MAUDE Adverse Event Report: DAVOL INC. 3DMAX MESH

DAVOL INC. 3DMAX MESH

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Catalog Number 0115311
Event Date 08/09/2012
Event Type Injury
Event Description

As alleged in medwatch report (b)(4): "had bi-lateral hernia surgery with mesh implanted. One large piece of bard 3d mesh used to cover a femoral and inguinal hernia together on the right and another large piece used to cover two inguinal hernias on the left. Since weeks after surgery, have had tremendous pain in right pelvis to pelvic bone and down front of leg, and some burning in left pelvis. Also had surgical clips used to hold right peritoneum closed. Surgical report says "it opened during the surgery. " pt reported: she has seen multiple doctors and the cause of her pain is not known. An ultrasound was inconclusive. She describes her pain as sometimes debilitating. The drs have made no direct connection between the pain and an issue with the implants at this time. On (b)(6) 2012, the pt had exploratory surgery at which time the dr noted inflammation and scar tissue. He removed adhesions, and scar tissue. He also removed some tacks to relieve tension. No problem was noted with the mesh and it was left in place. Pt says she is still experiencing pain which is sometimes burning and sometimes stabbing pain. Pt reports that during the recent procedure, the surgeon removed the sorbafix tacks and he flattened the mesh and used suture to secure them.

Manufacturer Narrative

We have contacted the initial reporter to request add'l info. This mdr includes all pt, event and device info davol has received to date. Based on the info provided it is unk whether the device may have caused or contributed to the reported event. The pt reports pain since the time of implant and underwent exploratory surgery where tacks were removed. The 3d max mesh was then flattened and sutured into place. Currently, medical records have not been provided and the mesh remains implanted. A review of the mfg records was performed and there was no evidence of a mfg related cause for the reported event. With the currently available info, no conclusion can be drawn. See mdr 1213643-2012-00563 for info related to the sorbafix tacks used in the repair. See mdr 1213643-2012-00564 for info related to the first 3d max mesh implanted.

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Brand Name 3DMAX MESH
Manufacturer *(Section D)* DAVOL INC.
Warwick RI
Manufacturer *(Section G)* BARD SHANNON LIMITED
Lot #1, Road #3, Km 79.7
San Geronimo Industrial Park
Humacao PR 00971
Manufacturer Contact Corie Vasquez
100 Crossings Blvd.
Warwick , RI 02886
8005566756
MDR Report Key 2727506
Report Number 1213643-2012-00565
Device Sequence Number 1
Product Code FTL[24]
Report Source Manufacturer
Source Type Other,Consumer

Reporter Occupation Patient
Type of Report Initial
Report Date 08/02/2012
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 08/30/2012
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device EXPIRATION Date 01/18/2016
Device Catalogue Number 0115311
Device LOT Number HUVJ0718
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Date Manufacturer Received 08/02/2012
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Date Device Manufactured 10/01/2011
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: 08/30/2012 Patient Sequence Number: 1

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