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SteriCUBE[®] MTS System

INSTRUCTIONS FOR USE

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The SteriCUBE® MTS System was developed for ***patient specific surgery.***

All instruments and devices processed in one container are for one patient's surgery. If, for any reason, the surgery is postponed or cancelled before the sterility continuity is interrupted, it may be used for "same type" surgery or stored up to 30 days before reprocessing is mandatory.



Indications for Use

The SteriCUBE® Multiple Tray Sterilization System is indicated for enclosing other 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 MTS System Transfer Cart, SteriCUBE MTS filters and integrity locks.

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

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

Cleaning Instructions:

- Prior to usage, proper decontamination of the SteriCUBE MTS System must be accomplished.

Cleaning the SteriCUBE® MTS System

RECOMMENDED CLEANERS

Use only non-chlorinated, sodium carbonate free, general purpose detergents with a neutral to mildly alkaline pH.

MANUAL CLEANING

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

- Remove all four (4) filter plates, filter separators, drain cover and drain screen (or ceramic filter if using ceramic and not paper filters in bottom drain – see special instructions for reusable ceramic filter below).
- Use a soft cloth or sponge saturated with a mild detergent and water to manually clean all surfaces free of visible gross soil.
- Use a soft non-abrasive brush with mild detergent and water to clean all interior corners.

- Rinse thoroughly with clean water to remove any residue.
- Visually inspect for cleanliness. If any contaminants are found, repeat the first three steps.
- Manually clean all surfaces with a hospital approved general-purpose germicidal solution that is indicated for stainless steel.
- Liberally apply to all surfaces with a saturated soft cloth or with a spray application bottle, inside and out.
- Follow the general-purpose germicidal solution manufacturer's recommendations.
- Rinse thoroughly with clean water to remove any residue.
- Dry with a clean, soft, lint free cloth.

If using the SteriCUBE® MTS System Reusable Ceramic Drain Filter

- Clean ceramic filters after every use to prevent clogging.
- Remove any excessive foreign material by soaking the filter in water until the foreign material is loose, then brush and rinse.
- Flush the filter from the backside with running water.
- The filter may also be processed in an ultrasonic cleaner or an automated washer disinfectant.
- Use heat resistant protection on the hands or allow ceramic filter to cool prior to removal from washing equipment.
- Crack lines on the top surface of the filter are considered evidence of damage and the ceramic filter should not be used.

CART WASHER

The SteriCUBE MTS System (Cabinet and Transfer Cart) may be cleaned with the aid of a cart washer system when available.

- Remove all four (4) filter plates, filter separators and the one (1) drain cover and place them on any of the shelves within the MTS Cabinet.
- Place the SteriCUBE MTS System (Cabinet and Transfer Cart) within cart washer, leaving the

door on the SteriCUBE MTS Cabinet in the open position, facing the cart washer's water delivery jets.

- Run cart washer cycle according to manufacturer's recommendations.
- Upon completion of cart washer cycle, remove the SteriCUBE MTS System (Cabinet and Transfer Cart) to allow cooling down prior to hand drying with a clean, soft, lint free cloth.

CLEANING AFTER EACH USE

- Remove used integrity locks, used filters, used locator tags, used integrators and any old paperwork and discard.
- Remove any and all contents (instruments and/or trays) from the shelves.
- Follow initial cleaning procedure after every use.

Set-up:

Loading the SteriCUBE® MTS System

- Position SteriCUBE MTS System in the Sterile Processing Department within easy access.
- Lock transfer cart in place by pressing all the way down on foot pedal. This engages all four castors to be in the locked position.
- Verify transfer cart is locked in place.

DRAIN FILTER

- Open main door by releasing both red-handled cam locks and remove bottom shelf.
- Open center drain cover located on **BOTTOM / INSIDE** of the SteriCUBE MTS Cabinet by pressing down cover plate and turning counter clockwise.
- Visually **INSPECT GASKETS** for a firm fit with no defects.
- **Replace gaskets every 6 months, if required.**

- Insert two (2) new SteriCUBE MTS System Drain Filters, one at a time to prevent improper placement. Inspect filters for any defects before putting them in place.
 - **Two filters per drain opening.**
 - **Single patient use, filters must be replaced prior to every sterilization cycle.**
 - ***DO NOT* use a substitute filter, only SteriCUBE MTS System Filters are validated for this device.**

OPTIONAL REUSABLE FILTER SEPARATORS

- Insert one (1) new SteriCUBE MTS System Drain Filter, then place reusable drain filter separator over this first filter, then place second new SteriCUBE MTS System Drain Filter.
 - **Two filters per drain opening with filter separator placed in between them.**
 - **Single patient use, filters must be replaced prior to every sterilization cycle. Do not discard reusable filter separator.**
 - ***DO NOT* use a substitute filter, only MTS SteriCUBE Filters are validated for this device.**

A Reusable SteriCUBE MTS System Ceramic Filter may be used in place of disposable drain filters, optional drain filter separator and gasketed drain screen.

- Visually **INSPECT GASKET** on ceramic filter for firm fit with no defects.
- Insert ceramic drain filter into round opening of drain, pressing down for firm fit.
- Close drain cover and lock in place by pressing down and turning into proper position clockwise under pressure of adjustable set screws.
- Replace bottom shelf.

FOUR EXTERNAL FILTER PLATES

- Remove filter plates located on **LEFT & RIGHT SIDES** and on the **TOP / OUTSIDE** of the MTS SteriCUBE Cabinet by elevating center handle of filter plate cover.
- Visually **INSPECT GASKETS** for firm fit with no defects.

- **Replace gaskets every 6 months, if required.**
- Insert eight (8) new SteriCUBE MTS System Filters, two at a time for easier alignment. Inspect filters for any defects before putting them in place.
 - **Use tab to hang filters in place.**
 - **Two filters per grate opening.**
 - **Single patient use, filters must be replaced prior to every sterilization cycle.**
 - ***DO NOT* use a substitute filter, only SteriCUBE® MTS System Filters are validated for this device.**

OPTIONAL REUSABLE FILTER SEPARATORS

- Insert one (1) new SteriCUBE MTS System Filter over each filter port post and tab, then place filter separator over this first filter, then place second new MTS SteriCUBE Filter over each filter port post and tab.
 - **Use tab to hang filters and filter separators in place.**
 - **Two filters per grate opening with filter separator placed in between them.**
 - **Single patient use, filters must be replaced prior to every sterilization cycle. DO NOT discard reusable filter separators.**
 - ***DO NOT* use a substitute filter, only SteriCUBE MTS System Filters are validated for this device.**
- Cover filters with filter plates, aligning with tabs and center over posts, confirming no accidental folds, then depress locking handle lever completely until center of filter plate becomes concave and is firmly secured.
- Confirm there is a little bit of blue filter paper showing around the entire perimeter of each filter plate.
- Place integrity lock through the hole in the center post under the filter plate handle snapping it into a locked position, with indicator dot facing out for easy visual inspection.

Loading:

- Insert shelves at appropriate heights to accommodate instrument trays using adjustable side

brackets.

- Visually confirm shelves are properly spaced with even alignment of side brackets. Be careful to make sure the shelves are not lower on one side than the other, causing an uneven surface.
- Place instrument trays onto the bottom shelf.
 - **Maintain recommended weight limitations of 25 lbs. per tray / 3 trays per shelf / maximum load weight of 300 lbs for the SteriCUBE® MTS300 System and 225 lbs for the SteriCUBE MTS225 System.**
 - **All manufacturers' instrument trays are to be used unlidded and unwrapped.**
 - **Confirm integrators are present in each tray per facility policy.**
- Place instrument trays onto the 2nd, 3rd and/or 4th shelves (when applicable).
- Best practice to place heavy trays on bottom and lighter trays on top.
- **EMPTY SteriCUBE MTS300 CONTAINER WEIGHS 212 LBS. WITH ALL 4 SHELVES / EMPTY SteriCUBE MTS225 CONTAINER WEIGHS 185 LBS WITH ALL 3 SHELVES. THE TOTAL WEIGHT OF THE CONTAINER FULLY LOADED MUST BE CONSISTENT WITH THE FDA-CLEARED CHAMBER CAPACITY FOR THE INTENDED STERILIZER.**

NOTE: THIS NEXT STEP IS OPTIONAL

REFER TO HOSPITAL STANDARDS FOR INSTRUMENT LOAD TRACKING

- Fill out destination card with appropriate information and place in bracket holder, located on outside of SteriCUBE® MTS Cabinet.
 - **Surgeon's name, surgery date, type of surgery, patient initials, and list of contents.**
 - **STEAMPlus® tray record cards with STEAMPlus sterilization integrators are provided as an option for use.**
 - **If desired, STEAMPlus tray record cards can be added to the patient chart or filed in SPD for infection control traceability.**

- Close door and latch cam lock handles to lock door into position.
- Place integrity locks through the holes that are in the top and bottom cam locks, snapping each lock into a locked position over handles, with indicator dot facing the front of the door for easy visual inspection.

Autoclaving:

- Dock transfer cart with autoclave; ensure that it is securely docked.
- Visually confirm cart has been securely locked to autoclave for smooth transition of the Cabinet from transfer cart into autoclave chamber.

➤ **APPLY ALL-WHEEL BRAKES.**

- Confirm the cart's brake system has been fully engaged by pressing all the way down on the foot pedal.
- If a biological challenge is required by hospital policy, place on pullout shelf bracket on either end of the SteriCUBE MTS Cabinet so it is positioned over the autoclave drain when in the chamber.
- Release SteriCUBE MTS Cabinet lock by squeezing the black plastic handle and pressing down on the cabinet release bar, then push unit into autoclave.
- Set sterilization cycle and dry time according to contents.

NOTE: The SteriCUBE® MTS System was tested and validated using a 270° pre vacuum cycle with a minimum exposure time of 4 minutes and a minimum dry time of 5 minutes.

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

- Upon completion of cycle, open autoclave door.
- Dock transfer cart with autoclave; ensure that it is securely docked.
- Visually confirm cart has been securely locked to autoclave for smooth transition of the Cabinet from the autoclave onto the transfer cart.
- Place the cart with cabinet in area for allowing it to cool.

Time will vary depending on ambient room temperature.

- Upon completion of cycle, if biological challenge was used, incubate according to manufacturer's recommendations or hospital policy.
- If option was used, verify STEAMPlus ® integrator (or hospital provided card) has passed.
 - **Confirm the Dark bar enters the SAFE area.**

Unloading in OR:

- Transfer SteriCUBE MTS System to appropriate operating room theatre.

Non – Sterile Member

- Position SteriCUBE MTS System in the operating room theatre within easy access of sterile field.

➤ APPLY ALL-WHEEL BRAKES.

- Visually inspect filters and integrity locks, located on **RIGHT SIDE, LEFT SIDE AND TOP / OUTSIDE** of the SteriCUBE® MTS Cabinet, verifying they are in place and intact. A small amount of blue filter should be visible around each filter plate. Verify indicator dots on integrity locks have changed color.
- Unlock integrity locks on door cam locks to access inside the Cabinet. Keep hand over integrity

lock when breaking to prevent any small fragments from flying away.

- Elevate door cam locks, allowing the door to open.
- Open the door in sterile fashion, remaining behind the door so as not to compromise the sterile field.

Secure the door in the open position from 180° to 270° depending upon allotted space.

Sterile Member

- If possible, visually inspect filters (disposable or reusable) located on **BOTTOM / INSIDE** of the SteriCUBE MTS Cabinet over drain, verifying they are in place and intact.
- Retrieve contents.
- Verify integrators placed within individual trays have all turned to indicate sterile processing.

Non - Sterile Member

- After the Sterile Member has emptied the contents, lift up or remove bottom shelf and open drain cover located on **BOTTOM/INSIDE** of the SteriCUBE MTS Cabinet.
- Remove the filters and verify sterility was not compromised.
 - No visible moisture.
 - No holes, folds or tears.
 - Two filters per grate opening.
- **Note: It is normal to find lint on the drain filter. This does not compromise sterility of the Cabinet's contents.**

If a Reusable SteriCUBE® MTS System Ceramic Filter was used in place of disposable drain filters and drain screen, visually confirm the placement and integrity of the ceramic filter.

- Open filter plates located on **LEFT AND RIGHT SIDES** and the TOP/OUTSIDE of the SteriCUBE MTS Cabinet by elevating each center cam handle.
- Remove the filters and verify sterility was not compromised.
 - No visible moisture.
 - No holes, folds or tears.
 - Two filters per grate opening.
- 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 Sterile Processing Department for reprocessing.
- If no moisture, holes, folds or tears are found, and each grate opening contained the correct two filters, contents are considered sterile and the empty Cabinet can be returned to Sterile Processing Department for processing another case.

OPTIONAL REUSABLE FILTER SEPARATORS

Non - Sterile Member

- Position SteriCUBE® MTS System in the operating room theatre within easy access of sterile field.
 - **APPLY ALL-WHEEL BRAKES.**
- Visually inspect filters and integrity locks, located on **RIGHT SIDE, LEFT SIDE AND TOP / OUTSIDE** of the SteriCUBE® MTS Cabinet, verifying they are in place and intact. A small amount of blue filter should be visible around each filter plate. Verify indicator dots on integrity locks have changed color.
- Open filter plates located on **LEFT AND RIGHT SIDES** and TOP/OUTSIDE of the SteriCUBE MTS Cabinet by elevating each center cam handle.
- Remove the **TOP** or **OUTER FILTER ONLY** from each filter port, leaving the bottom filter and filter separator in place but exposed. Visibly inspect the bottom filters for any potential

compromise without removing them from the cabinet. Hold each single top/outer filter up to the light to verify sterility was not compromised.

- No visible moisture.
 - No holes, folds or tears.
 - Two filters per grate opening, bottom or inner filter remains intact and in place on the cabinet as a dust cover.
- 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 Sterile Processing Department for reprocessing.
 - If no moisture, holes, folds or tears are found, and each grate opening contained the correct two filters, go to next step.
 - Unlock integrity locks on door cam locks to access inside the Cabinet. Keep hand over integrity lock when breaking to prevent any small fragments from flying away.
 - Elevate door cam locks, allowing the door to open.
 - Open the door in sterile fashion, remaining behind the door so as not to compromise the sterile field.
 - Secure the door in the open position from 180° to 270° depending upon allotted space.

Sterile Member

- If possible, visually inspect filters (disposable or reusable) located on **BOTTOM / INSIDE** of the SteriCUBE® MTS Cabinet over drain, verifying they are in place and intact.
- Retrieve contents.
- Verify integrators placed within individual trays have all turned to indicate sterile processing.

Non - Sterile Member

- After the Sterile Member has emptied the contents, lift up or remove bottom shelf and open drain cover located on BOTTOM/INSIDE of the SteriCUBE MTS Cabinet.
- Remove the disposable filters and verify sterility was not compromised.
 - No visible moisture.
 - No holes, folds or tears.
 - Two filters per grate opening.
- **Note: It is normal to find lint on the drain filter. This does not compromise sterility of the Cabinet's contents.**

If a Reusable SteriCUBE® MTS System Ceramic Filter was used in place of disposable drain filters and drain screen, visually confirm the placement and integrity of the ceramic filter.

- The empty Cabinet can be returned to Sterile Processing Department for processing another case.

All unused instruments at the end of the surgical procedure are to be considered unsterile, and must be reprocessed prior to next usage.

The SteriCUBE® MTS System was developed for patient specific surgery. If, for any reason, the surgery is postponed or cancelled before the sterility continuity is interrupted, it may be used for “same type” surgery or stored up to 30 days before reprocessing is mandatory.