



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Abbott Amplatzer Steerable Delivery Sheat for Potential Air Embolism**

Recall Date	Product Description	Recalling Firm	Recall Reason
7/19/2023	<b>Amplatzer Steerable Delivery Sheat</b> REF ASDS-14F-075, is a percutaneous catheter (cardiac).	<b>Abbott</b> Plymouth, MN	There is an overall reported incidence rate of 0.77% related to observed or potential air embolism during procedures in which the ASDS product was used.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Amplatzer Steerable Delivery Sheat</b> UDI/DI 05415067036025, Batch Numbers: 8597228, 8598983, 8601676, 8611443, 8619197, 8627877, 8650955, 8663679, 8795668, 8815423, 8824607, 8830530, 8846835	675 Units Nationwide	June 2023 and Prior

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