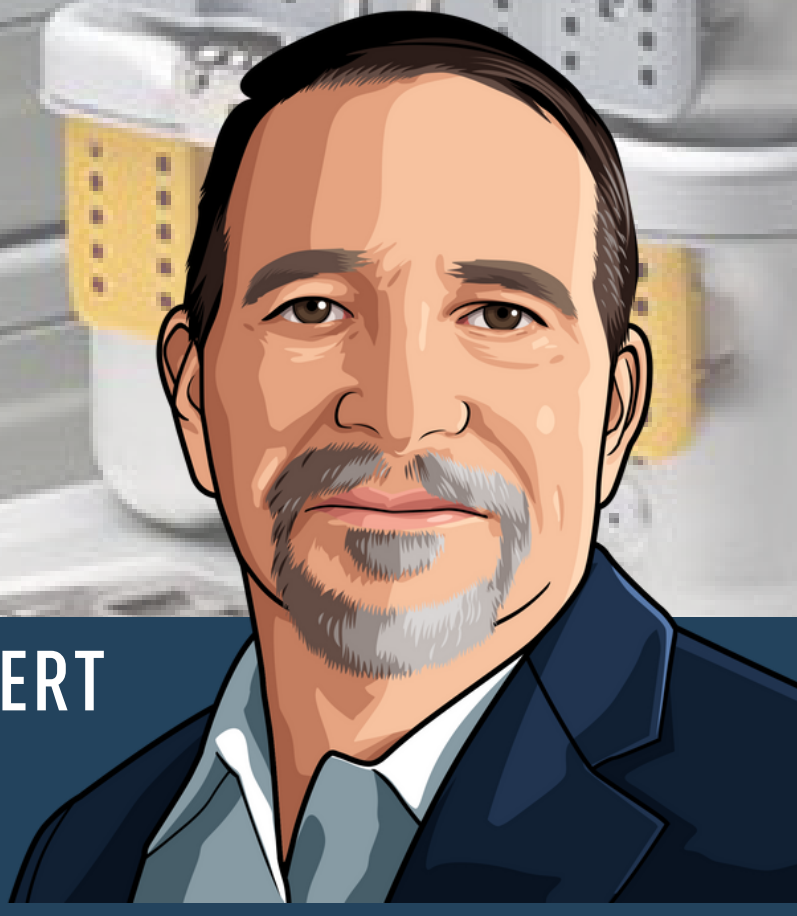
CONSIDERATIONS FOR SHELF LIFE



STERILE CONTAINERS EXPERT

BEYOND CLEAN

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Beyond Clean Sterile Containers Expert™:

CONSIDERATIONS FOR SHELF LIFE

Mike Strand | Retired Regional Sales Director, Aesculap

The sterile-barrier manufacturer's Instructions for Use (IFU) will always be the first 'go-to' for understanding the shelf life for sterilized items. Whether it is a sterilization container, blue flat wrap, or a peel pouch, the FDA requires that those manufacturers have tested and validated their packaging and will provide direction on shelf life.

The two considerations for shelf life are:

·Expiration Date – A time-related, shelf-life practice whereby a specific timeline is identified by the packaging manufacturer or by the hospital's policy and procedure, and an expiration date is labeled on the packaging at the time of sterilization in SPD. While an expiration date is specified on the packaging, the date is not the only determining factor for sterile efficacy. The more an item is handled, including moving, examining, transporting, etc., the higher the likelihood that packaging can become compromised. Additionally, poor storage configurations can negatively affect sterile package integrity.

·Event-Related Practice – In essence, the sterilized item should remain sterile unless an "event" occurs that could compromise the sterile barrier. An event may include a tear or hole in the packaging, exposure to moisture, improper stacking, missing tamper-evident device, wide swings in humidity, improper air flow, among others.

Whether a hospital employs an Expiration Date policy or adheres to an Event-Related policy, there are a number of guidelines that are important to follow to ensure sterile integrity of items on the shelf. AAMI identifies proper shelf clearance from floor and ceiling, notes temperature parameters, recommends systematic monitoring of HVAC performance in SPD, recommends daily SPD cleaning (including vents and ceiling tiles). AAMI's ST-77 and ST-79 industry standards will identify and provide guidelines on rigid containers and steam sterility and assurance, respectively. Together with Risk Management and Infection Prevention, Sterile Processing can develop industry best practices that are AAMI compliant.

Have more sterile container questions? Contact Mike at: mike.strand@aesculapusa.com

Beyond Clean Sterile Containers Expert™ Biography:

MIKE STRAND

RETIRED REGIONAL SALES DIRECTOR

AESCULAP®

Michael started his medical device journey in 1984 and has spent most of his career in Sales and Sales Management in the Pacific Northwest. The past 31 years have been with Aesculap, based in the Seattle area. Currently, Michael is Aesculap's Northwest Healthcare Solutions Regional Sales Director, responsible for 9 Sales Representatives and company growth.

With years of experience, Michael enjoys solution-oriented projects that create efficiency and focuses on industry standards and best practices. A passion for education and teaching keeps Michael engaged with Sterile Processing Departments and Operating Rooms, as well as new hires within his organization.

Aesculap is an industry leader in Surgical Instruments, Sterilization Containers and Technical Repair Services. Helping hospitals Operate with Greater Precision, Aesculap's products and services assist with enhanced Patient Outcomes, create Operational Efficiency, enable Sustainability initiatives, and provide Clinical and Staff Satisfaction.

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