Class 2 Device Recall Firebird Spinal Fixation System

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>February 10, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Status</td>
<td>Open</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-0797-2016</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>7306923</td>
</tr>
<tr>
<td>510(K)Number</td>
<td>K15148824</td>
</tr>
<tr>
<td>Product</td>
<td>Firebird Spinal Fixation System Torque Limiting Handle (PN 52-1512)</td>
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<td></td>
<td>Intended for posterior, non-cervical pedicle, and non-pedicle fixation (T1-S2/Ilium).</td>
</tr>
</tbody>
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[^26]: HXC[^26]
Class 2 Device Recall Firebird Spinal Fixation System

BS535418109, BS535420082, BS557717009, and BS56235023.

Recalling Firm/Manufacturer
Orthofix, Inc
3451 Plano Pkwy
Lewisville TX 75056-9453

For Additional Information Contact
Christopher Hack
214-937-2828

Manufacturer Reason for Recall
There is a possibility that the device may deliver a torque value less than the required setting after initial sterilization. In worst case, the unexpected drop in torque value may lead to the spinal construct loosening and requiring corrective surgical intervention.

FDA Determined Cause
Under Investigation by firm

Action
Affected consignees were notified via an Urgent Medical Device Recall Notification letter, dated 1/8/16. The letter identified the affected device and stated the reason for the recall. The recalling firm requests customers to remove the affected devices from their inventory and cease further distribution or use. Customers whom the devices were further distributed to should be notified that the affected devices cannot be used and must be returned to Orthofix per the instructions provided. The attached Acknowledgement Form should be completed and returned. Customers can contact their local Orthofix representative or customer service for further information, replacements, or disposal instructions.

Quantity in Commerce
36 units

Distribution
Worldwide Distribution – US, Spain, Italy, and Australia.

Total Product Life Cycle
TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmncfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/r1.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm