

OPERATIVE TECHNIQUE

Eight-Plate

Guided Growth System+™



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Contents

1	General Description
1	Implant Principles
2	Features and Benefits
2	Product Code Description
3	Sales Configuration
4	Equipment required
6	Surgical steps - eight-Plate application
15	Quad-Plate application
16	Plate removal
17	Cleaning Sterilization and Maintenance

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 Plus 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 Plus acts like a flexible hinge and it 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 placement) and quad-Plate (for four screws placement)
- Minimally invasive
- Early weight bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel

Surgeon Benefits

- Plate sizes: 12, 16 and 20mm
- Cannulated and solid screw options
- Titanium alloy implants
- Optimized and lean instrumentation
- Central "dome" designed to aid application and removal across the growth plate

Patient Benefits

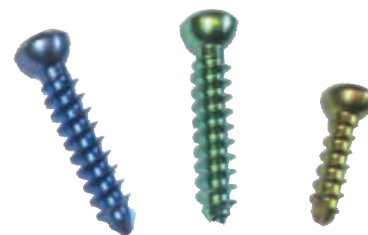
- Early weight bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel
- Minimally invasive

PRODUCT CODE DESCRIPTION

Implants	
	Description
eight-Plate	Color Coded eight-Plate Plus – Green 12mm
	Color Coded eight-Plate Plus – Blue 16mm
	Color Coded eight-Plate Plus – Purple 20mm
quad-Plate	Color Coded quad-Plate Plus – Blue 16mm
	Color Coded quad-Plate Plus – Purple 22mm



Ø3.5 Solid Screw eight-Plate Plus Color Coded - Yellow
 Ø4.5 Solid Screw eight-Plate Plus Color Coded - Blue
 Ø4.5 Cannulated Screw eight-Plate Plus Color Coded - Green



SALES CONFIGURATION

The tray can accommodate the quantity below

180991 - Eight Plate Plus Caddy (Empty)		
Part#	Description	Qty
T80212	Guided Growth Plate System Plus TI eight Plate L 12mm	8
T80216	Guided Growth Plate System Plus TI eight Plate L 16mm	8
T80116	Guided Growth Plate System Plus TI Cannulated Screw L 16mm D 4.5mm	12
T80124	Guided Growth Plate System Plus TI Cannulated Screw L 24mm D 4.5mm	12
T80132	Guided Growth Plate System Plus TI Cannulated Screw L 32mm D 4.5mm	12
T80136	Guided Growth Plate System Plus TI Cannulated Screw L 36mm D 4.5mm	12
T80024	Guided Growth Plate System Plus TI Solid Screw L 24mm D 4.5mm	8
T80032	Guided Growth Plate System Plus TI Solid Screw L 32mm D 4.5mm	8
T80036	Guided Growth Plate System Plus TI Solid Screw L 36mm D 4.5mm	8



180992 - Quad Plate Plus Caddy (Empty)		
Part#	Description	Qty
T80416	Guided Growth Plate System Plus TI quad-Plate L 16mm	4
T80422	Guided Growth Plate System Plus TI quad-Plate L 22mm	4



180993 - Extended Plus Line Caddy (Empty)		
Part#	Description	Qty
T80220	Guided Growth Plate System Plus TI eight-Plate L 20mm	8
T80312	Guided Growth Plate System Plus TI Solid Screw L 12mm D 3.5mm	8
T80314	Guided Growth Plate System Plus TI Solid Screw L 14mm D 3.5mm	8
T80316	Guided Growth Plate System Plus TI Solid Screw L 16mm D 3.5mm	8



All the implants are available also in sterile packaging

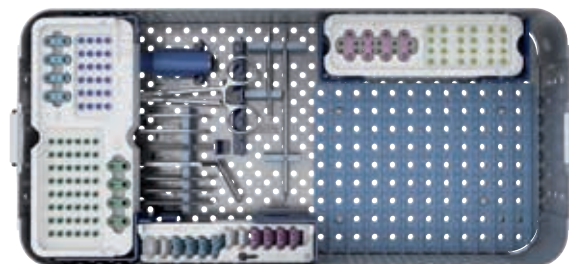
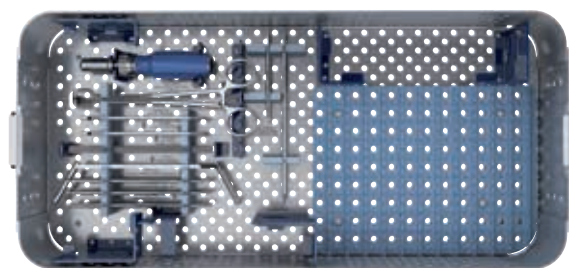
EQUIPMENT REQUIRED

Instruments

Part#	Description
GP540CE	K-Wire D 1.6mm L150mm
180005	Drill Guide
DH0455CE	Micro Ratcheting Handle with AO Connector Cannulated
GP520CE	Cannulated Drill Bit D 3.2mm with Quick Connect
180010	Cannulated Drill Bit D 2.4mm with Quick Connect
180035	Cannulated Tap D 3.5mm with Quick Connect
DH0464CE	Guided Growth Plate Holder
180015	Guided Growth Plate Bender
180020	Self-Retaining Cannulated Screwdriver Hex 3.5mm
DH0474CE	Guided Growth Screw Extractor
99-GP520CE	Cannulated Drill Bit D 3.2mm with Quick Connect Sterile
99-180010	Cannulated Drill Bit D 2.4mm with Quick Connect Sterile
99-180035	Cannulated Tap D 3.5mm with Quick Connect Sterile

Boxes

Part#	Description
180990	Sterilization Box Empty
180990C	Sterilization Box Complete
180996	Sterilization Box Lid
180991	Eight Plate Plus Caddy Empty
180992	Quad Plate Plus Caddy Empty
180993	Extended Plus Line Caddy Empty
180997	Guided Growth System Plus Update Kit



Implants – Non Sterile

	Part#	Description
eight-Plate	T80212	Guided Growth Plate System Plus TI eight-Plate L 12mm
	T80216	Guided Growth Plate System Plus TI eight-Plate L 16mm
	T80220	Guided Growth Plate System Plus TI eight-Plate L 20mm
quad-Plate	T80416	Guided Growth Plate System Plus TI quad-Plate L 16mm
	T80422	Guided Growth Plate System Plus TI quad-Plate L 22mm
Ø3.5 Solid Screw	T80312	Guided Growth Plate System Plus TI Solid Screw L 12mm D 3.5mm
	T80314	Guided Growth Plate System Plus TI Solid Screw L 14mm D 3.5mm
	T80316	Guided Growth Plate System Plus TI Solid Screw L 16mm D 3.5mm
Ø4.5 Solid Screw	T80024	Guided Growth Plate System Plus TI Solid Screw L 24mm D 4.5mm
	T80032	Guided Growth Plate System Plus TI Solid Screw L 32mm D 4.5mm
	T80036	Guided Growth Plate System Plus TI Solid Screw L 36mm D 4.5mm
Ø4.5 Cannulated Screw	T80116	Guided Growth Plate System Plus TI Cannulated Screw L 16mm D 4.5mm
	T80124	Guided Growth Plate System Plus TI Cannulated Screw L 24mm D 4.5mm
	T80132	Guided Growth Plate System Plus TI Cannulated Screw L 32mm D 4.5mm
	T80136	Guided Growth Plate System Plus TI Cannulated Screw L 36mm D 4.5mm

Implants – Sterile

	Part#	Description
eight-Plate	99-T80212	Guided Growth Plate System Plus TI eight-Plate L 12mm Sterile
	99-T80216	Guided Growth Plate System Plus TI eight-Plate L 16mm Sterile
	99-T80220	Guided Growth Plate System Plus TI eight Plate L 20mm Sterile
quad-Plate	99-T80416	Guided Growth Plate System Plus TI quad-Plate L 16mm Sterile
	99-T80422	Guided Growth Plate System Plus TI quad-Plate L 22mm Sterile
Ø3.5 Solid Screw	99-T80312	Guided Growth Plate System Plus TI Solid Screw L 12mm D 3.5mm Sterile
	99-T80314	Guided Growth Plate System Plus TI Solid Screw L 14mm D 3.5mm Sterile
	99-T80316	Guided Growth Plate System Plus TI Solid Screw L 16mm D 3.5mm Sterile
Ø4.5 Solid Screw	99-T80024	Guided Growth Plate System Plus TI Solid Screw L 24mm D 4.5mm Sterile
	99-T80032	Guided Growth Plate System Plus TI Solid Screw L 32mm D 4.5mm Sterile
	99-T80036	Guided Growth Plate System Plus TI Solid Screw L 36mm D 4.5mm Sterile
Ø4.5 Cannulated Screw	99-T80116	Guided Growth Plate System Plus TI Cannulated Screw L 16mm D 4.5mm Sterile
	99-T80124	Guided Growth Plate System Plus TI Cannulated Screw L 24mm D 4.5mm Sterile
	99-T80132	Guided Growth Plate System Plus TI Cannulated Screw L 32mm D 4.5mm Sterile
	99-T80136	Guided Growth Plate System Plus TI Cannulated Screw L 36mm D 4.5mm Sterile

SURGICAL STEPS - EIGHT-PLATE APPLICATION

Prior to use - precautions:

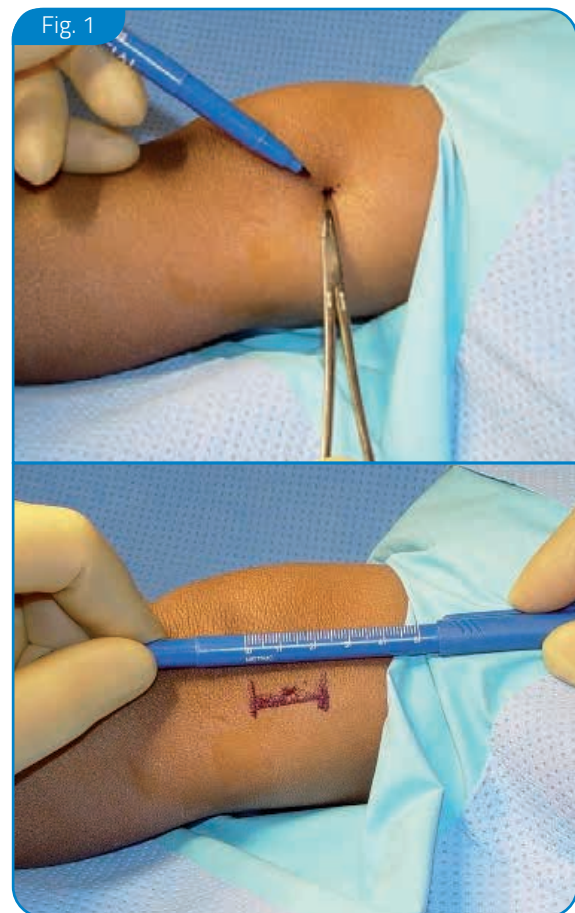
- It is essential that the proper operative technique be followed for implantation
- Examine all components carefully: product integrity, sterility (in the case of sterile products), and performance are assured only if the packaging is undamaged
- Do not use if packaging is compromised or if a component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



WARNING: The Guided Growth Plate System Plus 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 Plus 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 and make a 1-2cm incision (**Fig. 1**). Gently dissect down to the periosteum to exhibit the bone.

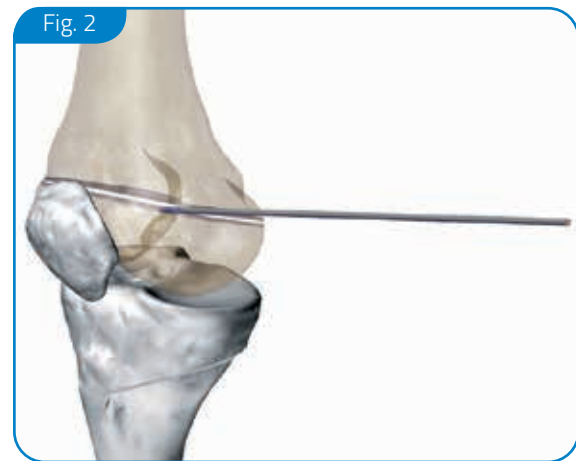


Surgical approach (i.e. distal femoral physis)

Plate positioning

Localize again the physis using the first 1.6mm guide wire (Cod. GP540CE) under image intensifier. Gently insert the guide wire in the physis with a power drill (**Fig. 2**).

To preserve the growth plate as much as possible, the guide wire should be inserted just enough to ensure its stability in the physis (usually no more than 1 cm in depth). After insertion, ensure the correct positioning of the localizing guide wire with fluoroscope.



Localizing guide wire insertion

For each patient and application, select the appropriate plate size (12mm, 16mm or 20mm) spanning the growth plate. Inappropriately sized plates, which allow the placement of a screw into the physis or the joint, must be avoided.

Using the plate holder forceps (Cod. DH0464CE), slide the selected plate over the localizing guide wire down to the bone and place the plate as close as possible to the exposed physis (**Fig. 3**).

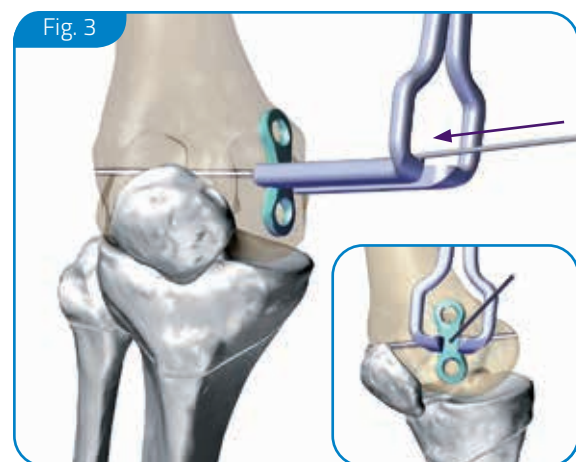


Plate placement



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 screws breakage.

Depending on patient's anatomy, using the plate bender (Cod. 180015) could be necessary to gently get the plate to fit onto the bone (**Fig. 4**).



WARNING: The plates already have a 10 degrees bending and may be bent an additional 10 degrees for more severe anatomical bone contours. Bending beyond 20 degree offset could result in injury or reoperation due to breakage.

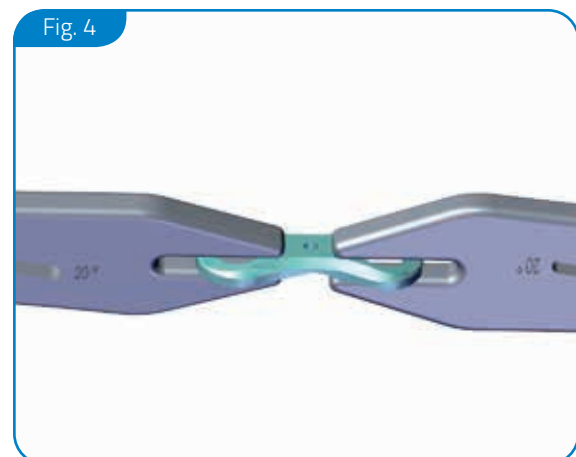


Plate bending (optional)

Using the 1.6 hole of the drill guide (Cod. 180005), under image intensifier first insert the epiphyseal guide wire with power drill followed by the metaphyseal guide wire (**Fig. 5**).

Prior to proceeding, check the guide wire positions with fluoroscope. It is not necessary for these two guide wires to be parallel, but it is mandatory to avoid the physis. If a wire is close to or through the physis, remove it and, reposition it and check the position.

Confirm the guide wire positions maintain the plate as close as possible to the exposed physis.



Epiphyseal and metaphyseal guide wires insertion

Screws insertion



Note: Select the appropriate screws based on diameter (4.5 or 3.5mm), 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 epiphyseal screw diameter will not affect the physis
- Make sure the screw length will be contained within the epiphysis and the metaphysis (avoid to penetrating the opposite 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

Bone pre-drilling



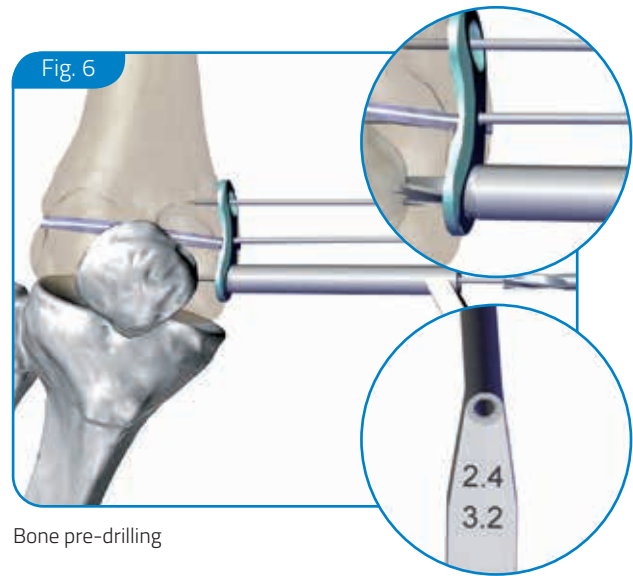
Precaution: After selecting the screw's diameter, select the appropriate cannulated drill bit:

- 2.4mm (Cod. 180010) for the 3.5mm diameter screws
- 3.2mm (Cod. GP520CE) for the 4.5mm diameter screws

Using the 2.4 - 3.2mm hole of the drill guide (Cod. 180005) and the selected cannulated drill bit, under power pre-drill the epiphyseal hole over the guide wires and then the metaphyseal hole (**Fig. 6**). The mechanical stop will ensure pre-drill depth of 5mm for screw insertion.



NOTE: If the stepped cannulated drill bit does not advance easily over the guide wire, remove the drill bit and check the guide wire integrity. If bent or damaged, the drill bit may lead to unwanted advancing of the guide wire. Replace the damaged guide wire with a new one.



Bone pre-drilling

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**).



PRECAUTIONS:

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



NOTE: Screw insertion procedure follows 3 different steps depending on the selected screw's diameter (4.5 or 3.5mm*) and the selected screw type (solid or cannulated):

- Procedure A for the 4.5mm cannulated screws
- Procedure B for the 4.5mm solid screws
- Procedure C for the 3.5mm solid screws



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.

Fig. 7



Assembling the screwdriver

Fig. 7a



Quick AO connection

Fig. 7b



3.5mm HEX self-retaining tip

Fig. 7c



Ratcheting handle

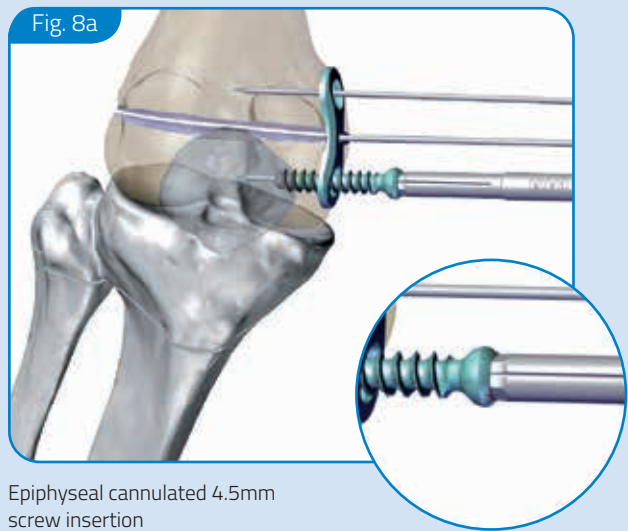
Procedure A:

**for the 4.5mm diameter cannulated screws
(Color coded - Green)**

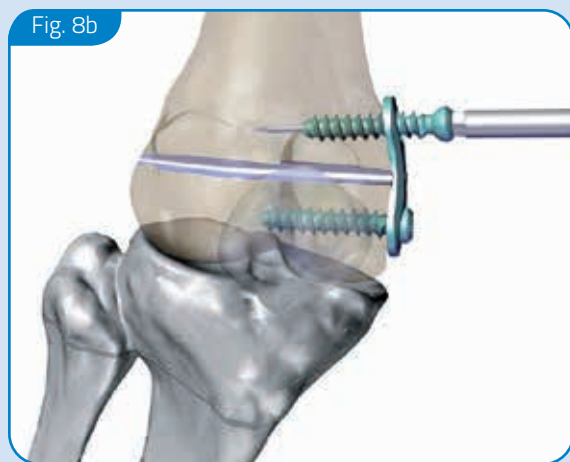
Using the pre-assembled screwdriver (Fig. 7), manually insert the epiphyseal cannulated screw first over the guide wire ensuring the screw is not completely tightened at this stage of insertion (Fig. 8a). Remove the epiphyseal guide wire as well as the guide wire in the growth plate. Next, repeat the same procedure for the metaphyseal cannulated screw (Fig. 8b).

Confirm the correct positioning of the screws using fluoroscopy and remove the remaining guide wire. Complete plate fixation by alternate tightening of the epiphyseal and metaphyseal screws.

Close the wound.



Epiphyseal cannulated 4.5mm
screw insertion



Metaphyseal cannulated 4.5mm screw insertion

Procedure B:

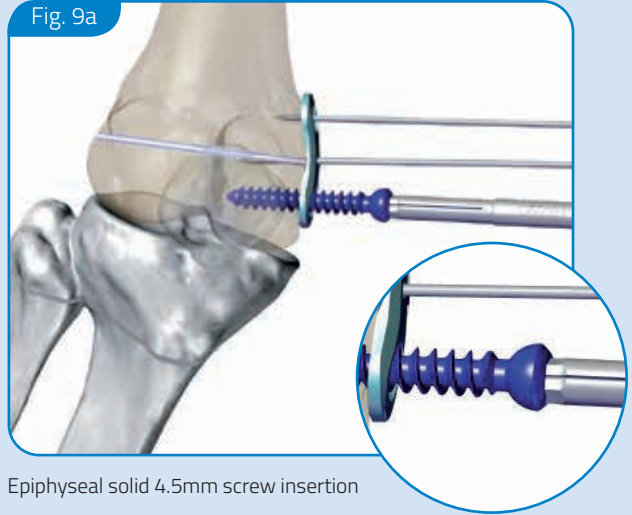
for the 4.5mm diameter solid screws (Color coded - Blue)

Remove the epiphyseal guide wire first and then, using the pre-assembled screwdriver (Fig. 7), manually insert the epiphyseal solid screw directly in the pre-drilled hole ensuring the screw is not completely tightened at this stage of insertion (Fig. 9a). Next, repeat the same procedure for the metaphyseal solid screw (Fig. 9b). Remove the guide wire in the growth plate.

Confirm the correct positioning of the screws using fluoroscopy and complete plate fixation by alternate tightening of the epiphyseal and metaphyseal screws.

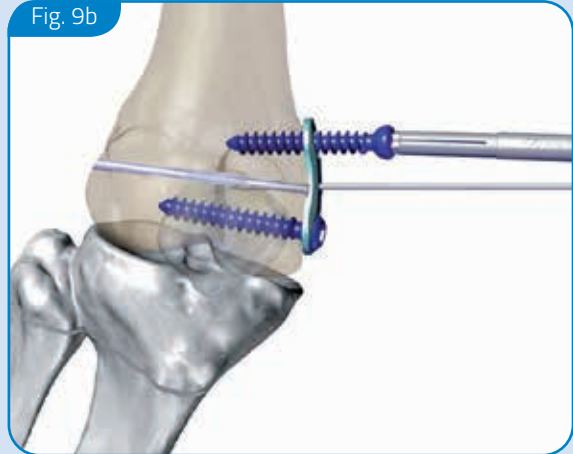
Close the wound.

Fig. 9a



Epiphyseal solid 4.5mm screw insertion

Fig. 9b



Metaphyseal solid 4.5mm screw insertion

Procedure C:

for the 3.5mm diameter solid screws (Color coded - Yellow)

Bone tapping (optional):

When appropriate, using the 2.4 – 3.2mm hole of the drill guide (Cod. 180005), insert the cannulated 3.5mm tap (Cod. 180035) over the guide wire and manually tap the pre-drilled epiphyseal hole (**Fig. 10a**). Remove the tap, the guide tool and the guide wire.



PRECAUTIONS:

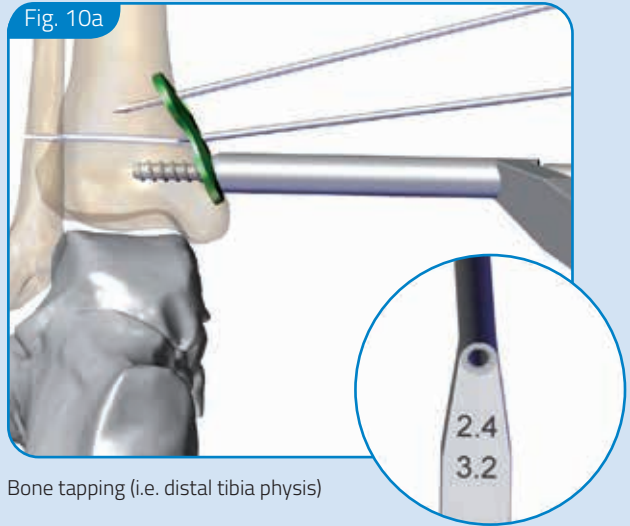
- Do not use the tap with power drill, only manually.
- Make sure not to overtap, and stop once the tap reaches the mechanical stop.

Using the pre-assembled screwdriver (**Fig. 7**), manually insert the epiphyseal solid 3.5mm screw directly in the pre-tapped hole ensuring the screw is not completely tightened at this stage of insertion (**Fig. 10b**). Next, repeat the same procedure for the metaphyseal screw (**Fig. 10c**).

Confirm the correct positioning of the screws using fluoroscopy and complete plate fixation by alternate tightening of the epiphyseal and metaphyseal screws.

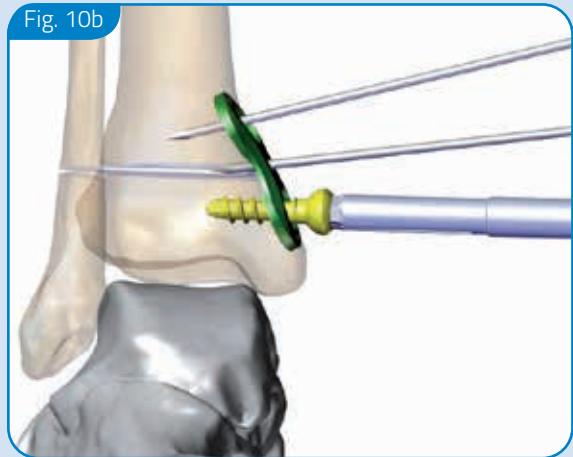
Close the wound.

Fig. 10a



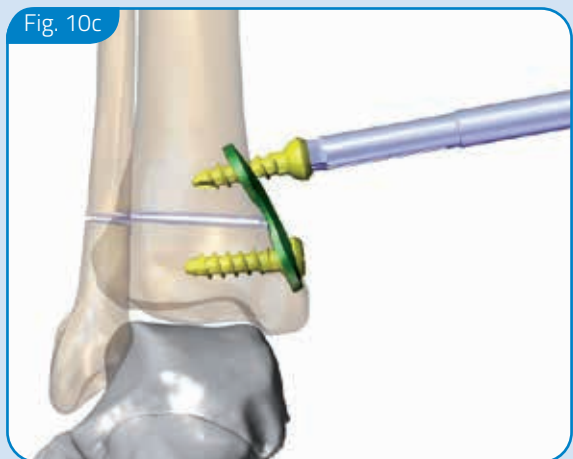
Bone tapping (i.e. distal tibia physis)

Fig. 10b



Epiphyseal screw insertion

Fig. 10c



Metaphyseal screw insertion

Correct positioning confirmation



PRECAUTION: After the final tightening, confirm correct positioning of the implants. Ensure via fluoroscopy the screws did not enter the physis, are fully seated and there is no gap between the screw-plate-bone interfaces (Fig. 11). Failure to eliminate spaces between these interfaces may lead to plate overbending and undue stress on the screws.

Re-operation may be necessary to reposition, replace or remove the bone plate and screws.

Fig. 11



Correctly positioned eight-Plate (ML and AP view)

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.

QUAD-PLATE APPLICATION

Quad-Plate (16mm or 22mm) application follows the same surgical steps, warnings and precautions described for eight-Plate.



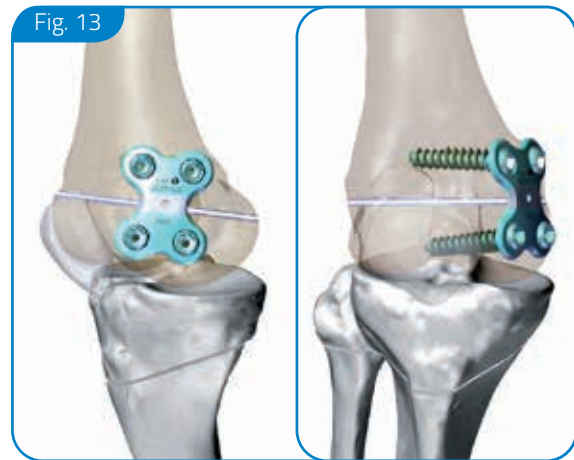
NOTES: When inserting the guide wires, first insert one of the two epiphyseal wires followed by the crossed metaphyseal one, next insert the remaining epiphyseal and finally the remaining metaphyseal (Fig. 12). The same sequence is recommended when inserting and tightening the screws (Fig. 13).

Fig. 12



Recommended sequence for quad-Plate guided wires and wire insertion

Fig. 13



Correctly positioned quad-Plate (ML and AP view)

PLATE REMOVAL



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

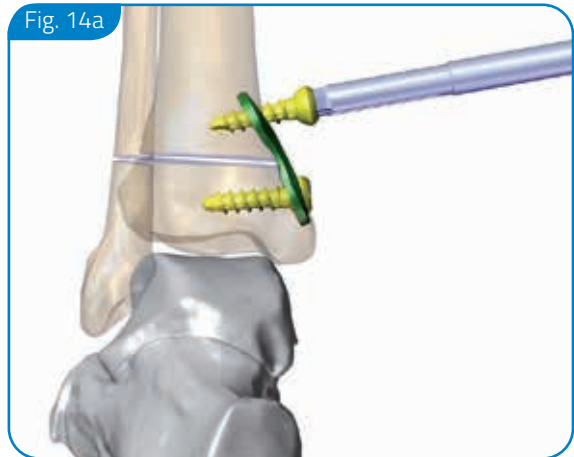
Using a radiopaque tool, under image intensifier locate the plate to be removed, mark the skin and make a 1-2 cm incision parallel to the plate. Gently dissect down to the periosteum to exhibit the plate.

Next, using the pre-assembled screwdriver (**Fig. 7**), manually remove all the screws (**Fig. 14a**) and finally extract the plate using the plate holder forceps (Cod. DH0464CE), (**Fig. 14b**).



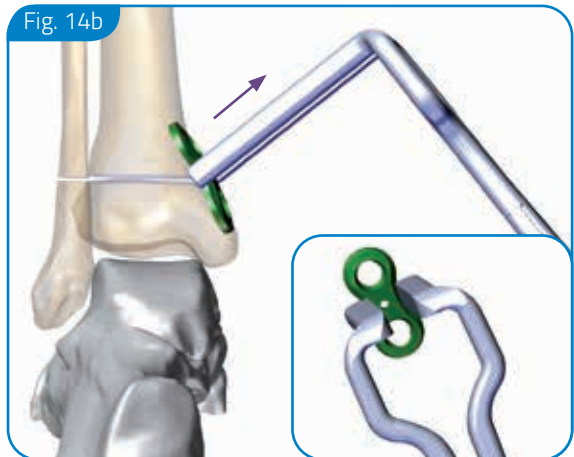
WARNING: Bone plates and screws must not be reused. If any implants have come into contact with any body fluid they should be considered to have been used. If repositioning of implants is required, new implants should be used.

Fig. 14a



Recommended sequence for quad-Plate or eight-Plate removal

Fig. 14b

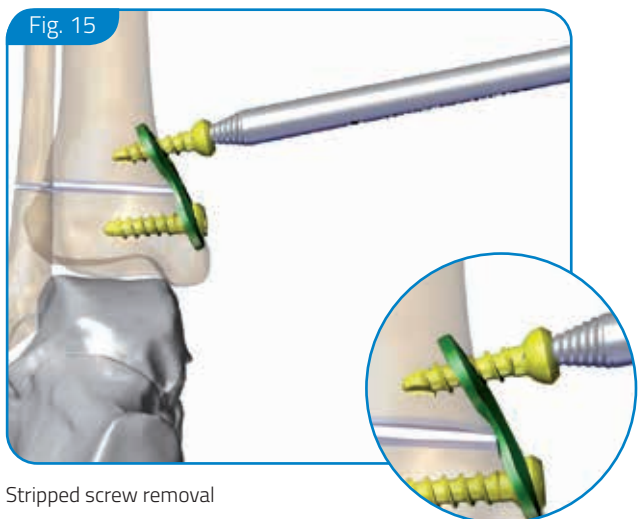


Removal procedure of plate using the plate holder forceps



NOTE: In case the hexagon on the head of the screw is stripped, assemble the micro ratcheting handle with AO cannulated connector (Cod. DH0455CE) to the screw extractor (Cod. DH0474CE) and manually remove the screws.

Fig. 15



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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