

Date: July XX, 2023

Olympus Reference: QIL FY24-EMEA-10-FY24-OMSC-05

URGENT FIELD SAFETY NOTICE

Recall - Market removal of PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU

Attention: Endoscopy Lab Manager, Risk Management Department

Material ID	Model Name	Model Description	Serial numbers
N5788540, N5788550	PSF-1	INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	All
N5788700	DPST-1	SINGLE USE POWERSPIRAL TUBE DPST-1	All
N6003260	PSCU	POWERSPIRAL CONTROL UNIT PSCU	All

Dear Healthcare Professional:

This Field Safety Notice Olympus is to inform you of a market removal action of all PowerSpiral Intestinal Videoscopes PSF-1, including the accessories PowerSpiral Tube DPST-1 and the PowerSpiral Control Unit PSCU.

The PowerSpiral system is indicated for use within the upper and the lower digestive tract allowing to reach deeply into the gastrointestinal tract by pleating the small bowel using a spiral segment. This is achieved by an integrated motor which rotates the PowerSpiral Tube.

INTESTINAL VIDEOSCOPE
PSF-1



POWERSPIRAL TUBE
DPST-1



POWERSPIRAL CONTROL UNIT
PSCU



Risk to Patient Health:

Olympus had become aware of a situation where the withdrawal of a PSF-1 by rotating the Tube DPST-1 from a patient was unsuccessful and had to be removed surgically. Inability to withdraw PSF-1/DPST-1 lead to catastrophic injury to the patient, contributing to the death of the patient.

Olympus conducted a post-market risk assessment, including an examination of adverse events and

complaints. The risk assessment indicates that during procedure, the rotation of the PowerSpiral may stop due to some reason, and it may be difficult to insert & withdraw the instrument. This could lead to various potential critical patient harms i.e., lacerations, hemorrhage/bleeding and retained foreign body, that may require additional procedures including surgical retrieval/removal, prolonged procedure time, hospitalization, and perforation of the digestive tract.

As a result, Olympus has determined to remove this product from the market.

Action steps to be taken by the end user:

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

1. Carefully read the content of this Field Safety Notice (FSN).
2. **Cease usage of PowerSpiral products with immediate effect.**
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
4. If you have further distributed this product, identify your customers, and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
5. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.
6. Your local Olympus representative will contact you to arrange return and appropriate reimbursement.

Your National Competent Authority has been informed of this Field Safety Notice.

We fully appreciate your prompt cooperation in addressing this situation and working with us to ensure your patients are treated only with safe and effective Olympus products that you have come to rely upon.

For physicians that have any questions, please contact Ajit Patwardhan, MD, Executive Medical Director Medical Safety at ajit.patwardhan@olympus.com

If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX.

Sincerely,



REPLY FORM – QIL FY24-EMEA-10-FY24-OMSC-05

OLYMPUS URGENT FIELD SAFETY NOTICE	
Market removal of PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Date]	
Model Name	Serial Numbers
INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	
SINGLE USE POWERSPIRAL TUBE DPST-1	
POWERSPIRAL CONTROL UNIT PSCU	

I herewith acknowledge the receipt of your Field Safety Notice.

Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX <mailto:>latest by XXXX.