# URGENT: FIELD SAFETY CORRECTIVE ACTION

# February 8, 2021

**PHIL TM (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.

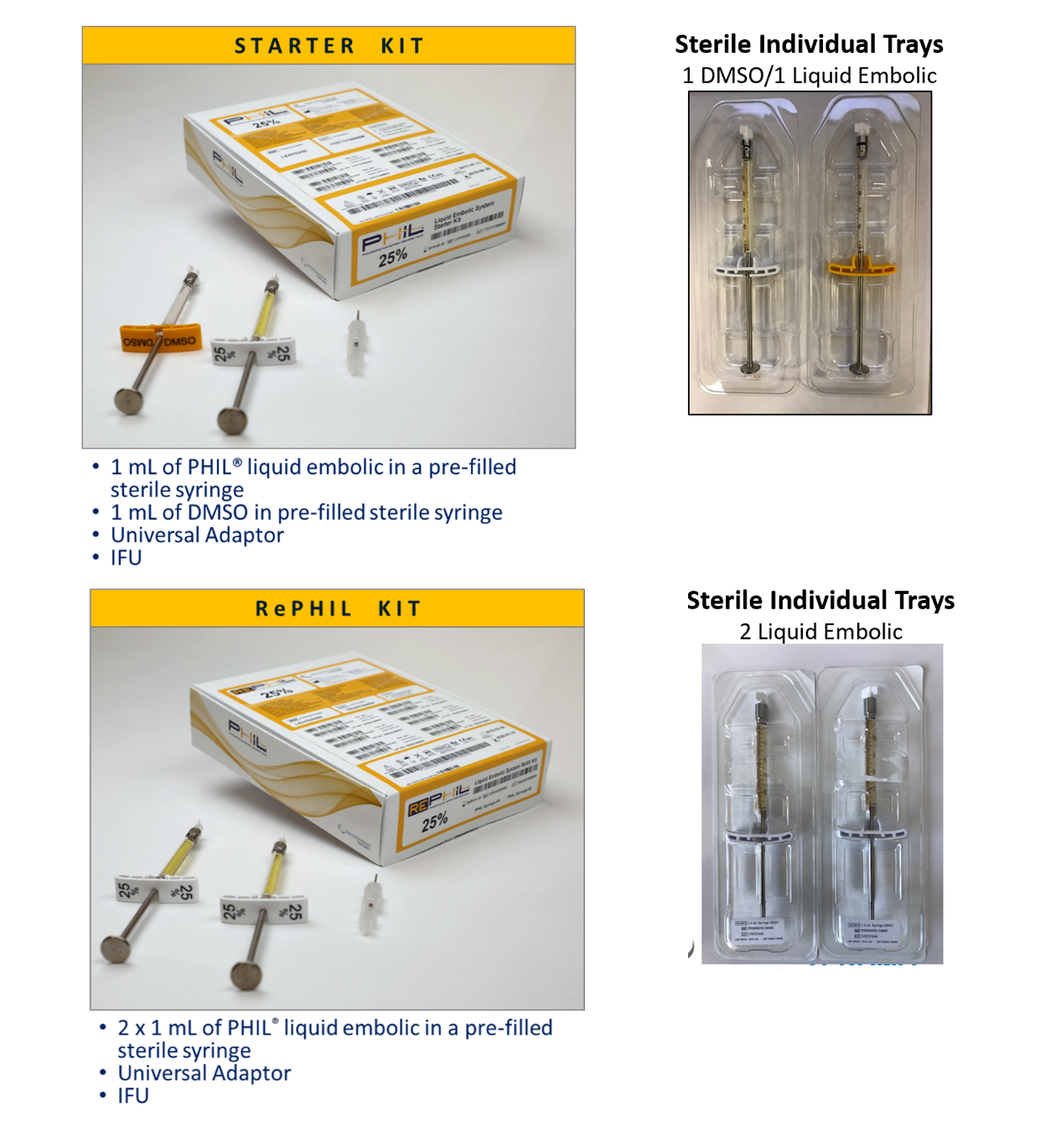
**Products Included In FSCA**

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

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| **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 |

**PRODUCT SUBJECT TO FSCA**

**PHIL™ Tray**



**PRODUCT NOT AFFCTED BY FSCA**

**PHIL™ Pouch**



**Product intended use:**

* PHILTM (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 PHILTM devices. MicroVention will continue to monitor any adverse events related to the issue.

**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:

Julie Lopez

Sr. Manager QA/RA EMEA

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,

Irina Kulinets, PhD, RAC

Sr. Vice President of Regulatory Affairs, Clinical Research, and Quality

MicroVention Inc., A **TERUMO** Group Company

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)*

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| **Product Name** | **PHILTM (Precipitating Hydrophobic Injectable liquid)** |
| **Catalog #** | LEN10250, LENI1025RE, LEN10300, LEN10300RE, LEN10350, LEN10350RE, LEN10LW250, LEN10LV250RE |

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| **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 |  |  |  |  |  |  |  |
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|  | 20032511T |  |  |  |  |  |  |  |
|  | 200519119 |  |  |  |  |  |  |  |
|  | 20051911A |  |  |  |  |  |  |  |
|  | 200521127 |  |  |  |  |  |  |  |
|  | 200521128M |  |  |  |  |  |  |  |
|  | 20070111Y |  |  |  |  |  |  |  |
|  | 20070912X |  |  |  |  |  |  |  |
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|  | 200727116 |  |  |  |  |  |  |  |
|  | 200727117 |  |  |  |  |  |  |  |
|  | 20072811H |  |  |  |  |  |  |  |
|  | 20081911F |  |  |  |  |  |  |  |
|  | 20101515G |  |  |  |  |  |  |  |
|  | 20101914A |  |  |  |  |  |  |  |
|  | 1907091DL |  |  |  |  |  |  |  |
|  | 2002181DG |  |  |  |  |  |  |  |

**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 PHILTM (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.

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| Catalog # | Lot # | Quantity Received | Quantity Used\* | Quantity to be Returned |
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*\*Quantity Used includes products that were used, opened in error, returned to manufacturer as product complaints, or discarded.*

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| --- | --- | --- |
| Representative Name (Print Name) | Signature | Date |

PLEASE EMAIL THE COMPLETED FORM to [mvexportcustomerservice@microvention.com](mailto:mvexportcustomerservice@microvention.com).

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

**--------------------------------------------- Internal use only (below) ---------------------------------------------**

**RGA#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CUSTOMER FIELD SAFETY CORRECTIVE ACTION**

**ACKNOWLEDGMENT AND RECONCILIATION FORM**

CUSTOMER NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ADDRESS: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CUSTOMER CONTACT PHONE #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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| Representative Name (Print Name) | Signature | Date |

PLEASE EMAIL THE COMPLETED FORM to [mvfrance.customerservice@microvention.com](mailto:mvfrance.customerservice@microvention.com).

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**ACKNOWLEDGMENT AND RECONCILIATION FORM**

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| Representative Name (Print Name) | Signature | Date |

PLEASE EMAIL THE COMPLETED FORM to [janet.stonehouse@microvention.com](mailto:janet.stonehouse@microvention.com).

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