NICE Cannulated Compression Screw

Surgical Technique

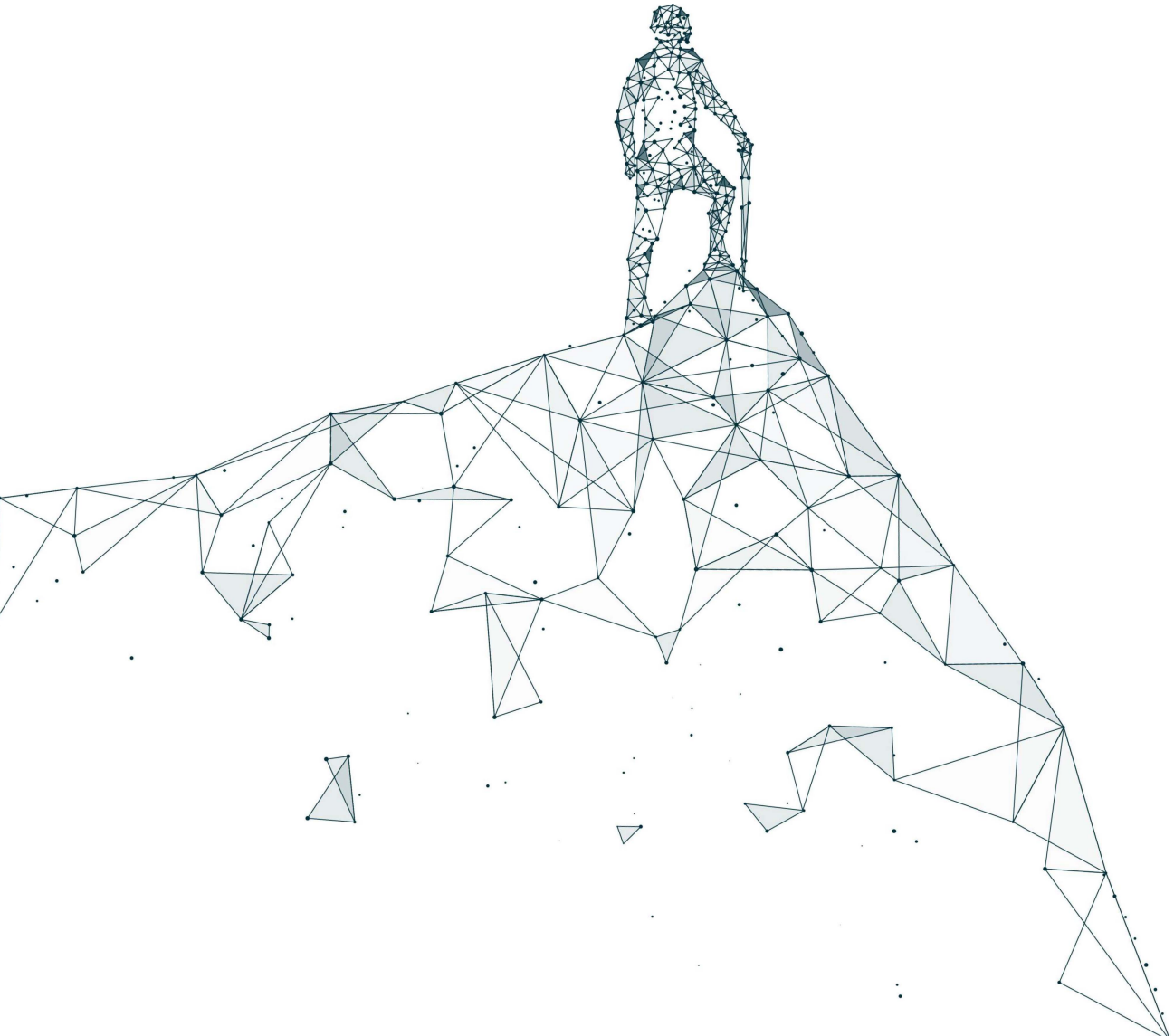
Dunitech
get better

About Us

We were established in 2012 to serve the healthcare industry by innovative technologies, superior quality materials and top-notch customer and after-sales services. Today, OLIGA is a medical technology company that engineers, designs, manufactures and markets osteosynthesis systems with 15 years of experience in orthopaedics.

Thanks to our dynamic, solution-oriented and expert staff, our pursuit for serving the best service possible approach helps us to contribute to orthopaedic community every single day. We provide high-quality products and services with prompt action at competitive costs.

For those who opt for Oliga; Success is a Choice



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INTRODUCTION

SURGICAL TECHNIQUE

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.

NICE — Design Features

Threaded Compression Nuts:
Neutral and Aggressive Compression Nuts provide a range of compression options from 4-8mm

Non-threaded Compression Nut (not shown) allows for additional compression

Constant Core Diameter of threaded Compression Nut options for better purchase

NICE Dimensions

Lengths: 45mm—120mm (5mm increments) Shaft Diamter: 6.2mm
Distal Thread Diamter: 7.5mm
Distal Thread Length: 16mm

ALL Claws ARE FULLY RETRACTABLE

NICE — Indications

Indications

Fracture fixation of small and long bones including use in:

- Intracapsular fractures of the femoral neck
- Tibial plateau fractures
- Ankle arthrodesis
- Supplementary fixation for fractures of the proximal and distal femur
- Intra-articular fractures of humerus, femur and tibia.

Contraindications

The system is not intended for spinal use.

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
- Compromised vascularity that would inhibit adequate blood supply to the operative site
- Obesity. An overweight or obese patient can produce loads on the implant which can lead to failure of the fixation of the device or to failure of the device itself
- Metal sensitivity or allergic reaction to foreign bodies
- Loss of bone stock or insufficient bone quality to support the device
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure

Precautions

The Cannulated Compression Device 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.

Inserting the Guide Wire

Make a stab incision and dissect a clean approach to the desired region of the bone where the cannulated compression device will be inserted.

Reduce bones or bone fragments intended to be repaired by the NICE.

Align the Guide Wire tip end of the Drill Guide 1.6mm-6.1mm in the direction of device insertion. Advance the Guide Wire through the Drill Guide 1.6mm-6.1mm and into the bone to the desired depth and position (Figure 6-1).
Fluoroscopy should be used to ensure correct Guide Wire position, alignment, and depth.

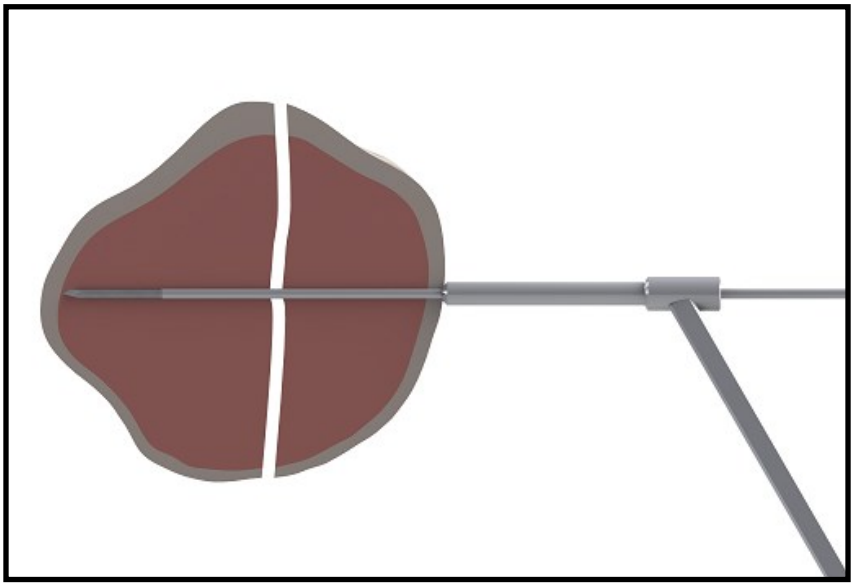


Fig. 6-1

Selecting NICE Length

With the Guide Wire in the proper position, slide the cannulated end of the Depth Gauge over the Guide Wire until it is flush with the bone (Figure 7-1).

Record the measurement from the measurement marking on the Guide Wire (Figure 7-2). This measurement is a direct measurement to the tip of the Guide Wire.

Use the direct measurement to determine the length of the NICE to be used.

Note that a shorter NICE length may be needed in the case of a large gap or in instances where the NICE will be countersunk.

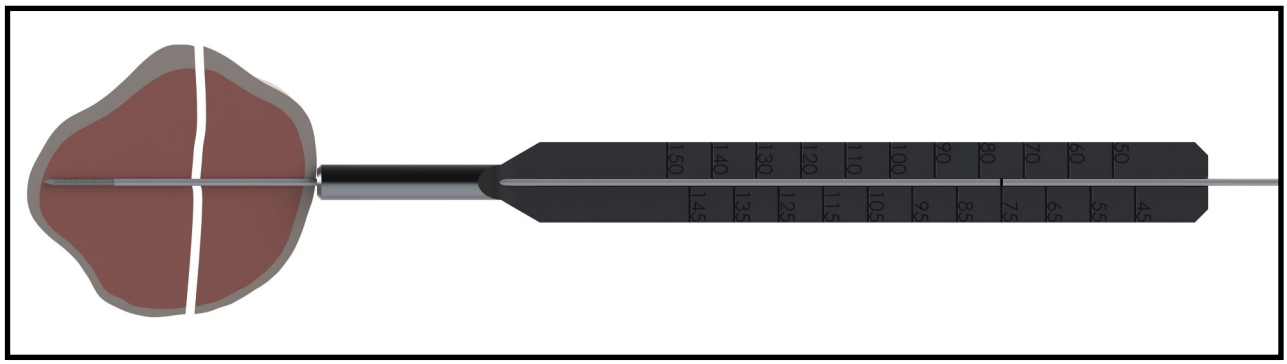


Fig. 7-1

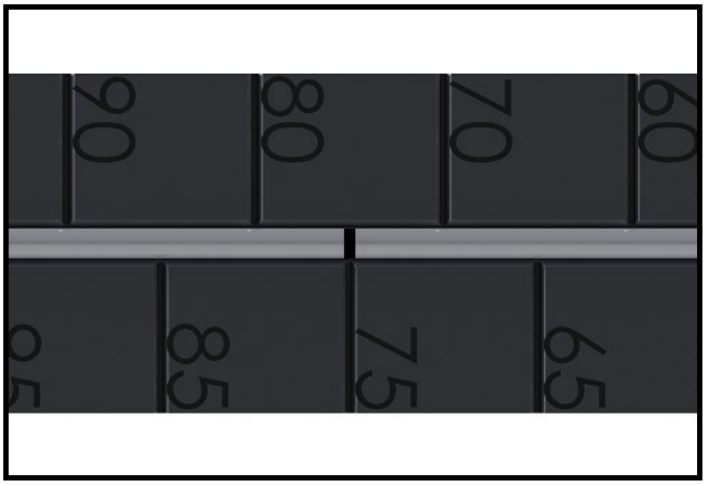


Fig. 7-2

Drilling for the NICE

Place the Drill Guide end of the 1.6mm-6.1mm Drill Guide over the Guide Wire and then place the 6.1mm Reamer over the Guide Wire and through the Drill Guide end of the 1.6mm-6.1mm Drill Guide.

Drill over the Guide Wire to the desired depth (Figure 8-1).

Drilling should always be performed under fluoroscopy to avoid incorrect drilling depth and misalignment.

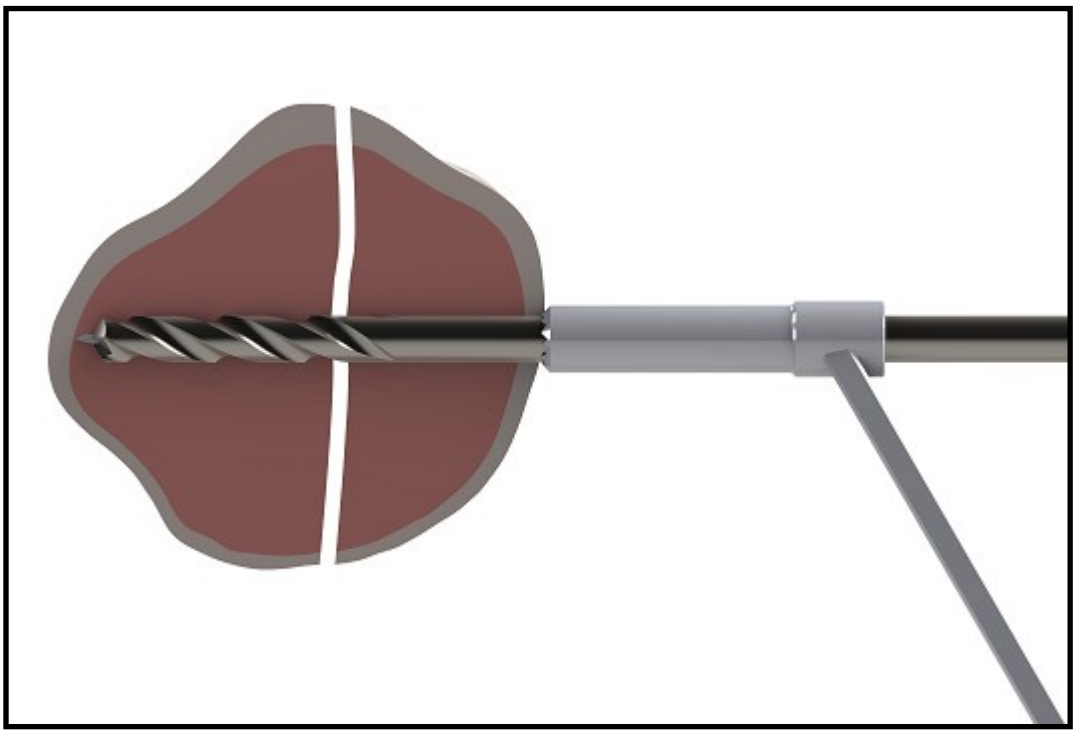


Fig. 8-1

Inserting the NICE

Load the selected Compression Nut onto the NICE by rotating it clockwise onto the proximal threads of the NICE. The Compression Nut should be advanced on the NICE only until the driving notches on the NICE proximal threads are no longer visible (Figure 9-1).

Connect the Driver Shaft to the Ratcheting Cannulated Axial Handle. Slide the Compression Nut Driver onto the Driver Shaft and thread onto the mating threads. If using the Compression Sleeve, it may be inserted onto the Driver Shaft as well.

Mate the NICE Driver assembly with the NICE.

Insert the NICE over the Guide Wire and into the drilled hole. Rotate the NICE clockwise until the Compression Nut Head makes contact with the bone (Figure 9-1).

Remove the Guide Wire.

Note: All distal threads must pass into the distal fragment to allow for compression.

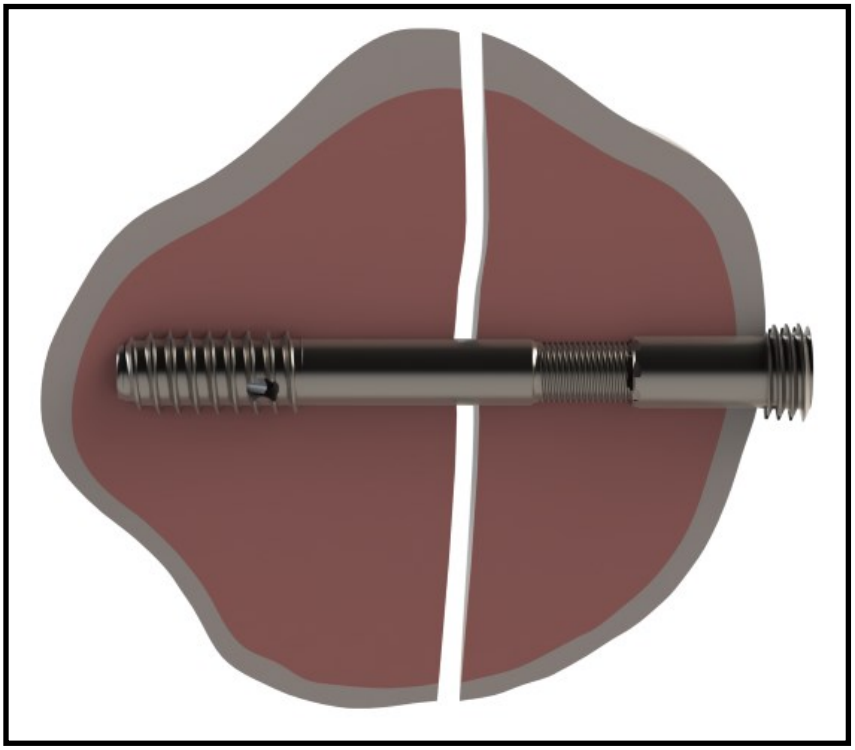


Fig. 9-1

Deploy Claws

Connect the NICE Anchor Deployment Driver to the Torque Limiting AO Handle 1.5Nm and introduce it through the Driver Shaft until contact is made with the Claws. **Do not thrust the driver in forcibly as this may damage the threads.** Turn the driver clockwise to deploy the Claws. While slight resistance may be felt while threading the driver through the Claws, deployment begins when greater resistance is felt.
Continue deploying until the Torque Limiting AO Handle 1.5 Nm trips (Figure 10-1).

Remove the Deployment Driver by turning it counter clockwise.

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

NOTE: Claws deployment should never be performed using a powered instrument.

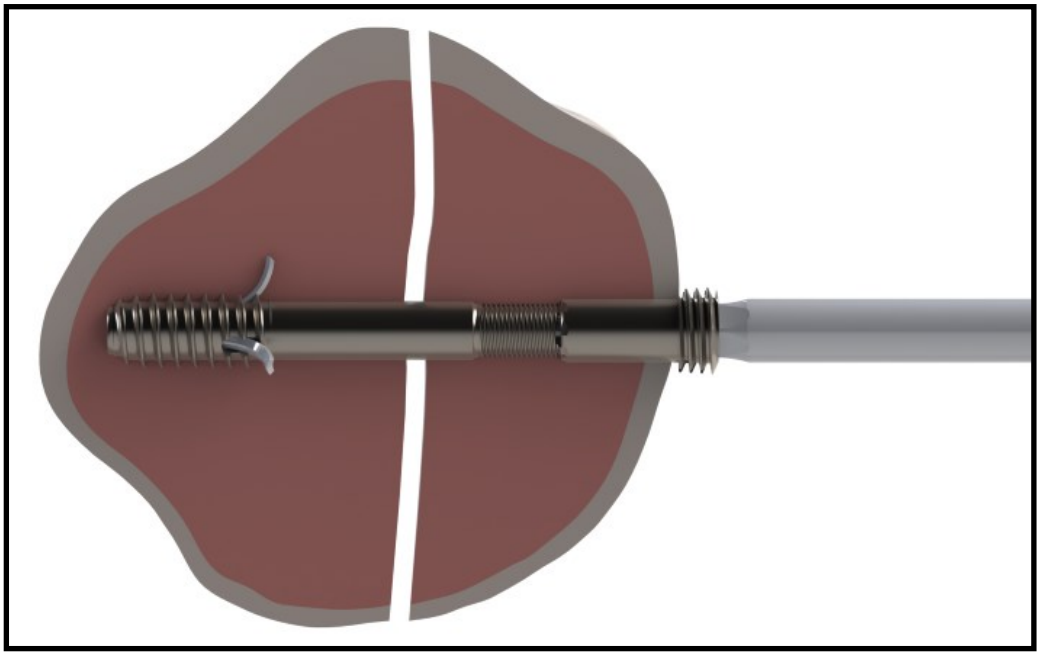


Fig. 10-1

Compression - Using Compression Nut Driver

Apply compression by rotating the Compression Nut clockwise (threaded Compression Nut will thread into the proximal bone fragment). Continue to rotate the Compression Nut. Partial compression is indicated by the yellow band on the Driver Shaft being shown (Figure 11-2). Full compression is indicated by the red band on the Driver Shaft being shown (Figure 11-3). Compression should be monitored radiographically. The threaded Compression Nut is designed to be seated below the cortical surface to avoid impingement (Figure 11-1).

Remove the Compression Nut Driver by pulling it back.

Using Compression Sleeve (Optional)

Thread the Compression Sleeve onto the outer threads of the Compression Nut until the Compression Sleeve makes contact with the bone surface. Continue rotating the Compression Sleeve clockwise to apply compression. Monitor compression radiographically.

NOTE: Using the Neutral Compression Nut will lock the compression obtained by the Compression Sleeve without applying further compression. Using the Aggressive Compression Nut will apply additional compression.

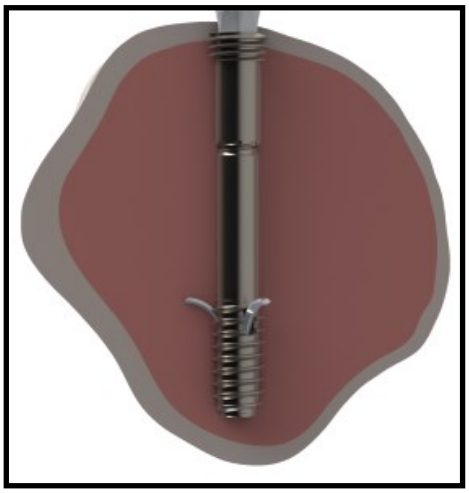


Fig. 11-1

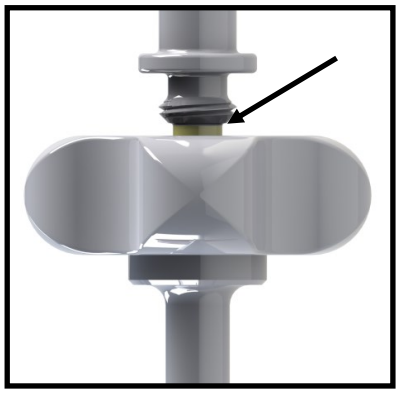


Fig. 11-2

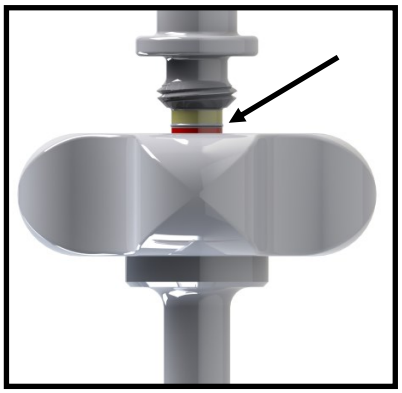


Fig. 11-3

Implant Removal

Remove the Compression Nut by inserting the Compression Nut Driver and rotating counterclockwise.

Pass the Guide Wire through the NICE to clear any debris. Use the Guide Wire to direct the NICE Retractor Driver to the end of the NICE. Mate NICE Retractor Driver with the driving notches of the NICE and thread the knobbed portion of the retractor clockwise onto the NICE until fully seated.

Remove the Guide Wire.

Insert the Retraction Driver through the NICE Retractor Driver until it no longer advances. Thread the Claw Retraction Driver clockwise into the NICE Retractor Driver to retract the Claws.

Alternatively, the Claws can be retracted by inserting the Claw Deployment Driver through the NICE Retractor Driver and threading into the Claws two (2) turns. The Claws Deployment Driver can then be tapped lightly with a mallet to retract the Claws.

Rotate the NICE Retractor Driver counterclockwise to remove the NICE.

NOTE: Claws retraction should never be performed using a powered instrument.

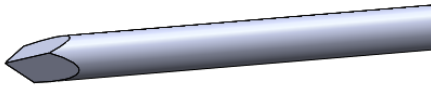
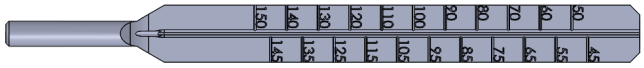
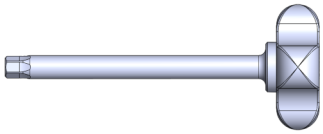
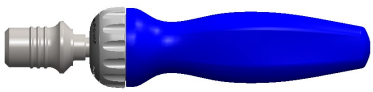
NICE Cannulated Compression Screw — Implants

Catalog Number	Description
NICE-75-045	NICE - Ø7.5mm x 45mm - 16mm Thread
NICE-75-050	NICE - Ø7.5mm x 50mm - 16mm Thread
NICE-75-055	NICE - Ø7.5mm x 55mm - 16mm Thread
NICE-75-060	NICE - Ø7.5mm x 60mm - 16mm Thread
NICE-75-065	NICE - Ø7.5mm x 65mm - 16mm Thread
NICE-75-070	NICE - Ø7.5mm x 70mm - 16mm Thread
NICE-75-075	NICE - Ø7.5mm x 75mm - 16mm Thread
NICE-75-080	NICE - Ø7.5mm x 80mm - 16mm Thread
NICE-75-085	NICE - Ø7.5mm x 85mm - 16mm Thread
NICE-75-090	NICE - Ø7.5mm x 90mm - 16mm Thread
NICE-75-095	NICE - Ø7.5mm x 95mm - 16mm Thread
NICE-75-100	NICE - Ø7.5mm x 100mm - 16mm Thread
NICE-75-105	NICE - Ø7.5mm x 105mm - 16mm Thread
NICE-75-110	NICE - Ø7.5mm x 110mm - 16mm Thread
NICE-75-115	NICE - Ø7.5mm x 115mm - 16mm Thread
NICE-75-120	NICE - Ø7.5mm x 120mm - 16mm Thread

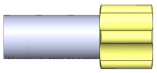
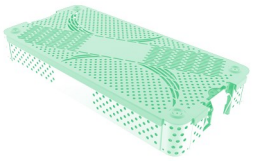
NICE-80-045	NICE - Ø8.0mm x 45mm - 16mm Thread
NICE-80-050	NICE - Ø8.0mm x 50mm - 16mm Thread
NICE-80-055	NICE - Ø8.0mm x 55mm - 16mm Thread
NICE-80-060	NICE - Ø8.0mm x 60mm - 16mm Thread
NICE-80-065	NICE - Ø8.0mm x 65mm - 16mm Thread
NICE-80-070	NICE - Ø8.0mm x 70mm - 16mm Thread
NICE-80-075	NICE - Ø8.0mm x 75mm - 16mm Thread
NICE-80-080	NICE - Ø8.0mm x 80mm - 16mm Thread
NICE-80-085	NICE - Ø8.0mm x 85mm - 16mm Thread
NICE-80-090	NICE - Ø8.0mm x 90mm - 16mm Thread
NICE-80-095	NICE - Ø8.0mm x 95mm - 16mm Thread
NICE-80-100	NICE - Ø8.0mm x 100mm - 16mm Thread
NICE-80-105	NICE - Ø8.0mm x 105mm - 16mm Thread
NICE-80-110	NICE - Ø8.0mm x 110mm - 16mm Thread
NICE-80-115	NICE - Ø8.0mm x 115mm - 16mm Thread
NICE-80-120	NICE - Ø8.0mm x 120mm - 16mm Thread

NICE-10-10	NICE 75 Compression Nut - 16mm x Non-Threaded
NICE-16-12	NICE 75 Compression Nut - 16mm x Aggressive
NICE-09-15	NICE 75 Compression Nut - 16mm x Neutral

NICE - Instruments

Part Number	Description	
N08-0010	1.6mm x 500mm Trocar Tip Guide Wire	
N08-0020	1.6mm x 500mm Trocar Tip Threaded Guide Wire	
N08-0040	Drill Guide 1.6mm - 6.1mm	
N08-0050	Nice Depth Gauge	
N08-0060	6.1mm Reamer	
N08-0070	Compression Nut Driver	
N08-0080	Driver Shaft	
N08-0090	NICE Anchor Deployment Driver	
N08-0100	Ratcheting Cannulated Axial Handle	

NICE - Instruments

Part Number	Description	
N08-0110	Torque Limiting AO Handle 1.5Nm	
N08-0120	Nice Retractor Driver	
N08-0130	Nice Anchor Retraction Driver	
N08-0140	Compression Sleeve	
N08-0000	Nice Instrument Tray	
N08-0005	NICE Screw Coddy	
N08-0030	NICE Adjustable Guide	

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

Method	Cycle	Temperature	Exposure Time	Minimum Dry Time*
Steam	Gravity	120°C	30 minutes	30 minutes
Steam	Gravity	130°C	15 minutes	30 minutes
Steam	Prevacuum	130°C	10 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.

NOTES

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