

POP Mesh Adverse Event Reports to the FDA



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Adverse Events for All Mesh Products as Reported to the FDA:

Through January 31, 2019 there have been over 139,000 adverse events reports for mesh products.

Over 132,280 of these were injuries.
1,107 patients died.

Search Term: “mesh, surgical”



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Mesh for Pelvic Organ Prolapse

As of January 31, 2019 there have been over 69,000 adverse events reports for POP mesh products.

64,600 of these reports cited injuries.
393 patients died.

Search details: "mesh, surgical" NOT (hernia OR sui OR "stress urinary incontinence" OR transobturator)



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- 66,260 reports were from the manufacturers.
- 292 reports were from User Facilities such as hospitals and ambulatory surgery centers.
- Very few reports are submitted directly to the FDA. Most reports go *through* the manufacturer.

Report Source

Check All

Uncheck All

- Manufacturer report (66,260)
- Distributor report (1,278)
- Voluntary report (1,203)
- User Facility report (292)



17% of Adverse Event Reports reports to the FDA are from Physicians.

With POP Mesh, that number increased to 26%.

Note: Only 18 reports came from Medical Device Company Sales Representatives.

Reporter Occupation

Check All Uncheck All

- OTHER (17,890)
- PHYSICIAN (17,781)
- ATTORNEY (15,126)
- NOT APPLICABLE (10,130)
- blank* (4,962)
- PATIENT (1,227)
- RISK MANAGER (371)
- NURSE (318)
- UNKNOWN (315)
- OTHER HEALTH CARE PROF... (288)
- HEALTH PROFESSIONAL (236)
- OTHER CAREGIVERS (142)
- PHYSICIAN ASSISTANT (53)
- NO INFORMATION (50)
- PATIENT FAMILY MEMBER ... (50)
- PHARMACIST (47)
- MEDICAL EQUIPMENT COMP... (18)
- DENTIST (9)
- BIOMEDICAL ENGINEER (8)

It is not clear why “Other” is so frequently selected by manufacturers.



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Device Problem

Check All

Uncheck All

- No Known Device Problem (12,710)
- Other (for use when an... (1,478)
- Material erosion (1,236)
- Migration of device or... (979)
- No Information (778)
- Detachment of device c... (447)
- No code available (400)
- Explanted (369)
- Unknown (for use when ... (328)
- Needle, separation (210)
- Implant extrusion (153)
- Device remains implanted (150)
- Implant, removal of (132)
- Defective item (117)
- Break (105)
- Material perforation (100)

Manufacturers most commonly coded the adverse events as “No Known Device Problem”.

“Material erosion” is the third most common code and was selected in 1.9% of the reports. However...

Under-coding of reports makes issues harder for the FDA to identify quickly.



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Example of Coded Report

Showing 1-25 of **17,619** in 0.270 seconds.

[Search Preview](#) [Chart](#)

PROSIMA PELVIC FLOOR REPAIR KIT - Johnson & Johnson , 2012-03-13 , 2489825

Problem: Material erosion ←

IT WAS REPORTED THAT A PATIENT UNDERWENT A PELVIC FLOOR REPAIR PROCEDURE ON (B)(6) 2010 DUE TO PROLAPSE AND A CYSTOCELE. THE PATIENT EXPERIENCED ABDOMINAL PAIN, BACK PAIN, HIP PAIN, VAGINAL DRYNESS, AND MESH **EROSION** . IT WAS REPORTED THAT THE PATIENT HAS UNDERGONE SURGERY TO REMOVE THE **ERODED** MESH, INCLUDING ANOTHER SURGERY ON (B)(6) 2010. NO ADDITIONAL INFORMATION WAS REPORTED ...2010. IT WAS REPORTED THAT THE PATIENT EXPERIENCE PAIN, **EROSION** , EXTRUSION, INFECTION

Example of an Un-coded Report

GYNECARE PROLIFT TOTAL PELVIC FLOOR REPAIR SYSTEM - Johnson & Johnson , 2013-08-28 , (B)(4). IT WAS REPORTED THAT THE PATIENT UNDERWENT A GYNECOLOGICAL PROCEDURE AND MESH WAS IMPLANTED DUE TO POP. IT WAS REPORTED THAT FOLLOWING INSERTION THE PATIENT EXPERIENCED EXTRUSION, URINARY PROBLEMS, RECURRENT URINARY INCONTINENCE, DYSpareunia, **EROSION** , INFECTION, BLEEDING AND OTHER UNSPECIFIED ISSUES. PATIENT ALSO UNDERWENT REMOVAL OF **ERODED** PROLIFT GRAFT ON (B)(6) 2008 DUE TO URINARY INCONTINENCE AND HAD MINI ARC SLING IMPLANTED. IT WAS REPORTED THAT THE PATIENT UNDERWENT RESECTION OF **ERODED** GRAFT, APPROXIMATION OF VAGINAL TISSUE AND

17,619 reports cite erosion but only 1,236 reports to the FDA were coded.



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Mesh Summary Reporting

Since 2008, mesh manufacturers have been submitting adverse events to the FDA via Summary Report.

Summary Reports are NOT publicly available via FOIA (Freedom of Information Act).

The true number of adverse events is difficult to quantify when summary reports are used.



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Example of a Mesh Summary Report that reveals the number of summarized events.

Catalog Number 810081

Device Problem Material Erosion

Event Type Injury

Manufacturer Narrative

(b)(4). Conclusion: no conclusion can be drawn at this time. Should additional information be obtained, a supplemental 3500a form will be submitted accordingly. In addition, a review of the batch manufacturing records was conducted and the batch met all finished goods release criteria. (b)(4). Total number of events - 1175. Gynecare tvt - 96. Gynecare tvt abrevo continence system - 67. Gynecare tvt exact continence system - 98. Gynecare tvt obturator system - 493. Gynecare tvt retropubic system -349. Gynecare tvt-aa abdominal - 72.

Manufacturer Narrative

Ethicon mdr summary reporting exemption (b)(4). Reporting period (b)(4) 2015.

1,175 reports count as 1 event if submitted
via Summary Report



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Example of a Mesh Summary Report that is highly redacted.

Catalog Number PMH

Device Problem Material Erosion

Event Type Injury

Event Description

Manufacturer Narrative

Under FOIA, b4 indicates the information is being redacted as a trade secret

Manufacturer Narrative

Ethicon mdr summary reporting exemption (b)(4). Reporting period april 1, 2015 through may 31, 2015.

Manufacturer Narrative

Ethicon mdr summary reporting exemption (b)(4) reporting period (b)(6) 2015 through (b)(6) 2015 supplemental 14 - attachment: [(b)(6) 2015 fl supplemental 14. Xlsx].

Under FOIA, b6 indicates the information is being redacted as protected health information

Manufacturer Narrative

(b)(4).

Summary Reports are not publicly available via FOIA.



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Innovation in the device industry is critical...but it must be weighed with the knowledge that MDUFA funding pays for pre-market approval only--not for post-market surveillance. Summary Reporting should not be the answer.

Device Registry data is not free and the data is not publicly available. When outcomes are unexpected, often a registry does not measure that outcome.

Questions? Email me at Madris@DeviceEvents.com

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