

Biological Membranes for Plastic and Reconstructive Surgery

WHAT IS IT?

Exashape is a membrane derived from processing pericardium from cattle under 24 months of age, selected and controlled at all stages of growth for feed and environment in which they grow¹.

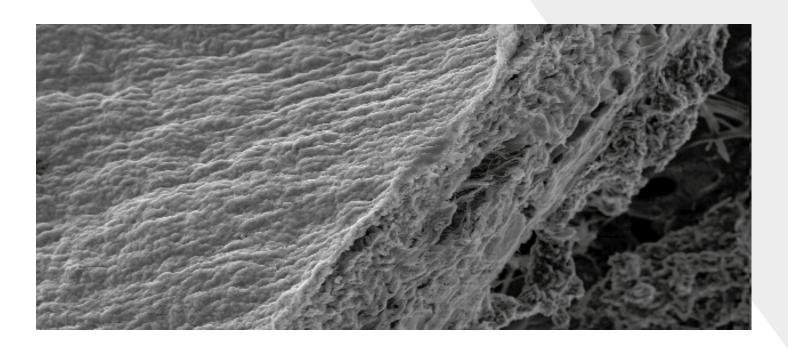
OUR SECRET IS BILAYER

Designed for Reconstructive Plastic Surgery, the Exashape membrane is processed through a proprietary method that maintains the unique qualities of natural pericardium¹.

Exashape guarantees fast integration times with cell ingrowth², minimal inflammation³ and negligible serum production, while maintaining remarkable mechanical properties¹. The two layers perform a specific task in the integration process.

Fibrous layer: highly porous, it welcomes cells and, together with the matrix components, allows cytokines and growth factors to trigger the immediate revitalization process and early neoangiogenesis².

Compact layer: it is quickly repopulated by fibroblasts and VEGF². After implantation, there is no accumulation of inflammatory or giant cells. It is the part that provides the most solid structural support.



THREE-STEP INTEGRATION

The **bilayer membrane** undergoes a 3-stage process of revitalization by endogenous connective tissue:



During implantation, the collagen matrix absorbs the blood and the revitalization process begins immediately, characterized by a controlled and short-lived inflammation phase with considerable neoformation of vessels^{2,3}.



Fibroblasts reactivate collagen by triggering the ingrowth of new vessels, which provide the metabolic needs. At this stage of the reparative process, cell proliferation prevails, which targets the growth of new tissue².



The actual remodeling phase begins its course and is the result of the precise balance in the synthesis of collagen, which becomes an integral part of the tissue³.

PRO-HEAL...BY NATURE

The cell-friendly process preserves the active elements in the repair process within the membrane: proteoglycans, hyaluronic acid, fibronectin, elastin and of course, native collagen. They represent a natural reservoir of bioactive factors, which participate in the revitalization process by controlling inflammation while promoting cell proliferation and migration². We limit the amount of biological mass implanted (up to 50% less, due to lower thickness of pericardium compared to dermis) promoting integration even in cases of poor blood supply, while maintaining the highest bio-mechanical performance^{1,4}.

REFERENCES

- 1 Bielli, A., Bernardini, R., et al. (2018) Characterization of a new decellularized bovine pericardial biological mesh: Structural and mechanical properties. Journal of the Mechanical Behavior of Biomedical Materials. 78 (2018) 420–426
- 2 Bernardini, R., Varvaras D., D'Amico F., et al. (2019) Biological acellular pericardial mesh regulated tissue integration and remodeling in a rat model of breast prosthetic implantation. J Biomed Mater Res. 2019;1-14
- **3** Varvaras, D., et al. (2017) Safety, tolerability, and efficacy evaluation of immediate total wrapping with biological mesh implant-based breast reconstruction: an under-estimated subcutaneous approach with "biological texturization" prostheses. Preclinical animal study. The Gulf Journal of Oncology, Supplement January 2017
- 4 Capuano, I., Bernardini, R., Varvaras, D., Mattei, M. (2020) Acellular Dermal Matrix in Prosthetic Breast Reconstructive Surgery with Prepectoral Technique: A Literature Review. Journal of Experimental Pathology. Volume 1, Issue 2: 50-59



Bioshield Pocket[®] (patented) meets your real clinical and surgical needs for the protection of the implant/tissue interface. Based on the *ratio* and pattern of incisions in the device, it is able to anteriorly cover virtually all sizes and models of breast implants on the market.

The unique design also revolutionizes the surgical procedure, as the rehydrated membrane allows anterior coverage of the implant in less than five minutes, without the need for time-consuming adaptation procedures that involve lengthy intra-operative time, risk of accidental damage to the silicone implant and protracted handling, with the associated risk of contamination that brings.

The preformed mesh is rehydrated in a sterile tray, included in the package, with the smooth side (intended to accommodate the implant) facing the operator and identified with the letter "P".

The anterior surface of the implant is placed on the membrane, the characteristic "petals" are tightened in a "double purse string" style, on the posterior side of the implant; thanks to the drapability of the material and the mesh configuration, **Bioshield Pocket®** wraps the breast implant without any unnecessary or redundant biological mass.

The implant and mesh assembly is now ready to be positioned within the breast skin flap pocket, even without the need for chest wall sutures. The high friction coefficient of the fibrous side and the mesh conformation in contact with the skin flap guarantee a remarkable grip.

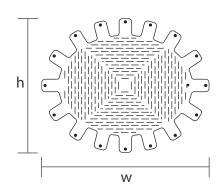


Meshed bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)144-188S	Pocket small	18 x 14 cm x 0,5 mm
AEPB(F)164-208S	Pocket medium	20 x 16 cm x 0,5 mm
AEPB(F)184-228S	Pocket large	22 x 18 cm x 0,5 mm
AEPB(F)204-238S	Pocket extra large	23 x 20 cm x 0,5 mm

Bioshield Pocket° is also available in a **KIT version**, including 2 resorbable monofilament PGCL sutures for the preparation of the "purse string" assembly.

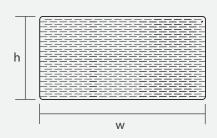
POCKETS 4.0	KIT Pocket small	18 x 14 cm x 0,5 mm
POCKET M 4.0	KIT Pocket medium	20 x 16 cm x 0,5 mm
POCKET L 4.0	KIT Pocket large	22 x 18 cm x 0,5 mm
POCKET XL 4.0	KIT Pocket extra large	23 x 20 cm x 0,5 mm



Exashape Prepec is a rectangular meshed membrane. Thanks to its expansion *ratio*, after rapid rehydration it is able to cover implants of all shapes and sizes, with minimum handling and maximum stretchability/drapability, without any change in your technique or operating time, whilst benefiting from the extraordinary performance of the bilayer pericardium.

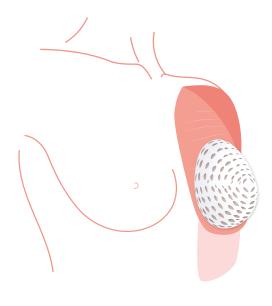
PREPEC Meshed bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)108-200S	Rectangular, meshed	20 x 10 cm x 0,5 mm
AEPB(F)158-200S	Rectangular, meshed	20 x 15 cm x 0,5 mm



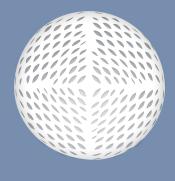
Placement

• BIOSHIELD POCKET



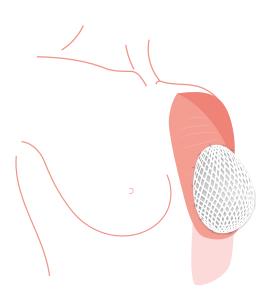
- The membrane has two sides, one smooth non-stick and one fibrous
- The smooth side must be placed in contact with the implant, and the fibrous side in contact with the skin flap.
- Rehydrate the Exashape membrane by total immersion in sterile saline solution.
- The smooth side to be in contact with the implant is marked with the letter "P".



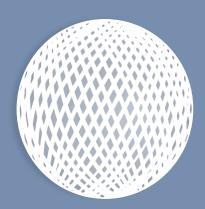




PREPEC





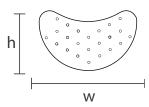


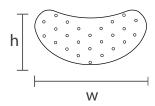


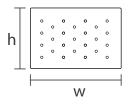
Exashape Grid comes in 2 anatomically shaped models and 1 rectangular one, fenestrated with circular holes to optimize the drainage capacity of fluids. Supplied sterile, the membrane rehydrates quickly and is immediately available for use. The range of sizes allows immediate use in most patients.

GRID bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)084-162S	Half-moon, perforated	16 x 8 cm x 0,5 mm
AEPB(F)074-172S	Half-moon, perforated	17 x 7 cm x 0,5 mm
AEPB(F)104-150S	Rectangular, perforated	15 x 10 cm x 0,5 mm



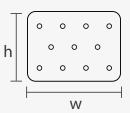




Exashape Expander is used in expander implantation procedures in breast reconstruction as a means of pocket closure. It is 'circular-hole' fenestrated to optimize drainage capacity of fluids.

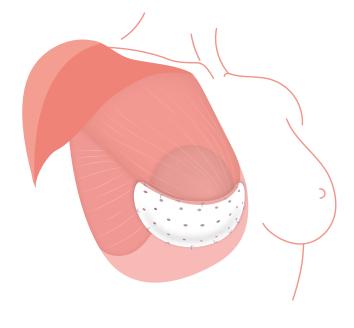
EXPANDER bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)064-080S	Rectangular, perforated	8 x 6 cm x 0,5 mm

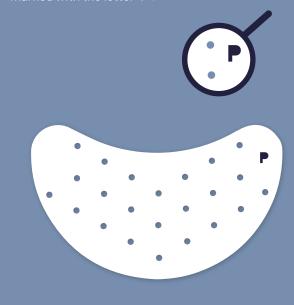


Placement

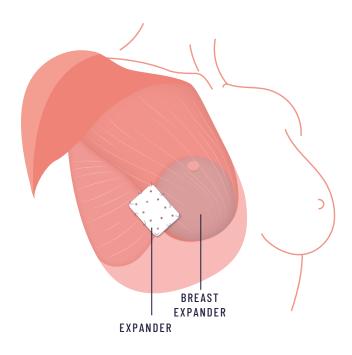
• GRID

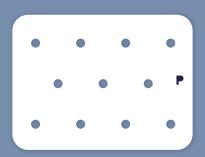


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EXPANDER







Bioshield PRo membrane is a multifunctional device (patent pending) for Plastic Surgery. It allows different usage options, such as selective coverage of the upper or lower quadrants of a silicone breast implant.

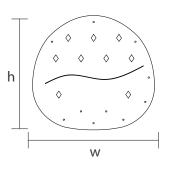
In addition, it can be used for wrapping a breast implant in combination with the Bioshield Pocket® membrane, if the goal is to achieve greater coverage increasing the containment capacity, to allow the coverage of large-sized implants.

The biological mass amount is still limited, thanks to the fenestration and the peculiar thinness of the raw material, the bilayer bovine pericardium.



bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)080-099S	BIOSHIELD PRo	8 X 9 cm x 0,5 mm
AEPB(F)100-119S	BIOSHIELD PRo	10 x 11 cm x 0,5 mm
AEPB(F)120-139S	BIOSHIELD PRo	12 x 13 cm x 0,5 mm
AEPB(F)140-159S	BIOSHIELD PRo	14 x 15 cm x 0,5 mm
AEPB(F)160-179S	BIOSHIELD PRo	16 x 17 cm x 0,5 mm



Exashape Belt is a multifunctional membrane which can be used for supporting tissues or as a reinforcing element in conjunction with the Exashape membranes.

It can be implanted alone or in combination with Bioshield Pocket® for completing the assembly, ensuring a minimum biological mass implanted.

It is a rectangular strip-shaped membrane, perforated symmetrically at both ends in order to simplify the running of the thread.

BELT bilayer bovine pericardium membrane

REF	DESCRIPTION	SIZE (w x h x th)
AEPB(F)015-120S	Rectangular, perforated	1,5 x 12 cm x 0,5 mm
AEPB(F)015-160S	Rectangular, perforated	1,5 x 16 cm x 0,5 mm
AEPB(F)035-120S	Rectangular, perforated	3,5 x 12 cm x 0,5 mm



BIOSHIELD PRo : : :

PROTECTION OF UPPER QUADRANTS





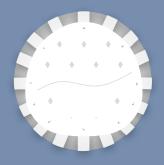






Placement

BIOSHIELD PRO IN CONJUNCTION
 WITH BIOSHIELD POCKET



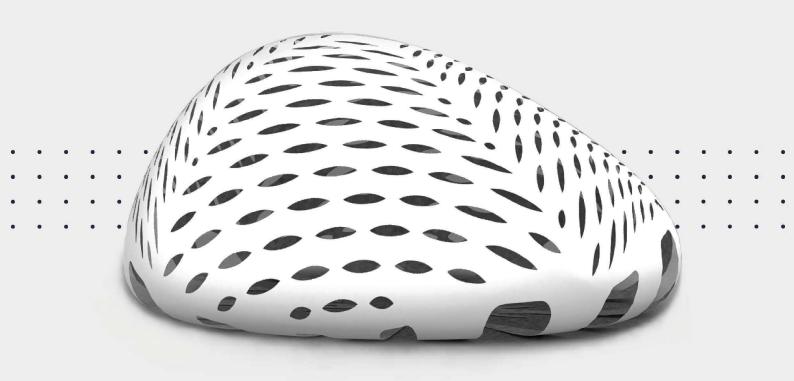






THIS CATALOGUE IS INTENDED FOR HEALTHCARE PROFESSIONALS.

Refer to the Instructions for Use for detailed information on Intended Use, Warnings and Precautions.



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