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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