PROCEED™ Surgical Mesh

Product Codes: PCDB1, PCDR1, PCDN1, PCDM1, PCDD1, PCDG1, PCDH1, PCDJ1, PCDT1, PCDW1, PCDL1

What is in this leaflet

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

PROCEED™ Surgical Mesh is a sterile, thin, flexible, mesh implant. It is comprised of an absorbable oxidised regenerated cellulose (ORC) fabric, and a non-absorbable polypropylene mesh that is surrounded by an absorbable polydioxanone polymer component.

After absorption of the absorbable components, the polypropylene mesh remains.

PROCEED™ Surgical Mesh is a long term implantable device. This device is MR Safe.

What is PROCEED™ Surgical Mesh used for?

PROCEED™ Surgical Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies 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.

How is PROCEED™ Surgical Mesh used?

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

When must PROCEED™ Surgical Mesh not be used?

There are no known contraindications to using PROCEED™ Surgical Mesh.

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

- Local or systemic infection
- Where there is the potential for growth or tissue expansion, such as for children or women who may become pregnant
- In the presence of uncontrolled and/or active bleeding during the surgical procedure

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

What to do after PROCEED™ Surgical Mesh has been implanted?

Adverse effects

Potential adverse effects of PROCEED™ Surgical 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

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.

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 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 PROCEED™ Surgical 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

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