

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

**Class 2 Device Recall AlloFuse DBM Putty 5cc**

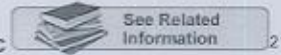


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup> | CFR Title 21<sup>15</sup> | Radiation-Emitting Products<sup>16</sup> | X-Ray Assembler<sup>17</sup> | Medsun Reports<sup>18</sup> | CLIA<sup>19</sup> | TPLC<sup>20</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Recall  
AlloFuse DBM Putty 5cc**



<b>Date Posted</b>	May 06, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1562-2014
<b>Recall Event ID</b>	<a href="#">67986<sup>22</sup></a>
<b>Premarket Notification 510(K) Number</b>	<a href="#">K071849<sup>23</sup></a>
<b>Product Classification</b>	Filler, Bone Void, Calcium Compound <sup>24</sup> - <b>Product Code MQV<sup>25</sup></b>
<b>Product</b>	AlloFuse DBM Putty 5cc, Catalog No. 90038005 AlloFuse is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. AlloFuse is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender.
<b>Code Information</b>	Lot numbers 132095-603, 608, 609, 611-618, 622-629, 631-634, and 636-638. Lot numbers 132095-604, 619, and 621.
<b>Recalling Firm/Manufacturer</b>	AlloSource, Inc. 6278 S Troy Cir Centennial, Colorado 80111-6422
<b>For Additional Information Contact</b>	Trevor Wright 720-873-4733
<b>Manufacturer Reason for Recall</b>	The donor was hemodiluted.
<b>FDA Determined Cause<sup>2</sup></b>	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
<b>Action</b>	AlloSource sent letter via USPS Certified Mail Receipt to all affected customers dated March 25, 2014, and March 26, 2014. The letter identified the product the problem and the action needed to be taken by the customer. AlloSource requested that the distributor consignee notify subsequent consignees to determine disposition and to request return of unused product. Returned inventory will be quarantined physically and electronically upon receipt. Product initially quarantined and product returned will be destroyed following established procedures. Further questions please call (720) 873-4733.
<b>Quantity in Commerce</b>	29
<b>Distribution</b>	Distribution US nationwide, including Michigan and a distributor in Colorado.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>26</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>27</sup>](#)

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

**510(K) Database** 510(K)s with Product Code = MQV and Original Applicant = ALLOSOURCE, INC.<sup>28</sup>

Links on this page: