KLS martin GROUP

IPS Implants®

One Patient. One Solution.

www.klsmartin.com

Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

Contents

Patient-specific Implants and anatomical Models

The loss of complex or extended bone structures due to trauma or tumor involves considerable physical and emotional stress for patients, while leaving the physician carrying out treatment with the consideration of how the defect can be covered in the best possible way.

IPS Implants® can be an effective solution in this situation, helping to overcome these difficulties and the resulting uncertainties.

Prof. Dr. Dr. Peter Keßler
Department of Oral and Maxillofacial Surgery,
Academic Hospital Maastricht

"Our hospital in Maastricht has been working with patient-specific implants to cover cranial defects for some time. The high degree of safety in planning, the significantly shorter operating times, and the improved aesthetic and functional results definitely justify the additional planning input that's initially required."

Advantages for Patient and Physician

Pre- and intraoperatively

- No need for autologous bone grafts or a second surgical site
- Significantly shorter operating times
- Lower complication rate
- Minimally invasive procedure – targeted intervention that protects surrounding tissue structures

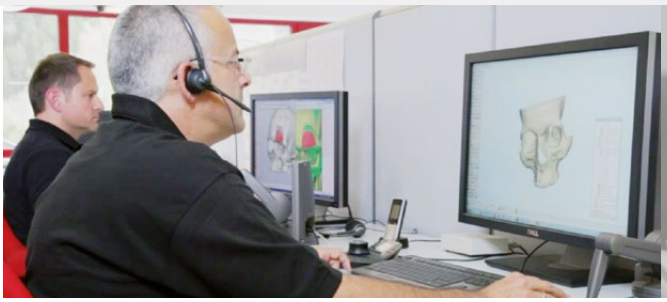
Postoperatively

- Perfect mechanical protection for the brain
- Lower risk of rejection
- Faster rehabilitation
- Restoration of original appearance
- Improved quality of life

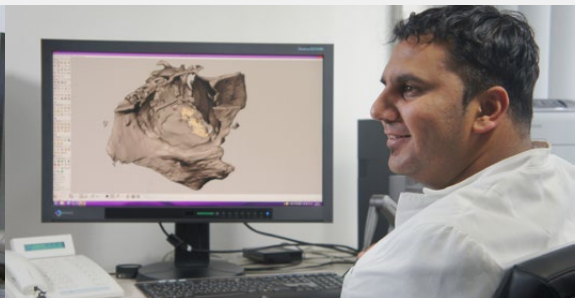
For the Healthcare System

- Solution for patients not previously or poorly covered
- Significantly shorter operating times
- Lower complication rate
- Shorter hospital stays
- Reduced overall treatment costs
- Faster rehabilitation

Comprehensively varied – KLS Martin Group Production Technology



Case planning by KLS Martin

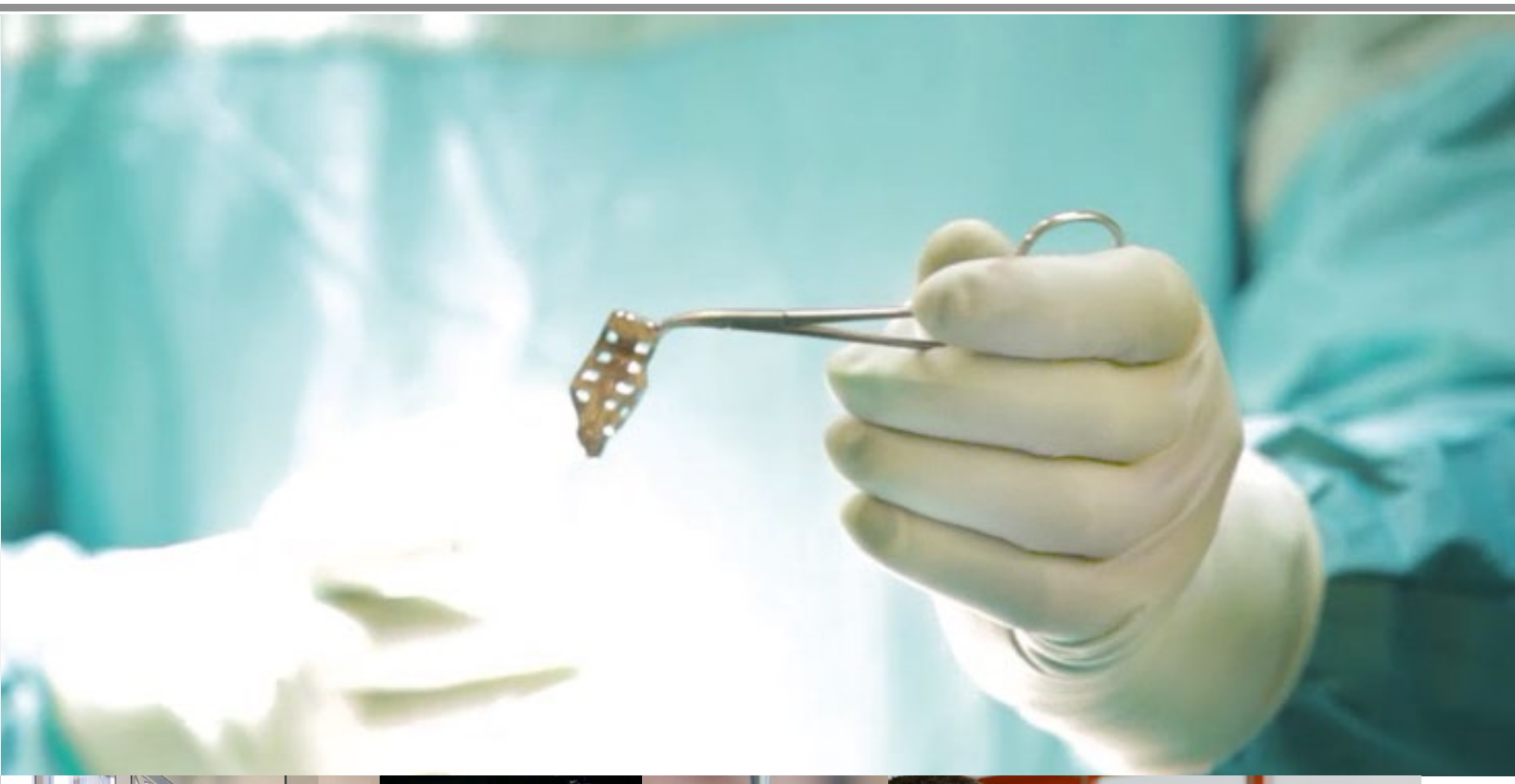


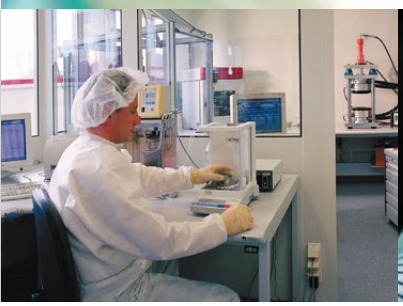
Case planning by the user

Patient-specific reconstructions and trauma treatments are very complex and differ greatly from one patient to another. Therefore, it is essential for clinical partners to enjoy the support of a service provider offering its own manufacturing capabilities in addition to the complete range of materials and manufacturing methods.

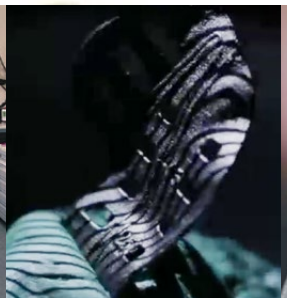
Whether deep drawing, milling, turning or machining, whether anatomical models or absorbable material in clean room technology, whether selective laser sintering or laser melting: The extraordinary diversity of requirements for an individual implant requires a supplier who combines everything under one roof.

The KLS Martin Group has decades of experience in the processing and remodeling of metals, plastics and resorbable materials. The new, generative manufacturing processes present completely new options for clinical users. In addition to the well-known large implants, which are often used for cranial and brain injuries, today we are also able to produce patient-specific “tailor-made” complex, small implants for use in reconstruction. This means that without a significant lead time, tools, or devices, we can offer our customers perfectly fitting implants for routine traumatology interventions, which fit when it really matters!

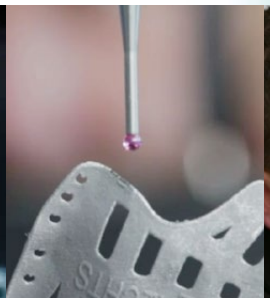




Production in clean room technology



Target/actual comparison



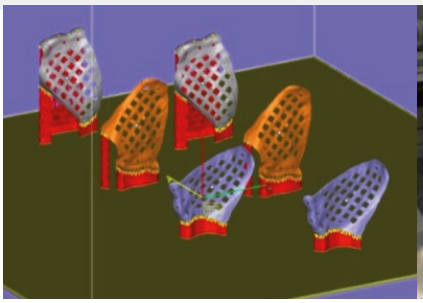
Metrology

QA and documentation

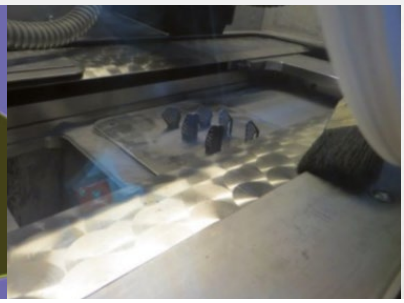
KLS Martin Range of Services:

- Complete design
- Accepting your datasets and joint non-binding discussion of a solution to the problem (e.g., online meeting)
- Three-dimensional virtual presentation of the defect reconstruction
- Conventional manufacturing technology (milling, turning, deep-drawing, machining, etc.)
- Resorbable materials in clean room technology
- Anatomical models
- Generative manufacturing procedures (laser melting and laser sintering)
- Quality assurance and validated process flows
- Non-binding consultation with qualified sales staff

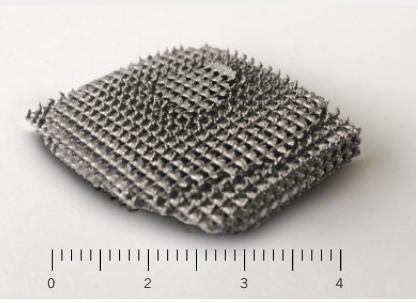
New
Additive Manufacturing (AM-Titanium)



Virtual projection of, for example, orbital floor implants in the workroom



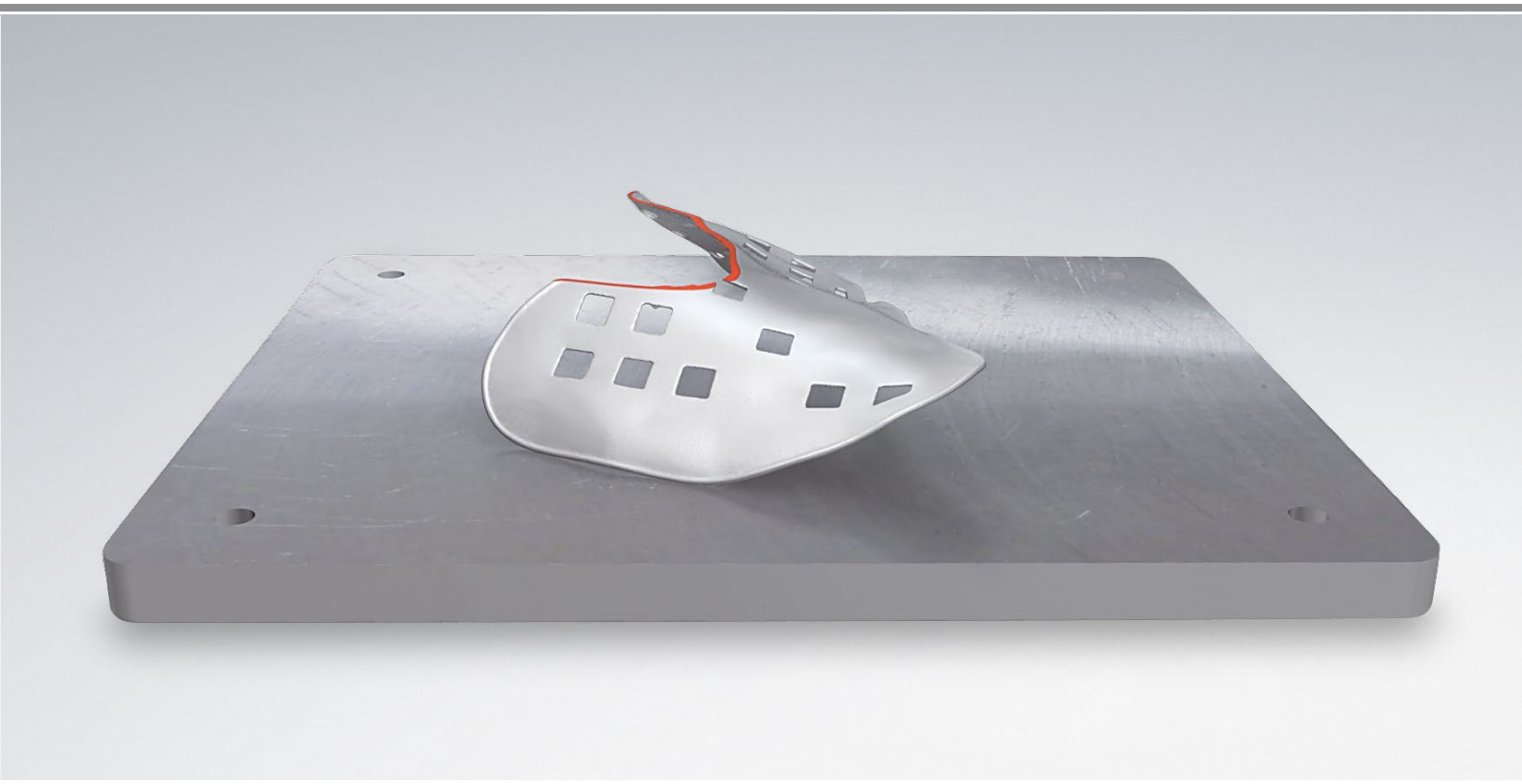
... and their actual manufacturing



Osteoconductive open support on the model

Additive Manufacturing (AM) presents completely new options for you in terms of implant design and surfaces!

How does it work?
Additive manufacturing is used to refer to a 3D printing process in the area of generative manufacturing procedures. In a high pressure chamber, titanium powder is transported into a working chamber using a scraper or roller. A laser beam is reflected into the working chamber via a mirror and hits the titanium powder there. The appearance of the laser beam causes the powder to melt (this is why it is also called laser melting) and therefore compresses the material. Once the laser has processed one working level, the working platform (table) is lowered and a new layer of titanium powder is applied. This means that the work piece is additively produced layer by layer. As the power density of the laser is extremely high, highly-compressed three-dimensional work pieces are produced.



What are the User‘s Advantages?

The main advantages of additive manufacturing can essentially be summarized in the following qualities:

- **Quick:** Additional tools and devices are no longer required
- **Varied:** Free design of implants and their surfaces
- **Osteoconductive:** An open design of the implant body allows for the incorporation of the body‘s own cell structures
- **Complex shapes** are possible, such as honeycombs, grids, or porous structures
- **High-strength:** The density, and therefore the strength, of the material will be greater than a comparable work piece made of pure titanium

Dr. Dr. Jan-Dirk Raguse
Department of Oral and Maxillofacial Surgery, Charité – Universitätsmedizin Berlin, CVK Campus

“The idea of an open, porous, fine-mesh titanium net structure, which promotes osteoconductive incorporation of bone cells, has long fascinated us. In addition, this three-dimensional open structure, unlike the otherwise standard solid bodies, allows for the option of charging the implant with autologous tissue (e.g., cancellous bone). With additively produced laser implants, we have been able to realize this vision in the current form for the first time. It is conceivable that there will be many adjoining applications in the future.“

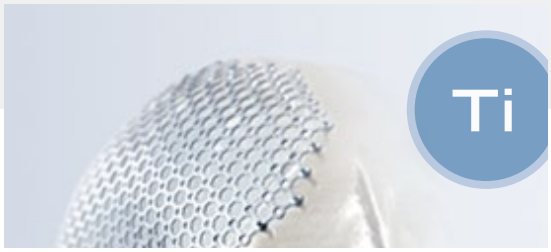
Materials
that give you Choice

This detailed description of the individual materials and their properties is designed to help you to choose your material.

	Additive Manufacturing Titanium	**PEEK – Polyether Ether Ketone**
Brief description	Completely free surfaces can be produced without tools or devices. There are previously unprecedented options for surface design. Reshaping processes are no longer required.	PEEK is a high-strength, thermostable, high-performance plastic. Thanks to its physical properties, which are comparable to those of cortical bone in humans, PEEK is the type of plastic most frequently used in orthopedics. The implants are available completely solid or solid with holes.
Material	Ti alloy Ti6Al4V	Polyether ether ketone
Specified acc. to	ASTM F136 -02a (ELI Grade 23)	ISO 10993
Sterilization	Steam sterilization at 134°C (273.2°F) EN 285 / ANSIA / AAMI / ISO 11134 – 1993	Steam sterilization at 134°C (273.2°F) EN 285 / ANSIA / AAMI / ISO 11134 – 1993
Advantages	▪ A wide selection of shapes, structures and styles is possible ▪ Precise fitting accuracy ▪ High stability ▪ Osteoconductive structures are possible ▪ Complete design freedom for the material and its surface ▪ Quick	▪ Highly elastic, yet very strong and impact resistant at the same time ▪ Optimal protective function for patients ▪ No increase in thermal sensitivity ▪ Low weight ▪ Resistant to gamma radiation and magnetic resonance imaging (MRI) ▪ Low artifact formation in X-rays ▪ Three-dimensional bone replacement
Limitations	▪ Any necessary revision surgery will only be possible with additional work ▪ Intraoperative cutting to length almost impossible	▪ Only conditional cell apposition potential ▪ Intraoperative adjustment or cutting to size is only possibly with additional effort ▪ Requires further plates for fixation

Individual Patient Solutions – which Base Material for which Purpose?

	AM Titanium	PEEK	Titanium Mesh	Solid Titanium
Subsequent implant correction	++	+	++	–
Mechanical strength	+++	+++	++	+++
Biocompatibility	+++	+++	+++	++
Thermal conductivity	+	+++	+	–
Price level	+	+	+++	++
Potential for osseous integration	+++	+	+++	++
Volume reconstruction	+++	+++	+	+++
Artifact likelihood	++	+++	++	+



Titanium Mesh

Brief description

Unlike conventional osteosynthesis materials, titanium mesh allows three-dimensional deep-drawing. A special thermal process ensures a closed microstructure. Therefore titanium mesh is stable and intact and offers very good biocompatibility as well as bone apposition potential.

Material

Pure titanium

Specified acc. to

ISO 5832-2, ASTM F 67

Sterilization

Steam sterilization at 134°C (273.2°F)
EN 285 / ANSIA / AAMI / ISO 11134 – 1993

Advantages

- Very good biocompatibility, potential for vascularization
- Favorable mechanical properties
- Can easily be cut to size
- Bone cell apposition potential
- Relatively low price level
- No further plates required for fixation

Limitations

- No three-dimensional bone substitute
- Need for tools

Solid Titanium

Brief description

Solid titanium represents a high-strength reconstruction alternative to titanium mesh. Even though it has been widely superseded by titanium mesh in recent years, it offers several advantages in specific fields of us – e.g., in relation to the mechanical protective function.

Material

Pure titanium

Specified acc. to

ISO 5832-3, ASTM F 67

Sterilization

Steam sterilization at 134°C (273.2°F)
EN 285 / ANSIA / AAMI / ISO 11134 – 1993

Advantages

- High-strength reconstruction alternative
- Best mechanical protective function
- No plates required for fixation

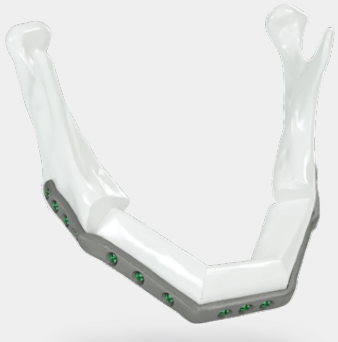
Limitations

- Increased thermal conductivity
- Subsequent bending not possible
- Subsequent cutting to size not possible

Indications
and Example Applications

Indications

- Posttraumatic reconstructions
- Loss of bone integrity
- Cranial brain injuries with an increase in intracranial pressure
- Reconstruction of defects caused by craniotomy
- Tumors, ulcers, and cysts
- Occurrences of infections or rejection reactions in the event of cranioplasty
- Limited supply of autologous bone transplants



Step by Step
through your own Project

Patient-specific implants are complex projects, which demand mutual trust and close coordination between all parties. The following chart shows the most important considerations during the implementation of your own project at a glance:

1 Online inquiry via IPS Gate®

In detail
- Patient data (name, age, planned surgery date)
- Treating physician, if necessary additional contacts at the hospital e.g., surgical staff, representatives
- Are there material preferences?
- Information on further treatment e.g., sketch of resection borders, fastening type, and fastening points
  IMPORTANT: The inquiry is non-binding for you. It is sent to all relevant departments at KLS Martin at the same time.

2 Data preparation (by the user)

We need your data in a compressed file – preferably in "ZIP" or "RAR" format. Please make sure that the compressed file to be sent to us contains the complete data structure including all sub-directories (if applicable).

3 Data transmission

Ideally, directly upload the data into the IPS Gate®.

Can the data be used?

No? You will be contacted immediately by KLS Martin.
Yes? You will be sent an offer and a proposal for implementation.

Has the offer been accepted?

No? Please inform us of the progress of the project.
In some cases, changes in design may result in price advantages.

Yes? Then please send us your order and the signed letter of approval.

4 Manufacturing

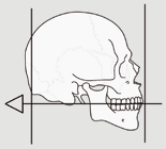
Please allow approx. 5-10 working days for manufacturing.

5 Shipment

Shipment is carried out unsterilized, including the relevant anatomical model.

Details on Ordering and Project Handling

1 **Scan**



2 **Prepare the Data**

Achieving optimum Scanning Results

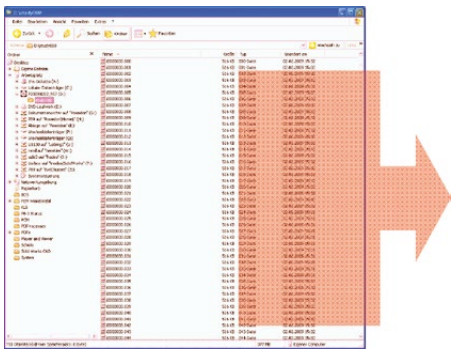
- Patient scans must be current and precise (< 4 months).
- The spatial resolution of the scans should range between 0.5 and 1.25 mm. In this case the interval must be no more than half the resolution of the individual planes.
- Orbital implants require a thin-layer CT scan with max. 1.00 mm spatial resolution.
- It is essential to avoid patient movement during the scanning process.
- Scans must be performed in an upright position. The image plane must be at right angles to the plane of occlusion in order to minimize artifacts.
- The target area of the scan should be as small as possible, but should include the region 2 cm above and below the defect region.
- The outer contours of the patient‘s head should also be included.
- Save the entire scan (incl. all sub-files) as a DICOM file.

KLS Martin can process data from all commonly used CT scanners and PCS systems, and can use almost all storage media. Should you have any queries, please do not hesitate to contact our **hotline +49 7463 838-222.**

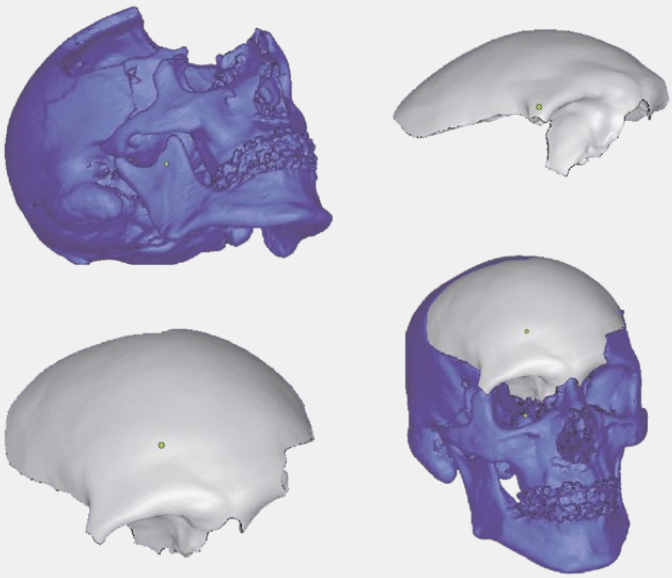
Preparing the Data

To process your inquiry as swiftly as possible, we suggest to upload your scanning data in a **single** compressed file — ideally in “ZIP” or “RAR” format. Please make sure that the compressed file to be sent to us contains the complete data structure including all sub-directories (if applicable).

If you do not have a suitable program, then you can easily download freeware for this purpose online, such as winzip, 7zip or IZarc.



Converting to a “ZIP” or “RAR” file.



3 Data Transfer

1. Sending or Uploading the CT Data

The fastest and easiest way is to send the data via our free-of-charge online upload and communication platform **IPS Gate®.** The web-based platform and app guides surgeons and users reliably and efficiently through the process of inquiring about, planning and completing patient-specific products. Thanks to the “HTTPS” standard, IPS Gate® ensures encrypted data transmission, which is additionally certified by the TÜV Süd seal.

https://ips.klsmartin.com

For further information kindly see our FAQ under
https://ips.klsmartin.com/social/ui/faq

2. The following Information is important to us:

- The data must be submitted by uploading it to IPS Gate®
- Name of the patient
- Name and hospital of treating physician
- KLS Martin specialist partner
- Patient-specific individual implant or anatomical model only
- Additional order information and comments, e.g., material preferred, thickness, points of anchorage
- Scheduled date of surgery/delivery date for the patient-specific implant

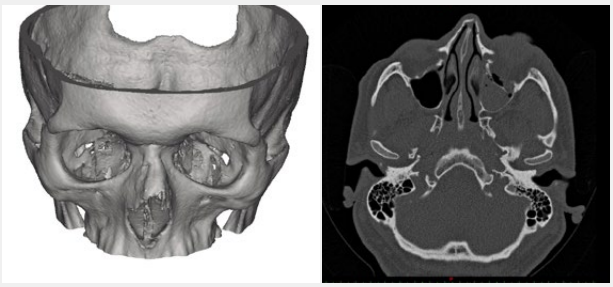
4 Start

Additional Information:

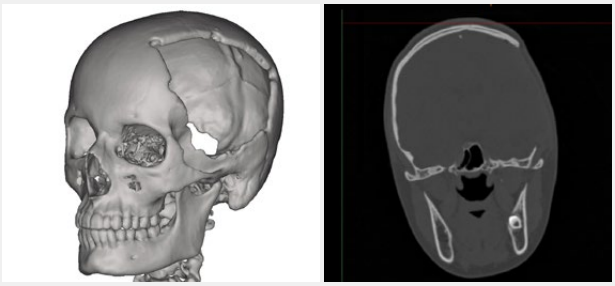
- We generally ship patient-specific implants with the corresponding anatomical model.
- Anatomical models and patient-specific implants are delivered **non-sterile**. Please observe the sterilization and cleaning instructions in the **Instructions for Use** supplied with the implant.
- Prior to initial use, patient-specific implants must be put through the **entire cleaning, disinfecting, and sterilization process.** Patient-specific implants are suitable for machine processing and thermal disinfection.
  They can be processed with any program approved for surgical instruments.

Adjustment of various Defects

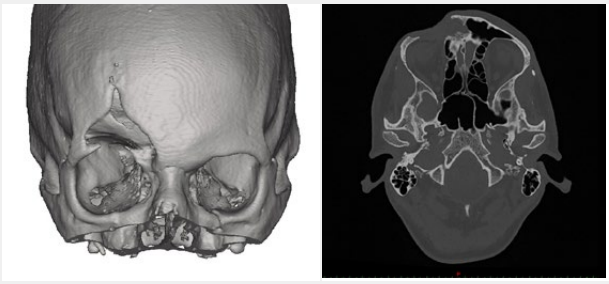
Secondary care for a maxillary defect



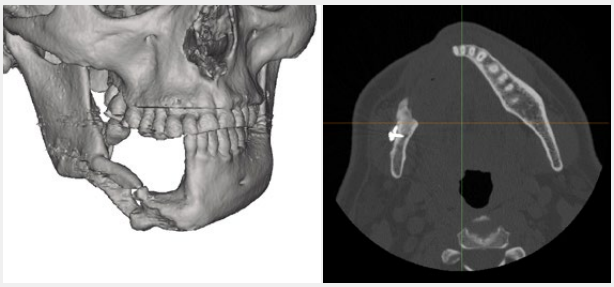
Orbital floor fracture



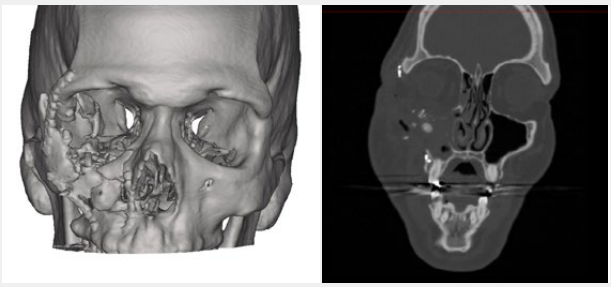
Reconstruction following craniectomy



Supraorbital defect

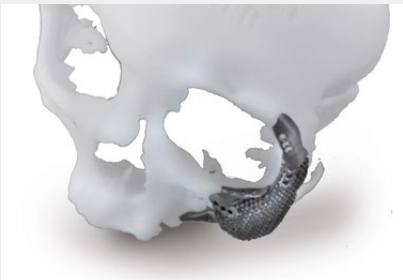


Revision of a mandible construction socket



Secondary intervention on midface and eye

Additive Manufacturing Titanium
Osteoconductive structures to restore the cheekbone/midface



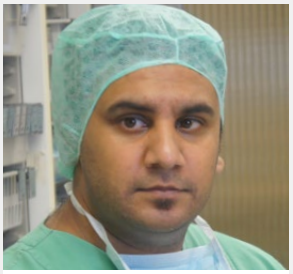
Three-dimensional defect construction

Additive Manufacturing Titanium
Precise coverage of an orbital floor defect without disruptive structures

Additive Manufacturing Titanium
Minimally invasive care for two orbital floor defects, including adjustment to partial anatomical models

Prof. Dr. Dr.
Nils-Claudius Gellrich
Department of Cranio-maxillofacial Surgery,
Hannover Medical School

"We combine several high-tech procedures into one process: exact diagnostics, CAD-supported implant design, and the latest manufacturing procedures from additive manufacturing technologies. The result is an implant, which corresponds precisely with our requirements and which can be inserted without complications during surgery."

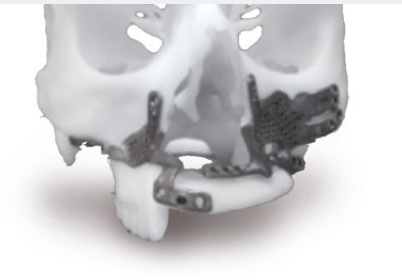


PD Dr. Dr. Majeed Rana
Department of Cranio-maxillofacial Surgery,
University Medical Center Düsseldorf

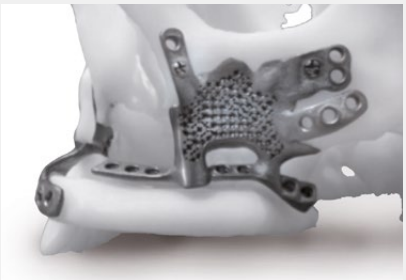
"The advantage of the additive manufacturing process is obviously that we can now produce a precisely-fitting implant in one piece, which corresponds exactly to our pre-planning with no sharp edges or disruptive structures. And all of this within a realistic timeframe."

Additive Manufacturing Titanium
Extremely delicate initial situation: The defect includes orbita, zygoma and the maxillar region. By using a 3-part implant, a patient-protective access is guaranteed.

Additive Manufacturing Titanium
Extensive orbital floor defect reconstructed by additive manufacturing



Additive Manufacturing Titanium
Osteoconductive structures for extensive reconstruction of the midface and the maxilla



The transplant is fixed in place using individually produced plates.

Additive Manufacturing Titanium
Three-dimensional shaped plate to restore the resected lower jaw

Fixed-angle holes for optimum fixing of a transplant with unconventional arrangement of the fixing points

Prof. Dr. Dr.
Carl-Peter Cornelius
Department of Oral and Maxillofacial Surgery,
LMU Munich

"For complex defects, we no longer want to make do with ready-made implants. We define an exact workflow and, as a result of this, an implant which gives optimum consideration to all of the circumstances of the patient, clinical picture, access, and expected clinical result. The fact that we are able to build patient-specific implants is a considerable advantage over traditional methods for us."

Prof. Dr. Dr. Max Heiland
Department of Oral and Maxillofacial Surgery, Charité University Medical Center Berlin

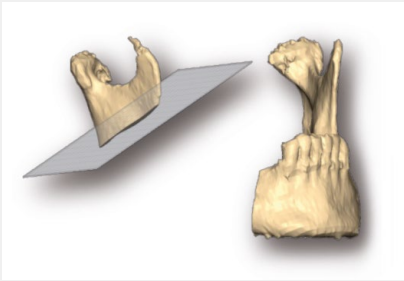
"Our hospital uses patient-specific implants and case planning, particularly in reconstruction. Conventional techniques often did not produce the standard we expect for our patients. Good case planning anticipates both the donor region and the receiving region, and includes all necessary templates. This means that it is possible to optimize both the design of the transplant and its positioning in terms of the patient's dental and aesthetic rehabilitation. We have come to know KLS Martin as a reliable partner in this area."

Integrated Case Planning

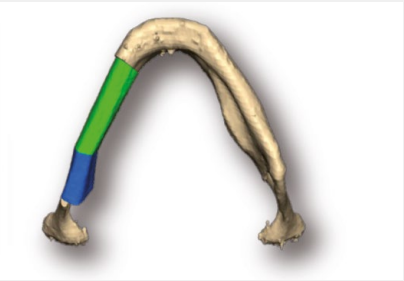
Complex reconstruction cases traditionally involve a large number of unknown factors. IPS Implants® uses considerable technical advances, brought about in recent years by computerized preoperative case planning, and implements the planning ideas into one entire package, which will withstand even critical surgical situations. From the anatomical models, resectioning and positioning templates, through to the implant which has been optimized specially for the specific patient, the surgical team has all of the tools needed for targeted implementation of their advance planning.

Case Example

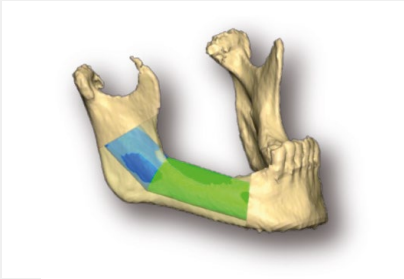
As an example, the case of a lower jaw reconstruction with a fibula transplant (shown on the right) will be described here.



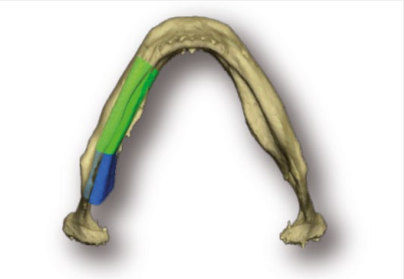
In a joint coordination process, the resection borders are first defined.



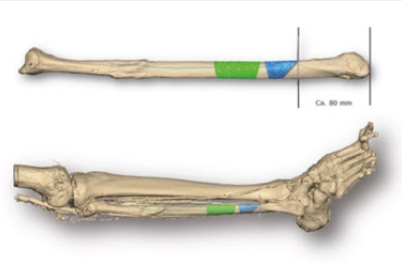
At the instruction of the treating physician, the defect needs to be reconstructed with a fibular transplant from the right fibula.



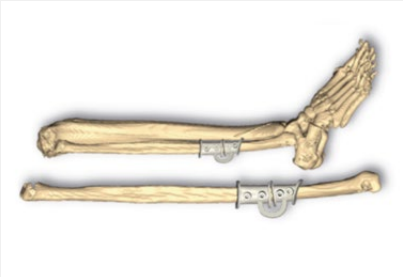
The donor region is virtually projected onto the receiver region, and the transplant...



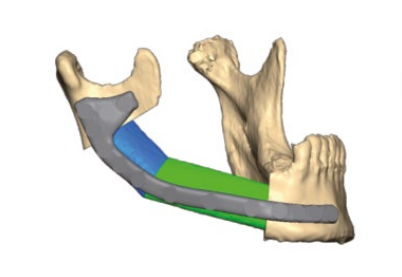
... is optimized to achieve the best possible aesthetic and prosthetic result.



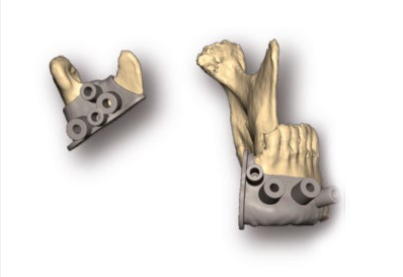
As agreed, the right fibula is examined to find the point which allows for optimal compliance.



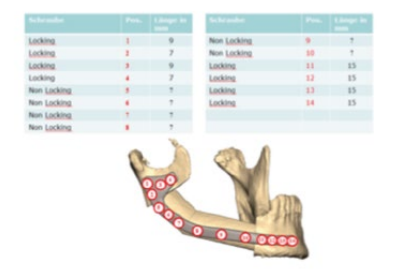
Anatomical considerations are respected and a resection template is produced.



Finally, an implant optimized for the specific case is generated.



In order to be able to carry out the resection as planned, resection templates are required which also reflect the cutting angle.



The type, diameter, and length of the osteosynthesis screws to be used are also defined.

An overview of the entire service package.

The IPS® Product Family

IPS CaseDesigner®

The IPS CaseDesigner® makes 3D virtual surgical planning easier and faster than ever before. With this brand-new, flexible software tool, planning and simulating surgical interventions become efficient and reliable. Individualized treatment concepts can be easily transferred through a virtual approach towards patients in the operating theater.

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Recommended computer specifications

- Broadband internet connection
- Windows 10, 64 bit or Mac OS X Yosemite or higher
- Good graphics card (NVIDIA, AMD)
- HD screen resolution
- Min. 8 GB RAM

Prof. Dr. Dr.
Gwen R.J. Swennen,
Bruges, Belgium

"After 20 years of personal experience with 3D virtual planning, I think that with IPS CaseDesigner® the next level of 3D virtual CMF planning software has been reached. As a part of its development I am sure it will further improve patient care in the future."

3D Virtual Treatment Planning of Orthognathic Surgery. A Step-by-Step Approach for Orthodontists and Surgeons. Springer.

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The web-based platform and app guides surgeons and users reliably and efficiently through the process of inquiring about, planning, and completing patient-specific products. With the HTTPS standard IPS Gate® guarantees encrypted data transmission, which is additionally certified by the TÜV Süd seal.

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