California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific Neuromodulation Corporation Recalls Superion Indirect Decompression System Kit

Recall Date	Product Description	Recalling Firm	Recall Reason
9/2/25	Superion IDS Kit Superion Indirect Decompression System 8MM, VF Implant 101-9808 00884662000529 Superion Indirect Decompression System 10MM, VF Implant 101-9810 00884662000536 Superion Indirect Decompression System 12MM, VF Implant 101-9812 00884662000543 Superion Indirect Decompression System 14MM, VF Implant 101-9814 00884662000550 Superion Indirect Decompression System 16MM, VF Implant 101-9816 00884662000567 Superion Indirect Decompression System Kit, VF Instrument 102-9800 00884662000574 The Vertiflex Procedure Instrument Platform, VF Instrument 140-9800 00884662000611 The Superion IDS Kit includes a set of proprietary instruments to deliver the Superion Implant in a minimally invasive manner. Instruments specifically designed for implanting the Superion Implant are sterile, single-use disposable instruments, consisting of a Dilator Assembly,	Boston Scientific Neuromodulation Corporation	As a result of a comprehensive product performance review it was determine that the device and instruments are not consistently meeting expected performance levels. Issues include breakage of the instruments and implant/device.

	Cannula Assembly, Interspinous Gauge, Inserter, Reamer, and Driver.		

Recall Class	Product Identification	Distribution	Affected Dates
II	Superion Indirect Decompression System 8MM, VF Implant UPN: 101-9808 GTIN (DI): 00884662000529 ALL Lot/Batch Number: 40280174 40145632 40117221 40113198 40113255 40113385 40113391 40113482 40106856 40027385 26176977 800276 800301 Superion Indirect Decompression System 10MM, VF Implant UPN: 101-9810 GTIN (DI): 00884662000536 ALL Lot/Batch Numbers: 40222297 40213592 40199967 40198809 40195249 40186649 40181505 40166300 40157622 40141657 40141770 40136859 40131798 40132036 40112806 40106870 40093564 40080016 40080111 40076497 40070306 40070307 40052009 40045101 40034339 40027338 40027364 40022398 40018296 40018338 40010128 40004038 40004068 40000647 30244690 30178729 29985230 29849515 29849969 29668712 29668713 29578948 29578949 29360265 29360263 29360264 29160559 29160625 28756501 28627193 28627192 28627194 28501592 28501591 28501593 28344375 28344376 28344377 28133122 800279 800345 800269 800278 800268 800280 800261 800270 700089 800259 800260 800258 800250 800317 800318 700085	7,197 devices were distributed in California.	June 2025.

	Superion Indirect Decompression System 12MM, VF Implant UPN: 101-9812 GTIN (DI): 00884662000543 ALL Lot/Batch Numbers: 40280071 40245960 40222355 40211234 40211404 40211463 40199117 40199211 40186760 40165937 40157506 40157279 40139759 40140041 40132011 40129328 40114193 40114290 40106757 40106924 40093299 40093565 40080015 40080124 40070323 40051777 40045673 40045706 40044635 40045080 40027314 40027337 40027346 40018297 40018311 40018344 40018360 40010112 40010126 40010144 40004051 40004081 40003228 40000665 30244396 30244397 29985232 29985233 29927752 29850082 29850085 29850083 29788495 29667699 29668637 29668640 29623992 29556093 29547992 29540069 29540067 29540068 29394426 29360815 29361201 29361220 29361221 29361159 29361200 29243822 29244010 29244067 29244068 29170416 29164935 28737193 28627392 28627985 28627195 28620905 28545960 28460945 28460942 28460944 28460941 28460943 28444915 28344378 28344379 28282295 28282296 28133124 28133125 28133123 28123077 28051836 28047778 28047777 28047779 27909032 27844690 27812316 27812317 27809085 27809084 27783073 27783072 27787123 27771035 27735759 27707788 27696311 27657263 27657244 27641430 27619527 27620200 27593135 27594003 27576476 27576376 27558963 27553036 27535575 27531204 27508978 27509115 27509116 26929604 26929605		

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	System Kit, VF Instrument UPN: 102-9800 GTIN (DI): 00884662000574 ALL Lot/Batch Numbers: 40277815 40277874 40277890 40277911 40278004 40278100 40278101 40276344 40276407 40276430 40276444 40276525 40276527 40276566 40276587 40276605 40276646 40276663 40276664 40271124 40262838 40262970 40263108 40257898 40258441 40258462 40257952 40258003 40258047 40258067 40258102 40258140 40258141 40256318 40256554 40256555 40256590 40256627 40256645 40256684 40256706 40254134 40254135 40254153 40254211 40254212 40254256 40254257 40254258 40254259 40254274 40254335 40254349 40254350 40254398 40254464 40254465 40254466 40254467 40254521 40254522 40254542 40245657 40240497 40240498 40240793 40240878 40240888 40240931 40240970 40240971 40240972 40241044 40241068 40241105 40241144 40241145 40235666 40233094 40232369 40232387 40232388 40232405 40232429 40232472 40232489 40232495 40232591 40232595 40232653 40232657 40225393 40224452 40223799 40223952 40223953 40223955 40223976 40223995 40223996 40224033 40224035 40224075 40224148 40224151 40224163 40224221 40224222 40224240 40224241 40213780 40207876 40207916 40207958 40208033 40208115 40208135 40208176 40208179 40208192 40208193 40208206 40208242 40208260 40208261 40203693 40200036 40200037 40200038 40200375 40200409 40200489 40200490		

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For additional information, please visit the FDA Website.