



Dear Physician,

Late last week (Sept. 8-9), the U.S. Food and Drug Administration (FDA) Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee met to discuss regulatory next steps for transvaginal surgical mesh. The panel examined the use of transvaginal surgical mesh products to treat both pelvic organ prolapse (POP) and stress urinary incontinence (SUI), which includes mesh products made by American Medical Systems®.

### **Industry Presentation**

Representatives of the Transvaginal Mesh Device Manufacturers' Working Group, (comprised of American Medical Systems, C.R. Bard, Boston Scientific, and Ethicon Women's Health and Urology, in collaboration with the Advanced Medical Technology Association (AdvaMed)), joined by Dr. Suzette Sutherland, a Board-certified urologist focused in the area of female pelvic medicine and reconstructive surgery, presented a strong case to the panel for safety, efficacy and continued classification of mesh as a Class II device to repair pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

### **Panel Recommendations**

Following the two days of presentations from physicians, patient and industry groups the panel recommended:

- Reclassification of transvaginal surgical mesh products for POP to Class III (pre-market approval) and to require manufacturers to conduct additional post-market surveillance studies
- Surgical mesh devices for SUI remain in Class II
- No additional post-market surveillance studies are necessary for retropubic and TOT slings
- Pre-market studies for new devices and additional post-market surveillance studies for mini-slings

Note: During the anticipated reclassification process for POP, products currently commercially distributed can continue to be marketed and sold.

### **AMS' Ongoing Commitment**

If the recommendations of the panel are adopted by the FDA, AMS is prepared to address the request for additional pre- and post-market clinical studies. We currently run robust clinical studies on all of our POP and SUI products which track adverse events and short and long-term outcomes. We also fund external clinical trials to further evaluate the benefits of mesh v. non-mesh repair in POP and mini-sling v. traditional sling in SUI.

Given AMS' ongoing commitment to rigorous clinical research and physician training, we are confident we can work collaboratively with the FDA to ensure women have access to the innovative, safe and effective surgical mesh therapies, which have transformed the treatment of both POP and SUI, two debilitating conditions that impact millions of women.

If you have further questions or needs from AMS during this time period, please contact your AMS Territory Manager or call 1-800-328-3881. For any additional questions, please do not hesitate to contact me directly at 952-930-6391.

Sincerely,



**John F. Nealon**

Senior Vice President and General Manager, Women's Health  
American Medical Systems

