AccuraMesh^{tm} Design Verification Form

Step 1:
Customer uses this order form and sends it together with CT/CBCT scan directly to ZimVie (we transfer) to accuramesh@zimvie.com and cc to info@implacom.nl

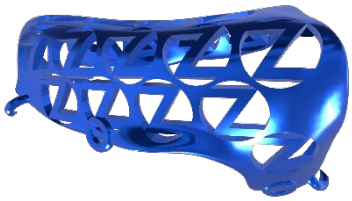
Step 2:
ZimVie sends design draft directly to client for approval and will cc Implacom in this mail info@implacom.nl

Step 3:
Once approved by client, client places the order using this order form and sends it to info@implacom.nl.
Implacom will place the order with ZimVie.

Please fill-in the following information

Account Number: _____
Customer name: _____
E-mail: _____
Patient ID (code, initials): _____
Defect Site: _____
Number of planned implants & length: _____

AccuraMesh



Design Revision Number: _____
Date of Revision: _____
Mesh Dimensions (….x….x….mm): _____
Mesh Material: _____
Total Grafting Volume cc: _____
Quantity of screws: _____
Length of screws: _____

Product Code	Description	Price excl 9% VAT	Quantity
TICMS	Titanium AccuraMesh Standard (until 6 missing teeth)	420,00 €	_____
TICML	Titanium AccuraMesh Grande (7 or more missing teeth)	670,00 €	_____
PCMS	PEEK AccuraMesh Standard (until 6 missing teeth)	585,00 €	_____
PCML	PEEK AccuraMesh Grande (7 or more missing teeth)	817,50 €	_____

*Prices are exclusive of VAT and shipping costs | the prices are given for information and can be subject to modification | Version 1 aug.2023 | D-IN-01b

AccuraMesh Validation Terms:

By placing an order at ZimVie, a unique lot number for the requested medical device will be created. This validation term informs you about the precision and conformity of the geometrical data of the mathematical files related to the clinical case, about the technical feasibility of the requested product that was verified by quality analysis staff. Based on the information and data provided, ZimVie confirms the technical feasibility of the manufacturer and deliver requested product under the following conditions:

1. Medical device design, according to (I) the anatomy shown in the provided patient CBCT-/CT scan and (II) the specifications defined by the prescribing physician, which will be kept on file in accordance with legal provisions.
2. Usage of (I) surgical grade titanium powder as raw material for the implant manufacturing process, by selective laser melting or (II) implantable grade PEEK by fused deposition molding (FDM)
3. Complying with all requirements of Regulation 2017/745 of 5 April 2017 in its actual redaction and the applicable Portuguese local law.
4. Prescribing physician will be responsible for the correct use of the medical device.
5. All the parameters used for the design are read from the DICOM file provided Dentist/Surgeon.

The Validation Term is an essential and mandatory element for the manufacturing of the custom-made medical device.
By signing this design verification form, I accept the design proposal in its revision number and date of revision shown above in accordance with the AccuraMesh Validation Terms. I shall be solely responsible for the information/data provided to ZimVie through the DICOM file.
For any clarification, contact us using contact details shown on the top of the form.

Full Name of Signatory: _____

Date & Signature (Dentist/Surgeon):
_____

Stamp