Class 2 Device Recall Firebird Spinal Fixation System

New Search

Back to Search Results

Class 2 Device Recall Firebird Spinal Fixation System

See Related Information[22]

Recall Date	February 10, 2016
Recall Status[1]	Open
Recall Number	Z-0797-2016
Recall Event ID	73069[23]
510(K)Number	K151488[24]
Product Classification	Wrench[25] - **Product Code** HXC[26]
Product	Firebird Spinal Fixation System Torque Limiting Handle (PN 52-1512) Intended for posterior, non-cervical pedicle, and non-pedicle fixation (T1-S2/Ilium).
Code Information	BS535418105, BS535419118, BS535420030, BS535419124, BS562325021, BS535418158, BS535418038, BS535418138, BS535418012, BS535419006, BS535420039, BS535418127, BS549024010, BS535419141, BS535418081, BS535418111, BS535418117, BS535420041, BS535418144, BS535420081, BS535419151, BS562325006, BS546825008, BS535418002, BS535418013, BS535418131, BS535420006, BS535420010, BS535420026, BS535420047, BS556219012, BS556219026,

	BS535418109, BS535420082, BS557717009, and BS562325023.
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 [2]	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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.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

15/3