ALPS

ANATOMIC LOCKED PLATING SYSTEM

Proximal Tibia
Plating System

Product Rationale & Surgical Technique

never stop moving™

DePuy TRAUMA

A division of DePuy Orthopaedics, Inc.

Contents

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Introduction

The A.L.P.S. Proximal Tibia plates represent the next generation in anatomic locked plating of tibial plateau fractures. It combines the benefits of low profile titanium plate metallurgy with the advantages of double row, multi-planar locked subchondral screw technology. These features allow the formation of a three dimensional matrix of fixed and variable angle screws beneath the articular surface to create a true subchondral scaffold that can provide strong fixation in both comminuted fractures and osteopenic bone.

This plate features a unique, double row of proximal screws designed to accommodate 4.0 mm and 3.5 mm locking and non-locking screws. This allows sequential stabilization in multiple planes. The superior row features an additional posterior screw hole with a divergent trajectory developed to capture the most posterio-medial aspect of the plateau. Similarly, the most anterior screw hole is angled to capture the anterior medial plateau. Thus, when all four subchondral screws are placed in the upper row, the spread of these screws stabilize the entire tibial articular surface. The row below features three screws in positions staggered between the upper row to offer a complete capture of the proximal tibia.

The plate features two kickstand screws, one angled anteriorly and one placed posteriorly. Both are positioned to thread between the screws of the upper two rows, maximizing the plate's ability to secure a wide array of metaphyseal area from the lateral side.

Prominent proximal tibia implants can cause discomfort and wound breakdown in the post-operative period. The low profile A.L.P.S. plates are specifically designed to match the anatomy of the proximal tibia, with minimal implant thickness, while still having the required strength. As a result of a thorough development process, using hundreds of CT scans from a variety of races and genders, the design team was able to match the diversity of proximal tibial anatomy into two unique lateral proximal tibia plate shapes. The distinction lies within the shape of the slope between the head and the shaft of the plate, at the metaphyseal flare. These two plates are categorized as the standard curve and large curve plates and are both available in 3, 5, 7, 9, 11, 13 and 15 hole plates.

The system features F.A.S.T. Guide® technology to facilitate the surgical procedure and save time in the operating room. F.A.S.T. Guide® inserts allow for accurate drilling and placement of screws. Additionally, these plates allow for the use of locking, variable angle, and non-locking screws. This hybrid fixation concept allows the surgeon to stabilize the fracture either by the use of standard lag screw techniques, locked plating techniques, or a combination of both methods.

Indications for Use:
The DePuy Proximal Tibia Plating System is intended for treatment of nonunions, osteotomies, malunions, osteopenic bone and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic and fractures with associated shaft fractures.

Low Profile

Anatomically Contoured

Proximal Tibia Plates

The A.L.P.S. Proximal Tibia Plate is pre-contoured to mimic the anatomy of the proximal tibia for optimum bone conformance

Low profile contouring helps minimize prominence and soft tissue irritation

Proximal Tibia Plates are available in standard curve and large curve sizes to accommodate the variance in the lateral metaphyseal flare from patient to patient

Bullet-tipped distal plate end minimizes soft tissue disruption during percutaneous insertion

Fast, Accurate Surgeries

F.A.S.T. Guide® Technology

F.A.S.T. Guide®

Facilitate accurate drilling

Pre-loaded and disposable

Save time in the OR since no intra-operative assembly is required

F.A.S.T. Guide® Adapters

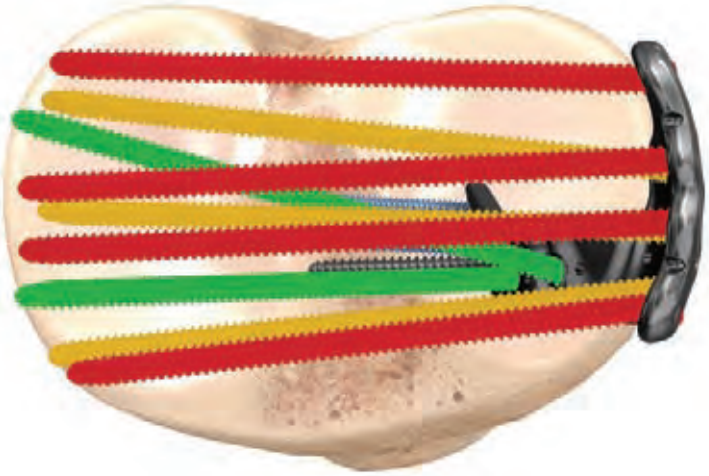
Adapters allow for 1.6 mm K-wires to be inserted over F.A.S.T. Guide® Inserts for optimal temporary fixation

To further facilitate surgical procedures, our Proximal Tibia Plates are pre-loaded with Fixed Angle Screw Targeting - F.A.S.T. Guide® Inserts. These guides direct the trajectory of the drill right into the plate.

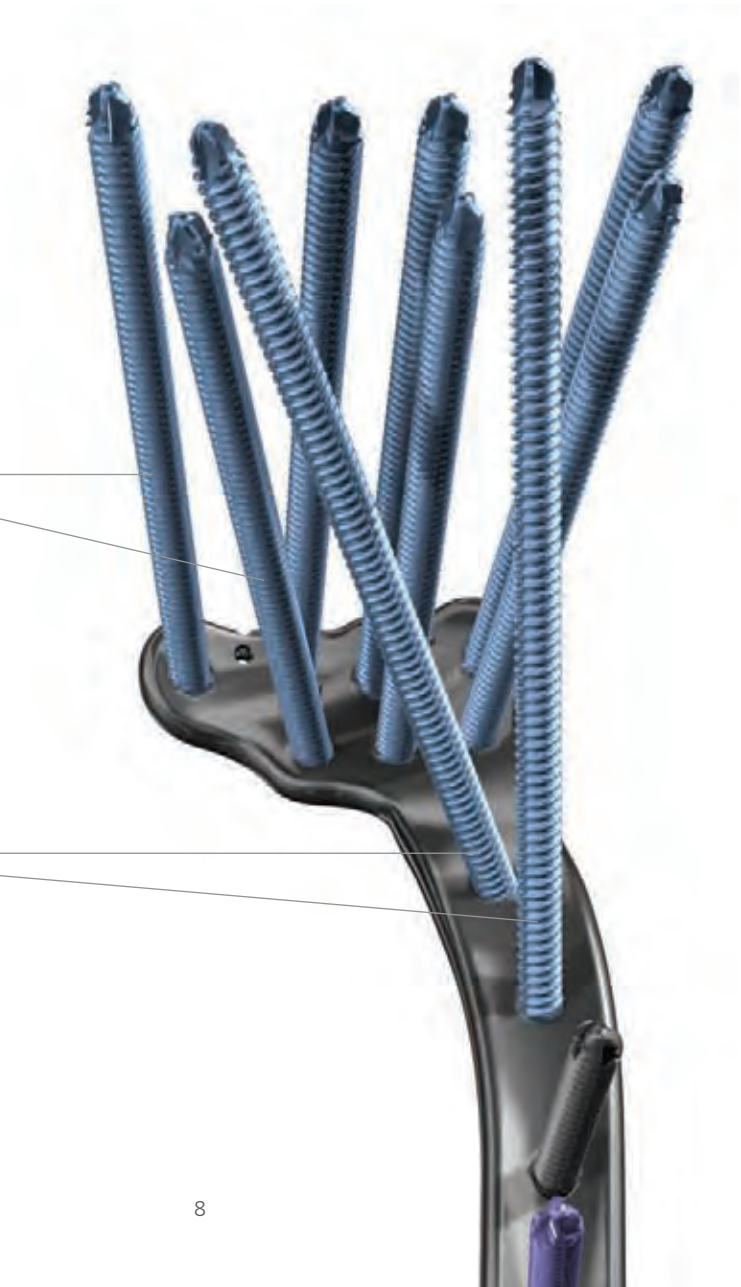
Axial View

The diagram on the right depicts the optimal screw trajectory and coverage offered by the system. The diagram has been color coded to clearly depict the distinction among the rows of screws within the plateau.

Red = Proximal raft row of screws
Yellow = Distal raft row of screws
Green = Kickstand screws



Medial View



Versatility in Construct

Strength and Support

Diverging raft row screws and dual kickstand screws offer optimum subchondral support

Dual Raft rows allow sequential stabilization among multiple planes

Engineered from TiMAX™ for strength, biocompatibility and enhanced imaging capabilities over stainless steel

Locking and Non-Locking Screw Options

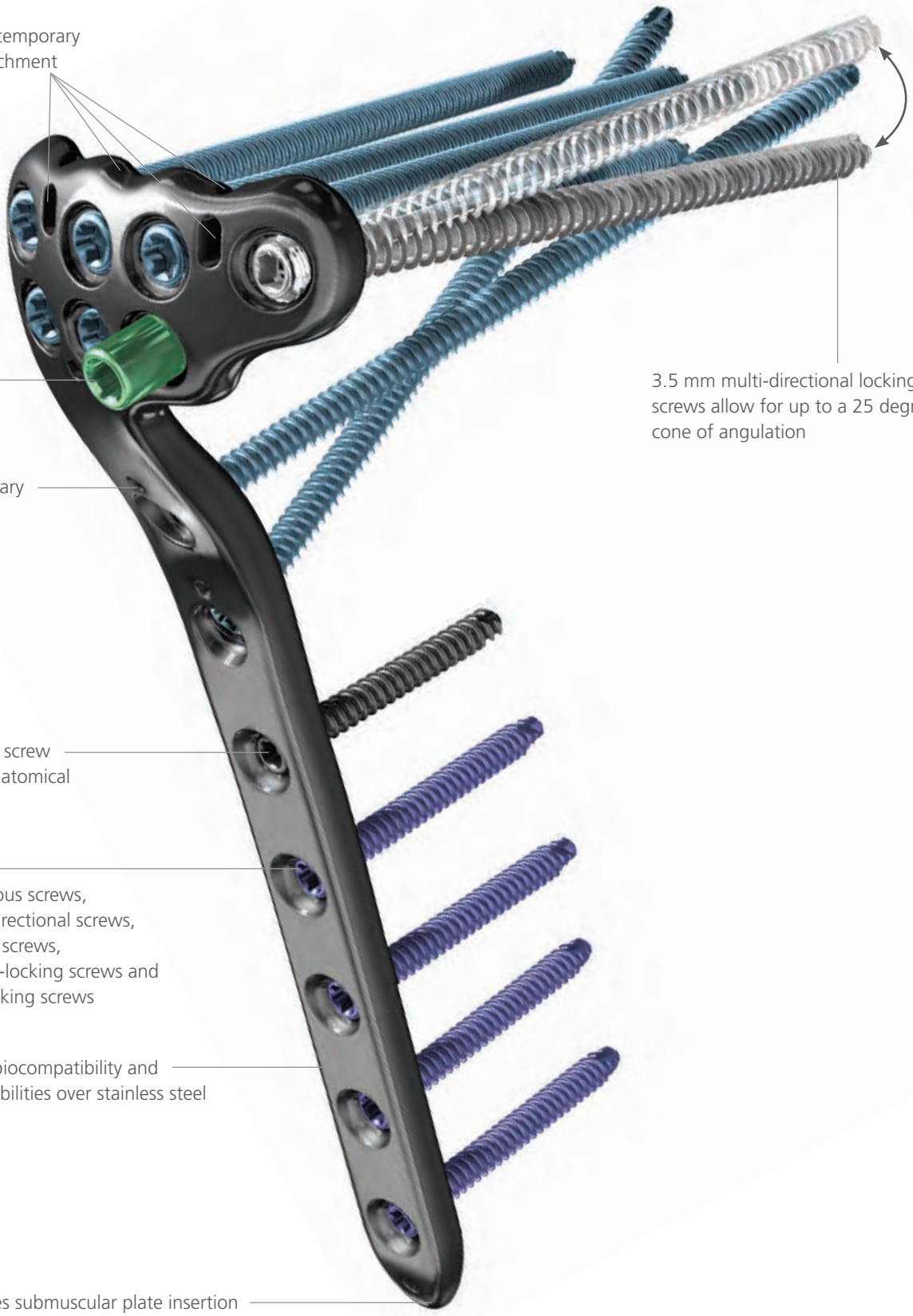
Choose locking or non-locking, according to need

4.0 mm and 3.5 mm tapered, threaded screws lock into position when tightened to establish a fixed angle construct for fixation or when optimal screw purchase is required

3.5 mm low profile non-locking screws provide the same low profile design as locking screws for minimum soft tissue irritation

3.5 mm locking multi-directional screws (MDS) allow for up to a 25 degree cone of angulation for greater fixation range

A.L.P.S. Proximal Tibia Locking Plate



Combination K-wire/suture holes

K-wires can be placed in the K-wire/suture holes in order to achieve temporary fixation...

..or a suture can be passed through the combination K-wire/suture hole if re-securing the meniscus is needed. Sutures do not need to be pre-loaded, they can be threaded when the plate is fully seated.

Optimum Plate Conformity

The A.L.P.S. Proximal Tibia Plates are specifically designed to match the anatomy of the proximal tibia while still having the required strength.

This is achieved by offering two unique lateral proximal tibia plate shapes. The distinction lies within the shape of the slope between the head and the shaft of the plate, at the metaphyseal flare. These two plates are categorized as the standard curve and large curve plates and are both available in 3, 5, 7, 9, 11, 13 and 15 hole plates.

The diagrams on the following two pages clearly capture the variance in the plates design at the point of the metaphyseal flare.

Incorrect placement of the standard curve plate on a large plateau

Standard Curve Plate

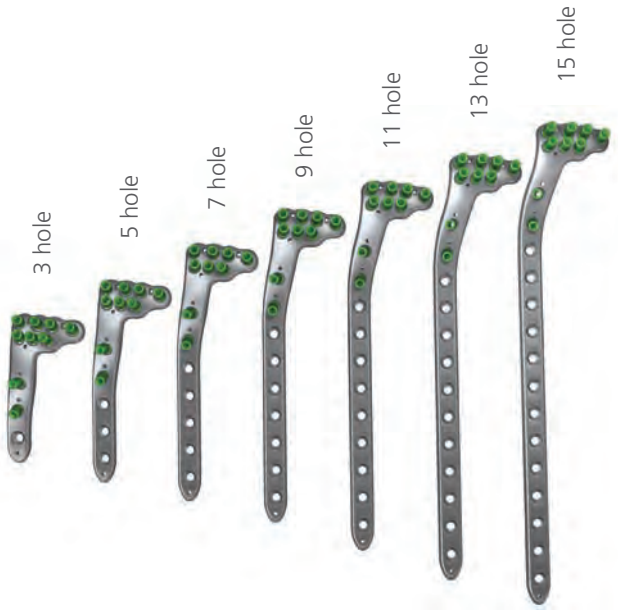
Standard Curve Plate (Left)
Large Curve Plate (Right)

Incorrect placement of
the large curve plate
on a standard plateau

Large Curve Plate

A.L.P.S. Proximal Tibia Plate Options and Specifications

Proximal Tibia	Standard Curve Plate	Large Curve Plate
Head Width	34 mm	34 mm
Head Thickness	3.7 mm	3.9 mm
Shaft Width	11 mm	11 mm
Shaft Thickness	3.7 mm	3.7 mm
Distance between center holes of shaft	13 mm	13 mm
Orientations	Left / Right	Left / Right
Sizes (holes)	3, 5, 7, 9, 11, 13, 15	3, 5, 7, 9, 11, 13, 15
Length (mm)	70.5, 96, 122, 148, 174, 200, 226	78.2, 103.8, 129.8, 155.8, 181.8, 207.8, 233.8



Standard Curve Plate Range

Large Curve Plate Range

Screw Specifications

3.5 mm Low Profile Non-Locking Screw:

- Low profile head design reduces prominence beyond the plate
- Self tapping tip eases screw insertion
- 2.2 mm Square driver for maximum torque delivery
- Type II anodized material for increased fatigue strength compared to stainless steel
- Screw (Cat. No.1312-18-0XX) uses the 2.5 mm Drill Bit 100 mm (Cat. No. 2142-35-007) and can be installed in any hole in the plate
- Available in lengths of 50 – 100 mm

3.5 mm Locking Cortical Screw:

- Larger core diameter and shallower thread pitch for improved bending and shear strength compared to a standard 3.5 mm cortical screw
- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- Tapered screw head helps ensure alignment of the screw head into the plate hole
- Tapered threaded head minimizes screw back-out and construct pullout
- T-15 driver
- Available in lengths of 75 – 100 mm
- Screw (Cat. No. 8161-35-0XX) uses a 2.7 mm Drill Bit 100 mm (Cat. No. 2142-35-006)

3.5 mm Locking Multi-Directional Screw:

- Cobalt-Chrome screw with large core diameter
- Multi-directional capability offers a 25 degree cone of angulation
- Creates own thread in plate to help provide strong and stable construct
- Screw head designed to prevent it from going through the threaded screw hole
- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- 2.2 mm square driver
- Available in lengths of 50 – 100 mm
- Screw (Cat. No. 8163-35-0XX) uses a 2.7 mm Drill Bit 100 mm (Cat. No. 2142-35-006)

4.0 mm Locking Cancellous Screw:

- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- Tapered screw head helps ensure alignment of the screw head into the plate hole
- Tapered threaded head minimizes screw back-out and construct pullout
- T-15 driver
- Available in lengths of 75 – 100 mm
- Screw (Cat. No. 8161-40-0XX) uses a 2.7 mm Drill Bit 100 mm (Cat. No. 2142-35-006)

Surgical Approach

Take pre-operative fluoroscopic images
Figure 1

S- shaped incision
Figure 2

Make anterolateral incision for more complex intra-articular injuries
Figure 3

Incision

Position the patient supine on a fluoroscopic table with the C-arm on the opposite side of the fractured extremity. Knee rolls or bumps can be used to aid in positioning. The flexion-extension of the distal fragment can be adjusted by moving the bumps proximally or distally under the calf (Figure 1).

Select a plate length that allows a minimum of three screw holes to be placed in the intact tibial shaft distal to the fracture. When in doubt, it is best to choose the longer of the two plates. A tourniquet can be applied if necessary for intra-articular visualization.

A standard lateral S-shaped incision is made, centered on Gerdy's tubercle (Figure 2). For extra-articular and relatively simple intra-articular fractures, this is often adequate exposure. For more extensive intra-articular fractures where intra-articular visualization is required, extend the incision (Figure 3) proximally and perform a formal submeniscal arthrotomy.

In many cases the lateral meniscus is trapped in the fracture, torn, and/or avulsed from its peripheral attachments. Once the injury to the meniscus is identified and addressed, the meniscus is lifted proximally to expose the articular surface. If the fracture is collapsed and unstable, a medial, lateral (or both) femoral distractor may be needed to maximize visualization of the articular surface. Open reduction and internal fixation of the articular surface is then performed by methods beyond the scope of this manual. K-wires and reduction clamps are used to secure the reduction. Before placing independent lag screws, the appropriate plate should be placed against the lateral proximal tibia to verify the correct placement of these screws.

Application of the Plate

Application of the Proximal Tibia Plate

The Plate Handle comes in right (Cat. No. 2142-35-013) and left (Cat. No. 2142-35-012) orientations. The Plate Handle is attached to the plate facilitating subcutaneous insertion and manipulation within the surgical site (Figures 4 and 5). The Plate Handle connects to the most proximal locking hole on the shaft of the plate. Do not attempt to connect the handle into one of the two kick stand locking holes. The plate handle is secured to the plate by tightening the set screw with the T-15 Driver (Cat. No. 2142-15-070) until secured tightly with 2 fingers.

The plate should be guided subperiosteally down the shaft by the bullet tipped distal end of the plate, and controlled by the handle. Proximally the plate should be visually placed in the correct position, which is then verified and adjusted with a fluoroscopic AP and lateral scan.

The low profile A.L.P.S. plates are specifically designed to match the anatomy of the proximal tibia. As a result, two unique lateral proximal tibia plate shapes are available in order to achieve optimal anatomic fit. The distinction among the two plates lies within the curvature of the slope between the head and the shaft of the plate, at the metaphyseal flare. When positioning the plate, allow for the plate's contour to most closely conform to the patient's anatomic metaphyseal flare. Choose the plate that best conforms to the patient's anatomy.

Note: A small number of instruments listed within this technique are found within the A.L.P.S. Small Fragment Plating System. Be sure to have access to this system prior to the initiation of this procedure. In addition, a wider range of 3.5 mm and 4.0 mm screw options are also available within the A.L.P.S. Small Fragment Plating system.

Figure 4

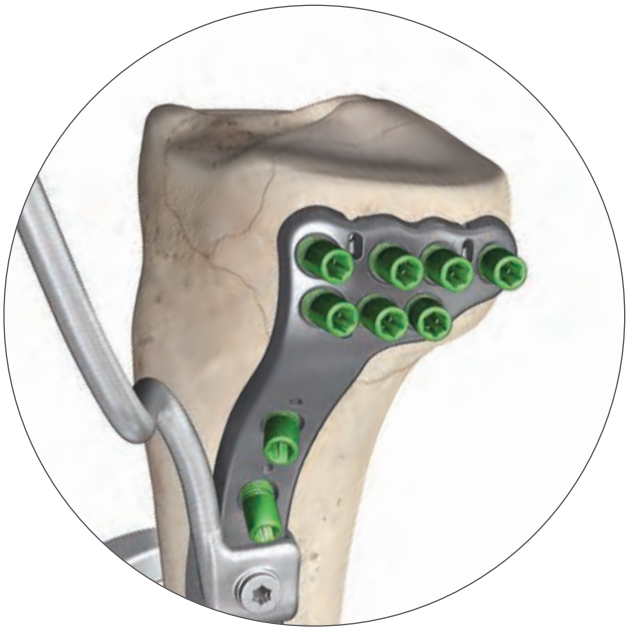


Figure 5

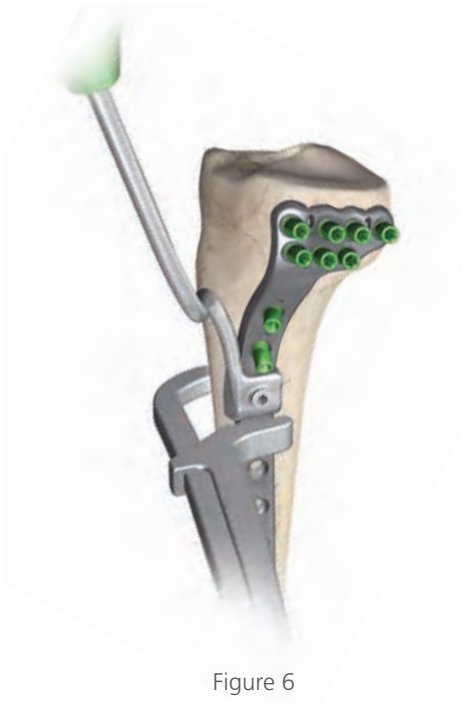


Figure 6

Temporary Fixation

The plate should also be placed as close to the joint to provide subchondral support without intra-articular screw placement. Temporary fixation is achieved by placing the Proximal Tibia Clamp (Cat. No. 2142-35-014) on the most proximal shaft hole. Do not position the proximal tibia clamp onto one of the kickstand screw holes.

The clamp is engaged with the locking holes on the plate (Figure 6).

Figure 7

Once the clamp is in place, the Plate Handle can be removed with the T-15 driver and temporary fixation is achieved (Figure 7).

Temporary fixation may also be achieved by positioning K-wires within the K-wire holes in the head and shaft of the plate or by inserting the 1.6 mm F.A.S.T. Guide Adapters (Cat. No. 2312-18-015) into an available F.A.S.T. Guide® and then inserting the K-wire through the 1.6 mm F.A.S.T. Guide Adapter.

Note: To ensure optimal fit, insert a 1.6 mm F.A.S.T. Guide Adapter (Cat. No. 2312-18-015) into one of the F.A.S.T. Guide® Inserts on the most proximal raft row and then insert a K-wire through the 1.6 mm F.A.S.T. Guide Adapter. The plate is in its optimal position when the K-wire runs parallel to the joint line. Check under fluoroscopy to verify.

Surgical Technique

Insertion of a 3.5 mm Low Profile Non-Locking Cortical Screw (Cat. No.1312-18-0XX) in the plateau or the shaft

3.5 mm Low Profile Non-Locking Cortical Screws (Cat. No. 1312-18-XXX) can be used in any screw hole on the plate to achieve adequate reduction.

In addition, the 3.5 mm Non-Locking Cortical Screws (Cat. No. 8150-37-0XX) may also be used to achieve adequate reduction in the shaft of the plate.

Note: If a 3.5 mm Low Profile Non-Locking Cortical Screw is to be inserted in a screw hole that currently contains a F.A.S.T. Guide® then that F.A.S.T. Guide® must be removed prior to drilling. Remove the F.A.S.T. Guide® with the T-15 Driver coupled to the Ratchet Handle (Cat. No. 8261-66-000) (Figure 8).

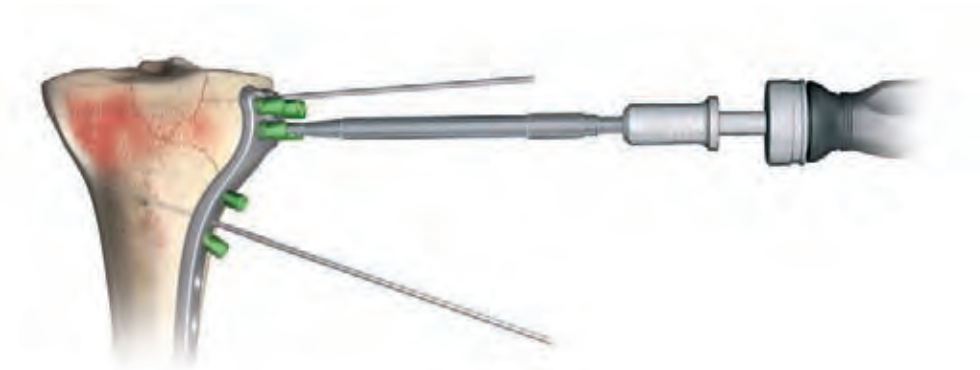


Figure 8

Insert the 2.5 mm end of the 2.5/3.5 mm Drill Guide (Cat. No. 8241-96-000) into the desired threaded hole and drill through both cortices with the 2.5 mm Drill Bit 100 mm (Cat. No. 2142-35-007) (Figure 9).

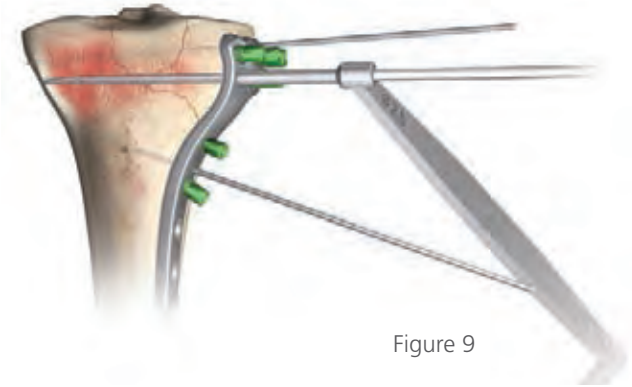


Figure 9

Note: If drilling through the plateau, the drill must be slowly reversed so that no amount of drill is protruding from the medial end of the proximal tibia. Verify under fluoroscopy.

Measure the drilled hole by taking a direct reading from the Non-LOCK line on the Bone Depth Gauge 100 mm (Cat. No. 2142-35-008) (Figure 10).

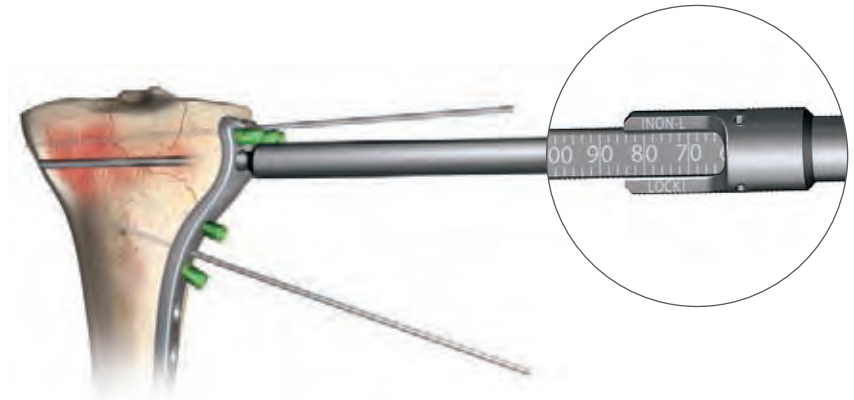


Figure 10

The appropriate 3.5 mm Low Profile Non-Locking Cortical Screw length is inserted by hand using the Black Ratchet Handle (Cat. No. 8261-66-000) with the 2.2 mm Square Driver (Cat. No. 8163-01-000) (Figure 11).

Figure 11

Surgical Technique

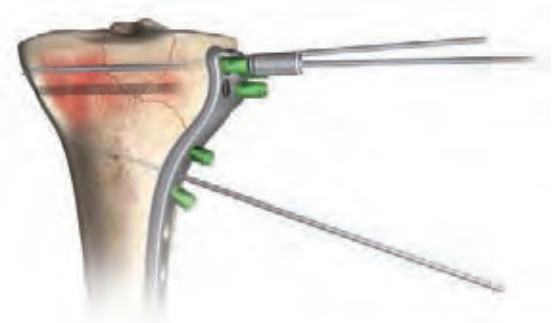


Figure 12

Figure 13

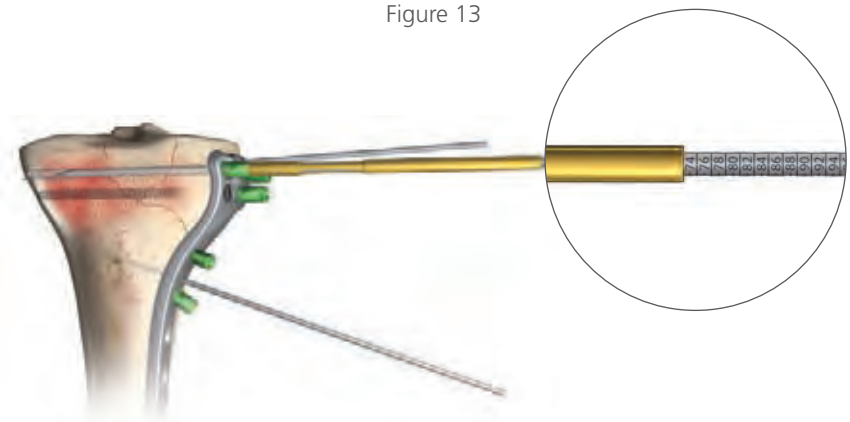


Figure 14

Figure 15

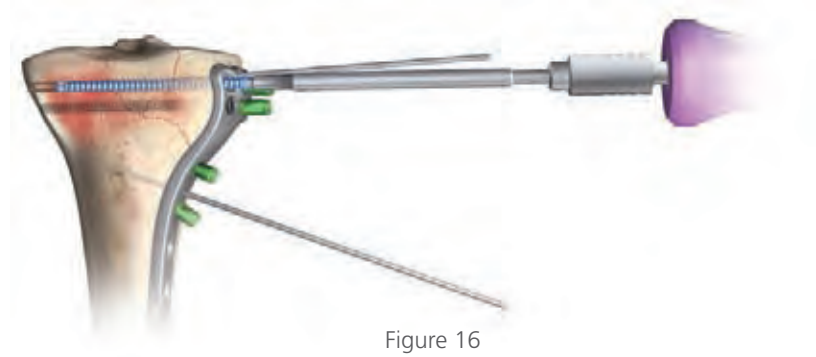


Figure 16

Insertion of a 4.0 mm Cancellous Locking Screw (Cat. No. 8161-40-0XX) or a 3.5 mm Cortical Locking Screw (Cat. No. 8161-35-0XX) into the two proximal raft rows

In order to obtain correct subchondral screw trajectory, the 1.6 mm F.A.S.T. Guide Adapter (Cat. No. 2312-18-015) is inserted into one of the most proximal F.A.S.T. Guide® screw holes. Then a 1.6 mm K-wire is inserted through the 1.6 mm F.A.S.T. Guide Adapter and into the bone (Figure 12). This position is checked under fluoroscopy. The plate is adequately positioned when the K-wire runs parallel to the articulating surface. Upon achieving this alignment, the K-wire and adapter are then removed.

Slide the Drill Measuring Sleeve 100 mm (Cat. No. 2142-35-200) onto the 2.7 mm Drill Bit 100 mm (Cat. No. 2142-35-006) (Figure 13). Drill through the F.A.S.T. Guide until the far cortex is penetrated. The drill is then slowly reversed so that no amount of drill is protruding from the medial end of the plateau.

Note: Drill while checking the trajectory under fluoroscopy.

Read the measurement of the locking screw length from the proximal end of the Drill Measuring Sleeve (Figure 14). Next, remove the F.A.S.T. Guide® with the T-15 Driver coupled to the Ratchet Handle (Cat. No. 8261-66-000) (Figure 15) and insert the pre-determined locking screw using the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Cat. No. 2141-18-001) (Figure 16).

Note: Using a power screwdriver is not recommended for insertion of any locking screws. If using power, it should be at a slow speed, with the Torque-Limiting adapter. Perform all final screw tightening by hand with the Torque-Limiting Screwdriver.

Surgical Technique

Insertion of a 4.0 mm Cancellous Locking Screw (Cat. No. 8161-40-0XX) or a 3.5 mm Cortical Locking Screw (Cat. No. 8161-35-0XX) into the shaft

Screw the 2.7 mm Locking Drill Guide 100 mm (Cat. No. 2142-35-016) into a threaded plate hole until fully seated. Drill both cortices with the 2.7 mm Drill Bit 100 mm to the desired depth and read the depth measurement from the drill bit at the top of the drill guide (Figure 17). Remove the 2.7 mm Locking Drill Guide.

Note: If a second method of measurement is desired, measure the drilled hole by taking a direct reading from the LOCK line on the Bone Depth Gauge 100 mm (Cat No. 2142-35-008) (Figure 18).

Insert the selected locking screw with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Figure 19).

Note: Now that solid fixation of the plate to the tibia is achieved, the K-wires can be removed.

Note: Using a power screwdriver is not recommended for insertion of any locking screws. If using power, it should be at a slow speed, with the Torque-Limiting adapter. Perform all final screw tightening by hand with the Torque-Limiting Screwdriver.

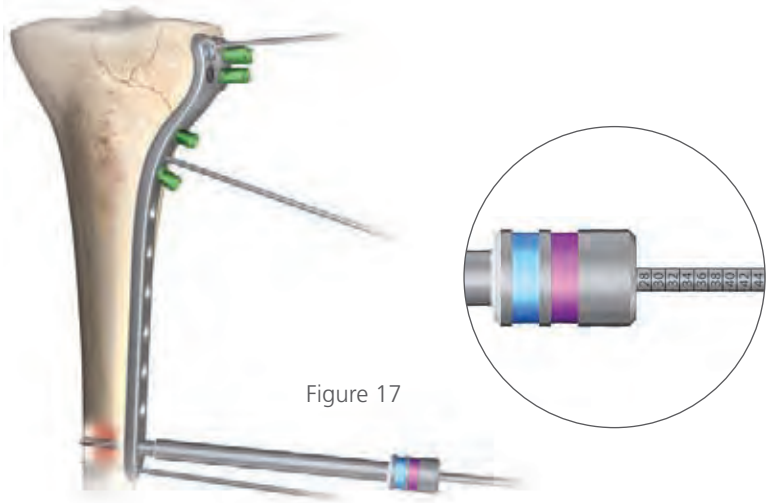


Figure 17

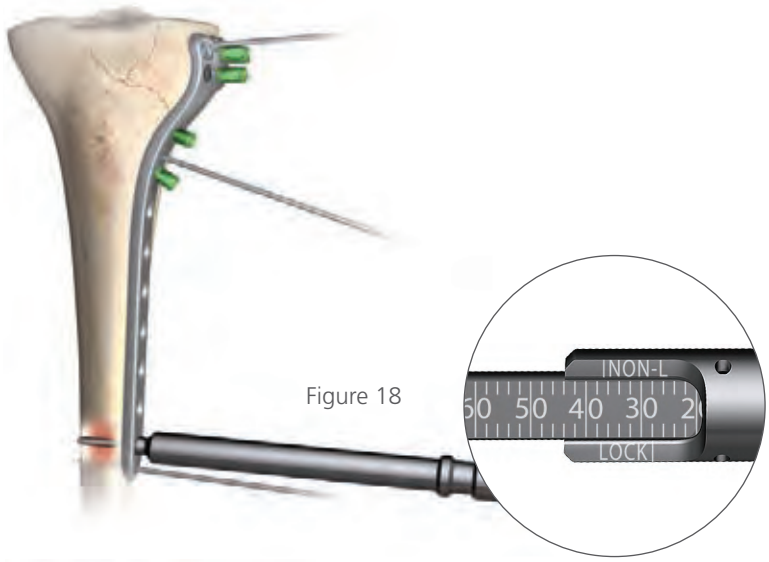


Figure 18

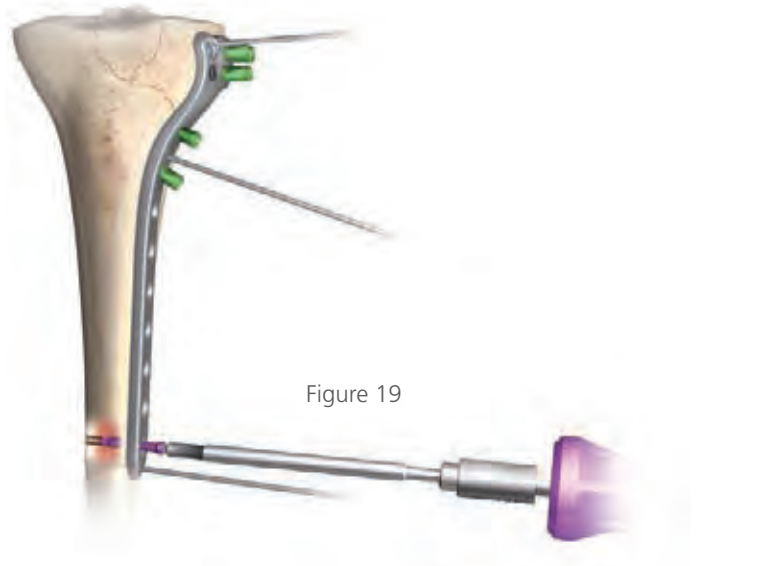


Figure 19

Surgical Technique

Figure 20

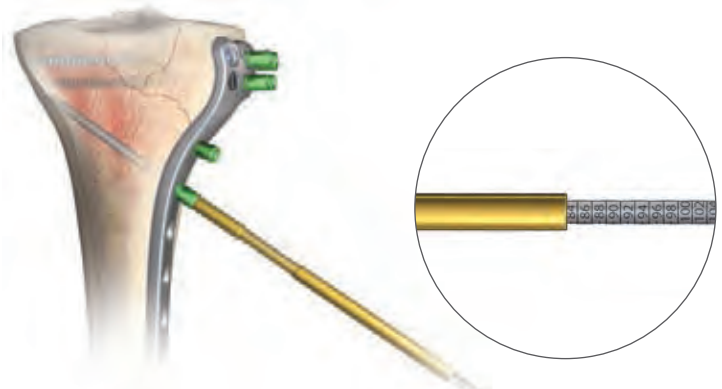


Figure 21

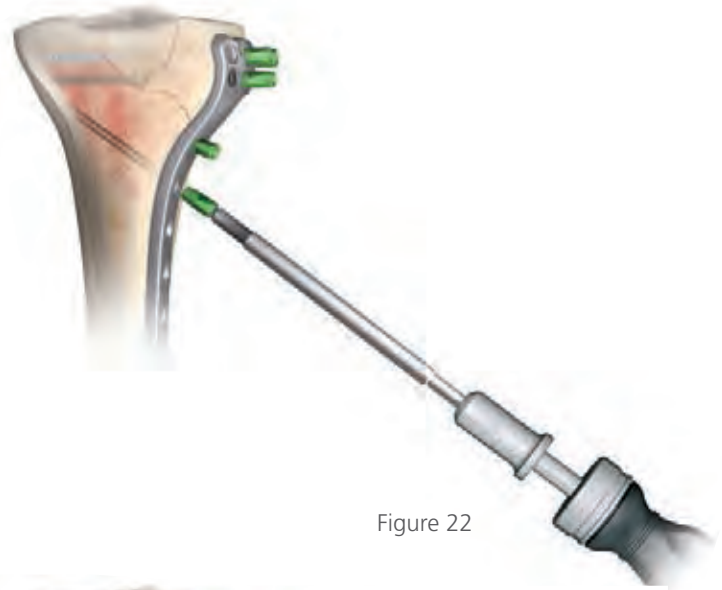


Figure 22

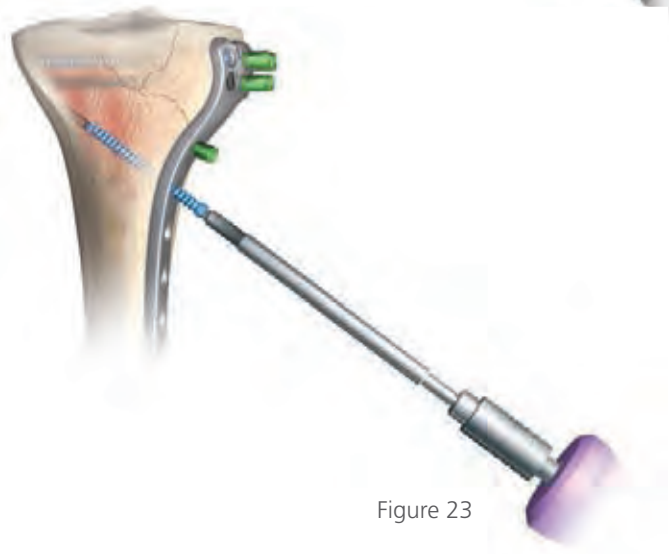


Figure 23

Insertion of the 4.0 mm Locking Cancellous Screw (Cat. No. 8161-40-0XX) in the Kickstand Holes

Slide the Drill Measuring Sleeve 100 mm (Cat. No. 2142-35-200) onto the 2.7 mm Drill Bit 100 mm (Cat. No. 2142-35-006) (Figure 20). Drill through the F.A.S.T. Guide® until the far cortex is penetrated. The drill is then slowly reversed so no amount of drill is protruding.

Note: Drill while checking the trajectory under fluoroscopy.

Read the measurement of the locking screw length from the proximal end of the Drill Measuring Sleeve (Figure 21).

Remove the F.A.S.T. Guide® with the T-15 Driver coupled to the Ratchet Handle (Cat. No. 8261-66-000) (Figure 22).

Note: To assure accurate screw trajectory prior to engaging the locking screws, insert K-wires into the K-wire holes located proximally to the kickstand screw holes. Then align the screw's insertion with the trajectory of the K-wire.

Insert the selected 4.0 mm cancellous screw with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Figure 23).

Note: Using a power screwdriver is not recommended for insertion of any locking screws. Doing so may likely cause the screw to cross thread the plate and damage the screw. It is recommended to perform by hand with the Torque-Limiting Screwdriver.

Surgical Technique

Insertion of a 3.5 mm Locking Multi-Directional Screw (Cat. No. 8163-35-0XX)

Note: If a 3.5 mm Locking Multi-Directional Screw is used in a screw hole that currently houses a F.A.S.T. Guide®, then that F.A.S.T. Guide® needs to be removed prior to drilling. Additionally, note that the Torque Limiting Handle should not be used.

Insert the 2.7 mm end of the 2.0/2.7 mm Drill Guide (Cat. No. 9399-99-435) into the plate hole and angle the drill as needed within an arc not to exceed 25 degrees. Drill through both cortices with the 2.7 mm Drill Bit (Figure 24).

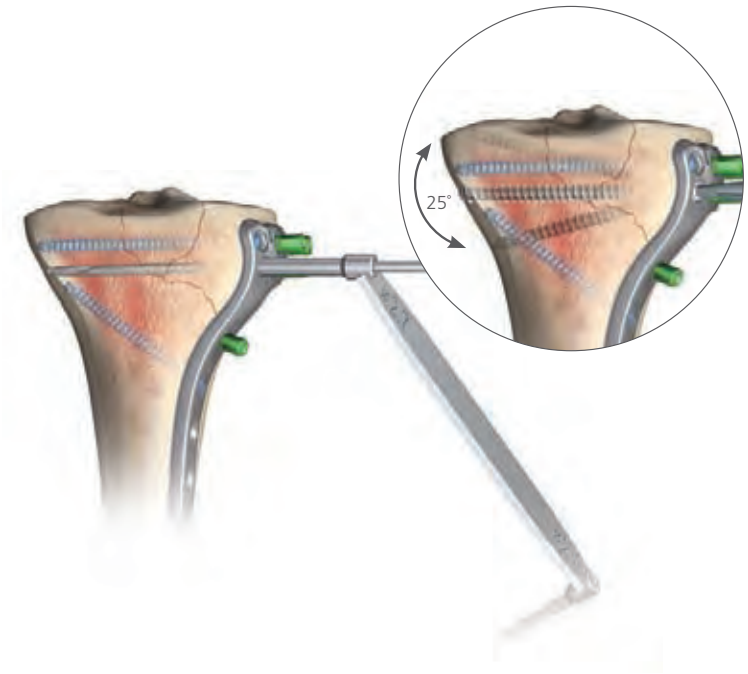


Figure 24

Measure the drilled hole with the Bone Depth Gauge 100 mm (Cat. No. 2142-35-008) by taking a direct reading from the LOCK line (Figure 25) and insert the appropriate length 3.5 mm Multi-Directional Screw with the 2.2 mm Square Driver (Cat. No. 8163-01-000) coupled to the Ratchet Handle (Cat. No. 8261-66-000) (Figure 26).

Note: Using a power screwdriver is not recommended for insertion of any locking screws. If using power, it should be at a slow speed, with the Torque-Limiting Adapter. Perform all final screw tightening by hand with the Torque-Limiting Screwdriver.

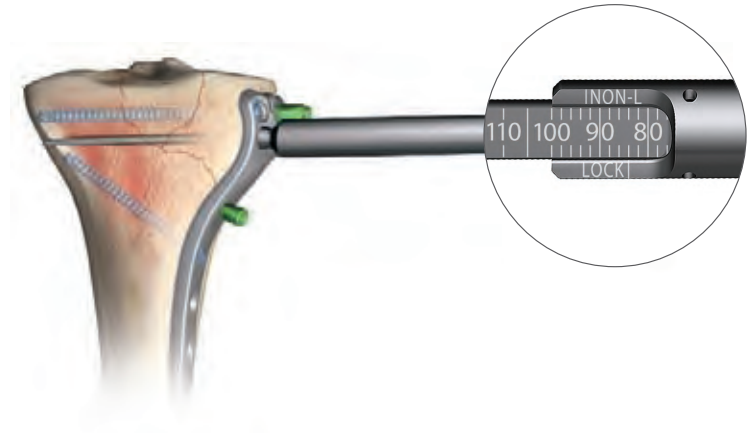


Figure 25

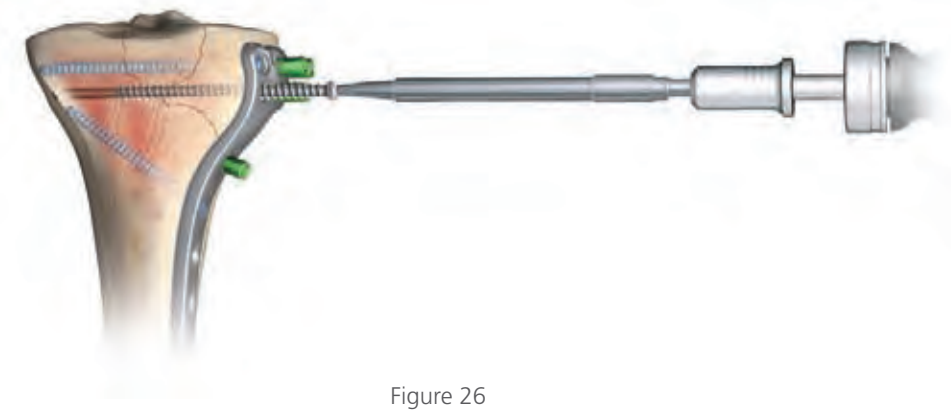
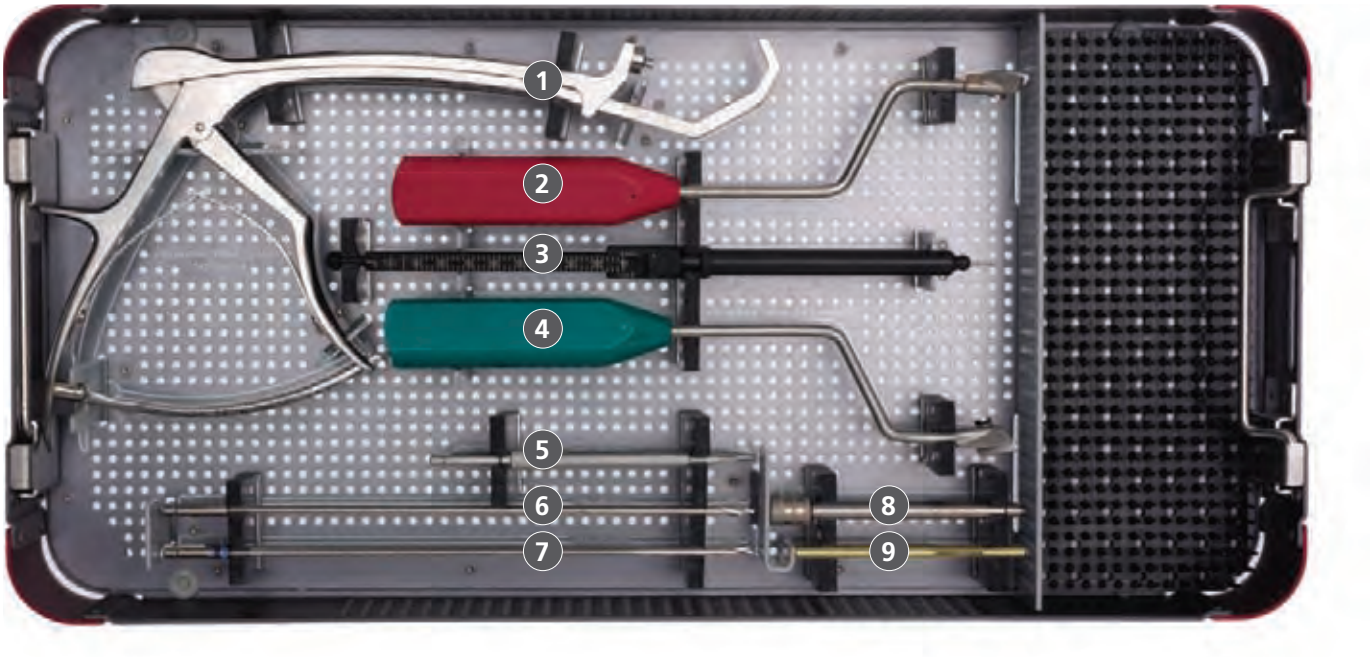


Figure 26

A.L.P.S. Proximal Tibia Set

The Proximal Tibia Plating System

Instrument Tray

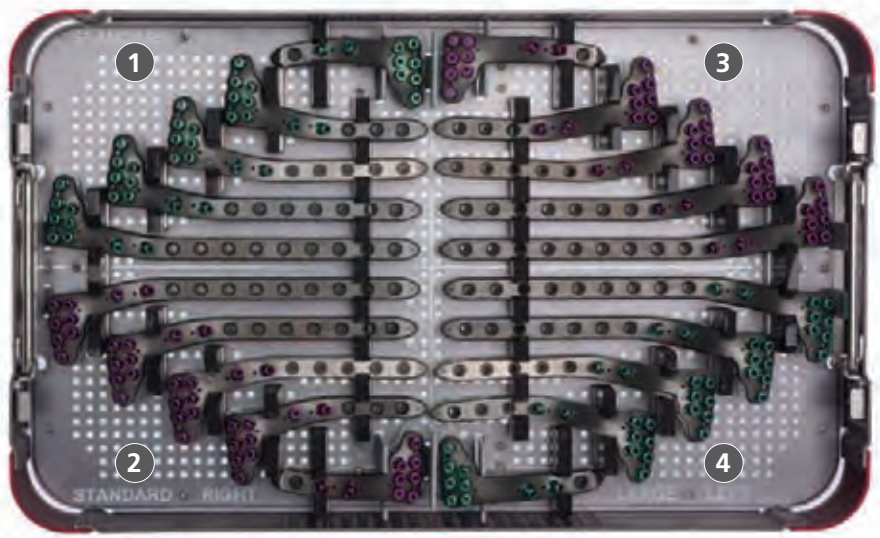


Instrument Tray

1.	2142-35-014	Proximal Tibia Clamp
2.	2142-23-013	Proximal Tibia Right Handle
3.	2142-35-008	Bone Depth Gauge 100 mm
4.	2142-35-012	Proximal Tibia Left Handle
5.	8163-01-000	2.2 mm Square Driver
6.	2142-35-007	2.5 mm Drill Bit 100 mm
7.	2142-35-006	2.7 mm Drill Bit 100 mm
8.	2142-35-016	2.7 mm Locking Drill Guide 100 mm
9.	2142-35-200	Drill Measuring Sleeve 100 mm

Note: A small number of instruments listed within this technique are found within the A.L.P.S. Small Fragment Plating System. Be sure to have access to this system prior to the initiation of the Proximal Tibia surgical procedure. In addition, a wider range of 3.5 mm and 4.0 mm screw options are also available within the A.L.P.S. Small Fragment Plating System.

Implant Tray



Implant Tray

1. Standard Curve Plates - Left

8162-35-703	Proximal Tibia Locking Plate Left 3 Hole Standard
8162-35-705	Proximal Tibia Locking Plate Left 5 Hole Standard
8162-35-707	Proximal Tibia Locking Plate Left 7 Hole Standard
8162-35-709	Proximal Tibia Locking Plate Left 9 Hole Standard
8162-35-711	Proximal Tibia Locking Plate Left 11 Hole Standard
8162-35-713*	Proximal Tibia Locking Plate Left 13 Hole Standard
8162-35-715*	Proximal Tibia Locking Plate Left 15 Hole Standard

2. Standard Curve Plates - Right

8162-35-815*	Proximal Tibia Locking Plate Right 15 Hole Standard
8162-35-813*	Proximal Tibia Locking Plate Right 13 Hole Standard
8162-35-811	Proximal Tibia Locking Plate Right 11 Hole Standard
8162-35-809	Proximal Tibia Locking Plate Right 9 Hole Standard
8162-35-807	Proximal Tibia Locking Plate Right 7 Hole Standard
8162-35-805	Proximal Tibia Locking Plate Right 5 Hole Standard
8162-35-803	Proximal Tibia Locking Plate Right 3 Hole Standard

3. Large Curve Plates - Right

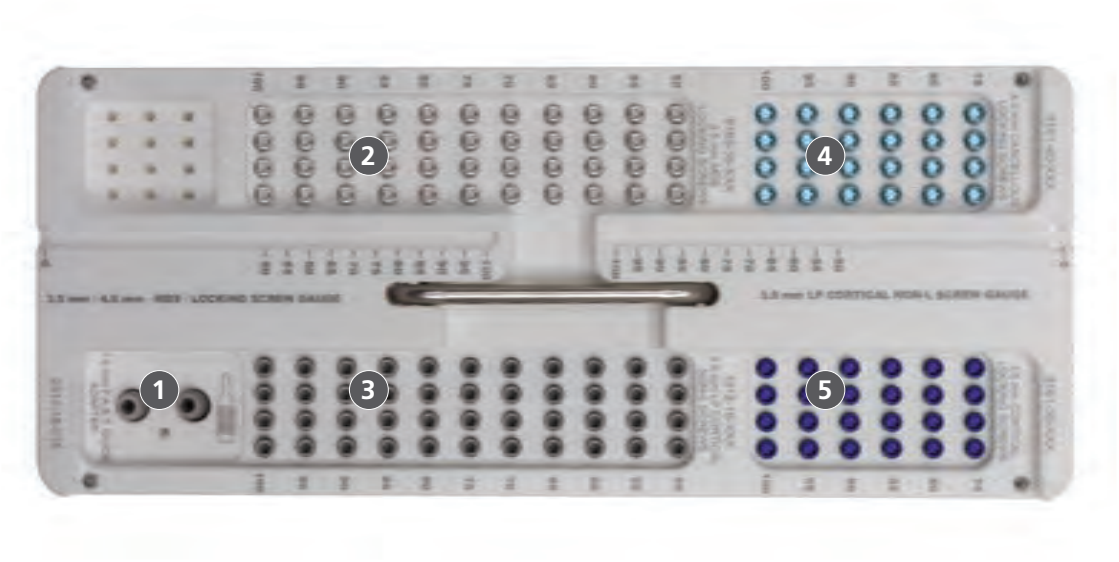
8162-35-603	Proximal Tibia Locking Plate Right 3 Hole Large
8162-35-605	Proximal Tibia Locking Plate Right 5 Hole Large
8162-35-607	Proximal Tibia Locking Plate Right 7 Hole Large
8162-35-609	Proximal Tibia Locking Plate Right 9 Hole Large
8162-35-611	Proximal Tibia Locking Plate Right 11 Hole Large
8162-35-613*	Proximal Tibia Locking Plate Right 13 Hole Large
8162-35-615*	Proximal Tibia Locking Plate Right 15 Hole Large

4. Large Curve Plates - Left

8162-35-515*	Proximal Tibia Locking Plate Left 15 Hole Large
8162-35-513*	Proximal Tibia Locking Plate Left 13 Hole Large
8162-35-511	Proximal Tibia Locking Plate Left 11 Hole Large
8162-35-509	Proximal Tibia Locking Plate Left 9 Hole Large
8162-35-507	Proximal Tibia Locking Plate Left 7 Hole Large
8162-35-505	Proximal Tibia Locking Plate Left 5 Hole Large
8162-35-503	Proximal Tibia Locking Plate Left 3 Hole Large

*Special Order

Screw Caddy



3.5/4.0 mm Screw Module

1. 2312-18-015 F.A.S.T. Guide® Adapter

2. 3.5 mm Locking Multi-Directional Screw

8163-35-050	3.5 mm Multi-Directional Screw 50 mm
8163-35-055	3.5 mm Multi-Directional Screw 55 mm
8163-35-060	3.5 mm Multi-Directional Screw 60 mm
8163-35-065	3.5 mm Multi-Directional Screw 65 mm
8163-35-070	3.5 mm Multi-Directional Screw 70 mm
8163-35-075	3.5 mm Multi-Directional Screw 75 mm
8163-35-080	3.5 mm Multi-Directional Screw 80 mm
8163-35-085	3.5 mm Multi-Directional Screw 85 mm
8163-35-090	3.5 mm Multi-Directional Screw 90 mm
8163-35-095	3.5 mm Multi-Directional Screw 95 mm
8163-35-100	3.5 mm Multi-Directional Screw 100 mm

3. 3.5 mm Low Profile Non-Locking Screw

1312-18-050	3.5 mm Low Profile Cortical 50 mm
1312-18-055	3.5 mm Low Profile Cortical 55 mm
1312-18-060	3.5 mm Low Profile Cortical 60 mm
1312-18-065	3.5 mm Low Profile Cortical 65 mm
1312-18-070	3.5 mm Low Profile Cortical 70 mm
1312-18-075	3.5 mm Low Profile Cortical 75 mm
1312-18-080	3.5 mm Low Profile Cortical 80 mm
1312-18-085	3.5 mm Low Profile Cortical 85 mm
1312-18-090	3.5 mm Low Profile Cortical 90 mm
1312-18-095	3.5 mm Low Profile Cortical 95 mm
1312-18-100	3.5 mm Low Profile Cortical 100 mm

4. 4.0 mm Cancellous Locking Screw

8161-40-075	4.0 mm Cancellous Locking Screw 75 mm
8161-40-080	4.0 mm Cancellous Locking Screw 80 mm
8161-40-085	4.0 mm Cancellous Locking Screw 85 mm
8161-40-090	4.0 mm Cancellous Locking Screw 90 mm
8161-40-095	4.0 mm Cancellous Locking Screw 95 mm
8161-40-100	4.0 mm Cancellous Locking Screw 100 mm

5. 3.5 mm Cortical Locking Screw

8161-35-075	3.5 mm Cortical Locking Screw 75 mm
8161-35-080	3.5 mm Cortical Locking Screw 80 mm
8161-35-085	3.5 mm Cortical Locking Screw 85 mm
8161-35-090	3.5 mm Cortical Locking Screw 90 mm
8161-35-095	3.5 mm Cortical Locking Screw 95 mm
8161-35-100	3.5 mm Cortical Locking Screw 100 mm

Notes

Notes

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 (screws, plates, intramedullary nails, compression hip screws, pins and wires) 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).

Note: The Pre-assembled F.A.S.T. Guide® inserts are NOT to be removed prior to sterilization. They should be removed and discarded only after use.

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