State of California—Health and Human Services Agency

California Department of Public Health

[Food and Drug Branch – Device Recalls]

California Device Recall Information Sheet

Olympus Corporation Of The Americas Recalls Everest Bipolar Cutting Forceps

Recall Date	Product Description	Recalling Firm	Recall Reason
8/8/2024	**Everest Bipolar Cutting Forceps** The Everest Bipolar Cutting Forceps are intended to be passed through a 5-mm or 10-mm cannula, depending on the model/outer diameter size of the forceps. Coagulation is achieved using electrosurgical energy under visualization. The device is to be used with bipolar outputs of compatible generators. The forceps' jaws are electrically isolated from each other enabling one jaw to act as a return electrode, eliminating the need for a return pad. To transect tissue, a cutting blade is actuated and moves between the electrode jaws. The connections (bipolar electrical signal) to the forceps are through either a hardwired cable (model 3006) or a connector at the bottom of the handle (models 3000 and 3005). The device includes mechanisms (switches and triggers) to provide coagulation using the bipolar electrical energy that reaches the forceps. The forceps are positioned in the desired location for grasping, coagulation, and transection of tissue. The anatomical structure to be coagulated is placed between the open	**OLYMPUS CORPORATION OF THE AMERICAS** Center Valley, Pennsylvania	Fractures and breakages in packaging trays and Tyvek Covers, which may result in a sterility breach.

	forceps jaws, and once the Forceps Grip trigger is squeezed, the forceps' jaws are closed onto tissue, followed by coagulation. The device includes a blade that is mechanically advanced to perform tissue cutting as needed.		

Recall Class	Product Identification	Distribution	Affected Dates
II	**Everest Bipolar Cutting Forceps** UDI: N/A Batch Numbers: FR150448 FR154445 FR173022	15 Units In California	July 2024 and prior.

For additional information, please visit the FDA website.