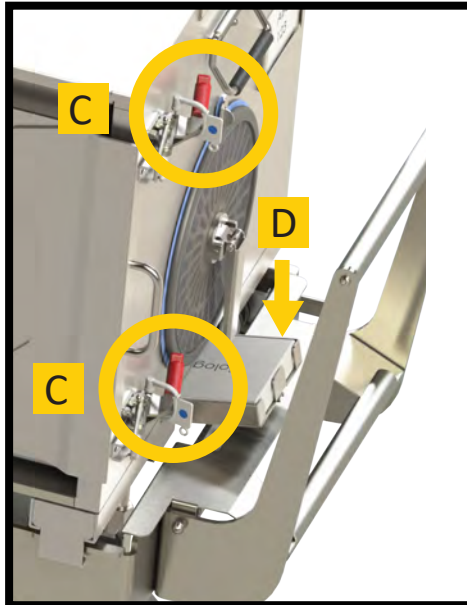
If necessary, hold the cart handle with the other hand as an anchor **(B)**.

NOTE: DO NOT pull the CUBE at an angle onto the rails.

3

Pull the CUBE all the way onto the cart until the primary and secondary locks are seen and heard to engage.

NOTE: Pulling the CUBE by a red handle latch **(C)** could break the lock and require resterilizing the whole CUBE load.



4

Carefully pull out the biological indicator pack **(D)** (if present) and run the incubator test.

5

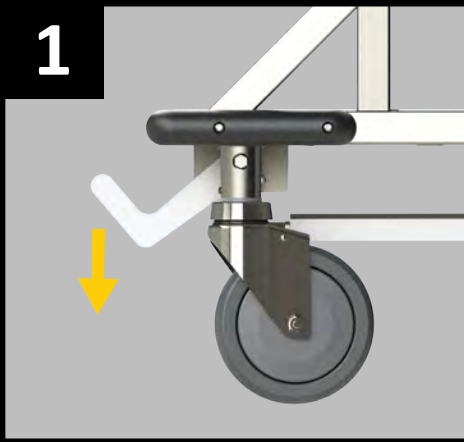
Remove the cart extension rails or lower the drop-down rails.

NOTE: If an STEAMPlus® integrator (or hospital provided card) was used on the outside of the CUBE, confirm the dark bar entered the safe area.

Unloading The CUBE In The OR

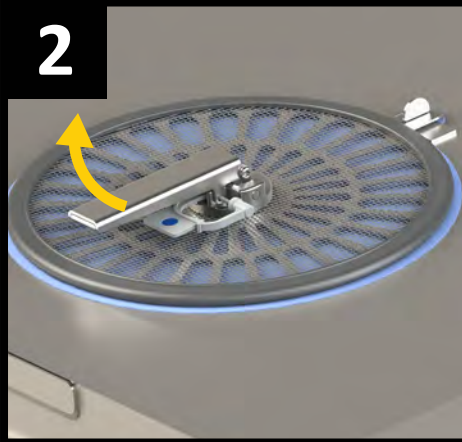
Non-sterile Employee

1



Push the foot pedal down to its lowest position to lock the wheels and immobilize the cart.

2



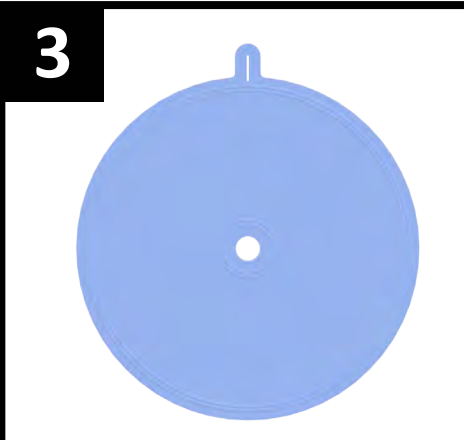
Check the cross-ventilation filters by lifting the handles on the filter plates (breaks the integrity locks). A small amount of blue filter should be visible around each filter plate.

NOTE: If any moisture, holes, folds or tears are detected, or if less than or more than two filters are found in any one of the grate openings, sterility is considered compromised and all instruments must be returned to the Sterile Processing Department (SPD) for reprocessing.

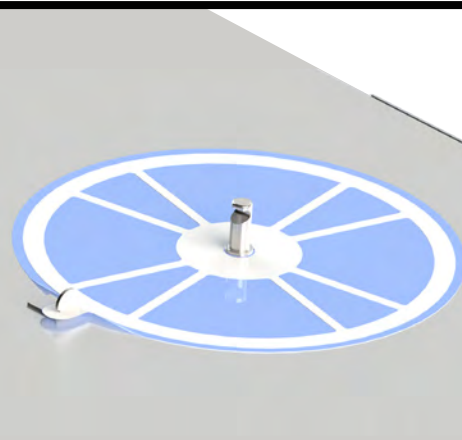
In the absence of these issues, the contents are considered sterile and the empty CUBE can be returned to SPD for processing another case.

NOTE: The filter separators are not disposable.

3

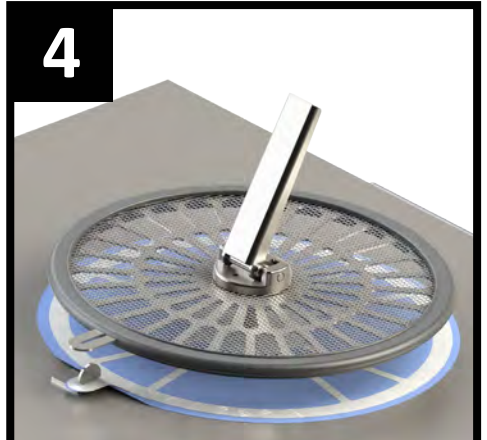


Check the outer filter for moisture, punctures, folds or tears. The gaskets impress three unbroken rings on the filter which should be visible.



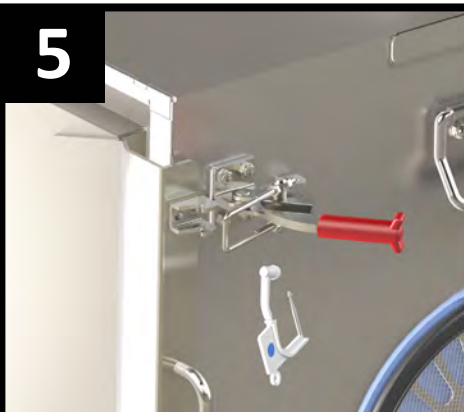
Visually inspect the inner filter; **leaving it and the filter separator in place.**

4



Reload the filter plates by first holding the handle in the open position and centering the plate over the filter post. Align the filter plate tab over the half-moon cabinet tab and seat the plate. Press the handle down to lock it in place.

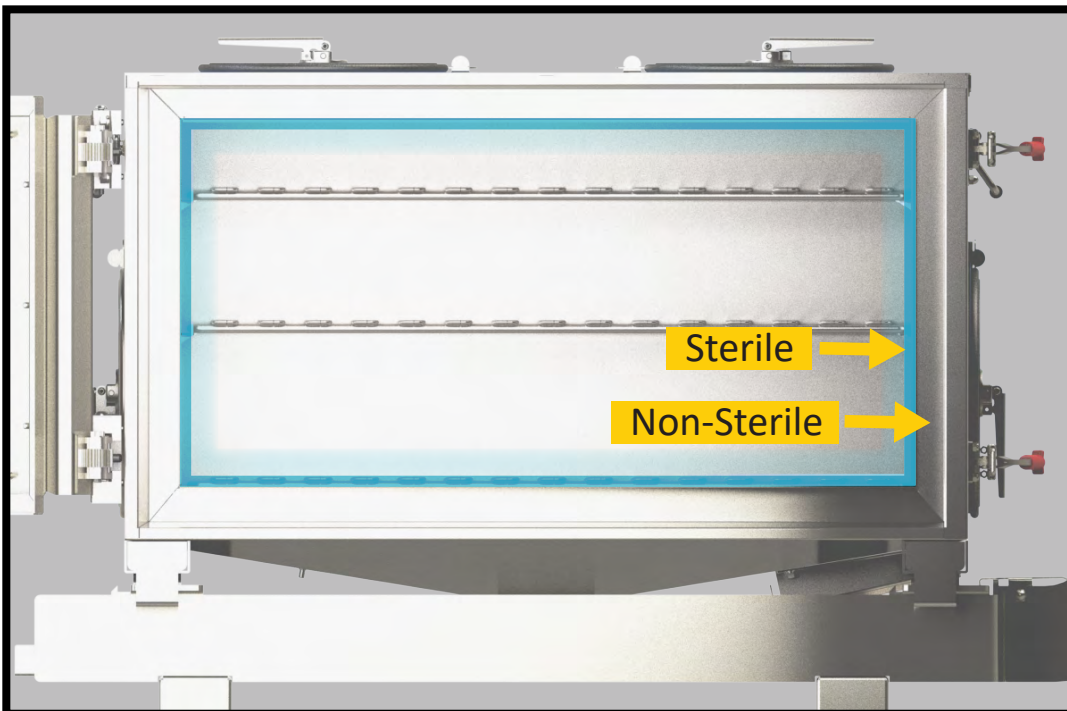
5



To open the door, unfasten the latch handles while placing a hand over the integrity locks to prevent them from flying onto the sterile field. To further avoid the sterile field, stand behind the door while opening it as far as possible (up to 270°).

NOTE: A non-sterile employee can go behind the CUBE to unlock the wheels to push the CUBE closer to the sterile field. Relock the foot pedal prior to unloading.

Unloading The CUBE In The OR Sterile Employee



NOTE: CUBEs feature a sterile frame around the edge of the opening that can be touched and not break sterility.

1



Carefully remove the CUBE contents.

Verify the integrators placed within the individual trays indicate sterility.

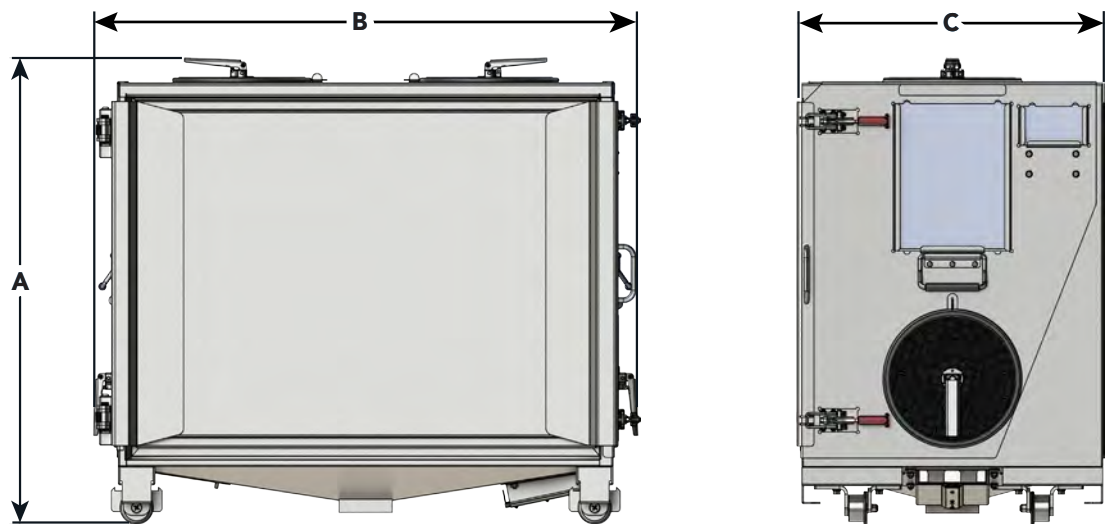
2

Inspect the inside of the CUBE for moisture.

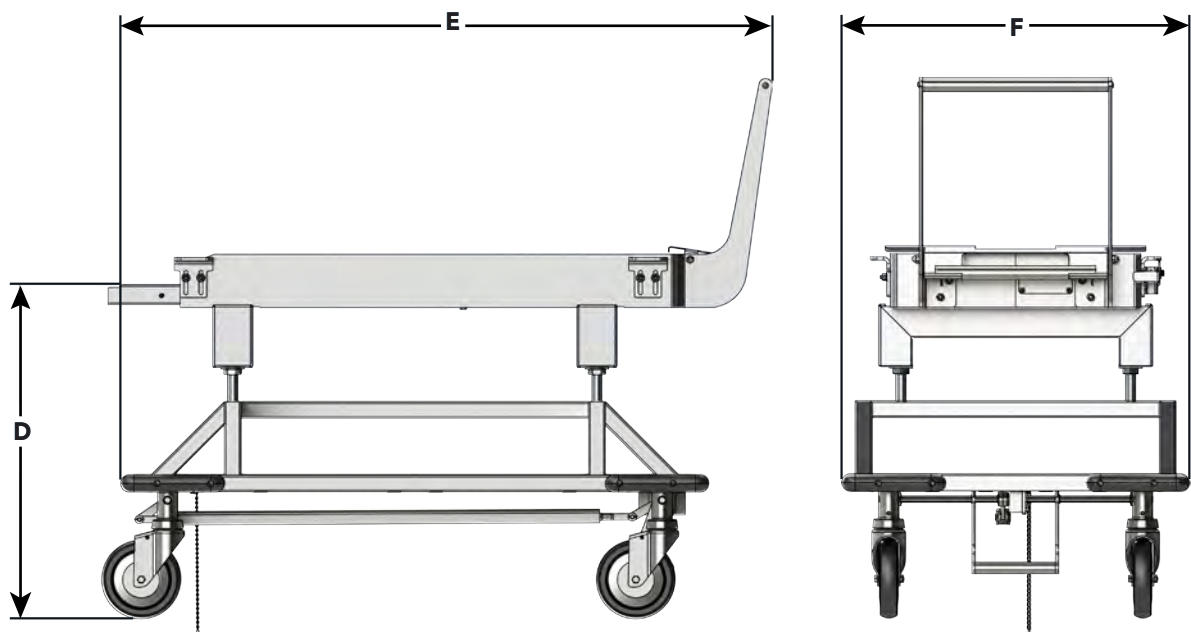
NOTE: Moisture anywhere in the CUBE is an indication that something went wrong and the contents should not be considered sterile.

NOTE: It is normal to find lint on the drain filter. This does not compromise sterility of the CUBE contents.

SteriCUBE System Dimensions



	A	B	C
	Height	Length	Width
MTS-300	34.4 inches	40.7 inches	23 inches
MTS-225	25.2 inches	39 inches	23 inches

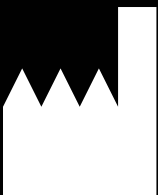


	D	E	F
	Height	Length	Width
Cart	Adjustable	48.5 inches	26 inches

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Manufactured by:
SteriCUBE Surgical Systems
1452 Hughes Road
Suite 200, PMB #550
Grapevine, TX 76051

www.thestericube.com
Email: info@thestericube.com
Phone: 833-411-CUBE