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URGENT MEDICAL DEVICE RECALL

Date: 28MAY2025

Subject: LIFEPEARL™ Drug Elutable Microspheres

Product Codes: 8LP2S200 and 8LP2S400 (LIFEPEARL™ size 200µm and size 400µm)

Lot Number and UDI Number: Impacted Lot #'s (see Attachment #1).

Dear Device Customer,

This notification is to inform you that we have initiated a voluntary recall of MicroVention Inc. LIFEPEARL™ Drug Elutable Microsphere Device, only specific lots of Product Codes 8LP2S200 and 8LP2S400 are impacted by this recall. MicroVention has determined that the actual average diameter of the LIFEPEARL™ microspheres is smaller than expected in the identified lots and are not within specification.

LIFEPEARL SIZE (µm)	PRODUCT CODE/ CATALOG #	Lot #	VOLUME OF MICROSPHERES (ML)	MICROSPHERE COLOR	LABEL COLOR
200 ± 50 µm	8LP2S200	See Attachment #1	2	Green	Yellow
400 ± 50 µm	8LP2S400	See Attachment #1	2	Green	Blue

Health Risk Assessment:

Clinically, variations of the microsphere diameter can cause potential harm as well as incompatibility with other devices. The level of harm is considered severe. The patient risks include the inability to reach the desired treatment location (non-targeted embolization), additional procedure/treatment required, blockage other than target vessel, increased procedure time (>15 minutes), incomplete embolization, and/or inability to treat the patient. To date, MicroVention has not received notification of any complaints or patient injuries associated with this issue; however, this may not be immediately perceived by the physician.

If the device has been implanted, you should monitor the patient for any potential adverse events associated with non-target embolization that could be attributed to the use of the affected product, which may include but not limited to tissue necrosis or damage to adjacent structures. Please see Attachment #2 for lots that have expired but are impacted by this condition.

MicroVention requests that you immediately stop using and quarantine all impacted lots of 200 ± 50 µm **(8LP2S200)** and 400 ± 50 µm (**8LP2S400)** LIFEPEARL™ Drug Elutable Microspheres (See Attachment #1). Only the impacted lots identified are impacted by this recall. All other lots have been tested and confirmed to meet all specifications.

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ACTIONS REQUESTED

1. Review Inventory

   Terumo Neuro records indicate that you have received an impacted lot. Please review your inventory for LIFEPEARL™ Drug Elutable Microspheres (8LP2S200 and 8LP2S400) devices.

2. Inform and Forward Recall Notice

   Inform all individuals within your organization of the recall and if the device(s) was transferred, forward the recall notice to any organizations that may have received the affected products.

3. Return Product

   Please complete and return the "CUSTOMER ACKNOWLEDGMENT FORM" via email at recalls@microvention.com.

4. Contact Quality Department.

   If your institution has affected inventory, call Customer Care at 800-888-3786 or email tmccustomer.admin@terumomedical.com to request a recall return, and Customer Service will provide the necessary RGA details to return the device(s).

5. Replacement or Credit of Returned Devices

   Suitable replacement LIFEPEARL™ devices are available and will be sent or a credit will be issued for all returned devices.

The United States Food and Drug Administration (FDA) has been notified of this recall, and we intend to provide the FDA routine updates on progress.

Adverse reactions or quality problems experienced with the use of this product may be reported to your local MicroVention Terumo Sales Representative or the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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Please direct any questions to the

Terumo Neuro Contact:

Ludovic Etcheverry
Director Regulatory & Quality Affairs
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye France
Hours: Monday - Friday 9:00 - 6:00 pm GMT+2

Email: MVEMEAQARA@microvention.com

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,

On Behalf of:

Scafford Serron, Ph.D.
Senior Vice President,
Global Regulatory and Quality
Terumo Neuro

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CUSTOMER ACKNOWLEDGMENT FORM

CUSTOMER NAME _____

Attn: Vendor Recall Department

Customer Address / Account number _____

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_____

Our records indicate your institution have ordered the LIFEPEARL™ Drug Elutable Microsphere device affected by this recall. Please complete the table below:

Affected Product Information				
Catalog#	Lot#	Quantity Shipped	Product Status (i.e. used, discarded)	Quantity to be Returned

Customer Representative Name /Print Name)	Signature	Date

PLEASE EMAIL THE COMPLETED FORM to recalls@microvention.com

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LIFEPEARL™ Drug Elutable Microsphere (200 um and 400 um) device
SAMPLE IMAGE: