



## California Device Recall Information Sheet

### Waldemar Link Gmbh & Co. Kg Recalls Spii Model Lubinus Due To Correction In Carton Label

Recall Date	Product Description	Recalling Firm	Recall Reason
3/20/2024	<b>Spii Model Lubinus, Hip Prosthesis Stem Standard Neck</b> Cemented	<b>WALDEMAR LINK GMBH &amp; CO. KG (MFG SITE)</b> Norderstedt, Germany	Due to two complaints, has come to our attention that additional guidance is required on the correct interpretation of the carton label <b>Size</b> and <b>Type</b> columns to avoid misinterpretation during surgery.
3/20/2024	<b>Spii Model Lubinus, Hip Prosthesis Stem XI Neck</b> Cemented	<b>WALDEMAR LINK GMBH &amp; CO. KG (MFG SITE)</b> Norderstedt, Germany	Due to two complaints, has come to our attention that additional guidance is required on the correct interpretation of the carton label <b>Size</b> and <b>Type</b> columns to avoid misinterpretation during surgery.
3/20/2024	<b>Spii Model Lubinus, Long Stem Prosthesis Standard Neck</b> Cemented	<b>WALDEMAR LINK GMBH &amp; CO. KG (MFG SITE)</b> Norderstedt, Germany	Due to two complaints, has come to our attention that additional guidance is required on the correct interpretation of the carton label

			\x1cSize\x1d and \x1cType\x1d columns to avoid misinterpretation during surgery.
3/20/2024	<b>Spii Model Lubinus, Long Stem Prosthesis XI Neck</b> Cemented	<b>WALDEMAR LINK GMBH &amp; CO. KG (MFG SITE)</b> Norderstedt, Germany	Due to two complaints, has come to our attention that additional guidance is required on the correct interpretation of the carton label \x1cSize\x1d and \x1cType\x1d columns to avoid misinterpretation during surgery.

Recall Class	Product Identification	Distribution	Affected Dates
II	<b>Spii Model Lubinus, Hip Prosthesis Stem Standard Neck</b> Product 1 Identification Details UDI etc	382 Units Nationwide	February, 2024 and prior
II	<b>Spii Model Lubinus, Hip Prosthesis Stem XI Neck</b> Product 2 Identification Details UDI etc	0 Units Nationwide	February, 2024 and prior
II	<b>Spii Model Lubinus, Long Stem Prosthesis Standard Neck</b> Product 3 Identification Details UDI etc	153 Units Nationwide	February, 2024 and prior
II	<b>Spii Model Lubinus, Long Stem Prosthesis XI Neck</b> Product 4 Identification Details UDI etc	34 Units Nationwide	February, 2024 and prior

For additional information, please visit the FDA website [Hip Prosthesis Standard](#), [Hip Prosthesis XL](#), [Long Prosthesis Standard](#), [Long Prosthesis XL](#)