FDA



## Class 2 Device Recall The UNICP bone fixation system

See Related Information 22

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| **Date Initiated by Firm** | May 22, 2018 |
| **Create Date** | July 16, 2018 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-2445-2018 |
| **Recall Event ID** | 80312[23] |
| **510(K)Number** | K093914[24] |
| **Product Classification** | Plate, fixation, bone[25] - **Product Code** HRS[26] |
| **Product** | ADVANSYS MLP/DLP, Model Numbers: 181051S, 181052S, 181041S, 181042S, 181031S, 181032S, 181033S, 181021S, 181022S & 181023S |
| **Code Information** | 181051S - Lot # FCK9, FG3H & FG3J 181052S - Lot # E8PA/G & EB1H/G 181041S - Lot # F0AS, F0AT & F0AU 181042S - Lot # E8P8/G & EB1F/G 181031S - Lot # E8N2/G, E8NL/G, E8P4/G, E8PS/G, EBKW/G, EBKW/G1 & F8EH 181032S - Lot # E8P5/G, E8P5/G1, E8PT/G, EB1C/G, EBKX/G & F8EJ 181033S - Lot # E8PU/G 181021S - Lot # E8NH/G & E8P1/G-EB18/G 181022S - Lot # E8MF/G, E8MF/G/Q, E8PQ/G & EBKU/G 181023S - Lot # E8MG/G, E8P3/G, E8PR/G & F8EG |
| **Recalling Firm/ Manufacturer** | NewDeal SA<br>Immeuble Sequoia 2 97 A<br>97 Allee Alexandre Borodineimmeuble Sequoia 2 97 Allee Alexandre Borodine<br>St Priest France |
| **Manufacturer Reason for Recall** | Use of the impacted product may cause a superficial infection requiring PO antibiotics and wound care or deep infection requiring IV antibiotics and device removal. |
| **FDA Determined Cause [2]** | Packaging change control |
| **Action** | On May 22, 2018 Newdeal SAS, a company of Integra LifeSciences, issued URGENT VOLUNTARY MEDICAL DEVICE RECALL notices to their customers. Customers were advised to take the following actions: 1. Examine your inventory to determine if you have any affected lots in original product packaging identified within the notice. 2. If you do have any of the affected lots in original product packaging, stop using the product immediately, remove them from service and place in quarantine until the product can be returned. 3. Complete the Acknowledgement and Return Form and check the box: I do have affected products on the list and record the lot number. 4. Or, complete the attached Acknowledgement and Return Form and check the box: I do not have affected products. 5. Complete the other information on the form as indicated on the form. Keep a copy of the form for your records. Return the completed Acknowledgement and Return Form by email or fax indicating your receipt and review of the notification. Customers with questions regarding the instructions, please contact Customer Service at 1-800-654-2873 Monday to Friday 8:00 AM 8:00 PM EST or custsvcnj@integralife.com . |
| **Distribution** | CA, CO, CT, ID, KS, MA, MD, MN, MO, MS, NC, NY, OH, OR, PA, SD, VA, WA & WI |
| **Total Product Life Cycle** | TPLC Device Report[27] |