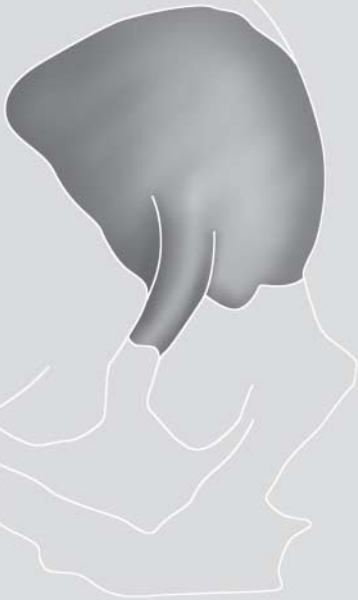
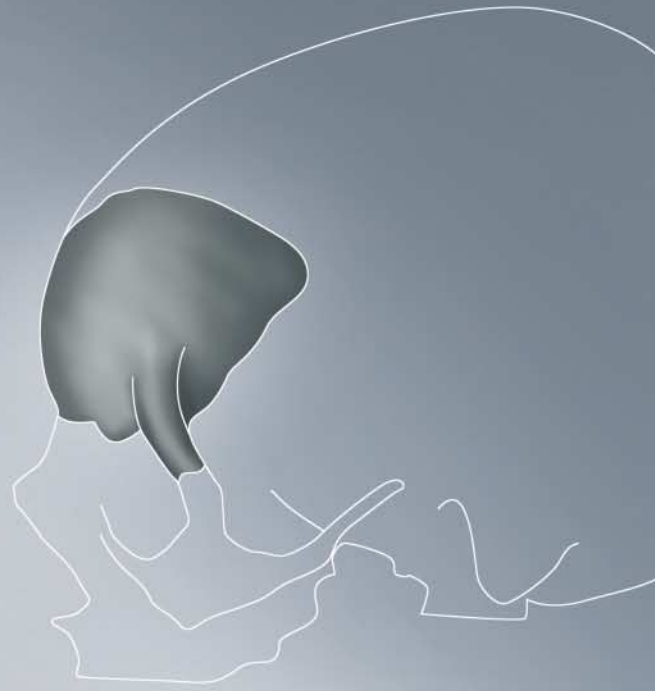


Craniofacial osteosynthesis



Patient-Specific Implants *and Anatomical Models*





Based on individual patient data, KLS Martin provides perfectly adapted implants to cover cranial defects.

These pages are intended to tell you more about our anatomical models, implants and materials – and how you can implement your project step by step in close collaboration with us.



Patient-specific implants and anatomical models

Loss of extended bone structures (e.g. due to trauma or tumor) involves considerable physical and emotional stress for patients while leaving the treating physician in doubt about how the defect can be covered in the best possible way. Commonly available mesh is only poorly suited for adaptation to the complex three-dimensional contours of the cranium, as the bending process is very time-consuming and weakens the implant in addition. Bone grafts, in contrast, are necessarily associated with a traumatic intervention and correspondingly long hospitalization times for patients. Bone substitute materials, as a third option, can usually be used only for partial coverage of the defect.

Patient-specific implants can be an effective solution in this situation, helping surgeons to overcome the difficulties involved and master resulting uncertainties.

Indications

- Posttraumatic reconstructions
- Loss of bony integrity
- High-speed traumas with increasing intracranial pressure
- Tumors, ulcers, cysts
- Manifest infections in cranioplasties
- Limited supply of autologous bone grafts

The KLS Martin
range of services



Range of services

- Utilization of your patient data as basic input (online upload)
- Virtual reconstruction of bone defects
- Complete manufacturing structure
- Selection of recognized biocompatible materials (titanium, titanium mesh or PEEK)
- Comprehensive documentation of all processes involved
- Free advice without any obligation



Prof. Dr. Peter Kessler
Hospital for OMF Surgery
Maastricht University Hospital

“Our hospital in Maastricht has been working with patient-specific implants for some time, using them for covering cranial defects. The high degree of planning safety, the significantly shorter operating times and the aesthetically and functionally superior 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 and a second surgical site
- Significantly shorter operating times
- Lower complication rate
- Minimally invasive procedure – highly targeted intervention that minimizes damage to 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 public health system

- Solution for patients previously not or poorly covered by adequate therapies
- Significantly shorter operating times
- Lower complication rate
- Shorter hospitalization times
- Reduced overall treatment costs
- Faster rehabilitation

Materials that give you choice

Patient-specific reconstructions 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 the whole range of materials and all the manufacturing capabilities required. The detailed descriptions of the various materials and their properties are intended to help you choose.



PEEK – Polyether ether ketone

Brief description	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.
Material	Polyether ether ketone
Specified acc. to	ISO 10993
Sterilization	Steam sterilization at 134°C (273.2°F) EN 285 / ANSIA / AAMI / ISO 11134-1993
Advantages	<ul style="list-style-type: none"> ▪ Highly elastic, yet very strong and impact-resistant at the same time ▪ Optimal protective function for patient ▪ Comes very close to the physical properties of human cortical bone ▪ 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 substitute
Limitations	None

Patient-specific implants – Which base material for which purpose?

	PEEK <small>PEEK</small>	Titanium mesh <small>Ti</small>	Solid titanium <small>Ti</small>
Subsequent implant correction	+	++	–
Mechanical strength	+++	++	+++
Biocompatibility	+++	+++	++
Thermal conductivity	+++	+	–
Price level	+	+++	++
Osseous integration potential	+	+++	++
Volume reconstruction	+++	+	+++
Artifact likelihood	+++	++	+



Titanium mesh

Solid titanium

Brief description	Unlike conventional osteosynthesis materials, titanium mesh allows three-dimensional deep-drawing. The use of a special thermal process ensures a closed microstructure and superior mechanical strength. Thanks to its 100% intact structure, titanium mesh provides absolute dimensional stability. Moreover, it offers the best biocompatibility and the best bone cell apposition potential.	Solid titanium represents a high-strength reconstruction alternative to titanium mesh. Even though it has been widely superseded by titanium mesh in recent years, solid titanium offers several advantages in specific fields of use – e.g. where the mechanical protective function is important.
Material	Pure titanium	Pure titanium
Specified acc. to	ISO 5832-2, ASTM F 67	ISO 5832-3, ASTM F 67
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	<ul style="list-style-type: none"> ▪ Best biocompatibility, best vascularization ▪ Very good mechanical properties ▪ Easy final adaptation; can also be done intraoperatively ▪ Can be easily cut to size ▪ Bone cell apposition potential ▪ Best material if paranasal sinuses are affected as well ▪ Relatively low price level 	<ul style="list-style-type: none"> ▪ High-strength reconstruction alternative ▪ Best mechanical protective function ▪ Complete three-dimensional reconstruction of the defect, taking bone thickness into consideration as well
Limitations	<ul style="list-style-type: none"> ▪ No three-dimensional bone substitute 	<ul style="list-style-type: none"> ▪ Increased thermal conductivity ▪ Subsequent adaptation (bending) not possible ▪ Subsequent “cutting to size” not possible



Patient 1:

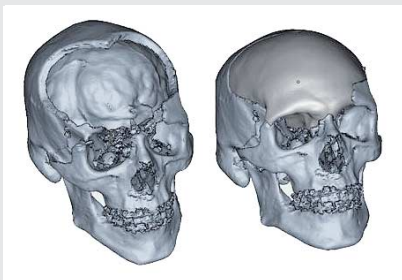
PEEK

Frontal defect

Typical traumatic defect in the frontal region.

To verify proper fit, the finished PEEK implant is projected onto the anatomical model.

Intraoperative situation: Thanks to the perfectly fitting implant, reconstruction is a matter of just a few minutes.



Patient 2:

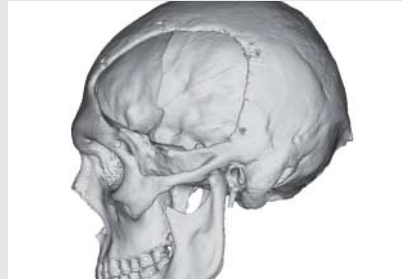
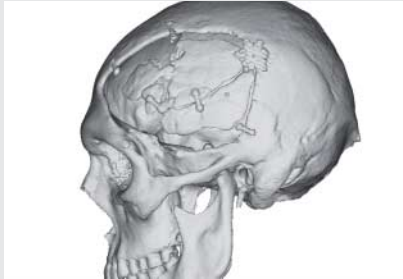
PEEK

Frontal defect

Scan of the frontal defect, and its virtual reconstruction by KLS Martin.

Isolated view of the patient-specific implant during the real operation. Microscrews and microplates are used for secure fixation.

Postoperative result.

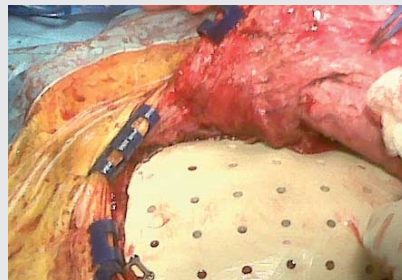


Patient 3:

PEEK

Frequent problem: The primary reconstruction is only partially tolerated in trauma patients. A revision operation is necessary.

Computer simulation of the revision:
The patient-specific implant can now be reconstructed by software.



The finished patient-specific implant fixed in place on the anatomical model ...

... and implanted in the patient.
As the operation can be completely anticipated, all uncertainties are automatically eliminated.



Prof. Dr. Dr. Jürgen Hoffmann
Hospital for OMF Surgery
Heidelberg University Hospital

“We have been working with patient-specific, customized implants for some time at our hospital. Based on our surgical case planning, technical implementation is done at KLS Martin. This has allowed us to achieve very good results both aesthetically and functionally, especially in orbital reconstruction.”



Patient 4:

Titanium mesh
Central midface defect

Complex situation: The defect involves the orbita, the zygoma and the maxilla.

Due to pre-shaping, the delicate titanium mesh implant offers an amazing natural strength.

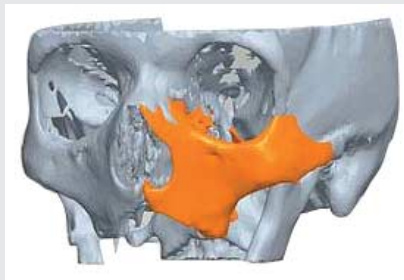


Patient 5:

Titanium mesh
Orbital floor defect

Isolated orbital floor defects require thin titanium mesh implants. They are fixed in place with 1.0-mm microscrews.

Detailed view of the implant: Rounded implant edges avoid soft tissue conflict situations while inserting the implant through minimally-invasive accesses.



Patient 6:

Solid titanium

Mix of different titanium components

Millimeter work on the PC: Extensive reconstruction of a zygomatic/orbital defect.

The finished implant fixed in place on the anatomical model.



Patient 7:

Adapting reconstruction plates

The anatomical model allows you to simulate the scheduled operation beforehand. Perfectly adapted reconstruction plates are a great step towards dependable surgical procedures, thus banning unwelcome surprises.

Patient 8:

Adapting reconstruction plates – Special tray design

Another example regarding mandibular reconstruction: A titanium mesh implant is welded in place on the pre-shaped reconstruction plate, to be subsequently filled with autologous bone and/or bone substitute materials.



Patient 9:

Solid titanium and titanium mesh

Mix of different titanium components

Different material components are used to match the heterogeneous biomechanical requirements of the various implant regions.

The implant is based on the 1.5-mm microsystem but comprises solid titanium and 3-D mesh components as well. The poster on the right shows the scientific publication of the case.

Reconstruction of the orbita and the lateral cranial base following ablative tumor surgery based on computerized planning and use of advanced CAD/CAM technology

C. Westendorff, J. Kaminsky*, M. Tatagiba*, S. Reinert, J. Hoffmann



Hospital and Polyclinic for Oral & Maxillofacial Surgery,
Hospital for Neurosurgery,
Tübingen University Hospital



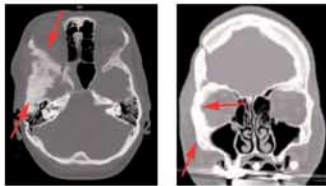
Introduction

Infiltration of the orbita due to intraosseous growth of sphenoid wing meningiomas frequently leads to severe functional and aesthetic impairment.

Tumor resection can result in a rather extensive bony defect. Anatomical reconstruction is difficult in such cases.

Using a case example, we are presenting and explaining advanced technical methods that facilitate the planning and performance of therapeutic interventions.

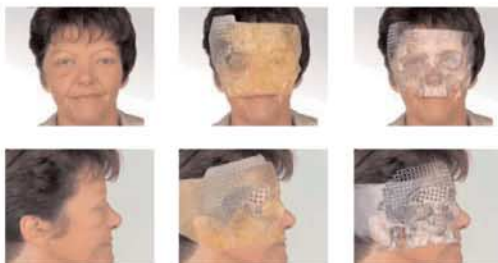
Figs. 1 and 2:
Osseous infiltration of a sphenoid wing meningioma in the region of the right-side cranial base and orbita (47-year-old female patient, CT scan).



Methods

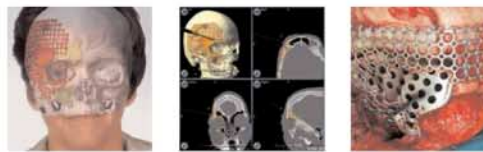
Using the patient CT data (Figs. 1 and 2), a stereolithographic (STL) model of the skull is created in a first step to provide the basis for intervention planning (Figs. 3 to 8).

Thereafter, the operation is simulated on the STL model with resection of the tumor-infiltrated bone sections. A CT scan of the STL model is then used to manufacture a hybrid CAD/CAM titanium implant featuring a solid central part and a titanium mesh welded in place all-round.



Figs. 3-8: Preoperative planning with tumor resection simulated on the STL model, creation of a hybrid titanium implant, and image data merging.

The CT data of the STL model with integrated patient-specific implant are subsequently merged with the patient CT data. Resection borders and structures posing risks (frontal sinus, brain nerves) are then segmented by virtual planning.

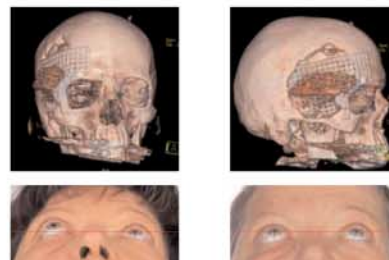


Figs. 9-11: Merging the image data obtained from STL model and patient (left), with segmentation of risk structures. Tumor resection under navigation control regarding resection borders (center); putting the patient-specific implant into place (right).

Navigation-guided tumor resection is then carried out, with careful regard to resection borders and risk structures. The size of the mesh section is precisely adjusted in the orbital region.

Results

The procedure described allows for adequate, extensive tumor resection as a first measure. Image data-based navigation enables preservation of risk structures and a highly precise surgical procedure that perfectly reflects the virtual planning process. Final precision adjustment of the patient-specific implant is achieved by reducing the titanium mesh portion as appropriate.



Figs. 12-15: Postoperative result in the female patient specified above, with accurate placement of the patient-specific implant (upper images) and significantly improved bulb position (lower images).

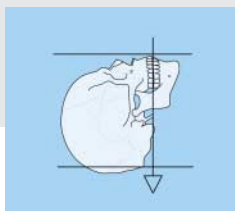
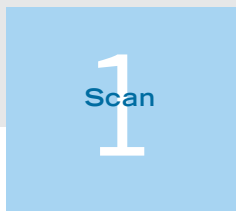
Conclusion

Extended osseous defects of the neuro- or viscerocranium are typically caused by radical tumor resections, high-speed traumas or – less frequently – infections. Reconstructive cranioplasty is mandatory in such cases, for brain protection as well as for aesthetic reasons.

Integration of computer-aided planning in conjunction with image data-based navigation allows radical tumor resection in a first step, while the use of advanced reconstructive methods – such as the hybrid CAD/CAM technology described – also ensures perfect reconstruction of the complex anatomical structures.

Contact: carsten.westendorff@med.uni-tuebingen.de

Details on ordering and project handling



How to secure optimal scanning results

- Patient scans must be current and precise.
- The spatial resolution of the scans should range between 0.75 and 1.25 mm but not exceed 2 mm.
- It is essential to avoid patient movement during the scanning process.
- Scans must be performed with the body in extended position, making sure that the image plane is at right angles to the plane of occlusion. This prevents artifacts.
- The target area of the scan should be small but should include 2 cm above and below the region to be reconstructed.
- The outer contours of the patient's head should be included as well.
- Save the entire scan (incl. all sub-files) as a DICOM file.

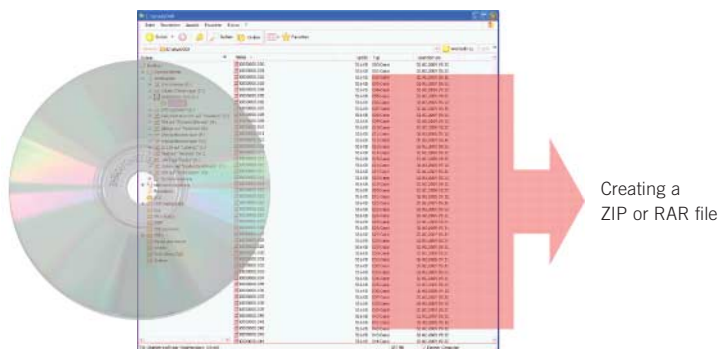
KLS Martin can process data from all commonly used CT scanners and PCS systems and almost all storage media can be accepted as well. Should you have any queries, please do not hesitate to contact our **hotline +49 7463 838-222**.

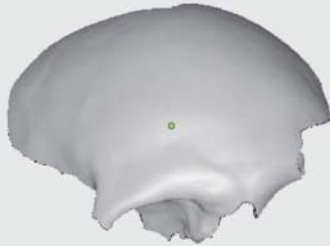
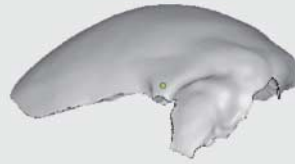
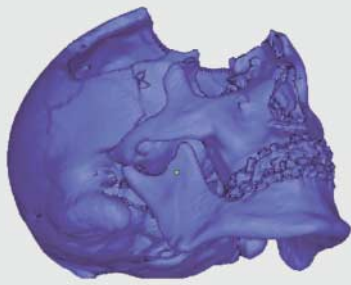
How to prepare your data

To process your request as speedily as possible, we need your scanning data in a **single** compressed file – ideally in a ZIP or RAR format. Please make sure that the compressed file to be transmitted to us contains the complete data structure including all sub-directories (if applicable).

If you are already in possession of the data on a CD-Rom, we recommend to use the freeware program „CD2ISO“ in order to provide us with an exact and complete data set. You will find the link to this freeware program on KLS Martin homepage under: Project guidance/2. Data preparation

http://kls-martin.com/Data-preparation.25949+B6Jkw9Mg_.0.html





3 Data transmission

1. How to transmit or upload your CT data

The fastest and easiest way is to use the Internet. Our website also enables you to check all the details involved in the process of creating anatomical models and patient-specific implants and upload your data directly.

<http://www.klsmartin.com/Projektanleitung.25940.0.html>

2. Important information to be provided

- Name of patient
- Name and hospital of treating physician
- KLS Martin partner (specialized dealer)
- Patient-specific implant or anatomical model
- Additional order information and comments, e.g. material preferred, thickness, points of anchorage, etc.
- Scheduled date of operation / requested delivery date for the patient-specific implant
- If you prefer, you are free to send us your data on CD, of course. The questionnaire at the back of this brochure is intended for this purpose, making documentation easy.

4 Start

Additional information

- Patient-specific implants are always shipped with the corresponding anatomical model.
- Anatomical models and patient-specific implants are delivered **non-sterile**. Please observe and follow the cleaning and sterilization instructions provided in the **Instructions for Use** supplied with the implant.
- Patient-specific implants must be sent through the **entire cleaning, disinfecting and sterilization cycle** prior to use. Patient-specific implants are suitable for machine processing and thermal disinfection. They can be processed with any program released for surgical instruments.

Anatomical models for preoperative planning



The success of a surgical procedure is very much a result of reliable surgical planning and predictable outcomes. The shorter the operation, the lower are the risks involved. Anatomical models of the affected body region are a great way for surgeons to visualize the whole intervention beforehand and go through all the details. By documenting the clinical picture in a most clear way, they help physicians as well as relatives to come to terms with the condition and the intended therapy.

Based on your digital data sets, KLS Martin manufactures patient-specific anatomical models from artificial resin, using a stereolithographic process.



Preoperative planning

- Implant selection and determination of the most appropriate surgical approach
- Selection of the diagnostic and surgical instruments required
- Simulation of the intervention, preadaptation of the osteosynthesis implants, and vector setting when using distractors
- Direct transfer of the therapeutic concept to the OR
- Shorter operating times, lower rate of complications

Case documentation

- Explanation of the condition and the intended operation to the patient and his/her relatives
- Documentation and visualization of the operation

Additional information

- Meaningful anatomical models can only be created from current digital data sets.
- Anatomical models may never be implanted and may never be allowed to come into contact with the blood circulation of the patient. The plastic material used is not biocompatible!
- Anatomical models can be worked or machined (e.g. by sawing, drilling). Such preparation must be performed prior to processing/sterilization and outside of the operating room.
- Be sure to observe the detailed Instructions for Use supplied with each anatomical model.

Should you have any queries ...
... we'll be glad to be at your service

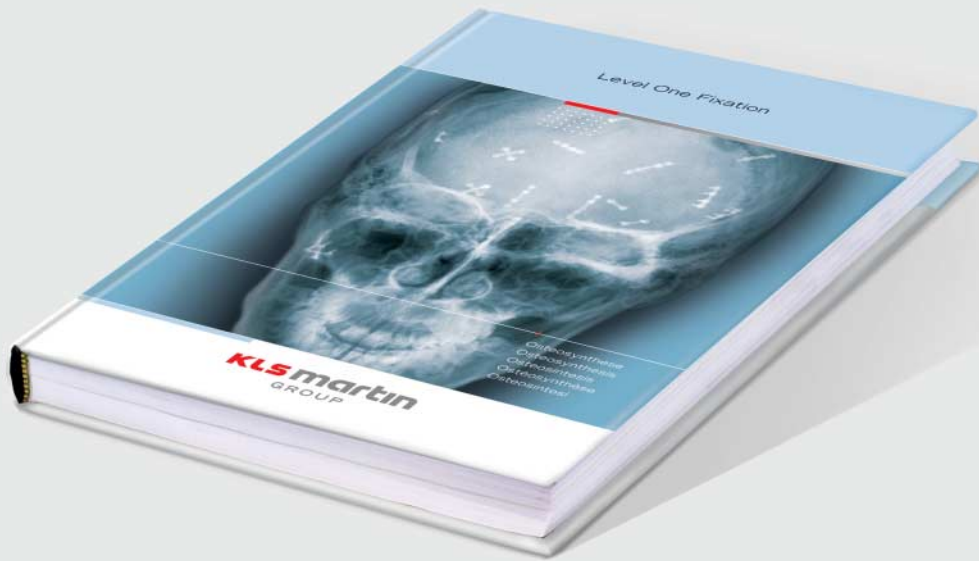
KLS Martin is an innovative group of companies with trail-blazing achievements, not least in distraction osteogenesis where we offer a specific product portfolio covering a wide range of indications.

Besides, however, KLS Martin's product range covers the entire spectrum of systems for traumatology, dental/oral surgery and reconstruction in the field of advanced OMF surgery. All osteosynthesis products are clearly presented in our standard work, the Level One Catalog.

One more tip: Don't miss out on SonicWeld Rx®, the patented and globally unique product line for resorbable osteosynthesis. Its hallmark are resorbable pins that are welded into the bone by using nothing else than ultrasound.

Resorbable osteosynthesis – and just so easy!

*Of course, you can reach us in person at your convenience –
either via e-mail or through our customer hotline.
E-mail: info@klsmartin.com
Hotline: +49-7461-706-0*



Level One Catalog
90-896-49-07



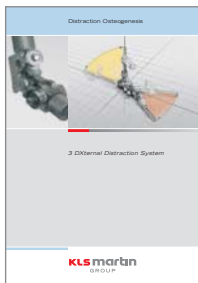
General Catalog
90-100-48-05



Dental Catalog
90-138-48-06



Distraction Devices
Overview
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3 DX
90-241-02-04



SonicWeld Rx®
Guided Bone Regeneration
and Preprosthetic Augmen-
tation
90-411-02-07



SonicWeld Rx® Catalog
90-300-02-07



SonicWeld Rx® CD-ROM
90-896-39-05

Gebrüder Martin GmbH & Co. KG
Customer Service
Ludwigstaler Str. 132
D-78532 Tuttlingen / Germany

Customer / Contact

Title, first name, last name*

Company/Hospital*

Street*

Postal/ZIP code, City/Town*

Telephone*

Fax

E-mail*

Treating Physician (if not identical with user data)

Title, first name, last name

Company/Hospital

Street

Postal/ZIP code, City/Town

Telephone

Fax

E-mail

Name of patient*

First name, last name

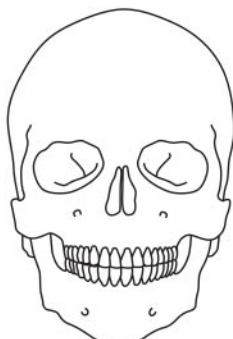
Date of birth

* Required fields. Please enter the required information!

Description of the defect region



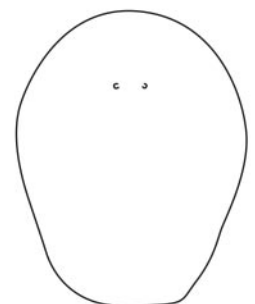
left



midface



right



top

The order comprises:

Anatomical model only

- Mandible only
- Mandible and maxilla
- Skull, complete
- Midface only
- Other / customer-specified _____

Patient-specific implant

- Material: Solid PEEK, no boreholes, incl. anatomical model
- Material: PEEK, with boreholes, incl. anatomical model
- Material: Titanium mesh, incl. anatomical model
- Material: Solid titanium, incl. anatomical model
- Suggestion requested from Gebrüder Martin GmbH & Co. KG

Mandibular reconstruction with an individually shaped reconstruction plate

- Secondary reconstruction plate, Threadlock TS, plate profile 3.0 mm
- Primary reconstruction plate, Threadlock TS, plate profile 2.0 mm
- ThreadLock plate, 3.5 mm
- Suggestion requested from Gebrüder Martin GmbH & Co. KG

Additional information

Scheduled date of operation / Requested delivery date

Please select how to send your data

- CD/DVD attached
- I prefer to mail my data
- I prefer to upload my data directly

Please fax the completed form to us, using the following number: +49 7461 706 193



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