BREAST

TIGR® matrix

Improving Patient Care

Novus Scientific®

TIGR® Matrix IS DEVELOPED & PRODUCED IN SWEDEN

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STRONG WHEN YOU NEED IT
GONE WHEN YOU DON´T

The ideal matrix for Breast Reconstruction with implant

TIGR® matrix


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

The Design

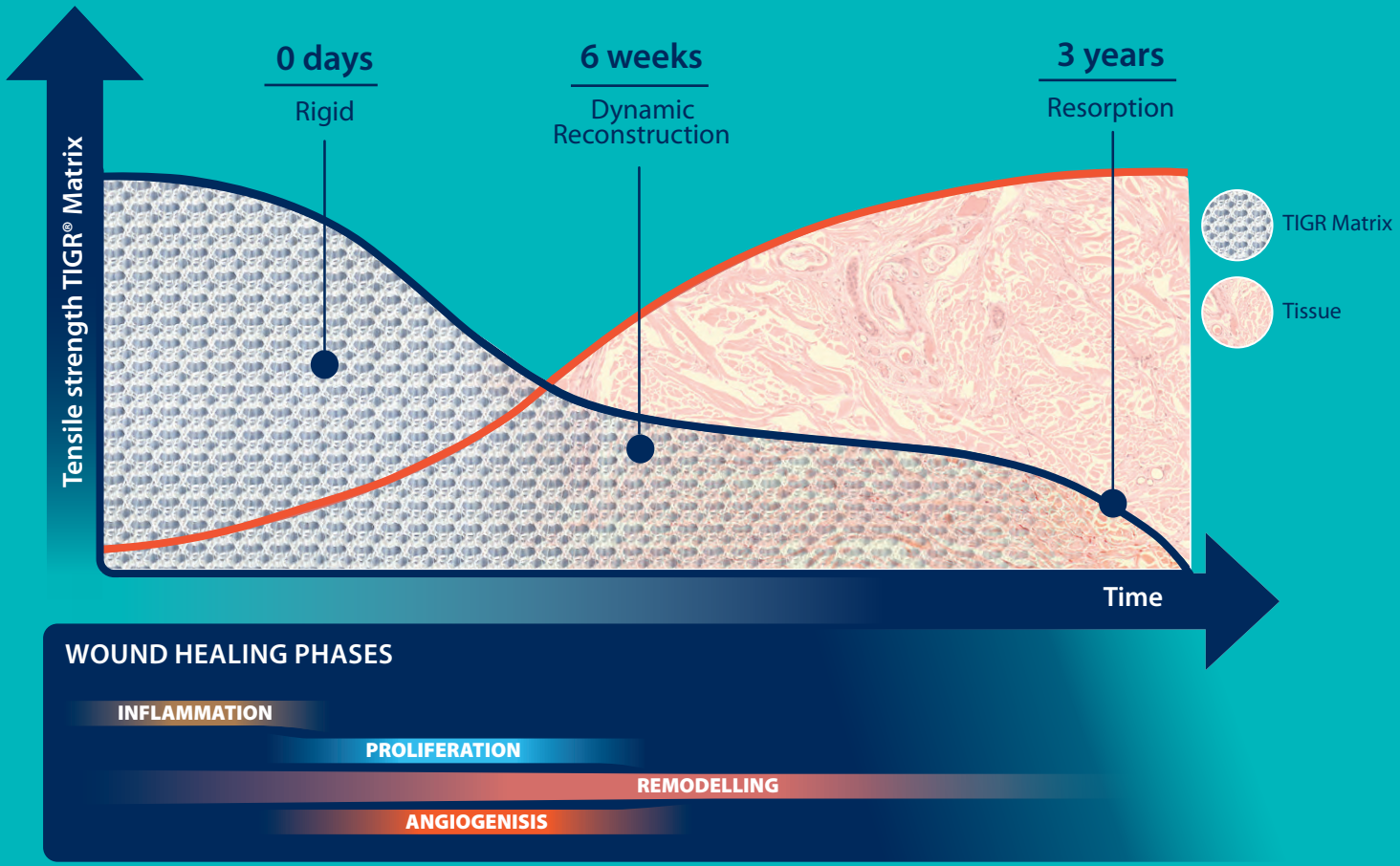
TIGR® Matrix Surgical Mesh is a resorbable surgical implant. It is made from two different synthetic polymer fibers that are knitted together to form a matrix.

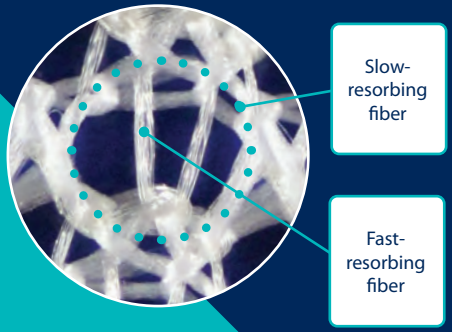
TIGR Matrix is characterized by long-term resorption and a dual stage degradation design that follows the natural wound healing and remodeling stages, this will allow the body to withstand the stresses after the matrix has been absorbed. The new connective tissue can then offer a long-term support.

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

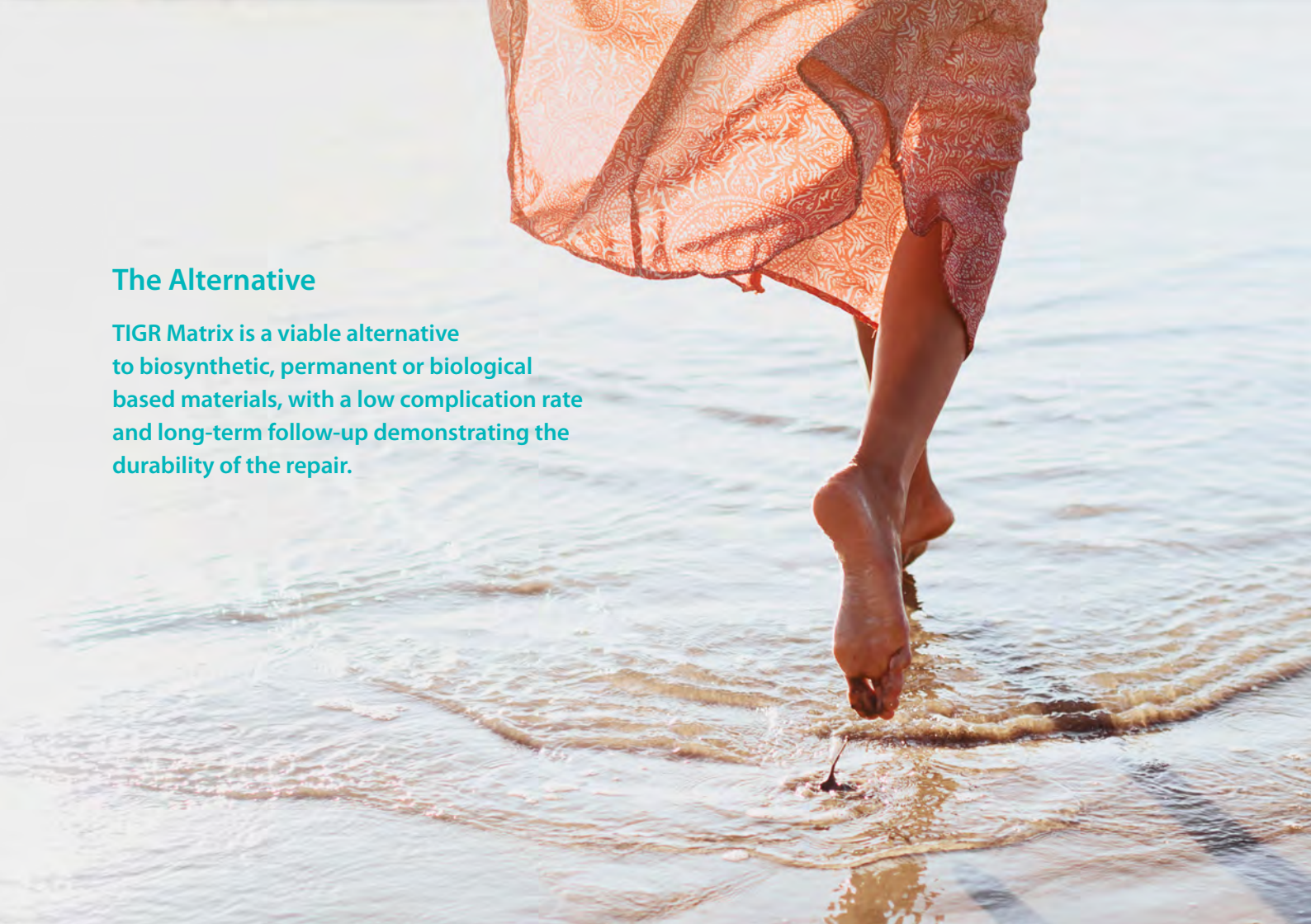
TIGR Matrix is designed with a multistage resorbable mechanism, defined by two fibers having different degradation characteristics.

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, 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/cm)	> 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

CLINICAL DATA USING TIGR® Matrix	Hallberg *49 patients*	Pompei *49 patients*	Sharma *105 patients*	Becker *62 patients*	Quinn* *121 patients*	Marthan** *195 patients*	
						145 sub-pec.	*78 pre-pec.*
Average follow-up	17 Months	12 Months	18 Months	16 Months	23,6 Months	32 Months	32 Months
Seroma	3.1%	3.3%	0%	1.8%	N/A	0.4%	3%
Hematoma	1.5%	6.7%	0%	N/A	1%	5%	4%
Infection	1.5%	1.7%	10.8%	3.6%	11%	7.6%	4%
Flap necrosis	1.5%	5.0%	0%	1.8%	2%	1.4%	2.6%
Implant loss	3.1%	N/A	6.7%	N/A	6%	10%	5%

CAPSULAR CONTRACTURE	Hallberg *49 patients*	Quinn* *121 patients*	Marthan** *195 patients*
No adjuvant radiotherapy	4.9%	6%	9% (154 breasts)
Adjuvant radiotherapy	N/A	N/A	51% (69 breasts)

CLINICAL DATA

Using TIGR® Matrix

TOTAL NUMBER OF PATIENTS 581

*In the skin-sparing mastectomy group

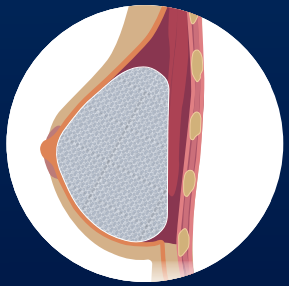
** No exclusion criteria, high risk cancer

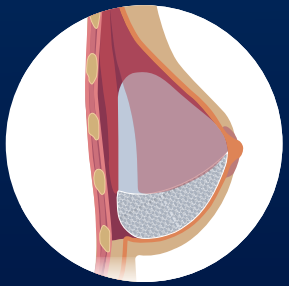
Please check www.novusscientific.com for the latest publications on TIGR Matrix.

TIGR® Matrix has been evaluated in clinical trials in more than 600 cases of breast reconstruction with an average follow-up time of at least 12 months in all studies. The material includes one-stage as well as two-stage procedures with submuscular or prepectoral placement of implant.

Prepectoral

- An implant is placed above the pectoralis major muscle and TIGR Matrix supports and stabilizes the implant in place while promoting tissue repair and long-term soft tissue support.
- Complete coverage or anterior coverage of the implant with TIGR Matrix is possible.
- The prepectoral procedure is a less invasive technique becoming more popular due to reduced post-operative pain and better quality of life for the patient.
- Immediate reconstruction after a mastectomy is possible, allowing the patient to recover faster, have a better body image as well as obtaining satisfying aesthetic outcome.





Submuscular

- Cutting the pectoralis major muscle at the low insertion and placing the breast implant under the muscle flap is the standard approach.
- Placing the implant behind the pectoralis major muscle may increase rates of acute and chronic post-operative pain due to muscle trauma and discomfort with any physical activity, a longer duration with drains, a higher rate of capsular contraction and implant displacement.
- Implant malposition and lack of tissue in the lower pole increases risks of implant exposure.
- To achieve coverage of the lower pole of the breast, TIGR Matrix is sutured to the inframammary fold and to the lower part of the pectoral muscle and laterally to the chest wall. Partial muscle coverage together with TIGR Matrix allows for better predictability.
- The introduction of TIGR Matrix long-term resorbable synthetic mesh offers a solution to many of the shortcomings associated with muscle coverage.

REASONS TO USE

TIGR® Matrix

- 100% synthetic
- 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
- 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

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 (2012) 16:191–197

The Use of Synthetic Mesh in Reconstruction, Revision, and Cosmetic Breast Surgery
Becker, H., Lind, J. G. Aesth Plast Surg (2013) 37:914–921

Immediate implant based breast reconstruction using the TIGR® Matrix
Schrenk, P. (2014). Breast Cancer Manag. 5(2), 53-59

De novo experience of resorbable woven mesh in immediate breast reconstruction post-mastectomy
Sharma, S., Van Barsel, S., Barry, M., Kell, R.M. (2016) Eur J. Plast Surg. 40(1):17-22

Bi-pedicle nipple-sparring mastectomy (modified Letterman technique) and TIGR® Matrix mesh-assisted immediate implant reconstruction, in a patient with Cowden syndrome
Todd, J. Gland Surg. 2016 Jun;5(3):306-11

The use of TIGR® Matrix in Breast Aesthetic and Reconstructive Surgery Is a Resorbable Synthetic Mesh a Viable Alternative to Acellular Dermal Matrices?
Pompei, S., Evangelidou, D., Arelli, F., Ferrante, G. (2018) Clin Plast Surg. 45(1):65

TIGR® Matrix surgical mesh – a two-year follow-up study and complication analysis in 65 immediate breast reconstructions
Hallberg, H., Lewin, R., Elander, A., Hansson, E. (2018)
J Plast Surg Hand Surg. 52(4):253

Comparison of inflammatory response and synovial metaplasia in immediate breast reconstruction with a synthetic and a biological mesh: a randomized controlled clinical trial
Hallberg, H., Hansson, E., Burian, P. (2019)

Reconstruction mammaire prothéthique immédiate avec matrice synthétique resorbable
Marthan, J. (2019) Thèse de doctorat, Université Paris Diderot,
Dr Jessica Marthan, Institut Gustave Roussy

Immediate implant reconstruction using absorbable TIGR® Matrix mesh after nipple-sparing mastectomy
Quinn, E.M., Barry,M., Kell,M.R.
European Journal of Plastic Surgery, 43, pages279–284(2020)

Prepectoral direct-to-implant breast reconstruction with complete ADM or synthetic mesh coverage – 36-Months follow-up in 200 reconstructed breasts
Reitsamera, R., Peintingerb, F., Klaassen-Federspiela, F., Andreas, S.

Drain secretion and seroma formation after immediate breast reconstruction with a biological and a synthetic mesh, respectively: A randomized controlled study
Hansson, E., Edvinsson, A-C., Elander, A., Kölby, L., Hallberg, H.
Breast J. 2020;26:1756–1759

First-year complications after immediate breast reconstruction with a biological and a synthetic mesh in the same patient: A randomized controlled study
Hansson, E., Edvinsson, A-C., Elander, A., Kölby, L., Hallberg, H.
J Surg Oncol. 2021;123:80–88


TIGR® matrix

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 and carries the CE-mark since 2011.