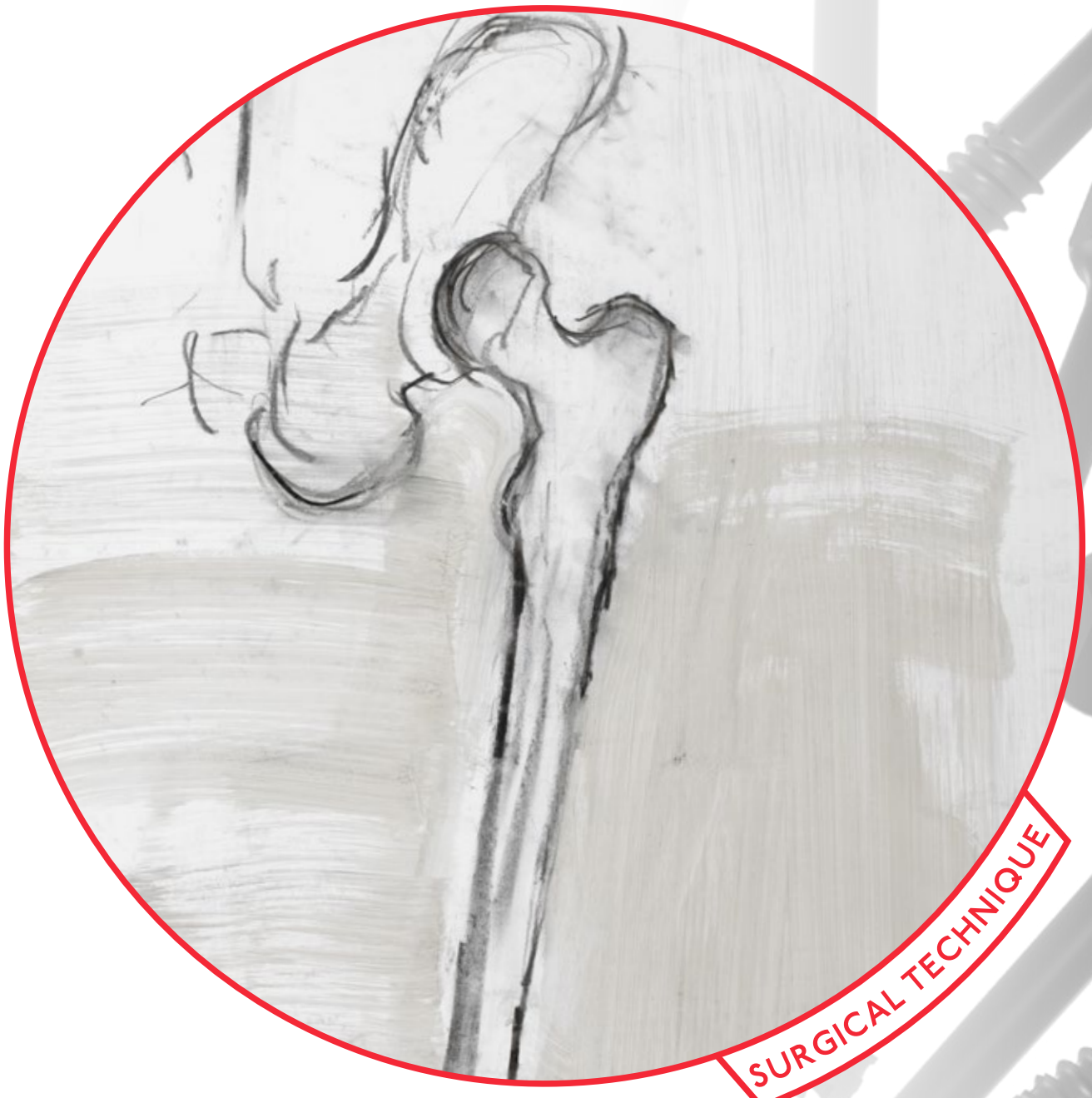
ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Epiphysis Screw

ITS.
Implants for Trauma Surgery

THE ART of TRAUMA SURGERY

The Art of Trauma Surgery is a collaborative project between ITS. 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 ITS. 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.

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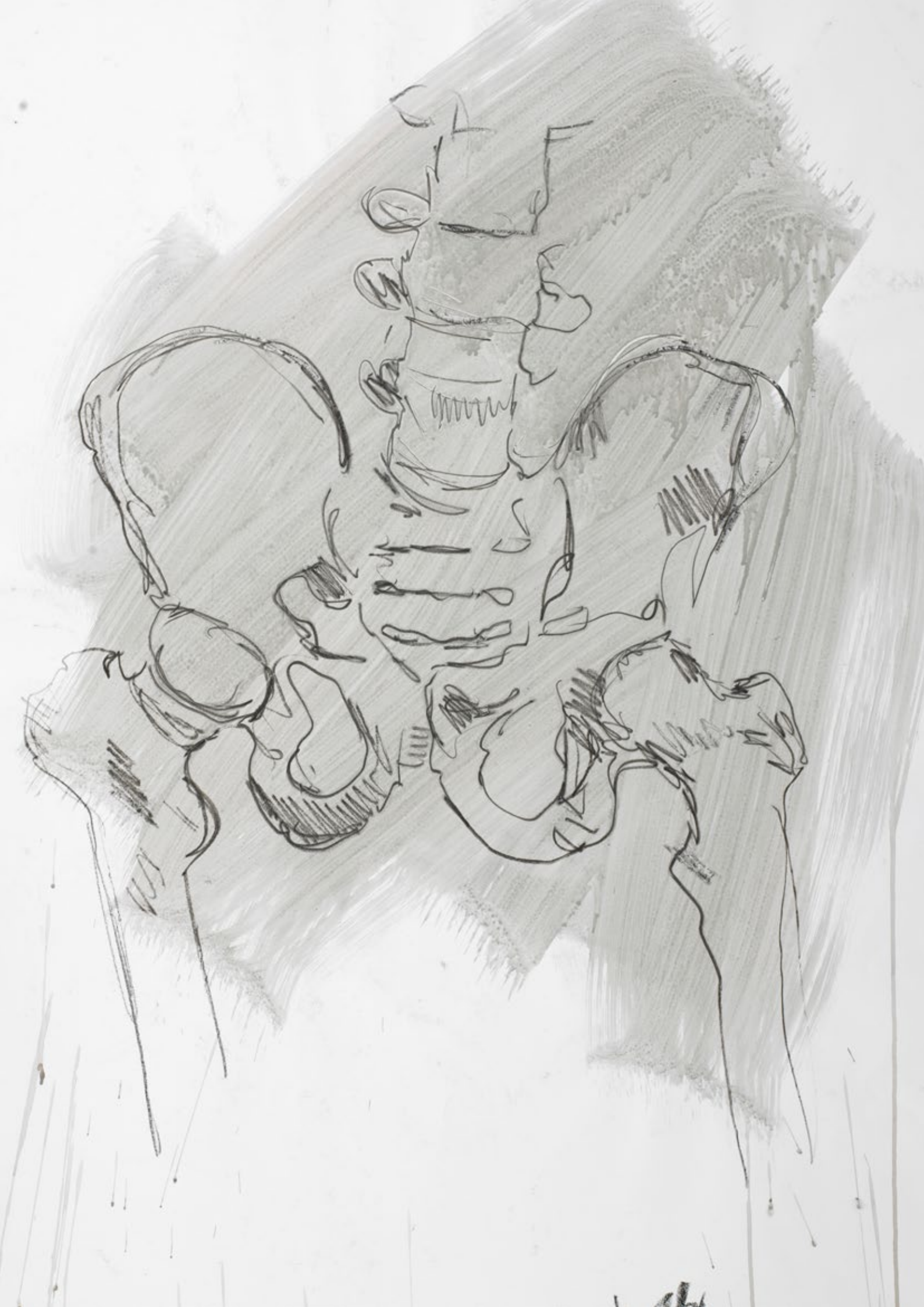


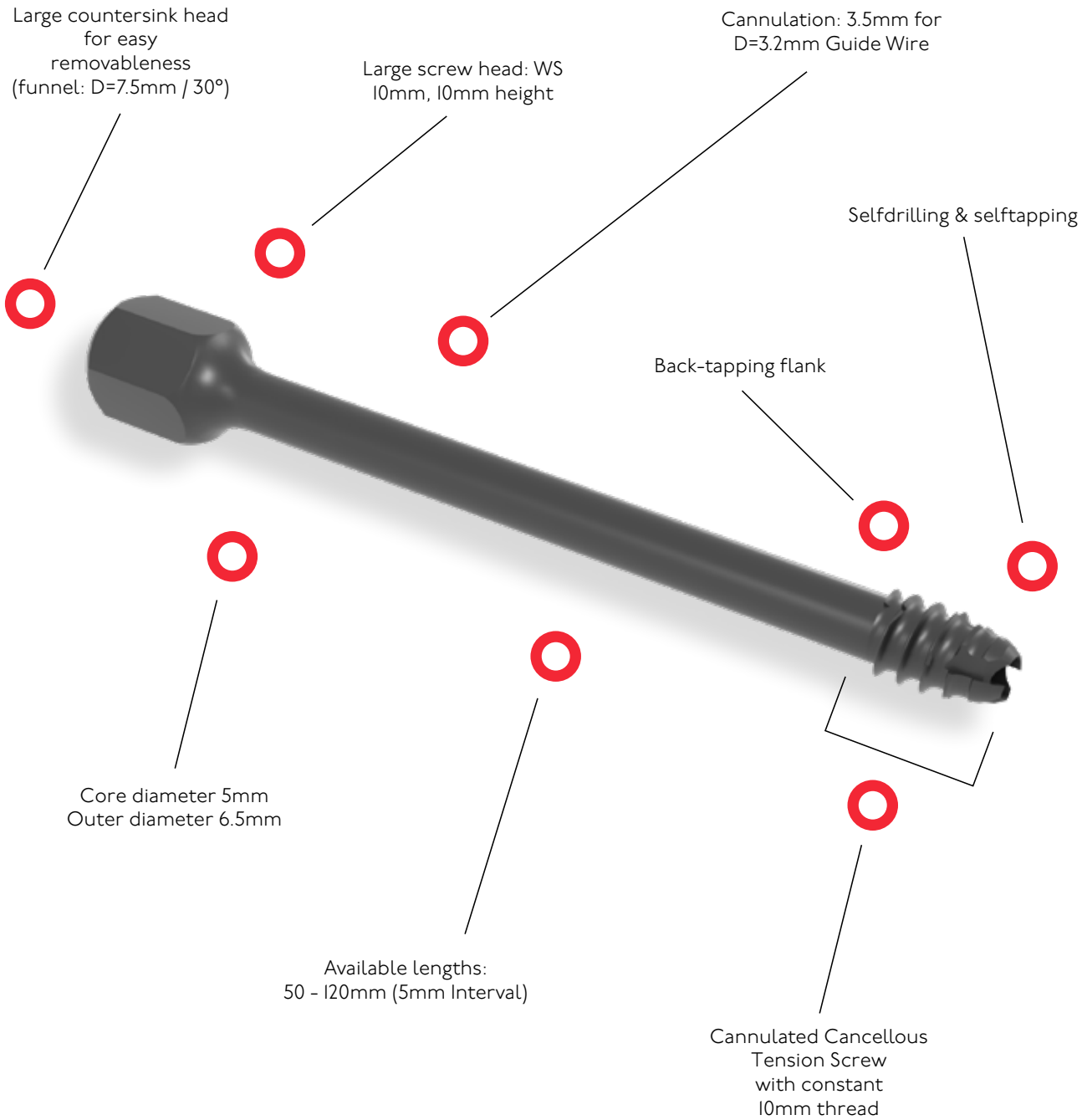
Introduction

System Overview

The ITS. Epiphysis Screw is designed for the treatment of Slipped Capital Femoral Epiphysis (SCFE). Its minimally invasive approach uses a central screw that preserves blood flow to the femoral neck and reduces the risk of joint perforation.

The screw stabilizes the femoral head for partial weight-bearing and features a short thread that acts as a tension screw without penetrating the joint. Its large screw head prevents bony ingrowth and allows easy percutaneous removal, avoiding open surgery.

Properties


Large countersink head for easy removableness (funnel: D=7.5mm / 30°)
Large screw head: WS 10mm, 10mm height
Cannulation: 3.5mm for D=3.2mm Guide Wire
Selfdrilling & selftapping
Back-tapping flank
Core diameter 5mm
Outer diameter 6.5mm
Available lengths:
50 - 120mm (5mm Interval)
Cannulated Cancellous Tension Screw with constant 10mm thread

Indications

- The indication for the use of a transcutaneous screw holds for all acute, acute to chronic and chronic loosening of the epiphysis.
- Another area of application is the transcutaneous or open screwing of fractures of the femoral head in childhood and other transcutaneous stabilisations by means of screws, where the screws have to be prevented from setting into the bony tissue but percutaneous removal is allowed.

Contraindications

- The screw connection of an epiphysiolysis (attachment of a foreign body) in the context of a septic joint inflammation which has led to the separation of the epiphysis.
- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Lack of patient compliance

Intended purpose

The implant screw product group – S04 are used for the fixation of fractures, arthrodeses and osteotomies.

Surgical Technique

2.

Slipped Capital Femora Epiphysiolysis (SCFE)

ECF is a disease of young people and occurs round about sexual maturity. Slippage of the head of the femur occurs on the growth groove. This is really misnamed since it is not the femoral head that moves but rather the metaphysis of the neck of the femur that slips forwards and upwards while the head of the femur is held in the acetabulum by the ligamentum capitis femoris *(Fig. 1)*.

The problem of this disease is the occurrence of complications such as avascular necrosis or chondrolysis of the head of the femur. Each of these complications can lead to premature attrition of the hip in childhood. Thus the supreme rule is to avoid both these complications and in no way to add further damage through treatment.
In the last 15 years, there has been a tendency towards surgical stabilisation but renouncing any attempt at a reposition.

It is stabilised by means of screws in the defective position only, thus leaving an option open for later correction.

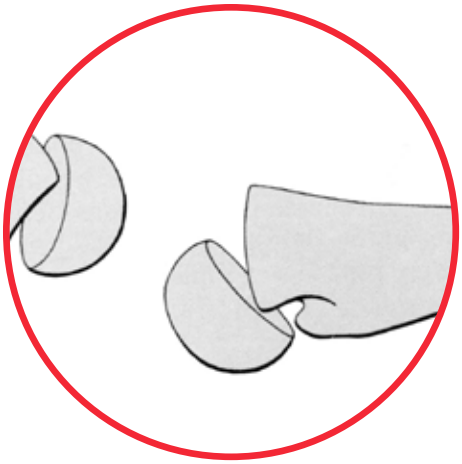
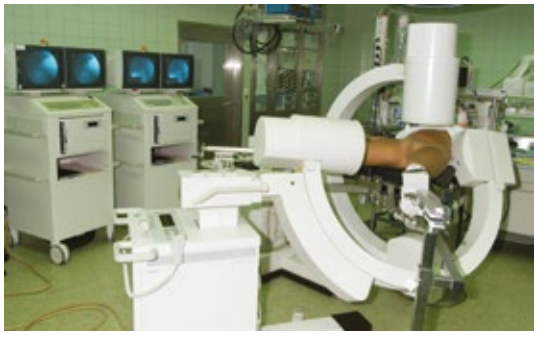


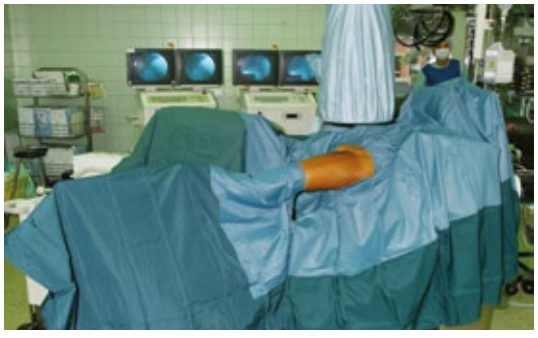
Fig. 1

Preparation of Operation

Instruments required:

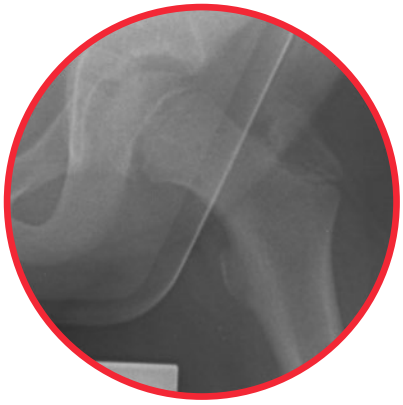
- Extension table and two image intensifiers

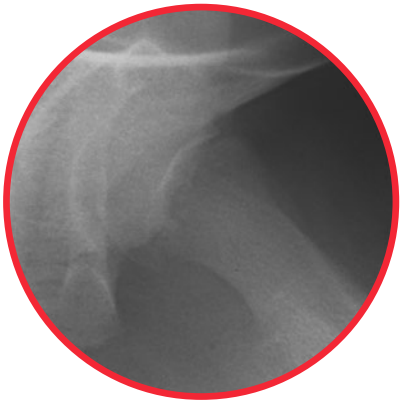




Preparation

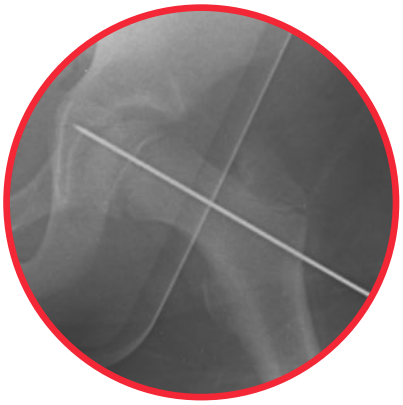
- The patient is placed on the extension table and two image intensifiers are arranged in such a way that the proximal end of the femur can be represented in two planes.
- The image intensifiers have to be placed in such a way that the X-ray tubes can be positioned respectively above (A-P level) and between the legs (sagittal level) in order to protect the operating team from X-rays as best as possible.
- The patient is placed on the extension table with carefully internally rotated leg (neutralising the femoral torsion).
- Care must be taken not to force the internal rotation of the leg – "iatrogenic reposition". First, the image intensifier depicting the sagittal level is adjusted at an acute angle to the patient.
- The second image intensifier for the frontal level is prepared afterwards.

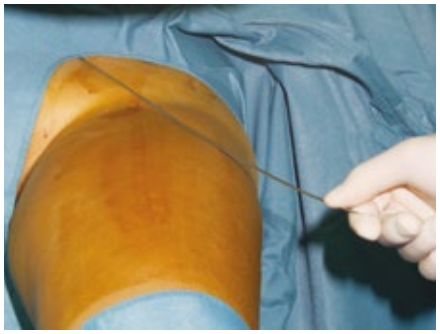


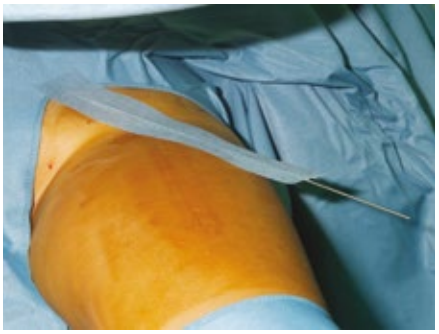


Surgical Technique - Step 1

- In the A-P plane, a free guide wire, Steel, D=3.2mm, L=260mm, TR, w. Thrd. *(35324-260)* is placed centrally over the course of the neck of the femur while being checked with the image intensifier and fastened to the skin using adhesive strip.
- This wire determines the middle of the neck of the femur in the A-P plane and thus all possible entry points of the cannulated screw.

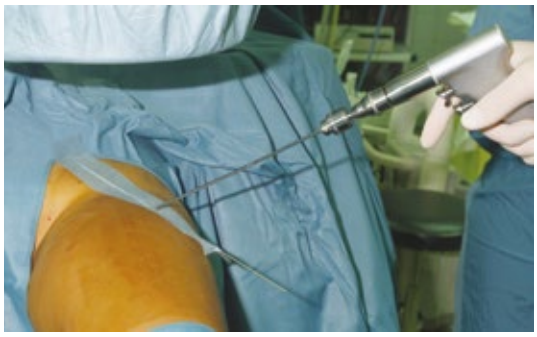


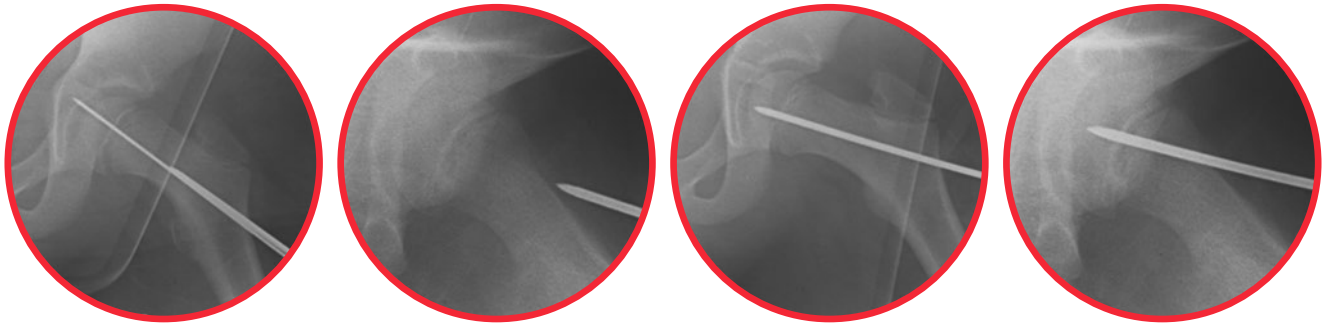




Surgical Technique - Step 2

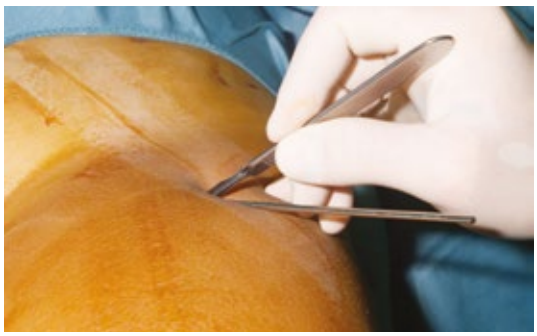
- Under observation from the image intensifiers in the lateral plane, the point at the centre of the neck of the femur in the A-P plane (where the guide wire was attached earlier) is determined to allow an additional central attachment to the epiphysis of the head of the femur in the sagittal plane.
- The greater the slippage of the head of the femur, the further ventral is the point of entry, and thus the steeper the guide wire must be in the lateral plane.
- Insertion of the guide wire under observation from the image intensifiers (both planes) centrally in the epiphysis of the head of the femur until about lcm in front of the joint cavity. This is necessary so that during positioning the cannulated screw over the guide wire, the screw does not subsequently push it forward into the joint due to shearing force.





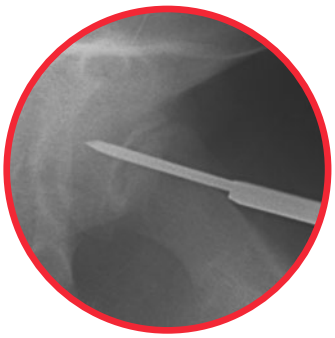
Surgical Technique - Step 3

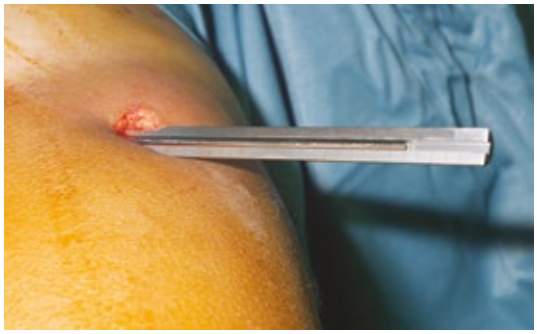
- Before the measuring device is placed in position, the incision lateral to the guide wire is made larger.



Surgical Technique - Step 4

- Using the depth gauge 3.2mm, L=260mm, Epiphys. Wire *(59322)*, the length of the appropriate cannulated screw is determined.
- It is necessary, however, to take the distance from the joint into account and therefore to choose a screw some 0.5cm longer since the guide wire stops about lcm in front of the joint cavity.

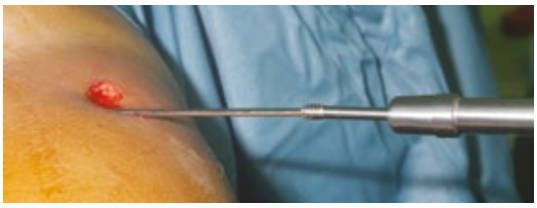


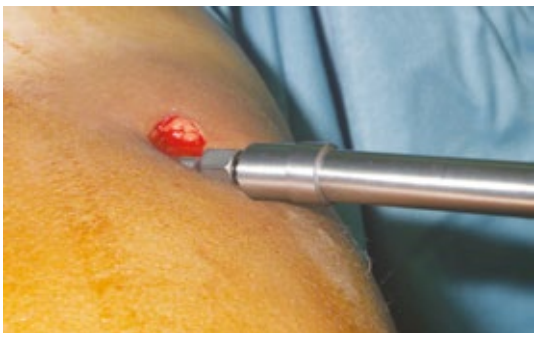


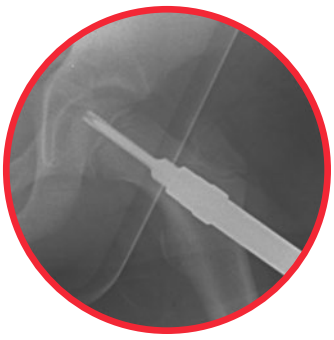
Surgical Technique - Step 5

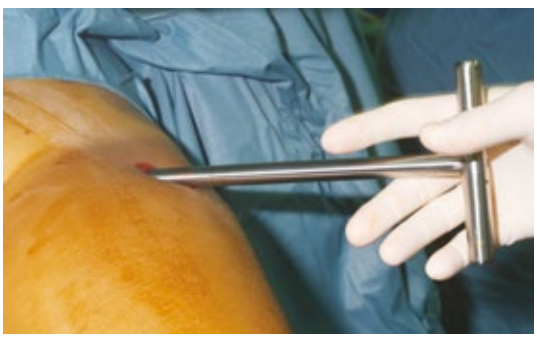
- The cannulated screw *(38651-XX)* is screwed in over the guide wire using the socket wrench, WS 10, L=250mm *(561002-250)* under X-ray fluoroscopy in both planes.

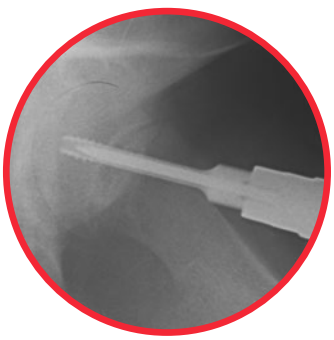
ATTENTION: Avoid joint perforation!











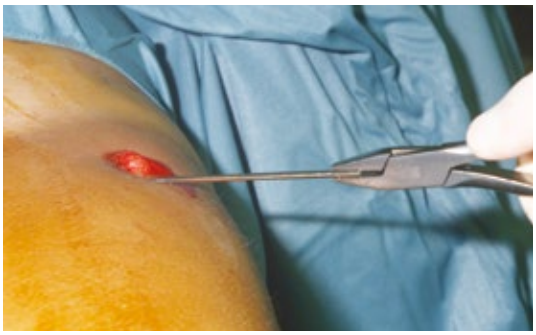
Surgical Technique - Step 6

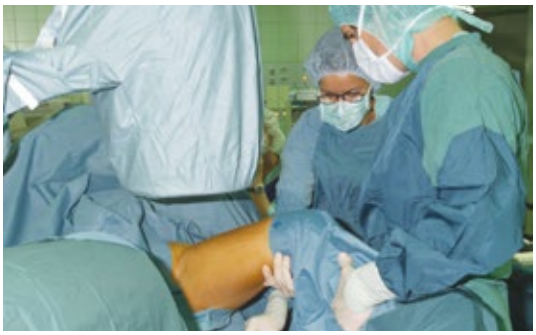
- Screw out the guide wire
- Release the leg
- Check mobility using the image intensifiers.

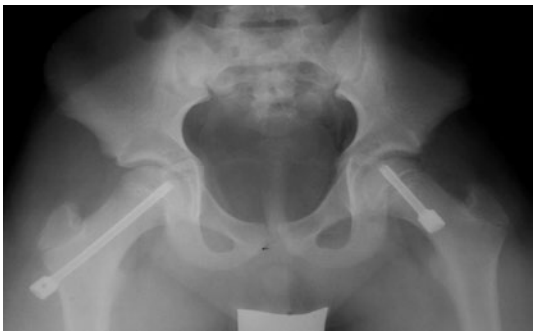
ATTENTION: Avoid joint perforation!

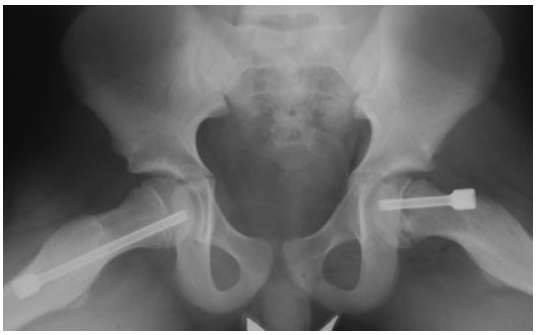
IMPORTANT: It is important not to countersink the bolt head into the bone, otherwise the easy percutaneous removeableness will not be able.

- Because of the short screw thread you can use the screw as a „dynamic“ one.
- This means that you should retighten the screw due to the growth.
- For that the head of the screw must stick out from the bone 0.5 - lcm.



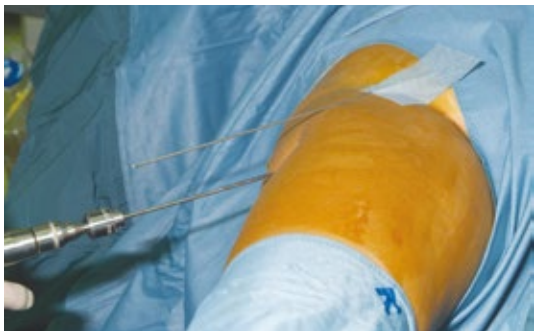


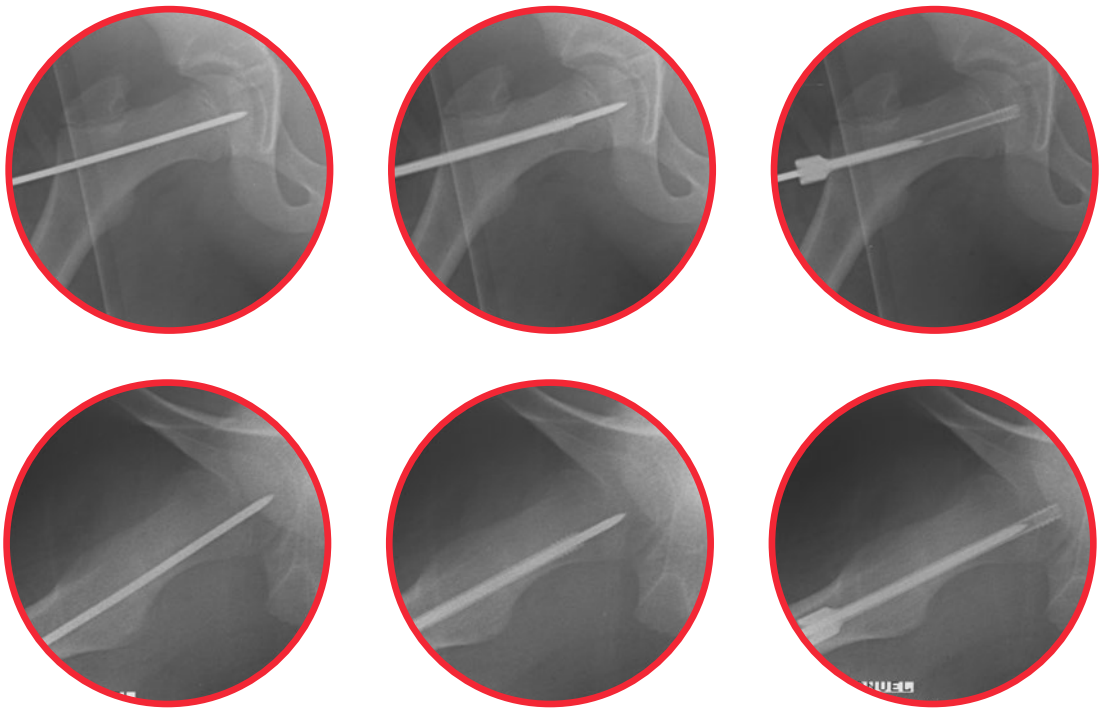




Attaching the screw on the other side

- The same procedure as in the steps of the operation, except that the guide wire is inserted parallel to the guide wire fastened to the skin distal to the tuberculum inominatum.





Explantation

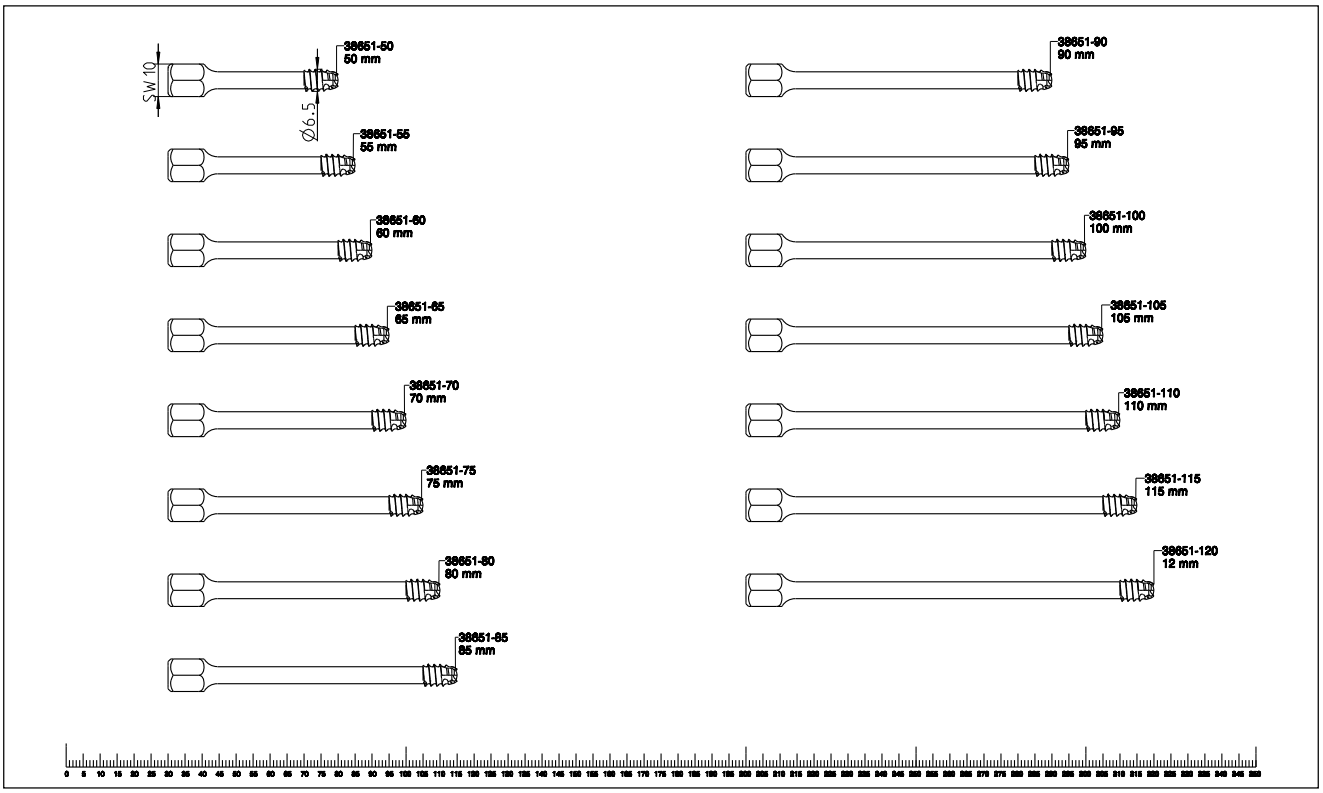
- Removal of the epiphysis screw is carried out after closure of the grwoth groove and checked using the image intensifiers and is carried out percutaneously.
- A guide wire starting from the scar of the screw attachment is introduced into the funnel shaped screw head of the epiphysis screw and the latter removed by means of the socket wrench, WS 10, L=250mm *(561002-250)* along with the guide wire.

The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants *(for more information, see p. 21)*.

Information

3.

Technical Information



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

Not true to scale

Type II Anodization

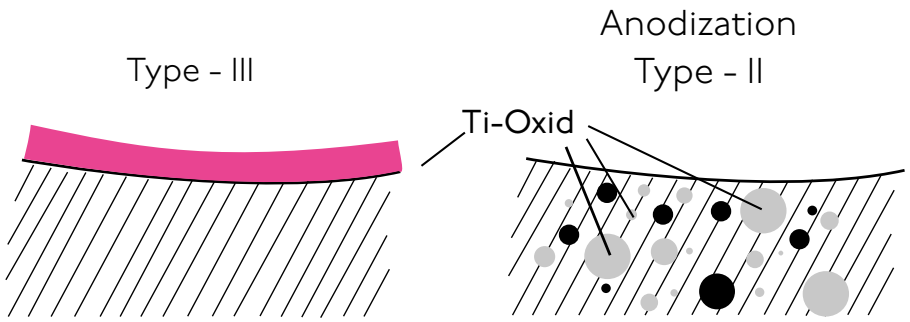
Chemical process - anodization in a strong alkaline solution*

Type III anodization

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

Type II anodization

- Layer thickness 2000-10 000nm
  - \+ Film becomes an interstitial part of the titanium
  - \- No visible cosmetic effect



Anodization Type II leads to the 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

Epiphysis Screw

Description	Length (mm)	Article Number
Epiphysis Screw, D=6.5mm, L=50mm, 10mm Thread	50	3865I-50
Epiphysis Screw, D=6.5mm, L=55mm, 10mm Thread	55	3865I-55
Epiphysis Screw, D=6.5mm, L=60mm, 10mm Thread	60	3865I-60
Epiphysis Screw, D=6.5mm, L=65mm, 10mm Thread	65	3865I-65
Epiphysis Screw, D=6.5mm, L=70mm, 10mm Thread	70	3865I-70
Epiphysis Screw, D=6.5mm, L=75mm, 10mm Thread	75	3865I-75
Epiphysis Screw, D=6.5mm, L=80mm, 10mm Thread	80	3865I-80
Epiphysis Screw, D=6.5mm, L=85mm, 10mm Thread	85	3865I-85
Epiphysis Screw, D=6.5mm, L=90mm, 10mm Thread	90	3865I-90
Epiphysis Screw, D=6.5mm, L=95mm, 10mm Thread	95	3865I-95
Epiphysis Screw, D=6.5mm, L=100mm, 10mm Thread	100	3865I-100
Epiphysis Screw, D=6.5mm, L=105mm, 10mm Thread	105	3865I-105
Epiphysis Screw, D=6.5mm, L=110mm, 10mm Thread	110	3865I-110
Epiphysis Screw, D=6.5mm, L=115mm, 10mm Thread	115	3865I-115
Epiphysis Screw, D=6.5mm, L=120mm, 10mm Thread	120	3865I-120

All implants are available sterile-packed optionally. Add „-S“ to the article number for sterile-packed implants (e.g. 37304-12-S; 21031-3-S). Delivery times, prices & minimum quantity vary from standard.

Instruments

Guide Wire

35324-260

Description	Article Number
Guide Wire, Steel, D=3.2mm, L=260mm, TR, w. Thrd.	35324-260

Depth Gauge

59322

Description	Article Number
Depth Gauge 3.2mm, L=260mm, Epiphys. Wire	59322

Socket Wrench

561002-250

Description	Article Number
Socket Wrench, WS 10, L=250mm	561002-250

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. All information herein is the intellectual property of I.T.S. GmbH.

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