September 9, 2020
Olympus reference: QIL 153-009

URGENT FIELD SAFETY NOTICE

RECALL OF CHF-CB30S CHOLEDOCHOFIBERSCOPES

Attention: **Endoscopy Department, Risk Management**

Model Name	Serial Number
OES CHOLEDOCHOFIBERSCOPE OLYMPUS CHF TYPE CB30S ("CHF-CB30S")	all

Dear Healthcare Professional:

Olympus Medical Systems Corporation ("Olympus") is writing to inform you of a removal action of all OES CHOLEDOCHOFIBERSCOPE OLYMPUS CHF TYPE CB30S ("CHF-CB30S") from the market.
The CHF-CB30S is intended for use with other supporting equipment for endoscopic diagnosis and treatment within the biliary tract (common bile duct, cystic duct and hepatic duct).

This removal action is being taken after Olympus conducted a retrospective review of modifications to the CHF-CB30S. As part of that review, Olympus conducted a postmarket risk assessment of the CHF-CB30S, which showed that this device has been associated with breakage of the insertion portion and protrusion of metal parts, as well as breakage and displacement of the rubber on the bending section during surgical procedures. To date, one of these complaints was associated with a serious adverse event, wherein surgery was required to remove rubber fragments which remained in the bile duct.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more CHF-CB30S Choledochoscopes. Therefore, Olympus requires you to take the following actions:

1. Inspect your inventory and identify any CHF-CB30S devices. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Cease any further use of any CHF-CB30S device you have, remove it from your inventory and quarantine it until it is shipped back to Olympus.
3. Please fill in the enclosed Reply Form confirming that you have quarantined the affected inventory and indicating the serial numbers, the fact if they are still actively used as well as the total number of CHF-CB30S Choledochoscopes in your possession.
4. Send the completed Reply Form back to your Olympus representative, regardless of whether you have any affected inventory at your facility.
5. After analysis of your feedback and our production capacity Olympus will contact you as soon as possible arranging the return of the affected inventory to Olympus and providing an alternative exchange proposal for the devices still actively used in your facility prior to this Field Safety Notice distribution.

6. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attachments and appropriately document your notification process.

Your national competent authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact Olympus directly by e-mail at ra@olympus-mea.com.

Sincerely,

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REPLY FORM – QIL 153-009

OLYMPUS URGENT FIELD SAFETY NOTICE **RECALL OF CHF-CB30S CHOLEDOCHOFIBERSCOPES**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**

Model name	**Serial numbers still available at your facility**	**Do you still actively use the mentioned serial number for Choledochoscopy?** (Yes/No)	**Total Quantities still available at your facility** (If no CHF-CB30S is available please insert 0)	**Quantities still available on stock** (If no stock is available please insert 0)
Olympus CHF-CB30S CHOLEDOCHOFIBERSCOPE				

I herewith acknowledge the receipt of your Field Safety Notice (FSN).
Further I confirm that I have trained the responsible personnel on the actions required in the FSN for the **CHF-CB30S Choledochofiberscope** and transferred the information to all affected departments on which this action may have an impact. I confirm that I have no more affected products on site besides the above mentioned quantities and that I have quarantined them according to the instructions in the attached FSN. I'll return my complete CHF-CB30S inventory to Olympus as requested in the FSN.

Name (Signature) _____

Name (Print) _____

Position _____

Please email this completed reply form to Olympus at ra@olympus-mea.com latest by 20.09.2020.