

# WHERE'S MY INDICATOR?

INSTRUMENT PROTECTION EXPERT

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Craig Ford | Founder & President SterileBits

*Beyond Clean Instrument Protection Expert:*

## WHERE'S MY INDICATOR?

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Sterility indicators are everywhere...and nowhere.

Every facility uses some form of process indicator to sterilize and store instruments. These chemical indicators are usually placed inside the sterilization package, but they also are sometimes integrated into or printed on products and packs themselves. Examples of integrated chemical indicators include sterilization tape, indicator dots on sterilization filters, and indicator dots on instrument protectors. Chemical indicators commonly have an area that changes color based on exposure to the sterilant. There is a standard for indicator requirements, but not specific to each vendor, and therefore no real standardization on what indicators will look like.

To that end, some products have integrated indicators. Having an indicator integrated onto the product creates an expiry date for that product. With many facilities following an event-related sterility policy, the facility will need to pay attention to the expiration dates of their sterilization packaging and determine how that expired product may affect the sterility of the product.

Even if indicators were integrated into or printed onto a product (limiting the shelf life), the hospital staff along the continuum of surgical care generally do not use that integrated indicator as their qualifier for determining sterility. More commonly, the internal, "free-floating" indicator that is placed into the package by SPD is what is scrutinized by the staff checking or opening the products. Rather than adding more integrated indicators, perhaps a better pursuit would be making the internal indicator easier to access and identify for the OR staff.

Any inserted indicator must remain visible to everyone who will handle or use the instrument, but those internal indicators have a way of falling behind the instrument in a peel pack or get buried in the bottom of the surgical tray. This poses a challenge for the scrubbed team in validating sterility before introducing it to the sterile field, since they cannot easily see and confirm that internal indicator. Having a standard place to secure the indicator in the proper place within the package can help alleviate these concerns without unnecessarily adding an expiration date to the set.

Have more instrument protection questions? Contact Craig at: [craig.ford@sterilebits.com](mailto:craig.ford@sterilebits.com)

*Beyond Clean Instrument Protection Expert Biography:*

**CRAIG FORD**

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Craig Ford is the Founder and President of SterileBits, Inc., a boutique company specializing in the design and manufacture of sterility assurance consumables and products used in surgery. SterileBits utilizes a virtual business model that offers a more cost-effective approach to product development. In order to eliminate waste, improve quality, and reduce costs, SterileBits created a team of clinicians, engineers, medical device packaging, manufacturing and operations specialists that operate remotely.

Combining the core competencies and vast experience of its team, with outsourced ISO certified and FDA registered suppliers, SterileBits can deliver high quality products and much needed savings to the healthcare supply chain.

Having stood in surgery for 20 years as a sales rep and distributor of spinal implants, Craig believes in listening to clinicians and technicians to make healthcare better. “New products don’t always have to be disruptive or come from big companies. Sometimes a small change to an old standard is the best way to go.” SterileBits feels this consultative approach to product development coupled with a virtual business model is the future. Their goal is to reduce costs and create lasting value for both the providers and patients.

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