OPERATIVE TECHNIQUE

Eight-Plate

Guided Growth System®

ORTHOFIX®
ORTHOPEDICS

Eight-Plate

Guided Growth System®

Contents

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

Operative Technique Contributing Surgeon:
Peter M. Stevens, M.D.

GENERAL DESCRIPTION

The Guided Growth Plate System consists of different sizes of eight-Plate and quad-Plate plus cannulated and solid screw options. The plates feature a contoured waist and low profile for pediatric usage. There is a center hole in the plates for a temporary guide pin to be implanted to aid application and removal of the plate. The plates are attached to the external surface of the bone over the growth plate by screws. These screws are not locked to the plate, but rather are allowed to swivel and diverge in their position as bone growth occurs. The implant acts like a flexible hinge, permitting growth at the growth plate to gradually straighten the limb.

IMPLANT PRINCIPLES

The Guided Growth Plate System acts like a flexible hinge and can temporarily inhibit bone growth in the area where plates and screws are applied.

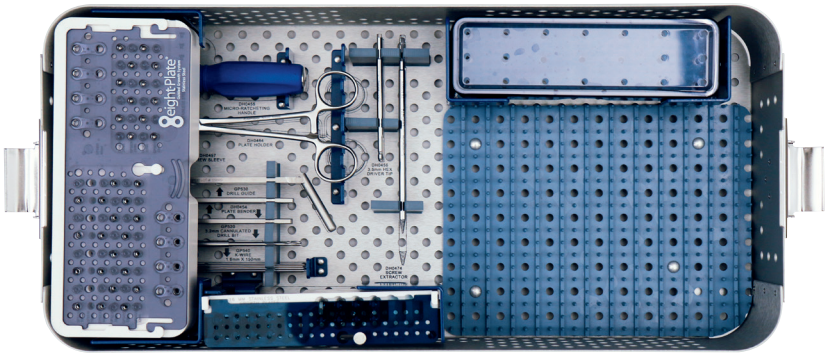
By tethering only one side of the physis (hemi- epiphysiodesis) bone growth is not inhibited in the remaining areas of the growth plate, providing the potential to redirect the growth of long bones to gradually correct angular deformities of lower limbs.

By tethering two opposite sides of the same physis the longitudinal bone growth is temporarily halted, providing the potential to correct limb length discrepancies

FEATURES AND BENEFITS

- Dedicated for gradually correcting deformities of long bones in growing children
- Color coded plates and screws
- Sterile and non-sterile implants
- eight-Plate (for two screws) and quad-Plate (for four screws)
- Minimally invasive
- Early weight bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel

SALES CONFIGURATION



GP801CE - Steri-Tray, Guided Growth (Empty)		
Part#	**Description**	**Qty**
GP200CE	Plate, Guided Growth, 12mm, Non-Sterile	8
GP400CE	Plate, Guided Growth, 16mm, Non-Sterile	8
GP224CE	Screw, Guided Growth Plate, 24mm, Non-Sterile	16
GP432CE	Screw, Guided Growth Plate, 32mm, Non-Sterile	16
GP624CE	Screw, Solid, eight-Plate, 24mm, Non-Sterile	12
GP632CE	Screw, Solid, eight-Plate, 32mm, Non-Sterile	12
GP116CE	Screw, Guided Growth, 16mm, Non-Sterile	8
GP520CE	Cannulated Drill Bit, eight-Plate, 3.2mm, Quick Connect	2
GP530CE	Drill Guide, Eight Plate	1
GP540CE	K-Wire, Ø 1.6 X 150mm	14
GPQ800CE	Guided Growth Quad Plate 16mm Hole Spacing, Non-Sterile	4
GPQ900CE	Guided Growth Quad Plate 22mm Hole Spacing, Non-Sterile	4
DH0454CE	Guided Growth Plate Bender	2
DH0455CE	Micro-Ratcheting Handle with AO Connector, Cannulated	1
DH0456CE	3.5mm Hex Driver Tip with AO Connector, Cannulated	2
DH0457CE	Screw Sleeve For Ø 5.0mm Shaft	1
DH0464CE	Guided Growth Plate Holder	1
DH0474CE	Guide Growth, Screw Extractor	1
GP800CE	**eight-Plate Steribox, complete**	

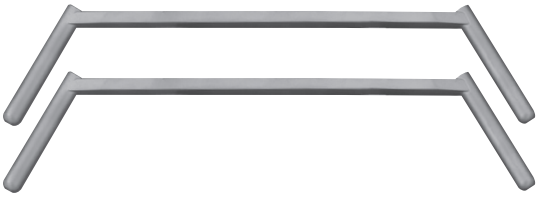
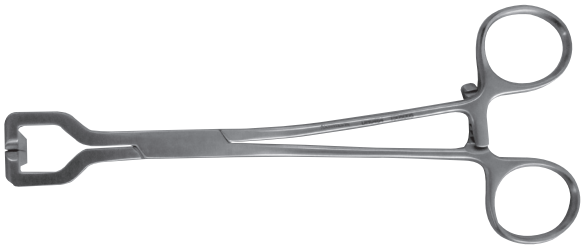
GP901CE, Guided Growth (Stainless Steel) Steribox, empty		
Part#	**Description**	**Qty**
GP520CE	Cannulated Drill Bit, eight-Plate, 3.2mm, Quick Connect	2
GP530CE	Drill Guide, eight-Plate	1
GP540CE	K-Wire, 1.6 X 150mm	14
DH0454CE	Guided Growth Plate Bender	2
DH0455CE	Micro-Ratcheting Handle with AO Connector, Cannulated	1
DH0456CE	3.5mm Hex Driver Tip with AO Connector, Cannulated	2
DH0457CE	Screw Sleeve For Ø 5.0mm Shaft	1
DH0464CE	Guided Growth Plate Holder	1
DH0474CE	Guide Growth, Screw Extractor	1
GPS224CE	Guided Growth, 4.5mmx24mm Cannulated Ss Screw, Full Thread, Non-Sterile	16
GPS432CE	Guided Growth, 4.5mmx32mm Cannulated Ss Screw, Full Thread, Non-Sterile	16
GPS116CE	Guided Growth, 4.5mmx16mm Cannulated Ss Screw, Full Thread, Non-Sterile	8
GPS624CE	Guided Growth, 4.5mmx24mm Solid SS Screw, Full Thread, Non-Sterile	12
GPS632CE	Guided Growth, 4.5mmx32mm Solid SS Screw, Full Thread, Non-Sterile	12
GPS200CE	Guided Growth, 12mm SS eight-Plate, Non-Sterile	8
GPS400CE	Guided Growth, 16mm SS eight-Plate, Non-Sterile	8
GPS800CE	Guided Growth, 16mm SS Quad Plate, Non-Sterile	4
GPS900CE	Guided Growth, 22mm SS Quad Plate, Non-Sterile	4
GP900CE	**Guided Growth (Stainless Steel) Steribox, complete**	

GP200KCE eight-Plate Guided Growth Plate Kit		
Part#	**Description**	**Qty**
GP200CE	eight-Plate Guided Growth Plate 12mm	1
GP224CE	eight-Plate Guided Growth Screw 24mm	2

GP400KCE eight-Plate Guided Growth Plate Kit		
Part#	**Description**	**Qty**
GP400CE	eight-Plate Guided Growth Plate 16mm	1
GP432CE	eight-Plate Guided Growth Screw 32mm	2

PRECAUTION: Combining implants of dissimilar metals may result in galvanic corrosion: do not combine titanium implant components with stainless steel implant components.

EQUIPMENT REQUIRED

Part#	Description	
GP530CE	Guide Tool	
GP520CE	Stepped Cannulated Drill Bit, Ø 3.2mm	
GP540CE	K-Wire, Ø 1.6mm	
DH0454CE	Guided Growth Plate Bender	
DH0455CE	Micro-Ratcheting Handle with AO Connector, Cannulated	
DH0456CE	3.5mm Hex Driver Tip with AO Connector, Cannulated	
DH0457CE	Screw Sleeve For Ø 5.0mm Shaft	
DH0464CE	Guided Growth Plate Holder	
DH0474CE	Guide Growth, Screw Extractor	

Screwdriver assembling

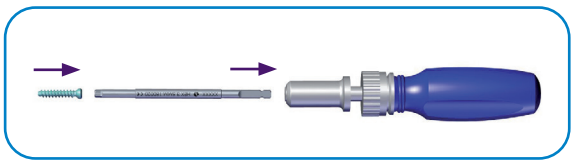
Assemble the screwdriver connecting the micro ratcheting handle with AO cannulated connector (Cod. DH0455CE) to the 3.5mm HEX self-retaining cannulated tip (Cod. 180020) **(Fig. 7)**.

PRECAUTION:
- **Do not use the tap with power drill, only manually.**
- **Make sure not to overtap and stop once the tap reaches the mechanical stop.**

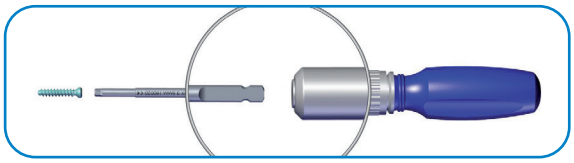
NOTE: Screw insertion procedure follows different steps depending on the selected screw type (solid or cannulated).

WARNING: Particular care should be taken that bone screws do not enter the joints or damage the growth plates in growing children.

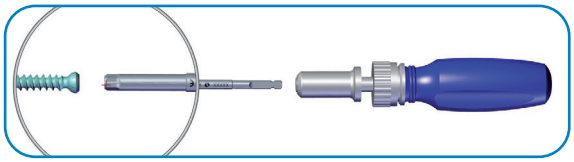
PRECAUTION: Advance bone screws until the screws are fully seated in the plate and the plate is flush with the bone.



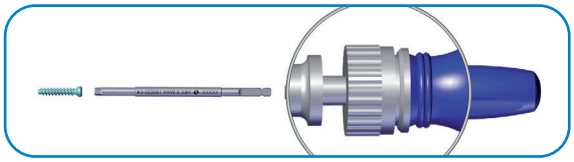
Assembling the screwdriver



Quick AO connection



3.5mm HEX self-retaining tip



Ratcheting handle

SURGICAL STEPS

EIGHT-PLATE APPLICATION - USING CANNULATED OR SOLID SCREWS

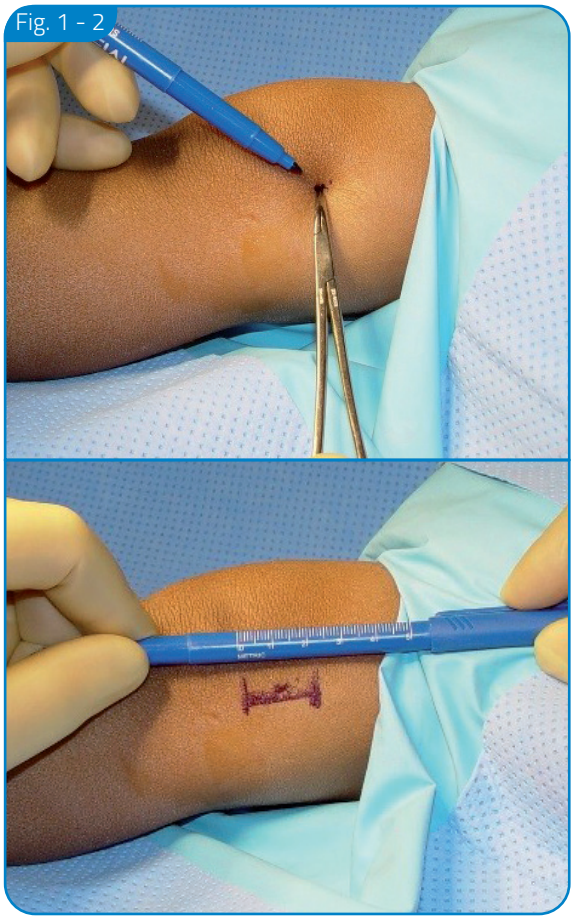
Prior to use - precautions:

- It is essential that the proper operative technique be followed for implantation
- Examine all components carefully: product integrity, sterility (in the case of sterile products), and performance are assured only if the packaging is undamaged
- Do not use if packaging is compromised or if a component is believed to be faulty, damaged or suspect
- Do not combine Guided Growth System Implantable Components with those from other systems, including the new version of the system (Guided Growth Plate System Plus).

WARNING: The Guided Growth System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Guided Growth Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Surgical approach

Using a radiopaque tool, under image intensifier locate the physis in the anatomic area where the plate and screws will be applied according to the desired correction to be achieved. Mark the skin at the physis **(Fig. 1 and 2)** and make a 1-2cm incision. Gently dissect down to the periosteum to exhibit the bone.



Surgical approach (i.e. distal femoral physis)

Insert 1.6mm localizing pin in physis and verify position with fluoroscope **(Fig. 3)**.

NOTE: Select the appropriate screw, length and type (solid or cannulated) according to patient's anatomy, physis thickness and desired correction to be achieved. When selecting the screws, the following criteria should be considered:

- **Make sure the screw's length will be contained within the epiphysis and the metaphysis (avoid to penetrating theopposite cortex)**
- **Solid screws are more resistant to breakage than cannulated screws, and this should be taken into consideration when treating heavy patients or when planning a long treatment time**

Fig. 3

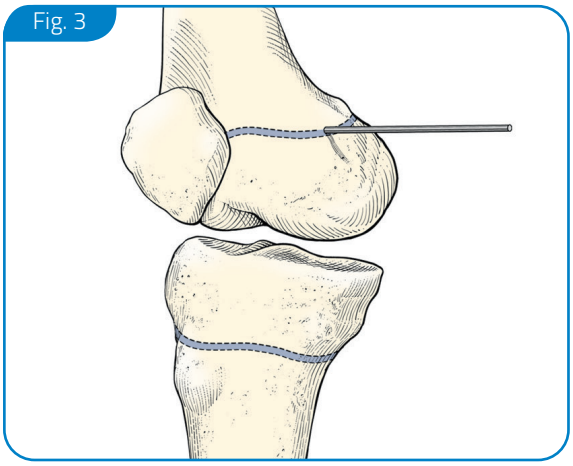


Plate Holder Orientation

The Guided Growth Plates come with a plate holder, which may be used to apply and secure the plates. If used, it is important to secure the plates at their narrowest point.

Fig. 4

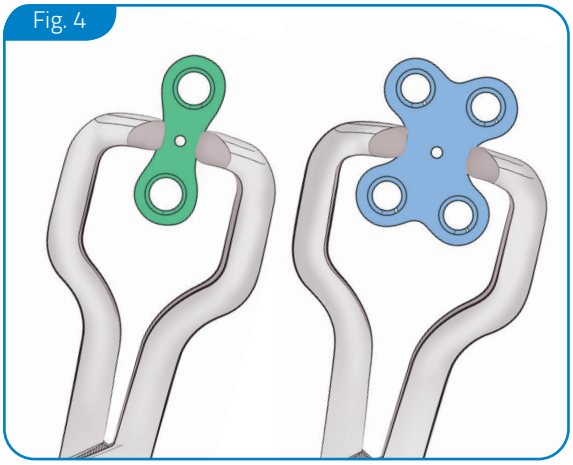
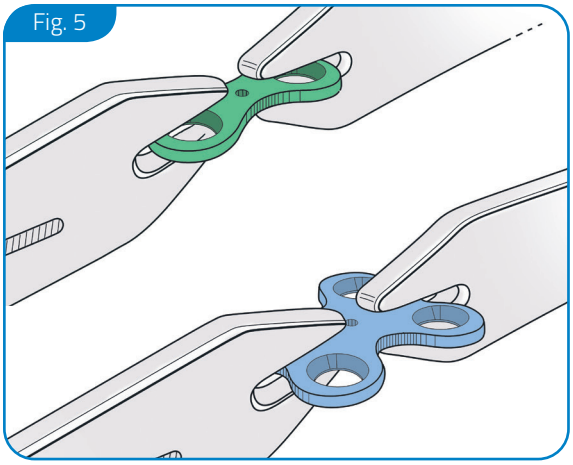


Plate Bender

The Guided Growth Plates come pre-contoured (10 degrees) and should fit most anatomies. If the plate requires further contouring, the plate benders may be used. The plate contour should be such that the plate sits flush with the bone.

- Bending beyond 20 degrees offset could result in injury or reoperation due to breakage

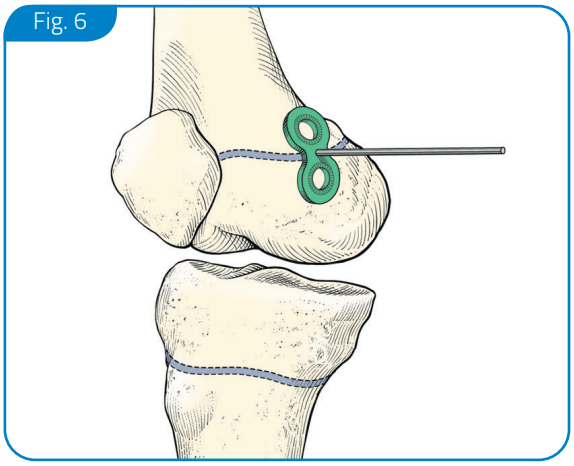
Fig. 5



Apply contoured eight-Plate over pin **(Fig. 6)**.

PRECAUTION: Before inserting the screws, ensure the plate is flush to the bone. If the plate is not adherent, bone growth may exert an additional stress onto the implants potentially leading to screw breakage.

Fig. 6



Using the Drill Guide, first insert the Epiphyseal Guide Wire, followed by the Metaphyseal Guide Wire. It is not necessary for these two wires to be parallel; it is more important to avoid the physis. Remove the center Guide Wire and check position with fluoroscope **(Fig. 7)**.

Fig. 7

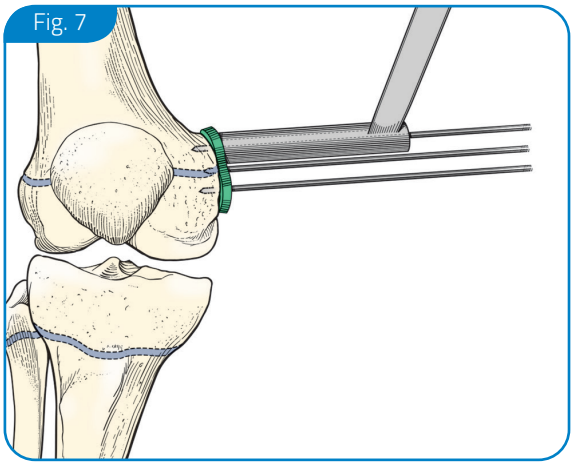
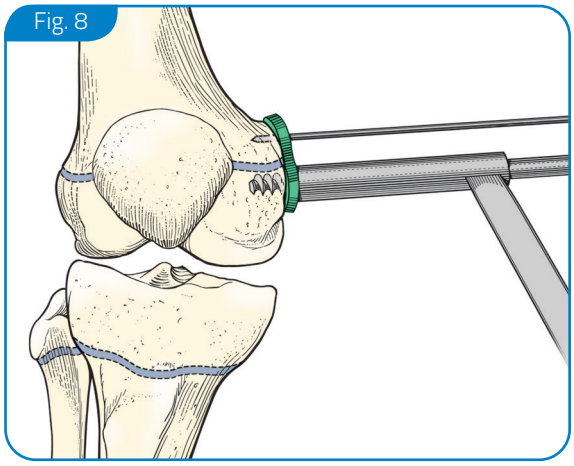


Plate bending (optional)

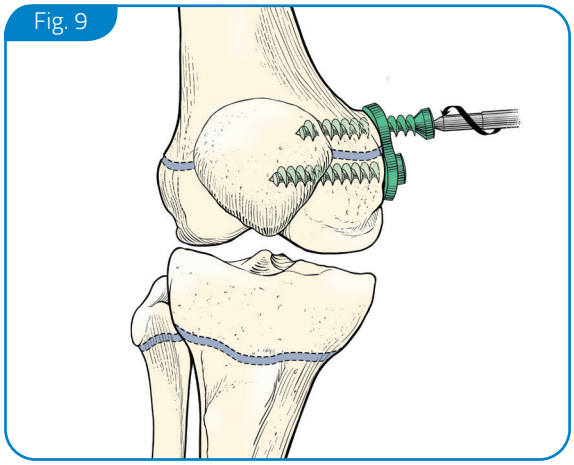
Drill using the Drill Guide and the Cannulated Step Drill Bit to a depth of 5mm. First, drill the Epiphyseal Hole, then the Metaphyseal Hole **(Fig. 8)**.

Fig. 8



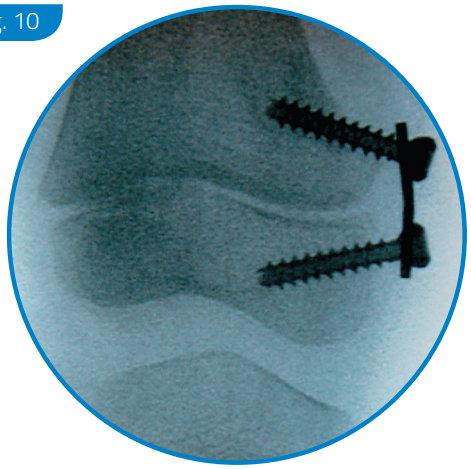
Using Cannulated or Solid Screws
After pre-drilling using the Cannulated Step Drill, insert the epiphyseal cannulated or solid screw. Prior to inserting a solid screw, remove only the Epiphyseal Guide Wire. Next, insert the Metaphyseal Screw. Prior to inserting a solid screw, remove the Metaphyseal Guide Wire. Screws do not need to be parallel but should never enter the physis. After removing the guide wires (if applicable), turn each screw 2-3 more times in an alternating manner **(Fig. 9)**.

Fig. 9



Ensure via fluoroscopy the screws are fully seated and there is no gap between the screw-plate-bone interface (fig 7). Failure to eliminate space between these interfaces may lead to 3-point bending and undue stress on the screw **(Fig. 10)**.

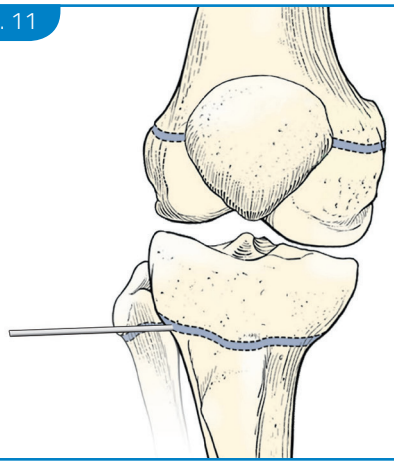
Fig. 10



QUAD-PLATE APPLICATION - USING CANNULATED SCREWS OR SOLID SCREWS

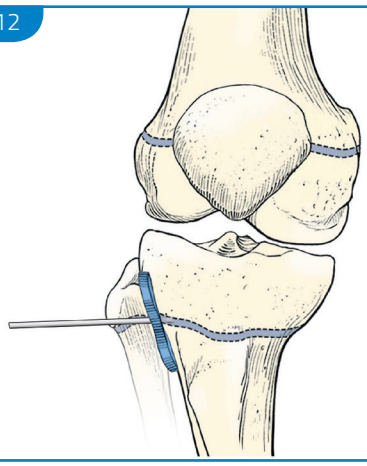
Insert 1.6mm localizing pin in physis and verify position with fluoroscope **(Fig. 11)**.

Fig. 11



Apply contoured eight-Plate over pin **(Fig. 12)**.

Fig. 12

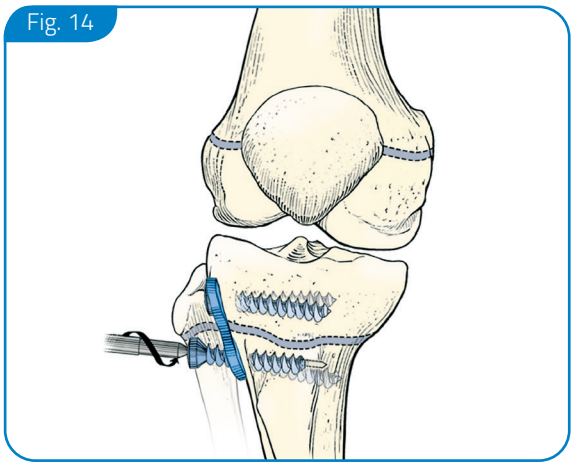


Using the Drill Guide, first insert the Epiphyseal Guide Wires, followed by the Metaphyseal Guide Wires.
It is not necessary for these wires to be parallel; it is more important to avoid the physis. Repeat to fill all holes **(Fig. 13)**. Remove the Center Guide Wire and check position with fluoroscope.

Fig. 13

Using Cannulated or Solid Screws
After pre-drilling using the Cannulated Step Drill, insert one of the Epiphyseal Cannulated or Solid Screws. Prior to inserting a solid screw, remove only the Epiphyseal Guide Wire. Next, insert one of the Metaphyseal Screws. Prior to inserting a solid screw, remove the Metaphyseal Guide Wire. Screws do not need to be parallel but should never enter the physis. After removing the guide wires (if applicable), turn each screw 2-3 more times in an alternating manner. Ensure via fluoroscopy the screws are fully seated and there is no gap between the screw-plate-bone interface. Failure to eliminate space between these interfaces may lead to 3-point bending and undue stress on the screw **(Fig. 14)**.

Fig. 14



POST-OPERATIVE CARE

Choose the appropriate post-operative care for each patient and application. The following are suggestions given by Orthofix, however, post-operative care will always remain the full responsibility of the surgeon:

- Usually, there is no need for a cast and the use of crutches is optional (for comfort). Physical therapy is seldom required
- Weight-bearing and early motion as tolerated are encouraged

Patients should be seen at least every 3 months to assess the deformity correction and determine when to remove the plate.

PLATE REMOVAL

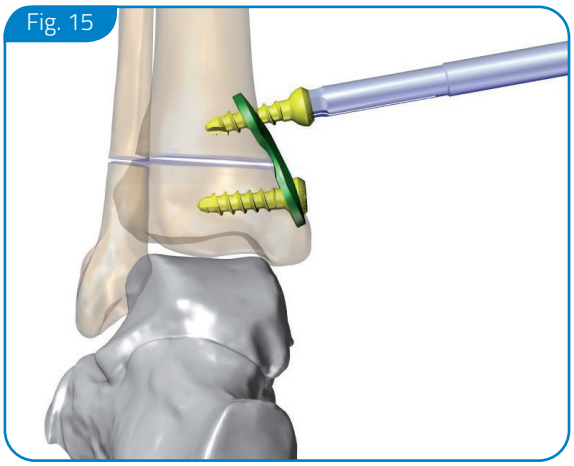
PRECAUTIONS: The implants should be removed when the deformity is corrected but before the screws reach their maximum angle.

Using a radiopaque tool, under image intensifier locate the plate to be removed, mark the skin and make a 1-2 cm incision parallel to the plate. Gently dissect down to the periosteum to exhibit the plate **(Fig. 15)**.

Next, using the pre-assembled screwdriver, manually remove all the screws and finally extract the plate using the plate holder forceps **(Fig. 16)**.

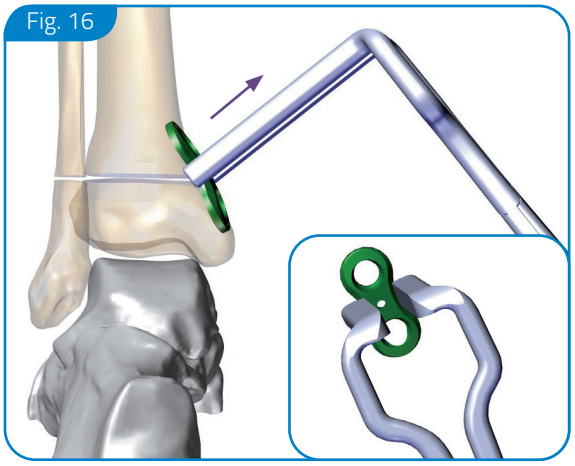
WARNING: Bone plates and screws must not be reused. If any implants have come into contact with any body fluid they should be considered to have been used. If repositioning of implants is required, new implants should be used.

Fig. 15



Recommended sequence for quad-Plate or eight-Plate removal

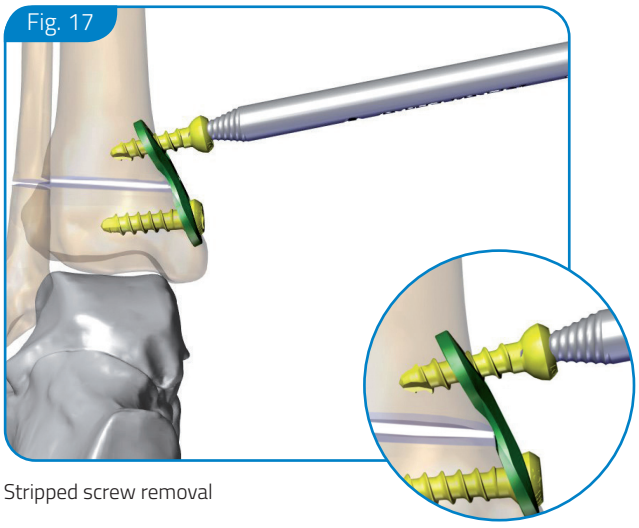
Fig. 16



Removal procedure of plate using the plate holder forceps

NOTE: In case the hexagon on the head of the screw is stripped, assemble the micro ratcheting handle with AO cannulated connector and manually remove the screws (Fig. 17).

Fig. 17



Stripped screw removal

CLEANING STERILIZATION AND MAINTENANCE

Refer to the product Instructions For Use.

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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