

# Innovative Sterilization Technologies

## An Efficient, Effective and Economical Approach to Medical Device Sterilization

In her long career as a clinical nurse, Barbara Ann Harmer, MHA, BSN, RN, saw numerous instances where ASCs and hospitals battled inadequate instrumentation to support the rising number of surgeries each day. It was customary for trays that were terminally sterilized earlier to be reused again later in the day for other patients by subjecting them to immediate use steam sterilization (IUSS). The disparity in sterilization methods for treating patients ignited Harmer's spirits to effect a change. As a clinician, she yearned to provide "one standard of care" for all.

The sterilization packaging technology that saw no major breakthrough since the 1970s witnessed a path-breaking development. Innovative Sterilization Technologies (IST)—the trailblazer behind the disruption—created ripples with its new design for rigid containers where the size, positioning, and filtering vent configuration led to the FDA clearance. ONE TRAY® rigid containers for terminal sterilization of medical devices is IST's flagship product offering in the sterilization field. "Packaging systems with storage are considered as a terminal sterilization product, while those without storage are defined by industry as IUSS," explains Harmer, director of clinical services, IST. Meeting the industry's definition of terminal sterilization, the ONE TRAY® product line is a harbinger of Harmer's vision to provide a single standard of care for all patients.

Harmer summarizes the features of ONE TRAY® containers using 3Es—Efficiency, Effectiveness, and Economics. The product's major push for economic viability comes from the elimination of dry time and cool time during the sterilization of medical devices, which significantly reduces the use of water

and power. The absence of dry and cool times enables medical devices to be processed in shorter timeframes. With regulations no longer encouraging IUSS, "ONE TRAY® can produce a terminally sterilized product in approximately the same time as IUSS," says Harmer, adding that faster sterilization voids the need for hospitals to invest in additional surgical instruments. The absence of idle time when using ONE TRAY® drives better employee productivity as staff members could be deployed for activities such as preparations for surgeries, equipment maintenance, or quality control. Furthermore, given the reduced use of sterilizers, the maintenance required for sterilizers can be significantly lower, making the use of a ONE TRAY® economically feasible.

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ONE TRAY® containers make an incredible difference in supply chain management as used containers can be sterilized and reused the same day to save the inventory space. The use of ONE TRAY® eliminates the ordering, stocking, and reordering of additional containers or instruments, thereby enhancing the ROI. IST also provides lifetime warranty



Barbara Ann Harmer

on its ONE TRAY® system. Products with concerns or issues can be returned to IST's manufacturing plant where they are repaired or replaced within a matter of days. Independent validation testing confirms that the superior delivery system of ONE TRAY®—a part of the packaging solution—prevents instruments from being exposed to environmental contaminants.

ASCs and hospitals can also use ONE TRAY® to sterilize their vendor-supplied trays with the added benefit of an incredible difference in the time factor. "Ten to fifteen trays that are ready for sterilization can be turned around in approximately 25 minutes, as opposed to standard packaging systems that take two to three hours," mentions Harmer. The ability of ONE TRAY® to deliver medical devices quickly helped several ASCs and hospitals eliminate IUSS for successful regulatory compliance.

Going forward, IST intends to increase its market share by catering to the pressing need for ASCs and hospitals to handle a larger volume of surgeries. As healthcare institutions seek to upgrade their sterilization process to comply with stringent regulations, ONE TRAY® is poised for greater market adoption. 