

Patient Information Leaflet for *GYNECARE INTERCEED™*

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 implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Product Code	M4350
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Implant Description

The GYNECARE INTERCEED™ device is sterile and for single use. It is a knitted fabric that is off-white in color.

The GYNECARE INTERCEED™ device is used to help reduce adhesions. Adhesions are scar tissues that form inside your body (joining two different surfaces). They can happen after surgery. The fabric helps separate tissues during the healing process. This helps stop two different tissue surfaces from joining after surgery.

The GYNECARE INTERCEED™ device is a plant-based product made of cellulose. The cellulose is prepared safely to be used in surgery and made to be fully absorbed by the body.

Information for Safe Use

Postsurgical adhesions may still occur in the presence of this implant. Adhesions can develop following any surgery, whether an Adhesion Barrier is used or not.

The GYNECARE INTERCEED™ device is absorbable and does not have to be removed after surgery.

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 an MRI. MRI means magnetic resonance imaging.

Possible Adverse Reactions

Your doctor will provide information about the side effects of your operation. All operations have risks. The risk of a serious adverse event is low. Please talk to your doctor if you have specific concerns about your procedure.

Possible adverse reactions may include:

- Adhesions (scar tissue joining two different surfaces)
- Infection
- Tissue Reaction

TV-TEC-216400

Revision: 01

Date of Revision: Nov 2021

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- Pain

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

You must tell your doctor if

- You are planning to become pregnant

No adequate and well-controlled studies have been conducted in women who become pregnant within the first month after exposure to GYNECARE INTERCEED™ Absorbable Adhesion Barrier. Therefore, an avoidance of becoming pregnant should be considered during the first complete menstrual cycle after use of GYNECARE INTERCEED™ Absorbable Adhesion Barrier.

Expected Implant Lifetime and Follow Up

The GYNECARE INTERCEED™ device is absorbed by the body. It takes about four weeks. Actual absorption rate depends on where and how much is used.

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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