VIGILENZ® INSTRUCTION FOR USE

VigiMesh®

Instruction for use VigiMesh®

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Description
VigiMesh is a sterile, non-absorbable, knitted polypropylene monofilament mesh material for tissue reinforcement.

Indication
VigiMesh is intended primarily for use in hernia repair.

Contraindications
VigiMesh is contraindicated where tissue may be contaminated or infected and in infants, children or pregnancy where future growth may be compromised by its use.

Warning Note
1. Do not re-sterilize mesh
2. Avoid direct contact with the viscera (intestines) to minimize the possibility of adhesions.
3. Use only non-absorbable sutures or staples devices with this mesh.

Precautionary measures
1. Handling of mesh should be with clean, sterile gloves and/or surgical instruments.
2. Peel open the package and remove the VigiMesh using sterile technique.
3. Careful attention to surgical mesh handling, suture or staples fixation is required in the presence of nerves and vessels in the surgical field.

Adverse Reactions
Complications that may occur with the use of any surgical mesh include, but are not limited to, inflammation, infection or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contact with the viscera (intestines).

Handling
VigiMesh should be shaped, cut to size, and affixed, taking into consideration the patient's posture, weight and anatomical location. Careful attention to suture/staple placement and spacing will help prevent excessive tension or disruption between the mesh material and connective tissue. It is recommended that suture/staple to be placed 6.5 mm from the edge of the mesh material for best results.

Storage
VigiMesh should be stored in cool and dry place.

Risk of Re-use
Re-use of the hernia mesh may cause a loss of the integrity, performance and efficacy of the mesh. The sterility of the product removed from its initial packing maybe compromised and its intended use may no longer be guaranteed by the manufacturer.

Symbols used on labelling

REF	Article Number
LOT	Batch Number
	Use until Year + Month
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide
	Do not re-use
	Caution
	Manufacturer
	Date of manufacture
CE 2292	CE-mark and identification no of Notified Body
EC REP	Authorized Representative in the European Community

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BD. GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM

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