



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Encore Medical Recalls DJO Surgical For Lack Of Final Sterilization

Recall Date	Product Description	Recalling Firm	Recall Reason
9/27/2023	Djo Surgical: Empowr Knee, Universal Tibia Baseplate 6R, REF: 352-02-106	ENCORE MEDICAL, LP Austin, Texas	Orthopedic device components were not subjected to final sterilization before shipment, which if implanted may lead to varying degrees of infection, which may require treatment, prolonged monitoring, and may lead to revision surgery
9/27/2023	Djo Surgical: Delta Ceramic Femoral Head 44 mm + 4.0 mm, REF: 400-03-443	ENCORE MEDICAL, LP Austin, Texas	Orthopedic device components were not subjected to final sterilization before shipment, which if implanted may lead to varying degrees of infection, which may require treatment, prolonged monitoring, and may lead to revision surgery
9/27/2023	Djo Surgical: Clp Hip, Stem, Polished Neck, Lateral Offset Implant Size#3, REF: 426-11-030	ENCORE MEDICAL, LP Austin, Texas	Orthopedic device components were not subjected to final sterilization before shipment, which if implanted may lead to varying degrees of infection, which may

			require treatment, prolonged monitoring, and may lead to revision surgery
9/27/2023	Djo Surgical: Reverse Shoulder System (Rsp) Semi Humeral Socket Insert 32mm, REF: 508-01-032; Baseplate, Glenoid HA-Coat, RSP, 6.5mm X 30mm, REF: 508-32-104; Reverse Shoulder System (RSP) Glenoid, Neutral Head W/ Retaining Screw, 36mm, REF: 508-36-101	ENCORE MEDICAL, LP Austin, Texas	Orthopedic device components were not subjected to final sterilization before shipment, which if implanted may lead to varying degrees of infection, which may require treatment, prolonged monitoring, and may lead to revision surgery
9/27/2023	Djo Surgical: Altvate Reverse, Humeral Stem, Small Shell Size 6 x 108mm, REF: 533-06-108	ENCORE MEDICAL, LP Austin, Texas	Orthopedic device components were not subjected to final sterilization before shipment, which if implanted may lead to varying degrees of infection, which may require treatment, prolonged monitoring, and may lead to revision surgery

Recall Class	Product Identification	Distribution	Affected Dates
II	Djo Surgical: Empowr Knee, Universal Tibia Baseplate UDI-DI/Lot/Expiration: 00190446258032/308V1112/Ma y 25, 2029	20 Units Nationwide including California	4 August 2023 and prior
II	Djo Surgical: Delta Ceramic Femoral Head UDI-DI/Lot/Expiration: 00888912076210/878B1171/Ma y 2, 2027	10 Units Nationwide including California	4 August 2023 and prior

II	Djo Surgical: Clp Hip, Stem, Polished Neck, Lateral Offset Implant UDI-DI/Lot/Expiration: 00888912079631/415N1014/May 3, 2028	0 Units Nationwide including California	4 August 2023 and prior
II	Djo Surgical: Reverse Shoulder System (Rsp) Semi Humeral Socket Insert REF/UDI-DI/Lot/Expiration: 508-01-032/00888912024693/859C1190/April 29, 2027; 508-32-104/00888912024754/866C3153/May 25, 2029 and 866C3147/April 3, 2029; 508-36-101/869C3539/April 30, 2028	64 Units Nationwide including California	4 August 2023 and prior
II	Djo Surgical: Altivate Reverse, Humeral Stem, Small Shell UDI-DI/Lot: 00190446259091/923W1411/April 3, 2029	15 Units Nationwide including California	4 August 2023 and prior

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