

ORDERING PROCESS

of 3D custom-made implants



3D custom-made implants

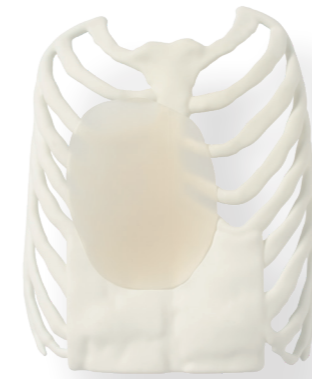


Sebbin
PARIS

The partner your body can trust

A Simple Process

The custom-made implant design and manufacturing process takes 8 to 12 weeks minimum after the surgeon has approved the design.



Thorax specimen with implant



Implant specimen



1

CT SCAN

The patient's entire chest is scanned

- Supine with arms along the body
- 1 to 1.2 mm thick DICOM standard-format cuts
- Medical tomography with a CT scan or mediastinal filter to achieve a good contrast



2

PATIENT SCAN AND PRESCRIPTION SENT

The surgeon gives the CD and the prescription to his Sebbin representative.

The prescription must include:

- Surgeon's name and contact details
- The identification of the patient: first and last name, gender, city or the identification code given by the prescriber allowing the traceability of the implant*
- Any technical particularities
- Sentence to be written: "This custom-made medical device is intended for the patient, subject of this prescription".

*Identifier code in the format AABbdmmyyCC (AA = first 2 letters of the patient's last name; BB = first 2 letters of the patient's first name; ddmmyy = date of the prescription; CC = first 2 letters of the prescriber's name).



3

QUOTE DRAWN UP

Once the quality of the scanner data and the feasibility of the project have been validated, Groupe Sebbin establishes a quotation.



4

QUOTE APPROVED AND ORDER CONFIRMED

The design of the implant can proceed only if payment conditions are fulfilled. For payment conditions, the surgeon should contact his Sebbin representative.



5

3D IMPLANT DESIGNED AND APPROVED BY THE SURGEON

AnatomikModeling starts the 3D implant design and sends to the surgeon a PDF file "3D_implant specifications / Validation-document.pdf" by email, including:

- The implant specifications: 3D images, size, volume, thickness, different views...
- Documents related to the placement of this implant and medical follow-up
- A form to approve the 3D implant design.

The surgeon must carefully review the proposed design of the implant, to ensure it meets his expectations. The surgeon may contact AnatomikModeling for any questions or requests for modifications.

In case a modification is required, a new specification document will be sent by AnatomikModeling to the surgeon for approval.



6

IMPLANT MANUFACTURED AND STERILISED

Once the design of the implant has been approved by the surgeon, AnatomikModeling makes the prototype and sends it to Groupe Sebbin.

From the prototype, Groupe Sebbin manufactures the mould and then the implant, which is then sterilised.

Once the implant has been sterilised, Groupe Sebbin prepares the packaging with the appropriate documents and establishes the CE declaration of conformity (available on request).



7

DELIVERY

The sterile implant and its non-sterile prototype are delivered.

The prototype will be used for preoperative marking.

8 TO 12 WEEKS



The partner your body can trust

IMPORTANT

This document is intended for health professionals. The custom-made implants are Class IIb devices designed to be used in plastic, reconstructive and cosmetic surgery. Groupe Sebbin only allows its devices to be used by medical professionals trained in plastic, reconstructive and cosmetic surgery.

In accordance with Medical Devices Directive 93/42/EEC, the custom-made implants are manufactured and distributed by Groupe Sebbin. Being custom-made, the product does not have a CE mark. However, it does meet all the requirements of Directive 93/42/EEC and is manufactured in line with our ISO 13485 quality management system.

The cost of custom-made implants may be refunded by health insurance providers with prior agreement.

Please check the arrangements in your country.

Please read the Instructions for use carefully before use. They are available in private access in www.mysebbin.com.

MANUFACTURER

Groupe Sebbin SAS

39 Parc d'Activités des Quatre Vents 95650 Boissy-l'Aillerie FRANCE

Email: contact@sebbin.com

 [@groupe_sebbin](#) -  [Groupe Sebbin](#)

www.sebbin.com

3D DESIGN AND TRAINING

AnatomikModeling

19 rue Jean Mermoz 31100 Toulouse FRANCE

Email: contact@anatomikmodeling.com

 [AnatomikModeling](#) -  [anatomikmodeling](#)

Professional documentation on 3D custom-made implant (surgical procedures, operation videos, webinars, etc.) is available in the professional area of the website.

www.anatomikmodeling.com

Postal address

39 Parc d'Activités des Quatre Vents CS80010 Boissy-l'Aillerie 95651 Cergy-Pontoise Cedex FRANCE