The medical device industry is one of the most highly regulated markets in the world and safety is critical. Of course, CE certification is very demanding in terms of clinical evaluation. But plastic surgeons are also increasingly influenced by the amount of clinical data supporting the safety and efficacy of medical devices and even more since the recent PIP story and other scandals.

In this challenging context, Sebbin has been building and supporting over 10 clinical trials throughout Europe with a clear objective: provide our customers and the competent authorities with strong data about the safety and efficacy of our products.

Our efforts are now starting to bear fruit with first publications and congress communications. The aim of this aptly named newsletter is to provide you with a FOCUS about new published data on our products, but also about recent or upcoming congress communication and studies in progress.

In this first release of FOCUS, among other topics, we are particularly proud to let you know we’ve just launched a PHD thesis with 2 major Universities on the very topical subject of breast implant texturation.

So stay up to date and FOCUS!
Sebbin lipofilling devices show improved fat graft survival

In a prospective study, Nelissen et al. recently included 23 patients having undergone breast reconstruction with DIEP and who required a lipofilling adjustment. All surgeries were performed using the MACROFILL single use kit. Fat resorption was analyzed using the three-dimensional photography VECTRA system. Injections were carried out on irradiated breasts in 73% of cases, and average injection volume was 124 mL (SD = 39 mL), whereas average operating time was 68 minutes (44-96 minutes). After an average follow-up period of 5 months (4-8 months), 70.9% of projection gain afforded by the lipofilling was still present.

In this study, Nelissen et al. demonstrated that the used of the MACROFILL system associated with its dedicated fat purification protocol permitted a drastic improvement in the fat survival rate when compared with conventional procedures, even including the most unfavorable case of post-irradiation DIEP breast reconstruction.


Fat graft survival represented as the evolution of breast projection at the injection area over the 4 months following surgery. Average for the population.
An analysis of Sebbin anatomically-shaped implants in the Aesthetic Plastic Surgery journal

The authors analyzed 5 commercially available anatomically-shaped breast implants from 3 different manufacturers (Allergan, Mentor, and Sebbin). Scanning electron microscopy, X-ray microtomography and mechanical scanning microscopy were used to characterize the shell texture. Human fibroblast adhesion to the shells was evaluated. 3D models of the implants were obtained using CT-scan acquisitions in order to analyze their shape. Implant stiffness was evaluated with a tractiome.

Major differences were observed in the topography of the textures of the shells, each having its “microscopic signature”. The data suggested superior adhesion for the Allergan and Sebbin textures compared with the Mentor texture; however, this difference was not statistically significant. The 3D analysis showed significant differences of shape between the anatomically-shaped implants of the 3 companies, despite their similar dimensions. Implant stiffness was comparable for the 3 brands.


You will find an updated list of publications about Sebbin products here.
In an in vitro study performed with the Massachusetts General Hospital, Boston, the authors compared Meso Biomatrix® with 5 others decellularized extracellular matrices (ECM) biomaterials (derived from dermis, small intestinal submucosa, and mesothelium).

The study included proliferation, apoptosis, chemotaxis, invasion and cell adhesion assays.

Meso BioMatrix® demonstrated characteristics that greatly facilitate scaffold incorporation, making it a promising choice for many clinical applications.


You will find an updated list of publications about Sebbin products [here](#).
The world’s largest experience on Sebbin custom thorax implants.
Presented at the 2015 London Breast Meeting and at the 2015 SOFCPRE congress.

Professor J-P. Chavoin (Toulouse, France) presented the world’s largest series of custom thorax implants obtained using the 3D technology with 484 cases operated to date. Spectacular outcomes were presented with only minor complications (only one reoperation out of 484 cases). The results of this study will be published in the May issue of PRS in: Correction of pectus excavatum by custom made silicone implant. Contribution of computer aided design reconstruction: 20 years of experience and 401 cases”.

**Chirurgie 3D par implants sur mesure, expérience de 484 cas et perspectives.**

Custom made implants for pectus excavatum
J-P. CHAVOIN. LONDON BREAST MEETING 2015.
**Evaluation of Sebbin gluteal implants in post-bariatric patients.**
Presented at the 2015 SOFCPRE congress.

Dr Philippe Levan’s team (Paris, France) presented a study comparing buttock augmentation using Sebbin implants and autologous flaps for patients having a bodylift after massive weight loss. The results showed an improved projection, and in particular an improved shape when using implants, with minimal complications.

**Bodylift associated to implant-based buttock augmentation. Preoperative (purple) and postoperative (blue) 3D models.**


**The first series of breast reconstruction using Meso Biomatrix®.**
Presented at the 2015 NVPC Congress.

The plastic surgery department of the Maastricht University Hospital presented their first experience with Meso Biomatrix® at the Dutch national congress. In twelve successive patients, one-stage implant-based breast reconstruction was performed using Meso Biomatrix® to cover the lower pole of the implant. Meso Biomatrix® was found to be thinner and more pliable when compared to other acellular matrices. Meso Biomatrix® proved simple to use and led to aesthetically satisfactory results.

Het gebruik van Meso Biomatrix® bij borstreconstructie met prothese: ‘one stage’- procedure

Sebbin new 10-year prospective study on silicone gel-filled implants.

In 2015, Sebbin launched its new 10 year prospective observational study of its silicone gel-filled breast implants. The study will include over 700 patients from all over Europe. Its main goal is to provide the scientific community with accurate data about the safety and effectiveness of Sebbin silicone gel-filled breast implants. The study is still at the patient inclusion phase, with more than 230 patients already included. Patients will receive follow-up for 10 years, with accurate monitoring of major and minor complications, patient satisfaction and their quality of life.

Multicenter observational study about Meso Biomatrix®.

A multicenter observational study began in mid-2016 about Meso Biomatrix®, a porcine peritoneum-based acellular matrix dedicated to breast reconstruction. The study covers the monitoring of about 70 patients undergoing immediate breast reconstruction. Its primary purpose is to evaluate the safety of the device.

Positioning of Meso Biomatrix

Already 18 patients have been included in the study, with extremely promising results so far!
Sebbin launches a PHD thesis about breast implant textures.

At the end of 2015, Sebbin officially launched a PHD thesis on the following subjects:

Morphological and physico-chemical characterization of the texture of breast implants and the relationship with their biocompatibility.
Upstream and clinical approaches.

The project is being hosted by Sebbin and two laboratories at major French Universities (LAMIH at the University of Valenciennes and IS2M at the University of Mulhouse)

The aim of this research is to improve understanding of the interaction between breast implant textures topographies and their biocompatibility. The project began with a detailed analysis of the different textures proposed by Sebbin. The LAMIH laboratory has been using cutting-edge technology imaging systems (electron scanning microscopy, interferometry and microtomography) to characterize all three textures of Sebbin implants.

Microtomography images of Sebbin microtexture (1), Sebbin texture on round implants (2), Sebbin texture on anatomically-shaped implants (3)

The research will last three years and this Newsletter will keep you informed about the results!
Breast implants


Tissue expanders


Macrofill/Microfill


- Girard, A.C., et al., [From biology to fat grafting: how to improve lipofilling]. Cir.plást. iberoameric, 2013. 39(Supl. 1).


Thorax implants


Meso Biomatrix
