



November 21, 2021

Dear Valued Customer:

After a careful business review, we have made the commercial decision to no longer market our urogynecological mesh products in Australia and New Zealand as of December 31, 2021. In exception, we will continue to offer our Capio™ SLIM Suture Capturing Device and sutures for sale.

It is important to note that this is not a recall and this decision is not due to any concern with the safety of these products.

We stand by the safety and quality of our products and are pleased that, after thorough assessment, the Therapeutic Goods Administration recently relisted several of our products on the Australian Register of Therapeutic Goods, including our Obtryx™ II Transobturator Mid-Urethral Sling, Advantage™ Blue Transvaginal Mid-Urethral Sling and Advantage Fit™ Blue Transvaginal Mid-Urethral Sling. We have chosen to withdraw our application with TGA for ARTG listing of Upsilon™ Y-Mesh. The withdrawal of this application is not due to any concern with safety of the product and is a result of our decision to not market this product in Australia and New Zealand.

If you have remaining inventory of these products, they can still be used until the shelf expiration date.

For your patients who already have these products implanted and are satisfied with their surgery, no special action is needed as a result of this business decision. Based on the clinical standard of care for women who currently have mesh implanted, it is recommended that patients continue with annual and other routine check-ups and follow-up care.

If you have any questions about this decision, your territory manager is available to help, and we are committed to supporting you through this transition.

Sincerely,

Pat Callanan
Business Unit Director, Australia & New Zealand
Urology and Pelvic Health