Date: XX.XX.XXXX

Olympus reference: QIL FY25-EMEA-05-FY24-OMSC-54-CH-S200-08-LB

URGENT FIELD SAFETY NOTICE

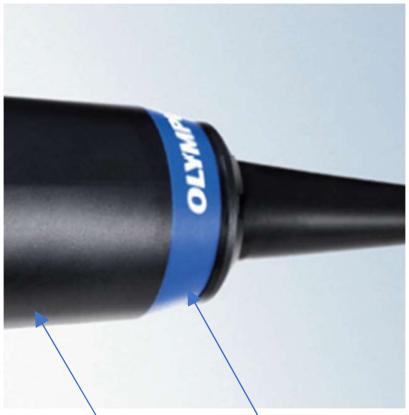
RE: HD Lightweight Pendulum Camera Head

Attention: Urology Department, Gynecology Department, ENT Department, Risk Management Department

Material ID	Model Number	Material Description	Serial Numbers	UDI-DI
N6131760	CH-S200-08-LB	HD Lightweight Pendulum Camera Head	7200153,7100128,7200194,7200720, 7200292,7200209,7200207,7200179, 7200178,7200175,7200210,7200176, 7300945,7200251,7200266,7200320, 7200712,7300774,7200205,7200342, 7100132,7200375,7100148,7200252, 7200167,7100141,7200166,7200285, 7200191,7200170,7200643	4953170421600

Dear HealthCare Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the HD Lightweight Pendulum Camera Head, model CH-S200-08-LB. These products are reusable components that have been designed to be used with rigid or flexible Olympus endoscopes and other ancillary equipment for urologic, gynecologic, and ear, nose, and throat procedures for observation, diagnosis, and treatment.



Reason for Action:

Olympus identified the repair process for 36 HD Camera Heads (CH-S200-08-LB) did not align with the manufacturing process final assembly. Specifically, the repair process did not include the application of adhesive to seal the blue ring to the main body of the HD Camera Head, creating a gap that may allow fluid ingress. The

blue ring is a non-patient contacting, cosmetic component located at the base of the main body of the HD Camera Head; it does not contribute to the functionality of the device.
This affects 36 products in the market and Olympus has not received any complaints or adverse events related to the identified issue.

Risk To Health:

Without the application of the adhesive under the blue ring, a gap between the blue ring and the main body is created which may allow the ingress of patient body fluids, particularly if the clinician touches the area around the blue ring during the procedure. If the camera head is not reprocessed after use, these body fluids can be transmitted to a patient during subsequent use which may result in infection. The gap may also permit residual sterilization fluid to remain after reprocessing. If reprocessing fluid comes into contact with intact skin or mucous membranes, it may lead to an allergic reaction.

Action Steps:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Examine your inventory and identify the above listed device(s) with serial number(s).
3. Please contact Customer Service at XXXX. Olympus will arrange for the return of your device to Olympus, and we will repair this device at no charge.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX.
5. If you have further distributed this product, identify your customers, and forward them this notification.

Your National Competent Authority is aware of the actions described in this letter.

Olympus requests that you report any complaints, including [general issue in letter], to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation.

Sincerely,
Name
Olympus title

REPLY FORM: QIL FY25-EMEA-05-FY24-OMSC-54-CH-S200-08-LB

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* *by* *XX.XX.XXXX*