

Transvaginal Placement of Surgical Mesh

U.S. Food & Drug Administration

[UPDATED 07/13/2011]

ISSUE: FDA is issuing an update to inform health care providers and patients that serious complications associated with surgical mesh for transvaginal repair of POP (Pelvic organ prolapse) are not rare. This is a change from what the FDA previously reported on Oct. 20, 2008.

BACKGROUND: The number of adverse events reported to the FDA for surgical mesh devices used to repair POP and stress urinary incontinence (SUI) for the previous 3-year period (2005 - 2007) was "over 1,000." Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, the agency is concerned that the number of adverse event reports remains high.

RECOMMENDATION: It is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. The Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP. The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.

FDA informed healthcare professionals of serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia. FDA provided recommended actions for both physicians and patients to reduce the risks.

[07/13/2011 - [FDA Safety Communication](#) [1] - FDA]

[07/13/2011 - [Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse \(July 2011\)](#) (PDF -

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Published on Medical Design Technology (<http://www.mdtmag.com>)

[243KB](#) [2] - FDA]

[October 21, 2008 - [Public Health Notification](#) [3] - FDA]

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[1] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>

[2] <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf>

[3] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm>

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