

FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

**Class 2 Device Recall Integra External Fixation System**

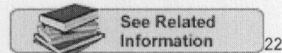


[6 510\(k\)](#) | [DeNovo<sup>8</sup>](#) | [Registration & Listing<sup>9</sup>](#) | [Adverse Events<sup>10</sup>](#) | [Recalls<sup>11</sup>](#) | [PMA<sup>12</sup>](#) | [HDE<sup>13</sup>](#) | [Classification<sup>14</sup>](#) | [Standards<sup>15</sup>](#)  
[CFR Title 21<sup>16</sup>](#) | [Radiation-Emitting Products<sup>17</sup>](#) | [X-Ray Assembler<sup>18</sup>](#) | [Medsun Reports<sup>19</sup>](#) | [CLIA<sup>20</sup>](#) | [TPLC<sup>21</sup>](#)

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Integra External Fixation System**



<b>Recall Date</b>	August 11, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-2386-2016
<b>Recall Event ID</b>	<u>74757<sup>23</sup></u>
<b>510(K)Number</b>	<u>K140463<sup>24</sup></u> <u>K160830<sup>25</sup></u>
<b>Product Classification</b>	<u>Appliance, fixation, nail/blade/plate combination, multiple component<sup>26</sup></u> - <b>Product Code</b> <u>KTT<sup>27</sup></u>
<b>Product</b>	Integra External Fixation System Universal Wire Fixation Bolt - 17.5 mm Catalogue #12224218 ; Integra External Fixation System Universal Wire Fixation Bolt - 23 mm Catalogue #12224219
<b>Code Information</b>	Lot # GT0420 and GT0419
<b>Recalling Firm/Manufacturer</b>	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344
<b>For Additional Information Contact</b>	Dr. Patricia Kihn 717-840-3431
<b>Manufacturer Reason for Recall</b>	Through the investigation of reported complaints Integra verified that there have been instances where the Universal Wire Fixation Bolts the Slotted Post broke during use at the surgical site.
<b>FDA Determined Cause<sup>2</sup></b>	Device Design
<b>Action</b>	Integra sent an Urgent - Voluntary Medical Device Recall letter dated July 20, 2016, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Integra is asking you to take the following actions: 1. Please check your Integra External Fixation System inventory to determine if you have the 17.5mm or 23mm Universal Wire Fixation Bolts and/or the large or small Slotted Posts. 2. If you do have 17.5mm or 23mm Universal Wire Fixation Bolts and/or large or small Slotted Posts, stop using them immediately. 3. Complete the attached "Acknowledgement and Return Form" and check the box: I do have affected products on the list and record the lot number. 4. Or, complete the attached "Acknowledgement and Return Form" and check the box: I do not have affected products. 5. Complete the other information as indicated on this form. Keep a copy of the form for your records. Return the completed "Acknowledgement and Return Form" by email or fax indicating your receipt and review of this notification. When your form is received, if you have noted you have affected products, an Integra Representative will contact you and provide you with directions to return the product, as well as input an order to replace the quantity you indicated on the form. Receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. We recommend you also maintain a copy of this notification and signed copy of the acknowledgement form for your records. Regulatory agencies such as the FDA perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action. Should you have any questions regarding these instructions, please contact Sales Operations at 888-601-0203, option 2. We apologize for any inconvenience this may cause and thank you for your cooperation in this effort. Fo