Patient Information Leaflet for SURGICEL™ Absorbable Haemostat

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.

SURGICEL™ Absorbable Haemostat

SURGICEL™ NU-KNIT Absorbable Haemostat

SURGICEL™ FIBRILLAR Absorbable Haemostat

SURGICEL SNoW™ Absorbable Haemostat

SURGICEL™ Powder Absorbable Haemostatic Powder

Implant Description

The SURGICEL™ device is sterile and single use. It can be made into many formats. Formats include a knitted fabric, loose fibers or a powder form.

The SURGICEL™ device is used to help control bleeding from different types of blood vessels.

The SURGICEL™ device is made from a plant-based product made of cellulose. It is made to be used safely in surgery. It is processed in a way that makes it absorbable in the body. Actual absorption time depends on where and how much is used.

Information for Safe Use

You should follow your doctor's advice both before and after surgery.

Postsurgical bleeding may still occur after surgery. Bleeding can develop following any surgery, whether a haemostat is used or not.

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:

- collection of fluid
- tissue reaction
- narrowing of tubular structures eg. vessel
- loss of movement
- loss of feeling
- damage to nerve
- loss of vision
- longer use of a drain
- difficulty urinating
- cannot urinate
- sense of burning
- stinging, sneezing
- Headache
- infection

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.

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 SURGICEL™ device is absorbed by the body over time. There is almost no tissue reaction. Absorption time depends on several things, including 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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