Why ONE TRAY®:

Surgical facilities are experiencing unprecedented demands for cost controls and improved efficiency.

Yet, many facilities are wasting money on archaic practices and redundant infrastructure, because they don't have effective solutions for improving the processing of surgical instrumentation and supplies.

The challenge is managing instrumentation in coordination with the surgical case load within a rapidly changing environment; especially where emergency cases are common.

Furthermore, existing technology limits the ability to safely respond to unexpected events in the operating room. The inability to rapidly process surgical assets in response to unexpected demand negatively impacts budgets, staffing, schedules, revenues, operational performance and patient outcome.

This situation forces facilities to spend considerable sums on redundancy of instrumentation and surgical supplies to maintain a marginally adequate responsiveness.

In meeting this challenge, ONE TRAY containers provide assured, ‘Just-In-Time’ rapid sterilization and delivery of surgical assets using either pre-vacuum or gravity displacement cycles.

The ONE TRAY ‘Just-In-Time’ Processing System optimizes the utilization of limited surgical assets and supplies by offering significant time and cost savings that are both immediate and ongoing.

Read more about the 'High Impact' benefits of ONE TRAY®:

- **Regulatory Compliant** with patented, 510(k) cleared technology that meets all FDA requirements.
- **Safe** for mobilization and sterile delivery of surgical assets.
- **Convenient**, ONE TRAY® uses the same assembly protocol as common filtered-vent containers.
- **Consistent** performance with 510(k) cleared ONE TRAY Processing Kits.
- **Adds Value**, through ‘Rapid’ sterilization processing. Allows for just-in-time return of assets to the surgery room.
- **Innovative** technology using a proprietary modification of reliable filtered-vent design.
- **Comply** with AAMI ST79 guidelines for rapid processing.
- **Eliminates** extended processing cycles.
- **Meets OSHA** weight requirements.
- **Flexibility** with user defined capacity.
- **Minimize capital investment** on surgical instruments sets and supplies.
- **Go Green** and support environmental initiatives with ONE TRAY®!
How it Works:

**ONE TRAY®** Sealed Containers deliver unprecedented ‘Rapid’ processing capability of surgical instrumentation which substantially improves the utilization of surgical instrumentation and reprocessed supplies.

**ONE TRAY®** is 510(k) cleared by the FDA to terminally sterilize temperature tolerant instrumentation in compliance with regulatory guidelines in a pre-vacuum cycle in just four minutes!

This enhanced performance is achieved by combining reliable filtered vent design with innovative breakthrough technology. The patented **ONE TRAY®** design takes advantage of the thermodynamic behavior of steam to efficiently and expeditiously attain terminal sterility within a sealed container.

The number, relative size and positioning of our filtered vent configuration creates a flow pattern that assures the expeditious and complete dispersal of saturated steam throughout the container. The patented **ONE TRAY®** design has the following features and performance benefits:

| One centrally located vent in the lid and two laterally displaced vents in the floor which offer twice the vapor exchange capacity of the single-entry vent in the lid. | Provides a circulation pattern that assures the complete and rapid dispersal of the sterilizing agent throughout the container. |
| Sloped floor with a centrally located retained moisture collection area. | Ensures sterility by eliminating prolonged contact between condensation and filter elements. |

The 'Rapid' processing performance of **ONE TRAY®** has the following features:

- Offers an enhanced ‘Just-In-Time’ processing alternative to ‘Flash’ sterilization.
- Eliminates backpressure that occurs with vents located only in the lid.
- Reduces the negative impact of ‘Cool Spots’.
- Addresses retained moisture concerns.
  - Eliminates drying time.
  - Ready for Immediate Use.
  - Reduces extended cycles.

**ONE TRAY®** Sealed Containers are 510(K) cleared by the FDA for “Rapid Processing by either Pre-Vacuum or Gravity Displacement Cycles".
Go GREEN:

Innovative 'Rapid' Sterilization Technology eliminates the waste associated with the wrapping of surgical instrumentation and orthopedic loaner sets.

Key environmental benefits offered by ONE TRAY®'s breakthrough technology:

• **Reduces Energy Use** - ONE TRAY® is validated and 510(k) cleared for the sterilization of surgical assets in just 4 minutes.

• **Reduces Waste** - ONE TRAY® eliminates the need for wrapping of orthopedic loaner sets.

• **Reduces Carbon Footprint** - With ONE TRAY®'s 'Rapid' sterile processing system; surgical facilities need fewer instrument sets.

• **Tamper evident protection** for the safe transport, secure holding and aseptic delivery of loaner instrumentation to the sterile field.

• **SCT supports Green environmental initiatives**.

For more information on the environmental benefits and the value proposition of the ONE TRAY® Rapid Processing System please contact admin@sctus.com.
Value:

The enhanced performance of ONE TRAY® Sealed Containers includes the unique ability to rapidly process and safely deliver entire sets of surgical instrumentation for immediate use in response to unexpected demand (including orthopedic loaner trays) on a Just-In-Time basis.

Many medical journals and trade magazines contain articles which state the clinical need for the rapid sterile processing of surgical instrument sets using a convenient, safe and 510(k) cleared methods.

ONE TRAY® was developed to offer clinicians an efficient, timesaving and reliable solution to substantially improve and safely expedite the processing of surgical instrumentation and temperature tolerant supplies.

ONE TRAY® is validated and 510(k) cleared by the FDA to rapidly sterilize a twenty five pound gross weight load of instruments in a pre-vacuum cycle at 270°F in just 4 minutes.

This 510(k) cleared capability offers unprecedented efficiency and value that substantially improves the utilization of surgical instrumentation as a valuable, but limited resource.

Value Benefits of ONE TRAY® include:

• Reduce capital investments on new surgical instrumentation and temperature tolerant supplies.
• Improve service levels by better utilizing existing instrumentation and temperature tolerant supplies.
• Enhance productivity by better managing workflow.
• Increase service capacity and velocity.
• Reduce costs, time, and effort associated with existing container systems.

ONE TRAY®’s breakthrough Rapid processing capability is accomplished by innovative design features and unique performance benefits which include the elimination of drying time. By eliminating drying time, ONE TRAY® is the first sealed container that accepts surgical instrumentation protected in their modular organizing trays for the “Rapid” processing of entire instrument sets for immediate use.

On behalf of ONE TRAY®, we welcome the opportunity to discuss particulars of creating a truly Rapid Processing System with high-impact benefits that meets your specific needs.
Regulatory Compliance:

**FDA Clearance**
The patented **ONE TRAY® Sealed Container System** is 510(K) cleared to rapidly sterilize a 25 pound gross weight load in a pre-vacuum cycle @ 270°F in just 4 minutes (K052567).

**ONE TRAY®** is the first sealed container to pass all of the rapid sterilization requirements of the FDA #1388 guidance document.

**ONE TRAY®** Sealed Containers combined with ‘Rapid Processing Solution’ form a Complete System offering peri-operative professionals unprecedented convenience and safety for the accelerated processing of surgical instrumentation.

**ONE TRAY®** allows for ‘Just-in-Time’ reprocessing of surgical instrumentation in response to unpredictable demand with the same reliable filtered-vent design used by standard rigid containers.

**ONE TRAY®** complies with both AORN and AAMI recommendations for the safe handling, transport and delivery of ‘Flash’ sterilized items.
Compliance FAQ's:

Q What is Rapid Processing?
A Rapid Processing usually means sterilization of a wrapped item (or items) resulting from 4 to 25 minutes of exposure to saturated steam at 270° F.

Q How does Rapid Processing differ from Flash Sterilization?
A Flash Sterilization was originally developed to process a single instrument for immediate use in an open tray.

Q Why use “Rapid sterilization”?
A “Rapid” sterilization allows for the routine processing of multiple instruments, supplies or devices for immediate use.

Q What are some of the primary concerns that are solved by proper Rapid Processing?
A According to AAMI:

- Work practices that ensure proper cleaning, decontamination, inspection and organization of instruments.
- Accurate documentation and consistent protocol.
- Potential contamination during transport and handling of “unwrapped” Flash sterilized items.

Q How can these concerns be adequately addressed?
A Properly decontaminate, clean and inspect before placing items in ONE TRAY®. As a sealed container, ONE TRAY® provides for safe handling and transport as recommended by AAMI.

Q How do I know sterilization was achieved?
A Place a Class 5 Multi-Parameter Steam Sterilization Integrator (such as SteriScan) on the top of the contents and enter all of the required information on the ONE TRAY® Load Record Card. Upon opening, visually check the Steam Sterilization Integrator to confirm the conditions for sterility were achieved inside the ONE TRAY® container before accessing the contents.

Q How long will the contents remain sterile?
A ONE TRAY® has a 510(k) cleared shelf life of 48 hours.

Q How does ONE TRAY® compare to specialized ‘Flash’ containers?
A ONE TRAY has no moving parts, daily maintenance requirements or operator involvement; while conveniently accepting instruments safely protected in their modular organizing trays.

Q How does ONE TRAY® compare to standard sterilization containers?
A ONE TRAY utilizes the proven filtered vent design of standard containers to provide the same convenience and reliability for the protection of surgical instrumentation.

Q How does ONE TRAY® differ from specialized ‘Flash’ containers and standard sterilization containers?
A As a sealed container, ONE TRAY allows for the rapid sterilization and safe transport of instrumentation using either Prevac or Gravity Displacement Cycles.

Q Why is this important?
A Since instruments do not have to be transferred from their modular organizing trays, ONE TRAY® saves time by eliminating extra handling whenever the immediate use of surgical instrumentation is necessary.
Flexibility:

ONE TRAY® allows for user-defined capacities with various base and lid height options and footprint sizes. The ONE TRAY® system includes a one-step 'Rapid Processing Solution' to further accelerate the cleaning cycle and provide 'Rapid' sterilization of surgical instrumentation that needs to be back in the field fast.
Convenience:

ONE TRAY® utilizes the same convenient preparation and familiar assembly protocol that has been widely used for traditional filtered vent containers (Aesculap, Genesis, etc).

In addition, ONE TRAY® facilitates work flow by accepting most instrumentation in their existing organizing trays.

ONE TRAY® also offers pre-packaged Processing Kits with all of the supplies necessary for each sterilization cycle.

The validated performance of ONE TRAY® Sealed Containers 510(k) clearance requires the exclusive use of ONE TRAY® Processing Kits.

ONE TRAY® Processing Kits contain all the supplies to consistently and safely process a 25lb gross weight load of surgical instruments in compliance with 510(k) requirements and approved by the United States Food & Drug Administration (FDA).

Each ONE TRAY® Processing Kit contains:

- Single-use Filters.
- 2 Tamper Evident Seals.
- 1 Load Record Card.
Safety:

ONE TRAY® containers enable the unprecedented 'Rapid' sterilization of surgical instrumentation; with the safety and assurance of FDA regulatory clearance and a 510(k) validated protocol.

The 510(k) clearance for ONE TRAY® includes rapid sterilization of a 25 pound gross weight load (including porous items, along with lumened and cannulated instrumentation) by either gravity displacement or pre-vacuum cycles in just 4 minutes.

ONE TRAY®'s air-tight seal and tamper-evident protection allows the container to be used as a safe vessel for transport and delivery of sterile assets from autoclave to surgery room.

ONE TRAY® Sealed Containers offer the perioperative professional the best possible blend of design and function.

The containers comply with strict FDA, AAMI and AORN guidelines and regulations.
Complete System:

ONE TRAY® sealed containers are the foundation of a complete Rapid Processing System that offers clinicians a more efficient, cost-effective, green alternative to conventional ‘Flash Sterilization’ containers.

ONE TRAY® containers are 510(k) cleared by the ‘U.S. Food and Drug Administration’ (FDA) to ‘Rapidly’ sterilize a 25lb gross weight load in a pre-vacuum cycle at 270° F in 4 minutes. As a modification of proven ‘filtered vent’ performance, ONE TRAY® containers are both convenient and easy to use. Utilizing the same assembly and preparation protocol as popular ‘filtered vent’ sterilization containers. ONE TRAY® containers also provide the safety of tamper evident protection for secure transport and assured delivery to the sterile field.

As the companion product to ONE TRAY®, Rapid Processing Solution (RPS) is specifically formulated to substantially accelerate the decontamination and cleaning of surgical instrumentation.

RPS is a neutral pH and concentrated triple enzyme formulation that cleans, combats corrosion, removes stains and rust; while consistently lubricating fine surgical instruments in just one step. RPS substantially reduces cycle times for the reprocessing of surgical instrumentation by effectively replacing: Enzyme Cleaners, Detergents, Stain Removers, Anti-Corrosive Agents, Ultrasonic Detergents and Lubricants. In addition, RPS is environmentally safe and economical to use while conveniently eliminating the confusion of what, when and how much to use!

Conventional indicators (such as chemical indicators or autoclave tape) only serve to inform the user that the package has been subjected to heat.

As a Class 5 Multiple Parameter Indicators (MPI) monitor time, the presence of steam and temperature to confirm and document that all the conditions to achieve sterility occurred within ONE TRAY. Since SteriScan can be read immediately after processing, loads can be accepted or rejected without quarantine of instruments while waiting for spore test results.