State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

BIOMET, INC. Recalls Biolox Ceramic For Incorrect Neck Length Adapter In The Packaging

Recall Date	Product Description	Recalling Firm	Recall Reason
12/27/2023	**Biolox Ceramic** Option Head Zimmer 12/14 40mm +0, Item Number 00-8777-040-02	**BIOMET, INC.** Warsaw, Indiana	One product complaint was received reporting that there was an incorrect adapter in the packaging. An adapter with neck length M/+0 was inside the product packaging, which should have contained an adapter with neck length S/-3.0. The difference in neck length may be recognized by the size (S or M) indicator on the device.
12/27/2023	**Biolox Ceramic** Option Head Zimmer 12/14 40mm -3, Item Number 00-8777-040-01	**BIOMET, INC.** Warsaw, Indiana	One product complaint was received reporting that there was an incorrect adapter in the packaging. An adapter with neck length M/+0 was inside the product packaging, which should have contained an adapter with neck length S/-3.0. The difference in neck length may be recognized by the size (S or M) indicator on the device.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Biolox Ceramic** UDI-DI: 00889024430563; Lot Number: 3145300	1 Units in California California	December, 2023 and prior
II	**Biolox Ceramic** UDI-DI: 00889024430556; Lot Number: 3145299	1Units in California California	December, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE, Option Head Zimmer 12/14 400mm +0, Option Head Zimmer 12/14 400mm -3