

SILMAX SHEETING PACKAGE INSERT

Indications For Silmax Sheeting

Silmax Sheeting comes in a variety of thicknesses for different surgical applications. For use in a specific application, the employment of Silmax Sheeting in surgery will be determined solely by the surgeon, clinic or hospital. Silmax Sheeting is indicated for the following surgical applications:

Nonreinforced Sheeting Device:

1. Surgical repair of fractured orbital floors; .005"-.010"
2. Surgical repair of nasal septum and perforated eardrum membrane; .005"
3. For lengthening extraocular muscles in select cases of strabismus; .010"
4. Used in anchoring hemodialysis shunts and other systems; .040"-.060"
5. Various Laboratory uses, including: vial covering, gaskets, stoppers and chromothography; All thicknesses
6. In surgical instrument applications with retractors and forceps as an instrument covering; All thicknesses

Reinforced Sheeting Device:

1. Used as a protective sheathing to facilitate osteogenesis; .010"
2. For surgical repair of urethral anatomy; .010"
3. To prevent synostosis in completed corrective surgery for cranial fusions and forearm fractures; .010"
4. Lessen soft-tissue fibrosis or bony growths following surgical correction of trismus; .010" - .020"
5. For use in fabricating components in artificial hearts and insulating material for electrostimulation devices; .020-.030"
6. As a temporary covering for prenatal rupture omphalocele during staged repair procedures; .010"

Contraindications For Silmax Sheeting

Contraindicated for use on patients who have, or are at risk to develop, one or more of the following disorders: autoimmune diseases; any debilitating disease or infection; lack of sufficient skin covering; or any disease which puts the patient at risk for surgery.

Complications and Warnings

Pillar Surgical relies on the surgeon, hospital and or clinic who utilizes this product to advise the patient of all complications and risks of both the implanted sheeting and the surgical procedures involved.

Complications associated with all surgical procedures should be discussed with the patient such as: infection, poor reaction to the medications and surgical procedures, poor wound healing, seroma/hematoma, serious fluid build up, nerve damage, nerve irritation, neuralgia, loss of sensation, or patient intolerance to any foreign material.

The relationship between silicone elastomer implants and collagen diseases such as Dermatomyositis, Lupus, Erythematosus, Rheumatoid Arthritis, Scleroderma and all other autoimmune phenomena remains unproven. Patients with collagen autoimmune disease should not be considered as candidates for silicone implant surgery. The patient must be told that silicone sheeting may cause autoimmune diseases such as the aforementioned before they consent to surgery for the use of this and other silicone products.

Instructions For Use

Proper surgical procedures are the responsibility of the surgeon. Each surgeon must evaluate the suitability of the procedure based upon current accepted techniques, individual judgment, and his or her surgical training and experience.

Supplied Non-Sterile

This Non-Sterile product is supplied precleaned in a sealed single package. Open the package under clean conditions and remove the sheet from the outer wrap and sterilize according the sterilization instructions below.

Cleaning and Sterilization Instructions

1. Inspect the sheeting to ensure that it is free of dust, lint, talc or skin oil that may be deposited during handling. Scrub the sheeting thoroughly with a soft-bristled brush in a hot water soap solution. Do not use synthetic detergents or oil based soaps, as these may be absorbed and subsequently leach out to cause tissue reaction.
2. Rinse thoroughly with sterile saline or distilled water.
3. Wrap in a suitable lint-free package or place on a clean open tray. Sterilize in a standard gravity autoclave at 250°F (121°C) for 30 minutes or 270°F (132°C) for 15 minutes. Or, use high-speed instrument sterilization or prevacuum sterilization at 270°F for 15 minutes.
4. Use of a biological indicator is recommended.

Product Handling and Examination

Prior to implantation, this product should be visually inspected for any evidence of particulate contamination, damage or other defect or contamination, which may have occurred during shipment.

This product should be kept submerged in sterile normal saline prior to implantation to prevent contact with airborne and surgical field particulate contamination.

Care must be taken to prevent possible surface contamination by talc, dust, surgical glove lubricants, or skin oils, which might adversely affect the suitability of this product.

Never, under any circumstances, reuse this product or accept this product if it is defective.