

Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA 95054 United States

Shockwave Medical
Urgent: Medical Device
Field Safety Corrective Action
Shockwave REDUCER Kits

Issued [date]

<Customer Name
Customer Address 1
Customer Address 2, Country>

Dear Customer,

The purpose of this letter is to advise you that Shockwave Medical, Inc. (a Johnson & Johnson company) is voluntarily conducting a field safety corrective action on select lots of **Shockwave Reducer kits due to the potential for a malfunction of the balloon catheter during deployment of the Reducer device during the implant procedure.**

Complaints received have reported difficulty or inability to deflate the balloon during the implant procedure. Investigation of returned product confirmed a device malfunction associated with manufacturing process used in specific lots of the Shockwave Reducer Kit. Refer to the product scope below. Only Shockwave Reducer Kit lots included in table below are affected by this action; lots not listed in the table can continue to be used. This product malfunction does not impact patients with an existing implanted Reducer device.

Risk to Health

Reported adverse events associated with this device malfunction include procedure prolongation, the need for additional percutaneous steps to deflate balloon, and device embolization in one case. In addition, although none of the reported device malfunctions have been associated with the need for surgical intervention or death, this device malfunction has the potential to cause serious events of this nature. In order to prevent these events from occurring, do not use any devices with the lot numbers listed below. Please return affected devices to Shockwave Medical as described below in the section on Action to Be Taken by Customer/User. Note that there is no risk or impact to patients who have an existing Reducer implant.

Action to be Taken by Customer/User

Customers should take the following actions:

- Immediately examine your inventory and quarantine product subject to field safety action.
- Request RMA from country contact list provided, reference on return product packaging.
- Return product with the lot numbers per table listed below to:

Shockwave Medical, **Attn QA-FSCA-2026-61**
5403 Betsy Ross Drive
Santa Clara, CA 95054 USA

- In case of an adverse event, report as per standard practice.
- Complete and return attached acknowledgement form.

Product and Distribution Information:

Immediately examine your inventory and quarantine product defined in the table below. In addition, if you may have further distributed this product, please notify the recipient at once of this product action and provide them with a copy of this advisory notice.

Affected Product Scope:

- Shockwave Reducer Kit, Packaged Sterile, Catalog R1385CEV
- Manufacturing Date Range: 28Sep2024 – 19Jan2026
- Expiration Date Range: 28Sep2026 – 25Sep2027
- Affected Lot Numbers:

01A250210A	03A250604A	04A251002A	05A251002A	07A250916A	10A250303A
01A260107A	03A260112A	04A251014A	05A260204A	07A260108A	12A251008A
01A260223A	04A250203A	04A251023A	05A260220A	07A260128A	12A260108A
02A260116A	04A250520A	05A250514A	06A241028A	08A260106A	14A250304A
03A250318A	04A250701A	05A250527A	06A250820A	09A250218A	14A250408A
03A250512A	04A250707A	05A250717A	06A251213A	09A250501A	17A250728A

Your assistance in completing and returning the enclosed acknowledgement form to swm-fieldaction@its.jnj.com is greatly appreciated and necessary to document efforts of this action. If you have any questions, please direct to swm-fieldaction@its.jnj.com.

This product field safety corrective action is being made with the knowledge of the local country regulatory authority.

Sincerely,

Peter Nowakowski
VP, Quality

Enclosed: Acknowledgement Response Form, Country Contact List for Product Return RMA request

Medical Device FSCA Acknowledgement

Response and Receipt Form

Response is Required

<Customer Name
Customer Address 1
Customer Address 2, Country>

Shockwave Reducer Kits

Please complete and return form regardless of whether you have any affected product:

Quantity Shipped to Customer: <#>

Disposition	Quantity
Affected Product to be Returned	
Consumed (prior to notice)	

By returning this form, I attest that I have received, read and understand the instructions provided in the Reducer Advisory Notice dated [date].

Printed Name/Title:	
Telephone:	
Email address:	

PLEASE SCAN AND RETURN COMPLETED FORM TO:

swm-fieldaction@its.inj.com

OR MAIL TO:

Shockwave Medical, **Attn QA-FSCA-2026-61**
5403 Betsy Ross Drive
Santa Clara, CA 95054 USA

Country Contact list for Product Return RMA Request:

COUNTRY	PHONE NUMBER	EMAIL
Austria	+43 800 018 051	cs.dach@shockwavemedical.com
France	+33 805 98 06 47	cs.france@shockwavemedical.com
Germany	+49 800 428 3280	cs.dach@shockwavemedical.com
Ireland	+353 1800 663 300	cs.ie@shockwavemedical.com
Italy	+39 800 829 651	cs.italy@shockwavemedical.com
Portugal	+351 800 600 007	cs.iberia@shockwavemedical.com
Spain	+34 900 838 749	cs.iberia@shockwavemedical.com
Switzerland	+41 800 000 510	cs.dach@shockwavemedical.com
UK	+44 808 304 8305	cs.uk@shockwavemedical.com
International Distributors	+33 1 57 95 06 72	cs.intl@shockwavemedical.com