Johnson&Johnson MedTech

Circulatory Restoration

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

Shockwave Medical

Urgent: Medical Device Field Safety Corrective Action

Shockwave REDUCER

Issued 04 November 2026

<Customer Name
Customer Address 1
Customer Address 2,
City, State Zip 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 the **Shockwave Reducer due to an observed safety signal that is under review.**

Risk to Health

This notification is being shared out of an abundance of caution while this signal is investigated. Additional information is necessary to make determination of the impact to health.

Action to be Taken by Customer/User

Customers should take the following actions:

- Immediately examine your inventory and quarantine all Reducer product.
- Request RMA from country contact list provided, reference on return product packaging.
- Return all product to:
  Shockwave Medical, **Attn QA-FSCA-2026-65**
  5403 Betsy Ross Drive
  Santa Clara, CA 95054 USA
- Complete and return enclosed acknowledgement form.
- Continue to monitor patients with implanted Reducer product as per the standard of care.
- In case of an adverse event, report as per standard practice.
- If you have further distributed this product, please notify the recipient at once and provide them with a copy of this advisory notice.

Do not distribute- DRAFT

DRAFT

Product and Distribution Information:

Affected Product Scope:

- Shockwave Reducer Kit, Packaged Sterile, Catalog R1385CEV, R1385GBV.
- Manufacturing Date Range: xxx
- Expiration Date Range: 09/25/2027- 01/28/2028
- Affected Lot Numbers: pending

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

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Medical Device FSCA Acknowledgement

Response and Receipt Form

Response is Required

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<Customer Name
Customer Address 1
Customer Address 2,
City, State Zip Country>

Shockwave Reducer

☐I have product to return, quantity: _____
☐I do not have product to return

By returning this form, I attest that I have received, read and understand the instructions provided in the Reducer Field Safety Notice dated 04November2026.

Site ID:	<merge data>
Printed Name/Title:	
Signature:	
Telephone:	
Email address:	

PLEASE SCAN AND RETURN COMPLETED FORM TO:
swm-fieldaction@its.jnj.com

OR MAIL TO:
Shockwave Medical, **Attn QA-FSCA-2026-65**
5403 Betsy Ross Drive
Santa Clara, CA 95054

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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

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