

INSTRUCTIONS FOR USE

POLYPROPYLENE MONOFILAMENT MESH FOR SURGICAL USE.

Read all instructions carefully. Failure to observe the following instructions may lead to incorrect use of the device and/or injuries to the patient. These instructions are general instructions for the use of polypropylene monofilament, non-absorbable meshes for the surgical repair of hernias and treatment of abdominal wall defects and are not to be considered a complete reference for the surgical technique to be adopted for the treatment of hernias and abdominal wall defects. The device is for the exclusive use of surgeons who have received suitable training for the treatment of abdominal wall defects. The procedure may vary depending on the adopted technique and the anatomical characteristics of the patient.

PATIENT FACTORS

The surgeon must use their own experience and good surgical practices to determine whether the polypropylene monofilament, non-absorbable mesh device for the surgical repair of hernias and abdominal wall defects is suitable for use in certain patients. Specific factors concerning patients may compromise healing of the wound with an increased possibility of adverse reactions.

Surgical risks not directly associated with use of the product, its functionality or method of implantation must be understood and evaluated by a qualified surgeon familiar with the anatomy, medical treatments and procedures for the proper treatment of the specific conditions that may be treated using this product. The doctor must provide the patient with accurate and detailed information regarding the possible risks and complications that may arise from the implantation and the adopted surgical procedure.

During the post-operative phase, the surgeon must advise the patient of actions that should be avoided and the possible precautions that should be taken during normal daily activities.

The patient must contact the surgeon immediately in case of fever, reddening and/or swelling of the wound, bleeding and any other new symptom that appears following surgery.

DESCRIPTION

Polypropylene monofilament, non-absorbable meshes for the surgical repair of hernias and abdominal wall defects with extraperitoneal positioning of the mesh.

INDICATIONS

Mesh for the surgical repair of hernias and abdominal wall defects, to guarantee the indications for use, the device must be correctly oriented and positioned.

The prosthesis must never be positioned using an intraperitoneal approach in contact with the intestine or visceral structures.

Basic: mesh for the surgical repair of hernias and abdominal wall defects. To guarantee the indication for use, the device must be correctly positioned.

P3: pre-shaped mesh for the repair of primary and recurrent inguinal hernias. To guarantee the indication for use, the device must be correctly oriented and positioned.

T: three-dimensional plug without base for the repair of primary and recurrent inguinal and femoral hernias. To guarantee the indication for use, the device must be correctly oriented and positioned.

TP: flat plug for the repair of primary and recurrent inguinal and femoral hernias. To guarantee the indication for use, the device must be correctly oriented and positioned.

TB: three-dimensional plug with base for the repair of primary and recurrent inguinal and femoral hernias. To guarantee the indication for use, the device must be correctly oriented and positioned.

PROCEDURE FOR USE

The device is for the exclusive use of specialised medical personnel, trained in its use. The product is a non-absorbable implantable medical device and can only be used in operating theatres.

The dimensions of the mesh must be determined in accordance with good surgical practices and depending on the size of the hernial defect, any possible narrowing of the prosthesis, the condition and pathology of the host tissue.

The mesh must be affixed as per the procedures required for the fixing system and according to best surgical practice.

In the event the device needs to be removed, the surgeon must use good clinical and surgical practices and ensure the relevant procedures are followed in order to guarantee the patient's safety.

USE AND POSITIONING

To guarantee its functionality it is essential that the product be correctly oriented. The surface of the prosthesis in polypropylene mesh must never be positioned in contact with the intestine or visceral structures.

CONTRAINDICATIONS

The prosthesis must never be positioned in contact with the intestine or visceral structures, as this may cause serious adhesions.

Do not use the mesh in growing patients, in patients who are pregnant or who are planning a pregnancy.

Do not use on infected and contaminated tissues.

WARNINGS

- The device is for the exclusive use of specialised medical personnel, trained in its use;
- The device is supplied sterile. Check the packaging and make sure the product is intact before use;
- The doctor and his/her collaborators must visually inspect the packaged device to check that the sterile barrier has not been damaged;
- Do not use if the package is open or damaged, insofar as the product's sterility may have been compromised;
- Do not use the device after the expiry date;
- Disposable device, intended to be used once only, for one patient only, insofar as it cannot be re-sterilised and is non-reusable. Reprocessing may compromise the stability of the chemical-physical-mechanical and biological properties of the device;
- Guarantee correct orientation and positioning;

- Never place the mesh in contact with visceral structures to prevent the occurrence of serious complications;
- Complications relative to use of the mesh may include intestinal obstruction, adhesions, extrusion, migrations, the formation of fistulas, relapses, seromas, haematomas and inflammations, infections;
- In case of infection or migration, the prosthesis may need to be removed;
- The user must evaluate the correct size of the prosthesis in relation to the defect to prevent any relapses;
- Use of any mesh in a contaminated context may lead to the formation of fistulas and/or extrusion of the prosthesis.
- During the introduction and positioning of the device, manoeuvres must be carried out taking care not to damage the device;
- The patient must contact the surgeon immediately in case of fever, reddening and/or swelling of the wound, bleeding and any other new symptom that appears following surgery.

PRECAUTIONS

- Read all the instructions carefully before use;
 - Open the package in the operating theatre and in accordance with good practices;
 - Once the mesh package has been opened, it cannot be re-sterilised or reused;
 - The package must be stored in a clean, dry place far from sources of light and heat;
 - Handle the device using sterile gloves and atraumatic instrumentation;
 - Medical staff must act in accordance with good clinical practices and instruct the patient during the post-operative phase regarding actions to be avoided and precautions to be taken during normal daily activities, such as absolute rest for the first 24 - 48 hours after the surgery;
- After the surgery and for a minimum of 30 days, the patient must avoid lifting weights, strain and sports activities involving the abdominal wall. Normal activities may be resumed after a check-up and authorisation by the doctor that performed the surgery.

ADVERSE REACTIONS

Possible adverse reactions include blockages, adhesions, extrusion, migration, formation of fistulas, relapses, seromas, haematomas and inflammations, infections, relapse of the hernial pathology. Other known adverse reactions relative to surgical procedures include pain, bleeding, failure of the procedure;

As with all implantations, local inflammation may occur in the wound site and/or a foreign body reaction;

As with all foreign bodies, the polypropylene mesh may cause the clinical worsening of an existing infection; in these circumstances, it may be necessary to remove the device.

STERILISATION

All meshes are disposable and sterilised by ethylene oxide (ETO).
Do not use the device if the package is damaged.

TRACEABILITY

Identification labels are included in each package for product traceability, as provided for by legislation in force.

DISPOSAL

After use, eliminate the product and its relative packaging in compliance with hospital, administrative and/or local regulations in force

EXPIRY DATE

The product has a 5-year expiry date.

EXPECTED LIFE


















For functional use the implanted device has a long-term life.

PACKAGING

The commercial box constitutes a unit of sale; the product inside is not sold separately.
Any infusions in the packaging do not constitute mobile particulate matter.

THE PRODUCT IS LATEX-FREE, PHTHALATE-FREE, NON-PYROGENIC.

In case of disputes regarding interpretation and/or the deviation of content, the Italian text shall prevail.

	IT ISTRUZIONI PER L'USO	EN INSTRUCTIONS FOR USE	FR MODE D'EMPLOI	DE BEDIENUNGSANLEITUNG
	CONSERVARE IN LUOGO ASCIUTTO	STORE IN A DRY PLACE	CONSERVER DANS UN LIEU SEC	AN EINEM TROCKENEN ORT AUFBEWAHREN
	NON RIUTILIZZARE	DO NOT REUSE	NE PAS RÉUTILISER	NICHT WIEDERVERWENDEN
	DATA DI SCADENZA	EXPIRY DATE	DATE D'EXPIRATION	ABLAUFDATUM
	CODICE DEL LOTTO	BATCH CODE	CODE DU LOT	LOSNUMMER
	DATA DI PRODUZIONE	PRODUCTION DATE	DATE DE FABRICATION	HERSTELLUNGSDATUM
	FABBRICANTE	MANUFACTURER	FABRICANT	HERSTELLER
	PROTEGGERE DAI RAGGI SOLARI	KEEP AWAY FROM SUNLIGHT	PROTÉGER DES RAYONS DU SOLEIL	VOR SONNENLICHT SCHÜTZEN
	LATEX FREE	LATEX-FREE	SANS LATEX	LATEXFREI
	NON-PYROGENIC	NON-PYROGENIC	APYROGÉNIQUE	NICHT PYROGEN
	NON USARE SE LA CONFEZIONE È DANNEGGIATA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE EST ENDOMMAGÉ	WENN DIE VERPACKUNG BESCHÄDIGT IST, NICHT VERWENDEN
	ATTENZIONE	CAUTION	ATTENTION	ACHTUNG
	STERILIZZATO AD OSSIDO DI ETILENE	STERILISATION BY ETHYLENE OXIDE	STÉRILISÉ À L'OXYDE D'ÉTHYLÈNE	MIT ETHYLENOXID STERILISIERT
	CONSULTARE LE ISTRUZIONI PER L'USO	SEE INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI	KONSULTIEREN SIE DIE GEBRAUCHSANWEISUNG
	CODICE	CODE	CODE	CODE
	MARCATURA CE	CE MARKING	MARQUAGE CE	CE-KENNZEICHNUNG
	MADE IN ITALY	MADE IN ITALY	MADE IN ITALY	MADE IN ITALY
	NON RISTERILIZZARE	DO NOT RE-STERILISE	NE PAS RESTÉRILISER	KEIN ZWEITES MAL STERILISIEREN



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