State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Balt Usa, Llc Recalls Neurovascular Embolization Device For Corrosion Of The Hypotube.

Recall Date	Product Description	Recalling Firm	Recall Reason
2/8/2024	**Neurovascular embolization device** There are a total of 208 Optima Coil models. Optima Coil Model Numbers and Product description: OPTI0101CSS10 Optima Coil 1mm x 1cm Complex-10 SuperSoft OPTI0101CSS10 Optima Coil 1mm x 1cm Complex-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft	**BALT USA, LLC** Irvine, California	This product was recalled due to discoloration identified along the delivery pusher which was attributed to corrosion of the hypotube. It is possible for the discoloration to mechanically break off from the delivery pusher, leaving the potential for the material to flow through the delivery system (i.e. microcatheter), and into the patient vasculature causing foreign emboli.

	OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0101HSS10 Optima Coil 1mm x 1cm Helical-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm Complex-10 SuperSoft OPTI0102CSS10 Optima Coil 1mm x 2cm		

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Recall Class	Product Identification	Distribution	Affected Dates
II	**Neurovascular Embolization Device** Optima Coils (Lot Number/Model Number/Product Description/UDI-DI Code: F201000528	2859 Units in California California	February, 2024 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE