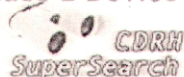




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Class 2 Device Recall TITAN

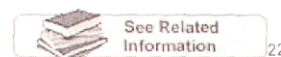


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Class 2 Device Recall TITAN



| | |
|---|---|
| Date Initiated by Firm | December 20, 2017 |
| Create Date | April 20, 2018 |
| Recall Status ¹ | Open ³ , Classified |
| Recall Number | Z-1463-2018 |
| Recall Event ID | 79597 ²³ |
| Product Classification | Template ²⁴ - Product Code HWT ²⁵ |
| Product | <p>The humeral stems trials are packaged in a kit for Titan Modular Shoulder System. Each kit contains 1 of each size. The kit components are packaged in individual corrugated cardboard boxes. Kits are then packaged as a case pack in cardboard boxes.</p> <p><i>This product is used for off-loading diabetic foot ulcer.</i></p> |
| Code Information | See Consignee List. |
| Recalling Firm/Manufacturer | Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344 |
| For Additional Information Contact | 609-275-0500 |
| Manufacturer Reason for Recall | Incidents of stem trial breakage were reported to the firm suggesting that these fractures all occurred during insertion/impaction or extraction of the humeral stem trial whiling preparing the humeral canal and/or trialing. All cases resulted in a delay in surgery, with a variance of <i>medical intervention required.</i> |
| FDA Determined Cause ² | Device Design |
| Action | Firm sent letters to consignees on December 20, 2017. Firm asked consignees to examine inventory and determine if consignee had affected product. Firm promised to send new stem trials along with a return shipping label. Firm asked to complete the Acknowledgment and Return Form and email or fax back to firm. For further questions, please call (609) 275-0500. |
| Quantity in Commerce | 1619 units |
| Distribution | Worldwide Distribution - USA (nationwide) Distribution. |
| Total Product Life Cycle | TPLC Device Report ²⁶ |

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](#)²⁷.

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

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be