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AFFIXUS® Natural Nail® Proximal Humeral System

Surgical Technique

Device Description

The Affixus Natural Nail Humeral Nail System are temporary fixation intramedullary nails designed for fixation and stabilization of fractures or osteotomies of the humerus. They restore the shape of preinjured bone and they are available in a variety of lengths and diameters to meet assorted anatomical needs. Nail caps are available to protect the nail threads from tissue ingrowth and extend the nail length if necessary. Each of the intramedullary nails is secured by a series of screws that pass through holes in the nail.

The Proximal Humerus Nail Caps, Washers, Cortical Bone Screws, and Blunt Tip Screws are made of Titanium alloy [Protasul®-64WF (Ti-6Al-4V) ISO 5832-3/ASTM F136] and Proximal Humerus Nails are made of Titanium alloy [Protasul-64WF (Ti-6Al-4V) ISO 5832-3/ASTM F136] and C.P Titanium [Protasul®-Ti ISO 5832-2/ASTM F67].

Package labels indicate the material of each component. Selected components of the Affixus Natural Nail Humeral Nail System instruments are color coded to aid in identifying which components should be used together. Refer to the surgical techniques for more detailed instructions on the use of Affixus Natural Nail Humeral Nail System components.

Intended Purpose

The Affixus Natural Nail Humeral Nail System nails are intramedullary nails intended for temporary internal fixation and stabilization of humeral fractures or osteotomies.

Indications and Contraindications

Indications

The Affixus Natural Nail Humeral Nail System nails are intramedullary nails intended for temporary internal fixation and stabilization of humeral fractures or osteotomies.

The Affixus Natural Nail Humeral Nail System is indicated for use in a variety of fractures, such as:

- Proximal fractures (proximal short and long nails only)
- Diaphyseal fractures (proximal long nails and antegrade/retrograde nails only)
- Open and closed fractures
- Comminuted fractures
- Nonunions and malunions
- Pathologic fractures

Contraindications

- Distal fracture involving the olecranon fossa.
- Bone shaft having excessive bow or deformity.
- A medullary canal obliterated by a previous fracture or tumor.
- Lack of bone substance or poor bone quality, which makes stable seating of the implant impossible.
- Acute or chronic, local or systemic infections
- Insufficient blood circulation.
- All concomitant diseases that may impair fixation of the implant and/or the success of the intervention
- Allergy to the implanted material.

For more information please refer to IFU D011500306

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Introduction

The Affixus Natural Nail Humeral Nail System is a long bone nailing system built on the Natural Nail and AFFIXUS Intramedullary Platforms. This system offers a complete portfolio of implants and instruments, which treats a wide range of humeral fractures using simple and efficient instrumentation.

Acute Fixation Options for Challenging Fracture Patterns:

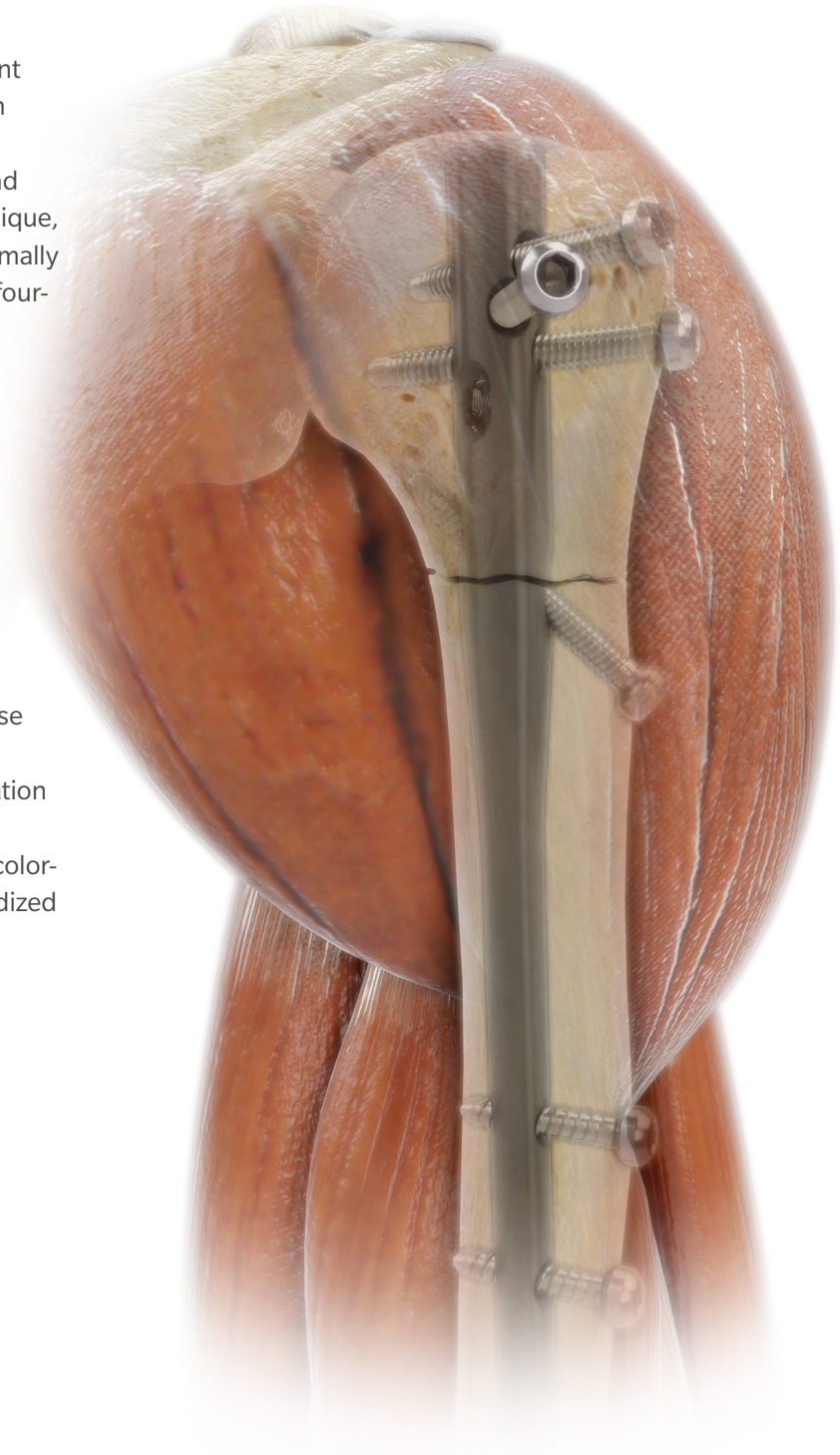
The AFFIXUS Natural Nail Proximal Nail implant contains proximal screw options positioned in multi-planar axis, including; Transverse L/M, Anterior and Posterior Oblique, Ascending and Descending A/P, and Ascending Anterior Oblique, which allow surgeons the ability to use a minimally invasive approach in even the most complex four-part proximal humeral fractures.

Integrated CoreLock™ Technology:

The AFFIXUS Natural Nail Proximal Humeral Implant integrates the CoreLock Fixed-Angle Interlocking Mechanism, allowing the user to lock all metaphysical screws in the construct at a fixed angle at once.

Simplistic & Efficient Instrumentation:

The case is in a simple step-wise layout for ease of use and reproducible procedures for the surgeon and OR staff teams. The instrumentation is designed to provide intraoperative options including entry portals, reduction tools, and color-coded screw placement, while being standardized to maintain harmony across the platform.



Targeting Guide Assembly

Numbers and Colors

Never use screw 5.1 alone. At least one further proximal screw (1,2...4.2) must be used additionally.

These numbered holes correlate to the number identifiers listed on the targeting guide.

Note: For hole positions 4, 4.1 or 4.2 can be used, but both positions can't be used at once.

Note: For hole positions 5, 5.1 or 5.2 can be used, but both positions can't be used at once.

Targeting Guide Ascending Module

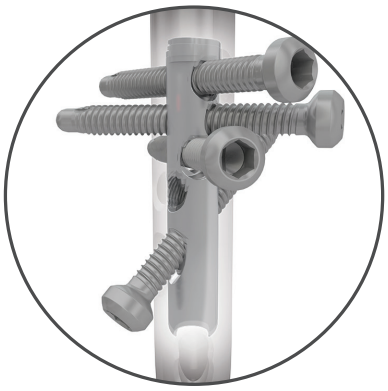
Targeting Guide Plate

Targeting Guide Side Arm

Targeting Guide Plate

Implant Specifications

CoreLock Mechanism



Nail Caps

0 mm | 2.5 mm | 5.0 mm | 7.5 mm

Screws

4.0 mm Blunt Tip

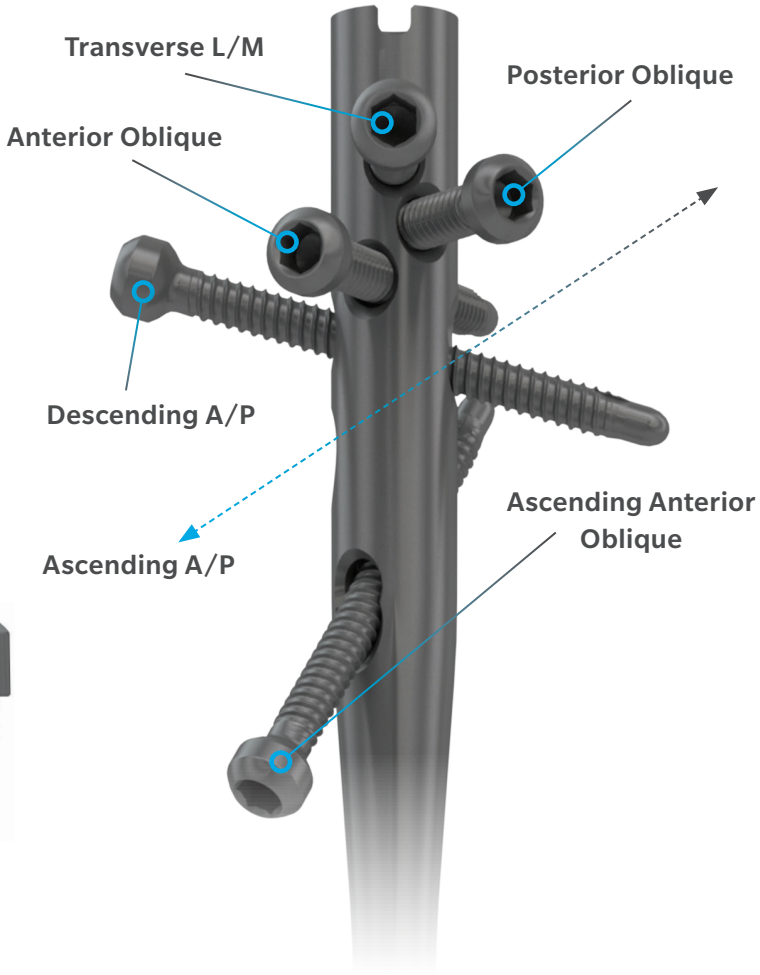
4.0 mm Cortical

Washers

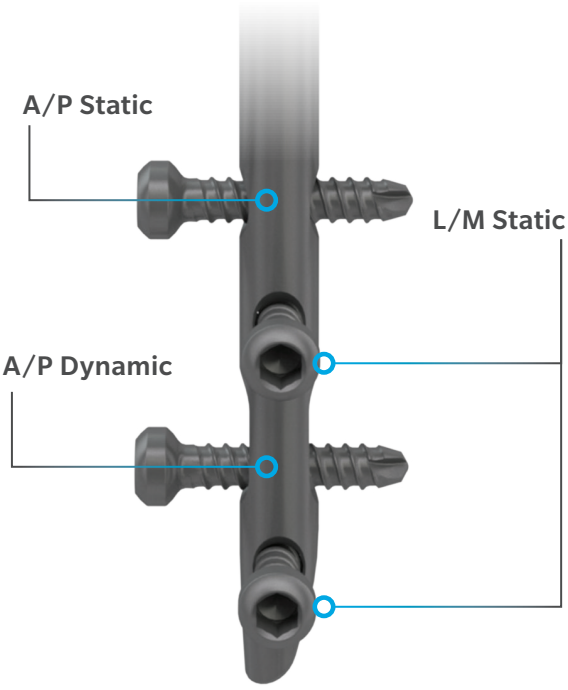
Small

Spider

Anterior *(Left nail shown)* **Posterior**



(Options shown are only available in the long nail)



Surgical Steps

Figure 1

Preoperative Planning and Patient Positioning

X-ray templates are available, if desired, to aid in pre-operative planning of implant sizing.

Note: Follow the magnification scale listed on the template.

Thorough evaluation of pre-operative radiographs of the affected extremity is critical to identify and prepare for potential intra-operative complications. The proper nail length when inserted antegrade should extend from subchondral bone proximally, to 2 cm above the olecranon fossa distally.

If desired, instruments are available to aid in determining the implant length and diameter. The ruler can be used to help determine nail length through X-ray or fluoroscopy (Figure 1).

Figure 2

Figure 3

Preoperative Planning and Patient Positioning (cont.)

Patient positioning is most optimal in either a beach chair position, or a supine position on a radiolucent table, with a 30 to 40 degree contra-lateral tilt. The patient positioning should allow the shoulder to be extended and adducted in order to get the ideal entry point (Figures 2 and 3).

The C-arm can be positioned at the head of the patient (Figure 2) or from the contralateral side (Figure 3).

After patient positioning on the operating table and before draping, unobstructed acquisition of scapular AP and the Y views of the proximal humerus is recommended.

Figure 4

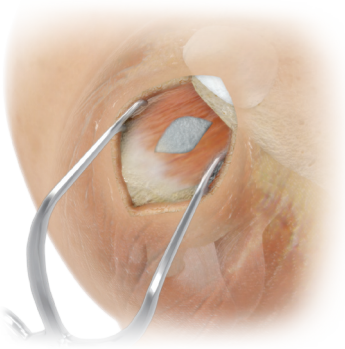


Figure 5

Surgical Approach and Entry Point

Incision and Soft Tissue Resection

A small incision should be made in line with the fibers of the deltoid muscle at the anterolateral corner of the acromion (Figure 4). The deltoid should be split to expose the subdeltoid bursa. Palpate to identify the anterior and posterior margins of the greater tuberosity and supraspinatus tendon. The supraspinatus tendon should then be incised in line with its fibers, and sutures can be placed at the margins of the incision for retraction and protection of the musculotendinous cuff (Figure 5).

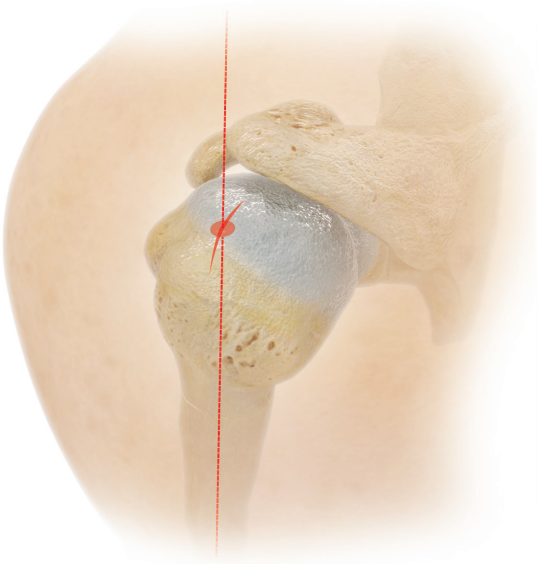


Figure 6

Figure 7

Entry Point

The rotation of the proximal fragment should be checked (internally or externally rotated), considering that the ideal entry point is situated at the apex of the humeral head, medial to the tip of the greater tuberosity, in line with the medullary canal in both AP and lateral views.

It is recommended to localize the ideal entry point under image intensifier control. Also palpating the bicipital groove, the portal is about 10 mm posterior to the biceps tendon. This will make the entry portal coaxial to the medullary canal (Figure 6).

Once entry point is determined, use the entry cannula, and the 2.5 mm pin to access the entry point. Verify the position of the K-wire (2.5 mm x 280 mm) into the proximal humerus in both AP and axillary view projections, before reaming the proximal entry (Figure 7).

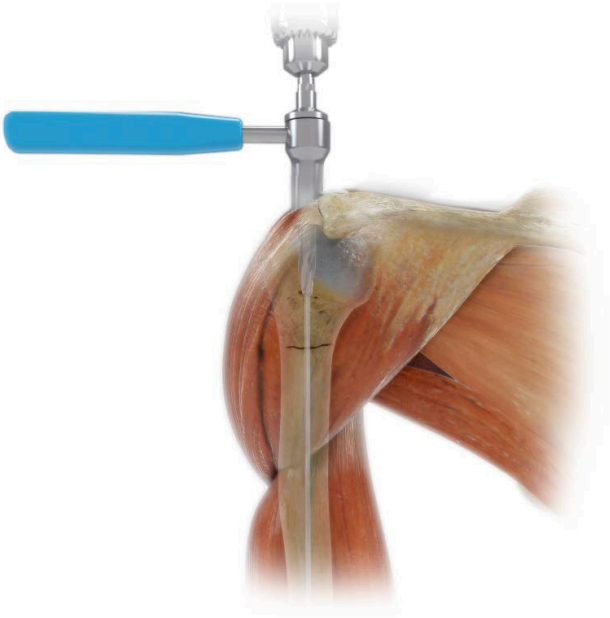


Figure 8

Figure 9

Entry Point (cont.)

Standard Opening with Cannulated Reamer:

With the 2.5 mm pin at the correct position into the humeral head and the proximal humerus, the entry point can be prepared using either the 10.5 mm or 11 mm tapered entry reamer.

The 10.5 mm tapered entry reamer is used for the nail diameter 7, 8.5, 9 and 10 mm.

The 11 mm tapered entry reamer is used for the 11 mm proximal humerus short nails.

The entry reamers should be inserted via the entry cannula to protect the soft tissues while reaming. The proximal metaphysis should be drilled to the depth at which the entry reamer stop collar contacts on the entry cannula (Figure 8).

Opening with Core Reamer:

With the coring pin at the correct position into the humeral head and the proximal humerus, the entry point is prepared using the 10.5 mm or 11 mm coring reamer.

The coring reamer should be inserted via the entry cannula to protect the soft tissues while reaming (Figure 9). The proximal metaphysis should be drilled to the depth at which the entry reamer stop collar contacts on the entry cannula.

Entry Reamers	Pins
Reamer Tapered 10.5 mm	2.5 mm x 280 mm pin
Reamer Tapered 11.0 mm	2.5 mm x 280 mm pin
Reamer Coring 10.5 mm	10.5 mm Coring Pin, 2.5 mm x 280 mm
Reamer Coring 11.0 mm	11.0 mm Coring Pin, 2.5 mm x 280 mm

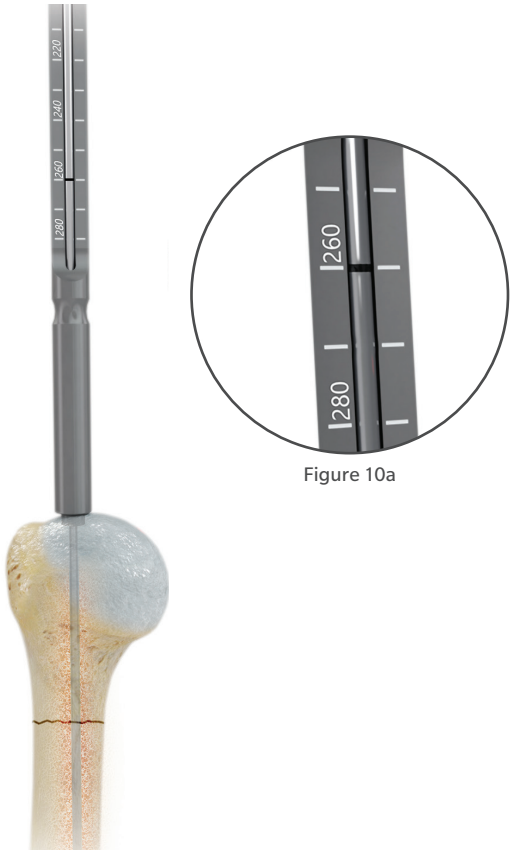


Figure 10

Figure 10a

Figure 11

Determining Nail Length

After preparation of the entry point, remove the 2.5 mm pin and insert the humerus long ball tipped guidewire (2.5 mm x 550 mm), into the medullary canal, across the fracture site, to the distal end of the humerus. Place the nail depth gauge on the end of the guidewire and read the measurement at the marking on the wire for the appropriate nail length (Figures 10 and 10a).

Reaming the Medullary Canal

After the ball nose guidewire is placed, sequential reaming is recommended to uniformly shape the endosteum of the medullary canal, and to allow an easy insertion of the selected nail to the distal end of the humeral diaphysis. Reaming should be performed through the entry cannula to protect the soft tissues. Available reaming diameters are listed in the back of this technique guide on page 30 (Figure 11).

Caution: Applying too much pressure while reaming can lead to iatrogenic fractures during canal preparation.

Figure 12

Figure 12a

Nail Assembly and Insertion

Assemble the connecting bolt through the guide barrel grip and mate to the desired nail implant (Figure 12). A hex/pin wrench is available to secure the connection of the jig to the nail. Assemble additional targeting modules, as needed with the targeting guide connecting screws. Care should be taken to follow implant markings, to ensure the modules are assembled in the correct orientation for the type of nail use (Left/Right) (Figure 12a).

Note: Ensure all packaging aides are removed from the nail implant prior to its assembly to the targeting guide, including the protection pin that holds the CoreLock Technology in place in the metaphyseal portion of the nail implant.

Note: Following nail assembly to the targeting guide, it is recommended to check the targeting accuracy of the interlocking holes with a screw cannula, sleeve, and drill to pass through the nail to ensure the correct nail is assembled properly. Please see page 5 for interlocking hole slot references.

Figure 13

Figure 14

Nail Assembly and Insertion (cont.)

Attach the impaction head to the targeting guide. The hex/pin wrench is available to aid connection to the targeting guide. Usually, after reaming an antegrade humeral nail can be inserted with minimal force, without the need for mallet strikes. When the slotted mallet is used, gently strike the impaction pad, driving the nail to the desired depth. Monitor the progression of the nail down the canal using C-arm, especially near the fracture site and at the distal end (Figures 13 and 14).

Caution: Do not pry nor strike excessively as damage to the guide and bone may result. Do not impact on any portion of the targeting guide.

Caution: Verify the connection bolt and connecting screws are tight during and after impaction.

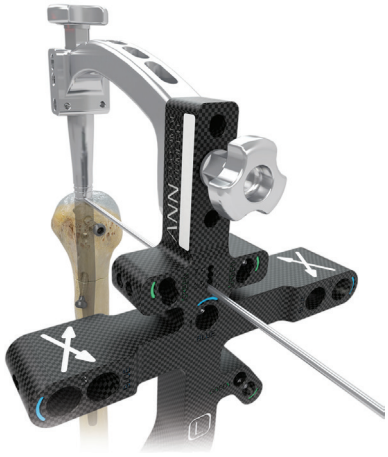


Figure 15

Figure 15a

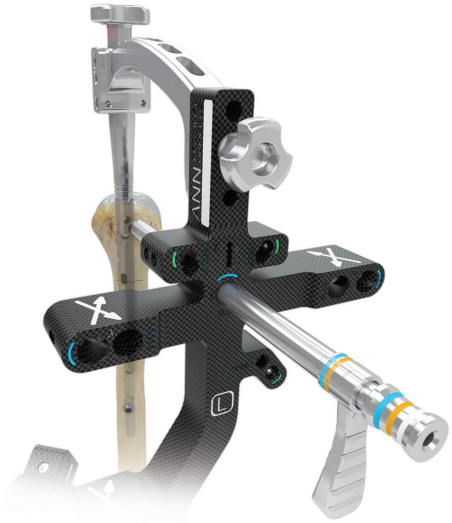


Figure 16

Nail Positioning

The proximal portion of the nail should be below the articular surface, and at the level of subchondral bone once fully inserted. When checking positioning under fluoroscopy, multiple 2.5 mm x 280 mm pins can be used to pass through the targeting guide to check nail height. Additionally, a 2.5 mm pin can be used to pass through the targeting guide barrel grip to check rotational alignment in reference to the forearm (Figure 15a). The alignment holes in the targeting guide side arm module can be used to ensure the correct height of the nail relative to the ascending screw position to the calcar (Figure 15). Temporary fixation required first.

Caution: Be sure to remove long ball tip guidewire from the nail after the nail is in final position and before placing the interlocking screws.

Proximal Screw Interlocking

Insert the 8 mm outer sleeve – screw cannula into the appropriate location on the targeting guide (blue marked holes for proximal screws). If placing a pin to verify screw position is desired, place the 2.5 mm pin sleeve into the placed screw cannula. Then insert 2.5 mm pin to verify desired location of screw placement under flouroscopy. Remove 2.5 mm pin, and insert 3.3 mm inner sleeve – drill cannula into the placed screw cannula (Figure 16).

Note: White markings are for drills.

White (Distal Locking)
Orange (Short Nail Only)
Blue (Proximal Locking)
Green (Miss-A-Nail Pins)

Instrument Color Coding Guide				
Targeting Guide Holes			X	
Screw Cannulas			X	X
2.5 mm Pin Sleeve			X	X
2.5 mm Miss- A -Nail Pin Sleeve	X	X	X	
Trocar				X
Drill Sleeves				X
3.3 mm Drill Sleeves	X	X		X

These colors coordinate with the colored lines on the instrumentation (Blue, Green, Orange, White)

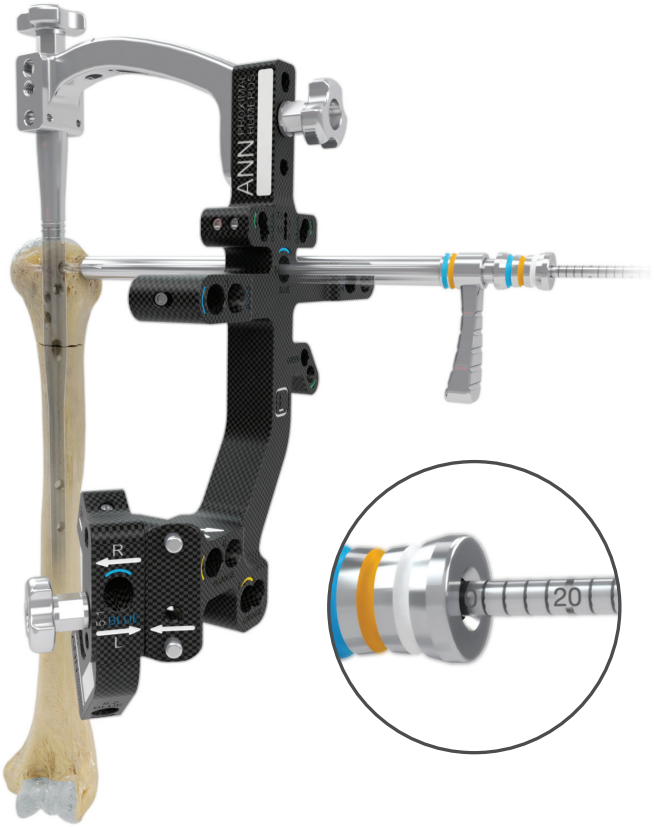


Figure 17

Proximal Screw Interlocking (cont.)

Next, insert the 3.3 mm trocar into the drill sleeve and use it to create a path through the surrounding soft tissue, down to the cortex of the humerus. Remove the trocar.

Note: The AP trajectory for the optional descending lesser tuberosity screw, can be used to determine correct rotational alignment of the nail into the proximal humerus. A sleeve/trocar can be inserted via the jig arm to this plane for that purpose. During drilling to this plane avoid injury to the biceps tendon using careful dissection and appropriate rotation of the jig to avoid the bicepital groove.

Use the 3.3 mm calibrated drill for preparation of screw insertion. Take note of the measurement of the calibration line on the drill bit that is referenced at the edge of the drill sleeve (Figure 17).

Figure 18

Figure 19

Proximal Screw Interlocking (cont.)

If desired, an optional screw depth gauge can be used to manually measure the appropriate length of screw needed (Figure 18). Assemble the appropriate screw implant to the hex screw driver, remove the drill bit and drill sleeve, and insert the screw into the Outer Sleeve / Screw Cannula. It is recommended to place at least 3 screws in the proximal portion of the humerus for stability of the nail/screw construct.

Caution: Do not drive the screws into the bone under power, as damage to the bone, screws and nail may occur.

Temporary Fracture Fixation

2.5 mm Pin

If necessary a number of instruments are available to aid in the temporary fracture fixation of proximal humerus fragments.

The 2.5 mm pin sleeve can be placed through the screw cannula prior to placing the drill sleeve to allow for insertion of a 2.5 mm pin through the nail. This allows for temporary stabilization of proximal fragments prior to the placement of the screws. These pins must be removed prior to placement of the screws through the same screw hole (Figure 19).

Figure 20

Figure 21

Figure 21a

Temporary Fracture Fixation

Miss-A-Nail Pins

The 2.5 mm pin can be placed through the Miss-A-Nail holes (green marked holes) to allow for fixation of fragments prior to the placement of the screws (Figure 20).

Optional Anterior Targeting Guide Side Arm

An optional targeting guide side arm is available for placement of either an AP ascending screw (hole location 4.2 on targeting guide) or AP descending screw (Hole Location 4.1 on targeting guide), if desired (Figure 21). This optional targeting guide side arm also has hole locations for Miss-A-Nail Pins for temporary reduction. Reference pages 4-5 for multiple placement options.

Ascending Screw Placement

Check positional alignment using multiple fluoroscopy images, along with 2.5 mm x 280 mm pins and the alignment holes in the targeting guide side arm module as a visualization aid to determine the appropriate angle of the ascending screw (Figure 21a). The Ascending Screw position in the nail is available in two angles; 30 degrees (Hole Location 5.1 on the targeting guide) and 50 degrees (Hole Location 5.2 on the targeting guide)

Caution: Before inserting the ascending screw, identify and protect the axillary nerve and its branches.

Figure 22

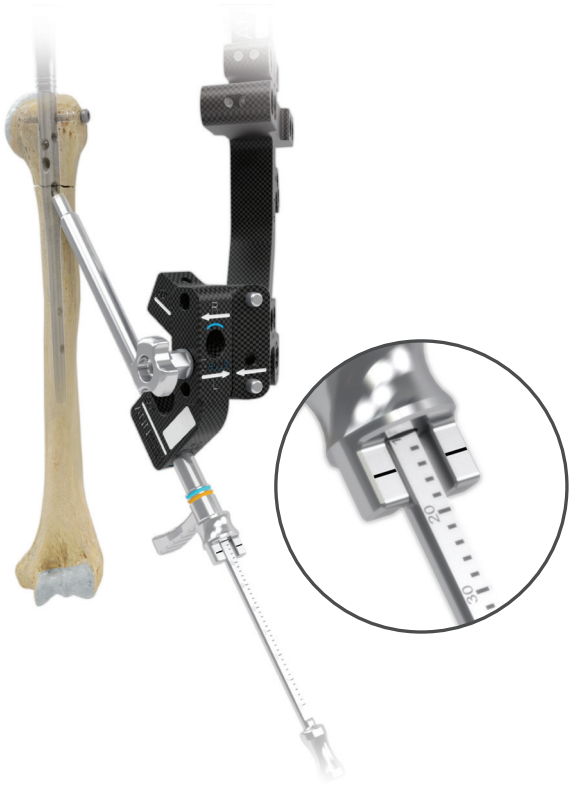


Figure 23

Ascending Screw Placement (cont.)

Insert the 8 mm outer sleeve - screw cannula into the appropriate location on the targeting guide. Insert the 3.3 mm inner sleeve - drill cannula into the screw cannula. Next, insert the trocar into the drill sleeve and use it to create a path through the surrounding soft tissue, down to the cortex of the humerus. Remove the trocar (Figure 22).

Use a 3.3 mm calibrated drill to drill for preparation of screw insertion. Take note of the measurement of the calibration line on the drill bit that is referenced at the edge of the drill sleeve. If desired, an optional screw depth gauge can be used to manually measure the appropriate length of screw needed. (Figure 23).

Assemble the appropriate screw implant to the hex screw driver remove the drill bit and drill sleeve. Insert the screw.

It is recommended to use the cortex pre-cutter to perforate the cortex before the calibrated drill when using the oblique angled screws. This will help to prevent skiving of the drill on the thick lateral cortex.

Figure 24

Figure 25

Optional Implants

Additionally, if desired, a small screw washer and a spider screw washer are available for additional fixation options for the proximal screws only. Washers are not recommended for use on ascending, descending, or distal interlocking screws. The washers all feature angled suture holes to accommodate suture placement and insertion after the washer has been inserted, if necessary (Figure 24).

If inserting a washer with sutures, first place sutures through the washer, then place washer over the screw. Next, drive the screw into desired position, and tighten sutures as desired.

Distal Screw Interlocking

For all short nails, distal screw interlocking can be targeted through the targeting guide in the same manner as the proximal screws. Insert the 8 mm outer sleeve – screw cannula into the appropriate location on the targeting guide (orange marking). Insert the 3.3 mm inner sleeve – drill cannula into the screw cannula. Next, insert the 3.3 mm trocar into the drill sleeve and use it to create a path through the surrounding soft tissue, down to the surface of the bone. Remove the trocar (Figure 25).

Figure 26

Figure 27

Distal Screw Interlocking (cont.)

Use, the 3.3 mm calibrated drill to drill for preparation of screw insertion. Take note of the measurement of the calibration line on the drill bit that is referenced at the edge of the drill sleeve. If desired, an optional screw depth gauge can be used to manually measure the appropriate length of screw needed (Figure 26).

Note: To ensure a bi-cortical screw fixation in the shaft, add 4 mm to the length of the screw measured.

Assemble the appropriate cortical screw implant to the hex screw driver. Remove the drill bit, drill sleeve, and insert the screw (Figure 27).

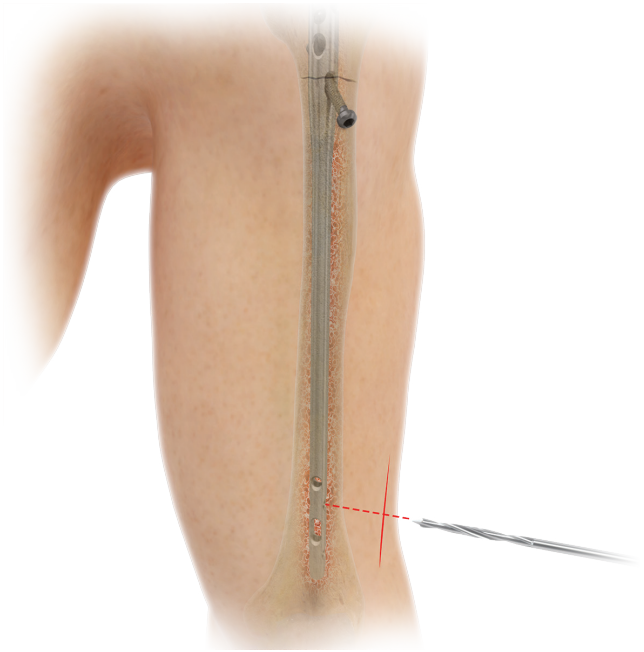


Figure 28

Freehand Distal Screw Targeting Technique

For all long nails, the freehand targeting technique is required. Position the C-arm in order to get a lateral or AP view depending on distal screw location. Adjust the angle of the C-arm so the hole through the nail appears as a perfect circle on the monitor. Bring the tip of the 3.3 mm freehand targeting drill to the skin and use the C-arm to center it over the hole that you desire to place a screw through (Figure 28). Make a stab wound at this point and dissect down to the bone. Place the tip of the drill bit against the bone. Verify that the tip of the drill bit is in the center of the hole. Align the drill bit with the C-arm beam. Slide the freehand tissue protection sleeve over the drill bit. Advance the drill bit through the bone. The use of the oscillating feature on power is sometimes helpful in freehand distal targeting drilling.

Verify that the drill bit has gone through the hole in the nail.

Assemble the appropriate cortical screw implant to the hex screw driver, remove the drill bit from the freehand tissue protection sleeve and insert the screw.

Caution: An incision larger than a stab incision may be needed if screw location is near the radial nerve. Be sure to locate axillary nerve prior to dissecting down to bone.

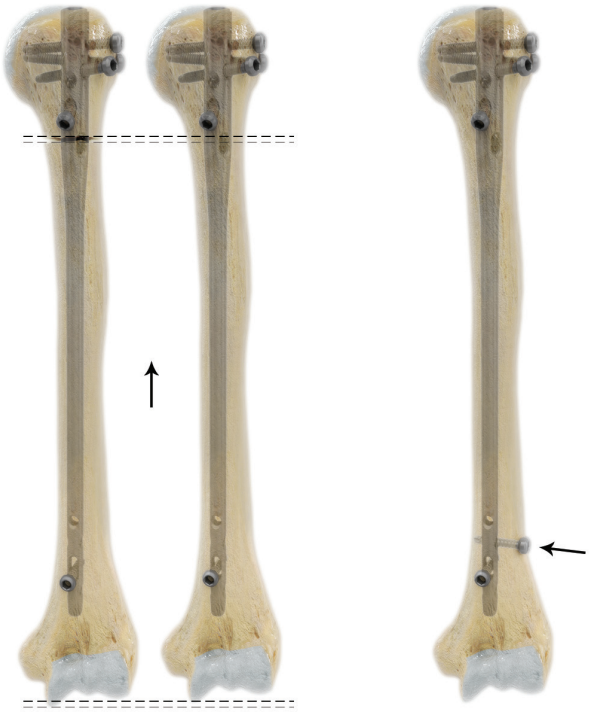


Figure 29

Axial Compression (Optional)

If compression is considered necessary, the distal oblong slot (at the AP plane) in the long nails can be utilized after proximal screws have been targeted to prevent having a proud nail.

Freehand target the distal end of the dynamic hole, put upwards pressure on the elbow and insert a second screw in an adjacent distal static hole to hold and maintain the compression (Figure 29).

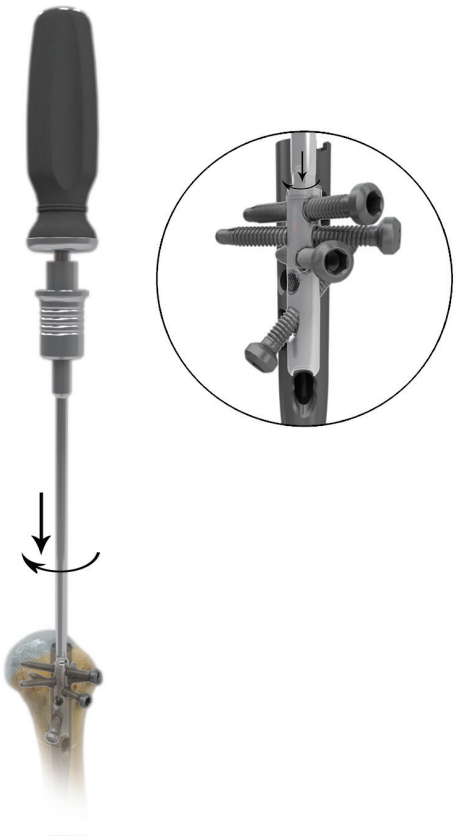


Figure 30

CoreLock Locking

For optimal stability and fixation, the proximal interlocking screws should be locked at a fixed angle following the placement of all screws. Insert the CoreLock Driver with torque limiting handle through the targeting guide, connecting bolt and into the proximal end of the nail. Turn slowly clockwise to tighten and engage the CoreLock Mechanism until 3-4 clicks are felt from the torque limiting handle. (Figure 30).

Note: If an ascending screw is used, the CoreLock Mechanism is recommended to be utilized and at least 2 screws must be applied to the proximal/ metaphyseal portion of the nail.

Note: The CoreLock Mechanism should only be engaged **AFTER** all desired screws are placed in the metaphyseal body of the nail. Do not engage or adjust CoreLock Mechanism prior to placing interlocking screws.

Figure 31

Figure 32

Nail Cap Insertion (Optional)

The use of a nail cap helps to prevent bone in growth in the metaphyseal end of the nail, as well as extends the working length of the nail if countersunk into the bone. If implant removal is expected, the use of a nail cap is recommended. If a nail cap is desired, use the visible grooves at the interface of the targeting guide, connecting bolt and nail implant to visualize an appropriate nail cap height. The grooves are calibrated to 2.5, 5 and 7.5 mm away from the end of the nail. If additional height is not required there is a 0 mm nail cap (Figure 31).

Select the appropriate size nail cap and assemble to the nail cap hex driver cannulated. Remove the connecting bolt from the nail and targeting guide, and then remove the targeting guide from the nail implant. The nail cap and driver assembly can then be inserted into the exposed top of the nail implant over a 2.0 mm x 280 mm pin if needed. Fully seat the nail cap into the nail implant, and disengage the 3.5 mm nail cap hex driver cannulated from the nail cap (Figure 32).

AFFIXUS Natural Nail PH System							
Nial Diameter & Nail Cap	0 mm	10.5 mm x 2.5 mm	10.5 mm x 5 mm	10.5 mm x 7.5 mm	11 mm x 2.5 mm	11 mm x 5 mm	11 mm x 7.5 mm
PH Nail 7.0 mm	X	X	X	X			
PH Nail 8.5 mm	X	X	X	X			
PH Nail 9.0 mm	X	X	X	X			
PH Nail 10.0 mm	X	X	X	X			
PH Nail 11.0 mm					X	X	X

Figure 33

Implant Removal

If implant removal is desired, use the 3.5 mm nail cap hex driver cannulated to remove the nail cap from the nail implant. Next, use the 4 mm a CoreLock Driver with the torque limiting handle to disengage the CoreLock Mechanism feature by turning counter-clockwise. Then use the hex screw driver (3.5 mm hex screwdriver) to remove the proximal and distal interlocking screws. If you are unable to disengage the CoreLock Mechanism, you are still able remove the interlocking screws with the appropriate hex screwdriver.

Lastly, attach the extraction adapter to the proximal end of the nail implant. A hex / pin wrench is available to aid connection to nail, and then attach the slaphammer to the extraction bolt. Backslap on the nail until fully extracted (Figure 33).

If needed the extraction adapter can be placed by using a 2.5 x 280 mm pin as well.

Caution: Bone screw removal from a locked CoreLock Mechanism can cause debris and measures should be taken to remove any debris.

Ordering Information – Implants

Intramedullary Nails

7.0 mm Proximal Humerus Intramedullary Nails, Left

Sterile Part Number	Description
47-2496-161-07	ANN, Proximal Humerus, Left, Ø 7 x 160 mm
47-2496-201-07	ANN, Proximal Humerus, Left, Long, Ø 7 x 200 mm
47-2496-221-07	ANN, Proximal Humerus, Left, Long, Ø 7 x 220 mm
47-2496-241-07	ANN, Proximal Humerus, Left, Long, Ø 7 x 240 mm
47-2496-261-07	ANN, Proximal Humerus, Left, Long, Ø 7 x 260 mm
47-2496-281-07	ANN, Proximal Humerus, Left, Long, Ø 7 x 280 mm

7.0 mm Proximal Humerus Intramedullary Nails, Right

Sterile Part Number	Description
47-2496-160-07	ANN, Proximal Humerus, Right, Ø 7 x 160mm
47-2496-200-07	ANN, Proximal Humerus, Right, Long, Ø 7 x 200 mm
47-2496-220-07	ANN, Proximal Humerus, Right, Long, Ø 7 x 220 mm
47-2496-240-07	ANN, Proximal Humerus, Right, Long, Ø 7 x 240 mm
47-2496-260-07	ANN, Proximal Humerus, Right, Long, Ø 7 x 260 mm
47-2496-280-07	ANN, Proximal Humerus, Right, Long, Ø 7 x 280 mm

8.5 mm Proximal Humerus Intramedullary Nails, Left

Sterile Part Number	Description
47-2496-201-08	ANN, Proximal Humerus, Left, Long, Ø 8.5 x 200 mm
47-2496-221-08	ANN, Proximal Humerus, Left, Long, Ø 8.5 x 220 mm
47-2496-241-08	ANN, Proximal Humerus, Left, Long, Ø 8.5 x 240 mm
47-2496-261-08	ANN, Proximal Humerus, Left, Long, Ø 8.5 x 260 mm
47-2496-281-08	ANN, Proximal Humerus, Left, Long, Ø 8.5 x 280 mm

8.5 mm Proximal Humerus Intramedullary Nails, Right

Sterile Part Number	Description
47-2496-200-08	ANN, Proximal Humerus, Right, Long, Ø 8.5 x 200 mm
47-2496-220-08	ANN, Proximal Humerus, Right, Long, Ø 8.5 x 220 mm
47-2496-240-08	ANN, Proximal Humerus, Right, Long, Ø 8.5 x 240 mm
47-2496-260-08	ANN, Proximal Humerus, Right, Long, Ø 8.5 x 260 mm
47-2496-280-08	ANN, Proximal Humerus, Right, Long, Ø 8.5 x 280 mm

9.0 mm Proximal Humerus Intramedullary Nails

Sterile Part Number	Description
47-2496-160-09	ANN, Proximal Humerus, Right, Ø 9 x 160 mm
47-2496-161-09	ANN, Proximal Humerus, Left, Ø 9 x 160 mm

Ordering Information – Implants (cont.)

Intramedullary Nails

10.0 mm Proximal Humerus Intramedullary Nails, Left

Sterile Part Number	Description
47-2496-201-09	ANN, Proximal Humerus, Left, Long, Ø 10 x 200 mm
47-2496-221-09	ANN, Proximal Humerus, Left, Long, Ø 10 x 220 mm
47-2496-241-09	ANN, Proximal Humerus, Left, Long, Ø 10 x 240 mm
47-2496-261-09	ANN, Proximal Humerus, Left, Long, Ø 10 x 260 mm
47-2496-281-09	ANN, Proximal Humerus, Left, Long, Ø 10 x 280 mm

10.0 mm Proximal Humerus Intramedullary Nails, Right

Sterile Part Number	Description
47-2496-200-09	ANN, Proximal Humerus, Right, Long, Ø 10 x 200 mm
47-2496-220-09	ANN, Proximal Humerus, Right, Long, Ø 10 x 220 mm
47-2496-240-09	ANN, Proximal Humerus, Right, Long, Ø 10 x 240 mm
47-2496-260-09	ANN, Proximal Humerus, Right, Long, Ø 10 x 260 mm
47-2496-280-09	ANN, Proximal Humerus, Right, Long, Ø 10 x 280 mm

11.0 mm Proximal Humerus Intramedullary Nails

Sterile Part Number	Description
47-2496-160-11	ANN, Proximal Humerus, Right, Ø 11 x 160 mm
47-2496-161-11	ANN, Proximal Humerus, Left, Ø 11 x 160 mm

Ordering Information – Implants (cont.)

Screws

4.0 mm Cortical Screws

Product	Sterile Part Number	Description
	47-2486-116-40	ANN, Cortical Bone Screw, Ø 4 x 16 mm
	47-2486-118-40	ANN, Cortical Bone Screw, Ø 4 x 18 mm
	47-2486-120-40	ANN, Cortical Bone Screw, Ø 4 x 20 mm
	47-2486-122-40	ANN, Cortical Bone Screw, Ø 4 x 22 mm
	47-2486-124-40	ANN, Cortical Bone Screw, Ø 4 x 24 mm
	47-2486-126-40	ANN, Cortical Bone Screw, Ø 4 x 26 mm
	47-2486-128-40	ANN, Cortical Bone Screw, Ø 4 x 28 mm
	47-2486-130-40	ANN, Cortical Bone Screw, Ø 4 x 30 mm
	47-2486-132-40	ANN, Cortical Bone Screw, Ø 4 x 32 mm
	47-2486-134-40	ANN, Cortical Bone Screw, Ø 4 x 34 mm
	47-2486-136-40	ANN, Cortical Bone Screw, Ø 4 x 36 mm
	47-2486-138-40	ANN, Cortical Bone Screw, Ø 4 x 38 mm
	47-2486-140-40	ANN, Cortical Bone Screw, Ø 4 x 40 mm

4.0 mm Blunt Tip Screws

Product	Sterile Part Number	Description
	47-2486-034-40	ANN, Blunt Tip Screw, Ø 4 x 34 mm
	47-2486-036-40	ANN, Blunt Tip Screw, Ø 4 x 36 mm
	47-2486-038-40	ANN, Blunt Tip Screw, Ø 4 x 38 mm
	47-2486-040-40	ANN, Blunt Tip Screw, Ø 4 x 40 mm
	47-2486-042-40	ANN, Blunt Tip Screw, Ø 4 x 42 mm
	47-2486-044-40	ANN, Blunt Tip Screw, Ø 4 x 44 mm
	47-2486-046-40	ANN, Blunt Tip Screw, Ø 4 x 46 mm
	47-2486-048-40	ANN, Blunt Tip Screw, Ø 4 x 48 mm
	47-2486-050-40	ANN, Blunt Tip Screw, Ø 4 x 50 mm
	47-2486-052-40	ANN, Blunt Tip Screw, Ø 4 x 52 mm
	47-2486-054-40	ANN, Blunt Tip Screw, Ø 4 x 54 mm
	47-2486-056-40	ANN, Blunt Tip Screw, Ø 4 x 56 mm
	47-2486-058-40	ANN, Blunt Tip Screw, Ø 4 x 58 mm
	47-2486-060-40	ANN, Blunt Tip Screw, Ø 4 x 60 mm
	47-2486-065-40	ANN, Blunt Tip Screw, Ø 4 x 65 mm
	47-2486-070-40	ANN, Blunt Tip Screw, Ø 4 x 70 mm
	47-2486-075-40	ANN, Blunt Tip Screw, Ø 4 x 75 mm
	47-2486-080-40	ANN, Blunt Tip Screw, Ø 4 x 80 mm

Nail Caps

Product	Sterile Part Number	Description
	47-2488-010-00	ANN, Proximal Humerus Nail Cap, 0 mm
	47-2488-010-02	ANN, Proximal Humerus Nail Cap, Ø 10.5 x 2.5 mm
	47-2488-010-05	ANN, Proximal Humerus Nail Cap, Ø 10.5 x 5 mm
	47-2488-010-07	ANN, Proximal Humerus Nail Cap, Ø 10.5 x 7.5 mm
	47-2488-011-02	ANN, Proximal Humerus Nail Cap, Ø 11 x 2.5 mm
	47-2488-011-05	ANN, Proximal Humerus Nail Cap, Ø 11 x 5 mm
	47-2488-011-07	ANN, Proximal Humerus Nail Cap, Ø 11 x 7.5 mm

Ordering Information – Implants (cont.)

Washers

Product	Sterile Part Number	Description
	47-2488-000-04	ANN, Washer Small
	47-2488-000-05	ANN, Spider Washer

Ordering Information – Instruments

Sterile Instruments

Sterile Part Number	Non-Sterile Part Number	Description
110035668	110035667	Affixus, Humerus Ball Nose Guidewire
110035651	110035650	Affixus, Humerus Calibrated Drill, 3.3 mm

Cases

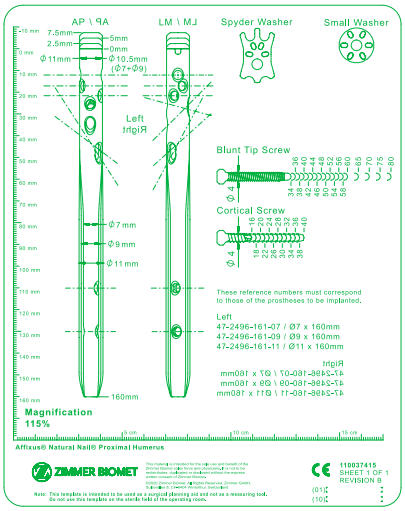
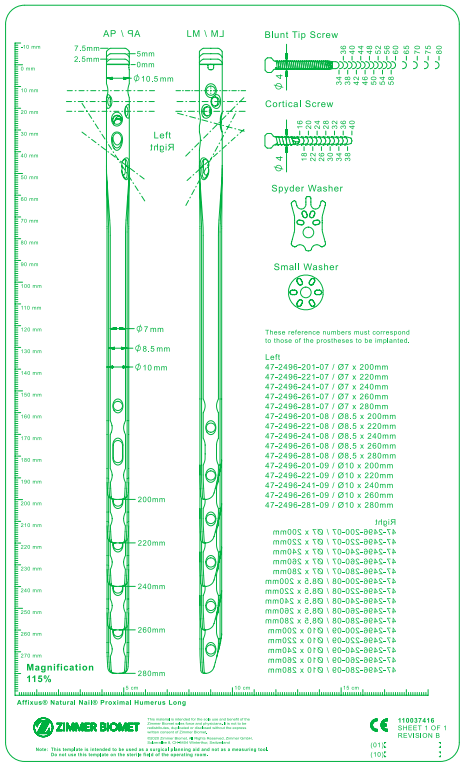
	Non-Sterile Part Number	Description
	110037243	Affixus, Humerus Instrument Case
	110038114	Affixus, Proximal System Case
	110038115	Affixus, Proximal System Tray
	110038118	Affixus, General Instruments Case
	110038119	Affixus, General Instruments Tray
	110039053	Half Size Lid
	110031221	Full Size Lid

Disposables

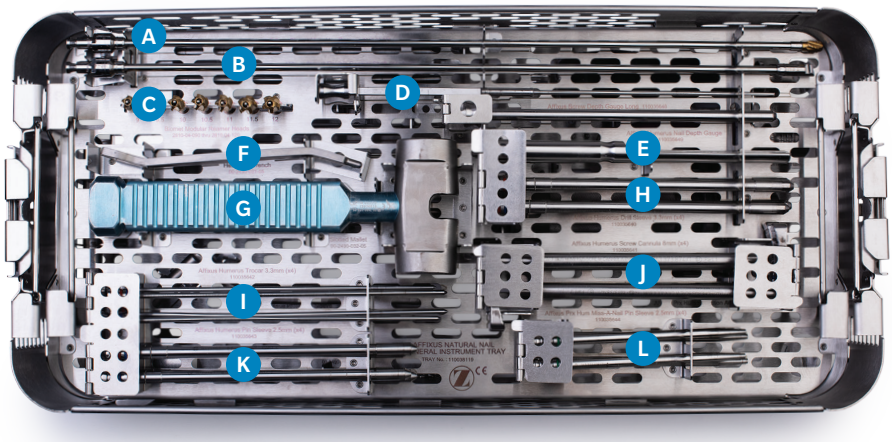
	Part Number	Description
	110037237	Affixus, Proximal Humerus Pin Coring, 2.5 x 280 mm, 10.5 mm
	110035664	Affixus, Proximal Humerus Pin Coring, 2.5 x 280 mm, 11.0 mm
	290.20.280	Kirschner Wire with Trocar Tip Ø 2 mm, 280 mm
	290.25.280	Kirschner Wire Trocar Tip, Ø 2.5mm, 280 mm

Ordering Information (cont.)

X-Ray Templates

Description	ANN Proximal Short Nail X-Ray Template	ANN Proximal Long Nail X-Ray Template
Magnification	115%	115%
Part Number	110037415	110037416
Product		

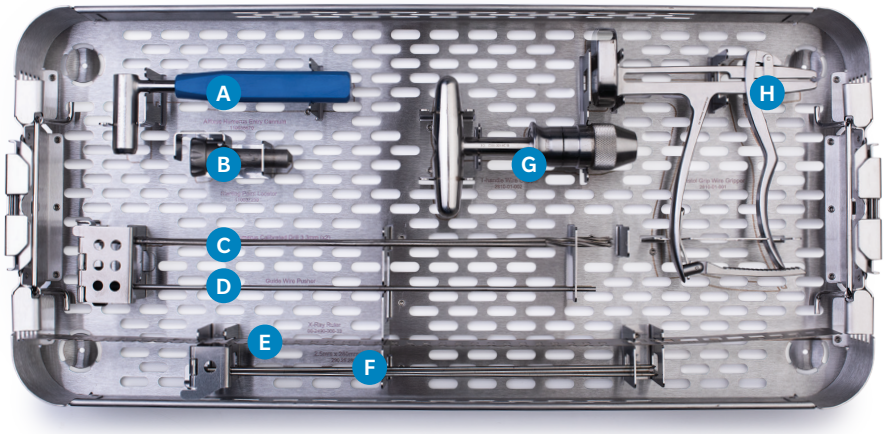
Ordering Information – Trays



AFFIXUS Natural Nail General Instruments Tray – 110038119

Label	Description	Quantity	Part Number
A	8 mm Monobloc Reamer Hudson	1	2810-02-080
B	470 mm Nitinol Mod Reamer Hudson	1	2810-02-470
C	9.0 mm Modular Reamer Head	1	2810-04-090
	9.5 mm Modular Reamer Head	1	2810-04-095
	10.0 mm Modular Reamer Head	1	2810-04-100
	10.5 mm Modular Reamer Head	1	2810-04-105
	11.0 mm Modular Reamer Head	1	2810-04-110
	11.5 mm Modular Reamer Head	1	2810-04-115
	12.0 mm Modular Reamer Head	1	2810-04-120
D	Affixus, Screw Depth Gauge, Long	1	110035648
E	Affixus, Humerus Nail Depth Gauge	1	110035649
F	Zimmer Natural Nail System Pin Wrench 11 mm Hex	1	00-2490-031-05
G	Zimmer Natural Nail System, Slotted Mallet	1	00-2490-032-05
H	Affixus, Humerus Drill Sleeve, 3.3 mm	4	110035640
I	Affixus, Humerus Trocar, 3.3 mm	4	110035642
J	Affixus, Humerus Screw Cannula, 8 mm	4	110035641
K	Affixus, Humerus Pin Sleeve, 2.5 mm	4	110035643
L	Affixus, Proximal Humerus Miss-A-Nail Pin Sleeve, 2.5 mm	4	110035644

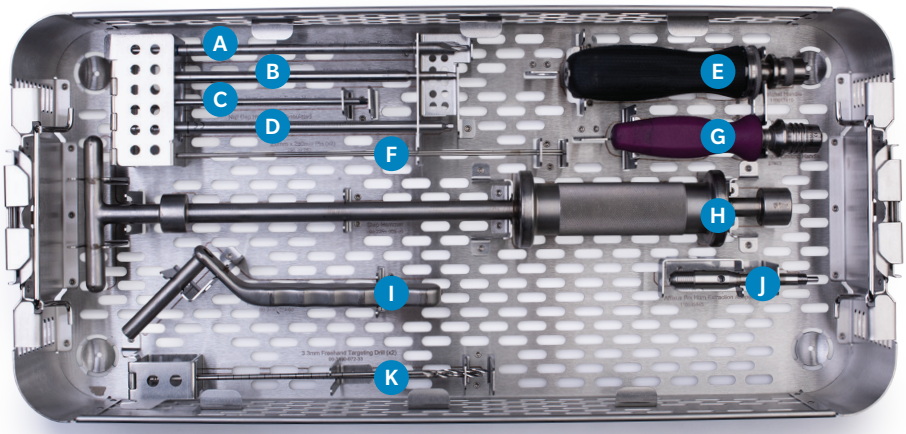
Ordering Information – Trays (cont.)



ANN Instrument Case – 110037243

Label	Description	Quantity	Part Number
A	Affixus, Humerus Entry Cannula	1	110035670
B	Starting Point Locator	1	110037239
C	Affixus, Humerus Calibrated Drill, 3.3 mm	2	110035650
D	Guidewire Pusher	1	2810-01-026
E	Zimmer Natural Nail System Ruler	1	00-2490-000-33
F	Kirschner Wire Trocar Tip, Ø 2.5 mm, 280 mm	6	290.25.280
G	T-Handle Guidewire Gripper	1	2810-01-002
H	Pistol Guidewire Gripper	1	2810-01-001

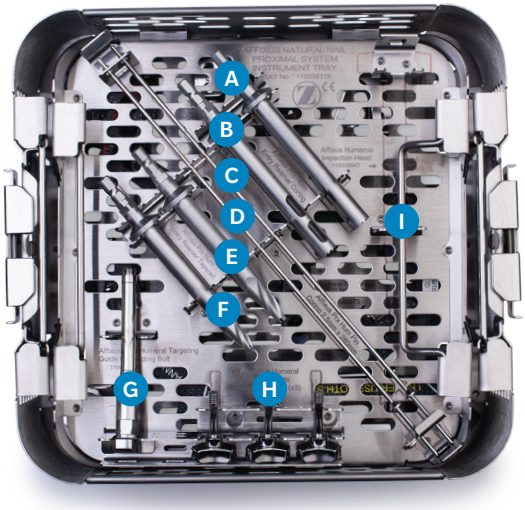
Ordering Information – Trays (cont.)



ANN General Instruments Case – 110038118

Label	Description	Quantity	Part Number
A	Affixus, Proximal Humerus Cortex Pre-Cutter	1	110035661
B	Affixus, Humerus Screwdriver, HEX, 3.5 mm	1	110035662
C	Affixus, Proximal Humerus CoreLock Driver, HEX, 4 mm	1	110035663
D	Nail Cap Hex Driver, Cannulated	1	110037242
E	Standard Ratchet Handle ZH	1	110017410
F	Kirschner Wire with Trocar Tip Ø 2 mm, 280 mm	1	290.20.280
G	Torque Limiting Handle, Straight	1	27923
H	Slap Hammer	1	00-2255-009-00
I	Zimmer Natural Nail System Freehand Tissue Protection Sleeve	1	00-2490-074-00
J	Affixus, Proximal Humerus Extraction Adapter	1	110035645
K	Zimmer Natural Nail System Freehand Targeting Drill 3.3 mm	1	00-2490-072-33

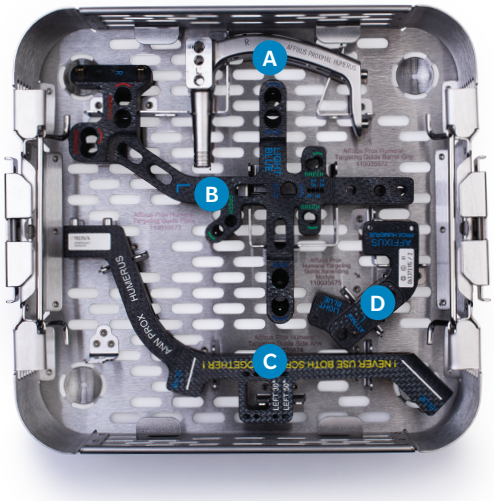
Ordering Information – Trays (cont.)



AFFIXUS Natural Nail Proximal Humerus 1/2 Case – 110038115

Label	Description	Quantity	Part Number
A	Affixus, Proximal Humerus Entry Reamer, Coring, 11.0 mm	1	110035652
B	Affixus, Proximal Humerus Entry Reamer, Coring, 10.5 mm	1	110037235
C	Affixus, Proximal Humerus Pin Coring, 2.5x280 mm, 11.0 mm	1	110035664
D	Affixus, Proximal Humerus Pin Coring, 2.5x280 mm, 10.5 mm	1	110037237
E	Affixus, Proximal Humerus Entry Reamer, Tapered, 11.0 mm	1	110035657
F	Affixus, Proximal Humerus Entry Reamer, Tapered, 10.5 mm	1	110037236
G	Affixus, Proximal Humerus Targeting Guide Connecting Bolt	1	110035671
H	Affixus, Proximal Humerus Targeting Guide Connecting Screw	3	110035676
I	Affixus, Humerus Impaction Head	1	110035647

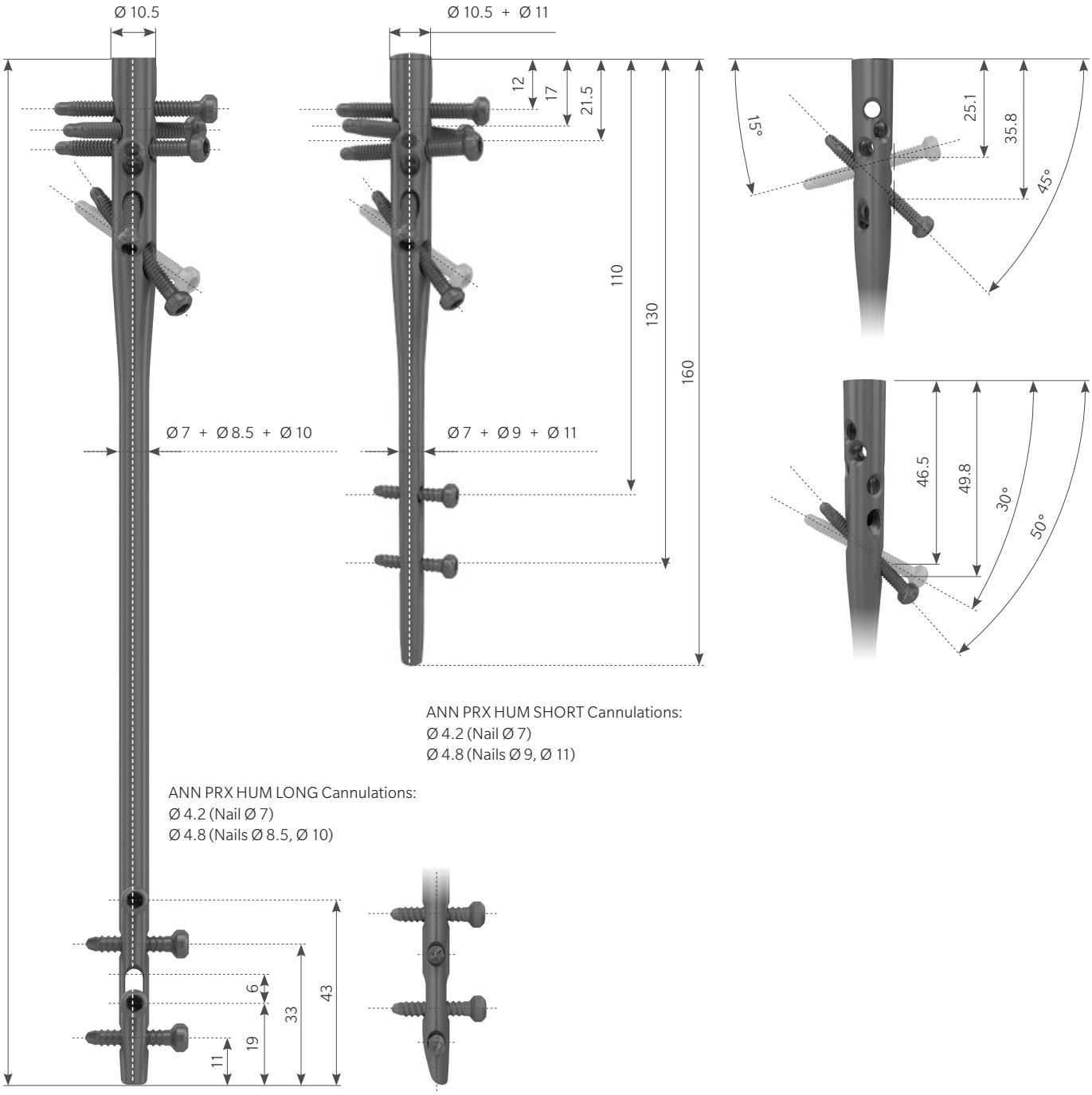
Ordering Information – Trays (cont.)



AFFIXUS Natural Nail Proximal System Case 1/2 Tray – 110038114

Label	Description	Quantity	Part Number
A	**Affixus, Proximal Humerus Targeting Guide Barrel Grip**	1	110035672
B	**Affixus, Proximal Humerus Targeting Guide Plate**	1	110035673
C	**Affixus, Proximal Humerus Targeting Guide Side Arm**	1	110035674
D	**Affixus, Proximal Humerus Targeting Guide Ascending Module**	1	110035675

Implant Dimensions



ANN PRX HUM SHORT Cannulations:
Ø 4.2 (Nail Ø 7)
Ø 4.8 (Nails Ø 9, Ø 11)

ANN PRX HUM LONG Cannulations:
Ø 4.2 (Nail Ø 7)
Ø 4.8 (Nails Ø 8.5, Ø 10)

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For Instructions for Care, Cleaning, Maintenance and Sterilization Manual refer to 3455.

For disassembly instructions (where applicable) refer to 1258 Disassembly Manual.

If damage or wear detected on instruments, please consult the Reusable Instrument Lifespan Manual 1219.

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