

URGENT FIELD SAFETY NOTICE

RE: Careful Handling of Endoscopes to Prevent Damage and Performing Leakage Testing

Attention: Operating Room Manager, Risk Management Department and Reprocessing Units

	Model Name	Serial number
OLYMPUS EVIS EXERA DUODENOVideoscope	OLYMPUS TJF-Q190V	All
OLYMPUS EVIS LUCERA ELITE DUODENOVideoscope	OLYMPUS TJF-Q290V	All

Dear Health Care Practitioner,

Our early warning system has recently signaled an increase in the number of complaints from customers who noticed air leakage from the distal of the above model during leakage testing, even after only a short time of usage. Olympus is not aware of any adverse events associated with this matter and is carefully investigating this issue. In the interim, we are reminding you to regularly perform the leakage test as described in the instructions for use and not to use any duodenoscope which fails the leakage test. Please return such duodenoscopes to your local Olympus service.

In an effort to minimize the chance of physical damage on the distal end that leads to failing leakage test, Olympus is reminding our customers of the need for careful device handling in accordance with the warning that the operation manual provides as follows.

WARNING

- Do not strike, hit, or drop the distal end, insertion tube, bending section, control section, universal cord, or endoscope connector of the endoscope. Also, do not bend, pull, or twist the distal end, insertion tube, bending section, control section, universal cord, or endoscope connector of the endoscope with excessive force.

This Field Safety Notice pertains to the above-referenced Olympus endoscope models only. Our records indicate that your facility has purchased one or more of the model.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,



REPLY FORM – QIL 152-002

OLYMPUS URGENT FIELD SAFETY NOTICE OLYMPUS TJF-Q190V & TJF-Q290V	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Date]	
OLYMPUS Endoscopes affected Models (Please insert the quantities available in your facility in front of the Model Name)	
OLYMPUS TJF-Q190V	OLYMPUS TJF-Q290V

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of inspection of the Duodenoscopes prior and after every use.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX