# 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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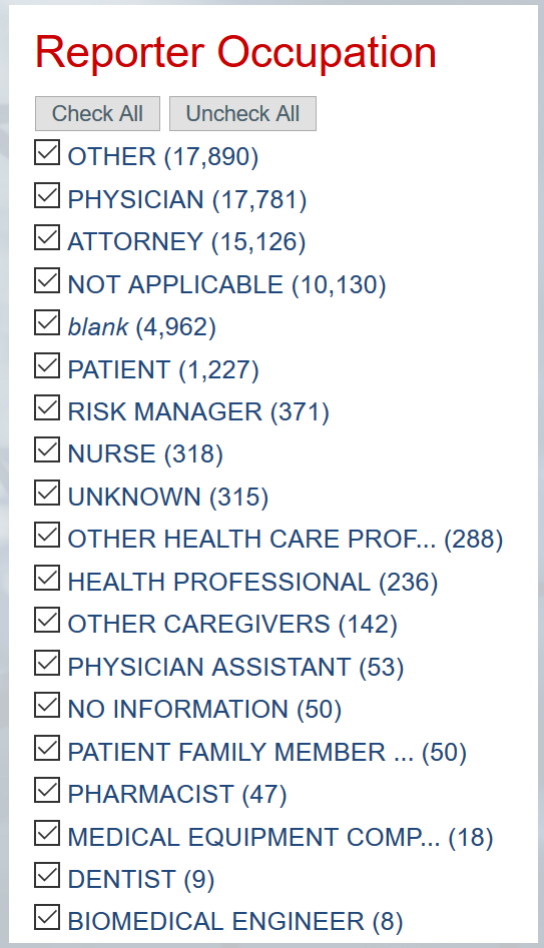
- 66,260 reports were from the manufacturers.
- 292 reports were from User Facilities such as hospitals and ambulatory surgery centers.

- Very few reports are submitted directly to the FDA. Most reports go *through* the manufacturer.

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.




**It is not clear why "Other" is so frequently selected by manufacturers.**

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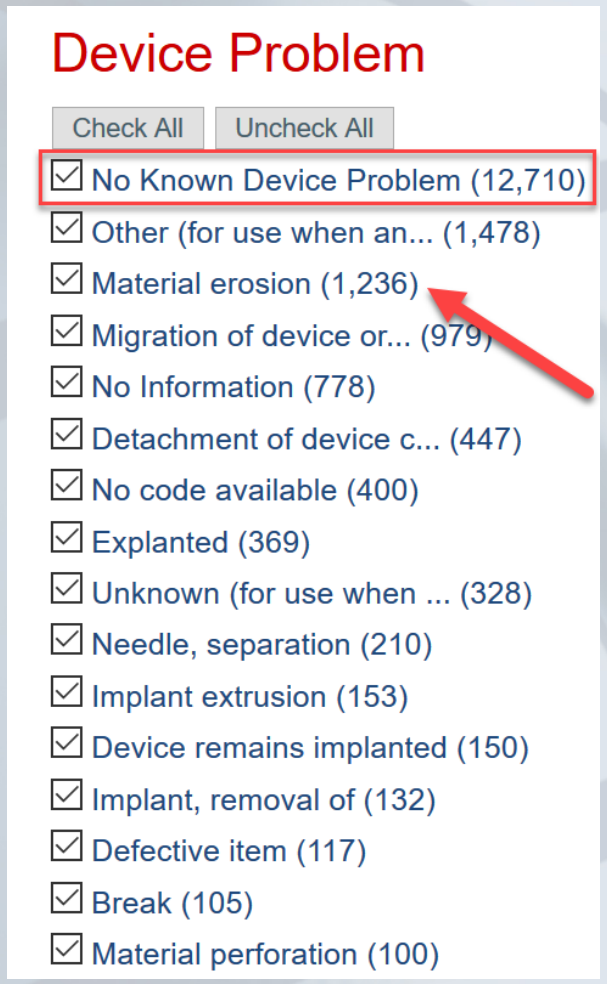


Manufacturers most commonly coded the adverse events as “No Known Device Problem”.

“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.*

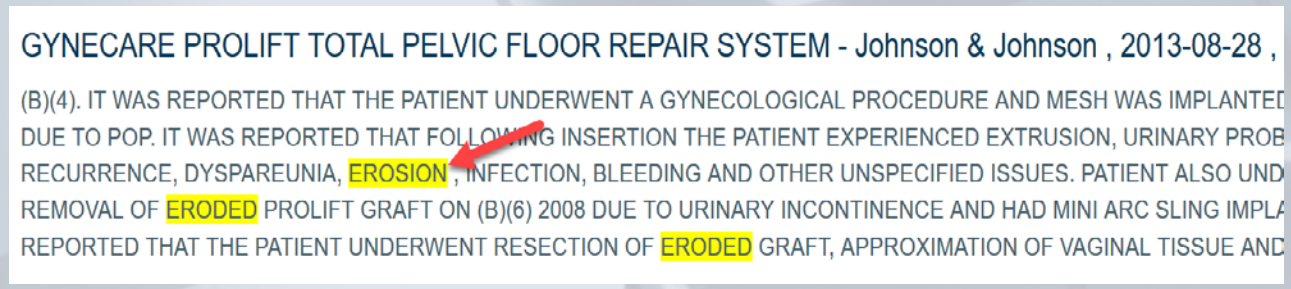
Search Preview | Chart

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) 20 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 REMOVE THE ERODED MESH, INCLUDING ANOTHER SURGERY ON (B)(6) 2010. NO ADDITIONAL INFO ...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 PROB RECURRENCE, DYSPAREUNIA, EROSION , INFECTION, BLEEDING AND OTHER UNSPECIFIED ISSUES. PATIENT ALSO UND REMOVAL OF ERODED PROLIFT GRAFT ON (B)(6) 2008 DUE TO URINARY INCONTINENCE AND HAD MINI ARC SLING IMPLA 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 ftl supplemental 14. Xlsx].

**Manufacturer Narrative**

(b)(4).

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

**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