# Class 2 Device Recall Endoform Dermal Template

<table>
<thead>
<tr>
<th>Date Initiated by Firm</th>
<th>September 18, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Date</td>
<td>November 02, 2018</td>
</tr>
<tr>
<td>Recall Status¹</td>
<td>Open³, Classified</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-0378-2019</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>81161²³</td>
</tr>
<tr>
<td>510(K)Number</td>
<td>K171231²⁴</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Dressing, wound, collagen²⁵ - Product Code KGN²⁶</td>
</tr>
<tr>
<td>Product</td>
<td>Endoform Dermal Template 2x2, SKU 529312</td>
</tr>
</tbody>
</table>

**Product Usage:**
Endoform Dermal Template is a sterile, single use ovine forestomach derived extracellular matrix intended to cover, protect and provide a moist wound environment.

**Code Information:**
Lot numbers: EDT-7I01 EDT-7K01 EDT-7L05

**Recalling Firm/Manufacturer:**
*Area Biosurgery*
2 Kingsford Place
Otara
Auckland New Zealand

**For Additional Information Contact:**
Kevin Sisk
860-3377730

**Manufacturer Reason for Recall:**
Potential for pouch seal failure

**FDA Determined Cause²**
Employee error

**Action**
The firm sent a Customer Notification letter dated September 2018. The letter identified the affected product, problem and actions to be taken. Customers are encouraged to visually inspect the seals on devices from these lots prior to use with particular care. Should you observe a compromised seal, please discard the device and select a new, fully sealed device for use.

**Quantity in Commerce**
8,853 total boxes

**Distribution**
US Nationwide Distribution

**Total Product Life Cycle**
TPLC Device Report²⁷

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¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=167603).

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=167603

11/14/2018