State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Philips North America Recalls Sense XL Torso Coil for Intera and Achieva MR

Recall Date	Product Description	Recalling Firm	Recall Reason
07/03/2024	**Sense XL Torso Coil 1.5T** 16-element receive only coil for torso and abdomen imaging in Philips MR Intera and Achieva Systems	**PHILIPS NORTH AMERICA LLC** Cambridge, Massachusetts	Potential for coils to heat up and harm patients (burn).
07/03/2024	**Sense XI Torso Coil 3.0T** 16-element receive only coil for torso and abdomen imaging in Philips MR Intera and Achieva Systems	**PHILIPS NORTH AMERICA LLC** Cambridge, Massachusetts	Potential for coils to heat up and harm patients (burn).
07/03/2024	**Sense XL Torso Coil 1.5T mk 2** 16-element receive only coil for torso and abdomen imaging in Philips MR Intera and Achieva Systems	**PHILIPS NORTH AMERICA LLC** Cambridge, Massachusetts	Potential for coils to heat up and harm patients (burn).

Recall Class	Product Identification	Distribution	Affected Dates
I	**Sense XL Torso Coil 1.5T** Model No. 453567141882, 453567141883, 989603014351 & 989603014352; UDI-DI: N/A; Serial No. 288 ... 1314; 300202352, 336 ... 1319	729 Units Nationwide	June 2024 and prior
I	**Sense XI Torso Coil 3.0** Model No. 453567394942, 453567394945, 453567394943, 989603050642 & 989603050641; UDI-DI: N/A; Serial No. 529 … 341	307 Units Nationwide	June 2024 and prior

I	**Sense XL Torso Coil 1.5T mk 2** Model No. 453567394942, 453567394945, 453567394943, 989603050642 & 989603050641; UDI-DI: N/A; Serial No. 16 … 40000	14 Units Nationwide	June 2024 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE FOR 1.5T , 3.0T and 1.5T MK2.