SteriCUBE®
STERILIZATION CABINETS

Product and Program Overview

For ASCs ... or hospitals that want to operate like one

LoanSTAR™
By SteriCUBE

Contents

Product Overview

SteriCUBE Sterilization Cabinets bring efficiency to sterile processing and the operating room (OR) by allowing the vendor trays, or all the instruments, for a surgery to be sterilized and delivered as one unit. Traditionally, instrument trays are sterile-processed separately in rigid containers or laboriously enveloped in “blue wrap”. Utilizing these technologies is time-consuming and can cause extensive delays due to residual moisture after autoclaving or holes in the fabric.

Instead of individual processing, SteriCUBEs allow the trays for a surgery to be efficiently sterilized and then rolled into the OR; even from offsite. This enables a single employee to quickly unload surgery-ready instruments and expedite OR turnover.

Cross-Ventilation Filters

Enable even steam distribution and evacuation

2 CUBE Sizes

- *9-tray up to 225 lbs.*
- *12-tray up to 300 lbs.*

Record Card and Documentation Holder

Adjustable Shelves

Biological Indicator Drawer

Funnel Floor with Ceramic Filter

Designed to avoid wet loads

In the OR, 1-person can unload all the trays in 1-minute.[1]

In the SPD, 1-person can load all the trays in 5-minutes.[1]

Time-Wasting Technologies

Time Is Valuable.
Why Waste It With Blue Wrap?

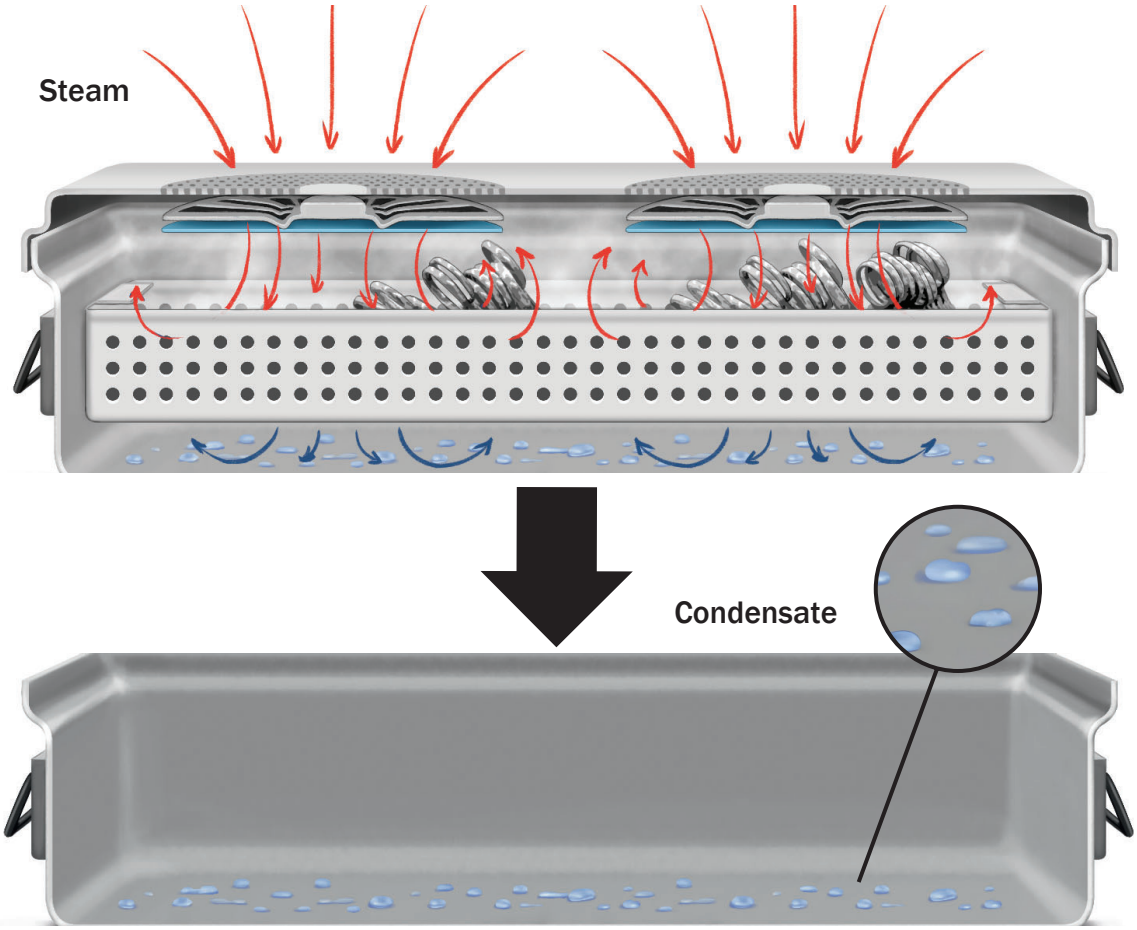
Unwrapping “blue wrap” and inspecting for perforations requires two employees and takes up a significant portion of the room set-up time. If any perforations are found, it triggers a cascade of delays — requiring immediate reprocessing, rescheduling, and often last-minute staff coordination; all of which disrupt workflow and increase operational costs.[2]

Flat Bottoms And Wet Packs

Like blue wrap, unpacking rigid containers involves two employees and causes significant disruptions if “wet packs” or “wet loads” are encountered.

Flat-bottomed rigid containers can collect condensate after autoclaving. 78% of hospitals admit to periodic wet packs that delay surgeries and create environments for microbe proliferation.[3]

Most rigid container feature top, lid filters. These lid filters are designed to allow steam infiltration, but may inhibit condensate clearing from the bottom of the container.[4]



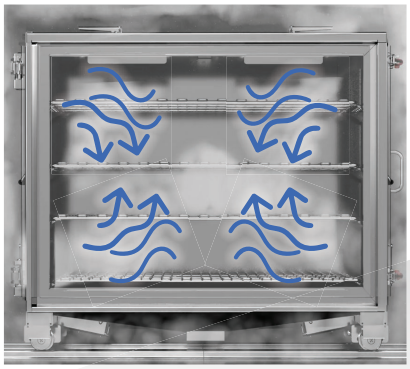
Top 3 SteriCUBE® Features

Cross-Ventilation Filters

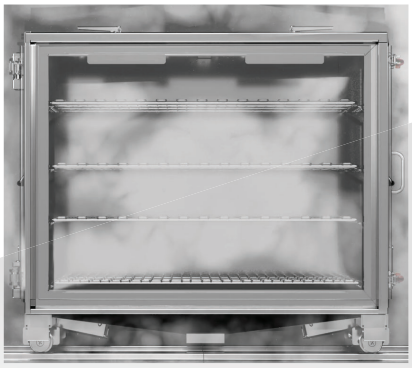
SteriCUBEs are like an autoclave within an autoclave...
SteriCUBEs feature four cross-ventilation filters to ensure dense steam distribution throughout autoclaving.

During the exposure cycle, steam quickly enters the filters and displaces air through the bottom ceramic filter with little resistance. This creates a constant, even steam-flow for superior sterilization.[5]

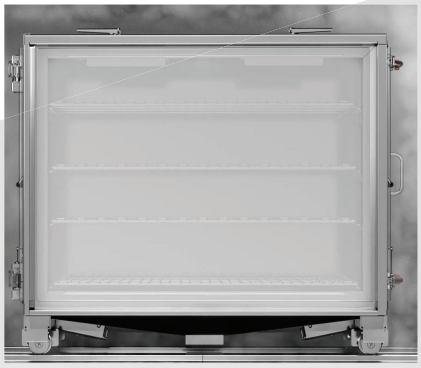
For this reason, SteriCUBEs are validated to sterilize smaller cannulas than any other similar device and have been validated for cannulas as small as 0.7mm in diameter and 20-inches long.



Steam enters through filters



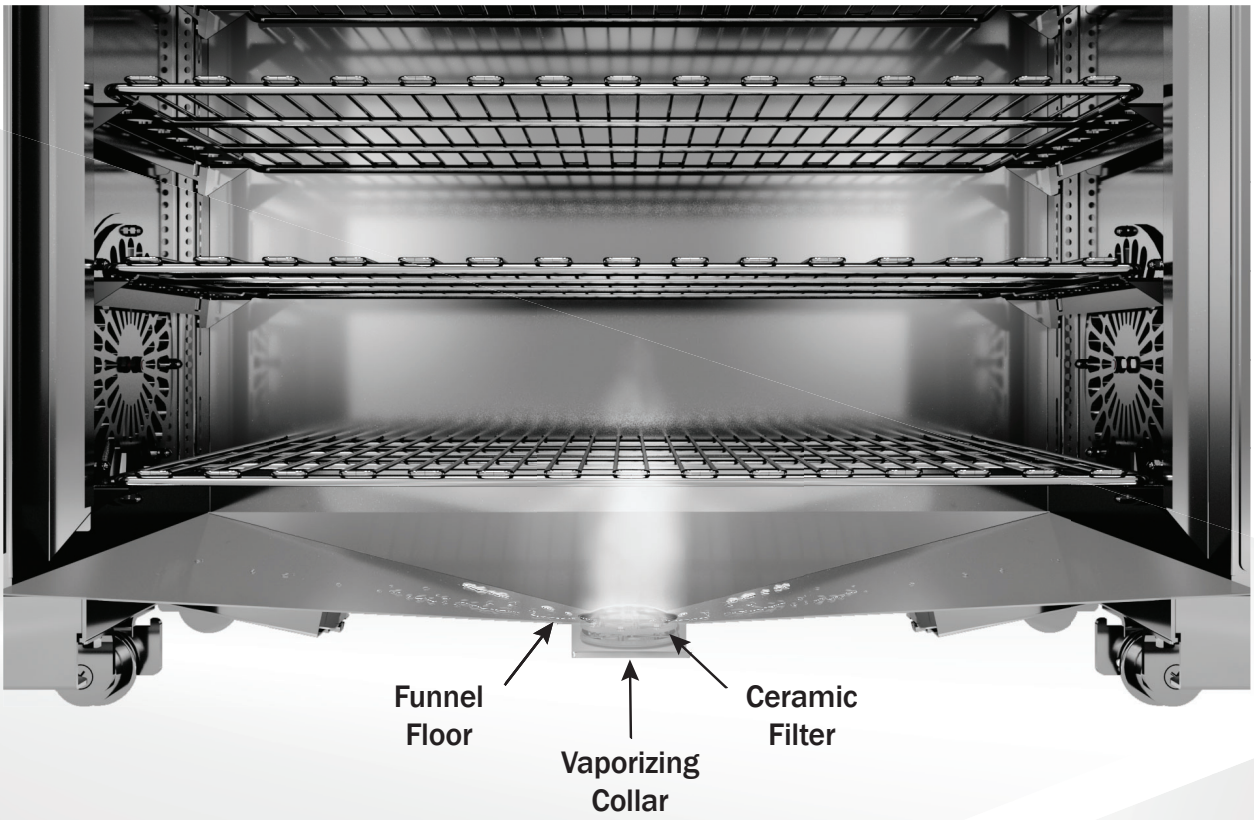
Steam begins to fill SteriCUBE



Dense steam distribution

Funnel Floor

Unlike traditional flat-bottom sterilization cases, SteriCUBEs feature a patented Funnel Floor to rapidly evacuate steam and condensate during the autoclave dry cycle. This results in much shorter drying times than blue wrapped trays and rigid containers. In fact, SteriCUBEs are validated for a 5-minute autoclave dry time.



We’ve Got Your Back

SteriCUBEs feature adjustable shelves to ease the loading of heavy trays.

Orthopedic instrument trays can weigh as much as 25 lbs.[6] Sterile processing these trays and holding them in the OR can exert tremendous stress on the spine.[7]

This is one of the reasons SteriCUBEs were designed with adjustable shelves.

SteriCUBE shelves support the far end of a heavy tray, allowing it to be slid-in without straining your back.

Efficiency Across Departments

SteriCUBE® Delivers Efficiency in Two Departments

ADVANTAGES IN THE OR:

- 1-person can unload all the trays for a surgery in 1-minute[1]
- Frees an employee
- Avoids blue wrap holes and wet loads
- Faster set-up time between cases

CUBE delivered to OR.

Circulating nurse can leave while scrub tech unloads CUBE.

ADVANTAGES IN THE SPD:

- Saves approximately 27-minutes of tray preparation time per surgery compared to blue wrap and rigid containers[1]
- Generally cools quickly due to high surface area. No need to “crack” the autoclave door before removal.
- 5-minute autoclave dry time validated but sterilize according to the instrument IFU

Load CUBE in SPD. Latch door and affix integrity locks.

Sterilize CUBE. Allow to cool.

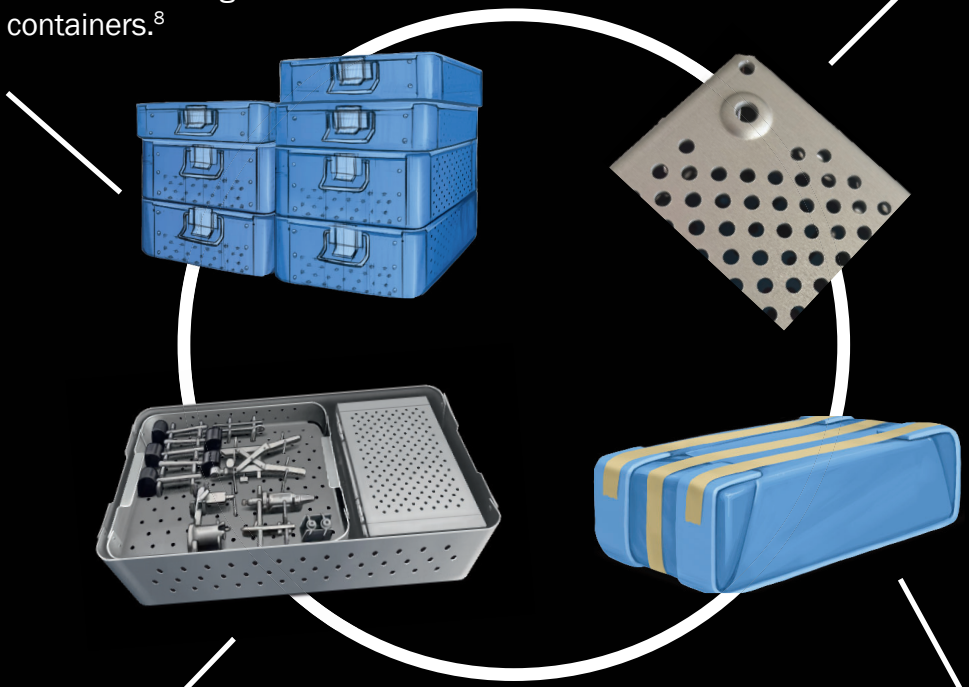
Loaner Trays

SteriCUBE® Solves Loaner Tray Issues

Instrument trays supplied by vendors are also known as “loaners”. These trays negatively impact efficiency due to several factors.

Random Drop-Off
Loaner trays are delivered at unpredictable times.
Tray counts vary (often 5 to 30+ trays)
Many loaners are too large for rigid containers.[8]

Prone To Wrap Tears
Heavier trays (up to 25 lbs.) with feet easily tear blue wrap.[2]



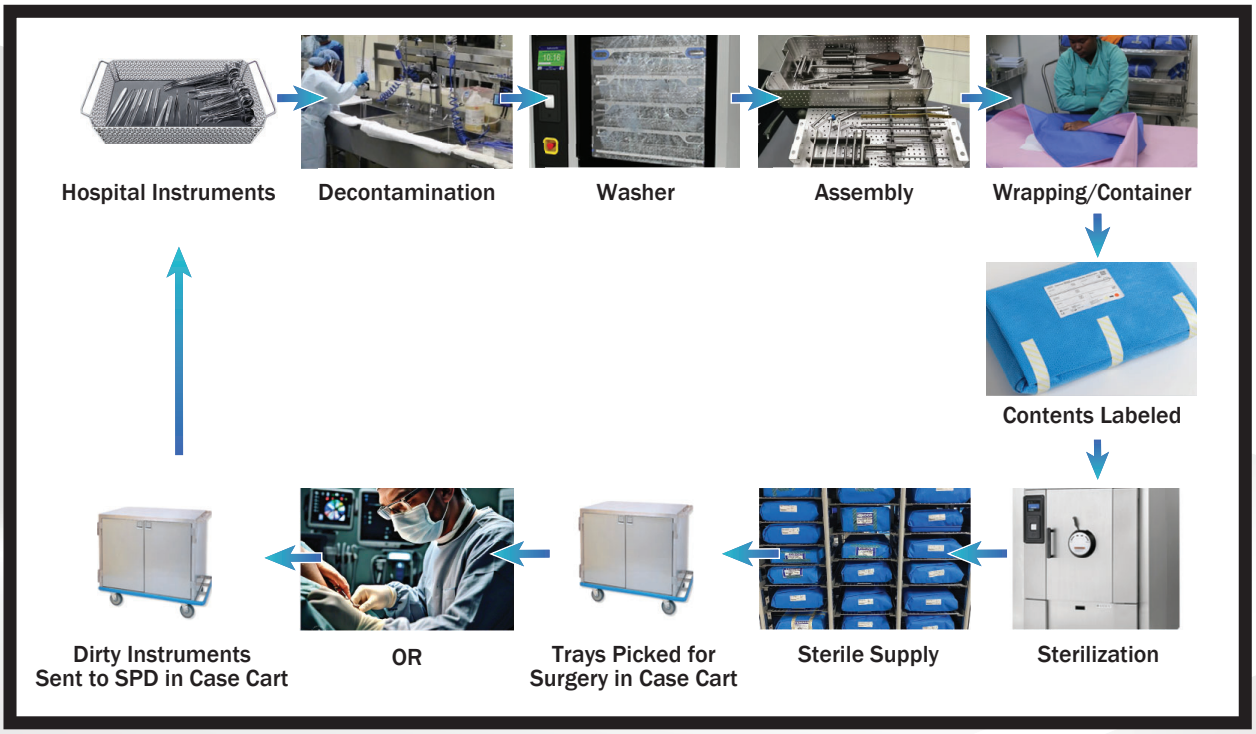
Varied Vendors
Varied vendors with complex and uncommon instruments make bioburden detection difficult.[9]

Lost Time
Wrapping loaners takes longer due to extra padding and protection.[2]

How Loaner Trays Slow Down Your Facility

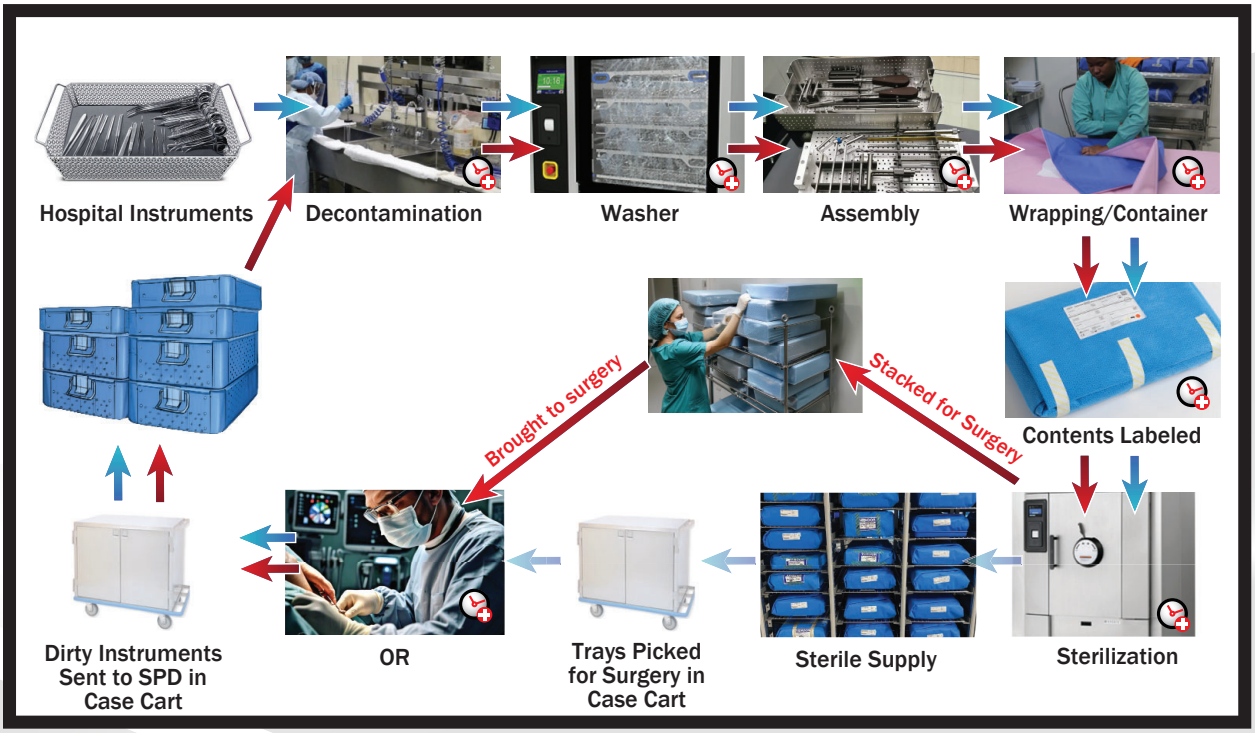
In most facilities, instrument tray processing for general surgical instruments is efficient and streamlined; ensuring quick turnover between surgeries. Automated systems, clear labeling, and staff training minimize handling time and maintain safety, creating a smooth workflow that enhances both patient care and staff comfort.[10]

General Instrument Flow



The influx of loaner trays from various vendors complicates tray processing due to the unpredictable delivery of heavy trays that must be carefully wrapped. This wrapping process increases the risk of perforation, potentially requiring resterilization and impacting patient safety. The unfamiliarity with the instruments further delays assembly, creating inefficiencies and slowing overall operations.[2]

General Instrument Flow + Loaner Trays



Loaner trays slow hospital processes at every stage of instrument sterilization and utilization.[11]

To help facilities with loaner tray processing, we offer the LoanSTAR™ Specialist Program. The program includes CUBEs and one or two Specialists to help your SteriCUBE process run efficiently.

Secondary Instrument Check

Coordinate and Load

Sterilize and Deliver

Q. What does a LoanSTAR Specialist do?

- Collaborate with orthopedic and spine coordinators on scheduling of CUBE cases
- Coordinate with SPD staff and vendors to determine tray needs for CUBE cases
- Provide a secondary check for loaner trays
- Load CUBEs per IFU – scan and load trays; place filters, integrity locks, BioPaks, etc.
- Provide CUBE delivery and pick-up service for the OR
- Keep CUBEs clean, optimized, and ready
- Maintain necessary sterilization records and documentation

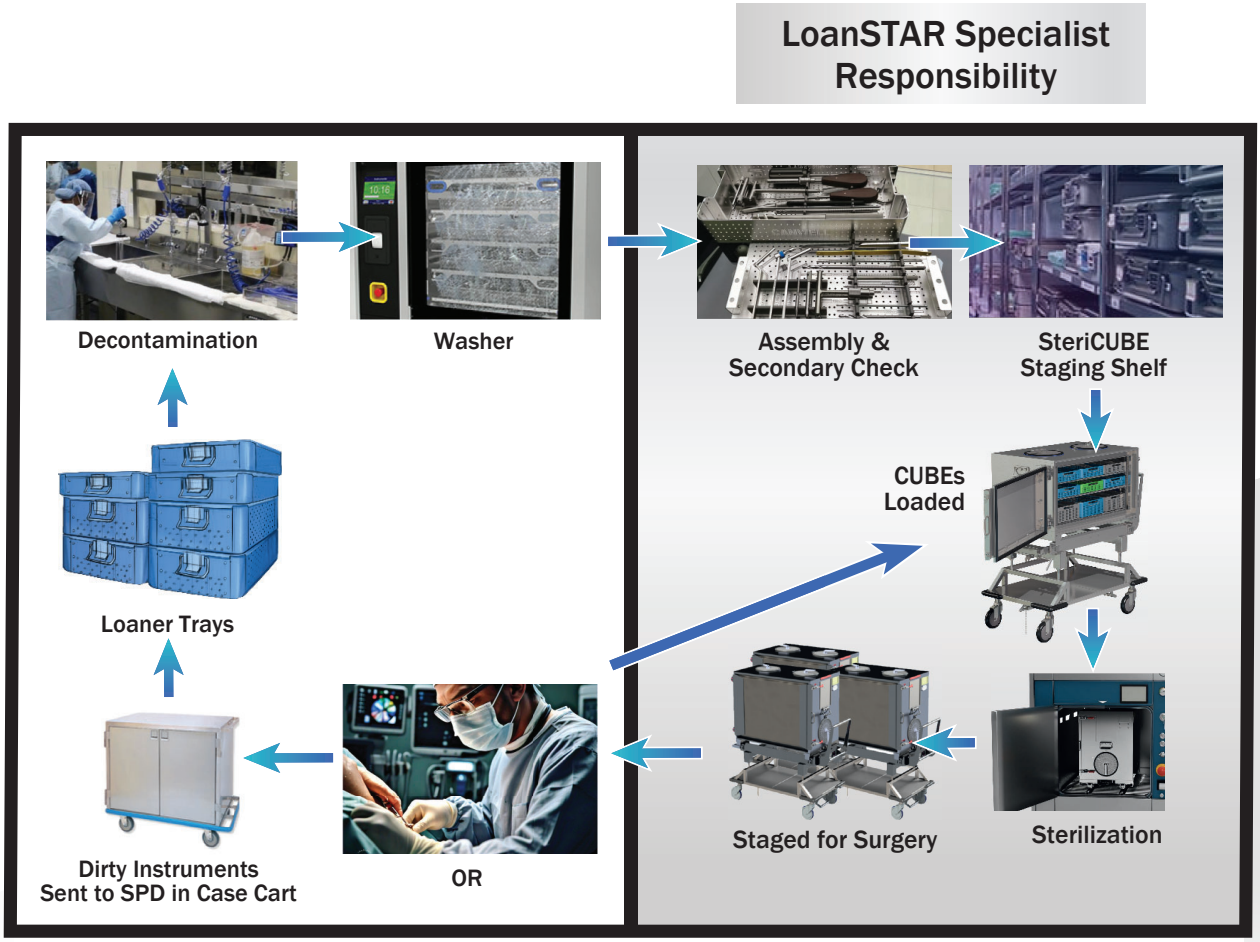
Q. What does a LoanSTAR Specialist cost?

The cost of the Specialist is fully covered through the disposable filter sets and does not incur any additional expense to your facility. We do this because we have found Specialists help ensure safety and increased utilization.

Q. How long will you have the LoanSTAR Specialist?

You can have your LoanSTAR Specialist for as long as necessary.
They are dedicated to your facility and will be on site when the CUBEs are used.

LoanSTAR™ Flow



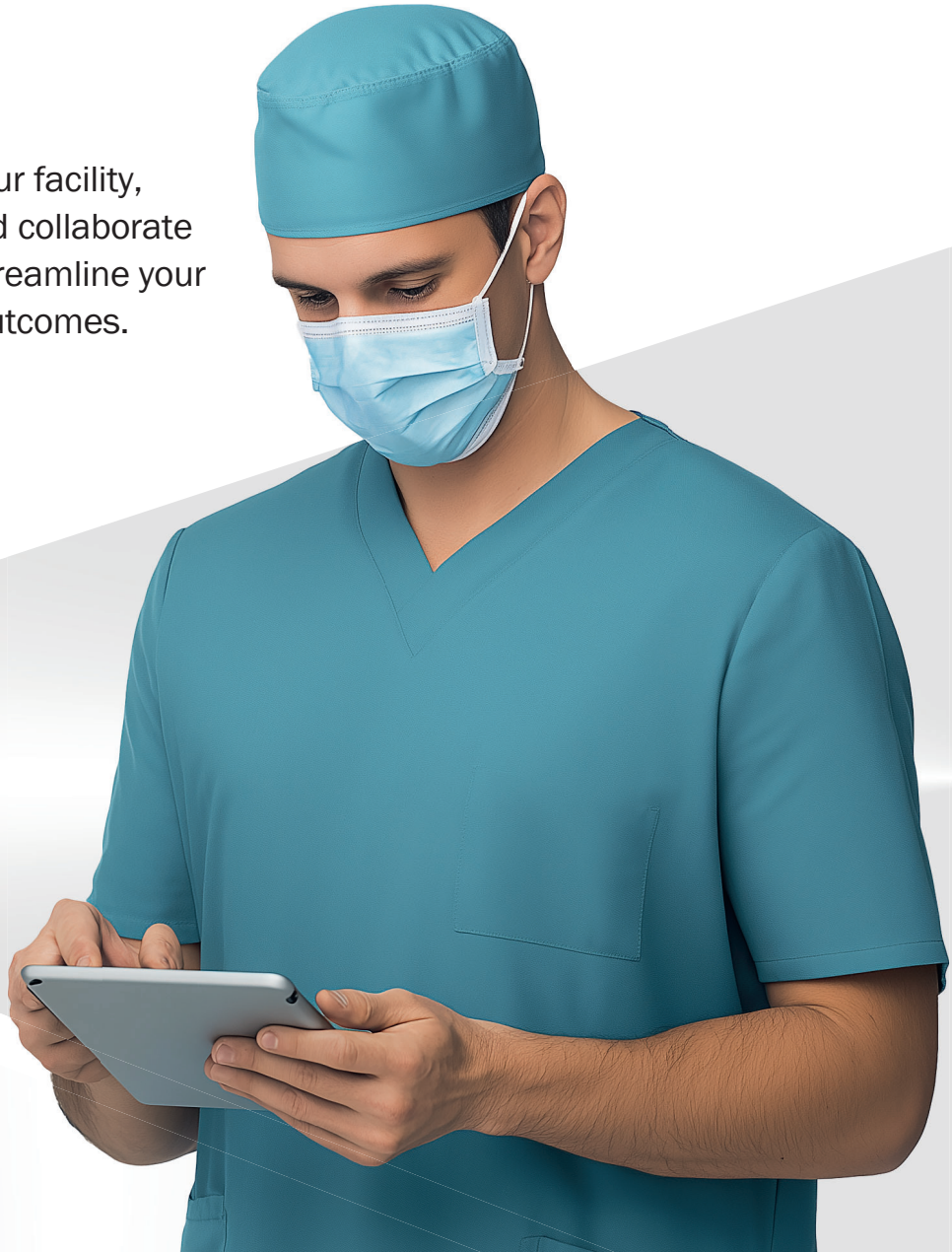
The LoanSTAR specialist will basically act as an additional SPD employee devoted to the SteriCUBEs.

Efficiency Help

Expert Help For Efficiency

For some facilities, adequate efficiency can be achieved just by incorporating SteriCUBEs. However, some facilities may benefit from a SteriCUBE efficiency professional who can help them take advantage of the efficiencies SteriCUBEs can deliver.

Our personnel can visit your facility, review your workflows, and collaborate with your teams to truly streamline your processes for improved outcomes.



Offsite Sterilization and Green Benefits

SteriCUBE® is Validated for Offsite Sterilization

The SteriCUBE system is validated for offsite sterilization; enabling healthcare facilities to streamline instrument processing without compromising sterility or efficiency. SteriCUBEs can be transported directly from the offsite sterilization facility with fully sterilized, surgery-ready instrumentation; reducing on-site workload, and supporting timely OR set-up.

Sustainability

SteriCUBEs take you from blue to green

SteriCUBEs are a sustainable, green alternative to “blue wrap” that can reduce the resultant space and bio-hazard waste-removal burden on your facility.

Studies have demonstrated approximately 24 pounds of disposable waste is created per surgery.[12] This can equate to 3 or more garbage bags full of material that must be disposed-of.

Clinical Substantiation

Clinical Evidence

Innovation in Sterilization
The Multiple Tray Sterilization System

Cory Nestman, BS, MS, ACE, CRCST, CHL, FCS
AVP Central Sterile Processing & DME Support Services,
Hospital for Special Surgery

Poster presented at OR Manager Conference. 2016

"The predicted savings generated by the use of this technology could be well over $7,000,000.00 annually for hospitals with high volumes of orthopedic procedures. The elements in calculating savings included costs of packaging materials, staff labor, overhead and waste."

"Not only have we been able to increase efficiencies within CSP and the OR while reducing our incidents of IUSS, but the Cube provides unexpected benefits in ergonomics, waste reduction and staff satisfaction as well."

Introduction

At HSS, we are always on the lookout for innovative technology that may improve an already efficient instrument process loop. The new MTS300 Multiple Tray Sterilization System (a.k.a."The Cube"; has proven to be an enormous success. Not only have we been able to increase efficiencies within CSP and the OR while reducing our incidents of IUSS, but the Cube provides unexpected benefits in ergonomics, waste reduction and staff satisfaction as well.

Most U.S. hospital OR and CSP departments are experiencing quality defects within the instrument tray process loop which result in case delay, customer and staff dissatisfaction, and the undesirable use of IUSS. CSP and OR team members are challenged to maintain sterility throughout the entire process loop while simultaneously meeting the best practice standards for aseptic technique when setting up the back table.

The MTS300 technology provides an effective solution to:

- ✓ Decreased OR Turnover Time
- ✓ Eliminate contaminated trays due to holes in wrappers or undetected moisture wicking
- ✓ Eliminate back and shoulder injuries caused by repetitive lifting and holding of heavy trays
- ✓ Eliminate potential for wet instrument trays
- ✓ Reduce OR turnover time due to rapid Cube unloading process
  (no wrap or individual container filter inspection)
- ✓ Reduce time spent looking for trays
- ✓ Reduce CSP process time by eliminating packaging and reducing sterilization dry times
- ✓ Reduce steps for handling of sterile trays in storage and case cart assembly process
- ✓ Reduce or eliminate IUSS
- ✓ Reduce pre-surgical waste to enhance green initiatives

Over the past several months at HSS we documented the improved efficiencies resulting from the Cube usage. We are pleased to present our internally validated Time and Motion Studies. We captured time savings and waste reduction experienced in the OR as well as steps eliminated in the instrument

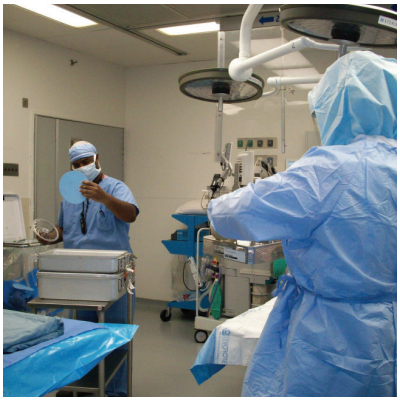
The Product

The SteriCUBE is best described as a “giant rigid container” or a “sterilizable case cart.” The FDA has cleared the SteriCUBE (Cube) to hold up to 300 pounds of any manufacturer’s instrument trays. There is room for three (3) trays on each of the four (4) adjustable shelves, making it ideal to use for joint replacements, spine and trauma cases. The cabinet holds all the instrument trays for a single procedure. The transfer cart acts as the sterilization load cart to safely deploy the cabinet into the steam sterilizer chamber. It is also used to transport those trays from CSP to the OR. The CUBE fits into most medium to large chambered steam sterilizers.

The Process

The instrument trays are put through the usual decontamination, washing and assembly processes, then loaded into the CUBE with no lids or packaging. The CUBE is then processed in accordance with the instrument manufacturer’s IFU, typically a 4 minute sterilization cycle followed by a 30 minute dry time. At HSS we found there was no need to preheat the autoclave chamber, extend the dry time, or allow the trays to remain in the autoclave after the cycle for additional drying. When using the CUBE to process our orthopedic trays, we are able to reduce our current cycle time by an average of 40 to 50 minutes. By eliminating the packaging process we saved on both materials and staff labor. Perhaps most important and valuable to our facility is the time saved in the OR when unloading the trays. Routinely it takes an average of 10 to 15 minutes for the nurse and scrub to unload the case cart, unopen and inspect the packaging materials and then place the trays onto the back table for our joint procedures. More complex spine cases take even longer. It took our staff an average of 3 minutes and 5 seconds to unload all the trays for a total joint onto the back table. We found our spine cases, with several more trays on average, saved even more time. Per published data, the average cost of OR time ranges from $100 to $120 per minute. Saving just a few minutes here or there may add up to enough time to perform additional procedures or at the very least reduce overtime expenses. Time saved absolutely gives the nurses more time for patient focused tasks.

Non-CUBE vs. SteriCUBE®



Unwrapping in the OR... The conventional way...
A bag of trash before case starts...

Unloading the SteriCUBE in the OR.

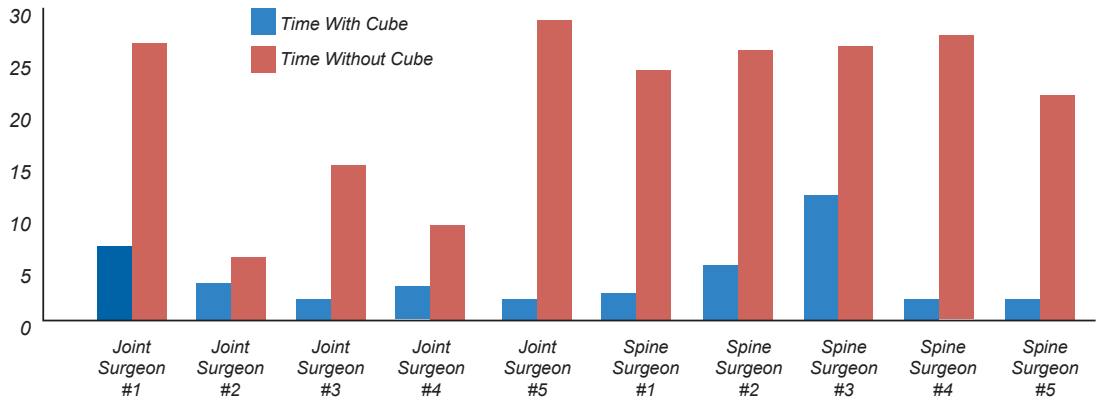
Discussion

Benefits

Decreased OR Turnover Time
Decreased Surgery Delays
Decreased IUSS/Flashing
Decreased Surgical Waste
Decreased Labor Expense
Decreased Case Cart Pilfering
Decreased Tray Handling
Decreased Misplaced Trays
Decreased Potential for Injury
Decreased Case Cart Pick Time
Decreased Wet Trays
Increased Staff Satisfaction
Increased CSP Throughput
Increased Tray Accountability
Increased Confidence in Sterility
Increased Efficiency in CSP Tray Turnover

In this evaluation, we have discovered the CUBE to be one of the most innovative devices that impacts efficiency in the CSP and OR instrument processing loop. It increases the collaboration between CSP and OR pertaining to the delivery of sterile trays for orthopedic procedures. It is such an intuitive idea that many people take one look at it and say “I thought of that a long time ago.” Of course, none of us took the extra steps necessary to file patents, build prototypes, undergo years of independent testing, receive FDA clearance, and finally bring the product to market. Fortunately someone did.

Results

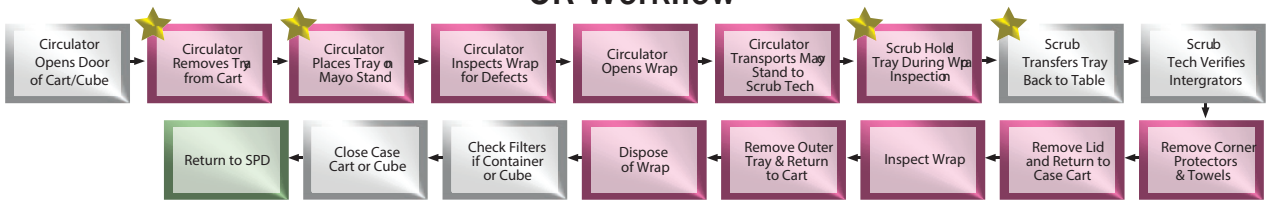


Time Savings in the OR

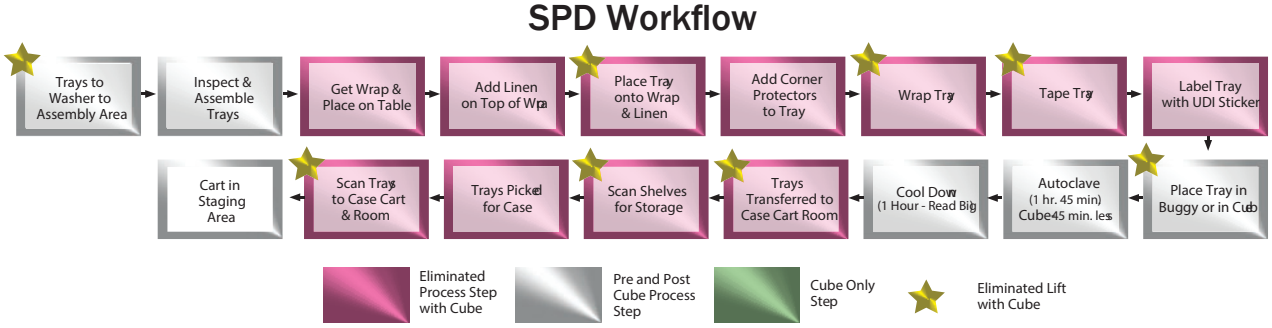
The chart above shows the average time saved by physician. The more instrument trays used in the procedure, the more time was saved during the unwrapping process. In addition, there were no defects that compromised sterility or caused delays in procedures.

Workflow Analysis

OR Workflow



SPD Workflow



Conclusions

After evaluating the product at HSS, we have determined that the SteriCUBE consistently saves approximately one minute per tray of OR room opening time. In addition, there was a significant reduction in packaging materials and CSP staff preparation time. At HSS, our #1 priority is patient safety and quality followed closely by patient and staff satisfaction. The CUBE affords us both.

The CUBE's unique design makes it nearly impossible for sterility to be compromised therefore Infection Control strongly supports this technology. During use in the OR, the CUBE allows the circulating nurse to focus more time on patient related tasks. The CUBE promotes employee safety and assists with green initiatives. Using the CUBE gave us the opportunity to identify waste that exists in our current instrument reprocessing workflow. We also used the evaluation period to identify opportunities for improvement in our preference cards.

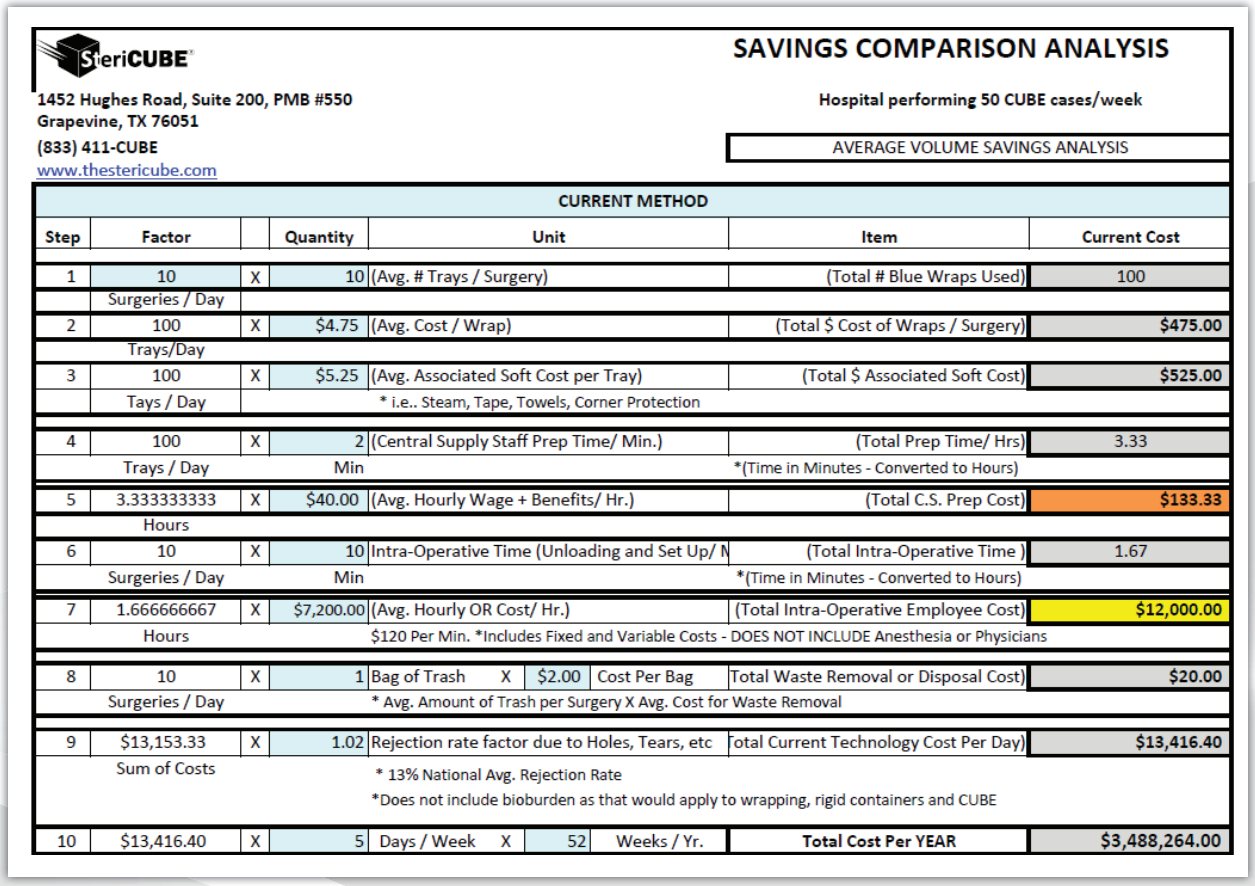
In addition to the benefits listed above, the predicted savings generated by the use of this technology could be well over $7,000,000.00 annually for hospitals with high volumes of orthopedic procedures. The elements in calculating savings included costs of packaging materials, staff labor, overhead and waste.

ROI + Savings

Economic Impact

SteriCUBE brings efficiency to multiple departments within a facility. This can demonstrate millions of dollars in cost reductions when holistically analyzed.

For visibility to the financial benefits, SteriCUBE can work with your facility to provide a comprehensive savings comparison analysis.



SteriCUBE

SAVINGS COMPARISON ANALYSIS

1452 Hughes Road, Suite 200, PMB #550
Grapevine, TX 76051
(833) 411-CUBE
www.thestericube.com

Hospital performing 50 CUBE cases/week

AVERAGE VOLUME SAVINGS ANALYSIS

CURRENT METHOD

Step	Factor		Quantity	Unit				Item	Current Cost
1	10	X	10	(Avg. # Trays / Surgery)				(Total # Blue Wraps Used)	100
	Surgeries / Day								
2	100	X	$4.75	(Avg. Cost / Wrap)				(Total $ Cost of Wraps / Surgery)	$475.00
	Trays/Day								
3	100	X	$5.25	(Avg. Associated Soft Cost per Tray)				(Total $ Associated Soft Cost)	$525.00
	Tays / Day			* i.e.. Steam, Tape, Towels, Corner Protection					
4	100	X	2	(Central Supply Staff Prep Time/ Min.)				(Total Prep Time/ Hrs)	3.33
	Trays / Day		Min					*(Time in Minutes - Converted to Hours)	
5	3.333333333	X	$40.00	(Avg. Hourly Wage + Benefits/ Hr.)				(Total C.S. Prep Cost)	$133.33
	Hours								
6	10	X	10	Intra-Operative Time (Unloading and Set Up/ M				(Total Intra-Operative Time)	1.67
	Surgeries / Day		Min					*(Time in Minutes - Converted to Hours)	
7	1.666666667	X	$7,200.00	(Avg. Hourly OR Cost/ Hr.)				(Total Intra-Operative Employee Cost)	$12,000.00
	Hours			$120 Per Min. *Includes Fixed and Variable Costs - DOES NOT INCLUDE Anesthesia or Physicians					
8	10	X	1	Bag of Trash	X	$2.00	Cost Per Bag	Total Waste Removal or Disposal Cost)	$20.00
	Surgeries / Day			* Avg. Amount of Trash per Surgery X Avg. Cost for Waste Removal					
9	$13,153.33	X	1.02	Rejection rate factor due to Holes, Tears, etc				Total Current Technology Cost Per Day)	$13,416.40
	Sum of Costs			* 13% National Avg. Rejection Rate					
				*Does not include bioburden as that would apply to wrapping, rigid containers and CUBE					
10	$13,416.40	X	5	Days / Week	X	52	Weeks / Yr.	**Total Cost Per YEAR**	$3,488,264.00

Note: The figures shown are for example purposes only and may not reflect actual hospital costs or savings

Education and Support

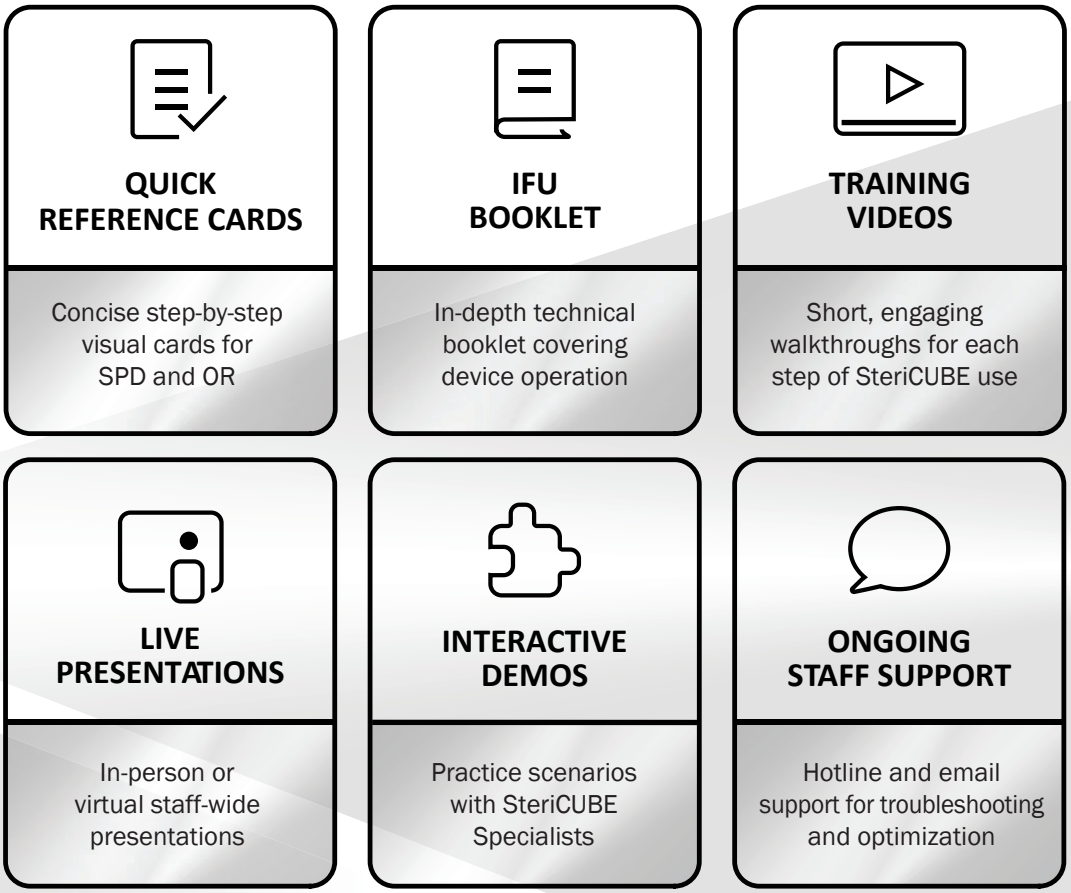
Onsite Support And Expert Guidance

SteriCUBE provides dedicated onsite personnel to guide your team through every step of adoption and optimization.

Our implementation experts stay until your staff is fully comfortable and compliant with sterilization workflows.

In addition to onsite personnel, SteriCUBE provides several different educational options.

Available Educational Resources



FDA Clearance Documentation

September 28, 2022

SteriCUBE, LLC
% Annette Hillring
President
Hillring & Associates, Inc.
3012 St. Charles Drive
Tampa, Florida 33618

Re: K222328
Trade/Device Name: SteriCUBE® Multiple Tray Sterilization Systems
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 29, 2022
Received: August 2, 2022

Dear Annette Hillring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222328

Device Name
SteriCUBE(R) Multiple Tray Sterilization Systems

Indications for Use *(Describe)*

The SteriCUBE Multiple Tray Sterilization System (SteriCUBE 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 System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks.

The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K222328 510(k) Summary

Submitter	SteriCUBE, LLC 2701 Beach Boulevard South Gulfport, FL 33707 Contact person: Michele E. Mauzerall, CEO Phone: 908-300-7093 Email: mem.pmbs@gmail.com Date prepared: September 27, 2022
Device	SteriCUBE® Multiple Tray Sterilization Systems
Predicate Device	MTS225 and MTS300 Multiple Tray Sterilization Systems ("MTS Systems") cleared most recently November 5, 2019, via K190541
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.

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Section 5: 510(k) Summary, continued

Indications for Use

The SteriCUBE Multiple Tray Sterilization System (SteriCUBE® 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 System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks.

The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

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.

Comparison of Technological Characteristics with the Predicate Device

There are no new technological characteristics associated with the modified SteriCUBE System. A comparison of the technological characteristics of the subject device, the SteriCUBE System (SteriCUBE MTS225 and SteriCUBE MTS300 Systems) to the predicate, the currently marketed MTS225 and MTS300 Systems, is provided in the table on the following pages.

Continued on next page

Section 5: 510(k) Summary, continued

Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: SteriCUBE® Systems (SteriCUBE MTS225 and SteriCUBE MTS300 Systems)	Predicate Device: MTS225 and MTS300 Systems (K190541)
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 System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks. The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray. 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.	The MTS System (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 MTS System Transfer Cart, MTS System Filters and MTS System Integrity Locks. The MTS System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray. The MTS 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 MTS System.
Sterilization Parameters	Prevacuum cycle of 270ºF and exposure time of 4 minutes	Prevacuum cycle of 270ºF and exposure time of 4 minutes
Minimum Drying Time	5 minutes	10 minutes

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Section 5: 510(k) Summary, continued

Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: SteriCUBE Systems (SteriCUBE MTS225 and SteriCUBE MTS300 Systems)	Predicate Device: MTS225 and MTS300 Systems (K190541)
Sterility Maintenance	30 days	30 days
Cabinet Material	16 gauge stainless steel	16 gauge stainless steel
Weight w/ Shelves	212 lbs (MTS300) and 185 lbs (MTS225)	212 lbs (MTS300) and 185 lbs (MTS225)
Filter Material	Heavy duty sterilization wrap by SPS Medical Optional ceramic drain filter Optional sterilization wrap filter separators	Heavy duty sterilization wrap by SPS Medical
Volume-to-Vent Ratio	129.131 (MTS300) and 94.725 (MTS225)	129.131 (MTS300) and 94.725 (MTS225)
Deployment into Sterilization Chamber	Adjustable transfer cart	Adjustable transfer cart
Recommended Sterilization Trays	All manufacturers' trays – uncovered, perforated or wire mesh general delivery trays	All manufacturers' trays – uncovered, perforated or wire mesh general delivery trays
Recommended Sterilizers	All makes and models with dimensions compatible with the SteriCUBE System	All makes and models with dimensions compatible with the MTS System

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Section 5: 510(k) Summary, continued

Comparison of Technological Characteristics with the Predicate Device, continued	Modifications introduced into the SteriCUBE® Multiple Tray Sterilization Systems do not affect the technological characteristics. The cabinet material remains stainless steel and a filtration system utilizing disposable paper filters of the same material from the same supplier is the method by which sterilization is achieved and maintained. The optional reusable drain ceramic filter and paper filter separators are available for user convenience and performance data confirms their effectiveness. The cabinet continues to be deployed into the sterilization chamber with an adjustable transfer cart. The sterilization parameters and sterility maintenance specifications are identical to the predicate device. The SteriCUBE Systems (both the SteriCUBE MTS225 and MTS300 Systems) have demonstrated the ability to: • achieve a 10^{-6} SAL when sterilizing longer and smaller lumen sized instruments (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), • meet the shorter minimum dry time of 5 minutes, and • maintain sterility for 30 days.
Performance Data	Nonclinical data was generated to ensure the SteriCUBE System continues to meet the intended use. Sterilization efficacy verification studies were performed in accordance with the appropriate requirements of ANSI/AAMI ST77:2013 *Containment devices for reusable medical device sterilization*.
Conclusions	In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR 807, and based upon the information and scientifically valid data provided in this premarket notification, SteriCUBE, LLC, concludes that the subject device, the SteriCUBE Systems (SteriCUBE MTS225 and MTS300 Systems) is as safe, as effective and perform as well as the predicate device, the MTS225 and MTS300 Multiple Tray Sterilization Systems (K190541).

Case Study

1 surgeon routinely performing
16 joint replacements
by 1pm

1
Surgeon

2
Operating Rooms

12
SteriCUBEs

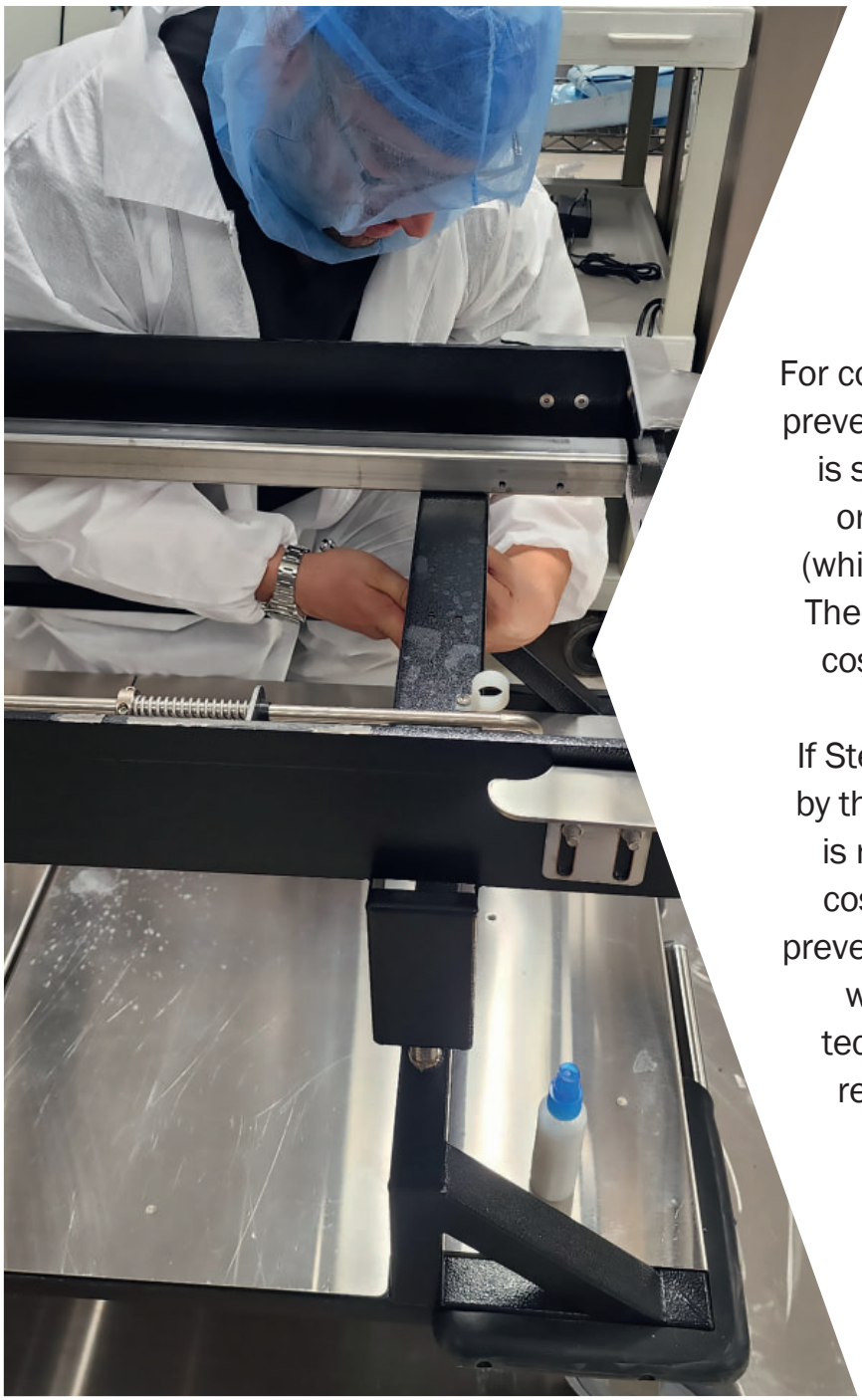
A Georgia-based surgery center is devoted to operative efficiency and reducing time-wasting activities. SteriCUBEs are a fundamental part of their process. For added efficiency, only primary hip and knee replacements are performed, and the same instruments are used for each case to reduce confusion. The day prior to surgery, instruments for the first 12 cases are sterilized and held in SteriCUBEs. During the day, instruments from the morning cases are reprocessed in SteriCUBEs and delivered to the later surgeries.

Bringing time transparency to critical aspects of the patient journey allows inefficiencies to be identified and minimized. This allows surgeons to focus only on surgery and ensure excellent patient outcomes with impressive throughput.

Scan to learn more

Maintenance and Specifications

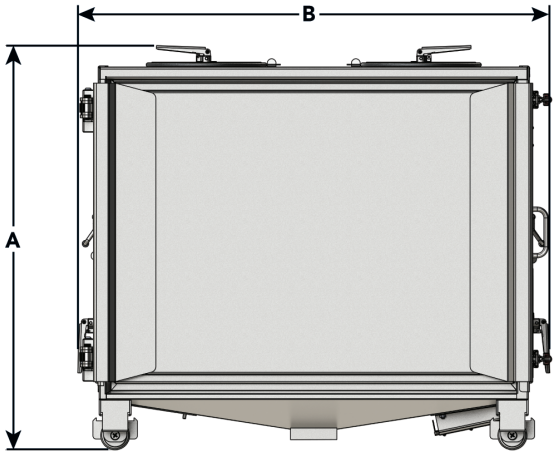
Preventative Maintenance

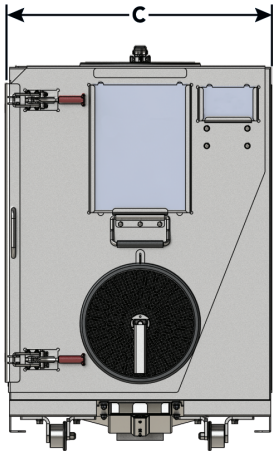


For consigned SteriCUBEs, preventative maintenance is scheduled annually or every 160 cases (whichever comes first). There are no additional costs for this service.

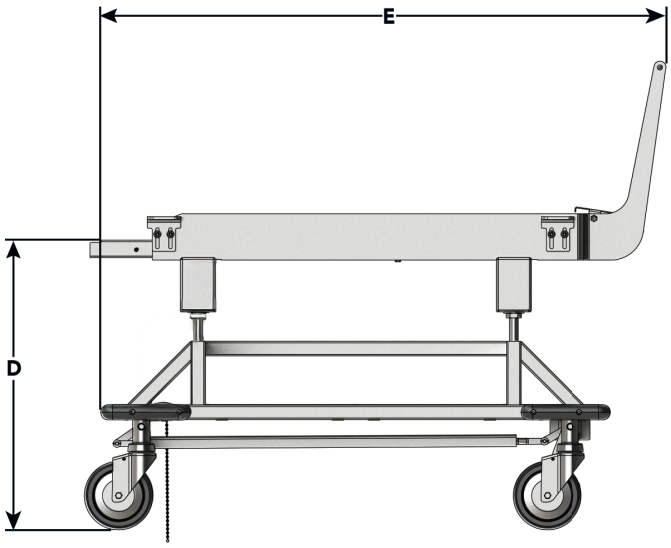
If SteriCUBEs are owned by the facility, the facility is responsible for the costsassociated with preventative maintenance which can include technician travel and replacement parts.

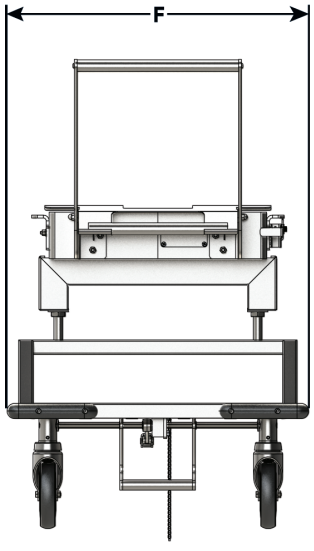
SteriCUBE® System Dimensions





	A Height	B Length	C Width	Weight
MTS-300	34.4 inches	40.7 inches	23 inches	212lbs
MTS-225	25.2 inches	39 inches	23 inches	185lbs





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

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