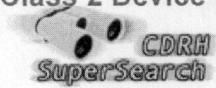


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

**Class 2 Device Recall COSEAL Surgical Sealant**

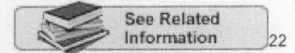


6 510(k)|DeNovo<sup>8</sup> | Registration & | Adverse | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 7 Listing<sup>9</sup> Events<sup>10</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18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

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**Class 2 Device Recall COSEAL Surgical Sealant**



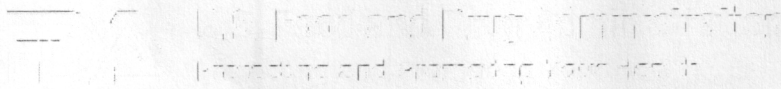
<b>Recall Date</b>	May 31, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1839-2016
<b>Recall Event ID</b>	<u>74139</u> <sup>23</sup>
<b>Product Classification</b>	Sealant,polymerizing <sup>24</sup> - <b>Product Code NBE</b> <sup>25</sup>
<b>Product</b>	COSEAL Surgical Sealant Kit, 4 mL, Product Code: 934071; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
<b>Code Information</b>	HA160151, HA151205, HA151036, HA151035, HA160229
<b>Recalling Firm/Manufacturer</b>	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
<b>For Additional Information Contact</b>	800-422-9837
<b>Manufacturer Reason for Recall</b>	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
<b>Quantity in Commerce</b>	6,804 units
<b>Distribution</b>	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>26</sup>

<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.

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**Class 2 Device Recall COSEAL Surgical Sealant**

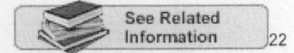


<sup>6</sup> 510(k) | <sup>7</sup> DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup> | CFR Title 21<sup>16</sup> | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup>

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**Class 2 Device Recall COSEAL Surgical Sealant**



<b>Recall Date</b>	May 31, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1838-2016
<b>Recall Event ID</b>	<a href="#">74139<sup>23</sup></a>
<b>PMA Number</b>	P030039 <sup>24</sup>
<b>Product Classification</b>	<a href="#">Sealant, polymerizing<sup>25</sup></a> - <b>Product Code</b> <a href="#">NBE<sup>26</sup></a>
<b>Product</b>	COSEAL Surgical Sealant Kit, 2 mL, Product Code: 934070; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
<b>Code Information</b>	HA160136
<b>Recalling Firm/Manufacturer</b>	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
<b>For Additional Information Contact</b>	800-422-9837
<b>Manufacturer Reason for Recall</b>	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
<b>Quantity in Commerce</b>	274 units
<b>Distribution</b>	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>27</sup></a>

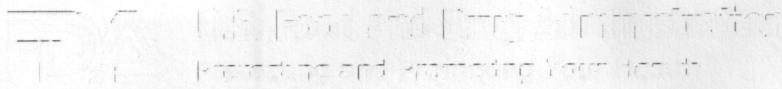
<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>28</sup>](#)

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

**PMA Database** [PMAs with Product Code = NBE and Original Applicant = BAXTER BIO SCIENCE<sup>29</sup>](#)

Links on this page:





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

**Class 2 Device Recall COSEAL Surgical Sealant**

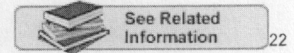


6 510(k)|DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
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**Class 2 Device Recall COSEAL Surgical Sealant**



<b>Recall Date</b>	May 31, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1839-2016
<b>Recall Event ID</b>	<u>74139</u> <sup>23</sup>
<b>Product Classification</b>	Sealant,polymerizing <sup>24</sup> - <b>Product Code NBE</b> <sup>25</sup>
<b>Product</b>	COSEAL Surgical Sealant Kit, 4 mL, Product Code: 934071; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
<b>Code Information</b>	HA160151, HA151205, HA151036, HA151035, HA160229
<b>Recalling Firm/Manufacturer</b>	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
<b>For Additional Information Contact</b>	800-422-9837
<b>Manufacturer Reason for Recall</b>	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
<b>Quantity in Commerce</b>	6,804 units
<b>Distribution</b>	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>26</sup>

<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.

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