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Reference: 2017-002W

Cc: Chairman Medical Board and relevant Head of Departments

May 08, 2017

**IMPORTANT SAFETY NOTICE**

**REDUCED LOOP WIRE DURABILITY OF MONOPOLAR HF RESECTION ELECTRODES (MODEL: A22201A and A22201C)**

Model Number	Lot Number
A22201A	16162P03L001, 16162P03L002, 16162P03L003, 16167P03L001, 16168P03L001, 16168P03L002, 16168P03L003, 16168P03L004, 16168P03L005, 16182P03L001, 16195P03L001, 16242P03L001, 16242P03L002, 16251P03L001, 16251P03L002, 16251P03L003, P1690001, P1690002, P1690003, P1690004, P1690005, P1690006, P1690007, P1690008, P1690009, P1690010, P1690011, P16X0001, P16X0002, P16X0003, P16X0004, P1710001, P1710002, P1710003, and P1710004
A22201C	16123P03L001, 16124P03L001, 16139P03L001, 16140P03L001, 16131P03L001, 16144P03L001, 16144P03L002, 16144P03L003, 16155P03L001, 16169P03L001, 16173P03L001, 16174P03L001, 16174P03L002, 16210P03L001, 16223P03L001, 16224P03L001, 16236P03L001, P16X0001, P16X0002, P16X0003, P16X0004, P16Y0001, P16Y0002, P16Y0003, P16Y0004, P16Y0005, P16Y0006, P16Y0007, P16Z0001, P16Z0002, P16Z0003, P1710001, P1720001, and P1720002

Dear Sir/Mdm,

Olympus has initiated to implement a Field Safety Corrective Action ("FSCA") on MONOPOLAR HF RESECTION ELECTRODES. This FSCA affects selected production lots of model numbers A22201A and A22201C only. The monopolar HF resection electrodes are used for endoscopic diagnosis and treatment in urological and gynecological applications.

Olympus has initiated this FSCA after receiving an increased number of complaints regarding loop wires breaking at the distal end of electrodes model numbers A22201A and A22201C. Investigation have confirmed that loop wires, from models and lot numbers identified in the table above, can break during intended use of these electrodes. The cause of this damage is defective manufacturing equipment and the damaged loop wires cannot be detected by visual inspection. As a result of broken loop wire during intended use of the electrodes, a fragment of loop wire may fall inside the patient and will need to be retrieved. Under certain circumstances, retrieval of this fragment could require additional surgical treatment. Furthermore, the procedure can be prolonged resulting in extended anesthesia.

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

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

1. **Complete "Response Form" to indicate that you have received this safety notice. In addition, kindly ensure that information in this notice is made available to all relevant personnel within your facility.**
2. **Inspect your inventory for the affected electrode models with lot numbers identified in the table above. The model and lot number can be found on packaging labels as illustrated in Annex 1.**
3. **Olympus recommends to discontinue the use of any affected electrodes identified in your inventory.**
4. **Olympus is providing one-to-one exchange of the affected electrodes identified in your inventory. Our Sales personnel will be contacting you to arrange for this free replacement.**
5. **Complete "Collection Form" to show that you have obtained replacement electrodes identified in your inventory.**

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact us for any additional information on this matter.

Contact for enquires

Regulatory Affairs Department

Email: [mes-ra.osp@olympus-ap.com](mailto:mes-ra.osp@olympus-ap.com)

Tel: 6833 4214

Fax: 6834 2438

Thank you for your patience and support.

Sincerely,



Loh E Thei

Deputy Division Manager

Medical Systems Business Division

Olympus Singapore Pte. Ltd.

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## ANNEX 1: LOCATION OF MODEL AND LOT NUMBER ON PACKAGING LABELS



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



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

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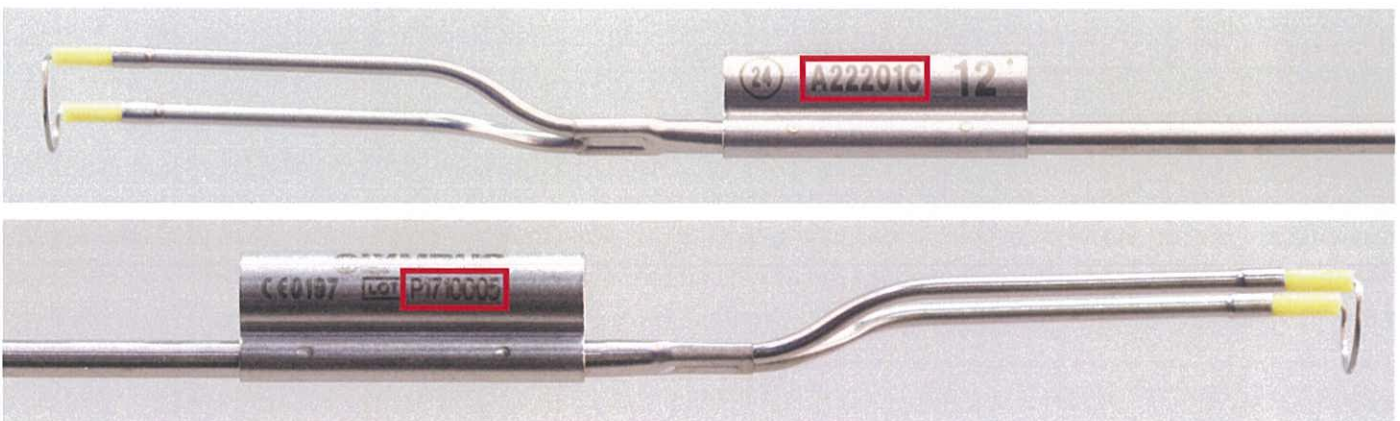
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Pictures 5 and 6: Blister packaging of the electrodes



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