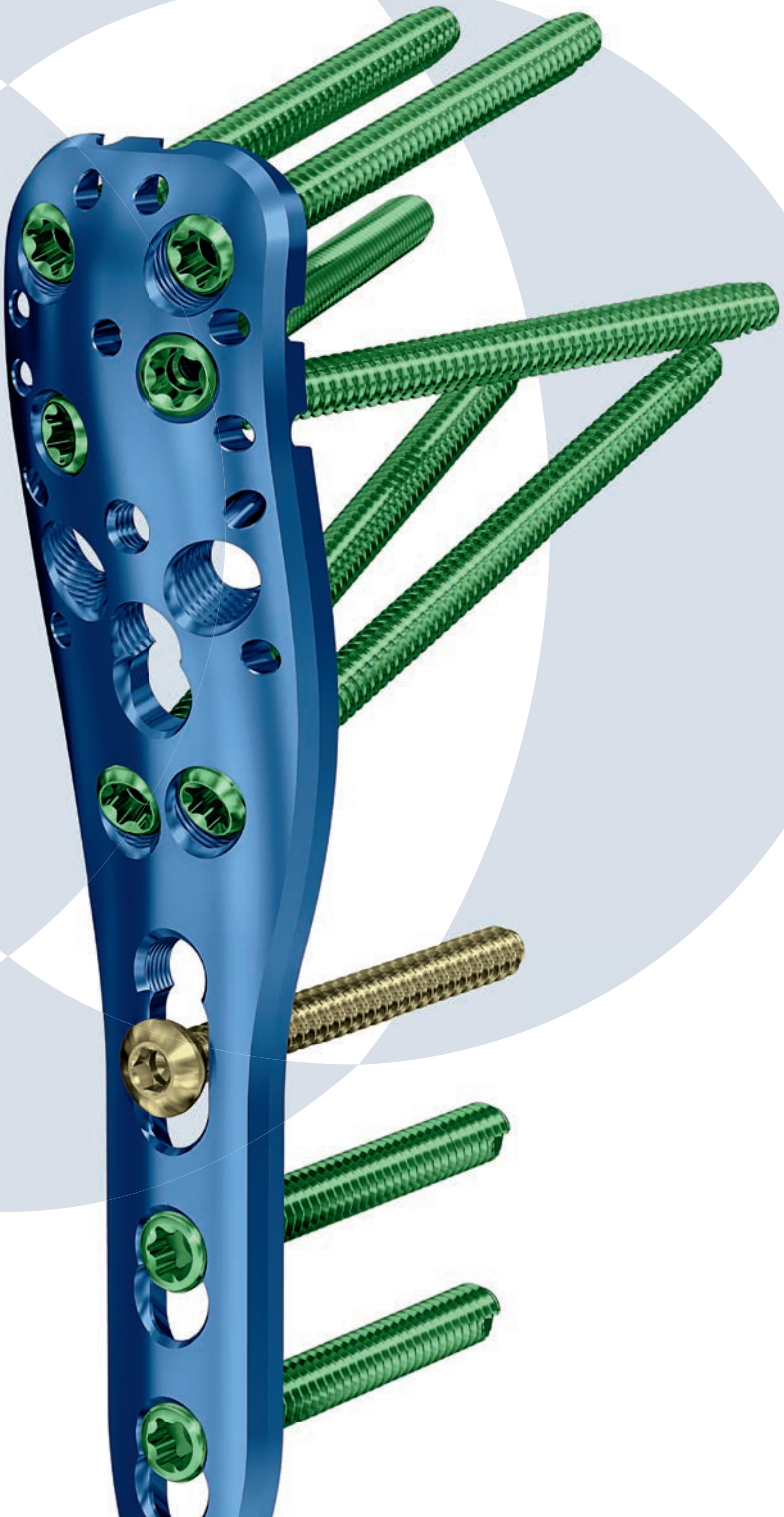
DePuy Synthes
COMPANIES OF Johnson & Johnson

PHILOS AND PHILOS LONG™

The anatomic fixation system for the proximal humerus



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

TABLE OF CONTENTS

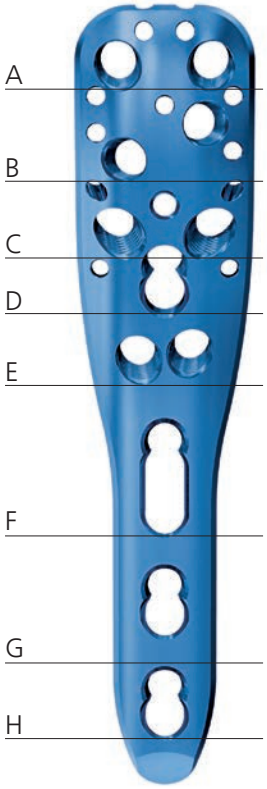
PHILOS PROXIMAL HUMERAL INTERNAL LOCKING SYSTEM

PHILOS

- 9 proximal screw holes in section A–E for LCP locking screws ∅ 3.5 mm enable an angular stable construct to enhance the grip in osteoporotic bone and multi-fragment fractures
- Carefully apply for osteoporotic bone
- Optimal screw placement
- 10 proximal holes for suturing to help maintain fracture reduction

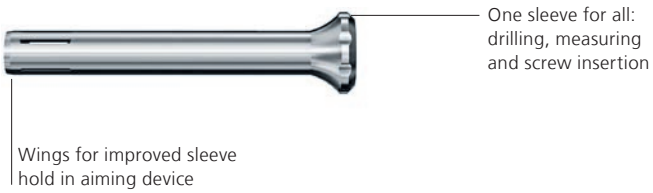
PHILOS Long

- Shaft reinforced to 3.7 mm
- Distal LCP long holes for maximum adaptability
- Plate length up to 290 mm

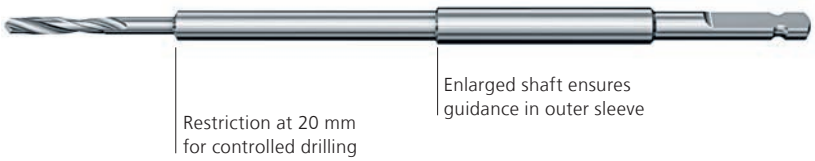


PHILOS INSTRUMENTS

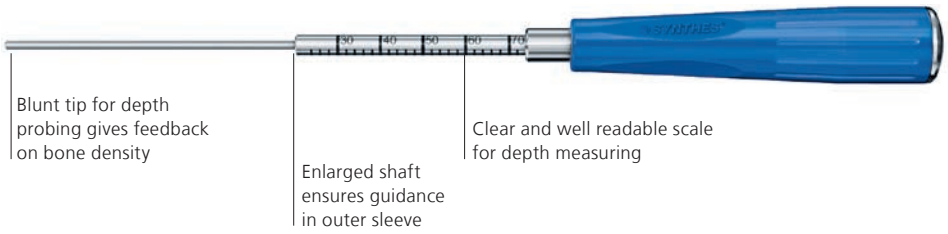
Outer sleeve



Restricted drill bit



Length probe

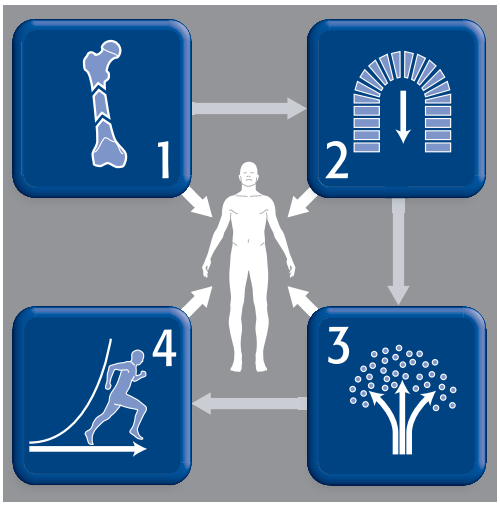


AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation[1, 2].

Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.



Stable fixation
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991.
[2] Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

INDICATIONS

PHILOS indications

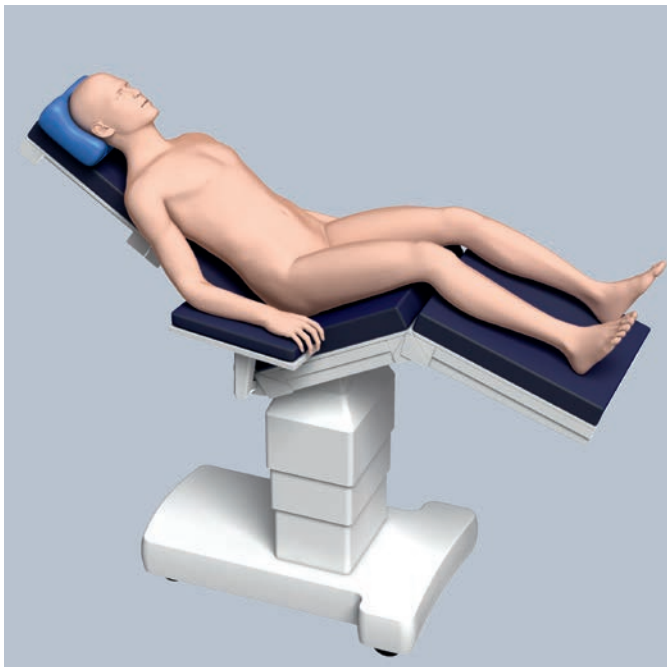
- Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone
- Pseudarthroses in the proximal humerus
- Osteotomies in the proximal humerus

PHILOS long indications

- As for PHILOS, but for fractures extending to the shaft or without medial support

PATIENT POSITIONING AND APPROACH

Note: **For information on fixation principles using conventional and locked plating techniques, please refer to the LCP Locking Compression Plate Surgical Technique (DSEM/TRM/0115/0278).**



1

Position the patient

Place the patient in the beach chair position or supine position on a radiolucent table.

Ensure the fluoroscope is positioned in a way that allows visualization of the proximal humerus in two axes (AP and lateral/axial).

Prepare the patient's arm so that it can be mobilized intraoperatively.

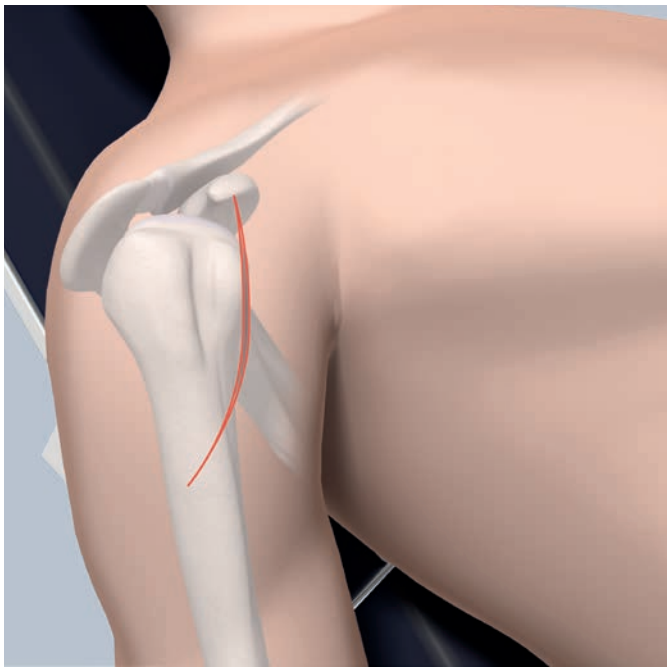
2
Approach

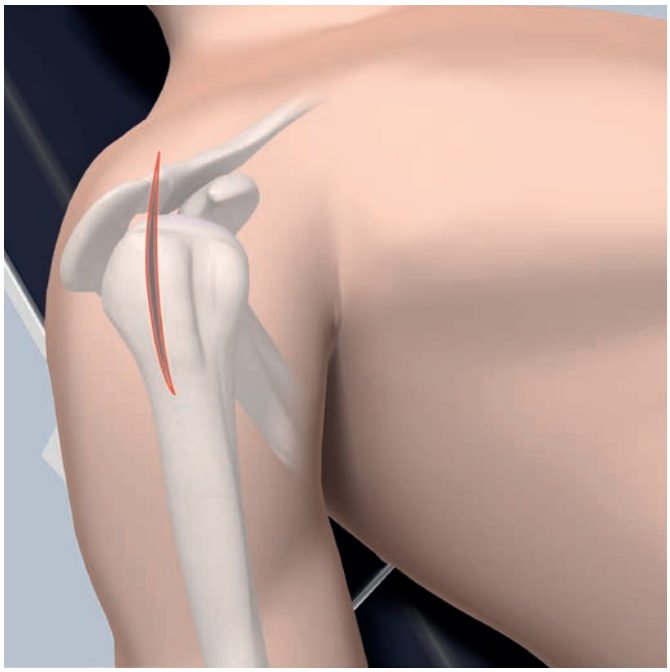
A deltopectoral or transdeltoid approach is recommended.

If the transdeltoid approach is performed, the use of the LCP Percutaneous Aiming System 3.5 for PHILOS is recommended.

Warnings:

- **Do not injure the axillary nerve. The axillary nerve can be palpated at the lower margin of the incision.**
- **To avoid damaging the axillary nerve, do not split the deltoid more than 4 cm distal to its origin.**





1
Reduce fracture and fix temporarily

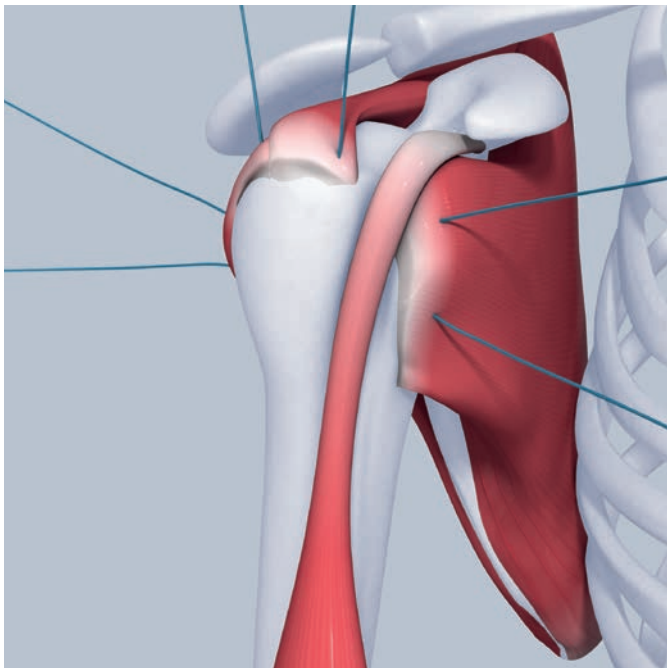
Proper reduction of the fracture is crucial for good bone healing and function. In some cases closed reduction before prepping the patient is beneficial.

Reduce the head fragments and check the reduction under image intensifier control.

Note: **The locking screws are not suitable for reduction since they cannot exert compression. The head fragments must be reduced before insertion of locking screws.**

Kirschner wires can be used for reduction as joysticks in the fragments as well as for temporary fixation. Ensure that Kirschner wires do not interfere with correct plate placement.

Suturing
Provisionally reduce the tubercles using sutures through the insertions of the musculi subscapularis, infra- and supra-spinatus. The sutures will help to maintain the stability of the reconstruction when fixing them to the plate later.



2
Attach aiming device to plate

Instruments	
03.122.057	PHILOS Aiming Device, without Nose
or	
03.122.067	PHILOS Aiming Device Stardrive, without Nose
or	
03.122.056	PHILOS Aiming Device, with Nose
or	
03.122.066	PHILOS Aiming Device Stardrive, with Nose
311.431	Handle with Quick Coupling
314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
or	
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling

Insert the stabilization pin of the aiming device in the specially provided hole on the PHILOS plate. Use the screwdriver to tighten the securing screw of the aiming device.

Precaution: **Intraoperative bending of the proximal portion of the plate is not recommended for maintaining proper alignment between the aiming device and the plate.**

3
Position plate

Position the plate 2–4 mm posterior to the bicipital groove and 5–7 mm distal to the top of the greater tubercule. Align the plate properly to the humeral shaft.

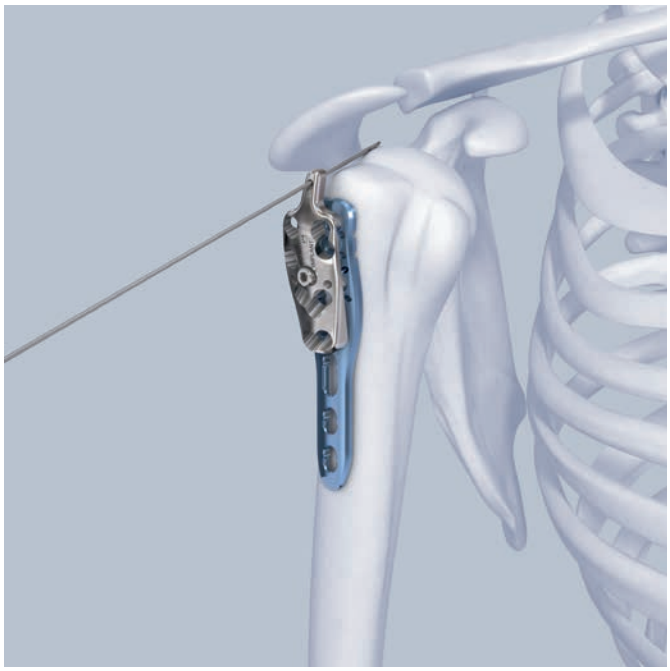
Precaution: **Placing the plate too high increases the risk of subacromial impingement. Placing the plate too low can prevent the optimal distribution of screws in the humeral head.**

Warnings:
- **Do not injure the axillary nerve. The axillary nerve can be palpated at the lower margin of the incision.**
- **To avoid damaging the axillary nerve, do not split the deltoid more than 4 cm distal to its origin.**

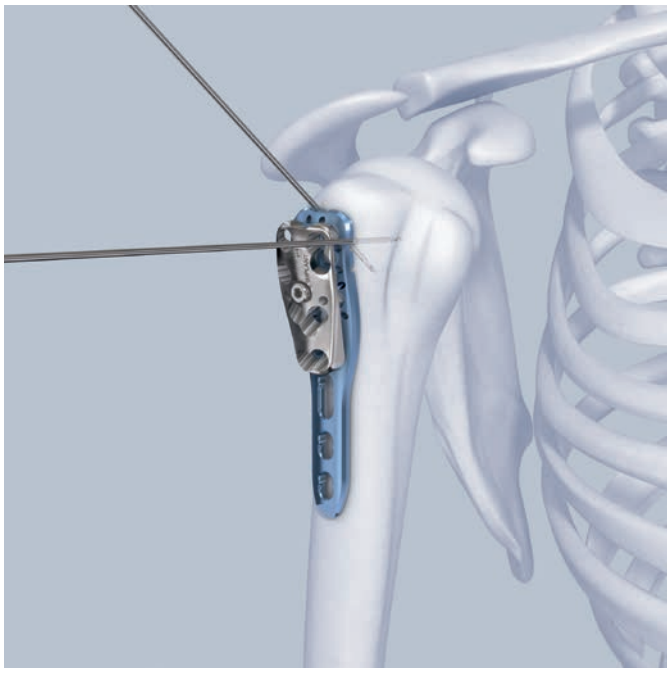
Alternative techniques

Instruments	
03.122.056	PHILOS Aiming Device, with Nose
03.122.066	PHILOS Aiming Device Stardrive, with Nose

Option A: Determine the position of the plate using the PHILOS aiming device with nose. Insert a Kirschner wire into the proximal guide hole below the rotator cuff so that the Kirschner wire aims at the proximal joint surface.



Option B: Insert two positioning Kirschner wires 2–4 mm lateral to the bicipital groove and 5–7 mm below the tip of the greater tubercule. Position the plate between the Kirschner wires.



4
Fix plate temporarily

Instruments	
310.250	Drill Bit ∅ 2.5 mm, length 110/85 mm, 2-flute, for Quick Coupling
323.360	Universal Drill Guide 3.5
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.070	Screwdriver, hexagonal, small, 2.5 mm, with Groove
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling
Optional instrument	
311.320	Tap for Cortex Screws ∅ 3.5 mm, length 110/50 mm

Fix the plate temporarily with a cortex screw in the elongated combi-hole in the plate shaft.

Use the ∅ 2.5 mm drill bit with the 3.5 universal drill guide to drill the bone through both cortices.

Determine the required length of the cortex screw using the depth gauge.

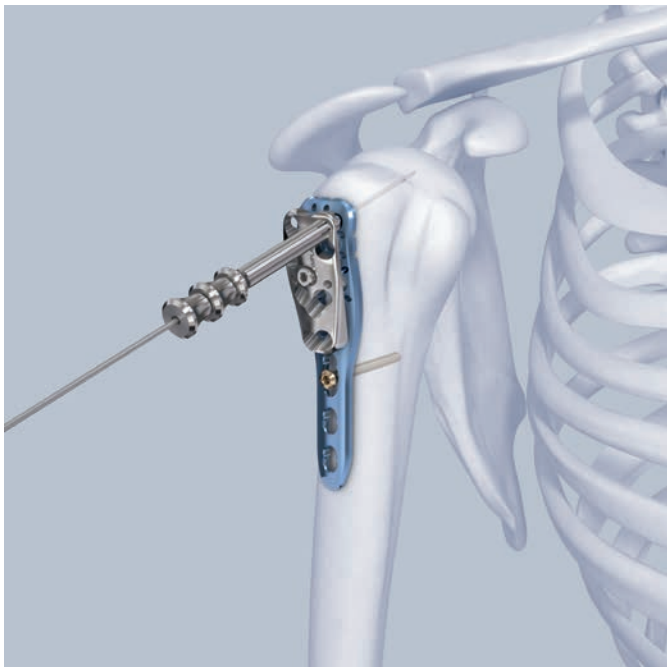
Insert the appropriate ∅ 3.5 mm cortex screw using the screwdriver.

Option: Temporary fixation with Kirschner wires

Instruments	
03.122.053	Outer Sleeve 6.0/5.0 for PHILOS Aiming Device
03.122.054	Drill Sleeve 5.0/2.9, for No. 03.122.053
03.122.055	Centering Sleeve for Kirschner Wire ∅ 1.6 mm, for No. 03.122.054

If required, use Kirschner wires through the triple sleeve system for temporary fixation of the humeral head.

Warning: **Do not penetrate the joint surface with the Kirschner wires.**

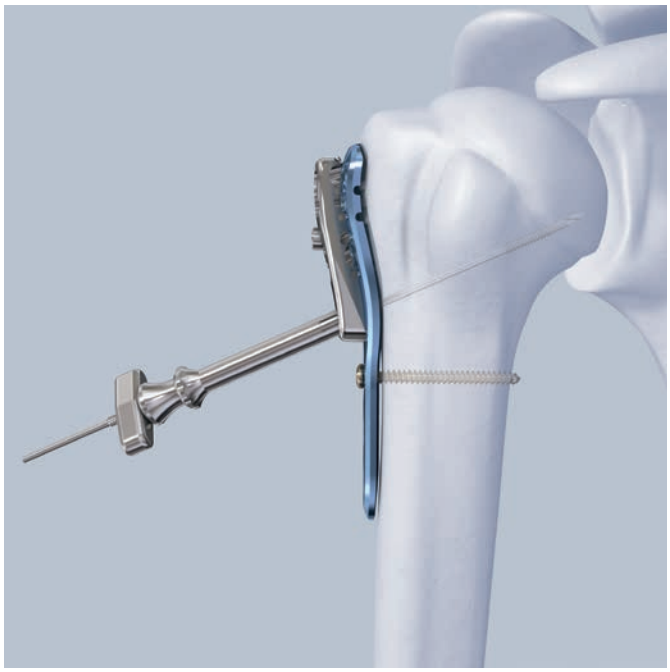


Option: Temporarily reduce with pull reduction device

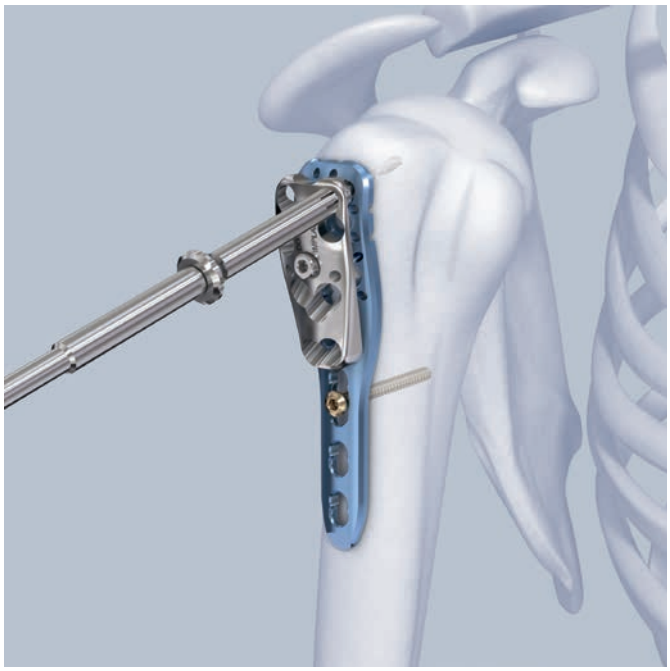
Instruments	
03.122.059	Pull Reduction Device for use with No. 03.122.060 for Drill Sleeves
03.122.060	Wing Nut for Pull Reduction for use with No. 03.122.059 for Drill Sleeves

In good bone stock, the pull reduction device can optionally be used for temporary reduction. Using a power tool, insert the pull reduction device through the drill sleeve to the desired depth. Slide the wing nut over the wire and tighten. In this way, bone fragments are pulled towards the plate.

Warning: **Do not penetrate the joint surface with the pull reduction device.**



5
Drill the lateral cortex and determine proximal screw length



5a Technique for osteoporotic bone:
The following technique describes screw depth measuring optimized for osteoporotic bone. In good bone stock, change to options A or B for drilling the screw hole and depth measuring.

Instruments	
03.122.053	Outer Sleeve 6.0/5.0 for PHILOS Aiming Device
03.122.051	Drill Bit ∅ 2.8 mm, with Stop, for Quick Coupling
03.122.052	Length Probe for Nos. 03.122.053 and 03.122.058

Insert the outer sleeve in the desired hole of the aiming device. Drill the lateral cortex using the drill bit with stop through the outer sleeve.

Warning: **In porotic bone, only drill the lateral cortex.**

Alternative instrument	
03.122.058	Drill Sleeve 6.0/2.9 with thread

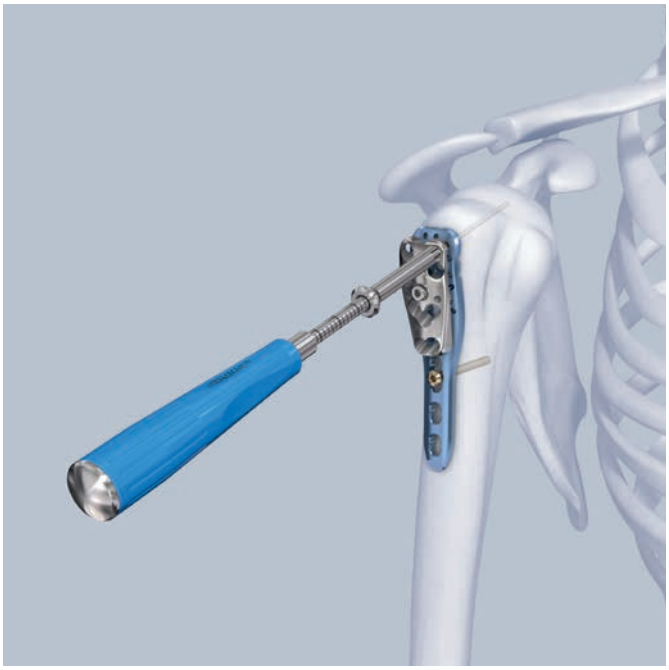
Use the drill sleeve with thread independently from the aiming device.

Warnings:
- **Do not drill through the joint surface.**
- **Do not insert overly long screws in order to prevent primary or secondary screw penetration.**

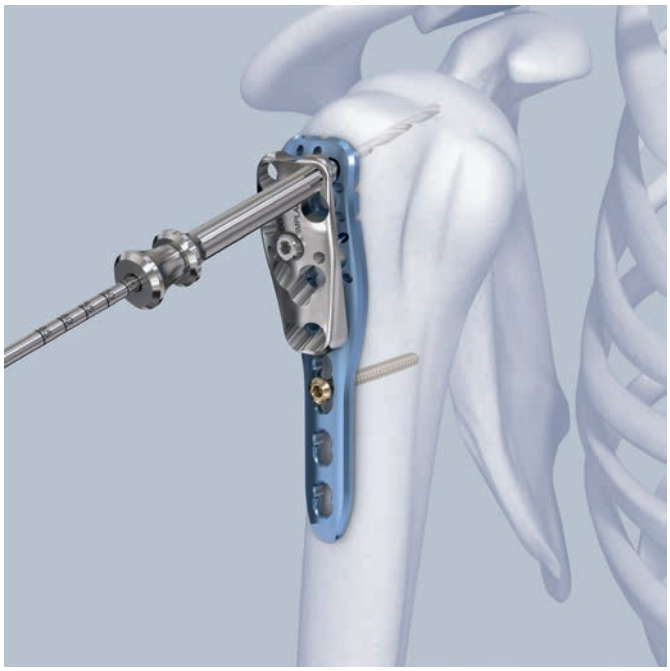
Use the length probe through the outer sleeve and push it carefully into the humeral head. Stop pushing when increased bone density is felt. Read off the required screw length from the length probe.

Warning: **Do not push the length probe through the joint surface.**

Note: **The tip of the length probe should be located approximately 5–8 mm below the joint surface for locking screws.**



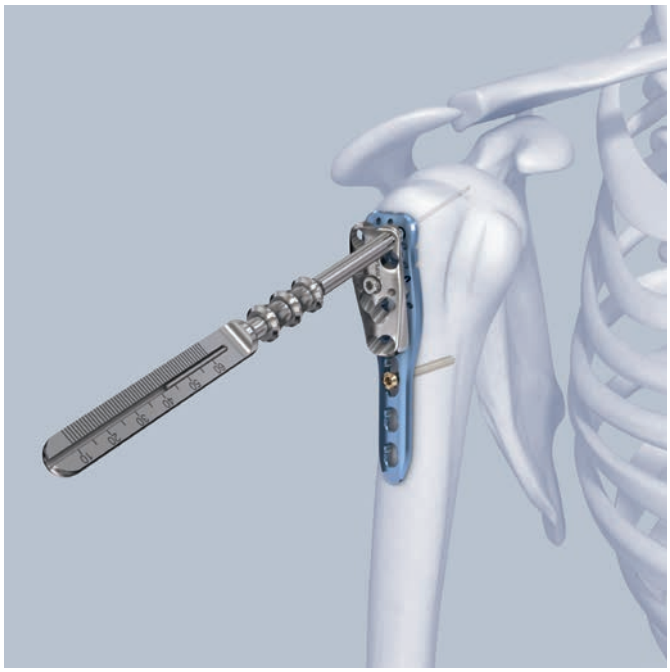
5b Alternative techniques for good bone stock
If the bone stock is good, choose one of the following options:



Option A: Use a ∅ 2.8 mm drill bit through the drill sleeve and drill 5–8 mm below the joint surface. Read the required screw length from the drill bit.

Note: **The drill bit tip should come as close as possible to the subchondral bone, approximately 5–8 mm from the joint surface. Since it may not always be possible to feel the resistance from the subchondral bone, and the drill bit represents the final position of the locking screw, the use of image intensification is recommended.**

Warning: **Do not push the drill bit through the joint surface.**



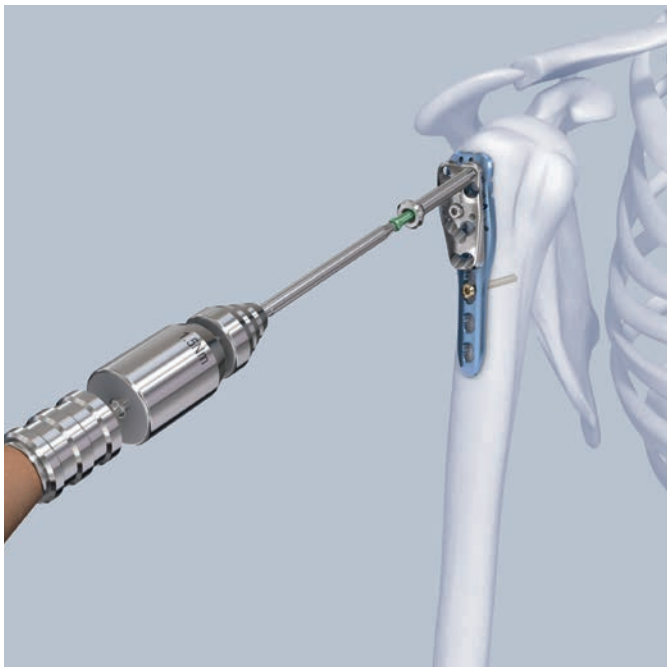
Option B: Check the subsequent position of the screws using Kirschner wires. Attach the triple sleeve system, consisting of a outer sleeve, a drill sleeve, and a centering sleeve for the Kirschner wire onto the aiming device and insert a Kirschner wire ∅ 1.6 mm, 150 mm long.

Check the position of the Kirschner wire. The tip of the Kirschner wire should be located in the subchondral bone (5–8 mm below the joint surface).

Slide the PHILOS direct measuring device for Kirschner wire 1.6 mm over the Kirschner wire and determine the length of the required screw.

6
Insert proximal screws

Instruments	
511.770 or 511.773	Torque limiter, 1.5 Nm
314.030 or 314.116	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
311.431 or 397.705	Handle with Quick Coupling Handle for Torque Limiter



Remove drill sleeve and insert the screw with the appropriate screwdriver shaft (hexagonal or Stardrive recess) and 1.5 Nm torque limiting attachment through the outer sleeve. The sleeve ensures that the locking screw is correctly locked in the plate. The angular stability is reduced if a locking screw is inserted obliquely.

Insert the screw manually or with power until a click is heard. If using power, reduce speed when tightening the head of the locking screw into the plate.

Repeat the above steps for all required proximal screw holes.

Warning: **Do not insert overly long screws in order to prevent primary or secondary screw penetration.**

Precaution: **The plate should be secured with at least 4 proximal screws of ∅ 3.5 mm. In poor bone stock, multiple fixation points using all screws is recommended.**

7
Insert shaft screws

After inserting the proximal screws, determine where locking or cortex screws will be used in the shaft.

Note: **If a combination of cortex and locking screws is used, cortex screws must be inserted first to pull the plate to the bone.**

7a

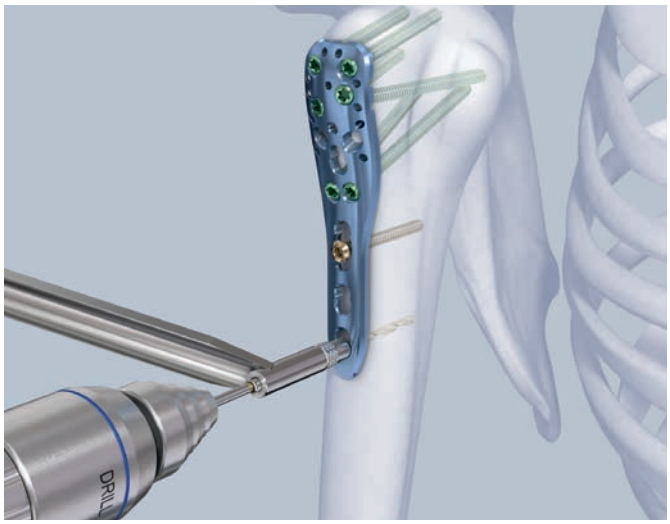
Fixation with ∅ 3.5 mm cortex screws

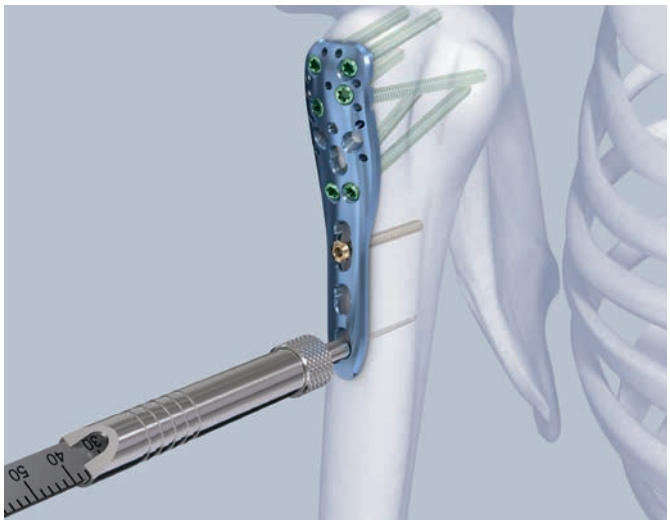
Instruments	
310.250	Drill Bit ∅ 2.5 mm, length 110/85 mm, 2-flute, for Quick Coupling
323.360	Universal Drill Guide 3.5
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.070	Screwdriver, hexagonal, small, 2.5 mm, with Groove
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling

Optional instrument	
311.320	Tap for Cortex Screws ∅ 3.5 mm, length 110/50 mm

Use the ∅ 2.5 mm drill bit with the 3.5 universal drill guide to drill the bone through both cortices.

To set screws in a neutral position, press the drill guide down in the non-threaded hole. To obtain compression, place the drill guide at the end of the non-threaded hole away from the fracture, avoiding downward pressure on the spring-loaded tip.

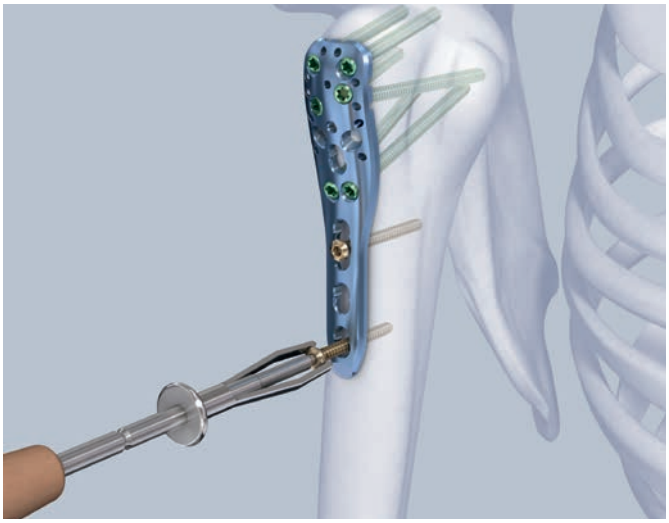




Determine the required length of the cortex screw using the depth gauge.

Insert the appropriate ∅ 3.5 mm cortex screw using the hexagonal or the Stardrive T15 screwdriver and PHILOS Long.

Plate holes in the plate shaft (distal to section E) are LCP combi-holes (see page 2). An LCP combi-hole can be fixed with a cortex screw to generate interfragmentary compression. In this case, the screws are inserted according to the technique for fixing LC-DCP standard plates, but using the universal drill guide instead of the LC-DCP drill sleeve.



7b

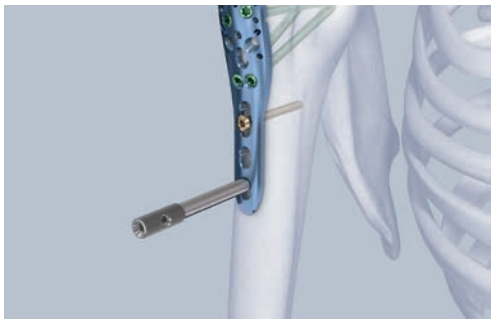
Fixation with ∅ 3.5 mm locking screws

Instruments	
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm
310.284	LCP Drill Bit ∅ 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
or	
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling

Insert the LCP Drill Sleeve 3.5 into the locking hole until fully seated. Drill through both cortices with the ∅ 2.8 mm drill bit and use the scale on the Drill Bit (Fig. 1) to read-off the screw length.

Alternative technique: Remove the drill sleeve. Use the depth gauge to determine the screw length.

Insert the locking screw with the appropriate screwdriver shaft (hexagonal or Stardrive recess) mounted on the 1.5 Nm torque limiter. Insert the screw manually or with the use of a power tool until a click is heard. If a power tool is used, reduce the speed when tightening the head of the locking screw into the plate.



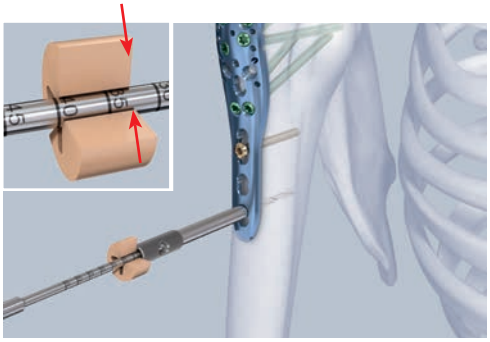
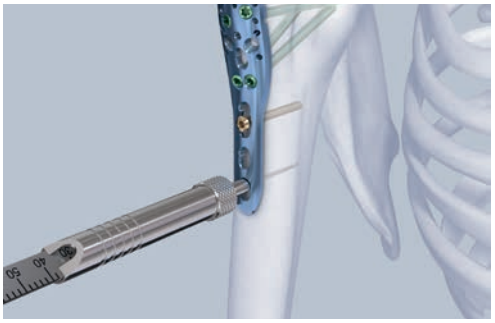
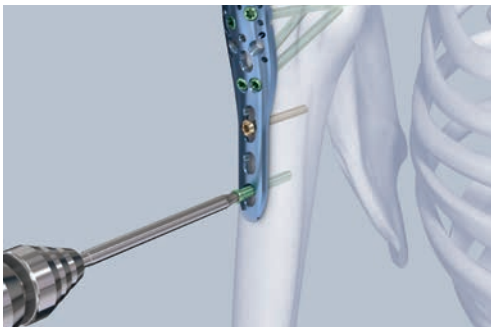
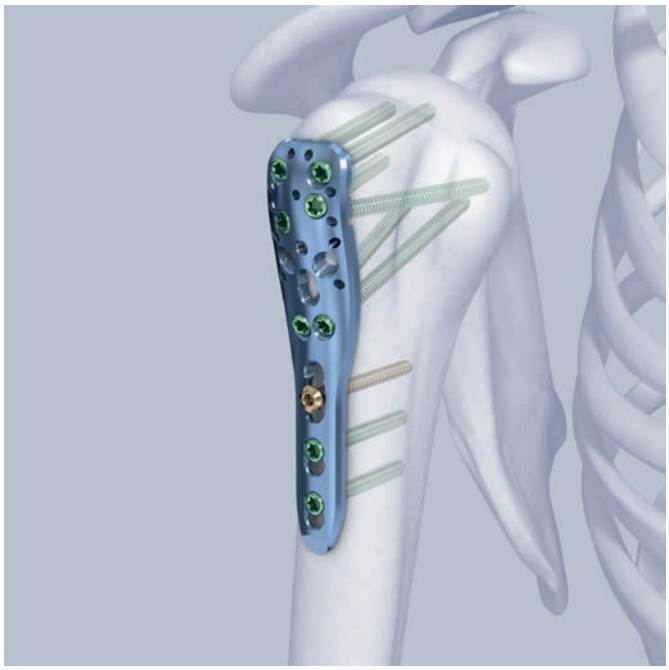


Fig. 1





Repeat the above steps for all required shaft holes.



8
Attach sutures

Remove the aiming device from the plate.

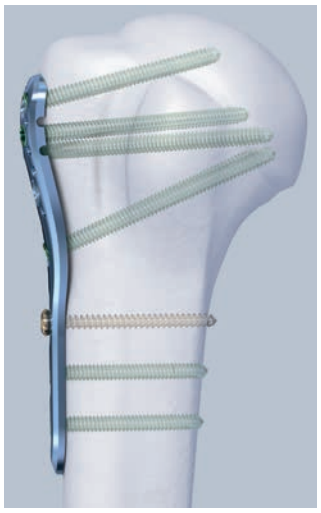
Knot the sutures through the designated holes in the plate if this has not already been done. This construct functions as a tension band and transmits the forces of the rotator cuff over the plate and into the shaft, while preventing fragment displacement during the early rehabilitation period.

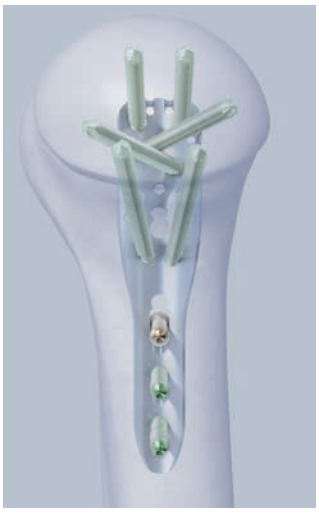
9
Check position of screw tips

Check the screw lengths under image intensifier control in the full range of gleno-humeral-motion and ensure that they do not penetrate the articular surface.

Precaution: **It is important to check the screw lengths in all planes as their angulation and direction may be difficult to visualize.**

Check the stability of the suture fixation. The sutures must not rupture during motion.



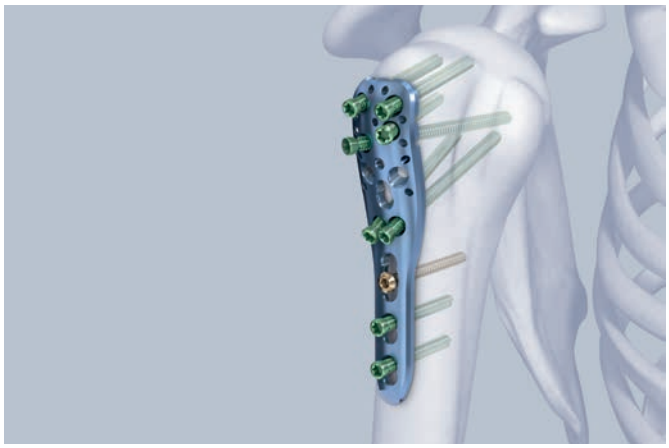


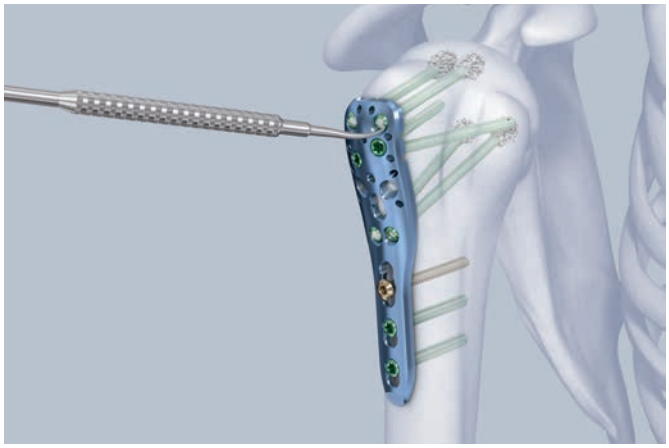
IMPLANT REMOVAL

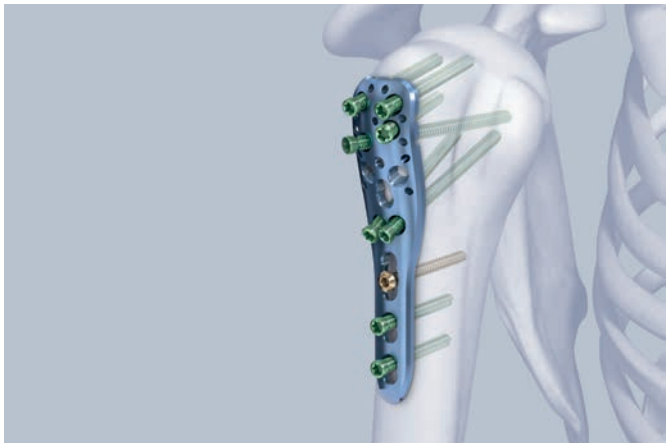
Instruments

314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
or	
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling
311.440	T-Handle with Quick Coupling
309.520	Extraction Screw, conical, for Screws ∅ 2.7, 3.5 and 4.0 mm
309.521	Extraction Screw for Screws ∅ 3.5 mm
319.390	Sharp Hook, length 155 mm

Unlock all screws from the plate, then remove the screws completely from the bone. This prevents simultaneous rotation of the plate when unlocking the last lock-screw. If a screw cannot be removed with the screw-driver (e.g. if the hexagonal or Stardrive recess of the locking screw is damaged or if the screw is stuck in the plate), use the T-Handle with Quick Coupling (311.440) to insert the Extraction Screw (309.520 or 309.521) into the screw head, and unscrew the screw in a counter-clock direction.







IMPLANTS

PHILOS – Proximal Humeral Plate 3.5

Stainless steel	Titanium	Shaft holes	Length (mm)
241.901	441.901	3	90
241.903	441.903	5	114

PHILOS Long – Proximal Diaphyseal Humeral Plate 3.5

Stainless steel	Titanium	Shaft holes	Length (mm)
241.916	441.916	3	106
241.917	441.917	4	124
241.918	441.918	5	142
241.919	441.919	6	160
241.920	441.920	7	178
241.921	441.921	8	196
241.922	441.922	9	214
241.923	441.923	10	232
241.924	441.924	11	250
241.925	441.925	12	268
241.926	441.926	13	286

All plates are available nonsterile or sterile packed.
Add suffix "S" to article number to order sterile product.

Screws used with PHILOS

X12.102 – X12.124	Locking Screw Stardrive ∅ 3.5 mm, length 12–60 mm, self-tapping	
X13.012 – X13.060	Locking Screw ∅ 3.5 mm, length 12–60 mm, self-tapping	
*X04.812 – X04.860	Cortex Screw ∅ 3.5 mm, length 12–60 mm, self-tapping	
0X.200.012 – 0X.200.060	Cortex Screw Stardrive ∅ 3.5 mm, self-tapping, length 12–60 mm	

Stardrive

Hexagonal

X = 2: Stainless steel
X = 4: TAN
*X = 4: TiCP

All screws are available nonsterile or sterile packed.
Add suffix "S" to article number to order sterile product.

INSTRUMENTS

PHILOS instruments

PHILOS sizing templates

	Shaft holes
03.122.003	3
03.122.004	5
03.122.005	long

03.122.051	Drill Bit ∅ 2.8 mm, with Stop, for Quick Coupling

03.122.052	Length Probe for Nos. 03.122.053 and 03.122.058

319.390	Sharp Hook, length 155 mm	
03.122.053	Outer Sleeve 6.0/5.0 for PHILOS Aiming Device	
03.122.054	Drill Sleeve 5.0/2.9, for No. 03.122.053	
03.122.055	Centering Sleeve for Kirschner Wire ∅ 1.6 mm, for No. 03.122.054	
03.122.056	PHILOS Aiming Device, with Nose	
03.122.057	PHILOS Aiming Device, without Nose	
03.122.066	PHILOS Aiming Device Stardrive, with Nose	
03.122.067	PHILOS Aiming Device Stardrive, without Nose	

Optional instruments

03.122.058	Drill Sleeve 6.0/2.9 with thread	
03.122.060	Wing Nut for Pull Reduction for use with No. 03.122.059 for Drill Sleeves	
03.122.059	Pull Reduction Device for use with No. 03.122.060 for Drill Sleeves	

Standard instruments

309.521	Extraction Screw for Screws ∅ 3.5 mm	
309.510	Extraction Screw, conical, for Screws ∅ 1.5 and 2.0 mm	
310.250	Drill Bit ∅ 2.5 mm, length 110/85 mm, 2-flute, for Quick Coupling	
311.431	Handle with Quick Coupling	

310.284	LCP Drill Bit ∅ 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling	
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm	
314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm	
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling	 
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm	
323.360	Universal Drill Guide 3.5	
314.070	Screwdriver, hexagonal, small, 2.5 mm, with Groove	
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling	

SETS

01.122.031	Proximal Humerus Instruments, in Modular Tray, Vario Case System
01.122.013	Small Fragment Basic Instruments, in Modular Tray, Vario Case System
01.122.015	Screw Insertion 3.5/4.0, in Modular Tray, Vario Case System
01.122.014	Small Fragment Reduction Instruments, in Modular Tray, Vario Case System

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MRI INFORMATION

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- **It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.**
- **Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.**
- **Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.**
- **Using the ventilation system may further contribute to reduce temperature increase in the body.**

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