Patient Information Leaflet for ULTRAPRO™ Hernia System

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team'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 the future if needed.

The name and number of your mesh implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Product Codes: UHSM1, UHSL1, UHSOV1

Implant Description

ULTRAPRO™ Hernia System is used to repair hernias in the groin that need added support. The device is a sterile, single-use mesh device. It has a three-dimensional shape. The shape is designed to fit groin hernias. It has two patches connected by a cylinder. One patch goes over the top of the hernia opening and one goes under it. The patch that goes under the hernia is marked with a blue dye. The device repairs and reinforces the hole in the abdominal wall.

The mesh device is made of different types of fibers. Some fiber types are absorbed by the body. It takes about 84 days for those fibers to absorb. Other fiber types are not absorbed. These fibers remain in the body for the life of the patient. Both fiber types are materials that have been used in sutures. Some fibers are marked with a blue dye.

The names of the components are listed below. Maximum amounts of each component based on the largest size (Oval) of the device is shown in parentheses.

Component	Material (max amount)
Absorbable fibers	Poliglecaprone-25 (2.0 grams)
Non-absorbable fibers	Polypropylene (0.7 grams)
Blue dye	Phthalocyanine blue [Color Index No. 74160] (500 micrograms)

Information for Safe Use

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 where temporary wound or organ support is required.

There is always a chance 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.

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

Possible Adverse Reactions

Your doctor will provide information about the adverse reactions of your operation. All operations have adverse reactions. The risk of a serious adverse event is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns about your procedure.

Possible adverse reactions may include:

- Infection
- Inflammation (redness, swelling, pain and feeling of heat)/foreign body reaction, including granuloma (a mass of tissue), and seroma formation (a mass of clear fluid)
- Immune/ allergic reaction
- Sudden, short-lasting pain and long-lasting pain
- Foreign body sensation
- Hematoma (a mass of blood)
- Nerve damage
- Soft tissue injury
- Adhesion formation (scar tissue joining two surfaces)
- Fistula formation (an abnormal connection between organs)
- Extrusion (organ or product thrusting out of its preferred position)/Erosion (tissue injury progressing to tissue loss)
- Excessive contraction or shrinkage of the tissue surrounding the mesh
- Mesh failure/hernia reoccurrence

These adverse reactions may require additional operations or treatments (including mesh removal). This list does not include all adverse reactions. Your doctor can further explain the adverse reactions of your operation.

Additional operations or treatments may not resolve the adverse reactions and may pose a risk of additional adverse reactions.

Expected Implant Lifetime and Follow Up

The absorbable fibers in the mesh device are gone after about 84 days. The non-absorbable fibers are present for life.

In some cases, all or part of the device may need to be removed. The removal would be surgical and could require significant dissection.

Reporting Adverse Reactions

If you wish to report any adverse reactions you believe are a result of your implant, please speak with your doctor/medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com or the Therapeutic Goods Administration at https://www.tga.gov.au

For access to this leaflet, please visit: https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

Sponsor

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