Navy A/R Femoral Nail

Surgical Technique

Dunitech

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Dunitech
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Get Better

Expertise and enthusiasm can be perfectly
combined into a top-notch medical engineering company!

We contribute to the development of health services by providing superior technology products at competitive costs.

We envision a socially conscious business environment serving the health industry and patients get better.

Dunitech branded products are designed and engineered to keep our promise;

Easier *Operation*
Better *Fixation*

Navy A/R Femoral Nail Specifications

Navy A/R Femoral Nail Indications

TABLE OF CONTENTS

Navy A/R Femoral Nail

INTRODUCTION

SURGICAL TECHNIQUE

RETROGRADE APPROACH

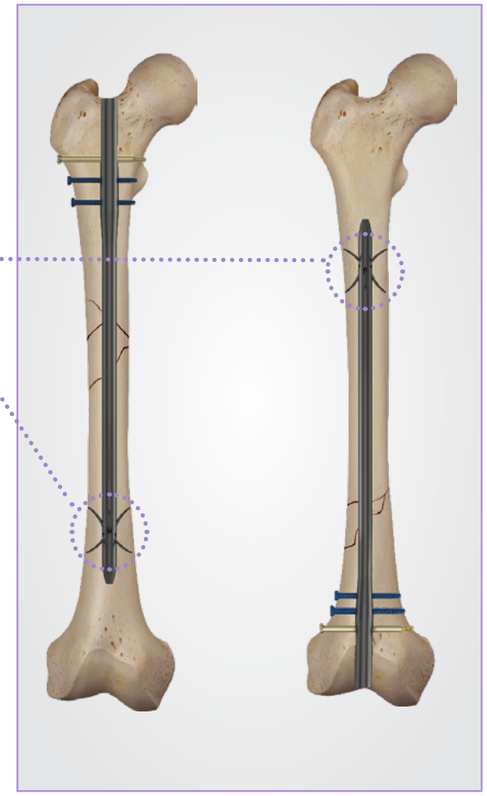
NAIL REMOVAL

Claw Technology

Dunitech leads innovational systems and aims to supply options for the surgeons to excel at their expertise. Claws are a novelty solution on distal locking systems designed to support the orthopedic trauma community.

Claws are titanium pins that act as anchors to provide a stable fixation, as well as other superior operative parameters.

- *Claws are made from titanium, and mechanically deploy from within the nail.*
- *Claws penetrate through the cancellous bone, and anchor in the cortical bone.*



We focus on operative parameters that are vital for the success of the fracture treatment.

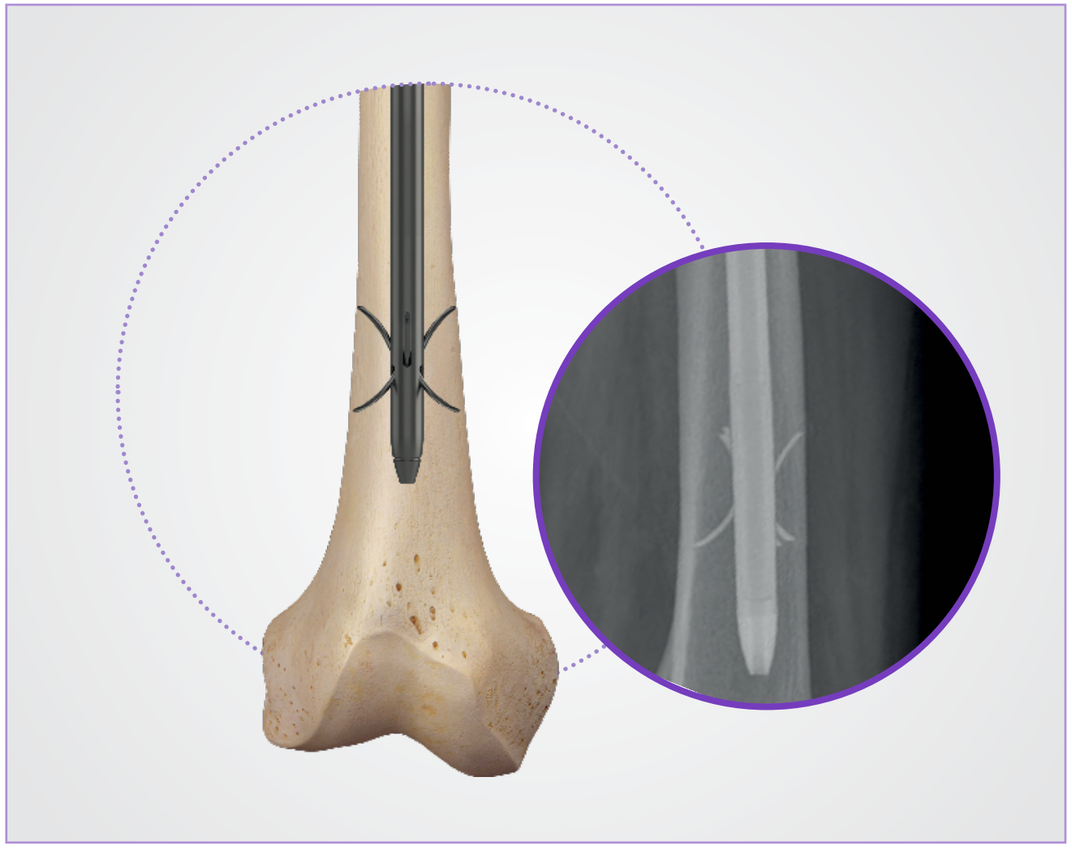
Dunitech's innovative devices allow healthcare professionals to reduce surgical time as well as the risk of pre - and postoperative complications.

By eliminating the distal incisions, Claws significantly reduce the radiation exposure and blood loss.

- *Increased stability*
- *Shorter operative time*
- *Lower radiation exposure*
- *Fewer incisions*
- *Easy revision*
- *No free-hand locking*
- *Less bone removal*

Get Better Stability!

Six retractable Claws are designed to penetrate the cortex and provide exceptional axial and rotational stability.



Less Radiation Exposure

Claws significantly reduce the radiation exposure of the team in the operating room by avoiding the need of targeting the distal hole, reaming and inserting a screw for distal locking.[1, 2]

Fewer Incisions

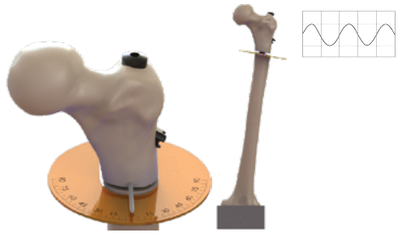
The nail is anchored by the Claws deployed from within the medullary canal. By avoiding extra incision, there will be fewer surgical scars, lower blood loss and shorter operative time while lowering the risk of infection.[2]

1. Çamurcu Y, Sofu H, Issın A, Koçkara N, Genç E, Çetinkaya M. Is talon tibial intramedullary nailing clinically superior compared to conventional locked nailing? Eklem Hastalik Cerrahisi. 2017 Dec; 28(3):152-7.
2. Zehir S, Şahin E, Zehir R. Comparison of clinical outcomes with three different intramedullary nailing devices in the treatment of unstable trochanteric fractures. Ulus Travma Acil Cerrahi Derg 2015, Vol. 21, No. 6.

Claws are
reliably retractable!

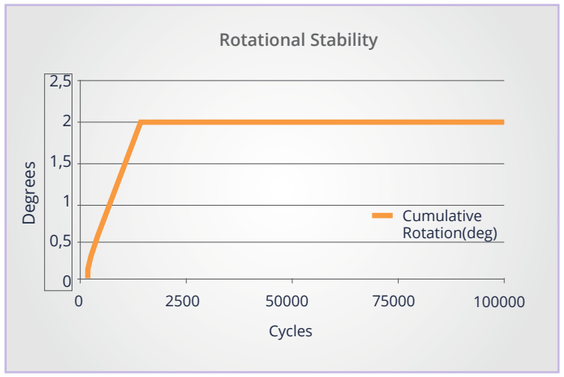
All Claws were **successfully retracted** after every test.

Conventional systems are subjected to screw breakage, screw head wear and drill bit breakage that may prevent the nail to be removed. Dunitech Claws are deployed within the nails from precise holes in a tight fit, preventing empty spaces for bone ingrowth.



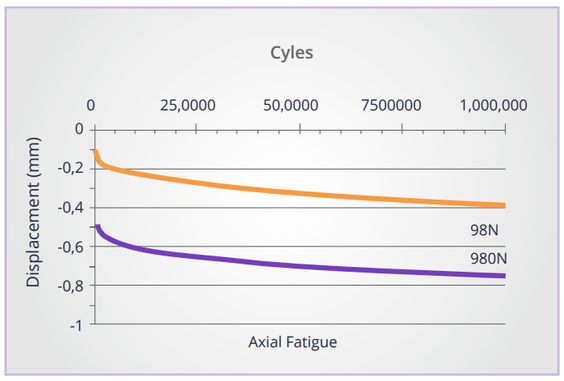
Rotational Stability

In unstable subtrochanteric fractures Claws provide superior rotational stability. After 10,000 cycles, the nail settled in and remained fixed until 100,000 cycles.



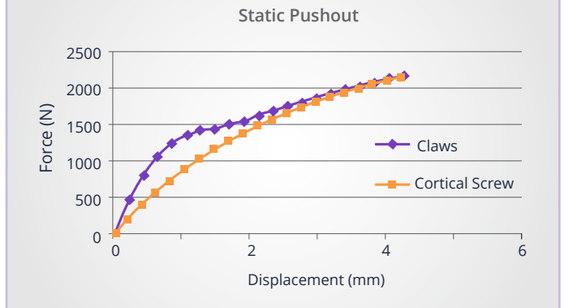
Claw's Axial Fatigue Strength

The average displacement observed at 1 million cycles was 0.74 mm.



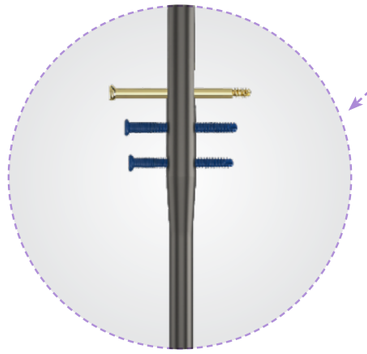
Claw's Axial Static Strength

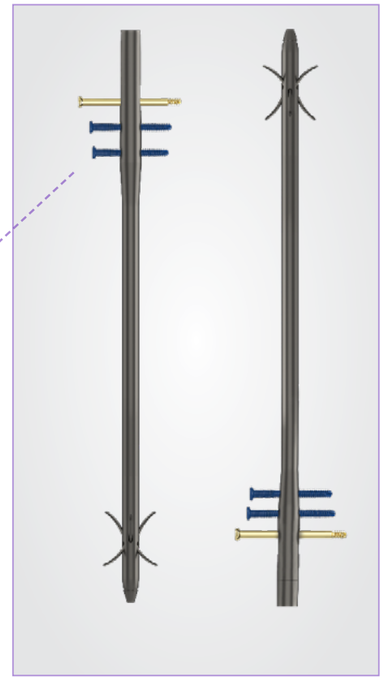
Claws resists to a higher force for a given displacement, compared to conventional stainless steel screws.



NAVY KEY FIGURES

- **Nail length:** 280 mm to 460 mm in 20 mm increment
- **Proximal Diameter:** 13 mm
- **Distal Diameter:** 10 mm to 13 mm in 1 mm increment
- **Distal Claw Maximum Span:** 38 mm (11-12-13 mm)
  26 mm (10 mm)
- **Compression Range:** 10 mm
- **End Cap Length:** 0 mm to 15 mm in 5 mm increments





COMPRESSION AND CORTICAL SCREWS' KEY FIGURES

- **Length:** 30 mm to 120 mm in 5 mm increment
- **Diameter:** 5 mm

Internal thread to secure the screw to the 5 mm Hex Driver

Compression Screw with threaded tip and 5 mm shaft to withstand compression load

Navy A/R Femoral Nail Indications

INDICATIONS

- Femoral Shaft Fractures
- Ipsilateral hip / shaft fractures
- Ipsilateral femur / tibia fractures (floating knee)
- Supracondylar fractures including those with intraarticular extension
- Fractures proximal to a knee implant
- Osteoporotic fractures
- Pathologic / impending pathologic fractures
- Malunions / nonunions

PRECAUTIONS

Navy A/R Femoral nails and accessories were not evaluated for safety and compatibility in magnetic resonance (MR) environment and no tests for heating or migration were conducted for this product in MR environment.

CONTRAINDICATIONS

- In a leg with a total knee implant (for retrograde technique)
- Fractures of the distal third (for antegrade technique)
- Femoral neck fractures

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

- Infection
- Incomplete fusion of the epiphysis
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure
- Metal sensitivity or allergic reaction to foreign bodies
- Loss of bone stock or insufficient bone quality to support the device
- Obliterated or narrow medullary canal
- Obese patients
- In the same region as a pre-implanted screw plate
- In comminuted and/or intraarticular fractures
- In open fractures with inadequate soft tissue cover and/or with associated arterial injury

Surgical Technique

1. Patient Positioning and Fracture Reduction

- Place the patient in the supine or lateral decubitus position according to surgeon preference on a fracture or other radiolucent table.
- Apply traction to the affected leg and place it in slight adduction to ease access to the piriformis fossa and intramedullary canal. Alternatively, the torso can be abducted 10-15° towards the unaffected leg. The unaffected leg should be placed in a leg holder or extended away from the affected leg (Fig-1 and Fig-2). Position the image intensifier as to ensure that AP and lateral views of the entire femur can be easily obtained.
- Reduce the fracture as anatomically as possible through closed reduction before prepping and draping the patient with the help of image intensifier. Manual traction or a distraction device may be used to assist in fracture reduction.

Fig-1

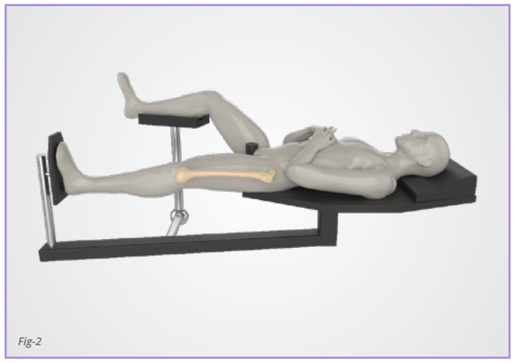


Fig-2

2. Incision and Entry Point

- Make a longitudinal incision proximal to the greater trochanter. Dissect down through the incision separating the gluteus medius in line with the fibers and palpate the proximal femur.
- The entry point is in line with the femoral medullary canal in both AP and lateral views. Typically, the entry point coincides with the piriformis fossa (Fig-3), but it may vary depending on the patient's anatomy.

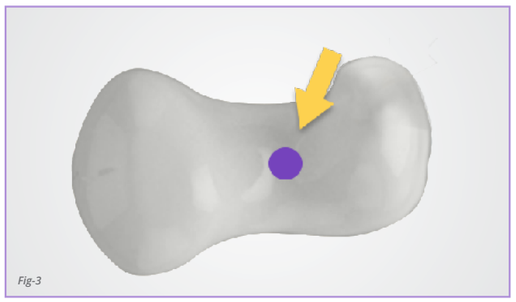
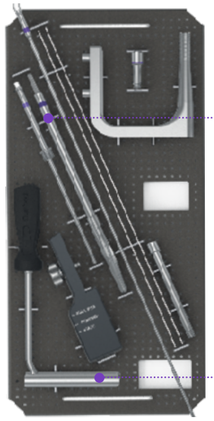


Fig-3

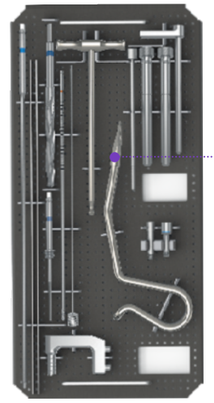
INSTRUMENTS FOR ACCESSING THE CANAL AND PROXIMAL REAMING



Navy Entry Reamer (N03-0030)

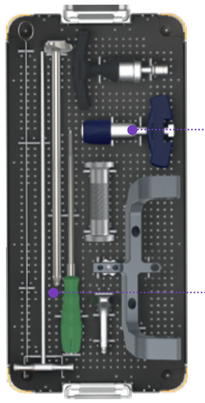
Tissue Protector (N01-0150)

Navy Set Tray 1



Entry Awl (N01-0040)

Navy Set Tray 2



Pin Puller (N01-0080)

Reduction Awl (N01-0090)

Navy Set Tray 3

Trocar Tip Guide Wire 3 mm x 600 mm (N01-0250)

Ball Tip Guide Wire 2 mm x 900 mm (N01-0290), for Navy 10 mm

2 mm Guide Wire Sheath (N01-0300), for Navy 10 mm

Ball Tip Guide Wire 3 mm x 900 mm (N01-0270), for Navy 11 mm to 13 mm

3 mm Guide Wire Sheath (N01-0280), for Navy 11 mm to 13 mm

3. Accessing the Canal

Option 1: Trocar Tip Guide Wire

INSTRUMENTS:

- ✔ *Trocar Tip Guide Wire 3 mm x 600 mm (N01-0250)*

- Advance the 3 mm Trocar Tip Guide Wire through the entry point and into the proximal femur with the help of a powered driver.
- The wire should be centered in the canal on the AP and lateral views (Fig-4 and Fig-5).
- Withdraw and reposition the wire as necessary.

Fig-4

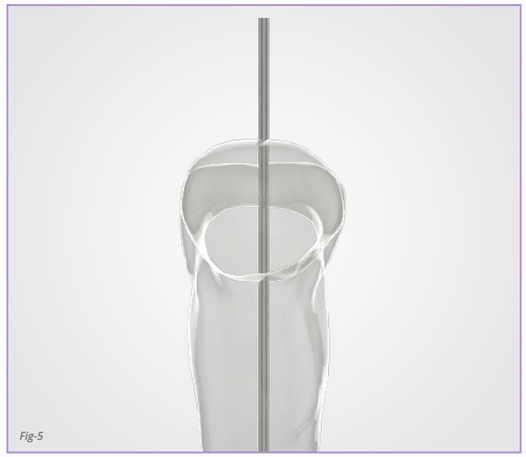


Fig-5

Option 2: Entry Awl and Trocar Tip Guide Wire

INSTRUMENTS:

- ✔ *Entry Awl (N01-0040)*
- ✔ *Trocar Tip Guide Wire 3 mm x 600 mm (N01-0250)*

- Insert the Entry Awl through the incision and down to the bone (Fig-6). Rotate the Entry Awl back and forth to penetrate the proximal femur. Care must be taken not to displace the fracture.
- Pass the 3 mm Trocar Tip Guide Wire through the Entry Awl and down to the bone. Withdraw and reposition the wire as necessary.

Fig-6

4. Proximal Reaming

INSTRUMENTS:

- ✔ *Tissue Protector (N01-0150)*
- ✔ *Navy Entry Reamer (N03-0030)*
- ✔ *Ball Tip Guide Wire 2 mm x 900 mm (N01-0290), for Navy 10 mm*
- ✔ *2 mm Guide Wire Sheath (N01-0300), for Navy 10 mm*
- ✔ *Ball Tip Guide Wire 3 mm x 900 mm (N01-0270), for Navy 11 mm to 13 mm*
- ✔ *3 mm Guide Wire Sheath (N01-0280), for Navy 11 mm to 13 mm*
- ✔ *Pin Puller (N01-0080)*
- ✔ *Reduction Awl (N01-0090)*

- Insert the Tissue Protector through the incision and down to the bone. Secure the Navy Entry Reamer to a powered driver. Pass it over the wire and through the Tissue Protector. Ream the proximal femur to the desired depth with the help of the image intensifier.
- The grooves on the cutting blade of the Navy Entry Reamer are templates that show the position of the screws (Fig-7). The step between the cutting blades and the shank represent the end of the nail.

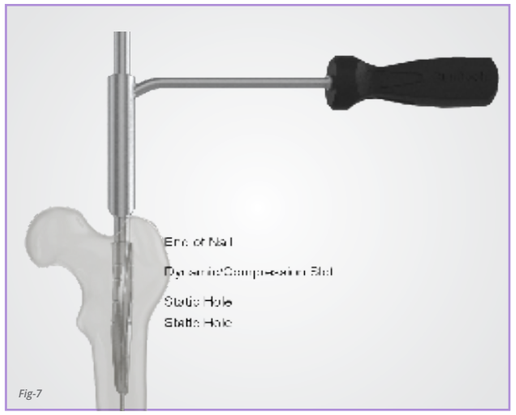


Fig-7

Note:

✔ If compression is necessary, the screws placement will be different than indicated during proximal reaming (e.g. if 5 mm compression is done, the static holes will be 5 mm more proximal than indicated by the Navy Entry Reamer).

- Exchange the 3 mm Trocar Tip Guide Wire to the Ball Tip Guide Wire and 3 mm Guide Wire Sheath. Loosen up the Pin Puller's lock and pass the Guide Wire through it. Lock the wire by rotating the Pin Puller's drum and move it to the desired depth (Fig-8). Ensure that the guide wire is in correct position with the help of image intensifier. Withdraw and reposition the wire as necessary.
- Confirm that the fracture is well reduced. If necessary use the Reduction Awl to assist with the fracture reduction or guide wire change.

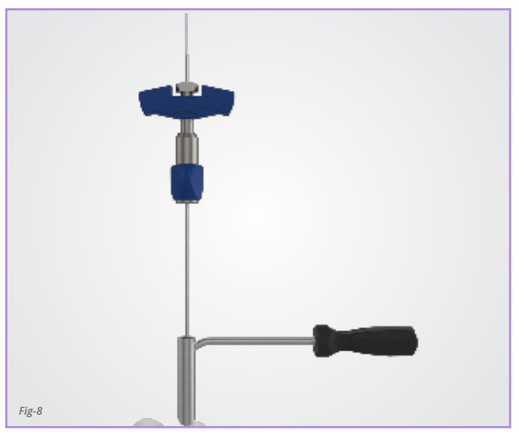
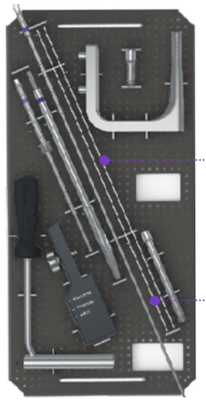


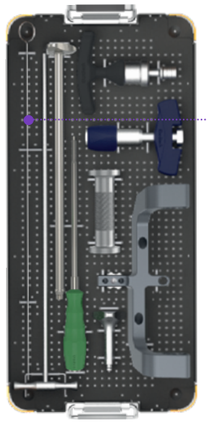
Fig-8



Navy Set Tray 1

Navy Radiographic Claw Template - 10 mm (N03-0080), for Navy 10 mm

Navy Radiographic Claw Template - 11-13 mm (N03-0090), for Navy 11-13 mm



Navy Set Tray 3

Guide Wire Pusher (N01-0060)

Modular Flexible Reamer Shaft (N01-0240)

Modular Reamer Cutter Head (N01-0XX0)

5. Determining the Nail Length

INSTRUMENTS:

- ✔ *Navy Radiographic Claw Template - 10 mm (N03-0080), for Navy 10 mm*
- ✔ *Navy Radiographic Claw Template - 11-13 mm (N03-0090), for Navy 11-13 mm*

- Confirm that the fracture is well reduced and place the appropriate Navy Radiographic Claw Template over the thigh (Fig-9). Use N03-0080 for nails with distal diameter of 10 mm and N03-0090 for nails with distal diameters between 11 to 13 mm. The template shows approximately the full opening of the Claws.
- Position the image intensifier in AP view over the distal femur to assist with the template placement. The four claws of the template should be just above the metaphyseal flare and well into the cortical bone (Fig-9b). This will help select the longest recommended nail and ensure that the Claws, when deployed, will anchor the nail correctly.
- Care should be taken to avoid placing the Claws close to the fractured site. The Claws must be deployed in unaffected bone to allow for strong nail fixation.
- Move the image intensifier to the proximal femur. Choose the length that corresponds to the nail depth defined during the proximal reaming (Fig-9a).

Note:

✔ If compression will be required, the final nail head position will be more proximal than what is read in the template. Consider the expected compression when choosing the nail's length.

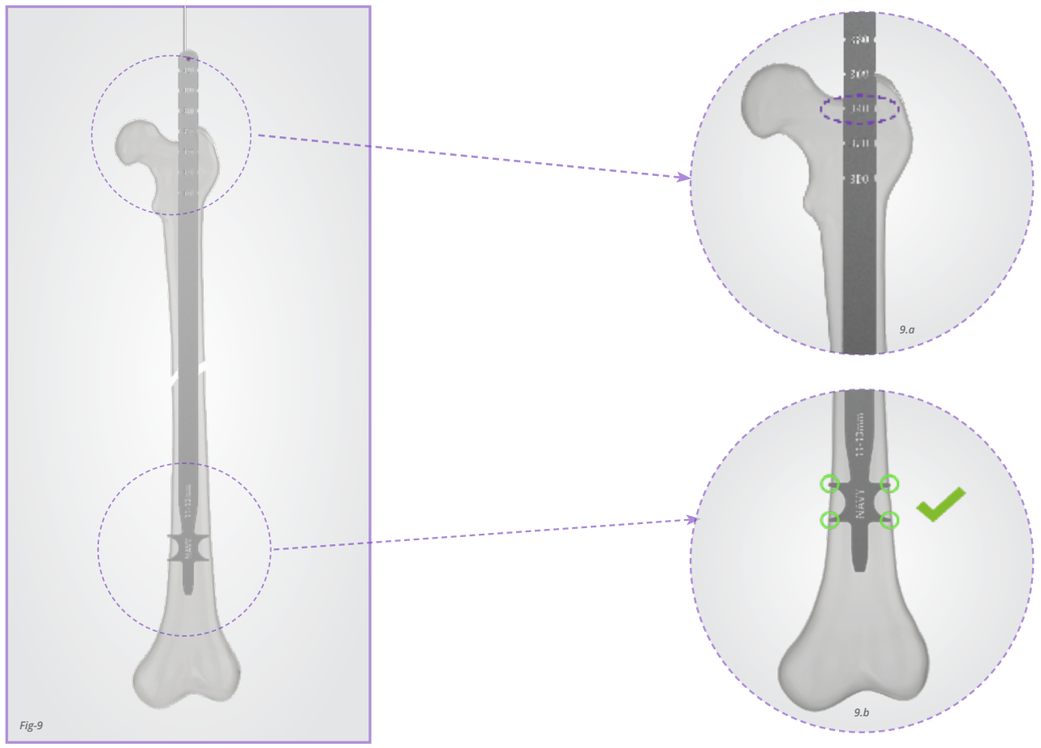


Fig-9

6. Distal Reaming

INSTRUMENTS:

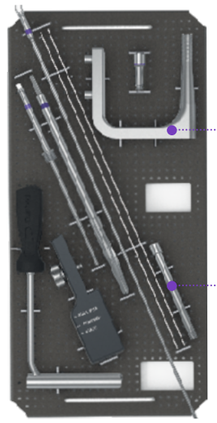
- ***Dunitech Intramedullary Reamer Set (INST-01-002)***
- ***Guide Wire Pusher (N01-0060)***

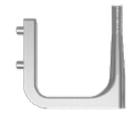
- Confirm that the fracture is well reduced. Starting from 8.5 mm Reamer Cutter Head, ream until the desired depth with a steady pressure. By each pass, increase the diameter of the Reamer Cutter Head in 0.5 mm increments. Use the Guide Wire Pusher to keep the guide wire in place. If the sheath comes out with the reamer, insert it back before starting the next pass.
- The canal should be reamed to at least 1 mm above the desired nail diameter. Ream to at least 11 mm (the nail with smallest diameter has 10 mm of distal diameter). If there's no resistance to reaming to 11 mm, increase the reaming diameter to fit the next size of nail to a maximum of 14 mm.
- To prevent accumulation of debris in the medullary canal, retract the reamer when necessary.
- After distal reaming, remove the sheath (Fig-11). The Sheath won't pass through the nail. If needed, use the Guide Wire Pusher to keep the Ball Tip Guide Wire in place.

Fig-10

Fig-11

INSTRUMENTS FOR ATTACHING THE NAIL

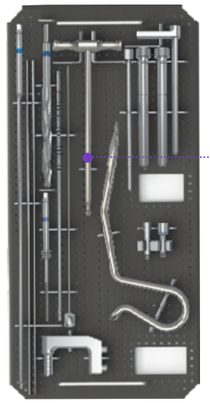




Navy Guide Handle (N03-0060)

Navy Handle-Nail Connector Screw (N03-0070)

Navy Set Tray 1



7 mm Hex Driver (N01-0030)

Navy Set Tray 2

7. Attaching the Nail

INSTRUMENTS:

- ***Navy Handle-Nail Connector Screw (N03-0070)***
- ***7 mm Hex Driver (N01-0030)***
- ***Navy Guide Handle (N03-0060)***

- The marks on the Guide Handle have the following meaning:
  - ✓ LA/RR for Left femur and Antegrade approach (LA) or Right femur and Retrograde approach (RR).
  - ✓ RA/LR for Right femur and Antegrade approach (RA) or Left femur and Retrograde approach (LR).
- For Antegrade approach, align the mark on the nail to the **LA/RR** mark on the Guide Handle for the **Left** leg or **RA/LR** for the **Right** leg.
- Mate the desired nail to the Navy Guide Handle and use the 7 mm Hex Driver to tighten the Handle-Nail Connector Screw (Fig-12). Ensure that the reference line on the nail is aligned with the correct line on the Guide Handle.
- Ensure that the connection is tight before proceeding.

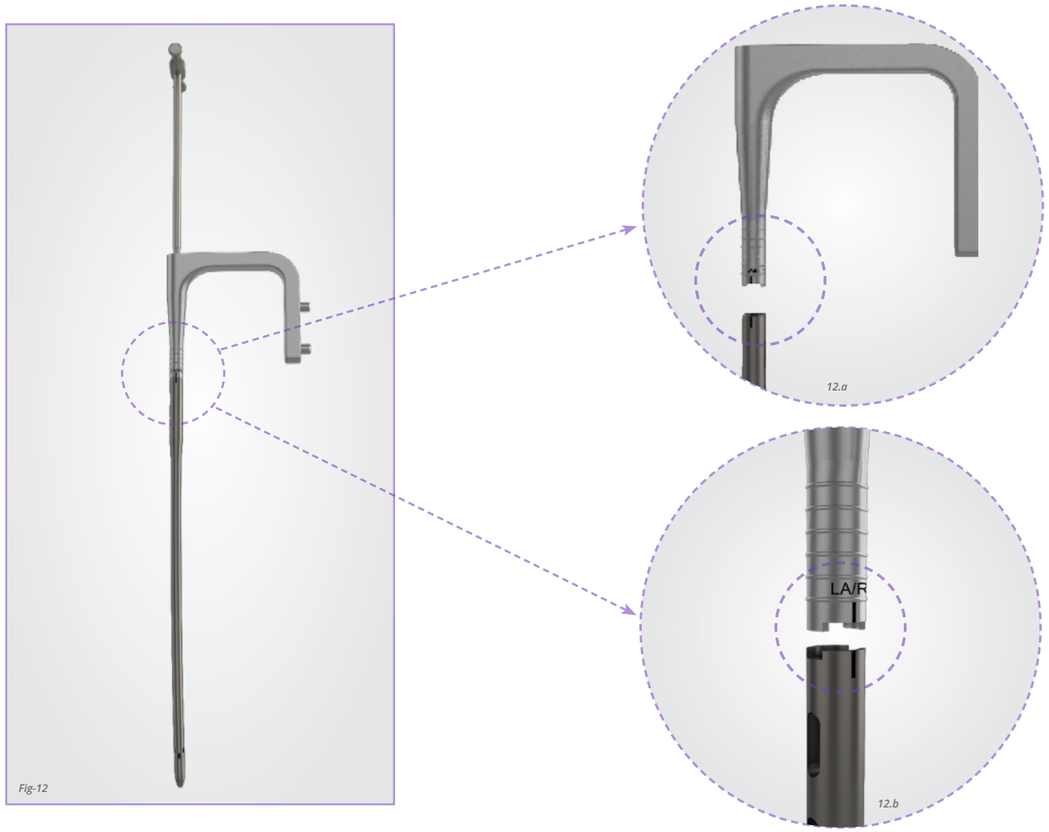
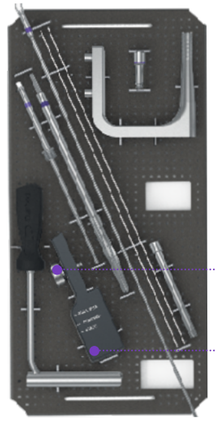
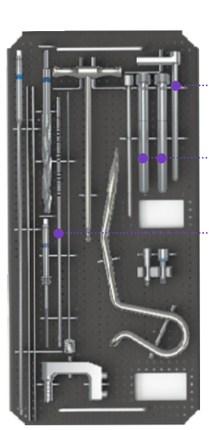


Fig-12

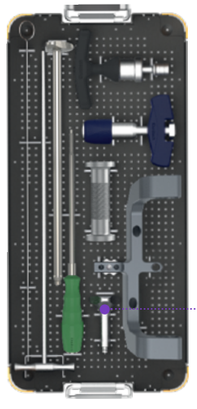
INSTRUMENTS FOR CHECKING ALIGNMENT AND INSERTING THE NAIL



Navy Set Tray 1



Navy Set Tray 2



Navy Set Tray 3

8. Checking Alignment

INSTRUMENTS:

- ✔ *Navy Guide Arm (N03-0050)*
- ✔ *Handle - Arm Connector Screw (N01-0140)*
- ✔ *Screw Sleeve (N01-0130)*
- ✔ *Drill Sleeve (N01-0120)*
- ✔ *4.2 mm Drill Bit (N01-0100)*

- Before inserting the nail check the nail's holes are correctly aligned to the holes of the Guide Arm.
- Mate the Navy Guide Arm with the Navy Guide Handle and secure them with the Handle-Arm Connector Screw.
- Insert the Drill Sleeve into the Screw Sleeve and insert this assembly into the most distal hole of the Guide Arm. Insert the 4.2 mm Drill bit through the Drill Sleeve and advance until it passes through the corresponding nail hole (Fig-13).
- Repeat the process in the other holes.
- Prior to inserting the nail, remove the Navy Guide Arm.

Fig-13

9. Inserting the Nail

INSTRUMENTS:

- ✔ *Impactor (N01-0070) - Optional*

Note:
- ✔ If the Guide Wire Sheath has not been removed, it has to be removed in before the insertion of the nail (Fig-11). The Sheath will not pass through the nail.
- ✔ If a traditional ball tip guide wire was used, it must be exchanged for a smooth guide wire. Its tip won't pass through the nail.

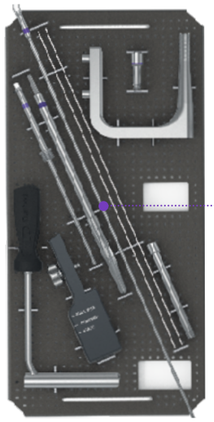
- Pass the nail over the guide wire, through the incision and into the bone. With steady pressure and gentle rotation movements, advance the nail (Fig-14). Monitor closely with the help of image intensifier the passage of the nail across the fracture site.
- If needed, the Impactor can be assembled in the Guide Handle for light hammer blows. If considerable resistance is encountered, do not use strong hammer strikes. It may cause loss of reduction or perioperative fracture. Instead, remove the nail, replace the sheath and further enlarge the medullary canal.
- The rings in the handle are spaced 5 mm from each other, they indicate the depth of the nail's head.

Note
- ✔ Do not strike the Guide Handle with a slap hammer or any other mallet.

- Once the nail is in its final position, remove the guide wire.

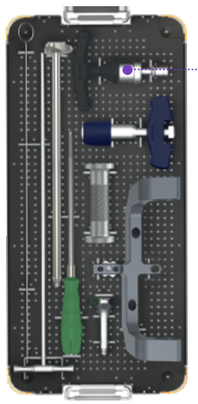

Fig-14


Fig-15



Navy Set Tray 1

Navy Claw Deployment Driver (N03-0020)



Navy Set Tray 3

Torque Limiting Handle (N01-0170)

10. Deploying Claws

INSTRUMENTS:

- ***Navy Claw Deployment Driver (N03-0020)***
- ***Torque Limiting Handle (N01-0170)***

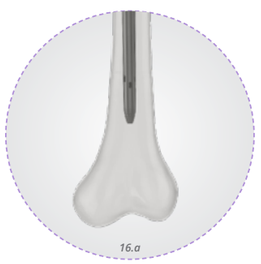
- Attach the Navy Claw Deployment Driver to the Torque Limiting Handle. Insert the driver down the nail until it engages the Claw mechanism. Rotate the handle clockwise to deploy the Claws (Fig-16). A steady low torque should be felt before the cortical bone is reached.
- An increase in torque will indicate that the Claws started penetrating the cortex. During this stage, monitor under image intensifier positioned for a lateral view to prevent excessive cortical penetration.
- Full deployment of the Claw system is reached after approximately 18 full turns of the handle. The amount of turns needed will depend on patient anatomy and nail placement.
- Stop deploying when full cortical anchoring is reached or when the Torque Limiting Handle trips to prevent excessive perforation through the cortical bone and into the soft tissue.

Note

- ✔ The Claws cannot be deployed using a powered driver. It may lead to excessive penetration and/or system failure due to over torque.
- ✔ Always use the Torque Limiting Handle to deploy the Claws.

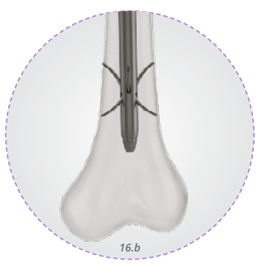
Fig-16

Before Deployment

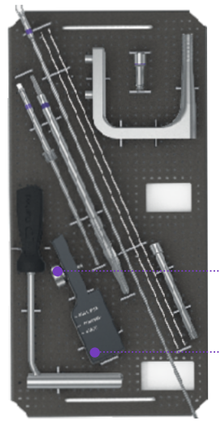


16.a

After Deployment



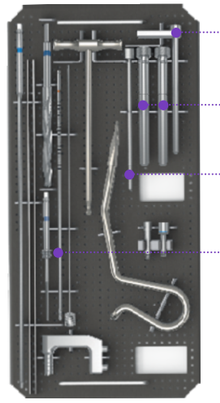
16.b



Handle-Arm Connector Screw (N01-0140)

Navy Guide Arm (N03-0050)

Navy Set Tray 1



Drill Sleeve (N01-0120)

Screw Sleeve (N01-0130)

Trocar (N01-0110)

4.2 mm Drill Bit (N01-0100)

Navy Set Tray 2

11. Proximal Locking – Drilling for Locking Screw

INSTRUMENTS:

- ✔ *Navy Guide Arm (N03-0050)*
- ✔ *Handle - Arm Connector Screw (N01-0140)*
- ✔ *Screw Sleeve (N01-0130)*
- ✔ *Drill Sleeve (N01-0120)*
- ✔ *Trocar (N01-0110)*
- ✔ *4.2 mm Drill Bit (N01-0100)*

Note

- ✔ The process for inserting any screw is the same.
- ✔ This document will use the Compression Cortical Screw placement as an example.

- Mate the Navy Guide Arm with the Navy Guide Handle and secure them with the Handle-Arm Connector Screw (Fig-17). Insert the Trocar into the Drill Sleeve and insert them into the Screw Sleeve.
- Pass the assembly through the Dyn/Comp hole in the guide arm, advance it until the skin and make a small incision. Advance the assembly until the Drill Sleeve touches the cortical bone. Tighten the Screw Sleeve to the guide arm if possible. Apply pressure with the Trocar over the bone to create a dimple in the lateral cortex (Fig-18).
- Remove the Trocar and pass the 4.2 mm Drill Bit through the Drill Sleeve. Drill through both cortices (Fig-19). With the drill bit in the far cortex and Drill Sleeve touching the lateral cortex, read the graduation in line with the Drill Sleeve (Fig-20). The measurement will indicate the screw length to be used.

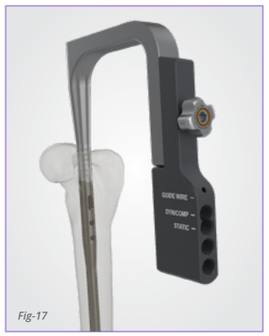
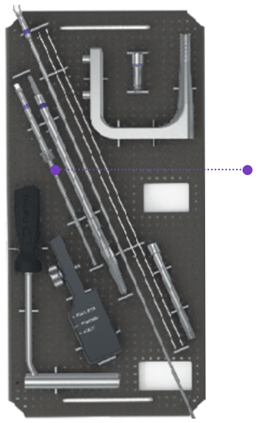


Fig-17

Fig-18

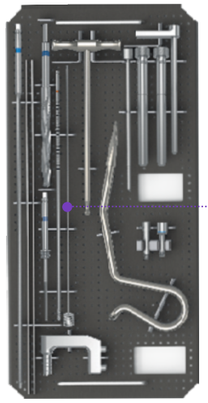
Fig-19

Fig-20



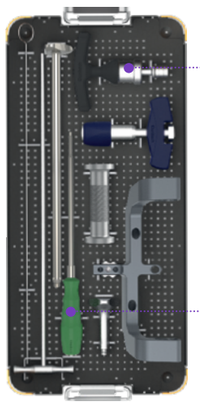
Navy Compressor (N03-0010)

Navy Set Tray 1



5 mm Hex Driver Connector Screw (N01-0010)

Navy Set Tray 2



Torque Limiting Handle (N01-0170)

5 mm Hex Driver (N01-0020)

Navy Set Tray 3

12. Proximal Locking – Inserting the Screw

INSTRUMENTS:

- ✔ *5 mm Hex Driver (N01-0020)*
- ✔ *5 mm Hex Driver Connector Screw (N01-0010)*

- Mate the 5 mm Hex Driver with the selected screw and secure with the 5 mm Hex Driver Connector Screw (Fig-21). Remove the Drill Sleeve.
- Insert the screw/driver assembly through the Screw Sleeve until it contacts the bone. Rotate the driver to thread up the screw until its head seats against the lateral cortex (Fig-22). Do not over tighten the screw as it may lead to screw stripping.
- Rotate the connector screw counterclockwise to disengage the driver from the screw (Fig-23).
- Remove the Screw Sleeve.

Note

✔ If compression is needed, make sure to use a Compression Cortical Screw. It is designed to withstand the compression loads.

Fig-21

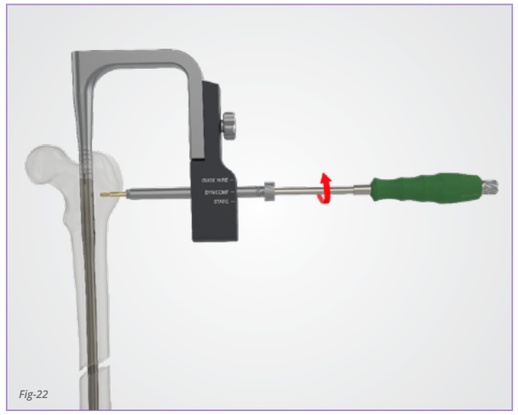


Fig-22

Fig-23

13. Proximal Locking – Compression

INSTRUMENTS:

- ***Torque Limiting Handle (N01-0170)***
- ***Navy Compressor (N03-0010)***

- Mate the Navy Compressor with the Torque Limiting Handle. Insert the compressor into the Guide Handle and through the nail. Rotate until the compressor engages the thread in the guide handle (Fig-24). Monitor the process with the help of image intensifier.
- As the compressor is rotated, the Compression Cortical Screw is pushed down the dynamic slot and the distal fragment is drawn towards the proximal fragment. Up to 10 mm of compression can be applied.
- Before releasing the compressor, insert one screw in one of the static holes to ensure that the compression will be maintained.

Note

✔ Do not over compress as it may cause the screw to fail.

✔ Do not backslap the nail against the deployed Claws to achieve compression.

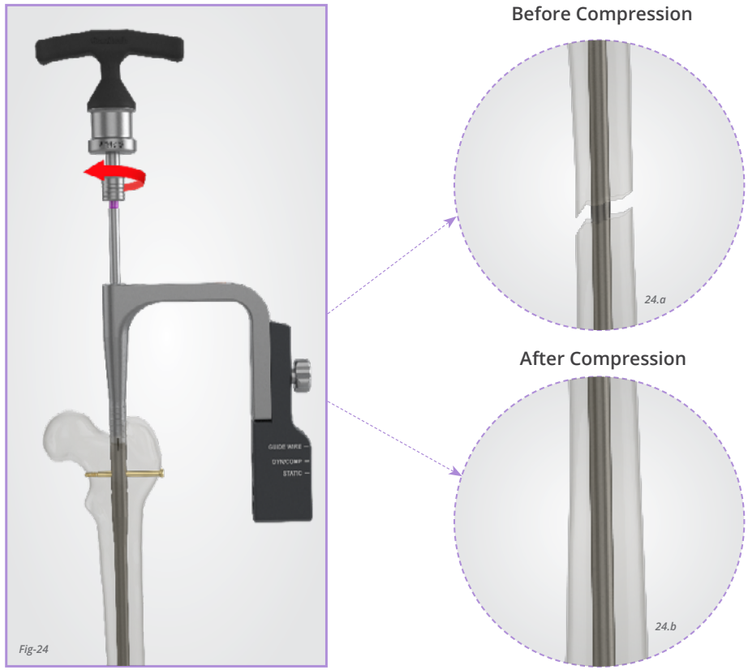


Fig-24

Before Compression

24.a

After Compression

24.b

The use of Cortical and Compression Screws are at the discretion of the surgeon, and should be tailored to the patient's needs. The common proximal locking configurations are presented below:

1. ***Static locking after fracture compression***

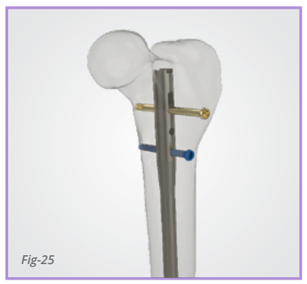


Fig-25

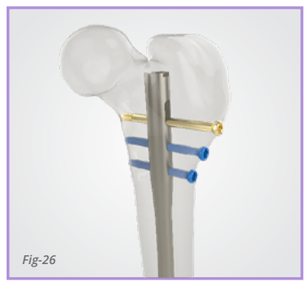


Fig-26

2. ***Dynamic configuration for postoperative compression***


Fig-27

3. ***Static configuration with possibility of future dynamization.***

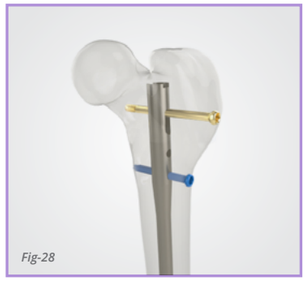
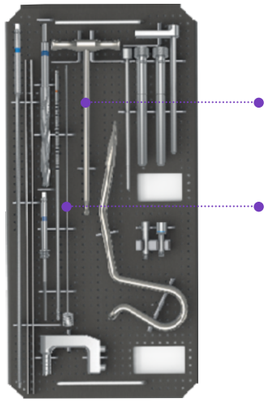


Fig-28

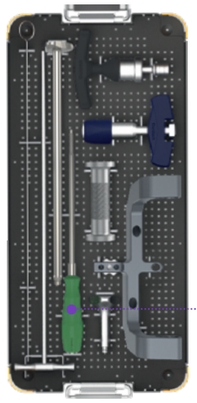
INSTRUMENTS FOR INSERTING END CAP



7 mm Hex Driver (N01-0030)

5 mm Hex Driver Connector Screw (N01-0010)

Navy Set Tray 2



5 mm Hex Driver (N01-0020)

Navy Set Tray 3

14. Inserting End Cap

INSTRUMENTS:

- *7mm Hex Driver (N01-0030)*
- *5 mm Hex Driver (N01-0020)*
- *5 mm Hex Driver Connector Screw (N01-0010)*

- Check the final nail head position, it may have changed if compression was applied. The rings in the handle are spaced 5 mm from each other, they indicate the depth of the nail's head.
- If satisfied with the final implant's position, remove the Screw Sleeve and use the 7 mm Hex Driver to release the nail from the Guide Handle.
- Mate the 5 mm Hex Driver to the chosen end cap and secure with the 5 mm Hex Driver Connector Screw (Fig-29). Pass the end cap/driver assembly through the incision and mate with the proximal end of the nail, rotating clockwise with the driver until it is fully threaded (Fig-30).
- Rotate the connector screw counterclockwise to disengage the driver from the end cap.

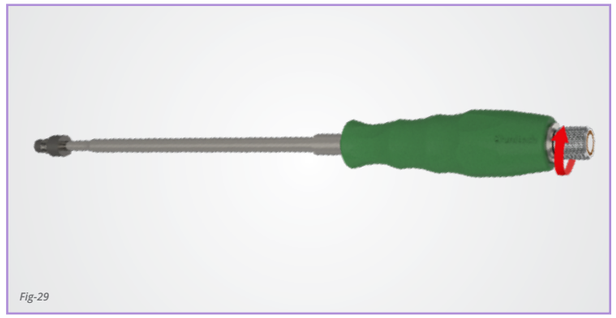


Fig-29

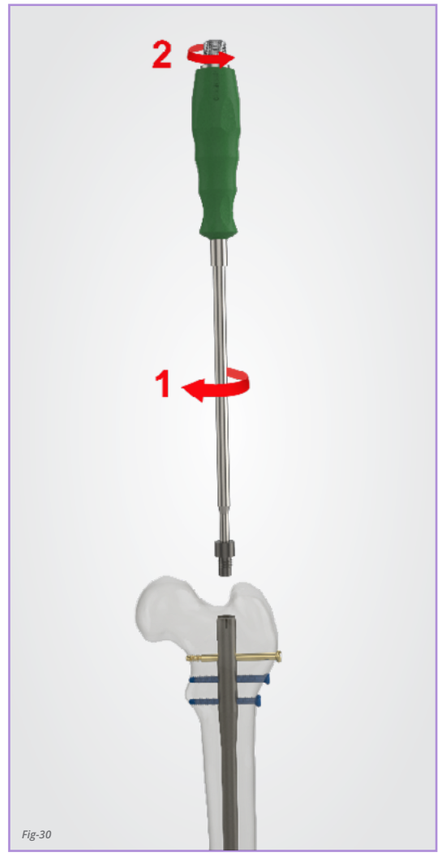


Fig-30

Retrograde Approach

1. Patient Positioning and Fracture Reduction

- Place the patient in the supine position according to surgeon preference on a fracture or other radiolucent table.
- With the knee over a bolster or a leg roll, flex the leg to 30-40°. This should assist in fracture reduction and limb stabilization (Fig-31 and Fig-32).
- Position the image intensifier as to ensure that AP and lateral views of the entire femur can be easily obtained.
- Reduce the fracture as anatomically as possible through closed reduction before prepping and draping the patient with the help of image intensifier. Manual traction or a distraction device may be used to assist in fracture reduction.

Fig-31

Fig-32

2. Incision and Entry Point

- Perform a midline skin incision extending from the inferior pole of the patella to the tibial tubercle.
- Make a medial parapatellar capsular incision to expose the articular surface (Fig-33).

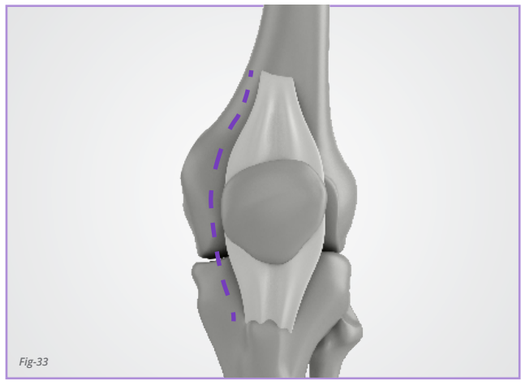


Fig-33

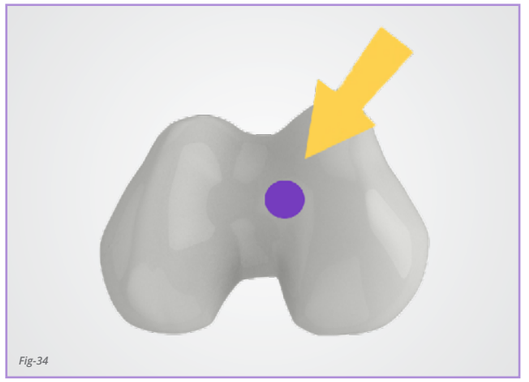


Fig-34

> Note
>
> ✔ In distal fractures presenting intra-articular complications, reduce and secure the fracture with interfragmentary screws prior to nail placement. Care should be taken to keep the nail's path clear.

- The entry point is in line with the femoral medullary canal in both AP and lateral views.
- Typically, the entry point coincides with the top of the intercondylar notch slightly anterior and lateral to the femoral origin of the posterior cruciate ligament (Fig-34), but it may vary depending on the patient's anatomy.

3. Accessing the Canal

Option 1: Trocar Tip Guide Wire

INSTRUMENTS:

- ***Trocar Tip Guide Wire 3 mm x 600 mm (N01-0250)***

- Advance the 3 mm Trocar Tip Guide Wire through the entry point and into the distal femur with the help of a powered driver (Fig-35). The wire should be centered in the canal on the AP and lateral views.
- Withdraw and reposition the wire as necessary.

Fig-35

Option 2: Entry Awl and Trocar Tip Guide Wire

INSTRUMENTS:

- ***Entry Awl (N01-0040)***
- ***Trocar Tip Guide Wire 3 mm x 600 mm (N01-0250)***

- Insert the Entry Awl through the incision and down to the bone (Fig-36). Rotate the Entry Awl back and forth to penetrate the distal femur. Care must be taken not to displace the fracture.
- Pass the 3 mm Trocar Tip Guide Wire through the Entry Awl and down to the bone. Withdraw and reposition the wire as necessary.

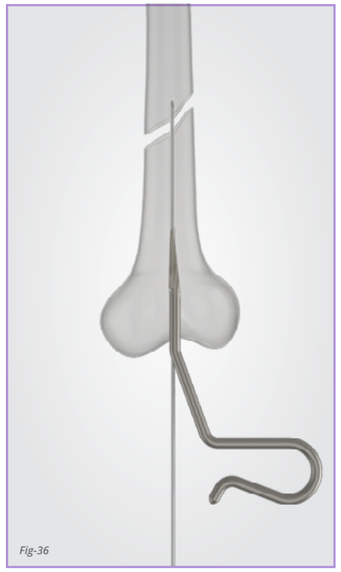


Fig-36

4. Proximal Reaming

INSTRUMENTS:

- ***Tissue Protector (N01-0150)***
- ***Navy Entry Reamer (N03-0030)***
- ***Ball Tip Guide Wire 2 mm x 900 mm (N01-0290), for Navy 10 mm***
- ***2 mm Guide Wire Sheath (N01-0300), for Navy 10 mm***
- ***Ball Tip Guide Wire 3 mm x 900 mm (N01-0270), for Navy 11 mm to 13 mm***
- ***3 mm Guide Wire Sheath (N01-0280), for Navy 11 mm to 13 mm***
- ***Pin Puller (N01-0080)***
- ***Reduction Awl (N01-0090)***

- Insert the Tissue Protector through the incision and down to the bone. Secure the Navy Entry Reamer to a powered driver. Pass it over the wire and through the Tissue Protector. Ream the distal femur to the desired depth with the help of the image intensifier.
- The grooves on the cutting blade of the Navy Entry Reamer are templates that show the position of the screws (Fig-37). The step between the cutting blades and the shank represent the end of the nail.
- Ream until the nail head position is deep enough with respect to the articular surface. Consider any need for compression or dynamization because this will cause the nail to migrate in the direction of the articulation.

Note

✔ If compression is necessary, the screws placement will be different than indicated during proximal reaming (e.g. if 5 mm compression is done, the static holes will be 5 mm more distal than indicated by the Navy Entry Reamer).

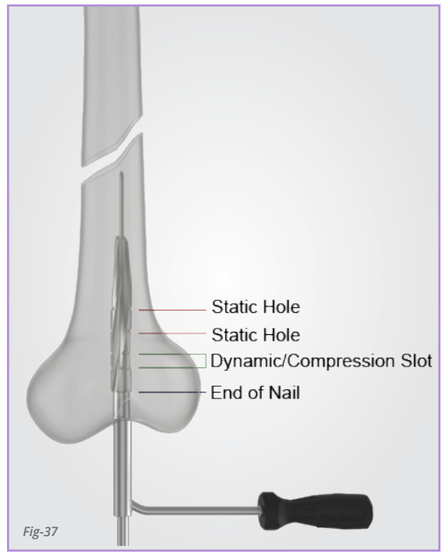


Fig-37

Fig-38

- Exchange the 3 mm Trocar Tip Guide Wire to the Ball Tip Guide Wire and 3 mm Guide Wire Sheath. Loosen up the Pin Puller's lock and pass the Guide Wire through it. Lock the wire by rotating the Pin Puller's drum and move it to the desired depth (Fig-38). Ensure that the guide wire is in correct position with the help of image intensifier. Withdraw and reposition the wire as necessary.
- Confirm that the fracture is well reduced. If necessary use the Reduction Awl to assist with the fracture reduction or guide wire change.

5. Determining the Nail Length

INSTRUMENTS:

- ✔ *Navy Radiographic Claw Template - 10 mm (N03-0080), for Navy 10 mm*
- ✔ *Navy Radiographic Claw Template - 11-13 mm (N03-0090), for Navy 11-13 mm*

- Confirm that the fracture is well reduced and place the appropriate Navy Radiographic Claw Template over the thigh. Use N03-0080 for nails with distal diameter of 10 mm and N03-0090 for nails with distal diameters between 11 to 13 mm. The template shows approximately the full opening of the Claws.
- Position the image intensifier in AP view over the proximal femur to assist with the template placement. The four claws of the template should be just below the metaphyseal flare and well into the cortical bone (Fig-39a). This will help select the longest recommended nail and ensure that the Claws, when deployed, will anchor the nail correctly.
- Care should be taken to avoid placing the Claws close to the fractured site. The Claws must be deployed in unaffected bone to allow for strong nail fixation.
- Move the image intensifier to the distal femur (Fig-39b). Choose the length that corresponds to the desired nail depth defined during reaming of the distal femur. Consider any need for compression or dynamization because this will cause the nail to migrate in the direction of the articulation.

Note

✔ If compression will be required, the final nail head position will be more distal than what is read in the template. Consider the expected compression when choosing the nail's length.

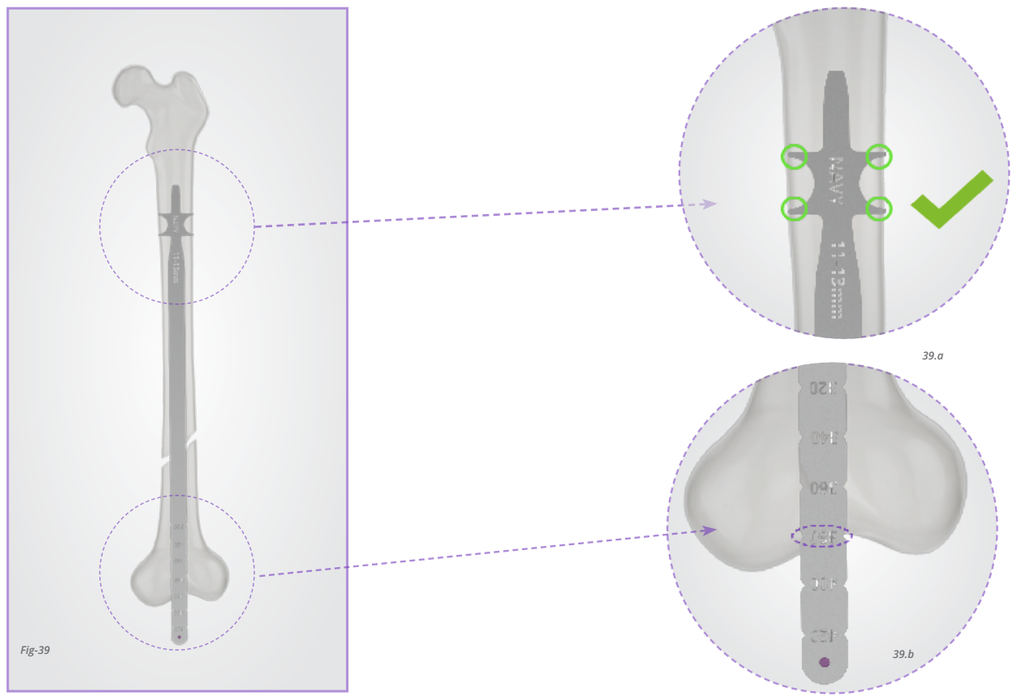


Fig-39

39.a

39.b

6. Distal Reaming

INSTRUMENTS:

- ✔ *Dunitech Intramedullary Reamer Set (INST-01-002)*
- ✔ *Guide Wire Pusher (N01-0060)*

- Confirm that the fracture reduction has been maintained. Starting from 8.5 mm Reamer Cutter Head, ream until the desired depth with a steady pressure. By each pass, increase the diameter of the Reamer Cutter Head in 0.5 mm increments. Use the Guide Wire Pusher to keep the guide wire in place. If the sheath comes out with the reamer, insert it back before starting the next pass.
- The canal should be reamed to at least 1 mm above the desired nail diameter. Ream to at least 11 mm (the nail with smallest diameter has 10 mm of distal diameter). If there's no resistance to reaming to 11 mm, increase the reaming diameter to fit the next size of nail to a maximum of 14 mm.
- To prevent accumulation of debris in the medullary canal, retract the reamer when necessary.
- After distal reaming, remove the sheath (Fig-41). The Sheath won't pass through the nail. If needed, use the Guide Wire Pusher to keep the Ball Tip Guide Wire in place.

Fig-40

Fig-41

7. Attaching the Nail

INSTRUMENTS:

- ✔ *Navy Handle - Nail Connector Screw (N03-0070)*
- ✔ *7 mm Hex Driver (N01-0030)*
- ✔ *Navy Guide Handle (N03-0060)*

- The marks on the Guide Handle have the following meaning:
  - ✔ LA/RR for Left femur and Antegrade approach (LA) or Right femur and Retrograde approach (RR).
  - ✔ RA/LR for Right femur and Antegrade approach (RA) or Left femur and Retrograde approach (LR).
- For Retrograde approach, align the mark on the nail to the **LA/RR** mark on the Guide Handle for the **Right** leg or **RA/LR** for the **Left** leg.
- Mate the desired nail to the Navy Guide Handle and use the 7 mm Hex Driver to tighten the Handle-Nail Connector Screw (Fig-42). Ensure that the reference line on the nail is aligned with the correct line on the Guide Handle.
- Ensure that the connection is tight before proceeding.

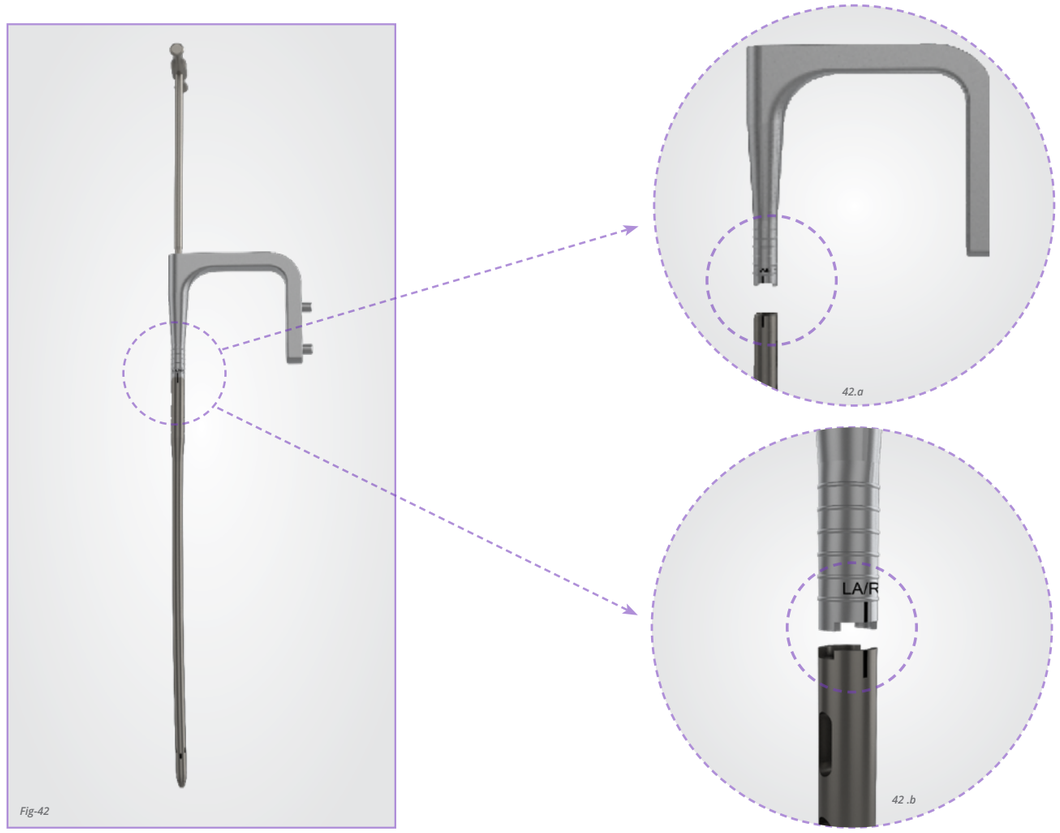


Fig-42

8. Checking Alignment

INSTRUMENTS:

- ✔ *Navy Guide Arm (N03-0050)*
- ✔ *Handle - Arm Connector Screw (N01-0140)*
- ✔ *Screw Sleeve (N01-0130)*
- ✔ *Drill Sleeve (N01-0120)*
- ✔ *4.2 mm Drill Bit (N01-0100)*

- Before inserting the nail check the nail's holes are correctly aligned to the holes of the Guide Arm.
- Mate the Navy Guide Arm with the Navy Guide Handle and secure them with the Handle-Arm Connector Screw.
- Insert the Drill Sleeve into the Screw Sleeve and insert this assembly into the most distal hole of the Guide Arm. Insert the 4.2 mm Drill bit through the Drill Sleeve and advance until it passes through the corresponding nail hole (Fig-43).
- Repeat the process in the other holes.
- Prior to inserting the nail, remove the Navy Guide Arm.


Fig-43

9. Inserting the Nail

INSTRUMENTS:

- ✔ *Impactor (N01-0070) - Optional*

> Note
> - ✔ If the Guide Wire Sheath has not been removed, it has to be removed in before the insertion of the nail (Fig-41). The Sheath will not pass through the nail.
> - ✔ If a traditional ball tip guide wire was used, it must be exchanged for a smooth guide wire. Its tip won't pass through the nail.

- Pass the nail over the guide wire, through the incision and into the bone. With steady pressure and gentle rotation movements, advance the nail (Fig-44). Monitor closely with the help of image intensifier the passage of the nail across the fracture site.
- If needed, the Impactor can be assembled in the Guide Arm for light hammer blows. If considerable resistance is encountered, do not use strong hammer strikes. It may cause loss of reduction or perioperative fracture. Instead, remove the nail, replace the sheath and further enlarge the medullary canal.
- The rings in the handle are spaced 5 mm from each other, they indicate the depth of the nail's head.

> Note
> - ✔ Do not strike the Guide Handle with a slap hammer or any other mallet.
> - ✔ Once the nail is in its final position, remove the guide wire.

Fig-44

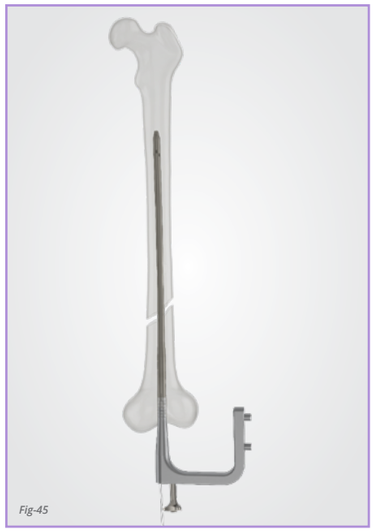


Fig-45

10. Deploying Claws

INSTRUMENTS:

- ✔ *Navy Claw Deployment Driver (N03-0020)*
- ✔ *Torque Limiting Handle (N01-0170)*

- Attach the Navy Claw Deployment Driver to the Torque Limiting Handle. Insert the driver down the nail until it engages the Claw mechanism. Rotate the handle clockwise to deploy the Claws (Fig-46). A steady low torque should be felt before the cortical bone is reached.
- An increase in torque will indicate that the Claws started penetrating the cortex. During this stage, monitor under image intensifier positioned for a lateral view to prevent excessive cortical penetration.
- Full deployment of the Claw system is reached after approximately 18 full turns of the handle. The amount of turns needed will depend on patient anatomy and nail placement.
- Stop deploying when full cortical anchoring is reached or when the Torque Limiting Handle trips to prevent excessive perforation through the cortical bone and into the soft tissue.

> Note
> - ✔ The Claws cannot be deployed using a powered driver. It may lead to excessive penetration and/or system failure due to over torque.
> - ✔ Always use the Torque Limiting Handle to deploy the Claws.

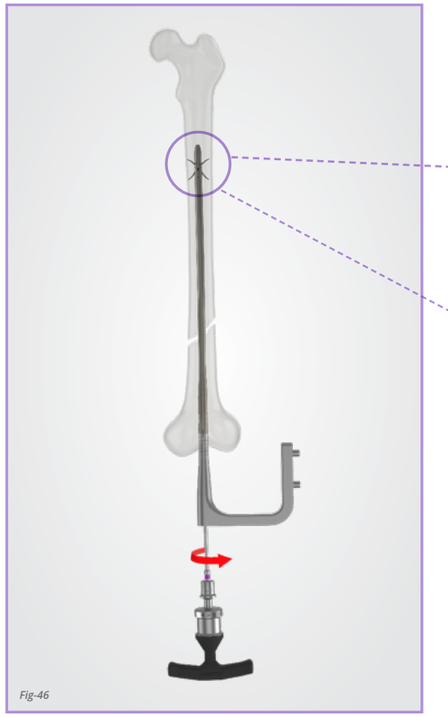
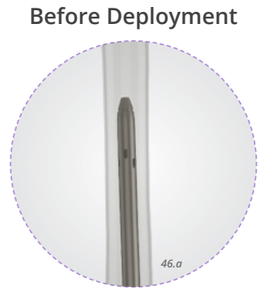
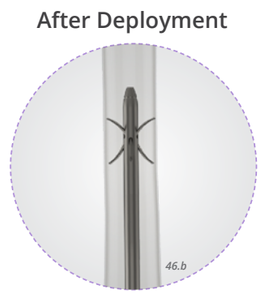


Fig-46





11. Distal Locking – Drilling for Locking Screw

INSTRUMENTS:

- ***Navy Guide Arm (N03-0050)***
- ***Handle - Arm Connector Screw (N01-0140)***
- ***Screw Sleeve (N01-0130)***
- ***Drill Sleeve (N01-0120)***
- ***Trocar (N01-0110)***
- ***4.2 mm Drill Bit (N01-0100)***

Note

- ✔ The process for inserting any screw is the same.
- ✔ This document will use the Compression Cortical Screw placement as an example.

- Mate the Navy Guide Arm with the Navy Guide Handle and secure them with the Handle-Arm Connector Screw (Fig-47). Insert the Trocar into the Drill Sleeve and insert them into the Screw Sleeve.
- Pass the assembly through the Dyn/Comp hole in the guide arm, advance it until the skin and make a small incision. Advance the assembly until the Drill Sleeve touches the cortical bone. Tighten the Screw Sleeve to the guide arm if possible. Apply pressure with the Trocar over the bone to create a dimple in the lateral cortex (Fig-48).
- Remove the Trocar and pass the 4.2 mm Drill Bit through the Drill Sleeve. Drill through both cortices (Fig-49). With the drill bit in the far cortex and Drill Sleeve touching the lateral cortex, read the graduation in line with the Drill Sleeve (Fig-50). The measurement will indicate the screw length to be used.

Fig-47

Fig-48

Fig-49

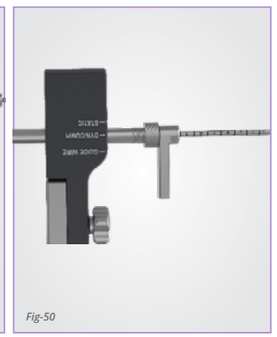


Fig-50

12. Distal Locking – Inserting the Cortical Screw

INSTRUMENTS:

- ***5 mm Hex Driver (N01-0020)***
- ***5 mm Hex Driver Connector Screw (N01-0010)***

- Mate the 5 mm Hex Driver with the selected screw and secure with the 5 mm Hex Driver Connector Screw (Fig-51). Remove the Drill Sleeve.
- Insert the screw/driver assembly through the Screw Sleeve until it contacts the bone. Rotate the driver to thread up the screw until its head seats against the lateral cortex (Fig-52). Do not over tighten the screw as it may lead to screw stripping.
- Rotate the connector screw counterclockwise to disengage the driver from the screw.
- Remove the Screw Sleeve.

Note

- ✔ If compression is needed, make sure to use a Compression Cortical Screw. It is designed to withstand the compression loads.

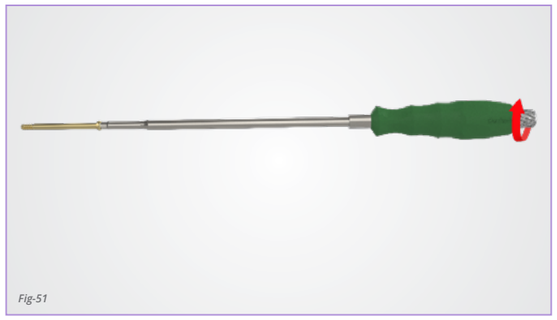


Fig-51

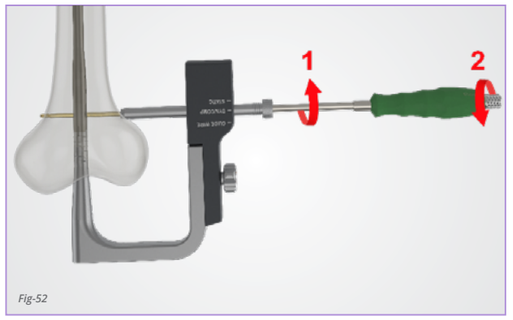


Fig-52

13. Distal Locking – Compression

INSTRUMENTS:

- ***Torque Limiting Handle (N01-0170)***
- ***Navy Compressor (N03-0010)***

- Mate the Navy Compressor with the Torque Limiting Handle. Insert the compressor into the Guide Handle and through the nail. Rotate until the compressor engages the thread in the guide handle (Fig-53). Monitor the process with the help of image intensifier.
- As the compressor is rotated, the Compression Cortical Screw is pushed down the dynamic slot and the proximal fragment is drawn towards the distal fragment. Up to 10 mm of compression can be applied.
- Before releasing the compressor, insert one screw in one of the static holes to ensure that the compression will be maintained.

Note

- ✔ Do not over compress as it may cause the screw to fail.
- ✔ Do not backslap the nail against the deployed Claws to achieve compression.

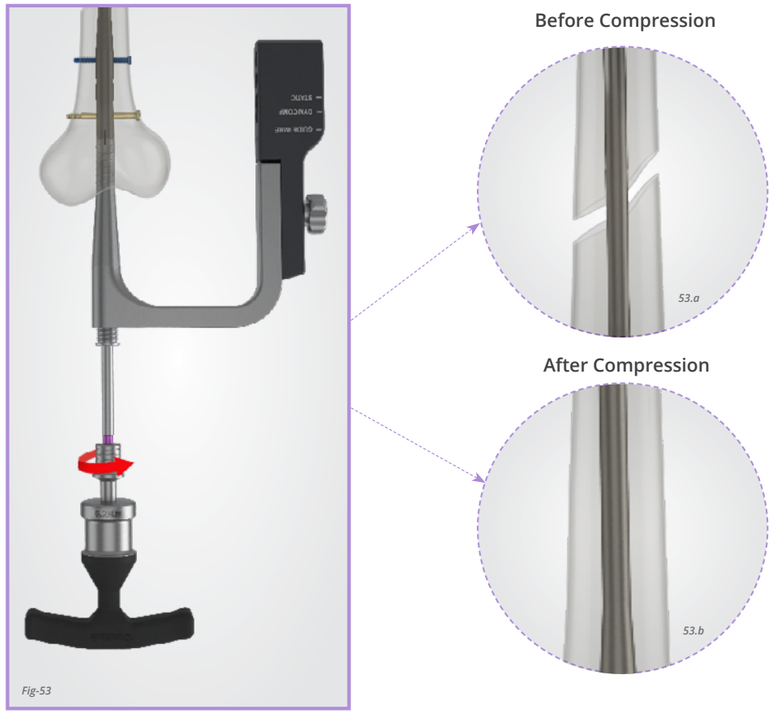


Fig-53

The use of Cortical and Compression Screws are at the discretion of the surgeon, and should be tailored to the patient's needs. The common proximal locking configurations are presented below:

1. Static locking after fracture compression


Fig-54


Fig-55

2. Dynamic configuration for postoperative compression


Fig-56

3. Static configuration with possibility of future dynamization.

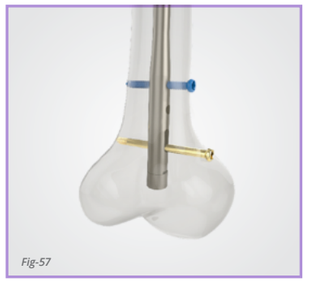


Fig-57

14. Inserting End Cap

INSTRUMENTS:

- *7 mm Hex Driver (N01-0030)*
- *5 mm Hex Driver (N01-0020)*
- *5 mm Hex Driver Connector Screw (N01-0010)*

- Check the final nail head position, it may have changed if compression was applied. The rings in the handle are spaced 5 mm from each other, they indicate the depth of the nail's head.
- If satisfied with the final implant's position, remove the Screw Sleeve and use the 7 mm Hex Driver to release the nail from the Guide Handle.
- Mate the 5 mm Hex Driver to the chosen end cap and secure with the 5 mm Hex Driver Connector Screw (Fig-58). Pass the end cap/driver assembly through the incision and mate with the proximal end of the nail, rotating clockwise with the driver until it is fully threaded (Fig-59).
- Rotate the connector screw counterclockwise to disengage the driver from the end cap.

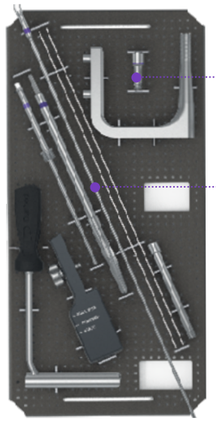
Fig-58

Fig-59

NOTES

Nail Removal

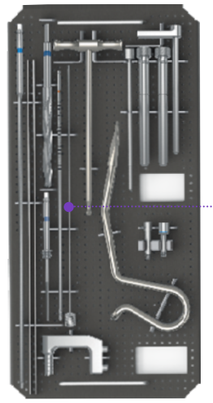
INSTRUMENTS FOT REMOVING THE NAIL



Navy Extractor Connector (N03-0040)

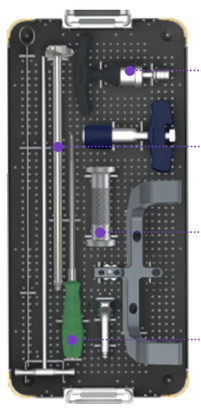
Navy Claw Deployment Driver (N03-0020)

Navy Set Tray 1



5 mm Hex Driver Connector Screw (N01-0010)

Navy Set Tray 2



Torque Limiting Handle (N01-0170)

Extractor (N01-0050)

Slide Hammer (N01-0160)

5 mm Hex Driver (N01-0020)

Navy Set Tray 3

1. Removing Nail End Cap

INSTRUMENTS:

- ✔ *5 mm Hex Driver (N01-0020)*
- ✔ *5 mm Hex Driver Connector Screw (N01-0010)*

Note

- ✔ The nail removal is an optional procedure.
- ✔ The steps for removing the nail are the same whether it has been inserted through a retrograde or antegrade approach.
- ✔ The removal of a nail inserted through retrograde approach is demonstrated.

- Insert the 5 mm Hex Driver Connector screw into the 5 mm Hex Driver and mate the driver to the nail end cap.
- Rotate the connector screw clockwise to secure the end cap to the driver.
- Rotate the driver counterclockwise until the end cap it is fully released (Fig-60).

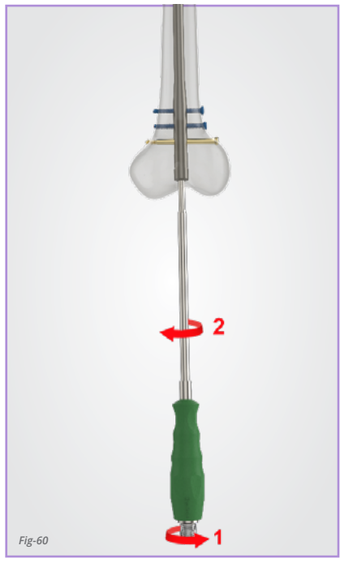


Fig-60

2. Removing the Cortical Screws

INSTRUMENTS:

- ✔ *5 mm Hex Driver (N01-0020)*
- ✔ *5 mm Hex Driver Connector Screw (N01-0010)*

- Insert the 5 mm Hex Driver Connector screw into the 5 mm Hex Driver and mate the driver to the cortical screw.
- Rotate the connector screw clockwise to secure the cortical screw to the driver.
- Remove the cortical screw by rotating the driver counterclockwise (Fig-61).
- Ensure all screws have been removed before proceeding.

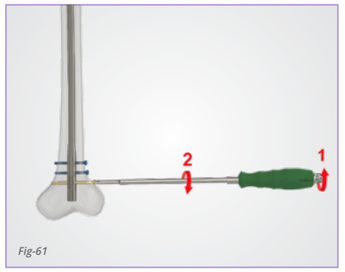


Fig-61

3. Retracting Nail Claws

INSTRUMENTS:

- ***Navy Claw Deployment Driver (N03-0020)***
- ***Torque Limiting Handle (N01-0170)***
- ***Distal Claw Deployment Driver - Long (N02-0220) - Optional (if using the Revision Set)***
- ***T Extraction Handle (N01-0320) - Optional (if using the Revision Set)***

- Attach the appropriate Navy Claw Deployment Driver or Distal Claw Deployment Driver - Long to the Torque Limiting Handle or T Extraction Handle.
- Insert the driver down the nail until it engages the distal Claw mechanism.
- Rotate the handle counterclockwise to retract the Claws (Fig-62).
- A fully deployed Claw mechanism would need 18 turns to be completely retracted but the amount of turns necessary will depend on how much the Claws had been deployed.
- Confirm the full retraction radiographically.

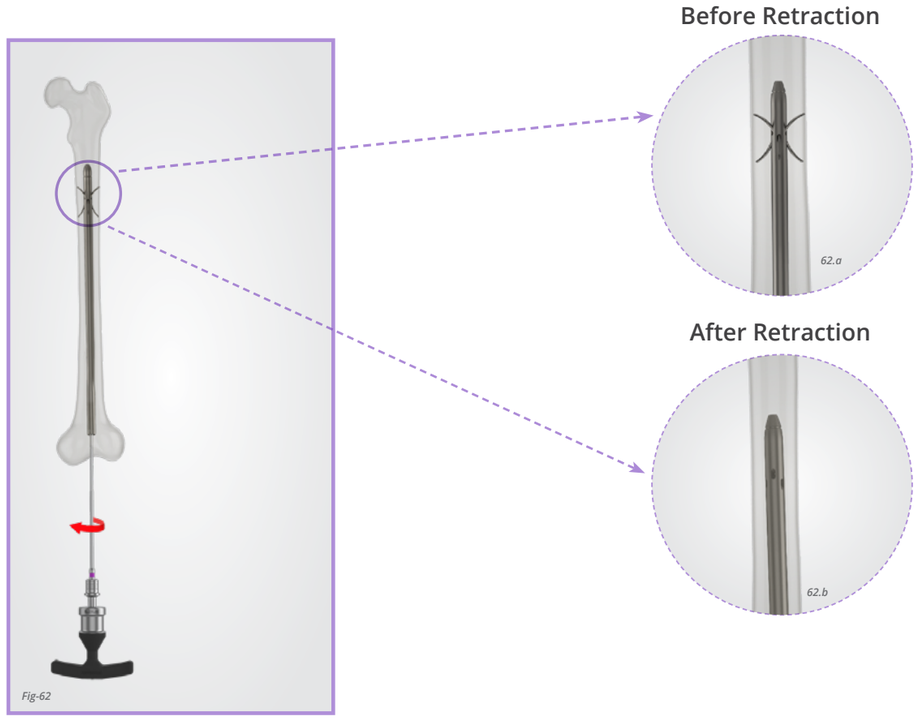


Fig-62

4. Removing the Nail

INSTRUMENTS:

- ***Extractor (N01-0050)***
- ***Slide Hammer (N01-0160)***
- ***Navy Extractor Connector (N03-0040)***

- Attach the Navy Extractor Connector into Extractor and pass the Slide Hammer over the assembly (Fig-63).
- Mate the Navy Extractor Connector with the nail and rotate the Extractor clockwise to secure the assembly to the nail.
- With gentle blows of the Slide Hammer, remove the nail from the femur (Fig-64).

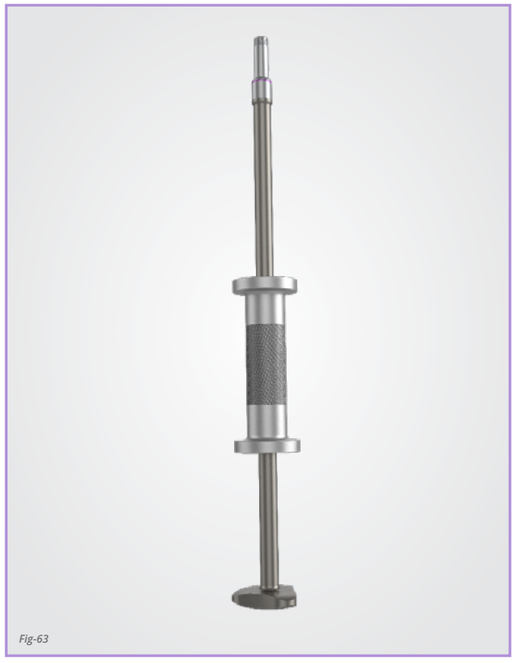


Fig-63

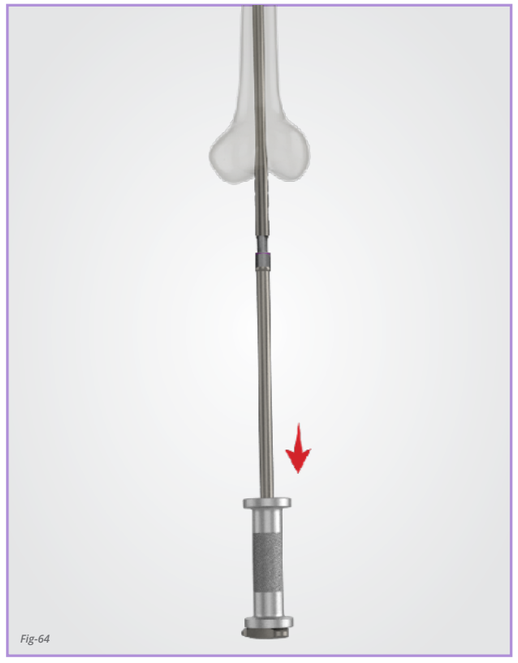
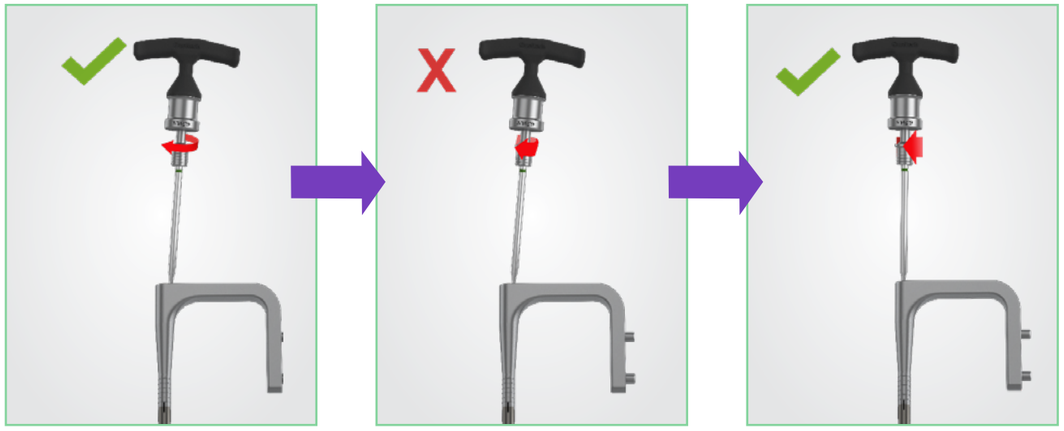


Fig-64

Correct Use of the Flexible Shaft

The Navy Claw Deployment Driver has a flexible shaft. The more the shaft is flexed, the less torque it can deliver before permanently deforming.

To ensure a continued functionality of the instrument, the shaft should be returned to a straight orientation when significant resistance is felt.



High Torque / Minimal Resistance

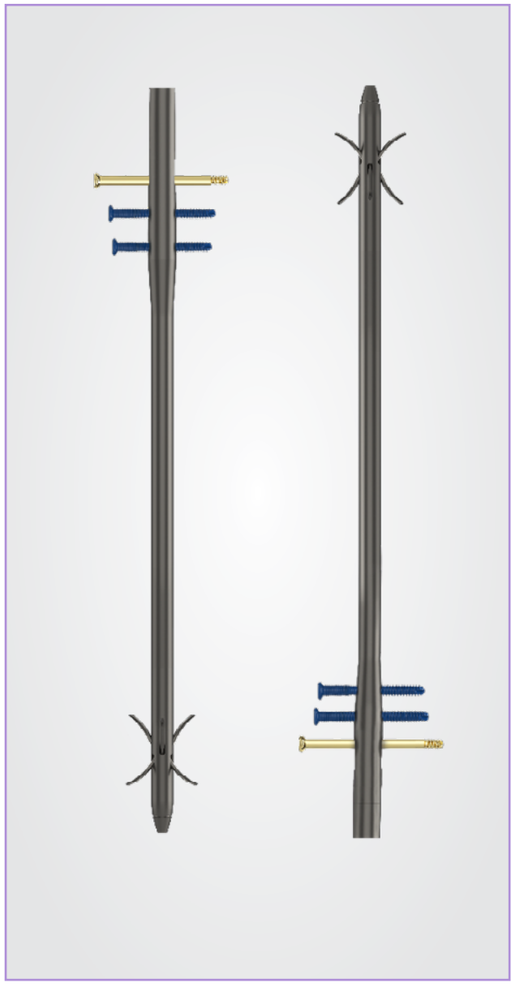
Low Torque / Significant Resistance

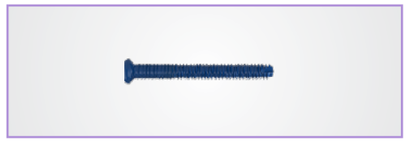
NOTES

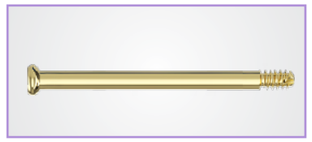
Catalogue Information

Navy A/R Femoral Nail

Distal Diameter	Lenght (mm)	Catalogue Code
10	280	NAVY-10-280
10	300	NAVY-10-300
10	320	NAVY-10-320
10	340	NAVY-10-340
10	360	NAVY-10-360
10	380	NAVY-10-380
10	400	NAVY-10-400
10	420	NAVY-10-420
10	440	NAVY-10-440
10	460	NAVY-10-460
11	280	NAVY-11-280
11	300	NAVY-11-300
11	320	NAVY-11-320
11	340	NAVY-11-340
11	360	NAVY-11-360
11	380	NAVY-11-380
11	400	NAVY-11-400
11	420	NAVY-11-420
11	440	NAVY-11-440
11	460	NAVY-11-460
12	280	NAVY-12-280
12	300	NAVY-12-300
12	320	NAVY-12-320
12	340	NAVY-12-340
12	360	NAVY-12-360
12	380	NAVY-12-380
12	400	NAVY-12-400
12	420	NAVY-12-420
12	440	NAVY-12-440
12	460	NAVY-12-460
13	280	NAVY-13-280
13	300	NAVY-13-300
13	320	NAVY-13-320
13	340	NAVY-13-340
13	360	NAVY-13-360
13	380	NAVY-13-380
13	400	NAVY-13-400
13	420	NAVY-13-420
13	440	NAVY-13-440
13	460	NAVY-13-460







End Caps

Extension (mm)	Catalogue Code
0 (flush)	NAVY-13-000
5	NAVY-13-005
10	NAVY-13-010
15	NAVY-13-015
20	NAVY-13-020
25	NAVY-13-025
30	NAVY-13-030
35	NAVY-13-035

Cortical Screws

Diameter (mm)	Length (mm)	Catalogue Code
5	30	CORS-05-030
5	35	CORS-05-035
5	40	CORS-05-040
5	45	CORS-05-045
5	50	CORS-05-050
5	55	CORS-05-055
5	60	CORS-05-060
5	65	CORS-05-065
5	70	CORS-05-070
5	75	CORS-05-075
5	80	CORS-05-080
5	85	CORS-05-085
5	90	CORS-05-090
5	95	CORS-05-095
5	100	CORS-05-100
5	105	CORS-05-105
5	110	CORS-05-110
5	115	CORS-05-115
5	120	CORS-05-120

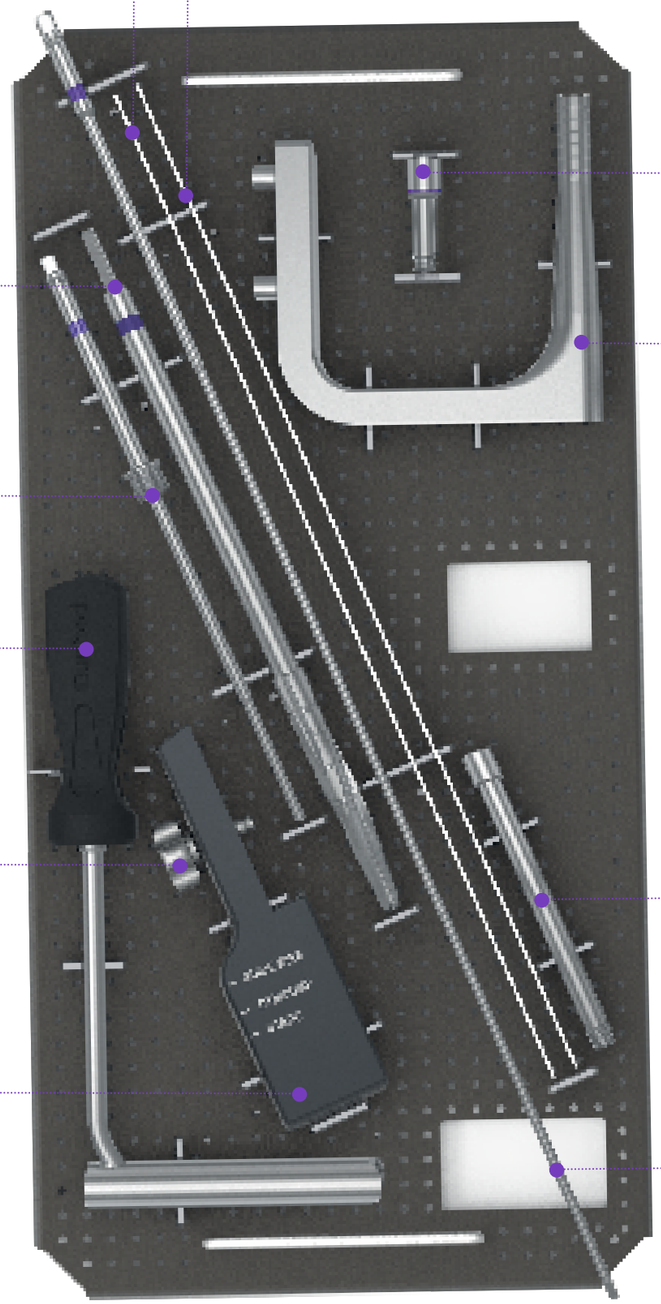
Compression Cortical Screws

Diameter (mm)	Length (mm)	Catalogue Code
5	30	COMS-05-030
5	35	COMS-05-035
5	40	COMS-05-040
5	45	COMS-05-045
5	50	COMS-05-050
5	55	COMS-05-055
5	60	COMS-05-060
5	65	COMS-05-065
5	70	COMS-05-070
5	75	COMS-05-075
5	80	COMS-05-080
5	85	COMS-05-085
5	90	COMS-05-090
5	95	COMS-05-095
5	100	COMS-05-100
5	105	COMS-05-105
5	110	COMS-05-110
5	115	COMS-05-115
5	120	COMS-05-120

Navy
Tool Set

- Navy Tray 1
- Navy Tray 2
- Navy Tray 3

Navy Tray 1



N03-0080
NAVY RADIOGRAPHIC CLAW TEMPLATE - 10 MM

N03-0090
NAVY RADIOGRAPHIC CLAW TEMPLATE 11 – 13 MM

N03-0040
NAVY EXTRACTOR CONNECTOR

N03-0030
NAVY ENTRY REAMER

N03-0060
NAVY GUIDE HANDLE

N03-0010
NAVY COMPRESSOR

N01-0150
TISSUE PROTECTOR

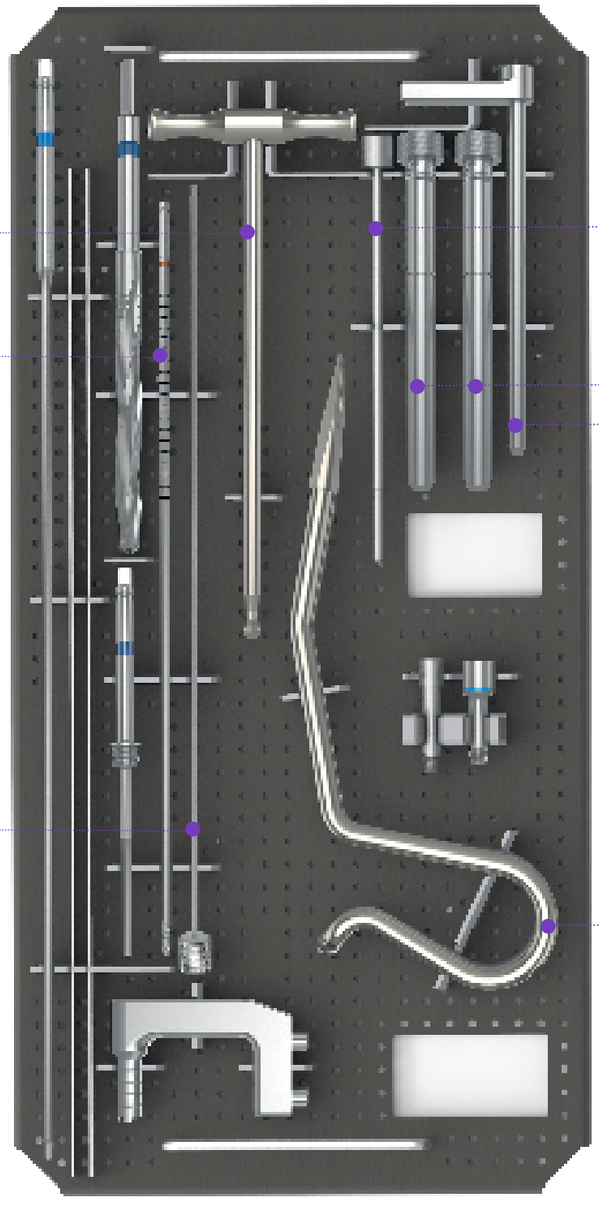
N01-0140
HANDLE-ARM CONNECTOR SCREW

N03-0070
NAVY HANDLE - NAIL CONNECTOR SCREW

N03-0050
NAVY GUIDE ARM

N03-0020
NAVY CLAW DEPLOYMENT DRIVER

Navy Tray 2



N01-0030
7 MM HEX DRIVER

N01-0100
4.2 MM DRILL BIT

N01-0010
5 MM HEX DRIVER
CONNECTOR SCREW

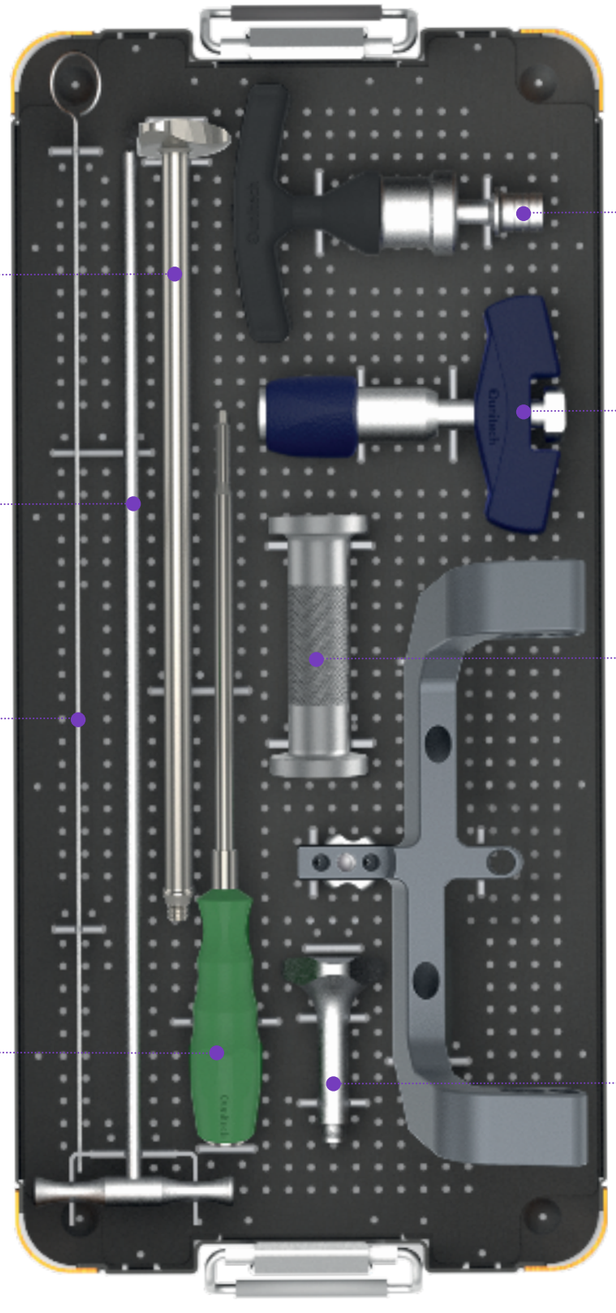
N01-0110
TROCAR

N01-0130
SCREW SLEEVE

N01-0120
DRILL SLEEVE

N01-0040
ENTRY AWL

Navy Tray 3



N01-0050
EXTRACTOR

N01-0090
REDUCTION AWL

N01-0060
GUIDE WIRE PUSHER

N01-0020
5 MM HEX DRIVER

N01-0170
TORQUE LIMITING
HANDLE

N01-0080
PIN PULLER

N01-0160
SLIDE HAMMER

N01-0070
IMPACTOR

NOTES

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