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 Synchro Guidewires

Recall Date	Product Description	Recalling Firm	Recall Reason
6/12/2024	**Synchro-14 Straight 200-35cm** The Synchro SELECT Guidewires are a steerable guidewire family with a shapeable tip and are available in straight and pre-shaped versions. The outside diameters of the guidewires are 0.014in. 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. For lubricity, the distal portion of the device is coated with a hydrophilic polymer and the proximal portion of the guidewire is coated with polytetrafluoroethylene (PTFE). The torque device included with the guide-wire attaches to the proximal end of the wire and functions as a steering guide. Rotation of this device facilitates guidewire placement into the appropriate vessel by precise directional manipulation of the guidewire tip. The introducer included with the guidewire is intended to aid insertion of the guidewire into the catheter hub and/or hemostasis valve.	**STRYKER NEUROVASCULAR** Fremont, California	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.

6/12/2024	**Synchro-14 Straight 300-35cm** M00313310	**Stryker Neurovascular** Fremont, California	PFTE Peeling
6/12/2024	**SYNCHRO-10 STRAIGHT 200CM** M00316310	**STRYKER NEUROVASCULAR** Fremont, California	PFTE Peeling
06/12/2024	**SYNCHRO-10 STRAIGHT 300CM** M00316330	**STRYKER NEUROVASCULAR** Fremont, California	PFTE Peeling

Recall Class	Product Identification	Distribution	Affected Dates
II	**Synchro-14 Straight 200-35cm** Catalog/UDI-DI/Lots: ; M00313010/07613252186922/0 000129027 - 0000193546	473 Units in California	May 2024 and prior
II	**Synchro-14 Straight 300-35cm** Catalog/UDI-DI/Lots: M00313310/07613252186946/0 000135007 - 0000180795	3 Units in California	May 2024 and prior
II	**Synchro-10 Straight 200cm** Catalog/UDI-DI/Lots: M00316310/07613252187158/0 000131357 - 0000173995	179 Units in California	May 2024 and prior
II	**Synchro-10 Straight 300cm** Catalog/UDI-DI/Lots:M00316330/07613252187165/0000142692, 0000158995	17 Units in California	May 2024 and prior

For additional information, please visit the FDA website or email Stryker Neurovascular.