State of California—Health and Human Services Agency

California Department of Public Health

[Food and Drug Branch – Device Recalls]

California Device Recall Information Sheet

Stryker Neurovascular Recalls Synchro2 Guidewire For Microcatheters

Recall Date	Product Description	Recalling Firm	Recall Reason
6/12/2024	**Synchro 2 Guidewire** Steerable guidewire family with a shapeable tip and are available in straight and pre-shaped versions. The outside diameters of the guidewires are 0.014 in. The guidewires are compatible with existing microcatheters used in common procedures such as those used in endovascular diagnosis and therapy of neurovascular disease. The distal portion of the guidewire tip is radiopaque.	**STRYKER NEROVASCULAR** Fremont, Ca	Stryker Neurovascular has observed an increased frequency of PTFE coating damage occurring on the Synchro Guidewires that may be caused by the practice of backloading the guidewire through the optional introducer accessory. This issue is limited to certain lots of the Synchro Guidewire that contain an older version of the introducer accessory. Due to variation in the manufacturing process of the supplier of the introducer accessory, certain lots of introducers have sharper than intended edges that can peel off the PTFE coating when physicians use a technique known as backloading. Users with impacted product in their inventory are cautioned not to use this backloading technique.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Synchro 2 Guidewire** Catalog/UDI-DI/Lots: M00326110/04546540688736/0 000064108-0000146841	10623 Units in California	May 2024 and prior

For additional information, please visit the FDA website.