



INSTRUCTIONS FOR USE

Installation Sterilization Test Results

All newly installed SteriCUBEs passed a sterilization test on _

day month year

Preventative Maintenance

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

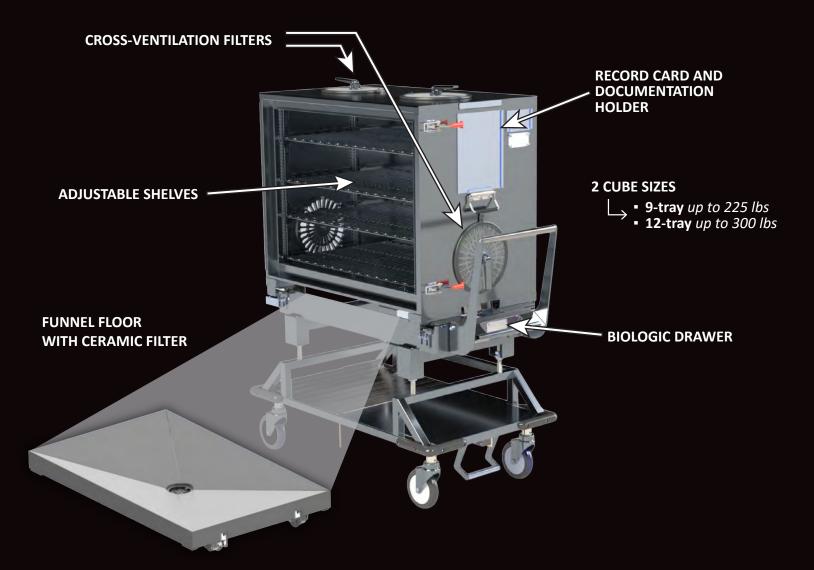
Email: info@thesteriCUBE.com Phone: 833-411-CUBE

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

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SteriCUBE® Sterilization Cabinet Instructions 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 instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length 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. An optional 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 optional 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. Sterility is maintained for up to 30 days.



FAQ Call the SteriCUBE Preventative Maintenance Hotline 833-411-CUBE (2823) to arrange a no-cost technician visit. Do not make adjustments to a SteriCUBE yourself!

How are the CUBEs cleaned?



CUBEs are compatible with cart washers. However, the washers can damage 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.



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

CUBEs maintain sterility for 30-days.



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.



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.



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



Follow your facility policy for multiple-layer trays.



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



No. Two blue filters must be used.



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.



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
- Iumens 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...).





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.





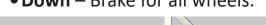
What is the CUBE sterile/drying cycle?

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.



How is the foot pedal used?

- Up Locks rotation of front wheels for 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.









DOWN

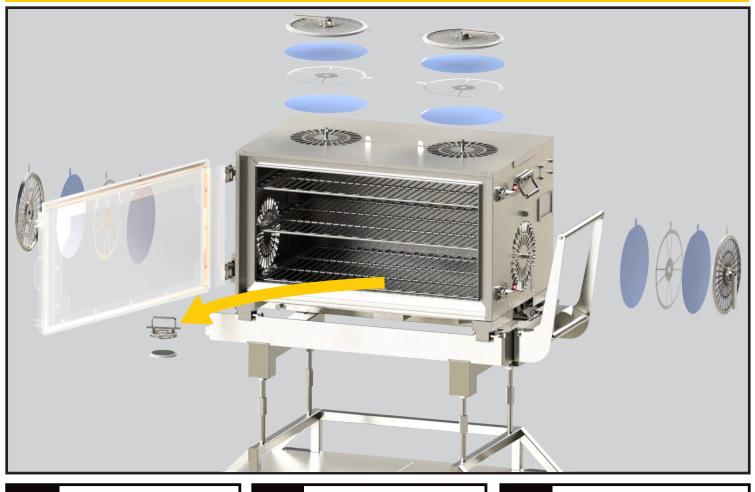
How To Clean The CUBE

MANUAL CLEANING

NOTE: The SteriCUBE cabinet and transfer cart should be cleaned after each use. Before cleaning, discard all used integrity locks, 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**.



Remove the filter plates, filter separators, filters, drain cover and the bottom ceramic filter. Use a soft cloth or sponge saturated with a mild detergent and water to clean all surfaces free of soil.

2

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.

1

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 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



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

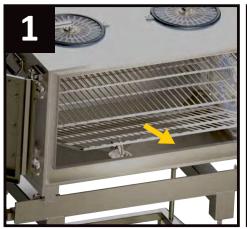
Run the cart washer cycle according to manufacturer recommendations.

4

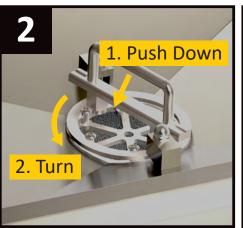
After the cart washer cycle, remove the CUBE and cart to allow cooling prior to hand drying with a clean, soft, lint-free cloth.

How To Clean The Ceramic Drain Filter

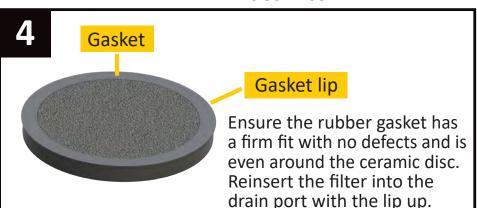
NOTE: The ceramic filter is reusable for up to 160 cycles. **NOTE:** Clean the ceramic filter after every use to prevent clogging.

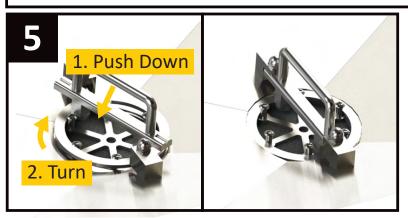


Lift the bottom shelf to access the drain cover.



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.

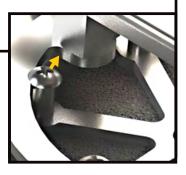
Remove any excessive foreign material by soaking the filter in water until the foreign material is loose, then brush and rinse the filter.

Flush the filter from the backside with running water

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

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.

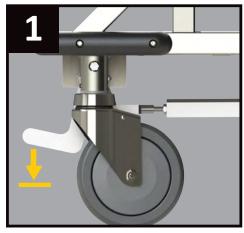




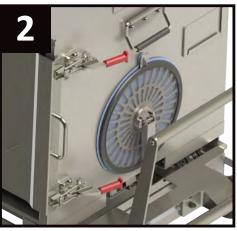
Replace the drain cover.

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.

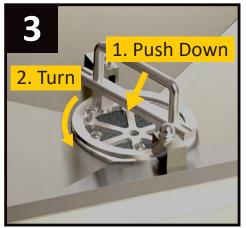
Preparing The CUBE For Loading With Contents



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



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



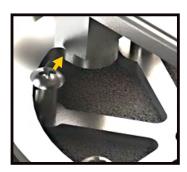
Remove the drain cover (by pushing down on the handle and rotating counterclockwise) to see if the ceramic drain filter is seated securely in the drain port.



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.



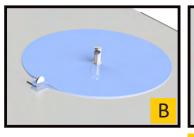
Preparing The CUBE For Loading With Contents Continued

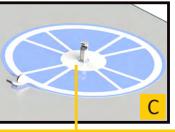
NOTE: Two blue filters must be used on each filter port. **NOTE:** Only SteriCUBE filters are validated for this device.

Load the Cross-Ventilation Filters.

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

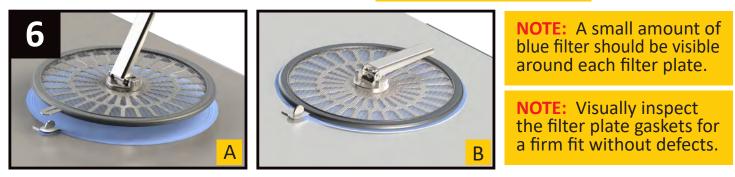




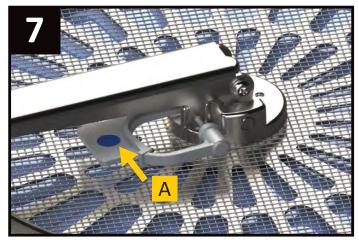




NOTE: If the center of a separator is tenting up, it should face out to avoid perforating the under filter.



Load the filter plates by first holding the handle in the open position (**A**) and centering the plate over the filter post, then aligning 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.

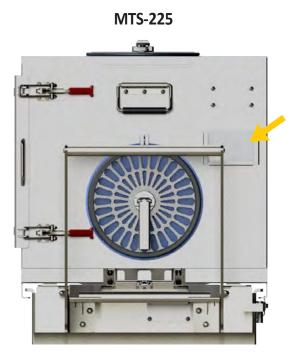


Load an integrity lock **(A)** through the holes in the filter plate handle and the base of the filter plate with the dot facing up. Confirm the lock is through both holes so the filter plate cannot be removed without breaking the lock.

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.

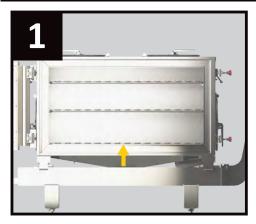


MTS-225 features a card holder

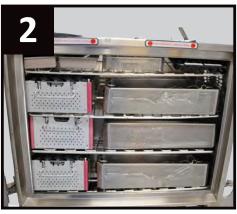


MTS-300 features a card holder and document holder

Loading The CUBE With Contents



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



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

Plastic and lighter trays should be placed on the higher shelves so rising heat from lower trays can 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.







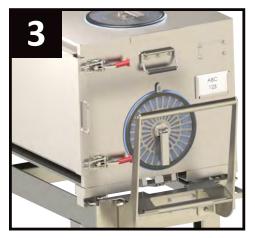
The CUBE shelves can be moved or removed to fit large or oddly shaped objects such as unassembled positioners.

Adjust the shelves by repositioning the shelf supports.

To reinsert a support, angle the support (A) and partially insert its **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)**.

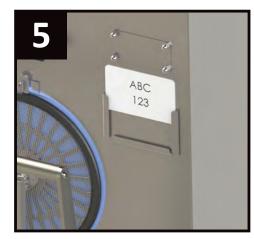
Loading The CUBE With Contents Continued



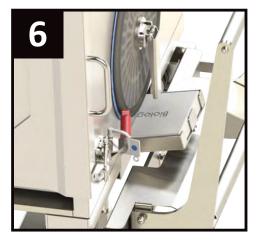
Lock the door closed with the two red-handled latches.



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.

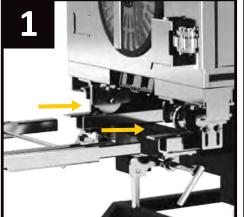


Insert the biological indicator pack (if necessary) in the Bio Pack Drawer.

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

How To Autoclave The CUBE

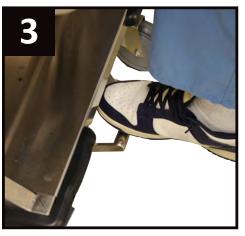
Loading CUBEs into an autoclave



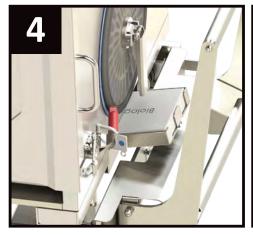
Insert and lock the extension rails into the SteriCUBe cart (or deploy drop down rails).



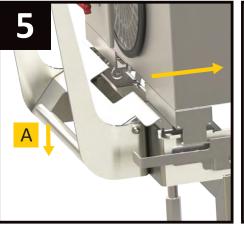
Dock with the autoclave; visually confirm secure docking.

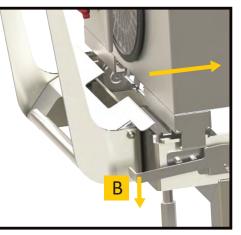


Push the foot pedal down to its lowest position to lock the wheels and immobilize the cart. Reconfirm docking alignment.



If required, place the biological indicator pack in the Bio Pack Drawer on the end of the CUBE that will positioned over the autoclave drain when in the chamber.





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.

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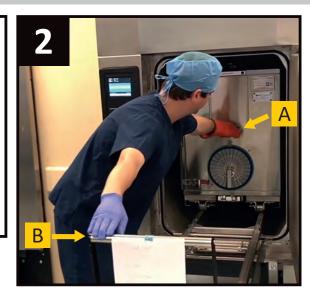
Initiate the autoclave cycle specific to the contents inside the cabinet.

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 sterlizer and the wheels are locked.



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

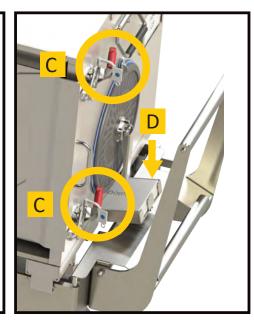
If necessary, hold the cart handle with the other hand as an anchor **(B)**.

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

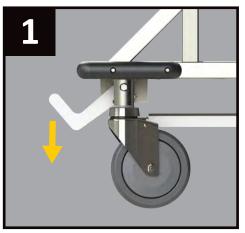
Carefully pull out the biological indicator pack **(D)** (if present) and run the incubator test.

5

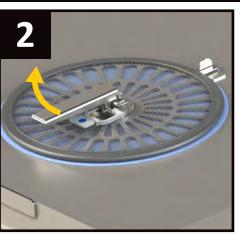
Remove the cart extension rails or lower the drop-down rails.

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



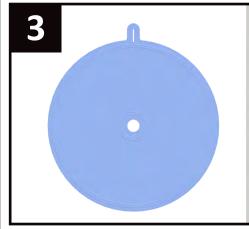
Push the foot pedal down to its lowest position to lock the wheels and immobilize the cart.



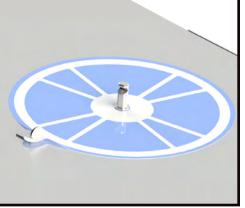
Check the cross-ventilation filters by lifting the handles on the filter plates (breaks the integrity locks). A small amount of blue filter should be visible around each filter plate. **NOTE:** If any moisture, holes, folds or tears are detected, or if less than or more than two filters are found in 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.

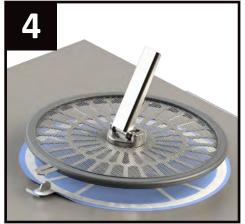
NOTE: The filter separators are not disposable.



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



Inspect the inner filter; leaving it and the filter separator in place.



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.

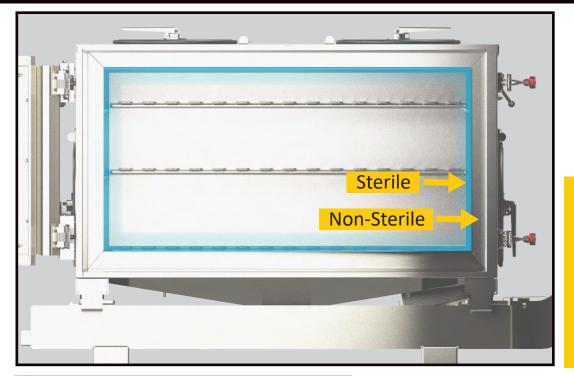


To open the door, unfasten the latch handles while placing a hand over the integrity locks to

prevent them from flying into 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.



Inspect the inside of the CUBE for moisture.

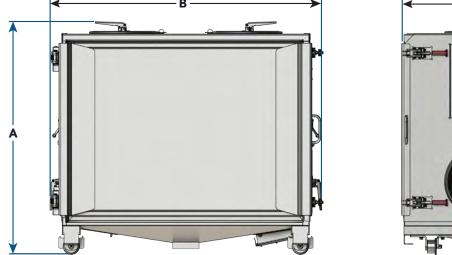
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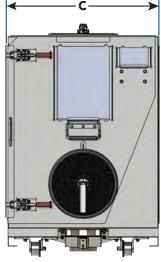
Pull-out the CUBE contents.

Verify the integrators placed within the individual trays indicate sterility.

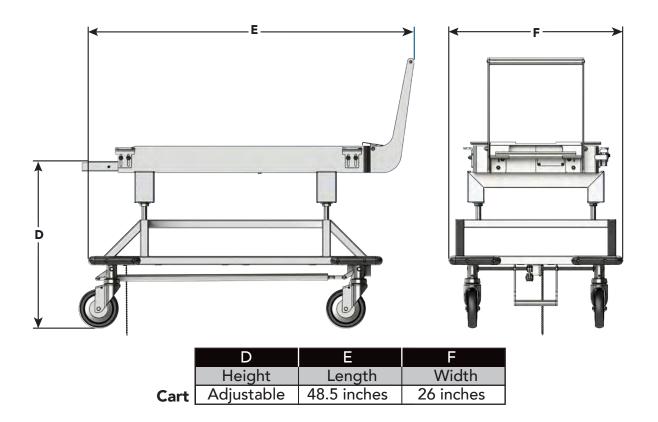
NOTE: Moisture anywhere in the CUBE is an indication that something went wrong and the contents should not be considered sterile.

SteriCUBE System Dimensions





	A	В	С
	Height	Length	Width
MTS-300	34.4 inches	40.7 inches	23 inches
MTS-225	25.2 inches	39 inches	23 inches



NOTES





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

Caution: Federal law restricts this device to sale by or on the order of a physician.