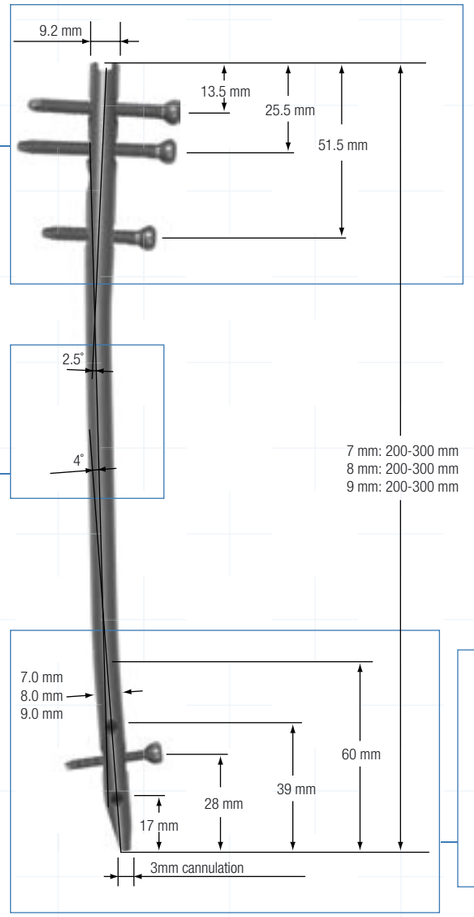
HUMERAL UNIVERSAL NAILING SYSTEM

Versatile proximal screw options:
- 4.5 mm and 4.8 mm for 7, 8, and 9 mm nails
- 3 transverse screws
- 1 oblique screw

End cap secures first proximal screw and prevents bone in-growth

3.0 mm cannulation facilitates nail insertion over guide wire

Two bends:
- Proximal bend ensures nail is located away from articular region when inserted in antegrade
- Distal bend facilitates retrograde nail insertion



Increased distal screw options:
- 3.5 mm for 7 and 8 mm nails
- 4.5 mm for 9 mm nail
- 2 transverse screws
- 1 transverse screw slot for dynamisation, if required

Chamfer facilitates retrograde nail insertion

Cat No: 0612-01-586 version 1

DePuy
a Johnson & Johnson company

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890

CE
0086

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VERSANAIL®
Humeral Universal

SURGICAL TECHNIQUE

HUMERAL UNIVERSAL NAILING SYSTEM

OPTIONS MADE EASY

- **DESIGNED** to treat both proximal and shaft fractures
- **UNIVERSAL** nail design
- **SIMPLIFIED** user-friendly instrumentation
- **INNOVATIVE** locking options

DePuy
a Johnson & Johnson company

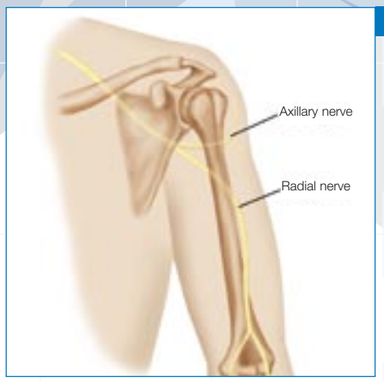
Note: This brochure presents a surgical technique available for use with the DePuy Orthopaedics, Inc., VersaNail® Platform instruments and implants. Surgeons may need to make modifications as appropriate in their own surgical technique with these devices depending on individual patient requirements.

MADE EASY OPTIONS

The efficacy of treating lower extremity fractures with intramedullary nailing has been documented in many studies.1,2,3 Intramedullary nailing offers the benefits of anatomical alignment, rigid fixation with limited soft tissue dissection and early rehabilitation of the injured limb. However, intramedullary nailing indications for humeral fractures should be viewed with caution. The anatomy and function of the humerus are quite different from the long bones of the lower extremity:

- The humerus is not a “weight-bearing” bone; therefore, rigid internal fixation is not needed to maintain limb function during fracture healing.
- Whereas the intramedullary canal widens in the metaphyseal area of the tibia and femur, the humeral canal narrows, significantly increasing the risk of distal fragment comminution.
- The anatomy of the upper arm also predisposes the patient to an increased risk of soft tissue injury, particularly the rotator cuff.
- The potential for neurovascular injury is greater in humeral nailing than in the nailing of lower extremity fractures.

Fig. 1



Before embarking on humeral nailing, one should understand the obstacles that can be encountered. Adequate planning will minimise these difficulties. Rotator cuff injury, proximal humerus articular cartilage destruction, radial nerve injury and extension of comminution are all possible complications of this procedure. Refer to Precautions on page 24.

1. Watson, J.T. and B.R. Moed. “Retrograde Nailing of the Femoral Diaphysis.” Techniques in Orthopaedics® 13(1): 38-50. Philadelphia: Lippincott-Raven Publishers, 1998.
2. Tyllianakis, M., P. Megas, D. Giannikas and E. Lambiris. “Interlocking Intramedullary Nailing in Distal Tibial Fractures.” Orthopedics 23(8), August 2000: 805-808.
3. Winquist, R.A., S.T. Hansen and D.K. Clawson. “Closed Intramedullary Nailing of Femoral Fractures.” The Journal of Bone and Joint Surgery 66, 1984: 529-539.

Implant Material

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

Implant Overview

The Humeral Universal Nail is intended for use in the following (please see the Essential Product Information on page 25 for a complete listing of indications and contraindications):

- Open and closed fracture patterns
- Humeral shaft fractures
- Fractures of the proximal and distal metaphysis
- Comminuted fractures of the humerus with small medullary canals
- Fracture nonunions and malunions
- Pathological fractures
- Floating elbow

Fig. 2 **Lateral-Medial (L-M) Locking Configurations**

Proximal holes:
-3 transverse holes
-1 oblique hole

Distal holes:
-1 transverse slot

Note: If using the oblique hole, do not use the second transverse hole.

Anterior-Posterior (A-P) Locking Configurations

Distal holes:
-2 transverse holes

HUMERAL UNIVERSAL ANTEGRADE SURGICAL TECHNIQUE

Fig. 3 **Patient Positioning**

Position the patient supine in the beach chair position on a radiolucent table (Fig. 3). 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 visualisation 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.

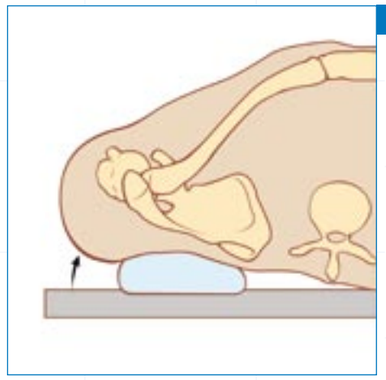


Fig. 4 A bolster can be utilised to elevate the shoulder from the table and to allow shoulder extension (Fig. 4).

Fig. 5 **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. 5).

Fig. 6 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. 6).

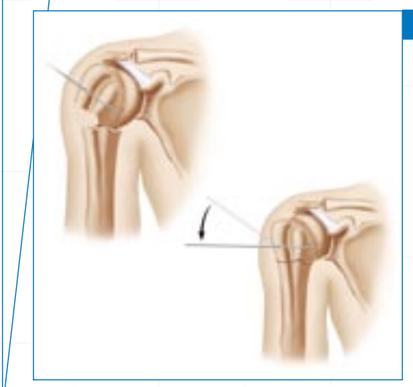


Fig. 7 **Humeral Head Reduction**

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. 7, 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. 7, right). K-wires can also act as joysticks during fracture reduction and to gain an orthogonal of the humeral head.

Using the K-wires, manipulate the humeral head lateral to medial out of varus or valgus and in proper coronal plane alignment.

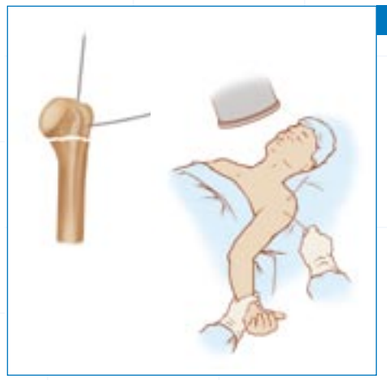


Fig. 8 Typically the K-wires should be drilled perpendicular to the anatomic neck (Fig. 8, left). These K-wires can then be used in a joystick fashion to adduct and extend the head, exposing the supraspinatus tendon and optimal entry site in the head from beneath the anterior edge of the acromion. Fracture 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. 8, right).

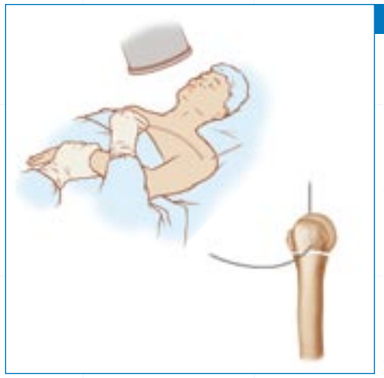


Fig. 9 Image intensification can be used to place a K-wire through the head in line with the intramedullary axis of the humerus (Fig. 9).

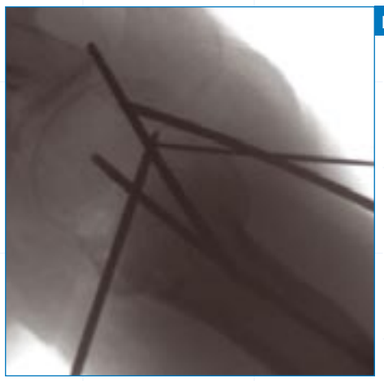


Fig. 10 There are some key considerations to this approach. The first is to use the joysticks to extend and adduct the proximal humeral head, exposing the anterolateral portion of the head from under the acromion while simultaneously distracting the distal shaft, thereby aligning the longitudinal intramedullary 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 perfect 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 (Fig. 10).

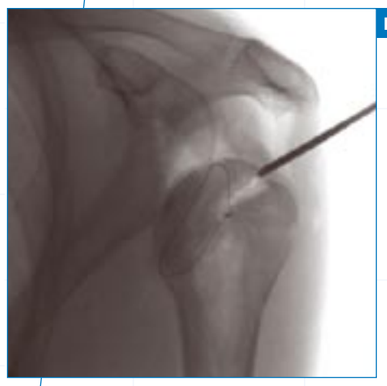


Fig. 11 **Entry Site and Incision Placement**

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. 11).

Fig. 12 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. 12).

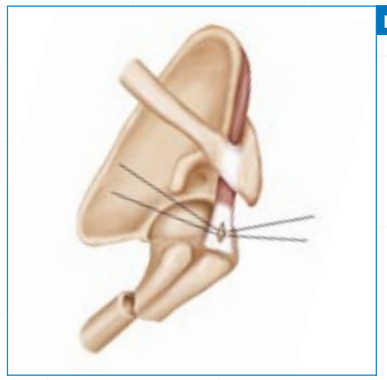


Fig. 13 **Soft Tissue Protection**

In cases where the greater tuberosity is intact or nondisplaced 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. 13). 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. 14 A starting point is made either with a threaded 3.2 mm x 14 inch guide pin (Cat. No. 14012-14) or a curved cannulated awl (Cat. No. 2810-01-005), based on the surgeon preference. Use A-P and lateral fluoroscopic views to confirm accurate placement. The entry site in the humeral head is made with the cannulated 9.4 mm entry reamer (Cat. No. 2810-17-003) 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. 14).

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. 15 Once access to the humeral canal has been gained, place the 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. 15).

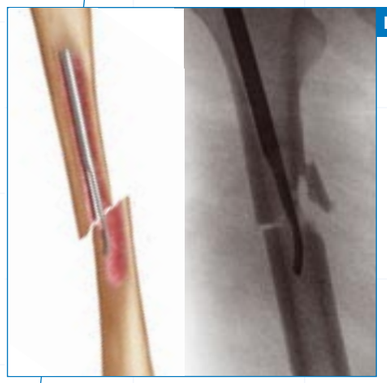


Fig. 16

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. 16) 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. Final positioning of the ball nose guide wire is at the distal end of the canal approximately 1 to 1.5 cm above the olecranon fossa.

Fig. 17

Canal Preparation; Flexible Reaming

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 (Cat. No. 2810-17-006). 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).

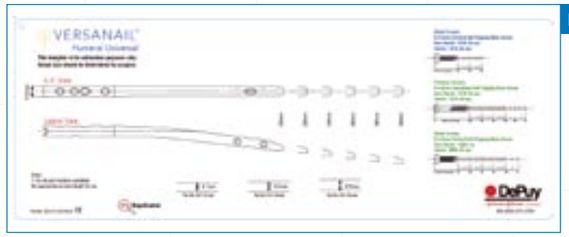


Fig. 18

Nail Size Selection

An x-ray template is available to determine nail size preoperatively (Cat. No. 2810-17-023) (Fig. 18).

Nail Diameter Selection

Choose a nail diameter 1 mm less than the final reamer diameter. When treating distalhumeral fractures with a humeral nail, stresses are increased on the nail's distal portion. For distal humeral fractures, it is recommended that the surgeon use the largest diameter that will fit in the medullary canal, without excessive thinning of the cortex After selecting the appropriate nail diameter (7, 8 or 9 mm option), secure the nail to the jig body (Cat. No. 2810-17-009) using the jig locking bolt (Cat. No. 2810-17-010).

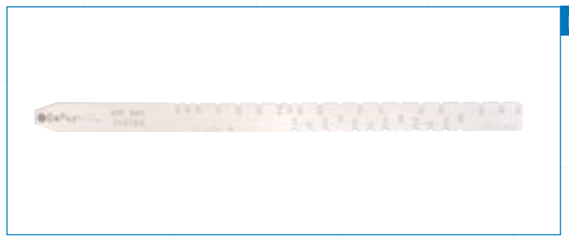


Fig. 18

Nail Length Selection, Radiographic Ruler

There are two methods to determine nail length, the use of a radiographic ruler or a nail length gauge.

Take a direct length measurement using radiographs of the contralateral uninjured extremity with magnification markers. Use the radiographic ruler (Cat. No. 1245) to determine the length of the nail (Fig. 19).

Fig. 20

Nail Length Gauge

Slide or snap the nail length gauge (Cat. No. 2810-01-009) onto the ball nose guide wire until it contacts the bone. Read the measurement that lines up with the etch mark on the guide wire to determine the nail length (Fig. 20).

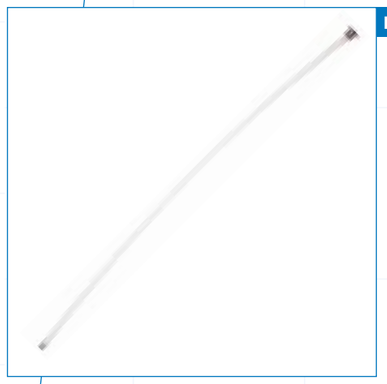


Fig. 21 Insert the guide wire exchange tube (Cat. No. 1127) (Fig. 21) over the ball nose guide wire. Remove the ball nose guide wire. Insert a 2.2 mm x 28 inch guide wire (Cat. No. 8092-22-028) through the exchange tube. Once the 2.2 mm x 28 inch guide wire is in place, remove the exchange tube.

Fig. 22 **Jig Assembly and Nail to Jig Attachment**

1. Insert the sliding jig locking bolt (Cat. No. 2810-17-010) through the jig body (Cat. No. 2810-17-009).
2. Mount the nail onto the nose and the protruding part of the jig locking bolt, so that the two alignment tabs of the nose engage fully with the keyways of the nail. The tabs are of different widths to prevent incorrect indexing of the nail onto the jig nose.
3. Tighten the jig locking bolt onto the nail using the sliding jig bolt driver (Cat. No. 2810-17-028) that engages the internal hex located inside the upper part of the jig locking bolt (Fig. 22).

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

Insert the nail over the 2.2 mm x 28 inch guide wire into the medullary canal. **Care should be taken to avoid striking the jig directly. Use the hammer pad (Cat. No. 2810-01-010) instead.** Avoid using excessive force when inserting the nail. In instances when a nail jams in the medullary canal, extract and choose the next smaller diameter size.

Fig. 23 Nail length should allow room for fracture impaction. Guide the nail into the medullary canal and confirm fracture reduction and distal placement using fluoroscopy. Assure nail position is beneath the proximal cortex. The final nail depth should be 5 mm below the articulating surface (Fig. 23).

Fig. 24 **Proximal and Distal Locking**

There are three L-M transverse and one L-M oblique locking holes (Fig. 24).

Note: If using the oblique hole, do not use the second transverse hole.

Proximal Locking

4.8 mm cancellous fully-threaded screws (Cat. No. 1819-48-0XX) are recommended for proximal locking. 4.5 mm cortical screws (Cat. No. 14022-XX) can also be used for proximal locking of the nail. Both 4.8 mm and 4.5 mm screws use the same instrumentation.

Typical Locking Configurations

Subcapital fractures:
- Screw 1 and 3 (optional) above fracture
- Screw 4 and distal (optional, as stem provides nail stability) screws below fracture

Antegrade shaft fractures:
- Screw 1, 3 and 4 (optional) or 2 and 4 above fracture
- 2 A-P distal screws below fracture

Fig. 25 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. A sheath locking nut (Cat. No. 2810-01-018) is available to help secure the sheath to the jig (Fig. 25).

Fig. 26 Remove the trocar and insert the humeral drill sleeve (Cat. No. 2810-17-014) into the sheath until the drill sleeve touches the bone (Fig. 26).

Fig. 27 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. Read the calibration on the drill bit that lines up with the drill sleeve. Should bicortical purchase be needed, 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).

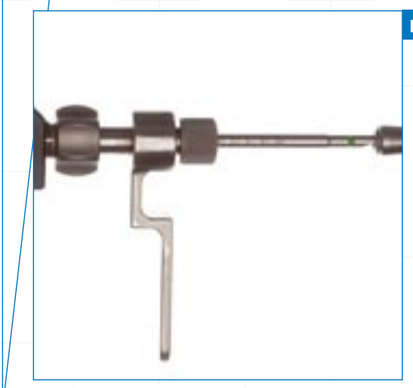


Fig. 28 Finish drilling through the far cortex. A screw depth gauge (Cat. No. 2810-17-020) is also provided for further screw length verification. A 4.5 mm screw length gauge (Cat. No. 2810-01-032) is also available for 4.5 mm cancellous screws. For an accurate reading, take care to ensure the sleeve of the depth gauge is fully seated on the bone.

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 (Fig. 28). 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.

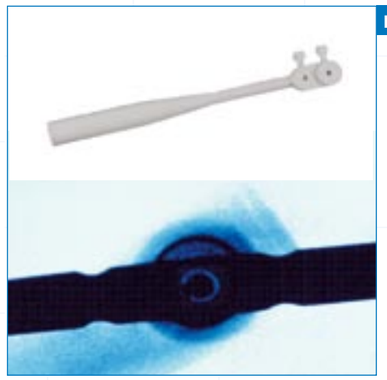


Fig. 29 **Distal Locking**

Prior to locking the distal screws, check humeral length and rotation under fluoroscopy. Distal locking should be conducted using the standard image intensification freehand technique. A radiolucent targeting wand (Cat. No. 2810-17-025) is available if desired (Fig. 29). Accurate C-arm position is confirmed when the nail hole appears to be a perfect circle.

Nail Diameter	Screw Size	Drill Bit
7 and 8 mm	3.5 mm Cortical	2.9 mm
9 mm	4.5 mm Cortical 4.8 mm Cancellous	3.8 mm

Fig. 30 After fluoroscopically verifying correct placement, make a stab wound in direct alignment with the nail hole. An open approach is recommended to protect the neurovascular structures during drilling and screw placement, particularly to prevent injuring the radial nerve.

Use the appropriate drill bit for the locking screw (Fig. 30).

Fig. 31 The distal screw holes should be drilled with the drill bit. Read the calibration marks on the drill bit to determine screw length using the 4.5 mm screw length gauge (Cat. No. 2810-01-032). Alternatively, the humeral screw depth gauge (Cat. No. 2810-17-020) can be used (Fig. 31).

Remove the drill bit and advance the screw.

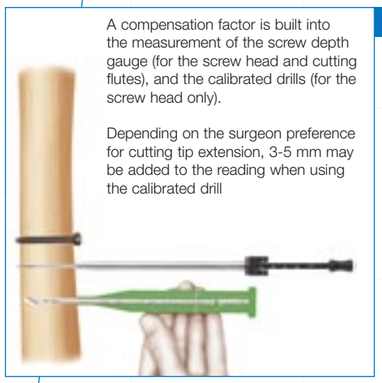


Fig. 32 **Determining Screw Length**

The screw size indicates the total measurement from the tip to the screw head. The calibrated drills and the screw depth gauges have a compensation factor built into the measurement such that the reading should indicate the exact size screw to achieve bi-cortical purchase. To ensure a proper reading, the screw depth gauge sheath and drill sleeves must be touching bone. Fluoroscopy is recommended to verify the correct screw length (Fig. 32).

Fig. 33 **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. 33). After drilling, the countersink is used on the lateral cortex. Care should be taken to avoid complete reaming of the lateral cortex.

HUMERAL UNIVERSAL RETROGRADE SURGICAL TECHNIQUE

Fig. 35 **Patient Positioning**

Place the patient in prone on a radiolucent table with the injured limb positioned such that the humerus is supported and the forearm is hanging off of the table (Fig. 34). The C-arm should be positioned parallel with the head of the patient, allowing anterior-posterior, medial-lateral and axillary views of the fracture site.

Fig. 36 **Entry Site and Incision Placement**

Incise the triceps tendon vertically at the midline (Fig. 35). Continue dissection of soft tissues in line with muscle fibers taking care to avoid critical neurovascular structures, such as the radial nerve. Expose the distal humerus and retract muscles.

Fig. 37 The entry site into the bone is made immediately above the olecranon fossa, at the end of the shaft and the end of the fossa on the dorsal aspect (Fig. 36).

Fig. 37 Place the retrograde entry portal with the inner sleeve (Cat. No. 2810-17-002) onto the bone at the entry site (Fig. 37). Connect the 3.2 mm x 14 inch guide pin (Cat. No. 14012-14) to a power drill and drill into the entry site through the entry portal sleeve. Perform this under fluoroscopy.

Fig. 38 Once the guide pin is in the correct position to allow access into the medullary canal, remove the inner sleeve of the entry portal, while leaving the entry portal itself in place to act as a soft tissue protector. The entry site is then enlarged with the 9.4 mm retrograde entry reamer (Cat. No. 2810-17-004) (Fig. 38).

Fig. 39 **Fracture Reduction**

Obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. Reduction can be achieved through the surgeon's preferred method such as traction, and can also be achieved using the short reduction tool (Cat. No. 2810-01-008) (Fig. 39, left) that is passed through the medullary canal and beyond the fracture site (Fig. 39, right). Once the fracture is in alignment, place a ball nose guide wire through the cannulation of the reduction tool using the wire gripper. Remove the reduction tool, and check reduction under image intensification.

Fig. 40 **Canal Preparation; Flexible Reaming**

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 (Cat. No. 2810-17-006). 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.

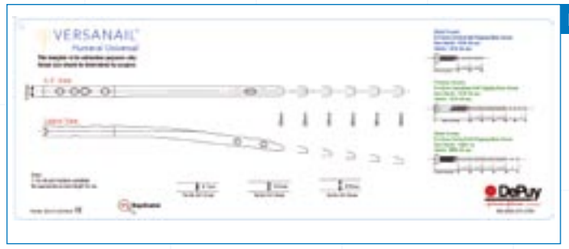


Fig. 41 **Nail Size Selection**

An x-ray template is available to determine nail size preoperatively (Cat. No. 2810-17-023) (Fig. 41).

Nail Diameter Selection

Choose a nail diameter 1 mm less than the final reamer diameter. When treating distal humeral fractures with a humeral nail, stresses are increased on the nail's distal portion. For distal humeral fractures, it is recommended that the surgeon use the largest diameter that will fit in the medullary canal, without excessive thinning of the cortex. After selecting the appropriate nail diameter (7, 8 or 9 mm option), secure nail to the jig body (Cat. No. 2810-17-009) using the jig locking bolt (Cat. No. 2810-17-010).

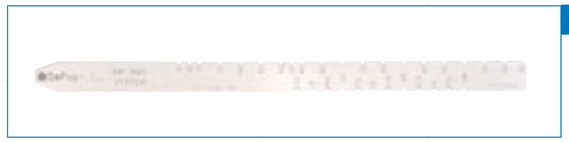


Fig. 42 **Nail Length Selection**

There are two methods to determine nail length, the use of a radiographic ruler or a nail length gauge.

Radiographic Ruler

Take a direct length measurement using radiographs of the contralateral uninjured extremity with magnification markers. Use the radiographic ruler (Cat. No. 1245) to determine the length of the nail (Fig. 42).

Fig. 43 **Nail Length Gauge**

Slide or snap the nail length gauge (Cat. No. 2810-01-009) onto the ball nose guide wire until it contacts the bone. Read the measurement that lines up with the etch mark on the guide wire to determine the nail length (Fig. 43).

Fig. 44 Insert the guide wire exchange tube (Cat. No. 1127) over the ball nose guide wire. Remove the ball nose guide wire. Insert a 2.2 mm x 28 inch guide wire (Cat. No. 8092-22-028) through the exchange tube. Once the 2.2 mm x 28 inch guide wire is in place, remove the exchange tube (Fig. 44).

Fig. 45 **Nail Insertion**

Insert the sliding jig locking bolt through the jig body (Fig. 45). Mount the nail onto the nose and the protruding part of the jig locking bolt, so that the two alignment tabs of the nose engage fully with the keyways of the nail. The tabs are of different widths to prevent incorrect indexing of the nail onto the jig nose. Tighten the jig locking bolt onto the nail using the sliding jig bolt driver that engages the internal hex located inside the upper part of the jig locking bolt.

Fig. 46 Insert the nail over the 2.2 mm x 28 inch guide wire into the medullary canal. **Care should be taken to avoid striking the jig directly. Use the hammer pad (Cat. No. 2810-01-010) instead.** Avoid using excessive force when inserting the nail. In instances when a nail jams in the medullary canal, extract and choose the next smaller diameter size. Nail length should allow room for fracture impaction. Guide the nail into the medullary canal and confirm fracture reduction and placement using fluoroscopy. Assure the distal nail position is well below the proximal cortex (Fig. 46).

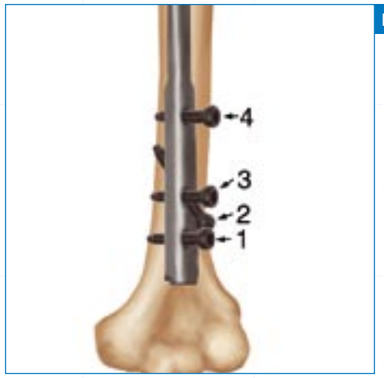


Fig. 47 **Proximal and Distal Locking**

Note: Distal locking is targeted through the jig.There are 3 L-M transverse and 1 L-M oblique locking holes (Fig. 47).
Note: If using the oblique hole, do not use the second transverse hole.

Distal Locking

4.8 mm cancellous fully threaded screws (Cat. No. 1819-48-0XX) are recommended for distal locking. 4.5 mm cortical screws (Cat. No. 14022-XX) can also be used for distal locking of the nail. Both 4.8 mm and 4.5 mm screws use the same instrumentation.

Typical Locking Configurations

Retrograde shaft fractures:

- Screw 1, 3 and 4 or 1, 2 (possible with small bone thickness) and 4 below fracture
- 2 A-P distal nail screws above fracture

Fig. 48 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 (Fig. 48). Make a stab incision longitudinally and bluntly dissect the subcutaneous tissues through the biceps and directly to the humerus. Caution should be used during drilling to avoid damage to neurovascular structures. An open approach is recommended using a finger to palpate the position of the screw sheath and trocar over the center of the humerus. A sheath locking nut (Cat. No. 2810-01-018) is available to help secure the sheath to the jig.

Fig. 49 Remove the trocar and insert the humeral drill sleeve (Cat. No. 2810-17-014) into the sheath until the drill sleeve touches the bone (Fig. 49).

Fig. 50 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. Read the calibration on the drill bit that lines up with the drill sleeve. Should bicortical purchase be needed, 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. 50).

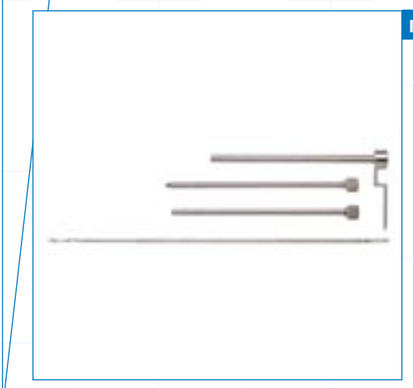


Fig. 51 Finish drilling through the far cortex. A screw depth gauge (Cat. No. 2810-17-020) is also provided for further screw length verification. A 4.5 mm screw length gauge (Cat. No. 2810-01-032) is also available for 4.5 mm cancellous screws. For an accurate reading, take care to ensure the sleeve of the depth gauge is fully seated on the bone (Fig. 51).

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 at the screw should be verified when the respective marking is flush to the drill sleeve. It is recommended to verify via fluoroscopy.

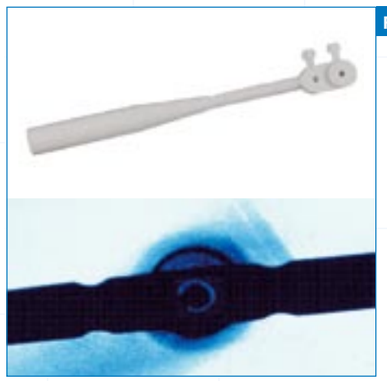


Fig. 52 **Proximal Locking**

Prior to locking proximal screws, check humeral length and rotation under fluoroscopy. Proximal locking should be conducted using the standard image intensification freehand technique. A radiolucent targeting wand (Cat. No. 2810-17-025) is available if desired (Fig. 52). Accurate C-arm position is confirmed when the nail hole appears to be a perfect circle.

Nail Diameter	Screw Size	Drill Bit
7 and 8 mm	3.5 mm Cortical	2.9 mm
9 mm	4.5 mm Cortical 4.8 mm Cancellous	3.8 mm

Fig. 53 After fluoroscopically verifying correct placement, make a stab wound in direct alignment with the nail hole. Dissect bluntly through the subcutaneous tissues and deltoid muscles to the lateral cortex. An open approach is recommended to protect the neurovascular structures and muscles during drilling and screw placement. Use the appropriate drill bit for the locking screw (Fig. 53).

Fig. 54 The distal screw holes should be drilled with the drill bit. Read the calibration marks on the drill bit to determine screw length using the screw length gauge (Cat. No. 2810-01-032). Alternatively, the humeral screw depth gauge (Cat. No. 2810-17-020) can be used (Fig. 54).

Remove the drill bit and advance the screw.

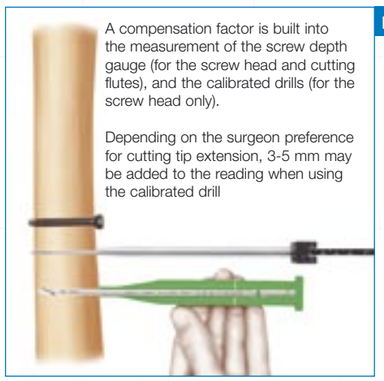


Fig. 55 **Determining Screw Length**

The screw size indicates the total measurement from the tip to the screw head. The calibrated drills and the screw depth gauges have a compensation factor built into the measurement such that the reading should indicate the exact size screw to achieve bi-cortical purchase. To ensure a proper reading, the screw depth gauge sheath and drill sleeves must be touching bone. Fluoroscopy is recommended to verify the correct screw length (Fig. 55).

Fig. 56 **End Cap Placement**

Impinging and non-impinging end caps are provided in the system to both prevent bony in-growth and add length when needed. The available end caps are (Fig. 56):

- Flush impinging on the 1st screw
- Flush impinging on the 2nd second screw
- 5 mm superior to nail end impinging on the 1st screw
- 5 mm superior to nail end impinging on the 2nd screw
- 10 mm superior to nail end impinging on the 1st screw

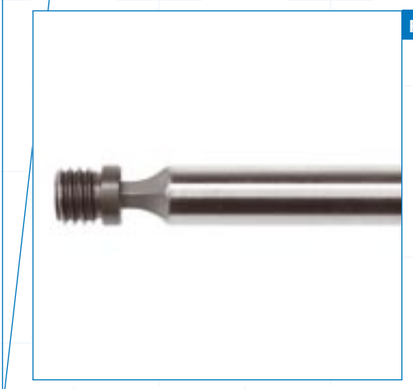


Fig. 57 Thread the end cap into place with the humeral screwdriver (Cat. No. 2810-17-017) and screwdriver handle (Cat. No. 2141-49-000). A second screwdriver such as the SolidLok™ screwdriver (Cat. Nos. 2810-01-021, inner shaft; 2810-01-019, tip; 2810-01-020, handle) is also available to aid in end cap placement (Fig. 57). Ensure the end cap is sufficiently tightened, and that it does not extend above the articulating surface of the humeral head. Irrigate the joint to make sure that no debris remains. Close the wound.

Fig. 58 **Nail Removal**

If the surgeon deems it appropriate to remove the nail, an extractor bolt (Cat. No. 2810-17-022), used with the 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. 58). Additionally, a sliding hammer (Cat. No. 1096) and impactor rod assembly (Cat. No. 1095) can also be used to aid in nail extraction.

Fig. 59 Locate the top of the nail through an appropriate incision. If present, 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 SolidLok™ screwdriver (Cat. Nos. 2810-01-021, inner shaft; 2810-01-019, tip; 2810-01-020, handle) is also available to aid in end cap removal (Fig. 59).

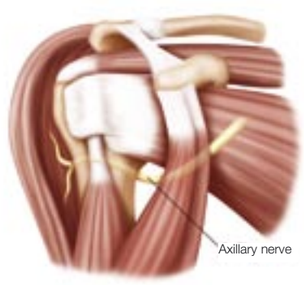


Fig. 56 **Axillary Nerve**

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 should be located about 10 mm below the oblique screw, about 30 degrees dorsally (Fig. 60).

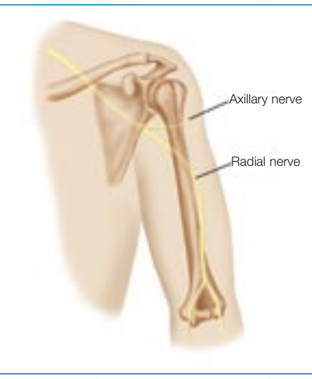


Fig. 57 **Radial Nerve**

Another feared complication is radial nerve palsy. In cases of secondary nerve palsy, exploration of the nerve is required (Fig. 61). Clinical literature has well-documented this. One noteworthy study describes the anatomical safe zone.1

Note: While inserting the nail and before proximal or distal locking is carried out, it is necessary to support the distal fragment and prevent distraction of the fracture, which could lead to radial nerve palsy.

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 stabilisation 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 stabilisation 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).

Universal nail size offering: Includes nail without end cap			Screw sizes (mm)	
Diameter (mm)	Length (mm)	Cat. No.	Proximal	Distal
7	200-300 in 20 mm incr.	1817-07-201/301	4.5/4.8	3.5
8	200-300 in 20 mm incr.	1817-08-201/301	4.5/4.8	3.5
9	200-300 in 20 mm incr.	1817-09-201/301	4.5/4.8	4.5

Proximal screws:		
Diameter (mm)	Length (mm)	Cat. No.
4.8 cancellous for 7-8-9 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 9 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: 14022-20/70
3.5 cortical for 7-8 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 UNIVERSAL NAIL SYSTEM

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)

4.8 mm Cancellous Screws: Non-Sterile

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

(Sterile 1818-48-030/076)

3.5 mm Cortical Screws: Non-Sterile

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

(Sterile: 1818-35-020/040)

Universal Nail: 7 mm Diameter

Cat. No.	Description
1817-07-201	Universal Humeral Nail 7 mm x 200 mm
1817-07-221	Universal Humeral Nail 7 mm x 220 mm
1817-07-241	Universal Humeral Nail 7 mm x 240 mm
1817-07-261	Universal Humeral Nail 7 mm x 260 mm
1817-07-281	Universal Humeral Nail 7 mm x 280 mm
1817-07-301	Universal Humeral Nail 7 mm x 300 mm

Universal Nail: 8 mm Diameter

Cat. No.	Description
1817-08-201	Universal Humeral Nail 8 mm x 200 mm
1817-08-221	Universal Humeral Nail 8 mm x 220 mm
1817-08-241	Universal Humeral Nail 8 mm x 240 mm
1817-08-261	Universal Humeral Nail 8 mm x 260 mm
1817-08-281	Universal Humeral Nail 8 mm x 280 mm
1817-08-301	Universal Humeral Nail 8 mm x 300 mm

Universal Nail: 9 mm Diameter

Cat. No.	Description
1817-09-201	Universal Humeral Nail 9 mm x 200 mm
1817-09-221	Universal Humeral Nail 9 mm x 220 mm
1817-09-241	Universal Humeral Nail 9 mm x 240 mm
1817-09-261	Universal Humeral Nail 9 mm x 260 mm
1817-09-281	Universal Humeral Nail 9 mm x 280 mm
1817-09-301	Universal Humeral Nail 9 mm x 300 mm

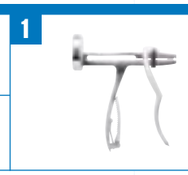
End Caps

Cat. No.	Description
1817-01-001	End Cap, Flush 1st Hole Imping
1817-01-002	End Cap, Flush 2nd Hole Imping
1817-01-051	End Cap, +5 mm 1st Hole Imping
1817-01-052	End Cap, +5 mm 2nd Hole Imping
1817-01-101	End Cap, +10 mm 1st Hole Imping

Indicates outlier size not included in standard set configuration

GENERAL

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




CANVAL PREP

2810-01-005	Curved Cannulated Awl	3
2810-01-025	Awl Stylus	4
2810-01-026	Guide Wire Pusher	5
2810-17-003	9.4 mm Entry Reamer	6
2810-17-004	9.4 mm Retrograde Entry Reamer	7
2810-18-002	11.5 mm Entry Reamer*	8
2810-17-101	Antegrade Entry Portal	9
2810-17-002	Retrograde Entry Portal	10
2810-01-008	Short Reduction Tool	11

*The 11.5 mm Entry Reamer is used with the Humeral Proximal Nail.









NAIL INSERTION

2810-17-009	Universal Jig Body	12
2810-17-010	Universal Jig Locking Bolt	13
2810-01-010	Hammer Pad Tibial Humerus	14
1095	Impactor Rod Assembly	15
1096	Hammer Sliding Impactor	16



PROXIMAL LOCKING

2810-17-007	3.2 mm Pin Sleeve Humeral	17
2810-17-011	Static Screw Sheath	18
2810-17-013	Trocar	19
2810-17-014	Drill Sleeve	20
2810-01-018	Sheath Locking Nut	21
2810-17-017	Humeral Screwdriver	22
2810-01-032	4.5 mm Screw Length Gauge	23
2810-17-024	Countersink	24







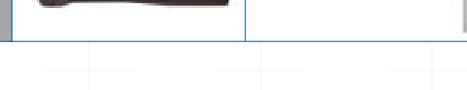

DISTAL LOCKING

2810-17-025	Humeral Nail Target Wand	25
2810-17-021	Dynamic Screw Sheath	26
2141-49-000	Lg Cann Screwdriver Handle	27
2810-17-020	Humeral Screw Depth Gauge	28
2810-01-020	SolidLok Screwdriver Handle	29
2810-01-021	SolidLok Driver Inner Shaft	30
2810-17-017	Humeral Screwdriver	31
2810-01-032	4.5 mm Screw Length Gauge	32









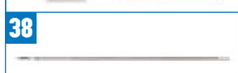
NAIL REMOVAL

2810-17-022	Universal Nail Extractor Bolt	33
2810-01-027	3/4 inch Hex Driver	34


DISPOSABLES

1401214	Guide Pin 3.2 mm x 14 inch	35
2810-01-019	SolidLok™ Hex Tip, 3.5 mm	36
2810-17-119	2.9 mm Drill Bit/Non-sterile	37
2810-17-115	3.8 mm Drill Bit/Non-sterile	38
2810-12-138	3.8 mm Drill Bit 6 inch NS	39
2810-17-129	2.9 mm Drill Bit Short NS	40
8092-22-028	Guide Wire 2.2 mm x 28 inch	41
2810-17-006	2.0 mm Ball Nose Guide Wire	42
1127	Humeral Nail Exchange Tube	43






CASES & TRAYS

2810-17-030	Humeral Nail Tray	44
2810-17-032	Humeral Nail Tray 2	45
2810-17-031	Humeral Nail Screw Caddie	46
8299-10-045	4.5 mm Cort Screw Module	47
8299-10-500	Mod Screw System Outer Case	48

NAIL MEASUREMENT

1245	Radiographic Ruler	49
2810-01-009	Nail Length Gauge	50
2810-13-025	Universal Nail X-ray Template	51

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2810-17-017	Humeral Screwdriver	52
2141-49-000	Lg Cann Screwdriver Handle	53
2810-01-020	SolidLok Screwdriver Handle	54
2810-01-021	SolidLok Driver Inner Shaft	55