MAUDE Adverse Event Report: JOHNSON & JOHNSON INTERNATIONAL PROCEED VENTRAL PATCH MESH, SURGICAL, POLYMERIC

JOHNSON & JOHNSON INTERNATIONAL PROCEED VENTRAL PATCH MESH, SURGICAL, POLYMERIC

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Catalog Number PVPM
Device Problem Material separation
Event Date 03/25/2017
Event Type Malfunction

Manufacturer Narrative

A used device of product code pvpm was returned for evaluation. During visual inspection of the sample it was observed body fluids on the mesh; also one strap was broken and the other was damaged in a corner. In addition, there are several fragments of the pds base plate present, indicating significant degradation. The partial separation of the straps at the welding with the load ring may occur during handling and does not have any effect on the product properties and functionality. During insertion, be certain to avoid kinking the patch (e. G. , by using clamp or extensive folding/rolling etc.). Once the mesh patch has been inserted through the defect, manipulate the strap carefully to facilitate proper positioning of the patch. Pulling carefully on the suture loops allows the mesh patch to flatten itself against the abdominal wall. The assignable cause suggests an improper handling of the sample.

Manufacturer Narrative

(b)(4). Attempts have been made to retrieve the device. To date the device has not been returned. If the device or further details are received at the later date a supplemental medwatch will be sent. Attempts are being made to obtain the following information. To date no response has been provided. If further details are received at the later date a supplemental medwatch will be sent. The 3rd follow-up: (b)(4) contacted the affiliate via email to request the following information: please indicate which portion of the proceed ventral patch (product pvmp) came away, for example was it the straps or the suture loops? will the device be returned in it's entirety, even is not one piece? procedure being performed when the difficulty occurred? procedure date if available? device lot number?.

Manufacturer Narrative

Additional information was requested and the following was obtained: please indicate which portion of the proceed ventral patch (product pvmp) came away, for example was it the straps or the suture loops? strap. Procedure being performed when the difficulty occurred? open ventral patch repair of umbilical hernia. Procedure date if available? (b)(6) 2017. Device lot number? unknown.

Event Description

It was reported that the patient underwent an unknown procedure on unknown date and the mesh was implanted. During the procedure, when the mesh was placed inside the abdomen, the surgeon had to remove it due to one of the longer ends of the mesh came away. There were no adverse consequences reported. Additional information has been requested.

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Brand Name PROCEED VENTRAL PATCH
Type of Device MESH, SURGICAL, POLYMERIC
Manufacturer *(Section D)* JOHNSON & JOHNSON INTERNATIONAL
Leonardo Da Vincilaan 15
Diegem 1831
BELGIUM 1831

Manufacturer *(Section G)* ETHICON INC.-GMBH
Robert-Koch Strasse 1
Norderstedt D-228 51
GERMANY D-22851

Manufacturer Contact Darlene Kyle
Route 22 West Po Box 151
Somerville , NJ 08876
9082182792

MDR Report Key 6512573
Report Number 2210968-2017-60190
Device Sequence Number 1
Product Code FTL[24]
Report Source Manufacturer
Source Type COMPANY REPRESENTATIVE,FOREIG
Reporter Occupation Other
Type of Report Initial,Followup,Followup
Report Date 03/31/2017
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 04/21/2017
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Device Catalogue Number PVPM
Was Device Available For Evaluation? Device Returned To Manufacturer
Date Returned to Manufacturer 06/20/2017
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Event Location No Information
Date Manufacturer Received 06/20/2017
Was Device Evaluated By Manufacturer? Yes
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: 04/21/2017 Patient Sequence Number: 1

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Page Last Updated: 06/30/2017

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