PROLENE™ Mesh

Product Codes: PMM3, PMR3, PML3, PMLK1, PMN3, PMSK1

What is in this leaflet

This leaflet answers some common questions about PROLENE™ Mesh. It does not contain all the available information. It does not take the place of talking to your surgeon.

All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using PROLENE™ Mesh against the benefits that are expected. This leaflet does not contain all the available information about PROLENE™ Mesh. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it in future if needed.

What is PROLENE™ Mesh?

PROLENE™ Mesh is a surgical mesh used in the repair of hernias that require the addition of a reinforcing or bridging material to obtain the desired surgical result

PROLENE™ Mesh is constructed of non-absorbable filaments of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin $(C_3H_6)_n$. The undyed polypropylene monofilament fibres have bi-directional elastic properties and available in a variety of square and rectangular sizes as well as specially shaped pieces. The mesh is approximately 0.5mm thick

What is PROLENE™ Mesh used for?

PROLENE™ Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.

Suitability of this device is determined by the surgeon and 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 (i.e., comorbidities), surgical technique, and size and location of the hernia. The physician is advised to consult the medical literature regarding techniques, complications, and adverse reactions before selecting a mesh.

How is PROLENE™ Mesh used?

PROLENE™ POLYPROPYLENE Mesh can only be implanted surgically, by a qualified surgeon. The PROLENE™ Mesh is present for life unless it is removed.

Removal of the mesh would require surgery. If it needs to be removed, significant dissection may be needed

When must PROLENE™ Mesh not be used?

PROLENE™ Mesh should:

- not be placed intraperitoneally.

Warnings

PROLENE™ Mesh should be used with caution under the following conditions:

- 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.
- This device is indicated for abdominal wall hernia repair and not for gynecologic procedures or pelvic organ prolapse repairs. Gynecologic procedures and pelvic organ prolapse repairs should be performed using devices that are indicated for gynecologic repairs these procedures.
- It is recommended that the device not be used in a contaminated field, because contamination of the device may lead to infection that may require removal of the device.
- As with any implant, an acute and permanent foreign body response will occur. In some patients, this response can result in one or more of the adverse reactions listed below.
- This device is a permanent implant that is designed to integrate into the tissue. In cases in which the device needs to be removed, in part or in whole, significant dissection may be required
- Insufficient overlap on any side of the defect may increase the risk of postoperative complications, including recurrence
- Insufficient or improper fixation may increase the risk of postoperative complications, including recurrence.
- Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients.

If you are unsure whether PROLENE™ Mesh **should be used in your treatment, talk to your surgeon.**

What to do after PROLENE™ Mesh has been implanted?

Things you must do

Talk to your surgeon if you have unusual symptoms. There is always a risk of adverse reactions with any type of surgery. Some reactions could be due to your overall health condition. Some reactions could be related to just having the surgery. Some reactions could be related to the materials being placed into the body. It is difficult to know the source of some adverse reactions.

Contact your doctor about any signs of infection or adverse reactions. Be sure to keep up with your doctor visits after surgery.

The device will not cause any issues with a medical test called MRI. MRI means magnetic resonance imaging

Adverse effects

Potential adverse effects of PROLENE™ Mesh are those typically associated with surgically implanted materials. These include, but are not limited to:

- Infection
- Inflammation
- Seroma formation
- Acute or chronic pain
- Foreign body sensation
- Hematoma
- Nerve damage
- tissue injury
- Adhesion formation
- Fistula formation
- Extrusion / erosion
- Excessive contraction or shrinkage of the tissue surrounding the mesh
- Mesh failure / hernia recurrence
- 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 adverse reactions.

Contact your surgeon if you experience residual chronic pain, sudden pain, experience any symptoms listed in this leaflet, or notice any change that makes you feel unwell.

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of PROLENE™ Mesh, please talk with your surgeon or report the information to Johnson & Johnson Medical Product Safety Department on:

Email:
productsafetyjjmanz@its.jnj.com

Reports may also be made directly to the Therapeutic Goods Administration via the website:

www.tga.gov.au/reporting-problems