

Patient Information Leaflet for PHYSIOMESH™ Open Flexible Composite Mesh Device

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: OPHY1010, OPHY1215, OPHY1520, OPHY1525, OPHY2030, OPHY2536

Implant Description

ETHICON PHYSIOMESH™ Open is a sterile, single use mesh device. It is used to repair hernias in the abdominal wall.

ETHICON PHYSIOMESH™ Open is made of three types of polymers. Two of the polymers are absorbed by the body. The other polymer is not absorbed and remains in the body for the life of the patient. The polymer types are materials that are used in sutures. Some polymers are colored with dye.

The components, materials and percentages are listed below.

Component	Material	Weight Percent
Absorbable	Polydioxanone	36%
Absorbable	Poliglecaprone-25	17%
Non-absorbable	Polypropylene	47%
Dye	D&C Violet No. 2	0.05%

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 risks may include:

- Sudden, short-lasting pain and/or long-lasting pain
- Adhesion formation (scar tissue joining two different surfaces)
- 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)
- Nerve damage
- Mesh failure/hernia reoccurrence
- Infection
- Soft tissue injury including extrusion (organ or product thrusting out of its preferred position), and erosion (tissue injury progressing to tissue loss)
- Fistula formation (an abnormal connection between organs)
- Hematoma (a mass of blood)
- Immune/ allergic reaction
- Excessive contraction or shrinkage of the tissue surrounding the mesh

These risks 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 parts of the mesh are gone after about 182 days. The polypropylene 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.

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 productsafetyjmanz@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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