

Field Safety Corrective Action

Dear Customer,

Olympus has become aware of an issue that requires your attention. This letter pertains to the

Olympus Winter & Ibe
Working Elements for Resectoscopes

LOT 118W, 119W and 11XW	Art. No.	WA22066A (active, monopolar)
		WA22067A (passive, monopolar)
		WA22366A (active, bipolar)
		WA22367A (passive, bipolar)

Dear Customer,

Olympus has become aware of a raw material inhomogeneity in the white Teflon subassemblies of its working elements for resectoscopes. In consequence, the insulation function may be impaired and the hazard of sparking during activation of HF energy cannot be fully excluded.

To date no impairment was reported to Olympus and the likelihood of occurrence of the scenario described above is ranked very low. Nevertheless to best serve our customers and reinsure our demand to always deliver the best quality it was decided to withdraw the relevant product batch from the market.

We kindly ask you to check your inventory if you have working elements of the respective article numbers in use or elsewhere in your stock that belong to the LOT numbers mentioned above. If so, please avoid further use and return them to Olympus for credit in clean and disinfected condition. In any case, please fill the reply form and send it to your local Olympus partner.

Olympus regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local Olympus partner who will be delighted to support or make the necessary arrangements.

Please return the completed reply form to

Olympus Subsidiary/Distributor {by end of [month]}

Yours sincerely,

Reply Form

Olympus Subsidiary/Distributor

[Dept/Attn]

[Street No.]

[ZIP City]

[Date]

[Ref No.]

[EXT-xxx]

Olympus Winter & Ibe
Working Elements for Resectoscopes

Dear Sirs,

Herewith we confirm the receipt of your customer letter and your recommendations to inspect the inventory if we have received items belonging to the suspected LOT numbers 118W, 119W or 11XW. We will quarantine the respective products and return them to Olympus for credit.

	WA22066A	WA22067A	WA22366A	WA22367A
LOT 118W	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none
LOT 119W	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none
LOT 11XW	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none	_____ items <input type="checkbox"/> none

Hospital		Name	
Street		Department	
Postal Code / City		Date / Signature	