SURGIMESH®WN

ABDOMINAL REINFORCEMENT MATERIAL OR MESH

ASPIDE MÉDICAL

Description

The **SURGIMESH®WN** implant is a non-woven, non-knitted reinforcement material made from 100% polypropylene, strengthened by thermal bonding.

The **SURGIMESH®WN** implants are non absorbable and free from any derivative of animal or human origin.

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 site.

Indications

The **SURGIMESH®WN** products range is used for the treatment of parietal insufficiency **without contact with the viscera**, either by open surgery or by laparoscopy, for example inguinal hernias, femoral hernias, eventrations.

Contraindications

The device should not be used on:

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

The **SURGIMESH®WN** implants are single-use and their reuse or resterilization is prohibited.

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 any responsibility concerning the accessories which are used during implantation and which are chosen by the individual practitioners.

Caution: Federal law restricts this device to sale by or on the order of a physician.

If you decide to fix 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

For hernias, the mesh can be fixed to Cooper's ligament and/or to the anterior muscular plane or between the posterior muscular plane and the anterior aponeurotic muscular plane according to the surgeon's preference.

For incisional hernias, the fixation must be placed at least 1cm from the mesh edges and the peritonization of the meshes must be as complete as possible at the end of the intervention. For every indication, it is advisable that the mesh largely covers the hernia orifice edges.

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

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CE 0459	CE mark and identification number of the notified organization. The product meets the essential requirements of MDD 93/42/CEE amended by MDD 2007/47/EEC.
STERILE EO	Sterile product. Sterilization by Ethylene Oxide.
	Sterile except if packaging is open or damaged.
	Use before year-month (end of month).
	Read carefully the indications and directions for use.
	Single use. Do not reuse.
LOT	Batch number.
	Store the product at room temperature and away from direct light.
	Do not resterilize.
Rx only	Federal law restricts this device to sale by or on the order of a physician.

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