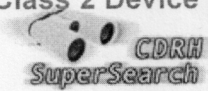


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Class 2 Device Recall Reprocessed Xcel Bladeless Trocar (H12LP)

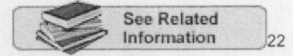


6 510(k)|DeNovo⁸ Registration & Listing⁹ Adverse Events¹⁰ Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵ CFR Title 21¹⁶|Radiation-Emitting Products¹⁷|X-Ray Assembler¹⁸|Medsun Reports¹⁹|CLIA²⁰|TPLC²¹

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Class 2 Device Recall Reprocessed Xcel Bladeless Trocar (H12LP)



Date Initiated by Firm November 11, 2016

Create Date December 14, 2016

Recall Status¹ Open³, Classified

Recall Number Z-0765-2017

Recall Event ID 75675²³

510(K)Number K062497²⁴

Product Classification Laparoscope, general & plastic surgery, reprocessed²⁵ - **Product Code** NLM²⁶

Product Reprocessed Xcel Bladeless Trocar (H12LP)
Model # H12LP
Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Code Information 3 6 9 8 943 6/4/2015 Jun-18, H12LP 3 7 0 3 025 6/4/2015 Jun-18, H12LP 3 7 0 7 017 6/4/2015 Jun-18, H12LP 3 7 0 8 496 6/5/2015 Jun-18, H12LP 3 7 0 8 546 6/5/2015 Jun-18, H12LP 3 7 1 0 388 6/5/2015 Jun-18, H12LP 3 7 1 0 498 6/5/2015 Jun-18, H12LP 3 7 1 1 263 6/5/2015 Jun-18, H12LP 3 7 1 2 572 6/5/2015 Jun-18, H12LP 3 7 1 2 909 6/5/2015 Jun-18, H12LP 3 7 1 2 913 6/9/2015 Jun-18, H12LP 3 7 1 3 407 6/9/2015 Jun-18, H12LP 3 7 1 3 901 6/9/2015 Jun-18, H12LP 3 7 1 4 983 6/9/2015 Jun-18, H12LP 3 7 1 5 570 6/9/2015 Jun-18, H12LP 3 7 1 5 589 6/9/2015 Jun-18, H12LP 3 7 1 6 638 6/9/2015 Jun-18, H12LP 3 7 1 5 074 6/11/2015 Jun-18, H12LP 3 7 1 7 973 6/11/2015 Jun-18, H12LP 3 7 1 9 225 6/11/2015 Jun-18, H12LP 3 7 2 0 057 6/11/2015 Jun-18, H12LP 3 7 2 2 329 6/15/2015 Jun-18, H12LP 3 7 2 5 181 6/15/2015 Jun-18, H12LP 3 7 2 6 772 6/15/2015 Jun-18, H12LP 3 7 2 7 435 6/15/2015 Jun-18, H12LP 3 7 3 0 715 6/17/2015 Jun-18, H12LP 3 7 3 1 099 6/17/2015 Jun-18, H12LP 3 7 3 2 833 6/17/2015 Jun-18, H12LP 3 7 3 2 851 6/17/2015 Jun-18, H12LP 3 7 3 2 898 6/17/2015 Jun-18, H12LP 3 7 3 7 917 6/19/2015 Jun-18, H12LP 3 7 4 1 225 6/22/2015 Jun-18, H12LP 3 7 4 1 256 6/22/2015 Jun-18, H12LP 3 7 4 2 041 6/22/2015 Jun-18, H12LP 3 7 4 4 436 6/22/2015 Jun-18, H12LP 3 7 4 6 004 6/22/2015 Jun-18, H12LP 3 7 4 8 349 6/24/2015 Jun-18, H12LP 3 7 5 1 993 6/29/2015 Jun-18, H12LP 3 7 5 2 003 6/29/2015 Jun-18, H12LP 3 7 5 8 494 6/29/2015 Jun-18, H12LP 3 7 5 9 302 6/29/2015 Jun-18, H12LP 3 7 5 9 534 6/29/2015 Jun-18, H12LP 3 7 6 0 136 6/30/2015 Jun-18, H12LP 3 7 6 2 495 6/30/2015 Jun-18, H12LP 3 7 6 2 972 6/30/2015 Jun-18, H12LP 3 7 6 5 649 6/30/2015 Jun-18, H12LP 3 7 6 8 045 7/6/2015 Jul-18, H12LP 3 7 6 9 980 7/6/2015 Jul-18, H12LP 3 7 7 1 161 7/6/2015 Jul-18, H12LP 3 7 7 5 668 7/8/2015 Jul-18, H12LP 3 7 7 5 681 7/8/2015 Jul-18, H12LP 3 7 7 9 516 7/8/2015 Jul-18, H12LP 3 7 8 3 776 7/10/2015 Jul-18, H12LP 3 7 8 6 146 7/10/2015 Jul-18, H12LP 3 7 8 6 957 7/10/2015 Jul-18, H12LP 3 7 7 8 024 7/13/2015 Jul-18, H12LP 3 7 8 2 202 7/13/2015 Jul-18, H12LP 3 7 8 4 430 7/13/2015 Jul-18, H12LP 3 7 9 2 212 7/15/2015 Jul-18, H12LP 3 7 9 4 403 7/15/2015 Jul-18, H12LP 3 7 9 4 419 7/15/2015 Jul-18, H12LP 3 7 9 9 917 7/16/2015 Jul-18, H12LP 3 7 9 9 929 7/16/2015 Jul-18, H12LP 3 8 0 0 013 7/16/2015 Jul-18, H12LP 3 8 0 3 761 7/20/2015 Jul-18, H12LP 3 8 0 3 918 7/20/2015 Jul-18, H12LP 3 8 0 4 868 7/20/2015 Jul-18, H12LP 3 8 0 7 840 7/22/2015 Jul-18, H12LP 3 8 0 9 891 7/22/2015 Jul-18, H12LP 3 8 1 0 037 7/22/2015 Jul-18, H12LP 3 8 1 0 783 7/22/2015 Jul-18, H12LP 3 8 1 0 806 7/22/2015 Jul-18, H12LP 3 8 1 1 525 7/23/2015 Jul-18, H12LP 3 8 1 1 778 7/23/2015 Jul-18, H12LP 3 8 1 3 019 7/23/2015 Jul-18, H12LP 3 8 1 3 042 7/23/2015 Jul-18, H12LP 3 8 1 5 917 7/28/2015 Jul-18,

H12LP 3 8 1 6 258 7/28/2015 Jul-18, H12LP 3 8 1 7 655 7/29/2015 Jul-18, H12LP 3 8 2 0 257 7/29/2015 Jul-18, H12LP 3 8 2 1 740 7/29/2015 Jul-18, H12LP 3 8 1 8 770 7/30/2015 Jul-18, H12LP 3 8 2 2 395 7/30/2015 Jul-18, H12LP 3 8 2 3 167 7/30/2015 Jul-18, H12LP 3 8 2 8 192 7/30/2015 Jul-18, H12LP 3 8 2 8 222 7/30/2015 Jul-18, H12LP 3 8 3 0 778 7/30/2015 Jul-18, H12LP 3 8 2 9 338 8/5/2015 Aug-18, H12LP 3 8 3 1 629 8/5/2015 Aug-18, H12LP 3 8 3 3 206 8/7/2015 Aug-18, H12LP 3 8 3 4 196 8/7/2015 Aug-18, H12LP 3 8 3 4 203 8/7/2015 Aug-18, H12LP 3 8 4 1 494 8/10/2015 Aug-18, H12LP 3 8 4 3 375 8/10/2015 Aug-18, H12LP 3 8 4 6 698 8/10/2015 Aug-18, H12LP 3 8 4 5 650 8/12/2015 Aug-18, H12LP 3 8 4 8 891 8/12/2015 Aug-18, H12LP 3 8 4 9 655 8/12/2015 Aug-18, H12LP 3 8 5 2 513 8/12/2015 Aug-18, H12LP 3 8 5 3 141 8/17/2015 Aug-18, H12LP 3 8 5 4 774 8/17/2015 Aug-18, H12LP 3 8 6 1 804 8/19/2015 Aug-18, H12LP 3 8 6 3 303 8/21/2015 Aug-18, H12LP 3 8 6 4 693 8/21/2015 Aug-18, H12LP 3 8 7 0 240 8/24/2015 Aug-18, H12LP 3 8 6 6 398 8/26/2015 Aug-18, H12LP 3 8 7 3 578 8/26/2015 Aug-18, H12LP 3 8 7 9 078 8/26/2015 Aug-18, H12LP 3 8 8 1 364 8/26/2015 Aug-18, H12LP 3 8 8 6 277 8/26/2015 Aug-18, H12LP 3 8 8 0 942 8/28/2015 Aug-18, H12LP 3 8 9 0 070 8/28/2015 Aug-18, H1

Recalling Firm/ Manufacturer	Stryker Sustainability Solutions 1810 W Drake Dr Tempe AZ 85283-4327
For Additional Information Contact	760-279-3180
Manufacturer Reason for Recall	An increase in reports indicating that the reprocessed H12LP Trocar adjustable plug may break in the packaging or during use.
FDA Determined Cause ²	Nonconforming Material/Component
Action	Stryker sent an Urgent Medical Device Recall letter to all affected customers on November 11, 2016. Customers were instructed to discontinue use of the affected lots and were asked to follow the link below to complete the Recall Effectiveness Check Form and indicate if any devices from the lots referenced in Attachment 1 remain in their inventory. This form must be completed even if no affected product is found. www.novasyte.com/sss142 Use the following reference number as you complete the form: [Ship to Account #]. If the form indicates that any affected devices remain in your inventory, a prepaid shipping label will be issued for the return of the product. Credit for all affected devices returned will be issued to your facility. Address any questions regarding the recall to Novasyste by calling (760) 279-3180 or emailing sss142@novasyte.com .
Quantity in Commerce	40,476 devices
Distribution	Worldwide Distribution - US (nationwide) and Internationally to Israel and Canada Foreign distribution to the following; IL and CA
Total Product Life Cycle	TPLC Device Report²⁷

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 recalls²⁸](#).

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 updated as the status changes.

510(K) Database [510\(K\)s with Product Code = NLM and Original Applicant = ASCENT HEALTHCARE SOLUTIONS²⁹](#)

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