State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

GE Healthcare Recalls MRI Software due to Slicing Error

Recall Date	Product Description	Recalling Firm	Recall Reason
03/30/2022	**BIOMET Sports Medicine JUGGERLOC SLOTTED REAMER** [Item # 110010371, 6MM], [Item #110010372, 7MM], [Item # 110010373, 8MM], [Item #110018275, 5MM]. Devices are packaged in a vacuum sealed nylon pouch, which is placed in a carton with the appropriate IFU and patient record labels. Identifying labels on the pouch and the carton.	**Biomet, Inc.** Warsaw, Indiana	Packaging of various implants may not have sufficient adhesion on all sides, leading to loss of sterile barrier integrity. Use of product poses risk of infection, leading to surgical intervention, and/or extension of surgery to find another part.
03/30/2022	**BIOMET Trauma** [Item # 1318-12-126, DVR CROSSLOCK Extra Long R Set	**Biomet, Inc.** Warsaw, Indiana	Packaging Error
03/30/2022	**BIOMET Trauma** [Item # 1318-22-126, DVR CROSSLOCK Extra Long L Set	**Biomet, Inc.** Warsaw, Indiana	Packaging Error
03/30/2022	**BIOMET TRAUMA** Item # 131812176. DVR LOCK EXTRA EXTRA LONG	**Biomet, Inc.** Warsaw, Indiana	Packaging Error

Recall Class	Product Identification	Distribution	Affected Dates
II	**BIOMET Sports Medicine JUGGERLOC SLOTTED REAMER** [Item # 110010371, 6MM]	8 Devices in California	February 2022 and prior

II	**BIOMET Sports Medicine JUGGERLOC SLOTTED REAMER** [Item #110010372, 7MM]	4 Devices in California	February 2022 and prior
II	**BIOMET Sports Medicine JUGGERLOC SLOTTED REAMER** [Item # 110010373, 8MM]	1 Devices in California	February 2022 and prior
II	**BIOMET Sports Medicine JUGGERLOC SLOTTED REAMER** [Item #110018275, 5MM]	1 Devices in California	February 2022 and prior
II	**BIOMET Trauma** [Item # 1318-12-126, DVR CROSSLOCK Extra Long R Set	3 Devices in California	February 2022 and prior
II	**BIOMET Trauma** [Item # 1318-22-126, DVR CROSSLOCK Extra Long L Set	1 Device in California	February 2022 and prior
II	**BIOMET Trauma** Item # 131812176. DVR LOCK EXTRA EXTRA LONG	2 Devices in California	February 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE