

# INSTRUCTIONS FOR USE FOR:

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POLYPROPYLENE

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## INSTRUCTIONS FOR USE

# GORE POLYPROPYLENE HERNIA MESH

### DESCRIPTION

The GORE Polypropylene Hernia Mesh is a sterile, non-absorbable, knitted polypropylene monofilament mesh intended for the reconstruction of hernias and soft tissue deficiencies.

### INDICATIONS

GORE Polypropylene Hernia Mesh is indicated for the reconstruction of hernias and soft tissue deficiencies.

### CONTRAINDICATIONS

- Not for reconstruction of cardiovascular defects.
- Not for use in infants, children or pregnancy where future growth may potentially be compromised.
- Not for use in infected or contaminated tissues.

### WARNINGS

- GORE Polypropylene Hernia Mesh is a single use device and is supplied STERILE. Do not resterilize.
- GORE Polypropylene Hernia Mesh should not be placed in direct contact with the viscera or potentially serious complications, such as adhesions, bowel obstruction, and / or enterocutaneous fistulas could result. For intra-abdominal applications, GORE DUALMESH® Biomaterial or GORE DUALMESH® PLUS Biomaterial are recommended.
- Use of this product in applications other than those indicated has the potential for serious complications.
- Use of the GORE Polypropylene Hernia Mesh in contaminated fields may require removal of the mesh if infection occurs.

### PRECAUTIONS

- Use of absorbable fixation devices with the GORE Polypropylene Hernia Mesh has not been evaluated.
- Ensure the size of the device is adequate for the intended repair.

### ADVERSE REACTIONS

Possible adverse reactions with the use of any tissue deficiency prosthesis may include, but are not limited to, contamination, infection, inflammation, adhesion, fistula formation, seroma formation, hematoma, and recurrence.

### STERILITY

GORE Polypropylene Hernia Mesh is supplied **STERILE** and is intended for **single use only**. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier until the "use by" (expiration) date printed on the box.

### RECOMMENDED TECHNIQUES

#### HANDLING

Use clean, sterile gloves and / or atraumatic instruments when handling the GORE Polypropylene Hernia Mesh.

#### SIZING


Shaping the GORE Polypropylene Hernia Mesh to the proper size is essential. Use sharp surgical instruments to trim the device. If the GORE Polypropylene Hernia Mesh is cut too small, excessive tension may be placed on the suture line, which may result in recurrence of the original, or development of an adjacent, tissue defect.


#### FIXATION

When suturing / stapling / tacking the GORE Polypropylene Hernia Mesh to the host tissue, careful attention should be taken to avoid excessive tension between the mesh and host tissue. For the best result use non-absorbable, monofilament suture, tacks, and staples. Use of absorbable fixation devices with the GORE Polypropylene Hernia Mesh has not been evaluated.

## DEFINITIONS

 Use By

 Attention, See Instructions for Use

 Do Not Re-Use

**REF** Catalogue Number

**LOT** Batch Code


**EC|REP** European Authorized Representative

**STERILE**

Contents sterile unless package has been opened or damaged.


**STERILE|EO**

Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.

 Do Not Re-Sterilize

**QTY** Quantity

**Rx** Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

 Store in a cool dry place



AM0216-ML1



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APRIL 2009