

OBSTETRICS & GYNECOLOGY DEVICES PANEL

September 8-9, 2011

Panel Discussion Questions

Day-2 *Suburethral Mesh Slings for Surgical Repair of Female Stress Urinary Incontinence (SUI)*

1.
 - a. The FDA believes that first-generation minimally invasive suburethral slings for surgical repair of female SUI provides equivalent clinical performance compared to open colposuspension. Please state if you agree with FDA's assessment.
 - b. Based on a review of the published literature and an evaluation of its Manufacturer and User Facility Device Experience (MAUDE) database, the FDA has identified numerous peri-operative and long-term risks associated with suburethral slings for surgical repair of female SUI:

Peri-Operative Risks

- Organ perforation
- Bleeding (including hemorrhage/hematoma)

Long Term Risks

- *Vaginal Mesh Exposure.* Clinical sequelae include pelvic pain, infection, dyspareunia (painful sex for patient or partner), vaginal bleeding, vaginal discharge, urinary problems, and the need for additional corrective surgeries.
- *Other Risks.* These risks include pelvic pain, infection, dyspareunia, urinary problems, recurrent incontinence, mesh erosion into bladder, and neuro-muscular problems.

Please comment on the accuracy of this list and whether it captures the most serious risks associated with suburethral slings. Given the incidence and severity of these adverse events, please discuss if there is reasonable assurance of the safety of suburethral slings for surgical repair of female SUI.

- c. Based on your assessment of the safety and effectiveness of these devices, please discuss whether the clinical benefit of using mesh suburethral slings for surgical repair of female SUI outweighs the risks associated with its use.
- d. Based on your assessment of the safety and effectiveness, should future premarket submissions for mesh products indicated for female stress urinary incontinence be supported by clinical performance data? If yes, please describe the appropriate study design. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.

Note: If FDA were to require premarket clinical study with a control arm employing a traditional repair without mesh, reclassification to Class III might be necessary.

- e. In light of the information available about safety and effectiveness, should manufacturers of currently marketed first generation suburethral slings conduct postmarket surveillance studies of devices already on the market? If yes, please discuss the type of clinical study needed. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.

2. Over the past several years, manufacturers have introduced single-incision mini-slings to the market. Like other mesh products, these devices were brought to market without supporting premarket clinical data. The FDA is concerned that the safety and effectiveness of this subset of suburethral slings for female SUI has not been established. Please discuss the following:

- a. Based on the available scientific evidence, is there adequate safety and effectiveness data on this subset of suburethral slings?
- b. Based on your assessment of their safety and effectiveness, should future premarket submissions for mesh mini-slings be supported by clinical performance data? If yes, please describe the appropriate study design. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.

Note: If FDA were to require premarket clinical study with a control arm employing a traditional repair without mesh, reclassification to Class III might be necessary.

- c. In light of the information available about safety and effectiveness, should manufacturers of currently marketed mini-slings conduct postmarket surveillance studies of devices already on the market? If yes, please discuss the type of clinical study needed. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.