MicroVention Inc.

URGENT: FIELD SAFETY NOTICE (RECALL)

WEB™ Detachment Controller (WDC-2)

Reference: FCA202301

January 12, 2023

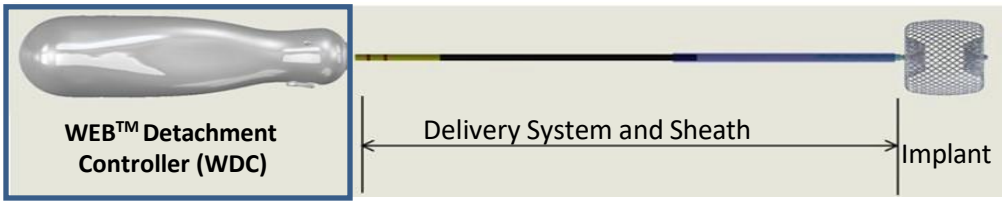
Dear Customer

MicroVention, Inc. is voluntarily recalling selected lots of WEB™ Detachment Controller.

Intended Use:

The WEB™ Detachment Controller (WDC) is a single-use, hand-held, battery-powered device designed for electro-thermal detachment of the WEB™ Aneurysm Embolization System.

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.



Reason for the Voluntary Recall:

Selected lots of WEB™ Detachment Controller could have an out-of-specification tunnel opening dimension of the device.

This recall is limited to following catalog #s, part #s, and lot #s. No other MicroVention products are affected by this field action.

Catalog #	Name	Lot #
WDC-2	WEB™ Detachment Controller (WDC-2)	0000095683; 0000205967

Risk to Health:

The WEB™ Detachment Controller being recalled has an out of specification tunnel opening dimension that may prevent the WEB™ implant device pusher from fully inserting into the controller. As a result, the controller may be unable to properly detach the WEB™ implant device.

Health consequences can include delays caused by the inability to detach the WEB™ device after positioning, excessive manipulation that can cause the implant to move and potentially damage vessels, and delays caused by removing the WEB™ Aneurysm Embolization System and changing the planned implantation to an alternative method of treatment.

MicroVention is in the process of investigating the cause of the issue. As of now, we have received 19 customer complaints associated with the issue. No patient injuries have been reported.

Relevant competent authorities have been informed about this recall.

Action to be taken by the Customer / User:

- Identify and quarantine all impacted WEB™ Detachment Controller devices in your possession.
- Immediately return the completed "Customer Acknowledgment and Device Reconciliation" form attached to this Field Safety Notice *via* email
- Please return the form even if you do not have the product lot subject to this recall.
- Return all impacted devices in your possession to the manufacturer (MicroVention) by February 15th, 2023; MicroVention will provide detailed instructions for product return once ACKNOWLEDGMENT AND RECONCILIATION FORM received by customer service
- Returned units subject to this recall will be eligible for credit or replacement

If you have additional questions regarding this Field Safety Notice, please contact MicroVention via the contact below:

Aurore Cholley
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We regret any inconvenience that this action may cause, however we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

…

MicroVention, Inc., A **TERUMO** Group Company
35 Enterprise, Aliso Veijo, CA 92656
Direct: +1.714.247.8000
Cell: +1.949.867.0794

Enclosed:
ACKNOWLEDGMENT AND RECONCILIATION FORM

(Ref : FCA# 202203)

CUSTOMER FIELD SAFETY CORRECTIVE ACTION

ACKNOWLEDGMENT AND RECONCILIATION FORM

Response is required

WEB™ Detachment Controller (WDC-2)

CUSTOMER NAME: _____

ADDRESS: _____

We have read and understood the Field Safety Corrective Action letter issued by MicroVention Inc. regarding the WEB ™ Detachment Controller (WDC-2) devices. 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 XXX

For returned product – our customer service will provide further instructions