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

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

Back to Search Results

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.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

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 FTL[24]
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 Received 05/02/2017
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device EXPIRATION Date 05/31/2011
Device Catalogue Number PVPS
Device LOT Number CE8KKBZ0
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Event Location No Information
Date Manufacturer Received 06/05/2017
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 05/01/2010
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: 05/02/2017 Patient Sequence Number: 1

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
23. https://www.accessdata.fda.gov/scripts/medwatch/
24. ../cfPCD/classification.cfm?start_search=&ProductCode=FTL

Page Last Updated: 06/30/2017

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
23. https://www.accessdata.fda.gov/scripts/medwatch/
24. ../cfPCD/classification.cfm?start_search=&ProductCode=FTL