

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Kirwan Surgical Products, LLC Ambler Surgical, Disposable, Optikon, and Walcott Bipolar Pencil
25 Gauge Straight

Recall Date	Product Description	Recalling Firm	Recall Reason
12/16/2024	<p>Ambler Surgical Bipolar Pencil 25 Gauge Straight Model/Catalog Number: PD7226 Component: No</p> <p>Kirwan Surgical Products LLC Disposable 25-gauge bipolar pencil, straight, Long Model/Catalog Number: 14-5011L</p> <p>Optikon Bipolar Pencil 25 Gauge Straight Model/Catalog Number: OPT14-5011</p> <p>Walcott Bipolar Pencil 25 Gauge Straight Model/Catalog Number: RX14-5011</p> <p>The Disposable Microsurgical Bipolar Pencil are designed for use in eye surgery, and other soft tissue procedures. For instance, the pencils are designed for cauterization of the retinal area during surgical procedures. The current line of pencils all have the same</p>	Kirwan Surgical Products, LLC	Potential for the outer stainless-steel tube to break or detach.

	molded handle. The pencils' tip outer diameter is 25 gauge.		
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Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Model/Catalog Number: PD7226 GTINs: Pouch – 00190660001025 Inner Pack – 10190660001022 All expiration dates from 2027-09-01(YYYY-MM_DD) on would encompass the for the recall</p> <p>Model/Catalog Number: 14-5011L GTINs: Pouch – 00841019101056 Inner Pack – 10841019101053 Case – 20841019101050 Sterile Lot Number: 221020 All expiration dates from 2027-09-01(YYYY-MM_DD) on would encompass the for the recall.</p> <p>Model/Catalog Number: OPT14-5011 Lot Code: J20499-01 - J30100-01 Component, no UDI held by Kirwan Surgical Products.</p> <p>Model/Catalog Number: RX14-5011 GTINs: Pouch – 00841019109922 Inner Pack – 10841019109929 Case – 20841019109926 All expiration dates from 2027-09-01(YYYY-MM_DD) on would encompass the for the recall.</p>	<p>4,470 units nationwide</p> <p>66 units nationwide</p> <p>2,999 units nationwide</p> <p>3,010 units nationwide</p>	November and prior

For additional information, please visit: [FDA Website \(Ambler Surgical\)](#), [FDA Website \(Disposable\)](#), [FDA Website \(Optikon\)](#), and [FDA Website \(Walcott\)](#).