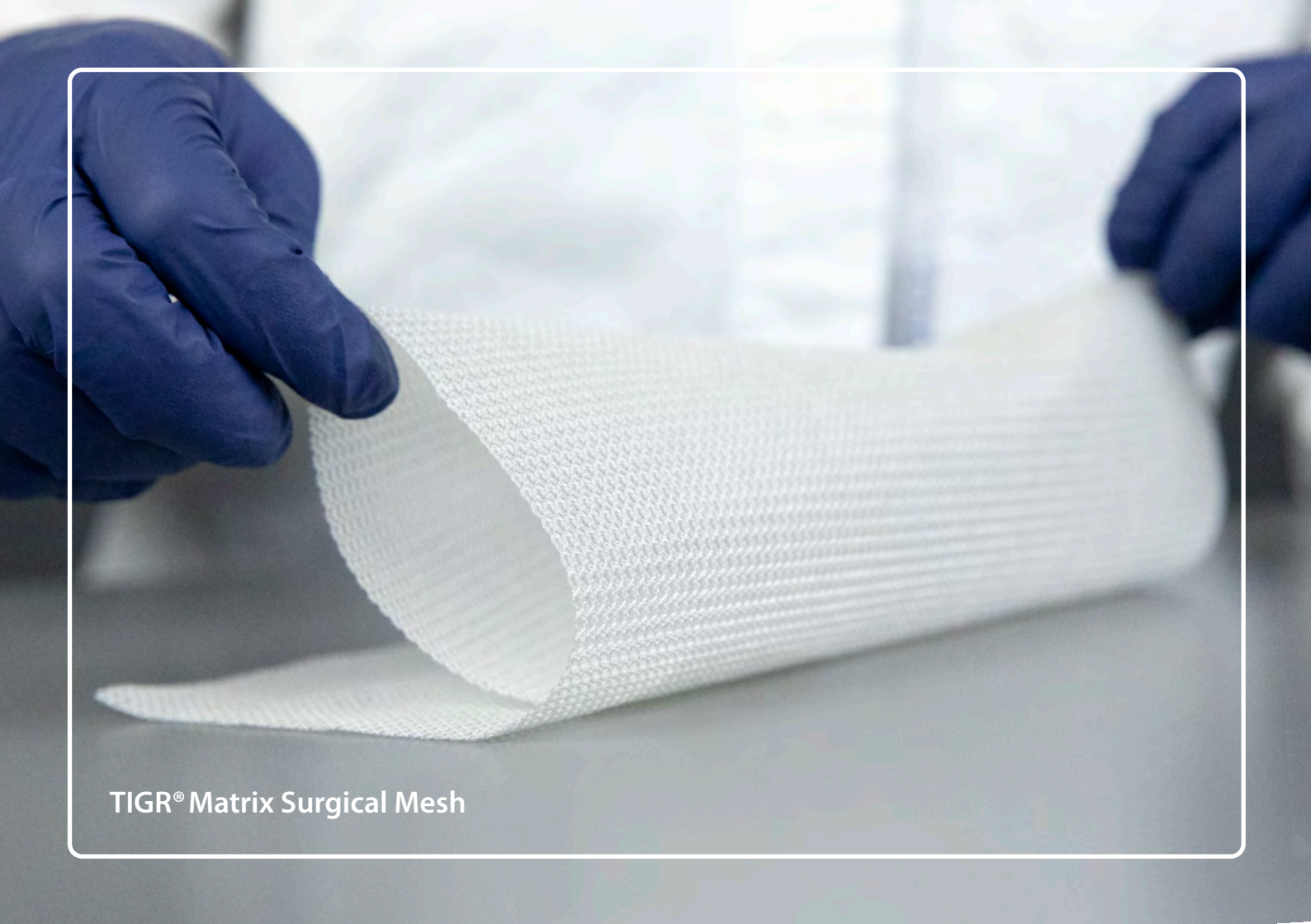
ABDOMINAL WALL REINFORCEMENT

TIGR® matrix

Improving Patient Care

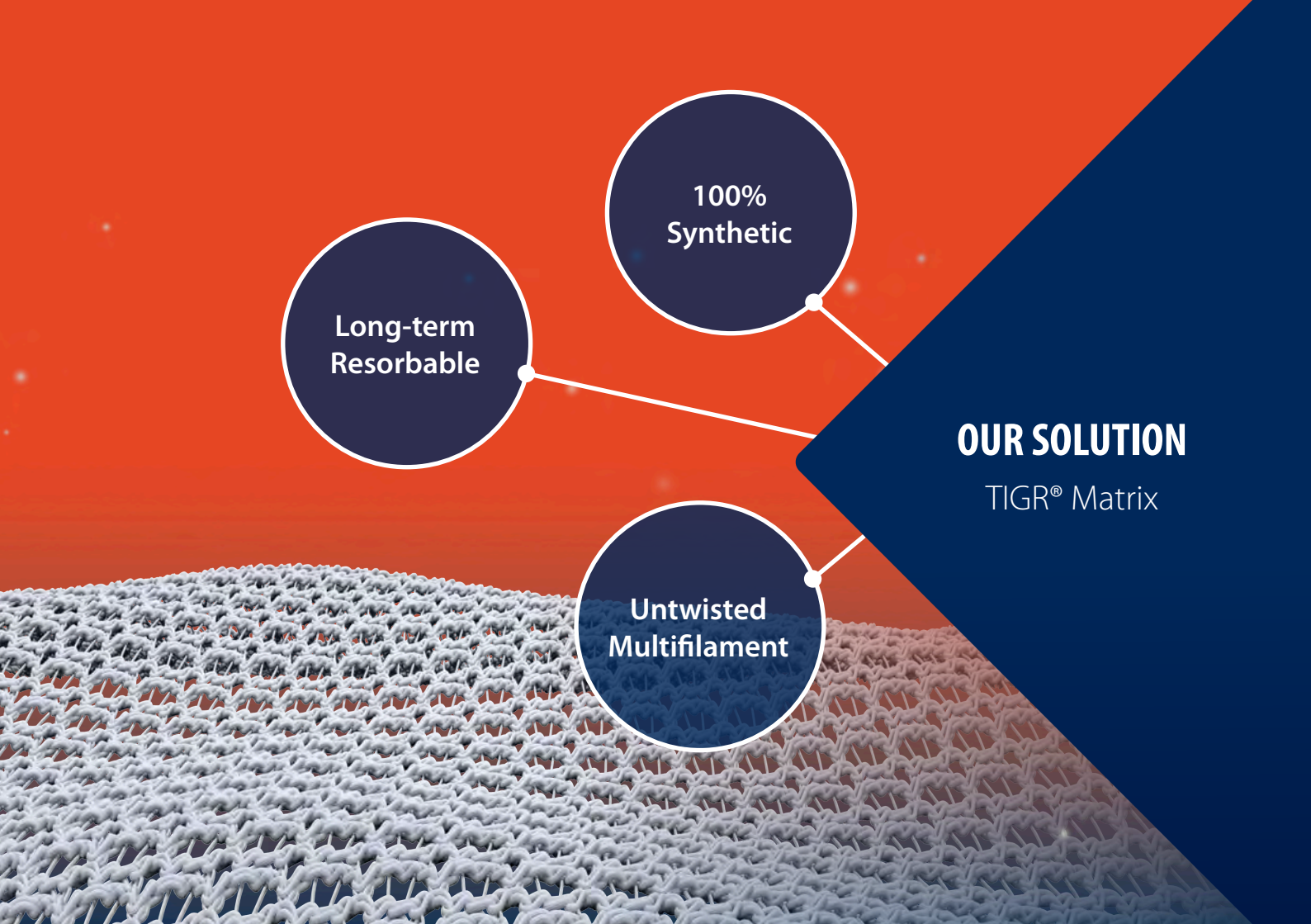
Novus Scientific®


TIGR® Matrix Surgical Mesh

STRONG WHEN YOU NEED IT
GONE WHEN YOU DON´T

Dynamic reconstruction with TIGR® Matrix
the world's first long-term resorbable surgical mesh

TIGR® matrix


100%
Synthetic
Long-term
Resorbable
OUR SOLUTION
TIGR® Matrix
Untwisted
Multifilament

The Design

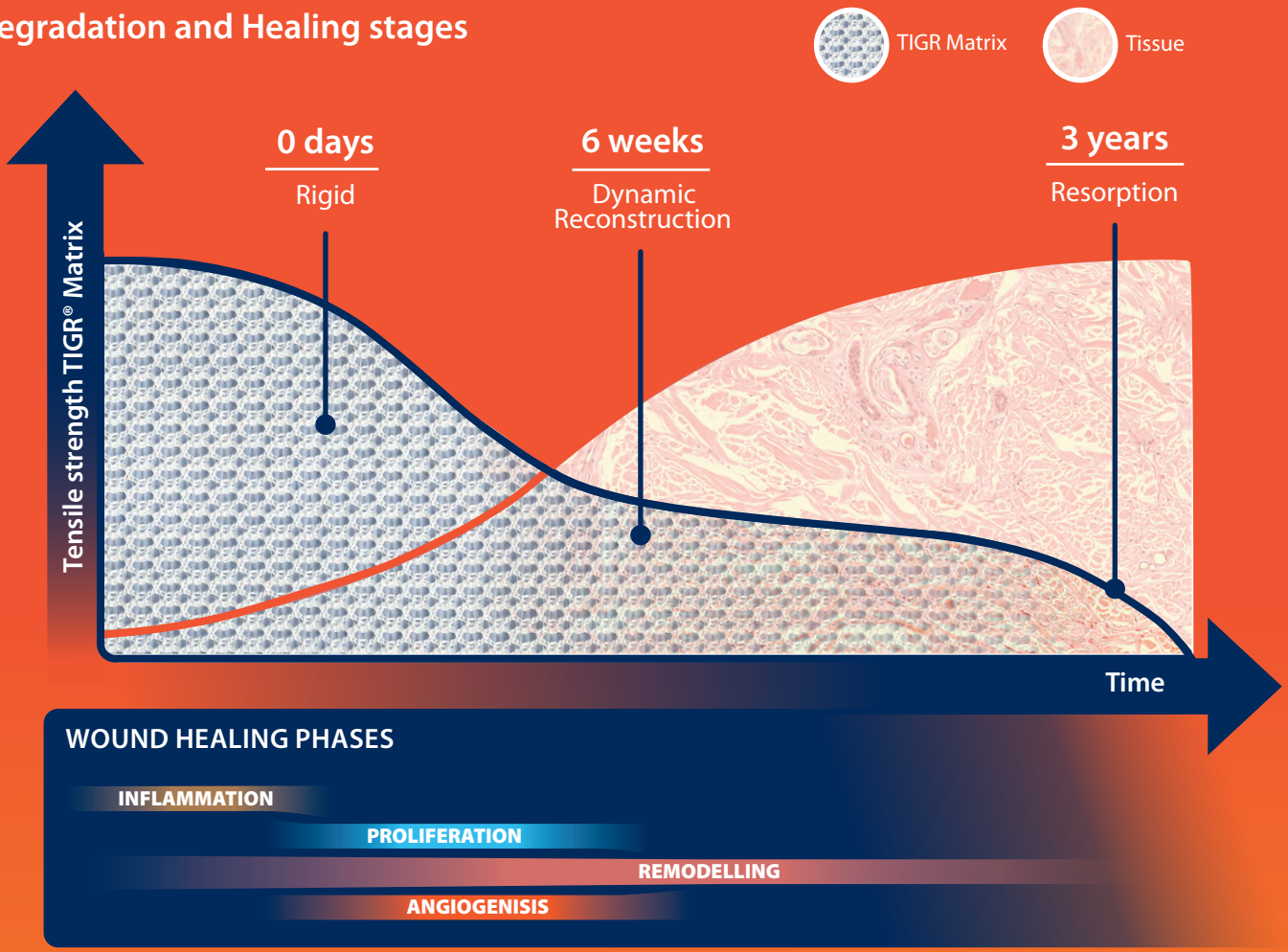
TIGR® Matrix Surgical Mesh is a resorbable surgical implant. It is made from two different synthetic polymer fibers that are knitted together to form a matrix.

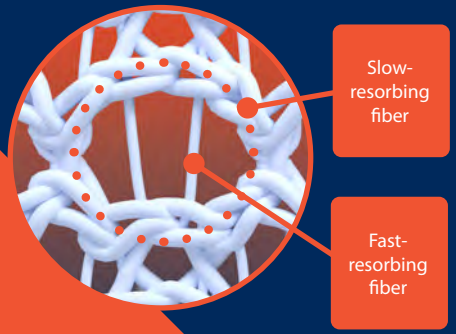
TIGR Matrix is characterized by long-term resorption and a dual stage degradation design that follows the natural wound healing and remodeling stages, this will allow the body to withstand the stresses after the matrix has been absorbed. The new connective tissue can then offer a long-term support.

The result is a surgical mesh that is easy to use for a variety of reconstructive surgery applications where a balance between mechanical support and degradation time is needed.

TIGR Matrix is made from materials that have been in clinical use since the 1970's and the product is supported by a growing body of peer-reviewed clinical evidence.

Degradation and Healing stages





THE MECHANISM

TIGR® Matrix

Dynamic Reconstruction

TIGR Matrix is designed with a multistage resorbable mechanism, defined by two fibers having different degradation characteristics.

The warp-knitted untwisted multifilaments give a unique structure which together with a macro-porosity design allows for good tissue integration. As the different fibers degrade, a gradual transfer of loads, from the mesh to the remodeling tissue occurs.

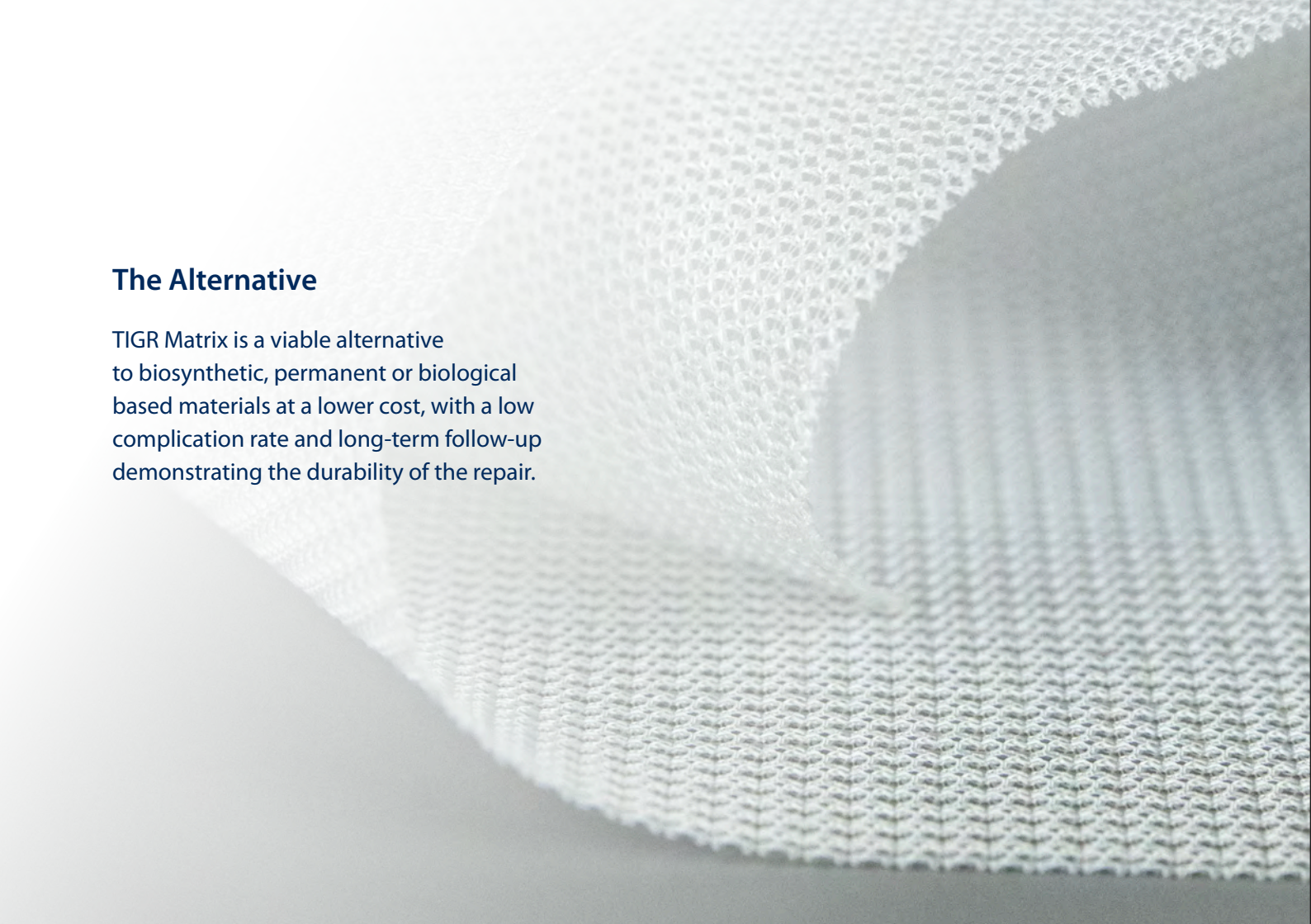
The result of this dynamic reconstruction is a more structured and hence stronger, connective tissue.

The fast-resorbing fiber, making up approximately 40% of the matrix by weight, is a copolymer of glycolide, lactide, and trimethylene carbonate. It loses its mechanical strength after 2 weeks and is fully absorbed after 4 months.

The slow-resorbing fiber, making up approximately 60% of the matrix by weight, is a copolymer of lactide and trimethylene carbonate. This fiber maintains its mechanical strength for 6 months and is absorbed after approximately 36 months.

The Alternative

TIGR Matrix is a viable alternative to biosynthetic, permanent or biological based materials at a lower cost, with a low complication rate and long-term follow-up demonstrating the durability of the repair.



TECHNICAL SPECIFICATION

TIGR® Matrix

Medical device	Yes
Manufactured by	Novus Scientific AB
Country of origin	Sweden
Ball burst strength, N	≥ 300
Certifying body's ID-number	2797 (BSI)
Macroporous Structure	Yes > 1mm
Device classification (EU)	CLASS III
Presence of latex	Latex free
Medical device supplied sterile	Yes
Shelf life	3 years
Chemical composition	Fast: PGA:PLLA:PTMC Slow: PLLA:PTMC
Storage	Room temp
Soaking	No
Method of sterilization	Ethylene oxide

The use of a novel synthetic resorbable scaffold (TIGR® Matrix) in a clinical quality improvement (CQI) effort for abdominal wall reconstruction (AWR)

Lewis, R., Forman, B., Preston, M., Heidel, E., Alvoid-Preston, B., Ramshaw, B. 2020

Inclusion:

91 patients with average BMI of 34. Recurrent hernia in 52 patients with average number of recurrences 3.4. Active wound infection in 21 patients (27%).

Results:

36 months follow-up time on all patients, average follow-up 42 months. Using TAR*) technique further decreases the recurrence rate (4.5%) and wound infection (4.5%).

Name	TIGR® Matrix	Phasix		Strattice
Month	36 months	18 months[1]	36 months[2]	24 months[3]
Seroma	3%	6%	6%	29%
Infection	10%/4.5%*)	9%	9%	38%
Recurrence	12%/4.5%*)	9%	15.7 %	28%

CLINICAL DATA

Using TIGR® Matrix

[1] Roth JS, et.al.; Surg Endosc. 32, 1929-1936, 2018
[2] Roth JS, et.al.; Presented at SAGES 2019 (Baltimore, MD), 2019
[3] Itani KMF, et.al.; Surgery 152, 498-505, 2012

Hernia prevention

After open abdomen

SCHAAF, S., ET.AL.; 2020

Material and Methods: Ten patients were prospectively enrolled, and prophylactic onlay mesh (long-term absorbable or non-absorbable) was implanted at the definitive fascial closure operation.

Results: OAT duration was 21.0 ± 12.6 days (95% CI: 16.9–25.1). Definitive fascial closure was achieved in all cases. No incisional hernias were present during a follow-up interval of 12.4 ± 10.8 months (range 1–30 months).

Conclusion: The prophylactic onlay mesh implantation of alloplastic, long-term absorbable, or non-absorbable meshes in OAT showed promising results and only a few complications that were of minor concern. Incisional hernias did not occur during follow-up. To validate the feasibility and safety of prophylactic onlay mesh implantation long-term data and large-scaled prospective trials are needed to give recommendations on prophylactic onlay mesh implantation after OAT.

In potentially contaminated setting

LYKKE, A., ET.AL.; 2017

Material and Methods: 2-year period, 109 patients undergoing emergency surgery with formation of ileostomy or colostomy. All patients received a retromuscular slowly resorbable synthetic mesh, TIGR Matrix at the stoma site. The reference group included 117 patient (receiving no mesh).

Results: Use of a resorbable synthetic mesh during emergency ostomy formation showed no significant preventive effect on formation of parastomal hernia after 1 year. Although surgery was often conducted in a severely contaminated field, the procedure was without significantly increased complication rate.

Conclusion: Use of a resorbable synthetic mesh during emergency ostomy formation showed no significant preventive effect on formation of parastomal hernia after 1 year. Although surgery was often conducted in a severely contaminated field, the procedure was without significantly increased complication rate.

In high risk patients

SÖDERBÄCK, H., ET.AL.; 2016

Method: Sixteen patients with three or more risk factors for wound dehiscence or incisional hernia were included. TIGR Matrix mesh, composed of a mixture of 40% copolymer fibers of polyglycolide, polylactide, and polytrimethylene carbonate, was placed on the aponeurosis with an overlap of five cm on either side and fixated with continuous monofilament polydioxanone suture.

Results: Mean follow-up was 9 months. One patient developed a seroma that needed drainage and antibiotic treatment. One patient had a wound infection that needed antibiotic treatment. There was no complication requiring a reoperation. No wound dehiscence or incisional hernia was seen.

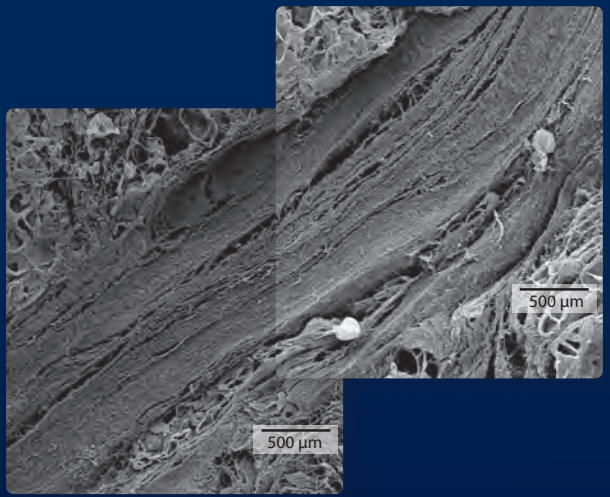
Conclusion: On-lay placement of TIGR Matrix is safe and may provide a feasible way of reinforcing the suture line in patients with high risk for postoperative wound dehiscence or incisional hernia. Larger samples are required, however, if one is to draw any conclusion regarding the safety and effectiveness of this technique.

Deposition of collagen

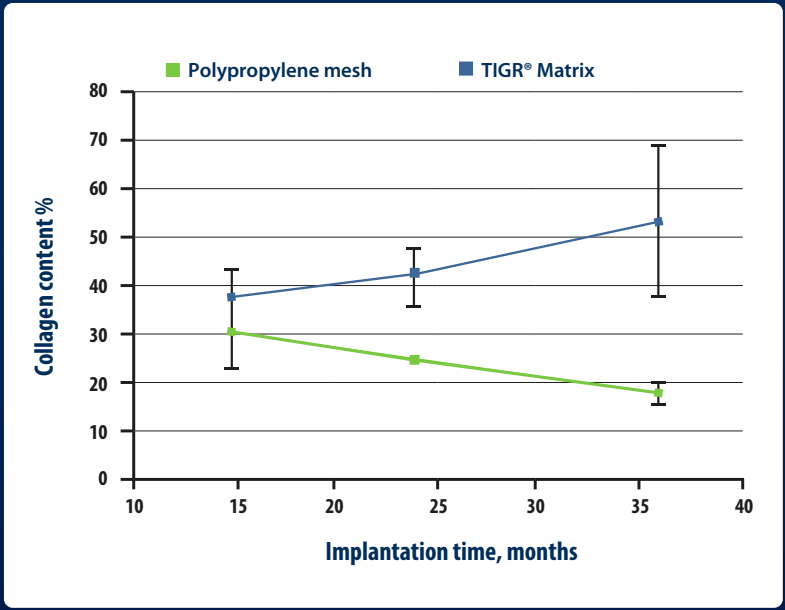
Three-year results from a preclinical implantation study of a long-term resorbable surgical mesh with time-dependent mechanical characteristics

Hjort, H., Mathisen, T., Alves, A., Clermont, G., Boutrand, J. P. Hernia. Apr;16(2):191-197, 2012

Deposition of new collagen is stimulated when cells integrate with the mesh during wound healing. Cells attach easily in and around the individual fibers gradually building type I collagen over time.



Thicker, healthy connective tissue.



REASONS TO USE

TIGR® Matrix

- 100% synthetic
- Non animal based
- Long-term resorbable
- Biocompatible
- Dual stage degradation
- Strong
- Multifilament
- Warp-knitted
- Untwisted fibers
- Macro-porosity design
- No preparation needed, no rinsing
- Pliable and easy to cut
- Low risk of recurrence
- Cost effective

Today TIGR® Matrix is a clinically proven medical device used by surgeons around the world, with long-term outcomes and experience demonstrating long-term durability

www.novusscientific.com

Developed & Produced In Sweden

Novus Scientific AB
Virdings Allé 2
SE-754 50 Uppsala, Sweden
Phone: +46 18 700 11 50
E-mail: info@novusscientific.com
www.novusscientific.com

TO ORDER

SIZE	REF. NO.
10 x 15 cm	NSTM1015E
15 x 20 cm	NSTM1520E
20 x 30 cm	NSTM2030E

CE 2797

Caution: Read instructions for use which accompany the product for indications, contraindications, warnings and precautions.
TIGR® Matrix Surgical Mesh received 510(k) clearance by the FDA in 2010, carries the CE-mark since 2011,
and is MDR approved under the new Medical Device Regulation EU 2017/745 (MDR) since 2021.