FDA Clears IST's ONE TRAY® for 365 Day Storage, Expanding Sterilization Flexibility for Surgical Facilities.

DAYTON OH – February 19th, 2026 - Innovative Sterilization Technologies (IST) announced today that the ONE TRAY® sterilization container has received a second clearance from the U.S. Food and Drug Administration (FDA), significantly expanding its use across hospital and surgical facility workflows.

ONE TRAY®'s original clearance in 2006 **(IFU K052567*)** included sterilization at 270°F (132°C), Exposure Time 4 minutes, Cycle Dry Time Not Required and validated to maintain the sterility of the contents for up to a 48 hour storage period.

ONE TRAY®s NEW additional clearance in 2025 (**IFU K250029****) maintains the same validated sterilization parameters - 270°F (132°C), Exposure Time 4 minutes, but with a 365 day event related shelf life/storage period with a 15 minute minimum dry time.

When introduced in 2006, ONE TRAY® represented a new approach to sealed sterilization container technology. Now, according to Barbara Ann Harmer MHA, BSN, RN, Vice President of Clinical Services at IST, the expanded storage window provides facilities with even more operational flexibility.

"The additional storage time gives the surgical department an alternative when unforeseen problems arise in the operating room," Harmer said. "Those surgical delays often ripple far beyond the OR."

"When patients arrive for surgery, they've already prepared, food and medications withheld, family schedules arranged, anxiety managed," she said. "If the schedule is seriously disrupted, so are their lives. ONE TRAY® provides two solutions to keep everything on track. If the instrumentation is available, we are the fastest option to maintaining the schedule."

"With the rising cost of healthcare, everyone is being asked to do more with less," President and CEO of IST Tim Tzimas said. "The dual FDA clearances improve efficiency across the entire chain of custody in the sterilization process - an increasingly important factor as healthcare systems face mounting costs and staffing pressures. It truly offers a total solution and total flexibility to respond to clinical urgency, optimize inventory, and standardize sterilization processes using a single, reusable sealed container platform."

IST encourages hospitals and surgical facilities to reach out to Barbara Ann at bharmer@onetray.com or 407-709-7209 for any questions related to the application of the new FDA clearance, in their facilities.

You can also visit onetray.com/ifucomparison to learn more about each IFU.

* Reference 510k summary- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052567

** Reference 510k summary- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K250029