STRONG WHEN YOU NEED IT
GONE WHEN YOU DON´T

The ideal matrix for Breast Reconstruction with implant

TIGR® matrix
Long-term Resorbable

100% Synthetic

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

WOUND HEALING PHASES

INFLAMMATION

PROLIFERATION

REMODELLING

ANGIOGENESIS

INFLAMMATION

PROLIFERATION

ANGIOGENESIS

REMODELLING

Time

Tensile strength TIGR® Matrix

0 days
Rigid

6 weeks
Dynamic Reconstruction

3 years
Resorption

TIGR Matrix

Tissue
The 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

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical device</td>
<td>Yes</td>
</tr>
<tr>
<td>Manufactured by</td>
<td>Novus Scientific AB</td>
</tr>
<tr>
<td>Country of origin</td>
<td>Sweden</td>
</tr>
<tr>
<td>Ball burst strength, N</td>
<td>≥ 300</td>
</tr>
<tr>
<td>Certifying body’s ID-number</td>
<td>2797 (BSI)</td>
</tr>
<tr>
<td>Macroporous structure</td>
<td>Yes &gt; 1 mm</td>
</tr>
<tr>
<td>Device classification (EU)</td>
<td>CLASS III</td>
</tr>
<tr>
<td>Presence of latex</td>
<td>Latex free</td>
</tr>
<tr>
<td>Medical device supplied sterile</td>
<td>Yes</td>
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<tr>
<td>Shelf life</td>
<td>3 years</td>
</tr>
</tbody>
</table>
| Chemical composition                         | Fast: PGA:PLLA:PTMC  
Slow: PLLA:PTMC |
| Storage                                      | Room temp |
| Soaking                                      | No      |
| Method of sterilization                      | Ethylene oxide |
|----------------------------------|---------------------------|--------------------------|---------------------------|--------------------------|---------------------------|---------------------------|-------------------|------------------------|
| Average follow-up                | 17 Months                 | 12 Months                | 18 Months                 | 16 Months                | 23.6 Months               | 32 Months               | 12 Month          | 20 Month               |
| Seroma                           | 3.1%                      | 3.3%                     | 0%                        | 1.8%                     | N/A                       | 0.4%                     | 3%                | N/A                    | N/A***                 |
| Hematoma                         | 1.5%                      | 6.7%                     | 0%                        | N/A                      | 1%                        | 5%                       | 4%                | 3.7%                   | 7%                     | 1.7%                    |
| Infection                        | 1.5%                      | 1.7%                     | 10.8%                     | 3.6%                     | 11%                       | 7.6%                     | 4%                | 2.2%                   | 2%                     | 4.3%                    |
| Flap necrosis                    | 1.5%                      | 5.0%                     | 0%                        | 1.8%                     | 2%                        | 1.4%                     | 2.6%              | 0.5%                   | 2.5%                   | 3.3%                    |
| Implant loss                     | 3.1%                      | N/A                      | 6.7%                      | N/A                      | 6%                        | 10%                      | 5%                | 6.4%                   | 9.2%                   | 8.1%                    |

<table>
<thead>
<tr>
<th>CAPSULAR CONTRACTURE</th>
<th>Hallberg 49 patients</th>
<th>Quinn* 121 patients</th>
<th>Marthan** 195 patients</th>
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<tbody>
<tr>
<td>No adjuvant radiotherapy</td>
<td>4.9%</td>
<td>6%</td>
<td>9% (154 breasts)</td>
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<tr>
<td>Adjuvant radiotherapy</td>
<td>N/A</td>
<td>N/A</td>
<td>51% (69 breasts)</td>
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</table>

TOTAL NUMBER OF PATIENTS 1095
* In the skin-sparing mastectomy group
** No exclusion criteria, high risk cancer
*** The level of seroma was two times higher in the subpectoral group

Please check www.novusscientific.com for the latest publications on TIGR Matrix.
TIGR® Matrix has been evaluated in clinical trials in more than a thousand 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
- 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
- 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

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**TO ORDER**

<table>
<thead>
<tr>
<th>SIZE</th>
<th>REF. NO.</th>
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<tbody>
<tr>
<td>10 x 15 cm</td>
<td>NSTM1015E</td>
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<tr>
<td>15 x 20 cm</td>
<td>NSTM1520E</td>
</tr>
<tr>
<td>20 x 30 cm</td>
<td>NSTM2030E</td>
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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.