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FSCA-ref:

172150407/16/26-006R July2026

URGENT FIELD SAFETY NOTICE (FSN)
Embosphere® Microspheres

1. Information on Affected Devices*

1. Device Type(s)*

The Embosphere® Microspheres are biocompatible, spherical, and non-absorbable acrylic polymer microspheres impregnated with porcine gelatin. They are designed to occlude blood vessels. They are hydrophilic to facilitate their passage through micro-catheters and produce total occlusion of the vessel's lumen. They are precisely calibrated and available in 7 size ranges for Embosphere® Microspheres.

2. Commercial name(s)

Embosphere® Microspheres

3. Primary clinical purpose of device(s)*

Embosphere® Microspheres are indicated for arterial embolization in patients undergoing treatment for the following clinical conditions: Hyper vascular tumors and processes, including uterine fibroids, meningiomas, and liver tumors, Benign Prostatic Hyperplasia (BPH) and associated prostate artery embolization (PAE), Arteriovenous malformation (AVM), Bleeding/hemorrhage.

4. Device Model/Catalogue/part number(s)*

DESCRIPTION	UDI	CATALOG CODE	LOT NUMBER
Embosphere®.500-700 µm.2 mL.Syringe.Sterile.Steam.	00884450116715	S420GH/EUA	X3467294-1
	00884450109519	S620GH/EUA	X3472987-1
Embosphere®.700-900 µm.2 mL.Syringe.Sterile.Steam.	00884450364154	S820GH/CAB	X3472923-A
Embosphere®.900-1200 µm.2 mL.Syringe.Sterile.Steam.	00884450403136	S1020GH/C	X3482321-5
	00884450109519	S1020GH/EUA	X3482321-1

2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

2.	Merit Medical Systems, Inc. (Merit) is voluntarily recalling specific lots of Merit Embosphere® Microspheres due to a supplier-related defect that may affect the device packaging sterile barrier. Specifically, certain lots may contain a hole in the blister packaging. This issue affects the lots and part numbers identified in the table below pertaining to the Merit Embosphere Microspheres Merit has chosen to remove the units from the market and request that you immediately stop using or distributing the affected lots and return the affected product to Merit as soon as possible. Risk to Health: According to Merit's evaluation of health hazard(s), use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection. To date, Merit has not received any complaints or reports of patient harm or injury associated with this issue.
2.	2. Hazard giving rise to the FSCA*
	Hole in Blister tray Packaging compromising the sterile barrier.
2.	3. Probability of problem arising
	This defect has a failure rate of 4,738 Parts Per Million (PPM)
2.	4. Predicted risk to patient/users
	Use of the affected product may result in exposure to pathogens/pyrogens, which could lead to infection.

	3. Type of Action to mitigate the risk*
3.	4. Action To Be Taken by the User* ☒ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

Actions required of you:

1. Immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
   a. A picture of the Embosphere® Microspheres is attached to help you identify the product (see image A).

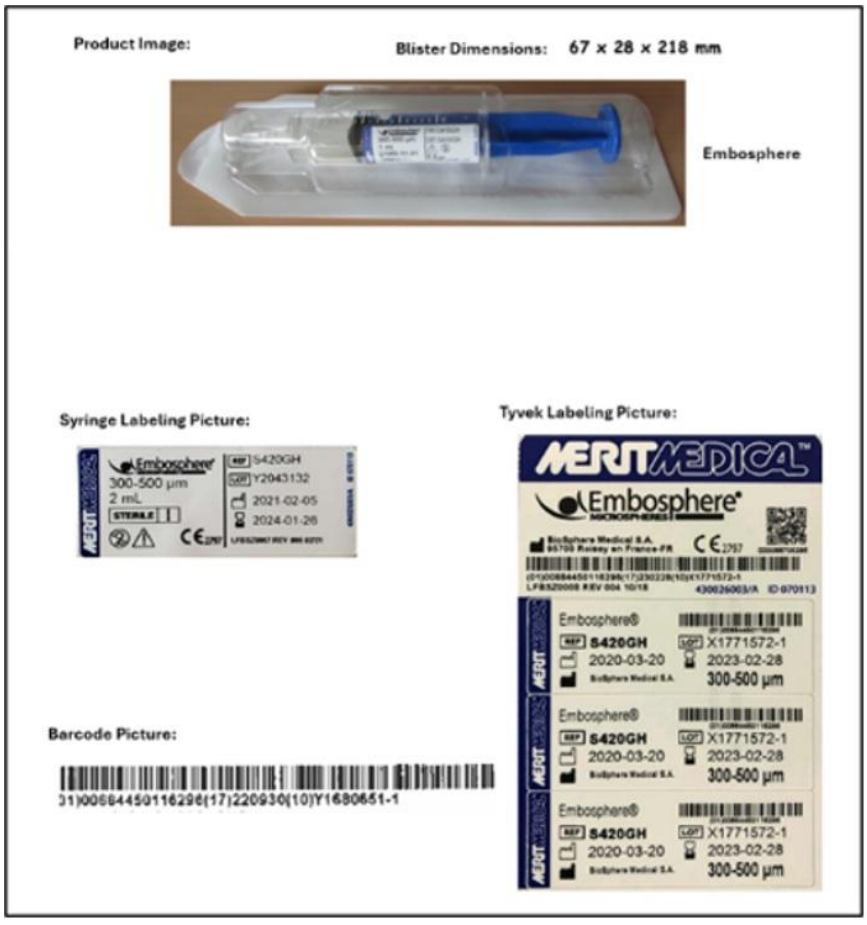

Image A. Embosphere® Microspheres Product / Label Images

1. Please immediately discontinue the use of the affected lots of the Embosphere® Microspheres.

	2. Ensure that applicable personnel within your organization are made aware of this recall. 3. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities. 4. Please immediately return all affected lots in your possession to Merit, per the instructions in the attached CRF. 5. Please fill out, scan and email the completed Customer Response Form to Customer Service at RESPONSE-EMEA@merit.com within 10 business days. All affected product shipped to you must be accounted for on the CRF. 6. When requesting replacement for the Embosphere® Microspheres please utilize the table below for the replacement part number and contact RESPONSE-EMEA@merit.com, along with the completed Customer Response Form. 7. Replacement of the affected product will be provided on a one-to-one basis. Replacement parts are subject to applicability to this recall and regional availability.	
3.	1. By when should the action be completed?	Immediately
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

Replacement Embosphere® Microspheres Catalog Codes
S820GH/CAB
S620GH/EUA
S420GH/EUA
S1020GH/EUA
S1020GH/C

	4. General Information*	
4.	1. FSN Type*	New

4.	2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	3. List of attachments/appendices:	If extensive consider providing web-link instead.

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.