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On June 17, 2026, Boston Scientific initiated the voluntary removal of Infinion™ CX leads due to higher-than-anticipated complaint rates related to high impedance and lead fractures. Infinion CX leads are components of the Boston Scientific Spinal Cord Stimulator (SCS) System, which is used as an aid in the management of chronic intractable pain of the trunk and/or limbs. Boston Scientific provided physicians with instructions for returning unused product. This action was subsequently classified by the U.S. Food and Drug Administration (FDA) through its standard classification process.

An investigation by Boston Scientific found that the lead body may be exposed to stress at the anchor site, which in some cases resulted in reports of high impedance or lead fractures.

The most frequently observed harm is inadequate stimulation. If reprogramming does not resolve the issue, additional intervention, including lead explant or replacement, may be required. These interventions represent the most serious harm observed.

It is important to distinguish the regulatory reporting category from the nature of the clinical harm observed. Under FDA reporting requirements, an event can be categorized as a “serious injury” when medical or surgical intervention is required.

Infinion CX leads were already being phased out, and Boston Scientific has ended manufacturing of the product. The newer Infinion™ Pro leads have replaced Infinion CX leads for new implants and lead replacements.

The action applies to unused Infinion CX leads and does not call for removal of leads that are already implanted. FDA states that no additional patient monitoring beyond routine clinical follow-up is recommended. For patients with implanted Infinion CX leads, the issue may present as high impedance, inadequate stimulation or loss of stimulation and can be evaluated through routine follow-up and standard device troubleshooting, including reprogramming when appropriate. If the issue cannot be resolved, the affected lead can typically be removed and replaced while the implanted stimulator remains in place.