

Adverse events may occur years after implantation. The risk will endure for as long as the implant remains in the patient. Each of these events may occur regardless of the skill of the surgeon.

While the true incidence of these complications is unknown, they are not rare.

One or more revision surgeries may be necessary to treat these adverse reactions. Revision surgeries may not resolve complications and are associated with a risk of adverse reactions. PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

Removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms. Removal of part of the implant can be difficult. Removal of the whole of the implant may be practically impossible. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of stress urinary incontinence.

Mesh erosion would likely require additional surgery (vaginal, laparoscopic or cystoscopic) to remove the mesh from the organ. Removal of the exposed or eroded mesh will not necessarily prevent further mesh exposure, mesh erosion or other adverse events.

Federal Court of Australia Advice

The Federal Court of Australia has ordered that none of the GYNECARE TVT™ FAMILY of PRODUCTS may be supplied, distributed, marketed or promoted after the 30 of June 2020 without including advice to address the following:

PROLENE mesh, being a polypropylene mesh, is designed to, and will elicit in all patients, an acute inflammatory reaction, followed by a chronic inflammatory response. The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant remains in the body. The scar tissue will cause the mesh to contract to some degree in all patients. It is not possible to predict the severity of the chronic inflammatory response in any individual patient. In some patients the chronic inflammatory response will have adverse effects. It is not possible to identify in advance the patients who will experience those effects, although some patients are at greater risk than others. Complications might also appear in patients without any known risk factors. The severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It can also be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor may influence the compatibility and function of the implant.

The adverse events which may result include:

- Infection
- Erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain
- There is a risk that the mesh material may be accidentally placed into or erode into another organ such as the bladder or urethra (mesh erosion) and cause damage to the organ, pain, blood in the urine, stone formation, and urinary tract infection
- Damage to nerves in the scar tissue surrounding the implant or elsewhere
- Punctures or lacerations or injury of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur and may require surgical repair
- Pain – which may be severe and chronic
- Pain with sexual intercourse (dyspareunia), which may be severe and may become chronic
- Loss of sexual function (apareunia), which may be ongoing and may not resolve in some patients
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area, and leg weakness, may occur
- Recurrence of stress urinary incontinence
- De novo urge urinary incontinence
- Temporary or chronic voiding dysfunction (or difficulty voiding) or urinary retention/obstruction independent from that caused by overcorrection or urethral hypermobility, i.e. too much tension applied to the tape, or from misplacement of the sling or placing the sling too tightly. This may also cause recurrent urinary tract infections.

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