# California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Biosense Webster, Inc. VARIPULSE Bi-Directional Ablation Catheter

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 02/28/2025 | VARIPULSE Bi-Directional Ablation Catheter<br><br>REF: D141201<br><br>The Field Catheter is indicated for use in catheter based cardiac electrophysiological mapping (stimulating and recording) and, when used for TRUPULSE Generator, for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. The catheter provides location information when used with the CARTO 3 System. | Biosense Webster, Inc. | Due to an observed trend of neurovascular events |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| I | Product Number: D141201-12<br><br>UDI-DI code: 10846835025460<br><br>Batch Numbers: 31483574L - 31483567L | 378 units nationwide | January and prior |

For additional information, please visit the FDA Website