Patient Information Leaflet for ULTRAPRO™ Plug

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: UPPL1, UPPM1, UPPS1

Implant Description

The ULTRAPRO™ Plug is a sterile, single use, mesh device. It is designed to fit groin hernias. A hernia is a weak spot or hole in the muscles of the abdominal wall. ULTRAPRO™ Plug is used to repair hernias that need added support. It is used in open surgery.

The mesh device is made of two different types of fibers. One type of fiber is absorbed by the body. The other is not absorbed and remains in the body for the life of the patient. Both fiber types are materials that are used in sutures. Some fibers are colored with dye.

The components, materials and percentages are listed below.

Component	Material	Percent
Absorbable fibers	Poliglecaprone-25	84%
Non-absorbable fibers	Polypropylene	16%
Blue dye	Phthalocyanine blue	<0.03%

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/or long-lasting pain
- Foreign body sensation
- Hematoma (a mass of blood)
- Nerve damage
- Soft tissue injury
- Adhesion formation (scar tissue joining two different 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 This list does not include all risks. Your doctor can further explain the risks of your operation.

Expected Implant Lifetime and Follow Up

The absorbable fibers in the mesh are gone after about 119 days. The non-absorbable fibers are present for life unless they are removed.

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

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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