

# INSTRUCTIONS FOR USE FOR:

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## INSTRUCTIONS FOR USE FOR GORE INFINIT Mesh

### INDICATIONS

**GORE INFINIT Mesh is indicated for use in the reconstruction of hernias and other soft tissue deficiencies.**

### DESCRIPTION

GORE INFINIT Mesh is a sterile, non-absorbable large pore knit mesh constructed of monofilament PTFE fibers.

### CONTRAINDICATIONS

- None

### STERILITY

GORE INFINIT Mesh is supplied **STERILE**. 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

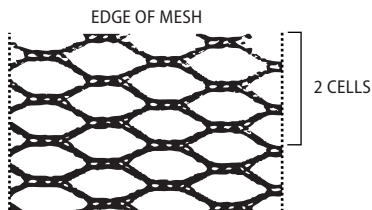
Use clean, sterile gloves and / or atraumatic instruments when handling GORE INFINIT Mesh.

#### SIZING

Shaping or cutting GORE INFINIT Mesh to the proper size is essential. Use sharp surgical instruments to trim the device to ensure overlap of the defect on all sides by about 5 cm. If GORE INFINIT Mesh is cut too small, excessive tension may be placed on the suture line, which may result in the recurrence of the original, or development of an adjacent, tissue defect.

#### SUTURE FIXATION

Use only a non-cutting needle, such as taper or piercing point of appropriate size to anchor the mesh. Careful attention should be taken to avoid excessive tension between the mesh and the host tissue. The mesh should be sutured a minimum distance of 1 cm (0.4") from the edge of the device to ensure at least two complete cells are captured by the suture line, as shown in the figure below.



For best results use non-absorbable, monofilament sutures, such as GORE-TEX® Suture. Suture size and spacing should be determined by surgeon preference and the nature of the reconstruction.

### ALTERNATIVE FIXATION

The use of helical tacks (also known as helical coils) with GORE INFINIT Mesh has been evaluated acutely. Tacks should be placed a minimum of 1 cm (0.4") from the edge of the device. Tack use and spacing should be determined by the surgeon.

The use of fibrin-based adhesives with GORE INFINIT Mesh has been evaluated acutely. Adhesive use should be determined by the surgeon.

Fixation methods other than those described above have not been evaluated for use with GORE INFINIT Mesh.

Use of absorbable fixation with GORE INFINIT Mesh has not been evaluated clinically.

All fixation devices should be used in accordance with the manufacturer's instructions.

### WARNINGS

- GORE INFINIT Mesh should not be placed in direct contact with the viscera due to the possibility of serious complications, such as adhesions, bowel obstruction, and / or enterocutaneous fistulas.
  - For intra-abdominal applications GORE DUALMESH® Biomaterial or GORE DUALMESH® PLUS Biomaterial are strongly recommended.
- The strength of GORE INFINIT Mesh may not be adequate for bridging of ventral fascial defects.
- Use of this product in applications other than those indicated has the potential for serious complications.
- As with any mesh, use of GORE INFINIT Mesh in contaminated fields may require removal of the mesh if infection occurs.

### PRECAUTIONS

- Use of GORE INFINIT Mesh in infants, children or pregnancy where future growth will occur has not been evaluated.
- Ensure the size of the device is adequate for the intended repair.
- Transvaginal insertion techniques, which expose the mesh to the vaginal flora, can increase the risk of contamination leading to colonization of the biomaterial. Prolonged exposure to bacteria may necessitate material removal.

## 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.

## RESTERILIZATION

GORE INFINIT Mesh can be resterilized no more than one time using steam or gas techniques without compromising its mechanical or structural quality.

**Do not resterilize GORE INFINIT Mesh in the original packaging materials.** GORE INFINIT Mesh must be repackaged in materials appropriate for sterilization. Sterility of repackaged product is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the material may be resterilized if handled with clean, sterile gloves and / or atraumatic instruments such as dry transfer forceps. Protect GORE INFINIT Mesh from heavy or sharp objects during resterilization.

- Do not expose GORE INFINIT Mesh to temperatures greater than 482°F (250°C).
- Do not resterilize GORE INFINIT Mesh using radiation.

## STEAM

Using a validated gravity-displacement steam sterilizer, autoclave at or above these minimum requirements; 250°F (121°C) for 30 minutes or 270°F (132°C) for 15 minutes.

Using a validated pre-vacuum (also known as high vacuum) steam sterilizer, autoclave at or above these minimum requirements; 270°F (132°C) for 4 minutes.

## ETHYLENE OXIDE

Because of the tremendous variation in gas sterilization equipment, the choice and validation of the specific cycles and aeration parameters are the responsibility of the health care institution.

## DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



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



Configured For Inguinal Hernia Repair



AL0790-ML4



**W. L. GORE & ASSOCIATES, INC.**

Flagstaff, Arizona 86004 • USA

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Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,  
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