Prolene mesh is designed to, and will invariably 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. At-risk patients include healthy patients. 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:

(a) infection;

(b) erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain;

(c) erosion of the mesh into surrounding organs such as the bladder, urethra or rectum which may cause pain and damage those organs;

(d) damage to nerves in the scar tissue surrounding the implant or elsewhere;

(e) chronic pain, which may be severe;

(f) dyspareunia, which may be severe and may become chronic;

(g) apareunia;

(h) leg weakness;

(i) de novo or recurrent urinary incontinence;

(j) difficulty voiding; and

(k) vaginal discharge.

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.

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.

Removal of the eroded mesh will not necessarily prevent further erosions or other adverse events.