California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Waldemar Link GmbH & Co. KG (Mfg Site) Distal Femoral, Posterior Femoral, L-Shaped Femoral, and Tibial Augments

Recall Date	Product Description	Recalling Firm	Recall Reason
04/30/2025	Distal Femoral Augment Posterior Femoral Augment L-Shaped Femoral Augment Tibial Augment	Waldemar Link GmbH & Co. KG (Mfg Site)	The device was delivered with a preassembled Femoral Augment screw that was missing its thread.

Recall Class	Product Identification	Distribution	Affected Dates
II	Sz. 0 - cemented sm Item Number: 880-300/11 UDI-DI: 04026575284931 Sz. 0 - cemented lg Item Number: 880-300/21 UDI-DI: 04026575257102 Sz. 1-2 - cemented sm Item Number: 880-301/11 UDI-DI: 04026575257133 Sz. 1-2 - cemented lg Item Number: 880-301/21 UDI-DI: 04026575257140 Sz. 3-4 - cemented sm Item Number: 880-303/11 UDI-DI: 04026575257171 Sz. 3-4 - cemented md Item Number: 880-303/12 UDI-DI: 04026575257188	4,300 units nationwide including California	April and prior

	Sz. 3-4 - cemented lg Item Number: 880-303/21 UDI-DI: 04026575257195 Sz. 3-4 - cemented x-lg Item Number: 880-303/22 UDI-DI: 04026575257201 Sz. 5-6 - cemented sm Item Number: 880-305/11 UDI-DI: 04026575257256 Sz. 5-6 - cemented md Item Number: 880-305/12 UDI-DI: 04026575257263 Sz. 5-6 - cemented lg Item Number: 880-305/21 UDI-DI: 04026575257270 Sz. 5-6 - cemented x-lg Item Number: 880-305/22 UDI-DI: 04026575257287 Sz. 7-8 - cemented sm Item Number: 880-307/11 UDI-DI: 04026575257379 Sz. 7-8 - cemented md Item Number: 880-307/12 UDI-DI: 04026575257386 Sz. 7-8 - cemented lg Item Number: 880-307/21 UDI-DI: 04026575257393 Sz. 7-8 - cemented x-lg Item Number: 880-307/22 UDI-DI: 04026575257409 Sz. 9-10 - cemented sm Item Number: 880-309/11 UDI-DI: 04026575257454 Sz. 9-10 - cemented md Item Number: 880-309/12 UDI-DI: 04026575257461 Sz. 9-10 - cemented lg Item Number: 880-309/21 UDI-DI: 04026575257478 Sz. 9-10 - cemented x-lg) Item Number: 880-309/22 UDI-DI: 04026575257485) Applies to all lots of the LINK SymphoKnee Femoral Augments listed, manufactured up until 03/01/2025. Sz. 0 - cemented sm		

	Item Number: 880-310/11 UDI-DI: 04026575257539 Sz. 0 - cemented lg Item Number: 880-310/21 UDI-DI: 04026575257546 Sz. 1-2 - cemented sm Item Number: 880-311/11 UDI-DI: 04026575257607 Sz. 1-2 - cemented lg Item Number: 880-311/21 UDI-DI: 04026575257584 Sz. 3-4 - cemented sm Item Number: 880-313/11 UDI-DI: 04026575257621 Sz. 3-4 - cemented md Item Number: 880-313/12 UDI-DI: 04026575257645 Sz. 3-4 - cemented lg Item Number: 880-313/21 UDI-DI: 04026575257669 Sz. 3-4 - cemented x-lg Item Number: 880-313/22 UDI-DI: 04026575257690 Sz. 5-6 - cemented sm Item Number: 880-315/11 UDI-DI: 04026575257768 Sz. 5-6 - cemented md Item Number: 880-315/12 UDI-DI: 04026575257775 Sz. 5-6 - cemented lg Item Number: 880-315/21 UDI-DI: 04026575257782 Sz. 5-6 - cemented x-lg Item Number: 880-315/22 UDI-DI: 04026575257799 Sz. 7-8 - cemented sm Item Number: 880-317/11 UDI-DI: 04026575257843 Sz. 7-8 - cemented md Item Number: 880-317/12 UDI-DI: 04026575257850 Sz. 7-8 - cemented lg Item Number: 880-317/21 UDI-DI: 04026575257867 Sz. 7-8 - cemented x-lg Item Number: 880-317/22 UDI-DI: 04026575257881 Sz. 9-10 - cemented sm		

	Item Number: 880-319/11 UDI-DI: 04026575257942 Sz. 9-10 - cemented md Item Number: 880-319/12 UDI-DI: 04026575257959 Sz. 9-10 - cemented lg Item Number: 880-319/21 UDI-DI: 04026575257966 Sz. 9-10 - cemented x-lg Item Number: 880-319/22 UDI-DI: 04026575257973 Applies to all lots of the LINK SymphoKnee Femoral Augments listed, manufactured up until 03/01/2025. Sz. 0 - cemented sm Item Number: 880-320/12 UDI-DI: 04026575258048 Sz. 0 - cemented lg Item Number: 880-320/22 UDI-DI: 04026575258055 Sz. 1-2 - cemented sm Item Number: 880-321/12 UDI-DI: 04026575258062 Sz. 1-2 - cemented lg Item Number: 880-321/22 UDI-DI: 04026575258079 Sz. 3-4 - cemented sm Item Number: 880-323/13 UDI-DI: 04026575258086 Sz. 3-4 - cemented lg Item Number: 880-323/23 UDI-DI: 04026575258109 Sz. 5-6 - cemented sm Item Number: 880-325/13 UDI-DI: 04026575258123 Sz. 5-6 - cemented lg Item Number: 880-325/23 UDI-DI: 04026575258147 Sz. 7-8 - cemented sm Item Number: 880-327/13 UDI-DI: 04026575258147 Sz. 7-8 - cemented lg Item Number: 880-327/23 UDI-DI: 04026575258161 Sz. 9-10 - cemented sm Item Number: 880-329/13		

	UDI-DI: 04026575258178 Sz. 9-10 - cemented lg Item Number: 880-329/23 UDI-DI: 04026575258185 Applies to all lots of the LINK SymphoKnee Femoral Augments listed, manufactured up until 03/01/2025 Sz. 1-2 - cemented x-sm Item Number: 880-331/11 UDI-DI: 04026575258192 Sz. 1-2 - cemented sm Item Number: 880-331/12 UDI-DI: 04026575258208 Sz. 1-2 - cemented md Item Number: 880-331/13 UDI-DI: 04026575258215 Sz. 1-2 - cemented lg Item Number: 880-331/21 UDI-DI: 04026575258222 Sz. 1-2 - cemented x-lg Item Number: 880-331/22 UDI-DI: 04026575258246 Sz. 1-2 - cemented xx-lg Item Number: 880-331/23 UDI-DI: 04026575258253 Sz. 3-4 - cemented x-sm Item Number: 880-333/11 UDI-DI: 04026575258260 Sz. 3-4 - cemented sm Item Number: 880-333/12 UDI-DI: 04026575258277 Sz. 3-4 - cemented md Item Number: 880-333/13 UDI-DI: 04026575258284 Sz. 3-4 - cemented lg Item Number: 880-333/21 UDI-DI: 04026575258291 Sz. 3-4 - cemented x-lg Item Number: 880-333/22 UDI-DI: 04026575258307 Sz. 3-4 - cemented xx-lg Item Number: 880-333/23 UDI-DI: 04026575258314 Sz. 5-6 - cemented x-sm Item Number: 880-335/11 UDI-DI: 04026575258321		

	Sz. 5-6 - cemented sm Item Number: 880-335/12 UDI-DI: 04026575258338 Sz. 5-6 - cemented md Item Number: 880-335/13 UDI-DI: 04026575258345 Sz. 5-6 - cemented lg Item Number: 880-335/21 UDI-DI: 04026575258352 Sz. 5-6 - cemented lg Item Number: 880-335/22 UDI-DI: 04026575258369 Sz. 5-6 - cemented xx-lg Item Number: 880-335/23 UDI-DI: 04026575258376 Sz. 7-8 - cemented x-sm Item Number: 880-337/11 UDI-DI: 04026575258383 Sz. 5-6 - cemented sm Item Number: 880-337/12 UDI-DI: 04026575258390 Sz. 7-8 - cemented md Item Number: 880-337/13 UDI-DI: 04026575258406 Sz. 7-8 - cemented lg Item Number: 880-337/21 UDI-DI: 04026575258413 Sz. 7-8 - cemented x-lg Item Number: 880-337/22 UDI-DI: 04026575258420 Sz. 7-8 - cemented xx-lg Item Number: 880-337/23 UDI-DI: 04026575258437 Sz. 9-10 - cemented x-sm Item Number: 880-339/11 UDI-DI: 04026575258475 Sz. 9-10 - cemented sm Item Number: 880-339/12 UDI-DI: 04026575258505 Sz. 9-10 - cemented md Item Number: 880-339/13 UDI-DI: 04026575258529 Sz. 9-10 - cemented lg Item Number: 880-339/21 UDI-DI: 04026575258536 Sz. 9-10 - cemented x-lg Item Number: 880-339/22 UDI-DI: 04026575258543		

	Sz. 9-10 - cemented xx-lg Item Number: 880-339/23 UDI-DI: 04026575258550 Applies to all lots of the LINK SymphoKnee Femoral Augments listed, manufactured up until 03/01/2025		

For additional information, please visit: FDA Website (Distal Femoral Augment), FDA Website (Posterior Femoral Augment), FDA Website (L-Shaped Femoral Augment), and FDA Website (Tibial Augment).