



SmartTray™ System

Instructions for Use

DEVICE DESCRIPTION

The SureCount Surgical™ SmartTray™ is a surgical tray constructed of an aluminum base with stainless-steel and silicone instrument brackets. The tray's brackets are anchored by the SmartBar™, which aids in the visual confirmation that all the required instruments are accounted for at the beginning and end of a surgical procedure. The trays are manufactured from materials compatible with standard hospital cleaning and sterilization processes.

INDICATIONS FOR USE

The SureCount Surgical™ SmartTray™ Systems are intended to enclose, organize, and protect manual surgical instruments during transport, sterilization, and storage. SmartTrays™ do not independently maintain sterility and must be used in conjunction with a validated rigid sterilization container or validated sterilization wrap to maintain sterility of the enclosed instruments. The SmartBars™ are intended to provide a visual aid to help confirm that the manual instrument count has been conducted and is correct. The device is intended for use by trained healthcare professionals.

PRECAUTIONS

- Trays may not be fully functional after multiple uses, misuse, or insufficient maintenance. The use of trays that are not fully functional may lead to product failure.
 - Inspect the trays for visible damage before use.
 - Check moving parts for free movement (latches, handles).
 - If unacceptable deterioration such as corrosion, discoloration, cracking, chipping, or pitting is noticed, do not use the tray.
- The use of nonabsorbent liners (such as plastic or silicone-fingered organizing mats) can cause condensation to pool.
- The tray should not be shaken aggressively or tipped. Doing so may result in loose and/or lost contents.
- The tray is not designed for use as a shipping container. To avoid damage, remove all components and pack them separately.

WARNINGS

- The trays must only be used for the purpose described in the Indications for Use. Deviation from the instructions in this document may lead to patient harm and/or contamination of the contents.
- The SmartBars™ are only intended to assist with visual confirmation and to be used in conjunction with manual instrument count practices. The use of the SmartBars™ does not replace the necessity for a manual count of instruments.
- The trays are provided non-sterile and must be reprocessed prior to use in a surgical case.
- Wear appropriate personal protective equipment (PPE) in accordance with facility policies.

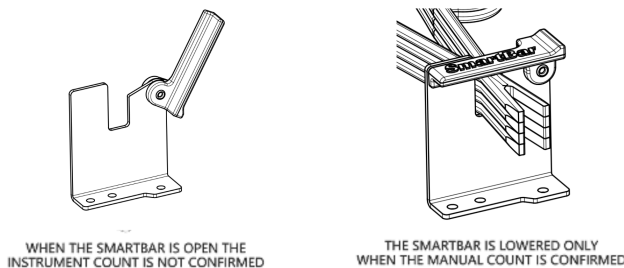
- These cleaning instructions are for the trays only and do not replace the cleaning instructions provided with the individual devices. Prior to sterilization, clean all devices as specified in their respective user manuals.
- The trays may be hot after sterilization. Adhere to your facility's PPE policies.
- Adhere to sterilizer IFUs and facility policies to ensure appropriate sterilization occurs.
- Ensure the total weight of the loaded tray system and sterilization wrap or rigid container is in compliance with the IFUs of the sterility maintenance device.
- Inspect and repair trays regularly for physical damage.

DIRECTIONS FOR USE

INITIAL TRAY SET-UP

1. Separate all tray levels from each other.
2. Flip all yellow SmartBars™ up to an open position, throughout the levels. (Refer to reference image below.)
3. Manually count the instruments and ensure the correct quantities are placed into their designated brackets. (Refer to images and instrument name assigned to each bracket in the tray.)
4. Lower the SmartBars™ to a closed position once brackets contain the correct instrument quantities. (Refer to reference image below.)
5. Confirm that the SmartBars™ are flat by running a finger along the top of them.
6. Once all tray levels have been loaded with the requested instrumentation, pick up the insert tray(s) by its handles and gently place it into the outer tray.
7. Place lid on the set by: releasing both latches on the sides, aligning the lid on the outer tray, then pressing down on the lid and confirming the latches are locked in place.

THE SMARTBAR PROVIDES A VISUAL AID TO HELP CONFIRM THAT THE MANUAL INSTRUMENT COUNT HAS BEEN CONDUCTED AND IS CORRECT



CLEANING

The SureCount Surgical™ SmartTray™ has been designed to be cleaned using current facility cleaning practices. This section provides recommendations for properly cleaning the SureCount Surgical™ SmartTray™. Follow all instrument manufacturer IFUs and validated facility reprocessing procedures.

POINT OF USE

Remove gross soil from the surfaces, crevices, mating surfaces and other hard-to-clean areas following facility procedures. Contaminated components should be kept moist until qualified cleaning processes can be applied.

MANUAL CLEANING

1. Soak Basin Preparation

- 1.1. Prepare a detergent solution according to the manufacturer's instructions.
- 1.2. Fully immerse the tray for 10 minutes and inject any crevices with 50 mL of the prepared cleaning agent.

2. Manual Cleaning

- 2.1. Using a soft bristled brush, brush the components of the tray for 1 minute to remove any soil present, paying close attention to crevices and mated surfaces.

Note: A syringe can be used to flush crevices and hard to reach areas.

- 2.2. While moving the latches on the lid between the extreme open and closed positions, brush between all crevices for 1 minute.

3. Rinsing/Inspection

- 3.1. Rinse the tray thoroughly using reverse osmosis or deionized water until there is no visible detergent.
- 3.2. Flush any mated surfaces and crevices as necessary.

4. Drying/Inspection

- 4.1. Remove any excessive water that may hinder the inspection process with medical air and/or a non-linting clean wipe.
- 4.2. Visually inspect the device for soil or detergent. If contaminants are present, repeat steps 1-4.

AUTOMATED CLEANING

1. Detergent Preparation

- 1.1. Prepare the detergent according to the manufacturer's recommended concentration.

2. Manual Cleaning

- 2.1. Using a soft bristled brush, brush the components of the tray for 1 minute to remove any soil present, focusing on crevices and mated surfaces.

Note: A syringe can be used to flush crevices and hard to reach areas.

- 2.2. While moving the latches on the lid between the extreme open and closed positions, brush between all crevices for 1 minute.

3. Rinsing/Inspection

- 3.1. Rinse the tray thoroughly using reverse osmosis or deionized water until there is no visible detergent.
- 3.2. Flush any mated surfaces and crevices as necessary.

4. Automated Wash

- 4.1. Trays should be placed flat in the washer to assist with drainage.
- 4.2. Operate the washer, using the following recommended parameters:

Cycle	Recirculation Time	Water Temperature and Type	Detergent Type
Pre-Wash	2-4 min	Cold Tap Water	-
Enzyme Wash ¹	1-2 min	Heated Tap Water	Enzymatic Detergent
Wash	2-4 min	Heated Tap Water	Non-Enzymatic Detergent
Rinse	2-4 min	Heated Tap Water	-
Thermal Rinse	1-5 min	90°C Heated Reverse Osmosis / Deionized Water	-
Dry	7-15 min	Drying Temperature 115°C	-

¹ Enzyme wash is optional.

5. Drying/Inspection

- 5.1. Remove the tray system from the washer at the end of the cleaning cycle.
- 5.2. Visually inspect the device for remaining soil or detergent. If contaminants are present, repeat steps 1-4.

STERILIZATION

This section provides details on how to properly sterilize and re-sterilize the SureCount Surgical™ SmartTray™.

- The SmartTray™ is provided non-sterile.
- Exact compliance with the manufacturer's user instructions for sterilization is required.
- The tray can be sterilized using the following recommended parameters:

Pre-Vacuum Steam Sterilization		
Step	Cycle 1	Cycle 2
Enclosure	Double Sterilization Wrap or Rigid Container	Double Sterilization Wrap or Rigid Container
Temperature	132°C	134°C ²
Exposure Time	4 min	3 min ³
Dry Time	30 min	30 min

² Sterilization temperature may be raised to 138°C outside of the United States.

³ Exposure time may be extended to 18 minutes outside of the United States.

STORAGE AND HANDLING

- The tray is not designed for use as a shipping container. To avoid damage, remove all components and pack them separately.
- The tray is not suitable for storage upside down.
- To prevent damage, trays should not be stacked or turned upside down during transport and/or in storage, when not in use.
- Store in a dry, clean, dust-free, temperature- and humidity-controlled environment to prevent product malfunction or damage.

PACKAGING AND LABELING

- SureCount Surgical™ devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact Customer Service at Tel: 888-340-5059 or info@surecountsurgical.com if the package has been opened or altered.

PRODUCT COMPLAINTS

Report any dissatisfaction with the product quality, labeling, or performance to SureCount Surgical™ at: 888-340-5059 or info@surecountsurgical.com.



Manufactured for:
SureCount Surgical, LLC
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Symbol Reference Key	
	Manufacturer
	Date of Manufacture
	Use by date
	Batch code
	Catalog number
	Distributor
	Caution/Warnings
	Medical Device
	Unique Device Identifier