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URGENT FIELD SAFETY NOTICE

Date: 28MAY2025

Subject: LIFEPEARL™ Drug Elutable Microspheres

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

Lot Number-: Impacted Lot Numbers (see Attachments No.1 and 2).

Dear Customer,

This notification is to inform you that we have initiated a voluntary recall of the MicroVention Inc. LIFEPEARL™ Drug Elutable Microsphere Device. Only specific lots with 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 they are not within specification.

LIFEPEARL SIZE (µm)	PRODUCT CODE/CATALOGUE NO.	Lot No.	VOLUME OF MICROSPHERES (ML)	MICROSPHERE COLOUR	LABEL COLOUR
200 ± 50 µm	8LP2S200	See Attachments No.1 and 2	2	Green	Yellow
400 ± 50 µm	8LP2S400	See Attachment No.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. Risks to the patient include the inability to reach the desired treatment location (non-targeted embolisation), additional procedure/treatment required, blockage other than target vessel, increased procedure time (>15 minutes), incomplete embolisation 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 embolisation that could be attributed to the use of the affected product, which may include but are not limited to tissue necrosis or damage to adjacent structures. Please see Attachment No.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 No.1). Only the impacted lots identified are impacted by this recall.

All other lots have been tested and are 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 organisation of the recall and if the device(s) were transferred, forward the recall notice to any organisations that may have received the affected products.

3. Return Product

   Please complete and return the "CUSTOMER ACKNOWLEDGEMENT FORM" via email to your local Terumo Europe contact.

4. 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.

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.

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CUSTOMER ACKNOWLEDGEMENT 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 that they are aware of this recall. This recall notice should also be shared with any organisation where the potentially affected devices have been transferred.

Yes____ No____

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

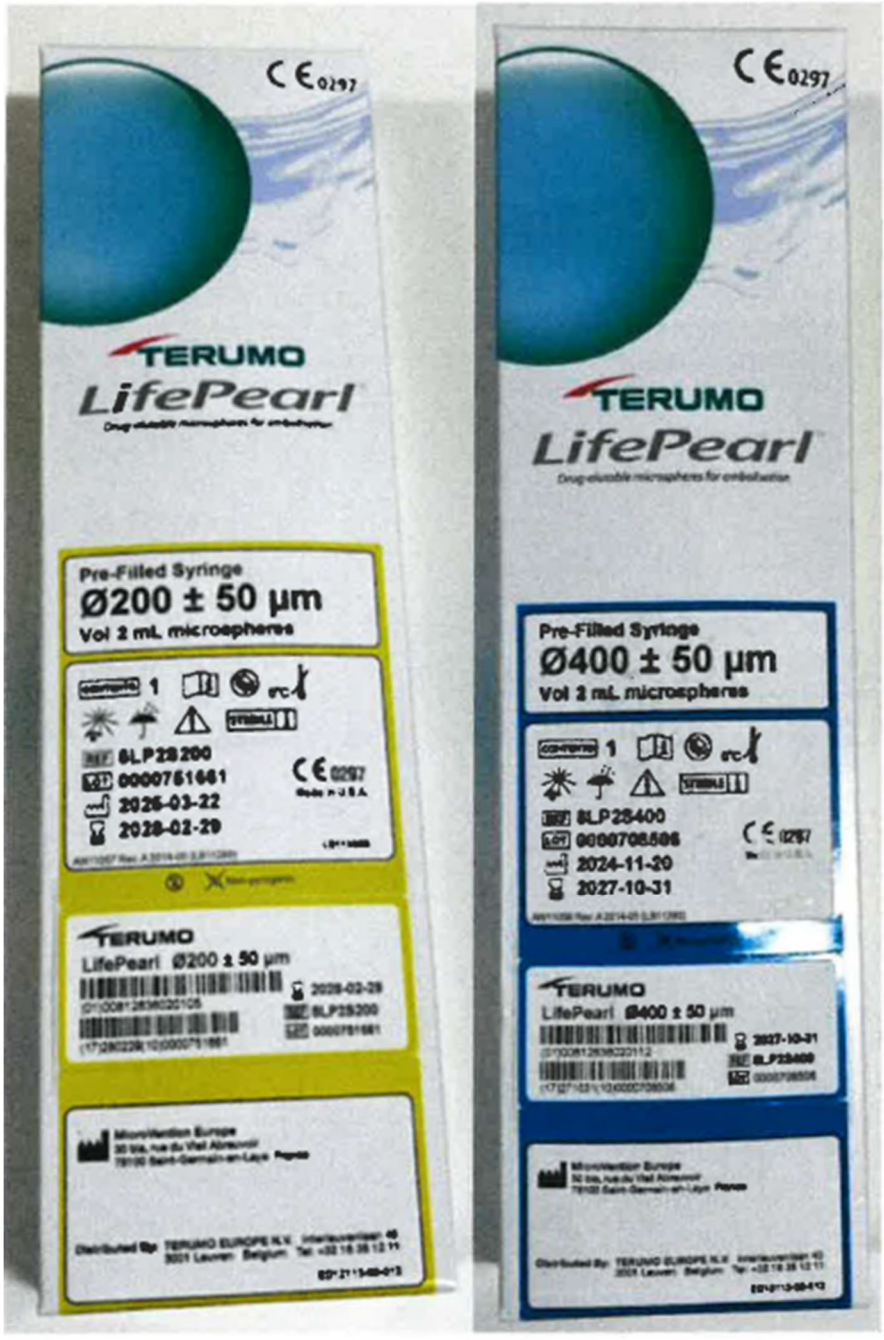
Affected Product Information				
Catalogue No.	Lot No.	Quantity Shipped	Product Status (e.g. used, discarded)	Quantity to be Returned

Customer Representative Name/Print Name)	Signature	Date

PLEASE EMAIL THE COMPLETED FORM to **your TERUMO EUROPE contact.**

LIFEPEARL™ Drug Elutable Microsphere (200 µm and 400 µm) device

SAMPLE IMAGE:



Attachment 1

Catalogue No.	Lot No.
8LP2S200	0000177644
8LP2S200	0000180340
8LP2S200	0000223990
8LP2S200	0000223990
8LP2S200	0000235256
8LP2S200	0000235256
8LP2S200	0000254142
8LP2S200	0000254143
8LP2S200	0000272315
8LP2S200	0000272316
8LP2S200	0000281719
8LP2S200	0000281719
8LP2S200	0000281719
8LP2S200	0000294361
8LP2S200	0000295741
8LP2S200	0000296446
8LP2S200	0000751661
8LP2S400	0000199869
8LP2S400	0000225205

Attachment 2

Catalogue No.	Lot No.
8LP2S200	0000061537
8LP2S200	0000061621
8LP2S200	0000061621
8LP2S200	0000065201
8LP2S200	0000065201
8LP2S200	0000081053
8LP2S200	0000119086
8LP2S200	0000119087
8LP2S200	0000119087
8LP2S200	0000119087
8LP2S200	17072511P
8LP2S200	17082912T
8LP2S200	17082912T
8LP2S200	18011512F
8LP2S200	18011512F
8LP2S200	21060812A
8LP2S200	21060812B
8LP2S200	21061811J
8LP2S200	21062815L