

ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Clavicle Locking Plates System

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.



STOCK

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.

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Introduction

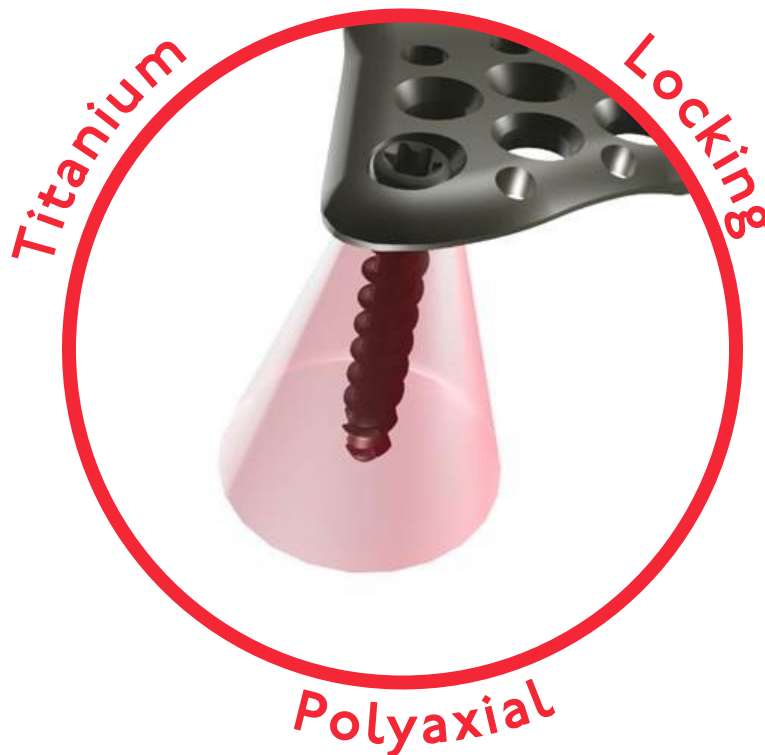


○ Plate Technology

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.

○NE 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 $\pm 15^\circ$ and can be re-positioned up to three times.

○ System Overview

The ITS. Clavicle family is a proven osteosynthesis system for various fractures of the clavicle. With this technology, an anatomical reduction is achieved and fixed until healing. The short immobilization time ensures rapid rehabilitation and early functionality.

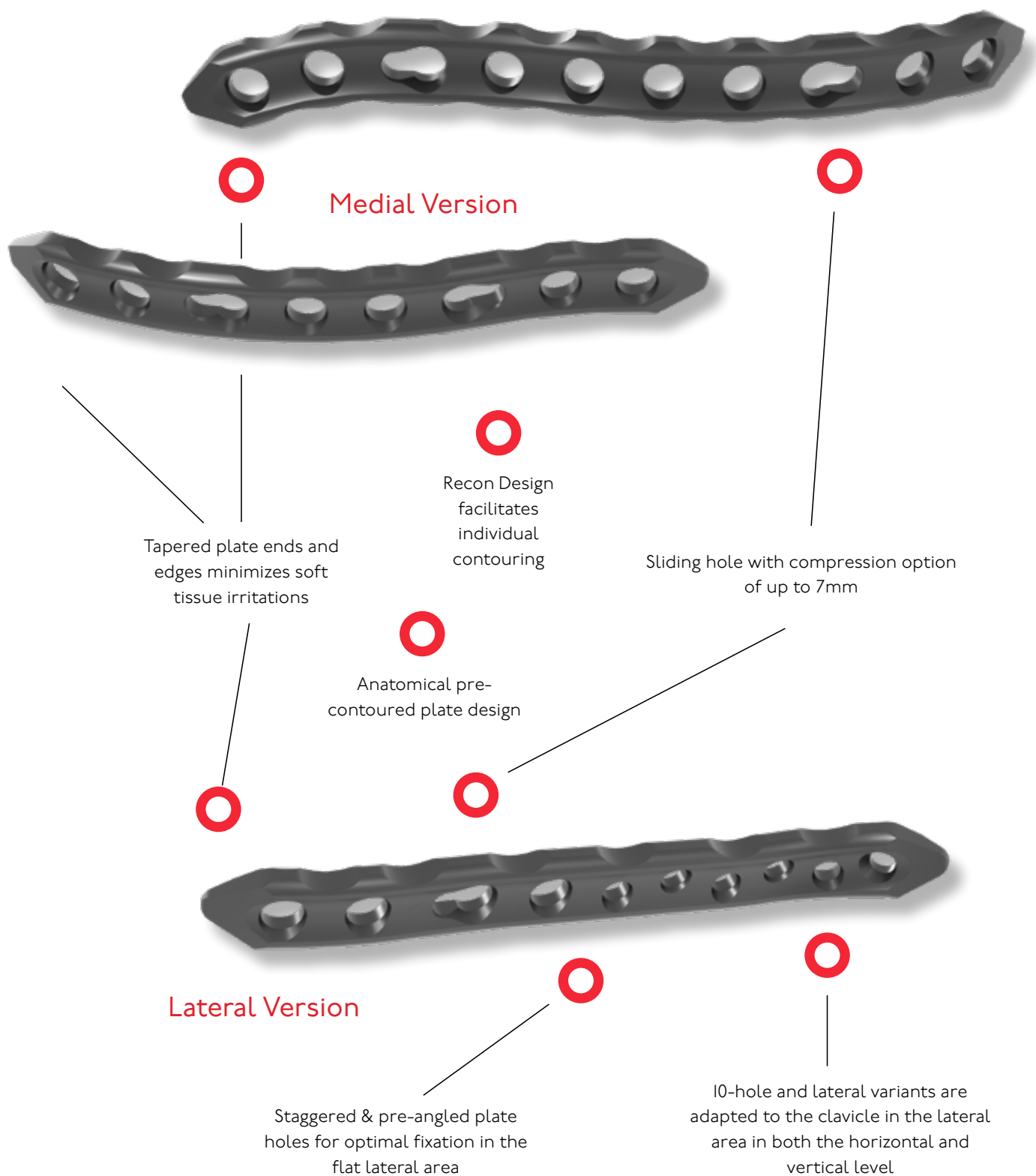
Both a superior and an anterior system are offered, each with anatomically shaped medial and lateral plates.

Although all plates are anatomically pre-contoured, they can be further contoured intraoperatively, to achieve the best anatomical fit for each individual patient.

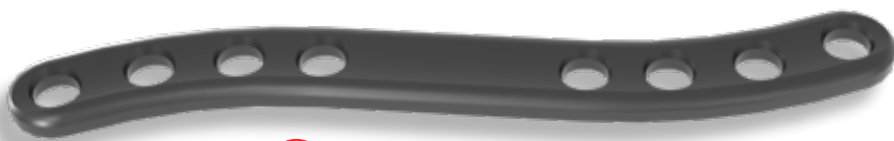


○ Properties

Anterior Clavicle Plates



Superior Clavicle Plates



Medial Clavicle Plate:

- Anatomical plate design
- Turn 180° for right and left versions
- Bridging middle section for additional strength



Lateral Clavicle Plates:



- Anatomical plate design
- Left & Right version
- Wide lateral section for holding several screws
- Pointed medial plate end for percutaneous insertion (long plate)



Lateral Clavicle Plate (Narrow):

- Anatomical plate design
- Lateral 25% narrower
- Waisted shape
- 8-Holes in the lateral section

○ Screws

37303-xx

LOCKING

Cancellous Stabilization Screw,
D=3.0mm
Spiral Drill, D=2.7mm
Torque, T9



32271-xx

NON-LOCKING

Cortical Screw, D=2.7mm
Spiral Drill, D=2.0mm
Torque, T9



37351-xx-N

LOCKING

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



32351-xx

NON-LOCKING

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



37351-xx-N

LOCKING

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



32351-xx

NON-LOCKING

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5



37303-xx**LOCKING**

Cancellous Stabilization Screw,
D=3.0mm
Spiral Drill, D=2.0mm
Torque, T9

**32271-xx****NON-LOCKING**

Cortical Screw, D=2.7mm
Spiral Drill, D=2.0mm
Torque, T9

**37351-xx-N****LOCKING**

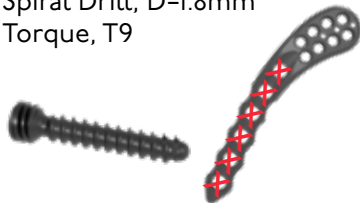
Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

**32351-xx****NON-LOCKING**

Cortical Screw, D=3.5mm
Spiral Drill, D=2.7mm
WS 2.5

**OPTIONAL****37241-xx****LOCKING**

Stabilization Screw, D=2.4mm
Spiral Drill, D=1.8mm
Torque, T9

**37304-xx****LOCKING**

Cortical Stabilization Screw,
D=3.0mm
Spiral Drill, D=2.4mm
Torque, T9



○ Indications

- All fractures of the clavicle in metaphyseal and diaphyseal areas
- Fixation of non-unions with or without cancellous graft
- Corrective osteotomy
- Open and closed fractures

○ Contraindications

- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis

○ Time of Operation

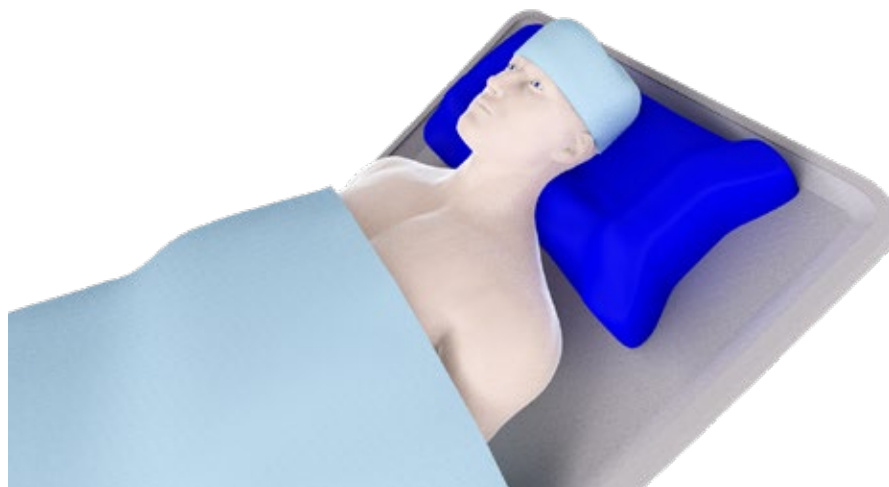
- Immediately after trauma or delayed
- After regression of swelling

Surgical Technique

2.

○ Pre-operative Patient Preparation

- Elevated upper body approx. 30° - 40° inclination, shoulder freely movable (optional shoulder-table).
- The arm should be freely movable to have the possibility of fracture reduction
- General anaesthesia, regional anaesthesia or a combination can be used
- Possible use of medication for blood arrest



○ Access

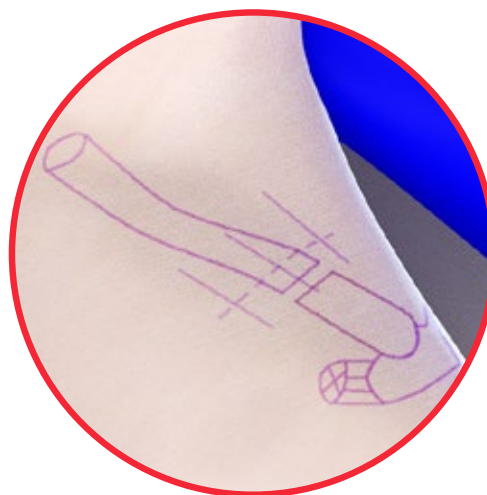
Outline the fracture and draw incision line on the skin. A horizontal dashed line marks the place for the skin incision. Vertical marks show the position for a tension free suture.

The incision should be made 1-2cm away from the fracture line to avoid placement of the suture directly over the plate.

Medial



Lateral



Anterior Clavicle Locking Plates

○ Exposure

Transverse approach (medial nach lateral):

- Transverse incision parallel to the long axis of the clavicle.

Anterosuperior approach (sabre-cut incision):

- Make a half-moon shaped incision over the middle of the clavicle with short dorsal branch.

○ Reduction

- Temporary fixation of the fracture parts using forceps
- Seek compression of the fracture
- Subsequent control under fluoroscopy

○ Plate Insertion

The following surgical steps are demonstrated using the Anteriore Clavicle Plate Medial and generally apply to other plates as well.

For details on screw, drill bit, and screwdriver allocation, *see the screw overview p. 12-13.*

Insert the plate from lateral to medial under a bone holding forceps and additionally fix in place with two clamps.

Subsequent control of the exact plate position under fluoroscopy.

○ OPTIONAL: Temporary Plate Fixation

Optionally, the plate can be stabilized using the Temporary Plate Holder (58164-150).



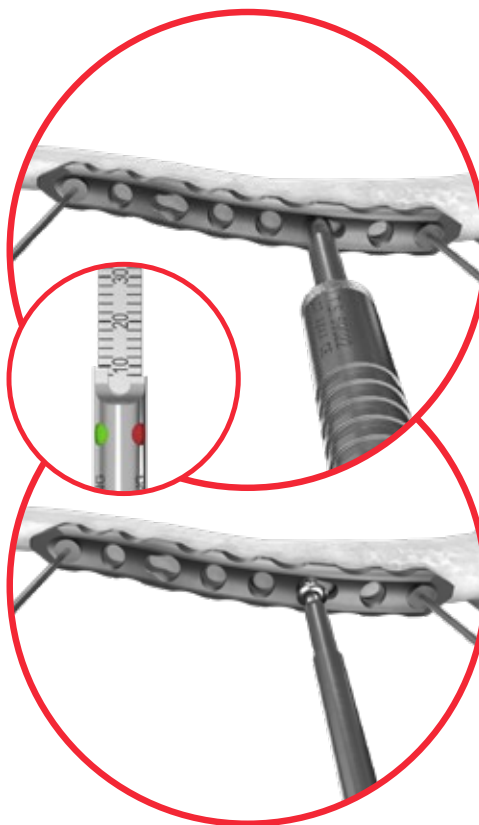
○ Screw Placement

- Use the drill guide, D=2.0/2.7mm (62202) to bore holes with the spiral drill D=2.7mm, L=100mm, AO Connector (61273-100) into the narrow area of the compression hole.

NOTE: It is recommend to drill oscillating, to avoid injuries of the artery subclavia and/or the brachial plexus. Do not use locking screws close to the fracture.

TIP: Angled drill holes avoid cortical bone giving way in the case of any fissures (fracture ridges).

- According to the measured length using the screw gauge, solid small fragment screws (59022) insert the D=3.5mm cortical screw (3235I-XX) with the screwdriver, WS 2.5, self-holding sleeve (56252).



If compression should be achieved, a D=3.5mm cortical screw has to be inserted in the narrow area of the compression hole.

IMPORTANT: A compression up to 3.5mm can be achieved per each compression hole.



- The remaining plate holes are then drilled using the appropriate drill from the previous step or according to the overview, *see p. 13*.

NOTE: It is recommended to drill oscillating, to avoid injuries of the artery subclavia and/or the brachial plexus. Do not use locking screws close to the fracture.



- According to the measured length using the screw gauge, solid small fragment screws (59022) either locking or non-locking cortical screws (3735I-XX-N / 3235I-XX) are used.

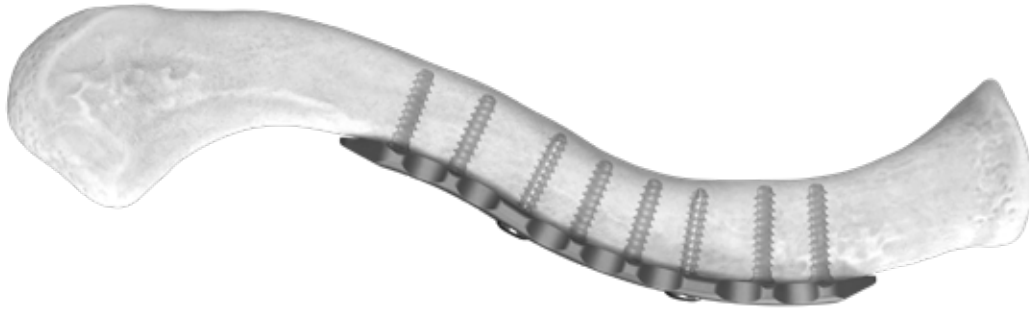


- Insert the screws with the screwdriver WS 2.5, with self-holding sleeve (56252).



- Subsequent control of the plate and screw position under fluoroscopy.

Anterior Clavicle Plate



Superior Clavicle Locking Plates

○ Exposure

Supraclavicular approach:

- Make a skin incision parallel to the clavicle in the supraclavicular fossa above the portion of the clavicle which is to be exposed.

Anterosuperior approach (sabre-cut incision):

- Make a half-moon shaped incision over the middle of the clavicle with short dorsal branch.

○ Reduction

- Temporary fixation of the fracture parts using forceps
- Seek compression of the fracture
- Subsequent control under fluoroscopy

Medial



Lateral



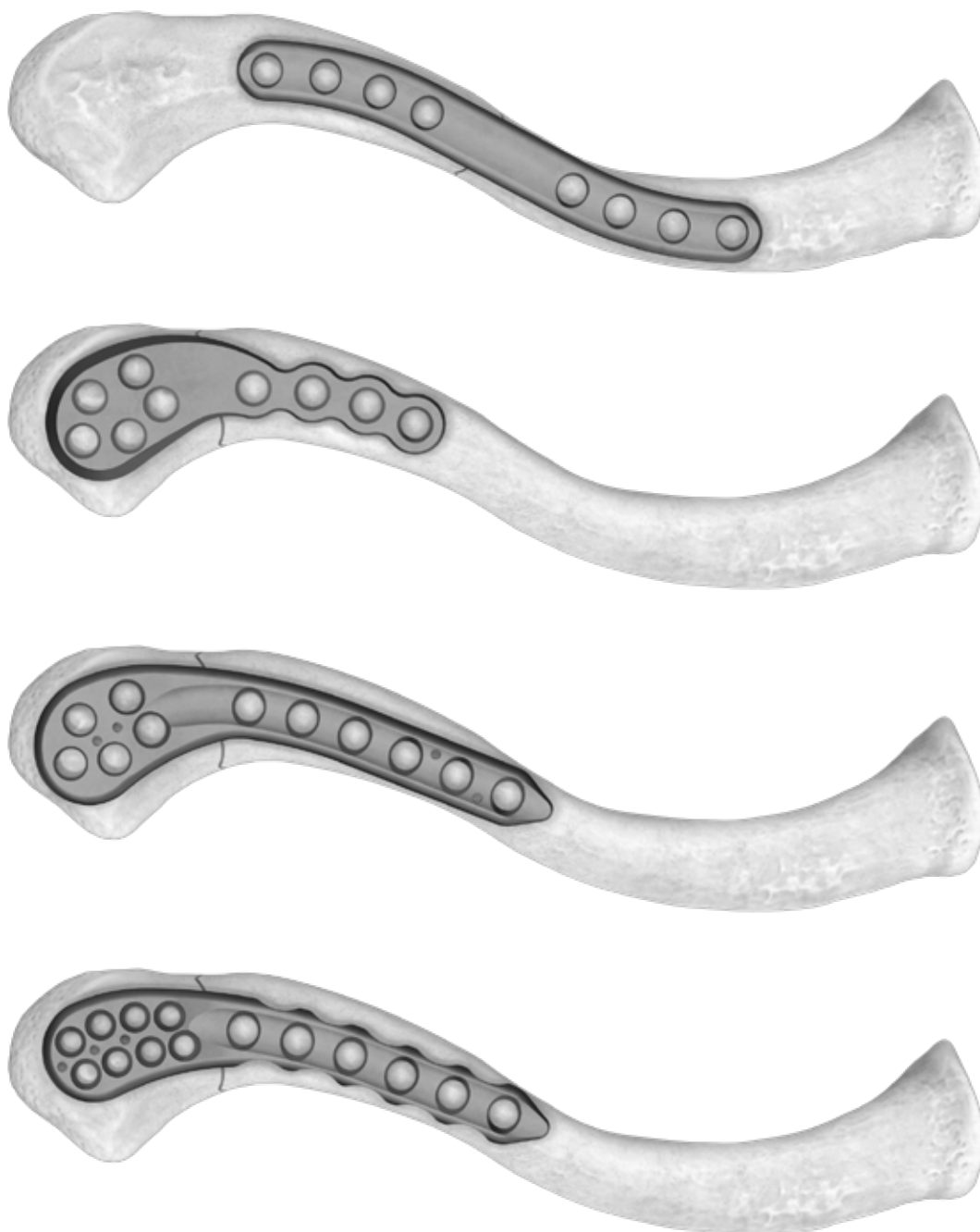
○ Plate Insertion

The following surgical steps are demonstrated using the Anteriore Clavicle Plate Medial and generally apply to other plates as well.

For details on screw, drill bit, and screwdriver allocation, see *the screw overview p. 12–13*.

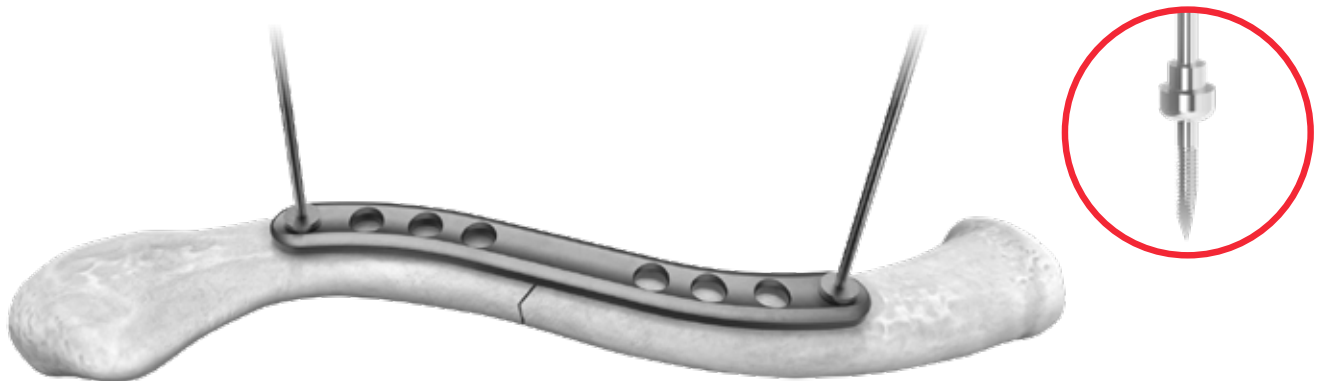
Insert the plate from lateral to medial under the bone holding forceps and additionally fix in place with two clamps.

Subsequent control of the exact plate position under fluoroscopy.



○ OPTIONAL: Temporary Plate Fixation

- Optionally, the plate can be stabilized using the Temporary Plate Holder (58164-150).



○ Screw Placement

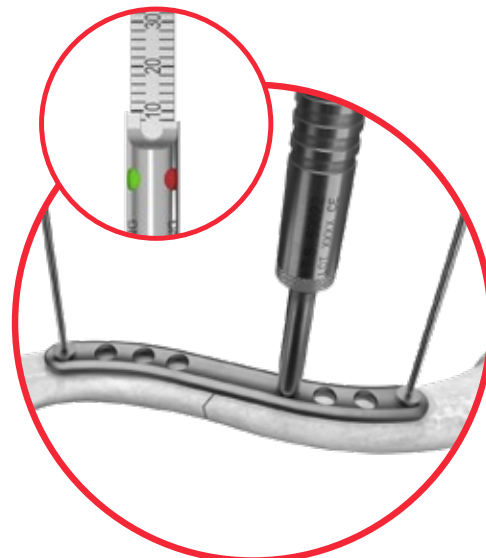
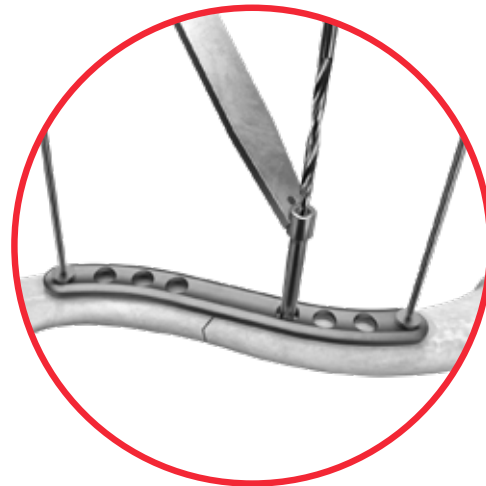
- Drill through the drill guide, D=2.7/2.0mm (62202), into the two plate holes close to the fracture using the spiral drill bit, D=2.7mm, L=100mm, AO-Connector (61273-100).

ATTENTION: To avoid disruption of soft tissue, nerves and/or blood vessels place a Hohmann retractor under the clavicle during drilling (or drill oscillating). It is recommended that locking screws are not used close to the fracture.

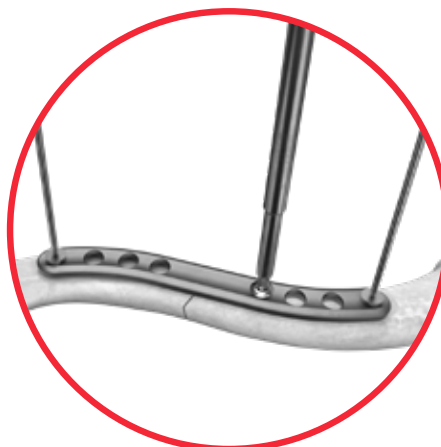
TIP: Angled drill holes avoid cortical bone giving way in the case of any fissures (fracture ridges).

- The screw length is determined using the depth gauge, solid small fragment screws (59022), to select a matching cortical screw D=3.5mm (32351-XX).

IMPORTANT: For the lateral narrow clavicle plate, the screw gauge PROlock II (59026) must be used in the head area – see article list p. 37.



- The selected screw is inserted using the screwdriver WS 2.5 with the self-holding sleeve (56252).



- Afterwards, the two adjacent plate holes are drilled with the spiral drill, D=2.7mm, L=100mm, AO-Connector (61273-100), using the drill guide, D=2.7/2.0mm (62202).



ATTENTION: To avoid disruption of soft tissue, nerves and/or blood vessels place a Hohmann retractor under the clavicle during drilling (or drill oscillating). It is recommended that locking screws are not used close to the fracture.

- The appropriate screw is now selected based on the length measured with the screw depth gauge, solid small fragment screw (59022), locking D=3.5mm cortical screw (3735I-XX-N) or non-locking D=3.5mm cancellous screw (3235I-XX).



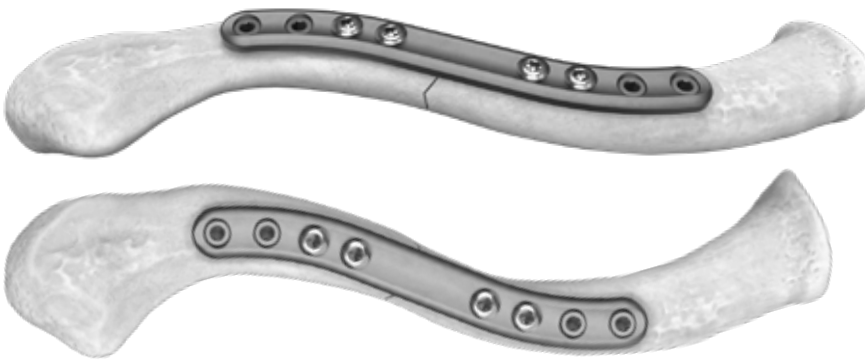
IMPORTANT: For the lateral narrow clavicle plate, the screw gauge PROlock II (59026) must be used in the head area – see article list p. 37.

- The selected screw is inserted using the screwdriver, WS 2.5, with self-holding sleeve (56252).

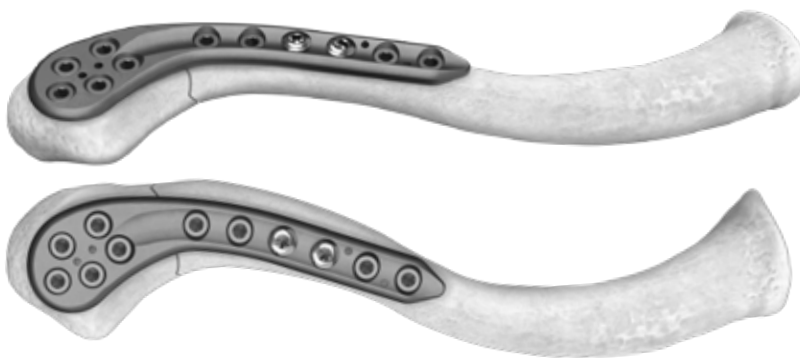


- Subsequent control of the plate and screw position under fluoroscopy.

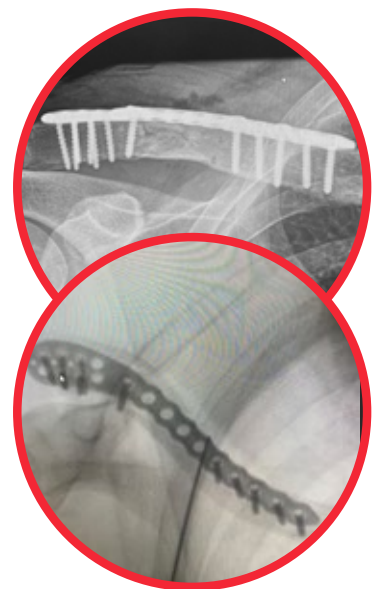
Superior Clavicle Plate Medial



Superior Clavicle Plate Lateral



Superior Clavicle Plate Lateral Narrow



○ Postoperative Treatment

- Shoulder-arm dressing until wound healing (approx. 2 weeks)
- Physical therapy
- Full exertion after fracture healing (approx. 5-7 weeks)

○ Explantation

Anterior & Superior Clavicle Plate

If desired by the patient, the implant can be removed.

Removal should be performed at the earliest 1 1/2 years later or after radiographic verification of the healed bone.

Clavicle Hook Plate

Explantation of the clavicle hook plate is necessary in any case due to the fact that the hook lies flush on the inferior part of the acromion.

ATTENTION: In order to prevent potential irritation of the acromion or impingement of the rotator-cuff the plate must be explanted.

The explantation should be performed after radiologically verified bone healing (not later than approx. 12 weeks).

The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants (*for more information, see p. 29*).

Information

3.

Technical Information



○ Type II Anodization

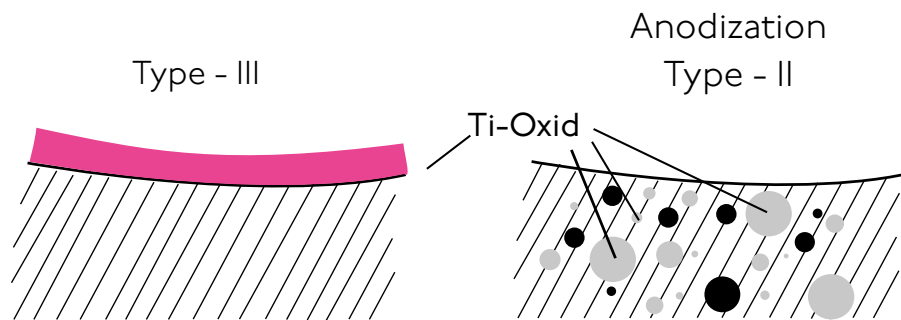
Chemical process - anodization in a strong alkaline solution*

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

Anterior Clavicle Plate



2III6-8



2III7-10



2III8-10

Description		Holes	Article Number
Anterior Clavicle Plate, Medial	Left & Right	8	2III6-8
Anterior Clavicle Plate, Medial	Left	10	2III7-10
Anterior Clavicle Plate, Medial	Right	10	2III8-10



2III9-4



2II20-4



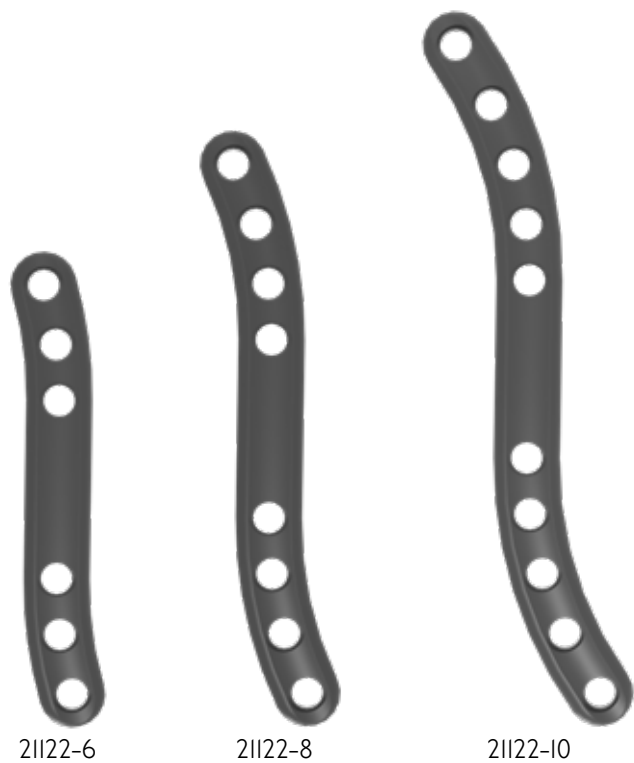
2III9-6



2II20-6

Description		Size	Holes	Article Number
Anterior Clavicle Plate, Lateral	Left		4	2II20-4
Anterior Clavicle Plate, Lateral	Right		4	2III9-4
Anterior Clavicle Plate, Lateral	Left		6	2II20-6
Anterior Clavicle Plate, Lateral	Right		6	2III9-6

Superior Clavicle Plate, Medial 3.5mm



Description	Holes	Article Number
Clavicle Plate, Medial, 3.5mm	6	21122-6
Clavicle Plate, Medial, 3.5mm	8	21122-8
Clavicle Plate, Medial, 3.5mm	10	21122-10

(Optional)



Description	Holes	Article Number
Clavicle Plate, Medial, 3.5mm	12	21122-12

Superior Clavicle Plate, Lateral

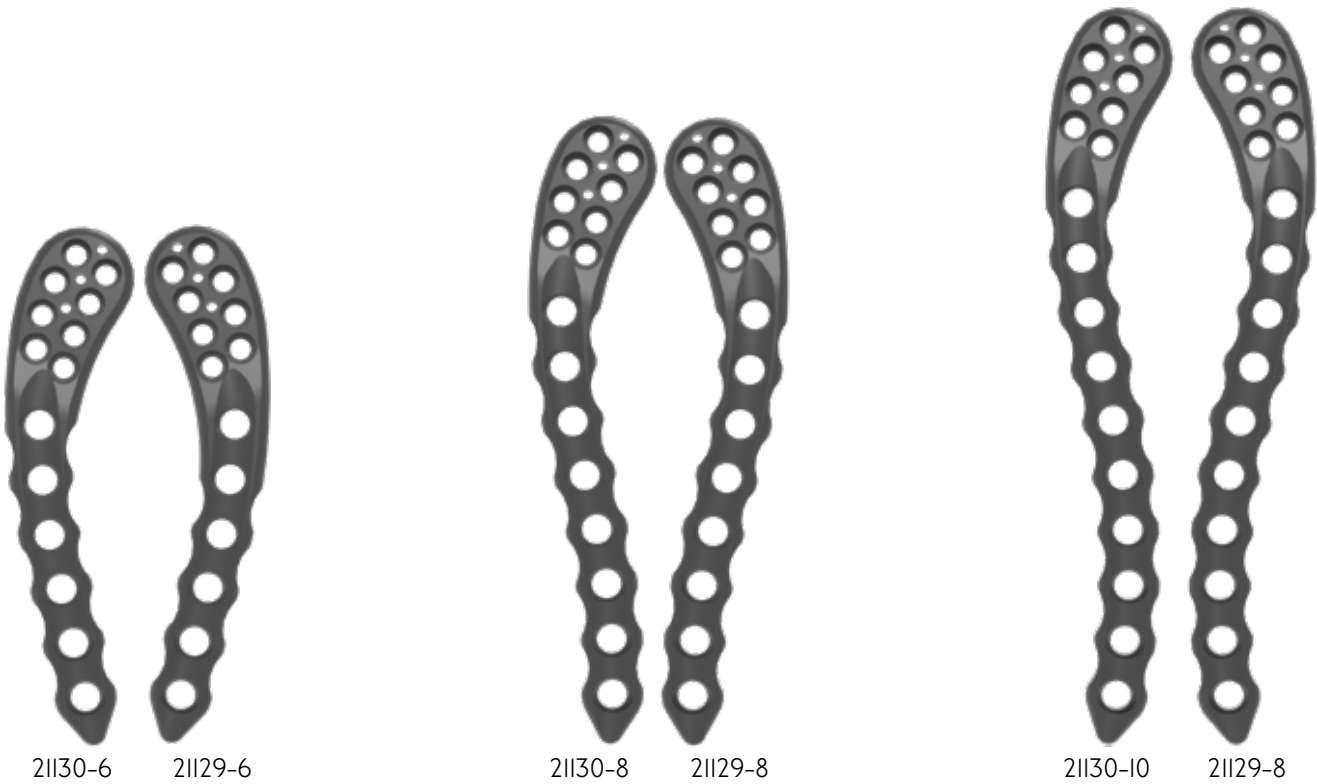


Description		Holes	Article Number
Clavicle Plate, Lateral	Left	4	21124-4
Clavicle Plate, Lateral	Right	4	21123-4




Description		Holes	Article Number
Clavicle Plate, Lateral	Left	6	21128-6
Clavicle Plate, Lateral	Right	6	21127-6


Superior Clavicle Plate, Narrow





Description		Holes	Article Number
Clavicle Plate, Lateral, Narrow	Left	6	21130-6
Clavicle Plate, Lateral, Narrow	Right	6	21129-6
Clavicle Plate, Lateral, Narrow	Left	8	21130-8
Clavicle Plate, Lateral, Narrow	Right	8	21129-8
Clavicle Plate, Lateral, Narrow	Left	10	21130-10
Clavicle Plate, Lateral, Narrow	Right	10	21129-10

Screws


Cancellous Sta- bilization Screw, D=3.0mm	Length	Article Number
	10	37303-10
	12	37303-12
	14	37303-14
	16	37303-16
	18	37303-18
	20	37303-20
	22	37303-22
	24	37303-24
	26	37303-26
	28	37303-28
	30	37303-30


Cortical Screw, D=3.5mm	Length	Article Number
	10	37351-10-N
	12	37351-12-N
	14	37351-14-N
	16	37351-16-N
	18	37351-18-N
	20	37351-20-N
	22	37351-22-N
	24	37351-24-N
	26	37351-26-N
	28	37351-28-N
	30	37351-30-N


Cortical Screw, D=2.7mm	Length	Article Number
	10	32271-10
	12	32271-12
	14	32271-14
	16	32271-16
	18	32271-18
	20	32271-20
	22	32271-22
	24	32271-24
	26	32271-26
	28	32271-28
	30	32271-30

Cortical Screw, D=3.5mm	Length	Article Number
	10	32351-10
	12	32351-12
	14	32351-14
	16	32351-16
	18	32351-18
	20	32351-20
	22	32351-22
	24	32351-24
	26	32351-26
	28	32351-28
	30	32351-30

(Optional)

Stabilization Screw, D=2.4mm	Length	Article Number
	10	3724I-10
	11	3724I-11
	12	3724I-12
	14	3724I-14
	16	3724I-16
	18	3724I-18
	20	3724I-20
	22	3724I-22
	24	3724I-24
	26	3724I-26
	28	3724I-28
	30	3724I-30

Cortical Stabilization Screw, D=3.0mm	Length	Article Number
	10	37304-10
	12	37304-12
	14	37304-14
	16	37304-16
	18	37304-18
	20	37304-20
	22	37304-22
	24	37304-24
	26	37304-26
	28	37304-28
	30	37304-30

Cancellous Screw, D=4.2mm	Length	Article Number
	10	37422-10-N
	12	37422-12-N
	14	37422-14-N
	16	37422-16-N
	18	37422-18-N
	20	37422-20-N
	22	37422-22-N
	24	37422-24-N
	26	37422-26-N
	28	37422-28-N
	30	37422-30-N

Instruments

Guide Wire



35I62-I50



35I64-I50

Description	Article Number
Guide Wire, Steel, D=1.6mm, L=150mm, TR, RD	35I62-I50
Guide Wire, Steel, D=1.6mm, L=150mm, TR, w. Thread	35I64-I50

(Optional) Plate Holder



58I64-I50

Description	Article Numer
Temporary Plate Holder, For 3.5/4.2mm Screws	58I64-I50

Spiral Drill



6I203-I00



6I273-I00

Description	Article Number
Spiral Drill, D=2.0mm, L=100mm, AO-Connector	6I203-I00
Spiral Drill, D=2.7mm, L=100mm, AO-Connector	6I273-I00

Drill Guide



62202



62215

Description	Article Number
Drill Guide, D=2.0/2.7mm	62202
Drill Guide, D=2.0/2.4mm	62215

Depth Gauge



59022



59026

Description	Article Number
Depth Gauge, Solid Small Fragment Screws	59022
Depth Gauge, PROlock II	59026

Screwdriver



56095-70



T9



56252



WS 2.5

Description	Article Number
Screw Driver, Torque, T9x70	56095-70
Screwdriver, WS 2.5, Self Holding Sleeve	56252

AO-Silicone Handle



53016

Description	Article Number
AO Silicone Handle	53016

Torque-Shank



54095-I00



T9

Description	Article Number
Torque-Shank, T9xI00, AO-Connector	54095-I00

Hexagon-Shank



KM 48-348  WS 2.5

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

Bending Irons



KJ.207.14

Description	Article Number
Bending Irons, 14cm, 3.5mm and 2.7mm	KJ.207.14

(Optional)



61183-100



61243-100



61353-110

Description	Article Number
Spiral Drill, D=1.8mm, L=100mm, AO-Connector	61183-100
Spiral Drill, D=2.4mm, L=100mm, AO-Connector	61243-100
Spiral Drill, D=3.5mm, L=110mm, AO-Connector	61353-110

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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