June XX, 2017

URGENT SAFETY NOTIFICATION
IMPORTANT FIELD SAFETY INFORMATION FOR THE CF-Y0067-L

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Dear Health Care Professional:

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Colonovideoscopes CF-Y0067-L (EWAVE scopes). The Colonovideoscopes CF-Y0067-L are indicated for use in the lower digestive tract (including the anus, sigmoid colon, colon and ileocecal valve). Our records indicate that an affected CF-Y0067-L is located at your facility.

Olympus is requiring that you immediately suspend the use of all CF-Y0067-L. The reason is that the Instruction Manual for the CF-Y0067-L states that the CF-Y0067-L is compatible with the ETD2/3/4 system. Although Olympus has validated the manual reprocessing methods of CF-Y0067-L as described in its Reprocessing Manual, the compatibility between the CF-Y0067-L/I and the ETD2/3/4 has not been validated yet.

Please determine whether there are any reports of patient infection or other adverse events associated with your facility's use of this device after reprocessing with the ETD2/3/4. There have not been any reports of patient infections to date. Olympus has assessed the risk and determined that there is minimal risk to patients or users. Please report to Olympus if you are aware of any adverse events associated with use of this device. Although there is a potential risk of patient infection if a device has not been reprocessed effectively, Olympus has not received any report of infection with this device to date."

Please suspend use of all CF-Y0067-L devices and quarantine the devices. After Olympus has completed the validation testing to confirm compatibility, you will be contacted by Olympus. We expect that the testing will take approximately 3 weeks .

Action steps to be taken by the end user:

Our records indicate that you belong to a small group of customers who are using the CF-Y0067-L. **OLYMPUS requires you to take the following actions:**

1. Please suspend the use of the CF-Y0067-L. Please quarantine the devices in your possession.
2. You will be contacted by an Olympus representative who will provide additional information.
3. Please sign and return the enclosed reply form to [Olympus].

The [local / national Competent Authority] is aware of this action.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at (XXX) XXX-XXXX Monday - Friday or by e-mail at XXX for any additional information on this matter.

Sincerely,

REPLY FORM

Field Safety Information: **FOR OLYMPUS CF-Y0067-L/I**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**
[**Serialnumber/Lotnumber]**

We herewith confirm the receipt of your Field Safety Corrective Action [Olympus].

We will share this information with the relevant departments.

Name (Signature) _____

Name (Print) _____

Position _____