November 26, 2019

URGENT: FIELD SAFETY CORRECTIVE ACTION

HydroCoil® Embolic System (HES) and MicroPlex® Coil System (MCS) Endovascular Embolization Coil

Customer Name & Address

Dear customer,

MicroVention is initiating a voluntary field safety corrective action (FSCA) for the HydroCoil Embolic System (HES) and MicroPlex Coil System (MCS) Endovascular Embolization products. Our records indicate that you may have received product from certain lot(s) of HES and MCS Endovascular Embolization products where a small number of the products may be missing the implant coil. A list of lots that may be affected by this issue is provided in Attachment 1.

These products are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. These products are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

MicroVention has received six (6) complaints related to devices missing the implant coil. There have been no adverse events related to missing coils reported to the manufacturer. MicroVention will continue to monitor for any adverse events related to the issue.

Product IFU (Instructions for Use) identifies a series of verification steps that must be performed prior to implant coil deployment including checking the product for irregularities or damage and monitoring for radiopaque marker location and implant presence.

If the verification steps are not performed per IFU, the user may potentially advance the delivery system without an implant into the neuro vasculature which may result in vessel wall damage and related complications. The company has concluded that the likelihood of this occurring is remote.

Immediately perform the following steps:

1. Identify list of affected products in your inventory and cease use of the listed products.
2. Account for products used*.
3. Complete and return the applicable **"ACKNOWLEDGMENT AND RECONCILIATION FORM"** form to the contact below. Contact customer service for instruction to return the product(s).

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

Please direct any questions to the MicroVention contact:

Julie Lopez
Sr. Manager QA/RA EMEA
MicroVention Europe SARL, A TERUMO Group Company
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Email : julie.lopez-genest@microvention.com

We regret any inconvenience 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 & Reconciliation Form

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 HydroCoil® Embolic System (HES) and MicroPlex® Coil System (MCS) Endovascular Embolization Products. 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.

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 MVE Customer Service - Export
mvexportcustomerservice@microvention.com

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

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

RGA#:_____