CALIFORNIA DEVICE RECALL INFORMATION SHEET

Xtant Medical recalls X060-0270 Axle Interspinous Fusion System for Out of Specification Proximal Opening that Prevents Crossbar Plate Engagement

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/29/2021</td>
<td>X060-0270 8mm Titanium Insert Axle Interspinous Fusion System</td>
<td>Xtant Medical Belgrade, Montana</td>
<td>Presence of undeclared methanol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>UDI (Primary DI Number): M697X06002701/$$7058963W Lot Number: 058963</td>
<td>3 Units in California</td>
<td>December 2021 and prior</td>
</tr>
</tbody>
</table>

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)