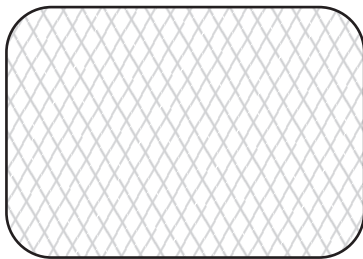


TiMESH®

Clarification regarding the Instructions for Use



GfE Medizintechnik GmbH
Höfener Strasse 45 D-90431 Nürnberg
Germany

Tel: (+49) (911) 93 15-601
 Fax: (+49) (911) 93 15-650

www.gfe-medical.de

Patented by US 6,057,031; further patents pending



MK-0000338_01

Federal law (USA) restricts this device to sale by or on the order of physician.

Description:

Prosthetic knitted fabric made from monofilament polypropylene fibres with all-round titaniferous coating. The mesh implants are available in various basis weights with defined shapes and dimensions.

Indications:

The TiMESH® is intended to be used for the reinforcement of tissue during surgical repair.

The TiMESH® is specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical and incisional hernias, including pre-peritoneal and intra-peritoneal; rectal, vaginal and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair.

TiMESH® is a prescriptive device and should only be used by a licensed physician.

Contraindications:

All the known usual contraindications and rules for soft tissue implants are valid for the use of TiMESH® tissue wall reinforcements.

These include, among others:

- Patients in the growth phase (the recognised ability of this reinforcement to extend can prove to be insufficient for the growth of children)
- Intervention in contaminated or inflamed locations
- With large hernias the suitability of TiMESH® extralight mesh implants must be checked and a corresponding overlap of the hernial orifice ensured.

The TiMESH® mesh implant is only intended for a single use and is not suitable for reuse.

The properties of the product can be change if resterilised.

Titaniferous coating:

Titanium is harmless in the body, has excellent biocompatibility and is used in medicine as the material of choice in many implants. All the physical properties, e.g. flexibility of the implant, are completely unaffected by the titaniferous coating (only a few atomic layers).

The extremely thin (only a few atomic layers) titaniferous coating cannot be recognised during an x-ray examination.

The titaniferous coating surrounds each individual thread of the mesh. The plastic is not exposed in the body. The titaniferous coating is not detached in the body (composite material), separation from the plastic only being possible through destruction of the plastic. After individual adaptation (cutting) of the TiMESH® implants, the cut edges of the individual threads are not coated. Non-coated cut edges of the TiMESH® can, however, be ignored in relation to the coating of the overall surface, as the size of their area is negligible.

Possible complications:

Complications which can occur during a reconstruction of the tissue walls with a wall reinforcement as a result of the foreign body reaction to plastics are greatly reduced by the titaniferous coating of TiMESH® implants. Although allergic reactions are significantly reduced, they cannot, however, be ruled out in principle (in particular with possible individual adaptation through cutting). We therefore recommend not damaging the titaniferous coating so as not to expose the plastic.

To guarantee the properties of the product, it must be ensured that sharp objects do not affect the mesh beyond the usual clinical application during the operation and that the titaniferous coating and plastic as carrier are not damaged.

Safety precautions:

- With incisional and abdominal wall hernias, the peritonealisation of the TiMESH® mesh implant at the end of the intervention should be as complete as possible.
- It is recommended to allow the hernia reinforcement to greatly overlap the edges of the hernial orifice.
- With a wide dissection and large tissue detachment, it is recommended to carefully check the haemostasis and avoid remaining cavities as far as possible, in order to facilitate the rapid integration of the hernia reinforcement.
- To counteract the inflammatory effect of foreign bodies, such as talcum, the implant should only be handled with unpowdered gloves.
- TiMESH® implants are supplied in sterile packaging. Carefully check whether the packaging is intact before use. On no account use the implant if the packaging is damaged, open or has been penetrated by moisture.
- The implant is sterile packed in a double package. The inner package should not be opened until the implant is used and then only handled with sterile gloves and sterile instruments.
- The TiMESH® implants are only sold to specialist surgeons. Implants are carried out entirely on the responsibility of the surgeon.
- Before using TiMESH® extralight hernia meshes, the physician should check the size of the hernial orifice and ensure a sufficient overlap.

Application for the inguinal hernia indication:

TiMESH® implants meet the demands of modern surgery and the current state of surgical mesh operation techniques, the foreign body reaction being clearly reduced as a result of the titaniferous layer in particular. They are used in both open (e.g. acc. to Lichtenstein etc.) and laparoscopic implantation (e.g. TAPP, TEP). Sufficient preparation, an adequate size of mesh and, if necessary, an anatomically suitable cutting to size must be ensured. To avoid a dislocation or distortion and to prevent the edges from rolling up, the mesh can be fixed with nonabsorbable threads or suitable clips in accordance with the respective operation technique, after placement free of tension, creases and cavities.

The excellent handling qualities of TiMESH® extralight hernia meshes ensures that rolling up or folding is not necessary before introduction into the trocar. The mesh is gripped in the middle with the forceps and introduced intracorporeally with a reduction sleeve. With the extralight version trocars with a small diameter (= 5 mm) can be used.

The mesh can be cut to size with scissors or a scalpel for individual requirements. Please observe our information on possible complications.

Application for the incisional hernia indication:

TiMESH® implants can be implanted either in the peritoneum, between the abdominal wall and the peritoneum, or before the deep muscle layer. TiMESH® can be placed pre-peritoneal and intra-peritoneal. Can be used as a whole or individually adapted (please observe our information on possible complications).

The fasteners should be sufficiently close to each other, so that no physical weak point occurs during the surgical repair or at the beginning of a possible recurrence. The fixation should be at least 1 cm (3/8") from the edge of the mesh. Clips or suture can be used for fastening to the surrounding tissue.

Storage:

Storage temperature should be kept below 25 °C / 80 °F, preferable in the original packaging protected from light.

Explanation of the symbols on the packaging:

LOT	Batch number		Use by
STERILE/EO	Sterilisation with ethylenoxide		Follow instructions
REF	Order number		Do not reuse