

IPS Implants®

Distraction

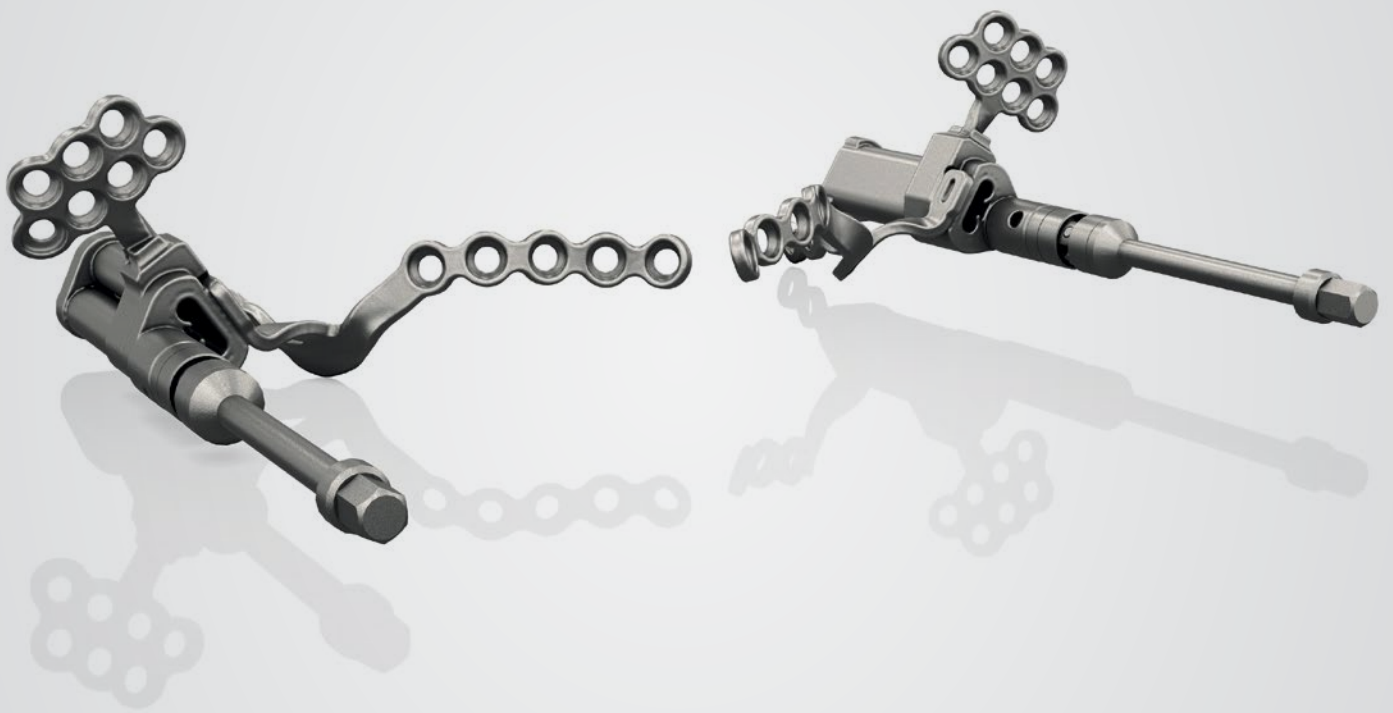




Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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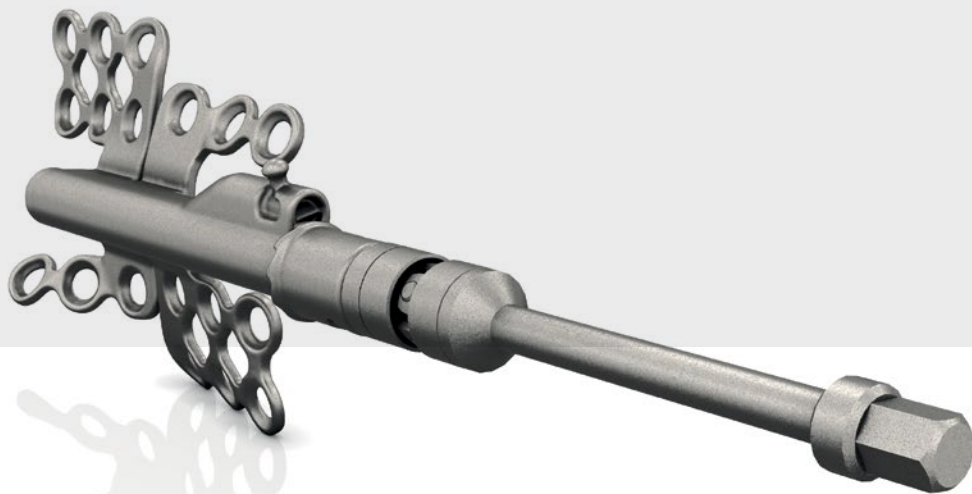
IPS Implants®

Distraction

Distraction osteogenesis is a technique that has been established for several decades and is used to treat major bone defects. The insights regarding bone lengthening gained by the Russian surgeon Gavril Ilizarov in the 1950s are standard knowledge today and have made their way into clinical practice in many fields of cranio-maxillofacial surgery.

From its early beginnings, KLS Martin has closely monitored and promoted the latest trends in distraction techniques. 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 its realization through patient-specific distractors and planning aids, further options have been created to reliably achieve predictable results. 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 distractors and planning aids.

Features, Function, and Benefits



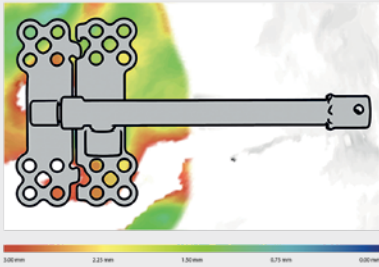
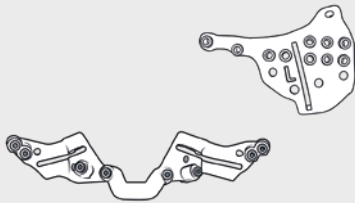
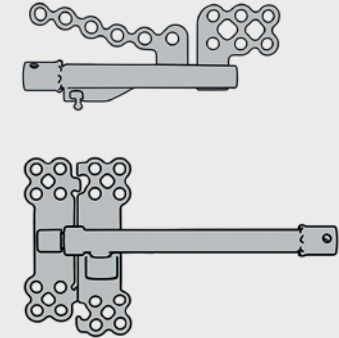
IPS® convinces by an easy and efficient process for individual patient solutions – from the planning up to the functionalized implant.

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 distractors, 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 distractors, 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® – Distraction

	Features and Function	Benefits
<p>Planning process</p> 	<ul style="list-style-type: none"> ■ Simple and efficient interaction with the user via IPS Gate® ■ Planning, fabrication, shipping from a single source ■ Range of options for planning <ul style="list-style-type: none"> – Planning and simulation of the postoperative situation (IPS® Planning Service) – Heat map of bone thickness – Planning and securing the distraction vectors – Mirroring of the intact bones and adaptation to the anatomical environment – Planning of the screw holes ■ Planning time 15-20 working days 	<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 ■ Save time with efficient case processing
<p>Drill and marking guides</p> 	<ul style="list-style-type: none"> ■ Transfer of virtual planning to the OR ■ Integrated steel sleeves ■ Made of polyamide or additive manufactured titanium alloy 	<ul style="list-style-type: none"> ■ Maximum safety through accurate determination of the position and screw holes ■ No need for additional drill guides ■ Variability in planning and high biocompatibility
<p>Distractors</p> 	<ul style="list-style-type: none"> ■ Manufactured as standard from high-strength Ti6Al4V titanium alloy ■ Fixation plates based on the individual CT scan of the patient, already checked for perfect fit ex-works ■ The standard distractors from the KLS Martin range serve as the basis ■ IPS® distractor with special components: consists in part of specially manufactured components ■ IPS® RED II according to Prof. J. Obwegeser: Planning and manufacturing of modified fixation and retention plates 	<ul style="list-style-type: none"> ■ High stability of the distractor and the plates ■ Dimensionally stable during insertion ■ Best possible three-dimensional precision-fit ■ Patient-friendly round edges, as trimming or bending is no longer necessary ■ Identical geometries and technical features as the standard distractors ■ All accessories (e.g., activators, instruments, etc.) can be used ■ Individual adaptation of the distractor to the anatomical characteristics of the patient ■ Stronger anchoring to the skull bone ■ Option of attachment in case of poor bone quality

Realization Options

The standard distractors serve as the basis for the IPS® distractors from KLS Martin. They not only act as a reference for planning, but also for the indications of the respective IPS® distractor.

IPS® distractors are available in two versions: as IPS® distractors with modified standard components consisting of the components of the respective standard distractor that have been adapted individually, while IPS® distractors with special components consist in part of specially manufactured components.

In addition, patient-specific planning aids tailored to the use of selected standard distractors can be manufactured to facilitate performing surgery. Here, the surgical procedure is simulated virtually and the markings of the osteotomy lines are transferred to the designed planning aids.

KLS Martin's comprehensive range of patient-specific IPS® distractors covers the following anatomical regions:



Alveolar ridge:
 ■ TRACK Distractors



Mandible:
 ■ Zurich II and Micro Zurich II Distractors
 ■ Zurich Pediatric Ramus Distractor
 ■ Horizontal and Ramus Distractors
 ■ Right Angle Driven Distractor
 ■ Mandibular Telescoping Distractor
 ■ Zurich Wood and Zurich Bidirectional Distractors
 ■ Ramus Transport Distractor
 ■ ThreadLock Transport and Herford Transport Distractors



Maxilla:
 ■ Zurich Pediatric Maxillary Distractor
 ■ Maxillary Telescoping Distractor
 ■ TS-MD Distractor
 ■ Liou Cleft Distractor



Transversal plane of the maxilla and mandible:
 ■ Rotterdam Palatal Distractor
 ■ Rotterdam Midline and Bologna Midline Distractors



Midface and cranium:
 ■ Arnaud and Marchac Distractors
 ■ Kawamoto Distractor
 ■ Posterior Cranial Vault Distractor



External midface distractor:
 ■ RED II Distractor

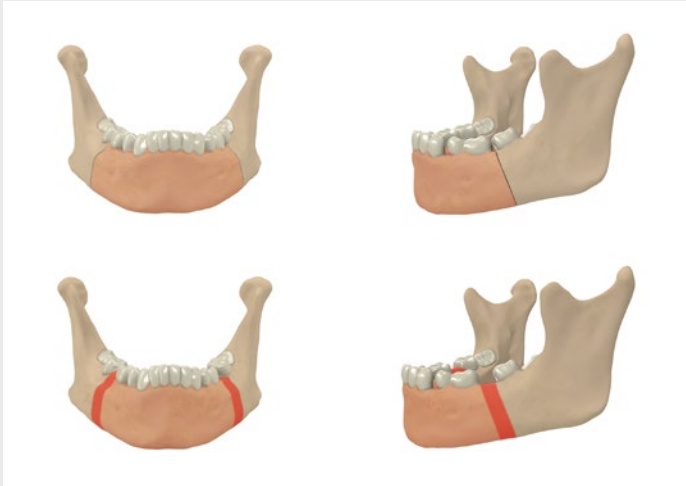


Surgical Technique

**Bilateral distraction of the mandibular body
using patient-specific Zurich II Distractors**

Pages 10-13





Virtual planning

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

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

In consultation with the user, the drill and marking guides as well as the distractors optimized for the specific case are generated.

At the end the user approves the design for production.

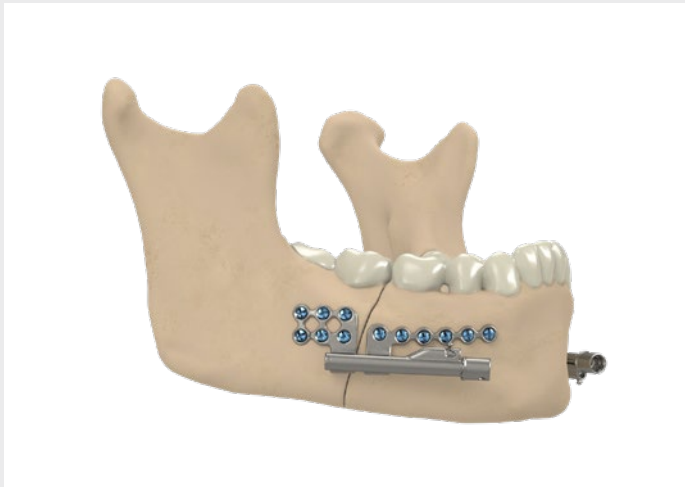
Insertion of the guides and performing the osteotomy

After completing vestibular access, the drill and marking guides are inserted. The osteotomy line is defined using the cutting mark.

Afterwards, the screws can be loosened again and the drill guide is removed again.

Osteotomy is now performed buccally using the marks.

In adults it is also necessary to mobilize the mandible lingually, in the area of the osteotomy, with a chisel.



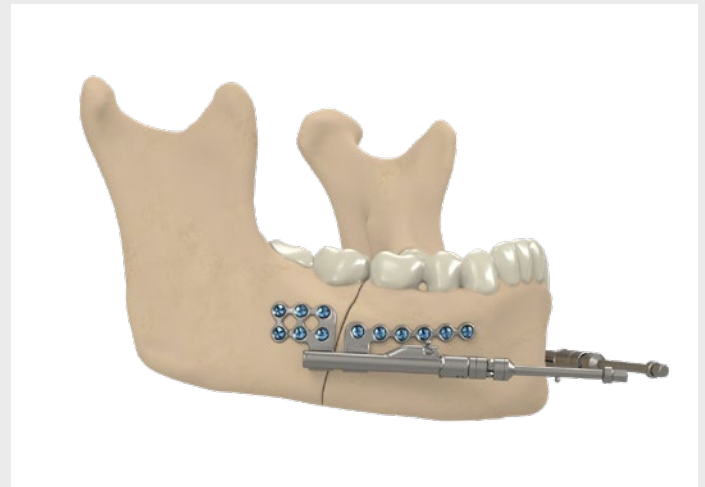
Fixation of the distractors

After ensuring mobility of the individual bone fragments, the distractor is attached with at least four screws on each side. The correct function of the distractor must be checked intraoperatively.

It should be noted that the activator must remain accessible and movable after closing the suture.

Note:

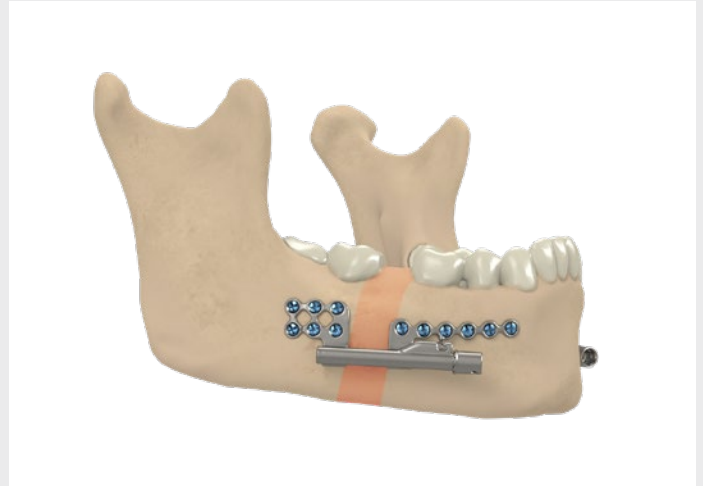
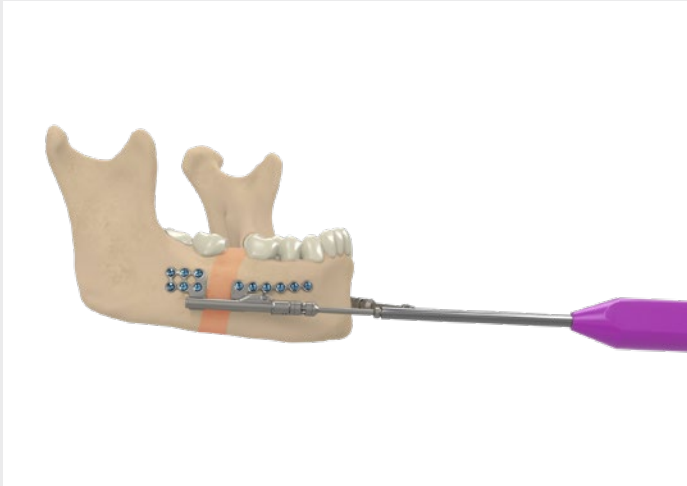
In addition to the IPS® distractor, the respective activator must be available in a sterile condition in addition to the necessary osteosynthesis accessories (KLS Martin osteosynthesis screws of the planned diameter as well as the matching twist drills and screwdrivers). They are not included in the IPS® package.



Latency period

After the implantation of a distraction system, a latency period must first be observed before the actual distraction period begins.

The latency period is to be assessed by the surgeon depending on the indication and usually lasts approx. 5–7 days, depending on the patient.



Distraction period

Active distraction begins at the end of the latency period.

The generally recommended distraction length per day is 1 mm. Active distraction is performed with a patient screwdriver (Ref. 51-500-90-07).

One complete turn corresponds to 0.5 mm here. It is recommended to make one complete turn ($360^\circ = 0.5 \text{ mm}$) each morning and evening. This value always corresponds to that of the standard distractor.

An arrow on the screwdrivers indicates the direction of activation.

Consolidation period

The consolidation period lasts approx. 8-12 weeks, depending on the patient.

The distraction system may only be removed after complete bony development (consolidation) so as not to endanger the outcome of the distraction.

However, the activator should be removed after the distraction period is completed. Remote Release Activators can be separated directly at the activation point after completion of the distraction period, while conventional activators must be detached from the distractor using special detachment forceps.

Orthodontic treatment can already be started during the consolidation period.



Removal of the distractor

Once the consolidation period has been completed, all distractor components must be removed.

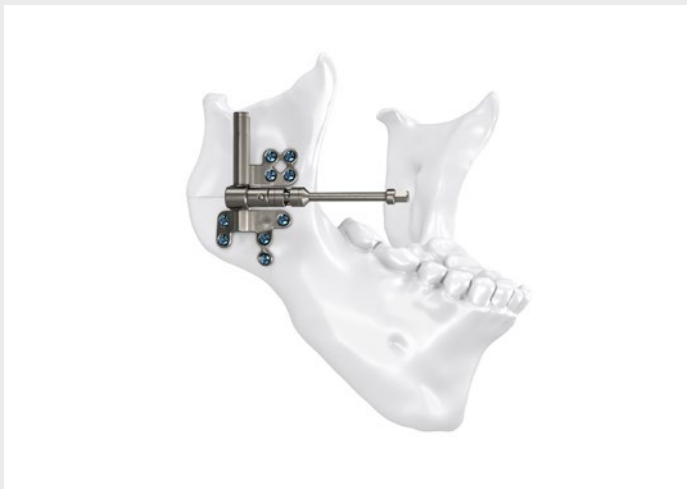
The type and extent of postoperative treatment and / or rehabilitation measures are to be coordinated with the patient by the attending user.



Alveolar ridge distraction
Patient-specific TRACK 1 Plus distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



Unilateral distraction of the mandibular body
Patient-specific Zurich II Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



Unilateral distraction of the ascending branch
Patient-specific Right Angle Driven Distractor with shortened spindle and individually fabricated plates.
Fixation with 1.5 mm standard screws.



Bidirectional distraction of the mandibular body and ascending branch
Patient-specific Zurich Bidirectional Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



Transport distraction of the condylar head
Patient-specific Ramus Transport Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



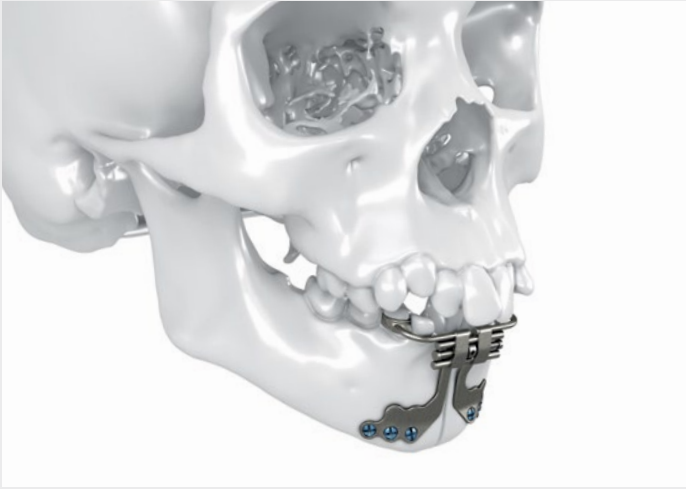
Transport distraction of the mandible
Patient-specific ThreadLock Transport Distractor with individually fabricated plates and optimized reconstruction plate.
Fixation with 1.5 mm standard screws.



Bilateral distraction of the maxilla
Patient-specific Zurich Pediatric Maxillary Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



Bilateral distraction of the maxilla
Patient-specific Maxillary Telescoping Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



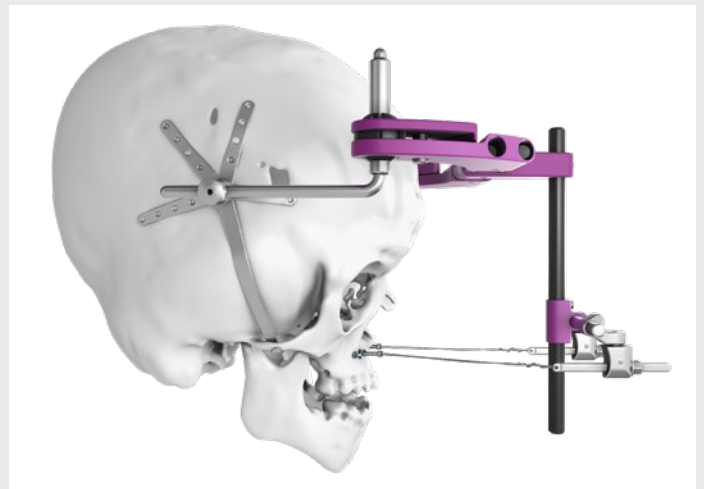
Transversal distraction of the mandible
Patient-specific Bologna Midline Distractor with individually fabricated plates.
Fixation with 2.0 mm standard screws.



Bilateral midface distraction
Patient-specific Kawamoto Distractor with individually fabricated plates.
Fixation with 1.5 mm standard screws.



Multipart distraction of the cranium
Patient-specific Posterior Cranial Vault Distractor with individually fabricated plates and additive manufactured fixation plate of the fronto-orbital ligament.
Fixation with 1.5 mm standard screws.



External midface distraction
Patient-specific RED II Distractor according to Prof. J. Obwegeser with individually fabricated fixation and retention plates.
Fixation with 1.5 mm standard screws.



Unilateral distraction of the mandible
Patient-specific marking guide for Zurich II Distractor



Bilateral distraction of the maxilla
Patient-specific drill and marking guide for Maxillary Telescoping Distractor

Osteosynthesis Accessories



In addition to the IPS® distractor, the following osteosynthesis accessories in sterile condition are required for the surgical restoration:

- If the IPS® distractor is not fitted with a fixed activator: an activator matching the IPS® distractor (standard or Remote Release)
- The patient screwdriver pertaining to the IPS® distractor and other necessary distraction instruments (e.g., plate holding instruments, activator arm separating forceps, etc.)
- Sufficient number of KLS Martin osteosynthesis screws in the planned diameters and matching lengths
- A screwdriver suitable for 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. Owing to this flexible software tool, orthognathic surgery can be efficiently and reliably planned, simulated, and individualized for treatment in the OR.



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.



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