

 **smith&nephew**  
**Fracture Fixation Devices,  
Compression Hip Screws,  
Cannulated/Bone Screws,  
Bone Plates, Pins, Wires**

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Compression Hip Screws  
Cannulated/Bone Screws  
Bone Plates, Pins, Wires  
Important Medical Information**

**Special Note**

Fracture fixation devices are used only as an aid to healing, they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws or barrel plates and thus the strength of implants is limited. Full weight bearing prior to complete bone healing is contraindicated. With repeated stress in patients with delayed healing or nonunion, the appliance will inevitably bend, break or pull out of bone.

Fracture fixation devices are available in many styles and sizes and are made from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals at any time. Components from different manufacturers should not be mixed, except when advised by the manufacturer (example: TC-100° Plating and Screw System). All implantable components are designed for single use only. Some of the instruments are also designed for single use only as noted on the package label.

**Indications**

**Bone Plates and Screws**

Bone plates and screws from the Smith & Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

The 4.0mm Cannulated Screws and associated washers are additionally intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 5.5mm, 6.5mm, 7.0mm, and 8.0mm Cannulated Screws and associated washers are additionally intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and ankle.

The PERI-LOC® Plate and Screw System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bone plates and bone screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.



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PERI-LOC Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC contoured VLP Plates and Screws are indicated for partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia, and for fracture fixation of the fibula. PERI-LOC VLP One-Third Tubular Locking Plates are indicated for, but not limited to, fixation of fractures, non-unions and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. PERI-LOC Proximal Femur Bone Plates, Bone Screws and Cable Accessories are indicated for fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with medial cortex instability; proximal femur fractures combined with ipsilateral shaft fractures; pathological fractures of the proximal femur including metastatic fractures; proximal femur osteotomies; fixation of fractures in osteopenic bone; fixation of nonunions and malunions; basi/transcervical femoral neck fractures; subcapital femoral neck fractures; and subtrochanteric femur fractures.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodeses of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The Smith & Nephew 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws are intended for fixation of intraarticular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodeses of small joints; bunionectomies and osteotomies; scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The Smith & Nephew 2.0mm QFX Screw is indicated for osteotomies of the lesser metatarsals, such as Weil osteotomies. Osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.

## Pins and Wires

- Pins and wires are indicated for pelvic, small and long bone fracture fixation.

## Compression Hip Screws

- Intracapsular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)

- Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
- Osteotomies for patients with diseases or deformities of the hip.
- Hip arthrodesis.
- Supracondylar fractures and distal femoral fractures using a supracondylar plate.
- Ipsilateral femoral shaft/neck fractures.

## Pediatric and Intermediate Compression Hip Screws

- Congenital coxa vara.
- Congenital dislocation of the hip.
- Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomeningocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
- Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

## InterTAN Compression Hip Screws

- Intracapsular fractures of the proximal femur (For certain high intracapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head).
- Intertrochanteric fractures.
- Stable and unstable fractures of the proximal femur in which medial cortex stability can be restored.
- Hip osteotomy.

## Intramedullary Hip Screws (IMHS®)

Intramedullary Hip Screws (IMHS) are indicated for intracapsular fractures of the femoral neck; trochanteric or subtrochanteric fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures using a supracondylar plate; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; femoral neck fractures; subcapital fractures; comminuted neck and shaft fractures; femur reconstruction following tumor resection; leg length discrepancies secondary to femoral inequality; and prophylactic nailing of impending pathologic fractures.

## Contraindications

- Physical conditions that would preclude adequate implant support or retard healing) such as, blood supply impairment, insufficient bone quality or quantity, previous infection, obesity, severe bow or gross distortion of the femur.
- Mental conditions that preclude cooperation with the rehabilitation regimen.

## Additional Contraindications for Pediatric and Intermediate Compression Hip Screws

- PERI-LOC VLP Plates and Screws are contraindicated for Type A and C (OTA fracture classification) fractures and fractures with extreme metaphyseal comminution or dissociation of the articular segment from the shaft.

## Additional Contraindications for Pediatric and Intermediate Compression Hip Screws

- Fracture of the neck of the femur. The capital femoral epiphysis or trochanteric epiphysis should not be violated by the lag screw. Cessation of growth may take place.
- Slipped upper epiphysis. The bone in the trochanteric area and in the center of the femoral neck are so dense and the target area in the head of the femur so small that other techniques are preferable.
- The Pediatric Compression Hip Screw is also contraindicated for patients under the age of 2 or over the age of 6 years.

## Warnings

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- Because of unbalanced muscle forces, subtrochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
- Subtrochanteric and comminuted trochanteric fractures and osteotomies place increased stresses on bone plates. Plate length should be increased to provide maximal fixation. The highest angle plate is recommended. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time or non- for limited weight bearing should be correspondingly increased until solid bony union occurs.
- The threads of an implanted lag screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
- Use only stainless steel screws with stainless steel devices, and Ti-6Al-4V screws with Ti-6Al-4V devices.
- For the PERI-LOC Proximal Femoral Plating System, titanium cable saddles should only be used with titanium screws, titanium screw hole plugs and cobalt chrome cables. Stainless steel cable saddles

should only be used with stainless steel screws, stainless steel screw hole plugs and stainless steel cables.

- PERI-LOC Periarticular Locked Plating System devices and accessory components should not be placed across growth plates in pediatric patients.

## Precautions

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
- Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery. Single use devices should not be reused due to risks of breakage, failure or patient infection.
- Continuous screening with an image intensifier (fluoroscopy) during guide wire insertion and whenever cannulated instruments are advanced over a guide wire is recommended to prevent unintended guide wire advancement and penetration into the surrounding tissues.
- Intra-operative cleaning of cannulated instruments is recommended to prevent accumulation of bone debris in the cannulation.
- If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.
- For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.
- Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

## Adverse Effects

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
- Leg length discrepancies and subsequent patient limp may occur.
- Screw cutting through the femoral head (usually associated with osteoporotic bone), penetration of the joint by a lag screw with or without chondrolysis, and failure of a lag screw to slide in the barrel, especially with low angle plates and/or improper screw plate assembly have been reported.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Penetration of a guide wire/screw into the pelvis can occur.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
- Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.

## Magnetic Resonance Imaging (MRI) Safety

Smith & Nephew fracture fixation devices have not been evaluated for safety and compatibility in the MR environment. Fracture fixation components have not been tested for heating or migration in the MR environment.

## Packaging and Labeling

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

## Sterilization

For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of  $10^{-6}$ . Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

If not specifically labeled sterile, components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile trauma implants (i.e. plates, nails, and screws) remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization. Please see the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

DO NOT REUSE implant components or single use disposable instruments.

**HA coated lag screws are provided STERILE packaged and cannot be resterilized.**

## Recommended Steam Sterilization Cycle Parameters

- **Dynamic Air Removal (Prevacuum) Steam Cycle:** 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- **Gravity Displacement Steam Cycle:** 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- **Flash Steam Cycle (Reusable instruments only):** 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- **United Kingdom Steam Cycle:** 134°C (273°F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.)

Containment devices should be wrapped with central supply wrap (CSR) or placed in reusable rigid container for sterilization.

**Note to U.S. Customers:** FDA cleared sterilizers and wraps are to be used in your sterilization processes.

## Retrieval And Analysis Of Removed Implants

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

## Information

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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