California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific Corporation Recalls Boston Scientific POLARx BALLOON CATHETER LT 28MM OUS

Recall Date	Product Description	Recalling Firm	Recall Reason
11/12/2024	Boston Scientific POLARx BALLOON CATHETER LT 28MM OUS, Material Number M004CRBS2100	Boston Scientific Corporation	Boston Scientific is updating the instructions for use of their POLARx and POLARx FIT Cryoablation Balloon Catheters related to Atrio-esophageal Fistula Risk.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN 08714729992660	20290 units Worldwide	October 2024 and Prior

For additional information, please visit the FDA Website.