

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Ethicon, LLC: Prolene Polypropylene Suture & Ethibond Excel Polyester Suture Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
2/4/2025	<p>Prolene Polypropylene Suture, REF: EH7585H, 8706H, 8833H, 8963H, 8935H Prolene Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures.</p> <p>Ethibond Excel Polyester Suture, REF: 6664H, X425H, X872H, EH7491H. Not sold in US</p>	Ethicon, LLC	Sutures may have an open seal on the primary packaging, due to a manufacturing issue on a specific machine, and if issue is undetected could lead to breach in sterility, could introduce pathogens to the patient and cause infection.

Recall Class	Product Identification	Distribution	Affected Dates
II	<p>VREF/UDI-DI-GTIN/Lot(expiration): EH7585H/10705031097254/103DQR(8/31/2029);</p> <p>8706H/10705031019430/103E22(8/31/2029), 103EMJ(8/31/2029);</p> <p>8833H/10705031021037/103HC4(8/31/2029);</p> <p>8963H/10705031091931/103E8Z(8/31/2029);</p> <p>8935H/10705031022089/103HBP(8/31/2029)</p> <p>REF/GTIN/Lot(expiration): W8003T/10705031231658/103GT2(8/31/2029)</p>	<p>0 Boxes distributed in California</p> <p>25 Boxes Distributed in California</p>	December 2024 and Prior

For additional information, please visit this [FDA Website Prolene Polypropylene Suture](#) and this [FDA Website Ethibond Excel Polyester Suture](#).