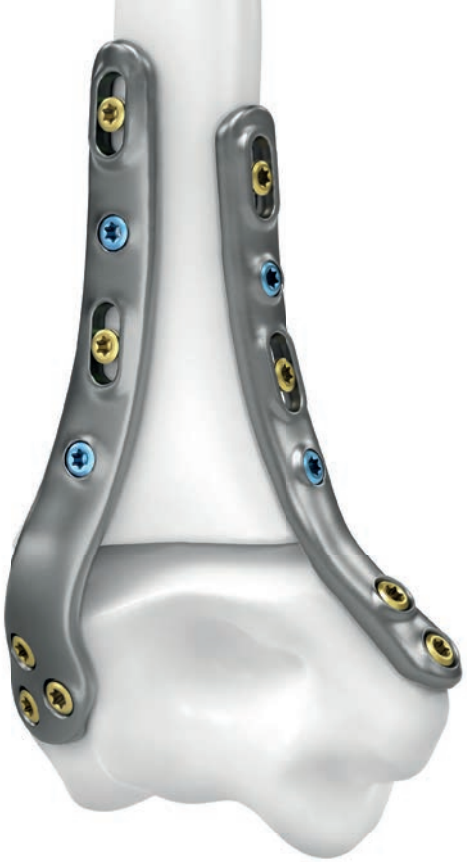
KLS martin GROUP



IPS Implants®

Distal Humerus Reconstruction

One patient. One solution.

www.klsmartin.com

Driving individual patient solutions 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® – Individual Patient Solutions

IPS Implants®

Distal Humerus Reconstruction

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

KLS Martin offers comprehensive custom-made solutions for distal humerus reconstructions, featuring individualized implants together with matching drill and marking guides. Especially for complex cases the custom-made distal humerus reconstruction can be a solution.

IPS Implants® for the distal humerus reconstruction are fixed with our proven smartDrive® and ContourDrive standard and/or locking screws of the Recos® and Fos 2 systems.

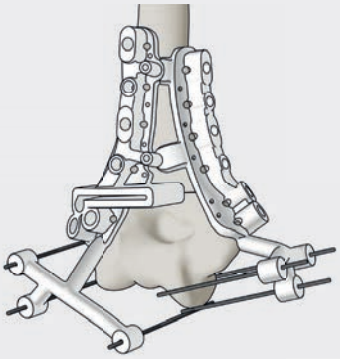
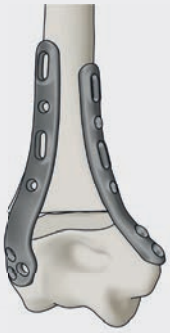
Feature, function, and benefit

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

To create a new IPS® case, the CT scans of the affected and unaffected, contralateral patient's humerus will be uploaded to the IPS Gate®. IPS Gate® is a platform that guides surgeons and users through the whole process of requesting, designing and finalizing custom-made solutions in a safe, flexible and efficient way. 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.

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® Distal Humerus Reconstruction – planning process

	Feature and function	Benefit
IPS Gate® 	■ Simple and efficient interaction with the IPS® engineers via IPS Gate® ■ Planning, production, shipping and local support from a single source	■ Maximum mobility, flexibility and functionality ■ Efficient and intuitive guidance through the whole process
Range of options for planning 	■ Anatomical reconstruction of the malunion is planned based on the healthy reference side ■ Virtual predetermination of the osteotomy line and screw positions for the custom-made 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 Implants® is guaranteed ■ Axial and rotational deformities are reconstructed and considered
	■ Planning with custom-made guides in combination with standard plates is a possibility for cases that do not require custom-made additive manufactured plates	■ Efficient and safe combination of standard plates with virtual planning leading to drill and marking guides 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

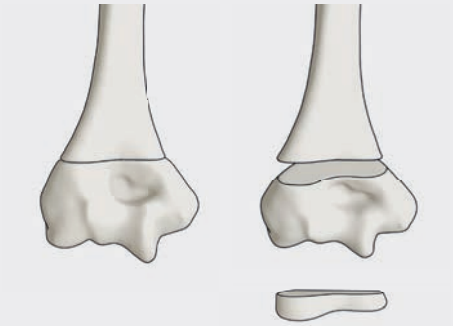
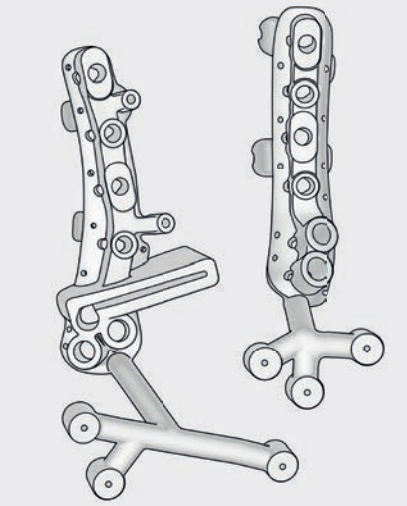
Feature, function, and benefit

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 guides and plates 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 implants bring the bone segments into the planned anatomical position and are fixed with Ø 3.0 mm smartDrive® and ContourDrive standard and/or locking screws of the Recos® and Fos 2 systems.

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® Distal Humerus Reconstruction – models, guides, implants

	Feature and function	Benefit
Models 	■ An anatomical bone model for the pre- and postoperative situation is produced and allows a “fit check” of the guides and the implants to the patient's anatomy	■ Best possible three-dimensional precision-fit
	■ Additionally, 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
Drill and marking guides 	■ Latest production technologies such as additive manufacturing	■ Additive manufacturing technology provides complete freedom of design for guides
	■ Fixation with Kirschner wires	■ Precise reconstruction result
	■ Holes for pre-drilling in the planned angulation	■ Efficient workflow
	■ Several marking slots can be combined in one guide	
	■ Positioning arms with Kirschner wires	■ Precise guide placement using imaging
	Specifically for the distal humerus reconstruction	
	■ Alignment features with Kirschner wire fixation	■ Precise relative orientation of the guides
Implants 	■ 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 TI6AI4V titanium alloy	■ High implant stability
	■ Possibility to fix the plate multi-vectorial with Ø 3.0 mm and/or Ø 3.5 mm standard or locking screws	■ High individuality and stability

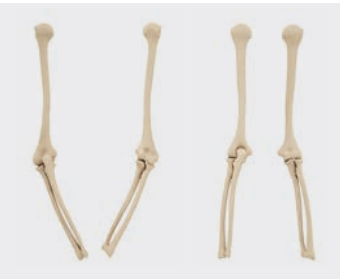
Step by step to optimal treatment

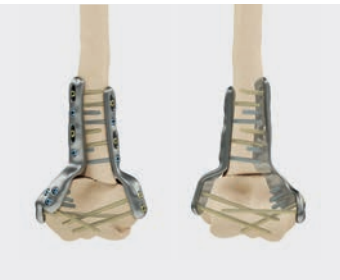
Fields of use

IPS Implants® Distal Humerus Reconstruction

- Correction osteotomies of the distal humerus

Typical example

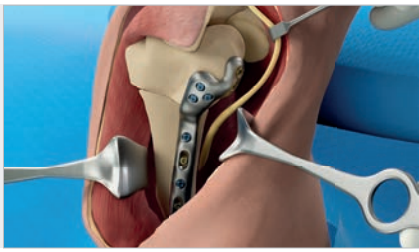


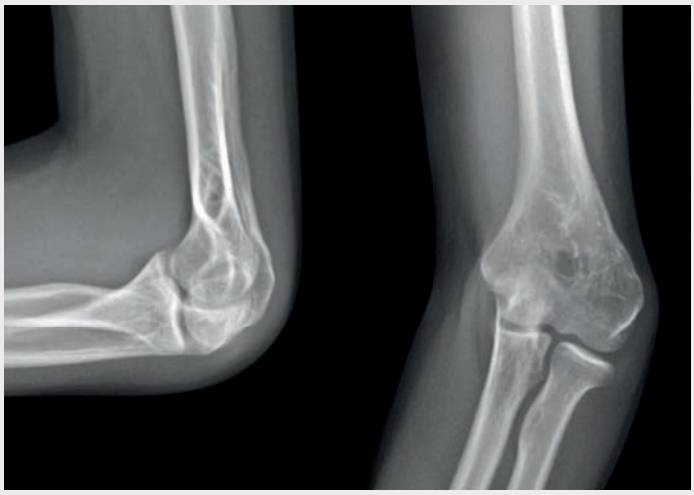


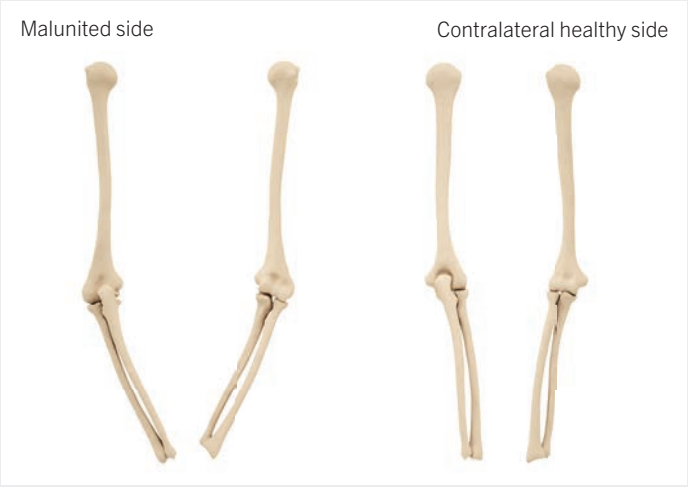
Extra-articular distal humerus reconstruction

Surgical technique

Custom-made distal humerus reconstruction with IPS Implants® Distal Humerus Reconstruction Pages 12 – 20
90° double-plate treatment
Prim. Dr. Michael Plecko







Preoperative presentation

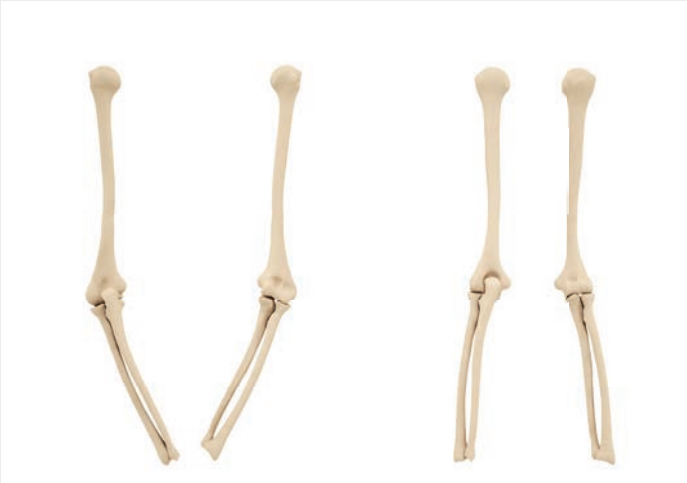
The patient is a 16-year old young man, who had a supra-condylar humerus fracture at the age of 4. At that time the fracture was treated surgically with K-wires followed by several surgeries over the subsequent 12 years. As a result, he ended up with a pronounced varus position, severe rotational deformity and mobility of S0/25/110 and pronation of 80°.

Due to the malalignment and after discussion with the patient, it was decided to perform corrective osteotomies of the distal humerus using custom-made planning, guides and implants.

Virtual planning

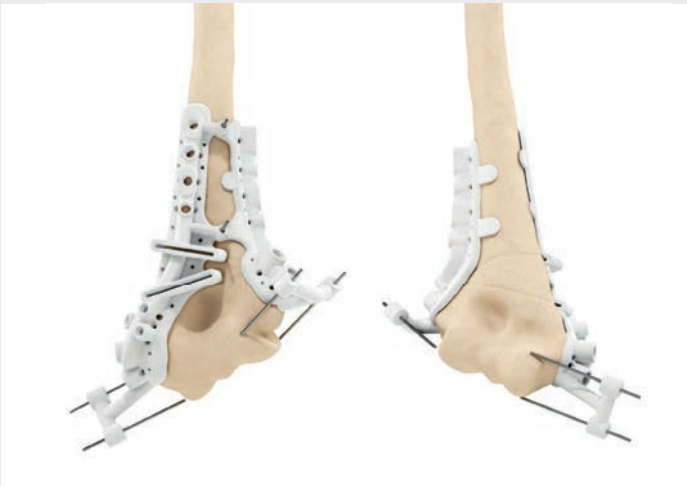
To create the case, the patient data of both distal humeri and other case-related information are uploaded to the web-based IPS Gate® platform.

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 throughout the planning process.



Virtual planning: mirroring and osteotomy line

The healthy anatomical side is mirrored and used as a reference for comparison with the affected region. With the clinical specification and requirements, the postoperative position and the osteotomy lines are defined.
The bony segments are positioned based on the healthy humerus.

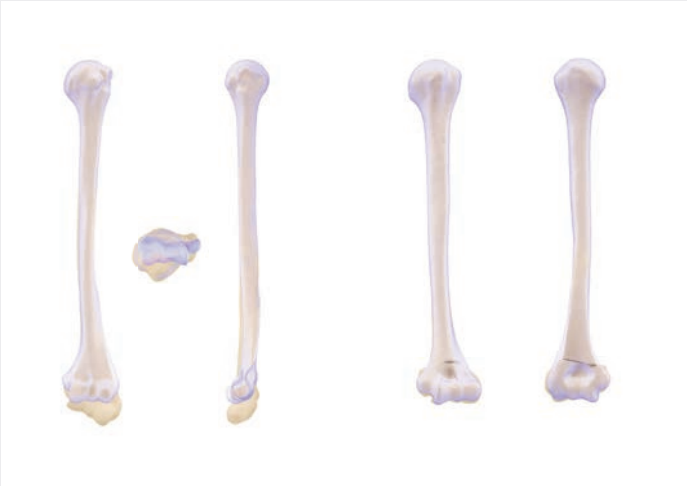


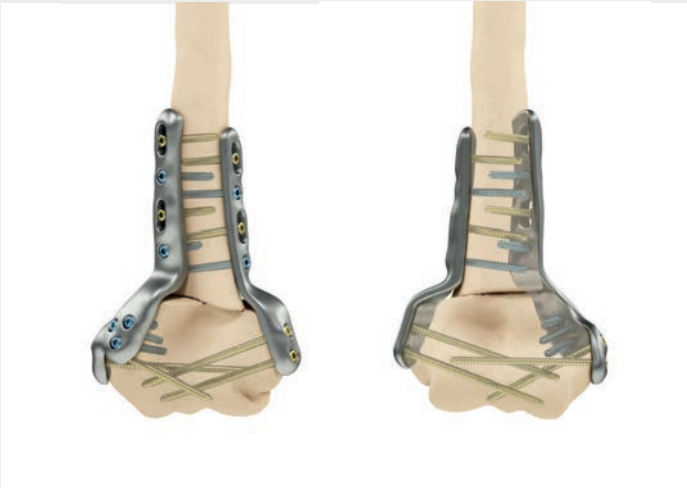
Virtual planning: guides and implants

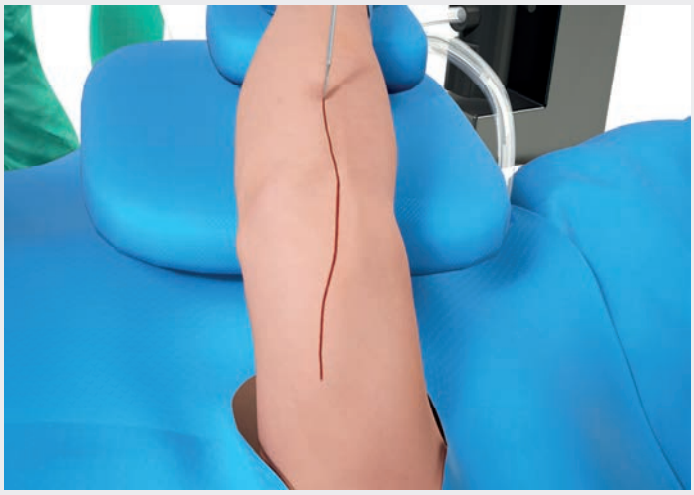
First, the number and position of the screw holes are determined. The surgical guides with marking slots for osteotomies and predictive screw holes are then designed in conjunction with the custom-made implants.

The drill and marking guides include a distal arm allowing Kirschner wires to aid in guide positioning and an alignment feature to ensure the relative orientation of the guides.

Obtaining surgeon approval is the final step prior to production.





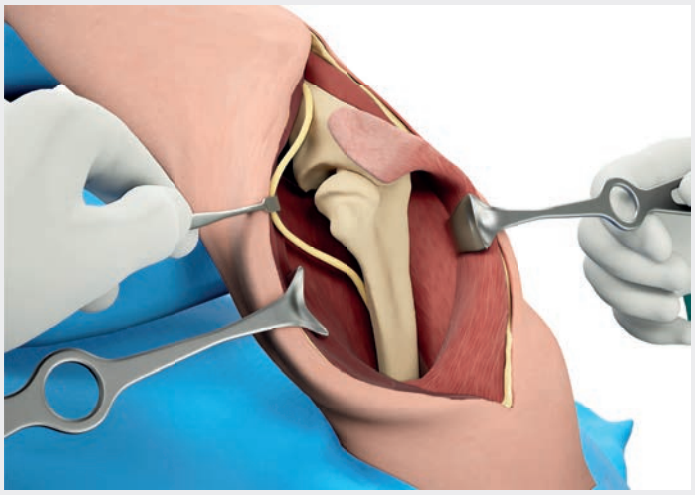


Patient positioning

The patient is placed in prone position, lateral decubitus or supine position with the arm on a radiolucent support, a padded post or a sterile draped Mayo tray from the other side. The forearm should be mobile, that the elbow can be flexed to an angle greater than 120 degrees.
A sterile tourniquet is used, and a fluoroscope should always be available during surgery.
For the following steps in this specific case, the patient is positioned in supine position.

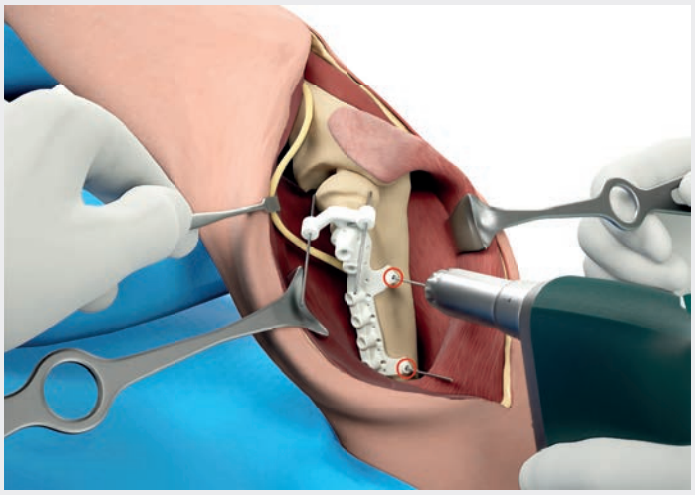
Approaches

The distal humerus can be approached via the posterior approach through a straight or slightly curved posterior skin incision just radial to the olecranon tip or a medial and lateral double incision approach depending on surgeons preference and the planned plate configuration of 90° or 180°.
The shown posterior approach (90° plate configuration) is the recommended standard approach. It is described as the primary choice in the following steps of the surgical technique.



Dissection and exposing the distal humerus

After dissection of the ulnar nerve, the nerve is securely transposed to an anterior position. The triceps muscle is mobilized from both sides and elevated from the humerus. In specific cases a triceps split approach may be a reasonable alternative.



Positioning and using the medial drill

The medial guide is positioned 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, ensuring that it precisely matches the distal humerus and is fixed in place. The exact guide positioning is supported by anatomical landmarks integrated in the guide.

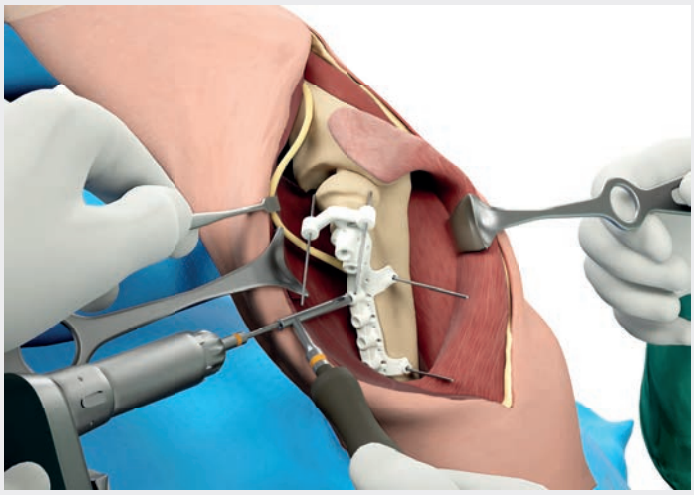
Kirschner wires are inserted into the guidance holes of the distal arms of the guide and slid down until they reach the skin. Visually and through palpation the correct guide position is checked according to the defined bony reference points where the Kirschner wires point to. The guide is then fixed to the humerus using Kirschner wires (mainly Ø 1.2 mm K-wires). Two Ø 2.0 mm K-wires are inserted in the overlapping K-wire-holes (marked red) as reference points for the medial and dorsolateral guides.

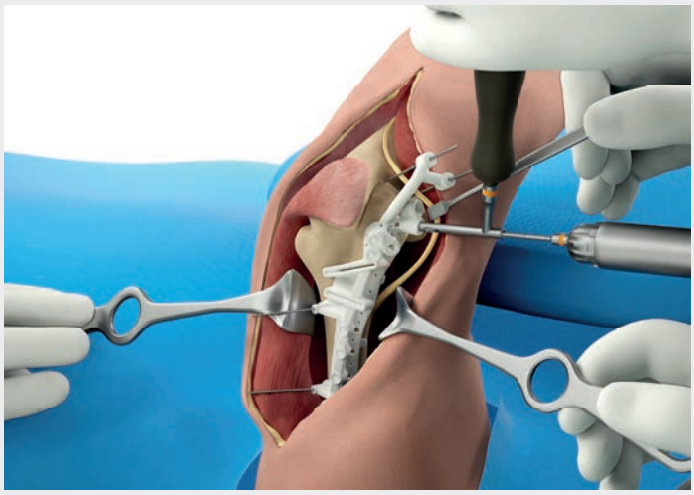
Fluoroscopy is used to confirm the correct position of the guide and to make corrections if necessary. Correct guide positioning is essential and should be confirmed prior to moving on to the next surgical step.

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.

In this exemplary case, the medial guide is positioned first, as it is only a drill guide and does not include a marking component.

22-627-12-05
K-wire
Ø 1.2x 150 mm





Pre-drilling

In the next step, the distal core holes are pre-drilled mono-cortically, and the shaft core holes are pre-drilled bicortically. This step is supported by the drill and marking guide in combination with the appropriate drill guide and drill bit from the Recos® or Fos 2 standard instrument sets.

For screws in the proximal part of the planned osteotomy:
- Use the Recos® monoaxial drill guide (orange color-coding) and drill bit (Ø 2.5 mm, orange color-coding) for pre-drilling.

For screws in the distal part of the planned osteotomy:
- Use the Fos 2 polyaxial drill guide (orange color-coding) and drill bit (for screws Ø3.0 mm, orange color-coding) for pre-drilling.

The case documentation also indicates where each system should be used.
Insert short K-wires or any other indicators as markers for the pre-drilled core holes before removing the medial guide.

Dorsolateral pre-drilling

After completion of the medial pre-drillling the beforehand steps (guide positioning & pre-drilling) are repeated on the dorsolateral side in the same manner.

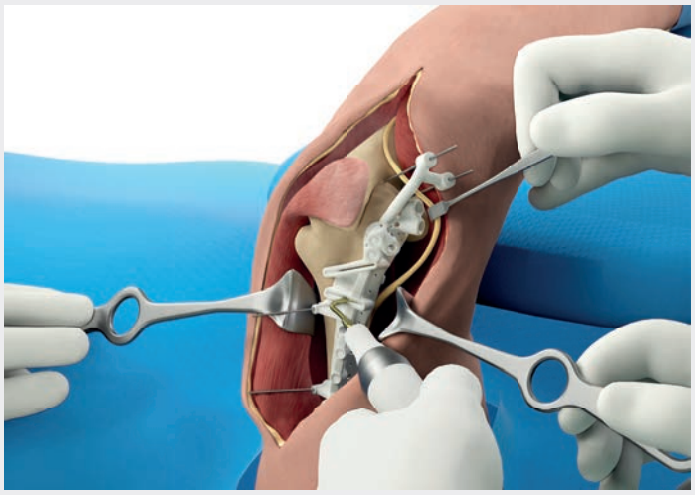
26-166-32-07
Recos® drill guide monoaxial, for Ø 2.5 mm drill

26-950-30-07
Recos® core hole drill Ø 2.5 mm

or

26-773-67-07
Drill guide POLY M2 for screws 2.7/3.0 mm

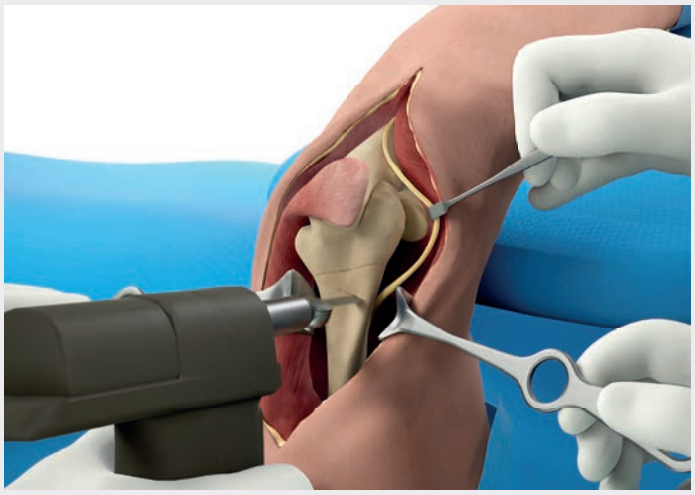
26-772-31-07
Core hole drill for screws Ø 3.0 mm



Marking the osteotomy line

Depending on the patients' malalignment and the resulting planned osteotomy the medial and/or the dorsolateral guides may include a marking guide.
In this exemplary case the dorsolateral guide was planned including a marking guide for the subsequent osteotomy.
The osteotomy lines are marked on the bone using a piezoelectric saw. After completion, the K-wires and the drill and marking guide are removed.

The information in the case report indicates on which side of the marking guide the osteotomy line needs to be marked.



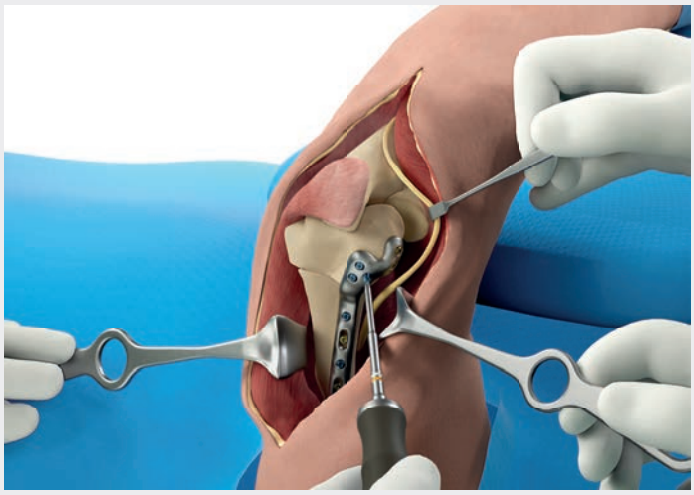
Completing the osteotomy

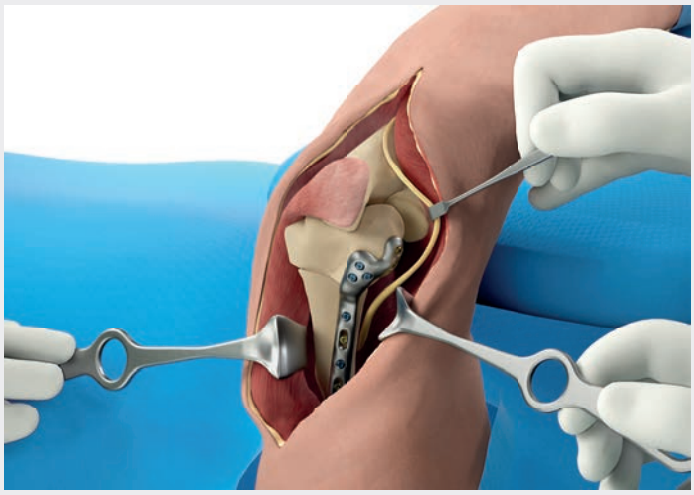
After a visual control, the osteotomy is performed. To achieve a precise osteotomy and reduce bone loss, a saw blade with the following blade dimensions can be used:

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

A saw blade with thickness of 0.38 mm is recommended.
A thinner saw blade allows for a more precise cut and minimizes bone loss.

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





Fixation dorsolateral implant – distally

After the reduction, the implant is placed in its correct anatomical position. Standard or locking screws from the Recos® or Fos 2 systems are then inserted in the distal part of the dorsolateral implant, according to the planned screws specified in the screw table of the case report.

For correct plate positioning, all screws should be inserted before the final tightening in the distal implant area. The cortical screw(s) are tightened first to pull the plate onto the bone fragment.
The correct screw lengths are determined with the depth gauge. Alternatively, the corresponding measurements are also provided in the case report.

Distal fixation of the dorsolateral implant is performed prior to the subsequent proximal fixation in the following steps.

or

26-166-21-07 Recos® depth gauge

26-166-18-07 Recos® screwdriver T8

26-773-57-07 Fos 2 depth gauge

59-933-10-07 Fos 2 handle AO

26-773-27-07 Fos 2 screwdriver blade

Fixation dorsolateral implant – proximally

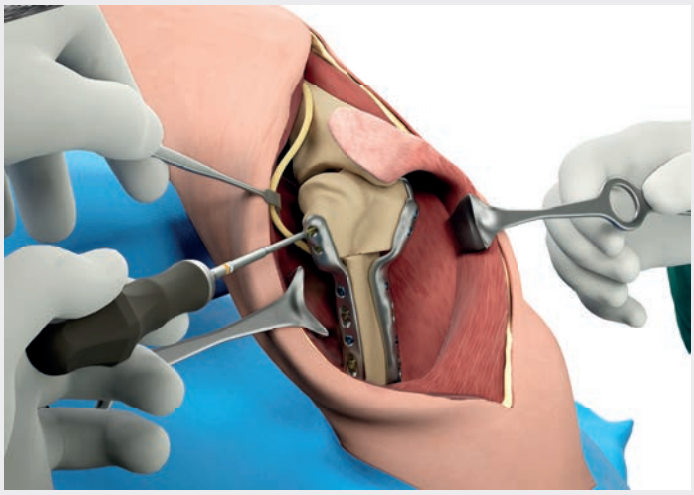
After the correct plate fixation to the distal fragment, the plate is reduced to the proximal fragment. For large corrections the use of reduction forceps is recommended.

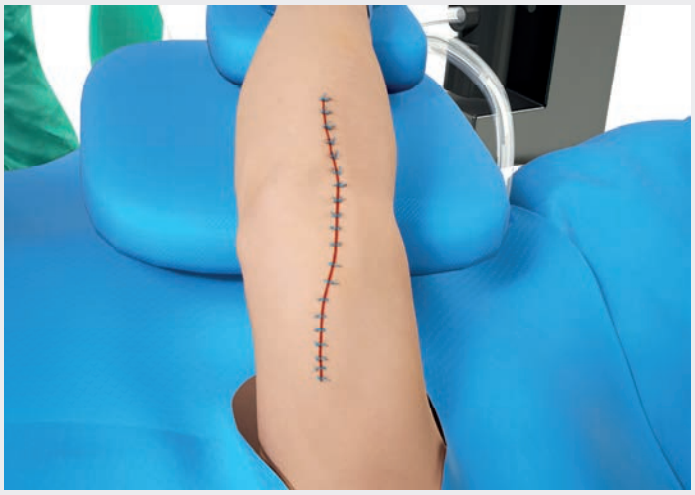
The pre-drilled oblong hole(s) in the proximal fragment should initially be secured with the corresponding standard screws to ensure correct positioning of the plate. If necessary, minor adjustments can be made by shifting the plate within the oblong hole(s). The remaining screw holes should be left unoccupied until the medial implant has been positioned properly and the overall alignment is satisfactory.

Depending on the level of correction, some cases may require bone grafting between the proximal and distal fragments, with autologous bone being recommended. Gaps of a few millimeters may usually be filled with autologous cancellous bone.

Alternatively, 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 shaped exactly according to the supplied bone wedge guide.

The screw lengths are determined using a depth gauge, and insertion is performed using the appropriate screwdriver handle and blade.





Fixation medial implant

The same steps as for fixation of the dorsolateral implant are performed, starting with distal fixation followed by proximal fixation. If required, the standard screws in the proximal fragment of the dorsolateral implant may be loosened to achieve more favorable conditions for overall alignment.

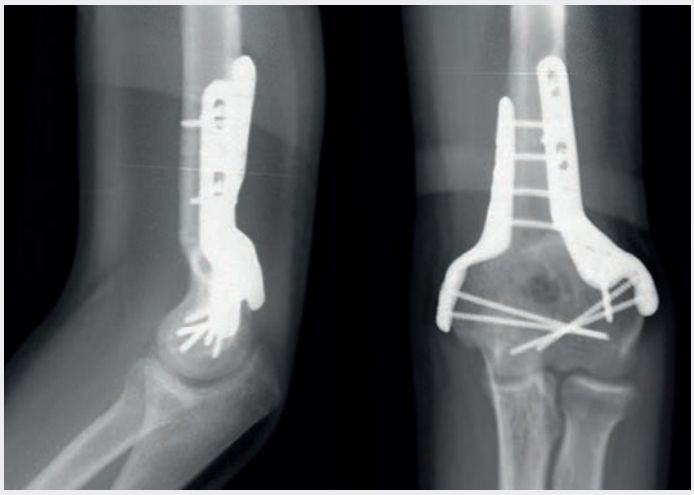
Compression at both columns is advantageous for more rapid bone healing. After correct alignment is achieved, all standard screws (medially & dorsolaterally) in the proximal fragment are tightened. Locking screws can be inserted in the remaining holes (medially & dorsolaterally) for final fixation.

Wound closure

After repositioning of the triceps, the ulnar nerve has to be brought back to its original bed or, if in conflict with the implant, placed into a subcutaneous soft tissue pocket. The tourniquet is released and hemostasis is performed. If required, a suction drain can be used. The wound is closed in layers using subcutaneous and atraumatic skin sutures. A sterile dressing is then applied.

Once the correction has been completed the result in the OR is documented by imaging and no upper arm cast should be necessary.

26-166-21-07	26-166-18-07	26-773-57-07	59-933-10-07	26-773-27-07
Recos® depth gauge	Recos® screwdriver T8	Fos 2 depth gauge	Fos 2 handle AO	Fos 2 screwdriver blade

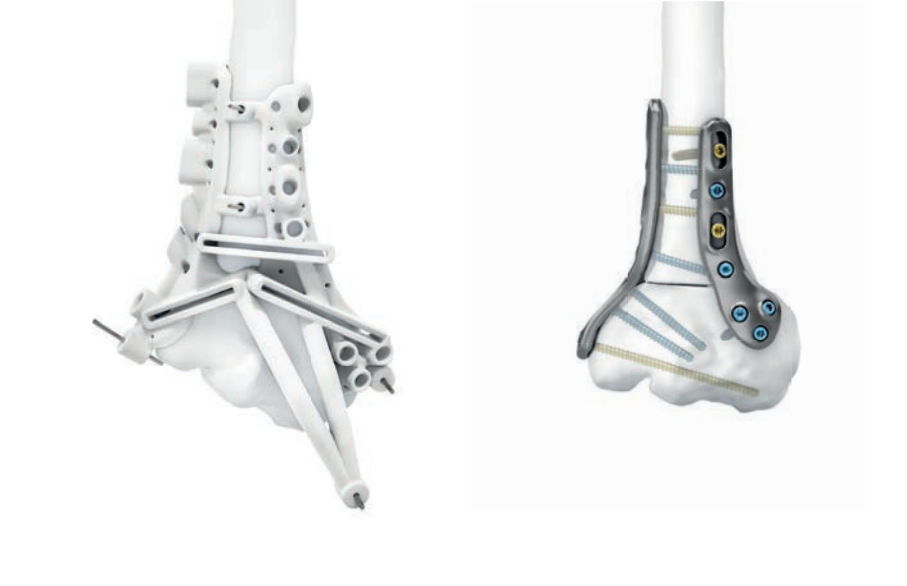


Postoperative care

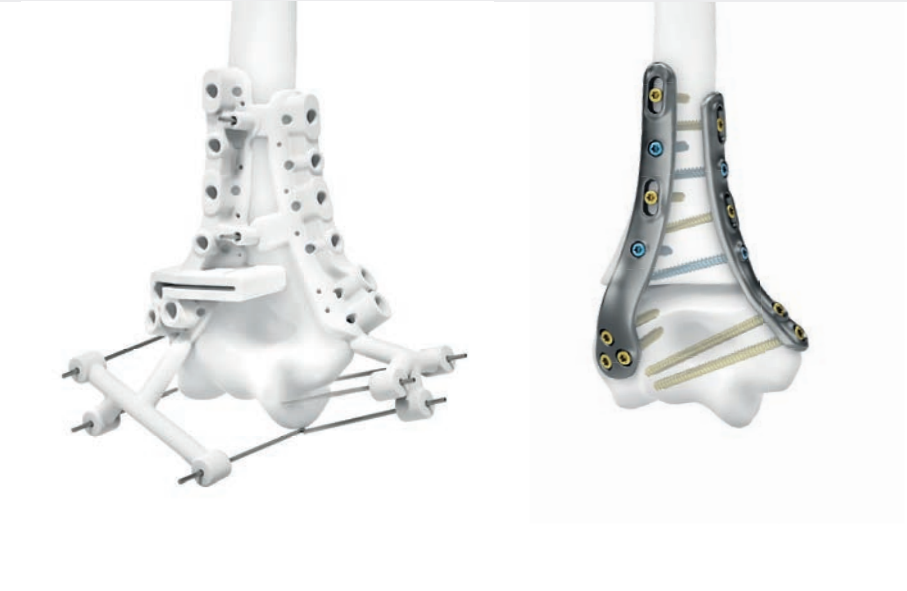
During the initial postoperative phase, the operated arm is elevated for 48 hours to minimize local hematoma and swelling and appropriate pain treatment is given. The arm should be observed for any change of temperature, color and/or sensation. Peripheral blood supply and neurologic status should be documented. Radiographs are usually taken in the operating room and are stored for documentation. Early motion of the elbow joint starts usually on day 2 depending on soft tissue conditions.

Tolerance to weight bearing activities should be assessed based on the level of osseous union.
The patient should come back for follow-up at defined timepoints until the osteotomies are healed.

Case studies
Distal Humerus Reconstruction

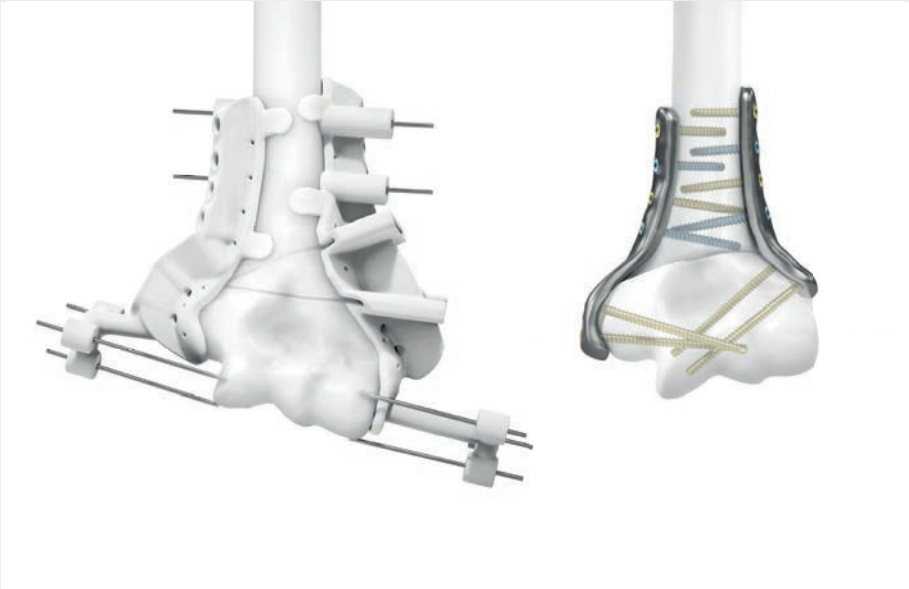


90° double-plate treatment of a distal humerus malunion with a distal humerus reconstruction including resections and rotational changes.



90° double-plate treatment of a distal humerus malunion with a distal humerus reconstruction including resections and rotational changes.

180° double-plate treatment of a distal humerus malunion with a distal humerus reconstruction including resections and rotational changes.



180° double-plate treatment of a distal humerus malunion with a distal humerus reconstruction including resections and rotational changes.

Osteosynthesis screws

Recos® smartDrive® screws

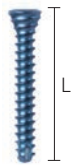
Ø 3.0 mm

STERILE R

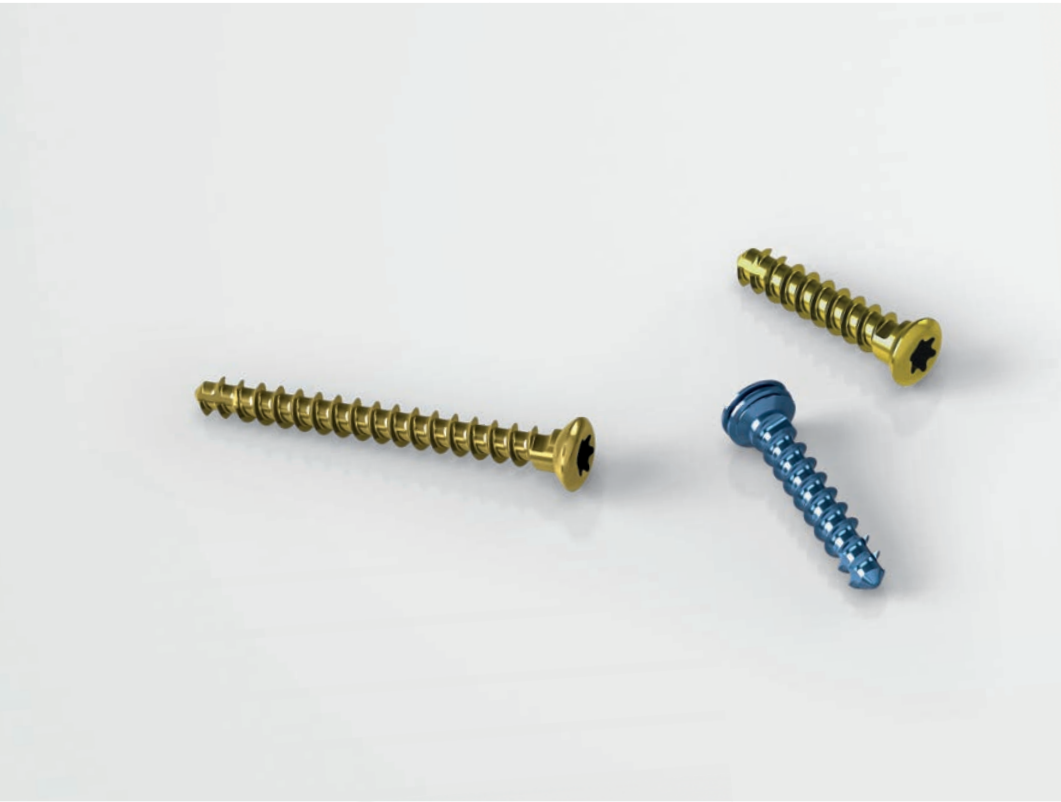
L (mm)	Standard screw	Standard screw
8 mm	26-909-08-09	26-909-08-71
9 mm	26-909-09-09	26-909-09-71
10 mm	26-909-10-09	26-909-10-71
11 mm	26-909-11-09	26-909-11-71
12 mm	26-909-12-09	26-909-12-71
13 mm	26-909-13-09	26-909-13-71
14 mm	26-909-14-09	26-909-14-71
15 mm	26-909-15-09	26-909-15-71
16 mm	26-909-16-09	26-909-16-71
17 mm	26-909-17-09	26-909-17-71
18 mm	26-909-18-09	26-909-18-71
19 mm	26-909-19-09	26-909-19-71
20 mm	26-909-20-09	26-909-20-71
22 mm	26-909-22-09	26-909-22-71
24 mm	26-909-24-09	26-909-24-71
26 mm	26-909-26-09	26-909-26-71
28 mm	26-909-28-09	26-909-28-71
30 mm	26-909-30-09	26-909-30-71

Ø 3.0 mm

STERILE R



L (mm)	Multidirectional locking screw	Multidirectional locking screw
8 mm	26-908-08-09	26-908-08-71
9 mm	26-908-09-09	26-908-09-71
10 mm	26-908-10-09	26-908-10-71
11 mm	26-908-11-09	26-908-11-71
12 mm	26-908-12-09	26-908-12-71
13 mm	26-908-13-09	26-908-13-71
14 mm	26-908-14-09	26-908-14-71
15 mm	26-908-15-09	26-908-15-71
16 mm	26-908-16-09	26-908-16-71
17 mm	26-908-17-09	26-908-17-71
18 mm	26-908-18-09	26-908-18-71
19 mm	26-908-19-09	26-908-19-71
20 mm	26-908-20-09	26-908-20-71
22 mm	26-908-20-09	26-908-22-71
24 mm	26-908-24-09	26-908-24-71
26 mm	26-908-26-09	26-908-26-71
28 mm	26-908-28-09	26-908-28-71
30 mm	26-908-30-09	26-908-30-71



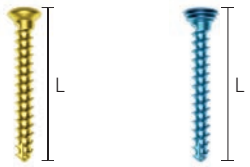
Explanation of icons

- Titanium alloy
- Screw diameter 3.0 mm
- ContourDrive
- Packaging unit
- STERILE R Sterile packaged implants

Fos 2 – ContourDrive screws

Ø 3.0 mm

STERILE R



L (mm)	Standard screw	Multidirectional locking screw
8	26-766-08-71	26-767-08-71
10	26-766-10-71	26-767-10-71
12	26-766-12-71	26-767-12-71
14	26-766-14-71	26-767-14-71
16	26-766-16-71	26-767-16-71
18	26-766-18-71	26-767-18-71
20	26-766-20-71	26-767-20-71
22	26-766-22-71	26-767-22-71
24	26-766-24-71	26-767-24-71
26	26-766-26-71	26-767-26-71
28	26-766-28-71	26-767-28-71
30	26-766-30-71	26-767-30-71
32	26-766-32-71	26-767-32-71
34	26-766-34-71	26-767-34-71
36	26-766-36-71	26-767-36-71
38	26-766-38-71	26-767-38-71
40	26-766-40-71	26-767-40-71
42	26-766-42-71	
44	26-766-44-71	
46	26-766-46-71	
48	26-766-48-71	
50	26-766-50-71	
52	26-766-52-71	
54	26-766-54-71	
56	26-766-56-71	

Osteosynthesis instruments
Recos® system

½

26-166-13-07

17.5 cm / 6 ¾"

K-wire dispenser
Ø 1.2 mm

St 1 QTY

½

22-627-12-05

12 cm / 4 ¾"

K-wires
Ø 1.2 mm

St 10

½

26-166-32-07

13.5 cm / 5 ¼"

Drill guide
monoaxial

St Sic 1 QTY

½

26-950-30-07

26-950-30-71

11 cm / 4 ¼"

Core hole drill
AO attachment Ø 2.5 mm

St 1 QTY

Explanation of icons

- System diameter 3.0 mm
- T-Drive
- AO connection
- St Steel
- Sic Silicone
- 1 QTY Packaging unit
- STERILE R Sterile packaged instruments

½

26-166-21-07

15 cm / 5 ¾"

Depth gauge
single-hand principle

½

26-166-18-07

18 cm / 7"

Screwdriver T8

½

26-166-19-07

19 cm / 7 ½"

Screwdriver T8
rotary

Osteosynthesis instruments
Fos 2 system

½

26-773-67-07

17.5 cm / 6 ⅞"

Fos 2 drill guide POLY
Ø 2.7/3.0 mm, module 2

½

26-772-31-07

14 cm / 5 ⅝"

Core hole drill Ø 2.1 mm,
for screws Ø 3.0 mm

½

26-773-27-07

12 cm / 4 ⅝"

ContourDrive screwdriver blade
Ø 2.7/3.0 mm, self-retaining

½

59-933-10-07

13 cm / 5 ⅛"

Handle Size M, AO

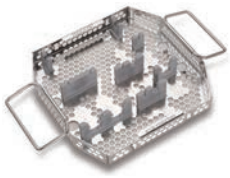
Explanation of icons

- System diameter 3.0 mm
- ContourDrive
- AO connection
- St Steel
- Sic Silicone
- 1 QTY Packaging unit

Storage system	
55-910-11-04	Storage set consisting of:
	lid, instrument insert, storage cage, circular screw rack Ø 2.5/3.0 mm, double-sided

55-910-59-04

Lid



55-910-13-04

Instrument insert
for storage system

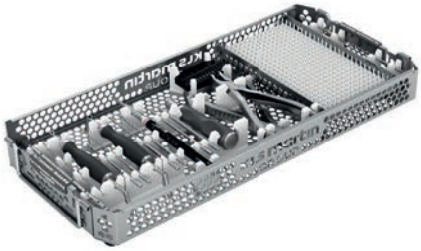
55-910-14-04

Storage cage

55-910-12-04

smartDrive® Ø 2.5/3.0 mm
circular screw rack,
double-sided

55-915-12-04	Storage tray instruments Fos 2 - module 2 (2.7 / 3.0 mm) and module 3 (3.5 / 4.0 mm)
55-981-70-04	Lid insert instrument storage



55-915-12-04

Storage cage Fos 2 – Modul 2 (2.7 / 3.0 mm)
and modul 3 (3.5 /4.0 mm)

55-981-70-04

Lid instrument storage cage

The IPS® product range

IPS Implants® I Distal Humerus Reconstruction

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

KLS Martin offers custom-made solutions for the distal humerus reconstruction procedure. Creating surgical plans with matching custom-made guides is an option. Additionally, custom-made implants achieved through additive manufacturing are also available for complex procedures.

IPS Implants® distal humerus reconstruction are fixed with smartDrive® and ContourDrive standard and/or locking screws of the Recos® and Fos 2 systems.

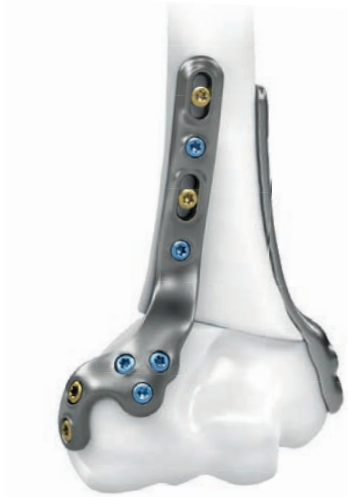
Instrumentation is limited to the essentials.

IPS Gate®

The web-based platform and app guide surgeons and users reliably and efficiently through the process of inquiring about, planning, and completing patient-specific 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 very high precision.



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