California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Zimmer Orthopedics Manufacturing Limited Comprehensive Shoulder Stem, Comprehensive Micro Stem, Comprehensive Mini Stem, and Uncemented shoulder prosthesis

Recall Date	Product Description	Recalling Firm	Recall Reason
03/20/2025	Comprehensive Shoulder Stem Model No.: 113605 Comprehensive Micro Stem Model No.: 113606 Comprehensive Mini Stem Model No.: 113607 Uncemented shoulder prosthesis Model No.: 113627	Zimmer Orthopedics Manufacturing Limited-Galway	Five complaints received where surgeon was unable to remove and/or connect the inserter with the stem during surgery due to excess material remaining within the taper. Issue may lead to clinically significant extension of surgery to find a replacement.

Recall Class	Product Identification	Distribution	Affected Dates
II	Item No.: 113605 UDI-DI: 00887868267550 Lots: 66173214, 66173215 Item No.: 113606 UDI-DI: 00887868267567 Lots: 66173216 - 66173219 Item No.: 113607 UDI-DI: 00887868267574 Lots: 66173220, 66173221	3 units in California	March and prior

	Item No.: 113627 UDI-DI: 00887868267741 Lots 65901697 - 65915809		

For additional information, please visit the FDA Website.