MAUDE Adverse Event Report: DAVOL INC., SUB. C.R. BARD, INC. 3DMAX LIGHT SURGICAI MESH

DAVOL INC., SUB. C.R. BARD, INC. 3DMAX LIGHT SURGICAL MESH Back to Search Results

Catalog Number 0117321
Device Problem Torn material
Event Date 03/09/2017
Event Type Malfunction
Event Description

It was reported that after inserting the 3dmax mesh into the patient, the surgeon noted torn mesh on the bottom edge of the device in two locations. There was no injury to the patient and the case was completed with another bard 3dmax mesh. The sample was returned for evaluation.

Manufacturer Narrative

The sample was returned and evaluated. The evaluation finds blood visible on the mesh which is consisted with the mesh having been inserted into the patient as reported. The evaluation found three breaks in the bottom edge seal and notes the mesh, in two of those areas was beginning to tear. The mesh had evidence of having been folded and two of the three breaks in the bottom edge seal were at the location of the fold. The evaluation also noted pulls in the mesh material. As reported this was not an out of the box condition and was only found after manipulation of the mesh. It is possible the user inadvertently damaged the mesh while manipulating before implantation. However, a definitive cause is unknown at this time. To date this is the only reported complaint for this manufacturing lot of 348 units released for distribution on 11/07/2016. A review of the manufacturing records was performed and found that the lot was manufactured to specification with no anomalies the information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.

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Brand Name 3DMAX LIGHT
Type of Device SURGICAL MESH
Manufacturer *(Section D)* DAVOL INC., SUB. C.R. BARD, INC.
100 Crossings Blvd.
Warwick RI 02886
Manufacturer *(Section G)* BARD SHANNON LIMITED -3005636544
San Geronimo Industrial Park
Lot #1, Road #3, Km 79.7
Humacao PR 00791
Manufacturer Contact Laura Berg
100 Crossings Blvd.
Warwick , RI 02886
4018258462
MDR Report Key 6483016
Report Number 1213643-2017-00230
Device Sequence Number 1
Product Code FTL[24]
Report Source Manufacturer
Source Type FOREIGN,HEALTH PROFESSIONAL,U
Reporter Occupation Physician

Type of Report Initial
Report Date 04/11/2017
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 04/11/2017
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Device Catalogue Number 0117321
Device LOT Number HUAX0144
Was Device Available For Evaluation? Device Returned To Manufacturer
Date Returned to Manufacturer 04/05/2017
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA?
Event Location No Information
Date Manufacturer Received 03/14/2017
Was Device Evaluated By Manufacturer? Yes
Date Device Manufactured 11/17/2016
Is The Device Single Use? Yes
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Initial

Patient TREATMENT DATA
Date Received: 04/11/2017 Patient Sequence Number: 1

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