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 mandates a maximum delay of 60 minutes between precleaning and the start of manual cleaning.

Together with the FDA, Olympus decided on a 60 minute dwell time to simulate worst-case drying of soils.

FDA Industry Guidance

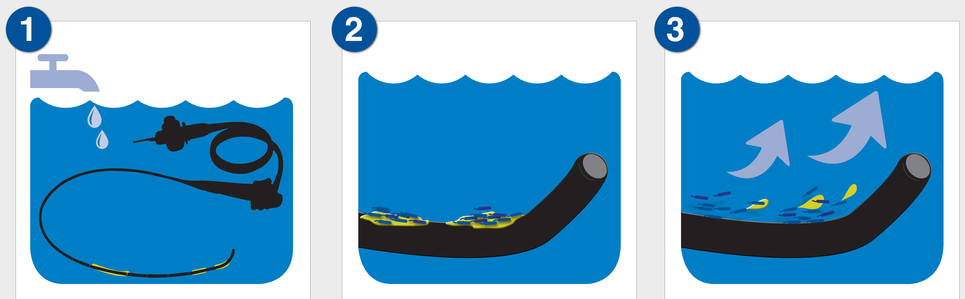
- The United States Food and Drug Administration (FDA) requires medical device manufacturers to validate their device cleaning protocols using worst-case scenario testing as part of the 510(k) Premarket Notification process.[2]
- Olympus designs their cleaning validation test protocols according to the FDA's Guidance For Industry "Reprocessing Medical Devices in Health Care Settings: Validations Methods and Labeling".
- 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.**
- As a result, the validated reprocessing instructions provided with each Olympus endoscope take into account a 60 minute maximum delay between precleaning and manual cleaning.

Extended soaking loosens dried and hardened debris making manual cleaning, high level disinfection, and sterilization more effective.

Extended Soaking Results

- **Olympus recommends performing an extended soaking procedure (often referred to as "presoaking") when endoscopes dwell <u>longer</u> 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.

When endoscope dwells >60 minutes after precleaning



If endoscope is allowed to dwell for >60 minutes after precleaning, perform leak testing and then submerge endoscope.

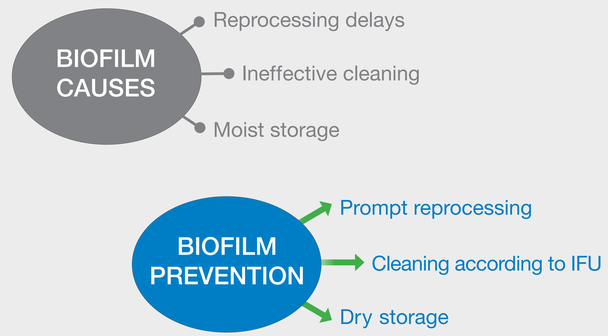
Soak for the amount of time indicated in the endoscope IFU.

Start manual cleaning with debris now loosened.

Any delays in the reprocessing journey can impair the efficacy of the decontamination process.

Patient Safety Concerns

- Any delays in the reprocessing journey can impair the efficacy of the decontamination process.[3]
- 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.[4,5]
- If this initial biofilm is not removed and the endoscope is subjected to repeated use and reprocessing cycles, the biofilm can mature and become irreversibly attached.[5,6]
- **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

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