State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Boston Scientific Corporation Recalls Obsidio Comformable Embolic For Failure To Support The Aliquot Technique For Gi Bleeding Embolization

Recall Date	Product Description	Recalling Firm	Recall Reason
4/3/2024	**Obsidio Conformable Embolic** Material Numbers (UPN): a) M0013972001010, b) M0013972101010	**Boston Scientific Corporation** Maple Grove, Minnesota	An investigation determined that delivery of the Obsidio embolic using the aliquot technique for lower gastrointestinal bleeding embo-lization poses a high risk of bowel ischemia. The most serious and the most common adverse health consequence, reasonably fore-seeable to occur, is the need to perform major surgery such as bowel resection and/or diverting co-lostomy. Therefore, Boston Scientific does not recommend that the aliquot tech-nique be used to deliver the Obsidio device for lower GI bleed embolization procedures.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Obsidio Conformable Embolic** a) M0013972001010, UDI/DI 00191506039332, ALL LOT CODES b) M0013972101010, UDI/DI 00191506043124, ALL LOT CODES	985 Units Nationwide	February, 2024 and prior

For additional information, please visit the FDA website

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov