



August 31, 2020

URGENT: MEDICAL DEVICE REMOVAL ACTION

Attention: **Endoscopy Department, Risk Management**

**Product: Olympus CHF-CB30S Choledochoscopes
All serial numbers**

Dear Healthcare Professional:

Olympus Medical Systems Corporation (“OMSC”) is writing to inform you of a removal action of all CHF-CB30S Fiberoptic Choledochoscopes (“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 OMSC conducted a retrospective review of past changes to the CHF-CB30S applying current FDA guidance for assessing device modifications, including FDA’s 2017 guidance on this topic. Although not every modification to a medical device requires the submission of a new 510(k) to FDA, we now believe, for some of these past changes where we did not submit a 510(k), a better approach would have been to submit a 510(k). However, since this product is now being recalled we do not plan to submit a new 510(k).

As part of this retrospective review, OMSC conducted a postmarket risk assessment of the CHF-CB30S, which showed that this device has been associated with breakage of the insertion section 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. OMSC requests 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 us.**
3. Call your Olympus customer service representative at 1-888-524-7266 option 1. Olympus will issue a Return Material Authorization for you to return any CHF-CB30S at no charge.
4. Olympus will reimburse you for each returned CHF-CB30S. Please contact our Customer Service representative as indicated in step 3 for the reimbursement amount for your CHF-CB30S choledochoscope.

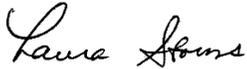
5. Access the Olympus recall portal to indicate that you have received this notification. Go to <https://olympusamerica.com/recall>. Enter the recall number Recall-0365 and provide your contact information as indicated in the portal.
6. If you may have further distributed the CHF-CB30S, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

The U.S. Food and Drug Administration is aware of the actions described in this letter.

OMSC requests you to report any patient injuries associated with any OMSC endoscope. Call our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 to report complaints.

OMSC regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com

Sincerely,

A handwritten signature in cursive script that reads "Laura Storms".

Laura Storms
V.P., Market Quality