Sequent Medical™

February 14, 2019

URGENT: Field Safety Notice

WEB® Detachment Controller

Catalogue number: WDC-1
Lot number: 18072301

Hospital Name and Address
Attention to: name if available

Dear Customer,

The purpose of this letter is to inform you that Sequent Medical, Inc. is voluntarily conducting a field action on one (1) lot of WEB® Detachment Controller because dust contamination material was found on the controller housing and pouch.

The field action is limited to one (1) lot # 18072301 of WEB® Detachment Controller. No other Sequent Medical, Inc. products are affected by this field action.

We are in the process of investigating the cause of this issue. No patient injuries have been reported.

The WEB® Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).

The WEB® Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.

Risk to Health

Health consequences that may result from the use of, or exposure to the affected device if the dust contamination material was transferred during use, from the WEB® controller to the catheter used with WEB® device or onto the WEB® device itself, could include stroke or diffuse brain damage.

Sequent Medical, Inc.
11 Columbia, Aliso Viejo, CA 92656 USA
1.949.830.9600 Phone 1.949.830.9658 Fax
www.sequentmedical.com

Actions to be taken by the Customer/User

- Immediately discontinue use of WEB® Detachment Controller from lot # 18072301
- Identify and quarantine all devices in your possession – immediately upon receiving this Urgent Field Safety Notice.
- Immediately return the completed "Customer Acknowledgment and Device Reconciliation" form attached to this Urgent Field Safety Notice via email. This information is essential to ensure effectiveness of the corrective action.
- Return all devices from this lot in your possession to Sequent Medical, Inc. within 2 weeks of receipt of this Urgent Field Safety Notice and include a copy of the completed "Customer Acknowledgment and Device Reconciliation" form with the returned devices. This information is essential to ensure effectiveness of the corrective action.
- Notify customers of this field action to whom you may have further distributed or transferred this product. This field action should be conducted to the medical facility/user level.
- If a device from this lot was used and there was a suspected adverse event associated with the device, report the issue to the Sequent Medical, Inc. using the form and the included contact information.
- Continue to report to the manufacturer any adverse events or quality problems in accordance with normal procedures.

Please send all "Customer Acknowledgment and Device Reconciliation" forms and direct questions to the contact detailed on this form.

We appreciate your understanding as we act to ensure patient safety and customer satisfaction.

Sincerely,

I. Kulinets

Irina Kulinets, PhD, RAC
Sr Vice President of Regulatory Affairs, Clinical Research and Quality
MicroVention Inc.

Enclosed

- Customer Acknowledgment and Device Reconciliation form

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URGENT – FIELD SAFETY CORRECTIVE ACTION

CUSTOMER ACKNOWLEDGMENT AND RECONCILIATION FORM

Product Name	WEB® Detachment Controller
Catalogue Number	WDC-1
Lot Number	18072301

Dear Customer,

Our records indicate your institution /company may possess the product that is affected by this field action. Please complete the table below.

Institution/Hospital Name :			**Institution/Hospital Address (including country):**		
Lot #	Quantity	Quantity Used	Quantity Discarded[1]	Quantity to be Returned[2]	Total Quantity
18072301					

[1] Quantity Discarded includes procedure aborted, products were opened in error, products were returned to manufacturer as product complaints, or product discarded for any other reasons.
[2] For returned products, please send this form completed and signed to the attention of
Mrs.Julie Lopez - materiovigilance@microvention.com
Mrs Julie Lopez – Quality and Regulatory Affairs Manager EMEA, MicroVention Europe
20 Quarter rue Schapper - FR-78100 Saint-Germain-en-Laye, France
Tel : +33 (0)1 39 21 12 12 Fax : +33 (0)1 39 21 16 01 - materiovigilance@microvention.com

or to the email of your local customer service in communication with you about this action. Customer service will coordinate the return of any remaining devices.

This recall is conducted to the medical facility/user level.
If you have provided/transferred these devices to someone else, please forward this notice.

We acknowledge the receipt of the Field Safety Notice regarding the Sequent product and catalog numbers listed above. We have received the notice, taken the appropriate action and disseminated this information to any affected staff, service and/or facilities.

Immediate upon receipt of this letter, please sign below and send the form by email to the attention of Julie Lopez - materiovigilance@microvention.com or to the email of your local customer service in communication with you about this action.

Hospital Representative (Print Name)	Signature	Date

Sequent Medical, Inc.
11A Columbia, Aliso Viejo, CA 92656
United States of America