ORTHOPEDIC DESIGNS
NORTH AMERICA, INC.

Cannulated Compression Device (CCD)

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.

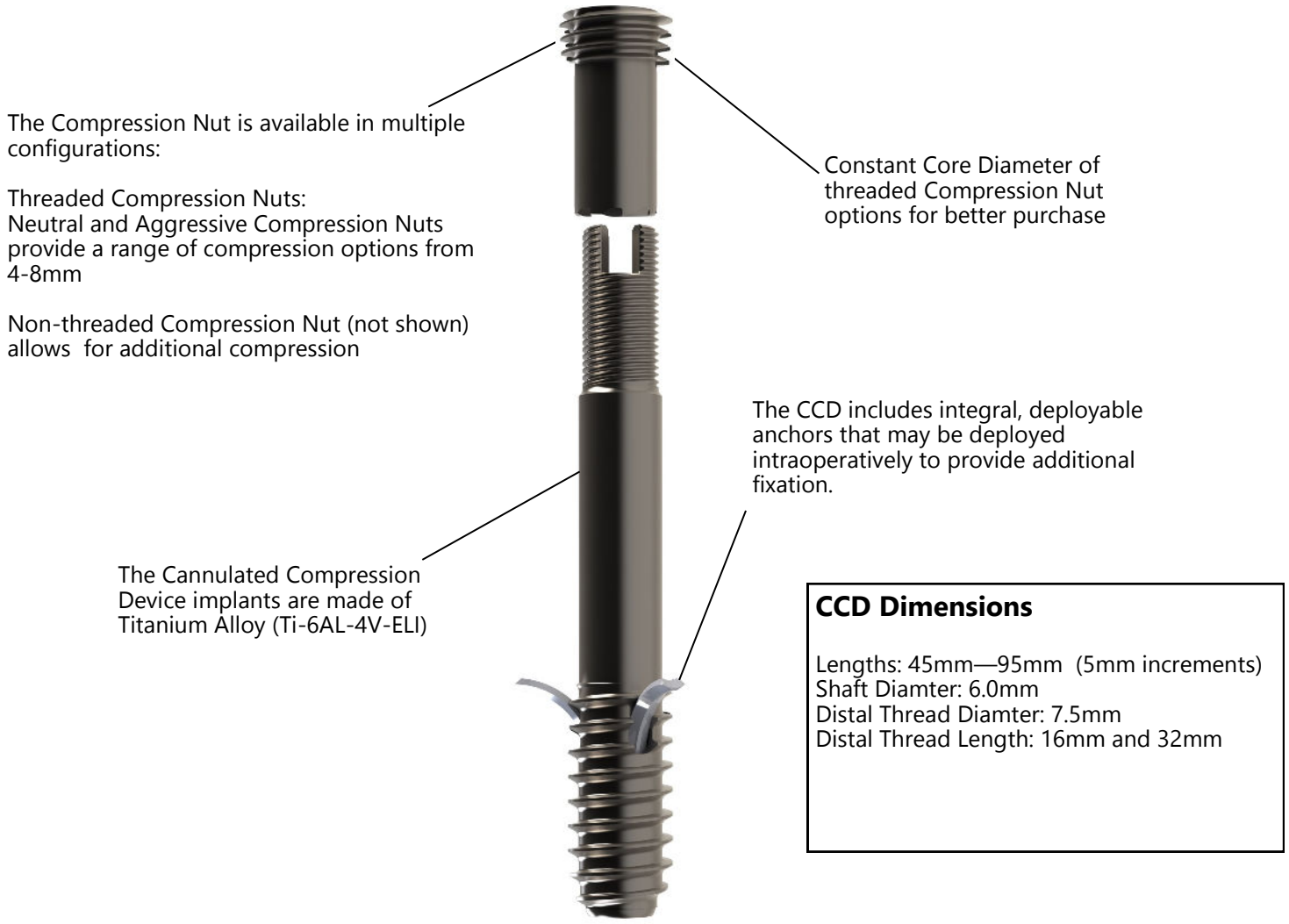
CCD — Design Features

Device Description

The Cannulated Compression Device System is used to aid in the alignment and stabilization of bone fractures. The system consists of the following parts:

- A **cannulated compression device body** with distal threads for bone engagement and distal portals that allow passage of deployable integral anchors to achieve stabilization distally within the bone. The anchors may be retracted for removal of the device if and when it is necessary. The device is provided with the deployable anchors pre-loaded. The device is available in a variety of lengths.
- A **compression nut** is provided separately in various configurations, including both threaded and non-threaded versions. The compression nut has a proximal head and internal threads. The proximal head engages the bone fragment. The internal threads allow engagement to the cannulated compression device body. As the compression nut is tightened onto the device body compression is achieved across the bone fragments. The rate of compression varies based on the proximal head configuration selected.

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).



CCD Dimensions

Lengths: 45mm—95mm (5mm increments)
Shaft Diamter: 6.0mm
Distal Thread Diamter: 7.5mm
Distal Thread Length: 16mm and 32mm

ALL FLEX ANCHORS ARE FULLY RETRACTABLE

CCD — Indications

Indications

The Cannulated Compression Device System is indicated for fracture fixation of small and long bones. The system is not intended for spinal use.

Applications

Applications include:

- Intracapsular fractures of the femoral neck
- Tibial plateau fractures
- Ankle arthrodesis
- Supplementary fixation for fractures of the proximal and distal femur

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

MRI Safety Information

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. The safety of the Cannulated Compression Device 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.

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 CCD.

Align the Guide Wire end of the Dual End Drill Guide in the direction of device insertion. Advance the Guide Wire through the Guide Wire end of the Dual End Drill Guide 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.

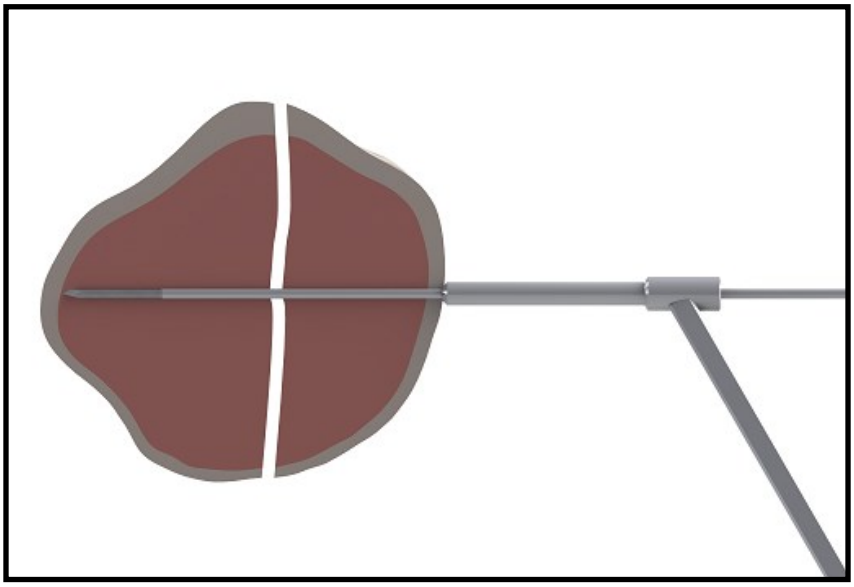


Fig. 6-1

Selecting CCD 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 CCD to be used.

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

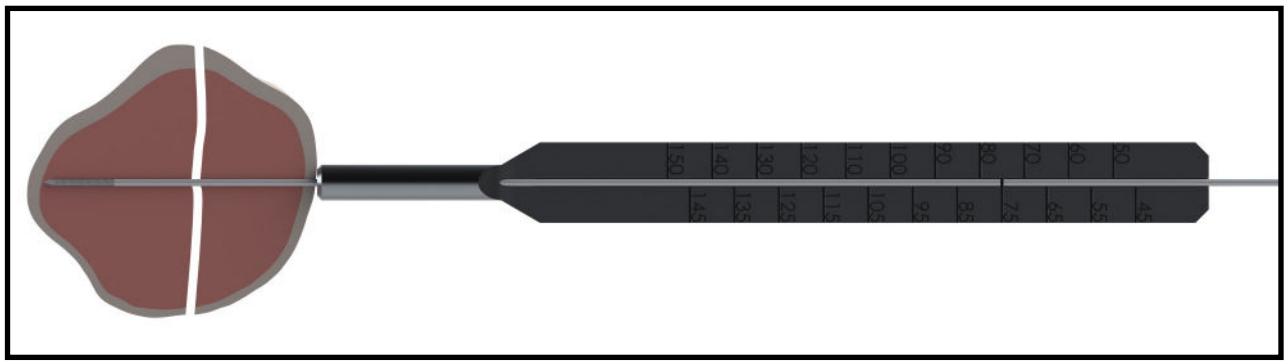


Fig. 7-1

Fig. 7-2

Drilling for the CCD

Place the Drill Guide end of the Dual End Drill Guide over the Guide Wire and then place the 6mm Reamer over the Guide Wire and through the Drill Guide end of the Dual End Drill Guide.

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

Dense bone may require use of the 7.5mm Tap to allow for easy CCD insertion.

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

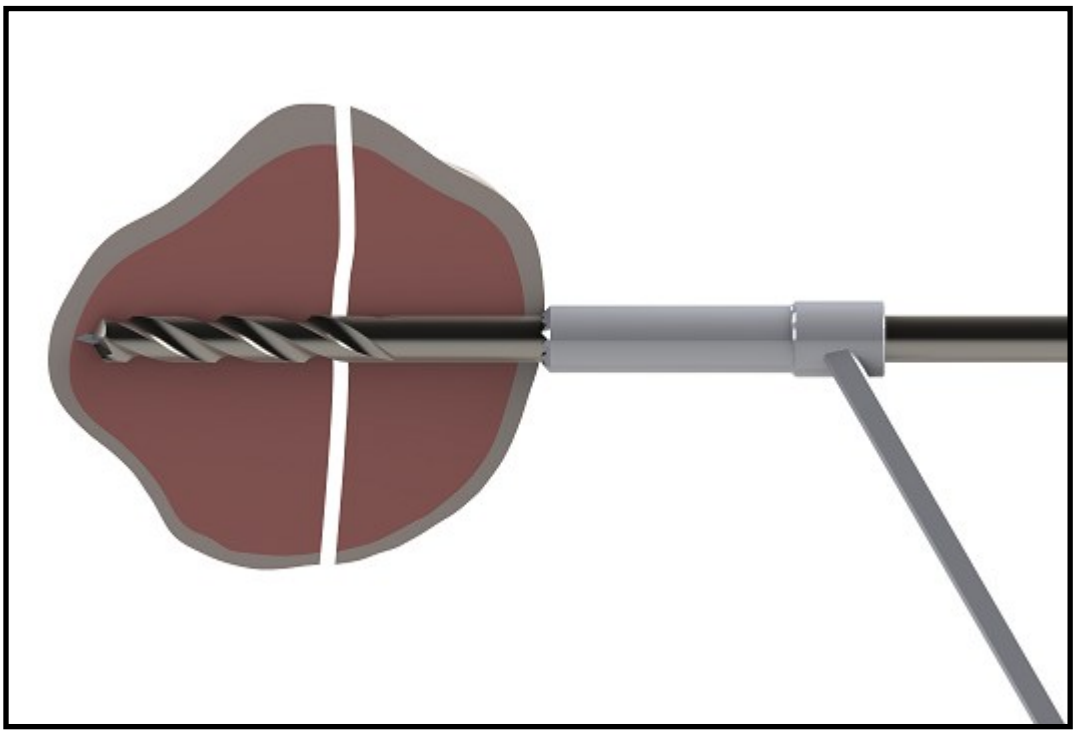


Fig. 8-1

Inserting the CCD

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

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

Mate the CCD Driver assembly with the CCD.

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

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

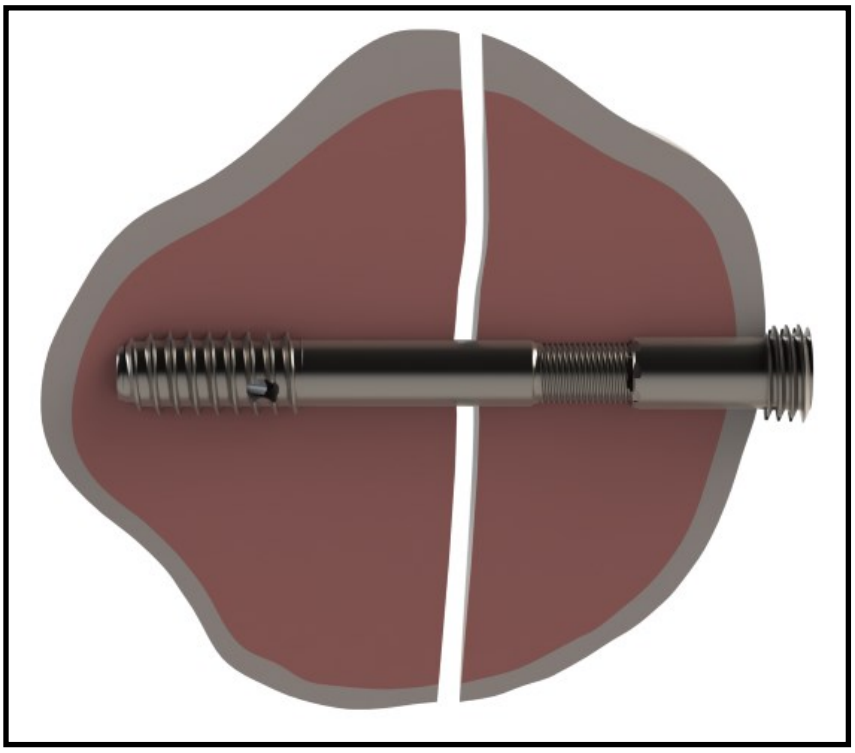


Fig. 9-1

Deploy Flex Anchors

Connect the Flex Anchor Deployment Driver to the Torque Limiting Handle and introduce it through the CCD Driver Shaft until contact is made with the Flex Anchors. **Do not thrust the driver in forcibly as this may damage the threads.** Turn the driver clockwise to deploy the Flex Anchors. While slight resistance may be felt while threading the driver through the Flex Anchors, deployment begins when greater resistance is felt.

Continue deploying until the Torque Limiting Handle trips (Figure 10-1).

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

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

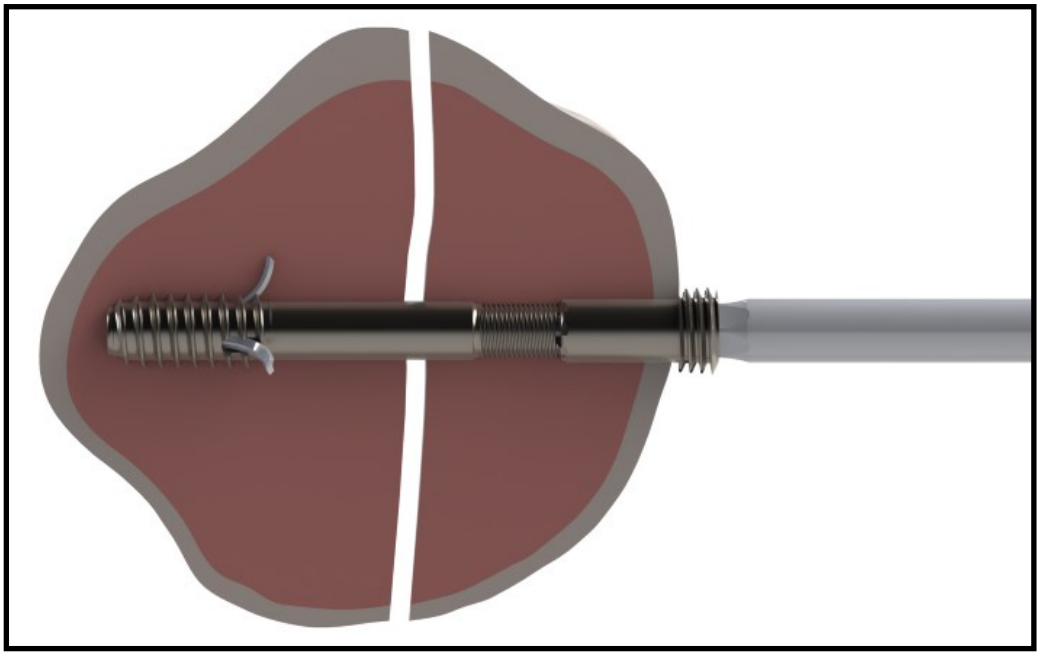


Fig. 10-1

Compress CCD - 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.

Compress CCD - Compression Nut

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 CCD Driver Shaft being shown (Figure 11-2). Full compression is indicated by the red band on the CCD 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).

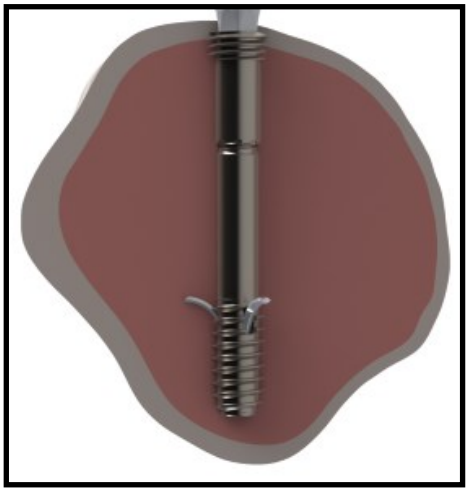


Fig. 11-1

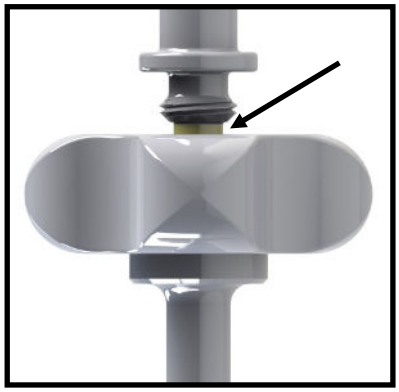


Fig. 11-2

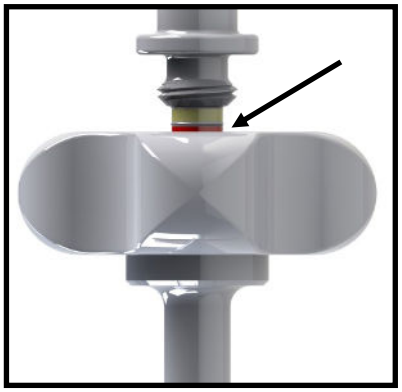


Fig. 11-3

Implant Removal

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

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

Remove the Guide Wire.

Insert the Flex Anchor Retraction Driver through the CCD Retractor until it no longer advances. Thread the Flex Anchor Retraction Driver clockwise into the CCD Retractor to retract the Flex Anchors.

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

Rotate the CCD Retractor counterclockwise to remove the CCD.

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

Cannulated Compression Device — Implants

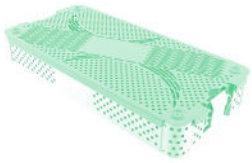
Catalog Number	Description
CCD-75-16-045	CCD - Ø7.5mm x 45mm - 16mm Thread
CCD-75-16-050	CCD - Ø7.5mm x 50mm - 16mm Thread
CCD-75-16-055	CCD - Ø7.5mm x 55mm - 16mm Thread
CCD-75-16-060	CCD - Ø7.5mm x 60mm - 16mm Thread
CCD-75-16-065	CCD - Ø7.5mm x 65mm - 16mm Thread
CCD-75-16-070	CCD - Ø7.5mm x 70mm - 16mm Thread
CCD-75-16-075	CCD - Ø7.5mm x 75mm - 16mm Thread
CCD-75-16-080	CCD - Ø7.5mm x 80mm - 16mm Thread
CCD-75-16-085	CCD - Ø7.5mm x 85mm - 16mm Thread
CCD-75-16-090	CCD - Ø7.5mm x 90mm - 16mm Thread
CCD-75-16-095	CCD - Ø7.5mm x 95mm - 16mm Thread
CCD-75-32-045	CCD - Ø7.5mm x 45mm - 32mm Thread
CCD-75-32-050	CCD - Ø7.5mm x 50mm - 32mm Thread
CCD-75-32-055	CCD - Ø7.5mm x 55mm - 32mm Thread
CCD-75-32-060	CCD - Ø7.5mm x 60mm - 32mm Thread
CCD-75-32-065	CCD - Ø7.5mm x 65mm - 32mm Thread
CCD-75-32-070	CCD - Ø7.5mm x 70mm - 32mm Thread
CCD-75-32-075	CCD - Ø7.5mm x 75mm - 32mm Thread
CCD-75-32-080	CCD - Ø7.5mm x 80mm - 32mm Thread
CCD-75-32-085	CCD - Ø7.5mm x 85mm - 32mm Thread
CCD-75-32-090	CCD - Ø7.5mm x 90mm - 32mm Thread
CCD-75-32-095	CCD - Ø7.5mm x 95mm - 32mm Thread

CCD-09-12	CCD Compression Nut - 16mm x Aggressive
CCD-09-15	CCD Compression Nut - 16mm x Neutral
CCD-10-00	CCD Compression Nut - 16mm x Non-Threaded

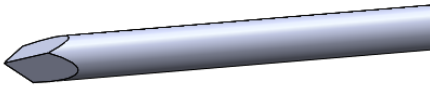
Cannulated Compression Device - Reusable Instruments

Part Number	Description	
ODI-T120	Ratcheting Axial Handle	
ODI-T133	Compression Sleeve	
ODI-T134	Flex Anchor Deployment Driver	
ODI-T135	6.1mm Reamer	
ODI-T136	Compression Nut Driver	
ODI-T137	7.5mm Tap	
ODI-T138	Depth Gauge	
ODI-T139	Dual End Drill Guide	
ODI-T141	CCD Driver Shaft	
ODI-T142	CCD Retractor	

Cannulated Compression Device - Reusable Instruments

Part Number	Description	
ODI-T143	Flex Anchor Retraction Driver	
ODI-T144	Torque Limiting Handle	
ODI-T145	Instrument Tray	

Cannulated Compression Device - Disposables

ODI-D103	Trocar Tip Guide Wire 1.6mm x 500mm	
ODI-D105	Trocar Tip Guide Wire 1.6mm x 500mm (Threaded)	

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 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)	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.

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

Manufactured By

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The symbols glossary is provided electronically at:

WWW.ODI-NA.COM/SYMBOLS-GLOSSARY

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