



IPS Implants®

TMJ Prosthesis





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.

Table of Contents

	Pages
Feature, function and benefit	6 - 7
Fields of use and surgical technique	8 - 15
Case examples	16 - 17
Osteosynthesis accessories	18
The IPS® product range	19



IPS® – Individual Patient Solutions

IPS Implants® TMJ Prosthesis

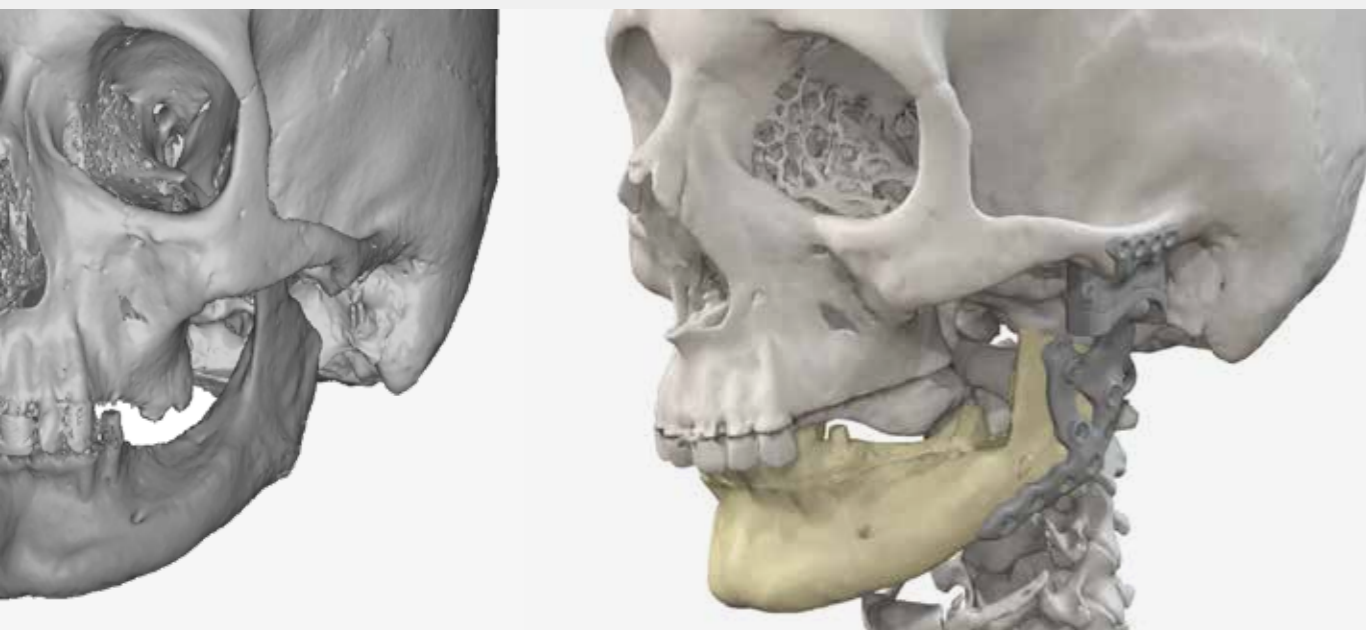
Innovative Solutions x Established Workflow

The temporomandibular joint is a unique joint in the human body due to the complexity of its geometry, function, the structures involved and the influences acting on it. It can be seen as a double joint in which the lower Articulatio Discomandibularis and the upper Articulatio Discotemporalis are working together as a union. These can be used separately or together to perform the various movements: opening/closing the mouth, moving sideways, advancing and retracting the lower jaw.

The temporomandibular joint is also susceptible to functional disorders and diseases due to its complexity. The majority of TMJ disorders in patients who complain of functional restrictions or pain can be treated using conservative and minimally invasive treatment methods. However, due to various causes, the temporomandibular joint can also be destroyed to such an extent that treatment is no longer possible without partial or complete replacement of the temporomandibular joint.

If the progression of the disease leads to a loss of the basic constitution of the joint structures, a surgical replacement is usually the only option, whereby the resection of diseased temporomandibular joint components and their artificial replacement with alloplastic prostheses is seen as a last chance.

Feature, Function and Benefit




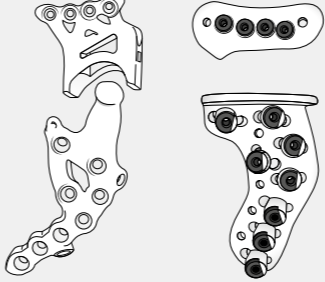

IPS® is ideal for solutions customized to the patient by a simple and efficient process – from planning to the functional implant.

We supply IPS Gate®, a platform that guides surgeons and users reliably and efficiently through the process of inquiring about, planning, and completing custom-made 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.

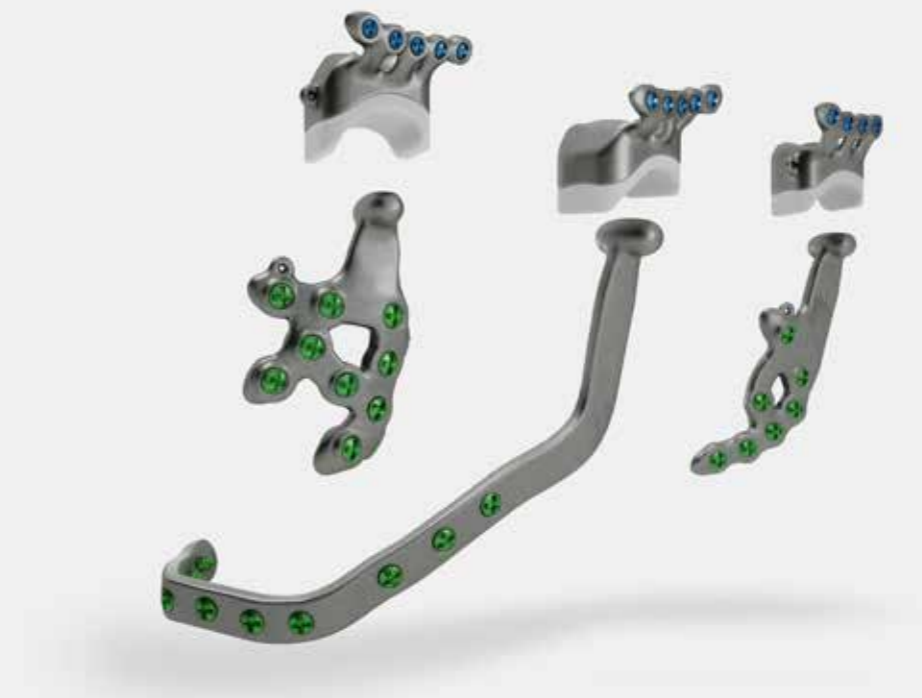
Custom-made implants, planning aids and anatomical models are made from various materials using state-of-the-art fabrication technologies. Thanks to computer-based planning and functionalized custom-made implants, preoperative planning can be implemented in surgery with unprecedented precision.

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

IPS Implants® – TMJ Prosthesis

	Features and functions	Benefits
Planning process 	<ul style="list-style-type: none"> Simple and efficient interaction with the user via the IPS Gate® Planning, fabrication, shipping from a single source Various planning options with obligatory check by FEM simulation with IPS inSilico® x VIT Planning time: 30 working days after case approval 	<ul style="list-style-type: none"> Maximum mobility, flexibility and functionality Complete service with the requirement for coordinating multiple services eliminated High degree of safety in planning the post-operative result Save time with efficient case processing
Planning aids 	<ul style="list-style-type: none"> Enables transfer of virtual planning to the OR Integrated steel sleeves Made of polyamid or additive manufactured titanium alloy 	<ul style="list-style-type: none"> Maximum safety with accurate determination of plate position and screw holes No need for additional drill guides Variability in planning options and high biocompatibility
Prosthesis 	<ul style="list-style-type: none"> Innovative, modern and anatomically inspired design Latest production technologies such as additive manufacturing Manufactured as standard from high-strength titanium alloy Ti6Al4V (condyle) in combination with UHMWPE (fossa) Prosthesis based on the individual CT scan of the patient, already checked for perfect fit ex-works Prosthesis can optionally be fixed with locking or non-locking screws Optionally with hooks on both components Prosthesis components are coming pre-sterilized 	<ul style="list-style-type: none"> Allows for more post-operative jaw movements Additive manufacturing technology provides complete freedom of design for implants Proven materials combined in a new way: leads to fewer foreign body reactions, ideal gliding properties and high stability of the implant Best possible three-dimensional precision fit Maximum flexibility and stability Allows for suture fixation Reducing risk of infection

Step by Step to Optimal Fixation



Fields of use

Reconstruction is indicated for patients with severe temporomandibular disorders (TMD), which may be associated with functional limitations of the masticatory system, restricted jaw opening or pain in the temporomandibular joint.

Surgical Technique

Unilateral TMJ reconstruction
via total joint prosthesis

Pages 10 - 14





Virtual planning

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

The IPS® engineer prepares the case plan based on the information and the requests of the user. An integrated chat function and web meetings are available for direct communication between the IPS® engineer and user.

Note:

More detailed information on how to prepare patient data for virtual planning can be found in our brochure "IPS Implants® Scan Protocol TMJ Prosthesis".

The resection lines are defined first. Then planning aids such as drill and marking guides as well as implant replicas and of course the prosthesis components are generated. The type, diameter and length of the osteosynthesis screws are defined.

The prosthesis components are additionally tested via FEM analysis with our IPS inSilico® tool before they are manufactured.

At the end the user approves the design for production.

Preparation of the implant

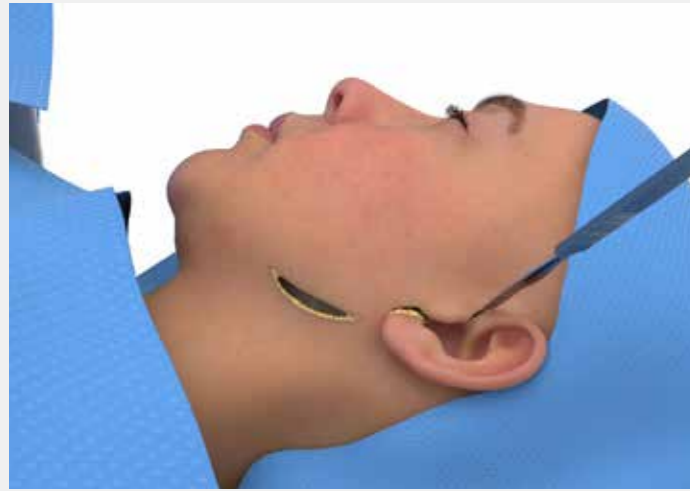
Following approval, the custom-made products are manufactured and shipped.

Then surgery can be initiated.

Note:

The custom-made prosthesis components are delivered sterile. The planning aids however are non-sterile. Before use, they must be removed from their packaging and subjected to a suitable cleaning, disinfection and sterilization procedure.





Incision

The ramus is exposed using a submandibular approach.

The condylar head and the fossa are accessed via a preauricular incision.

Optionally, the occlusion can be stabilized using intramaxillary fixation.



Preparation of the mandible via drill and marking guides

After preparation of the mandible, the drill and marking guides, which also predefine the cutting angle, are fixed to the mandible with 2.0 mm (alternatively 1.5 or 2.3 mm) osteosynthesis screws. The small holes in the drill and marking guides serve to fix the guide to the mandible.

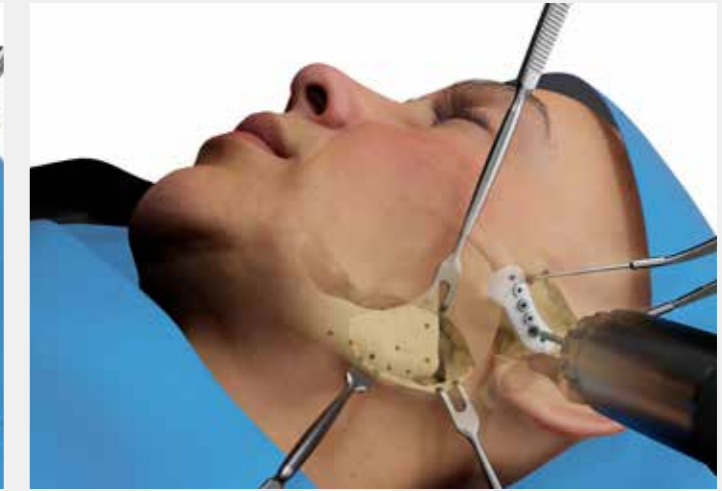
The resection lines are marked.

The screw holes for the implant are pilot-drilled through the large holes in the drill and marking guide. Steel guides are fitted into the holes, through which targeted drilling can be performed without additional drill guides.



Resection of the condylar area

The drill and marking guide is removed and the resection performed along the marked line.

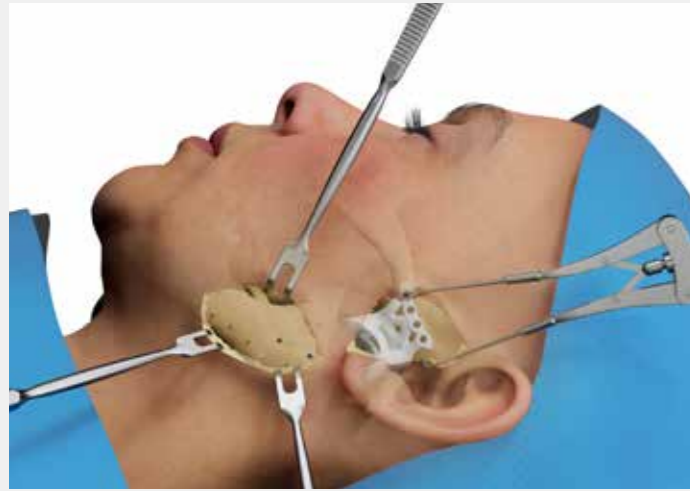


Preparation of the fossa

After resection of the condyle, respectively the ascending ramus, the fossa is prepared.

Similar to the condyle segment, a drilling and/or marking guide with osteosynthesis screws 1.5 mm (alternatively 2.0 mm) is fixated to the zygoma arch.

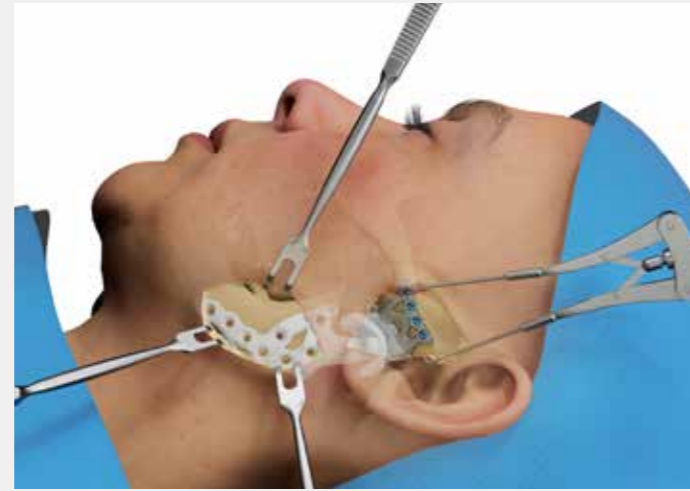
After the drilling the marking guides are removed from both the condylar and fossa segments.



Examination of the implant positions via planning aids

To check the positioning beforehand additional custom-made planning aids made of polyamide are used.

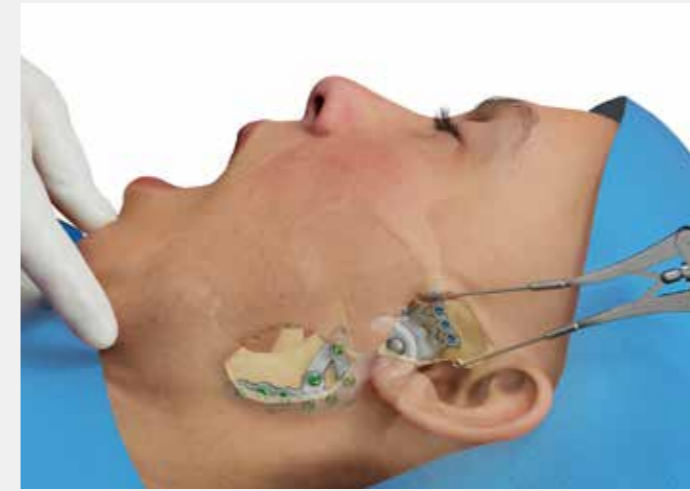
When the soft tissue is sufficiently prepared and the planning aids fit into the position the sterile prosthesis components can be opened.



Final fixation of the prosthesis components

After the drilling the marking guides are removed from both the condylar and fossa segments. Finally, the fossa component is fixed to the temporal bone (os temporale) or zygoma arch using the pre-drilled screw holes.

Following the fossa, the condylar segment is then fixated via the pre-drilled screw holes onto the mandible.



Merging of the fossa and condyle components

In order to enable movement both components are now brought together. The condyle head is inserted above the plate into the sliding surface of the fossa component.

The mouth opening, function and range of motion of the artificial joint are checked manually by the clinician.

Optional suture hooks on both implants can be used for connecting the prosthesis.

If necessary, an additional fat graft is performed for better healing. If intermaxillary fixation has been used, this is now released.



Wound closure

Finally, the wound is sutured.





**Uni- or bilateral total joint replacement
by a prosthesis**



**Orthognathic planning including a total
joint replacement**



**Mandibular reconstruction including a total
joint replacement**

Optionally with graft planning included

- Fibula
- Scapula
- Iliac crest

Osteosynthesis Accessories



In addition to the IPS® implant and the included drill and marking guides, the following osteosynthesis accessories in sterile condition are required for the surgical treatment:

- A sufficient number of KLS Martin osteosynthesis screws in the planned diameters and lengths
- A screwdriver to fit the planned osteosynthesis screws
- A twist drill to fit the planned osteosynthesis screws
- 2.0 mm osteosynthesis screws (alternatively 1.5 or 2.3 mm screws) for fixing the drill and marking guide with suitable twist drill and screwdriver

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 custom-made products. With the HTTPS standard IPS Gate® guarantees encrypted data transmission, which is additionally certified by the TÜV Süd seal.



IPS Implants®

Custom-made 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 custom-made implants, preoperative planning can be implemented in surgery with unprecedented precision.



KLS Martin Group

KLS Martin Australia Pty Ltd.

Sydney · Australia
Tel. +61 2 9439 5316
australia@klsmartin.com

KLS Martin do Brasil Ltda.

São Paulo · Brazil
Tel. +55 11 3554 2299
brazil@klsmartin.com

KLS Martin Medical (Shanghai) International Trading Co., Ltd

Shanghai · China
Tel. +86 21 5820 6251
info@klsmartin.com

KLS Martin India Pvt Ltd.

Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

KLS Martin Italia S.r.l.

Milan · Italy
Tel. +39 039 605 67 31
info@klsmartin.com

KLS Martin Japan K.K.

Tokyo · Japan
Tel. +81 3 3814 1431
info@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.

Penang · Malaysia
Tel. +604 261 7060
malaysia@klsmartin.com

KLS Martin de México, S.A. de C.V.

Mexico City · Mexico
Tel. +52 55 7572 0944
mexico@klsmartin.com

KLS Martin Nederland B.V.

Huizen · Netherlands
Tel. +31 35 523 45 38
infonl@klsmartin.com

KLS Martin SE & Co. KG

Moscow · Russia
Tel. +7 499 792 76 19
russia@klsmartin.com

KLS Martin Taiwan Ltd.

Taipei · Taiwan
Tel. +886 2 2325 3169
taiwan@klsmartin.com

KLS Martin SE & Co. KG

Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin UK Ltd.

Reading · United Kingdom
Tel. +44 118 467 1500
info.uk@klsmartin.com

KLS Martin LP

Jacksonville · Florida, USA
Tel. +1 904 641 77 46
usa@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.

Hanoi · Vietnam
Tel. +49 7461 706-0
vietnam@klsmartin.com

KLS Martin SE & Co. KG

A company of the KLS Martin Group

KLS Martin Platz 1 · 78532 Tuttlingen · Germany
PO Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com