



**NÄTIVE<sup>®</sup>**

Immediate bioavailability

# Innovation

## Safety

## Cost-saving

Recent studies have demonstrated that early complications after one-step breast reconstruction depend on the breadth and length of the inflammatory response and that such response, in turn, is affected by the foreign body effect exercised by the implanted biomaterial. It seemed logical to us to gear research towards a biomaterial which promotes its incorporation in the shortest time possible in order to minimise the risk of early complications. Ultimately the faster a matrix integrates the better it is.

## Innovation

Immediate bioavailability

The biomaterials available for breast reconstruction are generally the same ones used in hernia repair.

Polypropylene, engineered silk, ADM including cross-linked, possess the mechanical resistance aimed at supporting endo-abdominal pressure and when it happens, they are reabsorbed slowly to prolong over time the shield effect on the muscle fascia. Instead, breast reconstruction requires a biomaterial that stimulates the incorporation process as quickly as possible in order to reduce the risk of early complications such as prolonged collection of seroma.

A new biomaterial was needed, with biological and mechanical characteristics suitable for aesthetic breast reconstruction.

Native® is ADM which is only 0.6 mm thick. It is free from processing residue and preservatives in order to provide immediate bioavailability. Native® is regularly transformed into self tissue mitigating inflammatory phase complications.

# NATIVE®



## Safety

Primum non nocere

Quality controls make the difference between random and predictable performance. Strict compliance with European standards (CE Mark and ISO Standards) for the production process are the guidelines for processing a safe biomaterial, but in our company, quality control is the strictest phase because we know just what a patient's expectations mean to a surgeon.

## Cost-saving

Commitment to a sustainable cost

The drug-economics parameters for management of economic resources are the milestones which influenced the business plan of Native®. The stringent quality control protocol represents an important cost for the Company, but it is also a guarantee of a long product life on the market. This is our aim: to create a new, safe ADM proposed at an advantageous cost for many years of work.

# Biomaterials

## Incorporation

### Extracellular matrix

One-step breast reconstruction, when indicated, has revealed important benefits both for the patient who recovers her physical integrity with just one operation, and for its significant cost savings. The advent of biomaterials has greatly contributed to this method by substantially improving aesthetic results.

#### Biomaterials

##### with regular reabsorption

E.g.: Natural ECM, natural ADM. They are recognised by the body as one of its own parts to remodel. They act as a target site for migration of cells tasked with regeneration.<sup>1</sup>

They are progressively incorporated into the surrounding tissue protecting the implant from capsule formation.<sup>2</sup>

##### with slow reabsorption

E.g.: Polypropylene, silk fibroin, cross-linked collagen matrices. Passively tolerated by the body, they provoke a stronger foreign body reaction.<sup>3</sup>

They promote cell decision towards encapsulation or delayed reabsorption.<sup>4</sup>

##### Tissue Continuum

Once integrated, Native® becomes a tissue continuum with the surrounding tissues ensuring stability of the aesthetic result over time.

##### Fibrous capsule aggregate

Before transforming into fibrous capsule aggregate these grafts, used to complete the sub-muscle pocket, can provoke erosion of the skin with a stronger inflammatory response.

# NATIVE®

The extracellular matrix structure is essential for the regenerative process since it acts as a target site for the integrins. These glycoproteins are present on the cell membrane. One of their most important functions is the role they play in cell migration towards compatible environments. They determine the cell decision on which biological action to undertake and mediate the relationships between the extracellular matrix and the cell itself.

The main functions of the extracellular matrix are:

- ⊗ Acceleration of cell migration.
- ⊗ Maintenance of differentiated phenotype.
- ⊗ Scaffold for regeneration.
- ⊗ Accumulation and presentation of growth factors to target cells.

The Native® porcine dermal matrix has been designed to reduce negative inflammatory phenomena to a minimum such as body temperature changes, skin flare or prolonged seroma collection.

Some small steps during patient selection may promote a decrease in post-op complications: a pinch test not less than 1 cm is synonymous with a good subcutaneous layer while a body mass index of less than 30 and absence of hypertension guarantees excellent skin perfusion indispensable for matrix remodelling. Women who have undergone previous radiotherapy and heavy smokers should be excluded from this procedure.





# Characteristics

## Histology

### References

## Characteristics

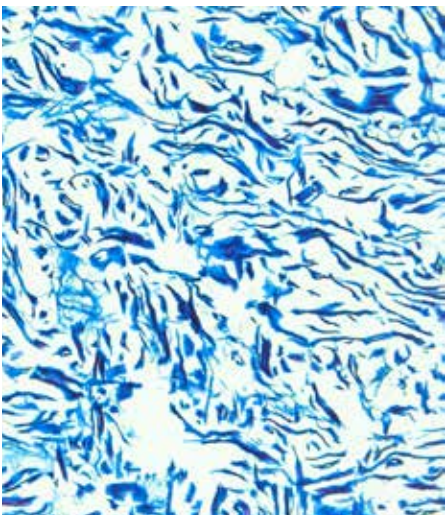
The Native® implant is composed of a porcine derived dermal matrix with a 0.6 mm thickness. The exclusive production process which Native® undergoes was developed in order to guarantee a completely natural product, not cross-linked, and without the presence of any chemicals which can amplify the inflammatory phenomenon and slow down the regular progression of tissue regeneration.

The native protein structure gives Native® immediate bioavailability.

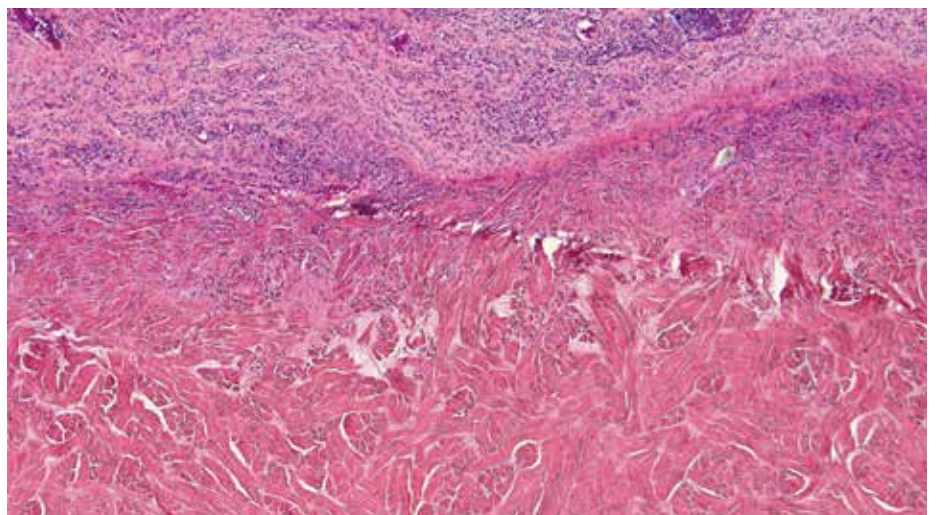
To guarantee the characteristics of Native® over time, the final phase of the production process includes freeze-drying to remove all liquids using exact pressure and temperature values.

This process makes the final product dry, excellent for correct storage at room temperature and which only requires simple rehydration before the implantation. The Native® membrane can be cut at the surgical site. Native®, not having metal powder added, reduces the risk of skin erosion to a minimum.

## Histology



Azan-Mallory. 5X magnification. Highlights the collagen fibres of the matrix. Observed absence of cellular material.



The histologic demonstrates the remodelling process performed by the Native® porcine dermal implant. In the upper part infiltration by the fibroblastic cells and rich neovascularisation can be observed.

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## References

Native®	Natural ADM	15cm x 8cm x 0,6mm	NT15-06
Native®	Natural ADM	18cm x 10cm x 0,6mm	NT18-06
Native®	Natural ADM	22cm x 12cm x 0,6mm	NT22-06

## Bibliography

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