



Sebbin  
PARIS

The partner your body can trust





SEBBIN

## The expert and partner you can trust

Sebbin has already provided you with excellent support for 30 years in your practice and your needs. Over three decades, Sebbin has developed unique expertise in the design and manufacture of implantable medical devices for cosmetic and reconstructive surgery, and has never stopped listening to you to innovate better.



## A large & comprehensive range of products

Serial or custom-made medical devices:

- Implants for the body (breast, gluteal, testicular, calf, thoracic)
- Implants for the face (chin and malar)
- Skin expanders
- Lipofilling and acellular matrix



## Manufactured in France

near Paris

## 200 associates

in France and internationally

## 20 professions

represented



## 2000 m<sup>2</sup> of surface

including 1000 m<sup>2</sup> of clean rooms

## A worldwide presence



- Headquarter and manufacturing site near Paris
- Subsidiaries - Direct sales
- Distributors in more than 60 countries
- ▨ Soon to be present



SEBBIN

## A committed brand

**Our expertise in silicone** allows us to offer a complete range of medical devices to meet your different needs, as well as a tailored approach of **custom-made medical devices** with a unique technology in the reconstruction market.



~  
Groupe Sebbin's  
commitment  
is empathized by  
our objectives  
~

#### YOUR SATISFACTION

As our customer and partner, our mission is to offer you the best possible products alongside premium services to ensure a complete satisfaction for you and your patients.

#### THE QUALITY OF OUR PRODUCTS

The quality of a product needs to be measured, verified and demands daily rigorous and precise monitoring. Each collaborator at Groupe Sebbin actively participates in this process.

At Sebbin, Quality is everyone's responsibility.

#### THE COMPLIANCE OF THE REGULATORY REQUIREMENTS

We must constantly adapt to attain **perfection**, improve our methods to remain efficient; and anticipate the changes in the market and its regulations.

We are subjected to regular inspections, both planned and unexpected, by our Notified Body as well as the French and International Health Authorities.



100%

of our products are controlled and verified one by one during the manufacturing process.<sup>(1)</sup>



3%

of our products are subjected to destructive mechanical tests to ensure continuous quality.<sup>(2)</sup>



Certifications

Our company is certified ISO 13485 and is in compliance with the requirements of the standard ISO 14607 for breast implants.



## Responsibility & transparency

### AS OUR CORE VALUES

Our **vision** of the plastic, reconstructive and aesthetic surgery market is **defined by the responsibility** that we share with our partners, both surgeons and patients, to empower each person that wishes to change or restore their body, **to do so with confidence** and with a sensible approach.

**Transparency** is one of Sebbin's core values: our production sites are open for visits, according to strict hygiene standards. Come to meet our team. (Please enquire to your local representative for more information).

Our clinical studies are fully published, without the parts written by the medical profession having been re-read, corrected or withdrawn.



SEBBIN

## Quality, diversity & creativity on all our ranges of products

We create, manufacture and distribute a wide range of implantable medical devices for plastic, reconstructive and aesthetic surgery.

In our manufacturing process, our company uses only medical grade, long term implantable raw materials, registered with the FDA (Food and Drug Administration).

Our silicone range covers **all breast surgery indications, with over 400 types of mammary implants available**, but also cases requiring gluteoplasty, skin repair, testicular or calf replacement.

We have also developed very specific products that can improve the aesthetics of congenital or acquired deformities such as nasal stents or facial implants.



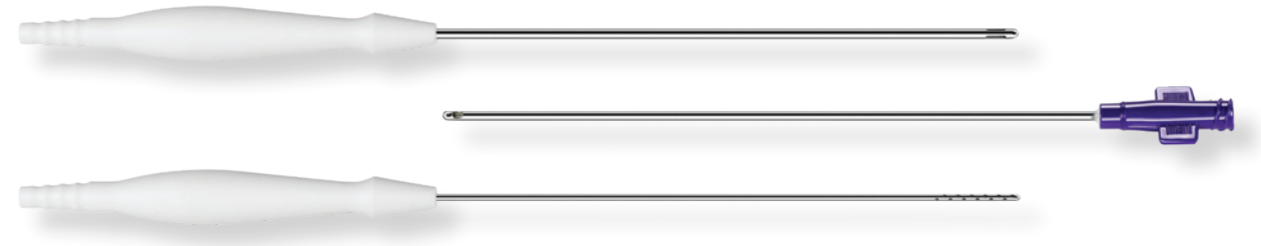
Smooth round breast implant



Micro-textured round breast implant



Smooth biconvex gluteal implant



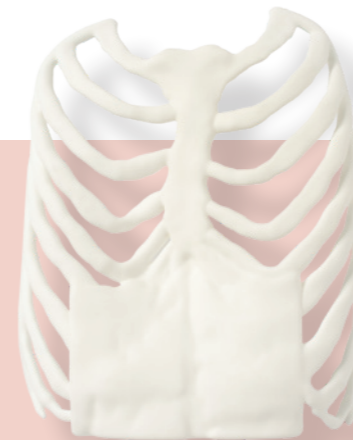
Cannulas for lipofilling procedures

### Comfort, peace of mind and safety with our additional products

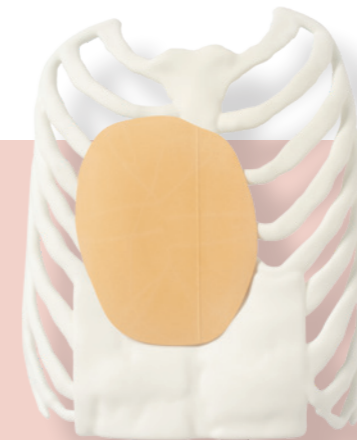
To allow maximum comfort in the use of our products, for you and the patients carrying them, we offer several options of additional related products.

The **lipofilling** range consists of single-use, sterile medical devices for the safety of the patients. It offers the tools to safely and confidently perform this fat treatment technique, after collection of the adipose cells and before their re-injection.

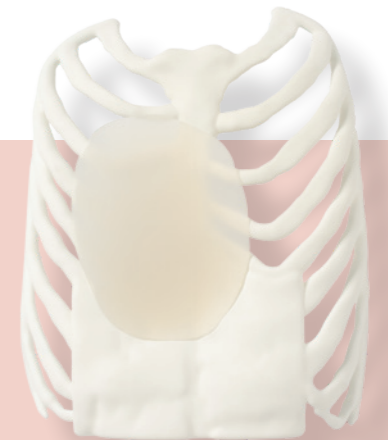
For breast reconstruction, our **acellular matrices** aim to strengthen the soft tissues that can be fragilized by post-mastectomy radiation treatments. These matrices reinforce a weakened skin to better support the implant and give more comfort to the patient<sup>(3)</sup>.



Deformed thorax



Deformed thorax with 3D prototype



Deformed thorax with definitive implant

### AnatomikModeling partnership: the strength of custom-made solutions

Thanks to our exclusive partnership with AnatomikModeling, we can offer unique solutions tailored for the treatment of **individual situations**, including cases of Pectus Excavatum or Poland's syndrome but also all types of custom-made implants. This is made possible by **millimeter-scale** accuracy cuts of the patient's scanner images. With this state-of-the-art technology, the aesthetic results of this type of surgery are improved and the lifetime of the implant extended<sup>(4)</sup>.



## The best of the safety guaranteed

As the surgeon's partner, we want you to trust that our commitment to quality is at the core of all our processes. For more than 30 years in the conception and fabrication of implantable medical devices for the plastic, reconstructive and aesthetic surgery, we guarantee:

- ✓ The use of biocompatible, medical grade, raw materials that can be implanted in the long term, in accordance with our specifications.
- ✓ The continuous improvement of our manufacturing processes and associated controls, recorded and archived for 30 years, in accordance with standards NF EN ISO 9001: 2015 and NF EN ISO 13485: 2016 which govern them.
- ✓ Products that comply with standards NF EN ISO 14630: 2013 and NF EN ISO 14607: 2009 to meet European directive 93/42.
- ✓ A traceability system to identify the raw material from which each implant was designed until its delivery, using the unique serial number associated with each medical device.

Strengthened by the results of a 10-year clinical study on our mammary implants<sup>(5)</sup> and to ensure our long-term commitment, Sebbin offers its warranty<sup>(6)</sup> to offer patients peace of mind.

SEBBIN

## Discover our manufacturing site & our professional training program



### AT THE HEART OF OUR PRODUCTION

We welcome you anytime to visit our factory. It gives us the chance to present our team, answer all your questions and reinforce the trust in our partnership, essential in our eyes, to the utmost use of our medical devices.

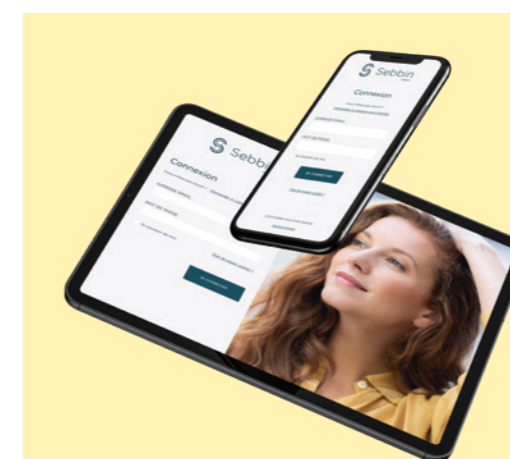
### WELCOME TO SEBBIN UNIVERSITY

At the cutting-edge of innovation and surgical technologies, we invite you to participate in our Sebbin University programs that we organize all around the world (Europe, Latin America, Asia...). Alongside your peers, you will attend broadcasted live surgeries or participate in workshops. These interventions cover various plastic surgery specialties, from composite breast augmentation to implant-based reconstruction, facial lipofilling or gluteal augmentation surgeries.

The Sebbin University, real training program, is also a moment of exchange and fellowship.



Sebbin **UNIVERSITY**



### MySebbin

#### AN INTERACTIVE CATALOGUE FOR A SMART CHOICE

To ease and secure your experience, the interactive catalogue MySebbin gives you the opportunity to select with a few clicks the best medical devices for the needs of your patients and to finalize your order after the patient's confirmed satisfaction.



SEBBIN

## The tradition of innovation

For the past 10 years, Groupe Sebbin has launched an average of two new products per year covering all plastic surgery specialties.



### A very active Scientific Board

Every launch of an innovative product is first discussed and approved by Sebbin's Scientific Advisory Board which is composed of scientific experts in each specialty of plastic surgery; they guide and approve each new product development.

It is our key surgeons, users of our products, that speak best about them in numerous publications.<sup>(7)</sup>

### Ongoing assessments

The clinical assessment of our products is conducted by independent surgeons. Groupe SEBBIN set up an international prospective multicenter study on the monitoring of over 900 patients over a period of 10 years.

This study, on prefilled silicone mammary implants, is conducted in 15 private medical facilities or universities all over Europe. To our knowledge, it is the largest of its kind industry-sponsored clinical trial in Europe.

Today, **9 clinical studies<sup>(8)</sup>**, French and International, are ongoing and concern over 3000 patients carrying our medical devices.



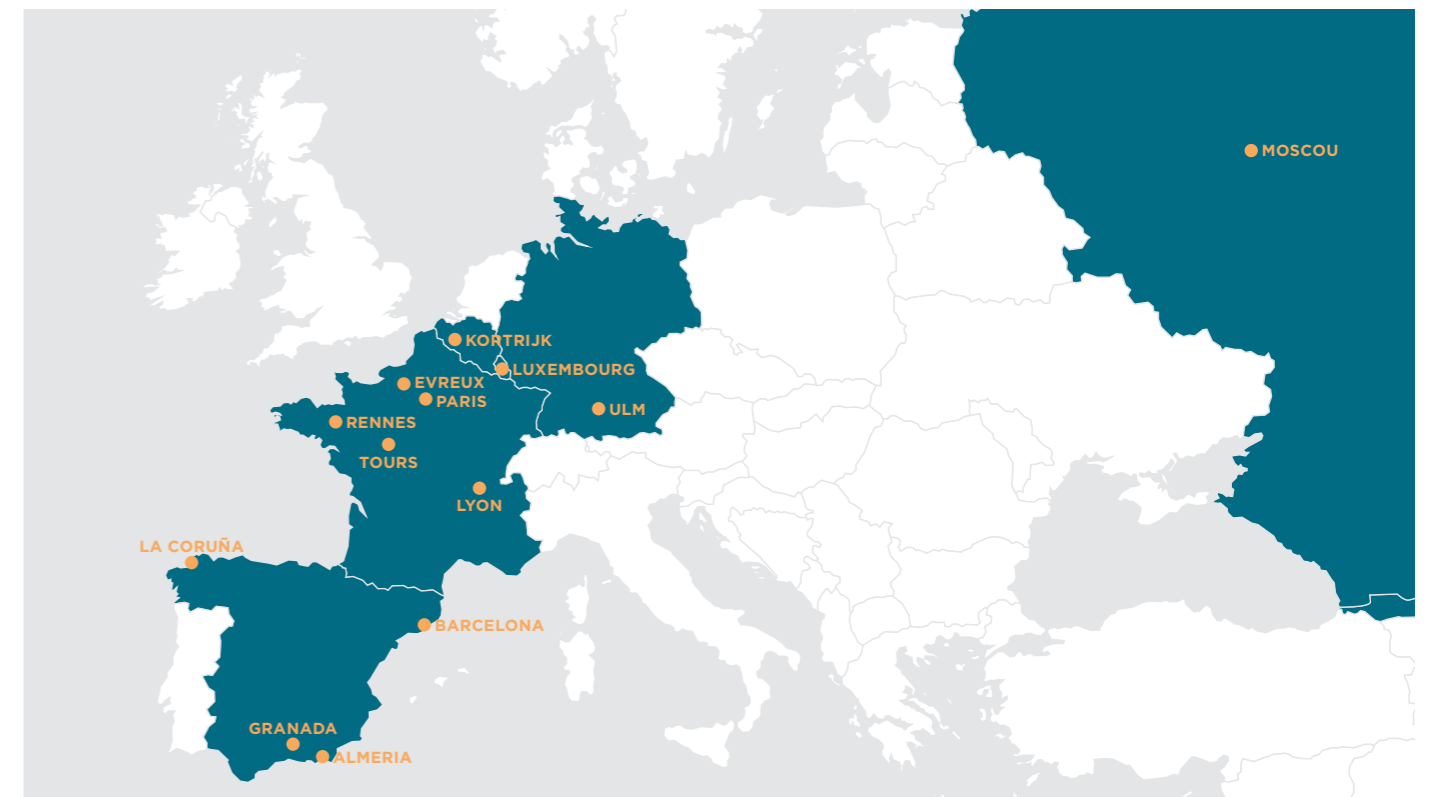
Nasal stent



Trimmed nasal stent



Fat Washer





## Sources

- (1) Production flowchart PROD-IT-7.5-001 à 011.
- (2) Production flowchart PROD-MOD-7.5-005.
- (3) DSM Biomedical internal data. In vitro and bench test results are not necessarily indicative of clinical performance.
- (4) Chavoïn J.P., André A., Chaput B., Garrido I., Moreno B., Dahan M., Grolleau J.L. Chirurgie des malformations congénitales et techniques de reconstructions assistées par l'informatique. Chirurgie Plastique de l'Enfant et de l'Adolescent, SAURAMPS MEDICAL 2015 sept 15:252-256.
- (5) Robert El-Haddad, MD, Béatrice Lafarge-Claoue, MD, Charles Garabedian, MSc, and Sylvain Staub, MD - A 10-Year Prospective Study of Implant-Based Breast Augmentation and Reconstruction.
- (6) GS166-F-Vxx-xxxx/xx.
- (7) List of publications about Sebbin products. Document du Groupe Sebbin reprenant les différentes publications avec leurs liens pour un accès direct vers les documents cités ou leur résumé.
- (8) IM02 - A ten-year prospective study of implant-based breast augmentation and reconstruction.  
  
IM11 - Analyses génomique et histologique d'échantillons de capsules périprothétiques d'implants mammaires.  
  
IM12 - Etude rétrospective monocentrique d'une série de patients ayant bénéficié d'augmentations ou reconstructions mammaires par implants gonflables SEBBIN.  
  
IM13 - Etude rétrospective d'une série de patientes ayant bénéficié d'une augmentation mammaire avec les implants INTEGRITY.  
  
AU08 - Retrospective analysis of a series of patients with calf augmentations performed using SEBBIN implants.  
  
AU09 - Prospective observational study about SEBBIN silicone gel-filled calf implants.  
  
AU10 - Prospective observational study about SEBBIN silicone gel-filled testicular implants.  
  
AU14 - Etude rétrospective d'une série de patients ayant bénéficié d'implants testiculaires du Groupe SEBBIN.  
  
LI09 - Etude rétrospective d'une série de patients ayant bénéficié d'un transfert de graisse autologue avec le dispositif Fat Washer 800.





This document is intended for healthcare professionals.  
According to the Medical Device Directive 93/42/EEC, products presented in this document are Class IIa to Class III medical devices. They are intended to be used in plastic, reconstructive and aesthetic surgery. GROUPE SEBBIN reserves the use of its devices for physicians trained in the techniques of plastic, reconstructive and aesthetic surgery.  
Please read the instructions for use carefully before use. They are available on the private access section of our website [www.sebbin.com](http://www.sebbin.com).



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