

# **IPS** Implants®

Radius | Forearm Reconstruction

One patient. One solution.



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## **IPS®** – Individual Patient Solutions

## **IPS** Implants®

## Radius | Forearm Reconstruction

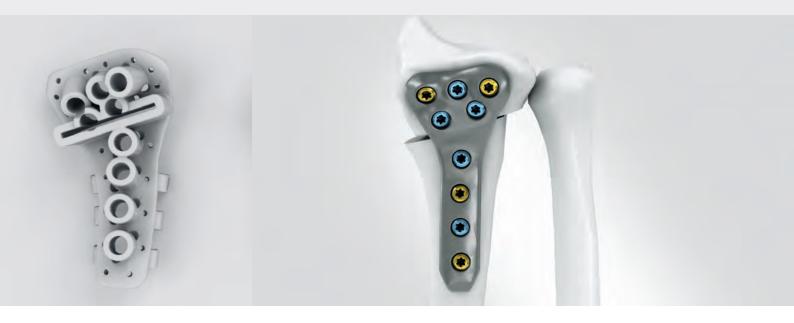
In some cases, malunions can occur following distal radius and forearm fracture treatments. This can lead to reduced strength, pain and decreased mobility. Similar limitations can be also seen in congenital malposition cases.

In addition to standard fracture and reconstruction plates, KLS Martin offers custom-made solutions for distal radius and forearm reconstructions. The portfolio ranges from the standard treatment to the combination with drill and marking guides up to the complete custom-made treatment. Especially for complex cases the custom-made radius or forearm reconstruction can be a solution.

IPS Implants® for the radius and forearm reconstruction are fixed with our proven standard and locking smartDrive® screws.

Limited instrumentation is required.

# Feature, function and benefit



To create a new IPS® case, the CT scans of the affected and unaffected, contralateral patient's forearm will be uploaded to the IPS Gate®. IPS Gate® is a web-based platform and app which guides users through the whole process of requesting, designing and finalizing custom-made solutions in a safe and efficient way. The integrated chat function allows direct contact and direct communication between the people involved. With the "HTTPS" standard, IPS Gate® ensures encrypted data transmission, which is additionally certified by the TÜV Süd seal.

Based on the CT scans of the patient, the IPS® engineer prepares and plans the custom-made reconstruction in coordination with the responsible surgeon. Afterwards, custom-made implants, drill and marking guides and anatomical models are manufactured and shipped to the hospital for the procedure.

# IPS Implants® | Radius and Forearm Reconstruction - planning process

### Feature Benefit

#### **IPS Gate®**



- Simple and efficient interaction with the IPS® engineers via IPS Gate®
- Planning, production, shipping and local support from a single source

malunion is planned based on the healthy

Anatomical reconstruction of the

reference side

- Maximum mobility, flexibility and functionality
- Efficient and intuitive guidance through the whole process

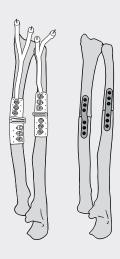
#### Range of options for planning

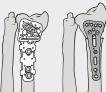




- Virtual predetermination of the osteotomy line and screw positions for the patientspecific guide
  - Planning and design of a custom-made implant with individual features (e.g. shape, design and plate profile)

- Best possible anatomical positioning and reconstruction
- Precise and predictable transformation of the planning into the treatment
- Anatomical fitting of the IPS Implant<sup>®</sup> is guaranteed
- Axial and rotational deformities are reconstructed and considered





- Planning with a custom-made guide in combination with a standard plate is a possibility for cases that do not require a custom-made additive manufactured plate
- Efficient and safe combination of a standard radius reconstruction plate with virtual planning leading to a drill and marking guide for simple reconstruction

### Treatment



- Planning and processing time for the custom-made solution (e.g. guide and implant) within 10 - 12 business days
- Time saving with efficient case processing

# Feature, function and benefit



Custom-made implants, drill and marking guides and anatomical models are made from various materials using state-of-the-art fabrication technologies.

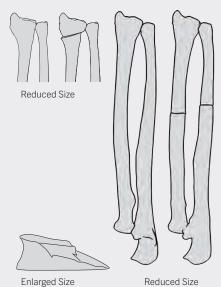
Anatomic models are great visual aids and also confirm that the surgical guide and plate fit as planned. The implants and guides transfer the previously created digital 3D plan into surgery. The guides are fixed on the bone with Kirschner wires. Predictive screw holes are built into the surgical guide. After the holes are pre-drilled, the osteotomies may be marked and performed following removal of the guide. Finally, the custom-made implant brings the bone segments into the planned anatomical position and is fixed with Ø 2.5 mm or 3.0 mm smartDrive® standard and/or locking screws.

Thanks to computer-based preoperative planning, functionalized custom-made drill- and marking guides and implants can be implemented in the surgery with unprecedented precision.

# IPS Implants® | Radius and Forearm Reconstruction models, guides, implants

**Function** 

#### Model

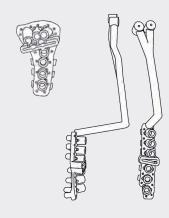


- An anatomical bone model for the pre- and postoperative situation is produced and allows a "fit check" of the guide and the implant to the patient's anatomy
- Best possible three-dimensional precision-fit

**Benefit** 

- Additional, a verification model of the exact anatomical shape and dimensions of the open wedge osteotomy is provided
- Precise preparation of the bone graft
- Support in positioning of distal bone segments for intra-articular and complex lengthening radius reconstructions

### Drill and marking guide



- Latest production technologies such as additive manufacturing
- Fixation with Kirschner wires
- Holes for pre-drilling in the planned angulation
- Several marking slots can be combined in one guide

Y-shaped arm with Kirschner wire fixation

- Additive manufacturing technology provides complete freedom of design for guides
- Precise reconstruction result
- Efficient workflow
- Specifically for the forearm reconstruction
- Precise positioning of the guide through imaging

#### **Implant**



- Latest production technologies such as additive manufacturing
- Additive manufacturing allows complete flexibility in implant design and funtionalized implants
- No sharp edges because cutting or bending is not needed
- Manufactured as standard from ■ High implant stability
- Possibility to fix the plate multi-vectorial with Ø 2.5 mm and /or Ø 3.0 mm standard or locking screws

TI6AI4V titanium alloy

Highest individuality and stability



# Step by step to optimal treatment

# Fields of use

IPS Implants® Radius Reconstruction

■ Correction osteotomies of the distal radius

IPS Implants® Forearm Reconstruction

■ Correction osteotomies of the radius and/or ulna

IPS Implants® Madelung deformity reconstruction

■ Reconstruction of congenital forearm malformations

# Typical examples



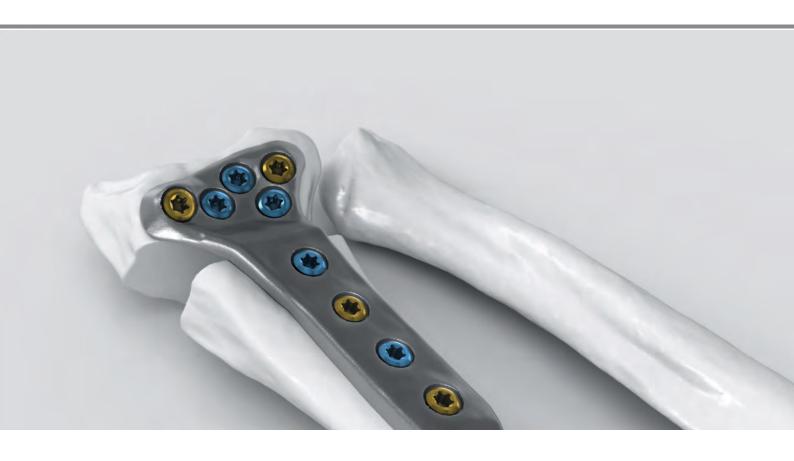
Extra-articular distal radius reconstruction



Forearm reconstruction including the radius and the ulna



Reconstruction of congenital forearm malformations (Madelung deformity reconstruction)



# Surgical techniques

Custom-made radius reconstruction with IPS Implants® Radius Reconstruction

Dr. med. Stephan Schindele

Pages 12 - 19



Custom-made forearm reconstruction with IPS Implants® Forearm Reconstruction

Dr. med. Jan-Ragnar Haugstvedt

Pages 20 - 29



Radius reconstruction for Madelung deformity | virtual planning with IPS Implants® Forearm Reconstruction

Prof. Dr. med. Hermann Krimmer

Pages 30 - 39







#### Preoperative presentation

This 17-year old patient was involved in a motor vehicle accident when he was 14 years old and suffered an extra-articular radius fracture of the non-dominant left side with dorsal dislocation. Primary treatment comprised of closed reduction, K-wire fixation and immobilization in a cast. Follow-up radiographs demonstrated increasing dorsal angulation which could not be adequately controlled by corresponding cast changes. The patient presented two years following the traumatic injury and his surgical options were discussed at this time. The patient noted weight bearing complaints and limitation in pronation/supination. Radiology reports showed a marked dorsal angulation of the distal radius with significant shortening. Less than a year later, the patient presented again at the hand surgery clinic with persistent pain during wrist movement, particularly in palmar flexion and when changing between pronation and supination. The definite radiological malalignment of the distal radius indicated the need for corrective osteotomy with 3D reconstruction and customized plating.

#### Virtual planning

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

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

Note that the upper and all subsequent illustrations display the palmar view. The left distal radius is affected.



### Virtual planning: mirroring and osteotomy gap

The healthy anatomical region is mirrored and compared with the affected region. The postoperative position and the osteotomy line are defined by the clinical parameters and requirements. The bone segments are positioned by referencing the healthy contralateral radius.

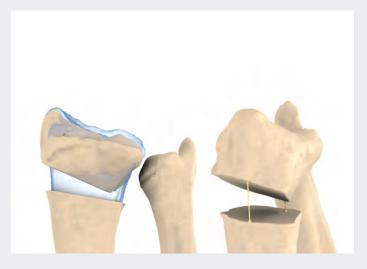
The resulting osteotomy gap is measured.



#### Virtual planning: guide and implant

In consultation between the IPS® engineer and the surgeon the optimized postoperative anatomical position is defined as well as the number and location of screw holes in the guide and the implant.

In the final step the user approves the implant design for production.









#### Patient positioning

Position the patient supine on the operating table. A tourniquet is applied to the upper arm and the hand is positioned on the operating table.

In addition to the general surgical instruments, this procedure requires intraoperative monitoring by fluoroscopy. The imaging machine used in the procedure should be prepared with sterile drapes and positioned accordingly in the operating room. This maintains the exact setting once selected and reduces the radiation dose for both the patient and surgeon. For certain indications the use of a horizontal hand distraction frame may be helpful.

#### Radiopalmar approach

Incise the skin over the distal radius in a straight line about 7 cm long. Depending on the malalignment, the incision may be extended distally and radially at an angle across the wrist crease. The longitudinal axis should run between the tendon of the flexor carpi radialis (FCR) muscle and the radial artery. If necessary, the skin incision may also be extended proximally in a straight line.





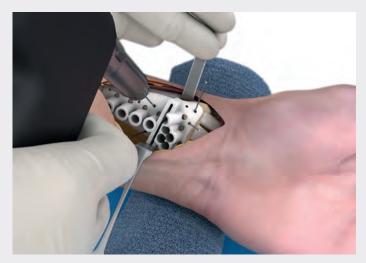


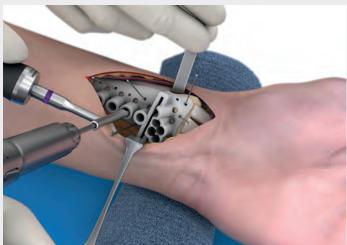
#### Dissection

After subcutaneous dissection and hemostasis, dissect down into the space between the FCR tendon and the radial artery. Spare any small skin nerves and especially the palmar branch of the median nerve. Retract the soft tissue radially and ulnar with blunt retractors. Free the flexor pollicis longus (FPL) tendon and muscle and retract it ulnar as well. Follow this with exposing the broad pronator quadratus muscle, which covers the distal radius.

#### **Exposing the radius**

Sharply dissect the pronator quadratus muscle together with its fascia radially off the distal radius in L-shaped fashion, continue the dissection ulnar and then retract the soft tissue. By now, the distal radius should be fully exposed on the palmar aspect and detached from the muscle. Continue the radial dissection to the dorsal aspect of the radius. To this end, the brachioradial tendon must be partially or completely detached from the radius and, in addition, for safe positioning of the guide it is recommended to open the first extensor tendon compartment and expose the tendons therein (APL and EPB). Carry the dissection close to the bone posterior to the fourth extensor tendon compartment. Leave the superficial branches of the radial nerve within the subcutaneous tissue. Also bluntly detach the second, third and fourth extensor tendon compartment from the radius. After opening the third extensor tendon compartment release the extensor pollicis longus (EPL) tendon. If possible, leave the radial artery and its accompanying veins protected in the subcutaneous tissue. Only dissect the radial artery and retract it ulnar in case of extensive and complex corrections as well as preexistent scarring on the extensor aspect following previous surgery. This provides a better overview of the distal radius on the extensor aspect. Retract the flexor carpi radialis, flexor pollicis longus and possibly other muscles together with the pronator quadratus with Langenbeck retractors. On the radial aspect, protect the radial artery together with the subcutaneous tissue and the extensor tendons with a Hohmann retractor.





#### Positioning and using the drill and marking guide

Position the guide as defined in the preoperative planning and as illustrated in the case report (customized planning documentation). It is recommended to check the guide position on the supplied bone model, e.g., that it precisely matches the distal radius and is fixed in place. Exact positioning of the guide on the bone is aided by the structural integration of anatomical landmarks. Temporarily fix the guide in place with at least three or four K-wires through the preferred holes.

Confirm the correct position of the guide by subsequent fluoroscopy. Only continue with the following steps of the procedure if the guide position is correct.

#### Pre-drilling

In the next step, with the help of the IPS Implants® drill and marking guide and the corresponding smartDrive® drill guide drill the core holes for the subsequent screw implantation. It is essential that the correct drill guide corresponding to the screw diameter is inserted into the predictive screw holes. Bicortical drilling and screw placement is mandatory in the proximal shaft. However, when placing distal screws monocortical drilling and fixation may suffice. Depending on the situation, 2.5 mm or 3.0 mm diameter screws may be used. In general, smartDrive® screws with a diameter of 2.5 mm are used.

smartDrive® screw	Core hole	Drill guide	Color coding
Ø 2.5 mm	Ø 2.0 mm	26-166-25-07	purple
Ø 3.0 mm	Ø 2.5 mm	26-166-27-07	orange





monoaxial

Ø 2.0 mm drill



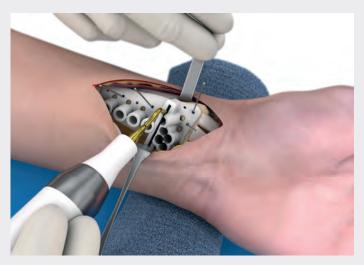
monoaxial

Ø 2.5 mm drill





Core hole drill AO attachment Ø 2.0 mm Core hole drill AO attachment Ø 2.5 mm





#### Marking the osteotomy line

Mark the osteotomy line in the guide with a piezoelectric saw. Once completed, remove the K-wires and the guide.

#### Completing the osteotomy

After another visual check of the marked osteotomy line, complete the planned osteotomy. A saw blade with the following dimensions may be used:

Cutting width (thickness): 0.38 - 0.8 mm
 Width of working blade: 9 - 15 mm
 Length: 31 - 40 mm

A 0.38 mm thick saw blade is recommended. The thinner the saw blade, the more precise the osteotomy will be with the least amount of bone loss.

With completing the osteotomy line retract the soft tissues ulnar, and on the radial aspect protect the radial artery together with the dorsal extensor tendons with a Hohmann retractor. Do not injure the extensor tendons with the saw blade, particularly on the extensor aspect. The tendons must be protected accordingly with a retractor from the radial aspect. After completion of the osteotomy, free the distal fragment from the proximal radius with a small arthrodesis retractor, thereby freeing the soft tissues on the extensor aspect. Insert the arthrodesis retractor on the dorsal aspect of the cortex.





#### **Distal implant fixation**

Position the customized implant on the distal fragment and then insert screws in all plate holes in the distal section of the plate. For complete fixation of the plate to the bone, one or two holes should be secured with standard cortical screws. Locking screws may be used to complete fixation in any remaining open screw holes. To ensure correct placement of the screws in the holes, place all screws in their appropriate hole before tightening. First, tighten the cortical screw(s) which will force the plate onto the fragment. Determine the length of each screw with the depth gauge. Alternatively, these measurements may be taken from the case report.

#### **Proximal implant fixation**

After correct plate fixation on the distal fragment, reduce the plate to the proximal radius. In large corrections with long extension of the distal fragment the use of reduction forceps is recommended. Now secure the predrilled holes on the radius shaft with the corresponding smartDrive® screws. Again, it is recommended to primarily secure two screw holes with standard smartDrive® screws to ensure correct placement of the plate on the shaft of the radius. Depending on the level of correction, some cases may require bone grafting between the proximal and distal fragments, autologous bone is recommended. Gaps of a few millimeters may usually be filled with autologous cancellous bone.

Optional: A bicortical bone chip from the iliac crest may be harvested with the iliac crest bone mill (23-190-05-07). Before insertion into the gap, the harvested bone chip can be modelled exactly according to the model supplied.

To determine the screw lengths, the depth gauge one-hand principle can be used again and the screwdriver to fix the screws.



Depth gauge single-hand principle



Srewdriver





#### Wound closure

As far as possible, reposition the pronator quadratus muscle over the plate to minimize any contact with the flexor tendons and muscles. After lavage and check for hemostasis place a suction drain and close the wound with subcutaneous sutures and atraumatic skin sutures.

Then document the postoperative result with a final radiograph. And finally, apply a sterile dressing and a forearm plaster cast.

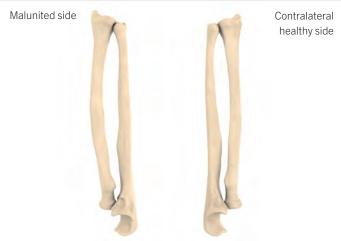
#### Postoperative care

During the initial postoperative phase, the patient should consistently elevate the affected arm and be instructed to perform appropriate finger exercises. Postoperative pain management should be considered.

With the first postoperative dressing change after 2 - 5 days, replace the forearm cast with a stable wrist splint. In addition, initiate non-weight bearing mobilization exercises for the wrist in all planes with the cuff in place.

After 6 - 8 weeks schedule the first clinical and radiological follow-up (affected wrist in two planes) with assessment of the consolidation. The splint should be worn until then. Tolerance to weight bearing activities should be assessed based on the level of osseous union.





#### Preoperative presentation

The patient is an 18-year old young man, who had a fracture of his left forearm when he was 14 years old. The fracture was conservatively treated. He ended up with malalignment on both his radius and ulna resulting in pain and reduced rotation of the forearm, especially in pronation. He aspires to be an electrician, however experiences problems when working. Due to the malalignment and after discussion with the patient, it was decided to perform correctional osteotomies of the forearm bones using custom-made planning, guides and implants.

#### Virtual planning

To create a case, the patient data of both forearms and case-related information are uploaded to the web-based platform IPS Gate®. The data is prepared by the IPS® engineer 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® engineer and user.





#### Virtual planning: mirroring and osteotomy line

The healthy anatomical side is mirrored and compared with the affected region. With the clinical specification and requirements, the postoperative position and the osteotomy lines are defined.

The bony segments are positioned on the basis of the healthy forearm.

#### Virtual planning: guides and implants

First, the number and position of the screw holes are determined. The surgical guides with marking slots for osteotomies and predictive screw holes are then designed in conjunction with the custom-made implants.

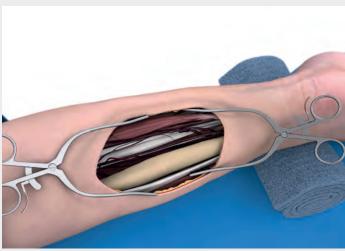
The drill and marking guides include a distal arm with a Y-shaped end allowing Kirschner wires to aid in guide positioning.

Obtaining surgeon approval is the final step prior to production.









#### Patient positioning

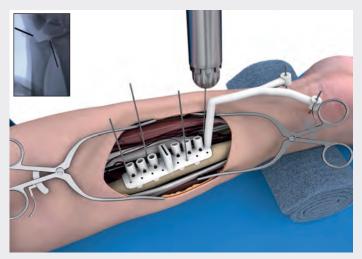
The patient is placed in supine position. The hand that requires surgery is placed on the extension table with a sterile drape up to the elbow, allowing flexion-extension of the elbow as well as full rotation of the forearm. A tourniquet is used, and a fluoroscope is available at all times during surgery.

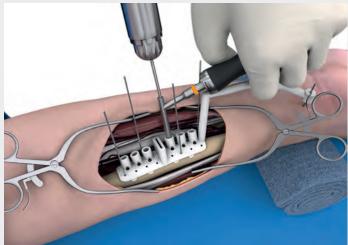
#### Ulnar approach and exposing the ulna

A skin incision with a length of approx.  $9-11\,\mathrm{cm}$  is made along the distal ulna between the ECU and the FCU. The incision is made according to the previously planned implant position which is shown in the case report.

After the skin is incised, the soft tissue is opened while taking care to protect the small branches of the nerves. The fascia is incised in line with the skin incision between the flexor and the extensor carpi ulnaris muscles down to the ulna. The ulnar nerve and the ulna artery should be retracted at all times. The periosteum over the ulna is incised and released so the volar side of the ulna is exposed for guide positioning and plate fixation.







#### Positioning of the drill and marking guide on the ulna

The drill and marking guide is aligned with the ulna as defined in the preoperative planning and illustrated in the case report. It is recommended to check the guide position on the bone model to aid in correct anatomic placement and fixation of the guide. The exact guide positioning is supported by anatomical landmarks integrated in the guide.

Kirschner wires are inserted into the two guidance holes of the distal arm of the guide and slid down until they reach the skin. Visually and through palpation the correct guide position is checked according to the defined bony reference points where the Kirschner wires point to. The guide is then fixed to the ulna using Kirschner wires.

Fluoroscopy is used to confirm the correct position of the guide and to make corrections if necessary. Correct guide positioning should be confirmed prior to moving onto the next surgical step. Note: Alternatively, it is possible to position the distal Kirschner wires percutaneously until they reach the bony reference points while ensuring no nerves, main blood vessels, muscles or tendons are affected.

#### Pre-drilling of the ulna

In the next step, the core holes are pre-drilled bicortically with the drill and marking guide and using the appropriate drill guide from the Recos® standard instruments. Usually, Ø 3.0 mm smartDrive® screws are used.

smartDrive® screw	Core hole	Drill guide	Color coding
Ø 2.5 mm	Ø 2.0 mm	26-166-25-07	purple
Ø 3.0 mm	Ø 2.5 mm	26-166-27-07	orange



Drill guide monoaxial Ø 2.0 mm drill



Drill guide monoaxial Ø 2.5 mm drill

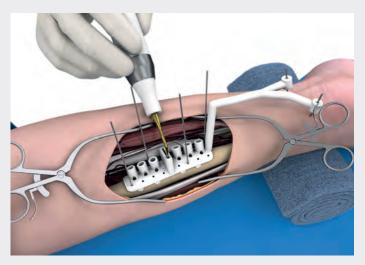


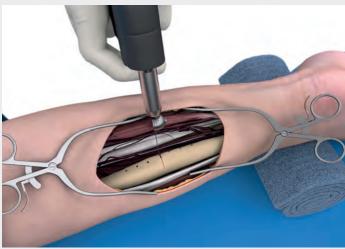
Core hole drill AO attachment Ø 2.0 mm



Core hole drill AO attachment Ø 2.5 mm

K-wire Ø 1.2 mm





#### Marking of the osteotomy line on the ulna

Now, the osteotomy line is marked on the bone using a piezoelectric saw.

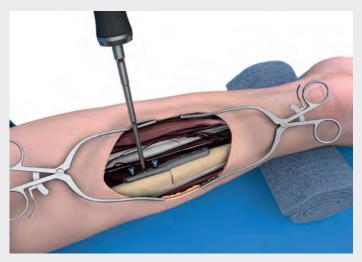
The Kirschner wires and the drill and marking guide are removed.

#### Completing the osteotomy on the ulna

After visual control, the ulna osteotomy is performed. The thinner the sawblade the more precise the osteotomy can be performed and the less bone will be lost. A saw blade with the thickness of 0.38 mm is recommended and the following blade dimensions can be used:

Cutting width (thickness): 0.38 - 0.8 mm
 Width of working blade: 9 - 15 mm
 Length: 31 - 40 mm

The soft tissue should be retracted and secured from the saw blade on both sides.





#### Proximal implant fixation on the ulna

First, the ulnar implant is placed in its correct anatomic orientation. It is recommended to insert standard smartDrive® screws into one or two core holes on the proximal side of the implant. For the other core holes locking smartDrive® screws can be used. For the correct plate positioning all screws should be inserted before the final screw tightening of the proximal implant area. The screw lengths are defined with the depth gauge. Alternatively, measurements will also be defined in the case report.

The ulnar implant will be fixed distally before the radius implant has been fixed proximally.

#### Henry approach and exposing the radius

With the arm in a supinated position, the Henry approach is used. The incision is made according to the previously planned implant position which is shown in the case report.

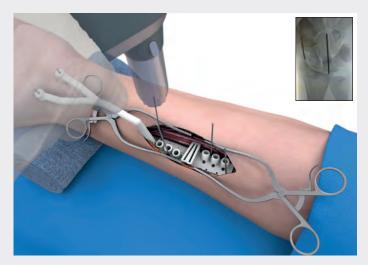
After the skin incision, the smaller nerves are protected and the fascia between the musculus brachioradialis and musculus flexor carpi radialis is dissected. The radial artery is identified and protected. Branches of the artery are ligated which allows moving the artery in order to approach the shaft of the radius. Nerves should be identified and protected. Muscles attached to the radius (musculus flexor pollicis longus and musculus pronator teres) are released.

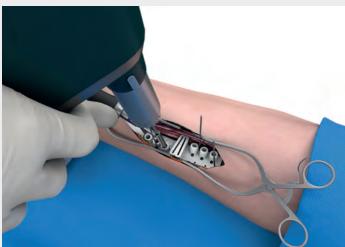


Depth gauge single-hand principle



Srewdriver





#### Positioning of the drill and marking guide on the radius

The drill and marking guide is aligned with the radius as defined in the preoperative planning and illustrated in the case report. It is recommended to check the guide position on the delivered bone model so that the guide can be positioned and fixed precisely. The exact guide positioning is supported by integrated anatomical landmarks in the guide.

Kirschner wires are inserted into the two guidance holes of the distal arm of the guide and slid down until they reach the skin. Visually and through palpation the correct guide position is checked according to the defined bony reference points where the Kirschner wires point to. Then the guide is provisionally fixed on the ulna using Kirschner wires. Fluoroscopy is used to confirm the correct position of the drill and marking guide and to make correction if necessary. Only when the correct guide position is achieved, the next steps should be performed.

Note: Alternatively, it is possible to position the wires percutaneously until they touch the bony reference point but no nerves, main blood vessels, muscles or tendons should be affected.

#### Pre-drilling of the radius

In the next step, the holes are pre-drilled bicortically with the drill and marking guide using the appropriate drill guide from the Recos® standard instruments. Usually, smartDrive® screws with a diameter of 3.0 mm are used.

smartDrive® screw	Core hole	Drill guide	Color coding
Ø 2.5 mm	Ø 2.0 mm	26-166-25-07	purple
Ø 3.0 mm	Ø 2.5 mm	26-166-27-07	orange



K-wire



Drill guide monoaxial Ø 2.0 mm drill



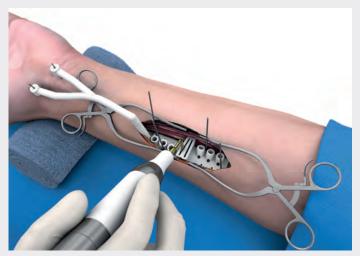
Drill guide monoaxial Ø 2.5 mm drill



Core hole drill AO attachment Ø 2.0 mm



Core hole drill AO attachment Ø 2.5 mm





#### Marking the osteotomy line on the radius

Now, the osteotomy line is marked on the bone using a piezoelectric saw.

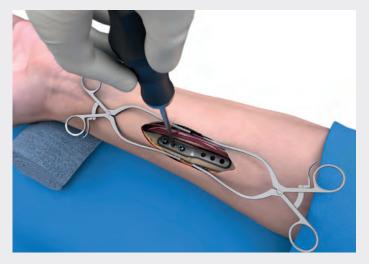
The Kirschner wires and the drill and marking guide are removed.

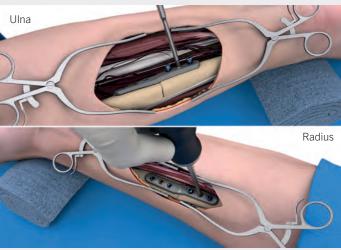
#### Completing the osteotomy on the radius

After visual control, the radius osteotomy is performed. The thinner the sawblade the more precise the osteotomy can be performed and the less bone will be lost. A saw blade with the thickness of 0.38 mm is recommended and the following blade dimensions can be used:

Cutting width (thickness): 0.38 - 0.8 mm
 Width of working blade: 9 - 15 mm
 Length: 31 - 40 mm

The soft tissue should be retracted and secured from the saw blade on both sides.





#### Distal implant fixation on the radius

First, the radius implant is positioned in its correct anatomic orientation. It is recommended to insert standard smartDrive® screws into one or two plate holes in the distal implant area. For the other plate holes locking smartDrive® screws can be used. For the correct plate positioning all screws should be inserted before the final screw tightening of the distal implant area. The screw lengths are defined with the depth gauge.

Alternatively, the lengths can also be taken from the case report.

#### Final implant fixations on the ulna and the radius

Autologous cancellous bone can be used for filling small gaps. The iliac crest or residual fragments from the distal radius can be used when bone grafting for larger gaps is required. For this purpose, the iliac crest bone mill (23-190-05-07) can be used.

Since the ulna is the stable bone of the forearm, the fixation of the ulna is completed first. Therefore, the distal part of the ulna is fixed now (upper picture). It is recommended to insert standard smartDrive® screws into one or two plate holes on the distal aspect of the plate. Locking smartDrive® screws may be used in the remaining holes. For the correct plate positioning all screws should be inserted before the final fixation of the distal implant area. The screw lengths are defined with the depth gauge. Alternatively, the lengths can also be taken from the case report.

After fixation of the ulna (and insertion of the bone graft), the proximal side of the radius plate can now be fixed (lower picture) as described above for the ulna.

To determine the screw lengths, the depth gauge one-hand principle can be used again and the screwdriver to fix the screws.







Srewdrive





#### Wound closure

The muscles are reattached wherever possible. The tourniquet is released, hemostasis is performed, and if necessary, a Redon suction drain is used. The wounds are closed in layers. The closed wounds are covered with sterile dressings and the arm is immobilized in a forearm cast. Once the correction has been completed the result in the OR is documented by imaging.

#### Postoperative care

In the first postoperative phase, the operated arm is elevated and appropriate pain treatment is given. The hand/arm should be observed for any change of temperature, color and/or sensation. If so, the cast should be opened or removed.

If radiographs are taken in the operating room and are stored for documentation, no radiographs are necessary postoperatively. The cast should be left on for 14 days and removed when the patient returns for removal of sutures and inspection of the wound. At this time radiographs are recommended. When a double osteotomy is performed, a cast should be left on for 4 - 6 weeks, however no upper arm cast should be necessary. The patient comes back for cast removal when radiographs are taken for evaluation of healing of the osteotomies. Usually the osteotomies are clearly visible for a longer time, however wrist motion and forearm rotation should be started under supervision of a hand therapist. The patient should come back for follow-up when the function returns, there is no pain and the osteotomies are healed.





#### Preoperative presentation

The patient is a 15-year-old female with congenital bilateral forearm deficiency (Madelung's deformity), which is associated with a characteristic malposition.

Prior to surgery, the patient presented with wrist pain, a typical three-dimensional radial deformity, and consequent incongruity of the distal radioulnar joint (DRUJ).

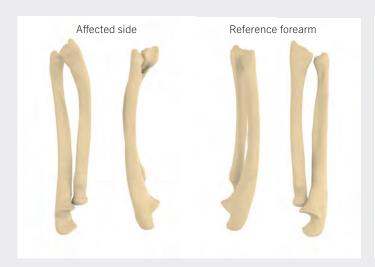
#### Virtual planning

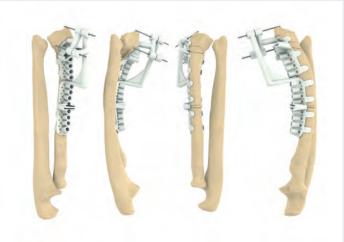
To create a case, the patient data of both forearms and other case-related information are uploaded to the web-based platform IPS Gate®.

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

#### Note:

The osteotomies are determined according to the individual characteristics of the findings. In extensive, widespread cases, the two osteotomies are each to be treated with two plates. In the case of a smaller distance between the osteotomies, a single, longer plate is used for stabilization. However, only a shorter distal plate is indicated for less pronounced cases.





#### Virtual planning: reference arm and osteotomy lines

Due to the congenital deformity of both forearms, the contra-lateral side can as a rule not be used as a reference. Therefore, a healthy reference forearm is used for planning.

Based on the clinical specifications and requirements, the correction of the forearm is planned and the necessary osteotomy lines are determined. The bone segments are then positioned based on the selected reference forearm.

#### Virtual planning: guides and implants

In consultation between the IPS® developer and the surgeon, the optimized correction of the forearm is defined as well as the number and location of screw holes in the guides and the implants.

The drill and marking guides for the distal radius and the radius shaft each feature identical, parallel distal arms with a Y-shaped end where Kirschner wires can be used to support optimal positioning of the guides on the radius bone. The reference arms can be applied to the radius at the same time.

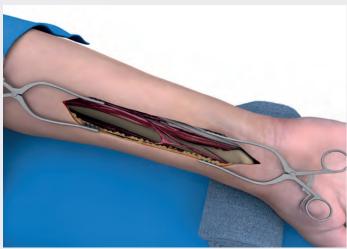
#### Note

After the surgeon and patient have discussed the case report preoperatively, the surgeon's approval is the last step before production.









#### Positioning of the patient

The patient is positioned in supine position on the operating table. The hand that requires surgery is placed on the extension table with a sterile drape up to the elbow, allowing flexion-extension of the elbow as well as full rotation of the forearm. A tourniquet is used, and a fluoroscope is available at all times during surgery.

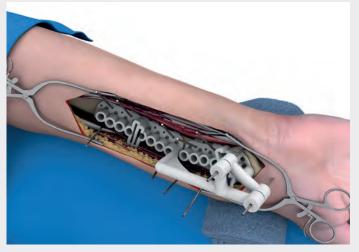
#### Henry approach and exposing the radius

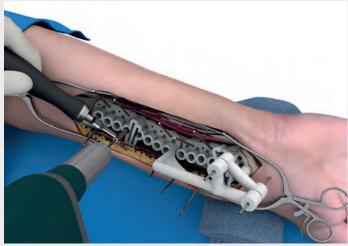
With the arm in supine position, the Henry approach is used. The incision is made according to the previously planned implant position. This is shown in the case report. After the skin incision, the smaller nerves are protected and the fascia between the musculus brachioradialis and musculus flexor carpi radialis is prepared. The radial artery is identified and protected. Branches of the artery are ligated which allows moving the artery in order to approach the shaft of the radius. Nerves should be identified and protected. The muscles on the radius (pronator quadratus muscle, flexor pollicis longus muscle and pronator teres muscle) are detached.

#### Note:

The length of the incision in the skin is determined based on the measurements of the models and the guides.







#### Positioning and using the drill and marking guide

The proximal and distal drill and marking guides are aligned with the radius at the same time, in accordance with the preoperative planning and the case report. It is advisable to check the position of the guides on the included bone model to ensure accurate placement and fixation. Anatomical reference points help to ensure precise positioning of the guides. The distal arms are positioned on top of each other and K-wires are inserted into the guide holes of the distal arms of both guides. The correct position of the guides is verified visually and by palpation using defined bone reference points indicated by the K-wires. The guides are then fixed to the radius using Kirschner wires. Fluoroscopy is used to verify the position of the drill and marking guides, and corrected if necessary. The next steps should only be taken after the guides have been positioned correctly.

#### Note:

Subsequently, the proximal implant is fixed first, followed by the distal implant. For minor corrections and only distal osteotomy, only a drill and marking guide as well as an implant are used.

#### Pre-drilling of the radius

In the next step, the core holes are pre-drilled bicortically using the proximal drill and marking guide and the appropriate drill guide from the Recos® standard instruments.

In general, smartDrive® screws with a diameter of 2.5 mm are used, if required a diameter of 3.0 mm can also be used.

smartDrive® screw	Core hole	Drill guide	Color coding
Ø 2.5 mm	Ø 2.0 mm	26-166-25-07	purple
Ø 3.0 mm	Ø 2.5 mm	26-166-27-07	orange







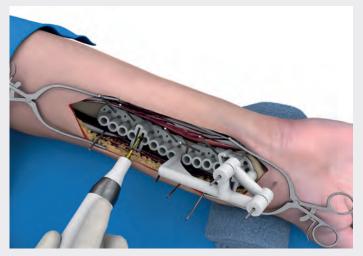
Drill guide monoaxial, for drill Ø 2.5 mm

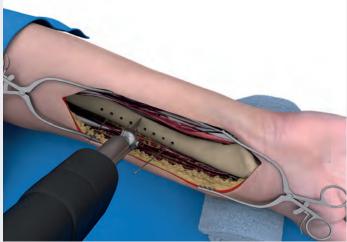


Core hole drill AO attachment Ø 2.0 mm



Core hole drill AO attachment Ø 2.5 mm





#### Marking the osteotomy on the radius

Now, the osteotomy line is sawn halfway through the bone, for example, using a piezoelectric saw.

The thinner the sawblade, the more precise the osteotomy can be performed and the less bone will be lost. Always use a new saw blade and a powerful oscillating saw with appropriate cooling to prevent unnecessary heat build-up and the associated risk of bone necrosis.

It is also advisable to check whether the saw blade fits through the osteotomy gap before sawing. A saw blade with a thickness of 0.38 mm is recommended and the following blade dimensions can be used:

Cutting width (thickness): 0.38 - 0.8 mm
 Width of working blade: 9 - 15 mm
 Length: 31 - 40 mm

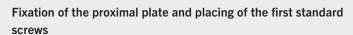
#### Completing the osteotomy on the radius

The Kirschner wires as well as the drill and marking guides are then removed.

Before removing the proximal drill and marking guide, Kirschner wires can be inserted into the 2 distally and 2 proximally predrilled screw holes, with which the implant can subsequently be positioned.

Radius osteotomy is completed after a visual check. The soft tissue should be retracted and secured from the saw blade on both sides.





For reasons of stability, the proximal plate is fixated first. It is recommended to insert non-locking smartDrive® standard screws proximally and distally (to pull the plate securely onto the bone) into one or two plate holes. Angular stable smartDrive® screws may be used for the remaining holes. The screw lengths are precisely calculated before surgery and used according to the planning protocol (case report). Alternatively, the depth gauge can be used to check the screw length.



#### Pre-drilling the distal radius

The next step is the fixation of the distal implant. For this purpose, the drill holes are pre-drilled using the distal drill and marking guide using the appropriate drill guide from the Recos® standard instrument set.

Bicortical drilling and screw placement is mandatory in the proximal shaft. However, when placing distal screws, monocortical drilling and fixation may suffice. Depending on the situation, Ø 2.5 mm or Ø 3.0 mm diameter screws may also be used. As a rule, smartDrive® screws with a diameter of 2.5 mm are used.

smartDrive® screw	Core hole	Drill guide	Color coding
Ø 2.5 mm	Ø 2.0 mm	26-166-25-07	purple
Ø 3.0 mm	Ø 2.5 mm	26-166-27-07	orange



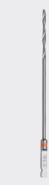




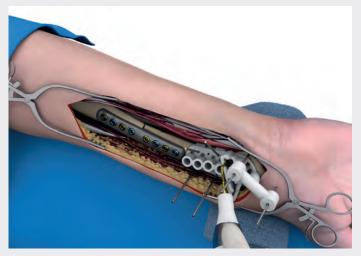
Drill guide Ø 2.5 mm

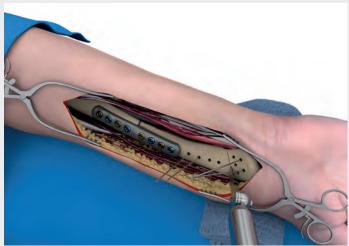


Core hole drill AO attachment Ø 2.0 mm



Core hole drill AO attachment Ø 2.5 mm





#### Marking the osteotomy on the distal radius

Osteotomy using the guide is again only performed halfway. Once this has been done, remove the K-wires and the guide.

#### Note:

Before removing the guide, Kirschner wires can be inserted in 2 distally and proximally pre-drilled screw holes each, through which the implant can subsequently be guided and positioned.

#### Completing the osteotomy on the distal radius

After repeated visual checking of the osteotomy line, the planned osteotomy can be completed. When completing the osteotomy, retract the soft tissues ulnar, and on the radial aspect protect the radial artery together with the dorsal extensor tendons with a Hohmann retractor. Do not injure the extensor tendons with the saw blade, particularly on the extensor aspect.

#### Note:

After completion of the osteotomy, the fragments can be mobilized using a small arthrodesis retractor.







Screwdriver





### **Distal implant fixation**

The custom-made implant is placed on the distal fragment, and then 2 non-locking screws are first inserted into the distal rows. Then another two non-locking screws are inserted into the proximal part of the plate. Angular stable screws can be used for the remaining open screw holes.

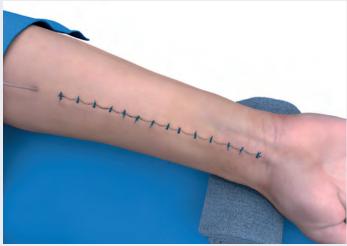
To ensure correct placement of the screws in the holes, place all screws in their appropriate hole before tightening. The cortical screws for pulling the plate to the fragment should be tightened first. The screw lengths are precisely calculated before surgery and used according to the planning protocol (case report). Alternatively, the depth gauge can be used to check the screw length.

## Fixation of the distal implant

Following correct fixation of the plate on the distal fragment, the plate can be fixed to the proximal fragment. In large corrections with long extension of the distal fragment the use of reduction forceps is recommended.

Now secure the predrilled holes on the radius shaft with the corresponding smartDrive® screws. Again, it is recommended to primarily secure two screw holes with standard smartDrive® screws to ensure correct placement of the plate on the shaft of the radius. Depending on the level of correction, some cases may require bone grafting between the proximal and distal fragments, whereby autologous bone is recommended. For gap sizes of a few millimeters, filling is usually not necessary.





# Wound closure

The tourniquet is released, hemostasis is performed, and a Redon suction drain is placed. The wounds are closed in layers.

# Wound closure

The closed wounds are covered with sterile dressings. Once the correction has been completed, the result in the OR is documented by imaging.



### Follow-up treatment

In the first postoperative phase, the operated arm is elevated and appropriate pain treatment is given. The hand/arm should be observed for any change of temperature, color and/or sensation. If changes become apparent, the cast should be opened or removed. X-ray images of sufficient quality taken in the operating room are kept for documentation purposes, thus eliminating the need for further postoperative X-rays.

In cases of complex/pronounced misalignments, postoperative computer tomography is recommended for documentation purposes. The forearm splint should be worn for 4 - 6 weeks, depending on the extent of the reconstruction. It is recommended to take X-rays after four weeks to check healing of the osteotomy. Usually the osteotomies are clearly visible for a longer time, however wrist motion and forearm rotation should be started under supervision of a hand therapist. Experience shows that bony union can be expected after 3 - 6 months. Until then, any heavy strain is to be avoided. The patient should return for a follow-up when function has been restored, when there is no pain and the osteotomies have healed.

# Case studies radius reconstruction



Treatment of a distal radius malunion, tilted to dorsal, with an extra-articular radius reconstruction and shift of the distal segment to volar and ulnar.



Treatment of a distal radius malunion tilted to dorsal with an extra-articular radius reconstruction including an opening wedge osteotomy.

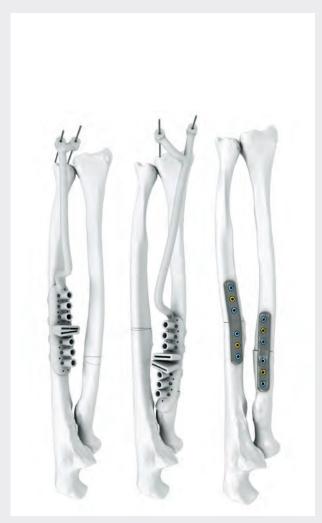


Treatment of a distal radius malunion with an extra-articular radius reconstruction. The distal segment was lengthened and rotated ulnar. An 8 to 18 mm large iliac crest bone graft was harvested and inserted into the gap.



Treatment of a distal radius malunion with an intra-articular radius reconstruction with three distal segments rotated to ulnar. All three marking osteotomies were incorporated into one single guide.

# Case studies forearm reconstruction



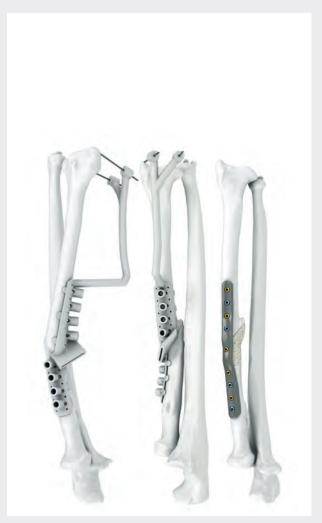
Treatment of a radius and ulna malunion with a forearm reconstruction. Resections and rotational changes were required on both bones.



Treatment of a radius and ulna malunion with a forearm reconstruction. The radius required the resection of a 1.8 mm-wedge of bone.



Treatment of a radius-ulna-synostosis with a forearm reconstruction including resections and rotational changes of both bones.



Treatment of a radius with a forearm reconstruction including a gap of 36 mm. The defect was grafted with a wedge shaped bone segment and fixed to the plate using one smartDrive® screw.

# Case studies Madelung deformity



Treatment of Madelung's deformity using corrective osteotomy of the forearm and the distal radius. A drill and marking guide was available for this purpose for the forearm and distal radius.



Treatment of Madelung's deformity using corrective osteotomy of the forearm and the distal radius. A drill and marking guide was available for this purpose for the forearm and distal radius. The radius required the resection of a 13 mm-wedge of bone.



In this Madelung's case, the two drilling and marking guides were equipped with identical, parallel reference arms to facilitate the pre-planned positioning of both guides.

After attaching the guides, the drill holes as well as the osteotomy were performed proximally first, and the plate attached before then making the distal correction using the second guide, including plate.



Treatment of a Madelung's deformity using distal correction osteotomy of the radius. In this less pronounced Madelung's deformity, reconstruction was achieved using a distal correction osteotomy. A drill and marking guide were available for this purpose.

# Optional standard implants for the custom-made planning

# Recos® radius reconstruction 3/2-hole

Length 70 mm Width 21 mm







**Plates** 







**Templates** 



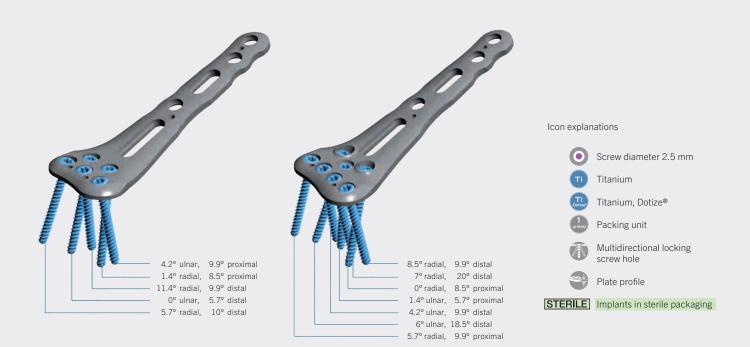








26-066-43-09



# Recos® radius reconstruction 4/3-hole

Length 70 mm Width 24 mm







**Plates** 









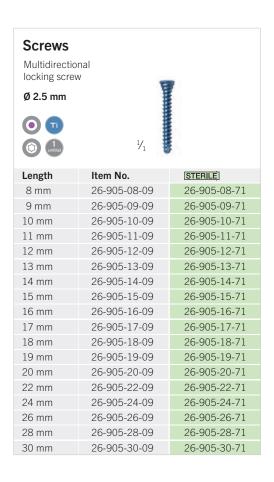






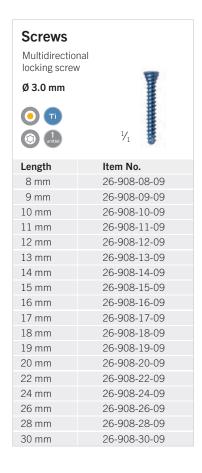
26-066-41-09

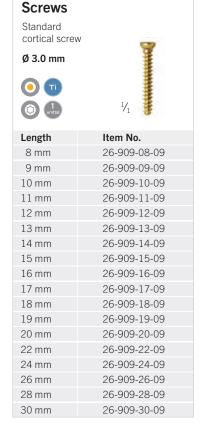
# Osteosynthesis screws











# Osteosynthesis instruments



K-wire dispenser Ø 1.2 mm 17.5 cm / 6 ¾"





22-627-12-05 K-wires Ø 1.2 mm 12 cm / 4 ¾"





26-166-27-07 Drill guide monoaxial 13.5 cm / 5 1/4"









26-166-32-07 Drill guide monoaxial 13.5~cm / 5~1/4"



























# Osteosynthesis instruments and storage system



26-166-21-07 Depth gauge single-hand principle  $15\,\mbox{cm}\,/\,5\,\mbox{3\!/}4\mbox{"}$ 







26-166-18-07 Screwdriver T8

18 cm / 7"



















Storage system	
55-910-10-04	Storage set consisting of:
	lid, instrument insert, storage cage, circular screw rack Ø 2.5 mm, single-sided
55-910-11-04	Storage set consisting of:









55-910-13-04 Instrument insert for storage system





lid, instrument insert, storage cage, circular screw rack  $\emptyset$  2.5/3.0 mm, double-sided

55-910-14-04 Storage cage





55-910-39-04 smartDrive® Ø 2.5 mm circular screw rack, single-sided





55-910-12-04 smartDrive® Ø 2.5/3.0 mm circular screw rack, double-sided



# The IPS® product range





# IPS Implants® | Radius and Forearm Reconstruction

The IPS Implants® | Radius and Forearm Reconstruction solution enables the user to address complex surgical procedures through a user-friendly individualized approach. CT-based planning and a 3D-printed implant allow the user to achieve the planned post-op result with a very stable construct.

Besides the standard treatment of radius malunion, KLS Martin offers custom-made solutions for the distal radius as well as forearm reconstruction procedures. Creating surgical plans and guides to our standard plates is an option. Additionally, custom-made implants achieved through additive manufacturing are also available for complex procedures.

IPS Implants® for radius and forearm reconstruction are fixed with a combination of our smartDrive® standard and locking screws. Instrumentation is limited to the essentials.



# 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.





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