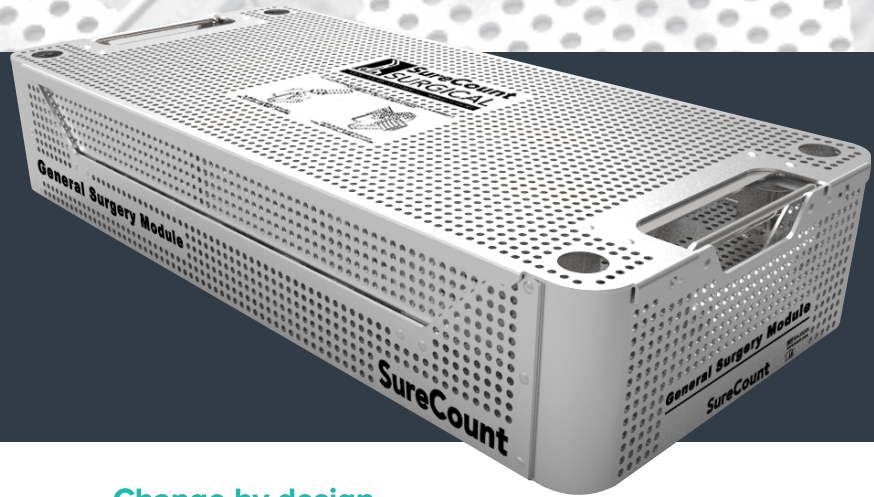


# Introducing the SmartTray<sup>™</sup>

A new system for managing surgical instruments brings accountability, efficiency and cost savings to healthcare



## Background

Dozens of clinical journal articles have chronicled the problems caused by an excess of surgical instruments in hospitals and surgery centers. Researchers have found that 40% to 80% of surgical tools are seldom or never used in procedures yet are routinely re-sterilized and returned to surgery trays in hundreds of procedure- and surgeon-specific configurations. This is the result of decades of physician preference requests and institutional inertia. The outcomes include overspending on procurement and reprocessing, unnecessary stress on staff and increased risk of surgical hardware being left in patients after closure.

There are no valid arguments for the status quo and every reason for change. Healthcare is burdened by cost, labor and quality problems. The surgical suite accounts for nearly 60% of hospital operational budgets, and surgical instruments are the largest source of non-labor spending for the OR. Today most physicians are employed by hospitals and have incentives to keep costs low. Indeed, the clinical literature strongly suggests that most surgeons, once provided solid data, are quite willing to help winnow tools and tray setups. Despite these changes, there has been no significant innovation in the instrument management space in decades.

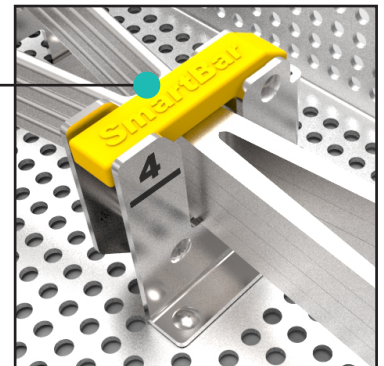
The SmartTray<sup>™</sup> is the first surgical tray to help staff in the OR and the Sterile Processing Department physically and visually identify, accommodate and secure only the essential instruments needed for a specific procedure.

## Change by design

The SureCount Surgical Instrument Management System represents an entirely new approach to surgical practices and protocols. The heart of this system is the SmartTray<sup>™</sup>, the first surgical tray to help staff in the OR and the Sterile Processing Department (SPD) physically and visually identify, accommodate and secure only the essential instruments needed for a specific procedure.

The SmartTray<sup>™</sup> has a modular design with an aluminum base and stainless steel, instrument-specific brackets that are geometrically arranged to maximize space and functionality for the user. The SmartTray<sup>™</sup> limits the number of instruments used during a procedure and the time nurses spend searching for missing items. The brackets are anchored by a unique device called a SmartBar<sup>™</sup>, which provides visual and tactile feedback on whether all necessary tools are in each bracket at the beginning and end of the surgery. Each bracket has the name and count for specific tools, with notches along the bracket that leave no doubt as to the correct instrument count.

The patented SmartBar<sup>™</sup> offers a visual aid to help confirm that the manual instrument count has been conducted and is correct.



The SmartTray<sup>™</sup> and SmartBar<sup>™</sup> establish a chain of custody from the SPD to the OR and back, assuring that all the instruments that have been used during the case have been returned to the SmartTray<sup>™</sup> and the OR nurse can say with confidence that the team can proceed to close.

This system also ends delays caused by nurses searching through multiple trays with hundreds of similar-looking instruments for the tool requested by the surgeon.

The standard surgical tray facilitates containment of wrapped instrument groups for sterilizing and use in the OR, but does little to facilitate efficiency in the handling, processing and use of instruments. Because so many items are unnecessarily flowing through the SPD, essential tools are often missing when trays arrive in the OR.

The SmartTray™ accommodates virtually all instruments, in any order or mix, from the six largest instrument manufacturers. This means that a variety of tools with different lengths, widths and depth will fit within the tray in any array, increasing the types of procedures for which it can be used.

SmartTrays are designed to extend the lifecycle of the instruments they contain for maximum utility for the customer. Today's trays and instruments have an expected lifecycle of 1,000 uses. However, due to the limitations of the standard tray design, the instruments are often lost or misplaced long before they wear out. The SureCount design and processes integrate the SmartTray™ and instruments to assure their durability.

When fully rolled out, the SureCount system will have a hub and spoke format. The hub – a stackable two-tray General Surgery set with room for 48 instruments – is already developed. The spokes will be procedure-specific trays for the most common surgeries, including labor and delivery, hysterectomies and vascular surgery. When all iterations of the standard SmartTrays are available, the system will cover more than 80% of all major surgeries.

SureCount has contracted with Paragon Medical, a leading worldwide supplier of sterilization cases and trays, to design, manufacture and distribute the SmartTray™.

The SmartTray™ is designed to be consistent with the sterilization containers that are already deployed and is compatible with existing sterilization processes and equipment.

SureCount will offer its General Surgery SmartTray™ for trials, early adopters and outpatient customers who may not need further customization.

The SmartTray™ accommodates virtually all instruments, in any order or mix, from the six largest instrument manufacturers.

## Fitting right in

The tools in the standard General Surgery SmartTray™ (see graphic) are based on feedback from surgeons at a number of prestigious academic medical centers and other experts.

The aluminum fabrication methodology allows for quick production of custom orders. SureCount will be able to offer standard, modified and customized SmartTrays across multiple surgical disciplines to all customers, based on their individual preferences, with 10-12 weeks' lead time.

Each SmartTray™ module is identified on its side panels, along with any needed identifiers such as barcodes. SureCount's standard instrument list is listed below, arrived at through painstaking surveys and research over the past few years (see page 3 for information about trays for other surgical disciplines.)

**Figure 1. Recommended instruments for the General Surgery SmartTray™**

| Instrument module 1   | Count | Instrument module 2 | Count |
|-----------------------|-------|---------------------|-------|
| Kelly clamp, curved   | 4     | Adson forceps       | 2     |
| Kelly clamp, straight | 4     | Allis clamp         | 2     |
| Kocher, short         | 2     | Large needle holder | 4     |
| Metz, curved          | 2     | Long Debakey        | 2     |
| Mosquito, curved      | 4     | Peaen clamp         | 2     |
| Mosquito, straight    | 4     | Small needle holder | 4     |
| Right angle clamps    | 4     | Tonsil clamp        | 2     |
| Straight/curved Mayo  | 4     | Toothed forceps     | 2     |

**Figure 2. Recommended procedures for the General Surgery SmartTray™**

|   |                                    |
|---|------------------------------------|
| Appendectomy                                  | Parathyroidectomy                  |
| Bleeding ulcer repair                         | Perforated ulcer repair            |
| Cholecystectomy                               | Retroperitoneal tumors excision    |
| Colectomy; right/transverse/left/low anterior | Small bowel resection              |
| Gastrectomy                                   | Splenectomy                        |
| Hernia repair                                 | Thyroidectomy                      |
| Mastectomy; partial/total/axillary dissection | Trauma surgery (part of all trays) |

The tray system is designed to fully integrate into existing workflows in the SPD and OR. At around 5 pounds fully loaded for each module, its weight will come as a major relief for SPD staff, who are used to much larger and heavier trays, many of which exceed guidelines established by the Association of periOperative Registered Nurses.

The SmartTray™ can be loaded in the SPD or the OR in less than 3 minutes per module, much faster than the typical tray build time today, which averages from 21 to 34 minutes, depending on the study. The SmartBar™ provides visual numerical confirmation of the right number of tools in each bracket.

Nurses can spray instruments with an anti-microbial agent – a national best practice – upon return to the tray as opposed to having to place them individually on stainless steel rods to do so.

The SmartTray™ is designed to be easily cleaned by SPD staff through soaking and mechanical processes so that it can be safely sterilized. The tray fits into sterilization containers or can be covered with standard central supply room wrap for steam sterilization. An aluminum lid helps keep instruments safe from damage.

A SureCount analysis of some two dozen clinical journal articles on excessive surgical instrumentation found that savings of \$60 to \$80 per procedure are achievable through the adoption of its system.

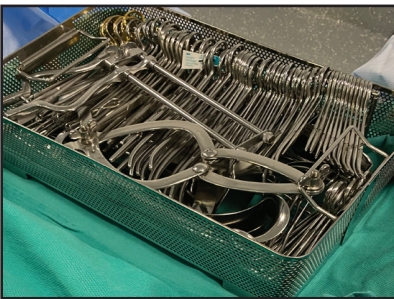
## Conclusion

SureCount Surgical was formed by physicians, nurses and technicians with a mission and passion to develop a repeatable, scalable and sustainable solution to a decades-old problem.

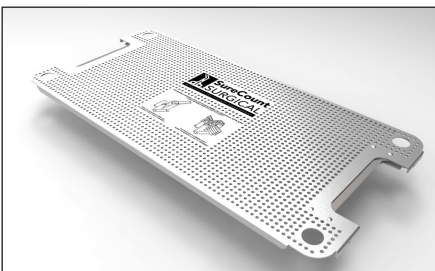
The design of the trays – a multi-year process informed by input from surgeons, perioperative nurses, sterile processing leaders, engineers and medical device experts – has resulted in a sustainable modular tray system that integrates easily into current processes and procedures. During a long lifecycle, it saves time, helps surgeries run more smoothly, frees valuable real estate in the OR and greatly reduces risk to staff and patients.

With the simple adoption of the SureCount Surgical Instrument Management System, medical facilities now have a clear and compelling path forward to improved financial, surgical and safety outcomes for almost all procedures.

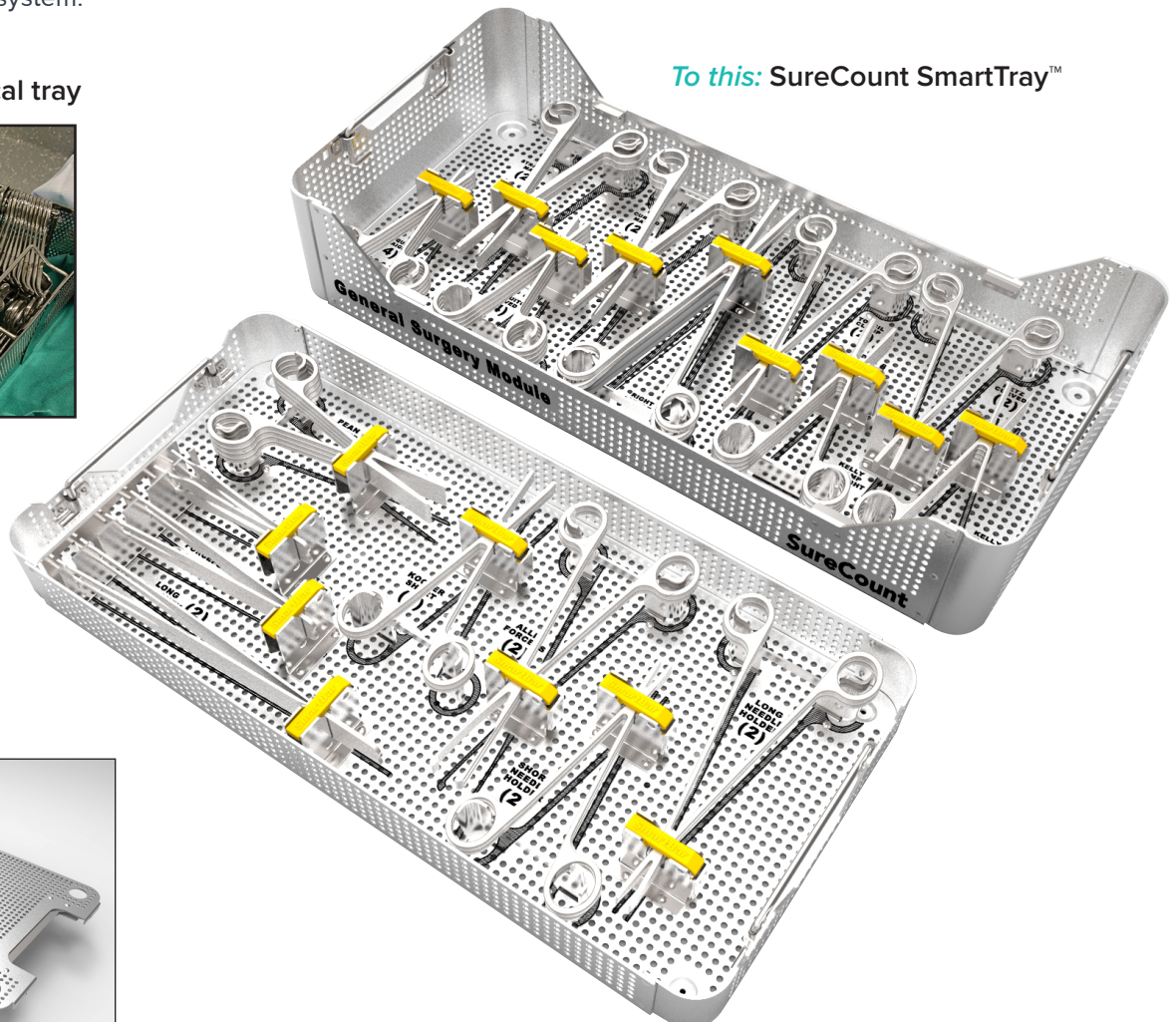
### From this: Today's surgical tray



The SmartTray™ lid protects surgical instruments from damage before procedures.



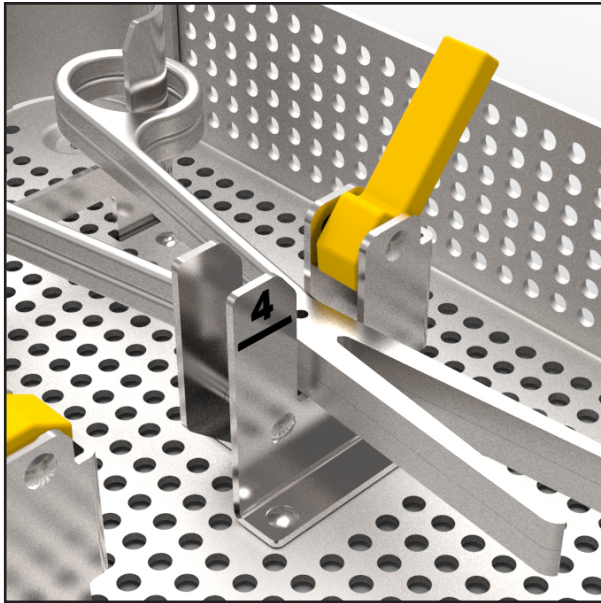
### To this: SureCount SmartTray™



More figures on next page.

The SmartBar™ provides a visual aid to help confirm that the manual instrument count has been conducted and is correct.

- When the SmartBar™ is open the instrument count is not confirmed.



- The SmartBar™ is lowered only when the manual count is confirmed.

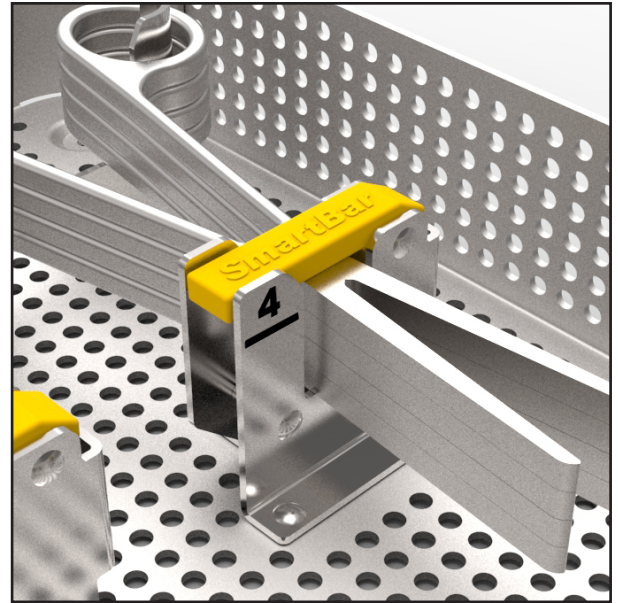


Figure 3. The hidden costs of unused surgical instruments

| Cause   | Cost   |
|---|--|
| Replacement costs for some general surgery tools                        | DeBakey 9.5-inch forceps, \$21<br>Metzenbaum dissecting scissors, \$38<br>7.5-inch Mayo-Hegar needle holder \$25 |
| Reprocessing costs, including chemicals, energy, labor and depreciation | \$0.65-\$0.98 per use*   |
| Cost when a tool goes missing   | \$43 per minute of OR time*  |
| RN time per surgery looking for tool (1 in every 8 cases)               | \$112 to \$161 per instance  |
| X-rays of body cavity when count is off (1 in every 7 cases)            | \$3,000 per instance   |
| Retained in patient following surgery                                   | Once in every 5,500 cases, total defense/settlement costs in successful cases of \$1.9 million                   |

Source: Published research, see Resources  
\*In 2022 \$

Figure 4. An ROI checklist: Discover how the SmartTray™ can help your bottom line

| Area of advantage  | Efficiencies  |
|--------------------|---|
| Supply chain       | Lower spend on stocking, replacing inventory<br>Fewer vendors, contracts and POs  |
| Sterile processing | Accelerated training and education<br>Faster tray setup time<br>Fewer loads in autoclave<br>Fewer injuries and repetitive stress disorders  |
| Surgical           | Reduction in lost, damaged, dropped and missing instruments<br>Immediate visual-tactile identification of missing instruments<br>Faster response to surgeons' instrument requests<br>Faster turnaround times from SPD |
| Risk management    | Fewer staff adverse events from excess instrument handling<br>Reduced potential for retained surgical instruments   |