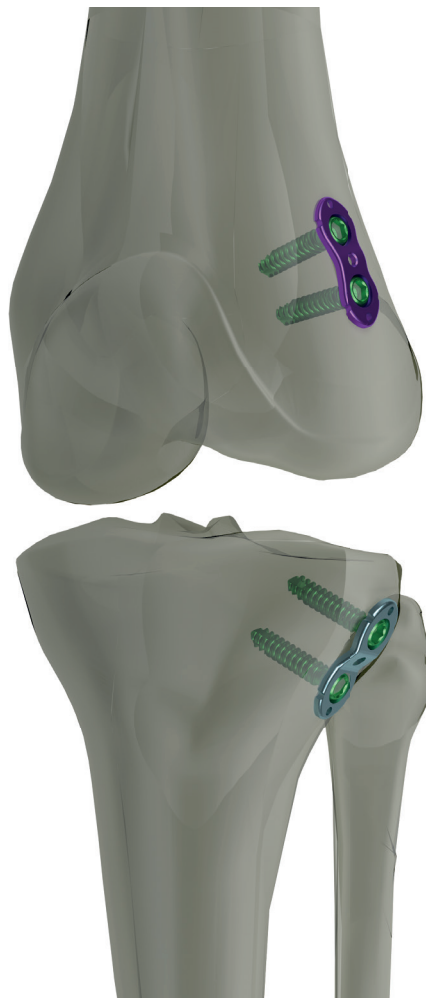


EpiFIX

Growth Control Plate



RESPONSE
ORTH



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Response Ortho is a global
orthopaedic trauma solutions manufacturer
offering premium products
created under its founding principles of
innovation, excellence by design
and functional superiority





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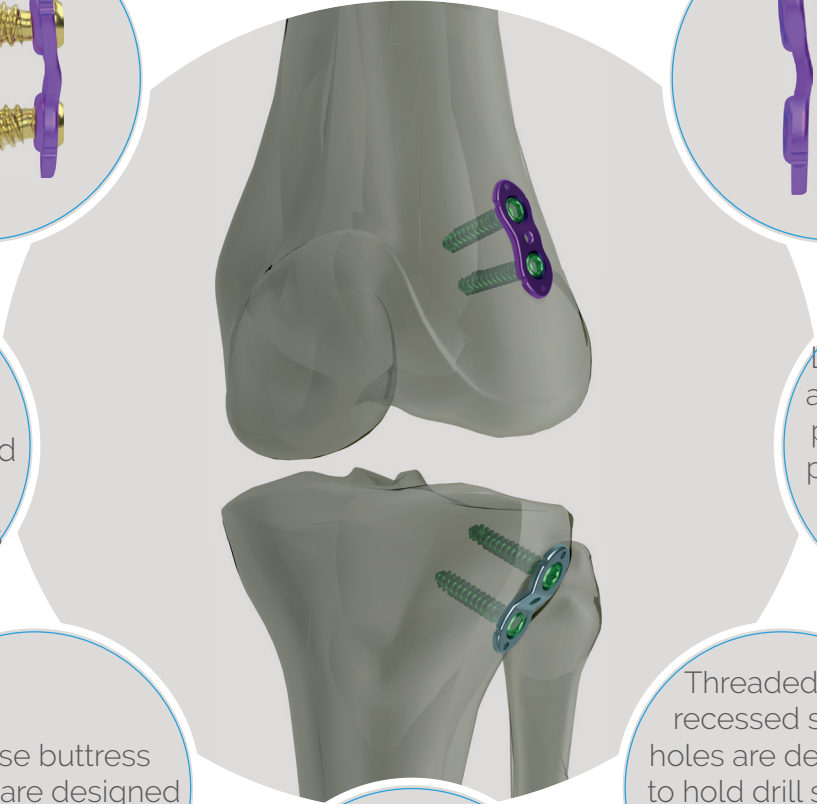
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INTRODUCTION

A significant number of children suffer from the pain of bowed legs, knock knees or difficulty in running.

Using a minimally invasive technique EpiFIX Growth Control Plate can be used as a growth guide through the retardation of growth at the epiphysis.

EpiFIX Growth Control Plates are available in both curved and stepped designs for use in the Tibia and Femur respectively. The application of the EpiFIX Growth Control Plate allows the physician to redirect the growth angle of the longbone gradually correcting the angular deformity in paediatric patients with open physis.



24mm, 32mm or 40mm cannulated and non-cannulated self-drilling cancellous screws

Low profile Arched and Offset Stepped plates conforms to patient anatomy for optimized fit and functionality

Reverse buttress threads are designed to resist pull out

Threaded and recessed screw holes are designed to hold drill sleeves securely and allow low profile screw seating

Elevated plates are designed for reduced contact with growth plate and periosteum

1. Before The Surgery

Patient Positioning

Patient should be in supine position and patient's leg should be abducted for fluoroscopy access and sterilized in the customary fashion.

2. Plate Sizing and Positioning

Before the incision, appropriate size and type of the EpiFIX Growth Control Plate is chosen according to patient's anatomy.

Using the plate holder (00-7019-00) the plate is placed on the skin on the site of the physis and the limb examined under fluoroscopy.

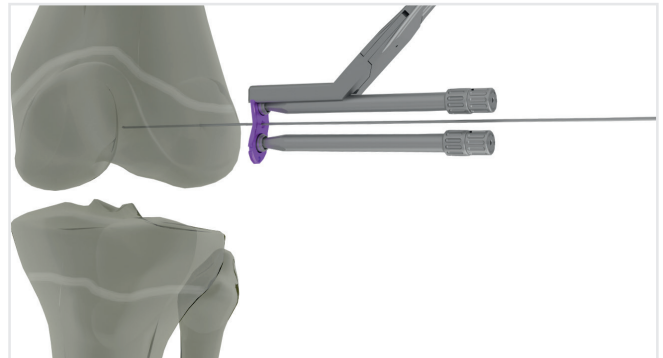
Once the physician is happy with the location a 3cm longitudinal incision is made. The skin and the fascia is divided, avoiding damage to the periosteum.

The plate is introduced in to the surgical site, and positioned in such a way as to avoid damage to the physal line. A 1.5mm K-wire (00-7023-00) is then inserted through the central hole K-wire hole and into the physis. The K-wire and plate position is verified using fluoroscopy.

Additional K-wire holes are provided for additional or alternative temporary fixation proximally or distally on the plate.

3. K-wire Insertion

The plate holder forecepts are removed. In order to provide protection to the soft tissues the EpiFIX Drill Guide Handle is seated on to the plate in the proximal position.



The appropriate 2.7 drill sleeve is selected

Non Locking 00-7015-00

Fixed Angle Locking 00-7019-00

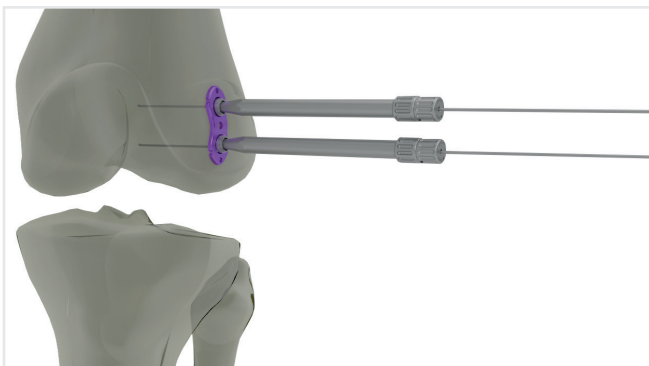
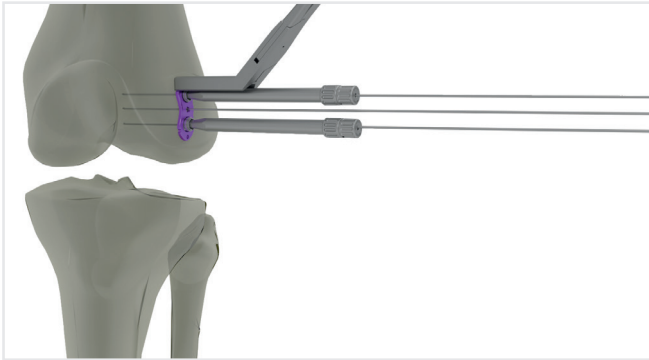
Variable Angle Locking 00-7016-00



The sleeve is threaded into the screw hole in the plate utilizing the drill guide handle. A K-wire sleeve (00-7018-00) is inserted into the drill sleeve. A second 1.5mm K-wire is introduced through the K-wire sleeve and into the epiphysis to a suitable depth. The drill guide handle is then removed.

For metaphyseal guide wire insertion

Seating the drill guide handle onto the distal side of the plate, the appropriate 2.7mm drill sleeve and K-wire sleeve are mounted on the plate in an identical fashion to those steps described above. A third K-wire is passed through the sleeves into the metaphyseal region to an appropriate depth.



Fluoroscopic A/P and lateral images are taken to assure that the wires are within the epiphysis and the metaphysis.

If the K-wires are close to, or breach the physis they should be removed and the plate repositioned

4. Screw Sizing

Three sizes of screws are available (both cannulated and non cannulated).

24mm

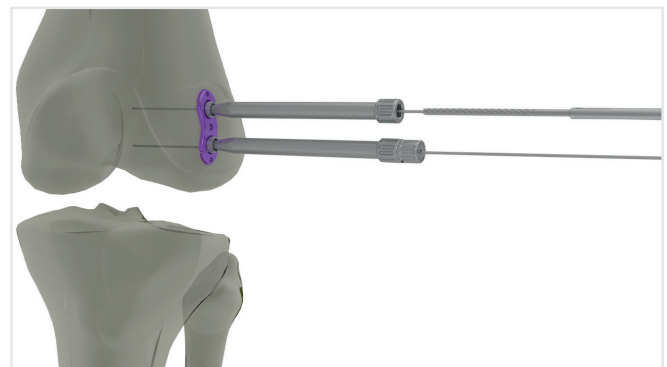
32mm

40mm

A measurement of the appropriate screw length can be taken. Remove the K-wire sleeve from the drill sleeve. Slide the K-wire depth gauge (00-7009-00) over the wire until the tip reaches the bone. Read the depth of the wire from the gauge and select the screw accordingly.

5. Drilling

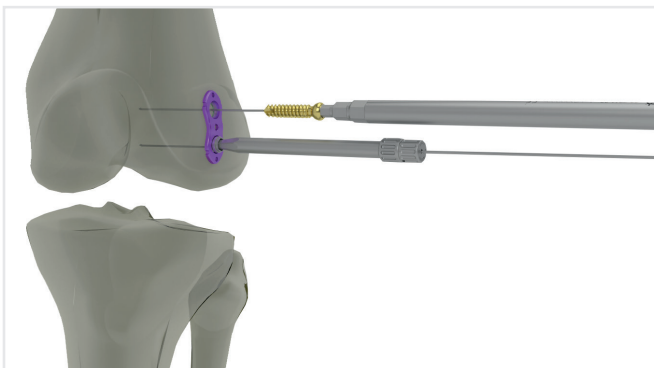
For the proximal screw insertion; remove the K-wire sleeve, leaving the drill sleeve in place. The 2.7mm Cannulated Quick Release Drill is passed over the 1.5mm K-wire, and through the sleeve. The bone is drilled to the appropriate depth under fluoroscopic examination. The drill is then withdrawn ensuring that K-wire remains in place.



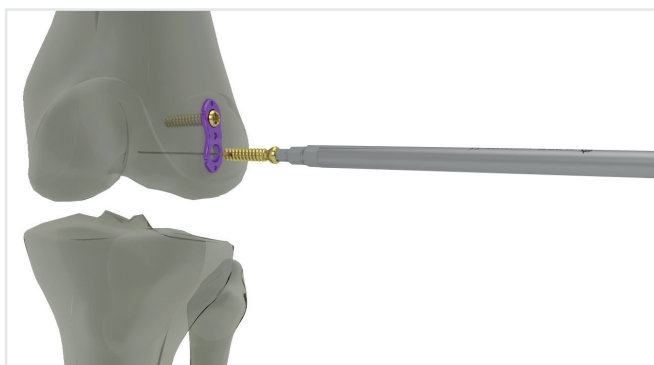
6. Screw Placement

After the drill is withdrawn the drill sleeve is also removed. The Quick Release Handle (00-1011-01) and the Quick Release Hex Driver tip (00-7011-00) are assembled to form the screwdriver. The appropriate screw is selected and seated on the tip of the screw driver assembly, and passed over the K-wire into the plate. The screw is lightly tightened into place. The screw driver is withdrawn and the K-wire removed.

If solid screw are to be used the K-wire is withdrawn prior to insertion.



Metaphyseal screw is inserted in the same fashion as the epiphyseal screw.



After the adjustment of the plate and screws, both screws are tightened slightly.

7. Final Control and Closure

Screws and plate are imaged fluoroscopically in order to ensure that screws are fully seated and there is no gap between plate-bone interfaces. The wound is closed in the customary fashion.



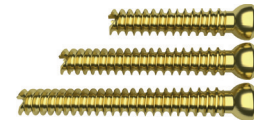
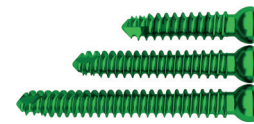
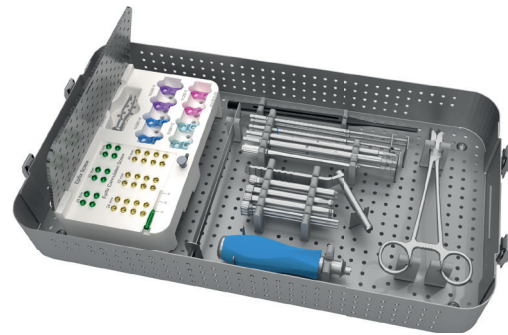
7. Removal

Before removing the screws, EpiFIX Growth Control Plate inserter/extractor (00-7020-00) is threaded into central hole of the plate.



Assemble the screw driver as described above, remove the screws. After screw removal the plate may be lifted from the surgical site using the plate extractor.

00-1011-01	Quick Release Handle	1
00-7019-00	EpiFIX Plate Holder	1
00-7011-00	QR Hex Driver Tip, 3.5/4.5/5.5mm, L, Can.	2
00-7020-00	EpiFIX Plate Inserter/Extractor	1
00-7016-00	EpiFIX Drill Sleeve, Var.Angle, 2.7mm	2
00-7017-00	EpiFIX Drill Sleeve, Fix Angle, 2.7mm	2
00-7013-00	QR Drill Bit, 2.7mm, Can.	2
00-7012-00	QR Drill Bit, 2.7mm	2
00-7014-00	EpiFIX Drill Guide Handle	1
00-7015-00	EpiFIX Drill Sleeve, Non-Locking	2
00-7018-00	EpiFIX Wire Sleeve	3
00-7009-00	Wire Depth Gauge, Long	1
00-7010-00	3.5mm Hex Screw Remover	2
00-2084-00	Screw Holder, Small Fragment	1
00-7023-00	EpiFIX Threaded Wire, 1.5/200mm	8
00-8140-00	EpiFIX Tray	1
10-2261-12	EpiFIX, Epiphysis Plate, Stepped, 12mm	4
10-2261-16	EpiFIX, Epiphysis Plate, Stepped, 16mm	4
10-2262-12	EpiFIX, Epiphysis Plate, Curved, 12mm	4
10-2262-16	EpiFIX, Epiphysis Plate, Curved, 16mm	4
30-3450-24	EpiFIX Screw, 24.0mm	4
30-3450-32	EpiFIX Screw, 32.0mm	4
30-3450-40	EpiFIX Screw, 40.0mm	4
30-3451-24	EpiFIX Cannulated Screw, 24.0mm	8
30-3451-32	EpiFIX Cannulated Screw, 32.0mm	8
30-3451-40	EpiFIX Cannulated Screw, 40.0mm	8



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