State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Boston Scientific Neuromodulation Corporation Superion Indirect Decompression System

Recall Date	Product Description	Recalling Firm	Recall Reason
6/21/2023	**Superion Indirect Decompression System** Driver Instrument, part of the Superion Indirect Decompression System, REF: 102-9800, used with the Superion Indirect Decompression System IFU, Superion IDS Kit IFU, Surgical Technique Manual	**Boston Scientific Neuromodulation Corporation** Valencia, CA	Pending update to indirect decompression system instructions for use informing users that excessive force during the implant procedure may cause driver instrument tip breaks, which may result in metal fragments (Driver teeth/tips) within the implant location; and if metal fragments are not removed and remain in situ, MRI scans are NOT advised due to potential risk of patient injury.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Superion Indirect Decompression System** Driver UDI-DI: 00884662000574, UPN: 102-9800, All Lots. Superion Indirect Decompression System IFU (92479815-02), Superion IDS Kit IFU (92479820-02), Surgical Technique Manual (92479821-02)	2,570 Units in California	May 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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