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A comprehensive report of differences and similarities on guidelines and standards on how to reprocess reusable medical devices by professional standard healthcare organizations, societies and government agency

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With the large number and variety of GI endoscopes procedures carried out, the documentation of infectious problems remain uncommon, with an estimated occurrence of 1 in 1.8 million procedures. Despite strong data regarding the safety of endoscope reprocessing, clinicians' concerns about the potential for pathogen transmission during endoscopy have raised questions about the best methods for disinfection or sterilization of these devices between patient uses.

To date, all published incidences of microorganism transmission related to GI follow established manufacturer instructions for use for cleaning and disinfecting reusable medical devices. Another problem is that manufacturer's instructions for use are hard to follow and understand. However professional healthcare standards organizations, societies, government agencies and accredited organization such as the joint commission do recommend that user follow manufacturer instructions for use.

According to the Food and Drug Administration "reuse" refers to the repeated use or multiple use of any medical device. Reprocessing includes all steps performed to make a medical device previously used on one patient ready for use on another patient.

Biography

Elijah N. Wreh has a Master of Science Degree in Regulatory Science from the University of St. Thomas. In 2011, the Medical Device Fellowship Program (MDFP) appointed him as a staff Fellow in the Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration (FDA). He is a Regulatory Affairs Specialist at Stryker Orthopaedics and president of Wreh Regulatory Affairs Consulting.

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