URGENT: FIELD SAFETY CORRECTIVE ACTION

April 18, 2022

CASPER™
(Carotid Artery Stent)

Dear Customer,

MicroVention has initiated a voluntary Field Safety Corrective Actions (FSCA) for one lot of CASPER™ products due to a potential of unsealed pouch packaging.

Catalog #/ Part #	Lot #
CPR-0830-143RX	2104225AH

Product Indications:

- The CASPER Carotid Stent System is indicated for use in patients with carotid arterial atherosclerotic disease.

There has been one customer complaint related to an open pouch for CASPER™ device. This incident can be detectable. There were no adverse events reported to the manufacturer.

The following actions are to be taken by the user:

- Identify list of affected products in your inventory and cease use of the listed products.
- Complete and return the applicable "ACKNOWLEDGEMENT AND RECONCILIATION FORM" via email – immediately upon receipt.
- Return the unused device(s) per instruction on the ACKNOWLEDGEMENT AND RECONCILIATION FORM

Please direct any questions to MicroVention contact below:

Julie Lopez, Sr. Manager QA/RA EMEA
MicroVention Europe SARL, A **TERUMO** Group Company
30 bis rue du Vieil Abreuvoir, 78100 Saint-German-en-Laye, France
Ph. +33(1)39 21 77 46; Fax +33(1)39 21 16 01
Email: MVEMEAQARA@microvention.com

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

Scafford Serron, Ph.D.
Vice President of Global Quality
Microvention Inc., A **TERUMO** Group Company

FIELD SAFETY CORRECTIVE ACTION
CUSTOMER
ACKNOWLEDGMENT AND RECONCILIATION FORM

CUSTOMER NAME: _____

ADDRESS: _____

CUSTOMER CONTACT PHONE #: _____

We have read and understood the Field Safety Corrective Action letter issued by MicroVention Inc. regarding the CASPER™ Carotid Stent System. We have taken the appropriate action and disseminated this information to any affected staff, service and/or facilities.

We have checked our stock and will be returning the quantity indicated in the table below.

Catalog #	Lot #	Quantity Received	Quantity Used*	Quantity to be Returned

**Quantity Used includes products that were used, opened in error, returned to manufacturer as product complaints, or discarded.*

_____ Representative Name (Print Name)	_____ Signature	_____ Date

PLEASE EMAIL THE COMPLETED FORM to assist@microvention.de.

For returned product – our customer service will provide instructions for product return.

---------- Internal use only (below) ----------

RGA#:_____

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