Olympus Service: Beyond What You Can See

Unmatched Protection with Reprocessing Validation

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What is Reprocessing Validation?

- **Reprocessing** is the validated process by which a contaminated reusable medical device is rendered safe for subsequent use. This process typically includes cleaning, disinfection, and/or sterilization in order to remove soils and inactive microorganisms.
  (FDA Guidance Reprocessing Reusable Medical Devices March 17, 2015)
- **Validation** is scientifically proven methodology used to ensure that a contaminated reusable medical device can be rendered safe for subsequent use. The FDA requires reprocessing validation data to be submitted as part of the 510(k) premarket notification process. This process demonstrates that a device is safe and effective for clinical use, and must be completed successfully before a device is able to be legally sold in the United States.

Why is Reprocessing Validation Important?

Reprocessing validation ensures that a reusable medical device can be safely used on multiple patients. It is your facility's responsibility to follow the reprocessing instructions within the IFUs for each endoscope.

Important:
It is your responsiblty to follow the reprocessing instructions within the IFUs for each endoscope!

Reprocessing Instructions for Olympus Endoscopes with Third-Party Repairs

Olympus 190 Endoscope Reprocessing Manual States:

"Instructions provided in this manual are not valid for Olympus devices repaired by a non-Olympus facility. The Olympus recommended reprocessing procedures have not been validated for reprocessing devices repaired by non-Olympus facility.

Once repaired and modified by a third-party repair company, Olympus can no longer guarantee the reprocessing instructions are still valid.

- Olympus does not have any knowledge of the parts and materials used or the final quality of the repair being provided by third-party.
- Instruction provided in the product-specific instruction manual are not valid for Olympus equipment that has been repaired by third-party.

Olympus and other major AER manufacturers all have the same response regarding third-party repairs and reprocessing validation.

- **Olympus states:** "The OER-Pro is not validated for high level disinfection of an endoscope repaired by a non-Olympus source."
- **Medivators states:** "We have been informed that some materials that are utilized in third-party repairs are not of the same specification as the OEM parts. Under these circumstances, Medivators cannot assume responsibility for inappropriate or incomplete disinfection due the incorrect repairs of the endoscope by a third party repair facility."
- **ASP states:** "ASP cannot guarantee the sterility or functionality of medical devices altered by a third party and then sterilized in STERRAD® System. ASP cannot guarantee that endoscopes repaired or altered by a third party or independent service organization and then processed in an EVOTECH® ECR will match the same parameters for cleaning and disinfection."

3rd Party Repairs Reprocessing Validation

OLYMPUS

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ASP®

OLYMPUS AMERICA INC.
3500 Corporate Parkway, PO Box 610, Center Valley, PA 18034

For more information, contact your Olympus sales representative, or call 800-848-9024.
www.medical.olympusamerica.com

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