Proximal Tibial Locked Plating System

Surgical Technique
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Introduction and Indications

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 over standard Titanium alloys and stainless steel, 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.

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-angle locking hole or polyaxial bushing.

Indications

The POLYAX Locked Plating System is intended for use in:

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

The POLYAX® Locked Plating System is intended for use in cases requiring stabilization of malunions, non-unions, and osteotomies of the distal femur and proximal tibia and Open Reduction Internal Fixation (ORIF) repair of closed and open fractures of the distal femur and proximal tibia including, but not limited to the following: periarticular fractures, such as simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression fractures with associated shaft fractures, and periprosthetic fractures.
System Features

The most proximal fixation of the tibial Polyax Locked Plating System construct includes a row of three 4.0 mm polyaxial bushings. Slightly distal to the 4.0 mm holes is a triangular arrangement of three 5.5 mm polyaxial bushings in the head/neck area of the plate. The distal plate stem provides fixed-locked screw holes for 4.5 mm locking or 4.5 mm non-locking screws. Plates are available in lengths of 2, 5, 8, 11 and 14 holes (Cat. No. 8141-32-0XX—right, 8141-33-0XX—left) and four K-wire holes are included in the plate for optional intra-operative temporary fixation.

Screws

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Patient Positioning and Templating

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 calf (Fig. 1).

Use the pre-operative tibial template (Cat. No. 2994-54-010) 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 tibial shaft distal 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 tibial template (Cat. No. 2141-01-001). 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).
Incision

Make an s-shaped incision centered on Gerdy's tubercle (Fig. 4). For extra-articular and relatively simple intra-articular fractures, this is often adequate exposure.

For more complicated intra-articular fractures where direct visualization of fragments is necessary, two incision options exist: 1) Extend the s-shaped incision in Fig. 4 proximally and perform a formal submeniscal arthrotomy, or 2) Make an anterolateral incision and perform a formal submeniscal arthrotomy (Fig. 5).

For elderly patients, especially those who may require knee arthroplasty at a later date, a more anterior incision is preferred. It is critical, regardless of surgical approach, that soft tissues are healed prior to surgery and that full-thickness flaps and gentle soft tissue handling techniques are used.
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 locking screw placement.

Non-locking screws can also be used in the
head of the plate to help achieve fracture
reduction. 4.0 mm partially threaded non-
locking screws (Cat. No. 8155-40-XXX) can
be used in any of the three 4.0 polaxial
bushings in the head of the plate to reduce
an intercondylar split. 5.5 mm partially
threaded non-locking screws (Cat. No.
8154-55-XXX) can be placed in any of the
5.5 mm polyaxial bushings in the head/neck
of the plate to aid in fracture reduction.
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, tibial target
guide (Cat. No. 2141-45-014), tibial
handle (Cat. No. 2141-04-000—right,
2141-05-000—left) and tibial connecting
screw (Cat. No. 2141-45-001) on the
back table (Fig. 6). Orient the tibial target
guide for the appropriate left or right
plate. The appropriate side will face up
and be readable once assembled.
Percutaneous Approach and Plate Placement

Using the target guide as a handle, insert the plate in a submuscular, extraperiosteal fashion along the lateral aspect of the tibia (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.

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

Tip: The POLYAX tibial plates are precontoured to the lateral tibia and sit more anteriorly on the lateral aspect of the lateral tibial plateau and approximately 2 mm from the joint line. The plates are designed to allow subchondral fixation though the plate allowing very proximal fixation while minimizing potential loss of reduction of the articular surface.
Preliminary Fixation

Obtain preliminary plate fixation to the proximal tibial plateau 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 three small holes on the head of the plate. Make a small medial incision for the other tip and clamp down to bring the proximal end of the plate flush to the bone (Fig. 9).

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

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

*Tip: After internal fixation is complete, the lateral meniscus, if torn or detached, can be sutured to the proximal K-wire holes in the POLYAX tibial plate.*
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 tibia. Ensure alignment using A/P and lateral fluoroscopic views (Fig. 11).

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 distal (or second most distal) 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. 12).

**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.
Remove the trocar and insert the anchor bolt (Cat. No. 2141-08-001) through the percutaneous sheath. Under power, advance the anchor bolt slowly until the shoulder of the bolt contacts the plate and pulls the plate down to the bone (Fig. 13). Advancing the bolt beyond this point could result in the threads stripping the bone.

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. 14).

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: tibial bone clamp, anchor bolt or 4.5 mm non-locking screws (suggested).

**Tibial Bone Clamp**  
**Cat. No. 2141-20-000**

Under fluoroscopy, identify the mid-portion of the plate. Make a small incision on the lateral calf, just anterior to the target guide. Spread the soft tissue down to the bone. Insert the tibial 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. 15).

**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. 16). 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. 17).

To achieve varus-valgus correction, advance the nut towards the sheath and monitoring progress under fluoroscopy, continue tightening the anchor bolt nut until the desired reduction is achieved (Fig. 18).

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 20-21.
At this step, it is critical to ensure appropriate limb length, alignment and rotation prior to locking screw placement. Reduction, length and alignment must be achieved prior to placement of any locking screws. Carefully assess for hyperextension or valgus deformity of the proximal fragment or any fracture site distraction.

4.0 mm non-locking lag screws (Cat. No. 8155-40-XXX) are provided in the set for obtaining articular reduction through the plate. Non-locking screws must be placed prior to the insertion of any locking screws.

Placement of 4.0 mm locking screws (Cat. No. 8153-04-XXX) is outlined in the following pages.

Thread the 2.5 mm threaded drill guide (Cat. No. 2141-07-029) into one of the three polyaxial bushings in the head of the plate (Fig. 19). 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:** When placing the 4.0 mm screws, select the hole of most critical screw placement first. Dispersing the screws to support the articular surface and provide optimum fixation is recommended.

Using the 2.5 mm calibrated drill bit (Cat. No. 2141-29-000), drill through the threaded drill guide across the plateau (Fig. 20).
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. 21).

**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.

If a second method of measurement is desired, insert 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. 22).

With the threaded drill guide removed, insert the appropriate length 4.0 mm cancellous screw using the small fragment screwdriver shank (Cat. No. 8241-57-071) on the black ratchet screwdriver handle (Cat. No. 2141-24-000) (Fig. 23). If using a locking screw, stop when the locking threads in the screw head engage the plate and switch to the purple 2.0 Nm torque-limiting screwdriver (Cat. No. 2141-18-001). If using a non-locking screw, tighten the screw in the plate hole until desired reduction is achieved. **The use of a power screwdriver is not recommended for insertion of locking screws.**
Perform final tightening of the 4.0 mm locking screw with the purple 2.0 Nm torque-limiting screwdriver. A palpable, audible click will be felt and heard when the screw is locked into the plate (Fig. 24).

Repeat the steps on pages 10-11 as necessary for additional 4.0 mm cancellous screw placement (Fig. 25).
5.5 mm Cancellous Locking and Non-Locking Screws

Use 5.5 mm cancellous locking screws (Cat. No. 8153-55-XXX) 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 proximal screws and at least four distal 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 three polyaxial bushings in the head/neck of the plate (Fig. 26). 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:** To achieve full 30-degree angulation in the two proximal 5.5 bushings, the target guide must be removed. The distal 5.5 mm screw in the neck of the plate can only be accessed after the percutaneous guide has been removed. Therefore, placing the three 5.5 mm locking screws after the target guide has been removed may be necessary.

Using the 3.8 mm calibrated drill bit (Cat. No. 2141-14-038), drill through the threaded drill guide across the tibial plateau (Fig. 27).
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. 28).

**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.

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. 29).

With the 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 black 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 green and gold 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. 30). **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. The longer, gold-banded 4.5 mm percutaneous screwdriver (Cat. No. 2141-11-001) should not be used to insert the 5.5 mm cancellous screw for protection of the screw hex.

Perform final tightening of the 5.5 mm locking screw with the green and gold 4.5 Nm torque-limiting screwdriver. A palpable, audible click will be felt and heard when the screw is locked into the plate (Fig. 31).

Repeat the steps on pages 17-19 as necessary for additional 5.5 mm cancellous screw placement (Fig. 32).
4.5 mm Non-Locking Shaft Screws

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 plate to the bone 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).

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).
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 non-locking cortical 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).

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 gold-banded 4.5 mm percutaneous screwdriver shank (Cat. No. 2141-11-001) either under power or by hand with the black ratchet screwdriver (Cat. No. 2141-24-000) (Fig. 36).

Repeat the previous steps until the plate has been pulled sufficiently to the bone or the desired shaft reduction has been achieved.
4.5 mm Locking Shaft Screws

Use 4.5 mm locking shaft screws (Cat. No. 8150-45-5XX) 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 proximal screws and at least four distal 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).

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).
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 locking cortical 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 locking cortical tap as needed prior to insertion of these screws.

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).
4.5 mm Locking Shaft Screws

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 shank (Cat. No. 2141-11-001) on the black ratchet screwdriver handle (Cat. No. 2141-24-000). Stop when the gold band on the screwdriver shank 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 green and gold 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.

Perform final tightening of the 4.5 mm locking screws with the green and gold 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.

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 proximal polyaxial holes and the most proximal threaded shaft hole. Follow the previously detailed steps for placement of the 5.5 mm locking screws in the head/neck of the plate and 4.5 mm locking screws in the shaft of the plate as necessary (Figs. 43 and 44).

Close the wound in layers over a suction drain. For proximal 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.
Instrument Catalog

**POLYAX Tibial Case Top**

**Tibial Plates, Sterile**

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4.0 mm Cancellous Locking Screw  
50–100 mm in 5 mm increments, 3 ea.

8155-40-XXX  
4.0 mm Cancellous Non-locking Screw  
50–100 mm in 5 mm increments, 2 ea.

2141-45-001  
Tibial Connecting Screw, 2 ea.
2141-20-000
Tibial Bone Clamp

2141-05-000
Left Tibial Handle

2141-04-000
Right Tibial Handle

2141-01-001
Intra-Operative Tibial Template

2141-45-014
14 Hole Tibial Target Guide
**POLYAX Tibial Case Bottom**

- **2141-18-001**
  - 2.0 Nm Torque-limiting Screwdriver
- **8241-57-071**
  - Small Fragment Screwdriver Shank, 2 ea.
- **2141-07-029**
  - 2.5 mm Bushing Drill Guide, 3 ea.
- **8241-61-120**
  - 4.0 mm Cancellous Tap, 2 ea.
- **8290-31-120**
  - 2.9 mm Drill Bit, 2 ea.
- **2141-29-400**
  - 2.9/4.0 mm Drill Guide
2141-29-000
2.5 mm Calibrated Drill Bit, 2 ea.

8241-00-120
Small Fragment Depth Gauge

8299-13-100
Tibial Case
**POLYAX Screw Case Top**

2141-08-001
Anchor Bolt, 3 ea.

2141-06-001
Percutaneous Trocar, 2 ea.

2141-06-003
Percutaneous Sheath, 3 ea.

2141-07-138
3.8 mm Threaded Drill Guide, 3 ea.

2141-16-545
4.5 mm Locking Cortical Tap, 2 ea.

2141-14-038
3.8 mm Calibrated Drill Bit, 2 ea.

2141-14-038
3.8 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.

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 mm Percutaneous Screwdriver Shank, 2 ea.

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

2141-11-001  4.5 mm Percutaneous Screwdriver Shank, 2 ea.

2141-24-000  Ratchet Screwdriver

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

**POLYAX Screw Case Bottom**

8153-55-XXX
5.5 mm Cancellous Locking Screws
25-100 mm in 5 mm increments, 4 ea.

8154-55-XXX
5.5 mm Cancellous Non-locking Screws
40, 45 mm, 2 ea.
50-100 mm in 5 mm increments, 4 ea.

8299-13-200
Common Screw Case
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.

8157-45-XXX
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.
Screws, Plates, Intramedullary Nails, Compression Hip Screws, Pins and Wires

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: The use of metallic surgical appliances provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

Contraindications: Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Orthopaedic Screws and Plates only: Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

Additional Contraindication for Retrograde Femoral Nailing: A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45° of flexion.

Additional Contraindications for Compression Hip Screws only: Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions: Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

Adverse Events: The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and allergies and adverse reactions to the device material. Surgeons should take care when targeting and drilling for the proximal screws in any tibial nail with oblique proximal screws. Care should be taken as the drill bit is advanced to penetrate the far cortex. Advancing the drill bit too far in this area may cause injury to the deep peroneal nerve. Fluoroscopy should be used to verify correct positioning of the drill bit.

Additional Adverse Events for Compression Hip Screw only: Screw cutout of the femoral head (usually associated with osteoporotic bone).