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



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## 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 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](#)<sup>24</sup>  
**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****Links on this page:**

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Page Last Updated: 06/30/2017

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