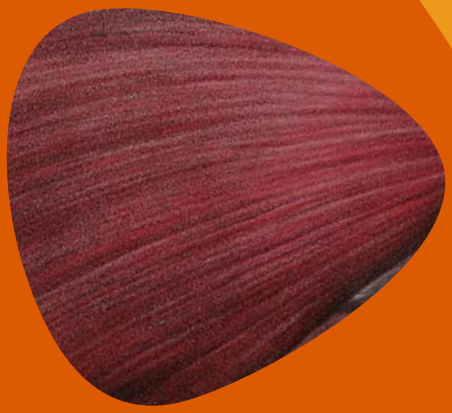
Patented by
DECOMED®
BIOLOGICAL IDENTITY



One-step breast reconstruction with Pectoralis Major intact

BRAXON®

Muscle sparing one-step reconstruction

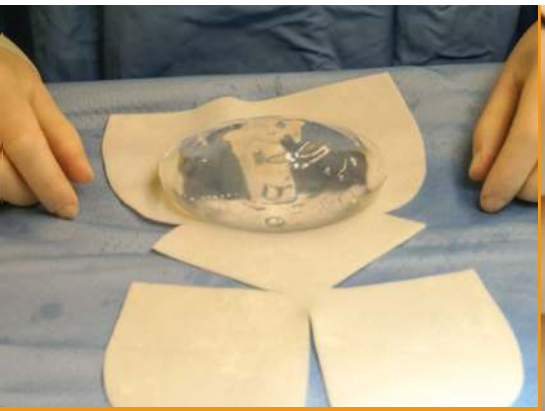
The simpler the better

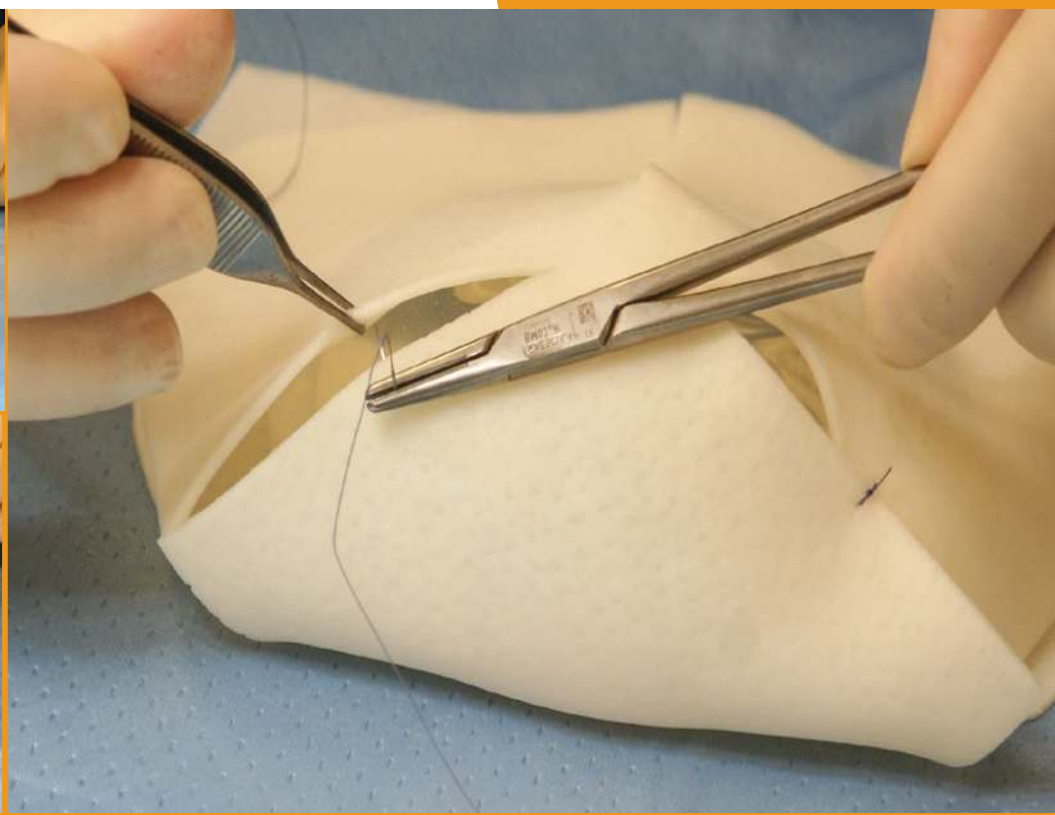
BRAXON® is fruit of the combined experience in the tissue engineering field and clinical practice.

In 2012, the heartfelt necessity of more conservative surgical procedures boosted innovation in reconstructive surgery. Giving a nod to biomaterials with regenerative capacities, DECO med® disclosed an innovatory surgical technique to the Scientific Community and ADM-assisted one-step prepectoral breast reconstruction was born.

When indicated, prepectoral breast reconstruction provides important benefits on multiple fronts. Firstly, to the patient, who has her physical integrity recovered in a single operation while obtaining a natural cosmetic outcome. Then, to the healthcare system, by cutting the costs associated with invasive and complications-prone surgical procedures.

BRAXON® is the all-round approach to breast reconstruction with the most advanced biomaterial and the least impact on patient's anatomy.





WHY

Because sparing the Pectoralis Major changes everything. Lifting it for submuscular breast reconstructions results in various functional deficits involving muscle strength and arm range of motion. Over time the interference in the synergy of the various muscle groups may result in weakness of humeral-scapular articulation with repercussions in movement, causing pain, and unsatisfying cosmetic results.

WHAT

BRAXON® is the pre-shaped porcine dermal matrix which allows the tailoring of an ADM suit around the mammary prosthesis and its fixing on the pectoralis muscle, which is kept intact.
Covered by several patents, the BRAXON® silhouette perfectly adapts to the shapes of all silicone prostheses. Publications from the last two decades have demonstrated a lower incidence of capsular contracture when the breast prosthesis is covered by a dermal matrix.

HOW

In case of one-step/immediate breast reconstruction, the creation of a sub-muscular pocket takes longer and requires complex postoperative rehabilitation. All this is avoided with BRAXON®-assisted prepectoral breast reconstruction. Creating a complete biological envelope for the synthetic implant, BRAXON® constitutes a new interface between implant and patient's soft tissues reducing foreign-body reaction. This allows the complete subcutaneous placement of the prosthetic implant where the breast belongs: above pectoral muscles.

WHEN

When breast reconstruction is planned following nipple- or skin-sparing mastectomy.
When a good, vascularised subcutaneous layer is present, in fact, previous radiotherapy or co-existing medical conditions such as diabetes or connective tissues disorders are contraindications. It is advised to maintain a viable subcutaneous tissue during mastectomy: the use of monopolar diathermy should be reduced to a minimum to prevent skin flap necrosis.

Natural, Artificial, Synthetic

We have been used to consider biocompatibility as a dichotomy splitting the world in what is biocompatible and what is not. Recent evidence shows how the effect of an implant varies depending on the surgical site, the aim of the surgery, the shape of the implant, and the nature of the material it is made of.

Natural matrices are made of native proteins (collagen) derived from acellularised animal tissues. The one BRAXON® is made of derives from porcine dermis: the organism recognises it as its own and transforms it into new self-tissue through the natural regenerative process (remodelling).

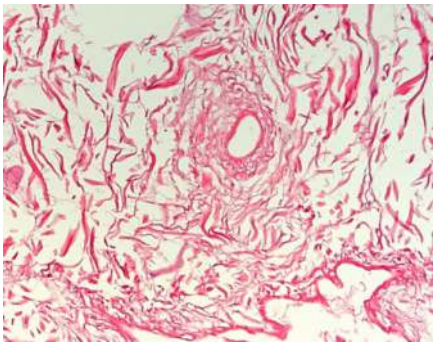
Artificial membranes derive from natural polymers, but they are chemically modified for reinforcement (e.g. cross-linked membranes). They can be either tolerated or digested by the organism, but they do not stimulate any regenerative process.

Synthetic meshes, made of polymers obtained by chemical synthesis (e.g. plastics like polyethylene, polylactide, polypropylene), are chemically tolerated but they do not stimulate a regenerative process, with the organism trying to confine them in a fibrous capsule.

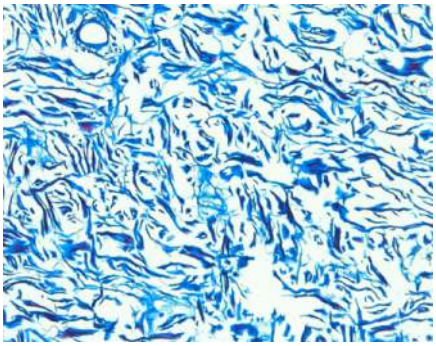
Nowadays the old concept of biocompatibility is not enough to define the effectiveness of a biomaterial.

Its performance must surpass passive tolerance.

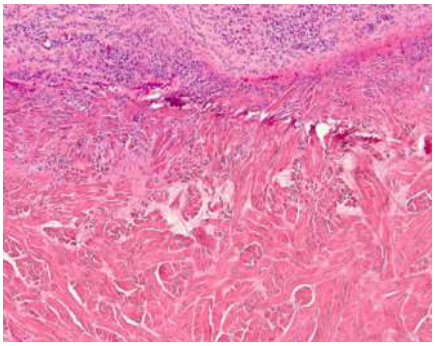
Histologies



I. Haematoxylin-Eosin staining of a sterile BRAXON® sample. The staining reveals the complete absence of cellular material.
100x magnification.



II. Azan-Mallory staining of a sterile BRAXON® sample. Collagen fibres of the matrix are highlighted, absence of cellular material.
50x magnification.



III. Haematoxylin-Eosin staining of a BRAXON® sample 4 weeks after implantation. Nuclei, stained darker, show a high degree of cell colonisation.
50x magnification.

Technical characteristics

BRAXON® is a 0.6 mm thick Acellular Dermal Matrix (*) derived from selected porcine dermis. It is specifically designed for fast integration without amplifying the inflammatory process.

The exclusive production process has been developed with the aim of generating a completely natural product. BRAXON® is not cross-linked and is free from any chemical substance which can amplify the inflammatory response and slow the path of tissue regeneration. The native protein structure provides immediate bio-availability for incorporation into the host tissue. A fast integration lessens the inflammatory response and its effects, such as redness and seroma which commonly derive from the implantation of other biomaterials in the breast.

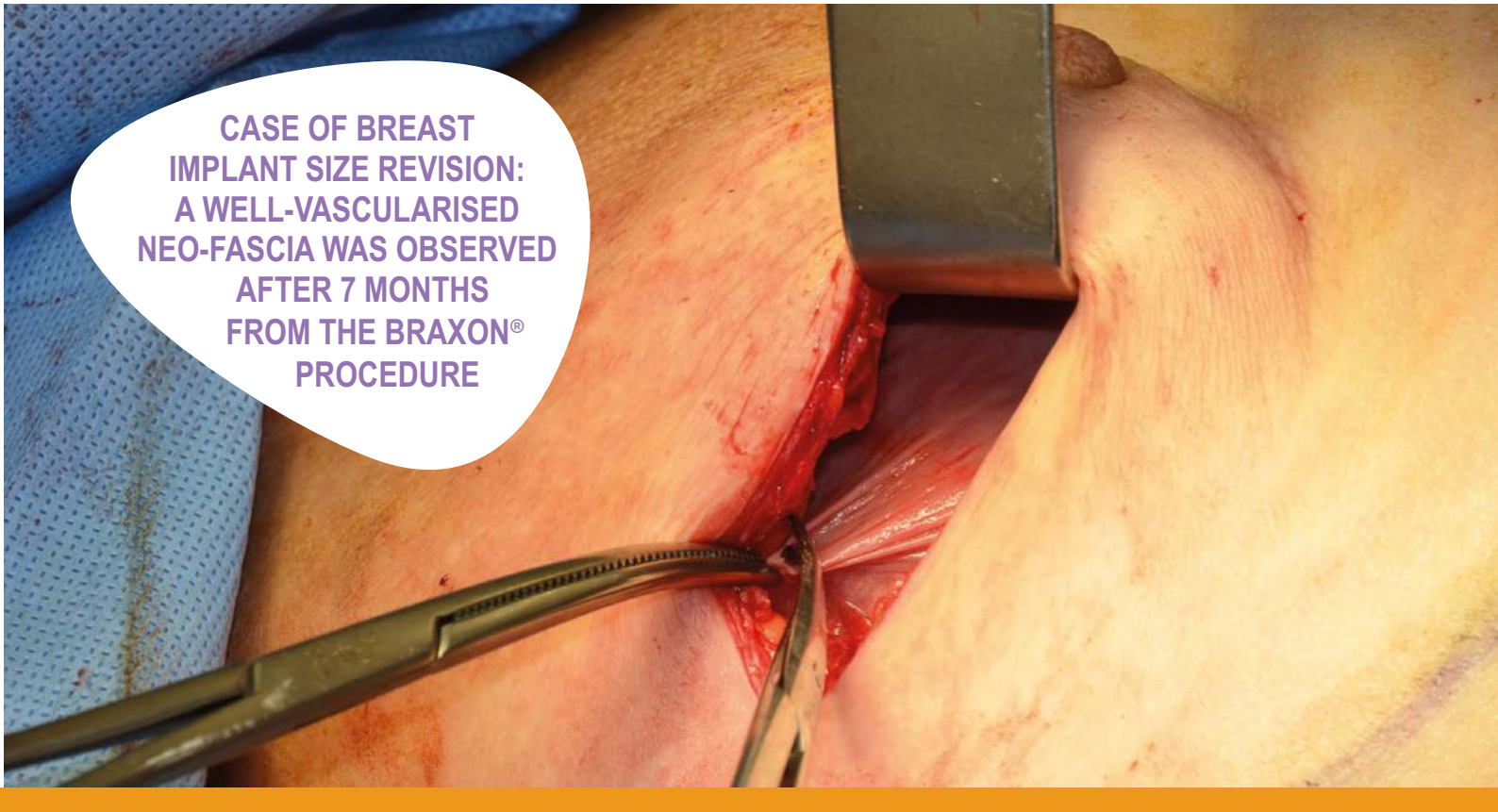
To preserve the genuine qualities of BRAXON® and to avoid preservatives that could amplify postoperative inflammation, in the final phases of the production a sublimation step is applied. This freeze-drying process allows the complete removal of any liquid through exact use of pressure and temperature. The result is a reliable product, optimal for long-lasting room temperature preservation. A simple rehydration before use is all it takes, without the need for repeated washings to attempt the removal of added chemicals which other products contain.

BRAXON® patented shape allows a perfect fit around the silicone prosthesis creating a new interface that can be sutured onto the muscle surface. It fits neatly under the skin in a perfect position, which can be reliably checked prior to closing the surgical access.

After surgery, early and prolonged use of a conforming bra for 3 or 4 weeks as well as a compressive dressing and reduced mobility of the arm will significantly decrease the risk of seroma formation.

A biomaterial must be active, not merely inert, with the aim of driving the biological process of guided tissue regeneration.

(*) Acellular Dermal Matrix: a complex net of extracellular macromolecules that, in addition to performing a connective function between cells and tissues, provides an organized structure in which cells can migrate and interact with each other.

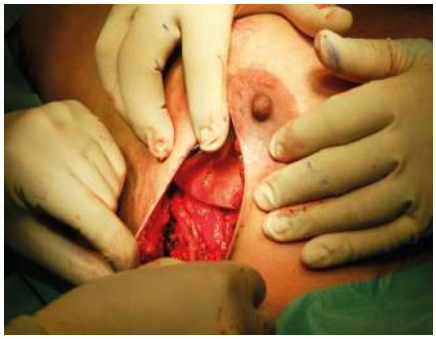


Surgical Steps

START 00′ — 05′ — 15′

START 00'
BRAXON® procedure begins during mastectomy

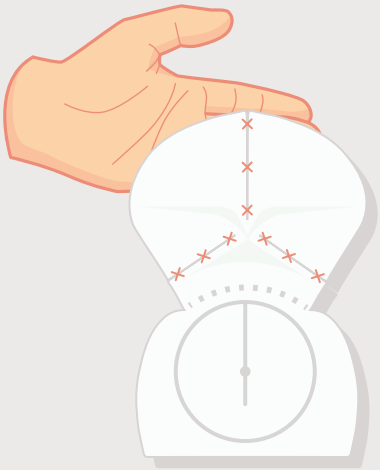
05'
BRAXON® is hydrated for 5 minutes to make it soft and pliable



15'
Use of sizer to choose the right size and shape of the breast implant

Tailoring BRAXON®

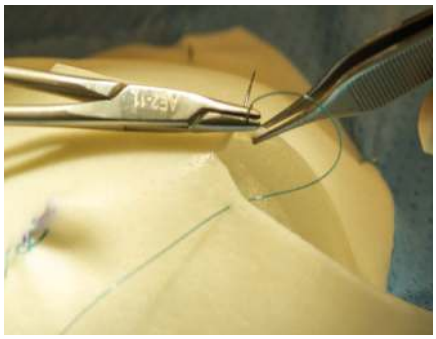
BRAXON® is pre-shaped in such a way as to contain a breast implant of any size and shape. Its use is intuitive and only requires scissors and sutures to “dress” the prosthesis and be sutured upon the pectoralis muscle.



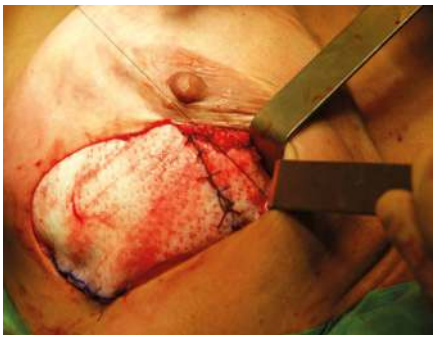
35′

45′

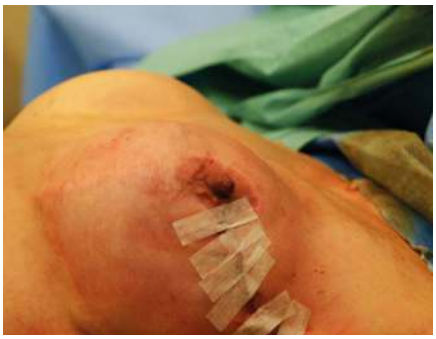
FINISH
60′



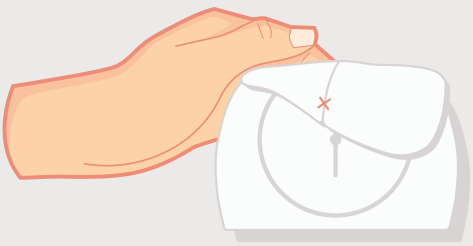
35'
BRAXON® tailoring around the mammary prosthesis

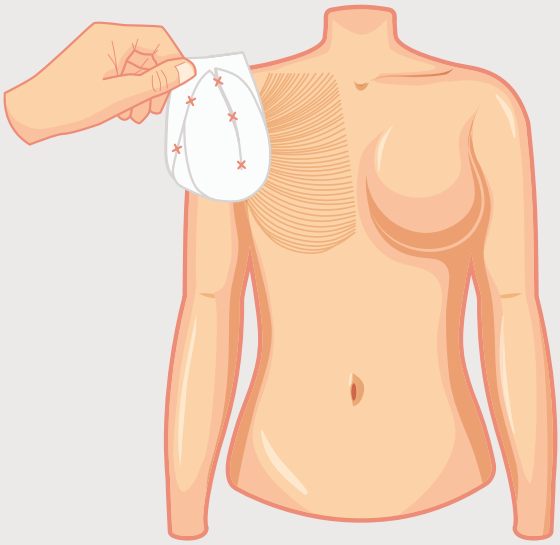


45'
The BRAXON®-implant construct is inserted and sutured to the chest



FINISH 60'
Skin is closed and an appropriate dressing is applied





The iBAG Study

THE LARGEST MULTICENTRE DATA COLLECTION ON PREPECTORAL BREAST RECONSTRUCTION: THE iBAG STUDY

Jaume Masiá | iBAG Working Group

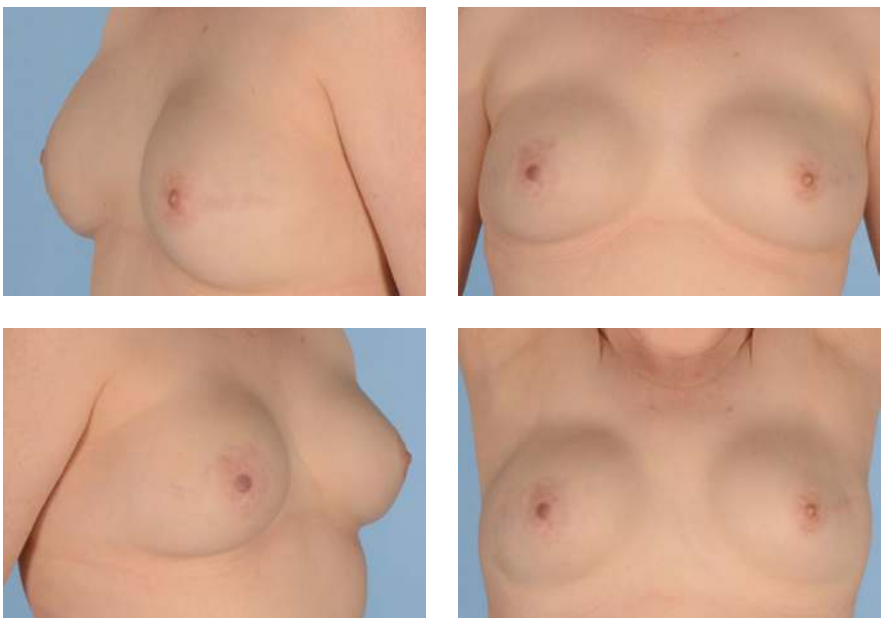
BRAXON® patented shape allowed for the standardised wrapping of the breast implant granting reproducible results.

This favoured the collection and analysis of 1450 cases of BRAXON® implantation from 30 international centres.

From the iBAG (international Braxon Audit Group) and with the endorsement from independent scientific organizations (INPECS and Cochrane collaboration), the widest and most solid scientific evidence on prepectoral breast reconstruction was elaborated.

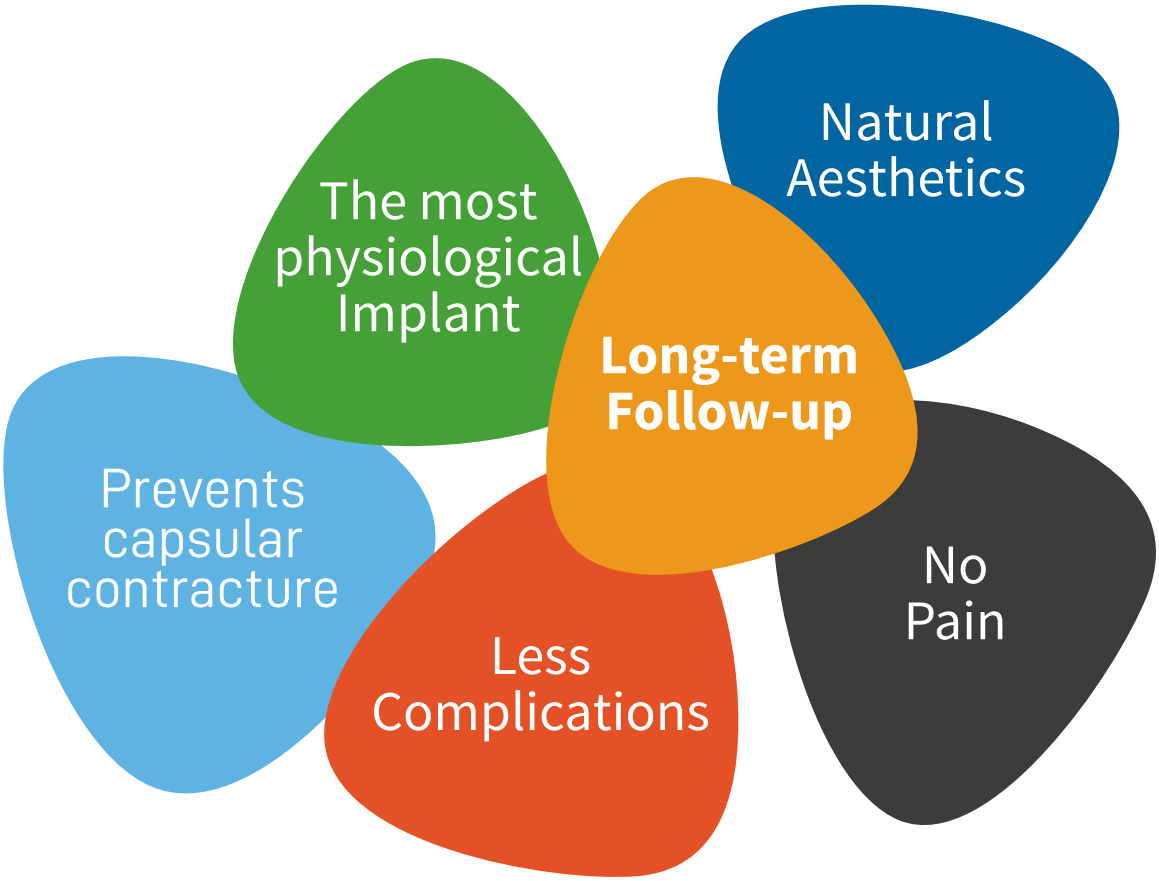
The study reports low complication rates together with natural and symmetrical aesthetic results. The statistical analysis confirms the guidelines proposed for patient selection, highlighting higher risks for smokers, immunosuppressed patients, those with diabetes, and in case of previous surgery or radiotherapy. On the other hand, a new possible indication is represented by those cases with planned postoperative radiotherapy (PMRT). In an average follow-up of 2 years, BRAXON® has been proven reducing the rate of capsular contracture and improving results in terms of tissue softness.

COMPLICATIONS	NON-IRRADIATED BREASTS N =1243	BREASTS WITH PMRT N =159
Seroma	7.0%	10.7%
Dehiscence	4.5%	4.4%
Haematoma	2.2%	2.5%
Necrosis	3.1%	3.8%
Infection	4.7%	5.0%
Extrusion	1.0%	1.3%
RBS	3.5%	2.5%
Fever	1.9%	0.6%
Implant rotation	0.2%	0.0%
Capsular contracture	1.7%	6.3%
Rippling	3.1%	0.0%
Other	3.1%	4.4%
Implant loss	5.6%	10.7%



Bilateral BRAXON® implantation with anatomical implants: 15 months postoperative photographs

THE WINNING IDEA



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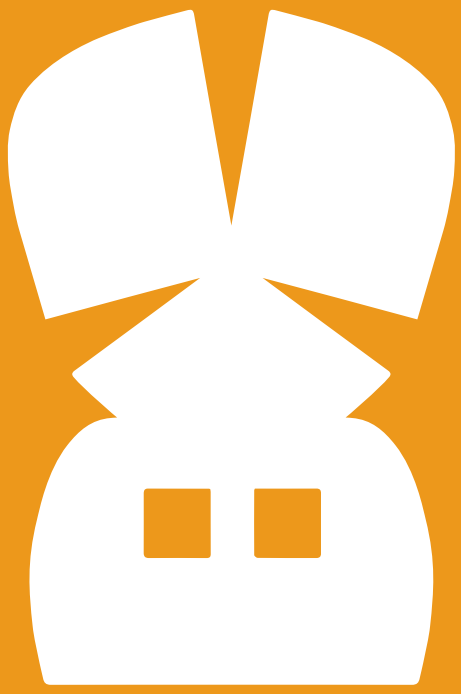
BRX06S

BRAXON® acellular dermal matrix.
Pre-shaped ADM for breast implant total coverage.



BRAXON® Scientific Evidence

More than 60 scientific studies demonstrate the safety and efficacy of Braxon technique exploring the different aspects of the original prepectoral surgery. Over 200 authors contributed to its scientific corpus, providing patients' selection criteria, surgical guidelines, and postoperative management tips.

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