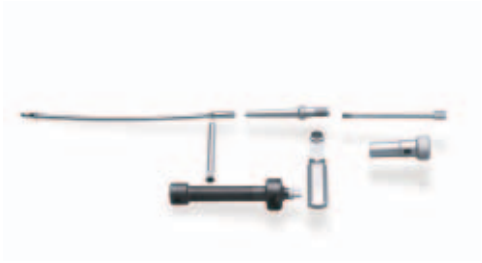
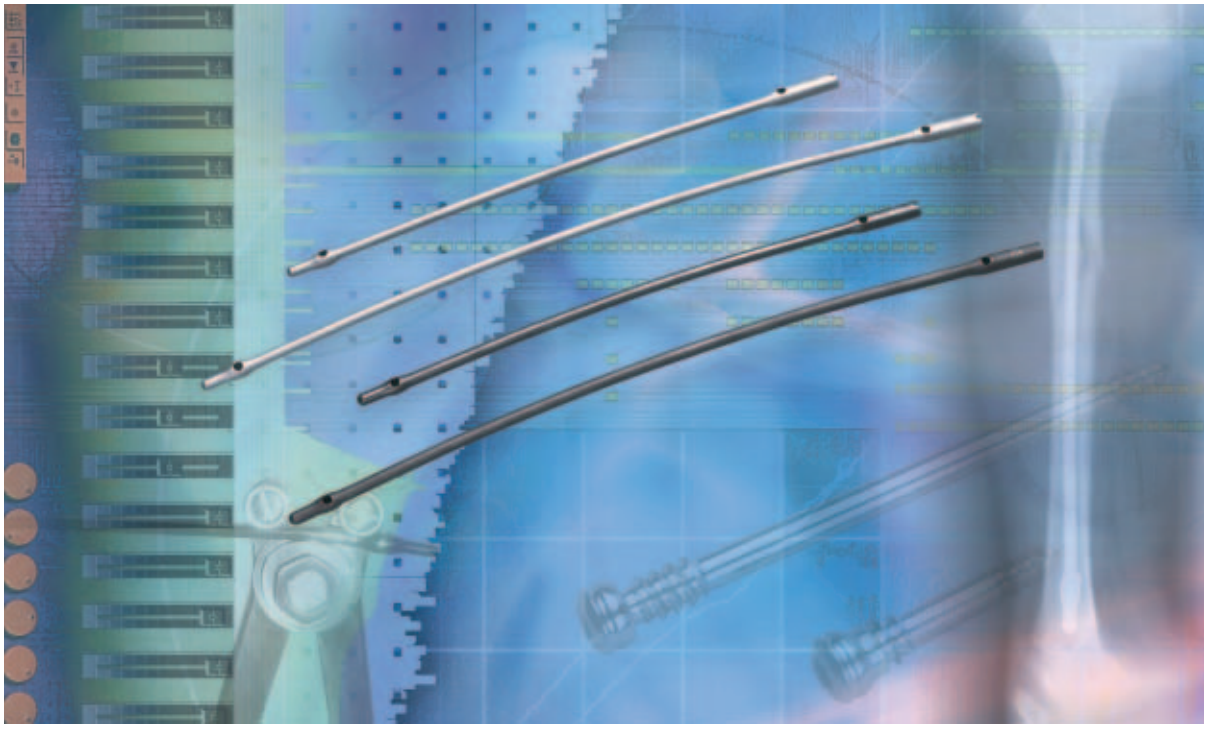
Innovation Meets Evolution...EBI Trauma is now:

BIOMET® TRAUMA

Biomet® Pediatric Locking Nail System

Surgical Technique





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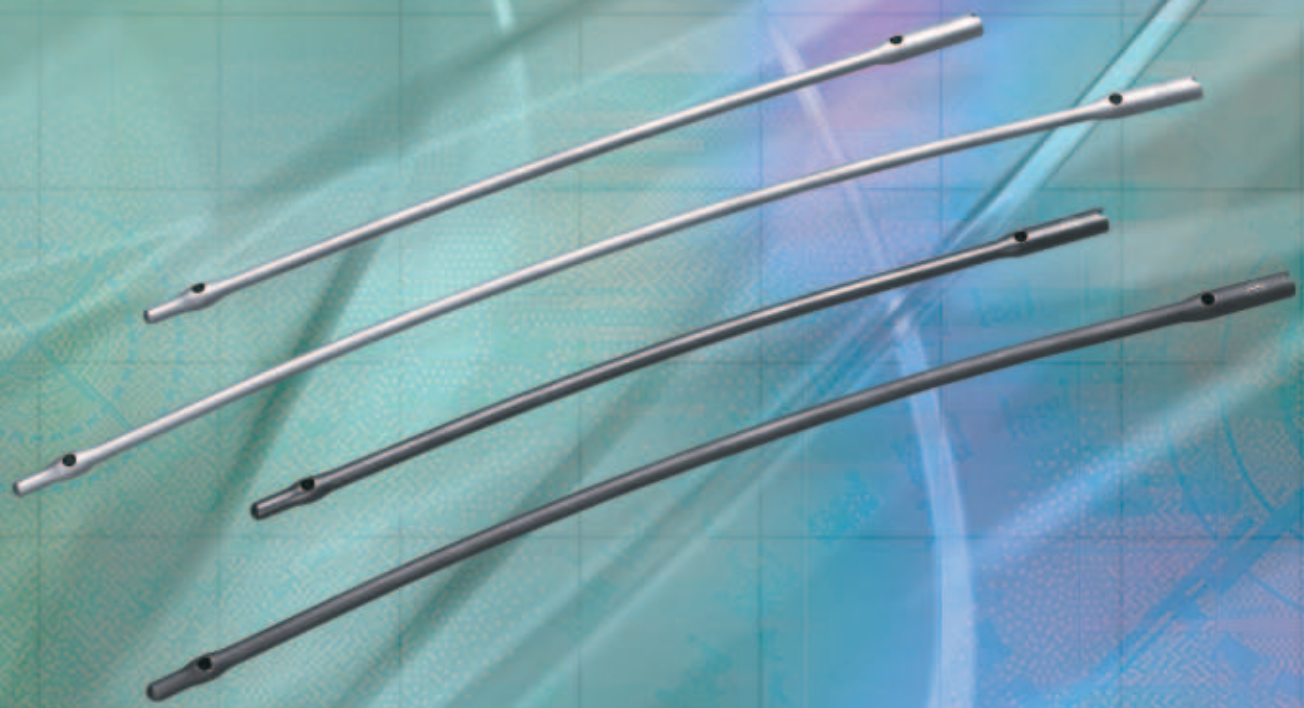
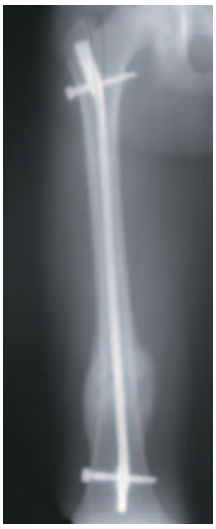
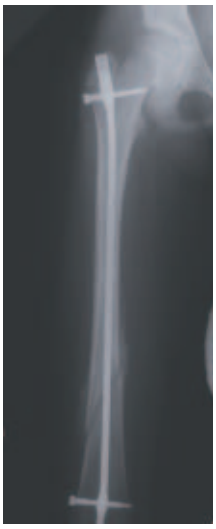


BIOMET®
TRAUMA

Introduction

The **Biomet** Pediatric Locking Nail (PLN) was designed to provide stable sub-rigid fixation of femur fractures in children. It is a locking nail, custom contoured to the individual. Its slight modulus of elasticity results in rapid fracture healing by callus, secondary to well-tolerated physiological stress transfer.


Design Rationale

Proximal and distal nail interlocking is achieved through widened areas in the nail's cross-section: i.e., a bulb distally and the wider attachment area proximally for the introduction assembly. The nail is pre-contoured with a nine-degree anterior bow and is universal for right and left femurs. Prior to insertion through a greater trochanteric entry portal, the nail should be contoured in the coronal plane to fit the left or right femur. A rod bender is used to create a 15-30 degree bendproximally and a 15-20 degree bend distally. The nail is non-cannulated. The bend in its distal tip, along with the smooth distal bulb configuration, allows steering of the nail during insertion across the reduced fracture. The nail is comprised of titanium alloy and available in 5.5cm and 6.5cm diameter sizes, and in various lengths (28cm-42cm). Interlocking is achieved with two screws. The interlocking screws, with a solid, non-threaded 4mm shank and a small 'pilot' thread distally, accommodate any slight misalignment during insertion. This also allows ease of passage across the interlocking holes. The aggressive subcapital locking screw thread achieves excellent purchase even if a unicortical technique is used. This, in addition to the slight distal angulation of the screw from perpendicular, (and more obvious proximal screw angulation in 'recon' fashion) provide excellent torsional and coronal stability. The modest flex characteristics of the nail avoid modulus mismatch in the healing fracture and results in rapid callus formation through load sharing. The nail avoids the distal femoral physis. Its passage across the trochanteric physis is through a small, nine millimeter, sharply reamed channel, which minimizes the risk of trochanteric damage. The nail is designed to avoid the piriformis fossa and damage to the vascular supply of the immature proximal femoral epiphysis.

Removal is recommended at or before one year post-fracture provided that healing is complete.

Patient Positioning

Position patient in the supine position on the appropriately sized fracture table, using boot or skin traction to help distract the fracture. Abduct the opposite leg for fluoroscopic unit access and drape in the customary fashion.

Surgical Technique

1. Perform fracture reduction and debride and irrigate any associated open wounds.

2. Under fluoroscope control, introduce the guide pin for the 9.0mm cannulated reamer. This should enter the lateral aspect of the greater trochanter just distal to its tip. Under no circumstances should the guide pin be introduced into the piriformis fossa in the skeletally immature patient. The guide pin can be placed percutaneously once familiar with the technique. A small incision can be used until familiarity is gained.

3. Guide pin position is critical to success of the procedure. The guide pin must enter the intramedullary canal of the proximal femur in the intertrochanteric region. Angles of approximately 40 degrees in the sagittal plane and 30 degrees posterior in the coronal plane will gain entry to the canal. The pin should not reach the calcar area since reaming this far causes pedestal formation, blocking passage of the nail. Check the pin position on AP and lateral by fluoroscopy, to ensure the distal guide pin tip is in the canal center.

4. If the guide pin is not perfectly centered, remove it and start again. The angle of insertion is particularly critical in proximal and subtrochanteric fractures since the pull of the psoas muscle causes significant flexion of the proximal fragment. Under these circumstances, the guide pin entry angle may be greater than a 45 degree angle in the sagittal plane, introduced in a quite posterior to anterior direction. Sagittal angulation of the fluoroscope in anterior, posterior, lateral and

medial planes is useful to ensure correct placement of the guide pin in the flexed proximal fragments. If the pin is introduced too parallel to the coronal plane (the 'floor') there is danger of penetration of the thin posterior wall of the femur in the intertrochanteric region.

5. Mount the 9.0mm cannulated reamer over the guide pin. Under fluoroscopy, ream the greater trochanter as far as the center of the intertrochanteric region. (The working cannula can be used for this process especially in the larger child). It is not necessary to ream further than this since the aim is to gain entry into the canal and not ream the canal itself. Nail placement is unreamed. Occasionally, a tighter than expected canal at the isthmus may require reaming, but a 'line to line' fit of the nail in the canal is not the intention. This device is considered an internal splint.

6. The instrument set contains two sizes of hand driven 'T' handled reamers useful for smoothing the slightly curved path of the contoured nail tip towards the fracture site. Gentle use of these reamers, starting with the smallest, is recommended to prepare a smooth path through the intertrochanteric region. The reamers can be passed across the fracture but this is not their purpose. The fracture area itself does not generally require reaming. Bending the reamers will help avoid cutting a medial pedestal at the calcar. In this fashion they act somewhat like a broach. A light to-and-fro twisting motion of these 'threaded' reamers greatly assists their passage.

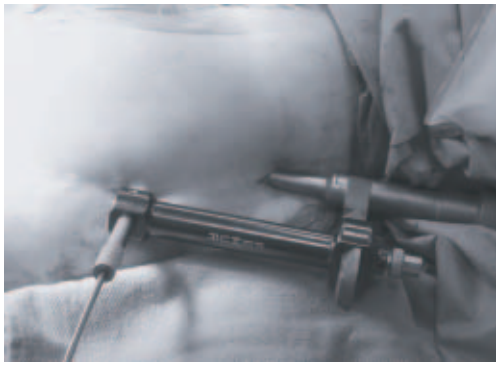
7. The proximal femur has now been prepared for passage of the nail.

8. Measure the length of nail required by placing the measuring ruler on the anterior thigh and using the fluoroscopy unit in an anterior-posterior projection to ascertain the dimensions. The distal tip of the nail should approach no closer than 5.0mm to the distal femoral physis. Proximally, the nail should be just subjacent to the lateral trochanteric entry point. Bending the nail prior to insertion slightly shortens its effective length, and this, along with radiographic magnification, should be taken into account when selecting appropriate nail length.

9. Select the appropriate nail diameter after the length has been determined. In general, children 45kg (100 lbs) or less have tighter canals and intertrochanteric dimensions. In these cases, the 5.5mm nail should be used for its greater flexibility through the intertrochanteric curved entry. In children and adolescents over 45kg, the 6.5mm nail is more appropriate for its greater strength and intertrochanteric entry zone length with a greater radius of curvature requiring slightly less flexibility of the nail as it passes this critical zone. Note that the larger nail has exactly the same maximum (8.5mm) proximal and distal diameters as the smaller nail.

10. Mount the nail on the introduction device. Be sure that the bow of the nail faces anteriorly and the proximal locking guide is appropriately aligned for left or right femurs. The proximal end of the nail has a notch in the coronal plane. This allows the targeting device

to be mounted for left or right femurs. Tighten the hex-headed link screw inside the tapered link bolt with the hex wrench. Place the side arm that accepts the carbon fiber target device over this and tighten using the top knob. This knob has a hole which lends itself to tightening using the shaft of a screwdriver also used for placing the interlocking screws. The top knob accepts the slap hammer assembly if necessary. Hand pressure is preferred for introducing the nail but occasionally light impaction with a mallet is needed.

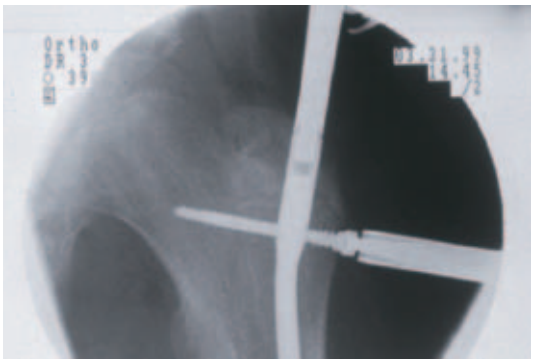


11. Check the entire assembly to make sure the nail is appropriately mounted on the introducer before inserting it into the femur.

12. Contour the nail distally and proximally with the rod bender, making sure not to distort the locking holes.

Achieve a 15º to 20º bend laterally in the tip (this bend allows an easier passage through the intertrochanteric region) and a slightly greater bend at the proximal nail, again lateralizing the proximal end so that it fits appropriately in the prepared curved channel from the lateral entry point in the greater trochanter. Under-bending the proximal end of the nail may result in the nail fracturing medially into the piriformis fossa, especially if the entry point is too close to the superior tip of the trochanter.

Under-bending will also result in the proximal interlocking zone of the nail lying too laterally next to the cortex, preventing the proximal locking screw from achieving adequate bone purchase. Adequate proximal bend will shift the shaft of the nail medially which is its ideal position both for aligning the fracture in the coronal plane and allowing good purchase of the proximal locking screw.



Shown here is appropriate insertion of the nail, allowing for the proximal threads of the 4.0mm Pilot Tipped Screw to have purchase into the lateral cortex of the femur.

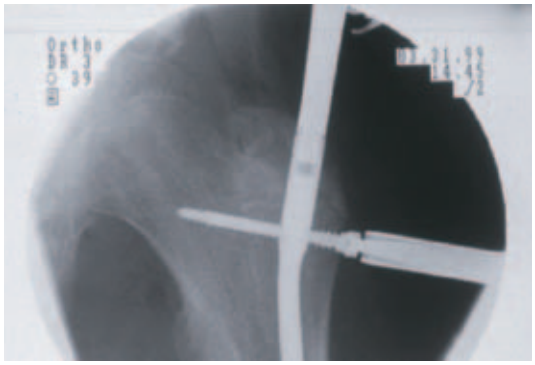
13. The resultant bends now give the nail a slight corkscrew appearance, with three dimensional complex compound curves which greatly ease the ability of the nail to be steered across the fracture site. The distal tip bend allows easy passage through the curved intertrochanteric entry zone. Be aware that over-bending the distal tip results in a greater effective diameter of the nail, producing increased tightness at the isthmus. If the nail passes very easily at the intertrochanteric region but is tight in the isthmus, removing some of the tip bend will help the isthmic passage.

14. Mount the side arm targeting device proximally, insert a drill sleeve assembly and insure sleeve alignment with the proximal locking hole by passing a 3.5mm drill bit through sleeves and nail. Any misalignment of the drill in the nail could result in damage to the targeting device and should be remedied. The distal locking hole should also be checked for ease of passage of the drill bit.

15. Introduce the nail into the femur under fluoroscopic control. Nail rotation as it passes the intertrochanteric region and the fracture site greatly eases the passage of the nail and should allow hand pressure with a to-and-fro rotatory motion to seat the nail. There is often need to use a mallet to tap the nail through the isthmus. Using the fracture reduction tool may help with difficult fractures.

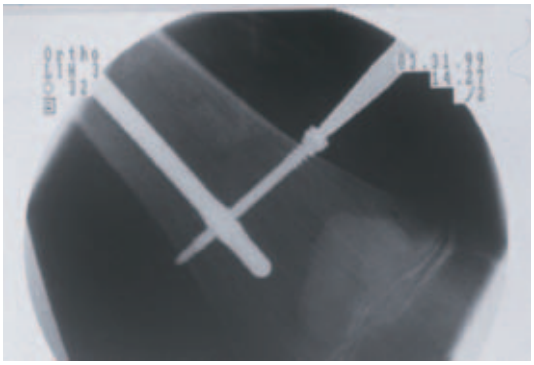
16. Seat the nail so its proximal end lies just in the subcortical area of the greater trochanter. Do not approach closer than 5.0mm to the distal femoral physis and do not distract the fracture.

17. Interlock the proximal end of the nail through the radiolucent guide. The drill sleeve assembly has inner and outer components. Introduce both through the lateral arm of the guide and make a stab incision just under the guide, deepening the dissection to the lateral cortex of the proximal femur. Using the 3.5mm drill, perforate the lateral cortex of the femur.
If bicortical purchase is desired, the medial femoral cortex is also drilled, taking care not to violate the territory of the medial femoral circumflex artery.
For this purpose, one should drill under fluoroscopic control.



18. Remove the inner drill sleeve and measure the screw depth with the depth gauge. Insert the appropriate length screw with the 'T' handled screwdriver. Check its length and position with anterior-posterior and lateral fluoroscopy views.

19. Remove traction from the femur, ensure correct rotational alignment and perform distal interlocking. The instrument set contains a simple but effective radiolucent awl, which can be used to perforate the lateral and medial cortex of the femur distally.
Alternatively, a power drill can be used. Utilize the technique of 'perfect circles' with lateral fluoroscopy. Take care with either technique not to enlarge the lateral cortical screw hole since the subcapital thread of the locking screw relies largely on the lateral cortex for its principally unicortical purchase.



20. Check final position of nail, screws and fracture by anterior-posterior and lateral fluoroscopic views, and close wounds in the usual manner.

Post OP Care/Nail Removal

Post OP Care

Postoperatively the patient is kept non weight bearing until some fracture callus is visible radiographically, then gradually resumes weight bearing. Full weight bearing is allowed once callus is seen bridging three cortices of the fracture site. This usually occurs at about 6 weeks.

External immobilization is not usually needed unless a distal fracture has been fixed, in which case a knee immobilizer can be useful for comfort for the first two weeks.

Nail Removal

Removal is recommended at or before one year post-fracture, provided that healing is complete. Nail removal is the reverse of insertion, with access to the proximal end of the nail performed utilizing a guide wire inserted under fluoroscopy into the end of the nail. Reaming is then performed down to the nail end and the slap hammer adapter is inserted.

At this point, the interlocking screws can be removed. The interlocking screws should only be removed after the extraction apparatus has been attached, as the nail may get pushed down into the femur.

Nail extraction can be performed by attaching the slide hammer and slap hammer adapter to the proximal threaded portion of the nail as demonstrated below. Once assembled, extract the nail with the slap hammer.

Implants Required

Nails

Part #	Description
24128	PLN Nail - 5.5mm x 28cm
24130	PLN Nail - 5.5mm x 30cm
24132	PLN Nail - 5.5mm x 32cm
24134	PLN Nail - 5.5mm x 33cm
24136	PLN Nail - 5.5mm x 36cm
24138	PLN Nail - 5.5mm x 38cm
24140	PLN Nail - 5.5mm x 40cm
24142	PLN Nail - 5.5mm x 42cm
24028	PLN Nail - 6.5mm x 28cm
24030	PLN Nail - 6.5mm x 30cm
24032	PLN Nail - 6.5mm x 32cm
24034	PLN Nail - 6.5mm x 34cm
24036	PLN Nail - 6.5mm x 36cm
24038	PLN Nail - 6.5mm x 38cm
24040	PLN Nail - 6.5mm x 40cm
24042	PLN Nail - 6.5mm x 42cm

24200
Nail End Cap

Screws

PLN 4.0mm Pilot Tipped Screws

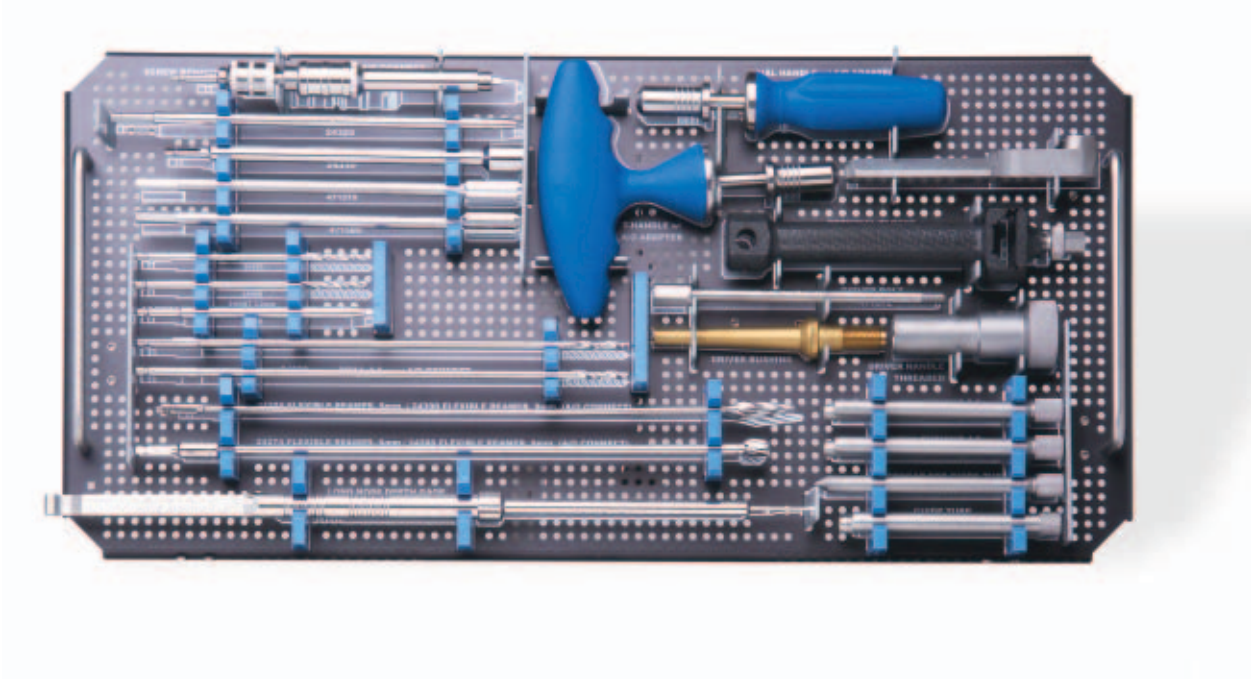
Part #	Description
24220	20mm Screw
24222	22mm Screw
24224	24mm Screw
24226	26mm Screw
24228	28mm Screw
24230	30mm Screw
24232	32mm Screw
24234	34mm Screw
24236	36mm Screw
24238	38mm Screw
24240	40mm Screw
24242	42mm Screw
24244	44mm Screw
24246	46mm Screw
24248	48mm Screw
24252	52mm Screw
24256	56mm Screw
24260	60mm Screw
24264	64mm Screw
24268	68mm Screw

The **Biomet PLN** is manufactured from polished Titanium alloy Ti6Al4V.

Tray Layout

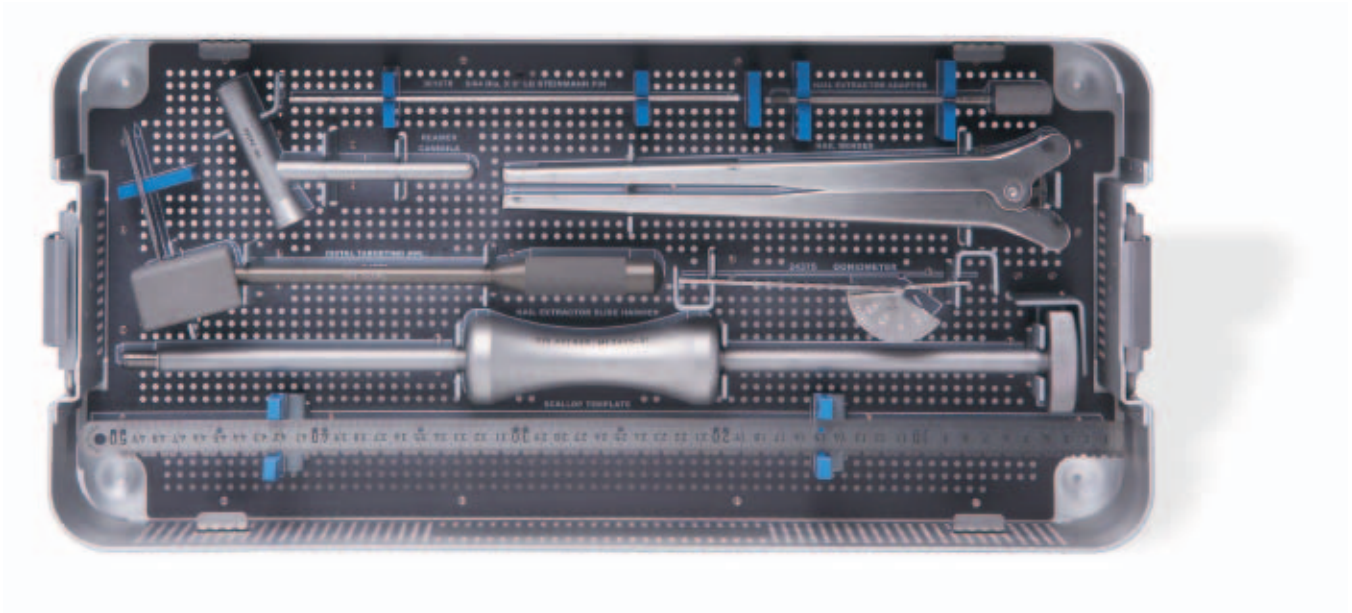
Top Level

Part #	Description
24295	Driver Bushing
471641	Proximal Target
471572	Driver Bolt
471535	Driver Handle - Threaded
471545	Guide Tube
24305	Drill Bushing 3.5mm
24300	Target Arm
24310	Drill Bushing 4.0mm
24315	Long A/O Connect Drill, 3.5mm
24320	Long A/O Connect Drill, 4.0mm
24355	Short A/O Connect Drill, 3.5mm
24360	Short A/O Connect Drill, 4.0mm
24365	Short A/O Connect 3.5mm Hex Driver
24325	3.5mm Hex A-O Quick Connect
24330	3/8" Hex Socket Quick Connect
24335	Screw Depth Gage (Long Nose)
471578	9.0mm Cannulated Reamer
471580	10mm Cannulated Reamer
24275	8.0mm Flexible Reamer Nitinol
24280	9.0mm Flexible Reamer Nitinol
24385	8.0mm Flexible Reamer Stainless
24390	9.0mm Flexible Reamer Stainless
471546	Trocar for Guide Tube
24340	Screw Remover
24345	T-Handle
22875	Axial Handle
24350	Instrument Tray



Bottom Level

Part #	Description
361878	9/64 X 9 Steinmann Pin
124777	Rod Bender
424285	Reamer Cannula
471793	Distal Targeting Awl
475920	X-ray scale
471565	Nail Extractor Slide Hammer
471588	Nail Extractor Adaptor
24375	Goniometer



Indications For Use

The **Biomet PLN** is indicated for fractures of the shaft, subtrochanteric region and distal third of the femur in appropriately sized children. It is generally contraindicated in children younger than eight years or in cases where the canal diameter is less than nine millimeters at the isthmus. It is contraindicated in low supracondylar fractures where distal interlocking purchase is not possible.

NOTE: This device should not be used in a canal less than 9.0mm in diameter.

This brochure describes the surgical technique used by Jonathan H. Phillips, Bsc., MB.BS, FAAP. **Biomet**, as the manufacturer of this device, does not practice medicine. And does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

Further Information

For further information, please contact the Customer Service Department at:

Biomet Trauma
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299-9300 - (800) 526-2579
www.biomettrauma.com

Notes:

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