



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Cardiovascular Systems Recall WIRION Embolic Protection System  
 for Difficulty while Withdrawing Filter Assembly**

Recall Date	Product Description	Recalling Firm	Recall Reason
11/11/2021	<b>WIRION EMBOLIC PROTECTION SYSTEM</b> Delivery Catheter and Filter and Retrieval Catheter, 6Fr, REF (Model Number) WRN-D6	<b>Cardiovascular Systems Inc</b> St. Paul, Minnesota	Under certain circumstances, the WIRION filter assembly may become difficult to withdraw. Under such circumstances, alternative means may be necessary for withdrawal and the device may be prone to tearing or separating which may result in a risk for embolization.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Numbers: Lot 67876-1019300, UDI 0110850000491-88217221221100000067876 to 01108500004918821723071710000101930	711 Units Nationwide including California	July 2020 - August 2020

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