Reference: 2015-001W

Date: 8 Dec 2015

Dear Sir/Mdm,

FIELD SAFETY NOTICE: Medical Device Recall

Olympus Singapore Pte Ltd (OSP) is initiating a Field Safety Corrective Action triggered by our manufacturer, Olympus Winter & Ibe.

We are writing to inform you that we are implementing a removal action of the OLYMPUS ENDOEYE HD II video telescopes ("ENDOEYE") referenced below. The ENDOEYE video telescopes are used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including the female reproductive organs.

Model Number
WA50040A
WA50042A

OLYMPUS has initiated this removal action following a complaint of a damaged temperature sensor at the ENDOEYE tip which caused the distal end to become abnormally hot. Although no patient or user injury occurred as a result of this reported complaint, excessive heating of the ENDOEYE distal end could result in patient or user injury.

In an effort to prevent a potential risk to patient or user health, OLYMPUS is undertaking this action to remove the affected model and serial numbers and to repair and return the devices.

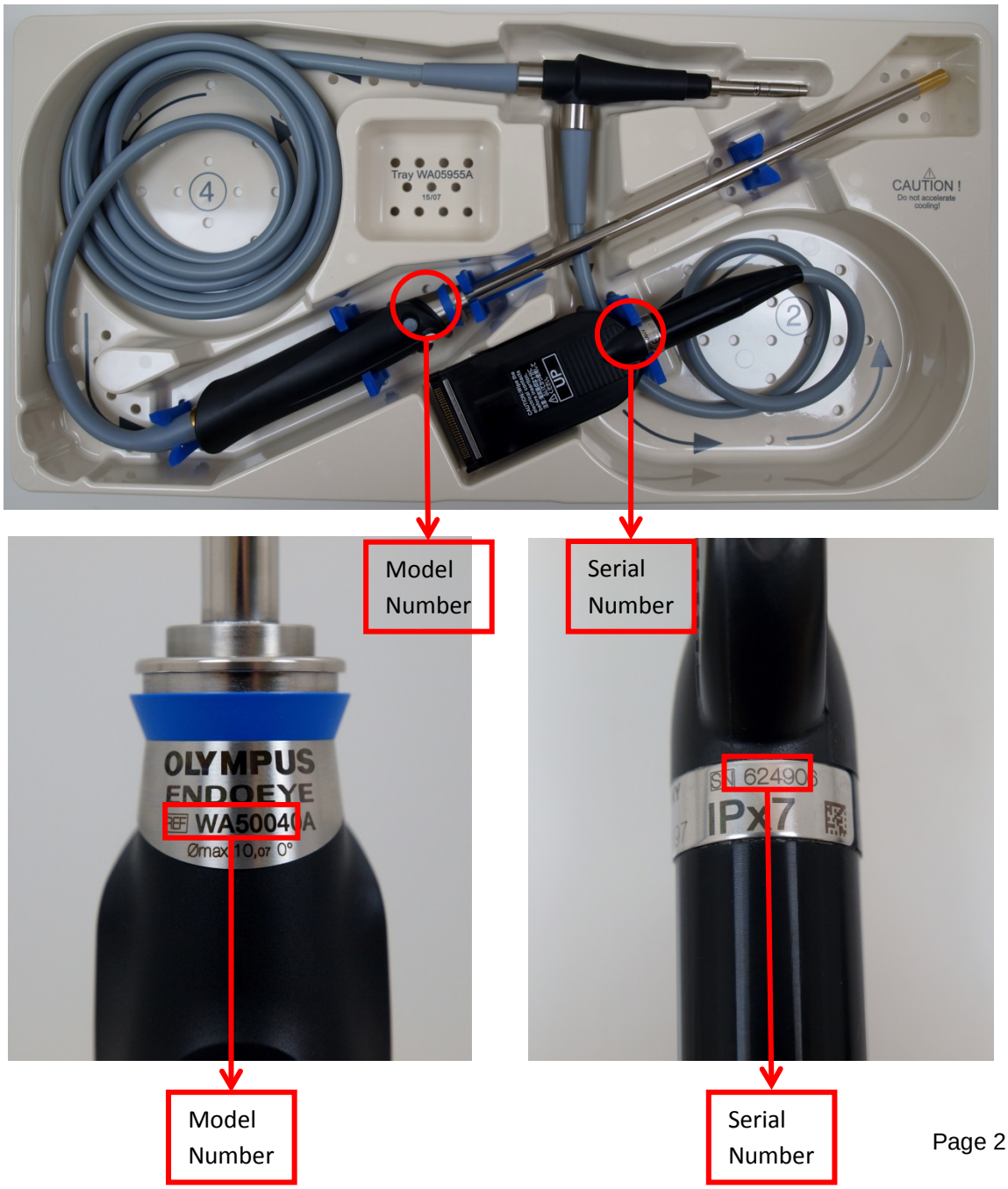
The repair to correct this problem will not be available until January 2016. However, we are requiring the return of your affected devices now so as to disable a feature on the video telescopes ("Fog Free") which will prevent excessive heating of the ENDOEYE distal end. Once the repair parts are available in January 2016, we will contact you again for return of your devices for the permanent corrective action.

Action Steps:

Our records indicate your facility has purchased one or more ENDOEYE with the affected serial numbers.

We request you take the following immediate action:

1. Inspect your inventory for the referenced devices and identify any of the specified OLYMPUS models and serial numbers identified above. The model and serial number can be found on the device as illustrated in the following pictures.



2. Discontinue use of any affected device identified in your inventory.
3. Retrieve the affected device from customer and return the affected device to OSP for repair.
4. Complete the Response Form with the necessary details of the affected models. You will be provided instructions on returning the ENDOEYE for repair and service.
    a. Option 1 for customer
        i. Inactivate the Fog-free function (Perform on-site or retrieve affected device)
        ii. Return the affected device to customer for their use
        iii. Retrieve the affected device and repair the device when the technical solution and repair parts are available
    b. Option 2 for customer
        i. Retrieve the affected device and hold the device until repair is completed
        ii. Provide a non-affected loan unit to customer until the technical solution and repair parts are available
5. Please note on the enclosed Response Form that you have received this important safety information and include the quantity of any affected device that you have identified.
6. Fax or Email the completed Response Form to OSP.

If you do not have any affected product left at your facility, please return the response form as this would preclude the need for further notices.

Olympus fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact us for more information.

Contact for enquiries
Regulatory Affairs Department
Email : mes-ra.osp@olympus-ap.com
Tel : 6833 4273
Fax : 6834 2438

We sincerely apologise for the inconvenience caused.

Thank you for your patience and support.

Yours sincerely,

……
Naoshi Kikumoto
Division Manager
Medical Business Systems Division

Enclosed: Response Form, Field Safety Notice

Response Form

To : Olympus Singapore Pte Ltd, Regulatory Affairs
Fax : 6834 2438
From : _____[Facility Name] Contact no.:_____
Date : _____
Ref : 2015-001W

Description

Product Name	ENDOEYE HD II video telescopes
Model No.	WA50040A / WA50042A

Serial No. of WA50040A / WA50042A in Facility	
Model	Serial No.

By signing below, the signatory documents that the facility has been dutifully informed of this Field Safety Notice and have inspected the inventory and quarantine any affected devices identified.

OLYMPUS will repair and service the video telescopes and return to your facility. You will be provided instructions on returning the ENDOEYE for repair and service.

Choose either A or B:

A) _____ I checked my inventory and do NOT have this device.

B) _____ I checked my inventory and I will return the following number of video telescopes:

_____.

Name: _____

Position: _____

…….. ……
Signature / Facility Stamp Date

Field Safety Notice

Commercial name of the affected product
ENDOEYE HD II video telescopes (WA50040A / WA50042A)

FSCA Reference: 2015-001W

Type of action: Medical Device Recall and Repair

Date: 08 Dec, 2015
Attention: Health Care Professionals, Distributors/Agents who utilize the products
Description of the problem:
Olympus Singapore Pte Ltd is retrieving the ENDOEYE HD II video telescopes (WA50040A / WA50042A) for repair and servicing. Due to complaint of a damaged temperature sensor at the ENDOEYE tip which caused the distal end to become abnormally hot. Although no patient or user injury occurred as a result of this reported complaint, excessive heating of the ENDOEYE distal end could result in patient or user injury.

Advice on action to be taken by the user:

1. **Inspect** your inventory of the affected devices
2. Discontinue use of any affected device identified in your inventory.
3. Return the affected device to Olympus
4. Complete and return the enclosed Response Form
5. Olympus shall return the affected device to you after the completion of the repair and servicing

Transmission of this Field Safety Notice:
This information in this notice is to be provided to surgeons, hospitals, distributors/agents and any medical personnel who utilise these products.

Contact reference person:
Olympus Singapore Pte Ltd
Regulatory Affairs Department
Email : mes-ra.osp@olympus-ap.com Tel : 6833 4273 Fax : 6834 2438

The undersigned confirms that this notice has been duly notified to the appropriate Regulatory Agency within Singapore (HSA).

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Naoshi Kikumoto
Division Manager
Medical Business Systems Division