



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 Migration of device or device component

Event Type Injury

Manufacturer Narrative

Manufacturer Narrative

(b)(4). 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.

Event Description

It was reported that the patient underwent an umbilical hernia repair procedure on (b)(6) 2010 and mesh was implanted. The patient experienced erosion and recurrent hernia. On (b)(6) 2011, the patient underwent removal of encapsulated ventral hernia mesh and scar revision, with midline diastasis plication and placement of strattice xenograph. No additional information was provided.

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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 6536967
Report Number 2210968-2017-60208
Device Sequence Number 1
Product Code FTL²⁴
Report Source Manufacturer
Source Type CONSUMER
Reporter Occupation Other
Type of Report Initial, Followup
Report Date 06/05/2017

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received05/02/2017

Is This An Adverse Event Report?Yes

Is This A Product Problem Report?No

Device OperatorHealth Professional

Device EXPIRATION Date05/31/2011

Device Catalogue NumberPVPS

Device LOT NumberCE8KKBZ0

Was Device Available For Evaluation?Yes

Is The Reporter A Health Professional?No

Was the Report Sent to FDA?No

Event LocationNo Information

Date Manufacturer Received06/05/2017

Was Device Evaluated By Manufacturer?No

Date Device Manufactured05/01/2010

Is The Device Single Use?Yes

Is this a Reprocessed and Reused Single-Use Device?No

Type of Device UsageInitial

Patient TREATMENT DATA

Date Received: 05/02/2017 Patient Sequence Number: 1

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