

Zorgservice XL
Department Recall Zorgservice XL
Verantwoordelijke field safety
Postbus 120
2640 AC PIJNACKER

Leiderdorp, 23 mei 2017

**SUBJECT: URGENT:
FIELD SAFETY CORRECTIVE ACTION
REGARDING: MONOPOLAR HF RESECTION ELECTRODES - REDUCED LOOP
WIRE DURABILITY**

| Model Number | Lot Number(s) |
|---------------------|----------------------------------|
| A22201A | 16242P03L001, P1690001, P1710001 |
| A22201C | n.v.t. |
| WA22037C | n.v.t. |

Dear Sir / Madam,

OLYMPUS is implementing a Field Safety Corrective Action "FSCA" of the monopolar HF resection electrodes referenced above. The 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 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 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 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.

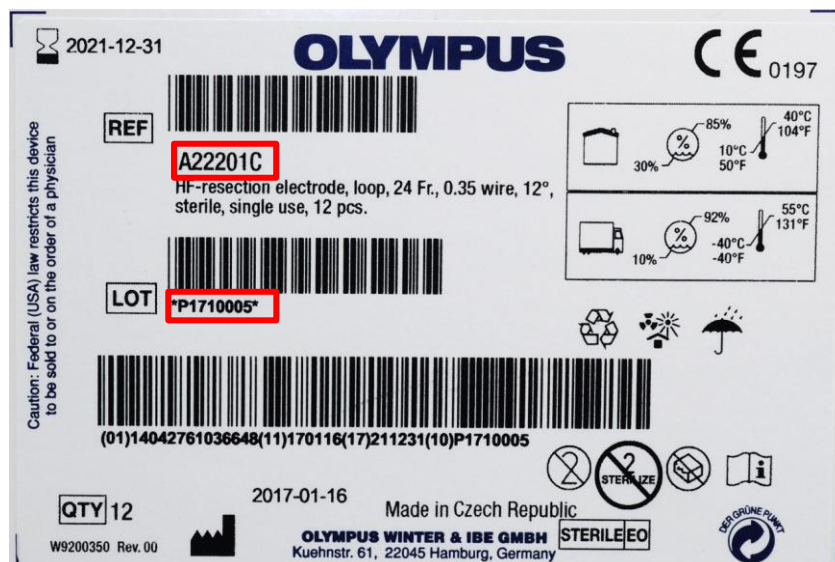
Action steps to be taken by the end user:

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. 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

2. OLYMPUS recommends to discontinue the use of any affected electrodes identified in your inventory.
3. Contact the Olympus front office at 088 – 450 8101 or surgical@olympus.nl. You will be provided with instructions on how to return the affected electrodes as well as getting a free replacement.
4. Please note on the enclosed reply form that you have received this Field Safety Notice. Please include the quantity of any affected electrodes you have identified in your inventory and intend to return.
5. Send the complete form to email address quality.assurance@olympus.nl before 22 May 2017.

The 'Inspectie van de Gezondheidszorg' 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 us if you have any questions on this matter. Contact person Mr. Niek Beukema – phone number 088 450 8000.

For urgent matters outside office hours, please contact the undersigned at telephone number: 06 250 02 210.

Kind regards,

Olympus

Enclosed documents: Reply Form 150-004

REPLY FORM
150-004

URGENT: FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION
Regarding: Monopolar HF Resection Electrodes - reduced loop wire durability

| Model Number | Lot Number(s) |
|--------------|----------------------------------|
| A22201A | 16242P03L001, P1690001, P1710001 |
| A22201C | n.v.t. |
| WA22037C | n.v.t. |

I have received the important safety information on the monopolar HF resection electrodes referenced above. I understand that I need to inspect my inventory and recognize that the use of affected electrodes is not recommended.

Contact the Olympus front office at 088 – 450 8101 or surgical@olympus.nl. You will be provided with instructions on how to return the affected electrodes as well as getting a free replacement.

Choose either A or B:

- A) _____ I checked my inventory and do NOT have any of the affected electrodes.
- B) _____ I checked my inventory and I will return the following number of affected electrodes:

| Model Number | Lot Number | Quantity |
|--------------|------------|----------|
| | | |
| | | |
| | | |
| | | |

Facility / Hospital Name: Zorgservice XL
City: PIJNACKER

Name: _____ **Title:** _____

Date: _____ **Signature:** _____

Please send the complete and signed reply form in return before 22 May 2017 to:
Olympus Nederland B.V.
Postbus 49, 2350 AA Leiderdorp
E-mail address: quality.assurance@olympus.nl

OLYMPUS

Your Vision, Our Future

OLYMPUS NEDERLAND B.V.

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