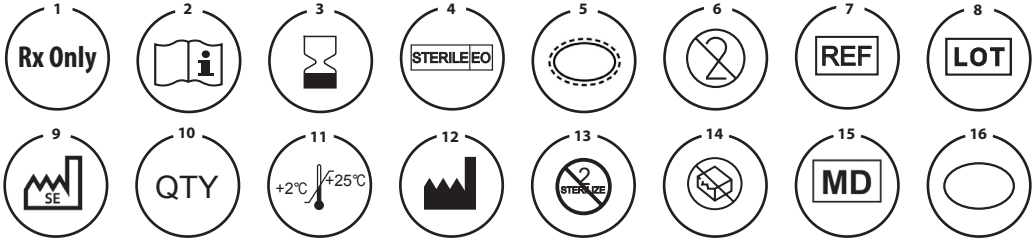
TIGR® Matrix Surgical Mesh

INSTRUCTIONS FOR USE

TIGR® matrix



EXPLANATION OF SYMBOLS

1. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Consult Instructions for Use.
3. Use before date.
4. Sterilized using ethylene oxide.
5. Single sterile barrier system with protective packaging outside. (Used on the aluminum pouch.)
6. For single use only.
7. Catalogue number.
8. Lot number.
9. Date and country of manufacture.
10. Quantity.
11. Storage conditions.
12. Manufacturer.
13. Do not resterilize.
14. Do not use if package is damaged.
15. Medical device.
16. Single sterile barrier. (Used on the Tyvek pouch.)

INSTRUCTIONS FOR USE - ENGLISH (EN)

DEVICE DESCRIPTION

TIGR® Matrix Surgical Mesh is a fully resorbable mesh knitted from two different synthetic fibers, possessing different degradation characteristics. The fast-resorbing fiber, making up approximately 40% of the matrix by weight, is a copolymer of glycolide, lactide, and trimethylene carbonate. The slow-resorbing fiber, making up approximately 60% of the matrix by weight, is a copolymer of lactide, and trimethylene carbonate. Both fibers degrade by bulk hydrolysis once implanted, resulting in a decreasing strength retention followed by mass loss of the fibers. In vitro testing show that the fast-resorbing fiber (glycolide, lactide, and trimethylene carbonate) loses its mechanical strength after 2 weeks and in vivo studies in the abdominal wall of sheep show that the fast-resorbing fiber is fully absorbed after 4 months. The same in vitro testing demonstrated that the slow-resorbing fiber (lactide, and trimethylene carbonate) maintains its mechanical strength for 6 months and in vivo studies in the abdominal wall of sheep indicated that the slow-resorbing fiber is absorbed after approximately 36 months.

INDICATIONS FOR USE

The TIGR® Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as for the repair of hernias or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result.

CONTRAINDICATIONS

TIGR® Matrix Surgical Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

WARNINGS

1. The safety and effectiveness of TIGR® Matrix Surgical Mesh has not been established for urogynecological use. Refer to safety communications from the FDA and from UK's National Institute for Health and Clinical Excellence (NICE) for guidance.
2. The safety and effectiveness of TIGR® Matrix Surgical Mesh in bridge repairs has not been evaluated or established.
3. TIGR® Matrix Surgical Mesh must not be put in direct contact with bowel or viscera.
4. The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh.
6. To prevent recurrences when repairing hernias, TIGR® Matrix Surgical Mesh must be large enough to provide sufficient overlap beyond the margins of the repair/primary closure. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.
7. The safety and effectiveness of TIGR® Matrix Surgical Mesh in the following applications has not been evaluated or established:

   a. Pregnant women
   b. Pediatric use
   c. Neural and Cardiovascular tissue

8. Product should be used once the exterior foil pouch has been opened. Do not store for later use.
9. Unused portions of the prosthesis should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh to prevent risk of transmission of viral and other infections.
10. This device is provided sterile and has been designed for single use only. Do not use after the expiration date – the biodegradable components may not perform adequately. Reuse, resterilization, reprocessing and/or repackaging of any portion of the TIGR® Matrix Surgical Mesh may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination

of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user.

11. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open or if the sterile barrier is not intact.
12. The safety and effectiveness of the TIGR® Matrix Surgical Mesh has not been evaluated or established with resorbable fixation devices, such as tissue adhesives, surgical glues, or other resorbable fixation devices, including sutures, tacks, and staples. Surgeons should select the method of fixation based on their professional clinical judgment and currently accepted surgical practices.

PRECAUTIONS

1. Please read all instructions prior to use.
2. Federal (USA) law restricts this device to sale by or on the order of a physician. Only physicians qualified in the appropriate surgical techniques should use this prothesis. Users should be familiar with strength and mesh size requirements. Improper selection, placement, positioning and fixation of the mesh can cause subsequent undesirable results.
3. Carefully check that the packaging is undamaged and unopened, and that the sterile barrier is intact before use.
4. The mesh should be large enough to extend beyond the margin of the defect.
5. Infections should be treated according to acceptable surgical practice to minimize the need for removal of the mesh.
6. The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity.

ADVERSE REACTIONS

Possible adverse reactions with the mesh are those typically associated with any implantable prosthesis, including, but not limited to, typical foreign body tissue response while mesh is being resorbed, seroma, adhesion, hematoma, pain, infection, inflammation, allergic reaction, hemorrhage, extrusion, erosion, adhesion, fistula formation and recurrence of the hernia or tissue defect.

PREPARATION FOR USE

1. Open the outer aluminum foil and remove the inner pouch containing the product. Be aware that the inner pouch is non-sterile on the outside.
2. Carefully open the inner pouch containing the mesh.
3. Aseptically remove the mesh from the inner pouch using sterile, or gloved hands or sterile forceps, and place the mesh in the sterile field.

DIRECTIONS FOR USE

1. Prepare the implantation site using standard surgical techniques.
2. Trim TIGR® Matrix Surgical Mesh so as to allow an adequate overlap of the defect area.
3. Implant TIGR® Matrix Surgical Mesh according to currently accepted surgical mesh procedures either open or laparoscopic.
4. Fixate TIGR® Matrix Surgical Mesh with sutures or staples according to currently accepted surgical practices.
5. Affix the traceability label in the patient's medical record.
6. Device may be used in dry state.

HOW SUPPLIED

TIGR® Matrix Surgical Mesh is available in sterile packages as a single flat mesh of varying widths and lengths.

STORAGE, PACKAGING AND DISPOSAL

1. Store at room temperature and avoid prolonged exposure to elevated temperatures.
2. Sterile in unopened and undamaged package with sterile barrier intact.
3. Dispose of contaminated units, components, and packaging materials in accordance with standard hospital procedures, universal precautions for biohazardous waste, and applicable local, state, and federal laws.

TRACEABILITY

A traceability label that identifies the type, size, expiration date and lot number of the device is attached to every package. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

If you experience a product failure, please contact Novus Scientific AB at +46 18 700 11 50 for instructions on returning the product.

DISCLAIMER OF WARRANTY

Although TIGR® Matrix Surgical Mesh (hereinafter referred to as "product") has been manufactured under carefully controlled conditions; Novus Scientific AB (hereinafter called Novus) has no control over the conditions under which the product is used. Novus, therefore, disclaims all warranties, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Novus shall not be liable to any person or entity for any medical expenses or any direct, indirect, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Novus to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law, including the Federal Drug, and Cosmetic Act. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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