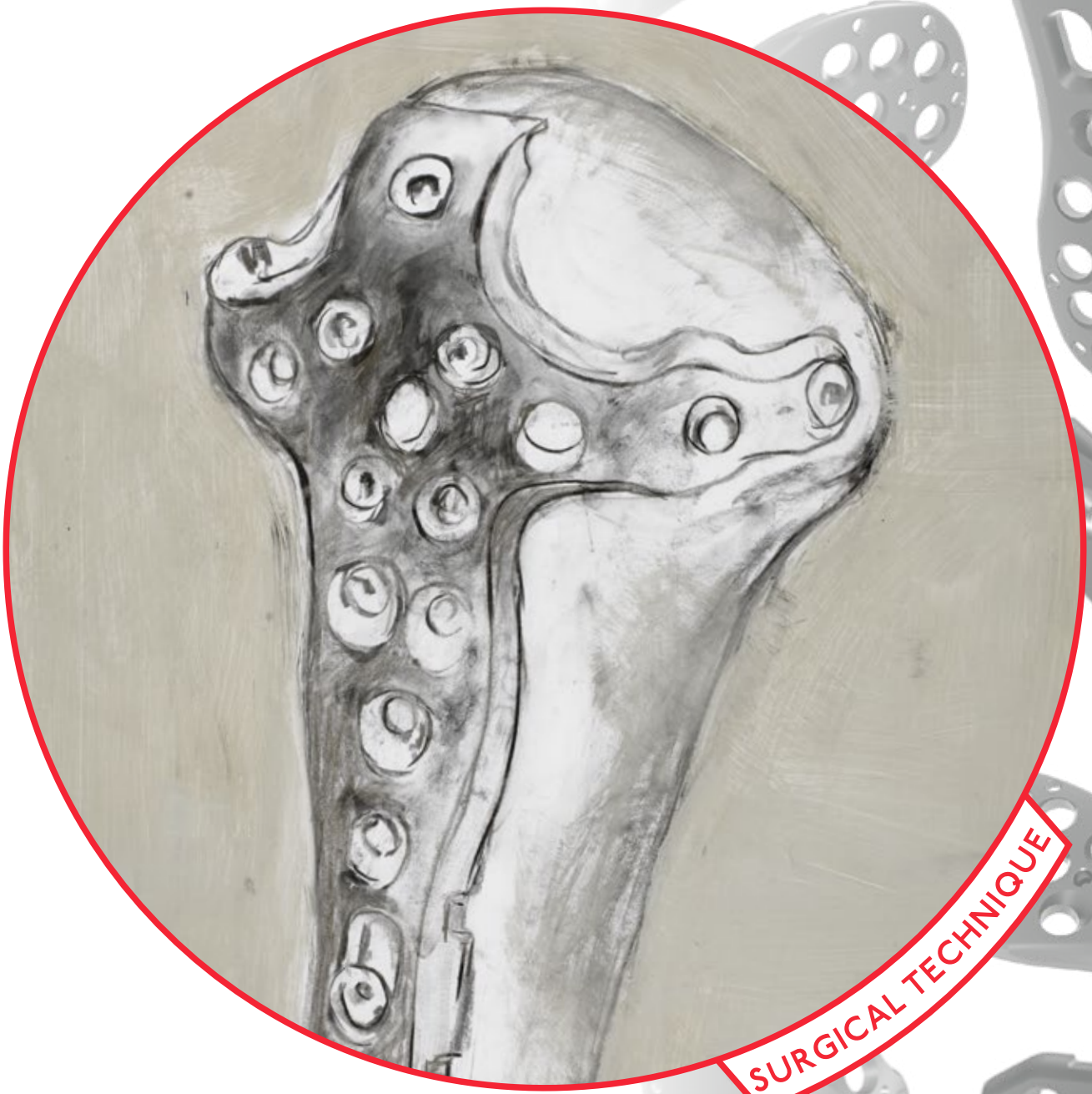
ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Proximal Humeral Locking Plates

PHOENIX

ITS.
Implants for Trauma Surgery

THE ART of TRAUMA SURGERY

The Art of Trauma Surgery is a collaborative project between I.T.S. and Austrian artist Oskar Stocker that celebrates the skill, perseverance, and artistry of surgeons and engineers who work tirelessly to improve outcomes for trauma patients.

At I.T.S., we stand for long-term, trusting relationships with our customers, suppliers, and development partners. Through our devotion to innovation and development, we continuously seek to improve and optimize products and techniques in the field of traumatology.

We believe that the success of our mission lies in the combination of the technical expertise, compassion and dedication of surgeons and engineers to help patients regain their health and well-being. Join us in celebrating these remarkable individuals and *The Art of Trauma Surgery!*

About the Artist

The Austrian artist Oskar Stocker (b. 1956) lives and works in Graz, Austria. He has become known internationally through the exhibition Facing Nations, which consists of portraits of more than 120 people of various nationalities living in Graz; it was shown first in Graz itself, then in Vienna, and later culminated in 2010 with its display at the UN Headquarters in New York City.

In addition to the portraits of individual people, he devotes himself to the depiction of landscapes and objects, down to the smallest detail.

All I.T.S. plates are preformed anatomically as a matter of principle. If adjustment of the plate to the shape of the bone is required, this is possible by carefully bending gently in one direction once. Particular care is required when bending in the region of a plate hole, as deformation of the plate may lead to a failure of the locking mechanism. The plate must not be buckled or bent several times. This is particularly important in the case of titanium implants, to prevent material fatigue and subsequent failure. The method of bending is the conscious responsibility of the operating doctor; I.T.S. GmbH can accept no liability whatsoever for this.

Table of Contents


STOIKER

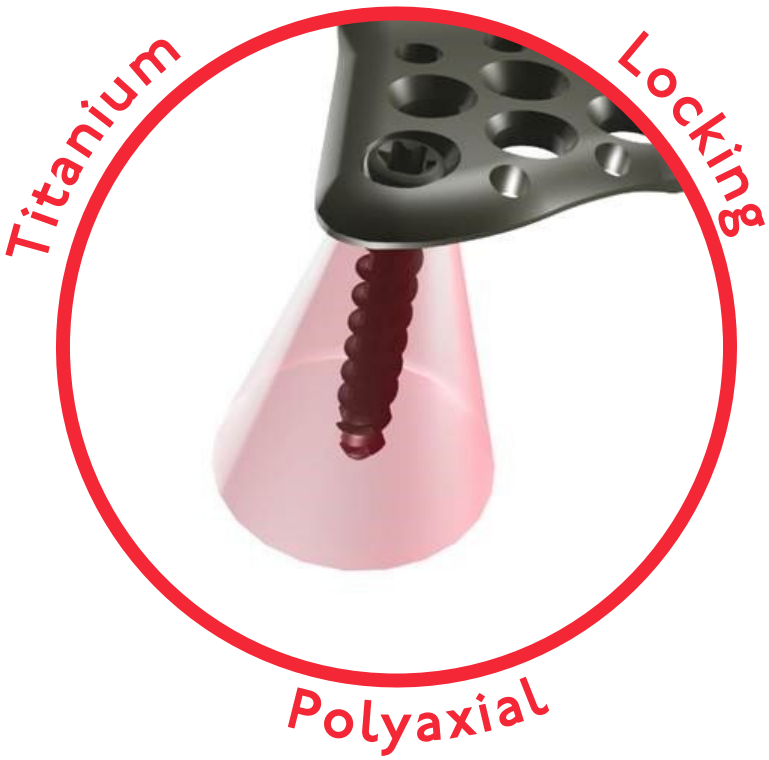
Introduction

Plate Technology

At I.T.S., we stand for long-term, trusting relationships with our customers, suppliers, and development partners. Through our dedication to innovation and development, we continuously seek to improve and optimize products and techniques for trauma surgery.

ONE Technology for all implants

All I.T.S. plates are made from Titanium Grade 2, whereas the screws are made of a harder titanium alloy. This allows the plates to have only non-threaded holes, which all (with the exception of oblong holes) accept both non-locking and locking screws.



When a locking screw is inserted, it forms threads into the plate. There is no cutting and thus no debris is created. Each locking screw can be locked at a free placement within a cone of angulation up to ± 15° and can be re-positioned up to three times.

System Overview

The I.T.S. Proximal Humeral Locking System Phoenix - Flanges aims to provide simplified solutions to complex problems. This versatile system enables the treatment of various proximal humeral fractures, with the contourable anterior/posterior flanges facilitating the proper fixation of the entire humeral head.

Adhering to the technology principles of all I.T.S. plates, this system offers the option of polyaxial locking capabilities in all screw holes (except oblong). The free choice of screw placement gives surgeons options to select the best screw type and angle, allowing for optimal positioning of the humeral head and maximum support, even for poor bone quality.

The plate is available in 3 different versions, 3 lengths (4,5 & 7 holes) and 2 flange widths (Small, Large) to meet the needs of each specific fracture pattern. All three flanges enable the plate to cradle and support the humeral head without relying soley a screw fixation.

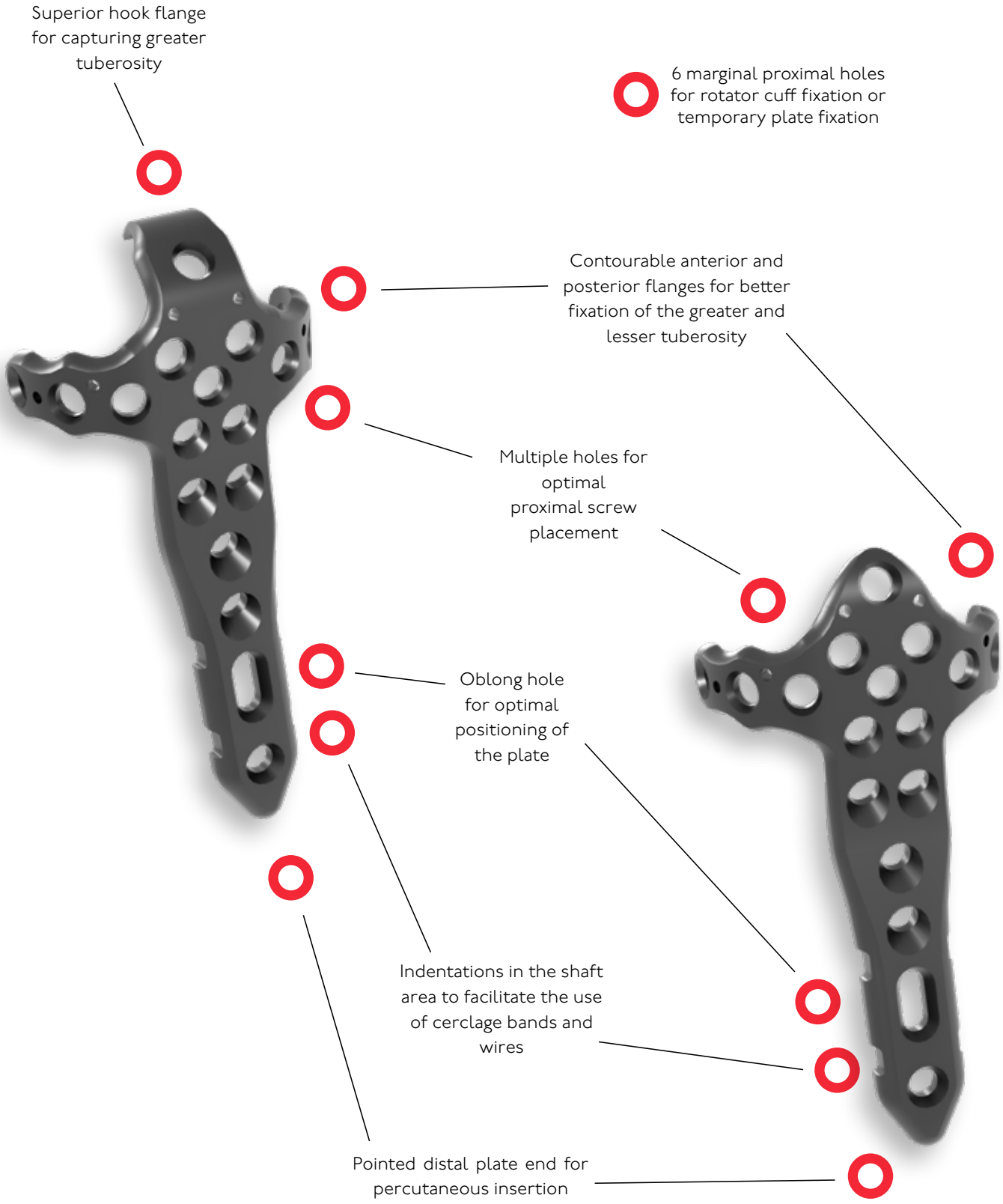
With the addition of the Proximal Humeral Locking System Phoenix - Standard, the system includes a standard plate without flanges for the more common, simple fractures.

The PHL Phoenix Standard features a wider head with multiple II hole options, including multiple options for the medial calcar screw: Together with polyaxial locking technology, this allows for the creation of a diverging and converging pattern of screws to best capture and support the complete humeral head.

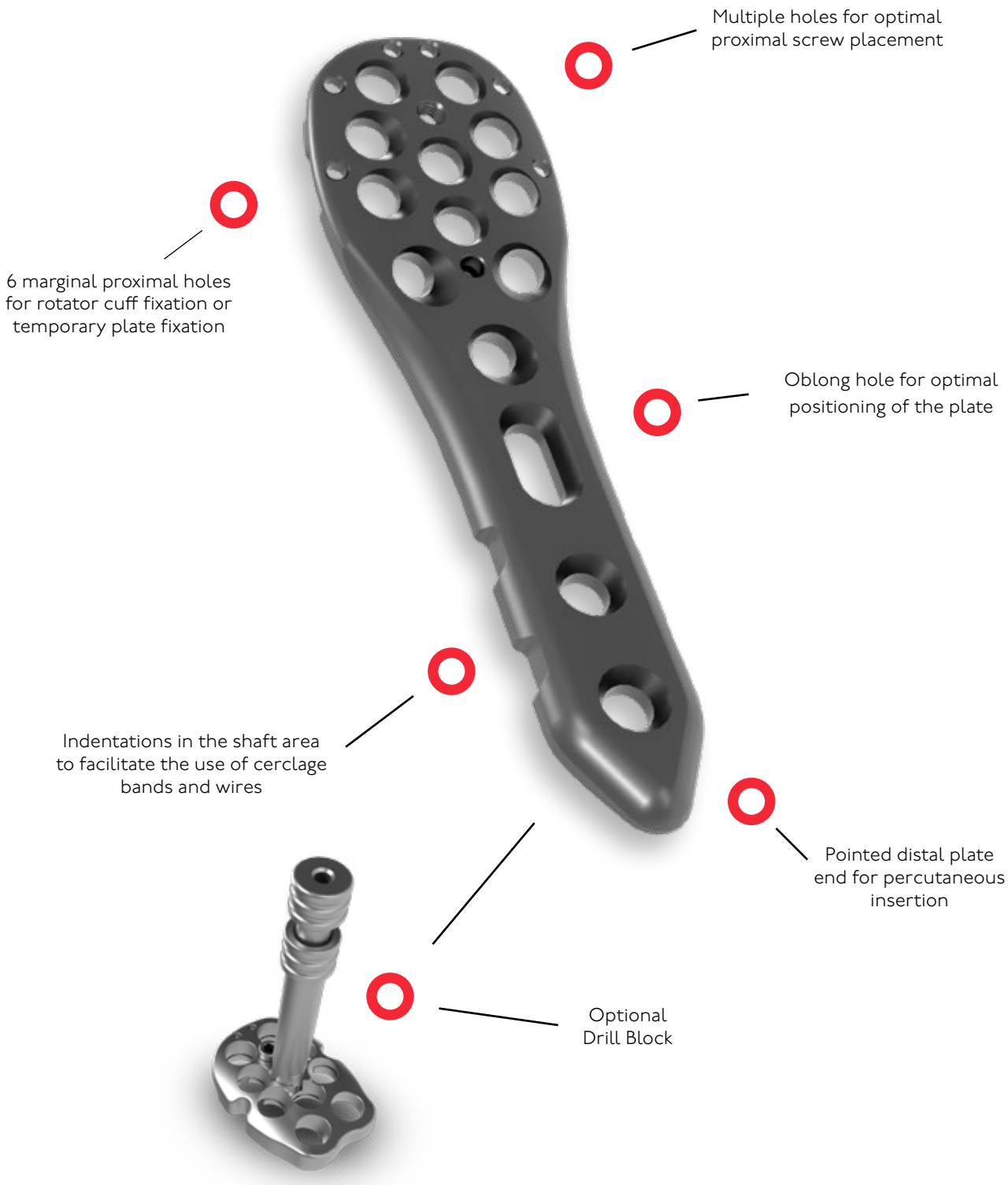
The plate is available in 4 different lengths with an optional drill-block available.

Properties

PHL PHX - Flanges



PHL PHX - Standard



OPTIONAL: Drill Block for PHL PHX Standard

ITS. offers an optional drill block for the PHL Phoenix Standard plate.

Features

- Precise drilling and screw placement
- Easy assembly and secure fixing of the sleeves in the drill block
- Universally usable on both sides

Screws

37351-xx-N **LOCKING**
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

37422-xx-N **LOCKING**
Cancellous Screw, D=4.2mm
Spiral Drill, D=2.5mm
WS 2.5

32351-xx **NON-LOCKING**
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

Indications

The I.T.S. Proximal Humerus Locking System Phoenix - Flanges and Standard is used to stabilize fractures of the proximal humerus (upper arm bone) in the shoulder.

PHL PHX - Flanges

- All stable and unstable humerus fractures with or without shaft involvement
- Fractures of the greater or lesser tuberosities.
- Repair of the greater tuberosity following prior fixation failure or tuberosity “escape”.
- Delayed or nonunion of the proximal humerus.
- Fixation following osteotomy of proximal humeral malunion.
- Displaced two, three and four part fracture of the proximal humerus.
- Displaced anterior and posterior fractures of the proximal humerus and greater tuberosity.
- Nonunion of two, three and four part fractures of the proximal humerus.
- Nonunion of anterior and posterior fracture-dislocations of the proximal humerus and greater tuberosity.

PHL PHX - Standard

- All stable and unstable fractures with and without shaft involvement of the proximal humerus
- Dislocated, unstable 2, 3 and 4-segment fractures of the humeral head
- Valgus-impacted 4-segment fractures of the humeral head
- Non-union of the humeral head

Contraindications

- Diapyhseal fractures

Time of Operation

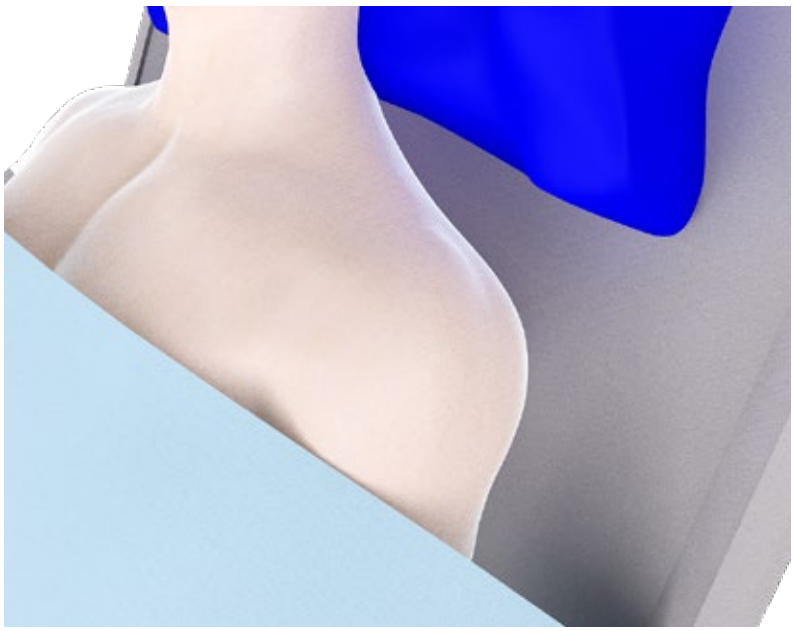
- Primary as well as secondary after swelling subsides and after temporary fixation

Surgical Technique

2.

Pre-operative Patient Preparation

- Positioning on a radiolucent surgical table
- Semi-sitting angle of about 30° - 40°, shoulder should be freely moveable (optional shoulder table)
- The arm should be freely moveable to allow fracture reduction
- General anaesthesia, regional anaesthesia or combination can be used

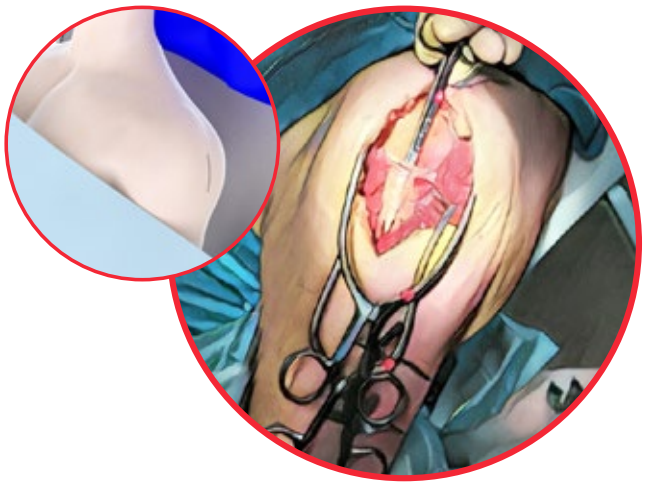


Exposure

1. Anterolateral access:

- Skin incision parallel to the anterior acromion and extension 5cm distally in fiber direction of the M. deltoideus.
- Detachment of the pars acromialis of the M. deltoideus.

CAUTION: The axillary nerve exits the lateral armpit dorsally and moves around the surgical neck (collum chirurgicum) of the humerus.

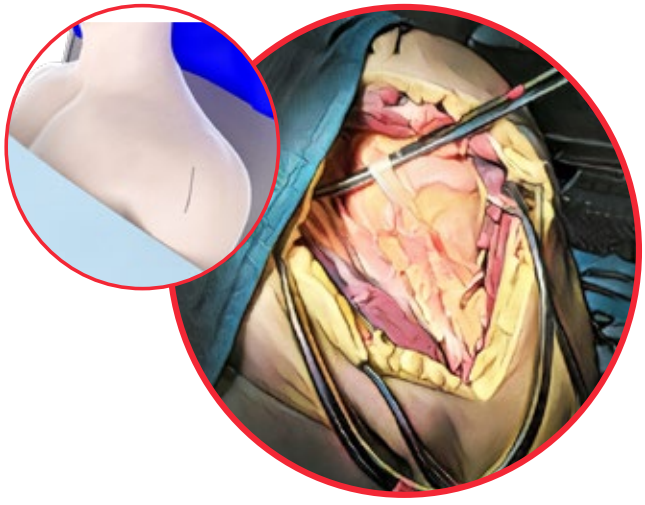


The illustration shows identification of the axillary nerve, a useful landmark.

2. Deltoid-pectoral approach:

- Skin incision parallel to the delto- pectoral groove.
- Identify the cephalic vein and develop the delto- pectoral interval.
- The first of the conjoint tendon can be released to improve exposure.

CAUTION: The axillary nerve exits the lateral armpit dorsally and moves around the surgical neck (collum chirurgicum) of the humerus.



The illustration shows identification of the biceps tendon, a useful landmark.

Reduction

- Anatomical reduction of the fracture under fluoroscopy.

Plate Selection

- Select the appropriate plate type and length/size *(see p. 28)*

NOTE: The PHL PHX Standard is available in 4-, 7-, or 10-hole lengths (5-hole plate available as optional).

For the PHL Phoenix, use the flange arrangement that best stabilizes the fracture pattern. The extended superior hooked plate is ideal for displaced or retracted tuberculum majus fragments and the anterior flange is indicated for tuberculum minus fragments for capture and fixation.

TIP: The flanges of the PHL Phoenix Flanges plates are contourable in situ, so that some adjustment is possible after the application. All three flanges enable the plate to cradle and support the humeral head without relying solely a screw fixation.

ATTENTION: The type of plate used will vary with the indications, i.e. for simple fractures, the PHL Standard Phoenix should be used, while the PHL Phoenix Flanges can be used to treat more complex cases. For severe cases with a greater tuberosity fragment the plate with the superior hook will be required.

Plate Insertion

- Insert the plate through the prepared incision.
- Keep plate in constant contact with the bone and slide distally.
- Align the proximal end of the plate on the tuberculum majus.
- Verify the correct plate position.

ATTENTION: Take care to avoid injuring the axillary nerve when inserting the plate.

TIP: A temporary plate holder *(58164-150)* can be inserted into any plate hole for temporary fixation. Additionally, K-wires can be placed through the marginal proximal holes.

Alternate open insertion (for PHL Phoenix Flanges)

- Apply the plate to reduced fracture.
- Keep the plate in central with the bone and center the humeral head inside the flanges of the plate: This prevents coronal translational malreduction of the head.
- Additionally, after the hook is engaged at the tuberosity - cuff junction, the plate can be manually translated distally to ensure reduction of the tuberosity, impacting the hook and minimizing the risk of impignement.

PHL Phoenix Flanges

PHL Phoenix Standard

Temporary Fixation throught the Oblong hole

- Mobilize the tuberculum fragment and place running locked sutures of #2 nonabsorbable material.
- Use the sutures are used to pull the greater tuberculum fragment into place.

TIP: Additionally, manual pressure can be applied!

- For optimal alignment of the plate to the humeral bone, use the spiral drill D=2.7mm, L=100mm, AO Connector *(61273-100)* with drill guide to drill both cortices through the oblong hole in the shaft of the plate.
- Determine appropriate length using the depth gauge, solid small fragment screws *(59022)*.
- Insert the D=3.5mm cortical non-locking screw *(32351-XX)* with the screwdriver, WS 2.5 *(56252-150)*.

TIP: If the screw is not fully tightened at this point, the position of the plate can be adjusted if necessary.

- Finally, the stitches are fixed to the plate to improve the reduction of the tuberculum fragment.

PHL Phoenix Flanges

PHL Phoenix Standard

Screw Placement

- Following temporary fixation through the oblong hole, a proximal screw should be placed and subsequently checked under fluoroscopy.

NOTE: All round holes allow for the use of both locking or non-locking screws. A locking screw can be locked at a free placement within a cone of angulation up to ± 15°. If a wider angulation is desired, a non-locking screw can be used.

TIP: For the superior hook plate, insert a superior screw (non-locking) to compress the greater tuberculum fragment and secure the superior portion of the plate to the bone. Use the spiral drill *(suitable drills see page 36)* and drill through the drill guide, D=2.7/2.0mm *(62202)* into the superior plate hole. Determine appropriate length using the depth gauge, solid small fragment screws *(59022)*. Insert a D=3.5mm cortical screw *(3235I-XX)* with the screwdriver, WS 2.5 *(56252-I50)*.

TIP: The flanges of the Phoenix plates can be adjusted to fit the bone with the in situ contouring tool *(66261, 66262, 66263)*.

- The remaining screws are placed alternating proximal and distal, aiming to angle the proximal screws to maximize the capture of the entire humeral head.
- Control of plate position under fluoroscopy.

PHL Phoenix Flanges

PHL Phoenix Standard

PHL Phoenix - Flanges

Radiographs reveal placement of the implant. For clarity, only the most critical screws are shown, including the tuberosity, calcar, and oblong hole screws.

PHL Phoenix - Standard

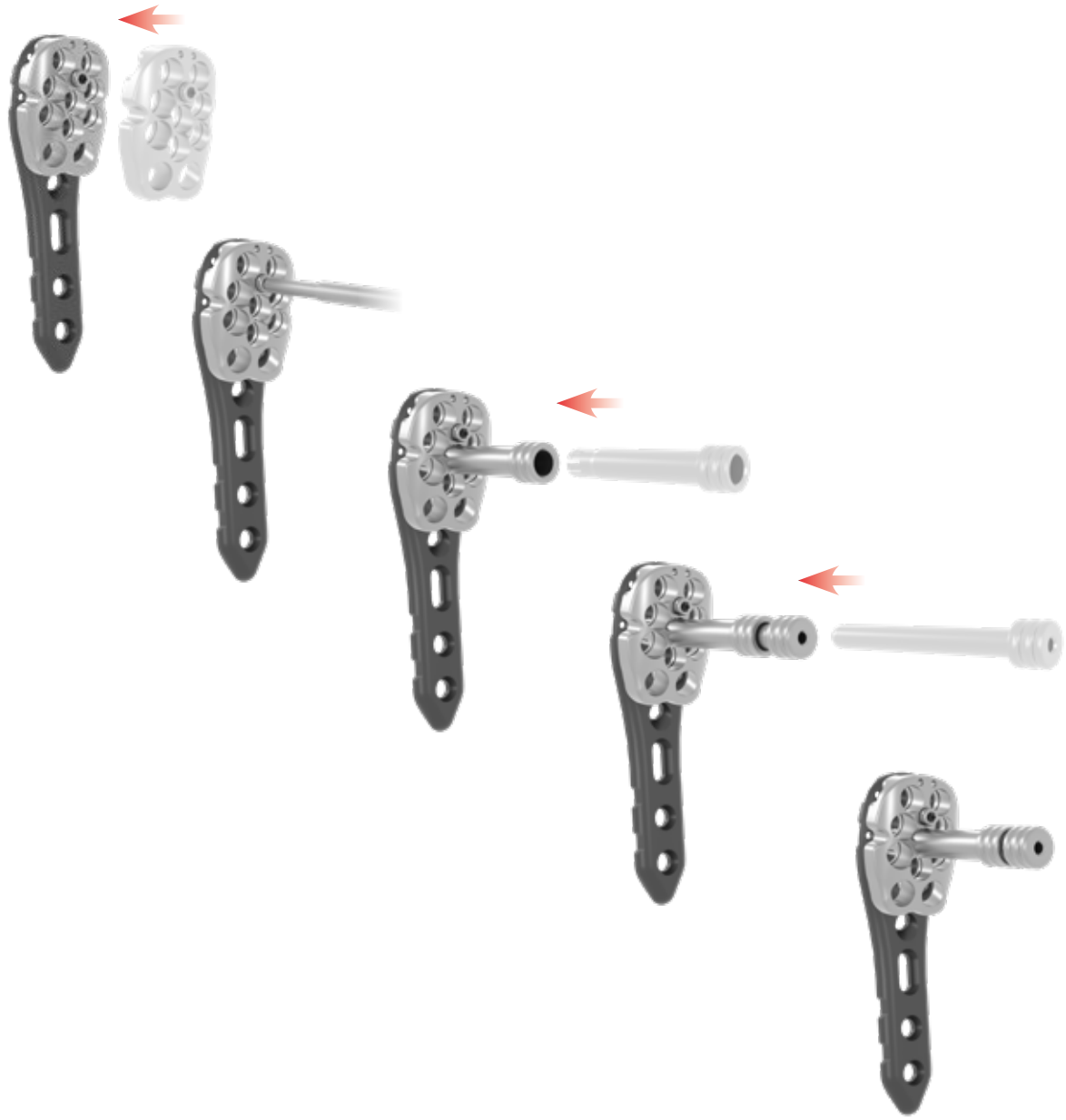
OPTIONAL: Drill Block Assembly

- The drill block is optionally attached to the plate before implantation. This can also be done during the procedure (in situ). The block is secured to the plate with the fixation screw *(62520-1)*.
- The tissue protection sleeve *(62520-2)* is fitted into any hole in the drilling block *(62520)*.

NOTE: The tissue protection sleeve must be inserted until an audible or tactile click is heard, indicating that it is correctly engaged.

- After this, the drill sleeve *(62520-3)* is inserted into the tissue protection sleeve.
- Once the drill sleeve has been positioned correctly, you can start drilling.

NOTE: If using the drilling block, measurement is only possible via the scaling of the drill.



OPTIONAL: Fixation of Soft Tissue

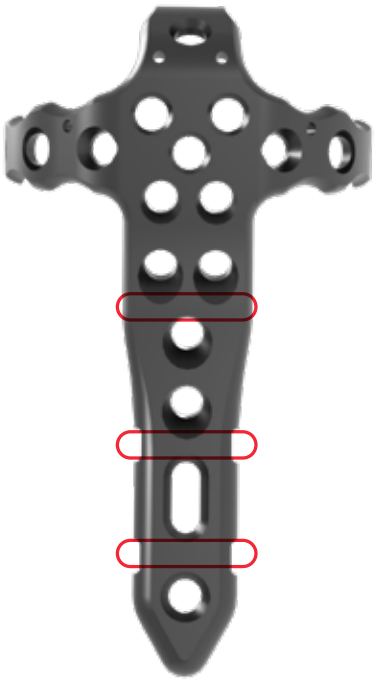
Soft tissue can be sutured to the marginal holes in the proximal area of the plate with special suture material (see picture below - RED marked).

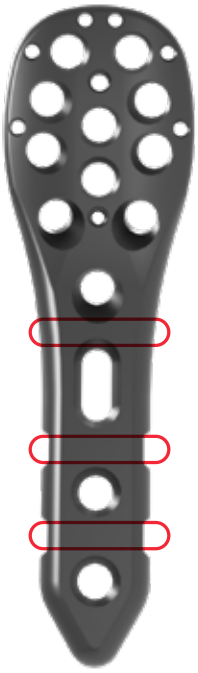
PHL Phoenix - Flanges

PHL Phoenix - Standard

OPTIONAL: Fixation in the shaft area with Cerclage

Millings in the shaft area of the plate facilitate the optional use of cerclage wire (see picture - marked RED).





Postoperative Treatment

As a rule, physical therapy immediately after surgery (passive motion exercices). Active motion exercices after 3-9 weeks. In case of poor bone quality or insecure fixation, immobilization for a maximum of 3 weeks.

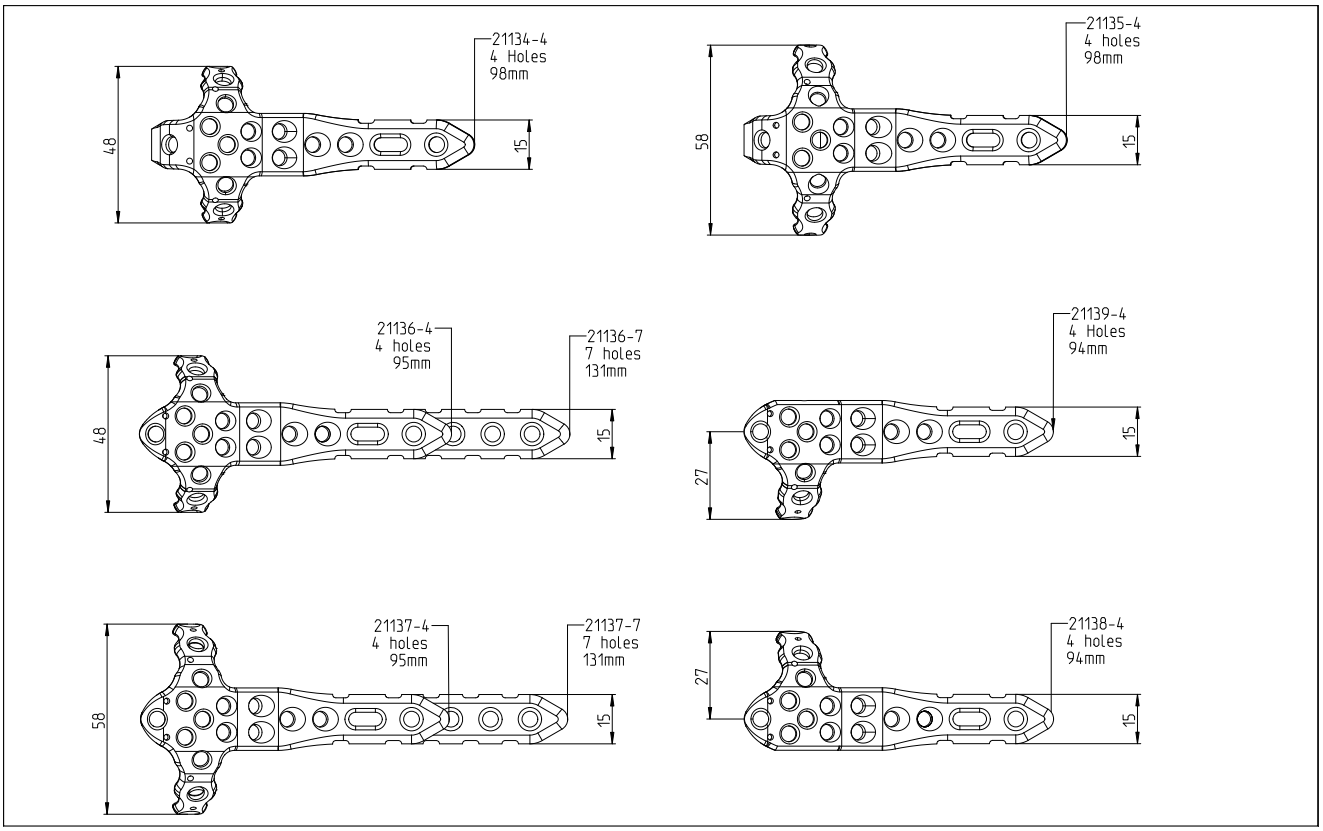
Explantation

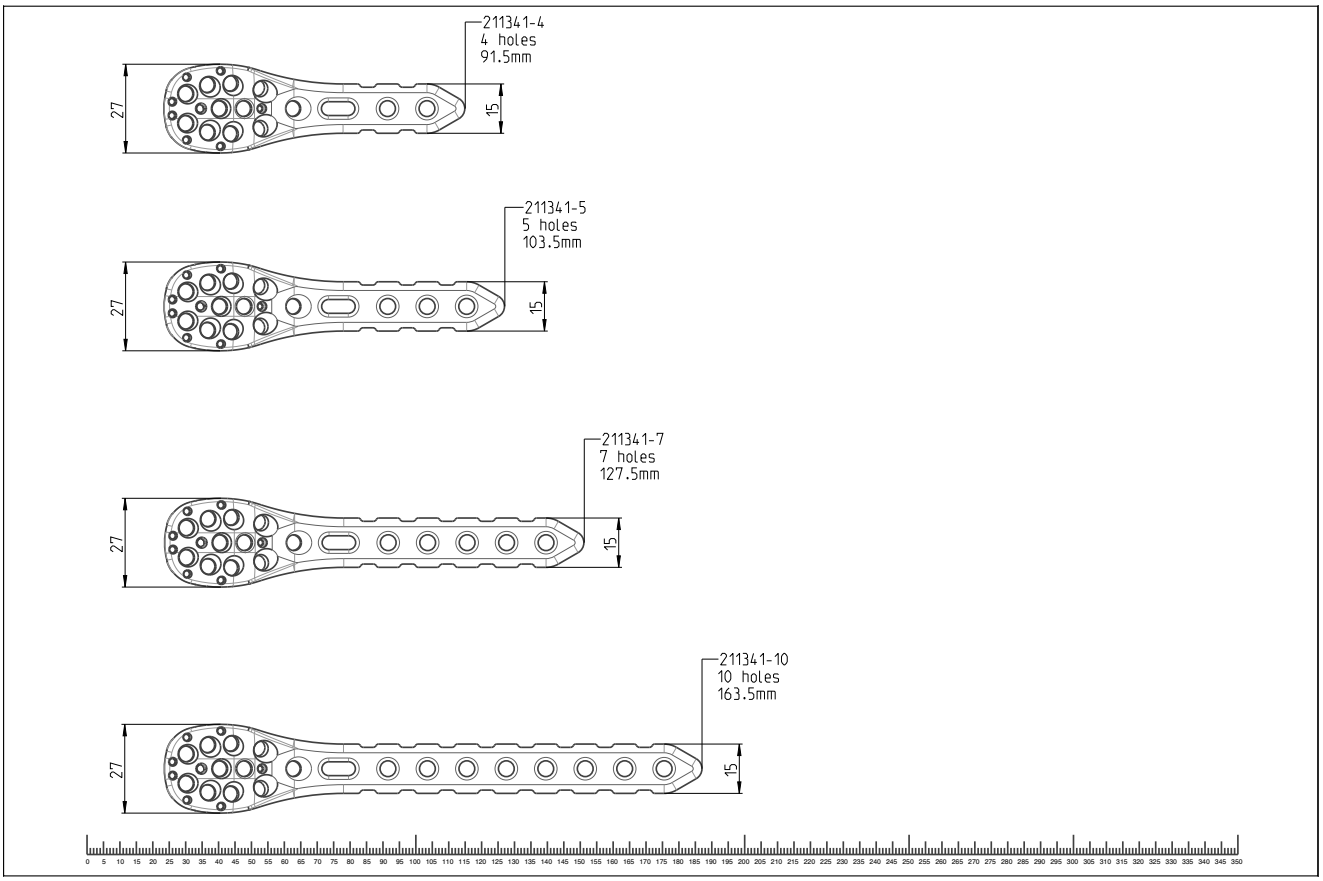
- Removal is possible, if desired by the patient. This is facilitated by the fact that cold welding never occurs. The problem of cold welding was resolved by using a special surface treatment *(for further information see page 29)*
- Implant removal is performed 18 months or after an fluoroscopy verification of the healed bone
- Vice versa of implantation
- Skin incision following the old scar
- Remove the screws with the screwdriver, WS 2.5 *(56252-150)*

Information

3.

Technical Information





For detailed cleaning and sterilization instructions, please refer to package insert.

Not true to scale

Type II Anodization

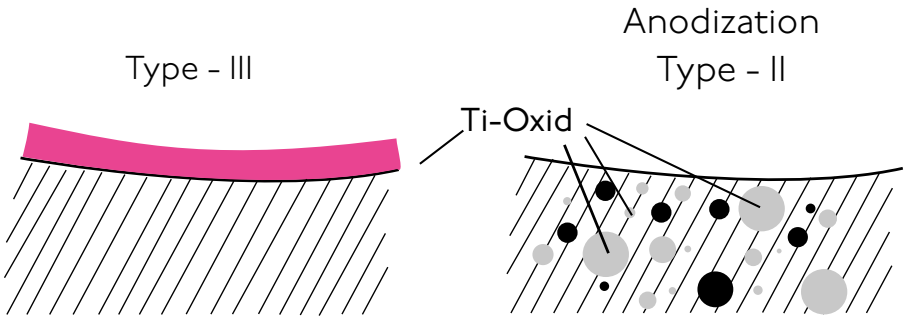
Chemical process - anodization in a strong alkaline solution*

Type III anodization

- Layer thickness 60-200nm
  - \+ Different colors
  - \- Implant surface remains sensitive to:
    Chipping
    Peeling
    Discoloration

Type II anodization

- Layer thickness 1000-2000nm
  - \+ Film becomes an interstitial part of the titanium
  - \- No visible cosmetic effect



Anodization Type II leads to following benefits*

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

* White Paper: Ti6Al4V with Anodization Type II: Biological Behavior and Biomechanical Effects; Axel Baumann, Nils Zander

Ordering Information

Proximal Humeral Phoenix - Flanges Plates

21134-4

21135-4

Description	Size	Holes	Article Number
Proximal Humeral Plate, SAP Flange	Small	4	21134-4
Proximal Humeral Plate, SAP Flange	Large	4	21135-4

21136-4

21136-7

21137-4

21137-7

Description	Size	Holes	Article Number
Proximal Humeral Plate, AP Flange	Small	4	21136-4
Proximal Humeral Plate, AP Flange	Large	7	21136-7
Proximal Humeral Plate, AP Flange	Small	4	21137-4
Proximal Humeral Plate, AP Flange	Large	7	21137-7

21138-4

21139-4

Description		Holes	Article Number
Proximal Humeral Plate, Flange	Right	4	21138-4
Proximal Humeral Plate, Flange	Left	4	21139-4

(Optional)

21134-5

21135-5

21136-5

21137-5

Description	Size	Holes	Article Number
Proximal Humeral Plate, SAP Flange	Small	5	21134-5
Proximal Humeral Plate, SAP Flange	Large	5	21135-5
Proximal Humeral Plate, AP Flange	Small	5	21136-5
Proximal Humeral Plate, AP Flange	Large	5	21137-5

21138-5

21139-5

Description		Holes	Article Number
Proximal Humeral Plate, Flange	Right	5	21138-5
Proximal Humeral Plate, Flange	Left	5	21139-5

Proximal Humeral Phoenix - Standard Plates

211341-4

211341-7

211341-10

Description	Holes	Article Number
Proximal Humeral Plate, Standard Phoenix	4	211341-4
Proximal Humeral Plate, Standard Phoenix	7	211341-7
Proximal Humeral Plate, Standard Phoenix	10	211341-10

(Optional)

211341-5

Description	Holes	Article Number
Proximal Humeral Plate, Standard Phoenix	5	211341-5

Screws

Cortical Screw, D=3.5mm	Length	Article Number
Locking	18	3735I-18-N
	20	3735I-20-N
	22	3735I-22-N
	24	3735I-24-N
	26	3735I-26-N
	28	3735I-28-N
	30	3735I-30-N
	32	3735I-32-N
	34	3735I-34-N
	36	3735I-36-N
	38	3735I-38-N
	40	3735I-40-N

Cancellous Screw, D=4.2mm	Length	Article Number
Locking	24	37422-24-N
	26	37422-26-N
	28	37422-28-N
	30	37422-30-N
	32	37422-32-N
	34	37422-34-N
	36	37422-36-N
	38	37422-38-N
	40	37422-40-N
	42	37422-42-N
	44	37422-44-N
	46	37422-46-N
	48	37422-48-N
	50	37422-50-N
	55	37422-55-N
	60	37422-60-N

Cortical Screw, D=3.5mm	Length	Article Number
Non-Locking	18	3235I-18
	20	3235I-20
	22	3235I-22
	24	3235I-24
	26	3235I-26
	28	3235I-28
	30	3235I-30
	32	3235I-32
	34	3235I-34
	36	3235I-36
	38	3235I-38
	40	3235I-40
	42	3235I-42
	44	3235I-44
	46	3235I-46
	48	3235I-48
	50	3235I-50
	55	3235I-55
	60	3235I-60

Instruments

Guide Wire

35162-150

35164-150

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=150mm, TR, RD	35162-150
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thread	35164-150

(Optional) Plate Holder

58164-150

Description	Article Numer
Temporary Plate Holder, For 3.5/4.2mm Screws	58164-150

Depth Gauge

59022

Description	Article Number
Depth Gauge, Solid Small Fragement Screws	59022

Spiral Drill

61253-180

61254-220

61273-100

61273-180

61274-220

Description	Article Number
Spiral Drill, D=2.5mm, L=180mm, AO-Connector D=2.5mm	61253-180
Spiral Drill, PRS Phoenix, D=2.5mm, L=220mm, AO Connector	61254-220
Spiral Drill, D=3.5mm, L=110mm, AO Connector D=2.7mm	61273-100
Spiral Drill, D=2.7mm, L=180mm, AO Connector D=2.7mm	61273-180
Spiral Drill, PRS Phoenix, D=2.7mm, L=220mm, AO Connector	61274-220

Drill Guide

62202

62223

Description	Article Number
Drill Guide, D=2.0/2.7mm	62202
Drill Guide, D=2.5/2.7mm, Centered	62223

Screwdriver

56252-150

SW 2.5

Description	Article Number
Screwdriver, SW 2.5, Conical Head	56252-150

Hexagon-Shank

KM 48-348 SW 2.5

Description	Article Number
Hexagon-Shank, WS 2.5,L=135mm, AO Connector	KM 48-348

Bending Irons

66261

66262

66263

Description	Article Number
In-Situ Bending Iron, D=4.8mm, Straight	66261
In-Situ Bending Iron, D=4.8mm, Oblique	66262
In-Situ Bending Iron, D=4.8mm, 90°	66263

Drill Block - Proximal Humerus Phoenix Standard

62520

62520-1

62520-2

62520-3

Description	Article Number
Drill Block, Proximal Humerus Plate Standard	62520
Fixing Screw, Drill Block, Proximal Humerus Plate Standard	62520-1
Tissue Protection Sleeve, Drill Block, Proximale Humerus Plate Standard	62520-2
Drill Sleeve, Drill Block, Proximale Humerus Plate Standard	62520-3

Disclaimer:

The intended users are limited to medical personnel with appropriate product training by the medical product consultants or knowledge of the surgical procedure to be applied. The medical staff must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the medical condition and medical history of the patient. Prior to product use, medical personnel must refer to complete information on product label and in IFU, including, but not limited to, indications, contraindications, warnings and preventative measures, and cleaning and sterilization instructions. Product availability is dependent on country registrations and clearances. For more information, please visit www.its-implant.com or contact us at office@its-implant.com. Unless otherwise noted, all information herein is the intellectual property of I.T.S. GmbH.

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