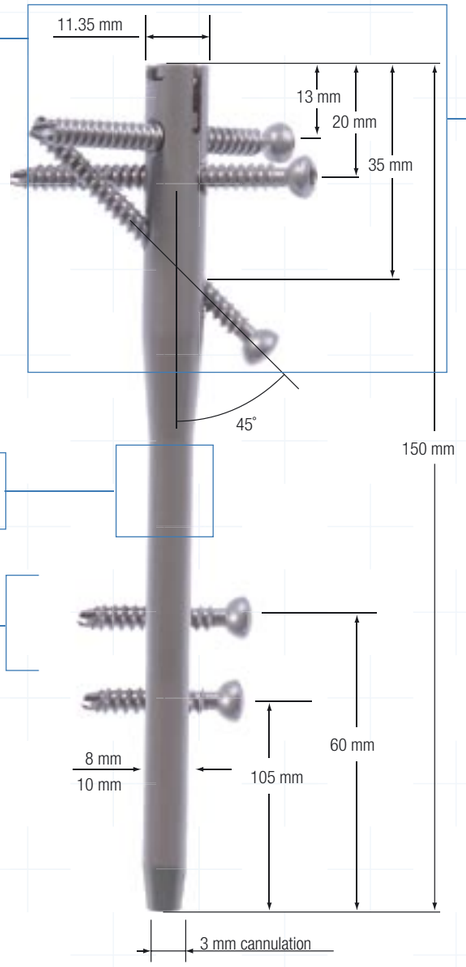
HUMERAL PROXIMAL NAILING SYSTEM

Locking sleeve and end cap prevent potential screw back-out



Proximal screws:
- Unique proximal screw configuration enhances fragment fixation
- 4.8 mm for 8 mm and 10 mm nails
- 2 L-M transverse screws: 30 degrees from oblique screw
- 1 L-M oblique screw: 45 degrees

3.0 mm cannulation accepts guide wire during nail insertion

Sizes: 8 mm and 10 mm, Length: 150 mm

Distal Screws:
- 3.5 mm for 8 mm nail
- 4.5 mm for 10 mm nail

Cat No: 0612-01-584 version 1

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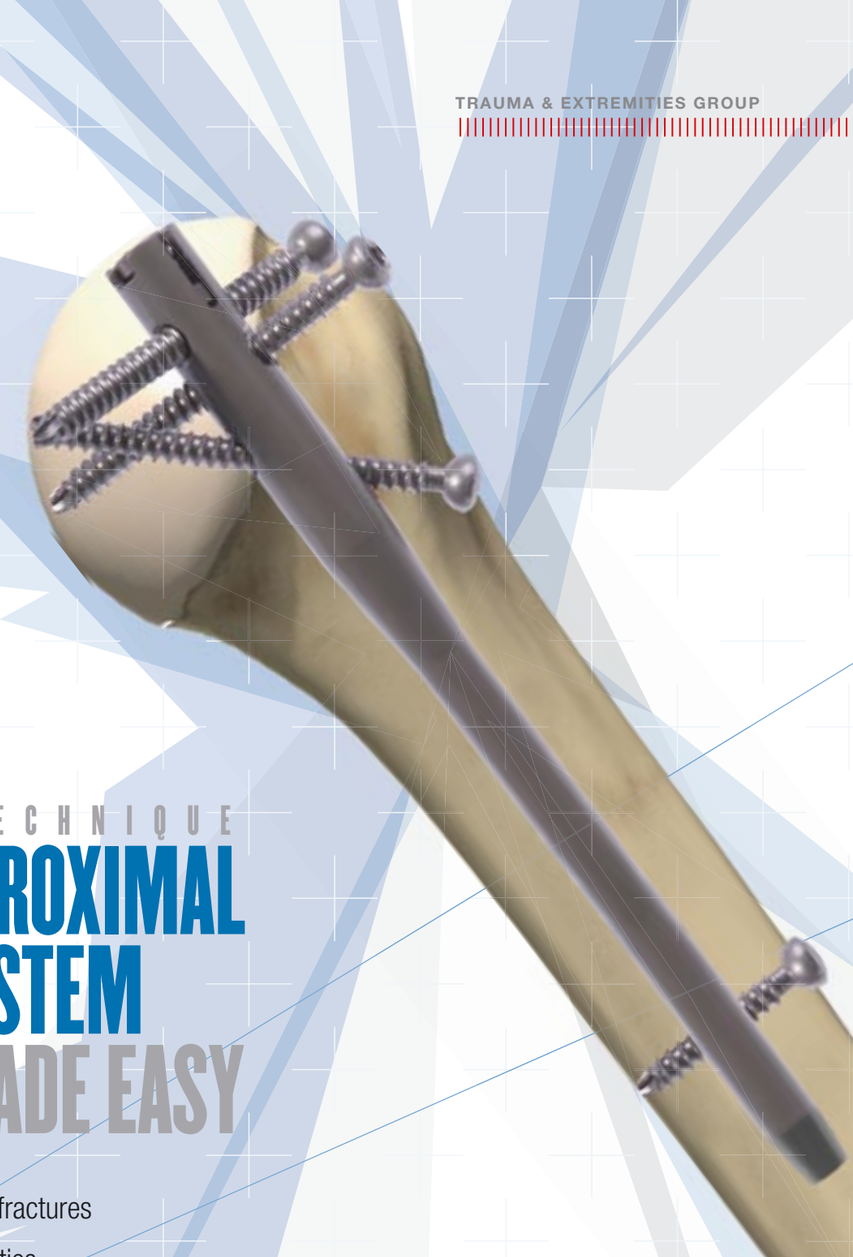

VERSANAIL®
Humeral Proximal

SURGICAL TECHNIQUE

HUMERAL PROXIMAL NAILING SYSTEM

OPTIONS MADE EASY

- **DESIGNED** to treat proximal fractures
- **INNOVATIVE** locking capabilities
- **SIMPLIFIED** user friendly instrumentation
- **ADJUSTABLE** targeting device

DePuy
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Note: This brochure presents a surgical technique available for use with the DePuy Orthopaedics, Inc., VersaNail® Platform instruments and implants. Surgeons may need to make modifications as appropriate in their own surgical technique with these devices depending on individual patient requirements.

OPTIONS MADE EASY

INTRAMEDULLARY FIXATION OF HUMERAL PROXIMAL FRACTURES

By J. Dean Cole, MD

OVERVIEW

Indications for humeral nail fixation are expanding from diaphyseal fractures to include proximal, distal and open fractures. The biological and mechanical advantages of intramedullary nail fixation, as well as the increasing number of surgeons who have become proficient in the technique, are the impetus for extended nail fixation indications. Good results in proximal fracture fixation require a surgeon to be proficient in conventional intramedullary nailing along with the ability to expand on experience gained from performing routine nailing of diaphyseal fractures. Expanding the nailing application to include treatment of humeral proximal fractures requires an appreciation of the unique characteristics of this procedure.

Due to the inherent difficulties associated with nailing proximal fractures, surgeons may prefer to continue stabilising these fractures by other methods. The following information summarises advantages and potential pitfalls of nailing humeral proximal fractures along with strategies to address them.

NAILING ADVANTAGES

Intuitively, there are several advantages to treating a humeral proximal fracture with an intramedullary nail.

- Mechanical stability can be accomplished with minimal dissection, allowing rapid mobilization of the patient and early range of motion (ROM) of the shoulder, elbow and wrist joints, thus improving rehabilitation potential.
- Periosteal stripping and soft tissue devitalization, compromising revascularization and periosteal callus formation, can also be minimised.
- When compared to traditional fixation with a plate, the intramedullary nail and locking screws combination decreases the amount of hardware susceptible to soft tissue irritation or impingement.

Additionally, the centrally placed intramedullary nail functions as an additional point of fixation for the humeral head, increasing the stability of the fracture complex. Such a construct reduces dependence on the screw to bone interfaces, which may be unreliable in osteoporotic bone treated with screws and plates.

Locked intramedullary nailing also has the potential to avoid problems, such as screw backout, impingement and loss of fixation inherent in the use of thin flexible rods or pins for humeral proximal fixation. Although application of intramedullary rods for humeral proximal fractures can overcome many problems associated with other fixation methods, it needs to be done carefully to avoid its own inherent pitfalls.

NAILING PITFALLS

Nail application in humeral proximal fractures has sometimes resulted in fixation constructs where the nail has a loose proximal fit resulting in increased dependence on locking screws for stability. Such methods are in sharp contrast to diaphyseal nailing in which endosteal cortical contact between the nail and the fragment is generally sufficient to accomplish alignment reduction and maintenance. The complications encountered when nailing humeral proximal fractures can be classified into the following categories:

- Implant design
- Surgical approach
- Reduction and anatomic alignment
- Nail insertion technique
- Skeletal anatomy

IMPLANT DESIGN

The fixation obtained in the proximal fragment is dependent upon nail contact with the subchondral bone of the humeral head at the entry site and one or two interlocking screws. Deforming forces during fracture healing stress the bone-fracture interface and may result in loss of alignment if fixation is dependent on the screw purchase alone. The shape of the implant also dictates the entry point. Implants with a pronounced lateral proximal bend require an entry point that potentially damages the insertion of the rotator cuff and makes alignment of the proximal fragments with the shaft more difficult.

A pronounced lateral bend also requires over-reaming of the entry site, decreasing contact between the top of the nail and the subchondral bone of the head. Most implant designs also do not have the ability to lock the proximal screw to the nail, resulting in a high incidence of screw migration. Thus, an implant with a relatively straight proximal section and the ability to accept proximal locking screws that can be placed both above and below the fracture line is important to help maintain if adequate control of the proximal fracture fragments. The resulting complications from a selection of implants with inappropriate designs for treatment of humeral proximal fractures are specific to the particular design of the implant. These include cutout, loss of alignment, loss of fixation, hardware impingement and rotator cuff pain.

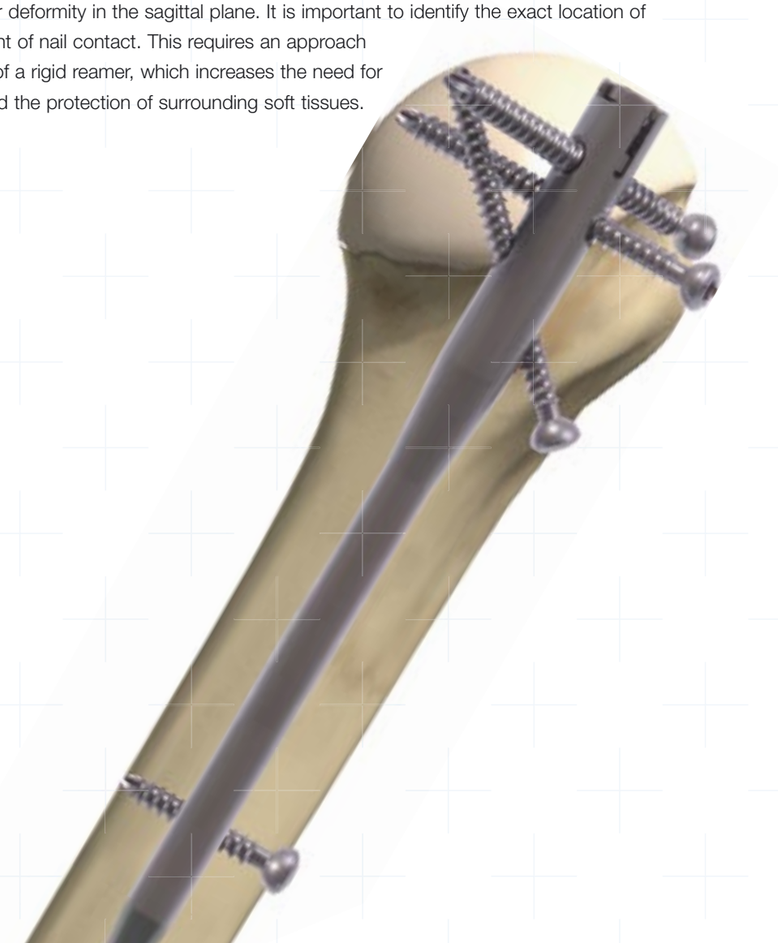
SURGICAL APPROACH AND FRACTURE REDUCTION

Familiarization with techniques to select and expose the correct entry site and nail entry angle as well as the use of the nail as a tool to align the fracture is necessary. It is also crucial to obtain orthogonal x-ray views and avoid destruction of the rotator cuff during implant/instrument insertion.

Reliance on the nail to anatomically align the fracture is expected in diaphyseal fractures since merely passing the nail across the fracture site is usually adequate to reduce the fracture. The nail insertion process must also align humeral proximal fractures. However, anatomic alignment of humeral proximal fractures depends upon the position of the entry site, the angle of the entry nail and the pathology of the humeral head fracture, if present. Use of K-wires as joysticks to manipulate the proximal head fragment is required. Orthogonal x-ray views are then used to identify and confirm the correct entry point and angle of entry required to align the fracture in two planes. Without shoulder extension, the surgeon is unable to achieve the correct angle of entry due to the position of the acromion. For this reason, the patient must be positioned in such a way that full extension of the shoulder can be achieved by rotating the humeral head into the correct position, which also exposes the entry point from under the acromion.

SKELETAL ANATOMY

Fracture site stability in classic nail application is determined by the amount of contact between the walls of the intramedullary canal of the primary fragments and the nail. The humeral proximal canal is usually large relative to the nail diameter. This means the nail will probably not contact the endosteal cortex of the humeral proximal fragment except at the entry site, thus limiting fracture site stability. In addition, bone density is not consistent throughout the humeral head. Usually, the only bone capable of supporting fixation is the thin subchondral layer under the articulating surface of the head. The entry site should be in line with the longitudinal axis of the humeral proximal shaft to reduce the risk of medial blowout to the shaft, which is sometimes associated with lateral insertion point, and to avoid generation of an angular deformity in the sagittal plane. It is important to identify the exact location of the nail entry site to optimise this point of nail contact. This requires an approach through the rotator cuff and the use of a rigid reamer, which increases the need for careful handling of the rotator cuff and the protection of surrounding soft tissues.



Implant Material

All implants are manufactured from Ti-6AI-4V grade, type II anodised titanium alloy (TiMAX™) due to this material's superior properties. TiMAX™ offers a lower modulus of elasticity and increased fatigue strength over stainless steel.

Implant Overview

The Humeral Proximal Nail is intended for use in the following (please see the Essential Product Information on page 21 for a complete listing of indications and contraindications):

- Proximal humeral fractures

Fig. 1 Jig

Humeral Proximal Jig

The proximal humeral trigger jig (Cat. No. 2810-18-007) is designed with the jig mechanics up and out of the way so that the entry site can be targeted from a distance. The targeting arm rotates with the push of a button to target the proximal locking options. The rotating design also allows the jig to be repositioned without disassembly for convenience during the nailing procedure to improve visualization of the nail seating and screw length (Fig. 1).

Fig. 2 Patient Positioning

Position the patient supine in the beach chair position on a radiolucent table (Fig. 2). To allow easy access to the proximal humerus, it is helpful and recommended to place the C-arm on the opposite side of the table of the injured limb. The C-arm should also be positioned so it is parallel with the head of the patient to allow an axial view of the humeral head.

Position the patient's affected shoulder on the table to allow visualization without interference of the table edge with the fluoroscopic imaging. Extend the shoulder to expose the humeral head. This will prevent the acromion from overlaying the center of the humeral head in the sagittal plane, thus potentially obscuring the entry site or directing an errant entry angle.

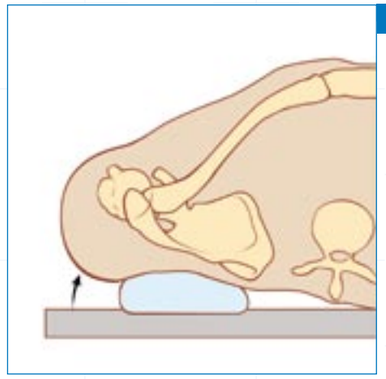


Fig. 3 A bolster can be utilised to elevate the shoulder from the table and to allow shoulder extension (Fig. 3).

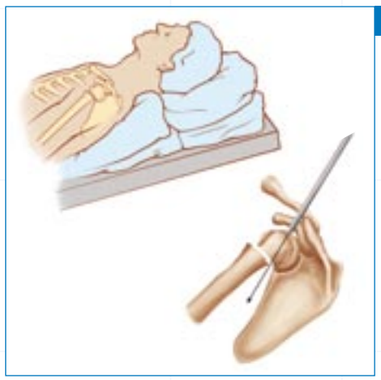


Fig. 4 **Note**: It is not possible to achieve the correct entry point and alignment of the humeral head with the shaft when the shoulder is not extended (Fig. 4).

Fig. 5 Extend the shoulder to allow the correct entry point and alignment of the humeral head and shaft. A K-wire inserted into the head of the shoulder may be required to achieve adequate extension of the head fragment (Fig. 5).

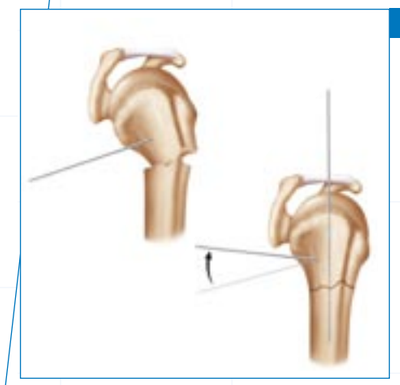


Fig. 6

Humeral Head Reduction

The humeral head is typically in a varus or valgus position due to contraction of the rotator cuff muscles and the force of impaction during injury (Fig. 6, left). Manipulation of the humeral head is accomplished by drilling one or two K-wires lateral to medial in the anterior and posterior portions of the humeral head (Fig. 6, right). Using the K-wires, manipulate the humeral head lateral to medial out of varus or valgus and in proper coronal plane alignment. K-wires can also act as joysticks during fracture reduction and to gain an orthogonal view of the humeral head.

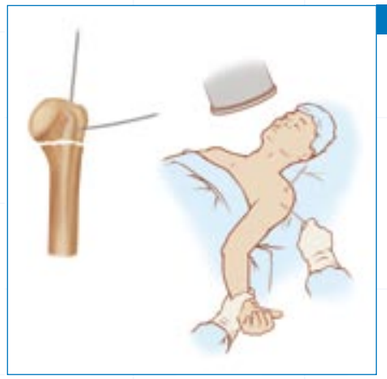


Fig. 7 Typically the K-wires should be drilled perpendicular to the anatomic neck (Fig. 7, left). These K-wires can then be used in a joystick fashion to adduct and extend the head, exposing the supraspinatus tendon and optimal entry site in the head from beneath the anterior edge of the acromion. Fracture reduction is accomplished by adducting and extending the proximal fragment with the aid of the joystick while an assistant simultaneously maintains longitudinal traction on the distal arm (Fig. 7, right).

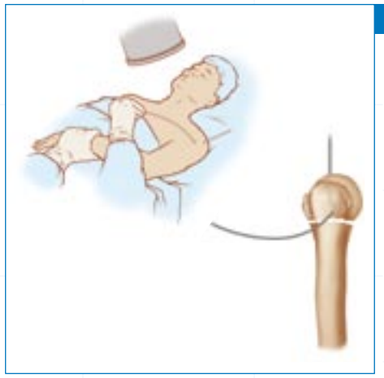


Fig. 8 Image intensification can be used to place a K-wire through the humeral head in line with the intramedullary axis of the humerus (Fig. 8).

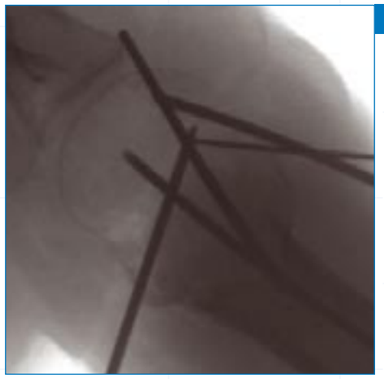


Fig. 9 There are some key considerations to this approach. The first is to use the joysticks to extend and adduct the humeral proximal head, exposing the anterolateral portion of the head from under the acromion while simultaneously distracting the distal shaft, thereby aligning the longitudinal intramedullary axis of the proximal and distal fragments.

The second is to drive the K-wire into the head in a central position with reference to the medullary canal in the sagittal plane and lateral to central in reference to the canal in the frontal plane. To achieve appropriate K-wire position, it is necessary to use the first joystick in the proximal fragment to rotate and stabilise the humeral head while simultaneously using the second joystick to rotate the distal shaft manually to obtain two orthogonal views of the head in reference to the shaft.

Finally, a guide pin centered axially and laterally through the frontal plane between the two K-wires will offer ideal nail entry site identification. The jig arm should go between both K-wires under the L-M laser mark setting via axial radiographic view (Fig. 9).

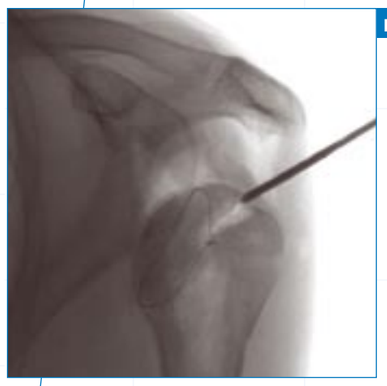


Fig. 10 **Entry Site and Incision Placement**

Make an incision just anterior to the anterior edge of the acromion. The anterior edge may be difficult to palpate and differentiate from the humeral head due to edema and hematoma from the fracture. Therefore, it is helpful to use a K-wire under image intensification to locate the anterior edge of the acromion angle where it intersects the longitudinal axis of the humerus (Fig. 10).

Fig. 11 Make a sharp 3 cm oblique skin incision in line with the deltoid fibers. Elevate the subcutaneous fat to expose the fascial plane between the anterior and middle third of the deltoid muscle fibers. Continue deep dissection in line with muscle fibers, taking care to avoid incising the coracoacromial ligament until exposing the sub deltoid bursa. Elevate the bursa to expose the supraspinatus tendon.

(For type C-3 injuries, a medial extension of the incision, necessary for medial access, is recommended along the anterior acromion toward the AC joint) (Fig. 11).

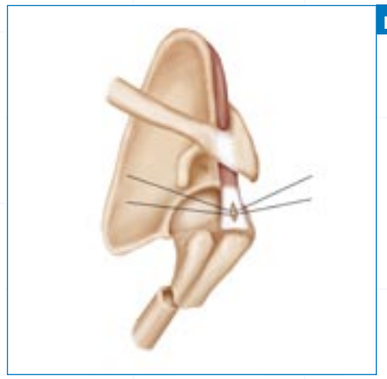


Fig. 12 **Soft Tissue Protection**

In cases where the greater tuberosity is intact or non-displaced, a 1 to 1.5 cm incision can be made in the supraspinatus tendon in line with its fibers, taking care not to extend it too far laterally and interrupt the tendon insertion. Care should be taken to avoid the tendon insertion site as the rotator cuff does not have enough mobility at its insertion site to allow adequate retraction for instruments to be used in subsequent steps. The medial entry site assures minimal trauma to the cuff insertion during the procedure.

To preserve soft tissue during the reaming process, pass a 2-0 braided non-absorbable suture on each side of the incision (Fig. 12). The sutures will aid in retracting the cuff during reaming and in closing the cuff at the completion of the procedure. The antegrade entry portal (Cat. No. 2810-17-101), a tissue protector, is available to aid in the protection of soft tissues during the reaming process.

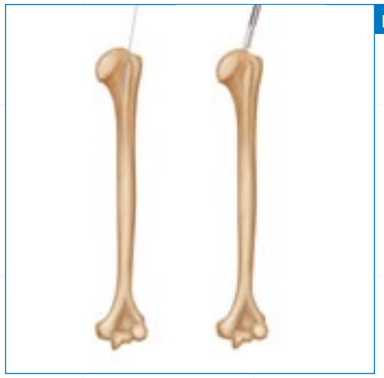


Fig. 13 A starting point is made with a threaded 3.2 mm x 14 inch guide pin (Cat. No. 14012-14) and a curved cannulated awl (Cat. No. 2810-01-005). Use A-P and lateral fluoroscope views to confirm accurate placement. The entry site in the humeral head is made with the cannulated proximal nail entry reamer (Cat. No. 2810-18-002) over the 3.2 mm x 14 inch guide pin about 1 to 1.5 mm above the bicipital groove, which is aligned with the intramedullary canal (Fig. 13).

Use the awl or cannulated entry reamer to open the humeral head. Hand reaming is recommended, using a reamer with a T-handle Hudson attachment (Cat. No. 2810-01-004). Slow-power reaming can also be used for the head only. Additionally, the reaming process can assist with gauging the diameter of the canal at the isthmus.

After the head has been reamed to the desired size, fluoroscopically verify the entry point and advance the awl or entry reamer in line with the humeral canal. The entry reamer is marked to identify the correct reaming depth.

Fig. 14 Once access to the humeral canal has been gained, place the 2.0 mm ball nose guide wire (Cat. No. 2810-17-006) into the entry site utilising the pistol guide wire gripper (Cat. No. 2810-01-001) (Fig. 14).

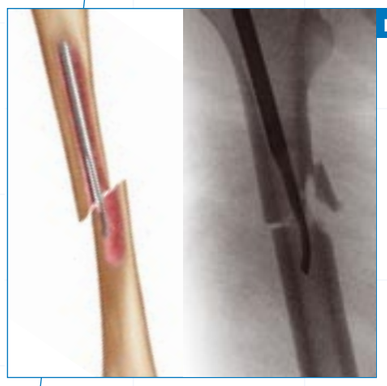


Fig. 15 Fracture Reduction

Obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. Reduction can be achieved using the reduction tool (Cat. No. 2810-01-008) (Fig. 15) that is passed through the medullary canal and beyond the fracture site. Once the fracture is in alignment, place a guide wire through the cannulation of the reduction tool using the wire gripper. Remove the reduction tool and check reduction under image intensification.

Fig. 16 Canal Preparation

It is recommended to avoid reaming in the case of humeral proximal fractures, particularly those fractures with poor bone quality. Rather, insert the proximal nail via the use of the 2.2 mm x 28 inch guide wire (Cat. No. 8092-22-028) and proximal nail jig assembly (Cat. No. 2810-18-007). The humeral proximal nail is designed with a short (150 mm) length so that the nail will not extend into the narrowing portion of the humeral shaft (Fig. 16).

Flexible Reaming (Optional)

Achieve alignment of the injured limb prior to reaming and maintain it throughout the reaming process to avoid eccentric reaming. Commence reaming by placing an intramedullary flexible reamer over the ball nose guide wire. Ream the medullary canal in half-millimeter increments until cortical bone is reached. Monitor the reaming procedure using image intensification to avoid eccentric or excessive reaming.

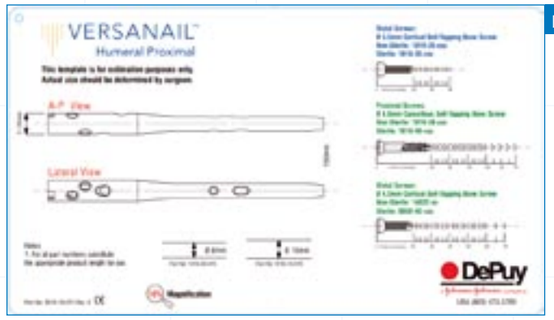


Fig. 17 Nail Size Selection

An x-ray template is available to determine nail size preoperatively (Cat. No. 2810-18-011). Nail length determination will not be necessary as both the 8 mm and 10 mm Humeral Proximal Nails are 150 mm in length. After selecting the appropriate nail diameter (8 mm or 10 mm option), secure the nail to the nose of the jig barrel using the jig bolt (Cat. No. 2810-18-009) (Fig. 17).

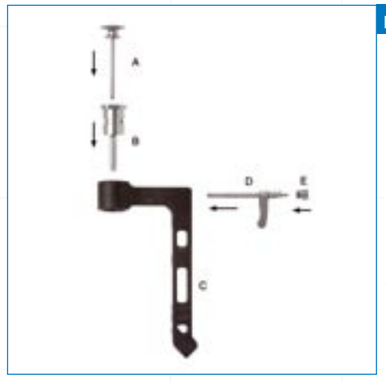


Fig. 18 Jig Assembly (Fig. 18)

1. Insert the jig bolt (A) over the barrel (B) and the aluminium body (C).
2. Insert the trigger (D) inside the aluminium body.
3. Insert and tighten the locking nut (E) over the back of the trigger onto the aluminium jig body.
4. The jig nose is indexed so that the line of the nose laser marked “L-M” is in line with the laser marked arrow located on the top of the aluminium body. When this position is achieved, the trigger will engage through the middle hole of the jig barrel.

Fig. 19 **Nail Insertion**

1. Insert the jig bolt through the jig barrel.
2. Mount the nail onto the nose of the jig barrel and the protruding part of the jig bolt so that the two alignment tabs of the nose engage fully with the keyways of the nail. The two tabs are of different widths to prevent incorrect indexing of the nail onto the nose of the jig barrel.
3. Tighten the jig bolt onto the nail using the jig bolt driver (Cat. No. 2810-17-028) that engages the internal hex located inside the upper part of the jig bolt (Fig. 19). Using the jig bolt driver, ensure that the push button is tightened securely to the barrel lock mechanism.

Note: The complete jig should be assembled and targeting checked to ensure accuracy prior to nail insertion.

Note: The jig should be disassembled prior to cleaning.

Fig. 20 Ensuring the humeral head is centered over the shaft, insert nail via jig into the entry site by hand as far as possible. Gentle tapping may be needed to advance the nail until it is approximately 5 mm below the articular surface. If the nail does not advance easily, it should be removed and the canal reamed an additional 0.5 mm (approximately 0.02 inches). Avoid excessive force to the nail. The top of the nail may be inserted up to 10 mm below the surface of the humeral head should additional depth be required to position the most distal proximal locking screw hole below the fracture line (Fig. 20).

Apply gentle upward blows to the proximal ulna while digitally maintaining pressure on the humeral head. An alternative method to achieve fracture reduction or impaction is by gently tapping on the outrigger. Ensure humeral head to shaft contact and impaction prior to proximal and distal locking. Confirm reduction fluoroscopically and prepare for drilling proximal interlocking screws.

Note: Take care to avoid placing the humeral nail too anterior or posterior relative to the center of the humeral head. It is recommended to verify nail placement and alignment via coronal, orthogonal and axial plane radiographic views.

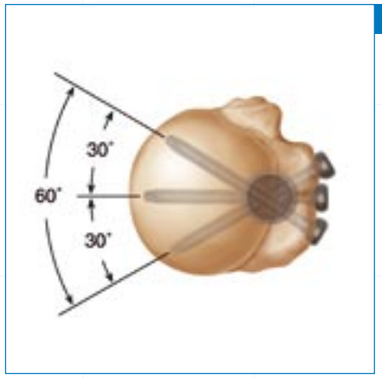


Fig. 21 **Proximal and Distal Locking**

The Humeral Proximal Nail offers three proximal locking options and two distal locking options (Figs. 21 and 22).

- Two transverse screws (60 degrees apart in the transverse plane, and 30 each from the oblique screw)
- One oblique proximal screw (located in L-M direction, 45 degrees upward in sagittal plane)
- One L-M transverse static distal screw
- One L-M transverse static/dynamic distal screw
  - Screw proximally for static (as shown)
  - Screw distally for dynamization

Fig. 22 **Proximal Locking**

4.8 mm cancellous fully-threaded screws (Cat. No. 1819-48-0XX) are recommended for proximal locking. The thread patterns of the 4.8 mm cancellous screws work optimally with the locking sleeve design within the Humeral Proximal Nail. For proximal locking of the nail, 4.5 mm cortical screws (Cat. No. 14022XX) can also be used. Both 4.8 mm and 4.5 mm screws use the same instrumentation.

Locking Through the Jig

Using the trigger located on the top of the arm, rotate the jig arm to target each hole in the nail. Position the targeting arm in the appropriate position to target the desired screw hole.

Recommended Order of Screw Placement:

1. Oblique Screw (L-M) – For fractures involving the humeral head, the first screw is placed to stabilise the head fragment and achieve initial head-shaft construct. Generally, a good landmark to determine proper placement is to target the middle of the greater tuberosity.
2. Transverse Screw (A) – Most proximal transverse screw, anterior to posterior.
3. Transverse Screw (B) – Second proximal transverse screw, most dorsal.

Note: It is recommended to verify screw configuration via axillary radiographic view after screw placement.

Fig. 23 **Rotating Mechanism Usage (Fig. 23)**

1. Pull the trigger and hold. This disengages the trigger pin from the hole of the barrel, enabling it to rotate to another position.
2. Rotate the body of the jig until the adequate barrel laser mark matches the adequate body laser mark. Options are as follows:
   a. The laser mark indicating “L-M” is dedicated to the oblique screw and the distal screws
   b. The laser mark indicating “A” is dedicated to the most proximal transverse screw
   c. The laser mark indicating “B” is dedicated to the second proximal transverse screw
3. Release the trigger. The spring will push the trigger pin back into the hole, securing the alignment of the nail for targeting.

Fig. 24 Place the protective static screw-sheath (Cat. No. 2810-17-011) and trocar (Cat. No. 2810-17-013) through the appropriate locking holes in the jig’s targeting arm. Make a stab incision and bluntly dissect through the subcutaneous tissues and deltoid muscle to the lateral cortex, taking care to avoid injury to the axillary nerve and muscles during drilling and screw placement to the bone (Fig. 24).

Fig. 25 Remove the trocar and insert the drill sleeve (Cat. No. 2810-17-014) into the sheath until the drill sleeve touches the bone (Fig. 25).

Fig. 26 Using the 3.8 mm drill bit (colour-coded green) (Cat. No. 2810-17-115), drill through the drill sleeve and sheath across the humeral canal until the far cortex is reached but not penetrated (Fig. 26).

Fig. 27 Read the calibration on the drill bit that lines up with the drill sleeve. Estimate in millimeters the far cortex and add to the calibrated reading. Use fluoroscopy in multiple planes to monitor appropriate drill depth during the drilling procedure (Fig. 27)

Fig. 28 **Countersinking Option**

To decrease the risk of impingement of the proximal locking screw(s) on the acromion, it is important to countersink the head of the proximal screw. A countersink (Cat. No. 2810-17-024) is provided in the set (Fig. 28). After drilling, the countersink is used on the lateral cortex. Care should be taken to avoid complete reaming of the lateral cortex.

Verify fluoroscopically to assure the proper screw length selection. Remove the drill guide. Using the humeral screwdriver (Cat. No. 2810-17-017), insert the 4.8 mm fully-threaded cancellous screw or 4.5 mm cortical screw through the sheath. The humeral screwdriver is etched with two markings, oblique and transverse, to identify proper screw seating for the proximal locking screw holes. Appropriate seating of the screw should be verified when the respective marking is flush to the drill sleeve. It is recommended to verify via fluoroscopy.

Fig. 29 **Distal Locking**

Repeat procedures on page 14-15 for distal locking using the jig's targeting arm (Fig. 29).

Fig. 30 The 8 mm Humeral Proximal Nail (Cat. No. 1818-08-015) should be locked distally using 3.5 mm cortical screws (Cat. No. 1819-35-0XX) and the following instrumentation (Fig. 30):

- 2.9 mm drill bit (Cat. No. 2810-17-119)
- Drill Sleeve (Cat. No. 2810-17-014)
- Static (Cat. No. 2810-17-011) or dynamic (Cat. No. 2810-17-012) screw-sheath
- Trocar (Cat. No. 2810-17-013)

The 10 mm Humeral Proximal Nail (Cat. No. 1818-10-015) should be locked distally using a 4.5 mm cortical screw (Cat. No. 14022XX) and the following instrumentation:

- 3.8 mm drill bit (Cat. No. 2810-17-115)
- Drill Sleeve (Cat. No. 2810-17-014)
- Static (Cat. No. 2810-17-011) or dynamic (Cat. No. 2810-17-012) screw-sheath
- Trocar (Cat. No. 2810-17-013

Fig. 31 **End Cap Placement**

The flush locking end cap is packaged in a sterile pouch along with the nail pouch. Take care that the locking end cap is not dropped or discarded when opening the nail. The locking end cap is inserted and threaded into the top of the nail. This locking end cap impinges on the locking sleeve within the nail, thereby locking all three screws in a solid construct. Ensure the end cap is tightened to secure the screws. Proper seating of the nail should ensure that the top of the end cap remains at least 5 mm below the articular surface (Fig. 31).

Note: The sleeve is captured inside the nail and should not be removed.

Fig. 32 The jig assembly is fully cannulated to accommodate the placement of the end cap into the nail. During proximal screw locking, i.e., transverse screws, and upon last placement of the proximal screw, allow the humeral screwdriver (Cat. No. 2810-17-017) to be engaged with the last proximal screw. This will maintain jig and nail construct for end cap insertion (Fig. 32).

Fig. 33 Remove the jig bolt and guide end cap with the humeral screwdriver through jig cannulation and activate locking system by tightening the end cap to the nail with the humeral screwdriver (Fig. 33).

Note: Moving the patient's arm before the end cap is completely seated may translate the nail from the entry site. This displaced alignment may cause difficulty in placing the end cap.

Note: If required, screws may be unlocked for removal or repositioning by removing the locking end cap.

Fig. 34 **Note**: The end cap must be tightened using the humeral screwdriver in order to activate the locking system. To facilitate end cap tightening, two screwdrivers can be used. A first screwdriver, such as the SolidLok™ screwdriver (inner shaft – Cat. No. 2810-01-021, tip – Cat. No. 2810-01-019, handle – Cat. No. 2810-01-020) is used to tighten the end cap. End cap locking can also be achieved using a humeral screwdriver with a round handle (Cat. Nos. 2810-17-017 and 2141-49-000) (Fig. 34).

Fig. 35 If the surgeon deems it appropriate to remove the nail, a proximal nail extractor bolt (Cat. No. 2810-18-010), used with a 3⁄4 inch hex driver (Cat. No. 2810-01-027) and T-handle Hudson (Cat. No. 2810-01-004), is provided to aid in nail extraction (Fig. 35)

Fig. 36 Locate the top of the nail through an appropriate incision. Remove the end cap using the humeral screwdriver (Cat. No. 2810-17-017) and screwdriver handle (Cat. No. 2141-49-000). A second screwdriver such as the SolidLock™ screwdriver (inner shaft – Cat. No. 2810-01-021, tip – Cat. No. 2810-01-019, handle – Cat. No. 2810-01-020) is also available to aid in end cap removal (Fig. 36).

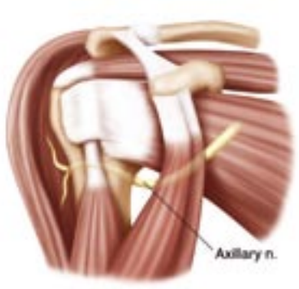


Fig. 37 Axillary Nerve

The axillary nerve is the nerve most often damaged during the injury and iatrogenically — even by closed manipulation and percutaneous fixation. During open reduction, the damage occurs especially during soft tissue retraction and percutaneous proximal screw drilling. To prevent axillary nerve damage, it is advisable to make small skin incisions and perform blunt dissection to bone, followed by drilling and interlocking.

Note: The axillary nerve is located approximately 10 mm below the oblique screw, approximately 30 degrees dorsally (Fig. 37).

Radial Nerve

Another feared complication is radial nerve palsy. In cases of secondary nerve palsy, exploration of the nerve is required. Clinical literature has well documented this. One noteworthy study describes the anatomical safe zone.[1]

Note: The radial nerve should be located well below the distal part of the proximal nail.

1. Tekdemir, I., U. Sayli, A. Elhan, K.M. Erbil and R. Basar. “Relation of the Radial Nerve With the Sulcus Nervi Radialis: a Morphometric Study.” Okajimas Folia Anat 76(4), 1999: 197-202.

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 (orthopaedic screws, intramedullary nails, plates, compression hip screws) 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

Orthopaedic screws, intramedullary nails, plates, and compression hip screws 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 post operative instructions during the healing process, and foreign body sensitivity.

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 utilised.

Additional Contraindications for Intramedullary Nails only: Cases where the nail would cross open epiphyseal plates in skeletally immature patients and obliterated medullary canal or other conditions which tend to retard healing such as blood supply limitations, or previous infections.

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

Additional Contraindications for Compression Hip Screws only: Cases where the screw-plate combination would cross open epiphyseal plates in skeletally immature patients, and 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, intramedullary nails, plates and compression hip screws: 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 adverse reactions to the device material.

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

Humeral Proximal Nail sizes (mm): Includes nail with captured sleeve and end cap in same package			Screw sizes (mm)	
Diameter	Length	Cat. No.	Proximal	Distal
8	150	1818-08-015	4.8	3.5
10	150	1818-10-015	4.8	4.5

Humeral Proximal Nail screws:

Proximal screws:

Diameter (mm)	Length (mm)	Cat. No.
4.8 cancellous for 8 mm and 10 mm nails 3.8 mm drill bit to be used	30-60 in 2 mm increments 60-76 in 4 mm increments	Sterile: 1818-48-030/076 Non-sterile: 1819-48-030/076

Distal screws:

Diameter (mm)	Length (mm)	Cat. No.
4.5 cortical for 10 mm nail 3.8 mm drill bit	20-60 in 2 mm increments 65-70 in 5 mm increments	Sterile: 8050-45-020/070 Non-sterile: 14022-20/070
3.5 cortical for 8 mm nail 2.9 mm drill bit	20-40 in 2 mm increments	Sterile: 1818-35-020/040 Non-sterile: 1819-35-020/040

Screw Dimensions	3.5 mm	4.5 mm	4.8 mm
Thread Major	3.5	4.7	4.9
Thread Minor	2.6	3.7	3.6
Thread Pitch	0.75	1.0	1.8
Head Diameter	7.0	7.7	7.8
Head Height	5.5	5.0	5.3
Hex Size	3.6	3.6	3.6

HUMERAL PROXIMAL NAIL SYSTEM

3.5 mm Cortical Screws: Non-Sterile

Cat. No.	Description
1819-35-020	3.5 mm Cortical Screw 20 mm
1819-35-022	3.5 mm Cortical Screw 22 mm
1819-35-024	3.5 mm Cortical Screw 24 mm
1819-35-026	3.5 mm Cortical Screw 26 mm
1819-35-028	3.5 mm Cortical Screw 28 mm
1819-35-030	3.5 mm Cortical Screw 30 mm
1819-35-032	3.5 mm Cortical Screw 32 mm
1819-35-034	3.5 mm Cortical Screw 34 mm
1819-35-036	3.5 mm Cortical Screw 36 mm
1819-35-038	3.5 mm Cortical Screw 38 mm
1819-35-040	3.5 mm Cortical Screw 40 mm
(Sterile: 1818-35-020/040)	

4.8 mm Cancellous Screws: Non-Sterile

Cat. No.	Description
1819-48-030	4.8 mm Cancellous Screw 30 mm
1819-48-032	4.8 mm Cancellous Screw 32 mm
1819-48-034	4.8 mm Cancellous Screw 34 mm
1819-48-036	4.8 mm Cancellous Screw 36 mm
1819-48-038	4.8 mm Cancellous Screw 38 mm
1819-48-040	4.8 mm Cancellous Screw 40 mm
1819-48-042	4.8 mm Cancellous Screw 42 mm
1819-48-044	4.8 mm Cancellous Screw 44 mm
1819-48-046	4.8 mm Cancellous Screw 46 mm
1819-48-048	4.8 mm Cancellous Screw 48 mm
1819-48-050	4.8 mm Cancellous Screw 50 mm
1819-48-052	4.8 mm Cancellous Screw 52 mm
1819-48-054	4.8 mm Cancellous Screw 54 mm
1819-48-056	4.8 mm Cancellous Screw 56 mm
1819-48-058	4.8 mm Cancellous Screw 58 mm
1819-48-060	4.8 mm Cancellous Screw 60 mm
1819-48-064	4.8 mm Cancellous Screw 64 mm
1819-48-068	4.8 mm Cancellous Screw 68 mm
1819-48-072	4.8 mm Cancellous Screw 72 mm
1819-48-076	4.8 mm Cancellous Screw 76 mm
(Sterile 1818-48-030/076)	

4.5 mm Cortical Screws: Non-Sterile

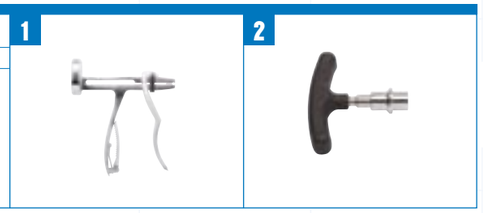
Cat. No.	Description
1402220	Cortical Bone Screw 20 mm
1402222	Cortical Bone Screw 22 mm
1402224	Cortical Bone Screw 24 mm
1402226	Cortical Bone Screw 26 mm
1402228	Cortical Bone Screw 28 mm
1402230	Cortical Bone Screw 30 mm
1402232	Cortical Bone Screw 32 mm
1402234	Cortical Bone Screw 34 mm
1402236	Cortical Bone Screw 36 mm
1402238	Cortical Bone Screw 38 mm
1402240	Cortical Bone Screw 40 mm
1402242	Cortical Bone Screw 42 mm
1402244	Cortical Bone Screw 44 mm
1402246	Cortical Bone Screw 46 mm
1402248	Cortical Bone Screw 48 mm
1402250	Cortical Bone Screw 50 mm
1402252	Cortical Bone Screw 52 mm
1402254	Cortical Bone Screw 54 mm
1402256	Cortical Bone Screw 56 mm
1402258	Cortical Bone Screw 58 mm
1402260	Cortical Bone Screw 60 mm
1402265	Cortical Bone Screw 65 mm
1402270	Cortical Bone Screw 70 mm
(Sterile 8050-45-020/070)	

Proximal Humeral Nail: Sterile

Cat. No.	Description
1818-08-015	Prox Humeral Nail 8mm x 150mm
1818-10-015	Prox Humeral Nail 10mm x 150mm

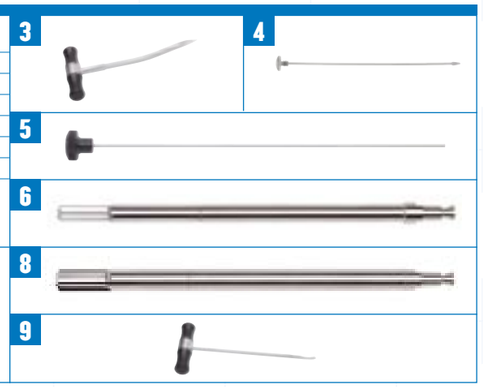
GENERAL

2810-01-001	Pistol Guide Wire Gripper	1
2810-01-004	T-handle Hudson	2



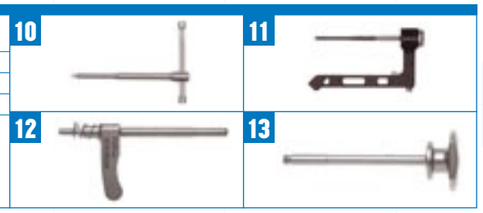
CANAL PREP

2810-01-005	Curved Cannulated Awl	3
2810-01-025	Awl Stylus	4
2810-01-026	Guidewire Pusher	5
2810-17-003	9.4 mm Entry Reamer	6
2810-18-002	Proximal Nail Entry Reamer	7
2810-17-101	Antegrade Entry Portal	8
2810-01-008	Short Reduction Tool	9



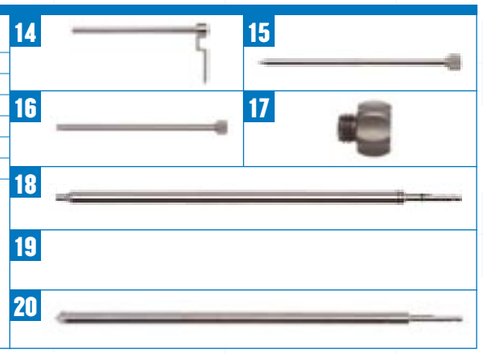
NAIL INSERTION

2810-17-028	Humeral Jig Bolt Driver	10
2810-18-007	Proximal Jig Complete Assembly	11
2810-18-008	Proximal Jig Trigger Assembly	12
2810-18-009	Proximal Jig Locking Bolt	13



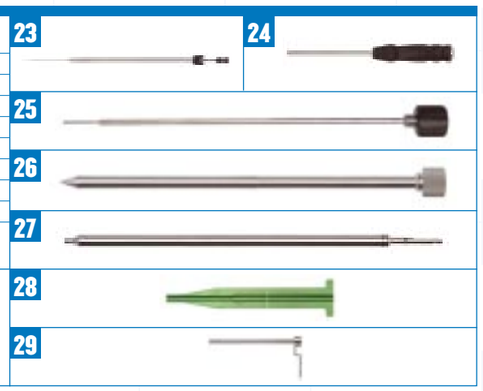
PROXIMAL LOCKING

2810-17-011	Static Screw Sheath	14
2810-17-013	Trocar	15
2810-17-014	Humeral Drill Sleeve	16
2810-01-018	Sheath Locking Nut	17
2810-17-017	Humeral Screwdriver	18
2810-01-032	4.5 mm Screw Length Gauge	19
2810-17-024	Countersink	20



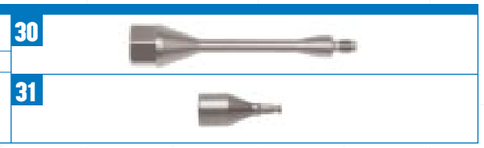
DISTAL LOCKING

2810-17-012	Dynamic Screw Sheath	21
2141-49-000	Lg Cann Screwdriver Handle	22
2810-17-020	Humeral Screw Depth Gauge	23
2810-01-020	SolidLock™ Screwdriver Handle	24
2810-01-021	SolidLock™ Driver Inner Shaft	25
2810-17-013	Trocar	26
2810-17-017	Humeral Screwdriver	27
2810-01-032	4.5 mm Screw Length Gauge	28
2810-17-011	Static Screw Sheath	29



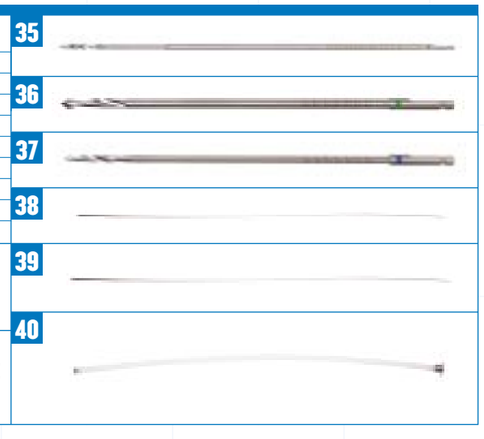
NAIL REMOVAL

2810-18-010	Proximal Nail Extractor Bolt	30
2810-01-027	3/4 inch Hex Driver	31



DISPOSABLES

1401214	Threaded Guide Pin 3.2 mm x 14 inch	32
2810-01-019	SolidLock™ Hex Tip, 3.5 mm	33
2810-17-119	2.9 mm Drill Bit/Non-sterile	34
2810-17-115	3.8 mm Drill Bit/Non-sterile	35
2810-12-138	3.8 mm Drill Bit 6 inch	36
2810-17-129	2.9 mm Drill Bit Short	37
8092-22-028	Guidewire 2.2 mm x 28 inch	38
2810-17-006	2.0 mm Ball Nose Guide Wire	39
1127	Humeral Nail Exchange Tube	40



CASES & TRAYS

2810-17-030	Humeral Nail Tray	41
2810-17-032	Humeral Nail Tray 2	42
2810-17-031	Humeral Nail Screw Caddie	
8299-10-045	4.5 mm Cort Screw Module	43
8299-10-500	Mod Screw System Outer Case	44

NAIL MEASUREMENTS

2810-18-011	Proximal Nail x-ray Template	45

ENDCAP PLACEMENT

2810-17-017	Humeral Screwdriver	46
2141-49-000	Lg Cann Screwdriver Handle	47
2810-01-020	SolidLock™ Screwdriver Handle	48
2810-01-021	SolidLock™ Driver Inner Shaft	49