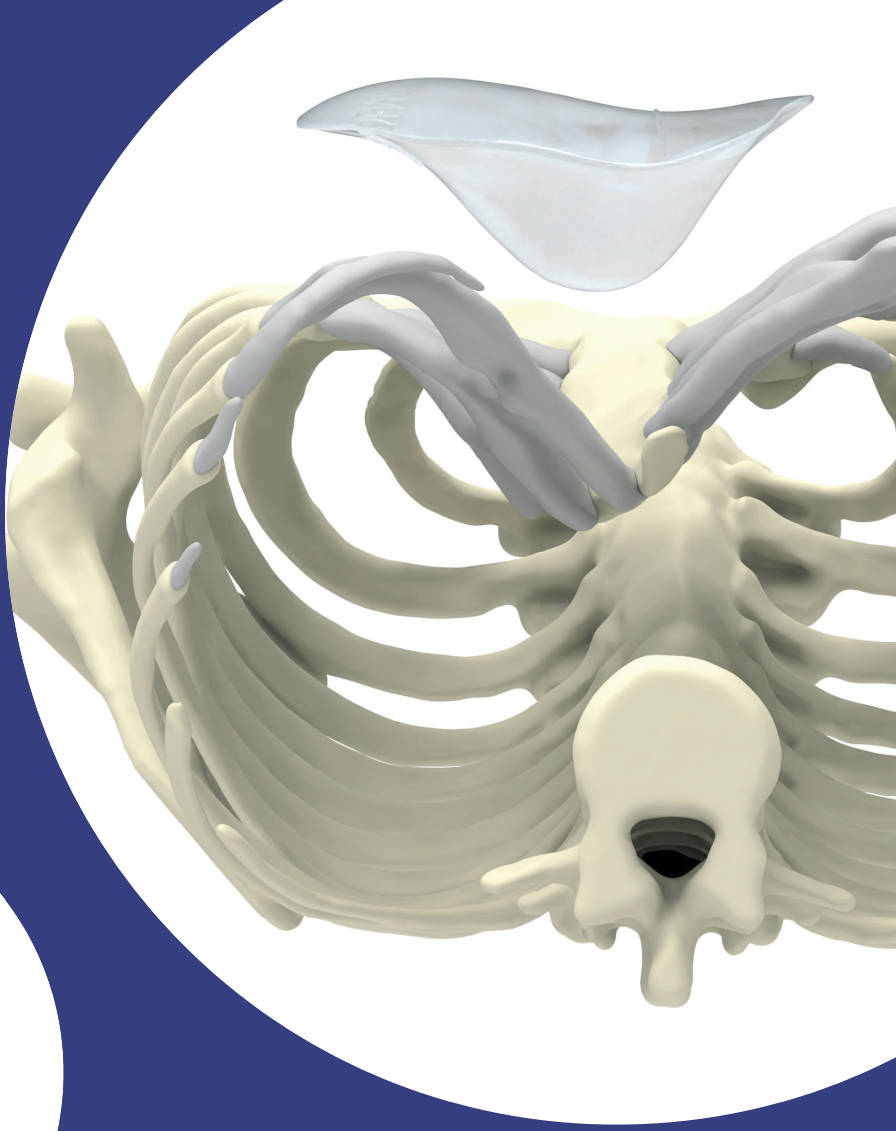


ORDERING PROCESS

of 3D custom-made implants

Anatomik Modeling

3D custom-made implants

Implantech®

Facial and Body Implants

A Simple Process

The custom-made implant design and manufacturing process takes 4 to 6 weeks after the surgeon has approved the design.

It is recommended to wait for the confirmed delivery date of the implant before setting a firm surgery date. If a specific date is required in the near future, the AnatomikModeling customer service must be notified by email to assess feasibility.

1

CT SCAN AQUISITION & PHOTOS

CT SCAN: The patient must undergo a CT scan of the entire area to be treated.
For Pectus Excavatum and Poland syndrome: patient lies in supine position with **arms on the sides along the body**, not elevated
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.
Specificities for each scanner:
• 1 to 1.2 millimeters thick slice DICOM Standard format,
• no need of contrast product.

PHOTOS: It is recommended to take photos of the patient (without distinctive signs) during the consultation:
• Poland and Pectus: front, 3/4 and low angle views of the chest, arms along the body
• Calves: front and back views of the legs, standing, feet parallel
These photos will help with the design beyond the CT scan, especially for women, adipomasties, subcutaneous tissue atrophies (Poland syndrome) or atypical cases.

2

SENDING OF PRESCRIPTION, CT SCAN & PHOTOS

The surgeon informs AnatomikModeling customer service by email of a new case and sends the completed and signed prescription to: customerservice@anatomikmodeling.com
Find the prescription model to complete here :
www.anatomikmodeling.com/sites/default/files/Prescription.pdf

AnatomikModeling sends a secure link to upload the CT scan datas and photos on our server.

Alternatives to send patient datas:
• via access to the hospital's PACS
• by mail to:

AnatomikModeling – Customer Service
7 bis rue des Capucines
31320 Castanet-Tolosan, France

3

QUOTATION ISSUING

Once the quality of the scanner data and the feasibility of the project have been validated, AnatomikModeling issues a quotation to be returned signed by the surgeon, along with a 100% deposit (Public hospital may issue a purchase order instead).

4

ORDER CONFIRMATION

Upon receipt of the signed quotation and the 100% deposit (or the hospital's purchase order), the order is confirmed. Implant design can begin.

5

3D IMPLANT DESIGN & VALIDATION

AnatomikModeling starts the 3D implant design and sends to the surgeon a Design Validation Document (PDF file) by email, including:
• The implant specifications: 3D images, size, volume, thickness, different views, durometer,
• Documents related to the placement of this implant and medical follow-up,
• A form to approve the 3D implant design and the implant's terms of use.

The surgeon must carefully review the proposed design of the implant, to ensure it meets his expectations. If it is the case, he has to fill out and sign the validation form and send it by email to: customerservice@anatomikmodeling.com.

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 MANUFACTURING

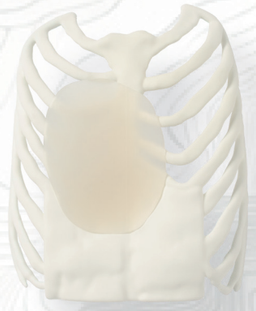
Once the implant design is approved, AnatomikModeling initiates the final manufacturing of the silicone implant with Implantech (3D Accuscan Patient-Specific® Implants).
The final silicone implant is sterilized and packaged with the necessary documentation, along with the template used for preoperative drawing.

Implantech issues the CE declaration of conformity (available upon request).

7

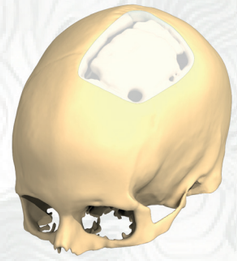
DELIVERY

AnatomikModeling receives the implant and forwards it to the healthcare facility.



Thorax specimen with an implant

Specimen of calf implants



Specimen of skull with implant

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IMPORTANT

This product was designed for use by licensed physicians with proper training and experience. Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the suitability of the procedure based upon current accepted techniques, a thorough evaluation of the patient, individual judgment, and experience.

In accordance with Medical Devices Directive 2005/745/EEC, the custom-made implants (3D Accuscan Patient-Specific®) are manufactured by Implantech and designed and distributed by AnatomikModeling. Being custom-made, the product does not have a CE mark. However, it meets all GSPR safety and performance requirements.

Professional documentation on 3D custom-made implant (surgical procedures, surgical videos, webinars, etc.) is available in the professional area of the website: www.anatomikmodeling.com/en/user/register

3D DESIGN, TRAINING AND DISTRIBUTION

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@implantechassociates - Implantech Associates, Inc.
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