IPS Implants®

Cranium

www.klsmartin.com
Oral and maxillofacial surgery is our passion! We also want to continue our development along with our customers. Day in, day out, we work to develop innovative products and services that satisfy the highest quality demands and contribute to the patient’s well-being.
Traumatic brain injuries, loss of bone integrity or reconstructions as a result of tumors, ulcers or cysts require restoration of the original shape and functions to restore the patient’s quality of life.

Despite advances in reconstruction techniques, it has always been a challenge to reconstruct the skull in its original shape.

The use of modern technologies opens up new options in the treatment of complex defect situations. With the development of preoperative virtual planning as well as patient-specific implants, another possibility to achieve a true-to-origin contour of resected bone has been established. IPS® offers matched solutions for the computer-based planning of surgical procedures, the efficient design of customized treatment concepts and the realization of these concepts in the operating theater with functionalized implants and planning aids.
# Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Features, functions and benefits</td>
<td>6-7</td>
</tr>
<tr>
<td>Indications and surgical technique</td>
<td>8-11</td>
</tr>
<tr>
<td>Case studies</td>
<td>12-13</td>
</tr>
<tr>
<td>Osteosynthesis accessories</td>
<td>14</td>
</tr>
<tr>
<td>The IPS® product range</td>
<td>15</td>
</tr>
</tbody>
</table>
Features, Functions and Benefits

IPS® is ideal for solutions customized to the patient by a simple and efficient process — from planning to the functional implant.

With IPS Gate®, we provide a platform which guides surgeons and users reliably and efficiently through the process of inquiring about, planning, and completing patient-specific products. The intuitive concept offers the user maximum mobility, flexibility, and functionality. With the "HTTPS" standard, IPS Gate® ensures encrypted data transmission, which is additionally certified by the TÜV Süd seal.

Patient-specific implants, planning aids, and anatomical models are made from various materials using state-of-the-art fabrication technologies. Thanks to computer-based planning and functionalized patient-specific implants, preoperative planning can be implemented in surgery with unprecedented precision.

The resulting advantages for patients are reduced complication rates, improved esthetic and functional results, shortened surgical time and faster rehabilitation.
IPS Implants® Cranium

<table>
<thead>
<tr>
<th>Features and Functions</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Planning process</strong></td>
<td></td>
</tr>
<tr>
<td>Simple and efficient interaction with the user via IPS Gate®</td>
<td>Maximum mobility, flexibility and functionality</td>
</tr>
<tr>
<td>Planning, fabrication, shipping from a single source</td>
<td>Complete service with the requirement for coordinating multiple services eliminated</td>
</tr>
<tr>
<td>Provision of three-dimensional planning data</td>
<td>High degree of safety in planning</td>
</tr>
<tr>
<td>Planning time 5-7 working days</td>
<td>Save time with efficient case processing</td>
</tr>
</tbody>
</table>

| **Drilling and marking guides** |          |
| Enable transfer of virtual planning to the OR | High planning and implementation reliability |
| In cranial reconstruction: enable precise determination of the implant position | Exact fit of the implant on the defective area |
| For the correction of congenital malformations: integration of bone rearrangement in one or more marking guides | Positioning aid for the correct arrangement of the bone segments |
| Manufactured from polyamide | High biocompatibility |

| **Implant** |          |
| High variety of materials | Wide range of choices within the context of best possible patient care |
| Option of overlapping the defect or covering it with a perfect fit | Additive manufacturing technology provides complete freedom of design for implants |
| Latest production technologies such as additive manufacturing | Maximum flexibility and stability |
| High-performance polymer PEEK (polyether ether ketone) | Physical properties similar to those of human cortical bone |
| Titanium mesh and solid titanium | Intraoperative adjustment possible if required |
| Implant based on the individual CT scan of the patient, already checked for perfect fit ex-works | High implant stability |
| | Cost-effective alternative through patient-specific preforming of the implant |
| | No sharp edges, as cutting or bending to size is no longer necessary |
Surgical Technique

Step by Step to Optimal Treatment

Indications

Cranial reconstructions due to infections, tumors, cysts or rejection reactions.

Restoration of form and function following trauma.

Correction of congenital deformities (craniofacial malformations).

Cranial reconstruction with
- Additively manufactured titanium implant (AMTi)
- PEEK implant
- Standard titanium mesh
- Standard solid titanium

(optional: use of a drilling and marking guide)

Correction of craniofacial malformations using drilling and marking guides
Surgical Technique

Cranial reconstruction with PEEK implant and drilling and marking guide
Surgical Technique

Virtual planning

To create the case the patient data and other case-related information are uploaded to the web-based platform IPS Gate®.

The data is prepared for case planning on the basis of the user's requirements and information. An integrated chat function and web meetings are available for direct communication between the IPS® developer and user.

In consultation with the user, the defective regions are identified and the resection limits defined.

Then the drilling and marking guide and a case-specific optimized implant are created. The type, diameter and size of the implant are defined exactly according to the user's wishes and are based on anatomical and clinical conditions.

At the end the user approves the design for production.

Note:
More detailed information on how to prepare patient data for virtual planning can be found in our brochure “IPS Implants® Scan Protocol Cranium / Midface / Midface Orbita / Mandible / Mandible Reconstruction”.

Resection of the defective region

To prepare the cranial vault, the drill and marking guide is placed and fixed.

This specifies the resection lines and angles for the preparation and resection of the defect. For example, marking can be performed with a piezo device.

Then the drilling and marking guide is removed and the resection performed along the marked line.
Placement of the implant

After the defective region has been prepared using a drill and marking guide, the IPS® implant is placed as a next step.

Based on the information stored in the drilling and marking guide, a fit with millimeter precision can be guaranteed.

Fixation of the implant

The IPS® implant is fixated to the native bone with osteosynthesis screws (e.g. 1.5-mm maxDrive® Drill-Free screws).

PEEK implants can also be fixated with osteosynthesis plates (e.g. with 1.5-mm Low Profile Neuro System).

Note:
In addition to the IPS® implant and the included drilling and marking guides, the required osteosynthesis accessories (KLS Martin osteosynthesis screws and plates in the planned diameters and lengths as well as the corresponding screwdriver and, if applicable, twist drill) must be available in sterile condition. They are not included in the IPS® package.
Case Studies

Cranial reconstruction with additively manufactured titanium implant
Restoration with laser-sintered titanium implant with osteo-conductive mesh structure

Cranial reconstruction with PEEK implant
Restoration with perforated PEEK implant to enable connective tissue ingrowth

Cranial reconstruction with titanium mesh
Restoration with patient-specific preformed titanium mesh

Cranial reconstruction with solid titanium
Restoration with patient-specific preformed solid titanium
Correction of craniofacial malformations
Restoration using additively manufactured drilling and marking guides made of polyamide
In addition to the IPS® implant and/or the included drilling and marking guides, the following osteosynthesis accessories are required:

- Sufficient number of KLS Martin osteosynthesis screws in the planned diameters (1.5 mm) for fixating the implant and drilling and marking guides.
- When using a PEEK implant: sufficient number of KLS Martin osteosynthesis plates (e.g. Low Profile Neuro System 1.5 mm or Level One 1.5-mm Micro System).
- A screwdriver to fit the planned osteosynthesis screws.
- If no Drill-Free screws are used: a twist drill suitable for the planned osteosynthesis screws.
The IPS® Product Range

**IPS CaseDesigner®**
The IPS CaseDesigner® makes virtual 3D surgical planning easier and faster than ever before. With this flexible software tool, orthognathic procedures can be efficiently and reliably planned and simulated, and then applied to treatment in the operation in a customized manner.

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

**IPS Implants®**
Patient-specific implants, planning aids, and anatomical models are made from various materials using state-of-the-art fabrication technologies. Due to computer-based planning and functionalized patient-specific implants, preoperative planning can be implemented in surgery with unprecedented precision.