

POLYAX™



WIDE ANGLE FREEDOM

SURGICAL TECHNIQUE

DISTAL FEMORAL LOCKED PLATING SYSTEM



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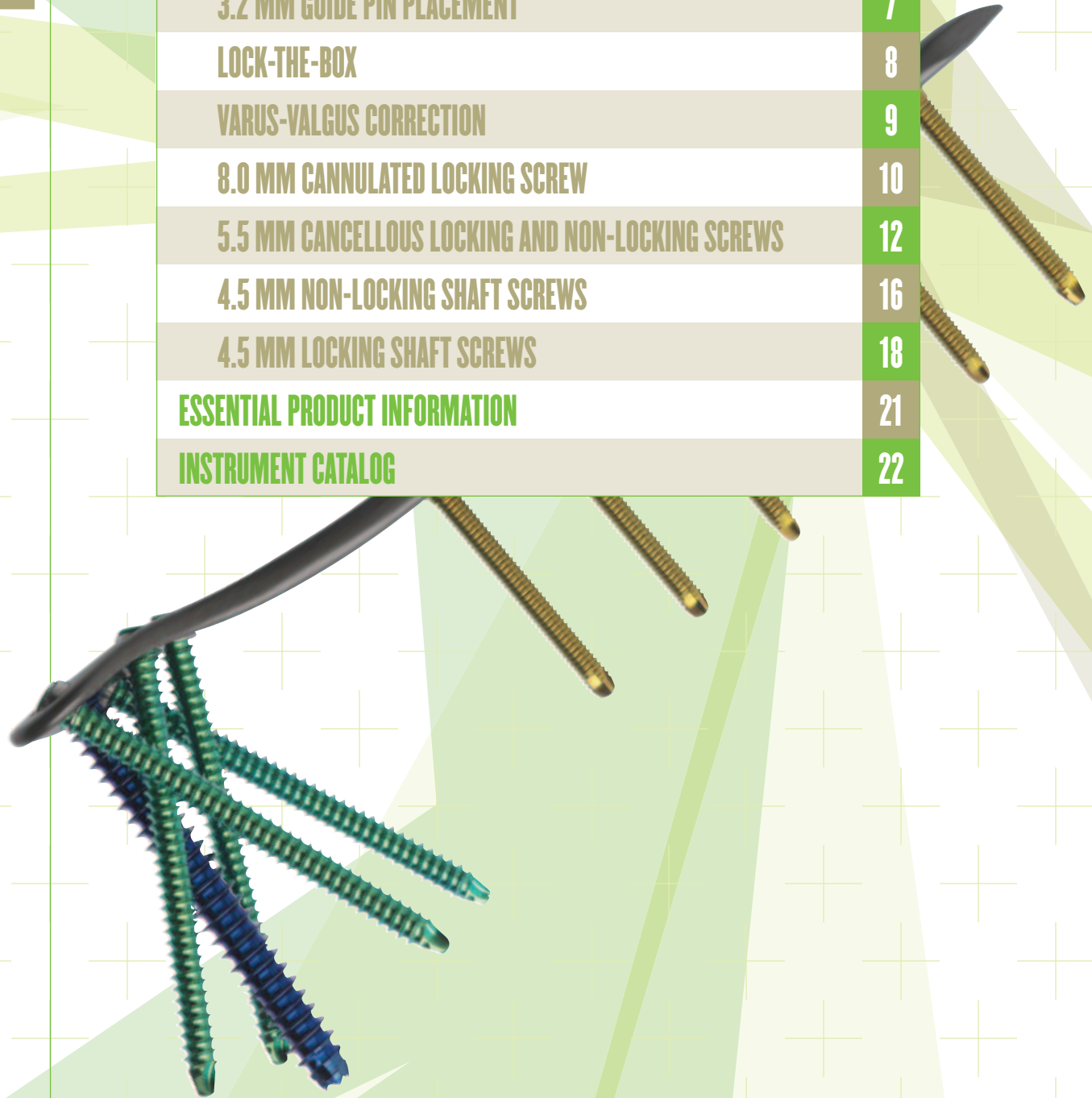
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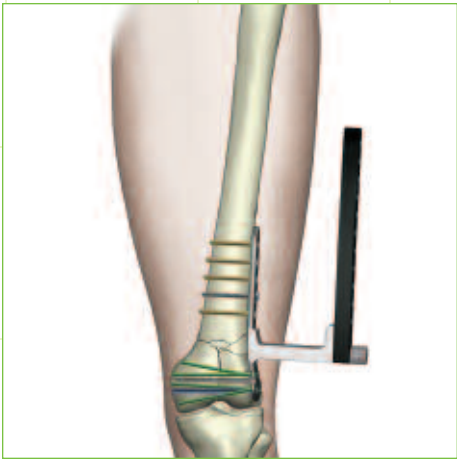


INTRODUCTION

The POLYAX™ Locked Plating System is indicated for the treatment of distal femur and proximal tibia fractures. The system is intended for use in open or percutaneous fracture fixation cases requiring Open Reduction Internal Fixation (ORIF) of closed and open fractures of the distal femur and proximal tibia, including repair of non-unions and malunions. The POLYAX Locked Plating System is designed to give the surgeon maximum flexibility with the use of fixed-angle locking, variable-angle locking and non-locking screw options. The result is fracture fixation based on each individual patient's fracture type, bone quality and anatomy.

The POLYAX femoral and tibial plates are designed for placement on the lateral side of the distal femur and proximal tibia, respectively, and are pre-contoured to closely match the anatomy of the bones. Each plate is manufactured from TiMAX™ anodized titanium alloy Ti-6Al-4V, which gives the plates superior fatigue strength, excellent biocompatibility and optimal stress transfer. The screws are manufactured from color-anodized titanium alloy Ti-6Al-4V for easy identification and selection in the OR.

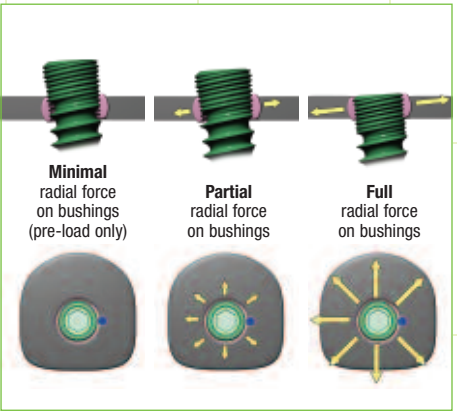
All instruments are color-coded in accordance with associated color-anodized screws to enhance surgical efficiency. The system includes a handle and radiolucent target guide that connects to the plate for minimally invasive plate and screw insertion, as well as several tools to aid in fracture reduction.



Femoral locked plating system.

LOCKING MECHANISM

Screw locking is accomplished either by threading a screw directly into the plate (fixed-angle construct) or into a patented polyaxial bushing (variable-angle construct) contained within the plate. The screw's locking portion consists of a triple-lead, tapered-thread on the screw head, which is designed to engage the plate or bushings. The bushings allow the surgeon to lock screws in place at a desired angle within a maximum 30-degree cone of angulation. Non-locking screws are provided for placement in either a fixed locking hole or polyaxial bushing.



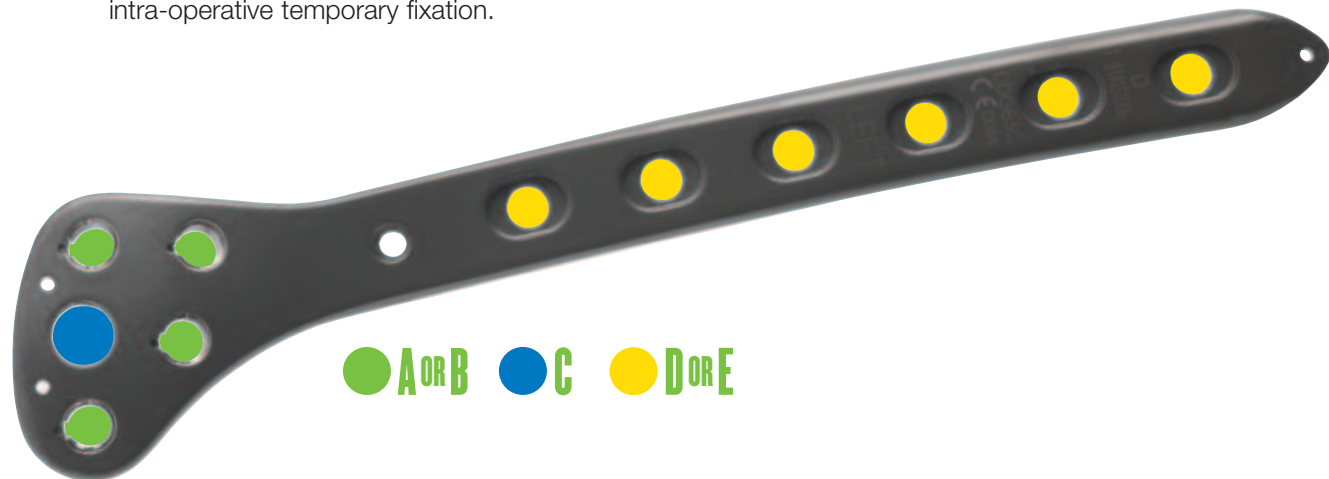
Polyaxial bushing operation.

INDICATIONS

The POLYAX Locked Plating System is intended for use in:

- Periarticular fractures
- Periprosthetic fractures
- Malunions
- Non-unions

Distal locking of the femoral POLYAX Locked Plating System construct is accomplished by one centrally located 8.0 mm fixed-angle locking screw surrounded by four 5.5 mm polyaxial locking bushings. The proximal plate stem has threaded holes for 4.5 mm fixed-angle locking or 4.5 mm non-locking screws and is anatomically contoured to match the femoral bow. Plates are available in lengths of 6, 9, 12, 15 and 18 holes (Cat. No. 8141-30-1XX—right, Cat. No. 8141-31-1XX—left). The plate has three K-wire holes for optional intra-operative temporary fixation.



S C R E W S				
A	B	C	D	E
5.5 mm Locking Cancellous	5.5 mm Non-locking Cancellous	8.0 mm Locking Cannulated Cancellous	4.5 mm Locking Cortical	4.5 mm Non-locking Cortical
Cat. No. 8153-55-XXX	Cat. No. 8154-55-XXX	Cat. No. 8153-08-OXX	Cat. No. 8150-45-5XX	Cat. No. 8157-45-0XX
25-100 mm in 5 mm increments	40-100 mm in 5 mm increments	25, 35, 50-90 mm in 5 mm increments	8-16, 20, 26-42 mm in 2 mm increments, 45-60 mm in 5 mm increments	14-60 mm in 2 mm increments, 65 mm, 70 mm
Self-tapping	Self-tapping	Self-drilling Self-tapping	Self-tapping	Self-tapping
3.8 mm Drill Bit	3.8 mm Drill Bit	5.5 mm Drill Bit	3.8 mm Drill Bit	3.2 mm Drill Bit
				
Common Screw Case	Common Screw Case	Femoral Case	Common Screw Case	Large Fragment Case

SURGICAL TECHNIQUE

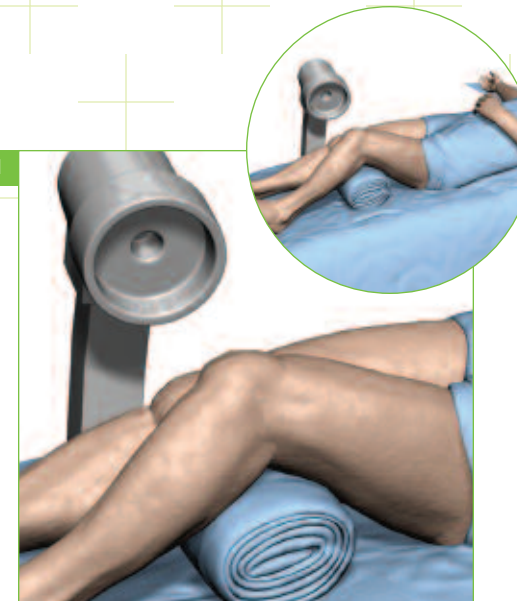
Position the patient supine on a fluoroscopic table with the C-arm on the opposite side of the fractured extremity. Prep both legs into the surgical field for ease of obtaining a lateral radiograph of the operative limb (accomplished by lifting the non-fractured limb out of the way) and for comparison of limb alignment, leg length and rotation.

“Learn” the fracture by determining the ideal amount of traction necessary to align the fracture on the A/P view. Bumps or surgical triangles can be utilized to aid in positioning. The flexion-extension of the distal fragment can be adjusted by moving the bumps proximally or distally under the thigh (Fig. 1).

Use the pre-operative template (Cat. No. 2994-54-000 – 6/9/12 hole, Cat. No. 2994-54-005 – 15/18 hole) on the preoperative A/P and lateral radiographs to determine the appropriate plate length (Fig. 2). Select a plate length that allows a minimum of four screw holes to be placed in the intact femoral shaft proximal to the fracture. If in between sizes, it is best to choose the longer of the two plates.

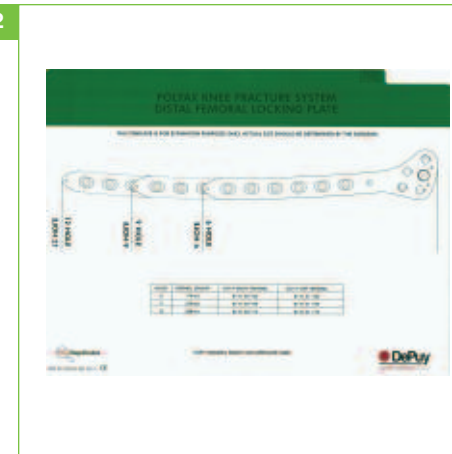
Verify plate length using the intra-operative femoral template (Cat. No. 2141-01-000). Place the template on the skin and take a fluoroscopic image of the fracture, reading the appropriate plate length on the numbered template (Fig. 3).

Fig. 1



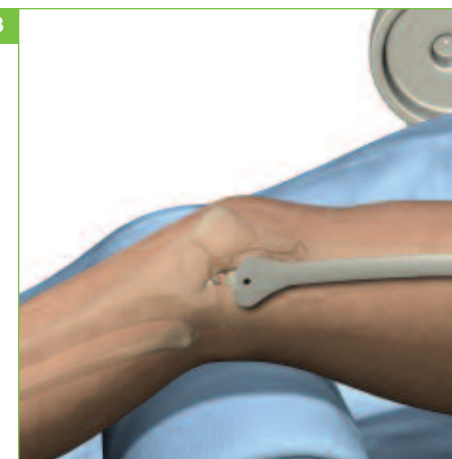
Take pre-operative fluoroscopic images.

Fig. 2



Template with pre-operative template.

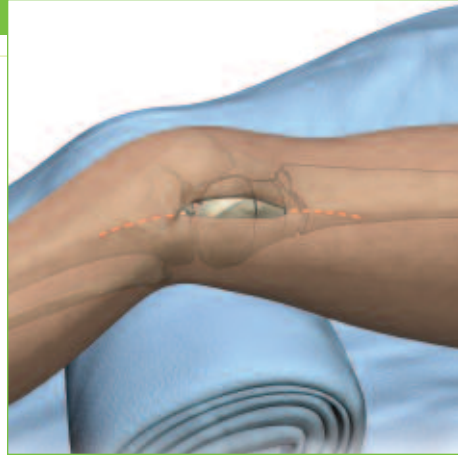
Fig. 3



Template with intra-operative template.

Make an anterolateral incision over the flare of the lateral femoral condyle (Fig. 4). For extra-articular and simple non-displaced intra-articular fractures, this is often adequate exposure.

Fig. 4



Make anterolateral incision for extra-articular and simple intra-articular fractures.

For more complex intra-articular extension, use a formal parapatellar arthrotomy (Fig. 5). Obtain articular visualization by subluxing the patella medially.

Fig. 5



Make parapatellar arthrotomy for complex intra-articular fractures.

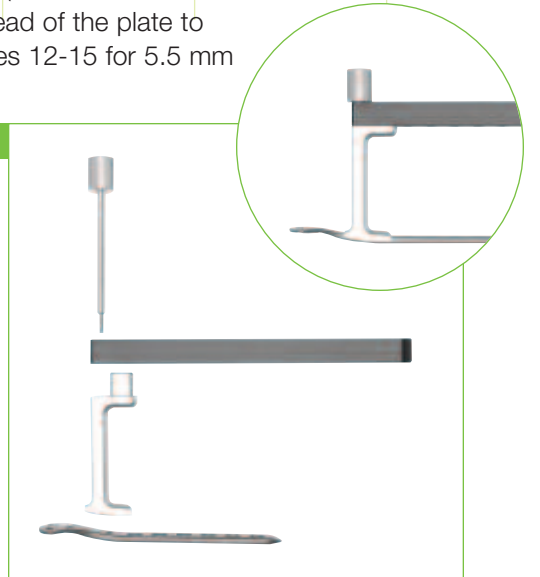
Perform standard open reduction internal fixation of the articular surfaces by obtaining anatomic reduction and fixation with individual lag screws. Place lag screws peripherally so as not to interfere with locked screw placement.

Non-locking screws can also be used in the head of the plate to help achieve fracture reduction. 5.5 mm partially threaded non-locking screws (Cat. No. 8154-55-XXX) can be placed in any of the four polyaxial bushings in the head of the plate to reduce an intercondylar split. Follow the technique found on pages 12-15 for 5.5 mm non-locking screw placement.

Percutaneous or standard open plating techniques can be utilized. The percutaneous technique, illustrated here, is typically chosen for longer plates and high energy fractures.

Assemble the selected plate, femoral target guide (Cat. No. 2141-02-012/018), femoral handle (Cat. No. 2141-02-000) and femoral connecting screw (Cat. No. 2141-02-001) on the back table (Fig. 6). Orient the femoral target guide for the appropriate left or right plate. The appropriate side will face up and be readable once assembled.

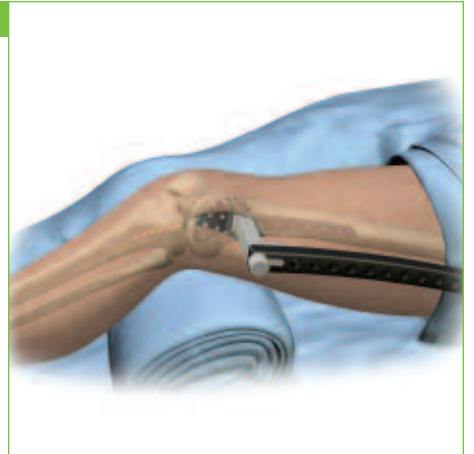
Fig. 6



Orient and assemble percutaneous instrumentation.

Using the target guide as a handle, insert the plate in a submuscular, extraperiosteal fashion under the vastus lateralis (Fig. 7). The end of the plate is bullet-shaped to assist in submuscular, percutaneous insertion. A Cobb elevator can be used submuscularly to aid in plate insertion as needed. Do not elevate the periosteum with the Cobb elevator, as locking plates should be extraperiosteal.

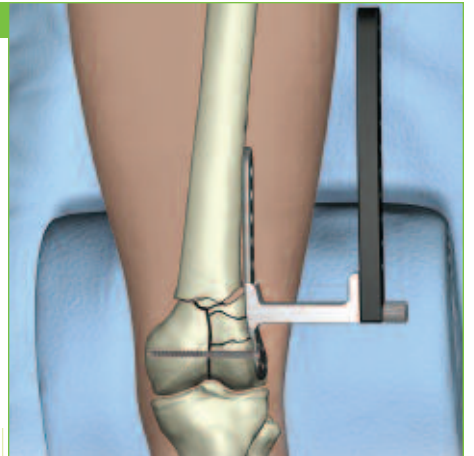
Fig. 7



Insert plate submuscularly.

Position the distal end of the plate along the lateral femur, verifying the position with A/P and lateral fluoroscopic views of the knee. Assure appropriate alignment of the distal condyles with the distal end of the plate. Place the plate 2 mm proximal to the distal end of the lateral condyle (Fig. 8). Apply gentle traction to the limb and grossly realign the femur at this time.

Fig. 8



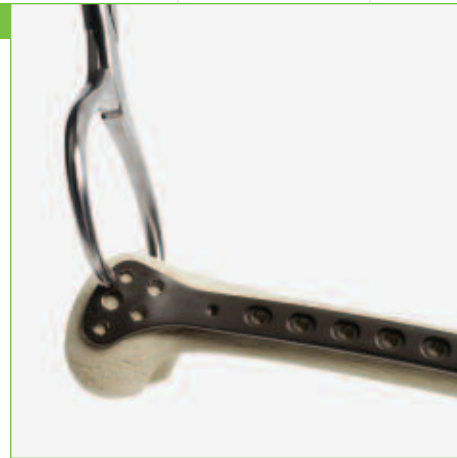
Align distal end of plate.

Tip: The POLYAX femoral plates are precontoured to the lateral femur and sit more anteriorly on the lateral aspect of the lateral femoral condyle and approximately 2 mm from the joint line.

Obtain preliminary plate fixation to the distal femoral condylar fragment using one of the following two methods: X-large Pe.R.I.™ tongs (suggested) or K-wires.

X-Large Pe.R.I. Tongs (Cat. No. 1919)

Place one of the tongs' pointed tips through one of the two small holes on the head of the plate. Make a small medial incision for the other tip and clamp down to bring the distal end of the plate flush to the bone (Fig. 9).

Fig. 9

Secure plate with Pe.R.I. tongs.

K-Wires (Cat. No. 14425-6)

Insert 1.6 mm K-wires into the two small holes in the head of the plate and check placement under fluoroscopy (Fig. 10).

Fig. 10

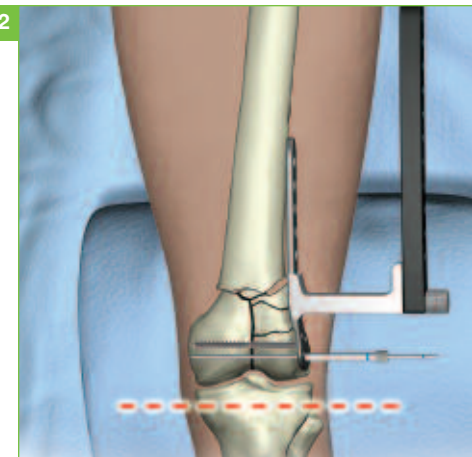
Secure plate with K-wires.

Thread the 3.2 mm pin guide (Cat. No. 2141-03-000) into the distal central hole in the femoral plate (Fig. 11). Visually ensure that the 3.2 mm pin guide is approximately 2 cm proximal to the distal end of the lateral condyle and is parallel to the knee joint. If the guide pin is not parallel, malalignment will result, typically in the form of valgus of the distal fragment.

Fig. 11

Thread 3.2 mm pin guide.

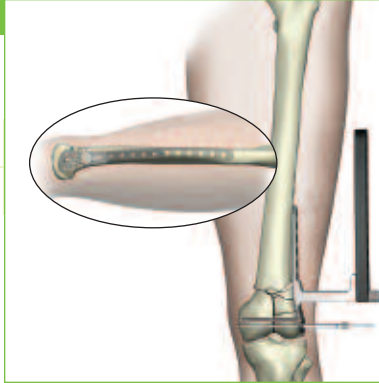
Using power, insert the 3.2 mm calibrated guide pin (Cat. No. 8290-32-009) into the 3.2 mm pin guide (Fig. 12). Verify that the guide pin is parallel to the joint line with an A/P fluoroscopic image. Take great care to avoid valgus and hyperextension malalignment of the distal fragment. If hyperextension is noted, leave the 3.2 mm guide pin in place, release the Pe.R.I. tongs and gently rotate the distal fragment into flexion. Reapply the Pe.R.I. tongs.

Fig. 12

Insert guide pin parallel to joint.

With an assistant placing gentle traction on the limb and while maintaining correct limb alignment, length, and rotation, center the plate on the shaft of the femur. Ensure alignment using A/P and lateral fluoroscopic views (Fig. 13).

Fig. 13



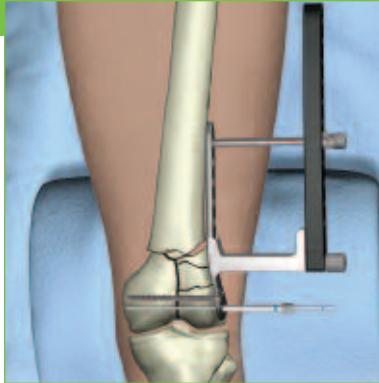
Center plate stem on femoral shaft.

Fracture alignment, rotation and length must be obtained prior to anchor bolt insertion.

Place the trocar (Cat. No. 2141-06-001) through the percutaneous sheath (Cat. No. 2141-06-003). Make a stab incision over the most proximal (or second most proximal) plate hole and insert the sheath and trocar through the incision. The “feet” of the sheath will give tactile feedback that the sheath is seated in the plate hole when the handle of the sheath is perpendicular to the target guide (Fig. 14).

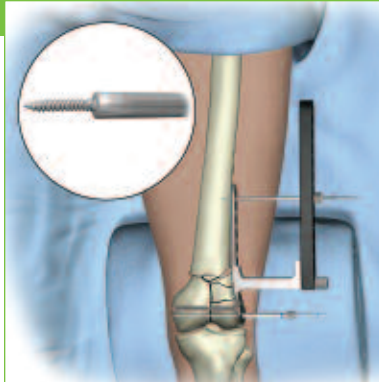
Tip: The holes of the radiolucent target guide are numbered. Find the desired plate hole by reading the corresponding numbered hole on the target guide.

Fig. 14



Insert sheath and trocar.

Fig. 15



Insert anchor bolt through sheath.

Remove the sheath and thread the anchor bolt nut (Cat. No. 2141-09-001) over the anchor bolt, directing the sheath of the nut into the hole in the target guide, to secure the assembly. Thread the nut only until its knurled end reaches the top of the target guide, advancing it to “two-finger tight.” This creates a stable rectangular construct and targeting accuracy is enhanced (Fig. 16).

Fig. 16



Place anchor bolt nut pointing “down”.

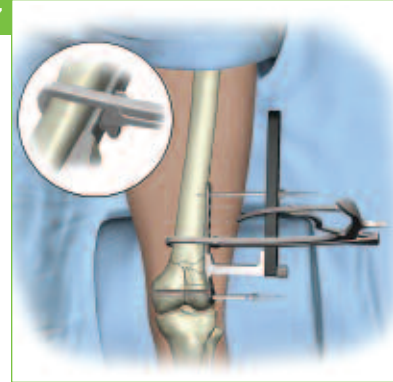
If additional stability is needed, repeat the previous three steps in a second hole with a second anchor bolt and anchor bolt nut.

If additional varus-valgus correction is needed, utilize one of the following methods: femoral bone clamp, anchor bolt or 4.5 mm non-locking screws (suggested).

Femoral Bone Clamp (Cat. No. 2141-19-000)

Under fluoroscopy, identify the mid-portion of the plate. Make a small incision on the lateral thigh, just anterior to the target guide. Spread the soft tissue down to the bone. Insert the femoral bone clamp through the incision and secure the plate to the bone. The foot of the clamp will fit into the plate hole and give tactile feedback that the clamp is seated properly in the plate. Confirm the clamp is ratcheted down snugly (Fig. 17).

Fig. 17



Secure plate with bone clamp.

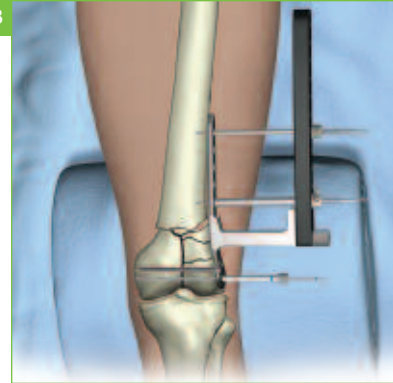
Anchor Bolt (Cat. No. 2141-08-001)

Place the trocar (Cat. No. 2141-06-001) through the percutaneous sheath (Cat. No. 2141-06-003) and insert it into the desired hole in the target arm. Make a stab incision and insert the sheath and trocar through the incision, advancing it down to the bone. The sheath’s “feet” will give tactile feedback that the sheath is seated in the plate hole when the sheath’s handle is perpendicular to the target guide.

Remove the trocar and insert the anchor bolt (Cat. No. 2141-08-001) through the percutaneous sheath (Fig. 18). Under power, advance the anchor bolt slowly until the shoulder of the bolt contacts the plate. Advancing it beyond this point could result in the threads stripping the bone.

Leaving the sheath in place, thread the anchor bolt nut (Cat. No. 2141-09-001) onto the anchor bolt. Orient the knurled end of the nut towards the sheath or away from the quick coupling end of the bolt (Fig. 19).

Fig. 18



Insert anchor bolt through sheath.

Fig. 19

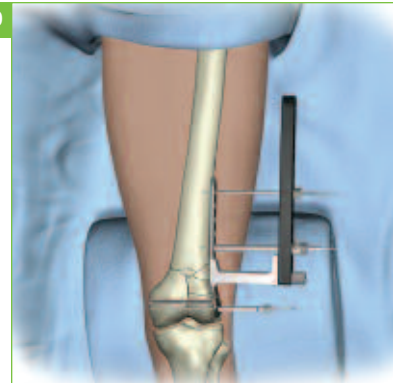


Place anchor bolt pointing “up”.

To achieve varus-valgus correction, advance the nut toward the sheath and monitoring progress under fluoroscopy, continue tightening the anchor bolt nut until the desired reduction is achieved (Fig. 20).

Tip: Use caution when using the anchor bolt for additional varus-valgus correction in osteoporotic or poor-quality bone.

Fig. 20



Advance nut to achieve reduction.

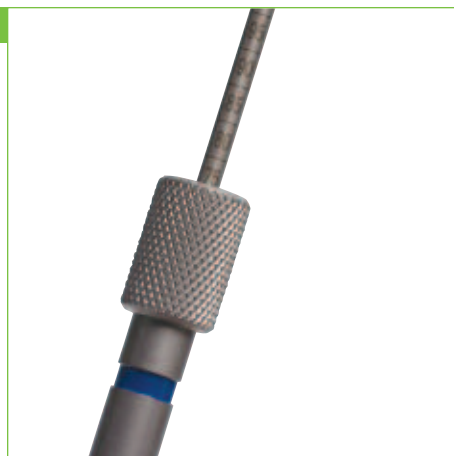
Repeat the previous steps until the desired reduction has been achieved.

4.5 mm non-locking shaft screws (Cat. No. 8157-45-0XX) can be used to pull the plate to the bone and help achieve fracture reduction. The technique for placement of 4.5 mm non-locking shaft screws is found on pages 16 and 17.

At this point, it is critical to ensure appropriate limb length, alignment and rotation. Reduction, length and alignment must be achieved prior to placement of any locking screws. Carefully assess for hyperextension or valgus deformity of the distal fragment or any fracture site distraction.

The first locking screw placed should be the 8.0 mm fixed-angle locking screw (Cat. No. 8153-08-0XX) in the head of the plate.

Re-check correct 3.2 mm guide pin position and depth using fluoroscopy. Note the correct screw length by taking a direct reading from the calibrated guide pin at the top of the pin guide (Fig. 21). Remove the 3.2 mm pin guide over the guide pin.

Fig. 21

Read screw length from calibrated pin guide.

If verification of screw length is desired, place the 3.2 mm guide pin depth gauge (Cat. No. 14115) over the guide pin and read the correct length using the top—not the blue color band—of the guide pin for reference (Fig. 22). Ensure that the depth gauge is down to the bone before taking a reading.

Fig. 22

Re-check length with depth gauge.

The 8.0 mm locking screw is self-drilling and self-tapping, but it may be necessary to pre-drill in certain cases. Drill the lateral cortex with the 5.5 mm cannulated drill bit (Cat. No. 2141-23-000) if necessary (Fig. 23).

Fig. 23

Drill lateral cortex as necessary.

Insert the appropriate length 8.0 mm cannulated cancellous locking screw (Cat. No. 8153-08-0XX) over the guide pin using the 5 mm hex cannulated screwdriver (Cat. No. 2141-21-000) coupled to the cannulated Hudson T-handle (Cat. No. 2141-22-000) (Fig. 24). **The use of a power screwdriver is not recommended for insertion of locking screws.**

Fig. 24

Insert 8.0 mm locking screw.

Use 5.5 mm cancellous locking screws (Cat. No. 8153-55-XXX) to obtain additional distal fixation as the fracture pattern dictates. The order (and quantity) of screw placement is left to the surgeon's discretion. In general, use all distal screws and at least four proximal shaft screws. The following is a guideline for screw placement.

Thread the 3.8 mm threaded drill guide (Cat. No. 2141-07-138) into one of the four polyaxial bushings in the head of the plate (Fig. 25). Avoid over-tightening the drill guide. Rotate the drill guide to the desired angle of screw insertion. Retighten the drill guide during orientation if necessary.

Tip: The two distal screws can be placed with the target guide in place. To achieve full 30-degree angulation in the two proximal 5.5 mm bushings, the target guide must be removed. Therefore, placing the two 5.5 mm locking screws after the shaft screws have been inserted and the target guide has been removed may be necessary.

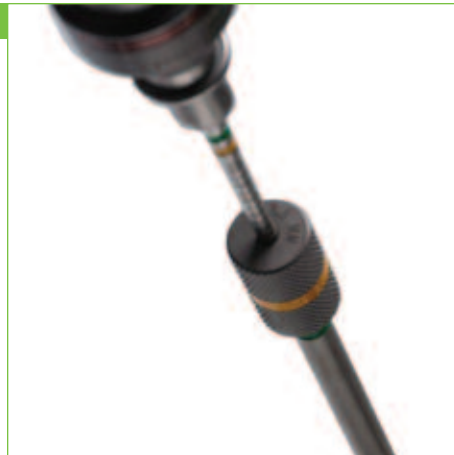
Fig. 25



Thread and orient 3.8 mm drill guide.

Using the 3.8 mm calibrated drill bit (Cat. No. 2141-14-038), drill through the threaded drill guide, across the condyles (Fig. 26).

Fig. 26



Drill through both cortices.

Verify the correct screw position and depth using fluoroscopy. Note the correct screw length by taking a direct reading from the calibrated drill bit at the top of the drill guide (Fig. 27).

Tip: To maintain bushing alignment during removal of the threaded drill guide, leave the drill bit in the bone, unscrew the drill guide and either tap the drill bit out of the bone with the drill guide or remove the drill bit using power. Place a K-wire into the drill hole to visualize screw trajectory prior to screw insertion.

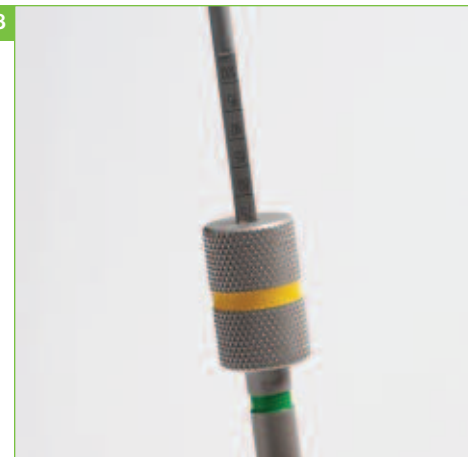
Fig. 27



Read screw length from calibrated drill bit.

If a second method of measurement is desired, use the universal depth gauge (Cat. No. 2141-10-100) through the threaded drill guide, reading the depth measurement at the top of the guide (Fig. 28).

Fig. 28



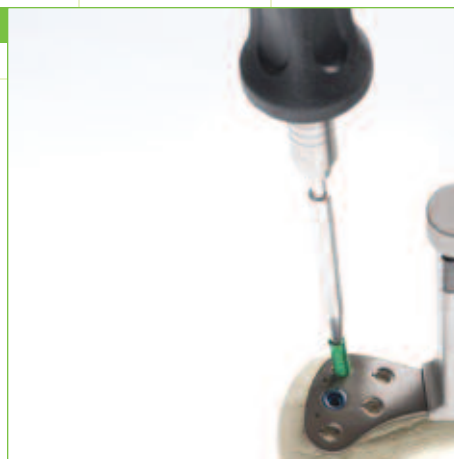
Re-check length with depth gauge.

With the 3.8 mm threaded drill guide removed, insert the appropriate length 5.5 mm cancellous locking (Cat. No. 8153-55-XXX) or non-locking screw (Cat. No. 8154-55-XXX) with the 4.5/6.5 mm large fragment screwdriver shank (Cat. No. 8242-19-000) on the ratchet screwdriver handle (Cat. No. 2141-24-000). If using a locking screw, stop when the locking threads in the screw head engage the plate and switch to the 4.5 Nm torque-limiting screwdriver (Cat. No. 2141-17-001). If using a non-locking screw, tighten the screw in the plate hole until desired reduction is achieved (Fig. 29). **The use of a power screwdriver is not recommended for insertion of locking screws.**

Tip: The 4.5/6.5 mm large fragment screwdriver shank is the shorter of the two screwdriver shanks and is not color-banded. Do not use the longer, yellow color-banded 4.5 mm percutaneous screwdriver (Cat. No. 2141-11-001) to insert the 5.5 mm cancellous screw as the torque generated on the screw will be greater than the 4.5 Nm torque limit.

Perform final tightening of the 5.5 mm locking screw with the 4.5 Nm torque-limiting screwdriver. A palpable, audible click will be felt and heard when the screw is locked into the plate (Fig. 30).

Fig. 29



Insert screw shaft with ratchet screwdriver.

Fig. 30



Lock screw with the 4.5 Nm torque-limiting screwdriver.

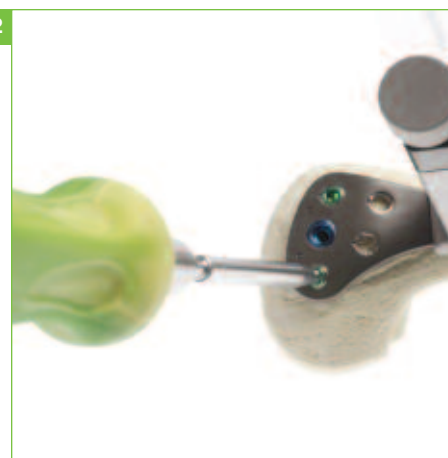
Repeat the steps on pages 12-15 as necessary for additional 5.5 mm cancellous screw placement (Figs. 31 and 32).

Fig. 31



Orient bushing and screw position.

Fig. 32

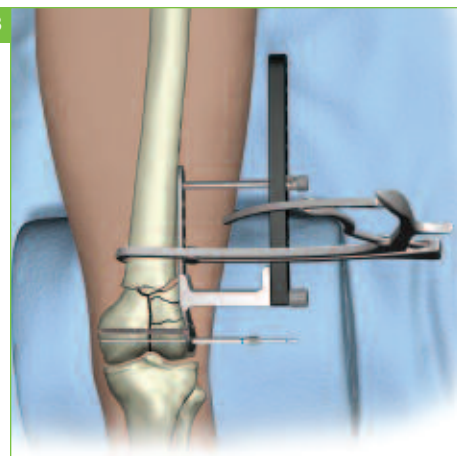


Insert 5.5 mm cancellous screw.

Non-locking screws can be used with caution to “pull the plate to the bone” and aid in fracture reduction. If the fracture is not yet reduced and the plate sits off the bone, pulling the bone to the plate may aid in reduction. If, however, the fracture is reduced and the plate sits off the bone a couple of millimeters, pulling the plate to the bone will actually cause a loss of reduction. If the fracture is reduced, it is acceptable for a locking plate to sit off the bone a few millimeters. Non-locking screws can be replaced with locking screws as needed.

Place the trocar (Cat. No. 2141-06-001) through the percutaneous sheath (Cat. No. 2141-06-003) and insert the assembly into the selected hole in the target guide. Make a stab incision through the skin and soft tissue to the plate. Advance the sheath and trocar into the plate hole and remove the trocar. The sheath’s “feet” will give tactile feedback that the sheath is seated in the plate hole when the sheath’s handle is perpendicular to the target guide (Fig. 33).

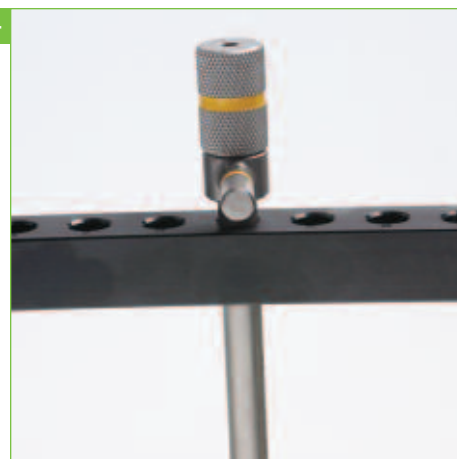
Fig. 33



Insert sheath and trocar.

Insert the 3.8 mm threaded drill guide (Cat. No. 2141-07-138) through the sheath and thread the guide into the plate hole (Fig. 34).

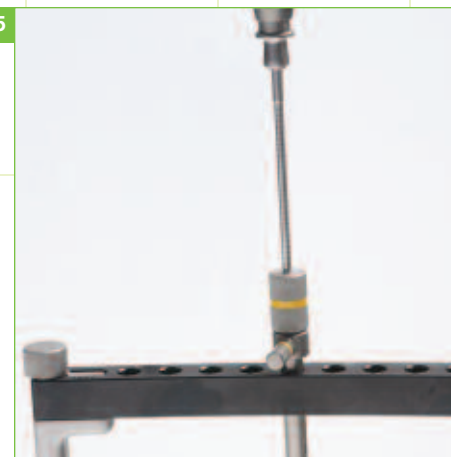
Fig. 34



Thread 3.8 mm drill guide through sheath.

Drill through the 3.8 mm threaded drill guide using the 3.2 mm calibrated drill bit (Cat. No. 2141-13-032). Use the 4.5 mm tap (Cat. No. 2141-16-000) as needed in dense bone. Determine the correct screw length by reading the depth measurement from the calibrated drill bit at the top of the guide. Add 4 mm to the depth measurement if it is desirable to have the tapping flutes extend past the far cortex (Fig. 35).

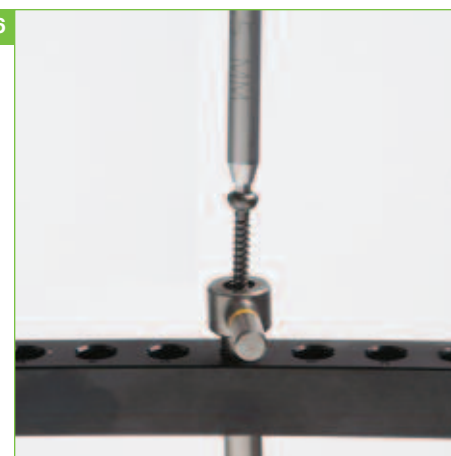
Fig. 35



Drill and determine screw length from calibrated drill bit.

Remove the 3.8 mm threaded drill guide. Place the appropriate length 4.5 mm non-locking cortical screw (Cat. No. 8157-45-0XX) through the percutaneous sheath with the 4.5 mm percutaneous screwdriver (Cat. No. 2141-11-001) either under power or by hand with the ratchet screwdriver (Cat. No. 2141-24-000) (Fig. 36).

Fig. 36



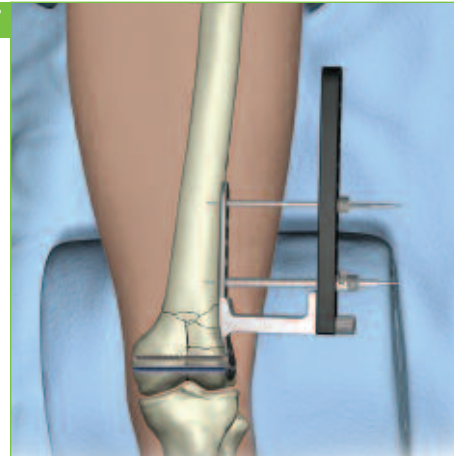
Insert 4.5 mm non-locking screw.

Repeat the previous steps until the plate has been pulled sufficiently to the bone or the desired shaft reduction has been achieved.

Use 4.5 mm locking shaft screws (Cat. No. 8150-45-5XX) to obtain additional proximal fixation as the fracture pattern dictates. The order (and quantity) of screw placement is left to the surgeon's discretion. In general, use all distal screws and at least four proximal shaft screws. The following is a guideline for screw placement.

Place the trocar (Cat. No. 2141-06-001) through the percutaneous sheath (Cat. No. 2141-06-003) and insert the assembly into the selected hole in the target guide. Make a stab incision through the skin and soft tissue to the plate. Advance the sheath and trocar into the plate hole and remove the trocar. The sheath's "feet" will give tactile feedback that the sheath is seated in the plate hole when the sheath's handle is perpendicular to the target guide (Fig. 37).

Fig. 37



Insert sheath and trocar.

Remove the trocar. Insert the 3.8 mm threaded drill guide (Cat. No. 2141-07-138) through the sheath and thread the guide into the plate hole (Fig. 38).

Fig. 38

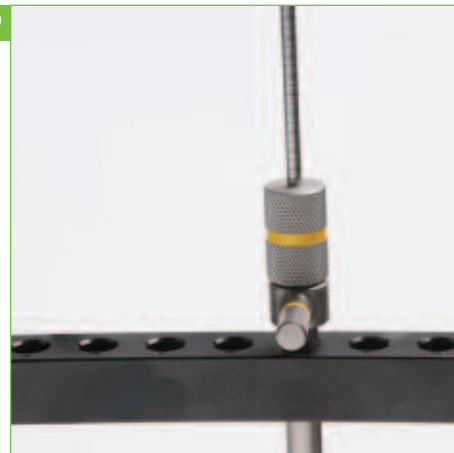


Thread 3.8 mm drill guide through sheath.

Drill through the 3.8 mm threaded drill guide using the 3.8 mm calibrated drill bit (Cat. No. 2141-14-038). Use the 4.5 mm tap (Cat. No. 2141-16-545) as needed in dense bone. Determine the correct screw length by reading the depth measurement from the calibrated drill bit at the top of the guide. Add 4 mm to the depth reading if it is desirable to have the tapping flutes extend past the far cortex (Fig. 39).

The 8 mm, 10 mm and 12 mm 4.5 mm cortical locking screws have a blunt tip. Use the 4.5 mm tap as needed prior to insertion of these screws.

Fig. 39



Drill and determine screw length from calibrated drill bit.

If a second method of measurement is desired, remove the drill bit, insert the universal depth gauge (Cat. No. 2141-10-100) and take a depth reading on the gauge at the top of the drill guide (Fig. 40).

Fig. 40

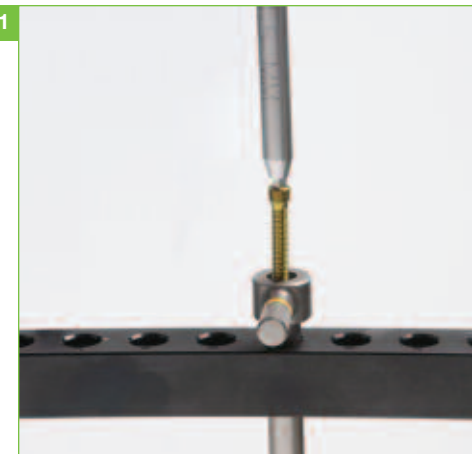


Re-check length with depth gauge.

With the 3.8 mm threaded drill guide removed, place the appropriate length 4.5 mm cortical locking screw (Cat. No. 8150-45-5XX) through the percutaneous sheath with the gold-banded 4.5 mm percutaneous screwdriver (Cat. No. 2141-11-001) on the ratchet screwdriver handle (Cat. No. 2141-24-000). Stop when the gold band on the screwdriver reaches the top of the sheath, as this indicates that the locking threads of the screw head will now engage the threaded plate hole, and switch to the 4.5 Nm torque-limiting screwdriver (Cat. No. 2141-17-001) for final tightening (Fig. 41).

The use of a power screwdriver is not recommended for insertion of locking screws.

Fig. 41



Insert screw shaft with ratchet screwdriver.

Perform final tightening of the 4.5 mm locking screws with the 4.5 Nm torque-limiting screwdriver (Fig. 42). A palpable, audible click will be felt and heard when the screw is locked into the plate.

Fig. 42



Lock screw with 4.5 Nm torque-limiting screwdriver.

Repeat the previous steps for the remaining threaded shaft holes as desired.

If using the anchor bolt, remove the anchor bolt nut and anchor bolt, and replace with a 4.5 mm locking screw following the above technique.

Remove the target assembly, gaining access to the remaining two proximal polyaxial holes and the most distal threaded shaft hole. Follow the previously detailed steps for placement of the 5.5 mm locking screws in the head of the plate and 4.5 mm locking screws in the shaft of the plate as necessary (Figs. 43 and 44).

Fig. 43



Fill remaining polyaxial screws.

Fig. 44



Fill proximal shaft hole.

Close the wound in layers over a suction drain. For distal fractures, a hinged knee brace adds coronal plane stability while allowing knee flexion. Begin physical therapy when the wound is dry and the swelling has subsided. Higher energy injuries may require a period of soft tissue healing after surgery and before range of motion can be addressed aggressively. Weight bearing is typically deferred for 10-12 weeks for fractures with intra-articular involvement. Patients with extra-articular fractures are allowed a gradual progression of weight bearing beginning at 6-8 weeks, if a callus is present.

IMPORTANT

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

Bone plates and screws are intended to provide a means of bone fixation and to aid in the management of fractures and reconstructive surgeries.

CONTRAINDICATIONS

- Active infection
- Presence of malignant primary or metastatic tumors
- Conditions which could retard normal healing, such as previous infections, etc.
- Insufficient bone quantity or quality
- Conditions that restrict the patient's ability to follow post-operative instructions
- Foreign body sensitivity

WARNINGS AND PRECAUTIONS

Device cannot be expected to withstand the unsupported stresses of full weight bearing. External support and restricted physical activities should be employed until firm bone union is achieved. Proper implant selection should be made for size and shape limitations. Implants should not be bent, notched or scratched during implantation and handling. If other metallic devices are used, they should be manufactured from a similar metal to avoid galvanic corrosion. **NO METALLIC IMPLANT SHOULD BE REUSED.** Patient should receive detailed instructions on the use and limitations of the device. Implants should be removed whenever possible. Screws are not approved for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

ADVERSE EFFECTS

The following are the most frequent adverse effects involving the use of bone plates and/or screws: Loosening, bending, cracking, or fracture of the components or loss of fixation due to non-union, osteoporosis, or unstable comminuted fractures; loss of anatomic position with non-union or malunion with rotation or angulation; infection; allergies or other reactions to device material.



FEMORAL PLATES, STERILE

Cat. No.	Description			
8141-30-106	6 Hole	Right	179.4 mm	
8141-30-109	9 Hole	Right	233.5 mm	
8141-30-112	12 Hole	Right	287.6 mm	
8141-30-115*	15 Hole	Right	341.7 mm	
8141-30-118*	18 Hole	Right	395.8 mm	
8141-31-106	6 Hole	Left	179.4 mm	
8141-31-109	9 Hole	Left	233.5 mm	
8141-31-112	12 Hole	Left	287.6 mm	
8141-31-115*	15 Hole	Left	341.7 mm	
8141-31-118*	18 Hole	Left	395.8 mm	

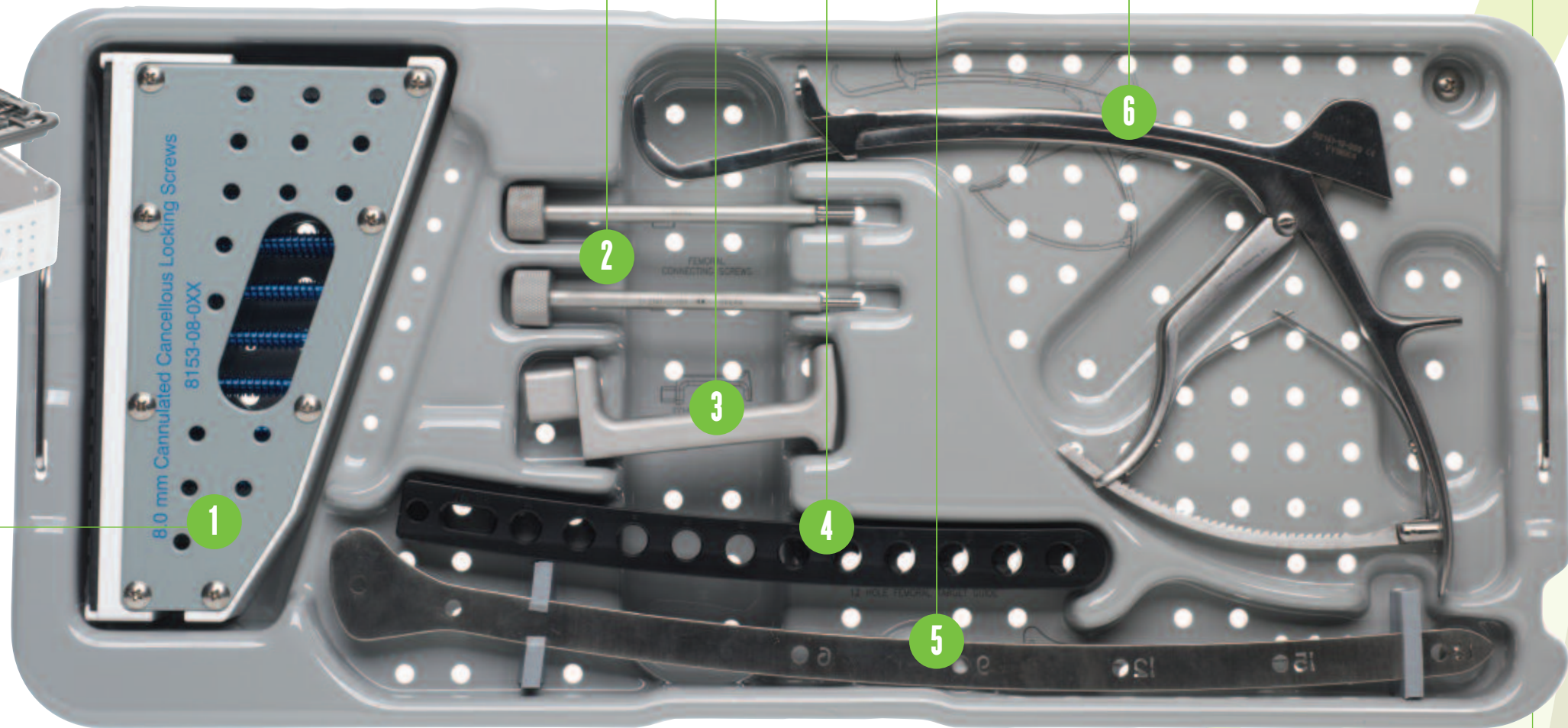
*Special order

POLYAX
FEMORAL CASE
TOP



8153-08-0XX

8.0 mm Cannulated Cancellous Screws
25, 35, 50-90 mm in 5 mm increments, 2 ea.



2141-02-001

Femoral Connecting Screw, 2 ea.

2141-02-000

Femoral Handle

2141-02-012

12 Hole Femoral Target Guide

2141-01-000

Intra-operative Femoral Template

2141-19-000

Femoral Bone Clamp

14115
3.2 mm Guide Pin Depth Gauge

2141-21-000
5.0 mm Cannulated Screwdriver, 2 ea.

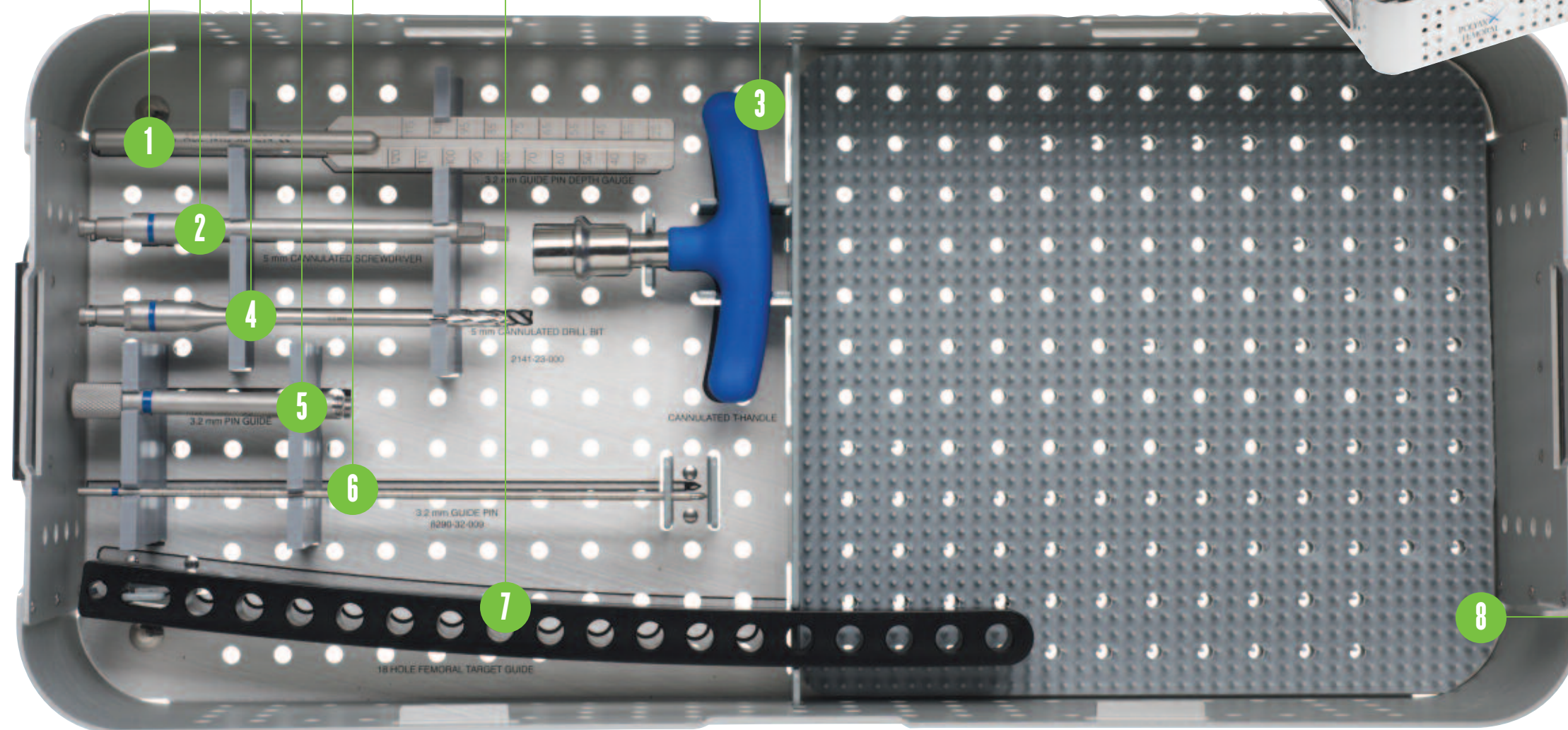
2141-23-000
5.5 mm Cannulated Drill Bit, 2 ea.

2141-03-000
3.2 mm Pin Guide

8290-32-009
3.2 mm Guide Pin, 2 ea.

2141-02-018
18 Hole Femoral Target Guide

2141-22-000
Cannulated T-handle



**POLYAX
FEMORAL CASE
BOTTOM**

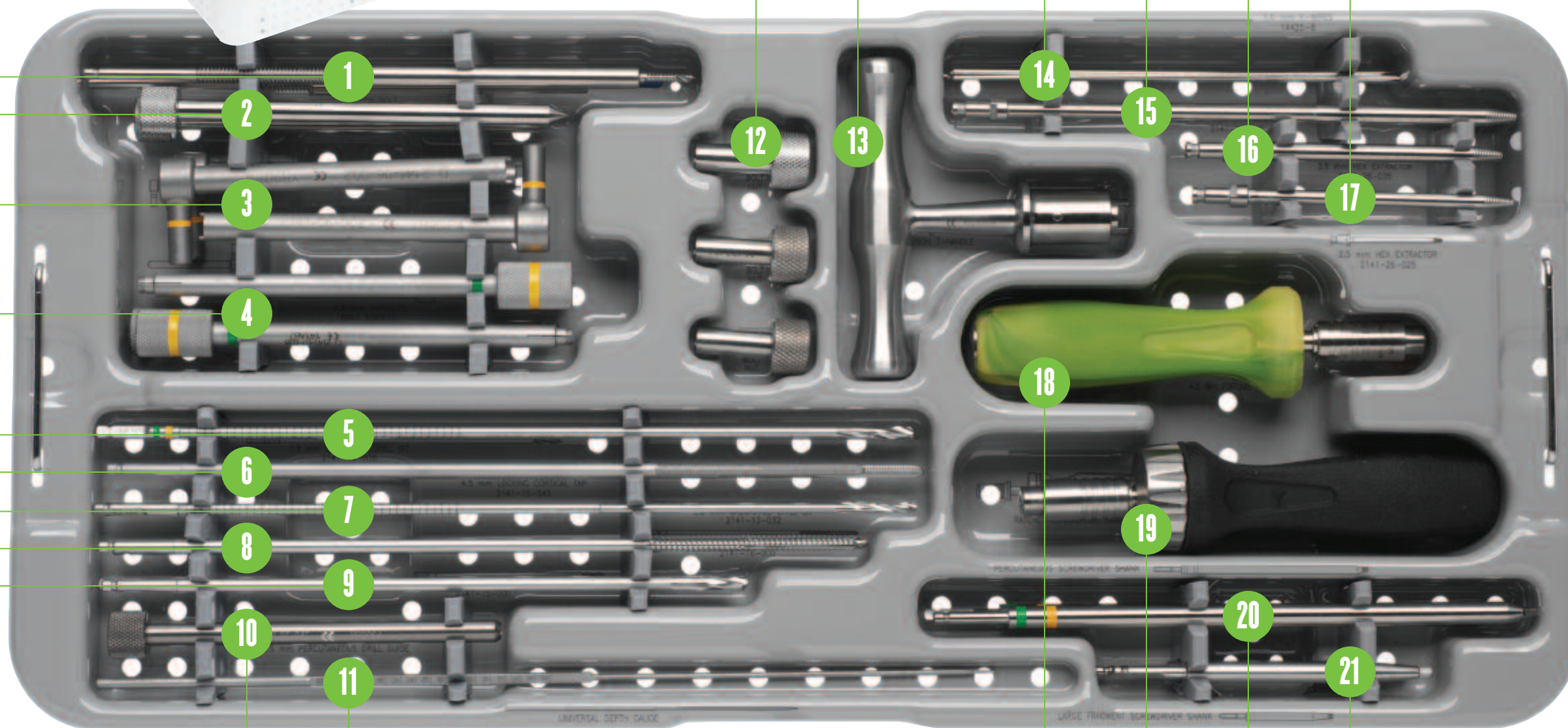
8299-13-000
Femoral Case

8

POLYAX SCREW CASE TOP



- 2141-08-001
Anchor Bolt, 3 ea.
- 2141-06-001
Percutaneous Trocar, 2 ea.
- 2141-06-003
Percutaneous Sheath, 2 ea.
- 2141-07-138
3.8 mm Threaded Drill Guide, 3 ea.
- 2141-14-038
3.8 mm Calibrated Drill Bit, 2 ea.
- 2141-16-545
4.5 mm Locking Cortical Tap, 2 ea.
- 2141-13-032
3.2 mm Calibrated Drill Bit, 2 ea.
- 2141-16-000
4.5 mm Non-locking Cortical Tap, 2 ea.
- 2141-15-000
4.5 mm Drill Bit, 2 ea.
- 2141-06-045
4.5 mm Percutaneous Drill Guide
- 2141-10-100
Universal Depth Gauge



2141-09-001
Anchor Bolt Nut, 3 ea.

2274-32-000
Hudson T-handle

14425-6
1.6 mm K-wires, 6 in, 12 ea.

2141-26-135
3.5 mm Hex Extractor, Long, 2 ea.

2141-26-035
3.5 mm Hex Extractor, 2 ea.

2141-26-025
2.5 mm Hex Extractor, 2 ea.

2141-17-001
4.5 Nm Torque-limiting Screwdriver

2141-24-000
Ratchet Screwdriver Handle

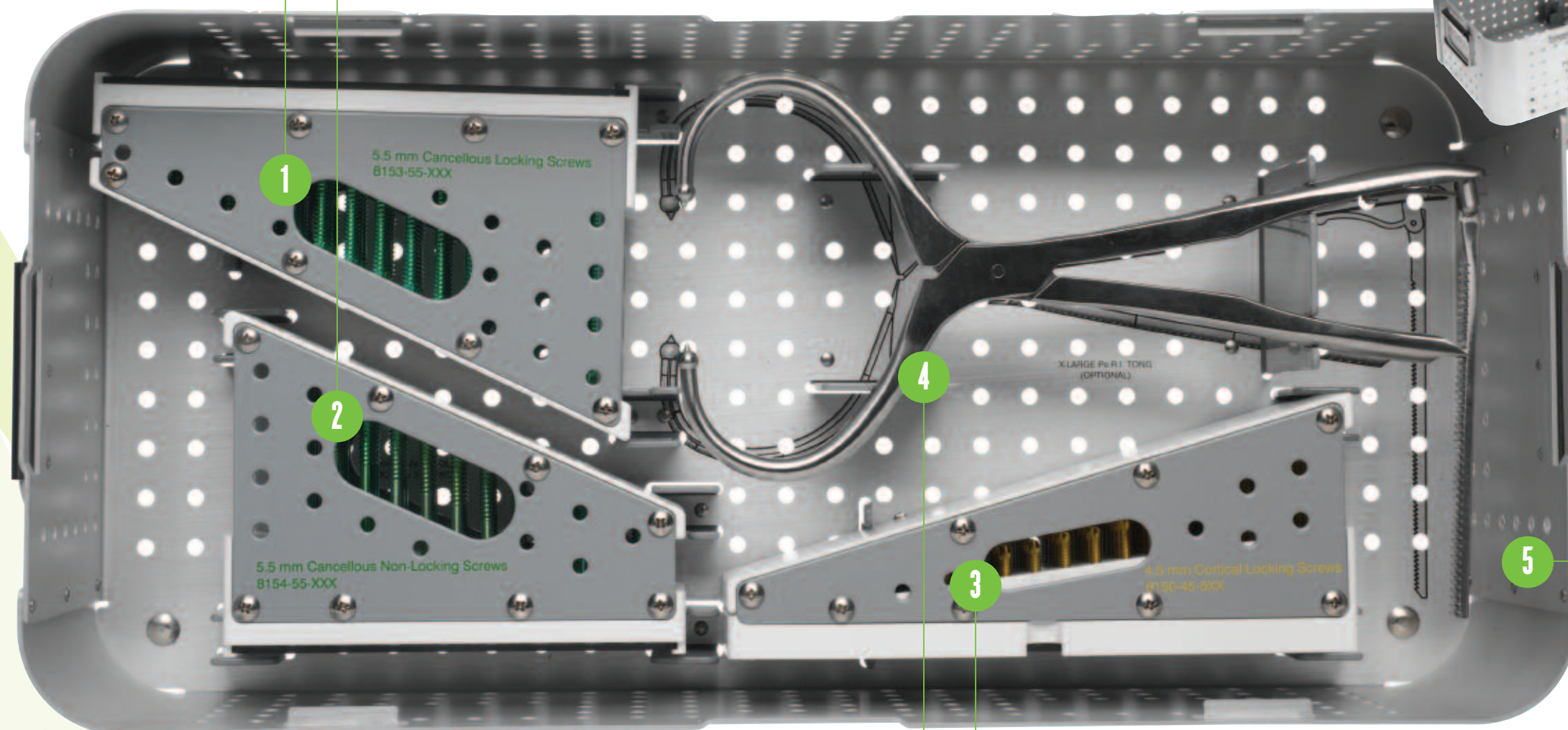
2141-11-001
Percutaneous Screwdriver Shank, 2 ea.

8242-19-000
Large Fragment Screwdriver Shank, 2 ea.

8153-55-XXX
5.5 mm Cancellous Locking Screws
25-100 mm, 4 ea.



8154-55-XXX
5.5 mm Cancellous Non-locking Screws
40, 45 mm, 2 ea.
50-100 mm, 4 ea.



1919
X-large Pe.R.I. Tong (optional)

8150-45-5XX
4.5 mm Cortical Locking Screws
8-16 mm in 2 mm increments, 6 ea.
20 mm, 6 ea.
26-42 mm in 2 mm increments, 6 ea.
45-60 mm in 5 mm increments, 6 ea.



POLYAX SCREW CASE BOTTOM



8299-13-200
Common Screw Case

REQUIRED SCREW

8157-45-0XX*

4.5 mm Cortical Non-locking Screws

- 14-18 mm in 2 mm increments, 4 ea.
- 20-28 mm in 2 mm increments, 8 ea.
- 30-40 mm in 2 mm increments, 12 ea.
- 42 mm, 8 ea.
- 44-60 mm in 2 mm increments, 4 ea.
- 65, 70 mm, 4 ea.



*8299-18-001 Large Fragment Case