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GLIKO MESH

Instruction for Use

Poly[glycolide(90%)-co-lactide(10%)]
STERILE SYNTHETIC ABSORBABLE SURGICAL MESH

INTRODUCTION
This package insert is designed to provide instructions for use of Gliko Mesh. It is not a comprehensive reference to surgical technique.
Gliko-Mesh is intended for use only by physicians who are trained in the surgical procedures and techniques required for repairs and the implantation of synthetic meshes. The selection of mesh for any given patient is a function of numerous factors including, but not limited to, the patient's past medical and surgical history, current medical condition, surgical technique, and size and location of the wound or organ support. The physicians is advised to consult the medical literature regarding techniques, complications, and adverse reactions before selecting a mesh.

DESCRIPTION
Gliko-Mesh is a synthetic absorbable sterile copolymer synthesized from 90% glycolide and 10 % L-lactide (derived from glycolic and lactic acids). The copolymer is identical in composition to that used in Glikolak synthetic absorbable suture.
The mesh is available in undyed (natural, beige) and violet form. Violet form's coloring material is D&C Violet no.2- C.I. 60725.
Gliko-Mesh is intended for use as a buttress to provide temporary support during the healing process.

INDICATIONS
Gliko-mesh may be used whenever temporary wound or organ support is required, particularly instances in which compliant and stretchable support is desired. Gliko-Mesh may be cut the shape or size desired for each specific application.

CONTRAINDICATIONS
Because Gliko-Mesh is absorbable, it should not be used where extended wound or organ support is required.

WARNINGS
- Failure to properly follow instructions may result in improper functioning of the device and could lead to injury. Please read all information carefully.
- If this device is used in patients with the potential for growth or tissue expansion (such as infants, children, or women who may become pregnant), the surgeon should be aware that the device will not stretch significantly as the patient grows.
- Gynecologic procedures should be performed using devices specifically designed for gynecologic repairs.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- As with any implant, an acute foreign body response will occur. Patients, this response will occur. In some patients, this response can result in one or more of the adverse reactions listed below.
- Insufficient or improper fixation may increase the risk of postoperative complications. Consult the application/instruction for use section.
- Do not resterilize/ reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may lead to infection or transmission of blood-borne pathogens to patients and anyone coming in contact with the device. which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and anyone coming in contact with the device.
- Inspect the mesh carefully before implantation. Do not use the device is it is damaged.

PRECAUTIONS
- The safety and effectiveness of treating Gliko-mesh with solutions (e.g., saline, medications) prior to implantation have not been studied.
- The safety and effectiveness of Gliko-mesh in neural tissue and in cardiovascular tissue has not been established.

ADVERSE REACTIONS
Potential adverse reactions are those typically associated with surgically implantable materials, including infection, inflammation, seroma formation, acute or chronic pain, foreign body sensation, hematoma, nerve damage, soft tissue injury, adhesion formation, fistula formation, extrusion/ erosion, excessive contraction or shrinkage of the tissue surrounding the mesh, mesh failure, and hernia.

One or more revision surgeries may be necessary to treat the above-mentioned adverse reactions. Revision surgery may not resolve the adverse reactions and may pose a risk of additional reactions.

APPLICATION/ INSTRUCTIONS FOR USE
It is recommended that absorbable sutures be placed at least 1 cm from the edge of the mesh. Some surgeons prefer to suture into position a mesh larger than the wound. The edges are then sutures to assure proper closure under correct tension. When all margin sutures have been places, the excess mesh is trimmed away, leaving at least 6 mm of mesh extending beyond the suture line. The use of thermal cutting devices is not recommended because it has not been tested.

PERFORMANCE / ACTIONS
Two important characteristics describe the in vivo function and behavior of Gliko-mesh: reinforced wound strength and the rate of absorption (loss of mass). In vivo studies indicate that the dehiscence force of healing abdominal wounds closed with size 4-0 absorbable sutures and reinforced with Gliko-mesh is significantly greater than the sutured incisional wound alone. Gliko Mesh was found to have 80% of its original burst strength remaining after fourteen days in vitro.
Gliko-Mesh is essentially absorbed within 90 days.

STERILITY
Gliko-mesh is sterilized using ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged.

STORAGE
Gliko Mesh should be stored under controlled conditions (5°C - 25°C) and keep away from sunlight. Protect from humidity. Do not use after expiry date.

HOW SUPPLIED
Gliko-mesh in available in single-use, sterile packets in a variety of sizes.

SYMBOLS USED ON LABELLING

Do not re-use	STERILE EO Sterile EO: Ethylene oxide	Protect from humidity
Do not resterilize	LOT Batch Number	Recyclable pack
Do not use if package is damaged	REF Catalogue Number	Attention, See instruction for use
Manufacturer	5°C 25°C Temperature Limit	Consult instructions for use
YYYY - MM Date of manufacture, year-month	Keep away from sunlight	CE 2292
YYYY-MM Expiry Date, year-month		

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