

# California Device Recall Information Sheet

## Food and Drug Branch – Device Recalls

### Boston Scientific Corporation Recalls POLARx FIT BALLOON CATHETER ST US

Recall Date	Product Description	Recalling Firm	Recall Reason
11/12/2024	Boston Scientific POLARx FIT BALLOON CATHETER ST US, Material Number M004CRBS2060	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 08714729992622	960 units Worldwide	October 2024 and Prior

For additional information, please visit the [FDA Website](https://www.fda.gov).