URGENT: FIELD SAFETY CORRECTIVE ACTION

February 8, 2021

PHIL ™ (Precipitating Hydrophobic Injectable liquid)

Dear Customer,

MicroVention has initiated a voluntary Field Safety Corrective Action (FSCA) for PHIL products packaged in recently introduced tray packaging configuration. MicroVention has identified a potential issue with the immediate PHIL container (syringe) in tray packaging configuration which may elute unintended elements into PHIL device formulation. All other packaging configurations of PHIL devices (pouches) are not included in or affected by this FSCA.

Products Included In FSCA

The FSCA concerns the following PHIL model names, numbers, and specific lot numbers:

Catalog Number	Product Name	Concentration	Product Barcode
LEN10250	PHIL Starter Kit	25%	0100842429101490
LEN10300	PHIL Starter Kit	30%	0100842429101506
LEN10350	PHIL Starter Kit	35%	0100842429101513
LEN10LV250	PHIL Starter Kit	25%	0100842429101520
LEN10250RE	RePHIL	25%	0100842429101537
LEN10300RE	RePHIL	30%	0100842429101544
LEN10350RE	RePHIL	35%	0100842429101551
LEN10LV250RE	RePHIL	25%	0100842429101568

MicroVention Europe S.A.R.L. au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper – 78100 Saint-Germain-en-Laye
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01
E-mail : contact.europe@microvention.com

PRODUCT SUBJECT TO FSCA

PHIL™ Tray

- 1 mL of PHIL® liquid embolic in a pre-filled sterile syringe
- 1 mL of DMSO in pre-filled sterile syringe
- Universal Adaptor
- IFU

Sterile Individual Trays
1 DMSO/1 Liquid Embolic

- 2 x 1 mL of PHIL® liquid embolic in a pre-filled sterile syringe
- Universal Adaptor
- IFU

Sterile Individual Trays
2 Liquid Embolic

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PRODUCT NOT AFFCTED BY FSCA

PHIL™ Pouch

Product intended use:

- PHIL™ (Precipitating Hydrophobic Injectable Liquid) System is intended for use in the embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

Description of the Issue:

It was determined that the PHIL container (syringe) may elute unintended elements (metals) into PHIL device formulation.

- There were no adverse events reported to the manufacturer with regard to this particular concern. Nor has MicroVention identified any specific risks to patients associated with the previous uses of PHIL™ devices. MicroVention will continue to monitor any adverse events related to the issue.

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The following actions are to be taken by the user:

- Identify list of affected products in your inventory and cease use of the listed products.
- Account for products used.
- Complete and return the applicable “ACKNOWLEDGEMENT AND RECONCILIATION FORM” to the email contact below – immediately upon receipt.

Your competent authority has been informed about this Field Safety Notice.

Please direct any questions to MicroVention contact below:

……..
……..
MicroVention Europe SARL, A **TERUMO** Group Company
30 bis rue du Vieil Abreuvoir, 78100 Saint-German-en-Laye, France
Ph. +33(1)39 21 77 46; Fax +33(1)39 21 16 01
Email: MVEMEAQARA@microvention.com

We regret any convenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

……..
……..

Enclosures:

Attachment 1 – List of potentially affected product lots
Attachment 2 – Acknowledgement and Reconciliation Form

Attachment 1: List of Affected Lots

(Ref : FCA# 2021-01)

Product Name	PHIL™ (Precipitating Hydrophobic Injectable liquid)
Catalog #	LEN10250, LENI1025RE, LEN10300, LEN10300RE, LEN10350, LEN10350RE, LEN10LW250, LEN10LV250RE

Catalog #	LEN10250	LEN10250RE	LEN10300	LEN10300RE	LEN10350	LEN10350RE	LEN10LV250	LEN10LV250RE
Lot #	19021214LM	19080514R	190307122M	19080514X	19021214PM	19080514Y	190103126	190103131
	190805135	19080514T	19080514L	19102114P	19080514N	190903125	190121124	19041211Q
	19080514J	19080514W	19090512C		19090512J	190924122	19031111T	19080513A
	19080514K	19090311Z	190924123		190924124		190722133	19090313N
	19090511Q	190903121	19102114G		19102114H		19072312T	19092411Z
	19090511R	190903122	191106142		19110613X		19080512Z	19102114T
	19090511T	190903123	200203132		200203133		190924121	19110614H
	190905127	19092311E	20070912E		20072811R		19102114R	200819129
	190923119		20080612Q		20072811RM		191106149	
	19092311A		20081911YM		1907091DP		200110123	
	19092311B		1907091DN				20030911U	
	19092311C						200518138	
	19102114B						200518138M	
	19102114C						20052813E	
	19102114E						20052813F	
	19102114F						20070912L	
	191106135							
	191106136							
	191106137							
	20032511T							
	200519119							
	20051911A							
	200521127							
	200521128M							
	20070111Y							
	20070912X							
	20070912Y							
	200727116							
	200727117							
	20072811H							
	20081911F							
	20101515G							
	20101914A							
	1907091DL							
	2002181DG							

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DISTRIBUTOR FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGMENT AND RECONCILIATION FORM

DISTRIBUTOR NAME: _____

ADDRESS: _____

DISTRIBUTOR CONTACT PHONE #: _____

We have read and understood the Field Safety Corrective Action letter issued by MicroVention Inc. regarding the PHIL™ (Precipitating Hydrophobic Injectable Liquid) devices. We have immediately disseminated this Field Safety Corrective Action letter to the affected customer(s), have requested the affected customers to complete the Customer Field Safety Corrective Action Acknowledgment and Reconciliation form, and to arrange proper return of all unused units.

We have checked our stock and will be returning the quantity indicated in the table below.

Catalog #	Lot #	Quantity Received	Quantity Used*	Quantity to be Returned

**Quantity Used includes products that were used, opened in error, returned to manufacturer as product complaints, or discarded.*

Representative Name (Print Name)	Signature	Date

PLEASE EMAIL THE COMPLETED FORM to mvexportcustomerservice@microvention.com.

For returned product – our customer service will provide instructions for product return.

---------- Internal use only (below) ----------
RGA#:_____

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CUSTOMER FIELD SAFETY CORRECTIVE ACTION

ACKNOWLEDGMENT AND RECONCILIATION FORM

CUSTOMER NAME: ___MEDFAU sh.p.k_____

ADDRESS: _____

CUSTOMER CONTACT PHONE #: _____

We have read and understood the Field Safety Corrective Action letter issued by MicroVention Inc. regarding the PHIL™ (Precipitating Hydrophobic Injectable Liquid) devices. We have taken the appropriate action and disseminated this information to any affected staff, service and/or facilities.

We have checked our stock and will be returning the quantity indicated in the table below.

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		1		

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