

Re: February 25-26, 2016: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting Announcement
(<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm480045.htm>)

According to the above FDA Meeting Announcement, on February 26, 2016 the panel “will discuss and make recommendations regarding the reclassification of urogynecologic surgical mesh instrumentation from class I to class II”. The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the American Urological Association (AUA) are very supportive of the FDA actions pertaining to these procedures in the interest of public safety.

SUFU and the AUA, dedicated to the advancement of pelvic floor surgery in women, would like to reinforce our previous positions that the polypropylene mesh midurethral sling (MUS) is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women. In addition, the abdominal sacral colpopexy (ASC) is also a very effective and safe treatment of advanced pelvic organ prolapse (POP) in women. We reiterate our previous support of the reclassification of transvaginal mesh for the treatment of POP to class 3, while recommending no alterations in the classifications or usage of the multi-incision MUS and the ASC procedures.

The multi-incision MUS and ASC procedures utilize instrumentation that is critical for proper performance. It is this instrumentation, in all of its iterations, that is apparently under consideration for reclassification. ***Our Societies support the proposed reclassification of urogynecologic surgical mesh instrumentation from class I to class II.*** This is a new proposed action that would seem to enhance public safety, while having little effect on the availability of these procedures, many of which remain a mainstay of the surgical treatment of stress urinary incontinence and POP surgery. Our support of the proposed reclassification of such instrumentation is predicated on the position that this action will not, in any way, limit access to the currently available multi-incision MUS and ASC procedures for patients or providers - now or in the future.

If these proposed actions will negatively impact the availability of the multi-incision MUS or the ASC procedures, our organizations would NOT be supportive of such a measure.

SUFU and AUA remain committed to the optimal care of our patients. The currently available multi-incision MUS and the ASC procedures are vital parts of our clinical armamentarium in providing such care.

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is a non-profit organization dedicated to improving the art and science of urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology and pelvic floor

dysfunction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals, and has grown to over 500 members.

AUA, the American Urological Association, was founded in 1902 and is a leading advocate for the specialty of urology. With more than 21,000 members around the world, the AUA provides support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

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