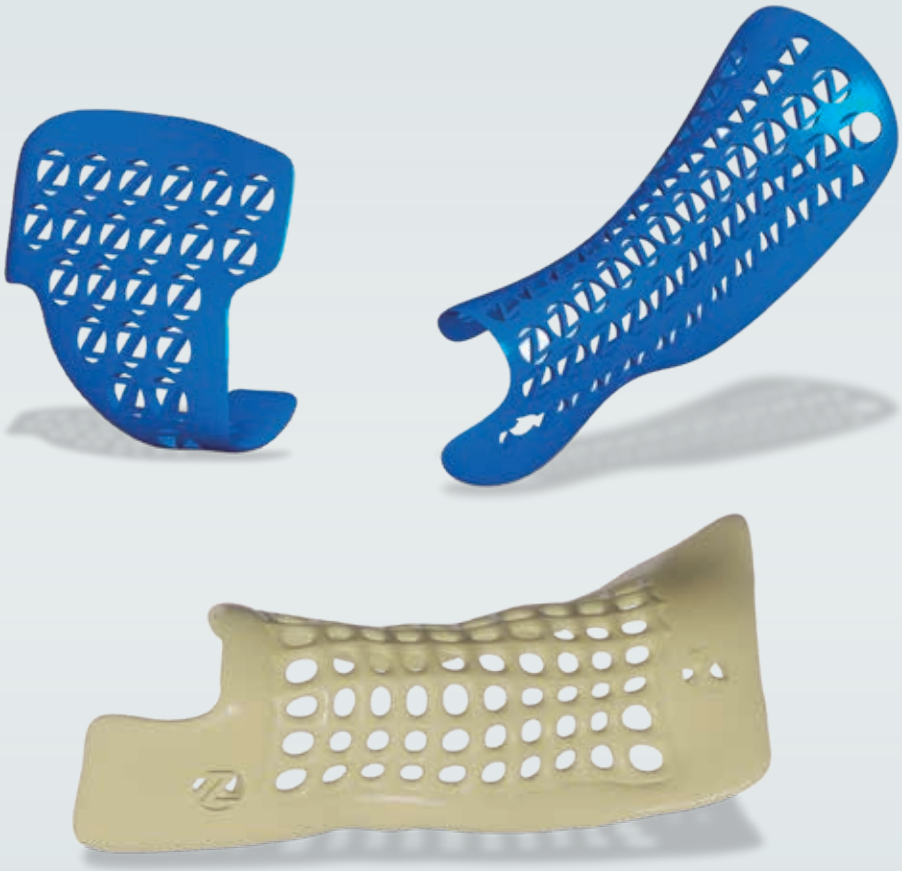
CuztomGraft Solutions™
for Guided Bone Regeneration

AccuraMesh™



ZimVie

AccuraMesh Products

CuztomGraft Solutions for Guided Bone Regeneration

Bone regeneration procedures and techniques have advanced the way that hard tissue is rebuilt prior to implant placement. Bone blocks and bone graft particulates are available from a choice of human, animal, or synthetic origin. However, most of the available products are pre-shaped and need to be adapted to the defect site. Their surfaces require manipulation in order to achieve ingrowth of blood vessels and vascularization of the graft material.[1]

Now, with the widespread use of digital technologies in modern dentistry, clinicians have the advantage of using 3D imaging systems, 3D-printed guides, or patient-specific prosthetic components to achieve customized solutions. Pre-designed bone grafting materials can be manufactured based on a CBCT/CT scan of the patient's defect area.

Introducing ZimVie Dental AccuraMesh! Available in either Titanium or PEEK, ZimVie Dental AccuraMesh is designed using a fully digital workflow. Data from 3D medical imaging devices combined with modern Computer-Aided Design (CAD) software and state-of-the-art Computer-Aided Manufacturing (CAM) processes result in high-quality customized medical devices for guided bone regeneration procedures.[2]

Your Benefits

ZimVie Dental AccuraMeshes have the following features:

1

Two Material Options Available

- PEEK
- Titanium

2

Pre-Planned Screw Positions

- Reliable fixation
- Reducing the risk of touching sensitive anatomical structures[3]

3

Sterile Packaged – Ready for Use

- 10^{-6} Sterility Assurance level[4, 5]

4

Space Maintaining

- Protects and secures bone graft particulates for undisturbed healing[6]

5

Reduced Surgery Time and Morbidity

- Additional manual adjustment of the defect and of the customized meshes is seldom required, allowing for reduced surgery time and reduced morbidity[7, 8]

Two Different Raw Materials, Two Different Products

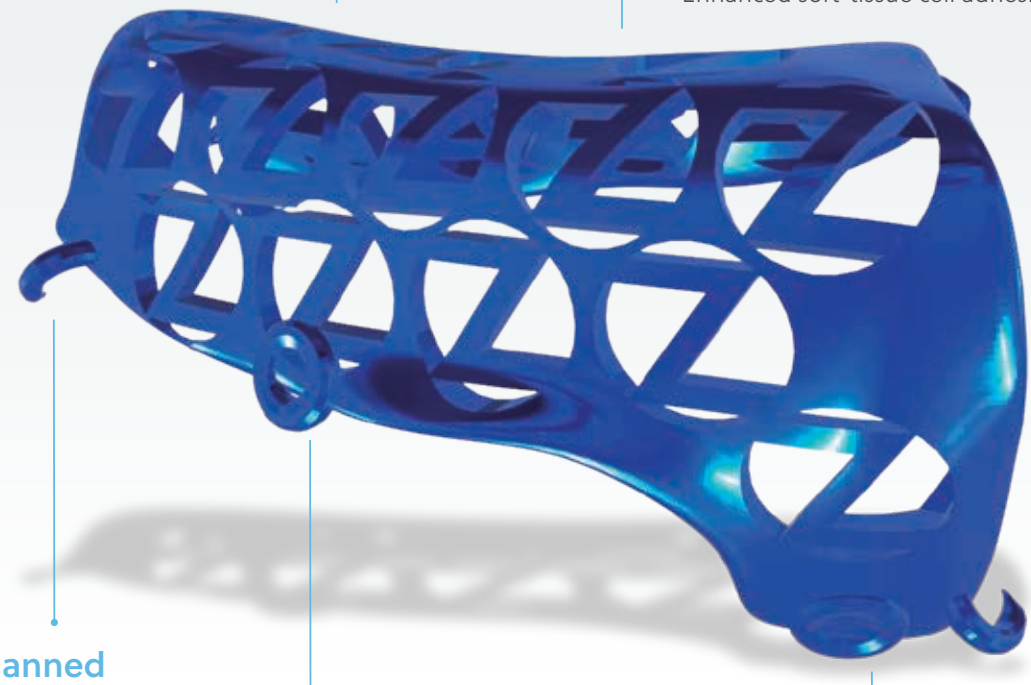
Titanium AccuraMesh

Made of Surgical Grade Titanium Alloy by Selective Laser Melting Technology[2,4]

- Proven biocompatibility[9]
- Strong enough to maintain space[4]
- High precision

Electropolished Surface[2]

- Reliable mesh removal[10]
- Reduced bacterial adhesion[11]
- Enhanced soft-tissue cell adhesion[12]



Pre-Planned Hooks

- Membrane fixation

Pre-Planned Screw Positions

- Reliable fixation

AccuraMesh Products

Two Different Raw Materials, Two Different Products

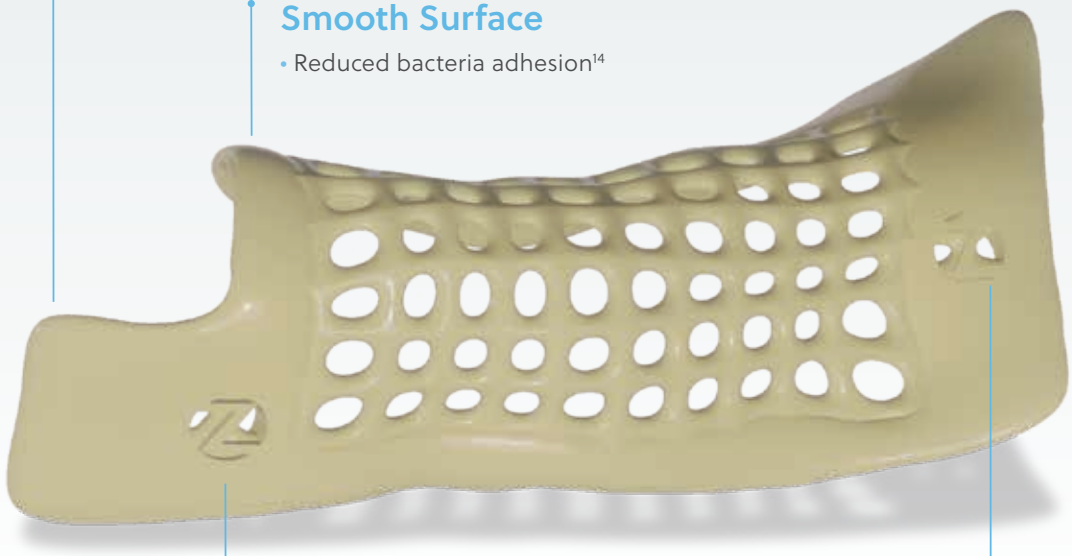
PEEK AccuraMesh

Made of Implantable Grade Polyether Ether Ketone Filament (PEEK) by Fused Deposition Modeling Technology

- Proven biocompatibility[13]
- Designed for long-term implantable medical devices[5]
- Residual metal ions according to ISO 10993-18 less than 0.5 ppm[13]

Smooth Surface

- Reduced bacteria adhesion[14]



Pre-Planned Screw Positions

- Reliable fixation

Please Note the Following Information

Imaging

Patient Preparation

- Remove temporaries and metal restorations, where possible
- Position patient in stable position

Imaging Requirements

- In general, most CT/CBCT devices are suitable
- Recommended slice thickness: 0.2 to 0.75 mm
- Gantry angle: 0°
- Open bite scan
- Please ensure that high-contrast imaging is achieved

Scan Data

- Do not use data compression
- Data must be provided in DICOM format only*
- Transfer the files using ZimVie Dental Upload website: **CuztomGraft.ZimVie.com**

Planning and Design

Design Draft

- You will receive by e-mail (I) a 3D-PDF file of the designed customized mesh and the defect site and (II) design & validation form
- To open the PDF files, Adobe Acrobat Reader is required
- Adjustments can be made at any time before final approval

Surgery

- Select proper flap design and soft-tissue management to ensure tension-free soft-tissue closure[15-18]
- Despite precise planning, the products may not fit as expected and minor manual adjustments may be required

Ordering Information

Item #	Description
TICMS	Titanium AccuraMesh Standard (up to 6 missing teeth)
TICML	Titanium AccuraMesh Large (7 or more missing teeth)
PCMS	PEEK AccuraMesh Standard (up to 6 missing teeth)
PCML	PEEK AccuraMesh Large (7 or more missing teeth)

AccuraMesh Products are class IIb medical devices.

* Please contact your radiologist or device manufacturer if you have any questions on DICOM export.

Design and Order Process

1. Data Submission

Fill in the product request form (online or using form ZV0586) and transfer together with CT/CBCT data (DICOM format required) using ZimVie Dental's upload website: **CuztomGraft.ZimVie.com**

2. Design Phase

The AccuraMesh will be designed according to the requirements written on the request form and you will receive an e-mail with a 3D-PDF file for review. Adjustments can be made to the design at any time prior to final approval.

3. Approval

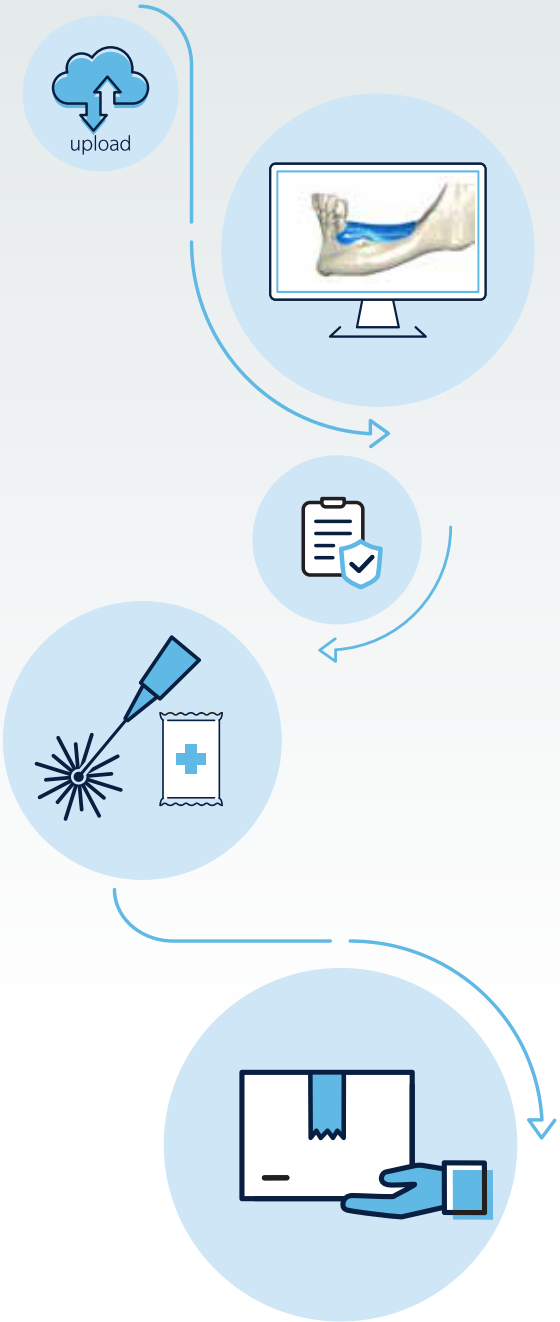
Once the design is finalized, your approval is required to release the mesh for manufacturing.

4. Manufacturing of the Mesh

Titanium AccuraMeshes are manufactured by Selective Laser Melting (SLM) and PEEK AccuraMeshes by Fused Deposition Modeling (FDM).
The final products are ETO sterilized and provided in a blistered, sterile packaging.

5. Shipment

Once the final design has been approved (step 3), the AccuraMesh will be released from manufacturing after approximately two weeks. The expected delivery date will be confirmed to allow you to schedule surgery accordingly.



Clinical Case

Fig. 1 Left posterior mandible defect.

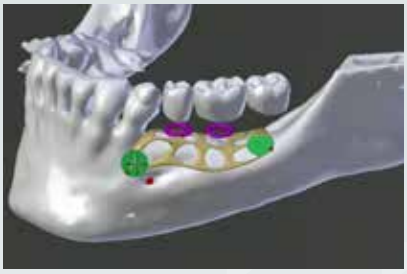


Fig. 2 Designed Titanium AccuraMesh, lateral view.

Fig. 3 Sterile Titanium AccuraMesh.

Fig. 4 Titanium AccuraMesh fixed in place with osteosynthesis screws. Site grafted with 50:50 mix of autogenous bone and xenograft.

Fig. 5 Titanium AccuraMesh covered with a collagen membrane.

Fig. 6 Radiograph taken after closing the surgical site.

Fig. 7 Soft-tissue after 6 months healing time before re-entry.

Fig. 8 Revascularized newly formed bone after mesh removal.

Fig. 9 Prosthetic restoration.

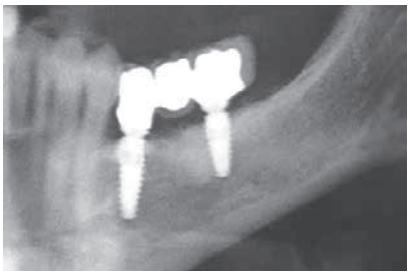


Fig. 10 Radiograph 1-year follow-up.

Clinical photographs courtesy of Dr. N. Cruz. Individual results may vary.

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Contact us by phone at
0800 652 1233 (UK) / 1 800 552 752 (Ireland)
or visit **ZimVie.com/dental**

ZimVie Dental Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: +1-561-776-6700
Fax: +1-561-776-1272
dentalCS@ZimVie.com

Biomet 3i (UK & Ireland) Ltd
Reading Business Centre
Suite 807, 8th Floor Fountain House
2 Queens Walk, Reading, Berks
RG1 7QF, United Kingdom
Phone (UK): 0800 652 1233
Phone (Ireland): 1 800 552 752
ZV.UKorders@ZimVie.com

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AccuraMesh products are class IIb medical devices.