Urgent: Medical Device Correction

12 May 2023

To: Physicians/Surgeons, Hospitals, Healthcare Professionals

Subject: Urgent Medical Device Correction – Use of Superion® Indirect Decompression System (IDS) Driver Instrument

Reference: Boston Scientific Field Action 97003015-FA

Dear Physician/Surgeon or Healthcare Professional:

Boston Scientific is informing you about the potential for Superion® Indirect Decompression System (IDS) Driver instrument tip breaks to occur with use of excessive force during the implant procedure. You are receiving this letter because you may have implanted one or more patients with a Superion IDS device and thus have used the Driver instrument from the Superion IDS kit (Table 1). This letter provides important information regarding the detection and management of Driver tip breaks. Boston Scientific is not removing Driver instruments from the field; all instruments remain available for use. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Table 1. Superion IDS Kit

Components	*UPN*	*GTIN*	*Lots*
Driver, Inserter, IS Gauge	102-9800	00884662000574	All

- **Based on reports received to date, Driver tip damage may occur with use of excessive force during deployment of the Superion implant.**
    - **Driver tip damage may include deformation/bending, cracking, fracture/breakage, or teeth shearing/tip breaks.**
    - **Driver tip damage may be readily detected via visual, audible and/or tactile signals.**

  - **Driver tip breaks may result in metal fragments (Driver teeth/tips) within the implant location.**

- **Although no serious injuries or long-term patient consequences have been reported to date, the potential exists for harm in association with generation of Driver tip metal fragments.**

  - **Based on review of previous reports regarding the detectability of Driver tip breaks, as well as visibility and successful removal of metal fragment(s), Boston Scientific estimates the risk associated with a prolonged implant procedure is low.**

  - **If metal fragment(s) are not removed and remain in situ, MRI scans are NOT advised due to potential risk of patient injury. Boston Scientific estimates the probability for this harm to occur as remote.**

- **Pending regulatory agency approval, Boston Scientific will be updating Superion IDS Instructions for Use (IFU) to advise against MRI scanning for patients with unretrieved metal fragments.**

- **Superion IDS devices, including the Driver instrument, continue to meet required specifications and remain available for implant.**

- **Please complete and return the enclosed account-specific Acknowledgment Form to Boston Scientific [refer to page 5 for instructions].**

Description

The Superion IDS 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.

Boston Scientific has received reports of Driver instrument tip breaks that have occurred during Superion IDS implants, some of which resulted in generation of metal fragments (i.e., Driver teeth shearing/tip breaks) within the implant location. Further investigation of these reports indicated that Driver tip breaks were readily identifiable (i.e., via audible, visual, or tactile signals) during the implant procedure. There were no reports of adverse patient effects or reports associated with difficulty retrieving observed metal fragments.

Clinical Impact
The Superion IDS IFU advises against forced deployment, as it could result in device breakage. An occurrence of Driver tip breakage can be readily identified via an audible click, a loss of tactile resistance during the implant procedure, and/or visual detection following removal of the Driver instrument from the inserter tool and subsequent inspection. Missing or bent teeth prevents Driver engagement with the Superion implant and requires exchange for a new/replacement Driver to complete deployment.

Field Performance Data
To date, Boston Scientific has received a total of sixty-three (63) reports of events associated with Driver tip damage (ranging from bending/deformation or cracking of the Driver instrument to Driver teeth shearing/tip breaks). Although only a subset of these events reported actual Driver tip breaks associated with metal fragments, Boston Scientific conservatively includes all reports of Driver damage in risk estimates. Note that all cases of Driver tip breakage that Boston Scientific has received to date were promptly addressed/resolved with no additional reports of patient complications.

Potential Harms or Risks to Patient Health
Although there have been no serious injuries nor long-term patient consequences reported to date, the potential exists for harm. Those foreseeable harms include prolongation of the implant procedure, inadvertent retention of (or inability to retrieve) metal fragments and subsequent exposure to MRI, and/or additional surgical intervention for removal (if a Driver tip break is not immediately identified at implant). Based on detailed review of the events reported to date, engineering analysis and testing, as well as detectability of potential Driver tip breaks during the implant procedure, Boston Scientific estimates the probabilities of patient harm associated with metal fragment(s) remaining in situ to be:

- Low risk of prolonged implant procedure;
- Remote risk of injury associated with magnetically induced migration due to MRI scans;
- Remote risk of injury with non-magnetically induced migration, as any metal fragment(s) remaining in situ would not be in immediate proximity to vital organs and would most likely be encapsulated in surrounding connective tissue; and
- No significant risk of systemic toxicity.

Recommendations

1. Review the Superion IDS IFU, Surgical Technique Manual, and Superion IDS Kit IFU [https://www.bostonscientific.com/elabeling/us/en/home.html]: Review existing guidance regarding proper Driver instrument use (i.e., avoid application of excessive force and use only two or three fingers when performing final tightening during device deployment).

2. Inspect the Driver instrument prior to and following use; if a Driver tip break is noted: Promptly retrieve metal fragment(s) and consider performing imaging (e.g., fluoroscopy) to confirm successful removal. Note that missing or bent teeth prevents Driver engagement with the Superion implant and requires exchange for a new/replacement Driver instrument to complete successful deployment. If metal fragment(s) are not successfully removed:

- **Due to potential risk of patient injury, MRI scans are NOT advised for patients with metal fragment(s) remaining in situ. Pending regulatory agency approval, Boston Scientific will be updating Superion IDS IFU to advise against MRI scanning for patients with unretrieved metal fragments.**
- **Append the patient's medical record with a copy of this letter to maintain awareness of metal fragment(s) remaining in situ for the remaining service life of the Superion device**.
- **Consider alternative imaging modalities for patients with metal fragment(s) remaining in situ** (e.g., X-ray, ultrasound, CT scan).

3. Documentation: Complete the attached, mandatory Acknowledgment Form and return it to Boston Scientific promptly (please refer to the enclosed Medical Device Recall Instructions).

Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific via email at BSN.ComplaintCallCenter@bsci.com or FDA's MedWatch Adverse Event Reporting program [www.fda.gov/MedWatch/report.htm or 1.800.FDA.1088 (332.1088)].

Additional Information
Patient safety is our highest priority. As such, we are committed to transparent communication to ensure that you have timely, relevant information for managing your patients. If you require additional information regarding this communication or would like to report a clinical event, please contact your local Boston Scientific representative.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance
Boston Scientific

Medical Device Correction Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned to Boston Scientific.

1. Immediately post this information in a visible location near the product(s) to ensure information is easily accessible to all users.
2. Complete and return the Acknowledgment Form to the Boston Scientific Field Action Center:

Email:	BSCFieldActionCenter@bsci.com; OR
Fax:	Field Action Center 1-866-213-1806