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Transvaginal Mesh–Related Adverse Events May Have Serious Consequences, FDA Warns

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October 21, 2008 — Clinicians should receive specialized training for the transvaginal placement of mesh products and be vigilant for adverse events, the US Food and Drug Administration (FDA) warned yesterday in a news release.

Though rare, complications associated with surgical mesh treatment of pelvic organ prolapse and stress urinary incontinence can have serious consequences. During the last 3 years, 9 surgical mesh manufacturers have submitted more than 1000 reports of complications that have included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence.

Although mesh placement procedures are considered to be minimally invasive, bowel, bladder, and blood vessel perforations have also been reported. In some cases, vaginal scarring and mesh erosion have led to significant discomfort and pain, significantly decreasing the patient's quality of life.

Moreover, treatment of these complications can be painful and require further surgery (some for mesh removal), intravenous therapy, blood transfusion, or hematoma/abscess drainage.

The FDA notes that although specific characteristics remain unclear, the risk for complications may be affected by overall patient health, mesh material, mesh size/shape, surgical technique used, and concomitant procedures such as hysterectomy. Estrogen status may also be a contributing risk factor.

Healthcare professionals are advised to obtain specialized training for each mesh placement technique and to be aware and vigilant for mesh-related adverse events (eg, erosion and infection) as well as placement-related complications (eg, perforation).

Patients should be informed that mesh placement is permanent and advised of the potential for and nature of related complications. If possible, a written copy of the patient labeling for the device should be made available.

Additional information regarding this alert may be obtained from the Office of Surveillance and Biometrics (HFZ-510) by mail at 1350 Piccard Drive, Rockville, Maryland, 20850; by fax at 240-276-3356; or by e-mail at phann@cdrh.fda.gov. Voicemail messages left at 240-276-3357 will be returned as soon as possible.

Patient information is also available online at http://www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html and http://www.fda.gov/cdrh/consumer/surgicalmesh-hernias.html.

Mesh-related adverse events should be reported to the FDA's MedWatch reporting program by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at http://www.fda.gov/medwatch, or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787.