Date: 5 May 2017

URGENT: MEDICAL DEVICE RECALL NOTICE

Action Identification Number: **242**

Type of Action: Medical Device Recall Notice

Affected Products:

Monopolar HF Resection Electrodes

Affected Part and Lot numbers:

Part Number	**Lot Number(s)**
A22201A	16242P03L001, 16242P03L002, P1690002, P1690008, P1690010, P1690001, P1690006, P16X0001, P16X0002, P16X0003, P1710004
A22201C	16124P03L001, 16144P03L002, 16144P03L003, 16155P03L001, 16155P03L001, 16174P03L001, P16X0001, P16X0002, P16X0004, P16Y0001, P16Y0002, P16Y0003, P16Y0005, P16Y0006, P16Y0007, P16Z0001, P176Z0003, P1710001, P1720002, P1720001
WA22037C	16195P04L001, P16Y0001

Dear Customer

Olympus is implementing a Medical Device Recall of the Monopolar HF Resection Electrodes referenced above. The electrodes are used for endoscopic diagnosis and treatment in urological and gynaecological applications.

Olympus has initiated this Medical Device Recall after receiving an increased number of complaints regarding loop wires breaking at the distal end of the referenced electrodes. Investigations have confirmed that loop wires can break during the intended use of the electrodes. As a result, a fragment may fall inside the patient and will need to be retrieved. Under certain circumstances, the retrieval of this fragment could require additional surgical treatment. Furthermore, the procedure can be prolonged resulting in extended anaesthesia.

There has been no report of an adverse event or patient injury. However, in an effort to prevent a potential risk to patient health, Olympus is undertaking this action to recall the model and lot numbers identified above.

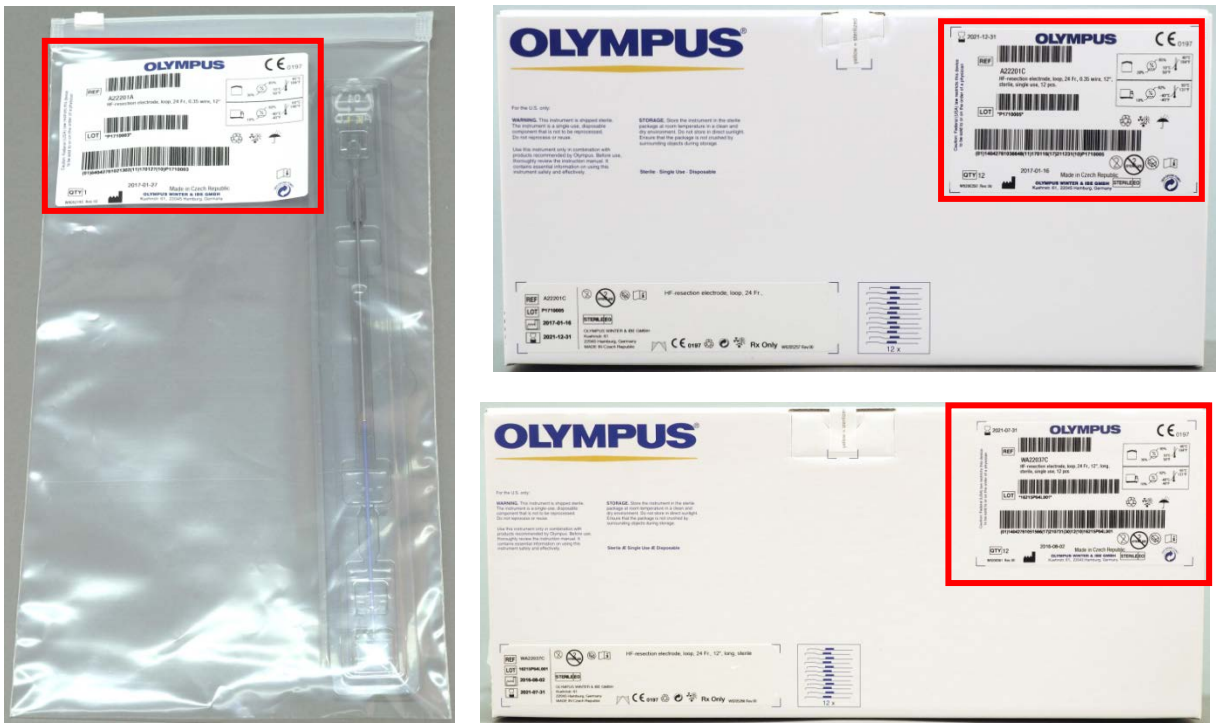
The investigation revealed that the loop wires of the affected electrodes were damaged during production. The cause of this damage is defective manufacturing equipment. The damaged loop wires cannot be detected by visual inspection.

<u>Action steps to be taken by the end user</u>:

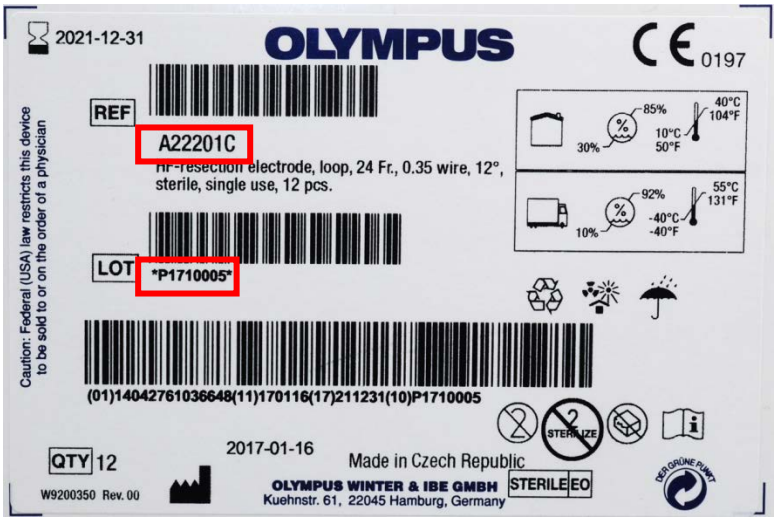
Our records indicate that your facility has purchased one or more of the affected electrode models with the lot numbers listed above. **Olympus requires you to take the following actions:**

1. Pass this notice to all those within your facility who need to be made aware of its contents;

2. Inspect your inventory for the referenced electrodes and identify any of the specified model and lot numbers identified above. The model and lot number can be found on the packaging labels as illustrated in the following pictures:



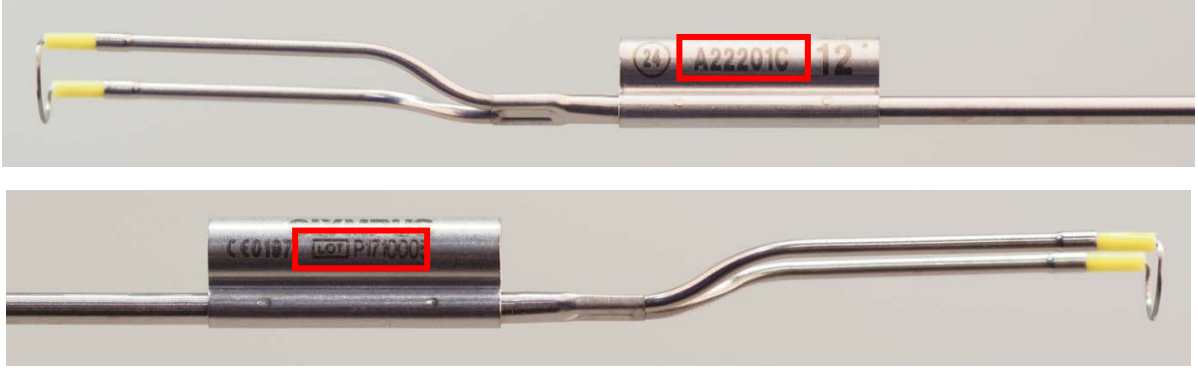
Pictures 1, 2 and 3: outer packaging of the electrodes



Picture 4: model (REF) and lot (LOT) number on the outer packaging label

Pictures 5 and 6: blister packaging of the electrodes

Picture 7: model (REF) and lot (LOT) number on the blister packaging label



Pictures 8 and 9: model and lot (LOT) number on the electrode

3. Cease any further use of affected products, remove them from your inventory and quarantine them until they are returned to Olympus;

4. Contact the Olympus Customer Care Department on 01702 616333. You will be provided with instructions on how to return the affected electrodes as well as getting free of charge replacement(s) or credit;

5. Please confirm you have received this information by completing and returning the attached Medical Device Recall Notice Reply Form. Please include the quantity of any affected electrodes you have identified in your inventory and intend to return.

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact the Olympus Customer Care Department on 01702 616 333.

Yours Sincerely

Robert Griggs

Quality and Regulatory Affairs General Manager

Enc. Medical Device Recall Notice Reply Form

Date: 5 May 2017

URGENT: MEDICAL DEVICE RECALL NOTICE REPLY FORM

Affected Products: **Monopolar HF Resection Electrodes**

Affected Part and Lot numbers:

Part Number	**Lot Number(s)**
A22201A	16242P03L001, 16242P03L002, P1690002, P1690008, P1690010, P1690001, P1690006, P16X0001, P16X0002, P16X0003, P1710004
A22201C	16124P03L001, 16144P03L002, 16144P03L003, 16155P03L001, 16155P03L001, 16174P03L001, P16X0001, P16X0002, P16X0004, P16Y0001, P16Y0002, P16Y0003, P16Y0005, P16Y0006, P16Y0007, P16Z0001, P176Z0003, P1710001, P1720002, P1720001
WA22037C	16195P04L001, P16Y0001

Please send the completed and signed reply form by post, fax or a digitally scanned e-mail to:

Mr Robert Griggs - Quality and Regulatory Affairs General Manager
Email: ra@olympus.co.uk
Fax: +44(0)1702 465677

Dear Mr Griggs

We confirm we have received your Medical Device Recall Notice on the Monopolar HF Resection Electrodes referenced above. We understand that we need to return any affected products in our inventory.

Model Number	**Lot Number**	**Quantity**

Name and Job Title: _____

Hospital name: _____

Address: _____

City: _____ Post Code: _____