

OLYMPUS

6. If you may have further distributed the TJF-Q180V, please identify your customers and notify them of this product recall and appropriately document your notification process.

Health Canada has been made aware of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to Olympus at OCI-Regulatory@Olympus.com or to Health Canada's Marketed Health Products Directorate Adverse Event Reporting program by e-mail, regular mail or by fax.

Olympus appreciates your prompt cooperation in addressing this situation. For any additional information on this matter, please contact OCI-TJFRecall@Olympus.com or call Cynthia Ow at 647-999-3203.

Sincerely,



Hirokuni Hibi
Executive Vice President
Olympus Canada Inc.



November 1, 2017

**URGENT MEDICAL DEVICE RECALL – Reply Form
REPAIRS FOR THE OLYMPUS TJF-Q180V DUODENOSCOPE**

I have received the Medical Device Recall Notification on the TJF-Q180V duodenoscopes referenced above. I understand my facility needs to immediately discontinue using the units specified below until they are inspected by Olympus.

I have reviewed the below list of units and identified the following serial number(s) at my facility as follows:

- The above applicable unit(s) is high-level disinfected prior to returning to OCI.
- Please send loaner(s) using PO
- Returns will be marked with “TJF Recall” on the outer package and paperwork. Send devices by collect shipment to the address in the footer of this letter.

Your Name: _____

Title: _____

Phone/E-mail: _____

Facility: (Please do not abbreviate) _____
If different from above

Address: _____

City: _____ Province: _____ Postal Code: _____

Please return the completed form to Olympus by e-mail at OCI-TJFRecall@Olympus.com.