SURIMESH ANATOMICAL MESH

Instructions for Use

Monofilament Knitted clear Polypropylene Hernia Anatomical Mesh

DESCRIPTION

SURGIMESH Anatomical Mesh is constructed from monofilament polypropylene and features an open-pore design, enabling a rapid fibroblastic response through the mesh's interstices. The three-dimensional (3D) curved shape and preformed, semi-rigid edges facilitate its fit with the inguinal anatomy. The orientation indicators assist in identifying the orientation and location of the SURGIMESH Anatomical Mesh relative to the anatomy of the groin.

INDICATIONS

SURGIMESH Anatomical Mesh is used to strengthen soft tissue areas where there is a lack of repair in inguinal hernias.

CONTRAINDICATIONS

- Avoid using the device with infants, children, or women who are pregnant or nursing, as its use may hinder future growth.
- Studies indicate that there could be a chance of adhesion formation when polypropylene mesh comes into contact with the bowel or internal organs.

WARNINGS

- The insertion of any permanent mesh or patch into a wound that is contaminated or infected may result in the development of fistula formation or the extrusion of the prosthesis.
- Should an infection arise, promptly administer treatment for the infection. Thought should be given to the necessity of removing the mesh. An unhealed infection necessitates the removal of the device.
- Should unused mesh come into contact with instruments or supplies used on a patient or be contaminated with bodily fluids, it should be disposed of carefully to avoid the risk of transmitting viral infections.
- To avoid future occurrences during hernia repairs, the mesh should be tailored with the right overlap size, considering the defect's dimensions and the patient's specific clinical circumstances. Diligent placement and proper spacing of mesh fixation points are crucial to avoid excessive tension or gaps between the mesh and fascial tissue.
- This apparatus is delivered in a sterile state. Check the packaging to ensure it is unbroken and not damaged before consumption.
- This apparatus is intended for exclusive use by one individual. Recycling, refurbishment, re-sterilization, or repackaging could jeopardize the device's structural stability and/or crucial material and design attributes, potentially causing malfunction and patient injury. Other methods like reuse, reprocessing, re-sterilization, or repackaging could lead to contamination of the device and result in patient infections or cross-infections, including the spread of infectious diseases from one patient to another. The device's contamination could result in harm to the patient or user.
- Ensuring safety, meticulous focus is necessary when manipulating the mesh near nerves, blood vessels, or the spermatic cord. Injuries to nerves or blood vessels beneath fasteners could necessitate medical or surgical treatment, potentially leading to severe harm or long-term disability.

PRECAUTIONS

Please read all instructions prior to use.

- Physicians proficient in proper surgical methods should employ this artificial limb.
- Avoid altering or modifying the SURGIMESH Anatomical Mesh; doing so could impair its efficacy.
- Employ a precisely sized trocar to facilitate the mesh's descent along the trocar with minimal exertion.

ADVERSE REACTIONS

Potential complications may include, but are not limited to, seroma formation, adhesions, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula development, allergic reactions, wound dehiscence, and recurrence of the hernia or soft tissue defect.

DIRECTIONS FOR USE

It is recommended that an 8 mm or larger internal diameter trocar be used to introduce the SURGIMESH Anatomical Mesh. *If the trocar includes a proximal cap, removing the cap may help ease insertion of the device. Insertion force can vary depending on the size of the rolled device and the type of grasper and/or trocar used.*

ROLLING AND INSERTING

- Place the device on the table with the concave surface facing upward.
- Roll the edges of the mesh inward along its long axis toward the midline.
- Bring the rolled sides together to fully close the device.
- While holding the rolled mesh, securely grasp the leading edge with an atraumatic grasper or a comparable instrument, ensuring the grasper is applied to either end of the rolled device.
- Advance the leading edge of the rolled device into the trocar and, in a single continuous motion, deploy it into the abdominal cavity.
- Ensure that the “M” marking is oriented toward the medial aspect of the inguinal space. Maintain laparoscopic visualization of the device throughout deployment.

Fixation may not be necessary, depending on factors such as defect size, surgical technique, anatomical structure quality, and tissue integrity. If fixation is performed, Bard® permanent or absorbable fixation devices or non-absorbable monofilament sutures are recommended to adequately secure the SURGIMESH Anatomical Mesh. If alternative fixation devices are used, they must be indicated for hernia repair. Care should be taken to avoid fixation near vessels and nerves.

SYMBOLS USED ON LABELING

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