Axis™ / Suspend® Brief Statement

Description – Axis Tutoplast® Processed Dermis and Suspend Tutoplast® Processed Fascia Lata are regulated as 361 human and cell tissue products and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional. This includes supplemental support and reinforcement of soft tissue, such as suburethral graft placement in stress urinary incontinence procedures, and support and reinforcement of fascial structures in the pelvic floor in pelvic organ prolapse procedures.

Warnings – The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

Precautions – Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant, as such conditions may compromise outcomes. The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determined that the clinical circumstances require implantation in a site that is contaminated, or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to success of the surgical procedure. The Suspend Tutoplast® Processed Fascia Lata implant should be used with caution in sites where it is placed perpendicular to native tissue.