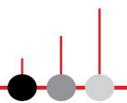


## **POLYAXIAL LOCKING PLATE SYSTEM**

**LOCKING PLATE SYSTEM**



**INSTRUCTIONS FOR USE 4.(GB)**

**Warning:** The implants described may only be used in combination with DIGI-MED products!

**OSTEOSYNTHESIS – TITANIUM IMPLANTS**

(Bone: Plates / Screws / Pins / Wires / Staples ) non-sterile

**IMPLANT MATERIAL:**

Implants made from titanium in accordance with ISO 5832-2 unalloyed Titanium; ISO 5832 – 3 Ti6A14V alloy ; ISO 5832 – 11 Ti6Al7Ni alloy manufactured by DIGI-MED. The surface of these implants is chemically passive: not magnetic. These implants can be combined with the standardised material provided that its composition lies within the analysis stipulated in the ISO 5832-2 / ISO 5832-3 / ISO 5832-11 standard and the required specifications. The material wrought unalloyed titanium and alloyed titanium, is biocompatible and prevents a so-called chrome-nickel allergy by its nature

**We would point that implants only function correctly if the following basic rules are observed:**

When selecting implants (bone: plates / screws / pins wires / clips), care must be taken to choose the appropriate implants on the basis of the weight and level of activity of the patient, and the bone fracture to be treated.

Note that by making the correct choice of biomechanics the forces to be transferred by the implants remain low.

Extreme deformation of the implants must be avoided; the cautious bending of wires, plates and pins does not, however, lead to implant damage provided it is done with sufficient care.

Repeated deformation should be avoided at all costs as it will fatigue the implant material. The re-use of implants is absolutely forbidden (single use).

We strongly advise you to inform patients of the advantages and disadvantages of implants.

Excessive strain as a result of body weight and the level of activity of the patient should be avoided due to the limited strength of the implants. Failure to observe these precautionary measures can have serious consequences for the healing process.

**INDICATIONS**

These relate to the current practice of applications of implants in osteosynthesis (e.g. see literature AO/ASIF Instruments and Implants Texhammer\*Colton ISBN 3-540-56895-6 / ISBN 0-387-56895-6).

**CONTRAINDICATIONS**

Acute and chronic infections; muscle, nerve or vascular diseases that endanger the affected extremity; a lack of bony tissue or poor bone quality (e.g. severe osteoporosis); local bone tumours. Systemic diseases and metabolic disorders; infections and falls; drug dependence; obesity; highly physical activities together with activities involving extreme vibrations which can lead to overstraining of the implants.

**NOTES**

The user should record and keep all information provided to the patient. It should be checked before use whether the patient tolerates the material to be implanted. The implants described in these instructions for use may only be used (implanted) by surgeons with the appropriate experience.

**POSSIBLE NEGATIVE EFFECTS (RISKS)**

Failure of the fracture to heal, allergy to the material, failure of the product (break, bending), bone deformation and refracture, infection.

**REMOVAL OF IMPLANTS**

The implants are normally removed once the fracture has healed.

**CLEANING AND STERILISATION OF UNSTERILE IMPLANTS**

Before use, the implants must be sterilised using a validated procedure (autoclaved).

**VALIDATED PROCEDURES**

STERILISER: Steam autoclave: Temperature = 121° to 123° Celsius; Pressure = 1 – 1.2 bar (15 to 17 psi) with an exposure time of at least 30 minutes in the packaged state.

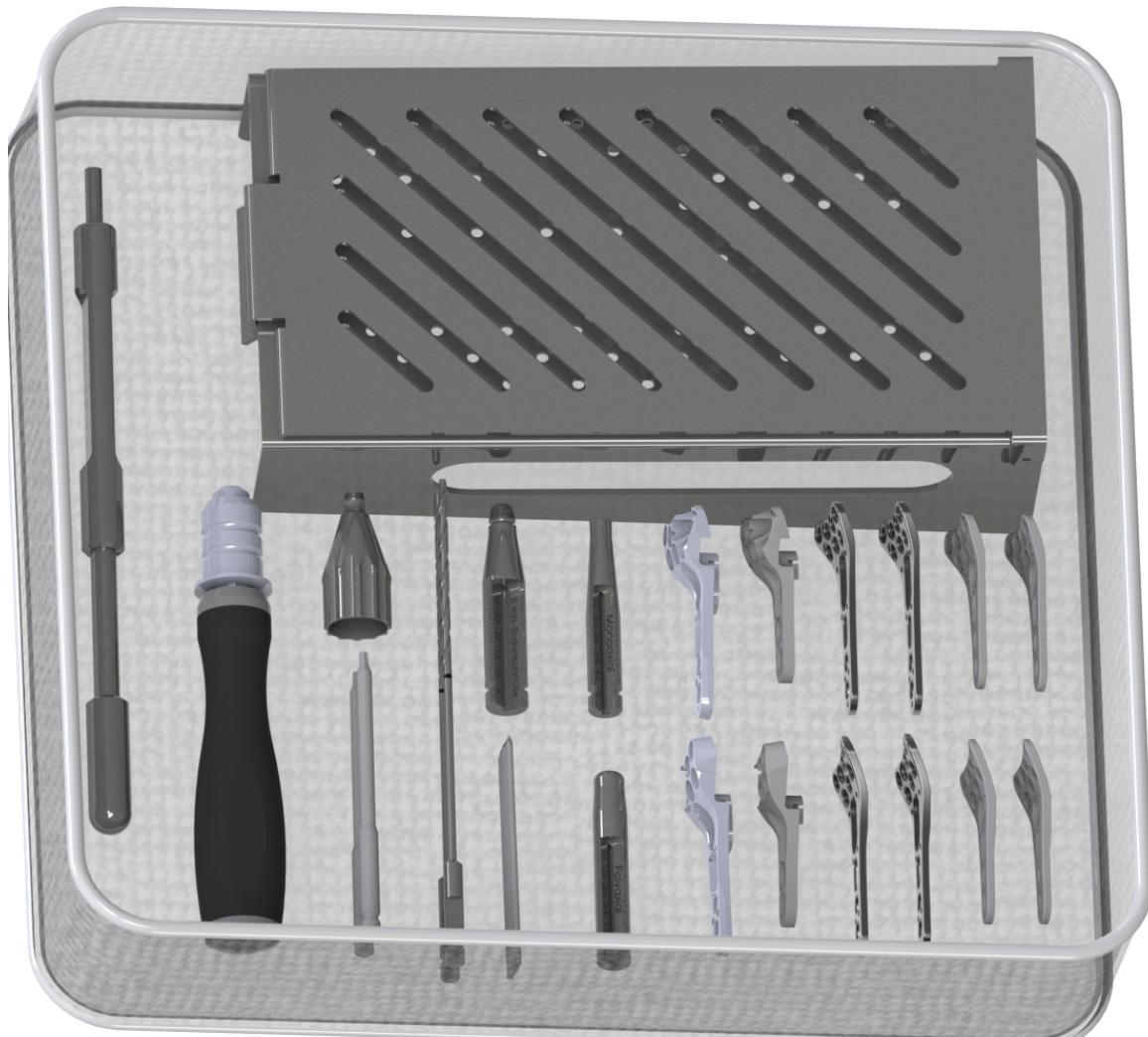
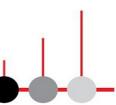
STERILISER: Autoclave with prevacuum: During the prevacuum phase the air is extracted from the chamber before the steam flows in. Standard circulation for packaged objects: 132° to 135° Celsius; Pressure = 2 – 3 bar (27 to 30 psi) with an exposure time of at least 4 to 10 minutes.

**IMPORTANT NOTES:**

**Every time the implants are used or sterilised you must first check that they function perfectly!**

In the event of failure to observe these instructions or demonstrable violation, no guarantee or compensation for damages can be provided.









Description	Order Number
DR-Platte,lang,7/3 Loch, links	93-6600-205
DR-Platte,kurz,7/3 Loch, links	93-6600-203
DR-Platte,lang,7/3 Loch, rechts	93-6600-204
DR-Platte,kurz,7/3 Loch, rechts	93-6600-202

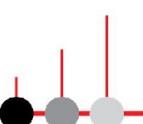


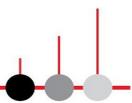


Description	Order Number
Bohrblock, lang, rechts, f.Radiuspl.	93-7100-204
Bohrblock, lang, links, f.Radiuspl.	93-7100-205



Description	Order Number
Bohrblock, kurz, rechts, f.Radiuspl.	93-7100-20
Bohrblock, kurz, rechts, f.Radiuspl.	93-7100-203



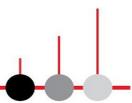


**7 degrees of Extensions angles**

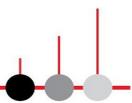


**12 degrees of Extensions angles**





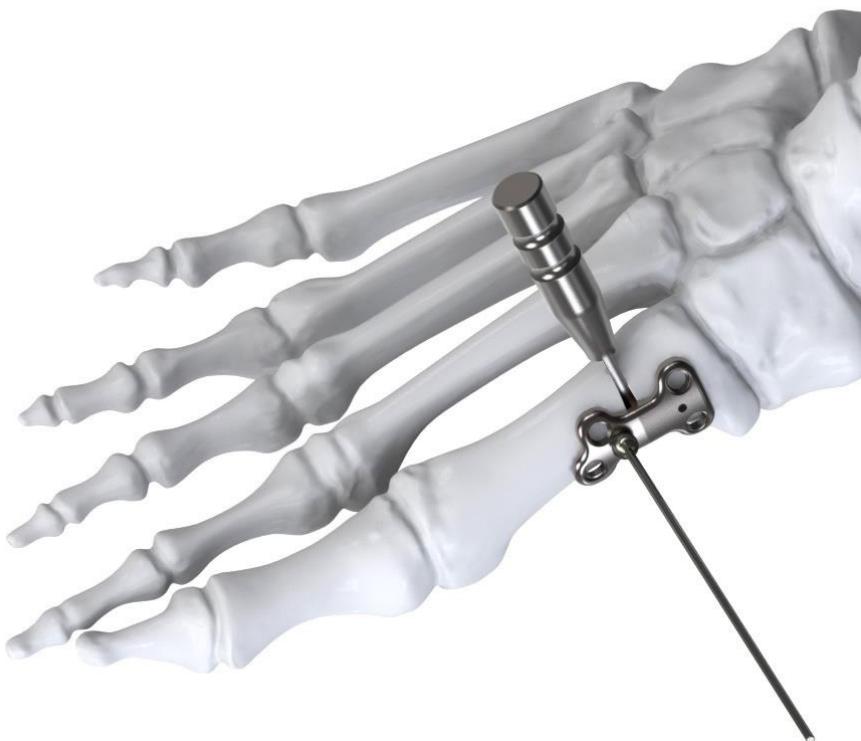




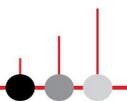
## Plates for Correction of Hallux Valgus











**PTXL Polyaxial stable-angle screw**  
AD thread 2.7 mm, ID core 1,9 mm, Torx 7

Description	Order Number
Kort.PTXL Schraube 2.7mm, L 10mm	93-6127-010PTXL
Kort.PTXL Schraube 2.7mm, L 12mm	93-6127-012PTXL
Kort.PTXL Schraube 2.7mm, L 14mm	93-6127-014PTXL
Kort.PTXL Schraube 2.7mm, L 16mm	93-6127-016PTXL
Kort.PTXL Schraube 2.7mm, L 18mm	93-6127-018PTXL
Kort.PTXL Schraube 2.7mm, L 20mm	93-6127-020PTXL
Kort.PTXL Schraube 2.7mm, L 22mm	93-6127-022PTXL
Kort.PTXL Schraube 2.7mm, L 24mm	93-6127-024PTXL
Kort.PTXL Schraube 2.7mm, L 26mm	93-6127-026PTXL
Kort.PTXL Schraube 2.7mm, L 28mm	93-6127-028PTXL
Kort.PTXL Schraube 2.7mm, L 30mm	93-6127-030PTXL
Kort.PTXL Schraube 2.7mm, L 32mm	93-6127-032PTXL
Kort.PTXL Schraube 2.7mm, L 34mm	93-6127-034PTXL
Kort.PTXL Schraube 2.7mm, L 36mm	93-6127-036PTXL





**TX non-stable-angle screw**  
AD thread 2,7 mm, ID core 1,9 mm, Torx7

Description	Order Number
Kort. TX Schraube. 2,7mm Tit. L. 10mm	93-6127-010TX
Kort. TX Schraube. 2,7mm Tit. L. 12mm	93-6127-012TX
Kort. TX Schraube. 2,7mm Tit. L. 14mm	93-6127-014TX
Kort. TX Schraube. 2,7mm Tit. L. 16mm	93-6127-016TX
Kort. TX Schraube. 2,7mm Tit. L. 18mm	93-6127-018TX
Kort. TX Schraube. 2,7mm Tit. L. 20mm	93-6127-020TX
Kort. TX Schraube. 2,7mm Tit. L. 22mm	93-6127-022TX
Kort. TX Schraube. 2,7mm Tit. L. 24mm	93-6127-024TX
Kort. TX Schraube. 2,7mm Tit. L. 26mm	93-6127-026TX
Kort. TX Schraube. 2,7mm Tit. L. 28mm	93-6127-028TX



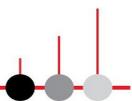


Description	Order Number
Eindrehbohrhülse ID 1,9 mm polyaxial	93-7100-009



Description	Order Number
Eindrehbohrhülse DI 1,9 mm	93-7100-019





Description	Order Number
Bohrer 1.9mm, m.AO-Anschl.	93-7100-010



Description	Order Number
Kirschner m. Trokarspitze, rd. Ende 1.6mm/6.0cm	93-0331-016



Description	Order Number
Schraubenmesslehre	93-8202-000





Description	Order Number
Schraubendrehergriff m.AO-Anschl.	93-7100-005



Description	Order Number
Schraubendreher TORX7	93-7100-004





## Notes

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

DIGI-Med Medizintechnik, Kreutzerstraße 1, D-78573 Wurmlingen, Germany

