



SURGIMESH® XB

ABDOMINAL REINFORCEMENT
MATERIAL OR MESH

	Sterile Product. Sterilization by Ethylene Oxide.
	Sterile except if packaging is open or damaged.
	Use before year-month-day.
	Read carefully the indications and directions for use.
	Single use. Do not reuse.
	Batch number.
	Store the product at room temperature and away from direct light.
	Do not resterilize.
	Federal law restricts this device to sale by or on the order of a physician.

BG Medical
21805 W. Field Pkwy
Suite 160 Deer Park, IL 60010

Tel: 847-304-4069



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Description

The implant is composite single layer of non-woven, non-knitted reinforcement material from 100% polypropylene, strengthened by thermal bonding and an impregnated layer of silicone. They have a strong framework with shape memory and a structure that is perforated with a large pore size ensuring ease of use, tissue integration and drainage of the tissue site. The **SURGIMESH® XB** product line is divided into 2 sublines:

- The single layer **SURGIMESH® XB** non-woven, non-knitted polypropylene with impregnated silicone and
- The double layer **SURGIMESH® XB Skirted** with a non-woven, non-knitted polypropylene skirted part on the polypropylene of the single layer **SURGIMESH® XB** non-woven, non-knitted polypropylene with impregnated silicone.

Indications

The **SURGIMESH® XB** products range is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernia, abdominal wall repair and parietal reinforcement of the tissues. **SURGIMESH® XB** implants are used via an intraperitoneal approach, either by open surgery or by laparoscopy.

Contraindications

The device should not be used on:

- Children during their growth,
- Persons with infectious diseases,
- Persons with a tendency to drug abuse or alcohol abuse,
- Persons who are allergic to the polymers,
- Persons wishing to be pregnant at a future date.

SURGIMESH® implants are single use and their reuse or resterilization is prohibited.

Minimize any mesh or material overlap during implantation and do not place two layers of XB mesh over each other.

The main risks associated with this possible practice are:

- Infection,
- Removal of the prosthesis,
- Various complications related to a potential infection, death of the patient.

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Precautions

The product is supplied in a sterile double package. Check that the package is intact before using the product.

DO NOT USE THE PROSTHESIS IF THE PACKAGE IS OPEN OR DAMAGED.

The product must be handled and/or implanted by persons who are trained and qualified to do so and who have previously read the instructions.

The general precautions required in the treatment of hernias must be respected.

When handling the implants, avoid contact with sharp objects which could damage the implant.

We cannot accept responsibility concerning the accessories which are used during implantation and which are chosen by the individual practitioners.

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If you decide to fixate the mesh, pay attention to **the neighboring nerves and vessels** to prevent unnecessary damage. **You should preferably use a prosthesis that is large enough to prevent recurrence.**

Directions for use

Correct surface orientation is extremely important for the intended function. The silicone layer should be placed adjacent to those tissues where minimal tissue attachment is desired.

The bi-dimensional textile flap of the **SURGIMESH® XB Skirted** product can help the placement and the fixation of the mesh when used in an open approach.

The fixation device should be determined by the surgeon. Non absorbable sutures are recommended. Strict aseptic techniques should be followed.



Possible Complications

Patients should avoid strenuous exercise and should not carry heavy loads following surgery.

Possible complications include:

- Seroma,
- Inflammation,
- Fistula formation,
- Extrusion,
- Neuralgia,
- Recurrence,
- Hematoma,
- Aggravation of an existing infection (treat infection aggressively, remove prosthesis if infection remains unresolved),
- Visceral adhesion,
- Allergic reactions to the components of the product.

Special storage conditions

The products must be stored at room temperature and away from direct light in a clean and dry room.