Medtrade
Innovative Medical Products

Date: 29 October 2025

Urgent Field Safety Notice
CELOX PPH Uterine Haemostatic Tamponade
Ref FSN 2025:001

For Attention of*
Obstetricians, Midwives and all Clinical Personnel that may be involved in the use of CELOX PPH for the treatment of Post-Partum Haemorrhage

For further information please contact Ian V Walker Quality Director Medtrade Products Ltd Electra House Crewe Business Park CreweCW16GL UK Email FSN@celoxmedical.com
Distributor Information – please add here

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Urgent Field Safety Notice (FSN)
CELOX PPH Uterine Haemostatic Tamponade
Notification of amendment/reinforcement of Instructions for Use (IFU)

	1. Information on Affected Devices*
1.	1. Device Type(s)* Sterile Uterine Haemostatic Tamponade
	CELOX™ PPH is a Sterile, single use uterine haemostatic tamponade provided in a z-fold/concertina format. 3m x 7.6cm individually pouched in a white coloured tearable sterile barrier.
1.	2. Unique Device Identifier(s) (UDI-DI) Pouch
	15060206631370, 15060206631486, 15060206631509, 15060206631660
1.	3. Primary clinical purpose of device(s)*
	CELOX PPH is intended as a physical haemostat for the control of emergency bleeding
1.	4. Device Model/Catalogue/part number(s)*
	FG08838281 FG08838171, FG08838291 and FG08838321

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	NONE – Field Safety Notice is to notify current users of the pending change to IFU
2.	2. Hazard giving rise to the FSCA*
	This communication is made as a precautionary measure following a recent low level of observations or reports of transient disturbances in visual and auditory function. To date these reports are inconclusive and have not established a causal relationship with the device *Medtrade Products has produced a revised IFU contains the following changes, this FSN is to provide the information prior to the new IFU being available* *Warning* *"This product contains chitosan derived from shellfish; clinicians should exercise caution with individuals with known shellfish allergies"* *"Postpartum haemorrhage (PPH) is a severe and multifaceted condition requiring the coordinated use of various medical interventions, in very rare instances, patients have reported transient disturbances in vision and auditory function. While no definitive causal relationship to specific treatments has been established, any occurrence of these symptoms warrants prompt medical evaluation and management"*

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	3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* ☒ Take note of amendment/reinforcement of Instructions for Use (IFU) • Continue using the product as intended in accordance with IFU with the additional warnings identified in the FSN until the updated IFU becomes available • Monitor for any sign and symptoms related to the reported effect and report any suspected adverse events.		
3.	2. By when should the action be completed?	The new IFU is in production and has been made available to the market 26 September 2025	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes
3.	4. Action Being Taken by the Manufacturer ☐ Product Removal ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☒ IFU or labelling change ☐ None The IFU has been amended and product made available for distribution, this FSN is to identify the changes prior to product containing the revised IFU being available to each user at each hospital/clinic		

	4. General Information*		
4.	1. FSN Type*		New
4.	2. Further advice or information already expected in follow-up FSN? *		Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)		
	a. Company Name		Medtrade Products Ltd
	b. Address		Electra house, Electra Way, Crewe Business Park, Crewe Cheshire CW1 6GL UK etc
	c. Website address		www.celoxpph.com
	d. SRN		GB-MF-000007864
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *		
4.	5. List of attachments/appendices:		FSN 2025:001 -Distributor/Importer Reply Form
4.	6. Name/Signature	[redacted]	

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	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *