FIELD SAFETY NOTICE

Date: 30th April 2026.

Subject: BOBBY™ Balloon Guide Catheter

Catalog Number/ Lot Number: Various (see Attachment 1)

Label Image: Attached on Page 5 of this Letter.

Dear Terumo Neuro Customer,

This notification is to inform you that the manufacturer of these products, MicroVention (hereinafter referred to as "Terumo Neuro"), is conducting **a voluntary recall** of BOBBY Balloon Guide Catheter. This action is based on complaints identified through established proactive post-market surveillance processes that have generated signal concerns which may impact the patient safety profile of BOBBY Balloon Guide Catheter. **No patient injuries have been reported**.

Health Risk Assessment:

Terumo Neuro has received complaints associated with these balloon inflation-related categories (including, for example: balloon catheter leak or rupture during setup/preparation, balloon catheter leak during procedure, communicating lumens, no/slow inflation or deflation during setup, asymmetrical balloon shape, and pinhole leak at the proximal marker band) which were reported for devices manufactured during the period November 2024 through December 2025.

Although no patient injuries have been reported, Terumo Neuro has made the voluntary decision to restrict product distribution and requests that you immediately stop using and quarantine the BOBBY Balloon Guide Catheter Catalog number from the impacted lots (See Attachment 1) and return the product in accordance with the instructions below.

MicroVention Europe, SARL, carrying on its activities under the business name « Terumo Neuro Europe »
Capital social : 40 000,00 € – 440 775 674 RCS Versailles – Code Naf : 4646Z – VAT : FR 45 440 775 674
Registered address : 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye – France
For any correspondence/ delivery : 1, avenue Edouard Belin – 92500 – Rueil-Malmaison – France
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 / Email : contact.europe@microvention.com

ACTIONS REQUESTED

Terumo Neuro's records indicate that you have received at least one of the recalled lots. Please review your inventory based on the attached list of lot numbers (Attachment #1) and immediately stop using and quarantine all recalled devices listed.

For Customers (including Distributors) - Immediately perform the following steps :

1. For Distributors, please provide this letter to the medical facilities or physicians to whom you have distributed recalled product(s).
2. Please complete, and return the "Customer Acknowledgment form" via email to bobbyrecall@expertinquiry.com
3. Please reconcile and return the recalled products.

Return Product :

- If you have product to return or have any questions regarding the return process, please email bobbyrecall@expertinquiry.com for return instructions and always copy the appropriate customer service email below :

  France : mvfrance.customerservice@microvention.com
  United Kingdom : mvukcs@microvention.com
  Germany, Austria, Switzerland : mvg.complaints@microvention.com
  Italy: mvitaliacs@microvention.com
  Other EMEA countries : mvexportcustomerservice@microvention.com

Please direct any other questions to the Terumo Neuro contact for EMEA:

Ludovic Etcheverry
Director Regulatory & Quality Affairs
1, avenue Edouard Belin, 92500 Rueil-Malmaison – France Hours: Monday – Friday 9:00 – 6:00 pm
Email: MVEMEAQARA@microvention.com

At Terumo Neuro patient safety is our highest priority. This action reflects our commitment to doing what is right, and we appreciate your partnership as we take proactive steps to uphold the highest standards of care.

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CUSTOMER ACKNOWLEDGMENT FORM

Our records indicate you have ordered BOBBY Balloon Guide Catheter affected by this recall. Please complete this form:

CUSTOMER NAME: _____

Attn: Vendor Recall Department

ADDRESS: _____

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 recalled devices have been transferred. YES_____ NO_____

Affected Product Information				
Catalog Number	**Lot Number**	**Quantity Provided**	**Quantity Used/Discarded**	**Quantity to be Returned**

Customer Name	**Signature**	**Date**

Please email the completed form to bobbyrecall@expertinquiry.com with a copy to customer service:

France : mvfrance.customerservice@microvention.com
United Kingdom : mvukcs@microvention.com
Germany, Austria, Switzerland : mvg.complaints@microvention.com
Italy: mvitaliacs@microvention.com
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Attachment 1:

Catalog Number	Lot Number	Catalog Number	Lot Number
BOB-895	0000756596	BOB-895	0000995565
	0000757384		0000996450
	0000758945		0001015817
	0000765270		0001016002
	0000767660		0001018992
	0000772588		0001021878
	0000774885		0001023107
	0000778089		0001025449
	0000779647		0001028255
	0000781240		0001029974
	0000784041		0001031633
	0000799436		0001053417
	0000802183		0001055173
	0000802619		0001056470
	0000809792		0001060464
	0000812812		0001061678
	0000814498		0001062354
	0000816560		0001068354
	0000818876		0001069356
	0000823404		0001071207
	0000823532		0001072898
	0000828250		0001074123
	0000830529		0001083156
	0000836906		0001085850
	0000837785		0001093696
	0000863256		0001101233
	0000866698		0001103095
	0000874138		0001104602
	0000875976		0001108650
	0000906381		0001112366
	0000912667		0001113474
	0000915955		0001115761
	0000919813		0001117185
	0000922930		0001120771
	0000927345		0001121934
	0000930383		0001123077
	0000937458		0001125524
	0000945855		0001128348
	0000976589		0001136555
	/		0001144745
	/		0001146471
	/		0001147975
	/		0001158399
	/		0001171840
	/		0001173474
	/		0001174976
	/		0001176501
	/		0001178541
	/		0001197582
	/		0001202766
	/		0001210548

BOBBY Balloon Guide Catheter Label Image :

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