State of California—Health and Human Services Agency

# California Department of Public Health

Food and Drug Branch – Device Recalls

# CALIFORNIA DEVICE RECALL INFORMATION SHEET

**Length Mislabeling for LimaCorporate Self-tapping Titanium Alloy Bone Screw**

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 10/27/2021 | **Bone Screw/Vite - Ti6Al4V, Self Tapping/Autofilettante, Dia=6.5mm, h=25mm**<br><br>151 units | **LimaCorporate USA,** Arlington, Texas | There is a potential that the length of bone screws identified on labeling may not correspond to the actual length of the screw included. |
| 10/27/2021 | **Bone Screw/Vite - Ti6Al4V, Self Tapping/Autofilettante, Dia=6.5mm, h=20mm**<br><br>200 Units | **LimaCorporate USA,** Arlington, Texas | There is a potential that the length of bone screws identified on labeling may not correspond to the actual length of the screw included. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| Voluntary | **Self-Tapping Titanium Alloy Bone Screw** | 1 25mm implanted<br>1 20mm implanted<br>1 25/20 mm stock<br>in California | September 2021 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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