



Your Vision, Our Future

April XX, 2015

FIELD SAFETY NOTICE
REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF.Q180V DUODENOSCOPE

Dear Health Care Professional,

You may be aware of the recent patient infections with multi-resistant bacteria in the United States following ERCP procedures involving duodenoscopes, including the OLYMPUS model TJF-Q180V Duodenoscope ("TJF-Q180V").

On March 26, Olympus America Inc informed users about issuing new, validated reprocessing instructions for the TJF-Q180V. The US Food and Drug Administration (FDA) has reviewed these new reprocessing instructions and the validation data and recommends that any facilities that are using the TJF-Q180V train staff on the new instructions and implement them as soon as possible.

As part of our ongoing commitment to patient safety and the safe and effective use of our products, we would like to take this as an opportunity to encourage you to rigorously follow the current reprocessing instructions for the TJF-Q180V we have provided you within *<your market>*.

Please refer to the reprocessing manual and quick reference guides for more detail on the cleaning steps of brushing and flushing around the forceps elevator, actuation of the forceps elevator while submerged in detergent and raising of the forceps elevator to the intermediate position prior to disinfection.

In addition, we would like to remind you of the Field Safety Corrective Action from last year in which Olympus contacted all users of the TJF-Q180V to raise the attention for proper reprocessing of duodenoscopes, especially brushing of the forceps elevator.

The emergence of drug-resistant microorganisms is a challenge to the entire healthcare community. Olympus is globally working with relevant health authorities, medical societies and our customers in research of this emerging issue and will continuously strive to develop additional safeguards in order to prevent infection associated with endoscopic procedures such as ERCP.

For any further inquiries, please contact Olympus "subsidiary, name" at "xxxxxxxxxxx", to obtain more information or material.

Yours sincerely,

Olympus
Address



Your Vision, Our Future

Phone

Fax

Email

Attachment:

Customer letter from Olympus America Inc

REPLY FORM

Olympus Subsidiary/Distributor
[Dept/Attn]
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Field Safety Information: REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-Q180V DUODENOSCOPE

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 _____

Date Signature