URGENT MEDICAL DEVICE RECALL

June 26, 2023

Subject: FRED® Flow Re-Direction Endoluminal Device: manufactured between June 1, 2020, and September 29, 2020.

Dear Device Customer,

This notification is to inform you that we have initiated a voluntary recall of our FRED® devices manufactured **between June 1, 2020,** and **September 29, 2020.** MicroVention has determined that product manufactured during this time frame may be manufactured with an incorrect inner stent length and may not perform as intended.

Health Risk Assessment:

MicroVention has not received notification of any patient injuries associated with this issue. This issue only affects the FRED® units manufactured between the dates above and listed in Attachment #1.

MicroVention requests that you immediately stop using and quarantine all impacted FRED® devices and return the product in accordance with the instructions below.

MicroVention has reviewed manufacturing and quality processes and implemented improvements to monitor the inner stent length in September 2020; therefore, product manufactured after 29SEP2020 will not be impacted.

ACTIONS REQUESTED

Immediately perform the following steps:

1. MicroVention's records indicate that you have received at least one of the impacted lots. Please review your inventory based on the attached list of lot numbers (Attachment #1) and manufacture dates noted above and immediately stop using and quarantine all impacted FRED® devices.

*Example of lot number and date of manufacture highlighted on the label above. Manufacture dates must be between 2020-06-01 and 2020-09-29.

2. Please complete and return the “CUSTOMER ACKNOWLEDGMENT FORM” via email to the attention of Aurore Cholley at MVEMEAQARA@microvention.com. Our Customer Service will contact you to arrange the product return as needed.
3. Suitable replacement FRED® devices are available and will be sent or a credit will be issued for all returned devices.
4. If the device has been implanted, there is no action or further notification required.

Competent Authorities are aware of this action.

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

Sincerely,

[redacted]
Vice President, Global Quality
MicroVention Terumo

MicroVention TERUMO

CUSTOMER ACKNOWLEDGMENT FORM

CUSTOMER NAME: _____

ADDRESS: _____

CUSTOMER CONTACT PHONE #: _____

I have read and understand the recall instructions provided in the letter and have shared this notification with all device users within the facility and network to ensure they are aware of this recall. This recall notice should also be shared with any organization where the potentially affected devices have been transferred. YES_____ NO_____

If you have had any adverse events associated with this recalled product, please submit your report to your local MicroVention Sales/Customer Service Representative.

Our records indicate your institution have ordered the FRED® Flow Re-Direction Endoluminal Device(s) that are affected by this recall. Please complete the table below:

Affected Product Information				
Catalog #	Lot #	Quantity Provided	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 MVEMEAQARA@microvention.com