

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Checkpoint Surgical Inc Checkpoint Guardian Intraoperative Lead, Small and Medium

Recall Date	Product Description	Recalling Firm	Recall Reason
03/26/2025	<p>Brand Name: Checkpoint Guardian Intraoperative Lead</p> <p>Product Name: Checkpoint Guardian Intraoperative Lead, Small</p> <p>Model/Catalog Number: REF# 9524 (Small)</p> <p>Product Name: Checkpoint Guardian Intraoperative Lead, Medium</p> <p>Model/Catalog Number: REF# 9525 (Medium)</p> <p>Product Description: The Checkpoint Guardian Intraoperative Leads are single-patient disposable accessories for providing stimulus to a targeted nerve. The accessories are intended for use with any device from the Checkpoint Stimulator/Locator Family. The lead electrode is intended to wrap around nerves that have been surgically exposed, allowing the surgeons to provide hands free stimulus to a targeted nerve.</p>	Checkpoint Surgical Inc	<p>Adhesive on the back of the lead may not fully encapsulate the metallic portion of the wire and button subassembly, potentially leading to exposed metal. There is a risk of electrical current leakage, which may lead to inconsistent or confusing muscle responses, potentially compromising the effectiveness of the intended use as the surgeon could take an incorrect clinical action.</p>

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: B13095240 Small Lot 4318 Expires 01Apr2026 Lot 4325 Expires 01Apr2026 Lot 4368 Expires 01Dec2026 UDI-DI: B13095250 Medium Lot 4322 Expires 01Apr2026 Lot 4326 Expires 01Apr2026 Lot 4333 Expires 01Jul2026 Lot 4352 Expires 01Jul2026	0 units in California 72 units in California	February and prior

For additional information, please visit [FDA Website \(small\)](#) and [FDA Website \(medium\)](#).