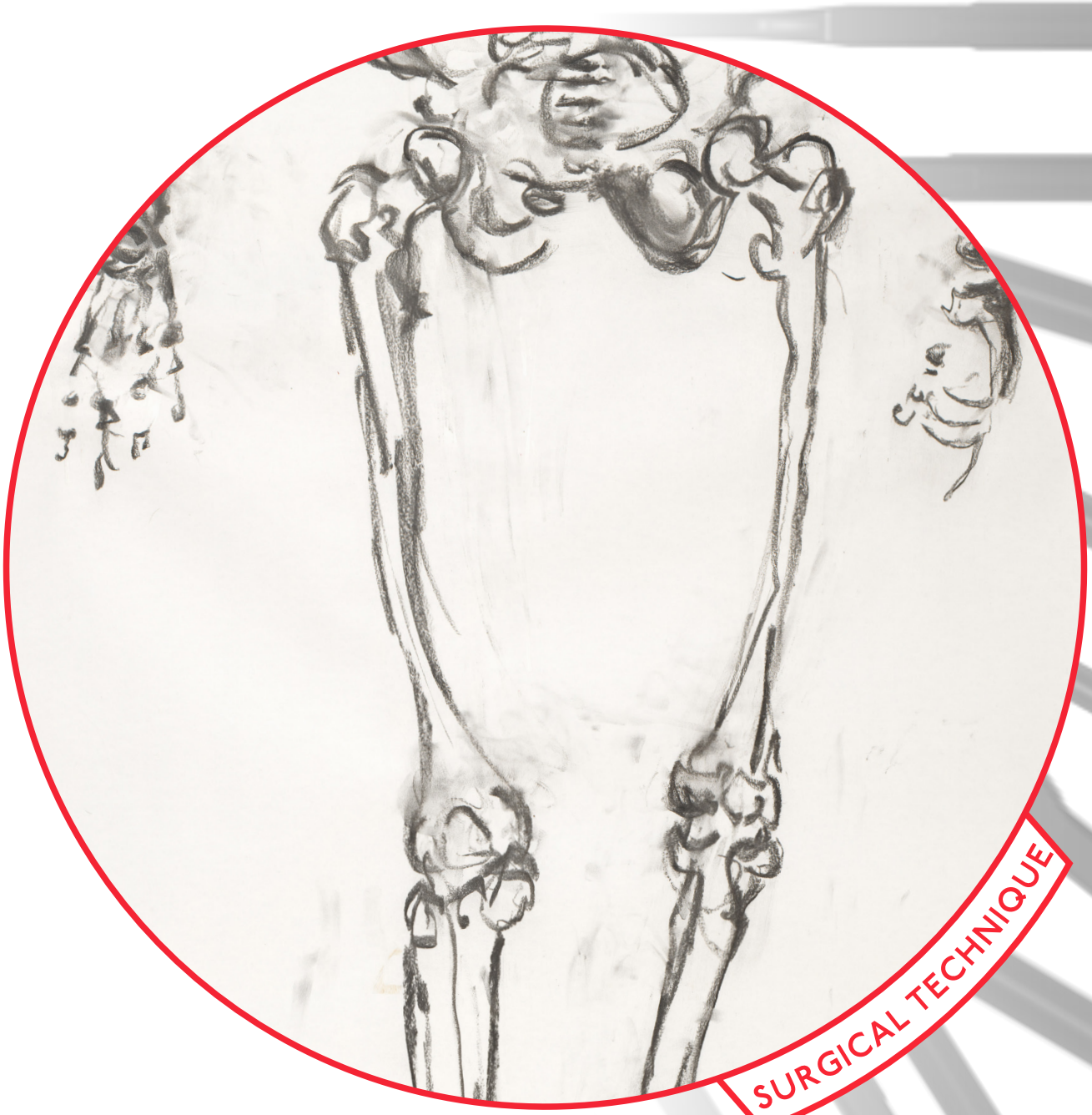
ITS.

Implants for Trauma Surgery



SURGICAL TECHNIQUE

Flexible Children Nail

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.

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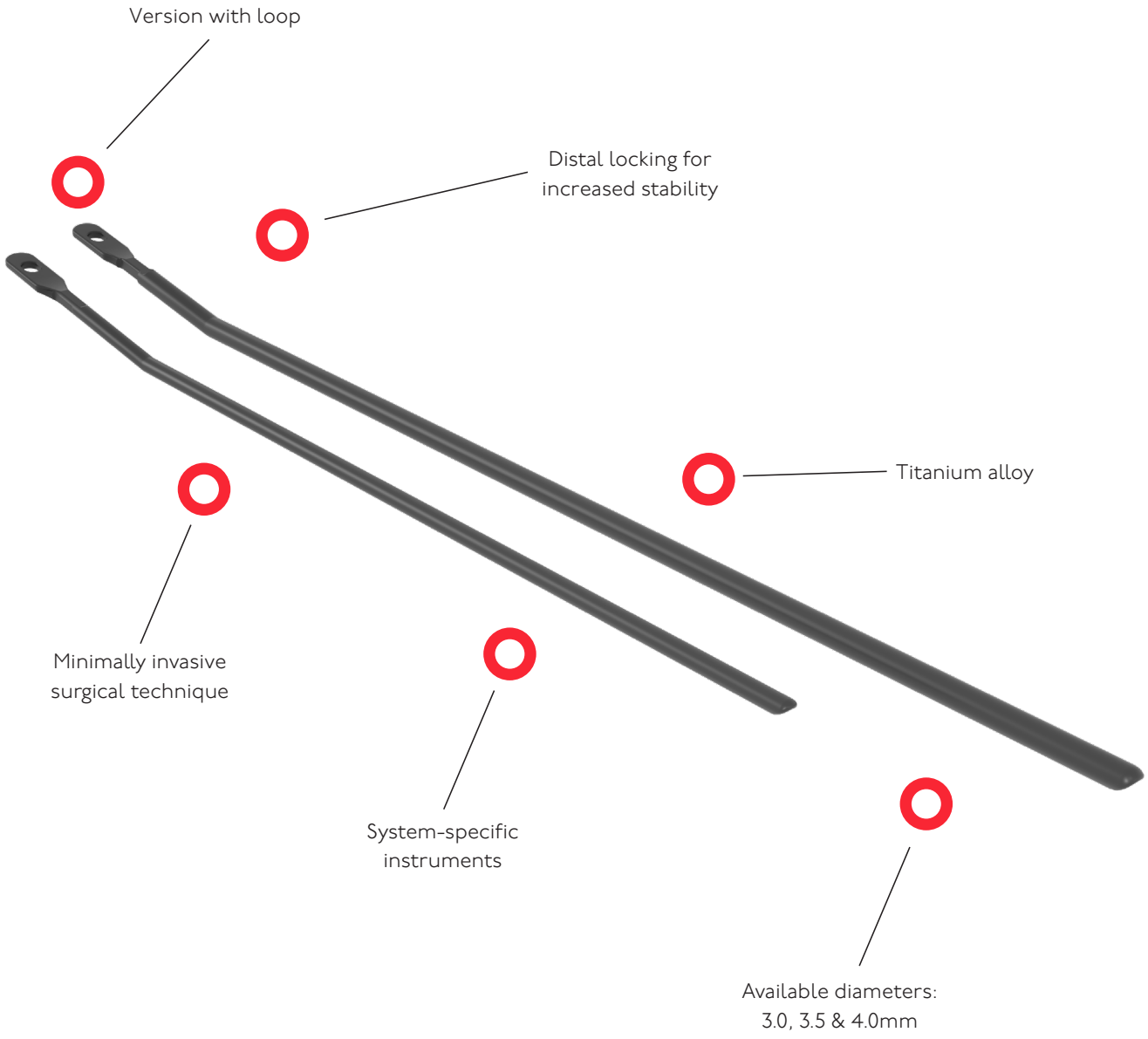
Introduction

System Overview

The elastic-stable fixation of pediatric shaft fractures via the medullary canal has proven to be the standard for the treatment of diaphyseal fractures. The ITS. children nails have been modified to suit children's conditions and are available in various lengths and diameters.

Ideal for fractures that are easy to stabilize, such as transverse or short oblique fractures in the middle of the diaphysis. Also suitable as a borderline indication for fractures that are difficult to stabilize, long oblique fractures, rotational fractures or comminuted fractures, at least on the upper extremity.

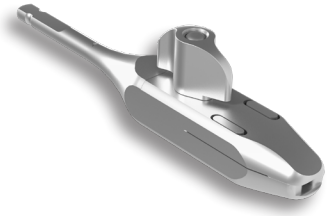
Properties


Version with loop
Distal locking for increased stability
Titanium alloy
Minimally invasive surgical technique
System-specific instruments
Available diameters: 3.0, 3.5 & 4.0mm

Instrumentation

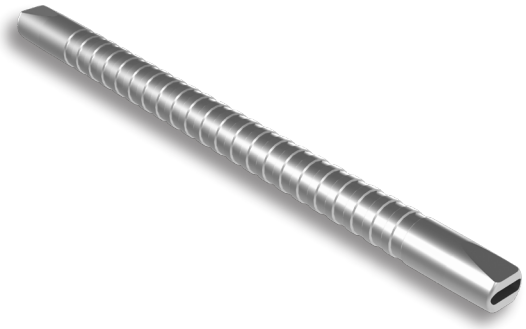
The instruments are used to introduce nails of various lengths and diameters (3.0 mm, 3.5 mm, and 4.0 mm) into the medullary cavity.

The instruments provide easy handling, comply with needs of shaft fracture treatment in children and thus allow for rapid and profound repair.



Insertion Instrument

- AO Connector



Impactor

Extraction Instrument

- AO Connector

Impaction, Extraction Instrument

- AO Connector

Screw

32346-XX **NON-LOCKING**
Cortical Screw, D=3.4mm
Spiral Drill, D=2.7mm
WS 3.5

Indications

- Ideal in cases of easily stabilisable fractures such as transverse or short oblique fractures of the medial diaphyseal area.
- Also suitable for borderline indications in difficultly stabilisable fractures, long oblique fractures, rotation or fragmented fractures, at least of the upper extremity.
- Pathologically benign fractures (e.g. juvenile bone cysts)

Contraindications

- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

Intended purpose

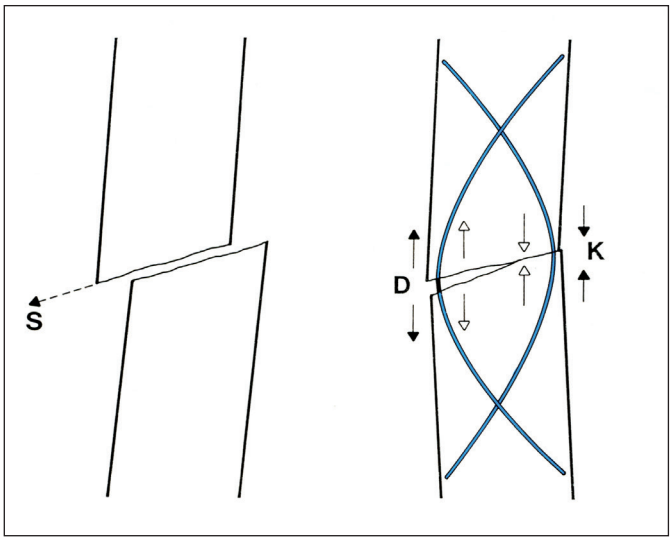
The flexible children's nail system FCN - N04 is used to treat easily stabilized fractures as well as transverse or short oblique fractures in the middle of the diaphysis as well as pathologically fractures in juvenile patients, combining the advantages of minimal-invasive osteosynthesis and intramedullary position.

Surgical Technique

2.

Biomechanics

- The principle of the paediatric medullary nail is based on an “elastic, yet stable fixation”.
- Due to the tolerance of the medullary nail to micro-movement, forces causing thrust and shear that may have negative impact on fracture healing will mainly be transformed into axial powers beneficial for fracture healing (pressure and traction).
- Due to early movement (muscle tension) and weight-bearing, such positive powers will even be enhanced. As a consequence, rapid fracture consolidation based on extensive callus formation is observed.
- Locking for increased stability is possible, particularly in fractures of the lower extremity.
- Locking prevents implant migration out of the distal end of the bone.



S = Thrust and shear forces
D = Axial distraction forces
K = Axial compression forces

Pre-operative Patient Preparation

- The patient is positioned with the leg isolated and covered with drapes (or on an extension table) using at least one fluoroscopy in order to display both planes simultaneously.
- Identification of the nail length is either performed using the fluoroscopy under consideration of magnification or intraoperatively directly aligned with the extremity.
- The nail will be pre-curved with the maximum curvature at the fracture level.

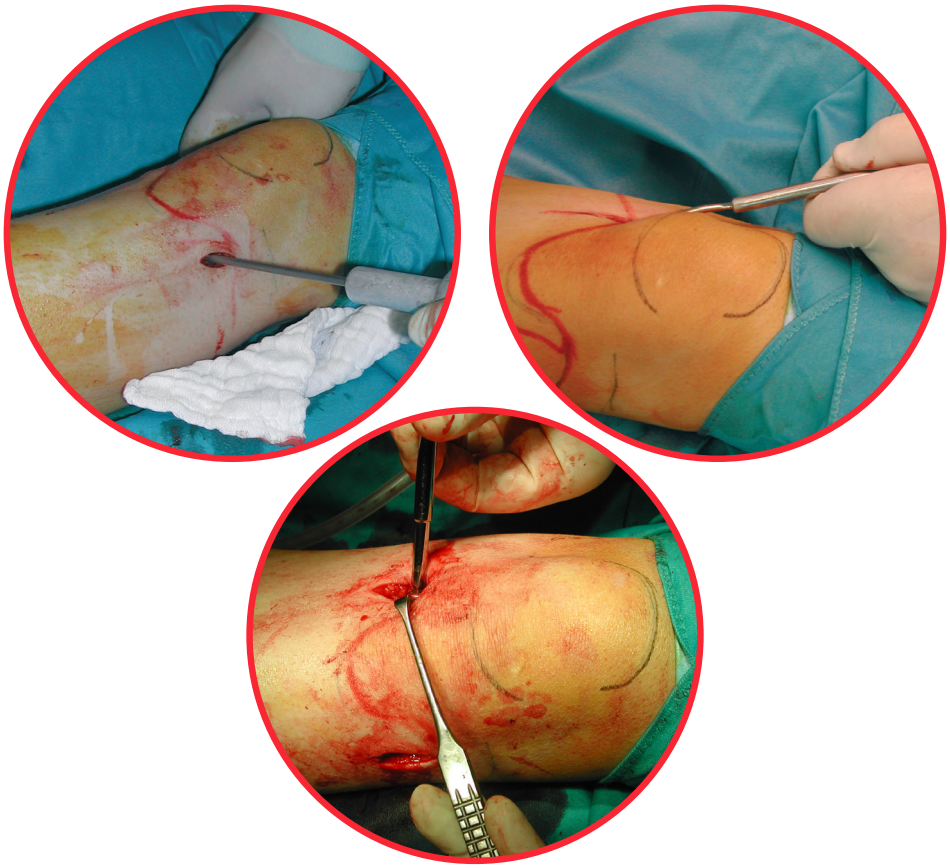
Surgical Procedure

- After the skin incision, the soft tissues are bluntly dissected. The entry hole is then prepared, and the first nail is carefully inserted into the created opening.
- Using an opening instrument (e.g., an awl), the drilling hole is positioned proximal to the epiphyseal plate, enabling subsequent locking to be performed without crossing the physis.

- The procedure is performed analogously on the contralateral side.
- Under fluoroscopic guidance, both nails are advanced sequentially across the fracture gap. This is initially performed using the insertion instrument *(I-I272)* in combination with the impaction, extraction instrument *(I-I278)*.
- For fine adjustment, the impactor *(I-I274)* is then used until the nails have reached their desired final position.

In femoral fractures:

- The procedure is performed analogously on the contralateral side.
- In case of persistent diastasis after nail insertion, the fracture may be interlocked by hits against the knee.
- Afterwards, the loop will be locked above the epiphyseal plate using a cortical screw, D=3.4mm *(32346-XX)*.
- Finally, the fracture situation must be checked on two levels under fluoroscopy.



Postoperative Treatment

- Mobilization with forearm crutches, while increasing weight-bearing (depending on pain).

Explantation

After 6-9 months (depending on age and fracture), the material is removed using appropriate removal instru-ments.

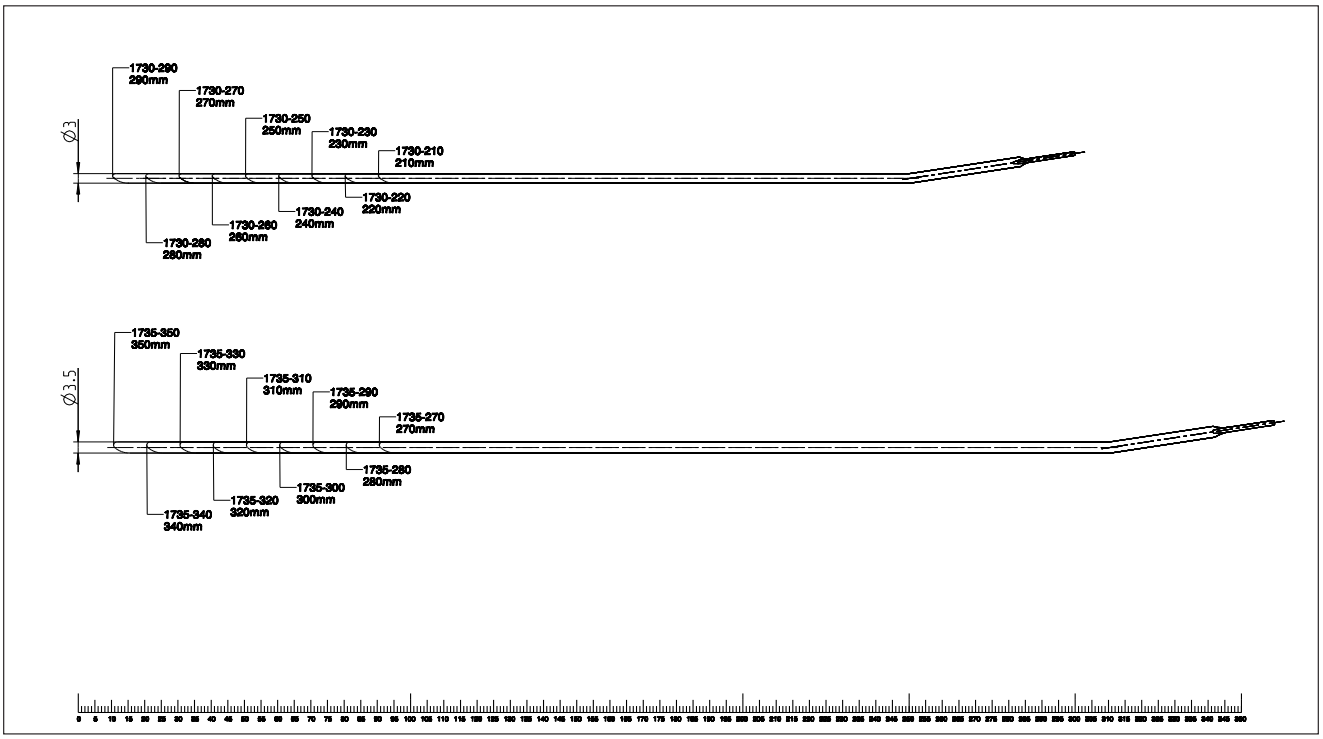
First, the screw is completely removed. The extraction instrument *(I-I280)* is then connected to the impaction, extraction instrument *(I-I278)* and guided through the loop of the nail until it audibly or tactilely clicks into place. Once properly locked, the nail is extracted from the medullary canal under controlled traction using the instrument.

The ITS. Type II anodization surface treatment reduces the risk of cold welding of titanium implants *(for more information, see p. 38)*.

Information

3.

Technical Information



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

Not true to scale

Type II Anodization

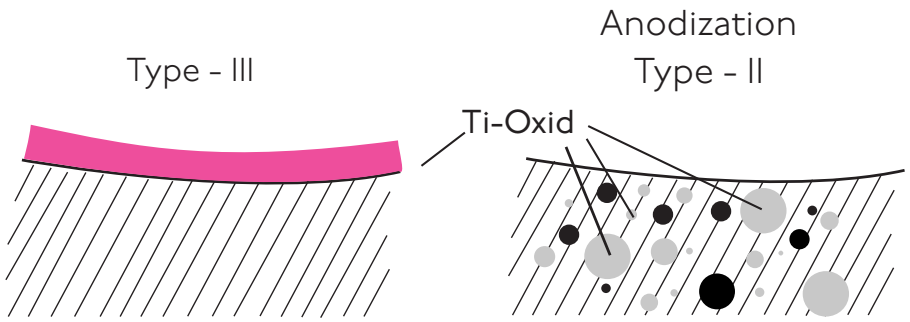
Chemical process - anodization in a strong alkaline solution*

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 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

Children Nail Ø3.0mm


1730-210


1730-220


1730-230


1730-240


1730-250


1730-260


1730-270


1730-280


1730-290

Description	Article Number
Children's Nail, D=3.0mm, L=210mm, with loop	1730-210
Children's Nail, D=3.0mm, L=220mm, with loop	1730-220
Children's Nail, D=3.0mm, L=230mm, with loop	1730-230
Children's Nail, D=3.0mm, L=240mm, with loop	1730-240
Children's Nail, D=3.0mm, L=250mm, with loop	1730-250
Children's Nail, D=3.0mm, L=260mm, with loop	1730-260
Children's Nail, D=3.0mm, L=270mm, with loop	1730-270
Children's Nail, D=3.0mm, L=280mm, with loop	1730-280
Children's Nail, D=3.0mm, L=290mm, with loop	1730-290

Children Nail Ø3.5mm

1735-270

1735-280

1735-290

1735-300

1735-310

1735-320

1735-330

1735-340

1735-350

Description	Article Number
Children's Nail, D=3.0mm, L=210mm, with loop	1730-210
Children's Nail, D=3.0mm, L=220mm, with loop	1730-220
Children's Nail, D=3.0mm, L=230mm, with loop	1730-230
Children's Nail, D=3.0mm, L=240mm, with loop	1730-240
Children's Nail, D=3.0mm, L=250mm, with loop	1730-250
Children's Nail, D=3.0mm, L=260mm, with loop	1730-260
Children's Nail, D=3.0mm, L=270mm, with loop	1730-270
Children's Nail, D=3.0mm, L=280mm, with loop	1730-280
Children's Nail, D=3.0mm, L=290mm, with loop	1730-290

Children Nail Ø4.0mm


1740-260


1740-270


1740-280


1740-290


1740-300


1740-310


1740-320


1740-330


1740-340


1740-350


1740-360


1740-370


1740-380


1740-390


1740-400

Description	Article Number
Children's Nail, D=4.0mm, L=260mm, with loop	1740-260
Children's Nail, D=4.0mm, L=270mm, with loop	1740-270
Children's Nail, D=4.0mm, L=280mm, with loop	1740-280
Children's Nail, D=4.0mm, L=290mm, with loop	1740-290
Children's Nail, D=4.0mm, L=300mm, with loop	1740-300
Children's Nail, D=4.0mm, L=310mm, with loop	1740-310

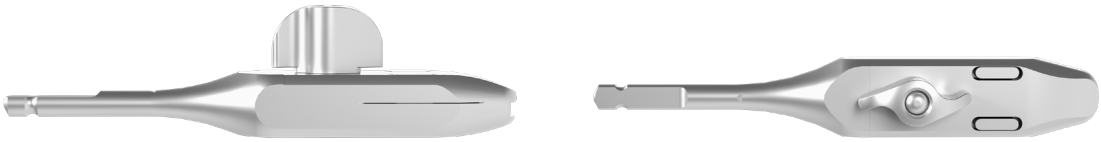
Description	Article Number
Children's Nail, D=4.0mm, L=320mm, with loop	1740-320
Children's Nail, D=4.0mm, L=330mm, with loop	1740-330
Children's Nail, D=4.0mm, L=340mm, with loop	1740-340
Children's Nail, D=4.0mm, L=350mm, with loop	1740-350
Children's Nail, D=4.0mm, L=360mm, with loop	1740-360
Children's Nail, D=4.0mm, L=370mm, with loop	1740-370
Children's Nail, D=4.0mm, L=380mm, with loop	1740-380
Children's Nail, D=4.0mm, L=390mm, with loop	1740-390
Children's Nail, D=4.0mm, L=400mm, with loop	1740-400

Screw

Cortical Screw, D=3.4mm	Length	Article Number
Non-Locking	30	32346-30
	32	32346-32
	34	32346-34
	36	32346-36
	38	32346-38
	40	32346-40
	42	32346-42
	44	32346-44
	46	32346-46
	48	32346-48
	50	32346-50
	52	32346-52
	54	32346-54
	56	32346-56
	58	32346-58
	60	32346-60

Instruments

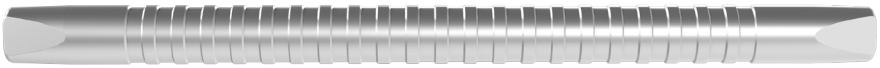
Insertion Instrument



I-I272

Description	Article Number
Insertion Instrument	I-I272

Impactor



I-I274

Description	Article Number
Impactor, Children's Nail	I-I274

Impaction, Extraction Instrument

I-I278

Description	Article Number
Impaction, Extraction Instrument	I-I278

Extraction Instrument

I-I280

Description	Article Number
Extraction Instrument	I-I280

Spiral Drill

61273-220

Description	Article Number
Spiral Drill, D=2.7mm, L=220mm, AO-Connector	61273-220

Screwdriver

56352-SH

WS 3.5

Description	Article Number
Screwdriver, WS 3.5, Conic, Self Holding	56352-SH

Notes

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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