



February 24, 2016

ATTENTION: Endoscopy Department, Infection Control and Reprocessing Units

RE: Approval to use ALDAHOL[®] 1.8 when reprocessing TJF-Q180V scopes in the OER-Pro

Dear Health Care Professional:

On February 22, 2016, the FDA agreed to grant Olympus permission to remove the statement that only Acecide-C[®] High Level Disinfectant is validated for reprocessing the TJF-Q180V duodenoscope in the OER-Pro Endoscope Reprocessor. This means that ALDAHOL 1.8 High Level Disinfectant is now approved to reprocess the TJF-Q180V in the OER-Pro.

Our records indicate that you have an OER-Pro Endoscope Reprocessor at your facility which uses ALDAHOL 1.8 High-Level Disinfectant. Olympus is notifying you that you can re-institute the use of ALDAHOL 1.8 in your OER-Pro to reprocess the TJF-Q180V

If you chose to have one of your OER-Pros converted from ALDAHOL 1.8 to Acecide-C as a result of the corrective action, Olympus will convert your unit back to ALDAHOL 1.8 at no charge.

Olympus will provide two cases of ALDAHOL 1.8 and one box of Aldechek Test Strips for each OER-Pro converted. You will be requested to provide a \$0.00 PO in order to execute the service and receive the items. You will not incur a service charge for this change.

Item Number	Description	Qty	List Price	Your Price
ALDAHOL1.8	ALDAHOL1.8 High Level Disinfectant (4btl/case)	2	\$129.00 ea	\$0.00
ALDECHEK	Aldechek Test Strips – ALDAHOL 1.8 HLD	1	\$116.00 ea	\$0.00

Olympus Field Service Engineers will reach out to you schedule a convenient time for this conversion. Olympus recommends coordinating the conversion to coincide with the depletion of your Acecide-C inventory.

While it is not yet posted to the FDA website, Olympus expects an update shortly indicating that Olympus submitted adequate test results for reprocessing of the TJF-Q180V in the OER-Pro Endoscope Reprocessor using Acecide-C and ALDAHOL 1.8 High Level Disinfectants.

As a reminder, the TJF-Q180V 510(k) clearance on January 15, 2016, there were changes in the reprocessing methods used for the TJF-Q180V. **Olympus will be sending updated TJF-Q180V Reprocessing Manuals in March 2016.**



Please note Olympus will determine if the provisioning of these items at no charge will require Olympus to report the exchange of value to the Centers for Medicare and Medicaid Services (CMS) per the Federal Open Payments Regulation. Additionally, this action constitutes a discount or reduction in price for the above items. Customers are obligated to properly disclose and appropriately reflect the net value or reduced prices of these items on applicable cost reports or in charges to Medicare, Medicaid, and other federal health insurance programs or state health insurance programs in accordance with Section 1128B(b)(3) of the Social Security Act, 42 U.S.C. §1320a-7b(b)(3).

This offer is available for any OER-Pro that was switched to Acecide-C as a result of the voluntary corrective action in January 2016.

This offer is available until September 30, 2016.

We thank you for your patience and understanding during this process.

Sincerely,

Olympus America Inc.