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Class 2 Device Recall Salto Talaris Total Ankle Prosthesis

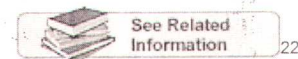
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Class 2 Device Recall Salto Talaris Total Ankle Prosthesis



| | |
|---|---|
| Date Initiated by Firm | March 08, 2019 |
| Create Date | April 16, 2019 |
| Recall Status ¹ | Open ³ , Classified |
| Recall Number | Z-1167-2019 |
| Recall Event ID | 82377 ²³ |
| 510(K)Number | K060544 ²⁴ K090076 ²⁵ K130533 ²⁶ |
| Product Classification | Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer ²⁷ - Product Code HSN ²⁸ |
| Product | Talar Dome Total Ankle Prosthesis, Flat Cut, Size 3, Right, Product No. LJU813T |
| Code Information | 180078 182903 183670 190799 |
| Recalling Firm/Manufacturer | Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344 |
| For Additional Information Contact | Customer Service 800-654-2873 |
| Manufacturer Reason for Recall | The Salto Talaris and Integra XT Revision implant labelling was found to list an incorrect metallic coating material symbol on the metallic implant labels (box and inner pouch) and IFU |
| FDA Determined Cause ² | Other |
| Action | On March 8, 2019, the firm notified affected customers and distributors of the product issue via Urgent Medical Device Correction letter. The letter advised customers that the incorrect metallic coating material symbol had been printed on the implants labeling. Customers were asked to do the following: Please examine your inventory to determine if you have any Salto Talaris Total Ankle Prosthesis implants and/or Integra XT Revision Total Ankle Replacement System implants. Customers: 1. If you do have any impacted lots of Salto Talaris Total Ankle Prosthesis implants and/or Integra XT Total If you have any impacted lots of Salto Talaris Total Ankle Prosthesis implants and/or Integra XT Total Revision Ankle Replacement System implants, please be aware the correct material symbol is CP Ti. The IFU containing the correct material symbol can be accessed at the link below. Product removal is not required. Distributors: 1. f you have any impacted lots of Salto Talaris Total Ankle Prosthesis implants and/or Integra XT Total Revision Ankle Replacement System implants, please be aware the correct material symbol is CP Ti. The IFU containing the correct material symbol can be accessed at the link below. Product removal is not required. "2. We also kindly ask that you provide this letter to impacted customers who may have affected products. IFU Link: Integra XT: https://www.integralife.com/file/general/1551465297.pdf Salto Talaris: |