# Section 14

## Proposed Packaging, Labeling and Instructions for Use

## Proposed Packaging, Labeling and Instructions for Use

### 14.1 Proposed Packaging

14.1.1 Proposed Primary Packaging
NanoMesh™ will be provided in 4" x 6" sheets. Each sheet will be double-pouched, inner pouch 5.5" x 8.25" and the outer pouch 7" x 10". The pouches will be vented to accommodate ethylene oxide (EO) sterilization.

14.1.2 Proposed Secondary Packaging
Three (3) pouches (described in Section 14.1.1) will be packaged in one (1) 10.5" x 7" x 1" box. Each box will also contain one (1) copy of the Instructions for Use (IFU), as presented in Section14.3.

### 14.2 Proposed Labeling

14.2.1 Proposed Labeling for Primary Packaging
Each pouch will have the following label (below) affixed to the top of each pouch. Each pouch label will contain a peel-off label which will be affixed to the patient's medical record (if applicable). As per FDA regulation 21 CFR 801.20, Class II medical device labeling must contain a Unique Device Identifier (UDI) bar code that includes relevant information to identify a specific product, lot, expiration date, etc. The peel-off label will also contain UDI code, which can be scanned into the patient's electronic medical record.

**[Product Code]** **Rx Only**

**NANOMESH™**

1 Pc - 4" x 6" (10cm x 15cm)
Polypropylene mesh
**Exogenesis Corporation**

**Sterile** **sterility of contents guaranteed unless package has been opened or damaged.**

**See Instructions for Use**
**Do Not Resterilize**

**[UDI Barcode]**

**Exp. [date]**

**NANOMESH™** 1 Pc - 4" x 6" (10cm x 15cm)
**[Product Code] Exp. [date] [UDI Barcode]**

14.2.2 Proposed Labeling for Secondary Packaging
Each box (secondary package) will have the following label (below) affixed. Each box will also contain the UDI bar code.

**NANOMESH™**
Polypropylene mesh

3 Pc - 4" x 6" (10cm x 15cm)

Sterile: Sterility **of contents guaranteed unless package has been opened or damaged.**

**[UDI Barcode]**

**14.3 Proposed Instructions for Use**

**NANOMESH™**
Polypropylene Mesh
Nonabsorbable Synthetic Surgical Mesh

# INSTRUCTIONS FOR USE

**PRODUCT DESCRIPTION**
**NanoMesh™** is composed of knitted filaments of extruded polypropylene, and knitted to provide elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. NanoMesh™ is treated with a proprietary technology to modify the surface creating a nanotextured surface that increases the surface area of the implant in direct contact with the tissue.

**ACTIONS**
**NanoMesh™** is constructed of polypropylene fibers warp knitted together to form the mesh. The knitting process creates a device with large pores and minimum density and thickness similar to the light meshes currently on the market. The result is an implant which encourages tissue ingrowth that reinforces the tissue defect, while minimizing the inflammatory response and fibrous encapsulation related to implant mass. The mesh possesses the mechanical and physical properties necessary for long term tissue support. The NanoMesh™ nanotextured surface in intended to facilitate tissue integration.

**INDICATIONS FOR USE**
NanoMesh™ is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue.

Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. NanoMesh™ is not indicated for transvaginal pelvic organ prolapse repair.

NanoMesh™ is intended for single patient one-time use only.

**CONTRAINDICATIONS**
**NanoMesh™** is NOT indicated for use in the following situations:

- In the reconstruction of cardiovascular defects,
- In infants or children with future growth potential,
- For transvaginal pelvic organ prolapse repair,
- For use as a plug.

Use of **NanoMesh™** in contaminated wounds is not recommended. If used, it should be understood that any infection may adversely affect proper wound healing and integration into the tissue and may result in the removal of the material.

**WARNINGS**
This device is supplied sterile. Inspect the packaging to be sure that it is intact and undamaged prior to use.
This device is for single use only. Do not resterilize! Product should be used once the pouch has been opened. Do not store for later use. Unused portions of the prosthesis should be discarded.
If unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent risk of transmission of any disease.

The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and extrusion of the prosthesis. If infection develops, treat the infection aggressively as per standard practice. The prosthesis may not have to be removed. An unresolved infection may require removal of the prosthesis.
To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.

**PRECAUTIONS**
A minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

**ADVERSE REACTIONS**
Potential adverse reactions with **NANOMESH™** implantation are those typically associated with surgically implantable materials, including inflammation, seroma formation, adhesion formation, fistula formation, extrusion and potentiation of infection. Please report any device-related Adverse Events to Exogenesis at XXX-XXX-XXX or via e-mail AT safety@exogenesis.us.

**INSTRUCTIONS FOR USE**
The mesh is implanted according to currently accepted surgical mesh procedures.

Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

Adequate mesh fixation is required to minimize post-operative complications and recurrence. The fixation technique, method and products used should follow the current standard of care. Careful attention to fixation and spacing will help prevent excessive tension or disruption between the mesh materials and connective tissue. When fixating with sutures or other mechanical fixation devices, a safe distance from the edge of the mesh of not less than 6.5mm (1/4") must be maintained. 6.5mm to 12.5mm (1/4" to 1/2") should be left between fixation points.

**HOW SUPPLIED**
**NANOMESH™** is supplied in sterile 4” X 6” sheets, and individually pouched.

**Manufactured by:** Exogenesis Corporation
20 Fortune Drive
Billerica, MA 01821
978-439-0120
www.exogenesis.us