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 PVPS
Device Problem Material separation
Event Type Injury
Manufacturer Narrative

(b)(4). Additional surgical intervention. To date the device has not been returned. If the device or further details are received at a later date a supplemental medwatch will be sent. In addition, a review of the batch manufacturing records was conducted and the batch met all finished goods release criteria. Maude report #: mw5068099.

Event Description

It was was reported that the patient underwent a surgery for incarcerated umbilical hernia in 2016 and mesh was implanted. The patient returned and required the mesh to be removed. During reoperation, it was found that the mesh was disintegrated into multiple small pieces. The mesh was removed from patient. No additional information is available.

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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	6449428
Report Number	2210968-2017-60151
Device Sequence Number	1
Product Code	FTL[24]
Report Source	Manufacturer
Reporter Occupation	Other
Type of Report	Initial
Report Date	03/16/2017
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/31/2017
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No

Device Operator Health Professional
Device Catalogue Number PVPS
Device LOT Number KE8DSSB0
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Was the Report Sent to FDA?
Event Location No Information
Date Manufacturer Received 03/16/2017
Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer
Date Device Manufactured 05/01/2016
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: 03/31/2017 Patient Sequence Number: 1

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Page Last Updated: 06/30/2017

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