ULTRAPRO™ Mesh

Product Codes: UNF1, UML1, UMM1, UMM3, UMN, UMN3, UMP3, UMR3, UMS1, UMS3, UMT1

What is in this leaflet

This leaflet answers some common questions about ULTRAPRO™ 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 ULTRAPRO™ Mesh against the benefits that are expected. This leaflet does not contain all the available information about ULTRAPRO™ 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 ULTRAPRO™ Mesh?

ULTRAPRO™ is a sterile, single use surgical mesh used for the repair of abdominal wall hernias which require the addition of a reinforcing material to obtain the desired surgical result. A hernia is a weak spot or hole in the abdominal wall. The device is used when added support is needed.

ULTRAPRO™ Mesh is partially absorbable. It is comprised of:

- absorbable poliglecaprone 25 monofilament fiber (45%)
- nonabsorbable polypropylene monofilament fiber (55%), and
- Blue dye phthalocyanine blue, Color Index No. 74160) less than 0.09%). The polypropylene monofilament fibers are both undyed and dyed .

The absorbable parts of the mesh are gone after about 91 days. The non-absorbable parts remain in the body for the life of the patient. unless they are removed. The remaining polypropylene mesh stretches to a greater degree perpendicular to the blue stripes.

What is ULTRAPRO™ Mesh used for?

ULTRAPRO™ Mesh is indicated for the repair of abdominal wall hernias which 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 ULTRAPRO™ Mesh used?

ULTRAPRO™ Mesh can only be implanted surgically, by a qualified surgeon.

The unabsorbable parts of ULTRAPRO™ Mesh remain in the body for the life of the patient. unless they are removed.

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

When must ULTRAPRO™ Mesh not be used?

ULTRAPRO™ Mesh should:

- not be placed intraperitoneally.
- not be used in patients following planned intraoperative or accidental exposure to a contaminated field (such as opening of the gastrointestinal tract). Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.
- not be used for gynecologic procedures. Gynecologic procedures should be performed using products indicated for gynecologic repairs.

Warnings

ULTRAPRO™ 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. Gynecologic procedures should be performed using products indicated for gynecologic repairs.
- 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.

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

What to do after ULTRAPRO™ Mesh has been implanted?

Adverse effects

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.

Potential adverse effects of ULTRAPRO™ 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
- Soft 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.

These adverse effects might cause the following signs and symptoms:

- Fever
- Discharge from the wound
- Redness
- Swelling/Oedema
- Tenderness
- Pain

Other symptoms and adverse effects not listed here may occur in some patients.

These events are rare. Do not be alarmed by the possible adverse events. You may not experience any of them. As a part of your normal follow-up appointments, your surgeon will monitor your condition for any adverse effects.

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

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 ULTRAPRO™ 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