MicroVention
TERUMO

February 2019

URGENT: Field Safety Notice

LifePearl® microspheres

Catalogue number: 8LP2S200
Lot number: 17032021 and 17121811V

Hospital Name and Address
Attention to: To whom it may concern

Dear Customer,

The purpose of this letter is to inform you that MicroVention Europe is voluntarily conducting a field action on two (2) lots of LifePearl® microspheres because of observed particulates in the LifePearl® syringe.

The field action is limited to two (2) lots #17032021 and #17121811V of LifePearl® microspheres. No other released MicroVention products are affected by this field action.

MicroVention is in the process of investigating the cause of this issue. No patient injuries have been reported.

LifePearl® microspheres are indicated for embolization of blood vessels supplying primary hypervascular tumors or metastases in the liver.

Risk to Health

The specific source and makeup of the particulates could not be identified at this time and the patient risk while using product lots in question is not known. Given the estimated size of the particulates relative to the LifePearl microspheres, these particulates may be lodged proximally to the implantation site. Given the limited number of particulates, these particulates may not have a significant impact on the therapeutic effect of the LifePearl® microspheres treatment.

MicroVention®
TERUMO

Actions to be taken by the Customer/User

- Immediately discontinue use of LifePearl® microspheres from lots #17032021 and #17121811V
- 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 Terumo Europe 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 distributor 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

URGENT – FIELD SAFETY CORRECTIVE ACTION

CUSTOMER ACKNOWLEDGMENT AND RECONCILIATION FORM

Product Name	LifePearl® Microspheres
Catalog Number	8LP2S200
Lot Numbers	17032021 and 17121811V

Dear Customer,Our records indicate your institution /company may possess the product that is affected by this field action. Please complete the table below.

Institution/Hospital Name :			**Institution/Hospital Address (including country):**		
Lot #	Quantity	Quantity Used	Quantity Discarded[1]	Quantity to be Returned[2]	Total Quantity
17032021					
17121811V					

[1] Quantity Discarded includes procedure aborted, products were opened in error, products were returned to manufacturer as product complaints, or product discarded for any other reasons.
[2] For returned products, please send this form completed and signed to ppr@terumo-europe.com or to the email of your local Terumo sales contact in communication with you about this action. Customer service will coordinate the return of any remaining devices.

This recall is conducted to the medical facility/user level. If you have provided/transferred thesedevices to someone else, please forward this notice.

Indicate if there have been any adverse events associated with this device. Yes: _____ No: _____
If yes, explain: _____

We acknowledge the receipt of the Field Safety Notice regarding the MicroVention product and catalog numbers listed above. We have received the notice, taken the appropriate action and disseminated this information to any affected staff, service and/or facilities.

Immediate upon receipt of this letter, please sign below and send the form by email to ppr@terumo-europe.com or to the email of your local Terumo sales contact in communication with you about this action.

Hospital Representative (Print Name)	Signature	Date