

Beyond Clean Instrument Protection Expert:

CAN WE HANDLE THE TRUTH?

Craig Ford | Founder and President, SterileBits

A few years ago, we conducted a study with the V.P. of The Musculoskeletal Infection Society, Dr. Antonia Chen, and Noreen Hickok, a PhD Chemist. The doctors designed the protocol and conducted the study at the Rothman Orthopedic Institute. The study compared the sterility of orthopedic drill bits in their reprocessed consigned trays to prepackaged sterile drill bits.

In each of 4 separate test events, 25% of the drill bits pulled from consigned trays had living fungus and bacteria on them.

What does this tell us? Does it mean that steam sterilization doesn't work or that blue wrap and sterilization containers don't work? Does it mean the manufacturers' IFU's are incorrect? Or perhaps the life of a sterilized instrument is just unpredictable once it leaves the sterilizer and sterility is not guaranteed?

Who knows? But data is data, and the quality of our data cannot be disputed. Maybe there should be more testing like the one in our study. Not just looking at a sterilization indicator to verify sterility but testing random lots of instruments post cycle. Until the mystery is solved, we must do everything we can to protect an instrument during and after sterilization so that it arrives to the surgeon's hands sterile.

When using peel packs, I suggest adding instrument protectors. Adding structure to the pack helps maintain the integrity of the sterile barrier. They help protect the seals by keeping an instrument immobile. They prevent crushing/creasing during storage, handling and transport. Well-designed instrument protectors allow for more sterilant contact and facilitates heat transfer, giving the instrument a better chance at getting (and staying) sterile in the first place.

(A summary of the study results can be found at www.sterilebits.com)

Have more instrument protection questions? Contact Craig at: craig.ford@sterilebits.com







Craig Ford is the Founder and President of SterileBits, Inc., a specializing in the company 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 engineers, medical device packaging. clinicians. 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.

