

Aug X, 2014

URGENT: Field Safety Corrective Action

Attention:

Re: EVIS EXERA II DUODENOVideoscope TJF-Q180V

Dear Customer,

Recently Olympus has received a few complaints of residual debris in the distal end of the TJF Q180V duodenoscope after reprocessing. Olympus is always very concerned about patient safety issues including the prevention of cross infection among patients through endoscopy.

As a result of our complaint investigations, Olympus has determined to revise our reprocessing instructions and recommends the use of an additional cleaning brush. The additional brush is the MAJ 1888. Olympus recommends brushing around the forceps elevator with the MAJ-1888 brush in addition to the existing MH-507 brush in order to adequately clean around the forceps elevator more thoroughly. The reprocessing manual was updated accordingly.

For a detailed procedure, please refer to the enclosed updated reprocessing manual.

OLYMPUS regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local vendor/OLYMPUS partner who will be delighted to support you or make the necessary arrangements.

Please fill out, sign and return the attached Reply Form to your local vendor/OLYMPUS partner.

Yours sincerely,

<Name>

<Position>

<Address>

<Contact information>

REPLY FORM

[Dept/Attn]
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Technical Advice: Additional Cleaning Procedure of TJF-Q180V

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____