

## STERILIZATION STRAIGHT TALK

# Conquering the Complexity of Sterilization Instructions for Use

Weston Balch

### About the Author



Weston "Hank" Balch, CRCST, CIS, CHL, is the director of sterile processing operations for University Health

System in San Antonio, TX, and cofounder and host of the Beyond Clean Podcast. Email: [hank@beyondclean.net](mailto:hank@beyondclean.net)

*Editor's note: This article marks the debut of Sterilization Straight Talk, a column that will focus on sterilization and sterilization-related topics.*

Whether you are a new leader taking over a bustling sterile processing department, a frontline technician handling a new loaner tray, or an infection control professional ensuring that your facility is setting the standard for industry best practice, instructions for use (IFUs) will be integral to your efforts.

But simply knowing you should follow IFUs when it comes to surgical instrument sterilization does not answer some of the common questions regarding how to start this process, what needs to be included in building a quality IFU program, or the pitfalls you may encounter along the way. Many times, department leaders can be left drowning in a sea of complex, and sometimes divergent, sterilization instructions from a myriad of manufacturer sources, all while trying to keep an already active surgery schedule afloat. Best practice ends up being more like "the best that we can do," and compliance gives way to complacency.

The good news is that there are answers to these challenges, and conquering the complexity of sterilization IFUs is possible. Here is how to get started.

### From Zero to 60 (Minutes)

The first step in overcoming the challenges of sterilization IFUs starts with identifying the three general categories of IFUs with which you need to be familiar: 1) instrument instructions, 2) packaging instructions, and 3) sterilizer instructions.

Instrument IFUs will outline the particular packaging and sterilization modalities (including cycle/dry times) for which the device has been validated. Packaging instructions will give their own clarifications on compliant accessories that can be used (e.g., specific locks, filters for rigid containers) and particular storage requirements (e.g., stacking prohibitions, shelf life). Sterilizer instructions will outline proper testing protocol, loading procedures for the units, and load weight restrictions. Sidestepping any one of these manufacturer's instructions can put your entire sterilization process at risk—whether it's how instruments are packaged, which sterilizer they go into, or how they are prepped for sterilization. These three categories of IFUs will create the foundation for the rest of your quality sterilization program.

### Improvement in the Middle of a Surgical Storm

As mentioned above, most sterile processing leaders do not have the luxury of shutting down the operating room (OR) for a couple of weeks to verify whether all aspects of

## Features

sterilization IFUs are rock solid. The expectation is that your processes are already correct—and if they are not, they must be fixed on the fly. This can cause a number of practical issues that must be confronted for your quality sterilization program to be successful.

First, the culture of trusting the status quo of your sterilization procedures should be replaced with frontline technicians who are empowered by department leadership to use critical thinking to question IFU compliance. Reprocessing personnel should be encouraged to scrutinize current processing procedures and receive answers that are backed up by information from the device or product manufacturer.

On this point, it is important to confront the complacency that can creep in when IFUs are made readily accessible in a department but are not regularly accessed by processing staff. Services that make IFU databases available online are helpful, but compliance is not merely having access to IFUs for processing. True compliance means ensuring that consistent application of IFUs actually happens on a daily basis.

In addition to developing a culture of “why” among your sterile processing team, the second step to creating a quality sterilization program is rewarding those technicians who identify an area of noncompliance in your current workflow. This can be anything from finding out a certain scope is not rated for steam sterilization to identifying the need for a different brush size in the decontamination stage. Your frontline team should be incentivized to constantly be on the lookout for opportunities to increase compliance across the entire scope of a sterilization workflow. These “good catches” can be recognized and rewarded at daily huddles, weekly staff meetings, or via email to sterile processing/OR peers.

## Hardwiring Compliance

After a department’s culture has shifted to question the status quo of instrument processing procedures and is incentivized to dig into existing IFUs, the next step is to hardwire this commitment to compliance into the current sterilization workflow.

If an instrument-tracking system is already being used, the specific instructions for sterilization should be tied to each unique product in the tracking system database so that technicians do not need to rely on memory or repetition to properly process each tray. Oftentimes this means the sterilization modality will be listed via on-screen assembly and printed out on barcodes or paper count sheets. As mentioned previously, though, sterilizer and cycle type are not the only data points necessary to hardwire processing compliance. Technicians also need to know what type of packaging method is allowed (wrap vs. container vs. peel pack) and whether other specific exceptions are included in the instrument’s IFUs. Listing this information on the count sheet or label is a critical aspect of both encouraging and enabling compliance on your team.

In departments without an automated tracking software, these IFU particularities should be clearly identified on permanent tray labels, at the assembly tables, and at the sterilization workstation, so that technicians can quickly and easily make correct, compliant processing decisions. Any opportunity you can take to move away from solely relying on experienced technicians acting as the keepers of processing knowledge for your team is a step in the right direction. Every technician should be comfortable and confident in his/her ability to read and understand equipment, device, and supply IFUs.

## Conclusion

Although certain sterilization workflows are more *common* than others, currently there are no *standard* workflows for how an item should be prepped, packaged, and processed. As new surgical technologies become more complex, we can assume that the complexity of sterilization IFUs also will increase. Therefore, success in sterile processing will depend on proper IFU knowledge by frontline technicians, a safe and rewarding culture of asking “why,” and a program for integrating specific manufacturer’s instructions into concrete processing steps. Taken together, these commitments will help your team conquer complexity in the name of compliance. And that’s one outcome where everyone wins. ■

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