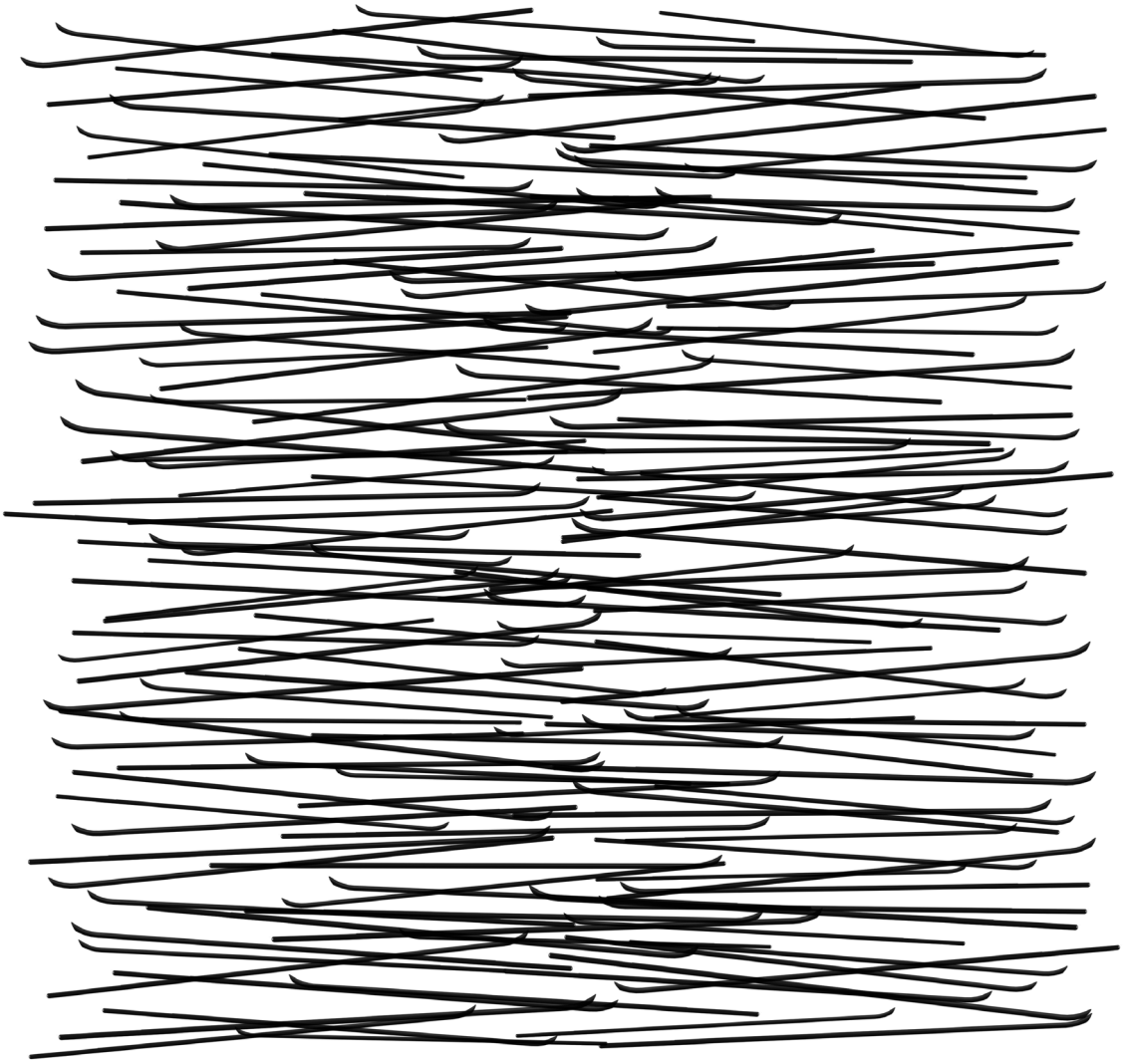
ITS.

Implants
trauma



FTN

Flexible Titanium Nail

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Introduction

1.

Preface

When used in appropriate indications, Flexible Titanium Nails offer the possibility for early functional treatment including minimally invasive fracture reduction, retention with elastical stable medullary nailing allowing for undisturbed periosteal bone healing.

Benefits are the minimally invasive surgical technique avoiding open reduction and soft tissue irritation, and the chance for undisturbed periosteal bone healing.

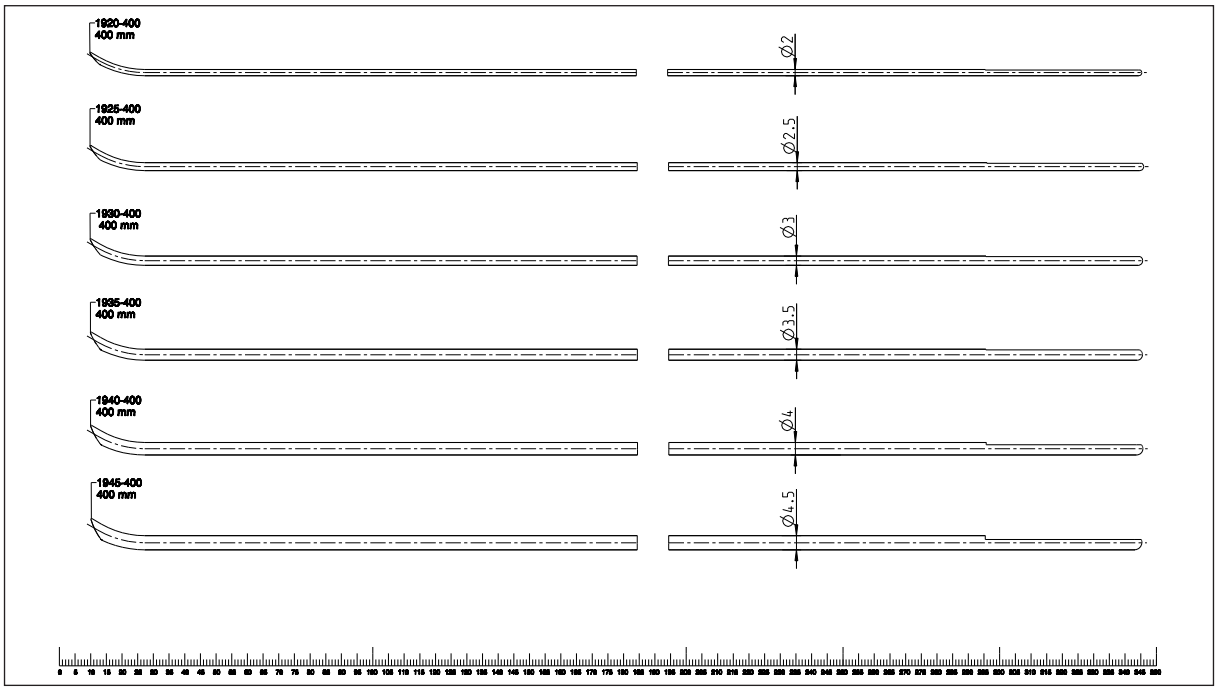
Properties

Properties of the material:

- Nail Material: TiAl6V4 ELI
- Easier removal of implant after fracture has healed
- Improved fatigue strength of implant
- Reduced risk of inflammation and allergy

Properties of the implant:

- Intraoperative cutting of the nail is possible
- Can be shortened individually in a flexible way
- Length: 400mm
- Curved, levelled nail tip facilitates insertion and fracture reduction



Indications & Contraindications

Indications:

- Lower leg shaft fractures in patients with open epiphyseal plate - oblique or transverse fractures without fragmentation
- Femoral shaft fractures in patients with open epiphyseal plate - oblique or transverse fractures without fragmentation
- Forearm shaft fractures / transverse or short oblique fractures
- Subcapital humeral fractures possibly involving greater and lesser tuberosity
- Supracondylar humeral fractures in children
- Dislocated metacarpal and metatarsal V-fractures
- Humeral shaft fractures in children (open epiphyseal plate)
- Dislocated clavicle

Contraindications:

- Fragmented fractures
- Fractures with larger bone wedge
- Existing infections in the fracture zone and operation area
- Common situations that do not allow osteosynthesis
- Obesity
- Lack of patient compliance

The flexible titanium nail system FTN - N07 is used to treat tibial fibula and femur shaft fractures with open epiphyses (oblique and transverse fractures without a comminution zone) as well as forearm shaft fractures (transverse and oblique). In addition, subcapital and supracondylar fractures, as well as forearm shaft fractures in children, can also be treated.

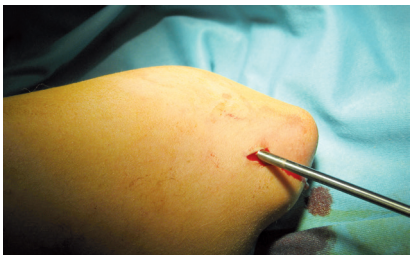
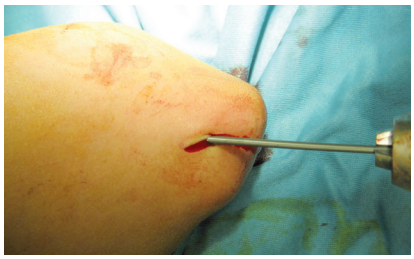
Surgical technique

2.

Surgical Technique - Forearm Fracture

- Radial insertion distally at the styloid process – ulnar insertion (sparing soft tissue) from proximal at the olecranon.
- Nail thickness approx. 1/3 to 1/2 of the minimum medullary diameter.
- Nails should be inserted into the opposite corticalis (radial head or distal ulna, respectively), otherwise there is a risk of delayed fracture healing.
- No cast required for immobilization
- Functional therapy, allows for exercise until pain indicates exact reduction




Surgical Technique - Humerus, Subcapital

- Insertion of nails - 3 nails after anterolateral incision slightly distal of the deltoid muscle attachment
- Drilling with awl
- Reduction closed
- Spread open nails 2.5 - 3.0mm in the humeral head
- Possibly percutaneous reposition of dislocated tuberosities, and fixation with cannulated screws
- Immobilization with Resch's bandage for 3 weeks



Surgical Technique - Shaft Fracture (femur, lower leg, humerus)

- Insertion via 2 opposing incisions (medial & lateral)
- Drilling - dilate with awl - nail diameter approx. 1/3 of the minimum medullary diameter
- No immobilization by cast or splint
- Functional therapy - exercise until pain occurs

Surgical Technique - Supracondylar Humeral Fracture in Children

- Closed reduction
- Insertion of 2 nails from proximal
- Cast for 3 weeks

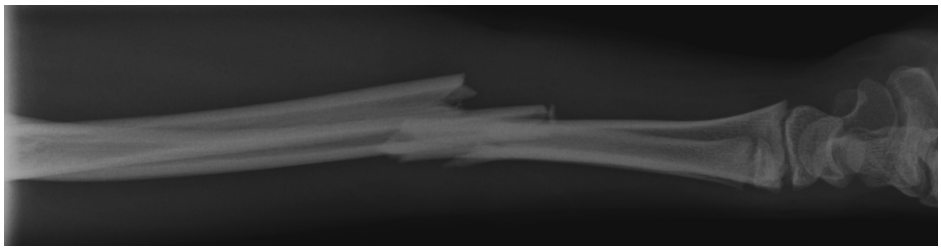
Surgical Technique - Metacarpal - Os metatarsal V

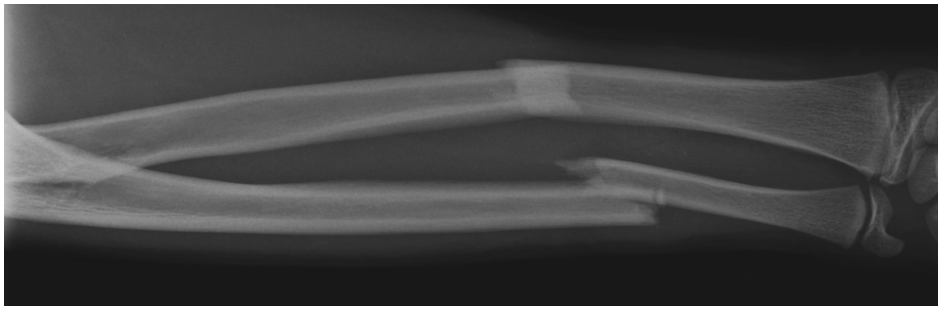
- Incision
- Drilling
- Reduction with nails

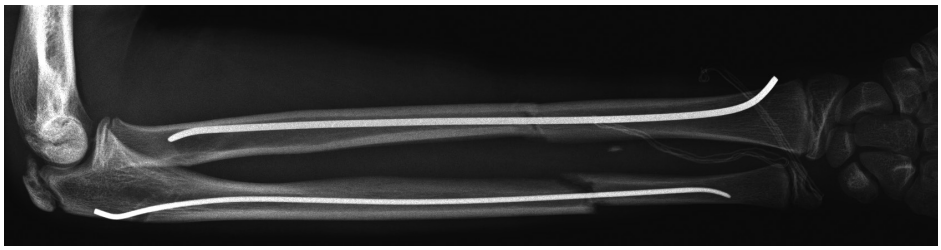
Explantation

- After 6-9 months (depending on age and fracture), the material is removed
- Early after bony consolidation

Case studies







Information

3.

Typ II Anodization

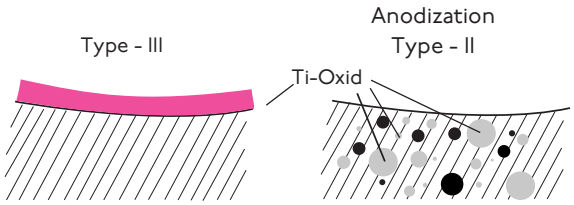
Chemical process - anodization in a strong alkaline solution*

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

Order list

Titanium Nail, Flexible, D=2.0mm, L=400mm	1920-400
Titanium Nail, Flexible, D=2.5mm, L=400mm	1925-400
Titanium Nail, Flexible, D=3.0mm, L=400mm	1930-400
Titanium Nail, Flexible, D=3.5mm, L=400mm	1935-400
Titanium Nail, Flexible, D=4.0mm, L=400mm	1940-400
Titanium Nail, Flexible, D=4.5mm, L=400mm	1945-400

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

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