

Accuracy

Efficiend

Patient Benefit



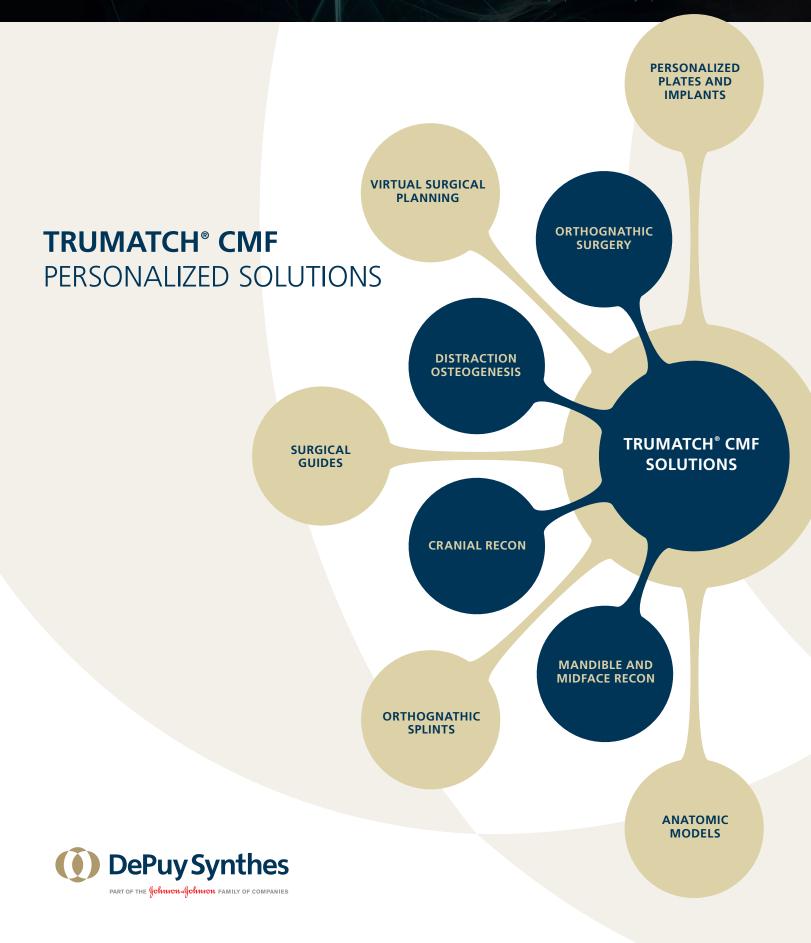




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Accuracy | Efficiency | Patient Benefit



TRUMATCH® CMF SOLUTIONS

Deliver advanced technology and procedural support for facial reconstruction, orthognathic surgery, distraction and cranial reconstruction.

Our total solution seamlessly integrates virtual surgical planning, intraoperative patient-specific tools and personalized implants to help achieve your goals of:

Accuracy

through visualization of anatomy and identification of surgical challenges within a 3D planning environment, intraoperative patient-specific tools to accurately transfer the plan to the OR, and personalized implants

Efficiency

through virtual surgical planning assisted by experienced clinical engineers to enhance preparation, surgical time and the number of procedural steps

Patient Benefit

by striving to achieve satisfying aesthetic results and reducing operative time¹⁻³

¹ Modabber A, Gerressen M, Stiller MB, Noroozi N, Füglein A, Hölzle F, Riediger D, Ghassemi A. Computer assisted mandibular reconstruction with vascularized iliac crest bone graft. Aesth Plast Surg 2012 Jun;36(3):653-659.

³ Hirsch JM, et al. A selective laser sintering guide for transferring a virtual plan to real time surgery in composite mandibular reconstruction with free fibula osseous flaps. Int J Oral Maxillofac Surg (2009), doi:10.1016/j. ijom.2008.11.026.



² Roser SM, Ramachandra S, Blair H, Grist W, Carlson GW, Christensen AM, Weimer KA, Steed MB. The accuracy of virtual surgical planning in free fibula mandibular reconstruction: comparison of planned and final results. J Oral Maxillofac Surg. 2010 Nov; 68(11):2824-32.



VIRTUAL SURGICAL PLANNING, PLATES, **GUIDES AND MODELS**

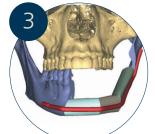
- Start by downloading the PROPLAN CMF[®] Connect and request a new account via the web interface (visit the North America section on www.trumatchcmf.com to access the download link and instructions)
- Alternatively, ask your Sales Consultant for support
- Create a new case, upload the patient CT Scan and fill in the preferences for the planning, guides, splints, models and implants
- Join the interactive virtual surgical planning session with an experienced clinical engineer
- Validate your virtual surgical plan, then the patient-specific tools and finally the personalized implants
- The guides, models and implants are manufactured and delivered to you
- You can now transfer the virtual plan to the patient, as you imagined it •
- The same process applies for the milled and 3D printed plates



CT Scan patient/ **Request for Service**



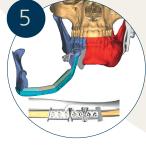
Interactive virtual planning



Approve plan and plate* preference



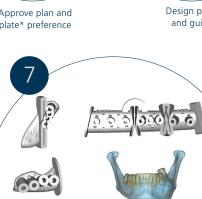
Design plate* and guides



Approve plate* and guides



Manufacture

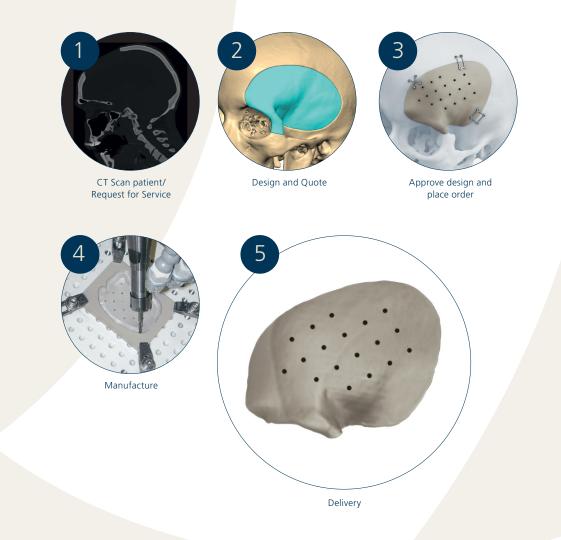




Deliver plate, guides, models, splints

PEEK (3D MILLED) AND TITANIUM (3D PRINTED) IMPLANTS

- Start by filling a Request for Service and upload the CT scan
- We will design the implant according to your instructions and provide a quote; if required, an interactive design session can be done
- Approve the implant when you are satisfied and place an order; your Sales Representative can help you with this
- We will manufacture the implant through milling or 3D printing, depending on the choice of implant
- The implant will be delivered to you



 The process for orthognathic surgery, distraction and cranial vault reconstruction follows a similar workflow. The process can be performed without personalized implants as well.



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VIRTUAL SURGICAL PLANNING

PROPLAN CMF®*

Technology for precise and accurate surgical planning

- 2D and 3D preoperative visualization of the patient anatomy and condition
- Virtual simulation and optimization of the skeletal osteotomies and reconstruction
- Improved communication between patient and surgery team
- Reduced surgical time¹—³**
- Making critical clinical decisions preoperatively
- Multiple cephalometric analysis options
- Soft-tissue simulation and photomapping (2D and 3D)
- Live interactive virtual planning session with a knowledgeable clinical engineering team
- No software installation or software knowledge required

PROPLAN CMF® Virtual Surgical Planning Services is the platform consisting of three modules:

PROPLAN CMF Software

Used to perform the virtual surgical planning. It is operated mostly by the clinical engineers located at Materialise during the live interactive sessions.

PROPLAN CMF Online

Web-based module intended to exchange information between DePuy Synthes sales representative, DePuy Synthes TRUMATCH[®] CMF Team and Materialise.

PROPLAN CMF Connect

The module for surgeon use. It allows case creation, data exchange, tracking and visualization of surgical plans, tools and implants.



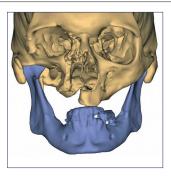






Mandible and Midface Reconstruction

- Preoperative planning for virtual simulation of resection, grafting and reconstruction
- Soft tissue simulation



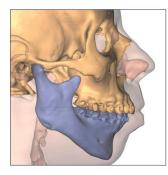


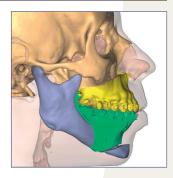
Orthognathic Surgery

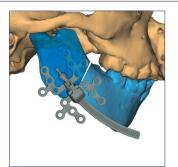
- Preoperative planning for virtual simulation of maxillary and mandibular osteotomies
- Cephalometric analysis
- Occlusion-based positioning
- Soft tissue simulation
- Photomapping

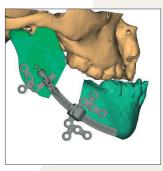
Distraction Osteogenesis

 Preoperative planning for virtual simulation of osteotomies, positioning of DePuy Synthes distractors and placement of footplates



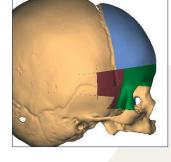


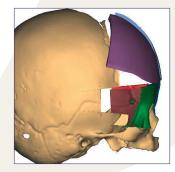




Cranial Vault Reconstruction

- Preoperative planning for virtual simulation of resection, grafting, reconstruction of bony segments
- Soft tissue simulation
- ** Results from case studies are not predictive of results in other cases. Results in other cases may vary.
- Modabber A, Gerressen M, Stiller MB, Noroozi N, Füglein A, Hölzle F, Riediger D, Ghassemi A. Computer assisted mandibular reconstruction with vascularized iliac crest bone graft. Aesth Plast Surg 2012 Jun;36(3):653-659.
- ² Roser SM, Ramachandra S, Blair H, Grist W, Carlson GW, Christensen AM, Weimer KA, Steed MB. The accuracy of virtual surgical planning in free fibula mandibular reconstruction: comparison of planned and final results. J Oral Maxillofac Surg. 2010 Nov; 68(11):2824-32.
- ³ Hirsch JM, et al. A selective laser sintering guide for transferring a virtual plan to real time surgery in composite mandibular reconstruction with free fibula osseous flaps. Int J Oral Maxillofac Surg (2009), doi:10.1016/j.ijom.2008.11.026.





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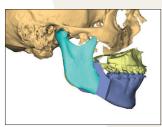


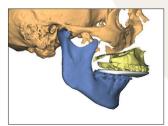
PATIENT-SPECIFIC ORTHOGNATHIC SPLINTS*

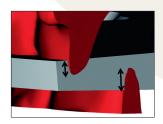
- TRUMATCH[®] CMF orthognathic splints are patient-specific surgical tools used to transfer the virtual plan to the OR, indicating the steps of the surgery based on the dentition (occlusal) information
- Intermediate and final occlusion splints available
- Multiple impression depth and buccal contour width available •
- Various options to submit occlusion data: physical plaster models, optical scans of the plaster models or intraoral scan (no plaster model needed at all)
- Made of sterilizable clear acrylic











Three tooth impression depths





Palatal strap for multi-piece maxilla



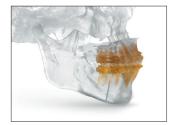
Wiring holes

ANATOMIC MODELS*

TruMatch[®]

- Tactile representation of the anatomy or preoperative plan for surgical simulation and communication to the patient
- Facilitate communication with the surgical team and patient
- Highlighted critical anatomical structures like tooth roots and nerves







*powered by materialise

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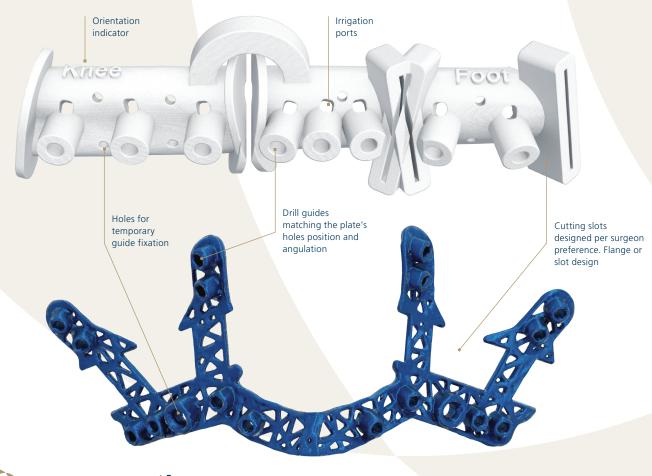
INTRAOPERATIVE PATIENT-SPECIFIC TOOLS

PATIENT-SPECIFIC SURGICAL GUIDES*

Designed to assist with osteotomies and to accurately transfer the virtual surgical plan to the surgical site

Some examples include, but are not limited to:

- Mandible and midface resection and drilling guides
- Graft harvesting and drilling guides (e.g. fibula, iliac crest, scapula)
- Osteotomy and plate positioning guide for placement of distractor footplates
- Surgical guides for segment and/or graft resection and segment (re)placement in cranial vault reconstruction
- Osteotomy and drill guide for orthognathic surgery (3D printed titanium)
- Osteotomy and drill guide for secondary osteotomy and repositioning of the Zygoma (3D printed titanium)







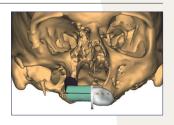
Resection and drilling guide for mandible reconstruction (polyamide)



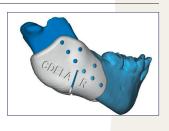
Graft harvesting and drilling guide (polyamide)



Resection guide for midface reconstruction (polyamide)



Osteotomy and foot plate positioning guide for distraction (polyamide)



Osteotomy guide for cranial vault reconstruction (polyamide)



Osteotomy and drill guide for secondary osteotomy and repositioning of the Zygoma (3D printed titanium)





Osteotomy and drill guide for orthognathic surgery (3D printed titanium)



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PERSONALIZED PLATES AND IMPLANTS

TITANIUM 3D PRINTED PLATES*

Guided system for bone part repositioning

TRUMATCH[®] CMF Titanium 3D Printed Plates and Guides is a direct and fully guided system for bone part repositioning. The system consists of patient-specific osteotomy and drill guides and patient-specific plates for the accurate transfer of the surgical plan to the operating room.

Orthognathics



TRUMATCH CMF Titanium 3D Printed Plates



TRUMATCH CMF Titanium 3D Printed Guides



Features and Benefits

Patient-Specific Plate Design

The location of screws and drilling vectors are defined in the planned position. Surgical access, bone volume and the avoidance of anatomical obstacles such as nerves and tooth roots are considered.

Retro Planning

Predetermined screw locations in the planned position are transposed back to the initial position.

Osteotomy and Drill Guide Design

Planned osteotomies, drill pilot hole locations and drilling vectors are integrated into the guide design, accurately transferring the surgical plan to the operating room.

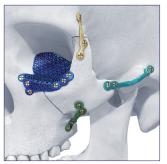
Plate-Guide Color Coding

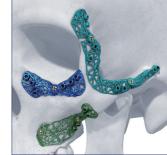
The guide and matching plate are color coded to help with identifying the right combination when multiple devices are used for the same surgery.

Designed for Matrix Compatibility

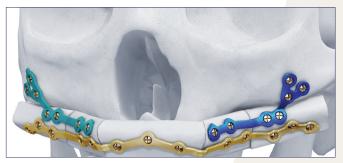
The plates and guides are designed and validated for compatibility with the MatrixMANDIBLE™, MatrixMIDFACE[™], MatrixORTHOGNATHIC[™] and MatrixNEURO[™] screws and drill bits, depending on the application.

Guided zygoma repositioning/ **Orbital floor reconstruction**





Midface reconstruction



Mandible reconstruction





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MANDIBLE RECONSTRUCTION

Titanium 3D Milled Reconstruction Plates

- Integrated with virtual planning and surgical guides
- Proven smooth and non-porous surface as for traditional implants
- Pure titanium grade 4

Features:

- Milled in 3D without bending for increased strength¹
- 2.0 and 2.5mm constant thickness for predictable strength across the plate length
- Locking holes that can be manufactured angled at up to 15° for improved access and avoidance of vital structures
- Compatible with all MatrixMANDIBLE[™] Locking and Nonlocking Screws for required stability
- Reduced hole spacing of 5.5mm between adjacent holes for increased number of fixation points in small spaces

Titanium 3D Printed Reconstruction Plates*

- Hole angulation of max 15°
- Thickness 2.0 to 3.0mm
- Minimum screw hole spacing of 8mm
- Compatible with all MatrixMANDIBLE Non-locking Screws
- 3D printed commercially pure titanium

Features:

- Increased flexibility in design
- Multiple levels bar design for double barrel reconstruction techniques
- Branches and loop design for space restricted situations
- Full integration with virtual planning, titanium and polymer surgical guides
- Holes manufactured at desired angulation to avoid vital structures and facilitate surgical access











Titanium 3D Printed Implants*

Features:

- Mesh like implants used as graft containers or onlays
- Provide soft tissue support
- Variable thickness between 1.2 and 10mm
- Choice of porous only or combination of porous and continuous sections
- Anatomical anchors and suture holes
- Porosity of 53%
- Compatible with all MatrixMANDIBLE Non-locking Screws
- Minimum screw hole space 4.5mm
- 3D printed commercially pure titanium

Titanium 3D Printed Mini Plates*

Features:

- For minimum implant size reconstruction
- Thickness 1.5. to 2.0mm
- Minimum screw hole space 4.5mm
- Compatible with all MatrixMANDIBLE Non-locking Screws
- 3D printed commercially pure titanium

Tanium 3D Printed Hybrid Implants* Features:

- Combination of plate and implant sections
- Reduced contact with the bone
- Anatomical anchors and suture holes
- Compatible with all MatrixMANDIBLE Non-locking Screws
- 3D printed commercially pure titanium

¹ Fatigue testing data shows increased fatigue life of both 2.0 and 2.5 mm profiles in comparison with MatrixMANDIBLE 2.5 mm thick plates. Test data does not indicate clinical performance. Test data on file at DePuy Synthes - MT 12-261: Dynamic Testing of Patient-Specific Mandible Plates (PSMP), 0000073412













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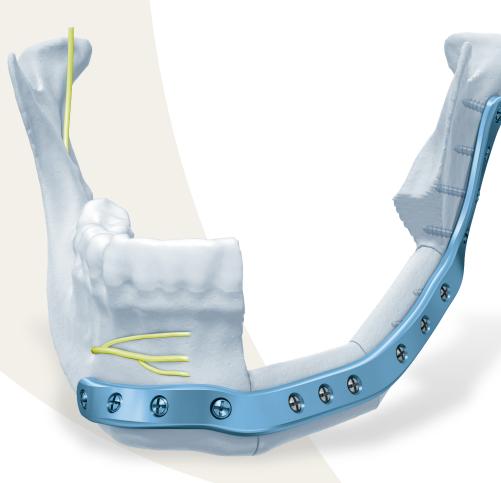
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TITANIUM 3D MILLED PLATE FOR

3D-milled for the patient

The design of the TRUMATCH[®] CMF Titanium 3D Milled Plate for Mandible is individually engineered to meet the needs of each patient and surgeon. By selecting plate design features, surgeons can customize the reconstruction plate to create a patient-specific solution. The Titanium 3D Milled Plate for Mandible is 3D-milled to the planned patient anatomy, eliminating the time needed for intraoperative adaption and creating a stronger plate* with a lower overall profile.

The plate is never bent, consequently there is no induced stress due to bending.





Features and Benefits

Derived from Patient CT Data

- Design fits the planned outcome for easy positioning of the grafts at the planned location
- Integration with virtual surgical planning service** for seamless transfer of the surgical plan into the OR, using patient-specific surgical guides** with built-in drill guides that align with the plate holes (optional)



Surgical Guide

Customizable Design Features

- Screw hole positions and angulations defined individually to avoid screw interference with nerves, tooth roots, osteotomies, existing or future implants
- Screw length prediction and pre-visualization of screw trajectories to ensure a collision free construct
- Minimum holes spacing of 5.5mm, allowing for closer screw placement than any other MatrixMANDIBLE[™] reconstruction plate

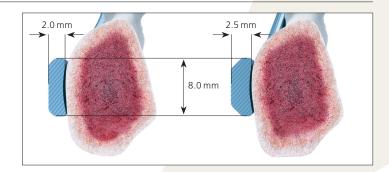








- Titanium 3D Milled Plate for Mandible eliminates induced mechanical stress from bending plates in OR
- 2.0 mm and 2.5 mm plate thicknesses for improved fatigue strength* with lower profiles compared to standard reconstruction plates



* Fatigue testing data shows increased fatigue life of both 2.0 and 2.5 mm profiles in comparison with MatrixMANDIBLE 2.5 mm thick plates. Test data does not indicate clinical performance. Test data on file at DePuy Synthes - MT12-261: Dynamic Testing of Patient-Specific Mandible Plates (PSMP), 0000073412

** Manufactured by Materialise and distributed by DePuy Synthes



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FOCUS MIDFACE

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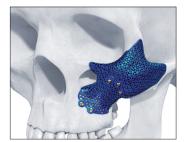
MIDFACE RECONSTRUCTION

Titanium 3D Printed Implants*

Features:

- High flexibility in design
- Mesh like implants used for midface reconstruction and augmenting of the bone through onlay designs
- Integrated fixation holes
- Single or multi-piece implants mating together
- Designed for energy absorption during impact¹ (local plastic deformation of implant)
- Variable thickness between 0.8mm and 10mm
- Choice of porous only or combination of porous and continuous sections
- Anatomical anchors and suture holes
- Anodized color coding with the matching guides for easy identification
- Porosity of 53%
- Compatible with all MatrixMIDFACE[™] and MatrixORTHOGNATHIC[™] screws
- 3D printed commercially pure titanium

Midface reconstruction



Single-piece implant



Three-piece implant



Two-piece implant

Guided zygoma repositioning



Plates and implant



Osteotomy and pre-drilling guides

Bone augmentation with onlays



Onlays for bone augmentation



Reconstruction with bone augmentation



TruMatch

Overview

PEEK Milled Implants

Features:

- Milled in 3D from PEEK Optima[™] polymer
- Alignment of the implant and bone surface
- Single or multi-piece implants
- Radiolucent
- Flexibility in determining the fixation points intraoperatively •
- Bone-like stiffness and strength •
- Used with DePuy Synthes cranial and craniofacial fixation systems
- Any necessary modifications of the implant (e.g. drainage, monitoring devices) can be performed in the OR with standard instruments



Features:

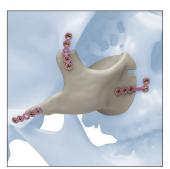
- Full integration with virtual planning, titanium and polymer surgical guides
- Single or multiple plate options
- Orientation markers for easy positioning •
- Osteotomy and predrilling surgical guides
- Anodized color coding with the matching surgical guides for easy identification
- Thickness of minimum 0.8mm
- Hole angulation of max 15° •
- Minimum screw hole space 4.5mm
- Compatible with all MatrixMIDFACE screws

¹ Based on static tensile tests: HW-PorousiTi-14101G-verA-Energy_Absorbation_Report

3D printed commercially pure titanium



Single-piece implant





Two-piece implant



Attachment with standard plates and screws

Three-piece implant

Maxilla reconstruction with graft



Reconstruction with single plate

+ +

Plates

--

Reconstruction with multiple plates



Osteotomy and pre-drilling guides





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TITANIUM 3D PRINTED IMPLANTS*

Flexible design for a broad range of clinical situations

Features¹

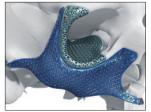
- High flexibility in design for a wide range of maxillofacial indications
- Porous structure (53%)
- Integrated fixation holes
- Single or mating multi-piece implants
- Complex anatomical shape
- Variable thickness up to 10 mm
- Predetermined screw locations
- Designed for energy absorption in case of impact (local plastic deformation of implant)

- Anatomical anchors & suture holes
- Drainage
- Choice of porous only or combination of porous and continuous sections
- Anodized color coding for easy identification and match with the surgical guides
- Compatible with all DePuy Synthes Matrix Non-locking Screws
- 3D printed commercially pure titanium



Orbital floor reconstruction





Extensive midface reconstruction



Bone augmentation with onlays



Mandible reconstruction



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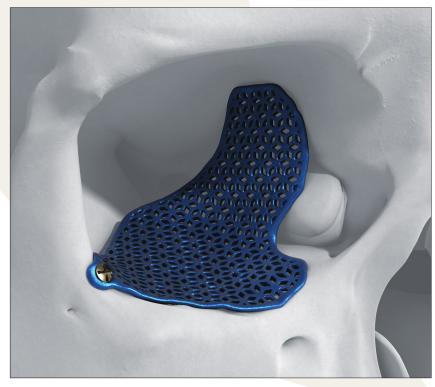
TITANIUM 3D PRINTED IMPLANTS

Flexible design for a broad range of clinical situations

Features:

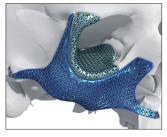
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- Anatomical anchors & suture holes
- Drainage
- Choice of porous only or combination of porous and continuous sections
- Anodized color coding for easy identification and match with the surgical guides
- Compatible with all Matrix Non-locking Screws
- 3D printed commercially pure titanium



Orbital floor reconstruction

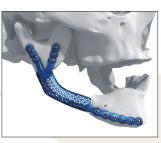




Extensive midface reconstruction



Bone augmentation with onlays



Mandible reconstruction

Workflow

TRUMATCH CMF Orbital implants can be designed using two workflows:

- 1. With a live virtual surgical planning session more complex cases
- 2. Without a live virtual surgical planning session reduced lead time

1. Cases requiring a live virtual surgical planning session²

- Damaged (affected) zygoma and/or inferior orbital rim
- Osteotomies and repositioning of bone needed to completely reconstruct orbit
- Metal inside the orbit or on the rim from a previous reconstructive surgery
- Lateral wall defect
- Contralateral orbit deviating from normal anatomical shape

2. Cases without the need of a live virtual surgical planning session²

- Intact zygoma
- Untouched (flawless) inferior orbital rim
- Healthy contralateral orbit
- First surgery to reconstruct the orbit
- Orbital floor defect or orbital floor + medial wall defect



Orbital reconstruction without a live virtual surgical planning session required

In order to reduce the lead time and allow Ti 3D Printed implants to be used for some of the primary orbital treatment, implants can be designed based on surgeon preferences collected at the case creation and predefined design rules.

- The design of the Ti 3D Printed patient specific implant is based on the mirroring of the patient's contralateral orbit
- Its design is personalized taking into account surgeon preferences
- Fast delivery as a result of convenient design process
 - No live virtual surgical planning session required
 - Review of the implant in Online 3D Viewer
- Surgical pre-drill guide option to aid with the implant positioning

Two implant thicknesses available for all design workflows



TruMatch

Orbital Reconstruction

Implant Design Preferences

Amount of MatrixMIDFACE® Screws 3 screws

2 screws

Screw length

 \Box 4 mm

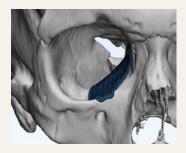
□ 5 mm 6 mm

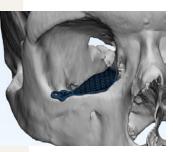
□ Based on bone thickness

Position of fixation screws □ Medial

□ Lateral

4 screws





Implant thickness

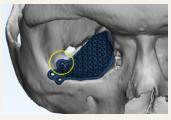
0.4 mm

0.8 mm

🗌 No

Optional lateral support on the implant

Yes**



**Note: dissecting the inferior orbital fissure might be required

Pre-drilling guide

□ Yes

🗌 No



Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions. The third party trademarks used herein are the trademarks of their respective owners.



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PERSONALIZED PLATES AND IMPLANTS

PEEK MILLED IMPLANTS (PEEK PSI)

Derived from CT data for satisfying reconstructive results*

- Better anatomic fit versus conventional fixation/reconstruction methods*
- Implant fixation with DePuy Synthes plates and screw systems
- Suitable material for definitive treatment





Features and Benefits

TruMatch

- Better anatomic fit versus conventional fixation/ reconstruction methods*
- Reduced operating time compared to traditional reconstruction methods that require extensive contouring*
- Satisfying aesthetic results for surgeon and patient*
- Suitable materials for definitive treatment
- Any necessary modifications of a PEEK implant (e.g. drainage, monitoring devices) can be performed in the OR with standard instruments
- Implant fixation with DePuy Synthes plates and screw systems
- Short turnaround time

PEEK (Polyetheretherketone)

- Engineered for strength and stability
- Radiolucent (reduced MRI artifact)
- Bone-like stiffness and strength
- Surgeon can determine plate and screw placement during surgery
- Lightweight
- Autoclavable

Other Services Offered

- One-to-one online design sessions for preoperative surgical planning
- Online surgeon accounts
- 3D tools for implant reviews
- Supply of 3D data (format STL)





Two-piece

Single-piece



Three-piece

* Jalbert F, Lauwers F. Rev Stomatol Chir Maxillofac Chir Orale. 2013 Aug 1. pii: S2213-6533(13)00183-3. Results from case studies are not predictive of results in other cases. Results in other cases may vary.



TruMatch[®] CMF PERSONALIZED SOLUTIONS

Overview

Accuracy | Efficiency | Patient Benefit

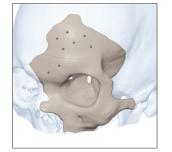
SERVICES AND PRODUCTS AT A GLANCE

Services and Products

Personalized Implants

- Titanium 3D Milled Plates for Mandible
- PEEK Milled Implants
- Titanium 3D Printed Plates*
- Titanium 3D Printed Implants*





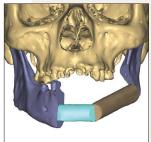


Virtual Surgical Planning*

- Planning kits
- Soft tissue simulation
- Photo mapping
- Outcome analysis
- STL file transfer







Patient-Specific Tools*

- Surgical guides
- Orthognathic splints
- Anatomic models







Accuracy | Efficiency | Patient Benefit

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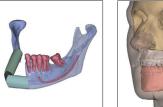
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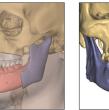
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