International patent

DECOmed MARKETING AND TRADE S.R.L.

One-step breast reconstruction with Pectoralis Major intact

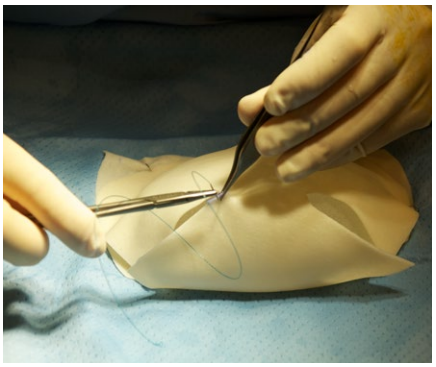
BRAXON®

Muscle sparing one-step reconstruction

The simpler the better

Braxon® is the result of the experience which has developed in the field of tissue bio-engineering joined with that of clinical practice aiming to create a more conservative surgical procedure.

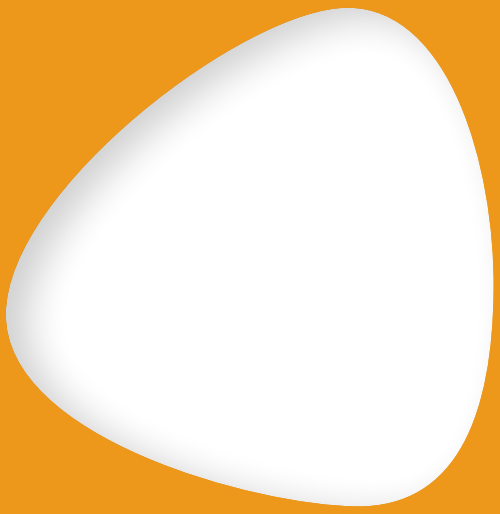
The study of the biomaterial's regenerative capacity applied together with the constantly ambitious challenges in the field of reconstructive surgery has led to the emergence in 2012 of an innovative surgical technique which signaled a further enhancement in the field of one-step breast reconstruction.



BRAXON® IS A SYNTHESIS BETWEEN THE MOST ADVANCED BIOMATERIAL AND THE MOST CONSERVATIVE ANATOMICAL IMPACT FOR THE PATIENT.

The one-step breast reconstruction, when indicated, has highlighted important benefits for the patient, who recovers her physical integrity in a single operation, together with significant cost savings for the health economy.

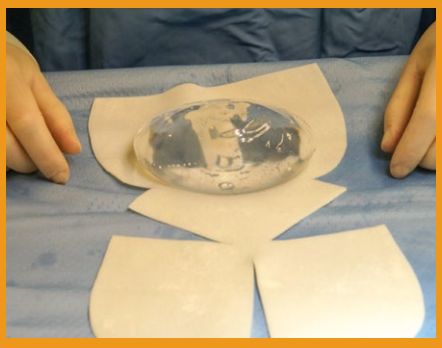
Innovations in the field of biomaterial have contributed in a major way to enabling this new operation to substantially improve the cosmetic outcomes of immediate breast reconstruction.



Muscle sparing WHY

The disinsertion of pectoralis results in a deficit of muscle function of arm flexion, internal rotation and adduction. Over time the interference in the synergy of the various muscle groups may result in weakness of humeral-scapular articulation with repercussions in movement, pain and also an impaired cosmetic result.

The creation of a sub-muscular pocket for the normal procedures, one-step or two-stage breast reconstruction is longer and more complicated and requires postoperative physiotherapy.



THE DISINSERTION OF THE MUSCLE CAUSES BLEEDING, POSTOPERATIVE PAIN AND SEROMA.

BRAXON®

BRAXON®

THE MOST PHYSIOLOGICAL IMPLANT

Braxon®

WHO

More than 40 scientific studies demonstrate the safety and efficacy of Braxon® prepectoral breast reconstruction. Our specialists are always available to inform you about the inclusion/exclusion criteria and surgical details.

Above muscular pocket

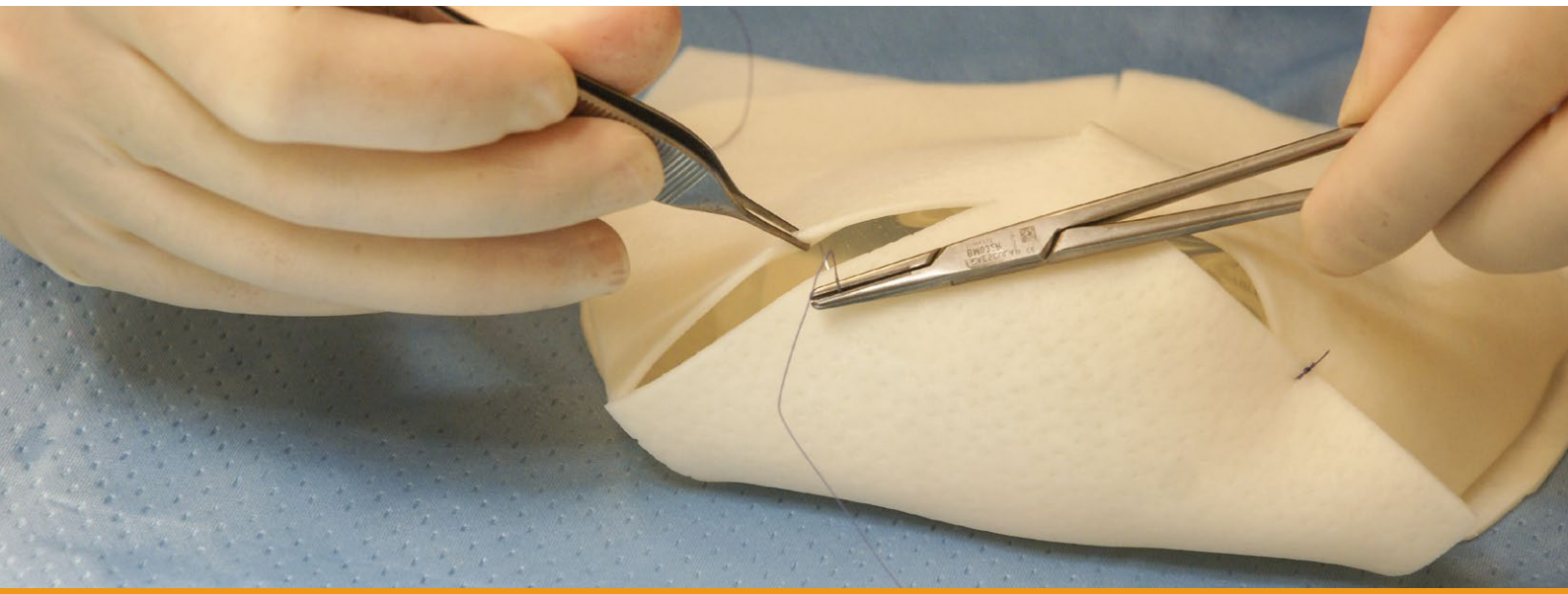
HOW

Recent publications have shown a lower ratio of capsular contractions if the breast prosthesis is wrapped in a biological matrix.
Braxon® is a pre-shaped porcine dermis which allows the tailoring of an ADM pocket around the mammary prosthesis and its fixing above the pectoralis muscle, which is kept intact.
Covered by several patents, the Braxon® shape perfectly matches the contours of a silicone prosthesis.

Braxon®

WHEN

In one-step reconstruction after nipple or skin sparing mastectomy. When there is a good vascularised sub-cutaneous layer.
Previous radiotherapy or co-existing medical conditions such as diabetes or connective tissue diseases are contra-indications. The use of monopolar diathermy in the mastectomy skin flap dissection should be reduced to a minimum to prevent skin flap necrosis.



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 (not crossed linked) without the presence of any chemical substance which can amplify the inflammatory response and slow the pathway of tissue regeneration. The native proteic structure provides the benefit of immediate bio-availability for incorporation into the host tissue with lower inflammatory responses such as seroma or the red-skin flare phenomenon seen following the implantation of other biomaterials used in breast reconstruction.

Natural, artificial and synthetic matrices.

The **natural** Braxon® matrix is made of native proteic polymers derived from acellularized porcine dermis (collagen). The organism recognises it as its own, and transforms it into self tissue through the natural regenerative process (remodelling).

Artificial meshes derive from natural polymers, but they are chemically modified for reinforcement (e.g.. Cross-linked meshes). They are tolerated by the organism but do not stimulate any regenerative process.

Synthetic meshes, made of polymers obtained by chemical synthesis (Polypropylene with metal coatings for example), are chemically and physically tolerated by the organism but they do not stimulate a regenerative process.

In order to allow Braxon® to be incorporated into the tissues without an amplified inflammatory response, the production process entails the sublimation (freeze drying) in the final phases of the newly created acellular graft, which allows the complete removal of the liquid chemicals used in its preparation through exact use of pressure and temperature. This process makes the product dry, optimal for correct conservation at room temperature, and only requires a simple rehydration before use, without the need for repeat washings to attempt the removal of damaging chemicals which other products require.

Its patented shape allows a perfect fit around the silicone prosthesis which creates a smooth surface with no graft over-lap after simple suturing to the muscle surface. It fits neatly under the skin in a perfect position, checked by the elevation of the patient prior to closing the skin wound.

Implantation technique

Braxon® must be sutured to the pectoralis major with single stitches to ensure primary stability of the matrix which requires intimate contact with vascularized tissue.

NOWADAYS THE CONCEPT OF BIOCOMPATIBILITY ISN'T ENOUGH TO DEFINE THE EFFECTIVENESS OF A BIOMATERIAL. ITS PERFORMANCE MUST SURPASS PASSIVE TOLERANCE. IT MUST BE ACTIVE, NOT SOLELY INERT, WITH THE AIM OF POWERING THE BIOLOGICAL PROCESS OF GUIDED TISSUE REGENERATION.

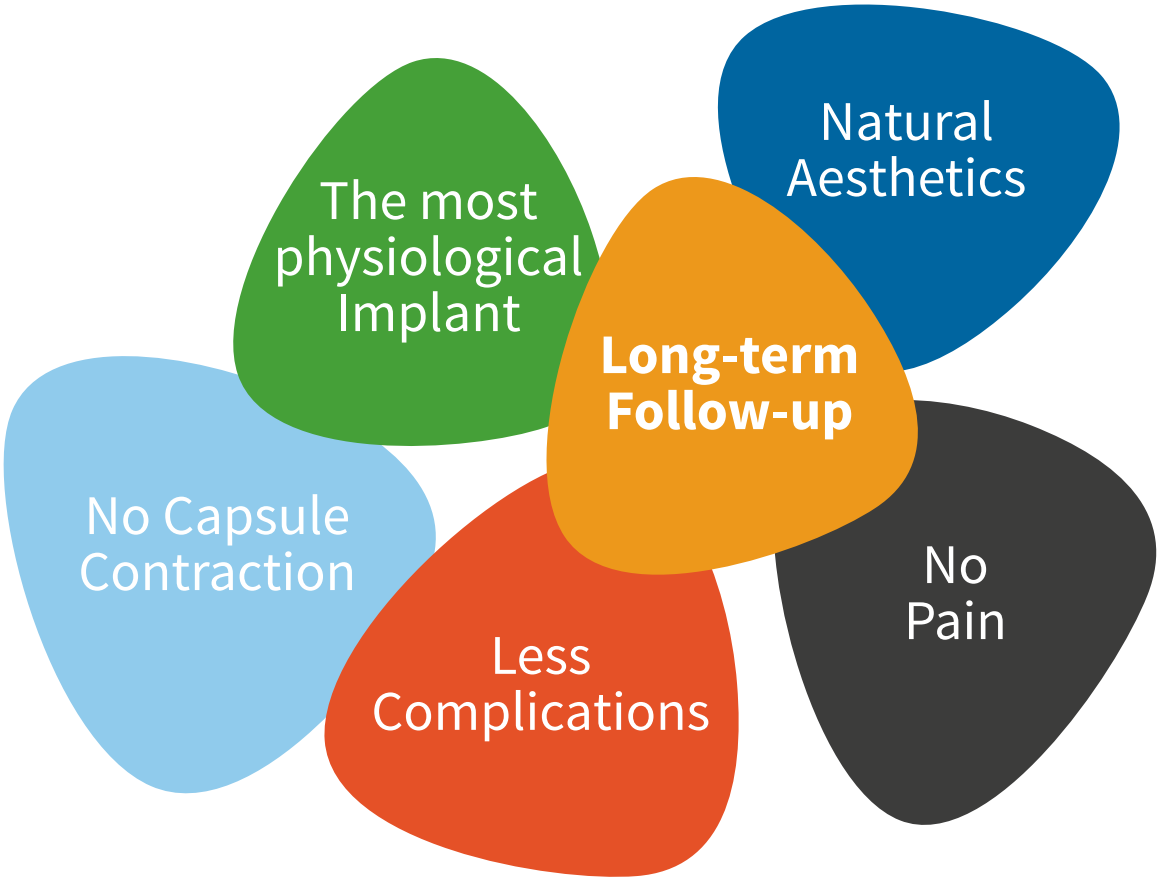
Postoperative management

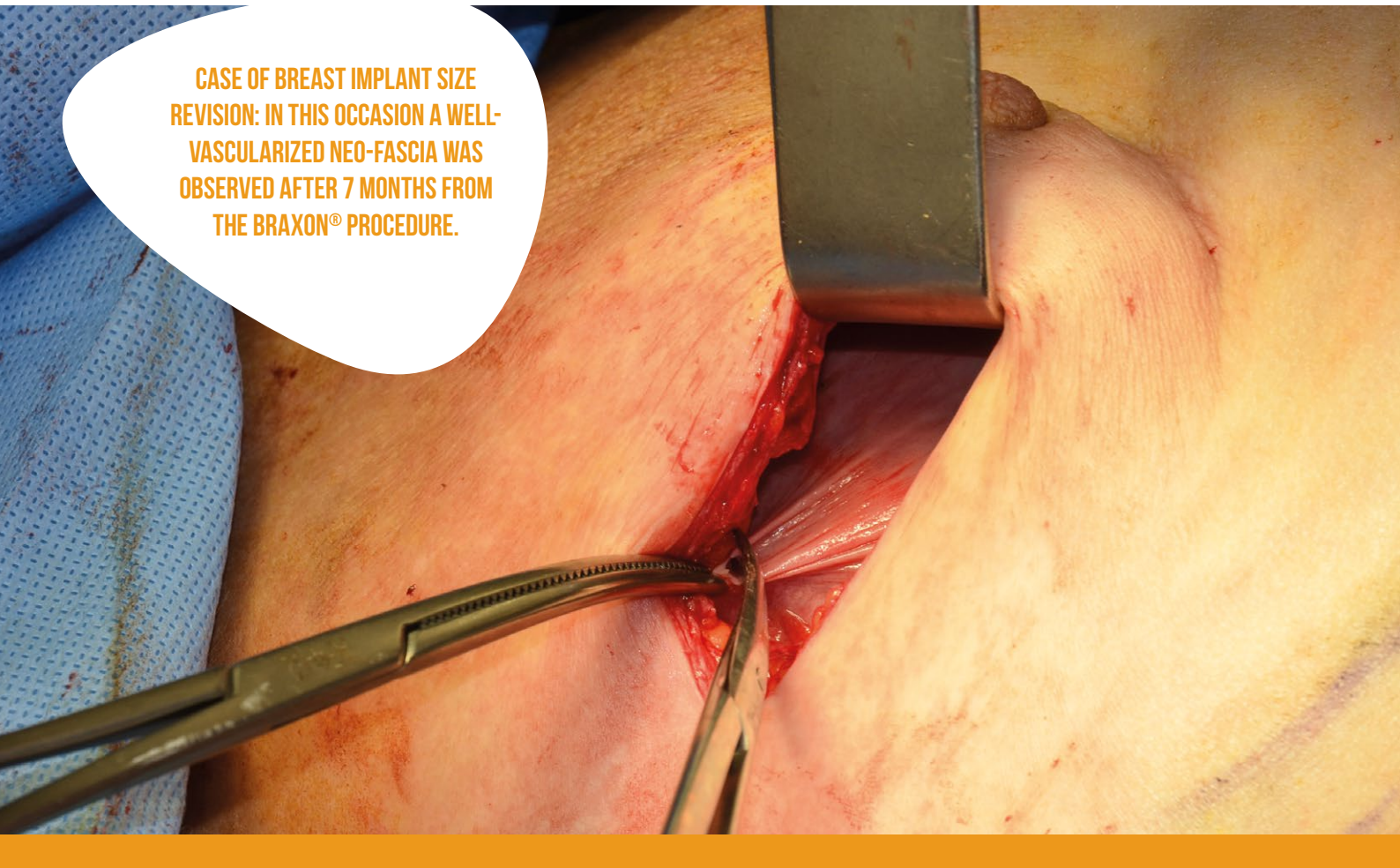
Early and prolonged use of a conforming bra for 3 or 4 weeks as well as a compressive dressing and reduced mobility of the arm will significantly decrease the seroma formation.

(*) Acellular Dermal Matrix:

A complex network of extracellular macromolecules that, in addition to performing a cementing function between cells and tissues, provides an organized structure in which the cells can migrate and interact with each other.

THE WINNING IDEA





CASE OF BREAST IMPLANT SIZE REVISION: IN THIS OCCASION A WELL-VASCULARIZED NEO-FASCIA WAS OBSERVED AFTER 7 MONTHS FROM THE BRAXON® PROCEDURE.

Surgical Steps

During mastectomy surgeon begins Braxon® procedure

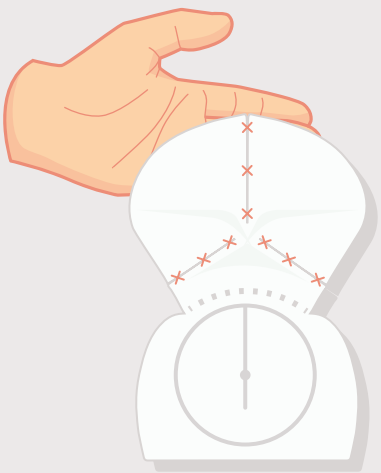
Braxon® must be hydrated for 5 minutes to make it soft and pliable

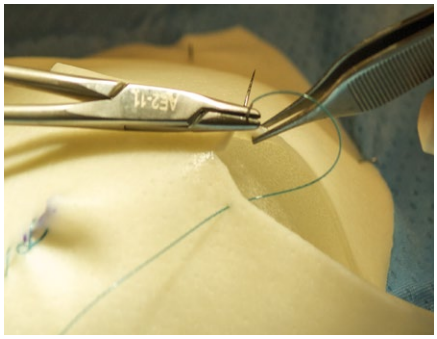
Use of sizer to choice the right size and shape of the breast implant

START 00′ — 05′ — 15′

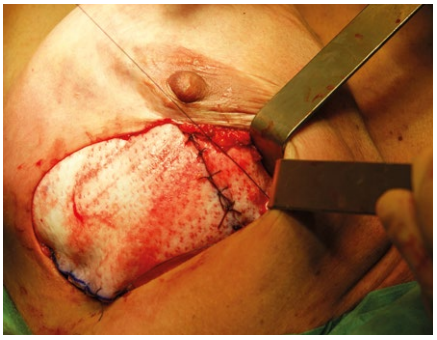
Tailoring Braxon®

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





Surgeon performs Braxon® tailoring around mammary prosthesis



Braxon® is inserted and sutured above the pectoralis major

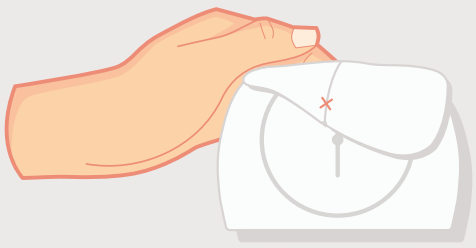
Skin closure

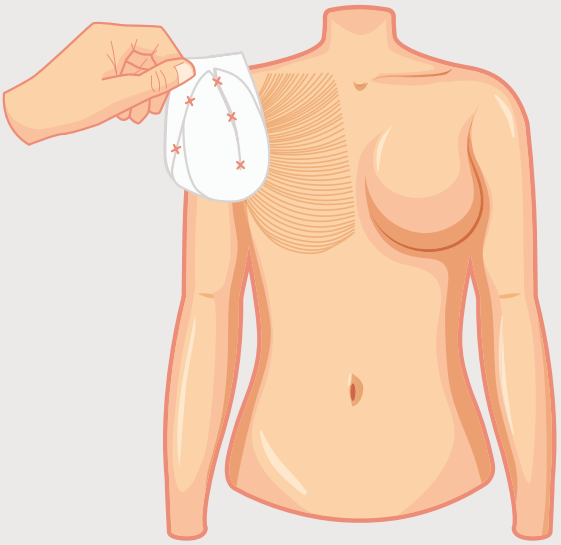
35′

45′

FINISH

60′





Questions & Answers

Is Braxon® supplied already shaped?
Yes – It is supplied pre-shaped to wrap around different sizes of mammary prosthesis.

How is the Braxon® customized to fit precisely around the chosen implant?
The surgeon adjusts the pre-shaped Braxon® on a sterile work surface as shown in the brochure.

Can I use different implant sizes and shapes?
Yes the pre-shaped Braxon® is adjusted to fit around any shape or sized implant.

What sutures should I use?
Absorbable 3/0 suture, single stiches.

How to suture?
Once the tailored customized ADM has been sutured in place around the chosen implant, the superior and upper medial and lateral edges are sutured onto the pectoralis muscle having elevated the patients upper body to check symmetry with the opposite breast.

How many drains and for how long?
The inflammatory response to the new Braxon® chemical-free ADM is much less, and as a result our experience has shown the drains can be safely removed within a few days, and certainly less than the 2 weeks necessary when alternative products are used.

What about capsular contraction and cosmesis?
To date, with long-term follow-up there has been no clinical evidence of capsular contraction around the sub-cutaneous placement of the Braxon®-wrapped implant.

Do I need to consider using a round implant to avoid the risk of rotation often seen in sub-muscular implant reconstruction?
No, since the Braxon®-wrapped implant is on top rather than underneath the muscle, it is not subjected to the rotational forces of muscular contraction, and also looks more natural when a shaped implant is employed. Nevertheless Braxon® can perfectly “dress” also a round implant, with same good cosmetic results.

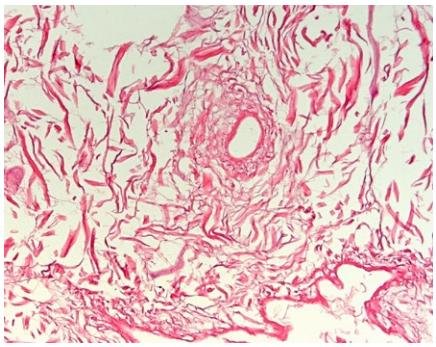
Braxon® bilateral implantation with anatomical implants 15 months postoperative photographs

References

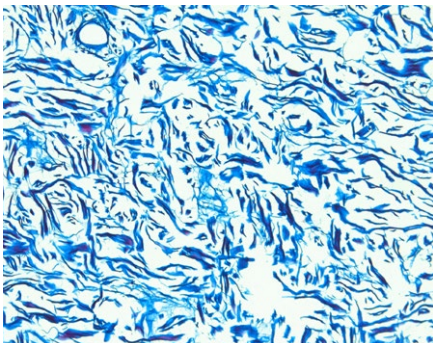
ADM Braxon® pre-shaped for total coverage of the breast implant.

BRX06S

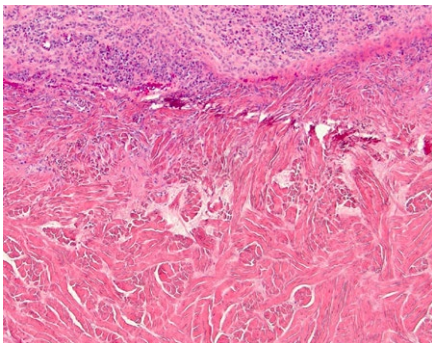
Histologies



I.



II.



III.

I. Hematoxylin-eosin staining of the sample implants Braxon® sterile, non-implanted. 10x magnification. The staining reveals the complete absence of cellular material. Observed transverse sections of pre-existing blood vessels which, while retaining their structure, ensure a more rapid permeation of the blood following implantation.

II. Azan-Mallory staining of sample Braxon® sterile prosthesis. 5X magnification. Highlights the collagen fibres of the matrix. Observed absence of cellular material.

III. Hematoxylin-eosin staining of the sample implants Braxon® 4 weeks following implantation. 5X magnification. The hematoxylin colours in violet cellular components showing a high degree of cellular infiltration.

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