Urgent Field Safety Notice

PHIL (Precipitating Embolic Injectable liquid) Non-Adhesive Liquid Embolic System

FSCA-identifier: FCA#2016-01

Type of action - return of a product to the supplier (MicroVention Europe, address is provided below).

Date:

Attention: To whom it may concern

Details on affected devices:

The PHIL device is intended for use in the embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors
Precipitating hydrophobic injectable liquid (PHIL) is a nonadhesive co-polymer (polylactide-co-glycolide and polyhydroxyethylmethacrylate)-based liquid embolic material dissolved in DMSO prior to use.

The FSCA concerns the following PHIL model names / numbers:

Catalog Number	Concentration	When to use	Volume of LE	Embolic capacity	Viscosity
LEN10250	**PHIL 25%**	• Low flow scenarios • Distal access	1mL	0.85mL	16 cSt
LEN10300	**PHIL 30%**	• Moderate flow scenarios • When feeding pedicle injections are conducted close to the nidus	1mL	0.87mL	36 cSt
LEN10350	**PHIL 35%**	• Higher flow scenarios • Large fistulous components embolization	1mL	0.94mL	72 cSt

The list of affected batches / manufacturing lots is attached

Description of the problem:
It was determined that the PHIL container (syringe) may elute unintended elements (metals) into PHIL device formulation. This elution may discolor the PHIL device or may not change the appearance of the device. At this point no adverse events related to product deficiency or specific patient reactions were reported to the manufacturer.
MicroVention has not currently identified possible risk to patients associated with previous uses of PHIL devices.

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

The following actions are to be taken by the user:

- Identifying and quarantining all devices in user's possession – immediately upon receiving this Urgent Field Safety Notice
- Return all devices in user's possession to the manufacturer (MicroVention Europe) – within 2 weeks of receipt of this Urgent Field Safety Notice
- Confirmation forms to be sent back to the manufacturer (attached):
    - Confirmation of receipt of this Urgent Field Safety Notice – immediately upon receipt
    - The form confirming the number / lot numbers of devices in possession and distributed (distribution records – within 2 business days of receipt of this Urgent Field Safety Notice
    - The form confirming number / lot numbers of devices returned to Manufacturer – within 2 weeks of receipt of this Urgent Field Safety Notice
- Recommended patient follow up – continue to collect and report to manufacturer any Adverse Events / Patient Reactions within one year from the date of this Urgent Field Safety Notice

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (as appropriate)

Please transfer this notice to other organizations upon 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 send all confirmation forms and questions to contact reference person below:

MicroVention Europe S.A.R.L
30 bis rue du Viei Abreuvoir
78100 Saint-German-en-Laye
France
Ph. +33(1)39 21 77 46
Fax +33(1)39 21 16 01
contact.europe@microvention.com

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agencies

Signature: