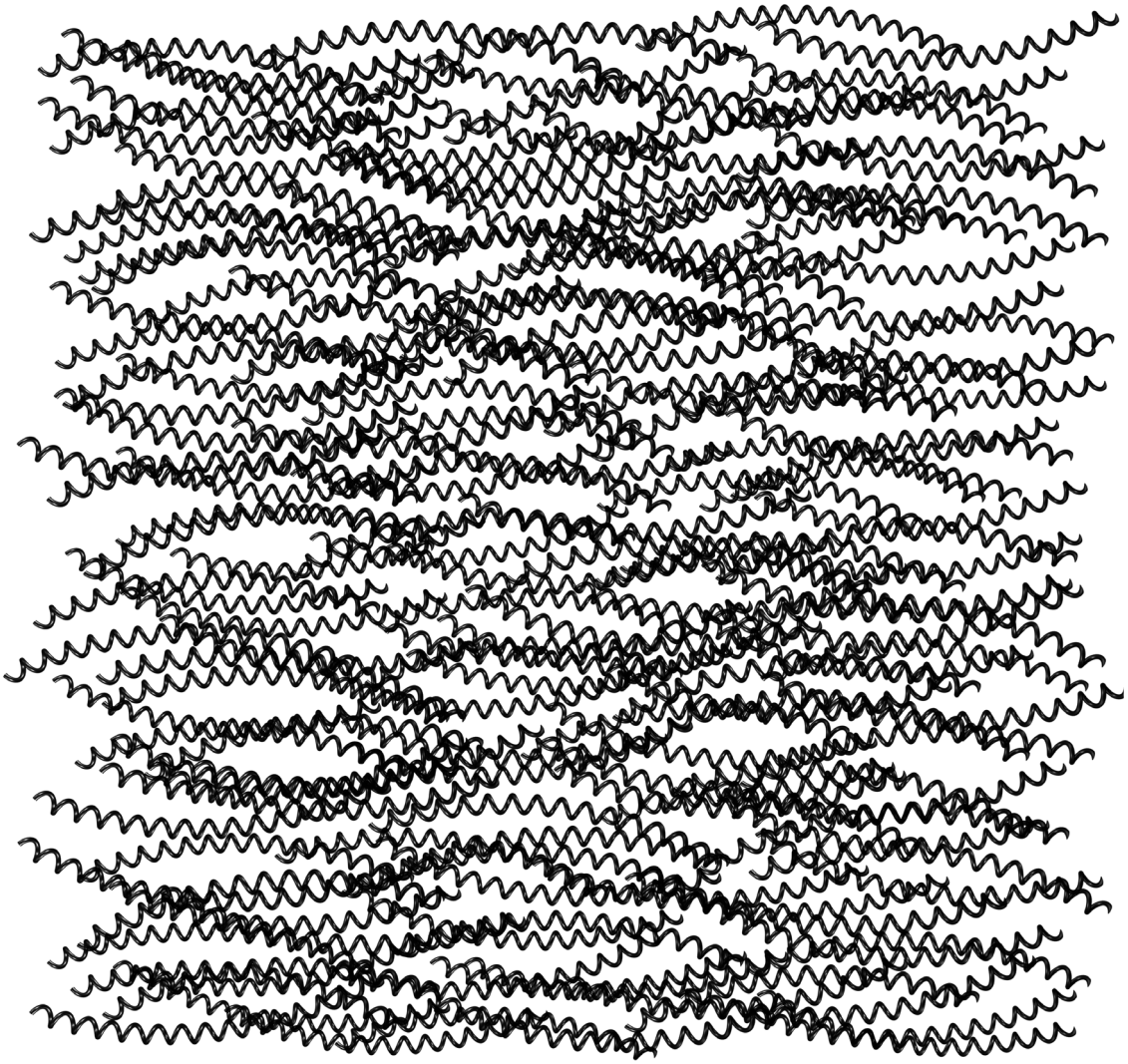
ITS.

Implants

trauma



HW

Helix Wire

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2. Surgical Technique

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Introduction

1.

Preface

In the case of the percutaneous intramedullary (K-wire) pinning procedure, which is in itself a relatively gentle technique and which reduces the risk of necrosis of the head compared to the open technique, the wires often slip out due to frequently occurring osteoporotic bones, and thus secondary displacements of fragments occur.
In order to avoid this disadvantage, the Helix Wire was developed in such a way that it combines in itself the advantages of minimal osteosynthesis, intramedullary position and spongiosa traction screw.
With its three-point support and capability to lock into place on the access drill hole distal to the joint and fracture, it is an implant which also finds a secure hold in osteoporotic bones.

Properties

Properties of the material:

- Material of the implant: 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:

- Dynamic intramedullary system
- Inexpensive procedure causing little soft-tissue trauma
- No need to expose the fracture site, thus reduced risk of avascular necrosis
- Negligible risk of vessel or nerve injury
- Early exercices possible in instances of stable fracture types A2 and A3

Helix-Design

- Only the helix configuration can utilize mechanical property of high grade materials in smallest space
- By design, the implant has exceptional stability based on 3-point support

3-point support

- Suitable for osteoporotic bone
- Within a minimally invasive procedure the Helix Wire is rotated into the intramedullary canal away from the fracture and tightens itself automatically between 3 points: the lateral entry point, the inner wall of the intramedullary canal and the cancellous bone of the head

Minimal invasive technique

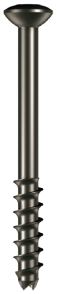
- Upkeeping of the head vascularsation
- No additional avascular necrosis risk
- Anatomic reconstruction of the shoulder function
- Low total costs for the treatment
- Short operation time with minimum stress for the patient
- Fast relief from pain
- Fast fracture healing
- Removal of the implant possible, but not necessarily required

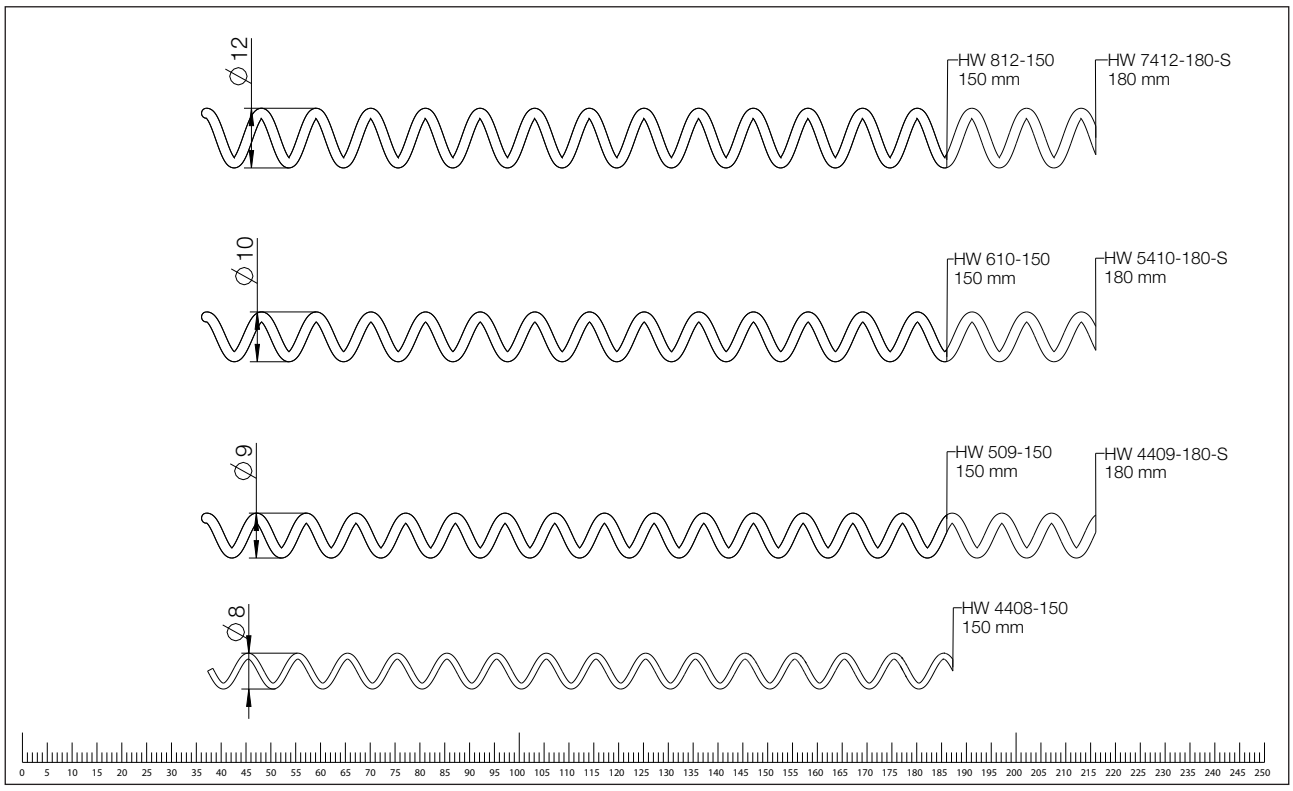
Stabilization wire

- Apart from the dynamic 3-point support of the titanium Helix Wire, among other things, the stabilization wire also offers additional rotation protection

D=4.0mm cannulated cancellous screw

- These give the problem fracture a reliable hold and thus bring about a stable connection with large fragments.
- For very osteoporotic bones, washers are available made of the same material - titanium - in two different designs: flat or curved





Indications & Contraindications

Indications:

- Dislocated, fractures of the proximal humerus of the types A2, A3 and B according to the AO classification
- It may be necessary to secure the tubercula by means of a screw
- C-fractures in accordance with attempts to preserve the head

Contraindications:

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

Surgical Technique

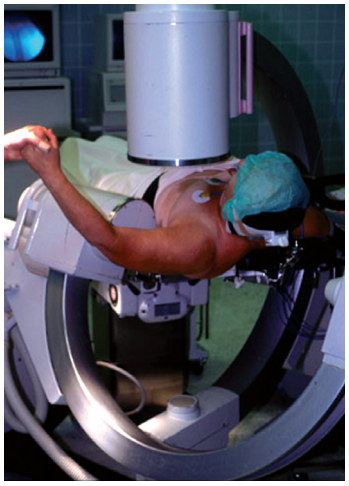
2.

Pre-operative

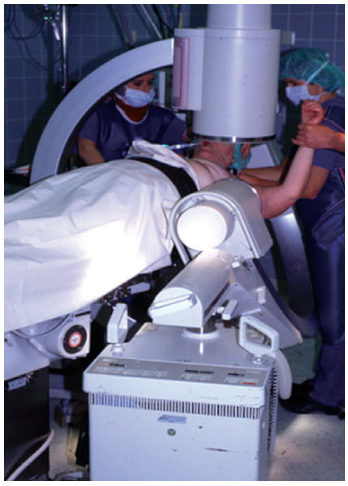
- In the case of conventional X-ray plates, the size of the implant can be ascertained by measuring. The outer diameter of the helix should be 20-25% less than the width of the medullary space.
- If only digital images are available, the size of the implant is established approximately by preoperative x-ray of the shoulder region with helix placed on the surface.

Pre-operative patient preparation

- The operation is carried out with the patient in the supine position with the upper body raised to 45° ("beach chair" position). The head is supported on a head support so that x-rays can be taken in the A-P and axial ray path.
- Two fluoroscopys are recommended. The successful x-ray image of the fracture is to be checked before sterile covers are applied.



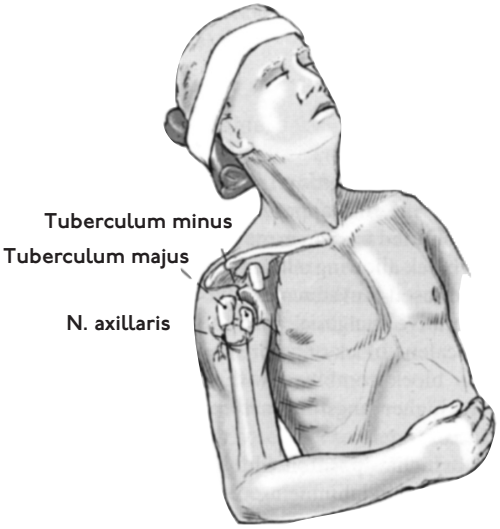
Supine position of the patient

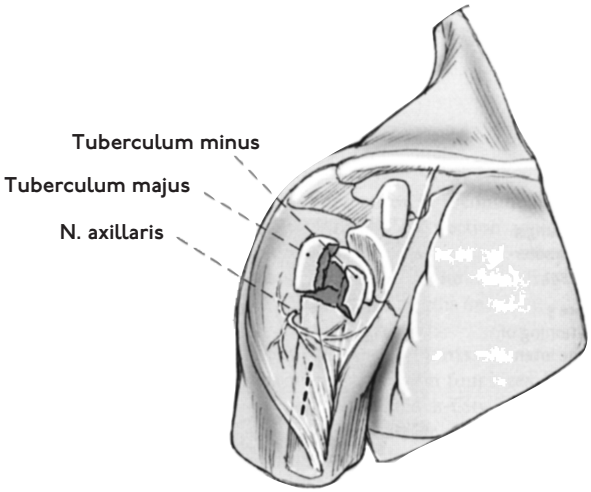


Fluoroscopy check at 2 levels

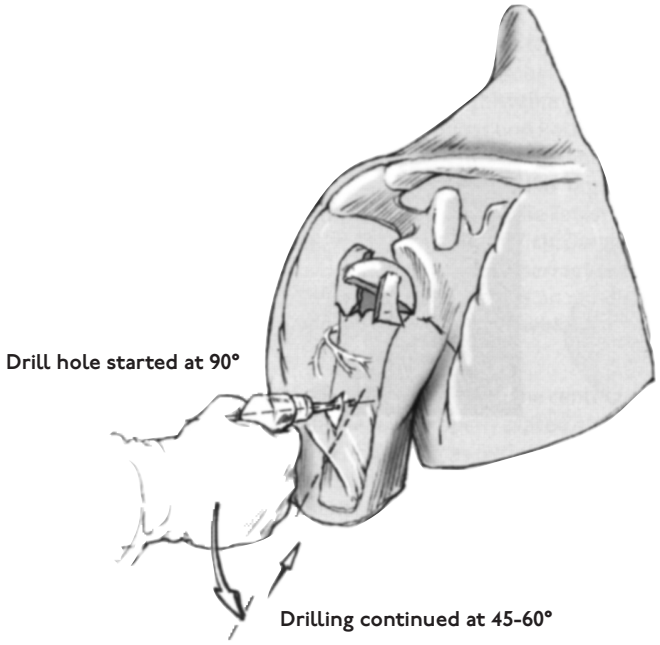
Surgical Technique

- 3cm longitudinal skin incision immediately anterior to the deltoid tuberosity, approximately 6cm distal to the fracture site. Splitting of the deltoid muscle and pushing back of the periosteum with an elevator.
- The optimal position of the drill hole lies in the proximal end of the incision. The axillary nerve lying two fingerbreadths more proximal is thus protected from injury.

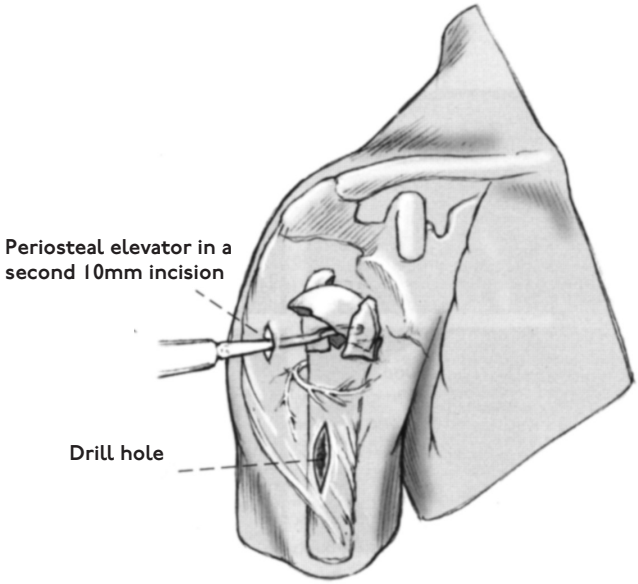


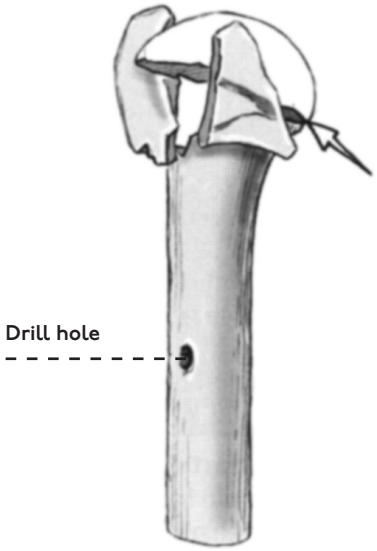


- Setting of a D=5mm drill hole into the medullary canal starting perpendicular to the shaft
- Then inclining the drill by 60-45° in a cranial direction.

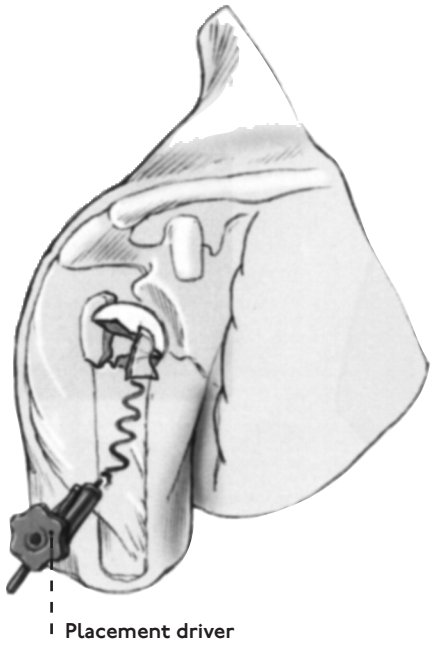


- Fractures impacted in valgus are carefully disengaged with an elevator introduced through a 10mm incision.

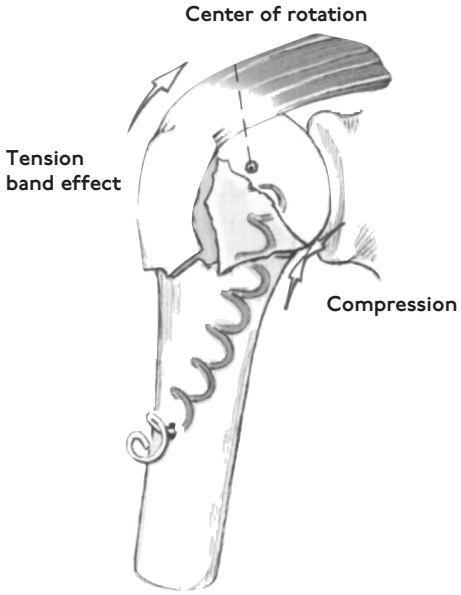




- The Helix Wire mounted on an adjustable placement driveris advanced to the level of the fracture site after change in direction.

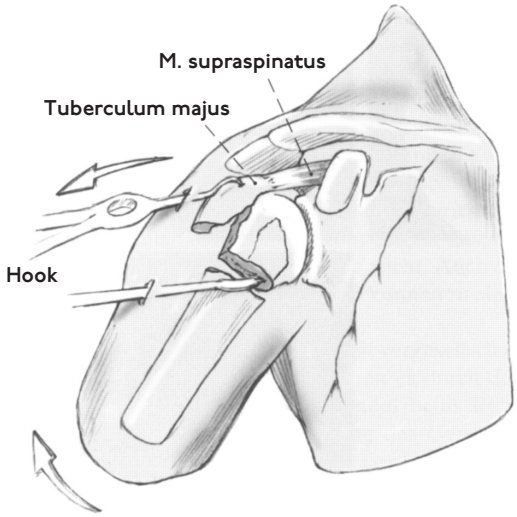


- The optimal position of the wire in the head lies medial to the center of rotation.The tip should lie 2 mm under the surface of the head.
- If properly placed,the implant prevents impaction and tilting of the head fragment.
- As long as periosteum and rotator cuff have not been severely damaged, the reduction of the articular fragments will exert a tension band effect on the intermediary fragments similar to a ligamentotaxis. Ideally, these fragments fit into their proper position spontaneously.
- Should a displacement of the tuberosities persist, a reduction and screw fixation may become necessary. Thereafter, the wire is shortened, leaving 5 - 15mm exceeding the cortex.
- The tension of the wire itself ensures an engagement of the threads in the drill hole causing a reliable anchorage.

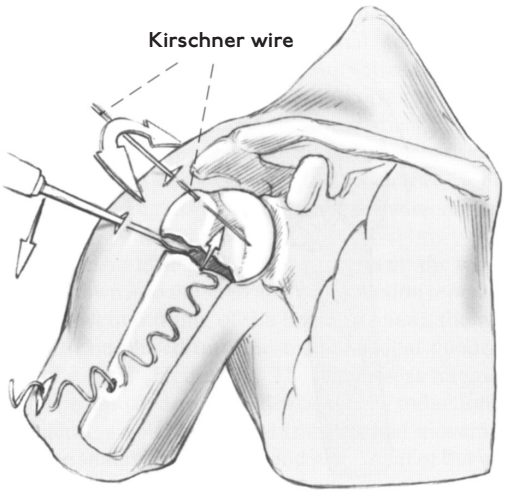


Special consideration

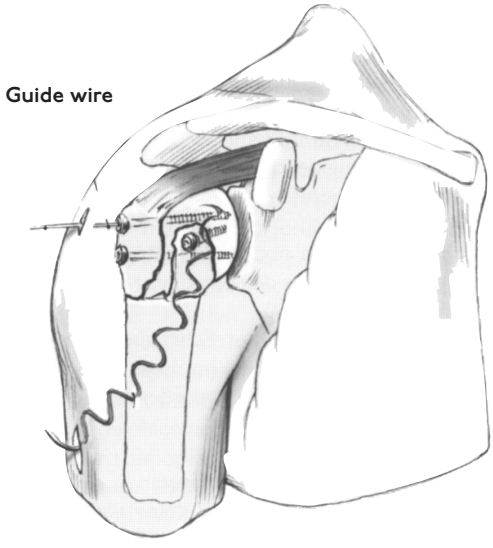
- To test the stability of reduction after internal fixation, the shoulder is put through full range of motion (rotation, traction, ab- and adduction) under image intensification. A tight dynamic, axial range of motion at the fracture site is not only permissible but desirable as it stimulates fractur healing.
- If in-stability is detected in spite of additional Kirschner wires or helix wires, a change to an arthroplasty is recommended.



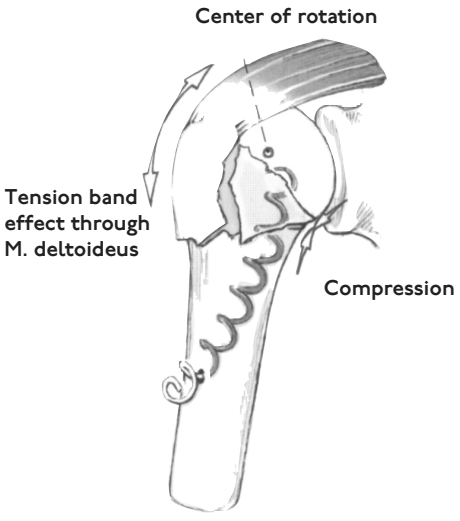
Closed reduction with hook



Joystick- maneuver



Screw fixation of the greater tuberosity



Test of stability under image intensification

Postoperative treatment

- Postoperative immobilzation in Gilchrist or Bauer dressing for 1-3 weeks.
- At the same time, passive physiotherapy should be started from the second postoperative week onwards, increasingly with active assistance from the patient.
- Functional postoperative treatment and duration of fixation <3 weeks are only recommended in the case of A2 fractures and A3 fractures with non-osteoporotic bones.

Explantation

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.

Information

3.

Dotize®

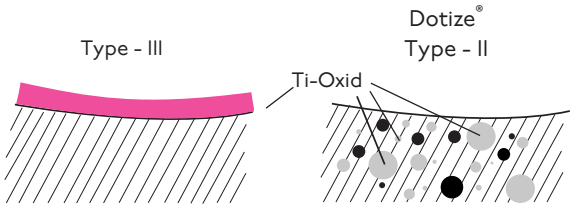
Chemical process - anodization in a strong alkaline solution*

Type III anodization

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

Dotize
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 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

Helix Wire, XS, 1.8mm Wire, L=150mm, OD=8.0mm	HW 4408-150
Helix Wire, XS, 2.3mm Wire, L=180mm, OD=9.0mm, PPS	HW 4409-180-S
Helix Wire, XS, 2.0mm Wire, L=150mm, OD=9.0mm	HW 509-150
Helix Wire, XS, 2.3mm Wire, L=180mm, OD=10.0mm, PPS	HW 5410-180-S
Helix Wire, XS, 2.0mm Wire, L=150mm, OD=10.0mm	HW 610-150
Helix Wire, XS, 2.3mm Wire, L=180mm, OD=12.0mm, PPS	HW 7412-180-S
Helix Wire, XS, 2.0mm Wire, L=150mm, OD=12.0mm	HW 812-150
Placement Driver, Helix Wire	HW 100-100
Handle, Helix Wire	HW 100-101
Clamping Sleeve, Helix Wire, XS, 8.0mm	HW 100-102
Clamping Sleeve, Helix Wire, S, 9.0mm	HW 100-103
Clamping Sleeve, Helix Wire, M, 10mm	HW 100-104
Clamping Sleeve, Helix Wire, L, 12mm	HW 100-105
Washer, Helix Wire	HW 100-108
Nut for placing instrument	HW 100-109
Drill, D=5.0mm, L=140mm	HW 100-140
Trochar, with sheath	57041
Depth Gauge 1.6mm Can. 4.0mm Screw, var. thread	59162
Guide Wire, Steel, D=1.6mm, L=228mm, TR, w. thread	35164-228
Screwdriver, Handle 25mm, WS 2.5, L=120mm, Can. 1.7mm	56253-120
Sterilization Tray	50109

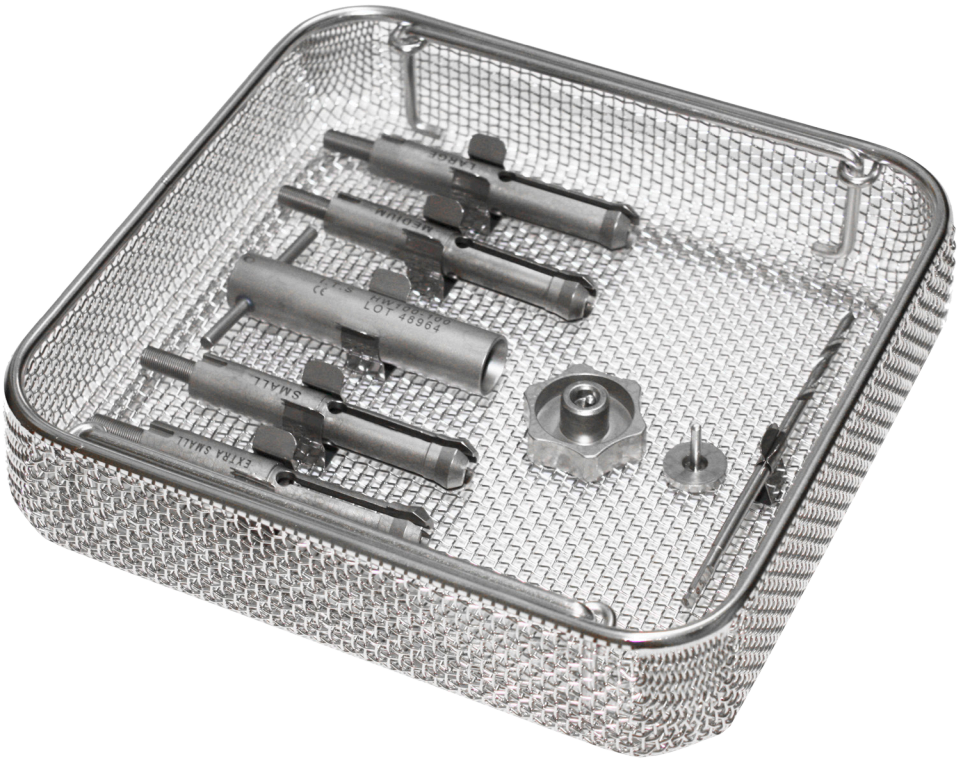
Optional (on request)

Cancellous Screw, Cannulated, D=4.0mm, L=16mm, Var. Thread	31404-16
Cancellous Screw, Cannulated, D=4.0mm, L=18mm, Var. Thread	31404-18
Cancellous Screw, Cannulated, D=4.0mm, L=20mm, Var. Thread	31404-20
Cancellous Screw, Cannulated, D=4.0mm, L=22mm, Var. Thread	31404-22
Cancellous Screw, Cannulated, D=4.0mm, L=24mm, Var. Thread	31404-24
Cancellous Screw, Cannulated, D=4.0mm, L=26mm, Var. Thread	31404-26
Cancellous Screw, Cannulated, D=4.0mm, L=28mm, Var. Thread	31404-28
Cancellous Screw, Cannulated, D=4.0mm, L=30mm, Var. Thread	31404-30
Cancellous Screw, Cannulated, D=4.0mm, L=32mm, Var. Thread	31404-32
Cancellous Screw, Cannulated, D=4.0mm, L=34mm, Var. Thread	31404-34
Cancellous Screw, Cannulated, D=4.0mm, L=36mm, Var. Thread	31404-36
Cancellous Screw, Cannulated, D=4.0mm, L=38mm, Var. Thread	31404-38
Cancellous Screw, Cannulated, D=4.0mm, L=40mm, Var. Thread	31404-40
Cancellous Screw, Cannulated, D=4.0mm, L=42mm, Var. Thread	31404-42
Cancellous Screw, Cannulated, D=4.0mm, L=44mm, Var. Thread	31404-44

Cancellous Screw, Cannulated, D=4.0mm, L=46mm, Var. Thread	31404-46
Cancellous Screw, Cannulated, D=4.0mm, L=48mm, Var. Thread	31404-48
Cancellous Screw, Cannulated, D=4.0mm, L=50mm, Var. Thread	31404-50
Cancellous Screw, Cannulated, D=4.0mm, L=55mm, Var. Thread	31404-55
Cancellous Screw, Cannulated, D=4.0mm, L=60mm, Var. Thread	31404-60
Cancellous Screw, Cannulated, D=4.0mm, L=65mm, Var. Thread	31404-65
Cancellous Screw, Cannulated, D=4.0mm, L=70mm, Var. Thread	31404-70
Cancellous Screw, Cannulated, D=4.0mm, L=75mm, Var. Thread	31404-75

Washer, Flat, OD=11.0mm, ID=4.5mm	36431
Washer, Concave, OD=11.0mm, ID=4.5mm	36432

Tray



Reconditioning Manual

The information below should help you in reconditioning medical devices.

IMPORTANT INDICATIONS FOR DOCTORS & OPERATING THEATRE PERSONNEL
This instruction leaflet refers to all supplied non-sterile implants and all reusable instruments from I.T.S. GmbH. Detailed information for the identification of the product (such as system classification, cat. no.) can be found in the product identification code and/ or on the packaging label. Make sure that you are familiar with the possible application, combinability and correct handling of the product. Please note that product systems can undergo modifications which can affect the combinability of the implant with other implants or instruments. Detailed user information can be found in the respective surgical instructions.

Intended Use of the Implant
The implant temporarily stabilises bone segments until bony consolidation has taken place. After this, the implant has no more use and can be removed.

Indications and Contra-Indications of the Implant
Indications and contra-indications are determined by current medical practice.

Side Effects of the Implant
Up to now, no allergic reactions have been identified with titanium implants. Allergic reactions to steel implants cannot be ruled out.

Warnings and Preventive Measures
- Pay attention to the instructions on the packaging.
- Implants are only to be used once.
- Always treat implants carefully to avoid surface damage or geometric alterations.
- Any alterations to the design of implants from I.T.S. GmbH are prohibited.
- Regular postoperative follow-up examinations (e.g. X-ray check-ups) are to be carried out.
- For metallurgical, mechanical and design reasons, never combine implants from different producers. The materials used are stated in the product catalogue or on the label.
- The length, angle and right or left version of a particular type of implant can differ.
- The precise positioning and fastening of a properly made connection between the implant and instrument must be repeatedly checked during the course of an operation.
- In the case of magnetic resonance imaging (MRI), it is generally recommended to check back with the manufacturer of the MR scanner. The use of MRI with steel implants is prohibited by I.T.S. GmbH, and in such cases the user must contact the manufacturer of the MRI scanner.
- Staff who come into contact with contaminated or potentially contaminated medical products should follow the generally recognised preventive measures. Due care is to be taken when handling medical products with sharp points or edges.
- Appropriate protective measures must be taken to ensure safe handling when dealing with contaminated or potentially contaminated medical products (e.g. gloves, etc.)
- In countries with stricter safety requirements regarding recycling medical products, these safety requirements apply and are to be adhered to.
- Any supplied non-sterile medical products must be thoroughly prepared according to these instructions before use.
- No metal brushes or abrasive cleaning materials are to be used for manual cleaning purposes. The use of these materials can lead to damage of surfaces and coatings. Instead, soft brushes made of nylon should be used.
- Steam (damp heat) is the recommended sterilization method of medical products from I.T.S. GmbH.
- All the following described steps for cleaning and sterilization are made easier when contaminants (e.g. blood) are not allowed to dry beforehand.

Restrictions
- Unless otherwise stated, repeated preparation of re-usable instruments of I.T.S. GmbH has minimal effects on them when following the procedures mentioned below.
- The end of the product service life is usually determined by wear and damage caused by use.
- Instruments containing aluminium or anodised aluminium can be damaged by alkaline (pH value > 7) cleaning agents and solutions.

INSTRUCTIONS FOR RECYCLING REUSABLE INSTRUMENTS
Preparation at the location of use
- Remove surface dirt using a disposable cloth or paper towel. Rinse out the hollow parts with A. dest. Saline solution (NaCl) may only be used if reconditioning is carried out immediately afterwards - risk of corrosion!

Storage and Transport
- No special requirements.
- It is recommended that medical products are reconditioned as soon as possible after their previous use.

Cleaning/Disinfection/Drying
Cleaning preparation
Each instrument that can be dismantled should be taken apart for cleaning.

Automatic cleaning/disinfection
Only a washer-disinfector (WD) that conforms to standards (in accordance with EN ISO 15883) and that is regularly maintained and inspected should be used for automatic cleaning and disinfection in accordance with the manufacturer's information.
Recommended equipment: Appropriate loading trolleys to accommodate all instruments (e.g. instrument trolleys with MIC bar, MIC trolleys); commercially available cleaning agent authorised for use with medical products (pH value 9-11) e.g. Neodisher® Mediclean forte by Dr. Weigert.
I.T.S. GmbH recommends the following validated steps for automatic cleaning and thermal disinfection. The basic device should be a Miele PG 8536 machine. Validation is carried out in accordance with EN ISO 15883 and guideline no. 3 of the Austrian Association for Sterile Services (ÖGSV).

Phase	Water quality	Temperature [°C]	Time [min]*	Dosage	
				ml/L	DT [°C]
Pre-rinsing 1	SW	cold	2	-	-
Pre-rinsing 2	SW	cold	5	-	-
Cleaning**	PW	55	10*	6	45
Rinsing	SW	50	3	-	-
Thermal disinfection	PW	90	5	-	-
Drying	-	110	15	-	-

SW: Softened water; **PW:** Purified water; **DT:** Dosage temperature
Cleaning agent: **Neodisher® Mediclean forte**
* When temperature is reached
** When using highly alkaline cleaners
(e.g. a neutralization step is required for Neodisher® FA)

Step 1 Jointed instruments are to be opened so that water can flow out of cannulae and blind holes. Place cannulated instruments onto or connect them to appropriate rinsing nozzles (use a rinsing adapter where necessary).
Step 2 Start the relevant cycle.
Adhere to the guidelines of the WD manufacturer.
Step 3 After removing the instruments from the disinfector, check the cannulae, blind holes, etc, for visible dirt. If required, repeat cycle or clean by hand.

Manual cleaning/disinfection
A manual cleaning and disinfection procedure, even when using an ultrasound bath, should generally be avoided and should only be used if an automatic process is not available, due to very low levels of efficacy. In addition, the manual procedure can be used to support automatic reconditioning, particularly in the case of heavily soiled instruments.
Recommended equipment: Commercially available cleaning agent authorised for medical products (pH value 9-11) or combined cleaning agent and disinfectant (e.g. Sekusept® Aktiv 2% by ECOLAB); nylon brushes with soft bristles; running water.

Accessories	Gentle automatic treatment of the instruments using lint-free soft cloths, paper towels or soft plastic brushes.
Soaking the instruments	Fully submerge and soak the instruments in a suitable cleaning agent and disinfectant solution. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed when using all agents.
Cleaning agent/ disinfectant	Use of a cleaning agent/disinfectant from the VAH list. I.T.S. GmbH recommends Sekusept® Aktiv 2% by ECOLAB. When using powdered products, it must first be checked that the powder has dissolved completely in the water before the instruments are added. In addition, adhere to the manufacturer's information regarding material tolerance. If applicable: the cleaning agent must be suitable for ultrasound cleaning. (Non-foaming). Do not use highly alkaline or acidic additives. Recommended pH range 4.5 - 10.5. Prepare freshly every day.
Ultrasound treatment	Treatment in an ultrasound bath is carried out for 5 minutes in the abovementi-oned cleaning agent/disinfectant. The instrument set is then left in the solution for 15 minutes.
Rinsing/drying the instruments	Remove the instruments from the solution and rinse thoroughly with running tap water until there are no visible traces of blood or other contaminants in the rinsing water. Particular attention should be paid to lumen, openings and other areas that are not easily accessible. Rubber and flexible plastics require longer rinsing times and any dirt that remains on the instruments may have to be removed manually (no metal brushes, no abrasive cleaners). Thorough final rinsing using purified water. Dry the instruments immediately (e.g. using a lint-free disposable cloth or pressurised air gun).

Manual disinfection
If a cleaning agent without a disinfectant effect is used, separate disinfection must be carried out after manual cleaning. (Order: Decontamination for staff protection, cleaning, disinfection).
Equipment: Commercially available disinfectant authorised for use with medical products from the VAH list. Manufacturer's information, e.g. concerning concentration, temperature and exposure time should be followed. The steps described in the table above also apply.

Drying
See table above.

Checking, Maintenance and Inspection
- Each instrument or implant is to be inspected carefully to make sure that all visible dirt has been removed. If any ingrained dirt is found, the cleaning/ disinfection cycled should be repeated.
- Any instruments with an attached movable mechanism should be treated with a commercially available lubricant authorized for sterilisable surgical instruments.
- The mobility of movable parts should be checked to ensure that the planned sequence of motion can be completely carried out.
- In the case of instruments which can be reassembled into larger units, check whether the single parts can be put together easily.

Packaging
The delivery packaging is purely for transport purposes and is not suitable for sterilisation.
The hospital is responsible for in-house procedures regarding assembly, inspection and packaging of instruments. Packaging is carried out in accordance with the general standard packaging guidelines of relevant standards and guidelines of specialist organisations using sterile barrier systems that conform with standards.

Sterilization
- All instruments and implants should be laid out in such a way that the steam can reach all the surfaces of the medical devices.
- Each instrument that can be dismantled should be taken apart for sterilisation.
- Carry out sterilisation of the products using the fractionated pre-vacuum procedure, in accordance with EN 285 (or EN 13060) and EN ISO 17665. I.T.S. GmbH recommends the following validated methods for sterilising instruments:

Sterilisation with steam: Fractionated vacuum procedure (at least 3 pre-vacuum phases)	
Temperature	**Duration of sterilization**
134°C (273°F)	5 minutes 18 minutes*

* Parameters for sterilisation with steam recommended by the World Health Organisation (WHO) for recycling instruments if contamination with Creutzfeldt-Jakob Disease (CJD) pathogens is suspected.

Disposal
The valid guidelines of the hospital operator apply for disposal.

Responsibility of the Hospital for Instruments lent by I.T.S. GmbH
- Surgical instruments generally have a long service life. But their life expectancy can be quickly reduced due to misuse or insufficient protection. Instruments which no longer work correctly, whether due to wear, misuse or improper care, have to be disposed of.
- Medical products which are returned to I.T.S. GmbH must undergo cleaning, disinfection, inspection and a final sterilization. Products returned to I.T.S. GmbH must be accompanied by a confirmation of the decontamination they were subjected to.

Important information
- The above-mentioned instructions have been validated by the manufacturer of medical devices for reconditioning a medical device, the re-use of which is deemed to be suitable. It is the responsibility of the reconditioner to ensure that reconditioning actually carried out using the equipment, materials and staff available in the preparation facility achieves the desired results. For this, validation and routine inspections of the process are necessary. Likewise, any deviation from the instructions provided by the reconditioner should be evaluated for its efficiency and possible negative consequences.
- Should you have questions or problems, please contact us at the address above.

Patient Information
Implantation has consequences for the discomfort, mobility and general life circumstances of the patient. For this reason, the patient should be given instructions about appropriate behaviour to adopt after implantation, and it should be explained to him or her the necessity and the importance of reporting negative changes in the area of the implant as well as any falls and accidents which may appear not to have damaged the implant or the site of the operation.

Symbols

Rx	Prescription
	Single use
	Expiry date (year/month)
LOT	Charge number
STERILE	Sterilization by steam
STERILE R	Sterilization by radiation
STERILE EO	Sterilization by ethylene oxide
REF	Order number
MAT	Material used
QTY	Package content (no. of items)
SIZE	Size
	Pay attention to instructions
	Latex Free
NON STERILE	Non Sterile
	Do not use if package is damaged

CE 0297
RL 93/42/EWG
ÖNORM EN ISO 13485
ISO 17664

Notes

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