

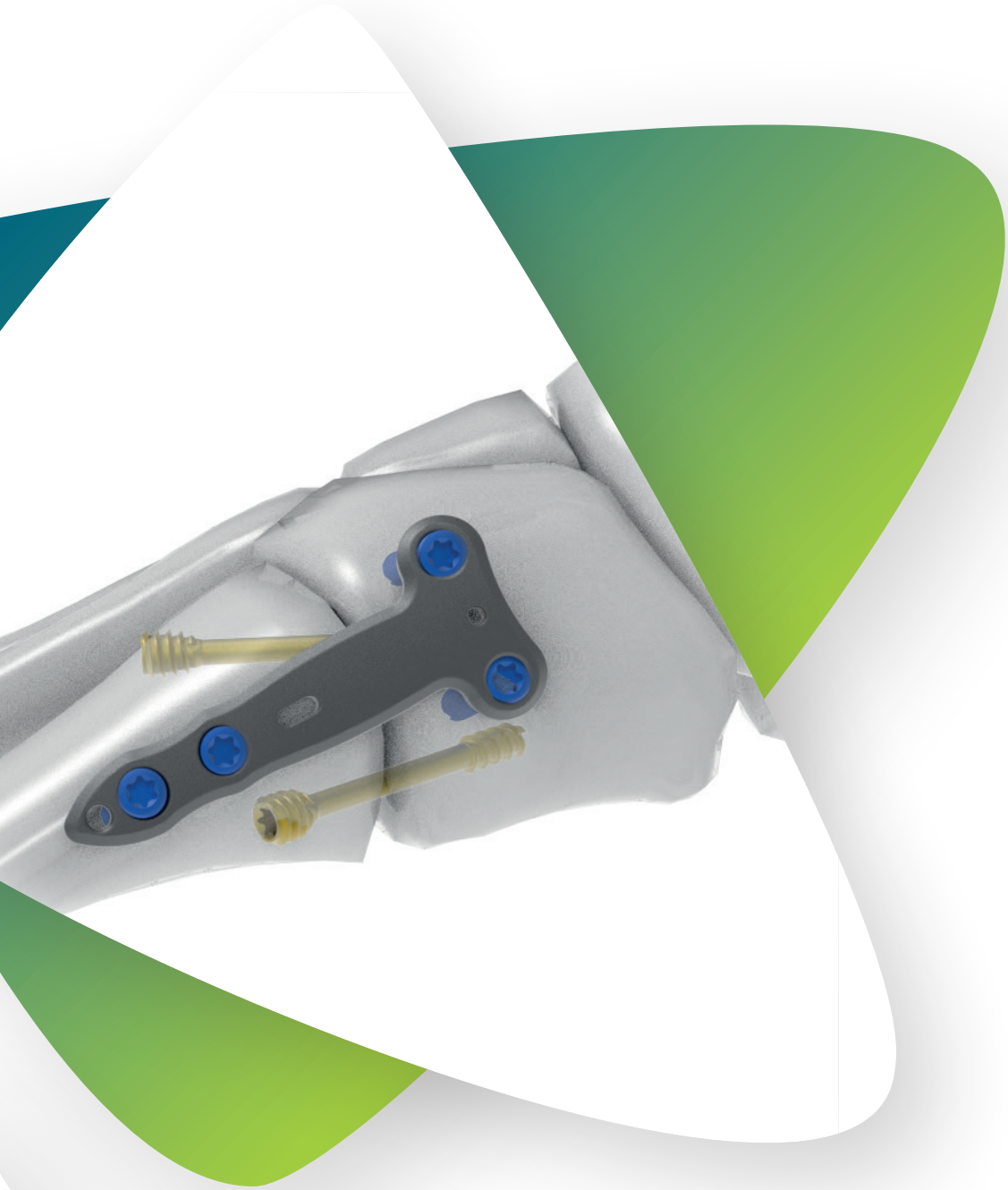


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Rev.00.0

MAXXOS MEDICAL



# P.A.C.E.

TMT-I Fusion Plate

Operation Manual



**P**recise.
**A**ccurate.
**C**omprehensive.
**E**ffective.

# CONTENTS

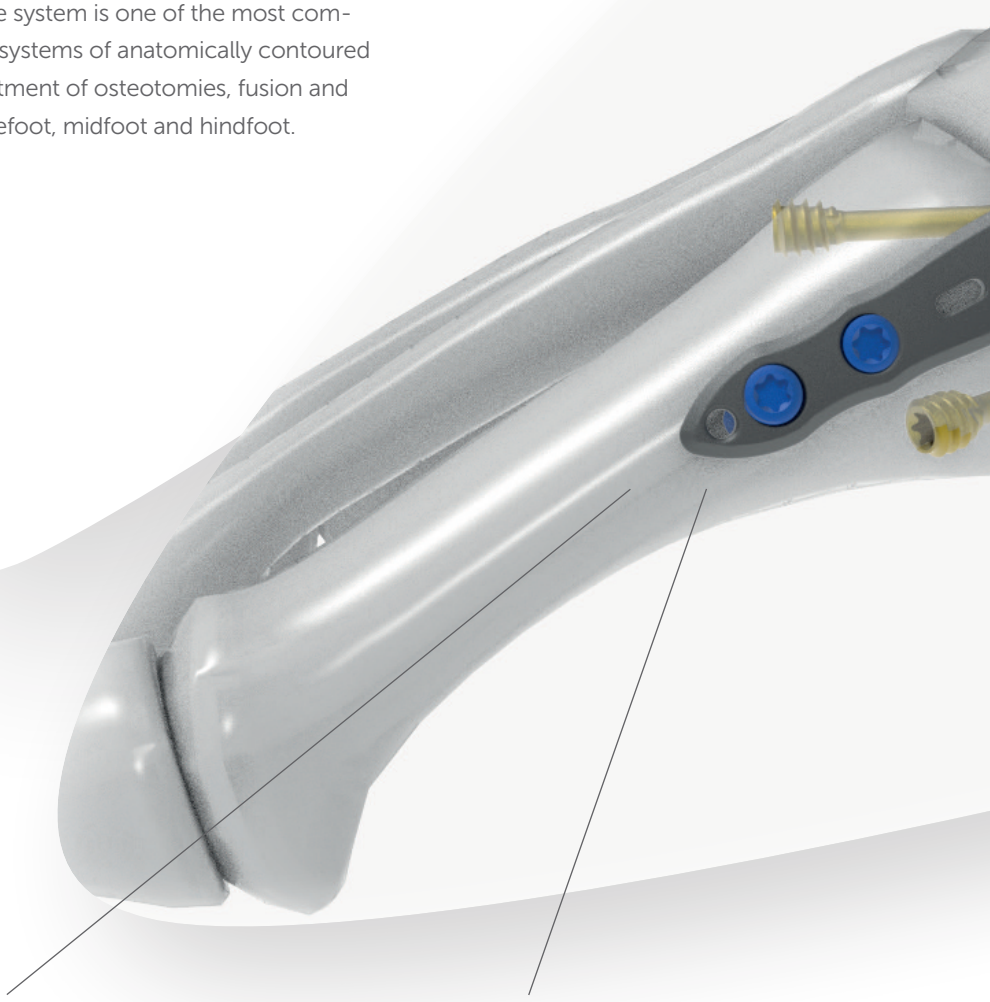

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**WARNING**

This Operation Manual alone does not provide sufficient background for direct use of the instrument and implant set. The usage of the system by a surgeon experienced in handling these implants and instruments is highly recommended for safe and effective use of this implant systems, the surgeon should be familiar with this recommened surgical technique for the device that has been choosen from the system. In every case, accepted surgical practice should be followed in postoperative care and the patient should be made aware about the operations and the allowed acitvities with these implants.

# 01
# PRODUCT FEATURES

The MAXXOS-Medical P.A.C.E. Foot Plating Systems offers a wide range of different plates for fore-, mid- and hindfoot as well as fracture specific plates for ankle fractures. The system is one of the most comprehensive plating systems of anatomically contoured to address the treatment of osteotomies, fusion and fractures in the forefoot, midfoot and hindfoot.

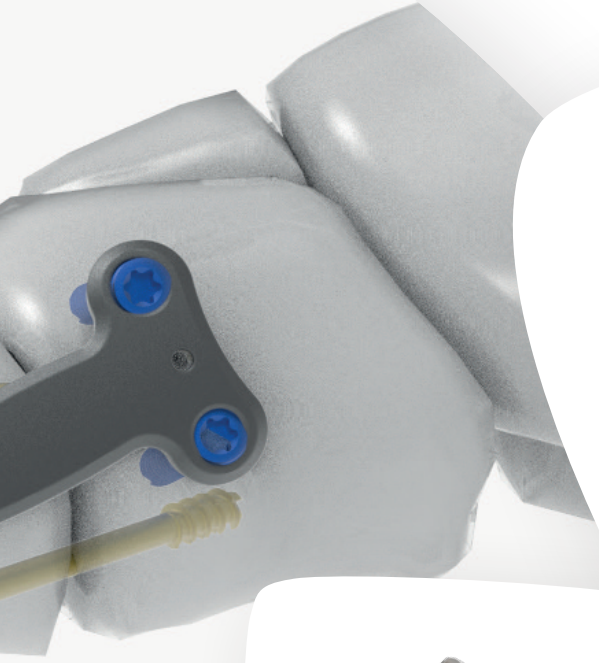


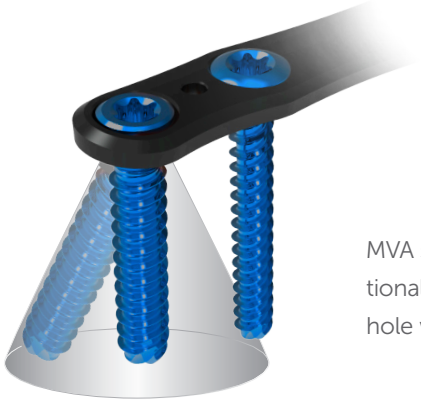
All plates are type II anodized, which makes the surface of the titanium about 15 % harder and reduces the risk of cold welding.

Special plate designs for the treatment of fractures, fusions and osteotomies in the mid- and hindfoot area.



Pre-contoured anatomically shaped plates for different indications in fore-, mid- and hindfoot procedures.





MVA solution allows the multidirectional usage of the screws in every hole with a total variability of 24°.




Colour coding systems allows an easy use of the instruments with the different plating systems. All instruments are colour coded with a ceramic mark related to the screw colour.

# 02
# GENERAL INFORMATION

## INDICATIONS

MAXXOS-Medical GmbH Osteosynthesis implants are used for fixation of fractures, fusions in case of osteoarthritis or corrective interventions in case of anatomical malalignments, osteotomies in case of malalignments and reconstructions of extremities. The use of MAXXOS-Medical GmbH Osteosynthesis implants for treating fractures, fusions, osteotomies and reconstructions of extremities requires the following, general indications:

- The patient is in a good condition
- Good neurovascular condition
- Sufficient skin cover
- Good bone substance for the implants
- Post-operative care is possible
- Patient is cooperative

## CONTRAINDICATIONS

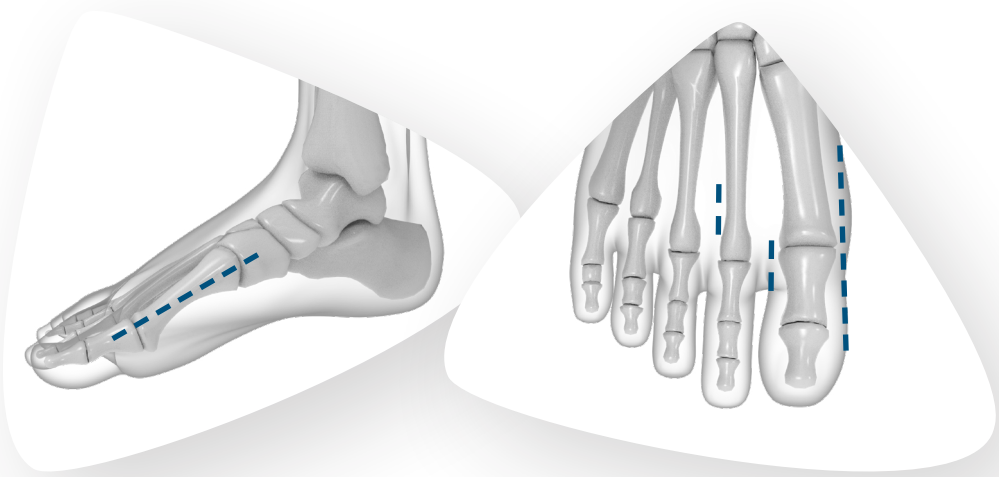
The P.A.C.E. Fracture and Fusion Plating system has no product specific limitation or contraindications. General contraindications are as follows:

- All concomitant diseases that can endanger / interfere with the fixation or the success of the surgery.
- Poor bone substance / structure which endangers or has a negative effect on the secure fixation of implants
- Serious muscular, neurological or vascular diseases that endanger or have a negative effect on the success of the procedure / surgery
- Patients with allergies susceptible to allergic shock / soft tissue reactions because of the material used in the implant
- Acute or chronic, local or systematic infections.
- Inflammations
- Smoking which can endanger the success of the procedure / surgery by delayed bone healing / wound healing.
- Physically or mentally unstable patient
- Option of conservative treatment
- Growing patient with open epiphyses
- Patient with high level of activity

# 03
# OPERATION MANUAL

01. Incision
02. Joint Preparation as per Surgeon's preference
2a. Joint preparation with a thin saw blade
2b. Joint preparation with osteotomes, curettes and burrs
03. Alignment of the 1st to the 2nd ray
04. Guide Wire insertion for the ø 3,0 / 4,0 mm DuoFix screws.
05. DuoFix ø 3,0 / 4,0 mm Screw Insertion
06. Medial TMT I plate placement
07. Drilling the hole
08. Determining the appropriate Screw length
09. Insertion of the appropriate locking or non locking screw
10. Insertion of the other screws
11. Removal of the MT1 / MT2 K-wire
12. Akin Closing wedge Osteotomy is performed at this point if required
13. Capsular Plication Closure as per Surgeon's preference
14. Check X-Ray and layered surgical closure per Surgeon's Preference

## 01 INCISION

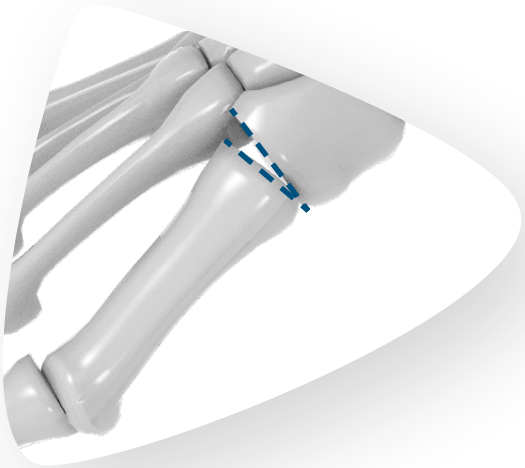


Medial Longitudinal Incision is made with a combined 1st Web dorsal incision for the modified McBride release and lateral to the midpoint of the 2nd Metatarsal Shaft. Medial Capsuloraphy is performed and the exostosis is removed ensuring the medial sesamoid groove is not involved.

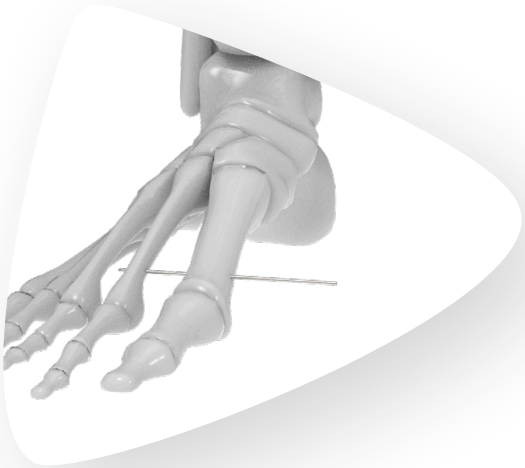
**OPERATION OPTION:** Pass a non-absorbable suture around the MT2 shaft, care is taken to avoid damage to the EDL tendons as described in the Paper: "Anatomical reconstruction of first ray instability hallux valgus with a medial anatomical TMTJ1 plate". After the incision a vertical incision of the medial capsule of the 1st TMTJ is being performed. Distract the joint by plantarflexing and abducting the MT1.

[1] Anatomical reconstruction of first ray instability hallux valgus with a medial anatomical TMTJ1 plate - F.J. McCabe*, P.M. McQuail, L. Turley, R. Hurley, R.A. Flavin

## 02 JOINT PREPARATION AS PER SURGEON'S PREFERENCE



## 03 ALIGNMENT OF THE 1ST TO THE 2ND RAY



Align MT1 to MT2 and pass a 1.4 / 1.6 mm K-Wire from the MT1 to the MT2 parallel to the "floor" to ensure temporary alignment fixation and ensure appropriate sagittal plane alignment.

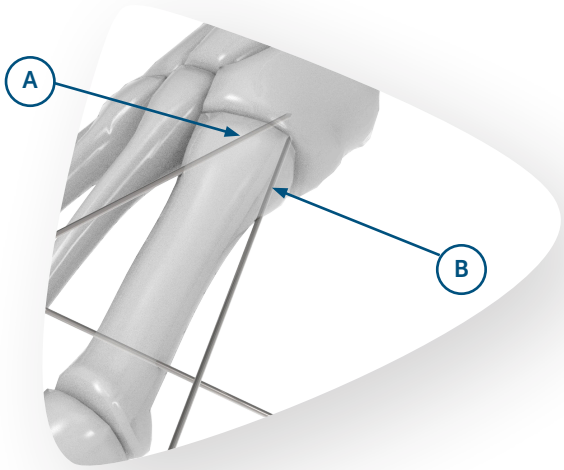
## 2A JOINT PREPARATION WITH A THIN SAW BLADE

Cut the bone and remove a lateral wedge on both bones, the Proximal Metatarsal and the Medial Cuneiform. Take care of the length of the first ray.

## 2B JOINT PREPARATION WITH OSTEOTOMES, CURETTES AND BURRS

Debride the cartilage with a small 3 – 4 mm Osteotome or Curette followed by subchrondral drilling with a ø 2 mm Drill Bit and using a ø 3 mm Spherical Burr to "sculpt" the fusion surfaces. Therefore ensuring minimal shortening of the 1st Metatarsal.

## 04 GUIDE WIRE INSERTION FOR THE Ø 3,0 / 4,0 MM DUOFIX SCREWS

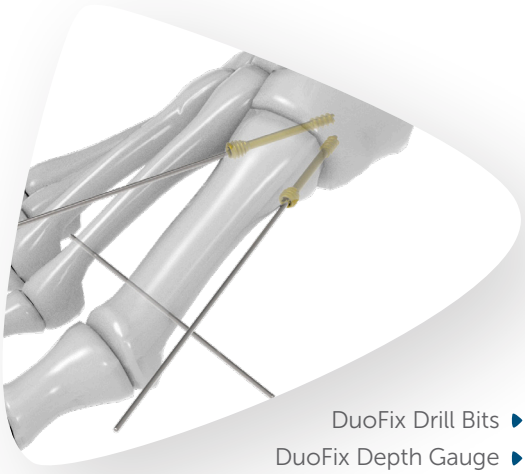



DuoFix Guide Wire ▸ P. 16

Insert two 1.0 mm Guide K-Wires.

**Wire ( A ):** Inserted dorsoplantar direction in the lateral 50 % of the TMTJ.
**Wire ( B ):** Inserted from medial MT1 to the Lateral portion of the Medial Cunieform in the plantar 50 % of the TMTJ.

## 05 DUOFIX Ø 3,0 / 4,0 MM SCREW INSERTION

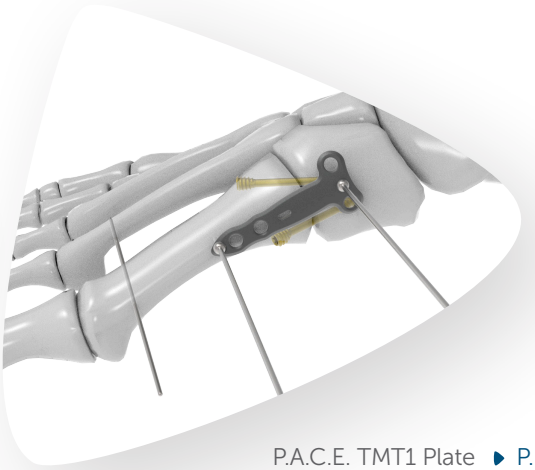


DuoFix Drill Bits ▸ P. 16
DuoFix Depth Gauge ▸ P. 16
DuoFix T8 Screwdriver cannulated ▸ P. 16

Insert two ø 3,0 / 4,0 mm Duofix Compression Screws over the Guide Wires in either the predrilled or self drilling method. The guide wires are placed and controlled under Fluorsocopy. Use the measuring device to determine the screw lengths.

**ATTENTION:** The cannulated ø 2,0 mm drill and the 3,0 / 4,0 mm countersink can be used to predrill the hole. After determining the appropriate screw length use the cannulated T8 Screw Driver Shaft and insert the required screws.

## 06 MEDIAL TMT I PLATE PLACEMENT

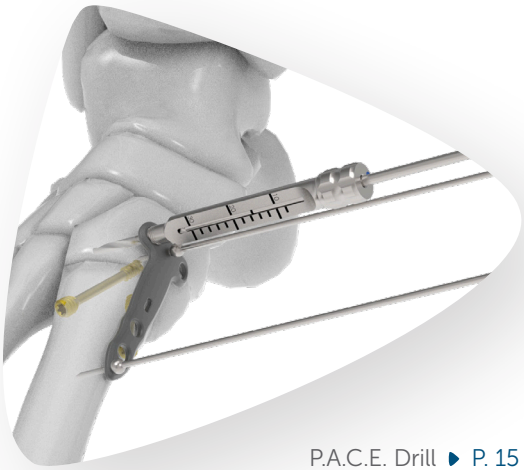


P.A.C.E. TMT1 Plate ▸ P. 14
1.2 mm wires with olives ▸ P. 17

Medial TMT1 Plate applied ensuring anatomical placement on the medial side and the temporary fixation of the plate to the bone with two ø 1.2 mm Wires with Olive. It is recommended to put the standard ø 2,8 mm Drill Guide to the dorsal / proximal screw hole for an easier insertion of the plate.

**ATTENTION:** Avoid the Tibialis Anterior Tendon.

## 07 DRILLING THE HOLE



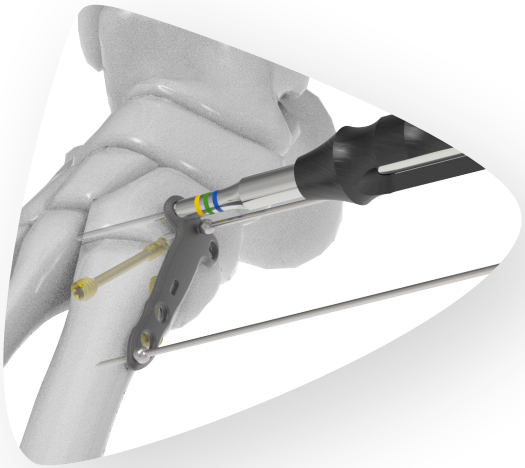
P.A.C.E. Drill ▸ P. 15
P.A.C.E. Drill Guide ▸ P. 14

Using the blue color coded ø 2,0 mm Drill to drill the hole for the first ø 2,8 mm Screw.

**ATTENTION:** Only in cases where you need to compress the plate to the bone a ø 2,8 mm Non Locking Screw can be inserted.

**ATTENTION:** Using the MVA Drill Guide. The divergent direction of the vertical T-limb holes offers enough space for the compression screws and therefore using the MVA is only required in special cases.

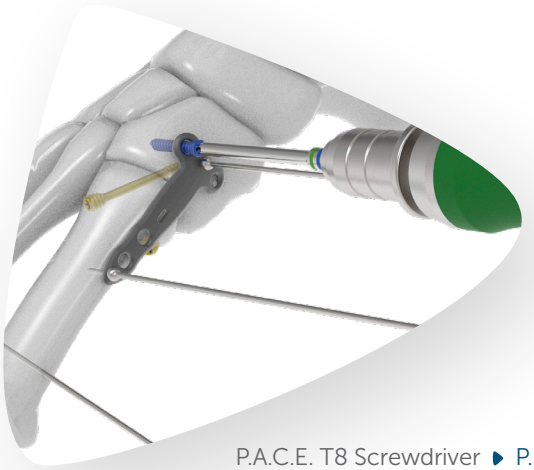
## 08 DETERMINING THE APPROPRIATE SCREW LENGTH



P.A.C.E. Depth Gauge ▸ P. 15

Determine the appropriate screw length with the blue color coded Depth Gauge. The screw length can be also determined with the mark on the blue color coded drill bit and the standard graduated Drill Guide with window.

## 09 INSERTION OF THE APPROPRIATE LOCKING OR NON-LOCKING SCREW

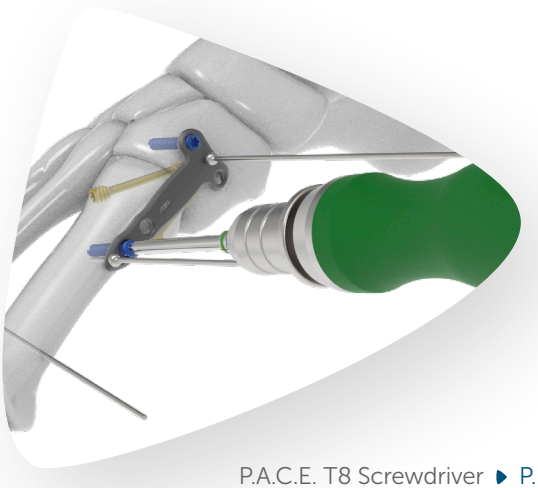


P.A.C.E. T8 Screwdriver ▸ P. 16
P.A.C.E. 2.8 mm MVA Screw ▸ P. 13

Inserting the appropriate screw size, either the Locking MVA or ø 2,8 mm Non Locking Screw, with the blue color coded T8 Screw Driver Shaft.

**ATTENTION:** Control the screw on the screw caddy.

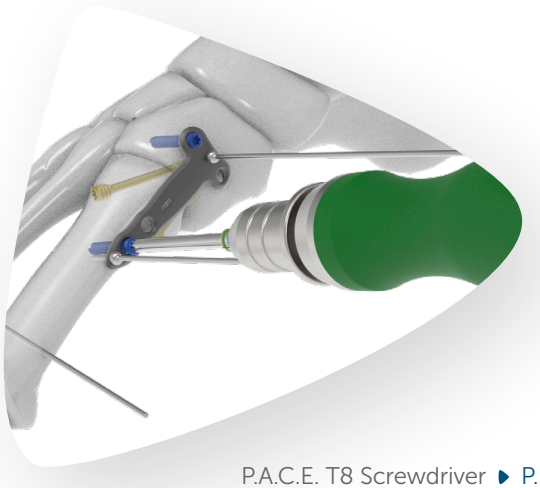
## 10 INSERTION OF THE OTHER SCREWS



P.A.C.E. T8 Screwdriver ▸ P. 16
P.A.C.E. 2.8 mm MVA Screw ▸ P. 13

Repeat steps 8 – 11 and insert the shaft screws in the Metatarsal and the plantar screw of the T-limb.

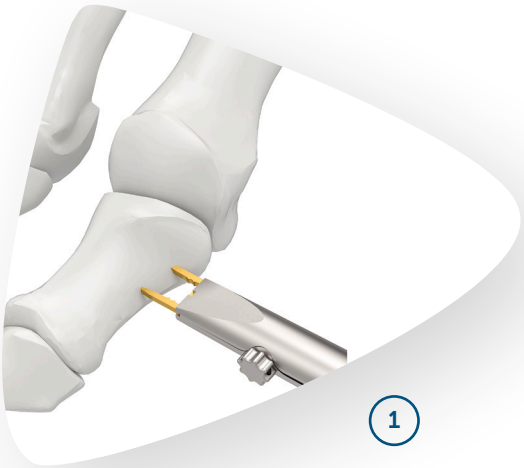
## 11 REMOVAL OF THE MT1 / MT2 K-WIRE



P.A.C.E. T8 Screwdriver ▸ P. 16
P.A.C.E. 2.8 mm MVA Screw ▸ P. 13

The temporary MT1 / MT2 k-Wire is removed.
**ATTENTION:** Operation Option: The plantar portion of the Suture around the MT2 is passed by a trans-osseus method through the MT1 wire hole and the dorsal portion is passed dorsal to the MT1, and tightened – augmenting the correction. (See step 1)

## 12 AKIN CLOSING WEDGE OSTEOTOMY IS PERFORMED AT THIS POINT IF REQUIRED



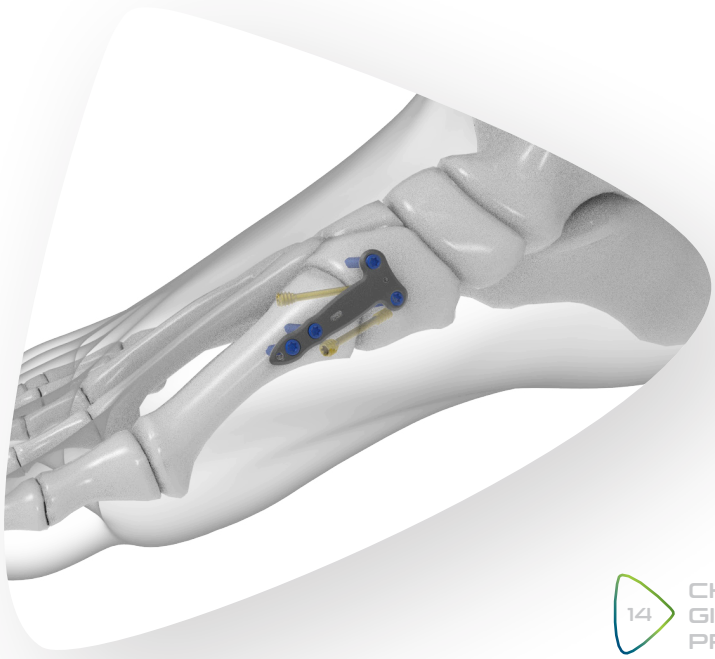




DuoFix C-Fix Staples ▸ P. 14

The incision is extended distally. The PP1 shaft is exposed dorsally and plantarly and Hoffmann's retractors are used to protect the FHL and EHL tendons.
An incomplete closing wedge Osteotomy is performed at least 10 mm from the PP1 MTPJ articular surface. The osteotomy is closed and using the MAXXOS Akin Staple Guide two 1.4 mm k-Wire holes are made on either side of the osteotomy 8 or 10 mm apart depending on which C-Fix Akin Staple is being used. Impact the chosen C-Fix Staple (Image **1**) till flush with the PP1 surface (Image **2**).

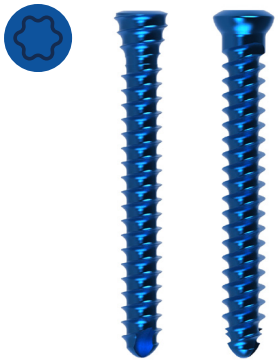
## 13 CAPSULAR PLICATION CLOSURE AS PER SURGEON'S PREFERENCE



## 14 CHECK XRAY AND LAYERED SURGICAL CLOSURE PER SURGEON'S PREFERENCE.

# 04
# IMPLANTS

## P.A.C.E.
## 2,8 MM CORTICAL SCREW



| LENGTH | ARTICLE NO. | |
|---|---|---|
| | Locking Screw (MVA) | Non Locking Screw |
| 8 mm | M113128-008 | M112128-008 |
| 10 mm | M113128-010 | M112128-010 |
| 12 mm | M113128-012 | M112128-012 |
| 14 mm | M113128-014 | M112128-014 |
| 16 mm | M113128-016 | M112128-016 |
| 18 mm | M113128-018 | M112128-018 |
| 20 mm | M113128-020 | M112128-020 |
| 22 mm | M113128-022 | M112128-022 |
| 24 mm | M113128-024 | M112128-024 |
| 26 mm | M113128-026 | M112128-026 |
| 28 mm | M113128-028 | M112128-028 |
| 30 mm | M113128-030 | M112128-030 |

## DuoFix
## Ø 3,0 / 4,0 MM SCREW FOREFOOT



| LENGTH | ARTICLE NO. |
|---|---|
| 10 mm | M111334-010 |
| 12 mm | M111334-012 |
| 14 mm | M111334-014 |
| 16 mm | M111334-016 |
| 18 mm | M111334-018 |
| 20 mm | M111334-020 |
| 22 mm | M111334-022 |
| 24 mm | M111334-024 |
| 26 mm | M111334-026 |
| 28 mm | M111334-028 |
| 30 mm | M111334-030 |
| 32 mm | M111334-032 |
| 34 mm | M111334-034 |
| 36 mm | M111334-036 |

## P.A.C.E.
## 2,8 MM MEDIAL TMT I FUSION PLATE



| INDICATION | DESCRIPTION | ARTICLE NO. | SCREW TYPE |
|---|---|---|---|
| ▸ Neutralizing plate for the Fusion of the TMT I Joint | 4 Hole | M211152-004 | |

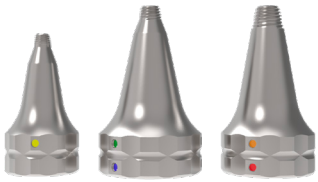
## DuoFix
## C-FIX STAPLES



| LENGTH | ARTICLE NO. 90° | ARTICLE NO. 26° |
|---|---|---|
| 8 mm | M5110810-10 | M5120810-10 |
| 10 mm | M5111010-10 | M5121010-10 |

# 04 INSTRUMENTS

## P.A.C.E.
## MVA DRILL GUIDE



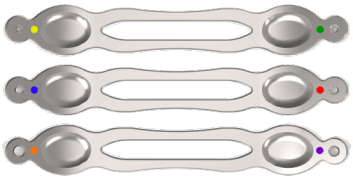
| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI05101-020 | ø 2,0 mm |
| MI05101-028 | ø 2,5 / 2,8 mm |
| MI05101-030 | ø 3,0 / 3,5 mm |

## P.A.C.E.
## LOCKING DRILL GUIDE WITH / WITHOUT WINDOW



| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI03101-020 | ø 2,0 / 1,5 mm Drill with window |
| MI03101-025 | ø 2,5 / 1,7 mm Drill with window |
| MI03101-028 | ø 2,8 / 2,0 mm Drill with window |
| MI03101-030 | ø 3,0 / 2,0 mm Drill with window |
| MI03101-035 | ø 3,5 / 2,5 mm Drill with window |
| MI03101-036 | ø 3,5 / 2,5 mm Drill without window |
| MI03101-040 | ø 4,0 / 3,0 mm Drill without window |

## P.A.C.E.
## DOUBLE DRILL GUIDE



| ARTICLE NO. | PLATTENSYSTEM |
|---|---|
| MI01201-015 | ø 2,0 / 2,5 mm / ø 1,5 / ø 1,7 mm |
| MI01201-020 | ø 2,8 / 3,0 mm / ø 2,8 / ø 3,0 mm |
| MI01201-030 | ø 3,5 / 4,0 mm / ø 3,5 / ø 4,0 mm |

## P.A.C.E.
## DRILL WITH / WITHOUT SCALE



| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI11115-115 | ø 2,0 mm / 115 mm |
| MI11117-115 | ø 2,5 mm / 115 mm |
| MI11120-115 | ø 2,8 mm / 115 mm |
| MI11120-1151 | ø 3,0 mm / 115 mm |
| MI11125-125 | ø 3,5 mm / 125 mm |
| MI11125-150 | ø 3,5 mm / 150 mm |
| MI11130-125 | ø 4,0 mm / 125 mm |
| MI11130-150 | ø 4,0 mm / 150 mm |

## P.A.C.E.
## DEPTH GAUGE



| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI51101-040 | ø 2,0 / 2,5 / 2,8 mm / 40 mm |
| MI51101-050 | ø 3,0 / 3,5 / 4,0 mm / 50 mm |
| MI51101-060 | ø 3,0 / 3,5 / 4,0 mm / 60 mm |

## P.A.C.E.
## BENDING AND POSITIONING INSTRUMENT



| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI71000-020 | ø 2,0 mm |
| MI71000-028 | ø 2,5 / 2,8 mm |
| MI71000-040 | ø 3,0 / 3,5 mm |

## P.A.C.E.
# SCREW DRIVER BLADE



| ARTICLE NO. | PLATING SYSTEM |
|---|---|
| MI41101-006 | ø 2,0 mm / T6 |
| MI41102-108 | ø 2,5 / 2,8 mm / T8 |
| MI41102-110 | ø 3,0 / 3,5 mm / T10 |

## DuoFix
# GUIDE WIRE



| ARTICLE NO. | DESCRIPTION / SYSTEM |
|---|---|
| M3211210-1001 | DuoFix Guide Wire, ø 1,0 mm x 100 mm |
| M321316-190 | DuoFix Guide Wire, ø 1,6 mm x 100 mm |

## DuoFix
# DRILL BITS, AO



| ARTICLE NO. | DESCRIPTION / SYSTEM |
|---|---|
| MI14534-056 | ø 3,0 / 4,0 mm, Step Drill Bit, cannulated, AO |
| MI11534-072 | ø 3,0 / 4,0 mm, Drill Bit, cannulated, AO |

## DuoFix
# SCREW DRIVER BLADE, AO



| ARTICLE NO. | DESCRIPTION / SYSTEM |
|---|---|
| MI41105-108 | Screw Driver Blade, MO-Drive, T8 |

## DuoFix
# COUNTERSINK, AO



| ARTICLE NO. | DESCRIPTION / SYSTEM |
|---|---|
| MI21134-056 | ø 3,0 / 4,0 mm, Step Drill Bit, cannulated, AO |

## DuoFix
# DEPTH GAUGE



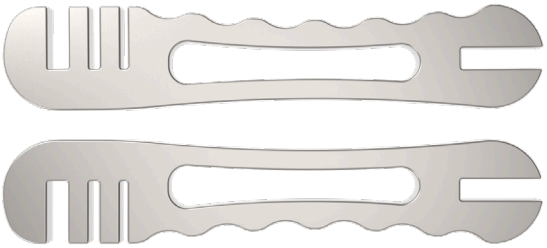

| ARTICLE NO. | DESCRIPTION / SYSTEM |
|---|---|
| MI54104-130 | DuoFix / DuoMISFix Measuring Device |

## P.A.C.E.
## K-WIRES WITH OLIVE



| ARTICLE NO. | VERSION |
|---|---|
| M321110-150 | ø 1,0 mm / 150 mm |
| M321112-150 | ø 1,2mm / 150 mm |
| M321112-1501 | ø 1,2 mm / 150 mm / long |
| M321114-150 | ø 1,4 mm / 150 mm |
| M321116-150 | ø 1,6 mm / 150 mm |

## P.A.C.E.
## BENDING IRON



| ARTICLE NO. | VERSION |
|---|---|
| MI71001-000 | Left |
| MI71001-001 | Right |

## P.A.C.E.
## HANDLES, AO



| ARTICLE NO. | VERSION |
|---|---|
| MI42101-001 | AO / QC small |
| MI42101-002 | AO / QC medium |
| MI42102-001 | AO / QC small, cannulated |

## P.A.C.E.
## HOHMANN RETRACTOR



| ARTICLE NO. | VERSION |
|---|---|
| MI71101-006 | 6 mm |
| MI71101-008 | 8 mm |

# 05
# CLEANING INSTRUCTIONS

**ATTENTION FOR CLEANING DEPTH GAUGE:**

The Depth Gauge needs to be disassambled complete into the three single parts (Outer Sleeve / Inner Sleeve and Measuring Needle) for cleaning. It is recommended to clean them first manually before putting them disassambled into the washing tray.

