ORDERING PROCESS

of 3D custom-made implants





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A Simple Process

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



CT SCAN

The patient must undergo a CT scan of the entire area to be treated.

For Pectus Excavatum and Poland syndrome: The patient should lie on the back with arms on the sides along the body

For calves: dorsal position, legs stretched out, wedge under the talons to avoid the calves to be crushed, and feet vertical to the zenith for a strict frontal and parallel incidence.

A photo of the front and back of the legs (standing with the feet parallel) is also required.

For the skull: the whole head, dorsal position and arms on the sides along the body.

Specificities for each scanner: - 1 to 1.2 thick DICOM Standard format cuts.

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 AABBddmmyyCC (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)

QUOTE DRAWN UP

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

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.



Thorax specimen with an implant

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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.

questions or requests for modifications. AnatomikModeling to the surgeon for approval.

IMPLANT MANUFACTURED AND STERILISED

makes the prototype and sends it to Groupe Sebbin. 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).

DELIVERY

The sterile implant and its non-sterile prototype are delivered. The prototype will be used for preoperative marking.







Specimen of calf implants

Specimen of skull with implant

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

In case a modification is required, a new specification document will be sent by

Once the design of the implant has been approved by the surgeon, AnatomikModeling

From the prototype, Groupe Sebbin manufactures the mould and then the implant,

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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 2005/745/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 meets all GSPR safety and performance requirements.

In France, custom-made implants can be reimbursed by health insurance organisations after prior agreement.

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

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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





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