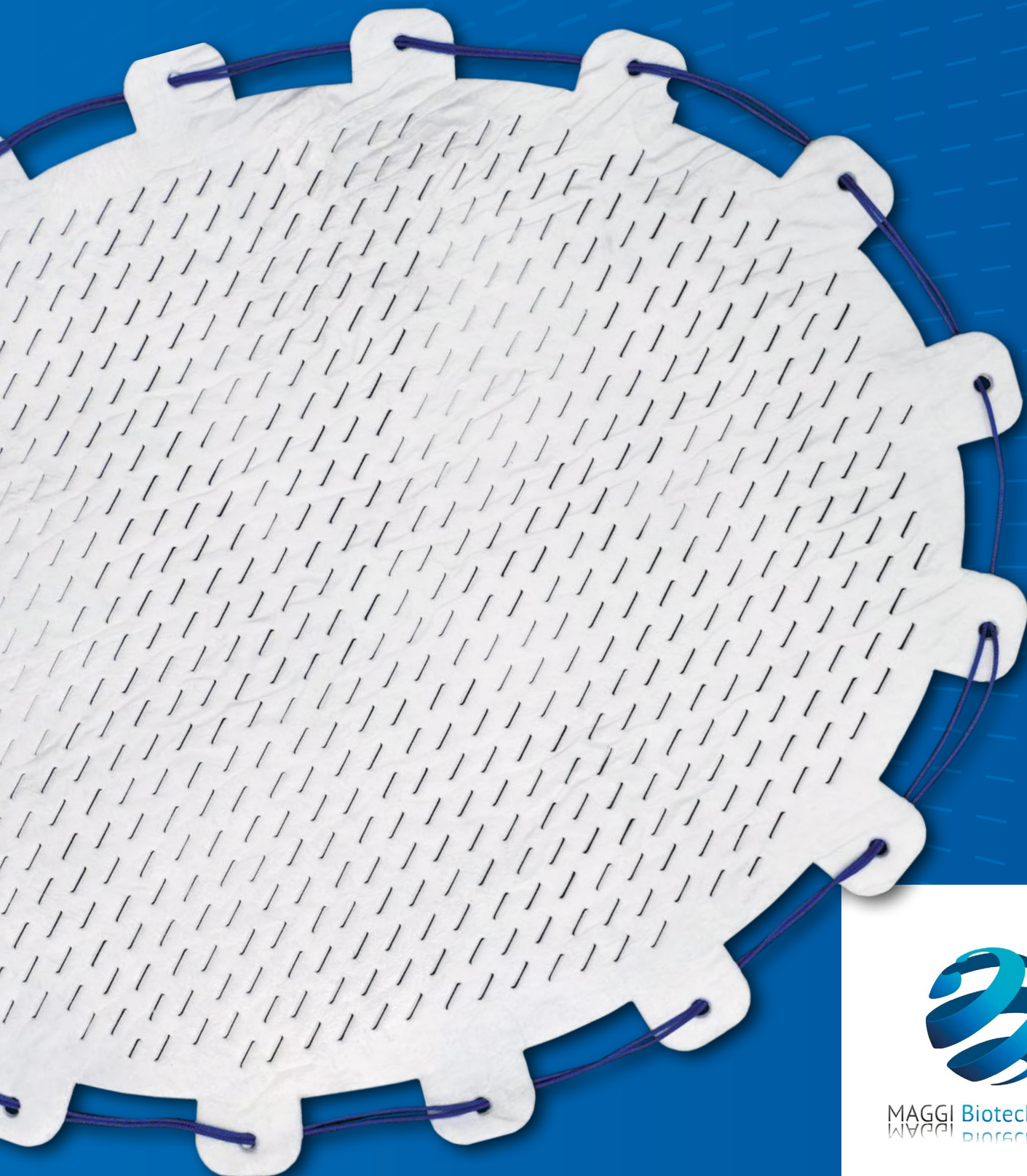


Exaflex

Membrane for tissue reconstruction
Bilayer bovine pericardium



MAGGI Biotechnology
BIORECONSTRUCTION

Exaflex

Bilayer bovine membrane for Breast Reconstruction

Exaflex is an innovative product for breast reconstruction. It is a bilayer, smooth, mesh or fenestrated collagen membrane made from selected bovine pericardium.

Developed in 2015 by Maggi Srl, Exaflex combines the mechanics of implant placement with the regenerative function of dermal tissue. The two-fold action allows correct implant positioning and promotes faster healing.

Strength

1 Exaflex is made with a proprietary process that maintains the particular natural properties of the pericardium.

together with cytokines and growth factors for immediate revitalisation and early neoangiogenesis.

Fast integration

2 It provides rapid integration times with intrinsic cell growth, minimal inflammation and negligible serum production.

4 The main purpose of the compact layer is to provide solid structural support. It is **rapidly repopulated by fibroblasts and VEGF***.

Minimal inflammatory response

3 It has a bilayer conformation with a highly porous fibrillar layer capable of accommodating the cells. The matrix components of the layers work

No accumulation of inflammatory or giant cells is noted after implantation.

* Vascular Endothelial Growth Factor (VEGF)

Material safety

Materials of bovine origin are considered at BSE risk and, for this reason, the EC certification procedure is different from that of other types of animal grafts.

The certification procedure requires the processes to be approved and validated by all the Institutes of Public Health of the European Union Member States to allow the free movement of the material.

The checks consist of the following steps:

- Analysis of the raw material origin and product traceability by a Notified Body.
- Annual inspection of the sampling station by the Notified Body.
- Check of the absence of cross-contamination during production.
- Check and validation by the Institutes of Public Health of the prion charge deactivation and inactivation processes.
- Quality system checks.
- Authorisation from all European Ministries of Health to issue CE certification.



EN ISO
13485:2016

Exaflex



Exaflex is a membrane made by processing pericardium from Italian cattle of under 20 months of age, carefully selected for their diet, breed and breeding environment. All stages of development are constantly monitored.

The proprietary manufacturing process is the other defining factor for the qualities of Exaflex.

Optimal tissue integration conditions after implantation are facilitated by a fractional freeze-drying process, which helps to maintain the natural structure of the collagen fibres.

The low probability of immunological reactions caused by Exaflex results from the use of Type I Collagen, which is essential throughout the manufacturing process.

*Non-collagenous components are removed during the procedure while retaining the active elements in the repair process, namely **Proteoglycans, Hyaluronic Acid, Fibronectin, Elastin** and, of course, **native Collagen**.*

*With these elements (that form a natural reservoir of bioactive factors), **Exaflex controls inflammation and improves cell proliferation and migration**.*

Consequently, integration is facilitated, even in cases of poor blood flow, because less biological mass is implanted (up to 50% less than dermal matrices), while high bio-mechanical performance is maintained.



Ready to use
Pre-assembled suture



It can be easily manipulated
after rehydration



Bilayer



Can be fixed by sutures



Deantigenated



Beta-ray sterilised



Suitable for storage at room
temperature for 5 years

Biological information

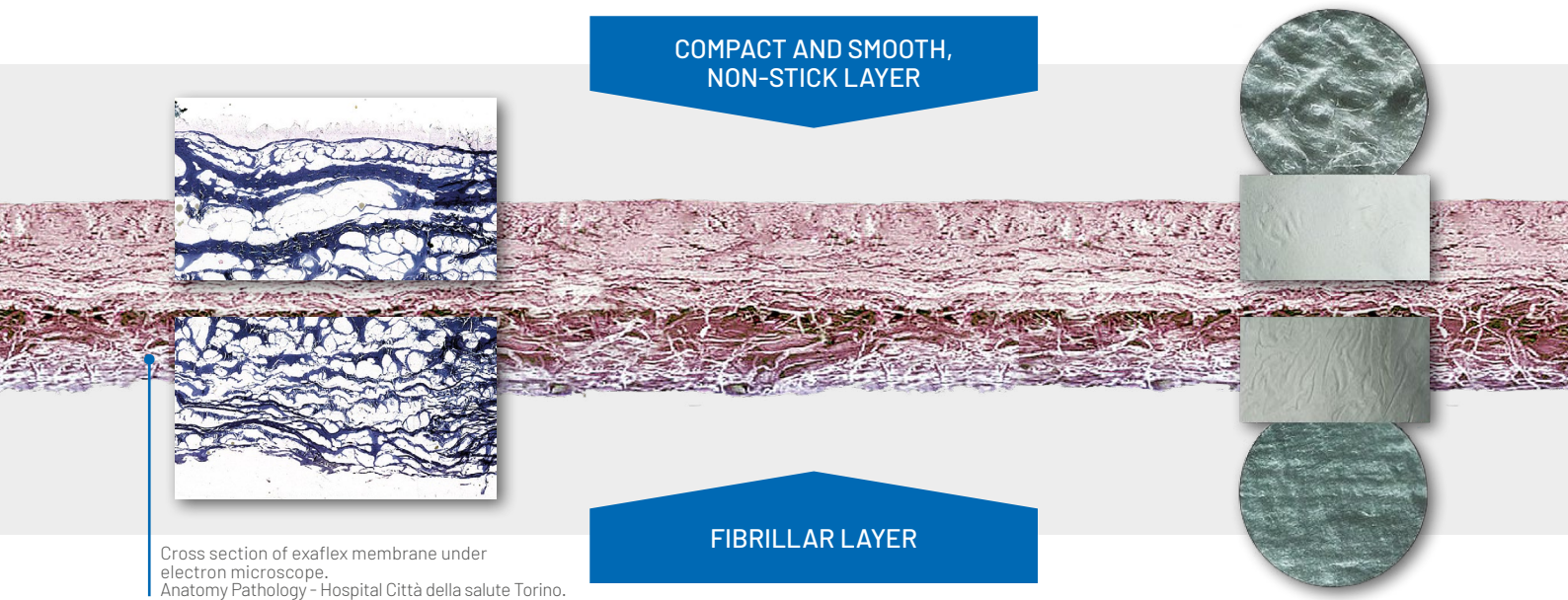
Bilayer: the double layer that makes the difference

Exaflex Bilayer bovine pericardium membrane is used in many medical areas in which the regeneration and repair of damaged tissue are required.

Exaflex consists of a double layer of multidirectional, cross-linked collagen fibre. One side is extremely compact, non-stick and very resistant to the passage of bacteria. The other fibrillar side provides an ideal environment for tissue revitalisation.

The bilayer membranes undergo revitalisation by the endogenous connective tissue in three stages (steps of incorporation and absorption of an ADM):

- 1 Fibrocytes migrate into the fibrillar layer and help anchor the membrane to the surrounding structures by forming a neomembrane surrounding the implant.
- 2 The fibrocytes migrated into the three-dimensional structure of the bilayer membrane adapt their metabolism to help maintain the existing collagen fibres without initially synthesising collagen.
- 3 The collagenase-induced degradation of the three-dimensional structure begins after a few months. The collagen is degraded and replaced by new fibrocytes. The neostructure is infiltrated and nourished by capillaries that grow easily in the three-dimensional matrix.



SURFACE TYPES



INTACT



FENESTRATED

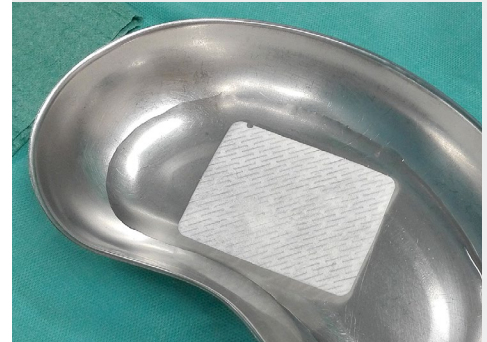


MESH

Exaflex applied to reconstructive plastic surgery

The Exaflex membrane is indicated for reconstructive and cosmetic plastic surgery, performed to reconstruct a biological interface between the implant (or breast expander) and the flap, to protect the latter.

Exaflex can be used in immediate or postponed reconstruction surgeries, with subpectoral or pre-pectoral implant sites. In particular, it is indicated for implantation over the pectoralis major muscle in breast surgery, for post-mastectomy breast reconstruction and cosmetic breast revision surgery.

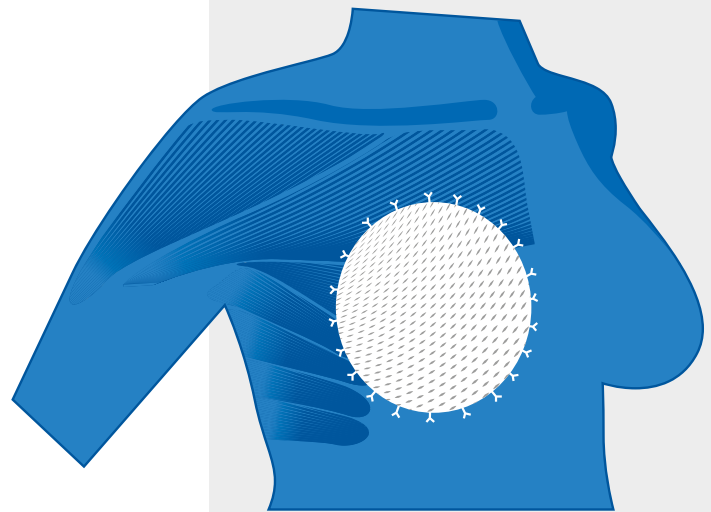


The Exaflex membrane is rehydrated by total immersion in sterile saline solution for at least 5 minutes

Immediate post-mastectomy reconstruction with pre-pectoral technique

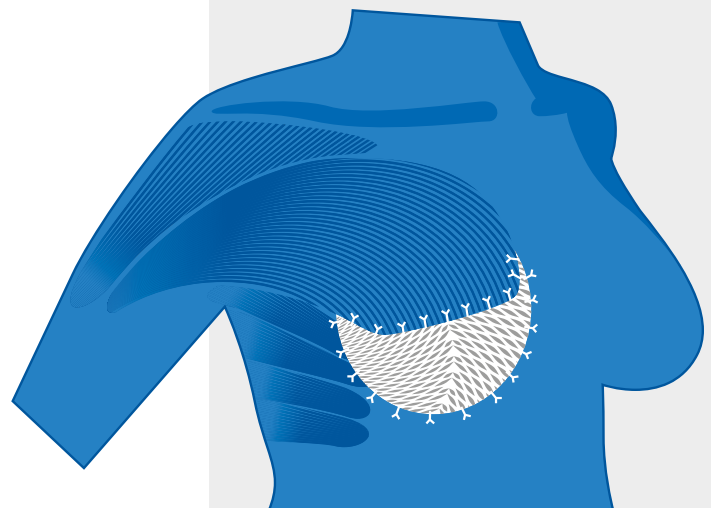
The pre-pectoral technique involves the use of a matrix to completely cover the implant.

The latter is positioned between the pectoral and the subcutis, preserving muscle functionality while the matrix protects the tissues from the implant.



Immediate post-mastectomy reconstruction using the Dual Plane technique

The pectoral muscle often does not provide sufficient coverage for the chosen definitive implant, making the use of a matrix necessary to expand the protective coverage of the pectoral muscle into the groove.

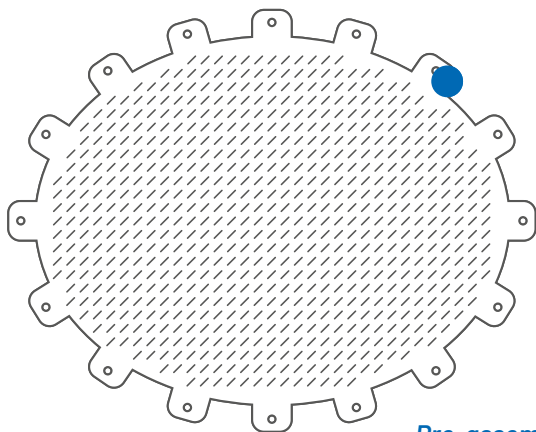


Exaflex for post-mastectomy reconstruction

Pre-pectoral technique

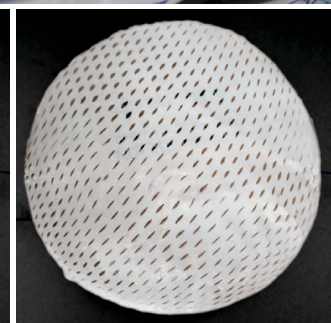


Exaflex FENESTRATED

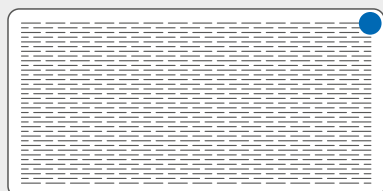


- Pre-assembled suture
- Pre-shaped

CODE	SIZE mm	IMPLANT COVERAGE
EXF-60	160x200x0,5	Up to 450 cc.
EXF-61	180x220x0,5	Over 450 cc.

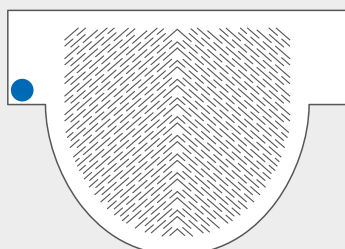


Exaflex MESH



- Rectangular
- Expands
- Can be trimmed
- Can be sutured

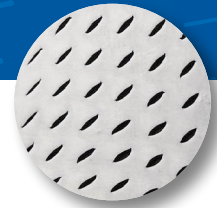
CODE	SIZE mm	EXPANDED SIZE mm
EXF-30	60x80x0,5	60x140x0,5
EXF-31	100x200x0,5	100x360x0,5
EXF-32	150x200x0,5	150x360x0,5



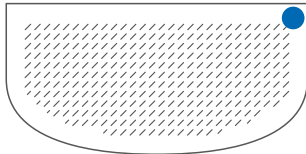
- Anatomical shape
- Expands
- Can be trimmed
- Can be sutured
- Forms an internal bra

CODE	SIZE mm	EXPANDED SIZE mm
EXF-49	130x180x0,5	130x198x0,5
EXF-50	150x220x0,5	150x270x0,5

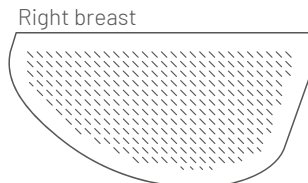
Dual Plane technique



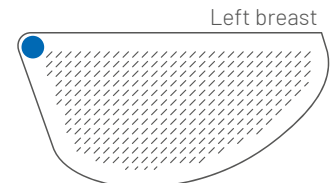
Exaflex FENESTRATED



- Anatomical shape
- Can be trimmed
- Can be sutured



Right breast

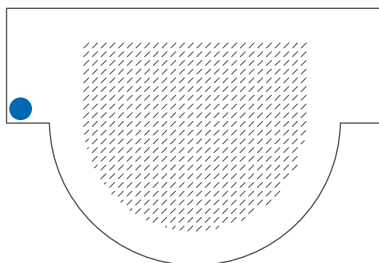


Left breast

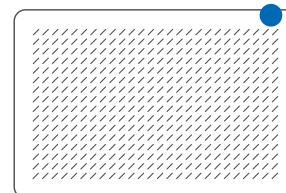
- Anatomical shape
- Can be trimmed
- Can be sutured

CODE	SIZE mm
EXF-51	80x160x0,5
EXF-52	90x180x0,5
EXF-53	70x170x0,5
EXF-54	100x220x0,5

CODE	SIZE mm	SIDE
EXF-45	80x160x0,5	Right / Left
EXF-46	80x160x0,5	Right
EXF-47	80x160x0,5	Left



- Anatomical shape
- Can be trimmed
- Can be sutured
- Forms an internal bra



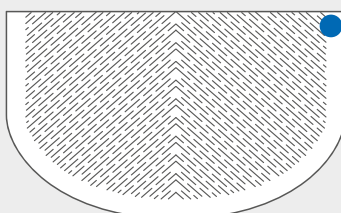
- Rectangular
- Can be trimmed

CODE	SIZE mm
EXF-48	150x220x0,5

CODE	SIZE mm
EXF-21	100x150x0,5



Exaflex MESH



- Anatomical shape
- Expands
- Can be trimmed
- Can be sutured

CODE	SIZE mm	EXPANDED SIZE mm
EXF-40	110x180x0,5	110x288x0,5
EXF-41	130x200x0,5	130x324x0,5



 **Exaflex**
in the world

CE 0373
EN ISO 13485:2016

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