



June 23, 2016

**IMPORTANT SAFETY NOTIFICATION -- UPDATED LABELING INFORMATION
NEW OPERATION MANUAL FOR THE OLYMPUS OER-Pro AUTOMATED ENDOSCOPE
REPROCESSOR**

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Dear Health Care Professional:

Olympus America Inc. (OAI) is writing to inform you that we are issuing an updated Operation Manual for the OER-Pro Automated Endoscope Reprocessor. The OER-Pro is intended for use in cleaning and high-level disinfection of Olympus flexible endoscopes, including duodenoscope models TJF-Q180V and TJF-160F/VF.

Olympus has previously notified TJF-Q180V and TJF-160F/VF duodenoscope users of updates to the duodenoscope reprocessing instructions, specifically the TJF-Q180V and TJF-160F/VF Reprocessing Manuals, to include a new warning requiring users to conduct duodenoscope precleaning and manual cleaning even when using an Automated Endoscope Reprocessor ("AER") that has instructions that may indicate a user could forego certain steps in precleaning and manual cleaning of the endoscopes.

Consistent with the Warnings added to the aforementioned Reprocessing Manuals, the OER-Pro Operation Manual has been revised to add a new Warning requiring users to conduct precleaning and manual cleaning as detailed in the duodenoscope's Reprocessing Manual(s).

Specifically, the new Warning, on pages 73 and 80 of the OER-Pro Operation Manual, states: "When reprocessing the JF-140F, TJF-140F, TJF-160F, TJF-160VF and TJF-Q180V duodenoscopes using the OER-Pro, conduct precleaning and manual cleaning as detailed in each duodenoscope's reprocessing manual." The new Warning has been added to the reference guide entitled List of Compatible Endoscopes/Connecting Tubes for the OER-Pro. Enclosed with this letter please find a new OER-Pro Operation Manual and a new List of Compatible Endoscopes/Connecting Tubes reference guide.

Action Steps:

Our records indicate your facility has purchased an OER-Pro. OAI requires you to take the following immediate action:

1. Olympus has discontinued previously distributed copies of the OER-Pro Operation Manual and List of Compatible Endoscopes/Connecting Tubes reference guide. Inspect your inventory of Operation Manuals and List of Compatible Endoscopes/Connecting Tubes reference guide and discard any existing inventory of OER-Pro Operation Manuals and List of Compatible Endoscopes/Connecting Tubes reference guides.

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2. Implement use of the enclosed OER-Pro Operation Manual, which contains the new Warning on pages 73 and 80.
3. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the requirement to perform precleaning and manual cleaning of Olympus duodenoscopes prior to placing the duodenoscopes in the OER-Pro for high level disinfection.
4. Additional copies of the new OER-Pro Operation Manual and List of Compatible Endoscopes/Connecting Tubes reference guide can be obtained by contacting our Technical Assistance Center at 1-800-848-9024, option 1, or by indicating on the enclosed questionnaire. Additional Operation Manuals will be mailed to your facility.
 - a. If you would like to download a copy of the new OER-Pro Operation Manual, please visit our OlympusConnect customer website: at <https://www.OlympusConnect.com> New users will need to register. Once registered select the Product Support button on the left navigation bar, select the [Instruction Manuals] button, locate the OER-Pro Operation Manual and select the [Download] button.
5. Please indicate on the enclosed questionnaire that you have received this notification. Fax the completed form to (484) 896-7128.

The U.S. Food and Drug Administration is aware of this action.

You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 Monday - Friday between 7AM EST - 8 PM EST. The TAC department can assist you in answering questions on the new OER-Pro Operation Manual.

Olympus fully appreciates your prompt cooperation in addressing this situation.

Sincerely,



Laura Storms
V.P., Regulatory Affairs & Quality Assurance

