

Urgent Medical Device Product Removal - Immediate Action Required
ROTAWIRE™ Drive and wireClip™ Torquer

March 8, 2022

Dear Materials Manager / Field Action Contact:

Boston Scientific is conducting a removal of specific batches of ROTAWIRE™ Drive and wireClip™ Torquer after determining that a small number of pouches containing these products may have a weak seal, which could open during normal shipping and handling and thus compromise the sterile barrier. Use of a ROTAWIRE Drive product from a package with a sterile barrier breach may present a risk of infection. The most serious health risk that could occur from use of a non-sterile ROTAWIRE Drive is a post-procedure endocarditis or access site infection that could be managed with medical evaluation and treatment with oral or intravenous antibiotics. We have received one complaint related to this issue and there have been no patient harms or adverse events reported.

This removal **only** affects the UPNs and specific batches of ROTAWIRE Drive listed in Attachment 1. Please cease further distribution or use of any product affected by this removal immediately.

No other UPNs or batches are affected by this removal. **The legacy Rotawire Floppy and Rotawire Extra Support are not included in this action.**

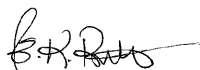
If you identify any product from the affected batches within your inventory, please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions. Please indicate on your Reply Verification Tracking Form (RVTF) the quantity of units from each batch that you will be returning.

If you are a distributor, please note that the depth of this removal is to the end user level and this notification should be forwarded to your customers. If you are a facility that has sent products to another hospital or facility within your network, please ensure that this notification is forwarded to them.

Boston Scientific is notifying regulatory authorities of this removal as required.

Boston Scientific is committed to continuous improvement in the interest of patient benefit, and patient safety remains our priority. We regret any inconvenience this action may cause, but believe transparent communication will ensure you have timely, relevant information for managing your patients. If you have any questions about this action, please contact your Boston Scientific sales representative

Sincerely,



Rebecca KinKead Rubio
Quality Manager

Encl: Removal Instructions
Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm
and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

Removal Instructions

The Reply Verification Tracking Form enclosed with this letter must be completed and returned **even if you do not have any product from the affected batches.**

- 1. Immediately discontinue use of and segregate affected product.**
 - Immediately remove all affected product from your inventory.
 - Segregate this product in a secure location for return to Boston Scientific.
- 2. You must complete and email or fax your Reply Verification Tracking Form(s) immediately to get an RGA # before you return any product.**

- Indicate on your RVTF the quantity of units from each lot/batch that you will be returning.
- Return the RVTF as described below:

Email: BSCFieldActionCenter@bsci.com

or

Fax to: Field Action Center 1-763-415-7708

You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number within 24-48 hours **after your RVTF is received**

- **Report all inventory to be returned and report in single-unit quantity(ies), not boxes.**
- NOTE: If you have responded to this Removal to anyone other than Boston Scientific, we would not have received your response. Please respond using the email/fax information provided above.

Credits will be issued for all affected product that is properly returned to Boston Scientific.

- 3. Package/Ship the Affected Product.**
 - Package any product that is being returned in an appropriate shipping box.
 - Affix the enclosed (red/white) return address label to the outside of the box.
 - Write the RGA number in large print on the outside of the box, on the return address label.
 - Feel free to use our Federal Express Number 9205-2515-6 to return this package via second day delivery.
 - Seal the box, and return to: **Boston Scientific Corporation
US Distribution Center
Boston Scientific Marina Bay
Customer Fulfillment Center
500 Commander Shea Blvd.
Quincy, Massachusetts 02171
RGA: _____**

Attachment 1 – Product Listing

Material	Material Description	GTIN	Batch Number	Expiration Date
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27622475	7-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27622478	7-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27691111	19-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27698472	20-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27706785	21-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27708190	21-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27756019	30-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27756205	30-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27756933	30-Jul-2023
H74939462005	ROTAWIRE DRIVE FLOPPY 5 PACK	08714729996262	27756935	30-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27630467	8-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27632712	8-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27701910	20-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27705926	21-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27749752	29-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27749754	29-Jul-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27792970	6-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27804244	9-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27805109	9-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27806091	9-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27826574	12-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27826576	12-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27853736	17-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27853738	17-Aug-2023
H74939463005	ROTAWIRE DRIVE EXTRA SUPPORT 5 PACK	08714729996248	27862767	18-Aug-2023