



NÄTIVE[®]

IMMEDIATE BIOAVAILABILITY

 **DECOMED**[®]
BIOLOGICAL IDENTITY

Multiple studies have demonstrated that post-operative complications following one-step implant-based breast reconstruction can depend on the duration and the intensity of the inflammatory response. The presence of the synthetic breast implant contributes to inflammation and triggers foreign body reaction. A biomaterial able to protect breast tissues and prevent this inflammatory response was needed, so to minimize complications risk and provide regenerative support to soft tissues. It seemed logical to us to investigate such biomaterial.¹⁻⁵

A breast-specific biological matrix is the solution to this biological problem.

INNOVATION

Immediate bioavailability

Biomaterials available for breast reconstruction are generally the same ones used in abdominal wall repair. Permanent biomaterials, such as polypropylene and cross-linked collagen matrices, possess the mechanical resistance necessary to support abdominal pressure. Resorbable plastics are slowly reabsorbed, and, in time, the mechanical support disappears with them. In addition, chemicals are often added to avoid mesh adherence to viscera.

Breast does not present the same mechanical need as the abdomen. In submuscular breast-reconstruction the biomaterial must sustain just the weight of the prosthesis and avoid its contact with the subcutaneous tissue to reduce the risk of complications.

NATIVE® is the immediately bioavailable Acellular Dermal Matrix (ADM) made of natural collagen. Free from preservatives, chemicals, and cross-linking agents that amplify inflammation, NATIVE® mitigates foreign body reaction and is recognised as self and promotes regeneration through integrating into the tissue. Its thickness of only 0.6 mm allows this process to happen in the physiological time of collagen turnover.

NATIVE® is the biological matrix specifically designed to satisfy the biological, mechanical, and aesthetic needs of subpectoral breast reconstruction.



SAFETY

Primum non nocere

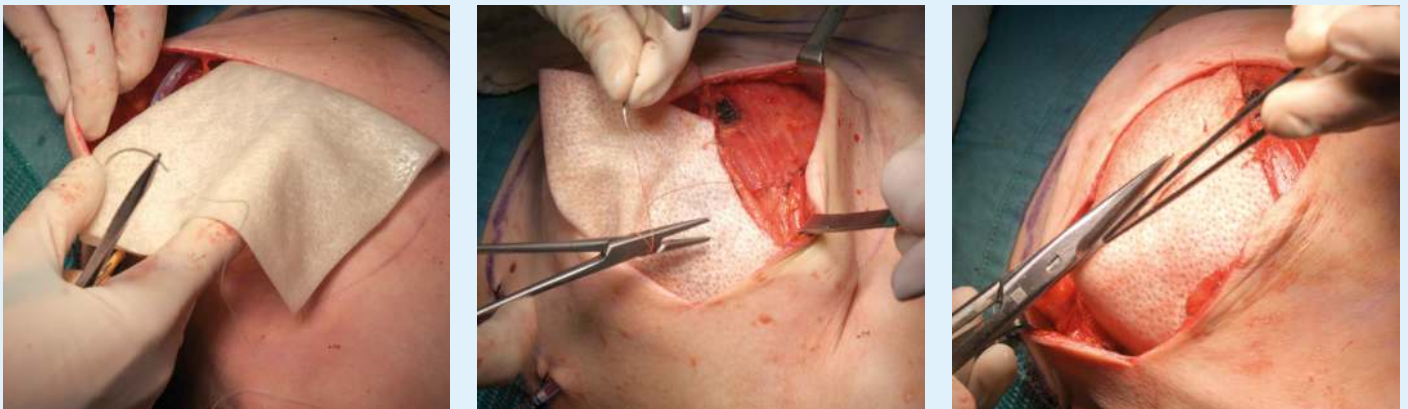
Quality controls make the difference between random and predictable performance. Compliance with international standards (CE Mark and ISO Standards) throughout the production process is the guideline for providing patients a safe biomaterial.

We know how much patients' expectations and safety mean to surgeons. NATIVE® was not borrowed from general surgery; instead, it was created specifically for the breast. The explicit indication in the instructions for use safeguards the safety of the patient and the operator.

EFFICACY

Mechanical support and soft capsule

As bioactive material, NATIVE® is involved in the physiological tissue healing process sustaining its completion without scar tissue formation. Host fibroblasts migrate into the microscopic 3D natural architecture of the matrix and repopulate it, while new vessels form. When this integration process is completed, NATIVE® has become a soft self-tissue. The implant is therefore sustained by a soft and naturally elastic capsule.⁶⁻⁹



In selected patients, one-step breast reconstruction can bring important benefits in multiple ways. The procedure is quick and reduces operative times together with costs. Moreover, most importantly, recovery is faster, and the patient has her physical integrity restored in just one operation. All of this results in an improvement of the Healthcare System. The advent of ADMs has greatly contributed to this method by substantially improving reconstructive outcomes, aesthetic results, and hence patients' quality of life.¹⁰

BIOMATERIALS

NATURAL

E.g.: Natural acellular matrices. They are recognised by the body as part of itself to be remodelled.

They are perfect homes for the cellular actors of regeneration.⁵

Physiological integration

They are integrated into the surrounding tissue and progressively remodelled following collagen physiological turnover. This prevents the silicone implant from causing the formation of a fibrous capsule.¹²

Tissue Regeneration

Once integrated, the biological matrix NATIVE® becomes a continuum with the surrounding tissues ensuring stability of the clinical and aesthetic results over time.⁶

SYNTHETIC

E.g.: Polypropylene, so-called bioplastics, silicone implants, crosslinked collagen matrices.

Passively tolerated by the body, they trigger foreign body reaction.¹¹

Slow or no reabsorption

Resorbable materials disappear over time leaving the tissue exposed to the implant, which will be encapsulated in a fibrotic collagen cage. Non-resorbable materials become part of the fibrous capsule.¹³

Fibrous capsule

These nets can cause erosions of surrounding tissues and eventually develop a fibrous capsule with contractile ability.¹⁴



EXTRACELLULAR MATRIX



In our bodies, our own cells create their own support network: the extracellular matrix (ECM). It is mainly composed of structural proteins (collagen and elastin) and is known to influence many cellular processes, including wound healing.

After injury, it releases signals that stimulate fibroblasts to deposit new ECM that will host the appropriate cells for complete healing and regeneration.

Hence, ECM provides signals for cells migration and differentiation.⁵

The main functions of the extracellular matrix are:

- Providing functional signals to target cells.
- Allowing cell migration.
- Influencing cell differentiation.
- Acting as scaffold for tissue healing and regeneration.

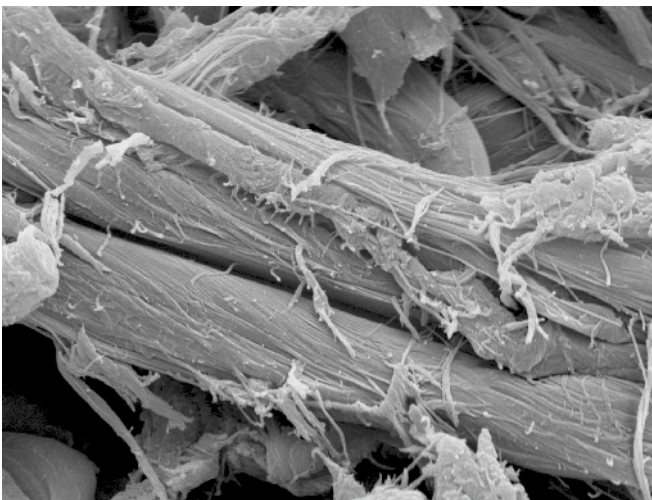
Acellular matrices retaining natural ECM characteristics are biomaterials which simplify fibroblasts task during the healing process as they are collagen scaffolds ready to be remodelled and inhabited by cells.

Xenogeneic acellular matrices are obtained processing tissues from animal sources.

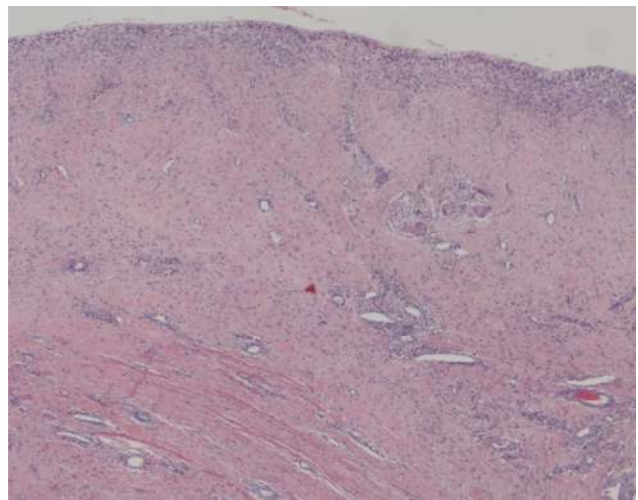
Through a deantigenation process all animal cells, which would cause immune reaction if implanted, are removed.

NATIVE[®] is derived from pig dermis, therefore it is an Acellular Dermal Matrix. NATIVE[®] has been designed to preserve the natural ECM structure so to be recognised as self-tissue and to house patients' cells.

The natural protein architecture gives NATIVE[®] immediate bioavailability.



The microscopic 3D natural architecture of NATIVE[®] ADM. (Scanning electron microscopy)



NATIVE[®] ADM integration at two months after implantation: neo-vascularisation and cell-infiltration can be seen. (Haematoxylin and eosin, 100x)

CHARACTERISTICS

- ADM from porcine dermis
- 0.6 mm thick
- Completely natural collagen, non-crosslinked matrix
- Free from inflammation-boosting chemicals and additives
- Freeze-dried for safer and longer preservation at room temperature
- Sterilized with ethylene oxide to preserve collagen fibres resistance

USE

After a quick hydration in sterile saline solution, NATIVE® becomes soft, pliable, and ready for implantation. It can be cut and shaped at the surgical site, and anchored to the inframammary fold and to the pectoralis major muscle for subpectoral pocket completion.

**We pledge ourselves to provide the best possible matrix.
Its proper use can only ensure that its regenerative potential is expressed.**

NATIVE® demands are limited:

- Presence of well-vascularized, viable tissue
- Intimate contact with surrounding tissues
- Mechanical stability

REFERENCES

NATIVE®, natural acellular dermal matrix

CODE	THICKNESS	WIDTH	HEIGHT
NT1506	0,6 mm	15 cm	8 cm
NT1806	0,6 mm	18 cm	10 cm
NT2206	0,6 mm	22 cm	12 cm



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