ORTHOPEDIC DESIGNS NORTH AMERICA, INC.

ATLAS™ Humeral Nail System

Surgical Technique

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Note: This publication is provided to set forth a suggested surgical procedure. The physician should tailor this procedure to the specific needs of the patient.

Atlas™ Humeral Nail System—Device Description

Nails

- Proximal Head Diameter: 11mm
- Shaft Diameters: 8, 9, 10mm
- Lengths: 165mm-315mm (15mm increments)
- Left and Right Orientations

Cortical Screws

- Head Diameter: 7.8mm
- Thread Diameter: 5mm
- Lengths: 18mm-120mm
  2mm increments (18-60mm)
  4mm increments (60-120mm)
- Self-tapping design
- T25 TORX Drive

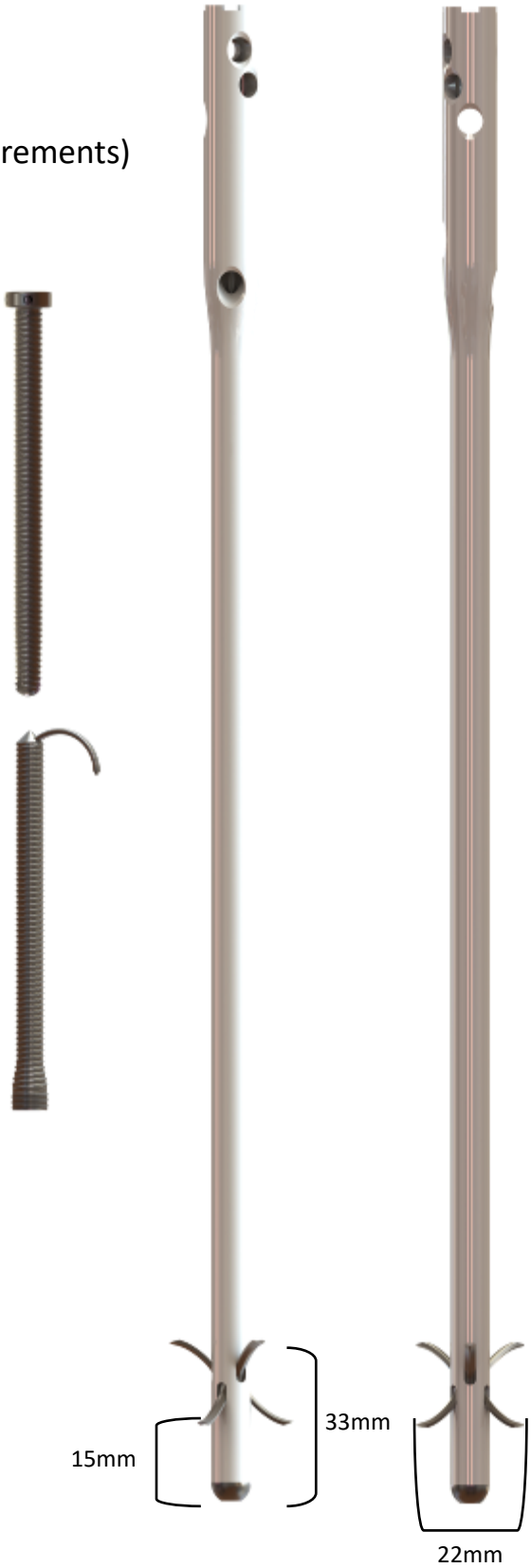
Atlas™ Screws

- Head Diameter: 6.5mm
- Thread Diameter: 5mm
- Lengths: 36mm-120mm
  2mm increments (36-60mm)
  4mm increments (60-120mm)
- T25 TORX Drive

End Caps

- Lengths: Flush, +2mm, +5mm, +10mm, +15mm
- T25 TORX Drive
- Locking version available

Locking version



ALL TALONS ARE FULLY RETRACTABLE

Note: All implants are single use only

U.S. Patents: 5,976,139 - 6,183,474 - 6,648,889 - 6,695,844 - 8,491,581 - 2022/0257295 A1

Atlas™ Humeral Nail System—Device Description

The Atlas™ Humeral Nail System is used to aid in the alignment and stabilization of humeral fractures. The system consists of the following parts:

- A **humeral nail** with proximal portals for passage of cortical locking screws and distal portals that allow passage of deployable integral talons to achieve distal fixation from within the intramedullary canal. These talons eliminate the need for distal locking screws. The nail is provided with the deployable distal nail talons and distal end cap already installed. The distal end type of the nail is determined by the shape of the end cap and may be varied to suit surgeon preference. The distal talons may also be retracted for removal of the intramedullary nail if and when it is necessary.

- A **proximal cortical locking screw** is provided separately. The cortical locking screws have a reduced minor diameter at the tip which provides increased purchase in cancellous bone by increasing the thread height and are provided for proximal fixation if desired.

- An **Atlas™ Screw** is provided separately. The Atlas™ Screw has integral talons that can be deployed for additional fixation and stability.

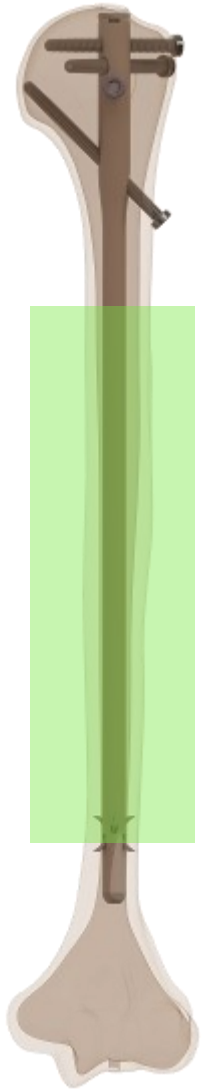
- A **proximal end cap** is provided separately. The end cap prevents bony ingrowth and preserves the threads which may be used for attachment of instrumentation during explantation of the nail. The proximal end cap also comes in a locking version which includes a distal shaft that locks the screw placed in the most proximal screw hole.

Implants are constructed of titanium alloy (Ti-6AL-4V-ELI). Patient contacting portions of the instrumentation are constructed of stainless steel (304, 316 or 17-4).

Indications

The Atlas™ Humeral Nail System is indicated to aid in the alignment and stabilization of humeral fractures, including:

- Diaphyseal fractures of the humeral shaft
- Proximal humeral fractures with diaphyseal extension
- Impending pathologic fractures



Relative Contraindications

The following conditions may present an increased risk of implant failure. It is not meant to be comprehensive. Physicians should use their clinical judgment when determining the appropriate implant and approach for a given patient.

- Active local infection
- Material sensitivity
- Loss of bone stock/insufficient bone quality to support the device
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure

Special Considerations

- Talons perform best when deployed into the cortical bone of the humeral shaft. Care should be taken to avoid deploying Talons through the cortex near the radial/ulnar nerves and other soft tissue considerations.
- Screws Warning: The cortical screws and Atlas™ screws are not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.

MRI Safety Information

The Atlas™ Humeral Nail System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Atlas™ Humeral Nail System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Patient Positioning

The patient is placed in a semireclined “beach chair position” or supine on a radiolucent table. Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the affected extremity (Fig. 6-1). The image intensifier is placed at the legside of the patient; the surgeon is positioned at the headside.

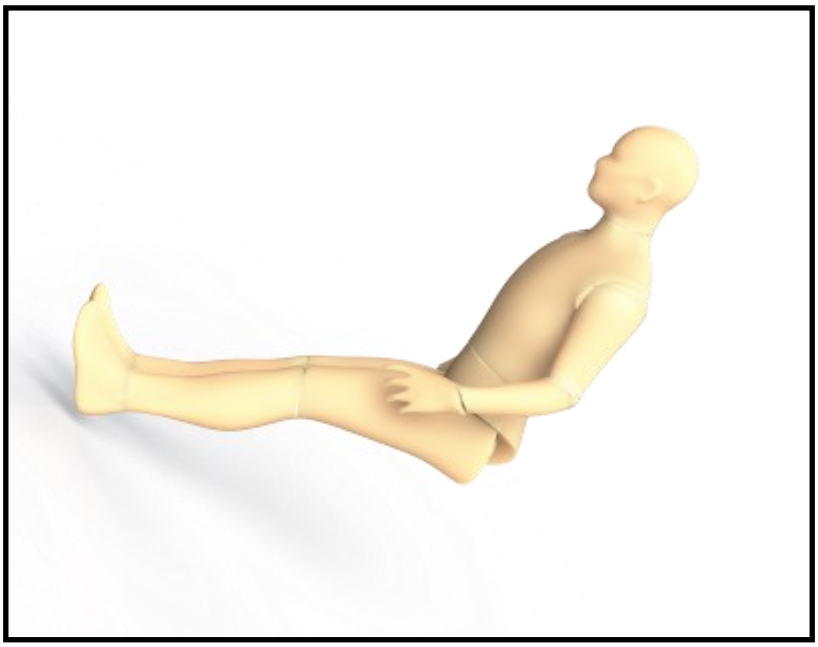


Fig. 6-1

Opening the Proximal Humerus

Perform an anterolateral approach. Begin the incision at the anterolateral tip of the acromion and carry it distally over the deltoid muscle. Split the deltoid muscle at the tendinous intersection between the anterior and the middle third along its fibers and retract it (Fig 6-2).

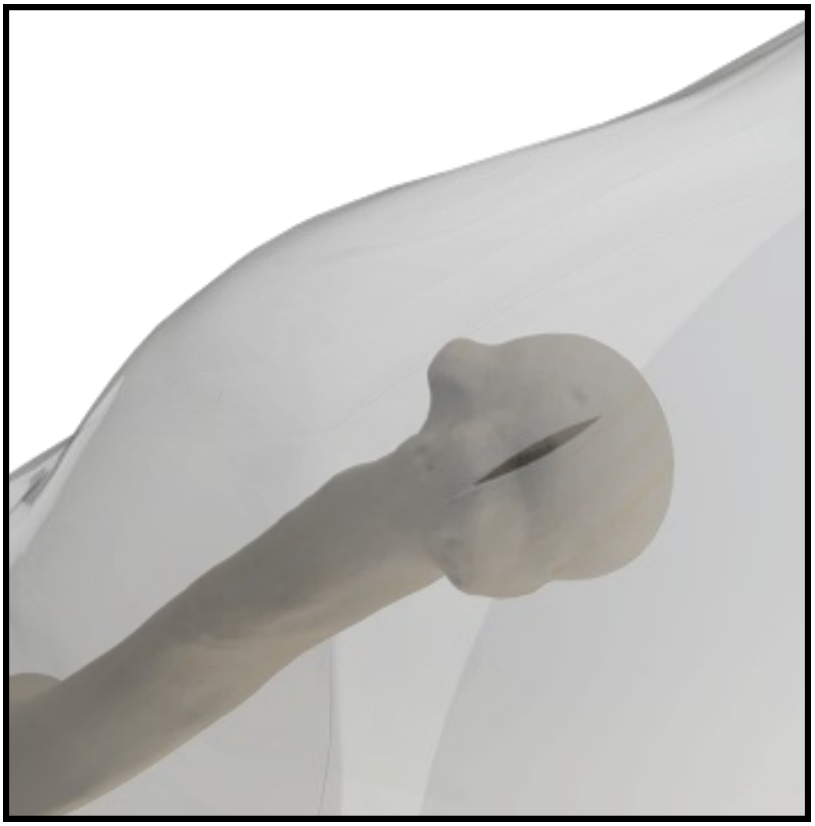


Fig. 6-2

Opening the Proximal Humerus (cont.)

The entry point for the Atlas™ Humeral Nail is in line with the medullary canal in the lateral view and AP (Fig. 7-1).

Advance the 2.5mm x 280mm Trocar Tip Guide Wire (ODI-D102) through the starting point with a powered driver. Confirm its position in the AP (Fig. 7-2) and lateral (Fig. 7-3) planes. Proper position is critical. Withdraw wire and reposition as necessary.

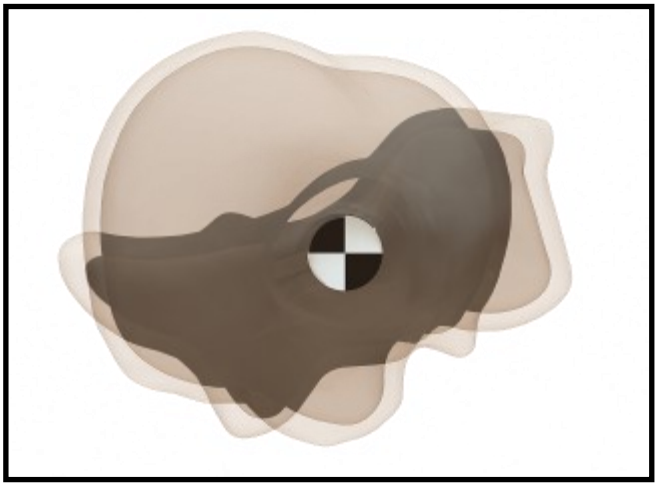


Fig. 7-1

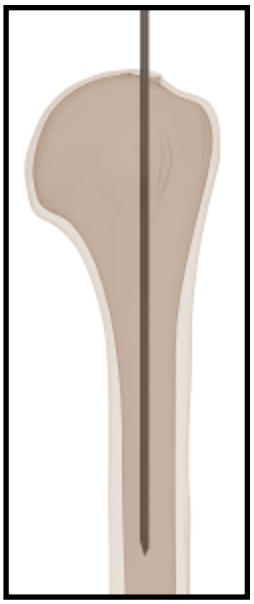


Fig. 7-2

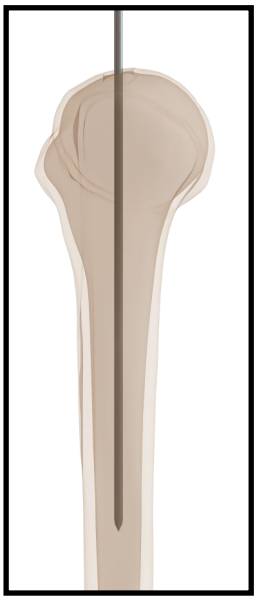


Fig. 7-3

SURGICAL TECHNIQUE

Opening the Proximal Humerus (cont.)

Pass the 11mm Entry Reamer (ODI-T175) and Tissue Protector (ODI-T160) over the guide wire to the level of the bone. Use a powered driver to advance the entry reamer into the proximal humerus (Fig. 8-1).

Exchange the Trocar Tip Wire for the Ball Tip Sheathed Guide Wire (ODI-D101). Advance the sheathed wire down the humeral canal and across the fracture site (Fig. 8-2). If desired, the Reduction Rod (ODI-T178) can be used to aid in the alignment of bone fragments.

Enlarge the medullary canal through distal reaming. It is recommended that the canal be reamed 1mm greater than the diameter of the desired nail.

Back reamer out using the Wire Pusher (ODI-T130). Remove the sheath from the wire.

Fig. 8-1

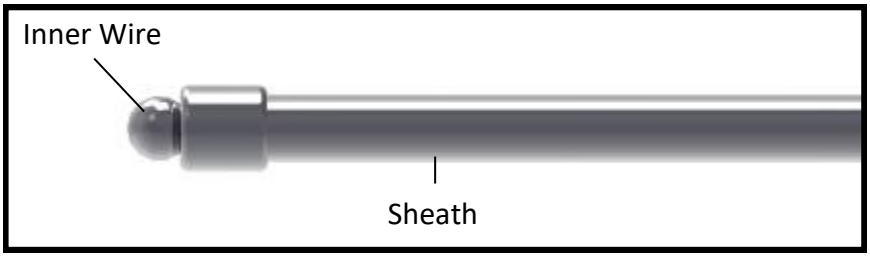


Fig. 8-2

Nail Diameter

Selection of the appropriate size implant—diameter and length—is of critical importance. Nail diameter can be determined through assessment of the intra-medullary reaming along with the use of the Radiographic Talon Template (ODI-T116) (Fig. 9-1).

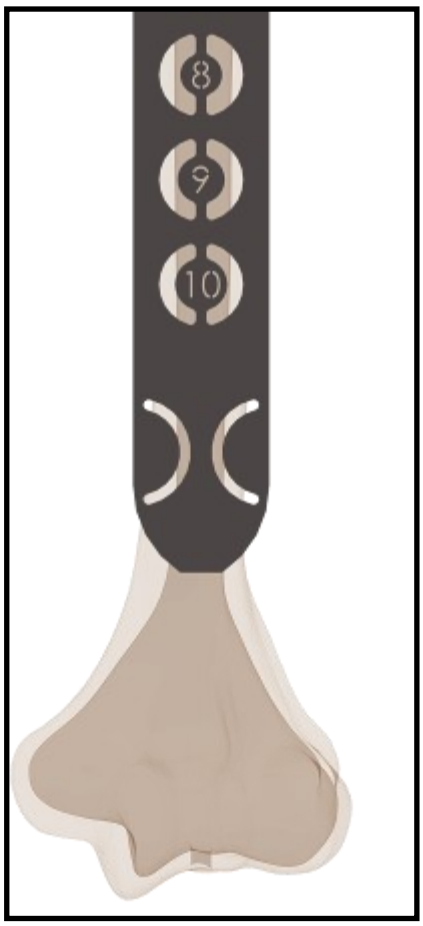


Fig. 9-1

Nail Length

Nail length can be determined via one of two methods—measuring off the guide wire or radiographically.

Method One: Measuring the Wire

Open the Guide Wire Ruler (ODI-T113) and pass it over the guide wire noting that the end of the Guide Wire Ruler is the measurement reference.

Adjust the guide wire until its tip is at the desired level of the distal end of the implant. Read the suggested nail length off the back of the wire (Fig. 9-2).

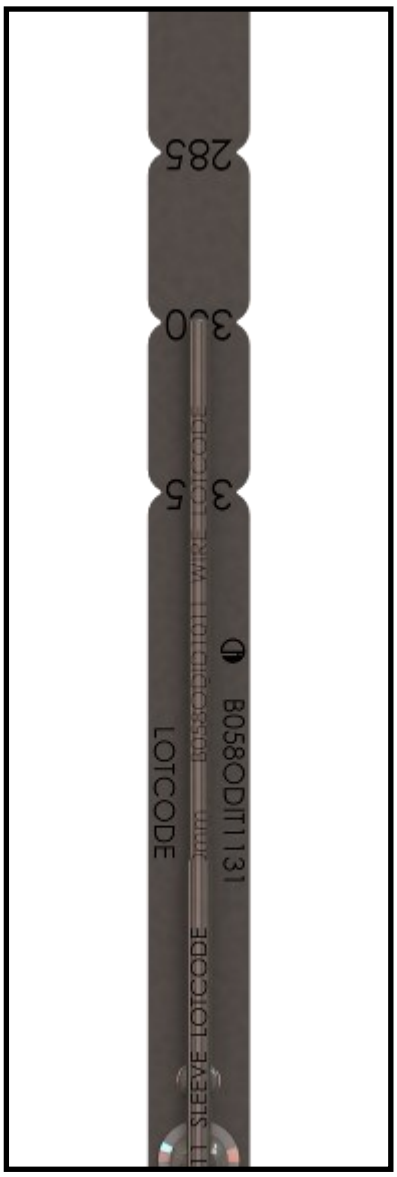


Fig. 9-2

Note that this measurement is a direct reading to the distal tip of the guide wire. A fracture that is not properly reduced may result in an artificially high or low measurement. Actual nail length is determined by the surgeon.

Nail Selection (cont.)

Method Two: Radiographically

Confirm that the fracture is well reduced and place the Radiographic Talon Template (ODI-T116) (Fig. 10-1) on the upper arm to determine the nail length of the longest nail. The distal edge of the template indicates the tip of the nail. Move the image intensifier to the proximal humerus and read the measurement radiographically at the desired position.

Note: Talon position is indicated on the distal end of the Radiographic Talon Template (ODI-T116) (Fig. 10-2).

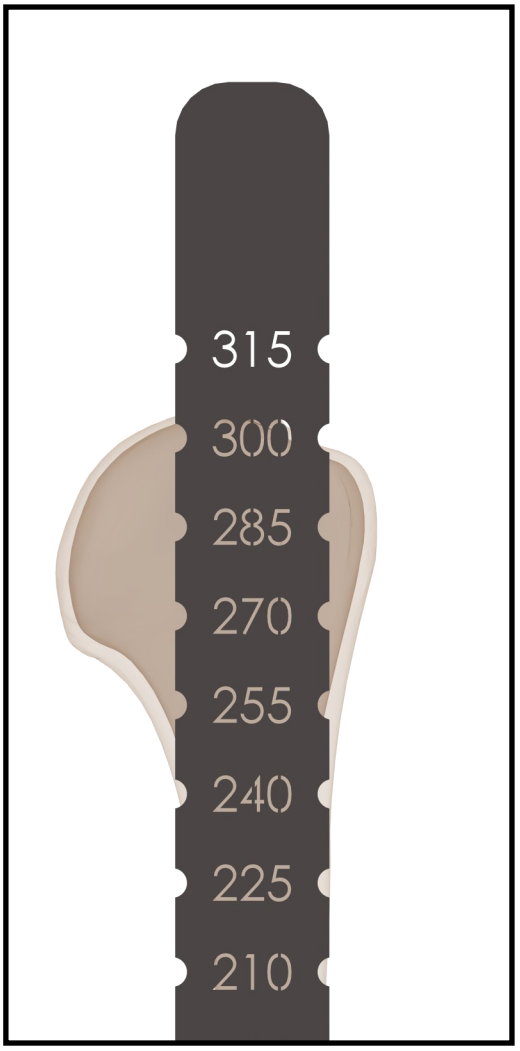


Fig. 10-1

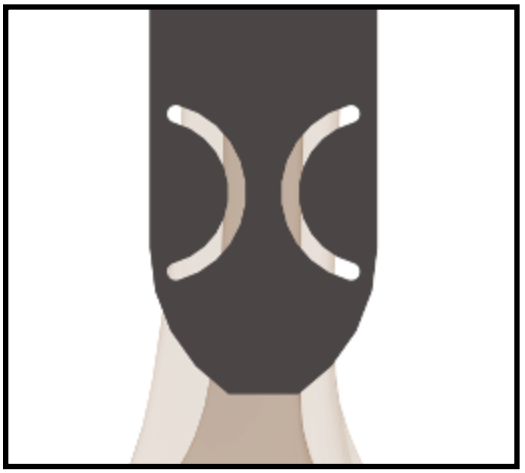


Fig. 10-2

Nail Insertion

Mate the chosen nail with the Guide Handle (ODI-T172). Take care to align the reference mark on the nail head with the appropriate corresponding mark on the handle (Fig. 11-1).

Secure the nail to the handle with the Nail -Handle Connector Screw (ODI-T171) using the 7mm Hex Driver (ODI-T161) (Fig. 11-2). Ensure the screw is tightly secured by turning the handle.

If not already done, remove the sheath from the Ball Tip Sheathed Guide Wire (ODI-D101) leaving the inner wire in place. The sheath will not pass through the nail.

Pass the nail over the wire and into the humerus. Apply steady pressure and use small oscillating motions to advance the nail (Fig. 11-3). Monitor passage of the nail across the fracture site radiographically. Rings on the guide handle indicate insertion depth. Insert the nail to the depth noted during nail selection.

An Impactor (ODI-T176) can be used to aid in placing the nail (Fig. 11-4). Never strike the guide handle directly. If significant resistance is encountered, remove the nail, replace the sheath, and further enlarge the medullary canal through reaming.

Once the nail is placed, confirm the reduction of the fracture in both the AP and lateral planes. If satisfied, remove the guide wire.

Fig. 11-1

Fig. 11-2

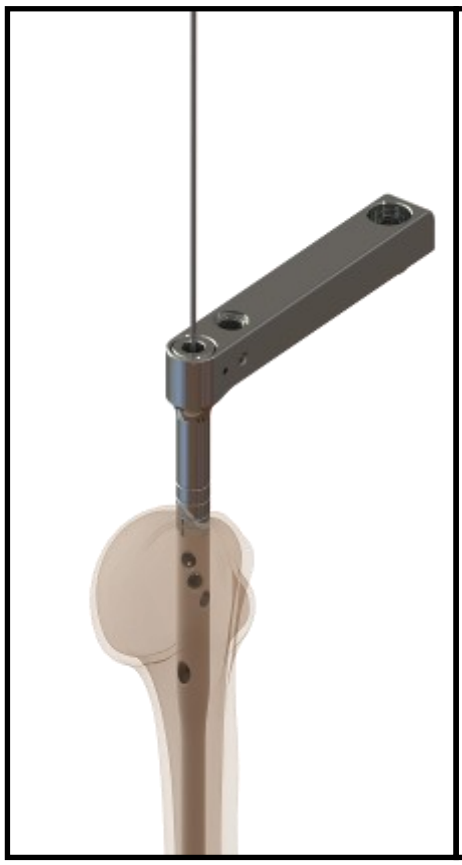


Fig. 11-3

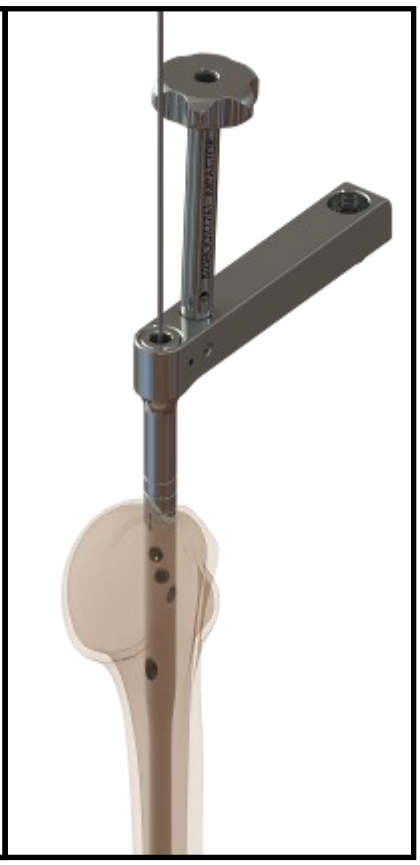


Fig. 11-4

Distal Locking—Talons

Attach the Talon Driver (ODI-T114) to the Torque Limiting Handle (ODI-T119) and pass the driver down the cannulation of the nail. Turn the driver clockwise to deploy the Talons (Fig. 12-1).

A consistent low resistance/torque should be felt during deployment until the cortex is reached. A sudden increase in resistance/torque marks cortical contact. Monitor the deployment progress in the distal humerus once cortical contact is made. Continue deploying until the torque-limiting handle trips or you are radiographically indicated to stop. If necessary, retract the Talons by turning the driver counterclockwise. Talons are shown fully deployed in Fig. 12-2 as an example.

NOTE: TALONS NEED NOT BE FULLY DEPLOYED. AT SURGEON'S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME. TALONS ARE DESIGNED TO PENETRATE THE CORTICAL BONE. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PERFORATION *THROUGH* THE CORTICAL BONE AND INTO SOFT TISSUE.

Fig. 12-1

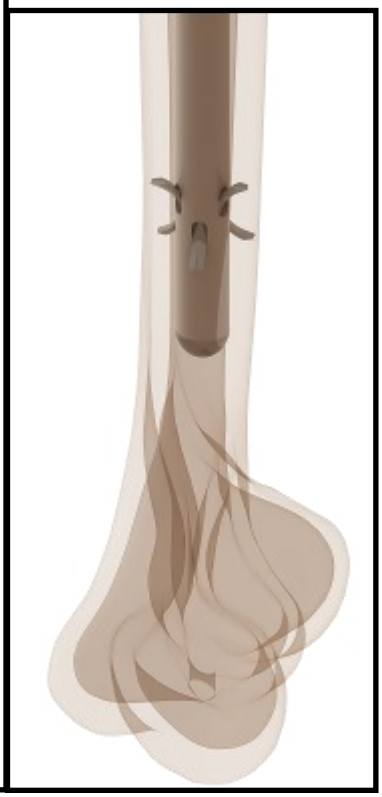


Fig. 12-2

TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.

Attach the Guide Handle (ODI-T172) to the Guide Arm (ODI-T174) and tighten the Handle-Arm Connector Screw (ODI-T173) (Fig. 13-1). The technique for placing cortical screws is identical for all screw hole positions. The procedure for placing the calcar screw will be demonstrated.

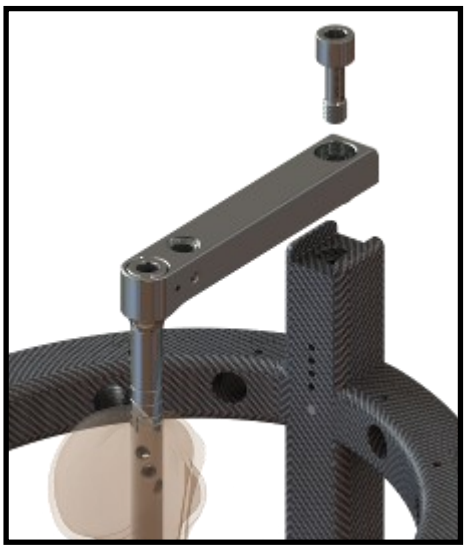


Fig. 13-1

Insert the triple sleeve assembly—Guide Sleeve (ODI-T153), Drill Sleeve (ODI-T154), and Obturator (ODI-T155)—through the desired hole in the Guide Arm (calcar hole pictured). Make a small incision in the skin and advance the sleeves to the cortical surface (Fig. 13-2). Apply pressure with the Obturator to create a dimple in the lateral cortex.

Fig. 13-2

Fig. 13-3

Remove the Obturator and pass the calibrated 4.3mm Cortical Drill (ODI-T157) through the Drill Sleeve and drill to desired depth (Fig. 13-3).

Read the drilled depth directly from the graduations on the drill (Fig. 13-4). Apply pressure to the Drill Sleeve to ensure it is in contact with the cortex. Graduations are calibrated to the tip of the drill and coincide with the available screw lengths. If using the Drill Depth Gauge (ODI-T180), seat it on the Drill Sleeve, allowing the cortical drill to rest in the channel. Take measurement from the back of the cortical drill (Fig 13-5).

Fig. 13-4

Fig. 13-5

Proximal Locking (cont.)

Standard Screw Placement

Mate the chosen cortical screw with the T25 Driver (ODI-T156) held by the Ratcheting Axial Handle (ODI-T120) (Fig. 14-1).
Note: Cortical screw length can be verified using cortical screw block measurement inlay.

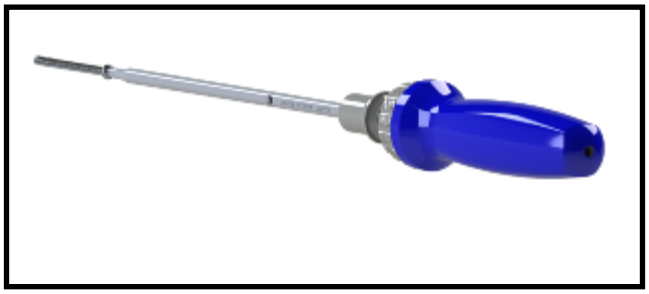


Fig. 14-1

Remove the Drill Sleeve (ODI-T154) and pass the cortical screw/driver assembly through the Guide Sleeve (ODI-T153) and into the bone (Fig. 14-2). Advance the screw until the screw head is seated against the lateral cortex. Do not over tighten as this may lead to the screw stripping. Remove the Guide Sleeve from the Guide Arm. Note: The T25 Driver may have a reference line indicating screw head position in reference to cortical sleeve.

Fig. 14-2

Place additional screws in additional holes as desired.

Atlas™ Screw Placement

Mate the chosen Atlas Screw with the Atlas Screw Deployment Driver (ODI-T168). Note that the T25 feature of the Atlas Screw Deployment Driver is keyed in order to align with the Atlas Screw (Fig15-1). Thread the Atlas Screw Deployment Driver's connection sleeve clockwise to fully mate the driver onto the threads of the Atlas Screw head (Fig 15-2). Once mated, the alignment mark on the Atlas Screw Deployment Driver will indicate the direction of the Atlas Screw's talon deployment.

Fig. 15-1

Remove the Drill Sleeve (ODI-T154) and pass the Atlas Screw Deployment Driver through the Guide Sleeve (ODI-T153) and into the bone. Advance the screw until the Atlas Screw Deployment Driver is seated at the lateral cortex. Do not over tighten as this may lead to the screw stripping. Attach the Palm Handle (ODI-T181) to the Atlas Screw Deployment Driver (Fig 15-3). Make note of the alignment marking on the Atlas Screw Deployment Driver to determine the direction of the Talon deployment. Rotate the Palm Handle clockwise to deploy the Talons. Resistance will be felt throughout the Talon deployment and will increase when Talons are fully deployed (Fig 15-4).

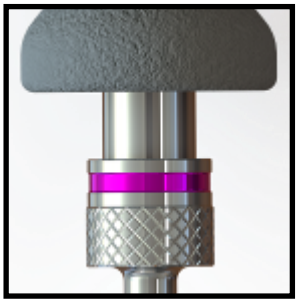


Fig. 15-2

Fig. 15-3

NOTE: THE TALONS NEED NOT BE FULLY DEPLOYED. AT THE SURGEON'S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME.

Disconnect the Atlas Screw Deployment Driver from the screw by rotating the connection knob counter clockwise. Remove the Atlas Screw Deployment Driver and the Guide Sleeve from the Guide Arm.

Place additional screws in additional holes as desired.

NOTE: WHEN USING THE ATLAS SCREW, A MINIMUM OF THREE (3) MUST BE EMPLOYED.

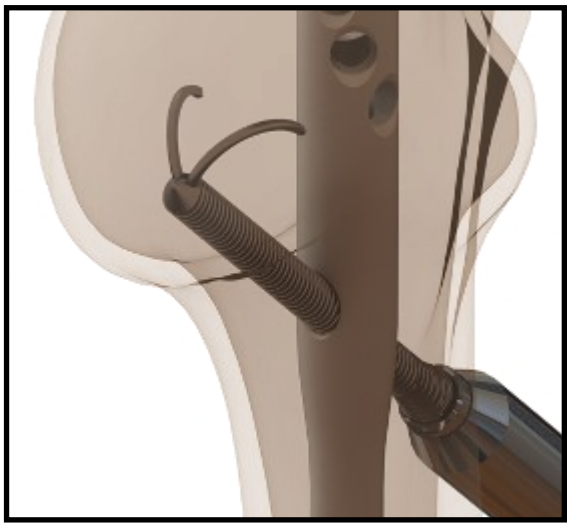


Fig. 15-4

TALONS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.

End Cap Selection and Placement

Note the proximal position of the nail after cortical screw placement (Fig 16 -1). **Final position should be 3-5mm below subcondylar bone**. The depth of the nail may have changed if compression was applied.

Confirm the final implant position—proximally and distally—with the image intensifier in both the AP and lateral planes. If satisfied, use the T25 Driver (ODI-T156) to loosen the Nail-Handle Connector Screw (ODI-T171) and remove the Guide Handle (ODI-T172).

Mate the chosen end cap with the T25 Driver (ODI-T156) (Fig. 16-2).

Bring the end cap to the head of the nail—the lead-in segment should help orient the end cap with the head of the nail. Turn the driver clockwise to engage the cap (Fig 16-3).

A locking end cap (AHN-11-CXX-L) may be chosen to create a fixed angle implant through static compression with proximal screw.

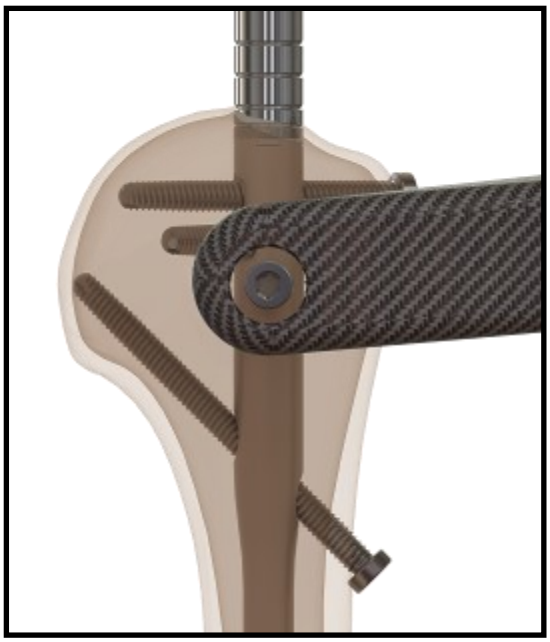


Fig. 16-1

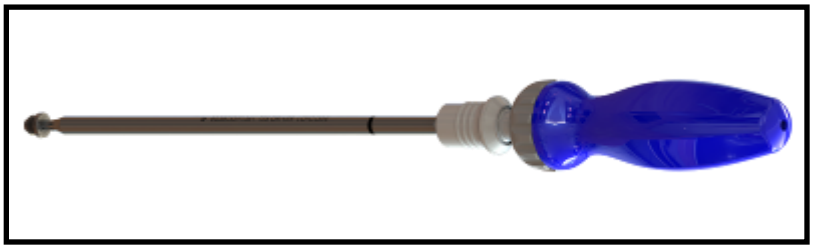


Fig. 16-2

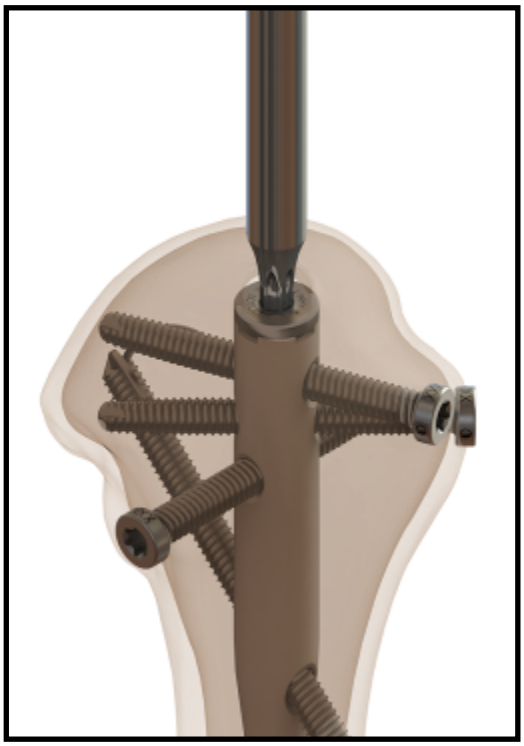
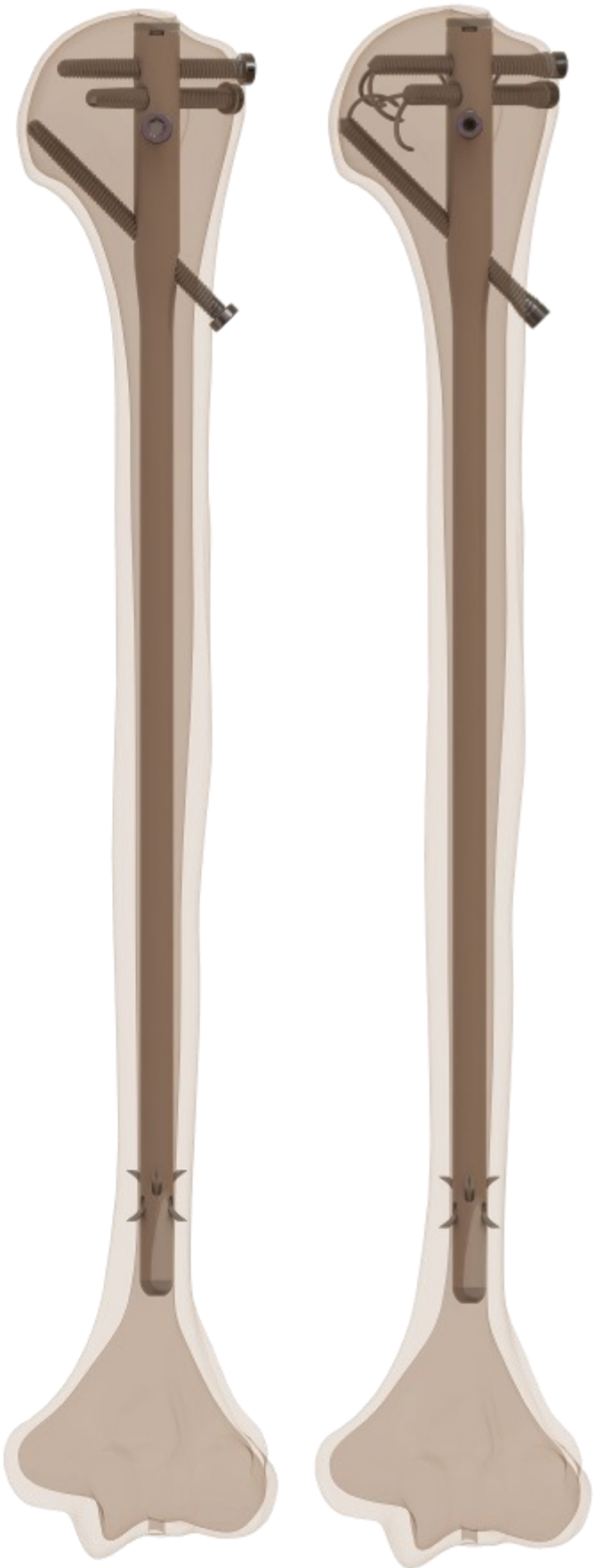


Fig. 16-3



Implant Removal—Optional

End Cap Removal

Implant removal is an elective procedure. Clear any blockage that may have grown into the hex socket of the end cap. Remove the end cap with the T25 Driver (ODI-T156) (Fig. 18-1).

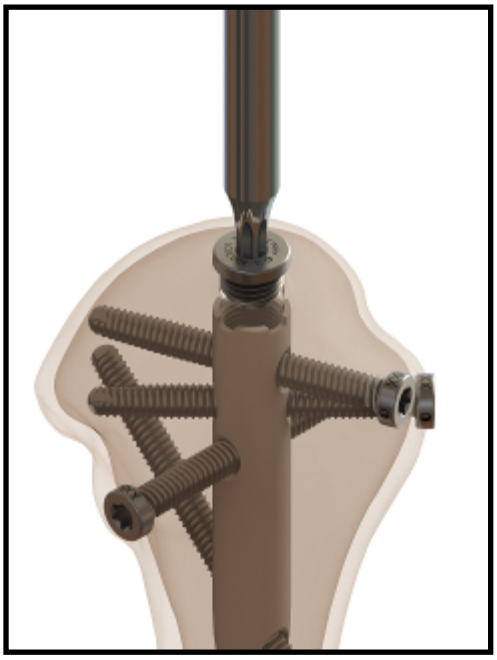


Fig. 18-1

Cortical Screw Removal

Clear any debris that may have grown into the T25 socket of the cortical screws. Remove cortical screws with the T25 Driver (ODI-T156) (Fig. 18-2).

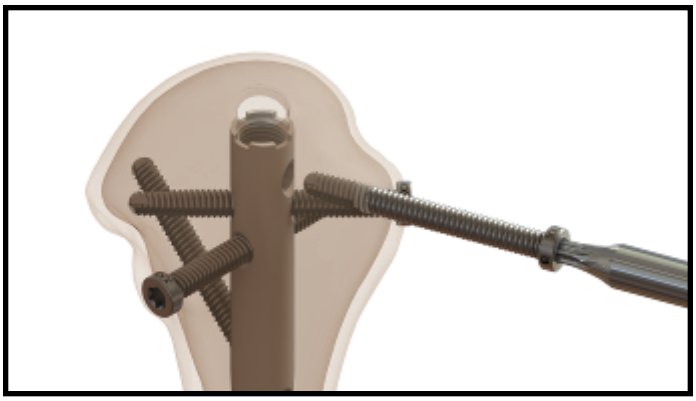


Fig. 18-2

Atlas™ Screw Removal

Clear any debris that may have grown into the T25 socket of the Atlas screws. Mate the Atlas Screw Retraction Driver (ODI-T169) with the Atlas screw and connect the Palm Handle (ODI-T181) to the Atlas Screw Retraction Driver. Insert the Atlas Screw Retraction Connector (ODI-T170) through the Atlas Screw Retraction Driver assembly and into the Atlas Screw (Fig 18-3). Thread the Retraction Connector into the Atlas Screw. Rotate the Palm Handle counter clockwise to retract the Talons.

Remove the Atlas Screw with the Atlas Screw Retraction Driver.

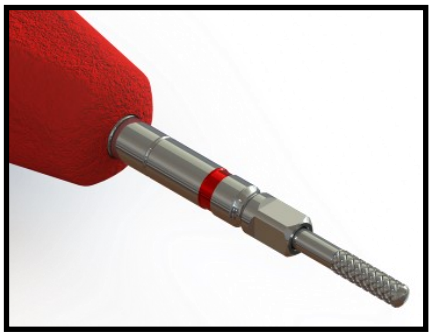


Fig. 18-3

Be sure to remove all screws before proceeding (Fig 18-4).

Fig. 18-4

MISCELLANEOUS

Implant Removal—Optional (cont.)

Connect the Talon Driver (ODI-T114) to the Torque-Limiting Handle (ODI-T119). Pass the driver down the nail and engage the Talon mechanism. Ensure the driver is fully seated in the mechanism before turning. Turn counterclockwise to retract the Talons (Fig. 19-1).

Confirm radiographically that the Talons are fully retracted (Fig. 19-2). Remove the Talon Driver.

Pass the Extractor Shaft (ODI-T177) through the Slide Hammer (ODI-T125) and connect the Extractor to the head of the nail. Extract the nail via gentle blows of the Slide Hammer against the Extractor (Fig. 19-3).

Note: Countertorque may be required to fully retract the talons. If required, the Guide Handle (ODI-T172) may be used to provide contertorque. Secure the nail to the handle with the Nail-Handle Connector Screw (ODI-T171) using the T25 Driver (ODI-T156). Ensure the screw is tightly secured before applying countertorque to handle.

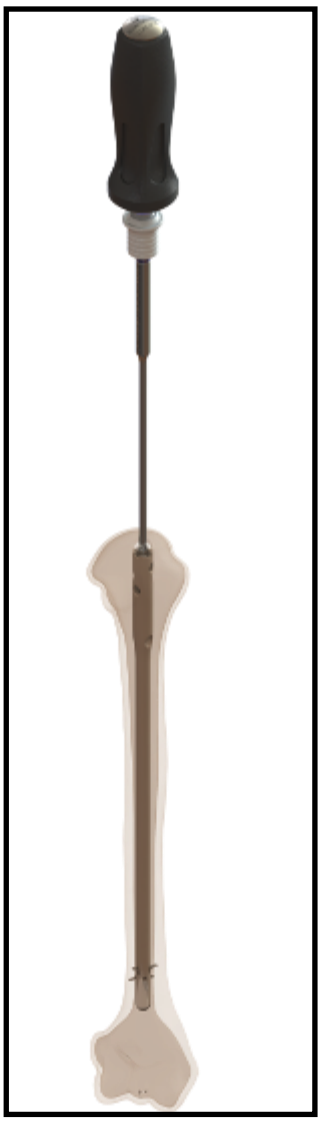


Fig. 19-1

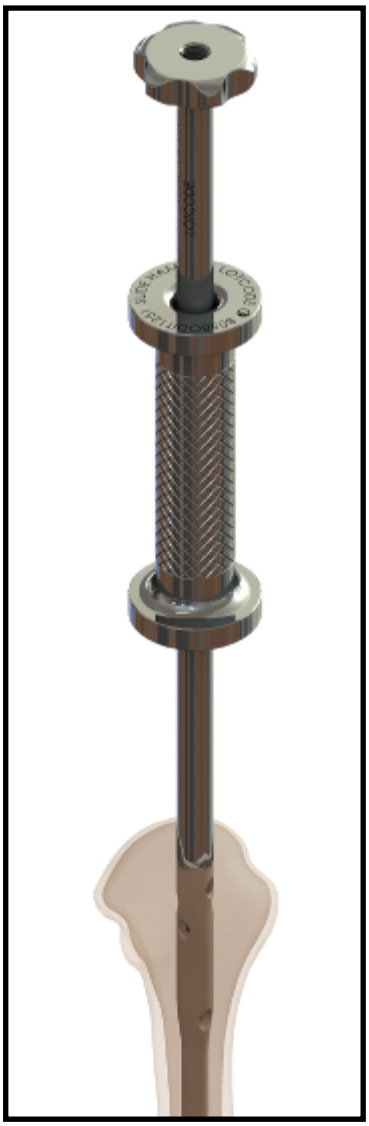


Fig. 19-3

Fig. 19-2

MISCELLANEOUS

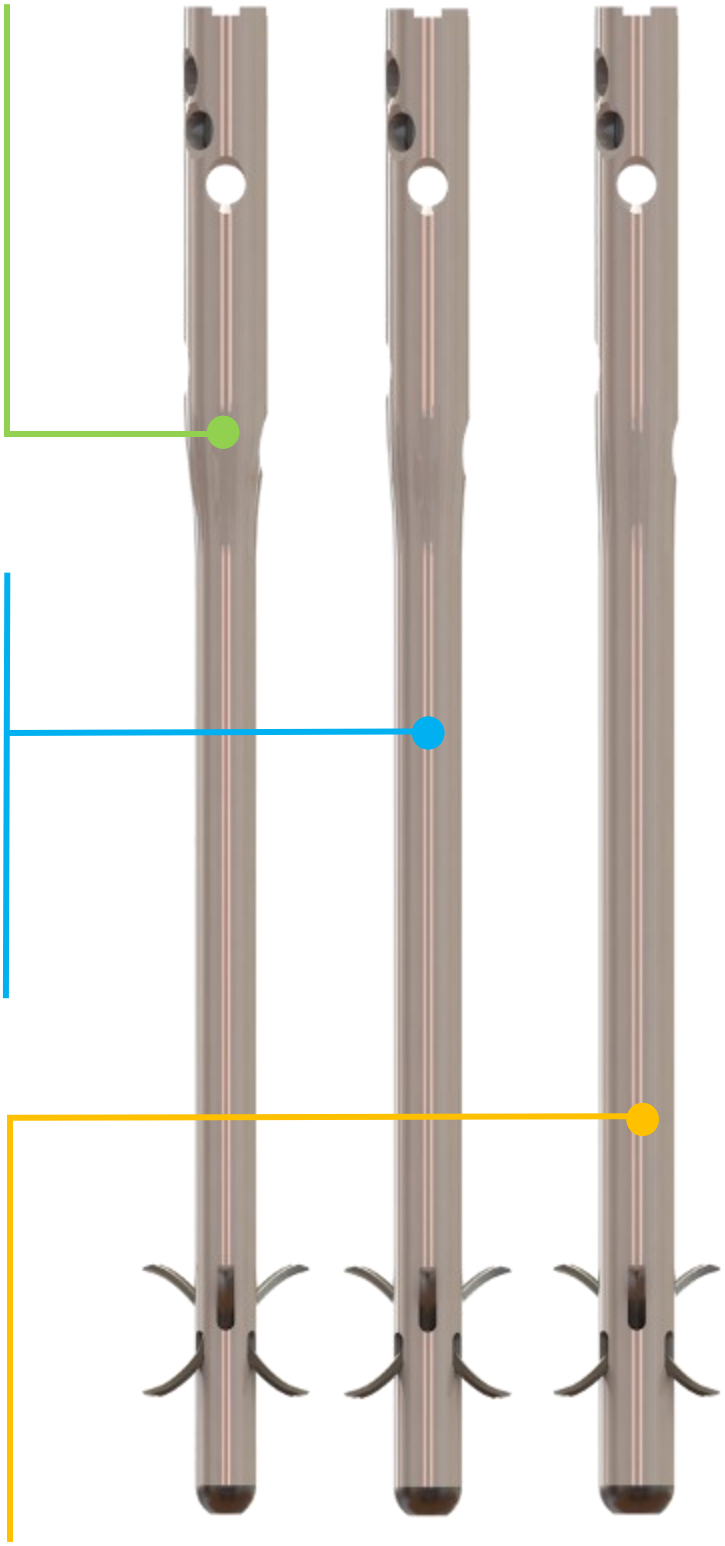
Implant Catalog — Single Use Only

Nails - Left

Length (mm)	8mm DIAMETER
165	AHN-08-165L
180	AHN-08-180L
195	AHN-08-195L
210	AHN-08-210L
225	AHN-08-225L
240	AHN-08-240L
255	AHN-08-255L
270	AHN-08-270L
285	AHN-08-285L
300	AHN-08-300L
315	AHN-08-315L

Length (mm)	9mm DIAMETER
165	AHN-09-165L
180	AHN-09-180L
195	AHN-09-195L
210	AHN-09-210L
225	AHN-09-225L
240	AHN-09-240L
255	AHN-09-255L
270	AHN-09-270L
285	AHN-09-285L
300	AHN-09-300L
315	AHN-09-315L

Length (mm)	10mm DIAMETER
165	AHN-10-165L
180	AHN-10-180L
195	AHN-10-195L
210	AHN-10-210L
225	AHN-10-225L
240	AHN-10-240L
255	AHN-10-255L
270	AHN-10-270L
285	AHN-10-285L
300	AHN-10-300L
315	AHN-10-315L

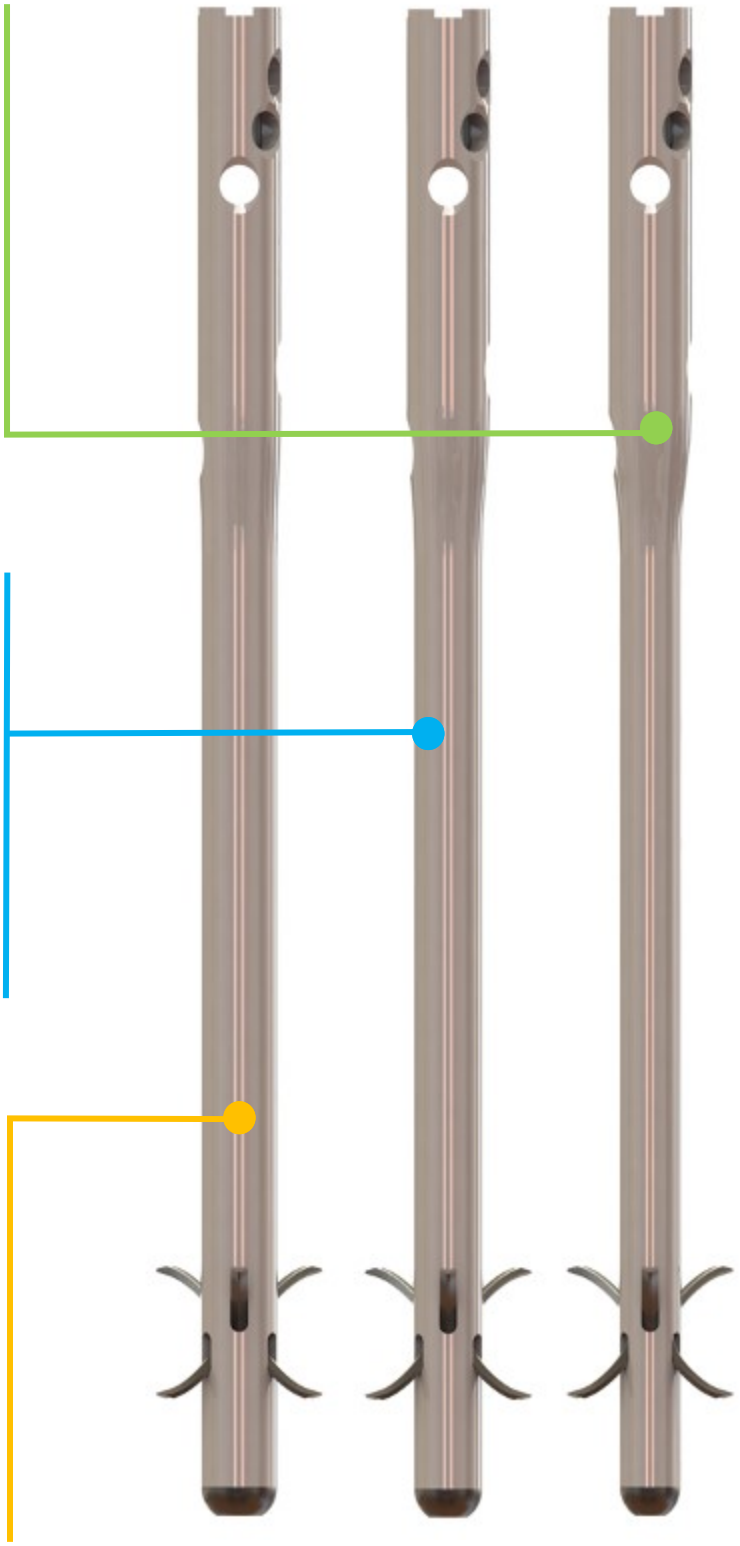


Nails - Right

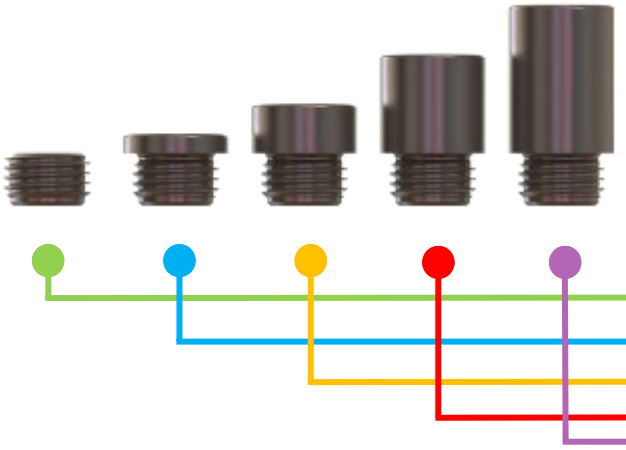
Length (mm)	8mm DIAMETER
165	AHN-08-165R
180	AHN-08-180R
195	AHN-08-195R
210	AHN-08-210R
225	AHN-08-225R
240	AHN-08-240R
255	AHN-08-255R
270	AHN-08-270R
285	AHN-08-285R
300	AHN-08-300R
315	AHN-08-315R

Length (mm)	9mm DIAMETER
165	AHN-09-165R
180	AHN-09-180R
195	AHN-09-195R
210	AHN-09-210R
225	AHN-09-225R
240	AHN-09-240R
255	AHN-09-255R
270	AHN-09-270R
285	AHN-09-285R
300	AHN-09-300R
315	AHN-09-315R

Length (mm)	10mm DIAMETER
165	AHN-10-165R
180	AHN-10-180R
195	AHN-10-195R
210	AHN-10-210R
225	AHN-10-225R
240	AHN-10-240R
255	AHN-10-255R
270	AHN-10-270R
285	AHN-10-285R
300	AHN-10-300R
315	AHN-10-315R

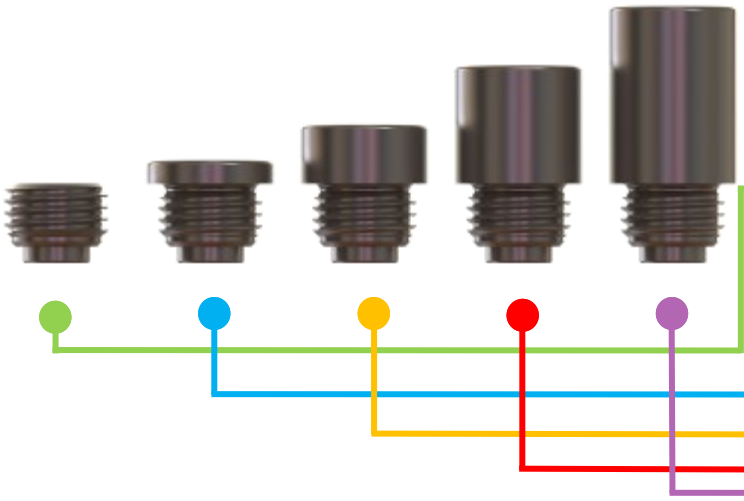


Implant Catalog — Single Use Only



End Caps

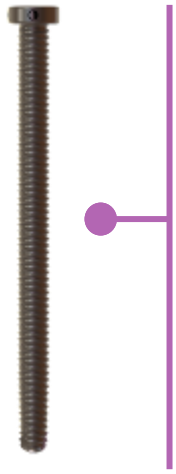
Length (mm)	11mm DIAMETER
0	AHN-11-C00
2	AHN-11-C02
5	AHN-11-C05
10	AHN-11-C10
15	AHN-11-C15



Locking End Caps

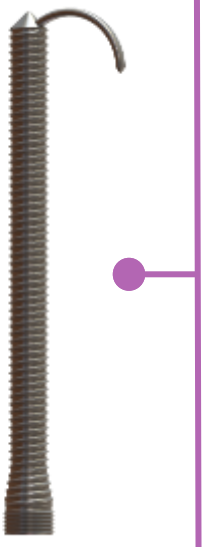
Length (mm)	11mm DIAMETER
0	AHN-11-C00-L
2	AHN-11-C02-L
5	AHN-11-C05-L
10	AHN-11-C10-L
15	AHN-11-C15-L

Cortical Screws



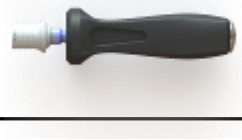
Length (mm)	5mm DIAMETER	Length (mm)	5mm DIAMETER
18	AHN-5-018	56	AHN-5-056
20	AHN-5-020	58	AHN-5-058
22	AHN-5-022	60	AHN-5-060
24	AHN-5-024	64	AHN-5-064
26	AHN-5-026	68	AHN-5-068
28	AHN-5-028	72	AHN-5-072
30	AHN-5-030	76	AHN-5-076
32	AHN-5-032	80	AHN-5-080
34	AHN-5-034	84	AHN-5-084
36	AHN-5-036	88	AHN-5-088
38	AHN-5-038	92	AHN-5-092
40	AHN-5-040	96	AHN-5-096
42	AHN-5-042	100	AHN-5-100
44	AHN-5-044	104	AHN-5-104
46	AHN-5-046	108	AHN-5-108
48	AHN-5-048	112	AHN-5-112
50	AHN-5-050	116	AHN-5-116
52	AHN-5-052	120	AHN-5-120
54	AHN-5-054		

Atlas™ Screws



Length (mm)	5mm DIAMETER	Length (mm)	5mm DIAMETER
36	AS-5-036	68	AS-5-068
38	AS-5-038	72	AS-5-072
40	AS-5-040	76	AS-5-076
42	AS-5-042	80	AS-5-080
44	AS-5-044	84	AS-5-084
46	AS-5-046	88	AS-5-088
48	AS-5-048	92	AS-5-092
50	AS-5-050	96	AS-5-096
52	AS-5-052	100	AS-5-100
54	AS-5-054	104	AS-5-104
56	AS-5-056	108	AS-5-108
58	AS-5-058	112	AS-5-112
60	AS-5-060	116	AS-5-116
64	AS-5-064	120	AS-5-120

Atlas™ Humeral Nail—Reusable Instruments

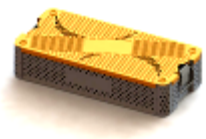
Part Number	Description	
ODI-T113	Guide Wire Ruler	
ODI-T114	Talon Driver	
ODI-T116	Radiographic Talon Template	
ODI-T119	Torque Limiting Handle (44 in-lb)	
ODI-T120	Ratcheting Axial Handle	
ODI-T125	Slide Hammer	
ODI-T130	Wire Pusher	
ODI-T153	Guide Sleeve	
ODI-T154	Drill Sleeve	
ODI-T155	Obturator	

MISCELLANEOUS

Atlas™ Humeral Nail—Reusable Instruments

Part Number	Description	
ODI-T156	T25 Driver	
ODI-T157	4.3mm Graduated Cortical Drill	
ODI-T160	Tissue Protector	
ODI-T161	7mm Hex Driver	
ODI-T168	Atlas Screw Deployment Driver	
ODI-T169	Atlas Screw Retraction Driver	
ODI-T170	Atlas Screw Retraction Connector	
ODI-T171	Nail-Handle Connector Screw	
ODI-T172	Guide Handle	
ODI-T173	Handle-Arm Connector Screw	

Atlas™ Humeral Nail—Reusable Instruments

Part Number	Description	
ODI-T174	Guide Arm	
ODI-T175	Entry Reamer	
ODI-T176	Impactor	
ODI-T177	Extractor Shaft	
ODI-T178	Reduction Rod	
ODI-T180	Drill Depth Gauge	
ODI-T181	Palm Grip Axial Handle	
ODI-T182	AHN Instrument Tray	

MISCELLANEOUS

Part Number	Description	
ODI-D101	Ball Tip Sheathed Guide Wire 2.2mm x 600mm	
ODI-D102	Trocar Tip Guide Wire 2.5mm x 280mm	

Notes

Important Medical Information

The use of surgical implants provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as an aid 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 subject to repeated stress in use, which can result in metal fatigue.

1. NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.

   Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses, which are transmitted by the body to any temporary internal fixation device, prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.

   Special precautions are necessary if a temporary internal fixation device is used to treat an unstable fracture. These fractures are more difficult to reduce and result in unusually strong unbalanced muscle forces, which cause greater stress to be transmitted to the temporary internal fixation device than with other types of humeral fractures. These stresses increase the possibility of implant bending or breakage.

   NOTE: Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instruction could lead to breakage of the implant, requiring revision surgery to remove the device.

2. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The size and shape of the human bone presents limiting restrictions on the size and strength of the implants.

3. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of temporary internal fixation devices. See the specific surgical technique for surgical procedure.

4. In evaluating patients for orthopedic appliance application, the patient's weight, occupation, activity level, mental condition, foreign body sensitivity, and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning.

5. CORRECT HANDLING OF IMPLANTS IS EXTREMELY IMPORTANT. The device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.

   If metal screws, wire bands or other metallic devices are to be used together with a particular temporary internal fixation device, all such devices should be manufactured from materials having similar composition, to avoid the possibility of galvanic corrosion or other metallic reactions.

6. NO METALLIC SURGICAL IMPLANT SHOULD BE REUSED. Any metal implant, once used, should be discarded. Even though it appears undamaged, stresses from prior use may create small defects and internal stress patterns which may lead to fatigue failure.

7. Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of weight bearing or muscle activity. An active patient, debilitated or demented patient, who cannot properly use weight support devices, may be particularly at risk during postoperative rehabilitation.

8. REMOVAL OF THE DEVICE. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.

9. SCREWS WARNING. This device is not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic, or lumbar spine.

10. Implants that are provided sterile should be stored unopened in their protective packaging. Inspect packages for damage prior to surgery. Products not labeled as sterile are non-sterile.
    Instruments should be cleaned between each surgical procedure. Orthopedic Designs North America recommends using the validated cleaning instructions provided in “Instructions for Use: Reusable Orthopedic Surgical Instruments” (7019).
    Prior to use, instruments and non-sterile implants should be steam sterilized after removal of any non-autoclavable protective packaging and labeling. Instruments and non-sterile implants should be sterilized using only FDA-cleared sterilization barriers (e.g. pouches, wraps or containers). The following process parameters are validated by Orthopedic Designs North America and recommended for sterilization and/or resterilization:

Method	Cycle	Temperature	Exposure Time	Minimum Dry Time*
Steam	Gravity	250°F (121°C)	30 minutes	30 minutes
Steam	Gravity	270°F (132°C)	15 minutes	30 minutes
Steam	Prevacuum	270°F (132°C)	4 minutes	30 minutes

*Refers to in chamber dry time. Please note that dry times may vary due to differences in the user’s packaging materials, environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. It is the user’s responsibility to validate the appropriate drying time with the sterilization equipment and sterilization load used.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

ORTHOPEDIC DESIGNS
NORTH AMERICA, INC.

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The symbols glossary is provided electronically at:

WWW.ODI-NA.COM/SYMBOLS-GLOSSARY

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