Patient Safety Alert

Veterans Health Administration Warning System
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Effective May 1, 2009 the Action item incorrectly listed as # 6 was corrected to be Action item # 5.

Item: **Transvaginal Placement of Surgical Mesh**

Specific Incident: FDA issued a Public Health Notification on October 21, 2008, regarding serious complications associated with transvaginal placement of surgical mesh in repair of Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI) (Attachment 1). The Notification alerted clinicians to the issues and provided recommendations to reduce the risks. Although rare, the complications can have serious consequences.

General Information: FDA reports that the most frequent complications associated with the placement of transvaginal surgical mesh includes 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. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement. In the VHA system, there are at least two suppliers (Boston Scientific and Coloplast).

Over a 3 year period FDA has received over 1,000 reports of complications from nine surgical mesh manufacturers.

Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.

Actions: 1. By close of business (COB) April 28, 2009, the Facility Directors shall ensure that all Gynecological Surgeons are informed of this Patient Safety Alert.

2. By COB April 30, 2009, all Gynecological Surgeons shall begin informing patients considering the procedure about the risks, benefits, and alternatives to the mesh treatment including the potential for

serious complications and their effect on quality of life, including scarring and pain during sexual intercourse. Patients should also be informed that implantation of surgical mesh is intended to be permanent, and that some complications associated with the mesh may require additional surgery that may or may not correct the problem. The surgeons shall also provide patients with a written copy of the patient product labeling from the surgical mesh manufacturer, if it is available and/or provide them the FDA's patient information in Attachment 2.

3. By COB April 30, 2009, all Gynecological Surgeons shall be vigilant for potential adverse events from the mesh, especially erosion and infection, and also from the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.

4. By COB May, 29, 2009, all Gynecological Surgeons shall obtain specialized training for each mesh placement technique and be aware of its risks. A statement regarding competency assessment shall be included in their requested privileges.

5. By COB June 1, 2009, the Patient Safety Manager shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website.
http://vaww.nbc.med.va.gov/visn/recalls/index.cfm

Source: FDA

Attachments:

1**.** FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence Issued: October 20, 2008

2**.** FDA Patient Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence

Contacts:

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ATTACHMENT 1: FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

Nature of the Problem

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. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.

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.

Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.

Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status.

Recommendations

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.

ATTACHMENT 1 (cont.)

- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

Additional patient information can be found on the following FDA Consumer website at http://www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of surgical mesh, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and Adverse Event Reporting program online at www.fda.gov/MedWatch/report.htm, by phone at 1-800-FDA-1088, or obtain the fillable form online at www.fda.gov/MedWatch/getforms.htm, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Getting More Information

If you have questions about this notification, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through e-mail each time a new Public Health Notification is added to our web page. To subscribe to this service, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39 .

Sincerely,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

ATTACHMENT 2: FDA Patient Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence

FDA wants to inform you about the complications that can occur when surgical mesh is used to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI), and provide you with questions to ask your surgeon before having these procedures. This is part of our commitment to keep healthcare professionals and the public informed about the medical products we regulate.

FDA has received reports of complications associated with the placement of mesh through an incision made in the wall of the vagina. Although rare, these complications can have serious consequences. The reports have not been linked to a single brand or model of mesh.

The most frequent complications included erosion through the vagina, infection, pain, urinary problems and recurrence of the prolapse and/or incontinence.

In some cases, erosion of the mesh and scarring of the vagina led to discomfort and pain, including pain during sexual intercourse. Some patients needed additional surgery to remove the mesh that had eroded into the vagina. Other complications included injuries to nearby organs such as the bowel and bladder, or blood vessels .

Background

A pelvic organ prolapse (POP) occurs when a pelvic organ, such as your bladder, drops ("prolapses") from its normal position and pushes against the walls of your vagina. This can happen if the muscles that hold your pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can drop at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

Pelvic organ prolapse can cause pain or problems with bowel and bladder functions or interfere with sexual activity.

Stress urinary incontinence (SUI) is a type of incontinence caused by leakage of urine during moments of physical stress.

Talking to your doctor

Before having an operation for POP or SUI, be sure to let your surgeon know if you've had a past reaction to mesh materials such as polypropylene.

Questions you should ask the surgeon before you agree to surgery in which mesh will be used:

- What are the pros and cons of using surgical mesh in my particular case? Can my repair be successfully performed without using mesh?

ATTACHMENT 2: (cont.)

- If a mesh is to be used, what's been your experience with implanting this particular product? What experience have your other patients had with this product?
- What's been your experience in dealing with the complications that might occur?
- What can I expect to feel after surgery and for how long?
- Are there any specific side effects I should let you know about after the surgery?
- What if the mesh doesn't correct my problem?
- If I have a complication related to the mesh, can the mesh be removed and what could the consequences be?
- If a mesh is to be used, is there patient information that comes with the product, and can I have a copy?

Reporting complications to the FDA

In order to help FDA learn more about possible problems with surgical mesh, it is important that both physicians and patients report complications that may be associated with this product.

You can report any problems to the FDA's MedWatch Adverse Event Reporting program either online, by mail or FAX.

- Online : www.fda.gov/MedWatch/report.htm
- Mail : use postage-paid FDA form 3500 available at:
  www.fda.gov/MedWatch/getforms.htm
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178

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