# SURGIMESH PLUG

*Instructions for Use*

Monofilament Knitted Clear Polypropylene Hernia Plug and Patch

**DESCRIPTION**

SURGIMESH Plug has a large pore design and is constructed of knitted polypropylene monofilaments. The pores in the mesh allow for tissue ingrowth.

The device is designed with pleated edges that conform readily to defects of various sizes. The inner petals allow the device to maintain its fluted form. The petals can be removed to customize SURGIMESH Plug to each individual patient.

A flat onlay patch is packaged with each SURGIMESH Plug.

The SURGIMESH Plug is available in several sizes. The onlay patch is one size only.

**INDICATIONS**

SURGIMESH Plug is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

**CONTRAINDICATIONS**

- Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.
- Do not use the SURGIMESH Plug in infants or children, whereby future growth will be compromised by use of such mesh material.

**WARNINGS**

The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh.

If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device.

This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.

This device is for single use only. Do not re-sterilize or reuse any portion of SURGIMESH Plug.

To avoid injury, careful attention is required if fixating the mesh in the presence of nerves or vessels.

Reuse, reprocessing, re-sterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.

Reuse, reprocessing, re-sterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.

**PRECAUTIONS**

Please read all instructions prior to use.

Only physicians qualified in the appropriate surgical techniques should use this device.

Care should be taken to ensure that the mesh is adequately fixated to the uncompromised tissue of the inguinal floor. If necessary, additional fasteners and/or sutures should be used.

Monofilament sutures are recommended to properly secure SURGIMESH Plug.

When two or more plugs are used for large direct or pantaloon hernias, they should be joined together with sutures where the plugs abut.

**ADVERSE REACTIONS**

Possible complications include seroma, adhesions, hematoma, inflammation, extrusion, infection, pain, mesh migration, fistula formation and recurrence of the hernia or soft tissue defect.

**DIRECTIONS FOR USE**

For indirect hernias, SURGIMESH Plug is inserted through the internal ring, tapered end first, and positioned just beneath the crura. SURGIMESH Plug should be secured with interrupted sutures. If the overall bulk of SURGIMESH Plug is deemed excessive, then some of the inside petals may be trimmed and removed.

For direct hernias, the defect is circumscribed at its base and the contents fully reduced. SURGIMESH Plug is then inserted through the defect and secured with interrupted sutures.

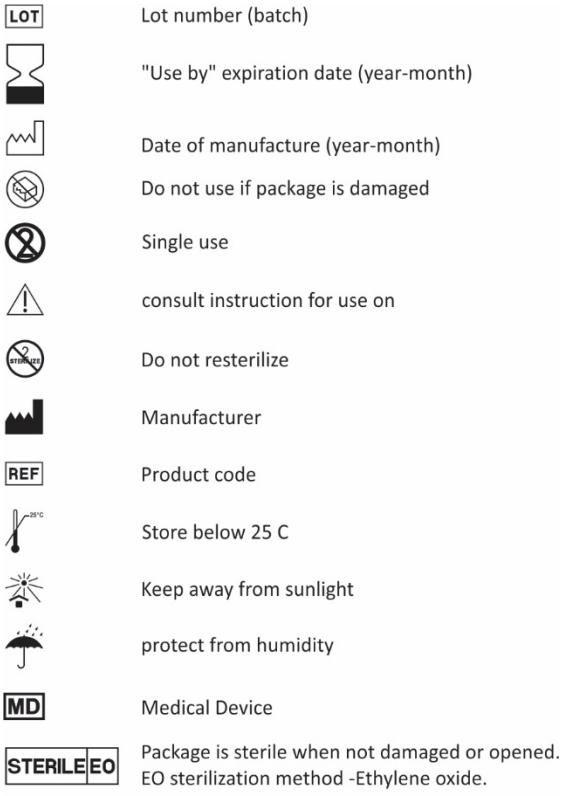
For femoral hernias, once the sac is reduced, a small SURGIMESH Plug is placed such that the top of SURGIMESH Plug Light Plug lies flush with the opening of the femoral canal. SURGIMESH Plug is secured to the surrounding tissue with interrupted sutures. Care must be taken when suturing the plug to prevent trauma to the femoral vessels and nerve. An onlay patch is used only if there is adequate space for it to be placed.

In all groin hernias, the onlay patch is used for reinforcement. It can be tailored to the appropriate shape. A slit may be placed in the onlay patch and the tails brought together with suture to help reinforce the internal ring. Nonabsorbable monofilament sutures are recommended. It is placed without sutures on the anterior surface of the posterior wall of the inguinal canal. Fibroblastic proliferation and collagen formation will infiltrate the mesh and secure it in place.

**CAUTION**

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

**SYMBOLS USED ON LABELING**

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