[Neuromodulation]

Urgent Medical Device Removal - Immediate Action Required
Superion™ Indirect Decompression System

6 June 2025

Dear Health Care Professional:

Boston Scientific has conducted a comprehensive performance review of the Superion system and determined that it is not consistently meeting expected performance levels during the implantation procedure including breakage of the instrument (e.g. driver tip and insertion tool) and device (e.g. spindle cap). In instances where the device has already been deployed, there is no clinical need for removal and routine standard of care should be followed.

The product performance review found that the most frequently reported issue associated with intraoperative breakage of the Superion device is procedural delay. However, if a Superion device is broken during the implant procedure and not removed and/or replaced intraoperatively, potential issues may include:

- Ineffective therapy; device migration which may increase the risk for spinous process fracture; or additional surgery to explant and/or replace the broken Superion device with inherent risks such as infection, pain, and discomfort.

In addition, the instruments used to implant the Superion device have been reported to fracture when excessive force is applied, most commonly resulting in prolongation of procedure time. If the distal portion of an instrument is fractured intraoperatively and not removed, potential issues may include:

- Additional surgery to retrieve retained fragments, with associated risks such as infection, pain, and discomfort; surgical site more prone to infection; serious or life-threatening complications if a patient with retained instrument fragments undergoes MRI, due to possible fragment displacement caused by the magnetic field.

Description

The Superion Indirect Decompression System consists of the sterile Superion implant and a kit that includes sterile, single-use manual instruments specifically designed for implanting the Superion device. The Superion device is implanted by percutaneous means through a cannula inserted between adjacent spinous processes. The sterile, single-use manual instruments are employed to access the interspinous process space and to position the device. The Superion device is introduced through the cannula in its closed or undeployed state. Once positioned at the desired location (interspinous process space), the distal tip of the stainless-steel Driver instrument engages the deployment mechanism (spindle) at the proximal end of the Superion device. Rotation of the Driver instrument deploys the Superion device by rotating the cam lobes to secure the implanted device.

Actions to be Taken

Physicians should stop all implants of the Superion Indirect Decompression System. Further distribution or use of any remaining affected product should cease immediately.

This recall notification <u>does not</u> apply to Superion devices that have already been implanted and they can continue to remain in use.

Boston Scientific is not recommending explant of successfully implanted Superion devices.

Affected Product Listing

Our records indicate that your facility received affected product(s). The table below provides a complete list of all affected products, including Product Description, Material Number (UPN) and GTIN. Please note that only the devices listed below are affected. No other Boston Scientific product is involved in this communication.

Product Description	Material Number (UPN)	GTIN Number	Lot Number
Superion Indirect Decompression System 8MM, VF Implant	101-9808	00884662000529	ALL
Superion Indirect Decompression System 10MM, VF Implant	101-9810	00884662000536	ALL
Superion Indirect Decompression System 12MM, VF Implant	101-9812	00884662000543	ALL
Superion Indirect Decompression System 14MM, VF Implant	101-9814	00884662000550	ALL
Superion Indirect Decompression System 16MM, VF Implant	101-9816	00884662000567	ALL
Superion Indirect Decompression System Kit, VF Instrument	102-9800	00884662000574	ALL
The Vertiflex Procedure Instrument Platform, VF Instrument	140-9800	00884662000611	ALL

Upon receipt of this Notice, please do the following:

1. Continue to report all device-related incidents or quality concerns experienced with the Superion Indirect Decompression System to Boston Scientific.

2. Please segregate all Superion Indirect Decompression System product immediately and return it to Boston Scientific in accordance with the enclosed instructions.

3. A thorough review of the explant data was also completed which demonstrates that the instruments used in the explant procedures do not break at the same rate as observed in the implant procedure. If you require a Superion Driver instrument for an explant procedure contact your Boston Scientific Representative.

Share this information (as appropriate) to provide awareness, particularly with clinicians in your hospital who use Superion Indirect Decompression System. Also share this information with any other organization to which these devices may have been transferred.

Maintain a copy of this notice in your records.

If you are a facility that has sent products to another hospital or a facility within your network, ensure this notification is forwarded to them.

We appreciate your understanding as we take action to address this issue. At Boston Scientific, patient safety and customer satisfaction are our priority. We are committed to continuing to offer products that meet the quality standards that you expect from Boston Scientific.

Sincerely,

John Donohue
Vice President, Global Quality

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

Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any Affected Product.

Upon receipt of this Notice, please do the following:

1. Immediately discontinue use and segregate Affected Product.
2. Complete and return the RVTF to get a Return Goods Authorization (RGA) number.
    - Indicate the quantity of SINGLE units you will be returning for credit
    - If you have product that is listed in Attachment 1 (Affected Products) that is not included on your RVTF, provide the material number, lot number, and quantity you intend to return on your RVTF
    - Return the RVTF via:
      Email: BSCFieldActionCenter@bsci.com
      or
      Fax: BSC Field Action Center 1-763-415-7708
3. Once Boston Scientific receives your completed RVTF, you will be contacted within 2 business days and provided an RGA number for product return.
4. Package and ship affected product:
    - Write the RGA number in large print on the enclosed (red/white) return address label
    - Affix the return address label to the outside of box
    - Use our Federal Express account number: 9205-2515-6 to return package via second-day delivery
    - Seal box and return to:
      Boston Scientific Corporation
      US Distribution Center
      500 Commander Shea Blvd
      Quincy, MA 02171
      RGA: _____
5. If you send a response to this Removal Notice to anyone other than Boston Scientific, we will not receive your response. Please ensure your response is sent to the email or fax indicated above.
6. Credit will be issued for all returned Affected Product once received and confirmed by Boston Scientific.