Delays in Endoscope Reprocessing

Endoscope reprocessing can be time consuming and technically complex. The average hands-on reprocessing time required for each endoscope is 76 minutes.\(^1\) Often, there are timing requirements for reprocessing set by the endoscope manufacturer. Olympus Corporation mandates a maximum delay of 60 minutes between precleaning and the start of manual cleaning.

### FDA Industry Guidance

- The United States Food and Drug Administration (FDA) requires medical device manufacturers to validate their device cleaning protocols using worst-case scenario testing as part of the 510(k) Premarket Notification process.\(^2\)
- Olympus designs their cleaning validation test protocols according to the FDA’s Guidance For Industry “Reprocessing Medical Devices in Health Care Settings: Validations Methods and Labeling”.\(^3\)
- This requirement encompasses the most challenging reprocessing situations and worst-case use conditions that may realistically be encountered during normal utilization of the device in a clinical setting.
- The FDA requires device manufacturers to take into account possible cleaning delays in order to best simulate worst-case use conditions.
- Together with the FDA, Olympus decided on a 60 minute dwell time to simulate worst-case drying of soils.

### Extended Soaking Results

- Olympus recommends performing an extended soaking procedure (often referred to as “presoaking”) when endoscopes dwell longer than 60 minutes after precleaning.
- This procedure consists of soaking the endoscope in detergent solution until visible debris is loosened from the exterior of the endoscope.
- Extended soaking can loosen dried and hardened debris making manual cleaning, high level disinfection, and sterilization more effective.
- Failure to loosen and remove dried bioburden from an endoscope encourages the formation and growth of biofilms and is an infection control risk.
- This procedure is not intended for routine use and should be utilized only when necessary.

### Patient Safety Concerns

- Any delays in the reprocessing journey can impair the efficacy of the decontamination process.
- Dried debris is difficult to remove during the cleaning process.
- Initial adherence of bacteria to a surface is the first stage of biofilm formation. This stage can happen quickly but can be reversed with timely manual cleaning.\(^4\)
- When endoscope dwells >60 minutes after precleaning
  - Failure to loosen and remove dried bioburden from an endoscope encourages the formation and growth of biofilms and is an infection control risk.
- Failure to adhere to the endoscope manufacturer’s reprocessing protocol and delaying the cleaning of endoscopes without proper remedial action encourages biofilm growth, compromises patient safety, and is an infection control issue.

### References