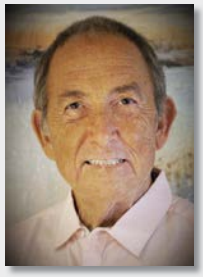
SUBMIT YOUR QUESTIONS: **editor@hpnonline.com**



Removing biofilms; using indicators in sterilization assurance

by Ray Taurasi, MBA, CRCST, CHL, FCS, ACE, Principal, Healthcare CS Solutions

Q Over the past few years I have heard a lot about biofilms and how bad they are in sterile processing, but I have to admit I really don't understand what they are or why they are so bad for us. I have worked in sterile processing for over 20 years and now we have biofilms to worry about. Why is that and what's next?

A Over the years we have made many scientific discoveries and advances and have developed lots of new technologies that have changed and improved the way we do things. While biofilms have existed forever, through more advanced study, we have learned more about them and how they can present a significant challenge to effective cleaning and sterilization.

So, what is a biofilm? Well, just as the name implies it is a biological film. This film, or slime, often consists of diverse colonies of tiny microorganisms bound together in a "matrix," or a thick, sticky substance. This "matrix" consists of both living and dead cells as well as polysacharides or carbohydrates.

Biofilms often are not detectable by touch or visible to the naked eye. However, in extreme cases and with multiplication, biofilms may become more visible and become slippery to touch. Biofilms form when single microorganisms attach to a hydrated surface and undergo a "lifestyle switch," giving up their life as a single cell to live on a surface in an adhesive cell formation (matrix) with other microorganisms.

When soiled medical devices and surgical instruments are left for prolonged periods of time soaking in water or a water-based substance, the formation of biofilm is likely (see figure 1). Biofilms can irreversibly attach to the surfaces of these medical devices and instruments and, once attached, it is extremely difficult and very challenging to remove them. Our standard cleaning protocols may not be effective. If biofilms are not thoroughly removed, they will present a barrier to intimate disinfectant and or sterilant contact, resulting in processing failures and the potential for cross contamination and transmission of infectious agents, placing patients at risk.

Figure 1: 579 x 326 magnification biofilm on medical device

Q I am a second-year nursing student and have been working part time in sterile processing. I recently listened to a podcast on sterilization quality control. I believe I heard one of the speakers say that neither a chemical indicator nor biological indicator ensure that the contents of a sterile package are sterile. I, as well as my co-workers, found his comment very confusing and contradictory. How can a "sterile package" not contain sterile items? If that were so, it would not be a sterile package. Further, why do we use these indicators and tests if they cannot ensure the items are sterile?

A The sucess of a sterilization process is dependent on many factors. Foremost, the sterilizer must be functioning properly, and the sterilization cycle must meet the required conditions and sterilization parameters of proper steam, temperature, pressure, and time; together these elements assure the effectiveness of this sterilization process.

Figure 2

Type 1: Process	One or more critical variables in the sterilization process The unit has been exposed to the sterilization process	Autoclave tape or chemical indicator strips Located inside or attached to the outside of packs
Type 2: Specific-Use	Defined in relevant sterilization standards for specific test procedure	Test air removal in a prevacum steam sterilization cycle
Type 3: Single-Variable	One critical variable in the sterilization process Exposure to a sterilization process at a stated value (SV) of the variable	Demonstrates the steam sterilization process has achieved a specified temperature
Type 4: Multi-Variable	Two or more critical variables in the sterilization process Exposure to a sterilization cycle at stated values (SVs) of the variables	Change color only when exposed to a given temperature for a specified time in a steam sterilization application
Type 5: Integrating (Integrators)	All critical variables in the sterilization process Stated values (SVs) meet or exceed performance requirements in the ISO 11138 series for biological indicators	Respond to all critical process parameters
Type 6: Emulating (Cycle Verification)	All critical variables for specified sterilization cycles Stated values (SVs) are generated from the critical variables of the specified sterilization process	Cycle-specific indicators Respond to all critical process parameters for a specified sterilization cycle

There are six different types of chemical indicators – each type monitors or measures one or more specific parameters or critical variables of the sterilization process (see figure 2). A biological indicator (BI) is a challenge test, which consists of vial that contains active spores. The BI is placed within the sterilizer and/or in containers and packages to be sterilized. Post sterilization and incubation, the BIs are evaluated to verify that the spores were adequately exposed to the required sterilization parameters and destroyed.

Chemical and biological indicators tell us that the sterilization parameters were achieved within the sterilization cycle, thus providing confidence that the conditions were adequate to sterilize all contents in the sterilizer, pending the efficacy of the human element performance, e.g. cleaning, following the device manufacturer's IFU, packaging, and loading the sterilizer. If there are failures in staff performance, it could be possible to have an unsterile item next to a passed BI in a sterile container or package. **HPN**